Pooyandegan Rah Saadat

Operator's Manual

Aria TC Patient Monitor

CE 2195

D00794-10

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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 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
August 2020	D00794-10

Aria TC User Manual

Chapter 1, Introduction

Contents

Symbols

The following symbols are used in this manual:

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

A WARNING symbol advises against certain actions or situations that could result in personal injury or equipment damage.

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.

General Warning

⚠ Warning ⚠

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

⚠ 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.

General Warning

⚠ 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 equipment. 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.

General Warning

⚠ 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.

General Warning

⚠ 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.

⚠ 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.

General Warning

⚠ Warning ⚠

Before using the system, check the battery charge status.

⚠ Warning ⚠

Do not touch the screen with sharp objects.

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.

▪ 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 System Configuration, PATIENT INFORMATION)
- Patient mode (Adult/Neonate/ Pediatric) before NIBP measurement
- Alarm sound
- Alarm limits
- Pulse oximetry
- RESP

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

- **Connect the sensors to patient**

Connect all necessary accessories to the monitor and the patient.

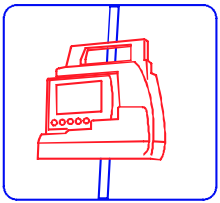
For more information about accessories, please refer to each module's chapter

1-3 Continuous Patient Monitoring

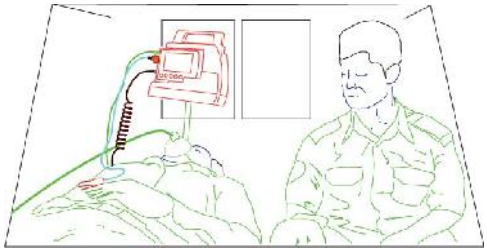
The Aria monitor is intended to be used as a full- function monitoring system. By connecting some accessories to the monitor, it will be usable in different units of the hospital.

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.

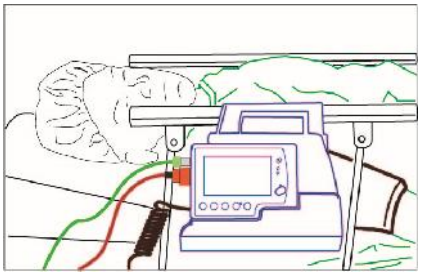


Installation on the roll stand



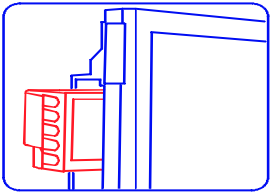
Monitoring in ambulance

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



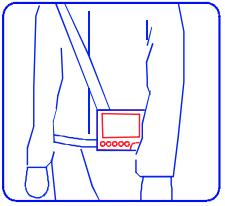
Installation on bed rail

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	0 ~ 55 ◦c
Storage and transportation temperature	-25~ 60 ◦c
Operating humidity	10~ 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 monitor with TC station is used to monitor patient's vital sign parameters in ambulance, emergency department and accident scene. It has been designed to send real-time patient data to contact center of the emergency department via the internet network (wired or wireless). Paramedics could communicate orally with specialist via this system and get real- time medication advices.

The vital sign parameters such as ECG, TEMP, NIBP, SPO2 and RESP can be monitored via the Aria TC system. This system is a portable monitor that is equipped with built-in battery, a recorder and an alarm system and can be connected to Wi-Fi network of the Central system (optional).

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
NIBP	Systolic pressure, Diastolic pressure and Mean arterial pressure(MAP)
TEMP	Temperature channel (T)

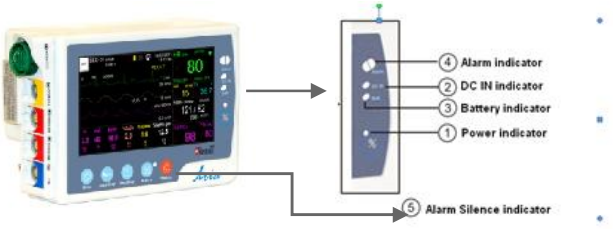
The Aria TC monitor is equipped with Visual & Audible alarms and can store Trend and NIBP data.
The monitor provides storage of arrhythmia events (ARR List) as well as trend data and NIBP measurements.
The monitor is a user-friendly device which can be easily operated via the front panel keys and touch 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, Connectors and controls

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

Indicators

Turn off the monitor in the Aria TC system, TC station will be turned off automatically after 20 seconds.

Turn on the monitor in the Aria TC system, TC station will be turned on automatically and will be ready for use after 20 seconds.

⚠ Warning ⚠

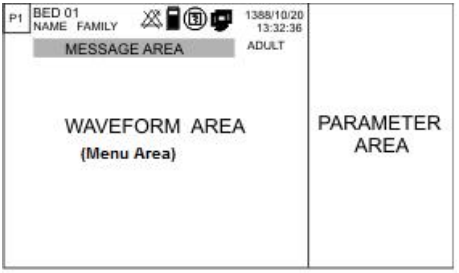
The alarm indicator in normal condition is off. It flashes when an alarm occurs.

⚠ 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.

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

Main Screen

	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 the Aria TC system when connection of the Aria monitor to TC station and internet is made. If the monitor is connected to the internet, the symbol will be displayed in green; otherwise it is white.

- **Waveform / Menu Area**

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

Gain, filter, lead and sweep speed of the ECG waveform are also displayed in this area.

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 pages in the Aria TC system by default to display parameters and waveforms.

P1 :In this page you can monitor HR, NIBP, SPO2, PR, RR and TEMP parameters as well as ECG, SPO2 and RESP waveforms.

Select CALL in P1 to ensure that PHONE NUM and DEVICE ID have been entered; otherwise the system will not be able to send vital signs data.

Different Page

P2 :In this page you can monitor HR, NIBP, SPO2, PR, RR and TEMP parameters and 12-lead ECG waveforms.

P2 only displays 12 traces of ECG signal. MENU key is inactive in this page and you cannot access parameters menu.

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.

Different Page

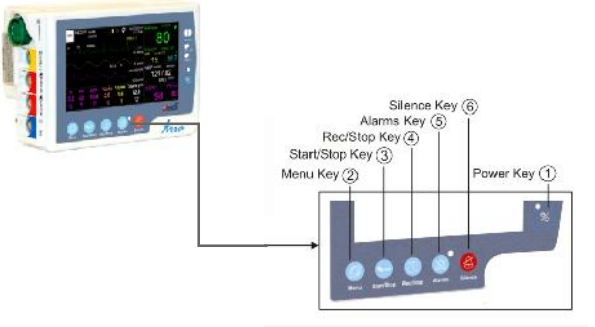
1-When using the monitor, the screen should be protected from direct sunlight in order to get a clear view of what is displayed.

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 Key Function

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



Keys Function

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

Keys Function

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.

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.

⚠ Warning ⚠

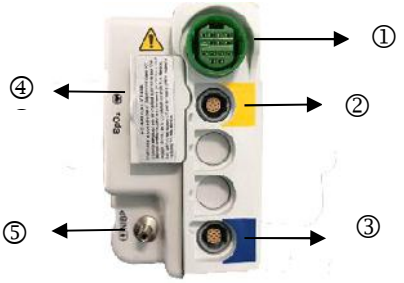
Before monitoring the patient, check the keys function and make sure that they are in proper working condition.

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.

Connectors of Aria TC system



①	ECG cable
②	TEMP1 probe
③	Programming cable
④	Masimo SPO2 sensor
⑤	NIBP cuff

Interfaces

⚠ Warning ⚠

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

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 TC Station

TC station is shown in the below figure:

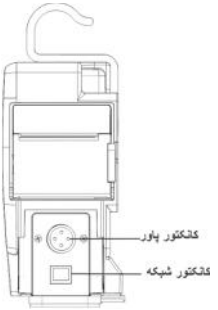
Aria monitor with TC station

⚠ Warning ⚠

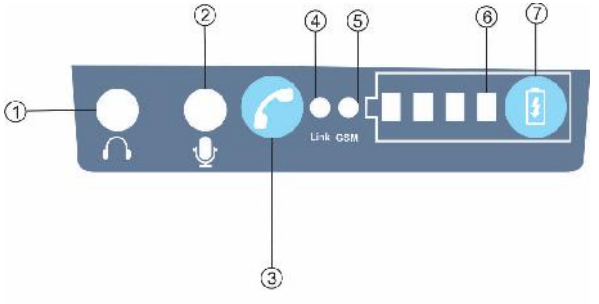
The alarm indicator in normal condition is off. It flashes when an alarm occurs.

TC Station

The power and network connectors are located at the right side of the TC station .



1-10 Indicators of TC station

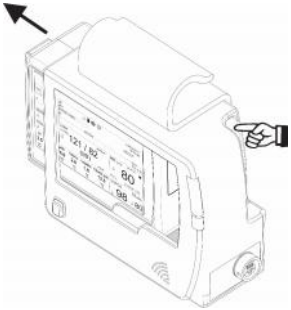


①	**Headphone**	
②	**Microphone**	
③	**Call/End Key**	
④	**Link LED**	indicates connection to server
⑤	**GSM LED**	indicates connection to GSM network - LED flashes every second if the system is not connected to GSM network - LED flashes every 3 seconds if the system is connected to GSM network.
⑥	**Battery LEDs**	if the battery charging fails, all four LEDs will flash simultaneously.
⑦	**Battery key**	to indicate the battery charge status when the station is off.

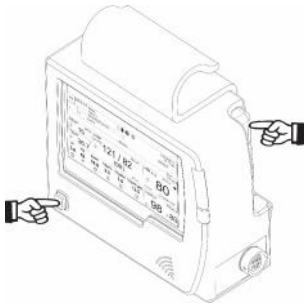
For battery and adaptor information, please refer to the Technical Specifications chapter.

1-11 Removing the Aria monitor from the station

Press and hold the eject button in front of the station (See figure 1-8) and simultaneously pull out the monitor. When the monitor moves in its position, release the eject button and remove the monitor.



1-8 b



1-8 a

Removing the Aria from the station

TC Station

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 TC 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

1-12 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.

Rechargeable Battery

3.6 V , 2500 mAh

NICKEL-METAL HYDRIDE

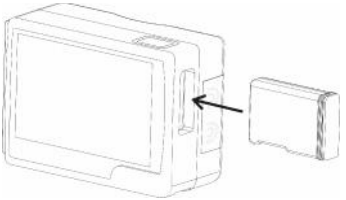
For optimal performance use recommended charger.

Recycle or dispose of properly.

⚠ 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.

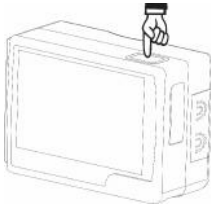
To insert the battery into the monitor, slide the battery into the compartment in the direction shown in the figure 1-9.



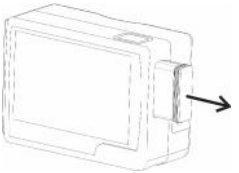
Battery insertion into the monitor

Built-in Battery

To remove the battery, press the battery eject button (see figure 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.

Built-in Battery

⚠ 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, Contact Center

Contents

2-1 Contact Center

Contact center is a location to receive, manage, and record phone calls, emergency missions and activities using information technology and telecommunication.

There is a tele cardiology server in the contact center to synchronize the Aria monitor and TC station and to save the received ECG records from the Aria TC and transmit these records to ECG-Viewer software. In addition, this server saves the missions data in its database.

2-2 Internet connection status

The Aria TC system continuously requests date and time of ECG record from TC server. The Aria monitor is set according to received date and time and “INTERNET CONNECT” appears on the screen. When connection to the station is established, relevant

symbol is displayed in green, the monitor beeps twice and Link LED lights up.

2-3 Internet disconnection status

If connection to the internet or central server fails, "INTERNET DISCONNECT" will appear and relevant symbol to the internet connection will change to the gray. In this condition the monitor beeps every 10 seconds and Link LED turns off.

⚠ Warning ⚠

If the Aria TC system is turned on and not connected to the internet, date and time will be set by the Aria monitor. Thus you should note that ECG records are saved in correct date and time and the contact center does not consider wrong date /time for the ECG records.

2-4 Mobile network connection status

Turn on the Aria TC system. The mobile modem will be turned on and connection to the modem will be established. In this condition "Phone Ready" is displayed on the Aria monitor and GSM LED flashes.

⚠ Warning ⚠

Always ensure that data SIM card has sufficient credit for sending data to the contact center.

2-5 Phone call

Make the system ready for calling and press Call/End key for one second to call up "DIAL:021...." on the screen. Release the key and press it again for one second to end the phone call. If you receive any call, "INCOMING CALL" will appear on the screen. Press and hold Call/End key for one second to answer the phone call; otherwise the call will be made automatically after 3 seconds.

⚠ Warning ⚠

Always check that GSM SIM card has sufficient credit to call the contact center.

2-6 Sending ECG record to the emergency department

Before ECG recording, check date and time of the Aria monitor and set them if necessary. If the internet connection is established, date and time setting will not be required.

Connect the electrodes to patient and wait until the signals are stabilized and HR value is displayed. Press REC key to record ECG data and save 10 seconds of ECG signal in the Aria TC system.

If the internet connection is established, all saved data will automatically be sent to the contact center. In this condition “SENDING FILE” is displayed and if the data is sent successfully, “FILE SENDING OK” will

be displayed and the system will continually beep three times.

If the internet connection is not established, all saved ECG signals will be preserved and “File Remained: n” will be displayed. “n” indicates number of ECG records which has not been sent to the contact center.

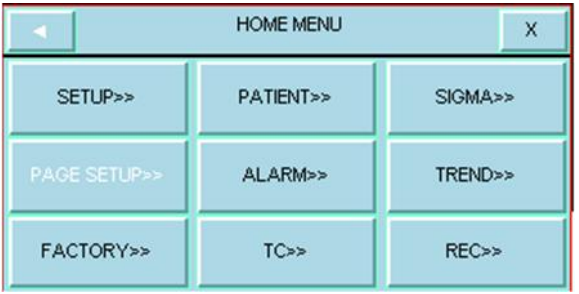
About 20 seconds after Turning off the Aria TC, its station will be turned off.

Chapter 3, System Configuration

Contents

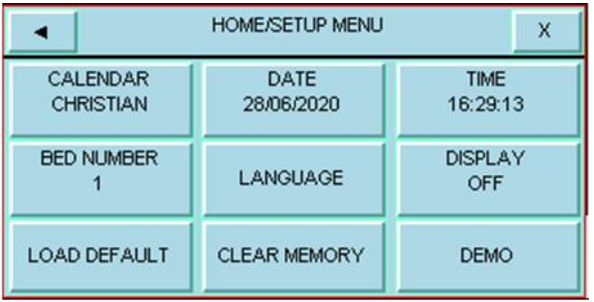
3-1 HOME MENU

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.



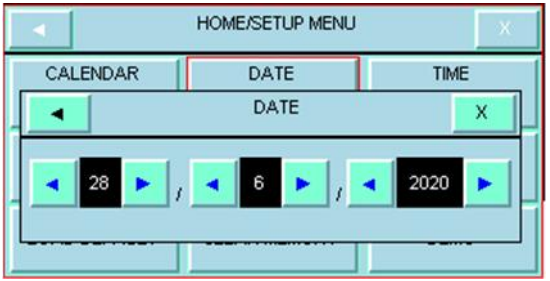
3-2 SETUP

By pressing SETUP, you can access the following menu:

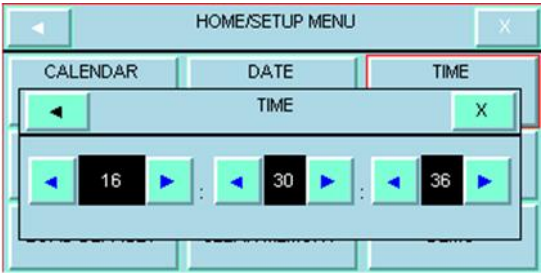


The below settings can be performed in this menu:

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

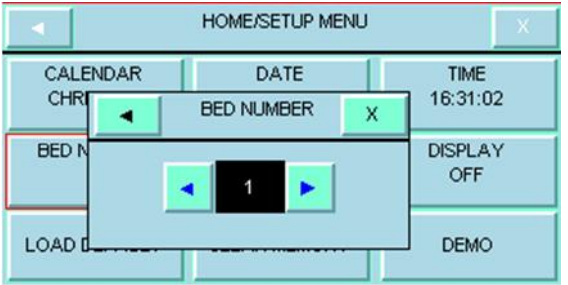


- **TIME**: Press this item to set time in the following window:

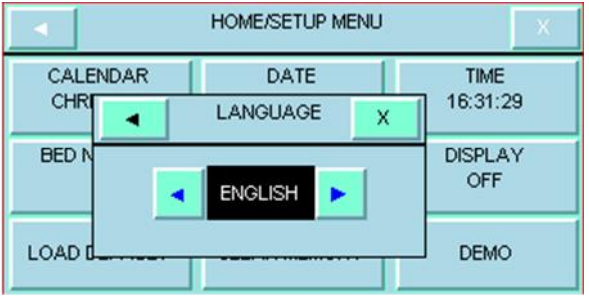


The monitor synchronizes with the Central system upon its connection to this system. In this condition, date and time settings will be inactive in SETUP menu.

- **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".



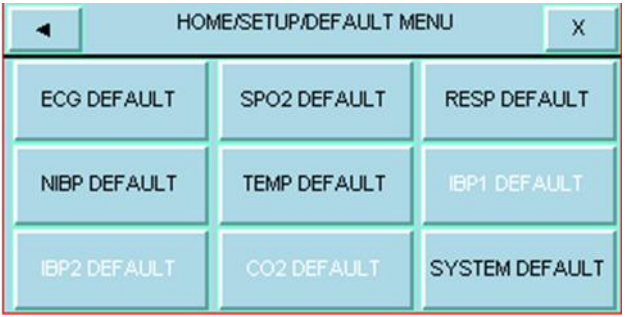
- **DISPLAY OFF**: Select this item to turn off the display screen until a key is pressed or an alarm occurs.

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

- **LOAD DEFAULT:** Select this item to access SETUP/ DEFAULT MENU 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.

ARE YOU SURE YOU WANT TO LOAD ECG DEFAULT?
YES NO



IBP1 DEFAULT, IBP2 DEFAULT and MODULE DEFAULT items are inactive in this version.

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 and NIBP LIST data. Press this item to call up the following menu. An alert message will ask for your confirmation before clearing the selected item.

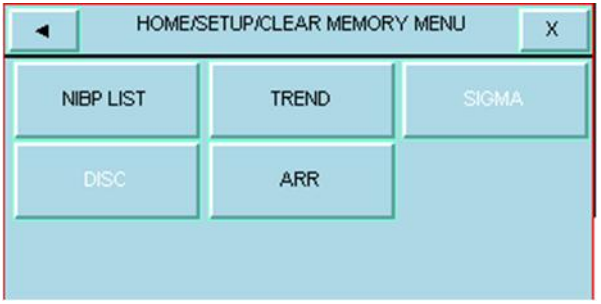
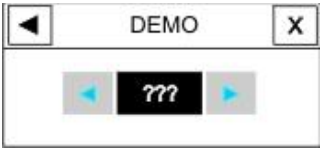


Figure 3-9- ALERT message

- **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.



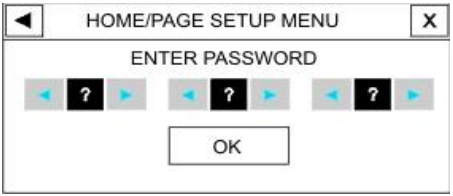
The operator cannot access this menu and only authorized personnel of the manufacturer can use this menu.

3-3 PAGE SETUP

PAGE SETUP is inactive.

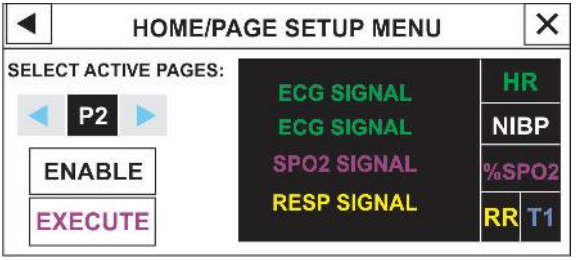
The operator has not access to this menu and only authorized personnel of the manufacturer can perform settings of this menu.

By pressing "PAGE SETUP", you can access this menu:



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

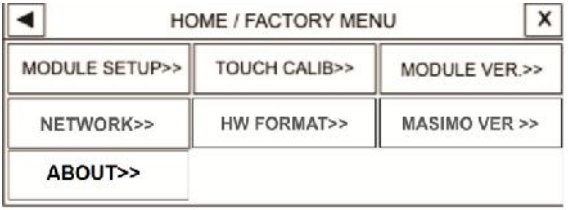
message “WRONG PASSWORD” will appear in the red color.



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

3-4 FACTORY

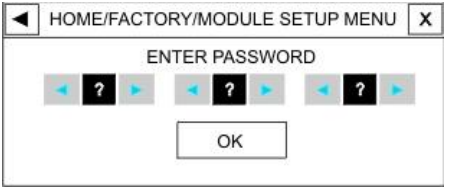
By pressing FACTORY, you can access this menu:



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.

Module Setup is inactive.

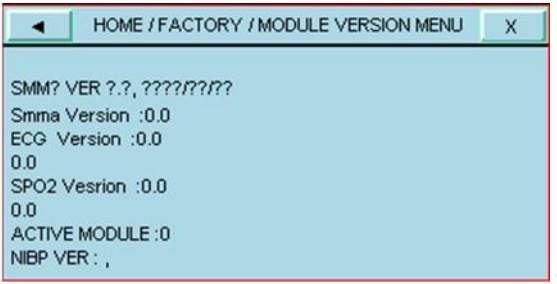
■ TOUCH CALIB

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.

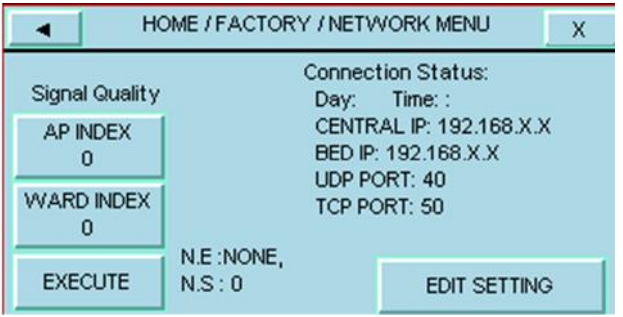
■ **MODULE VER.**

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



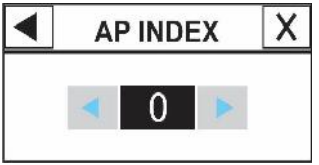
■ **NETWORK**

Press this item to access the below menu:

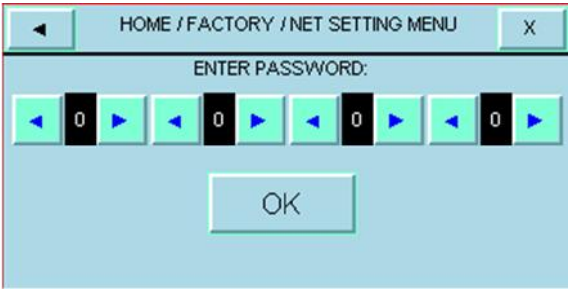


FACTORY

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.

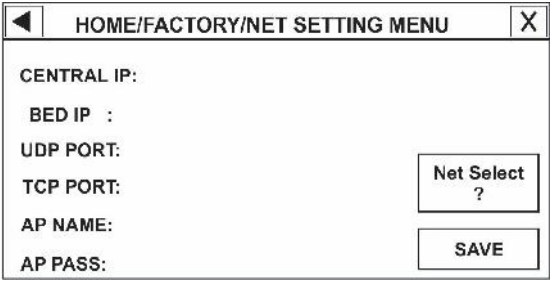


By pressing EDIT SETTING, you can access the below menu:



FACTORY

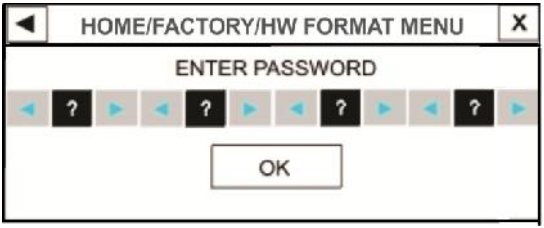
If you enter correct password and press OK, the following menu will appear in which you can perform the network setting.



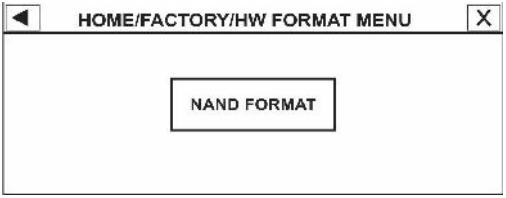
This item is optional and is inactive.

■ 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 .

3-5 TC MENU

For direct connection of voice and data channels to the contact center of the emergency department, the following information must be entered in Home /ARIA TC/SETTING Menu.

The below information must be set by trained customer service experts.

HOST: IP address or domain of TC server.

SERVICE: name of service in TC server.

DEVICE ID: identification number of the device.

PHONE-NUM: phone number of the contact center.

ARIA PHONE: number of inserted SIM card in the device.

⚠ Warning ⚠

To prevent interference of data sent from different devices, select a unique ID for each device.

To enter the above information, you must know the device passwords.

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Chapter 4, Alarm

Contents

This chapter gives general information about alarm and its functions.

⚠ Warning ⚠

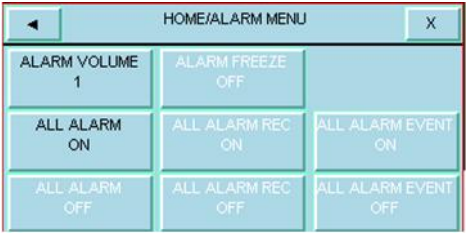
Always verify the audible and visual alarms when the monitor is powered on.

ALARM

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

4-1 ALARM MENU

The following settings can be done in this menu.



ALARM FREEZE, ALL ALARM REC, ALL ALARM EVENT are inactive.

- **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 YOU WANT TO ON ALL ALARM?
YES NO

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).

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.

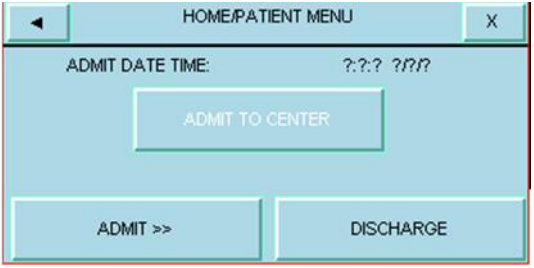
5- After removing the alarm cause, check that the alarm system is working properly.

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

Chapter 5, Patient Information

PATIENT MENU

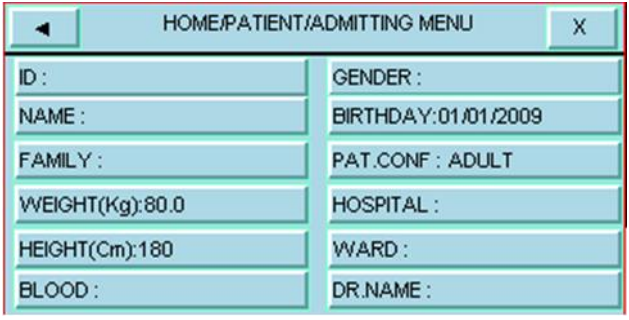
By pressing PATIENT, you can access the below menu:



"ADMIT TO CENTER" item is inactive.

PATIENT MENU

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



ID Patient code in hospital (Up to 15 characters)

NAME Up to 15 characters

FAMILY Up to 15 characters

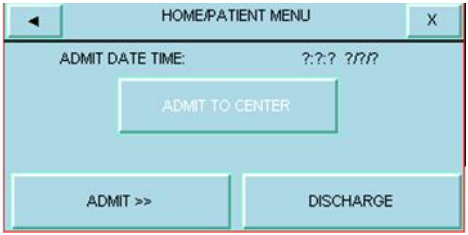
PATIENT MENU

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
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

PATIENT MENU

ADMIT button of HOME/ PATIENT MENU will change to EDIT as far as information of new patient is entered.



If the patient mode (Neonate, Pediatric, and 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

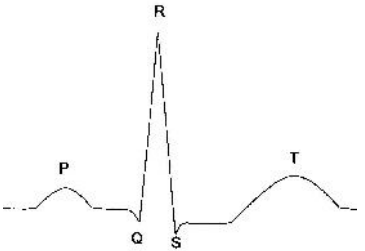
Contents

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

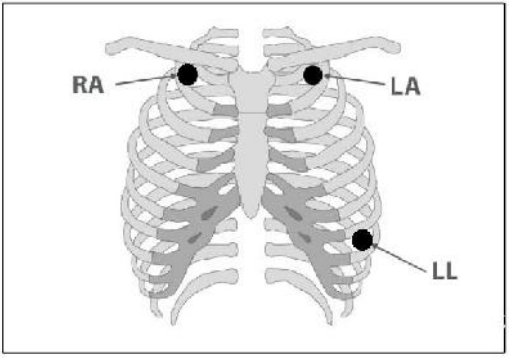
The ECG patient cable consists of 2 parts: The trunk cable that is connected to the monitor and the patient lead wires that are connected to the patient. Available cable types and the various methods of lead placement are described in following part

- **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**

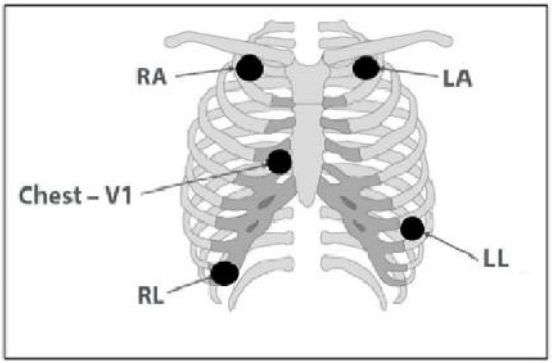
Right arm (RA): red electrode, be placed near the right

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.

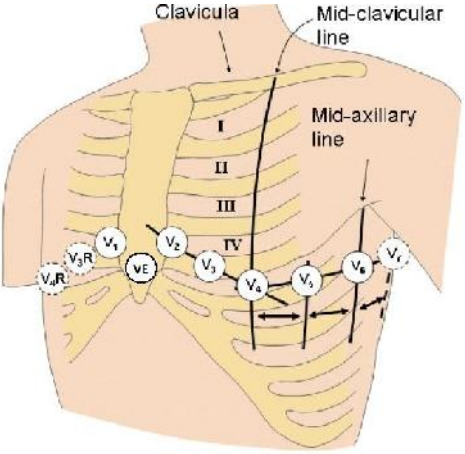


- Electrode's **locations** for 5-wire ECG Cable

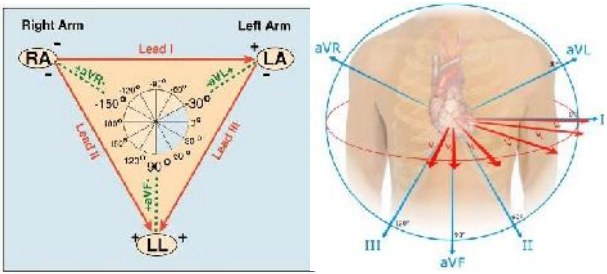
For ECG 5-WIRE mode, attach the C-electrode to different positions on the chest:

●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

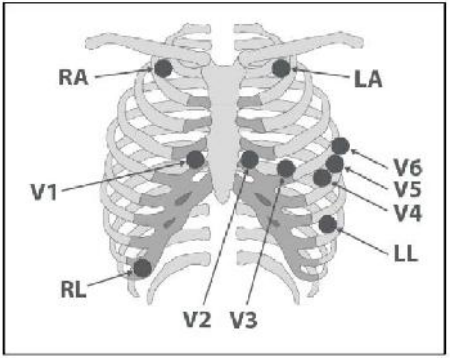


ECG Leads

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.

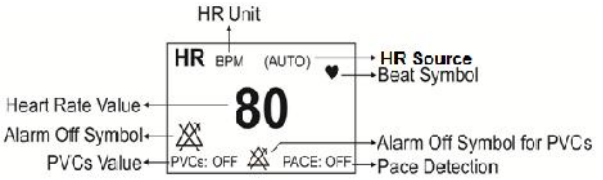
.

⚠ 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.

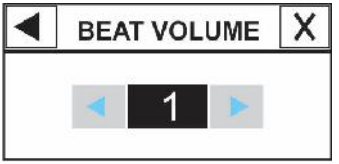
2- The RL electrode is disconnected or not connected properly.

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 sec and AUTO.

Select this item to determine the maximum time of displaying HR changes. For example, if HR AVERAGE is set to 8 sec and HR value changes from 90 to 200, it will take maximum 8 seconds to display HR changes.

	Response	
	HR Avg.= 4s	HR Avg.= 8s
HR= 80 to 120 BPM	5	6
HR= 80 to 40 BPM	7	8

The above results are for lead II.

- When Tachycardia (HR>120 bpm) happens, it takes 6 seconds to activate alarm sound. (If low alarm limit is 60 bpm and high alarm limit is 100 bpm).
- It takes 10 seconds to activate alarm sound by the system when a cardiac arrest happens (from 80 bpm to 0 bpm)
- The ECG module is able to reject 1.2 mV TALL T-pulses.
- The current that is applied to the patient for lead-sensing is 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.

- Hear rates measured for the 4 irregular rhythms according to IEC 60601-2-27:2011 are as follow:

Irregular rhythm	HR (bpm)-adult	HR (bpm)-pediatric	HR (bpm)-neonate
3a ventricular bigeminy	85	85	85
3b slow alternating ventricular bigeminy	30	50	67
3c rapid alternating ventricular bigeminy	126	126	126
3d bidirectional systoles	40-105	40-105	84-109

- **HR SOURCE**

The heart rate may be derived from “ECG” or “SPO2” signals. In AUTO mode if ECG cable is connected to the patient, the monitor automatically will derive heart rate from ECG signal. If ECG signal is not present, depending on priority of SPO2 signal the heart rate will be derived from every signal that is being monitored.

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 and cable of the module is not connected to the system, HR value will not be displayed.

- **LEAD TYPE**

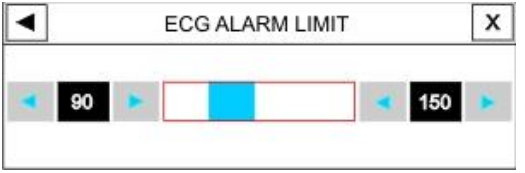
Select this item to access different ECG modes including 3-wire and 5-wire and 10-wire.

- **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 electro surgery 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

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	0.05-150 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:

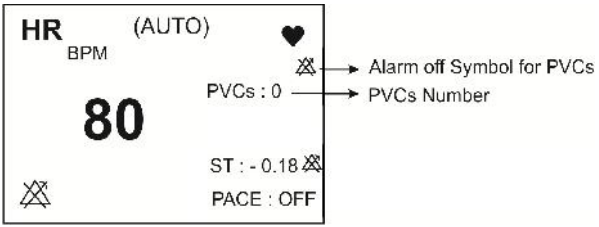
Arrhythmia	Event and Beat Classification
ECG ASYSTOLE	5 seconds pass without the detection of valid QRS complex.
VFIB ARRHYTHMIA	Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics. (Certain ventricular tachycardias have sinusoidal waveforms closely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

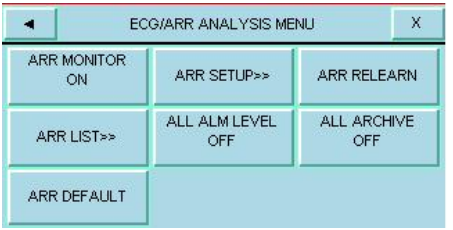


PVC value in ECG parameter area

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:

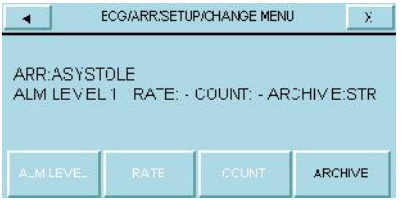
The ARR SETUP table allows you to configure arrhythmia monitoring accordingly to your patient’s needs. All detectable arrhythmia events listed in the first column of the table .Using the remaining columns, you can modify the attributes of each event. Fields that are not applicable for certain event category 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:

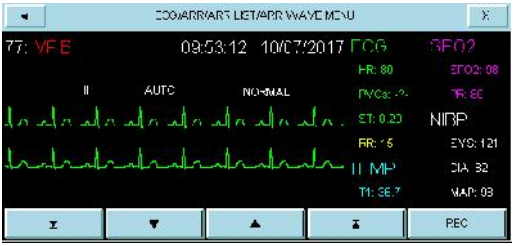
Maximum 5 arrhythmia events can be displayed in each page of “ARR LIST” menu. When there is more than 5 events, different pages are available.

Press ⏫ ⏬ to review different pages.

Press ▲ ▼ to select an arrhythmia event.

■ **To see detailed information of an arrhythmia event:**

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.

■ **REC in ARR LIST Menu**

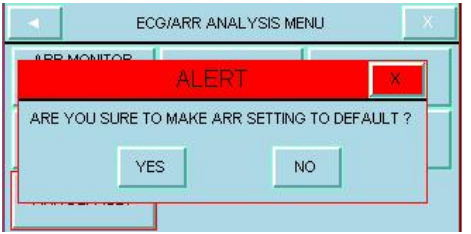
This item allows you to record the arrhythmias list.

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)

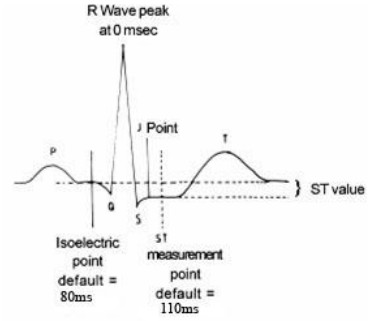
Chapter 8, ST Monitoring

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.

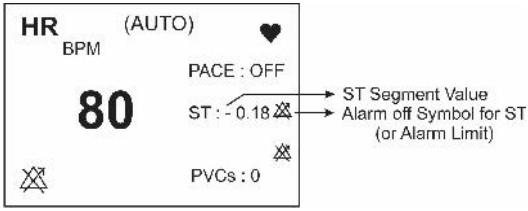
To ensure proper analysis of ST segment deviation, it is recommended to use extended filter.

ST monitoring function is “OFF” as a default. You can switch it “ON”, when this monitoring is necessary.

General Information

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”.



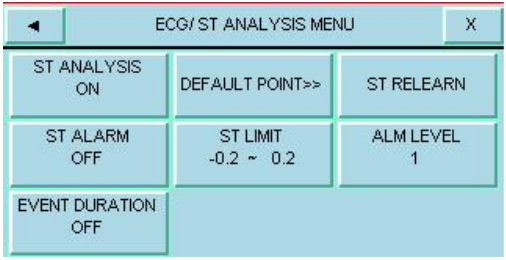
ST value in ECG parameter area

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.

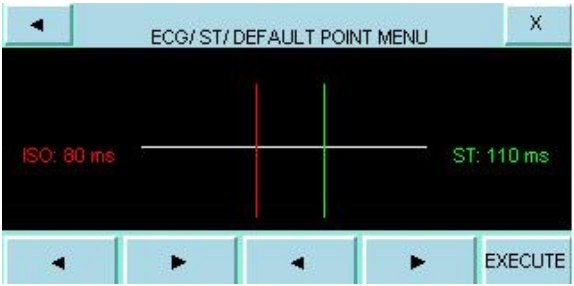
The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ST ANALYSIS is ON and there is no technical ECG alarm active, like CHECK LEAD):

- 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 from the amount of thoracic impedance between two ECG electrodes (RA-LL, RA-LA). The changes of impedance between the two electrodes (due to the thoracic movement) produce 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.

Preparing patient for RESP monitoring:

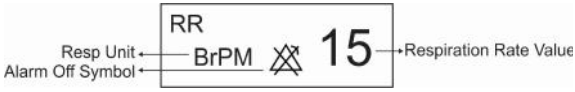
1- Prepare the patient's skin before placing the electrodes.

2- Attach the electrodes to the patient and the cable.

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 artifacts from pulsating blood flow. This is particularly important for neonates

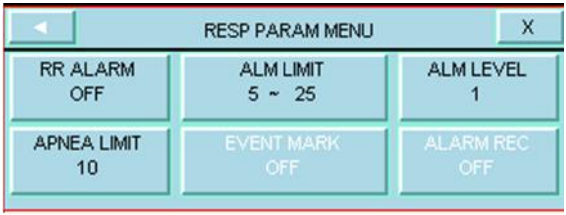
RESP parameter window is as below:



RESP Window

9-2 RESP PARAM MENU

Touch RESP parameter area to access the below menu:

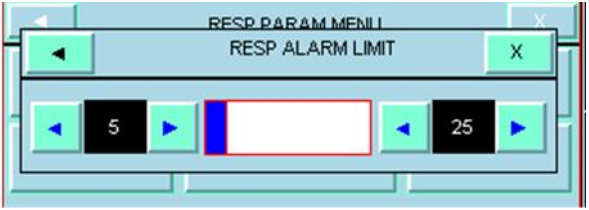


■ **RR ALARM**

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

Low limit: 5 ~ (High limit- 1)

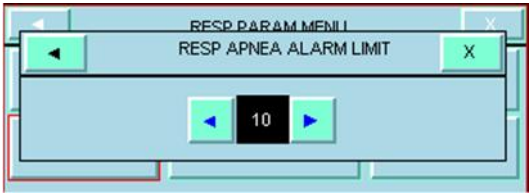
High limit: (Low limit +1) ~ 150

■ **ALM LEVEL**

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

■ **APNEA LIMIT**

Press this item to access the below window:



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 10 sec.

9-3 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.

9-4 RESP Alarm Messages

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

a) Physiological Alarms

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

RESP messages include:

b) Technical Alarms

Message	Cause/Solution	Remarks
RESP CHECK LEADS	Cause: The RESP leads are not properly connected. Solution: Make sure that all electrodes are properly connected.	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.

Chapter 10, SPO2 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

% 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

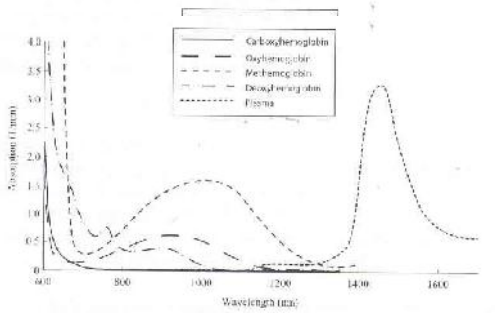
PR indicates the Heart Rate per minute which SpO2 module extracts from the pulse oximetry signal.

■ 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).



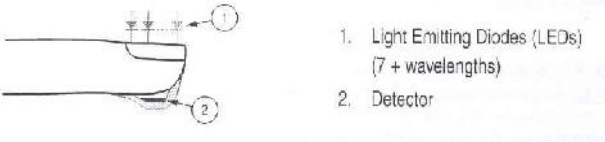
Absorption Spectra

2. The amount of arterial blood in the tissues changes with your pulse (photoplethysmography). Therefore, the
3. 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.



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.

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

10-2 Warning & Note

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

⚠ Warning ⚠

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

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 ⚠

Pulse oximetry 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.

Warning & Note

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.

Warning & Note

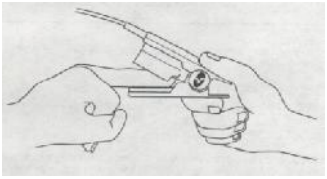
Measurement range of SPO2 and PR parameters is as follows:

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

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



SPO2 sensor placement

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

- 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 ⚠

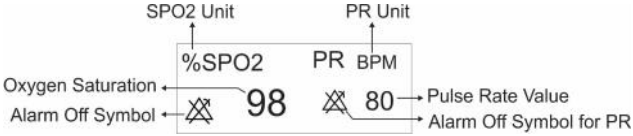
Tissue damage or inaccurate measurement can be caused by incorrect application or use of an SPO2 sensor, for example by wrapping the sensor too tightly or by applying supplemental tape.

⚠ 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.

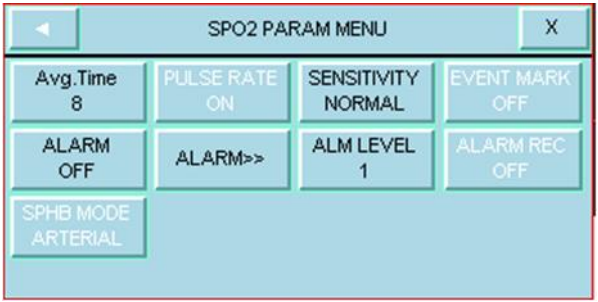
10-3 SPO2 PARAM MENU

SPO2 parameter window is as below:



SPO2 Window

Touch SPO2 parameter area to access the below menu:



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.

SpO2 PARAM MENU

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

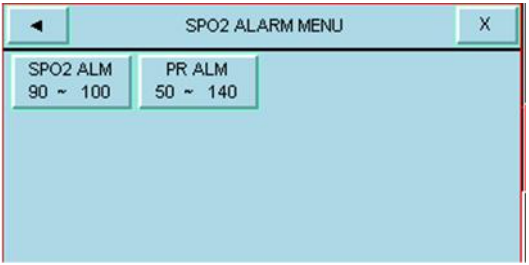
■ **ALARM ON/OFF**

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**

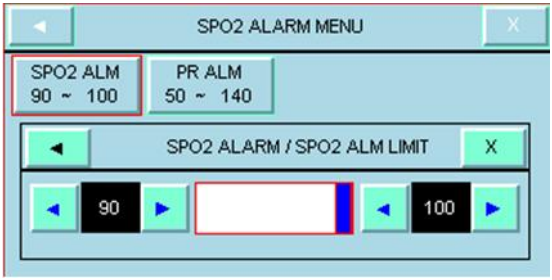
By pressing this item, you can access SPO2 ALARM MENU and adjust SPO2 and PR alarm limits.

SpO2 PARAM MENU



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

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

■ **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 occurs when the SPO2 and PR values violate adjusted alarm limits.

Alarm	Situation	Visual Alarm	Audio Alarm
%SPO2 HIGH	SPO2 violates adjusted high alarm limit	●SPO2 value blinks. ●Alarm indicator flashes ●The message is displayed in a background color corresponding to its level.	Activated
%SPO2 LOW	SPO2 violates adjusted low alarm limit	●SPO2 value blinks. ●Alarm indicator flashes ● The message is displayed in a background color corresponding to its level.	Activated

SPO2 Alarm Messages

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

SPO2 messages include:

b) Technical Alarms

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

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

	2. SpO2 sensor is not compatible.	properly attached to the cable connector. 2. Restore power to the instrument. If this message is displayed again, replace sensor.	SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 SENSOR OFF	1-SpO2 Sensor may be detached from the patient. 2-Sensor not connected to patient properly. 3-Sensor is damaged.	1-Disconnect and reconnect sensor. Reattach sensor. 2-Properly reapply the sensor on the patient and reconnect the sensor to the monitor or	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

		patient cable. 3-Replace the sensor.	
SPO2 NO AD SENSOR	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	Ensure the adhesive portion is firmly connected to the sensor.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 REPLACE AD SENSOR	When a single-patient-use sensor is used, the life of the adhesive portion of the sensor has expired.	Replace the adhesive portion of the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 AD SENSOR DEFECT	When a single-patient-use sensor is :used 1. The	1. Make sure that SpO2 sensor is properly attached	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the

	adhesive portion of the sensor .is damaged 2. SpPO2 sensor is not proper.	to the cable connector. 2. Power off and then on the system. If this message is displayed again, replace the adhesive portion of the sensor.	alarm is disabled and ignores this fault.
SPO2 AMBIENT LIGHT	This may be caused by excessive ambient light sources such as surgical lights or direct sunlight, or other.	In the case of using rainbow sensor, place a Masimo Optical Light Shield over the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec. The alarm is activated when SpO2 ALARM is "ON".

SPO2 Alarm Messages

SPO2 RAINBOW HARDWARE FAIL	SpO2 hardware error	Restore power to the instrument. If this message is displayed again,contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec. The alarm is activated when SPO2 ALARM is "ON".
SPO2 PROBE DEFECT	Failure to properly operate sensor or cable or both of them.	Check the function of the sensor and the cable separately and replace the defective part.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec. The alarm is activated when SPO2 ALARM is "ON".
SPO2 SENSOR CHECK CONNECTION	The sensor connection to the system is not correct	Check the sensor connection and, if necessary, replace the	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120

		sensor and/or cable.	sec. The alarm is activated when SPO2 ALARM is "ON".
SPO2 LOW SIGNAL IQ	SpO2 measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 LOW PR CONFIDENCE	Pulse rate measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.

c)Messages		
Message	**Cause/Solution**	**Explanation**
SPO2 CABLE NEAR EXP	The SpO2 cable is near expiration.	In this condition SPO2 parameter is displayed.
SPO2 SENSOR NEAR EXP	The SpO2 sensor is near expiration	In this condition SPO2 parameter is displayed.
SPO2 AD SENSOR NEAR EXP	The SpO2 adhesive sensor is near expiration.	In this condition SPO2 parameter is displayed.
SPO2 SEARCH	**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.	In this condition SPO2 parameter is displayed blank.
SPO2 SIGNAL WEAK	**Cause** /The SPO2 signal amplitude is too weak or undetectable. / **Solution**/ Change the place of the probe.	In this condition SPO2 parameter is displayed.

SPO2 Alarm Messages

SPO2 DEMO MODE RUN	The SpO2 measurement is in demo mode.	
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.	In this condition SPO2 parameter is displayed.

After taking the above mentioned actions, if the problem persists, check the probe for any damage and contact the Customer service department.

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 electrosurgery 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.

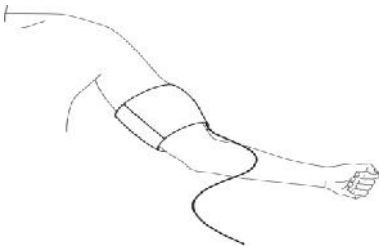
Preparatory steps for pressure measurement:

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.

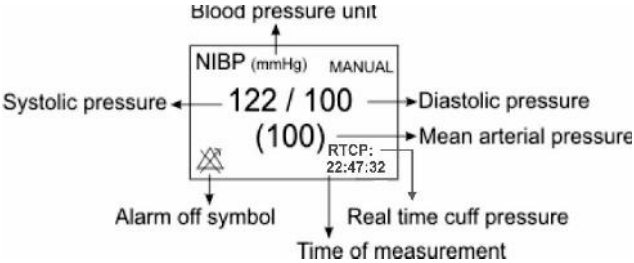
- **Severe Shock**

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

- **Abnormal Heart Rate**

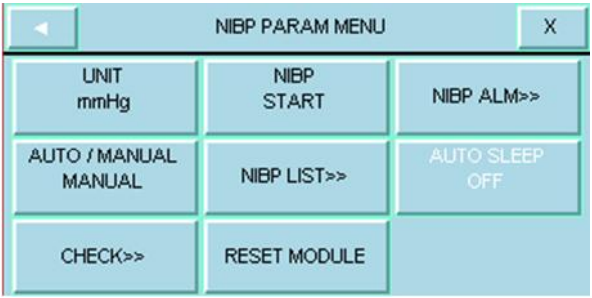
Measurement cannot be performed at a heart rate of less than 40 bpm and greater than 240 bpm.

11-2 NIBP PARAM MENU



NIBP Window

NIBP PARAM MENU is as follows:



NIBP PARAM MENU

■ **UNIT**

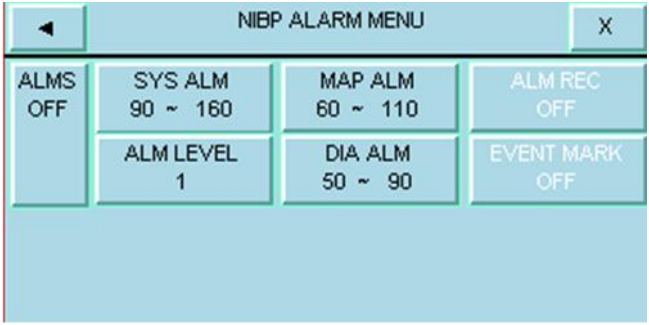
Select to adjust measurement unit. Available options are mmHg and KPa.

■ **NIBP START/ STOP**

Select this item to start or stop NIBP measurement.

■ **NIBP ALM**

Press this item to access NIBP ALARM MENU.



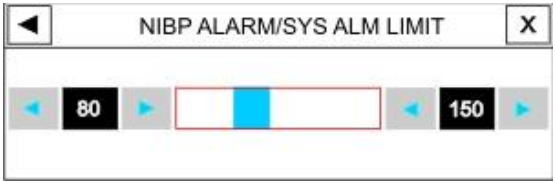
- **NIBP ALM ON/OFF**

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.



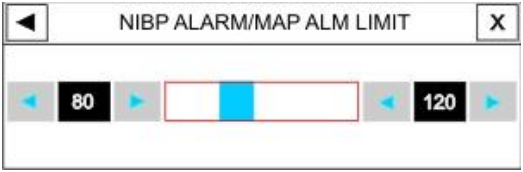
NIBP ALARM/SYS ALM LIMIT

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

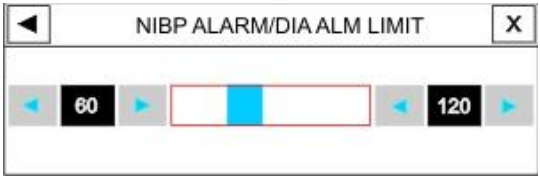
Neonatal → Low limit: 20 ~ (High limit -5), High limit: (Low limit +5) ~ 125

- **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.

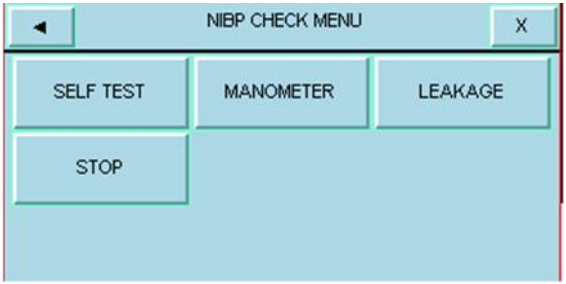
■ AUTO SLEEP

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 Alarm Messages

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

	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 electrosurgery device or other RF source. If probe must be used simultaneously with electrosurgery 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**

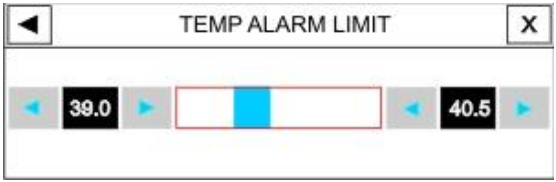
Select to set measurement unit. Available options are ºC and ºF.

■ **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

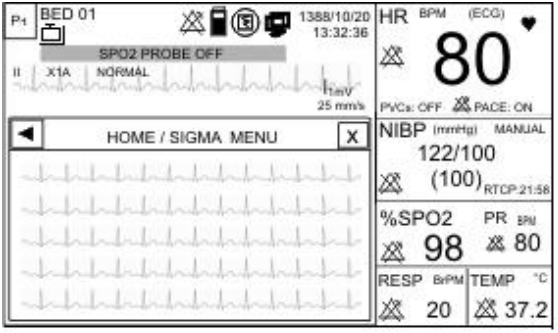
Chapter 13, TREND, SIGMA

Contents

13-1 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.



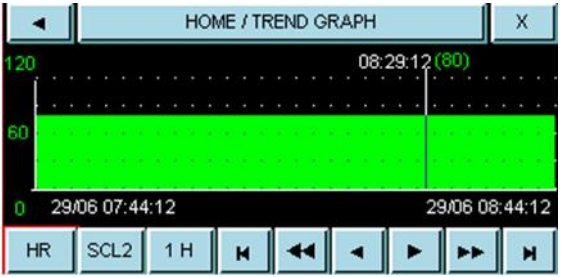
13-2 TREND

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.

TREND

■ **Selecting parameter values:**

Press the first left item in the trend graph to select your desired parameter. Available options are:
HR, SPO2, PR, RESP, TEMP.

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.

PARAM	SCL1		SCL2		SCL3		SCL4	
	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	-	-

■ 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 14, Recorder

Contents

14-1 General Information

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

Performance of the Recorder

- Recording speed is adjustable to 6, 12.5 and 25 mm/s.
- Single-lead ECG waveform recording
- 12-lead ECG waveform recording
- The real time and freeze recording
- The automatic recording at set time intervals

14-2 Recorder Menu

Select “REC” from HOME MENU to access the below menu:

■ **TRACE1**

To select waveform of the recorder first channel in Manual recording. Available options are “ECG Ref”, “ECG All” and “OFF”.

■ **TRACE 2**

TRACE2 is inactive.

■ **REC SWEEP**

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

■ **PERIODIC TRACE 2**

PERIODIC TRACE 2 is inactive.

■ **INTERVAL**

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

14-3 Type of Recording

- Real-time recording (Single lead and 12-lead ECG)
- Automatic waveform recording
- Freeze recording
- Parametric recording
- TREND recording
- NIBP LIST recording
- ARR LIST and ARR WAVE recording

Parametric Recording

Set “OFF” both traces in RECORDER WINDOW to enable Parametric recording.

Manual Recording

Select “Trace 1” to start Continuous or 10, 20 and 30 s recording for selected ECG lead. Select ECG ALL to start 5,10 s recording for 12-lead ECG waveform.

Type of Recording

- **10, 20 and 30 s Recording**

Real time recording starts from the last 5 seconds when you press “Rec/Stop” and it will automatically stop after 10, 20 or 30 seconds depending on your setting. Only one ECG lead is recorded during these intervals. If you select ECG ALL, all leads of ECG waveform will be recorded during 5 or 10 sec.

- **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.

Automatic Recording

The monitor starts the recording for 10 seconds according to time interval set in “PERIODIC INTERVAL” from the RECORDER menu.

Type of Recording

Alarm Recording (this item is not active)

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 WINDOW or in each parameter menu.

Freeze Waveform Recording

The monitor prints out the selected waveforms and numeric parameters in Freeze mode.

Type of Recording

- Set TRACE 1 to “ECG Ref”, the selected waveform will be recorded for 20 sec.
- Set TRACE 1 to “ECG ALL”, all waveforms will be recorded for 5 sec.

TREND Recording

The monitor can print out the trend graph and numeric parameters in the 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 LIST. Select REC in ARR/ARR LIST MENU to start recording.

ARR WAVE Recording

The monitor can print out the saved Arrhythmia waveforms in ECG/ARR/ARR LIST/ARR WAVE MENU. Select REC in this menu to start recording.

Type of Recording

The following information are recorded on the paper:

- Recording Type:

  MANUAL RECORD

  PERIODIC RECORD

  ALARM RECORD (name of the parameter triggered the alarm), inactive

  FREEZE RECORD

  (Parameter) TREND RECORD

  NIBP LIST RECORD

  ARR LIST RECORD

  ARR WAVE RECORD

- Recording Date and Time
- Bed number
- Patient name, Patient ID, Gender, Height, Weight, Date of birth
- Parameter name and value
- Sweep Speed

Type of Recording

- ECG lead, filter and gain or RESP lead on the waveform
- Hospital and ward name
- Physician name

14-4 Recorder paper

You should use only 57mm thermo-sensitive paper (length of 18 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.

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

⚠ 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.

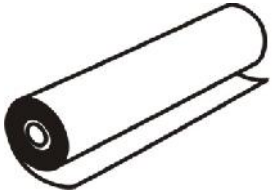
Do not use paper with edges that are pasted or have turnups at the start of the roll. If they need to be used unavoidably, replace with new paper roll as soon as possible before entire roll is used up.

Loading the paper:

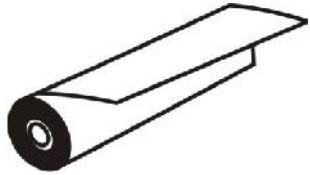
■ Pull up ejector of the recorder door.

■ 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.



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.

14-5 Recorder Alarm Messages

Alarm	Rec. Software Error
Cause	Software error
Solution	Turn the system off and on. If the problem persists, contact the Customer services.
Description	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Alarm	**Recorder Fault**
Cause	Hardware error
Solution	Turn the system off and on. If the problem persists, contact the Customer services.
Description	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

Alarm	**REC. OPENED DOOR**
Cause	The recorder door is open.
Solution	Close the recorder door.
Description	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Alarm	**REC Paper Out**
Cause	Recorder paper has been finished.
Solution	Insert a new paper roll.
Description	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Alarm	**Printhead Hight Temp**
Cause	The thermal head is too hot.

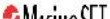
Solution	Stop operation for a few minutes.
Description	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Alarm	**Printhead Hight Vol**
Cause	Printhead voltage is high.
Solution	Turn the system off and on. If the problem persists, contact the Customer services.
Description	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Alarm	**Printhead Low Vol**
Cause	Printhead voltage is low.
Solution	Disconnect and reconnect the station from/to the AC power. If the problem persists, contact the Customer services.
Description	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the

	message background will change to the gray and the system will ignore this fault.
Alarm	**Time out Error**
Cause	The recorder cannot record.
Solution	Disconnect and reconnect the station from/to the AC power. If the problem persists, contact the Customer services.
Description	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

Chapter 15, 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 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
	Non-ionizing electromagnetic radiation Indicate that the equipment includes RF transmitters.
	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.

CLASSIFICATION	
Protection against electroshock	Class I, Type CF for all modules (except NIBP module that is 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 anesthetic mixture with air or with oxygen or nitrous oxide.
General	
Display	COLOR TFT 480 × 272, 5” Flexible display Configuration
Waveforms	ECG, SpO2, RESP (Freezable)
Numeric Parameters	HR, SpO2 (%SpO2, PR),ST,PVCs NIBP (SYS, DIA, MAP), RR, TEMP

Operation Method	Membrane, Touch screen
Application	Compact and Mobile Monitor.
Safety	Based on IEC 60601-1, Class I
Protection	Against Electro surgery and Defibrillator and EMC
AC Power(Adaptor)	Input:100 - 240 VAC, 50/60 Hz , Ip:1.4-0.7A Output:15VDC,4A

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, 0.5, 0.25, Auto

Calibration	1mV, 0.5 sec	
Filters	"MONITOR" (0.5 - 24 Hz)	
	"NORMAL" (0.5 - 40 Hz)	
	"EXTENDED" (0.05-150 Hz)	
CMRR	> 98 dB	
Internal Noise	< 30 μV RTI	
Input Impedance	> 5 MΩ	
QRS Detection	Duration	40 to 120 msec
		0.25 to 5 mV for Adult/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	Duration	0.1 - 2 msec

Detection/Rejection	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	
ARRHYTHMIA ANALYSIS		
Type	ASYS, VFIB, VTAC, RUN, AIVR, COUPLET, BIGEMINY, TRIGEMINY, TACHY, BRADY, AFIB, PAUS, FREQUENT PVCs	
Learning	Rapid Learning: only 20 seconds required for recognition of dominant rhythm.	
Method	Real time arrhythmia detection with innovative feature.	

Memory	Capability of storing the latest 150 ARR event (waveform and Parameters)	
ST ANALYSIS		
Display resolution	0.01 mV	
Measurement Range	-2mv to +2mv	
Alarm Range	-2mv to +2mv	
Features	User Adjustable Isoelectric and ST point trending of ST values	
Update period	5 Sec.	
NIBP		
Measurement method	Oscillometric	
Measurement mode	Manual/Automatic/Stat	
Measurement time	20-25 sec (excluding cuff inflation time)	
Measurement	Adult	SYS 30 ~ 255 mmHg

Range		DIA	15 ~ 220 mmHg
		MAP	20 ~ 235 mmHg
	Neonate	SYS	30 ~ 135 mmHg
		DIA	15 ~ 110 mmHg
		MAP	20 ~ 125 mmHg
	Pediatric	SYS	30 ~ 240mmHg
		DIA	15 ~ 220 mmHg
		MAP	20 ~ 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 Set)		
Spo2 Parameters	Spo2, PR	
Method	2 Wave length pulse wave type	
Range	SpO2	0 – 100 %
	PR	25 – 240 bpm
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)
Resolution	SpO2	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	1 Channel
Probe Type	YSI 400 Compatible
Range	0 - 50 °C
Accuracy	± 0.2 °C

RESPIRATION

Method	Impedance
Base Resistance	250 -1250 Ohm

Dynamic Range	0.2 - 2 Ohm
Breath Rate Range	0 - 253 BrPM
Accuracy	±2% or 2 BrPM

Recorder

Model	SAADAT Thermal Printer
Channel	1 waveforms (ECG)
Printing Speed	6, 12.5, 25 mm/sec
Paper Size	57mm by 59 foot roll .

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, SpO2, PR, RR, T1, PVCs, ST, AFIB

Trend Time Save	96 Hours
Trend Time Interval	5, 10, 15, 30, 45 Min, 1, 2, 4 Hours
Resolution	1 sec

Viewer Specification

Storage	
12 Lead ECG Signal	1000 Records
Physician Measurement and Interpretation	1000 Records
Physiological Parameters	1000 Records
Print	
Laser Printer	Print in Any Size paper
File	PDF/ JPEG Format
Filters	
Notch Filter	50/60 Hz

Drift Filter	0.5 Hz
Display	
12 Lead ECG Signal	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
ECG Sample Rate	500
ECG Symbol Length	16 bit
ECG Signal Length	10 Sec
Physiological Parameters	Heart Rate, NIBP, SPO2, TEMP1, RR
Calibration Signal	1 mV, 200 ms
Manually Lead selection	Yes
Superimposition	Yes
Patient information	Name, Patient ID, Gender, Age
Sender Information	Ambulance ID

Time Sweep	(12.5/25/50) mm/Sec
Voltage Gain	(5/10/20/40) mm/mV
Physician information	Name, ID, Interpretation Note
Measurement	
Automatic Measurement	Optional
Manual Measurement	P and QRS Duration, PQ and QT Intervals
Heart Axis	P, QRS, T Axis
Other	
Portable Software	Yes
Touch Screen	Yes
Compatibility	Win XP/Vista/7/8/10
Upgrade Capability	Manual
Connection	
Connecting to Data Repository	Online/ Offline

Data Base	Costume Format

INPUT/OUTPUT(OPT.)			
Network	TCP/IP (Wi-Fi)		2.4 GHz
	3G/4G Modem (GPRS)	Frequency	HSPA/UMTS: 1900/2100MHz GSM/GPRS/EDGE: 850/900/1800/1900MHz
	GSM		0.9/1.8 GHz

Internal Battery		
Nickel-Metal Hydride 3.6V,2.5AH Lithium ion 11.1V,3.3AH		
System Model	Nickel-Metal Hydride	
	Charge time	Usage
ARIA	Min 3 hours	Max 2:30 hours
System Model	Lithium ion	
	Charge time	Usage

TC Station	Max 6 hours	Max 5 hours

Physical Specification

Dimension (mm)		Weight (approximately)	
ARIA Monitor	155(W) × 107(H) × 65(D)	ARIA Without Station	Less than 800g
ARIA With TC Station	235(W) ×225 (H) × 90 (D)	ARIA With Station	Less than 3Kg

ENVIRONMENTAL

Temperature	Operating:	0 to 55 °C
	Storage & Transport:	-25to 60 °C
Humidity	Operating:	10-90 % (Non-condensing)
	Storage & Transport:	10-100 % (Non-condensing)
Altitude	-200 to 3000 m	

Chapter 17, 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

●ECG patient cable, 3 leads

PART. #:10003

●ECG patient cable, 5 leads

PART. #:10038

●Data Cable for Redel Connector to ECG 10 Lead

PART.#:10066

●ECG PATIENT CABLE - Neonate - FMT (E201-3000)
PART. #:10-055

● ECG Lead Wire - Neonate
PART. #:03-122

SPO2 (Masimo)

● Adult Digit Reusable Sensor - > 30 Kg (LNCS DCI)

PART. #:18-045

● SPO2 Probe, Y- Sensor - > 1 Kg (LNCS)-MASIMO

PART.#:18-049

● SPO2 Extension – Red LNC-10 - MASIMO

Accessories

PART. #:18-060

●SPO2 Sensor - Reuseable - Finger/Toe - Adulat > 30 Kg, Red DCI-dc12

PART. #:18-055

●SPO2 Extension Cable

PART. #:18-056

●M-LNCS DCI, Reuseable, Adult, (SpO2)

PART. #:18-070

● SPO2 Probe, Disposable,Neonate, Adhesive , < 1 Kg ,LNCS,Masimo

PART. #:18-046

● SPO2 Probe, Disposable,Neonate, Adhesive , < 3 Kg or >40Kg,LNCS,Masimo

PART. #:18-047

● SPO2 SPO2 Disposable Sensor, 3-20 Kg, (LNCS Inf)

PART. #:18-075

NIBP

● NIBP Cuff Reusable - Neonate-Single M 5301 Bladderless,Tube length 20cm

PART. #: 13-077

● NIBP Cuff Reusable - Infant - Single M5302 Bladderless Tube length 20cm -

PART. #: 13-078

● NIBP Cuff Reusable - Pediatric - Single M5303 Bladderless Tube Length 20 cm

PART. #:13-079

● NIBP Cuff Reusable - Adult - Single M5304 Bladderless, Tube Length 20 cm

PART. #: 13-080

● NIBP Cuff Reusable - Large Adult - Single M5305 Bladderless, Tube Length 20 cm

PART. #:13-081

● NIBP Cuff Reusable - Adult - Thigh, Single M5306 Bladderless, Tube Length 20 cm

PART. #:13-082

Accessories

● NIBP Cuff Reusable – Adault – Single M5114PU, TPU Bladder, Tube Length 20 cm

PART. #:13-083

● NIBP Cuff Reusable – Adult – Single M5104 Nylon, TPU Bladder, Tube Length 20 cm

PART. #:13-084

● NIBP Cuff Disposable – Neonate – Single M5541-1# with CT-167 Connector

PART. #:13-085

● NIBP Cuff Disposable, Neonate, Single M5541-2# with CT-167 Connector

PART. #:13-086

● NIBP Cuff Disposable – Neonate, Single M5541-3# with CT-167 Connector

PART. #:13-087

● NIBP Cuff Disposable – Neonate, Single M5541-4# with CT-167 Connector

PART. #:13-088

TEMP

- TEMP Probe – Skin –LAUNCH (98ME04GA634)

  PART. #:10-083

- TEMP Probe –Rectal –LAUNCH (98ME04GA635)

  PART. #:10-084

- TEMP Interface Probe– Data Cable for Redel Connector to Temp Probe

  PART. #:24-073

Adaptor

- Saadat Adaptor 60W, 15v for Aria

  PART. # 09263

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

ECG Elecrodes

- Adults ECG Disposable Electrodes, FIAB Manufacturer REF: F9060
- Pediatric ECG Disposable Electrodes, FIAB Manufacturer REF: F9060P

or

- Arbo H124SG, COVIDIEN Manufacturer REF: 31.1245.21

Chapter18, Care and Cleaning (PM)

Contents

18-1 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.

18-2 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.

Cleaning and Disinfection

⚠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[1] and extension cables[2] (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.

[1] Holders (or Bracket, Clamp) for accessories such as IBP and GAS.

[2] Extension cables for accessories such as IBP and BFA.

⚠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 Maintenance Schedule.
BFA module	disposable electrodes			
*** Trolley/ Wall stand, * Holders of accessory, * Extension cables**	-		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		
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 the paper and close the recorder door.	use as required ■ Isopropyl alcohol	
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	-	

18-3 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)			
		NIBP window settings (Adult, Pediatric			

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**
		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)			
		Cleaning and disinfection according to			

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**
		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 19, 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.

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
TC		
● Data transmission failure ● "INTERNET DISCONNECT" appears on the screen. ● Link LED does not light up. ●The green symbol of the internet connection is not displayed.	● No internet coverage in the location of data transmission ●Data SIM card has not sufficient credit ●Failure of TC station's 3G modem ●The Aria monitor fails to connect to TC station, so no ECG record is taken. ●The station's battery is discharged. ●The internet connection is impossible because DEVICE ID has not Been set. ●The internet connection is impossible because SERVICE and IP address of TC server Have not been set. ● There is no access to TC server because	● Other device or Smart phone is connected to the same data network (MTN or MCI). ● Check credit of data SIM card ● Test 3G modem on other device or a computer ● Replace the Aria monitor and TC station to detect problem ● Check the station's battery and charger circuits and ensure that the station can be turned on (Check the beep sound) ● Check power cable to recharge the battery ● Check that DEVICE ID has been set (Refer to setting instruction) ● Check that SERVICE and IP address of TC sever have been set (Refer to setting

	of the internet connection failure or power failure	instruction) ● Run Ping command Via a computer connected to the internet to check accessibility to TC server. **"ping** 188.208.148.219 **"** ● Check status of internet service, power and modem of TC server (Call the Customer service department). ●Call the Customer service department.
● No phone call is made ● GSM LED does not flash	● Inserted SIM card in the mobile has not sufficient credit ● No mobile network coverage ● The mobile antenna failure ● Phone number of the contact center has not been set or set incorrectly ● Failure of Fast dial key ● Failure of the	● Insert the SIM card in another mobile phone to check its credit ● Buy credit for the SIM card. ● Check PHONE- NUM setting (Refer to setting instruction). ● Call the contact center using the mobile phone to ensure integrity of the phone line. ● Call the Customer service department

	contact center phone	
One side of conversation is heard or conversation is not heard at all.	● Microphone or speaker failure	● Call the Customer service department
Beep sound is not heard	● The station does not turn on ● Buzzer failure	● Check the battery charge and power circuits. ● Call the Customer service department
Messages of TC station are not displayed on the monitor.	● The station is off. ● The monitor is not connected to the station.	● Check the battery charge status, the station status (on/off) and power supply. ● Replace TC station. ● 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.

Chapter 20, TC Viewer

Contents

20-1 Introduction

Early diagnosis of heart attack and early and timely care and treatment are one way to reduce or prevent deaths from this complication in emergency missions.

The telecardiography system is a set of patient monitors, plus telecommunication equipment and diagnostic software. With the help of the TC device, the patient's heart disease and other vital signs such as noninvasive pressure, oxygen saturation and body temperature are taken. Then the data will be sending to TC-Server and archived via internet platform (wired or wireless).

Cardiologist doctor in emergency center can receive and monitor the records by TC-Viewer system. In case of diagnosis or probability of occurrence of a heart attack in a patient, sending necessary commands to the emergency team and also coordinate with the hospital center where the Cath lab is ready for heart surgery. Therefore, the patient directly and without delay can enter to the Cath lab.

20-2 Description

This product is one of the equipment of Telecardiogram system and displaying ECG records received from TC-Server. Some features are as the following:

It has diagnostic assistance features such as Notch and Drift filters.

It is possible to measure the distance between different points of the ECG signal.

The gain and speed of signal trace can be set.

The desired signals can be removed or added.

20-3 Specification record of vital signs

The record of vital signs includes:
10 seconds of 12 lead ECG
(I, II,III,aVR,aVL,aVF,V1,V2,V3,V4,V5,V6)
Which is at a rate of 500 samples per second and a length of 16 bits.

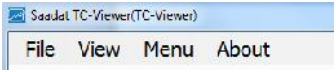
- Parameters (HR, SPO2, PR, TEMP, NIBP, (SYS/DIA/MAP) and ARR
- Device Phone number

User

The user of this system is a cardiologist specialist. By detecting heart attacks via this system, cardiologist can guide emergency care team technicians and also coordinate with the hospital for preparation the cath lab.

20-4 User interface

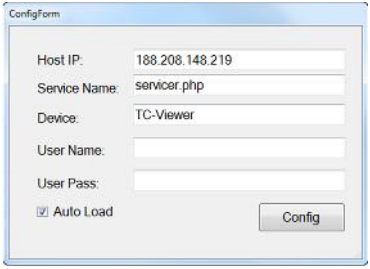
- **Menus:**
  Menus include: File, View, Menu, and About.



  - **File includes:** Open, Close, Save As, Exit

  - **View includes:**
    - Superimposition: Displaying 12 lead ECG
    - Annotation: Displaying or hiding annotation
    - Calibration Signal: Displaying or hiding index

- **Menu**
  - Config: Contact Settings of TC Server can be done. It includes:
    - Host IP
    - Service name
    - Device name
    - User name and Password are inactive.
    - Auto Load



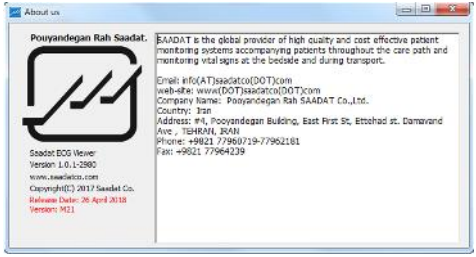
Enabling the Auto Load option means getting automatic records from the server. If this option is inactive, user shall click on the Release key to get each file, which will be explained below.

- Login/Register: This option is inactive.

▪ **About**

The About menu includes software version, release date and information about manufacturer.

User interface of TC Viewer



About

- **Toolbar**

  Toolbar includes

  - **Open**: ECG file displayed with txt format.
  - **Open XML**: ECG file displayed with xml format.
  - **Save**: ECG file is saved with XML file format.
  - **Print**: ECG file and displayed data will be sent to the default printer of TC-Viewer system.
  - **Filter Drift**: The drift filter is applied to the ECG signals and traces its effect.
  - **Filter Notch**: The Notch filter is applied to the ECG signals and traces its effect.

- **Time coefficient**: The ECG speed options are 12.5, 25, and 50 mm/s.
- **Gain**: The ECG gain options are 5, 10, 20, and 40 mm/mv.

▪ Back up

By pressing this key, ECG record which is selected for tracing is removed from the LocalRepo list and it is transfered from the C: \ ECG_Data path to the C: \ ECG_Data_Backup path.

▪ All Back up

By pressing this key, all ECG record files are removed from the LocalRepo list, and they are transfered from the C: \ ECG_Data path to the C: \ ECG_Data_Backup path.

▪ Server Available

When the connection to the server is established over the Internet, the Server Available tag is ticked and displayed in green.

By changing the IP address in the TC Viewer,

if the server cannot connect to the new address, the Server Un-Available is shown in red.

- **Release and Busy button**

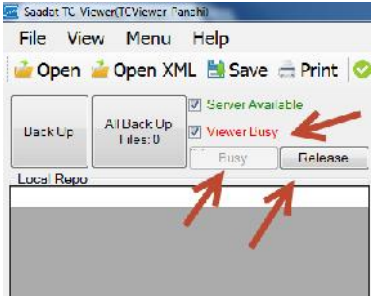
If the TC Viewer is used by several users, these buttons will be applicable (Busy and Release).

• If system has only one user, the Auto Load option shall be ticked in the Server Configuration Settings and click Release button. In this case, all ECG records are automatically loaded on the TC Viewer and displayed in LocalRepo, and the Viewer Release is displayed in green and ticked.

Busy button

User interface of TC Viewer

When TC server has several users, the ECG record shall be sent to the specialist who declares readiness, so in this case the tick of Auto Load check box is removed from all systems and the user shall click the Release button to get each record. The received record is automatically displayed and system status changes to busy mode. For the next record, user shall click Release button. By clicking the Release button for a moment is displayed in green, then the next file will be downloaded and the state returned to busy mode.



Release button

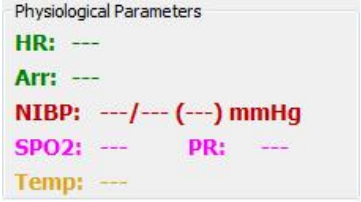
- **Patient Info**

Patient info includes Ambulance ID (it is registered Device ID in TC), Phone (it is TC phone number), date and time (according to the received record), and Patient information (not applicable yet) such as ID, name, gender and age are shown.

Figure 20-7 Patient Info

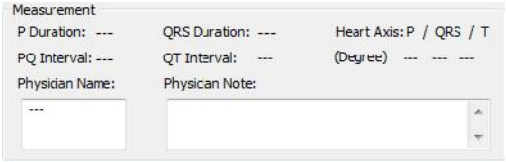
- **Physiological Parameters**

In this section, the parameters of the vital signs sent by the TC system are displayed.
These parameters are as the following:
HR, ARR, NIBP, SPO2, PR, TEMP



- **Measurement**

In this section, specialist specifications and diagnostic parameters such as P Duration, QRS Duration, PQ Interval, QT Interval, Heart Axix, and Degree are shown.



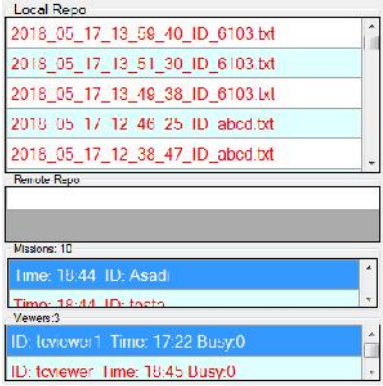
- **Selected Leads**

In this section, different ECG lead for display in TC Viewer can be selected.

- Selectable leads are: I ، II ، III ، aVR ، aVL ، aVF ،V1 ، V2 ، V3 ، V4 ، V5و V6.
- By Clicking the Select all button, all the leads select.
- By pressing the Clear all buttons, all the leads are deleted.

- **Sidebar**

The left sidebar shows the following:



Sidebar

- Local Repo

The list of files sent from the TC system is displayed with the specified name in this section and can be seen by clicking on the relevant record. The name of the file uploaded to the TC Viewer system is as follows: Device Name-Time-Date

- Remote Repo

The list of files of TC Server which is loaded by TC device is displayed.

- Missions

The list of the 10 TCs that have just completed the mission is based on the latest mission time is displayed. If the Internet is connected, this list will be updated per minute.

- Viewers

In this section, Active TC Viewers are displayed.

Chapter 21, TC Server (Virtual machine installation)

Introduction

TC server is installed and started up using image of virtual machine in datacentre of the emergency department and in the environments with ESX virtualization infrastructure.

Networking infrastructure preparation

- Set a static IP address with bandwidth of minimum 1 Mbps and make connection to physical port connected to TC server.
- Make 80 and 220 ports available on TCP protocol and enable ICMP protocol for above static address on firewall (two –way)

Virtual machine creation

- Upload image file of virtual machine (. ova) in virtualization infrastructure wizard.

- Create a virtual machine with the following specifications from image:

- Number of processors: 2
- RAM memory: 8 G
- Hard disk: 500 G
- Network: 1000 GB/s

- Connect the virtual machine of TC server to physical network port in ESX virtualization infrastructure.
- Turn on the virtual machine.

Virtual machine test

- Ping static IP address displayed on each computer. You will receive response packets.
- Run TC-Viewer software and set it in static IP address and service.php to make connection to the service.

AppendixI (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	30 to HR HIGH ALARM -5	50bpm
ECG FILTER	MONITOR,NORMAL, EXTENDED	NORMAL
HR SOURCE	ECG,SPO2, 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	4,8, SEC	8SEC

AVERAGE		
LEAD TYPE	3 Wires,5 Wires, 10 Wires	3 Wires
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	ON ,OFF	OFF
RR ALARM	ON ,OFF	OFF
RR HIGH ALARM	RR LOW ALARM +1 to 150	25Brpm
RR LOW ALARM	5 to RR HIGH ALARM -1	5Brpm
APNEA LIMIT	10,15,20,25,30,35, 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	1,2	1

LEVEL		
ALARM	ON,OFF	OFF
SPO2 HIGH ALARM	SPO2 LOW ALARM +1 to 100	100
SPO2 LOW ALARM	1 to SPO2 HIGH ALARM -1	90
PR HIGH ALARM	PR LOW ALARM +5 to 235	140
PR LOW ALARM	20 to PR HIGH ALARM -5	50
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	160 mmHg
	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 ALARM	Adult	DIA LOW ALM +5 to 220	Adult	90 mmHg
	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

AUTO SLEEP	ON,OFF	OFF

The parameters in TEMP menu		
TEMP UNIT	ºC,ºF	ºC
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	0.0 to T1 HIGH ALARM -0.5	35.0
TEMP LOW ALARM	0.0 to T1 HIGH ALARM -0.5	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
	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	-	-

The parameters in ST menu		
ST ANALYSIS	ON, OFF	OFF
ST ALARM	ON, OFF	OFF
ALARM LEVEL	1, 2	1
ST LOW ALARM	-2 to ST HIGH ALARM -0.1	-0.2
ST HIGH ALARM	ST LOW ALARM +0.1 to 2	0.2
EVENT DURATION	15S, 30S, 45S, 60S, OFF	OFF

SYSTEM DEFUALT		
PAGE	P1,P2	P1
ALARM VOLUME	1,2,3,4,5,6,7,8	1
CALENDAR	SOLAR, CHRISTIAN	CHRISTIAN
PAT. CONF	ADULT,NEONATE, PEDIATRIC	ADULT
BED NUMBER	1 … 99	01

Module Color		
ECG	-----	Green
SPO2	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	Magenta
RESP	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	Yellow
TEMP	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	Cyan
NIBP	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light	White

	Orange, Light Magenta, Dark Orange, Dark Cyan	

APPENDIX II EMC

⚠ Warning ⚠

Use only the recommended manufacturer accessories. Using the accessories 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.

APPENDIX II EMC

⚠ 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.

APPENDIX II EMC

Guidance and manufacturer's declaration – electromagnetic emissions		
The ARIA TC Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ARIA TC should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The ARIA TC must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

APPENDIX II EMC

RF emissions CISPR 11	Class B	The ARIA TC 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	

APPENDIX II EMC

Guidance and manufacturer's declaration – electromagnetic immunity			
The ARIA TC Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ARIA TC should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least

			30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short	<5% U_T (>95% dip in U_T)	Complies	Mains power quality should be

interruptions and voltage variations on power supply input lines IEC 61000-4-11	for 0.5 cycle 40% U_T (>60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec		that of a typical commercial or hospital environment. If the user of the ARIA TC requires continued operation, it is recommended that the ARIA TC be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of test level.			

APPENDIX II EMC

Guidance and manufacturer's declaration – electromagnetic immunity			
The ARIA TC Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ARIA TC should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the ARIA TC, including cables, than the recommended separation distance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output

			power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b]

			Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an

electromagnetic site survey should be considered. If the measured field strength in the location in which the ARIA TC is used exceeds the applicable RF compliance level above, the ARIA TC should be observed to verify normal operation. If abnormal performance is observed, additional measures may necessary, such as reorienting or relocating the ARIA TC**.**

[b] Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.

APPENDIX II EMC

Recommended separation distances between

Portable and mobile RF communications equipment and the

Vital Sign Monitor

The ARIA TC Patient Care Monitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARIA TC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARIA TC as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.