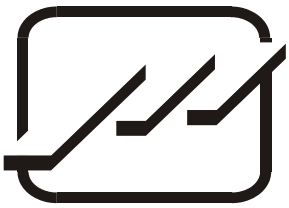
POOYANDEGAN RAH SAADAT

OPERATOR'S MANUAL

NOVIN S1600 Patient Monitor

CE 2195

D00022-5



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✓ **Note:**

This guide describes all features and functions of SAADAT Co. patient monitors. Your monitor is highly customizable and may not have some of these features. Optional features are marked with*.

Chapter 1, Introduction

Manual Purpose

This manual provides the instructions necessary to operate bedside monitor in accordance with its intended use. It also describes all parameters and options that your monitor may have depending on the way it has been customized.

Study of this manual is a prerequisite for proper operation and ensures patient and operator safety. If you have any question about the bedside, please contact our customer service. This manual is an essential part of and should always be kept close to the bedside monitor to be available whenever necessary.

Intended Audience

This manual is provided for the clinical medical professionals. Clinical medical professionals are expected to have working knowledge of medical terminology and procedures as required for patient monitoring.

Version Information

This manual has a version number. The version number changes whenever the manual is updated due to software or technical specification changes. The version information of this manual is as follows.

Release date	Version number
Feb 2021	D00022-5

1.1 General Warnings

⚠ **Warning** ⚠

Patient monitor is intended for clinical monitoring application with operation only granted to appropriate medical staff.

⚠ **Warning** ⚠

Before use, carefully read this manual, directions for use of any accessories, all precautions, and all specifications.

⚠ **Warning** ⚠

The vital sign monitor is intended for use only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

⚠ **Warning** ⚠

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the monitor for proper functioning.

⚠ **Warning** ⚠

To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

⚠ **Warning** ⚠

Do not use the patient monitor during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of monitor measurements.

⚠ **Warning** ⚠

Do not place the monitor in any position that might cause it to fall on the patient.

⚠ **Warning** ⚠

There could be hazard of electrical shock by opening the monitor casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by manufacturer.

⚠ **Warning** ⚠

Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or oxygen.

⚠ **Warning** ⚠

The operator must check that system and accessories function safely and see that it is in proper working condition before being used (e.g. Calibration date of the system must be valid).

⚠ **Warning** ⚠

Alarm must be set according to different situations of individual patient. Make sure that audio sounds can be activated when an alarm occurs.

⚠ **Warning** ⚠

Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the monitor performance.

⚠ **Warning** ⚠

Do not touch the patient, table nearby, or the equipment during defibrillation.

⚠ **Warning** ⚠

The equipment and devices connected to it should form an equipotential body to ensure effective grounding.

⚠ **Warning** ⚠

The physician shall consider all well-known side-effects when using the patient monitor.

⚠ **Warning** ⚠

There will be some risks of polluting the environment associated with the disposal of the device and cables at the end of their useful lives. The device and accessories shall be

disposed in accordance with national laws after their useful lives. Contact your municipality to check where you can safely dispose of old batteries.

⚠ Warning ⚠
Do not expose the system near any local heating item such as the direct radiation.

⚠ Warning ⚠
Do not use one monitor for two or more patients at the same time.

⚠ Warning ⚠

It is possible to increase leakage current when several systems are connected to the patient simultaneously.

⚠ Warning ⚠

Monitor software is designed in a way that hazards arising from errors in the software programmed are minimized.

⚠ Warning ⚠
Do not connect items not specified as parts of the monitor.

⚠ Warning ⚠

Vital sign monitor needs to be installed and put into service according to the EMC information provided in the APPENDIX IV.

⚠ Warning ⚠

To prevent EMC effect on the monitor, the system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

⚠ Warning ⚠

If any liquid is spilled on the system or accessories, immediately turn off the system and wipe up it by a soft cloth.

⚠ Warning ⚠

Make sure that cables and accessories are not under tension during monitoring.

⚠ **Warning** ⚠

When using a defibrillator, parameters and signals will be temporarily interrupted until electroshock is finished.

1.2 General Information

Environment:

Temperature		
	Operating	5 to 40ºC
	Transport and Storage	-25 to 60ºC
Humidity		
	Operating	20-90%
	Transport and Storage	10-100%
	Altitude	-200 to 3000m
	Power Supply	100-240 VAC, 50/60Hz P_{max}= 72W

The monitoring system (Figure 1-1) is used for effective and safe patient care and is adaptable to adult, pediatric and neonatal patients in healthcare centers. It can continuously display vital signs data such as ECG, Respiratory Rate, ST Segment, 13 types of Arrhythmia, Rainbow parameters, (AWRR, RR), SpO2, CO2, N2O, O2, AA, NIBP, C.O, 2 channels IBP, Dual-TEMP . The patient monitor consists of different modules, a recorder and an alarm system and can be connected to the Central system and slave monitor.

Power switch is located on the front panel (① in the figure 1-1). There are three indicators for power, alarm and battery on the front panel of the system. The green indicator lights when the device is powered on (② in the figure 1-1). The alarm indicator flashes when an alarm occurs (③ in the figure 1-1). Vital signs monitor is a user-friendly device which can be easily operated using some buttons, a rotary knob (④ in Figure 1-1) . The battery indicator is green when the battery is fully charged, otherwise it is orange (⑤ in Figure 1-1).

. Refer to **1.4 Buttons Function** for details.

⚠ **Warning** ⚠

To verify proper function of indicators, they light when the system is powered on.

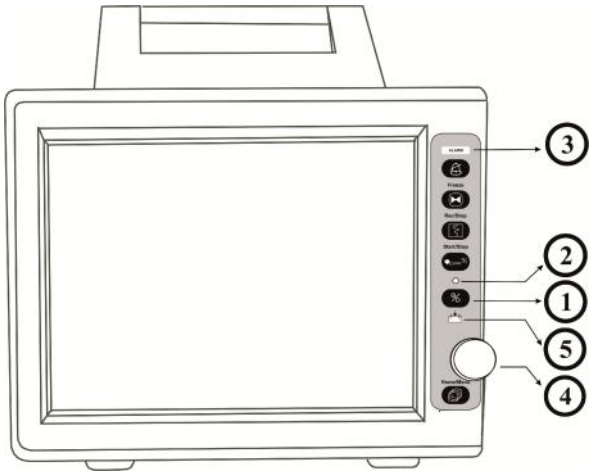


Figure 1-1 Novin S1600 Monitor

Portable Patient Monitor will provide you with the following vital signs data:

ECG	Heart Rate (HR), ST segment, PVCs/min, Arrhythmias, ECG waveforms
RESP	Respiratory Rate (RR) , Respiration Waveform
SpO2	Saturation pulse oximetery (SpO2), Pulse Rate (PR),SpO2 Plethysmogram If MASIMO Rainbow* module is used, the following parameters will be measurable: **Note:** Each of the below parameters can be used only if its software is enabled by the manufacturer and its specific probe is available. • Arterial pulse signal strength (PI) • Total amount of hemoglobin in the blood (SpHb) • Oxygen content in the blood (SpOC) • Carboxyhemoglobin saturation percent in the blood (SpCO) • Methemoglobin saturation percent in the blood (SpMet) • Index for PI changes that occur during the respiratory cycle (PVI)
NIBP	Systolic pressure(SYS), Diastolic pressure (DIA), Mean arterial pressure (MAP)
TEMP	Channel-1 temperature (T1), Channel-2 temperature (T2)
IBP*	2-channel IBP (IBP1, IBP2)
CO2*	EtCo2, FiCo2, AWRR
Multi-gas*	EtN2O, FiN2O, EtO2, FiO2, EtAA, FiAA, AA is included 5 anesthesia agents (DES, ISO, SEV, HAL and ENF)

CO* Cardiac output

Vital signs monitor provides different functions such as visible & audible alarms, storage of trend data, NIBP measurements and 150 arrhythmia events.

1.3 Display Screen

Patient monitor has a color LED display. The patient Parameters, waveforms, alarm messages, bed number, date, system status and error messages are displayed on the screen.
The screen is divided into four areas: Header Area; Waveform Area/ Menu Area; Parameter Area and Message Area (see figure 1-2).

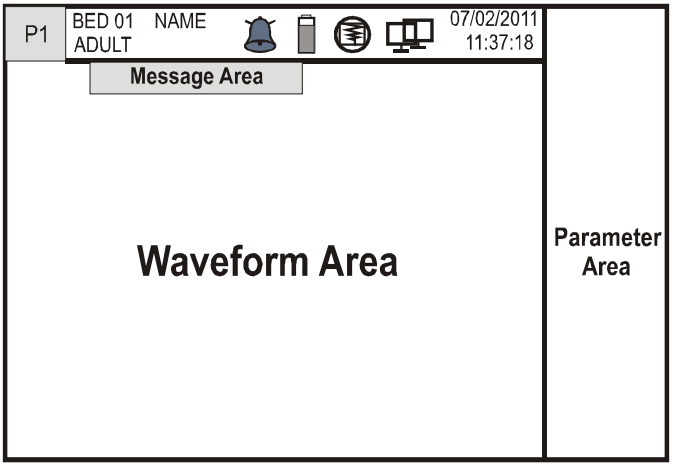


Figure1-2 Monitor Main Display

Header Area

The Header Area is at top of the screen displaying operating state of the monitor and status of the patient.
The parameters in Header Area are page number, bed number, type of patient (adult, pediatric or neonate), patient name, current date and time.
The above information appears on the screen throughout the monitoring process.
Other information of the Header Area comes up only with respective monitoring status.
They are:

-  appears when the system is connected to central system.
-  appears when the system is recording.
-  indicates the remaining battery charge.
-  blinks along with a countdown timer (120 sec) when the alarm silence button is pressed.

Waveform / Menu Area :

All waveforms can be displayed at the same time. The waveforms from top to bottom are: ECG, SpO2, IBP1, IBP2 and RESP/CO2/Multi-gas.
Gain, filter, lead and sweep of the ECG are displayed as well .The three dotted lines from top to bottom show the highest scale, cursor and lowest scale of IBP waveform. These values can be manually set.
All menus in monitor always appear at fixed areas on the screen. When a menu is displayed, some waveforms become invisible. The menu with regard to its size will cover 2, 3, 4 or 5 waveforms.

Parameter Area:

Numeric values of each parameter are displayed at a fixed position on the screen and with a color corresponding to its waveform. The parameters values refresh every second, except that the NIBP and CO values refresh each time the measurement is over.

Message Area:

Different messages are displayed based on alarm priority in this area. Background color changes for different alarm levels (I, II and III).

Level I alarm message: Red background – Black text

Level II alarm message: Yellow background – Black text

Level III alarm message: Cyan background – Black text

If no alarm is triggered, the message will be displayed with gray background.

NOTE:

1- **When using the monitor, the screen should be protected from direct sunlight in order to get a clear view of what is displayed.**
2- **To make the monitor readable outdoor, transfer it to shade or a dark environment.**

3- If the monitor is used outdoor, place it in a location that is not exposed to direct sunlight.

Alarm indicator:

In normal mode, the alarm indicator is not lit.

In alarm mode, the alarm indicator lights and flashes.

⚠ **Warning** ⚠

Always verify the audible and visible alarms when monitor is powered on. Please refer to chapter Alarm for details.

1.4 Buttons Function

The monitor can be operated via the front panel buttons, rotary knob and touch screen*(See the figure 1-3).

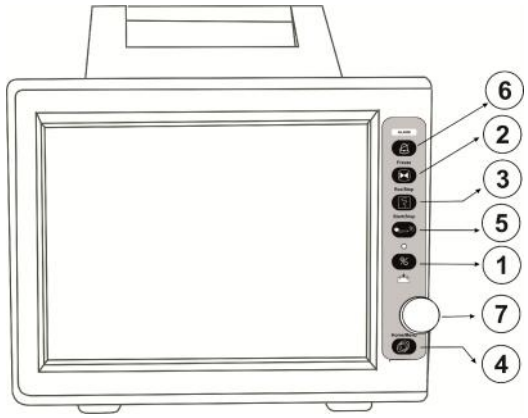


Figure 1-3 Functional Buttons and Rotary Knob

① **Power**

Press to power on or off the system.

② **Freeze**

When in normal mode, press to freeze all waveforms on the screen. When in freeze mode, press to restore the waveform refreshing.

③ **REC/STOP:**

Press to start a real time recording of ECG signal and all monitoring parameters by the central system or internal recorder of the monitor. Press during recording to stop it.

④ **HOME/MENU:**

Press to open HOME WINDOW. Please refer to Chapter Configuration for details.

⑤ **START/STOP:**

Press to start a blood pressure measurement. While measuring, press it again to stop the measurement.

⑥ **Alarm Silence:**

Press it to disable alarm for 120 s. A countdown timer appears and Silence symbol blinks on the Header area every 5 sec. If you press it again, the system will exit from silence mode and alarm sound will be enabled.

NOTE:

For more specific information on alarms of each parameter, refer to Appendix II.

NOTE:

If a new alarm occurs under alarm silence condition, silence mode will be removed.

⑦ **Rotary Knob**

This knob can be used to select and change the settings. Operations can be performed by turning it clockwise, counter clockwise or pressing it down.
The square frame that moves with the knob turning, functions as a "cursor".

When no menu is displayed, turning the knob clockwise can locate the cursor at: ECG, NIBP, SpO2, IBP, TEMP or RESP/CO2/Multi gas parameter area of the screen. When the cursor is located on a specific parameter area, you can change setting of that parameter as follows:

1. A menu pops up, by pressing the knob.
2. Move the cursor frame to related parameter in opened menu by turning the knob.
3. Change the content by pressing the knob on the special parameters and choose your setting and confirm your selection by pressing it.

⚠ **Warning** ⚠

Before using the system on the patient, user must check the buttons function and make sure that it is in proper working condition as described above.

1.5 Interfaces

① Connector for ECG cable
② Connector for Spo2 Sensor
③ Connector for IBP1 transducer
④ Connector for IBP2 transducer
⑤ Connector for NIBP cuff
⑥ Connector for TEMP1 probe
⑦ Connector for TEMP2 probe
⑧ Connector for CO2/ GAS sensors
⑨ Connector for CO catheter

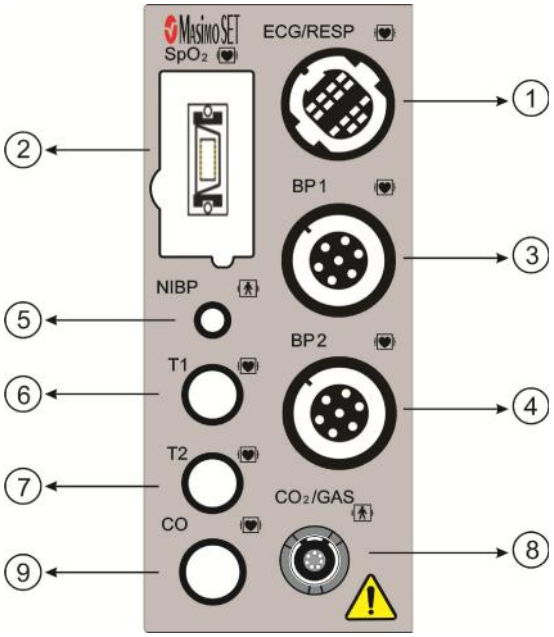


Figure 1-4 Side panel

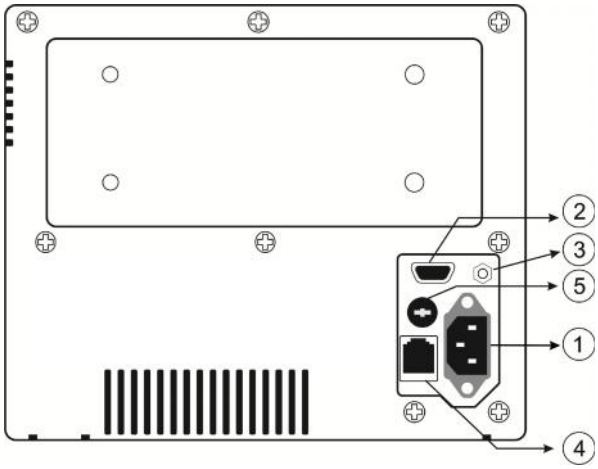


Figure 1-5 Power plate sockets and fuse

The following sockets are located on the side panel (Figure 1-5).

■ Power Supply: 100-240 (VAC), 50/60 Hz (Socket ①)

■ VGA SLAVE MONITOR (Socket ②)

Monitor interface for external standard VGA color monitor.

Working mode: 800×600,256 colors

Interface: D-sub 15 pins

Pin 1. Red Video	Pin 9. NC
Pin 2. Green Video	Pin 10. Ground
Pin 3. Blue Video	Pin 11. NC
Pin 4. Ground	Pin 12. NC
Pin 5. NC	Pin 13. Horizontal Sync
Pin 6. Red Ground	Pin 14. Vertical Sync.
Pin 7. Green Ground	Pin 15. NC
Pin 8. Blue Ground	

How to use:

1) Install the VGA slave monitor in the same room with the patient but keep it away from the patient more than 1.5m. The monitor is intended to be used as an assistant monitoring device.
2) Plug the connection cable while the VGA slave monitor is off.
3) Power on the VGA slave monitor, same time or after powering on the monitor.
4) Adjust brightness and contrast properly.

■  (Jack③)

Equipotential grounding terminal for connection to the hospital's grounding system.

■ Central Network Interface (Socket④):

Data transmission between the central system and the bedside monitor

⚠ **Warning** ⚠

Patient monitor must be only connected to manufacturer's central system.

⚠ **Warning** ⚠

Use only the recommended central cable for connecting monitor to central system.

⚠ **Warning** ⚠

If the network cable plug is broken, please contact after sale service to replace it.

■ 250 V/3A Fuse (Socket⑤)

⚠ **Warning** ⚠

If you are going to store the patient monitor or you don't want to use it for a long time (more than 10 days), remove the fuse from the system to prevent battery discharging.

■ ECG OUTPUT
Analog ECG signal output (e.g. for defibrillator device)

1.6 Built-in Battery

The patient monitor is equipped with a rechargeable battery. The battery will be automatically recharged when the monitor connects to the AC INPUT. When the AC INPUT is plugged in, turning the system on or off does not have any effect on charging process of the battery.

- If sealed lead acid battery is used, it takes about 4 to 5 hours to charge the battery. You should get one and a half hours (normal usage) of run time on a new and fully charged battery.

- If lithium battery is used, it takes about 6 to 7 hours to charge the battery. You should get about 4 hours (normal usage) of run time on a new and fully charged battery.

✓ Normal usage of the device includes the below conditions:
Brightness is automatically set by system, ECG/Resp, SpO2, TEMP measurements in Use, NIBP measurement every 15 minutes.

- The above conditions are applicable to a new battery. Power saving and run-time of the battery decrease over time.
- The factors like high environment temperature, the battery age, full discharging, high number of charge cycles and long- term storage (several months) will reduce “the battery power saving”.

⚠ **Warning** ⚠

If operating time with the battery is less than the specified time, the battery needs to be replaced. Please Contact local After Sale Service for battery replacement.

The symbol  is displayed on the Header area to indicate the battery charging status. The yellow part of the symbol represents the remaining battery charge. This symbol is only displayed when the AC INPUT is not plugged in. If the AC INPUT is plugged in, the battery charging status also will be shown by the battery indicator on the front panel. The battery indicator lights green when the battery is about 90% charged and lights orange when the battery is being charged.

The fuse on the side panel protects the battery during charging or when the system is not connected to AC INPUT.

When the fuse is damaged, the system cannot run on the battery power and the battery symbol blinks on the screen.

⚠ **Warning** ⚠

The monitor will shut down automatically if the battery power is low. Before the battery is completely depleted, the alarm will sound and "LOW BATTERY" will appear in the Header area. When the battery is running out of power, level III alarm is activated. If user does not apply AC power to the monitor, level II and I alarms are displayed respectively as the charge level decreases.

⚠ **Warning** ⚠

Use only the recommended manufacturer batteries in the monitor.

⚠ **Warning** ⚠

Connect the monitor to the mains supply and check the battery status LED to ensure that the battery functions correctly.

⚠ **Warning** ⚠

If the battery malfunctions and the monitor stays off for a long time, date and time may be reset.

Chapter 2, System Configuration

Patient care monitor has a flexible configuration. Press HOME/MENU key on the front panel or the rotary switch in Header area to enter HOME WINDOW and set configuration (Figure 2-1).

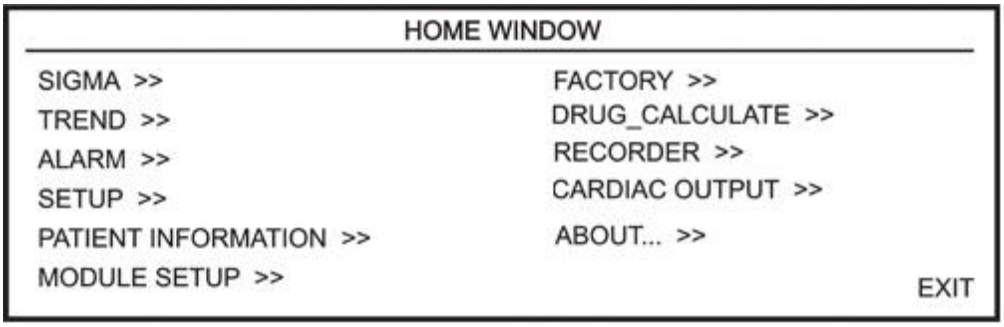


Figure 2-1 HOME WINDOW

NOTE:
The settings will not be changed by turning off the device or power failure.

2.1 SIGMA

The patient care monitor is able to save and display 10 traces of ECG signal in SIGMA WINDOW. The time of displaying ECG signal is 160 sec.
Pick "SIGMA" in HOME WINDOW to call up the following window:

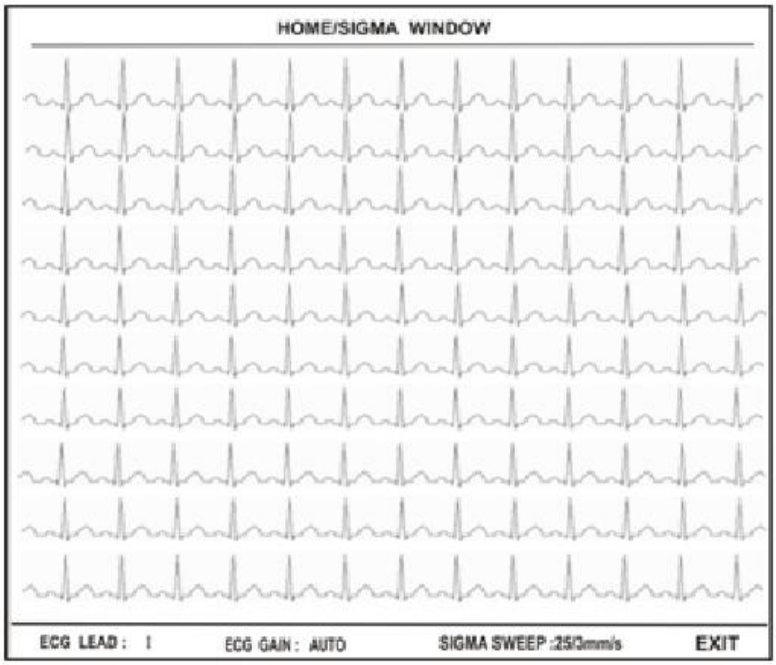


Figure 2-2 HOME/SIGMA WINDOW

You can view ECG settings including ECG LEAD, ECG GAIN and SIGMA SWEEP SPEED in this window. Refer to Chapter ECG MONITORING for details.

2.2 TREND

The latest 96 hours of parameters values are recorded every second in Trend Window. Pick "TREND" in the HOME WINDOW to call up the following menu:

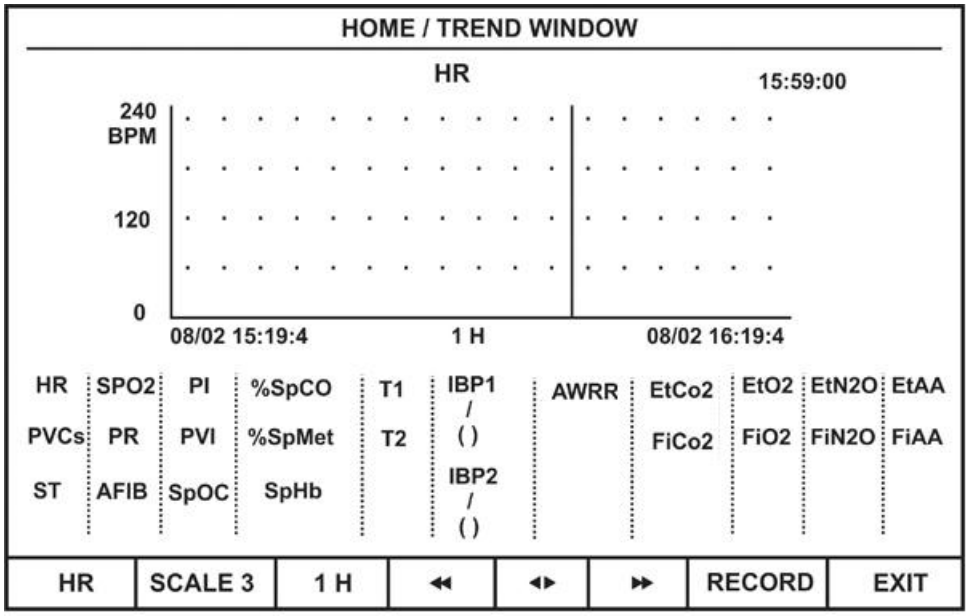


Figure 2-3 HOME/TREND WINDOW

Y-axis stands for related parameter value and X-axis for time.

NOTE:

If Multi-gas module is enabled, FiO2, EtO2, FiN2O, EtN2O, EtAA and FiAA parameters will be displayed in the trend window.

■ To select trend graph of a specific parameter:

Pick parameter name (the most left item) and select your intended parameter by turning the knob. Available options are HR, SpO2, RESP, T1, T2, IBP1, IBP2, AWRR, CO2, EtCo2, FiCo2, N2O, O2,FiO2, EtO2, FiN2O, EtN2O, AA, FiAA, EtAA, PVCs, ST, AFIB, PR, PI, PVI, SPOC,%SpCo,%SpMet, SpHb.

■ **To change the display scale:**

Pick "SCALE" (the second left item) to adjust the Y-axis scale and thus change the trend curve in proportion.

PARAMETER	SCALE1		SCALE2		SCALE3		SCALE4		SCALE5		SCALE6	
	MIN	MAX	MIN	MIN	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX
HR	0	60	0	120	0	240	-	-	-	-	-	-
SpO2	80	100	60	100	0	100	-	-	-	-	-	-
T1/ T2	30	42	24	48	0	48	-	-	-	-	-	-
IBP1/IBP2/	-20	50	-20	100	-20	200	-50	300	50	250	-	-
RESP	0	60	0	120	0	240	-	-	-	-	-	-
AWRR	0	60	0	120	0	240	-	-	-	-	-	-
Co2/ EtCo2/ FiCo2	0	50	0	100	-	-	-	-	-	-	-	-
O2/ EtO2/ FiO2	0	50	0	100	-	-	-	-	-	-	-	-
N2O/ EtN2O/ FiN2O	0	50	0	100	-	-	-	-	-	-	-	-
AA/ EtAA/ FiAA	0	1.0	0	2.0	0	3.0	0	5.0	0	10.0	0	20.0
PVCs	0	20	0	50	0	100	-	-	-	-	-	-
ST	-0.2	0.2	-0.5	0.5	-1	+1	-2	2	-	-	-	-
AFIB	0	1	-	-	-	-	-	-	-	-	-	-
PR	0	60	0	120	0	240	-	-	-	-	-	-
PI	0	20	0	10	0	5	-	-	-	-	-	-
PVI	0	30	0	100	-	-	-	-	-	-	-	-
SpOC	0	36	6	20	-	-	-	-	-	-	-	-
SpCo	0	12	0	24	0	50	-	-	-	-	-	-
SpMet	0	6	0	20	-	-	-	-	-	-	-	-
SpHb	6	20	2	14	0	25	-	-	-	-	-	-

■ **To select time interval of displaying numeric values:**

Pick the third left item, available options are 15 min, 30 min and 45 min, 1, 2 and 4 hours.

■ **To select time intervals of trend in x-axis**

Select ⏪ or ⏩ to change time interval in the X-axis and to adjust start time and end time. By every click on these buttons, you can change the time interval of x-axis to the extent of the specified time in the third left item.

■ To obtain trend data of a specific time:

Select ◄► to view trend values of a specific time. By clicking on this button and turning rotary, you can move the cursor line through the graphic trend that points to specific times. This time is displayed at the right side of the TREND WINDOW and related numeric value to this time is displayed below the parameter. You can do this only for 15, 30, 45 min and 1, 2 hr intervals (set in the third left item).

2.3 ALARM

Pick "ALARM" in HOME MENU to call up the following window:

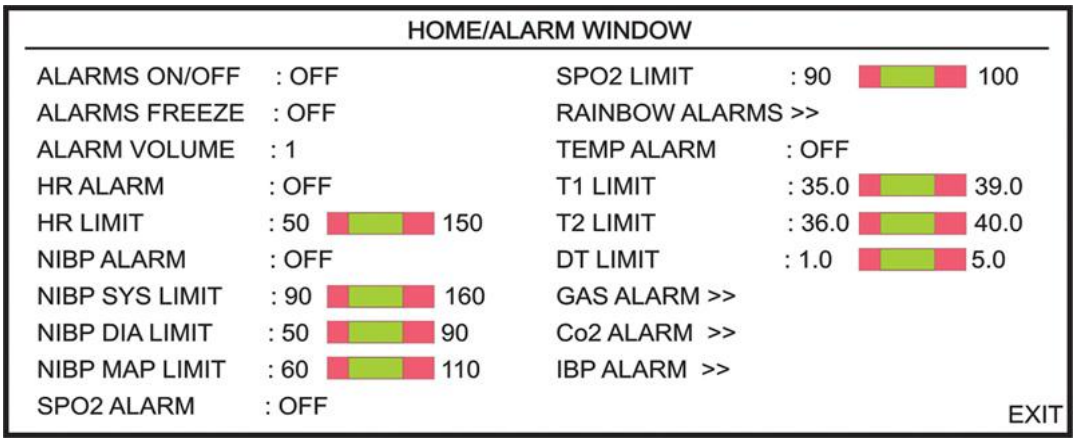


Figure 2-4 HOME/ALARM WINDOW

■ ALARMS ON/OFF

Pick "ON" to enable the alarm functions.

Pick "OFF" to disable the alarm functions such as audio alarm, parameters blinking and alarm light indicator. In "OFF" mode there will be ⚠ symbol beside all parameters. This function changes alarm settings of all parameters, but you are able to turn on/off alarm of a specific parameter in its own window.

■ ALARM FREEZE

Pick "ON" to freeze all the related signals when parameter's value violates adjusted alarm limits. In freeze mode, press "Freeze" button on the front panel to release the waveform refreshing.

Pick "OFF" to disable ALARM FREEZE.

■ ALARM VOLUME

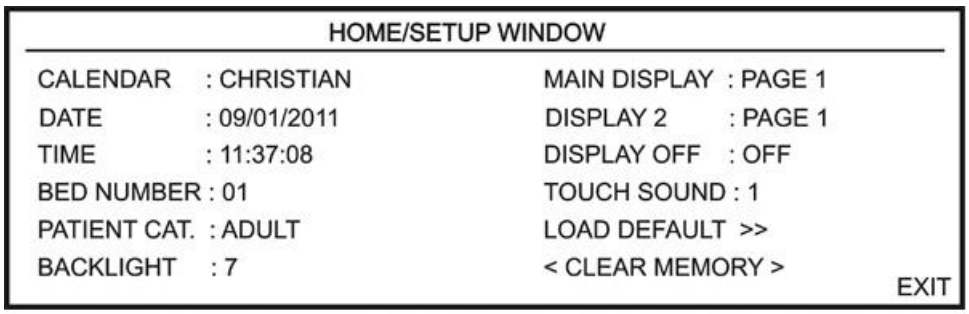
Pick "ALARM VOLUME" to set the volume of alarm sound. The selection ranges from 1 to 7. 1 represents minimum volume, while 7 represents maximum volume.

NOTE:

All other settings in this menu are about alarm ON/OFF and alarm high/low limit of measurable parameters. You are able to set these items in the related parameters menu. Refer to each module's chapter for details.

2.4 SETUP

Choose "SETUP" in HOME WINDOW to call up the following menu:



2-5 HOME / SETUP WINDOW

CALENDAR	available options are "SOLAR" and "CHRISTIAN".
DATE	current date of monitoring.
TIME	current time of monitoring.
BED NUMBER	patient bed number (1-150).
PATIENT CAT.	available options are "ADULT", "NEONATE " and "PEDIATRIC'
BACKLIGHT	ranges from 1 to 6 for S1600 monitor
MAIN DISPLAY	available options for when IBP: OFF are "PAGE1", "PAGE 2" and "PAGE 3"and for IBP: ON are "PAGE 1" to "PAGE 5" and "PUMP PAGE"

Different page configurations

There are pages with different configurations to display parameters and waveforms:

- If IBP module is OFF:

P1: You can monitor ECG (two traces), SpO2 and RESP/GAS signals as well as numeric parameters HR, SpO2%, PR, RESP/GAS, NIBP and TEMP (MAIN DISPLAY= PAGE 1 mode)
(When Display Format is set to 4 Traces, four traces of ECG signal as well as SpO2 and RESP/GAS signals are displayed in this page.

When Display Format is set to7 Traces, seven traces of ECG signal are displayed).

P2: You can monitor same parameters and signals as P1, but arrangement of parameters windows differ slightly from P1. (MAIN DISPLAY= PAGE 2 mode)
(When Display Format is set to 4 Traces, four traces of ECG signal as well as SpO2 and RESP/GAS signals are displayed in this page.
When Display Format is set to7 Traces, seven traces of ECG signal are displayed).

P3 : You can monitor ECG (2 traces), CO2 (RESP) and SpO2 signals as well as all numeric parameters (special page for Rainbow parameters) (MAIN DISPLAY= PAGE 3 mode)

P4: You can monitor ECG signal (12 traces) and numeric parameters of P1.
(Only with settings of CABLE TYPE: 10WIRES and DISPLAY FORMAT: 12 TRACES, you can access this page)

- If IBP module is ON:

P1: The following signals will be displayed in this page for different Display Formats:
a) CASCADE/2 TRACES: ECG signal (two traces), SpO2, IBP1, IBP2 and RESP/CO2
b) 4 TRACES: ECG (four traces), IBP1 and IBP2 signals
c) 7 TRACES: Seven traces of ECG signal
Numeric parameters HR, PVCs, ST, SpO2%, PR, IBP1, IBP2, RESP/CO2, NIBP and TEMP are also displayed in this page. (MAIN DISPLAY= PAGE 1 mode)

P2 : You can monitor same parameters and signals as P1, but arrangement of parameters windows differ slightly from P1. (MAIN DISPLAY= PAGE 2 mode)
(When Display Format is set to 4 Traces, four traces of ECG signal as well as SpO2 and RESP/GAS signals are displayed in this page.
When Display Format is set to7 Traces, seven traces of ECG signal are displayed).

P3* **:** You can monitor ECG (2 traces), CO2 (RESP), IBP1/IBP2 and SpO2 signals as well as all numeric parameters (special page for Rainbow parameters) (MAIN DISPLAY= PAGE 3 mode).

P4: You can monitor ECG, IBP1 and IBP2 signals (in a larger scale) as well as numeric parameters HR, PVCs, ST, SpO2%, PR, IBP1,IBP2, NIBP and TEMP (special page for large scale IBP) (MAIN DISPLAY= PAGE 4 mode)

P5: You can monitor ECG (two traces), IBP1, SpO2 and RESP signals as well as all numeric parameters of P1 except IBP2 (MAIN DISPLAY= PAGE 5 mode).

P6*: You can monitor ECG, SpO2, IBP1, IBP2 and RESP signals as well as numeric parameters HR, PVCs, ST, SpO2%, PR, IBP1,IBP2, NIBP,TEMP and RESP/CO2 (MAIN DISPLAY= PUMP PAGE mode).

NOTE:

To access PUMP Page, select SETUP from Home menu and then set MAIN DISPLAY to PUMP Page.

P7*: You can monitor ECG signal (12 traces) and numeric parameters of P1.

(Only with settings of CABLE TYPE: 10WIRES and DISPLAY FORMAT: 12 TRACES, you can access this page).

NOTE:

To access P7, select ECG LEAD from ECG window and then set CABLE TYPE to 10WIRES and DISPLAY FORMAT to 12.

PUMP PAGE

PUMP page is an operating mode that can be selected via SETUP menu. This page provides the following conditions depending on events occurring for ECG and IBP modules during open heart operation.

1- The word “PUMP” is shown on ECG signal.

2- If ASYSTOLE condition occurs, the message “ECG ASYSTOLE” will be shown and audible alarm with high level will be activated.

3-You can disable the alarm sound by pressing Alarm Silence key, but the message “ECG ASYSTOLE” will remain on the screen.

4- If other alarm except ASYSTOLE alarm occurs, audible alarm will sound corresponding to new alarm level.

5-If “IBP Static Pressure” alarm occurs, SYS and DIA values will be removed and Mean value will be displayed in larger size.

6-IBP scales are adjusted automatically and “AUTO SCALE: ON” appears on IBP signals.

⚠ **Warning** ⚠

This page has specific usability and should be used only in the operating room.

DISPLAY 2

The display 2 has same page configuration as the monitor.

DISPLAY OFF	The display screen is turned off, until a button is pressed or an alarm occurs. If Alarm Silence is activated, the display will not be turned off.
TOUCH SOUND	Available options are 1-3 and OFF.
LOAD DEFAULT	Pick it to call up the following window:

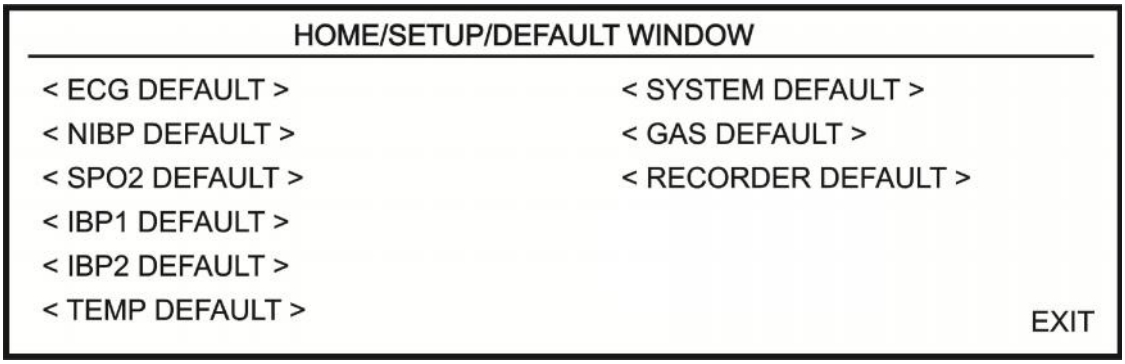


Figure 2- 6 HOME/SETUP/DEFAULT WINDOW

If you choose any option in this window, the system will load the factory settings of related parameter. (Refer to appendix I for factory settings of parameters). Because of changing all your previous settings, the system will ask if you are sure to change settings by this message:

ARE YOU SURE TO LOAD ECG DEFAULT?

YES NO

CLEAR MEMORY	To delete stored parameters in the system such as parameters saved in TREND, NIBP LIST, and ARR EVENT LIST .

A message will appear on the screen for each of above items that asks you whether to clear that item or not. These messages are as follows:

ARE YOU SURE TO CLEAR TREND?
YES NO”

ARE YOU SURE TO CLEAR NIBP LIST?
YES NO”

ARE YOU SURE TO CLEAR ARR LIST?
YES NO”

2.5 PATIENT INFORMATION

Choose "PATIENT INFORMATION" in HOME WINDOW to call up the following window:

Figure 2-7 HOME/PATIENT INFORMATION WINDOW

Press "NEW" to enter new patient information. The below confirmation message will appear.

ARE YOU SURE TO CLEAR ALL DATA?

YES NO

If you select YES, ARR LIST, NIBP LIST, TREND and BFA TREND will be cleared and PATIENT CAT will be set to ADULT mode.
The information menu is as follows:

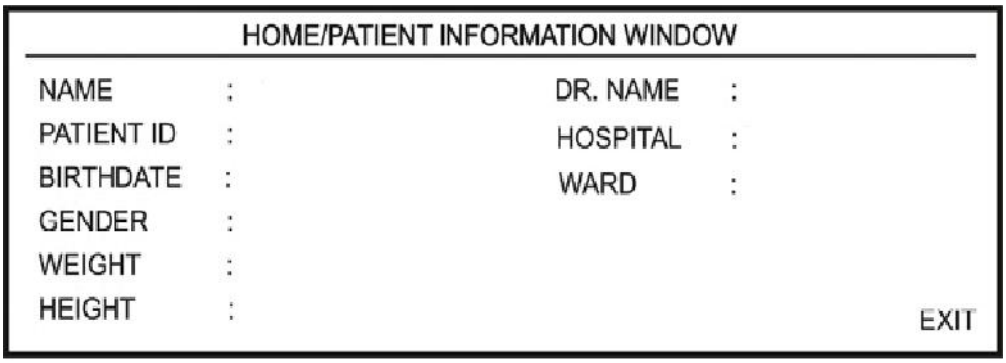


Figure 2-8 HOME/PATIENT INFORMATION WINDOW

Press "EDIT" to edit the previous patient information.

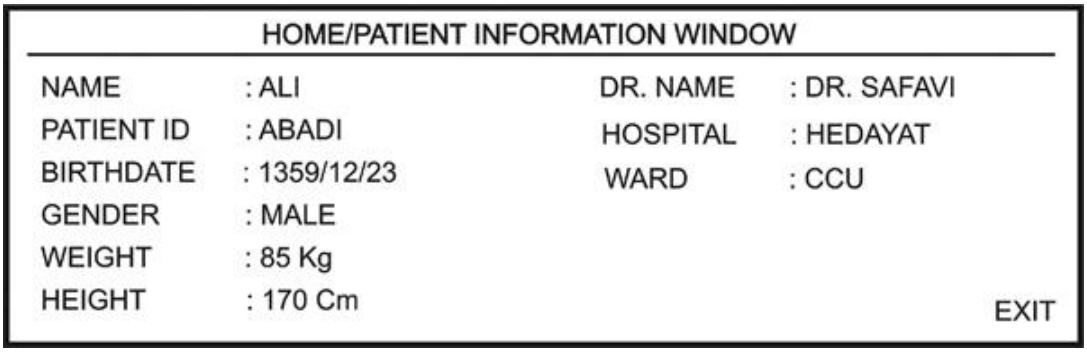


Figure 2-9 HOME/PATIENT INFORMATION WINDOW

Pick an item to call up the following window in which you can input data:

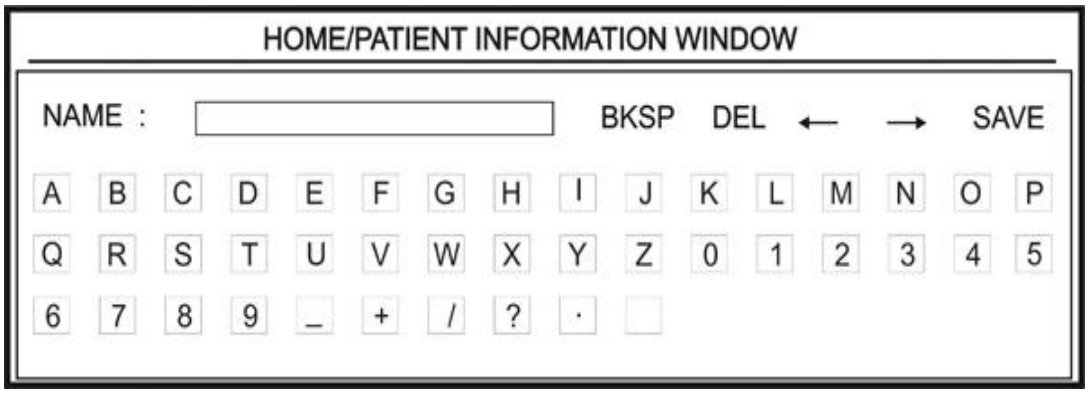


Figure 2-10 HOME/PATIENT INFORMATION WINDOW

NAME	Patient name (length: 18 characters)
PATIENT ID	Hospital ID for patient (length: 18 characters)
BIRTH DATE	Date of the birth
GENDER	Available options are MALE and FEMALE
WEIGHT	Available between 0.5 to 300 Kg
HEIGHT	Available between 20 to 250 cm
DR. NAME	Physician name (length: 16 characters)
HOSPITAL	Hospital name (length: 16 characters)
WARD	Hospital ward name (length: 16 characters)

2.6 MODULE SETUP

Choose "MODULE SETUP" in HOME WINDOW to call up the following window:

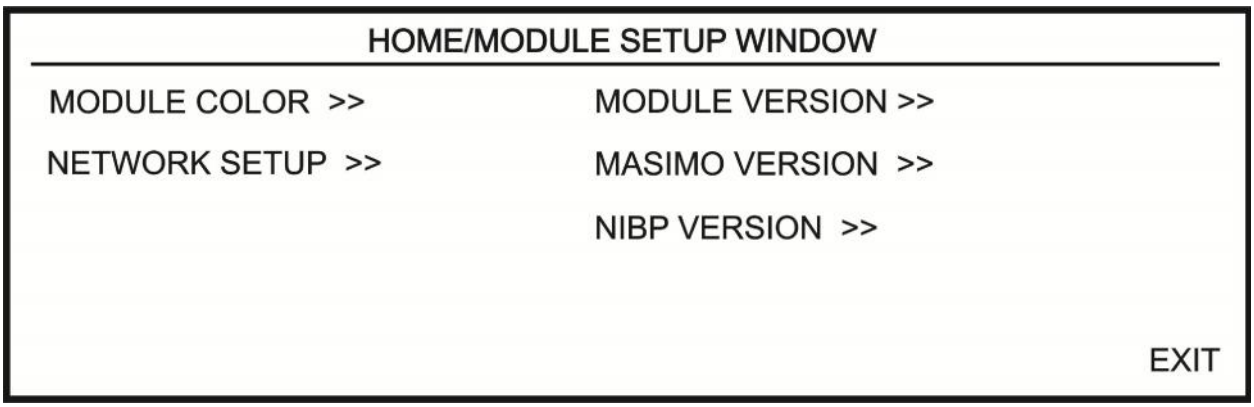


Figure 2-11 HOME/ MODULE SETUP WINDOW

Pick "MODULE COLOR" in MODULE SETUP window to call up the following window. You can set color of all parameters except ECG in this window. Select <DEFAULT COLOR> to restore default color of all modules as shown in the below figure.

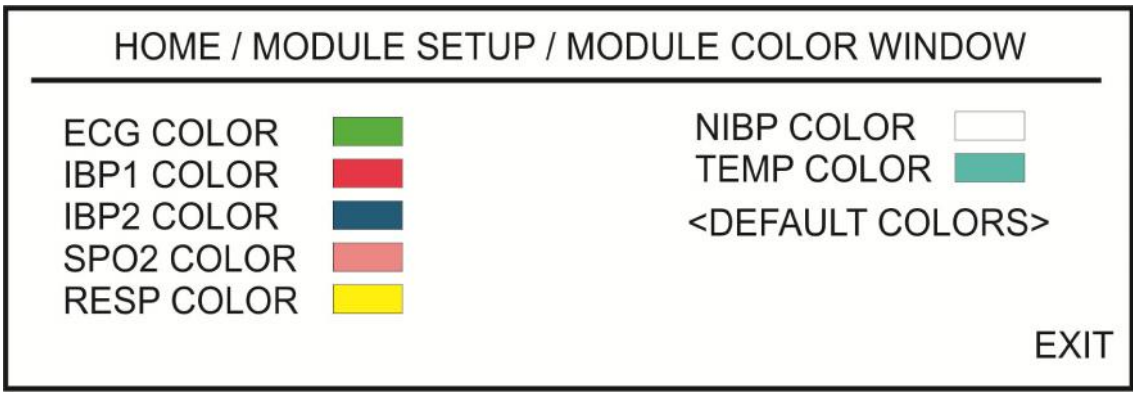


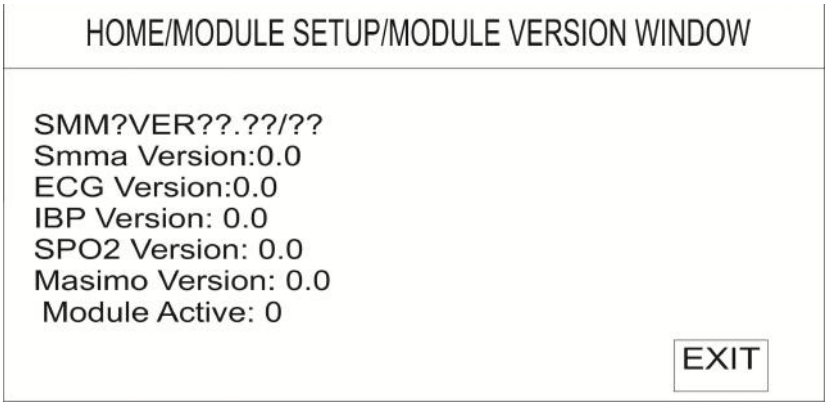
Figure 2-12 HOME/ MODULE SETUP / MODULE COLOR WINDOW

For each change in parameters color, the following message will appear on the screen that asks you whether to change color or not.

ARE YOU SURE TO CHANGE COLOR?

YES NO

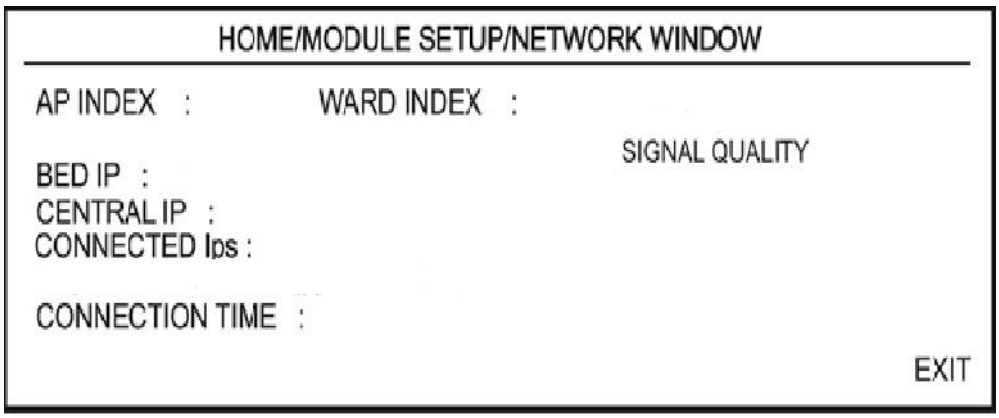
Choose "MODULE VERSION" in MODULE SETUP window to access the following window in which you can see version of all modules.



2-13 HOME/ MODULE SETUP/MODULE VERSION WINDOW

Choose "NETWORK SETUP" in MODULE SETUP window to call up the following window in which you can perform the Central system settings and see bedside and Central IP addresses, time of network connection and etc.

SIGNAL QUALITY: The signal strength during WiFi connection of the bedside to the Central system.

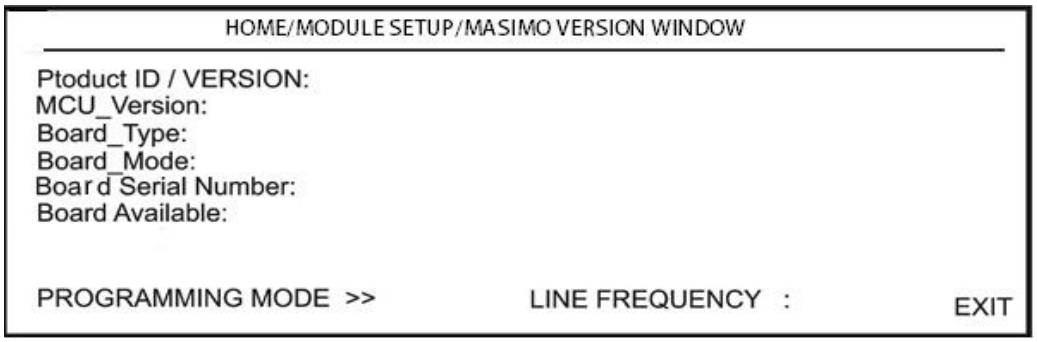


2-14 HOME/ MODULE SETUP/ NETWORK WINDOW

Choose "MASIMO VERSION" in MODULE SETUP window to call up the following window in which you can observe MASIMO module information, set frequency and enable intended MASIMO parameter by connecting programmer.

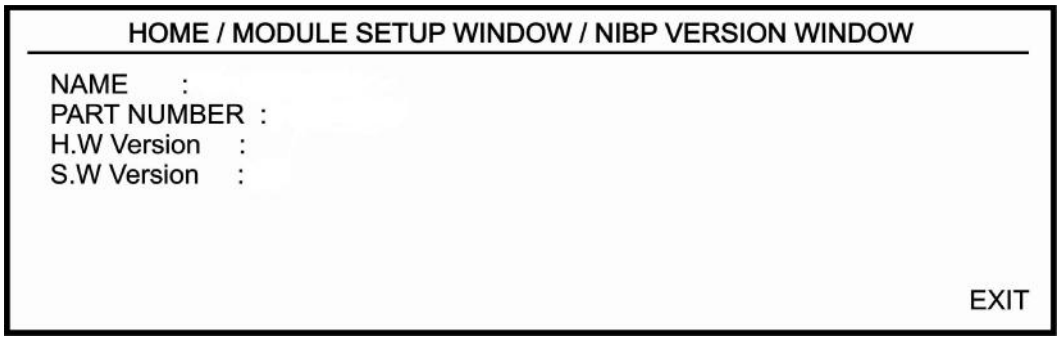
Choose PROGRAMMING MODE >> in HOME/MODULE SETUP/MASIMO VERSION WINDOW to open the respective menu after a delay of 5 seconds. If programming procedure is not done, the system will exit from this mode and return to normal working mode.

This item is only available to trained and authorized personnel.



2-15 HOME/ MODULE SETUP/ MASIMO VERSION WINDOW

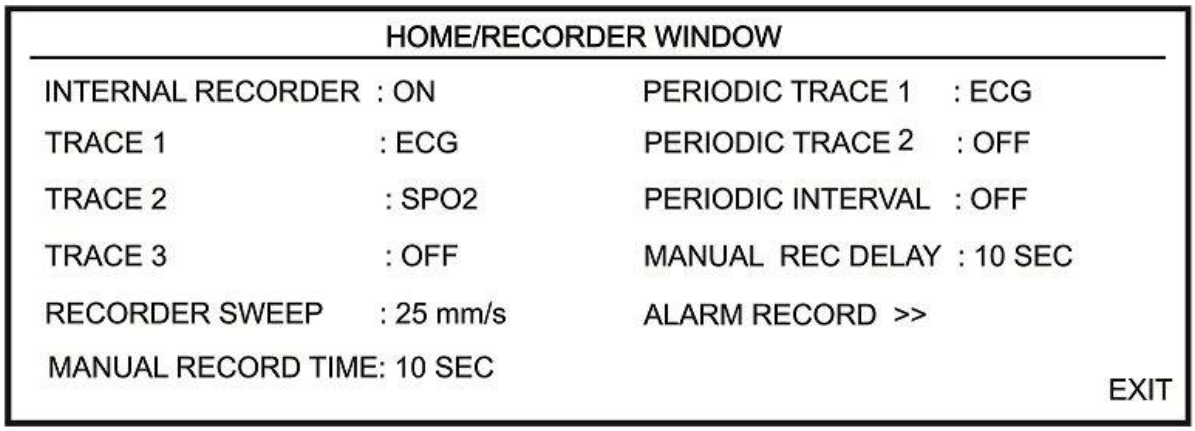
Choose “NIBP VERSION” in MODULE SETUP window to call up the following window in which you can observe NIBP module information.



2-16 HOME/ SETUP/NIBP VERSION WINDOW

2.7 RECORDER*

Choose "RECORDER" in HOME WINDOW menu to call up the following window:



2-17 HOME/RECORDER WINDOW

- **INTERNAL RECORDER**
  Pick "ON" to record via internal recorder.
  Pick "OFF" to disable the internal recorder and record via the Central system.

- **TRACE1**
  To choose the first trace of printout record in manual recording.
  Available options are ECG, SpO2, IBP1, IBP2, RESP, GAS and OFF.

- **TRACE2**
  To choose the second trace of printout record in manual recording.
  Available options are ECG, SpO2, IBP1, IBP2, RESP, GAS and OFF.

NOTE:

You cannot choose same signal for TRACE 1 and TRACE 2.

- **TRACE3**
  To choose the third trace of print out record in manual recording.
  Available options are ECG (different leads) and OFF.

Depending on the selected ECG CABLE TYPE in ECG menu, different options will be available for TRACE 3.

- If ECG CABLE TYPE is set to 3 WIRE, only OFF will be available for TRACE 3.
- If ECG CABLE TYPE is set to 5 WIRE, ECG-I, ECG-II, ECG -III, ECG-V, ECG-aVR, ECG-aVF, ECG-aVL and OFF will be available.

- If ECG CABLE TYPE is set to 10 WIRE, ECG-I, ECG-II, ECG -III, ECG-V, ECG-aVR, ECG-aVF , ECG-aVL , V1, V2, V3, V4, V5, V6 and OFF will be available.

If available options for TRACE 3 are not suitable for the selected CABLE TYPE, the system will automatically set TRACE 3 to OFF in 3WIRE mode and to ECG-II in 5 WIRE mode.

NOTE:

When TRACE3 is active, the maximum gain option will be 0.5 mV.

- **RECORDER SWEEP**

  Available options for RECORDER SWEEP are 6, 12.5 and 25 mm/s.

- **MANUAL RECORD TIME**

  Available options for MANUAL RECORD TIME are “MANUAL”, “10 sec”, “20 sec”, “30 sec” and "CONTINUOUS".

- **PERIODIC TRACE 1**

  To choose the first channel trace of printout record in automatic recording.
  Available options are ECG, SpO2, IBP1, IBP2, RESP, GAS and OFF.

- **PERIODIC TRACE2**

  To choose the second channel trace of printout record in automatic recording.
  Available options are ECG, SpO2, IBP1, IBP2, RESP, GAS and OFF.

- **PERIODIC INTERVAL**

  To choose time interval in periodic recording. Available selections are 15min, 30min,1h,2h,4h,8h,12h,24h and OFF.

- **MANUAL REC DELAY**

  To create delay in manual recording. For example if you set this item to 10 seconds and press Record button, data of the latest 10 seconds will be recorded.
  Available options are 5 sec to 15 sec by step of 1 sec.

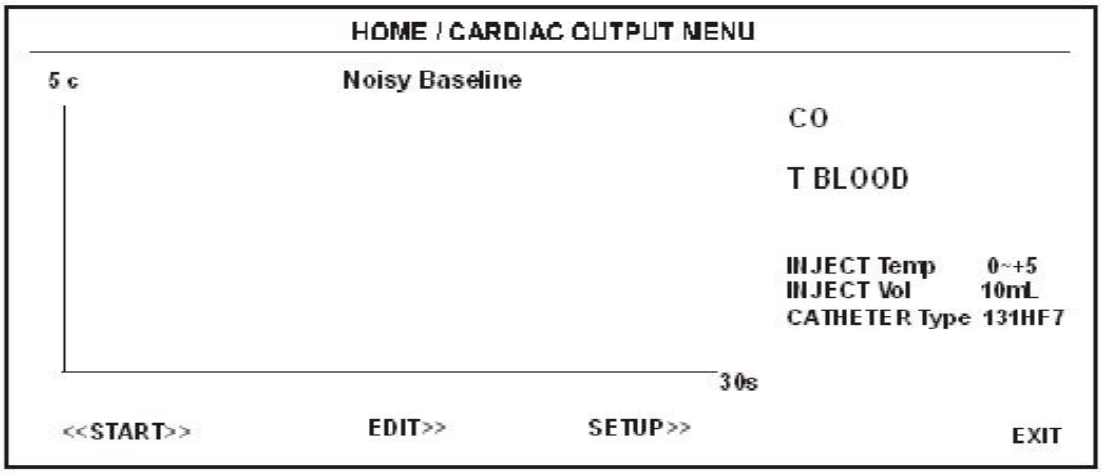
- **ALARM RECORD**

  If alarm recording for each parameter is set ON, it automatically starts recording when alarms happen.

  See the chapter “Recording for details.

2.8 CARDIAC OUTPUT*

Choose “CARDIAC OUTPUT” in HOME WINDOW to access the following window.

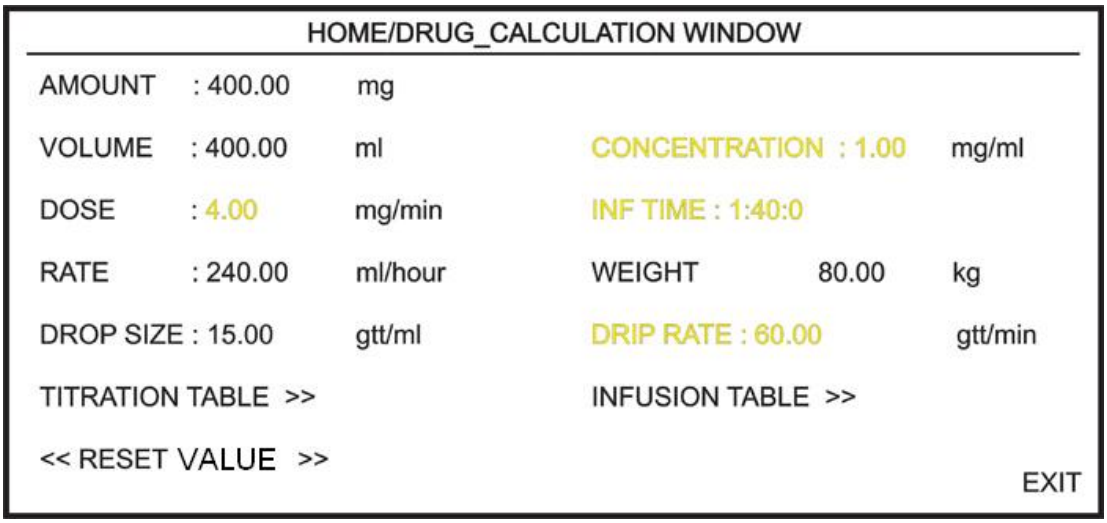


2-18 HOME/ CARDIAC OUTPUT MENU

Please refer to the chapter “**CO Monitoring**” for details.

2.9 DRUG_CALCULATOR*

Choose “DRUG_CALCULATOR” in HOME WINDOW to access the following window.



2-19 HOME/ DRUG_CALCULATION WINDOW

This window is used to calculate rate, dosage, amount or volume, capacity and time of drug infusion. Infusion rate based on Drop Size is defined as Drip Rate.

- Three of parameters AMOUNT, VOLUME, DOSE and RATE are entered by user as input, and output values are automatically calculated and displayed in yellow color.

- Measurement unit of AMOUNT and DOSE can be selected by user.
  Available units for AMOUNT and DOSE are as follows:
  AMOUNT: mg ,mcg
  DOSE: mg/min , mg/kg//min ,mcg/min and mcg/kg/min

- Weight is adjustable by user, but weight value adjusted in PATIENT INFORMATION menu is displayed in this window by default.

- User can select << RESET VALUE >> to delete all input values and calculations for new input data and calculations.

- Calculation is automatically performed as user changes inputs.

- DRIP RATE is automatically calculated as user defines DROP SIZE.

Choose TITRATION TABLE >> to access the following window in which you can review the relation between rate and dosage of drug infusion.

HOME/DRUG/TITRATION TABLE

AMOUNT : 400.00 mg VOLUME: 400.00 ml WEIGHT:80.00 kg DOSE UNIT: mg/min

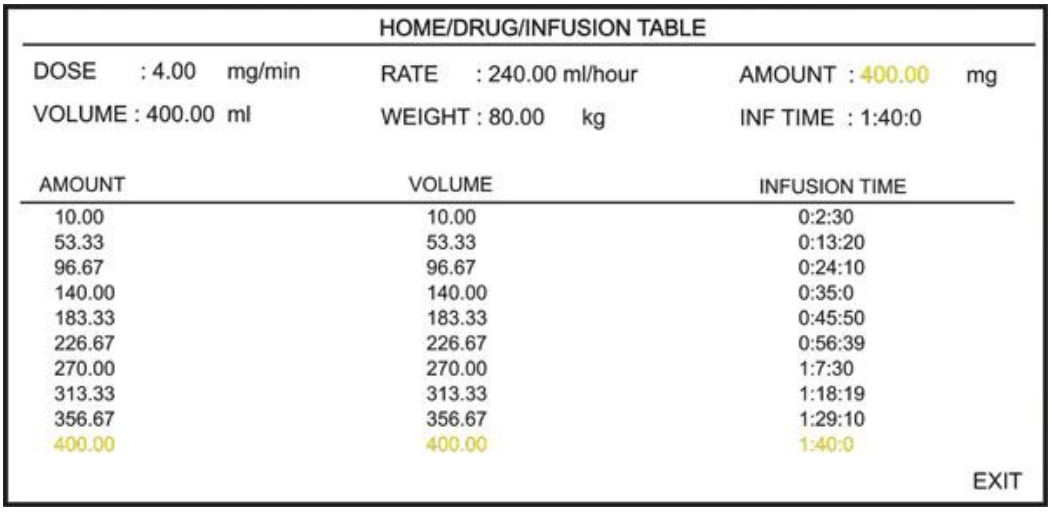
DOSE	INF RATE	DOSE	INF RATE	DOSE	INF RATE	DOSE	INF RATE
0.50	30.00	5.50	330.00	10.50	630.00	15.50	930.00
1.00	60.00	6.00	360.00	11.00	660.00	16.00	960.00
1.50	90.00	6.50	390.00	11.50	690.00	16.50	990.00
2.00	120.00	7.00	420.00	12.00	720.00	17.00	1020.00
2.50	150.00	7.50	450.00	12.50	750.00	17.50	1050.00
3.00	180.00	8.00	480.00	13.00	780.00	18.00	1080.00
3.50	210.00	8.50	510.00	13.50	810.00	18.50	1110.00
4.00	240.00	9.00	540.00	14.00	840.00	19.00	1140.00
4.50	270.00	9.50	570.00	14.50	870.00	19.50	1170.00
5.00	300.00	10.00	600.00	15.00	900.00	20.00	1200.00

EXIT

2-20 HOME/ DRUG/ TITRATION TABLE

- To review the relation between different doses of drug and time of their infusion, INF RATE for doses 0.5 to 20 (according to adjusted unit in HOME/DRUG_CALCULATION WINDOW) is displayed in this window.
- Adjusted AMOUNT, VOLUME and WEIGHT values and DOSE UNIT in HOME / DRUG_CALCULATION WINDOW are automatically displayed in this window.

Choose INFUSION TABLE >> in HOME/ DRUG_CALCULATION WINDOW to access the following window in which you can observe the relation between amount and volume of infused drug and infusion time.



2-21 HOME/ DRUG/ INFUSION TABLE

- You can review the relation between AMOUNT and VOLUME values and their corresponding INFUSION TIME in this table.

- Adjusted DOSE，RATE，AMOUNT，VOLUME，WEIGHT and INF TIME in HOME/ DRUG_CALCULATION WINDOW are automatically displayed in this window.

- User selection and calculations of HOME/ DRUG_CALCULATION WINDOW are displayed clearly in this table. AMOUNT value as well as VOLUME value and INFUSION TIME are displayed at the bottom of the table in yellow.

2.10 ABOUT

Choose "ABOUT" in HOME WINDOW to call up the following window in which you can observe the system and manufacturer information and displaying battery type.

Chapter 3, Alarm

This chapter gives general information about alarm and related functions.

⚠ **Warning** ⚠
Always verify the audible and visible alarms when monitor is powered on.

3.1 Alarm Categories

Alarms can be classified into three categories: Physiological, Technical and Prompt messages.

3.1.1 Physiological alarms

Physiological alarms also called patient status alarms are triggered by a parameter value that violates adjusted alarm limits or an abnormal patient condition.

3.1.2 Technical alarms

Technical alarms also called system status alarms are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems.

3.1.3 Prompt messages

In fact, prompt messages are not alarm messages. In addition to physiological and technical alarm messages, the patient monitor displays some messages indicating the system status. All messages are displayed in the **Message Area**.

3.2 Alarm Modes

3.2.1 Alarm Level and Setup

Portable Patient Monitor offers three levels of alarm.

Level I alarm indicates the patient's life is in danger or the monitor under use has serious problems. It is the most serious alarm.
Level II alarm means serious warning.
Level III alarm is a general warning.
Patient monitor has preset the alarm level for the parameters. You can also modify alarm level of each module in its own window.

3.2.2 Alarm Modes

Alarm messages, LEDs and sounds are designed in such a manner that can be recognizable by the operator from a distance of 1 m.

Display Screen

When an alarm is triggered by a parameter, the parameter value will blink on the screen and alarm message with regard to its level will be displayed in different backgrounds.

Level I alarm message: Red background – Black text

Level II alarm message: Yellow background – Black text

Level III alarm message: Cyan background – Black text

If the monitor displays an informative message (or if Alarm silence key is pressed), the background will change to gray.

Alarm Indicator

Alarm indicator flashes red for Level I alarm and yellow for Level II alarm and lights yellow for Level III alarm.

Alarm Sound

Corresponding alarm sound will be activated, if the alarm is not silent (i.e., the SILENCE button has not been pressed). The sounds of the alarm for the three levels are different:
Level I alarm sounds "DO-DO-DO--DO-DO" every 10 seconds;
Level II alarm sounds "DO- DO-DO" every 20 seconds;
Level III alarm sounds "DO-" every 30 seconds.

Alarm volume is adjustable in the range of 1 to 7. The sound pressure in front of the monitor and at the distance of 1m is in the range of 48 dB (A) to 63dB (A) depending on the selected volume.

NOTE:

When alarms of different levels occur at the same time, the alarm LED prompts the alarm of the highest level (red color) and the other alarms are displayed alternately in a background color corresponding to their levels.

NOTE:

If two or more alarms of the same level occur simultaneously, the alarm messages will be displayed alternately.

3.2.3 Alarm verification when the system is powered on

During the monitor is being powered on, audible and visible (yellow and red indicators) alarms will be self tested.
The monitor beeps every time it is powered on and yellow and red indicators light concurrently. The indicators turn off after the monitor powers on completely. If no beep sound is heard or no alarm indicator lights, do not use the monitoring system on any patient and notify After Sales Service.

3.3 Alarm Causes

Alarms are triggered by a parameter or by technical problems of the patient monitor. The delay time from an alarm occurrence to alarm manifestation (parameter blinking, alarm message, alarm sound) is less than 1 second (Delay time of APNEA alarm is corresponding to APNEA LIMIT setting in RESP menu)

Condition activating alarm of a parameter:
When the measurement value exceeds the adjusted alarm limits and the alarm is in "ON" mode.
If the monitor detects situations like ASYSTOLE or APNEA, alarm will be activated even when it is in "OFF" mode.

3.4 Alarm Silence Button Function

Pressing the "Alarm Silence" button once can suspend all alarm sounds for 2 minutes. Message "ALARM SILENCE" prompts in the Header Area for 120 seconds. During the 2 minutes if new alarm occurs, the Silence status will be terminated and both audible and visible alarms are triggered. If within the 2 minutes of alarm suspension the operator presses "Alarm Silence" button, the alarm suspension status will be ended and the normal alarm status resumed immediately.

3.5 Parameter Alarm

Alarm setting of each parameter can be found in its specific window. You can observe and set the alarm limits and alarm features of each parameter in its specific window.

When a parameter alarm is 'OFF', this symbol "  " is displayed beside the parameter.
When parameter alarm is 'ON', alarm limits are displayed beside the parameter. If parameter value exceeds the adjusted alarm limits, the alarm will be triggered and the following actions will take place:

1. Alarm message is displayed on the screen.

2. The monitor beeps in its corresponding alarm level and volume.
3. Alarm indicator flashes.

NOTE:

For more specific information on alarms of each parameter, refer to Appendix II.

⚠ **Warning** ⚠

Alarm settings including priority, limits and volume should be done with regard to the patient and environment conditions in a way that the patient life is not threatened and reoccurrence of alarms is prevented.

3.6 When an alarm occurs

1. Check the patient's condition.
2. Recognize related alarms to each module.
3. Identify the alarm cause.
4. Press Silence button, if necessary.
5. After removing the alarm cause, enable the alarm sound.

You will find the alarm messages of each module in its own chapter.

Chapter 4, ECG Monitoring

4.1 GENERAL

Monitoring the ECG produces a continuous waveform of the patient's cardiac electric activity for an accurate assessment of his current physiological state. The process of depolarization and repolarization of the myocardium generates electric potential that are sensed by ECG electrodes on the skin. These electrodes are typically attached to the patient's right arm, left arm and left leg. The monitor processes and amplifies these signals and presents the ECG waveform on the screen. Only proper connection of the ECG cables can ensure satisfactory measurement.

- To calculate HR value average, the values are sent per second to averaging section and any change based on user setting is made in output data.

- Response time of Saadat monitor to HR change with regard to different HR averages is as follows:

	Response Time in SAADAT monitor (s)		
	HR Avg.= 4s	HR Avg.= 8s	HR Avg.= 16s
HR= 80 to 120 BPM	5	6	11
HR= 80 to 40 BPM	7	8	13

The above results are for lead II as reference lead.

- When Tachycardia (HR >120 bpm) happens, the alarm is activated in 6 seconds. (Alarm limit between 60 bpm and 100 bpm).

- In case of cardiac arrest, the alarm is activated in 10 seconds (from 80 bpm to 0 bpm).

- The ECG module is able to reject 1.2 mV TALL-T pulses.

- The current that is applied to the patient for lead-sensing is maximum 90nA.

- Specification of noise suppression circuit:
The common noise signal with maximum current of 10μA is applied reversely to the main lead.

- The ECG patient cable consists of 2 parts: The cable that is connected to the monitor and the lead set that is connected to the patient.
- Hear rates measured for the 4 irregular rhythms according to EC 13: 2002 are as follow:

Irregular rhythm	**Measured HR**
3a ventricular bigeminy	85
3b slow alternating ventricular bigeminy	67
3c rapid alternating ventricular bigeminy	127
3d bidirectional systoles	100

⚠**Warning**⚠
Do not touch the patient, bed, table nearby or the monitor during defibrillation.

⚠**Warning**⚠
Use only the recommended manufacturer ECG cable for monitoring. Other ECG cables and leads may cause improper performance and/or reduce protection during defibrillation.

⚠**Warning**⚠
Before monitoring check ECG cable safety and replace cables that are damaged, scratched, torn, or their lead-wires distorted.

⚠**Warning**⚠
Pay attention that ECG cable is not subjected to tension during connection.

⚠**Warning**⚠
Line Isolation Monitor (LIM) transient may resemble actual cardiac waveforms and thus inhibit heart rate alarms. Such transients may be minimized by proper electrode and cable placement, as specified in this manual.

⚠**Warning**⚠
When you connect the cables and electrodes, make sure that no metal part is in contact with the earth. Verify that all ECG electrodes are correctly attached to the patient.

⚠**Warning**⚠
Select patient mode carefully because QRS detection limits and HR measurement algorithm are different in Adult and Neonate modes.

NOTE:

Interference from a non-grounded instrument near the patient and/or ESU (Electro Surgical Unit) interference can cause the waveform inaccuracy.

1. Prepare the patient's skin prior to place the electrodes.
■ The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.
■ Shave hair from the selected sites, if necessary.
■ Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because increases skin impedance).
■ Rub the skin briskly to increase capillary blood flow in the tissues.

2. Put the electrodes on the patient body. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not self-supplied electrolyte. (Figure 4-1, 4-2, 4-5)
3. Attach clip or snap to electrodes prior to placement.

⚠Warning⚠

Use only one type of electrode on the same patient to avoid variations in electrical resistance. For ECG monitoring, it is recommended to use silver/silver chloride electrode. When dissimilar metals are used for different electrodes, the electrodes may cause large offset potentials due to polarization, which may be severe enough to prevent obtaining an ECG trace. Using dissimilar metals may also increase recovery time after defibrillation.

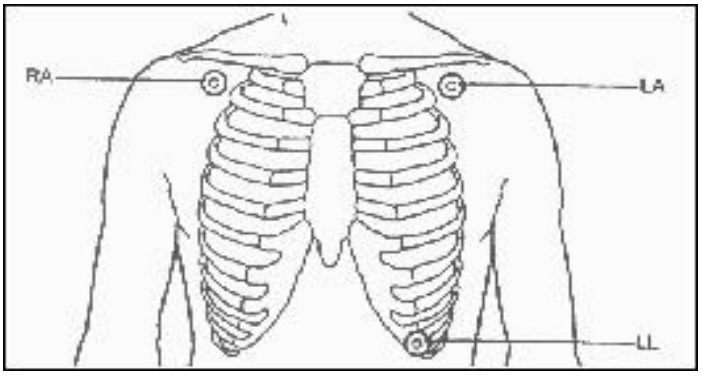


Figure 4-1 ECG 3-lead placement

Electrode placement for 3-lead set (figure 4-1)
Right Arm (RA): red electrode, be placed near the right shoulder, directly below the clavicle.
Left Arm (LA): yellow electrode, be placed near the left shoulder, directly below the clavicle.
Left Arm (LL): green electrode, be placed on the left hypogastrium.

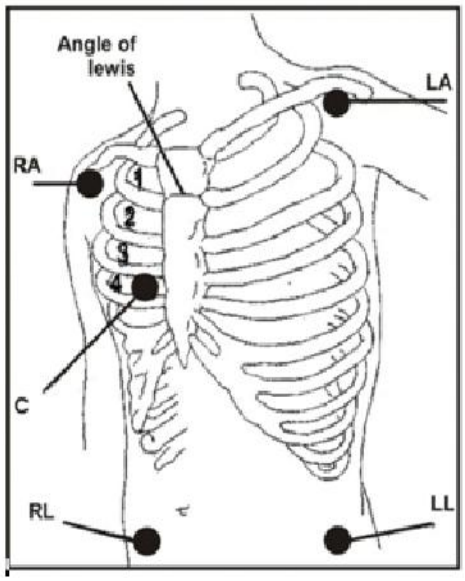


Figure 4-2 ECG 5-WIRE placement

Electrode placement for ECG 5 -WIRE (figure 4-2)
Right Arm (RA): red electrode, be placed near the right shoulder, directly below the clavicle.
Left Arm (LA): yellow electrode, be placed near the left shoulder, directly below the clavicle.
Chest (C): white electrode, be placed on the chest as illustrated in figure 4-2
Right Leg (RL): black electrode, be placed on the right hypogastrium.
Left Leg (LL): green electrode, be placed on the left hypogastrium.

NOTE:
To ensure patient safety, all leads must be attached to the patient. Make sure that there is no contact between metallic or conductive parts of electrodes and other conductive or metallic parts and/or protective earth.

For ECG 5-WIRE mode, attach the C-electrode to different positions on the chest:
- V1 on 4th intercostal space at the right sterna margin.
- V2 on 4th intercostal space at the left sterna margin.
- V3 midway between V2 and V4 electrodes.
- V4 on the 5th intercostal space at the left clavicular line.
- V5 on the left anterior axillary line, horizontal with V4 electrode.
- V6 on the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R on the right side of the chest in positions corresponding to those of V3-V6.
- VE over the xiphoid position.

For posterior C lead placement, place the C electrode at one of the following locations.
- V7 on the 5th intercostal space at the left posterior axillary line of back.
- V7R on the 5th intercostal space at the right posterior axillary line of back

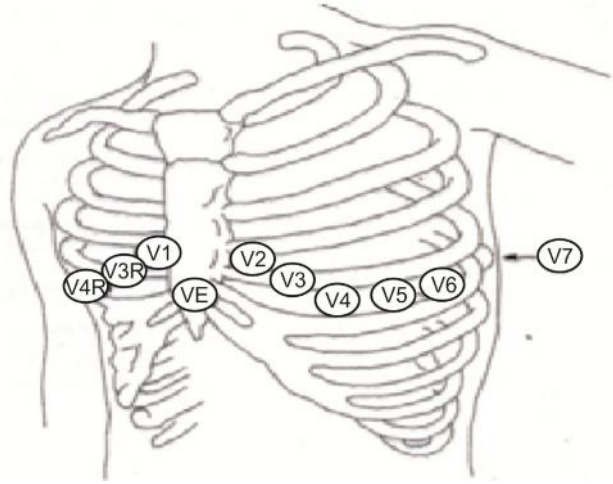


Figure 4-3 C-electrode placement for ECG 10-WIRE mode

Depending on lead type (3-WIRE or 5-WIRE), you can choose different leads I, II, III, aVR, aVL, aVF and V.

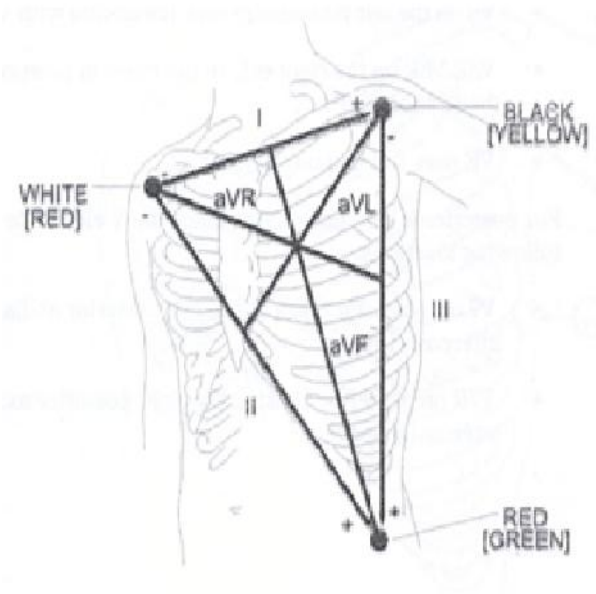


Figure 4-4 ECG leads

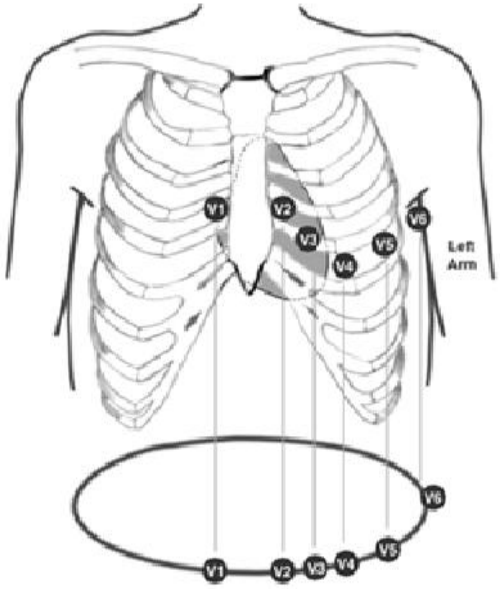


Figure 4-5 ECG 12-lead placement

Electrode placement for ECG 12-lead set (figure 4-5)

Right Arm (RA): red electrode, be placed near the right shoulder, directly below the clavicle.
Left Arm (LA): yellow electrode, be placed near the left shoulder, directly below the clavicle.
Right Leg (RL): black electrode, be placed on the right hypogastrium.
Left Leg (LL): green electrode, be placed on the left hypogastrium.
Chest (V1 –V6): white electrode, be placed on the chest as illustrated in figure 4-5

For ECG 10 -WIRE mode, attach the C electrodes (V1-V6) to different positions on the chest:

- V1 on 4th intercostal space at the right sterna margin.
- V2 on 4th intercostal space at the left sterna margin.
- V3 midway between V2 and V4 electrodes.
- V4 on the 5th intercostal space at the left clavicular line.
- V5 on the left anterior axillary line, horizontal with V4 electrode.
- V6 on the left middle axillary line, horizontal with V4 electrode.

NOTE:

Main lead is adjusted in ECG menu. In pages that more than one trace of ECG signal is displayed, the first trace is related to the main lead.

⚠**Warning**⚠

Check everyday whether there is skin irritation resulted from the ECG electrodes. If so, replace electrodes or change their sites.

⚠**Warning**⚠

Verify lead fault detection prior to the start of monitoring phase.

⚠**Warning**⚠

Unplug the ECG cable from the socket, the screen will display the error message "ECG NO CABLE"

⚠**Warning**⚠

When using Electrosurgery equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the grounding plate to avoid burning. The placing of the ECG leads will depend on the type of surgery that is being performed. For example, with open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts can sometimes affect the ECG waveform due to the use of ESU (Electro Surgical Unit). To reduce this effect, you can place the electrodes on the right and left shoulders and on the left side of hypogastrium. Avoid placing the electrodes on the upper arms (except when the ECG waveform is too weak).

⚠**Warning**⚠

When using ESU, never place an electrode near the grounding plate of the Electrosurgery device, otherwise there will be a great deal of interference with the ECG signal.

⚠**Warning**⚠

It is possible for the patient to be burnt due to an improper connection of the natural electrode of ESU.

⚠**Warning**⚠

ECG cable may be damaged if they are connected to a patient during defibrillation. Cables that have been connected to a patient during defibrillation should be checked for functionality before being used again.

NOTE:

If an ECG waveform is not accurate while the electrodes are tightly attached, try to change the lead.

NOTE:

Interference from a non-grounded instrument near the patient and/or ESU interference can cause inaccuracy of the waveform.

NOTE:

Applied lead for ST, ARR, Pace and HR is main lead that is displayed in the first trace and can be adjusted in ECG menu.

NOTE:

Due to high voltage of signal amplitude in leads II and V, it is recommended to select one of these leads as main lead.

Normal QRS complex is:

- With tall R-wave completely above or below the baseline
- With T -wave less than one-third of the R-wave height.
- With P-wave much smaller than the T -wave.

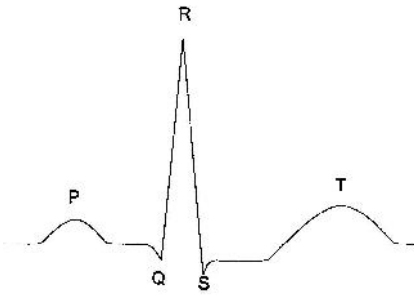


Figure 4-6 Standard ECG waveform

⚠Warning⚠

Do not immerse ECG leads completely in water, solvents or cleaning solutions because the connectors are not waterproof. Do not sterilize ECG cable by irradiation, steam, or ethylene oxide.

⚠Warning⚠

For the patients with pacemaker, the monitor may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon monitor alarms. Keep the patients with pacemaker under close surveillance. (Refer to 4-2 for relevant information about Pace pulses).

4.2 ECG WINDOW

The following items can be monitored in ECG parameter window:

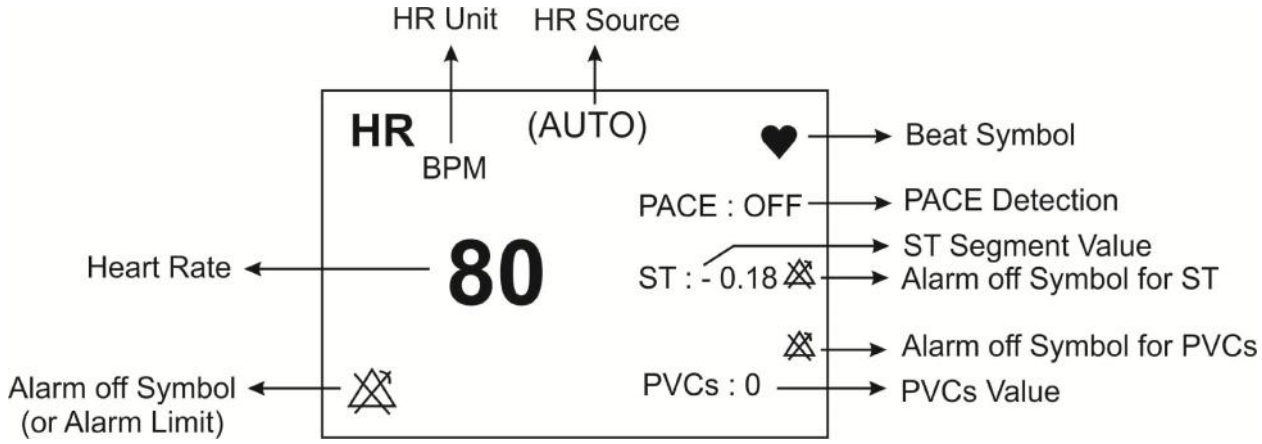


Figure 4-7 ECG PARAMETER WINDOW

Pick ECG, the following menu will pop up:

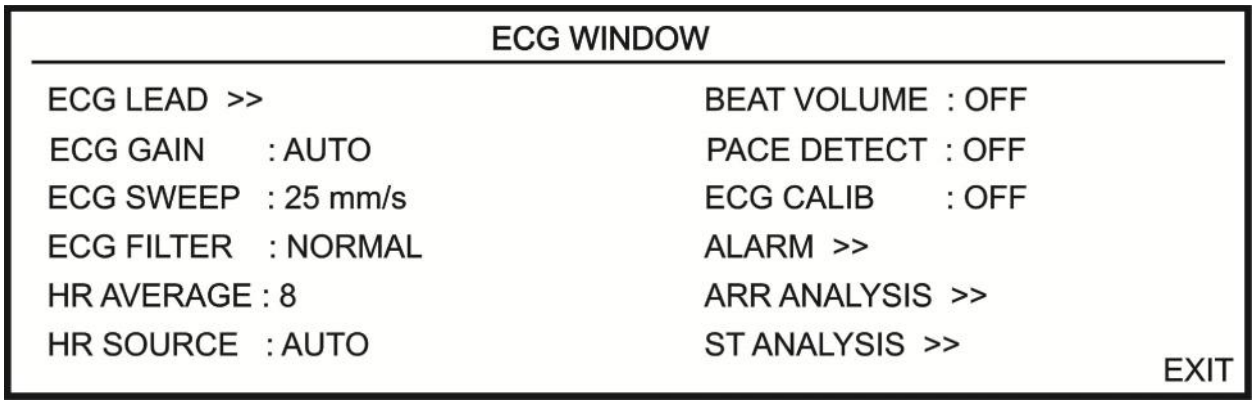


Figure 4-8 ECG WINDOW

- **ECG LEAD**: by pressing ECG LEAD, the following menu will pop up:

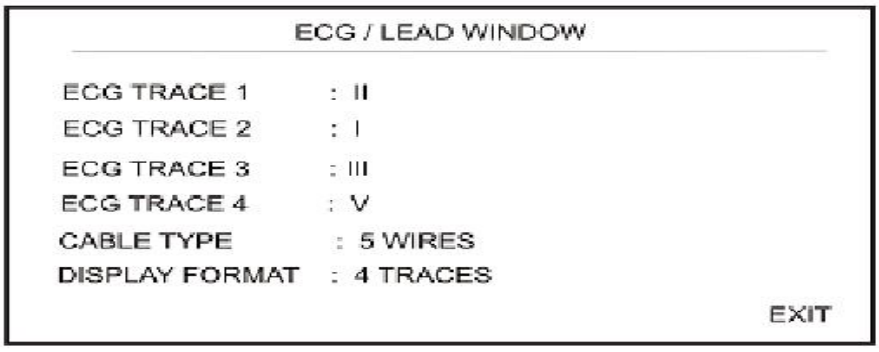


Figure 4-8 ECG / LEAD WINDOW

- **ECG TRACE**:

You can choose the following leads for traces 1 to 7:

"I" to count the heart rate and show RA-LA waveform

"II" to count the heart rate and show RA-LL waveform

"III" to count the heart rate and show LA-LL waveform

"aVR" to count the heart rate and show RA-$\frac{LA+LL}{2}$ waveform

"aVL" to count the heart rate and show LA-$\frac{RA+LL}{2}$ waveform

"aVF" to count the heart rate and show LL-$\frac{RA+LA}{2}$ waveform

"V" to count the heart rate and show C-$\frac{RA+LA+LL}{3}$ waveform

NOTE:

In the absence of a proper signal, the monitor is not able to count the heart rate and instead of the HR number, the mark (-?-) is displayed in the ECG window.
The following are the reasons for this:
- For 3-wire cables:
Each of the electrodes is disconnected or not connected properly.
- For 5 or 10-wire cables:
1- Both or one of the electrodes of reference lead are disconnected or not connected properly.
2- The RL electrode is disconnected or not connected properly.

You can choose aVR, aVL, aVF and V just when ECG is in 5-WIRE mode. The leads V2,V3,V4,V5 and V6 can be observed only in 12-lead ECG mode.

NOTE:

ECG signal saturation occurs when the signal is not displayed and exceeds lower or upper limits of the display area.

- **CABLE TYPE**

To adjust ECG measurement mode to "3 WIRES", "5 WIRES "and "10 WIRES".

- **DISPLAY FORMAT**

If you select "3 WIRES" for CABLE TYPE, only Cascade mode is applicable.

If you set CABLE TYPE to"5 WIRES", the following options will be available for DISPLAY FORMAT:
Cascade: in this mode, only main lead (ECG TRACE 1) can be changed and ECG signal is displayed in two traces.
2 TRACES: the signals of two leads are displayed in two traces. You can select any lead for ECG TRACE 1, but selected leads for TRACE 2 and TRACE 1 cannot be the same.
4 TRACES: the signals of four leads are displayed in this mode. You can select any lead for ECG TRACE 1, but selected leads for ECG TRACE 2, TRACE 3 and TRACE 4 cannot be the same.
7 TRACES: the signals of the seven ECG leads are displayed in this mode. Only main lead can be changed.
If you set CABLE TYPE to"10 WIRES", 12TRACES as well as above options will be available for DISPLAY FORMAT:

12 TRACES: ECG signals of twelve leads are displayed in 12 traces. The main lead in this mode always is **I** and cannot be changed.

■ **ECG GAIN**

To adjust the size of ECG waveform, select gain value for each lead from ×0.25, ×0.5, ×1, ×2, ×4 and AUTO.
In "AUTO" mode, the monitor chooses an appropriate gain automatically.

■ **ECG SWEEP**

Available options for ECG SWEEP are 12.5, 25, and 50 mm/s.

■ **ECG FILTER**

For clearer and more detailed waveform.

FILTER TYPE	FREQUENCY RANGES	APPLICATION
NORMAL	**0.5-40HZ**	In normal use.
EXTENDED	**0.05-100HZ**	In diagnostic application. but the ECG waveform might have some noises
MONITOR	**0.5-24HZ**	This mode may reduce interference from Electrosurgery equipment or can be used when the system has high noises or doesn't have equipotential earth.

■ **HR AVERAGE**

Available options for HR AVERAGE are 4, 8 and 16 sec.
Maximum time of HR value changing is based on the selected HR AVERAGE value. For example, if HR AVERAGE is set to 8 sec and HR value changes from 90 to 200, it will take maximum 8 seconds to display HR changes.

■ **HR SOURCE**

The heart rate may be derived from “ECG”, “SpO2”, “IBP1”, “IBP2”, “IBP3” and “IBP4” signals. Default setting for this item is AUTO.

In AUTO mode the below conditions will be provided:

- The heart rate is derived from every signal that is being monitored.
- If two or more signals are being monitored simultaneously, the heart rate derivation will be done based on the signals priority, i.e. the heart rate will be derived respectively from ECG, SpO2, IBP1, IBP2, IBP3 or IBP4 signal.

- If the heart rate is derived from any signal except ECG, PR alarms will be enabled based on HR alarm settings (Alarm Level and Alarm Limit).

NOTE:

IBP3 and IBP4 can only be active in the ALBORZ B9 system

NOTE:

If HR SOURCE is set to any signal except ECG, beat symbol and sound will be according to the selected signal.

NOTE:

If HR SOURCE is set to any module except ECG, HR will change to PR and its color unit will change corresponding to the selected module for HR SOURCE.

NOTE:

Deriving HR from IBP signal is possible just in ART, PAP, RVP, LVP and IBP labels.

NOTE:

If "HR SOURCE" is set to any module and cable of the module is not connected to the system, HR value will not be displayed.

NOTE:

Deriving HR value from IBP signal is not possible in the following conditions and the HR value will be displayed "---":

- **"IBP1/IBP2 STATIC PRESSURE" message on the display**
- **"IBP1/IBP2 SEARCH" message on the display**
- **HR value less than 25**
- **Selecting CVP, LAP and RAP labels.**

NOTE:

HR value measurement range is 25 ~240 bpm, when the HR is derived from IBP signal.

■ **BEAT VOLUME**

Range: 1-7; "OFF" indicates silence, while 7 indicates maximum volume.

■ **PACE DETECT**

"ON" for patient with pacemaker," OFF" for patient without pacemaker.

When PACE DETECT is "ON", the ECG monitoring system detects and rejects pacemaker-generated signals from ECG signal so that they will be ignored in determining heart rate.

Detected pacemaker signals will be marked on the ECG waveform as 1 centimeter spike. Monitoring of patients with pacemaker is not generally affected when PACE DETECT is enabled. However, in some instances if the patient does not have a pacemaker, it may be desirable to turn the detection function OFF so that artifacts in the waveform will not be mistaken for a pacemaker signal.

NOTE:

ECG signals with the slope of up to 1 V/s will not be counted as Pace signal.

NOTE:

Ineffectively paced QRS beside atrial pace pulses which precede ventricular paces by 150 ms to 250 ms will be rejected in addition to normal pace pulses.

⚠**Warning**⚠

For patients with pacemaker, PACE DETECT must be switched "ON", otherwise, the pace pulses may affect HR counting and result in low precision of HR value.

- **ECG CALIB**

Pick "ON" to view 1mV calibrated ECG wave. When it is "ON", the calibration waveform will be displayed until closing the ECG WINDOW or turning the rotary switch.

- **ALARM**

Pick "ALARM" in ECG WINDOW to call up the following menu:

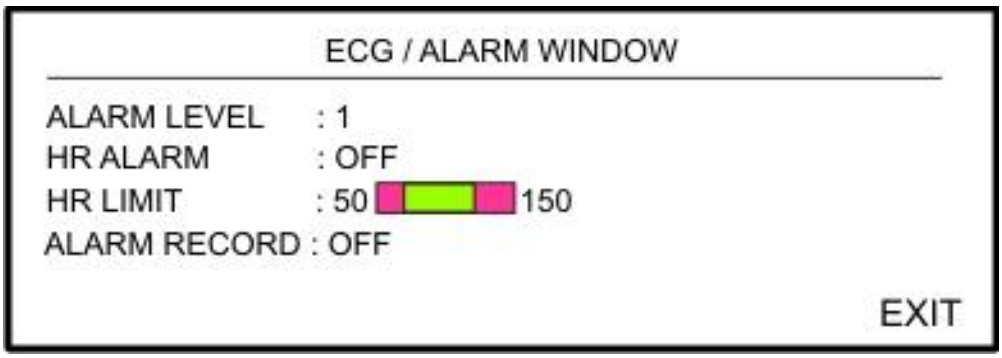


Figure 4-9 ECG/ALARM WINDOW

- **ALARM LEVEL**

Selectable between 1and 2. Level 1 represents the most serious case.

- **HR ALARM**

Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions and there will be a "  " symbol in the Parameter Area.

- **HR LIMIT**

ECG alarm is activated when the heart rate exceeds adjusted ALARM HIGH value or falls below adjusted ALARM LOW value.(min:30 and max:250)

■ ALARM RECORD

See the chapter **"RECORDING"**.

■ ARR ANALYSIS

Pick "ARR ANALYSIS" in ECG WINDOW to call up the window for arrhythmia analysis setting. This monitor is able to detect up to 13 types of arrhythmia. Refer to the chapter **"ARR MONITORING"** for detailed information about arrhythmia analysis in the system.

■ ST ANALYSIS

Pick "ST ANALYSIS" in ECG WINDOW to call up the window for ST analysis setting. The system is able to monitor ST segment deviation. Refer to the chapter **"ST MONITORING"** for detailed information about ST analysis in the system.

4.3 ECG OUTPUT *

An analog ECG signal is obtained from ECG OUTPUT connector located on the power plate. This signal is similar to the displayed ECG signal on the monitor and can be used as an input for some devices such as Electro shock.

⚠**Warning**⚠

Use the company designed cable to make connection between ECG OUTPUT connector and other devices.

⚠**Warning**⚠

To avoid any cable strain or damage, bedside monitor should be placed in a proper distance from reference device.

⚠**Warning**⚠

For patient with pacemaker, the PACE DETECT function must be switched "ON".

NOTE:

Pace signals will be marked on ECG OUTPUT signal as a square pulse with amplitude of 5 Volt and width of 5 ms.

NOTE:

If the patient does not have a pacemaker, it may be desirable to turn the detection function OFF, so that artifacts in the waveform will not be mistaken for a pacemaker signal.

4.4 ECG Alarms

a) Physiological alarms

The alarm sounds when:

1. The heart rate violates the adjusted alarm limits, and/or,
2. The ECG ASYSTOLE occurs.

Alarm	Situation	Visual prompts	Audio sound
HR HIGH	Heart rate violates adjusted high limit	●HR value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
HR LOW	Heart rate violates adjusted low limit	●HR value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
ECG ASYSTOLE	Heart beat is not detected in last 10 seconds.	● HR is "0" and blinks ●The alarm indicator flashes. ●The alarm message is displayed in red background.	Activated

b) Technical alarms

Alarm	cause	solution	explanation
ECG NO CABLE	ECG cable is not connected to the system	Connect ECG cable.	Alarm level 3- the message is displayed in cyan background. By Pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault until reconnecting the cable.
ECG CHECK LA, RA, LL	Mentioned leads are not properly connected.	Make sure that mentioned electrode is properly connected.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

ECG DEFECT	ECG module failure	Power off and then on the system .If this message is displayed again the user should contact local After Sale Service.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
ECG CHECK RL OR ALL	RL or other leads are not properly connected to the patient.	Make sure that all electrodes esp. RL and ECG cable are properly connected.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
ECG CHECK LL OR ALL	LL or other leads are not properly connected to the patient.	Make sure that all electrodes esp. LL and ECG cable are properly connected.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
ECG CHECK LA OR ALL	LA or other leads are not properly connected to the patient.	Make sure that all electrodes esp. LA and ECG cable are properly connected.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
ECG CHECK RA OR ALL	RA or other leads are not properly connected to the patient.	Make sure that all electrodes esp. RA and ECG cable are properly connected.	Alarm level 2-the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
ECG CHECK C (C2, C3, C4, C5, C6)	C lead is not properly connected to the patient.	Make sure that all electrodes esp. C and ECG cable are properly connected.	Alarm level 2-the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

The last four alarms in the table are just for 5-WIRE mode.

After checking the mentioned solution, if above mentioned messages are displayed again, the ECG cable may be damaged and you should contact with local After Sales Services.

4.5 ECG CABLE CLEANING

If there is any sign indicating that the ECG cable may be damaged or deteriorated, replace it with a new one instead of continuing its application on the patient.

- **Cleaning**
  Use soft cloth moistened in mild soap liquid or cleaning agent containing 70% ethanol to clean the ECG cable.

- **Disinfection**
  To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

Chapter 5 RESP Monitoring

5.1 GENERAL

The monitor measures respiration rate from the amount of thoracic impedance between two ECG electrodes (RA-LL or RA-LA). The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

The signal with frequency greater than 62.5KHZ is applied to the patient for respiration measurement.

For RESP monitoring, it is not necessary for additional electrodes, however, place of electrodes is important. Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.

NOTE:

The RESP monitoring is not recommended to be used on patients who are very active as this can cause false alarms.

Checklist for RESP Monitoring:

1. Prepare the patient's skin prior to placing the electrodes.
2. Attach the electrodes to the patient and attach snap or clip to the electrodes.
3. Switch on the monitor.

NOTE:

Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes to prevent cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

5.2 RESP WINDOW

If RESP is used for respiration assessment, RESP parameter window will be as below:

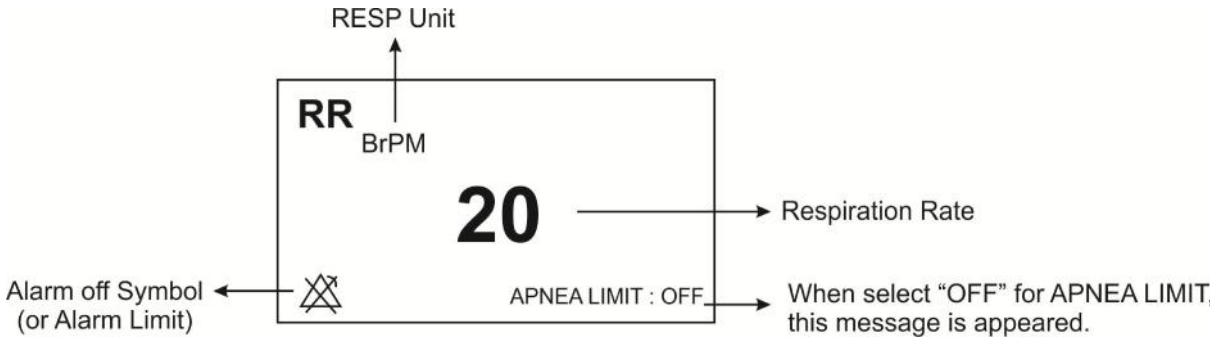


Figure 5-1 RESP PARAMETER WINDOW

Pick RESP to call up the following menu:

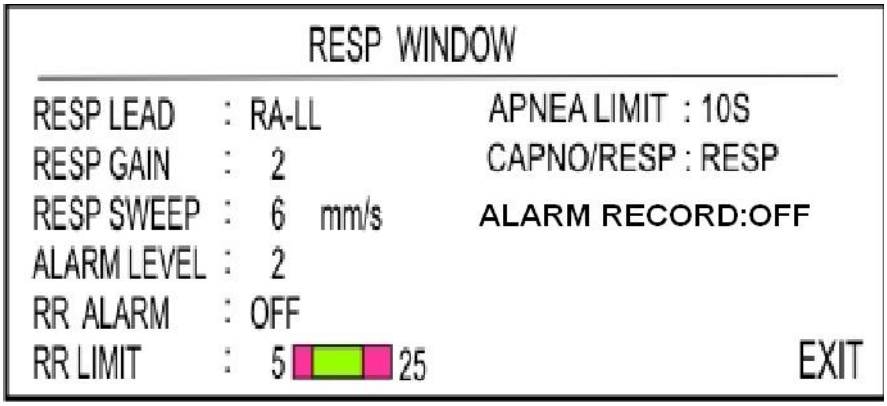


Figure 5-2 RESP WINDOW

- **RESP LEAD**

Available options for RESP LEAD are "RA-LA" and "RA-LL"

- **RESP GAIN**

To adjust the size of RESP waveforms, select gain value for each channel from ×0.25, ×0.5, ×1, ×2 and ×4.

- **RESP SWEEP**

Available options for RESP SWEEP are 3, 6, 12/5, and 25 mm/s.

- **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

- **RR ALARM**

Pick "ON" to enable RESP alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions, and there will be a" ⚠"symbol in the Parameter Area.

- **RR LIMIT**

RESP alarm is activated when the respiration rate exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (min:5 and max:150)

- **APNEA LIMIT**

To set the standard of judging an apnea case. It can be set to 10 – 40 seconds and OFF and increases/decreases by 10s. When you select OFF, the message “APPNEA LIMIT: OFF” will appear at the bottom of RR window in red color.

NOTE:

APNEA alarm is always enabled with level 1 and ON/OFF status of RR ALARM has not any effect on it.

- **CAPNO/RESP**

To select “RESP” or “CAPNO” module for measuring respiratory rates. Available options are “RESP” and “CAPNO”. In “RESP” mode, CAPNO module is set to standby mode and RESP parameters and waveform are displayed.

- **ALARM RECORD**

See the chapter **“RECORDING”**.

5.3 RESP Alarm Messages

a) Physiological alarms

The alarm is activated when the respiration rate exceeds the adjusted alarm limits.

Alarm	Situation	Visual prompt	Audio sound
RR HIGH	Respiration rate violates adjusted high limit	●RESP value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
RR LOW	Respiration rate violates adjusted low limit	●RESP value blinks ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
APNEA	Non-respiration condition overruns adjusted time	● The alarm indicator flashes ●The message "RESP APNEA" is displayed in red background.	Activated

a) Technical alarms

Alarm	Cause	Solution	Explanation
RESP CHECK LEADS	The RESP leads are not properly connected to the patient.	Make sure that all electrodes are properly connected.	Alarm level 3- The message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault. The alarm is activated when RR ALARM is "ON".

Chapter 6, SPO2 and Rainbow* Parameters Monitoring

6.1 GENERAL

SpO2 Rainbow module is the only technology which measures multiple blood parameters as well as common pulse oximetry parameters (SpO2 and Pulse Rate) in a continuous and non-invasive method that traditionally measured through the invasive and time-consuming methods. This module is designed by Masimo Company and submitted to its approved companies.

Measurable physiological parameters by Masimo Rainbow module

SpO2
Pulse Rate
Perfusion Index (PI)
and optional parameters such as:
SpHb
SpOC
SpCo
SpMet
Pleth Variability Index (PVI)

% SpO2

Extent of oxygen saturation in hemoglobin of arterial blood can be detected from the SpO2 waveform. For example, if 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has an oxygen saturation of 97%. The SpO2 value on the monitor will be 97%. The SpO2 value shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin.

$$SPO_2 = \frac{O_2Hb}{O_2Hb + HHb} \times 100$$

Pulse rate

PR indicates the Heart Rate per minute which SpO2 module extracts from the pulse oximetry signal.

Perfusion Index

Perfusion index (PI) indicates arterial pulse signal strength as a ratio of pulsatile blood flow to the non-pulsatile blood.

Perfusion Index enables you to choose the best position for sensor placement.

$$\mathbf{PI = \frac{AC}{DC} \times 100\%}$$

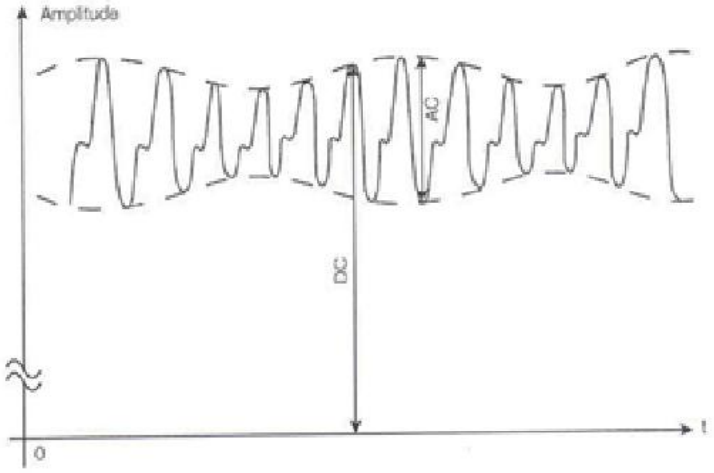


Figure 6-1 PI definition

PI greater than 1% is preferable.

SpHb

SpHb indicates the level of total hemoglobin in the arterial blood. The unit of measurement is grams per decilitre (g/dL).

SpOC

SpOC indicates oxygen content in the blood. Neither SpO2 nor Hb parameter by itself can indicate the actual amount of oxygen in the blood. A patient with normal SpO2 or Hb may have low levels of oxygen. In fact, both SpO2 and Hb are considered by SpOC parameter. The unit of measurement is ml/dL (milliliters of oxygen per deciliter of blood).

SpCO

This parameter indicates the level of carbon monoxide concentration in arterial blood. It is expressed as a percentage of hemoglobin bound with carbon monoxide.

SpMet

This parameter indicates the level of methemoglobin concentration in arterial blood. The amount is expressed as percentage (ratio of methemoglobin to total hemoglobin in blood)

Pleth Variability Index

This parameter is to measure dynamic changes in PI during the respiratory cycle which can be extremely associated with intrathoracic pressure changes.

PVI can be a useful noninvasive monitoring method or an advanced indicator to detect physiological changes of intrathoracic pressure. During one or two complete respiratory cycle, PVI is calculated as follows:

$$PVI = \frac{PI_{Max} - PI_{Min}}{PI_{Max}} \times 100\%$$

PVI can help clinicians predict fluid responsiveness in patients.

■ The %SpO2, PR, PI, PVI, SpOC, %SpMet, %SpCo and SpHb values can be displayed on the main screen. The Pleth waveform is displayed as normalized waveform and its amplitude does not comply with real blood volume variations.

■ User can be informed of inadequacy of signal and physiological parameters values by various messages and alarms in necessary situations.

Operating Principals

1.Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxhygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

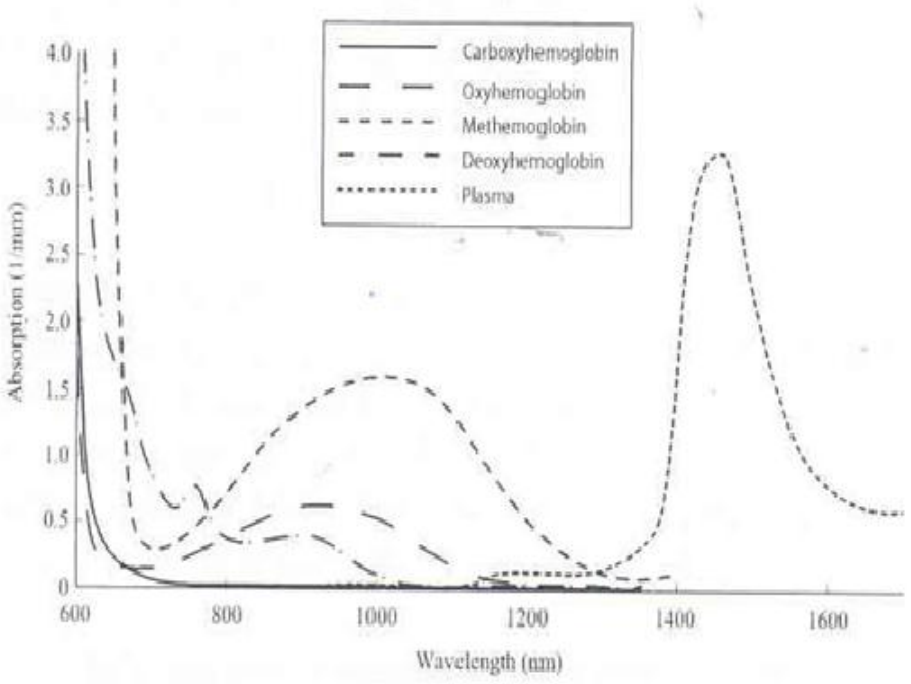


Figure 6-2 Absorption Spectra

2.The amount of arterial blood in the tissues changes with your pulse (photoplethysography).Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

A multi-wavelength sensor is used to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma. This sensor is utilized with various light-emitting diodes (LEDs) that pass light through the site to a photodiode (detector). Signal data is obtained by passing various visible and infrared lights (LED's, 500 to

1400 nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful for clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the module for calculation.

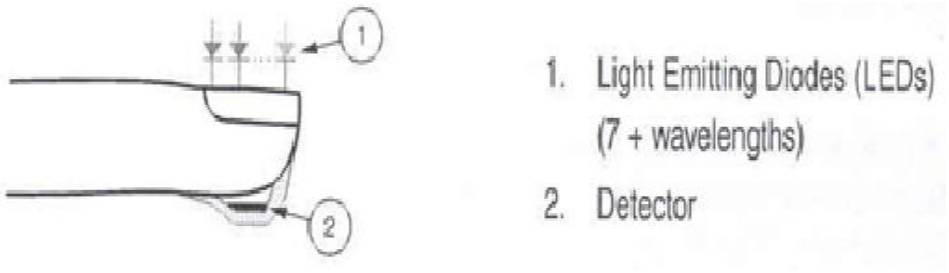


Figure 6-3 Light Emitting Diodes and Detector

Once the signal is received from the sensor, it utilizes Masimo Rainbow SET signal extraction technology to calculate the patient's functional oxygen saturation (SPO2 (%)), blood levels of carboxy hemoglobin (SpCO (%)), methemoglobin (SpMet (%)), Total Hemoglobin concentration (SpHb g/dl) and pulse rate (PR (PPM)).

Signal Extraction Technology (SET)

Masimo (SET) signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise).

Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform (DST), readily identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

NOTE:

For more information about Masimo Rainbow module, please refer to APPENDIX III. Also, For Masimo patent information, please refer to the following address: "www.masimo.com/patents.htm"

NOTE:

A pulseoximetry is an early warning device .Use lab co-oximeter to understand the patient's condition completely.

NOTE:

A functional tester cannot be used to assess the accuracy of the pulse co-oximeter.

⚠**Warning**⚠

The pulse co-oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

⚠**Warning**⚠

Use only the recommended manufacturer SpO2 sensor for monitoring. Other SpO2 sensors may cause monitor malfunction, thus operator is responsible to select an appropriate sensor before use.

⚠**Warning**⚠

Regarding the selected module, use accessories specified for each SpO2 module (refer to chapter Accessories)

⚠**Warning**⚠

While choosing sensor, consider sensor direction for use, written on the package such as patient's age and weight or if the sensor is reusable or disposable.

⚠**Warning** ⚠

Do not use the SpO2 sensors if the packaging or the sensor is damaged and return them to the vendor.

⚠**Warning**⚠

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

⚠Warning⚠

Do not place the accessories in any position that might cause it to fall on the patient.

⚠Warning⚠

Do not immerse sensor and patient cable completely in water, solvents, or cleaning solutions because the sensor and patient cable are not waterproof.

⚠Warning ⚠

ESU wire and SpO2 cable must not be tangled up.

⚠Warning⚠

Do not use the sensor on extremities with arterial catheter or venous syringe.

⚠Warning⚠

Do not start or operate the pulse co-oximeter unless the setup was verified to be correct.

⚠Warning⚠

Verify sensor cable fault detection before monitoring. Unplug the SpO2 sensor cable from its socket, the screen will display the error message "SpO2 NO PROBE"

⚠Warning ⚠

Do not repair or modify the pulse co-oximeter accessories. Injury to user or equipment damage could occur. Contact with After Sales Services for servicing if necessary.
Changes or modifications shall void the guaranty for the pulse co-oximeter accessories.

⚠Warning⚠

Explosion hazard: Do not use the pulse co-oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

⚠Warning⚠

To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.

⚠Warning⚠

If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse co-oximeter for proper functioning.

⚠Warning ⚠

The pulse co-oximeter is not an apnea monitor.

⚠Warning ⚠

The pulse co-oximeter should not be used for arrhythmia analysis.

⚠Warning⚠

Pulseoximetry can overestimate the SpO2 value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.

⚠Warning⚠

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor and result in inaccurate measurements. To prevent interference from ambient light, cover the Rainbow sensor with an ambient light shield.

⚠Caution

When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

⚠Caution

If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the instrument might read zero for the duration of the active irradiation period.

⚠Caution

To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse co-oximeter is used.

⚠Caution

Variation in haemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any result exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments

NOTE:

SpO2 module updates SpO2 and pulse rate values every 1 sec.

NOTE:

Do not perform SpO2 and NIBP measuring in same arm simultaneously; because obstruction of blood flow during NIBP measuring may adversely affect the SpO2 value.

Measurement range of SpO2 and PR parameters in SpO2 MASIMO module is as follows:

Parameter	Measurement Range
SpO2	0 – 100%
Pulse Rate	25 – 240 bpm

Measurement range of MASIMO Rainbow set is as follows:

Parameter	Measurement Range
SpMet	0.0 – 99.9%
SpCO	0.0 – 99%
SpHb	0.0 – 25.0 g/dL
SpOC	0.0 – 35.0 ml /dL
Perfusion Index	0.0 – 20%
PVI	0 – 100%

Materials used in our SpO2 sensors are innoxious.

SpO2 measurement:

1.Turn on the monitor.

2.Attach the sensor to the appropriate site of the patient finger (Refer to Figure 6-4 for the proper method)

3.Plug the connector of the sensor extension cable into the SpO2 socket on the left side of the device.

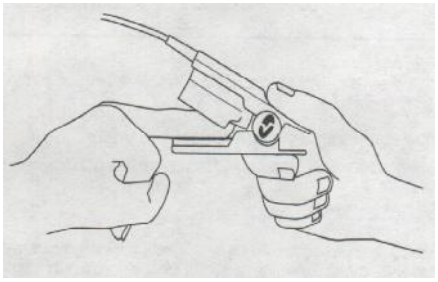


Figure 6-4 SPO2 sensor placement

NOTE:

- **Make sure the nail covers the light window.**
- **The wire should be on the backside of the hand.**

NOTE:

SpO2 value is always displayed in a fixed position of SpO2 window and Pulse Rate is displayed beside it, but if "HR SOURCE" is set to "SpO2", PR value will be eliminated from SpO2 window and displayed instead of HR value in the ECG WINDOW.

⚠**Warning** ⚠

Measurement limitations

a) The accuracy of all SpO2 parameters measurement can be affected by:

- **Improper sensor application.**
- **Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2.**
- **Intravascular dyes, such as indocyanine green or methylene blue.**
- **Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.**
- **Elevated levels of bilirubin.**
- **Severe anemia.**
- **Low arterial perfusion.**
- **Motion artifact.**
- **Sensor temperature (maintain between 28° C and 42° C for best operation)**
- **Electroshock and electrosurgical interference**

- **External illumination more than 5,000 lumens/square meter (typical office lighting)**
- **Venous pulsations**
- **Cabling entanglement or strangulation**
- **Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line**
- **Do not use pulse co-oximeter during magnetic resonance imaging (MRI) or in an MRI environment. Induced current could potentially cause burns.**

b) The accuracy of SpCO and SpMet parameters measurement can be affected by:

- **Abnormal haemoglobin levels.**
- **Low arterial oxygen saturation levels including altitude induced hypoxemia.**
- **Elevated total bilirubin levels.**

c) The accuracy of SpHb and SpOC parameters measurement can be affected by:

- **Elevated PaO2 levels.**
- **Low arterial oxygen saturation levels**
- **Elevated carboxyhemoglobin levels.**
- **Elevated methemoglobin levels.**
- **Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.**
- **Vasospastic disease such as Raynaud's.**
- **Elevated altitude.**
- **Peripheral vascular disease.**
- **Liver disease.**
- **EMI radiation interference.**

⚠**Warning** ⚠

Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

⚠**Warning** ⚠

SpO2, SpCO, SpMet, and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

⚠**Caution**

If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

⚠Caution

If "SpO2 LOW PERFUSION" message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

⚠Warning⚠

Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion. Check per 2-3 hours the sensor placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.

⚠Warning⚠

Tissue damage or inaccurate measurement can be caused by incorrect application or use of an SpO2 sensor, for example by wrapping the sensor too tightly or by applying supplemental tape.

⚠Warning⚠

Loss of pulse signal can occur when

- **The patient is in cardiac arrest or in shock.**
- **The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.**
- **There is arterial occlusion proximal to the sensor.**

6.2 SPO2 WINDOW

The following items are displayed in SpO2 parameter window:

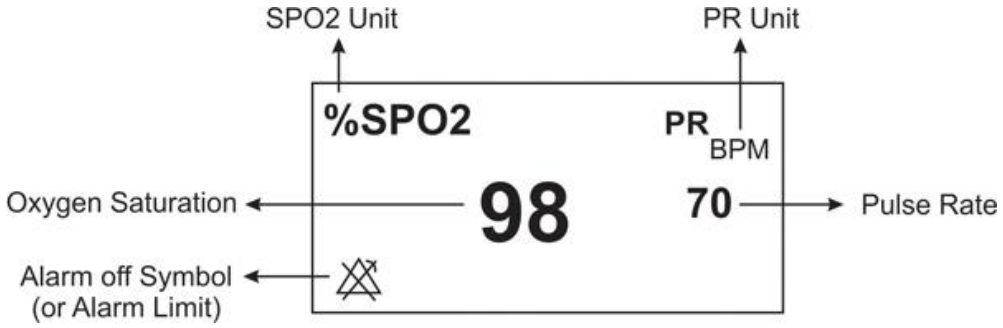


Figure 6-5 SPO2 PARAMETER WINDOW

SpO2 parameter window (special page for Rainbow parameters) is as follows:

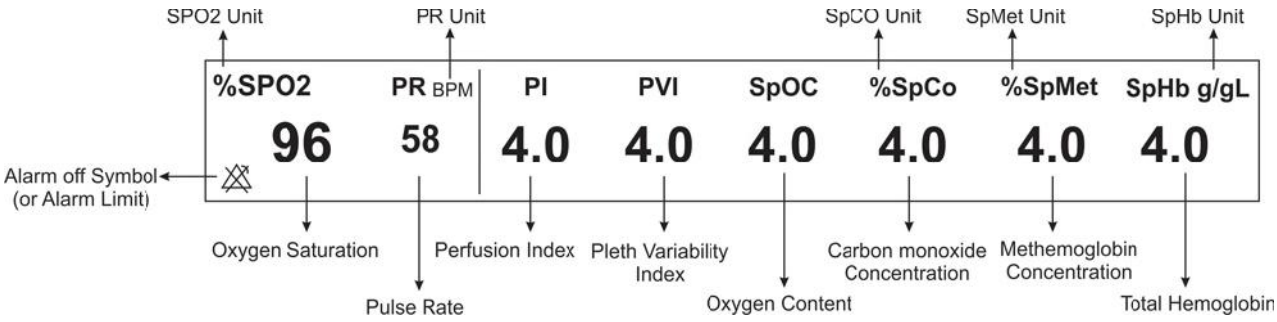


Figure 6-6 RAINBOW PARAMETERS WINDOW

The SpO2 WINDOW is as follows:

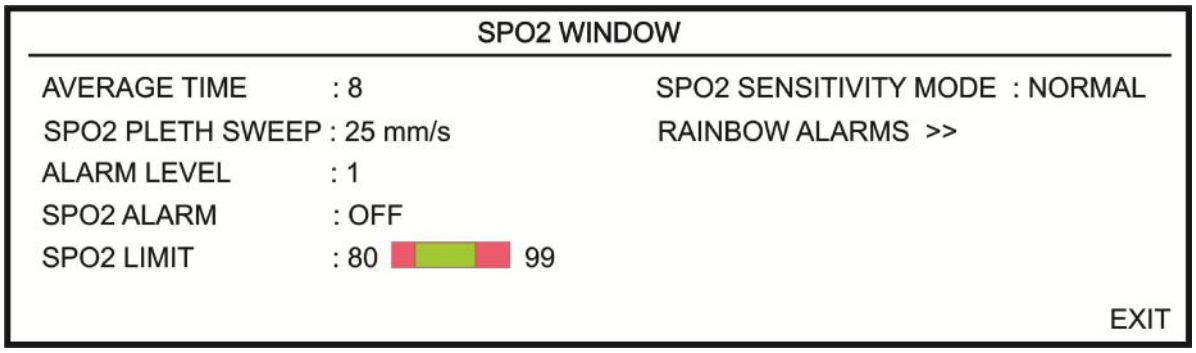


Figure 6-7 SPO2 WINDOW

- **AVERAGE TIME**

Available options are 2-4, 4-6, 8, 10, 12, 14 and 16.

- **SPO2 PLETH SWEEP**

Available options for SpO2 PLETH SWEEP are 12.5 mm/s and 25 mm/s.

- **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

- **SpO2 ALARM**

Pick "ON" to enable SpO2 alarm functions such as parameters blinking, audio alarm, and light indicator. Pick "OFF" to disable the alarm functions and there will be a"⚠"symbol in the Parameter Area.

- **SpO2 LIMIT**

SpO2 alarm is activated when the SpO2 exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (min: 1 and max: 100, by step 1)

- **SpO2 SENSITIVITY MODE**

It is only applicable to Masimo module. Available options for SpO2 SENSITIVITY are NORMAL, MAX and APOD.

NORMAL: The perfusion threshold has different limits as the perfusion calculation is data dependent .Specially; there is an intelligent algorithm which adjusts the low perfusion limit in accordance with the quality of the incoming plethysmography waveform between 0.5% and 0.02%. This mode provides the best combination of sensitivity and probe-off detection performance. This mode is recommended for the majority of patients.

MAX: Recognizing that some clinicians may want the absolute low perfusion performance (0.02%) all of the time and may be willing to sacrifice sensor off detection, Masimo provides a maximized sensitivity mode. This mode should be used for the sickest patients, where obtaining a reading is most difficult. Maximum Sensitivity is designed to interpret and display data for even the weakest of signals. This mode is recommended during procedures and when clinician and patient contact is continuous.
In MAX mode, the message "SpO2 MAX SENS." displays on the screen with yellow colour.

⚠**Warning**⚠

When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the instrument is in the setting and the sensor become dislodged from the patient, the potential for false reading may occur due to environmental "noise" such as light, vibration, and excessive air movement.

APOD (Adaptive Probe Off Detection): This mode is not advisable for patients with low perfusion because the system has the least sensitivity to signal changes in this mode. It is used in situations having risk of probe detachment (e.g. children or uneasy patients).
By selecting this mode, "SpO2 APOD MODE" appears on the screen with yellow colour.

- **RAINBOW ALARMS**

You can change alarm limits of PI, PVI, SpOC, SpCO, SpMet and SpHb parameters in SpO2/MASIMO ALARMS window (Figure 6-6).

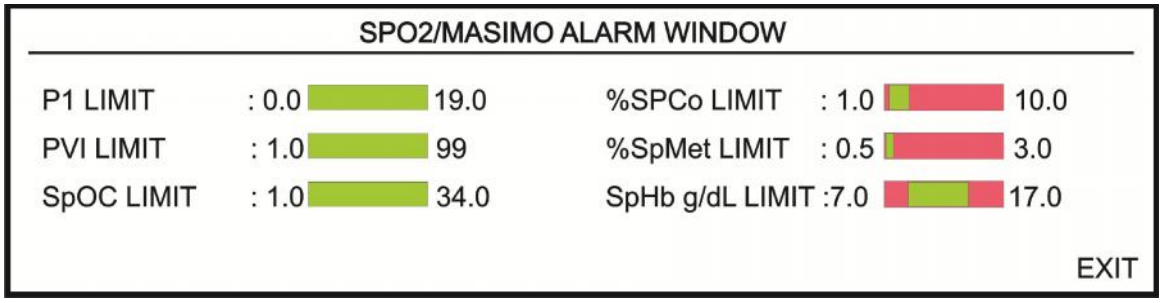


Figure 6-8 SpO2/ MASIMO ALARM WINDOW

Alarm limit of Rainbow parameters is as follows:

Parameter		**Alarm Limit**
PI	HIGH Alarm	PI LOW Alarm +0.1 to 19.0
	LOW Alarm	0.0 to PI HIGH Alarm -0.1
PVI	HIGH Alarm	PVI LOW Alarm +1 to 99
	LOW Alarm	1 to PVI HIGH Alarm -1
SpCO	HIGH Alarm	SpCO LOW Alarm +1 to 99
	LOW Alarm	1 to SpCO HIGH Alarm -1
SpMet	HIGH Alarm	SpMet LOW Alarm +0.5 to 99.5
	LOW Alarm	0.5 to SpMet HIGH Alarm -0.5
SpHb	HIGH Alarm	SpHb LOW Alarm +0.1 to 24.5
	LOW Alarm	0.5 to SpHb HIGH Alarm -0.1
SpOC	HIGH Alarm	SpOC LOW Alarm +1 to 34
	LOW Alarm	1 to SpOC HIGH Alarm -1

6.3 SpO2 and Rainbow Parameters Alarm Messages

a) Physiological alarms

The alarm occurs when SpO2 and PR values exceed the adjusted alarm limits.

Alarm	Situation	Visual alarm	Audio alarm
%SpO2 HIGH	SpO2 violates adjusted high limit	●SpO2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
% SpO2 LOW	SpO2 violates adjusted low limit	●SpO2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PR HIGH	PR value violates adjusted high limit.	● PR value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PR LOW	Pulse rate violates adjusted low limit	●PR value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

If the MASIMO Rainbow module is used, alarm occurs when each of the Rainbow parameters exceed the adjusted alarm limits.

Alarm	Situation	Visual alarm	Audio alarm
PI HIGH	PI violates adjusted high alarm limit	● PI value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PI LOW	PI violates adjusted low alarm limit	● PI value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

Alarm	Situation	Visual alarm	Audio alarm
PVI HIGH	PVI value violates adjusted high alarm limit.	● PVI value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PVI LOW	PVI value violates adjusted low alarm limit.	● PVI value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
SpOC HIGH	SpOC violates adjusted high alarm limit	● SpOC value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
SpOC Low	SpOC violates adjusted low alarm limit	● SpOC value blinks. ● The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.	Activated
SpCO HIGH	SpCO violates adjusted high alarm limit	● SpCO value blinks. ● The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.	Activated
SpCO LOW	SpCO violates adjusted low alarm limit	● SpCO value blinks. ● The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.	Activated
SpMet HIGH	SpMet violates adjusted high alarm limit	● SpMet value blinks. ● The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.	Activated
SpMet LOW	SpMet violates adjusted low alarm limit	● SpMet value blinks. ● The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.	Activated

Alarm	Situation	Visual alarm	Audio alarm
SpHb HIGH	SpHb violates adjusted high alarm limit	● SpHb value blinks. ● The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.	Activated
SpHb LOW	SpHb violates adjusted low alarm limit	● SpHb value blinks. ● The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.	Activated

b) Technical alarms

Alarm	Cause	Solution	Explanation
SpO2 NO CABLE	The SpO2 cable is not securely connected to the patient monitor.	Make sure that the SpO2 cable is correctly connected to the monitor.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SpO2 REPLACE CABLE	The life of the SpO2 cable has expired.	Replace the SpO2 cable.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
SpO2 CABLE DEFECT	1.The SpO2 cable is damaged. 2.The SpO2 cable is not compatible.	1. Make sure that the Masimo SpO2 cable is correctly connected to the monitor. 2.Turn the system off and on. If this message is displayed again, replace the cable.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 NO SENSOR	The SpO2 sensor is not securely connected to the system.	Make sure that the SpO2 sensor is correctly connected to the interface cable.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

SpO2 REPLACE SENSOR	The life of the SpO2 sensor has expired.	Replace the SpO2 sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 SENSOR DEFECT	1. The SpO2 sensor is damaged 2.The SpO2 sensor is not compatible.	1. Make sure that the SpO2 sensor is correctly connected to the monitor. 2.Turn the system off and on. If this message is displayed again, replace the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 SENSOR OFF	1-The SpO2 sensor may be detached from the patient. 2-The sensor is not connected to patient properly. 3-The sensor is damaged.	1-Detach the sensor from the patient, then reattach it. 2-Properly attach the sensor to the patient and then connect it to the cable or the monitor. 3-Replace the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 NO AD SENSOR	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	Ensure that the adhesive portion is firmly connected to the sensor.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 REPLACE AD SENSOR	When a single-patient-use sensor is used, the life of the adhesive portion of the sensor has expired.	Replace the adhesive portion of the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 AD SENSOR DEFECT	When a single-patient-use sensor is used: 1.The adhesive portion of the sensor is damaged. 2.Inappropriate SpO2 sensor .	1. Make sure that the Masimo SpO2 cable is correctly connected to the monitor. 2.Turn the system off and on. If this message is displayed again, replace	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

		the sensor.	
SpO2 AMBIENT LIGHT	Excessive ambient light sources such as surgical lights or direct sunlight may decrease the measurement accuracy.	In the case of using rainbow sensor, cover the sensor with ambient light shield.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
SpO2 RAINBOW HARDWARE FAIL	The SpO2 hardware error	Turn the system off and on. If this message is displayed again, contact After sales service of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
SpO2 PROBE DEFECT	The sensor or cable failure	Check function of the sensor and the cable separately and replace defective part, if necessary.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
SpO2 SENSOR CHECK CONNECTION	Failure of connection between the sensor and the monitor.	Check the connections and replace the sensor and/or cable, if necessary.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
SpO2 LOW SIGNAL IQ	The SpO2 measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interferences.	1-Check the patient condition. 2-Check proper connection of the sensor to the patient. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SpO2 LOW PR CONFIDENCE	The pulse rate measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interferences.	1-Check proper connection of the sensor to the patient. 2-Change the sensor site. 3-Calm the patient.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SpO2 LOW PI CONFIDENCE	The PI measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interferences.	1-Check proper connection of the sensor to the patient. 2-Change the sensor site. 3-Calm the patient.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SpO2 LOW PVI CONFIDENCE	The PVI measurement does not have confidence	1-Check proper connection of the sensor to the patient.	Alarm level 3- the message is displayed in cyan background. By

	due to poor signal quality caused by excessive motion or other signal interferences.	2-Change the sensor site. 3-Calm the patient.	pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SpO2 LOW SPOC CONFIDENCE	The SpOC measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interferences.	1-Check proper connection of the sensor to the patient. 2-Change the sensor site. 3-Calm the patient.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SpO2 LOW SPCO CONFIDENCE	The SpCO measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interferences.	1-Check proper connection of the sensor to the patient. 2-Change the sensor site. 3-Calm the patient.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SpO2 LOW SPMET CONFIDENCE	The SpMet measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interferences.	1-Check proper connection of the sensor to the patient. 2-Change the sensor site. 3-Calm the patient.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SpO2 LOW SPHB CONFIDENCE	The SpHb measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interferences.	1-Check proper connection of the sensor to the patient. 2-Change the sensor site. 3-Calm the patient.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

After taking the mentioned actions if above messages are displayed again, the SpO2 probe may be damaged and you should contact local After Sales Services.

c) Messages

Message	Cause	Solution	Explanation
SpO2 CABLE NEAR EXP	The SpO2 cable is nearing expiration.	Make new cable available to replace the cable, if necessary.	
SpO2 SENSOR NEAR EXP	The SpO2 sensor is nearing expiration.	Make new sensor available to replace the sensor, if necessary.	
SpO2 AD SENSOR NEAR EXP	The SpO2 adhesive sensor is nearing expiration.	Replace the adhesive sensor.	
SpO2 SEARCH	The instrument is searching for pulse.	If the instrument fails to display within 30 seconds, disconnect and reconnect the sensor. If pulse search continues, change the sensor site.	
SpO2 SIGNAL WEAK	The SpO2 signal amplitude is too weak or undetectable.	Change the sensor site.	
SpO2 DEMO MODE RUN	The SpO2 is in demo mode.		
SpO2 ONLY MODE	Measuring rainbow parameters is not possible (due to the ambient light or the dark skin pigmentation).	Use a Masimo light shield to cover the sensor	

6.4 SpO2 PROBE CLEANING

⚠**Warning**⚠

To clean the sensor, first remove it from the patient and disconnect it from the monitor.

You may then clean the probe by wiping it with a 70% isopropyl alcohol pad. Allow the probe to dry prior to placement on a patient.

⚠**Warning**⚠

Do not sterilize the patient cable and probes by autoclave, irradiation, steam or ethylene oxide.

⚠**Warning**⚠

To prevent damage, do not immerse the probe in any liquid solution.

Chapter 7 NIBP Monitoring

Contents

7.1 GENERAL

NIBP (Non-invasive Blood Pressure) measurement is based on the oscillometric technique. Initially, cuff is inflated to a pressure greater than systolic pressure as blood flow in the extremity occludes effectively. Then the pressure in the cuff is gradually reduced until the patient pressure is detected and the cuff is deflated completely.

Systolic, Diastolic and Mean Arterial pressures can be calculated using pressure pulses detected during pressure drop. Oscillation amplitude increases to a maximum peak and then decreases. If the process of the cuff pressure reduction is done appropriately and pulses detected between systolic and diastolic pressures are collected, the profile curve can be obtained using pulses' pressure and amplitude. The peak oscillation amplitude is defined as the Mean Arterial Pressure (MAP). Systolic and diastolic pressures can be obtained from suitable thresholds before and after MAP pressure.

These thresholds are based on a data set containing a large number of measurements that are obtained in comparison with the IBP pressure. It should be noted that in patients with high pressure, the systolic and diastolic values may have lower accuracy than those with normal pressure. This restriction is not specific to the SAADAT monitor and includes all monitors that use an oscillometric method to measure NIBP.

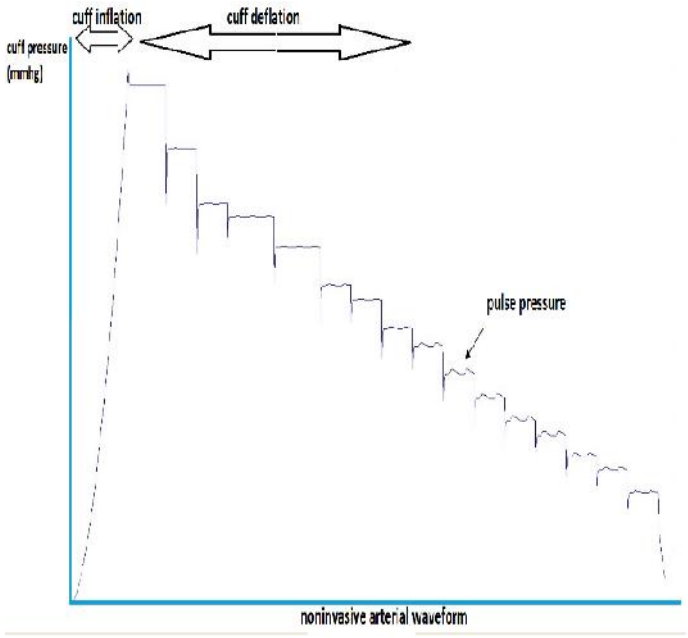


Fig 1.7: Changes in cuff pressure during measurement

A set of comprehensive and extensive internal and clinical tests was performed on individuals using the SAADAT NIBP Module and the results were compared with IBP measurements and the measurements taken by approved devices in the market. The results of these tests represent reliability of the SAADAT NIBP module. The SAADAT NIBP module is also compatible with BS ISO 81060-2: 2009 standard and has a credible CE marking that indicates its high quality.
Also the NIBP module is designed according to EN 1060-1 standard.

Steps to prepare the system and cuff for pressure measurement:

1. Plug in the air hose and switch on the system.
2. Apply the blood pressure cuff to the patient's arm or leg following the instructions below (Figure 7-2).

- Ensure that the cuff is completely deflated.
- Apply the appropriate size cuff to the patient. Choosing a small cuff size increases the pressure value and choosing a large cuff size decreases the pressure value and thus results in the measurement inaccuracy.
- The inflatable part of the cuff should be long enough to encircle 80% of the limb and the width of the cuff should be either 40% of the limb circumference.
- The cuff should not be placed on the patient’s clothing.
- The cuff should be placed about 2.5cm above the elbow.
- The cuff and artery should be aligned.
- The limb chosen for taking the measurement should be placed at the same level as the patient's heart.
- Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia.

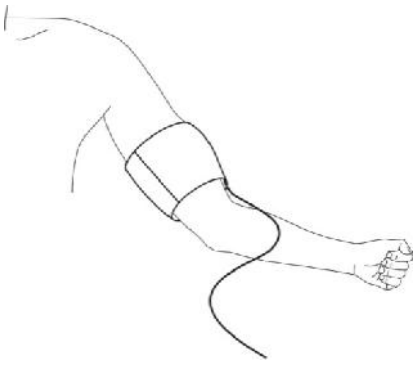


Figure 7-2 Applying Cuff

3. Connect the cuff to the air hose.

4. Check whether the patient mode is appropriately selected. To change the patient mode, choose PATIENT CAT. from the HOME/SETUP WINDOW. In this section, there are three modes to choose: Neonate (from birth to three years), Pediatric (from three to twelve years) and Adult (over twelve years).

5. Select a measurement mode (Automatic, Stat and Manual) in the NIBP WINDOW:
   - □ In the MANUAL mode, only one measurement is performed.
   - □ In the AUTO mode, the measurement is cycled. You can set the interval time to 1,2,3,5,10,15,20, 30, 45, 60, 90 minutes and 2, 4, 8,12,16,20 and 24 hours.
   - □ In the STAT mode, the measurement is performed up to ten times within 5 minutes with 30s interval between measurements. If an error occurs, NIBP measurement is suspended.

6. Press the START/STOP button on the front panel to start the NIBP measurement.

The points to be considered during the NIBP measurement:

- Since in measuring blood pressure, the initial pump pressure depends on the previously measured pressure, it is best to switch off the monitor to maintain patient comfort and clear the patient's data at the time of the patient discharge.
- Keep the patient calm for 5 minute before measurement.
- Between the two measurements should be 5 minutes apart.
- The patient should be calm and silent during the measurement.
- The cuff should be placed at the same level as heart.
- The cuff size must be selected correctly:
  - Selecting a very small size will increase the measured pressure.
  - Selecting a very large size will reduce the pressure value.
- Before starting a measurement, verify that you have selected an appropriate setting for your patient (Neonate, Adult or Pediatric**)**
-
  - If the neonate mode is used for adult or pediatric, the pressure measurement will be impossible because of the limitation of pumping in the neonate's mode.
  - The pressure measurement for pediatric in adult mode causes high pressure and injury to the limb, thus ensure that correct settings have been selected for pediatric patient.
  - Do not measure NIBP if the tissue is damaged or likely to be damaged.

NOTE:

- NIBP measurements can be performed adjacent to electrosurgical unit.

⚠**Warning**⚠

Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

⚠**Warning**⚠

Do not wrap the cuff around the arm on the same side as mastectomy surgery has been performed.

⚠**Warning**⚠

Use only recommended manufacturer Blood Pressure Cuffs and Hose. Using other cuffs or hoses may result in inaccuracies.

⚠**Warning**⚠

Blood pressure measurement can be affected by the position of the cuff and patient's physiological condition.

⚠**Warning**⚠

According to general requirement for safety, Luer lock connectors are not used .Don't use NIBP cuff with Luer lock connector because if Luer lock connector is used, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into blood vessel.

⚠**Warning**⚠

Make sure that the air hose of the cuff is neither blocked nor tangled.

⚠**Warning**⚠

Before starting a measurement, verify that you have selected an appropriate setting for your patient (Neonate, Adult or Pediatric).

⚠**Warning**⚠

The maximum cuff inflation pressure is 290 mmHg in adult mode, 240mmHg in pediatric mode and 145 mmHg in neonate mode. Furthermore, independent maximum pressure control preservative is forecasted inside the system.
Also maximum time of being under pressure in each measurement has been limited to 2 minutes (90 seconds in neonate). However, operators should note that long-time and continuous measurements can lead to muscular and neurotic harms, dermal injuries or

circulatory system failure. Thus examine the limb wearing cuff regularly.

⚠Warning⚠

NIBP measurement may not be appropriate for some patients especially the patients with arrhythmia, preeclampsia, specific cardiovascular diseases and pregnant women.

⚠Warning ⚠

Please take into account the following items as you perform blood pressure measurement particularly in patients with hypertension.

- The patient is placed in a comfortable position.
- The patient's feet are not on each other.
- The feet should be on a flat floor.
- The back and arm of the patient have a good support (for example a chair with back and arms)
-The cuff is placed at the same level as heart.
- Keep patient calm and silent during measurement.
Keep patient calm for 5 minutes before measurement is performed.

Operation Hints

1. To start a MANUAL measuring, press the START/STOP button on the front panel.
2. To stop a MANUAL measuring, repress the START/STOP button on the front panel.
3. To start AUTO measuring, select NIBP WINDOW menu and pick AUTO for measuring interval setting, then press START/STOP button on the front panel.

⚠Warning ⚠

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the limb frequently for normal colour, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

4. To start a MANUAL measuring during the AUTO mode, Press START/STOP button on the front panel.
5. To stop AUTO measuring, Select the NIBP WINDOW and set MANUAL mode.
6. To start STAT measuring, Press START/STOP button on the front panel.

⚠Warning ⚠

If the NIBP is set to AUTO mode and the cuff is not attached to the patient, lots of “loose cuff” and/or “weak signal” messages appear in the NIBP LIST. This setting also causes the pump to operate when it is not needed and the life of the module decreases.

⚠**Warning** ⚠

Prolonged non-invasive blood pressure measurements in STAT mode may be associated with ischemia, neuropathy or dermal injuries in the limb wearing the cuff.

NOTE:

If you are in doubt about the accuracy of any measurement(s), check the patient's vital signs by an alternative method before checking the functionality of the monitor. Then check the correct connections, cuffs, hoses and system performance

Measurement Limitations

In different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances, when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere the measurement and make the measurement unreliable or longer. In some cases, the patient's condition will make a measurement impossible.

●Patient Movement

Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

●Cardiac Arrhythmias

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia causes an irregular heart beat. Thus the measuring time will be prolonged.

●Heart-lung Machine

Measurements will not be possible if the patient is connected to a heart-lung machine.

●Pressure Changes

Measurements will be unreliable and may not be possible if the patient's blood pressure changes rapidly over a short period of time.

●Severe Shock

If the patient is in severe shock or hypothermia, measurements will be unreliable because of reduced pulsation of the arteries.

●Irregular Heart Rate

Measurements cannot be performed at a heart rate of less than 40 bpm and greater than 240 bpm.

7.2 NIBP WINDOW

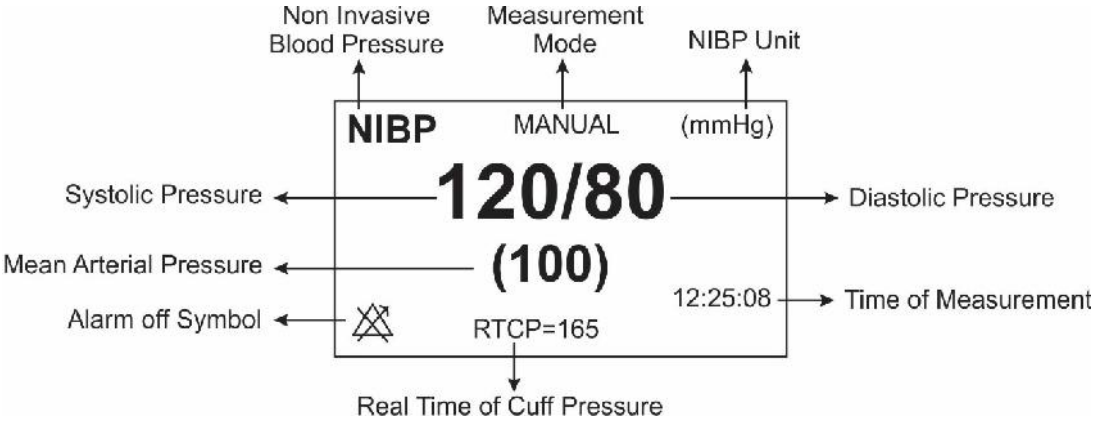


Figure 7-3 NIBP PARAMETER WINDOW

In pages which IBP parameter is not displayed (RESP mode), PR value will also be displayed in this window, Figure 7-4.

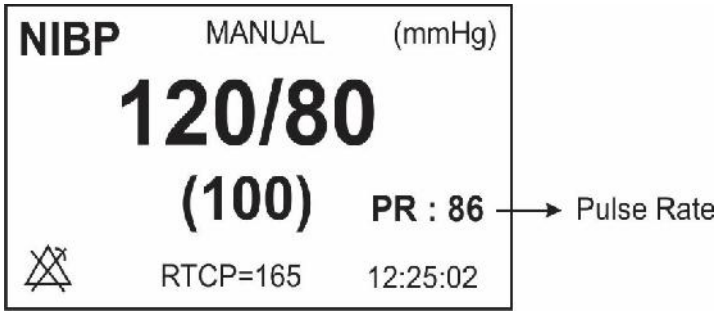


Figure 7-4 NIBP PARAMETER WINDOW (Pages without IBP)

Heart rate measured by NIBP module is in the range of 40 to 240 BPM.

NIBP window is as follows:

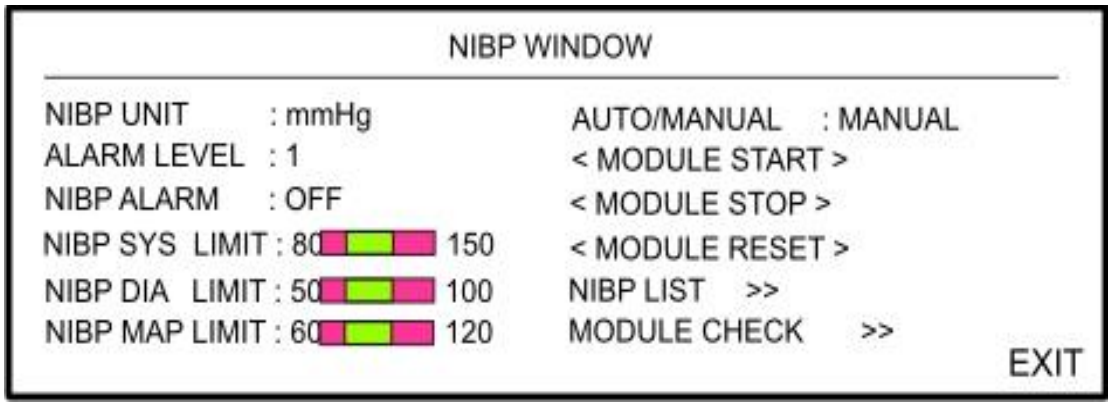


Figure 7-5 NIBP WINDOW

■ **NIBP UNIT**

Pick this item to adjust measurement unit. (Options: mmHg or KPa)

■ **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

■ **NIBP ALARM**

Pick "ON" to enable NIBP alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions and there will be a "⚠"symbol in the Parameter Area.

■ **NIBP SYS LIMIT**

SYS alarm is activated when the systolic pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.
Adult → Max: 255, Min: 30
Pediatric → Max: 240, Min: 30
Neonate → Max: 135, Min: 30

■ **NIBP DIA LIMIT**

DIA alarm is activated when the diastolic pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.
Adult → Max: 220, Min: 15
Pediatric → Max: 220, Min: 15
Neonate → Max: 110, Min: 15

■ **NIBP MAP LIMIT**

MAP alarm is activated when the mean arterial pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.(min:25 and max:200)

Adult → Max: 235, Min: 20
Pediatric → Max: 230, Min: 20
Neonate → Max: 125, Min: 20

■ **AUTO/MANUAL/STAT**

There are three modes of measurement available: MANUAL, AUTO and STAT. In the MANUAL mode, only one measurement is performed. In the AUTO mode, measurement is repeated over a specified period of time ; available intervals are 1,2,3,5,10,15,20,30,45, 60, 90 minutes and 2, 4, 8, 12,16,20,24 hours. In STAT mode,

measurement is performed up to ten times within 5 minutes with 30s interval between measurements. If an error occurs, NIBP measurement is suspended.

<MODULE START>
To start measurement

<MODULE STOP>
To stop measurement

<MODULE RESET>
To set maximum inflation pressure of cuff to 150 mmHg for adult, 140 mmHg for pediatric and 85 mmHg for neonate.

■ **NIBP LIST**

Patient monitor can store the latest 500 NIBP measurement data.
Pick "NIBP LIST" in the NIBP WINDOW to view the result and time of the latest NIBP measurements, as shown in Figure 7-6.

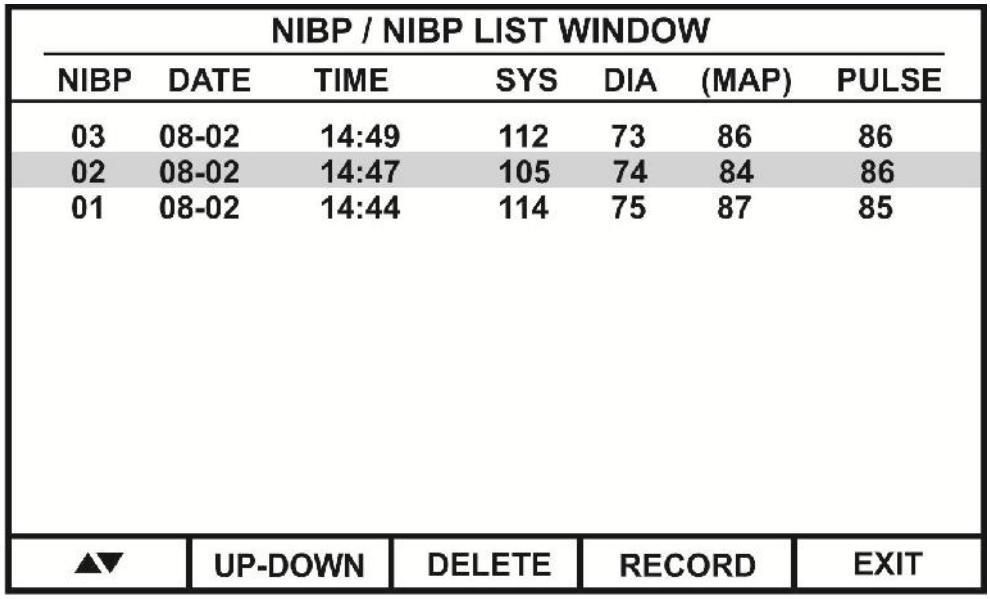


Figure 7-6 HOME/NIBP LIST WINDOW

By clicking on the first left item you can select a line of NIBP measured data.
By clicking on "UP-DOWN" you can access previous and next pages of NIBP LIST.
By clicking on "DELETE" you can delete selected data in NIBP LIST.
By clicking on "RECORD" you can record NIBP LIST data.

■ **MODULE CHECK**

Select this item to open the respective menu after 5 seconds delay.Available options are "NIBP MANOMETER","NIBP LEAKAGE","MODULE SELF TEST" and "MODULE STOP".

NOTE:

Below tests must only be done by trained and authorized personnel.

■ NIBP MANOMETER

Wrap the cuff around a rigid cylinder. Connect a calibrated reference manometer and a ball pump by means of a T-piece connector and hoses to the monitor. Set the monitor in" NIBP MANOMETER" mode. Inflate the pneumatic system to 0, 50 and 200 mmHg by ball pump separately. The difference between the indicated pressure of the reference manometer and the indicated pressure of the monitor should not exceed ±3 mmHg.

■ NIBP LEAKAGE

Wrap the cuff around a cylinder of an appropriate size, and the circumference of the applied cuff does not exceed that of the cylinder more than 7%.Set the monitor in "NIBP LEAKAGE" mode. The monitor inflates the cuff up to 200mmHg and keeps it constant for 20 sec .If air leakage result is satisfactory, "NIBP LEAKAGE OK" message is displayed; otherwise you will receive "PNUMATIC LEAK" message.

■ NIBP SELFTEST

The general objective of the SELFTEST is to check the general status of the NIBP module, including the function of sensors and valves.

7.3 NIBP Alarm Messages

a) Physiological alarms

The alarm occurs when the pressure (SYS. DIA or MAP) value exceeds the alarm limits.

Alarm	Situation	Visual prompt	Audio sound
NIBP SYS HIGH	SYS violates adjusted high limit	● SYS value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP SYS LOW	SYS violates adjusted low limit	● SYS value blinks ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP DIA HIGH	DIA violates adjusted high limit	● DIA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP DIA LOW	DIA violates adjusted low limit	● DIA value blinks ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP MAP HIGH	MAP violates adjusted high limit	● MAP value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

NIBP MAP LOW	MAP violates adjusted high limit	● MAP value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

a) Technical alarms

Alarm	Cause
SELF-TEST FAILED	NIBP hardware module failure
NIBP LOOSE CUFF	Cuff is completely unwrapped, no cuff attached
NIBP MODE ERROR	Adult mode instead of neonate mode (while neonate cuff is applied) or occlusion happened in air way
NIBP AIR LEAK	Air leak in cuff, hose or connector
NIBP AIR PRESSURE ERROR	Unstable pressure value (e.g. kinked hoses)
NIBP SIGNAL WEAK	Very weak patient signal due to a loosely wrapped cuff or extremely weak pulse from patient.
NIBP RANGE EXCEED	Measuring pressure is more than upper limit (255mmHg) for adult or (135mmHg) for neonate.
NIBP EXCESSIVE MOTION	Arm movement, noisy signal or irregular pulse(e.g. arrhythmia)
NIBP OVER PRESSURE SENSED	Measured pressure exceeds safe software limit, 290 mmHg for adult, 240 mmHg for pediatric and 145 mmHg for neonate.
NIBP SIGNAL SATURATED	Large motion artifact that saturates the amplifier's amplitude handling capability
NIBP PNEUMATIC LEAK	Air leakage during leak test
NIBP TIME OUT	Measurement time exceeds 3 minutes (2 minutes in CAS module) for adults and pediatrics or 90 seconds for neonates.
SYSTEM FAILURE	Error occurs in pump, A/D sampling, pressure transducer or software.
NIBP NO MODULE	No NIBP module is installed.
NIBP LOW BATTERY	The battery charge is not enough to measure NIBP.
NIBP MODULE ERROR	Some errors occur during measurement.

Alarm level of above messages is set in NIBP WINDOW. By pressing ALARM SILENCE, alarm will be disabled and ignores this fault and message background will change to gray.

c) Messages

Alarm	Cause
NIBP STOP PRESSED	NIBP stop key is pressed during measurement.
NIBP LEAKAGE O.K	Successful leakage test.

7.4 NIBP CUFF CLEANING

- **Cleaning**

  Durable one-piece cuffs may be safely cleaned with a damp cloth (70% alcohol or 0.5% bleach solution may be used) or washed in water (60ºC maximum) with soap or detergent.

- **Disinfection**

  Glutaraldehyde type liquid disinfectants may be used on durable cuffs. Prolonged use of these disinfectants at full strength may cause discoloration of the white cuff marking.

7.5 Frequently Asked Questions

1- Why does the monitor sometimes reinflate the NIBP cuff?

- The monitor will typically pump to an initial pressure of 150 mmHg or 30 mmHg higher than the last systolic reading in subsequent measurements. If the patient's systolic pressure is higher than this initial pressure, reinflation will occur.
- Repeated re-inflation during a measurement may be an indication of patient motion, inappropriate cuff size, the cuff leakage, insecure connection of tubes to rectus or the monitor failure.

2- Can an oscillometric NIBP simulator be used to determine accuracy of the NIBP modules?

- The NIBP module manufacturers use different criteria to calculate the systolic and diastolic pressure values; it is unreasonable to expect a single NIBP simulator to achieve universal agreement with all clinically approved oscillometric blood pressure modules. In the area of blood pressure simulation, it is not the absolute agreement between the oscillometric blood pressure monitor and an NIBP simulator that matters, but how repeatable the results produced by the monitor under test are when using the simulator.

3- What are the variables influencing the accuracy of blood pressure read by the device?

- Patient movement: (shivering, tremors, seizures, and flexing the arm in reaction to cuff pressure) may interfere with a blood pressure reading and consequently the measurement time will be increased or reinflation will occur (maximum 3 times). In this condition the measurement may be unreliable or may be impossible and error message "NIBP EXCESSIVE MOTION" appears.
- Low blood pressures: such as those found in patients in shock, produce low pressure amplitudes that can be difficult to detect and as a result the module may not be able to measure.
- Atrial fibrillation (AF) and Arrhythmias: Irregular pulses in terms of occurrence time or amplitude increase the length of measurement step and time. Sometimes reinflation or even measurement failure occurs. If the measurement is done, the pressure value may be inaccurate and unreliable.
- Cuff size: the cuff bladder length should be approximately 80% of the circumference of the upper arm and the cuff bladder width should be optimally 40% of the circumference of the upper arm. Incorrect cuff size may impact the accuracy of NIBP readings.

4- How often should the device be calibrated?

- It is recommended to check the device calibration every year and calibrate it, as required.

5- What is age range of individuals for using different device modes?

- Neonate: Newborn to 3 years, Pediatric: 3 to 12 years, Adult: >12 years

6- Can we use a cuff produced by another company?

- No, using other cuffs may influence the accuracy of NIBP readings.

7- What should we do if NIBP Start button does not function?

- Is the Start button pressed immediately after that the monitor has turned on? ⟶ If so, turn off and on the monitor. Wait one minute until the monitor boots up and then try again.
- Enter NIBP menu and press "Module Start" to ensure correct function of NIBP Start button.
- Check whether pressing NIBP Start button will call up the message "NIBP Low Battery". ⟶ If so, inspect the power connections.

- Contact the manufacturer.

8- The module is not able to measure the patient's pressure and the question mark (?) appears:

- Choosing measurement mode: Is the measurement mode correctly selected? If you have used the neonate mode for pediatric or adult, there's a chance that you will not be able to measure it.
- Cuff Size: If inappropriate cuff size is used (for example a cuff larger than correct size), the patient's pulses will be weakened and the module may not be able to measure.
- Patient movement: During the pressure measurement, the patient should avoid moving, talking and laughing. Any motion can affect the measurement accuracy and, in some cases, lead to the measurement failure.
- Patient conditions: Some diseases, such as arrhythmias, may cause inconsistency between the patient's pulses and in some situations may lead to the measurement failure.

Chapter 8, TEMP Monitoring

8.1 GENERAL

Measurement of patient temperature is accomplished by processing the signal from a probe containing temperature dependent resistor called thermistor .Value of this resistor is measured by the monitor continuously and displayed on screen. Patient monitor has two different kinds of temperature probe, a probe for esophageal /rectal temperature measurement and other for skin temperature measurement.

Specification:

Measuring and Alarm Range		0~ 50 ºC
Accuracy		± 0.2 º C
Delay time	For rectal/esophageal probe	50 sec
	For skin probe	20 sec

Two TEMP probes can be used together to obtain 2 temperature data and compare them to determine the temperature difference.
Accuracy of measured temperature is checked per minute by an internal reference resistor calibrated on temperature 37.1˚C.

TEMP monitoring setup:

- Plug TEMP probe directly into the monitor.
- Attach the TEMP probe(s) properly to the patient.
- Switch on the system.

Inspection and recalibration

Visually inspect the probe for cracks, holes, crazing etc, prior to each use. If any such degradation in the cable jacket is discovered, discard probe according to your hospital's procedure for medical waste. When using temperature probe, the user must determine that a probe style is suitable and sufficiently flexible for esophageal or rectal use.
Probe cannot be "recalibrated" per se, but should be inspected monthly by the hospital Biomedical Equipment group to ensure they are working properly. Probes can be tested by plugging into a patient monitor and looking for an electrical open or short–circuit, Intermittent reading or extremely inaccurate readings which would indicate probe wire damage. The sensor stability is well-documented; Probe accuracy should not drift out of tolerance over the normal life of probe.

⚠WARNING⚠

Use only the recommended manufacturer TEMP probe for monitoring, other probes may cause system malfunction.

NOTE:
Please be noted that the metal side of probe should be used for making measurements.

⚠WARNING⚠
Using ESU with temperature measurement simultaneously may cause patient burn. If possible, remove the probe from patient contact before activating the surgical unit or other RF source. If probe must be used simultaneously with electrosurgical apparatus, hazards can be reduced by selecting a temperature monitoring point which is remote from the expected RF current path to the ground return pad.

⚠WARNING⚠
Over straining will result in mechanical damage of the probes.

⚠WARNING⚠
The temp probes should be calibrated every two years or according to hospital calibration schedule. Contact After Sale Service to perform probe calibration.

⚠WARNING⚠
The temperature probes carry a one-year warranty on workmanship, components and accuracy tolerances. Probe life with normal use should exceed one year.

8.2 TEMP WINDOW

The following items are displayed in TEMP parameter window.

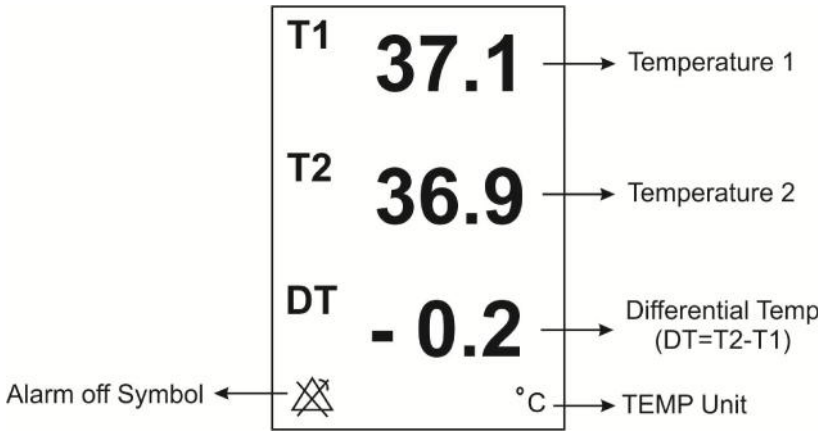


Figure 8-1 TEMP PARAMETER WINDOW

The TEMP WINDOW is as follows:

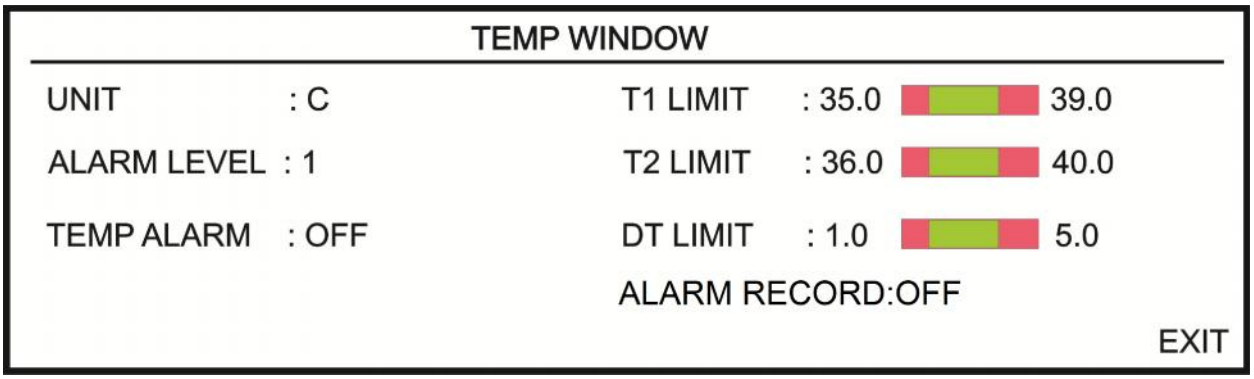


Figure 8-2 TEMP WINDOW

■ **UNIT**

Pick this item to set measurement unit. (options: ºC or ºF)

■ **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

■ **TEMP ALARM**

Pick "ON" to enable TEMP alarm functions such as parameters blinking, audio alarm, and light indicator.Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in the Parameter Area.

■ **T1 LIMIT**

T1 alarm is activated when the channel-1 temperature exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.(min:0.0 and max:50.0)

■ **T2 LIMIT**

T2 alarm is activated when the channel-2 temperature exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.(min:0.0 and max:50.0)

■ **DT LIMIT**

DT alarm is activated when the difference between channel-1 and channel-2 exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (min:0.0 and max:50.0).

T1 is Channel-1 of temperature.
T2 is Channel-2 of temperature
DT is the temperature difference between the above two.

8.3 TEMP ALARM MESSAGES

The alarm occurs when the alarm function is "ON" and the temperature exceeds the adjusted alarm limits.

Alarm	Situation	Visual prompt	Audio sound
T1 HIGH	The temperature (T1) violates adjusted high limit	● T1 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
T1 LOW	The temperature (T1) violates adjusted low limit	● T1 value blinks ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
Alarm	Situation	Visual prompt	Audio sound
T2 HIGH	The temperature (T2) violates adjusted high limit	● T2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
T2 LOW	The temperature (T2) violates adjusted low limit	● T2 value blinks ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
DT HIGH	Difference between two channels temperature (DT) violates adjusted high limit	● DT value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
DT LOW	Difference between two channels temperature (DT) violates adjusted low limit	● DT value blinks. ● The alarm indicator flashes.	Activated

	● The alarm message is displayed in a background corresponding to its level.

8.4 TEMP SENSOR CLEANING AND MAINTENANCE

To clean the temp sensor, first remove it from the patient and disconnect it from the monitor.

NOTE:

Reusable temperature probes are sold non- sterile.

■ **Cleaning**

When wiping clean, hold the probe in one hand at the sensing tip and wipe the probe and lead wire toward the plug. Excessive pressure could stretch the cable jacket and break the internal wires, destroying the probe .Continued flexing of lead wires in use and cleaning can also break the internal wire.

Avoid contact with materials such as ketone, ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly alkaline solutions will cause the vinyl to lose flexibility. The probe plugs should not be immersed.

⚠**Warning**⚠

Never immerse the probe plug in any liquid.

■ **Disinfection**

Probes may be disinfected by washing with 60% isopropanol, activated dialdehyde (Cidex) or sodium hypochlorite (bleach diluted 1:10 minimum in water.) After washing, probes should be rinsed thoroughly with water. Brief immersion of the probe in detergent solutions is not harmful. Manufacturer does not make any claim as to the efficacy of these chemicals for infection control. Please consult your hospital's Infection Control Officer for the applicable disinfection policies.

⚠**Warning**⚠

Never boil the temperature probes.

Storage and Handling

When not in use, probes and leads should be loosely coiled and stored at room temperature. Do not wrap probes around equipment cases to avoid damaging internal wires.

Chapter 9, IBP Monitoring *

9.1 GENERAL

Specification:

Displaying and measuring range (for all labels)		-50~300(mmHg)
Alarm ranges		
	IBP	-50~300(mmHg)
	ART	-50~300(mmHg)
	LVP	-50~300(mmHg)
	PAP	-50~120(mmHg)
	RVP	-50~100(mmHg)
	CVP	-50~100(mmHg)
	LAP	-50~100(mmHg)
	RAP	-50~100(mmHg)
	ICP	-40~100(mmHg)
Resolution	1 (mmHg)	
Accuracy	±2 % or 2mmHg each one is greater	

IBP stands for Invasive Blood Pressure. Patient Monitor measures direct blood pressure (Systolic, Diastolic and Mean) of the selected blood vessel through two channels, and displays two IBP waveforms.

⚠**Warning**⚠
The operator should avoid contacting with the conductive parts of the system when being applied.

⚠**Warning**⚠
When using ESU (Electrosurgery equipment), the transducer and the cables should not contact with the conductive part of ESU to protect patient against burns.

⚠**Warning**⚠
Disposable IBP transducer or domes should not be reused.

⚠**Warning**⚠
Before using dome make sure that its package is safe and check its expiry date.

⚠**Warning**⚠
Use only the pressure transducers listed in the Accessories Chapter .

The specified transducers are designed to have the special ability to protect patient against the electrical shock (especially for the leak current allowed), and it is protected against the effects of a discharge of a cardiac defibrillator. It can be used in the surgical operation. During defibrillation, the IBP waveform may be distorted temporarily.

⚠Warning⚠

Do not use the sterile supplied IBP transducers if the packaging or the transducer is damaged and return them to the vendor.

⚠Warning⚠

Verify transducer cables fault detection prior to the start of monitoring phase. Unplug the transducer of the channel 1 from the socket, the screen will display the error message "IBP1 NO SENSOR" and the audible alarm is activated with level 2. Next channel is the same.

Preparatory steps for IBP measurement (Figure 9-1):
1. Plug the pressure cable into corresponding socket.
2. Prepare the pressure tube and transducer by flushing through the tubing system with normal saline solution. Ensure that the tubing system is free of air bubbles.
3. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.

⚠Warning⚠

If there are air bubbles in the pressure line or the transducer, you should flush the solution to the system.

4. Place the transducer at the same level with the patient's heart.
5. Check if you have selected the correct label name. See the next chapter for details.
6. Zero the transducer. See the next section for details.
7. Calibrate the IBP monitor with a reference pressure if you have changed the transducer or if you are not sure about the accuracy.See the next section for details.

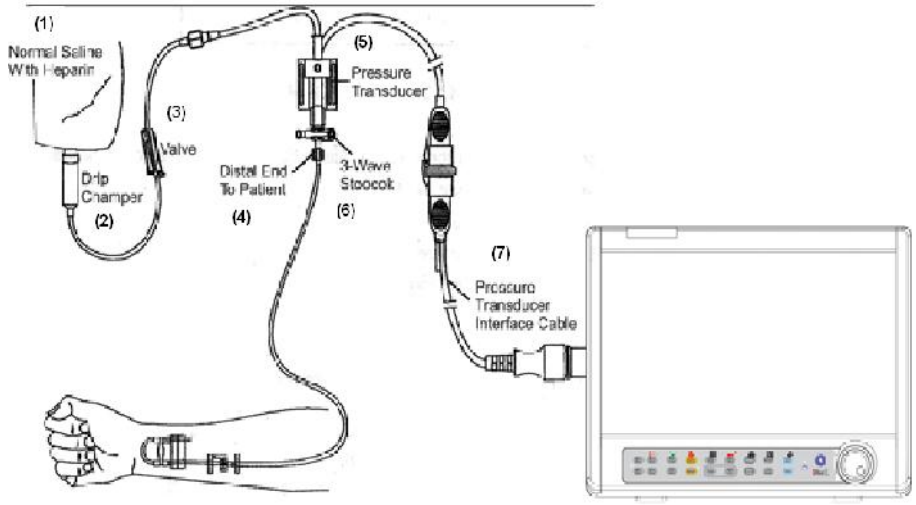


Figure 9-1 IBP Monitoring

(1) Normal Salin with Heparin

(2) Drip Chamber

(3) Valve

(4) Distal End to Patient

(5) 3-way Stopcock

(6) Pressure Transducer

(7) Pressure Transducer Interface Cable

9.2 IBP WINDOW

The following items are displayed in IBP parameter window.

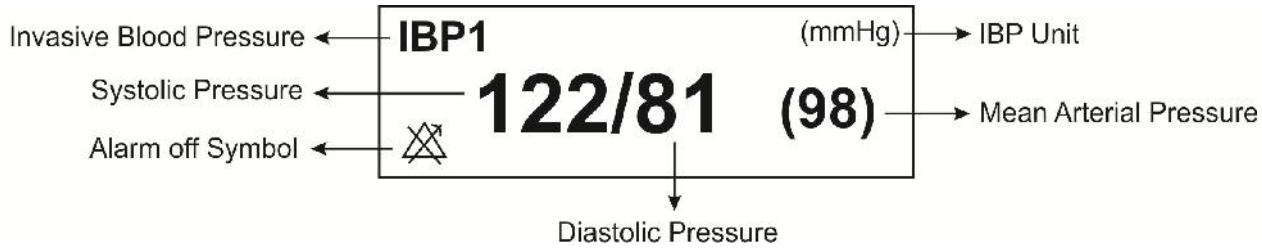


Figure 9-2 IBP PARAMETER WINDOW

The IBP WINDOW is as follows:

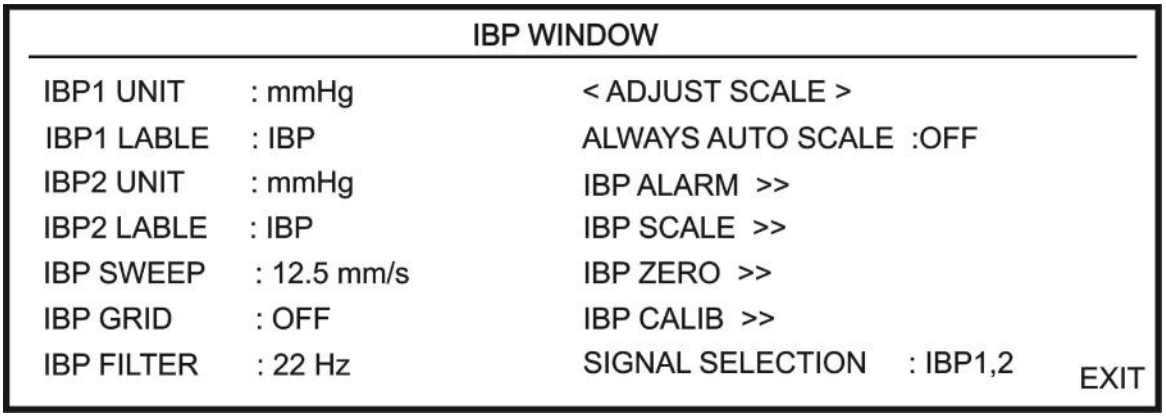


Figure 9-3 IBP WINDOW

- **IBP1/IBP2/IBP3/IBP4 UNIT**

Pick this item to adjust measurement unit. (Options: mmHg, Kpa, cmH2O)

Note:

To access PUMP PAGE in open heart surgery, select **HOME > SETUP WINDOW >MAIN DISPLAY >PUMP PAGE**

For more information, see different page configurations in the configuration chapter.

Note:

IBP3 and IBP4 are only active in the ALBORZ B9 system.

- **IBP1/IBP2/IBP3/IBP4 LABEL**

Suitable label should be selected, regarding the place of measurement. The available pressure labels are:

Label	Definition
IBP	Invasive Blood Pressure
ART	Arterial Blood Pressure
LVP	Left Ventricle Pressure
PAP	Pulmonary Artery Pressure
RVP	Right Ventricle Pressure
CVP	Central Venous Pressure
LAP	Left Atrium Pressure
RAP	Right Atrium Pressure
ICP	Intracranial Pressure

⚠Warning⚠

IBP algorithm will vary according to the selected label. Therefore in the case of improper label selecting, the accuracy of the measurement may be decreased.

⚠Warning⚠

When using PUMP PAGE, the IBP label must be set to CVP.

■ **IBP SWEEP**

Available options for IBP SWEEP are 3,6,12.5 and 25mm/s.

■ **IBP GRID**

Select "ON" to divide each IBP signal to 5 parts with white dot lines.

■ **IBP FILTER**

In order to have a more clear and detailed waveform, 3 filter types can be selected:
Available options are 22Hz, 16Hz, and 8Hz.

22Hz : Recommended in normal use and the most clinical situation. It has the most measuring accuracy among the called filters.

16Hz : When the signal is a bit noisy.

8Hz : This mode is recommended to reduce noise and interface resulted from ESU and also when the system has a high noise level or doesn't have equipotential earth. While using this filter the measuring accuracy might be decreased.

■ **ADJUST SCALE**

Pick < ADJUST SCALE> in IBP WINDOW to adjust the scale automatically. The scales are adjusted in a way that IBP signal occupies minimum 80% of IBP waveform area.

■ **ALWAYS AUTO SCALE**

This item will be available in IBP WINDOW if you set AUTO SCALE to ON. Set ON this item to adjust the scale automatically. In this condition High, Low and Sign scales are not displayed. This item is applicable for when there are large pressure variations and IBP signal exceeds the selected scale. Set OFF this item to see scale values (High, Low and Sign). In this condition you can adjust scale manually or using ADJUST SCALE.

NOTE:

When "ALWAYS AUTO SCALE" is set ON:

- **Scale values (High, Low and Sign) are not displayed.**
- **Sign scale is displayed in the area between High and Low scales.**
- **AUTO SCALE and IBP SCALE become inactive.**

Set OFF this item to terminate above condition.

■ **ALARM**

Pick "IBP ALARM" in IBP WINDOW to call up the following menu:

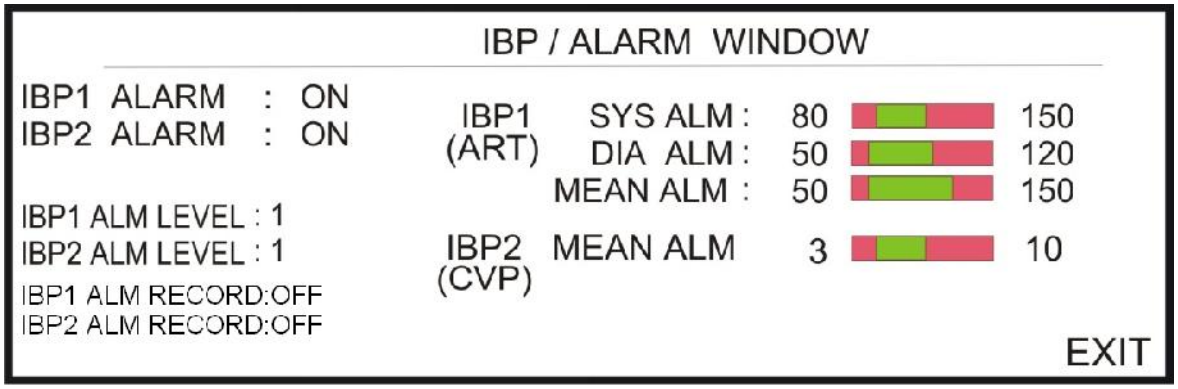


Figure 9-4 IBP/ALARM WINDOW

■ **IBP1/IBP2/IBP3/IBP4 ALARM**

Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in the Parameter Area.

■ **IBP1/IBP2/IBP3/IBP4 ALARM LEVEL**

Selectable between 1and 2. Level 1 represents the most serious case.

■ **IBP ALARM RECORD**

See the chapter "**RECORDER**".

■ **SYS ALM**

SYS alarm is activated when the systolic pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.

■ **DIA ALM**

DIA alarm is activated when the diastolic pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.

■ **MEAN ALM**

MEAN alarm is activated when the mean pressure exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.

NOTE:

The alarm High/Low limits for SYS, DIA and MEAN of all labels are listed below. Note that the CVP, LAP, RAP and ICP only have MEAN pressure, therefore the alarm limits are only for MEAN. The alarm is enabled when the value exceeds the adjusted limits.

Label	Min Alarm Limit (mmHg)	Max Alarm Limit (mmHg)	Step (mmHg)
IBP	-50	300	5
ART	-50	300	5
LVP	-50	300	5
PAP	-50	120	1
RVP	-50	100	1
CVP	-50	100	1
LAP	-50	100	1
RAP	-50	100	1
ICP	-40	100	1

- **IBP SCALE**

Pick "IBP SCALE" in IBP WINDOW to call up the following menu:

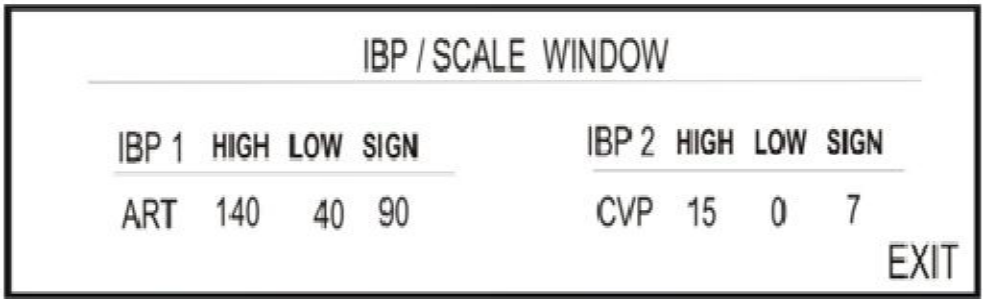


Figure 9-5 IBP/SCALE WINDOW

The waveform and corresponding scale appears in the IBP waveform area with 3 dotted lines representing HIGH limit scale, SIGN cursor, and LOW limit scale from the top to the bottom that values of the three scales can be manually set or automatically by Auto scale. You can change the high and low scales for IBP, ART and LVP labels by step of 10 and for PAP, RVP, CVP, ICP, LAP and RAP labels by step of 5. The cursor changes by step of 1 for all labels.

■ **IBP ZERO**

Pick < ZERO> in IBP WINDOW to call up the following menu:

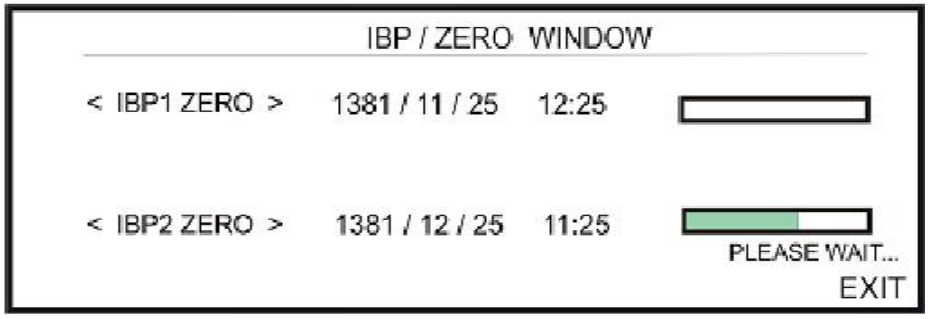


Figure 9-6 IBP/ZERO WINDOW

NOTE:

Zero procedure should be performed before starting the monitoring and at least once a day after each disconnection and connection of the cable.

Zero the transducer:

1-The transducer should be placed at mid-heart level.
2-Turn off patient stopcock.
3-The transducer must be vented to atmospheric pressure.
4-Select < IBP1/IBP2 ZERO > to start zeroing procedure for each channel.

The message "PLEASE WAIT" will be displayed during the procedure. When the procedure finished successfully the message "IBP1/IBP2 ZERO OK" appears.
The last zeroing time will be saved and displayed in its corresponding place.

5-Turn stopcock to patient on and the other stopcock to atmospheric pressure off.

The following messages may prompt up in ZERO WINDOW:

■ **"IBP1/IBP2 NO SENSOR, UNABLE TO ZERO"**

Make sure that the transducer is connected or not, then start zeroing.

■ **"IBP1/IBP2 OVERANGE, FAILED ZEROING**"

Make sure that the stopcock is vented to atmosphere. If the problem persists, contact After Sale Service.

■ **"IBP1/IBP2 UNSTABLE PRESSURE, UNABLE TO ZERO"**

Make sure that the stopcock is vented to atmosphere or perhaps the tubing system is hit accidentally .If the problem persists, contact After Sales Service.

- **IBP CALIB**

Pick IBP CALIB>> in IBP WINDOW to open the following menu after 5 seconds delay:

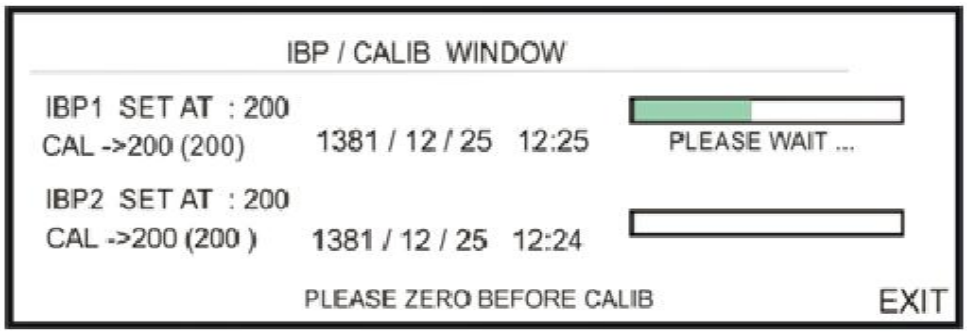


Figure 9-7 IBP/CALIB WINDOW

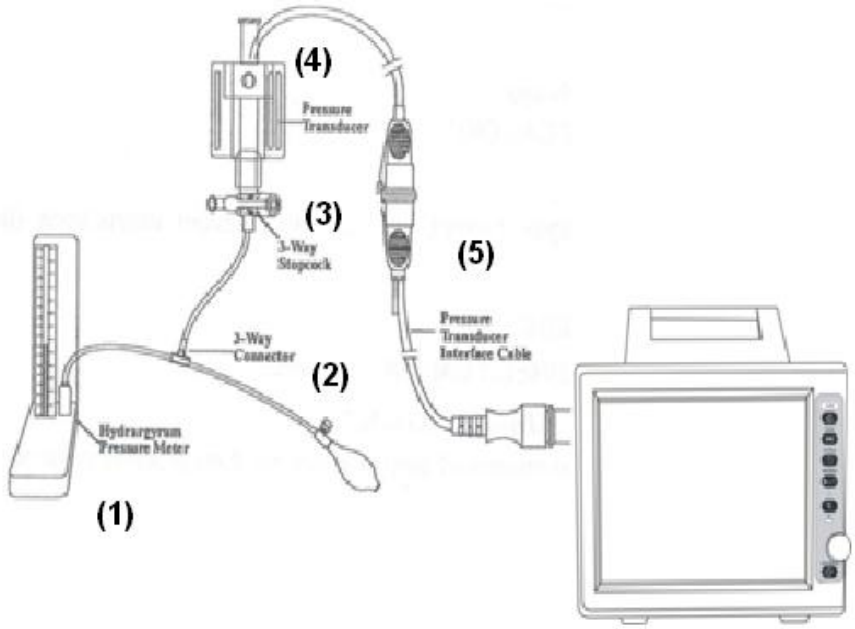


Figure 9-8 IBP CALIBRATION

(1) Hydrargyrum Pressure Meter

(2) 3-way Connector

(3) 3-way Stopcock

(4) Pressure Transducer

(5) Pressure Transducer Interface Cable

- Mercury calibration should be performed by the biomedical engineering department either whenever a new transducer is used, or when system accuracy is in doubt.

- The purpose of the calibration is to ensure that the system gives you accurate measurements.

- Before starting a mercury calibration, a zero procedure must be performed.

⚠Warning⚠
You must never perform this procedure while patient is being monitored.

Transducer calibration:

1. Attach the tubing to the sphygmomanometer.
2. Ensure that connection that would lead to patient is off.
3. Connect the 3-way connector to the 3-way stopcock that is not connected to the patient catheter.
4.Open the port of the 3-way stopcock to the sphygmomanometer.
5. Raise the sphygmomanometer to set value that you adjusted in CALIB WINDOW menu.
6. Choose a CAL-> in the CALIB WINDOW menu.
7. Press the rotary knob to start the calibration.

The message "PLEASE WAIT" will be displayed during the procedure. "IBP1/IBP2 CALIBRATION OK" indicates that the calibration procedure is completed successfully.The last calibration time will be saved and displayed in its corresponding place.

The following messages may prompt up in CALIB WINDOW:

- **"IBP1/IBP2 NO SENSOR, UNABLE TO CALIBRATE"**
  Make sure that the transducer is connected or not, then start calibration procedure.

- **"IBP1/IBP2 OVERANGE, UNABLE TO CALIBRATE"**
  Verify that adjusted pressure in the menu and sphygmomanometer pressure are equal.If the problem still exists, contact after sale service.

- **"IBP1/IBP2 UNSTABLE PRESSURE, UNABLE TO CALIBRATE"**
  Make sure that the transducer is not attached to the patient or perhaps the tubing system is hit accidentally .If the problem persists, contact after sales service.

8. Remove the sphygmomanometer tubing and extra connector.

NOTE:

Take the following actions for calibration if MEDEX transducer is used:

Pick <CALIB> in IBP WINDOW to access the window shown in Figure 9-7.
Set IBP1 and IBP2 to 100mmHg and push down Calib button of the transducer for about 10 seconds.

■ SIGNAL SELECTION

This option is only available in the page that four channels of IBP are displayed. (This item only active in Alborz B9)

Select “IBP1,2” to observe IBP1 and IBP2 signals and select “IBP3,4” to monitor IBP3 and IBP4 signals.

■ ART CATH. DISCONNECT ALM

If catheter is disconnected from the patient during the pressure measurement, the following conditions will occur:

- The pressure drops dramatically.
- IBP signal becomes static and the MEAN pressure falls below 10 mmHg.
- The heart activity is not shown and the signal is displayed as a flat line.

In this condition, “IBP CATHETER DISCONNECT” alarm with level 1 will be enabled for maximum 10 seconds.
To trigger the alarm, set label to ART or IBP and enable “ART CATH. DISCONNECT”.

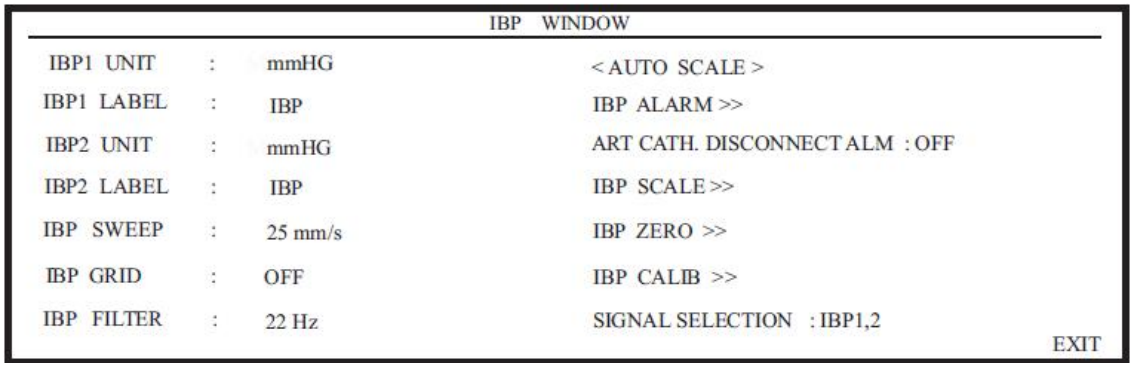


Figure 9-9 (a) IBP WINDOW

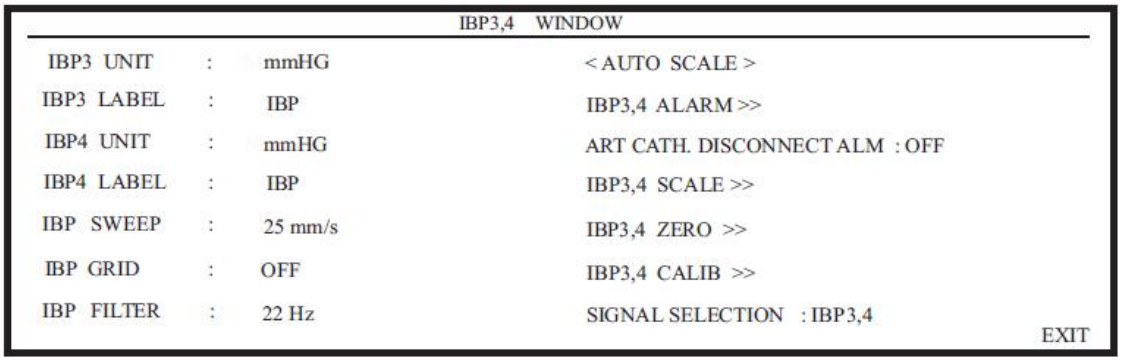


Figure 9-9 (b) IBP WINDOW

9.3 IBP Alarm Messages

a) Physiological alarms

The alarm occurs when the pressure (SYS, DIA or MEAN) violates the adjusted alarm limits.

Alarm	Situation	Visual prompt	Audio sound
IBP SYS HIGH	SYS violates adjusted high limit	● SYS value blinks ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
IBP SYS LOW	SYS violates adjusted low limit	● SYS value blinks ● The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
IBP DIA HIGH	DIA violates adjusted high limit	● DIA value blinks. ● The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
IBP DIA LOW	DIA violates adjusted low limit	● DIA value blinks ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
IBP MEAN HIGH	MEAN violates adjusted high limit	● MEAN value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
IBP MEAN LOW	MEAN violates adjusted low limit	● MEAN value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background	Activated

corresponding to its level.

b) Technical alarms

Alarm	Cause	Solution	Explanation
IBP1/IBP2 NO SENSOR	Channel 1 or 2 transducer is not connected.	Check the transducer connection.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, the background becomes gray and the alarm is disabled and ignores this fault.
IBP1/IBP2 STATIC PRESSURE	This condition occurs when the maximum and minimum values of a pulsatile pressure signal (Just for IBP, ART, PAP, RVP and LVP labels) differ by less than 3mmHg.In this case, only Mean pressure is displayed. This message can be caused by the following reason: ● A physiological condition e.g. asystole ● Transducer turned off to the patient. ● A catheter tip lodged against a vessel wall. ● A clot on the catheter tip.	●Check patient and do necessary treatment ●Turn on the stopcock to patient and turn it off to the atmospheric pressure. ●Follow hospital procedure for dislodging catheter. ●Follow hospital procedures for clotted catheters.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, the background becomes gray and the alarm is disabled and ignores this fault.
IBP1/IBP2 CATHETER DISCONNECT	The catheter is disconnected from the patient during the pressure measurement (only IBP and ART labels). In this condition, the pressure drops dramatically, IBP signal becomes static and the MEAN pressure falls below 10 mmHg.	● Check the catheter connection to the patient and take necessary medical actions. ●3-way stopcock is disconnected from the patient due to zeroing, washing the tubing or blood sampling	Alarm level 1- The message is displayed in red background. By pressing ALARM SILENCE, the background becomes gray and the alarm is disabled and ignores this fault.

c) Messages

Message	Cause	Solution	Explanation
IBP1/IBP2 ADJUST SCALE	IBP1 or IBP2 signal is out of display range for about 5 seconds.	Press <AUTO SCALE> in IBP WINDOW menu.	
IBP1/IBP2 SEARCH	IBP signal can't be processed by the software because the signal is weak or less pulsatile.	●Check all IBP measurement setup is suitable or not. ●Check patient status and treat him, if necessary.	

9.4 IBP TRANSDUCER CLEANING

Clean all blood and other outer materials from the external surface of the transducer and cable using a slightly damp cloth and a mild detergent solution. Do not immerse the transducer in water and rinse it thoroughly.

NOTE:
The disposable transducers or domes must not be re-sterilized or re-used.

NOTE:
For protecting environment, the disposable transducers or domes must be recycled or disposed according to local regulations.

⚠**Warning**⚠
Do not autoclave or ETO sterilize the transducer.

Chapter 10, GAS Monitoring (Mainstream) *

10.1 GENERAL

Patient Monitor provides mainstream method for Gas measurement.
The IRMA mainstream gas analyzer is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases of adults, pediatrics and infant patient during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit (ICU), patient room. IRMA CO2 may also be used in the emergency medical services environment and road ambulances.

The sensor head is available in various configurations for ICU and OR applications. Concentrations of carbon dioxide (CO2), nitrous oxide (N2O), Halothane (HAL), Enflurane (ENF), Isoflurane (ISO), Sevoflurane (SEV) and Desflurane (DES) in different combinations are determined together with derived parameters such as respiratory rate, waveform and inspired/expired concentrations of all gases.

It is available in various parameter configurations as follow:

CO2 only sensor: CO2
AX+ sensor: CO2, N2O, one anaesthesia agent (HAL, ISO, ENF, SEV, DES), automatic gas detection, MAC

⚠**Warning**⚠
The IRMA probe is intended for use by qualified medical personnel only, and who are familiar with this manual.

⚠ **Warning** ⚠
The IRMA probe is intended for use only as an adjunct in patient assessment .It must be used in conjunction with clinical signs and symptoms.

⚠**Warning**⚠
No modification of this equipment is allowed.

NOTE:
(U.S. only) Federal law restricts this device to sale by or on the order of a physician.

The combination of IRMA and base monitor considered a ME SYSTEM and all ME SYSTEM requirements were complied with.

Measuring principle

The IRMA sensor head snaps in place on the top of the airway adapter that includes the optical components for measuring all gases. The IRMA airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained by continuously measuring the infrared gas absorption through the XTP windows in the gas flow through the adapter. The XTP windows are transparent to light in the wavelength ranges of interest and they are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission.

To measure the concentrations and identify the gases, absorption of up to nine different wavelengths of infrared light is measured.
The measurement of CO2, N2O and anaesthetic agents in the breathing gas mixture is based on the fact that the different gas components absorb infrared light at specific wavelengths. A microprocessor continuously calculates the CO2, N2O and anaesthetic agent concentrations from the infrared light absorption measurements. Using matrix calculations to identify which anaesthetic agents are present in the gas mixture.
(For more information about IRMA sensor, refer to APPENDIX V).

The measured parameters are EtCo2, EtN2O, EtAA (End Tidal CO2/N2O, Anesthesia Agent), FiCo2, FiN2O, FiAA (Fraction Inspiratory CO2/N2O/Anesthesia Agent), AWRR (Air Way Respiratory Rate) and MAC.

Fi and Et values are displayed after a breath and average of RESP value is updated regularly. If the respiration rate (RR) violates 80 bpm, Et value for Anesthesia agent and N2O will fall below nominal value (Et_{nom}) according to below formula:

$$Et = 80*Et_{nom} /RR$$

EtCO2 value for the respiration rate below 150 bpm will be in the specified range (IRMA CO2 and IRMA AX+).

MAC (Minimum alveolar concentration)

Minimum alveolar concentration or MAC is a concept used to compare the strengths of anesthetic vapors; in simple terms, it is defined as the concentration of the vapor in the lungs that is needed to prevent movement (motor response) in 50% of subjects in response to surgical (pain) stimulus.

The MAC value may be calculated and displayed by using end-tidal (ET) gas concentrations according to the following formula:

$$MAC = \%ET(AA_1)/X(AA_1) + \%ET(AA_2)/X(AA_2) + \%ET(N2O)/100$$

X(AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

NOTE:

The patient age as well as other individual factors is not taken into account in the above described formula. ET gas concentrations for secondary agent (AA2) is only available for IRMA AX+/OR+ probes.

Airway adapter:

The IRMA airway adapter is designed as a non-sterile single patient use disposable for both Adult/Pediatric and Infant applications. The IRMA Infant airway adapter has specially designed connectors for minimizing the dead space and can be used even for very small patients.

Figure 10-1 IRMA airway adapters: Adult/ Pediatric and infant

⚠**Warning**⚠

Do not use the IRMA adult/pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.

⚠**Warning**⚠

Do not use the IRMA infant airway adapter with adults as this may cause excessive flow resistance.

⚠**Warning**⚠

Do not use the adapter if it or its package is damaged and return it to the vendor.

⚠**Warning**⚠

Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.

⚠**Warning**⚠

Replace the airway adapter if rainout/condensation occurs inside the airway adapter.

⚠**Warning**⚠

Use only the recommended IRMA airway adapters for monitoring. Other airway adapters may cause improper performance. (Refer to Accessories chapter for detail)

Preparatory steps for gas measurement:

1. Connect the IRMA probe interface cable to the bedside monitor side panel and switch the power on.

2. Snap the IRMA probe on top of the IRMA airway adapter. It will click into place when properly seated.

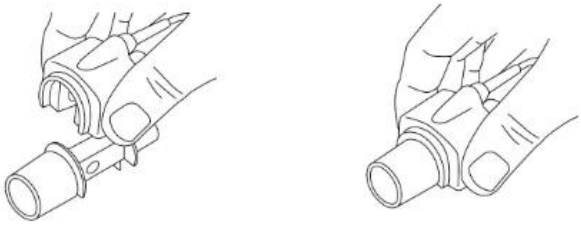


Figure 10-2 a. Preparatory Step2

3. Depending on IRMA model, perform the following:

IRMA AX+	IRMA CO2
• Wait minimum 30 seconds • Perform zeroing	• Wait minimum 10 seconds • Perform zeroing, if gas readings does not show 0% or if an unspecified accuracy message is displayed

4. A green LED indicates that the IRMA probe is ready for use.

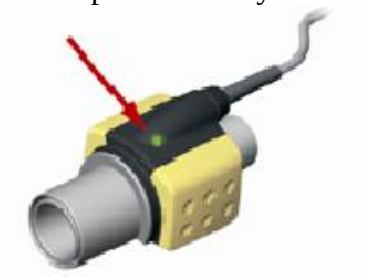


Figure 10-2 b. Preparatory Step 4

5. Connect the IRMA/airway adapter 15 mm male connector to the breathing circuit Y-piece.

Figure 10-2 c. Preparatory Step 5

6. Connect the IRMA/airway adapter 15 mm female connector to the patient's endotracheal tube.

Figure 10-2 d. Preparatory Step 6

Alternatively, connect an HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing an HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapour and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.

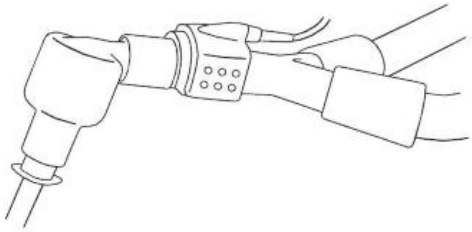


Figure 10-2 e. HME option

7. Unless the IRMA probe is protected with a HME always position the IRMA probe with the status LED pointing upwards.

Figure 10-2 f. Preparatory Step 7

⚠**Warning**⚠
To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.

⚠**Warning**⚠
Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.

⚠**Warning**⚠
Disposable airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.

⚠**Warning**⚠
Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.

Placement of IRMA Probe

When connecting the IRMA probe to an infant patient circuit it is important to avoid a direct contact between the IRMA probe and the infant's body due to the elevated surface temperature of the IRMA Probe.

⚠**Warning**⚠
The IRMA probe is not intended to be in patient contact.

⚠**Warning**⚠
If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.

⚠Warning⚠
Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA sensor is used in the electromagnetic environment specified in this manual.

⚠Warning⚠
The IRMA probe is not designed for MRI-environments.

⚠Warning⚠
Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.

NOTE:
Do not apply tension to the sensor cable.

NOTE:
Do not operate the IRMA probe outside the specified operating temperature environment. (Refer to the Specification chapter for detail)

Gas span check

Gas reading should be verified at regular intervals with a reference instrument or with calibration gas. The suggested interval for gas span check is once every year.

Pre-use check

Perform the tightness check of the patient circuit according to the User Manual for the monitor with the IRMA probe snapped on the IRMA airway adapter.
Always verify gas readings and waveforms on the monitor before connecting the IRMA airway adapter to the patient circuit.

⚠Warning⚠
Don't use the device in the environment which contains flammable anesthetic gas.

⚠Warning⚠
Before any interpretations are made of parameters readings and waveforms one, assure that the multi-gas probe is functioning correctly. Partial obstruction of airway with water can result in distorted waveforms. A leak in the airway may result in low parameters measurements. Check the monitor to see if it is functioning properly.

⚠Warning⚠

Verify sensor detection before starting GAS monitoring. Unplug the sensor from IRMA connector to verify that the error message "CO2 NO SENSOR "is displayed.

NOTE:

For more information of IRMA module, refer to the chapter “Technical Specifications” and APPENDIX V.

10.2 GAS WINDOW

The following items are displayed in CO2 parameter window:

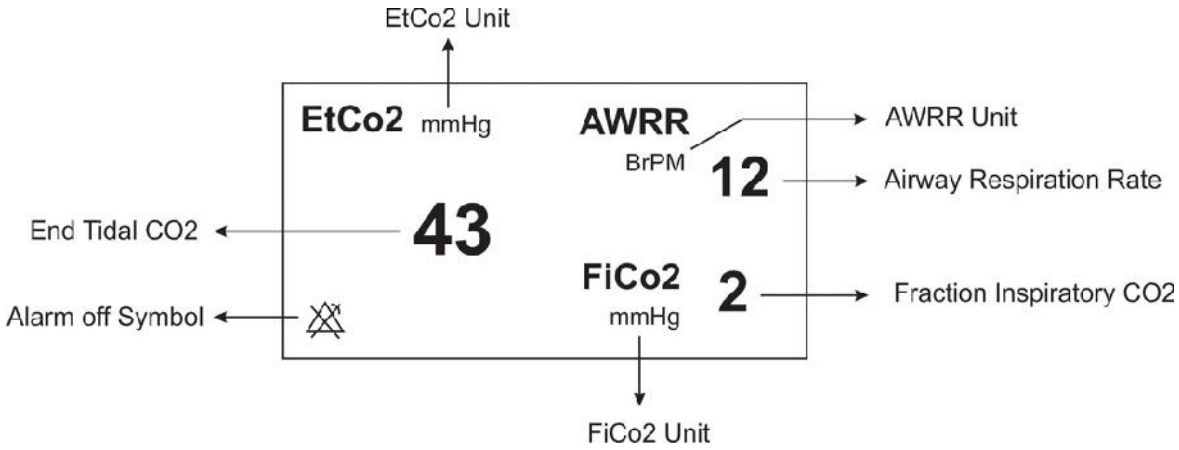


Figure 10-3 CO2 PARAMETER WINDOW

If Multi-gas sensor is used, GAS parameter window will be as follows:

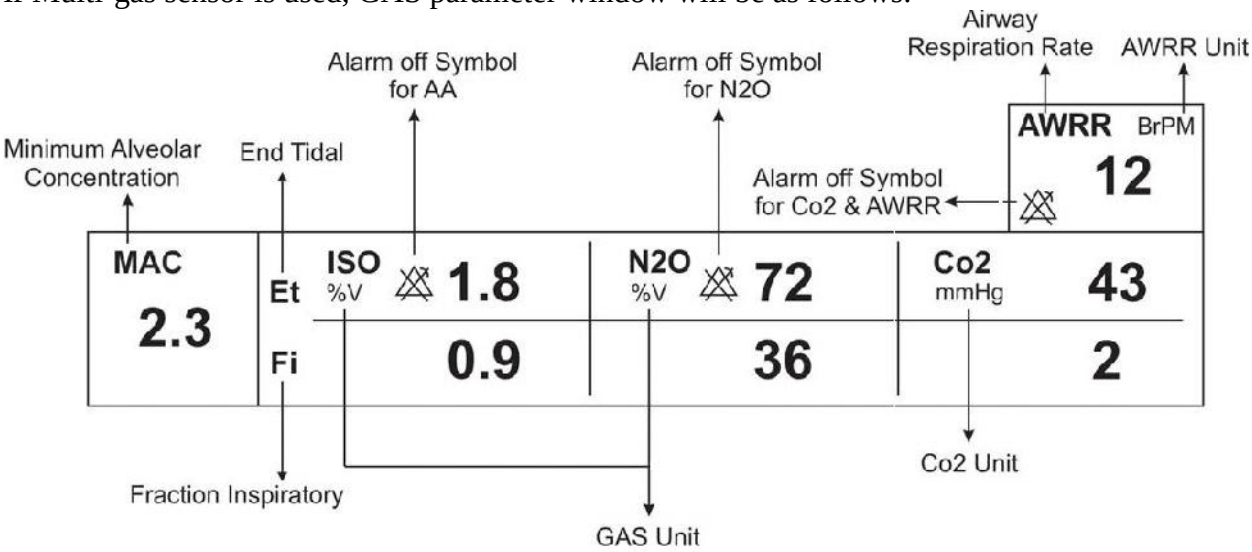


Figure 10-4 GAS PARAMETER WINDOW

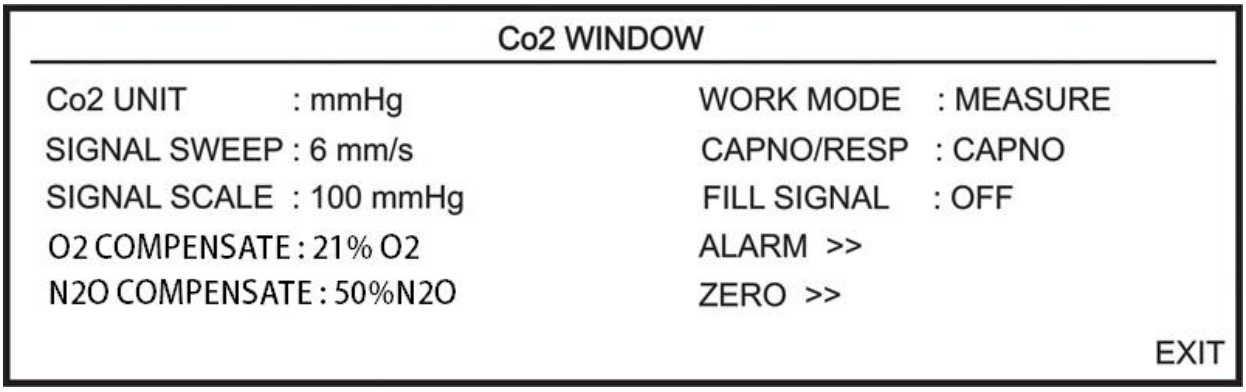
NOTE:

After Masimo Sweden AB capnography probe is connected to the monitor, at first sensor type (ISA or IRMA) is detected by the system and then displayed in front of the CO_2 signal.

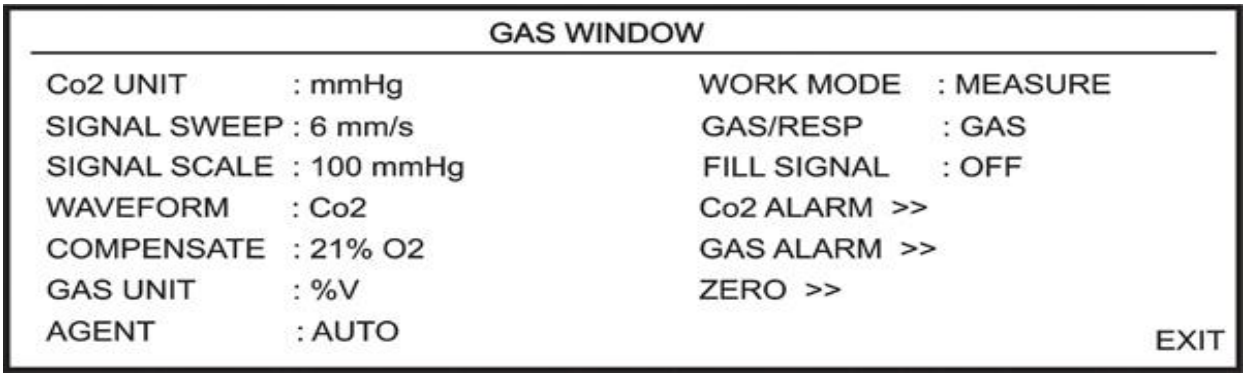
NOTE:

System displays Gas window for IRMA sensor as default. If when Gas window is open ISA probe is connected to the system, by exiting this window and entering it again you can change this window for ISA sensor.

The Capnography window for Mainstream sensor in different modes is as follows:



a) CO2 WINDOW in CO2 (ONLY) mode



b) GAS WINDOW in AX+ mode

Figure 10-5 Capnography window of Mainstream sensor in different modes

■ **Co2 UNIT**

Pick this item to adjust measurement unit. (Options: mmHg, KPa, %V)
$EtCo_2$ in %V is the Co_2 value (in mmHg) divided by ambient barometric pressure (in mmHg) which is a percentage of the barometric pressure.

$$\frac{P_{EtCo2(mmHg)}}{p_{Brometric(mmHg)}} = \text{EtCo2(\%V)}$$

$$\frac{133.322 \times P_{EtCo2(mmHg)}}{1000} = \text{EtCo2(KPa)}$$

■ **SIGNAL SWEEP**

Available options for SIGNAL SWEEP are 3, 6, 12/5 and 25mm/s.

■ **SIGNAL SCALE**

Depending on selected signal by user different scale options is available as following table:

CO2 Waveform Scale	N2O Waveform Scale	AA Waveform Scale
0-50 mmHg, 0-6% 0-100 mmHg, 0-10% 0-200 mmHg, 0-20%V <AUTOSCALE>	0-50% 0-100% <AUTOSCALE>	1,2,3,5,10,20% <AUTOSCALE>

AUTOSCALE is an option to adjust the scale automatically to display waveform in the best way.

■ **WAVEFORM**

Pick this item to select which gas waveform is displayed on the screen. Available Options are CO2, N2O, and AA.

NOTE:

If Gas system is activated, the WAVEFORM in the menu is displayed.

■ **COMPENSATE**

The presence of oxygen and nitrous oxide can cause some interference in CO_2 measurement. This is known as spectral broadening, and must be compensated.

N2O is measured and automatically compensated for in all IRMA sensors. Only when IRMA II (CO_2) probe is connected to the monitor, N_2O concentrates can be transmitted to the sensor. Available options for N_2O COMPENSATE are 0-100% N_2O.

■ **GAS UNIT**

Pick this item to adjust measurement unit for N2O, AA (DES, HAL, ISO, ENF, SEV) (Options: KPa, %V)

■ **AGENT**

In IRMA AX+ mode, anesthesia agent is identified automatically by the system and "AUTO" appears in the menu and couldn't be changed.

NOTE:

In IRMA AX+, if the concentration of anesthesia agent doesn’t exceed agent detection threshold, "AA?" will be displayed instead of the name of anesthesia agent in Multi-gas parameters window.

NOTE:

In IRMA AX+, if there are two anesthesia agent mixtures in patient airway and their concentration exceeds agent detection thresholds, the message "AGENT MIXTURE" is displayed on the screen.

- **WORK MODE**

Available options for WORK MODE are "standby" and "measure".
The default is "measure" mode .When gas monitoring is required, select "measure" mode. "standby" mode disables monitoring to decrease the power consumption and extend the life cycles of IR source and IRMA sensor.

NOTE:

When not using gas monitoring functions, it is suggested to disconnect the sensor.

NOTE:

If the monitor doesn't detect any CO2 signal for 30 minutes, after connecting IRMA sensor, the monitor automatically disables gas monitoring to decrease the power consumption and extend the life cycles of IR source and sensor. The monitor will be set in "standby" mode.

NOTE:

If the monitor doesn't detect adapter of IRMA sensor for 10 minutes, after connecting IRMA sensor, the monitor automatically will be set in "standby" mode.

NOTE:

When the system is in standby mode, you can enable GAS monitoring in GAS window by setting work mode to Measure.

- **GAS/RESP**

Pick to determine that respiration evaluation is performed by "Multi-gas" or "RESP" module. Available options are "GAS" and "RESP". When selecting "RESP", the system switches GAS module to standby mode, and toggle to display RESP waveform and parameters.

NOTE:

If only CO2 module is enabled, the CAPNO / RESP for this option will be displayed, otherwise the GAS / RESP will be displayed.

- **FILL SIGNAL**

Pick "ON" to show the waveform in a filled form.

■ CO2 ALARM

Pick "CO2 ALARM" in GAS WINDOW to call up the following menu:

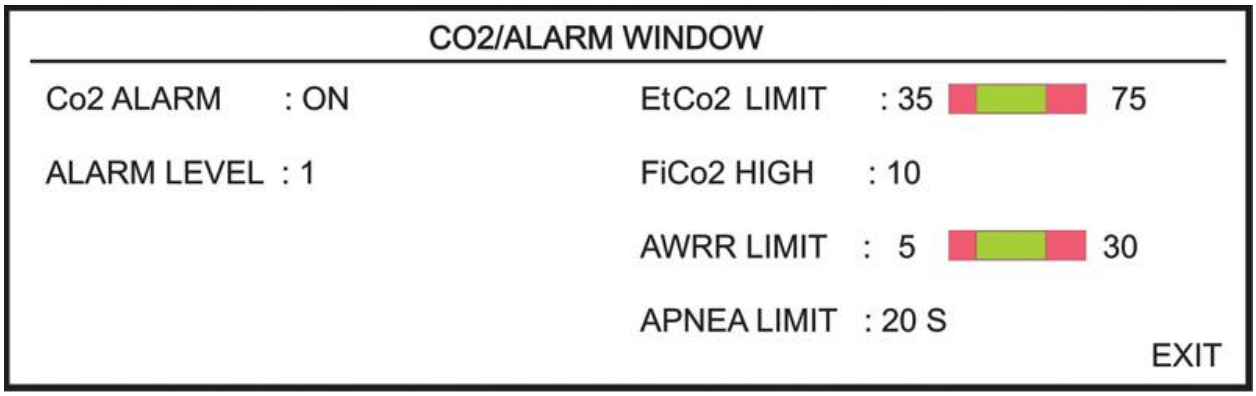


Figure 10-6 CO2 /ALARM WINDOW

- **CO2 ALARM**

Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in the Parameter Area.

- **ALARM LEVEL**

Selectable between 1and 2. Level 1 represents the most serious case.

- **EtCO2 LIMIT**

Alarm is activated when the EtCo2 exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (Range: 0.4~13%V step 0.1%V)
Default for upper limit is 6.5%V and for lower limit is 2.6%V.

- **FiCO2 HIGH**

Alarm is activated when the FiCo2 exceeds adjusted ALARM HIGH limit.
(Range: 0.4~13 %V step 0.1%V), Default for upper limit is 1.3%V.

- **AWRR LIMIT**

Alarm is activated when the AWRR exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.(Range :1-120BrPM)
Default for upper limit:

Adult/Pediatric: 30BrPM
Neonate: 60BrPM

Default for lower limit:

Adult/ Pediatric: 5BrPM
Neonate: 15BrPM

- **APNEA LIMIT**

Pick it to set the standard of judging an apnea case. It sets to 20 - 60 seconds and "OFF", increases/decreases by 5s. Select OFF to disable alarm.

■ **GAS ALARM**

Pick "GAS ALARM" in GAS WINDOW to call up the following menu:

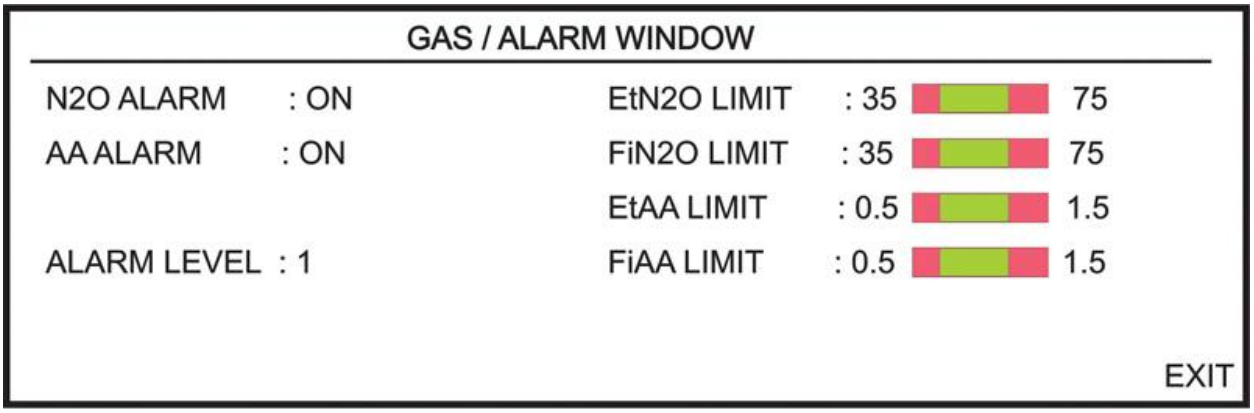


Figure 10-7 GAS/ALARM WINDOW

- **N2O ALARM and AA ALARM**

Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in the Parameter Area.

- **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

- **EtN2O LIMIT**

Alarm is activated when the EtN2O exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (Range: 1~100%V, step1%V)
Default for upper limit is 75%V and for lower limit is 35%V.

- **FiN2O LIMIT**

Alarm is activated when the FiN2O exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (Range: 1~82%V, step1%V)
Default for upper limit is 75%V and for lower limit is 35%V.

- **EtAA LIMIT**

Alarm is activated when the EtAA exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.

- **FiAA LIMIT**

Alarm is activated when the FiAA exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.

NOTE:

FiAA and EtAA have different alarm ranges for each anesthesia agent as a follow:

Anesthesia agent	Alarm range	Step	Alarm limit default
HAL	0.1~5%	0.1%	0.5~1.5%
DES	0.1~18%	0.1%	5~10%
ISO	0.1~5%	0.1%	0.8~2%
SEV	0.1~8%	0.1%	1~3%
ENF	0.1~5%	0.1%	0.5~1.5%

■ **Zeroing**

Pick "ZERO" in GAS WINDOW to call up the following menu:

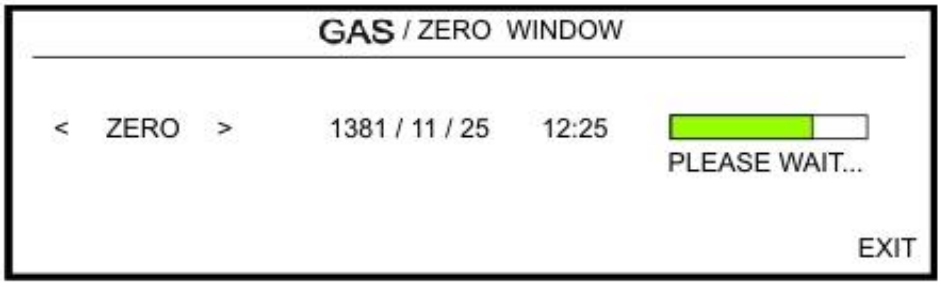


Figure 10-8 GAS/ZERO WINDOW

In order to secure high precision of the IRMA probe measurements the following zeroing recommendations should be followed.

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the monitor to transmit a Zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air in the IRMA airway adapter is of crucial importance for a successful Zeroing. If a “CO2 ZERO REFERENCE CALIB REQUIRED” alarm should appear directly after a Zeroing procedure, the procedure has to be repeated.

Always perform a pre-use check after Zeroing the probe.

⚠**Warning**⚠
Incorrect probe Zeroing will result in false gas readings.

NOTE:

If the adapter is not connected to the IRMA probe, the Zeroing will be impossible and "CO2 NO ADAPTER" will appear on the screen.

IRMA CO2 probes:
Zeroing needs to be performed ONLY when an offset in gas values is observed, or when an unspecified accuracy message is displayed, "CO2 ACCURACY INVALID, PLEASE ZERO".

Allow 10 seconds for warm up of the IRMA CO2 probes after power on before proceeding with the Zeroing Procedure.

Allow the IRMA probe to warm up for at least 10 seconds after changing the IRMA airway adapter before transmitting the Zero reference command.

IRMA AX+ probes:

Zeroing should be performed **every time the IRMA airway adapter is replaced**, or whenever an offset in gas values or an unspecified gas accuracy message is displayed, "CO2 ACCURACY INVALID, PLEASE ZERO".

Allow 30 seconds for warm up of the IRMA AX+ probes after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

If you press zero before passing this time, the message "CO2 UNABLE TO ZERO, SENSOR WARMING UP" will be shown and zeroing procedure won't be done.

10.3 GAS Alarm Messages

a) Physiological alarms

The alarm is activated when GAS parameters exceed the adjusted alarm limits:

Alarm	Situation	Visual prompt	Audio sound
AWRR HIGH	Respiration rate violates adjusted high limit	●AWRR value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
AWRR LOW	Respiration rate violates adjusted low limit	●AWRR value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 HIGH	End Tidal Co2 violates adjusted high limit	●EtCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 LOW	End Tidal Co2 violates adjusted low limit	●EtCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiCo2 HIGH	FiCo2 violates adjusted high limit	●FiCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

CO2 RESP APNEA	Non-respiration condition overruns adjusted time	● The alarm indicator flashes. ●The message "CO2 RESP APNEA" blinks in red background.	Activated
EtN2O HIGH	End Tidal N2O violates adjusted high limit	●EtN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtN2O LOW	End Tidal N2O violates adjusted low limit	●EtN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O HIGH	FiN2O violates adjusted high limit	●FiN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O LOW	FiN2O violates adjusted low limit	●FiN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtAA HIGH	End Tidal AA violates adjusted high limit	●EtAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtAA LOW	End Tidal AA violates adjusted low limit	●EtAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

FiAA HIGH	FiAA violates adjusted adjusted high limit	●FiAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiAA LOW	FiAA violates adjusted adjusted low limit	●FiAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

b) Technical alarms

Alarm	Cause	Solution	Explanation
CO2 SYSTEM FAULT # 1,2,3,4	Sensor error	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 REPLACE ADAPTER	IR signal low	Change adapter	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO ADAPTER	There is no adaptor connected to the sensor.	Connect adapter	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 INVALID	CO2 outside specified accuracy range.	Zero the sensor, if the problem still exists, contact after sales service of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
N2O INVALID	N2O outside specified accuracy range.	Zero the sensor, if the problem still exists, turn off and on the system and if again this message appears contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

AGENT INVALID	Agent outside specified accuracy range.	Zero the sensor, if the problem still exists, turn off and on the system and if again this message appears contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
AGENT UNRELIABLE	- The accuracy of the agent identification and measurement could not be guaranteed. - More than 2 anesthetic agents are present in the breathing circuit - High concentrations of solvents, cleaning agents or other interfering gases are present in the breathing circuit		Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 ACCURACY INVALID, PLEASE ZERO	Two or more agent are out of accuracy range except O2	Zero the sensor, if the problem persists contact after sales service of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 INVALID AMBIENT PRESSURE	Ambient pressure outside operating range.	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID AMBIENT TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO SENSOR	Sensor is disconnected from system	Connect sensor if problem exist again, Contact after sales service of manufacturer.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 ZERO REFERENCE CALIB REQUIRED	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.	Perform automatic zeroing procedure in an environment with CO2 less than 0.80%V.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

c) Messages

Message	Cause	Solution	Explanation

CO2 SENSOR STANDBY MODE	Manual setting and if no breath is detected for 30 min and ETCO2 is less than 4 mmHg for more than 30 min or when the monitor does not detect adapter of IRMA sensor for 10 min.	Enter GAS window and set WORK MODE on MEASURE.
CO2 UNABLE TO ZERO, SENSOR WARMING UP	Zero button is pressed before waiting for the sensor to be warmed up (30 sec).	

Status LED on the IRMA probe:

Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light[1]	Anesthetic agent present
Steady red light	Sensor error
Flashing red light	Check adapter

10.4 IRMA PROBE CLEANING

The IRMA probe can be cleaned using a cloth moistened with ethanol or isopropyl alcohol (< 70%).

⚠**Warning**⚠
The IRMA system (sensor and airway adapter) are non-sterile devices. Do not autoclave the devices as this will damage them.

⚠**Warning**⚠
Never sterilize or immerse the IRMA probe in liquid.

[1] Valid for IRMA AX+ probes only.

Chapter 11, GAS Monitoring (Sidestream) *

11.1 GENERAL

GAS monitoring provides a continuous waveform of airway gas concentration as a function of time. The waveform enables physician to evaluate adequacy of gas exchange in the lungs, integrity of the patient's airway, cardiopulmonary function and ventilator function.

Vital sign monitor uses sidestream method for gases measurement.
The ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+), intended to be connected to the monitor for monitoring of breath rate and the following breathing gases:

ISA CO2: CO2
ISA AX +: CO2, N2O, Halothane (HAL), Enflurane (ENF), Isoflurane (ISO), Sevoflurane (SEV) and Desflurane (DES)
ISA OR +: CO2, O2, N2O, Halothane (HAL), Enflurane (ENF), Isoflurane (ISO), Sevoflurane (SEV) and Desflurane (DES)

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances.
The intended patient population is adult, pediatric and infant patients.The Nomoline Product Family is intended to be used with systems that include the Masimo ISA gas measurement technology (ISA). The Nomoline Product Family is indicated for the measurement of respiratory rate and respiratory and anesthetic gases in adult, pediatric and infant patients. The Nomoline Product Family includes single use and multi-use devices for gas sampling and/or oxygen delivery. The Nomoline Product Family is indicated for use by clinical professionals in healthcare environments, including mobile

⚠**Warning**⚠
The device is intended for use by authorized healthcare professionals and are familiar with this manual only.

⚠ **Warning** ⚠
The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

NOTE:

An ISA sidestream gas analyzer shall only be connected to medical devices approved by Masimo Sweden AB.

NOTE (U.S. Only):

Federal law restricts this device to sale by or on the order of a physician.
For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

The combination of ISA and monitor shall be considered a ME SYSTEM.

➢ Measuring principle

Gas monitoring uses infrared (IR) spectroscopy method to measure and identify different gases. Infrared spectroscopy is used to measure the concentration of molecules that absorb infrared light. Since the absorption is proportional to the concentration of gas molecule, the concentration can be determined by comparing its absorption.

For ISA AX+ or ISA OR+ sensor, absorption of nine different wavelengths of infrared light is measured in order to identify the gases and measure their concentrations.

The measurement of CO2, N2O and anaesthetic agents in the breathing gas mixture is based on the fact that the different gases absorb infrared light at specific wavelengths. Since ISA analyzer analyzes the breathing gas mixture, the amount of infrared light absorbed by the gases is measured continuously by the infrared spectrometer.
A microprocessor continuously calculates the CO2, N2O and anesthetic agent concentrations from the infrared light absorption measurements using matrix calculations to identify which anesthetic agents are present in the gas mixture.

The sampling flow rate for all applications of ISA analyzer is 50 ± 10 sml/min.

Measurable parameters by ISA sensor are:

EtCO2, EtN2O, EtAA (End tidal of these gases), FiCO2, FiN2O and FiAA (Fraction inspiratory of these gases) and Air Way Respiratory Rate and MAC.

Fi and Et values are displayed after a breath and average of RESP value is updated regularly.

For more details, please refer to Technical Specification section.

NOTE:

It takes less than 10 seconds to display gas waveform data and 1 minute that the accuracy and other operating specification of the system comply with technical specification in Specification chapter.

MAC (Minimum alveolar concentration)

Minimum alveolar concentration or MAC is a concept used to compare the strengths of anesthetic vapors; in simple terms, it is defined as the concentration of the vapor in the lungs that is needed to prevent movement (motor response) in 50% of subjects in response to surgical (pain) stimulus.
The MAC value may be calculated and displayed by using end-tidal (ET) gas concentrations according to the following formula:

$MAC = \%ET(AA_1)/X(AA_1) + \%ET(AA_2)/X(AA_2) + \%ET(N2O)/100$
X(AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

NOTE:

The patient age as well as other individual factors is not taken into account in the above described formula. ET gas concentrations for secondary agent (AA2) are only available for ISA (Multi-gas) probe.

11.2 Nomoline Family sampling lines

ISA samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO_2 possible for adult, pediatric and infant patients.

The Nomoline Family sampling lines incorporate a unique water separation (**NO MO**isture) section, which removes condensed water. The NOMO section is also fitted with a bacteria filter that protects the gas analyzer from water intrusion and cross contamination.

As long as no sampling line is connected, the ISA gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the ISA gas analyzer switches to measuring mode and starts delivering gas data.

The Nomoline Family sampling lines are available in a wide variety of versions for both intubated and spontaneously breathing patients and in both disposable and re-sposable configurations – intubated patients can for instance be monitored using the disposable Nomoline Nasal CO_2 Cannula or a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Nasal CO_2 Cannula with Luer Connector.

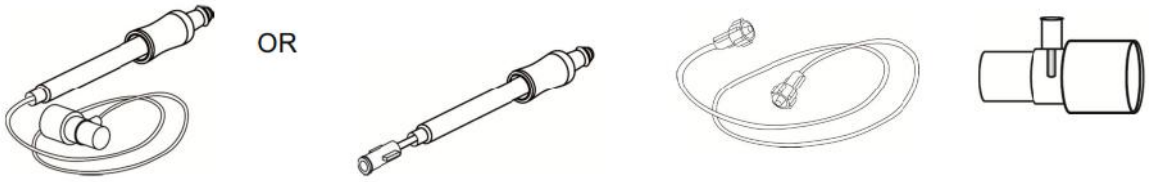


Figure 11-1 The disposable Nomoline Airway Adapter Set is an alternative to using a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter.

NOTE:

The ISA system is not design for use with water traps. The "Nomoline Adapter" (CAT no 108220) is designed and stated for Multi Patient Use and do replace the need of a watertrap.

The Nomoline Adapter may be used with other third party sampling lines and cannulas. Please however note that the Nomoline Family of sampling lines are designed for optimal performance and measurement fidelity when used with the ISA gas analyzers. For instance, when connecting to a respiratory circuit, the Masimo T-adapter provides a central gas sampling point thereby minimizing the risk of sampling line occlusion (see below)

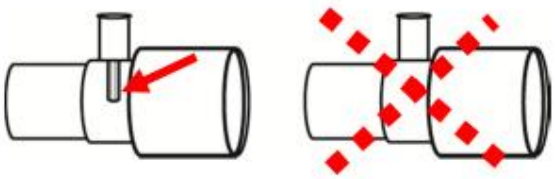


Figure 11-2 For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left above.

Warnings related to sampling line

⚠ **Warning** ⚠

Use only airway T-adapters with the sampling point in the center of the adapter.

⚠ **Warning** ⚠

Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.

⚠ **Warning** ⚠

Do not apply negative pressure to remove condensed water from the Nomoline Family sampling line.

⚠ **Warning** ⚠

Too strong positive or negative pressure in the patient circuit might affect the sample flow.

⚠ **Warning** ⚠

Strong scavenging suction pressure might affect the sample flow.

⚠ **Warning** ⚠

Do not lift the ISA gas analyzer by the sampling line as it could disconnect from the ISA, causing the ISA gas analyzer to fall on the patient.

NOTE:

Using sample tubes or cannulas with larger inner diameter than 1 mm will increase ISA's total system response time.

11.3 Nomoline Family sampling line replacement

Nomoline Family sampling lines should be replaced according to good clinical practice or when the sampling line gets occluded. Occlusion occurs when water, secretion etc. is aspired from the respiratory circuit to such extent that ISA cannot maintain the normal 50 sml/min sample flow. This situation is indicated by a red flashing gas inlet connector and an alarm message; Replace the Nomoline and wait until the gas inlet connector switches to green indicating that the ISA gas analyzer is ready for use.

⚠ **Warning** ⚠

Replace the sampling line if the sampling line input connector starts flashing red, or the Monitor displays a "Check sampling line" message.

⚠ **Warning** ⚠

Do not use sampling line if it or its package is damaged and return it to the vendor.

⚠ **Warning** ⚠

Use only the recommended ISA sampling line by the manufacturer. Other sampling lines may cause sensor improper performance. (Refer to Accessories chapter for more detail)

⚠ **Warning** ⚠

If sampling line is connected to the patient for a long time period, you should replace it every two weeks or when "Sampling line clogged" message is displayed (Each one happens earlier).

⚠**Warning**⚠

Do not use the infant sampling line with adults as this may cause excessive flow resistance.

The sampling line has specially designed connectors for minimizing the dead space and can be used even for very small patients.

11.4 Preparatory steps for Multi-gas monitoring

1. Securely mount the ISA analyzer. Connect the ISA analyzer interface cable into corresponding connector on the side panel of patient monitor.

⚠**Warning**⚠

Do not operate the ISA sidestream gas analyzer if the enclosure is damaged.

⚠**Warning**⚠

Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.

NOTE:

The ISA analyzer should be securely mounted in order to avoid the risk of damage to the ISA.

⚠ **Warning** ⚠

Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.

⚠ **Warning** ⚠

Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

NOTE:

Do not operate the ISA sidestream gas analyzer outside the specified operating environment.

⚠**Warning**⚠

Measurements can be affected by mobile and portable RF communications equipment. It should be assured Make sure that the ISA gas analyzer is used in the electromagnetic environment specified in EMC section of this manual.

⚠**Warning**⚠

The ISA sidestream gas analyzers are not designed for MRI (magnetic resonance imaging) environments. During (MRI) scanning, ISA must be placed outside the MIR suite.

⚠**Warning**⚠

Use of high frequency electrosurgical equipment in the vicinity of the ISA/monitor may produce interference and cause incorrect measurements.

2. Connect a Nomoline Family sampling line to the ISA analyzer input connector. It will click into place when properly seated.

⚠**Warning**⚠

Do not use the Nomoline Airway Adapter Set Infant with adult/pediatric patients.

⚠ **Warning** ⚠

Do only use sample lines intended for anesthetic agents if N_2O and/or anesthetic agents are being used.

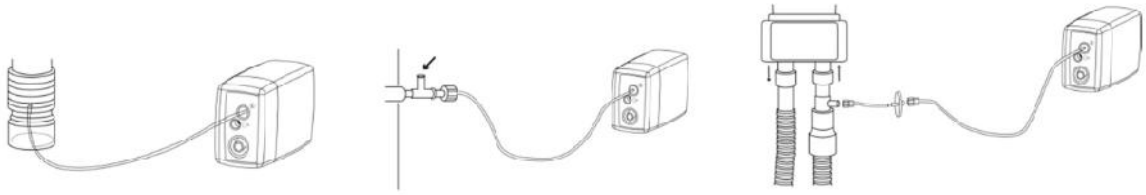
⚠ **Warning** ⚠

Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination.

3. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit to prevent pollution of the operation room when N_2O and/or anesthetic agents are being used.

⚠ **Warning** ⚠

Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.



NOTE:

Returning the ISA's exhaust gas to the patient circuit is not allowed in the USA.

⚠ **Warning** ⚠

Exhaust gases should be returned to the patient circuit or to a scavenging system.

4. Power on the monitor.
5. A green indicator indicates that the ISA analyzer is ready for use.

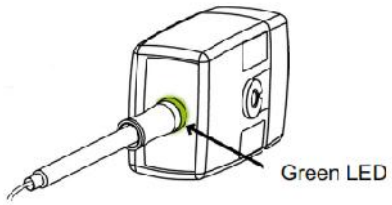


Figure 11-3 Fifth Preparatory Step

6. Perform a pre-use check as a following (11-5 section):

11.5 Pre-use check

Before connecting the Nomoline Family sampling line to the breathing circuit, do the following:

1. Connect the sampling line to the ISA gas inlet connector.

2. Check that the gas inlet connector is lit with a steady green light.

3. *For ISA OR+:*
   Check that the O2 reading on the monitor is correct (21 vol%).

4. Breathe briefly into the sampling line and check that monitor displays a valid CO_2 waveform and valid values.

5. Occlude the sampling line with a fingertip and wait for 10 seconds.

6. Check that occlusion alarm is displayed on the monitor and that the gas inlet connector shows a flashing red light.

7. *If applicable:*
Perform a tightness check of the patient circuit with the sampling line attached.

NOTE:

Variations in barometric pressure do not have any effects due to internal barometric pressure compensation.

NOTE:

There are no adverse effects on stated performance due to cycling pressure of up to 10 KPa.

⚠**Warning**⚠
Don't use the device in the environment which contains flammable anesthetic gas.

⚠**Warning**⚠
Before any interpretations are made of EtCo2 reading and waveform, assure that the capnography system is functioning correctly. Monitor contamination by secretions and Partial obstruction of sampling line with water can result in distorted CO2 waveforms. A leak in the sampling line may result in low EtCo2 measurements. Check the monitor to see if it is functioning properly.

⚠**Warning**⚠
Returning sampled gas to the patient breathing system may cause infection.

⚠**Warning**⚠
Do not expose the monitor with sidestream capnography module to vibration and impact.

NOTE:

Do not apply tension to the ISA sensor cable.

⚠Warning⚠

Verify ISA sensor detection before starting GAS or CO2 monitoring. Unplug the ISA sensor from its connector to verify that the error message " CO2 NO SENSOR "is displayed.

NOTE:

Refer to APPENDIX VI for more information about ISA module.

⚠Warning⚠

Positioning the monitor lower than the patient may facilitate condensed water and secretions move towards the system thereby resulting in blockage of filters. Keep the system preferably above the patient level. This prevents secretions and water dribbling down the tube towards the monitor end and extends the lifetime of the filters.

11.6 Zeroing procedure

The gas analyzer needs from time to time to establish a zero reference level for the gas measurements and the flow. The zero calibration is here referred to as “zeroing".

ISA performs zeroing by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed 1 to 3 times per day, and takes less than 3 seconds for ISA CO_2 gas analyzers and less than 10 seconds for ISA Multigas analyzers.

After zeroing procedure is completed, a flat line signal and message “ZEROING IN PROGRESS” will be displayed.

During zeroing, if ISA’s exhaust gas is returned to the patient circuit, the returned gas level will be different from the gas level at the sampling site.

⚠Warning⚠

Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.

NOTE:

Using special clamps, designed by the manufacturer, for connecting ISA sensors to serum stand.

11.7 GAS WINDOW

The following items are displayed in CO2 parameter window:

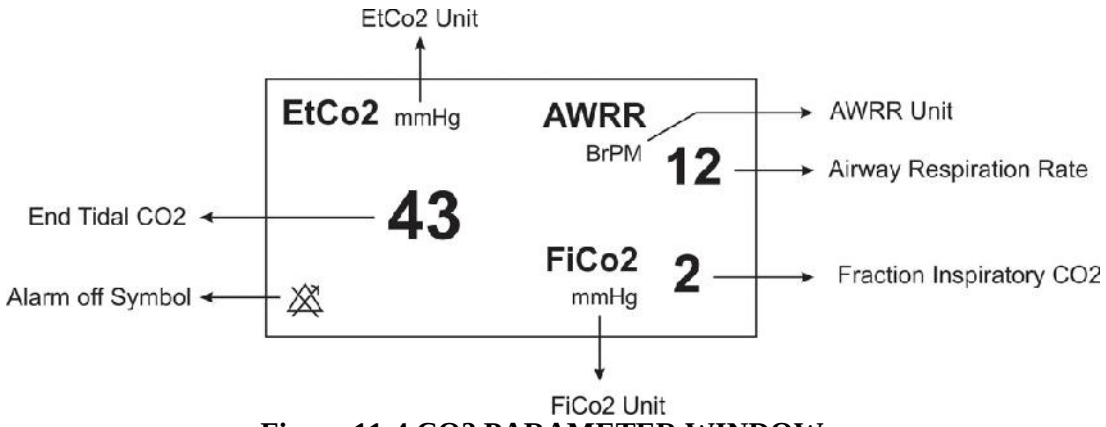


Figure 11-4 CO2 PARAMETER WINDOW

If Multi-gas sensor is used, GAS parameter window will be as follows:

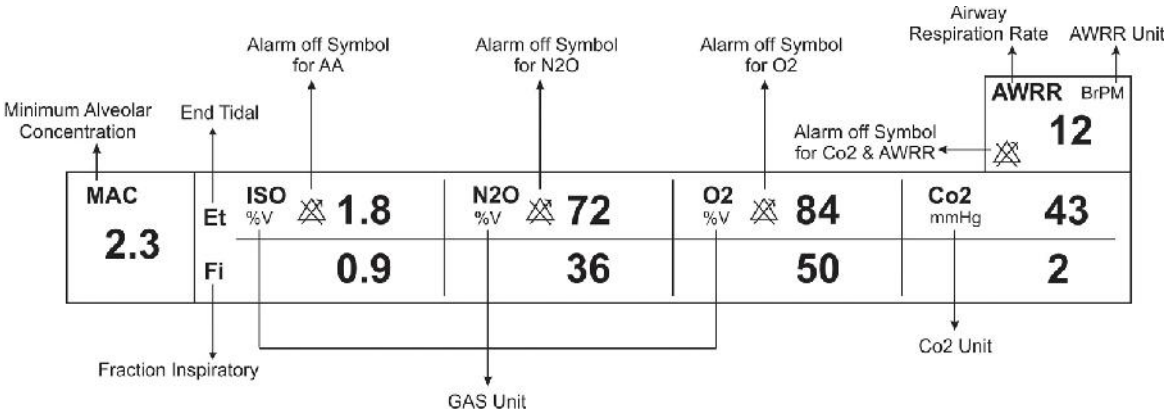


Figure 11-5 GAS PARAMETER WINDOW

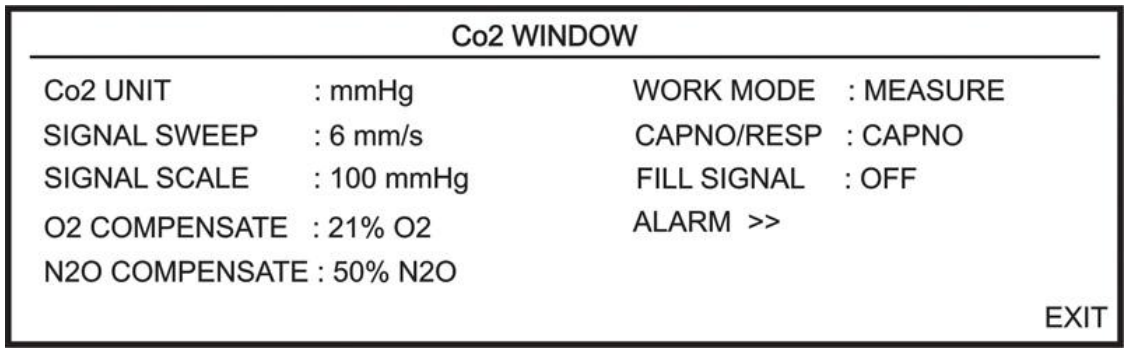
NOTE:

After capnography probe is connected to the monitor, at first sensor type (ISA or IRMA) is detected by the system and then displayed in front of the CO2 signal.

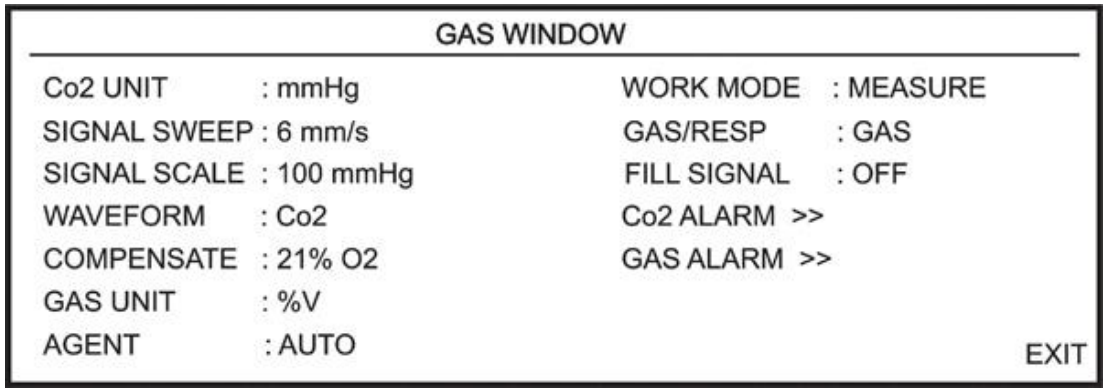
NOTE:

The system displays Gas window for IRMA sensor as default. To observe Gas window for ISA sensor, exit Gas window and enter it again while ISA probe is connected to the system.

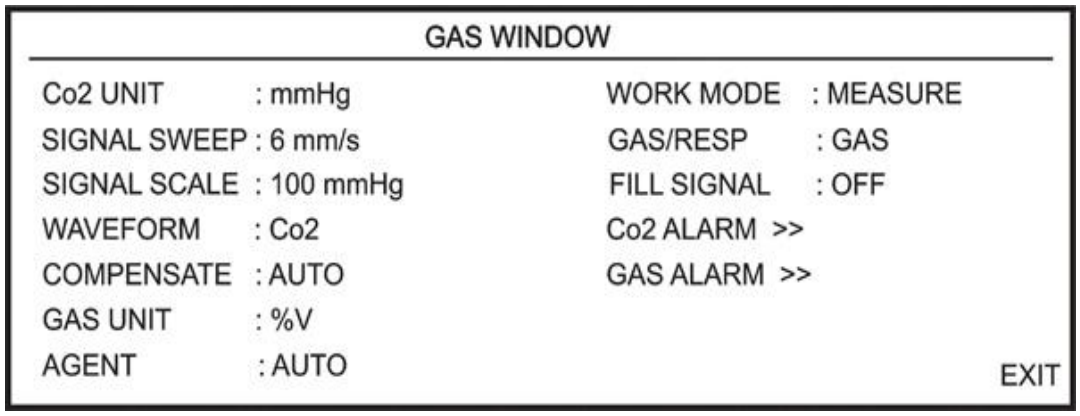
The Capnography Window for Sidestream sensor in different modes is as follows:



CO2 WINDOW in CO2(ONLY) mode



a) GAS WINDOW in AX+ mode



GAS WINDOW in OR+ mode

Figure 11-6 Capnography Window of sidestream sensor in different modes

- **Co2 UNIT**

Pick this item to adjust CO2 measurement unit. (Options: mmHg, KPa, %V)
EtCo2 in %V is the EtCo2 value (in mmHg) divided by ambient barometric pressure (in mmHg) which is a percentage of the barometric pressure.

$$\text{EtCo2(\%V)} = \frac{P_{EtCo2(mmHg)}}{p_{Brometric(mmHg)}}$$

$$\text{EtCo2(KPa)} = \frac{133.322 \times P_{EtCo2(mmHg)}}{1000}$$

- **SIGNAL SWEEP**

Select it to adjust Multi-gas signals sweep. Available options for SIGNAL SWEEP are 3, 6, 12/5 and 25mm/s.

- **SIGNAL SCALE**

Depending on selected signal chosen by user different scale options are available as following table:

CO2 Waveform Scale	O2 Waveform Scale	N2O Waveform Scale	AA Waveform Scale
0-50 mmHg, 0-6% 0-100 mmHg, 0-10% 0-200 mmHg, 0-20%V <AUTOSCALE>	0-50% 0-100% <AUTOSCALE>	0-50% 0-100% <AUTOSCALE>	1,2,3,5,10,20% <AUTOSCALE>

AUTOSCALE is an option to adjust the scale automatically to display waveform in the best way.

- **WAVEFORM**

Pick this item to select which gas waveform is displayed on the screen. Available Options are CO2, N2O, O2, and AA.

- **O2 COMPENSATE**

The presence of oxygen can cause some interference in CO2 measurement. This is known as spectral broadening, and must be compensated.
The O2 compensation is performed automatically for all ISA sensors with the oxygen sensor available on it. When using an ISA without an oxygen sensor, i.e. when oxygen measurement is performed by the other device like anesthesia machines and ventilators, the current oxygen concentration should be transmitted to the sensor.
When there is not O2 sensor, available options for COMPENSATE are OFF and 1-100% O2. If there is O2 sensor, only "AUTO" will be available and it cannot be changed.

■ **N2O COMPENSATE**

The presence of N2O can cause some interference in CO2 measurement. This is known as spectral broadening and must be compensated.

N2O is measured and automatically compensated for in ISA sensors (AX+/OR+). Therefore N2O concentration should be transmitted to ISA sensor (CO2).

Available options are 0-100% N2O.

NOTE:

You can see this option only when ISA (CO2) sensor is connected to the system. In other modes (ISA AX+/OR+), this option is eliminated from the respective menu. In other words CO2 menu for ISA (CO2) and IRMA (CO2) is similar except for "N2O COMPENSATE" option.

■ **GAS UNIT**

Pick this item to adjust measurement unit for O2, N2O, AA (DES, HAL, ISO, ENF, SEV) (Options: KPa, %V)

■ **AGENT**

In ISA AX+/OR+, there is automatic identification of anesthesia agent and "AUTO" is displayed in menu and couldn't change.

NOTE:

In ISA OR+, if the concentration of anesthesia agent doesn't exceed agent detection threshold, "AA?" will be displayed instead of the name of anesthesia agent in Multi-gas parameters window.

NOTE:

In ISA OR+, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds, the message "AGENT MIXTURE" is displayed on the screen.

■ **WORK MODE**

Available options for WORK MODE are "standby" and "measure".

The default is "measure" mode .When gas monitoring is required, select "measure" mode." standby" mode disables monitoring to decrease the power consumption and extend the life cycles of IR source and ISA module.

NOTE:

When not using gas monitoring functions, it is suggested to disconnect the sensor. When gas monitoring is not used, it is suggested to disconnect the sensor.

NOTE:

If the monitor doesn't detect any CO2 signal for 30 minutes after connecting ISA sensor, the sensor is automatically disabled and goes to "standby" mode to decrease the power consumption and extend the life cycle of IR source and ISA sensor.

NOTE:

ISA sensor remains in standby mode until the sampling line is connected to it. As soon as the sampling line is connected, the sensor switches on and starts measurement.

NOTE:

For enabling ISA sensor, you can enter Gas window and set the monitor to Measure mode.

■ **GAS/RESP**

Select this item to determine that respiration evaluation is performed by "Multi-gas" or "RESP" module. Available options are "GAS" and "RESP". When selecting "RESP", the system switches Multi-gas module to standby mode, and displays RESP waveform and parameters.

■ **FILL SIGNAL**

Pick "ON" to show the waveform in filled form.

■ **CO2 ALARM**

Pick "CO2 ALARM" in GAS WINDOW to call up the following menu:

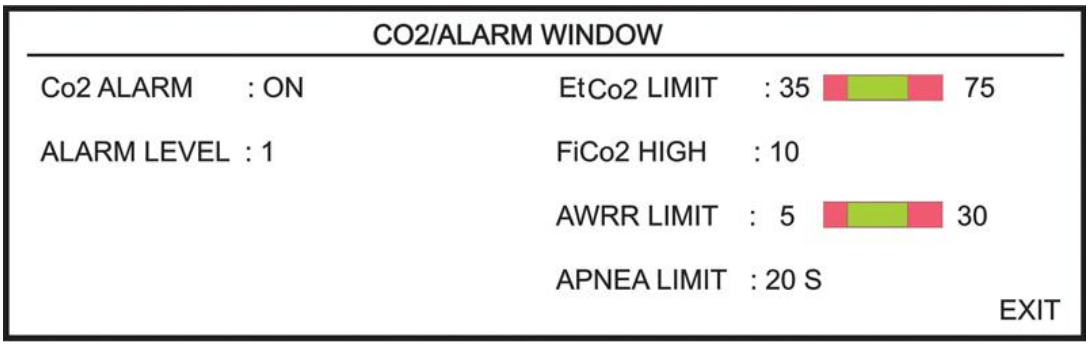


Figure 11-7 CO2/ALARM WINDOW

- **CO2 ALARM**

Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in Multi-gas Parameter Area.

- **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

- **EtCO2 LIMIT**

Alarm is activated when the EtCo2 exceeds adjusted ALARM HIGH or LOW limit (Range: 0.4~13%V step 0.1%V)
Default for upper limit is 6.5%V and for lower limit is 2.6%V.

- **FiCO2 HIGH**

Alarm is activated when the FiCo2 exceeds adjusted ALARM HIGH limit (Range: 0.4~13 %V step 0.1%V). Default for upper limit is 1.3%V.

- **AWRR LIMIT**

Alarm is activated when the AWRR exceeds adjusted ALARM HIGH or LOW limit. (Range: 1-120BrPM)
Default for upper limit:

Adult/Pediatric:	30BrPM
Neonate:	60BrPM

Default for lower limit:

Adult/Pediatric:	5BrPM
Neonate:	15BrPM

- **APNEA LIMIT**

Pick it to set the standard of judging an apnea case. It sets to 20 - 60 seconds and "OFF" and increases/decreases by 5s.

■ **GAS ALARM**

Pick "GAS ALARM" in GAS WINDOW to call up the following menu:

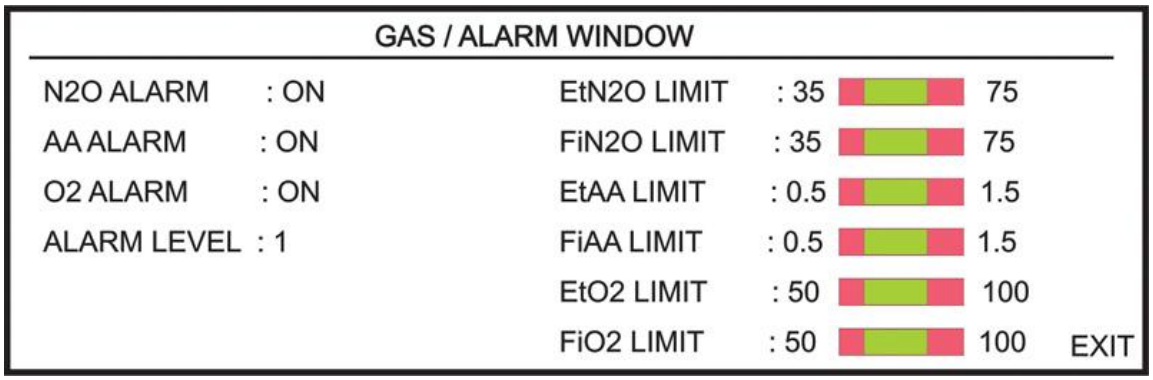


Figure 11-8 GAS/ALARM WINDOW

- **N2O ALARM, AA ALARM and O2 ALARM**

Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in Multi-gas Parameter Area.

- **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

- **EtN2O LIMIT**

Alarm is activated when the EtN2O exceeds adjusted ALARM HIGH or LOW limit.
(Range: 1~100%V step1%V)
Default for upper limit is 75%V and for lower limit is 35%V.

- **FiN2O LIMIT**

Alarm is activated when the FiN2O exceeds adjusted ALARM HIGH or LOW limit.
(Range: 1~82%V, step1%V)
Default for upper limit is 75%V and for lower limit is 35%V.

- **EtAA LIMIT**

Alarm is activated when the EtAA exceeds adjusted ALARM HIGH or LOW limit.

- **FiAA LIMIT**

Alarm is activated when the FiAA exceeds adjusted ALARM HIGH or LOW limit.

NOTE:

Alarm range and alarm limit default of different anesthesia agents are mentioned in the table below:

Anesthesia agent	Alarm range	Step	Alarm limit default
HAL	0.1~5%	0.1%	0.5~1.5%
DES	0.1~18%	0.1%	5~10%
ISO	0.1~5%	0.1%	0.8~2%
SEV	0.1~8%	0.1%	1~3%
ENF	0.1~5%	0.1%	0.5~1.5%

- **EtO2 LIMIT**

Alarm is activated when the EtO2 exceeds adjusted ALARM HIGH or LOW limit.
(Range: 18~105%V step1%V)
Default for upper limit is 100% and for lower limit is 50%.

- **FiO2 LIMIT**

Alarm is activated when the FiO2 exceeds adjusted ALARM HIGH or LOW limit.
(Range: 18~105%V step 1%V)
Default for upper limit is 100%V and for lower limit is 50%V.

11.8 GAS (Sidestream) Alarm Messages

a) Physiological alarms

The alarm occurs when Gas parameters exceed the adjusted alarm limits:

Alarm	Situation	Visual prompt	Audio sound
AWRR HIGH	Respiration rate violates adjusted high limit	●AWRR value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
AWRR LOW	Respiration rate violates adjusted low limit	●AWRR value blinks. ● The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 HIGH	End Tidal Co2 violates adjusted high limit	●EtCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 LOW	End Tidal Co2 violates adjusted low limit	●EtCo2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiCo2 HIGH	FiCo2 violates adjusted high limit	●FiCo2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated

CO2 RESP APNEA	Non-respiration condition overruns adjusted time	● The alarm indicator flashes. ●The message "CO2 RESP APNEA" blinks in red background.	Activated
EtN2O HIGH	End Tidal N2O violates adjusted high limit	●EtN2O value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtN2O LOW	End Tidal N2O violates adjusted low limit	●EtN2O value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O HIGH	FiN2O violates adjusted high limit	●FiN2O value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O LOW	FiN2O violates adjusted low limit	●FiN2O value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtAA HIGH	End Tidal AA violates adjusted high limit	●EtAA value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtAA LOW	End Tidal AA violates adjusted low limit	●EtAA value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated

FiAA HIGH	FiAA violates adjusted adjusted high limit	●FiAA value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiAA LOW	FiAA violates adjusted adjusted low limit	●FiAA value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtO2 HIGH	End Tidal O2 violates adjusted high limit	●EtO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtO2 LOW	End Tidal O2 violates adjusted low limit	●EtO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 HIGH	FiO2 violates adjusted high limit	●FiO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 LOW	FiO2 violates adjusted low limit	●FiO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 Too Low	FiO2 falls below 18%.	●FiO2 value blinks. ●The alarm indicator flashes. ●The alarm Level 1- the message is displayed in red background.	Activated

b) Technical alarms

Alarm	Cause	Solution	Explanation
CO2 SYSTEM FAULT #1,2,3,4	Sensor error	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CHECK SAMPLING LINE	IR signal low	Replace the sampling line	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
SAMPLING LINE CLOGGED	Sampling line occlusion	Remove obstruction otherwise change the sampling line by a correct one.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID	CO2 outside specified accuracy range.	Zero the system. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
O2 INVALID	O2 outside specified accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
N2O INVALID	N2O outside specified accuracy range.	Zero the sensor. If the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
AGENT INVALID	Agent outside specified accuracy range.	Zero the sensor. If the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

AGENT MIXTURE	In ISA OR+, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds		Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
AGENT UNRELIABLE	- The accuracy of the agent identification and measurement could not be guaranteed. - More than 2 anesthetic agents are present in the breathing circuit - High concentrations of solvents, cleaning agents or other interfering gases are present in the breathing circuit		Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 ACCUTACY INVALID, PLEASE ZERO	Anesthesia agents are out of accuracy range except O2	Zero the sensor. If the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 INVALID AMBIENT PRESSURE	Ambient pressure outside operating range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID AMBIENT TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
REPLACE O2 SENSOR	O2 sensor lifetime is passed.	Replace O2 sensor by a new one.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
O2 SENSOR ERROR	Sensor failure	Replace O2 sensor by a new one.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
O2 SPAN CALIB REQUIRED	If the sensor operate for a long time period without being disconnected from the sampling line or the operating temperature for oxygen sensor changes significantly	Perform room air calibration.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

CO2 ZERO REFERENCE CALIB REQUIRED	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.	Perform automatic zeroing procedure in an environment with CO2 less than 0.80%V.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO SENSOR	Sensor is disconnected from the system	Connect the sensor to the system. If the problem still exists, contact after sales service of manufacturer.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

c) Messages

Message	Cause	Solution	Explanation
CO2 SENSOR STANDBY MODE	Manual setting and if no breath is detected for 30 min and ETCO2 is less than 4 mmHg for more than 30 min or when the monitor does not detect the sampling line.	Enter GAS window and set WORK MODE to MEASURE.	
ZEROING IN PROGRESS	The zeroing procedure is being conducted.		After that the zeroing procedure is completed, this message and a flat line signal will be displayed.

Indicator status on the ISA sensor:

Steady green light	ISA in operation and OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	ISA sensor error
Blinking red light	Check sampling line

11.9 ISA system Cleaning

The ISA sidestream gas analyzers and the Nomoline Adapter may be cleaned using a cloth moistend (not wet) with max 70% ethanol or isopropyl alcohol.

To prevent cleaning liquids and dust from entering the ISA gas analyzer through its sampling gas inlet connector, keep the Nomoline Family sampling line fitted while cleaning the analyzer.

⚠Warning⚠
Never sterilize or immerse the ISA sidestream gas analyzer in liquid.

⚠Warning⚠
Do not sterilize or immerse Nomoline Family sampling lines in liquid.

⚠Warning⚠
The ISA system (sensor and sampling line) is non-sterile device. Do not autoclave the sampling line as this may damage it.

11.10 ISA system Maintenance

⚠Warning⚠
No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.

⚠ Warning ⚠
Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.

Chapter 12, Depth of Anesthesia Monitoring *

12.1 GENERAL

Anesthesiologists have been using hemodynamic and clinical characteristics such as heart rate, blood pressure, tears, facial variations, pupil diameter and perspiration as well as different stimulations and personal experiences to measure the level of patient consciousness for many years. They also use devices such as Capnography and pulse oximetry in this regard. Since none of these parameters is directly associated with the level of consciousness, Physicians must use indirect measurement methods to apply appropriate dosage for each patient in order to make the patient feel no pain during surgery.
There are some standards to determine required dosage for each patient, for example one standard is based on needs of a middle-aged man. This standard is certainly not suitable for females, patients of different ages or patients with dangerous and unknown diseases.

There are common cases in which the patient is overdosed (receives excessive amount of drug) and this results in long wake-up time after anesthesia, prolonged recovery accompanied by nausea as well as economic loss.
A rare and chronic condition is when the patient receives low amount of drug and does not lose his consciousness completely (subconsciousness level), but due to the injection of muscle relaxant drugs he is unable to react during surgery and has a vague picture of what is going on around him. This can cause long-term emotional consequences and subsequent psychological traumas. The most of these patients suffer nightmare during few days after surgery.
A lot of attempts were made to measure the level of consciousness using patient vital signs signals, a method through which the required dosage of drug for each patient can be estimated without considering physiological factors such as weight, age, etc.

The Brain Function Assessment Monitor (BFA) is a non-invasive measurement tool for use by trained professionals to measure the level of consciousness (LOC) in all area of the hospital. BFI index is calculated through EEG signals. BFA module displays the related indexes but does not perform any data interpretation. All data interpretation is performed by a physician.
The monitor is intended for use in monitoring the hypnotic state of the brain by data acquisition of EEG signals of the anesthetized or sedated patient in all areas of the hospital.

Measurement principle
An instrumentation amplifier collects ongoing EEG with a high Common Mode Rejection Ratio (CMRR) ensuring a high-quality EEG acquisition. Special algorithms that eliminate their effects on subsequent BFI calculations detect artefacts.
The performance of the BFI is based on the analysis of the frequency content and phase of the EEG signals.
The monitor also evaluates the amount of burst suppression (BS) in each fifty-second period of the EEG. This measurement quantifies the amount of "silent" or "flat" EEG periods characteristic of the deepest levels of hypnosis.

The measured parameters in BFA monitor are EMG (Electromyography) and SQI (Signal Quality Index).

BFA Index (BFI)

The BFI is a unit-less index from 0 to 100, where 0 indicates a flat EEG and 100 indicates EEG activity in awake state. BFI range in adequate anaesthesia is designed to be between 40 and 60. All values in the table are approximate values based on the mean values of the patient behaviour. The relationship between BFI and the clinical state of patient is shown in the table below:

BFI	Clinical State
80-100	Awake
60-80	Light/Moderate sedation
40-60	Range considered as adequate for surgical anesthesia (General Anesthesia)
20-40	Deep anesthesia, in most cases accompanied by burst suppression (Deep Hypnotic State).
0-20	Close to coma with BS pattern. EEG is generally iso-electric (Burst Suppression).

EMG

High levels facial muscular or electromyographic (EMG) activity can interface with the BFI under certain circumstance .The monitor incorporates an EMG filter that removes most of the potential interfering EMG activity. The EMG bar shows the energy of the EMG level in the 30-47 Hz frequency band (0-100 logarithmic).

EMG activity is expected to be present when the patient is awake. When the patient is asleep, EMG activity can increase due to:

- Reflex reactions to painful stimuli during surgery.
- Lack of muscular relaxation.
- Muscular rigidity caused by some opioids (analgesics).
- Presence of large external electrical fields, e.g. electrosurgical unit.

The EMG bar should be checked frequently, especially in case of a sudden increase in the BFI. If BFI increases along with muscular activity, there will be risk of EMG interference. When this happens, attention must be paid to the stimuli received from the patient during surgery. In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent will decrease BFI. Since patients receiving neuromuscular blocking agents cannot exhibit movement as a sign of arousal, the BFI is a valuable tool in their anaesthetic management.

Burst Suppression Indicator (BS)

The monitor includes a Burst Suppression indicator to show periods when the EEG is iso-electric or “flat”. The indication appears in the BFI window and shows the percentage of burst suppression over the last 50 seconds of EEG signal. A BS% =20 readouts means that the EEG has been iso-electric during 20% of the last 50 seconds. In normal and low level of unconsciousness, BS value is usually 0 and it increases in deeper levels of unconsciousness. For patients who are close to coma state, BS value is usually 75%.

SQI: Signal Quality Index

The artefact rejection algorithm ensures that the incoming EEG is not contaminated with noise. When excessive noise is detected, the signal quality is reduced reflecting the disturbance. The artifact rejection algorithm will be active especially when patient is awake or moves and twinkles, and also when equipment creating external interference is used. In fact SQI value indicates that Brain Function Index (BFI) to what extent is reliable. When the SQI is 100, show that the EEG signal is in the best quality.

⚠**Warning**⚠

The monitor will not render accurate readings when used on patients with severe neurological disorders and patients under 2 years of age.

⚠**Warning**⚠

The monitor will not render accurate readings when used on patients weight less than 70% or more than 130% of ideal body weight and recent use of psycho-active medication, including alcohol

⚠**Warning**⚠

The use of pacemakers might cause either long periods of artifacts or elevated BFI values.

⚠**Warning**⚠

Do not use the monitor when cardiac defibrillator is used. Patient cables are not protected against defibrillation.

NOTE:

Operating the monitor close to equipment radiating high-energy radio frequencies (electrosurgical/cauterizing equipment, portable radios, cellular telephones, etc.) may cause signal disturbance. If this happens, reposition the monitor away from the source of interference.

⚠**Warning**⚠

When used with electro surgical unit please note the positioning of the neuro sensors. In order to reduce the hazard of burns, the neuro sensors should not be located between the surgical site and the electro surgical unit return electrode.

⚠**Warning**⚠

Not to be used in the presence of flammable gases; explosion risk.

⚠Warning⚠
Pay attention if the BFA monitor is connected to a patient connected to other equipment. The total of leakage current may exceed the allowable limit and cause a possible hazard to the patient.

⚠Warning⚠
The conductive parts of neuro sensor should not contact other conductive parts including earth.

⚠Warning⚠
The monitor should be used in conjunction with other patient monitoring parameters and clinical signs. This will ensure the optimum balance of the anesthesia/sedation administration.

⚠Warning⚠
Do not open the BFA case. There are no user-serviceable parts inside. The case should only be opened by qualified service personnel using proper grounding techniques. When the case is opened, an electrical shock hazard exists which can result in serious injury to persons and instrument component damage.

Skin Preparation and Placement of Sensors

To ensure low sensor impedance, clean skin with mild soap and water is recommended as a skin cleanser.

NOTE:

Alcohol is not recommended as a skin cleanser; it leaves a film layer that may cause high sensor impedance. If alcohol is used, ensure 30 second dry time.

NOTE:

The performance of the BFA module is only guaranteed by the manufacture when the BFA Procedure Pack is used.

Rub the skin gently using wash cloth or gauze dampened with the skin prep product to remove the non-conductive skin layer, then clean it using a dry cloth.

Position of the three neuro sensors is shown in figure12-1. The advanced signal processing of the monitor ensures that a deviation in the positioning of the sensors up to 2 cm (0.78 in) has no significant influence on the index. However, it is recommended to place the sensors on an area of the skull where only a few muscle fibres are present in order to achieve the best quality signal.

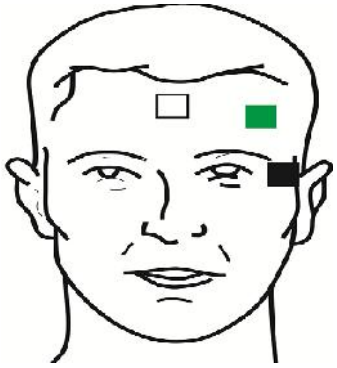


Figure 12-1 Neuro Sensor Placement

White electrode (1): middle of forehead
Green electrode (2): left side of forehead
Black electrode (3): on temple

NOTE:

- **Make sure no part of the neuro sensors is in contact with any other conductive parts including earth/ground**
- **If skin rash or other unusual symptoms develop, remove sensors from patient.**
- **Change neuro sensors every 24 hours to check skin integrity.**

⚠**Warning**⚠

Neuro sensors are disposable and should not be reused. Before use pay attention to the expiry date.

NOTE:

Once the neuro sensors have been secured on the skin, attach the colour-coded wires on the patient cable to appropriate sensor.

NOTE:

A left sided setup is shown in figure 12-1. Right sided is also acceptable.

NOTE:

BFA module accuracy may be low in head and facial surgeries.

Picture below shows how to use neuro sensor.

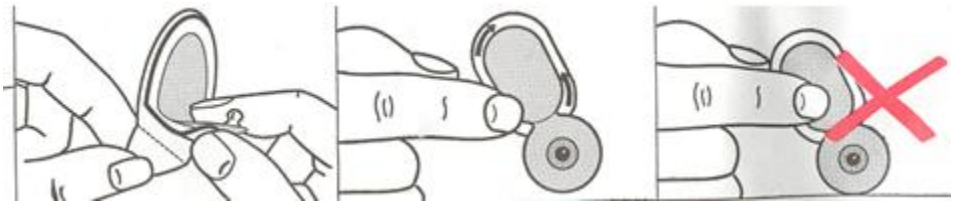


Figure 12-2 Correct use of neuro Sensors

After opening the BFA neuro sensors package, close the package like figure below. If you don't perform as figure below, the neuro sensors loose their quality.

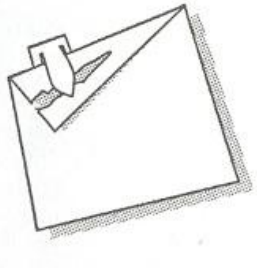


Figure 12-3 Correct maintenance of neuro sensors in its package

12.2 BFA monitoring system

The monitor can show and record online BFA data on the patient monitor for this reason it needs BFA module. This part connects to patient monitor through an interface cable and then monitor displays the related information. The module power is also supplied by the monitor.

12.2.1 BFA module

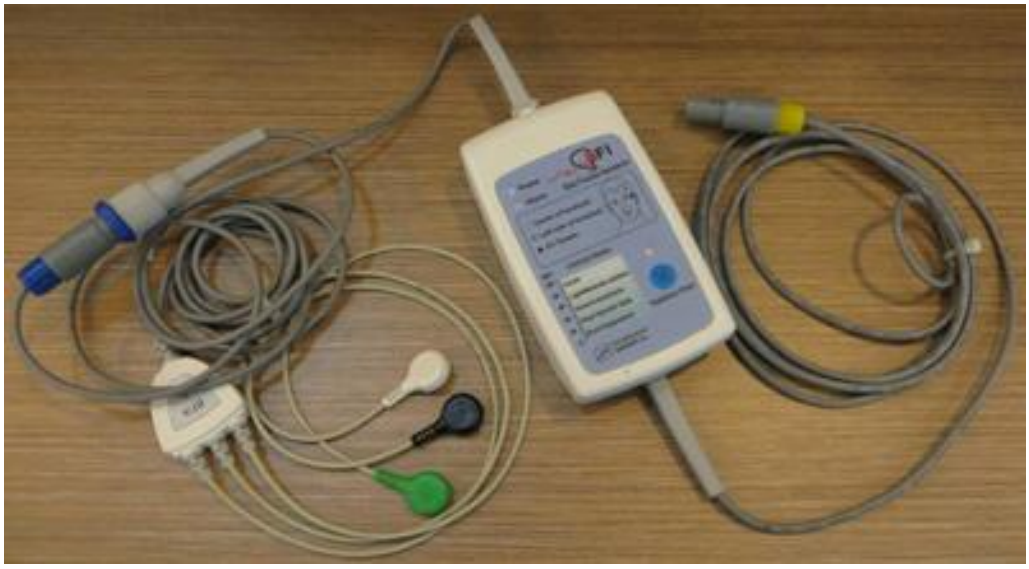


Figure 12-4 BFA module

BFA module keys and indicators

Power Indicator: This indicator is turned on as BFA module is connected to the monitor and remains ON until the module is disconnected (12-5①).

Alarm Indicator: If "BFA ELECTRODE ALARM" occurs (resulting from inappropriate connection of neuro sensors), this indicator will flash with frequency of 1 Hz (Figure 12-5②).

Impedance key: Impedance measurement is initiated by pressing this key (Figure 12-5③) and its indicator (Figure 12-5④) flashes on the module for one second.

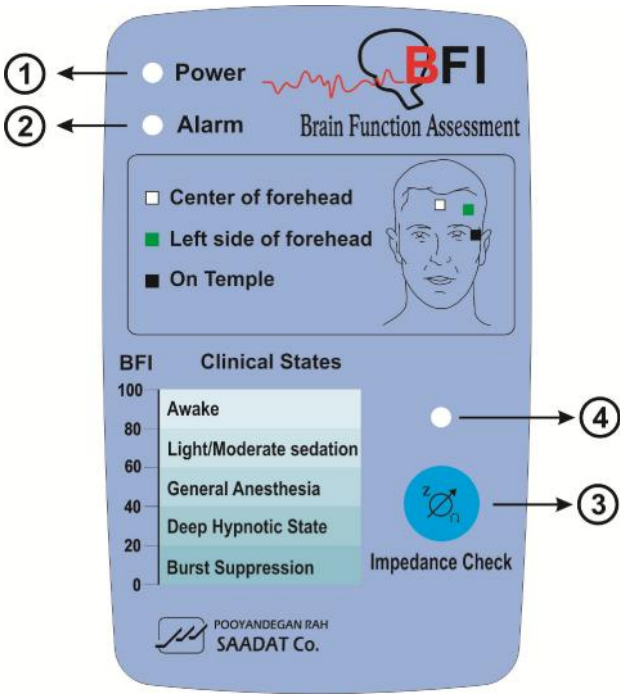


Figure 12-5 BFA module keys and indictors

12.2.2 BFA on patient monitor

BFA Module Setup

1- Turn on BFA module by connecting it to the monitor.

2- Connect the patient cable to BFA module.

⚠Warning⚠
Because the BFA patient cable are too thin pay attention not to subject them under tension.

⚠Warning⚠
Use only the recommended BFA cable and neuro sensor for BFA monitoring. Other accessory may cause improper performance.

⚠Warning⚠
Do not repair defective BFA cables and send it for after sale service. Manufacturer does not take responsibility for measurement accuracy of repaired cable.

3- After communication is established, you can monitor different BFA parameters such as BFI%, BS%, SQI%, EMG% and also EEG signal on the patient monitor.(At first only EEG signal can be monitored and after 20 seconds, other parameters appear on the monitor).

BFA on patient monitor

When highlight is placed at BFA area, press the knob, the following window (BFA large page) will pop up:

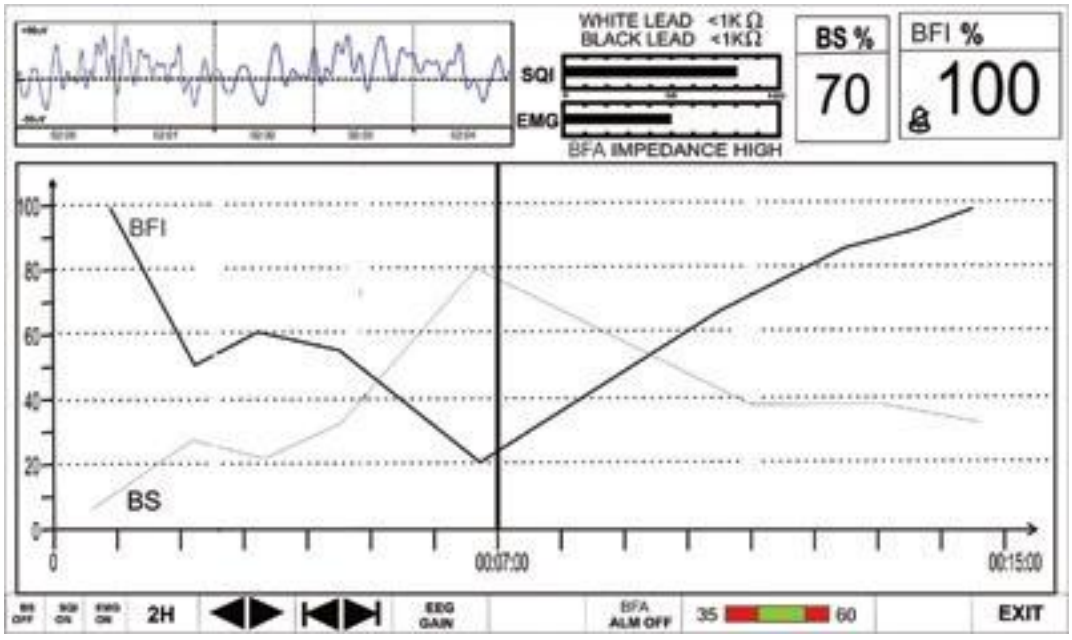


Figure 12-6 BFA large page

This window is a special page for BFA display to show detail information of BFA parameters in lager area and also you can change the different settings of BFA on it.

- **To enable or disable trend graph of BS parameter:**

Pick the most left item to enable or disable the BS trend.

- **To enable or disable trend graph of SQI parameter:**

Pick the second left item to enable or disable the SQI trend.

- **To enable or disable trend graph of EMG parameter:**

Pick the third left item to enable or disable the EMG trend.

NOTE:

The BFI parameter trend always shows on this page and the user is not able to disable displaying of it.

- **To select how long the trend graph is displayed:**

Pick the fourth left item, available options are 15min, 30min and 1, 2 and 4 H.
As long as the cursor line is not moved in BFA large page, every click on the fourth left item will change the x -axis based on the selected interval.
Moving the cursor to choose a specific time and pressing trend time interval item (the forth left item), x -axis will be zoomed in and zoomed out equal to the trend interval according to the specific time the cursor line shows.

- **To obtain trend data of specific time:**

The cursor line in trend graph shows specific time. Click on the fifth left item and turn the rotary to set the interval on 15, 30 min and 2 H. The specific time to which the cursor points will change and numeric parameters of this time will be displayed on the right side of the BFA large page.

- **To select time interval of trend in x-axis:**

Pick  (the sixth left item) to adjust the start time and end time of x-axis. By every click on  , the x- axis will change to extent of the adjusted time in the fourth left item.

- **To change EEG gain:**

Pick “EEG GAIN” (the seventh left item) to set gain of EEG signal. The Y-axis of EEG signal changes according to the selected gain. Available options are 25µV and 50-250µV by step of 50µV.

■ **To enable or disable the BFA alarm limit:**

Pick “BFA ALM ON/OFF” to enable BFI alarm function such as parameters blinking, audio alarm and light indicator. Pick “OFF” to disable the alarm functions and there will be a will be a "⚠" symbol in the Parameter Area.

■ **To set the BFI alarm limit:**

Press the 10th left item to set the BFI limit. Alarm is activated when the BFI parameter exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (default: min= 35, max=60)

NOTE:

BFI alarm level is always II.

NOTE:

Every change in BFA large page setting is seen in BFA window in normal state.

NOTE:

In case of sudden and strange changes in BFI or SQI index, it is necessary to measure impedance manually.

12.3 BFA Alarm Messages and Troubleshooting

The alarm occurs when BFI value exceeds the adjusted alarm limits:

Alarm	Situation	Visual prompt	Audio sound
BFI HIGH	Cerebral state index violates adjusted high limit	●BFI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in yellow background.	Activated
BFI LOW	Cerebral state index violates adjusted low limit	●BFI value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in yellow background.	Activated

The BFA messages on the patient monitor are:

Message	**Cause**	Solution
BFA ELECTRODE ALARM	Placement of neuro sensors or their connections might be faulty or the impedance of the sensors may exceed 10k Ω. This alarm can also be caused by high frequency instrument.	●Check all neuro sensors and their connections. ●Check the patient cable. If it is not connected or is faulty, please connect it or replace it. ●Check if either of the neuro sensors are disconnected or badly connected. ●Replace faulty sensor. ●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin.
BFA SQI LOW	If the impedance of white and black sensors exceed 1kΩ, SQI will decrease gradually. Artifacts resulting from high frequency instruments and EMG.	●Check that all neuro sensors and cables are securely connected. ●Has the use of any mechanical or electrical device that could generate high frequency activity (e.g. patient warmer) been initiated or is any such device in close proximity to the BFA neuro sensors? If possible move disturbing device away from the neuro sensors. ●Check grounding of disturbing device.

BFA IMPEDANCE HIGH	If sensor impedance is more than 5kΩ, the %BFI, %BS, %EMG and %SQI will be blanked.	●Check that neuro sensors are not dry. ●Check that the skin has been cleaned properly. ●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin.
BFA LINK OFF	BFA module is off.	Establish the connection between the module and the monitor via interface cable.

Alarm level 3 is enabled for all above messages. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault.

Troubleshooting

- **BFA module does not turn on when it is connected to the monitor.**
  - Check interface cable between the module and the monitor.
  - If the problem persists, contact after sale service of manufacturer.

- **BFI is higher than expected range**
  - Check anesthetic delivery systems: IV lines and status of vaporizers.
  - Some patients require more doses of drug to reach intended level of anesthesia.
  - Drug dosage is not sufficient for Maintenance phase, so BFI increases during painful stimulations.

- **BFI rises along with EMG**
  High levels of facial muscular or electromyographic (EMG) activity can elevate the BFI under certain circumstances. When this happens, attention must be paid to reactions of patient against the stimuli during surgery. When the patient is asleep, EMG activity may increase due to reactions to painful stimuli during surgery, lack of muscular relaxation or muscular rigidity caused by some opioids (analgesics). In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent may decrease BFI.

12.4 BFA module cleaning and maintenance

Cleaning

Please pay special attention to the following items for cleaning BFA module and patient cable:

1. Don't use strong solvents such as acetone or ammonia.
2. Most cleaning agents must be diluted before use.
3. Don't use rough material, such as steel wool etc.
4. Don't leave the cleaning agents on any part of the equipment

NOTE:

The BFA module should be cleaned with hospital-grade ethanol and then dried by a clean cloth.

Storage

Store in a clean, dry atmosphere at room temperature and, if available, use the original packaging for protection.

⚠ **Warning** ⚠

The BFA module should be disposed of taking into consideration environmental factors, local laws and regulations. All components can be safely disposed of in the approved manner as per hospital or locally regulated guidelines.

Maintenance

To ensure the monitor remains in good operating condition, it is important to keep it clean and carry out the routine maintenance procedures. There are no serviceable parts in this instrument and all service is to be carried out by the manufacturer.

NOTE:

If the monitor is dropped, damaged or subjected to excessive moisture or high temperature, immediately be taken out of service for examination by qualified service personnel.

NOTE:

As required clean the external surfaces of the monitor thoroughly before and after a prolonged period of storage

NOTE:

If the module is dropped or severely shaken, it should immediately be taken out of service and inspected by qualified service personnel to ensure its proper function prior to use.

Chapter 13, ST Monitoring

13.1 GENERAL

ST segment deviation is defined as the displacement above or below the isoelectric level. The measurement of deviation compares the isoelectric point to the ST measurement point.
The isoelectric point defines the point of zero voltage (no electrical activity) with a default position of 80ms from R wave as 0msec in the horizontal (time) axis. The ST point occurs in the ST segment between J-point and the T wave, at a default position of 110 ms after R wave. The following figure illustrates a typical QRS complex.

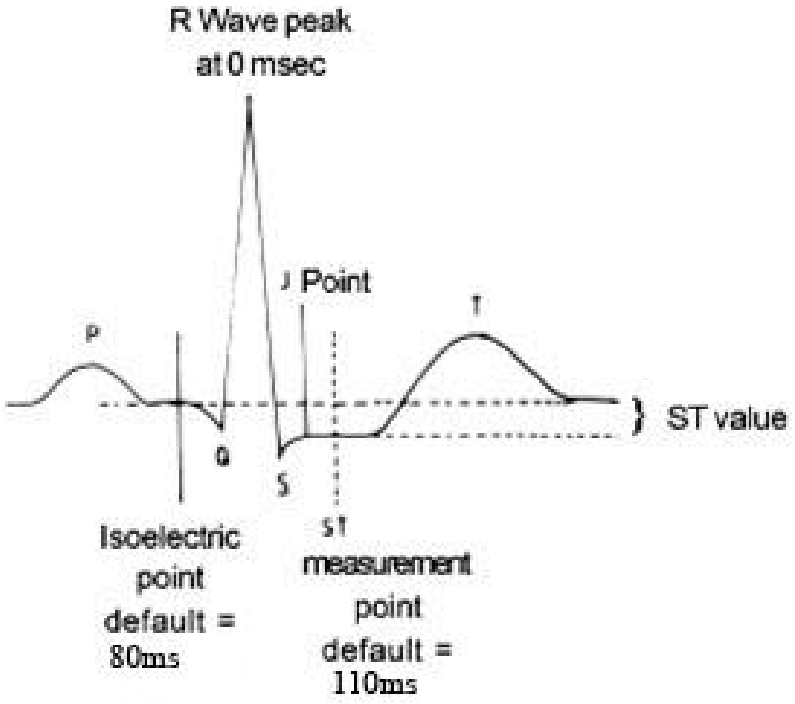


Figure 13-1 ST Measurement Algorithm

The ST measurement for each beat complex is vertical difference between the two measurement points, ST and ISO.

The ST analysis examines QRS complexes classified as normal beats (beat detection and classification information provided by the arrhythmia algorithm are used to eliminate beat that are ventricular in origin). The monitor combines the measurements and features of normal beats into a composite (or average) QRS complex. It derives the ST segment deviation from this average.

The ST segment algorithm documents changes in ST segment in adult patients that can be indicative of the severity and duration of myocardial ischemia. Since many ischemic episodes are silent or painless, continuous monitoring of ST segment changes can provide the earliest warning of ischemic events.

NOTE:

ST monitoring is available for adult and pediatric patient and it is not recommended for neonates.

NOTE:

If there are not at least 5 normal complexes in the last 50 beats of ECG signal, the ST value will not be displayed.

NOTE:

Applied lead for ST, ARR, Pace and HR is reference lead that is displayed in the first trace and can be adjusted in ECG menu.

NOTE:

To ensure proper analysis of ST segment deviation, it is recommended to use Extended filter.

ST monitoring function is “OFF” as a default. You can switch it “ON”, when this monitoring is necessary.

When ST monitoring is enabled, current ST values are trended and can be reviewed on the TREND window.

NOTE:

Measurement unit of ST segment is “mV”.

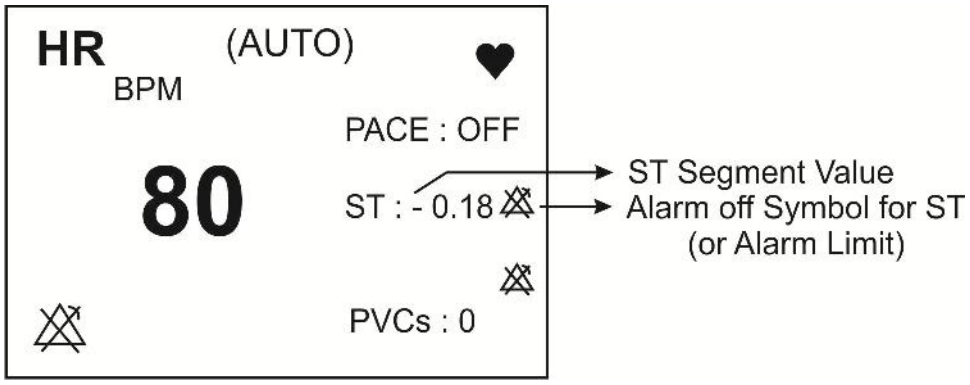


Figure 13-2 ST value in ECG parameters area

Measurement range of ST segment is between -2.0 mV to +2.0 mV.

Measurement symbol of ST segment “+” means elevating and “-“means depressing.

13.2 ST ANALYSIS WINDOW

Pick "ST ANALYSIS “in the ECG WINDOW to call up the following menu:

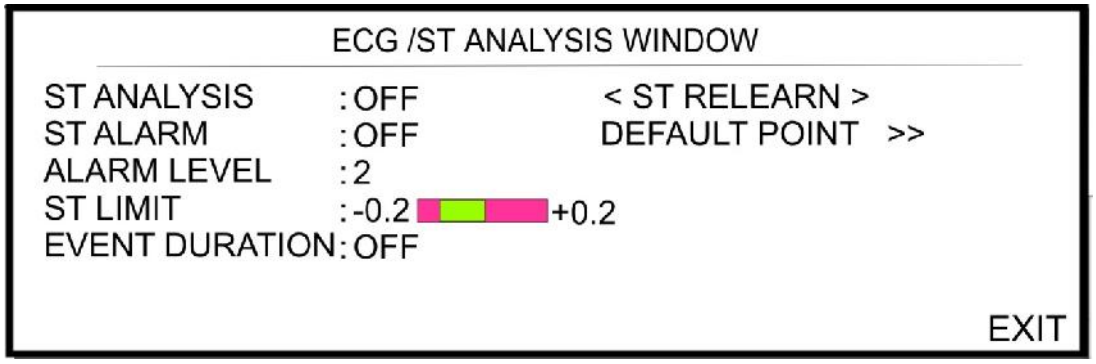


Figure 13-3 ECG/ ST ANALYSIS WINDOW

■ **ST ANALYSIS**

Pick this item to enable or disable ST monitoring. The default is OFF. When the ST monitoring is disabled “ST OFF” is displayed in ECG parameter area.

■ **ST ALARM**

Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator.Pick "OFF" to disable the alarm functions and there will be a "⚠" symbol in the Parameter Area.

■ **ALARM LEVEL**

Selectable between 1 and 2. Level 1 represents the most serious case.

■ **ST LIMIT**

ST alarm is activated when the ST segment value exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (Range: -2.0 ~ +2.0 step 0.1)
Default for upper limit is +0.2 and for lower limit is -0.2.

■ **EVENT DURATION**

Pick this item to determine the time that a potential ST alarm condition must persist on ECG waveform before the monitor classifies it as a valid alarm condition.
Available options for EVENT DURATION are OFF, 15s, 30s, 45s and 60s.The default is OFF and alarm will be activated immediately if alarm condition happens.

■ **ST REALERN**

Pick to start a learning procedure. The message “RELEARN” is displayed in the message area. The procedure will take about 20 seconds.

During the learning procedure the following actions will be taken:

- Average stored dominant QRS complex currently displayed on the DEFAULT POINT window is deleted.
- New dominant QRS complex template is identified.
- New complex is displayed on DEFAULT POINT window.

NOTE:

You can do relearn procedure by selecting <ARR RELEARN> in ECG/ARR ANALYSIS window.The message "RELEARN" will be displayed in the message area.

NOTE:

The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ST ANALYSIS is ON and there is no technical ECG alarm active, like CHECK LEAD):

- **Turning on the monitor**
- **Connecting ECG cable.**
- **Changing an ECG lead configuration.**
- **Choosing "NEW" in HOME / PATIENT INFORMATION**

NOTE:

A yellow vertical marker with "LRN" label On ST in TREND window shows the time in which the learning procedure has been done.

■ DEFAULT POINT

Pick "DEFAULT POINT" in the ST ANALYSIS WINDOW to adjust the position of both ISO and ST measurement points. When you change the ST and ISO measuring points on the DEFAULT POINT Window, the monitor recomputes the ST deviation value accordingly.

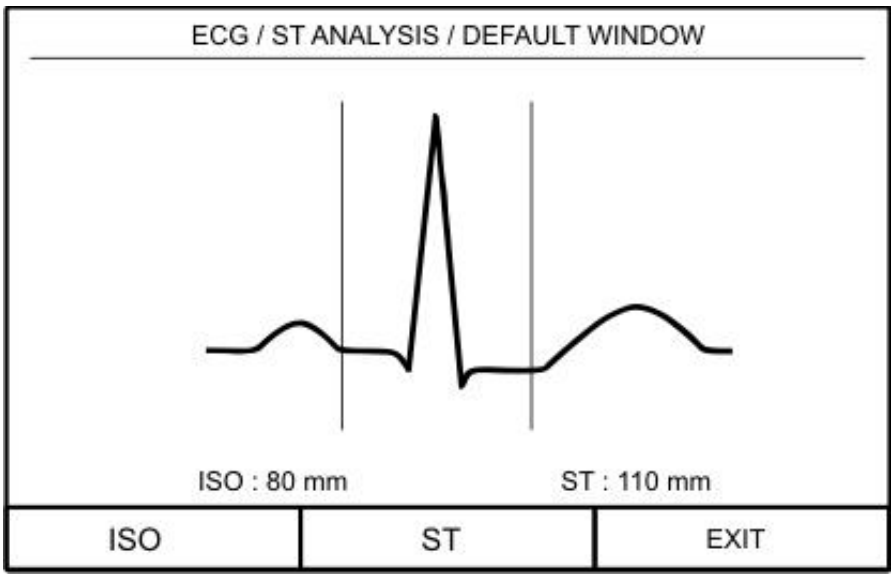


Figure 13-4 ECG/ST ANALYSIS/DEFAULT WINDOW

As shown above, the DEFAULT POINT WINDOW shows the dominant QRS complex template. Two vertical lines indicate the positions of the ISO and ST points.
ISO: It is the base point, used to indicate the baseline point of the ST analysis. The default is 80ms.
ST: It is the ST measurement point. The default is 110ms.
(Selectable between 5 to 400 ms by step of 5ms)
The reference point is the position where the peak of R-wave locates.

NOTE:

It is good clinical practice to check the position of ISO and ST measuring points before starting ST monitoring and finishing learning procedure.

NOTE:

In practice, the accurate determination of ISO and ST measuring points requires careful clinical evaluation.

NOTE:

The ST measurement point should be adjusted if patient's HR or ECG morphology changes significantly.

If the template is not established, a horizontal line will be displayed and if the ST ANALYSIS is "OFF", the message "ST ANALYSIS KEY IS OFF" appears in this window.
You may select ISO or ST, and then switch the knob left or right to move the cursor line. When the cursor is at the intended position, you may select the base point or the measurement point.

NOTE:

Abnormal QRS complex is not considered in ST segment analysis.

NOTE:

If pace is ON (for patient with pacemaker) or while learning procedure, there is no waveform in DEFAULT POINT Window and you can see just ISO and ST lines. In this condition, ST value will not be measured.

NOTE:

A red vertical marker with "CHG" label on ST in TREND window shows the time in which the measuring point has been changed.

13.3 ST Alarm Messages

The alarm occurs when ST value exceeds the adjusted alarm limits:

Alarm	Situation	Visual prompt	Audio sound
ST HIGH	ST segment value violates adjusted high limit	●ST value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
ST LOW	ST segment value violates adjusted low limit	●ST value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

ST messages include:

Message	**Cause**	**Solution**
ST OUT OF RANGE HIGH	The ST algorithm has calculated value +1mV outside the high end of the ST measurement range.	●Check the ISO and ST measuring points. ●Observe the patient and treat if clinically indicated.
ST OUT OF RANGE LOW	The ST algorithm has calculated value -1mV outside the low end of the ST measurement range.	●Check the ISO and ST measuring points. ●Observe the patient and treat if clinically indicated.

Alarm level of above messages is set in ST WINDOW. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled for 120S.

Chapter 14, Arrhythmia Monitoring

14.1 GENERAL

Arrhythmia means any disturbance or irregularity of cardiac rhythm. Stability of the cardiac rhythm is essential for sufficient pumping function of the heart and adequate cardiac output. Maintaining adequate cardiac output is vital for organ perfusion and survival. Arrhythmia can cause a decrease in cardiac output. Therefore fast and accurate detection of arrhythmia is critical.

The medical professionals can use the arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and give proper treatment.

NOTE:

If arrhythmia monitoring is "ON", the heart rate is calculated by the arrhythmia software.

NOTE:

This monitor can detect up to 13 types of arrhythmias.

NOTE:

Arrhythmia monitoring is available for adult and pediatric patients and it is not recommended for neonates.

NOTE:

Applied lead for ST, ARR, Pace and HR is reference lead that is displayed in the first trace and can be adjusted in ECG menu.

⚠**Warning**⚠

The ARR monitor can only be operated by personnel who have passed professional training and are familiar with this manual.

⚠ **Warning** ⚠

The ARR monitor is intended for use only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

NOTE:

It is recommended to use ECG lead I or II to have the best accuracy of ARR software.

Arrhythmia detection algorithm principle

The arrhythmia algorithm is based on template matching. (A template is a group of beats matching the same morphology). The algorithm detects QRS complexes, generates QRS templates and performs beat labelling. This algorithm is divided into three parts: detector, classifier and labelling.

The detector algorithm detects waves in ECG signal that could be QRS complexes.

The classifier algorithm forms templates of similar QRS complexes. During the learning phase an initial set of QRS template is built. Then the monitor creates a reference template based on its identification of the patient's dominant QRS pattern. When a new true QRS complex is detected, it is compared with the existing templates. If no match is found, a new QRS template is added to the template set.
The labelling algorithm analyses all templates. Each template and the beats belonging to it are labelled with one of the following names: normal beats, ventricular beats and questionable beats. Through this process, the monitor can verify an arrhythmia event's occurrence.
Parallel to this process there is an algorithm for detection of ventricular fibrillation.

Detection of ventricular fibrillation is based on waveform analysis. AFIB arrhythmia is detected through obtained parameters in the previous parts and analysis of R-R intervals. Maximum one minute after occurring AFIB arrhythmia, related alarm will be activated and time of arrhythmia occurrence will be recorded in the Trend window.

Beat and rhythm classification

Beat classification refers to the analysis of individual beats. If the new beat's features do not match those of the normal template, the new beat is classified as premature or questionable.
The monitor uses all detected beats to calculate the heart rate, eliminating questionable beats from arrhythmia classification.
Rhythm classification refers to analysis of sequences of beats. The monitor compares the sequence of the last twelve beats with the sequences stored in the monitor's memory. If it detects two or more events simultaneously, the monitor alarms in order of event priority.

The following table describes available beat classifications:

Arrhythmia	**Event and Beat Classification**
ECG ASYSTOLE	5 seconds pass without the detection of valid QRS complex.
VFIB ARRHYTHMIA	Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics. (Certain ventricular tachycardias have sinusoidal waveforms closely resembling those of ventricular fibrillation. Because of the similarity of these waveforms, the monitor may classify such types of ventricular tachycardia as ventricular fibrillation) .
VTAC ARRHYTHMIA	Ventricular Tachycardia: N or more PVC's are detected in a time interval T= (60*(N-1))/R, where N is defined as the VTAC count and R is defined as the VTAC rate.
RUN ARRHYTHMIA	Ventricular Run: Series of 3 to N-1 consecutive PVCs with a beat to beat rate ≥ the VTAC rate.
AIVR ARRHYTHMIA	Accelerated Idioventricular Rhythm: Series of 3 or more PVCs with a beat rate less than the VTAC rate.
BIGEMINY ARRHYTHMIA	Ventricular Bigeminy: Sequence of beats with the pattern : normal, PVC, normal, PVC, normal, PVC
TRIGEMINYARRHYTHMIA	Ventricular Trigeminy: Sequence of beats with the pattern : normal, normal, PVC, normal, normal, PVC

COUPLET ARRHYTHMIA	Ventricular Couplet: Sequence of beats with the pattern : normal, PVC, PVC, normal, PVC, PVC
TACHY ARRHYTHMIA	Sinus Tachycardia: HR ≥ TACHY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.
BRADY ARRHYTHMIA	Sinus Bradycardia: HR≤ BRADY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.
AFIB ARRHYTHMIA	Atrial Fibrillation: Formation of QRS complexes in irregular intervals
PAUS ARRHYTHMIA	Actual R-R interval more than 2.1 times of the average R-R interval.
FREQUENT PVCs	More than N (event count set in the ARR SETUP WINDOW) PVC per minute.

Premature Ventricular Contraction (PVC) is ectopic impulse originating from ventricles, before the normal electrical activation sequence of the heart has occurred.

The PVC value is shown in ECG parameter window and updated every 5 seconds.

When ARR analysis is enabled, current PVC values are trended every 20 seconds and can be reviewed on the TREND window.

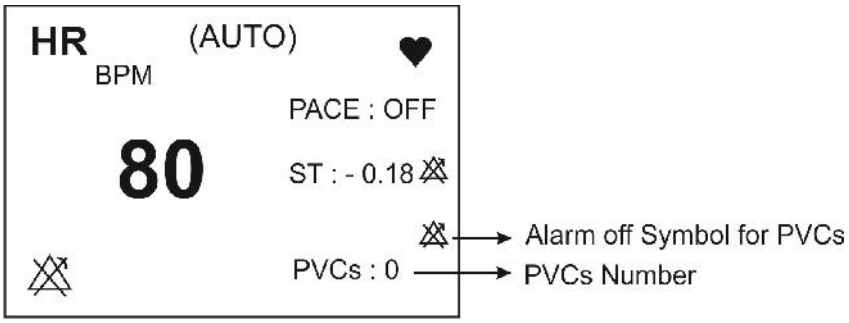


Figure 14-1 PVC value in ECG parameters area

NOTE:

When PACE is turned ON, for patient with pacemaker, the system will not detect the arrhythmia relating to premature ventricular beats.

14.2 ARR ANALYSIS WINDOW

Pick "ARR ANALYSIS“in the ECG WINDOW to call up the following menu:

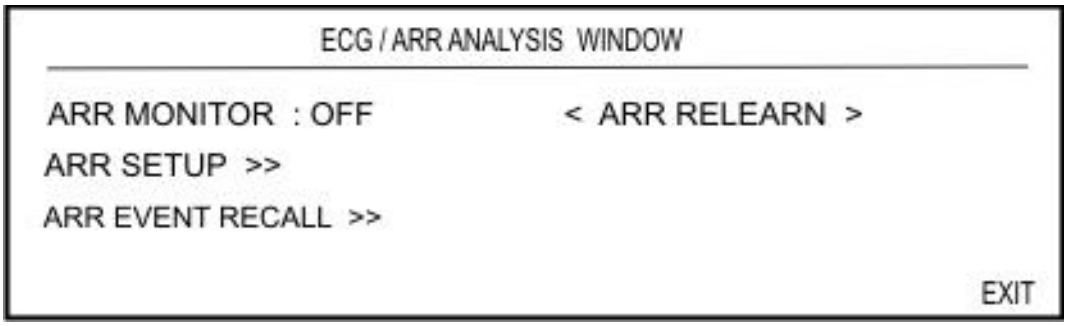


Figure 14-2 ECG/ARR ANALYSIS WINDOW

- **ARR MONITOR**

  Pick this item to enable or disable arrhythmia monitoring. The default is “OFF”. When the Arrhythmia monitoring is disabled “PVCs OFF” is displayed in ECG parameters area.

- **ARR SETUP**

  Pick “ARR SETUP” in ARR ANALYSIS Window to call up the following menu:

ECG/ARR ANALYSIS/ARR SETUP WINDOW

	ALARM LEVEL	RATE	COUNT	ARCHIVE
ASYSTOLE	1	-	-	STR
VFIB	1	-	-	STR
VTAC	1	>=120	>=5	STR
RUN	1	>=120	>=3	STR
AIVR	2	>=119	>=3	STR
COUPLET	2	-	-	STR
BIGEMINY	2	-	-	STR
TRIGEMINY	2	-	-	STR
TACHY	2	>=120	-	OFF
BRADY	2	<=50	-	OFF
AFIB	1	-	-	STR
PAUSE	2	-	-	OFF
FREQUENT PVCs	OFF	-	>=10	-

ALL ALARM LEVEL:NONE ALL ARCHIVE:NONE

EXIT

Figure 14-3 ECG/ARR ANALYSIS /ARR SETUP WINDOW

The ARR SETUP table allows you to configure arrhythmia monitoring accordingly to your patient's needs. All detectable arrhythmia events listed in the first column of the table .Using the remaining columns, you can modify the attributes of each event. Fields that are not applicable for certain event category are shown with dash symbol, while those that cannot be modified are ghosted. Arrhythmia default settings are shown in figure 14-3

Modifying arrhythmia settings:
1. Scroll the cursor frame to parameters whose arrhythmia functions you wish to configure and click.
2. Scroll to the function you wish to modify. (The first column, "ALARM LEVEL ", is highlighted when you first click on a parameter.)
3. Click to access settings of the selected arrhythmia function.
4. Dial through settings and click to confirm your selection.
5. Repeat step 1-4 to configure additional arrhythmia functions or parameters.

- **ALARM LEVEL**

Available options are 1, 2 and OFF to set the level of alarm for every arrhythmia event. (For more detail about alarm levels refer to chapter ALARM.)
ALARM LEVEL for "ASYSTOLE" cannot be modified and always is in level 1.

- **RATE**

With count, you can determine the point at which an event call is triggered.
You can't modify the rate for "ASYSTOLE", "VFIB", "COUPLET", "BIGEMINY", "TRIGEMINY", "PAUS", " AFIB" and "FREQUENT PVCs" .
"RUN" and "AIVR" derive their rate settings from "VTAC" and cannot be modified.

Arrhythmia event	Rate setting
VTAC	100-200 step by 10
RUN	Same as VTAC rate
AIVR	<VTAC rate-1
TACHY	100-200 step by 10
BRADY	30-105 step by 5

- **COUNT**

With rate, you can determine the point at which an event call is triggered.
You can't modify the count for "ASYSTOLE", "VFIB", "COUPLET", "BIGEMINY", "TRIGEMINY","TACHY","BRADY", "AFIB" and "PAUS".
Count of "AIVR" is ≥3 and cannot be modified.

Arrhythmia event	Count setting
VTAC	5-12 step by 1
RUN	($VTAC_{count}$ -1) ~3 step by 1
FREQUENT PVCs	1-15 step by 1

- **ARCHIVE**

You can determine whether the selected event is stored, recorded automatically or both. You can view stored events on ARR EVENT RECALL Window.

STR: Stores selected arrhythmia event.
REC: Automatically generates a recording of selected event.
STR/REC: Event is stored and recorded simultaneously.
OFF: No action if arrhythmia event activates.

- **ALL ALM LEVEL**

Press to set the level of all arrhythmia alarms to the same value or to disable all of them.

- **ALL ARCHIVE**

Press to set all arrhythmia ARCHIVE condition to the same state.

■ **ARR EVENT RECALL**

Pick " ARR EVENT RECALL**”** in ARR ANALYSIS WINDOW to call up the following menu:

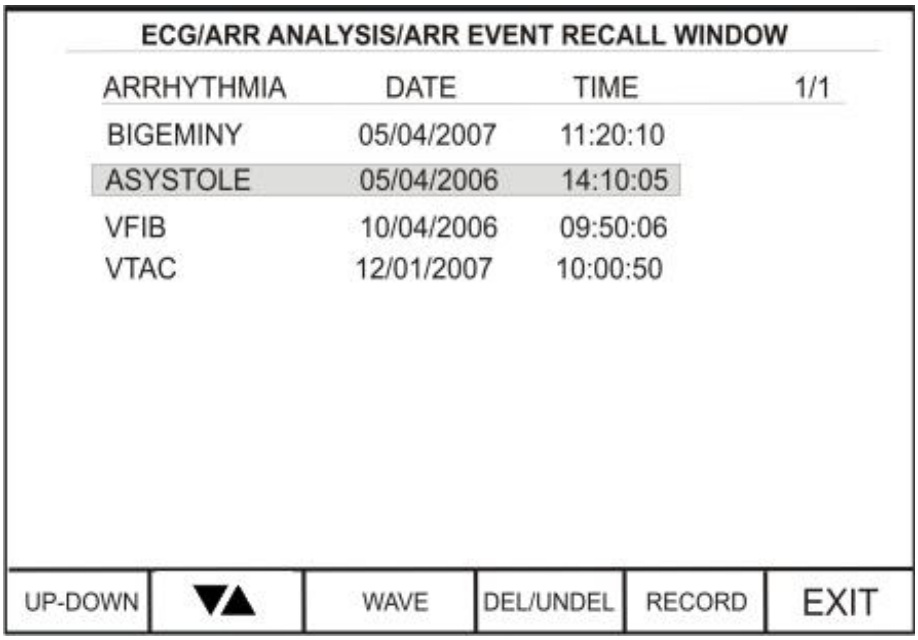


Figure 14-4 ECG/ARR ANALYSIS / ARR EVENT RECALL WINDOW

You can review any stored arrhythmia event (maximum 150 events) in this window.

NOTE:

If an arrhythmia event occurs and persists, it will be stored in ECG/ARR ANALISIS/ARR EVENT RECALL WINDOW for one time, but if this event is removed and then occurs again, it will be stored twice.

■ **To review different event pages:**

Maximum of 8 arrhythmia events can be displayed in each page of "ARR EVENT RECALL" window simultaneously. When there is more than 8 events, different pages are available. Pick "UP-DOWN" (the most left item) to review different pages.

■ **To select an arrhythmia event:**

Pick the second left item to select an arrhythmia event displayed in the window.

■ **To delete an arrhythmia event:**

Pick the forth left item to choose an arrhythmia event for removing from the list. When you click on "DEL/UNDEL" button, the selected event will be highlighted and removed if you exit the window.

NOTE:

To ignore deleting a selected item, click on the "DEL/UNDEL" key one more time before exiting from the window.

■ **To see detail information of arrhythmia event:**

Pick the third left item to call up the following window:

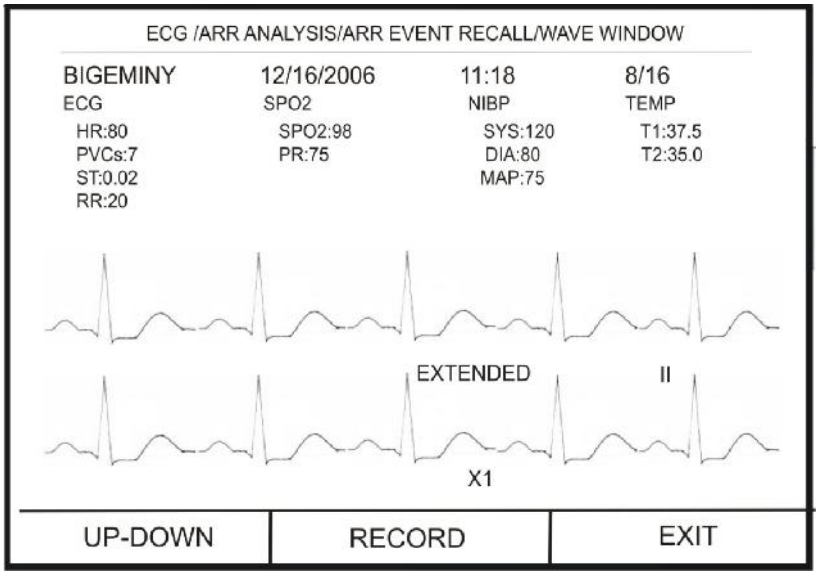


Figure 14-5 ECG/ARR ANALYSIS /ARR EVENT RECALL/WAVE WINDOW

In this window, waveform and time of selected arrhythmia event as well as other vital sign parameters values at the event time are displayed.

- **UP-DOWN**

This option allows you to page up and down to review the waveform and the parameters of other arrhythmia events.

- **RECORD**

This option allows you to record the arrhythmia signal. If settings of RECORDER SWEEP: 25mm/s and MANUAL RECORD TIME:10 sec are selected in HOME /RECORDER WINDOW, arrhythmia signal will be recorded for about 20 seconds. This record starts from10 seconds before arrhythmia occurrence and will continue until 10 seconds after that.

■ **ARR RELEARN**

Pick to start a learning procedure. The "RELEARN" message is displayed in the ECG waveform area.

NOTE:

You can do relearn procedure by selecting <ST RELEARN> in ECG/ST ANALYSIS window.

NOTE:

In most situations the learning phase takes about 20 seconds.

NOTE:

If the monitor couldn't find 6 matching beats after 20 seconds, the relearn procedure continues and the "RELEARN" message remains on the display, till acceptable condition happens.

NOTE:

While the monitor is in learning phase, all arrhythmia alarms and trend collection are suspended.

NOTE:

Before starting learning procedure, verify the quality of the ECG signal and ensure that the patient's ECG displays a normal reference pattern.

NOTE:

The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ARR ANALYSIS is ON and there is no technical ECG alarm active, like CHECK LEAD):

- **Turning on the monitor**
- **Connecting ECG cable.**
- **Changing ECG lead configuration.**
- **Choosing "NEW" in HOME / PATIENT INFORMATION**

NOTE:

It is recommended to perform relearn procedure under the following conditions:

- **A lead is reconnected or electrodes are repositioned.**
- **Eight hours have passed since last reference complex learned.**
- **Other significant changes appear on the morphology of the patient's ECG.**

Chapter 15, C.O. Monitoring *

15.1 GENERAL

Cardiac Output (C.O.) is the volume of blood pumped by the heart ventricle per minute. The measurement unit is litres per minute (L/min).

To understand the clinical importance of measuring cardiac output, consider that the primary function of the heart is to deliver sufficient oxygenated blood to meet the metabolic needs of the body tissues. The cardiac output measurement invasively measures cardiac output and other hemodynamic parameters using a technique called thermodilution. C.O. measurements in SAADAT monitors are carried out using the right heart thermodilution method. This method is known as “gold standard” of C.O. measurement.

C.O. Measurement using the Right Heart Thermodilution Method

In the right heart thermodilution method, a cold fluid of known volume and temperature is injected into the right atrium thought a pulmonary artery catheter (PAC). The injected fluid mixes with the blood in the right ventricle and the change in blood temperature is measured with a thermostat situated in the distal end of the catheter in the pulmonary artery.

After injection, the blood temperature descends and then rises smoothly to reach its initial state. The lower cardiac output value, the colder temperature of injectate solution. Cardiac output is inversely proportional to the area under the thermodilution curve (Refer to figure 15-1).

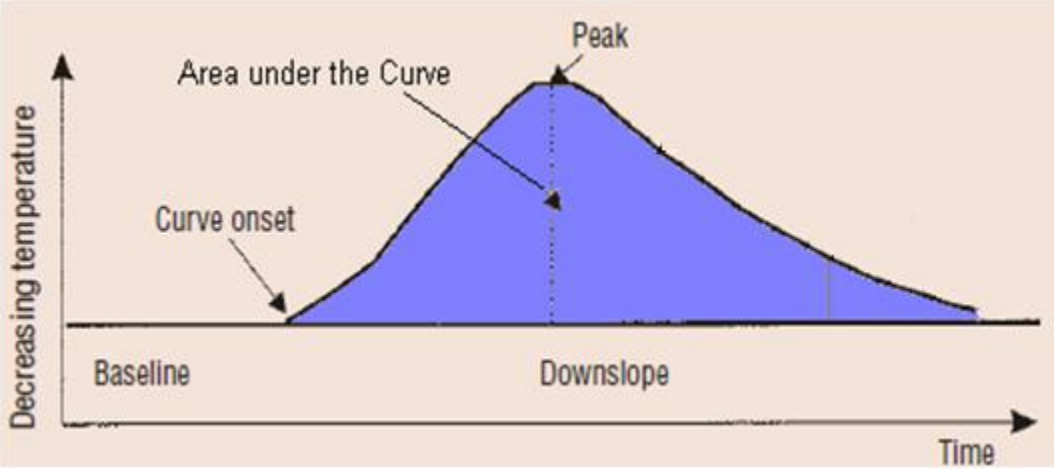


Figure 15-1- Thermodilution curve after injecting injectate (Note that the curve peak indicates the lowest temperature).

NOTE:

Fluid injection must be carried out smoothly.

⚠**Warning**⚠

C.O. measurement must be carried out by trained and qualified individuals.

C.O. value is influenced by injection technique. As mentioned above, the curve should have a steep rise and gradual return to baseline (See figure 15-2). Other curves are samples of high cardiac output, low cardiac output and prolonged injection. A series of measurements must be carried out to achieve a reliable C.O. value and average of multiple thermodilution measurements is used for therapy decisions.

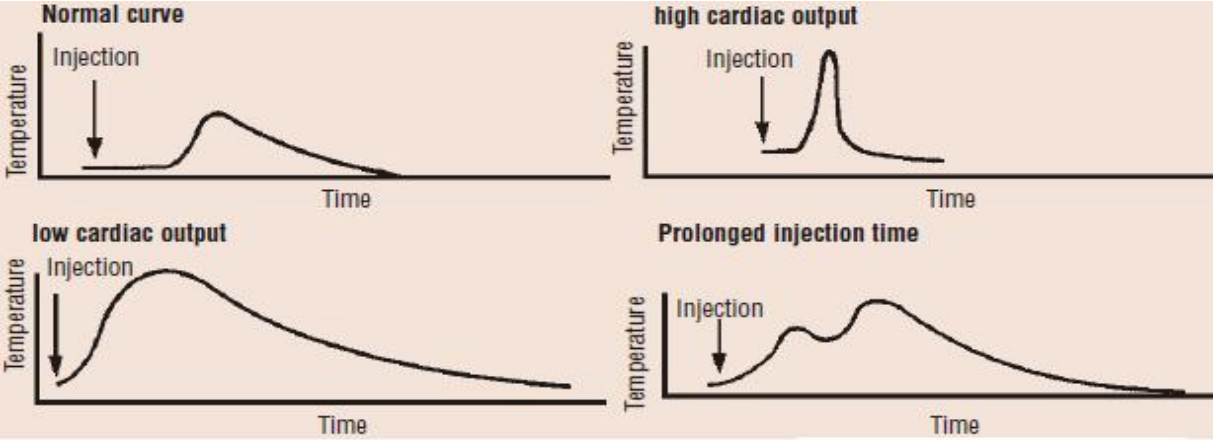


Figure 15-2 Sample curves of temperature change in C.O. measurement

Setting up RH C.O. Measurements

1. Enter the catheter into the heart and place it in proper position (Follow your hospital standards to avoid unintentional extraction of C.O. catheter).
2. Connect the other side of the catheter to SAADAT C.O. cable.
3. Connect C.O. cable to the respective connector on the side panel of SAADAT monitor.
4. Prepare ice bath (water) and injected solution (0 °C).

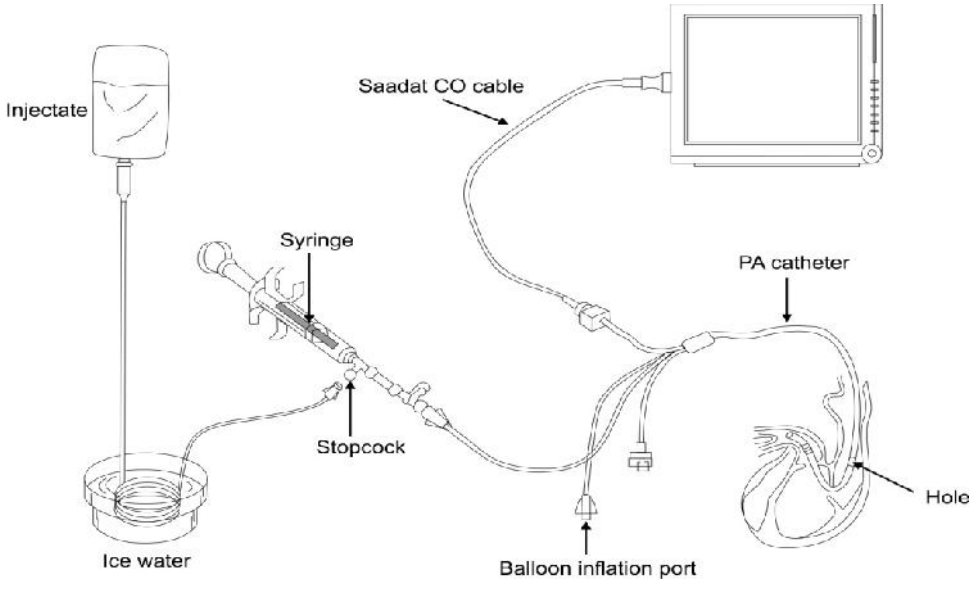


Figure 15-3 Setting up RH C.O. Measurement

⚠Warning⚠

C.O. module calculates cardiac output based on injectate temperature of 0 °C. There will be measurement error if the temperature of injectate solution is not zero.

⚠Warning⚠

Use only the accessories specified in this manual.

⚠Warning⚠

Make sure that no part of accessories is in contact with any other conductive parts.

NOTE:

If the patient condition is unstable, the measurement cannot be done or is unreliable.

⚠Warning⚠

Don't use electrosurgical equipment during C.O. measurement.

⚠Warning⚠

Disposable catheter should not be reused.

NOTE:

Do not use the catheter if its package is damaged.

NOTE:

Before using catheter, inflate the balloon to make sure that it is not damaged.

NOTE:

Before using catheter, inject the solution by syringe to check path of injectate.

15.2 CARDIAC OUTPUT MENU

Pick "CARDIAC OUTPUT" in HOME MENU to call up the following menu:

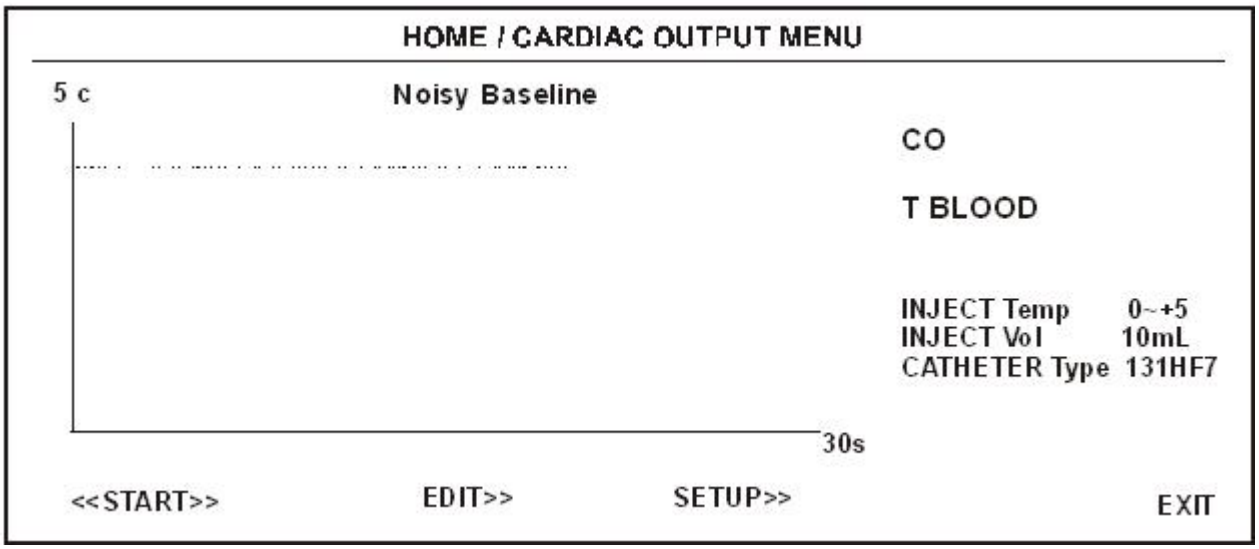


Figure 15-4 HOME/CARDIAC OUTPUT MENU

If C.O. cable and catheter are not firmly connected to the monitor, the message “No Cable” will appear on the screen. If after connecting C.O. cable, “Noisy Baseline” appears, the monitor can not start measurement. If the message does not disappear after a while, possible causes can be improper placement of the catheter or interference of other devices such as electrosurgical unit in the vicinity of the monitor. When you see the message “Ready For Measurement”, start measurement by selecting **Start** key.

The blood temperature is displayed in front of **TBlood** in this window. If the temperature is out of the range 25 – 45 °C, the message “Out Of Range” appears on the screen. In this condition C.O. measurement is impossible.

- **START**

When you see the message “**Ready for Measurement**”, press the Start key and then when you see the message “**Inject Now**”, inject the solution.

During measurement, the thermodilution curve is displayed and the message “**CALCULATING**” will appear above the curve when C.O. value is calculated by the system.

At the end of the measurement C.O. value will be displayed on the screen. After each measurement if the curve appears abnormal (due to noise or inappropriate injection), a

question mark symbol (“?”) will appear next to the calculated C.O. value. The thermodilution curve, cardiac output numeric value and measurement time are stored in one of five EDIT windows. Press STOP key during measurement to stop it.

NOTE:

Sudden variations in pulmonary artery blood temperature resulted from e.g. patient movement or drug injection may cause C.O calculation. To avoid incorrect curve detection, immediately after “Inject Now” appears, inject the solution.

- **EDIT**

Pick "EDIT" in HOME/CARDIAC OUTPUT MENU to call up the following window:

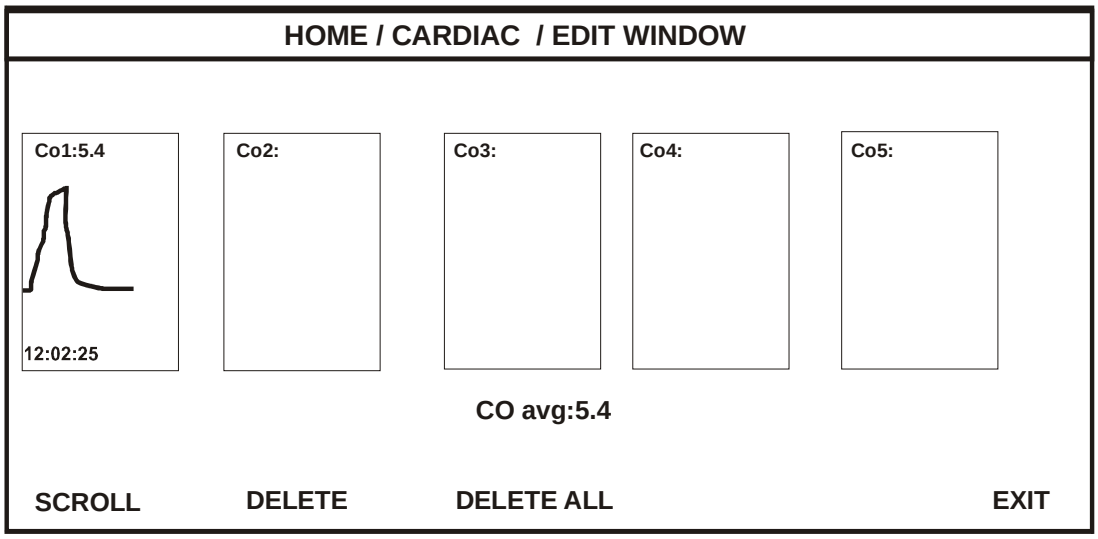


Figure 15-5 HOME/CARDIAC/EDIT WINDOW

Numeric value, curve and time of the last five C.O. measurements are displayed in this window. Averaged C.O. value is displayed below the window. User can identify and delete erroneous measurements and then average value of other measurements will be recalculated by the system.

If you perform more than five measurements without rejecting any, the first measurement will automatically be deleted when sixth curve is stored.

- **SCROLL**

Press SCROLL to move red frame between curves and press ENTER to select one curve.

- **DELETE**

Press to delete the selected curve.

- **DELETE ALL**

Press to delete all stored C.O. curves.

- **SETUP**

C.O. settings can be changed in the Setup menu. Pick SETUP in HOME/CARDIAC OUTPUT MENU to call up the following menu (Figure 15-6):

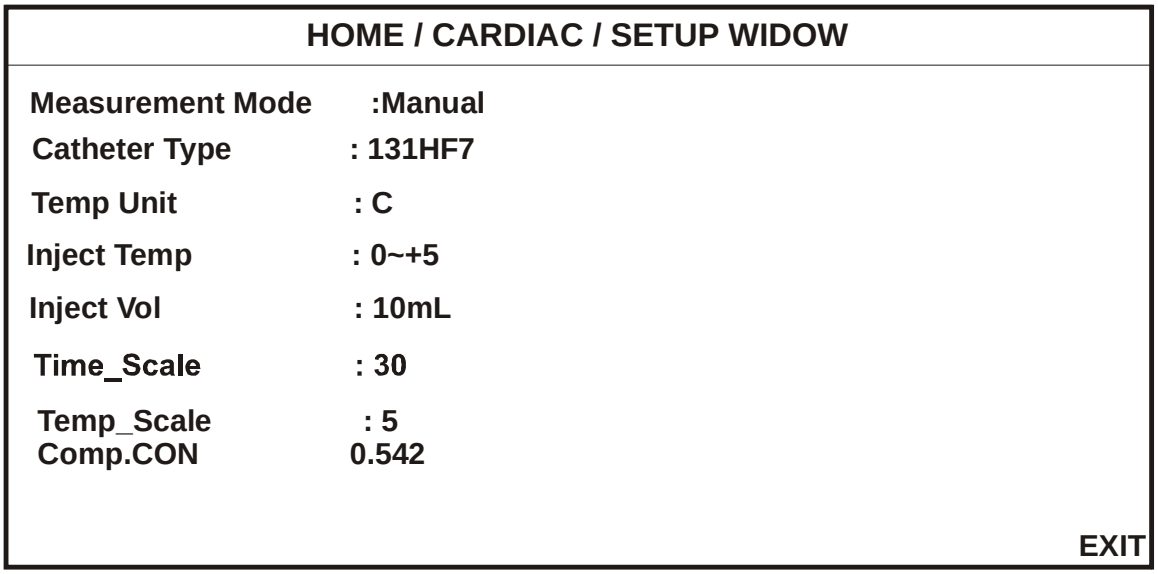


Figure 15-6 HOME/CARDIAC/SETUP WINDOW

- **Measurement Mode**

To start measurement in MANUAL mode, press START key in CARDIAC OUTPUT MENU after you prepared injectate solution.

- **Catheter Type**

To select catheter type. Available options are “131HF7” and “139HF75P” Edwards catheters and “Simulator”. The last option is intended to use simulator with Comp.Con. of 0.542.

- **Comp. Con.**

The computation constant changes based on catheter type. Make sure that appropriate catheter is selected, because computation constant directly influences C.O. measurement.

C.O. settings in SETUP menu can be monitored in CARDIAC OUTPUT MENU to check and modify any possible error occurred in data input.

15.3 C.O. Alarm Messages

Message	Explanation
No Cable	C.O. cable is not connected to the monitor.
Ready for measurement	The system alerts user to start measurement
Noisy Baseline	The system is not ready for measurement. (If the message does not disappear after a while, possible cause can be improper placement of the catheter. Make sure that the catheter is placed properly in the patient body).
Start pressed when not ready please wait	If Start button is pressed before the message "Ready for measurement" appears, the measurement will not be started and this message will appear. To start measurement, wait until "Ready for measurement" is displayed.
Inject now	Start injection procedure.
Not injected in the expected time	Injection is not performed long time after Start C.O. is selected.
Minimum not detected in the expected time	The curve peak has not been detected in the expected time.
Calculating	C.O. is being calculated.
Curve end not detected!	The curve end has not been detected in the expected time.
Minimum and End Not Confirmed-Noisy Curve	C.O. calculation is stopped due to noisy curve
Done! Check edit menu or oldest curve is replaced!	All five C.O. measurement windows are filled. In order to observe average value and deleting/selecting measurements, refer to Edit window, otherwise start a new measurement the oldest measurement data will be replaced by new one.

15.4 C.O. Cable Cleaning

Disconnect the cable from monitor. Use a soft cloth moistened with 70% isopropyl alcohol to clean the cable and then dry it with a clean cloth.

⚠Warning⚠

Do not sterilize the C.O. cable by autoclave, irradiation or ethylene oxide.

⚠Warning⚠

To prevent damage, do not immerse the cable in any liquid solution.

NOTE:

To avoid environment pollution, catheters shall be disposed in accordance with hospital regulations.

Chapter 16, RECORDER *

16.1 General

SAADAT thermal recorder can be installed on the bedside monitor optionally.

Performance of the Recorder

- Recording speed is adjustable to 6, 12.5, 25 mm/s.
- Up to 3 selectable waveforms recording.
- The real time and freeze recording.
- The automatic recording with selectable time intervals
- The selectable automatic alarm recording.
- The manual recording delay

16.2 Recording type

Monitor provides several recording types:

- Continuous real-time recording.
- 10, 20 and 30 seconds real-time recording.
- 10 seconds automatic recording.
- Alarm recording.
- Frozen waveform recording.
- Parametric recording.
- TREND recording.
- NIBP LIST recording.
- ARR EVENT LIST recording.
- ARR WAVE recording.

Parametric Recording

Parametric recording starts when you press “Rec/Stop” key if both traces in RECORDER WINDOW are set to “OFF”.

Manual Recording

Manual recording includes two recording modes as follow:

Continuous Recording:

Continuous real-time recording starts from last 5 seconds when you press the “Rec/Stop” key and stops when you press it again.

10, 20 and 30 s Recording:

Real time recording starts from last 5 seconds when you press “Rec/Stop” and it will automatically stop after 10, 20 or 30 seconds depending on your setting.

Automatic Recording

The monitor starts the recording for 10 seconds according to time interval which is set in the "PERIODIC INTERVAL" of the "RECORDER WINDOW". Refer to **2.6 Recorder** for details.

Alarm Recording

If “ALARM REC” is set ON in each parameter’s window, the system automatically starts recording when an alarm occurs. Alarm recording is activated when the numeric parameters violate adjusted alarm limits or when an arrhythmia event occurs.
When an alarm of parameters has occurred only numeric parameters will be recorded and parameter’s value that triggered the alarm record is marked with an arrow.
During HR alarm recording, the monitor also records 20 seconds ECG waveform.
You can “ON” or “OFF” alarm recording in HOME /RECORDERWINDOW and also it can be set in each parameter menu.

Freeze Waveform Recording
The monitor prints out 20 seconds of the selected waveforms and numeric parameters in FROZEN mode. So you can freeze the abnormal waveforms on the screen and record them.

TREND Recording
The monitor can print out the trend graph and numeric parameters in the current TREND WINDOW. Select "RECORD" in TREND WINDOW to start recording.

NIBP LIST Recording
The monitor can print out NIBP LIST. Select "RECORD" in NIBP LIST WINDOW to start recording.

ARR EVENT LIST Recording
The monitor can print out ARR EVENT LIST. Select "RECORD" in ARR EVENT LIST WINDOW to start recording.

ARR WAVEFORM Recording
The monitor can print out stored arrhythmia waveforms in ARR WAVEFORM LIST WINDOW. Select "RECORD" in ARR EVENT RECAL/WAVE WINDOW to start recording.

16.3 Recorder operation and status messages

The following data are printed on the paper:

- Recording Type

MANUAL RECORD
PERIODIC RECORD
ALARM RECORD (name of the alarm parameter)
FREEZE RECORD

(Parameter) TREND RECORD
NIBP LIST RECORD
ARR EVENT LIST RECORD
ARR WAVEFORM RECORD
NIBP LIST RECORD

- Recording Date and Time
- Bed number
- Patient name, Patient ID, Gender, Height, Weight, Date of birth
- Parameter name and value
- Sweep Speed
- ECG lead, filter and gain or RESP lead on the waveform
- Hospital and ward name
- Physician name

16.4 Recorder paper

You should use only 57mm thermo-sensitive paper for SAADAT recorder.

NOTE:

Use only manufacturer recommended white thermosensitive record paper, otherwise the recording quality may be poor and the thermosensitive printhead may be damaged.

NOTE:

Do not use grid paper.

NOTE:

Do not use paper with edges that are pasted or have turnups at the start of the roll. If they need to be used unavoidably, replace with new paper roll as soon as possible before entire roll is used up.

⚠**Warning**⚠

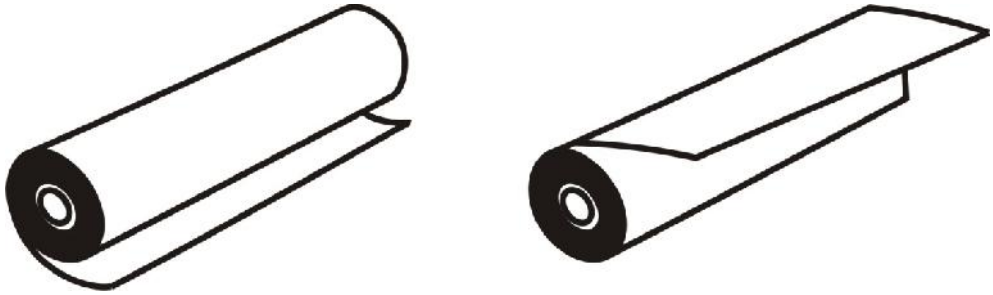
Do not touch the recorder head while recording and immediately after recording because it is so hot and may lead to personal injury including burns.

Loading the paper:

- Pull down the switch on the recorder case.
- Insert a new roll of paper into the paper cassette. Printing side of the paper should face the thermo sensitive printhead.
- Close the recorder door.

NOTE:

Thermo sensitive surface of paper should be placed facing the head. make sure to place the paper correctly.



a. incorrect placement **b. correct placement**

Figure 16-1 recorder paper placement

NOTE:

The paper detector may not operate properly if covered with foreign matter. Therefore, if you find foreign matter on the sensor, remove it and clean the sensor.

⚠**Warning**⚠

While the recorder is working, the record paper goes out steadily. By pulling the paper, the recorder will be damaged.

NOTE:

If the paper is jammed, open the recorder door and remove the paper. Do not pull the paper by force.

NOTE:

Be careful when inserting paper. Avoid damaging the thermosensitive printhead. Do not touch thermosensitive print head.

NOTE:

It is recommended to use the paper with coloured marks intended to aware that the paper is near to finish. Otherwise, the operator should be sure about sufficient paper for recording.

16.5 Recorder Alarm Messages

Message	Cause	Solution
Rec. Software Error	Software error	Turn the system off and then on .If the problem persists, contact after sales service of manufacturer.
Recorder Fault	Hardware error	Turn the system off and then on. If the problem persists, contact after sales service of manufacturer.
Rec Door Open	The recorder door is open	Close the recorder door.
Rec Paper Out	Recorder paper has been finished.	Insert a new paper roll.
Print head High Temp	The thermal head is too hot.	Stop operation for some minutes.
Print head High Vol.	Print head voltage is high.	Turn the system off and then on. If the problem persists, contact after sales service of manufacturer.
Print head Low Vol.	Print head voltage is low.	Turn the system off and then on. If the problem persists, contact after sales service of manufacturer.
Time out Error	The recorder could not record.	Turn the system off and then on. If the problem persists, contact after sales service of manufacturer.

All alarm messages of the recorder are level 2. The messages are displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

16.6 Recorder cleaning

Accumulation of paper powder or foreign matter between the thermal head and platen roller will deteriorate the print quality. Clean the head elements and platen roller surface using alcohol and a cotton swab. Wait until the alcohol dries then close the recorder door.

⚠Warning⚠

Do not clean the printer immediately after printing because thermal head and its periphery are hot during and after printing.

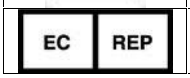
NOTE:

Do not use sandpaper, cutter knifes, etc to clean the recorder.

Chapter 17, Patient Safety

The patient monitor is designed to comply with the international safety standard requirements for medical electrical equipment. This device has floating inputs and is protected against the effects of defibrillation and ESU. If the correct electrodes are used in accordance with the manufacturer instructions, the display screen will recover within 10 seconds after defibrillation.

Explanation of Symbols in the Monitor

	This symbol indicates that the monitor has CF type and Defibrillation Proof applied part according to IEC60601-1.The modules with this symbol contain a CF-Type isolated (Cardiac Float) patient applied part providing a high degree of protection against shock, and is usable during defibrillation.
	This symbol indicates that the monitor has BF type and Defibrillation Proof applied part according to IEC60601-1. The modules with this symbol contain a BF-Type isolated (Body Float) patient applied part which contains a high degree of protection against shock, and is usable during defibrillation.
	This symbol means that consult user manual of the monitor and pay attention to the warnings and cautions.
	This symbol indicates that the equipment shall be disposed of in an environmentally-friendly manner.
	This symbol beside the patient connector indicates that a part of protection against effects of defibrillator is provided by the accessory connected to patient. Therefore, use only accessories approved by the manufacturer.
	Equipotential grounding system.
100-240 VAC 0.9-0.4 A 50/60 Hz	AC POWER SUPPLY
	3A fast fuse
S/N	Serial number
	Manufacture date
	Manufacturer information
	European community representative

⚠ **Warning** ⚠

Do not touch the patient, bed or instrument during defibrillation.

Follow the instructions below to ensure a completely safe electrical installation.

The environment where the Portable Patient Monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity and so on.

The Patient Monitor operates within specifications at ambient temperatures between 0ºC and 40ºC. Ambient temperatures that exceed these limits could affect the accuracy of the monitor and cause damage to the modules and circuits.

Grounding the patient monitor

To protect the patient and hospital personnel, the case of patient monitor must be grounded. The patient monitor is equipped with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle .If a 3-wire receptacle is not available, consult the hospital electricians. If there is any doubt regarding the completeness of the protective grounding wire, the equipment must be operated with internal battery or DC input.

Equipotential Grounding

Protection class I instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, the portable Patient Monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the rear panel of the monitor and the other end to one point of the equipotential grounding system.

The equipotential grounding system is for the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in medically used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order.

⚠ **Warning** ⚠

Possible explosion hazard if the monitor is used in the presence of flammable anaesthetic.

Chapter 18, Getting Started

18.1 Open the Package and Check

Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage.

- Check for any mechanical damage.
- Check for the existence of the power cable and accessories.

If there is any problem, contact the distributor immediately.

18.2 Place the battery fuse

When you use the system for the fist time, you should place the fuse on the rear panel.

18.3 Connect the Power Cables

Connection procedure of the AC power line:

- Make sure the AC power supply complies with following specification: 100-240 VAC, 50 /60Hz
- Plug the power cable to power supply socket of the monitor. Connect the other end of the power cable to a grounded power receptacle.

NOTE:

Make sure that the battery indicator lights. If it does not light, check your local power supply and power cable connection. If the problem still exists, contact the local After Sale Service.

18.4 Power on the Monitor

Press POWER key to power on the monitor. At the same time a beep sound will be heard and yellow and red indicators light simultaneously. After 30 seconds or more that the system self-tests are performed, the main screen will be displayed and you can start monitoring.

Perform the following settings before monitoring:

- New patient information (For details, please refer to chapter Configuration, PATIENT INFORMATION)
- Patient mode (Adult/Neonate/ Pediatric) before NIBP measurement
- Alarm sound
- Alarm limits
- Zeroing before IBP measurement (For more information, see chapter IBP)
- Pulse oximetry (For more information, see chapter SpO2)
- RESP (For more information, see chapter RESP)

NOTE:

Check all the functions of modules that may be used and make sure that the monitor is in good connection.

⚠**Warning**⚠

If any sign of damage is detected, or the monitor displays any error messages, do not use it on any patient. Contact biomedical engineer in the hospital or local After Sale Service immediately.

18.5 Connect Patient Sensors

Connect all the necessary accessories between the monitor and the patient.

NOTE:

For any information about correct connection of accessories, refer to each module's chapter.

Chapter 19,Technical Specification

Contents

CLASSIFICATION	
Protection against electroshock	Class I, Type CF for all modules (except Multi-gas, NIBP and modules that are BF) (based on IEC 60601-1).
Protection	Against Electro surgery and Defibrillator
Mode of operation	Continues operation equipment
Harmful Liquid Proof Degree	IPX1
Method of disinfection	Refer to each module's chapters and chapter chapter Care & Cleaning for detail.
Safety of anesthetic mixture	Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

General			
Display			
Novin S1800	TFT/LED COLOR	800 × 600	10”
Waveforms	ECG, SPO2, IBP1, IBP2, RESP/GAS, (Freezable), C.O.		
Numeric Parameters	HR,PVCs,ST,SPO2, PR, NIBP (SYS, DIA, MAP), IBP1(SYS,DIA,MAP), IBP2(SYS,DIA,MAP), RR, T1, T2, DT, EtCo2, FiCo2, AWRR, EtN2O, FiN2O, EtO2, FiO2, EtAA, FiAA, C.O, Alarm Limits.		
Operation Method	Membrane/Keys and rotary knob		
AC Power	100 - 240 VAC, 50/60 Hz , Ip: 0.9 – 0.4 A		

ECG			
Lead & Wire Options			
Selectable: 3 ,5 or 12 Leads		Selectable: 3 ,5 or 10 Wires	
3 ECG Leads I, II, III		3 Lead wires ECG Cable	
5 Leads ECG: I,II,III,V,aVR,aVF,aVL		5 Lead wires ECG Cable	
12 Leads ECG : I,II,III, aVR,aVF,aVL ,V1, V2, V3, V4,V5,V6		10 Lead wires ECG Cable	
Dynamic Range	± 5 mV		
Lead Off Current	< 90 nA		
Gain	4, 2, 1, 1/2, 1/4, Auto		
Calibration	1mV, 0.5 sec		
Filters	“MONITOR”	0.5 - 24 Hz	
	“NORMAL”	0.5 - 40 Hz	
	“EXTENDED”	0.05-100 Hz	
CMRR	> 98 dB		
Internal Noise	< 30 µV RTI		
Input Impedance	> 5 MΩ		
QRS Detection	Duration	40 to 120 msec	
	Amplitude	0.25 to 5 mV	for Adult/Pediatric
		0.2 to 5 mV	for Neonate
Heart Rate Range	15 - 300 BPM	for adult/Pediatric	
	15 - 350 BPM	for neonate	

Accuracy	±1% or 2 BPM		
Tall T-Wave	Reject up to 1.2 mV Amp.		
Pacer Detection/Rejection	Duration	0.1 - 2 msec	
	Amp	±2 to ± 700 mV (Without over/undershoot)	
	Reject from heart rate counter		
	Re-insert into ECG to display on screen		
	Ineffective pace rejection	HR:0, Pace: 60	
		HR:60, Pace:60	
		HR:30, Pace:80	
	Beside rejection of atrial paces preceed ventricular paces by 150 or 250 ms		
Protection	Defibrillator and Electrosurgery		

ANALOG OUTPUT

Signals	ECG	
Maximum delay	≤30 ms	
Output range	± 5 V	
Signal gain	1000 (1V/mV)	
Gain accuracy	± 20 mV	
Maximum offset	± 50 mV	
ECG bandwidth	"MONITOR"	0.5 - 24 Hz
	"NORMAL"	0.5 - 40 Hz
	"EXTENDED"	0.05-100 Hz
Pacemaker pulses	Amplitude:	5 V (nominal)
	Duration:	5 ms
ECG range	-5 to 5 mV	
Output impedance	249 Ω ± 5%	
Data rate	400 samples/sec	

ARRHYTHMIA ANALYSIS

Type	ASYS, VFIB, VTAC, RUN, AIVR, COUPLET, BIGEMINY, TRIGEMINY, TACHY, BRADY, AFIB, PAUS, FREQUENT PVCs
Learning	Rapid Learning: only 20 seconds required for recognition of dominant rhythm.
Method	Real time arrhythmia detection with innovative feature.
Memory	Capability of storing the latest 150 ARR event (waveform and Parameters)

ST ANALYSIS

Display resolution	0.01 mV
Measurement Range	-2mv to +2mv
Alarm Range	-2mv to +2mv
Features	User Adjustable Isoelectric and ST point trending of ST values
Update period	5 Sec.

NIBP

Measurement method	Oscillometric		
Measurement mode	Manual/Automatic/Stat		
Measurement time	20-25 sec (excluding cuff inflation time)		
Cuff pressure rang	Adult	0-290 mmHg	
	Neonate	0-145 mmHg	
Measurement Range	Adult	SYS	30 ~ 255 mmHg

		DIA	15 ~ 220 mmHg
		MAP	20 ~ 235 mmHg
	Neonate	SYS	30 ~ 135 mmHg
		DIA	15 ~ 110 mmHg
		MAP	20 ~ 125 mmHg
	Pediatric	SYS	30 ~ 240mmHg
		DIA	15 ~ 220 mmHg
		MAP	20 ~ 230mmHg
Pressure Transducer accuracy	±3 mmHg full range		
Initial Inflation Target	Adult : 150 mmHg Pediatric: 140mmHg Neonate: 85 mmHg		
Memory	500 Records		

SpO2 (Masimo Rainbow Set)

Spo2 Parameters	Spo2,PI,PR		
Method Spo2	2 Wavelengths of light used		
Rainbow parameters	SpOC		
	SpCO		
	SpMet		
	SpHb		
	PVI		
Method Rainbow	7+Wavelengths of light used		
Range	SpO2	0 – 100 %	
	SpMet	0 – 99.9 %	
	SpCO	0 – 99 %	
	SpHb	0 – 25.0 g/dL	
	SpOC	0 – 35.0 ml/dL	
	PR	25 – 240 bpm	
	PI	0 – 20.0 %	
	PVI	0 – 100 %	
Accuracy	Oxygen Saturation		
	No motion conditions	Adult/Pediatric	±2% (SPO2 70 ~ 100%)
		Neonate	±3% (SPO2 70 ~ 100%)
	Motion conditions	Adult/Pediatric/Neonate	±3% (SPO2 70 ~ 100%)
	Low perfusion conditions	Adult/Pediatric/Neonate	±2% (SPO2 70 ~ 100%)
	Pulse Rate		
	No motion conditions	Adult/Pediatric/Neonate	±3bpm (PR 25 ~ 240)
	Motion conditions	Adult/Pediatric/Neonate	±5bpm (PR 25 ~ 240)
	Low perfusion conditions	Adult/Pediatric/Neonate	±5bpm (PR 25 ~ 240)
	Carboxyhemoglobin Saturation		
	Carboxyhemoglobin Saturation	Adult/Pediatric	±3% (1 - 40)
	Methemoglobin Saturation		
	Methemoglobin Saturation	Adult/Pediatric/Neonate	±1% (1 – 15)
	Total Hemoglobin		
	Total Hemoglobin	Adult/Pediatric	±1g/dL (8 – 17) g/dL

Resolution	SpO2	1 %
	SpCO	1.0 %
	SpMet	0.1 %
	SpHb	0.1 g/dL
	PI	0.1%
	PVI	1%
	SpOC	0.1 ml/dL
	PR	1 BPM
Please note that pulse-oximetry method (SPO2) is compared to laboratory spectroscopy of sample blood (SaO2). This method measures precision of SPO2 measurement using statistical analysis. Therefore, measurement precision is reliable for at least two third of measurements.		

TEMPERATURE(2 Channel)

Probe Type	YSI 400 Compatible
Range	0 - 50 °C
Accuracy	± 0.2 °C

RESPIRATION

Method	Impedance
Base Resistance	250 -1250 Ohm
Dynamic Range	0.2 - 2 Ohm
Breath Rate Range	0 - 253 BrPM
Accuracy	±2% or 2 BrPM

IBP

Channel	2 Channel	
Measurement Range	SYS	-50 ~ 300 mmHg
	DIA	-50 ~ 300 mmHg
	MAP	-50 ~ 300 mmHg
Pressure Filter	8Hz, 16Hz,22Hz selectable	
Press Sensor Sensitivity	5 µV / V / mmHg	
Press Sensor Impedance	300 ~ 2500 Ohm	
Resolution	1 mmHg	
Accuracy	2 % or 2mmHg (each one is greater) without transducer	
IBP Auto Scale		
Pump Page		

Multi-gas, Mainstream (MASIMO SWEDEN AB)

IRMA CO2	CO2
IRMA AX+	CO2, N2O, primary and secondary agents (HAL, ISO, ENF, SEV, DES)
Gas /CO2 Interface	Connector and S/W Interface Driver, Applicable for All Gas and CO2 Modules.

Description	Extremely compact infrared mainstream multigas probe available in two parameter configurations.	
Cable length	2.5 m ±0.1 m	
Recovery time after defibrillator test	Unaffected	
Drift of measurement accuracy	No drift	
Surface temperature (at ambient temp. 23°C)	IRMA CO2	Max 39°C / 102°F
	IRMA AX+	Max 46°C / 115°F
Interface	Modified RS-232 serial interface operating at 9600 bps.	
Airway adapters	Disposable adult/pediatric:	- Adds less than 6 ml deadspace.
		- Pressure drop less than 0.3 cm H2O @ 30 LPM.
	Disposable infant:	- Adds less than 1 ml deadspace.

		- Pressure drop less than 1.3 cm H2O @ 10 LPM.
	(Infant Airway Adapter recommended for Tracheal Tube ID size = 4 mm)	
Degree of protection against harmful ingress of water or particulate matter	IP44	
Method of sterilization	The IRMA system contains no sterile parts.	
Mode of operation	CONTINUOUS OPERATION	
Data output		
Breath detection	Adaptive threshold, minimum 1 vol% change in CO2 concentration.	
Respiration rate[1]	0–150 ±1 bpm. The respiration rate is displayed after three breaths and the average value is updated every breath.	
Fi and ET[2] Fi and ET are displayed after one breath and have a continually updatedbreath average. The following methods are used to calculate end-tidal (ET) values: -CO2: The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end ofthe cycle. -N2O and anesthetic agents: The momentary gas concentration at the time point where ETCO2 is detected. ET-values for anaesthetic agents and N2O (IRMA AX+) will typically decrease below nominal value when respiration rate exceeds 80 bpm. The maximum decrease is described by the formula ET = 80*ETnom/RR. ETCO2 will be within specification for all respiration rates up to 150 bpm (IRMA AX+ and IRMA CO2)		
Automatic agent identification	IRMA AX+: Primary and secondary agent.	
Gas Analyzer		
Probe	2-9 channel NDIR type gas analyzer measuring at 4-10 µm. Pressure, temperature and full spectral interference correction.	
Calibration	Zeroing recommended when changing Airway adapter (IRMA AX+) No span calibration required for the IR bench.	
Warm-up time	IRMA CO2: < 10 seconds (concentrations reported and full accuracy)	
	IRMA AX+: < 20 seconds (concentrations reported, automatic agent identification enabled and full accuracy)	
Rise time[3] (@10 l/min)	CO2 ≤ 90 ms	
	N2O ≤ 300 ms	
	HAL, ISO, ENF, SEV, DES ≤ 300ms	
Primary agent threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.	
Secondary agent threshold	0.2 vol% +10% of total agent concentration	
Agent identification time	<20 seconds. (Typically < 10 seconds)	
Total system response time[4]	< 1 second	
Accuracy - standard conditions		
The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa		
Gas	Range	Accuracy
CO2	0 to 15 vol%	±(0.2 vol% +2% of reading)
N2O	0 to 100 vol%	±(2 vol% +2% of reading)
HAL,ISO,ENF	0 to 8 vol%	±(0.15 vol% +5% of reading)
SEV	0 to 10 vol%	±(0.15 vol% +5% of reading)
DES	0 to 22 vol%	±(0.15 vol% +5% of reading)
Accuracy - all condition		
The following accuracy specifications are valid for all specified environmental conditions except for interference specified in the table “Interfering gas effects” and the section “Effects from water vapor partial pressure on gas readings” below.		
Gas	Accuracy	

[1] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

[2] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

[3] Measured @ 10 l/min with gas concentration steps corresponding to 30% of total measuring range for each gas.

[4] Measured according to EN ISO 80601-2-55.

CO2	±(0.3 kPa + 4% of reading)
N2O	±(2 kPa + 5% of reading)
Agents[5]	±(0.2 kPa + 10% of reading)

Gas concentration conversion

Gas concentration is reported in units of volume percent. The concentration is defined as:

$$\%\,gas = \frac{(Partial\ pressure\ of\ gas\ component)}{(Total\ pressure\ of\ gas\ mixture)} * 100$$

The total pressure of the gas mixture is estimated by measuring the actual atmospheric pressure in the IRMA probe.

Effects from water vapor partial pressure on gas readings

The effects of water vapor are illustrated by the examples in the following table. The two columns to the right show the relative error in displayed concentrations when adding or removing water vapor from the gas mixture, and referencing the measurement to dry gas conditions at actual temperature and pressure (ATPD) or saturated conditions at body temperature (BTPS).

Temp [C]	RH [%]	P [hPa]	H2O part.pres. [hPa]	errrel [%]	errrel ATPD [%]	errrel [%] BTPS
10	20	1013	2	0	-0.2	+6.0
20	20	1013	5	0	-0.5	+5.7
25	0	1013	0 (ATPD)	0	0	+6.2
25	23	1013	7.3	0	-0.7	+5.5
25	50	1013	16	0	-1.6	+4.6
30	80	1013	42	0	-4.1	+2.0
37	100	1013	63 (BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

The table illustrates that the gas concentrations in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

Interfering gas effects

Gas or vapour	Gas level	CO2		Agents	N2O
		IRMA CO2	IRMA AX+		
N2O-note4)	60 vol%	- note1&2)	- note1&2)	- note1)	- note1)
HAL-note4)	4 vol%	- note1)	- note1)	- note1)	- note1)
ENF, ISO, SEV-note4)	5 vol%	+8% of reading-note3)	- note 1)	- note1)	- note1)
DES-note4)	15 vol%	+12% of reading-note3)	- note 1)	- note1)	- note1)
Xe (Xenon)-note4)	80 vol%	-10% of reading-note3)		- note1)	- note1)
He (Helium)-note4)	50 vol%	-6% of reading-note3)		- note1)	- note1)
Metered does inhaler propellants-note4)	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol)-note4)	0.3 vol%	- note1)	- note1)	- note1)	- note1)
C3H7OH (Isopropanol)-note4)	0.5 vol%	- note1)	- note1)	- note1)	- note1)
CH3COCH3 (Acetone)-note4)	1 vol%	- note1)	- note1)	- note1)	- note1)
CH4 (Methane) -note4)	3 vol%	- note1)	- note1)	- note1)	- note1)
CO (Carbon monoxide) -note5)	1 vol%	- note1)	- note1)	- note1)	- note1)
NO (Nitrogen monoxide)-note5)	0.02 vol%	- note1)	- note1)	- note1)	- note1)
O2-note 5)	100 vol%	- note1&2)	- note1&2)	- note1)	- note1)

Note 1 : Negligible interference, effect included in the specification " Accuracy all conditions" above.

[5] The accuracy specification for IRMA AX+ is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

Note 2 : For probes not measuring N2O and/or O2 the concentrations shall be set from host according to the instructions. (IRMA CO2 measures neither N2O, nor O2. IRMA AX+ dose not measure O2.)	
Note 3 : Interference at indicated gas level. for example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture contaning 5.0 vol% CO2 and 50 vol% Helium, the measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.	
Note 4 : According to the EN ISO 80601-2-55:2011 standard.	
Note 5 : In addition to the EN ISO 80601-2-55:2011 standard.	
Multi-gas, Sidestream (MASIMO SWEDEN AB)	
ISA CO2	CO2, CO2 waveform
ISA AX+	CO2,O2, N2O, primary and secondary Agents (HAL, ISO, ENF, SEV, DES)
ISA OR+	CO2,O2, N2O, primary and secondary Agents (HAL, ISO, ENF, SEV, DES)
Gas /CO2 Interface	Connector and S/W Interface Driver, Applicable for All Gas and CO2 Modules.
Description	Compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Ambient CO2	≤ 800 ppm (0.08 vol%)
Recovery time after defibrillator test	Unaffected
Water handling	Nomoline Family sampling lines with proprietary water removal tubing.
Sampling flow rate	50 ± 10 sml/min[6]
Degree of protection against harmful ingress of water or particulate matter	IP44
Method of sterilization	The ISA system contains no sterile parts.
Mode of operation	CONTINUOUS OPERATION
Degree of protection against electric shock	Nomoline Family sampling lines are classified as DEFIBRILLATION-PROOF TYPE BF APPLIED PART
Data output	
Breath detection	Adaptive threshold, minimum 1 vol% change in CO2concentration.
Respiration rate [7]	0 to150 ± 1 breaths/min (or BrPM)
Fi and ET[8] Fi and ET are displayed after one breath and have a continually updated breath average. The following methods are used to calculate end-tidal (ET) values: -CO2: The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. -O2: The highest/lowest concentration of O2during the expiratory phase (depending on whether ETO2 is higher or lower than FiO2 -N2O and anesthetic agents: The momentary gas concentration at the time point where ETCO2 is detected. ET will typically decrease below nominal value (ETnom) when respiration rate (RR) exceeds the RR threshold (RRth) according to the following formulas:	
ISA CO2 CO2 ISA OR+/AX+	ET=ETnom×(125⁄RR)_for RRth >125
CO2	ET=ETnom×$\sqrt{(70 / RR)}$ for RRth >70
N2O, O2, DES, ENF, ISO, SEV	ET=ETnom×$\sqrt{(50 / RR)}$ for RRth >50
HAL	ET=ETnom×$\sqrt{(35 / RR)}$ for RRth >35
Automatic agent identification	ISA OR+/AX+: primary and secondary agent.
Gas analyzer	
Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 µm.
	Data acquisition rate 10 kHz (sample rate 20 Hz / channel).
	O2 measurements by Servomex's paramagnetic sensor.
Calibration	No span calibration is required for the IR bench. An automatic zeroing is performed 1 to 3 times per day.
Compensation	ISA CO2: Automatic compensation for pressure and temperature.
	ISA CO2: Manual compensation for broadening effects on CO2.

[6] Volumetric flow rate of air corrected to standardized conditions of temperature and pressure.

[7] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

[8] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

	ISA OR+/AX+	Automatic compensation for pressure, temperature and broadening effects on CO2.	
Warm-up time	ISA CO2:	<10 seconds (concentrations reported and full accuracy)	
	ISA OR+/AX	+: <20 seconds (concentrations reported, automatic agent identification enabled and full accuracy	
Rise time[9]	CO2		≤ 200 ms(≤ 300 ms for ISA OR+/AX+)
	N2O, O2, ENF, ISO, SEV, DES		≤ 400 ms
	HAL		≤ 500 ms
Primary agent threshold (ISA OR+/AX+)	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%		
Secondary agent threshold (ISA OR+/AX+)	0.2 vol% +10% of total agent concentration		
Agent identification time (ISA OR+/AX+)	<20 seconds (typically <10 seconds)		
Total system response time[1]	ISA CO2:	< 3 seconds	
	ISA OR+/AX+:	< 4 seconds (with 2m Nemoline Airway Adapter Set sampling line)	

Accuracy standard conditions		
The following accuracy specifications are valid with no drift for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:		
	Range[1]	Accuracy
CO2	0 to15 vol%	±(0.2 vol% +2% of reading)Unspecified
	15 to 25 vol%	
N2O	0 to 100 vol%	±(2 vol% +2% of reading)
HAL, ENF, ISO	0 to 8 vol%	±(0.15 vol%+5% of reading)Unspecified
	8 to 25 vol%	
SEV	0 to 10 vol%	±(0.15 vol% +5% of reading)Unspecified
	10 to 25 vol%	
DES	0 to 22 vol%	±(0.15 vol% +5% of reading)Unspecified
	10 to 25 vol%	
O2	0 to 100 vol%	±(1 vol% +2% of reading)

Accuracy - all conditions	
The following accuracy specifications are valid with no drift for all specified environmental conditions, except for interference from water vapor in the below section “Effects from water vapor partial pressure on gas readings”.	
GAS	Accuracy
CO2	±(0.3 kPa + 4% of reading)
N2O	±(2 kPa + 5% of reading)
Agents[1]	±(0.2 kPa + 10% of reading)
O2	±(2 kPa + 2% of reading)

Effects from water vapor partial pressure on gas readings
When the breathing gas flows through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The measurement of all gases will always show the actual partial pressure at the current humidity level in the gas sample. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. However at an ambient temperature of 37 °C and a breathing gas with a relative humidity of 95% the gas reading will typically be 6% lower than corresponding partial pressure after removal of all water.
Interfering gas and vapor effects

[9] Measured according to EN ISO 80601-2-55.

[1] Measured according to EN ISO 80601-2-55.

[1] All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

[1] The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

Gas or vapour	Gas level	CO2		Agents	N2O
		ISA CO2	ISA AX+/OR+		
N2O-note4)	60 vol%	- note2)	- note1)	- note1)	- note1)
HAL-note4)	4 vol%	- note1)	- note1)	- note1)	- note1)
ENF, ISO, SEV-note4)	5 vol%	+8% of reading-note3)	- note1)	- note1)	- note1)
DES-note4)	15 vol%	+12% of reading-note 3)	- note1)	- note1)	- note1)
Xe (Xenon)-note4)	80 vol%	-10% of reading-note3)		- note1)	- note1)
He (Helium)-note4)	50 vol%	-6% of reading-note3)		- note1)	- note1)
Metered does inhaler propellants-note4)	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol)-note4)	0.3 vol%	- note1)	- note1)	- note1)	- note1)
C3H7OH (Isopropanol)-note4)	0.5 vol%	- note1)	- note1)	- note1)	- note1)
CH3COCH3 (Acetone)-note4)	1 vol%	- note1)	- note1)	- note1)	- note1)
CH4 (Methane)-note4)	3 vol%	- note1)	- note1)	- note1)	- note1)
CO (Carbon monoxide)-note5)	1 vol%	- note1)	- note1)	- note1)	- note1)
NO (Nitrogen monoxide)-note5)	0.02 vol%	- note1)	- note1)	- note1)	- note1)
O2-note5)	100 vol%	- note۲)	- note2)	- note1)	- note1)

Note 1 : Negligible interference, effect included in the specification " Accuracy all conditions" above.

Note 2 : Negligible interference with N2O/O2concentrations correctly set, effect included in the specification " Accuracy all conditions" above.

Note 3 : Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture contaning 5.0 vol% CO2and 50 vol% Helium, the actual measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.

Note 4 : According to the EN ISO 80601-2-55:2011 standard.

Note 5 : In addition to the EN ISO 80601-2-55:2011 standard.

Cardiac Output

Method	Right Heart Thermodilution
Range	0.5-18 l/min
Resolution	0.01l/min
Reproducibility	±3%

Recorder

Model	Internal Thermal Recorder SP58
Channel	Up to 3 waveforms
Printing Speed	6,12.5,25 mm/sec
Paper Size	57mm by 59 foot roll

DRUG CALCULATE

To calculate the dose and time of medication

ALARM

Sources	Error messages, All other parameter limits
Alarm On/Off	Selectable for all parameters
Alert	Blinking on Display, Volume Selectable Audio Alarms, Light indicator

TREND	
Sources	HR,PVCs,ST,AFIB,SPO2, RR, T1, T2, IBP1(SYS,DIA,MAP), IBP2(SYS,DIA,MAP), EtCo2,FiCo2,AWRR(sidestream, mainstream), EtN20,FiN2O,EtO2,FiO2,EtAA,FiAA(ISO, DES, ENF, HAL, SEV)
Trend Time Save	96 Hours
Trend Time Interval	15, 30, 45 Min, 1, 2 and 4 Hours
Resolution	1 sec
INPUT/OUTPUT	
Network	TCP/IP Protocol Ethernet LAN with RJ45 Interface
VGA Connection	VGA output with same page

Internal Battery				
Sealed Lead Acid, Rechargeable, 12 V, 3.3 AH				
Lithium Polymer: 11.1V,4.3AH				
System Model	Sealed Lead Acid		Lithium Polymer	
	Charge time	Usage (New & Full Charged)	Charge time	Usage (New & Full Charged)
Novin S1600	4 ~ 5 hours	Approximately 2 hours	6 ~ 7 hours	Approximately 4 hours
Basic monitoring configuration: Brightness is automatically set by system, ECG/Resp,SpO2,TEMP measurements in Use, NIBP measurement every 15 minutes				

Physical Specification			
Model	Dimension (Cm)	Weight (approximately)	
		With Lithium Polymer Battery	with Sealed Lead Acid Battery
Novin S1600	26(W) × 21(H) × 18(D)	3.9 Kg	4.8 Kg

ENVIRONMENTAL		
Temperature	Operating:	5 to 40 °C
	Storage & Transport:	-25 to 60 °C
Humidity	Operating:	20-90 % (Noncondensing)
	Storage & Transport:	10-100 % (Noncondensing)
Altitude	-200 to 3000 m	

Chapter 20, Accessories

Information

This chapter lists the recommended accessories used for patient monitor and their part codes.

⚠ **Warning** ⚠

The accessories listed below are specified to be used for bedside monitor. Manufacturer does not take responsibility for any possible hazard to the patient or monitor if other accessories are used.

⚠ **Warning** ⚠

Patient protection against defibrillator effects requires using accessories specified in this chapter.

20.1 ECG Accessories

Part NO Saadat	ECG	Brand/Manufacture
P10003	ECG PATIENT CABLE 3 WIRES	Saadat
P10038	ECG PATIENT CABLE 5 WIRES	Saadat
P10066	ECG PATIENT CABLE 10 WIRES	Saadat
P03122	ECG Lead Wire - Neonate	Saadat

20.2 SpO2 (MASIMO & RAINBOW) Accessories

Part NO Saadat	SpO2	Brand/Manufacture	Manufacture/ Part
P 18045	Adult Reusable Sensor, > 30 Kg, (LNCS DCI)	Masimo	1863
P 18046	SpO2 Disposable Sensor, <1 Kg, (LNCS NeoPt)	Masimo	2330
P 18047	SpO2 Disposable Sensor, <3 Kg or >40 Kg, (LNCS Neo)	Masimo	2329
P 18049	SpO2 Reusable Y- Sensor, > 1 Kg (LNCS)	Masimo	2258
P 18060	SpO2 Extension Cable, (Red LNC-10)	Masimo	2404
P 18055	SpO2 Reuseable Sensor,Finger/Toe, Adulat > 30 Kg, Red DCI-dc12	Masimo	2201
P 18056	SpO2 Extension Cable	Masimo	2056
P 18062	Rainbow R25 Sensor, Adult, Adhesive, >30Kg, (SpO2,SPCo,SPMet)	Masimo	2221
P 18063	Rainbow Resposable R2-25a Sensor, Disposable, Adult, >30Kg, (SpO2,SPHb,SPMet)	Masimo	2753
P 18064	Rainbow Resposable R2-25r Sensor, Reusable, Adult, >30Kg, (SpO2,SPHb,SPMet)	Masimo	2754
P 18066	Rainbow Resposable R2-20r Sensor, Reusable, Pediatric, 10-50KG, (SpO2,SPHb,SPMet)	Masimo	2756
P 18068	Rainbow DC-3 SC 360, Reuseable, Adult, (SpO2,SpMet,SpHb)	Masimo	2241+D40
P 18069	Rainbow DCI, Reuseable, Adult, (SpO2,SpCO,SpMet)	Masimo	2696
P 18070	M-LNCS DCI, Reuseable, Adult, (SpO2)	Masimo	2501
P 18072	Rainbow R1-20L Pulse Co-Oximeter Sensor, Disposable, Pediatric, (SPHb ,SpO2,SPMet)	Masimo	3793
P18075	SpO2 Disposable Sensor, 3-20 Kg, (LNCS Inf)	Masimo	2319
P18067	Ambient Shield Accessory for Rainbow Sensor	Masimo	2815

20.3 TEMP Accessories

PART NO Saadat	TEMP	Brand/Manufacture	Manufacture/Part
P10083	TEMP Probe, Skin, LAUNCH	Shenzhen Launch Electrical Co. (LNHmed)	98ME04GA634
P10084	TEMP Probe, Rectal, LAUNCH	Shenzhen Launch Electrical Co. (LNHmed)	98ME04GA635

20.4 NIBP Accessories

PART NO Saadat	NIBP	Brand/Manufacture	Manufacture/Part
P13052	NIBP Child Cuff, Ultra Check (US1320)		
P13077	NIBP Cuff Reusable – Neonate – Single M5301 Bladderless, Tube Length 20Cm	MaiCuff	M5301
P13078	NIBP Cuff Reusable – Infant – Single M5302 Bladderless, Tube Length 20Cm	MaiCuff	M5302
P13079	NIBP Cuff Reusable – Pediatric – Single M5303 Bladderless, Tube Length 20Cm	MaiCuff	M5303
P 13080	NIBP Cuff Reusable – Adult – Single M5304 Bladderless, Tube Length 20Cm	MaiCuff	M5304
P 13081	NIBP Cuff Reusable – Large Adult – Single M5305 Bladderless, Tube Length 20Cm	MaiCuff	M5305
P 13082	NIBP Cuff Reusable – Thigh – Single M5306 Bladderless, Tube Length 20Cm	MaiCuff	M5306
P 13085	NIBP Disposable Cuff, Neonate, 3-5.5cm, PRS (M5541-1#	MaiCuff	M5541-1
P 13086	NIBP Disposable Cuff, Neonate, 4-8cm, PRS (M5541-2#)	MaiCuff	M5541-2
P13087	NIBP Disposable Cuff, Neonate, 6-11cm, PRS (M5541-3#)	MaiCuff	M5541-3
P13088	NIBP Disposable Cuff, Neonate, 7-13cm, PRS (M5541-4#)	MaiCuff	M5541-4
P M13097	PU Legthing Tube (Black)		

20.5 IBP Accessories

Part NO Saadat	IBP	Brand/Manufacture	Manufacture/Part
P16001	IBP Transducer, MEDEX - .MX860/866 Novatrans	MEDEX	MX860P1
P16031	IBP Disposable Dome – MEDEX - MX860/866 Novatrans Dome	MEDEX	MX860/866(848)
P16032	IBP Extension Cable – MEDEX - MX860/866 Novatrans Extension	MEDEX	MX860/866(MX900-42)
P16002	IBP Transducer, MEDEX	MEDEX	MX960
P16033	IBP Transducer, Dome, MEDEX	MEDEX	MX960XXP1
P16034	IBP Extension Cable – MEDEX - MX960 Logical Extension	MEDEX	MX961Z04P1
P16037	IBP Transducer Cable – TRUWAVE	MEDEX	PX1800/896019021
P16036	IBP Transducer , Disposable – RX only	MEDEX	PX260
P16030	IBP Holder		
P16050	IBP Extension Cable, for MX960	Saadat	BKT-164ET
P16046	IBP Transducer kit, Disposable	iPeX brand/ BL Lifesciences Pvt.	BKT-164ET
P16053	IBP Cable, Ipex,		BKT-164ET

Part NO Saadat	ICP	Brand/Manufacture	Manufacture/Part
P23007	ICP-TEMP-Cable	RAUMEDIC	094328
P23008	NPS2 SpaceLabs for ICP	RAUMEDIC	091715
P23009	NEUROVENT-P-TEMP for ICP	RAUMEDIC	094268

20.6 GAS Accessorie

Part NO Saadat	GAS(Mainstream)	Brand/Manufacture	Manufacture/Part
P20066	Airway Adapter, Disposable , IRMA	Masimo	106220

20.7 GAS Accessories (Sidestream)

Part NO Saadat	GAS(Sidestream)	Brand/Manufacture	Manufacture/Part
P20046	ISA CO2 Sidestream Analyzer	Masimo	800101
P20045	Nomoline with luer lock connector. 2 m. Box of 25	Masimo Sweden AB (Phasein)	108210
P20077	VersaStream, CO2/Gas Airway Adapter Sampling Line, Adult / Pediatric	Viamed	4420827
P 20078	VersaStream, CO2/Gas Airway Adapter Sampling Line, Infant	Viamed	4420828
P20079	VersaStream, CO2/Gas Sampling Line with Luer Lock Male (it uses with Sidestream Airway Adapter-Adault/Pediatric, part number:4420531)	Viamed	4420829

20.8 BFA Accessories

Part NO Saadat	BFA
P 22028	BFA Accessory Patient Cable, SAADAT

20.9 C.O. Accessories

Part NO Saadat	C.O	Brand/Manufacture	Manufacture/Part
P19069	SAADAT CO Cable	SAADAT	
P20061	Intro-Flex, Percutaneous sheath Introducer	EDWARDS Lifesciences	I301BF85H
P20062	Swan-Ganz CCO/VIP, Thermodilution Catheter	EDWARDS Lifesciences	139HF75P

20.10 Power Cable

Power Cable			
Part Name	**Part NO Saadat**	**Brand/Manufacture**	**Manufacture/Part**
AC Power Cable	P03018	Sheng	6266694
OR			
AC Power Cable	P09270	volex	2111H 10 C3

NOTE:

The following accessories are recommended, otherwise accessories with CE marking or Biocompatibility test report shall be used.

20.11 ECG Electrodes

Part NO Saadat	ECG	Manufacture/Part
P28042	Adults ECG Disposable Electrodes, FIAB Manufacturer	F9060
P28047	Pediatric ECG Disposable Electrodes, FIAB Manufacturer	F9060P
P10079	Arbo H124SG, COVIDIEN Manufacturer	31.1245.21

20.12 EEG Electrodes

Part NO Saadat	EEG	Manufacture/Part
P22009	Neuroline 720, AMBU Manufacturer	REF: Neuroline720

Chapter 21, Care and Cleaning

21.1 System Check

Before using the monitor,

■ Check if there is any mechanical damage in the system and accessories.

■ Check if all the power cable and accessories are firmly connected.

■ Check all the functions of keyboard and modules to make sure that the monitor is in proper condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or local After Sale Service.

The overall check of the monitor, including the safety check, should be performed only by qualified personnel.

All checks which need the monitor to be opened and safety and maintenance checks should be performed by After Sales Service.

Note:

It is recommended that the system is calibrated by manufacturer every year, but it has to be calibrated once every 2 years. In addition, the system lifetime is 10 years. The medical canter can request the system calibration whenever the system accuracy is in doubt.

⚠ **Warning** ⚠

If user does not follow a satisfactory maintenance schedule, the monitor may become invalid, and human health may be endangered.

Note:

To ensure maximum battery life, it is recommended that, at least once a month, the monitor runs on battery until it turns itself off and then recharged.

21.2 Cleaning and Disinfection

- **General Points**

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment.
Manufacturer makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. See also any local policies that apply within your hospital.

⚠ **Warning** ⚠

1) Before cleaning the monitor or the sensors, make sure that the equipment is switched off and disconnected from the power line.

2) Sterilization may cause damage to the device and is therefore not recommended for this patient monitor otherwise indicated in the instructions delivered with accessories or your hospital's servicing schedule.

3) If you see any signs of damage or deterioration in the device and its accessories, do not use it, and if necessary, contact the after-sales service company.

4) Allow the monitoring system to dry completely before making connections. And please make sure all connectors tightly connected to the system before using the system.

Please pay special attention to the following items:

1.The Patient Monitor and its belongings shall be kept dust-free.

2. Do not use strong solvents such as acetone or ammonia.

3. Most cleaning agents must be diluted before use.

4. Don't use rough or sharp material or your fingernail to remove stubborn stains.

5. Do not let the cleaning agent enter into the chassis of the system.

6. Do not leave the cleaning agents on any part of the equipment.

⚠ **Warning** ⚠

Do not use ETO gas to disinfect the monitor.

- ## External surfaces

  In-between patients and as required:

  For cleaning: wipe gently using a moist cloth and warm soapy water or mild detergent and for disinfection use the following recommended agents:

  ■ Alcohol 70%

  ■ Isopropyl alcohol

  ■ N-propanol

Note:

For cleaning and disinfection of BFA module must act as external surfaces of the device.

- ## Display screen

  In-between patients and as required use clean and soft cloth with screen cleaner or mild soapy water and with Isopropyl alcohol may be used for cleaning and disinfection.

Note:

1) Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing.

2) Don't spray a liquid directly on the screen.

- ## Recorder

Accumulation of paper powder or foreign matter between the thermal head and platen roller deteriorates the print quality. Clean the head elements and platen roller surface using alcohol and a cotton swab. Wait until the alcohol dries then close the recorder door.

⚠**Warning**⚠

Do not clean the recorder immediately after recording because thermal head and its surrounding area are hot during and after recording.

- ## Accessories

  To clean, disinfect and sterilize reusable transducers, sensors, cables, leads, and so forth, refer to the instructions delivered with the accessories.

  Also, trolley/ wall stand, accessory holders and extension cables, NIBP Hose, CO2 Mainstream and Sidestream Analyzer (if applicable) should be cleaned and disinfected after each patient or when necessary, using a soft, clean cloth soaked in mild soapy water and, if necessary, Isopropyl alcohol, and then wiped with a soft and dry cloth.

⚠ **Warning** ⚠

1) To avoid damaging of the cable, probe, sensor or connector, do not immerse it in any liquid.

2) Disposable accessories shall not be sterilized or reused.

3) To prevent environmental pollution, the disposal of single-use accessories shall be done in accordance with the policies of the hospital.

The following table summarizes the methods of cleaning, disinfecting and sterilizing different parts of the device:

<table>
<tr><th>Device parts</th><th>Single-use</th><th>Cleaning</th><th>Disinfection</th><th>Sterilization</th></tr>
<tr><td>External surface of device</td><td>-</td><td rowspan="3">In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.</td><td>In-between patients and as required use
■ Alcohol 70%
■ Isopropyl alcohol
■ N-propanol</td><td rowspan="5">To avoid extended damage to the equipment, sterilization is not recommended for this monitor, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies or when stipulated as necessary in the Hospital Maintenance Schedule.</td></tr>
<tr><td>BFA module</td><td>disposable electrodes</td><td rowspan="2">In-between patients and as required use
■ Isopropyl alcohol</td></tr>
<tr><td>* Trolley/ Wall stand,
* Holders of accessory,
* Extension cables
* NIBP Hose,
* CO2 Mainstream and Sidestream Analyzer</td><td>-</td></tr>
<tr><td>Display screen</td><td>-</td><td>In-between patients and as required:
Clean and soft cloth with screen cleaner or mild soapy water</td></tr>
<tr><td>Recorder (printhead)</td><td>-</td><td>as required:
1.Gently wipe around the printhead using cotton swabs dampened with alcohol.

2.After the alcohol has completely been dried, reload the paper and close the recorder door.</td><td>use as required
■ Isopropyl alcohol</td></tr>
<tr><td>ECG Accessory</td><td>disposable electrodes</td><td colspan="3" rowspan="7">According to the instructions delivered with the reusable accessories
To clean, disinfect and sterilize reusable transducers, sensors, cables, leads, and so forth, refer to the instructions delivered with the accessory.</td></tr>
<tr><td>SpO2 Accessory</td><td>disposable sensor</td></tr>
<tr><td>NIBP Cuff</td><td>-</td></tr>
<tr><td>TEMP Accessory</td><td>-</td></tr>
<tr><td>IBP Accessory</td><td>disposable transducers and Domes</td></tr>
<tr><td>GAS Accessory
(Main-stream/Side-stream)</td><td>disposable Airway Adapter, Nemoline family sampling lines</td></tr>
<tr><td>CO Accessory</td><td>-</td></tr>
</table>

21.3 Preventive Maintenance (PM)

To ensure that the device is kept in the best condition, it shall be kept clean and all points related to the maintenance of the system shall be observed. There are no repairable parts in the system and all repairs shall be done by the manufacturer.

Storage

The storage environment shall be clean and dry. If possible, use the original packaging of the device.

Note:

If the monitor or equipment falls from a height and is damaged or in the vicinity of a very high temperature and high humidity, contact the company's after-sales service at the earliest opportunity to ensure the correct operation.

Note:

Thoroughly clean the system before and after the system is not used for a while.

Weekly check of the following items is recommended:	Monthly check of the following items is recommended:
1. Device cleanness 2. Visual inspection of device (case, screen, keys and indicators) 3. Visual inspection of accessories 4. Function of accessories 5. Disposable accessories and accessories with limited time of use.	1. Calibration label (Sending the device to the manufacturer for calibration at the specified date). 2. Visual inspection of device 3. Device cleanness 4. Function of keys and indicators 5. Visual inspection of accessories

The preventive maintenance (PM) checklist #PL-F-24 should be completed by responsible individuals of healthcare center. It should be noted that PM checklist only is used to perform systematic inspection of the equipment and will not guarantee their correct function.

Preventive Maintenance (PM) Checklist

SAADAT Co.					
Form No. : PL-F-24		PM Form (BEDSIDE)			
State:	City:	Medical center:	Ward:		
Device model:	Serial number:	Installation date:	Inspection date:		
No.	Test and Inspection Item		OK	NOK	N/A
1	Visual inspection	No damage or breakage in the back case and panel			
		Cleaning and disinfection according to the user manual			
2	Rotary	Correct function			
3	Keyboard	Correct function			
4	Touch	Correct function			
5	Display screen	Correct display of Waveform area, Parameter area and Message area			
6	Battery	Unplugging the system (check the battery function)			
		Check the fuse			
		Periodic usage of the battery			
7	Alarm	Alarm activation			
		Clarity of alarm sound			
		Correct function of alarm LEDs			
8	Setup	Saving date& time settings			
9	ECG	Check ECG cable (clamps, leadwire, trunk)			
		Check ECG window (Pacemaker, beat sound, etc)			
		Cleaning and disinfection according to the user manual			

SAADAT Co.

Form No. : PL-F-24 **PM Form (BEDSIDE)**

State: **City:** **Medical center:** **Ward:**

Device model: **Serial number:** **Installation date:** **Inspection date:**

No.	Test and Inspection Item		OK	NOK	N/A
10	RESP	Check parameters of RESP window			
11	TEMP	Check TEMP probe			
		Cleaning and disinfection according to the user manual			
12	SpO2	Check SpO2 probe (extension, if any)			
		SpO2 window settings (Measurement mode and sensitivity)			
		Cleaning and disinfection according to the user manual			
13	NIBP	Check NIBP cuff and hose			
		Check accuracy of NIBP measurement			
		NIBP window settings (Adult, Pediatric and Neonate modes, measurement unit, Automatic mode)			
		Cleaning and disinfection according to the user manual			
14	IBP	Flushing the tubing system and perform zeroing			
		Check transducer and accessories			
		IBP window settings (Measurement unit, filter, Auto Scale and etc)			
		Cleaning and disinfection according to the user manual			
15	CAPNO	Check CAPNO probe and ISA Sampling line			
		Check CAPNO probe and IRMA Adaptor			
		CAPNO window settings (Measurement unit, COMPENSATE and etc)			
		Cleaning and disinfection according to the user manual			

SAADAT Co.

Form No. : PL-F-24 **PM Form (BEDSIDE)**

State: **City:** **Medical center:** **Ward:**

Device model: **Serial number:** **Installation date:** **Inspection date:**

No.	Test and Inspection Item		OK	NOK	N/A
16	BFA	Check Neuro sensors and BFA device			
		Check expiry date of Neuro sensors			
		Check Link status with the bedside (green LED)			
		Cleaning and disinfection according to the user manual			
17	Recorder	Appropriate size of the recorder paper			
		Close door of the recorder during recording			
		Recorder window settings			
18	Connection to the Central System	Check secure connection of the cable to both bedside and central system			
		Check Network indicator on the bedside and waveforms and parameters on the central system			
		Check connection between the bedside and the central system			

Final decision: **Pass** **Fail**

Recommendation:

Name and signature of responsible individual: **Name and signature of expert:**

Chapter 22, Troubleshooting

Repairing the internal parts of the monitor must be only done by trained and authorized personnel of After Sale Service; otherwise manufacturer will not take any responsibility for any possible hazard to the patient and the monitor.

Troubleshooting guide is intended to help users to solve minor problems caused by incorrect use of the monitor or failure of accessories.

When you face any problem, please be sure that you have followed all procedure mentioned in Correct Action column before you contact with After Sale Service.

Fault Symptoms	Possible Cause	Correct Action
The monitor does not turn on		●Check POWER AC path ●Call for service
The monitor is unable to run on battery	●Battery is discharged ●Fuse of the battery is faulty ●etc.	●Charge the battery according to the specified charge time in the Technical Specification Chapter. ●Check fuse existence ●Call for service
NO ECG waveform	●ECG cable is not connected correctly ●Bad placement of leads and electrodes ●etc.	●Connect ECG cable correctly ●Check leads and electrodes. ● Short-circuit all the leads, if the cable is perfect, no error message will be displayed. ●Don't use old and faulty electrodes ●Call for service
Noisy ECG waveform	●Loose connection of electrodes ●Earth connection failure ●Wrong ECG filter ●etc.	●Check electrodes and leads ● Check applied gel on the chest lead or change the chest lead, if necessary. ●Check earth ●Set filter mode correctly ●Call for service
Spike on ECG waveform	●If "PACE ON"for patient without Pace marker , ECG noise will be received as PACE. ●etc.	●Turn "Paced detection" OFF in ECG menu
Unstable HR	●ECG signal is noisy or isn't suitable ●etc.	●Check leads and electrodes. ●Change lead to display the best ECG signal ●Call for service
No "RESP" signal No good waveform Unstable RR	●Electrodes are not connected correctly ●Patient moves during measurement ●etc.	●Check leads and electrodes. ●change RESP lead ●Calm patient ●Call for service
Invalid T1/T2 value	●Location of sensor isn't suitable ●Faulty sensor ●etc.	●Put the sensor in suitable place ●Change sensor ●Call for service
No SpO2 waveform Noisy SpO2 waveform	● The SpO2 probe in an unsuitable place. ●Faulty sensor ●etc.	●Change the place of probe on patient ● Change the probe and check the waveform. Contact the manufacturer to replace the probe with a new one, if necessary. ●Call for service

Fault Symptoms	Possible Cause	Correct Action
Invalid SpO2 value	●Patient movement during measurement ●Probe is placed in an unsuitable position. ●etc	●Calm patient ●Change the place of probe ●Call for service
NIBP cuff could not inflate	●Incorrect air hose connection. ●Air hose occluded or tangled. ●Air hose or cuff leakage ●etc	●Check connection ●Check Air hose ●Change faulty accessory ●Call for service
NIBP measurement is not successful Invalid NIBP value	●No cuff or Air hose is connected ●Wrong cuff placement ●Patient movement during measurement ●Low battery charge ●etc	●Check cuff and air hose ●Change cuff position ●Calm patient ●Connect the system to the mains power. ●Call for service
Invalid IBP value Noisy IBP signal	●No zeroing before use ●Noisy source exists nearby the system or accessories ●Faulty sensor ●etc	●Perform zeroing ●Keep system and cable away from noise source ●Change the sensor ●Call for service
After the catheter is inserted into the patient body, the message “ready for measurement” does not appear and the message “Noisy baseline” remains on the screen.	●The catheter is not placed in proper position. There is other noise source, for example Electrocautery	● Make sure that the catheter is inserted properly. Turn off the device caused noise and then use C.O measuring module.
Inaccurate C.O value	● The manufacturer recommended accessories are not used. ● Catheter type is not selected properly in C.O Setup menu. Injectate solution temperature is not zero (the range of -5 to 5 0 °C)	● Use the manufacturer recommended accessories. ● Select the catheter type correctly in Setup menu. Make sure that the temperature of injectate solution is zero.

Some advices to reduce measurement errors:

- **NIBP**

When NIBP measurement is taken, it is an important factor to set the measurement unit on mmHg and connect the pressure cuff to the patient properly and according to instructions of this manual. The most likely reason that the system doesn’t display NIBP value is cuff failure or leakage, therefore when dealing with this problem, use an intact cuff to test the system and check air hose connection and other connections. If the problem is not removed, contact the manufacturer’s after sale service.

NOTE:

Adjust the system measuring mode (Adult, Pediatric or Neonate) and choose a proper size of cuff with regard to patient weight and age for NIBP measurement.

Please observe the following instructions for pressure measurement:

1- Delete information of discharged patients and prepare the system for monitoring of new patient. You may turn off the system in the meantime and relax new patient in a comfortable position.
2- Deflate the cuff completely by hand.
3- The patient should sit quietly in a comfortable place with good back support to lean and the feet resting on the floor.
4- Relax patient in a comfortable position for 2-3 minutes before measurement.
5- Remain quiet during measurement.
6- Attach the cuff to patient arm and keep the arm in same level with the patient heart.
7- The cuff should be placed on upper arm.
8- Place the cuff tight enough so that you can only slip two fingertips under it.
9- Position of the cuff and artery on the forearm should be adjusted properly.
10- Remove any tight fitting clothing before taking measurement.
11- Apply proper size of cuff for the patient.

- Too small cuff results in too high pressure values.
- Too large cuff results in too low pressure values.

- **IBP**

The most important factors to check in IBP measurement are air bubbles in tubing system and the transducer dome. In the most cases by changing dome, the problem is removed (as mentioned in this manual, disposable dome must not be reused and must be changed for each patient). It should also be checked that proper label with regard to place of measurement is selected. If the problem is not resolved, change the transducer and if even after all above actions the problem still persists, contact manufacturer's after sale service.

- **Multi Gas**

If any problem occurs in CO2 or anesthesia gas measurement, the adapter is the first thing that you should check. If after replacing adapter the problem is not resolved, contact the manufacturer. You can perform zeroing procedure according to instructions of this manual to obtain an accurate reading.

- **BFA**

If any problem occurs in BFA monitoring, the most important item that you should check is proper attachment of neuro sensors. Please clean the skin before attaching the sensor or use a new sensor, if necessary. If the problem is not resolved, contact after sale service.

- **Central**

- When there is any problem in function of different parts of the central system such as touch screen, recorder and etc, turn off and on the system. If the problem is not resolved, contact after sale services.
- If no connection is made with the central system, check proper connection of the cable between the central and bedside monitor. If the problem persists, contact after sale services.
- Delete information of discharged patient in the monitor.
- Apply the recorder paper of 50 mm width and 58 mm for the Sahand central system.

APPENDIX I

LIST OF MONITOR PARAMETERS (SELECTIONS AND DEFAULTS)

Menu item	selection	Default
The parameters in ECG menu		
ECG LEAD	I,II,III,aVR,aVF,aVL,V1,V2,V3,V4,V5,V6	II
CABLE TYPE	3 Wires,5 Wires, 10 Wires	3 Wires
DISPLAY FORMAT	Cascade, 2Traces, 4Traces, 7Traces, 12Traces	Cascade
ECG GAIN	×0.25,×0.5,×1,×2,×4,AUTO	AUTO
ECG SWEEP	12.5,25,50mm/s	25
ECG FILTER	MONITOR,NORMAL,EXTENDED	NORMAL
HR AVERAGE	4,8,16SEC	8SEC
HR SOURCE	ECG,SpO2,IBP1,IBP2,AUTO	AUTO
BEAT VOLUME	1,2,3,4,5,6,7,OFF	1
PACE DETECT	ON,OFF	OFF
ECG CALIB	ON,OFF	OFF
ALARM LEVEL	1,2	1
HR ALARM	ON,OFF	OFF
HR HIGH ALARM	HR LOW ALARM +5 to 250	150Bpm
HR LOW ALARM	30 to HR HIGH ALARM -5	50Bpm
The parameters in RESP menu		
RESP LEAD.	RA-LA,RA-LL	RA-LA
RESP GAIN	×0.25,×0.5,×1,×2,×4	×1
RESP SWEEP	3,6,12.5,25mm/s	6mm/s
ALARM LEVEL	1,2	1
RR ALARM	ON ,OFF	OFF
RR HIGH ALARM	RR LOW ALARM +1 to 150	25Brpm
RR LOW ALARM	5 to RR HIGH ALARM -1	5Brpm
APNEA LIMIT	10 to 40S, OFF	10S
Menu item	**selection**	**Default**
The parameters in SpO2 menu		
AVERAGE TIME	2-4,4-6,8,10,12,14,16	8
SpO2 PLETH SWEEP	12.5,25mm/s	25mm/s
ALARM LEVEL	1,2	1
SpO2 ALARM	ON,OFF	OFF
SpO2 HIGH ALARM	SpO2 LOW ALARM +1 to 100 (with step 1)	100
SpO2 LOW ALARM	1 to SpO2 HIGH ALARM -1 (with step 1)	90
SpO2 SENSITVITY MODE	NORMAL , MAX , APOD	NORMAL
PI HIGH ALARM	PI LOW ALARM +0.1 to 19.0 (with step 0.1)	19.0
PI LOW ALARM	0.0 to PI HIGH ALARM -0.1 (with step 0.1)	0.0
PVI HIGH ALARM	PVI LOW ALARM +1 to 99 (with step 1)	99
PVI LOW ALARM	1 to PVI HIGH ALARM -1 (with step 1)	1
SpOC HIGH ALARM	SpOC LOW ALARM +1 to 34.0 (with step 1)	34.0

SpOC LOW ALARM	1.0 to SpOC HIGH ALARM -1 (with step 1)	1.0
SpCO HIGH ALARM	SpCO LOW ALARM +1 to 99.0 (with step 1)	10.0
SpCO LOW ALARM	1.0 to SpCO HIGH ALARM -1 (with step 1)	1.0
SpMet HIGH ALARM	SpMet LOW ALARM +0.5 to 99.5 (with step 0.5)	3.0
SpMet LOW ALARM	0.5 to SpMet HIGH ALARM -0.5 (with step 0.5)	0.5
SpHb HIGH ALARM	SpHb LOW ALARM +0.1 to 24.5 (with step 0.1)	17.0
SpHb LOW ALARM	0.5 to SpHb HIGH ALARM -0.1 (with step 0.1)	7.0
Menu item	**selection**	**Default**
The parameters in NIBP menu		
NIBP UNIT	mmHg , KPa	mmHg
ALARM LEVEL	1,2	1
NIBP ALARM	ON,OFF	OFF
SYS HIGH ALARM	Adult: SYS LOW ALARM +5 to 255 Neonate: SYS LOW ALARM +5 to 135 Pediatric: SYS LOW ALARM +5 to 240 (with step 5)	Adult: 160mmHg Neonate: 90mmHg Pediatric: 120mmHg
SYS LOW ALARM	Adult: 30 to SYS HIGH ALARM -5 Neonate: 30 to SYS HIGH ALARM -5 Pediatric: 30 to SYS HIGH ALARM -5 (with step 5)	Adult: 90mmHg Neonate: 40mmHg Pediatric: 70mmHg
DIA HIGH ALARM	Adult: DIA LOW ALARM +5 to 220 Neonate: DIA LOW ALARM +5 to 110 Pediatric: DIA LOW ALARM +5 to 220 (with step 5)	Adult: 90mmHg Neonate: 60mmHg Pediatric: 70mmHg
DIA LOW ALARM	Adult: 15 to DIA HIGH ALARM -5 Neonate: 15 to DIA HIGH ALARM -5 Pediatric: 15 to DIA HIGH ALARM -5 (with step 5)	Adult: 50mmHg Neonate: 20mmHg Pediatric: 40mmHg
MAP HIGH ALARM	Adult: MAP LOW ALARM +5 to 235 Neonate: MAP LOW ALARM +5 to 125 Pediatric: MAP LOW ALARM +5 to 230 (with step 5)	Adult: 110mmHg Neonate: 70mmHg Pediatric: 90mmHg
MAP LOW ALARM	Adult: 20 to MAP HIGH ALARM -5 Neonate: 20 to MAP HIGH ALARM -5 Pediatric: 20 to MAP HIGH ALARM -5 (with step 5)	Adult: 60mmHg Neonate: 25mmHg Pediatric: 50mmHg
AUTO/MANUAL	1min, 2min, 3min,5min,10min,15min,20min, 30min,45min, 60min, 90min, 2hr,4hr, 8hr, 12hr, 16hr, 20hr, 24hr,MANUAL, STAT	MANUAL
Menu item	selection	Default
The parameters in TEMP menu		
TEMP UNIT	ºC,ºF	ºC
ALARM LEVEL	1,2	1
TEMP ALARM	ON ,OFF	OFF
T1 HIGH ALARM	T1 LOW ALARM +1 to 50	39
T1 LOW ALARM	0 to T1 HIGH ALARM -1	35
T2 HIGH ALARM	T2 LOW ALARM +1 to 50	40
T2 LOW ALARM	0 to T2 HIGH ALARM -1	36

DT HIGH ALARM	DT LOW ALARM +1 to 50	5
DT LOW ALARM	0 to DT HIGH ALARM -1	1.0
Menu item	selection	Default
The parameters in IBP menu		
IBP UNIT	mmHg , KPa,cmH2O	mmHg
IBP LABEL	IBP, ART, PAP, CVP, LAP, RAP, LVP, RVP,ICP	IBP
IBP SWEEP	3,6,12.5,25 mm/s	12.5 mm/s
IBP GRID	ON, OFF	OFF
IBP FILTER	8, 16, 22 Hz	16 Hz
ALWAYS AUTO SCALE	ON,OFF	OFF
IBP ALARM	ON,OFF	OFF
ART CATH. DISCONNECT ALM	ON , OFF	OFF
ALARM LEVEL	1,2	1
IBP HIGH ALARM	IBP LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
IBP LOW ALARM	-50to IBP HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
ART HIGH ALARM	ART LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
ART LOW ALARM	-50to ART HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
LVP HIGH ALARM	LVP LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 20 mmHg MEAN: 80 mmHg
LVP LOW ALARM	-50 to LVP HIGH ALARM -5	SYS: 80 mmHg DIA: -5 mmHg MEAN: 20 mmHg
PAP HIGH ALARM	PAP LOW ALARM +1 to 120	SYS: 40 mmHg DIA: 20 mmHg MEAN: 30 mmHg
PAP LOW ALARM	-50 to PAP HIGH ALARM -1	SYS: 5 mmHg DIA: -5 mmHg MEAN: 0 mmHg
RVP HIGH ALARM	RVP LOW ALARM +1 to 100	SYS: 40 mmHg DIA: 15 mmHg MEAN: 30 mmHg
RVP LOW ALARM	-50 to RVP HIGH ALARM -1	SYS: 5mmHg DIA: -5 mmHg MEAN: 0 mmHg
CVP HIGH ALARM	CVP LOW ALARM +1 to 100	15 mmHg

CVP LOW ALARM		-50 to CVP HIGH ALARM -1	-5 mmHg
LAP HIGH ALARM		LAP LOW ALARM +1 to 100	20 mmHg
LAP LOW ALARM		-50 to LAP HIGH ALARM -1	-5 mmHg
RAP HIGH ALARM		RAP LOW ALARM +1 to 100	15 mmHg
RAP LOW ALARM		-50 to RAP HIGH ALARM -1	-5 mmHg
Menu item		**selection**	**Default**
ICP HIGH ALARM		ICP LOW ALARM +1 to 100	Adult: 10mmHg Neonate: 4mmHg Pediatric: 4mmHg
ICP LOW ALARM		-40 to ICP HIGH ALARM -1	0 mmHg
IBP SCALE			
IBP	**HIGH**	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	-20
	SIGN	(HIGH+LOW)/2	90
ART	**HIGH**	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	40
	SIGN	(HIGH+LOW)/2	120
PAP	**HIGH**	LOW +5 TO 300 (with step 5)	80
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	35
CVP	**HIGH**	LOW +5 TO 300 (with step 5)	30
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	10
LAP	**HIGH**	LOW +5 TO 300 (with step 5)	40
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	15
RAP	**HIGH**	LOW +5 TO 300 (with step 5)	30
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	10
LVP	**HIGH**	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	-20
	SIGN	(HIGH+LOW)/2	90
RVP	**HIGH**	LOW +5 TO 300 (with step 5)	80
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	35
ICP	**HIGH**	LOW +5 TO 100 (with step 5)	40
	LOW	-40 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	15

Menu item		selection	Default
The parameters in ARR menu			
ARR MONITOR		ON, OFF	OFF
ALARM LEVEL	ASYSTOLE	1	1
	VFIB	1	1
	VTAC	1	1
	RUN	1, 2, OFF	1
	AIVR	1, 2, OFF	2
	COUPLET	1, 2, OFF	2
	BIGEMINY	1, 2, OFF	2
	TRIGEMINY	1, 2, OFF	2
	TACHY	1, 2, OFF	2
	BRADY	1, 2, OFF	2
	AFIB	1, 2, OFF	1
	PAUS	1, 2, OFF	2
	FREQUENT PVCs	1, 2, OFF	OFF
RATE	VTAC	100 to 200 (with step 10)	>=120
	RUN	$VTAC_{rate}$	>=120
	AIVR	$<VTAC_{rate}-1$	>=119
	TACHY	100 to 200 (with step 10)	>=120
	BRADY	30 to 105 (with step 5)	<=50
COUNT	VTAC	5 to 12 (with step 1)	>=5
	RUN	3 to $VTAC_{count}-1$ (with step 1)	>=3
	AIVR	-	>=3
	FREQUENT PVCs	1 to 15 (with step 5)	>=10
ARCHIVE	ASYSTOLE	STR, STR/REC, OFF, REC	STR
	VFIB	STR, STR/REC, OFF, REC	STR
	VTAC	STR, STR/REC, OFF, REC	STR
	RUN	STR, STR/REC, OFF, REC	STR
	AIVR	STR, STR/REC, OFF, REC	STR
	COUPLET	STR, STR/REC, OFF, REC	STR
	BIGEMINY	STR, STR/REC, OFF, REC	STR
	TRIGEMINY	STR, STR/REC, OFF, REC	STR
	TACHY	STR, STR/REC, OFF, REC	OFF
	BRADY	STR, STR/REC, OFF, REC	OFF
	AFIB	STR, STR/REC, OFF, REC	STR
	PAUS	STR, STR/REC, OFF, REC	OFF
	FREQUENT PVCs	-	-

Menu item	Selection	Default
The parameters in ST menu		
ST ANALYSIS	ON, OFF	OFF
ST ALARM	ON, OFF	OFF
ALARM LEVEL	1, 2	1
ST LOW ALARM	-2 to ST HIGH ALARM -0.1	-0.2
ST HIGH ALARM	ST LOW ALARM +0.1 to 2	0.2
EVENT DURATION	15S, 30S, 45S, 60S, OFF	OFF

Menu item	selection		Default	
The Parameters in GAS WINDOW(Mainstream & Sidestream)				
CO2 UNIT	KPa ,%V ,mmHg		mmHg	
SIGNAL SWEEP	3mm/s, 6mm/s, 12.5mm/s, 25mm/s		12.5mm/s	
SIGNAL SCALE	**CO2**	6%,10%,Auto scale	10%	
	O2/N2O	0-50%,0-100%, Auto scale	100%	
	AA	1,2,3,5,10,20%, Auto scale	20%	
WAVEFORM (Mainstream)	CO2, N2O, AA		CO2	
WAVEFORM (Sidestream)	CO2, O2, N2O, AA		CO2	
O2 COMPENSATE	1-100 vol%, OFF		21% , AUTO	
N2O COMPENSATE	0-100 vol% (ONLY FOR ISA CO2, IRMA2 CO2)		0%	
GAS UNIT	KPa ,%V		%V	
AGENT	ISO,ENF,HAL,DES,SEV		HAL AUTO (For IRMA(AX+) & ISA(OR+) & ISA(AX+))	
WORK MODE	MEASURE, STANDBY		MEASURE	
GAS/RESP	GAS, RESP		GAS	
FIIL SIGNAL	ON,OFF		OFF	
CO2 ALARM	ON,OFF		OFF	
N2O ALARM	ON,OFF		OFF	
AA ALARM	ON,OFF		OFF	
O2 ALARM	ON,OFF		OFF	
ALARM LEVEL	1,2		2	
APNEA ALARM	20s,25s,30s,35s,40s,45s,50s, 55s,60s, OFF		20s	
			ADULT/PED	NEONATE
AWRR LOW	1~(HIGH-1)		5 BrPM	15 BrPM
AWRR HIGH	(LOW+1) ~120		30 BrPM	60 BrPM
EtCo2 LOW	0.4~(HIGH-0.1) (%V)		2.6%V	
EtCo2 HIGH	(LOW+0.1)~13(%V)		6.5%V	
FiCo2 HIGH	0.4~ 13(%V)		1.3%V	

EtO2,FiO2 LOW (sidestream)	18~(HIGH-1) (%V)	50%
EtO2,FiO2 HIGH (sidestream)	(LOW+1)~105(%V)	100%
EtN2O ,FiN2O LOW	1~(HIGH-1) (%V)	35%
EtN2O HIGH	(LOW+1)~100(%V)	75%
FiN2O HIGH	(LOW+1)~82(%V)	75%
EtDES ,FiDES LOW	0.1~(HIGH-0.1) (%V)	5%
EtDES ,FiDES HIGH	(LOW+0.1)~18(%V)	10%
EtISO ,FiISO LOW	0.1~(HIGH-0.1) (%V)	0.8%
EtISO ,FiISO HIGH	(LOW+0.1)~5(%V)	2%
EtENF ,FiENF LOW	0.1~(HIGH-0.1) (%V)	0.5%
EtENF ,FiENF HIGH	(LOW+0.1)~5(%V)	1.5%
EtSEV ,FiSEV LOW	0.1~(HIGH-0.1) (%V)	1%
EtSEV ,FiSEV HIGH	(LOW+0.1)~8(%V)	3%
EtHAL ,FiHAL LOW	0.1~(HIGH-0.1) (%V)	0.5%
EtHAL ,FiHAL HIGH	(LOW+0.1)~5(%V)	1.5%
ZERO	Only for Mainstream	

Menu item	selection	Default
The Parameters in BFA WINDOW		
EEG Gain	25uV,50-250uV	100uV
BFA ALARM	ON,OFF	OFF
BFI LOW	1~(HIGH-1)	35%
BFI HIGH	(LOW+1)~100	60%
The Parameters in Cardiac Output WINDOW		
Catheter Type	131HF7,139HF75P,Simulator	131HF7
Temp_Scale	1,2,4	1
SYSTEM DEFUALT		
ALARM VOLUME	1,2,3,4,5,6,7	1
CALENDAR	SOLAR, CHRISTIAN	CHRISTIAN
PATIENT CAT.	ADUL,NEONATE,PEDIATRIC	ADULT
BED NUMBER	1..150	01
TOUCH SOUND	1, 2, 3, OFF	1
BACK LIGHT	1 to 8	18.5” Monitor: 7
	1 to 6	12” Monitor: 5
		10” Monitor: 3
		15” Monitor: 2
BED TO BED	DURATION :1,2,3,4,5	1 Min

Module Color		
ECG COLOR	Green	GREEN
IBP1 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	LIGHT RED
IBP2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	LIGHT BLUE
IBP3 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	DARK ORANGE
IBP4 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	DARK CYAN
SpO2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	MAGENTA
CO2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	YELLOW
RESP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	YELLOW
NIBP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light	WHITE

	Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	
TEMP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	CYAN

APPENDIX II
Messages and Alarms

Technical Alarms

SYSTEM ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
LOW BATTERY	insufficient battery charge	Connect the power cable to the system.	When the battery is running out of power, level III alarm is activated. If user does not apply AC power to the monitor, level II and I alarms are displayed respectively as the charge level decreases.
ECG ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
ECG NO CABLE	ECG cable is not connected to the system	Connect ECG cable	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
ECG CHECK LA,RA,LL	Mentioned leads are not properly connected.	Make sure that mentioned electrode is properly connected	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
ECG DEFECT	ECG module failure	Power off and then on the system .If this message is displayed again the user should contact local After Sale Service.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
ECG CHECK RL OR ALL	RL or other leads are not properly connected when ECG lead is V, aVR, aVF or aVR.	Make sure that all electrodes and patient cable are properly connected	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
ECG CHECK LL OR ALL	LL or other leads are not properly connected when ECG lead is I	Make sure that all electrodes and patient cable are properly connected	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the

			alarm is disabled and ignores this fault.
ECG CHECK LA OR ALL	LA or other leads are not properly connected when ECG lead is II	Make sure that all electrodes and patient cable are properly connected	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
ECG CHECK RA OR ALL	RA or other leads are not properly connected when ECG lead is III	Make sure that all electrodes and patient cable are properly connected	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
ECG CHECK C (C2, C3, C4, C5, C6)	C lead is not properly connected to the patient.	Make sure that all electrodes esp. C and ECG cable are properly connected.	Alarm level 2-the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
RESP ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
RESP CHECK LEADS	The RESP leads are not properly connected.	Make sure that all electrodes, lead are properly connected	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault. The alarm is activated when RR ALARM is "ON".
SPO2 ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
SPO2 NO CABLE	SpO2 cable is not fully inserted to the patient monitor system.	Make sure that the SpO2 cable is correctly connected into the monitor.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

SPO2 REPLACE CABLE	The life of the SpO2 cable has expired.	Replace the SpO2 cable.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 CABLE DEFECT	1. The SpO2 cable is damaged 2. SpO2 cable is not compatible.	1. Make sure that the Masimo SpO2 cable is correctly connected into the monitor. 2. Restore power to the instrument. If this message is displayed again, replace cable.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 NO SENSOR	SpO2 Sensor is not fully inserted into the connector.	Make sure that SpO2 sensor is correctly connected into the patient cable connector.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 REPLACE SENSOR	SpO2 sensor has used all its available monitoring time.	Replace the SpO2 sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 SENSOR DEFECT	1. The SpO2 sensor is damaged 2. SpO2 sensor is not compatible.	1. Make sure that SpO2 sensor is properly attached to the cable connector. 2. Restore power to the instrument. If this message is displayed again, replace sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 SENSOR OFF	1-SpO2 Sensor may be detached from the patient. 2-Sensor not connected to patient properly. 3-Sensor is damaged.	1-Disconnect and reconnect sensor. Reattach sensor. 2-Properly reapply the sensor on the patient and reconnect the sensor to the monitor or patient cable. 3-Replace the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

SPO2 NO AD SENSOR	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	Ensure the adhesive portion is firmly connected to the sensor.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 REPLACE AD SENSOR	When a single-patient-use sensor is used, the life of the adhesive portion of the sensor has expired.	Replace the adhesive portion of the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 AD SENSOR DEFECT	When a single-patient-use sensor is used: 1. The adhesive portion of the sensor is damaged. 2. SpPO2 sensor is not proper.	1. Make sure that SpO2 sensor is properly attached to the cable connector. 2. Power off and then on the system. If this message is displayed again, replace the adhesive portion of the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 AMBIENT LIGHT	This may be caused by excessive ambient light sources such as surgical lights or direct sunlight, or other.	In the case of using rainbow sensor, place a Masimo Optical Light Shield over the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec. The alarm is activated when SpO2 ALARM is "ON".
SPO2 RAINBOW HARDWARE FAIL	SpO2 hardware error	Restore power to the instrument. If this message is displayed again,contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec. The alarm is activated when SPO2 ALARM is "ON".
SPO2 PROBE DEFECT	Failure to properly operate sensor or cable or both of them.	Check the function of the sensor and the cable separately and replace the defective part.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec. The alarm is activated when SPO2 ALARM is "ON".
SPO2 SENSOR CHECK	The sensor connection to the system is not correct	Check the sensor connection and, if	Alarm level 2- the message is displayed in yellow background.

CONNECTION		necessary, replace the sensor and/or cable.	By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec. The alarm is activated when SPO2 ALARM is "ON".
SPO2 LOW SIGNAL IQ	SpO2 measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 LOW PR CONFIDENCE	Pulse rate measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 LOW PI CONFIDENCE	PI measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 LOW PVI CONFIDENCE	PVI measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 LOW SPOC CONFIDENCE	SpOC measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 LOW SPCO CONFIDENCE	SpCO SpO2 measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 LOW SPMET CONFIDENCE	SpMet measurement does not have confidence due to poor signal quality caused by excessive motion or other signal	1-Assess the patient. 2-Check the sensor and ensure proper sensor application.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the

	interference.	3-Change the sensor site.	alarm is disabled and ignores this fault.
SPO2 LOW SPHB CONFIDENCE	SpHb measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
NIBP ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
SELF-TEST FAILED	NIBP hardware module failure		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP LOOSE CUFF	Cuff is completely unwrapped or no cuff attached.		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP MODE ERROR	Adult mode is used instead of neonate mode (while neonate cuff is applied) or an occlusion happens in air way		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP AIR LEAK	Air leak in cuff, tube or connector		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP AIR PRESSURE ERROR	Unstable pressure value (e.g. kinked hoses)		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP SIGNAL WEAK	Very weak patient signal due to a loosely wrapped cuff or extremely weak pulse from patient.		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the

			alarm is disabled and ignores this fault.
NIBP RANGE EXCEEDED	Measuring pressure is more than upper limit (255mmHg)for adult or (135mmHg) for neonate		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP EXCESSIVE MOTION	Arm movement, noisy signal or irregular pulse(e.g. arrhythmia)		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP OVER PRESSURE SENSED	Measured pressure exceeds safe software limit, 290 mmHg for adult, 240 mmHg for pediatric and 145mmHg for neonate. (NIBP SAADAT: measured pressure exceeds safe software limit, 290 mmHg for adult and 150 mmHg for neonate)		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP SIGNAL SATURATED	Large motion artifact that saturates the amplifier's amplitude handling capability.		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP PNEUMATIC LEAK	Leakage during leak test		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP TIME OUT	Measurement time exceeds 3 minutes (2 minutes in CAS module) for adults and pediatrics or 90 seconds for neonates.		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
SYSTEM FAILURE	Error occurs in pump, A/D sampling, pressure transducer or software.		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.

NIBP NO MODULE	No NIBP module is installed.		Alarm level is set in NIBP Window. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP LOW BATTERY	The battery charge is not enough to measure NIBP.		Alarm level is set in NIBP ALARM MENU. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
NIBP MODULE ERROR	Some errors occur during measurement.		Alarm level is set in NIBP ALARM MENU. By pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
IBP ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
IBP1/IBP2 NO SENSOR	Channel 1 or 2 transducer is not connected.	Check the transducer connection.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, the background becomes gray and the alarm is disabled and ignores this fault.
IBP1/IBP2 STATIC PRESSURE	This condition occurs when the maximum and minimum values of a pulsatile pressure signal (Just for IBP, ART, PAP, RVP and LVP labels) differ by less than 3mmHg.In this case, only Mean pressure is displayed in this state. This message can be caused by the following reason: ● A physiological condition e.g. asystole ● Transducer turned off to the patient. ● A catheter tip lodged against a vessel wall. ● A clot on the catheter tip.	●Check patient and do necessary treatment ●Turn on the stopcock to patient and turn it off to the atmospheric pressure. ●Follow hospital procedure for dislodging catheter. ●Follow hospital procedures for clotted catheters.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE,the background becomes gray and the alarm is disabled and ignores this fault.
IBP1/IBP2 CATHETER DISCONNECT	The catheter is disconnected from the patient during the pressure measurement (only IBP and ART labels). In this condition, the pressure	● Check the catheter connection to the patient and take necessary medical actions. ●3-way stopcock is	Alarm level 1- The message is displayed in red background. By pressing ALARM SILENCE, the background becomes gray and the alarm is disabled and

	drops dramatically, IBP signal becomes static and the MEAN pressure falls below 10 mmHg.	disconnected from the patient due to zeroing, washing the tubing or blood sampling	ignores this fault.

GAS (Mainstream) ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
CO2 SYSTEM FAULT # 1,2,3,4	Sensor error	Turn the system off and on and if problem still exists, contact the manufacturer service department.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
CO2 REPLACE ADAPTER	IR signal low	Change the adaptor	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
CO2 NO ADAPTER	There is no adaptor connected to the sensor.	Connect the adaptor	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
CO2 INVALID	CO2 outside specified accuracy range.	Zero the sensor, if the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
N2O INVALID	N2O outside specified accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
AGENT INVALID	Agent outside specified accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
AGENT UNRELIABLE	-The accuracy of the agent identification and measurement could not be guaranteed. -More than 2 anesthetic agents are present in the breathing circuit - High concentration of solvents, cleaning agents or other interfering gases in the breathing circuit		Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
CO2 ACCURACY INVALID, PLEASE ZERO.	Anesthesia agents are out of accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
CO2 INVALID AMBIENT	Ambient pressure outside operating range.	Turn the system off and on. If the problem still exists, contact after sales	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE,

PRESSURE		service of manufacturer.	background becomes gray and the alarm is disabled for 120 sec.
CO2 INVALID AMBIENT TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
CO2 NO SENSOR	The sensor is disconnected from the system.	Connect the sensor. If the problem still exists, contact after sales service of manufacturer.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
CO2 ZERO REFERENCE CALIB REQUIRED	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.	Perform automatic zeroing procedure in an environment with CO2 less than 0.80%V.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.

GAS (SIDESTREAM) ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
CO2 SYSTEM FAULT #1,2,3,4	Sensor error	Turn the system off and on and if problem still exists, contact the manufacturer service department.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
CHECK SAMPLING LINE	IR signal low	Change sampling line	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SAMPLING LINE CLOGGED	Sampling line occlusion	Remove obstruction otherwise change the sampling line by a correct one.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
CO2 INVALID	CO2 outside specified accuracy range.	Zero the sensor, if the problem still exists, turn off and on the system and if again this message appears contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
O2 INVALID	O2 outside specified accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
N2O INVALID	N2O outside specified accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
AGENT INVALID	Agent outside specified accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
AGENT MIXTURE	In ISA OR+ mode, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds.		Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.

AGENT UNRELIABLE	-The accuracy of the agent identification and measurement could not be guaranteed. -More than 2 anesthetic agents are present in the breathing circuit - High concentration of solvents, cleaning agents or other interfering gases in the breathing circuit		Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
CO2 ACCURACY INVALID, PLEASE ZERO.	Anesthesia agents are out of accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
CO2 INVALID AMBIENT PRESSURE	Ambient pressure outside operating range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
CO2 INVALID AMBIENT TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
REPLACE O2 SENSOR	O2 sensor lifetime has expired.	Replace O2 sensor by a new one.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
O2 SENSOR ERROR	sensor failure	Replace O2 sensor with a new one.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
O2 SPAN CALIB REQUIRED	If the sensor operates for a long time without being disconnected from the sampling line or if the operating temperature of the oxygen sensor changes significantly.	Perform room air calibration.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
CO2 ZERO REFERENCE CALIB REQUIRE	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.	Perform automatic zeroing procedure in an environment with CO2 less than 0.80%V.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
CO2 NO SENSOR	The sensor is disconnected from the system.	Connect the sensor. If the problem still exists, contact after sales service of manufacturer.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

BFA ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
BFA ELECTRODE ALARM	Placement of neuro sensors or their connections might be faulty or the impedance of the sensors may exceed 10k Ω. This alarm can also be caused by high frequency instrument.	●Check all neuro sensors and their connections. ●Check the patient cable. If it is not connected or is faulty, please connect it or replace it. ● Check if either of the neuro sensors is disconnected or wrongly connected. ●Replace faulty sensor. ●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin.	Alarm level 3- the message is displayed in cyan background. By Pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
BFA SQI LOW	If the impedance of the white or black sensors exceeds 1kΩ, the SQI will fall gradually. Artefacts can have many causes including high - frequency instruments, EMG, etc.	●Check that all neuro sensors and cables are correctly connected. ●Has the use of any mechanical device that could generate high frequency activity (e.g. patient warmer) been initiated or is any such device in close proximity to the CSM neuro sensors? If possible move disturbing device away from the neuro sensors. ●Check grounding of disturbing device.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
BFA IMPEDANCE HIGH	If sensor impedance is > 5kΩ the BFI, %BS and %EMG will be blanked.	●Check that neuro sensors are not dry. ●Check that the skin has been cleaned properly. ●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
BFA LINK OFF	BFA module is off.	●Connect the module to the monitor through interface cable.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

ST ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
ST OUT OF RANGE HIGHT	The ST algorithm has calculated value +1mV outside the high end of the ST measurement range.	●Check the ISO and ST measuring points. ●Observe the patient and treat if clinically indicated.	The alarm level is set in ST WINDOW.
ST OUT OF RANGE LOW	The ST algorithm has calculated value -1mV outside the low end of the ST measurement range.	●Check the ISO and ST measuring points. ●Observe the patient and treat if clinically indicated.	The alarm level is set in ST WINDOW.
RECORDER ALARMS			
Alarm	**Cause**	**Solution**	**Explanation**
Rec. Software Error	Software error	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Recorder Fault	Hardware error	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Rec Door Open	The recorder door is open	Close the recorder door.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Rec Paper Out	Recorder paper has been finished.	Insert a new paper roll.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Printhead Hight Temp	The thermal head is too hot.	Stop operation for a few minutes.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Printhead Hight Vol	Print head voltage is high.	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

Printhead Low Vol	Print head voltage is low.	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Time out Error	The recorder can not record.	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

MESSAGES

SPO2 MESSAGES			
Message	**Cause**	**Solution**	**Explanation**
SPO2 CABLE NEAR EXP	The SpO2 cable is near expiration.		In this condition SPO2 parameter is displayed.
SPO2 SENSOR NEAR EXP	The SpO2 sensor is near expiration.		In this condition SPO2 parameter is displayed.
SPO2 AD SENSOR NEAR EXP	The SpO2 adhesive sensor is near expiration.		In this condition SPO2 parameter is displayed.
SPO2 SEARCH	Instrument is searching for pulse.	If instrument fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.	In this condition SPO2 parameter is displayed blank.
SPO2 SIGNAL WEAK	The SPO2 signal amplitude is too weak or undetectable.	Change the place of the probe.	In this condition SPO2 parameter is displayed.
SPO2 DEMO MODE RUN	The SpO2 measurement is in demo mode.		
SPO2 ONLY MODE	Measuring rainbow parameters is not possible (due to the ambient light or the dark skin pigmentation).	Use a Masimo light shield to cover the sensor and adjust the sensor.	In this condition SPO2 parameter is displayed.

NIBP MESSAGES			
Message	**Cause**	**Solution**	**Explanation**
NIBP STOP PRESSED	NIBP stop key is pressed during measurement.		
NIBP LEAKAGE O.K	Successful leakage test		

IBP MESSAGES			
Message	**Cause**	**Solution**	**Explanation**
IBP1/IBP2 ADJUST SCALE	IBP1 or IBP2 signal is out of display range for about 5 seconds.	Press <AUTO SCALE> in IBP WINDOW.	
IBP1/IBP2 SEARCH	IBP signal can't be processed by the software because the signal is weak or less pulsatile.	●Check all IBP measurement setup is suitable or not. ●Check patient status and treat him, if necessary	

GAS MESSAGES			
Message	**Cause**	**Solution**	**Explanation**
CO2 SENSOR STANDBY MODE	Manual setting and if no breath is detected for 30 min and ETCO2 is less than 4 mmHg for more than 30 min or when the monitor does not detect adapter of IRMA sensor for 10 min.	Enter GAS window and set WORK MODE on MEASURE.	
CO2 UNABLE TO ZERO, SENSOR WARMING UP (for Mainstream)	Zero button is pressed before waiting for the sensor to be warmed up (30 sec).		
ZEROING IN PROGRESS (for Sidestream)	The zeroing procedure is being conducted.		After that the zeroing procedure is completed, this message and a flat line signal will be displayed.
C.O. MESSAGES			
Message	**Cause**	**Solution**	**Explanation**
No Cable	C.O. cable is not connected to the monitor.	●Check that catheter cable is connected to the monitor firmly.	
Ready for measurement	The system alerts user to start measurement		

Noisy Baseline	The system is not ready for measurement. (If the message does not disappear after a while, possible cause can be improper placement of the catheter. Make sure that the catheter is placed properly in the patient body).	● Make sure that the catheter is placed properly in the patient body.	
Start pressed when not ready please wait	If Start button is pressed before the message "Ready for measurement" appears, the measurement will not be started and this message will appear. To start measurement, wait until "Ready for measurement" is displayed.		
Inject now	Start injection procedure.		
Not injected in the expected time	Injection is not performed long time after Start C.O. is selected.		
Minimum not detected in the expected time	The curve peak has not been detected in the expected time.		
calculating	C.O. is being calculated.		
Curve end not detected!	The curve end has not been detected in the expected time.		
Minimum and End Not Confirmed-Noisy Curve	C.O. calculation is stopped due to noisy curve		
Done! Check edit menu or oldest curve is replaced!	All five C.O. measurement windows are filled. In order to observe average value and deleting/selecting measurements, refer to Edit window, otherwise start a new measurement the oldest measurement data will be replaced by new one.		

PHYSIOLOGICAL ALARMS

ECG ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
HR HIGH	Heart rate violates adjusted high limit	●HR value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
HR LOW	Heart rate violates adjusted low limit	●HR value blinks. ● The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
ECG ASYSTOLE	Heart beat is not detected in last 10 seconds.	●HR is "00" and blinks ● The alarm indicator flashes. ● The message "ECG ASYSTOLE" is displayed in red background.	Activated
RESP ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
RR HIGH	Respiration rate violates adjusted high limit	●RESP value blinks ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
RR LOW	Respiration rate violates adjusted low limit	●RESP value blinks ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
APNEA	Non-respiration condition overruns adjusted time	● The alarm indicator flashes. ●"RESP APNEA" is displayed in red background.	Activated

SPO2 ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
%SPO2 HIGH	SPO2 violates adjusted high limit	●SPO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
% SPO2 LOW	SPO2 violates adjusted low limit	●SPO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PR HIGH	Pulse rate violates adjusted high limit	●PR value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PR LOW	Pulse rate violates adjusted low limit	●PR value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PI HIGH	PI violates adjusted high limit	●PI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PI LOW	PI violates adjusted low limit	●PI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
PVI HIGH	PVI violates adjusted high limit	●PVI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

PVI LOW	PVI violates adjusted low limit	●PVI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
SpOC HIGH	SpOC violates adjusted high limit	● SpOC value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
SpOC LOW	SpOC violates adjusted low limit	● SpOC value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
SpCO HIGH	SpCO violates adjusted high limit	● SpCO value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
SpCO LOW	SpCO violates adjusted low limit	● SpCO value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
SpMet HIGH	SpMet violates adjusted high limit	● SpMet value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
SpMet LOW	SpMet violates adjusted low limit	● SpMet value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
SpHb HIGH	SpHb violates adjusted high limit	● SpHb value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated

SpHb LOW	SpHb violates adjusted low limit	● SpHb value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
NIBP SYS HIGH	SYS violates adjusted high limit	● SYS value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP SYS LOW	SYS violates adjusted low limit	● SYS value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP DIA HIGH	DIA violates adjusted high limit	● DIA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP DIA LOW	DIA violates adjusted low limit	● DIA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP MAP HIGH	MAP violates adjusted high limit	● MAP value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
NIBP MAP LOW	MAP violates adjusted low limit	● MAP value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

TEMP ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
T1 HIGH	The temperature (T1) violates adjusted high limit	● T1 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
T1 LOW	The temperature (T1) violates adjusted low limit	● T1 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
T2 HIGH	The temperature (T2) violates adjusted high limit	● T2 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
T2 LOW	The temperature (T2) violates adjusted low limit	● T2 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
DT HIGH	Difference between two channels temperature (DT) violates adjusted high limit	● DT value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
DT LOW	Difference between two channels temperature (DT) violates adjusted low limit	● DT value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

IBP ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
IBP SYS HIGH	SYS violates adjusted high limit	● SYS value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
IBP SYS LOW	SYS violates adjusted low limit	● SYS value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
IBP DIA HIGH	DIA violates adjusted high limit	● DIA value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
IBP DIA LOW	DIA violates adjusted low limit	● DIA value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
IBP MEAN HIGH	MEAN violates adjusted high limit	● MEAN value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
IBP MEAN LOW	MEAN violates adjusted low limit	● MEAN value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

GAS (sidestream & Mainstream) ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
AWRR HIGH	Respiration rate violates adjusted high limit	●AWRR value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
AWRR LOW	Respiration rate violates adjusted low limit	●AWRR value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 HIGH	End Tidal CO2 violates adjusted high limit	●EtCo2 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 LOW	End Tidal CO2 violates adjusted low limit	●EtCo2 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiCo2 HIGH	FiCo2 violates adjusted high The alarm limits	●FiCo2 value blinks ●The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.	Activated
CO2 RESP APNEA	Non-respiration condition overruns in adjusted time	●The alarm indicator flashes ●"CO2 RESP APNEA" blinks in red background.	Activated
EtN2O HIGH	End Tidal N2O violates adjusted high limit	●EtN2O value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtN2O LOW	End Tidal N2O violates adjusted low limit	●EtN2O value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

FiN2O HIGH	FiN2O violates adjusted high limit	●FiN2O value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O LOW	FiN2O violates adjusted low limit	●FiN2O value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtAA HIGH	End Tidal AA violates adjusted high limit	●EtAA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtAA LOW	End Tidal AA violates adjusted low limit	●EtAA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiAA HIGH	FiAA violates adjusted high limit	●FiAA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiAA LOW	FiAA violates adjusted low limit	●FiAA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

EtO2 HIGH	End Tidal O2 violates adjusted high limit	●EtO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtO2 LOW	End Tidal O2 violates adjusted low limit	●EtO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 HIGH	FiO2 violates adjusted high limit	●FiO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 LOW	FiO2 violates adjusted low limit	●FiO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 Too Low	FiO2 falls below 18%.	●FiO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
BFA ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
BFI HIGH	Cerebral state index violates adjusted high limit	● BFI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in yellow background.	Activated
BFI LOW	Cerebral state index violates adjusted low limit	● BFI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in yellow background.	Activated

ST ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
ST HIGH	ST segment value violates adjusted high limit	●ST value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
ST LOW	ST segment value violates adjusted low limit	●ST value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
ARRHYTHMIA ALARMS			
ALARM	**SITUATION**	**VISUAL PROMPTS**	**AUDIO SOUND**
ASYSTOLE ARRHYTHMIA	5 seconds pass without the detection of valid QRS complex.	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
VFIB ARRHYTHMIA	Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics.(Certain ventricular tachycardias have sinusoidal waveforms closely resembling those of ventricular fibrillation. Because of the similarity of these waveforms, the monitor may classify such types of ventricular tachycardia as ventricular fibrillation).	●The alarm indicator flashes. ●The alarm message is displayed in the red background.	Activated (If ARR MONITOR is ON)
VTAC ARRHYTHMIA	Ventricular Tachycardia: N or more PVCs are detected in a time interval T= (60*(N-1))/R, where N is defined as the VTAC count and R is defined as the VTAC rate.	●The alarm indicator flashes. ●The alarm message is displayed in the red background.	Activated (If ARR MONITOR is ON)
RUN ARRHYTHMIA	Ventricular Run: Series of 3 to N-1 consecutive PVCs with a beat to beat rate ≥ the VTAC rate.	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)
AIVR ARRHYTHMIA	Accelerated Idioventricular Rhythm: Series of 3 or more PVCs with a beat rate less than the VTAC rate.	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)

COUPLET ARRHYTHMIA	Ventricular Couplet: Sequence of beats with the pattern: normal, PVC, PVC, normal, PVC, PVC	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)
BIGEMINY ARRHYTHMIA	Ventricular Bigeminy: Sequence of beats with the pattern : normal, PVC, normal, PVC, normal, PVC	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)
TRIGEMINY ARRHYTHMIA	Ventricular Trigeminy: Sequence of beats with the pattern : normal, normal, PVC, normal, normal, PVC	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)
TACHY ARRHYTHMIA	Sinus Tachycardia: HR ≥ TACHY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)
BRADY ARRHYTHMIA	Sinus Bradycardia: HR≤ BRADY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)
AFIB ARRHYTHMIA	Atrial Fibrillation: Formation of QRS complexes in irregular intervals	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)
PAUS ARRHYTHMIA	Actual R-R interval more than 2.1 times of the average R-R interval.	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)
FREQUENT PVCs	More than N (event count set in the ARR SETUP WINDOW) PVC per minute.	●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated (If ARR MONITOR and Alarm Level are switched ON)

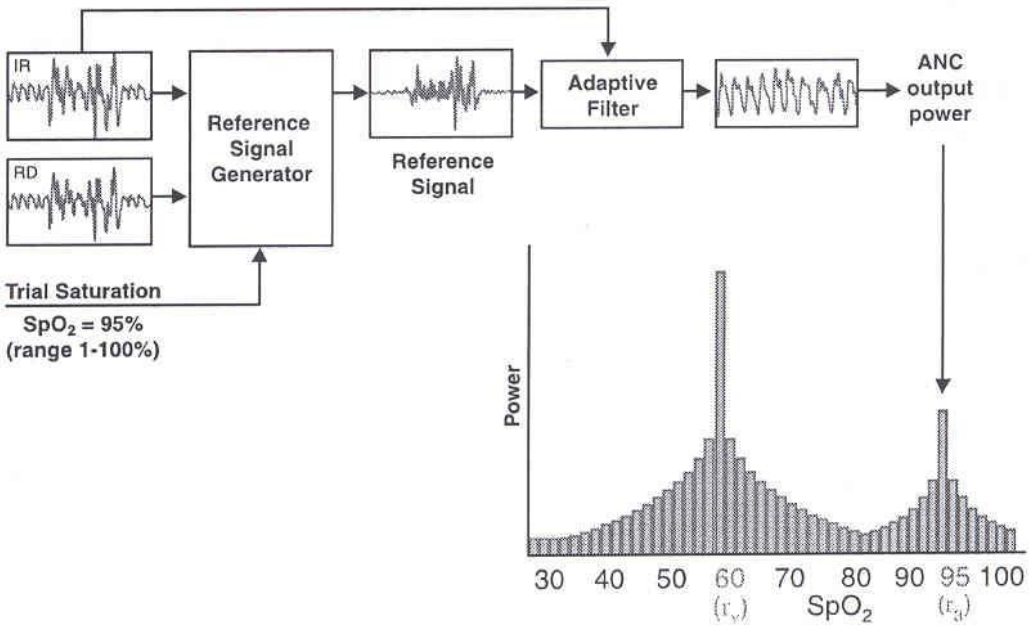
APPENDIX III
MASIMO MODULE

Signal Extraction Technology

INTRODUCTION

Masimo SET® pulse oximetry is a new and fundamentally distinct method of acquiring, processing and reporting arterial oxygen saturation and pulse rate. As illustrated below, Masimo SET technology enables the power of adaptive filters to be applied to real-time physiologic monitoring by utilizing proprietary techniques to accurately establish a “noise reference” in the detected physiologic signal, thus enabling the direct calculation of arterial oxygen saturation and pulse rate. Because it is not bound by a conventional “red over infrared” ratio approach, the Masimo SET system substantially eliminates the problems of motion artifact, low peripheral perfusion and most low signal-to-noise situations. This greatly extends the utility of SpO2 in high motion, low signal and noise intensive environments.

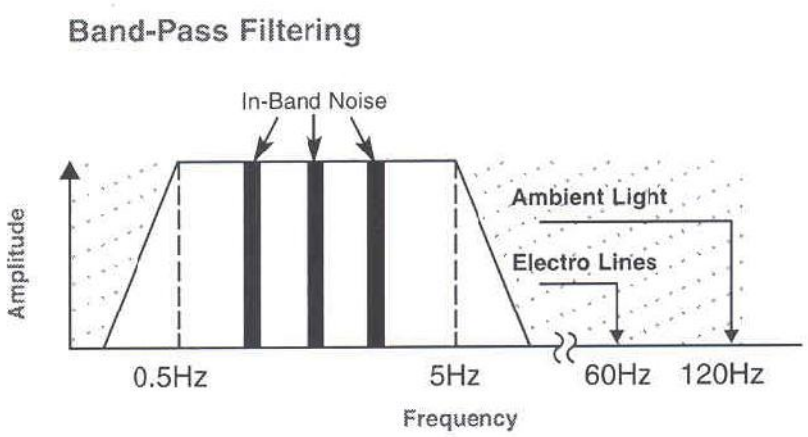
Discrete Saturation Transformation (DST®) Algorithm



Masimo SET's most powerful algorithm is DST. All algorithms depend upon assumptions. The more assumptions, the weaker the algorithm. DST makes only one assumption - that arterial blood has a higher oxygenation than venous – making it the most powerful pulse oximetry algorithm.

CONVENTIONAL FILTERS

While pulse oximetry is readily accepted as a standard of care in the Operating Room, Recovery Room and most Intensive Care Units, its performance in high motion environments or in patients with low perfusion is substantially less than ideal. The reported high incidence of false alarms due to motion artifact and the inability of conventional pulse oximetry systems to provide information during times of crisis have led to its characterization as a “fair weather friend.” Confronted with the problem of motion artifact, false alarms and poor "signal to noise" environments, medical equipment manufacturers have utilized band-pass filtering in an attempt to address these confounding clinical problems. Band-pass filters, whether in analog or digital form, are designed to allow only a physiologic window of interest to pass while rejecting frequencies outside the desired frequency band. With the advent of Digital Signal Processing (Digital Filtering), the performance of band-pass filtering was improved, but was still unable to address the problem of noise occurring within the bandwidth of interest.

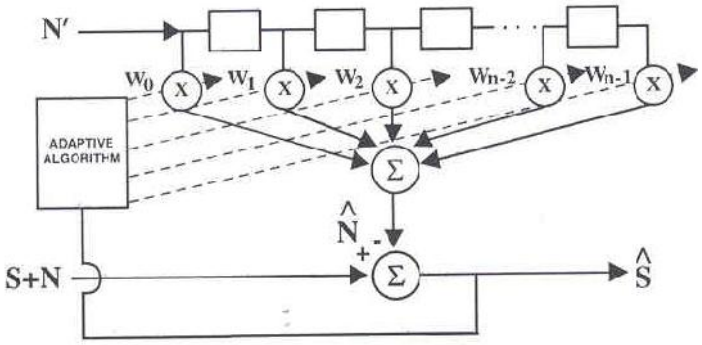


ADAPTIVE FILTERS

To address the confounding issue of "in-band" noise, a class of filters known as adaptive digital filters has evolved. These filters take advantage of the fact that the construction of the filter itself is contained within the memory of the microprocessor, allowing its multiplication coefficients, symbolized as W0, W1,...Wn-1, to be changed in real time, hence altering the filter's characteristic. Thus, the filter can be tuned “on the fly.” The multiplication coefficients determine whether the frequency components of an input signal should be cancelled (e.g., multiplied by zero) or allowed to pass (e.g., multiplied by one). Given that the filter's coefficients can be rapidly changed, adaptive filters derive their name in their ability to change their filtering characteristics in response to changing in-band noise.

The detected physiologic signal is generally composed of both desired signal (S) and undesired signal (N) or noise portions. To remove the effects of the undesired signal, some knowledge of the noise characteristics, or equivalently its noise reference (N'), must be known. The adaptive filter will adjust its filtering characteristics, so that the noise reference input is transformed into an estimate of the undesired signal portion (N^) of the physiologic signal. A subtracter subsequently removes the undesired signal from the physiologic signal to yield an estimate of the

desired signal portion (S^). The combination comprising the adaptive filter and the subtracter is commonly called an adaptive noise canceller (ANC).

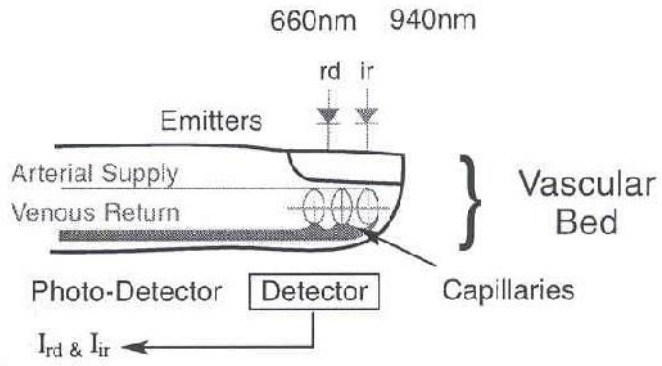


Adaptive Noise Canceller (ANC) block diagram

This approach has been widely used in the telecommunications and aerospace industries where a suitable noise reference is accessible. Probes are utilized to obtain a noise reference that can then be used in conjunction with an adaptive noise canceller to extract a desired signal portion from a composite signal containing both desired and undesired signal portions. The problem in applying this technique to physiological monitoring is that a noise reference is rarely available. In addition, both the noise and the desired signal vary from patient to patient and are quickly and continually changing in terms of frequency, amplitude and phase, even within the same patient. In pulse oximetry, the noise reference signal required to make an adaptive noise canceller work in real time was unavailable until the advent of Masimo Signal Extraction Technology.

CONVENTIONAL PULSE OXIMETRY

The conventional "red over infrared" approach measures the differential optical density of red (o) and infrared (Iir) light as projected through a vascular bed and calculates a ratio (r) of the optical densities. Utilizing the optical density ratio, an arterial oxygen saturation (SpO2) value is empirically reported based on the ratio obtained.



Basis For Measurement:

$$\frac{I_{rd}}{I_{ir}} = \frac{S_{rd} + N_{rd}}{S_{ir} + N_{ir}} = \text{Ratio (r)} \rightarrow \%\ SpO_2$$

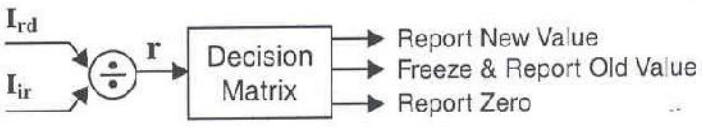
In the presence of patient motion, the optical densities of red and infrared light contain noise portions (Nrd, Nir), thereby falsely altering the optical density ratio and providing an inaccurate saturation value. During periods of routine patient motion or low perfusion, the noise components within the physiologic signals can be much larger than the desired signals (Srd, Sir). In these cases, the optical density ratio is primarily determined by the noise contributions. This represents a situation whereby the noise is simply “drowning out” the desired signal.

In a large noise environment, conventional wisdom holds that pulse oximetry will yield an optical density ratio substantially equivalent to "noise over noise" or a ratio of one. This is equivalent to a saturation value of approximately 82% in most conventional systems.

If: $N >> S$,

Then: $\frac{I_{rd}}{I_{ir}} = \frac{N_{rd}}{N_{ir}} \cong 1 \rightarrow 82\%\ SpO_2$

Confronted with the problems of overwhelming noise and prevented from utilizing adaptive digital filters, pulse oximetry manufacturers have resorted to “managing” false alarms. This can include extending averaging times or employing a decision matrix to freeze when it decides it has detected motion. If the motion persists, it reports zero.



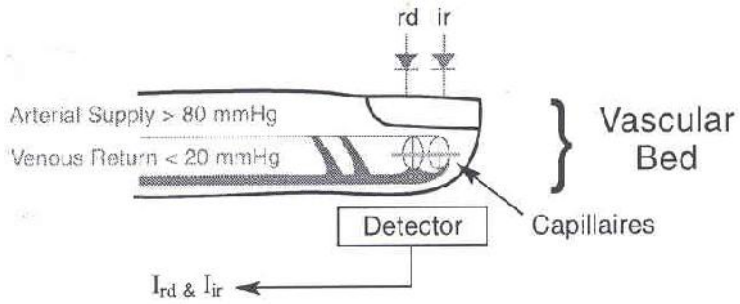
The attempt to treat the "symptom" rather than the “core problem” does not provide clinicians with continuous real-time information and can be unreliable in critical medical situations.

MASIMO SET® PULSE OXIMETRY

Masimo Signal Extraction Technology rejects the conventional wisdom and begins with an understanding that during patient motion the venous blood, being at a relatively low pressure, is quite susceptible to the local effects of perturbation during motion. Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion,

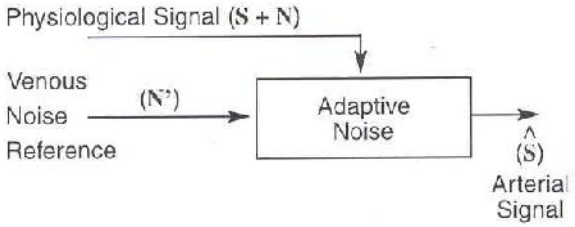
representing a significant source of in-band noise within the frequency bandwidth of interest. In addition, the venous blood is a strong absorber of light. Hence, it can represent a significant contributor to the total optical density during motion episodes. Furthermore, the venous blood saturation is normally lower than the arterial blood saturation. This explains why saturation values tend to drop in conventional pulse oximeter systems during episodes of patient motion.

During routine patient motions (shivering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio based oximetry system. Having identified the venous blood as a significant contributor to noise during motion, it follows that if the noise reference corresponding to the venous component could be measured, then an adaptive noise canceller might be utilized to cancel its contribution.



GENERATING A NOISE REFERENCE

The detected physiologic signals in response to both red (Ird) and infrared (Iir) light consist of desired signal portions (Srd, Sir) as well as undesired signal portions (Nrd, Nir). It is commonly understood in pulse oximetry that the desired signal portions are proportional to one another through the arterial optical density ratio (ra). This suggests that one should simply subtract the product of the arterial optical density ratio and the physiologic signal due to infrared light from the physiologic signal due to red light. The resultant is a reference signal that contains only noise portions. This is the noise reference signal (N')



If the arterial optical density ratio is known, one can easily calculate the noise reference as just described. However, if it were known, one could simply calculate the arterial oxygen saturation directly. One would not need to utilize the adaptive noise cancellation process. How does one

then use the power of adaptive filters and noise reference signals for pulse oximetry? The answer lies in the Discrete Saturation Transform® algorithm.

DISCRETE SATURATION TRANSFORM®

The Discrete Saturation Transform algorithm allows one to separate and, consequently, calculate the optical density ratios that correspond to both the arterial oxygen saturation (ra) and an estimate of the venous oxygen saturation (rv).

These optical densities are not known beforehand but are required to obtain the appropriate reference signals for adaptive noise cancellation. Every optical density ratio, corresponding to the patient's physiological range (SpO2 = 1% to 100%) must be considered. Therefore, the DST® algorithm not only uses a noise reference signal, but a whole family of reference signals. Each reference signal is used in the adaptive noise cancellation process and each yields information regarding the oxygen saturation content of the physiological signals.

If:

① $I_{rd} = S_{rd} + N_{rd}$

② $I_{ir} = S_{ir} + N_{ir}$

③ $r_a = \frac{S_{rd}}{S_{ir}}$

$S_{rd} = r_a \cdot S_{ir}$

Then:

$I_{rd} - [I_{ir} \cdot r_a] = [S_{rd} + N_{rd}] - [S_{ir} r_a + N_{ir} r_a]$

Substituting $S_{ir} r_a$ for S_{rd}, we get:

$= [S_{ir} r_a + N_{rd}] - [S_{ir} r_a + N_{ir} r_a]$

$= N_{rd} - N_{ir} r_a$

$= N'$ (Noise Reference)

A family of reference signals, N'(r), is generated similar to that of a noise reference signal. The reference signal, as discussed earlier, is the difference between the physiologic signal due to red light (Ird) and the product of an arbitrary optical density ratio (r) and the physiologic signal due to infrared light (Ird). Although there is a family of reference signals, based on the selected optical density ratio, there are only three distinct cases to consider. If one selects an optical density ratio that does not correspond to either arterial or venous oxygen saturation (Case I), the reference signal consists of a desired signal portion and an undesired signal portion. In the adaptive noise cancellation process, such a signal will not only remove the undesired signal portions of the physiologic signal, but also remove the desired signal portions. When an optical density ratio that corresponds to the venous oxygen saturation is selected (Case II), the reference signal only contains signal portions. Therefore, the output of the adaptive noise canceller will consist of the undesired signal portions only. Similarly, when an optical density ratio that corresponds to the arterial oxygen saturation is selected (Case III), the reference signal only contains noise portions. Therefore, the output of the adaptive noise canceller will consist of the desired signal portions only.

$I_{rd} = S_{rd} + N_{rd}$, $I_{ir} = S_{ir} + N_{ir}$

$S_{rd} = r_a S_{ir}$, $N_{rd} = r_v N_{ir}$

r: optical density ratio
r_a: arterial optical density ratio
r_v: venous optical density ratio

Reference Signal: $N'(r) = I_{rd} - r\, I_{ir}$

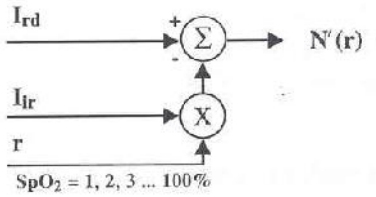
Case I: $r \neq r_a, r_v$ $N'(r) = (r_a - r) S_{ir} + (r_v - r) N_{ir}$

Case II: $r = r_v$ $N'(r_v) = (r_a - r_v) S_{ir}$

Case III: $r = r_a$ $N'(r_a) = (r_v - r_a) N_{ir}$

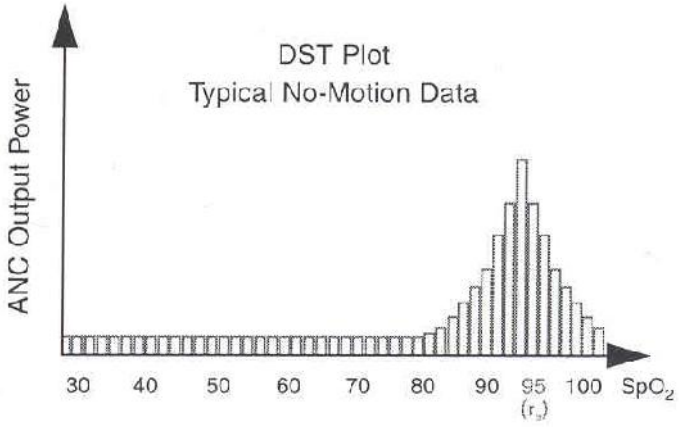
For each selected value of the optical density ratio, the corresponding reference signal is calculated and subsequently processed through an adaptive noise canceller.

$I_{rd} - [I_{ir} * r] = N'(r)$ Or :



When the selected value for the optical density ratio does not correspond to either the arterial or the venous oxygen saturation (Case I), the corresponding output signal will contain little power. When the selected value for the optical density corresponds to either the venous oxygen saturation (Case II) or the arterial oxygen saturation (Case III), the output signal will contain significant output power.

The power output of the adaptive noise canceller represents the probability that the selected optical density ratio, or its corresponding saturation value, is present in the physiologic signal. The output power or probability value is plotted for a series of consecutive ratio values generating the DST transform. During periods of no motion, a singular peak is generated in the DST transform corresponding to the arterial oxygen saturation.



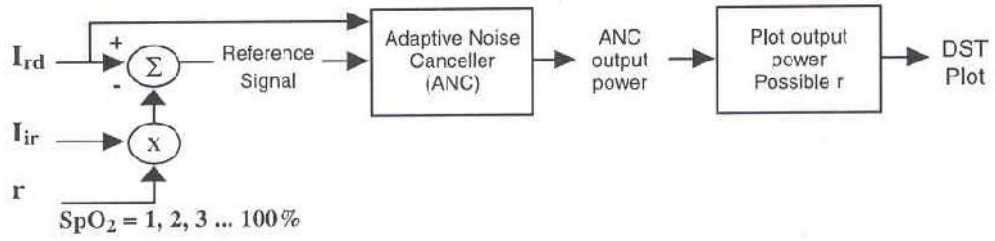
In summary, the procedure for determining the arterial oxygen saturation utilizing Masimo SET processing is as follows:

1) Sweep all optical density ratios that correspond to oxygen saturations of 1% to 100%.

2) Compute the reference signal for each optical density ratio.

3) Measure the output power of the adaptive noise canceller for each reference signal.

4) Identify the appropriate peak in the DST transform that corresponds to the arterial oxygen saturation (largest SpO2 value).



The procedure demonstrates another important feature of Masimo SET pulse oximetry. It is able to calculate the arterial oxygen saturation without first extracting or determining discrete pulses in the physiologic data. For Masimo SET processing, the saturation algorithm is independent of the pulse rate algorithm. This is a significant distinction between Masimo SET systems and conventional pulse oximetry systems where the recognition of a clean pulse is a prerequisite for the calculation of accurate arterial oxygen saturation. Another advantage of Masimo SET technology is that it can monitor arterial oxygen saturation and pulse rate even if the motion starts before the pulse oximeter is turned on. It does not require clean data during instrument start-up.

Results of clinical research and evaluation performed for determining Rainbow measurement accuracy

1. SPO2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SPO2, 0-40% SpCO, and 0-15% SpMet against a laboratory CO-Oximeter. SPO2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SPO2 and 0.9% SpMet.
2. The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SPO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
3. The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SPO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
4. The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation wich encompasses 68% of the population.
5. The Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
6. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8-17 g/dl SpHb against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.
7. The following substances may interfere with pulse CO-Oximetry measurements:

    - Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SPO2 and SpCO measurements.
    - Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SPO2 measurements.
    - Very low arterial Oxygen Saturation (SPO2) levels may cause inaccurate SpCO and SpMet measurements.
    - Severe anemia may cause erroneous SPO2 readings.
    - Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
    - Elevated levels of total bilirubin may lead to inaccurate SPO2, SpMet, SpCO and SpHb readings.

APPENDIX IV
EMC

⚠Warning⚠

Use only the recommended manufacturer accessory .Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.

⚠Warning⚠

Measurements can be affected by mobile and RF communications equipment. It should be assured that the bedside monitor is used in the electromagnetic environment specified.

⚠ Warning ⚠

To prevent EMC effect on the monitor, the system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

⚠ Warning ⚠

Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the monitor performance.

Guidance and manufacturer's declaration – electromagnetic emissions		
The patient care monitors are intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that they are used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The monitors are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The patient care monitors are intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that they are used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The patient care monitors are intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the monitor***)*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitors are used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may necessary, such as reorienting or relocating the Monitor.

[b] Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between
Portable and mobile RF communications equipment and the Monitor.

The patient care monitors are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

APPENDIX V
IRMA Design and theory

This section describes the basic concepts used in MASIMO SWEDEN AB IRMA in terms of design, technical solutions and gas measurement.

1. Basic design features

MASIMO SWEDEN AB IRMA mainstream multi-gas probe consists of an IRMA sensor head, and an airway adapter. As all necessary calibration constants are stored within each IRMA sensor head, the probes can be replaced without the need for recalibration.

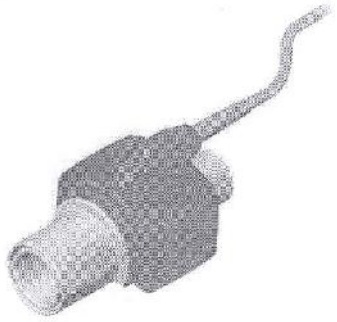


Figure 1. *MASIMO SWEDEN AB probe with airway adapter.*

The IRMA sensor head includes a multi-channel IR bench, a barometric pressure sensor, a signal processor, a power regulator, and a RS-232 digital interface.
The ultra compact multi-channel IR micro bench comprises a high reliability infrared source, an infrared chopper wheel with an integrated brush less DC micro motor, an infrared detector and all necessary components for processing the infrared measurement signal.

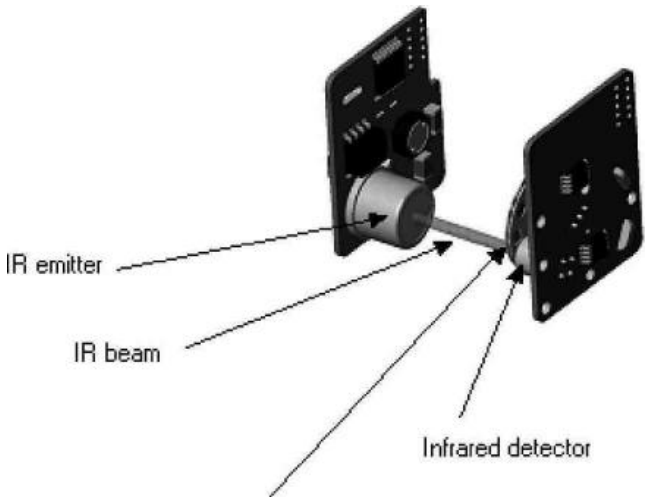


Figure 2. *IRMA multi-channel IR micro bench.*

The airway adapter without an oxygen port, includes the optical components for measuring gases - the XTP™ windows that are transparent to light in the wavelength ranges of interest.

Figure 3. *IRMA airway adapter without an oxygen port.*

2 Gas measurement and identification

The IRMA probe snaps in place on the top of the airway adapter. The IRMA airway adapter is, for example inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained by continuously measuring the infrared light absorption, through the XTP windows in the gas flow through the adapter.
To measure the concentrations and identify the gases, absorption of up to nine different wavelengths of infrared light is measured.

Figure 4. *MASIMO SWEDEN AB IRMA IR light path through the IRMA airway adapter.*

The measurement of CO2, N2O and anesthetic agents in the breathing gas mixture is based on the fact that the different gas components absorb infrared light at specific wavelengths.
A microprocessor continuously calculates the CO2, N2O and anesthetic agent concentrations from the infrared light absorption measurements, using matrix calculations to automatically

identify which anesthetic agents are present in the gas mixture. Mixtures of maximum two anesthetic agents are automatically identified and both agents are measured. If more than two agenets are present simultaneously in a gas mixture, an alarm will be set.

2.1 Infrared measurement technology

The absorption spectra for CO2, N2O and the five anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane are shown in the figure below.

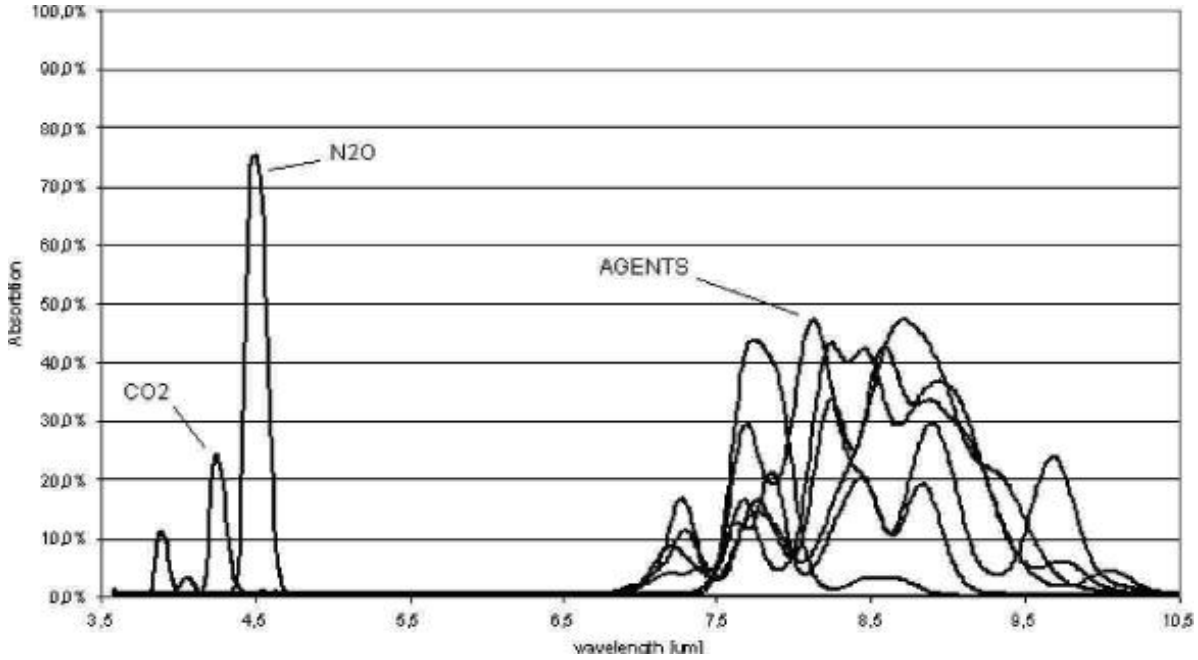


***Figure* 5.** *Absorption spectra*.

MASIMO SWEDEN AB IRMA uses the absorption peaks at 4.2 and 3.9 µm for the measurement of CO2 and N2O respectively, and five different wavelengths in the 8-12 µm range for anesthetic agent measurements. Two additional wavelengths beside the absorption peaks are used as references. To measure the absorption of light at these wavelengths, a broadband infrared radiation source is used. The light transmitted from the infrared source passes through the XTP windows in the airway adapter and is then filtered using a set of narrow optical band pass filters. The individual filters are mounted in a rapidly rotating filter wheel that intersects the light path before the light reaches the infrared detector.

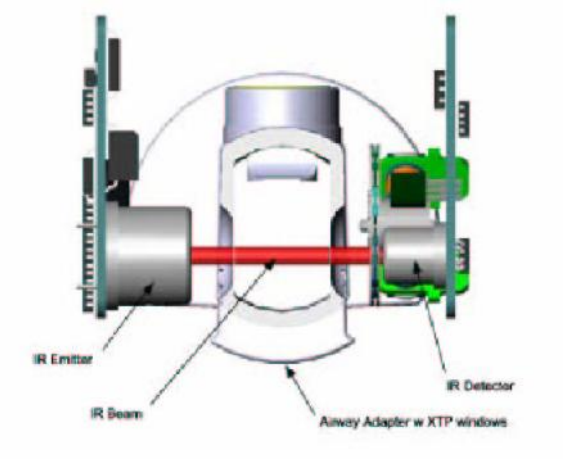


Figure 6. *Optical path*

No radiation will be absorbed if the airway adapter is empty. The output signal from the detector will thus have its maximum amplitude at a concentration of zero, with lower amplitudes at higher concentrations.

3 MASIMO SWEDEN AB XTP™ airway adapter

The IRMA disposable airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained through the XTP windows in the sides of the adapter.
As the airway adapter is positioned directly in the airway, its performance can be affected by water vapor, patient secretions or nebulized medications that can accumulate on the adapter's windows. The use of metered does inhalers can also affect the adapter.The water vapor can condense on the surface of the adapter windows in the format of small discrete water droplets. This condensation can affect the light absorption through the windows thus affecting the precision of the measurement.

The design and material technology of the XTP windows have special features that prevent a decrease in performance when water vapor is present.

The root cause of water droplet formation is the difference in surface tension between the plastic and water. This mismatch means that the water condenses into discrete droplets with a high contact angle. Figure 7 illustrates a water droplet with various contact angles showing the effects of condensed water on light transmission.

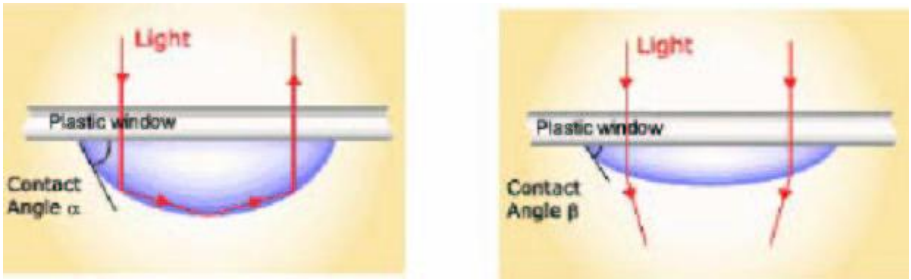


Figure 7. *Effect of condensed water on light transmission.*

The XTP windows are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission. Figure 8 illustrates the light transmission in a XTP window.

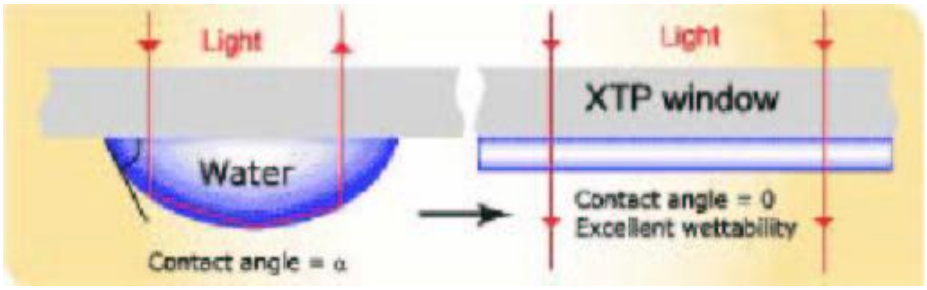


Figure 8. *Light transmission through a XTP window*

For optimal results, the airway adapter shall not be placed between an endotracheal tube and an elbow, as this may allow patient secretions to block the adapter windows. The IRMA airway adapter shall be positioned with its windows in a vertical position to help keep patient secretions from pooling on the windows.

The airway adapter is designed as a disposable for both adult/pediatric and infant applications. The adult/pediatric adapter is available, Fig. 9.

Figure 9. *IRMA airway adapters: Adult/pediatric and infant adapter.*

⚠ **Warning** ⚠

Do not use the IRMA adult/pediatric airway adapter with infants as the adapter add 6 ml dead space to the patient circuit.

The IRMA infant airway adapter has specially designed connectors for minimizing the dead space (see fig. 9) and can be used even for very small patients.

Effect of water vapor

The total pressure of the gas mixture is estimated by measuring the actual barometric pressure in the IRMA sensor .The partial pressure and the volume percentage of CO2 , N2O, and anaesthetic agents depend on the amount of water vapor in the breathing gas.

20.8 vol % O2 corresponds to the actual O2 concentration in room air with 0.7 vol% H2O concentration (at 1013hPa this equals for example at 25°C and 23% RH). The measurement of CO2, N2O and anaesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

The effects of water vapor are illustrated by the examples in the following table.O2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H2O. The two columns to the right show the relative error in displayed concentrations when adding or removing water vapor from the gas mixture, and referencing the measurement to dry gas conditions at actual temperature and pressure (ATPD) or saturated conditions at body temperature (BTPS).

Temp [C]	RH [%]	P [[hPa]	H2O part. pres. [[hPa]	Err(rel) [%]	err(rel) ATPD[%]	err(rel)[%] BTPS
10	20	1013	2	0	-0.2	+6.0
20	20	1013	5	0	-0.5	+5.7
25	0	1013	0(ATPD)	0	0	+6.2
25	23	1013	7.3	0	-0.7	+5.5
25	50	1013	16	0	-1.6	+4.6
30	80	1013	42	0	-4.1	+2.0
37	100	1013	63(BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

The table above illustrates that the gas concentrations in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

If calibration of O2 is not performed with room air humidity equal to 0.7 vol% H2O ,the difference between the O2 concentration delivered by IRMA and the actual partial pressure of O2 will be equal to the concentration of ambient water vapor -0.7%(O2 diff [%] = Conc H2O[%]-0.7%.

For example, if a room air calibration of O2 is performed at a humidity of 1.6 vol% H2O (corresponding to 50% RH at 25°C and 1013 hPa) the standard calibration value of 20.8 vol% O2 will be 1.6%-0.7%=0.9% too large. The correct O2 concentration (actual partial pressure of O2) at theses conditions is (1-0.009)*20.8=20.6 vol%O2.

Multi-gas (Mainstream) Technical specifications

For more details, please refer to specification section, Multi-gas (Mainstream) part.

• **General specifications**	
Dimension (W×D×H)	38×37×34mm (1.49” × 1.45” × 1.34”)
Cable length	2.5 m ±0.1 m
Weight	<25 g (cable excluded)
Operating temperature	IRMA CO2: 0–40°C (32–104°F) IRMA AX+: 10–40°C (50–104°F)
Storage temperature	-40–75°C (-40–167°F)
Operating humidity	< 40 hPa H_2O (non-condensing) (95 %RH at 30 °C)
Storage humidity	5–100% RH (condensing)[1], at a water vapor partial pressure not exceeding 74 hPa (100 %RH at 40 °C)
Operating atmospheric pressure	525–1200 hPa (525 hPa corresponding to an altitude of 5 211 m / 17 100 feet)
Storage atmospheric pressure	500 to 1200 hPa (500 hPa corresponding to an altitude of 5 572 m / 18 280 feet)
Mechanical strength	Withstands repeated 1.8 m drops on a hard surface. Complies with requirements for shock and vibration for professional transportation according to EN ISO 80601-2-55:2011 and requirements for road ambulances according to EN1789:2007 (clause 6.4).
Power supply	IRMA CO2: IRMA AX+: 4.5-5.5 VDC, max 1.0 W 4.5-5.5 VDC, max 1.4 W (power on surge @ 5 V less than 350 mA during 200 ms)
Recovery time after defibrillator test	Unaffected
Drift of measurement accuracy	No drift
Surface temperature (at ambient temp. 23°C)	IRMA CO2: Max 39°C / 102°F IRMA AX+: Max 46°C / 115°F
Interface	Modified RS-232 serial interface operating at 9600 bps.

[1] After being in a condensing atmosphere, the unit shall be stored for more than 24 h in an environment equivalent to the operating humidity.

Airway adapters	Disposable adult/pediatric: - Adds less than 6 ml deadspace. - Pressure drop less than 0.3 cm H_2O @ 30 LPM. Disposable infant: - Adds less than 1 ml deadspace. - Pressure drop less than 1.3 cm H_2O @ 10 LPM. (Infant Airway Adapter recommended for Tracheal Tube ID size = 4 mm)
Compliance	MDD 93/42/EEC EN ISO 80601-2-55:2011 IEC 60601-1:2005 IEC 60601-1-2:2007 EN ISO 5356-1:2004 EN 1789:2007 (IRMA CO2)
Degree of protection against harmful ingress of water or particulate matter	IP44
Method of sterilization	The IRMA system contains no sterile parts.
Mode of operation	CONTINUOUS OPERATION
Degree of protection against electric shock	The IRMA probe is classified as DEFIBRILLATION-PROOF TYPE BF APPLIED PART

APPENDIX VI
ISA Design and Theory

1. Gas measurements

The measurement of CO2, N2O and anesthetic agents is based on the fact that different gases absorb infrared light at specific wavelengths. The analysis of respiratory gases by the ISA gas analyzers are therefore performed by continuously measuring the infrared light absorption in the gas flow through an infrared spectrometer. Oxygen, on the other hand, does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods.

The gas analysis

At the heart of an ISA gas analyzer, the SIGMA spectrometer is seated. The SIGMA spectrometer uses a proprietary broadband infrared radiation source to transmit light through the gas sample. Before reaching the gas sample, the light path is intersected by narrowband optical filters that only let through light corresponding to selected wavelength peaks of the measured gases. At the other end of the light path, a sensor detects the portion of the light that is not absorbed by the gas. The amplitude of the detector output is an inverse function of the gas concentration. Thus, at a concentration of zero, the amplitude is at its maximum.

If the gas sample is a mixture of several components that absorb light at the same wavelength, such as a mixture of two anesthetic agents, the absorbed radiation will be the sum of the absorption of the agents. To determine the concentration of each of the individual gases, several filters have to be used. The ISA gas analyzers therefore uses the SIGMA spectrometer, which contains up to nine different narrowband filters to facilitate simultaneous measurement of CO2, N2O and a mixture of any two of the five anesthetic agents.

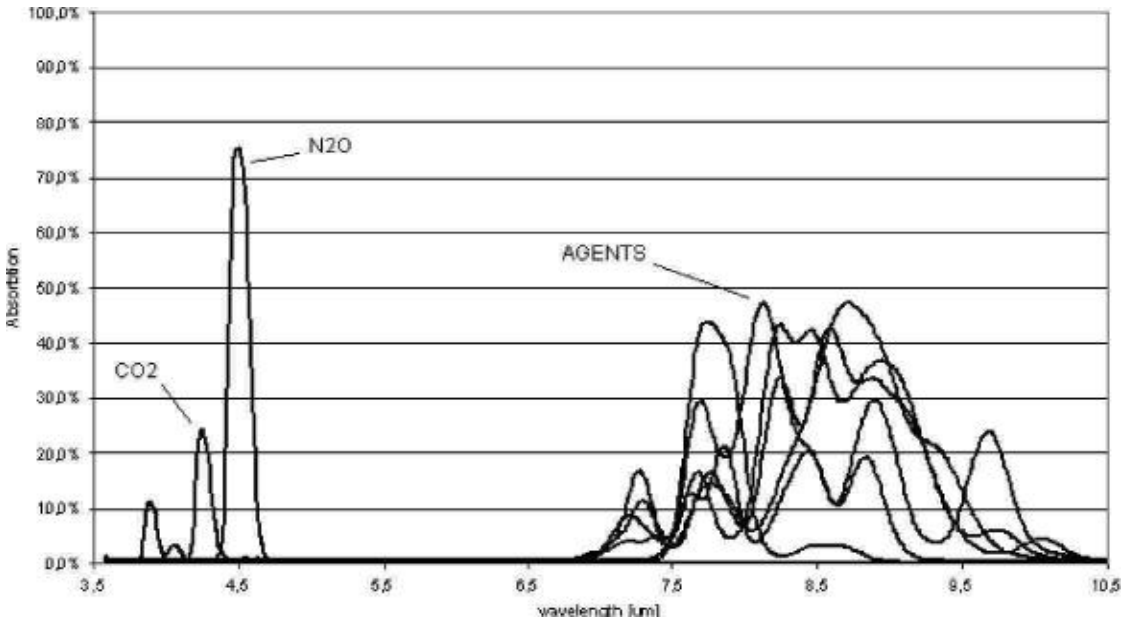


Figure 1. *Gas absorption spectra*

The selection of the optical filters within the spectrometer is crucial to the characteristics and performance of the gas analyzers. The SIGMA spectrometer uses the strong absorption peaks at 4.2 and 4.5 µm for CO2 and N2O measurements and five wavelengths in the 8 to 10 µm long wave infrared range (LWIR) for the anesthetic agent calculations. The LWIR contains strong absorption peaks for the anesthetic agents and negligible interference from other common respiratory gases, such as alcohol and acetone, that could degrade measurement accuracy.

In addition to the measurement filters, two optical filters appropriately located within the 4 to 10 µm range are used as references.

2. Oxygen measurement

Oxygen does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods. The ISA OR+ analyzer is fitted with a paramagnetic oxygen sensor, and the ISA AX+ module is designed be fitted with either a paramagnetic or a galvanic (fuel-cell) oxygen sensor.

Paramagnetic oxygen analysis

Paramagnetic oxygen analyses are based on measurements of the attractive force exerted by a strong magnetic field applied to the oxygen molecules in a gas mixture. The paramagnetic analyzer distinguishes oxygen from other gases as a function of their magnetic susceptibility. Due to its paramagnetic nature, oxygen is attracted into the magnetic field, while most other gases are not. On a scale, where oxygen is assigned the value 100, most other gases have a magnetic susceptibility of close to zero.

The Servomex sensor

An oxygen sensor well suited for the ISA gas analyzer is the PM1116 paramagnetic oxygen sensor from Servomex. In this sensor, a symmetrical non-uniform magnetic field is created. If oxygen is present, it will be attracted into the strongest part of this field. Two nitrogen-filled glass spheres are mounted on a rotating suspension within the magnetic field. Centrally on this suspension, a mirror is mounted. A light beam projected on the mirror is reflected onto a pair of photocells. Oxygen attracted into the magnetic field will push the glass spheres from the strongest part of the magnetic field, causing the suspension to rotate. When this rotation is detected by the photocells, a signal is generated and passed to a feedback system. The feedback system will pass a current around a wire mounted on the suspension, causing a restoring torque that keeps the suspension in its original position. The current flowing around the wire is measured. This current is directly proportional to the oxygen concentration.

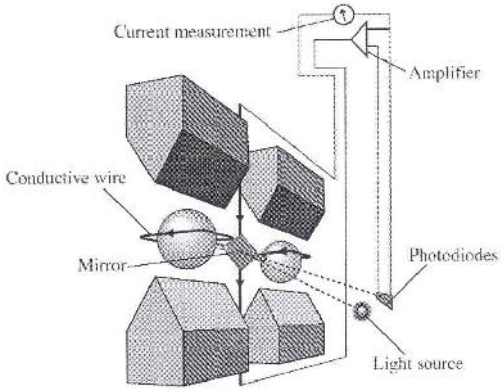


Figure 2. *Oxygem measurement with Servomex PM1116 paramagnetic oxygen sensor.*

The most important benefits of the paramagnetic oxygen sensor are:

•Fast rise time

•High stability and accuracy

•No chemicals to replace or renew

•Low maintenance requirements

Galvanic oxygen analysis

As an alternative to the paramagnetic sensor, the ISA gas analyzer is designed be fitted with a galvanic oxygen sensor. A galvanic fuel-cell oxygen sensor uses a membrane that allows diffusion of O2 into the sensor. Inside the sensor, there is a sensing electrode (cathode) made of a noble metal such as gold or platinum, and a working electrode made of a base metal such as lead or zinc. The electrodes are immersed in an electrolyte. Fuel-cell oxygen sensors are current generators and do not require any external power supply. By connecting a resistor between the anode and the cathode, a voltage proportional to the O2 concentration is generated.

Since the measurement involves a chemical reaction, the fuel cell is gradually consumed during the process (also when the equipment is not in use), and requires replacement at regular intervals.

3. Sampling

A sidestream gas analyzer continuously removes a gas sample flow from the respiratory circuit, for example a nasal cannula, a respiratory mask or the Y-piece of an intubated patient. The gas sample is fed through a sampling line to the gas analyzer. The sampled gas is usually warm and humid, and cools down in contact with the wall of the sampling line. Water therefore condenses in form of droplets on the inner wall of the sampling line. These droplets could potentially occlude the sampling line and interfere with the gas measurement.

The Nomoline

To overcome the shortfalls of current gas sampling solutions, the Nomoline sampling line has been developed for the ISA sidestream gas analyzers.

⚠**Warning**⚠

Do only use sample lines intended for anesthetic agents if N2O and/or anesthetic agents are being used.

Unlike traditional solutions that remove water vapor and collect water in a container, the Nomoline sampling line incorporates a unique water separation section, the NOMO section. This section is made of a special polymer and a hydrophobic bacteria filter that removes water vapor and aspired or condensed water. Water and water vapor passes through the membrane-like surface of the sampling line and evaporates into the surrounding air, while leaving O2, CO2 and anesthetic gases unaffected.

Figure 3. *The Nomoline (no moisture) sampling line.*

To protect the ISA analyzer, the Nomoline includes a filter with the bacterial filter efficiency of ≥ 99.9980 %. It is important to be aware that secretions and nebulized medications may attach to the surface of the bacteria filter, and may cause clogging.

Warning: Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

The Nomoline sampling lines are specially designed for 50 ml/min low sample flow applications. The Nomoline has a very low dead space that results in an ultra-fast rise time, making measurements of CO2, N2O and anesthetic agents possible even at high respiratory rates. ISA sidestream gas analyzers are therefore suitable for adult, pediatric and infant patients.

The Nomoline sampling line is available in 2 and 3 meter versions and comes with a male Luer Lock type connector to work with different kinds of third-party sampling equipment, including patient interfaces for intubated, nasal and oral sampling. Although the selection of optimal patient interfaces is crucial, the Nomoline sampling line fits in any normal configuration.

Flow control

During normal operation, a sidestream gas analyzer is continuously fed with a small sample gas flow. To pull the gas through the sampling line and maintain a steady flow, a high-precision flow control system is required. In ISA sidestream gas analyzers, the flow control system consists of an integrated micro pump, a zero valve and a flow controller. The pump is fitted with a low-power brushless motor having three miniature ball bearings to ensure trouble free operation without regular maintenance. Its balanced shaft design and integrated pneumatic filter virtually eliminate pressure and flow variations.

System response

In any sidestream gas monitoring system, there are three major time parameters involved:
•Total system response time
•Delay time
•Rise time

When designing a sidestream gas monitoring system, the physical characteristics of several components have to be considered. Parameters such as sampling volume, tubing material, tubing diameter and the physical design of the sampling interfaces play decisive roles in determining the responsiveness of the system.

Generally, the total system response time equals the delay time plus the rise time.

The delay time is defined as the time required for a step function change at the sampling site to result in 10% of the final value. Parameters affecting the delay time are the sample flow rate, tubing length and tubing inner diameter. In mainstream gas monitoring, where no tubing exist, the delay time is virtually zero, whereas a sidestream system has a sample delay time of a few seconds.

The rise time is defined as the time required for a step function change at the sampling site to bring about a rise from 10% to 90% of the final gas concentration value.

4. Gas data concentration

Gas measurement units

Gas concentration is reported in units of volume percent. The concentration is defined as:

$$\% \text{ gas} = \frac{\text{Partial pressure of gas component}}{\text{Total pressure of gas mixture}} * 100$$

The total pressure of the gas mixture is measured by a cuvette pressure sensor in the ISA gas analyzer.
For conversion to other units, the actual atmospheric pressure sent from the ISA sidestream analyzer may be used, e.g.
CO2 in mmHg = (CO2 concentration) x (atm. pressure value in kPa from ISA) x (750 / 100).
Example: 5.0 vol% CO2 @ 101.3 kPa Ö 0.05 x 101.3 x 750 / 100 = 38 mmHg

Effects of humidity

The partial pressure and the volume percentage of CO2, N2O, O2 and anesthetic agents depend on the amount of water vapor in the measured gas. The O2 measurement will be calibrated to show 20.8 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure. 20.8 vol% O2 corresponds to the actual O2 concentration in room air with 0.7 vol % H2O concentration (at 1013 hPa this equals for example 25°C and 23% RH). The measurement of CO2, N2O, and anesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS).

When the breathing gas is sampled, and passing the sampling line, the gas temperature will get close to the ambient temperature before reaching the ISA sidestream gas analyzer. As the Nomoline removed all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.
If CO2 values at BTPS are required, the following equation can be used:
EtCO2 (BTPS) = EtCO2 * (1 – (3.8 / Pamb))
where:
EtCO2 = EtCO2 value sent from ISA [vol %] Pamb = Ambient pressure sent from ISA [kPa]
3.8 = Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa]
EtCO2(BTPS) = EtCO2 gas concentration at BTPS [vol%]
O2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H2O.

Spectral broadening
The presence of oxygen and nitrous oxide can cause some interference in the CO2 measurement. This is known as spectral broadening.

Nitrous oxide, N2O:
ISA sidestream analyzers capable of N2O measurements automatically compensates for spectral broadening caused by nitrous oxide.

When using an ISA sidestream gas analyzer without this capability, the current nitrous oxide concentration should be transmitted to the ISA Gas analyzer using the SetN2O command.
For most applications, sufficient accuracy in CO2 measurement will be achieved by setting N2O to one standard concentration used always with N2O in use, as recommendation 50 vol%, SetN2O 50 for actual concentrations in the span 30 – 70 vol% N2O. When N2O is not in use send SetN2O 0. The default value is 0.

By using this range, see table below, the maximum CO2 error with N2O compensation on (30-70%) will be limited to 3.2 % relative.

N2O range	N2O parameter
0-30 vol%	0
30-70 vol%	50

Oxygen, O2:
ISA sidestream analyzers capable of O2 measurements automatically compensates for spectral broadening caused by nitrous oxide.

When using an ISA sidestream gas analyzer without this capability, the current nitrous oxide concentration should be transmitted to the ISA Gas analyzer using the SetO2 command.

For most applications, sufficient accuracy in CO2 measurement will be achieved by dividing the oxygen concentration into three ranges: “high”, “medium” and “low”. By using these ranges, along with the Set O2 values in the table below, the maximal relative CO2 error will be limited to 1.2%.

O2 range	O2 parameter
0-30 vol%	0
30-70 vol%	50
70-100 vol%	85

5. Multi-gas (Sidestream) Technical specifications
For more details, please refer to specification section, Multi-gas (Sidestream) part.

• **General specifications**	
Description	Compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Dimensions (W×D×H)[1]	ISA CO2/AX+: 33×78×49 mm (1.3” ×3.1”×1.9”) ISA OR+: 49×90×100 mm (1.9” ×3.5”×3.9”)
Weight	ISA CO2/AX+: <130 g (including cable) ISA OR+: <420 g (including cable)

[1] Excluding cable, tubing and Nomoline.

Operating temperature	ISA CO_2: 0 to 50°C (32 to 122 °F) ISA OR+/AX+: 5 to 50°C (41 to 122 °F)
Storage temperature	-40 to 70°C (-40 to 158 °F)
Operating humidity	<4 kPa H_2O (non-condensing) (95 %RH at 30°C)
Storage humidity	5 to 100 %RH (condensing)[2] (100 %RH at 40°C)
Operating atmospheric pressure	525 to 1200 hPa (Corresponding to a max altitude of 5211 m/17100 feet)
Storage atmospheric pressure	25 to 1200 hPa (corresponding to a max altitude of 5211 m / 17100 feet)
Ambient CO_2	≤ 800 ppm (0.08 vol%)
Mechanical robustness	ISA CO2: Meets the shock and vibration requirements for transport of EN ISO 80601-2-55:2011 clause 201.15.3.5.101.2 and EN 1789:2007 clause 6.3.4.2. ISA OR+/AX+: Meets the shock and vibration requirements of EN ISO 80601-2-55:2011 clause 201.15.3.5.101.1
Power supply	4.5 to 5.5 VDC, ISA CO2: <1.4 W (normal op.), <1.8 W (peak @ 5 VDC) ISA AX+: <1.6 W (normal op.), <2.0 W (peak @ 5 VDC) ISA OR+: <2.0 W (normal op.), <2.4 W (peak @ 5 VDC)
Recovery time after defibrillator test	Unaffected
Water handling	Nomoline Family sampling lines with proprietary water removal tubing.
Sampling flow rate	50 ± 10 sml/min[3]
Degree of protection against harmful ingress of water or particulate matter	IP44
Method of sterilization	The ISA system contains no sterile parts.
Mode of operation	CONTINUOUS OPERATION
Degree of protection against electric shock	Nomoline Family sampling lines are classified as DEFIBRILLATION-PROOF TYPE BF APPLIED PART

[2] The unit shall after condensation be stored for more than 24h in an environment with relative moisture content below 95 %RH (non-condensing).

[3] Volumetric flow rate of air corrected to standardized conditions of temperature and pressure.