Pooyandegan Rah Saadat

Operator's Manual

Aria Patient Monitor

CE 2195

D00035-11

POOYANDEGAN RAH SAADAT CO.

No.4, 1st East St., Ettehad Blvd., Damavand St.,

TEHRAN,IRAN

Post box: 1658916599
Tel: +98 21 77960719
,+98 21 77962181
Fax: +98 21 77964239

Customer Services:

Tel: +98 21 73098000,
+98 21 77798910
Fax: +98 21 77960761
Cell: +98 912 1977157

Legal responsible:

Trionara Technologies AB
Polygonvägen 21. 18766. Täby.
Sweden
Tel: +46-31-135514

Web site: www.saadatco.com
Email: info@saadatco.com

Manual Purpose

This manual provides the instructions necessary to operate Aria patient monitor in accordance with its intended use. Study of this manual is a prerequisite for proper operation and ensures patient and operator safety. If you have any question about the monitor, please contact our Customer service department. This manual should always be kept close to the monitor to be available whenever required.

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 the patient monitoring and electrocardiography.

Version Information

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

Release date	Version number
Feb 2021	D00035-11

Aria User Manual

✓ Note:

This guide describes all features and functions of the Aria monitor and its different stations. Your monitor is highly customizable and may not have some of these features. Optional features are marked with *.

Chapter 1, Introduction

Contents

Symbol

The following symbols are used in this manual:

A NOTE symbol provides useful information and recommendations about the device function.

1-1 General Warnings

⚠ Warning ⚠

Vital signs monitoring through the patient monitor should be performed by qualified health care professionals.

⚠ Warning ⚠

Before monitoring, carefully read this manual

and directions for use of accessories.

⚠ Warning ⚠

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

⚠ Warning ⚠

Before monitoring, the operator must check that the device and accessories function safely and are in proper working condition.

⚠ Warning ⚠

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

⚠ Warning ⚠

If the accuracy of measurements is in doubt, firstly check the patient's vital signs by alternate means and then check the monitor for proper functioning.

⚠ Warning ⚠

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

⚠ Warning ⚠

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

⚠ Warning ⚠

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

⚠ Warning ⚠

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

⚠ Warning ⚠

To prevent EMC effects, the system should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, normal operation of the monitor should be verified under conditions of use.

⚠ Warning ⚠

Alarm should be set according to patient condition. Before monitoring, make sure that the audio alarm system functions correctly.

⚠ Warning ⚠

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

⚠ Warning ⚠

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

⚠ Warning ⚠

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

⚠ Warning ⚠

When using a defibrillator, parameters and signals will be temporarily interrupted until a few seconds after defibrillation.

⚠ Warning ⚠

Do not expose the device to any local heat source such as direct sunlight.

⚠ Warning ⚠

There will be some risks of polluting the environment associated with the disposal of the single-use accessories and specific parts of the system (e.g. defective and decommissioned battery). The device and accessories shall be disposed of in accordance with national laws after their useful lives. Contact your municipality to check where you can safely dispose of old batteries.

⚠ Warning ⚠

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

⚠ Warning ⚠

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

General Warnings

⚠ Warning ⚠

Do not connect items not specified as part of the monitor. The system needs to be installed and put into service according to EMC information provided in the APPENDIX II.

⚠ Warning ⚠

In case of water splash on the system or accessories, please turn off the monitor, wipe it with a soft cloth and then turn it on.

⚠ Warning ⚠

The monitor software is designed in a way that hazards arising from the software bugs are minimized.

⚠ Warning ⚠

To avoid risk of electric shock, this equipment must only be connected to recommended medical-grade adaptor.

⚠ Warning ⚠

If the system should be used outdoor or in rainy condition, use special bag recommended by the manufacturer.

⚠ Warning ⚠

Before using the system, check the battery charge status.

⚠ Warning ⚠

Do not touch the screen with sharp objects.

General Warnings

This guide describes all features and functions of the device. Your device is highly customizable and may not have some of these features.

If the monitor turns off due to power failure or battery discharging, all current settings will be retained.

1-2 Getting Started

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.

Insert the battery

When you use the system for the first time, you should insert the battery into the monitor.

Place the monitor in the station base

Put the monitor in the station base.

Connect the power cable to the system

- Make sure that AC power supply is 100 ~ 240 VAC and 50/60Hz (Ip: 1.4 -0.7 A).

- Connect one end of the power cable to the relevant socket on the station base and the other end to a grounded power receptacle.

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 Customer Service.

The battery needs to be charged after transportation or storage. If the power cable is not properly connected before turning on the monitor, it may not work properly because of insufficient power. Connect the power supply to charge the battery for about 24 hours while the monitor is off.

Power on the monitor

Press the Power key to turn on the monitor. At the same time a beep sound will be heard and the yellow and red indicators light about 4 seconds separately. After a few seconds and performing self-test, the system will display main screen 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
- Pulse oximetry
- RESP

Check the functions of all modules and make sure that the monitor is in good connection.

Recharge the battery after that the monitor operates on it for a while. To do so, simply plug the Aria station into AC power line.

⚠ Warning ⚠

If any sign of damage is detected, or the monitor displays an error message, do not use the monitor on patient until the problem is resolved.

Connect the sensors to patient

Connect all necessary accessories to the monitor and the patient.

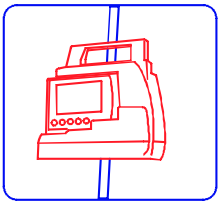
For more information about accessories, please refer to each module's chapter.

1-3 Continuous Patient Monitoring

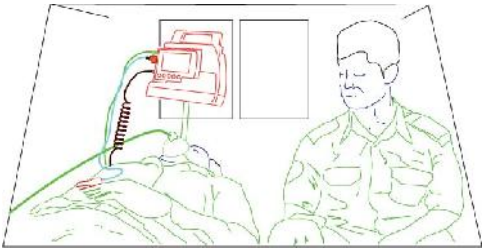
The Aria monitor is intended to be used as a full- function monitoring system. By connecting some accessories to the monitor, it will be usable in different units of the hospital.

You can simply connect the monitor to peripheral devices or change its usability during the monitoring without any interruption in measurement and storage of vital signs parameters.

The monitor can be used in an ambulance by mounting it on the roll stand as shown.

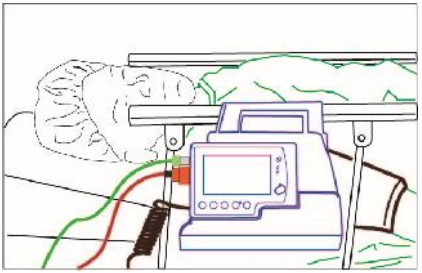


Installation on the roll stand



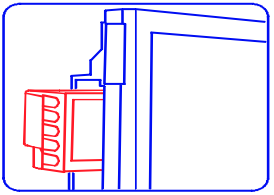
Monitoring in ambulance

During patient transport to different wards or operation room of hospital, the monitor can be hung from the bed rail by its base.



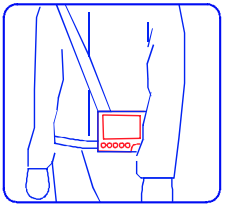
Installation on bed rail

Aria monitor can also be used as a detachable multi-module in Alborz monitor (Modular) when patient is transferred to different wards of hospital.



Detachable multi-module

The monitor can be placed in a special shoulder bag and easily carried by patient with regard to its portable and lightweight features.



Placement of Aria in special bag

1-4 General Information

Environmental conditions

Operating temperature	5 ~ 40 ◦c
Storage and transportation temperature	-25~ 60 ◦c
Operating humidity	20~ 90 %
Storage and transportation humidity	10~ 100 %
Altitude	-200~3000m
Power supply	100 ~240 Vac Ip:1.4 -0.7A 50/60 Hz Pmax = 60 W

The Aria monitoring system has been designed to monitor patient's condition continuously from the moment of incident until medical care and full recovery.

The Aria portable monitor is adaptable to adult, pediatric and neonatal patients.

General Information

The Aria monitor consists of different modules, a recorder and an alarm system and can communicate with the Central monitoring system. The monitor features in compactness, lightweight and portability and its built-in battery facilitates transportation of the patient. It is a compact, lightweight and portable monitor and its built-in battery facilitates transportation of the patient.

The patient monitor can monitor the following parameters:

ECG	Heart Rate(HR)
	ECG waveform
	ST segment
	PVCs/min and Arrhythmias
RESP	Respiratory rate(RR)
	Respiration waveform
SpO2	Percentage of pulse oximetry Saturation(SpO2)
	Pulse Rate(RR)
	SpO2 waveform

measurable:

If MASIMO Rainbow* module is used, the following parameters will be

Each of the below parameters can be used only if its software is enabled by the manufacturer and its specific probe is available.

SpO2	Measurement of artery pulse signal pressure (PI)
	Measurement of total hemoglobin content(SPHb)
	Measurement of oxygen content (SpOC)
	Percentage of Carboxyhemoglobin saturation (SPCO)
	Percentage of methemoglobin saturation(SPMet)
	Pleth variability index(PVI)
NIBP	Systolic pressure, Diastolic pressure and Mean arterial pressure (MAP)

TEMP	Temperature channel (T1)
	Temperature channel (T2)
IBP	Channel 1 IBP (IBP1/IBP3)
	Channel 2 IBP (IBP2/IBP4)
CO2	EtCo2, FiCo2, AWRR
BFA	Anesthetic depth index(BFI)
	Percentage of Burst Suppression (BS%)
	Signal Quality Index(SQI)
	Electromyogram index(EMG%)

The Aria monitor is equipped with Visual & Audible alarms and can store Trend and NIBP data.

The monitor is a user-friendly device which can be easily operated via the front panel keys and touch screen. Refer to "Keys Function" for details.

In all menus when setting is changed, Back key (◄) changes to Ok. In order to apply new setting **OK** should be pressed and if Close key (**X**) is pressed, the menu will be closed and setting will not change.

1-5 Indicators

There are five indicators for power, alarm, DC IN, battery and alarm silence on the front panel of the Aria monitor.

Indicators

①	Power	The power indicator lights green when the monitor is powered on
②	DC IN	If the monitor is placed in the station connected to the mains power, DC IN indicator will light up
③	BATT	The battery indicator is green when the battery is fully charged, otherwise it is orange
④	ALARM	The alarm indicator flashes when an alarm occurs
⑤	ALARM 	If alarm indications are disabled for an unlimited time, the alarm indicator flashes red

⚠ Warning ⚠

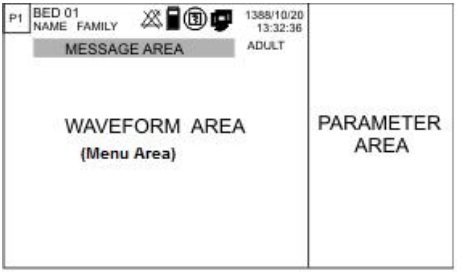
The alarm indicator in normal condition is off. It flashes when an alarm occurs.

⚠ Warning ⚠

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

1-6 Main Screen

The vital sign monitor has a color TFT screen. The patient parameters, waveforms, alarm messages, bed number, date, time, system status and error messages are displayed on the main screen. The main screen is divided into four areas Header area, Waveform area, Parameter area and Message area.



- **Header Area**

The header area of the screen displays operating status of the monitor and patient information. Bed number, patient mode (adult, pediatric or neonatal), patient name, date & time and page number are displayed in this area. This information is displayed on the screen during monitoring.

Only 6 characters of patient name (maximum number of characters is 15) are displayed in the header area. You can observe full name of the patient in PATIENT menu.

Main Screen

The below symbols appear in the header area with regard to the monitoring status.

	Indicates the remaining battery charge.
	Indicates that the battery is not loaded in the battery compartment
	Appears when the system is recording.
	Appears when the system is connected to Central monitoring system.
	Appears when Alarms key is pressed.
	Blinks along with a countdown timer of 120 sec when the system is in the silence mode.
	Appears in white color when connection of the Aria monitor to the station is established. If the Aria is connected to other devices (e.g. Modular system), a green symbol as well as white symbol will be displayed.

- **Waveform / Menu Area**

All waveforms can be displayed simultaneously in this area. The waveforms from top to bottom are: ECG, SpO2, RESP, IBP, CO2 and BFA.

Gain, filter, lead and sweep speed of the ECG waveform are also displayed in this area. The three dotted lines from top to bottom show the highest scale, cursor and the lowest scale of IBP waveform. These scales can be manually set by the operator.

Each menu depending on its size may cover 2 or 3 waveforms.

- **Parameter Area**

Parameters values always are displayed in same color as their corresponding waveforms and at a certain position on the screen. The parameters values are measured and refreshed every second. (Except NIBP values which are refreshed with each measurement).

- **Message Area**

Different messages are displayed in this area based on priority. Background color changes with regard to alarm level (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

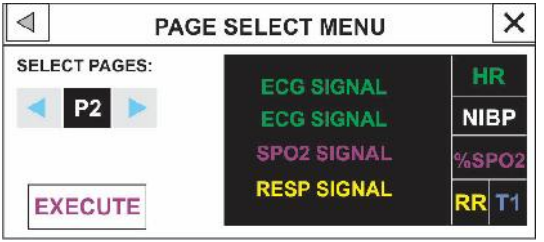
When there is no alarm, the message is displayed on gray background.

Different page configurations

There are two ways to change page setting:

1- Press PAGE button above the screen to access next page.

2- Press and hold PAGE button (for less than 2 sec) to access PAGE SELECT menu. Select your desired page and press EXECUTE to open that page.



PAGE SELECT MENU

Main Screen

There are 23 pages in the Aria monitor by default, with different configurations to display parameters and waveforms. According to the table below:

Page	Parameter	Signal
P1	HR,SpO2,RR,T1,NIBP	ECG,SpO2,RR
P2	HR,SpO2,RR,T1,NIBP	ECG 2Trace,SpO2,RR
P3	HR,SpO2,RR,T1,NIBP	ECG 4Trace
P4	HR,SpO2,RR,T1,NIBP	ECG 7Trace
P5	HR,SpO2,RR,T1,NIBP	ECG 12Trace
P6	HR,SpO2(PI, PVI,SpOC,%SpCo %SpMet,SpHb),RR,T1,NIBP	ECG, RR, SpO2
P7	HR,SpO2(PI, PVI,SpOC,%SpCo %SpMet,SpHb),RR,T1,NIBP	ECG
P8	SpO2,PR,T1,T2,NIBP	SpO2
P9	SpO2,PR	SpO2
P10	HR,IBP,SpO2,NIBP	ECG, IBP, SpO2

P11	HR,IBP,T1,RR,NIBP	ECG, IBP
P12	HR,IBP,SpO2(PI, PVI,SpOC,%SpCo,%SpMet ,SpHb)	ECG, IBP
P13	HR,IBP,NIBP,SpO2(PR,PI, PVI,SpOC,%SpCo%SpMet,SpHb)	ECG
P14	HR,2IBP,SpO2,NIBP	ECG,2IBP
P15	HR,2IBP SpO2(PR,PI, PVI,SpOC,%SpCo,%SpMet,SbHb)	ECG,2IBP
P16	HR,2IBP,SpO2,NIBP	ECG
P17	HR,2IBP, SpO2(PR,PI, PVI,SpOC,%SpCo,%SpMet,SpHb)	ECG
P18	HR,NIBP,SpO2,PR,T1,CO2(AWRR,EtCo2,FiC o2	ECG,CO2
P19	HR,NIBP,SpO2,PR, CO2(AWRR,EtCo2,FiCo2)	ECG,SpO2,CO2
P20	HR,CO2(AWRR,EtCo2,FiCo2),NIBP SpO2(PR,PI, PVI,SpOC,%SpCo %SpMet,SpHb)	ECG
P21	HR, SpO2,PR,2IBP,T1 ,CO2(AWRR,EtCo2,FiCo2)	ECG,SpO2,IBP
P22	HR, SpO2,PR,2IBP,NIBP ,CO2(AWRR,EtCo2,FiCo2	ECG
P23	HR,BFI%,BS%,SQI%,EMG%	ECG,EEG

When the monitor is turned on for the first time, P1 is displayed by default. Afterwards each time you turn on the monitor, the last active page on which you have turned off the monitor will appear.

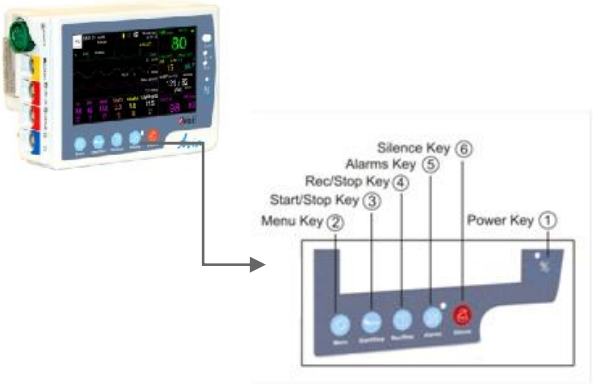
1-When using the monitor, the screen should be protected from direct sunlight in order to get a clear view of what is displayed.

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.

1-7 Keys Function

All operations are performed through the front panel keys and touch screen.



①	**Power**	press this key to turn the monitor On and Off.
②	**Menu**	press to open HOME MENU or return to the main screen.
③	**Start/Stop**	press this key to start blood pressure measurement and press it again to stop measurement.
④	**Rec/Stop**	press to record ECG waveform and all numeric parameters via the Central monitoring system or recorder of TC station. Press it again to stop recording.
⑤	**Alarms**	press this key to disable alarms unlimitedly. Even if a new alarm occurs, alarm indications (light indicator and alarm sound) will be inactive until you press the key again. This key is currently inactive to meet standard requirements, but it will be activated for user in the future.
⑥	**Silence**	press to disable alarm sound for 120 sec. A countdown timer appears and Silence symbol blinks in the Header area every 5 sec. If you press this key again, the system will exit from silence mode and the alarm sound will be enabled.

If you press Start/Stop key in pages which do not include NIBP parameter, the measurement will not be done. If you enter these pages during the measurement and press Start/Stop key, the measurement will be stopped.

If a new alarm occurs in the silence mode, the monitor will exit from this mode. This event will not happen within 120 sec after the monitor is turned on.

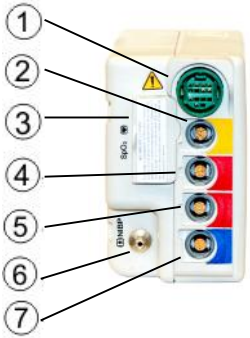
⚠ Warning ⚠

Before monitoring the patient, check the keys function and make sure that they are in proper working condition.

When you touch the left side of the first waveform, all waveforms will be frozen and “FROZEN” is displayed in the Waveform area. Touch this area again, the waveforms will be unfrozen and a vertical white line will appear in the freezing point.

1-8 Interfaces

The connectors for patient cables and sensors are placed at the left side of the monitor.



①	ECG cable
②	TEMP1,2 probe
③	Masimo SPO2 sensor
④	IBP1/3 transducer
⑤	IBP2/4 transducer
⑥	NIBP cuff
⑦	CO2/Multi-gas sensor or the system programming able,BFA

Multi-gas module is currently inactive.

⚠ Warning ⚠

To make a secure connection, the connectors and cables should match each other properly.

The following symbols are marked on the labels of the side plate and the back case:

Connection to the Central System

The Aria monitor has a wireless connection to the Central system.

Wi-Fi connection of the Aria to the central system is made via an access point.

Only SAADAT monitors can be connected to network of the SAADAT Central system (SAHAND series).

Before connecting the Aria monitor to the network, the operator shall perform relevant settings such as AP Index and Bed Number.

1-9 Built-in Battery

Portable patient monitor is equipped with a rechargeable battery. If you place the monitor in the station and connect the station to AC power adaptor, the battery will recharge automatically. When the battery is depleted, it takes at least 3 hours to charge it. When the battery is fully charged, the monitor can run minimum two hours and maximum two and a half hours on the battery power.

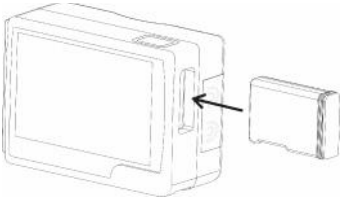
The symbol  in the Header area indicates the battery charge status. The yellow part represents the remaining battery charge. When AC power is plugged in, an indicator at the right side of the screen indicates the battery charge status. When the battery indicator is green, the battery is fully charged and when it is orange, the battery is being charged.

For battery information, please refer to the Technical Specifications chapter.

⚠ Warning ⚠

Opening the battery pack, disposing of in fire and short-circuiting may result in explosion and ignition. If the battery leaks or gets too hot, personal injury will occur.

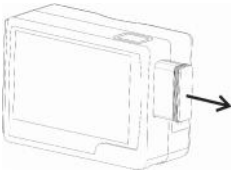
To insert the battery into the monitor, slide the battery into the compartment in the direction shown in the figure 1-8.



Battery insertion into the monitor

To remove the battery, press the battery eject button (see a). When the battery is released you can remove it from the compartment.

a: Eject button



b: Removing the battery

The battery specifications including voltage, current consumption, charging current, temperature, remaining time to battery depletion and remaining time to battery discharge are displayed by the Aria monitor. The battery voltage, current and current consumption can be monitored in ABOUT menu.

⚠ Warning ⚠

The batteries of the Aria monitor and the station can be recharged at least 500 times.

⚠ Warning ⚠

If the battery charge gets too low, the monitor will turn off automatically. Before the battery power becomes insufficient for monitoring, the alarm sound will be activated and "BATTERY LOW" will appear in the Header area. If the battery voltage is in the range of 3.6 to 3.48 V, level III alarm will be activated. If AC power is not plugged in and the battery voltage is in the range of 3.36 to 3.48 V, level II alarm will be activated. Finally, if the battery voltage is in the range of 3.25 to 3.36 (before the monitor turns off), level I alarm will be activated. Connect the station to AC mains power to charge the battery; otherwise the monitor will turn off automatically.

Chapter 2, Complementary equipment

Contents

2-1 General

The Aria monitor through connection to a number of accessories can easily be changed to an appropriate monitor for different parts of hospital.

The accessories can be connected to the monitor without disconnecting the monitor from the patient, so no interruption is made in the monitoring and storage of patient vital signs.

The accessories of the Aria monitor are:

1. F1 station
2. F1R station
3. Modular system

2-2 Accessories

F1 Station

F1 station is shown in the below figure:

Aria Station (F1)

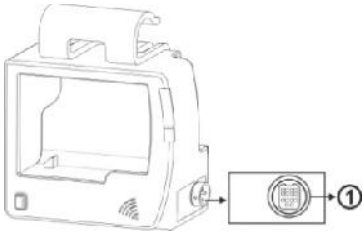
Auxiliary battery of F1 station makes continuous monitoring of the patient possible during long-time transportation.

Two alarm indicators and a speaker have been used in the station to make visual and audible alarms more recognizable when the monitor is placed in the station.

The alarm indicators of the station are larger than the monitor's indicators. When an alarm occurs, the station's indicators are enabled simultaneously with the monitor's

alarm indicators. The alarm sound or beat sound is disabled in the monitor and amplified by the station when the monitor is placed in the station.

The connector of adaptor and digital data output is located at the right side of the station .



Connector of F1 Station

- Power adaptor (Socket ①)

  Connector of Power adaptor with the following specification and digital output with RS422 protocol

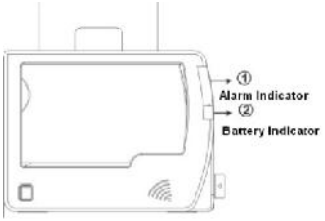
⚠ Warning ⚠

Use Only SAADAT approved adapters, otherwise the patient and user safety may be endangered.

For more information about the battery, refer to “Technical Specifications” chapter.

Indicators of F1 Station

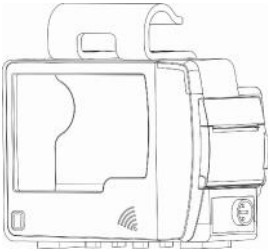
There are two indicators for the alarm and the battery in F1 station. When an alarm occurs, the alarm indicator of the station flashes corresponding to the monitor's alarm indicators (Figure ①). The battery indicator is green when the battery is fully charged, otherwise it is orange. If the battery is not charged for any reason, the battery indicator will flash orange (Figure ②).



Indicators of F1 Station

F1R Station

F1R station is shown in the below figure:

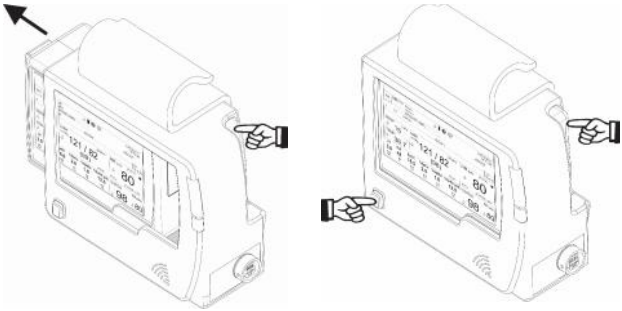


Aria Station (F1R)

The only difference between F1R and F1 stations is that F1R is equipped with a recorder to record the signals and numeric parameters.

Removing the Aria monitor from the station

Press and hold the eject button in front of the station (See figure) and simultaneously pull out the monitor. When the monitor moves in its position, release the eject button and remove the monitor.



b **a**

Removing the Aria from the station

⚠ Warning ⚠

If the Aria monitor is placed in the station and the power cable is plugged in, you will be able to:

1. Charge auxiliary battery of the station (in case of using F1, F1R stations) and the Aria built-in battery
2. Hang the monitor from the bed rail during the patient transportation
3. Mount the monitor on the roll stand and trolley

For battery and adaptor information, please refer to the Technical Specifications chapter.

⚠ Warning ⚠

The patient monitor shall only be connected to SAHAND series Central system.

If a new alarm occurs in the silence mode, the monitor will exit from this mode. This event will not happen within 120 sec after the monitor is turned on.

Aria monitor and Modular system

One of advantages of the Aria monitor is that this monitor can be placed in Modular system during patient transportation from the operation room to ICU and the operator can observe the patient data in larger size on the Modular screen. When the Aria monitor is inserted into the Modular system, different pages, menus and settings of the Modular system will be available. For more information, please refer to the user manual of the Modular system.

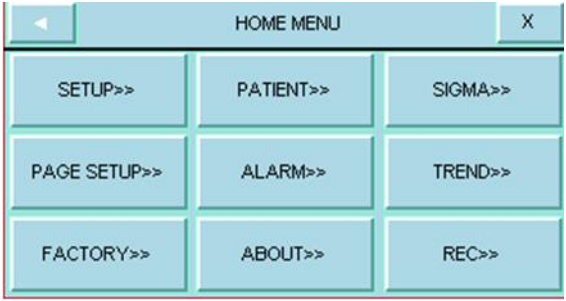
Aria monitor in Modular system

Chapter 3, System Configuration

Contents

3-1 HOME MENU

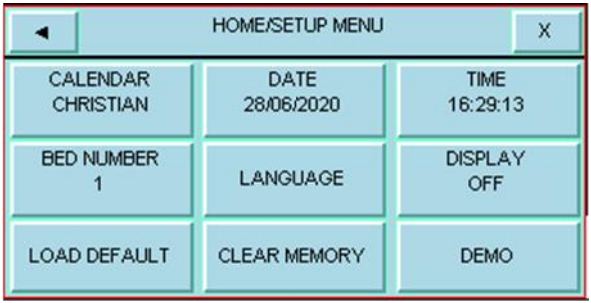
Patient monitor contains a flexible configuration. The configuration setting is done through HOME MENU. You can access this menu by pressing the MENU key on the front panel or touching middle part of the header area on the screen.



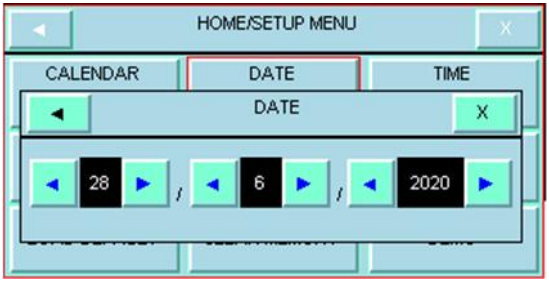
3-2 SETUP

By pressing SETUP, you can access the following menu:

The below settings can be performed in this menu:



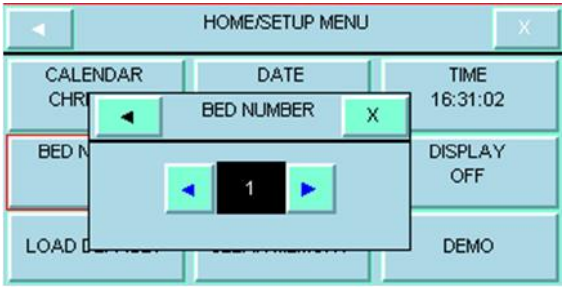
- **CALENDER:** Available options are "SOLAR" and "CHRISTIAN"
- **DATE:** Press this item to set date in the following window:



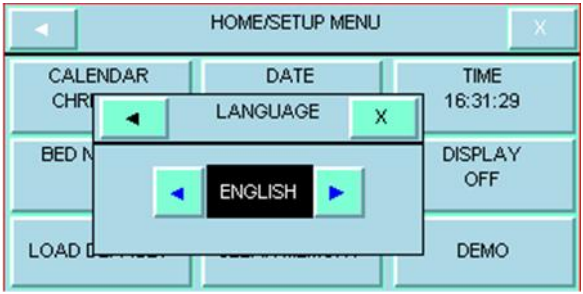
- **TIME**: Press this item to set time in the following window:

The monitor synchronizes with the Central system upon its connection to this system. In this condition, date and time settings will be inactive in SETUP menu.

- **BED NUMBER**: Press this item to set bed number in the following window (from 1 to 99):



- **LANGUAGE:** Press this item to select the desired language in the following window. Available options are ENGLISH, ITALIAN, SPANISH POLISH, RUSSIAN,TURKISH,GERMAN and FRENCH, PORTUGUESE.



- **DISPLAY OFF**: Select this item to turn off the display screen until a key is pressed or an alarm occurs.

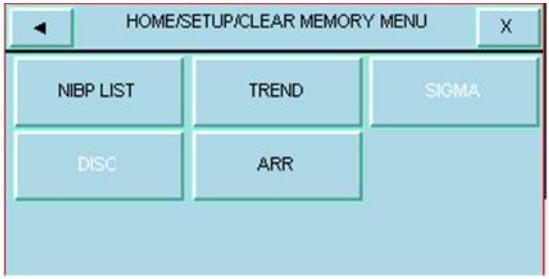
When the monitor is in the Silent mode, this item becomes inactive.

- **LOAD DEFAULT:** Select this item to access SETUP/ DEFAULT MENU (figure 3-7a) and to load the manufacturer default settings for the desired parameter. (Refer to Appendix I for default settings). Because all your previous
-
- settings will be missed by selecting this item, the system asks for your confirmation before changing settings .

ALERT message

Only specific parameters of each page are active in DEFAULT menu.

- **CLEAR MEMORY:** You can clear the stored parameters in the system such as TREND , NIBP LIST data and ARR. Press this item to call up the following menu .



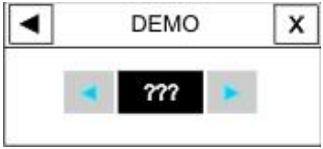
An alert message will ask for your confirmation before clearing the selected item.

ARE YOU SURE TO CLEAR NIBP LIST?

YES **NO**

- **DEMO**: Enter the defined code in the following window to see demo waveforms and parameters. In this mode, “Demo” is displayed on the ECG waveform.

  Enter a code other than the defined code to exit the demo mode.



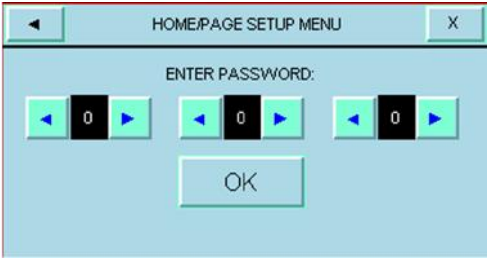
DEMO

The operator cannot access this menu and only authorized personnel of the manufacturer can use this menu.

3-3 PAGE SETUP

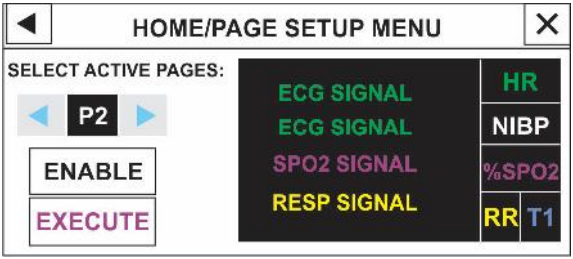
In the Aria monitor, different pages can be configured through PAGE SETUP menu.

The operator has not access to this menu and only authorized personnel of the manufacturer can perform settings of this menu.
By pressing "PAGE SETUP", you can access this menu:



FACTORY

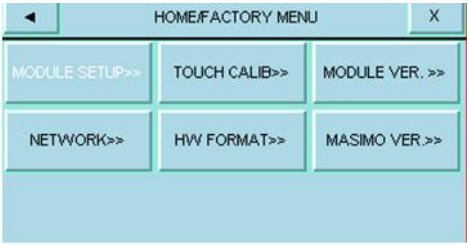
Enter correct password and press OK, the following menu will appear in which you can enable or disable different pages except P1. If you enter incorrect password, the message “WRONG PASSWORD” will appear in the red color.



Change settings and press EXECUTE button. A confirmation message will appear that if you select Yes, new setting will be applied.

3-4 FACTORY

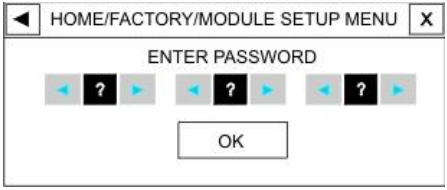
By pressing FACTORY, you can access this menu:



The operator does not have access to "MODULE SETUP", "HW FORMAT", "TOUCH CALIB" and "NETWORK" menus and only authorized personnel of the manufacturer can perform settings of these menus.

■ **Module Setup**

By pressing this item, you can access the below menu:



If you enter correct password and press OK, a window will appear in which you can enable or disable different modules.

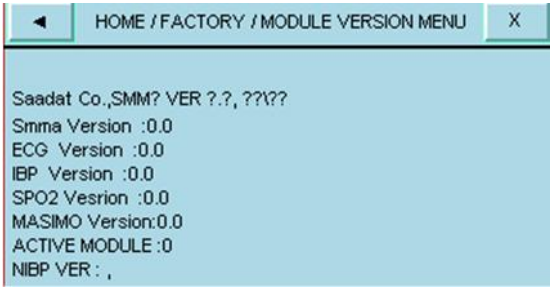
■ TOUCH CALIB

Press this item to access the below menu:

If you enter correct password and press OK, the following window will appear in which you can calibrate the touch screen in the four corners and center of the screen.

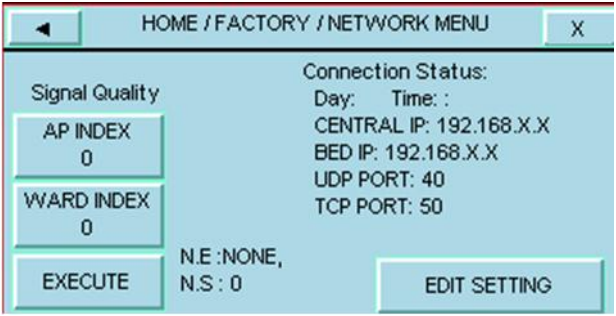
■ MODULE VER.

Press this item, the following menu will appear in which you can record and view software version of different modules.

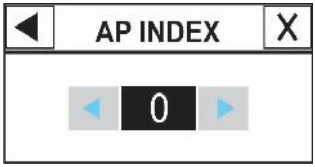


■ NETWORK

Press this item to access the below menu:

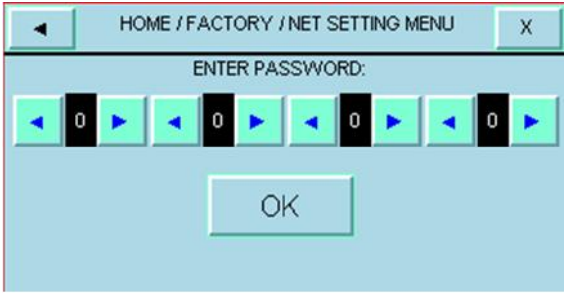


Select AP INDEX or WARD INDEX to call up a window in which you can set AP or Ward index. Press EXECUTE button to change setting.

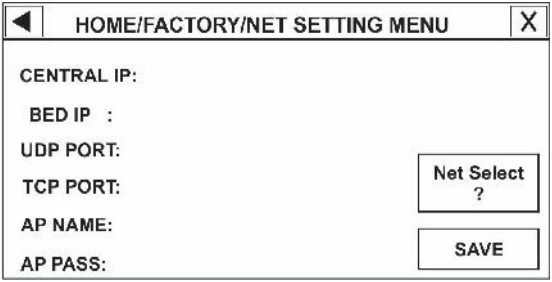


FACTORY

By pressing EDIT SETTING, you can access the below menu:

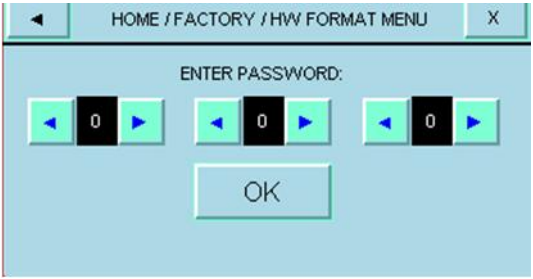


If you enter correct password and press OK, the following menu will appear in which you can perform the network setting.

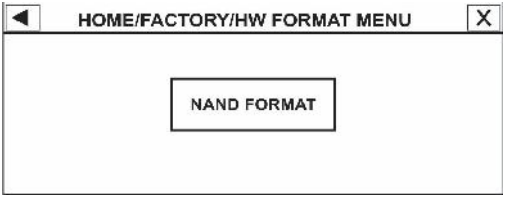


■ HW FORMAT

Press HW FORMAT to access the below menu:



Enter correct password and press OK to call up the following menu:



Pressing NAND FORMAT will call up the below alert message. If you select Yes, NAND flash will be formatted. During NAND flash formatting, the signals sweep slowly

and after the formatting procedure ends, the monitor shall be restarted.

■ **MASIMO VER.**

Press this item to call up MASIMO MENU in which you can access MASIMO module specifications and PROGRAMMING MODE and LINE FREQUENCY buttons.

ABOUT

Select "ABOUT" in HOME MENU to see the system, battery and manufacturer information in the menu.

Chapter 4, Alarm

Content

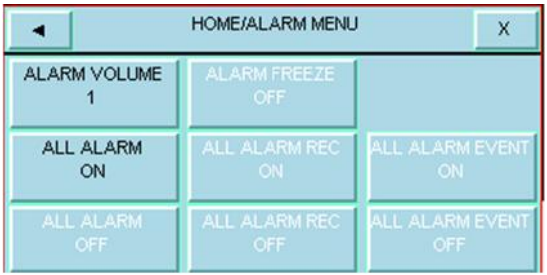
This chapter gives general information about alarm and its functions.

⚠ Warning ⚠

Always verify the audible and visual alarms when the monitor is powered on.

4-1 ALARM MENU

By pressing "ALARM" in HOME MENU, you can access the below menu.



The following settings can be done in this menu.

- **ALARM VOLUME**

Select "ALARM VOLUME" to set the volume of alarm sound. The volume ranges from 1 to 8. 1 is minimum volume and 8 is maximum volume.

- **All ALARM ON/OFF**

Select this item to call up the below alert message. By selecting YES, you can turn on/off all alarms.

ARE YOU SURE TO ACTIVATE ALL ALARMS?

Select "ON" to enable all alarm indications. Select "OFF" to disable the alarm indications such as alarm sound, parameters blinking and light indicator. In "OFF" mode you can see  symbol in front of all parameters. This item changes alarm of all parameters, but you can turn on/off alarm of each parameter separately in its own window.

4-2 Alarm Categories

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

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.

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.

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.

4-3 Alarm Modes

Alarm level and setup

The patient monitor offers three levels of alarm.

High level alarm (level I) indicates that patient is in a life threatening situation or monitor has a serious problem.

Medium level alarm (level II) indicates a serious warning.

Low level alarm (level III) indicates a general warning.

The patient monitor has preset the alarm level of different parameters. User can modify alarm level of each parameter in its own window.

When an alarm occurs, the patient monitor will inform user through the messages with various backgrounds (based on alarm level), light indicators and different levels of alarm sound.

- **Display screen**

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

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 message is informative (or if Silence key is pressed), the background color will change to gray.

- **Alarm indicator**

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

- **Alarm sound**

Alarm sound will be enabled if the system is not in silence mode (i.e. Alarms key has not been pressed).

The patient monitor uses different alarm tone patterns to match the alarm levels:

High level alarm sounds "DO-DO-DO--DO-DO "every 10 seconds.

Medium level alarm sounds "DO-DO-DO" every 20 seconds.

Low level alarm sounds "DO" every 30 seconds.

Alarm sound pressure in front of the monitor and at the distance of 1m ranges from 50 dB(A) to 66 dB(A) depending on the selected volume (1 to 8).

When multiple alarms with different levels occur simultaneously, alarm indicator flashes red (high level) and alarm messages will appear alternatively in a background corresponding to their level.

If two or more alarms with same level occur simultaneously, the alarm messages will be displayed alternatively on the screen.

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.

4-4 Alarm verification when the system is powered on

When the monitor is powered on, audible and visible alarms are self- tested. The monitor beeps every time it is powered on and yellow and red indicators light simultaneously for about 4 seconds. If no beep is heard or no alarm indicator lights, do not use the monitor on any patient and notify Customer Service department.

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 indication (parameter blinking, alarm message and light indicator) is maximum 50 ms. The Aria monitor is designed in such a way that alarm occurrence can be recognized by the operator from a distance of 1 m.

Condition triggering alarm of a parameter:

When the measured value exceeds the adjusted alarm limits and the parameter alarm is in "ON" mode. In case of ASYSTOLE or APNEA detection, the alarm will be enabled even if it is in "OFF" mode.

SILENCE Key

By pressing "Silence" key, you can disable all alarm sounds for 2 minutes. A countdown timer (120 seconds) and a Silence symbol are displayed alternately every 5 sec in the Header area. If a new alarm occurs during 2 minutes, the silence status will be terminated and both audible and visible alarms will be enabled again. If user presses "Silence" key during 2 minutes of alarm silence, the alarm suspension status will be ended and normal alarm status resumed immediately.

ALARMS Key

By pressing "Alarms" key, you can disable all alarm indications for an unlimited period until the key is pressed again (even if a new alarm occurs, silence status will remain).

Alarms and Silence keys

When the Alarms key is pressed, its indicator flashes on the front panel.

This key is not currently active.

Parameters Alarm

The alarm setting of each parameter can be found in its specific window. You can observe and set alarm limits of each parameter in its own specific window.

When a parameter alarm is "OFF", symbol  is displayed beside the parameter. When a 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 in a background corresponding to its level on the screen.

2-The monitor beeps corresponding to alarm level and volume.

3-Alarm indicator flashes.

4-5 When an alarm occurs

You need to identify the alarm and act appropriately according to the cause of the alarm.

1- Check the patient's condition.

2- Identify related alarms to each module.

3- Identify the alarm cause.

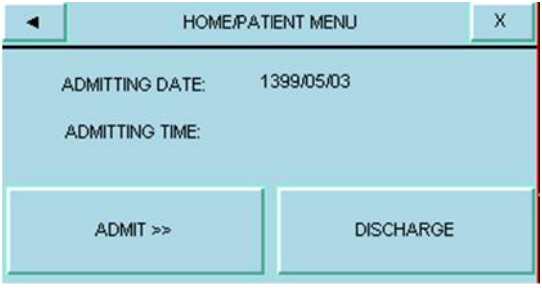
4- Press Silence button, if necessary.

5- After removing the alarm cause, check that the alarm system is working properly.

Chapter 5, PATIENT INFORMATION

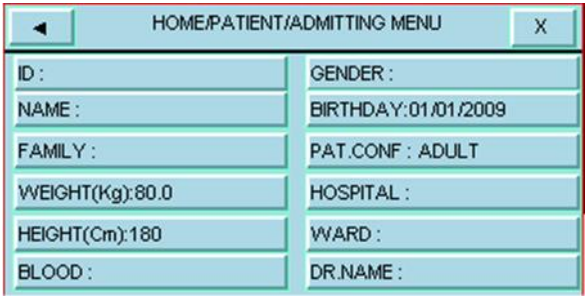
5-1 PATIENT

By pressing PATIENT in the Aria monitor, you can access the below menu:



Select ADMIT in the Patient menu to enter HOME /PATIENT/ ADMITTING MENU. You can enter patient demographic information in this menu (

PATIENT



ID	Patient code in hospital (Up to 15 characters)
NAME	Up to 15 characters
FAMILY	Up to 15 characters
WEIGHT	Optional from 0.5 to 300 Kg
HEIGHT	Optional from 20 to 250 cm
BLOOD TYPE	Available options are A+, A-, B+, B-, AB+, AB-, O+ and O-.
GENDER	Available options are Female and Male
BIRTHDAY	Date of the birth

PATIENT

PAT. CONF	Available options are Neonate, Pediatric and Adult
HOSPITAL	Up to 15 characters
WARD	Up to 15 characters
Dr.NAME	Up to 15 characters

If the patient mode (Neonate, Pediatric, Adult) is changed, HR value will disappear for a few seconds and then appear again.

To save information of a new patient, select DISCHARGE in the Patient menu. A confirmation message appears that if you select Yes, all stored data (e.g. Trend, NIBP LIST data) for the previous patient will be deleted.

Chapter 6, ECG Monitoring

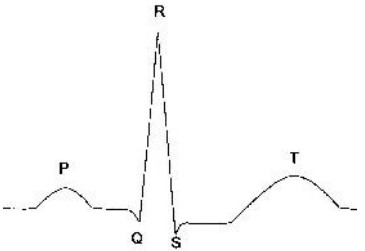
Contents

6-1 General Information

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.

Normal QRS complex involves:

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



Standard ECG waveform

⚠ Warning ⚠

This device is defibrillator proof, and this feature requires use of manufacture specified accessory including electrodes, lead wires, and patient cable.

⚠ Warning ⚠

Do not touch patient, monitor and bed during defibrillation.

⚠ Warning ⚠

Interference from non-grounded devices near the patient or electrosurgical unit can cause inaccuracy of ECG waveform.

⚠ Warning ⚠

Select the patient mode carefully, because QRS detection's thresholds and algorithms are working different in Adult and Neonatal modes.

6.2 Patient Preparation

1. Prepare the patient's skin prior to electrodes placement.
   - 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 gently to increase the capillary blood flow in the tissues.
2. Put the electrodes on the patient body. Before attachment, apply some conductive gel on the electrodes if the electrodes are not self-supplied with electrolyte

3. Attach clip or snap to the electrodes prior to placement.

6-3 ECG Lead Wire Placement

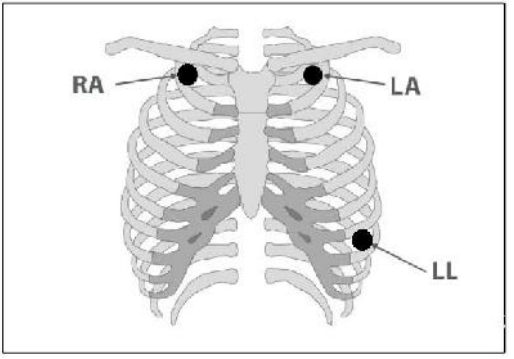
The ECG patient cable consists of 2 parts: The trunk cable that is connected to the monitor and the patient lead wires that are connected to the patient. Available cable types and the various methods of lead placement are described in following part

Electrode placement for 3-wire cable

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 Leg (LL): green electrode, be placed on the left hypogastrium.



Electrode's locations for 3-wire ECG Cable

Electrode placement for 5-lead wire cable

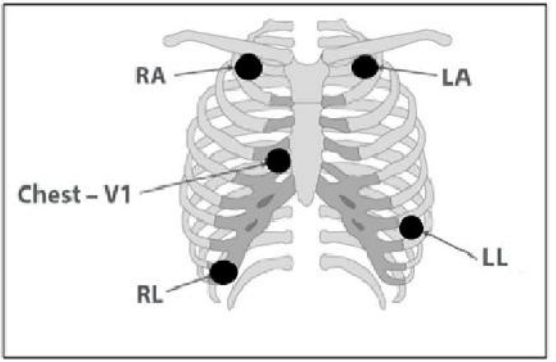
Right arm (RA): red electrode, be placed near the right

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 .

Right Leg (RL): black electrode, be placed on the right hypogastrium.

Left Leg (LL): green electrode, be placed on the left hypogastrium.



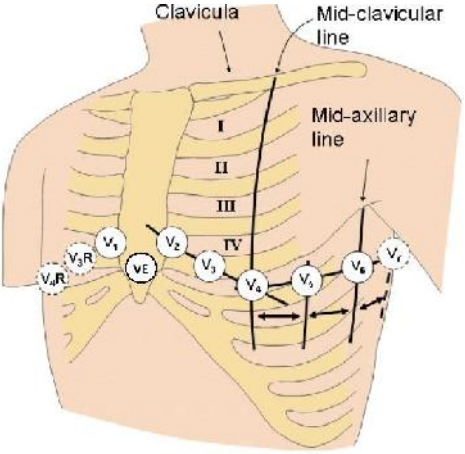
Electrode's locations for 5-wire ECG Cable

For ECG 5-WIRE mode, attach the C-electrode to different positions on the chest:

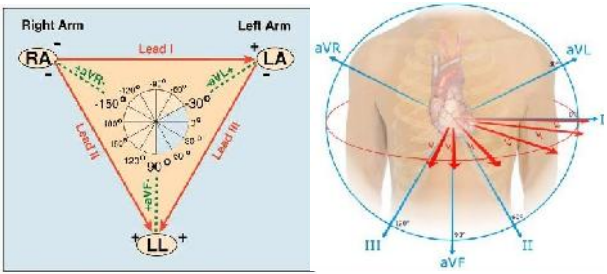
- V1 on 4th intercostal space at the right sternal margin.
- V2 on 4th intercostal space at the left sterna margin.
- V3 midway between V2 and V4 electrodes.
- V4 on 5th intercostal space at the left clavicular line.
- V5 on the left anterior axillary line, horizontal with V4 electrode .
- V6 on the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

- V7 on 5th intercostal space at the left posterior axillary line of back.
- V7R on 5th intercostal space at the right posterior axillary line of back.



C or V electrode's locations for 5/10-wire ECG Cables

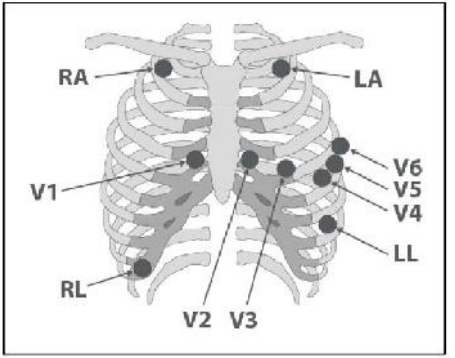


ECG Leads

Depending on cable's type (3-Wire or 5-Wire), you can choose different leads including I, II, III, aVR, aVL, aVF and V.

Electrode placement for 10-Wire cable

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 the figure .



Electrode's locations for 10-wire ECG Cable (Standard 12 lead)

⚠ Warning ⚠

Unplug the ECG cable from the socket, the error message "ECG NO CABLE "should be displayed on screen.

⚠ Warning ⚠

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

⚠ Warning ⚠

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

⚠ 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.

⚠ Warning ⚠

To ensure patient safety, all leads must be attached to the patient. Make sure that there is no contact between the conductive parts of electrodes, including the neutral electrode and any other conductive parts including earth.

⚠ 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.

⚠ Warning ⚠

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

⚠ Warning ⚠

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

⚠ Warning ⚠

Line Isolation Monitor (LIM) fluctuations may resemble actual cardiac waveforms and thus activate heart rate alarms. Such fluctuations may be minimized by proper electrode and cable placement, as specified in this manual.

⚠ Warning ⚠

When using Electro surgery equipment, leads should be placed in the furthest possible distance from Electro surgery electrodes and its 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 heart surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artefacts 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 or left side of shoulders and on the top side of the stomach. Avoid

placing the electrodes on the upper arms (except when the ECG waveform is too weak).

⚠ Warning ⚠

Improper connection of the ESU return electrode might lead to patient severe burn.

⚠ Warning ⚠

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

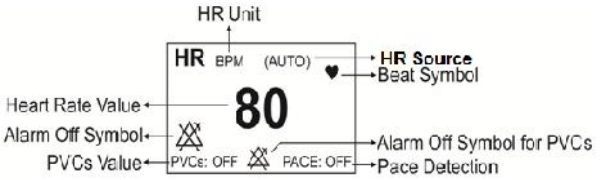
.

⚠ 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.

6-4 ECG PARAM MENU

ECG parameter window is as below:



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.

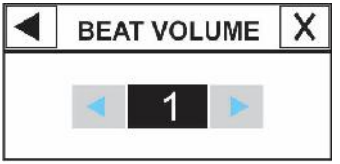
2- The RL electrode is disconnected or not connected properly.

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

Touch ECG parameter area to access the below menu:

- **BEAT VOLUME**

Select this item to access the below window. Beat Volume ranges from 1 to 8. Select "OFF" to disable beat sound and 8 to hear the highest volume.



- **ECG AVERAGE**

Available options for ECG average are 4, 8, 16 and AUTO sec.

- 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		
	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 HR High (for instance when HR reaches to 120 bpm) happens, the alarm is activated in 6 seconds. (by setting HR alarm limits between 60 bpm and 100 bpm).

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

- The ECG module is able to reject TALL-T pulses greater than 1.2 mv.
- The current that is applied to the patient for lead-sensing is 90nA.
- Noise suppression circuit: A noise signal of 10 μA is applied reversely to the reference 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.
- According to EC13:2002 standard the measured HR for 4 irregular rhythms is as follows:

Irregular rhythm	**Measured HR**
3a ventricular bigeminy	85
3b slow alternating ventricular bigeminy	42-89
3c rapid alternating ventricular bigeminy	127
3d bidirectional systoles	81-109

- **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 calculated from the module that its accessory is connected to the monitor.
- If two or more signals are being monitored simultaneously, the heart rate calculation will be done based on the signals priority, i.e. ECG, SpO2, IBP1, IBP2, IBP3 or IBP4 signal respectively.
- If the heart rate is calculated from any signal except ECG, PR alarms will be enabled based on HR alarm settings (Alarm Level and Alarm Limit).

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

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

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

Calculating HR from IBP signal is possible just from ART, PAP, RVP, LVP and IBP labelled signal.

Calculating 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.

HR value measurement range is 25~240 bpm

when the HR is calculated from IBP signal

- **LEAD TYPE**

Select this item to access different ECG modes including 3-wire and 5-wire and 10-wire.

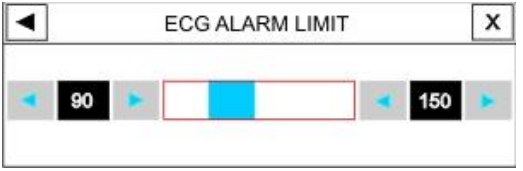
- **HR ALARM**

Select "ON" to enable all alarm indications such as parameters blinking, audio alarm and light indicator. Select "OFF" to disable the alarm indications and call up

" " symbol in the ECG parameter area.

- **ALM LIM**

By selecting "ALM LIM" in ECG PARAM MENU, you can access the below window:



The ECG alarm is triggered when the heart rate violates adjusted ALARM HIGH or LOW limit.

Low limit: 30~ (high limit - 5)

High limit: (low limit + 5)~ 250

- **ALARM LEVEL**

Available options are 1and 2. Level 1 means the most serious case.

■ **ST ANALYSIS**

Select this item in ECG window to access the window for ST analysis setting. Refer to ST Monitoring chapter for detailed information about ST analysis in the system.

■ **ARR ANALYSIS**

Select this item in ECG window to access the window for arrhythmia analysis setting. This monitor is able to detect up to 13 types of arrhythmia. Refer to ARR Monitoring chapter for detailed information about arrhythmia analysis in the system.

- **ECG EVENT**

This item is inactive.

- **ALARM REC**

See the chapter “RECORDING”.

⚠ Warning ⚠

Use only the manufacturer recommended ECG cable for monitoring. Other ECG cables and leads may cause improper system performance and reduce safety during defibrillation.

To ensure the patient safety, all leads must be attached to the patient.

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

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

⚠ Warning ⚠

When using the electrosurgical unit, never place ECG electrodes near the grounding plate of the electrosurgery device, otherwise there will be a great deal of interference with the ECG signal.

The lead which is used for Pace and HR signals is the main lead. In all pages (except P2) this lead is displayed in the first trace and can be set in ECG Trace menu.

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

Warning

For the patients with pacemaker, the monitor may continue to count the pacemaker pulses as heart rate during occurrence of arrhythmias. Do not rely entirely upon the monitoring system. Keep the patients with pacemaker under close surveillance (Refer to ECG TRACE for more information about Pace pulses).

Any reason that causes circuit saturation (e.g Discharge of defibrillator), the constant signal will be displayed, which usually does not last more than 5 seconds.

6-5 ECG TRACE MENU

Touch the ECG waveform area to access the below menu:

■ ECG LEAD

LEAD	Explanation
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

ECG TRACE MENU

You can choose V, aVF, aVL and aVR just in ECG 5-lead mode.

The leads V2, V3, V4, V5 and V6 can only be selected in ECG 12-lead mode.

- **ECG SIZE**

Select to adjust the height of ECG waveform. Gain options are CHANGE (five modes) and AUTO. In AUTO mode, the monitor chooses the best level automatically.

- **ECG SWEEP**

Available options for ECG SWEEP are 12.5, 25 and 50 mm/s. 50 mm/s is not available in P4 and changes to 25 mm/s.

■ ECG FILTER

There are four filter modes to obtain clearer and more accurate ECG waveform:

Filter mode	Frequency Range	Application
NORMAL	0.5-40 HZ	In normal use.
EXTENDED	0.05-100 HZ	In diagnostic application, but the ECG waveform might have some noises.
MONITOR	0.5-24 HZ	This mode may reduce interference from the electrosurgery equipment. This mode can be used when the system has high noises or does not have equipotential earth.

- **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 calculating the heart rate. Detected pacemaker signals will be marked on the ECG waveform as 1 centimeter spike. 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

Monitoring of patients with pacemaker is not generally affected when PACE DETECT is enabled.

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

⚠ 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**

Set this item to "ON" or open ECG TRACE MENU to display a 1 mv calibrated ECG signal. In this condition “CALIB” is shown above the signal.

■ **LARGE SIGNAL**

You can set this item to ON or OFF in ECG TRACE MENU of P1. Select ON to display only ECG signal in the waveform area.

6-6 ECG EXTRA MENU

If more than one ECG signal (2 or 4 signals) is displayed in the selected page, you can choose the lead of each signal separately by pressing that signal. Each lead can be selected once.

6-7 ECG Alarm Messages

Alarm sound is activated when:

The heart rate exceeds adjusted alarm limits, and/or the ECG ASYSTOLE happens.

a) Physiological Alarms

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

b) Technical Alarms

Message	Cause/Solution	Remarks
ECG NO CABLE	Cause: ECG cable is not connected to the system. Solution: Connect ECG cable	Level 3 alarm. The message is displayed in the cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
ECG CHECK LA,RA,LL	Cause: The mentioned leads are not properly connected to the patient. Solution: Make sure that the electrodes are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

ECG ALARM

Message	Cause/Solution	Remarks
ECG DEFECT	Cause: ECG module fault Solution: Turn off and then on the system .If the message is displayed again, contact the Customer Services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
CHECK RL OR ALL	Cause: RL or other leads are not properly connected to the patient. Solution: Make sure that all electrodes especially RL and also ECG cable are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

ECG ALARM

Message	Cause/Solution	Remarks
CHECK LL OR ALL	Cause: LL or other leads are not properly connected to the patient. Solution: Make sure that all electrodes especially LL and also ECG cable are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
CHECK LA OR ALL	Cause: LA or other leads are not properly connected to the patient. Solution: Make sure that all electrodes especially LA and also ECG cable are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
CHECK RA OR ALL	Cause: RA or other leads are not properly connected to the patient Solution: Make sure that all electrodes especially RA and also ECG cable are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

ECG Cable Cleaning

Message	Cause/Solution	Remarks
ECG CHECK C (C2, C3, C4, C5, C6)	Cause: C lead is not properly connected to the patient. Solution: Make sure that all mentioned electrodes and ECG cable are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE,background becomes gray and alarm is disabled and ignores this fault.

Chapter 7, ARR Monitoring

Contents

7-1 General Information

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.

If arrhythmia monitoring is “ON”, the heart rate is calculated by the arrhythmia software.

This monitor can detect up to 13 types of arrhythmias.

Arrhythmia monitoring is available for adult and pediatric patients and it is not recommended for neonates.

Applied lead for ST, ARR, Pace and HR is main lead. In all pages (except P2) this lead is displayed in the first trace and can be set in ECG Trace menu.

⚠ Warning ⚠

The ARR monitoring can only be carried out by trained personnel who are knowledgeable about this manual.

⚠ Warning ⚠

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

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 detectable arrhythmias by the monitor:

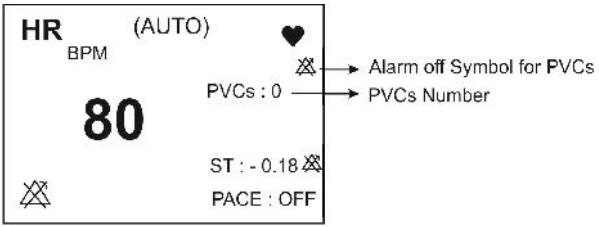
Arrhythmia	Event and Beat Classification
ECG ASYSTOLE	5 seconds pass without the detection of valid QRS complex.
VFIB ARRHYTHMIA	Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics. (Certain ventricular tachycardias have sinusoidal waveforms closely 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.

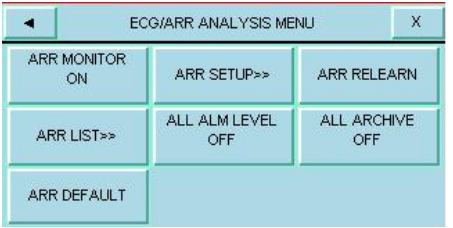


PVC value in ECG parameter area

When PACE is turned on (for patient with pacemaker), the system will not detect the relevant arrhythmias to premature ventricular beats.

7-2 ARR ANALYSIS Menu

Select ARR ANALYSIS in ECG PARAM MENU to access the below menu.



■ **ARR MONITOR**

Select this item to enable or disable arrhythmia monitoring. The default is “OFF”. When the Arrhythmia monitoring is disabled, “PVCs OFF” is displayed in ECG parameter area.

■ ARR SETUP

Select “ARR SETUP” in ARR ANALYSIS menu to access the below menu:

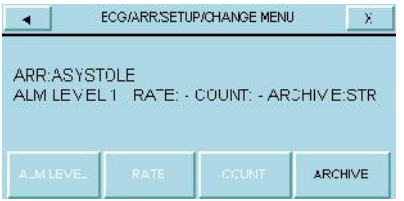
The ARR SETUP table allows you to configure arrhythmia monitoring accordingly to your patient’s needs. All detectable arrhythmia events listed in the first column of the table .Using the remaining columns, you can modify the attributes of each event. Fields that are not applicable for certain event category are shown with dash symbol, while those that cannot be modified are ghosted. Arrhythmia default settings are shown in the figure 11-3.

ARR Analysis Menu

1.Press ▲ ▼ to scroll up or down and select your desired arrhythmia event to configure.

2.Press ⏫ ⏬ to scroll through pages.

3.Press CHANGE to access settings of the selected arrhythmia event in the below menu.



ECG/ARR/ SETUP/CHANGE MENU

■ **ALM LEVEL**

Available options are 1and 2. Level 1 means the most serious case (For more information about alarm levels, refer to the Alarm chapter).

ALARM LEVEL cannot be set for “ASYSTOLE”, “VFIB” and “VTAC” arrhythmias and always is 1.

- **RATE**

With count, you can determine the point at which an event call is triggered.

You cannot modify the rate for “ASYSTOLE”,” VFIB”, ”COUPLET”, ”BIGEMINY”, ”TRIGEMINY”, “PAUS”, “ AFIB” and “FREQUENT PVCs” .

Rate setting of “RUN” and “AIVR” is taken from “VTAC” and cannot be set.

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 cannot set the count for “ASYSTOLE”, “VFIB”, “COUPLET”,“BIGEMINY”,“TRIGEMINY”, “TACHY”, “BRADY”,“AFIB” and “PAUSE”.

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 occurs.

- **ALL ALARM 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 RELEARN**

Select to start a learning procedure. The message "RELEARN" is displayed in the message area.

In most situations the learning procedure takes about 20 seconds.

You can do relearn procedure by selecting <ARR RELEARN> in ECG/ARR ANALYSIS menu.

If the monitor couldn't find 6 matching beats after 20 seconds, the relearn procedure continues and the "RELEARN" message remains on the screen till acceptable condition happens.

Before starting learning procedure, verify quality of the ECG signal and ensure that it displays a normal reference pattern.

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

■ ARR LIST

Select “ARR LIST” in ECG/ARR ANALYSIS menu to access the below menu:

You can review any stored arrhythmia event (maximum 80 events) in this menu.

■ To review different pages of ARR list:

Maximum 5 arrhythmia events can be displayed in each page of “ARR LIST” menu. When there is more than 5 events, different pages are available.

Press ⏫ ⏬ to review different pages.

Press ▲ ▼ to select an arrhythmia event.

■ To see detailed information of an arrhythmia event:

ARR Analysis Menu

Select WAVE to access the below menu.

In this menu, waveform and time of the selected arrhythmia event as well as other vital sign parameters at the event time are displayed.

▲ ▼ and ⏫ ⏬ buttons allow you to page up and down to review the waveforms and the parameters of different arrhythmia events.

■ REC in ARR WAVE Menu

This item allows you to record the arrhythmia signal. If settings of REC SWEEP: 25mm/s and REC TIME:12 sec are selected in HOME /RECORDER menu, arrhythmia signal will be recorded for about 12 seconds. This record starts from 6 seconds before arrhythmia event and will continue until 6 seconds after that.

■ To delete/undelete an arrhythmia event:

Select “DEL/UNDEL” to choose an arrhythmia event for removing from the list. When you select this item, the selected event will be highlighted and deleted if you exit the ARR LIST menu.

ARR Analysis Menu

■ REC in ARR LIST Menu

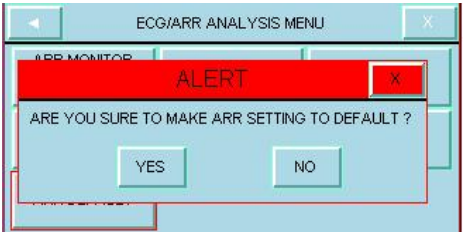
This item allows you to record the arrhythmias list.

If an arrhythmia event persists, it will be stored in ECG/ARR ANALISIS/ARR LIST MENU for one time, but if this event is removed and then reoccurs, it will be stored twice.

To ignore deleting a selected item, press the "DEL/UNDEL" button one more time before exiting the menu.

■ ARR DEFAULT

Select this item to load the manufacturer default settings for ARR parameter. Because all your previous settings will be missed by selecting this item, the system asks for your confirmation before changing settings (figure 11-7).



7-3 ARR Alarm Messages

Alarm	Situation	Visual Alarm	Audio Alarm
ASYSTOLE ARRHYTHMIA	5 seconds pass without the detection of valid QRS complex.	● Alarm indicator flashes. ● Alarm message is displayed in red background.	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	● Alarm indicator flashes. ● Alarm message is displayed in red background.	Activated (If ARR Monitoring is ON)

	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.	● Alarm indicator flashes. ● Alarm message is displayed in red background.	Activated (If ARR Monitoring is ON)
RUN ARRHYTHMIA	Ventricular Run: Series of 3 to N-1 consecutive PVCs with a beat to beat rate ≥ the VTAC rate.	● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)

ARR Alarm Messages

Alarm	Situation	Visual Alarm	Audio Alarm
AIVR ARRHYTHMIA	Accelerated Idioventricular Rhythm: Series of 3 or more PVCs with a beat rate less than the VTAC rate.	● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)
BIGEMINY ARRHYTHMIA	Ventricular Bigeminy: Sequence of beats with the pattern : normal, PVC, normal, PVC, normal, PVC	● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)
COUPLET ARRHYTHMIA	Ventricular Couplet: Sequence of beats with the pattern : normal, PVC, PVC, normal, PVC, PVC	● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)

ARR Alarm Messages

Alarm	Situation	Visual Alarm	Audio Alarm
TRIGEMINY ARRHYTHMIA	Ventricular Trigeminy: Sequence of beats with the pattern : normal, normal, PVC, normal, normal, PVC	● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)
TACHY ARRHYTHMIA	Sinus Tachycardia: HR ≥ TACHY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.	● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)
BRADY ARRHYTHMIA	Sinus Bradycardia: HR≤ BRADY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.	● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)

ARR Alarm Messages

Alarm	Situation	Visual Alarm	Audio Alarm
AFIB ARRHYTHMIA	Atrial Fibrillation: Formation of QRS complexes in irregular intervals	●Alarm indicator flashes. ●Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)
PAUS ARRHYTHMIA	Actual R-R interval more than 2.1 times of the average R-R interval.	●Alarm indicator flashes. ●Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)
FREQUENT PVCs	More than N (event count set in the ARR SETUP WINDOW) PVC per minute.	●Alarm indicator flashes. ●Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)

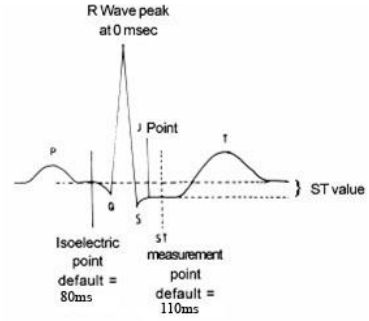
Chapter 8, ST Monitoring

Contents

8-1 General Information

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.



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.

ST monitoring is available for adult and pediatric patient and it is not recommended for neonates.

 If there are not at least 5 normal complexes in the last 50 beats of ECG signal, the ST value will not be displayed.

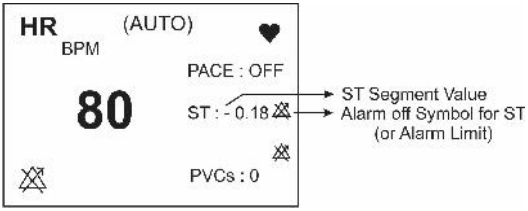
Applied lead for ST, ARR, Pace and HR is reference lead that is displayed in the first trace and can be adjusted in ECG menu.

Applied lead for ST, ARR, Pace and HR is main lead. In all pages (except P2) this lead is displayed in the first trace and can be set in ECG Trace menu.

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.

Measurement unit of ST segment is “mV”.



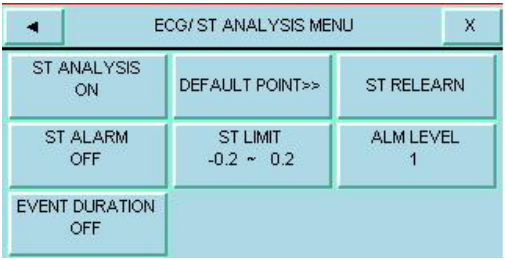
ST value in ECG parameter area

Measurement range of ST segment is between -2.0 mV to +2.0 mV.

Positive ST segment value (+) means elevating and negative value (-) means depressing.

8-2 ST ANALYSIS

Select ST ANALYSIS in ECG PARAM MENU to access the below menu.



■ **ST ANALYSIS**

Select 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 ANALYSIS MENU

■ ST ALARM

Select "ON" to enable ST alarm indications such as parameters blinking, audio alarm and light indicator.

Select "OFF" to disable the alarm indications and call up "  "symbol in the ST parameter area.

■ ALM LEVEL

Available options are 1and 2. Level 1 means 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

Select 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

Select 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.

 You can do relearn procedure by selecting ST RELEARN in ECG/ST ANALYSIS window. The message “RELEARN” will be displayed in the message area.

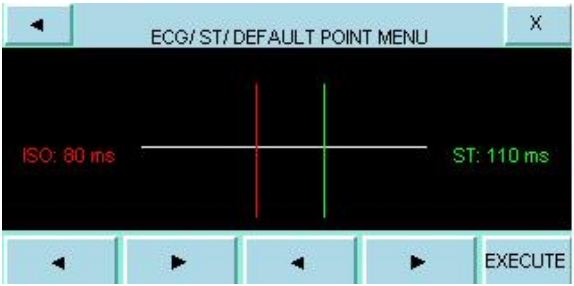
The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ST ANALYSIS is ON and there is no technical ECG alarm active, like CHECK LEAD):

- Turning on the monitor
- Connecting ECG cable.
- Changing an ECG lead configuration.
- Choosing “NEW” in HOME / PATIENT INFORMATION

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**

Select "DEFAULT POINT" in the ST ANALYSIS MENU to access the below menu in which you can adjust the position of both ISO and ST measurement points. When you change the ST and ISO measuring points, the monitor recomputes the ST deviation value accordingly.



As shown above, the DEFAULT POINT MENU 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.

It is good clinical practice to check the position of ISO and ST measuring points before starting ST monitoring and finishing learning procedure.

In practice, accurate determination of ISO and ST measuring points requires careful clinical evaluation.

The ST measurement point should be adjusted if patient's HR value or ECG signal 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.

Abnormal QRS complex is not considered in ST segment analysis.

When Pace is ON (for patient with pacemaker) or during learning procedure, there is no waveform in DEFAULT POINT Menu and you can see just ISO and ST lines. In this condition, ST value will not be measured.

A red vertical marker with “CHG” label on ST in TREND window shows the time in which the measuring point has been changed.

8-3 ST Alarm Messages

The alarm is triggered when ST value violates the adjusted alarm limits.

a) Physiological Alarms

Alarm	Situation	Visual Alarm	Audio Alarm
ST HIGH	ST segment value violates adjusted high limit	●ST value blinks. ●Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
ST LOW	ST segment value violates adjusted low limit	●ST value blinks. ●Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
APNEA	No respiration is detected for a certain time	●Alarm indicator flashes. ●"RESP APNEA" message is displayed in red background.	Activated

ST messages include:

b) Technical Alarms

Message	Cause/Solution	Remarks
ST OUT OF RANGE HIGH	The ST value has been calculated outside the high level 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 value has been calculated outside the low level 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. If you press ALARM SILENCE key, the message background will change to the gray and the alarm is disabled for 120 s.

Chapter 9, RESP Monitoring

Contents

9-1 General Information

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

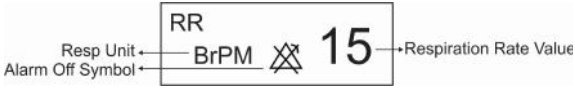
The RESP monitoring is not recommended to be used on patients, with extra movements, as this can cause false alarms.

9-2Patient Preparation

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.

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.

RESP parameter window is as below:



RESP Window

9-3 RESP PARAM MENU

Touch RESP parameter area to access the below menu:

RESP PARAM MENU

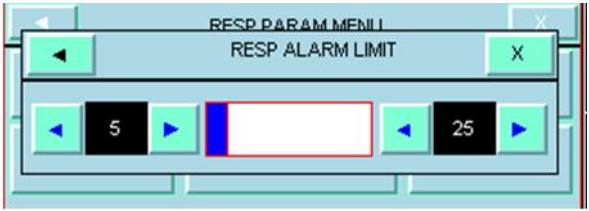
■ **RR ALARM**

Select "ON" to enable RESP alarm indications such as parameters blinking, audio alarm and light indicator.

Select "OFF" to disable the alarm indications and call up " " symbol in the RESP parameter area.

■ **ALM LIMIT**

Press this option to access the below window:



RESP PARAM MENU

RESP alarm is activated when the respiration rate (RR) violates adjusted ALARM HIGH and LOW limits.

Low limit: 5 ~ (High limit- 1)

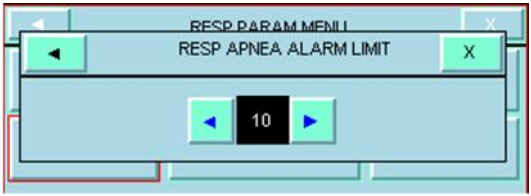
High limit: (Low limit +1) ~ 150

■ **ALM LEVEL**

Available options are 1and 2. Level 1 means the most serious case.

■ **APNEA LIMIT**

Press this item to access the below window:



RESP PARAM MENU

You can set the standard of judging an apnea case in this window. It ranges from 10 to 40 and OFF and increases /decrease by 5 sec.

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

.

9-4 RESP TRACE MENU

Touch RESP waveform area to access the below menu:

■ **LEAD**

Available options are "RA-LA ”and “RA-LL".

■ **GAIN**

Select to adjust the size of RESP waveform. Gain options for each lead are ×0.25, ×0.5, ×1, ×2 and ×4.

■ **SWEEP**

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

9-5 RESP Alarm Messages

The alarm is triggered when the respiration rate violates adjusted alarm limits.

a) Physiological Alarms

ALARM	**R HIGH**
SITUATION	Respiration rate violates adjusted high limit
VISUAL PROMPTS	●RESP value blinks ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**R LOW**
SITUATION	Respiration rate violates adjusted low limit
VISUAL PROMPTS	●RESP value blinks ● The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.
AUDIO OUND	Activated
ALARM	**PNEA**
SITUATION	Non-respiration condition overruns adjusted time
VISUAL PROMPTS	● The alarm indicator flashes. ●"RESP APNEA" is displayed in red background.
AUDIO SOUND	

RESP Alarm Messages

RESP messages include:

b) Technical Alarms

Alarm	RESP CHECK LEADS
Cause	The RESP leads are not properly connected.
Solution	Ensure that all electrodes are connected properly.
Explanation	Level 3 alarm. The alarm is displayed in the cyan background. By pressing Silence key, the alarm background will change to gray and the system will ignore this fault.

Chapter 10, SPO2 & Masimo Rainbow ✳ Monitoring

Contents

10-1 General Information

Masimo Rainbow module is the only technology which measures multiple blood parameters as well as common pulse oximetry parameters in a continuous and noninvasive method that traditionally measured through the invasive and time-consuming methods. This module has been designed by Masimo Company and offered 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

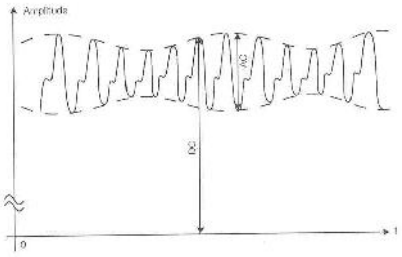
PR indicates the Heart Rate per minute which SpO2 module extracts from the pulse oximetry signal.

Perfusion Index

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

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

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



PI definition

PI greater than 1% is preferable

Each of the below parameters can be used only if its software is enabled by the manufacturer and its specific probe is available.

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:

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

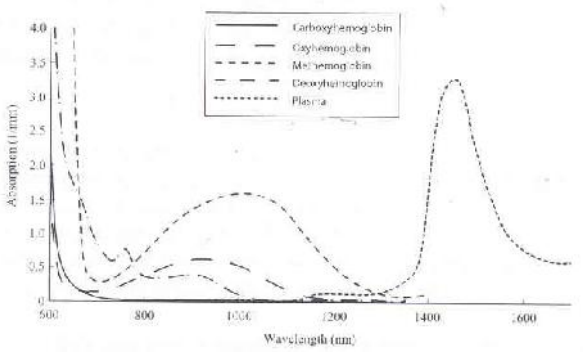
PVI can help clinicians predict fluid responsiveness in patients.

■ 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.

Principle of operation:

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).

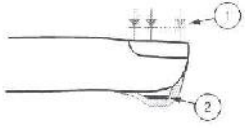


Absorption Spectra

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.



1. Light Emitting Diodes (LEDs) (7 + wavelengths)
2. Detector

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.

10-2 Nots & Warning

A pulse oximetry is an early warning system. Use lab co-oximeter to check the patient's condition completely.

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.

Assessment of pulse oximeter probe or pulse oximeter monitor accuracy cannot be performed by simulators and functional testers.

⚠ 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 module in chapter accessories .

⚠ **Warning** ⚠

While choosing sensor, consider the 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 sensor if its packaging or the sensor is damaged and return it 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 them 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 after- sales service for servicing, if necessary.

Changes or modifications will void guaranty of 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 against 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 SPO2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied and cover the sensor site with opaque material. Failure to take this action in high ambient light conditions may result in inaccurate measurements.

⚠ Warning ⚠

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.

⚠ Warning ⚠

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.

⚠ Warning ⚠

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

⚠ Warning ⚠

Variation in hemoglobin 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.

SPO2 module updates parameters values every 1 second.

Do not perform SPO2 and NIBP measurements on the obstruction of blood same arm simultaneously; because flow during NIBP measurement may adversely affect the SPO2 value.

Measurement range of SPO2 and PR parameters is as follows:

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

Measurement range of MASIMO Rainbow set is as follows:

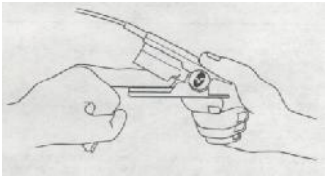
Parameter	Measurement range
SpMet	0.0 – 99.9%
SpCO	0.0 – 99%
SpHb	0.0 – 25.0 g/dL
SpOC	0.0 – 35.0 ml /dL
Perfusion Index	0.0 – 20%
PVI	0 – 100%

Nots & Warning

The materials used in 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 7-4 for proper method).
3. Connect the sensor cable to the SPO2 socket on the left side of the device.



SPO2 sensor placement

Nots & Warning


Make sure the nail covers the light window.


The sensor wire should be placed above the hand.


SPO2 value always is displayed in a fixed position in 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**

Nots & Warning

- **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).

⚠ Warning ⚠

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

⚠ Warning ⚠

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 SPO2 monitoring may cause 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.

⚠ 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.

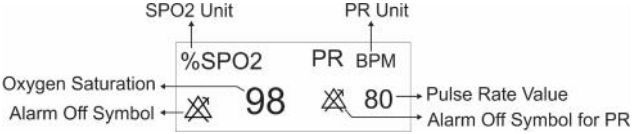
⚠ Warning ⚠

Low pulse signal can occur when:

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

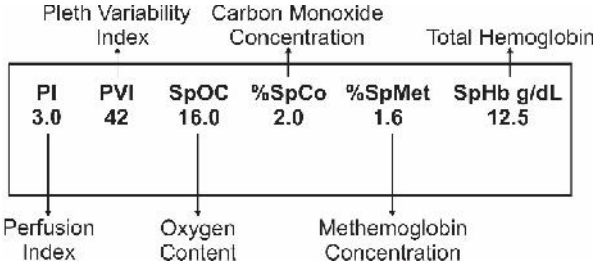
10-3 SPO2 PARAM MENU

SPO2 parameter window is as below:



SPO2 Window

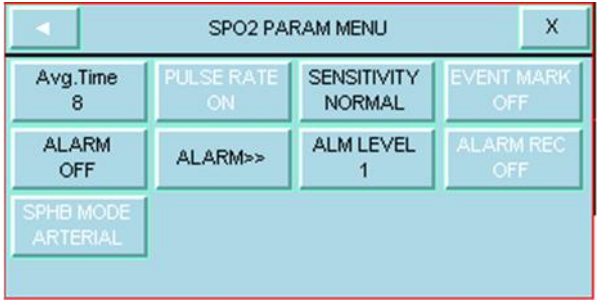
In the pages which contain Rainbow parameters, you can see the following window beside the SPO2 window:



Rainbow Window

SPO2 PARAM MENU

Touch SPO2 parameter area to access the below menu:



In P8 and P9 you can set Beat Volume in SPO2 PARAM MENU.

■ AVERAGE TIME

Available options for this item are 2~ 4, 4~ 6, 8, 10, 12, 14 and 16 seconds.

■ SENSITIVITY

Available options for SPO2 SENSITIVITY are "NORMAL", "MAX SENSE" 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 SENSE**：

Recognizing that some clinicians may want the absolute low perfusion performance (0.02%) in all of the monitoring time and may be willing to ignore sensor off detection, they can achieve this by setting SPO2 SENS MODE to MAX. This mode is recommended for patients in critical conditions. Maximum Sensitivity is designed to interpret and display data for even the weakest of signals.

This mode is recommended during surgeries and when clinician and patient contact is continuous.

In MAX mode, the message "MAX SENS" is displayed on the screen in white color.

⚠ 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** :

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).

In this mode, “APOD” appears in white color on the screen.

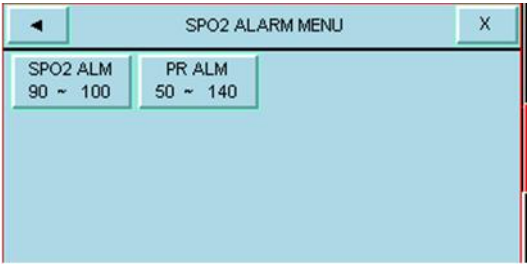
Every time that the system is turned off and on, SENSETIVITY changes to NORMAL mode.

■ ALARM ON/OFF

Select "ON" to enable SPO2 alarm indications such as parameters blinking, audio alarm, and light indicator. Select "OFF" to disable the alarm indications and call up " " symbol in the SPO2 and PR parameters area.

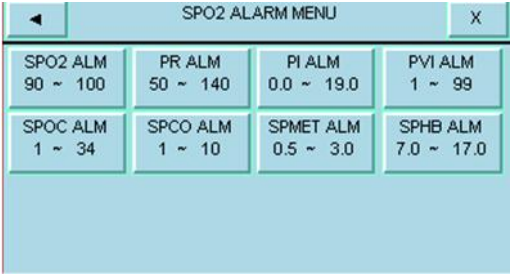
■ ALARM

By pressing this item, you can access SPO2 ALARM MENU and adjust SPO2 and PR alarm limits.



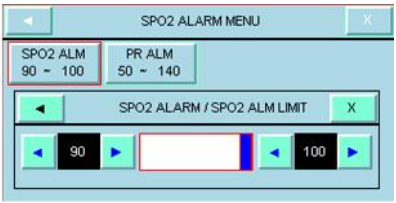
SPO2 PARAM MENU

You can set alarm limits of PI, PVI, SpOC, SpCO, SpMet and SpHb in the pages which contain Rainbow parameters. SPO2 ALARM MENU in these pages is as below:



SPO2 ALARM MENU (Rainbow parameters)

By selecting each parameter in SPO2 ALARM MENU, you can access Alarm Limit window of that parameter as shown ..



SPO2 PARAM MENU

Alarm limits of SPO2, PR and Rainbow parameters are as follows:

Parameter		Alarm Limit
SPO2	HIGH Alarm	SPO2 LOW Alarm +1 to 100
	LOW Alarm	SPO2 HIGH Alarm -1 to 1
PR	HIGH Alarm	PR LOW Alarm +5 to 235
	LOW Alarm	PR HIGH Alarm -5 to 20

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	PVI HIGH Alarm -1 to 1
SpCO	HIGH Alarm	SpCO LOW Alarm +1 to 99.0
	LOW Alarm	SpCO HIGH Alarm -1 to 1.0
SpMet	HIGH Alarm	SpMet LOW Alarm +0.5 to 99.5
	LOW Alarm	SpMet HIGH Alarm -0.5 to 0.5
SpHb	HIGH Alarm	SpHb LOW Alarm +0.1 to 24.5
	LOW Alarm	SpHb HIGH Alarm -0.1 to 0.5
SpOC	HIGH Alarm	SpOC LOW Alarm +1 to 34.0
	LOW Alarm	SpOC HIGH Alarm -1 to 1.0

■ ALARM LEVEL

Available options are 1and 2. Level 1 means the most serious case.

10-4 SPO2 TRACE MENU

Touch the SPO2 waveform area to access the below menu:

■ PLETH SWEEP

Available options for this item are 12.5 m/s and 25m/s.

10-5 SpO2 Alarm Messages

a) Physiological Alarms

ALARM	**%SPO2 HIGH**
SITUATION	SPO2 violates adjusted high limit
VISUAL PROMPTS	●SPO2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**% SPO2 LOW**
SITUATION	SPO2 violates adjusted low limit
VISUAL PROMPTS	●SPO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**PR HIGH**
SITUATION	Pulse rate violates adjusted high limit
VISUAL PROMPTS	●PR value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated

SPO2 Alarm Messages

ALARM	**PR LOW**
SITUATION	Pulse rate violates adjusted low limit
VISUAL PROMPTS	●PR value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**PI HIGH**
SITUATION	PI violates adjusted high limit
VISUAL PROMPTS	●PI value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**PI LOW**
SITUATION	PI violates adjusted low limit
VISUAL PROMPTS	●PI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**PVI HIGH**
SITUATION	PVI violates adjusted high limit
VISUAL PROMPTS	●PVI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO	Activated

SPO2 Alarm Messages

SOUND	
ALARM	**PVI LOW**
SITUATION	PVI value violates adjusted low alarm limit.
VISUAL PROMPTS	● PVI value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**SpOC HIGH**
SITUATION	SpOC violates adjusted high limit
VISUAL PROMPTS	● SpOC value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**SpOC LOW**
SITUATION	SpOC violates adjusted low limit
VISUAL PROMPTS	● SpOC value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**SpCO HIGH**
SITUATION	SpCO violates adjusted high limit
VISUAL PROMPTS	● SpCO value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.

SPO2 Alarm Messages

AUDIO SOUND	Activated
ALARM	**SpCO LOW**
SITUATION	SpCO violates adjusted low limit
VISUAL PROMPTS	● SpCO value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**SpMet HIGH**
SITUATION	SpMet violates adjusted high limit
VISUAL PROMPTS	● SpMet value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**SpMet LOW**
SITUATION	SpMet violates adjusted low limit
VISUAL PROMPTS	● SpMet value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**SpHb HIGH**
SITUATION	SpHb violates adjusted high limit
VISUAL PROMPTS	● SpHb value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background

	corresponding to its level.
AUDIO SOUND	Activated

b)Technical Alarms

Alarm	**SPO2 NO CABLE**
Cause	SpO2 cable is not fully inserted to the patient monitor system.
Solution	Make sure that the SpO2 cable is correctly connected into the monitor.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 REPLACE CABLE**
Cause	The life of the SpO2 cable has expired.
Solution	Replace the SpO2 cable.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 CABLE DEFECT**
Cause	1. The SpO2 cable is damaged 2. SpO2 cable is not compatible.
Solution	1. Make sure that the Masimo SpO2 cable is correctly connected into the monitor. 2. Restore power to the instrument. If this alarm is displayed again, replace cable.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE,

	background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 NO SENSOR**
Cause	SpO2 Sensor is not fully inserted into the connector.
Solution	Make sure that SpO2 sensor is correctly connected into the patient cable connector.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 REPLACE SENSOR**
Cause	SpO2 sensor has used all its available monitoring time.
Solution	Replace the SpO2 sensor.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 SENSOR DEFECT**
Cause	1. The SpO2 sensor is damaged 2. SpO2 sensor is not compatible.
Solution	1. Make sure that SpO2 sensor is properly attached to the cable connector. 2. Restore power to the instrument. If this alarm is displayed again, replace sensor.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 SENSOR OFF**

SPO2 Alarm Messages

Cause	1-SpO2 Sensor may be detached from the patient. 2-Sensor not connected to patient properly. 3-Sensor is damaged.
Solution	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.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 NO AD SENSOR**
Cause	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.
Solution	connected to Ensure the adhesive portion is firmly the sensor.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 REPLACE AD SENSOR**
Cause	When a single-patient-use sensor is used, the life of the adhesive portion of the sensor has expired.
Solution	Replace the adhesive portion of the sensor.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 AD SENSOR DEFECT**
Cause	:When a single-patient-use sensor is used

SPO2 Alarm Messages

	.1. The adhesive portion of the sensor is damaged 2. SpPO2 sensor is not proper.
Solution	1. Make sure that SpO2 sensor is properly attached to the cable connector. 2. Power off and then on the system. If this alarm is displayed again, replace the adhesive portion of the sensor.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 AMBIENT LIGHT**
Cause	This may be caused by excessive ambient light sources such as surgical lights or direct sunlight, or other.
Solution	In the case of using rainbow sensor, place a sensor. Masimo Optical Light Shield over the
Explanation	Alarm level 2- the alarm 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".
Alarm	**SPO2 RAINBOW HARDWARE FAIL**
Cause	SpO2 hardware error
Solution	Restore power to the instrument. If this alarm is displayed again,contact After sales service of manufacturer.
Explanation	Alarm level 2- the alarm 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 Alarm Messages

Alarm	**SPO2 PROBE DEFECT**
Cause	Failure to properly operate sensor or cable or both of them.
Solution	Check the function of the sensor and the cable separately and replace the defective part.
Explanation	Alarm level 2- the alarm 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".
Alarm	**SPO2 SENSOR CHECK CONNECTION**
Cause	The sensor connection to the system is not correct
Solution	Check the sensor connection and, if necessary, replace the sensor and/or cable.
Explanation	Alarm level 2- the alarm 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".
Alarm	**SPO2 LOW SIGNAL IQ**
Cause	SpO2 measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.
Solution	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.

Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 LOW PR CONFIDENCE**
Cause	Pulse rate measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.
Solution	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 LOW PI CONFIDENCE**
Cause	PI measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.
Solution	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 LOW PVI CONFIDENCE**
Cause	PVI measurement does not have confidence due to poor signal quality caused by excessive motion or

SPO2 Alarm Messages

	other signal interference.
Solution	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 LOW SPOC CONFIDENCE**
Cause	SpOC measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.
Solution	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 LOW SPCO CONFIDENCE**
Cause	SpCO SpO2 measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.
Solution	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled

	and ignores this fault.
Alarm	**SPO2 LOW SPMET CONFIDENCE**
Cause	SpMet measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.
Solution	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**SPO2 LOW SPHB CONFIDENCE**
Cause	SpHb measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.
Solution	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

c)Messages

Message	**SPO2 CABLE NEAR EXP**
Cause	The SpO2 cable is near expiration.
Solution	
Explanation	In this condition SPO2 parameter is displayed.
Message	**SPO2 SENSOR NEAR EXP**
Cause	The SpO2 sensor is near expiration
Solution	
Explanation	In this condition SPO2 parameter is displayed.
Message	**SPO2 SENSOR NEAR EXP**
Cause	The SpO2 sensor is near expiration.
Solution	
Explanation	In this condition SPO2 parameter is displayed.
Message	**SPO2 AD SENSOR NEAR EXP**
Cause	The SpO2 adhesive sensor is near expiration.
Solution	If instrument fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
Explanation	In this condition SPO2 parameter is displayed blank.
Message	**SPO2 SEARCH**
Cause	Instrument is searching for pulse.
Solution	If instrument fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
Explanation	In this condition SPO2 parameter is displayed blank.
Message	**SPO2 SIGNAL WEAK**

SPO2 Alarm Messages

Cause	The SPO2 signal amplitude is too weak or undetectable.
Solution	Change the place of the probe.
Explanation	In this condition SPO2 parameter is displayed.
Message	**SPO2 DEMO MODE RUN**
Cause	The SpO2 measurement is in demo mode.
Solution	
Explanation	
Message	**SPO2 ONLY MODE**
Cause	Measuring rainbow parameters is not possible (due to the ambient light or the dark skin pigmentation).
Solution	Use a Masimo light shield to cover the sensor and adjust the sensor.
Explanation	In this condition SPO2 parameter is displayed.

Chapter 11, NIBP Monitoring

Contents

11-1 General Information

NIBP (Non-invasive Blood Pressure) processing by the monitor is based on the oscillometric measuring 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 and Diastolic 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 considering suitable thresholds before and after MAP pressure.

■ NIBP module has been designed in accordance with EN 1060-3.

■ Blood pressure measurement in this method is equivalent to the cuff- Stethoscope method.

■ This module is applicable to neonates, pediatrics and adults.

■ There are three modes of measurement available: Manual , Automatic and STAT.

- 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, 24 hours.
- In STAT mode, measurement is performed up to ten times during 5 minutes and with 30s interval between measurements. In case of any error, the pressure measurement is suspended.

■ No problem occurs in using NIBP module adjacent to electro surgery equipment.

⚠ Warning ⚠

Use only manufacturer recommended blood pressure cuff and hose. Using other cuffs or hoses may result in inaccurate measurements.

⚠ Warning ⚠

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

⚠ 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 ⚠

1. You must not perform NIBP measurement on patients under any condition which the skin is damaged or expected to be damaged.

2. Ensure that the correct setting is selected when performing measurements on children. Pressure measurement for children in adult mode may cause damage to extremity.

⚠ Warning ⚠

According to safety standard, 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 unintentionally connected to intravascular fluid systems, allowing air to be pumped into blood vessel.

⚠ Warning ⚠

Before measurement check that appropriate setting has been selected for the patient (Adult, Pediatric or Neonate).

⚠ Warning ⚠

In this module 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 min in adult and pediatric modes and 90 seconds in neonate mode. 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 ⚠

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

⚠ Warning ⚠

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

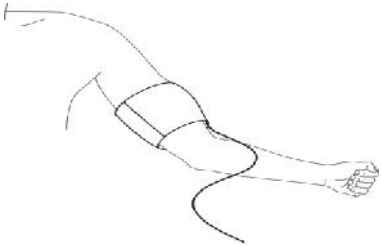
Preparatory steps for pressure measurement:

1- Plug in the air hose and switch on the system.

2- Apply the blood pressure cuff to the patient's arm or leg (Figure 8-1) and follow the instructions below.

- Ensure that the cuff is completely deflated.

- Apply the appropriate size cuff to the patient. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and dermal sensitivity.



Applying Cuff

The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous measurement. If the cuff size is in question, then use a larger cuff. (Refer to Accessories chapter for details).

3-Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart.

4-The patient mode should be selected appropriately. To select the patient mode, press Menu key to enter HOME/MENU, then by selecting PATIENT-ADMIT, you can access HOME/PATIEN/ADMIT MENU and perform your settings through PAT CONF item.

5- Select a measurement mode (Manual, Auto) in the NIBP WINDOW.

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

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

1. The patient is placed in a comfortable position.

2. The patient's feet are not on each other.

3. The feet should be on a flat floor.

4. The back and arm of the patient have a good support (for example a chair with back and arms)

5. 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 key on the front panel.

2-To stop MANUAL measuring, press the START/STOP key on the front panel.

3-To start AUTO measuring, select measuring intervals in NIBP window and then Press START/STOP key on the front panel.

⚠ Warning ⚠

Prolonged NIBP measurements in Auto mode may cause irritation and neuropathy in the limb wearing the cuff. Before monitoring a patient, examine the limb for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

4- To start a MANUAL measuring during the AUTO mode, press the START/STOP key on the front panel.

5- To stop AUTO measuring, Select the NIBP Window and set AUTO mode to MANUAL.
6- To start a STAT measuring, press the START/STOP key on the front panel.

⚠ Warning ⚠

Long-time and continuous measurements in STAT mode can result in muscular and neurotic harms or dermal injuries.

If you are in doubt about the accuracy of any measurement, check the patient's vital signs by an alternative method before checking connections, cuff, hose and the system functionality.

Measurement Limitations

In different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulses. 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 Arrhythmia**

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia causes an irregular heartbeat.

- **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.

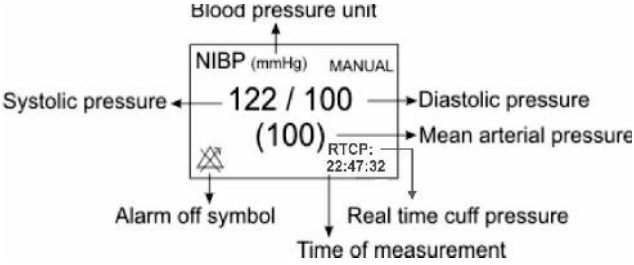
- **Severe Shock**

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

- **Abnormal Heart Rate**

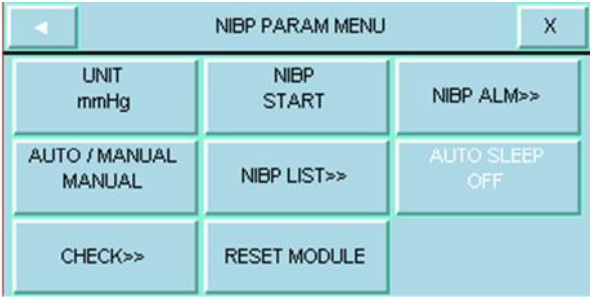
Measurement cannot be performed at a heart rate of less than 40 bpm and greater than 240 bpm.

11-2 NIBP PARAM MENU



NIBP Window

NIBP PARAM MENU is as follows:



NIBP PARAM MENU

■ **UNIT**

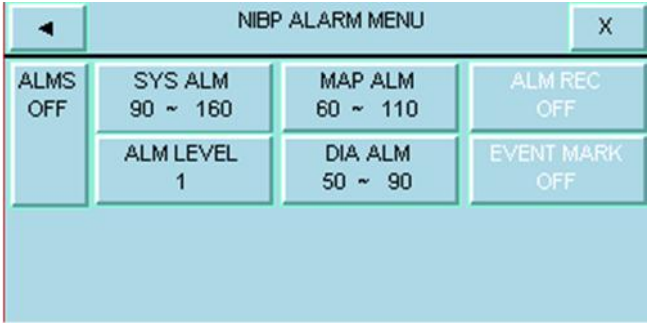
Select to adjust measurement unit. Available options are mmHg and KPa.

■ **NIBP START/ STOP**

Select this item to start or stop NIBP measurement.

■ **NIBP ALM**

Press this item to access NIBP ALARM MENU.



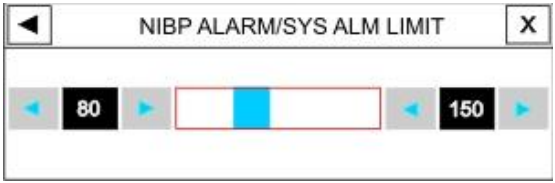
- **NIBP ALM ON/OFF**

Select "ON" to enable all alarm indications such as parameters blinking, audio alarm, and light indicator.

Select "OFF" to disable the alarm indications and call up "🔕"symbol in the NIBP parameter area.

- **SYS LIM**

By pressing this item, you can access NIBP ALARM/SYS ALM LIMIT window.



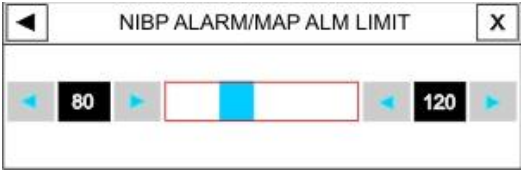
NIBP ALARM/SYS ALM LIMIT

SYS alarm is activated when the systolic pressure violates adjusted ALARM HIGH and LOW limits.

Adult → Low limit: 30 ~ (High limit -5), High limit: (Low limit + 5) ~ 255
Pediatric → Low limit: 30 ~ (High limit -5), High limit: (Low limit +5) ~ 240
Neonatal → Low limit: 30 ~ (High limit -5), High limit: (Low limit +5) ~ 135

- **MAP LIM**

By pressing this item, you can access NIBP ALARM/MAP ALM LIMIT window.



MAP alarm is activated when the mean arterial pressure violates adjusted ALARM HIGH and LOW limits.

Adult → Low limit: 20 ~ (High limit -5), High limit: (Low limit + 5) ~ 235

Pediatric → Low limit: 20 ~ (High limit -5), High limit: (Low limit +5) ~ 230

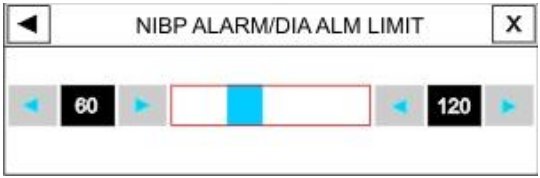
Neonatal → Low limit: 20 ~ (High limit -5), High limit: (Low limit +5) ~ 125

- **ALARM LEVEL**

Available options are 1and 2. Level 1 means the most serious case.

- **DIA LIM**

By pressing this item, you can access NIBP ALARM/DIA ALM LIMIT window.



DIA alarm is activated when the diastolic pressure violates adjusted ALARM HIGH and LOW limits.

Adult → Low limit: 15 ~ (High limit -5), High limit: (Low limit + 5) ~ 220
Pediatric → Low limit: 15 ~ (High limit -5), High limit: (Low limit +5) ~ 220
Neonatal → Low limit: 15 ~ (High limit -5), High limit: (Low limit +5) ~ 110

"ALARM REC" and "EVENT MARK" items are inactive.

■ STAT \AUTO \MANUAL

There are three modes of measurement available: MANUAL, AUTO and STAT. In the MANUAL mode, only one measurement is perfor

med. 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 and

90 minutes and 2, 4, 8, 12, 16, 20 and 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.

■ **NIBP LIST**

Patient monitor can store the latest 100 NIBP measurement values.

Press "NIBP LIST" in the NIBP WINDOW to review the results and times of the latest NIBP measurements, as shown in the figure.

NIBP PARAM MENU

Press ⏬ or ⏫ to select first or last measurement data.

Press ⏬or⏫ to scroll down or up and view preceding or following page.

Press ▼or ▲ to scroll down or up and select previous or next measurement data.

By pressing “DEL” button, you can delete selected data in this menu.

You can also delete all stored measurement values in this menu by selecting “DEL ALL” and pressing YES in alert message window.

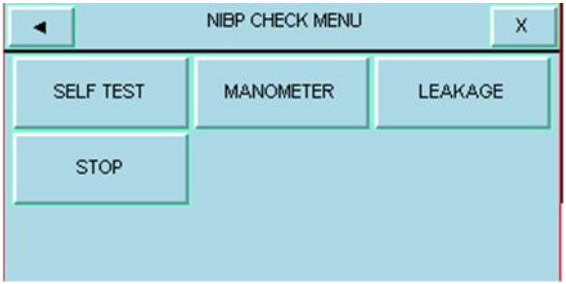
■ AUTO SLEEP

This item is currently inactive.

Select “ON” and press START button until the message “WAKEUP AT 9” appears in red on the NIBP window. Measurement resumes after 10 sec and a “SELF TEST is done during this time. (SELF TEST should be “ON”).

■ CHECK

By pressing this item, you can access the following menu:



The below tests must only be carried out by authorized and trained personnel.

- **SELF TEST**

Select this item to perform a self test on the NIBP module and check its general status, especially sensors and valves.

- **MANOMETER**

Wrap the cuff around a rigid cylinder. Connect a mercurial reference manometer and a ball pump by means of a T-piece connector and hose to the monitor. Set the monitor to "MANOMETER" mode. Inflate the pneumatic

system to 0, 50 and 200 mmHg by ball pump separately. The difference between the indicated pressure by the reference manometer and the indicated pressure by the monitor should not exceed ±3 mmHg.

- **LEAKAGE**

Wrap the cuff around a cylinder of an appropriate size, (The circumference of the applied cuff does not exceed that of the cylinder more than 7%). Set the monitor to

"LEAKAGE" mode. The monitor inflates the cuff up to 200 mmHg and keeps it constant for 15 sec .If air leakage result is satisfactory, "NIBP LEAK OK" message is displayed; otherwise you will receive "PNEUMATIC LEAK" message.

Above tests must only be done by the manufacturer trained and authorized personnel.

- **STOP**

To stop the NIBP measurement.

■ RESET MODULE

To set maximum inflation pressure of cuff to 150 mmHg for adults, 140 mmHg for pediatrics and 85 mmHg for neonates.

11-3 NIBP Alarm Messages

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

a) Physiological alarms

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

NIBP Alarm Messages

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

NIBP messages include:

b) Technical alarms

Message	**SELF-TEST FAILED**
Cause	NIBP hardware module failure
Explanation	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.
Message	**NIBP LOOSE CUFF**
Cause	Cuff is not properly wrapped or no cuff applied.
Explanation	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.
Message	**NIBP MODE ERROR**
Cause	Adult cuff is used instead of neonate cuff or occlusion happened in air way.

NIBP Alarm Messages

Explanation	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.
Message	**NIBP AIR LEAK**
Cause	Air leak in cuff, hose or connector.
Explanation	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.
Message	**NIBP AIR PRESSURE ERROR**
Cause	Unstable pressure value (e.g. tangled hose) because valves cannot open normally
Explanation	. 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.
Message	**NIBP SIGNAL WEAK**
Cause	Very weak patient signal due to a tightly wrapped cuff or weak pulse from patient.

NIBP Alarm Messages

Explanation	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.
Message	**NIBP RANGE EXCEED**
Cause	Measuring pressure is more than upper limit (255mmHg)for adult or (135mmHg) for neonate
Explanation	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.
Message	**NIBP EXCESSIVE MOTION**
Cause	Arm movement, noisy signal or irregular pulse (e.g. arrhythmia)
Explanation	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 Alarm Messages

Message	NIBP OVER PRESSURE SENSED
Cause	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)
Explanation	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.
Message	**NIBP SIGNAL SATURATED**
Cause	Large motion artifact that saturates the amplifier's amplitude handling capability.
Explanation	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.
Message	**NIBP PNEUMATIC LEAK**
Cause	Leakage during leak test
Explanation	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.
Message	**NIBP TIME OUT**
Cause	Measurement time exceeds 3 minutes (2 minutes in CAS module) for adults and pediatrics or 90 seconds for neonates.
Explanation	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.
Message	**SYSTEM FAILURE**
Cause	Error occurs in pump, A/D sampling, pressure transducer or software.
Explanation	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.
Message	**NIBP NO MODULE**
Cause	No NIBP module is installed.
Explanation	Alarm level is set in NIBP Window. By

NIBP Alarm Messages

	pressing ALARM SILENCE, the message background becomes gray and the alarm is disabled and ignores this fault.
Message	**NIBP LOW BATTERY**
Cause	The battery charge is not enough to measure NIBP.
Explanation	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.
Message	**NIBP MODULE ERROR**
Cause	Some errors occur during measurement.
Explanation	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.

c) Messages

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

If the message “NIBP MODULE ERROR” appears, wait about 10 seconds and then start the measurement again.

The alarm level for above messages is set in NIBP ALARM MENU.

By pressing SILENCE key, the message background will change to the gray and the system will ignore this fault.

11-4 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 12, TEMP Monitoring

Contents

12-1 General Information

Measurement of patient temperature is accomplished by processing the signal from a probe which is equipped with a temperature-dependent resistor (thermistor). The resistance value is measured by the monitor continuously and displayed on the screen. The patient monitor has two different kinds of temperature probe, a probe for esophageal/rectal temperature measurement and the 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

Accuracy of measured temperature is checked per minute by an internal reference resistor calibrated on temperature of 37.1˚C.

Inspection and recalibration

Inspect the probe for cracks, holes, breaks and etc prior to each use. If such degradation in probe is discovered, discard the probe according to your hospital's regulations for medical waste. When using temperature probe, the user must ensure that a probe style is suitable and sufficiently flexible for esophageal or rectal use.

TEMP probe cannot be recalibrated for each use, but it should be inspected monthly by the hospital Biomedical Equipment personnel to ensure that it is working properly. Two TEMP probes can be used together to obtain 2 temperature data and compare them to determine the temperature difference.

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

Plug the probe into a patient monitor and look for an electrical open or short–circuit, Intermittent reading or extremely inaccurate readings which would indicate probe wire damage. The probe stability is well-documented; the probe accuracy should not exceed the tolerance over the normal life of the probe.

⚠ Warning ⚠

Use only the manufacturer approved probes. Other probes may interfere with the system function.

Please note that the metal side of the probe contacts with the body.

⚠ Warning ⚠

Over straining will result in mechanical damage to the probes.

⚠ Warning ⚠

Using electrosurgical equipment with TEMP probe simultaneously may cause patient burn. If possible, remove the probe from patient contact before activating electro surgery device or other RF source. If probe must be used simultaneously with electro surgery apparatus, hazards can be reduced by selecting a temperature measurement point which is remote from the expected RF current path to the ground return plate.

⚠ Warning ⚠

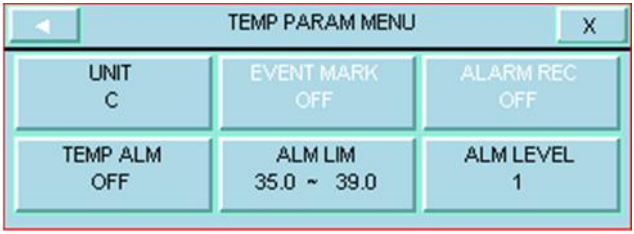
The calibration of the temperature measurement is necessary every two years or according to hospital procedures. When you need to calibrate the temperature measurement, contact the Manufacturer Customer Service.

The temperature probe carries a one-year warranty and normal and proper use will increase life time more than one year.

12-2 TEMP PARAM MENU

TEMP parameter window is as below:

Touch the TEMP parameter area to access the below menu:



TEMP PARAM MENU

■ **UNIT**

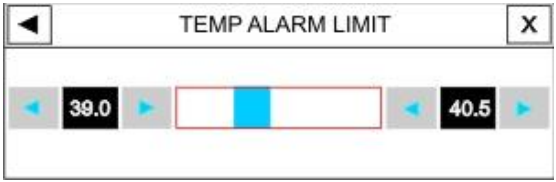
Select to set measurement unit. Available options are ºC and ºF.

■ **TEMP ALM**

Select "ON" to enable all alarm indications such as parameters blinking, audio alarm, and light indicator. Select "OFF" to disable the alarm indications and call up " " symbol in the TEMP parameter area.

■ **ALM LIM**

By pressing this item, you can access TEMP ALARM LIMIT window.



TEMP PARAM MENU

The TEMP alarm is activated when the temperature value violates adjusted ALARM HIGH and LOW limits.

LOW limit: 0 ~ (HIGH limit – 0.5) ˚C

HIGH limit: (LOW limit + 0.5) ~ 50 ˚C

■ ALARM LEVEL

Available options are 1and 2. Level 1 means the most serious case.

12-3 Physiological Alarms TEMP

ALARM	**T1 HIGH**
SITUATION	The temperature (T1) violates adjusted high limit
VISUAL PROMPTS	● T1 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**T1 LOW**
SITUATION	The temperature (T1) violates adjusted low limit
VISUAL PROMPTS	● T1 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated

Chapter 13, IBP Monitoring ✳

Contents

13-1 General Information

Specification:

Displaying and measuring ranges (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)

IBP PARAM MENU

Resolution 1 (mmHg)
Accuracy ±2 % or 2 mmHg each one is greater

IBP stands for Invasive Blood Pressure. Patient Monitor measures direct blood pressure (SYS, DIA and MEAN) of the selected blood vessel through two channels, and displays differential pressure between these channels.

⚠ Warning ⚠

The operator should avoid contacting with the metal parts of the system when it is being used.

⚠ Warning ⚠

When Electro surgery equipment is used simultaneous with IBP monitoring, the transducer and the cables should not be in contact with the conductive parts of Electro surgery to protect patient against burns.

⚠ Warning ⚠

Disposable IBP transducer should not be reused or sterilized.

⚠ Warning ⚠

Be careful that all packages are safe before using domes, and make sure that they are sterilized and pay attention to their expiry date.

Use only the pressure transducers listed in the Accessories chapter.

IBP PARAM MENU

IBP transducer is 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 ⚠

Check transducer cable fault detection before IBP monitoring. Unplug the transducer cable from the socket of channel 1, the monitor will display the error message "IBP NO SENSOR" and the audible alarm is activated with level 3. The second channel is the same.

⚠ Warning ⚠

Do not use the IBP cable and transducer which their packaging is damaged and return them to the vendor.

Preparatory steps for IBP measurement :

1. Plug the transducer 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 and make sure that there is no air in the catheter or pressure line.

⚠ Warning ⚠

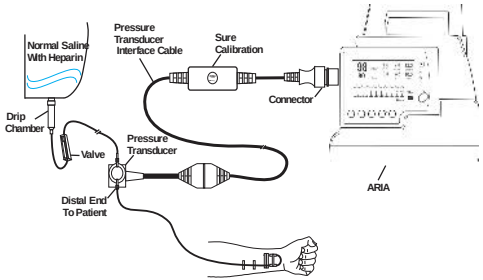
If there are air bubbles in the pressure line or the transducer, you should flush the solution through the system.

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.

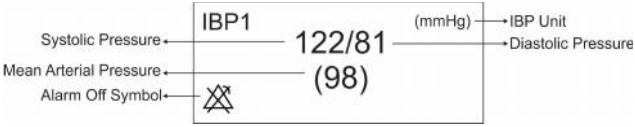
6. Zero the transducer. See the next section for details.

7. Calibrate the 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.



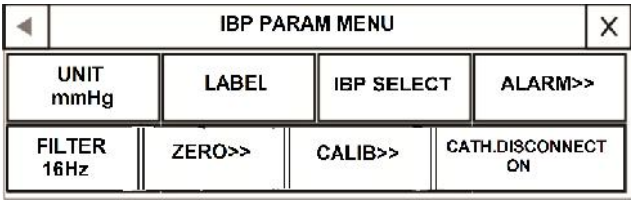
13-2 IBP PARAM MENU

IBP parameter window is as below:



IBP Window

The IBP PARAM MENU is as follows:



IBP PARAM MENU

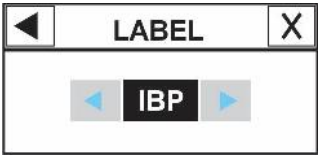
IBP PARAM MENU

- **UNIT**

Select this item to set measurement unit. Available options are KPa, mmHg and cmH2O.

- **LABEL**

By pressing this item, you can access the below window:



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

Label	Definition
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

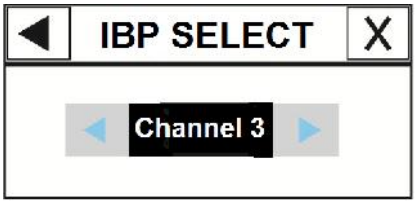
⚠Warning ⚠

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.

- **IBP SELECT**

By pressing this item, you can access the below window:

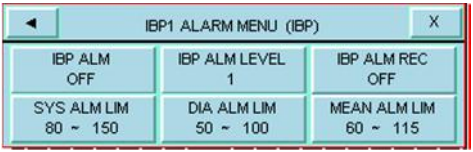
By selecting each IBP channel, you can view signal and parameter of the selected channel.



IBP PARAM MENU

■ ALARM

By pressing this item, you can access IBP ALARM MENU.



- **IBP ALM**

Select "ON" to enable all alarm indications such as parameters blinking, audio alarm, and light indicator. Select "OFF" to disable the alarm indications and call up "" symbol in the IBP parameter area.

- **IBP ALM LEVEL**

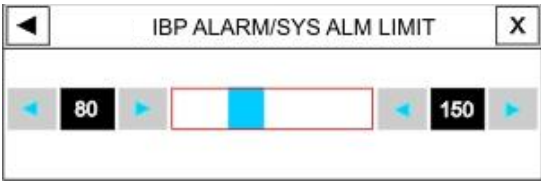
Available options are 1and 2. Level 1 means the most serious case.

- **IBP ALM REC**

See the chapter RECORDER.

- **SYS ALM LIM**

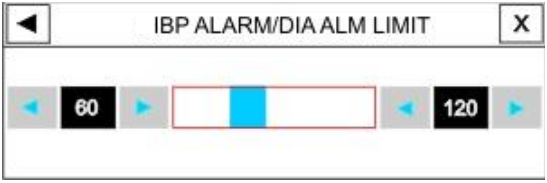
By pressing this item, you can access IBP ALARM/SYS ALM LIMIT.



SYS alarm is activated when the systolic pressure violates adjusted ALARM HIGH and LOW limits.

- **DIA ALM LIM**

By pressing this item, you can access IBP ALARM/DIA ALM LIMIT.

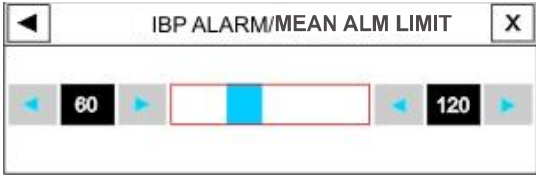


DIA alarm is activated when the diastolic pressure violates adjusted ALARM HIGH and LOW limits.

- **MEAN ALM LIM**

By pressing this item, you can access IBP ALARM/ MEAN ALM LIMIT.

IBP PARAM MENU



MEAN alarm is activated when the mean pressure violates adjusted ALARM HIGH and LOW limits.

The alarm High/Low limits for SYS, DIA and MEAN of ART, LVP, PAP, RVP, CVP, LAP, RAP and ICP labels are listed as follow. Note that the CVP, LAP and RAP only have MEAN pressure, therefore the alarm limits are only for MEAN.

The alarm enables when the parameters values violate 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

■ **FILTER**

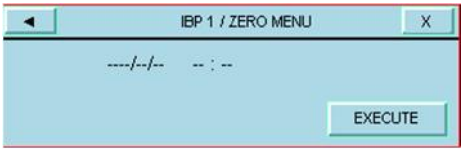
In order to have a clearer and more detailed waveform, three filter types can be selected:

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 mentioned filters.
16Hz: When the signal is a bit noisy.
8Hz: This mode is recommended to reduce noise and interference resulted from Electro surgery device 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.

■ **ZERO**

> in IBP PARAM MENU, you can >By pressing ZERO access the below menu:



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

Zero the transducer:

1-The transducer should be placed at mid-heart level.

2- Close the patient stopcock.

3-The transducer must be vented to atmospheric pressure.

4-Press < EXECUTE > to start zeroing procedure for each channel.

The message "PLEASE WAIT" will be displayed during the procedure. When the procedure is finished successfully, the message "IBP ZERO OK" appears.

The last zeroing time will be saved and displayed in its corresponding place.

5-Open the stopcock to the patient and close it to atmospheric pressure.

IBP PARAM MENU

The following messages may prompt up in ZERO WINDOW:

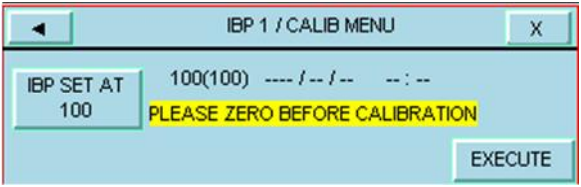
■ **"IBP NO SENSOR, UNABLE TO ZERO"**
Make sure that the transducer is connected or not, then start zeroing.

■ **"IBP OVERANGE, FAILED ZERO"**
Make sure that the stopcock is vented to atmosphere. If the problem persists, contact customer service.

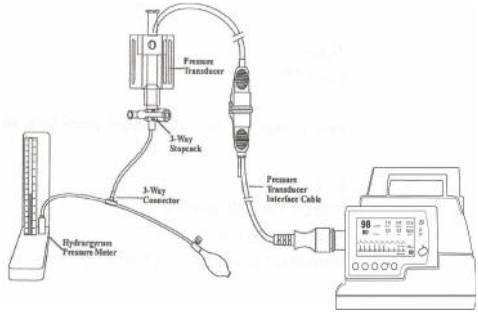
■ **"IBP UNSTABLE PRESSURE, UNABLE TO ZERO"**
Make sure that the transducer is not attached to the patient and that the stopcock is closed to atmosphere. It is also likely the tubing system is hit accidentally during zeroing. If the problem persists, please contact customer service.

■ **CALIB**

> in IBP PARAM MENU, you can >By pressing CALIB access this menu:



IBP/CALIB MENU



IBP CALIBRATION

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

■ The purpose of the calibration is to ensure that the system gives you accurate measurements and is compatible with applied transducer.

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

⚠ Warning ⚠

You must never perform calibration while patient is being monitored.

1. Attach the tubing system 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.
4. Open the port of the 3-way stopcock to the sphygmomanometer.
5. Raise the sphygmomanometer to set value that you adjusted in CALIB MENU.
6. Press EXECUTE in the CALIB MENU to start calibration.

The message "PLEASE WAIT" will be displayed during the procedure. "IBP CALIB 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:

■ **"IBP NO SENSOR, UNABLE TO CALIB"**

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

■ **"IBP OVERANGE, FAILED CALIB"**

Make sure that adjusted pressure in the menu and sphygmomanometer is equal. If the problem persists, contact customer service.

■ **"IBP UNSTABLE PRESSURE, UNABLE TO CALIB"**

Make sure that the transducer is not attached to the patient or the tubing system has not been hit accidentally. If the problem persists, contact customer service.

7. Remove the sphygmomanometer tubing and extra connector.

■ ART CATH. DISCONNECT ALM

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

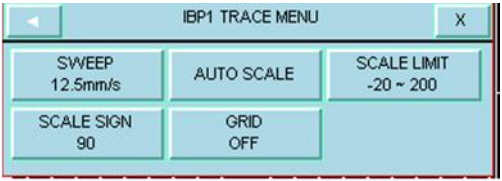
- The pressure drops dramatically.
- IBP signal becomes static and the MEAN pressure falls below 10 mmHg.
- The heart activity is not shown and the signal is displayed as a flat line.

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”.

13-3 IBP TRACE MENU

Touch the IBP waveform area to access the below menu:



■ **SWEEP**

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

■ **AUTO SCALE**

Select AUTO SCALE in IBP TRACE MENU to adjust the scale automatically. The scales are adjusted in a way that signal occupied approximately 80% of IBP waveform area.

■ SCALE LIMIT

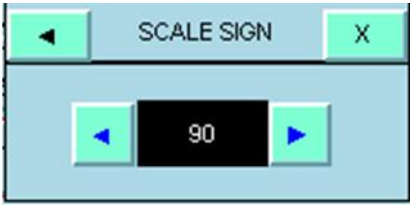
By pressing SCALE LIMIT in IBP TRACE MENU, you can access the below menu:

SCALE LIMIT

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. These scales can be set manually or automatically (Auto scale). You can change the scales for IBP, ART and LVP labels by step of 10 and for PAP, RVP, CVP, LAP, RAP and ICP labels by step of 5 (mmHg).

■ **SCALE SIGN**

By pressing SCALE SIGN in IBP TRACE MENU, you can access this menu:



SCALE SIGN of all IBP, ART, LVP, PAP, RVP, CVP, LAP, RAP and ICP labels can be changed by step of one.

■ **GRID**

Select "ON" to divide IBP signal area into 5 parts using white dotted lines.

13-4 IBP Alarm Messages

a) Physiological alarms

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

ALARM	**IBP SYS HIGH**
SITUATION	SYS violates adjusted high limit
VISUAL PROMPTS	● SYS value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**IBP SYS LOW**
SITUATION	SYS violates adjusted low limit
VISUAL PROMPTS	● SYS value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**IBP DIA HIGH**
SITUATION	DIA violates adjusted high limit
VISUAL PROMPTS	● DIA value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.

IBP Alarm

AUDIO SOUND	Activated
ALARM	**IBP DIA LOW**
SITUATION	DIA violates adjusted low limit
VISUAL PROMPTS	● DIA value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**IBP MEAN HIGH**
SITUATION	MEAN violates adjusted high limit
VISUAL PROMPTS	● MEAN value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**IBP MEAN LOW**
SITUATION	MEAN violates adjusted low limit
VISUAL PROMPTS	● MEAN value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated

b) Technical alarms

Alarm	IBP1/IBP2 NO SENSOR
Cause	Channel 1 or 2 transducer is not connected.
Solution	Check the transducer connection.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, the background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**IBP1/IBP2 STATIC PRESSURE**
Cause	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 alarm 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.
Solution	●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.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE,the background becomes gray and the alarm is disabled and ignores this fault.

IBP Alarm

Alarm	IBP1/IBP2 CATHETER DISCONNECT
Cause	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.
Solution	● 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
Explanation	Alarm level 1- The alarm 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	**IBP1/IBP2 ADJUST SCALE**
Cause	IBP1 or IBP2 signal is out of display range for about 5 seconds.
Solution	Press <AUTO SCALE> in IBP Menu.
Message	**IBP1/IBP2 SEARCH**
Cause	IBP signal can't be processed by the software because the signal is weak or less pulsatile.
Solution	●Check all IBP measurement setup is suitable or not. ●Check patient status and treat him, if necessary

Chapter 14,CO2 (Mainstream) Monitoring✳

Contents

14-1 General Information

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 follows:

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.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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.

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 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. 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.

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.

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 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.

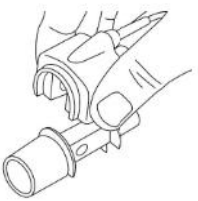
⚠Warning⚠

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.



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.

b. Preparatory Step 4

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

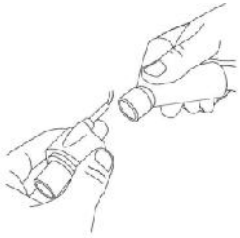
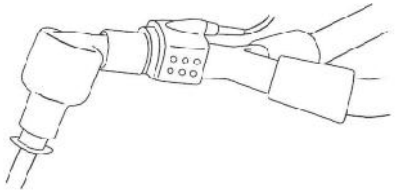


Figure c. Preparatory Step 5

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

Figure 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.



e. HME option

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

f. Preparatory Step 7

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

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.

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

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.

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.

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.

Do not apply tension to the sensor cable.

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

Always verify gas readings and waveforms on the patient monitor before connecting the IRMA airway adapter to the patient circuit. 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.

Perform the tightness check of the patient circuit with the IRMA sensor head snapped on the IRMA airway adapter.

Verify that there has not been any accumulation of gas between the IRMA sensor head and the XTP windows by checking that the CO2

readings on the monitor are correct before connecting a patient to the breathing circuit. Check that the connections have been made correctly by verifying an actual CO2 waveform on the monitor display

⚠Warning⚠

Don’t use the device in the environment which contains flammable anesthetic gas.

⚠Warning⚠

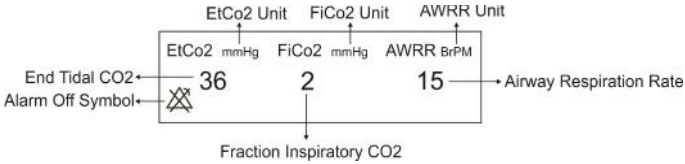
Before any interpretations are made of parameters readings and waveforms one, assure that the multi-gas probe is functioning correctly. Partial obstruction of airway with water can result in distorted waveforms. A leak in the airway may result in low

parameters measurements. Check the monitor to see if it is functioning properly.

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

14-2 GAS PARAM MENU

CO2 parameter window is as below:



Touch CO2 parameter area to access the below menu:

GAS PARAM MENU

After PHASEIN 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.

The system displays the Gas menu for IRMA sensor as default. If you connect ISA probe to the system and then exit the menu and enter it again, the menu will change for ISA sensor. This change also can be made in GAS ALARM menu.

- **UNIT**

Pick this item to adjust measurement unit. (Options: mmHg, KPa, %V)

EtCo2 in %V is the Co2 value (in mmHg) divided by ambient barometric pressure (in mmHg) which is a percentage of the barometric pressure.

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

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

- **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 cycle of IR source and IRMA sensor.

GAS PARAM MENU

If the monitor does not 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 cycle of IR source and IRMA sensor. The monitor will be set to "standby" mode.

When gas monitoring is not used, it is recommended to disconnect the sensor.

If the monitor does not detect adapter of IRMA sensor for 10 minutes after connecting IRMA sensor, the monitor automatically will be set to "standby" mode.

To reuse IRMA sensor, set the work mode to Measure.

- **ZERO**

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

A zero reference calibration should be performed whenever IRMA adapter is replaced or an offset in gas reading is discovered or when the message "CO2/N2O/AGENT INVALID, PLEASE ZERO" appears.

Zero reference calibration should only be performed by qualified service technicians, and should NOT be a part of normal operating procedures.

- After turning the monitor on, wait about 10 sec for IRMA (CO2) sensor to warm up and then start zeroing.
- After replacing the adapter, wait about 10 sec for IRMA (CO2) sensor to warm up and then start zeroing.

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

⚠ Warning ⚠

For accurate measurements, IRMA sensor should be set zero to room air.

⚠ Warning ⚠

Incorrect zeroing will result in false gas readings.

1. Select well ventilated room to perform the calibration.
2. Make sure the sensor is connected to the system and no error message is displayed (except APNEA)
3. Choose EXECUTE in the ZERO menu.

The message "PLEASE WAIT" will be displayed during the procedure. "ZERO IS OK." indicates that the zeroing procedure is completed successfully. The last zeroing time will be saved and displayed in its corresponding place. If an error happened during zeroing the error message will be displayed in the ZERO menu.

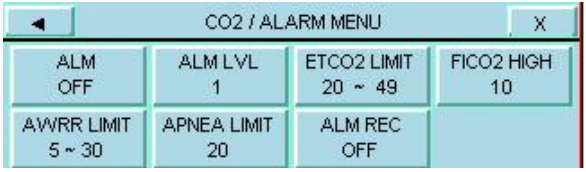
Special care should be taken to avoid breathing into the adapter during the zero reference calibration procedure.

GAS PARAM MENU

The presence of ambient air (21% O2 and 0%CO2) in the IRMA airway adapter is of crucial importance for a successful zero reference calibration. Always perform a pre-use check after performing zero reference calibration.

- **ALARM**

By pressing this item, you can access CO2 ALARM MENU.



- **ALM**

Select "ON" to enable all alarm indications such as parameters blinking, audio alarm, and light indicator. Select "OFF" to disable the alarm indications and call up "⚠" symbol in the multi-gas parameter area.

- **ALM LVL**

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

- **EtCO2 LIMIT**

The alarm is activated when the EtCo2 exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit (Range: 0.4~13.0%V , step 0.1%V).
Default for upper limit is 6.5%V and for lower limit is 2.6%V.

- **FiCO2 HIGH**

The alarm is activated when the FiCo2 exceeds adjusted ALARM HIGH limit.
(Range: 0.1~13.0%V, step 0.1%V), Default for upper limit is 1.3%V.

- **AWRR LIMIT**

The alarm is activated when the AWRR value 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 10 - 40 seconds and "OFF", increases/decreases by 5s. Select OFF to disable the alarm.

- **COMPENSATE**

The presence of oxygen and nitrous oxide 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 all IRMA sensors. Only when IRMA II (CO2) probe is connected to the monitor, N2O concentrates can be transmitted to the sensor. Available options for N2O COMPENSATE are 0-100%N2O.

The O2 compensation is performed automatically for all IRMA sensors with the oxygen sensor available on it. When using an IRMA without an oxygen sensor, i.e. when the oxygen measurement is performed by the other device like anesthesia machines and ventilators already have been

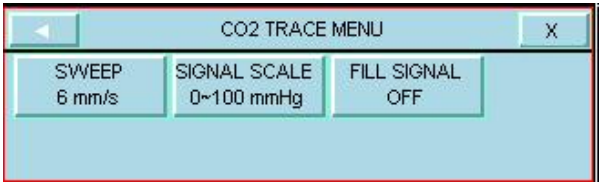
equipped with O2 measuring devices, the current oxygen concentration should be transmitted to the sensor.

When there is not O2 sensor, available options for O2 COMPENSATE are OFF and 1-100%O2. If there is O2 sensor, only "AUTO" option will be available and cannot be changed.

N2O COMPENSATE and O2 COMPENSATE are currently inactive.

14-3 GAS TRACE MENU

Touch the CO2 waveform area to access the below menu:



- **SWEEP**

Select this item to adjust speed of the CO2 signal sweeping. Available options for SWEEP are 3, 6, 12.5 and 25mm/s.

- **SIGNAL SCALE**

Depending on selected signal by user, different scales are available as the following table:

GAS TRACE MENU

Waveform Scale	
CO2	O2
0-50 mmHg, 0-6% 0-100 mmHg, 0-10% 0-200mmHg,0-20%V AUTOSCALE	0-50% 0-100% AUTOSCALE

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

- **FILL SIGNAL**

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

Indicator status on the IRMA sensor:

Steady green light	System OK
Flashing green light [1]	Zero Reference check in progress
Flashing blue light [2]	Existence of anesthetic agents
Steady red light	Sensor error
Flashing red light	Check adaptor

14-4 GAS Alarm Messages

a) Physiological alarms

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

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

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

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

Audio sound	Activated
Alarm	**FiN2O HIGH**
Situation	FiN2O violates adjusted high limit
Visual prompt	●FiN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
Audio sound	Activated
Alarm	**FiN2O LOW**
Situation	FiN2O violates adjusted low limit
Visual prompt	●FiN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level
Audio sound	Activated
Alarm	**EtAA HIGH**
Situation	End Tidal AA violates adjusted high limit
Visual prompt	●EtAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.

Audio sound	Activated
Alarm	**EtAA LOW**
Situation	End Tidal AA violates adjusted low limit
Visual prompt	●EtAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
Audio sound	Activated
Alarm	**FiAA HIGH**
Situation	FiAA violates adjusted adjusted high limit
Visual prompt	●FiAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
Audio sound	Activated
Alarm	**FiAA LOW**
Situation	FiAA violates adjusted adjusted low limit
Visual prompt	●FiAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.

Audio sound	Activated

b) Technical alarms

Alarm	**CO2 SYSTEM FAULT # 1,2,3,4**
Cause	Sensor error
Solution	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.
Explanation	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.
Alarm	**CO2 REPLACE ADAPTER**
Cause	IR signal low
Solution	Change adapter
Explanation	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.
Alarm	**CO2 NO ADAPTER**
Cause	There is no adaptor connected to the

	sensor.
Solution	Connect adapter
Explanation	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.
Alarm	CO2 INVALID
Cause	CO2 outside specified accuracy range.
Solution	Zero the sensor, if the problem still exists, contact after sales service of the manufacturer.
Explanation	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.
Alarm	**N2O INVALID**
Cause	N2O outside specified accuracy range.
Solution	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.
Explanation	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.
Alarm	**AGENT INVALID**
Cause	Agent outside specified accuracy range.
Solution	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.
Explanation	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.
Alarm	**AGENT MIXTURE**
Cause	In IRMA AX+ mode, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds.
Solution	
Explanation	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.
Alarm	**AGENT UNRELIABLE**
Cause	-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
Solution	
Explanation	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.
Alarm	**CO2 INVALID AMBIENT PRESSURE**
Cause	Ambient pressure outside operating range.
Solution	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.
Explanation	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
Alarm	**CO2 INVALID AMBIENT TEMPERATURE**
Cause	Internal temperature outside operation range.
Solution	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.
Explanation	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
Alarm	**CO2 NO SENSOR**
Cause	Sensor is disconnected from system
Solution	Connect sensor if problem exist again, Contact after sales service of manufacturer.
Explanation	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.

GAS ALARM

Alarm	**CO2 ZERO REFERENCE CALIB REQUIRED**
Cause	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.
Solution	Perform zeroing procedure in an environment with CO2 less than 0.80%V.
Explanation	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	**CO2 SENSOR STANDBY MODE**
Cause	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.
Solution	Enter GAS window and set WORK MODE on MEASURE.
Message	**CO2 UNABLE TO ZERO, SENSOR WARMING UP**
Cause	Zero button is pressed before waiting for the sensor to be warmed up (30 sec).

Chapter 15, CO2 (Sidestream) Monitoring✳

Contents

 Multi-gas module is not active in this version.

15-1 General Information

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.

The Vital signs monitor uses sidestream method for gases measurement.

General Information

A Nomoline sampling line is connected to patient respiratory circuit in ISA analyzers for monitoring of inhaled and exhaled gases during anesthesia, recovery or respiratory cares. ISA sensors may be used in operation room, ICU or patient room for emergency medical services or transportation emergency and they are applicable for neonates, pediatrics and adults.

Different configurations of this sensor are available in the market. The sensor has ability to identify CO2 gas by parameters as respiratory rate, waveform and concentration of inhaled/exhaled gases.

Different types of the sensor are as follows:

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 environments.

Warning

The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals 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.

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

(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.

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%

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.

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 CO2 possible for adult, pediatric and infant patients.

The Nomoline Family sampling lines incorporate a unique water separation (NO MOisture) 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.

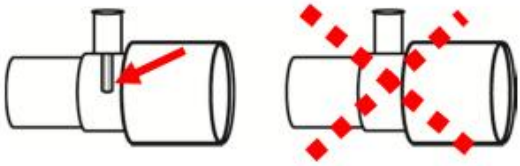
As long as no sampling line is connected, the ISA gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the ISA gas analyzer switches to measuring mode and starts delivering gas data.

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 CO2 Cannula or a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Nasal CO2 Cannula with Luer Connector.

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.

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)



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.

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

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)**

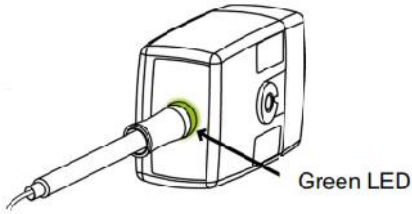
Preparatory steps for Multi-gas monitoring

To set up ISA analyzer, follow these steps:

1. Securely mount the ISA analyzer.
2. Connect the ISA analyzer interface cable into corresponding connector on the side panel of patient monitor.
3. Connect a Nomoline Family sampling line to the ISA analyzer input connector. It will click into place when properly seated.
4. 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.

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

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



Fifth Preparatory Step

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

⚠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.

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.

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.

⚠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 N2O 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.

⚠ 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.

⚠ Warning ⚠

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

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

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.

Variations in barometric pressure do not have any effects due to internal barometric pressure compensation.

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.

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.

⚠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.

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 CO2 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.

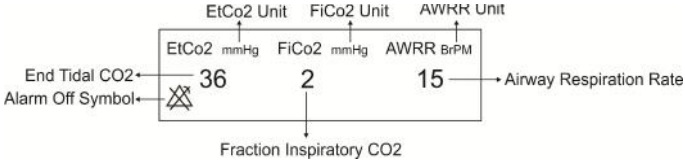
Warning

Since a successful zeroing requires the presence of ambient air (21% O2 and 0% CO2), 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.

Using special clamps, designed by the manufacture, for connecting ISA sensors to serum stand.

15-2 CO2 PARAM MENU

The CO2 parameter window is as below:



Touch the CO2 parameter area to access the below menu:

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.

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.

- **UNIT**

Pick this item to adjust the 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.

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

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

- **WORK MODE**

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

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.

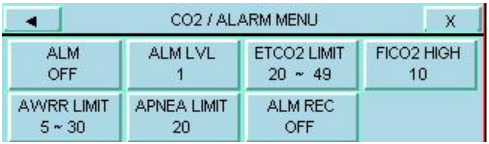
When not using gas monitoring functions, it is suggested to disconnect the sensor. When gas monitoring is not used, it is suggested to disconnect the sensor.

For enabling ISA sensor, you can enter Gas window and set the monitor to Measure mode.

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.

- **ALARM**

By pressing this item, you can access CO2 ALARM MENU.



CO2 PARAM MENU

- **ALM**

Select "ON" to enable all alarm indications such as parameters blinking, audio alarm, and light indicator. Select "OFF" to disable the alarm indications and call up "  " symbol in the GAS parameter area.

- **ALM LVL**

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

- **EtCO2 LIMIT**

The alarm is activated when the EtCo2 exceeds adjusted ALARM HIGH or LOW limit (Range: 0.4~13.0 %, step 0.1%)
Default for upper limit is 6.5%V and for lower limit is 2.6%V.

- **FiCO2 HIGH**

The 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**

The 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 10 - 40 seconds and "OFF" and increases/decreases by 5s.

- **COMPENSATE**

The presence of oxygen and N2O 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. 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.

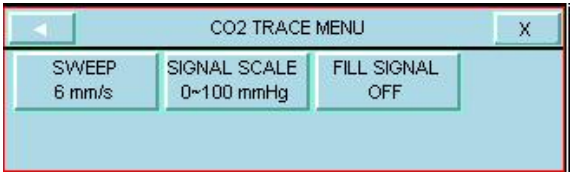
When there is not O2 sensor, available options for COMPENSATE are OFF and 1-100% O2. If there is O2

sensor, only "AUTO" will be available and it cannot be changed.

N2O 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.

15-3 CO2 TRACE MENU

Touch the GAS waveform area to access the below menu:



- **SWEEP**

Select this item to adjust speed of the Multi-gas signals sweeping. Available options are 3, 6, 12.5 and 25mm/s.

- **SIGNAL SCALE**

Depending on signal chosen by user, different scales are available as the following table:

Waveform Scale	
CO2	O2
0-50 mmHg, 0-6% 0-100 mmHg, 0-10% 0-200mmHg,0-20%V AUTOSCALE	0-50% 0-100% AUTOSCALE

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

- **FILL SIGNAL**

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

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

15-4 GAG ALARMS

a) Physiological alarms

The alarm occurs when the CO2 value violates the adjusted alarm limits.

ALARM	**AWRR HIGH**
SITUATION	Respiration rate violates adjusted high limit
VISUAL PROMPTS	●AWRR value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**AWRR LOW**
SITUATION	Respiration rate violates adjusted low limit
VISUAL PROMPTS	●AWRR value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**EtCo2 HIGH**
SITUATION	End Tidal CO2 violates adjusted high limit
VISUAL PROMPTS	●EtCo2 value blinks ●The alarm indicator flashes.

	● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**EtCo2 LOW**
SITUATION	End Tidal CO2 violates adjusted low limit
VISUAL PROMPTS	●EtCo2 value blinks ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**FiCo2 HIGH**
SITUATION	FiCo2 violates adjusted high The alarm limits
VISUAL PROMPTS	●FiCo2 value blinks ●The alarm indicator flashes ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**CO2 RESP APNEA**
SITUATION	Non-respiration condition overruns in adjusted time
VISUAL PROMPTS	●The alarm indicator flashes ●"CO2 RESP APNEA" blinks in red background.
AUDIO SOUND	Activated
ALARM	**EtN2O HIGH**
SITUATION	End Tidal N2O violates adjusted high limit
VISUAL	●EtN2O value blinks.

PROMPTS	●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**EtN2O LOW**
SITUATION	End Tidal N2O violates adjusted low limit
VISUAL PROMPTS	●EtN2O value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**FiN2O HIGH**
SITUATION	FiN2O violates adjusted high limit
VISUAL PROMPTS	●FiN2O value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**FiN2O LOW**
SITUATION	FiN2O violates adjusted low limit
VISUAL PROMPTS	●FiN2O value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated

ALARM	**EtAA HIGH**
SITUATION	End Tidal AA violates adjusted high limit
VISUAL PROMPTS	●EtAA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**EtAA LOW**
SITUATION	End Tidal AA violates adjusted low limit
VISUAL PROMPTS	●EtAA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**FiAA HIGH**
SITUATION	FiAA violates adjusted high limit
VISUAL PROMPTS	●FiAA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**FiAA LOW**
SITUATION	FiAA violates adjusted low limit
VISUAL PROMPTS	●FiAA value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.

GAS ALARMS

AUDIO SOUND	Activated
ALARM	**EtO2 HIGH**
SITUATION	End Tidal O2 violates adjusted high limit
VISUAL PROMPTS	●EtO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**EtO2 LOW**
SITUATION	End Tidal O2 violates adjusted low limit
VISUAL PROMPTS	●EtO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**FiO2 HIGH**
SITUATION	FiO2 violates adjusted high limit
VISUAL PROMPTS	●FiO2 value blinks. The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated

GAS ALARMS

ALARM	FiO2 LOW
SITUATION	FiO2 violates adjusted low limit
VISUAL PROMPTS	●FiO2 value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated
ALARM	**FiO2 Too Low**
SITUATION	FiO2 falls below 18%.
VISUAL PROMPTS	●FiO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.
AUDIO SOUND	Activated

b) Technical alarms

Alarm	**CO2 SYSTEM FAULT #1,2,3,4**
Cause	Sensor error
Solution	Turn the system off and on and if problem still exists, contact the manufacturer service department.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**CHECK SAMPLING LINE**
Cause	sampling line is not working
Solution	Replace the sampling line
Explanation	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
Alarm	**SAMPLING LINE CLOGGED**
Cause	Sampling line occlusion
Solution	Replace the sampling line
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
Alarm	**CO2 INVALID**
Cause	CO2 outside specified accuracy range.
Solution	Zero the sensor, if the problem still exists, turn off

	and on the system and if again this alarm appears contact after sales service of manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**O2 INVALID**
Cause	O2 outside specified accuracy range.
Solution	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**N2O INVALID**
Cause	N2O outside specified accuracy range.
Solution	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**AGENT INVALID**
Cause	Agent outside specified accuracy range.
Solution	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

GAS ALARMS

Alarm	AGENT MIXTURE
Cause	In ISA AX+ mode, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds.
Solution	
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
Alarm	**AGENT UNRELIABLE**
Cause	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
Solution	
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**CO2 INVALID AMBIENT PRESSURE**
Cause	Ambient pressure outside operating range.
Solution	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.

GAS ALARMS

Alarm	CO2 INVALID AMBIENT TEMPERATURE
Cause	Internal temperature outside operation range.
Solution	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
Alarm	**O2 SENSOR ERROR**
Cause	sensor failure
Solution	Please contact after sales service of manufacturer
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
Alarm	**CO2 ZERO REFERENCE CALIB EQUIRED**
Cause	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.
Solution	Perform automatic zeroing procedure in an environment with CO2 less than 0.80%V.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
Alarm	**CO2 NO SENSOR**
Cause	The sensor is disconnected from the system.
Solution	Connect the sensor. If the problem still exists, contact after sales service of manufacturer.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled

	and ignores this fault.

C)Messages

Message	**CO2 SENSOR STANDBY MODE**
Cause	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.
Solution	Enter GAS window and set WORK MODE on MEASURE.
Message	**CO2 UNABLE TO ZERO, SENSOR ARMING UP(for Mainstream)**
Cause	Zero button is pressed before waiting for the sensor to be warmed up (30 sec).
Message	**ZEROING IN PROGRESS(for Sidestream)**
Cause	The zeroing procedure is being conducted.
Solution	
Explanation	After that the zeroing procedure is completed, this message and a flat line signal will be displayed.

Chapter, 16 BFA Monitoring

Contents

16-1 General Information

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.

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.

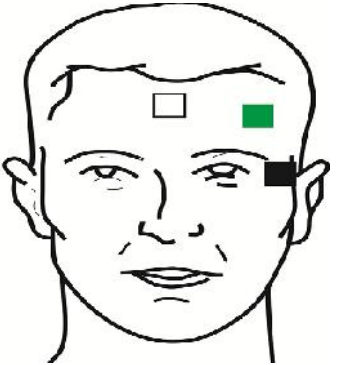
Alcohol is not recommended as a skin cleanser; it leaves a film layer that may cause high sensor impedance. If alcohol is used, ensure 30 second dry time.

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 figure8-1. 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.



Neuro Sensor Placement

White electrode (1): middle of forehead

Green electrode (2): left side of forehead

Black electrode (3): on temple

●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

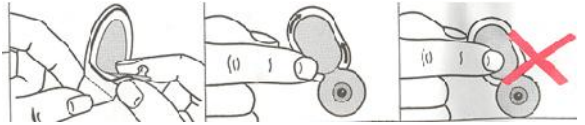
Neuro sensors are disposable and should not be reused. Before use pay attention to the expiry date

Once the neuro sensors have been secured on the skin, attach the colour-coded wires on the patient cable to appropriate sensor.

A left sided setup is shown in figure 8-1. Right sided is also acceptable.

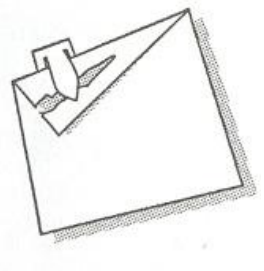
BFA module accuracy may be low in head and facial surgeries.

Picture below shows how to use neuro sensor.



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.

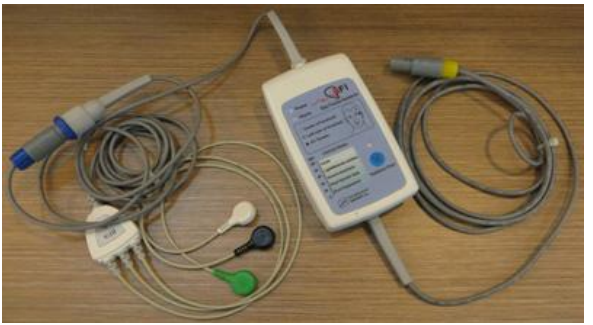


Correct maintenance of neuro sensors in its package

16-2 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.

a) BFA module



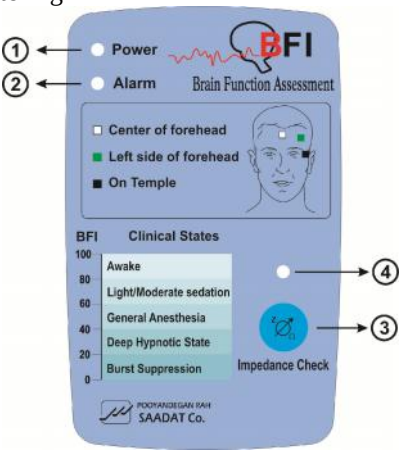
BFA module

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 (①).

Alarm Indicator: If "BFA ELECTRODE ALARM" occurs (resulting from inappropriate connection of neuro sensors), this indicator will flash with frequency of 1 Hz (②).

Impedance key: Impedance measurement is initiated by pressing this key (③) and its indicator (④) flashes on the module for one second.



BFA module keys and indictors

b) 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.

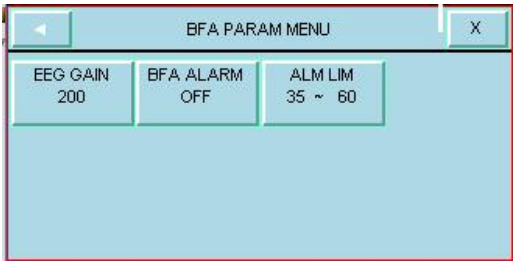
3- After communication is established, you can monitor different BFA parameters such as BFI%, BS%, SQI%, EMG% and also EEG signal on the patient monitor.(At first only EEG signal can be monitored and after 20 seconds, other parameters appear on the monitor).

16-3 BFA PARAM MENU

BFA parameter window is as below:

BFA Window

Touch EEG parameter area to access the below menu:



BFA PARAM MENU

■ **To change EEG gain:**

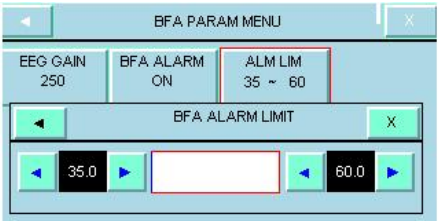
Pick “EEG GAIN” in BFA PARM MENU to set gain of EEG signal. Available options are 25μV and 50-250μV by step of 50μV.

■ **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 ”ALM LIM” 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)



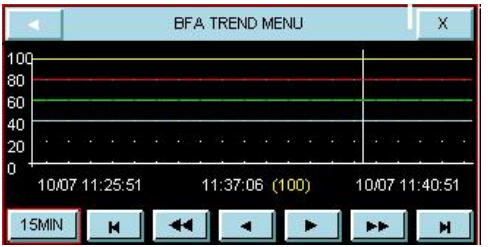
BFI alarm level is always II.

In case of sudden and strange changes in BFI or SQI index, it is necessary to measure impedance manually.

The BFI parameter trend always shows on this page and the user is not able to disable displaying of it.

16-4 BFA TREND MENU

Touch EEG area to access the below menu:



BFA TREND MENU

- Pick the first left item. Available options are 15min, 30min and 1, 2 and 4 H.

- As long as the cursor line is not moved in TREND menu, every click on the first 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 first 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.

- The cursor line in trend graph shows specific time. Click on the fourth and fifth left items to set the interval on 15, 30 min and 1 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 TREND menu.

- 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 and sixth left item.

- Select ▌◀ or ▶▌ to access the last or the first BFA TREND page.

Every change in BFA large page setting is seen in BFA window in normal state.

16-5 BFA Alarm

Alarm limit is activated as a follow:

a)Physiological alarms

ALARM	BFI HIGH
SITUATION	Cerebral state index violates adjusted high limit
VISUAL PROMPTS	● BFI value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in yellow background.
AUDIO SOUND	Activated
ALARM	**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

b) Technical alarms

BFA messages on patient monitor include:

Alarm	**BFA ELECTRODE ALARM**
Cause	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.
Solution	●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.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By Pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**BFA SQI LOW**
Cause	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.
Solution	●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.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**BFA IMPEDANCE HIGH**
Cause	If sensor impedance is > 5kΩ the BFI, %BS and %EMG will be blanked.
Solution	●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.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**BFA LINK OFF**
Cause	BFA module is off.
Solution	Connect the module to the monitor through interface cable.
Explanation	Alarm level 3- the alarm is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

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.

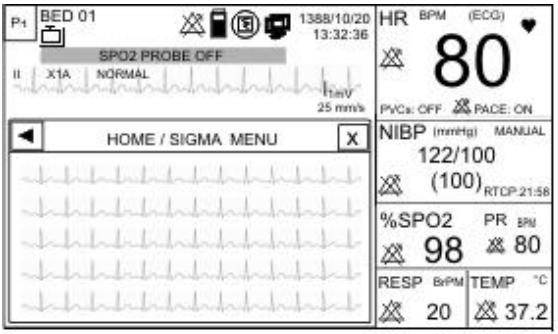
Chapter 17, TREND, SIGMA

Contents

17-1 SIGMA

The patient monitor is able to store 35 seconds of ECG signal that is visible in 5 traces in HOME/SIGMA MENU.

By pressing "SIGMA" in the HOME MENU, you can access this window.



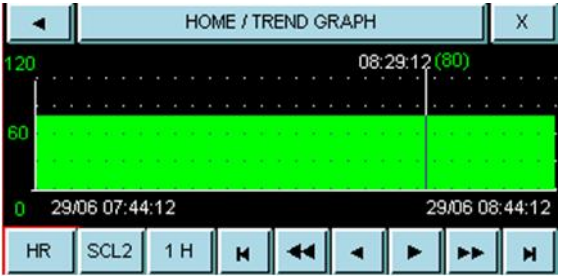
17-2 TREND

The latest 96 hours of data is stored and displayed in graphic and tabular trends.

Data is stored every second and displayed based on the selected interval in this way:

If Interval (sec) /300 ≤ 5s, data will be displayed every 5 seconds. Otherwise data will be displayed according to (Interval /300). For example, if the interval is set to 30 min, data will be displayed every 6 seconds.

Select TREND in HOME MENU to access TREND GRAPH. You can also select "HOME/TREND GRAPH" to access TREND TABLE.



X-axis in the trend graph indicates the time and Y-axis indicates numeric parameter.

■ **Selecting parameter values:**

Press the first left item in the trend graph to select your desired parameter. Available options are:

HR, PVCs,ST,AFIB

RESP

TEMP1,2

IBP1,2,3,4

SpO2, PR, SpHb,PI,SpCO,SpMet,PVI,SpOc,

AWRR ,EtCo2, FiCo2

Only available parameters in each page can be selected. This item is not active in the trend table and you can only view the selected parameter in the graph. If Masimo Rainbow set is used, you will see one of the selected Rainbow parameters instead of TEMP parameter in the trend table.

- **Changing the graph scale:**

Press the second left item in the trend graph to adjust scale. You can set scale of the Y-axis in proportion to the parameter values.

TREND

PARAM	SCL1		SCL2		SCL3		SCL4		SCL5	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
HR	0	60	0	120	0	240	-	-	-	-
PVCs	0	20	0	50	0	100	-	-	-	-
ST	-0.2	0.2	-0.5	0.5	-1	+1	-2	2	-	-
AFIB	0	1	-	-	-	-	-	-	-	-
SPO2	80	100	60	100	0	100	-	-	-	-
PR	0	60	0	120	0	240	-	-	-	-
RESP	0	60	0	120	0	240	-	-	-	-
TEMP	30	42	24	48	0	48	-	-	-	-
IBP1,3	-20	50	-20	100	-20	200	-50	300	50	250
SpHb	6	20	2	14	0	25	-	-	-	-
PI	0	20	0	10	0	5	-	-	-	-
SpCo	0	12	0	24	0	50	-	-	-	-
SpMet	0	6	0	20	-	-	-	-	-	-
PVI	0	30	0	100	-	-	-	-	-	-
SpOC	0	36	6	20	-	-	-	-	-	-

AWRR	0	60	0	120	0	240	--	---	--	---
EtCo2	0	50	0	100	--	---	--	---	--	---
FiCo2	0	50	0	100	--	---	--	---	--	---

■ **Selecting time interval of displaying numeric parameters**

Press the third left item in the trend graph to set time interval of displaying numeric parameters. Available options are 5, 10, 15, 30, 45min and 1, 2, 4 hours.

This item is not active in the trend table and you can only view the selected interval in the graph.

■ **Viewing numeric values in a specific time**

Press ◄ or ► in the trend graph to view numeric values in a specific time. When you press these buttons, the cursor moves through the graph and points to a specific time. This is only possible for 5, 10, 15, 30, 45 min, and 1, 2 hr

intervals. The related numeric value to this time is displayed above the cursor.

Press ▲ or ▼ in the trend table to move up or down in the table and view numeric values of specific times.

■ **Selecting the previous or next page in the trend**

Press ◀◀ or ▶▶ in the trend graph to view the previous or next page of a parameter trend. In other words, you can adjust start and end times of the x-axis. Every time you press these buttons, the time scale of x-axis will change to the extent of the adjusted interval in the third left item.

Press ⏫ or ⏬ to view the previous or next page of the trend table.

■ **Viewing the first or last page of the trend**

Press ⏮ or ⏭ in the trend graph to view the last or the first page of the trend of each parameter.

Press ⏫ or ⏬ in the trend table to view the first or the last page of the table.

Chapter 18, Recorder

Contents

18-1 General Information

The Aria monitor can record the signals and parameters through SAADAT thermal recorder embedded in F1R station.

Performance of the Recorder

- Recording speed is adjustable to 6, 12.5 and 50 mm/s.
- Up to 2 selectable waveforms recording in F1R station.
- The real time and freeze recording.
- The selectable automatic alarm recording.

18-2 RECORDER MENU

Select "REC" in HOME MENU to access the below menu.

■ TRACE1

To select waveform of the recorder first channel in Manual recording. Available options are ECG, SPO2, IBP1,2,3,4, RESP/CO2 and OFF.

■ TRACE 2

To select waveform of the recorder second channel in Manual recording. Available options are ECG, SPO2, IBP1,2,3,4, RESP/CO2 and OFF.

■ REC SWEEP

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

■ MANUAL REC TIME

Available options are MANUAL, 10 sec, 20 sec, 30 sec and CONTINUOUS.

■ PERIODIC TRACE1

To select waveform of the recorder first channel in Automatic recording. Available options are ECG, SPO2, IBP1,2,3,4, RESP/CO2 and OFF.

■ PERIODIC TRACE 2

To select waveform of the recorder second channel in Automatic recording. Available options are ECG, SPO2, IBP1,2,3,4, RESP/CO2 and OFF.

■ INTERVAL

To select time interval in Automatic recording. Available options are 15 min, 30 min, 1, 2, 4, 8, 12, 24 hr and OFF.

18-3 Recording type

The monitor provides different types of recording:

- Continuous real-time recording
- 10, 20 and 30 seconds real-time recording via F1R station
- 10 seconds automatic recording
- Freeze recording
- Parametric recording
- TREND recording
- NIBP LIST recording
- ARR LIST recording
- ARR WAVE recording

Parametric Recording

Set “OFF” both traces in RECORDER MENU to enable Parametric recording via F1R station.

Recording Type

Manual Recording

■ Internal recorder of F1R station can record the below modes.

- **Continuous Recording**

Continuous real-time recording starts from the last 5 seconds when you press the “Rec/Stop” key and stops when you press this key again.

- **10, 20 and 30 s Recording via F1R Station**

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 interval time set in the RECORDER menu.

Recording Type

Alarm Recording

If this item is set ON, 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 occurs 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 set "ON" or "OFF"

ALARM REC in HOME /RECORDER MENU or in each parameter menu.

Freeze Waveform Recording

The monitor prints out 20 seconds of the selected waveforms and numeric parameters in Freeze 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 LIST Recording

The monitor can print out ARR EVENT LIST. Select "REC" in ECG/ARR/ARR LIST MENU to start recording.

ARR WAVEFORM Recording

The monitor can print out stored arrhythmia waveforms in ARR WAVEFORM LIST. Select "REC" in

Recording Type

ECG/ARR/ARR LIST/ARR WAVE MENU to start recording.

The following information are recorded on the paper:

- Recording Type:

  MANUAL RECORD
  PERIODIC RECORD
  ALARM RECORD (name of the parameter triggered the alarm)
  FREEZE RECORD
  (Parameter) TREND RECORD
  NIBP LIST RECORD
  ARR LIST RECORD

  ARR WAVE RECORD
- Recording Date and Time
- Bed number

Recording Type

- 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

18-4 Recorder paper

You should use only 57mm thermo-sensitive paper (length of 15 m) for SAADAT recorder.

Use only manufacturer recommended white thermosensitive record paper, otherwise the recording quality may be poor and the thermosensitive printhead may be damaged.

Do not use grid paper.

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.

Recorder Paper

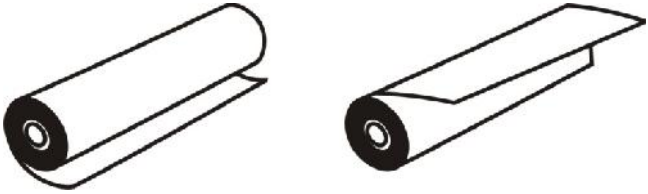
Do not use paper with edges that are pasted or have turnups at the start of the roll. If they need to be used unavoidably, replace with new paper roll as soon as possible before entire roll is used up.

Loading the paper:

- Pull up ejector of the recorder door .
- 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.

Thermo sensitive surface of paper should be placed facing the head. make sure to place the paper correctly.

Recorder Paper



a. incorrect placement

b. correct placement

recorder paper placement

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.

If the paper is jammed, open the recorder door and remove the paper. Do not pull the paper by force.

Be careful when inserting paper. Avoid damaging the thermosensitive printhead. Do not touch thermosensitive print head.

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.

18-5 RECORDER ALARM

Alarm	**Rec. Software Error**
Cause	Software error
Solution	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**Recorder Fault**
Cause	Hardware error
Solution	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**Rec Door Open**
Cause	The recorder door is open
Solution	Close the recorder door.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**Rec Paper Out**
Cause	Recorder paper has been finished.

Solution	Insert a new paper roll.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**Printhead Hight Temp**
Cause	The thermal head is too hot.
Solution	Stop operation for a few minutes.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**Printhead Hight Vol**
Cause	Print head voltage is high.
Solution	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
Alarm	**Printhead Low Vol**
Cause	Print head voltage is low.
Solution	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

RECORDER ALARM

Alarm	**Time out Error**
Cause	The recorder can not record.
Solution	Turn the system off and on. If the problem persists, contact after sales service department of the manufacturer.
Explanation	Alarm level 2- the alarm is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

Chapter 19, Patient Safety

The Patient Monitor is designed to comply with the international safety standard requirements for medical electrical equipment. This device has floating inputs (i.e. Accessories are isolated against AC power) and it is protected against the effects of Defibrillator and Electrosurgical unit. If the correct electrodes are used and applied in accordance with the manufacturer instructions, the system will recover within 10 seconds after defibrillation.

Monitor Symbols	
	This symbol indicates that the device is IEC60601-1 Type CF (Defibrillation proof applied part) equipment. The units displaying this symbol contain an F-type isolated (floating) patient applied part providing a high degree of protection against shock and is suitable for use during defibrillation.
	This symbol indicates that the device is IEC60601-1 Type BF (Defibrillation proof applied part) equipment. The units displaying this symbol contain an F-type isolated (floating) patient applied part providing a high degree of protection against shock and is suitable for use during defibrillation.
	This symbol indicates that the device is IEC60601-1 Type BF equipment.
	This symbol indicates 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.

	The equipment shall be disposed of in an environmentally-friendly manner.
	Manufacture date
	Manufacturer information
	European community representative
S/N	Serial number
	Use the Masimo Pulse Oximeter Module

⚠ **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 patient monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature and humidity.

The patient monitor properly operates at ambient temperature between 0ºC to 40ºC. Ambient temperatures that exceed these limits could affect the accuracy of the monitor and cause damage to the modules and electric circuits.

Grounding the patient monitor

To protect the patient and hospital personnel, the case of patient monitor should 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 device should be operated on the battery.

⚠ Warning ⚠

There is possible explosion hazard if the system is used in the presence of flammable anesthetic agents.

Chapter 20, Technical Specification

Technical Specification

CLASSIFICATION	
Protection against electroshock	Class I, Type CF for all modules (except CO2 module & NIBP module that are BF) (based on IEC 60601-1)
Mode of operation	Continuous operation equipment
Harmful Liquid Proof Degree	Aria monitor: IP32 Stations & Adaptor: IPX1
Method of disinfection	Refer to each module's chapters and 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.

Technical Specification

General	
Display	COLOR TFT 480 × 272” 5” Flexible display Configuration
Waveforms	ECG, SPO2, RESP/CO2,IBP1,IBP2,IBP3,IBP4 ,EEG(Freezable)
Numeric Parameters	HR, PVCs,ST, SPO2 (%SPO2, PR, PI), Rainbow (SpMet, SpCO, SpHb, SpOC, PVI), NIBP (SYS, DIA, MAP), RR, TEMP1,2, IBP1,2,3,4 (SYS, DIA, MAP), EtCo2, FiCo2, AWRR, BFI, BS%, EMG%, SQI%,
Operation Method	Membrane, Touch screen
AC Power(Adaptor)	100 - 240 VAC, 50/60 Hz , Ip: 1.4 – 0.7 A, Output:15VDC,4A
Application	Compact and Mobile Monitor.
Safety	Based on IEC 60601-1, Class I
Protection	Against Electro surgery and Defibrillator and EMC.

Technical Specification

ECG	
Leads	Selectable: 3 ,5 or 10 Wires
	For 3 wire: I, II, III
	For 5 wire :I,II,III,V,aVR,aVF,aVL
	For 10 wire : I,II,III, aVR,aVF,aVL , V1,V2, V3, V4, V5. V6
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)

Technical Specification

CMRR	> 98 dB	
Internal Noise	< 30 μV RTI	
Input Impedance	> 5 MΩ	
QRS Detection	Duration	40 to 120 msec
		0.25 to 5 mV forAdult/Pediatric
	Amplitude	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	

NIBP			
Measurement method	Oscillometric		
Measurement mode	Manual/Automatic/Stat		
Measurement time	20-25 sec (excluding cuff inflation time)		
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

Technical Specification

		DIA	15 ~ 220 mmHg
		MAP	20 ~ 230 mmHg
Pressure Transducer accuracy	±3 mmHg full range		
Initial Inflation Target	Adult 150 mmHg, Pediatric 140mmHg, Neonate 85 mmHg		
Overall System Efficacy	ISO 81060-2 IEC 80601-2-30		
Memory	100 Records		

SPO2 (Masimo Rainbow Set)	
Spo2 Parameters	SpO2,PI,PR
Rainbow parameters	SpOC
	SpCO
	SpMet
	SpHb
	PVI
Method	2 Wave length pulse wave type

Technical Specification

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/Pediatr: ±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 %
	SpMet	1 %
	SpHb	1 %

	PI	1 %
	PVI	1 %
	SpOC	1 %
	PR	1 %

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

Channel	2 Channel Monitoring 2 channel.
Probe Type	YSI 400 Compatible
Range	0 - 50 °C
Accuracy	± 0.2 °C

RESPIRATION

Method	Impedance

Technical Specification

Base Resistance	250 -1250 Ohm
Dynamic Range	0.2 - 2 Ohm
Breath Rate Range	0 - 253 BrPM
Accuracy	±2% or 2 BrPM

IBP

Channel	4 Channels
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
Resolution	1 mmHg
Accuracy	2 % or 2mmHg (each one is greater)

CO2 (Mainstream)

Power supply	4.5-5.5 VDC, max 1.4W

Technical Specification

Method	Infrared absorption
Measuring mode	Mainstream
IRMA Harmful Liquid Proof Degree	IPX1
Et and Fi Parameters Fi and ET are displayed after one breath and have a continually updated breath average.	
IRMA CO2	CO2, CO2 waveform
Sensor head	3-10 channel NDIR type gas analyzer measuring at 4-10μm. pressure, temperature and full spectral interference correction.
Sensor Dimension (W×D×H)	IRMA CO2/AX+: 38×37×34mm
Sensor weight	<25g(cable excluded)
	<38g(O2 sensor XL included, cable excluded)
Oxygen sensor	integrated ultra-fast response time galvanic oxygen sensor
	>100000 oxygen hours

Technical Specification

Calibration	No routine calibration required Room air calibration of O2 sensor performed automatically when changing airway adapter (<5sec)
Warm-up time	concentrations reported in less than 10s,
	full accuracy with in 10s for IRMA CO2
Operating temperature	IRMA CO2: 0 to 40°C
Storage and transportation temperature	IRMA CO2: -40 to 75°C
Operating humidity	10 to 95% RH, non-condensing
Storage and transportation humidity	5 to 100% RH, condensing
Operating atmospheric pressure	IRMA CO2: 525 to 1200hPa
Storage and transportation pressure	500 to 1200hPa
Surface temperature	max 50ºC / 122ºF
Rise time (@10 l/min)	CO2≤ 90ms

Technical Specification

Delay time	≤ 140ms
Agent identification time	<20 seconds
Total system response time	< 1 second
Respiration rate	0~150BrPM

Accuracy specification-during standard condition

Gas	Measuring range	Accuracy
CO2	0-15%	$\pm(0.2\%_{ABS}+2\%_{REL})$
	15-25%	Unspecified

Note 1 : The accuracy specification is valid for all specified environment conditions

Accuracy specification-during standard condition

CO2	$\pm(0.3\%_{ABS}$ or $\pm4\%_{REL})$

Sample Rate: 20 Hz / channel

Technical Specification

Power supply	4.5-5.5 VDC, ISA CO2: <1.4 W (normal op.), <1.8 W (peak @ 5 VDC)
Method	Infrared absorption
Measuring mode	Sidestream
Et and Fi Parameters Fi and ET are displayed after one breath and have a continually updated breath average	
ISA CO2	CO2, CO2 waveform
Sensor head	2-9 channel NDIR type gas analyzer measuring at 4-10μm
Sensor Dimension (W×D×H)	ISA CO2: 33x78×49mm
Sensor weight	ISA CO2: 130g (including cable)
Calibration	No span calibration is required for the IR bench. An automatic zero reference calibration is performed at startup and then every 24 hours.
Compensation	
ISA CO2	Automatic compensation for pressure

Technical Specification

	and temperature. Manual compensation for broadening effects on CO2.
Warm-up time	
ISA CO2	<10 seconds (concentrations reported and full accuracy)
Operating temperature	ISA CO2: 0 to 50°C
Storage temperature	-40 to 70°C
Operating humidity	<4 kPa H2O (non-condensing)
	(95 %RH at 40°C)
Storage humidity	5 to 100 %RH (condensing)
	(100 %RH at 40°C)
Operating atmospheric pressure	52.5 to 120 kPa (Corresponding to a max altitude of 4572 m/15000 feet)
Storage atmospheric	20 to 120 kPa
Typical rise time at 50 l/min sample flow	
CO2	≤200ms

Technical Specification

Total system response time	< 3 second (with 2m sampling line)	
Sampling flow rate	50 ± 10 ml/min	
Respiration rate	0~150BrPM	
Accuracy specifications-during standard conditions		
Gas	Measuring Range	Accuracy
CO2	0~15%	±(0.2 V% +2% of reading)
	15~25%	Unspecified
Accuracy specification-during all condition		
CO2	±(0.3 kPa + 4% of reading)	
Note 1: The accuracy specification is valid for all specified environment conditions. **Sample Rate**: 20Hz/channel		

Technical Specification

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

Technical Specification

Features	User Adjustable Isoelectric and ST point trending of ST values
Update period	5 Sec.

BFA (Brain Function Assesment)	
BFA Interface	Required for Integratig BFA mdule and monitors
EEG sensitivity	±450µV
Noise	<2µVp-p <0.4µV RMS, 0.25-250 Hz
CMRR	>140dB
Input impedance	>50MΩ
Sample rate	1000 samples/sec(16 bits equivalent)
Brain Function Index (BFI)	0-100. Filter 1-47Hz, 1sec. update
EMG	0-100. Filter 30-47 Hz,1 sec. update

Technical Specification

BSR	0-100. Filter 2-47 Hz, 1 sec. update
Signal Quality Index (SQI)	0-100. 1 sec. update
EEG Waveform	±250µV, user-adjustable, 5 sec
Alarms	Auditory and visual, user-adjustable limits
Artifact rejection	Automatic
Sensor impedance measurement	0-30kOhm / Manual-Automatic/ measurement current 0.06µA
Power supply	5 VDC
Power Consumption	Less than 0.5 W
Weight	100 gr
Dimensions	111×64×25 mm
Classification	Class I, type BF, continuous use
Sensors	Ambu Neuro Sensors
Cable length	195 cm/ 77” with 35 cm/ 14” split

Technical Specification

Memory	Data recording (96 hours)	
Trend	BFI/EMG/SQI/BS, 10 sec. update	
Environment - Operation	Temperature	5-40°C
	Rel humidity	20~96%
	Altitude	-200~3000m

Recorder	
Model	SAADAT Thermal Printer
Channel	Up to 2 waveforms
Printing Speed	6, 12.5, 25 mm/sec
Paper Size	57mm

Technical Specification

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,ST,PVCs,AFIB, RESP, T1,T2, IBP1(SYS,DIA,MAP), IBP2(SYS,DIA,MAP) IBP3(SYS,DIA,MAP) IBP4(SYS,DIA,MAP) SPO2, PR,SpHb, PI, SpCo, SpMet, PVI, SpOc, EtCo2,FiCo2,AWRR
Trend Time Save	96 Hours
Trend Time Interval	5, 10, 15, 30, 45 Min, 1, 2, 4 Hours
Resolution	1 sec

Technical Specification

INPUT/OUTPUT	
Network	Digital, TCP/IP (WiFi)and TCP/IP (Wire)
	TCP/IP (WiFi)

Internal Battery		
Nickel-Metal Hybride 3.6V,2.5AH Lithium Polymer 11.1V,4.3AH Lithium ion 11.1V,3.3AH		
System Model	Nickel-Metal Hybride	
	Charge time	Usage
ARIA	~ 3hours	~ 2:30hours
F1		
F1R		
System Model	Lithium Polymer	
	Charge time	Usage
ARIA		

F1	~ 6hours	~ 5hours
F1R	~ 6hours	~ 4hours
System Model	Lithium ion	
	Charge time	Usage
ARIA		
F1	~ 6hours	~ 10hours
F1R	~ 6hours	~ 8hours

Physical Specification

Model	Dimension (mm)	Weight (approximately)
ARIA Monitor	155(W) × 107(H) × 65(D)	Less than 800g
F1 Station	190(W) × 155(H) × 80(D)	800g
F1R Station	220(W) × 155(H) × 90(D)	1100g

Technical Specification

ENVIRONMENTAL		
Temperature	Operating:°C	5 to 40°C
	Storage & Transport:	-25 to 60 °C
Humidity	Operating: (Noncondensing)	20-90 % (Noncondensing)
	Storage & Transport: (Noncondensing)	10-100 %
Altitude	-200 to 3000 m	

Chapter21, Accessories

General Information

This chapter lists the recommended accessories for patient monitor and their part number.

⚠ Warning ⚠

The accessories listed below are specified to be used for patient monitor. Manufacturer does not take responsibility for any possible hazard to the patient or monitor if other accessories are used.

⚠ **Warning** ⚠

To protect patient against defibrillator effects, use only accessories specified in this chapter.

Accessories

ECG Accessories	PART #
ECG patient cable, 3 leads	#10003
ECG patient cable, 5 leads	#10038
ECG patient cable, 10 leads	#10066
SPO2 (Masimo Rainbow)	**PART #**
Adult Digit Reusable Sensor - > 30 Kg (LNCS DCI)	#18-045
SPO2 Probe , Y- Sensor - > 1 Kg (LNCS)-MASIMO	#18049
SPO2 Extension – Red LNC-10 - MASIMO	#18060
SPO2 Sensor - Reuseable - Finger/Toe - Adulat > 30 Kg, Red DCI-dc12	#18055
SPO2 Extension Cable	#18056
Rainbow R25 Sensor, Adult, Adhesive, >30Kg, (SPO2,SPCo,SPMet)	#18062
Rainbow Resposable R2-25a Sensor, Disposable, Adult, >30Kg, (SPO2,SPHb,SPMet)	#18063
Rainbow Resposable R2-25r Sensor, Reusable, Adult, >30Kg, (SPO2,SPHb,SPMet)	#18064
Rainbow Resposable R2-20r Sensor, Reusable, Pediatric, 10-50KG, (SPO2,SPHb,SPMet)	#18066
Rainbow DC-3 SC 360, Reuseable, Adult, (SpO2,SpMet,SpHb)	#18068

Accessories

Rainbow DCI, Reuseable, Adult, (SpO2,SpCO,SpMet)	#18069
M-LNCS DCI, Reuseable, Adult, (SpO2)	#18070
Rainbow R1-20L Pulse Co-Oximeter Sensor, Disposable, Pediatric, (SPHb ,SPO2,SPMet)	#18072
SPO2 Probe, Disposable,Neonate, Adhesive , < 1 Kg ,LNCS,Masimo	#18046
SPO2 Probe, Disposable,Neonate, Adhesive , < 3 Kg or >40Kg,LNCS,Masimo	#18047
SPO2 SPO2 Disposable Sensor, 3-20 Kg, (LNCS Inf)	#18045
NIBP	**PART #**
NIBP Cuff Reusable - Neonate-Single M 5301 Bladderless,Tube length 20cm	#13077
NIBP Cuff Reusable - Infant - Single M5302 Bladderless Tube length 20cm	#13078
NIBP Cuff Reusable - Pediatric - Single M5303 Bladderless Tube Length 20 cm	#13079
NIBP Cuff Reusable - Adult - Single M5304 Bladderless, Tube Length 20 cm	#13080
NIBP Cuff Reusable - Large Adult - Single M5305 Bladderless, Tube Length 20 cm	#13081

Accessories

NIBP Cuff Reusable - Adult - Thigh, Single M5306 Bladderless, Tube Length 20 cm	#13082
NIBP Cuff Reusable – Adault – Single M5114PU, TPU Bladder, Tube Length 20 cm	#13083
NIBP Cuff Reusable – Adult – Single M5104 Nylon, TPU Bladder, Tube Length 20 cm	#13084
NIBP Cuff Disposable – Neonate – Single M5541-1# with CT-167 Connector	#13085
NIBP Cuff Disposable, Neonate, Single M5541-2# with CT-167 Connector	#13086
NIBP Cuff Disposable – Neonate, Single M5541-3# with CT-167 Connector	#13087
NIBP Cuff Disposable – Neonate, Single M5541-4# with CT-167 Connector	#13088

Accessories

TEMP	PART #
TEMP Probe – Skin –LAUNCH (98ME04GA634)	#10083
TEMP Probe –Rectal –LAUNCH (98ME04GA635)	#10084
TEMP Interface Probe– Data Cable for Redel Connector to Temp Probe	#24073
IBP	**PART #**
IBP Transducer , MEDEX - .MX860/866 Novatrans	#16001
IBP Disposable Dome – MEDEX - MX860/866 Novatrans Dome	#16031
IBP Extension Cable – MEDEX - MX860/866 Novatrans Extension	#16042
IBP Transducer – MEDEX - MX960 Logical	#16002
IBP Disposable Dome – MEDEX - MX960 Logical Dome	#16033
IBP Extension Cable – MEDEX - MX960 Logical Extension	#16043
IBP Transducer Cable – TRUWAVE	#16037
IBP Transducer , Disposable – RX only – PX260	#16036
IBP Interface Probe– One channel IBP interface	#16051

Accessories

IBP Interface Probe– Two channel IBP interface	#16052
IBP Transducer kit, Disposable, iPex, Ref BKT-164ET	#16046
IBP Cable, Ipex, P/N: BKT-164ET	#16053
IBP Bracket for iPex Trancducer	#16047
CO2 (Mainstream)	**PART #**
IRMA Disposable Airway Adapter without O2 port	# 20025
IRMA Disposable Airway Adapter for infant	# 20035
IRMA Adapter Cable	# 24111
Probe Holder for IRMA sensor	# 20043
CO2 Airway Adaptor,Disposable,neonate/pediatric	# 20091
CO2 (Sidestream)	**PART #**
Nomoline with luer lock connector. 2 m. Box of 25	# 20045
Clamp of ISA Module Holder	# 20055
VersaStream, CO2/Gas Airway Adapter Sampling Line, Adult / Pediatric	# 20077
VersaStream,CO2/Gas Airway Adapter Sampling Line, Infant	# 20078
VersaStream, CO2/Gas Sampling Line with Luer Lock Male (it uses with Sidestream Airway Adapter-Adault/Pediatric, part number:4420531)	# 20079

Accessories

T4F Water Filter for Capno-S+	# 20094
Sample line for Capno-S+	# 20095
T Airway Adapter for Capno-S+	# 20096
BFA	**PART #**
BFA Accessory Patient Cable, SAADAT	# 22028
Adaptor	**PART #**
Saadat Adaptor 60W, 15v for Aria	# 09263

The following accessories are recommended, otherwise accessories with CE marking or Biocompatibility test report shall be used.

ECG Electrodes	**REF**	**PART #**
Adults ECG Disposable Electrodes, FIAB Manufacturer	F9060	P28042
Pediatric ECG Disposable Electrodes, FIAB Manufacturer OR Arbo H124SG, COVIDIEN Manufacturer	F9060P 31.1245.21	P28047 P10079
EEG Electrodes	**PART #**	
Neuroline 720, AMBU Manufacturer	Part.#Neuroline720	P22009

Chapter 22, Care and Cleaning (PM)

Contents

22-1 System Check

Before using the monitor:

■ Check if there is any mechanical damage on 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.

System Check

All checks which need the monitor to be opened and safety and maintenance checks should be performed by the Customer Service.

To ensure maximum battery life, let the electrocardiograph runs on the battery, at least once a month, until it turns itself off and then recharge the battery.

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 center can request the system calibration whenever the system accuracy is in doubt.

⚠Warning⚠

If users do not follow a satisfactory maintenance schedule, the monitor may become invalid, and human health may be endangered.

22-2 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.

Cleaning and Disinfection

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

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.

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.

Cleaning and Disinfection

Device parts	Single-use	Cleaning	Disinfection	Sterilization
External surface of device	-	In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.	In-between patients and as required use ■ Alcohol 70% ■ Isopropyl alcohol ■ N-propanol	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
BFA module	disposable electrodes			
- Trolley/ Wall stand, **- Holders of accessory,** **- Extension cables** **-NIBP Hose, CO2 Mainstream and Sidestream Analyzer**	-		In-between patients and as required use ■ Isopropyl alcohol	

Display screen	-	In-between patients and as required: Clean and soft cloth with screen cleaner or mild soapy water		Maintenance Schedule.
Recorder (printhead)	-	as required: 1.Gently wipe around the printhead using cotton swabs dampened with alcohol. 2.After the alcohol has completely been dried, reload	use as required ■ Isopropyl alcohol	

		the paper and close the recorder door.		
ECG Accessory	disposable electrodes	**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.		
SpO2 Accessory	disposable sensor			
NIBP Cuff	-			
TEMP Accessory	-			
IBP Accessory	disposable transducers and Domes			
GAS Accessory (Main-stream/Side-stream)	disposable Airway Adapter, Nemoline family sampling lines			
CO Accessory	-			

22-3 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.

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.

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.

Periodic Inspection

SAADAT Co.					
Form No. : PL-F-68		**PM Form (ARIA)**			
State:		**City:**	**Medical center:**		**Ward:**
Device model:	**Serial number:**	**Installation date:**	**Inspection date:**		
No.	**Test and Inspection Item**		**N/A**	**NOK**	**OK**
1	Visual inspection	No damage or breakage in the back case, panel and station			
		Cleaning and disinfection according to the user manual			
2	Keyboard	Correct function			
3	Touch	Correct function			
4	Display screen	Correct display of Waveform area, Parameter area and Message area			
5	Battery	Check the Aria power when disconnected from the station			
		Periodic usage of the battery			
6	Alarm	Alarm activation			
		Clarity of alarm sound			
		Correct function of alarm LEDs			
7	Setup	Saving date& time settings			

SAADAT Co.					
Form No. : PL-F-68		**PM Form (ARIA)**			
State:		**City:**	**Medical center:**		**Ward:**
Device model:		**Serial number:**	**Installation date:**	**Inspection date:**	
No.	**Test and Inspection Item**		**N/A**	**NOK**	**OK**
8	ECG	Check ECG cable (clamps, leadwire, trunk)			
		Check ECG window (Pacemaker, beat sound, etc)			
		Cleaning and disinfection according to the user manual			
9	RESP	Check parameters of RESP window			
10	TEMP	Check TEMP probe			
		Cleaning and disinfection according to the user manual			
11	SpO2	Check SpO2 probe (extension, if any)			
		SpO2 window settings (Measurement mode and sensitivity)			
		Cleaning and disinfection according to the user manual			
12	NIBP	Check NIBP cuff and hose (No leakage)			
		Check accuracy of NIBP measurement			

SAADAT Co.					
Form No. : PL-F-68		**PM Form (ARIA)**			
State:		**City:**	**Medical center:**		**Ward:**
Device model:	**Serial number:**	**Installation date:**	**Inspection date:**		
No.	**Test and Inspection Item**		**N/A**	**NOK**	**OK**
		NIBP window settings (Adult, Pediatric and Neonate modes, measurement unit, Automatic mode)			
		Cleaning and disinfection according to the user manual			
13	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			
14	CAPNO	Check CAPNO probe and ISA Sampling line			
		Check CAPNO probe and IRMA Adaptor			
		CAPNO window settings (Measurement unit, COMPENSATE and etc)			

Periodic Inspection

SAADAT Co.					
Form No. : PL-F-68		**PM Form (ARIA)**			
State:		**City:**	**Medical center:**		**Ward:**
Device model:	**Serial number:**	**Installation date:**	**Inspection date:**		
No.	**Test and Inspection Item**		**N/A**	**NOK**	**OK**
		Cleaning and disinfection according to the user manual			
15	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			
16	Recorder	Appropriate size of the recorder paper			
		Close door of the recorder during recording			
		Recorder window settings			

Final decision: Pass ☐ Fail ☐

Expert Recommendation:

Periodic Inspection

Name and signature of responsible individual:

Name and signature of expert:

Chapter 23, Troubleshooting

Repairing the internal parts of the monitor must be only done by trained and authorized personnel of Customer Service; otherwise manufacturer will not take any responsibility for any possible hazard to the patient and the monitor.

This section 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 mentioned procedures before you contact with Customer Service.

Problem	Possible Cause	Correct Actions
System		
The monitor does not turn on	●Power cable is not connected securely. ●Power connector of the station is dirty. ●etc	● Check the power cable path. ● Check power connector for connection of the monitor to the station. ●Call the Customer service department.
The monitor is not able to run on battery	●The battery is not fully charged. ●The battery is not inserted properly. ● etc	●Charge the battery for 6 hours (if the monitor is placed correctly in the station, DC-IN indicators will light up) ●Check that the battery is inserted properly in the compartment. ●Call the Customer service department.

Troubleshooting

Problem	Possible Cause	Correct Actions
ECG		
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 the Customer service department.
NO ECG waveform	●ECG cable is not connected securely. ●Improper 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. ●Do not use old and faulty electrodes. ● Call the Customer service department.

Spike on ECG waveform	●If PACE is "ON" for patient without Pace marker, ECG noise will be counted as PACE pulse. ●etc	●Set OFF “Pace detection” in ECG window.
Unstable HR	●ECG signal is noisy or is not suitable. ●etc	●Check leads and electrodes. ●Change leads to monitor the best ECG signal. ● Call the Customer service department.
Problem	**Possible Cause**	**Correct Actions**
RESP		
- No “RESP” signal -No good waveform -Unstable RR	●The electrodes are not connected properly. ●The patient moves extremely during measurement. ●etc	●Check leads and electrodes. ●Change RESP lead. ●Calm the patient. ● Call the Customer service department.
RESP APNEA	No respiration is detected for a specific time.	● Call the Customer service department.

Troubleshooting

Problem	Possible Cause	Correct Actions
TEMP		
Strange T1	●Improper placement of the probe. ●Faulty sensor ●etc	●Place the probe in appropriate location. ●Replace the probe. ● Call the Customer service department.
Problem	**Possible Cause**	**Correct Actions**
SPO2		
-No SPO_2 waveform -Noisy waveform	●SPO_2 probe is not placed in appropriate location. ●Faulty sensor ●etc	●Check the probe placement. ● Change the probe and check the waveform. Contact the manufacturer to replace the probe ,if necessary. ● Call the Customer service department.
-No SPO2 value -Strange SPO2 value	●Patient movement during measurement ●Improper placement of the probe. ●etc	●Calm the patient. ●Change the probe position. ●Call the Customer service department.

Problem	Possible Cause	Correct Actions
NIBP		
NIBP cuff cannot inflate	●Improper connection of air hose. ●The air hose has been occluded or tangled. ● Leakage of the air hose or cuff. ●etc	●Check connections. ●Check the air hose. ●Replace the hose and the cuff, if necessary. ●Call the Customer service department.
-NIBP cannot be measured -Strange NIBP value	●The cuff or air hose is not connected to the system. ●Improper cuff placement ●Patient movement during the measurement ●Low battery power ● etc	●Check the cuff and the air hose ●Change the cuff position ●Calm the patient ●Connect the monitor to the mains power. ●Call the Customer service department.

Problem	Possible Cause	Correct Actions
IBP		
Strange IBP value Noisy IBP signal	● Zeroing has not been performed before measurement. ●Noisy source nearby the system or accessories. ●Faulty sensor ● etc	●Perform zeroing ●Keep the system and cable away from any noise source. ●Replace the sensor. ●Call the Customer service department.

Problem	Possible Cause	Correct Actions
CO2		
CO2 System fault #01	Software error	Call the Customer service department.
CO2 System Fault#02	Hardware error	Call the Customer service department.
CO2 System Fault#03	The engine speed is out of range.	Call the Customer service department.
CO2 System fault#04	The device is out of calibration.	Call the Customer service department.
CO2 No Adapter/Sampling line	There is no adaptor/ sampling line connected to the system.	● Connect adaptor/sampling line. ● Call the Customer service department.
SAMPLING LINE IS CLOGGED	Sampling line occlusion	● Replace the sampling line with a correct one. ● Call the Customer service department.
RESP APNEA	Non-respiration condition overruns the specified time	Call the Customer service department.
CO2 NO SENSOR	The sensor is not connected or there is not CO2 module.	● Connect CO2 sensor. ● Call the Customer service department.

Some advices to reduce measurement errors:

- **NIBP**

When NIBP measurement is made, 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 customer service.

Adjust the system measuring mode (Adult, Pediatric and 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-Align the cuff and artery properly.

10-Remove any tight fitting clothing before taking measurement.

11-Apply proper size of cuff for the patient.

- Too small size of the cuff results in too high pressure values.
- Too large size of the cuff results in too low pressure values.

BFA

- **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.

APPENDIX I

(Default Settings)

Menu item	Selection	Default
The parameters in ECG menu		
ECG LEAD	I,II,III,aVR,aVF,aVL,V1,V2,V3,V4,V5,V6	II
ECG SIZE	CHANGE,AUTO	AUTO
ECG SWEEP	12.5,25,50mm/s	25
ALARM LEVEL	1,2	1
HR ALARM	ON,OFF	OFF
HR HIGH ALARM	HR LOW ALARM +5 to 250	150bpm
HR LOW ALARM	HR HIGH ALARM -5 to 30	50bpm
ECG FILTER	MONITOR,NORMAL, EXTENDED	NORMAL
HR SOURCE	ECG,SPO2,IBP1,IBP3, IBP2,IBP4,AUTO	AUTO
BEAT VOLUME	1,2,3,4,5,6,7,8.OFF	1
PACE DETECT	ON,OFF	OFF
ECG CALIB	ON,OFF	OFF
ECG AVERAGE	4,8,16SEC	8SEC
LEAD TYPE	3 Wires,5 Wires, 10 Wires	3 Wires

APPENDIX I

(Default Settings)

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	RR HIGH ALARM -1 to 5	5Brpm
APNEA LIMIT	10,15,20,25,30,35, 40S , OFF	10S
The parameters in SPO2 menu		
Avg. Time	2~4, 4~6, 8, 10, 12, 14, 16	8
SPO2 PLETH SWEEP	12.5,25mm/s	12.5mm/s
ALARM LEVEL	1,2	1
ALARM	ON,OFF	OFF
SPO2 HIGH ALARM	SPO2 LOW ALARM +1 to 100	100
SPO2 LOW ALARM	SPO2 HIGH ALARM -1to 1	90

APPENDIX I

(Default Settings)

PR HIGH ALARM	PR LOW ALARM +5 to 235	140
PR LOW ALARM	PR HIGH ALARM -5 to 20	50
SpMet HIGH ALARM	SpMet LOW ALARM +0.5 to 99.5	3.0
SpMet LOW ALARM	0.5 to SpMet HIGH ALARM -0.5	0.5
SpCO HIGH ALARM	SpCO LOW ALARM +1 to 99.0	10.0
SpCO LOW ALARM	SpCO HIGH ALARM -1 to 1.0	1.0
SpHb HIGH ALARM	SpHb LOW ALARM +0.1 to 24.5	17.0
SpHb LOW ALARM	SpHb HIGH ALARM -0.1 to 0.5	7.0
PI HIGH ALARM	PI LOW ALARM +0.1 to 19.0	19.0
PI LOW ALARM	PI HIGH ALARM -0.1 to 0.0	0.0
PVI HIGH ALARM	PVI LOW ALARM +1 to 99	99
PVI LOW ALARM	PVI HIGH ALARM -1 to 1	1
SpOC HIGH	SpOC LOW ALARM +1 to 34.0	34.0

APPENDIX I

(Default Settings)

ALARM				
SpOC LOW ALARM	SpOCI HIGH ALARM -1 to 1.0			1.0
SPO2 SENSITVITY	NORMAL , APOD,MAX SENS			NORMAL
SPO2 PULSE RATE	ON,OFF			OFF
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 ALM +5 to 255	Adult	160mmgh
	Neonate	SYS LOW ALM +5 to 135	Neonate	90 mmHg
	Pediatric	SYS LOW ALM +5 to 240	Pediatric	120 mmHg
SYS LOW ALARM	Adult	30 to SYS HIGH ALM -5	Adult	90 mmHg
	Neonate	30 to SYS HIGH ALM -5	Neonate	40 mmHg
	Pediatric	40 to SYS HIGH ALM -5	Pediatric	70 mmHg
DIA HIGH	Adult	DIA LOW ALM +5 to 220	Adult	90 mmHg

APPENDIX I

(Default Settings)

ALARM	Neonate	DIA LOW ALM +5 to 110	Neonate	60 mmHg
	Pediatric	DIA LOW ALM +5 to 220	Pediatric	70 mmHg
DIA LOW ALARM	Adult	15 to DIA HIGH ALM -5	Adult	50 mmHg
	Neonate	15 to DIA HIGH ALM -5	Neonate	20 mmHg
	Pediatric	15 to DIA HIGH ALM -5	Pediatric	40 mmHg
MAP HIGH ALARM	Adult	MAP LOW ALM +5 to 235	Adult	110 mmHg
	Neonate	MAP LOW ALM +5 to 125	Neonate	70 mmHg
	Pediatric	MAP LOW ALM +5 to 230	Pediatric	90 mmHg
MAP LOW ALARM	Adult	20 to MAP HIGH ALM - 5	Adult	60 mmHg
	Neonate	20 to MAP HIGH ALM - 5	Neonate	25 mmHg
	Pediatric	20 to MAP HIGH ALM - 5	Pediatric	50 mmHg
AUTO/ Manual/ STAT	MANUAL, STAT, AUTO 1min, 2min, 3min,5min,10min,15min,20min, 30min,45min,60min,90 min,2H,4H, 8H, 12H, 16H, 20H, 24H.			MANUAL

APPENDIX I

(Default Settings)

AUTO SLEEP	ON,OFF	OFF

The parameters in TEMP menu

TEMP UNIT	℃,℉	℃
ALARM LEVEL	1,2	1
TEMP ALARM	ON ,OFF	OFF
TEMP HIGH ALARM	T1 LOW ALARM +0.5 to 50.0	39.0
TEMP LOW ALARM	T1 HIGH ALARM -0.5 0.0 to	35.0
TEMP LOW ALARM	T1 HIGH ALARM -0.5 to 0.0	35.0

The parameters in ARR menu

ARR MONITOR		ON, OFF	OFF
ALARM LEVEL	ASYSTOLE	1	OFF
	VFIB	1	1
	VTAC	1	1
	RUN	1, 2, OFF	1
	AIVR	1, 2, OFF	1
	COUPLET		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	2

APPENDIX I

(Default Settings)

	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 VTACcount-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	-	-

APPENDIX I

(Default Settings)

The parameters in ST menu		
ST ANALYSIS	ON, OFF	OFF
ST ALARM	ON, OFF	OFF
ALARM LEVEL	1, 2	1
ST LOW ALARM	ST HIGH ALARM -0.1 to -2	-0.2
ST HIGH ALARM	ST LOW ALARM +0.1 to 2	0.2
EVENT DURATION	15S, 30S, 45S, OFF	OFF
The parameters in IBP menu		
IBP UNIT	mmHg , KPa,cmH2O	mmgh
IBP LABEL	IBP,ART,PAP,CVP,LAP, RAP,LVP,RVP,ICP	IBP
ALARM LEVEL	1,2	1
IBP ALARM	ON,OFF	OFF
IBP HIGH ALARM	IBP LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
IBP LOW ALARM	IBP HIGH ALARM -5 to -50	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
ART HIGH	ART LOW ALARM +5 to 300	SYS: 150 mmHg

APPENDIX I

(Default Settings)

ALARM		DIA: 100 mmHg MEAN: 115 mmHg
ART LOW ALARM	ART HIGH ALARM -5 to -50	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	LVP HIGH ALARM -5 to -50	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	PAP HIGH ALARM -1to -50	SYS: 5 mmHg DIA: -5 mmHg MEAN: 0 mmHg

APPENDIX I

(Default Settings)

RVP HIGH ALARM	RVP LOW ALARM +1 to 100	SYS: 40 mmHg DIA: 15 mmHg MEAN: 30 mmHg
RVP LOW ALARM	RVP HIGH ALARM -1to -50	SYS: 5mmHg DIA: -5 mmHg MEAN: 0 mmHg
CVP HIGH ALARM	CVP LOW ALARM +1 to 100	15 mmHg
CVP LOW ALARM	CVP HIGH ALARM -1 to -50	-5 mmHg
LAP HIGH ALARM	LAP LOW ALARM +1 to 100	20 mmHg
LAP LOW ALARM	LAP HIGH ALARM -1 to -50	-5 mmHg
RAP HIGH ALARM	RAP LOW ALARM +1 to 100	15 mmHg
RAP LOW ALARM	-40 to RAP HIGH ALARM -1	-10 mmHg
ICP HIGH ALARM	ICP LOW ALARM +1 to 100	Adult: 10mmHg Neonate: 4mmHg

APPENDIX I

(Default Settings)

			Pediatric: 4mmHg
ICP LOW ALARM	ICP HIGH ALARM -1 to -40		0 mmHg
IBP FILTER	22Hz,16Hz,8Hz		16Hz
IBP SWEEP	3mm/s,6mm/s,12.5mm/s,25mm/s		12.5mm/s
IBP SCALE			
IBP	HIGH	LOW +10 TO 300 (with step 10)	200
	LOW	HIGH -10 to -50	-20
	SIGN	(HIGH+LOW)/2	90
ART	HIGH	LOW +10 TO 300 (with step 10)	200
	LOW	HIGH -10 to -50	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

APPENDIX I

(Default Settings)

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

APPENDIX I

(Default Settings)

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
IBP GRID	ON,OFF		OFF
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 GAS WINDOW(Mainstream & Sidestream)			

APPENDIX I

(Default Settings)

CO2 UNIT	KPa ,%V ,mmHg	mmHg	
WORK MODE	MEASURE, STANDBY	MEASURE	
ZERO	Only for Mainstream		
ALARM	ON,OFF	OFF	
ALARM LEVEL	1,2	2	
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	18~(HIGH-1) (%V)	50% - (For IRMA ICU: 25)	
EtO2,FiO2 HIGH	(LOW+1)~105(%V)	100%	
AWRR LOW	1~(HIGH-1)	NEONATE	ADULT
		15 BrPM	5 BrPM
AWRR HIGH	(LOW+1) ~120	30 BrPM	60 BrPM
APNEA LIMIT	10s,15s,20s,25s,30s,35s,40s,OFF	30S	15S
O2 COMPENSATE	1-100 vol%, OFF	21% , AUTO	

APPENDIX I

(Default Settings)

N2O COMPENSATE	0-100 vol% (ONLY FOR ISA CO2, IRMA2 CO2)		0%
SWEEP	3mm/s, 6mm/s, 12.5mm/s, 25mm/s		12.5mm/s
SIGNAL SCALE	CO2	6%,10%,Auto scale	10%
	O2	0-50%,0-100%, Auto scale	100%
FIIL SIGNAL	ON,OFF		OFF
WAVE FORM	CO2, O2		CO2
GAS UNIT	KPa ,%V		%V
SYSTEM DEFUALT			
PAGE	ARIA	P1 … P23	P1
ALARM VOLUME	1,2,3,4,5,6,7,8		1
CALENDAR	SOLAR, CHRISTIAN		CHRISTIAN
PAT. CONF	ADUL,NEONATE, PEDIATRIC		ADULT
BED NUMBER	1 … 99		01

APPENDIX I

(Default Settings)

Module Color		
ECG	-----	Green
SPO2	-----	Magenta
RESP	-----	Yellow
TEMP1,2	-----	Cyan
IBP1	-----	Light Red
IBP2	-----	Light Blue
IBP3	-----	Light Orange
IBP4	-----	Cyan
NIBP	-----	White
CO2	-----	Yellow
BFA	-----	White

APPENDIX II
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 – Patient monitor emissions		
The patient monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor, should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The patient monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The patient monitor is 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 monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor should assure that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Patient coupling		
	Signal input/output parts		
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	± 2 kV, 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 1 kV 100 kHz repetition frequency	
Surge IEC 61000-4-5	Input a.c. power	± 0,5 kV, ± 1 kV Line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 2 kV Line-to ground	
Voltage dips, IEC 61000-4-11	Input a.c. power	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	Input a.c. power	0 % U_T; 250/300 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	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 monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor should assures that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	Input a.c. power	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	
	PATIENT coupling		
	Signal input/output parts		
Radiated RF IEC 61000-4-3	ENCLOSURE	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2015)	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because

while it does not represent actual modulation, it would be worst case.