URUK MEDICAL EQUIPMENT

OPERATOR'S MANUAL

LM1810Patient Monitor

CE 2195

D00009-V3

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Manual Purpose

This manual provides the instructions necessary to operate bedside monitor in accordance with its intended use. It also describes all parameters and options that your monitor may have depending on the way it has been customized.
Study of this manual is a prerequisite for proper operation and ensures patient and operator safety. If you have any question about the bedside, please contact our customer service. This manual is an essential part of and should always be kept close to the bedside monitor to be available whenever necessary.

Intended Audience

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

Version Information

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

Release date	Version number
Apr. 2023	D00009-V3

Chapter	Title
01	Introduction
02	System Configuration
03	ALARM
04	Patient Information
05	ECG
06	Arrhythmia
07	ST
08	RESP
09	SPO2 & Rainbow*
10	NIBP
11	TEMP
12	IBP*
13	GAS (Mainstream)*
14	GAS (Sidestream)*
15	BFA*
16	C.O*
17	SIGMA, TREND, ALARM RECALL, EVENT LOG
18	Recorder
19	Drug Calculation
20	Bed to Bed*
21	Patient Safety
22	Technical Specification
23	Accessories
24	Care & Cleaning (PM)
25	Troubleshooting
APPENDIX I	Default Settings
APPENDIX II	EMC

✓ **Note:**

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

Chapter 1, Introduction

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1.1 General Warnings

Warning

- The patient monitor is intended for clinical monitoring application with operation only granted to appropriate medical staff.
- Before use, carefully read this manual, directions for use of any accessories, all precautions, and all specifications.
- 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.
- 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.
- To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective earth.
- Do not use the patient monitor during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of monitor measurements.
- The patient monitor is not designed to be used in homecare, helicopters and oxygen-enriched atmosphere.
- The patient monitor is not intended for therapy or treatment.
- Do not place the monitor in any position that might cause it to fall on the patient.
- There could be hazard of electrical shock by opening the monitor casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by manufacturer.
- Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or oxygen.
- The operator must check that system and accessories function safely and see that it is in proper working condition before being used (e.g. Calibration date of the system must be valid).
- Alarm must be set according to different situations of individual patient. Make sure that audio sounds can be activated when an alarm occurs.

- 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.
- Do not touch the patient, table nearby, or the equipment during defibrillation.
- The equipment and devices connected to it should form an equipotential body to ensure effective grounding.
- The physician shall consider all well-known side-effects when using the patient monitor.
- There will be some risks of polluting the environment associated with the disposal of the device and cables at the end of their useful lives. The device and accessories shall be disposed in accordance with national laws after their useful lives. Contact your municipality to check where you can safely dispose of old batteries.
- Do not expose the system near any local heating item such as the direct radiation.
- Do not use one monitor for two or more patients at the same time.
- It is possible to increase leakage current when several systems are connected to the patient simultaneously.
- Monitor software is designed in a way that hazards arising from errors in the software programmed are minimized.
- Do not connect items not specified as parts of the monitor.
- The installation and use of the monitor must comply with the EMC conditions mentioned in the relevant chapter.
- 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.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- If any liquid is spilled on the system or accessories, immediately turn off the system and wipe up it by a soft cloth.
- Make sure that cables and accessories are not under tension during monitoring.
- When using a defibrillator, parameters and signals will be temporarily interrupted until electroshock is finished.

1.2 General Information

The monitoring system continuously collects patient vital signs data to monitor, display, review, store, record and raise the alarm about physiological/technical parameters. The patient monitor can connect to the Central system and slave monitor through LAN network (wired/wireless). The monitor is compact, lightweight and has built-in battery and handle facilitate transportation.

The monitor is used for effective and safe patient care and is adaptable to adult, pediatric and neonatal patients in healthcare centers.

The patient monitor can be installed in all sections of the healthcare center that comply with applicable local requirements, for example Emergency room, ICU, CCU, NICU, General operating room and open-heart surgery room, recovery and etc.

1.3 Main functions

The patient monitor can monitor the following parameters (The number of channels related to each parameter can be different according to the device model):

ECG	Heart Rate (HR), ST segment, PVCs/min, Arrhythmias, ECG waveforms
RESP	Respiratory Rate (RR), Respiration Waveform
SpO2 & Rainbow*	Saturation pulse oximetry (SpO2), Pulse Rate (PR), SpO2 Plethysmogram * If MASIMO Rainbow module is used and if its software is enabled by the manufacturer and its specific probe is available, the following parameters will be measurable: • Arterial pulse signal strength (PI) • Total amount of hemoglobin in the blood (SpHb) • Oxygen content in the blood (SpOC) • Carboxyhemoglobin saturation percent in the blood (SpCO) • Methemoglobin saturation percent in the blood (SpMet) • Index for PI changes that occur during the respiratory cycle (PVI)
NIBP	Systolic pressure (SYS), Diastolic pressure (DIA), Mean arterial pressure (MAP)
TEMP	Channel-1 temperature (T1), Channel-2 temperature (T2)
IBP*	4-channel IBP (IBP1, IBP2, IBP3, IBP4)
CO2*	EtCo2, FiCo2, AWRR

Multi-gas*	EtN2O, FiN2O, EtO2, FiO2, EtAA, FiAA, AA including 5 anesthesia agents (DES, ISO, SEV, HAL and ENF)
BFA*	BFI %, BS%, SQI%, EMG%
CO*	Cardiac output
IR TEMP*	Temperature (T2) via Ario module
Ext SpO2*	Saturation pulse oximetry (SpO2) via external SoO2 module
Other*	OXY-CRG, Alarm Recall, EVENT LOG, Bed to Bed and etc.

The parameters marked with an asterisk (*) are optional.

1.4 Installation

The monitor can be installed on:

- ✓ the wall mounting
- ✓ the trolley
- ✓ the desk

1.5 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.
■ In case of any problem, contact local dealer.

- **Place the battery fuse**

When you use the system for the first time, you should place the fuse on the rear panel.

- **Connect the Power Cable**

■ Make sure the AC power supply complies with following specification: 100-240 VAC, 50 /60Hz
■ Plug the power cable to power supply socket of the monitor. Connect the other end of the power cable to a grounded power receptacle.

- **Power on the Monitor**

Press POWER key to power on the monitor. At the same time a beep sound will be heard and yellow and red indicators light simultaneously. After 30 seconds or more that the system self-tests are performed, the main screen will be displayed and you can start monitoring.

NOTE

Perform the following settings before monitoring:

- New patient information (For details, please refer to chapter PATIENT INFORMATION)
- Patient mode (Adult/Neonate/ Pediatric) before NIBP measurement
- Alarm sound
- Alarm limits
- Zeroing before IBP measurement (For more information, see chapter IBP)
- Pulse oximetry (For more information, see chapter SpO2)
- RESP (For more information, see chapter RESP)

- **Connect Patient Sensors**

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

NOTE

- Check all the functions of modules that may be used and make sure that the monitor is in good connection.
- Make sure that the battery indicator lights. If it does not light, check your local power supply and power cable connection. If the problem still exists, contact the local After Sale Service.
- For any information about correct connection of accessories, refer to each module's chapter.

Warning

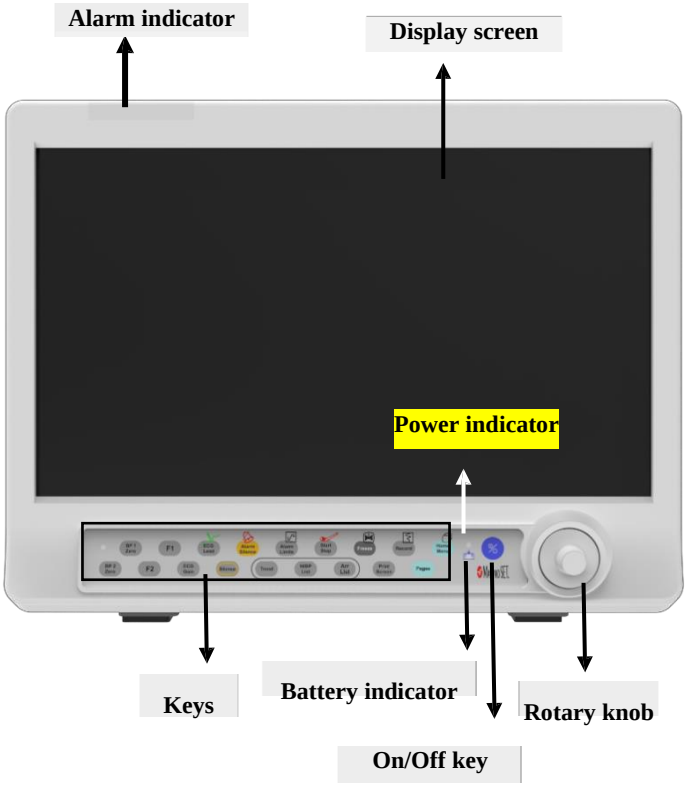
If any sign of damage is detected, or the monitor displays any error messages, do not use it on any patient.

1.6 Environmental Requirements

The operating environment of the monitor must meet the specified requirements in this manual. The environment should be free from noise, vibration, dust, corrosive, flammable and explosive substances. Furthermore, to maintain ventilation, the monitor should be placed at least 5 cm away from around the cabinet.

1.7 Keys and Indicators

The monitor can be operated via the front panel keys, rotary knob and touch screen*.



Alarm indicator	If a physiological or technical alarm occurs, the alarm indicator will flash based on alarm level as follows: The alarm indicator flashes red in level 1, and flashes yellow in level 2. The indicator lights steady yellow in level 3.
Rotary knob	This knob can be used to select and change the settings. Operations can be performed by turning it clockwise, counter clockwise or pressing it down.
On/Off Key	Press this key to turn on the device and turn on the green indicator. When the monitor is on, press and hold the power key to turn off the monitor.
Battery indicator	When the device is connected to AC power, the battery indicator shows the battery charging status. It is green when the battery is fully charged (at least 90%) and it is orange when the battery is being charged.
Display screen	Physiological parameters and waveforms are displayed on the screen. You can also use touch screen (optional) to operate the system.
Key function	All settings can be done via front panel's keys and rotary knob.

- **Front Panel Keys**

	LM1810

NOTE

- Some keys may not be used on your device.

- **The keys' function is as follows:**

Home Menu	Press to open HOME WINDOW (Please refer to Configuration Chapter for details).
Pages	Press to access different pages of the system.
Record	Press to start recording of ECG signal and all numeric parameters by the central system or recorder connected to the monitor. Press it again to stop recording.
Print Screen	Press to capture a picture of the screen and save it (This button currently is not applicable).
Freeze	Press to freeze all signals on the screen. Press the key again to restore the signal sweeping.
Start/Stop	Press to start blood pressure measurement. Press it again to stop the measurement.
Alarm Limits	Press to call up HOME/ALARM Window and change the alarm settings of each parameter.
Alarm Silence	Press it to disable alarm for 120 s. If you press it again, the system will exit from silence mode and alarm sound will be enabled.
Silence	This button currently is not applicable
ECG Lead	Press to call up ECG/LEAD Window and change lead setting.
ECG Gain	Press to call up ECG/GAIN Window and change gain setting.
BP1,2 Zero	Zeroing procedure of IBP 1 & 2
F1, F2	Zeroing procedure of IBP 3 & 4 (F1 key for IBP3 and F2 key for IBP4)
Trend	Press to call up HOME/TREND Window.
NIBP List	Press to call up NIBP/NIBP LIST Window.
Arr List	Press to call up ARR LIST Window.
BP AUTO SCALE	Automatic adjustment of BP signal amplitude.
SIGMA	Displaying ECG in SIGMA window
SETUP	Opening the SETUP window

NOTE

- For more information about the alarms of different parameters, refer to Appendix 2.

- If a new alarm occurs in the alarm silence mode, the device will exit the silence mode.

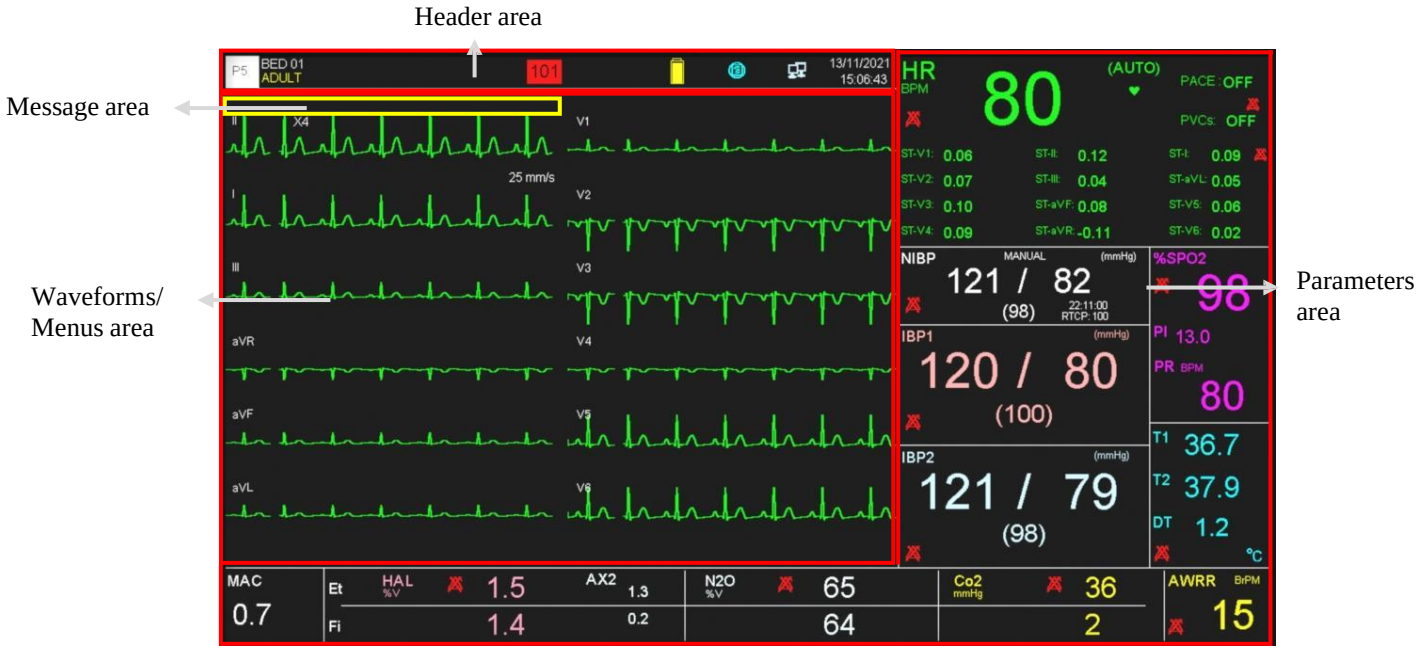
Warning

- Before using the system on the patient, user must check the keys' function and make sure that they are in proper working condition as described above.
- Always verify the audible and visible alarms when the monitor is powered on
- To verify proper function of indicators, they light when the system is powered on (Please refer to Alarm chapter for details).

1.8 Display screen

Patient monitor has a color LED display. The patient Parameters, waveforms, alarm messages, bed number, date, system status and error messages are displayed on the screen.

The screen is divided into four areas: Header Area; Waveform Area/ Menu Area; Parameter Area and Message Area



Main page in LM1810

Header area

The Header Area is at top of the screen displaying operating state of the monitor and status of the patient.

The parameters in Header Area are page number, bed number, type of patient (adult, pediatric or neonate), patient name, current date and time.

The above information appears on the screen throughout the monitoring process.

Other information of the Header Area comes up only with respective monitoring status. They are:

Appears when the system is connected to Central system.

Appears when the system is recording.

Illustrates the remaining battery charge.

Blinks along with a countdown timer (120 sec.) when the alarm silence button is pressed.

Waveforms/Menus area

All waveforms can be displayed at the same time. The waveforms from top to bottom are: ECG, SpO2, IBP1, IBP2, EEG and RESP/CO2/Multi-gas.

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

All menus in monitor always appear at fixed areas on the screen. When a menu is displayed, some waveforms become invisible. The menu with regard to its size will cover 2, 3, 4 or 5 waveforms.

Parameters area

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

Messages area

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

Level I alarm message: red background – Black text.

Level II alarm message: yellow background – Black text.

Level III alarm message: cyan background – Black text

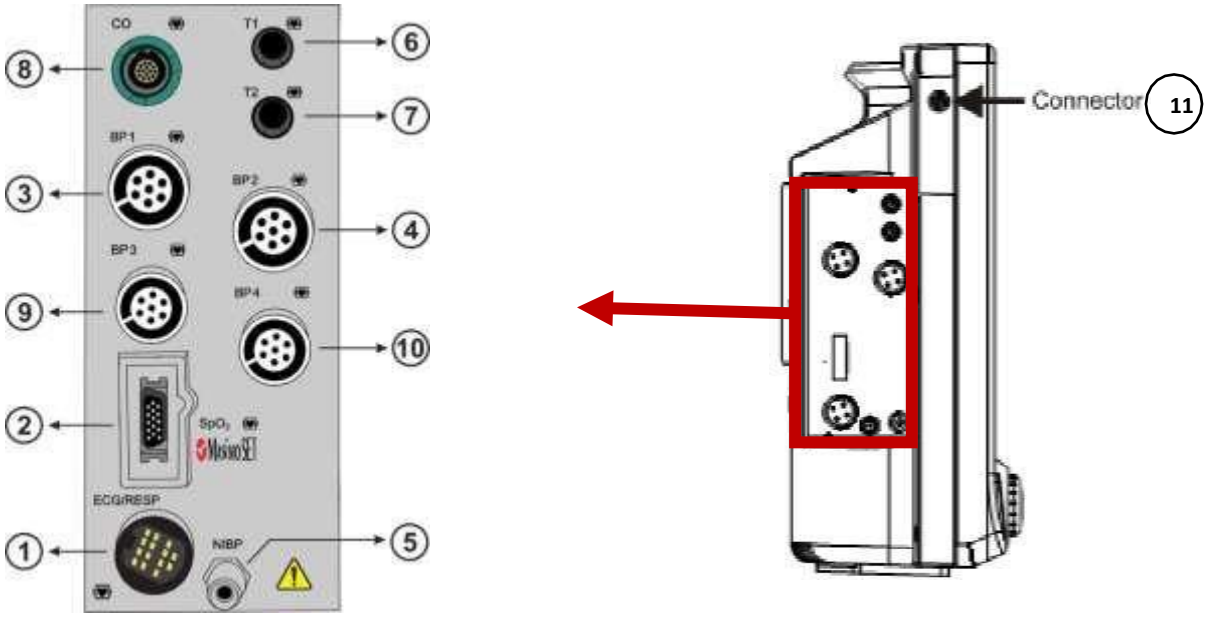
If no alarm is triggered, the message will be displayed with gray background.

NOTE

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

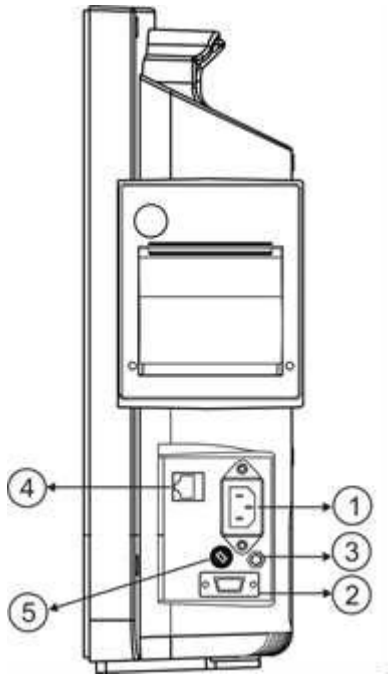
1.9 Connectors of LM1810 monitor

- **Left view**



①	Connector for ECG cable
②	Connector for Spo2 Sensor
③	Connector for IBP1 transducer
④	Connector for IBP2 transducer
⑤	Connector for NIBP cuff
⑥	Connector for TEMP1 probe
⑦	Connector for TEMP2 probe
⑧	Connector for CO catheter
⑨	Connector for IBP3 transducer
⑩	Connector for IBP4 transducer
⑪	Connector for CO2/ GAS and BFA sensors

- **Right view**



①	Power Supply: 100-240 VAC, 50/60 Hz
②	Monitor interface for external standard VGA color monitor (VGA SLAVE MONITOR)
③	Jack, Equipotential grounding terminal for connection to the hospital's grounding system.
④	Central Network Interface: Data transmission between the central system and the bedside monitor
⑤	250 V/3A Fuse

Warning

- The patient monitor must be only connected to the manufacturer's Central system.
- Use only the recommended central cable.
- If the network cable plug is broken, please contact after sale service to replace it.
- If you are going to store the patient monitor or you don't want to use it for a long time (more than 10 days), remove the fuse from the system to prevent battery discharging.

1.12 Built-in Battery

The patient monitor is equipped with a rechargeable battery. The battery will be automatically recharged when the monitor connects to the AC INPUT. For more information about charge and discharge time of a fully-charged battery during normal usage, refer to chapter Technical Specifications.

NOTE

- Normal usage of the device includes the below conditions:

Brightness is automatically set by system, ECG, RESP, SpO2 and TEMP measurements in Use, NIBP measurement every 15 minutes.

- When the AC INPUT is plugged in, turning the system on or off does not have any effect on charging process of the battery.
- Power saving and run-time of the battery decrease over time.
- The factors like high environment temperature, the battery age, full discharging, high number of charge cycles and long- term storage (for months) will reduce “the battery power saving”.
- The fuse on the side panel protects the battery during charging or when the system is not connected to AC INPUT. When the fuse is damaged, the system cannot run on the battery power and the battery indicator flashes.

Warning

- If operating time with the battery is less than the specified time, the battery needs to be replaced. Please Contact local After Sale Service for battery replacement.
- Use only the recommended batteries by the manufacturer.
- Connect the monitor to the mains supply and check the battery indicator to ensure that the battery functions correctly.
- If the battery malfunctions and the monitor stays off for a long time, date and time may be reset.

- When the battery is running out of power, “Low Battery” alarm (audible and visual) with level III is activated. If user does not apply AC power to the monitor, level II and I alarms will be displayed respectively as the charge level decreases. Also, the corresponding messages will be shown in the message area.

The fuse in side panel, protects the battery during charging or when the system is not connected to AC INPUT.
When the fuse is damaged, the system cannot run on the battery power and the battery symbol blinks on the screen.

1.13 Communication with Central Monitoring System

The CMS (central monitoring system) is intended to conduct centralized monitoring of vital signs information from multiple monitors in hospitals or medical institutions. It is not intended for home use.

The CMS is powerful software with high performance that constructs a monitoring network by connecting bedsides. By storing, processing, analyzing and displaying the bedsides information, the CMS is capable of providing a centralized monitoring for all patients that greatly promotes the efficiency and quality of the monitoring.

■ Waveforms, parameters and alarms of the CMS are only a reference for physicians and cannot be used directly for clinical treatment.

Chapter 2, System Configuration

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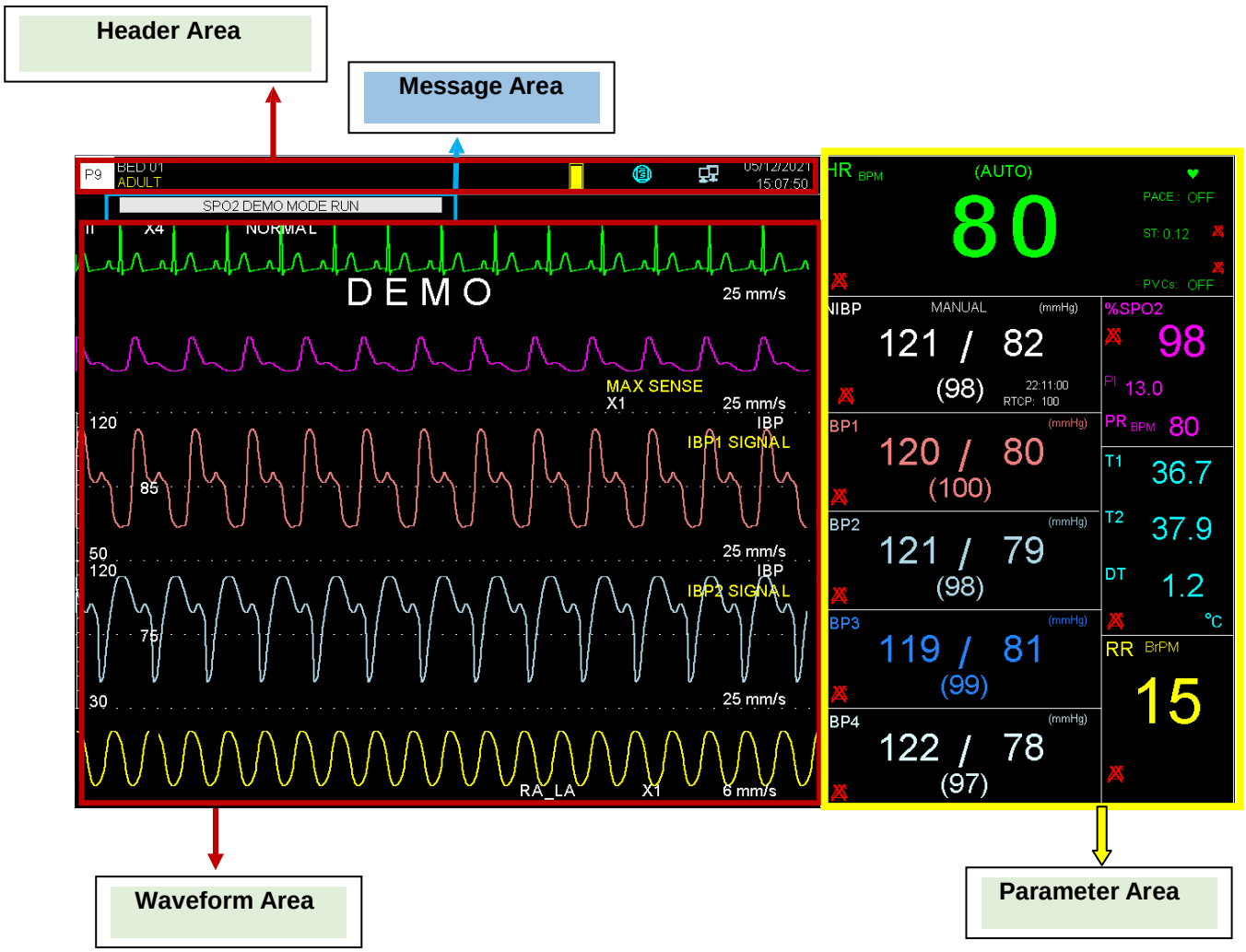
2.1 Display Screen

The patient monitor has a color LED display. The patient Parameters, waveforms, alarm messages, bed number, date, system status and error messages are displayed on the screen.
The screen is divided into four areas:

- ✓ Header Area
- ✓ Waveform Area/ Menu Area
- ✓ Parameter Area
- ✓ Message Area



NOTE

1- When using the monitor, the screen should be protected from direct sunlight in order to get a clear view of what is displayed.
2- To make the monitor readable outdoor, transfer it to shade or a dark environment.
3- If the monitor is used outdoor, place it in a location that is not exposed to direct sunlight.

Header Area:

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

	appears when the system is connected to central system.
	appears when the system is recording.
	indicates the remaining battery charge. This symbol appears only when the system is not plugged in.
	blinks along with a countdown timer (120 sec) when the alarm silence button is pressed.

Waveform / Menu Area :

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

Parameter Area:

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

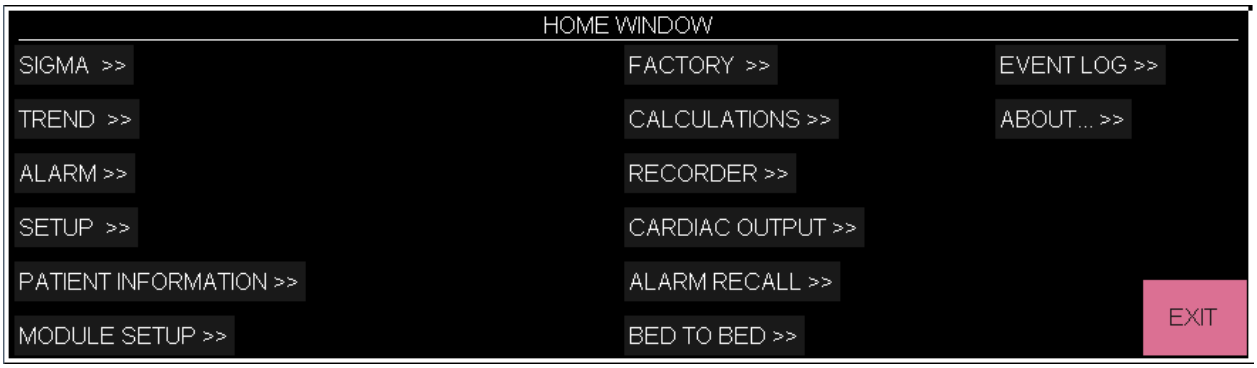
Message Area:

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

Level I alarm message	Red background – Black text
Level II alarm message	Yellow background – Black text
Level III alarm message	Cyan background – Black text
If no alarm is triggered, the message will be displayed with gray background.	

2.2 HOME WINDOW

Patient care monitor has a flexible configuration. Press HOME/MENU key on the front panel or the rotary switch in Header area to enter HOME WINDOW and set configuration. The information about Setup, Module Setup and About menus is provided in this section. For more information about other items, please refer to respective chapter.

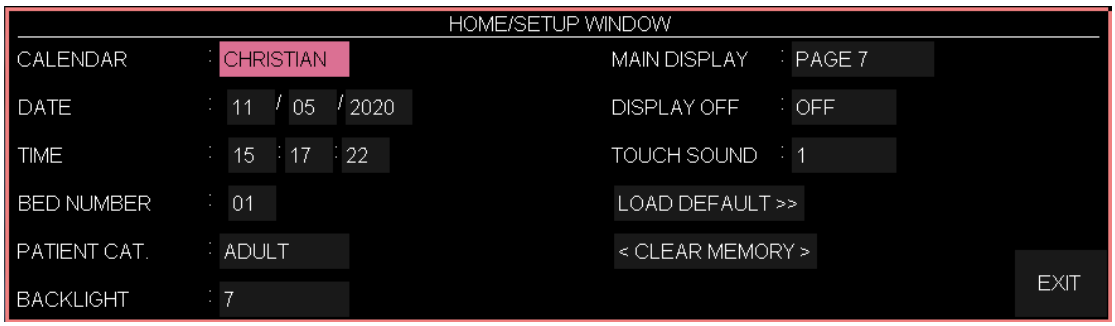


NOTE

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

SETUP

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



CALENDAR	Available options are "SOLAR" and "CHRISTIAN".
DATE	Current date of monitoring.
TIME	Current time of monitoring.
BED NUMBER	Patient bed number (1-150).
PATIENT CAT.	Available options are "ADULT", "NEONATE " and "PEDIATRIC'
BACKLIGHT	Ranges from 1 to 8 for 18" monitor, ranges from 1 to 6 for 10" and 12" monitors
MAIN DISPLAY	Available options for **IBP: OFF** are “PAGE1” to “PAGE 6” and for **IBP: ON** are “PAGE 1” to “PAGE 9” and "PUMP PAGE"
DISPLAY OFF	The display screen turns off until a button is pressed or an alarm occurs. If Alarm Silence is activated, the display will not turn off.
TOUCH SOUND	Available options are 1 to 3 and OFF.
LOAD DEFAULT	If you choose any option in this window, the system will load the factory settings of related parameter. (Refer to appendix I for factory settings of the parameters).
CLEAR MEMORY	To delete the stored parameters in the system.

NOTE

- **The same pages and information are displayed on the second display.**
- **If you choose LOAD DEFAULT, all your previous settings will be changed and the system will ask if you are sure to change settings by this message:**

ARE YOU SURE TO LOAD ECG DEFAULT?
NO YES

- **If you choose CLEAR MEMORY, all saved data will be deleted and a message will appear on the screen for each of above items that asks you whether to clear that item or not:**

ARE YOU SURE TO CLEAR TREND?
YES NO"

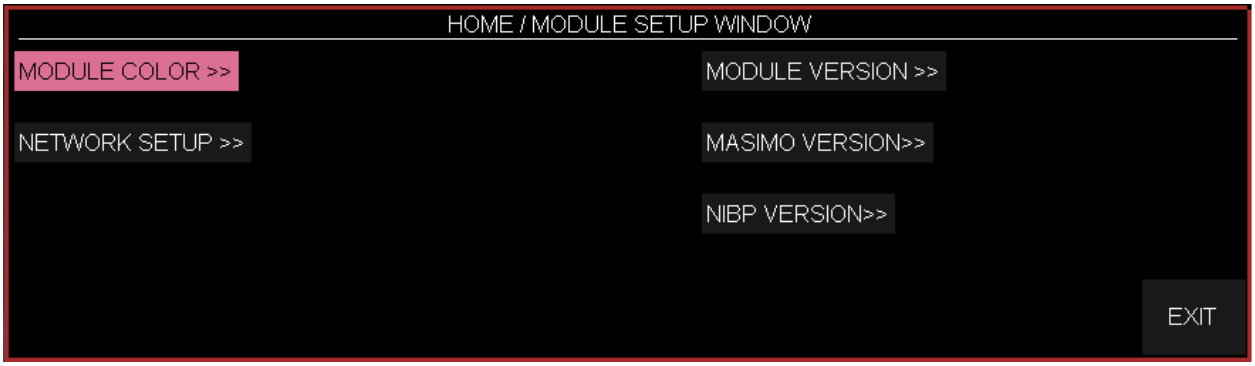
ARE YOU SURE TO CLEAR NIBP LIST?
YES NO"

ARE YOU SURE TO CLEAR ARR LIST?
YES NO"

ARE YOU SURE TO CLEAR ALARM RECALL LIST?
YES NO"

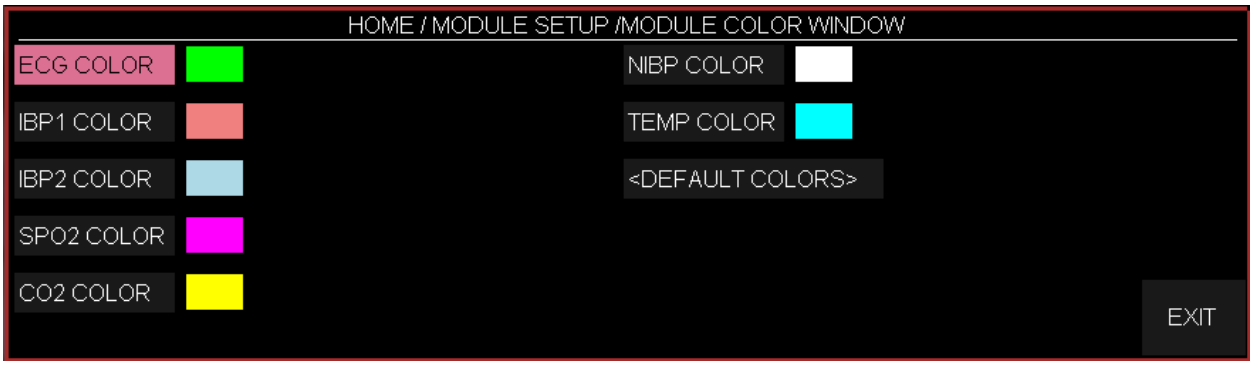
MODULE SETUP

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



MODULE COLOR

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



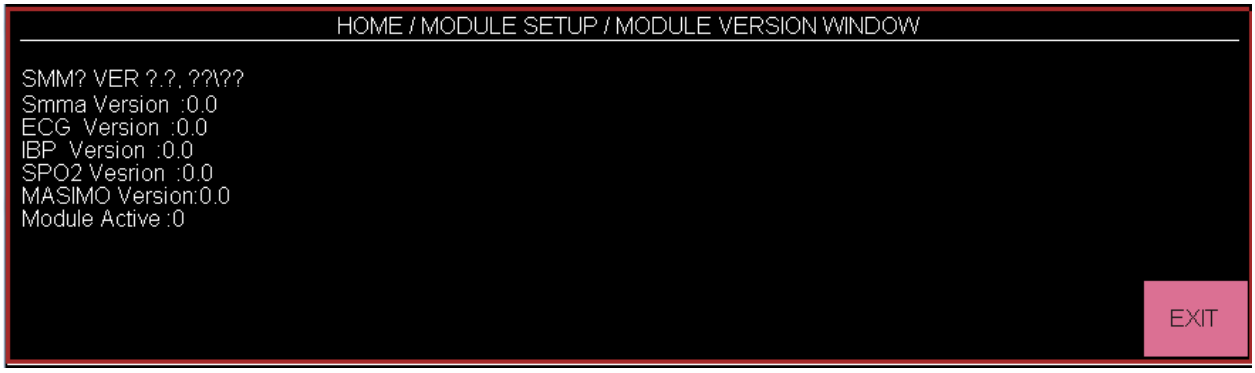
For each change in parameters color, the following message will appear on the screen that asks you whether to change color or not.

ARE YOU SURE TO CHANGE COLOR?

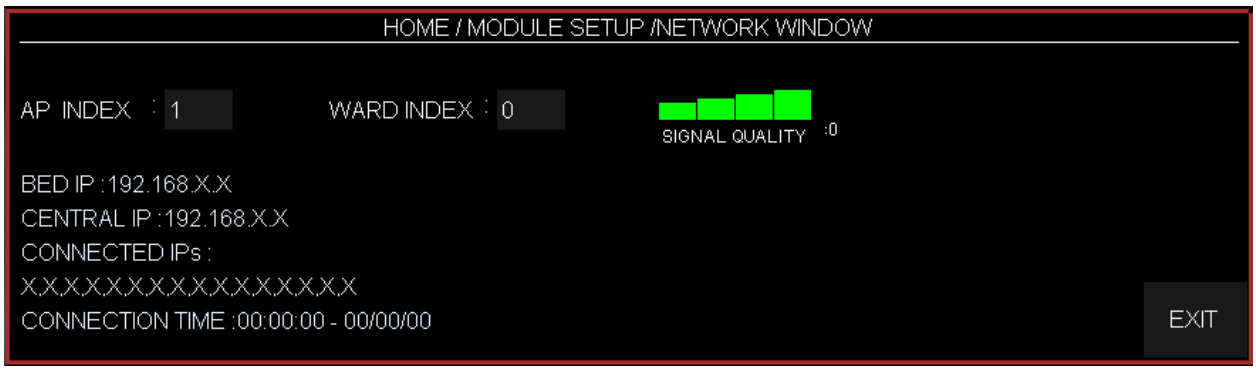
YES **NO**

MODULE VERSION

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



Choose “NETWORK SETUP” from MODULE SETUP window to call up the following window in which you can perform the Central system settings and see bedside and Central IP addresses, time of network connection and etc.
SIGNAL QUALITY: The signal strength during WiFi connection of the bedside to the Central system.



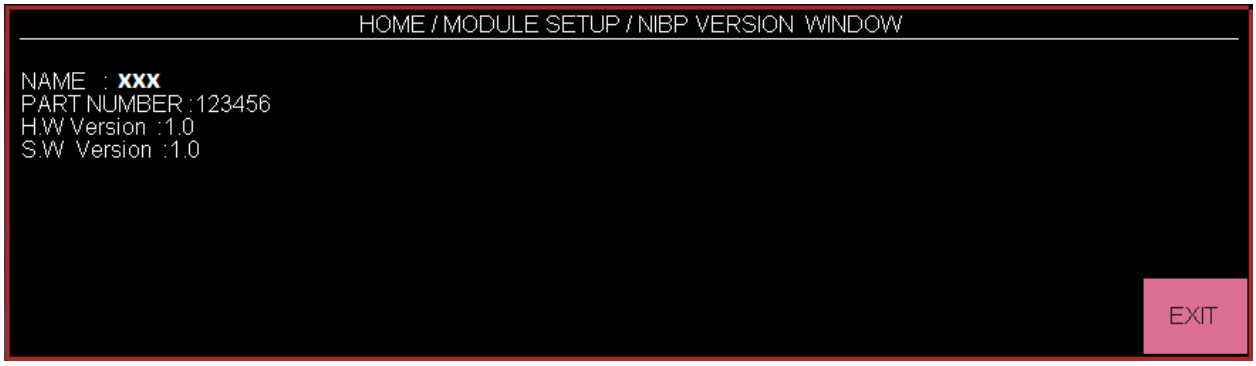
MASIMO VERSION

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

Choose PROGRAMMING MODE >> from HOME/MODULE SETUP/MASIMO VERSION WINDOW to enter the respective menu with a delay of 5 seconds. If programming procedure is not carried out, the system will exit from this mode and return to normal working.
This item is only available to trained and authorized personnel.

NIBP VERSION

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



ABOUT

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

2.3 Page Configuration

Page Configuration														
PAGES	ECG		SPO2			NIBP	TEMP	RESP	IBP				GAS	BFA
	ECG Signals	Multi ST	SPO2, PI, PR	Rainbow	DUAL SPO2				IBP1	IBP2	IBP3	IBP4		
P1	Trace 1	×	✓	×	×	✓	✓	✓	✓	✓	×	×	✓	✓
P2	Trace 1,2	✓	✓	×	×	✓	✓	✓	✓	✓	×	×	✓	✓
P3	Trace 1..4	✓	✓	×	×	✓	✓	✓	✓	✓	×	×	✓	✓
P4	Trace 1..7	✓	✓	×	×	✓	✓	✓	✓	✓	×	×	✓	✓
P5	Trace 1..12	✓	✓	×	×	✓	✓	✓	✓	✓	×	×	✓	✓
P6	Trace 1,2	×	✓	✓	×	✓	✓	✓	✓	✓	×	×	✓	✓
P7	Trace 1	×	✓	×	×	✓	✓	×	✓	✓	×	×	×	✓
P8	Trace 1,2	×	✓	×	✓	✓	✓	✓	✓	×	×	×	✓	✓
P9	Trace 1	×	✓	×	×	✓	✓	✓	✓	✓	✓	✓	✓	✓
P10 (PUMP PAGE)	Trace 1	×	✓	×	×	✓	✓	✓	✓	✓	×	×	✓	✓

- If IBP module is disabled:

1. The pages 7 to 10 will be removed.
2. The space of IBP parameters is devoted to other parameters in the pages 1 to 6.
3. DualSPO2 parameters are displayed in the page 6.

NOTE

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

PUMP PAGE

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

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

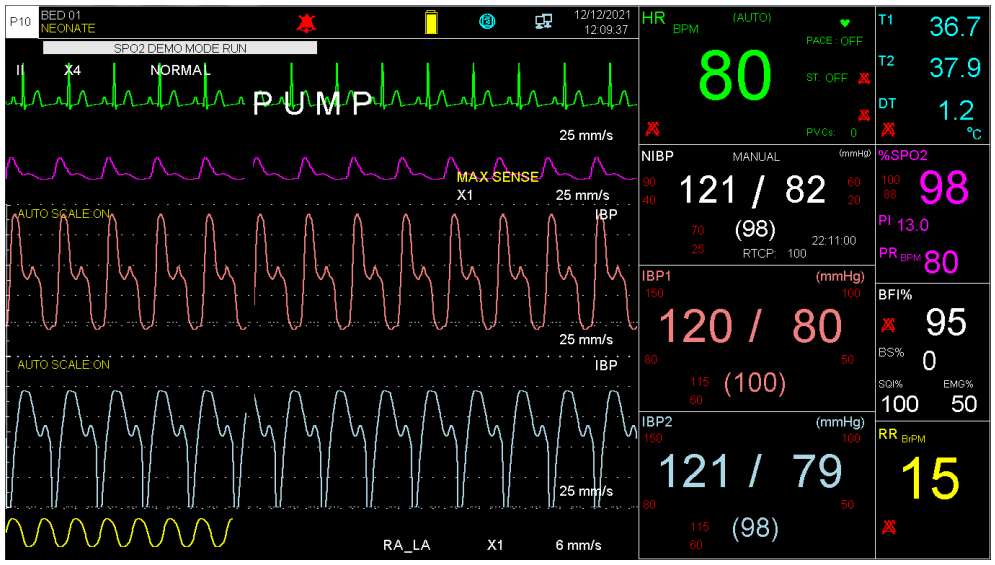
2- If ASYSTOLE condition occurs, the message “ECG ASYSTOLE” will be shown and audible alarm with high level will be activated.

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

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

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

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

PUMP PAGE


Warning

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

Chapter 3, Alarm

3.1 Alarm Categories 2
Physiological alarms.....2
Technical alarms 2
Prompt messages 2
3.2 Alarm Level 2
3.3 Alarm Modes 3
Display Screen 3
Alarm Indicator.....3
Alarm Sound.....3
3.4 Alarm verification 4
3.5 ALARM.....4
3.6 Alarm Silence Key.....5
3.7 Alarm Causes.....6

This chapter gives general information about alarm and related functions.

3.1 Alarm Categories

Alarms can be classified into three categories: Physiological, Technical and Prompt messages. All alarm messages are displayed in the Message Area.

Physiological alarms

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

Technical alarms

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

Prompt messages

In fact, prompt messages are not alarm messages. In addition to physiological and technical alarm messages, the patient monitor displays some messages indicating the system status.

3.2 Alarm Level

The Patient Monitor offers three levels of alarm.

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

3.3 Alarm Modes

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

Display Screen

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

Level I alarm message: Red background – Black text

Level II alarm message: Yellow background – Black text

Level III alarm message: Cyan background – Black text

Alarm Indicator

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

Alarm Sound

The alarm sound is activated in three levels:

Level I alarm sounds "DO-DO-DO--DO-DO" every 10 seconds;
Level II alarm sounds "DO- DO-DO" every 20 seconds;
Level III alarm sounds "DO-" every 30 seconds.

NOTE

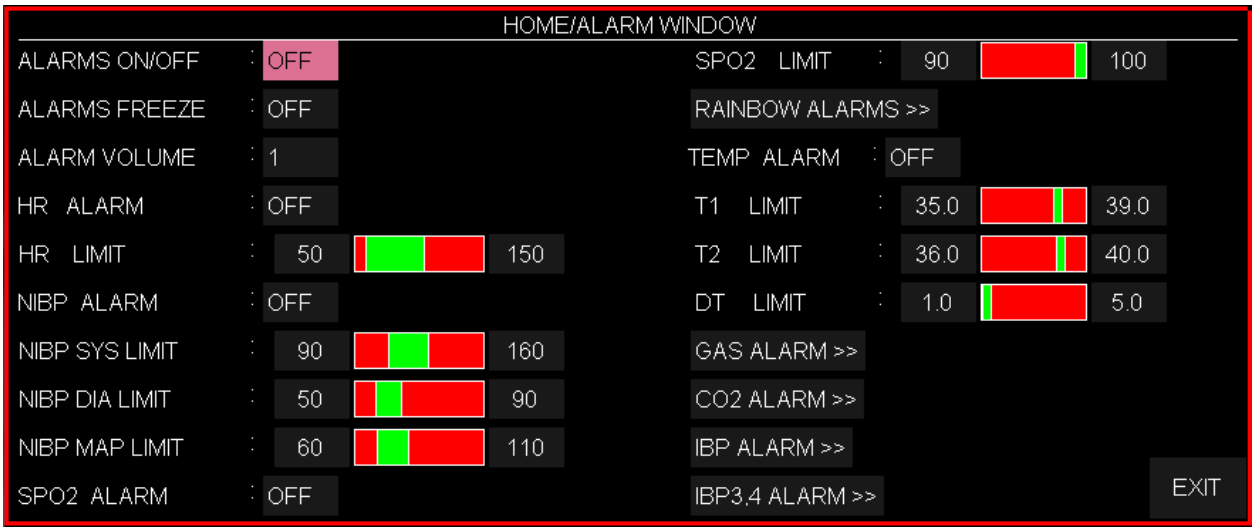
- **When alarms of different levels occur at the same time, the alarm LED prompts the alarm of the highest level (red color) and the other alarms are displayed alternately in a background color corresponding to their levels.**
- **If two or more alarms of the same level occur simultaneously, the alarm messages will be displayed alternately.**

3.4 Alarm verification

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

3.5 ALARM

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



■ ALARMS ON/OFF

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

NOTE

- **If the monitor detects situations like ASYSTOLE or APNEA, alarm will be activated even when it is in "OFF" mode.**
- **When a technical alarm occurs, you can press Alarm Silence key to disable the alarm.**

■ ALARM FREEZE

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

■ ALARM VOLUME

Pick "ALARM VOLUME" to set the volume of alarm sound. The selection ranges from 1 to 7. 1 represents the lowest volume and 7 represents the highest volume. The sound pressure in front of the monitor and at the distance of 1m:in the range of 47 dB(A) to 69dB(A) depending on the selected volume.

NOTE

- **All other settings in this menu are about alarm ON/OFF and alarm high and low limits of measurable parameters. You can set these items in the related parameter menu. Refer to each module‘s chapter for details.**

3.6 Alarm Silence Key

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

Pressing the Alarm Silence key will disable the current technical alarm and will change the alarm message background color to gray. If a new technical alarm occurs in this condition, the silence mode will be terminated and both audible and visible alarms will be triggered.

User should identify the alarm causes. You will find the alarm messages of each module in its own chapter. When an alarm occurs, take the actions below:

1. Check the patient's condition.

2. Press Silence button, if necessary.
3. After removing the alarm cause, enable the alarm sound.

Warning

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

3.7 Alarm Causes

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

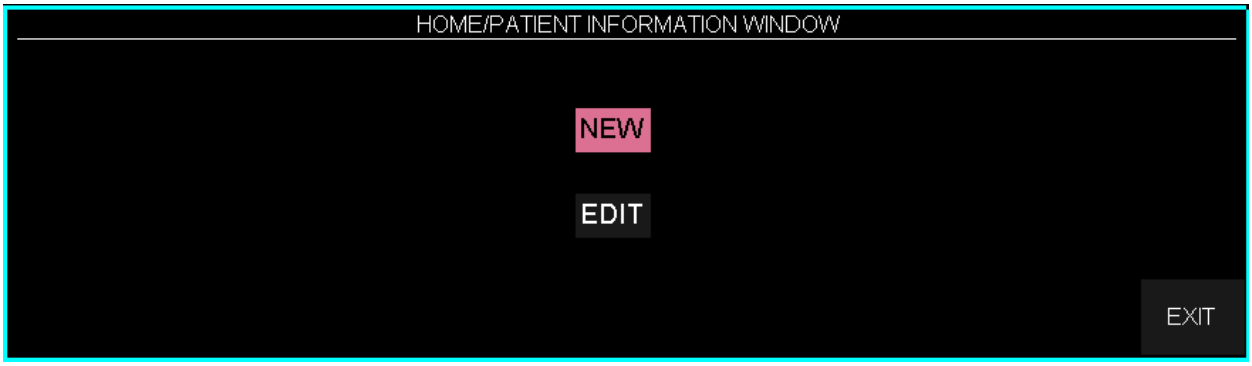
Chapter 4, PATIENT INFORMATION

4.1 Enter Patient Information.....2

4.2 Edit Patient Information 3

4.1 Enter Patient Information

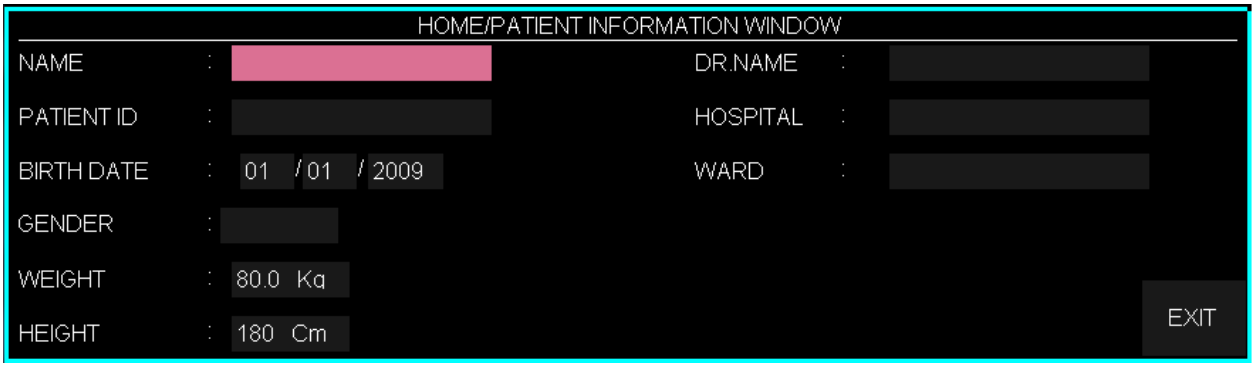
Choose "PATIENT INFORMATION" from HOME WINDOW to call up the following window:



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

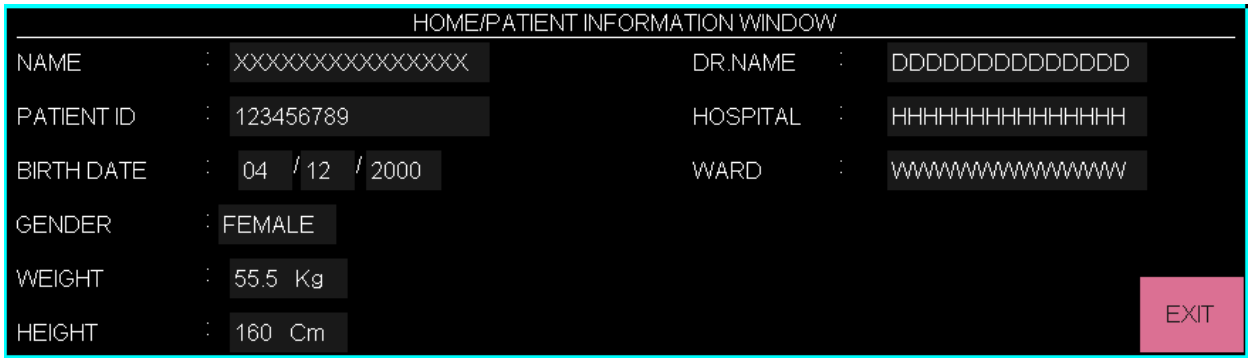
ARE YOU SURE TO CLEAR ALL DATA?
YES NO

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

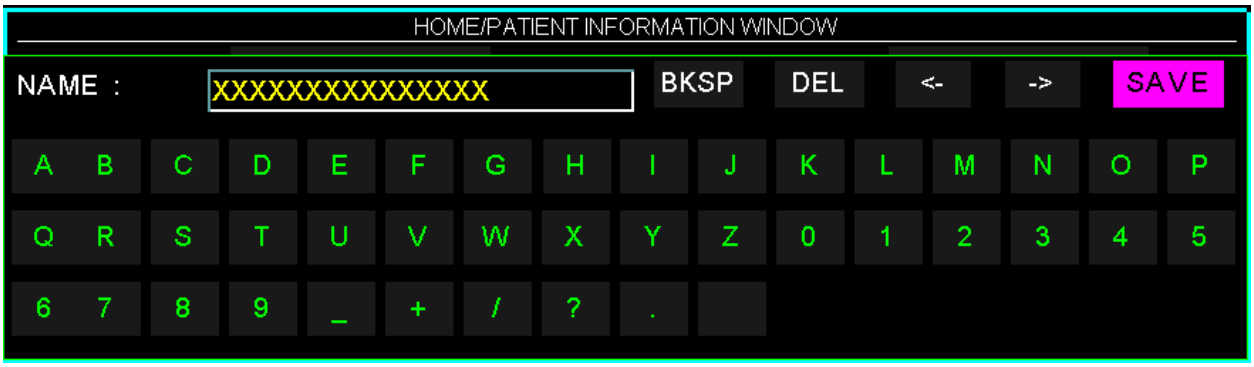


4.2 Edit Patient Information

Press "EDIT" to edit the previous patient information.



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



NAME	Patient name (up to18 characters)
PATIENT ID	Hospital ID for patient (up to18 characters)
BIRTH DATE	Date of the birth
GENDER	Available options are MALE and FEMALE
WEIGHT	Available between 0.5 to 300 Kg
HEIGHT	Available between 20 to 250 cm
DR.NAME	Physician name (up to 16 characters)
HOSPITAL	Hospital name (up to 16 characters)
WARD	Hospital ward name (up to16 characters)

Chapter 5. ECG Monitoring

5.1 GENERAL.....2

5.2 Patient Preparation 3

5.3 ECG Lead Wire Placement 3

Electrode placement for 3-Wire cable.....3

Electrode placement for 5-Wire cable.....4

Electrode placement for 10-Wire cable.....6

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5.6 ECG Alarms 19

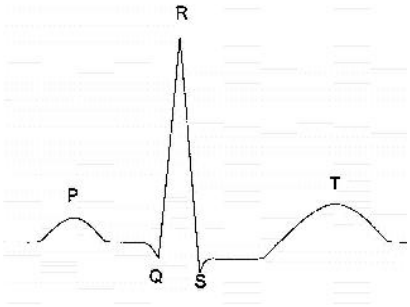
a) Physiological alarms 19

b) Technical alarms.....20

5.1 GENERAL

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

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



Standard ECG waveform

Warning

- **This device is defibrillator proof, and this feature requires use of manufacture specified accessory including electrodes, lead wires, and patient cable.**
- **Do not touch the patient, bed, table or the monitor during defibrillation.**
- **Interference from a non-grounded instrument near the patient and/or ESU (ElectroSurgical Unit) interference can cause the waveform inaccuracy.**
- **Select patient mode carefully, because QRS detection's thresholds and algorithms are working different in Adult and Neonate modes.**

5.2 Patient Preparation

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

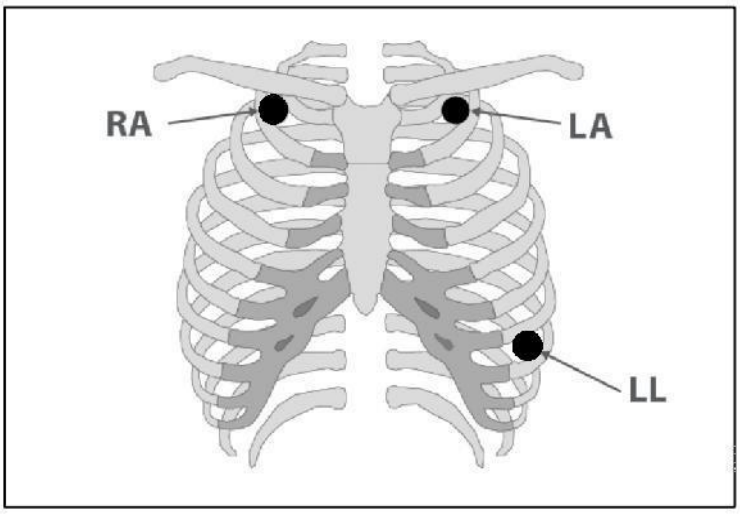
2. Put the electrodes on the patient body. Before attachment, apply some conductive gel on the electrodes if the electrodes are not self-supplied with electrolyte.
3. Attach clip or snap to electrodes prior to placement.

5.3 ECG Lead Wire Placement

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

Electrode placement for 3-Wire cable

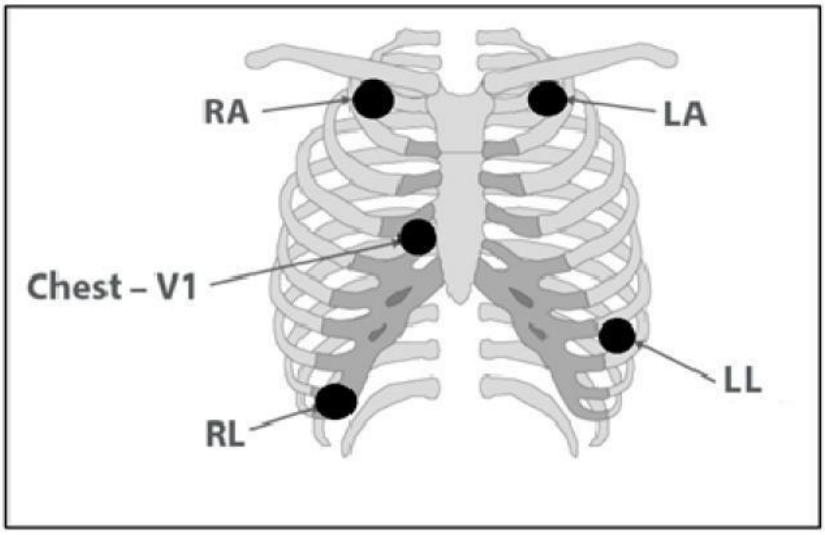
Right Arm (RA): red electrode, be placed near the right shoulder, directly below the clavicle.
Left Arm (LA): yellow electrode, be placed near the left shoulder, directly below the clavicle.
Left Leg (LL): green electrode, be placed on the left hypogastrium.



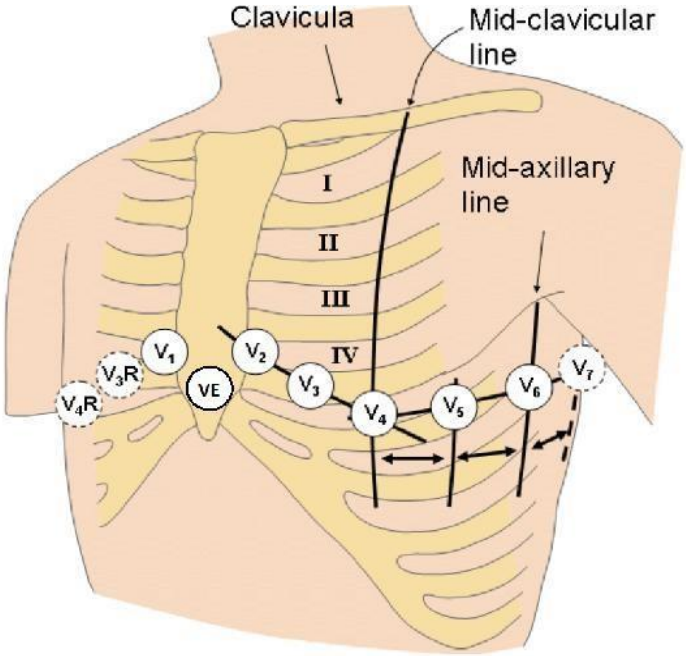
Electrode's locations for 3-wire ECG Cable

Electrode placement for 5-Wire cable

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



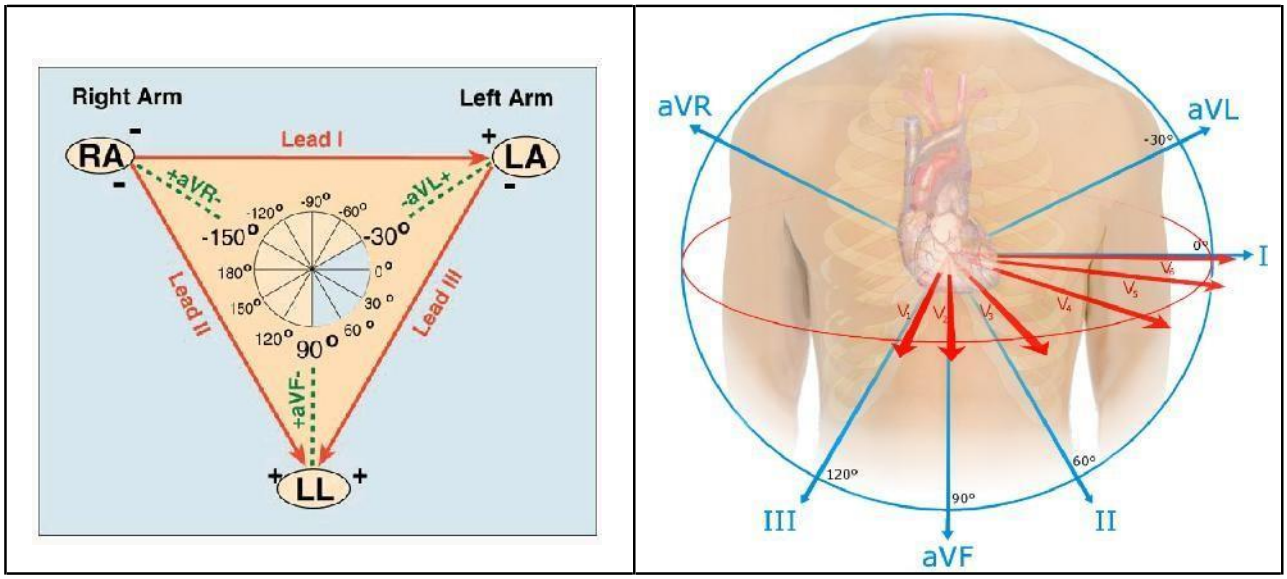
Electrode's locations for 5-wire ECG Cable



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

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

- V1 on 4th intercostal space at the right sterna margin.
- V2 on 4th intercostal space at the left sterna margin.
- V3 midway between V2 and V4 electrodes.
- V4 on the 5th intercostal space at the left clavicular line.
- V5 on the left anterior axillary line, horizontal with V4 electrode.
- V6 on the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R on the right side of the chest in positions corresponding to those of V3-V6.
- VE over the xiphoid position.
- V7 on the 5th intercostal space at the left posterior axillary line of back.
- V7R on the 5th intercostal space at the right posterior axillary line of back

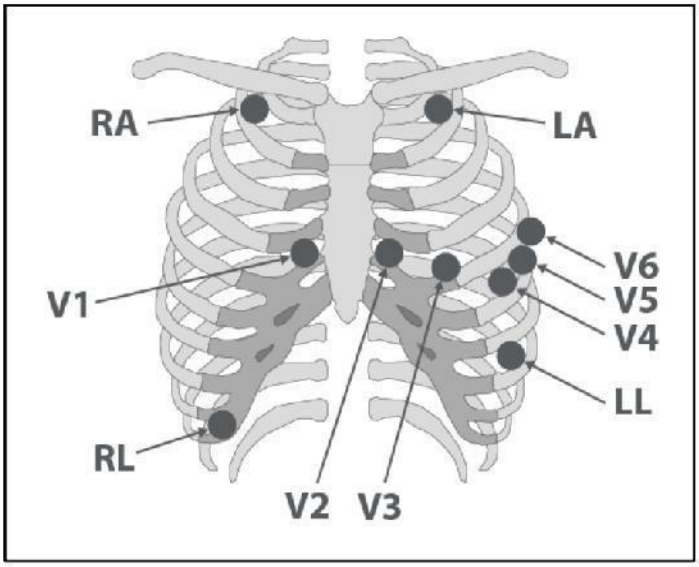


ECG Leads

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

Electrode placement for 10-Wire cable

Right Arm (RA): red electrode, be placed near the right shoulder, directly below the clavicle.
Left Arm (LA): yellow electrode, be placed near the left shoulder, directly below the clavicle.
Right Leg (L[redacted] black electrode, be placed on the right hypogastrium.
Left Leg (LR): green electrode, be placed on the left hypogastrium.
Chest (V1 –V6): white electrode, be placed on the chest as illustrated.



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

Warning

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

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

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

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

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

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

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

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

• When using Electro surgery equipment, leads should be placed in the furthest possible distance from Electro surgery electrodes and its grounding plate to avoid burning.

• The placing of the ECG leads will depend on the type of surgery that is being performed. For example, with open heart surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artefacts can sometimes affect the ECG waveform due to the use of ESU (Electro Surgical Unit). To reduce this effect, you can place the electrodes on the right or left side of shoulders and on the top side of the stomach. Avoid placing the electrodes on the upper arms (except when the ECG waveform is too weak).

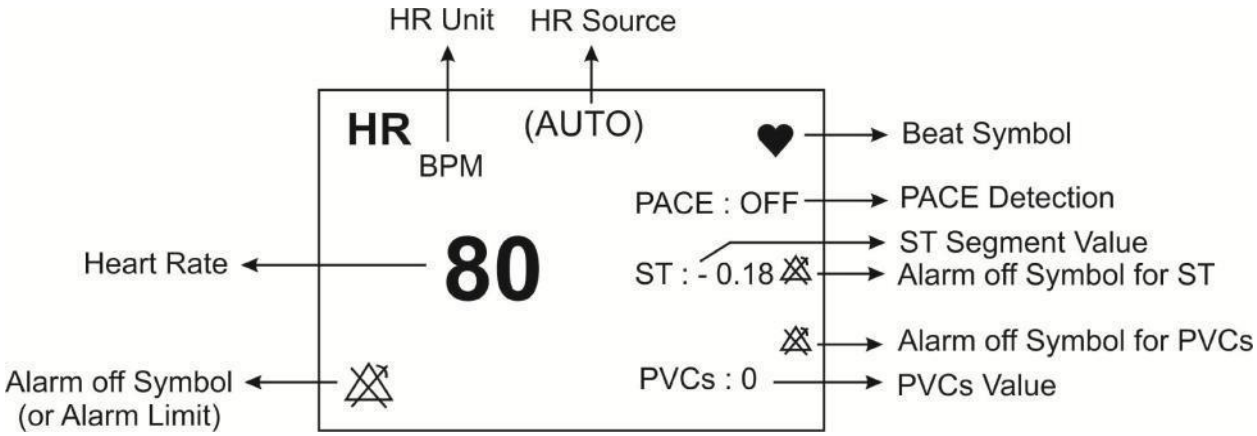
• Improper connection of the ESU return electrode might lead to patient severe burn.

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

• 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.

5.4 ECG WINDOW

The following items can be monitored in ECG parameter window:



ECG PARAMETER WINDOW

NOTE

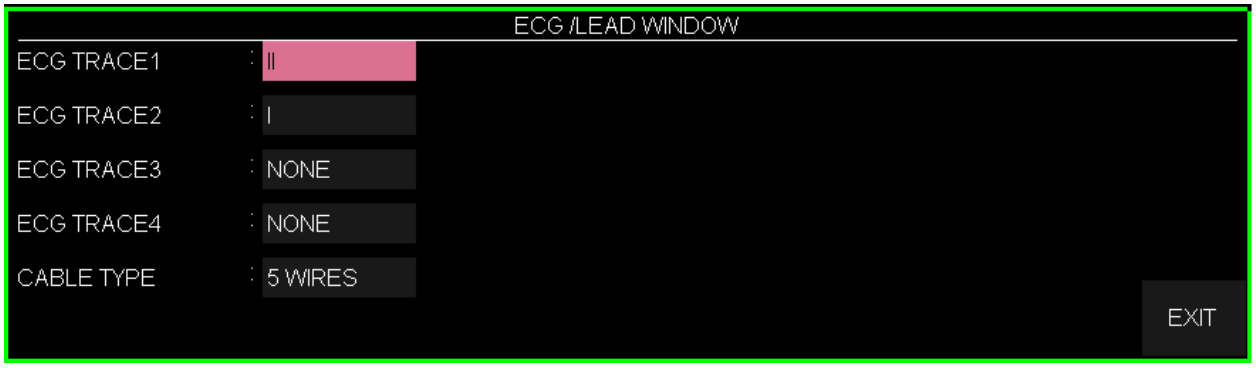
- **In the absence of a proper signal, the monitor is not able to count the heart rate and instead of the HR number, the symbol (-? -) is displayed in the ECG window. The following are the reasons for this:**
  - **For 3-wire cable:**
    - **Each of the electrodes is disconnected or not connected properly.**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

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

Click on ECG parameter, the following window will pop up:

■ **ECG LEAD**:

Click on ECG LEAD, the following window will pop up:



- **ECG TRACE**:

You can choose the following leads for traces 1 to 4:

"I" to show RA-LA waveform
"II" to show RA-LL waveform
"III" to show LA-LL waveform
"aVR" to show RA- $\frac{LA + LL}{2}$ waveform
"aVL" to show LA- $\frac{RA + LL}{2}$ waveform
"aVF" to show LL- $\frac{RA + LA}{2}$ waveform
"V" to show C- $\frac{RA + LA + LL}{}$ waveform

3

NOTE

- **You can choose aVR, aVL, aVF and V just when ECG is in 5-WIRE mode.**
- **The leads V2, V3, V4, V5 and V6 can be observed only in 12-lead ECG mode.**
- **Main lead is selectable in ECG menu. In pages that more than one trace of ECG signal is displayed, the first trace is related to the main lead.**
- **ST, ARR, Pace and HR values are calculated using the main lead that is displayed as TRACE 1.**
- **Calculated ST values for all ECG leads can be monitored in the pages 2 to 5.**
- **Due to higher amplitude of signal voltage in leads II and V, it is recommended to select one of these leads as main lead.**
- **If an ECG waveform is not accurate while the electrodes are properly attached, try to change the lead.**
- **In any situation that causes circuit saturation (such as Discharge of defibrillator), the constant signal will be displayed, which usually does not last more than 5 seconds.**

- **CABLE TYPE**

To adjust ECG cable type to "3 WIRES", "5 WIRES “and "10 WIRES". As you can see in the table below, different leads can be monitored in the pages.

Page	Leads		
	Cable type 3	Cable type 5	Cable type 10
P1	TRACE 1	TRACE 1	TRACE 1
P2	TRACE 1	TRACE 1,2	TRACE 1,2
P3	TRACE 1	TRACE 1..4	TRACE 1..4
P4	TRACE 1	TRACE 1..7	TRACE 1..7
P5	TRACE 1	TRACE 1..7	TRACE 1..12
P6	TRACE 1	TRACE 1,2	TRACE 1,2
P7	TRACE 1	TRACE 1	TRACE 1
P8	TRACE 1	TRACE 1,2	TRACE 1,2
P9	TRACE 1	TRACE 1	TRACE 1

■ ECG GAIN

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

■ ECG SWEEP

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

■ ECG FILTER

For noises reduction, smoother waveforms or detailed waveforms, there are three options for filtering the ECG:

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

■ HR AVERAGE

Available options for HR AVERAGE are 4, 8 and 16 sec.

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

Available options for HR AVERAGE are 4s, 8s and 16s.

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

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

The above results are for lead II as reference lead.

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

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

- The ECG module is able to reject TALL-T pulses greater than 1.2 mv.
- Heart rates measured for 4 irregular rhythms according to IEC 60601-2-27:2011 are as follows:

Irregular rhythm	**HR (bpm)- adult**	**HR (bpm)- pediatric**	**HR (bpm)- neonate**
3a ventricular bigeminy	85	85	85
3b slow alternating ventricular bigeminy	30	30	67
3c rapid alternating ventricular bigeminy	126	126	126
3d bidirectional systoles	40-105	40-105	87-105

■ **HR SOURCE**

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

In AUTO mode the below conditions will be provided:

- The heart rate is calculated from the module that its accessory is connected to the monitor.
- If two or more signals are being monitored simultaneously, the heart rate calculation will be done based on the signals priority, i.e. ECG, IBP1, IBP2, IBP3, IBP4 and SPO2 signals respectively.
- If the heart rate is calculated from any signal except ECG, PR alarms will be enabled based on HR alarm settings (Alarm Level and Alarm Limit).

NOTE

- **If HR SOURCE is set to any module except ECG, HR will change to PR and its features (e.g. unit) will change corresponding to the selected module for HR SOURCE.**
- **If HR SOURCE is set to any signal except ECG, beat symbol and sound will be according to the selected signal.**
- **If "HR SOURCE" is set to any module and cable of the module is not connected to the system, HR value will not be displayed**
- **IBP3 and IBP4 can only be enabled in the LM1810 system.**
- **Calculating HR from IBP signal is possible just from ART, PAP, RVP, LVP and IBP labelled signal.**
- **Calculating HR value from IBP signal is not possible in the following conditions and the HR value will be displayed "---":**
  - **"IBP1/IBP2 STATIC PRESSURE" message on the screen**
  - **"IBP1/IBP2 SEARCH" message on the screen**
  - **HR value less than 25**
  - **Selecting CVP, LAP and RAP labels.**
- **HR value measurement range is 25~240 bpm, when the HR is calculated from IBP signal**

■ **BEAT VOLUME**

Available options for are between "1" to "7" and "OFF"; "OFF" indicates silence, while 7 indicates maximum volume.

■ **PACE DETECT**

"ON" is for patient with pacemaker and " OFF" is for patient without pacemaker. When PACE DETECT is "ON", the ECG monitoring system detects and rejects pacemaker-generated signals from ECG signal, so that they will be ignored in calculating the heart rate. Detected pacemaker signals will be marked on the ECG waveform as 1 centimeter spike. If the patient does not have a pacemaker, it may be desirable to turn the detection function OFF, so that artifacts in the waveform will not be mistaken for a pacemaker signal.

Warning

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

- **For the patients with pacemaker, the monitor may continue to count the pacemaker rate as heart rate during the occurrence of cardiac arrest or some arrhythmias. Do not rely entirely upon monitor alarms. Keep the patients with pacemaker under close surveillance.**

NOTE

- **Monitoring of patients with pacemaker is not generally affected when PACE DETECT is enabled.**
- **ECG signals with the slope of up to 1 V/s will not be counted as Pace signal.**

■ **ECG CALIB**

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

■ **ALARM**

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

- **ALARM LEVEL**

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

- **HR ALARM**

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

- **HR LIMIT**

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

■ **ALARM RECORD**

Pick “ALARM RECORD” from ECG WINDOW to record the specified parameters upon an alarm occurrence. See the chapter **“RECORDING”**.

■ **ARR ANALYSIS**

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

■ **ST ANALYSIS**

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

5.5 ECG OUTPUT *

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

Warning

- **Use the company designed cable to make connection between ECG OUTPUT connector and other devices.**
- **To avoid any cable strain or damage, bedside monitor should be placed in a proper distance from reference device.**
- **For patient with pacemaker, the " PACE DETECT" must be switched ON to remove the pace pulses from analog output signal (Pace signals will be marked on ECG OUTPUT signal as a square pulse with amplitude of 5 Volt and width of 5 ms).**
- **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.**

5.6 ECG Alarms

a) Physiological alarms

The audible alarm sounds when:

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

Physiological Alarms		
ALARM	**SITUATION**	**DESCRIPTION**
HR HIGH	Heart rate violates adjusted high limit	● HR value blinks. ● The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
HR LOW	Heart rate violates adjusted low limit	
ECG ASYSTOLE	Heart beat is not detected in last 10 seconds.	● HR value is "00". ● The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in red background .

b) Technical alarms

Technical Alarms			
Alarm	**Cause**	**Solution**	**Explanation**
ECG NO CABLE	ECG cable is not connected to the system.	Connect ECG cable.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
ECG CHECK LA،RA،LL	The leads are not properly connected.	Make sure that the mentioned leads are properly connected to patient.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
ECG DEFECT	ECG module failure	Turn off and on the system. If this message is displayed again, contact local After Sale Service.	
ECG CHECK RL OR ALL	RL or other leads are not properly connected.	Make sure that all leads (esp. RL) and patient cable are properly connected to patient.	
ECG CHECK LL OR ALL	LL or other leads are not properly connected.	Make sure that all leads (esp. LL) and patient cable are properly connected to patient.	
ECG CHECK LA OR ALL	LA or other leads are not properly connected.	Make sure that all leads (esp. LA) and patient cable are properly connected to patient.	
ECG CHECK RA OR ALL	RA or other leads are not properly connected.	Make sure that all leads (esp. RA) and patient cable are properly connected to patient.	
ECG CHECK C (C2، C3 ،C4 ،C5 ،C6)	C lead is not properly connected to the patient.	Make sure that C lead and ECG cable are properly connected to patient.	

If the alarm persists after checking the mentioned solution, inspect the ECG cable for any damage. For more information, contact local After Sale Service.

Chapter 6, Arrhythmia Monitoring

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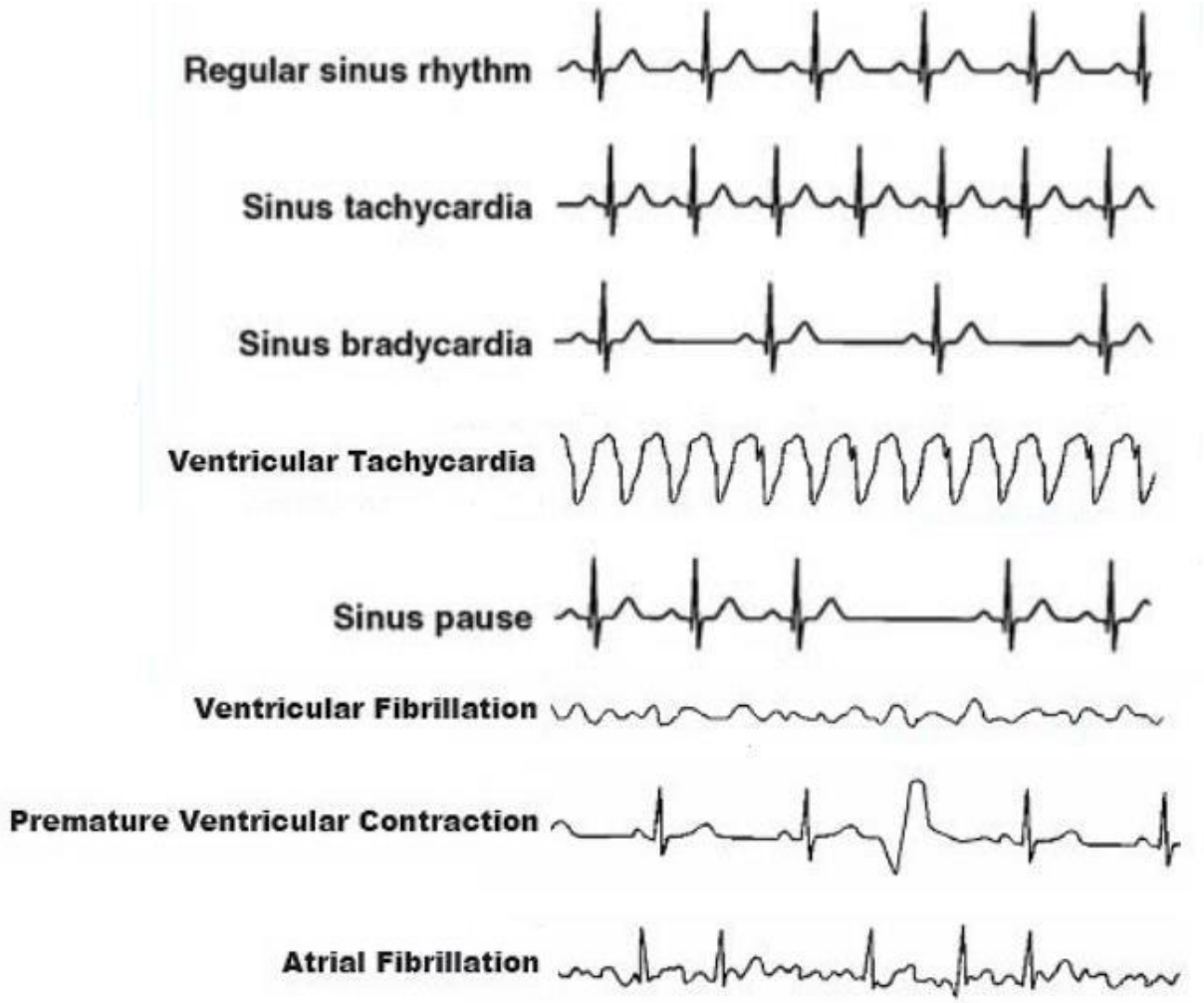
6.1 Introduction

Arrhythmia means any disturbance or irregularity of cardiac rhythm. Stability of the cardiac rhythm is essential for sufficient pumping function of the heart and adequate cardiac output. Maintaining adequate cardiac output is vital for organ perfusion and survival. Arrhythmia can cause a decrease in cardiac output. Therefore fast and accurate detection of arrhythmia is critical.

The medical professionals can use the arrhythmia analysis to evaluate patient's condition (such as heart rate, rhythm and ectopic beat) and give proper treatment.

The following image shows normal signal and some detectable arrhythmias in this monitoring system.



Warning

- The ARR monitor can only be operated by personnel who have passed professional training and are familiar with this manual.
- The ARR monitor is intended for use only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

NOTE

- **This monitor can detect up to 21 types of arrhythmias.**
- **Arrhythmia monitoring is available for adult and pediatric patients and it is not recommended for neonates.**
- **Applied lead for arrhythmia detection is reference lead that is displayed in the first trace and can be adjusted in ECG menu.**
- **It is recommended to use ECG lead I or II to have the best accuracy of ARR software.**

Arrhythmia detection algorithm principle

The arrhythmia algorithm is based on template matching. (A template is a group of beats matching the same morphology). This algorithm is divided into four parts: detection, feature extraction, labelling ,and rhythm classification .

Detection algorithm: detects waves in ECG signal that could be QRS complexes.

Feature extraction algorithm: During the learning phase an initial set of QRS templates or complexes is built. Beats that have a similar shape are placed in the same pattern. Then the monitor creates a reference template based on its identification of the patient's dominant QRS pattern. When a new true QRS complex is detected, it is compared with the existing templates. If no match is found, a new QRS template is added to the template set.

Labelling algorithm: analyses all templates. Each template and the beats belonging to it are labelled with one of the following names: normal beats, premature ventricular beats (PVC: Premature Ventricular Contraction) and unknown beats. Premature Ventricular Contraction (PVC) is ectopic impulse originating from ventricles, before the normal electrical activation sequence of the heart has occurred.

Rhythm classification algorithm: refers to analysis of sequences of beats. The monitor compares the sequence of the last twelve beats with the sequences stored in the monitor's memory. With this process, the monitor can confirm the occurrence of an arrhythmia

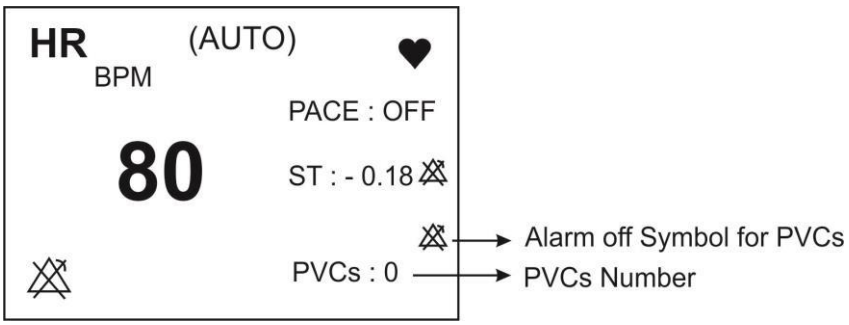
NOTE

- **Parallel to this process there is an algorithm for detection of ventricular fibrillation and atrial fibrillation that is based on waveform analysis and R-R intervals analysis.**
- **If two or more arrhythmias are detected simultaneously, the monitor alarms in order of event priority.**
- **When PACE is turned ON for patient with pacemaker, the system will detect relevant arrhythmias to PACE (i.e. Pacemaker Not Capture(PNC) and Pacemaker Not Pace(PNP). In this condition, the system cannot detect PVC arrhythmias.**

Enabling Arrhythmia

Enter the ECG settings window. Select ARR ANALYSIS item to open the following window:

The ARR MONITOR item is used to enable or disable arrhythmia monitoring. The default is "OFF".
When arrhythmia monitoring is active, the PVC value is shown in ECG parameter window in the following figure and updated every 5 seconds. When the Arrhythmia monitoring is disabled "PVCs OFF" is displayed in ECG parameters area. When ARR analysis is enabled, current PVC values are trended every 20 seconds and can be reviewed on the TREND window.



NOTE

- **If ARR MONITOR is turned Off, alarm of VTAC, VFIB and Asystole arrhythmias will be enabled (In other words, user cannot disable alarm of these vital arrhythmias).**

Arrhythmia Relearning

To perform learning procedure on arrhythmias, follow these steps:

- Enter the ECG settings window.
- Open ARR ANALYSYS window and select ARR RELEARN item. Learning procedure starts and the "RELEARN" message is displayed in the message area.

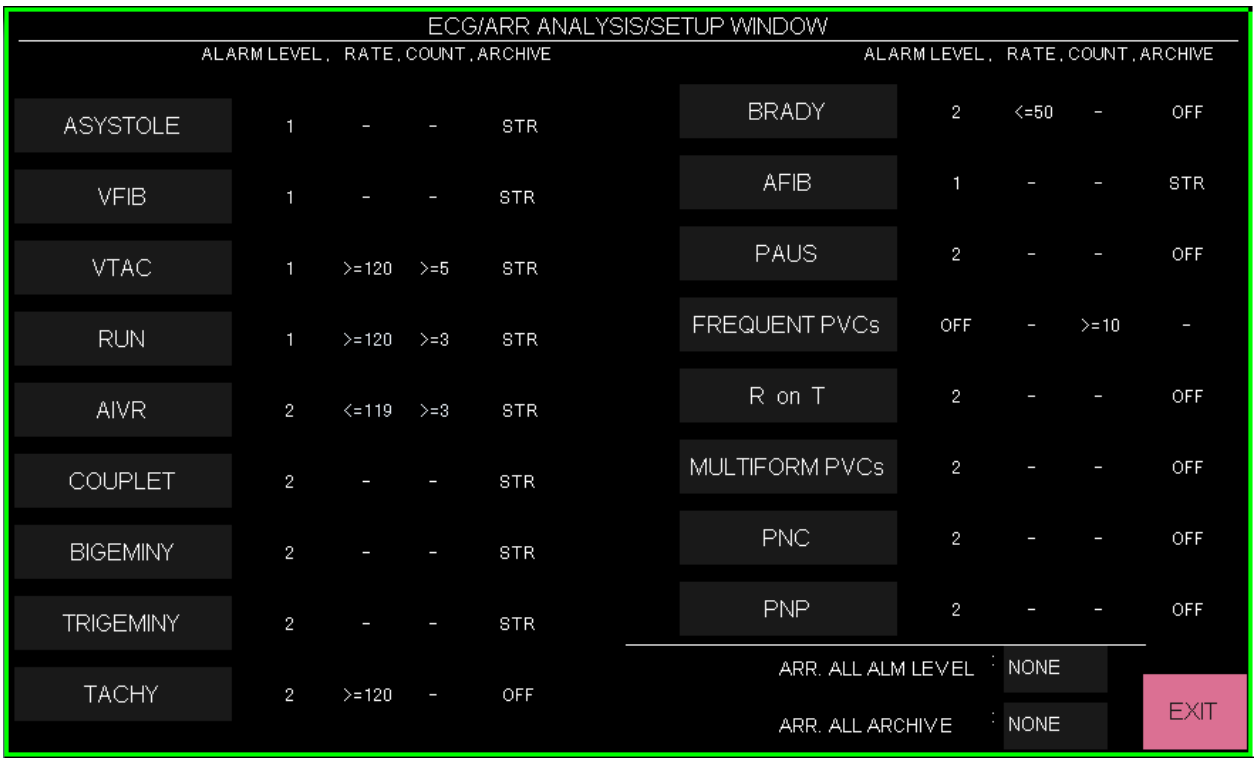
NOTE

- **In most situations the learning phase takes about 20 seconds.**
- **If the monitor couldn't find 6 matching beats after 20 seconds, the relearn procedure continues and the "RELEARN" message remains on the display, till acceptable condition happens.**
- **While the monitor is in learning phase, all arrhythmia alarms and trend collection are suspended.**
- **Before starting learning procedure, verify the quality of the ECG signal and ensure that the patient's ECG displays a normal reference pattern.**
- **The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ARR ANALYSIS is ON):**
  - **Turning on the monitor**
  - **Connecting ECG cable.**
  - **Changing ECG lead configuration.**
  - **Choosing "NEW" from HOME / PATIENT INFORMATION**

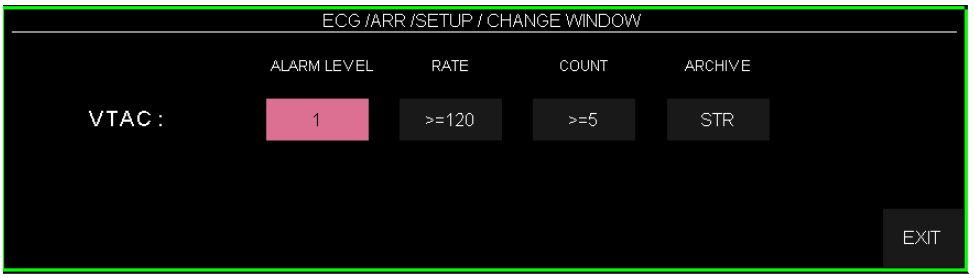
- **It is recommended to perform relearn procedure under the following conditions:**
  - **A lead is reconnected or electrodes are repositioned.**
  - **Eight hours have passed since last reference complex learned.**
  - **Other significant changes appear on the morphology of the patient's ECG.**

ARR SETUP

- Enter the ECG settings window
- Open ARR ANALYSIS item and select ARR SETUP to open the following menu:



ARR SETUP Window allows you to set the arrhythmia monitoring based on the patient needs. The arrhythmia events and relevant settings are displayed in two columns. Unrelated settings to a specific arrhythmia are shown by a dash and the settings which could not be changed for a specific arrhythmia are dimmed (arrhythmia default settings are as shown in the above figure).
Click on an arrhythmia event to set the arrhythmia via the below window.



The adjustable parameters are as follows:

- **ALARM LEVEL**

This item is used to set the alarm level of each arrhythmia event. Available options are 1, 2 and OFF. (For more detail about alarm levels, refer to the chapter Alarm).
Select “ALL ALM LEVEL” item to set the level of all arrhythmia alarms to the same value or disable all of them.

NOTE

- **ALARM LEVEL for "ASYSTOLE", "VFIB" and "VTAC" cannot be set and always is level 1.**

➢ **RATE**

This parameter determines the heart rate in each arrhythmia. By setting this parameter as well as Count, you can determine the point at which an event call is triggered.
You cannot modify the rate for "ASYSTOLE", "VFIB", "COUPLET", "BIGEMINY", "TRIGEMINY", "PAUS", "AFIB", "PNP", "PNC", "MULTIFORM PVCs" and "FREQUENT PVCs".
"RUN" and "AIVR" get their rate settings from "VTAC" and rate cannot be set for these arrhythmias. In addition, rate of RonT arrhythmia is detected less than or equal to 100 and cannot be set.

Arrhythmia event	Rate setting
VTAC	100-200 step by 10
RUN	Same as VTAC rate
AIVR	<VTAC rate-1
TACHY	100-200 step by 10
BRADY	30-105 step by 5

➢ **COUNT**

This parameter specifies the number of PVCs in each arrhythmia. By setting this parameter and rate, you can determine the point at which an event call is triggered.
You can't modify the count for "ASYSTOLE","VFIB", "COUPLET", "BIGEMINY", "TRIGEMINY", "TACHY", "BRADY", "AFIB" ,"PAUS", "PNP", "PNC", "MULTIFORM PVCs and "R on T".
Count setting cannot be changed for "AIVR", "MULTIFORM PVCs" and "RonT" and is as below:
"AIVR" Count ≥3, "MULTIFORM PVCs" Count ≥4, "RonT" Count ≥1.

Count setting for other arrhythmias is as the table below.

Arrhythmia event	Count setting
VTAC	5-12 step by 1
RUN	$(VTAC_{count} -1)$ ~3 step by 1
FREQUENT PVCs	1-15 step by 1

➢ **ARCHIVE**

You can determine whether the selected event and its information are stored and recorded automatically or both. You can view the stored events in ARR EVENT RECALL Window.

STR: Stores the selected arrhythmia event.
REC: Automatically records the selected event.
STR/REC: Stores and records the selected event simultaneously.
OFF: No action if arrhythmia event activates.

You can use "ALL ARCHIVE" in SETUP window to set all arrhythmias ARCHIVE condition to the same state.

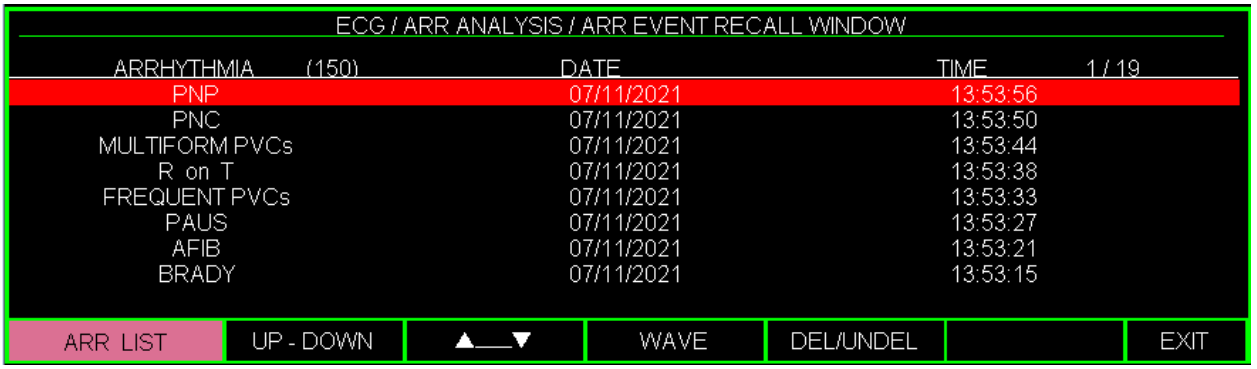
Arrhythmia information and waveform

Arrhythmia events are displayed in two modes:

1. ARR LIST

- Enter the ECG setting window.
- Open ARR ANALYSIS window and select ARR EVENT RECALL.
- Set the first left item to ARR LIST.

List of occurred arrhythmia events are displayed based on their date and time (See the table below).



You can store and review maximum 150 events in this window. If an arrhythmia event occurs and persists, it will be stored in ARR EVENT RECALL WINDOW for one time, but if this event is removed and then occurs again, it will be stored twice.

UP-DOWN: To review different event pages. Maximum of 8 arrhythmia events can be displayed in each page of ARR EVENT RECALL window. When there are more than 8 events, different pages are available. Click "UP-DOWN" (the second left item) to review different pages.

▼ ▲: Pick the third left item to select an arrhythmia event in the window.

WAVE: Pick this item to view ECG waveform in time of arrhythmia occurrence.

DEL/UNDEL: Pick the fifth left item to choose an arrhythmia event and remove it from the list. When you click on "DEL/UNDEL" button, the selected event will be highlighted and removed if you exit the window.

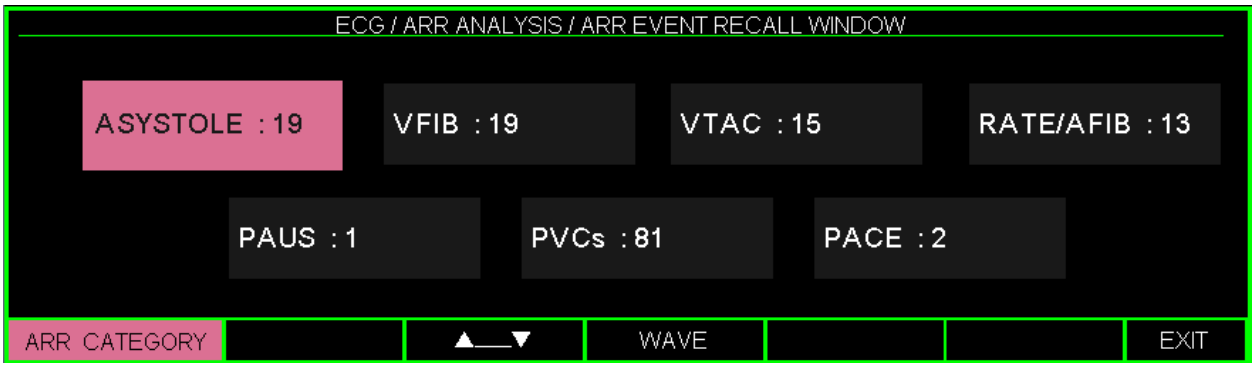
NOTE

- **To ignore deleting a selected item, click on the "DEL/UNDEL" key one more time before exiting from the window.**

1. ARR CATEGORY

- Enter the ECG setting window.
- Open ARR ANALYSIS window and select ARR EVENT RECALL.
- Set the first left item to ARR CATEGORY.

Seven categories of arrhythmia are displayed in this window. Number of occurred arrhythmia events is displayed beside each category.



Category	ASYSTOLE	VFIB	VTAC	PAUS	RATE/AFIB	PACE	PVCs
Arrhythmia	ASYSTOLE	VFIB	VTAC	PAUS	AFIB BRADY TACHY	PNP PNC	RUN AIVR COUPLET BIGEMINY TRIGEMINY FREQUENT PVCs R on T MULTIFORM PVCs

▼ ▲: Pick this item to select your desired arrhythmia category.

WAVE: Pick this item to view ECG waveform in time of arrhythmia occurrence.

WAVE

To see detail information of an arrhythmia event, click the forth left item to open following window:

The waveform and time of the selected arrhythmia event as well as other vital sign parameters at the event time are displayed in this window. ECG waveform of each arrhythmia is displayed for 12 seconds, 6 seconds before and after arrhythmia detection.

DURATION shows time of arrhythmia condition for a patient. This item is displayed for COUPLET, AIVR, RUN, VTAC, VFIB, ASYSTOLE, AFIB, TACHY, TRIGEMINY and BIGEMINY arrhythmias.

PREVIOUS – NEXT item allows you to move between different arrhythmia events.

NOTE

- **If you enter this window through ARR LIST window, PREVIOUS-NEXT item can be used to move and select different arrhythmias based on time of their occurrence. In case of ARR CATEGORY window, this item is used to move between different category of arrhythmia.**

RECORD item allows you to record the arrhythmia signal. Recording speed is 25 mm/s.

6.2 Arrhythmia Alarm Messages

The following table describes the related alarms to detectable arrhythmias by the monitoring system and their time of occurrence (Arrhythmias are in order of priority):

Physiological Alarms	
ALARM	**Time of occurrence**
ASYSTOLE ARRHYTHMIA	5 seconds pass without the detection of valid QRS complex.
VFIB ARRHYTHMIA	Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics.)Certain ventricular tachycardias have sinusoidal waveforms closely resembling those of ventricular fibrillation. Because of the similarity of these waveforms, the monitor may classify such types of ventricular tachycardia as ventricular fibrillation(.
VTAC ARRHYTHMIA	Ventricular Tachycardia: N or more PVC's are detected in a time interval T= (60*(N-1))/R, where N is defined as the VTAC count and R is defined as the VTAC rate.
ARRHYTHMIA RUN (NonSustain VT)	Ventricular Run: Series of 3 to N-1 consecutive PVCs with a beat to beat rate ≥ the VTAC rate.
AIVR ARRHYTHMIA	Accelerated Idioventricular Rhythm: Series of 3 or more PVCs with a beat rate less than the VTAC rate.
COUPLET ARRHYTHMIA	Ventricular Bigeminy: Sequence of beats with the pattern: normal, PVC, normal, PVC, normal, PVC
BIGEMINY ARRHYTHMIA	Ventricular Trigeminy: Sequence of beats with the pattern: normal, normal, PVC, normal, normal, PVC
TRIGEMINY ARRHYTHMIA	Ventricular Couplet: Sequence of beats with the pattern: normal, PVC, PVC, normal, PVC, PVC
TACHY (HR HIGH) ARRHYTHMIA	Sinus Tachycardia: HR ≥ TACHY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.

BRADY (HR LOW) ARRHYTHMIA	Sinus Bradycardia: HR≤ BRADY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.
AFIB ARRHYTHMIA	Atrial Fibrillation: Formation of QRS complexes in irregular intervals
PAUS (MISSED BEAT) ARRHYTHMIA	Actual R-R interval more than 2.1 times of the average R-R interval.
FREQUENT PVCs	More than N (event count set in the ARR SETUP WINDOW) PVC per minute.
RonT ARRHYTHMIA	A PVC beat falls after a normal beat with interval of one third of average RR and interval to the following normal beat is equal to 1.25 times of average RR. Two PVC beats occur with interval of maximum 5 min (interval from each beat to the preceding normal beat is one third of average RR)
MULTIFORM PVCs	Two PVCs with different morphologies that occurred at least twice within the preceding 300 beats and one time of their occurrence is within preceding 60 beats.
PNC ARRHYTHMIA	Pacemaker Not Capture: no QRS complex is detected for a specific period after Pace pulse (in patients with Pacemaker(.
PNP ARRHYTHMIA	Pacemaker Not Pace: no QRS complex and Pace pulse are detected for a specific period)in patients with Pacemaker(.

Chapter 7. ST Monitoring

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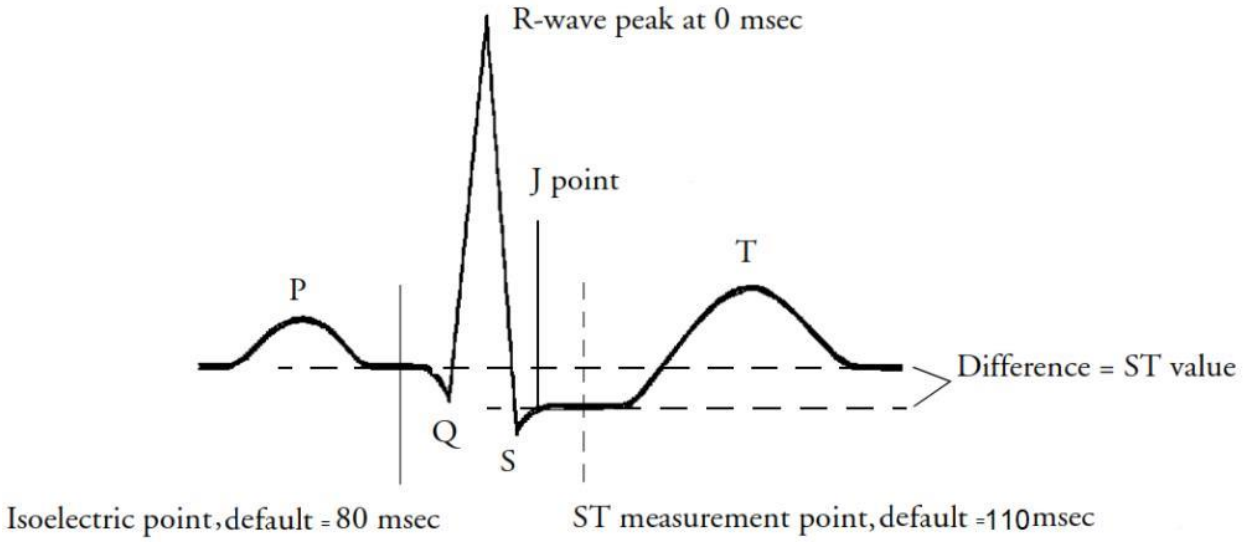
7.1 Introduction

ST segment deviation is defined as the displacement above or below the isoelectric level. The ST segment algorithm documents changes in ST segment in adult patients that can be indicative of the severity and duration of myocardial ischemia. Since many ischemic episodes are silent or painless, continuous monitoring of ST segment changes can provide the earliest warning of ischemic events. The measurement of deviation compares the isoelectric point to the ST measurement point.

The isoelectric point defines the point of zero voltage (no electrical activity) with a default position of 80ms from R wave as 0msec in the horizontal (time) axis. The ST point occurs in the ST segment between J-point and the T wave, at a default position of 110 ms after R wave. The ST measurement for each beat complex is vertical difference between the two measurement points, ST and ISO. The following figure illustrates a typical QRS complex.



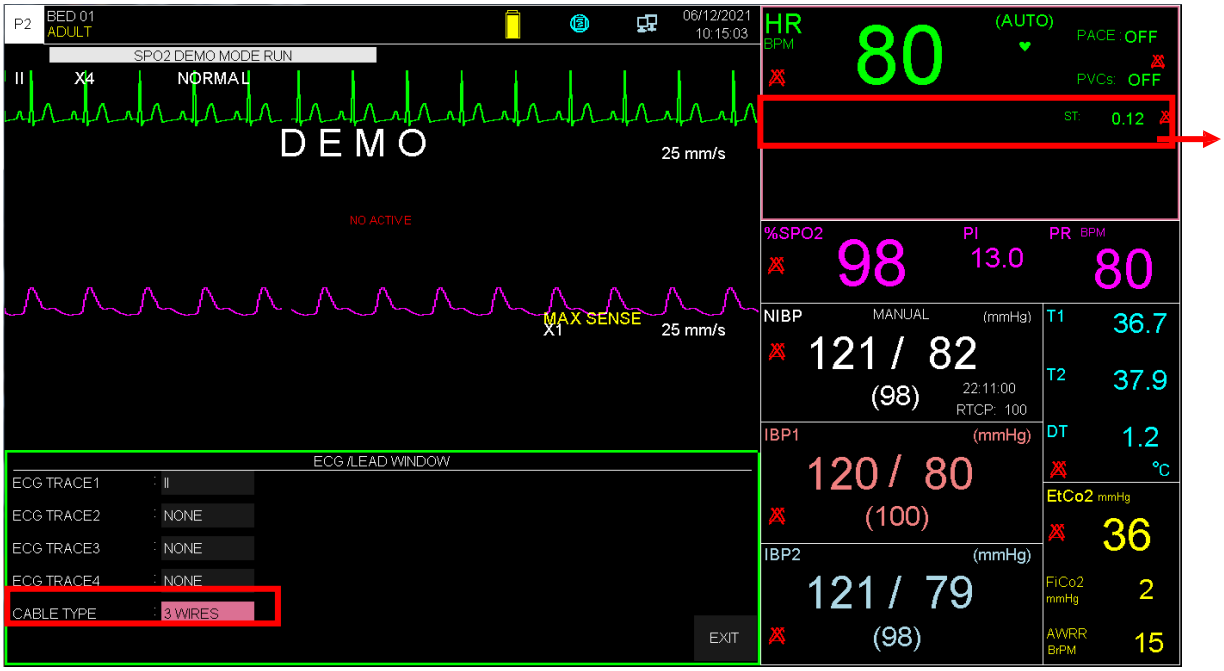
ST monitoring function is “OFF” as a default. You can switch it “ON”, when this monitoring is necessary.

NOTE

- **When ST monitoring is enabled, current ST value is stored and can be reviewed in the TREND window.**
- **Only normal beats are considered in calculation of ST value, and beats with ventricular origin or abnormal QRS complexes are not considered in the ST analysis**
- **If ECG signal is noisy or arrhythmias such as AF/Flutter are present, it is difficult to achieve reliable ST monitoring.**
- **ST monitoring is available for adult and pediatric patients, but it is not recommended for neonates.**
- **To clearly show ST segment deviation, it is recommended to use Extended filter.**
- **Measurement unit of ST segment is "mV".**
- **Measurement range of ST segment is between -2.0 mV to +2.0 mV. Measurement symbol of ST segment "+" means elevating and "- " means depressing.**

Displaying ST value:

- **ST value in CABLE TYPE: 3 WIRES mode**

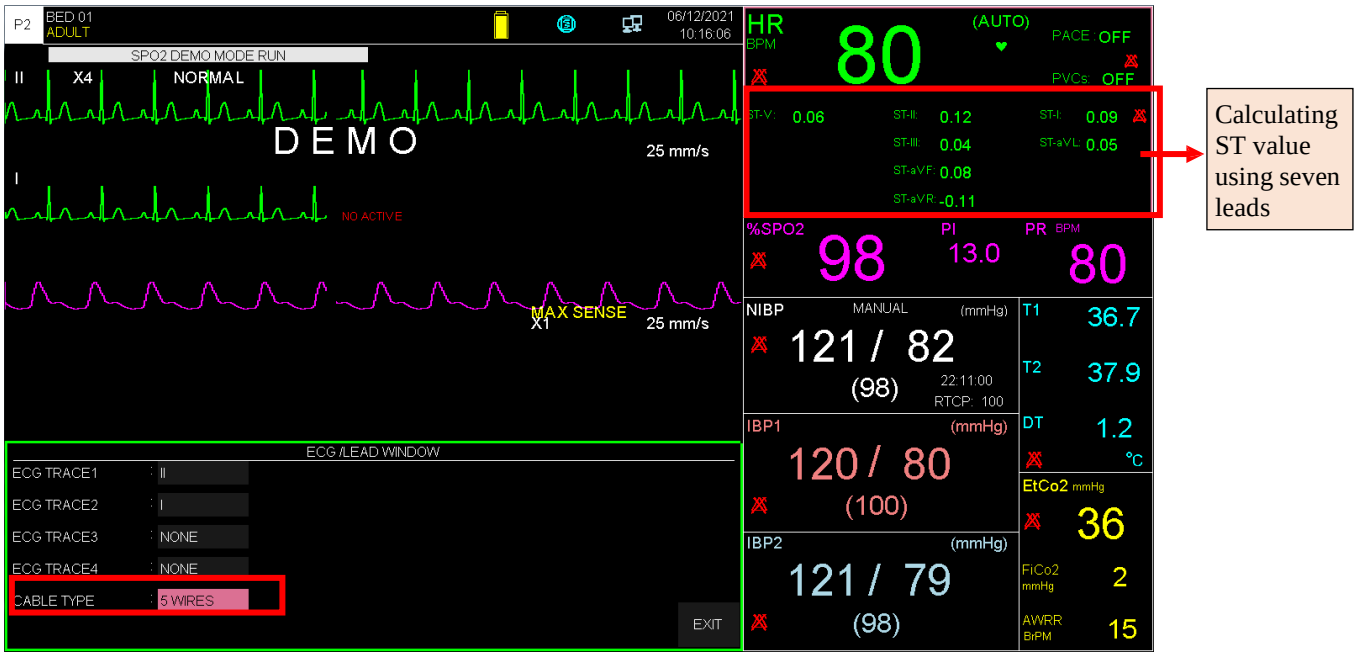


Calculating ST value using one lead

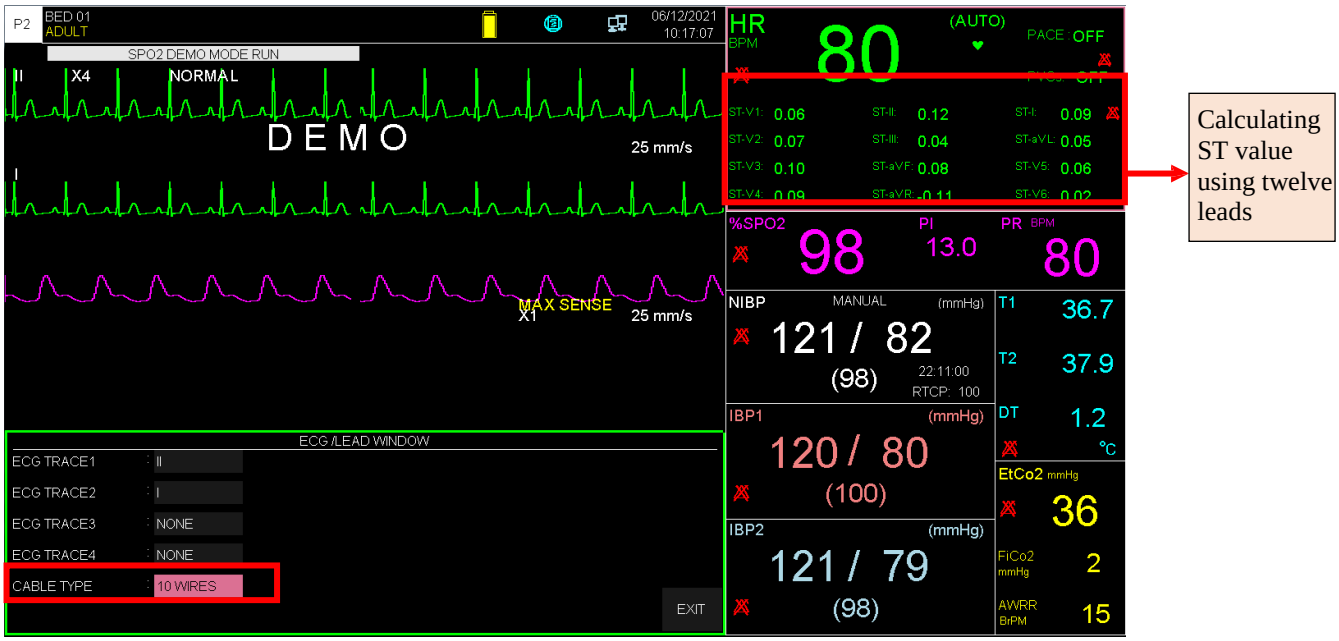
NOTE

- **ST value is calculated using main lead. You can set this lead in ECG menu.**

- **ST value in CABLE TYPE: 5 WIRES mode**

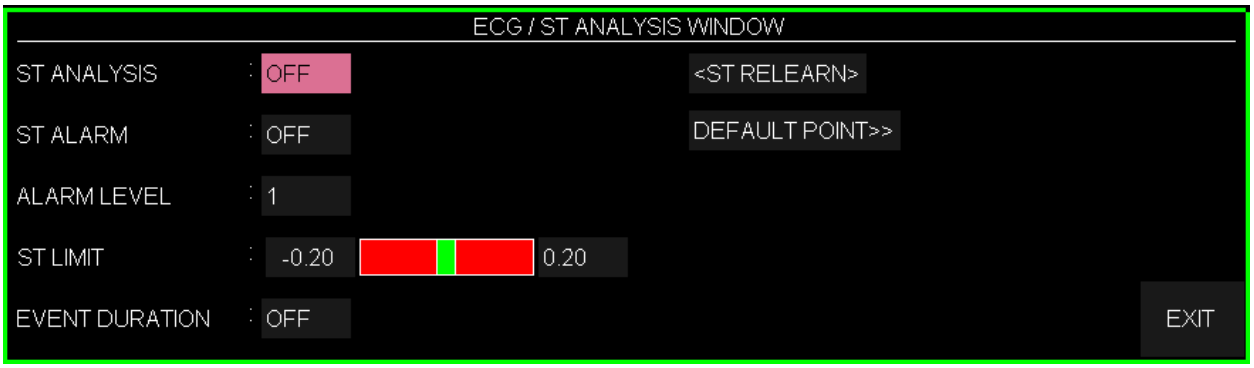


- **ST value in CABLE TYPE: 10 WIRES mode**



7.2 Enabling ST monitoring

Enter the ECG settings window. Click on ST ANALYSIS to open the following window:



The ST ANALYSIS is used to enable or disable ST monitoring. ST monitoring is OFF by default. When ST monitoring is disabled, "ST OFF" is displayed in the ECG parameter area.

7.3 ST Relearning

Click on ST RELEARN in the ST ANALYSIS window to start learning procedure. The message "RELEARN" is displayed in the message area. The procedure will take about 20 seconds.
During the learning procedure, the following actions will be taken:

- Average stored dominant QRS complex currently displayed on the DEFAULT POINT window is deleted.
- New dominant QRS complex template is identified.
- New complex is displayed in DEFAULT POINT window.

NOTE

- The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ST ANALYSIS is ON):
  - Turning on the monitor
  - Connecting ECG cable.
  - Changing an ECG lead configuration.
  - Choosing "NEW" from HOME / PATIENT INFORMATION

- A yellow vertical marker with "LRN" label On ST in TREND window shows the time in which the learning procedure has been done.

7.4 ST Setting

Enabling ST Alarm
By selecting "ON" for ST ALARM, you can enable 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 parameter area.

NOTE

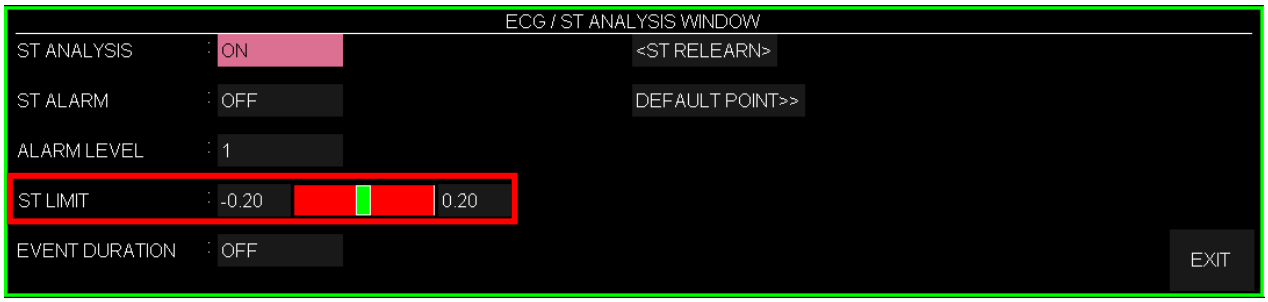
- If the alarm condition occurs, the audio-visual alarm is activated and the ST value blinks outside the normal range.

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

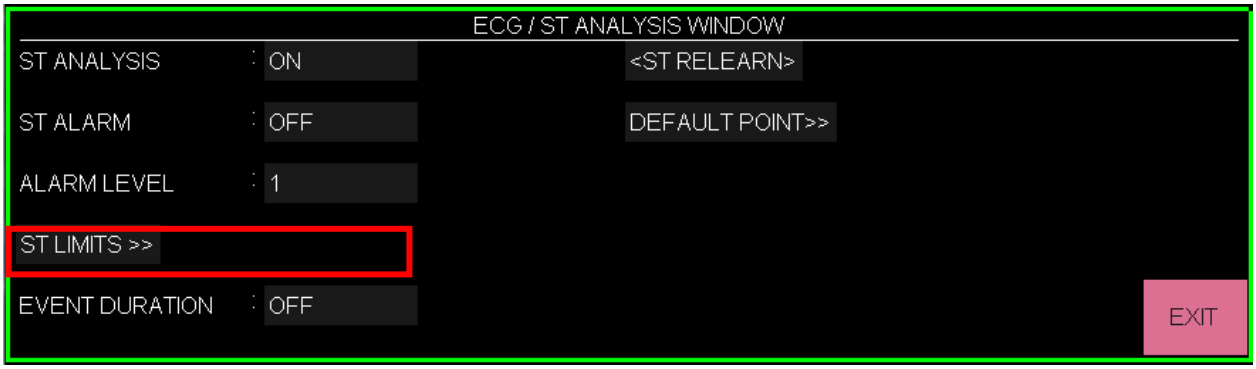
Setting ST Alarm Limits
The alarm range for all leads will be adjustable. ST alarm is activated when the ST segment value exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.

- ST alarm range for all leads is -2 mv to -2 mv.
- Default for upper limit is +0.2 mv and for lower limit is -0.2 mv.

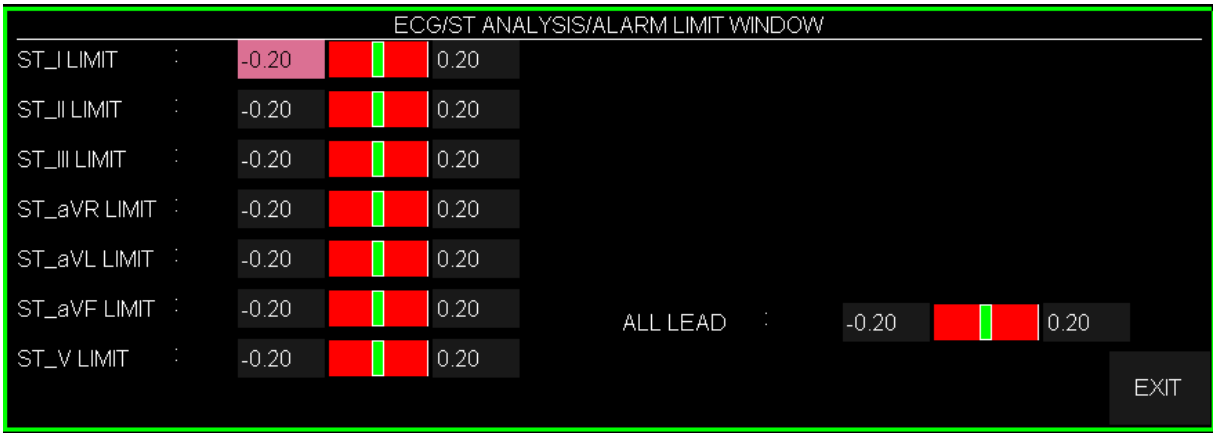
- **ST ANALYSIS window in 3 WIRE mode:**



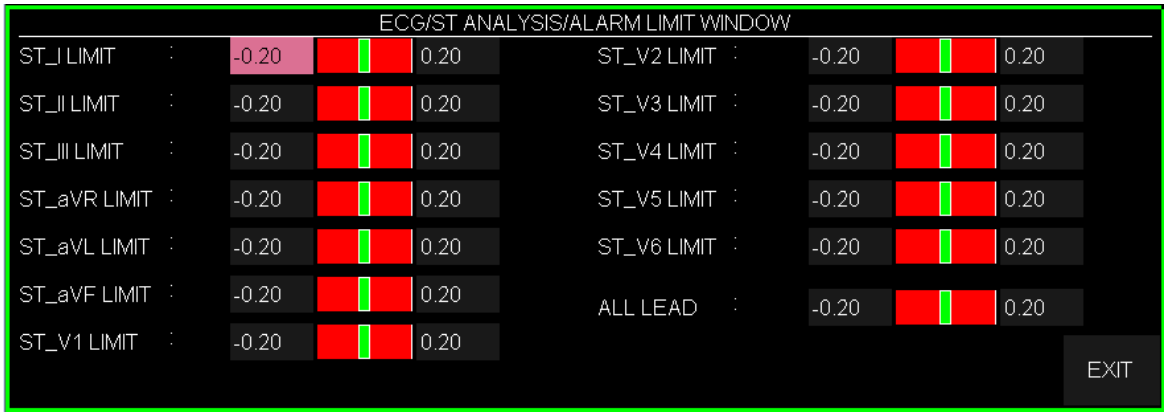
- **ST ANALYSIS window in 5/10 WIRES mode:**



- **ST ANALYSIS/ST LIMITS window in 5 WIRES mode:**



- **ST ANALYSIS/ST LIMITS window in 10 WIRES mode:**

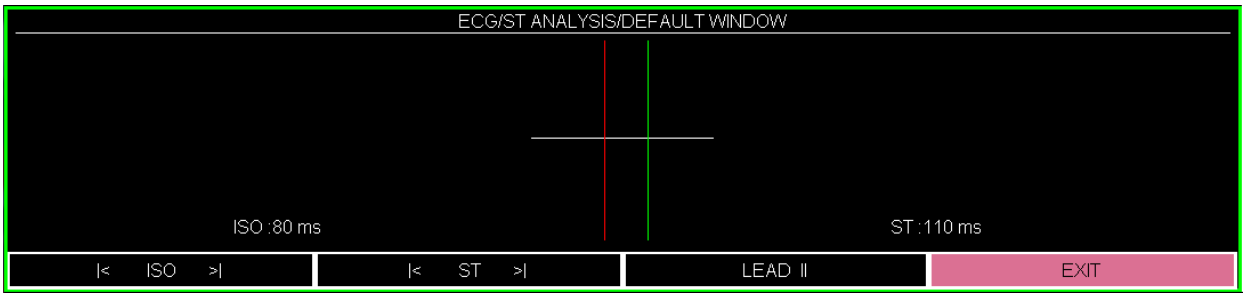


Event Duration

This item determines the time that a potential ST alarm condition must persist on ECG waveform before the monitor classifies it as a valid alarm condition.
Available options for EVENT DURATION are OFF, 15s, 30s, 45s and 60s.The default is 15s and alarm will be activated immediately if alarm condition happens.

7.5 DEFAULT POINT Window

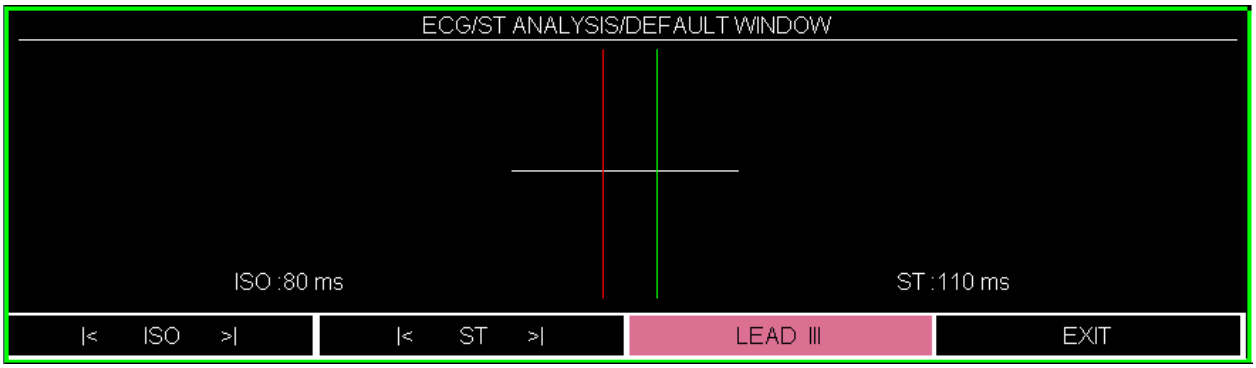
By selecting DEFAULT POINT from the ST ANALYSIS WINDOW, you can access the below window:



This window is used to adjust the position of both ISO and ST measurement points. When you change the ST and ISO measuring points on the DEFAULT POINT window, the monitor recomputes the ST deviation value accordingly.
As shown above, the DEFAULT POINT WINDOW shows the dominant QRS complex template. If the template is not established, a horizontal line will be displayed and if the ST ANALYSIS is “OFF”, the message “ST ANALYSIS KEY IS OFF” will appear in this window.

- **LEAD**

Select LEAD and turn the rotary knob to change lead.



- **ST, ISO**

You may select ISO or ST, and then switch the knob left or right to move the cursor line. When the cursor is at the intended position, you may select the base point or the measurement point for all leads.
Two vertical lines indicate the positions of the ISO and ST points.

- ➢ ISO: It is the base point used to indicate the baseline point of the ST analysis. The default is 80ms.
- ➢ ST: It is the ST measurement point. The default is 110ms.

Peak of R-wave is the reference point for ST calculation and changing range of ST and ISO are 5 to 400 ms by step of 5ms.

NOTE

- It is good clinical practice to check the position of ISO and ST measuring points before starting ST monitoring and completing learning procedure.
- In practice, accurate determination of ISO and ST measuring points requires careful clinical evaluation.
- The ST measurement point should be adjusted if patient's HR or ECG morphology changes significantly.
- If pace is ON (for patient with pacemaker) or during learning procedure, there is no waveform in DEFAULT POINT Window and you can see just ISO and ST lines. In this condition, ST value will not be measured.
- A red vertical marker with "CHG" label on ST in TREND window shows the time in which the measuring point has been changed.

7.6 ST Alarm Messages

a) Physiological alarm

The alarm occurs when ST value of a lead exceeds the adjusted alarm limits:

Physiological alarms	
Alarm	**Cause**
ST_... HIGH	ST segment value of a lead violates adjusted high limit.
ST_... LOW	ST segment value of a lead violates adjusted low limit.

b) Technical alarm

ST messages include:

Technical alarms			
Alarm	**Cause**	**Solution**	**Description**
ST_... OUT OF RANGE HIGH	The ST algorithm has calculated value +1mV outside the high limit of the ST measurement range.	● Check the ISO and ST measuring points. ●Observe the patient and treat if clinically indicated.	The alarm level is set in the relevant WINDOW.
ST_... OUT OF RANGE LOW	The ST algorithm has calculated value -1mV outside the low limit of the ST measurement range.	● Check the ISO and ST measuring points. ●Observe the patient and treat if clinically indicated.	

Chapter 8. RESP Monitoring

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8.1 GENERAL

The monitor measures respiration rate from the amount of thoracic impedance between two ECG electrodes RA-LL) corresponding to ECG Lead II (or RA-LA)corresponding to ECG Lead I). The change of impedance between the two electrodes (due to the thoracic movement) produces a respiratory waveform on the screen.
place of electrodes is important. Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of chest movement to optimize the respiratory waveform.

Patient Preparation

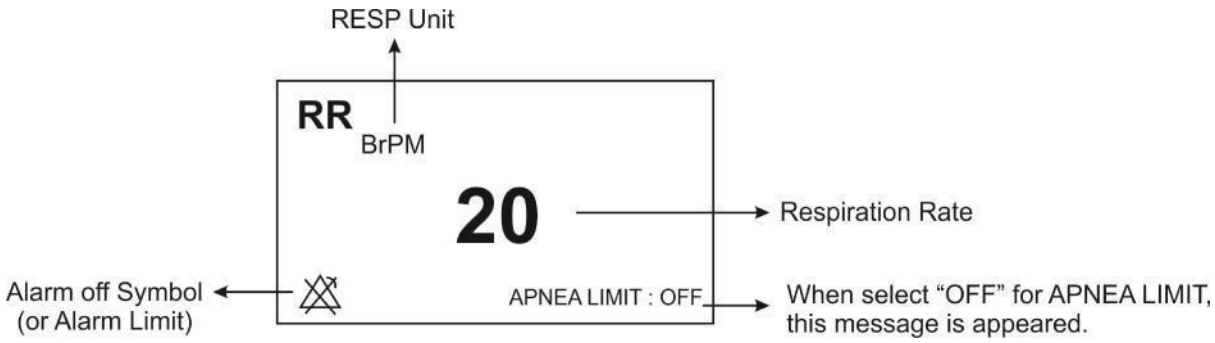
1. Prepare the patient's skin prior to placing the electrodes.
2. Attach the electrodes to the patient and attach snap or clip to the electrodes.
3. Switch on the monitor.

NOTE

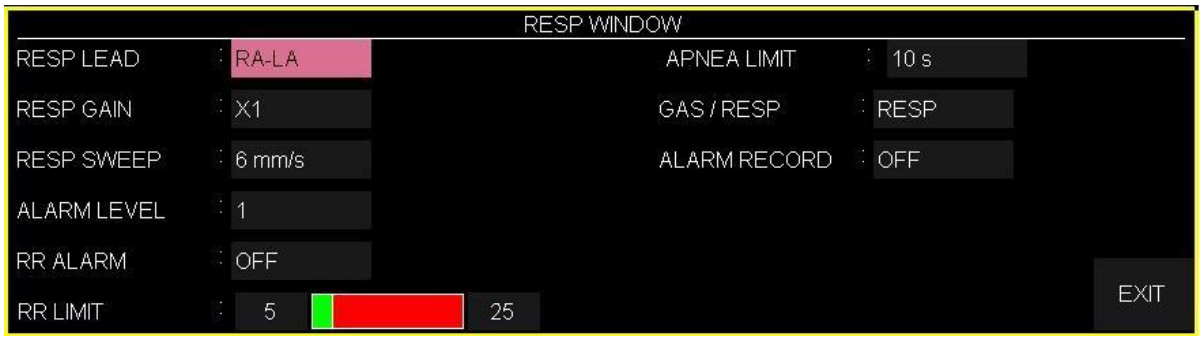
- **The RESP monitoring is not recommended to be used on patients, with extra movements, as this can cause false alarms.**
- **Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes to prevent cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.**

8.2 RESP WINDOW

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



Pick RESP to call up the following menu:



■ **RESP LEAD**

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

■ **RESP GAIN**

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

■ **RESP SWEEP**

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

■ **ALARM LEVEL**

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

■ **RR ALARM**

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

■ **RR LIMIT**

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

■ **APNEA LIMIT**

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

NOTE

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

■ **CAPNO/RESP**

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

■ **ALARM RECORD**

Pick "ON" to record the specified parameters once an alarm occurs (See the Recorder chapter).

8.3 RESP Alarm Messages

a) Physiological alarms

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

Physiological Alarms		
ALARM	**SITUATION**	**DESCRIPTION**
RR HIGH	Respiration rate violates adjusted high limit.	●RR value blinks ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.
RR LOW	Respiration rate violates adjusted low limit.	
APNEA	Non-respiration condition overruns adjusted time.	● The alarm indicator flashes. ●"RESP APNEA" is displayed in red background.

b) Technical alarms

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

Chapter 9, SPO2 and Rainbow Parameters Monitoring

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9.1 Introduction

Masimo SET® Pulse oximeter is a continues and non-invasive monitor that measures arterial oxygen saturation (SpO2), pulse rate (PR), Perfusion Index (Pi), and Pleth Variability Index (PVi®).

Some of the Masimo SET® Pulse oximeter modules also measure rainbow® parameters optionally including hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC™), methemoglobin (SpMet®) and oxygen reserve index (ORi™).

The Masimo SET® technology is designed by Masimo and only available to Masimo-approved Company.

The pulse oximetry accessory of this monitor includes the following parts:

1. Patient cable
2. Sensor

The sensor is placed on a thin part of the patient' body, usually a fingertip or earlobe, or in the case of an infant, across a foot. The connector of sensor is connected to the patient cable and finally, the patient cable is connected to the monitoring system.

SpO2 accessory: Sensor and patient cable (left to right)

Masimo Technology

Signal Extraction Technology ® (SET ®)

Signal Extraction Technology® (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).

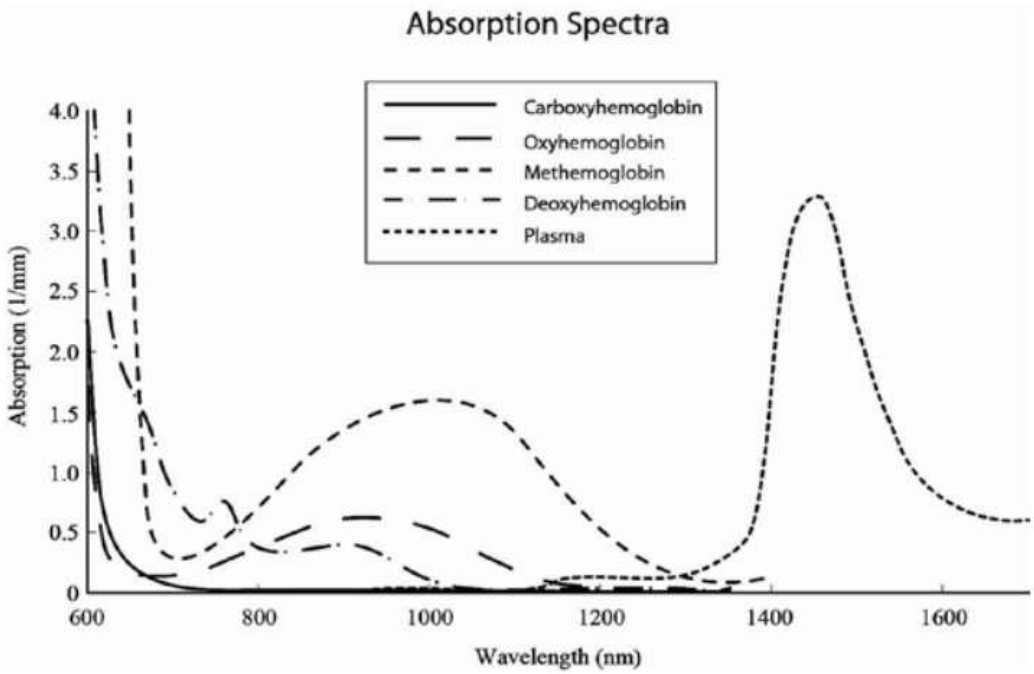
Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal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

Rainbow Pulse CO-Oximetry Technology®

Rainbow Pulse CO-Oximetry technology is governed by the following principles:

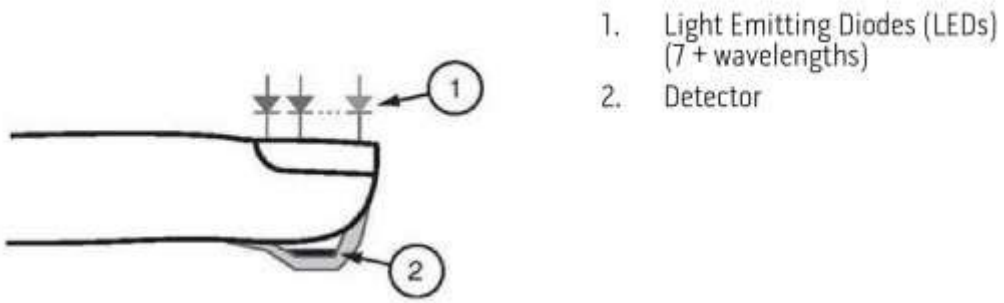
1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxhygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

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.



Absorption Spectra

A multi-wavelength sensor is used to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma. This sensor is utilized with various light-emitting diodes (LEDs) that pass light through the site to a photodiode (detector). Signal data is obtained by passing various visible and infrared lights (LED's, 500 to 1400 nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful for clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the module for calculation.



Light Emitting Diodes and Detector

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

NOTE

- **For Masimo patent information, please refer to the following address:**
  "www.masimo.com/patents.htm"

- **No Implied License**
  Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

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

- **A functional tester cannot be used to assess the accuracy of the Pulse CO-Oximeter.**

SpO2 Safety Information

Warning

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

- **Do not place the accessories in any position that might cause it to fall on the patient.**
- **Do not start or operate the pulse co-oximeter unless the setup was verified to be correct.**
- **Do not immerse sensor and patient cable completely in water, solvents, or cleaning solutions because the sensor and patient cable are not waterproof.**
- **Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.**
- **Do not use pulse co-oximeter during magnetic resonance imaging (MRI) or in an MRI environment. Induced current could potentially cause burns.**
- **Do not use the Pulse CO-Oximeter if it appears or is suspected to be damaged.**
- **Explosion hazard: Do not use the pulse co-oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.**
- **To protect against injury, follow the directions below:**
  - **-Avoid placing the device on surfaces with visible liquid spills.**
  - **-Do not soak or immerse the device in liquids.**
  - **-Do not attempt to sterilize the device.**
  - **-Use cleaning solutions only as instructed in this operator's manual.**
  - **-Do not attempt to clean the device while monitoring a patient.**
- **To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.**
- **The Pulse CO-Oximeter should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.**
- **The Pulse CO-Oximeter is not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.**
- **The pulse co-oximeter is not an apnea monitor.**

- **Do not adjust, repair, open, disassemble, or modify the Pulse CO-Oximeter or accessories. Injury to personnel or equipment damage could occur. Return the Pulse CO-Oximeter for servicing if necessary.**
- **Changes or modifications shall void the guaranty for the pulse co-oximeter accessories.**
- **The pulse co-oximeter should not be used for arrhythmia analysis.**
- **Do not place the monitoring system where the controls can be changed by the patient.**
- **Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect it from any power source.**
- **When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.**
- **Do not place the Pulse CO-Oximeter on electrical equipment that may affect the device, preventing it from working properly.**
- **If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.**
- **If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the instrument might read zero for the duration of the active irradiation period.**
- **To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the Pulse CO-Oximeter.**

NOTE

- **Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.**

9.2 Monitoring SpO2

- **Oxygen Saturation (SpO2):** The amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.
- **Pulse Rate (PR):** Measurement of beats per minute (BPM) based on the optical detection of peripheral flow pulse.
- **Perfusion Index (Pi):** The ratio of pulsatile blood flow to the non-pulsatile blood in peripheral tissue that allows clinicians to place sensors on optimal sites.
- **Pleth Variability Index (PVi):** The dynamic changes in PI during the respiratory cycle that can help clinicians predict fluid responsiveness in patients.

NOTE

- **For measuring PVi there is no need to use special or rainbow sensor but this is an optional parameter and it should be activated.**

SpO2 Measurement Limitations

The following factors may influence the accuracy of SpO2 measurement:

- Improper sensor application and placement
- Elevated levels of COHb[1] or MetHb[2]: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed
- Elevated levels of bilirubin[3]
- Elevated levels of dyshemoglobin
- Vasospastic disease, such as Raynaud's[4], and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Severe anemia
- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders

---

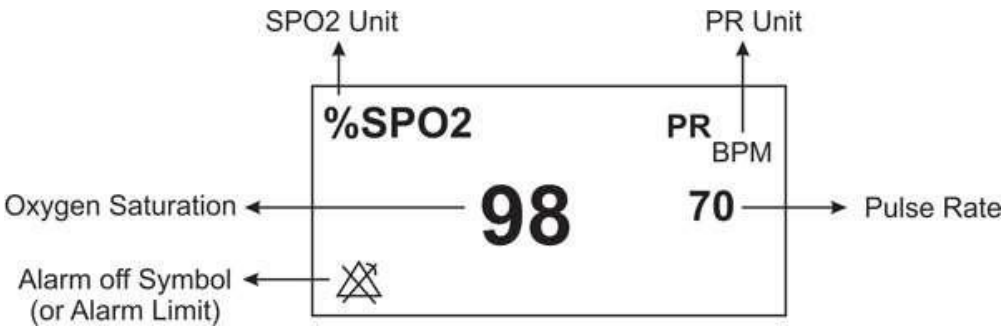
[1] MetHb
[2] COHb
[3] bilirubin
[4] Raynaud

Warning

- **The Pulse CO-Oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.**
- **The Pulse CO-Oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.**

SpO2 Parameters Display

The following items are displayed in SpO2 parameter display window:



SpO2 PARAMETER DISPLAY

NOTE

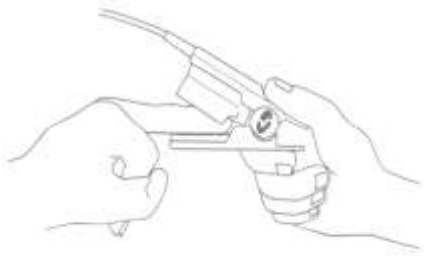
- **SpO2 value is always displayed in a fixed position of SpO2 window and Pulse Rate is displayed beside it, but if "HR SOURCE" is set to "SpO2", PR value will be eliminated from SpO2 window and displayed instead of HR value in the ECG WINDOW.**
- **The Pleth waveform is displayed as normalized waveform and its amplitude does not comply with real blood volume variations.**

- **User can be informed of inadequacy of signal and physiological parameters values by various messages and alarms in necessary situations.**
- **SpO2 module updates SpO2 and pulse rate values every 1 sec.**

Measuring SpO2

To monitor SpO2, follow this procedure:

1. Select an appropriate sensor according to the patient category and weight.
2. Remove colored nail polish from the application site.
3. Clean the contact of surface the reusable sensor.
4. Apply the sensor to the patient according to picture (The wire should be on the backside of the hand).



SPO2 sensor placement

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

Warning

- **If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse co-oximeter for proper functioning.**
- **Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.**
- **Use only the recommended manufacturer SpO2 sensor for monitoring. Other SpO2 sensors may cause monitor malfunction, thus operator is responsible to select an appropriate sensor before use.**
- **High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor and result in inaccurate measurements. To prevent interference from ambient light, cover the rainbow sensor with an ambient light shield.**
- **Verify sensor cable fault detection before monitoring. Unplug the SpO2 sensor cable from its socket, the screen will display the error message "SpO2 NO PROBE"**
- **To select the appropriate sensor, refer to the accessories chapter.**
- **Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion. See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.**
- **Tissue damage or inaccurate measurement can be caused by incorrect application or use of an SpO2 sensor, for example by wrapping the sensor too tightly or by applying supplemental tape.**
- **If "SpO2 LOW PERFUSION" message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.**
- **Change the application site or replace the sensor and/or patient cable when a "SPO2 REPLACE SENSOR" and/or "SPO2 REPLACE CABLE", or a persistent poor signal**

quality message (such as “SPO2 LOW SIGNAL IQ”) is displayed. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.

- The device must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.
- Replace the cable or sensor when “IQ SPO2 LOW SIGNAL” or “REPLACE SENSOR” or “REPLACE CABLE” message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

NOTE

- Make sure the nail covers the light window.
- Do not perform SpO2 and NIBP measuring in same arm simultaneously; because obstruction of blood flow during NIBP measuring may adversely affect the SpO2 value.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the Pulse CO-Oximeter to obtain vital sign readings.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Cables and sensors are provided with X-Cal technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.
- Materials used in our SpO2 sensors are innoxious.

Changing SpO2 Settings

The SpO2 Setting is as follows:

Setting the "SPO2 AVERAGE TIME"

The averaging time represents the approximate time period used for the calculation. The longer the averaging time, the longer the time needed until the SpO2 related values reflect the physiological event. Shorter averaging time is useful for situations where extremely fast responses of the measurements to changes are required or few artifacts are expected. Use longer averaging time where you expect the number of artifacts to be relatively high.

To set the SpO2 average time, follow this procedure:

1. In the SpO2 setting window, select AVERAGE TIME.
2. Select the required averaging time from the list. Available options are 2, 4, 8, 10, 12, 14 and 16.

Setting the "SPO2 PLETH SWEEP"

To set the SpO2 sweep speed of Pleth waveforms, follow this procedure:

1. In the SpO2 setting window, select SPO2 PLETH SWEEP.
2. Select the required sweep from the list. Available options for SpO2 PLETH SWEEP are 12.5 mm/s and 25 mm/s.

Setting the "ALARM LEVEL"

To set the SpO2 alarm level, follow this procedure:

1. In the SpO2 setting window, select ALARM LEVEL.
2. Select the required level from the list. Available options are 1 and 2 that level 1 represents the high level alarm.

Setting the “SPO2 ALARM”

To set the SpO2 alarm, follow this procedure:

1. In the SpO2 setting window, select ALARM LEVEL.
2. Pick "ON" to switch on SpO2 alarm functions such as parameters blinking, audio alarm, and light indicator. Pick "OFF" to switch off the alarm functions and there will be a"⚠"symbol in the Parameter Area.

Setting the “SPO2 LIMIT”

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

To set the SpO2 alarm limit, follow this procedure:

1. In the SpO2 setting window, select SPO2 LIMIT.
2. Set the Minimum and maximum of the SpO2 alarm limit.

Setting the “SpO2 SENSITIVITY MODE”

The sensitivity mode setting allows the clinician to adapt the SPO2 measurement sensitivity to the patient’s level of SPO2 signal strength and quality at the measurement site. The sensitivity levels are as follows:

- **NORM (Normal Sensitivity)**

NORM is the recommended for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).

- **APOD[1]**

APOD is the recommended where there is a high probability of the sensor becoming detached

[1] Adaptive Probe Off Detection® Sensitivity

due to excessive movement. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings. By selecting this mode, “SPO2 APOD MODE” appears on the screen with yellow color.

- **MAX (Maximum Sensitivity)**

MAX is recommended sensitivity mode for patients with low perfusion or when a low perfusion message displays in APOD or NORM mode. MAX mode is not recommended for care areas where patients are not monitored visually, such as general wards. In MAX mode, the message "SpO2 MAX SENS." displays on the screen with yellow color.

To set the SpO2 sensitivity modes, follow this procedure:

1.In the SpO2 setting window, select SPO2 SENSITIVITY MODE.
2.Set the sensitivity to MAXI, NORMAL, or APOD

Warning

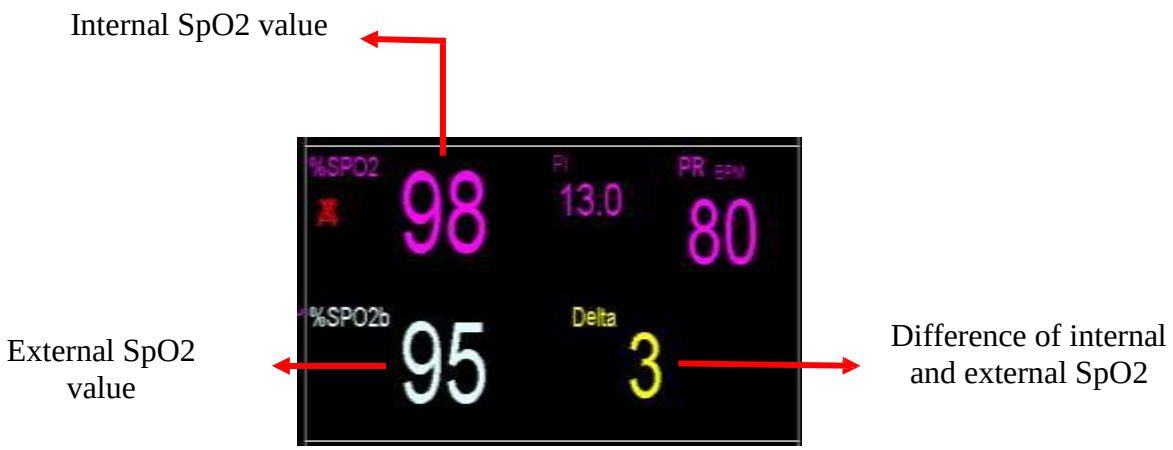
- **When using the Maximum Sensitivity setting, performance of the “Sensor Off” detection may be compromised. If the instrument is in the setting and the sensor become dislodged from the patient, the potential for false reading may occur due to environmental “noise” such as light, vibration, and excessive air movement.**
- **APOD mode is not advisable for patients with low perfusion because the system has the least sensitivity to signal changes in this mode.**

Dual SpO2

2 per 1000 infants are born with Persistent Pulmonary Hypertension syndrome (PPHN[1]/PDA[2]) . Dual SpO2 provides assessment of oxygenation in two points of newborn infant body at the same time. Through continuous pulse oximetry monitoring of two different points of premature infants body, early diagnosis of this congenital heart disease becomes possible.

This function is intended to be used specifically in NICU. To examine oxygenation status, sensors should be placed on the sites of the body that are influenced by ductus arteriosus. Right arm and leg are usually appropriate for this test. If the oxygen saturation (SpO2) difference in these two points is more than 10%, ductus arteriosus may occur.

In order to perform this examination, connect an external SpO2 module to the respective socket on the side panel of the device. The SpO2 window will be shown as below in the page 6 or 8:



Delta value is difference between SpO2 value measured by the external and internal modules. If the delta value is equal to 10, it will blink on the screen and if it is > 10, **(++)** will blink on the screen.

[1] Persistent Pulmonary Hypertension in the Neonate
[2] Patent ductus arteriosus

9.3 SpO2 Parameters Alarm Messages

Note: If both SpO2 modules are connected to the device, the same alarm messages will be displayed for them. To distinguish the alarm messages of these modules, "**EXT**" will be displayed beside the alarm messages of the external SpO2 module.

a) Physiological alarms

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

Physiological Alarms		
ALARM	**SITUATION**	**DESCRIPTION**
%SPO2 HIGH	SPO2 violates adjusted high limit.	●SPO2 value blinks. ●The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
% SPO2 LOW	SPO2 violates adjusted low limit.	
PR HIGH	Pulse rate violates adjusted high limit.	●PR value blinks. ●The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
PR LOW	Pulse rate violates adjusted low limit.	
PI HIGH	PI violates adjusted high alarm limit.	● PI value blinks. ● The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
PI LOW	PI violates adjusted low alarm limit.	
PVI HIGH	PVI value violates adjusted high alarm limit.	● PVI value blinks. ● The alarm indicator flashes.

PVI LOW	PVI value violates adjusted low alarm limit.	● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.

b) Technical alarms

Technical Alarms			
Alarm	**Cause**	**Solution**	**Description**
SPO2 NO CABLE	SpO2 cable is not properly connected to the patient monitor.	Make sure that the SpO2 cable is correctly connected to the monitor.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 NO AD* SENSOR	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	Ensure that the adhesive portion is firmly connected to the sensor.	
SPO2 NO SENSOR	SpO2 Sensor is not fully inserted into the connector.	Make sure that SpO2 sensor is correctly connected to the patient cable connector.	
SPO2 LOW SIGNAL IQ**	SpO2 measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	
SPO2 LOW PR CONFIDENCE	Pulse rate measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	
SPO2 LOW PI CONFIDENCE	PI measurement does not have confidence due to poor signal quality caused by excessive motion or	1-Assess the patient. 2-Check the sensor and ensure proper sensor application.	

Technical Alarms			
Alarm	**Cause**	**Solution**	**Description**
	other signal interference.	3-Change the sensor site.	
SPO2 LOW PVI CONFIDENCE	PVI measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	
SPO2 REPLACE CABLE	The life of the SpO2 cable has expired.	Replace the SpO2 cable.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 CABLE DEFECT	1. The SpO2 cable is damaged. 2. SpO2 cable is not compatible.	1. Make sure that the Masimo SpO2 cable is correctly connected to the monitor. 2.Turn the device on and off. If this message is displayed again, replace the cable.	
SPO2 REPLACE SENSOR	SpO2 sensor has used all its available monitoring time.	Replace the SpO2 sensor.	
SPO2 SENSOR DEFECT	1. The SpO2 sensor is damaged. 2. SpO2 sensor is not compatible.	1. Make sure that SpO2 sensor is properly attached to the cable connector. 2. Turn the device on and off. If this message is displayed again, replace sensor.	
SPO2 SENSOR OFF	1-SpO2 Sensor may be detached from the patient. 2-The sensor is not connected to patient properly. 3-The sensor is damaged.	1-Disconnect and reconnect the sensor to the patient. 2-Properly reapply the sensor on the patient and reconnect the sensor to the monitor or patient cable. 3-Replace the sensor.	
SPO2 REPLACE AD* SENSOR	When a single-patient-use sensor is used, the life of the adhesive portion of the sensor has expired.	Replace the adhesive portion of the sensor.	
SPO2 AMBIENT LIGHT	This may be caused by excessive ambient light sources such as surgical lights or direct sunlight, or other.	In the case of using rainbow sensor, place a Masimo Optical Light Shield over the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and

Technical Alarms			
Alarm	**Cause**	**Solution**	**Description**
SPO2 RAINBOW HARDWARE FAIL	SpO2 hardware error	Restore power to the instrument. If this message is displayed again, contact After sales service of the manufacturer.	the alarm is disabled and ignores this fault.
SPO2 PROBE DEFECT	Failure to properly operate the sensor or cable or both of them.	Check the function of the sensor and the cable separately and replace the defective part.	
SPO2 SENSOR CHECK CONNECTION	The sensor connection to the system is not correct.	Check the sensor connection and, if necessary, replace the sensor and/or cable.	

* AD SENSOR stands for Adhesive Sensor.

* SIGNAL IQ stands for Signal Identification and Quality Indicator.

C) Massages

Message	Cause	Solution
SpO2 CABLE NEAR EXP	The SpO2 cable is near expiration.	
SpO2 SENSOR NEAR EXP	The SpO2 sensor is near expiration.	
SpO2 AD* SENSOR NEAR EXP	The SpO2 adhesive sensor is near expiration.	
SpO2 SEARCH	The instrument is searching for pulse.	If instrument fails to display within 30 seconds, disconnect and reconnect the sensor. If pulse search continues, move the sensor to better perfused site.

SpO2 SIGNAL WEAK	The SPO2 signal amplitude is too weak or undetectable.	Change the place of the probe.
SpO2 DEMO MODE RUN	The SpO2 measurement is in demo mode.	
SpO2 ONLY MODE	Measuring rainbow parameters is not possible (due to the ambient light or the dark skin pigmentation).	Use a Masimo light shield to cover the sensor and adjust the sensor.

9.4 Monitoring Rainbow Parameters

Masimo rainbow SET technology provides the following optional measurements, in addition to the standard SpO2 measurement:

- **SpHb** measures the level of total hemoglobin in arterial blood. The unit of measurement is gram per deciliter (g/dL).
- **SpOC** calculates the levels of total oxygen content in the arterial 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 of oxygen per dL of blood (mL/dL).
- **SpCO** measures the levels of carboxyhemoglobin saturation (reflecting the blood levels of carbon monoxide bound to hemoglobin) in arterial blood.
- **SpMet** calculates levels of methemoglobin in the blood (Percentage of methemoglobin to total hemoglobin).
- **ORi:** a noninvasive and continuous parameter intended to measure patient's oxygen status. ORi is an index with unit-less scale between 0.00 and 1.00. This parameter can be considered as a supplement, not replacement, to SpO2/SaO2 and PaO2 parameters. ORi measures a

patient's oxygen reverse status in the moderate hyperoxic range (PaO2> 100 and ≤ 200 mm Hg).

Successful Monitoring for rainbow parameters

A stable reading of Co-oximetery parameters, including SpHb, SpOC, %SpMet and %SpCO are associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See Warnings and Cautions.

Measurement limitations

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

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Abnormal hemoglobin levels
- Low arterial perfusion
- Low arterial oxygen saturation levels including altitude induced hypoxemia
- Elevated total bilirubin levels
- Motion artifact

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

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated PaO2 levels
- Elevated levels of bilirubin[1]
- Low arterial perfusion

[1] Total bilirubin

- Motion artefact
- Low arterial oxygen saturation levels
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Vasospastic disease such as Raynaud's[1]
- Elevated altitude
- Peripheral vascular disease
- Liver disease
- EMI radiation interference

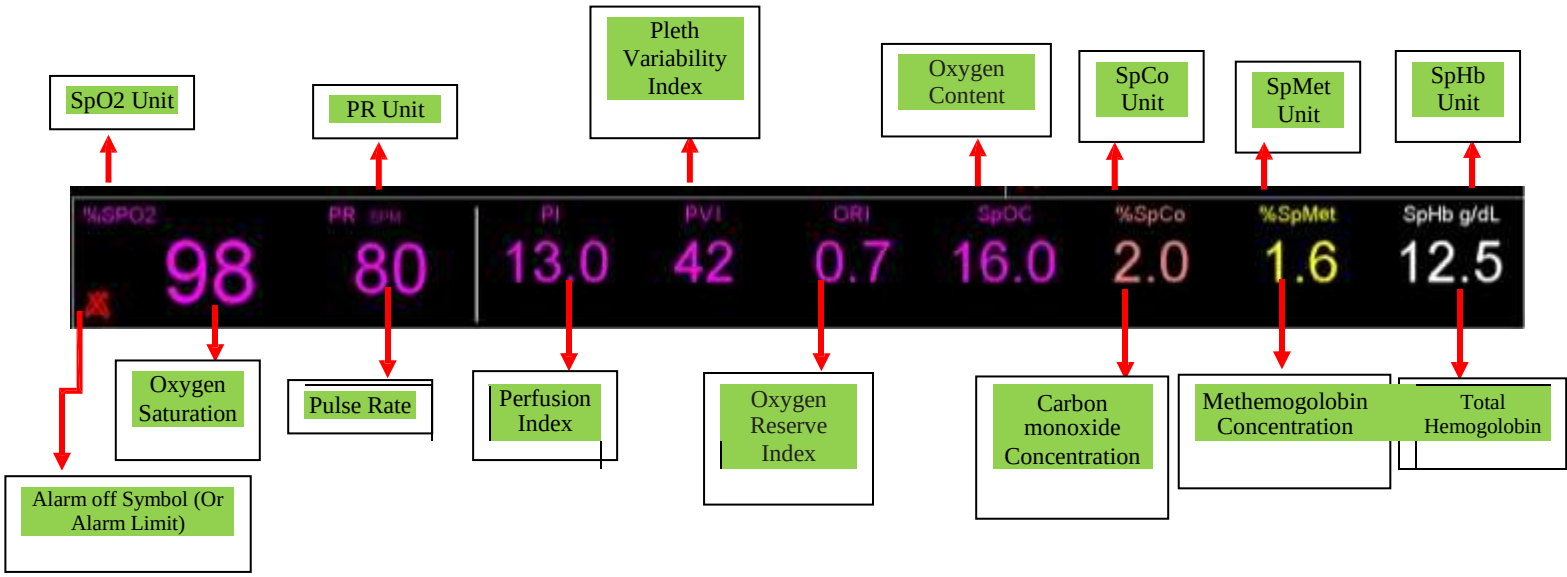
Warning

- **SpO2, SpCO, SpMet, and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).**
- **To avoid interference of ambient lights, place an optical shield over the Rainbow sensors.**
- **Variation in haemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any result exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory devices prior to clinical decision making to completely understand the patient's condition.**

[1] Raynaud's

Rainbow Parameters

Rainbow parameters are displayed in a special page for SpO2 and rainbow parameters:



Setting the "RAINBOW ALARMS"

You can change alarm limits of PI, PVI, SpOC, SpCO, SpMet, SpHb and ORi parameters in MASIMO ALARM window.

Warning

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

9.5 Rainbow Parameters Alarm Messages

a) Physiological alarms

The alarm occurs when Rainbow parameters values exceed the adjusted alarm limits.

Physiological Alarms		
ALARM	**SITUATION**	**DESCRIPTION**
SpOC HIGH	SpOC violates adjusted high limit.	● SpOC value blinks. ●The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
SpOC LOW	SpOC violates adjusted low limit.	
SpCO HIGH	SpCO violates adjusted high limit.	● SpCO value blinks. ●The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
SpCO LOW	SpCO violates adjusted low limit.	
SpMet HIGH	SpMet violates adjusted high alarm limit.	● SpMet value blinks. ● The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
SpMet LOW	SpMet violates adjusted low alarm limit.	
SpHb HIGH	SpHb value violates adjusted high alarm limit.	● SpHb value blinks. ● The alarm indicator flashes.

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

b) Technical alarms

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

Technical Alarms			
Alarm	**Cause**	**Solution**	**Description**
	by excessive motion or other signal interference.		

Chapter 10. NIBP Monitoring

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10.1 Introduction

The monitor uses the oscillometric method for measuring Non-Invasive Blood Pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall.
In this method, the cuff is pumped to a pressure higher than the systolic pressure, and then the pressure starts to decrease gradually. During pressure reduction, amplitude and pressure fluctuations are revealed. The amplitude of fluctuations initially has an upward trend. As the pressure decreases further, the fluctuation amplitude increases and reaches its maximum value at one point, which is considered as MAP pressure (pressure with maximum fluctuation amplitude). In the following, the amplitude of fluctuations decreases and eventually the fluctuations disappear. In the oscillometric method, the MAP pressure is detected and the systolic and diastolic pressures are revealed based on the MAP pressure.
NIBP monitoring is intended for adult, pediatric, and neonatal patients.

NOTE

- **Measuring blood pressure with this device in terms of accuracy is equivalent to invasive blood pressure measurement or measurements that are performed by a trained person by listening method.**
- **NIBP measurement can be performed during electro-surgery and discharge of a defibrillator.**

10.2 NIBP Safety Information

Warning

- **Make sure to select the correct patient category setting for your patient before NIBP measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise, it may lead to a safety hazard.**
- **If the neonate mode is used for adult or pediatric, the pressure measurement will be impossible because of the limitation of pumping in the neonate's mode.**
- **Do not measure NIBP on patients with inflammation or on the limb where skin damage has occurred or is expected.**
- **Do not measure NIBP if the tissue is damaged or is likely to be damaged.**
- **Use clinical judgment to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
- **The monitor may not operate correctly if used or stored outside the relevant temperature, altitude or humidity ranges described in the Performance Specifications.**

- **Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during the cuff inflation.**
  - **Do not apply cuff on the arm on the side of a mastectomy.**
  - **Continuous cuff pressure measurement due to connection tubing kinking may cause blood flow interference and result in harmful injury to the patient.**
  - **NIBP reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition. If you doubt the NIBP measurements, determine the patient's vital signs by alternative means, and then verify that the monitor is working correctly.**
  - **There is a possibility of purpura, ischemia, and neuropathy when the cuff is closed continuously on the tissue. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal colour, warmth and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site or stop the blood pressure measurements immediately. Check more frequently when making automatic or STAT measurements. Auto NIBP measurements with one and two minute intervals are not recommended for extended periods of time.**
  - **Do not modify or replace connectors of the NIBP air hose except with URUK-approved connectors. Use only recommended manufacturer Blood Pressure Cuffs and Hose. The use of other cuffs and hoses has a negative effect on the accuracy of the measurement.**
  - **Never connect intra-arterial or intra-venous lines, or any other incompatible connectors to the NIBP hose. This can cause serious injury or death.**
  - **NIBP diagnostic significance must be decided by the hospital's clinician staff.**
  - **Accuracy of NIBP measurement depends on using proper size of the cuff . It is essential to measure limb circumference and choose a cuff with proper size.**
    - **Selecting a very small size will increase the measured pressure.**
    - **Selecting a very large size will reduce the measured pressure.**

NOTE

- **Only use parts and accessories specified in this manual. Follow the instructions for use and adhere to all warnings and cautions.**

NIBP Measurement Limitations

Measurements are impossible with heart rate extremes of less than 30 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine. The measurement may be inaccurate or impossible in the following situations:

- Regular arterial pressure pulses are hard to detect
- Excessive and continuous patient movement such as shivering or convulsions
- Cardiac arrhythmias
- Rapid blood pressure changes
- Severe shock or hypothermia that reduces blood flow to the peripheries
- On an edematous extremity
- Obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.

NOTE

- **The performance of NIBP module in dialysis patients was evaluated and the results showed a reliable measurement of the NIBP module in theses patient.**

- **The performance of NIBP module in pregnant (including pre-eclampsia) patients was evaluated and the results showed a reliable measurement of the NIBP module in these patients.**

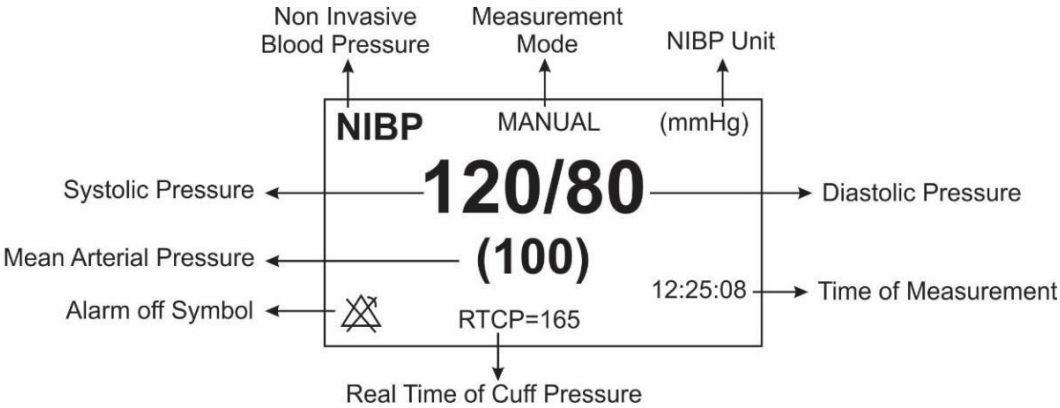
Measurement Modes

There are three NIBP measurement modes:

- Manual: measurement on demand.
- Auto: repeated measurements at set interval.
- STAT: continual rapid series of measurements over a five-minute period.

10.3 NIBP WINDOW

The NIBP window shows only numeric parameter.



NOTE

- **If NIBP measurement fails, "?" is displayed. If NIBP measurement is not taken or NIBP measurement exceeds the measurement ranges, "--" is displayed.**

10.4 Preparing for NIBP Measurements

Preparing the Patient for NIBP Measurements

In normal use, perform NIBP measurement on a patient who is in the following position:

- Comfortably seated
- Legs uncrossed
- Feet flat on the floor
- Back, arm and feet supported
- rest for five minutes before reading the pressure.

NOTE

- **It is recommended that the patient remains calm and relaxes as much as possible before performing the measurement and that the patient does not talk during the measurement.**
- **Other factors that result in an overestimation of blood pressure are labored breathing, full bladder, pain etc.**

Placing the NIBP Cuff

To place the NIBP cuff, follow this procedure:

1.Verify that the patient category setting is correct.
2.Connect the air tubing to the NIBP connector on the NIBP module. Make sure the cuff hose is not twisted or clogged.
3.Select an appropriately sized cuff for the patient, and then wrap it around the limb directly over the patient's skin as follows:

a. Measure the patient's limb circumference.
b. Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the length of the upper arm or the thigh. The inflatable part of the cuff should be long enough to encircle to overlap at least 50% to 80% of the limb.
c. Apply the cuff to the patient's upper arm or leg and make sure the cuff and artery are aligned.
d. The cuff should fit snugly, but with enough room for two fingers to be placed between the cuff and the patient's arm (on adults), and loosely on neonates with little or no air present within the cuff. Otherwise it may cause discoloration and ischemia of the extremities. Make sure that the cuff index line falls within the range markings on the cuff. If it does not, use a cuff that fits better.
e. Middle of the cuff should be at the level of the right atrium of the heart. If it is not, use the measurement correction formula to correct the measurement.
f. Connect the cuff to the air tubing. Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.

Warning

- **Do not touch or apply external pressure against the cuff and air tubing during NIBP measurement. This may cause inaccurate blood pressure values.**
- **Take care when placing the cuff on an extremity used for monitoring other patient parameters.**

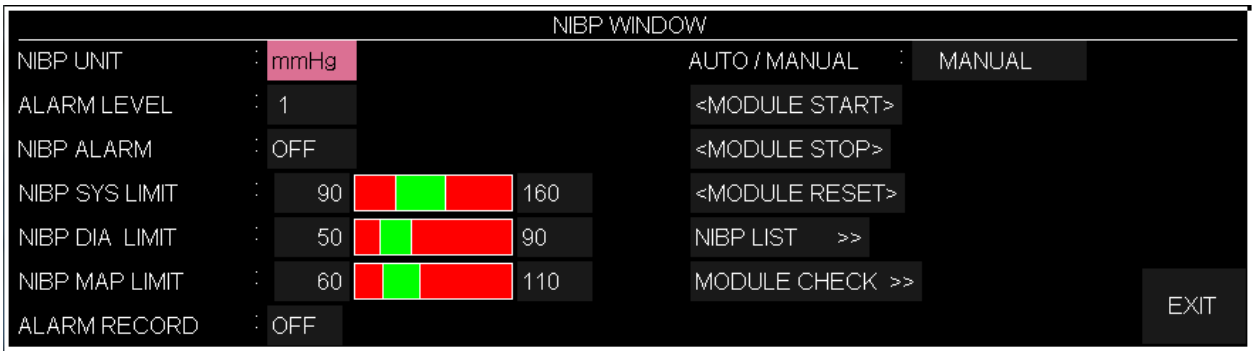
Starting and Stopping NIBP Measurements

Start and stop NIBP measurement using NIBP quick keys or through the NIBP window.

Task	Quick key	NIBP window
Start a Manual measurement	Start/ stop button on the front panel	Module start
Start Auto NIBP series	Start/ stop button on the front panel Set the measurement intervals through the NIBP window	Module start
Start STAT measurement	Start/ stop button on the front panel	Module start
Stop the current NIBP measurement	Start/ stop button on the front panel	Module stop
Stop Auto NIBP measurement	Start/ stop button on the front panel	Module stop
Stop STAT measurement	Start/ stop button on the front panel	Module stop

Changing NIBP Settings

The NIBP window is as follows:



Setting NIBP UNIT

To set NIBP UNIT, follow this procedure:

- Enter the NIBP setting window.
- Select NIBP UNIT. Available options for this item are: mmHg and KPa.

Enabling NIBP Alarm

To set the NIBP alarm, follow this procedure:

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

Setting NIBP Alarm level

To set NIBP alarm level, follow this procedure:

- Enter the NIBP setting window.
- Select the NIBP ALARM.
- Set the alarm level as desired (selectable between 1 and 2). Level 1 represents the high level alarm.

Setting NIBP SYS LIMIT

To set NIBP sys alarm limit, follow this procedure:

- Enter the NIBP setting window.
- Select NIBP SYS LIMIT and set it.

Setting NIBP DIA LIMIT

To set NIBP dia alarm limit, follow this procedure:

- Enter the NIBP setting window.
- Select NIBP DIA LIMIT and set it.

Setting NIBP MAP LIMIT

To set NIBP map alarm limit, follow this procedure:

- Enter the NIBP setting window.
- Select NIBP MAP LIMIT and set it.

Setting NIBP mode

To set NIBP mode, follow this procedure:

- Enter the NIBP setting window.
- Select AUTO/ MANUAL. Available options are AUTO or MANUAL or STAT.

NOTE

- **In the MANUAL mode, only one measurement is performed. In the AUTO mode, measurement is repeated over a specified period of time; available intervals are 1,2,3,5,10,15,20,30,45, 60, 90 minutes and 2, 4, 8, 12,16,20,24 hours. In STAT mode, the measurement is performed up to ten times within 5 minutes with 30s interval between measurements. If an error occurs, the NIBP measurement is suspended.**

MODULE RESET

To reset the module, follow this procedure:

- Enter the NIBP setting window.
- Select MODULE RESET. By selecting this option, the maximum initial inflation pressure is set to 150 mmHg in adult mode, 140 mmHg in pediatric mode and 85 mmHg in neonate mode.

NOTE

- **The initial inflation pressure in the first measurement is 150 mmHg in adult mode, 140 mmHg in pediatric mode and 85 mmHg in neonate mode. In the second measurement, the initial inflation pressure depends on the previously measured pressure (30 mmHg higher than the last systolic reading in previous measurement).**

Warning

- **Since in measuring blood pressure, the initial inflation pressure depends on the previously measured pressure, it is better to select module reset option in the setting window when changing the patient to maintain the comfort of the patient.**

View NIBP LIST

To view NIBP list:

- Enter the NIBP setting window.
- Select NIBP LIST. You can view the result and time of the latest NIBP measurements. The patient monitor can store the latest 500 NIBP measurements data.

NIBP / NIBP LIST WINDOW

NIBP	DATE	TIME	SYS	DIA	(MAP)	PULSE
213	22-09	10:43	121	82	98	80
212	22-09	10:43	121	82	98	80
211	22-09	10:43	121	82	98	80
210	22-09	10:43	121	82	98	80
209	22-09	10:43	121	82	98	80
208	22-09	10:43	121	82	98	80
207	22-09	10:43	121	82	98	80
206	22-09	10:43	121	82	98	80
205	22-09	10:43	121	82	98	80
204	22-09	10:43	121	82	98	80
203	22-09	10:43	121	82	98	80
202	22-09	10:43	121	82	98	80
201	22-09	10:43	121	82	98	80
200	22-09	10:43	121	82	98	80
199	22-09	10:43	121	82	98	80
198	22-09	10:43	121	82	98	80

▼——▲ | UP - DOWN | DELETE | RECORD | EXIT

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

NIBP TESTS

To perform the NIBP module tests, follow this procedure:

- Enter the NIBP setting window.
- Select MODULE CHECK.
- By select this item, the respective menu opens after 5 seconds delay. Available options are “NIBP MANOMETER” (a test mode to verify the calibration of the module), “NIBP LEAKAGE” (a test mode for leakage test), “MODULE SELF TEST” (check the general status of the NIBP module, including the function of sensors and valves) and “MODULE STOP”.

Warning

- **The tests of Module Check section must only be carried out by trained and authorized personnel.**

10.5 NIBP Alarm Messages

a) Physiological alarms

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

Physiological Alarms		
ALARM	**SITUATION**	**Solution**
NIBP SYS/ DIA/ MAP HIGH	The NIBP SYS/ DIA/ MAP value exceeds the alarm high limit.	•Check the patient's condition •check if the alarm limit settings are correct
NIBP SYS/ DIA/ MAP LOW	The NIBP SYS/ DIA/ MAP value exceeds the alarm low limit.	•Check the patient's condition •check if the alarm limit settings are correct

b) Technical alarms

Technical alarms		
Alarm	**Cause**	**Solution**
SELF-TEST FAILED	The NIBP hardware module failure.	•Select the module reset option in the settings window. If the problem persists, contact after-sales service.
NIBP LOOSE CUFF	There is a leak in the cuff or air tubing.	•Choose a cuff with the appropriate size for the patient and attach the cuff to the patient correctly.
NIBP MODE ERROR	The cuff type mismatches the patient category.	•Check the selected patient group on the device and change the set mode if necessary. •If the patient mode is selected correctly, check the cuff and replace the cuff if necessary. • Check that the air hose is not kinked and that the airway is not obstructed.
NIBP AIR LEAK	Air leak in cuff, tube or connector.	•Check the NIBP cuff, tube or connector for leakages.
NIBP AIR PRESSURE ERROR	The air tubing may be occluded.	•Check the air tubing for an occlusion or kinking. If the alarm persists, contact your service personnel.

Technical alarms		
Alarm	**Cause**	**Solution**
NIBP SIGNAL WEAK	The patient's pulse is weak or the cuff is loose.	•Check the patient's condition and change the cuff application site.
NIBP RANGE EXCEED	Measuring pressure is more than upper limit (255mmHg) for adult or (135mmHg) for neonate.	•Check the patient's condition.
NIBP EXCESSIVE MOTION	Arm movement, noisy signal or irregular pulse (e.g. arrhythmia).	•Check the patient's condition and reduce patient motion.
NIBP OVER PRESSURE SENSED	Measured pressure exceeds safe software limit, 290 mmHg for adult, 240 mmHg for pediatric and 150 mmHg for neonate).	•The NIBP airway may be occluded. Check the airway and measure again. If the alarm persists, contact your service personnel.
NIBP PNEUMATIC LEAK	Airway leakage is found during the NIBP leakage test.	•Check the NIBP cuff and pump for leakages.
NIBP TIME OUT	Measurement time exceeds 3 minutes for adults and pediatric or 90 seconds for neonates. and the BP value cannot be obtained.	•Check the patient's condition and NIBP connections, or replace the cuff and measure again.
SYSTEM FAILURE	Error occurs in pump, A/D sampling, pressure transducer or software.	•Select the module reset option in the settings window. If you see it again, contact the after-sales service.
NIBP NO MODULE	No NIBP module has been installed.	•Contact your service personnel.
NIBP LOW BATTERY	The battery charge is not enough to measure NIBP.	•Connect the system to the power supply or put a fully charged battery in the system.

c) Messages

NIBP MESSAGES	
Message	**Cause**
NIBP STOP PRESSED	The NIBP stop key is pressed during the measurement.

NIBP LEAKAGE O.K	Successful leakage test.

Chapter 11, TEMP Monitoring

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11.4 TEMP ALARM MESSAGES.....5

11.1 GENERAL

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

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

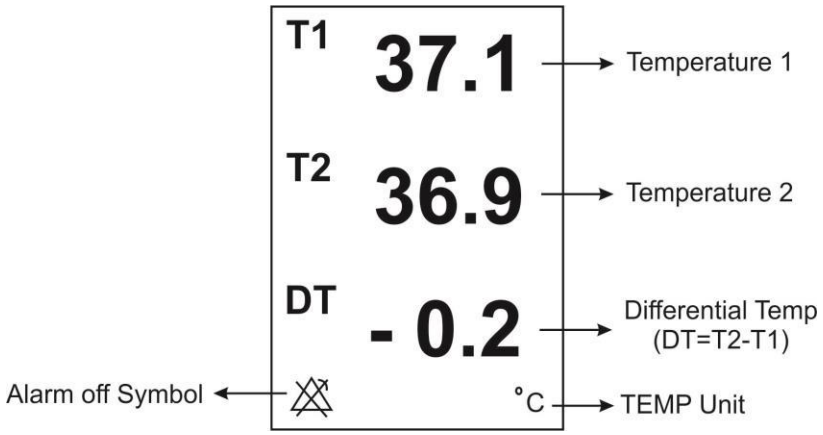
Specifications	
Dynamic Range	0-50 ºC
Accuracy	0±0.2 ºC
Measuring delay for Rectal/Esophageal Probe	50 Secs
Measuring delay for Skin Probe	20 Secs

TEMP monitoring setup:

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

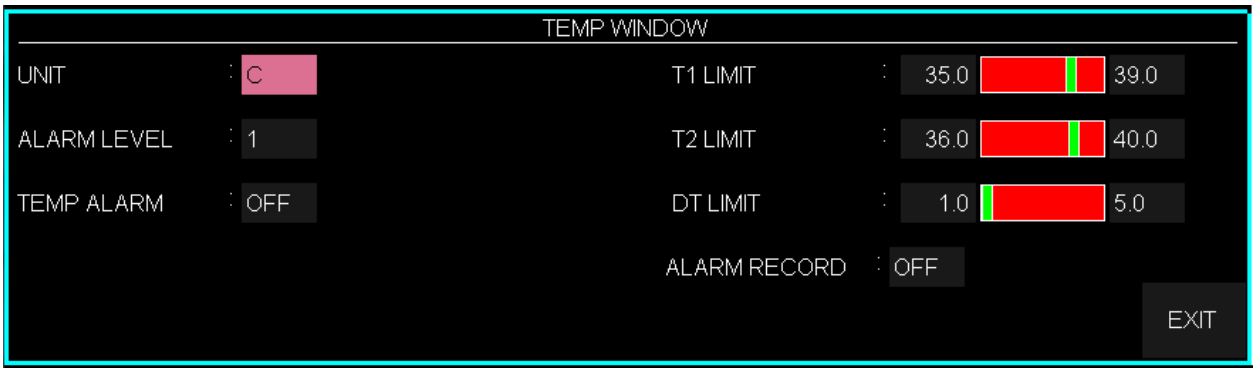
11.2 TEMP WINDOW

The following items are displayed in TEMP parameter window.



TEMP PARAMETER WINDOW

The TEMP WINDOW is as follows:



■ **UNIT**

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

■ **ALARM LEVEL**

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

■ **TEMP ALARM**

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

■ **T1 LIMIT**

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

■ **T2 LIMIT**

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

■ **DT LIMIT**

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

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

11.3 TEMP Measurement using Ario Thermometer

Ario thermometer could be connected to the device as an external module and used to measure the patient temperature. The measured temperature is displayed in the TEMP window as T2.

NOTE

- **If both Ario thermometer and T2 sensor are connected to the device, firstly the measured value by the Ario will be displayed on the screen.**
- **The measured temperature value by the Ario will remain on the screen until new measurement is taken.**
- **For more information about measurement technique of the Ario thermometer, please refer to Operator's manual of this device.**

11.4 TEMP ALARM MESSAGES

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

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

Inspection and recalibration

Visually inspect the probe for cracks, holes, crazing etc, prior to each use. If any such degradation in the cable jacket is discovered, discard probe according to your hospital's procedure for medical waste. When using temperature probe, the user must determine that a probe style is suitable and sufficiently flexible for esophageal or rectal use.

Probe cannot be "recalibrated" per se, but should be inspected monthly by the hospital Biomedical Equipment group to ensure they are working properly. Probes can be tested by plugging into a patient monitor and looking for an electrical open or short–circuit, Intermittent reading or extremely inaccurate readings which would indicate probe wire damage. The sensor stability is well-documented; Probe accuracy should not drift out of tolerance over the normal life of probe.

Warning

- **Use only the recommended manufacturer TEMP probe for monitoring, other probes may cause system malfunction.**
- **Using ESU with temperature measurement simultaneously may cause patient burn. If possible, remove the probe from patient contact before activating the surgical unit or other RF source. If probe must be used simultaneously with electrosurgical apparatus, hazards can be reduced by selecting a temperature monitoring point which is remote from the expected RF current path to the ground return pad.**
- **Over straining will result in mechanical damage of the probes.**
- **The temp probes should be calibrated every two years or according to hospital calibration schedule. Contact After Sale Service to perform probe calibration.**

NOTE

- **Please be noted that the metal side of probe should be used for making measurements.**
- **The temperature probes carry a one-year warranty on workmanship, components and accuracy tolerances. Probe life with normal use should exceed one year.**

Chapter 12, IBP Monitoring

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12.1 Introduction

In Invasive Blood Pressure (IBP), blood pressure pulses are transmitted through a cannula needle and sterile fluid to a sensor (elastic diaphragm) and converted into an electrical signal. Blood pressure has a maximum value (Systole: SYS) and a minimum value (Diastole: DIA).
The patient monitor measures direct blood pressure (Systolic, Diastolic and Mean) of the selected blood vessel through two channels, and displays two IBP waveforms. It has the ability of measuring four channels and displaying changes in these pressures.

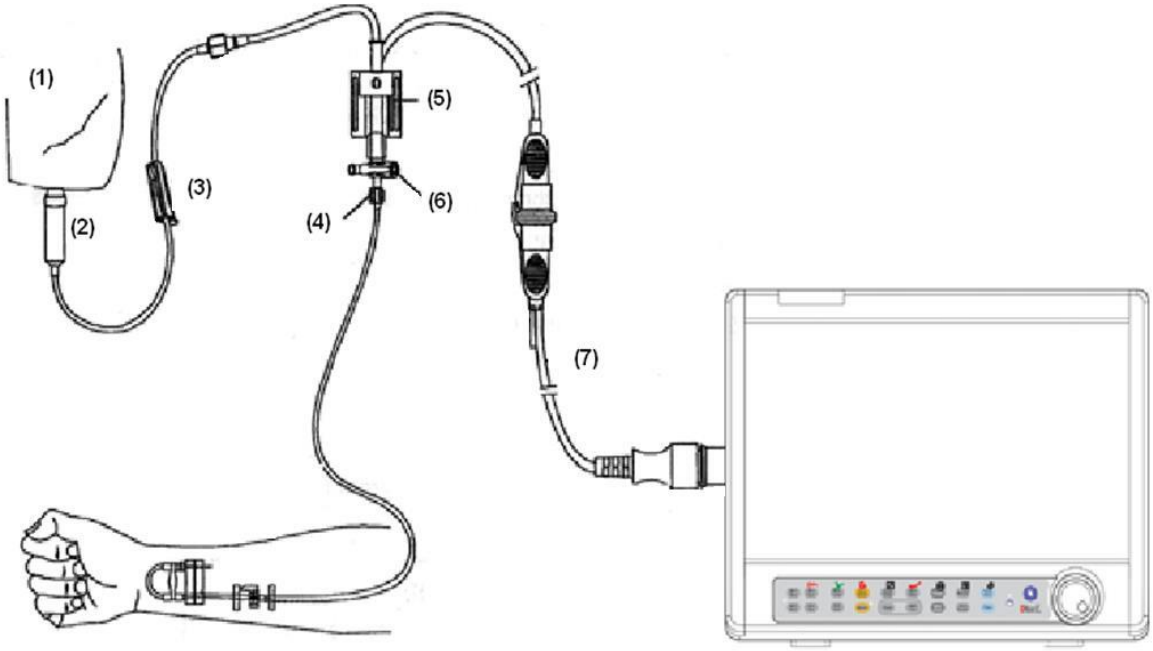
Warning

- **The operator should avoid contacting with the conductive parts of the system when being applied.**
- **When using ESU (Electrosurgery equipment), the transducer and the cables should not contact with the conductive part of ESU to protect patient against burns.**
- **Disposable IBP transducer or domes should not be reused.**
- **Before using dome, make sure that its package is safe and check its expiry date.**
- **Do not use the sterile supplied IBP transducers if the packaging or the transducer is damaged and return them to the vendor.**
- **Verify transducer cables fault detection prior to the start of monitoring phase. Unplug the transducer of the channel 1 from the socket, the screen will display the error message "IBP1 NO SENSOR" and the audible alarm is activated with level 2. Next channel is the same.**

NOTE

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

12.2 IBP equipment connection



1. Normal salin with Heparin
2. Drip chamber
3. valve
4. Distal end to patient
5. 3-way stopcock
6. Pressure Transducer
7. Pressure transducer interface cable

12.3 Preparatory steps for IBP measurement

1. Plug the pressure cable into corresponding socket.
2. Prepare the pressure tube and transducer by flushing through the tubing system with normal saline solution. Ensure that the tubing system is free of air bubbles.
3. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.
4. Place the transducer at the same level with the patient's heart.
5. Check if you have selected the correct label name.
6. Zero the transducer.

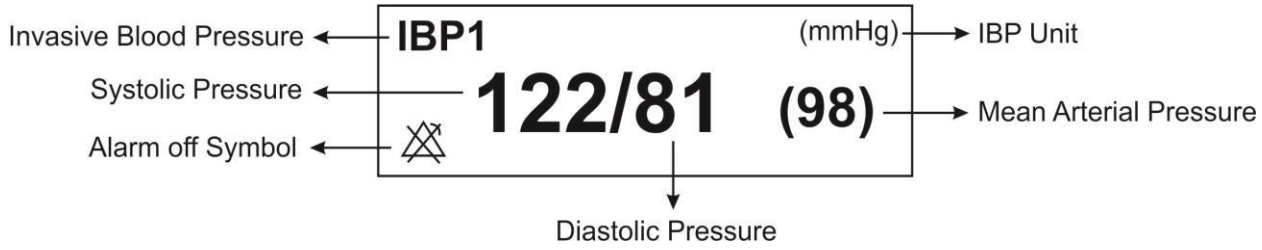
7. After successful zeroing, close the three-way valve from the air and open it to the patient.

Warning

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

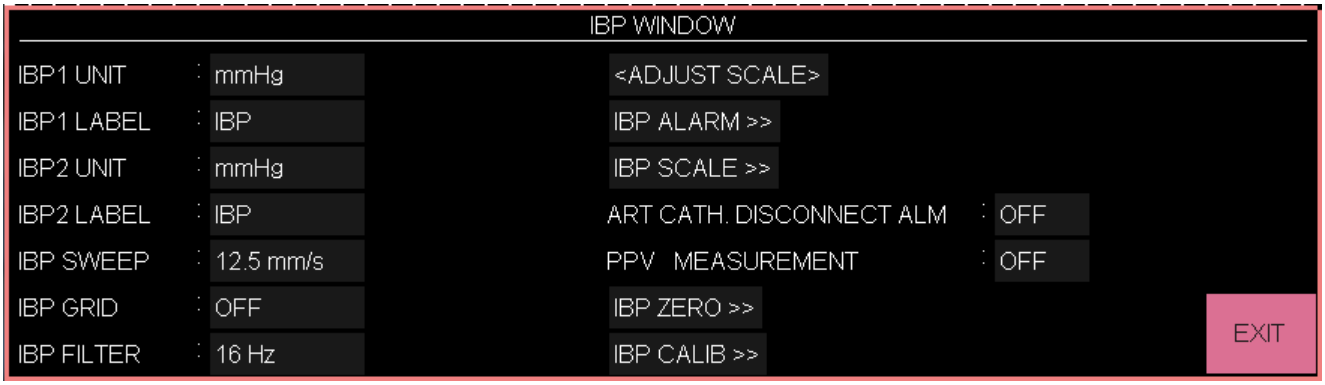
12.4 IBP window

The following items are displayed in IBP parameter window.



Changing IBP settings

IBP WINDOW is as follows:



Setting IBP unit

To set the IBP UNIT, follow this procedure:

- Enter the IBP settings window.
- Select IBP UNIT. There are three options to choose: mmHg, KPa, cmH2O

Setting IBP LABEL

To set the IBP measurement site, follow this procedure:

- Enter the IBP settings window.
- Select IBP LABEL. See the available labels in the table below:

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

Warning

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

NOTE

- **In open heart surgery, by stopping the heart, the patient enters the PUMP state. In this situation, you must enter PUMP PAGE and set the label to CVP (For more information, see page configuration in the configuration chapter).**

Setting IBP SWEEP

To set the speed of signal sweeping on the screen, follow this procedure:

- Enter the IBP settings window.
- Select IBP SWEEP. Available options are 3, 6, 12.5 and 25 mm/s.
-

Enabling IBP GRID

You can divide each IBP signal display area into 5 equal sections by white dot lines. For this purpose, follow this procedure:

- Enter the IBP settings window.
- Turn ON “IBP GRID” .

Setting IBP FILTER

Filters are used to have a more clear and detailed waveform. To set IBP filters, follow this procedure:

- Enter the IBP settings window.
- Select IBP FILTER. Available options are 22Hz, 16Hz, and 8Hz.

  - 22Hz: Recommended in normal use and most of clinical situations. It has the highest measurement accuracy among the called filters.
  - 16Hz: When the signal is a bit noisy.
  - 8Hz: This mode is recommended to reduce noise and interface resulted from ESU and also when the system has a high noise level or doesn’t have equipotential earth. Using this filter might decrease the measuring accuracy.

Enabling IBP ADJUST SCALE

To return out of range signal to the screen, follow this procedure:

- Enter the IBP settings window.
- Enable “IBP ADJUST SCALE”. Clicking on this item will place three scale dotted lines automatically on the best position and the scales are adjusted in a way that IBP signal occupies minimum 80% of IBP waveform area.

Enabling IBP ALWAYS AUTO SCALE

Set ON this item to adjust the scale automatically. This item is applicable when there are large pressure variations and IBP signal exceeds the defined scale.
Therefore, if the signal deviates from the display range, the display range will be adjusted automatically in a few seconds and the signal will be visible.
When the ALWAYS AUTO SCALE is set ON, The following changes will be made:

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

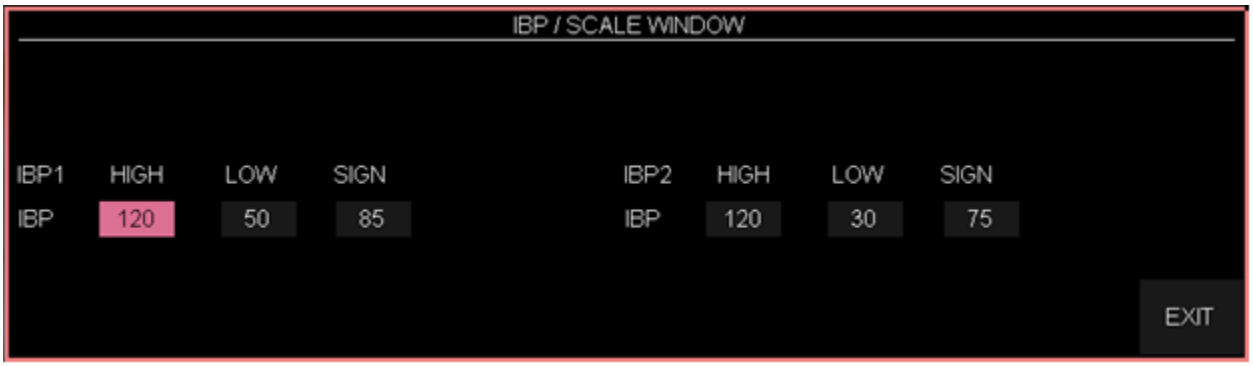
Warning

Since the scale is not displayed in ALWAYS AUTO SCALE mode, if the physician does not pay attention to SYS, DIA and MEAN values , decrease or increase in pressure may not be recognized from the signal morphology and lead to a misdiagnosis.

Setting IBP SCALE

You can set high, sign and low scale values (the three dotted lines) manually or automatically as below:

- Enter the IBP settings window.
- Select IBP SCALE to access the following window:

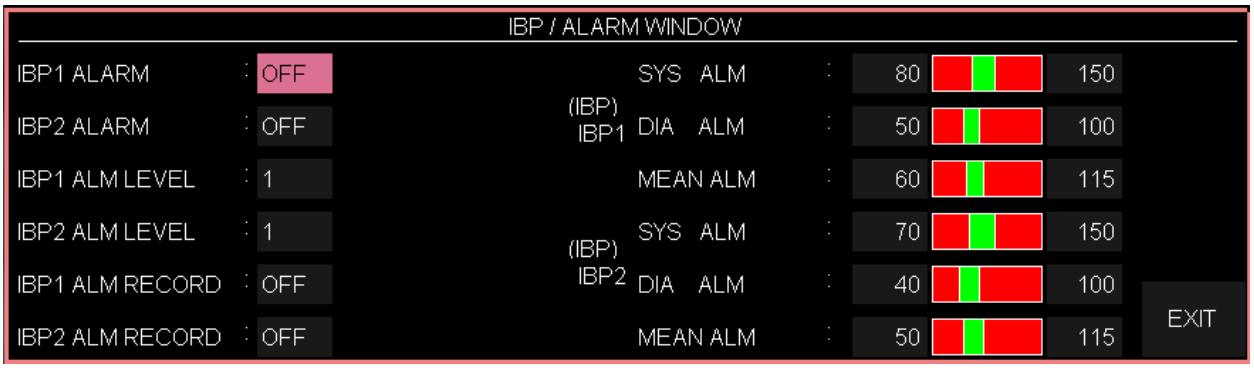


- Make your desired settings as shown in the above figure.

Enabling IBP ALARM and setting ALARM limits

To enable IBP alarm and set the alarm limits, follow this procedure:

- Enter the IBP settings window.
- Select IBP ALARM to enter Alarm window.



- **Enabling IBP ALARM**

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

- **Setting IBP ALM LEVEL**

Select this item to set the alarm level for each label. Available options are 1 and 2. Level "1" is the most serious alarm.

- **Enabling IBP ALM RECORD**

Enable this item to record signal upon an alarm occurrence.

- **Setting SYS ALM**

Select this item to set the upper and lower alarm limits of the systolic pressure.

- **Setting DIA ALM**

Select this item to set the upper and lower alarm limits of the diastolic pressure.

- **Setting MEAN ALM**

Select this item to set the upper and lower alarm limits of the mean pressure.

NOTE

- **Note that CVP, LAP, RAP and ICP labels are applied only for the Mean pressure.**

Warning

- **Make sure that the alarm limits are set correctly for each label. The alarm limits you set are stored only for that particular label. Changing the label will change the alarm limits.**

Enabling ART CATH. DISCONNECT ALM

To enable the alarm of arterial catheter disconnection, follow this procedure:

- Enter the IBP settings window.
- Set ART CATH. DISCONNECT ALM to ON.

If the catheter is disconnected from the patient during the arterial pressure measurement, “IBP CATHETER DISCONNECT” alarm will be triggered with level 1within maximum 10 seconds.

Symptoms of the catheter disconnection are as follows:

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

NOTE

- **To activate the catheter disconnection alarm, the label must be set to ART or IBP and the ART CATH DISCONNECT must be ON.**

Enabling PPV parameter

The Pulse Pressure Variation (PPV) is a dynamic indicator of pulse pressure fluctuations and is used to diagnose fluid volume and optimizes it in mechanically ventilated patients (in cardiac surgery or in intensive care unit). This index is obtained from the beat-to-beat arterial waveform (label: ART).
Pulse Pressure Variation (PPV) is calculated from beat-to-beat arterial pressure values. Pulse pressure is the difference between the systolic and the diastolic pressure values for a single beat.

Pulse pressure variation is defined as the maximum pulse pressure less the minimum pulse pressure divided by the average of the two. The average variation in pulse pressure is calculated over periods of 30 seconds.

Warning

- **This monitor can calculate PPV using beat-to-beat values of any arterial pulsatile pressure. The circumstances under which PPV value is calculated is clinically meaningful and its appropriateness and reliability must be determined by a physician. The clinical value of the derived PPV information should be determined by a physician. According to recent scientific literature, the clinical relevance of PPV information is restricted to sedated patients under controlled mechanical ventilation and free from cardiac arrhythmia.**
- **PPV calculation may lead to inaccurate values in the following situations:**
  - **at respiration rates below 8 rpm**
  - **during ventilation with tidal volumes lower than 8 ml/kg**
  - **for patients with acute right ventricular dysfunction ("cor pulmonale").**
- **The PPV measurement is validated only for adult patients.**

To enable PPV diagnostic parameter, follow this procedure:

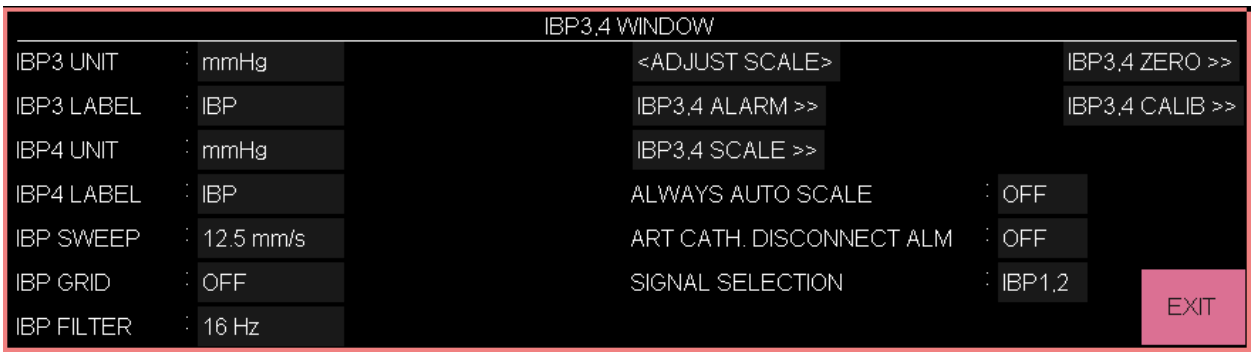
- Enter the IBP settings window.
- Turn the PPV MEASUREMENT to ON.

If PPV MEASUREMENT is enabled , the IBP window will be displayed as follows:

Setting IBP Channels

If the monitor supports four IBP channels, you can select IBP1 and IBP2 signals or IBP3 and IBP4 signals as follows:

- Enter the IBP settings window.
- Select SIGNAL SELECTION. Two options "IBP1,2" and "IBP3,4" are available for this item. In this condition, the IBP window is displayed as follows:

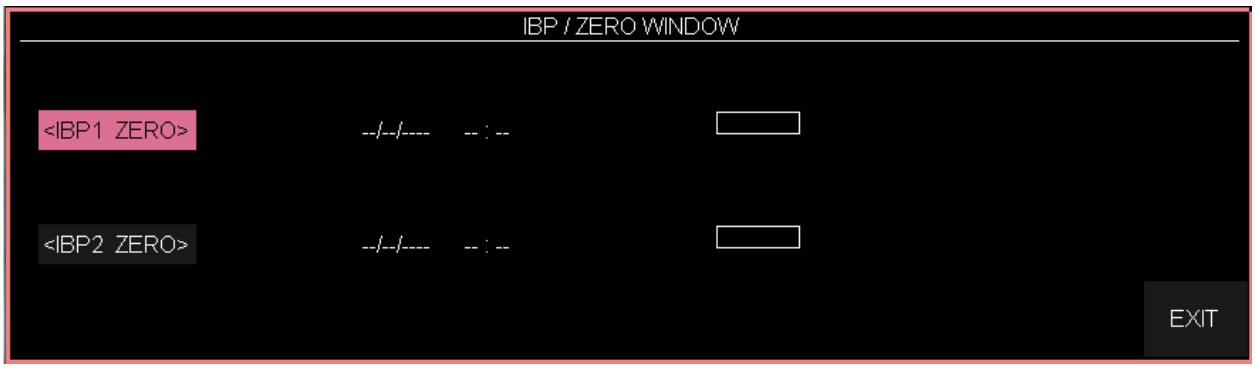


12.5 Zeroing

To avoid inaccurate pressure readings, the monitor requires a valid zeroing.

Zeroing procedure

1. The transducer should be placed at mid-heart level.
2. Turn off patient stopcock.
3. The transducer must be vented to atmospheric pressure.
4. Enter the IBP settings window.
5. Select IBP ZERO to open the Zeroing window:



6. In this window select < IBP ZERO > to start zeroing procedure.

The message "PLEASE WAIT" will be displayed during the procedure. When the procedure is completed successfully, the message "IBP1/IBP2 ZERO OK" appears.
The last zeroing time will be saved and displayed in the window .

7. After successful zeroing, you can turn stopcock to patient on and the other stopcock to atmospheric pressure off.

Warning

- **When using high-frequency ventilation, ensure that the tubing from the ventilator does not touch the arterial line, or connect with it indirectly. This could cause small pressure variations which can interfere with the zeroing procedure.**

The zeroing procedure must be performed in the below conditions:

- before starting the monitoring
- every time you reconnect the transducer cable to the monitor.
- when you use a new transducer or tubing.
- if you think the monitor's pressure readings are not correct.

Troubleshooting the Zeroing

Probable causes of unsuccessful zeroing are provided in the table below :

Massage	Corrective action
IBP1/ IBP2 NO SENSOR , UNABLE TO ZERO	Make sure that the transducer is connected , then start zeroing.
IBP1/ IBP2 OVERANGE, FAILED ZEROING	Make sure that the stopcock is vented to atmosphere. If the problem still exists, contact After Sales Services.
IBP1/ IBP2 UNSTABLE PRESSURE, UNABLE TO ZERO	Make sure that the stopcock is vented to atmosphere or perhaps the tubing system or cable or other connections are damaged accidentally during the zero procedure and should be checked. If the problem still exists, contact After Sales Services.

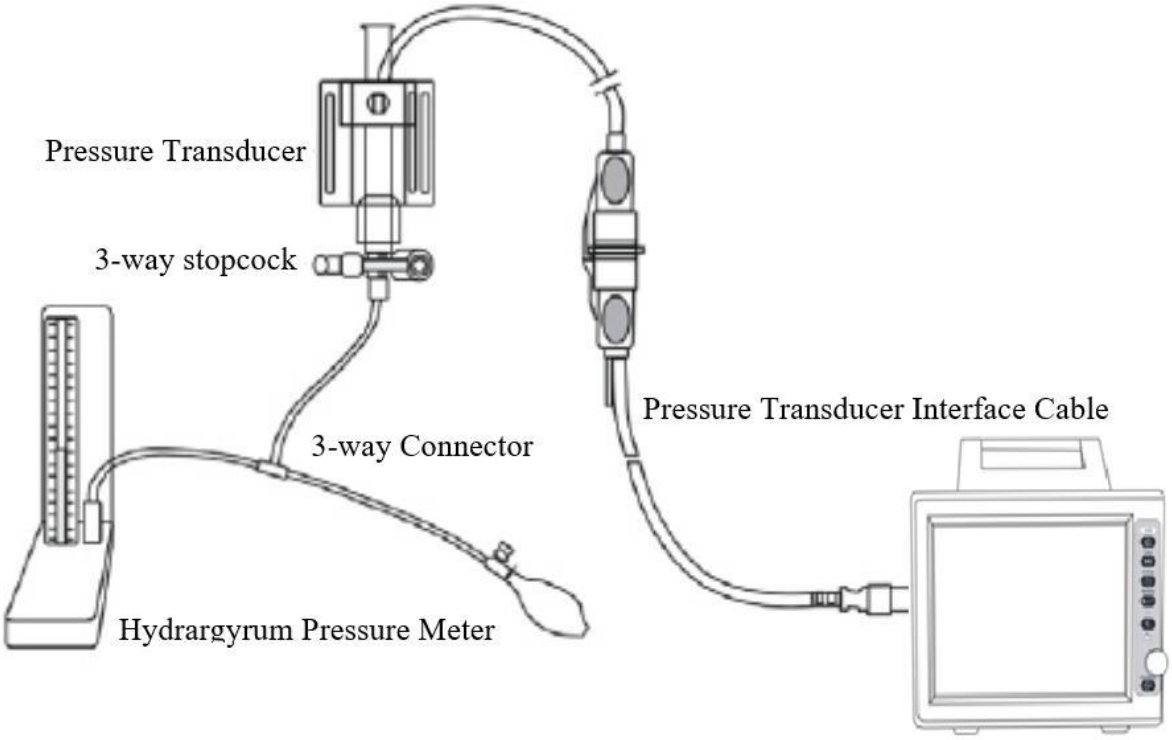
12.6 Calibration

The purpose of calibration is to ensure the accuracy of the system measurement and compatibility of the system with the transducer. Therefore, if the transducer model is changed or when you are not sure about the accuracy of the monitor, calibrate the monitor with the reference pressure.

Warning

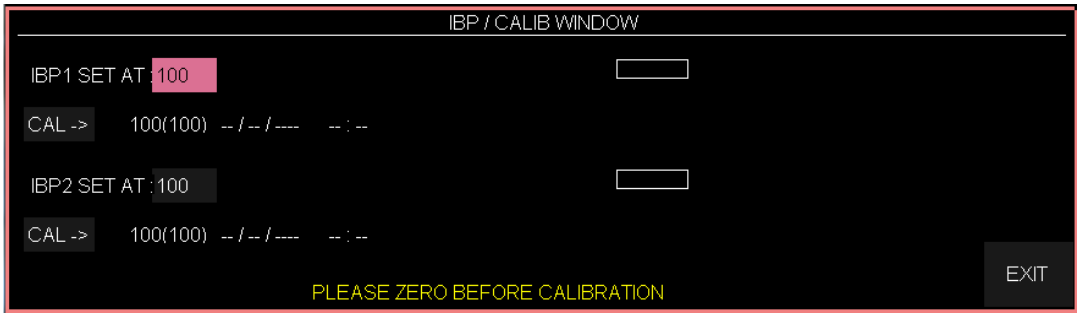
- **The calibration should be performed by hospital medical engineers.**

The calibration equipment is connected as follows:



Calibration procedure

1. At first you must zero the monitor.
2. Attach the tubing to the sphygmomanometer.
3. Ensure that connection that would lead to patient is off.
4. Connect the 3-way connector to the 3-way stopcock that is not connected to the patient catheter.
5. Open the port of the 3-way stopcock to the sphygmomanometer.
6. Enter the IBP settings window.
7. Hold down IBP CALIB for 5 seconds to open the calibration window:



8. Raise the sphygmomanometer to set value that you adjusted in CALIB WINDOW.
9. Press the rotary knob on CAL-> to start the calibration.

The message "PLEASE WAIT" will be displayed during the procedure. "IBP1/IBP2 CALIBRATION OK" indicates that the calibration procedure has been completed successfully. The last calibration time will be saved and displayed in the window.

Warning

- **Never perform the invasive pressure calibration while a patient is being monitored.**

Troubleshooting the Calibration

Probable causes of unsuccessful calibration are provided in the table below:

Message	Corrective action
IBP1/ IBP2 NO SENSOR , UNABLE TO CALIBRATE	Make sure that the transducer is connected, then start calibration procedure.
IBP1/IBP2 OVERANGE, UNABLE TO CALIBRATE	Verify that adjusted pressure in the menu and sphygmomanometer pressure are equal. If the problem still exists, contact after sales services.
IBP1/IBP2 UNSTABLE PRESSURE, UNABLE TO CALIBRATE	Make sure that the transducer is attached to the patient or perhaps the tubing system or other connections are damaged accidentally and should be checked. If the problem still exists, contact after sales services.

NOTE

- **Take the following actions for calibration of MEDEX transducer: press >CALIB< in the IBP WINDOW. Set IBP1 and IBP2 to 100mmHg and push down Calib button of the transducer for about 10 seconds.**

12.7 IBP Alarm Messages

a) Physiological alarms

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

Alarm	Cause and solution
IBP SYS/DIA/MEAN HIGH	SYS/DIA/MEAN violates adjusted high limit. Check the patient's condition. Check the defined limits that are suitable for alarm or not.
IBP SYS/DIA/MEAN LOW	SYS/DIA/MEAN violates adjusted low limit. Check the patient's condition. Check the defined limits that are suitable for alarm or not.

Physiological Alarms		
ALARM	**SITUATION**	**DESCRIPTION**
IBP SYS / DIA / HIGH	SYS/DIA value violates the adjusted high limit.	● SYS/DIA value blinks. ● The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
IBP SYS / DIA / LOW	SYS/DIA value violates the adjusted low limit.	
IBP SYS / DIA / MEAN HIGH	SYS/DIA/MEAN value violates the adjusted high limit.	● SYS/DIA/MEAN value blinks. ● The alarm indicator flashes. ● The alarm sound is enabled. ● The alarm message is displayed in a background corresponding to its level.
IBP SYS / DIA / MEAN LOW	SYS/DIA/MEAN value violates the adjusted low limit.	

b) Technical alarms

Technical Alarms			
Alarm	**Cause**	**Solution**	**Description**
IBP1/IBP2 NO SENSOR	Channel 1 or 2 transducer is not connected.	Check the transducer connection.	
IBP1/IBP2 STATIC PRESSURE	This condition occurs when the maximum and minimum values of a pulsatile pressure signal (Just for IBP, ART, PAP, RVP and LVP labels) differ by less than 3mmHg.In this condition, only the Mean pressure is displayed. This message could be resulted from: ● Patient physiological condition e.g. asystole. ● The transducer turned off to the patient. ● The catheter tip lodged against a vessel wall. ● A clot on the catheter tip.	●Check the patient condition and take clinical actions. ●Turn on the stopcock to patient and turn it off to the atmospheric pressure. ●Follow medical procedures for dislodging the catheter. ●Follow medical procedures for cleaning or changing clotted catheters.	
IBP1/IBP2 CATHETER DISCONNECT	The catheter is disconnected from the patient during the pressure measurement (only IBP and ART labels). In this condition, the pressure drops dramatically, IBP signal becomes static and the MEAN pressure falls below 10 mmHg.	● Check the catheter connection to the patient and take necessary medical actions. ●Perhaps 3-way stopcock may be disconnected from the patient during the zeroing, tubing washing or blood sampling. Check it and take necessary medical actions.	

c) Messages

IBP Messages		
Message	**Cause**	**Solution**
IBP1/IBP2 ADJUST SCALE	IBP1 or IBP2 signal is out of display range for about 5 seconds.	Press <AUTO SCALE> in IBP WINDOW.
IBP1/IBP2 SEARCH	IBP signal cannot be processed by the software because the signal is weak or less pulsatile.	●Check all IBP measurement setup and connections. ●Check the patient status and take necessary medical actions.

Chapter 13, GAS Monitoring (Mainstream)

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13.1 GENERAL

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

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

It is available in various parameter configurations as follow:

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

Warning

- **The IRMA probe is intended for use by qualified medical personnel only, and who are familiar with this manual.**
- **The IRMA probe is intended for use only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**
- **No modification of this equipment is allowed.**

NOTE:

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

The combination of IRMA and base monitor considered a ME SYSTEM and all ME SYSTEM requirements were complied with.
For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.
Measuring principle

The IRMA sensor head snaps in place on the top of the airway adapter that includes the optical components for measuring all gases. The IRMA airway adapter is inserted between

the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained by continuously measuring the infrared gas absorption through the XTP windows in the gas flow through the adapter. The XTP windows are transparent to light in the wavelength ranges of interest and they are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission.

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

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

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

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

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

MAC (Minimum alveolar concentration)

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

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

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

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

NOTE

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

Airway adapter:

The IRMA Airway Adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained through the XTP™ windows in the sides of the adapter. The XTP windows are transparent to light in the wavelength ranges of interest and they are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission.

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

IRMA airway adapters: Adult/ Pediatric and infant

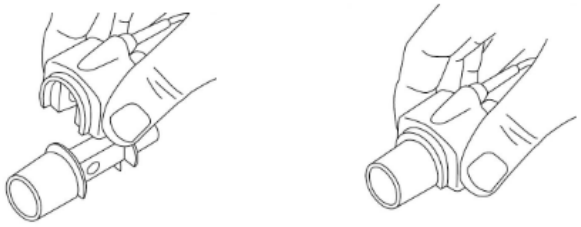
Warning

- **Do not use the IRMA adult/pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.**
- **Do not use the IRMA infant airway adapter with adults as this may cause excessive flow resistance.**
- **Do not use the adapter if it or its package is damaged and return it to the vendor.**
- **Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.**
- **Replace the airway adapter if rainout/condensation occurs inside the airway adapter.**
- **Use only the recommended IRMA airway adapters for monitoring. Other airway adapters may cause improper performance. (Refer to Accessories chapter for detail)**

Preparatory steps for gas measurement:

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

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

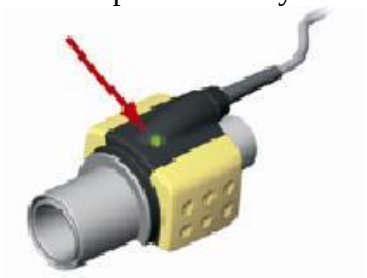


a. Preparatory Step2

3. Depending on IRMA model, perform the following:

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

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



b. Preparatory Step 4

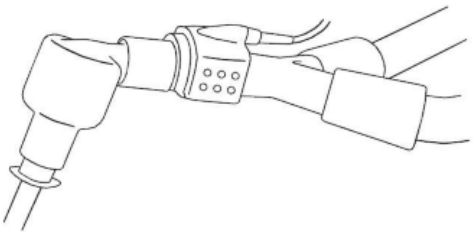
5. Connect the IRMA/airway adapter 15 mm male connector to the breathing circuit Y-piece.

Figure c. Preparatory Step 5

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

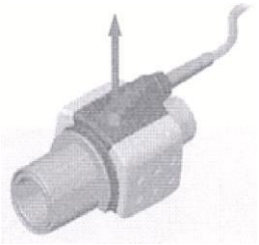
Figure d. Preparatory Step 6

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



e. HME option

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



f. Preparatory Step 7

Warning

- **To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.**
- **Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.**
- **Disposable airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.**
- **Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.**

Placement of IRMA Probe

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

Warning

- **The IRMA probe is not intended to be in patient contact.**
- **If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.**
- **Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA sensor is used in the electromagnetic environment specified in this manual.**
- **The IRMA probe is not designed for MRI-environments.**
- **Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.**

NOTE

- **Do not apply tension to the sensor cable.**
- **Do not operate the IRMA probe outside the specified operating temperature environment. (Refer to the Specification chapter for detail)**

Gas span check

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

Pre-use check

Always verify gas readings and waveforms on the patient monitor before connecting the IRMA airway adapter to the patient circuit .Perform the tightness check of the patient circuit according to the User Manual for the monitor with the IRMA probe snapped on the IRMA airway adapter.
Perform the tightness check of the patient circuit with the IRMA sensor head snapped on the IRMA airway adapter.
Verify that there has not been any accumulation of gas between the IRMA sensor head and the XTP windows by checking that the CO2 readings on the monitor are correct before connecting a
patient to the breathing circuit.
Check that the connections have been made correctly by verifying an actual CO2 waveform on

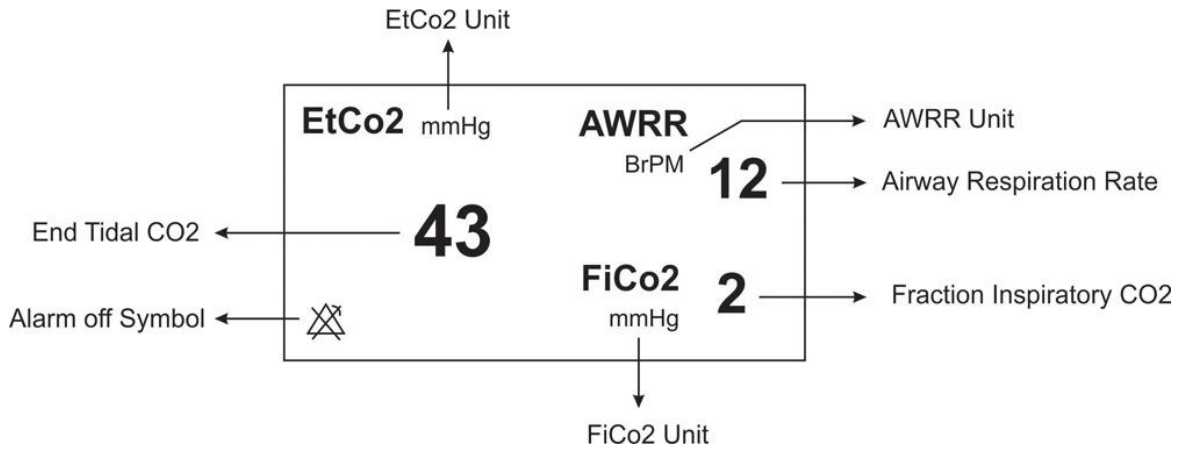
the monitor display.

Warning

- **Don't use the device in the environment which contains flammable anesthetic gas.**
- **Before any interpretations are made of parameters readings and waveforms one, assure that the multi-gas probe is functioning correctly. Partial obstruction of airway with water can result in distorted waveforms. A leak in the airway may result in low parameters measurements. Check the monitor to see if it is functioning properly.**
- **Verify sensor detection before starting GAS monitoring. Unplug the sensor from IRMA connector to verify that the error message "CO2 NO SENSOR "is displayed.**

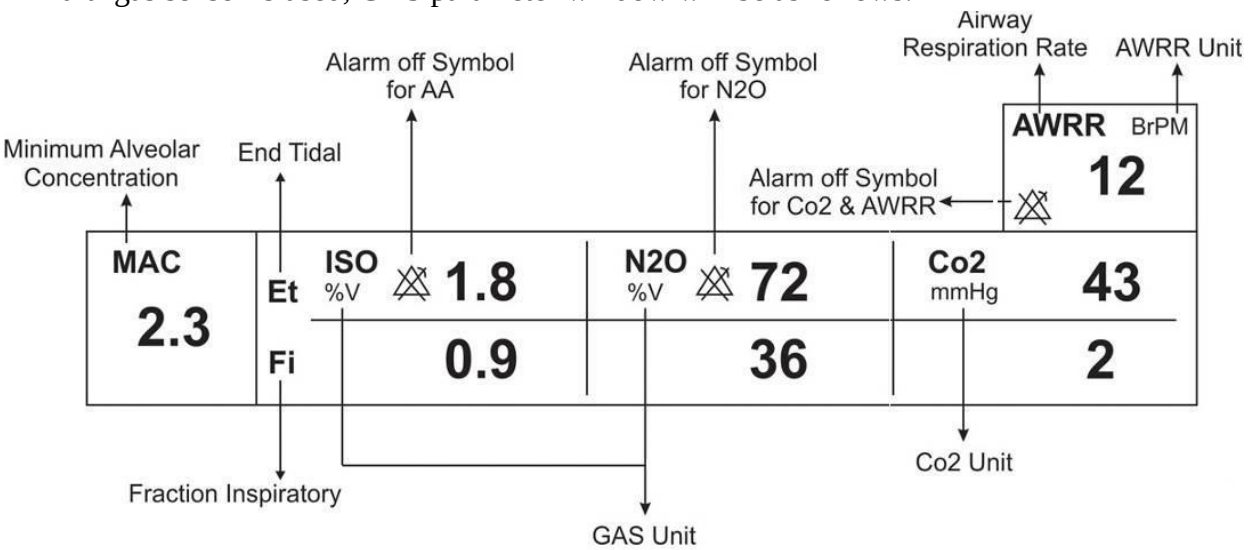
13.2 GAS WINDOW

The following items are displayed in CO2 parameter window:



CO2 PARAMETER WINDOW

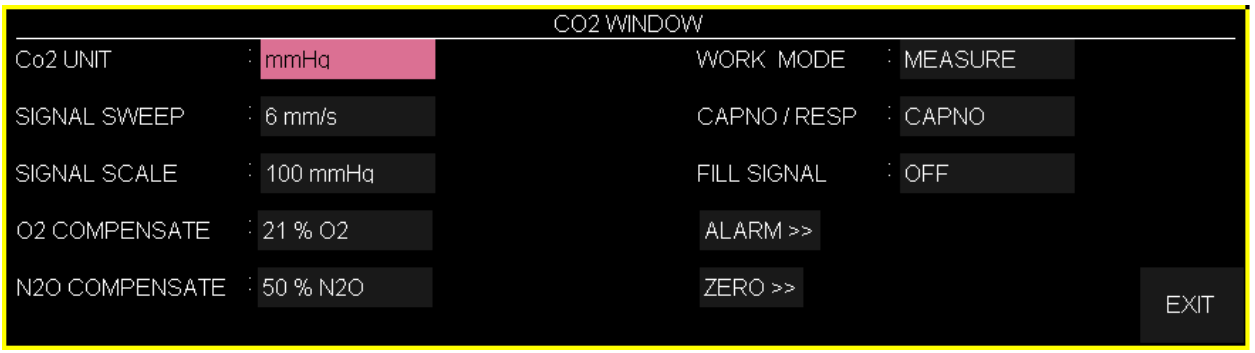
If Multi-gas sensor is used, GAS parameter window will be as follows:



GAS PARAMETER WINDOW

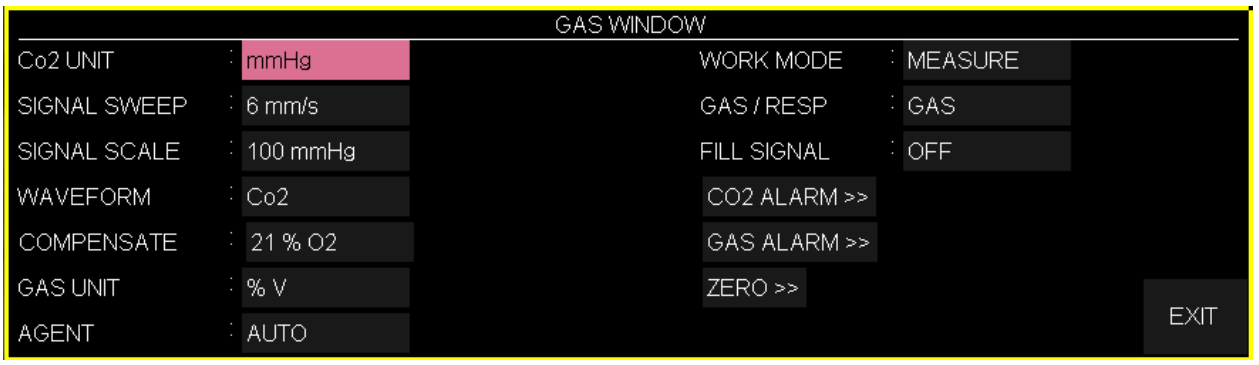
NOTE

- **After Masimo Sweden AB capnography probe is connected to the monitor, at first sensor type (ISA or IRMA) is detected by the system and then displayed in front of the CO2 signal.**
- **System displays Gas window for IRMA sensor as default. If when Gas window is open ISA probe is connected to the system, by exiting this window and entering it again you can change this window for ISA sensor.**



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

a) CO2 WINDOW in CO2 (ONLY) mode



b) GAS WINDOW in AX+ mode

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

■ **Co2 UNIT**

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

$EtCo_2$ in %V is the Co_2 value (in mmHg) divided by ambient barometric pressure (in mmHg) which is a percentage of the barometric pressure.

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

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

■ **SIGNAL SWEEP**

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

■ **SIGNAL SCALE**

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

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

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

■ **WAVEFORM**

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

NOTE

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

■ **COMPENSATE**

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

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

■ **GAS UNIT**

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

■ **AGENT**

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

NOTE

- **In IRMA AX+, if the concentration of anesthesia agent doesn't exceed agent detection threshold, "AA?" will be displayed instead of the name of anesthesia agent in Multi-gas parameters window.**
- **In IRMA AX+, if there are two anesthesia agent mixtures in patient airway and their concentration exceeds agent detection thresholds, the message "AGENT MIXTURE" is displayed on the screen.**
- **When not using gas monitoring functions, it is suggested to disconnect the sensor.**
- **If the monitor doesn't detect any CO2 signal for 30 minutes, after connecting IRMA sensor, the monitor automatically disables gas monitoring to decrease the power consumption and extend the life cycles of IR source and sensor. The monitor will be set in "standby" mode.**
- **If the monitor doesn't detect adapter of IRMA sensor for 10 minutes, after connecting IRMA sensor, the monitor automatically will be set in "standby" mode.**
- **When the system is in standby mode, you can enable GAS monitoring in GAS window by setting work mode to Measure.**

■ **WORK MODE**

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

■ **GAS/RESP**

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

NOTE

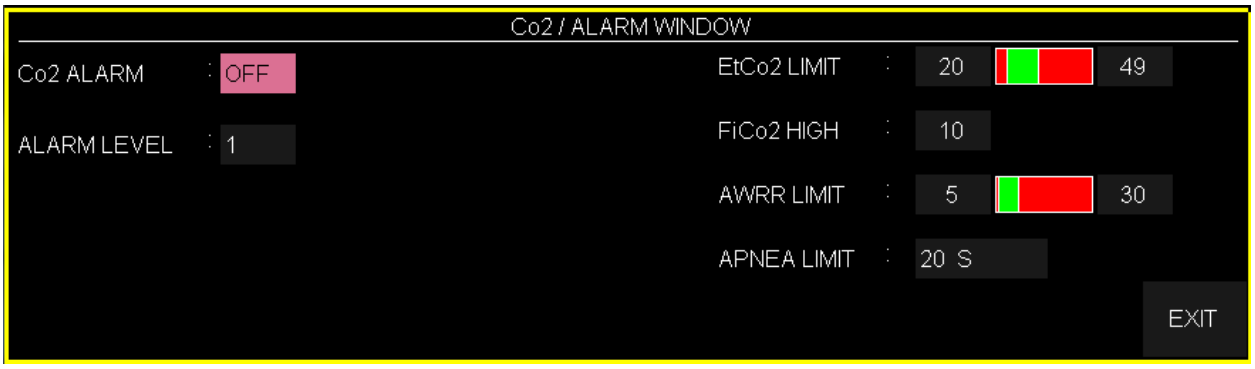
If only CO2 module is enabled, the CAPNO / RESP for this option will be displayed, otherwise the GAS / RESP will be displayed.

■ **FILL SIGNAL**

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

■ **CO2 ALARM**

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



CO2 /ALARM WINDOW

- **CO2 ALARM**

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

- **ALARM LEVEL**

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

- **EtCO2 LIMIT**

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

- **FiCO2 HIGH**

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

- **AWRR LIMIT**

Alarm is activated when the AWRR exceeds adjusted ALARM HIGH limit or

falls below adjusted ALARM LOW limit.(Range :1-120BrPM)
Default for upper limit:

Adult/Pediatric:	30BrPM
Neonate:	60BrPM

Default for lower limit:

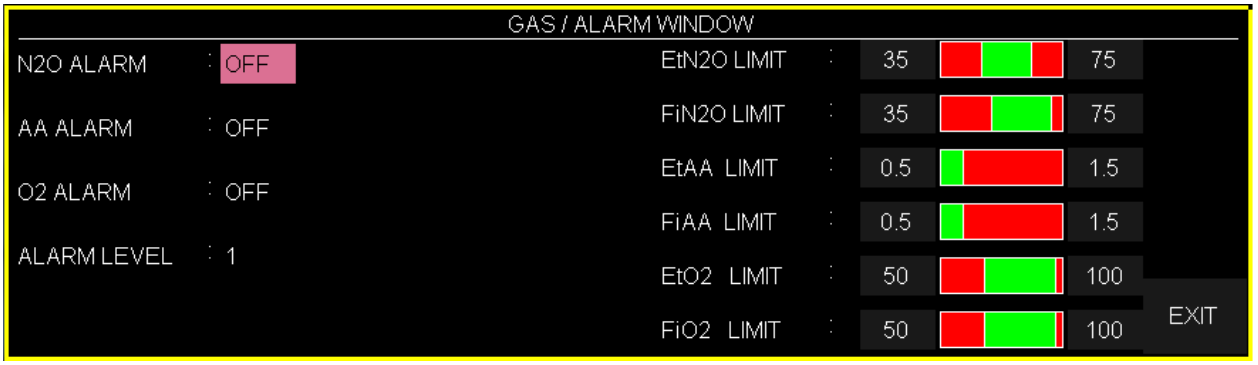
Adult/ Pediatric:	5BrPM
Neonate:	15BrPM

- **APNEA LIMIT**

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

■ **GAS ALARM**

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



GAS/ALARM WINDOW

- **N2O ALARM and AA ALARM**

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

- **ALARM LEVEL**

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

- **EtN2O LIMIT**

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

- **FiN2O LIMIT**

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

- **EtAA LIMIT**

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

- **FiAA LIMIT**

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

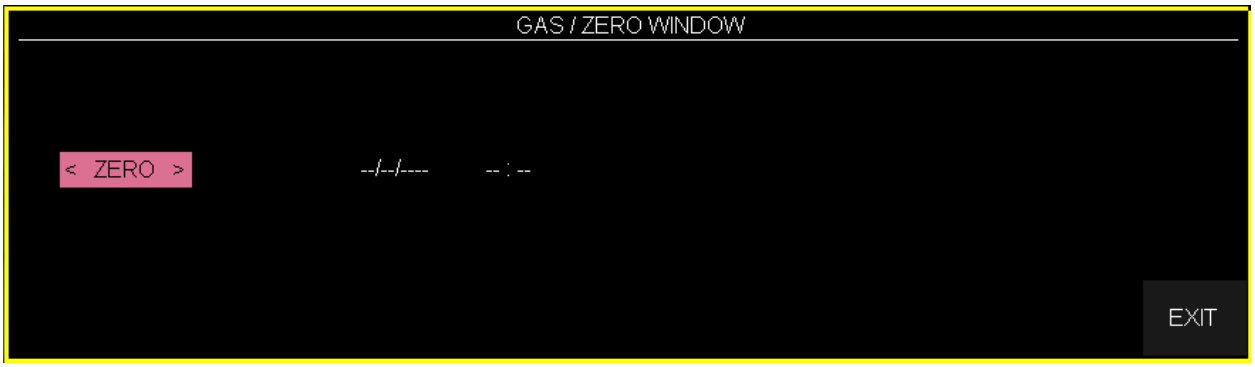
NOTE:

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

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

■ **Zeroing**

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



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

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

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

IRMA AX+ probes:

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

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

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

Zeroing:

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

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then choose a < ZERO> in the ZERO WINDOW menu.

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

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

Warning
Incorrect probe Zeroing will result in false gas readings.

NOTE

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

13.3 GAS Alarm Messages

a) Physiological alarms

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

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

FiCo2 HIGH	FiCo2 violates adjusted high limit	●FiCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
CO2 RESP APNEA	Non-respiration condition overruns adjusted time	● The alarm indicator flashes. ●The message "CO2 RESP APNEA" blinks in red background.	Activated
EtN2O HIGH	End Tidal N2O violates adjusted high limit	●EtN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtN2O LOW	End Tidal N2O violates adjusted low limit	●EtN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O HIGH	FiN2O violates adjusted high limit	●FiN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O LOW	FiN2O violates adjusted low limit	●FiN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtAA HIGH	End Tidal AA violates adjusted high limit	●EtAA value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

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

b) Technical alarms

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

N2O INVALID	N2O outside specified accuracy range.	Zero the sensor, if the problem still exists, turn off and on the system and if again this message appears contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
AGENT INVALID	Agent outside specified accuracy range.	Zero the sensor, if the problem still exists, turn off and on the system and if again this message appears contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
AGENT MIXTURE	In IRMA AX+ mode, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds.		Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
AGENT UNRELIABLE	- The accuracy of the agent identification and measurement could not be guaranteed. - More than 2 anesthetic agents are present in the breathing circuit - High concentrations of solvents, cleaning agents or other interfering gases are present in the breathing circuit		Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 INVALID AMBIENT PRESSURE	Ambient pressure outside operating range.	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID AMBIENT TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO SENSOR	Sensor is disconnected from system	Connect sensor if problem exist again, Contact after sales service of manufacturer.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 ZERO REFERENCE CALIB REQUIRED	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.	Perform zeroing procedure in an environment with CO2 less than 0.80%V.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

c) Messages

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

Status LED on the IRMA probe:

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

[1] Valid for IRMA AX+ probes only.

Chapter 14, GAS Monitoring (Sidestream)

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14.1 GENERAL

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

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

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

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

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

Warning

- **The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals only**
- **The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**

NOTE

- **An ISA sidestream gas analyzer shall only be connected to medical devices approved by Masimo Sweden AB.**
- **(U.S. Only):**
  Federal law restricts this device to sale by or on the order of a physician.
  For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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

➢ Measuring principle

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

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

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

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

Measurable parameters by ISA sensor are:

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

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

For more details, please refer to Technical Specification section.

NOTE

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

MAC (Minimum alveolar concentration)

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

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

NOTE

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

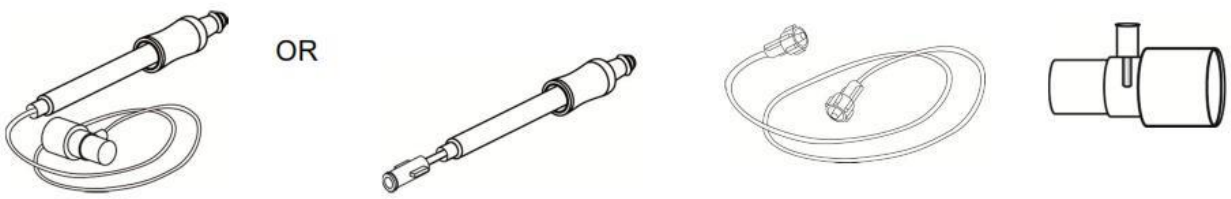
14.2 Nomoline Family sampling lines

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

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

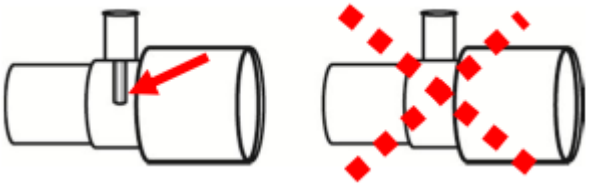
As long as no sampling line is connected, the ISA gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the ISA gas analyzer switches to measuring mode and starts delivering gas data.

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



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

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



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

Warnings related to sampling line

Warning

- **Use only airway T-adapters with the sampling point in the center of the adapter.**
- **Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.**
- **Do not apply negative pressure to remove condensed water from the Nomoline Family sampling line.**
- **Too strong positive or negative pressure in the patient circuit might affect the sample flow.**
- **Strong scavenging suction pressure might affect the sample flow.**
- **Do not lift the ISA gas analyzer by the sampling line as it could disconnect from the ISA, causing the ISA gas analyzer to fall on the patient.**

NOTE

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

14.3 Nomoline Family sampling line replacement

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

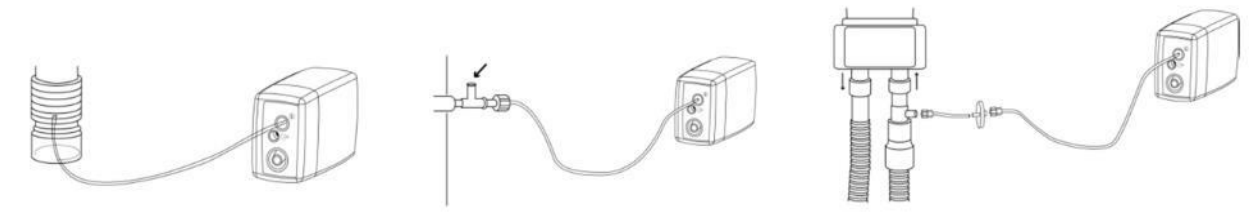
Warning

- **Replace the sampling line if the sampling line input connector starts flashing red, or the**
- **Monitor displays a "Check sampling line" message.**
- **Do not use sampling line if it or its package is damaged and return it to the vendor.**
- **Use only the recommended ISA sampling line by the manufacturer. Other sampling lines may cause sensor improper performance. (Refer to Accessories chapter for more detail)**

14.4 Preparatory steps for Multi-gas monitoring

To set up ISA analyzer, follow these steps:

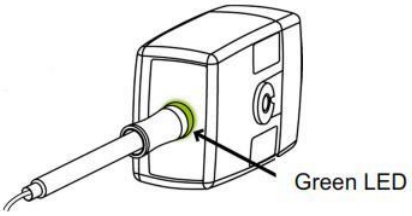
1. Securely mount the ISA analyzer.
2. Connect the ISA analyzer interface cable into corresponding connector on the side panel of patient monitor.
3. Connect a Nomoline Family sampling line to the ISA analyzer input connector. It will click into place when properly seated.
4. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit to prevent pollution of the operation room when N_2O and/or anesthetic agents are being used.



NOTE

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

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



Fifth Preparatory Step

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

Warning

- **Do not operate the ISA sidestream gas analyzer if the enclosure is damaged.**
- **Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.**
- **Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.**
- **Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.**
- **Measurements can be affected by mobile and portable RF communications equipment. It should be assured Make sure that the ISA gas analyzer is used in the electromagnetic environment specified in EMC section of this manual.**
- **The ISA sidestream gas analyzers are not designed for MRI (magnetic resonance imaging) environments. During (MRI) scanning, ISA must be placed outside the MIR suite.**
- **Use of high frequency electrosurgical equipment in the vicinity of the ISA/monitor may produce interference and cause incorrect measurements.**
- **Do not use the Nomoline Airway Adapter Set Infant with adult/pediatric patients.**
- **Do only use sample lines intended for anesthetic agents if N_2O and/or anesthetic agents are being used.**
- **Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination**

- **Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.**
- **Exhaust gases should be returned to the patient circuit or to a scavenging system.**

NOTE

- **The ISA analyzer should be securely mounted in order to avoid the risk of damage to the ISA.**
- **Do not operate the ISA sidestream gas analyzer outside the specified operating environment.**

14.5 Indicator status on the ISA sensor:

Steady green light	ISA in operation and OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	ISA sensor error
Blinking red light	Check sampling line

14.6 Pre-use check

Before connecting the Nomoline Family sampling line to the breathing circuit, do the following:

1. Connect the sampling line to the ISA gas inlet connector.

2. Check that the gas inlet connector is lit with a steady green light.

3. *For ISA OR+:*
   Check that the O2 reading on the monitor is correct (21 vol%).

4. Breathe briefly into the sampling line and check that monitor displays a valid CO_2 waveform and valid values.

5. Occlude the sampling line with a fingertip and wait for 10 seconds.

6. Check that occlusion alarm is displayed on the monitor and that the gas inlet connector shows a flashing red light.

7. *If applicable:*
   Perform a tightness check of the patient circuit with the sampling line attached.

NOTE

- **Variations in barometric pressure do not have any effects due to internal barometric pressure compensation.**
- **There are no adverse effects on stated performance due to cycling pressure of up to 10 KPa.**

Warning

- **Don't use the device in the environment which contains flammable anesthetic gas.**
- **Before any interpretations are made of EtCo2 reading and waveform, assure that the capnography system is functioning correctly. Monitor contamination by secretions and Partial obstruction of sampling line with water can result in distorted CO2 waveforms. A leak in the sampling line may result in low EtCo2 measurements. Check the monitor to see if it is functioning properly.**
- **Returning sampled gas to the patient breathing system may cause infection.**
- **Do not expose the monitor with sidestream capnography module to vibration and impact.**
- **Verify ISA sensor detection before starting GAS or CO2 monitoring. Unplug the ISA sensor from its connector to verify that the error message " CO2 NO SENSOR "is displayed.**
- **Positioning the monitor lower than the patient may facilitate condensed water and secretions move towards the system thereby resulting in blockage of filters. Keep the system preferably above the patient level. This prevents secretions and water dribbling down the tube towards the monitor end and extends the lifetime of the filters.**

NOTE

Do not apply tension to the ISA sensor cable.

14.7 Zeroing procedure

The gas analyzer needs from time to time to establish a zero reference level for the gas measurements and the flow. The zero calibration is here referred to as “zeroing".

ISA performs zeroing by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed 1 to 3 times per day, and takes less than 3 seconds for ISA CO_2 gas analyzers and less than 10 seconds for ISA Multigas analyzers.

After zeroing procedure is completed, a flat line signal and message “ZEROING IN PROGRESS” will be displayed.

During zeroing, if ISA’s exhaust gas is returned to the patient circuit, the returned gas level will be different from the gas level at the sampling site.

Warning

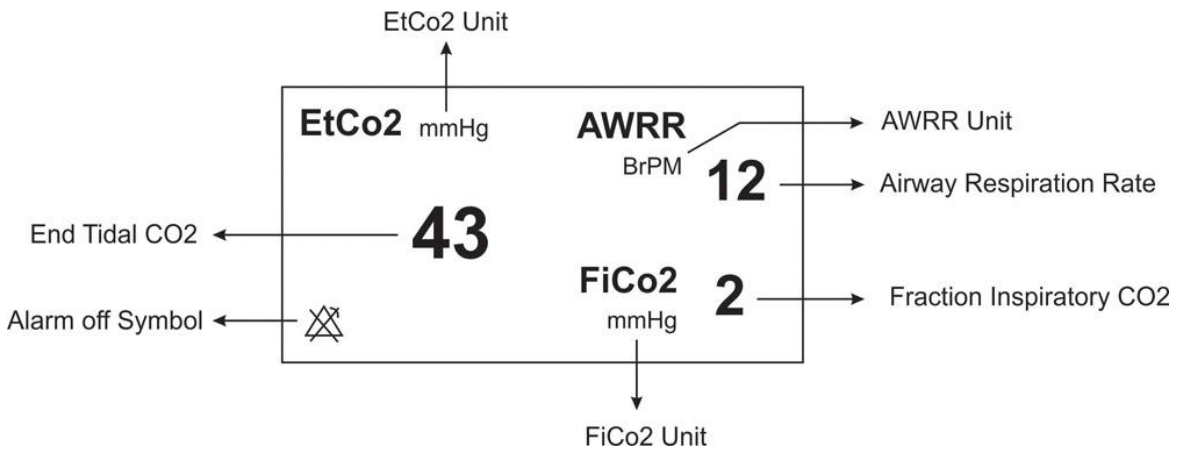
Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.

NOTE

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

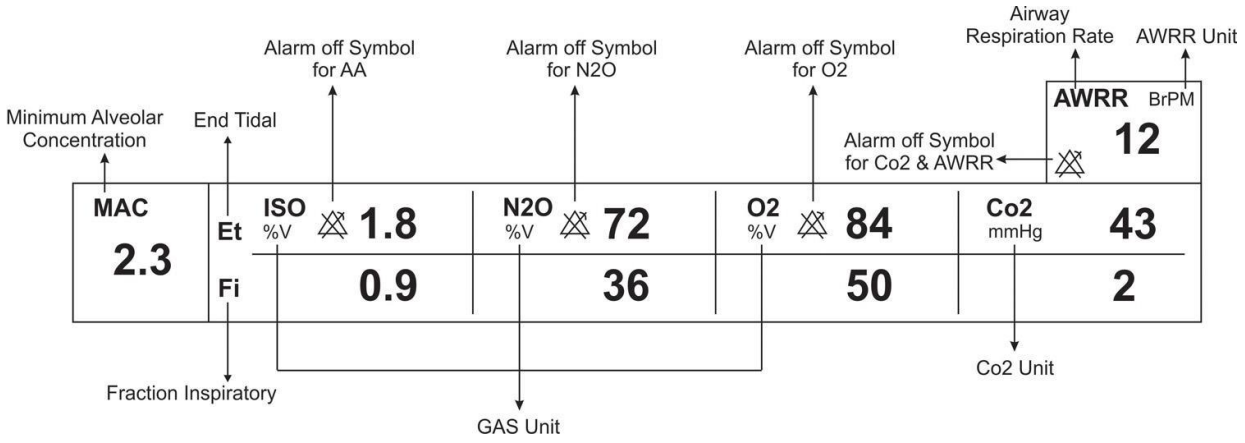
14.8 GAS WINDOW

The following items are displayed in CO2 parameter window:



CO2 PARAMETER WINDOW

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



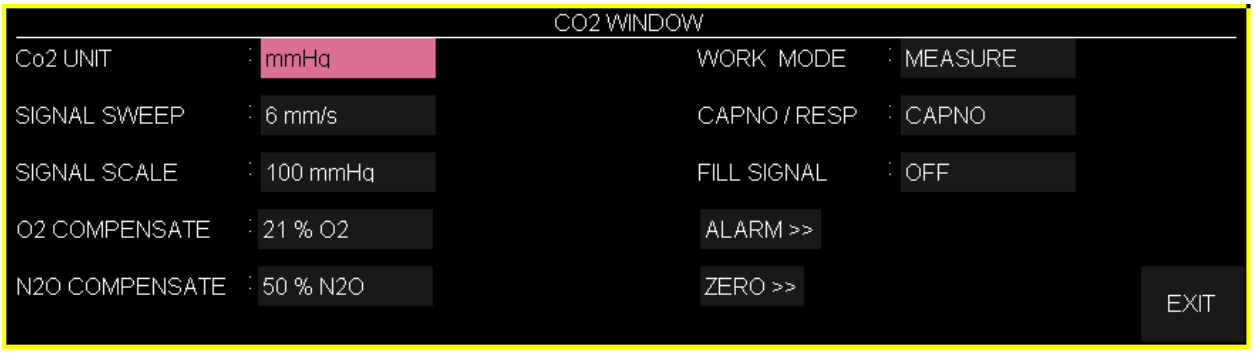
GAS PARAMETER WINDOW

NOTE

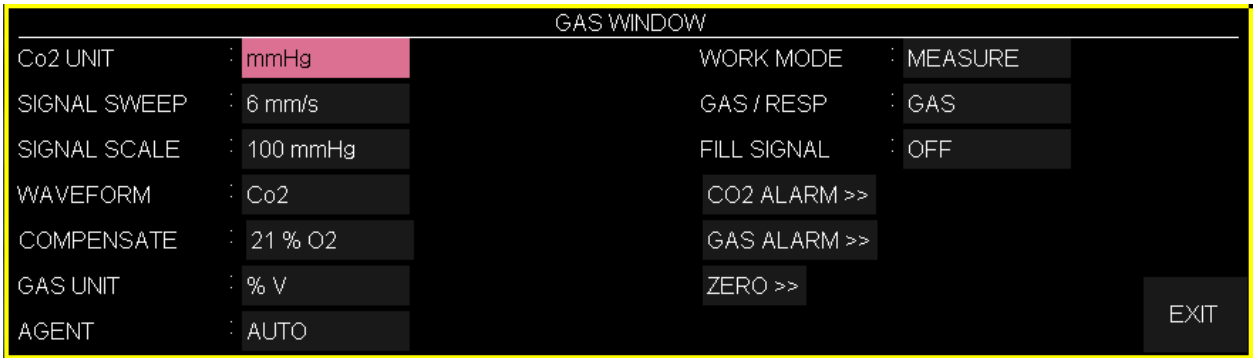
- **After capnography probe is connected to the monitor, at first sensor type (ISA or IRMA) is detected by the system and then displayed in front of the CO2 signal.**
- **The system displays Gas window for IRMA sensor as default. To observe Gas window for ISA sensor, exit Gas window and enter it again while ISA probe is connected to the system.**

The Capnography Window for Sidestream sensor in different modes is as follows:

CO2 WINDOW in CO2(ONLY) mode



GAS WINDOW in AX+ mode



GAS WINDOW in OR+ mode

Capnography Window of sidestream sensor in different modes

■ **Co2 UNIT**

Pick this item to adjust CO2 measurement unit. (Options: mmHg, KPa, %V)
EtCo2 in %V is the EtCo2 value (in mmHg) divided by ambient barometric pressure (in mmHg) which is a percentage of the barometric pressure.

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

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

■ **SIGNAL SWEEP**

Select it to adjust Multi-gas signals sweep. Available options for SIGNAL SWEEP are 3, 6, 12/5 and 25mm/s.

■ **SIGNAL SCALE**

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

CO2 Waveform Scale	O2 Waveform Scale	N2O Waveform Scale	AA Waveform Scale
0-50 mmHg, 0-6% 0-100 mmHg, 0-10% 0-200 mmHg, 0-20%V <AUTOSCALE>	0-50% 0-100% <AUTOSCALE>	0-50% 0-100% <AUTOSCALE>	1,2,3,5,10,20% <AUTOSCALE>

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

■ **WAVEFORM**

Pick this item to select which gas waveform is displayed on the screen. Available Options are CO2, N2O, O2, and AA.

■ **O2 COMPENSATE**

The presence of oxygen can cause some interference in CO2 measurement. This is known as spectral broadening, and must be compensated.

The O2 compensation is performed automatically for all ISA sensors with the oxygen sensor available on it. When using an ISA without an oxygen sensor, i.e. when oxygen measurement is performed by the other device like anesthesia machines and ventilators, the current oxygen concentration should be transmitted to the sensor.

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

■ **N2O COMPENSATE**

The presence of N2O can cause some interference in CO2 measurement. This is known as spectral broadening and must be compensated.

N2O is measured and automatically compensated for in ISA sensors (AX+/OR+). Therefore N2O concentration should be transmitted to ISA sensor (CO2).

Available options are 0-100% N2O.

NOTE

- **You can see this option only when ISA (CO2) sensor is connected to the system. In other modes (ISA AX+/OR+), this option is eliminated from the respective menu. In other words CO2 menu for ISA (CO2) and IRMA (CO2) is similar except for "N2O COMPENSATE" option.**
- **In ISA OR+, if the concentration of anesthesia agent doesn't exceed agent detection threshold, "AA?" will be displayed instead of the name of anesthesia agent in Multi-gas parameters window.**
- **In ISA OR+, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds, the message "AGENT MIXTURE" is displayed on the screen.**
- **When not using gas monitoring functions, it is suggested to disconnect the sensor. When gas monitoring is not used, it is suggested to disconnect the sensor.**
- **If the monitor doesn't detect any CO2 signal for 30 minutes after connecting ISA sensor, the sensor is automatically disabled and goes to "standby" mode to decrease the power consumption and extend the life cycle of IR source and ISA sensor.**
- **ISA sensor remains in standby mode until the sampling line is connected to it. As soon as the sampling line is connected, the sensor switches on and starts measurement.**
- **For enabling ISA sensor, you can enter Gas window and set the monitor to Measure mode.**

■ **GAS UNIT**

Pick this item to adjust measurement unit for O2, N2O, AA (DES, HAL, ISO, ENF, SEV) (Options: KPa, %V)

■ **AGENT**

In ISA AX+/OR+, there is automatic identification of anesthesia agent and "AUTO" is displayed in menu and couldn't change.

■ **WORK MODE**

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

■ **GAS/RESP**

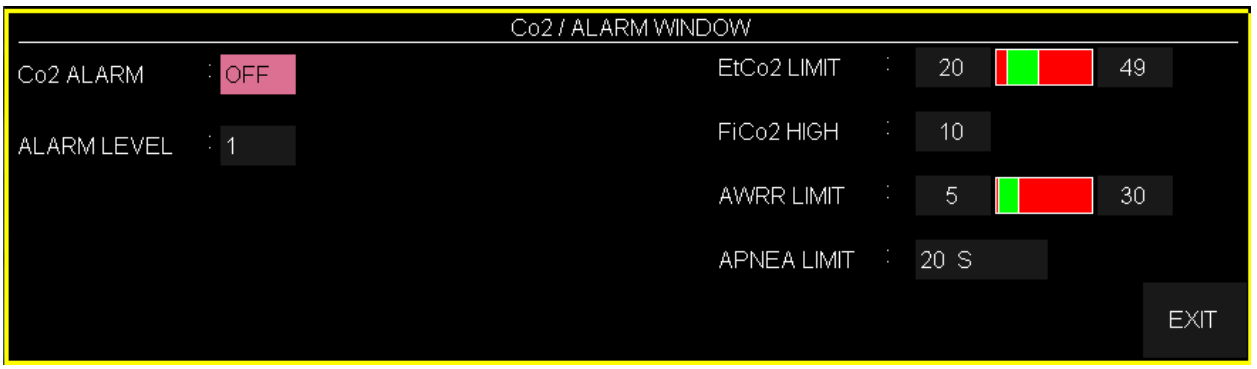
Select this item to determine that respiration evaluation is performed by "Multi-gas" or "RESP" module. Available options are "GAS" and "RESP". When selecting "RESP", the system switches Multi-gas module to standby mode, and displays RESP waveform and parameters.

■ **FILL SIGNAL**

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

■ **CO2 ALARM**

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



- **CO2 ALARM**

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

- **ALARM LEVEL**

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

- **EtCO2 LIMIT**

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

- **FiCO2 HIGH**

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

- **AWRR LIMIT**

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

Adult/Pediatric:	30BrPM
Neonate:	60BrPM

Default for lower limit:

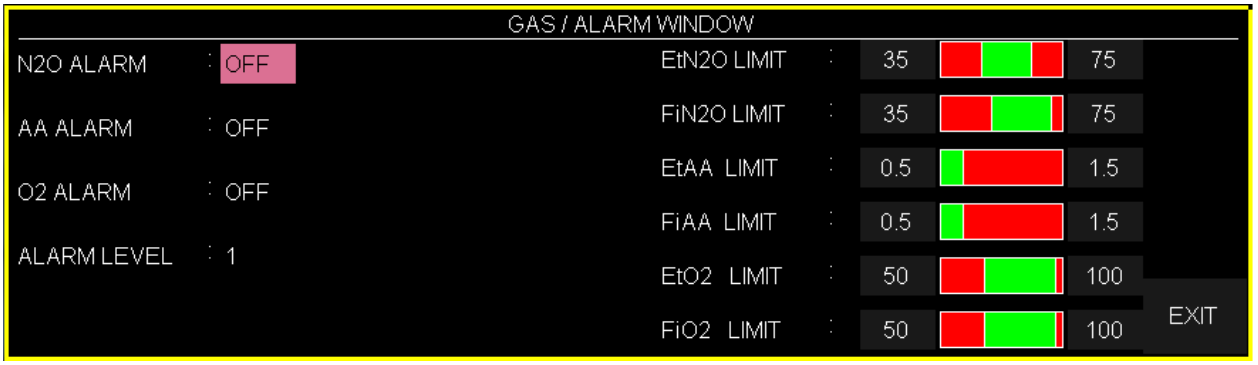
Adult/Pediatric:	5BrPM
Neonate:	15BrPM

- **APNEA LIMIT**

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

■ GAS ALARM

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



- **N2O ALARM, AA ALARM and O2 ALARM**

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

- **ALARM LEVEL**

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

- **EtN2O LIMIT**

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

- **FiN2O LIMIT**

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

- **EtAA LIMIT**

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

- **FiAA LIMIT**

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

NOTE:

Alarm range and alarm limit default of different anesthesia agents are mentioned in the table below:

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

- **EtO2 LIMIT**

Alarm is activated when the EtO2 exceeds adjusted ALARM HIGH or LOW limit.
(Range: 18~105%V step1%V)
Default for upper limit is 100% and for lower limit is 50%.

- **FiO2 LIMIT**

Alarm is activated when the FiO2 exceeds adjusted ALARM HIGH or LOW limit.
(Range: 18~105%V step 1%V)
Default for upper limit is 100%V and for lower limit is 50%V.

14.8 GAS (Sidestream) Alarm Messages

a) Physiological alarms

The alarm occurs when Gas parameters exceed the adjusted alarm limits:

Alarm	Situation	Visual prompt	Audio sound
AWRR HIGH	Respiration rate violates adjusted high limit	●AWRR value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
AWRR LOW	Respiration rate violates adjusted low limit	●AWRR value blinks. ● The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 HIGH	End Tidal Co2 violates adjusted high limit	●EtCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 LOW	End Tidal Co2 violates adjusted low limit	●EtCo2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiCo2 HIGH	FiCo2 violates adjusted high limit	●FiCo2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
CO2 RESP APNEA	Non-respiration condition overruns adjusted time	● The alarm indicator flashes. ●The message "CO2 RESP APNEA" blinks in red background.	Activated

EtN2O HIGH	End Tidal N2O violates adjusted high limit	●EtN2O value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtN2O LOW	End Tidal N2O violates adjusted low limit	●EtN2O value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O HIGH	FiN2O violates adjusted high limit	●FiN2O value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiN2O LOW	FiN2O violates adjusted low limit	●FiN2O value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtAA HIGH	End Tidal AA violates adjusted high limit	●EtAA value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtAA LOW	End Tidal AA violates adjusted low limit	●EtAA value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiAA HIGH	FiAA violates adjusted adjusted high limit	●FiAA value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated

FiAA LOW	FiAA violates adjusted adjusted low limit	●FiAA value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtO2 HIGH	End Tidal O2 violates adjusted high limit	●EtO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
EtO2 LOW	End Tidal O2 violates adjusted low limit	●EtO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 HIGH	FiO2 violates adjusted high limit	●FiO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 LOW	FiO2 violates adjusted low limit	●FiO2 value blinks. ●The alarm indicator flashes. ●The alarm message is displayed in a background corresponding to its level.	Activated
FiO2 Too Low	FiO2 falls below 18%.	●FiO2 value blinks. ●The alarm indicator flashes. ●The alarm Level 1- the message is displayed in red background.	Activated

b) Technical alarms

Alarm	Cause	Solution	Explanation
CO2 SYSTEM FAULT #1,2,3,4	Sensor error	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CHECK SAMPLING LINE	sampling line is not working	Replace the sampling line	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec
SAMPLING LINE CLOGGED	Sampling line occlusion	Replace the sampling line	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID	CO2 outside specified accuracy range.	Zero the system. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
O2 INVALID	O2 outside specified accuracy range.	Zero the sensor, if the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
N2O INVALID	N2O outside specified accuracy range.	Zero the sensor. If the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
AGENT INVALID	Agent outside specified accuracy range.	Zero the sensor. If the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

AGENT MIXTURE	In ISA AX+, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds		Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
AGENT UNRELIABLE	- The accuracy of the agent identification and measurement could not be guaranteed. - More than 2 anesthetic agents are present in the breathing circuit - High concentrations of solvents, cleaning agents or other interfering gases are present in the breathing circuit		Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 INVALID AMBIENT PRESSURE	Ambient pressure outside operating range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID AMBIENT TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
O2 SENSOR ERROR	Sensor failure	Please contact after sales service of manufacturer	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 ZERO REFERENCE CALIB REQUIRED	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.	Perform automatic zeroing procedure in an environment with CO2 less than 0.80%V.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO SENSOR	Sensor is disconnected from the system	Connect the sensor to the system. If the problem still exists, contact after sales service of manufacturer.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

c) Messages

Message	Cause	Solution	Explanation
CO2 SENSOR STANDBY MODE	Manual setting and if no breath is detected for 30 min and ETCO2 is less than 4 mmHg for more than 30 min or when the monitor does not detect the sampling line.	Enter GAS window and set WORK MODE to MEASURE.	
ZEROING IN PROGRESS	The zeroing procedure is being conducted.		After that the zeroing procedure is completed, this message and a flat line signal will be displayed.

Indicator status on the ISA sensor:

Steady green light	ISA in operation and OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	ISA sensor error
Blinking red light	Check sampling line

Chapter 15. Brain Function Assessment Monitoring (BFA)

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15.1 GENERAL

Anesthesiologists have been using hemodynamic and clinical characteristics such as heart rate, blood pressure, tears, facial variations, pupil diameter and perspiration as well as different stimulations and personal experiences to measure the level of patient consciousness for many years. They also use devices such as Capnography and pulse oximetry in this regard. Since none of these parameters is directly associated with the level of consciousness, Physicians must use indirect measurement methods to apply appropriate dosage for each patient in order to make the patient feel no pain during surgery.
There are some standards to determine required dosage for each patient, for example one standard is based on needs of a middle-aged man. This standard is certainly not suitable for females, patients of different ages or patients with dangerous and unknown diseases.

There are common cases in which the patient is overdosed (receives excessive amount of drug) and this results in long wake-up time after anesthesia, prolonged recovery accompanied by nausea as well as economic loss.
A rare and chronic condition is when the patient receives low amount of drug and does not lose his consciousness completely (subconsciousness level), but due to the injection of muscle relaxant drugs he is unable to react during surgery and has a vague picture of what is going on around him. This can cause long-term emotional consequences and subsequent psychological traumas. The most of these patients suffer nightmare during few days after surgery.
A lot of attempts were made to measure the level of consciousness using patient vital signs signals, a method through which the required dosage of drug for each patient can be estimated without considering physiological factors such as weight, age, etc.

The Brain Function Assessment Monitor (BFA) is a non-invasive measurement tool for use by trained professionals to measure the level of consciousness (LOC) in all area of the hospital. BFI index is calculated through EEG signals. BFA module displays the related indexes but does not perform any data interpretation. All data interpretation is performed by a physician.
The monitor is intended for use in monitoring the hypnotic state of the brain by data acquisition of EEG signals of the anesthetized or sedated patient in all areas of the hospital.

Measurement principle
An instrumentation amplifier collects ongoing EEG with a high Common Mode Rejection Ratio (CMRR) ensuring a high-quality EEG acquisition. Special algorithms that eliminate their effects on subsequent BFI calculations detect artefacts.
The performance of the BFI is based on the analysis of the frequency content and phase of the EEG signals.
The monitor also evaluates the amount of burst suppression (BS) in each fifty-second period of the EEG. This measurement quantifies the amount of "silent" or "flat" EEG periods characteristic of the deepest levels of hypnosis.

The measured parameters in BFA monitor are EMG (Electromyography) and SQI (Signal Quality Index).

BFA Index (BFI)

The BFI is a unit-less index from 0 to 100, where 0 indicates a flat EEG and 100 indicates EEG activity in awake state. BFI range in adequate anaesthesia is designed to be between 40 and 60. All values in the table are approximate values based on the mean values of the patient behaviour. The relationship between BFI and the clinical state of patient is shown in the table below:

BFI	Clinical State
80-100	Awake
60-80	Light/Moderate sedation
40-60	Range considered as adequate for surgical anesthesia (General Anesthesia)
20-40	Deep anesthesia, in most cases accompanied by burst suppression (Deep Hypnotic State).
0-20	Close to coma with BS pattern. EEG is generally iso-electric (Burst Suppression).

EMG

High levels facial muscular or electromyographic (EMG) activity can interface with the BFI under certain circumstance .The monitor incorporates an EMG filter that removes most of the potential interfering EMG activity. The EMG bar shows the energy of the EMG level in the 30-47 Hz frequency band (0-100 logarithmic).

EMG activity is expected to be present when the patient is awake. When the patient is asleep, EMG activity can increase due to:

- Reflex reactions to painful stimuli during surgery.
- Lack of muscular relaxation.
- Muscular rigidity caused by some opioids (analgesics).
- Presence of large external electrical fields, e.g. electrosurgical unit.

The EMG bar should be checked frequently, especially in case of a sudden increase in the BFI. If BFI increases along with muscular activity, there will be risk of EMG interference. When this happens, attention must be paid to the stimuli received from the patient during surgery. In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent will decrease BFI. Since patients receiving neuromuscular blocking agents cannot exhibit movement as a sign of arousal, the BFI is a valuable tool in their anaesthetic management.

Burst Suppression Indicator (BS)

The monitor includes a Burst Suppression indicator to show periods when the EEG is iso-electric or “flat”. The indication appears in the BFI window and shows the percentage of burst suppression over the last 50 seconds of EEG signal. A BS% =20 readouts means that the EEG has been iso-electric during 20% of the last 50 seconds. In normal and low level of unconsciousness, BS value is usually 0 and it increases in deeper levels of unconsciousness. For patients who are close to coma state, BS value is usually 75%.

SQI: Signal Quality Index

The artefact rejection algorithm ensures that the incoming EEG is not contaminated with noise. When excessive noise is detected, the signal quality is reduced reflecting the disturbance. The artifact rejection algorithm will be active especially when patient is awake or moves and twinkles, and also when equipment creating external interference is used. In fact SQI value indicates that Brain Function Index (BFI) to what extent is reliable. When the SQI is 100, show that the EEG signal is in the best quality.

Warning

- **The monitor will not render accurate readings when used on patients with severe neurological disorders and patients under 2 years of age.**
- **The monitor will not render accurate readings when used on patients weight less than 70% or more than 130% of ideal body weight and recent use of psycho-active medication, including alcohol.**
- **The use of pacemakers might cause either long periods of artifacts or elevated BFI values.**
- **The EEG signal should not be used for diagnostic interpretations and patient's clinical assessment. This signal only is used to check status of electrodes connection to the patient.**
- **Do not use the BFA module when cardiac defibrillator is used. EEG cable is not protected against defibrillation.**
- **When used with electro surgical unit please note the positioning of the neuro sensors. In order to reduce the hazard of burns, the neuro sensors should not be located between the surgical site and the electro surgical unit return electrode.**
- **Not to be used in the presence of flammable gases; explosion risk.**
- **Pay attention if the BFA monitor is connected to a patient connected to other equipment. The total of leakage current may exceed the allowable limit and cause a possible hazard to the patient.**
- **The conductive parts of neuro sensor should not contact other conductive parts including earth.**
- **The monitor should be used in conjunction with other patient monitoring parameters and clinical signs. This will ensure the optimum balance of the anesthesia/sedation administration.**

- **Do not open the BFA case. There are no user-serviceable parts inside. The case should only be opened by qualified service personnel using proper grounding techniques. When the case is opened, an electrical shock hazard exists which can result in serious injury to persons and instrument component damage.**
- **Neuro sensors are disposable and should not be reused. Before use pay attention to the expiry date.**

NOTE

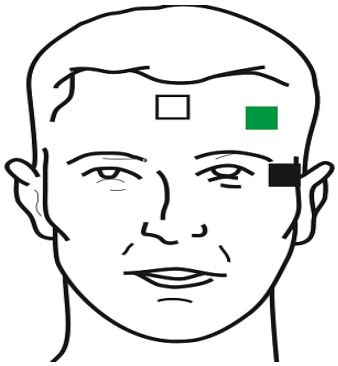
- **Operating the monitor close to equipment radiating high-energy radio frequencies (electrosurgical/cauterizing equipment, portable radios, cellular telephones, etc.) may cause signal disturbance. If this happens, reposition the monitor away from the source of interference.**

Skin Preparation and Placement of Sensors

To ensure low sensor impedance, clean skin with mild soap and water is recommended as a skin cleanser.

Rub the skin gently using wash cloth or gauze dampened with the skin prep product to remove the non-conductive skin layer, then clean it using a dry cloth.

Position of the three neuro sensors is shown in figure12-1. The advanced signal processing of the monitor ensures that a deviation in the positioning of the sensors up to 2 cm (0.78 in) has no significant influence on the index. However, it is recommended to place the sensors on an area of the skull where only a few muscle fibres are present in order to achieve the best quality signal.



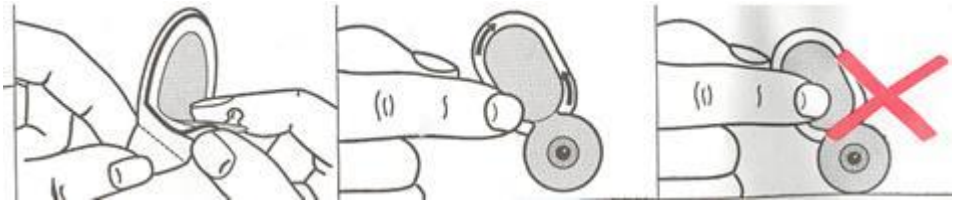
Neuro Sensor Placement

White electrode (1): middle of forehead
Green electrode (2): left side of forehead
Black electrode (3): on temple

NOTE

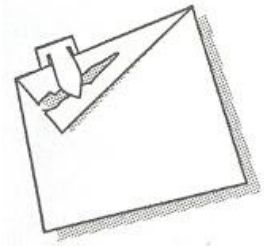
- **Alcohol is not recommended as a skin cleanser; it leaves a film layer that may cause high sensor impedance. If alcohol is used, ensure 30 second dry time.**
- **The performance of the BFA module is only guaranteed by the manufacture when the BFA Procedure Pack is used.**
- **Make sure no part of the neuro sensors is in contact with any other conductive parts including earth/ground.**
- **If skin rash or other unusual symptoms develop, remove sensors from patient.**
- **Change neuro sensors every 24 hours to check skin integrity.**
- **Once the neuro sensors have been secured on the skin, attach the colour-coded wires on the patient cable to appropriate sensor.**
- **A left sided setup is shown in figure. Right sided is also acceptable.**
- **BFA module accuracy may be low in head and facial surgeries.**

Picture below shows how to use neuro sensor.



Correct use of neuro Sensors

After opening the BFA neuro sensors package, close the package like the figure below. If you don't perform as the figure below, the neuro sensors may lose their quality.



Correct maintenance of neuro sensors in its package

15.2 BFA monitoring system

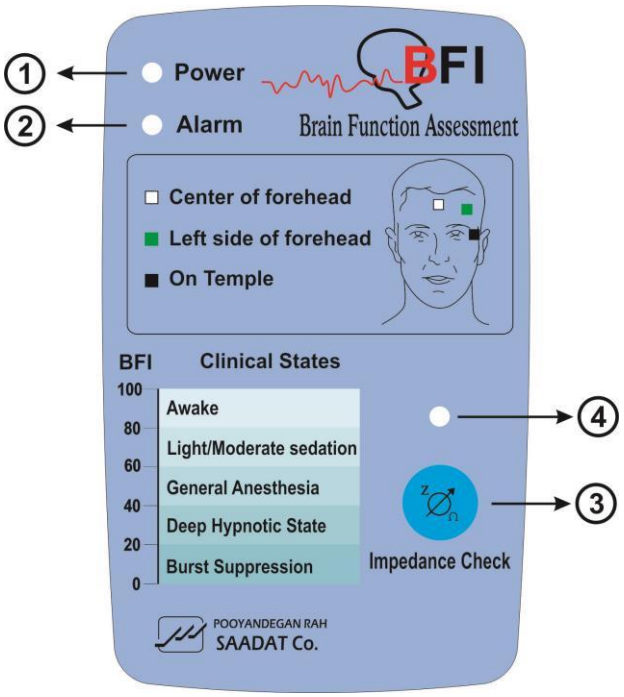
The monitor can show and record online BFA data on the patient monitor for this reason it needs BFA module. This part connects to patient monitor through an interface cable and then monitor displays the related information. The module power is also supplied by the monitor.

15.2.1 BFA module

BFA module

BFA module keys and indicators

①	**Power**	This indicator is turned on as BFA module is connected to the monitor and remains ON until the module is disconnected.
②	**Alarm**	If "BFA ELECTRODE ALARM" occurs (resulting from inappropriate connection of neuro sensors), this indicator will flash with frequency of 1 Hz.
③	**Impedance key**	Impedance measurement is initiated by pressing this key and its indicator flashes on the module for one second.



BFA module keys and indictors

15.2.2 BFA on patient monitor

BFA Module Setup

1- Turn on BFA module by connecting it to the monitor.

2- Connect the patient cable to BFA module.

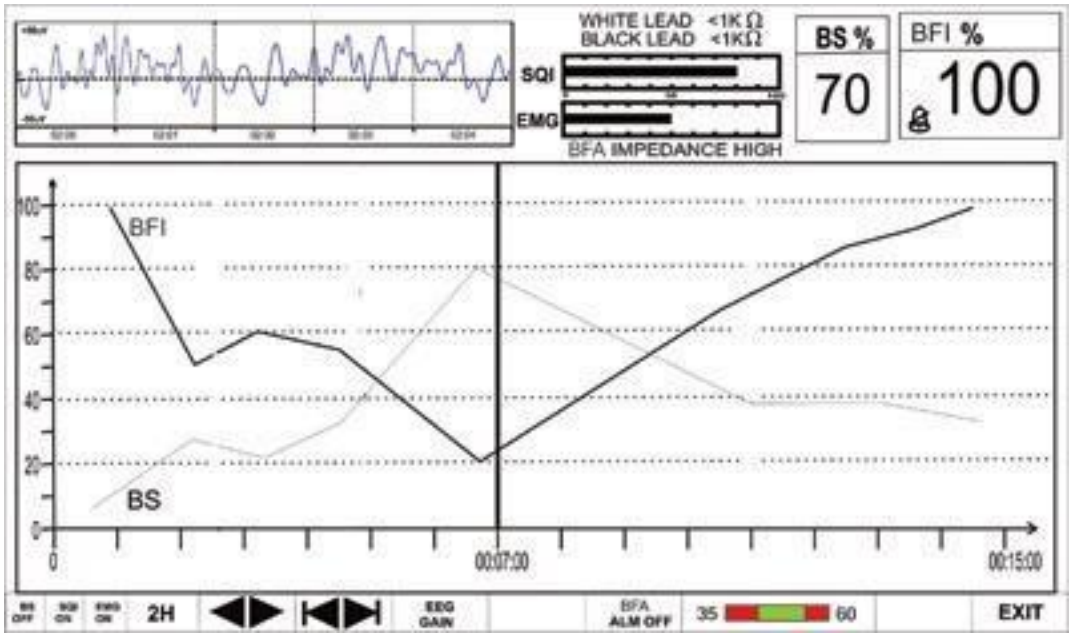
3- After communication is established, you can monitor different BFA parameters such as BFI%, BS%, SQI%, EMG% and also EEG signal on the patient monitor.(At first only EEG signal can be monitored and after 20 seconds, other parameters appear on the monitor).

Warning

- **Because the BFA patient cable are too thin pay attention not to subject them under tension.**
- **Use only the recommended BFA cable and neuro sensor for BFA monitoring. Other accessory may cause improper performance.**
- **Do not repair defective BFA cables and send it for after sale service. Manufacturer does not take responsibility for measurement accuracy of repaired cable.**

BFA on patient monitor

When highlight is placed at BFA area, press the knob, the following window (BFA large page) will pop up:



BFA large page

This window is a special page for BFA display to show detail information of BFA parameters in lager area and also you can change the different settings of BFA on it.

■ **To enable or disable trend graph of BS parameter:**
Pick the most left item to enable or disable the BS trend.

■ **To enable or disable trend graph of SQI parameter:**
Pick the second left item to enable or disable the SQI trend.

■ **To enable or disable trend graph of EMG parameter:**
Pick the third left item to enable or disable the EMG trend.

■ **To select how long the trend graph is displayed:**
Pick the fourth left item, available options are 15min, 30min and 1, 2 and 4 H.
As long as the cursor line is not moved in BFA large page, every click on the fourth left item will change the x -axis based on the selected interval.
Moving the cursor to choose a specific time and pressing trend time interval item (the forth left item), x -axis will be zoomed in and zoomed out equal to the trend interval according to the specific time the cursor line shows.

■ **To obtain trend data of specific time:**

The cursor line in trend graph shows specific time. Click on the fifth left item and turn the rotary to set the interval on 15, 30 min and 2 H. The specific time to which the cursor points will change and numeric parameters of this time will be displayed on the right side of the BFA large page.

■ **To select time interval of trend in x-axis:**

Pick ⏮⏭ (the sixth left item) to adjust the start time and end time of x-axis. By every click on ⏮⏭, the x- axis will change to extent of the adjusted time in the fourth left item.

■ **To change EEG gain:**

Pick "EEG GAIN" (the seventh left item) to set gain of EEG signal. The Y-axis of EEG signal changes according to the selected gain. Available options are 25µV and 50-250µV by step of 50µV.

■ **To enable or disable the BFA alarm limit:**

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

■ **To set the BFI alarm limit:**

Press the 10th left item to set the BFI limit. Alarm is activated when the BFI parameter exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (default: min= 35, max=60)

NOTE

- **The BFI parameter trend is always shown on this page and the user is not able to disable it.**
- **BFI alarm level is always II.**
- **Every change in BFA large page setting is shown on BFA window in normal state.**
- **In case of sudden and strange changes in BFI or SQI index, it is necessary to measure impedance manually.**

15.3 BFA Alarm Messages

a) Physiological alarms

The alarm occurs when BFI value exceeds the adjusted alarm limits:

Physiological Alarms		
ALARM	**SITUATION**	**DESCRIPTION**
BFI HIGH	Cerebral state index violates adjusted high limit.	● BFI value blinks. ●The alarm indicator flashes. ● Audio alarm is enabled. ● The alarm message is displayed in yellow background.
BFI LOW	Cerebral state index violates adjusted low limit.	

b) Technical alarms

Alarm level 3 is enabled for all below messages. By pressing ALARM SILENCE, the message background becomes gray and alarm is disabled and ignores this fault.

Technical Alarms			
Alarm	**Cause**	**Solution**	**Explanation**
BFA ELECTRODE ALARM	Placement of neuro sensors or their connections might be faulty or the impedance of the sensors may exceed 10k Ω. This alarm can also be caused by high frequency instrument.	●Check all neuro sensors and their connections. ●Check the patient cable. If it is not connected or is faulty, please connect it or replace it. ● Check if either of the neuro sensors is disconnected or wrongly connected. ●Replace faulty sensor. ●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
BFA SQI LOW	If the impedance of the white or black sensors exceeds 1kΩ, the SQI will fall gradually. Artefacts can have many causes including high - frequency instruments, EMG and etc.	●Check that all neuro sensors and cables are correctly connected. ●Has the use of any mechanical device that could generate high frequency activity (e.g. patient warmer) been initiated or is any such device in close proximity to the CSM neuro sensors? If possible move disturbing device away from the neuro sensors. ●Check grounding of disturbing device.	
BFA IMPEDANCE HIGH	If sensor impedance is > 5kΩ the BFI, %BS and %EMG will be blank.	●Check that neuro sensors are not dry. ●Check that the skin has been cleaned properly. ●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin.	
BFA LINK OFF	BFA module is off.	●Connect the module to the monitor through interface cable.	

Chapter 16, C.O. Monitoring

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16.1 GENERAL

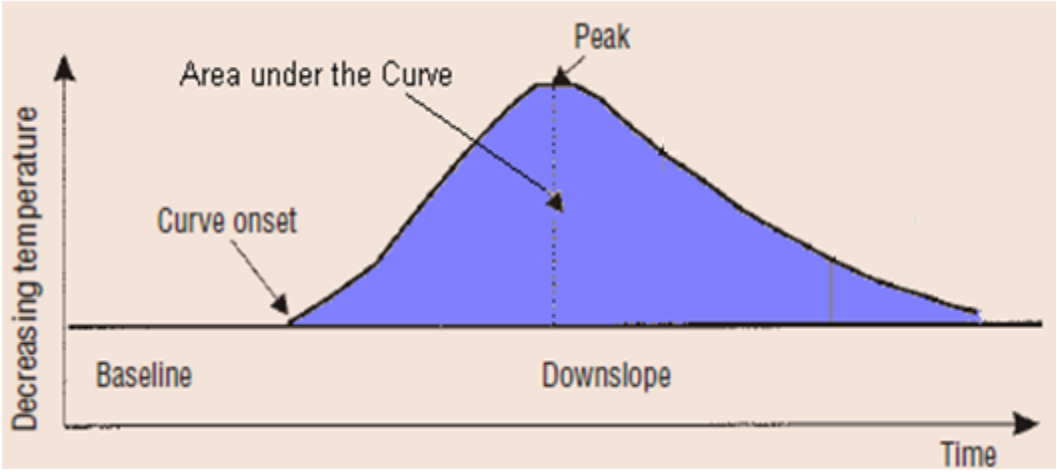
Cardiac Output (C.O.) is the volume of blood pumped by the heart ventricle per minute. The measurement unit is litres per minute (L/min).

To understand the clinical importance of measuring cardiac output, consider that the primary function of the heart is to deliver sufficient oxygenated blood to meet the metabolic needs of the body tissues. The cardiac output measurement invasively measures cardiac output and other hemodynamic parameters using a technique called thermodilution. C.O. measurements in URUK monitors are carried out using the right heart thermodilution method. This method is known as "gold standard" of C.O. measurement.

C.O. Measurement using the Right Heart Thermodilution Method

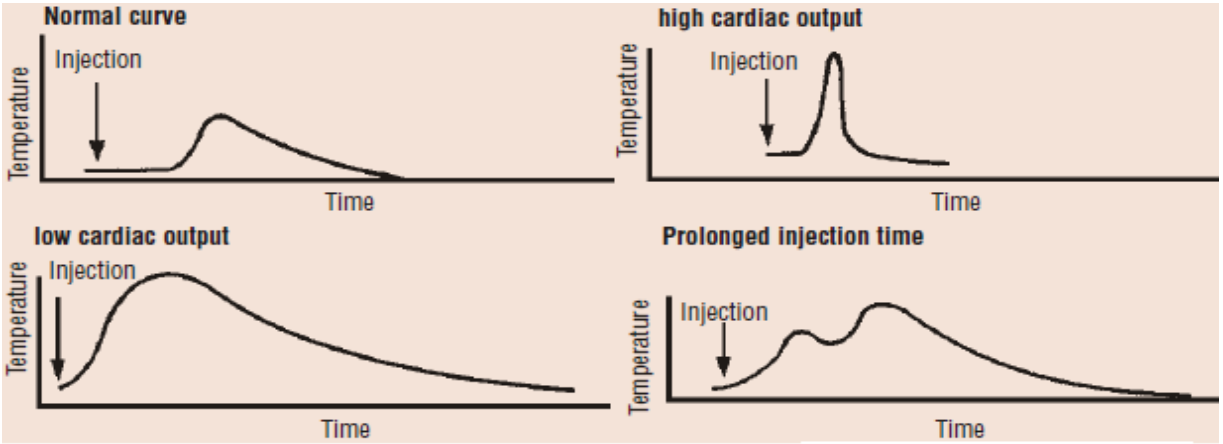
In the right heart thermodilution method, a cold fluid of known volume and temperature is injected into the right atrium thought a pulmonary artery catheter (PAC). The injected fluid mixes with the blood in the right ventricle and the change in blood temperature is measured with a thermostat situated in the distal end of the catheter in the pulmonary artery.

After injection, the blood temperature descends and then rises smoothly to reach its initial state. The lower cardiac output value, the colder temperature of injectate solution. Cardiac output is inversely proportional to the area under the thermodilution curve (Refer to the figure below).



Thermodilution curve after injection

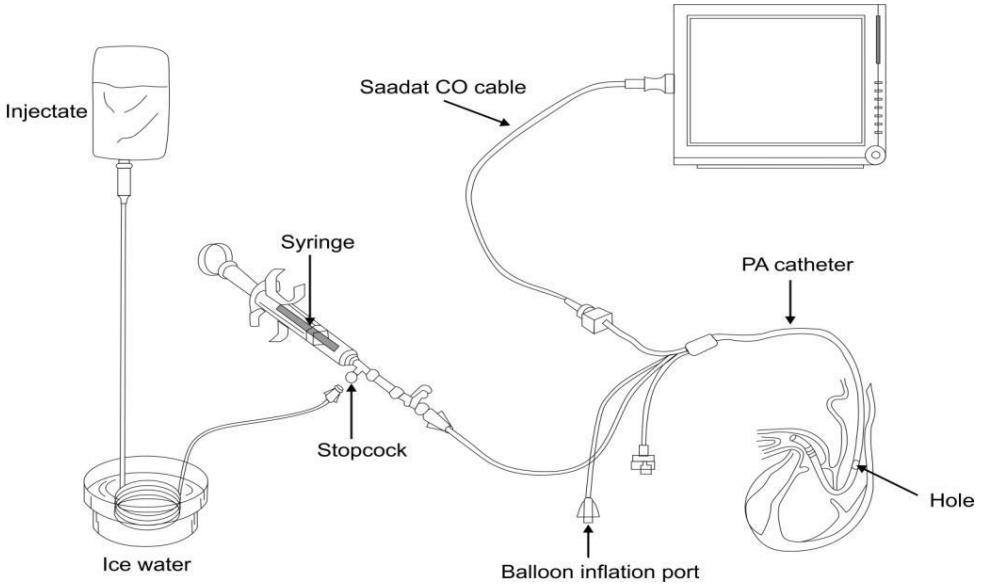
C.O. value is influenced by injection technique. As mentioned above, the curve should have a steep rise and gradual return to baseline (See the figure below). Other curves are samples of high cardiac output, low cardiac output and prolonged injection. A series of measurements must be carried out to achieve a reliable C.O. value and average of multiple thermodilution measurements is used for therapy decisions.



Samples of thermodilution curves in C.O. measurement

Setting up RH C.O. Measurements

1. Enter the catheter into the heart and place it in proper position (Follow your hospital standards to avoid unintentional extraction of C.O. catheter).
2. Connect the other side of the catheter to URUK C.O. cable.
3. Connect C.O. cable to the respective connector on the side panel of URUK monitor.
4. Prepare ice bath (water) and injected solution (0 °C).



Setting up RH C.O. Measurement

Warning

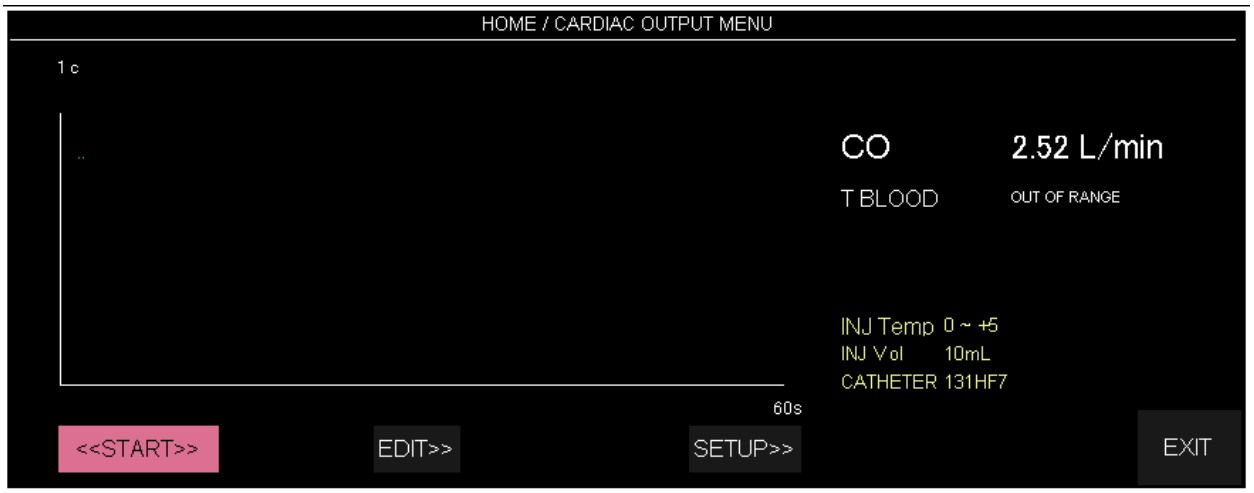
- **C.O. measurement must be carried out by trained and qualified individuals.**
- **Fluid injection must be carried out smoothly.**
- **C.O. module calculates cardiac output based on injectate temperature of 0 °C. There will be measurement error if the temperature of injectate solution is not zero.**
- **Use only the accessories specified in this manual.**
- **Make sure that no part of accessories is in contact with any other conductive parts.**
- **Don't use electrosurgical equipment during C.O. measurement.**
- **Disposable catheter should not be reused.**

NOTE

- **If the patient condition is unstable, the measurement cannot be done or is unreliable.**
- **Do not use the catheter if its package is damaged.**
- **Before using catheter, inflate the balloon to make sure that it is not damaged.**
- **Before using catheter, inject the solution by syringe to check path of injectate.**

16.2 CARDIAC OUTPUT MENU

Pick "CARDIAC OUTPUT" in HOME MENU to call up the following menu:



If C.O. cable and catheter are not firmly connected to the monitor, the message “No Cable” will appear on the screen. If after connecting C.O. cable, “Noisy Baseline” appears, the monitor can not start measurement. If the message does not disappear after a while, possible causes can be improper placement of the catheter or interference of other devices such as electrosurgical unit in the vicinity of the monitor. When you see the message “Ready For Measurement”, start measurement by selecting **Start** key.

The blood temperature is displayed in front of **TBlood** in this window. If the temperature is out of the range 25 – 45 °C, the message “Out Of Range” appears on the screen. In this condition C.O. measurement is impossible.

▪ START

When you see the message "**Ready for Measurement**", press the Start key and then when you see the message "**Inject Now**", inject the solution.

During measurement, the thermodilution curve is displayed and the message "**CALCULATING**" will appear above the curve when C.O. value is calculated by the system.

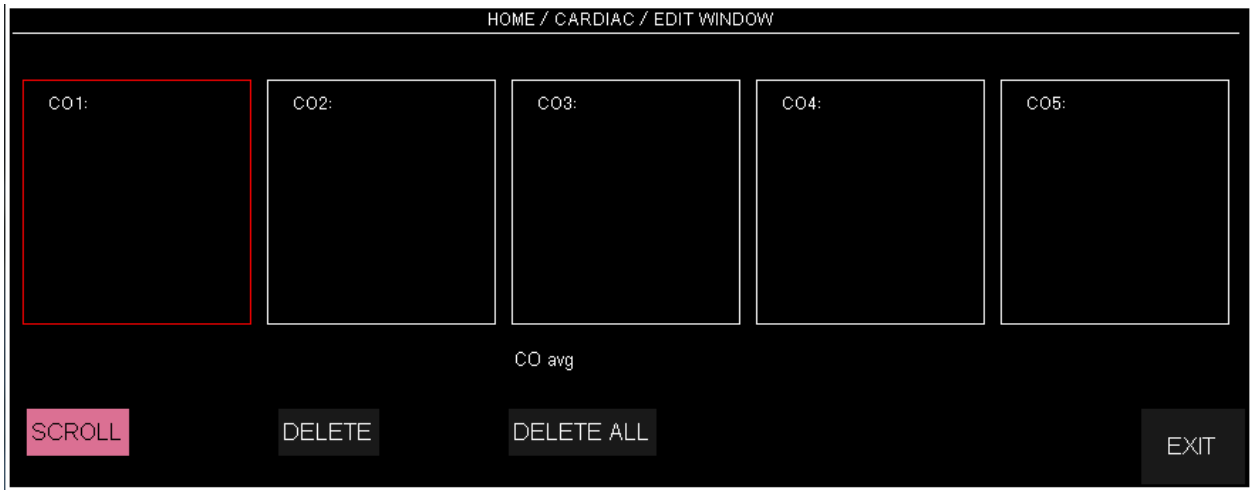
At the end of the measurement C.O. value will be displayed on the screen. After each measurement if the curve appears abnormal (due to noise or inappropriate injection), a question mark symbol ("?") will appear next to the calculated C.O. value. The thermodilution curve, cardiac output numeric value and measurement time are stored in one of five EDIT windows. Press STOP key during measurement to stop it.

NOTE

- **Sudden variations in pulmonary artery blood temperature resulted from e.g. patient movement or drug injection may cause C.O calculation. To avoid incorrect curve detection, immediately after "Inject Now" appears, inject the solution.**

▪ The Last five C.O. measurements

Pick "EDIT" in HOME/CARDIAC OUTPUT MENU to call up the following window:



Numeric value, curve and time of the last five C.O. measurements are displayed in this window. Averaged C.O. value is displayed below the window. User can identify and delete erroneous measurements and then average value of other measurements will be recalculated by the system.

If you perform more than five measurements without rejecting any, the first measurement will automatically be deleted when sixth curve is stored.

- ## SCROLL

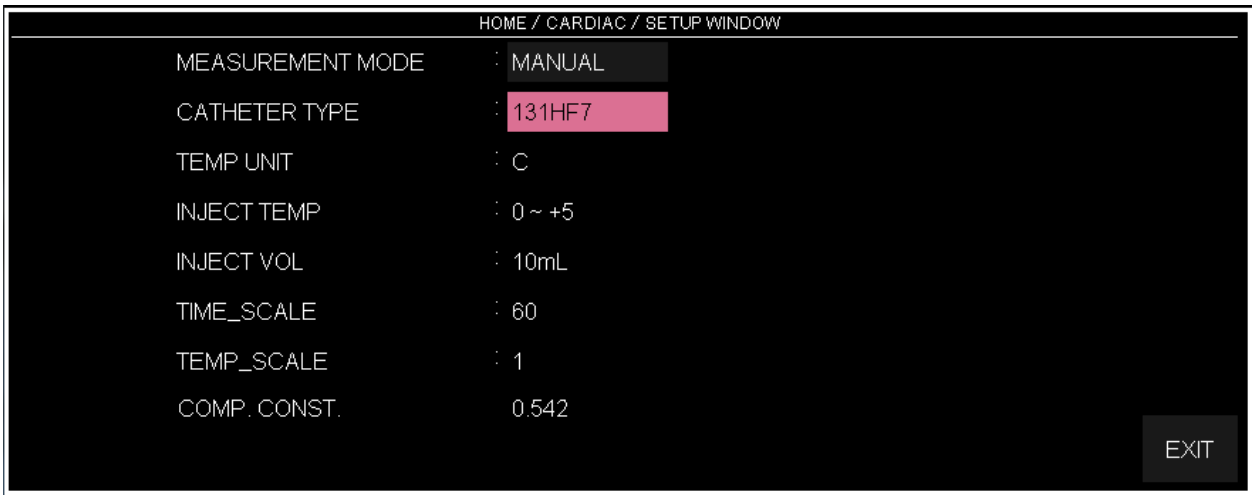
Press SCROLL to move red frame between curves and press ENTER to select one curve.

- ## DELETE

Press to delete the selected curve. Press **Delete All** to delete all stored C.O. curves.

- ## SETUP

C.O. settings can be changed in the Setup menu. Pick SETUP in HOME/CARDIAC OUTPUT MENU to call up the following menu:



- **Measurement Mode**

To start measurement in MANUAL mode, press START key in CARDIAC OUTPUT MENU after you prepared injectate solution.

- **Catheter Type**

To select catheter type. Available options are “131HF7” and “139HF75P” Edwards catheters and “Simulator”. The last option is intended to use simulator with Comp.Con. of 0.542.

- **Comp. Con.**

The computation constant changes based on catheter type. Make sure that appropriate catheter is selected, because computation constant directly influences C.O. measurement.

C.O. settings in SETUP menu can be monitored in CARDIAC OUTPUT MENU to check and modify any possible error occurred in data input.

16.3 C.O. Alarm Messages

Message	Explanation
No Cable	C.O. cable is not connected to the monitor.
Ready for measurement	The system alerts user to start measurement
Noisy Baseline	The system is not ready for measurement. (If the message does not disappear after a while, possible cause can be improper placement of the catheter. Make sure that the catheter is placed properly in the patient body).
Start pressed when not ready please wait	If Start button is pressed before the message “Ready for measurement” appears, the measurement will not be started and this message will appear. To start measurement, wait until “Ready for measurement” is displayed.
Inject now	Start injection procedure.
Not injected in the expected time	Injection is not performed long time after Start C.O. is selected.
Minimum not detected in the expected time	The curve peak has not been detected in the expected time.
Calculating	C.O. is being calculated.
Curve end not detected!	The curve end has not been detected in the expected time.
Minimum and End Not Confirmed-Noisy Curve	C.O. calculation is stopped due to noisy curve
Done! Check edit menu or oldest curve is replaced!	All five C.O. measurement windows are filled. In order to observe average value and deleting/selecting measurements, refer to Edit window, otherwise start a new measurement, the oldest measurement data will be replaced by new one.

Chapter 17. SIGMA, TREND, EVENT LOG & ALARM RECALL

17.1 SIGMA 2

17.2 TREND 3

TREND Window 3

Trend keys 4

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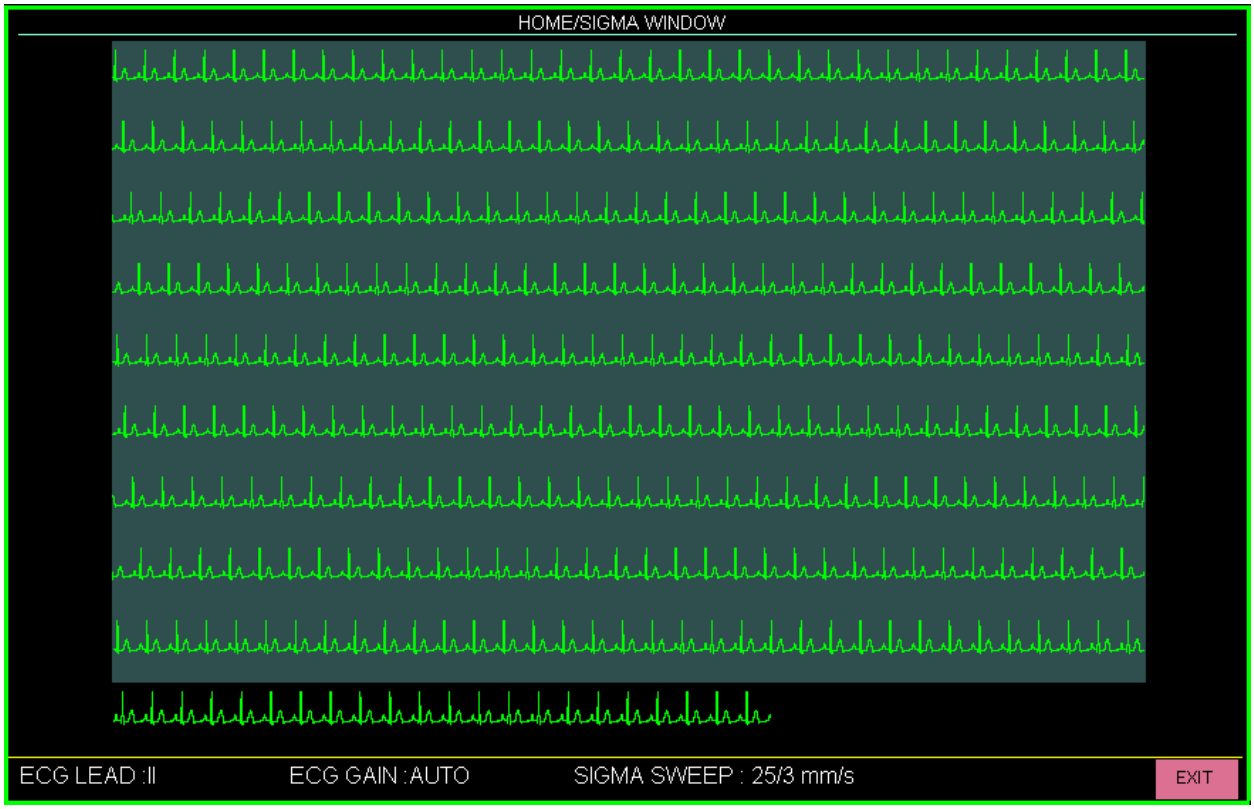
17.1 SIGMA

The patient care monitor is able to save and display 10 traces of ECG signal in SIGMA WINDOW. The time of displaying ECG signal for 19inch monitors is 260 sec and for 12inch monitors is 220 sec.
Pick "SIGMA" from HOME WINDOW to call up the following window:



You can view ECG settings including ECG LEAD, ECG GAIN and SIGMA SWEEP SPEED in this window.

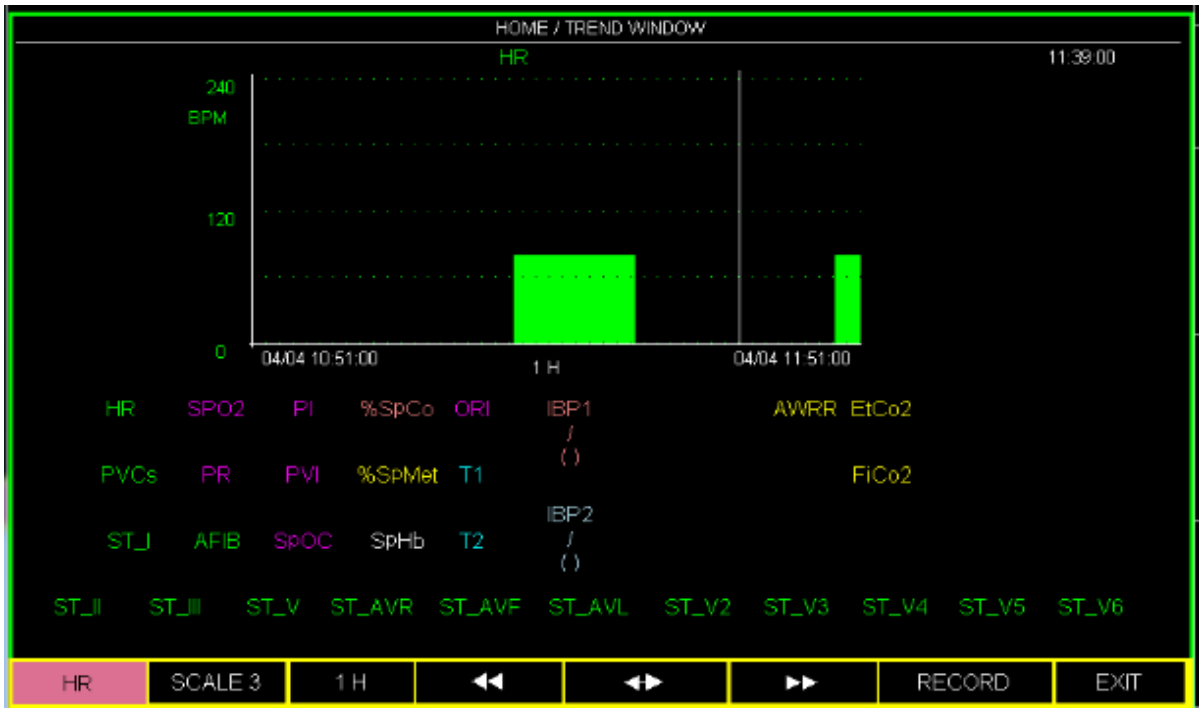
Item	Setting
ECG LEAD	**According to the selected reference lead in the ECG menu.**
ECG GAIN	**According to the Gain setting in the ECG menu.**
SIGMA SWEEP	**Fixed value of 25/3 mm/s(equal to 8.33 mm/s).**

17.2 TREND

The latest 96 hours of parameters values are recorded every second in Trend Window (Tabular and Graphic trends) to control patient status continuously.

TREND Window

Pick "TREND" from the HOME WINDOW to call up the following window:



Y-axis stands for a specific parameter value and X-axis for time. Numeric values corresponding to the cursor time are displayed below the trend graph.

Trend keys

Key	Function
Parameter (the most left item)	**To select trend graph of a specific parameter** Click on this key and turn the rotary to view trend of a specific parameter: HR, SpO2 , RESP, T1 , T2, IBP1, IBP2 ,AWRR , Co2 ,FiCo2 .EtCo2 , O2, FiO2- EtO2, EtN2O,FiN2O, N2O, AA, EtAA-FiAA, PVCs , ST ,(ALL LEAD), AFIB , PR , PI , PVI , SPOC , %SpCo , %SpMet , SpHb , ORi, 6PARAMS and OXY CRG
SCALE	To adjust the Y-axis scale and thus change the trend curve in proportion (see the below table).
Interval (the third left item	Click on this key to set interval of numeric parameters Available options are: 15 min ,30 min, 45 min, 1 h, 2 h and 4 h
⏪ or ⏩	Click on these keys to change the time interval of x-axis to the extent of the specified time in the third left item.
◀ ▶	**To obtain trend data of a specific time** Click on this key and turn the rotary to move the cursor line through the graphic trend that points to specific time. Numeric values corresponding to this time are displayed below the trend graph. ⁕ You can do this only for 15, 30, 45 min and 1, 2 hr intervals (set in the third left item).
RECORD	Click to record the trend data.
EXIT	To exit from the trend window.

NOTE

- **If one of physiological modules is not active, its respective parameter will not be displayed in the trend window.**

Trend scales

	SCALE1		SCALE2		SCALE3		SCALE4		SCALE5		SCALE6	
	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX
HR	0	60	0	120	0	240	-	-	-	-	-	-
SpO2	80	100	60	100	0	100	-	-	-	-	-	-
T1/ T2	30	42	24	48	0	48	-	-	-	-	-	-
IBP1/IBP2/ IBP3/IBP4	-20	50	-20	100	-20	200	-50	300	50	250	-	-
RESP	0	60	0	120	0	240	-	-	-	-	-	-
AWRR	0	60	0	120	0	240	-	-	-	-	-	-
Co2/ EtCo2/ FiCo2	0	50	0	100	-	-	-	-	-	-	-	-
O2/ EtO2/ FiO2	0	50	0	100	-	-	-	-	-	-	-	-
N2O/ EtN2O/ FiN2O	0	50	0	100	-	-	-	-	-	-	-	-
AA/ EtAA/ FiAA	0	1.0	0	2.0	0	3.0	0	5.0	0	10.0	0	**20.0**
PVCs	0	20	0	50	0	100	-	-	-	-	-	-
ST (All leads)	-0.2	0.2	-0.5	0.5	-1	+1	-2	2	-	-	-	-
AFIB	0	1	–	–	–	–	–	–	–	–	–	
PR	0	60	0	120	0	240	–	–	–	–	–	
PI	0	20	0	10	0	5	–	–	–	–	–	
PVI	0	30	0	100	-	-	–	–	–	–	–	
SpOC	0	36	6	20	-	-	–	–	–	–	–	
SpCo	0	12	0	24	0	50	–	–	–	–	–	
SpMet	0	6	0	20	-	-	–	–	–	–	–	
SpHb	6	20	2	14	0	25	–	–	–	–	–	
ORi	**0**	**1**	-	-	-	-	-	-	-	-	-	-

According to the above table, six scales are selectable for each parameter.

6-PARAM TREND* (only for 19 inch monitor)

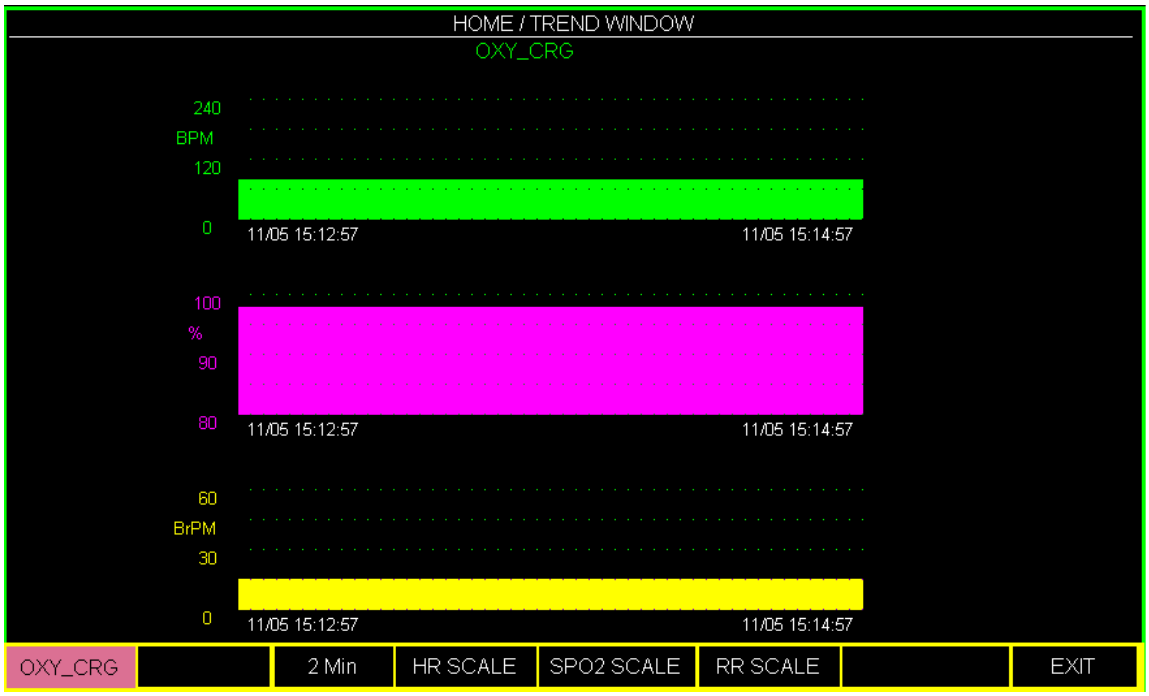
Select 6-PARAM in HOME/TREND WINDOW (for the first left item) to access the following window in which you can monitor TREND graph of six parameters simultaneously.

NOTE

- **Select the third left item in the window to set time interval of displaying the trend graph.**
- **By turning the rotary and clicking it down on a parameter, you can select your desired parameter and view its trend graph.**
- **The trends scales cannot be set in this window.**
- **Select "RECORD" in this window to record all six trend graphs.**

OXY-CRG TREND *(only for 19 inch monitor)

Select OXY-CRG in HOME/TREND WINDOW (for the first left item) to access the following window in which you can monitor HR, SpO2 and RESP signals simultaneously. OXY-CRG aids clinician to detect and evaluate patient critical conditions e.g. apnea and breathing disorder especially in neonates.



Select the third left item to set time interval of displaying the trend graph. Available options are 2, 4 and 8 minutes.

To change the display scale of each of three trend curves, click on HR SCALE, SpO2 SCALE or RR SCALE.

17.3 ALARM RECALL *(only for 19 inch monitor)

Choose “ALARM RECALL” from HOME WINDOW to access the following window in which you can store and review data of the alarm occurrence time.

HOME / ALARM RECALL WINDOW

#N	DATE TIME		HR	%SPO2	IBP1-SYS/DIA(MAP)	IBP2-SYS/DIA(MAP)	RR	T1	T2	ETCO2	FICO2	NIBP	1 / 3
19	23/11/2016	11:59:01	80	98	120 / 80(100)	121 / 79(98)		36.7	37.9			121 / 82(98)	
18	23/11/2016	11:12:32	80	98	120 / 80(100)	121 / 79(98)		36.7	37.9			121 / 82(98)	
17	02/09/1395	10:53:04	80	98	120 / 80(100)	121 / 79(98)		36.7	37.9			121 / 82(98)	
16	23/11/2016	10:52:15	80	98	120 / 80(100)	121 / 79(98)		36.7	37.9			121 / 82(98)	
15	19/11/2016	09:46:38	80	98	120 / 80(100)	121 / 79(98)		36.7	37.9			121 / 82(98)	
14	16/11/2016	16:21:51	80	98	120 / 80(100)	121 / 79(98)		36.7	37.9			121 / 82(98)	
13	16/11/2016	08:57:46	80	98	120 / 80(100)	121 / 79(98)		36.7	37.9			121 / 82(98)	

UP - DOWN | ▲__▼ | DELETE | WAVE | | EXIT

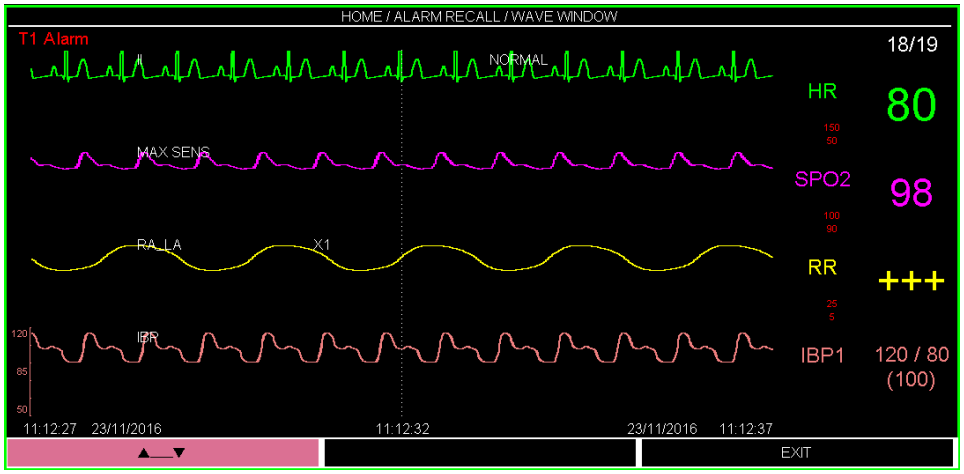
Alarm data including date, time and number of the alarm event and parameters values (HR, SpO2, IBP1, IBP2, PR, T1, T2, ETCo2, FICo2 and NIBP) are displayed in this window.

Data of 20 alarm events are saved in HOME/ALARM RECALL WINDOW. Up to seven alarm events are displayed in each page of this window.

NOTE

- **The parameter value which triggered the alarm will be displayed in the red.**
- **The parameter value of the previously triggered alarm which is still active will be displayed in the yellow color.**
- **The parameter value of inactive alarm is displayed in the white color.**

Alarm Recall keys

Key	Function
UP-DOWN	To access different pages of the Alarm Recall window.
▲ ▼	To move up and down the list and select an alarm event.
DELETE	To delete the selected alarm event.
WAVE	To monitor different signals and numeric parameters of alarm occurrence time.  ※ The time of alarm occurrence is displayed by a vertical dotted line. The signals of 5 seconds before and after this time are displayed in the window.
EXIT	To exit from the Alarm Recall window.

NOTE

- **If a new alarm occurs after that the Alarm Recall list is filled up, the last alarm event will be deleted and new alarm event will be shown at the top of the list.**

17.4 EVENT LOG

Pick "EVENT LOG" from the HOME WINDOW to call up the following window:

List of changes made in modules setting and data/time of these changes are displayed in this window.

The Event log window includes some records of the below changes:

- Enabling/disabling alarm
- Alarm limits
- Arrhythmias setting in HOME /ARR ANALYSIS/ SETUP MENU

▲ ▼	Select to move between the list records
UP-DOWN	Select to access previous and next pages
EXIT	Select to exit the window

NOTE

100 records can be saved in the EVENT LOG window

Chapter 18, RECORDER

18.1 General 2

18.2 RECORDER 3

18.3 Recording type 5

18.4 Recorder operation and status messages 6

18.5 Recorder paper 7

18.6 Recorder Technical Alarms 9

18.1 General

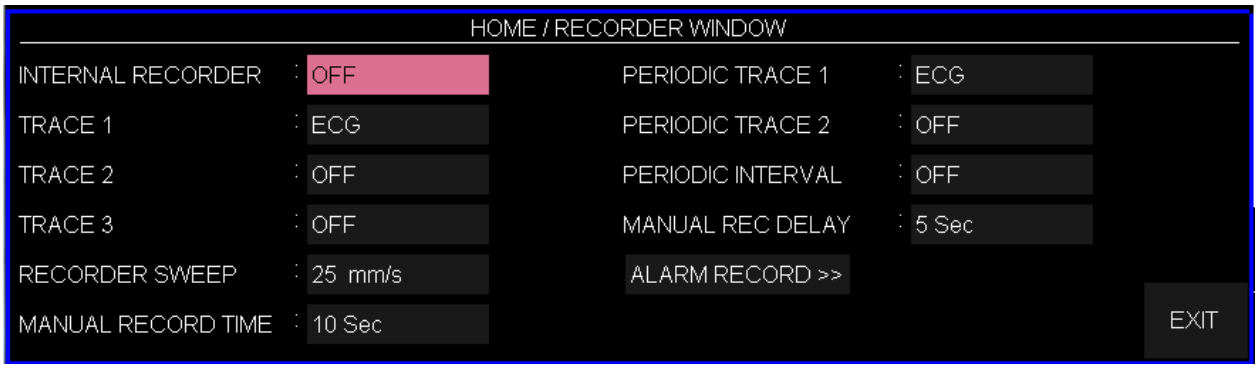
URUK thermal recorder can be installed on the bedside monitor optionally.

Performance of the Recorder

- Recording speed is adjustable to 6, 12.5 and 25 mm/s.
- Up to 3 selectable waveforms recording.
- The real time and freeze recording.
- The automatic recording with selectable time intervals
- The selectable automatic alarm recording.
- The manual recording delay

18.2 RECORDER

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



- **INTERNAL RECORDER**

  Pick "ON" to record via internal recorder.
  Pick "OFF" to disable the internal recorder and record via the Central system.

- **Selecting traces**

  You can choose three traces for printout record. The trace of each channel can be set separately.
  Available options for TRACE 1 and TRACE 2 are ECG, SpO2, IBP1, IBP2, RESP, GAS and OFF.

  Available options for the third trace of print out record are ECG (different leads) and OFF.

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

CABLE TYPE ECG	Available options for TRACE 3
3 WIRE	Only OFF (No option)
5 WIRE	Available options are ECG-I, ECG-II, ECG -III, ECG-V, ECG-aVR, ECG-aVF, ECG-aVL and OFF
10 WIRE	Available options are ECG-I, ECG-II, ECG -III, ECG-V, ECG-aVR, ECG-aVF , ECG-aVL , V1, V2, V3, V4, V5, V6 and OFF.

NOTE

- **You cannot choose same signal for TRACE 1 and TRACE 2.**
- **If available options for TRACE 3 are not suitable for the selected CABLE TYPE, the system will automatically set TRACE 3 to OFF in 3WIRE mode and to ECG-II in 5 WIRE mode.**
- **Reference lead is derived from ECG module. So if you set TRACE 1 or TRACE 2 to ECG, reference lead will not be selectable for TRACE 3.**

■ **RECORDER SWEEP**

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

■ **MANUAL RECORD TIME**

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

■ **PERIODIC INTERVAL**

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

You can select trace of each channel (TRACE 1, 2, 3) separately in this mode of recording.

■ **MANUAL REC DELAY**

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

■ **ALARM RECORD**

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

18.3 Recording type

The monitor provides several recording types:

- Continuous real-time recording.
- 10, 20 and 30 seconds real-time recording.
- 10 seconds automatic recording.
- Alarm recording.
- Freeze recording.
- Parametric recording.
- TREND recording.
- NIBP LIST recording.
- ARR EVENT LIST recording.
- ARR WAVE recording.

Parametric Recording
Parametric recording starts when you press “Rec/Stop” key if both traces in RECORDER WINDOW are set to “OFF”.

Manual Recording
Manual recording includes two recording modes as follow:

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

10, 20 and 30 s Recording:
Real time recording starts from last 5 seconds when you press “Rec/Stop” and it will automatically stop after 10, 20 or 30 seconds depending on your setting.

Automatic Recording

The monitor starts the recording for 10 seconds according to time interval which is set in the "PERIODIC INTERVAL" of the "RECORDER WINDOW". Refer to **18.2** for details.

Alarm Recording

If “ALARM REC” is set ON in each parameter’s window, the system automatically starts recording when an alarm occurs. Alarm recording is activated when the numeric parameters violate adjusted alarm limits or when an arrhythmia event occurs.
When an alarm of parameters has occurred, only numeric parameters will be recorded and parameter’s value that triggered the alarm record is marked with an arrow.
During HR alarm recording, the monitor also records 20 seconds of ECG waveform.
You can “ON” or “OFF” alarm recording in HOME /RECORDERWINDOW and also it can be

set in each parameter menu.

Freeze Recording
The monitor prints out 20 seconds of the selected waveforms and numeric parameters in FROZEN mode. So you can freeze abnormal waveforms on the screen and record them.

TREND Recording
The monitor can print out the trend graph and numeric parameters in the current TREND WINDOW. Select "RECORD" in TREND WINDOW to start recording.

NIBP LIST Recording
The monitor can print out NIBP LIST. Select "RECORD" in NIBP LIST WINDOW to start recording.

ARR EVENT LIST Recording
The monitor can print out ARR EVENT LIST. Select "RECORD" in ARR EVENT LIST WINDOW to start recording.

ARR WAVEFORM Recording
The monitor can print out stored arrhythmia waveforms in ARR WAVEFORM LIST WINDOW. Select "RECORD" in ARR EVENT RECAL/WAVE WINDOW to start recording.

18.4 Recorder operation and status messages

The following data are printed on the paper:

- Recording Type

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

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

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

18.5 Recorder paper

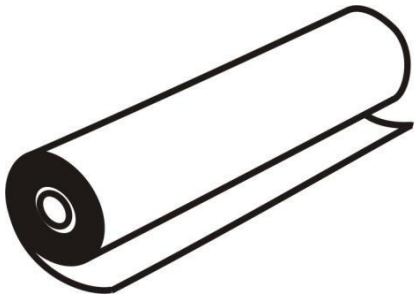
You should use only 57mm thermo-sensitive paper for URUK recorder.

Loading the paper:

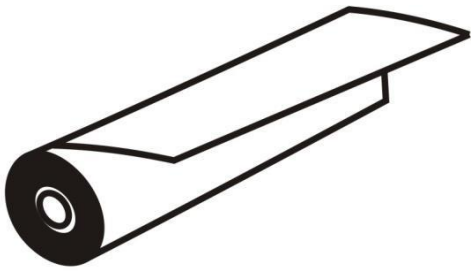
- Pull down the switch on the recorder case.
- Insert a new roll of paper into the paper cassette. Printing side of the paper should face the thermo sensitive printhead.
- Close the recorder door.

NOTE

- **Use only manufacturer recommended white thermosensitive record paper, otherwise the recording quality may be poor and the thermosensitive printhead may be damaged**.
- **Do not use grid paper.**
- **Do not use paper with edges that are pasted or have turnups at the start of the roll. If they need to be used unavoidably, replace with new paper roll as soon as possible before entire roll is used up.**
- **Thermo sensitive surface of paper should be placed facing the head. Make sure to place the paper correctly.**



a. incorrect placement



b. correct placement

- **The paper detector may not operate properly if covered with foreign matter. Therefore, if you find foreign matter on the sensor, remove it and clean the sensor.**
- **If the paper is jammed, open the recorder door and remove the paper. Do not pull the paper by force.**
- **Be careful when inserting paper. Avoid damaging the thermosensitive printhead. Do not touch thermosensitive print head.**
- **It is recommended to use the paper with coloured marks intended to aware that the paper is near to finish. Otherwise, the operator should be sure about sufficient paper for recording.**

Warning

- **Do not touch the recorder head while recording and immediately after recording because it is so hot and may lead to personal injury including burns.**
- **While the recorder is working, the record paper goes out steadily. By pulling the paper, the recorder will be damaged.**

18.6 Recorder Technical Alarms

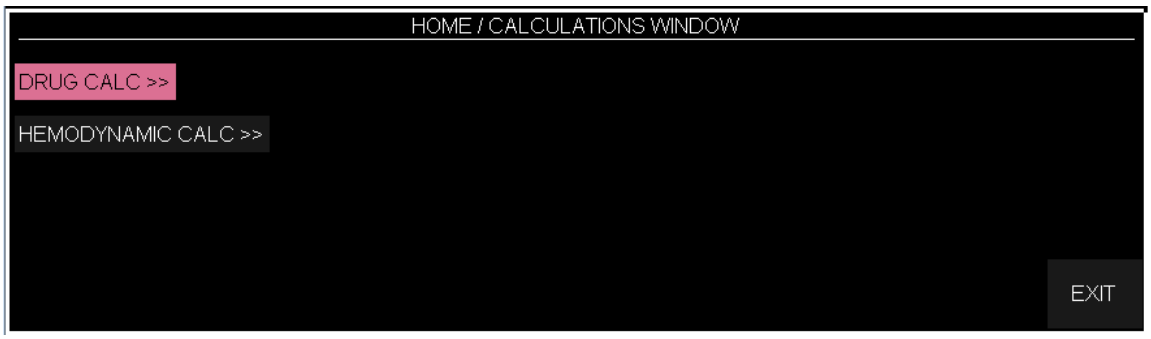
Message	Cause	Solution	Explanation
Rec. Software Error	Software error	Turn the system off and then on .If the problem persists, contact after sales service of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
Recorder Fault	Hardware error	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	
Rec Door Open	The recorder door is open	Close the recorder door.	
Rec Paper Out	Recorder paper has been used up.	Insert a new paper roll.	
Print head High Temp	The thermal head is too hot.	Stop operation for a few minutes.	
Print head High Vol.	Print head voltage is high.	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	
Print head Low Vol.	Print head voltage is low.	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	
Time out Error	The recorder could not record.	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	

Chapter 19, CALCULATIONS

19.1 DRUG CALC.....2

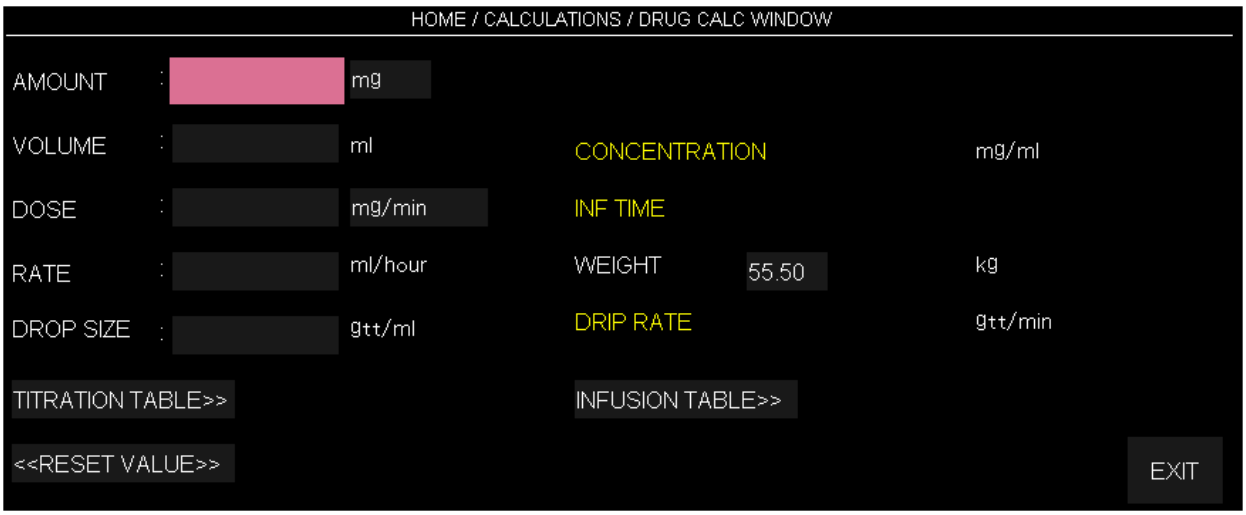
19.2 HEMODYNAMIC CALC.....5

Select CALCULATIONS from HOME WINDOW to open the following window:



19.1 DRUG CALC

This item is used to calculate rate, dosage, amount or volume, capacity and time of drug infusion. Infusion rate based on Drop Size is defined as Drip Rate.
Choose “DRUG CALC” to access the following window.



- **Input data**

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

- Measurement unit of AMOUNT and DOSE can be selected by user.

- Available units for AMOUNT are mg and mcg.
- Available units for DOSE are mg/min, mg/kg//min ,mcg/min and mcg/kg/min

- **Weight**

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

- **RESET VALUE**

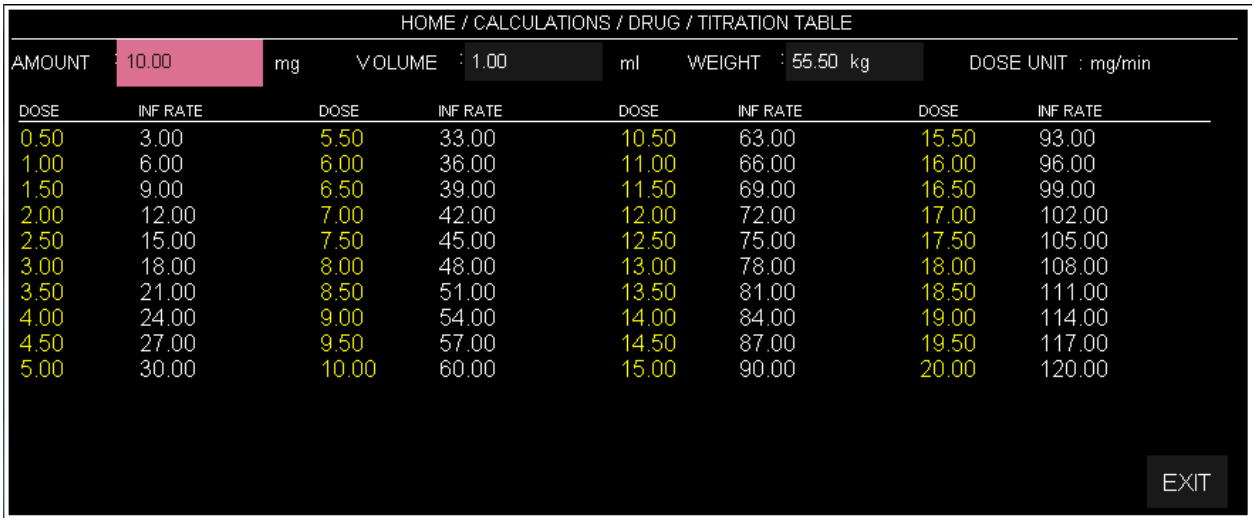
User can select << RESET VALUE >> to delete all input values and calculations for new input data and calculations.
Calculation is automatically performed as user changes inputs.

- **DRIP RATE**

DRIP RATE is automatically calculated as user defines DROP SIZE.

- **TITRATION TABLE**

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



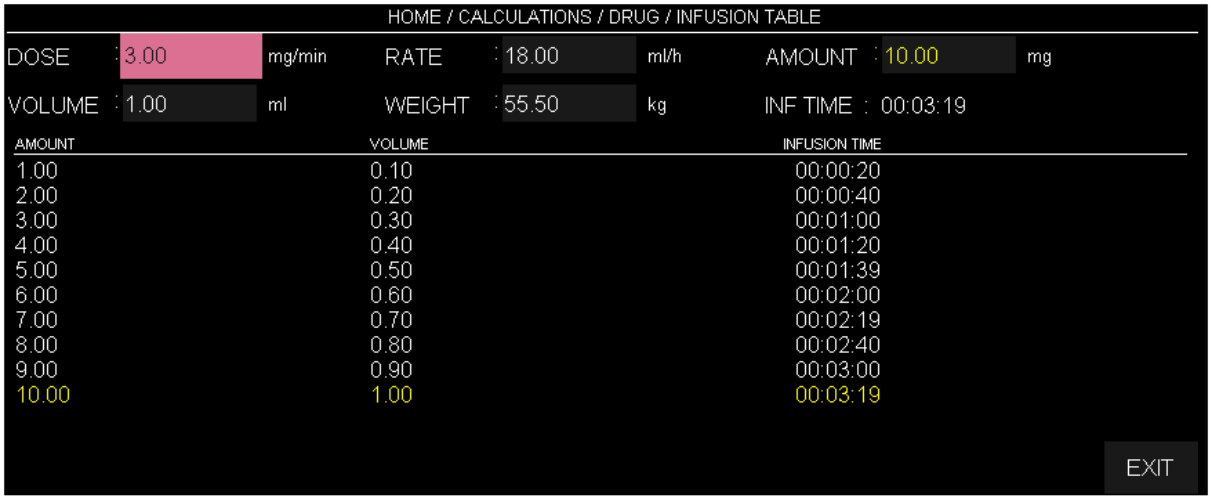
DOSE	INF RATE	DOSE	INF RATE	DOSE	INF RATE	DOSE	INF RATE
0.50	3.00	5.50	33.00	10.50	63.00	15.50	93.00
1.00	6.00	6.00	36.00	11.00	66.00	16.00	96.00
1.50	9.00	6.50	39.00	11.50	69.00	16.50	99.00
2.00	12.00	7.00	42.00	12.00	72.00	17.00	102.00
2.50	15.00	7.50	45.00	12.50	75.00	17.50	105.00
3.00	18.00	8.00	48.00	13.00	78.00	18.00	108.00
3.50	21.00	8.50	51.00	13.50	81.00	18.50	111.00
4.00	24.00	9.00	54.00	14.00	84.00	19.00	114.00
4.50	27.00	9.50	57.00	14.50	87.00	19.50	117.00
5.00	30.00	10.00	60.00	15.00	90.00	20.00	120.00

- To review the relation between different doses of drug and time of their infusion, INF RATE for doses 0.5 to 20 (according to adjusted unit in HOME/ CALCULATIONS/ DRUG CALC WINDOW) is displayed in this window.

- Adjusted AMOUNT, VOLUME and WEIGHT values and DOSE UNIT in HOME/ CALCULATIONS/ DRUG CALC WINDOW are automatically displayed in this window.

- **INFUSION TABLE**

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



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

- Adjusted DOSE ،RATE ،AMOUNT ،VOLUME ،WEIGHT and INF TIME in HOME/ CALCULATIONS/ DRUG CALC WINDOW are automatically displayed in this window.

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

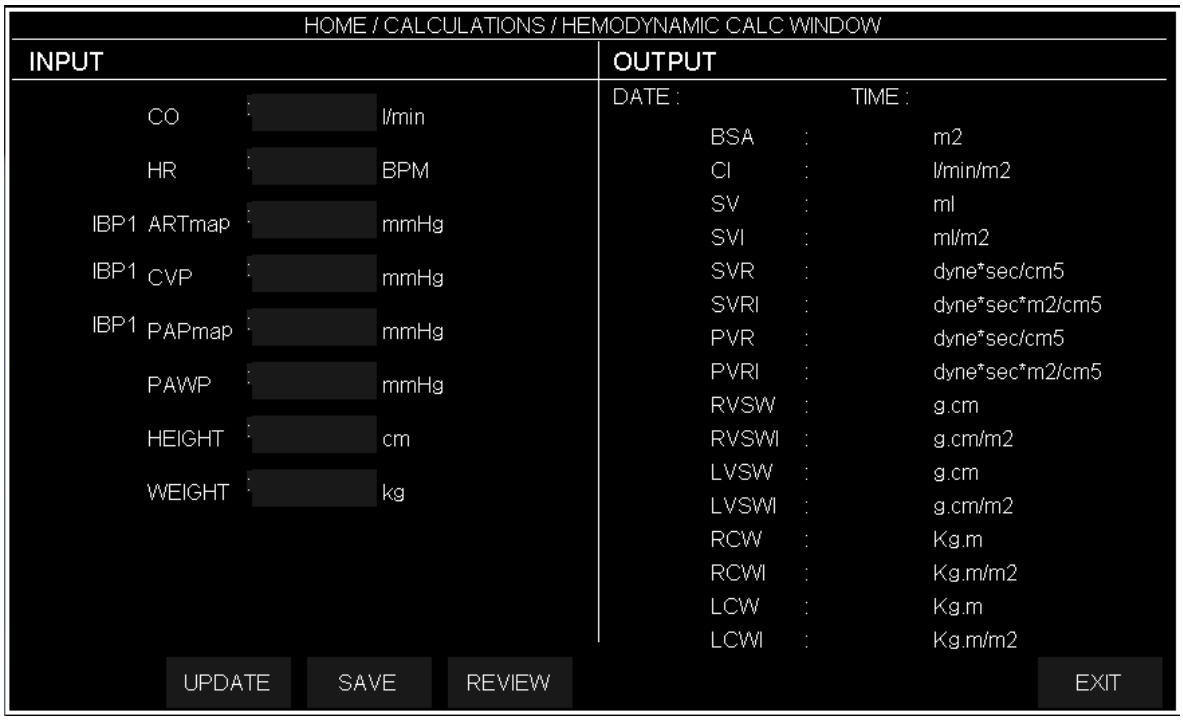
19.2 HEMODYNAMIC CALC

Hemodynamic is analysis of dynamics of blood and adequacy of oxygenation and perfusion in body's tissues.

Hemodynamic Instability can be defined as failure of oxygen delivery to tissues which can cause abnormal function of body's organs. One of the most important hemodynamic parameters is Cardiac Output (C.O) which can be measured by URUK monitor.
In addition to CO parameter, other hemodynamic parameters can be measured through Hemodynamic Calculator and inputting data by user or the system. The hemodynamic parameters include SVR, SVI, SV, CI, BSA, LCWI, LCW, RCWI, RCW, LVSWI, LVSW, RVSWI, RVSW, PVRI, PVR and SVRI.

- **HEMODYNAMIC WINDOW**

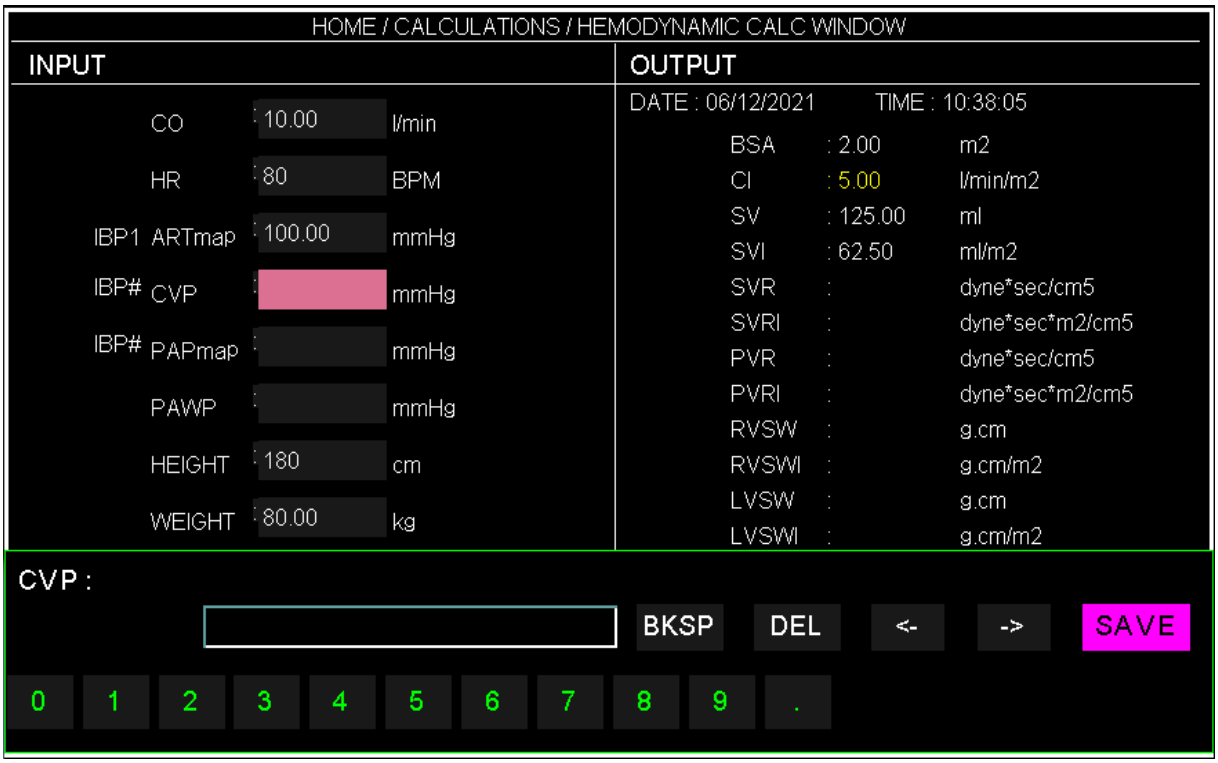
Select HEMODYNAMIC CALC from HOME/CALCULATIONS window to open the following window (default window is as below):



- **UPDATE**

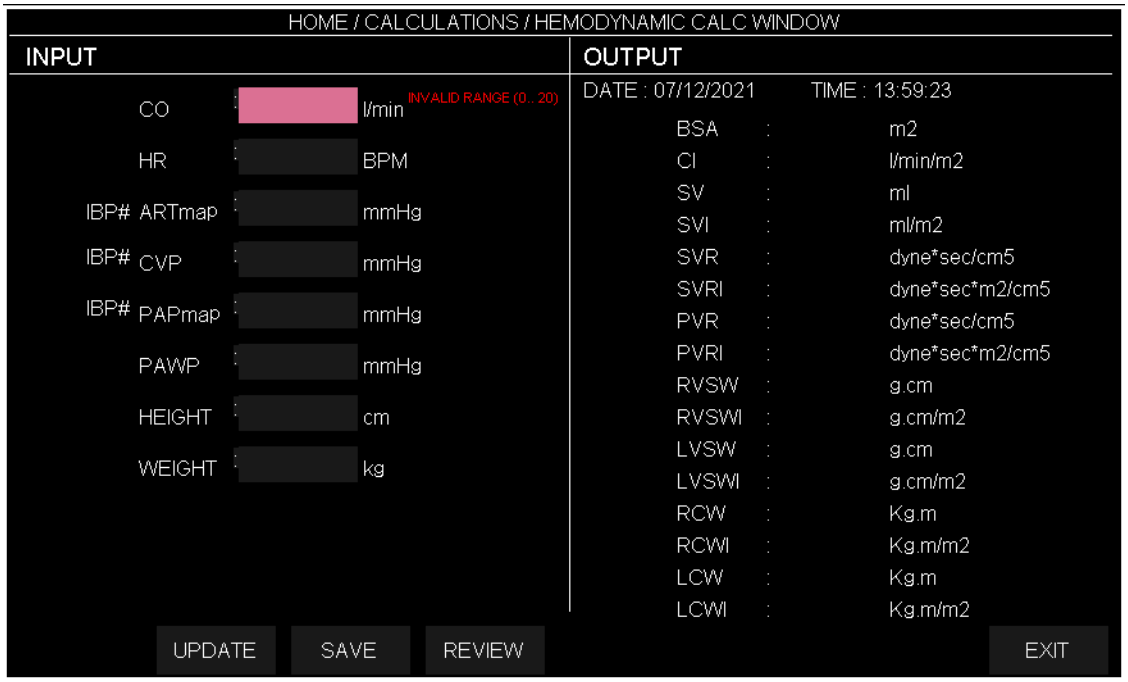
Click on this item to update numeric parameters in INPUT section.

Click on field of each parameter, a keyboard will pop up to enter parameter value.



After inputting parameters values in the INPUT section, measured values by the system will be displayed in OUTPUT section.

If you enter a value out of parameter range, the message INVALID RANGE as well as the parameter range will appear next to the parameter value (See the figure below).

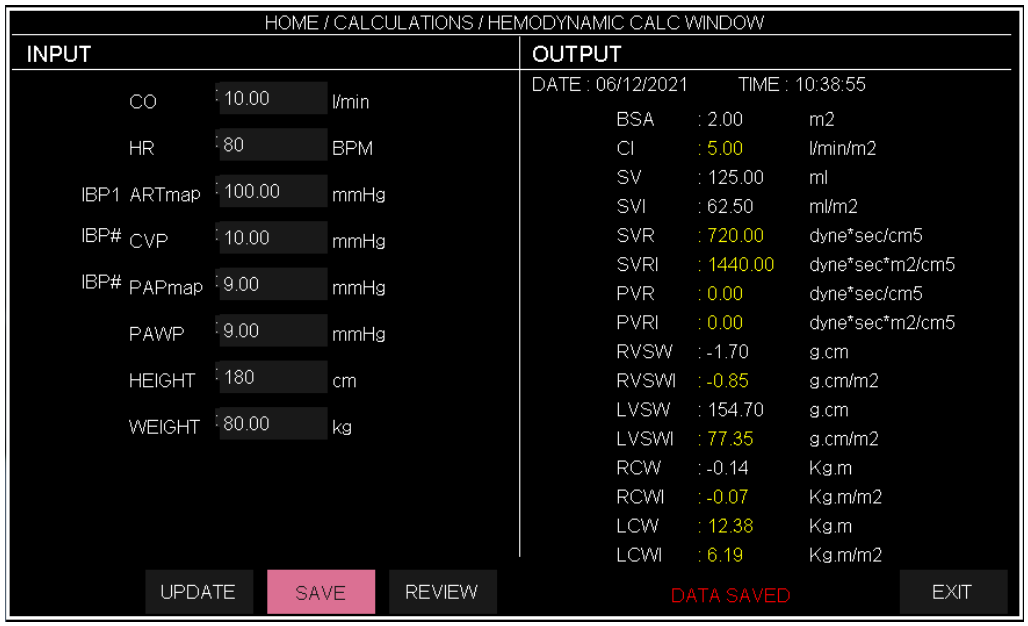


The range of different parameters is as the table below:

Parameter (INPUT)	INVALID RANGE
CO	0-20
HR	0-300
IBP ART map	0-300
IBP CVP	0-40
IBP PAP map	0-120
PAWP	0-40
HEIGHT	20-300
WEIGHT	2-200

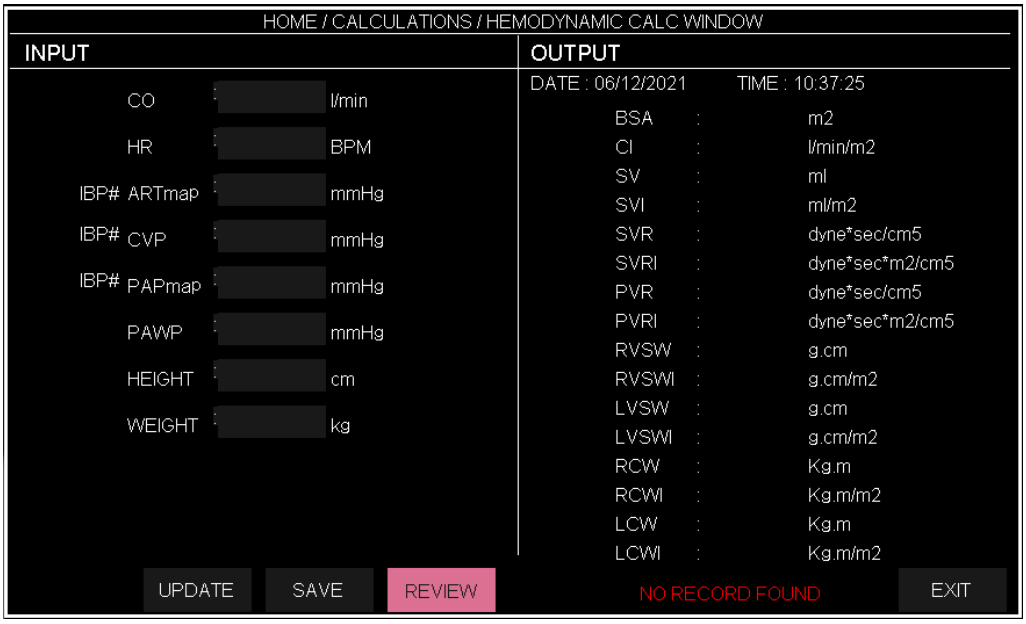
- ## SAVE

Click on this item to save a record of INPUT and OUTPUT values. The message “DATA SAVED” appears below the window. Up to 5 records can be saved.



- ## REVIEW

Click on this item to review saved records. Each record includes INPUT and OUTPUT values of different parameters and date and time of the record.



- NEXT, PREVIOUS

Select these items to view different records.

-DELETE

Select this item to delete current record.

-BACK

Select this item to turn black to Hemodynamic window.

Chapter 20, Bed to Bed *

"Bed to Bed" function is intended to display information of one bedside connected to the central system on target bedside.

Numeric parameters and signals of ECG, RESP and SPO2 modules and numeric parameters of TEMP and NIBP modules are displayed in "Bed to Bed" window.

Figure 1: When "Bed to Bed" function is disabled.

Figure 2: When "Bed to Bed" function is enabled.

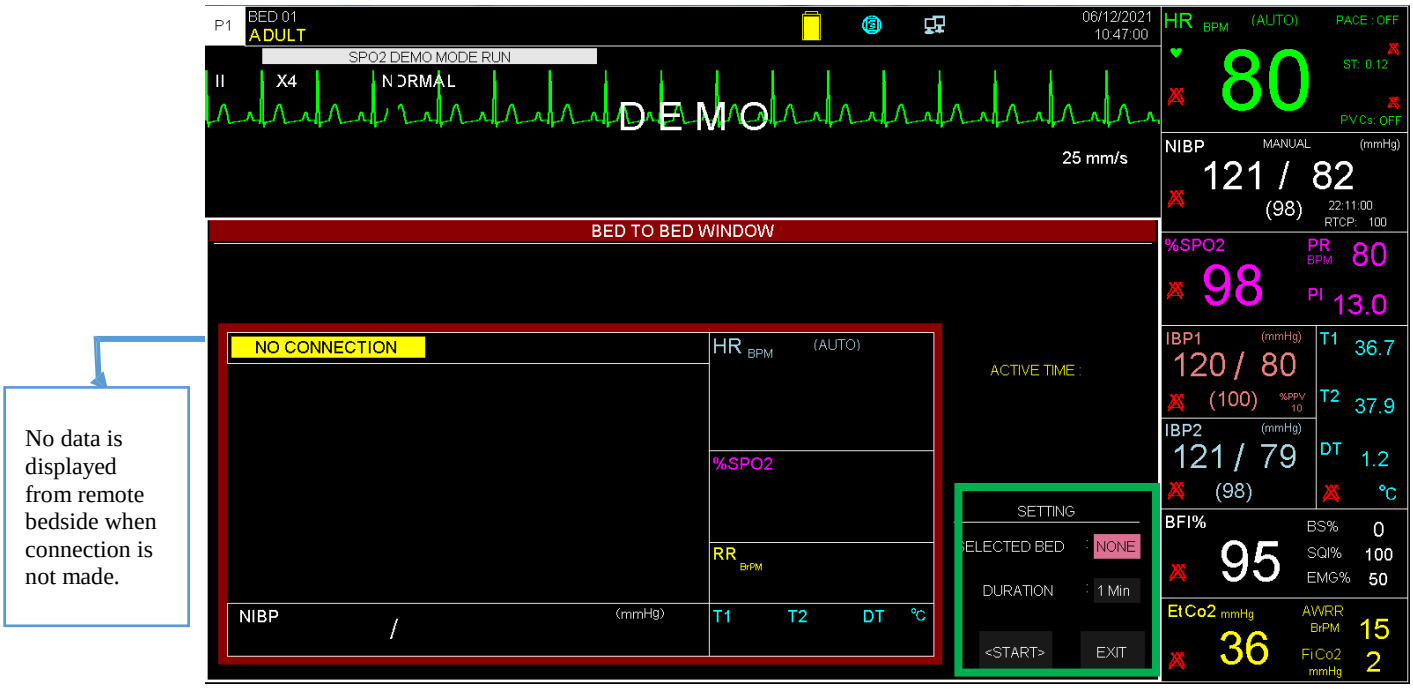


Figure 1

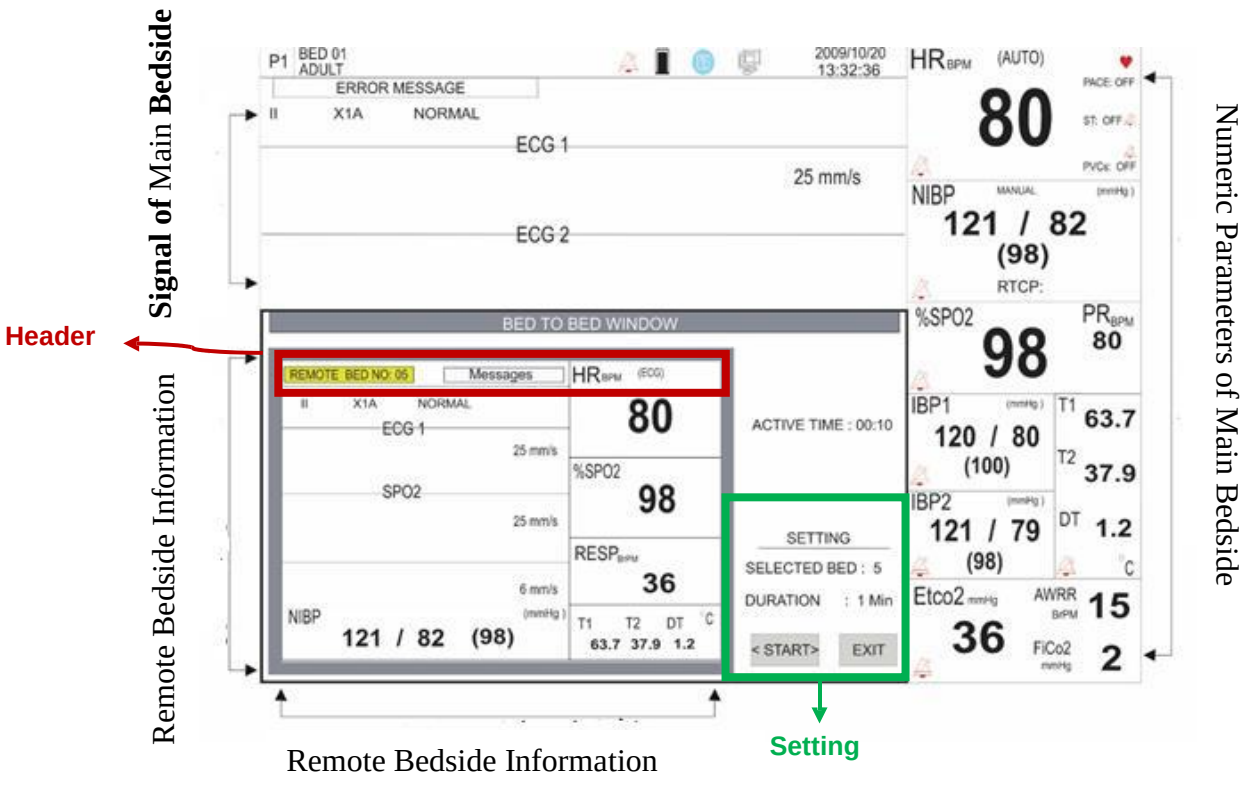


Figure 2

Bed number of the connected bedside (Remote Bed No.) and also all error messages of the bedside are shown in the header area of this window.

Setting

You can set this window through Setting section. This section includes the following items:

- Selected Bed

Choose this item to select one bedside and view its information on “Bed to Bed” window. Default setting is NONE. Turn the rotary knob or touch the screen to change setting.

- Duration

Select this item to set duration of displaying the selected bedside information. Default setting

is 1 min. Available options are 2 to 5 min. For example, if you select 2 min, the bedside information will be displayed for 2 min and then the “Bed to Bed” window will be closed. ACTIVE TIME is a counter that starts from zero to the time set for Duration.

- Displaying Bedside information

Press <STATR> to view the selected bedside information. In this condition, the button will change to <STOP>. Press it again to stop information displaying.

NOTE

- **The items “Selected Bed” and “Duration” will be disabled during displaying the bedside data. To set these items, at first stop data displaying.**

Chapter 21, Patient Safety

The patient monitor is designed to comply with the international safety standard requirements for medical electrical equipment. This device has floating inputs and is protected against the effects of defibrillation and ESU. If the correct electrodes are used in accordance with the manufacturer instructions, the display screen will recover within 10 seconds after defibrillation.

Explanation of Symbols in the Monitor

Symbol	Explanation
	This symbol means that consult user manual of the monitor and pay attention to the warnings and cautions.
	This symbol indicates that the monitor has CF type and Defibrillation Proof applied part according to IEC60601-1. The modules with this symbol contain a CF-Type isolated (Cardiac Float) patient applied part providing a high degree of protection against shock, and is usable during defibrillation.
	This symbol indicates that the monitor has BF type and Defibrillation Proof applied part according to IEC60601-1. The modules with this symbol contain a BF-Type isolated (Body Float) patient applied part which contains a high degree of protection against shock, and is usable during defibrillation.
	This symbol indicates that the device is IEC60601-1 Type BF equipment.
	This symbol indicates that the equipment shall be disposed of in an environmentally-friendly manner.
	This symbol beside the patient connector indicates that a part of protection against effects of defibrillator is provided by the accessory connected to patient. Therefore, use only accessories approved by the manufacturer.
	Equipotential grounding system.
100-240 VAC 0.9-0.4 A 50/60 Hz	AC POWER SUPPLY
	3A fast fuse
S/N	Serial number
	Manufacture date
	Manufacturer information
	European community representative
MASIMO SET	Use the Masimo Pulse Oximeter Module

Warning

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

Follow the instructions below to ensure a completely safe electrical installation.

The environment where the Patient Monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity and so on.

The Patient Monitor operates within specifications at ambient temperatures between 0ºC and 40ºC. Ambient temperatures that exceed these limits could affect the accuracy of the monitor and cause damage to the modules and circuits.

Grounding the patient monitor

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

Equipotential Grounding

Protection class I instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, the Patient Monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the rear panel of the monitor and the other end to one point of the equipotential grounding system.

The equipotential grounding system is for the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in medically used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order.

Warning

- **Possible explosion hazard if the monitor is used in the presence of flammable anaesthetic**

CLASSIFICATION	
Protection against electroshock	Class I, Type CF for all modules (except Multi-gas, NIBP and BFA modules that are BF) (based on IEC 60601-1).
Protection	Against Electro surgery and Defibrillator (Except BFA)
Mode of operation	Continues operation equipment
Harmful Liquid Proof Degree	IPX1
Method of disinfection	Refer to each module's chapters and chapter Care & Cleaning for detail.
Safety of anesthetic mixture	Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

General			
Display			
LM1810	TFT/LED COLOR	1366 × 768	18.5”
Numeric Parameters	ECG (HR,PVCs,ST, RR)		
	Cardiac output (C.O.)		
	SpO2(SpO2, PR, PI)		
	NIBP (SYS, DIA, MAP)		
	IBP(SYS,DIA,MAP)		
	TEMP(T1, T2, DT)		
	GAS(EtCo2, FiCo2, AWRR, EtN2O, FiN2O, EtO2, FiO2, EtAA, FiAA)		
	BFA(BFI, BS%, EMG%, SQI%)		
	Alarm limits		
Waveforms	ECG, SPO2, IBP, RESP/GAS, EEG		
Operation Method	Membrane/Keys and rotary knob, Touch Screen		
AC Power	100 - 240 VAC, 50/60 Hz , current: 0.9 – 0.4 A		

ECG			
Lead & Wire Options			
Selectable: 3 ,5 or 12 Leads		Selectable: 3 ,5 or 10 Wires	
3 ECG Leads I, II, III		3 Lead wires ECG Cable	
5 Leads ECG: I,II,III,V,aVR,aVF,aVL		5 Lead wires ECG Cable	
12 Leads ECG : I,II,III, aVR,aVF,aVL , V1,V2, V3, V4, V5. V6		10 Lead wires ECG Cable	
Dynamic Range	± 5 mV		
DC offset voltage range	± 300 mV		
Lead Off Current	< 90 nA		
Gain	4, 2, 1, 1/2, 1/4, Auto		
Calibration	1mV, 0.5 sec		
Filters	“MONITOR”	0.5 - 24 Hz	
	“NORMAL”	0.5 - 40 Hz	
	“EXTENDED”	0.05-100 Hz	
CMRR	> 98 dB		
Internal Noise	< 30 μV RTI		
Input Impedance	> 5 MΩ		
QRS Detection	Duration	40 to 120 msec	
	Amplitude	0.25 to 5 mV	for Adult/Pediatric

		0.2 to 5 mV	for Neonate
Heart Rate Range	15 - 300 BPM	for adult/Pediatric	
	15 - 350 BPM	for neonate	
Accuracy	±1% or 2 BPM		
Tall T-Wave	Reject up to 1.2 mV Amp.		
Pacer Detection/Rejection	Duration	0.1 - 2 msec	
	Amp	±2 to ± 700 mV (Without over/undershoot)	
	Reject from heart rate counter		
	Re-insert into ECG to display on screen		
	Ineffective pace rejection	HR:0, Pace: 60	
		HR:60, Pace:60	
		HR:30, Pace:80	
	Beside rejection of atrial paces preceed ventricular paces by 150 or 250 ms		
Protection	Defibrillator and Electrosurgery		
ANALOG OUTPUT			
Signals	ECG		
Maximum delay	≤30 ms		
Output range	± 5 V		
Signal gain	1000 (1V/mV)		
Gain accuracy	± 20 mV		
Maximum offset	± 50 mV		
ECG bandwidth	"MONITOR"	0.5 - 24 Hz	
	"NORMAL"	0.5 - 40 Hz	
	"EXTENDED"	0.05-100 Hz	
Pacemaker pulses	Amplitude:	5 V (nominal)	
	Duration:	5 ms	
ECG range	-5 to 5 mV		
Output impedance	249 Ω ± 5%		
Data rate	400 samples/sec		
ARRHYTHMIA ANALYSIS			
Type	ASYS, VFIB, VTAC, RUN (NonSustain VT), AIVR, COUPLET, BIGEMINY, TRIGEMINY, TACHY (HR HIGH), BRADY (HR LOW), AFIB, PAUS (MISSED BEAT), FREQUENT PVCs, R on T, MULTIFORM PVCs, PNC, PNP		
Learning	Rapid Learning: only 20 seconds required for recognition of dominant rhythm.		
Method	Real time arrhythmia detection with innovative feature.		
Memory	Capability of storing the latest 150 ARR event (waveform and Parameters)		
ST ANALYSIS			
Display resolution	0.01 mV		
Measurement Range	-2mv to +2mv		
Alarm Range	-2mv to +2mv		
Features	User Adjustable Isoelectric and ST point trending of ST values		
Update period	5 Sec.		

NIBP			
Physical dimensions	Width: 2.52 in (64 mm) Length: 3.11 in (79 mm) Height: 0.96 in (24.5 mm) Weight: 0.25lbs (0.11kg)		
Operating voltage	5V DC ± 5% Input Voltage		
Current Consumption	Idle: 52mA Measurement: 190mA Inflation: 350 mA		
Communication Protocol	Serial RS232 or TTL		
Operating Conditions	Temperature: 50C to 400C Humidity: 20% to 90%		
Storage Conditions	Temperature: -250C to 600C Humidity: 10% to 100%		
Technique	Oscillometry		
Measurement time	20-25 sec (excluding cuff inflation time)		
Safety & Regulatory Standards	IEC 60601-1, AAMI SP10, EN1060-1, EN 1060-3, EN1060-4, IEC 80601-2-30, ISO 81060-2: 2014		
NIBP Accuracy	Meets BS EN ISO 81060-2:2014		
Mode of operation	Manual/Automatic/Stat		
Auto mode repetition intervals	1,2,3,5,10,15,20, 30, 45, 60, 90 minutes and 2, 4, 8,12,16,20 and 24 hours.		
STAT mode cycle time	5 min		
Max measurement time	Adult, pediatric: 180 s Neonate: 90 s		
Heart rate Range	30 to 240 bpm		
Cuff pressure Rang	Adult		0-290 mmHg
	Neonate		0-145 mmHg
Measurement Range (mmHg)	Adult	SYS	30 ~ 255 mmHg
		DIA	15 ~ 220 mmHg
		MAP	20 ~ 235 mmHg
	Neonate	SYS	30 ~ 135 mmHg
		DIA	15 ~ 110 mmHg
		MAP	20 ~ 125 mmHg
	Pediatric	SYS	30 ~ 240mmHg
		DIA	15 ~ 220 mmHg
		MAP	20 ~ 230mmHg
Software overpressure protection	Adult: 290 ± 3 mmHg Pediatric: 240 ± 3 mmHg Neonate: 145 ± 3 mmHg		
Resolution	1mmHg		
Transducer Accuracy	±3 mmHg over full range in operating conditions		
Heart Rate Accuracy	±2% or ±2 BPM whichever is greater		
default initial cuff inflation pressure (mmHg)	Adult : 150 mmHg Pediatric: 140mmHg Neonate: 85 mmHg		
Memory	500 Records		

SpO2 (Masimo Rainbow Set)			
Methods	SpO2 (2 Wavelengths of light used), Rainbow (7+Wavelengths of light used)		
SpO2 Parameters	SpO2, PI, PR, PVI		
Rainbow parameters	SpOC, SpCO, SpMet, SpHb, ORi		
Range	SpO2	0 – 100 %	
	PR	25 – 240 bpm	
	PI	0.02– 20.0 %	
	SpMet	0 – 99.9 %	
	SpCO	0 – 99 %	
	SpHb	0 – 25.0 g/dL	
	SpOC	0 – 35.0 ml/dL	
	PVI	0 – 100 %	
	ORi	0.0 – 1.0	
Accuracy	Oxygen Saturation		
	No motion conditions	Adult/Pediatric	±2% (SpO2 70 ~ 100%) Unspecified (SpO2 0 ~ 69%)
		Neonate	±3% (SpO2 70 ~ 100%) Unspecified (SpO2 0 ~ 69%)
	Motion conditions	Adult/Pediatric/Neonate	±3% (SpO2 70 ~ 100%) Unspecified (SpO2 0 ~ 69%)
	Low perfusion conditions	Adult/Pediatric/Neonate	±2% (SpO2 70 ~ 100%) Unspecified (SpO2 0 ~ 69%)
	Pulse Rate		
	No motion conditions	Adult/Pediatric/Neonate	±3bpm (PR 25 ~ 240)
	Motion conditions	Adult/Pediatric/Neonate	±5bpm (PR 25 ~ 240)
	Low perfusion conditions	Adult/Pediatric/Neonate	±5bpm (PR 25 ~ 240)
	Carboxyhemoglobin Saturation		
	Carboxyhemoglobin Saturation	Adult/Pediatric	±3% (1 - 40)
	Methemoglobin Saturation		
	Methemoglobin Saturation	Adult/Pediatric/Neonate	±1% (1 – 15)
	Total Hemoglobin		
	Total Hemoglobin	Adult/Pediatric	±1g/dL (8 – 17) g/dL
Resolution	SpO2	1%	
	PI	0.1%	
	PVI	1%	
	PR	1 BPM	
	SpCO	1.0 %	
	SpMet	0.1 %	
	SpHb	0.1 g/dL	
	SpOC	0.1 ml/dL	
	ORi	0.1	
Please note that pulse-oximetry method (SpO2) is compared to laboratory spectroscopy of sample blood (SaO2). This method measures precision of SpO2 measurement using statistical analysis. Therefore, measurement precision is reliable for at least two third of measurements.			

1. The Masimo SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
2. The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population.
3. The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
4. The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.
5. The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
6. See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.
7. Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent A (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of $\pm A_{rms}$ compared to the reference value. Unless otherwise noted, SpO2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.
8. Masimo M-LNCS, LNOP, RD SET, and LNCS sensors types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8 pin modular plug, RD 15 pin modular plug, LNCS 9 pin, cable based, and M-LNCS 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.

TEMPERATURE(2 Channel)

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

RESPIRATION

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

IBP

Channel	2 (UP to 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) without transducer	
IBP Auto Scale		

Pump Page	
PPV Measurement	
Arterial Catheter Disconnection Alarm	
Multi-gas, Mainstream (MASIMO SWEDEN AB)	
IRMA CO2	CO2
IRMA AX+	CO2, N2O, primary and secondary agents (HAL, ISO, ENF, SEV, DES)
Gas /CO2 Interface	Connector and S/W Interface Driver, Applicable for All Gas and CO2 Modules.
Description	Extremely compact infrared mainstream multigas probe available in two parameter configurations.
Cable length	2.5 m ±0.1 m
Recovery time after defibrillator test	Unaffected
Drift of measurement accuracy	No drift
Surface temperature (at ambient temp. 23°C)	IRMA CO2: Max 39°C / 102°F
	IRMA AX+: Max 46°C / 115°F
Interface	Modified RS-232 serial interface operating at 9600 bps.
Airway adapters	Disposable adult/pediatric: - Adds less than 6 ml deadspace.
	- Pressure drop less than 0.3 cm H2O @ 30 LPM.
	Disposable infant: - Adds less than 1 ml deadspace.
	- Pressure drop less than 1.3 cm H2O @ 10 LPM.
	(Infant Airway Adapter recommended for Tracheal Tube ID size = 4 mm)
Degree of protection against harmful ingress of water or particulate matter	IPX4
Method of sterilization	The IRMA system contains no sterile parts.
Mode of operation	CONTINUOUS OPERATION
Data output	
Breath detection	Adaptive threshold, minimum 1 vol% change in CO2 concentration.
Respiration rate[1]	0–150 ±1 bpm. The respiration rate is displayed after three breaths and the average value is updated every breath.
Fi and ET[2] Fi and ET are displayed after one breath and have a continually updatedbreath average. The following methods are used to calculate end-tidal (ET) values: -CO2: The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end ofthe cycle. -N2O and anesthetic agents: The momentary gas concentration at the time point where ETCO2 is detected. ET-values for anaesthetic agents and N2O (IRMA AX+) will typically decrease below nominal value when respiration rate exceeds 80 bpm. The maximum decrease is described by the formula ET = 80*ETnom/RR. ETCO2 will be within specification for all respiration rates up to 150 bpm (IRMA AX+ and IRMA CO2)	
Automatic agent identification	IRMA AX+: Primary and secondary agent.
Gas Analyzer	
Probe	2-9 channel NDIR type gas analyzer measuring at 4-10 µm. Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing Airway adapter (IRMA AX+) No span calibration required for the IR bench.
Warm-up time	IRMA CO2: < 10 seconds (concentrations reported and full accuracy)
	IRMA AX+: < 20 seconds (concentrations reported, automatic agent identification enabled and full accuracy)
Rise time[3] (@10 l/min)	CO2 ≤ 90 ms

[1] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

[2] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

[3] Measured @ 10 l/min with gas concentration steps corresponding to 30% of total measuring range for each gas.

	N2O ≤ 300 ms
	HAL, ISO, ENF, SEV, DES ≤ 300ms
Primary agent threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.
Secondary agent threshold	0.2 vol% +10% of total agent concentration
Agent identification time	<20 seconds. (Typically < 10 seconds)
Total system response time[4]	< 1 second

Accuracy - standard conditions

The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa

Gas	Range	Accuracy
CO2	0 to 15 vol%	±(0.2 vol% +2% of reading)
N2O	0 to 100 vol%	±(2 vol% +2% of reading)
HAL,ISO,ENF	0 to 8 vol%	±(0.15 vol% +5% of reading)
SEV	0 to 10 vol%	±(0.15 vol% +5% of reading)
DES	0 to 22 vol%	±(0.15 vol% +5% of reading)

Accuracy - all condition

The following accuracy specifications are valid for all specified environmental conditions except for interference specified in the table "Interfering gas effects" and the section "Effects from water vapor partial pressure on gas readings" below.

Gas	Accuracy
CO2	±(0.3 kPa + 4% of reading)
N2O	±(2 kPa + 5% of reading)
Agents[5]	±(0.2 kPa + 10% of reading)

Gas concentration conversion

Gas concentration is reported in units of volume percent. The concentration is defined as:

$$\%\,gas = \frac{(Partial\ pressure\ of\ gas\ component)}{(Total\ pressure\ of\ gas\ mixture)} * 100$$

The total pressure of the gas mixture is estimated by measuring the actual atmospheric pressure in the IRMA probe.

Effects from water vapor partial pressure on gas readings

The effects of water vapor are illustrated by the examples in the following table. The two columns to the right show the relative error in displayed concentrations when adding or removing water vapor from the gas mixture, and referencing the measurement to dry gas conditions at actual temperature and pressure (ATPD) or saturated conditions at body temperature (BTPS).

Temp [C]	RH [%]	P [hPa]	H2O part.pres. [hPa]	errrel [%]	errrel ATPD [%]	errrel [%] BTPS
10	20	1013	2	0	-0.2	+6.0
20	20	1013	5	0	-0.5	+5.7
25	0	1013	0 (ATPD)	0	0	+6.2
25	23	1013	7.3	0	-0.7	+5.5
25	50	1013	16	0	-1.6	+4.6
30	80	1013	42	0	-4.1	+2.0
37	100	1013	63 (BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

The table illustrates that the gas concentrations in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

[4] Measured according to EN ISO 80601-2-55.

[5] The accuracy specification for IRMA AX+ is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

Interfering gas effects					
Gas or vapour	Gas level	CO2		Agents	N2O
		IRMA CO2	IRMA AX+		
N2O-note4)	60 vol%	- note1&2)	- note1&2)	- note1)	- note1)
HAL-note4)	4 vol%	- note1)	- note1)	- note1)	- note1)
ENF, ISO, SEV-note4)	5 vol%	+8% of reading-note3)	- note 1)	- note1)	- note1)
DES-note4)	15 vol%	+12% of reading-note3)	- note 1)	- note1)	- note1)
Xe (Xenon)-note4)	80 vol%	-10% of reading-note3)		- note1)	- note1)
He (Helium)-note4)	50 vol%	-6% of reading-note3)		- note1)	- note1)
Metered dose inhaler propellants-note4)	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol)-note4)	0.3 vol%	- note1)	- note1)	- note1)	- note1)
C3H7OH (Isopropanol)-note4)	0.5 vol%	- note1)	- note1)	- note1)	- note1)
CH3COCH3 (Acetone)-note4)	1 vol%	- note1)	- note1)	- note1)	- note1)
CH4 (Methane) -note4)	3 vol%	- note1)	- note1)	- note1)	- note1)
CO (Carbon monoxide) -note5)	1 vol%	- note1)	- note1)	- note1)	- note1)
NO (Nitrogen monoxide)-note5)	0.02 vol%	- note1)	- note1)	- note1)	- note1)
O2-note 5)	100 vol%	- note1&2)	- note1&2)	- note1)	- note1)

Note 1 : Negligible interference, effect included in the specification " Accuracy all conditions" above.

Note 2 : For probes not measuring N2O and/or O2 the concentrations shall be set from host according to the instructions. (IRMA CO2 measures neither N2O, nor O2. IRMA AX+ dose not measure O2.)

Note 3 : Interference at indicated gas level. for example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture contaning 5.0 vol% CO2 and 50 vol% Helium, the measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.

Note 4 : According to the EN ISO 80601-2-55:2011 standard.

Note 5 : In addition to the EN ISO 80601-2-55:2011 standard.

Multi-gas, Sidestream (MASIMO SWEDEN AB)

ISA CO2	CO2, CO2 waveform
ISA AX+	CO2, N2O, primary and secondary Agents (HAL, ISO, ENF, SEV, DES)
ISA OR+	CO2,O2, N2O, primary and secondary Agents (HAL, ISO, ENF, SEV, DES)
Gas /CO2 Interface	Connector and S/W Interface Driver, Applicable for All Gas and CO2 Modules.
Description	Compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Ambient CO2	≤ 800 ppm (0.08 vol%)
Recovery time after defibrillator test	Unaffected
Water handling	Nomoline Family sampling lines with proprietary water removal tubing.
Sampling flow rate	50 ± 10 sml/min[6]
Degree of protection against harmful ingress of water or particulate matter	IPX4
Method of sterilization	The ISA system contains no sterile parts.
Mode of operation	CONTINUOUS OPERATION
Degree of protection against electric shock	Nomoline Family sampling lines are classified as DEFIBRILLATION-PROOF TYPE BF APPLIED PART
Data output	
Breath detection	Adaptive threshold, minimum 1 vol% change in CO2concentration.
Respiration rate [7]	0 to150 ± 1 breaths/min (or BrPM)

[6] Volumetric flow rate of air corrected to standardized conditions of temperature and pressure.

[7] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

Fi and ET[8] Fi and ET are displayed after one breath and have a continually updated breath average. The following methods are used to calculate end-tidal (ET) values: -CO2: The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. -O2: The highest/lowest concentration of O2during the expiratory phase (depending on whether ETO2 is higher or lower than FiO2 -N2O and anesthetic agents: The momentary gas concentration at the time point where ETCO2 is detected. ET will typically decrease below nominal value (ETnom) when respiration rate (RR) exceeds the RR threshold (RRth) according to the following formulas:			
ISA CO2	ET=ETnom×(125⁄RR)_for RRth >125		
CO2			
ISA OR+/AX+			
CO2	ET=ETnom×$\sqrt{(70 / RR)}$ for RRth >70		
N2O, O2, DES, ENF, ISO, SEV	ET=ETnom×$\sqrt{(50 / RR)}$ for RRth >50		
HAL	ET=ETnom×$\sqrt{(35 / RR)}$ for RRth >35		
Automatic agent identification	ISA OR+/AX+: primary and secondary agent.		
Gas analyzer			
Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 µm.		
	Data acquisition rate 10 kHz (sample rate 20 Hz / channel).		
	O2 measurements by Servomex's paramagnetic sensor.		
Calibration	No span calibration is required for the IR bench. An automatic zeroing is performed 1 to 3 times per day.		
Compensation	ISA CO2	Automatic compensation for pressure and temperature.	
		Manual compensation for broadening effects on CO2.	
	ISA OR+/AX+	Automatic compensation for pressure, temperature and broadening effects on CO2.	
Warm-up time	ISA CO2:	<10 seconds (concentrations reported and full accuracy)	
	ISA OR+/AX	+: <20 seconds (concentrations reported, automatic agent identification enabled and full accuracy	
Rise time[9]	CO2	≤ 200 ms(≤ 300 ms for ISA OR+/AX+)	
	N2O, O2, ENF, ISO, SEV, DES	≤ 400 ms	
	HAL	≤ 500 ms	
Primary agent threshold (ISA OR+/AX+)	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%		
Secondary agent threshold (ISA OR+/AX+)	0.2 vol% +10% of total agent concentration		
Agent identification time (ISA OR+/AX+)	<20 seconds (typically <10 seconds)		
Total system response time[10]	ISA CO2:	< 3 seconds	
	ISA OR+/AX+:	< 4 seconds (with 2m Nomoline Airway Adapter Set sampling line)	
Accuracy standard conditions			
The following accuracy specifications are valid with no drift for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:			
	Range[11]	Accuracy	
CO2	0 to15 vol%	±(0.2 vol% +2% of reading)	
N2O	0 to 100 vol%	±(2 vol% +2% of reading)	
HAL, ENF, ISO	0 to 8 vol%	±(0.15 vol%+5% of reading)	

[8] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

[9] Measured according to EN ISO 80601-2-55.

[10] Measured according to EN ISO 80601-2-55.

[11] All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

SEV	0 to 10 vol%	±(0.15 vol% +5% of reading)
DES	0 to 22 vol%	±(0.15 vol% +5% of reading)
O2	0 to 100 vol%	±(1 vol% +2% of reading)

Accuracy - all conditions	
The following accuracy specifications are valid with no drift for all specified environmental conditions, except for interference from water vapor in the below section “Effects from water vapor partial pressure on gas readings”.	
GAS	Accuracy
CO2	±(0.3 kPa + 4% of reading)
N2O	±(2 kPa + 5% of reading)
Agents[12]	±(0.2 kPa + 10% of reading)
O2	±(2 kPa + 2% of reading)

Effects from water vapor partial pressure on gas readings
When the breathing gas flows through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The measurement of all gases will always show the actual partial pressure at the current humidity level in the gas sample. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. However at an ambient temperature of 37 °C and a breathing gas with a relative humidity of 95% the gas reading will typically be 6% lower than corresponding partial pressure after removal of all water.

Interfering gas and vapor effects					
Gas or vapour	Gas level	CO2		Agents	N2O
		ISA CO2	ISA AX+/OR+		
N2O-note4)	60 vol%	- note2)	- note1)	- note1)	- note1)
HAL-note4)	4 vol%	- note1)	- note1)	- note1)	- note1)
ENF, ISO, SEV-note4)	5 vol%	+8% of reading-note3)	- note1)	- note1)	- note1)
DES-note4)	15 vol%	+12% of reading-note 3)	- note1)	- note1)	- note1)
Xe (Xenon)-note4)	80 vol%	-10% of reading-note3)		- note1)	- note1)
He (Helium)-note4)	50 vol%	-6% of reading-note3)		- note1)	- note1)
Metered dose inhaler propellants-note4)	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol)-note4)	0.3 vol%	- note1)	- note1)	- note1)	- note1)
C3H7OH (Isopropanol)-note4)	0.5 vol%	- note1)	- note1)	- note1)	- note1)
CH3COCH3 (Acetone)-note4)	1 vol%	- note1)	- note1)	- note1)	- note1)
CH4 (Methane)-note4)	3 vol%	- note1)	- note1)	- note1)	- note1)
CO (Carbon monoxide)-note5)	1 vol%	- note1)	- note1)	- note1)	- note1)
NO (Nitrogen monoxide)-note5)	0.02 vol%	- note1)	- note1)	- note1)	- note1)
O2-note5)	100 vol%	- note2)	- note2)	- note1)	- note1)

Note 1 : Negligible interference, effect included in the specification “ Accuracy all conditions” above.
Note 2 : Negligible interference with N2O/O2concentrations correctly set, effect included in the specification “ Accuracy all conditions” above.
Note 3 : Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture contaning 5.0 vol% CO2and 50 vol% Helium, the actual measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.
Note 4 : According to the EN ISO 80601-2-55:2011 standard.
Note 5 : In addition to the EN ISO 80601-2-55:2011 standard.

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

[12] The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

Brain Function Index (BFI)	0-100. Filter 1-47Hz, 1sec. update	
EMG	0-100. Filter 30-47 Hz,1 sec. update	
BSR	0-100. Filter 2-47 Hz, 1 sec. update	
Signal Quality Index (SQI)	0-100. 1 sec. update	
EEG Waveform	±250µV, user-adjustable, 5 sec	
Alarms	Auditory and visual, user-adjustable limits	
Artifact rejection	Automatic	
Sensor impedance measurement	0-30kOhm / Manual-Automatic/ measurement current 0.06µA	
Power supply	5 VDC	
Power Consumption	Less than 0.5 W	
Weight	100 gr	
Dimensions	111×64×25 mm	
Classification	Class I, type BF, continuous use	
Sensors	Ambu Neuro Sensors	
Cable length	195 cm/ 77” with 35 cm/ 14” split	
Memory	Data recording (96 hours)	
Trend	BFI/EMG/SQI/BS, 10 sec. update	
Environment - Operation	Temperature	5-40°C
	Rel humidity	20~96%
	Altitude	-200~3000m

Cardiac Output

Method	Right Heart Thermodilution
Range	0.5-18 l/min
Resolution	0.01l/min
Reproducibility	±3%

Recorder

Model	Internal Thermal Recorder SP58
Channel	Up to 3 waveforms
Printing Speed	6,12.5,25 mm/sec
Paper Size	57mm by 59 foot roll

CALCULATION

DRUG CALC	To calculate the dose and time of medication
HEMODYNAMIC CALC	Monitoring hemodynamic events provides information about the adequacy of a patient's circulation, perfusion, and oxygenation of the tissues and organ systems. The objective of hemodynamic monitoring is to ensure optimal tissue perfusion and oxygen delivery while maintaining adequate mean arterial blood pressure.

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

ALARM RECALL	
Displaying occurred alarms along with ECG/SpO2/2IBP/RESP/GAS waveforms (20 recent alarm)	
BED to BED	
"Bed to Bed" function is intended to display information of one bedside connected to the central system on target bedside.	
TREND	
Sources	HR,PVCs,ST(All Leads),AFIB, RR
	SpO2,PR,PI,PVI,SpOC,%SpCo,%SpMet,SpHb g/dl,ORi
	T1, T2
	IBP1(SYS,DIA,MAP)
	IBP2(SYS,DIA,MAP)
	IBP3(SYS,DIA,MAP)
	IBP4(SYS,DIA,MAP)
	EtCo2,FiCo2,AWRR(sidestream, mainstream), EtN20,FiN2O,EtO2,FiO2,EtAA,FiAA(ISO, DES, ENF, HAL, SEV)
Trend Time Save	96 Hours
Trend Time Interval	15, 30, 45 Min, 1, 2 and 4 Hours
Resolution	1 sec
OXY-CRG	
6 Parameters Trend	
EVENT LOG	
Prepare reports of system events.	
INPUT/OUTPUT	
Network	TCP/IP Protocol Ethernet LAN with RJ45 Interface WLAN IEEE 802.11a/b/g/n, Wireless
VGA Connection	VGA output with same page

Internal Battery					
Battery type	**Charge time [hours]**	**Usage [hours]** (New & Full Charged)	**Voltage [Volt]**	**Capacity [AH]**	Device Model **LM1810**
Sealed Lead Acid (Rechargeable battery)	~4	~2	12	3.5	☑
Sealed Lead Acid (Rechargeable battery)	~4	~3	12	2.8	-
Li-ION 2200	~4	~2 (LM1810)	11.1	2.2	☑
Li-ION 3500	~5	~3 (LM1810)	11.1	3.5	☑
Li-ION 4000	~6	~4 (LM1810)	11.1	4.0	☑
Li-ION 5000	~7	~5 (LM1810)	11.1	5.0	☑

Physical Specification		
System Model	Dimension (Cm)	Weight (approximately)
LM1810	45(W) × 36(H) × 17(D)	~7.5 Kg

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

Chapter 23, Accessories

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Information

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

Warning

- The accessories listed below are specified to be used for bedside monitor. Manufacturer does not take responsibility for any possible hazard to the patient or monitor if other accessories are used.
- Patient protection against defibrillator effects requires using accessories specified in this chapter

23.1 ECG Accessories

Part NO URUK	ECG	Brand/Manufacture
P10003	ECG PATIENT CABLE 3 WIRES	URUK
P10038	ECG PATIENT CABLE 5 WIRES	URUK
P10066	ECG PATIENT CABLE 10 WIRES	URUK
P03122	ECG Lead Wire - Neonate	URUK

23.2 SpO2 (MASIMO & RAINBOW) Accessories

URUK Part NO	SpO2		Brand/ Manufacture	Manufacture Part No.
	Model	Description		
P18045	**DCI**	Adult Reusable Finger Sensor, Weight > 30 Kg, (LNCS)	Masimo	1863
P18049	**YI**	Reusable Multi-site Sensor (Y- Sensor), Weight > 1 Kg (LNCS)	Masimo	2258
P18046	**NeoPt**	Sensitive Skin Neonate Adhesive Sensor, 18 in. (Disposable Sensor), Weight <1 Kg, (LNCS)	Masimo	2330
P18047	**Neo**	Neonate Adhesive Sensor, 18 in. (Disposable Sensor), Weight <3 Kg or >40 Kg, (LNCS)	Masimo	2329
P18075	**Inf-3**	Infant Adhesive Sensor, 3 ft. (Disposable Sensor), Weight 3-20 Kg, (LNCS)	Masimo	2319
P18056	**Red LNC-10**	LNCS Series 20-pin SpO2 Patient Cable, 10 ft. (Extension Cable)	Masimo	2056

URUK Part NO	Rainbow	Brand/ Manufacture	Manufacture Part No.
P18055	SpO2 Reusable Sensor, Finger/Toe, Adult > 30 Kg, Red DCI-dc12	Masimo	2201
P18068	Rainbow DC-3 SC 360, Reusable, Adult, (SpO2,SpMet,SpHb)	Masimo	2241
P18062	Rainbow R25 Sensor, Adult, Adhesive, >30Kg, (SpO2,SPCo,SPMet)	Masimo	2221
P18072	Rainbow R1-20L Pulse Co-Oximeter Sensor, Disposable, Pediatric, (SPHb ,SpO2,SPMet)	Masimo	3793
P18063	Rainbow Reusable R2-25a Sensor, Disposable, Adult, >30Kg, (SpO2,SPHb,SPMet)	Masimo	2753
P18064	Rainbow Reusable R2-25r Sensor, Reusable, Adult, >30Kg, (SpO2, SPHb, SPMet)	Masimo	2754
P18065	Rainbow ReSposable R2-20a Sensor, Disposable, Pediatric, 10-50KG, (SPO2,SPHb,SPMet)- Masimo	Masimo	2755
P18066	Rainbow Reusable R2-20r Sensor, Reusable, Pediatric, 10-50KG, (SpO2, SPHb, SPMet)	Masimo	2756
P18069	Rainbow DCI, Reuseable, Adult, (SpO2,SpCO,SpMet)	Masimo	2696
P18060	SpO2 Extension Cable, (Red LNC-10)	Masimo	2404
P18067	Ambient Shield Accessory for Rainbow Sensor	Masimo	2815

23.3 TEMP Accessories

PART NO URUK	TEMP	Brand/Manufacture	Manufacture/Part
P10083	TEMP Probe, Skin, LAUNCH	Shenzhen Launch Electrical Co. (LNHmed)	98ME04GA634
P10084	TEMP Probe, Rectal, LAUNCH	Shenzhen Launch Electrical Co. (LNHmed)	98ME04GA635

23.4 NIBP Accessories

URUK Part NO	NIBP		Brand/ Manufacture	Manufacture Part No.
	Model	Description		
P13077	M5301/Single	Reusable Neonate White NIBP Cuff (Nylon Laminated TPU Cuff With Bladderless) Limb Circumference:9-14.5cm	MaiCuff	03-0201-097
P13078	M5302/Single	Reusable Infant White NIBP Cuff (Nylon Laminated TPU Cuff With Bladderless) Limb Circumference:13-21.5cm	MaiCuff	03-0201-101
P13079	M5303/Single	Reusable Pediatric White NIBP Cuff (Nylon Laminated TPU Cuff With Bladderless) Limb Circumference:21-27cm	MaiCuff	03-0201-105
P13080	M5304/Single	Reusable Adult White NIBP Cuff (Nylon Laminated TPU Cuff With Bladderless) Limb Circumference:26-35.5cm	MaiCuff	03-0201-109
P13081	M5305/Single	Reusable Large Adult White NIBP Cuff (Nylon Laminated TPU Cuff With Bladderless) Limb Circumference:35-45cm	MaiCuff	03-0201-121
P13082	M5306/Single	Reusable Thigh White NIBP Cuff (Nylon Laminated TPU Cuff With Bladderless) Limb Circumference:44-55cm	MaiCuff	03-0201-125
P13083	M5114/Single	Reusable Adult Brown NIBP Cuff (PU Cuff with TPU Bladder) Limb Circumference:27-35cm	MaiCuff	03-0201-045
P13084	M5104/Single	Reusable Adult White NIBP Cuff (Nylon Cuff with TPU Bladder) Limb Circumference:25-35cm	MaiCuff	03-0201-077
P13085	M5541-1#/Single	Disposable Neonate-1# Blue NIBP Cuff Limb Circumference:3-5.5cm	MaiCuff	03-0201-185
P13086	M5541-2#/Single	Disposable Neonate-2# Blue NIBP Cuff Limb Circumference:4-8cm	MaiCuff	03-0201-189
P13087	M5541-3#/Single	Disposable Neonate-3# Blue NIBP Cuff Limb Circumference:6-11cm	MaiCuff	03-0201-193
P13088	M5541-4#/Single	Disposable Neonate-4# Blue NIBP Cuff Limb Circumference:7-13cm	MaiCuff	03-0201-197

23.5 IBP Accessories

Part NO URUK	IBP	Brand/Manufacture	Manufacture/Part
P16001	IBP Transducer, MEDEX - .MX860/866 Novatrans	MEDEX	MX860P1
P16031	IBP Disposable Dome – MEDEX - MX860/866 Novatrans Dome	MEDEX	MX860/866(848)
P16032	IBP Extension Cable – MEDEX - MX860/866 Novatrans Extension	MEDEX	MX860/866(MX900-42)
P16002	IBP Transducer, MEDEX	MEDEX	MX960
P16033	IBP Transducer, Dome, MEDEX	MEDEX	MX960XXP1
P16034	IBP Extension Cable – MEDEX - MX960 Logical Extension	MEDEX	MX961Z04P1
P16037	IBP Transducer Cable – TRUWAVE	MEDEX	PX1800/896019021
P16036	IBP Transducer , Disposable – RX only	MEDEX	PX260
P16030	IBP Holder		
P16050	IBP Extension Cable, for MX960	URUK	BKT-164ET
P16046	IBP Transducer kit, Disposable	iPeX brand/ BL Lifesciences Pvt.	BKT-164ET
P16053	IBP Cable, Ipex,		P/N: BKT-164ET

Part NO URUK	ICP	Brand/Manufacture	Manufacture/Part
P23007	ICP-TEMP-Cable	RAUMEDIC	094328
P23008	NPS2 SpaceLabs for ICP	RAUMEDIC	091715
P23009	NEUROVENT-P-TEMP for ICP	RAUMEDIC	094268

23.6 GAS Accessories (Mainstream)

Part NO URUK	GAS(Mainstream)	Brand/Manufacture	Manufacture/Part
P20053	IRMA CO2 only probe (2++)	Masimo	200101
P20039	IRMA AX+ probe	Masimo	200601
P19145	IRMA & BFA Extension to IRMA	URUK	P19145
P20066	Airway Adapter, Disposable, IRMA	Masimo	106220

23.7 GAS Accessories (Sidestream)

Part NO URUK	Description	Division	Brand/ Manufacture	Manufacture Part#
P20099	NomoLine HH Adult/Pediatric Airway Adapter Set, 25 pcs./box, Length:2m	Long Term, Airway adaptor Set	Masimo Sweden AB	3827
P20100	NomoLine HH Infant/Neonatal, Airway Adapter Set, 25 pcs./box, Length: 2m	Long Term, Airway adaptor Set	Masimo Sweden AB	4367
P20101	VersaStream, CO2 Airway Adapter Sampling Line, Adult / Pediatric, 25 pcs./box, Length: 2.0m	Long Term, Airway adaptor Set	Viamed	4420823
P20102	VersaStream, CO2 Airway Adapter Sampling Line, Infant /Neonatal ID ≤ 4.0 mm, 25 pcs./box, Length: 2.0m	Long Term, Airway adaptor Set	Viamed	4420824
P20103	VersaStream, CO2 Sampling Line with Luer Lock Male connection, 25 pcs./box, Length: 2.0m	Long Term, LLM Sampling Line	Viamed	4420826
P20055	Clamp of ISA Module Holder			

23.8 BFA Accessories

Part NO URUK	BFA	Brand/Manufacture
P22028	BFA Accessory Patient Cable, URUK	URUK

23.9 C.O. Accessories

Part NO URUK	C.O	Brand/Manufacture	Manufacture/Part
P19069	URUK CO Cable	URUK	P19069
P20061	Intro-Flex, Percutaneous sheath Introducer	EDWARDS Lifesciences	I301BF85H
P20062	Swan-Ganz CCO/VIP, Thermodilution Catheter	EDWARDS Lifesciences	139HF75P

23.10 Power Cable

Power Cable			
Part Name	**Part NO URUK**	**Brand/Manufacture**	**Manufacture/Part**
AC Power Cable	P03018	Sheng	6266694
OR			
AC Power Cable	P09270	volex	2111H 10 C3

NOTE

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

23.11 ECG Electrodes

Part NO URUK	ECG	Manufacture/Part
P28042	Adults ECG Disposable Electrodes, FIAB Manufacturer	F9060
P28047	Pediatric ECG Disposable Electrodes, FIAB Manufacturer	F9060P
P10079	Arbo H124SG, COVIDIEN Manufacturer	31.1245.21

23.12 EEG Electrodes

Part NO URUK	EEG	Manufacture/Part
P22009	Neuroline 720, AMBU Manufacturer	REF: Neuroline720

Chapter 24, Care and Cleaning

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24.1 System Check

Before using the monitor,

■ Check if there is any mechanical damage in the system and accessories.

■ Check if all the power cable and accessories are firmly connected.

■ Check all the functions of keyboard and modules to make sure that the monitor is in proper condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or local After Sale Service.

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

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

NOTE

- It is recommended that the system is calibrated by manufacturer every year, but it has to be calibrated once every 2 years. In addition, the system lifetime is 10 years.
  The medical canter can request the system calibration whenever the system accuracy is in doubt.
- 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.

Warning

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

24.2 Cleaning and Disinfection

General Points

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment.
Manufacturer makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. See also any local policies that apply within your hospital.

Warning

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

2) Sterilization may cause damage to the device and is therefore not recommended for this patient monitor otherwise indicated in the instructions delivered with accessories or your hospital's servicing schedule.

3) If you see any signs of damage or deterioration in the device and its accessories, do not use it, and if necessary, contact the after-sales service company.

4) Allow the monitoring system to dry completely before making connections. And please make sure all connectors tightly connected to the system before using the system.

Please pay special attention to the following items:

1.The Patient Monitor and its belongings shall be kept dust-free.

2. Do not use strong solvents such as acetone or ammonia.

3. Most cleaning agents must be diluted before use.

4. Don't use rough or sharp material or your fingernail to remove stubborn stains.

5. Do not let the cleaning agent enter into the chassis of the system.

6. Do not leave the cleaning agents on any part of the equipment.

Warning

Do not use ETO gas to disinfect the monitor.

External surfaces

In-between patients and as required:

For cleaning: wipe gently using a moist cloth and warm soapy water or mild detergent and for disinfection use the following recommended agents:

- Alcohol 70%
- Isopropyl alcohol
- N-propanol

NOTE

For cleaning and disinfection of BFA module must act as external surfaces of the device.

Display screen

In-between patients and as required use clean and soft cloth with screen cleaner or mild soapy water and with Isopropyl alcohol may be used for cleaning and disinfection.

NOTE

1) Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing.

2) Don't spray a liquid directly on the screen.

Recorder

Accumulation of paper powder or foreign matter between the thermal head and platen roller deteriorates the print quality. Clean the head elements and platen roller surface using alcohol and a cotton swab. Wait until the alcohol dries then close the recorder door.

Warning

Do not clean the recorder immediately after recording because thermal head and its surrounding area are hot during and after recording.

Accessories

To clean, disinfect and sterilize reusable transducers, sensors, cables, leads, and so forth, refer to the instructions delivered with the accessories.

Also, trolley/ wall stand, accessory holders and extension cables, NIBP Hose, CO2 Mainstream and Sidestream Analyzer (if applicable) should be cleaned and disinfected after each patient or when necessary, using a soft, clean cloth soaked in mild soapy water and, if necessary, Isopropyl alcohol, and then wiped with a soft and dry cloth.

Warning

1) To avoid damaging of the cable, probe, sensor or connector, do not immerse it in any liquid.

2) Disposable accessories shall not be sterilized or reused.

3) To prevent environmental pollution, the disposal of accessories shall be done in accordance with the policies of the hospital.

The following table summarizes the methods of cleaning, disinfecting and sterilizing different parts of the device:

Device parts	Single-use	Cleaning	Disinfection	Sterilization
External surface of device	-	In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.	In-between patients and as required use ■ Alcohol 70% ■ Isopropyl alcohol ■ N-propanol	To avoid extended damage to the equipment, sterilization is not recommended for this monitor, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies or when stipulated as necessary in the Hospital Maintenance Schedule.
BFA module	disposable electrodes			
*** Trolley/ Wall stand,** *** Holders of accessory,** *** Extension cables** *** NIBP Hose,** *** CO2 Mainstream and Sidestream Analyzer**	-		In-between patients and as required use ■ Isopropyl alcohol	
Display screen	-	In-between patients and as required: Clean and soft cloth with screen cleaner or mild soapy water		
Recorder (printhead)	-	as required: 1.Gently wipe around the printhead using cotton swabs dampened with alcohol. 2.After the alcohol has completely been dried, reload the paper and close the recorder door.	use as required ■ Isopropyl alcohol	
ECG Accessory	disposable electrodes	**According to the instructions delivered with the reusable accessories** To clean, disinfect and sterilize reusable transducers, sensors, cables, leads, and so forth, refer to the instructions delivered with the accessory.		
SpO2 Accessory	disposable sensor			
NIBP Cuff	-			
TEMP Accessory	-			
IBP Accessory	disposable transducers and Domes			
GAS Accessory **(Main-stream/Side-stream)**	disposable Airway Adapter, Nemoline family sampling lines			
CO Accessory	-			

24.3 Preventive Maintenance (PM)

To ensure that the device is kept in the best condition, it shall be kept clean and all points related to the maintenance of the system shall be observed. There are no repairable parts in the system and all repairs shall be done by the manufacturer.

Storage

The storage environment shall be clean and dry. If possible, use the original packaging of the device.

NOTE

- If the monitor or equipment falls from a height and is damaged or in the vicinity of a very high temperature and high humidity, contact the company's after-sales service at the earliest opportunity to ensure the correct operation.
- Thoroughly clean the system before and after the system is not used for a while.

Weekly check of the following items is recommended:	Monthly check of the following items is recommended:
1. Device cleanness 2. Visual inspection of device (case, screen, keys and indicators) 3. Visual inspection of accessories 4. Function of accessories 5. Disposable accessories and accessories with limited time of use.	1. Calibration label (Sending the device to the manufacturer for calibration at the specified date). 2. Visual inspection of device 3. Device cleanness 4. Function of keys and indicators 5. Visual inspection of accessories

The preventive maintenance (PM) checklist #PL-F-24 should be completed by responsible individuals of healthcare center. It should be noted that PM checklist only is used to perform systematic inspection of the equipment and will not guarantee their correct function.

Preventive Maintenance (PM) Checklist

URUK Co.					
Form No. : PL-F-24-V1		PM Form (BEDSIDE)			
State:	City:	Medical center:	Ward:		
Device model:	Serial number:	Installation date:	Inspection date:		
No.	Test and Inspection Item		OK	NOK	N/A
1	Visual inspection	No damage or breakage in the back case and panel			
		Cleaning and disinfection according to the user manual			
2	Rotary	Correct function			
3	Keyboard	Correct function			
4	Touch	Correct function			
5	Display screen	Correct display of Waveform area, Parameter area and Message area			
6	Battery	Unplugging the system (check the battery function)			
		Check the fuse			
		Periodic usage of the battery			
7	Alarm	Alarm activation			
		Clarity of alarm sound			
		Correct function of alarm LEDs			
8	Setup	Saving date& time settings			
9	ECG	Check ECG cable (clamps, leadwire, trunk)			
		Check ECG window (Pacemaker, beat sound, etc)			
		Cleaning and disinfection according to the user manual			

URUK Co.					
Form No. : PL-F-24-V1		PM Form (BEDSIDE)			
State:	City:	Medical center:	Ward:		
Device model:	Serial number:	Installation date:	Inspection date:		
No.	Test and Inspection Item		OK	NOK	N/A
10	RESP	Check parameters of RESP window			
11	TEMP	Check TEMP probe			
		Cleaning and disinfection according to the user manual			
12	SpO2	Check SpO2 probe (extension, if any)			
		SpO2 window settings (Measurement mode and sensitivity)			
		Cleaning and disinfection according to the user manual			
13	NIBP	Check NIBP cuff and hose			
		Check accuracy of NIBP measurement			
		NIBP window settings (Adult, Pediatric and Neonate modes, measurement unit, Automatic mode)			
		Cleaning and disinfection according to the user manual			
14	IBP	Flushing the tubing system and perform zeroing			
		Check transducer and accessories			
		IBP window settings (Measurement unit, filter, Auto Scale and etc)			
		Cleaning and disinfection according to the user manual			
15	CAPNO	Check CAPNO probe and ISA Sampling line			
		Check CAPNO probe and IRMA Adaptor			
		CAPNO window settings (Measurement unit, COMPENSATE and etc)			
		Cleaning and disinfection according to the user manual			

URUK Co.

Form No. : PL-F-24-V1 **PM Form (BEDSIDE)**

State: **City:** **Medical center:** **Ward:**

Device model: **Serial number:** **Installation date:** **Inspection date:**

No.	Test and Inspection Item		OK	NOK	N/A
16	BFA	Check Neuro sensors and BFA device			
		Check expiry date of Neuro sensors			
		Check Link status with the bedside (green LED)			
		Cleaning and disinfection according to the user manual			
17	Recorder	Appropriate size of the recorder paper			
		Close door of the recorder during recording			
		Recorder window settings			
18	Connection to the Central System	Check secure connection of the cable to both bedside and central system			
		Check Network indicator on the bedside and waveforms and parameters on the central system			
		Check connection between the bedside and the central system			

Final decision: **Pass** ☐ **Fail** ☐

Recommendation:

Name and signature of responsible individual: **Name and signature of expert:**

Chapter 25, Troubleshooting

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

Troubleshooting guide is intended to help users to solve minor problems caused by incorrect use of the monitor or failure of accessories.

When you face any problem, please be sure that you have followed all procedure mentioned in Correct Action column before you contact with After Sale Service.

Fault Symptoms	Possible Cause	Correct Action
The monitor does not turn on		●Check POWER AC path. ●Call for service.
The monitor is unable to run on battery	●Battery is discharged. ● The battery fuse is faulty. ●etc.	●Charge the battery according to the specified charge time in the Technical Specification Chapter. ●Check fuse existence ●Call for service
ECG		
Fault Symptoms	**Possible Cause**	**Correct Action**
NO ECG waveform	●ECG cable is not connected correctly. ● ECG cable is faulty. ●Improper placement of leads and electrodes. ●etc.	●Connect ECG cable correctly ●Check leads and electrodes. ● Short-circuit all the leads, if the cable is perfect, no error message will be displayed. ●Don’t use old and faulty electrodes ●Call for service
Noisy ECG waveform	●Loose connection of electrodes ●Earth connection failure ●Wrong ECG filter ●etc.	●Check electrodes and leads. ● Check applied gel on the chest lead or change the chest lead, if necessary. ●Check the earth. ●Set filter mode correctly ●Call for service
Spike on ECG waveform	●If "PACE: ON" is selected for patient without Pace marker , ECG signal will be received as PACE. ●etc.	●Turn OFF “Pace detection” in ECG menu.
Unstable HR	●ECG signal is noisy or isn’t suitable ●etc.	●Check leads and electrodes. ●Change lead to display the best ECG signal. ●Call for service
RESP		
No “RESP” signal No good waveform Unstable RR	●Electrodes are not connected correctly. ●Patient moves during the measurement. ●etc.	●Check leads and electrodes. ●change RESP lead. ●Calm patient. ●Call for service.

TEMP		
Fault Symptoms	**Possible Cause**	**Correct Action**
Invalid T1/T2 value	●Location of the sensor isn't suitable. ●Faulty sensor. ●etc.	●Put the sensor in suitable position. ●Change the sensor. ●Call for service
SpO2		
Measurement failure	AC noise interferes with the signal. Inappropriate size of sensor High ambient light sources	● Set AC frequency through the below window (Chapter 2, Setting): HOME/MODULE SETUP/MASIMO VERSION WINDOW ● Use appropriate sensor regarding patient weight and intended use. ● Reduce ambient light.
Reading does not match clinical evaluation results or blood test	Low arterial perfusion or incorrect probe connection	● Check the relevant alarm message. ● Make sure that the sensor has not been connected too tight. ● Set Sensitivity on MAX and make sure that the sensor has been connected correctly to the patient. Refer to operating instructions of the sensor for correct usage.
Measurement results are in doubt	Low perfusion or low signal amplitude Inappropriate sensor size or incorrect sensor placement	● Place the sensor in a better perfused monitoring site. ● Place the sensor in three different sites and check measurement accuracy in these sites. ● Record the blood test results to make a comparison with the sensor readings. ● Check that the sensor has been selected correctly. Check that the sensor has been placed in appropriate site.
SpCO value is displayed blank.	SpO2 value is lower than 90% SpMet value is more than 2% SpCO value is unstable.	● Evaluate the patient status. ● Perform laboratory analysis of the blood sample. ● Use appropriate sensor regarding patient weight and intended use. ● Wait until the parameter value becomes stable.
No SpO2 waveform Noisy SpO2 waveform	● The SpO2 probe in an unsuitable place. ●Faulty sensor ●etc.	●Change the place of probe on patient ●Change the probe and check the waveform. Contact the manufacturer to replace the probe with a new one, if necessary. ●Call for service.
Invalid SpO2 value	●Patient movement during measurement ●Inappropriate placement of the probe. ●etc	●Calm the patient ●Change the place of the probe. ●Call for service.

Fault Symptoms	Possible Cause	Correct Action
NIBP		
Sometimes the monitor ~~reinflates~~**reinflate** the cuff.	● The initial inflation pressure in the first measurement is 150 mmHg in adult mode. In the next measurements, inflation continues to 30 mmHg higher than the last successful measurement. If the first measurement is more than 150 mmHg or more than 30 mmHg in the next measurements, the monitor will reinflate the cuff. ● Patient movement during the measurement ● inappropriate cuff size ● Airway leakage ● Incorrect connection of air tubing to the rectus ● The monitor failure	● **In case of changing the patient, be sure to select the module reset option in the settings window.** ~~**In case of changing the patient, be sure to reset the module once**Turn off and on the monitor for new patient.~~ ● Check connections. ● Check air tubing. ● Select appropriate cuff size. ● Check the patient status. Prevent the patient movement. ● Call for service.
NIBP START button does not function.	● The Start button is pressed immediately after turning on the monitor. ● The Start button is faulty. ● The battery charge is too low and the monitor is not plugged in.	● Turn the monitor off and on. Wait a minute until the monitor starts up. Now try the button function again. ● Open NIBP menu and click on MODULE START to check function of the NIBP Start button. ● Plug in the monitor. ● Call for service.
The module is not able to measure the blood pressure and ? appears on the screen.	● Inappropriate measurement mode. ● Improper cuff size ● Patient movement ● Some diseases such as cardiac arrhythmia cause conflict in patient pulses and consequently could result in measurement failure.	● Make sure that correct mode has been selected for the patient. For example, if neonate mode is selected for adult or pediatric patient, the module might not be able to measure. ● If the cuff size is not selected correctly, the module might not be able to measure. For example, if the selected cuff is larger than proper size, the patient's pulse becomes weak and the measurement failure occurs. ● Remain the patient calm and relaxed during the measurement and make sure that the patient does not talk or laugh. Any movement could affect the measurement accuracy and lead to measurement failure. ● Check the patient status. ● Call for service.
NIBP module low accuracy	~~●~~● **Incompatibility between the number measured by the monitor and the pressure set by the simulator** ● **Incompatibility of pressure measured by NIBP and pressure measured by IBP** ● **Inconsistency of the pressure measured by NIBP and the pressure measured by the doctor**~~**Mismatch between the number measured by the module and the pressure set by the simulator**A simulator has been used in assessment of the module accuracy.~~**.** ~~● The module is out of calibration.~~	● **The simulator is not a suitable reference for evaluating the accuracy of the blood pressure monitor. Use alternative methods such as IBP or auscultatory to assess accuracy.** ● **The accuracy of blood pressure measurement in the IBP method depends on settings such as ZEROING, use of appropriate accessories, IBP calibration and catheter level. First, make sure the IBP settings are correct.** ●**The monitor may be out of calibration and needs calibration. Call**

		after sales services for the module calibration. ~~It is not supposed that measured value by the simulator should be equal to the set value, but in case of using simulator for test, the measured value by the module should be repeated.~~ ~~● Call after sales services for the module calibration.~~
IBP		
Fault Symptoms	**Possible Cause**	**Correct Action**
Invalid IBP value Noisy IBP signal	●No zeroing before use. ●Existence of air bubbles in tubing system or the transducer dome. ●Noisy source exists nearby the system or accessories ●Faulty sensor ●etc	●Perform zeroing ●Keep the system and cable away from noise source. ● Check that proper label with regard to place of measurement is selected. ● Wash up the tubing system and dome. ● Change the dome. ●Change the sensor. ●Call for service
C.O (Cardiac Output)		
After the catheter is inserted into the patient body, the message “ready for measurement” does not appear and the message “Noisy baseline” remains on the screen.	●The catheter is not placed in proper position. ●There is other noise source, for example Electrocautery.	● Make sure that the catheter is inserted properly. ●Turn off the device caused noise and then use C.O measuring module.
Inaccurate C.O value	● The manufacturer recommended accessories are not used. ● Catheter type is not selected properly in C.O Setup menu. ● Injectate solution temperature is not zero (the range of -5 to 5 0 °C)	● Use the manufacturer recommended accessories. ● Select the catheter type correctly in Setup menu. Make sure that the temperature of injectate solution is zero.
MULTIGAS		
Fault Symptoms	**Possible Cause**	**Corrective Action**
Problem in CO2 measurement	● Adaptor failure ●No zeroing before measurement.	●Replace adapter for each patient. ●Perform zeroing procedure according to instructions of this manual. ●If the problem is not resolved, contact after sale service of the manufacturer.
BFA		
BFA module does not turn on when it is connected to the monitor		● Check interface cable between the module and the monitor. ● Check proper attachment of neuro sensors.

		Clean the skin before attaching the sensor or use a new sensor, if necessary ● If the problem persists, contact after sale service of the manufacturer.
BFI is higher than expected range		● Check anesthetic delivery systems: IV lines and status of vaporizers. ● Some patients require more doses of drug to reach intended level of anesthesia. ● Drug dosage is not sufficient for Maintenance phase, so BFI increases during painful stimulations.
BFI rises along with EMG	● High levels of facial muscular or electromyographic (EMG) activity ● Attention must be paid to reactions of patient against the stimuli during surgery. ● When the patient is asleep, EMG activity may increase due to reactions to painful stimuli during surgery. ●Lack of muscular relaxation or muscular rigidity caused by some opioids (analgesics).	● In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent may decrease BFI.
Central		
Fault Symptoms	**Possible Cause**	**Corrective Action**
Problem in function of different parts of the central system such as touch screen, recorder and etc		●Turn off and on the system. ●If the problem is not resolved, contact after sale services.
No connection is made with the central system.	● Check proper connection of the cable between the central and bedside monitor.	● If the problem persists, contact after sale services.

The parameters in ECG menu		
Menu item	selection	Default
ECG LEAD	I,II,III,aVR,aVF,aVL,V1,V2,V3,V4,V5,V6	II
CABLE TYPE	3 Wires,5 Wires, 10 Wires	3 Wires
ECG GAIN	×0.25,×0.5,×1,×2,×4,AUTO	AUTO
ECG SWEEP	12.5,25,50mm/s	25
ECG FILTER	MONITOR,NORMAL,EXTENDED	NORMAL
HR AVERAGE	4,8,16SEC	8SEC
HR SOURCE	ECG, SpO2,IBP1,IBP2,AUTO	AUTO
BEAT VOLUME	1,2,3,4,5,6,7, OFF	1
PACE DETECT	ON, OFF	OFF
ECG CALIB	ON, OFF	OFF
ALARM LEVEL	1,2	1
HR ALARM	ON, OFF	OFF
HR HIGH ALARM	HR LOW ALARM +5 to 250	150Bpm
HR LOW ALARM	30 to HR HIGH ALARM -5	50Bpm
The parameters in RESP menu		
Menu item	selection	Default
RESP LEAD.	RA-LA,RA-LL	RA-LA
RESP GAIN	×0.25,×0.5,×1,×2,×4	×1
RESP SWEEP	3,6,12.5,25mm/s	6mm/s
ALARM LEVEL	1,2	1
RR ALARM	ON ,OFF	OFF
RR HIGH ALARM	RR LOW ALARM +1 to 150	25Brpm
RR LOW ALARM	5 to RR HIGH ALARM -1	5Brpm
APNEA LIMIT	10 to 40S, OFF	10S
The parameters in SpO2 menu		
Menu item	selection	Default
AVERAGE TIME	2-4,4-6,8,10,12,14,16	8
SpO2 PLETH SWEEP	12.5,25mm/s	25mm/s
ALARM LEVEL	1,2	1
SpO2 ALARM	ON,OFF	OFF
SpO2 HIGH ALARM	SpO2 LOW ALARM +1 to 100 (with step 1)	100
SpO2 LOW ALARM	1 to SpO2 HIGH ALARM -1 (with step 1)	90
SpO2 SENSITVITY MODE	NORMAL , MAX , APOD	NORMAL

PI HIGH ALARM	PI LOW ALARM +0.1 to 19.0 (with step 0.1)	19.0
PI LOW ALARM	0.0 to PI HIGH ALARM -0.1 (with step 0.1)	0.0
PVI HIGH ALARM	PVI LOW ALARM +1 to 99 (with step 1)	99
PVI LOW ALARM	1 to PVI HIGH ALARM -1 (with step 1)	1
SpOC HIGH ALARM	SpOC LOW ALARM +1 to 34.0 (with step 1)	34.0
SpOC LOW ALARM	1.0 to SpOC HIGH ALARM -1 (with step 1)	1.0
SpCO HIGH ALARM	SpCO LOW ALARM +1 to 99.0 (with step 1)	10.0
SpCO LOW ALARM	1.0 to SpCO HIGH ALARM -1 (with step 1)	1.0
SpMet HIGH ALARM	SpMet LOW ALARM +0.5 to 99.5 (with step 0.5)	3.0
SpMet LOW ALARM	0.5 to SpMet HIGH ALARM -0.5 (with step 0.5)	0.5
SpHb HIGH ALARM	SpHb LOW ALARM +0.1 to 24.5 (with step 0.1)	17.0
SpHb LOW ALARM	0.5 to SpHb HIGH ALARM -0.1 (with step 0.1)	7.0
ORi HIGH ALARM	ORi LOW ALARM + 0.1 to 1.0 (with step 0.1)	0.8
ORi LOW ALARM	0.0 to ORi HIGH ALARM-0.1 (with step 0.1)	0.0

The parameters in NIBP menu

Menu item	selection	Default
NIBP UNIT	mmHg , KPa	mmHg
ALARM LEVEL	1,2	1
NIBP ALARM	ON, OFF	OFF
SYS HIGH ALARM	Adult: SYS LOW ALARM +5 to 255 Neonate: SYS LOW ALARM +5 to 135 Pediatric: SYS LOW ALARM +5 to 240 (with step 5)	Adult: 160mmHg Neonate: 90mmHg Pediatric: 120mmHg
SYS LOW ALARM	Adult: 30 to SYS HIGH ALARM -5 Neonate: 30 to SYS HIGH ALARM -5 Pediatric: 30 to SYS HIGH ALARM -5 (with step 5)	Adult: 90mmHg Neonate: 40mmHg Pediatric: 70mmHg
DIA HIGH ALARM	Adult: DIA LOW ALARM +5 to 220 Neonate: DIA LOW ALARM +5 to 110 Pediatric: DIA LOW ALARM +5 to 220 (with step 5)	Adult: 90mmHg Neonate: 60mmHg Pediatric: 70mmHg

DIA LOW ALARM	Adult: 15 to DIA HIGH ALARM -5 Neonate: 15 to DIA HIGH ALARM -5 Pediatric: 15 to DIA HIGH ALARM -5 (with step 5)	Adult: 50mmHg Neonate: 20mmHg Pediatric: 40mmHg
MAP HIGH ALARM	Adult: MAP LOW ALARM +5 to 235 Neonate: MAP LOW ALARM +5 to 125 Pediatric: MAP LOW ALARM +5 to 230 (with step 5)	Adult: 110mmHg Neonate: 70mmHg Pediatric: 90mmHg
MAP LOW ALARM	Adult: 20 to MAP HIGH ALARM -5 Neonate: 20 to MAP HIGH ALARM -5 Pediatric: 20 to MAP HIGH ALARM -5 (with step 5)	Adult: 60mmHg Neonate: 25mmHg Pediatric: 50mmHg
AUTO/MANUAL	1min, 2min, 3min,5min,10min,15min,20min, 30min,45min, 60min, 90min, 2hr,4hr, 8hr, 12hr, 16hr, 20hr, 24hr,MANUAL, STAT	MANUAL

The parameters in TEMP menu

Menu item	selection	Default
TEMP UNIT	ºC,ºF	ºC
ALARM LEVEL	1,2	1
TEMP ALARM	ON ,OFF	OFF
T1 HIGH ALARM	T1 LOW ALARM +1 to 50	39
T1 LOW ALARM	0 to T1 HIGH ALARM -1	35
T2 HIGH ALARM	T2 LOW ALARM +1 to 50	40
T2 LOW ALARM	0 to T2 HIGH ALARM -1	36
DT HIGH ALARM	DT LOW ALARM +1 to 50	5
DT LOW ALARM	0 to DT HIGH ALARM -1	1.0

The parameters in IBP menu

Menu item	selection	Default
IBP UNIT	mmHg , KPa,cmH2O	mmHg
IBP LABEL	IBP, ART, PAP, CVP, LAP, RAP, LVP, RVP,ICP	IBP
IBP SWEEP	3,6,12.5,25 mm/s	12.5 mm/s

IBP GRID	ON, OFF	OFF
IBP FILTER	8, 16, 22 Hz	16 Hz
ALWAYS AUTO SCALE	ON,OFF	OFF
IBP ALARM	ON,OFF	OFF
ART CATH. DISCONNECT ALM	ON , OFF	OFF
PPV MEASUREMENT	ON , OFF	OFF
ALARM LEVEL	1,2	1
IBP HIGH ALARM	IBP LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
IBP LOW ALARM	-50to IBP HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
ART HIGH ALARM	ART LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
ART LOW ALARM	-50to ART HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
LVP HIGH ALARM	LVP LOW ALARM +5 to 300	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	5 mmHg SYS: DIA: -5 mmHg MEAN: 0 mmHg
RVP HIGH ALARM	RVP LOW ALARM +1 to 100	40 mmHg SYS: DIA: 15 mmHg MEAN: 30 mmHg
RVP LOW ALARM	-50 to RVP HIGH ALARM -1	5mmHg SYS: 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
ICP HIGH ALARM	ICP LOW ALARM +1 to 100		Adult: 10mmHg Neonate: 4mmHg Pediatric: 4mmHg
ICP LOW ALARM	-40 to ICP HIGH ALARM -1		0 mmHg
IBP SCALE			
IBP	HIGH	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	-20
	SIGN	(HIGH+LOW)/2	90
ART	HIGH	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	40
	SIGN	(HIGH+LOW)/2	120
PAP	HIGH	LOW +5 TO 300 (with step 5)	80
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	35
CVP	HIGH	LOW +5 TO 300 (with step 5)	30
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	10
LAP	HIGH	LOW +5 TO 300 (with step 5)	40
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	15
RAP	HIGH	LOW +5 TO 300 (with step 5)	30
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	10
LVP	HIGH	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	-20
	SIGN	(HIGH+LOW)/2	90
RVP	HIGH	LOW +5 TO 300 (with step 5)	80
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	35
ICP	HIGH	LOW +5 TO 100 (with step 5)	40

	LOW	-40 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	15

The parameters in ST menu

Menu item	Selection	Default
ST ANALYSIS	ON, OFF	OFF
ST ALARM	ON, OFF	OFF
ALARM LEVEL	1, 2	1
ST LOW ALARM	-2 to ST HIGH ALARM -0.1	-0.2
ST HIGH ALARM	ST LOW ALARM +0.1 to 2	0.2
EVENT DURATION	15S, 30S, 45S, 60S, OFF	OFF

The parameters in ARR menu

Menu item	Selection		Default
ARR MONITOR	ASYSTOLE	1	1
	VFIB	1	1
	VTAC	1	1
	RUN	1, 2, OFF	1
	AIVR	1, 2, OFF	2
	COUPLET	1, 2, OFF	2
	BIGEMINY	1, 2, OFF	2
	TRIGEMINY	1, 2, OFF	2
ALARM LEVEL	TACHY	1, 2, OFF	2
	BRADY	1, 2, OFF	2
	AFIB	1, 2, OFF	1
	PAUS	1, 2, OFF	2
	FREQUENT PVCs	1, 2, OFF	OFF
	R on T	1, 2, OFF	2
	MULTIFORM PVCs	1, 2, OFF	2
	PNC	1, 2, OFF	2
	PNP	1, 2, OFF	2
RATE	VTAC	100 to 200 (with step 10)	>=120
	RUN	$VTAC_{rate}$	>=120
	AIVR	$<VTAC_{rate}-1$	>=119

COUNT	TACHY	100 to 200 (with step 10)	>=120
	BRADY	30 to 105 (with step 5)	<=50
	VTAC	5 to 12 (with step 1)	>=5
	RUN	3 to $VTAC_{count}$-1 (with step 1)	>=3
	AIVR	-	>=3
ARCHIVE	FREQUENT PVCs	1 to 15 (with step 5)	>=10
	ASYSTOLE	STR, STR/REC, OFF, REC	STR
	VFIB	STR, STR/REC, OFF, REC	STR
	VTAC	STR, STR/REC, OFF, REC	STR
	RUN	STR, STR/REC, OFF, REC	STR
	AIVR	STR, STR/REC, OFF, REC	STR
	COUPLET	STR, STR/REC, OFF, REC	STR
	BIGEMINY	STR, STR/REC, OFF, REC	STR
	TRIGEMINY	STR, STR/REC, OFF, REC	STR
	TACHY	STR, STR/REC, OFF, REC	OFF
	BRADY	STR, STR/REC, OFF, REC	OFF
	AFIB	STR, STR/REC, OFF, REC	STR
	PAUS	STR, STR/REC, OFF, REC	OFF
	FREQUENT PVCs	-	-
	R on T	STR, STR/REC, OFF, REC	OFF
	MULTIFORM PVCs	STR, STR/REC, OFF, REC	OFF
	PNC	STR, STR/REC, OFF, REC	OFF
	PNP	STR, STR/REC, OFF, REC	OFF

The Parameters in GAS WINDOW(Mainstream & Sidestream)			
Menu item	selection		Default
CO2 UNIT	KPa ,%V ,mmHg		mmHg
SIGNAL SWEEP	3mm/s, 6mm/s, 12.5mm/s, 25mm/s		12.5mm/s
SIGNAL SCALE	CO2	6%,10%,Auto scale	10%
	O2/N2O	0-50%,0-100%, Auto scale	100%
	AA	1,2,3,5,10,20%, Auto scale	20%
WAVEFORM (Mainstream)	CO2, N2O, AA		CO2

WAVEFORM (Sidestream)	CO2, O2, N2O, AA		CO2
O2 COMPENSATE	1-100 vol%, OFF		21% , AUTO
N2O COMPENSATE	0-100 vol% (ONLY FOR ISA CO2, IRMA2 CO2)		0%
GAS UNIT	KPa ,%V		
AGENT	ISO,ENF,HAL,DES,SEV	HAL AUTO (For IRMA(AX+) & ISA(OR+) & ISA(AX+))	
WORK MODE	MEASURE, STANDBY	MEASURE	
GAS/RESP	GAS, RESP	GAS	
FIIL SIGNAL	ON,OFF	OFF	
CO2 ALARM	ON,OFF	OFF	
N2O ALARM	ON,OFF	OFF	
AA ALARM	ON,OFF	OFF	
O2 ALARM	ON,OFF	OFF	
ALARM LEVEL	1,2	2	
APNEA ALARM	20s,25s,30s,35s,40s,45s,50s, 55s,60s, OFF	20s	
		NEONATE	ADULT/PED
AWRR LOW	1~(HIGH-1)	15 BrPM	5 BrPM
AWRR HIGH	)LOW+1) ~120	60 BrPM	30 BrPM
EtCo2 LOW	0.4~(HIGH-0.1) (%V)	2.6%V	
EtCo2 HIGH	)LOW+0.1)~13(%V)	6.5%V	
FiCo2 HIGH	0.4~ 13(%V)	1.3%V	
EtO2,FiO2 LOW (sidestream)	18~(HIGH-1) (%V)	50%	
EtO2,FiO2 HIGH (sidestream)	)LOW+1)~105(%V)	100%	
EtN2O ,FiN2O LOW	1~(HIGH-1) (%V)	35%	
EtN2O HIGH	)LOW+1)~100(%V)	75%	
FiN2O HIGH	)LOW+1)~82(%V)	75%	
EtDES ,FiDES LOW	0.1~(HIGH-0.1) (%V)	5%	
EtDES ,FiDES HIGH	)LOW+0.1)~18(%V)	10%	
EtISO ,FiISO LOW	0.1~(HIGH-0.1) (%V)	0.8%	
EtISO ,FiISO HIGH	)LOW+0.1)~5(%V)	2%	
EtENF ,FiENF LOW	0.1~(HIGH-0.1) (%V)	0.5%	
EtENF ,FiENF HIGH	)LOW+0.1)~5(%V)	1.5%	
EtSEV ,FiSEV LOW	0.1~(HIGH-0.1) (%V)	1%	
EtSEV ,FiSEV HIGH	LOW+0.1)~8(%V))	3%	

EtHAL ,FiHAL LOW	0.1~(HIGH-0.1) (%V)	0.5%
EtHAL ,FiHAL HIGH	LOW+0.1)~5(%V))	1.5%
ZERO	Only for Mainstream	

The Parameters in BFA WINDOW		
Menu item	selection	Default
EEG Gain	25uV,50-250uV	100uV
BFA ALARM	ON, OFF	OFF
BFI LOW	1~(HIGH-1)	35%
BFI HIGH	(LOW+1) ~100	60%
The Parameters in Cardiac Output WINDOW		
Menu item	selection	Default
Catheter Type	131HF7,139HF75P, Simulator	131HF7
Temp_Scale	1,2,4	1
SYSTEM DEFUALT		
Menu item	selection	Default
ALARM VOLUME	1,2,3,4,5,6,7	1
CALENDAR	SOLAR, CHRISTIAN	CHRISTIAN
PATIENT CAT.	ADUL, NEONATE, PEDIATRIC	ADULT
BED NUMBER	1..150	01
TOUCH SOUND	1, 2, 3, OFF	1
BACK LIGHT	1 to 8	18.5” Monitor: 7
	1 to 6	12” Monitor: 5
		10” Monitor: 3
		15” Monitor: 2
BED TO BED	DURATION :1,2,3,4,5	1 Min
Module Color		
ECG COLOR	Green	Default
IBP1 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	LIGHT RED
IBP2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	LIGHT BLUE

IBP3 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	DARK ORANGE
IBP4 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	DARK CYAN
SpO2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	MAGENTA
CO2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	YELLOW
RESP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	YELLOW
NIBP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	WHITE
TEMP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	CYAN

APPENDIX II
EMC

Warning

- **Use only the recommended manufacturer accessory. Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.**
- **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 – Patient monitor emissions		
The patient monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor, should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The patient monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The patient monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The patient monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor should assure that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Patient coupling		
	Signal input/output parts		
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	± 2 kV, 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 1 kV 100 kHz repetition frequency	
Surge IEC 61000-4-5	Input a.c. power	± 0,5 kV, ± 1 kV Line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 2 kV Line-to ground	
Voltage dips, IEC 61000-4-11	Input a.c. power	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	Input a.c. power	0 % U_T; 250/300 cycle	

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The patient monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor should assure that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	Input a.c. power	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	
	PATIENT coupling		
	Signal input/output parts		
Radiated RF IEC 61000-4-3	ENCLOSURE	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2015)	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band a) (MHz)**	**a) Service**	**b) Modulation**	**Maximum power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM C) ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28
1845						
1970						

2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b)] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b)] 217 Hz	0.2	0.3	9

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.