Pooyandegan Rah Saadat

Operator’s Manual

Aria Patient Monitor

CE 1254

POOYANDEGAN RAH SAADAT CO.

No. 48, Elm-o-Sanat university st., Hengam st., Resalat highway,
TEHRAN
IRAN

Post box: 16765-965
Tel: +98 21 77180630
Fax: +98 21 77180629

Customer Services:
Tel: +98 21 77180645
Fax: +98 21 77180655
Cell: +98 912 1977157

Legal responsible:
HEYER Medical AG
Mrs. Gertrud Werner
Carl-Heyer – Str. 1-3
56130 Bad Ems, Germany
Tel: +49 2603 791-145
Fax: +49 2603 791-209
E-Mail: Info@heyermedical.de

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

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Introduction

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■ For an overall introduction to the monitor, please refer to **General information**.

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■ For basic operating instructions, please refer to **Keys function**.

■ For description of the system connectors, please refer to **Interfaces**.

■ For important facts to be noted during the battery recharging procedure, please refer to **Battery**.

General Warnings

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

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

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

General Warnings

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

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 monitor measurements.

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

General Warnings

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

 The user should make sure that equipment and accessories function safely and see that it is in proper working condition before being used.

 To prevent EMC effects 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 conditions in which it will be used.

General Warnings

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

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

 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.

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

General Warnings

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

Do not expose the system near any local heating item such as the direct sunlight.

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

General Warnings

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

 Do not connect items not specified as parts of the monitor. Vital sign monitor needs to be installed and put into service according to the EMC information provided in the APPENDIX IV.

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

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

General Information

Environmental conditions

Operating temperature	5 ~ 40 ◦c
Storage and transport temperature	20~ 60 ◦c
Humidity	20~ 90 %
Altitude	200~3000m
Power supply	90 ~240 Vac 50/60 Hz Pmax = 15 W

Aria Patient Monitor (Figure 1-1) is adaptable to adult and neonatal usage. It can monitor vital signals as ECG, Respiratory Rate (AWRR, RR), NIBP, SPO2, CO2, N2O, O2, Anesthesia Agent (AA), Dual-channel TEMP and four- channel IBP. It contains modules measuring various parameters and features in compactness, lightweight and portability. Battery facilitates transportation of patient.

General Information

Portable Patient Monitor performs monitoring of the following parameters:

ECG

- Heart Rate(HR)
- ST segment
- PVCs/min and Arrhythmias
- ECG waveform

RESP

- Respiratory rate(RR)
- Respiration waveform

SPO2

- Percentage of pulse oximetery Saturation (SPO2)
- Pulse Rate (PR)
- SPO2 waveform

If Masimo Rainbow set is used in the monitor, the following parameters can be measured:

- Measurement of artery pulse signal pressure (PI)
- Measurement of total hemoglobin content(SPHb)
- Measurement of oxygen content (SpOC)
- Percentage of Carboxyhemoglobin saturation (SPCO)
- Percentage of methemoglobin saturation(SPMet)
- Pleth variability index(PVI)

NIBP

- Systolic pressure, Diastolic pressure and Mean arterial pressure (MAP)

TEMP

- Channel-1 temperature(T1) and channel-2 temperature(T2)

IBP

- Channel-1 IBP (IBP1/IBP3) and Channel-2 IBP (IBP2/IBP4).

ARIA vital sign monitor provides several functions as visible & audible alarms, Trend and NIBP data storage. ARIA vital sign monitor is a user-friendly device with operations conducted by a few keys and touch screen. Refer to Keys Function for more details.

 Don’t touch the screen with sharp objects.

Indicators, Connectors and Controls

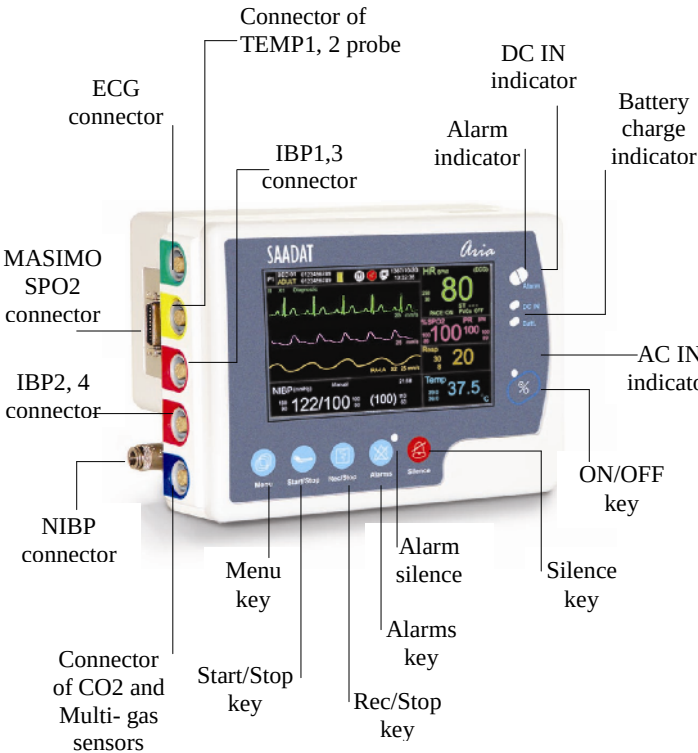


Figure 1-1

Indicators

There are five indicators for power, alarm, battery and alarm silence on the front panel of the system. The green indicator lights, when the device is powered on (Figure 1-2①), the battery indicator is green when the battery is fully charged otherwise it is orange (Figure 1-2③). The alarm indicator flashes when an alarm occurs (Figure 1-2④). If alarm indications are disabled for an unlimited period of time, alarm indicator flashes red.

(Figure 1-2⑤)

Alarm indicator in normal situation is off, when an alarm occurs this indicator turns on and flashes.

Indicators

When the monitor is powered on, verify that all indicators light and function properly.

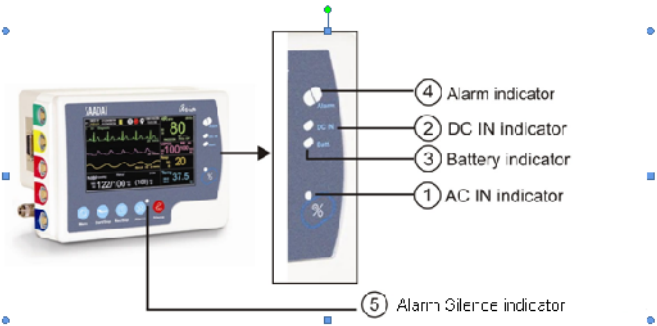


Figure1-2 Indicators

Main screen

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 screen can be divided into four areas: (figure 1-3)

Header area, Waveform area, Parameter area and Message area.

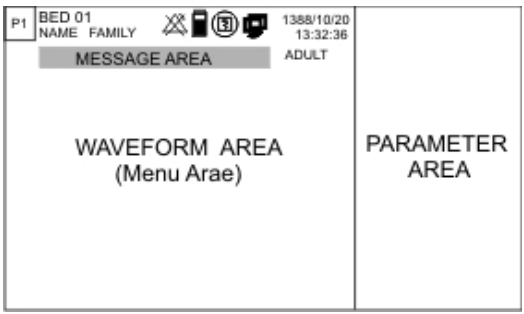


Figure 1-3 Main screen

- ## Header Area

The Header area is at the top of the screen displaying operating state of the monitor and patient information. Bed number, type of patient (adult or neonate), patient name, date & time and page number are displayed in the header area. The above information is displayed on the screen throughout the monitoring process.

Other information of the Header area comes up only with regard to the monitoring status.

1-  indicates the remaining battery charge.

2-  appears when the system is recording.

3-  appears when the system is connected to central system.

4-  appears when Alarms key is pressed .

5-  blinks when the system is in the silence mode.

- **Waveform / Menu Area**

All waveforms can be displayed at the same time. The waveforms from top to bottom are: ECG, SpO2, RESP and IBP.

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

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

- **Parameter Area**

Parameters values are always 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 that refresh with each new measurement).

- **Message Area**

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

Level I alarm message: Red background – Black text

Level II alarm message: Yellow background – Black text

Level III alarm message: Cyan background – Black text

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

Different page configurations

By default, there are nine pages with different configurations to display parameters and waveforms:

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

P2: You can monitor parameters of P1 as well as 2-lead ECG, SPO2 and RESP waveforms.

P3 :You can monitor parameters of P1 and four ECG waveforms with different leads.

P4: You can monitor parameters of P1 and 7-lead ECG waveform.

P5: You can monitor parameters and waveforms of P1 as well as PI, PVI, SpOC ,%SpMet ,%SpCo and SpHb parameters .

P6 : You can monitor parameters of P5 and ECG waveform.

P7: You can monitor SPO2, PR and NIBP parameters as well as SPO2 waveform.

P8: You can monitor SPO2 and PR parameters and SPO2 waveform.

P9: You can monitor NIBP, PR, SPO2, IBP and HR parameters as well as ECG and IBP waveforms.

 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 page on which you have turned off the monitor will appear.

Keys function

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

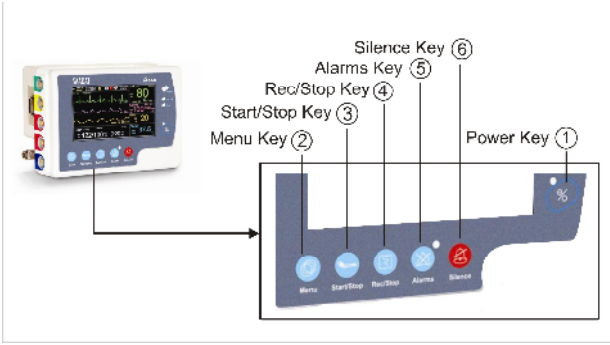


Figure 1-4 Keys

① **Power**: press this key to turn the patient monitor on and off.

② **Menu**: press to enter 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 through the central system and 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 audio alarm) will be inactive until you press the key again.

Due to standard requirements, this key is not currently accessible for users, but it may be available in the future.

Silence: press to disable alarm for 120 s. A countdown timer appears and Silence symbol blinks in the Header area

every 5 sec. If you press it again, the system will exit from silence mode and alarm sound will be enabled.

 If a new alarm occurs in silence mode, the monitor will exit from this mode.

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

Interfaces

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

Figure 1-5 Connectors

① ECG cable
② TEMP1/2 probe
③ Masimo SPO2 sensor
④ IBP1/3 transducer
⑤ IBP2/4 transducer
⑥ NIBP cuff
⑦ CO2 and Multi-gas sensors or system programmer cable

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

Symbols on the side plate label are as follows:

 Means that consult user manual of the monitor and pay attention to the warnings and cautions.

 Means that the applied part according to standard IEC-601-1 is type CF. The modules with CF-type (Cardiac Float) and Defibrillation-proof applied part have high degree of protection against shock and can be used during defibrillation.

 Means that the applied part according to standard IEC-601-1 is type BF. The modules with BF-type (Body Float) and Defibrillation-proof applied part have high

degree of protection against shock and can be used during defibrillation.

The battery is installed at the right side of the Aria monitor.

By placing the Aria monitor into the station, you can:

1- Charge the built-in battery and connect the monitor to DC IN

2- Connect it to the central system through wired network (LAN)

3- Hang it from the stretcher rail while transporting the patient

4- Install it on the infusion rod

AC IN, DC IN and network sockets are placed in the right side of the station, and VGA connector is at the back of the station.

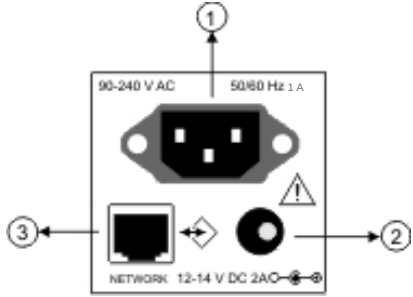


Figure 1-6 Power plate

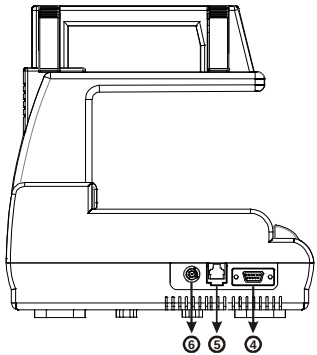


Figure 1-7 External connections of Aria Station

Interfaces

■ Power Supply: 90-240 V and 50/60 Hz (Socket①)

■ DC Input (socket②)

12-14 V/DC external power supply (e.g. in ambulances)

■ Network Interface (socket③)

The data transmission is full duplex and is done through LAN.

■ VGA Slave monitor (socket ④)

Monitor interface for external VGA color monitor.

Working mode:	800×600,256 colors
Interface:	D_sub15 pins
Pin 1. Red Video	Pin 9.NC
Pin 2. Green Video	Pin 10.Ground
Pin 3. Blue video	Pin 11. NC
Pin 4. Ground	Pin 12.NC
Pin 5. NC	Pin 13 Horizontal Sync
Pin 6. Red Ground	Pin 14. Vertical Sync.
Pin 7. Green Ground	Pin 15. NC
Pin 8. Blue Ground	

How to use slave monitor?

1- Install the VGA slave monitor in a distance of 1.5 m from the patient bed. The monitor is intended to be used as an assistant monitoring device.

2- Plug the cable while the VGA slave monitor is off.

3- Power on slave monitor and then patient monitor.

4- Adjust monitor brightness and contrast properly.

■ Connector of second monitor (socket ⑤)

Data transmission between Aria monitor and ARC (Aria Remote Control) is digital duplex and is done based on RS232 standard.

■ Socket ⑥

Only trained and authorized personnel of manufacturer can use this socket.

Network connection

There are two parts for network connection, first network software in the monitor mother board and second network hardware drive embedded in the station.

Aria monitor connects to the station through SPI (Serial Peripheral Interface) protocol.

Aria network is defined as local network, Aria monitor uses TCP/IP protocol and 100/10MPS for data communication.

 Saadat's monitors can only be connected to the Saadat central network.

 Don't connect various Hub switches to local network as this may cause network interference.

 Before connecting Aria monitor to the network, operator should specify bed number of the monitor.

 If Aria monitor connects to the network through the station and then is removed from the station for a special reason . In order to re-establish network connection, you should unplug/plug AC power cable when Aria is placed into the station.

Use only the SAADAT manufactured station base in the following situations:

- Aria monitor runs on AC power
- Aria monitor runs on DC- IN.
- For network connection.
- For charging battery.

Aria patient monitor can only be connected to SAHAND series of the central system.

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

If DC-IN power supply in cars such as ambulance is used (ambulance body is connected to the negative pole of the battery), for safety requirements, DC to DC or DC to AC converter with the isolation of 1500Vac (at least) must be used. Using of 20V power in the ambulance is recommended. To provide mentioned DC-DC or DC- AC converter, please contact technical department of the manufacturer.

Battery

Portable Patient Monitor is equipped with a rechargeable battery. When the monitor is connected to the AC power, the battery starts to be charged automatically. When the battery is completely discharged, it takes at least 3 hours to charge it again.

Symbol  in Header area of the screen indicates battery charge capacity. Yellow part represents the remaining battery charge. This symbol is only displayed when the AC Input is not plugged in and the system works with battery. If the AC Input is plugged in, an indicator at the right side of the screen will represent the battery charge level .When the battery indicator is green, the battery is fully charged and when it is orange means that the battery is being charged.

When the system is connected to the DC Input (e.g. ambulance power), the battery can not be charged.

Battery

Features of the battery including battery voltage, battery current consumption, charging current, temperature, time to empty and time to full can be displayed by Aria monitor.

Among the above items, battery voltage, current and power consumption are displayed in ABOUT menu.

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

The battery of Aria monitor can be charged at least 500 times.

2
System Configuration

- For last stored ECG signals, please refer to **SIGMA**.
- For previous values of measured parameters, please refer to **TREND**.
- For alarm setting including alarm volume adjustment, please refer to **ALARM**.
- For date and time setting, please refer to **SETUP**.
- For modules setting, software versions of modules and Touch calibration , please refer to **FACTORY**.
- For page setting, please refer to **PAGE SETUP**.
- For patient information setting, please refer to **PATIENT**.
- For manufacturer information , please refer to **ABOUT**.

System Configuration

Patient monitor contains a flexible configuration. The configuration setting is done through HOME MENU (figure 2-1). You can access this menu by pressing the MENU key on the front panel or touching the middle of Header area on the screen.

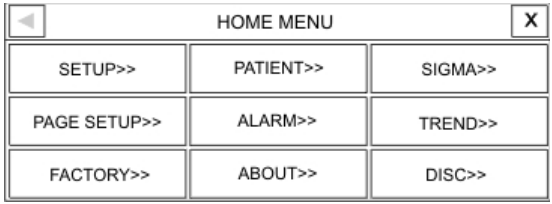


Figure 2-1 HOME/MENU

SETUP

By pressing SETUP, you can access the following menu.

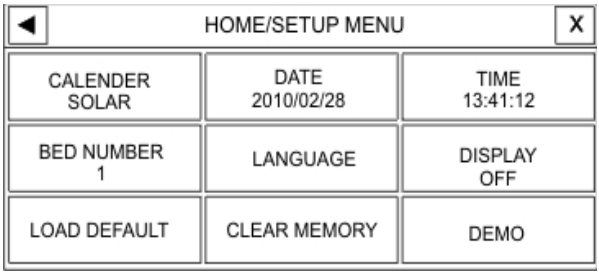


Figure 2-2 HOME/SETUP MENU

These 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:

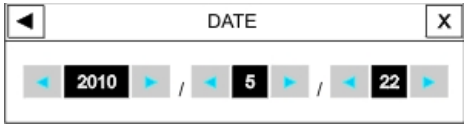


Figure 2-3 DATE

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

Figure 2-4 TIME

- **BED NUMBER**: (from 1to 99)
- **LANGUAGE**: Press this item to select the desired language in the following window. Available options are "ENGLISH" "FRENCH"," RUSSIAN ", "TURKISH"," GERMAN" and "POLISH".

Figure 2-5 LANGUAGE

- **DISPLAY OFF**: Select this item to turn the display screen off until a key is pressed or an alarm occurs.
- **LOAD DEFAULT:** Select this item to access SETUP/ DEFAULT MENU (Fig. 2-6) and to load the manufacturer default settings for the desired parameter. (Refer to appendix I for default settings). Because all your previous settings by selecting default mode will be missed, the system asks if you are sure to change setting or not. (Fig. 2-7)

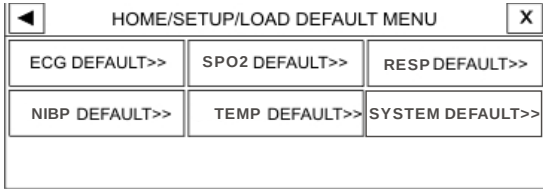


Figure 2-6 SETUP/DEFAULT MENU

Figure 2-7 ALERT

- **CLEAR MEMORY:** You can clear stored parameters in the system such as parameters saved in TREND window and NIBP LIST.
- A message will appear on the screen which asks you whether to clear that item or not (Fig. 2-8)

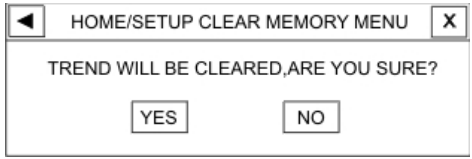


Figure 2-8 SETUP/CLEAR MEMORY MENU

- **DEMO**: Enter specific password in the following window to see demo waveforms and parameters. In this mode, word “Demo” is displayed on the ECG signal.

  To exit demo mode, you should enter a password other than specific password.

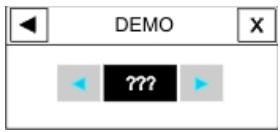


Figure 2-9 DEMO

Operator cannot access to this menu and only authorized personnel of the manufacturer can use this menu.

PATIENT

By pressing PATIENT, you can access this window:

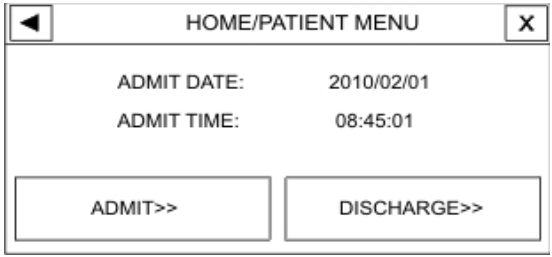


Figure 2-10 HOME/PATIENT MENU

Select ADMIT in Patient Menu, HOME/PATIENT/ADMIT MENU will appear in which you can enter patient demographic information (Fig 2-11).

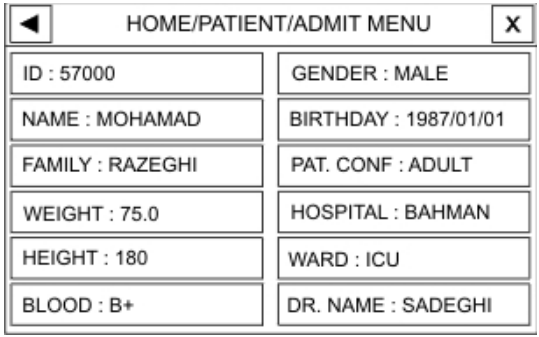


Figure 2-11 HOME/PATIENT/ADMIT MENU

ID Patient code in hospital (Up to 15 characters)

NAME Patient name (Up to 15 characters)

FAMILY Patient family (Up to 15 characters)

WEIGHT Optional from 0.5 to 300 Kg

HEIGHT Optional from 20 to 250 cm

BLOOD TYPE Available options are A+, A-, B+, B-, AB+, AB-, O+ and O-.

GENDER Available options are Female and Male

PATIENT

BIRTH DAY Date of the birth

PAT. CONF Available options are neonate and adult

HOSPITAL (Up to 15 characters)

WARD (Up to 15characters)

DR.NAME (Up to 15 characters)

To store information of a new patient, select DISCHARGE in the patient menu to recall following message:

Figure 2-12 ALERT

SIGMA

Patient monitor is able to store last 35 seconds of ECG signal that it is visible in 5 traces in "HOME/SIGMA MENU".

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

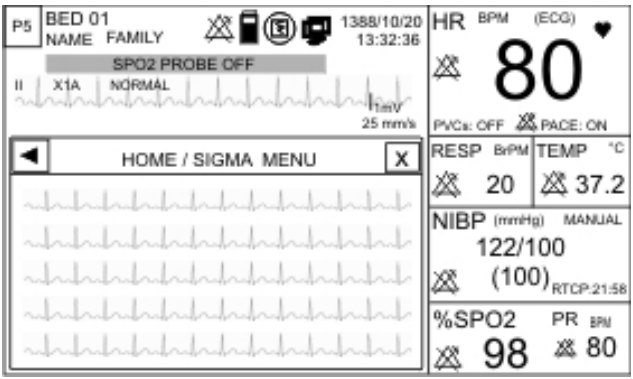


Figure 2-13 HOME/SIGMA MENU

PAGE SETUP

Different page configurations with desired waveforms and parameters can be set in this part.

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

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

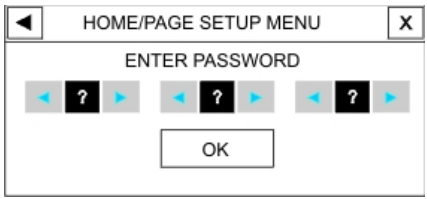


Figure 2-14 HOME/PAGE SETUP MENU

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

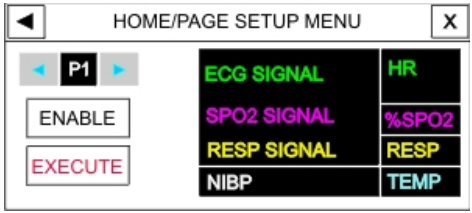


Figure 2-15 HOME/PAGE SETUP MENU

When you change setting and press EXECUTE button, the following message will appear that by selecting YES all settings will be applied.

Figure 2-16 ALERT

ALARM

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

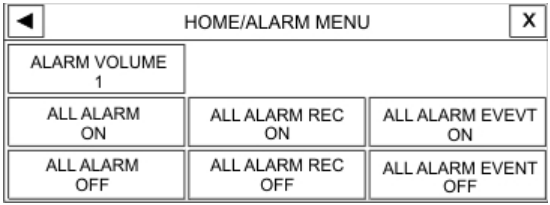


Figure 2-17 HOME/ALARM MENU

These alarm settings can be performed in this menu.

- **ALARM VOLUME**

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

- **All ALARM ON/OFF**

Press this item, an alert message will appear that by selecting YES you can turn on/off all alarms of the monitor.

Press this item to turn ON/OFF all alarms using the following window.

Figure 2-18 ALERT

Select "ON" to enable all alarm functions. Select "OFF" to disable the alarm functions such as alarm sound, parameters blinking and alarm light indicator. In "OFF" mode you can see  symbol beside all parameters. This function changes alarm of all parameters ON or OFF, but you are able to change alarm of each parameter separately in its own window.

TREND

The latest 96 hours of trend data is stored and displayed in both graphical and tabular forms.

Data is recorded every 1 second and parameters numeric values of Trend (Graphic or Tabular) in case of (Interval/300) ≤5s , data is updated every 5 seconds otherwise it is updated to extent of Interval/300 . For example if the interval is set to 30 min, new data will be displayed every 6 seconds.

Data is stored every second and numeric values of all parameters are displayed based on adjusted interval in the Trend window (Tabular or Graphical).

In case of (Interval/300) ≤5s , data will be updated every 5 seconds, otherwise it will be updated to the extent of Interval/300. For example if the interval is set to 30 min, new data will be displayed every 6 seconds.

TREND

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

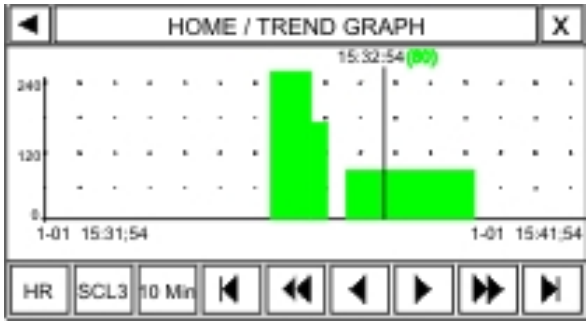


Figure 2-19 HOME/TREND GRAPH

Figure 2-20 HOME/TREND TABLE

In figure 2-19 Y-axis stands for related parameter value and X-axis for time.

■ **Selecting trend graph or parameter values:**

Press the first left item in the Trend graph to select your desired parameter. Available options are HR, SPO2, PR, IBP, RESP, TEMP, SpHb, PI, SpCo, SpMet, PVI and SpOc.

This item is not active in Trend Table and you can only view selected parameter in the graph.

If SPO2 module of Masimo Rainbow set is used, you will see one of selected Rainbow parameters in the graph instead of TEMP parameter in the Trend Table.

TREND

- **Changing the display scale:**

Press the second left item in the Trend graph to adjust display scale. You can set the Y-axis scale in proportion to the parameters values.

PARAM	SCL1		SCL2		SCL3		SCL4		SCL5	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
HR	0	60	0	120	0	240	-	-	-	-
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	-	-	-	-
IBP	-20	50	-20	100	-20	200	-50	300	50	250
SpHb	0	25	5	17	-	-	-	-	-	-
PI	0	20	0	12	0	12	-	-	-	-
SpCo	0	60	0	42	-	-	-	-	-	-
SpMet	0	70	0	16	-	-	-	-	-	-
PVI	0	100	0	30	-	-	-	-	-	-
SpOc	0	36	8	20	-	-	-	-	-	-

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

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

Press the third left item in the Trend graph to select time interval of displaying numeric parameters. Available options are 5, 10, 15, 20, 30, 45min and 1, 2, 4, 8, 12, 16, 24,36,48,72 and 96 hours.

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

■ **Obtaining Trend values of a specific time**

Select ◄ or ► in the Trend graph to view trend values of a specific time. When you press these buttons, the cursor moves through the Trend graph and indicates specific times. This is only possible for 5, 10, 15, 20, 30, 45 min, and 1, 2, 4, 8 and 12 hr intervals (set in the third left item). Numeric parameters related to these times are displayed above the cursor.

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

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

Press ◀◀ or ▶▶ in the Trend graph to view the previous or next page of the Trend. In other word, you can adjust start and end time of the x-axis. Every time you press these buttons, the time scale of x-axis will be changed 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 First and Last pages of Trend**

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

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

FACTORY

Parameters or signals of different modules can be set ON /OFF in this menu.

By pressing FACTORY, you can access this menu:

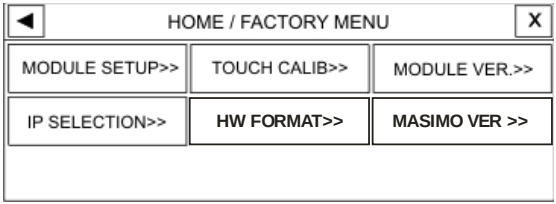


Figure 2-21 HOME/FACTORY MENU

The operator does not have access to "MODULE SETUP ", "HW FORMAT", "TOUCH CALIB" and "IP SELECTION" menus and only authorized personnel of the manufacturer can apply necessary settings through these menus.

■ **Module Setup**

By pressing this item, you can access this window:

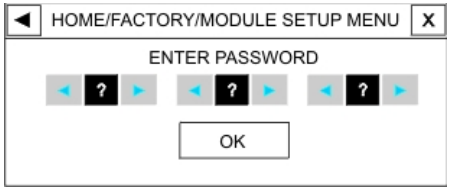


Figure 2-22 HOME/FACTORY/MODULE SETUP MENU

If you enter correct password and press OK, the following menu will appear in which you can set ON/OFF your desired modules.

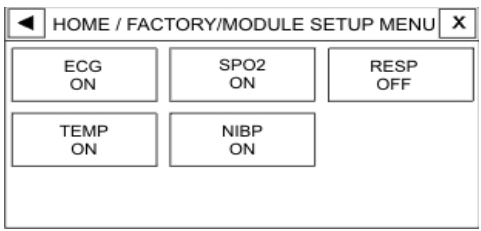


Figure 2-23 HOME/FACTORY/MODULE SETUP MENU

■ **TOUCH CALIB**

By pressing this item, you can access this window:

Figure 2-24 HOME/FACTORY/TOUCH CALIB MENU

If you enter correct password and press OK, the following menu will appear in which you can calibrate touch in four points.

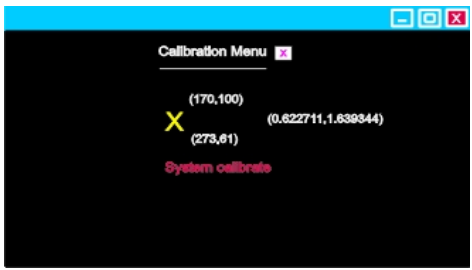


Figure 2-25 HOME/FACTORY/TOUCH CALIB MENU

■ MODULE VER

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

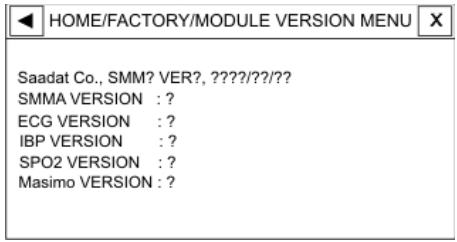


Figure 2-26 HOME/FACTORY/MODULE VER MENU

■ IP SELECTION

By pressing this item, you can access this window:

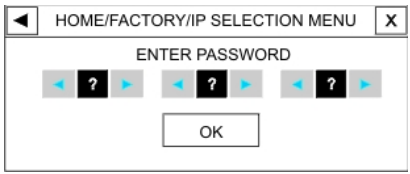


Figure 2-27 HOME/FACTORY/IP SELECTION MENU

FACTORY

If you enter correct password and press OK, the following menu will appear in which you can select your desired IP.

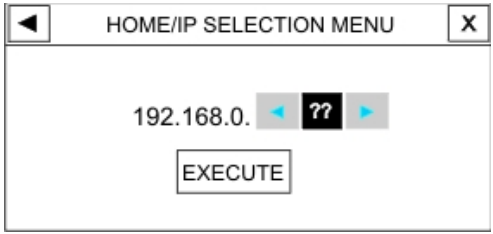


Figure 2-28 HOME/FACTORY/IP SELECTION MENU

- **MASIMO VER.**

By pressing this item, you can access MASIMO MENU and in which see specifications of MASIMO module.

ABOUT

By pressing "ABOUT" in HOME MENU, you can see the system and manufacturer information in this menu.

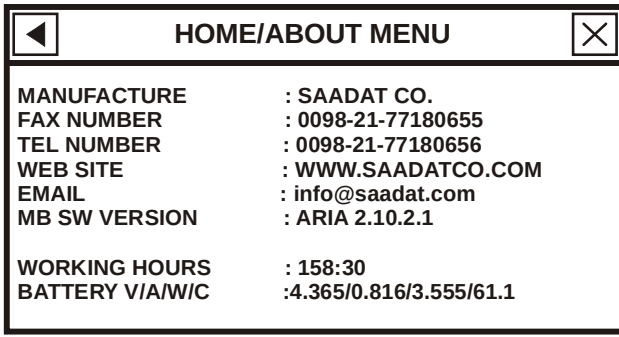


Figure 2-29 HOME/ABOUT MENU

3
Alarm

This chapter gives general information about alarm and its functions.

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

Alarm Categories

Alarm level and its setting

Patient Monitor offers three levels of alarm.

High level alarm (level 1) indicates that patient is in a life threatening situation or monitor has a serious problem.

Medium level alarm (level 2) indicates an abnormal vital signs and serious warning.

Low level alarm (level 3) indicates general warning.

Patient monitor has some predefined alarm levels for parameters but user can also adjust alarm level of each module in its own menu.

 Alarm setting will not change for maximum 30 seconds after power failure.

Alarm Categories

When an alarm occurs, the patient monitor will inform user through the messages with various background colors (based on alarm level), indicators or by different levels of audio alarm.

- **Display screen**

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

Level I alarm message: Red background – Black text

Level II alarm message: Yellow background – Black text

Level III alarm message: Cyan background – Black text

Informative messages (or when SILENCE key is pressed), are displayed in gray background.

Alarm Categories

- **Alarm indicator**

Alarm indicator flashes red for level I alarm and yellow for level II alarm and has steady yellow light in level III alarms.

- **Alarm sound**

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

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 25 seconds.

Low level alarm sounds "DO" every 50 seconds.

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

Alarm Categories

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 several alarms with similar levels occur simultaneously, their messages will be displayed alternatively on the screen.

Alarm verification when the system is powered on

When the monitor is being powered on, audible and visible alarms (yellow and red indicator) will be self tested. Every time the monitor is powered on, the system beeps and yellow and red indicators light about 4 seconds simultaneously. If no beep is heard or no alarm indicator lights, please do not use this device for any patient and contact customer Service.

Alarm Causes

An alarm occurs when it is triggered by a parameter or when there is some system problem.

The delay time from an alarm occurrence to alarm indication (parameter blinking, alarm message and light indicator) is up to 50 ms.

ARIA monitor is designed so as alarm occurrence can be recognized from a distance of 1 meter in front of it.

Conditions that trigger the parameters alarm:

When the measurement value exceeds the adjusted alarm limits and the parameter alarm is in "ON" mode, an alarm occurs. In case of ASYSTOLE or APNEA detection, alarm will occur even if the alarm 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. During the 2 minutes if a new alarm occurs, the silence status will be terminated and both audible and visible alarms will be triggered again. If within the 2 minutes of alarm silence, the user presses "Silence" key again, the alarm suspension status will be ended and the 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 still will remain).

Alarms and Silence keys

When Alarms key is pressed, its indicator blinks in the front panel.

This key is not currently accessible for users, but it may be available in the future.

Parameters Alarm

The alarm setting of the parameters can be found in related menus separately. You can monitor alarm limits and alarm status of each parameter in its own specific window.

When a parameter alarm is "OFF", this symbol  is displayed near the parameter. For the parameter which its alarm is "ON", an alarm will be triggered when it exceeds adjusted alarm limits. In this situation 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 adjusted alarm volume.

3- Alarm indicator flashes.

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 alarms related to each module.

3- Identify the alarm cause.

4- Silence alarm (press Silence key), if necessary.

5- When alarm condition is removed, check that the alarm is working properly.

You will find the alarm messages of the individual parameter in each module's chapter.

4
ECG Monitoring

General Information

Through the ECG Monitoring, you can see a continuous waveform of the patient's cardiac electric activity which enables physician to perform a precise assessment of patient current physiological condition. The process of depolarization and repolarization of the myocardium generates an 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 this signal and displays it as ECG waveform on the screen. Proper connection of the ECG cables and electrodes can ensure accurate assessment.

- According to standard AAMI:EC13:2002, it shall take up to 10 seconds to change heart rate from 80 to 120 bpm which in Aria monitor is about 6 seconds.
- According to standard AAMI:EC13:2002 it shall take up to 10 seconds to change heart rate from 80 to 40 bpm which in Aria monitor is 8 seconds.
- When Tachycardia (HR >200 bpm) happens, system takes 6 seconds to sound alarm. (In this case the low alarm limit should be set to 60 bpm and high alarm limit to 100 bpm.)
- It takes 10 seconds to sound alarm when a cardiac arrest happens (from 80 bpm to 0 bpm)
- The above results are for HR average of 4 seconds.

- The ECG module is able to reject 1.2 mV TALL-T.
- The current that is applied to the patient for lead-sensing is 90nA.
- Noise suppression circuit: A noise signal of 10 μA is given 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.

 Do not touch patient, monitor and bed during defibrillation.

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

Line Isolation Monitor (LIM) transient may generate waveforms similar to the actual cardiac waveforms and thus trigger heart rate alarms. Such transients may be minimized by proper electrode and cable placement as later described in this chapter.

Interference from non-grounded devices near the patient or electrosurgical units can cause inaccurate ECG waveform.

When you connect the cables and electrodes, make sure that no metal part of electrods is in contact with the safety ground. Check that all ECG electrodes are correctly attached to the patient.

1. Prepare the patient's skin before electrode placement.
   - Proper skin preparation is necessary for good electrode placement, as the skin is a poor conductor of electricity.
   - Shave hair from the selected sites, if necessary.
   - Cleanse the site with a mild soap and water solution. (Never use pure alcohol, because it increases body resistance.)
   - Gently rub the skin surface to increase capillary blood flow in the tissues .
2. Place chest leads on the patient. If your chest lead has not conductive gel, apply some conductive gel on intended site of the skin.(figures 4-1 and 4-2)
3. Attach the clips or snaps to the chest leads before placing them.

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 it can cause problems with ECG waveform. Using dissimilar metals may also increase recovery time after defibrillation.

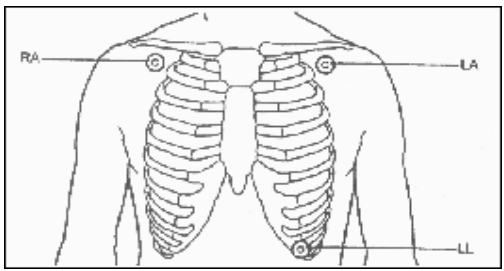


Figure 4-1 ECG 3-lead electrode placement

3-lead electrode placement (Figure 4-1)

Right arm (RA) placement: red electrode, near the right shoulder, directly below the clavicle.

Left Arm (LA): yellow electrode, near the left shoulder, directly below the clavicle.

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

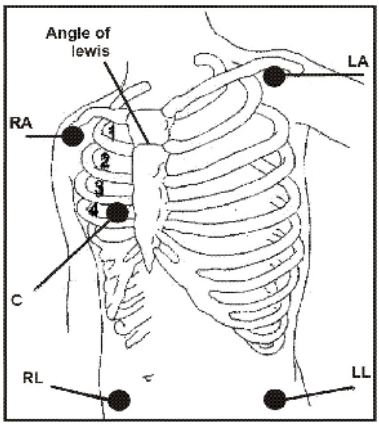


Figure 4-2 ECG 5-lead electrode placement

5-lead electrode placement (Figure 4-2)

Right arm (RA) placement: red electrode, near the right shoulder, directly below the clavicle.

Left Arm (LA): yellow electrode, near the left shoulder, directly below the clavicle.

Chest (C): white electrode, placement is shown in the figure 4-2.

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

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

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

For 5-lead set, the C electrode can be placed on one of the following positions:

●V1 on the fourth intercostal space at the right sternal border.

●V2 on the fourth intercostal space at the left sternal border.

●V3 midway between V2 and V4 electrode positions.

●V4 on the fifth intercostal space at the left midclavicular 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 on the left.

●VE over the xiphoid position.

For posterior C lead placement, place the C electrode at one of the following positions.

●V7 on posterior chest at the left posterior axillary line in the fifth intercostal space.

●V7R on posterior chest at the right posterior axillary line in the fifth intercostal space.

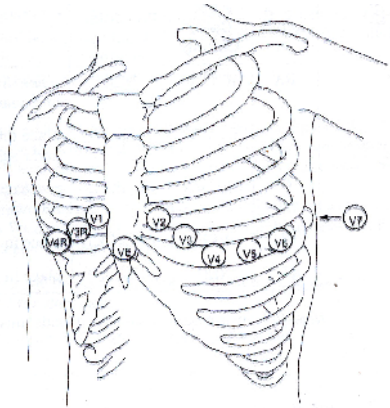


Figure 4-3 placement of the C electrode for 5-lead ECG

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

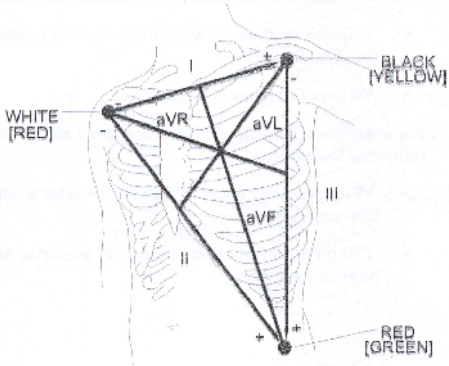


Figure 4-4 ECG leads

Periodically inspect the electrode application site to ensure skin quality. If there is skin irritation, replace the electrodes or change the application site.

Verify the cable fault detection prior to start monitoring phase. Unplug the ECG cable from the socket, the monitor will display the error message "ECG NO CABLE" on the screen.

ECG cable may be damaged if it is connected to the patient during defibrillation. Cables which have been connected to the patient during defibrillation should be checked functionally before being used again**.**

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

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

 When using Electrosurgery equipment, leads should be placed in a long distance from the grounding plate and electrosurgical pencil to prevent unwanted burns.

Depending on type of surgery, ECG leads are placed in different positions. For example electrodes should be placed horizontally on the chest (rib cage) or back in open heart surgery. Interferences from electrosurgery equipment may cause problems with the ECG waveform. To avoid these interfaces, place electrodes near the right or left shoulder and above the tummy. Never place electrodes on the upper arms (except when ECG signal is weak).

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

 Patient burning is possible due to an improper connection of the grounding plate of the electrosurgical device.

Normal QRS waveform contains:

- ☐ 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.

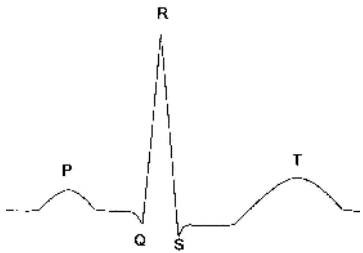


Figure 4-5 Standard ECG waveform

 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.

 For the patients with pacemaker, the monitor may continue to count the pacemaker heartbeat rates during occurrence of arrhythmia. Do not rely entirely upon monitor alarms. Keep paced patients under close surveillance. (Refer to ECG WAVEFORM for relevant information about Pace pulses).

ECG PARAM MENU

By touching ECG parameter area on the screen, you can access this menu:

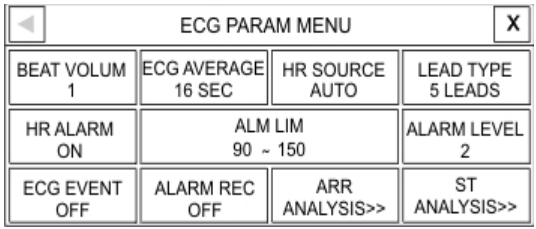


Figure 4-6 ECG PARAM MENU

- **BEAT VOLUME**

It ranges from 1 to 8. Select "OFF" to turn off heart beat sound and 8 to hear the highest volume.

- **ECG AVERAGE**

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

- **HR SOURCE**

Heart rate may be derived from “ECG” or “SPO2”. In AUTO mode if ECG cable is connected to the patient, the

monitor automatically derives heart rate from ECG, otherwise the heart rate value is derived from SPO2 signal.

- **LEAD TYPE**

Select it to access different ECG modes including 3-lead and 5-lead.

- **HR ALARM**

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

- **ALM LIM**

By pressing "ALM LIM" in ECG PARAM MENU, you can access this window:

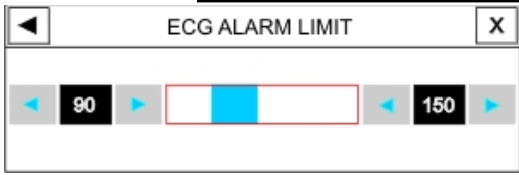


Figure 4-7 ECG ALARM LIMIT

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.

ECG TRACE MENU

By touching ECG waveform area on the screen, you can access this menu:

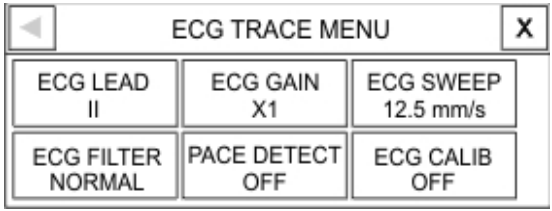


Figure 4-8 ECG TRACE MENU

- **ECG LEAD**

LEAD	
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 for 5-lead ECG mode.

ECG TRACE MENU

- **ECG GAIN**

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

- **ECG FILTER**

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

ECG TRACE MENU

Filter mode	Frequency Range	Application
NORMAL	0.5-40 HZ	In normal conditions
EXTENDED	0.05-100 HZ	In diagnostic application, but the ECG waveform might have some noises.
MONITOR	0.5-24 HZ	This mode reduces Interference from electrosurgery equipment. This mode also can be used when the system has high noises or doesn't have equipotential earth.

- **PACE DETECT**

For patient with pacemaker, set PACE DETECT to "ON" and for patient without pacemaker, set it to "OFF". When PACE DETECT is "ON", the system detects and rejects pacemaker-generated signals from ECG signal so that they will be ignored in calculating 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.

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

 For patients with pacemaker, set PACE DETECT to "ON", otherwise pacing impulse may be counted as normal QRS complex.

- **ECG CALIB**

Select "ON", 1 mv calibrated ECG wave will appear and

"CAL" is shown above it. When it is ON the calibration waveform will not disappear even if you close ECG TRACE MENU.

If more than one ECG signal is displayed in the selected page, you can choose lead of each signal separately by pressing that signal. For example if you press the third signal in P3 , ECG EXTRA MENU will appear.

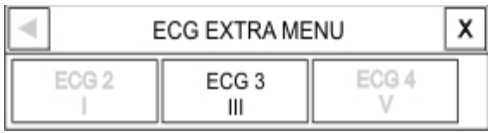


Figure 4-9 ECG EXTRA MENU

ECG Alarm Messages

Alarm sounds when:

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

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	Activated

displayed in red background.

ECG alarm messages include:

Message	Cause/Solution	Remarks
ECG NO CABLE	Cause: ECG cable is not connected to the system. Solution: Connect ECG cable	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
ECG NOISE	Cause: ECG signal is noisy or saturated. Solution: Check for any possible source of signal noise from the area around the cable and electrode, and check the patient for great motion or improper placement of the lead wires.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

ECG Alarm Messages

Message	Cause/Solution	Remarks
ECG CHECK LA,RA,LL	Cause: Mentioned leads are not properly connected to the patient. Solution: Make sure that the electrodes are properly connected.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
ECG SIGNAL WEAK	Cause: ECG amplitude is lower than standard limit. Solution: Check the position of the chest leads.	

ECG Alarm Messages

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

ECG Alarm Messages

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

The last 4 messages in the table are displayed just for 5-lead mode.

After performing the mentioned solution, if above messages are displayed again, the ECG cable may be damaged and you should contact the customer Service.

ECG Cable Cleaning

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

- **Cleaning**

Use soft cloth moistened with mild soap and water solution or cleaning agent containing 70% ethanol to clean the ECG cable.

- **Sterilization**

To avoid extended damage to the system, sterilization should be performed only according to the hospital maintenance schedule. Sterilization facilities should be cleaned first.

It is recommended to use 70% alcohol or isopropanol 70% as sterilization material.

- **Disinfection**

To avoid extended damage to the system, disinfection should be performed only according to the hospital maintenance schedule. Disinfection tools should be cleaned first.

5
RESP Monitoring

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.

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

RESP General Information

For RESP monitoring, it is not necessary for additional electrodes, however, position 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 auxiliary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.

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

RESP General Information

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 PARAM MENU

By touching RESP parameter area, you can access this menu:

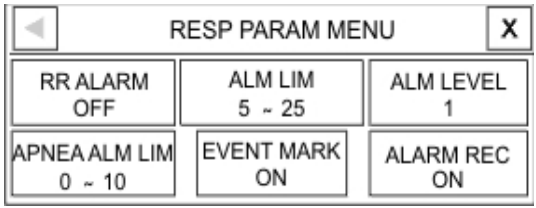


Figure 5-1 RESP PARAM MENU

■ **RR ALARM**

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

Select "OFF" to disable the alarm functions, and there will be a"⚠"symbol in the RESP parameter area.

■ **ALM LIMIT**

Press this option to access this window:

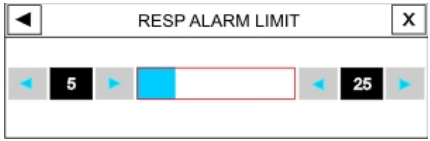


Figure 5-2 RESP ALARM LIMIT

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

Low limit: 5 ~ (High limit- 5)

High limit: (Low limit +5) ~ 250

■ **ALM LEVEL**

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

■ **APNEA LIMIT**

Press this option to set the standard of judging an apnea case.

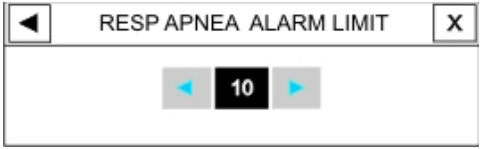


Figure 5-3 RESP APNEA ALARM LIMIT

It ranges from 5 to 40 and increases/decrease by 5 sec. (Low limit: 5, High limit: 40).

RESP TRACE MENU

By touching RESP waveform area, you can access the following menu:

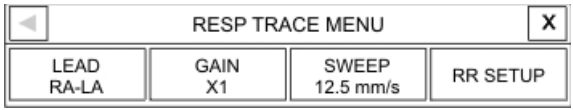


Figure 5-4 RESP TRACE MENU

- **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.

RESP Alarm Messages

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

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

RESPAlarm Messages

RESP messages include:

Message	Cause/Solution	Remarks
RESP CHECK LEADS	Cause: The RESP leads are not properly connected. Solution: Make sure that all electrodes are properly connected.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

6
SPO2 & Rainbow Parameters Monitoring

General Information

SPO2 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 is designed by Masimo Company and offered to its approved companies.

Measurable physiological parameters by Masimo Rainbow module

SpO2

Pulse Rate

Perfusion Index (PI)

and optional parameters such as:

SpHb

SpOC

SpCo

SpMet

Pleth Variability Index (PVI)

% SPO2

Extent of oxygen saturation in hemoglobin of arterial blood can be detected from the SPO2 waveform. For example, if 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has an oxygen saturation of 97%. The SPO2 value

on the monitor will be 97%. The SPO2 value shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin.

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

Pulse Rate

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

Perfusion Index

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

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

$$PI = \frac{AC}{DC} \text{ x } 100\%$$

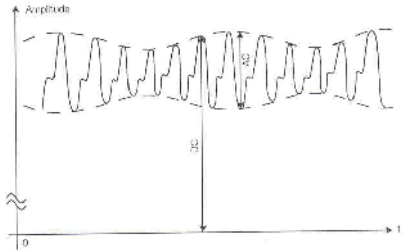


Figure 6-1 PI definition

PI greater than 1% is preferable

SpHb

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

SpOC

SpOC indicates oxygen content in the blood. Neither SpO2 nor Hb parameter by itself can indicate the actual

amount of oxygen in the blood. A patient with normal SpO2 or Hb may have low levels of oxygen. In fact, both SpO2 and Hb are considered by SpOC parameter. The unit of measurement is ml/dL (milliliters of oxygen per deciliter of blood).

SpCO

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

SpMet

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

Pleth Variability Index

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

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

$$PI_{Max} - PI_{Min}$$

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

PVI can help clinicians predict fluid responsiveness in patients.

■ The %SPO2, PR, PI, PVI, SPOC, %SpMet, %SpCo and SpHb values can be displayed on the main screen. The

SPO2 General Information

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).

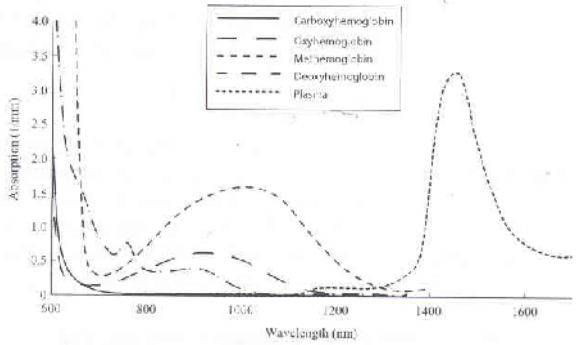


Figure 6-2 Absorption Spectra

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

A multi-wavelength sensor is used to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma. This sensor is utilized with various light-emitting diodes (LEDs) that

pass light through the site to a photodiode (detector). Signal data is obtained by passing various visible and infrared lights (LED's, 500 to 1400 nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful for clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the module for calculation.

Figure 6-3 Light Emitting Diodes and Detector

Once the signal is received from the sensor, it utilizes Masimo Rainbow SET signal extraction technology to calculate the patient's functional oxygen saturation (SPO2

(%)), blood levels of carboxy hemoglobin (SpCO (%)), methemoglobin (SpMet (%)), Total Hemoglobin concentration (SpHb g/dl) and pulse rate (PR (PPM)).

Signal Extraction Technology (SET)

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

Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or separate them by looking at the whole

signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform (DST), readily identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

 For more information about Masimo Rainbow module, please refer to APPENDIX III.

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

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

SPO2 General Information

Use only manufacturer recommended SPO2 sensors. Other SPO2 sensors may cause improper monitor performance.

Regarding the installed SPO2 module in the system, use suitable sensor specified in chapter 14.

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

Pulseoximetry may overestimate the SPO2 value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.

 ESU (electrosurgical unit) wire and SPO2 cable must not be tangled up.

 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 an SPO2 sensor. To prevent interference from ambient lights, 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.

 Do not apply the sensor on the hand with arterial catheter or venous syringe.

SPO2 General Information

 SPO2 module updates parameters values every 1 second.

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

Parameter	Measurement Range
SpO2	0 – 100%
SpMet	0.0 – 100.0%
SpCO	0.0 – 100.0%
SpHb	0.0 – 100.0 g/dL
SpOC	0.0 – 40.0 ml /dL
Pulse Rate	0 – 240%
Perfusion Index	0.0 – 20.0%
PVI	0 – 100%

Materials used in our SPO2 sensors are innoxious.

SPO2 Measurement

1. Turn on the monitor.
2. Attach the sensor to the appropriate site of the patient finger. (Refer to Figure 6-4 for the proper method.)
3. Plug the connector of the sensor cable into the SPO2 socket on the left side of the device.

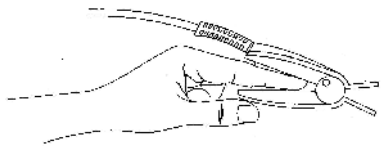


Figure 6-4 placing the SPO2 sensor

Make sure the nail covers the light window.

SPO2 General Information

 The sensor wire should be placed above the hand.

SPO2 value is always displayed in the SPO2 window.
PR value will be displayed in ECG window (instead of HR) as well as SPO2 window, if you set it "ON" and adjust "HR SOURCE" on SPO2.

 Verify sensor cable fault detection before beginning SPO2 monitoring. Unplug the SPO2 sensor cable from the socket, the screen will display the message "SPO2 NO PROBE".

 Do not use the SPO2 sensor which its packaging or the sensor is damaged and return it to the vendor.

Measurement Limitations

During operation, the accuracy of SPO2 measurement can be affected by:

- Using Electrosurgical and defibrillator devices simultaneously
- Excessive Patient movement
- Injection of intravascular dye such as indocyanine methylene blue or green.
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin.
- Increase or decrease of sensor temperature (best functional temperature is between 28° C and 42° C)
- Excessive illumination (more than 5000 lumens /Square meter)
- Improper sensor application.
- Venous pulsations
- Cabling entanglement or strangulation.

- Placement of the sensor on a site that has a blood pressure cuff, arterial catheter, or intravascular line.
- Do not use oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.

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

Tissue damage can be caused by incorrect application of sensors, for example by pasting the sensor or by wrapping it too tightly.

SPO2 General Information

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.

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.

SPO2 PARAM MENU

By touching SPO2 parameter area, you can access this menu:

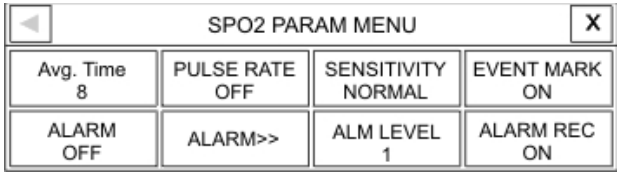


Figure 6-5 SPO2 PARAM MENU

■ **Avg. Time**

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

■ **SENSITIVITY**

Available options for SPO2 SENSITIVITY are "NORMAL", "MAX" and "APOD".

SPO2 PARAM MENU

- **NORMAL**：

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

- **MAX**：

Recognizing that some clinicians may want the absolute low perfusion performance (0.02%) 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.

- **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.

■ **ALARM ON/OFF**

Select "ON" to enable SPO2 alarm functions such as parameters blinking, audio alarm, and light indicator. Select "OFF" to disable the alarm functions and there will be a "  " symbol in the SPO2 and PR parameters area.

SPO2 PARAM MENU

■ ALARM

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

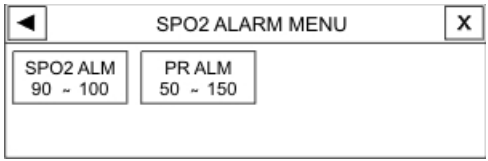


Figure 6-6 SPO2 ALARM MENU

You can change alarm limits of PI, PVI, SpOC, SpCO, SpMet and SpHb by pressing this item in P5 and P6 (including Rainbow parameters).

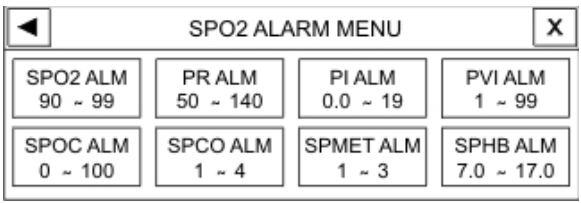


Figure 6-7 SPO2 ALARM MENU (including Rainbow parameters)

SPO2 PARAM MENU

By selecting each parameter in SPO2 ALARM MENU, you can access alarm limits window of that parameter as shown in the figure 6-8.

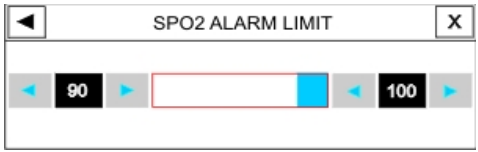


Figure 6-8 SPO2 ALM LIMIT

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

.Parameter		Alarm Limit
SPO2	HIGH Alarm	SPO2 LOW Alarm +1 to 99
	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
PI	HIGH Alarm	PI LOW Alarm +0.1 to 19.0
	LOW Alarm	0.0 to PI HIGH Alarm -0.1
PVI	HIGH Alarm	PVI LOW Alarm +1 to 99
	LOW Alarm	1 to PVI HIGH Alarm -1
SpCO	HIGH Alarm	SpCO LOW Alarm +1 to 99
	LOW Alarm	1 to SpCO HIGH Alarm -1

SPO2 PARAM MENU

SpMet	HIGH Alarm	SpMet LOW Alarm +0.5 to 99.5
	LOW Alarm	0.5 to SpMet HIGH Alarm -0.5
SpHb	HIGH Alarm	SpHb LOW Alarm +0.1 to 99.0
	LOW Alarm	1.0 to SpHb HIGH Alarm -0.1
SpOC	HIGH Alarm	SpOC LOW Alarm +1 to 39
	LOW Alarm	1 to SpOC HIGH Alarm -1

■ **ALARM LEVEL**

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

SPO2 TRACE MENU

By touching SPO2 waveform area, you can access this menu:

Figure 6-9 SPO2 TRACE MENU

■ **PLETH SWEEP**

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

Signal quality detection

In addition to plethysmograph waveform, there is SIQ or SQ waveform which indicates signal quality simultaneous to plethysmograph pulse. The height of vertical lines indicates the quality of the signal (i.e. the lines are higher, signal quality is better).

SPO2 Alarm Messages

Alarm occurs when SPO2 and PR values violate adjusted 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 ASYSTOLE	Pulse beat is not detected in last 10 sec.	●HR is "0" and blinks. ●Alarm indicator flashes. ●The message is displayed in red backgrounds	Activated

SPO2 Alarm Messages

Alarm	Situation	Visual Alarm	Audio Alarm
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

Rainbow Parameters Alarm Messages

Alarm occurs when Rainbow parameters violate adjusted alarm limits in P5 and P6.

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

SPO2 Alarm Messages

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

SPO2 Alarm Messages

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

SPO2 Alarm Messages

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

SPO2 Alarm Messages

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

SPO2 Alarm Messages

SPO2 messages include:

Message	Cause/Solution	Remarks
SPO2 NO PROBE	Cause: SPO2 probe is disconnected from the monitor. Solution: Make sure that the probe is correctly connected to the monitor.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
SPO2 PROBE DEFECT	Cause: The SPO2 probe is damaged. Solution: Change the SPO2 probe.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

SPO2 Alarm Messages

Message	Cause/Solution	Remarks
SPO2 PROBE OFF	Cause: SPO2 probe may be detached from the patient finger. Solution: Make sure that SPO2 probe is properly attached to the patient.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
SPO2 CHECK PROBE	Cause: SPO2 probe is not properly attached to the patient. Solution: Make sure that SPO2 probe is properly connected to the patient (refer to figure 6-1).	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and alarm is disabled for at least 120s.

SPO2 Alarm Messages

Message	Cause/Solution	Remarks
SPO2 HIGH AMBIENT LIGHT	Cause: This may be caused by entering environmental light into the probe. Solution: Make sure that SPO2 probe is properly connected to the patient.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and alarm is disabled for at least 120s.
SPO2 SEARCH	Cause: SPO2 is not calculable due to different reasons such as long time motions. Solution: Move the sensor to another place, provoke blood recycle, and calm the patient.	
SPO2 SIGNAL WEAK	Cause: The SPO2 signal amplitude is too weak or undetectable. Solution: Change the place of the probe.	

SPO2 Alarm Messages

Message	Cause/Solution	Remarks
SPO2 DEFECT	Cause: SPO2 module failure. Solution: turn off and then on the system .If this message is displayed again, the user should contact local customer Service.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

After performing the mentioned solutions if above mentioned messages are displayed again, the SPO2 probe may be damaged and you should contact with local customer Service.

SPO2 Probe Cleaning

To clean the probe, first remove it from the patient and disconnect it from the monitor. Clean the probe by a cloth damping with 70% isopropyl alcohol and then dry it prior to placement on a patient.

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

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

 Do not use any probe or cable that may be damaged or deteriorated.

7
NIBP Monitoring

General Information

NIBP (Non-invasive Blood Pressure) processing by the monitor uses the oscillometric measuring technique. A motorized pump inflates the cuff initially, until the pressure effectively occludes flow of blood in the extremity. Then, under monitor control, the pressure in the cuff is gradually reduced, until a pressure transducer detects air pressure and transmits a signal to the NIBP circuit.

As the cuff pressure is reduced, blood flows in the previously occluded artery and changes the measured pressure values sensed by the transducer. The point at which oscillation increases sharply is defined as systolic pressure. As the cuff continues to deflate, oscillation amplitude increases to a maximum, and then decreases. The peak oscillation amplitude is defined as the mean arterial pressure. The point at which the system detects a loss of oscillation is defined as the diastolic pressure.

Blood pressure measurement according to this method is equivalent to the cuff-stethoscope method.

■ This module has been designed in accordance with EN 1060-1: Non-invasive sphygmomanometers Part 1: General requirements

■ This module is applicable for adults and neonates.

■ 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 minutes and 1, 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.

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

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.

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.

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

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

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.

In this module the maximum cuff inflation pressure is 288 mmHg in adult mode and it is 146 mmHg for neonate mode. Furthermore independent maximum pressure control preservative is forecasted inside the system.
Also maximum time of being under pressure for cuff has been limited to 2 minutes in each measurement, however it is necessary that operators pay attention that long-time and continuous measurements can result in muscular and neurotic harms or dermal injuries.

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 7-1) 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.

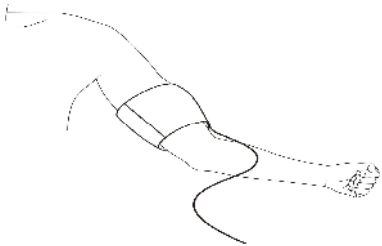


Figure 7-1 Applying Cuff

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 chapter 17 for more detail.)

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 in PAT CONF.

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.

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.

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.

 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 heart beat.

- **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.

NIBP PARAM MENU

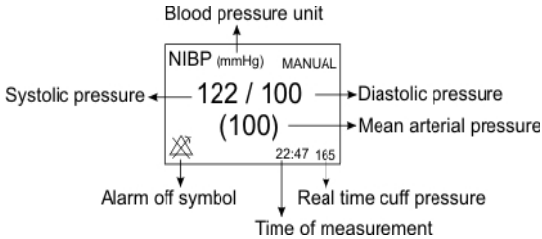


Figure 7-2 Different parameters of NIBP

NIBP PARAM MENU is as follows:

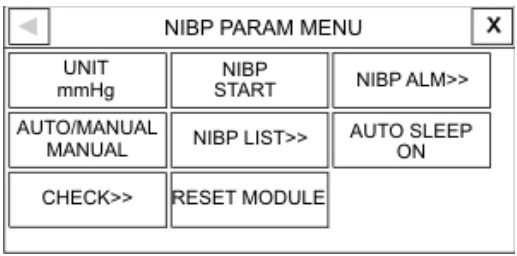


Figure 7-3 NIBP PARAM MENU

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**

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

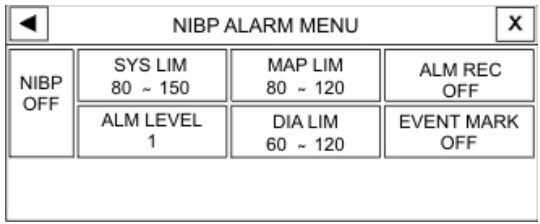


Figure 7-4 NIBP ALARM MENU

- **NIBP ALM ON/OFF**

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

Select "OFF" to disable the alarm functions and there will be a"🔕"symbol in the NIBP Parameter area.

- **SYS LIM**

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

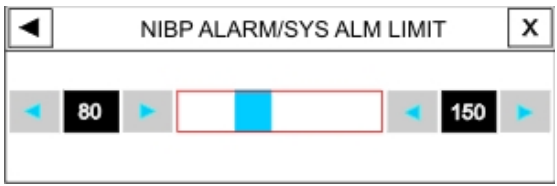


Figure 7-5 NIBP ALARM/SYS ALM LIMIT

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

LOW limit: 30 ~ (HIGH limit - 5)

HIGH limit: (LOW limit + 5) ~ 300

- **MAP LIM**

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

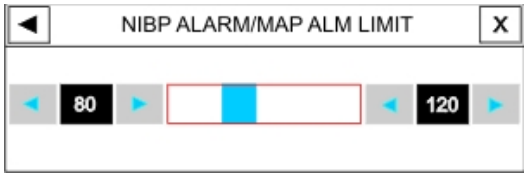


Figure 7-6 NIBP ALARM/MAP ALM LIMIT

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

LOW limit: 30 ~ (HIGH limit - 5)

HIGH limit: (LOW limit + 5) ~ 300

- **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.

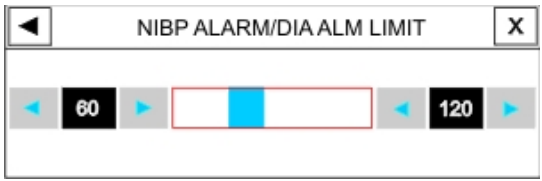


Figure 7-7 NIBP ALARM/DIA ALM LIMIT

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

LOW limit: 30 ~ (HIGH limit - 5)

HIGH limit: (LOW limit + 5) ~ 300

■ **STAT \AUTO \MANUAL**

There are three modes of measurement available: MANUAL, AUTO and STAT. In the MANUAL mode, only one measurement is performed. In the AUTO mode, measurement is repeated over a specified period of time ; available intervals are 1,2,3,5,10,15,20,30 and 45 minutes and 1, 2, 4, 8,12,16,20 and 24 hours. In STAT mode, measurement is performed up to ten times in 5 minutes and 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 Figure 7-8.

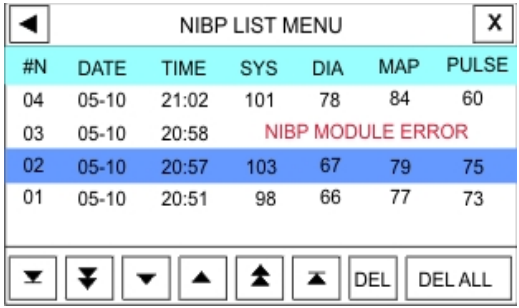


Figure 7-8 NIBP LIST MENU

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” button and pressing YES in prompt alert window.

Figure 7-9 ALERT

■ **AUTO SLEEP**

Select “ON” and press START button until the message “WAKEUP AT 9” appears in red on the NIBP window. Measurement resumes after 10 s 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:

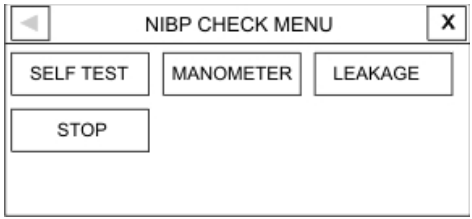


Figure 7-10 NIBP CHECK MENU

- **SELF TEST**

Select this item to perform a self test on the NIBP module.

- **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 170 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 manufacturer trained and authorized personnel.

- **STOP**

To stop the NIBP measurement.

■ RESET MODULE

To set maximum inflation pressure of cuff to 150mmHg for adults and 70mmHg for neonates.

NIBP Alarm Messages

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

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
NIBP DIA 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:

Message	Cause
SELF-TEST FAILED	NIBP hardware module failure
NIBP LOOSE CUFF	Cuff is not properly wrapped or no cuff applied.
NIBP MODE ERROR	Adult cuff is used instead of neonate cuff or occlusion happened in air way.
NIBP AIR LEAK	Air leak in cuff, hose or connector.
NIBP AIR PRESSURE ERROR	Unstable pressure value (e.g. tangled hose) because valves cannot open normally.
NIBP SIGNAL WEAK	Very weak patient signal due to a tightly wrapped cuff or weak pulse from patient.

NIBP Alarm Messages

Message	Cause
NIBP RANGE EXCEED	Measuring pressure exceeded the upper limit (255mmHg) for adult or (135mmHg) for neonate.
NIBP EXCESSIVE MOTION	Arm movement, noisy signal or irregular pulse (e.g. arrhythmia)
NIBP OVER PRESSURE SENSED	Measuring pressure exceeded safe software limit, 290 mmHg for adult and 145mmHg for neonate.
NIBP SIGNAL SATURATED	Large motion artifact and noise that saturates the amplifier's amplitude handling capability.
NIBP PNEUMATIC LEAK	Leakage during leak test
NIBP TIME OUT	Measuring time exceeds 120 seconds for adult or 90 seconds for neonate.

NIBP Alarm Messages

Message	Cause
SYSTEM FAILURE	Error occurs in pump, A/D sampling, pressure transducer or software.
NIBP DEFECT	NIBP module failure
NIBP LOW BATTERY	The Charge of battery is low so NIBP measurement is not possible (while the monitor is working with battery).
NIBP NO MODULE	No NIBP module is installed.
NIBP MODULE ERROR	There is a failure during measurement.
NIBP STOP PRESSED	Stop key has been pressed during measurement.
NIBP STOP	Measurement is stopped by NIBP module because of a special reason.
NIBP LEAKAGE O.K	Successful leakage test.

NIBP Alarm Messages

Alarm level for above messages (except the last three messages) is set in NIBP ALARM MENU.

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

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

NIBP Cuff Cleaning

- **Cleaning**

Reusable cuffs can be safely cleaned with a cloth damped with 70% alcohol or 0.5% bleach solution or washed in water and soap solution (maximum 60ºC).

- **Sterilization**

Do not use steam or heat to sterilize the cuff. Gas sterilization can be used if necessary.

- **Disinfection**

Glutaraldehyde type liquid disinfectants may be used on reusable cuffs. Prolonged use of these disinfectants may cause discoloration of cuff and its marking.

8
TEMP Monitoring

General Information

Measurement of patient temperature is accomplished by processing the signal from a probe containing temperature dependent resistor called thermistor. Value of this resistor is measured by the monitor continuously and displayed on screen.

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

Inspection and recalibration

Inspect the probe for cracks, holes, cracking, 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.

TEMP General Information

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; Probe accuracy should not exceed the tolerance over the normal life of the probe.

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

Over straining will result in mechanical damage to the probes.

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.

TEMP General Information

 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.

TEMP PARAM MENU

TEMP PARAM MENU is as follows:

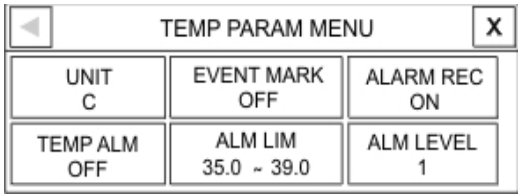


Figure 8-1 TEMP PARAM MENU

- **UNIT**

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

- **TEMP ALM**

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

TEMP PARAM MENU

■ **ALM LIM**

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

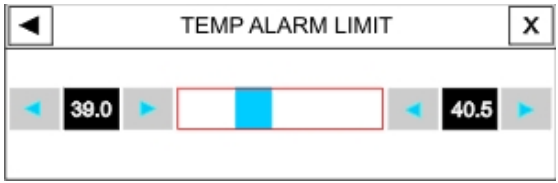


Figure 8-2 TEMP ALARM LIMIT

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.

TEMP Alarm Messages

Alarm occurs when TEMP alarm is “ON” and violates the adjusted limits.

TEMP Sensor Cleaning and Maintenance

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

 Temperature sensors are sold non- sterile.

- **Cleaning**

When wiping clean, hold the probe in one hand at the sensing tip and wipe the probe and cable toward the connector. Excessive pressure and stretch could damage cable jacket and break the internal wires, destroying the probe. Avoid cleaning the sensor with substances such as ether, ketone, or ester solvents.

 Don’t immerse the probe connector in the water.

- **Sterilization**

Ethylene oxide is the preferred substance to sterilize the sensor. After sterilization, probes must be thoroughly ventilated before handling or use. Use a generic EtO sterilizing procedure. An aeration time of 12 hours to dissipate residual EtO in probe is recommended.

- **Disinfection**

Probes may be disinfected by washing with 70% isopropanol, activated dialdehyde (Cidex) or sodium hypochlorite (bleach diluted 1:10 minimum in water.) After disinfecting the probes should be washed thoroughly with water. Brief immersion of the probe in detergent solutions is not harmful.

Manufacturer does not make any claim as to the efficacy of these chemicals for infection control. Please consult your hospital's Infection Control Officer for more disinfection guides.

TEMP Sensor Cleaning and Maintenance

 Never immerse the temperature probes in the boil water.

Sensor Maintenance

When not in use, probes should be loosely twisted and stored at room temperature .Do not wrap sensor around the monitor to avoid damaging it.

9
IBP Monitoring

General Information

Specification:

Displaying and measuring ranges (for all labels)
-50~300(mmHg)

Alarm ranges

IBP	-50~300(mmHg)
ART	-50~300(mmHg)
LVP	-50~300(mmHg)
PAP	-50~120(mmHg)
RVP	-50~100(mmHg)
CVP	-50~100(mmHg)
LAP	-50~100(mmHg)
RAP	-50~100(mmHg)

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

IBP General Information

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

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

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

Disposable IBP transducer should not be reused or sterilized.

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

 Use only the pressure transducers listed in the Chapter 13.

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

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

Preparatory steps for IBP measurement (Figure 9-1):

1. Plug the transducer cable into corresponding socket.
2. Prepare the pressure tube and transducer by flushing through the tubing system with normal saline solution. Ensure that the tubing system is free of air bubbles.
3. Connect the patient catheter to the pressure line and make sure that there is no air in the catheter or pressure line.

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

Place the transducer at the same level with the patient's heart.

5. Check if you have selected the correct label name .See the next chapter for details.

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

7. Calibrate the monitor with a reference pressure if you have changed the transducer or if you are not sure about the accuracy. See the next section for details.

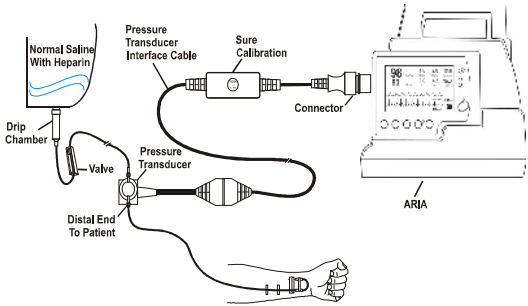


Figure 9-1 IBP Monitoring

IBP PARAM MENU

IBP PARAM MENU is as follows:

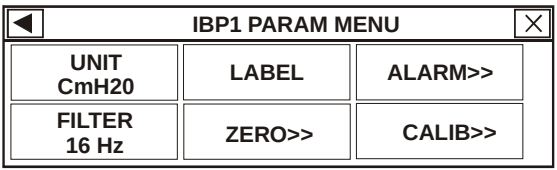


Figure 9-2 IBP PARAM MENU

IBP PARAM MENU

■ **UNIT**

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

■ **LABEL**

By pressing this item, you can access this window:

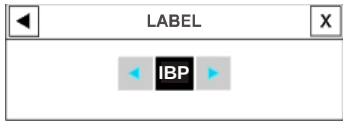


Figure 9-3 LABEL

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

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

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

■ **ALARM**

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

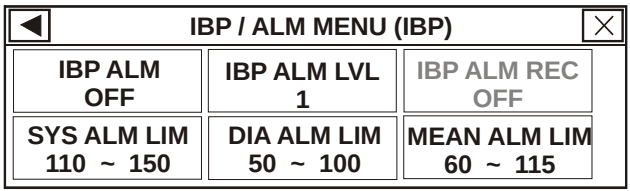


Figure 9-4 IBP/ALM MENU (IBP)

IBP PARAM MENU

- **IBP ALM**

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

- **IBP ALM LVL**

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

- **SYS ALM LIM**

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

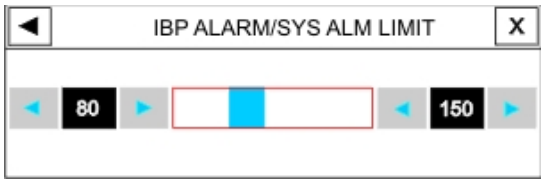


Figure 9-5 IBP ALARM/SYS ALM LIMIT

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

- **DIA ALM LIM**

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

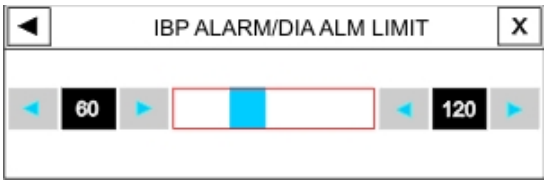


Figure 9-6 IBP ALARM/DIA ALM LIMIT

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

- **MEAN ALM LIM**

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

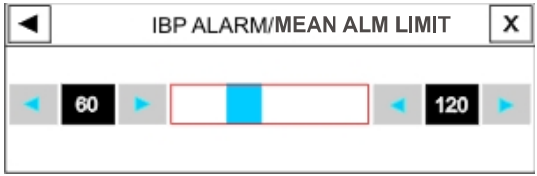


Figure 9-7 IBP ALARM/MEAN ALM LIMIT

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

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

The alarm enables when the value violates the adjusted limits.

IBP PARAM MENU

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

■ **FILTER**

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

Available options are 22Hz, 16Hz, and 8Hz.

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

16Hz: When the signal is a bit noisy.

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

■ **ZERO**

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

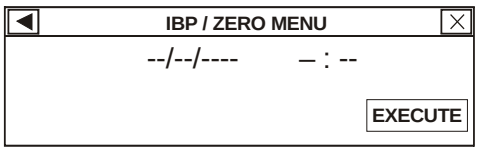


Figure 9-8 IBP/ZERO MENU

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

IBP PARAM MENU

Zero the transducer:

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

2- Close the patient stopcock.

3-The transducer must be vented to atmospheric pressure.

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

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

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

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

The following messages may prompt up in ZERO WINDOW:

IBP PARAM MENU

■ **"IBP NO SENSOR, UNABLE TO ZERO"**

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

■ **"IBP OVERANGE, FAILED ZERO"**

Make sure that the stopcock is vented to atmosphere. If the problem persists, contact customer service.

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

Make sure that the transducer is not attached to the patient and that the stopcock is closed to atmosphere. It is also likely the tubing system is hit accidentally during zeroing. If the problem persists, please contact customer service.

■ **CALIB**

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

IBP PARAM MENU

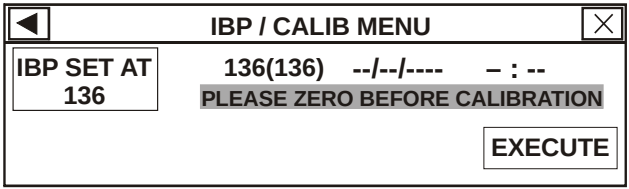


Figure 9-9 IBP/CALIB MENU

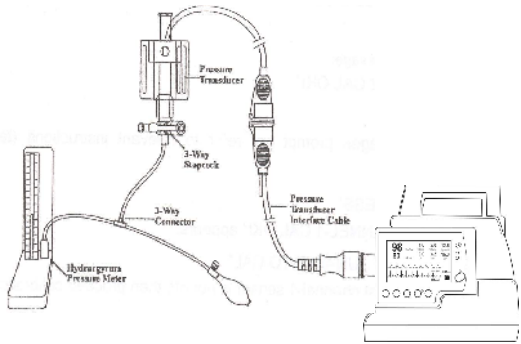


Figure 9-10 IBP CALIBRATION

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

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

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

You must never perform calibration while patient is being monitored.

1. Attach the tubing system to the sphygmomanometer.
2. Ensure that connection that would lead to patient is off.
3. Connect the 3-way connector to the 3-way stopcock.
4. Open the port of the 3-way stopcock to the sphygmomanometer.

5. Raise the sphygmomanometer to set value that you adjusted in CALIB MENU.
6. Press EXECUTE in the CALIB MENU to start calibration.

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

The following messages may prompt up in CALIB WINDOW:

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

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

■ **"IBP OVERANGE, FAILED CALIB"**

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

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

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

7. Remove the sphygmomanometer tubing and extra connector.

IBP TRACE MENU

By touching IBP waveform area on the screen, you can access this menu:

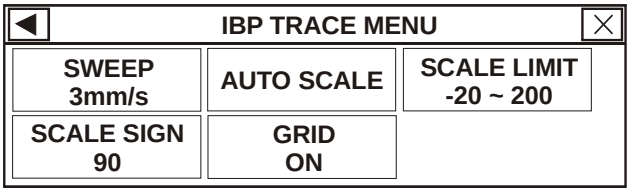


Figure 9-11 IBP TRACE MENU

■ **SWEEP**

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

■ **AUTO SCALE**

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

■ **SCALE LIMIT**

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

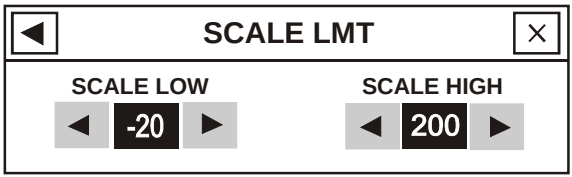


Figure 9-12 SCALE LIMIT

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

■ **SCALE SIGN**

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

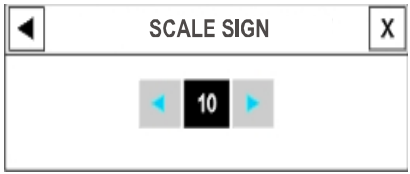


Figure 9-13 SCALE SIGN

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

■ **GRID**

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

IBP Alarm Messages

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

ALARM	Situation	Visual Alarm	Audio Alarm
SYS ALARM	Systolic pressure violates adjusted alarm limit.	● SYS value blinks. ●Alarm indicator flashes.	Activated
DIA ALARM	Diastolic pressure violates adjusted alarm limit.	● DIA value blinks. ●Alarm indicator flashes.	Activated
MEAN ALARM	Mean pressure violates adjusted alarm limit.	● MEAN value blinks. ●Alarm indicator flashes.	Activated

IBP Alarm Messages

IBP messages include:

Message	Cause/Solution	Remarks
IBP1/IBP2 NO SENSOR	Cause: Channel 1 or 2 transducer is not connected. Solution: Check the transducer connection.	Alarm level 3- The message blinks and by pressing Alarm Silence key, alarm is disabled and the system ignores this fault.
IBP1/IBP2 ADJUST SCALE	Cause: IBP1 or IBP2 signal is out of display range for about 5 seconds. Solution: Press <AUTO SCALE> in IBP WINDOW.	Alarm level 3- The message blinks and by pressing Alarm Silence key, alarm is disabled and the system ignores this fault.

IBP Alarm Messages

Message	Cause/Solution	Remarks
IBP1/IBP2 STATIC PRESSURE	Cause: This condition occurs when the maximum and minimum values of a pulsatile pressure signal (Just for IBP, ART, PAP, RVP and LVP labels) differ by less than 3mmHg.In this condition, only Mean pressure is displayed. This message can be caused by the following reasons: - A physiological condition e.g. asystole	

	- Transducer stopcock is closed to the patient. - A catheter tip lodged against a vessel wall. - A clot on the catheter tip. Solution: - Check patient and do necessary treatment. - Open the stopcock to patient and close it to the atmospheric pressure. - Follow hospital procedure for dislodging catheter. - Take necessary medical actions to remove clot from the catheter.	

IBP Alarm Messages

Message	Cause/Solution	Remarks
IBP1/IBP2 SEARCH	Cause: IBP signal can't be processed by the software because the signal is weak or less pulsatile. Solution: - Check that all IBP measurement setup is suitable or not. - Check patient status and treat him, if necessary.	

IBP Transducer Cleaning

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

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

To avoid environment pollution, the disposable transducers or domes must be recycled or disposed properly.

Don’t autoclave or ETO sterilize the transducer.

10
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.

Patient Safety

This symbol means that the applied part according to standard IEC-601-1 is type CF. The modules with CF-type (Cardiac Float) and Defibrillation-proof applied part have high degree of protection against shock and can be used during defibrillation.

This symbol means that the applied part according to standard IEC-601-1 is type BF. The modules with BF-type (Body Float) and Defibrillation-proof applied part have high degree of protection against shock and can be used during defibrillation.

Do not touch the patient, bed or instrument during defibrillation.

Patient Safety

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 temperatures between 0ºC and 40ºC. Ambient temperatures that exceed these limits could affect the accuracy of the monitor and cause damage to the modules and electric circuits.

Grounding the patient monitor

To protect the patient and hospital personnel, the case of patient monitor must be grounded. The patient monitor is equipped with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle .If a 3-wire receptacle is not available, consult the hospital electricians. If there is any doubt regarding the completeness of the protective grounding wire, the device must be operated with internal battery or DC input.

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

Monitor Symbols

This symbol means "BE CAREFUL". Please consult the user manual before using the device and pay attention to warnings and cautions.

11
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 into the station base

Set the monitor in the station base.

Connect the Power Cable to the system

- Make sure the AC power supply is 200-240 VA and 50/60Hz.
- Connect one end of the power cable to the relevant socket on the station base and the other end to a grounded power receptacle.

 Make sure that the battery indicator lights. If it does not light, check your local power supply and power cable connection. If the problem still exists, contact the local Customer Service.

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

Power on the monitor

Press the Power key to turn on the monitor. At the same time a beep sound will be heard and 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.

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

 Recharge the battery after using it. To do so, simply plug the Aria station into AC line power.

 If any sign of damage is detected, or the monitor displays any error messages, do not use it on any patient until resolving that problem.

Attach the Sensors to the patient

Connect all the necessary accessories between the monitor and the patient.

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

12
Continuous patient monitoring

Aria monitor is intended to be used as a full-function monitoring system. By connecting some accessories to the monitor, it will be applicable in different sites.

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

The monitor can be used in an ambulance by mounting it on the roll stand as shown in figure 12-1 and 12-2.

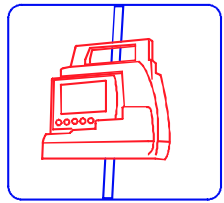


Figure 12-1 Installation on the roll stand

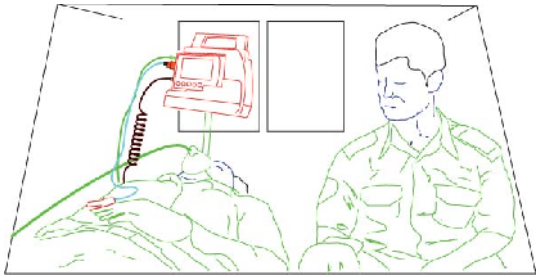


Figure 12-2 Monitoring in ambulance

During patient transport to different wards or operation room of hospital, the monitor can be hung from the bed rail by its base (figure 12-3).

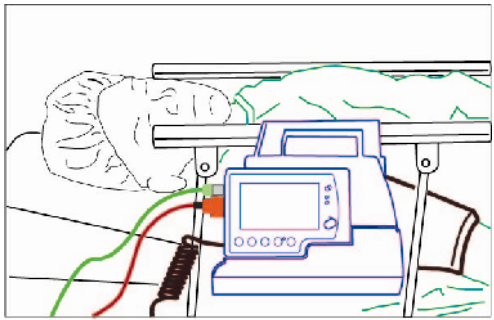


Figure 12-3 Installation on bed rail

In order to have a suitable and clear view of the screen in ICU, CCU or operation room, you can connect the monitor to a large LCD as second monitor (installed above patient bed). (Figure 12-4)

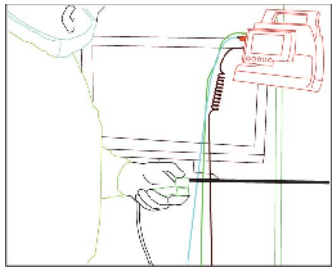


Figure 12-4 Connection to large LCD

Aria monitor can also be used as a detachable multi-module in Zagros and Alborz monitors when patient is transferred to different wards of hospital. (Figure 12-5)

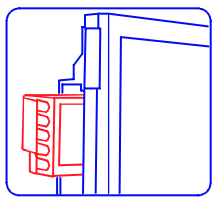


Figure 12-5 Detachable multi-module

The monitor can be placed in a special shoulder bag and easily carried by patient with regard to its portable and lightweight features. (Figure 12-6)

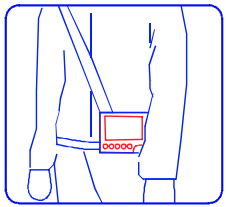


Figure 12-6 Aria special bag

13
Technical Specifications

CLASSIFICATION

Protection against electroshock

Class I, Type CF for all modules (except Multi-gas module & NIBP module that are BF) (based on IEC 60601-1)

Mode of operation

Continuous operation equipment

Harmful Liquid Proof Degree

IPX2

Method of sterilization and disinfection

Refer to each module's chapters and chapter 14 for detail.

Safety of anesthetic mixture

Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

DISPLAY

ARIA Display
COLOR TFT 480 × 272, 4.3”
Waveforms
ECG, SPO2, RESP, IBP
Numeric Parameters
HR, SPO2, NIBP (SYS, DIA, MAP) , RR, T1, T2 , IBP (SYS,DIA,MEAN)
Operation Method
Membrane and Touch screen

ECG

Leads Selectable 3 or 5 Wires
For 3 wire: I, II, III
For 5 wire :I,II,III,V,aVR,aVF,aVL
Dynamic Range
± 5 mV
Leakage Current
< 10 μA
Lead Off Current
< 90 μA
Gain 4, 2, 1, 1/2, 1/4, Auto

Calibration

1mV, 0.5 sec

Filters "MONITOR" (0.5 - 24 Hz)
"NORMAL" (0.5 - 40 Hz)
"EXTENDED" (0.05 - 100 Hz)

CMRR > 98 dB

Internal Noise

< 30 μV RTI

Input Impedance

> 5 Mohm

QRS Detection

Duration : 40 to 120 msec
Amplitude : 0.25 to 5 mV for Adult
0.2 to 5 mV for Neonate

Heart Rate Range

15 - 300 bpm for adult
15 - 350 bpm for neonate

Accuracy

±1% or 2 bpm

Tall T-Wave

Reject up to 1.2 mV Amp.

Pacer Detection/Rejection

Duration : 0.1 - 2 msec
Amp: ±2 to ± 700 mV (Without over/undershoot)
Reject From Heart Rate Counter
Re-insert into ECG to display on screen

Ineffective pace rejection: HR:0, Pace: 60
HR:60, Pace:60
HR:30, Pace:80

Beside rejection of atrial paces preceded ventricular paces by 150 or 250 ms

Protection

Defibrillator and Electrosurgical unit

Standards

ANSI/AAMI EC-13, IEC 60601-2-27

NIBP (CAS ND)

Measurement method

Oscillometric

Measurement mode

Manual/Automatic/Stat

Measurement time

20-25 sec (excluding cuff pressurization time)

Measurement Range

Adult:	SYS	25 ~ 250 mmHg
	DIA	10 ~ 220 mmHg
	MAP	15 ~ 250 mmHg
Neonate:	SYS	25 ~ 135 mmHg
	DIA	10 ~ 110 mmHg
	MAP	15 ~ 125 mmHg

Pressure Transducer accuracy

±3 mmHg full range

Initial Inflation Target

Adult 150 mmHg, Neonate 85 mmHg

Overall System Efficacy

ANSI/AAMI SP-10/2002

Memory

100 Records

SPO2 & Rainbow parameters

MASIMO Rainbow -MX Series

Method

2 WaveLength Pulse Wave Type

Range

SpO2	0 – 100 %
SpMet	0 – 99.9 %
SpCO	0 – 99 %
SpHb	0 – 25 g/dL
SpOC	0 – 35 ml/dL
PR	25 – 240 bpm
PI	0.02 – 20 %
PVI	0 – 100 %

Technical Specifications

Accuracy

Oxygen Saturation

During no motion conditions:

Adult: ±3% (SPO2 60 ~ 80%)

±2% (SPO2 70 ~ 100%)

Neonate: 3% (SPO2 70 ~ 100%)

During motion conditions:

±3% (SPO2 70 ~ 100%)

During low perfusion conditions:

±2% (SPO2 70 ~ 100%)

Pulse Rate

During no motion conditions:

±3bpm

During motion conditions:

±5bpm

During low perfusion conditions:

±3bpm

Carboxyhemoglobin Saturation

Adult: 1% - 40% ±3%

Methemoglobin Saturation

1% - 15% ±1%

Total Hemoglobin

Adult: 8 – 17 g/dL ±1g/dL

Resolution

SpO2 1 %

SpCO 1 %

SpMet 0.1 %
SpHb 0.1 g/dL
PR 1 bpm

TEMPERATURE

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

RESPIRATION

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

IBP

Channel		4
Measurement Range	SYS	-50 ~ 300 mmHg
	DIA	-50 ~ 300 mmHg
	MAP	-50 ~ 300 mmHg
Pressure Filter	8Hz,16Hz,22Hz selectable	
Press Sensor Sensitivity	5 μV / V / mmHg	
Press Sensor Impedance	300 ~ 2500 Ohm	
Resolution	1 mmHg	
Accuracy	2 % or 2mmHg each one is greater	

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, Resp, TEMP, IBP (SYS, DIA, MEAN), SpHb, PI, SpCo, SpMet, PVI, SpOc

Trend Time

5, 10, 15,20, 30, 45 Min, 1, 2, 4, 8, 12,16, 24, 36, 48, 72, 96 Hours

Resolution

1 sec

INPUT/OUTPUT

Network

Digital, Serial, RS422 , Full Duplex

Connection

8/12 BED to One CENTRAL system

GENERAL

Application

Compact and Mobile Monitor

Safety

Based on IEC 60601-1, Class I

Protection

Against Electrosurgery, Defibrillator and EMC

AC Power

90 - 240 VAC, 50/60 Hz

Maximum Rated Input 1A

Internal Battery

Nickel-Metal Hydride (Ni-MH), user replaceable rechargeable battery

Usage: Over 90 min with ECG, Resp, Temp, SPO2

DC Power Plug

12-14 V, Maximum 3 A

Dimension

150 (W) × 109 (H) × 67 (D)

Weight

< 800 g

ENVIRONMENTAL

Temperature

Operating: 5 to 40 °C

Storage: -20 to 60 °C

Humidity

20-90 % (Noncondensing)

Altitude

-200 to 3000 m

14
Accessories

General Information

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

 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.

Accessories

ECG

●ECG PATIENT CABLE 3 LEAD

PART.#:10-003

●ECG PATIENT CABLE 5 LEAD

PART.#:10-038

SPO2 (Masimo Rainbow)

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

PART.#:18-55

●SPO2 Extension Cable

PART.#:18-56

●Rainbow R25 Sensor, Adult, Adhesive, >30Kg, (SPO2, SPCo, SPMet)

PART.#:18-62

●Rainbow Resposable R2-25a Sensor, Disposable, Adult, >30Kg, (SPO2, SPHb, SPMet)

PART.#:18-63

●Rainbow Resposable R2-25r Sensor, Reusable, Adult, >30Kg, (SPO2, SPHb, SPMet)

PART.#:18-64

●Rainbow Resposable R2-20a Sensor, Disposable, Pediatric, 10-50KG, (SPO2, SPHb, SPMet)

PART.#:18-65

●Rainbow Resposable R2-20r Sensor, Reusable, Pediatric, 10-50KG, (SPO2,SPHb,SPMet)

PART.#:18-66

●Rainbow DC-3 SC 360, Reuseable, Adult, (SpO2,SpMet,SpHb)

PART.#:18-68

●Rainbow DCI, Reuseable, Adult, (SpO2,SpCO,SpMet)

PART.#:18-69

●M-LNCS DCI, Reuseable, Adult, (SpO2)

PART.#:18-70

●Rainbow R1-20L Pulse Co-Oximeter Sensor, Disposable, Pediatric, (SPHb ,SPO2,SPMet)

PART.#:18-72

Accessories

- NIBP Cuff – Adult thigh - 18×36cm – MINDRA

PART.#:13-026

- NIBP Cuff – Large Adult - 15×33 cm - MINDRAY

PART.#:13-027

- NIBP Cuff – Adult - 12×23cm – MINDRAY

PART.#:13-028

- NIBP Cuff – Child - 9×18cm – MINDRAY

PART.#:13-029

- NIBP Cuff – Infant - 6×12 cm – MINDRAY

PART.#:13-030

- CUFF HOSE - MINDRAY

PART.#:13-031

- NIBP Cuff – Infant - 6×18 cm – CAS - CR5206

PART.#:13-019

- NIBP Cuff - Small Child - 7×21cm – CAS - CR5207

PART.#:13-020

- NIBP Cuff - Child - 9×27 cm – CAS - CR5209

PART.#:13-021

Accessories

- NIBP Cuff - Small Adult - 12×30 cm – CAS - CR5212

  PART.#:13-022

- NIBP Cuff – Adult – 14 ×37.5cm – CAS -CR5214

  PART.#:13-023

- NIBP Cuff - Large Adult - 16×42 cm – CAS - CR5216

  PART.#:13-024

- CUFF HOSE – CAS

  PART.#:13-025

TEMP

- TEMP Probe – Skin – Adult - FMT400AS

  PART.#:10-045

- TEMP Probe – Esophageal / Rectal –Adult – FMT

  PART.#:10-046

IBP

- IBP Transducer, MEDEX - .MX860/866 Novatrans

  PART.#:16-00 1

Accessories

● IBP Disposable Dome – MEDEX - MX860/866 Novatrans Dome PART.#:16-031

● IBP Extension Cable – MEDEX - MX860/866 Novatrans Extension PART.#:16-032

● IBP Transducer – MEDEX - MX960 Logical PART.#:16-00 2

● IBP Disposable Dome – MEDEX - MX960 Logical Dome PART.#:16-033

● IBP Extension Cable – MEDEX - MX960 Logical Extension PART.#:16-034

● IBP Transducer - Capto SP844 PART.#:16-028

● IBP Disposable Dome - Capto SP844 Dome PART.#:16-029

● IBP CAPTO Cover Holder - Capto SP844 Cover Holder PART.#:16-035

● IBP CAPTO Holder - Capto SP844 Holder PART.#:16-030

15
Care and Cleaning (PM)

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.

System Check

The overall check of the monitor, including the safety check, should be performed only by qualified personnel.

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

 To ensure maximum battery life, it is recommended that, at least once a month, the monitor runs on battery until it turns itself off and then recharged.

 It is recommended that the system is calibrated by manufacturer every 2 years. The IBP module should be calibrated every 6 months.

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

Cleaning

Before cleaning the monitor or the sensors, make sure that the equipment is switched off and disconnected from the power line.

The Patient Monitor must be kept dust-free.
Regular cleaning of the monitor shell and the screen is strongly recommended. Use detergents such as soap and water to clean the monitor shell.

Please pay special attention to the following items:
1. Don't use strong solvents such as acetone or ammonia .
2. Most cleaning agents must be diluted before use.
3. Don't use rough material, such as steel wool etc.
4. Don't let the cleaning agent enter into the chassis of the system.
5. Don't leave the cleaning agents on any part of the equipment.

Cleaning

 The monitor and sensor surface can be cleaned with hospital-grade ethanol and dried with a clean cloth.

Please observe the following precautions when cleaning the accessories:

ECG Cable:
Use soft cloth moistened with mild soap liquid or cleaning agent containing 70% ethanol to clean the ECG cable.

SPO2 Probe:
To clean the probe, first remove it from the patient and disconnect it from the monitor. Use a soft cloth moistened with 70% isopropyl alcohol to clean the probe and then dry it with a clean cloth.

Cleaning

NIBP Cuff:

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

TEMP Probe:

Probe should be cleaned prior to disinfection or sterilization to improve the effectiveness (as recommended in ANSI/AAMI ST35: Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Device,1991)

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

Avoid contact with strong, aromatic, chlorinate, ketone, ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly

alkaline solutions will cause the vinyl to lose flexibility. The probe plugs should not be immersed.

 Never boil the temperature probe.

IBP Transducer:

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

Sterilization

To avoid extended damage to the equipment, sterilization should be performed according to the Hospital Maintenance Schedule.
Recommended sterilization material: Activated dialdehyde (Cidex)

■ Do not let liquid enter the monitor.
■ No part of the monitor can be subjected to immersion in liquid.
■ Do not pour liquid onto the monitor during sterilization.
■ Use a soft cloth to wipe up any agent remaining on the monitor.

Sterilization

Please observe the following precautions when sterilizing the accessories:

ECG Cable:

Use 70% alcohol or isopropanol 70% to sterilize the ECG cable.

SPO2 Probe:

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

NIBP Cuff:

Do not use steam or heat to sterilize the cuff. Gas sterilization may be used if necessary.

TEMP Probe:

Ethylene oxide is the preferred sterilization method. After sterilization, probes must be safely and thoroughly ventilated before handling or use. Use a generic EtO sterilizing procedure and an aeration time of minimum 12

hours is recommended to dissipate residual EtO on the probe.

IBP Transducer:

Disposable IBP transducer or domes should not be reused.

 To avoid environment pollution, the disposable transducers or domes must be recycled or disposed properly.

 Don’t autoclave or ETO sterilize the transducer.

Disinfection

Examples of disinfectants that can be used for the case of monitor are listed below:

- Hydrogen Peroxide 3%
- Alcohol 70%
- Isopropanol
- Enpropanol

To avoid damage to the equipment, disinfection should be performed according to the Hospital Maintenance Schedule.

Do not use EtO gas to disinfect the monitor.

Manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

Disinfection

Please observe the following precautions when disinfecting the accessories:

NIBP Cuff:

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

TEMP Probe:

Probes may be disinfected by washing with 70% isopropanol, activated dialdehyde (Cidex) or sodium hypochlorite (bleach diluted 1:10 minimum in water.) After washing, probes should be rinsed thoroughly with water. Brief immersion of the probe in detergent solutions is not harmful. Manufacturer does not make any claim as to the efficacy of these chemicals for infection control. Please consult your hospital's Infection Control Officer for the applicable disinfection policies.

 Slave monitor should be cleaned, sterilized and disinfected like the bedside monitor.

Regular Inspection

More information about cleaning, sterilization and disinfection of the accessories are provided in each module's chapter.

Weekly check of these cases is recommended:

1. System cleanness
2. Visual inspection of device (case, screen, keys and indicators) and accessories in terms of mechanical damage
3. Function of accessories
4. Disposable accessories and accessories with limited time of use

Monthly check of these cases is recommended:

1. Calibration label (Send the system to the manufacturer for calibration at the specified date).
2. Visual inspection of device and accessories in terms of mechanical damage
3. System cleanness
4. Function of keys, touch screen and indicators

16
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.

Troubleshooting

Problem	Possible Cause	Correct Action
Not to be turned		●Check power cable path. ●Call Customer service.
Unable to work with Battery	●Battery is fully discharged ●Fuse of Battery is faulty. ●Others	●Charge the battery for 10 hours. ●Check fuse existence. ●Call Customer service.
Noisy ECG waveform	●Loose connection of electrodes. ●Earth connection failure. ●Wrong ECG filter ●Others	●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 Customer service.

Troubleshooting

Problem	Possible Cause	Correct Action
NO ECG waveform	●ECG cable is not connected correctly. ●Wrong placement of leads and electrodes ●Others	●Connect ECG cable correctly. ●Check leads and electrodes. ● Short-circuit all the leads, if the cable is perfect , no error message will be displayed. ●Don't use old and faulty electrodes. ●Call Customer service.
Spike on ECG waveform	●If PACE is "ON" for patient without Pace marker, ECG noise will be received as PACE. ●Others	●Turn "Pace detection" OFF in ECG menu.

Troubleshooting

Problem	Possible Cause	Correct Action
Unstable HR	●ECG signal is noisy or isn't suitable ●Others	●Check leads and electrodes. ●Change lead to display the best ECG signal ●Call for service
- No "RESP" signal -No good waveform -Unstable RR	●Electrodes are not connected correctly ●Patient moves during measurement ●Others	●Check leads and electrodes. ●change RESP lead ●Calm the patient. ●Call for service
Strange T1,T2	●Location of sensor isn't suitable ●Faulty sensor ●Others	●Put the sensor in suitable place ●Change sensor ●Call for service
-No SPO_2 waveform -Noisy waveform	●SPO_2 probe in an unsuitable place. ●Faulty sensor ●Others	●Check the probe placement on patient. ● Change the probe and check the waveform. Contact the manufacturer to replace the probe with a new one, if necessary. ●Call for service

Troubleshooting

Problem	Possible Cause	Correct Action
-No SPO2 value -Strange SPO_2 value	●Patient movement during measurement ●Improper placement of probe. ●Others	●Calm the patient. ●Change the probe position. ●Call for service
NIBP cannot inflate	●Incorrect air hose connection. ●Air hose occluded or tangled. ●Air hose or cuff leakage ●Others	●Check connection ●Check Air hose ●Change faulty accessory ●Call for service
NIBP measurement is not successful	●No cuff or air hose is connected to the system. ●Incorrect cuff placement ●Patient movement during measurement ●Others	●Check cuff and air hose ●Change cuff position ●Calm the patient ●Call for service
Strange IBP value Noisy IBP signal	●No zeroing before use ●Noisy source nearby the system or accessories. ●Faulty sensor ●Others	●Perform zeroing ●Keep the system and cable away from noise source ●Change sensor ●Call for service

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.

NOTE:

Adjust the system measuring mode (Adult, Neonate) and choose a proper size of cuff with regard to patient weight and age for NIBP measurement.

Troubleshooting

Please observe the following instructions for pressure measurement:

1- Delete information of discharged patients and prepare the system for monitoring of new patient. You may turn off the system in the meantime and relax new patient in a comfortable position.
2- Deflate the cuff completely by hand.
3- The patient should sit quietly in a comfortable place with good back support to lean and the feet resting on the floor.
4- Relax patient in a comfortable position for 2-3 minutes before measurement.
5- Remain quiet during measurement.
6- Attach the cuff to patient arm and keep the arm in same level with the patient heart.
7- The cuff should be placed on upper arm.
8- Place the cuff tight enough so that you can only slip two fingertips under it.

9-Position of the cuff and artery on the forearm should be adjusted properly.

10-Remove any tight fitting clothing before taking measurement.

11-Apply proper size of cuff for the patient.

- Too small size of the cuff results in too high pressure values.
- Too large size of the cuff results in too low pressure values.

- **IBP**

The most important factors to check in IBP measurement are air bubbles in tubing system and the transducer dome. In the most cases by changing dome, problem is removed (as mentioned in this manual, disposable dome must not be reused and must be changed for each patient). It should also be checked that proper label with regard to place of measurement is selected. If the problem is not resolved, change the transducer and if even after all above actions

the problem still persists, contact the manufacturer's customer service.

- **Central**

▪ When there is any problem in function of the central system such as data display, touch screen, recorder, etc, turn off and then on the system. If problem is not resolved, contact customer service.

▪ If no connection is made with the central system, check secure connection of the cable between the central and bedside monitor. If problem is not resolved, contact customer service.

▪ Delete the information related to discharged patient in the monitor.

▪ Apply the recorder paper of 50 mm width for SC1201 central and 58 mm for the Sahand central.

APPENDIX I
LIST OF MONITOR PARAMETERS (SELECTIONS AND DEFAULTS)

Menu item	Selection	Default
The parameters in ECG menu		
ECG LEAD	I,II,III,aVR,aVF,aVL, V	II
ECG GAIN	×0.25,×0.5,×1,×2,×4, AUTO	AUTO
ECG SWEEP	12.5,25 and 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 AVERAGE	4,8,16SEC	8SEC
LEAD TYPE	3LEAD,5 LEAD	3LEAD
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	12.5mm/s
ALARM LEVEL	1,2	1
RR ALARM	ON ,OFF	OFF
RR HIGH ALARM	RR LOW ALARM +5 to 250	25Brpm
RR LOW ALARM	5 to RR HIGH ALARM -5	5Brpm
APNEA LIMIT	0 to 40S	10S
The parameters in SPO2 menu		
Avg. Time	2, 4, 8, 10, 12, 14, 16	8
SPO2 PLETH SWEEP	12.5,25mm/s	12.5mm/s

ALARM LEVEL	1,2	1
ALARM	ON,OFF	OFF
SPO2 HIGH ALARM	SPO2 LOW ALARM +1 to 99	99
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
SpMet HIGH ALARM	SpMet LOW ALARM +0.5 to 99.5	3
SpMet LOW ALARM	0.5 to SpMet HIGH ALARM -0.5	0.5
SpCO HIGH ALARM	SpCO LOW ALARM +1 to 99	10
SpCO LOW ALARM	1 to SpCO HIGH ALARM -1	1
SpHb HIGH ALARM	SpHb LOW ALARM +0.1 to 99.0	17
SpHb LOW ALARM	1.0 to SpHb HIGH ALARM -0.1	7
PI HIGH ALARM	PI LOW ALARM + 0.1 to 19.0	19

PI LOW ALARM	0.0 to PI HIGH ALARM -0.1	0
PVI HIGH ALARM	PVI LOW ALARM +1 to 99	99
PVI LOW ALARM	1 to PVI HIGH ALARM -1	1
SpOC HIGH ALARM	SpOC LOW ALARM +1 to 39	34
SpOC LOW ALARM	1 to SpOC HIGH ALARM -1	1
SPO2 SENSITVITY	NORMAL , MAX , APOD	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	SYS LOW ALARM +5 to 300	150 mmHg
SYS LOW ALARM	30 to SYS HIGH ALARM -5	80 mmHg
DIA HIGH ALARM	DIA LOW ALARM +5 to 300	120 mmHg

DIA LOW ALARM	30 to DIA HIGH ALARM -5	60 mmHg
MAP HIGH ALARM	MAP LOW ALARM +5 to 300	120 mmHg
MAP LOW ALARM	30 to MAP HIGH ALARM -5	80 mmHg
AUTO/Manual /STAT	MANUAL, STAT, AUTO, 1min, 2min, 3min,5min,10min, 15min,20min, 30min,45min, 1hr 2hr,4hr, 8hr, 12hr, 16hr, 20hr, 24hr	MANUAL
AUTO SLEEP	ON, OFF	ON
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 +1 to 50	39
TEMP LOW ALARM	0 to T1 HIGH ALARM -1	35

The parameters in IBP menu		
IBP UNIT	mmHg , KPa,cmH2O	mmHg
ALARM LEVEL	1,2	1
IBP ALARM	ON,OFF	OFF
IBP HIGH ALARM	IBP LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
IBP LOW ALARM	-50to IBP HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
ART HIGH ALARM	ART LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
ART LOW ALARM	-50to ART HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg

		MEAN: 60 mmHg
LVP HIGH ALARM	LVP LOW ALARM +5 to 300	150 mmHg SYS: DIA: 20 mmHg MEAN: 80 mmHg
LVP LOW ALARM	-50 to LVP HIGH ALARM -5	80 mmHg SYS: DIA: -5 mmHg MEAN: 20 mmHg
PAP HIGH ALARM	PAP LOW ALARM +1 to 120	SYS: 40 mmHg DIA: 20 mmHg MEAN: 30 mmHg
PAP LOW ALARM	-50 to PAP HIGH ALARM -1	SYS: 5 mmHg DIA: -5 mmHg MEAN: 0 mmHg
RVP HIGH	RVP LOW ALARM	40 mmHg

ALARM	+1 to 100	SYS: DIA: 15 mmHg MEAN: 30 mmHg
RVP LOW ALARM	-50 to RVP HIGH ALARM -1	SYS: 5mmHg DIA: -5 mmHg MEAN: 0 mmHg
CVP HIGH ALARM	CVP LOW ALARM +1 to 100	15 mmHg
CVP LOW ALARM	-50 to CVP HIGH ALARM -1	-5 mmHg
LAP HIGH ALARM	LAP LOW ALARM +1 to 100	20 mmHg
LAP LOW ALARM	-50 to LAP HIGH ALARM -1	-5 mmHg
RAP HIGH ALARM	RAP LOW ALARM +1 to 100	15 mmHg
RAP LOW ALARM	-50 to RAP HIGH ALARM -1	-5 mmHg
SYSTEM DEFAULT		
PAGE	P1, P2, P3, P4, P5, P6	P1
ALARM	1, 2, 3, 4, 5, 6, 7, 8	1

VOLUME		
CALENDAR	SOLAR, CHRISTIAN	CHRISTIAN
ADULT/ NEONATE	ADULT,NEONATE	ADULT
BED NUMBER	1….250	01

APPENDIX II
Technical Alarms

Message	Cause	Solution	Explanation
SYSTEM ERROR MESSAGES			
BATTERY LOW	insufficient battery charge	Place the monitor on the station and connect the power cable to the station.	When the battery is running out of power, level III alarm is activated. If user does not apply AC power to the monitor, level II and I alarms are displayed respectively as the charge level decreases.

Message	Cause	Solution	Explanation
ECG ERROR MESSAGES			
ECG NO CABLE	ECG cable is not connected to the system.	Connect ECG cable.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
ECG NOISE	Noisy or saturated ECG signal.	Inspect existence of a noise source around the cable and electrode. Noise source may be patient movement or improper lead placement.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
ECG CHECK LA,RA,LL	Mentioned lead is not properly connected.	Ensure that mentioned lead is connected properly.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
ECG SIGNAL WEAK	ECG amplitude is lower than standard limit.	Check chest leads placement.	
ECG DEFECT	ECG module failure	Turn off and on the monitor, if problem still exists contact Customer Service.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
CHECK RL OR ALL	RL or other leads are not properly connected to the patient.	Ensure that RL lead and ECG cable are connected properly.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
CHECK LL OR ALL	LL or other leads are not properly connected to the patient.	Ensure that all leads esp. LL and ECG cable are connected properly.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
CHECK LA OR ALL	LA or other leads are not properly connected to the patient.	Ensure that all leads esp. LA and ECG cable are connected properly.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
CHECK RA OR ALL	RA or other leads are not properly connected to the patient.	Ensure that all leads esp. RA and ECG cable are connected properly.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
RESP ERROR MESSAGES			
RESP CHECK LEADS	The RESP leads are not properly connected.	Ensure that all electrodes are connected properly.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
SPO2 NO PROBE	SPO2 probe is disconnected from the monitor.	Ensure that SPO2 probe is connected properly to the monitor.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
SPO2 ERROR MESSAGES			
SPO2 PROBE DEFECT	The SPO2 probe is damaged	Change SPO2 probe by a correct one.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
SPO2 PROBE OFF	SPO2 probe may be detached from the patient finger.	Ensure that the probe is connected properly to the patient.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
SPO2 CHECK PROBE	SPO2 probe is not properly positioned to the patient	Make sure that the probe is attached properly to the patient. (Refer to Fig. 6-1)	Alarm level 2 - The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and alarm is disabled for at least 120s.
SPO2 HIGH AMBIENT LIGHT	This may be caused by entering environmental light into the probe	Make sure that the probe is attached properly to the patient. (Refer to Fig. 6-1)	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and alarm is disabled for at least 120s.

Message	Cause	Solution	Explanation
SPO2 SEARCH	SPO2 is not calculable due to some reasons such as long time motions	Attach the sensor to another place, provoke blood recycle, and calm the patient.	Alarm level 2- The message is displayed in yellow background . By pressing Silence key, the message background will change to gray and the system will ignore this fault.
SPO2 SIGNAL WEAK	The SPO2 signal amplitude is too weak or undetectable .	Change the probe position.	
SPO2 DEFECT	SPO2 module failure	Turn off and then on the monitor, if problem still exists, contact Customer Service.	Alarm level 2- The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
NIBP ERROR MESSAGES			
SELF-TEST FAILED	NIBP hard ware module failure		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP LOOSE CUFF	Cuff is not completely wrapped, no cuff attached.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP MODE ERROR	Use adult cuff instead of neonate cuff or occlusion happened in air way		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
NIBP AIR LEAK	Air leak in cuff, hose or connector		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP AIR PRESSURE ERROR	Unstable pressure value (e.g. tangled hoses) because valve cannot open normally.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP SIGNAL WEAK	Very weak patient signal due to a loosely wrapped cuff or extremely weak pulse from patient.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
NIBP RANGE EXCEED	Measuring pressure is more than upper limit (255mmHg for adult or 135mmHg for neonates)		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP EXCESSIVE MOTION	Arm movement, noisy signal or irregular pulse (e.g. arrhythmia)		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP OVER PRESSURE SENSED	Measuring pressure exceeded safe software limit, 290 mmHg for adult and 145mmHg for neonate.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
NIBP SIGNAL SATURATED	Large motion artifact and extreme noise that saturate the amplifier's amplitude handling capability		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP PNEUMATIC LEAK	Air leakage during leak test		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP TIME OUT	Measuring time exceeds 120 seconds for adult or 90 seconds for neonates.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
SYSTEM FAILURE	Error occurs in pump, A/D sampling, pressure transducer or software.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP DEFECT	NIBP module failure		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP LOW BATTERY	The charge of battery is low so NIBP measurement is not possible.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
NIBP MODULE ERROR	Failure during measurement	Wait for 10 seconds, then measure.	Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP NO MODULE	No NIBP module is installed.		
NIBP STOP PRESSED	NIBP stop key has been pressed during measurement		
NIBP STOP	Measurement i stopped by NIBP module because of a special reason.		

Message	Cause	Solution	Explanation
NIBP LEAKAGE O.K	Successful leakage test		
IBP ERROR MESSAGES			
IBP NO SENSOR	Channel 1 or 2 transducer is not connected.	Check the transducer connection.	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background changes to gray and alarm is disabled.
IBP ADJUST SCALE	IBP signal is out of display range for about 5 sec.	Press <AUTO SCALE> in IBP WINDOW.	

Message	Cause	Solution	Explanation
IBP STATIC PRESSURE	This condition occurs when the maximum and minimum values of a pulsatile pressure signal (Just for IBP, ART, PAP, RVP and LVP labels) differ by less than 3mmHg.In this condition, only Mean pressure is displayed. This message can be	- Check patient and do necessary treatment. - open the stopcock to patient and close it to the atmospheric pressure. - Follow hospital procedure for dislodging catheter. - Take	Alarm level 3- The message is displayed in cyan background. By pressing Silence key, the message background changes to gray and alarm is disabled.

	caused by the following reasons: - A physiological condition e.g. asystole - Transducer stopcock is closed to the patient. - A catheter tip lodged against a vessel wall. - A clot on the catheter tip.	necessary medical actions to remove clot from the catheter.	

Message	Cause	Solution	Explanation
IBP SEARCH	IBP signal can't be processed by the software because the signal is weak or less pulsatile.	- Check that IBP measurement setup is suitable or not. - Check patient status and treat him ,if necessary.	

Physiological Alarms

Alarm	Situation	Visual Alarm	Audio Alarm
ECG 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 is "00" and blinks ●"ECG ASYSTOLE" is displayed. ●Alarm indicator flashes. ● Alarm message is displayed in a background color corresponding to its level.	Activated

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

Alarm	Situation	Visual Alarm	Audio Alarm
SPO2 Alarm			
%SPO2 HIGH	SPO2 violates adjusted high alarm limit.	●SPO2 value blinks. ●Alarm indicator flashes. ●Alarm 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. ●Alarm message is displayed in a background color corresponding to its level.	Activated
SPO2 ASYSTOLE	Pulse beat is not detected in last 10 seconds.	●HR is "0" and blinks. ●Alarm indicator flashes. ●The message "SPO2 ASYSTOLE" is displayed in red background.	Activated

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

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

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

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

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

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

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

Alarm	Situation	Visual Alarm	Audio Alarm
IBP DIA LOW	Diastolic pressure violates adjusted low limit.	● DIA value blinks. ●Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
IBP MEAN HIGH	Mean pressure violates adjusted high limit.	● MEAN value blinks. ●Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
IBP MEAN LOW	Mean pressure violates adjusted low limit.	● MEAN value blinks. ●Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated

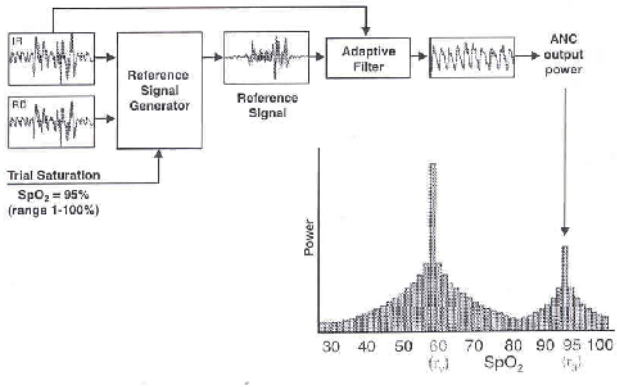
APPENDIX III
MASIMO MODULE

Signal Extraction Technology

INTRODUCTION

Masimo SET® pulse oximetry is a new and fundamentally distinct method of acquiring, processing and reporting arterial oxygen saturation and pulse rate. As illustrated below, Masimo SET technology enables the power of adaptive filters to be applied to real-time physiologic monitoring by utilizing proprietary techniques to accurately establish a “noise reference” in the detected physiologic signal, thus enabling the direct calculation of arterial oxygen saturation and pulse rate. Because it is not bound by a conventional “red over infrared” ratio approach, the Masimo SET system substantially eliminates the problems of motion artifact, low peripheral perfusion and most low signal-to-noise situations. This greatly extends the utility of SpO2 in high motion, low signal and noise intensive environments.

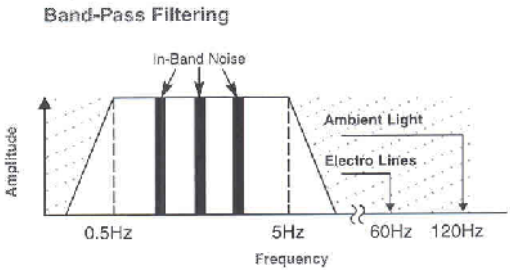
Discrete Saturation Transformation (DST®) Algorithm



Masimo SET's most powerful algorithm is DST. All algorithms depend upon assumptions. The more assumptions, the weaker the algorithm. DST makes only one assumption - that arterial blood has a higher oxygenation than venous – making it the most powerful pulse oximetry algorithm.

CONVENTIONAL FILTERS

While pulse oximetry is readily accepted as a standard of care in the Operating Room, Recovery Room and most Intensive Care Units, its performance in high motion environments or in patients with low perfusion is substantially less than ideal. The reported high incidence of false alarms due to motion artifact and the inability of conventional pulse oximetry systems to provide information during times of crisis have led to its characterization as a “fair weather friend.” Confronted with the problem of motion artifact, false alarms and poor "signal to noise" environments, medical equipment manufacturers have utilized band-pass filtering in an attempt to address these confounding clinical problems. Band-pass filters, whether in analog or digital form, are designed to allow only a physiologic window of interest to pass while rejecting frequencies outside the desired frequency band. With the advent of Digital Signal Processing (Digital Filtering), the performance of band-pass filtering was improved, but was still unable to address the problem of noise occurring within the bandwidth of interest.

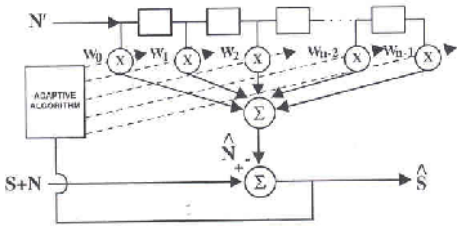


ADAPTIVE FILTERS

To address the confounding issue of "in-band" noise, a class of filters known as adaptive digital filters has evolved. These filters take advantage of the fact that the construction of the filter itself is contained within the memory of the microprocessor, allowing its multiplication coefficients, symbolized as W0, W1,...Wn-1, to be changed in real time, hence altering the filter's characteristic. Thus, the filter can be tuned “on the fly.” The multiplication coefficients determine whether the frequency components of an input signal should be cancelled (e.g., multiplied by zero) or allowed to pass (e.g., multiplied by one). Given that the filter's coefficients can be rapidly changed, adaptive filters derive their name

in their ability to change their filtering characteristics in response to changing in-band noise.

The detected physiologic signal is generally composed of both desired signal (S) and undesired signal (N) or noise portions. To remove the effects of the undesired signal, some knowledge of the noise characteristics, or equivalently its noise reference (N'), must be known. The adaptive filter will adjust its filtering characteristics, so that the noise reference input is transformed into an estimate of the undesired signal portion (N^) of the physiologic signal. A subtracter subsequently removes the undesired signal from the physiologic signal to yield an estimate of the desired signal portion (S^). The combination comprising the adaptive filter and the subtracter is commonly called an adaptive noise canceller (ANC).

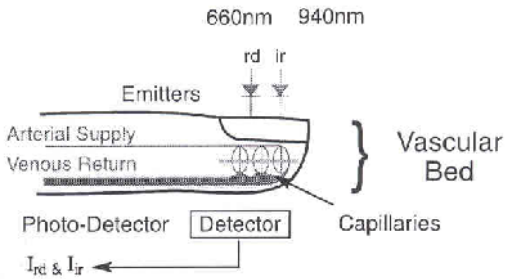


Adaptive Noise Canceller (ANC) block diagram

This approach has been widely used in the telecommunications and aerospace industries where a suitable noise reference is accessible. Probes are utilized to obtain a noise reference that can then be used in conjunction with an adaptive noise canceller to extract a desired signal portion from a composite signal containing both desired and undesired signal portions. The problem in applying this technique to physiological monitoring is that a noise reference is rarely available. In addition, both the noise and the desired signal vary from patient to patient and are quickly and continually changing in terms of frequency, amplitude and phase, even within the same patient. In pulse oximetry, the noise reference signal required to make an adaptive noise canceller work in real time was unavailable until the advent of Masimo Signal Extraction Technology.

CONVENTIONAL PULSE OXIMETRY

The conventional "red over infrared" approach measures the differential optical density of red (o) and infrared (Iir) light as projected through a vascular bed and calculates a ratio (r) of the optical densities. Utilizing the optical density ratio, an arterial oxygen saturation (SpO2) value is empirically reported based on the ratio obtained.



Basis For Measurement:

$$\frac{I_{rd}}{I_{ir}} = \frac{S_{rd} + N_{rd}}{S_{ir} + N_{ir}} = \text{Ratio (r)} \rightarrow \% \, SpO_2$$

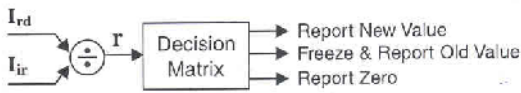
In the presence of patient motion, the optical densities of red and infrared light contain noise portions (Nrd, Nir), thereby falsely altering the optical density ratio and providing an inaccurate saturation value. During periods of routine patient motion or low perfusion, the noise components within the physiologic signals can be much larger than the desired signals (Srd, Sir). In these cases, the optical density ratio is primarily determined by the noise contributions. This represents a situation whereby the noise is simply “drowning out” the desired signal.

In a large noise environment, conventional wisdom holds that pulse oximetry will yield an optical density ratio substantially equivalent to "noise over noise" or a ratio of one. This is equivalent to a saturation value of approximately 82% in most conventional systems.

$$\text{If: } N >> S,$$

$$\text{Then: } \frac{I_{rd}}{I_{ir}} = \frac{N_{rd}}{N_{ir}} \cong 1 \rightarrow 82\%\ SpO_2$$

Confronted with the problems of overwhelming noise and prevented from utilizing adaptive digital filters, pulse oximetry manufacturers have resorted to “managing” false alarms. This can include extending averaging times or employing a decision matrix to freeze when it decides it has detected motion. If the motion persists, it reports zero.

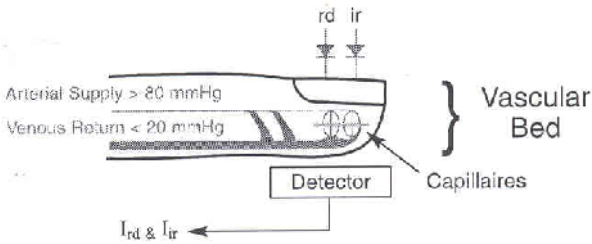


The attempt to treat the "symptom" rather than the “core problem” does not provide clinicians with continuous real-time information and can be unreliable in critical medical situations.

MASIMO SET® PULSE OXIMETRY

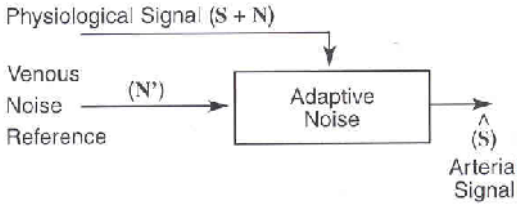
Masimo Signal Extraction Technology rejects the conventional wisdom and begins with an understanding that during patient motion the venous blood, being at a relatively low pressure, is quite susceptible to the local effects of perturbation during motion. Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion, representing a significant source of in-band noise within the frequency bandwidth of interest. In addition, the venous blood is a strong absorber of light. Hence, it can represent a significant contributor to the total optical density during motion episodes. Furthermore, the venous blood saturation is normally lower than the arterial blood saturation. This explains why saturation values tend to drop in conventional pulse oximeter systems during episodes of patient motion.

During routine patient motions (shivering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio based oximetry system. Having identified the venous blood as a significant contributor to noise during motion, it follows that if the noise reference corresponding to the venous component could be measured, then an adaptive noise canceller might be utilized to cancel its contribution.



GENERATING A NOISE REFERENCE

The detected physiologic signals in response to both red (Ird) and infrared (Iir) light consist of desired signal portions (Srd, Sir) as well as undesired signal portions (Nrd, Nir). It is commonly understood in pulse oximetry that the desired signal portions are proportional to one another through the arterial optical density ratio (ra). This suggests that one should simply subtract the product of the arterial optical density ratio and the physiologic signal due to infrared light from the physiologic signal due to red light. The resultant is a reference signal that contains only noise portions. This is the noise reference signal (N')



If the arterial optical density ratio is known, one can easily calculate the noise reference as just described. However, if it were known, one could simply calculate the arterial oxygen saturation directly. One would not need to utilize the adaptive noise cancellation process. How does one then use the power of adaptive filters and noise reference signals for pulse oximetry? The answer lies in the Discrete Saturation Transform® algorithm.

DISCRETE SATURATION TRANSFORM®

The Discrete Saturation Transform algorithm allows one to separate and, consequently, calculate the optical density ratios that correspond to both the arterial oxygen saturation (ra) and an estimate of the venous oxygen saturation (rv).

These optical densities are not known beforehand but are required to obtain the appropriate reference signals for

adaptive noise cancellation. Every optical density ratio, corresponding to the patient's physiological range (SpO2 = 1% to 100%) must be considered. Therefore, the DST® algorithm not only uses a noise reference signal, but a whole family of reference signals. Each reference signal is used in the adaptive noise cancellation process and each yields information regarding the oxygen saturation content of the physiological signals.

If:	Then:
① $I_{rd} = S_{rd} + N_{rd}$	$I_{rd} - [I_{ir} * r_a] = [S_{rd} + N_{rd}] - [S_{ir} r_a + N_{ir} r_a]$
② $I_{ir} = S_{ir} + N_{ir}$	Substituting $S_{ir} r_a$ for S_{rd}, we get:
③ $r_a = \frac{S_{rd}}{S_{ir}}$	$= [S_{ir} r_a + N_{rd}] - [S_{ir} r_a + N_{ir} r_a]$
$S_{rd} = r_a * S_{ir}$	$= N_{rd} - N_{ir} r_a$
	$= N'$ (Noise Reference)

A family of reference signals, N'(r), is generated similar to that of a noise reference signal. The reference signal, as discussed earlier, is the difference between the physiologic signal due to red light (Ird) and the product of an arbitrary optical density ratio (r) and the physiologic signal due to infrared light (Ird). Although there is a family of reference signals, based on the selected optical density ratio, there are only three distinct cases to consider. If one selects an optical density ratio that does not correspond to either arterial or venous oxygen saturation (Case I), the reference signal consists of a

desired signal portion and an undesired signal portion. In the adaptive noise cancellation process, such a signal will not only remove the undesired signal portions of the physiologic signal, but also remove the desired signal portions. When an optical density ratio that corresponds to the venous oxygen saturation is selected (Case II), the reference signal only contains signal portions. Therefore, the output of the adaptive noise canceller will consist of the undesired signal portions only. Similarly, when an optical density ratio that corresponds to the arterial oxygen saturation is selected (Case III), the reference signal only contains noise portions. Therefore, the output of the adaptive noise canceller will consist of the desired signal portions only.

$I_{rd} = S_{rd} + N_{rd}$, $I_{ir} = S_{ir} + N_{ir}$

$S_{rd} = r_a S_{ir}$, $N_{rd} = r_v N_{ir}$

r: optical density ratio
r_a: arterial optical density ratio
r_v: venous optical density ratio

Reference Signal: $N'(r) = I_{rd} - r I_{ir}$

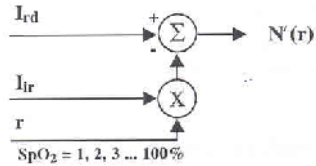
Case I: $r \neq r_a, r_v$ $N'(r) = (r_a - r) S_{ir} + (r_v - r) N_{ir}$

Case II: $r = r_v$ $N'(r_v) = (r_a - r_v) S_{ir}$

Case III: $r = r_a$ $N'(r_a) = (r_v - r_a) N_{ir}$

For each selected value of the optical density ratio, the corresponding reference signal is calculated and subsequently processed through an adaptive noise canceller.

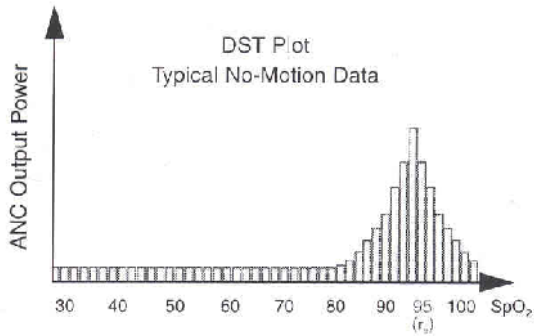
$I_{rd} - [\, I_{ir} \bullet r] = N'(r)$ Or :



When the selected value for the optical density ratio does not correspond to either the arterial or the venous oxygen saturation (Case I), the corresponding output signal will contain little power. When the selected value for the optical density corresponds to either the venous oxygen saturation (Case II) or the arterial oxygen saturation (Case III), the output signal will contain significant output power.

The power output of the adaptive noise canceller represents the probability that the selected optical density ratio, or its corresponding saturation value, is present in the physiologic signal. The output power or probability value is plotted for a series of consecutive ratio values generating the DST transform. During periods of no

motion, a singular peak is generated in the DST transform corresponding to the arterial oxygen saturation.



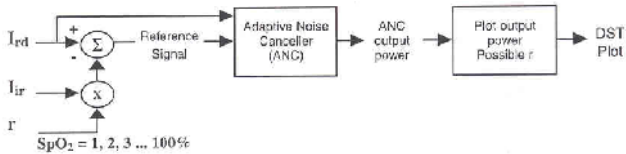
In summary, the procedure for determining the arterial oxygen saturation utilizing Masimo SET processing is as follows:

1) Sweep all optical density ratios that correspond to oxygen saturations of 1% to 100%.

2) Compute the reference signal for each optical density ratio.

3) Measure the output power of the adaptive noise canceller for each reference signal.

4) Identify the appropriate peak in the DST transform that corresponds to the arterial oxygen saturation (largest SpO2 value).



The procedure demonstrates another important feature of Masimo SET pulse oximetry. It is able to calculate the arterial oxygen saturation without first extracting or determining discrete pulses in the physiologic data. For Masimo SET processing, the saturation algorithm is independent of the pulse rate algorithm. This is a significant distinction between Masimo SET systems and conventional pulse oximetry systems where the recognition of a clean pulse is a prerequisite for the calculation of accurate arterial oxygen saturation. Another advantage of Masimo SET technology is that it can monitor arterial oxygen saturation and pulse rate even if the motion starts before the pulse oximeter is turned on. It does not require clean data during instrument start-up.

APPENDIX IV
EMC

 Use only the recommended manufacturer accessory .Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.

 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.

 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.

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The ***ARIA*** Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ***ARIA*** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **ARIA** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **ARIA** 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ***ARIA*** Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ***ARIA*** 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		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		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		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (>60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of the **ARIA** requires continued operation, it is recommended that the ***ARIA*** be powered from an uninterruptible power supply or a battery.

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The **ARIA** Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ***ARIA*** 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ***ARIA***, including cables, than the recommended separation distance 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*** is used exceeds the applicable RF compliance level above, the ***ARIA*** should be observed to verify normal operation. If abnormal performance is observed, additional measures may necessary, such as reorienting or relocating the ***ARIA.***

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

Recommended separation distances between Portable and mobile RF communications equipment and the *Vital Sign Monitor*

The ***ARIA*** 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*** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***ARIA*** 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.