URUK Medical Equipment Co.

Operator's Manual

PM4010 Patient Monitor

D00010-V1

URUK Medical Equipment Co.

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PM4010 User Manual

Note:

This guide describes all features and functions of the PM4010 monitor and its different stations. Your monitor is highly customizable and may not have some of these features. Optional features are marked with *.

Chapter 1, Introduction

Contents

Manual Purpose

This manual provides the instructions necessary to operate PM4010 patient monitor in accordance with its intended use. Study of this manual is a prerequisite for proper operation and ensures patient and operator safety. If you have any question about the monitor, please contact our Customer service department. This manual should always be kept close to the monitor to be available whenever required.

Intended Audience

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

Version Information

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

Release date	Version number
June 2020	D00010-V0

Symbols

The following symbols are used in this manual:

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

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

General Warnings


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


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


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


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

General Warnings

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

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

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

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

General Warnings

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

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

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

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

General Warnings

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

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

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

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

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

General Warnings

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

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

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

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

General Warnings

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

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

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

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

Before using the system, check the battery charge status.

General Warnings

 Do not touch the screen with sharp objects.

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

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

General Information

Environmental conditions

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

The PM4010 monitoring system has been designed to monitor patient's condition continuously from the moment of incident until medical care and full recovery.

The PM4010 portable monitor is adaptable to adult, pediatric and neonatal patients. It can monitor vital signs such as ECG, Respiratory Rate (AWRR, RR), NIBP, SPO2, BFA, CO2 (AWRR,FiCo2,FiCo2), 4 channels IBP

and 2 channels TEMP. The PM4010 monitor consists of different modules, a recorder and an alarm system and can communicate with the Central monitoring system. The monitor features in compactness, lightweight and portability and its built-in battery facilitates transportation of the patient. It is a compact, lightweight and portable monitor and its built-in battery facilitates transportation of the patient.

The patient monitor can monitor the following parameters:

ECG

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

RESP

- Respiratory rate(RR)
- Respiration waveform

SpO2

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

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

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

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

NIBP

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

TEMP

- Temperature channel (T1)
- Temperature channel (T2)

IBP

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

CO2

- EtCo2, FiCo2, AWRR

BFA

- Anesthetic depth index(BFI)
- Percentage of Burst Suppression (BS%)
- Signal Quality Index(SQI)
- Electromyogram index(EMG%)

General Information

The PM4010 monitor is equipped with Visual & Audible alarms and can store Trend and NIBP data.

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

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

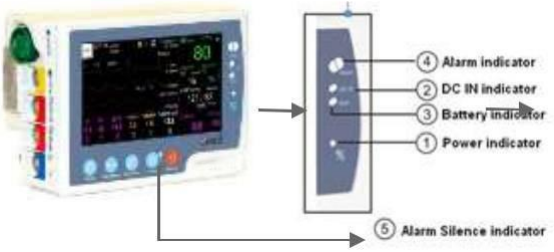
Indicators

There are five indicators for power, alarm, DC IN, battery and alarm silence on the front panel of the PM4010

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

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

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



Indicators Figure1-1

Main Screen

The vital sign monitor has a color TFT screen. The patient parameters, waveforms, alarm messages, bed number, date, time, system status and error messages are displayed on the main screen. The main screen is divided into four areas (See figure 1-2):

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

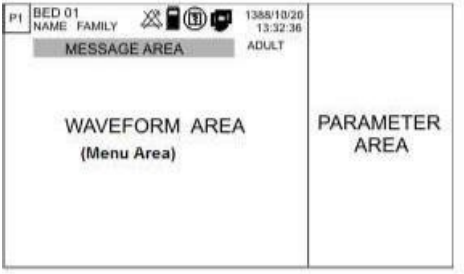


Figure 1-2 Main screen

- **Header Area**

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

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

Main Screen

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

	Indicates the remaining battery charge.
	Indicates that the battery is not loaded in the battery compartment
	Appears when the system is recording.
	Appears when the system is connected to Central monitoring system.
	Appears when Alarms key is pressed.
	Blinks along with a countdown timer of 120 sec when the system is in the silence mode.
	Appears in white color when connection of the PM4010 monitor to the station is established. If the PM4010 is connected to other devices (e.g. Modular system), a green symbol as well as white symbol will be displayed.

- **Waveform / Menu Area**

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

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

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

- **Parameter Area**

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

- **Message Area**

Different messages are displayed in this area based on priority. Background color changes with regard to alarm level (I, II and III).

Level I alarm message: Red background – Black text

Level II alarm message: Yellow background – Black text

Level III alarm message: Cyan background – Black text

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

Different page configurations

There are two ways to change page setting:

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

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

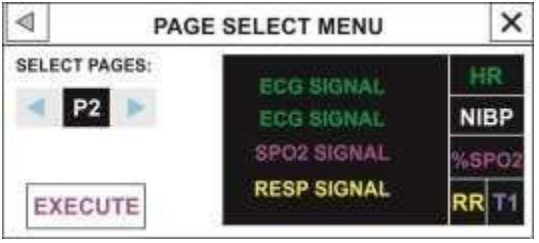


Figure 1-4 PAGE SELECT MENU

There are 23 pages in the PM4010 monitor by default, with different configurations to display parameters and waveforms. According to the table below:

Page	Parameter	Signal
P1	HR,SpO2,RR,T1,NIBP	ECG,SpO2,RR
P2	HR,SpO2,RR,T1,NIBP	ECG 2Trace,SpO2,RR
P3	HR,SpO2,RR,T1,NIBP	ECG 4Trace

P4	HR,SpO2,RR,T1,NIBP	ECG 7Trace
P5	HR,SpO2,RR,T1,NIBP	ECG 12Trace
P6	HR,SpO2(PI, PVI,SpOC,%SpCo %SpMet,SpHb),RR,T1,NIBP	ECG, RR, SpO2
P7	HR,SpO2(PI, PVI,SpOC,%SpCo %SpMet,SpHb),RR,T1,NIBP	ECG
P8	SpO2,PR,T1,T2,NIBP	SpO2
P9	SpO2,PR	SpO2
P10	HR,IBP,SpO2,NIBP	ECG, IBP, SpO2
P11	HR,IBP,T1,RR,NIBP	ECG, IBP
P12	HR,IBP,SpO2(PI, PVI,SpOC,%SpCo,%SpMet ,SpHb)	ECG, IBP
P13	HR,IBP,NIBP,SpO2(PR,PI, PVI,SpOC,%SpCo%SpMet,SpHb)	ECG
P14	HR,2IBP,SpO2,NIBP	ECG,2IBP
P15	HR,2IBP SpO2(PR,PI, PVI,SpOC,%SpCo,%SpMet,SbHb)	ECG,2IBP
P16	HR,2IBP,SpO2,NIBP	ECG
P17	HR,2IBP, SpO2(PR,PI, PVI,SpOC,%SpCo,%SpMet,SpHb)	ECG
P18	HR,NIBP,SpO2,PR,T1,CO2(AWRR,EtCo2,FiCo2)	ECG,CO2

P19	HR,NIBP,SpO2,PR, CO2(AWRR,EtCo2,FiCo2)	ECG,SpO2,CO2
P20	HR,CO2(AWRR,EtCo2,FiCo2),NIBP SpO2(PR,PI, PVI,SpOC,%SpCo %SpMet,SpHb)	ECG
P21	HR, SpO2,PR,2IBP,T1 ,CO2(AWRR,EtCo2,FiCo2)	ECG,SpO2,IBP
P22	HR, SpO2,PR,2IBP,NIBP ,CO2(AWRR,EtCo2,FiCo2	ECG
P23	HR,BFI%,BS%,SQI%,EMG%	ECG,EEG

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

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

2- To make the monitor readable outdoor, transfer it to shade or a dark environment.

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

Keys Function

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

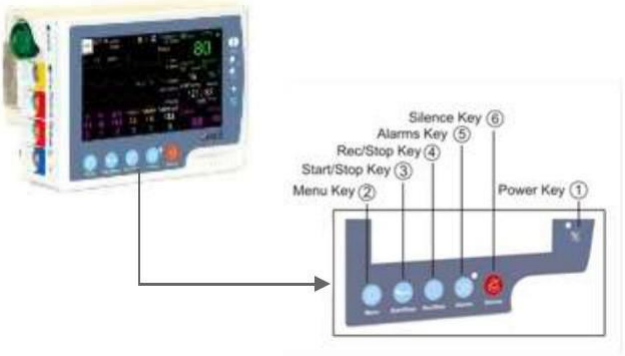


Figure 1-5 Keys

① **Power:** press this key to turn the monitor On and Off.

② **Menu:** press to open HOME MENU or return to the main screen.

③ **Start/Stop:** press this key to start blood pressure measurement and press it again to stop measurement.

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

④ **Rec/Stop:** press to record ECG waveform and all numeric parameters via the Central monitoring system or recorder of F1R station. Press it again to stop recording.

③ **Alarms:** press this key to disable alarms unlimitedly. Even if a new alarm occurs, alarm indications (light indicator and alarm sound) will be inactive until you press the key again.

This key is currently inactive to meet standard requirements, but it will be activated for user in the future.

⑥ **Silence:** press to disable alarm sound for 120 sec. A countdown timer appears and Silence symbol blinks in the Header area every 5 sec. If you press this key again, the system will exit from silence mode and the alarm sound will be enabled.

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

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

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

Interfaces

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

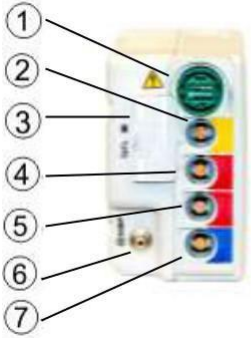


Figure 1-6 PM4010 connectors

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

 Multi-gas module is currently inactive.

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

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

Connection to the Central System

The PM4010 monitor has a wireless connection to the Central system.

Wi-Fi connection of the PM4010 to the central system is made via an access point.

 Only URUK monitors can be connected to network of the URUK Central system (Central CS110 series).

Before connecting the PM4010 monitor to the network, the operator shall perform relevant settings such as AP Index and Bed Number.

Built-in Battery

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

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

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

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

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

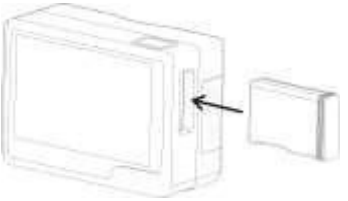


Figure 1-7 Battery insertion into the monitor

To remove the battery, press the battery eject button (see figure 1-8-a). When the battery is released you can remove it from the compartment.

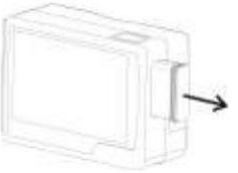


Figure1-8-a Eject button **Figure1-8-b Removing the battery**

The battery specifications including voltage, current consumption, charging current, temperature, remaining time to battery depletion and remaining time to battery discharge are displayed by the PM4010 monitor. The battery voltage, current and current consumption can be monitored in ABOUT menu.

Built-in Battery

The batteries of the PM4010 monitor and the station can be recharged at least 500 times.

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

Chapter 2, External Device

Contents

General

The PM4010 monitor through connection to a number of accessories can easily be changed to an appropriate monitor for different parts of hospital. The accessories can be connected to the monitor without disconnecting the monitor from the patient, so no interruption is made in the monitoring and storage of patient vital signs.

The accessories of the PM4010 monitor are:

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

Accessories

- **F1 Station**

F1 station is shown in the below figure:

Figure 2-1 PM4010 Station (F1)

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

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

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

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

The connector of adaptor and digital data output is located at the right side of the station (See figure 2-2).

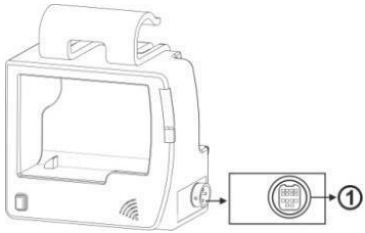


Figure 2-2 Connector of F1 Station

■

Power adaptor (Socket ⏻)

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

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

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

Indicators of F1 Station

There are two indicators for the alarm and the battery in F1 station. When an alarm occurs, the alarm indicator of the station flashes corresponding to the monitor’s alarm indicators (Figure 2-3①). The battery indicator is green when the battery is fully charged, otherwise it is orange. If the battery is not charged for any reason, the battery indicator will flash orange (Figure 2-3②).

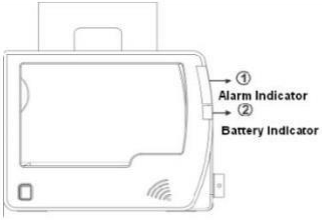


Figure 2-3 Indicators of F1 Station

■

F1R Station

F1R station is shown in the below figure:

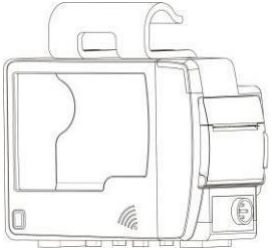
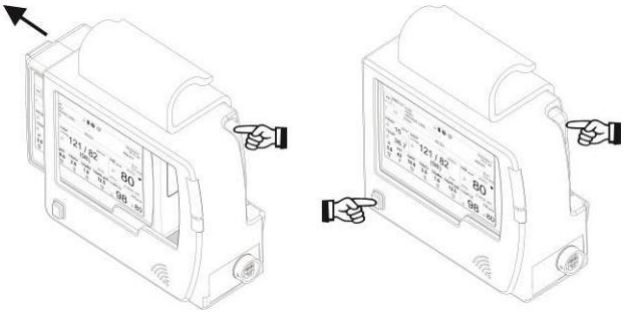


Figure 2-4 PM4010 Station (F1R)

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

Removing the PM4010 monitor from the station

Press and hold the eject button in front of the station (See figure 2-5) and simultaneously pull out the monitor. When the monitor moves in its position, release the eject button and remove the monitor.



2-5 b **2-5 a**

Figure 2-5 Removing the PM4010 from the station

Removing the PM4010 monitor from the station

If the PM4010 monitor is placed in the station and the power cable is plugged in, you will be able to:

1. Charge auxiliary battery of the station (in case of using F1, F1R stations) and the PM4010 built-in battery
2. Hang the monitor from the bed rail during the patient transportation
3. Mount the monitor on the roll stand and trolley

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

 The patient monitor shall only be connected to CS110 series Central system.

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

PM4010 monitor and Modular system

One of advantages of the PM4010 monitor is that this monitor can be placed in Modular system during patient transportation from the operation room to ICU and the operator can observe the patient data in larger size on the Modular screen. When the PM4010 monitor is inserted into the Modular system, different pages, menus and settings of the Modular system will be available. For more information, please refer to the user manual of the Modular system.

Figure 2-6 PM4010 monitor in Modular system

Chapter 3, System Configuration

Contents

Patient monitor contains a flexible configuration. The configuration setting is done through HOME MENU (Figure 3-1). You can access this menu by pressing the MENU key on the front panel or touching middle part of the header area on the screen.

Figure 3-1- HOME/MENU

SETUP

By pressing SETUP, you can access the following menu:

Figure 3-2 HOME/SETUP MENU

The below settings can be performed in this menu:

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

Figure 3-3 DATE

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

Figure 3-4 TIME

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

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

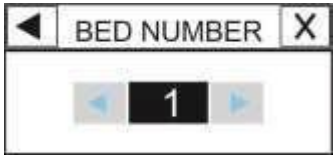


Figure 3-5 BED NUMBER

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

Figure 3-6 LANGUAGE

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

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

- **LOAD DEFAULT:** Select this item to access SETUP/ DEFAULT MENU (figure 3-7) and to load the manufacturer default settings for the desired parameter. (Refer to Appendix I for default settings). Because all your previous
- settings will be missed by selecting this item, the system asks for your confirmation before changing settings (figure 3-8).

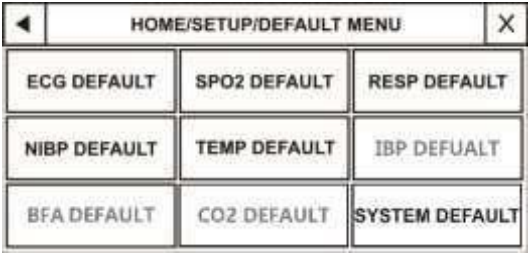


Figure 3-7-SETUP/DEFAULT MENU

Figure 3-8 ALERT message

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

- **CLEAR MEMORY:** You can clear the stored parameters in the system such as TREND and NIBP LIST data. Press this item to call up the following menu (figure 3-9).

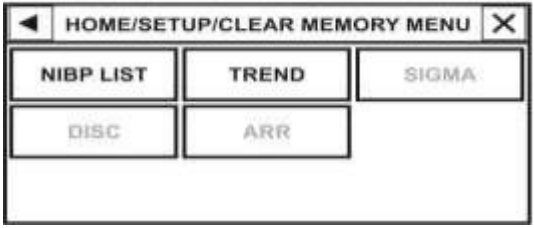


Figure 3-9 SETUP/CLEAR MEMORY MENU

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

ARE YOU SURE TO CLEAR NIBP LIST?

YES **NO**

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

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

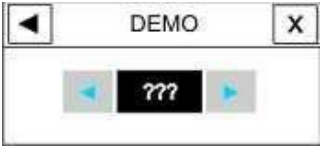


Figure 3-10 DEMO

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

PATIENT

By pressing PATIENT in the PM4010 monitor, you can access the below menu:

Figure 3-11- HOME/PATIENT MENU

Select ADMIT in the Patient menu to enter HOME /PATIENT/ ADMITTING MENU. You can enter patient demographic information in this menu (figure 3-12).

PATIENT

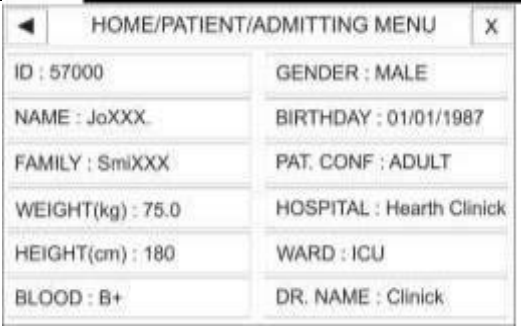


Figure 3-12 HOME/PATIENT/ADMITTING MENU

ID Patient code in hospital (Up to 15 characters)

NAME Up to 15 characters

FAMILY Up to 15 characters Optional

WEIGHT from 0.5 to 300 Kg Optional

HEIGHT from 20 to 250 cm

BLOOD TYPE Available options are A+, A-, B+, B-,

GENDER Available options are Female and Male

PATIENT BIRTHDAY Date of the birth

PATIENT

PAT. CONF Available options are Neonate, Pediatric and Adult

HOSPITAL Up to 15 characters

WARD Up to 15 characters

Dr.NAME Up to 15 characters

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

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

Figure 3-13 ALERT message

SIGMA

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

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

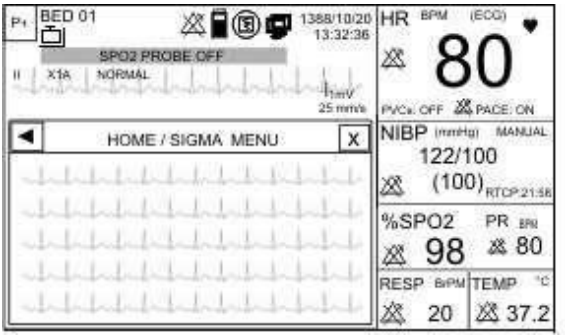


Figure 3-14 HOME/SIGMA MENU

PAGE SETUP

In the PM4010 monitor, different pages can be configured through PAGE SETUP menu.

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

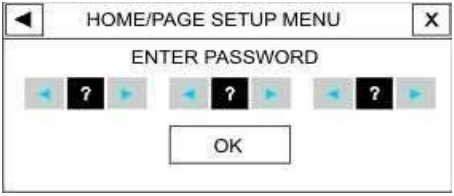


Figure 3-15 HOME/PAGE SETUP MENU

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

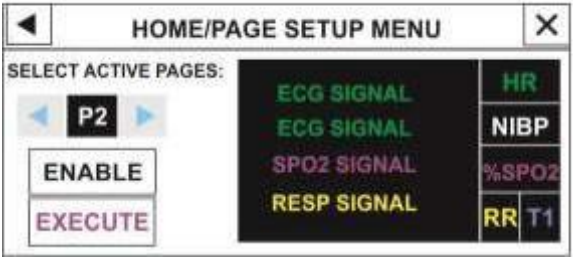


Figure 3-16 HOME/PAGE SETUP MENU

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

Figure 3-17 ALERT message

ALARM

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

Figure 3-18 HOME/ALARM MENU

The following settings can be done in this menu.

- **ALARM VOLUME**

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

ALARM

- **All ALARM ON/OFF**

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

ARE YOU SURE TO ACTIVATE ALL ALARMS?

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

TREND

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

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

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

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

Figure 3-21 HOME/TREND GRAPH

Figure 3-19 HOME/TREND TABLE

In figure 3-19 X-axis in the trend graph indicates the time and Y-axis indicates numeric parameter.

■ **Selecting parameter values:**

Press the first left item in the trend graph to select your desired parameter. Available options are: HR, SPO2, PR, IBP1, IBP3, IBP2, IBP4, RESP, T1, T2, SpHb, PI, SpCo, SpMet, PVI, SpOc, EtCo2, AWRR and FiCo2

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

■ Changing the graph scale:

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

PARAM	SCL1		SCL2		SCL3		SCL4		SCL5	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
HR	0	60	0	120	0	240	-	-	-	-
PVCs	0	20	0	50	0	100	-	-	-	-
ST	-0.2	0.2	-0.5	0.5	-1	+1	-2	2	-	-
AFIB	0	1	-	-	-	-	-	-	-	-
SPO2	80	100	60	100	0	100	-	-	-	-
PR	0	60	0	120	0	240	-	-	-	-
RESP	0	60	0	120	0	240	-	-	-	-
TEMP1,2	30	42	24	48	0	48	-	-	-	-
IBP1,3 IBP2,4	-20	50	-20	100	-20	200	-50	300	50	250
SpHb	6	20	2	14	0	25	-	-	-	-
PI	0	20	0	10	0	5	-	-	-	-

TREND

SpCo	0	12	0	24	0	50	-	-	-	-
SpMet	0	6	0	20	-	-	-	-	-	-
PVI	0	30	0	100	-	-	-	-	-	-
SpOc	0	36	6	20	-	-	-	-	-	-
AWRR	0	60	0	120	0	240	--	---	--	---
EtCo2	0	50	0	100	--	---	--	---	--	---
FiCo2	0	50	0	100	--	---	--	---	--	---

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

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

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

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

Press ◄ or ► in the trend graph to view numeric values in a specific time. When you press these buttons, the cursor moves through the graph and points to a specific time.

This is only possible for 5, 10, 15, 30, 45 min, and 1, 2 hr intervals. The related numeric value to this time is displayed above the cursor.

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

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

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

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

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

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

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

FACTORY

By pressing FACTORY, you can access this menu:

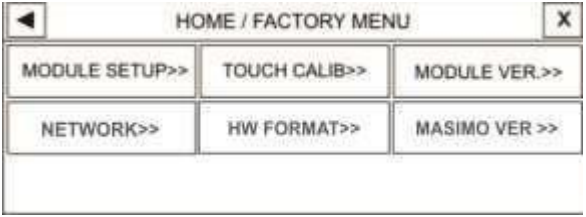


Figure 3-20-HOME/FACTORY MENU

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

■ **Module Setup**

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

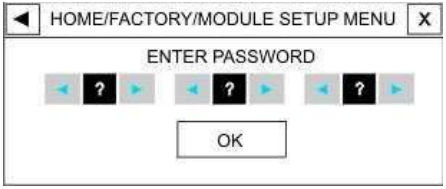


Figure 3-21 HOME/FACTORY/MODULE SETUP MENU

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

FACTORY

■ TOUCH CALIB

Press this item to access the below menu:

Figure 3-22 HOME/FACTORY/TOUCH CALIB MENU

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

Figure 3-23 HOME/FACTORY/TOUCH CALIB MENU

■ MODULE VER.

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

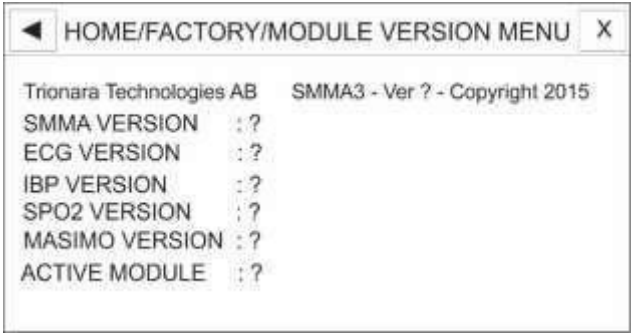


Figure 3-24- HOME/FACTORY/MODULE VER. MENU

■ NETWORK

Press this item to access the below menu:

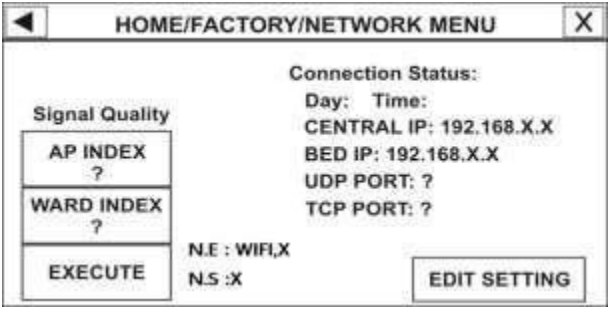


Figure 3-25 HOME/FACTORY/NETWORK MENU

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

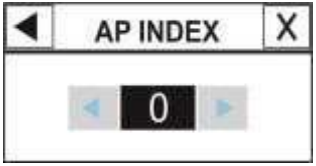


Figure 3-26 AP INDEX

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

Figure 3-27 HOME/FACTORY/NET SETTING MENU

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

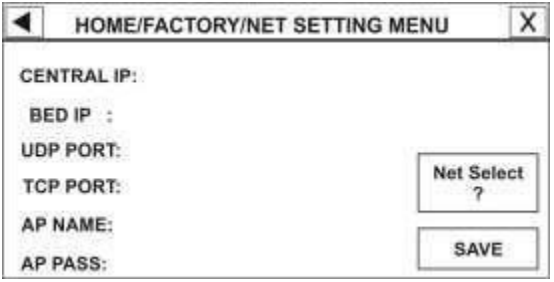


Figure 3-28 HOME/FACTORY/ NETWORK

■ HW FORMAT

Press HW FORMAT to access the below menu:

Figure 3-29 HOME/FACTORY/HW FORMAT MENU

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

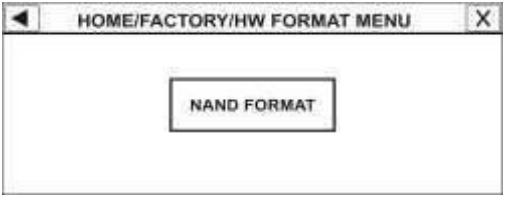


Figure 3-30 HOME/FACTORY/HW FORMAT MENU

Pressing NAND FORMAT will call up the below alert message. If you select Yes, NAND flash will be formatted.

FACTORY

During NAND flash formatting, the signals sweep slowly and after the formatting procedure ends, the monitor shall be restarted.

Figure 3-31 ALERT message

■ **MASIMO VER.**

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

ABOUT

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

RECORDER

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

Figure 3-32- HOME/RECORDER MENU

■ TRACE1

To select waveform of the recorder first channel in Manual recording. Available options are ECG, SPO2, IBP12,3,4, RESP/CO2 and OFF.

■ TRACE 2

To select waveform of the recorder second channel in Manual recording. Available options are ECG, SPO2, IBP12,3,4, RESP/CO2 and OFF.

■ REC SWEEP

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

■ MANUAL REC TIME

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

■ PERIODIC TRACE1

To select waveform of the recorder first channel in Automatic recording. Available options are ECG, SPO2, IBP12,3,4, RESP/CO2 and OFF.

■ PERIODIC TRACE 2

To select waveform of the recorder second channel in Automatic recording. Available options are ECG, SPO2, IBP12,3,4, RESP/CO2 and OFF.

■ INTERVAL

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

Chapter 4, Alarm

Contents

This chapter gives general information about alarm and its functions.

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

Alarm Categories

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

Physiological alarms

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

Technical alarms

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

Prompt messages

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

Alarm Modes

Alarm level and setup

The patient monitor offers three levels of alarm.

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

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

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

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

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

- **Display screen**

When an alarm is triggered by a parameter, the parameter value will blink on the screen and alarm message will be displayed in appropriate background with regard to itslevel.
Level I alarm message: Red background – Black text

Level II alarm message: Yellow background – Black text

Level III alarm message: Cyan background – Black text

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

- **Alarm indicator**

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

- **Alarm sound**

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

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

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

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

Low level alarm sounds "DO" every 30 seconds.

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

Alarm Modes

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

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

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

Alarm verification when the system is powered on

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

Alarm Causes

Alarms are triggered by a parameter or by technical problems of the patient monitor. The delay time from an alarm occurrence to alarm indication (parameter blinking, alarm message and light indicator) is maximum 50 ms.
The PM4010 monitor is designed in such a way that alarm occurrence can be recognized by the operator from a distance of 1 m.

Condition triggering alarm of a parameter:

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

SILENCE Key

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

ALARMS Key

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

Alarms and Silence keys

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

This key is not currently active.

Parameters Alarm

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

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

1- Alarm message is displayed in a background corresponding to its level on the screen.

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

3- Alarm indicator flashes.

When an alarm occurs

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

1- Check the patient's condition.

2- Identify related alarms to each module.

3- Identify the alarm cause.

4- Press Silence button, if necessary.

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

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

Chapter 5, ECG Monitoring

Contents

General Information

Through ECG monitoring you can see a continuous waveform of the patient's cardiac electric activity which enables physician to perform a precise assessment of patient current physiological condition. The process of depolarization and repolarization of the myocardium generates an electric potential that are sensed by ECG electrodes on the skin.

These electrodes are typically attached to the patient's right arm, left arm and left leg. The monitor processes and amplifies this signal and displays it as ECG waveform on the screen. Proper connection of the ECG cables and electrodes can ensure accurate assessment.

- In order to calculate HR Average, heart rate is sent to averaging section every second and based on the user setting the calculated average value is displayed. The time of changing or updating the heart rate in the PM4010 monitor with regard to HR average is as below:

  - To change HR from 80 to 120 bpm
    i. 5 sec for HR Avg of 4s
    ii. 6 sec for HR Avg of 8s
    iii. 11 sec for HR Avg of 16s
  - To change HR from 80 to 40 bpm
    i. 7 sec for HR Avg of 4s
    ii. 8 sec for HR Avg of 8s

iii. 13 sec for HR Avg of 16s

The above results are for lead II.

- When Tachycardia (HR>120 bpm) happens, it takes 6 seconds to activate alarm sound. (If low alarm limit is 60 bpm and high alarm limit is 100 bpm).
- It takes 10 seconds to activate alarm sound by the system when a cardiac arrest happens (from 80 bpm to 0 bpm)
- The ECG module is able to reject 1.2 mV TALL T-pulses.
- The current that is applied to the patient for lead-sensing is 90nA.
- Noise suppression circuit: A noise signal of 10 μA is applied reversely to the reference lead.

- The ECG patient cable consists of 2 parts: The cable that is connected to the monitor and the lead set that is connected to the patient.
- According to EC13:2002 standard the measured HR for 4 irregular rhythms is as follows:

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

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

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

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

Before monitoring check ECG cable to ensure that there is no sign of damage. Do not use scratched or torn cables or the cables with flexed lead -wires.

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

Do not touch patient, monitor and bed during defibrillation.

Make sure that ECG cable is not under tension during monitoring.

Select the patient mode carefully, because QRS detection limits and HR measurement algorithm are different in Neonatal and Adult modes.

1. Prepare the patient's skin before electrodes placement.
   - Proper skin preparation is necessary for good electrode placement, as the skin is a poor conductor of electricity.
   - Shave hair from the selected sites, if necessary.

■ Cleanse the site with a mild soap and water solution. (Never use pure alcohol, because it increases skin impedance).

■ Gently rub the skin to increase capillary blood flow in the tissues .

2. Place the electrodes on the patient body. If the electrodes are not self-supplied electrolyte, apply some conductive gel on the site (figures 5-1 and 5-2)
3. Attach the clip or snap to the electrodes before placement.

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

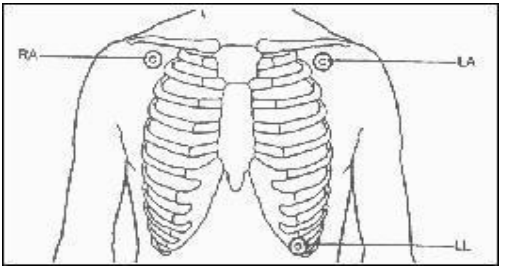


Figure 5-1 ECG 3-lead electrode placement

Electrode placement for 3-lead set (figure 5-1)
Right arm (RA): red electrode, be placed near the right shoulder, directly below the clavicle.
Left Arm (LA): yellow electrode, be placed near the left shoulder, directly below the clavicle.
Left Leg (LL): green electrode, be placed on the left hypogastrium.

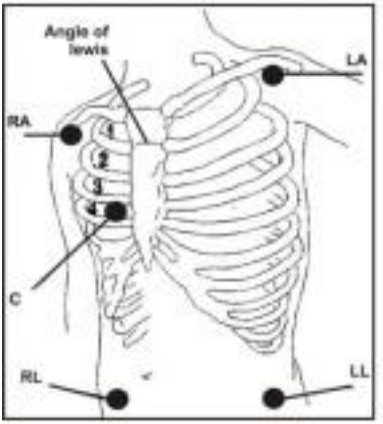


Figure 5-2 ECG 5-lead electrode placement

Electrode placement for 5-lead set (figure 5-2)

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

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

Chest (C): white electrode, be placed on the chest as shown in the figure 5-2.

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

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

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

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

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

●V3R-V6R on the right side of the chest in positions corresponding to those of V3-V6. ●VE over the xiphoid position.

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

●V7 on 5th intercostal space at the left posterior axillary line of back.

●V7R on 5th intercostal space at the right posterior axillary line of back.

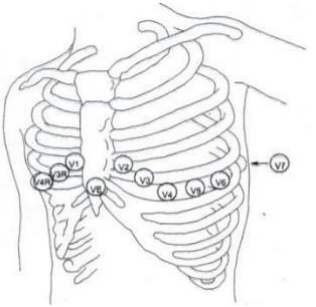


Figure 5-3 C-electrode placement in ECG 5-lead mode

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

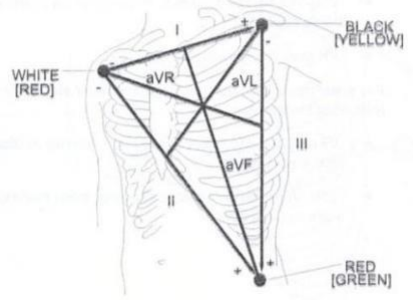


Figure 5-4 ECG leads

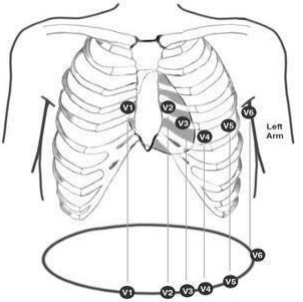


Figure 5-5 C-electrode placement in ECG 12-lead mode

ECG 12-lead set is not active in this version.

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

Right Arm (RA): red electrode, be placed near the right shoulder, directly below the clavicle.
Left Arm (LA): yellow electrode, be placed near the left shoulder, directly below the clavicle.
Right Leg (RL): black electrode, be placed on the right hypogastrium.
Left Leg (LL): green electrode, be placed on the left hypogastrium.
Chest (V1-V6): white electrode, be placed on the chest as illustrated in the figure 5-5.
For ECG 10 -WIRE mode, attach the C electrodes (V1-V6) to different positions on the chest:

- V1 on 4th intercostal space at the right sterna margin.
- V2 on 4th intercostal space at the left sterna margin.

- V3 midway between V2 and V4 electrodes.
- V4 on 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.

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

If ECG monitoring is carried out for a long time, regularly check whether there is skin irritation resulted from the ECG electrodes. If so, replace the electrodes or change their site.

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

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

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

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

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

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

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

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

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

Normal QRS waveform contains:

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

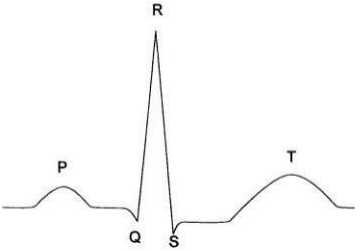


Figure 5-6 Standard ECG waveform

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

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

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

ECG PARAM MENU

ECG parameter window is as below:

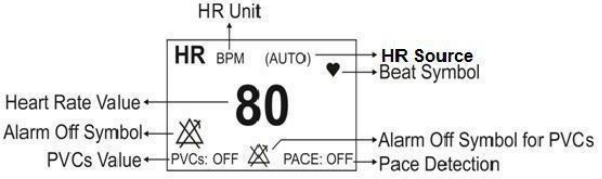


Figure 5-7 ECG Window

Touch ECG parameter area to access the below menu:

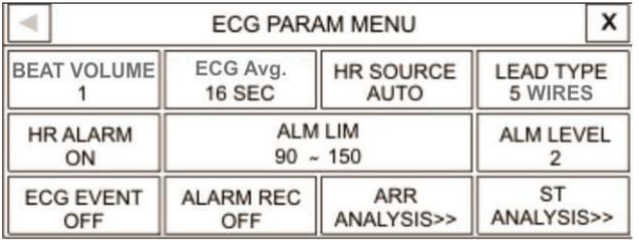


Figure 5-8 ECG PARAM MENU

- **BEAT VOLUME**

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

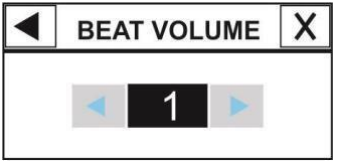


Figure 5-9 BEAT VOLUME

- **ECG AVERAGE**

Available options for ECG average are 4, 8 and 16 sec. Select this item to determine the maximum time of displaying HR changes. For example, if HR AVERAGE is set to 8 sec and HR value changes from 90 to 200, it will take maximum 8 seconds to display HR changes.

- **HR SOURCE**

The heart rate may be derived from “ECG”, “SPO2” or “IBP” signals. HR SOURCE can be set to “IBP” only in the pages which contain this parameter. In AUTO mode if ECG cable is connected to the patient, the monitor automatically will derive heart rate from ECG signal. If ECG signal is not present, depending on priority of SPO2 or IBP signal the heart rate will be derived from every signal that is being monitored.

Take the following points into the account if SPO2 is selected as HR SOURCE:

1- In the pages with ECG window, PR value is not displayed in SPO2 window.

2- In the pages with ECG window, PR alarm will be enabled based on HR alarm settings (Alarm Level and Alarm Limits) and in the pages without ECG window, PR alarm will be enabled based on SPO2 alarm settings.

If HR SOURCE is set to IBP1 or IBP2, ECG AVERAGE will become AUTO and cannot be changed.

- **LEAD TYPE**

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

- **HR ALARM**

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

" " symbol in the ECG parameter area.

- **ALM LIM**

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

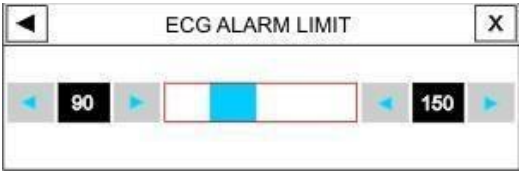


Figure 5-10 ECG ALARM LIMIT

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

Low limit: 30～(high limit - 5)

High limit: (low limit + 5)~250

- **ALARM LEVEL**

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

- **ST ANALYSIS**

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

- **ARR ANALYSIS**

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

- **ECG EVENT**

This item is inactive.

- **ALARM REC**

This item is inactive.

ECG TRACE MENU

Touch the ECG waveform area to access the below menu:

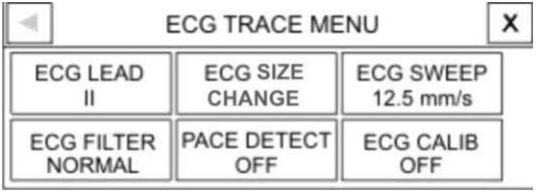


Figure 5-11 ECG TRACE MENU

ECG TRACE MENU in P1 is as follows:

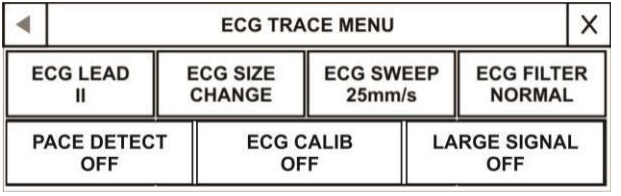


Figure 5-12 ECG TRACE MENU (P1)

- **ECG LEAD**

LEAD	Explanation
I	to count the heart rate and show RA-LA waveform
II	to count the heart rate and show RA-LL waveform
III	to count the heart rate and show LA-LL waveform
aVR	to count the he rt rate and show RA - $\frac{LA+LL}{2}$ Waveform
aVL	to count the heart rate and show LA- $\frac{RA+LL}{2}$ waveform
aVF	to count the heart rate and show LL - $\frac{RA+LA}{2}$ Waveform
V	to count the heart rate and show C - $\frac{RA+LA+LL}{3}$ waveform

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

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

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

ECG TRACE MENU

- **ECG SIZE**

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

- **ECG SWEEP**

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

■ **ECG FILTER**

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

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

- **PACE DETECT**

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

Detected pacemaker signals will be marked on the ECG waveform as 1 centimeter spike. If the patient does not have a pacemaker, it may be desirable to turn the detection function OFF so that artifacts in the waveform will not be mistaken for a pacemaker signal.


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


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

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

- **ECG CALIB**

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

- **LARGE SIGNAL**

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

ECG EXTRA MENU

If more than one ECG signal (2 or 4 signals) is displayed in the selected page, you can choose the lead of each signal separately by pressing that signal. Each lead can be selected once. For example if you press the third ECG signal in P3, the following menu will appear.

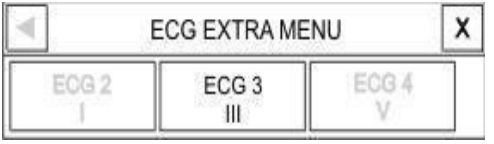


Figure 5-12 ECG EXTRA MENU

ECG Alarm Messages

Alarm sound is activated when:

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

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

background.

ECG alarm messages include:

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

ECG Alarm Messages

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

ECG Alarm Messages

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

ECG Alarm Messages

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

The last 5 messages in above table are displayed just for 5-lead and 12-lead modes (four messages for 5-lead and the last message for 12-lead).

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

ECG Cable Cleaning

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

- **Cleaning**

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

- **Disinfection**

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

Chapter 6, RESP Monitoring

Contents

General Information

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

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

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

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

Preparing patient for RESP monitoring:

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

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

3- Switch on the monitor

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

RESP parameter window is as below:

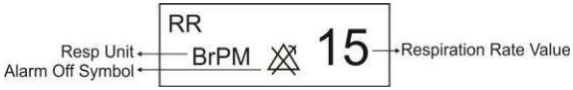


Figure 6-1 RESP Window

RESP PARAM MENU

Touch RESP parameter area to access the below menu:

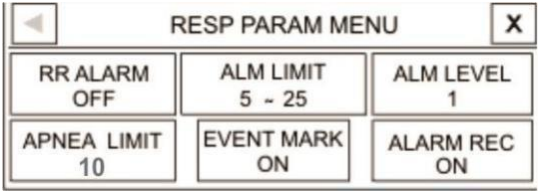


Figure 6-2 RESP PARAM MENU

■ **RR ALARM**

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

■ **ALM LIMIT**

Press this option to access the below window:

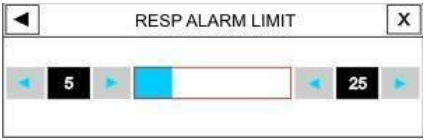


Figure 6-3 RESP ALARM LIMIT

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

Low limit: 5 ~ (High limit- 1)

High limit: (Low limit +1) ~ 150

■ **ALM LEVEL**

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

■ **APNEA LIMIT**

Press this item to access the below window:

Figure 6-4 RESP APNEA ALARM LIMIT

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

RESP TRACE MENU

Touch RESP waveform area to access the below menu:

Figure 6-5 RESP TRACE MENU

- **LEAD**

Available options are RA-LA and RA-LL.

- **GAIN**

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

- **SWEEP**

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

RESP Alarm Messages

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

Alarm	Situation	Visual Alarm	Audio Alarm
RR HIGH	Respiration rate violates adjusted high alarm limit	• RR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background color corresponding to its level.	Activated
RR LOW	Respiration rate violates adjusted low alarm limit	• RR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background color corresponding to its level.	Activated
APNEA	No respiration is detected for a certain time	• Alarm indicator flashes. • ”RESP APNEA” message is displayed in red background.	Activated

RESP Alarm Messages

RESP messages include:

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

Chapter 7, SPO2 & Masimo Rainbow Monitoring

Contents

General Information

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

Measurable physiological parameters by Masimo Rainbow module

SpO2
Pulse Rate

Perfusion Index (PI)

and optional parameters such as:

SpHb

SpOC

SpCo

SpMet

Pleth Variability Index (PVI)

% SPO2

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

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

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

Pulse Rate

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

Perfusion Index

Perfusion index (PI) indicates arterial pulse signal strength as a ratio of pulsatile blood flow to the nonpulsatile blood. Perfusion Index enables you to choose the best position for sensor placement.

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

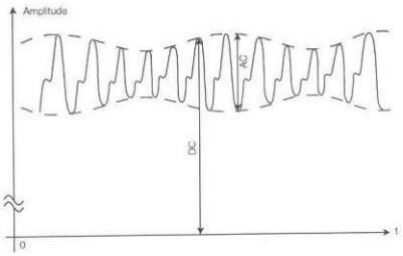


Figure 7-1 PI definition

PI greater than 1% is preferable

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

SpHb

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

SpOC

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

SpCO

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

SpMet

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

Pleth Variability Index

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

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

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

PVI can help clinicians predict fluid responsiveness in patients.

■ The %SPO2, PR, PI, PVI, SPOC, %SpMet, %SpCo and SpHb values can be displayed on the main screen. The Pleth waveform is displayed as normalized waveform and its amplitude does not comply with real blood volume variations.

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

Principle of operation:

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

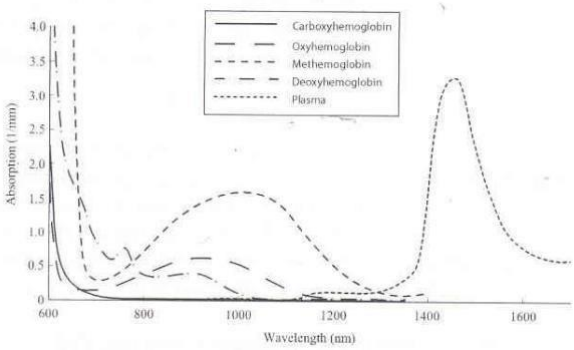
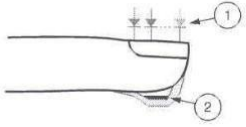


Figure 7-2 Absorption Spectra

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

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

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



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

Figure 7-3 Light Emitting Diodes and Detector

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

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

Signal Extraction Technology (SET)

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

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

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

 For more information about Masimo Rainbow module, please refer to APPENDIX III. Visit the below website for Masimo patent information: www.masimo.com/patents.htm

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


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


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


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


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.

Regarding the selected module, use accessories specified for each module in chapter 18.

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

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

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 them to fall on the patient.

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

ESU wire and SPO2 cable must not be tangled up.

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

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

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".

Do not repair or modify the pulse co-oximeter accessories. Injury to user or equipment damage could occur. Contact after- sales service for servicing , if necessary.

Changes or modifications will void guaranty of the pulse co-oximeter accessories.

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

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.

The pulse co-oximeter is not an apnea monitor.

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

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

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps and direct sunlight can interfere with the performance of SPO2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied and cover the sensor site with opaque material. Failure to take this action in high ambient light conditions may result in inaccurate measurements.

 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.

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

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

 SPO2 module updates parameters values every 1 second.

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

Measurement range of SPO2 and PR parameters is as follows:

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

Measurement range of MASIMO Rainbow set is as follows:

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

The materials used in SPO2 sensors are innoxious.

SPO2 Measurement

1. Turn on the monitor.
2. Attach the sensor to the appropriate site of the patient finger (Refer to figure 7-4 for proper method).
3. Connect the sensor cable to the SPO2 socket on the left side of the device.

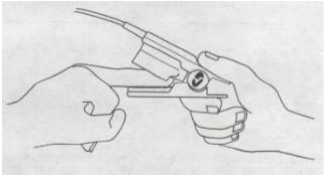


Figure 7-4 SPO2 sensor placement

Make sure the nail covers the light window.

The sensor wire should be placed above the hand.

SPO2 value always is displayed in a fixed position in SPO2 window and Pulse Rate is displayed beside it, but if "HR SOURCE" is set to "SPO2", PR value will be eliminated from SPO2 window and displayed instead of HR value in the ECG WINDOW.

Measurement Limitations

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

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

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

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

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

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

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

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

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

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

 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.

 Prolonged and continuous SPO2 monitoring may cause unexpected change of dermal condition such as abnormal sensitivity, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion. Check per 2-3 hours the sensor placement and move it when the skin deteriorates.

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.

Low pulse signal can occur when:

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

SPO2 PARAM MENU

SPO2 parameter window is as below:

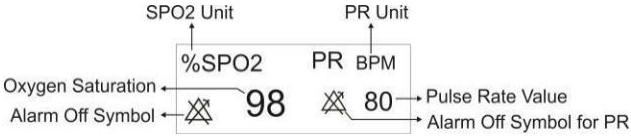


Figure 7-5 SPO2 Window

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

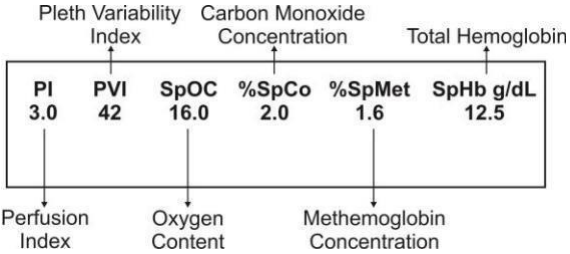


Figure 7-6 Rainbow Window

SPO2 PARAM MENU

Touch SPO2 parameter area to access the below menu:

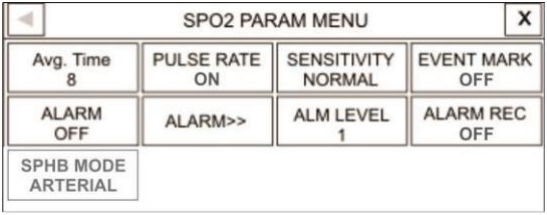


Figure 7-7 SPO2 PARAM MENU

In P7 and P8 you can set Beat Volume in SPO2 PARAM MENU.

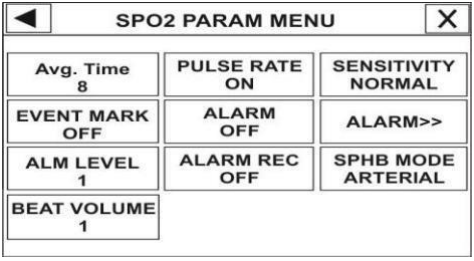


Figure 7-8 SPO2 PARAM MENU (P7 and P8)

SPO2 PARAM MENU

■ AVERAGE TIME

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

■ SENSITIVITY

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

- **NORMAL** :

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

- **MAX SENSE** :

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

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

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

- **APOD** :

This mode is not advisable for patients with low perfusion because the system has the least sensitivity to signal changes in this mode. It is used in situations having risk of probe detachment (e.g. children or uneasy patients).

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

SPO2 PARAM MENU

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

■ **ALARM ON/OFF**

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

■ **ALARM**

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

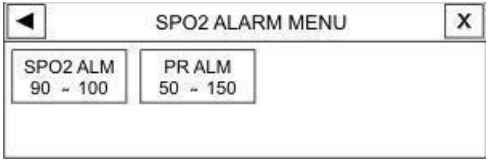


Figure 7-9 SPO2 ALARM MENU

SPO2 PARAM MENU

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

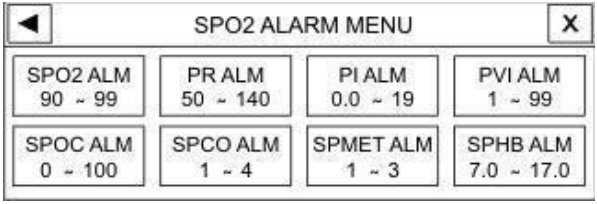


Figure 7-10 SPO2 ALARM MENU

(Rainbow parameters)

By selecting each parameter in SPO2 ALARM MENU, you can access Alarm Limit window of that parameter as shown in the figure 7-11.

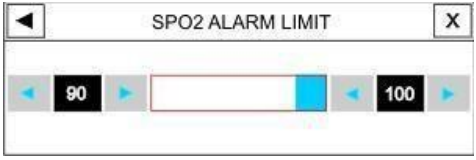


Figure 7-11 SPO2 ALM LIMIT

SPO2 PARAM MENU

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

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

Parameter		Alarm Limit
PI	HIGH Alarm	PI LOW Alarm +0.1 to 19.0
	LOW Alarm	0.0 to PI HIGH Alarm - 0.1
PVI	HIGH Alarm	PVI LOW Alarm +1 to 99
	LOW Alarm	1 to PVI HIGH Alarm -1
SpCO	HIGH Alarm	SpCO LOW Alarm +1 to 99.0
	LOW Alarm	1.0 to SpCO HIGH Alarm -1
SpMet	HIGH Alarm	SpMet LOW Alarm +0.5 to 99.5
	LOW Alarm	0.5 to SpMet HIGH Alarm -0.5
SpHb	HIGH Alarm	SpHb LOW Alarm +0.1 to 24.5
	LOW Alarm	0.5 to SpHb HIGH Alarm -0.1
SpOC	HIGH Alarm	SpOC LOW Alarm +1 to 34.0
	LOW Alarm	1.0 to SpOC HIGH Alarm -1

■ **ALARM LEVEL**

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

SPO2 TRACE MENU

Touch the SPO2 waveform area to access the below menu:

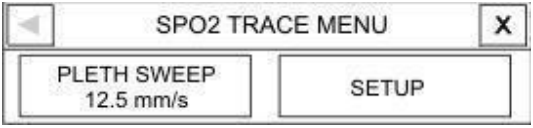


Figure 7-12 SPO2 TRACE MENU

■ **PLETH SWEEP**

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

SPO2 Alarm Messages

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

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

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

Rainbow Parameters Alarm Messages

Alarm occurs when Rainbow parameters violate adjusted alarm limits.

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

SPO2 Alarm Messages

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

SPO2 Alarm Messages

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

SPO2 Alarm Messages

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

SPO2 Alarm Messages

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

SPO2 Alarm Messages

SPO2 message include:

Message	Cause/Solution	Remarks
SPO2 NO PROBE	Cause: SPO2 probe is disconnected from the monitor. Solution: Make sure that the probe is correctly connected to the monitor.	Level 3 alarm. The message is displayed cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
SPO2 PROBE DEFECT	Cause: The SPO2 probe is damaged. Solution: Replace SPO2 probe by a correct one.	Level 2 alarm. The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
SPO2 HIGH AMBIENT LIGHT	Cause: This may be caused by entering environmental light into the probe. Solution: Make sure that SPO2 probe is properly connected to the patient.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and alarm is disabled for at least 120s.

SPO2 Alarm Messages

Message	Cause/Solution	Remarks
SPO2 DEFECT	Cause: SPO2 module failure. Solution: Turn the system off and on. If the message persists, contact the Customer services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
SPO2 SEARCH	Cause: SPO2 is not calculable due to different reasons such as long time motions. Solution: Attach the sensor to the other finger, provoke blood cycle, and calm the patient.	In this condition SPO2 value is not displayed.
SPO2 SIGNAL WEAK	Cause: The SPO2 signal amplitude is too weak or undetectable. Solution: Change the place of the probe.	In this condition SPO2 value is displayed.

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

SPO2 Probe Cleaning

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

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

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

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

Chapter 8, NIBP Monitoring

Contents

General Information

NIBP (Non-invasive Blood Pressure) processing by the monitor is based on the oscillometric measuring technique. Initially, cuff is inflated to a pressure greater than systolic pressure as blood flow in the extremity occludes effectively. Then the pressure in the cuff is gradually reduced until the patient pressure is detected and the cuff is deflated completely. Systolic and Diastolic pressures can be calculated using pressure pulses detected during pressure drop.

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

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

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

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

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

- In the manual mode, only one measurement is performed.
- In the AUTO mode, the measurement is cycled. You can set the interval time to 1, 2, 3, 5, 10, 15, 20, 30, 45, 60, 90 minutes and 2, 4, 8, 12, 16, 20, 24 hours.
- In STAT mode, measurement is performed up to ten times during 5 minutes and with 30s interval between measurements. In case of any error, the pressure measurement is suspended.

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

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

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

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

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

1. You must not perform NIBP measurement on patients under any condition which the skin is damaged or expected to be damaged.
2. Ensure that the correct setting is selected when performing measurements on children. Pressure measurement for children in adult mode may cause damage to extremity.

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

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

In this module the maximum cuff inflation pressure is 290 mmHg in adult mode, 240mmHg in pediatric mode and 145 mmHg in neonate mode. Furthermore independent maximum pressure control preservative is forecasted inside the system. Also maximum time of being under pressure in each measurement has been limited to 2 min in adult and pediatric modes and 90 seconds in neonate mode.

However operators should note that long-time and continuous measurements can lead to muscular and neurotic harms, dermal injuries or circulatory system failure. Thus examine the limb wearing cuff regularly.

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

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

Preparatory steps for pressure measurement:

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

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

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

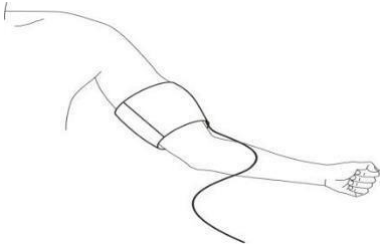


Figure 8-1 Applying Cuff

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

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

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

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

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

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

1. The patient is placed in a comfortable position.

2. The patient's feet are not on each other. 3.The feet should be on a flat floor.

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

5. The cuff is placed at the same level as heart.

 Keep patient calm and silent during measurement.

 Keep patient calm for 5 minutes before measurement is performed.

Operation Hints

1- To start a MANUAL measuring, press the START/STOP key on the front panel.

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

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

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

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

5- To stop AUTO measuring, Select the NIBP Window and set AUTO mode to MANUAL.

6- To start a STAT measuring, press the START/STOP key on the front panel.

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

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

Measurement Limitations

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

- **Patient movement**

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

- **Cardiac Arrhythmia**

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

- **Heart - Lung Machine**

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

- **Pressure Changes**

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

- **Severe Shock**

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

- **Abnormal Heart Rate**

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

NIBP PARAM MENU

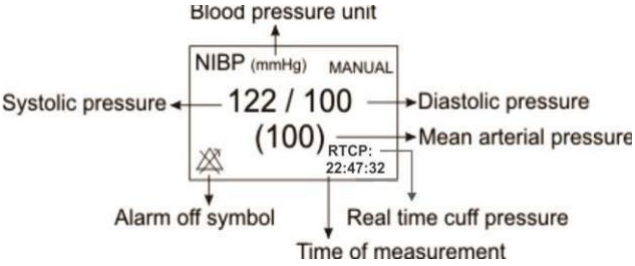


Figure 8-2 NIBP Window

NIBP PARAM MENU is as follows:

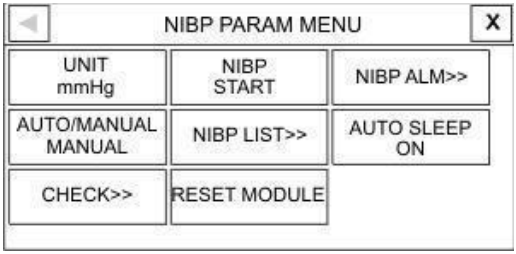


Figure 8-3 NIBP PARAM MENU

NIBP PARAM MENU

■ **UNIT**

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

■ **NIBP START/ STOP**

Select this item to start or stop NIBP measurement.

■ **NIBP ALM**

Press this item to access NIBP ALARM MENU.

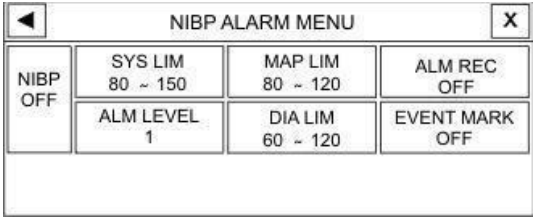


Figure 8-4 NIBP ALARM MENU

- **NIBP ALM ON/OFF**

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

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

- **SYS LIM**

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

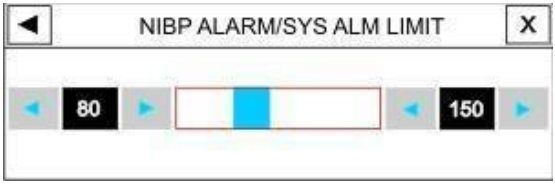


Figure 8-5 NIBP ALARM/SYS ALM LIMIT

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

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

- **MAP LIM**

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

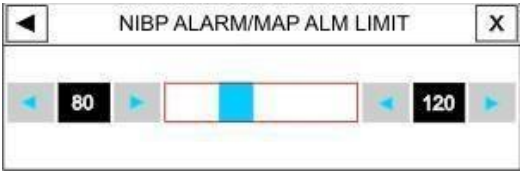


Figure 8-6 NIBP ALARM/MAP ALM LIMIT

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

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

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

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

- **ALARM LEVEL**

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

- **DIA LIM**

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

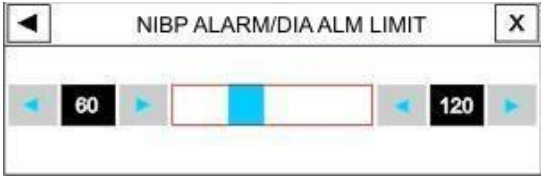


Figure 8-7 NIBP ALARM/DIA ALM LIMIT

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

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


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

■ **STAT \AUTO \MANUAL**

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

90 minutes and 2, 4, 8, 12, 16, 20 and 24 hours. In STAT mode, measurement is performed up to ten times within 5 minutes with 30s interval between measurements. If an error occurs, NIBP measurement is suspended.

■ **NIBP LIST**

Patient monitor can store the latest 100 NIBP measurement values.

Press "NIBP LIST" in the NIBP WINDOW to review the results and times of the latest NIBP measurements, as shown in the figure 8-8.

Figure 8-8 NIBP LIST MENU

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

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

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

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

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

Figure 8-9- ALERT message

■ **AUTO SLEEP**

This item is currently inactive.

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

■ **CHECK**

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

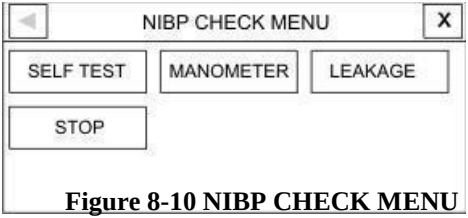


Figure 8-10 NIBP CHECK MENU

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

NIBP PARAM MENU

- **SELF TEST**

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

- **MANOMETER**

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

- **LEAKAGE**

Wrap the cuff around a cylinder of an appropriate size, (The circumference of the applied cuff does not exceed that of the cylinder more than 7%). Set the monitor to "LEAKAGE" mode. The monitor inflates the cuff up to 200 mmHg and keeps it constant for 15 sec .If air leakage

result is satisfactory, "NIBP LEAK OK" message is displayed; otherwise you will receive "PNEUMATIC LEAK" message.

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

- **STOP**

To stop the NIBP measurement.

■ RESET MODULE

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

NIBP Alarm Messages

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

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

alarm.	corresponding to its level.

NIBP Alarm Messages

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

NIBP Alarm Messages

NIBP messages include:

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

NIBP Alarm Messages

Message	Cause
NIBP RANGE EXCEED	Measuring pressure exceeded the upper limit (255mmHg) for adults or (135mmHg) for neonates.
NIBP EXCESSIVE MOTION	Arm movement, noisy signal or irregular pulse (e.g. arrhythmia)
NIBP OVER PRESSURE SENSED	Measuring pressure exceeded safe software limit, 290 mmHg for adults, 240 mmHg for pediatrics and 145mmHg for neonates.
NIBP SIGNAL SATURATED	Large motion artifact and noise that saturates the amplifier's amplitude handling capability.
NIBP PNEUMATIC LEAK	Leakage during leak test
NIBP TIME OUT	Measuring time exceeds 3 minutes (2 minutes for CAS module) in adult and pediatric modes or 90 seconds in neonatal mode.

NIBP Alarm Messages

Message	Cause
SYSTEM FAILURE	Error occurs in pump, A/D sampling, pressure transducer or software.
NIBP DEFECT	NIBP module failure
NIBP LOW BATTERY	The Charge of battery is low so NIBP measurement is not possible (while the monitor is working with battery).
NIBP NO MODULE	No NIBP module is installed.
NIBP MODULE ERROR	There is a failure during measurement.

NIBP Alarm Messages

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

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

Message	Cause
NIBP STOP PRESSED	Stop key has been pressed during measurement.
NIBP LEAKAGE O.K	Successful leakage test.

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

NIBP Cuff Cleaning

■ **Cleaning**

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

■ **Disinfection**

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

Frequently Asked Questions

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

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

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

- The NIBP module manufacturers use different criteria to calculate the systolic and diastolic pressure values; it is unreasonable to expect a single NIBP simulator to achieve universal agreement with all clinically approved oscillometric blood pressure

modules. In the area of blood pressure simulation, it is not the absolute agreement between the oscillometric blood pressure monitor and an NIBP simulator that matters, but how repeatable the results produced by the monitor under test are when using the simulator.

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

- Patient movement: (shivering, tremors, seizures, and flexing the arm in reaction to cuff pressure) may interfere with a blood pressure reading and consequently the measurement time will be increased or reinflation will occur (maximum 3 times). In this condition the measurement may be unreliable or may be impossible and error message “NIBP EXCESSIVE MOTION” appears.
- Low blood pressures: such as those found in patients in shock, produce low pressure amplitudes that can be difficult to detect and as a result the module may not be able to measure.

- Atrial fibrillation (AF) and Arrhythmias: Irregular pulses in terms of occurrence time or amplitude increase the length of measurement step and time. Sometimes reinflation or even measurement failure occurs. If the measurement is done, the pressure value may be inaccurate and unreliable.
- Cuff size: the cuff bladder length should be approximately 80% of the circumference of the upper arm and the cuff bladder width should be optimally 40% of the circumference of the upper arm. Incorrect cuff size may impact the accuracy of NIBP readings.

4- How often should the device be calibrated?

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

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

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

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

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

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

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

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

- Choosing measurement mode: Is the measurement mode correctly selected? If you have used the neonate mode for pediatric or adult, there's a chance that you will not be able to measure it.

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

Monitoring Chapter 9, TEMP

Contents

General Information

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

Specification:

Measuring and alarm range		0~50 ºC
Accuracy		±0.2ºC
Delay time	For Rectal/esophageal probe	50 sec
	For skin probe	20 sec

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

Inspection and recalibration

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

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

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

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

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

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

 Over straining will result in mechanical damage to the probes.

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

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

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

TEMP PARAM MENU

TEMP parameter window is as below:

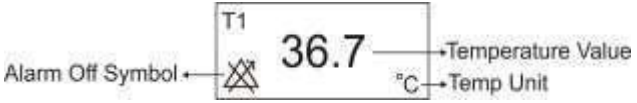


Figure 9-1 TEMP Window

Touch the TEMP parameter area to access the below menu:

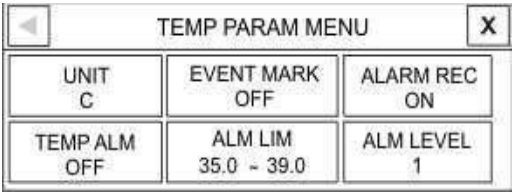


Figure 9-2 TEMP PARAM MENU

TEMP PARAM MENU

■ UNIT

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

■ TEMP ALM

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

■ ALM LIM

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

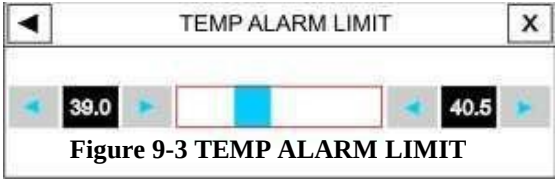


Figure 9-3 TEMP ALARM LIMIT

The TEMP alarm is activated when the temperature value violates adjusted ALARM HIGH and LOW limits. LOW limit: 0 ~ (HIGH limit – 0.5) ◦C

TEMP PARAM MENU

HIGH limit: (LOW limit + 0.5) ~ 50 °C

■ **ALARM LEVEL**

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

TEMP Sensor Cleaning and Maintenance

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

 Temperature sensors are sold non- sterile.

- **Cleaning**

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

 Do not immerse the probe connector in the water.

TEMP Sensor Cleaning and Maintenance

■ Disinfection

Probes may be disinfected by washing with 60% isopropanol, activated dialdehyde (Cidex) or sodium hypochlorite (bleach diluted 1:10 minimum in water.) After disinfecting the probes should be washed thoroughly with water. Brief immersion of the probe in detergent solutions is not harmful.

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

Never immerse the temperature probes in the boil water.

Sensor Maintenance

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

 For more information about alarms and messages of TEMP module, please refer to Appendix II.

Chapter 10, IBP Monitoring

Contents

General Information

Specification:

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

Alarm ranges

IBP	-50~300(mmHg)
ART	-50~300(mmHg)
LVP	-50~300(mmHg)
PAP	-50~120(mmHg)
RVP	-50~100(mmHg)
CVP	-50~100(mmHg)
LAP	-50~100(mmHg)
RAP	-50~100(mmHg)
ICP	-40~100(mmHg)

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

General Information

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

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

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

Disposable IBP transducer should not be reused or sterilized.

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

Use only the pressure transducers listed in the Accessories chapter.

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

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

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

Preparatory steps for IBP measurement (figure 10-1):

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

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

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

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

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

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

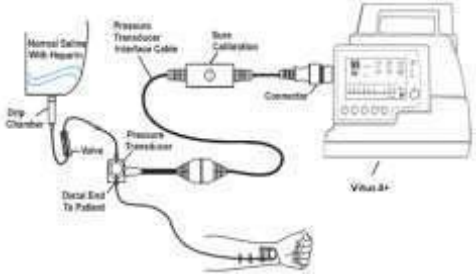


Figure 10-1 IBP Monitoring

IBP PARAM MENU

IBP parameter window is as below:

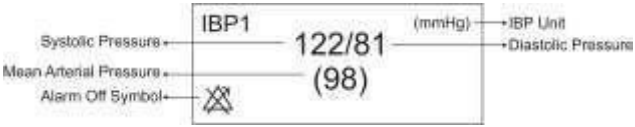


Figure 10-2 IBP Window

The IBP PARAM MENU is as follows:

Figure 10-3 IBP PARAM MENU

IBP PARAM MENU

■ **UNIT**

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

■ **LABEL**

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

Figure 10-4 LABEL

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

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

IBP PARAM MENU

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

■ IBP SELECT

By pressing this item, you can access the below window: By selecting each IBP channel, you can view signal and parameter of the selected channel.

Figure 10-5 IBP SELECT

■ ALARM

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

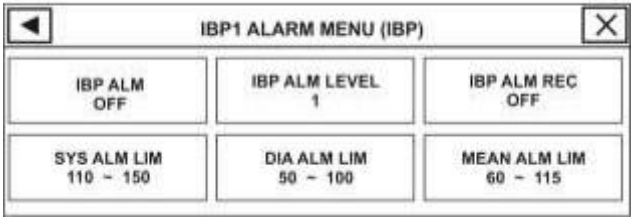


Figure 10-6 IBP1 ALARM MENU (IBP)

- **IBP ALM**

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

- **IBP ALM LEVEL**

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

- **SYS ALM LIM**

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

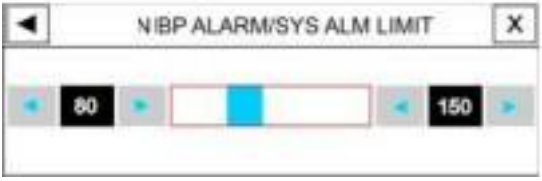


Figure 10-7 IBP ALARM/SYS ALM LIMIT

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

- **DIA ALM LIM**

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

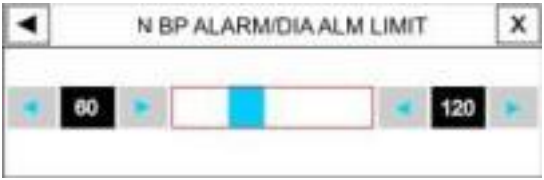


Figure 10-8 IBP ALARM/DIA ALM LIMIT

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

IBP PARAM MENU

- **MEAN ALM LIM**

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

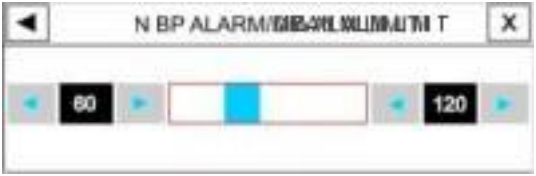


Figure 10-9 IBP ALARM/MEAN ALM LIMIT

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

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

The alarm enables when the parameters values violate the adjusted limits.

IBP PARAM MENU

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

■ **FILTER**

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

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

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

16Hz: When the signal is a bit noisy.

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

■ ZERO

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

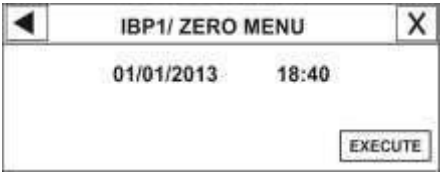


Figure 10-10 IBP/ZERO MENU

IBP PARAM MENU

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

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

2- Close the patient stopcock.

3-The transducer must be vented to atmospheric pressure.

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

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

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

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

The following messages may prompt up in ZERO WINDOW:

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

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

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

■ **CALIB**

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

IBP PARAM MENU

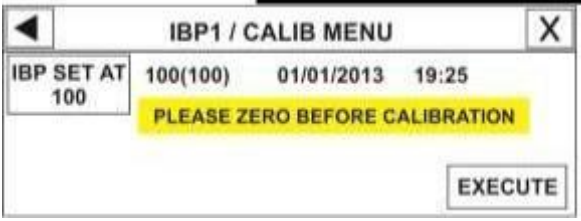


Figure 10-11 IBP/CALIB MENU

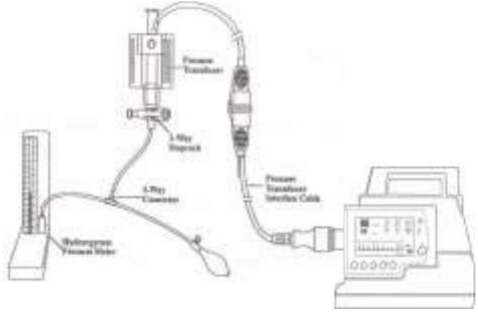


Figure 10-12 IBP CALIBRATION

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

IBP PARAM MENU

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

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

You must never perform calibration while patient is being monitored.

1. Attach the tubing system to the sphygmomanometer.
2. Ensure that connection that would lead to patient is off.
3. Connect the 3-way connector to the 3-way stopcock.
4. Open the port of the 3-way stopcock to the sphygmomanometer.
5. Raise the sphygmomanometer to set value that you adjusted in CALIB MENU.
6. Press EXECUTE in the CALIB MENU to start calibration.

The message "PLEASE WAIT" will be displayed during the procedure. "IBP CALIB OK" indicates that the

calibration procedure is completed successfully. The last calibration time will be saved and displayed in its corresponding place.

The following messages may prompt up in CALIB WINDOW:

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

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

■ **"IBP OVERANGE, FAILED CALIB"**

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

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

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

7. Remove the sphygmomanometer tubing and extra connector.

■ ART CATH. DISCONNECT ALM

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

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

In this condition, “IBP CATHETER DISCONNECT” alarm with level 1 will be enabled for maximum 10 seconds.

To trigger the alarm, set label to ART or IBP and enable “ART CATH. DISCONNECT”.

IBP TRACE MENU

Touch the IBP waveform area to access the below menu:

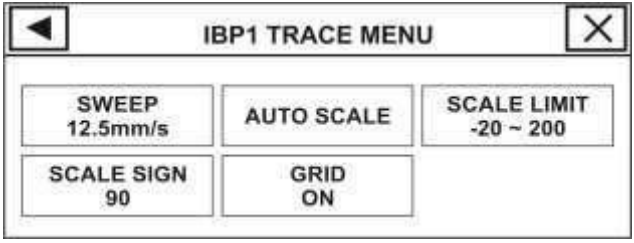


Figure 10-13 IBP TRACE MENU

■ **SWEEP**

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

■ **AUTO SCALE**

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

■ **SCALE LIMIT**

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

Figure 10-14 SCALE LIMIT

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

■ **SCALE SIGN**

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

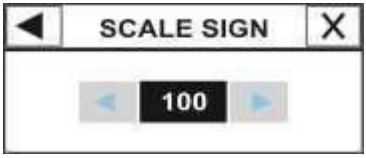


Figure 10-15 SCALE SIGN

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

■ **GRID**

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

IBP Transducer Cleaning

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

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

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

 Do not autoclave or ETO sterilize the transducer.

 For more information about alarms and messages of IBP module, please refer to Appendix II.

Chapter 11,CO2 (Mainstream) Monitoring

Contents

Multi-gas module is not active in this version.

General Information

The patient monitor provides mainstream method for Gas measurement.

The mainstream multi-gas probe 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 and emergency medicine settings.

The sensor head is available in various configurations for ICU and OR applications. Concentration of carbon dioxide (CO2) is determined together with derived parameters such as respiratory rate, waveform and inspired/expired concentrations of all gases.

It is available in various parameter configurations as follows:

CO2 only sensor:	CO2
ICU sensor:	CO2, O2
OR sensor:	CO2, N2O, O2, one anaesthesia agent (HAL, ISO, ENF, SEV, DES), MAC
OR+ sensor:	CO2, N2O, O2, one anaesthesia agent (HAL, ISO, ENF, SEV, DES) , automatic gas detection, MAC
AX sensor:	CO2, N2O, one anaesthesia agent (HAL, ISO, ENF, SEV, DES), MAC
AX+ sensor:	CO2, N2O, one anaesthesia agent

(HAL, ISO, ENF, SEV, DES), automatic gas detection, MAC

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 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.

To measure the concentrations and identify the gases, absorption of up to nine different wavelengths of infrared light is measured.

The measurement of CO2 in the breathing gas mixture is based on the fact that the different gas components absorb infrared light at specific wavelengths. Matrix calculations

are used to identify which anaesthetic agents are present in the gas mixture.

A microprocessor continuously calculates the CO2 concentrations from the infrared light absorption measurements.

The oxygen measurements are obtained through an oxygen port at the top of the airway adapter. Oxygen does not absorb infrared light to the same extent as other breathing gases and is therefore measured using an ultra rapid response time oxygen sensor.

(For more information about IRMA sensor, refer to APPENDIX V).

The measured parameters are EtCo2, EtO2, FiCo2, FiO2 (Fraction Inspiratory CO2/O2) and AWRR (Air Way Respiratory Rate) .

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, EtCO2 value for the respiration rate

below 150 bpm will be in the specified range (IRMA CO2).

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.

Oxygen sensor:

IRMA mainstream multi-gas probe consists of an O2 sensor cell as an option.

IRMA oxygen sensor is specially designed to provide an ultra fast response time, thus allowing a breath-by-breath analysis of the oxygen waveform at a proximal location (i.e. between the patient's endotracheal tube and the Y- piece of the breathing circuit). The vast majority of oxygensensors available on the market are normally too slow for abreath-to-breath gas analysis.

For anaesthesia machines and ventilators already equipped with oxygen measuring devices, the IRMA sensor is available with an O2 sensor dummy instead of the normal oxygen sensor. Figure 10-1 shows both IRMA sensor and oxygen sensor.

Figure11-1 IRMA sensor with oxygen sensor and Airway adaptor

The oxygen sensor dummy can be replaced at any time by a normal sensor to allow oxygen measurements with the IRMA sensor.

To replace the oxygen sensor, remove the depleted oxygen sensor by using a screwdriver or other suitable tool and turn in a counterclockwise direction. Remove the depleted

sensor and carefully screw the new oxygen sensor into position.

Oxygen sensor for replacement should be stored in a cold environment (+2°C~+8°C) and should be taken into operation before the expired date printed on the package.

Replace the oxygen sensor every six months, when the system warns to change the sensor with "REPLACE O2 SENSOR" message or when the oxygen readings are questionable.

Use only the recommended oxygen sensor for O2 monitoring .Other oxygen sensors may cause improper performance. (Refer to Accessories chapter for details)

Depleted oxygen sensors shall be disposed of in accordance with local regulations for biologically hazardous materials.

Do not leave depleted oxygen sensors mounted in the IRMA probe, even if the probe is not in use.

Do not try to open the oxygen sensor assembly. The oxygen sensor is a disposable product and contains a caustic electrolyte and lead.

Airway adapter:

Disposable airway adapter is designed for both adult/pediatric and infant applications. The adult/pediatric adapter is available with or without an oxygen port.

The airway adapter with an oxygen port is equipped with a hydrophobic bacteria filter to protect the oxygen sensor from contamination. For patient monitors, anaesthesia machines and ventilators already equipped with oxygen measuring device, the airway adapter is available without an oxygen port.

Figure 11-2 IRMA airway adapters: Adult/ Pediatric with and without an oxygen port and infant adapter

Disposable airway adapters shall not be reused. Used airway adapters shall be disposed of in accordance with local regulations for contaminated and biologically hazardous fluids.

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

Disposable parts shall not be reused to prevent contamination.

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

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

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

The infant airway adapter has specially designed connectors for minimizing the dead space and can be used even for very small patients. The infant adapter is available without an oxygen port only.

Preparatory steps for CO2 measurement (Figure 11-3)

1. Plug the IRMA connector into the bedside monitor side panel.

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

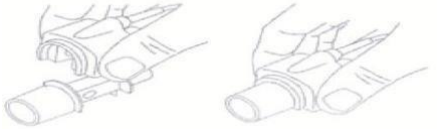


Figure 11-3 a. Preparatory Step2

3. A green indicator indicates that the IRMA sensor is ready for use.

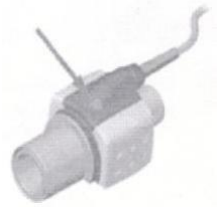


Figure 11-3 b. Preparatory Step 3

4. Connect IRMA airway adapter to the breathing circuit Y-piece.

Figure 11-3 c. Preparatory Step 4

5. Connect the other end of IRMA airway adapter to the patient's endotracheal tube.

Figure 11-3 d. Preparatory Step 5

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

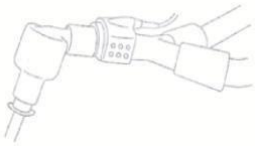


Figure 11-3 e. HME option

6. Unless the IRMA probe is protected by a HME, always position the IRMA sensor with the indicator pointing upwards.

Figure 11-3 f. Preparatory Step 6

IRMA probe should not be in contact with patient body.

Avoid any direct contact of IRMA probe with neonate body while connecting the probe to neonate breathing circuit.

If the probe has contact with a part of neonate body due to a special reason, use insulation material to isolate it from body.

Pre-use check:

Before connecting the IRMA airway adapter to the breathing circuit, verify the O2 calibration by checking that the O2 reading on the monitor is correct (21%).See Room air calibration section for instructions on how to perform room air calibration.

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.

There is no drift in measurement accuracy.


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.

Room air calibration of oxygen sensor

Room air calibration of oxygen sensor will be performed automatically at regular intervals whenever the IRMA sensor head is disconnected from the IRMA airway adapter.

If IRMA sensor is kept in operation for a long time period without being disconnected from the airway adapter, or if the operating temperature for oxygen sensor changes significantly, the message "ROOM AIR CALIB REQUIRED" will appear on the screen.

Use the following procedure to perform a room air calibration of the sensor:

1. Disconnect the IRMA sensor from the airway adapter.
2. Wait until the indicator starts blinking with red light.
3. Snap the IRMA sensor back on the airway adapter.
4. Check that the indicator turns green.
5. While not connected to the breathing circuit, check that the O2 reading on the monitor is 21%.

Gas span check:

Gas reading should be verified at regular intervals with a reference instrument. (It should be done just by trained and authorized personnel of manufacturer.)

General Information

 The device can only be operated by personnel who have passed professional training and are familiar with this manual.

 Do not use the device in the environment which contains flammable anesthetic gas.

 Before any interpretations are made of parameters readings and waveforms, ensure 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.

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.

Do not place the IRMA airway adapter between the ET tube and an elbow, as this may allow patient secretions to block the adapter windows.

Figure 11-4 airway adapter connection

To keep secretions from pooling on the windows, position the IRMA airway adapter with its windows in a vertical position and not in a horizontal position.

Figure 11-5 IRMA airway adapter position

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

Do not apply tension to the sensor cable.

General Information

 Do not operate the device at temperature outside operating range as below:

IRMA ICU: 10~35°C
IRMA CO2: 0~40°C

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

 For more information about IRMA module, please refer to APPENDIX V.

GAS PARAM MENU

CO2 parameter window is as below:

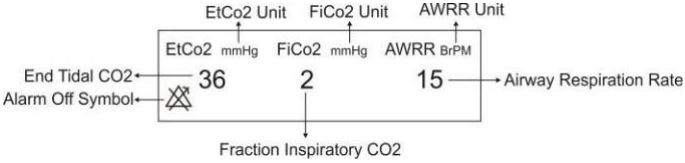


Figure 11-6 CO2 WINDOW

Touch CO2 parameter area to access the below menu:

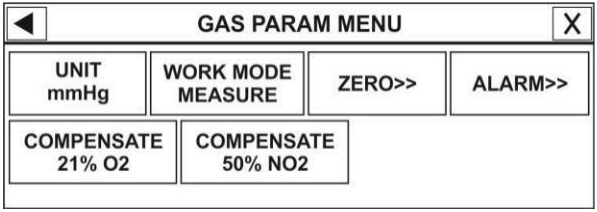


Figure 11-7 GAS PARAM MENU

After PHASEIN capnography probe is connected to the monitor, at first sensor type (ISA or IRMA) is detected by the system and then displayed in front of the CO2 signal.

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

- **UNIT**

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

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

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

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

- **WORK MODE**

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

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

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

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

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

- **ZERO**

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

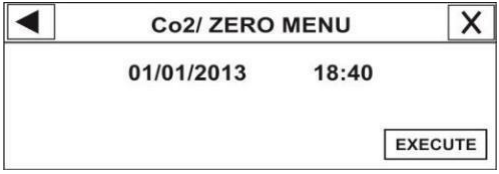


Figure 11-8 CO2/ZERO MENU

GAS PARAM MENU

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

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

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

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

GAS PARAM MENU

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

Incorrect zeroing will result in false gas readings.

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

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

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

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

- **ALARM**

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

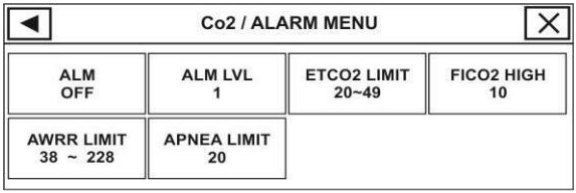


Figure 11-9 CO2 ALARM MENU

GAS PARAM MENU

- **ALM**

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

- **ALM LVL**

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

- **EtCO2 LIMIT**

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

GAS PARAM MENU

- **FiCO2 HIGH**

The alarm is activated when the FiCo2 exceeds adjusted ALARM HIGH limit.

(Range: 0.1~13.0%V, step 0.1%V), Default for upper limit is 1.3%V.

- **AWRR LIMIT**

The alarm is activated when the AWRR value exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit.(Range :1-120BrPM)

Default for upper limit:

Adult/Pediatric:	30BrPM
Neonate:	60BrPM

Default for lower limit:

Adult/ Pediatric:	5BrPM
Neonate:	15BrPM

GAS PARAM MENU

- **APNEA LIMIT**

Pick it to set the standard of judging an apnea case. It sets to 10 - 40 seconds and "OFF", increases/decreases by 5s. Select OFF to disable the alarm.

- **COMPENSATE**

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

N2O is measured and automatically compensated for in all IRMA sensors. Only when IRMA II (CO2) probe is connected to the monitor, N2O concentrates can be transmitted to the sensor. Available options for N2O COMPENSATE are 0-100%N2O.

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

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

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

N2O COMPENSATE and O2 COMPENSATE are currently inactive.

GAS TRACE MENU

Touch the CO2 waveform area to access the below menu:

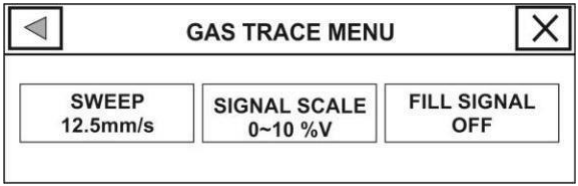


Figure 11-10 GAS TRACE MENU

- **SWEEP**

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

- **SIGNAL SCALE**

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

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

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

- **FILL SIGNAL**

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

CO2 Alarm Messages

Alarm occurs when CO2 parameters values violate the adjusted limits.

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

CO2 Alarm Messages

	violates adjusted high limit	• Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	
EtCo2 LOW	End Tidal Co2 violates adjusted low limit	• EtCo2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
FiCo2 HIGH	FiCo2 violates adjusted high limit	• FiCo2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
CO2 RESP APNEA	Non-respiration condition overruns	• Alarm indicator flashes. • Message "CO2 RESP APNEA"	Activated

	adjusted time	blinks in red background.	
EtO2 HIGH	End Tidal O2 violates adjusted high limit	●EtO2 value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
EtO2 LOW	End Tidal O2 violates adjusted low limit	●EtO2value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
FiO2 HIGH	FiO2 violates adjusted high limit	●FiO2 value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
FiO2 LOW	FiO2 violates	●FiO2 value blinks. ● Alarm indicator flashes.	Activated

	adjusted low limit	• Alarm message is displayed in a background corresponding to its level.	
FiO2 Too LOW	FiO2 falls below 18%.	•FiO2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated

CO2 Alarm Messages

The CO2 alarm messages are as follows:

Alarm	Cause	Solution	Explanation
CO2 SYSTEM FAULT # 1,2,3,4	Sensor failure	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 REPLACE ADAPTOR	IR signal low	Change adapter	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
CO2 NO ADAPTOR	There is no adaptor connected to the sensor.	Connect adapter	Level 2 alarm. 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 system. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. 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 system. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
CO2 INVALID PRESSURE	Ambient pressure outside operating range.	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
O2 PORT FAILURE	Adapter O2 port clogged or plugged.	Change the adapter.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
REPLACE O2 SENSOR	O2 sensor lifetime is finished.	Use a new O2 sensor.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
ROOM AIR O2 CALIB REQUIRED	If the sensor operate for a long time period without being disconnected from the adapter or the operating temperature for oxygen sensor changes significantly.	Perform room air calibration.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
CO2 ZERO CALIB REQUIRED	Ambient Co2 is more than 800 PPM (0.08% V). In this condition measurement accuracy is low.	Automatic zeroing shall be performed in an environment with CO2 level less than 0.08% V.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO SENSOR	The sensor is disconnected from the system	Connect the sensor. If the problem still exists, contact the Customer services of the manufacturer.	Level 3 alarm. The message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

CO2 Alarm 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.	

Indicator status on the IRMA sensor:

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

IRMA Sensor Cleaning

1. The IRMA sensor can be cleaned using a cloth moistened with ethanol or 70% isopropyl alcohol.
2. Do not reuse, sterilize, or clean airway adapter on another patient as they are designed for single use.

1- Only available for ISA AX+/OR+
2- Only available for ISA Multi-gas probes.

IRMA Sensor Cleaning

The IRMA oxygen sensor cell and IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.

Never sterilize or immerse the IRMA sensor in liquids.

Chapter 12, O2 (Sidestream) Monitoring

Contents

Multi-gas module is not active in this version.

General Information

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

The Vital signs monitor uses sidestream method for gases measurement.

General Information

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

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

ISA CO2: CO2

ISA AX +: CO2, N2O, two anesthetic agent (DES, SEV, ENF, ISO and HAL), MAC and Automatic agent identification

ISA OR +: CO2, O2, N2O, two anesthetic agent (DES, SEV, ENF, ISO and HAL), MAC and Automatic agent identification

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 for all applications of ISA analyzer is 50 ml/min.

Measurable parameters by ISA sensor are:

EtCO2 (End tidal of CO2 gas), FiCO2((Fraction inspiratory of Co2 gas) and AWRR (Air Way Respiratory Rate).

Fi and Et values are displayed after a breath and average of RESP value is updated regularly. If the respiration rate (RR) violates the specified threshold (RR_{th}), Et value will fall below nominal value (Et_{nom}) according to below formula:

ISA CO2

CO2: $Et = Et_{nom} \times (125/RR)$ for $RR_{th} > 125$

The monitor displays gas waveform in less than 10 seconds and it takes 1 minute that the measurement accuracy and operating condition of the system comply with Technical Specification of this manual.

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

ISA probe should be connected only to approved devices of PHASEIN Company.

Disposable parts shall not be reused to prevent contamination.

Sampling Line

ISA sidestream analyzer continuously removes sampled gas from respiratory circuit (Nasal cannula, respiration mask or Y-piece connected to breathing tube). Sampled gas enters the analyzer through the sampling line; it is usually warm and humid and cools down in contact with the walls of a sampling line and condenses in form of water droplets. These droplets could occlude the sampling line and interfere with gas measurements.

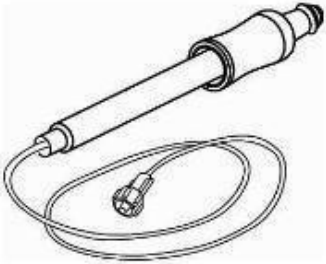


Figure 12-1 Sampling Line

Nomoline sampling line protects ISA sidestream analyzer from these problems. Unlike traditional methods that remove water vapor and collect it in a container, Nomoline removes water and water vapor by a water separation section in a unique method. This section made of a special polymer and bacterial filter that removes water vapor and condenses it and passes through a membrane surface while has no effect on CO2 and anesthetic agents. Nomoline sampling line has a lock connector through which can be connected to Nasal cannula.

ISA sensor goes to Standby mode when sampling line is not connected to it, as soon as the sampling line is connected to ISA sensor; it turns on and starts measurement.

Nomoline has rapid response time that it makes CO2, N2O, and anesthetic agent measurement possible even at high respiratory rates. ISA analyzer is applicable for adults, pediatrics and neonates.


ISA analyzer cannot be used with water trap. Thus Nomoline adapter (CAT # 108220) has been designed to be used for several patients.

Warnings related to sampling line


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


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


Disposable sampling lines shall not be reused .Used sampling lines shall be disposed of in accordance with local regulations for biologically hazardous materials.

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

Do not place sampling line in a way that it is tangled around the patient neck and cause suffocation.

Do not use the adult/pediatric sampling line with infants as the adapter adds dead space to the patient circuit.

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

Do not use ISA probe with artificial breathing devices or Nebulizer as this may cause bacterial filter occlusion.

Never use a syringe to extract settled water in Nomoline.

Preparatory steps for CO2 monitoring

1. Plug the ISA sensor into corresponding connector on the side panel of patient monitor.
2. Snap the sampling line head on the ISA sensor. It will click into place when properly seated.

Figure 12-2 Second Preparatory Step

3. Power on the monitor.

4. A green indicator indicates that the ISA sensor is ready for use.

5. Connect the ISA sampling line to the patient's endotracheal tube.

Figure 12-3 Fifth Preparatory Step

Pre-use check

Before connecting the sampling line to the breathing circuit, perform the following steps to ensure accuracy of patient circuit connections.

1. Snap the sampling line head on the ISA sensor.

2. A green indicator on ISA sensor indicates that it is ready for use.

3. Breathe into the sampling line to check that displayed CO2 value and waveform on the monitor are correct.

4. Occlude the sampling line by your finger and wait for 10 sec.

5. Check if occlusion message is displayed on the monitor and ISA sensor indicator flashes in red.

6. Verify that sampling line is connected to patient's breathing tubes securely.

 There is no drift in measurement accuracy.

 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.


The device can only be operated by personnel who have passed professional training and are familiar with this manual.


Do not 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.

Do not use ISA probe during magnetic resonance imaging (MRI) scanning. Therefore transfer it outside the MIR room.

Using electro surgery devices (High frequency equipments) adjacent to ISA probe may cause measurement interference.

Do not apply tension to the ISA sensor cable.


Measurements can be affected by mobile and RF communications equipment. It should be assured that the ISA sensor is used in an environment without electromagnetic radiations.


Do not operate the ISA sensor at temperature outside operating range as a below:

ISA CO2: 0~50°C
ISA OR+/ AX+: 5~50°C


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.


Refer to APPENDIX VI for more information about ISA module.

Positioning the monitor lower than the patient may facilitate condensed water and secretions move towards the system thereby resulting in blockage of filters. Keep the system preferably above the patient level. This prevents secretions and water dribbling down the tube towards the monitor end and extends the lifetime of the filters.

Zeroing procedure

ISA gas analyzer should have a reference zero level for CO2, N2O and anesthetic agent measurement that this calibration process is called zeroing.

ISA probe automatically perform zeroing procedure by switching the sampling line from respiratory tubes. Automatic zeroing procedure is performed one to three times every 24 hours. It takes up to 3 sec to perform zeroing for ISA (CO2) probe and up to 10 sec for ISA

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

If ISA probe is used accompanied by oxygen sensor, in automatic zeroing room air will be used for O2 sensor calibration.

Special care should be taken to avoid breathing into the adapter during the zero reference calibration procedure. The presence of ambient air (21% O2 and 0%CO2) in the ISA probe is of crucial importance for a successful zero reference calibration.

Use manufacturer especial fasteners to connect ISA sensor to the infusion stand.

GAS PARAM MENU

The CO2 parameter window is as below:

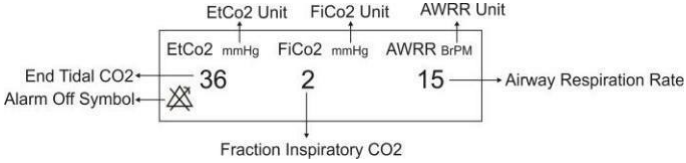


Figure 12-4 CO2 Window

Touch the CO2 parameter area to access the below menu:

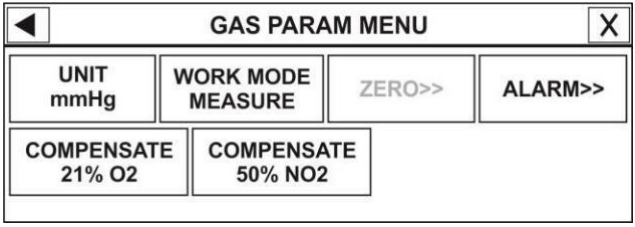


Figure 12-5 GAS PARAM MENU


After PHASEIN capnography probe is connected to the monitor, at first sensor type (ISA or IRMA) is detected by the system and then displayed in front of the CO2 signal.


The system displays 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. This can be also applied to GAS ALARM window.

- **UNIT**

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

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

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

- **WORK MODE**

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

If the monitor doesn't detect any CO2 signal for 30 minutes after connecting ISA sensor, the sensor is automatically disabled and goes to "standby" mode to decrease the power consumption and extend the life cycle of IR source and ISA sensor.

 When CO2 monitoring is not used, it is recommended to disconnect the sensor.

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

 ISA sensor remains in standby mode until the sampling line is connected to it. As soon as the sampling line is connected, the sensor switches on and starts measurement.

- **ALARM**

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

GAS PARAM MENU

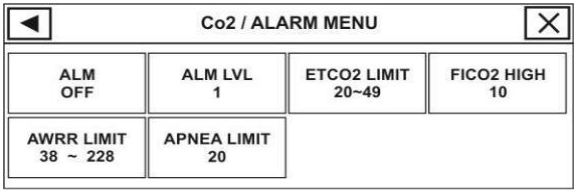


Figure 12-6 CO2 ALARM MENU

- **ALM**

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

- **ALM LVL**

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

GAS PARAM MENU

- **EtCO2 LIMIT**

The alarm is activated when the EtCo2 exceeds adjusted ALARM HIGH or LOW limit (Range: 0.4~13.0 %, step 0.1%)

Default for upper limit is 6.5%V and for lower limit is 2.6%V.

- **FiCO2 HIGH**

The alarm is activated when the FiCo2 exceeds adjusted ALARM HIGH limit (Range: 0.4~13 %V, step 0.1%V).

Default for upper limit is 1.3%V.

- **AWRR LIMIT**

The alarm is activated when the AWRR exceeds adjusted ALARM HIGH or LOW limit. (Range: 1-120BrPM)

Default for upper limit:

Adult/Pediatric:	30BrPM
Neonate:	60BrPM

Default for lower limit:

Adult/Pediatric:	5BrPM
Neonate:	15BrPM

- **APNEA LIMIT**

Pick it to set the standard of judging an apnea case. It sets to 10 - 40 seconds and "OFF" and increases/decreases by 5s.

- **COMPENSATE**

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

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

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

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

N2O is measured and automatically compensated for in ISA sensors (AX+/OR+). Therefore N2O concentration should be transmitted to ISA sensor (CO2). Available options are 0-100% N2O.

GAS TRACE MENU

Touch the GAS waveform area to access the below menu:

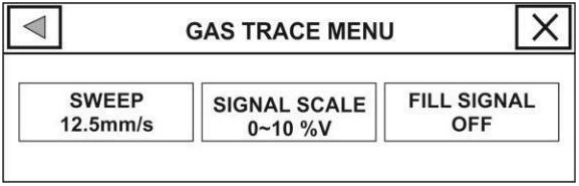


Figure 12-7 GAS TRACE MENU

- **SWEEP**

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

- **SIGNAL SCALE**

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

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

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

- **FILL SIGNAL**

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

CO2 Alarm Messages

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

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

CO2 Alarm Messages

HIGH	Co2 violates adjusted high limit	blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	
EtCo2 LOW	End Tidal Co2 violates adjusted low limit	●EtCo2 value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
FiCo2 HIGH	FiCo2 violates adjusted high limit	●FiCo2 value blinks. ●Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
CO2 RESP APNEA	Non-respiration condition	●Alarm indicator flashes. ●Message "CO2	Activated

	overruns adjusted time	RESP APNEA" blinks in red background.	
EtO2 HIGH	End Tidal O2 violates adjusted high limit	●EtO2 value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
EtO2 LOW	End Tidal O2 violates adjusted low limit	●EtO2value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
FiO2 HIGH	FiO2 violates adjusted	●FiO2 value blinks. ● Alarm indicator flashes. ● Alarm message is	Activated

high limit	displayed in a background corresponding to its level.

CO2 Alarm Messages

FiO2 LOW	FiO2 violates adjusted low limit	●FiO2 value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
FiO2 Too LOW	FiO2 falls below 18%.	●FiO2 value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated

CO2 Alarm Messages

The CO2 alarm messages are as follows:

Alarm	Cause	Solution	Explanation
CO2 SYSTEM FAULT # 1,2,3,4	Sensor failure	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.
CHECK SAMPLING LINE	IR signal low	Change sampling line	Level 3 alarm. The message is displayed in the cyan background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
SAMPLING LINE CLOGGED	Sampling line occlusion	Remove obstruction otherwise change the sampling line by a correct one.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the 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 the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.
O2 INVALID.	O2 outside specified accuracy range.	Zero the system. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
CO2 INVALID PRESSURE	Ambient pressure outside operating range.	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID TEMPERATURE	Internal temperature is outside operating range.	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.
REPLACE O2 SENSOR	O2 sensor lifetime is finished.	Replace O2 sensor with a new one.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores

			this fault.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
O2 SENSOR ERROR	The Sensor failure	Replace O2 sensor by a new one.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.
O2 SPAN CALIB REQUIRED	If the sensor operate for a long time period without being disconnected from the sampling line or the operating temperature for oxygen sensor changes significantly.	Perform room air calibration.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
CO2 ZERO CALIB REQUIRED	Ambient Co2 is more than 800 PPM (0.08% V). In this condition measurement accuracy is low.	Automatic zeroing shall be performed in an environment with CO2 level less than 0.08% V.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.
CO2 NO SENSOR	The sensor is disconnected from the system	Connect the sensor. If the problem still exists, contact the Customer services of the manufacturer.	Level 3 alarm. The message is displayed in the cyan background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.

CO2 Alarm Messages

Alarm	Cause	Solution	Explanation
CO2 SENSOR STANDBY MODE	Manual setting. No breath is detected for 30 min and ETCO2 is less than 4 mmHg for more than 30 min. The monitor does not detect the sampling line.	Enter GAS window and set WORK MODE on MEASURE.	

Indicator status on the ISA sensor:

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

ISA Sensor Cleaning

1. The ISA sensor should be cleaned regularly by using a cloth moistened with ethanol or 70% isopropyl alcohol.
2. Connect the sampling line to the corresponding connector on the ISA sensor when you clean the sensor to prevent dust and liquid entering.

1- Only available for ISA AX+/OR+
2- Only available for ISA Multi-gas probes.

ISA Sensor Cleaning

 The ISA sampling line is non-sterile device. Do not autoclave the sampling line as this may damage it.

 Never sterilize or immerse the ISA sensor in liquids.

Chapter 13, Recorder

Contents

General Information

The PM4010 monitor can record the signals and parameters through URUK thermal recorder embedded in F1R station.

Performance of the Recorder

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

Recording type

The monitor provides different types of recording:

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

Parametric Recording

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

Recording Type

Manual Recording

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

- **Continuous Recording**

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

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

Real time recording starts from last 5 seconds when you press “Rec/Stop” and it will automatically stop after 10, 20 or 30 seconds depending on your setting.

Automatic Recording

The monitor starts the recording for 10 seconds according to interval time set in the RECORDER menu.

Recording Type

Alarm Recording (this item is not active in this version)

If this item is set ON, the system automatically starts recording when an alarm occurs. Alarm recording is activated when the numeric parameters violate adjusted alarm limits or when an arrhythmia event occurs.

When an alarm occurs only numeric parameters will be recorded and parameter's value that triggered the alarm record is marked with an arrow.

During HR alarm recording, the monitor also records 20 seconds ECG waveform. You can set "ON" or "OFF"

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

Freeze Waveform Recording

The monitor prints out 20 seconds of the selected waveforms and numeric parameters in Freeze mode. So

you can freeze the abnormal waveforms on the screen and record them.

TREND Recording

The monitor can print out the trend graph and numeric parameters in the current TREND window. Select RECORD in TREND window to start recording.

NIBP LIST Recording

The monitor can print out NIBP LIST. Select RECORD in NIBP LIST window to start recording.

The following information are recorded on the paper:

- Recording Type:

  MANUAL RECORD
  PERIODIC RECORD
  ALARM RECORD (name of the parameter triggered the alarm), inactive
  FREEZE RECORD (Parameter)
  TREND RECORD

Recording Type

NIBP LIST RECORD

- Recording Date and Time
- Bed number
- Patient name, Patient ID, Gender, Height,

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

Recorder paper

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

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

 Do not use grid paper.

 Do not touch the recorder head while recording and immediately after recording because it is so hot and may lead to personal injury including burns.

Recorder Paper

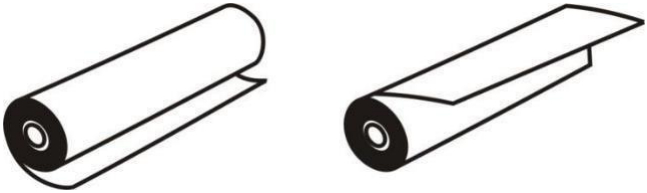
 Do not use paper with edges that are pasted or have turnups at the start of the roll. If they need to be used unavoidably, replace with new paper roll as soon as possible before entire roll is used up.

Loading the paper:

- Pull up ejector of the recorder door .
- Insert a new roll of paper into the paper cassette. Printing side of the paper should face the thermo sensitive printhead.
- Close the recorder door.

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

Recorder Paper



a. incorrect placement

b. correct placement

Figure 13-1 recorder paper placement

The paper detector may not operate properly if covered with foreign matter. Therefore, if you find foreign matter on the sensor, remove it and clean the sensor.

While the recorder is working, the record paper goes out steadily. By pulling the paper, the recorder will be damaged.

Recorder Paper


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.

Recorder Alarm Messages

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

Recorder Alarm Messages

Message	Cause/Solution	Remarks
Rec Opened Door	Cause: The recorder door is open Solution: Close the recorder door.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Rec Paper Out	Cause: Recorder paper has been finished. Solution: Insert a new paper roll.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

Message	Cause/Solution	Remarks
Printhead Hight Temp	Cause: The thermal head is too hot. Solution: Stop operation for a few minutes.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Printhead Hight Vol	Cause: Printhead voltage is high. Solution: Turn the system off and on. If the problem persists, contact the Customer services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

Recorder Alarm Messages

Message	Cause/Solution	Remarks
Printhead Low Vol	Cause: Printhead voltage is low. Solution: Disconnect the station from AC power. If the problem persists, contact the Customer services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Time out Error	Cause: The recorder cannot record. Solution: Disconnect the station from AC power. If the problem persists, contact the Customer services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

Recorder Cleaning

Accumulation of paper powder or foreign matter between the thermal head and platen roller will deteriorate the print quality. Clean the head elements and platen roller surface using alcohol and a cotton swab. Wait until the alcohol dries then close the recorder door.

 Do not clean the printer immediately after printing because thermal head and its periphery are hot during and after printing.

 Do not use sandpaper, cutter knifes, etc to clean the recorder .

Chapter 14, Patient Safety

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

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

Patient Safety

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

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

Follow the instructions below to ensure a completely safe electrical installation.

Patient Safety

The environment where the patient monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature and humidity. The patient monitor properly operates at ambient temperature between 0ºC to 40ºC. Ambient temperatures that exceed these limits could affect the accuracy of the monitor and cause damage to the modules and electric circuits.

Grounding the patient monitor

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

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

Chapter 15, Getting Started

Open the Package and Check

Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage.

■ Check for any mechanical damage.

■ Check for the existence of the power cable and accessories.

If there is any problem, contact the distributor immediately.

Insert the battery

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

Place the monitor in the station base

Put the monitor in the station base.

Connect the power cable to the system

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

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

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

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

Power on the monitor

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

Perform the following settings before monitoring:

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

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

 Recharge the battery after that the monitor operates on it for a while. To do so, simply plug the PM4010 station into AC power line.

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

Connect the sensors to patient

Connect all necessary accessories to the monitor and the patient.

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

Chapter 16, Continuous Patient Monitoring

The PM4010 monitor is intended to be used as a full-function monitoring system. By connecting some accessories to the monitor, it will be usable in different units of the hospital.

You can simply connect the monitor to peripheral devices or change its usability during the monitoring without any interruption in measurement and storage of vital signs parameters. The monitor can be used in an ambulance by mounting it on the roll stand as shown in figure 16-1 and 16-2.

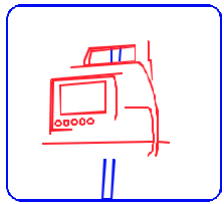


Figure 16-1 Installation on the roll stand

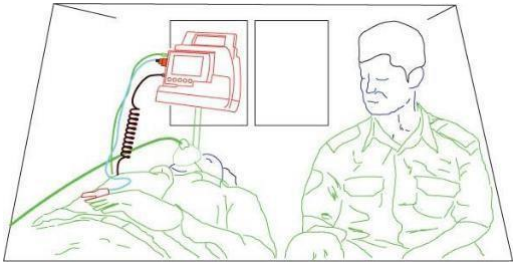


Figure 16-2 Monitoring in ambulance

During patient transport to different wards or operation room of hospital, the monitor can be hung from the bed rail by its base (figure 16-3).

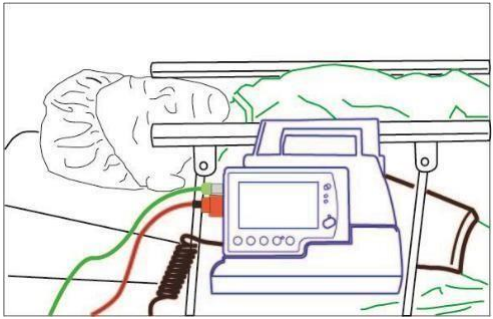


Figure 16-3 Installation on bed rail

PM4010 monitor can also be used as a detachable multi-module in Alborz monitor (Modular) when patient is transferred to different wards of hospital (figure 16-4).

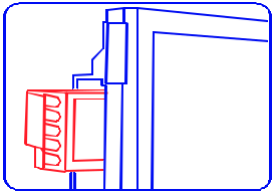


Figure 16-4 Detachable multi-module

The monitor can be placed in a special shoulder bag and easily carried by patient with regard to its portable and lightweight features (figure 16-5).

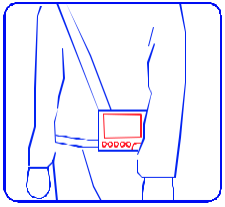


Figure 16-5 Placement of PM4010 in special bag

Chapter 17, Technical Specifications

Contents

CLASSIFICATION	
Protection against electroshock	Class I, Type CF for all modules (except CO2 module & NIBP module that are BF) (based on IEC 60601-1)
Mode of operation	Continuous operation equipment
Harmful Liquid Proof Degree	PM4010 monitor: IP32 Stations & Adaptor: IPX1
Method of disinfection	Refer to each module's chapters and chapter Care&Cleaning for detail.
Safety of anesthetic mixture	Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
General	
Display	COLOR TFT 480 × 272, 4.3”/5” Flexible display Configuration
Waveforms	ECG, SPO2, RESP/CO2, IBP1,IBP2 (Freezable)
Numeric Parameters	HR, SPO2 (%SPO2, PR, PI), Rainbow (SpMet, SpCO, SpHb, SpOC, PVI), NIBP (SYS, DIA, MAP), RR, TEMP, IBP1 (SYS,

Technical Specifications

	DIA, MAP), IBP2 (SYS, DIA, MAP), EtCo2, FiCo2, AWRR
Operation Method	Membrane, Touch screen

ECG	
Leads	Selectable: 3 ,5 or 10 Wires
	For 3 wire: I, II, III
	For 5 wire :I,II,III,V,aVR,aVF,aVL
	For 10 wire : I,II,III, aVR,aVF,aVL V1 ,V2, V3, V4, V5. V6
Dynamic Range	± 5 mV
Lead Off Current	< 90 nA
Gain	4, 2, 1, 1/2, 1/4, Auto
Calibration	1mV, 0.5 sec
Filters	"MONITOR" (0.5 - 24 Hz)
	"NORMAL" (0.5 - 40 Hz)
	"EXTENDED" (0.05-100 Hz(
CMRR	> 98 dB
Internal Noise	< 30 µV RTI

Technical Specifications

Input Impedance	>5MΩ	
QRS Detection	Duration	40 to 120 msec
		0.25 to 5 mV for Adult/Pediatric
	Amplitude	0.2 to 5 mV for Neonate
Heart Rate Range	15 - 300 BPM for adult/Pediatric	
Accuracy	15 - 350 BPM for neonate	
Tall T-Wave	±1% or 2 BPM	
	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
Standards	ANSI/AAMI EC-13, IEC 60601-2-27

NIBP		
Measurement method	Oscillometric	
Measurement mode	Manual/Automatic/Stat	
Measurement time	20-25 sec (excluding cuff pressurization time)	
Measurement Range	Adult	SYS 30 ~ 255 mmHg
		DIA 15 ~ 220 mmHg
		MAP 20 ~ 235 mmHg
	Neonate	SYS 30 ~ 135 mmHg
		DIA 15 ~ 110 mmHg
		MAP 20 ~ 125 mmHg
	Pediatric	SYS 30 ~ 240mmHg
		DIA 15 ~ 220 mmHg
		MAP 20 ~ 230 mmHg
Pressure Transducer accuracy	±3 mmHg full range	
Initial Inflation	Adult 150 mmHg, Pediatric 140mmHg, Neonate 85 mmHg	

Technical Specifications

Target	
Overall System Efficacy	ANSI/AAMI SP-10/2002
Memory	100 Records

SPO2 (Masimo Rainbow Set)

Method	2 Wave length pulse wave type	
Range	SpO2	0 –100%
	SpMet	0 – 99.9 %
	SpCO	0 –99%
	SpHb	0 – 25.0 g/dL
	SpOC	0 – 35.0 ml/dL
	PR	25 – 240 bpm
	PI	0 – 20.0 %
	PVI	0 –100%
Accuracy	Oxygen Saturation	
	No motion conditions	Adult/Pediatric: ±2% (SPO2 70 ~ 100%)
		Neonate: ±3% (SPO2 70 ~ 100%)

Technical Specifications

	Motion conditions	Adult/Pediatric/Neonate: ±3% (SPO2 70 ~ 100%)
	Low perfusion conditions	Adult/Pediatric/Neonate: ±2% (SPO2 70 ~ 100%)
	Pulse Rate	
	No motion conditions	Adult/Pediatric/Neonate: ±3bpm (PR 25 ~ 240)
	Motion conditions	Adult/Pediatric/Neonate: ±5bpm (PR 25 ~ 240)
	Low perfusion conditions	Adult/Pediatric/Neonate: ±5bpm (PR 25 ~ 240)
	Carboxyhemoglobin Saturation	
	Carboxyhemoglobin Saturation	Adult/Pediatr: ±3% (1- 40)
	Methemoglobin Saturation	
	Methemoglobin Saturation	Adult/Pediatric/Neonate: ±1% (1-15)
	Total Hemoglobin	
	Total Hemoglobin	Adult/Pediatric: ±1g/dL (8 – 17) g/dL
Resolution	SpO2	1 %
	SpCO	1 %
	SpMet	1 %

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

Please note that pulse-oximetry method (SPO2) is compared to laboratory spectroscopy of sample blood (SaO2). This method measures precision of SPO2 measurement using statistical analysis. Therefore, measurement precision is reliable for at least two third of measurements.

TEMPERATURE

Channel	1 Channel Monitoring 1 channel.
Probe Type	YSI 400 Compatible
Range	0-50°C
Accuracy	± 0.2 °C

RESPIRATION

Method	Impedance
Base Resistance	250 -1250 Ohm

Technical Specifications

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

IBP	
Channel	2 Channels
Measurement Range	SYS -50 ~ 300 mmHg
	DIA -50 ~ 300 mmHg
	MAP -50 ~ 300 mmHg
Pressure Filter	8Hz, 16Hz,22Hz selectable
Press Sensor Sensitivity	5 μV / V / mmHg
Resolution	1 mmHg
Accuracy	2 % or 2mmHg (each one is greater)
CO2 (Mainstream)	
Power supply	4.5-5.5 VDC, max 1.4W
Method	Infrared absorption
Measuring mode	Mainstream

Technical Specifications

IRMA Harmful Liquid Proof Degree	IPX1
Et and Fi Parameters Fi and ET are displayed after one breath and have a continually updated breath average.	
IRMA CO2	CO2, CO2 waveform
Sensor head	3-10 channel NDIR type gas analyzer measuring at 4-10µm. pressure, temperature and full spectral interference correction.
Sensor Dimension (W×D×H)	IRMA CO2/AX+: 38×37×34mm
Sensor weight	<25g(cable excluded)
	<38g(O2 sensor XL included, cable excluded)
Oxygen sensor	integrated ultra-fast response time galvanic oxygen sensor
	>100000 oxygen hours
Calibration	No routine calibration required Room air calibration of O2 sensor performedautomaticallywhen changing airway adapter (<5sec)
Warm-up time	Concentrations reported in less than 10s,
	full accuracy with in 10s for IRMA

Technical Specifications

	CO2
Operating temperature	IRMA CO2: 0 to 40°C
Storage and transportation temperature	IRMA CO2: -40 to 75°C
Operating humidity	10 to 95% RH, non-condensing
Storage and transportation humidity	5 to 100% RH, condensing
Operating atmospheric pressure	IRMA CO2: 525 to 1200hPa
Storage and transportation pressure	500 to 1200hPa
Surface temperature	max 50ºC / 122ºF
Rise time (@10 l/min)	CO2≤ 90ms
Delay time	≤ 140ms
Agent identification time	<20 seconds
Total system response time	< 1 second
Respiration rate	0~150BrPM

Accuracy specification-during standard condition

Gas	Measuring range	Accuracy
CO2	0-15%	±(0.2%ABS+2%REL)
	15-25%	Unspecified

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

Accuracy specification during standard condition

CO2	±(0.3%ABS or ±4%REL)

Sample Rate: 20 Hz / channel

Power supply	4.5-5.5 VDC, ISA CO2: <1.4 W (normal op.), <1.8 W (peak @ 5 VDC)
Method	Infrared absorption
Measuring mode	Sidestream

Technical Specifications

Et and Fi Parameters Fi and ET are displayed after one breath and have a continually updated breath average	
ISA CO2	CO2, CO2 waveform
Sensor head	2-9 channel NDIR type gas analyzer measuring at 4-10μm
Sensor Dimension (W×D×H)	ISA CO2: 33x78×49mm
Sensor weight	ISA CO2: 130g (including cable)
Calibration	No span calibration is required for the IR bench. An automatic zero reference calibration is performed at startup and then every 24 hours.
Compensation	
ISA CO2	Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO2.
Warm-up time	
ISA CO2	<10 seconds (concentrations reported and full accuracy)
Operating temperature	ISA CO2: 0 to 50°C

Technical Specifications

Storage temperature	-40 to 70°C
Operating humidity	<4 kPa H2O (non-condensing) (95 %RH at 40°C)
Storage humidity	5 to 100 %RH (condensing) (100 %RH at 40°C)
Operating atmospheric pressure	52.5 to 120 kPa (Corresponding to a max altitude of 4572 m/15000 feet)
Storage atmospheric	20 to 120 kPa

Typical rise time at 50 l/min sample flow

CO2	≤200ms

Total system response time	< 3 second (with 2m sampling line)
Sampling flow rate	50 ± 10 ml/min
Respiration rate	0~150BrPM

Accuracy specifications-during standard conditions

Gas	Measuring Range	Accuracy
CO2	0~15%	±(0.2 V% +2% of

		reading)
	15~25%	Unspecified
Accuracy specification-during all condition		
CO2	±(0.3 kPa + 4% of reading)	
Note 1: The accuracy specification is valid for all specified environment conditions. **Sample Rate**: 20Hz/channel		
Recorder		
Model	URUK Thermal Printer	
Channel	Up to 2 waveforms	
Printing Speed	6, 12.5, 25,50mm/sec	
Paper Size	57mm	

ALARM	
Sources	Error messages, All other parameter limits
Alarm On/Off	Selectable for all parameters
Alert	Blinking on Display, Volume Selectable Audio Alarms, Light indicator
TREND	
Sources	HR, SPO2, PR,RESP, TEMP, IBP1(SYS,DIA,MAP), IBP2(SYS,DIA,MAP), SpHb, PI, SpCo, SpMet, PVI, SpOc, EtCo2, FiCo2, AWRR(sidestream, mainstream), EtN20, FiN2O,EtO2,FiO2,EtAA, FiAA(ISO, DES, ENF, HAL, SEV)
Trend Time Save	96 Hours
Trend Time Interval	5, 10, 15, 30, 45 Min, 1, 2, 4 Hours
Resolution	1 sec
INPUT/OUTPUT	
Network	Digital, TCP/IP (WiFi)and TCP/IP (Wire)
Connection	8/16 BED TO CENTRAL system.

Technical Specifications

GENERAL	
Application	Compact and Mobile Monitor.
Safety	Based on IEC 60601-1, Class I
Protection	Against Electro surgery and Defibrillator and EMC.
AC Power	100 - 240 VAC, 50/60 Hz , Ip:1.4-0.7A

Internal Battery

Nickel-Metal Hybride 3.6V,2.5AH
Lithium Polymer 11.1V,4.3AH
Lithium ion 11.1V,3.3AH

System	Nickel-Metal Hybride	
Model	Charge time	Usage
PM4010	~ 3hours	~ 2:30hours
F1		
F1R		
PM4010		
F1	~ 6hours	~ 5hours

F1R	~ 6hours	~ 4hours
System	Lithium ion	
Model	Charge time	Usage
PM4010		
F1	~ 6hours	~ 10hours
F1R	~ 6hours	~ 8hours

Physical Specification

Dimension (mm)	Weight (approximately)
155(W) × 107(H) × 65(D)	Less than 800g

ENVIRONMENTAL

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

Chapter18, Accessories

General Information

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

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

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

Accessories

ECG

- ECG patient cable, 3 leads PART.#:24-226
- ECG patient cable, 5 leads PART.#:24-227
- Data Cable for Redel Connector to ECG 12 Lead PART.#:24-264
- Data Cable for Redel Connector to ECG 3 Lead FMT PART. #:24-258

SPO2 (Masimo Rainbow)

- Adult Digit Reusable Sensor - > 30 Kg (LNCS DCI) PART.#:18-045
- SPO2 Probe , Y- Sensor - > 1 Kg (LNCS)-MASIMO PART.#:18-049
- SPO2 Extension – Red LNC-10 - MASIMO PART.#:18-060

Accessories

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

PART.#:18-055

●SPO2 Extension Cable

PART.#:18-056

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

PART.#:18-062

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

PART.#:18-063

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

PART.#:18-064

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

PART.#:18-065

Accessories

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

PART.#:18-066

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

PART.#:18-068

●Rainbow DCI, Reuseable, Adult,

(SpO2,SpCO,SpMet) PART.#:18-069

●M-LNCS DCI, Reuseable, Adult, (SpO2)

PART.#:18-070

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

PART.#:18-072

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

PART.#:18-046

Accessories

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

PART.#:18-047

● SPO2 SPO2 Disposable Sensor, 3-20 Kg, (LNCS Inf) PART.#:18-075

NIBP

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

PART.#: 13-077

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

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

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

● NIBP Cuff Reusable - Large Adult - Single

M5305 Bladderless, Tube Length 20 cm

PART.#:13-081

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

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

PART.#:13-083

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

PART.#:13-084

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

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

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

PART.#:13-087

Accessories

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

PART.#:13-088

TEMP

● TEMP Probe – Skin –LAUNCH (98ME04GA634) PART.#:10-083

● TEMP Probe –Rectal –LAUNCH (98ME04GA635) PART.#:10-084

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

PART.#:24-073

IBP

● IBP Transducer , MEDEX - .MX860/866 Novatrans PART.#:16-001

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

Accessories

- IBP Extension Cable – MEDEX - MX860/866 Novatrans Extension PART.#:16-042

- IBP Transducer – MEDEX - MX960 Logical PART.#:16-002
- IBP Disposable Dome – MEDEX - MX960 Logical Dome PART.#:16-033
- IBP Extension Cable – MEDEX - MX960 Logical

- IBP Transducer Cable – TRUWAVE PART.#: 16-037
- IBP Transducer , Disposable – RX only – PX260 PART.#:16-036
- IBP CAPTO Holder - Capto SP844 Holder PART.#:16-030
- IBP Interface Probe– One channel IBP interface PART.#:16-051
- IBP Interface Probe– Two channel IBP interface PART.#:16-052

●IBP Transducer kit, Disposable, iPex, Ref BKT-164ET

PART #:16-046

●IBP Cable, Ipex, P/N: BKT-164ET

PART #:16-053

● IBP Bracket for iPex Trancducer

PART #:16-047

CO2 (Mainstream)

● IRMA CO2 only probe(2++)

PART. # 20-053

● IRMA ICU probe

● IRMA Disposable Airway Adapter without O2 port

PART. # 20-025

● IRMA Disposable Airway Adapter with O2

port PART. # 20-026

Accessories

- IRMA Disposable Airway Adapter for infant

  PART. # 20-035

- IRMA Adapter Cable

- IRMA O2 sensor

  PART. # 20-024

- Probe Holder for IRMA sensor

  PART. # 20-043

CO2 (Sidestream)

- ISA CO2 only probe .

  PART. # 20-046

- Nomoline with luer lock connector. 2 m. Box of 25

  PART. # 20-045

- Clamp of ISA Module Holder

  PART. # 20-055

Adaptor

- Uruk Adaptor 60W, 15v for PM4010

  PART. # 09263

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

ECG Electrodes

- Adults ECG Disposable Electrodes, FIAB

  Manufacturer REF: F9060

- Pediatric ECG Disposable Electrodes, FIAB

Manufacturer REF: F9060P

or

- Arbo H124SG, COVIDIEN Manufacturer

  REF: 31.1245.21

Chapter19, Care and Cleaning (PM)

Contents

System Check

Before using the monitor:

■ Check if there is any mechanical damage on the system and accessories.

■ Check if all the power cable and accessories are firmly connected.

■ Check all the functions of keyboard and modules to make sure that the monitor is in proper condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or local After Sale Service.

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

System Check

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

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

 It is recommended that the system is calibrated by manufacturer every year, but it has to be calibrated once every 2 years. In addition, the system lifetime is 10 years.

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

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

Cleaning and Disinfection

General Points

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Manufacturer makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. See also any local policies that apply within your hospital.

Cleaning and Disinfection

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

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.

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.

Allow the monitoring system to dry completely before making connections. And please make sure all connectors tightly connected to the system before using the system.

Cleaning and Disinfection

Please pay special attention to the following items:

1. The Patient Monitor and its belongings shall be kept dust-free.

2. Do not use strong solvents such as acetone or ammonia.

3. Most cleaning agents must be diluted before use.

4. Don't use rough or sharp material or your fingernail to remove stubborn stains.

5. Do not let the cleaning agent enter into the chassis of the system.

6. Do not leave the cleaning agents on any part of the equipment.

 Do not use ETO gas to disinfect the monitor.

External surfaces

In-between patients and as required:

For cleaning: wipe gently using a moist cloth and warm soapy water or mild detergent and for disinfection use the following recommended agents:

- Alcohol 70%
- Isopropyl alcohol
- N-propanol

 For cleaning and disinfection of BFA module must act as external surfaces of the device.

Display screen

In-between patients and as required use clean and soft cloth with screen cleaner or mild soapy water and with Isopropyl alcohol may be used for cleaning and disinfection.

 Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing.

 Don't spray a liquid directly on the screen.

Cleaning and Disinfection

Recorder:

Accumulation of paper powder or foreign matter between the thermal head and platen roller will deteriorate the print quality. Clean the head elements and platen roller surface using alcohol and a cotton swab. Wait until the alcohol dries then close the recorder door.

Do not clean the printer immediately after recording because thermal head and its surrounding area are hot during and after recording.

Accessories

To clean, disinfect and sterilize reusable transducers, sensors, cables, leads, and so forth, refer to the instructions delivered with the accessories.

Also, trolley/ wall stand, accessory holders[1] and extension cables[2] (if applicable) should be cleaned and disinfected after each patient or when necessary, using a soft, clean cloth soaked in mild soapy water and, if necessary, Isopropyl alcohol, and then wiped with a soft and dry cloth.

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

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

Cleaning and Disinfection

To avoid damaging of the cable, probe, sensor or connector, do not immerse it in any liquid.

Disposable accessories shall not be sterilized or reused.

To prevent environmental pollution, the disposal of single-use accessories shall be done in accordance with the policies of the hospital.

Cleaning and Disinfection

Device parts	Single-use	Cleaning	Disinfection	Sterilization
External surface of device	-	In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.	In-between patients and as required use ■ Alcohol 70% ■ Isopropyl alcohol ■ N-propanol	To avoid extended damage to the equipment, sterilization is not recommended for this monitor, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies or when stipulated as necessary in the Hospital Maintenance Schedule.
BFA module	disposable electrodes			
*** Trolley/ Wall stand,** *** Holders of accessory,** *** Extension cables**	-		In-between patients and as required use ■ Isopropyl alcohol	
Display screen	-	In-between patients and as required: Clean and soft cloth with screen cleaner or		

Cleaning and Disinfection

		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	-	

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.

Preventive Maintenance (PM)

 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

Preventive Maintenance (PM)

The preventive maintenance (PM) checklist 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.

Chapter 20, Troubleshooting

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

This section is intended to help users to solve minor problems caused by incorrect use of the monitor or failure of accessories.

When you face any problem, please be sure that you have followed all mentioned procedures before you contact with Customer Service.

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

Problem	Possible Cause	Correct Actions
ECG		
Noisy ECG waveform	• Loose connection of electrodes. • Earth connection failure. • Wrong ECG filter • etc	• Check electrodes and leads • Check applied gel on the chest lead or change the chest lead , if necessary. • Check earth • Set filter mode correctly. • Call the Customer service department.
NO ECG waveform	• ECG cable is not connected securely. • Improper placement of leads and electrodes • etc	• Connect ECG cable correctly. • Check leads and electrodes. • Short-circuit all the leads, if the cable is perfect, no error message will be displayed. • Do not use old and faulty electrodes. • Call the Customer

Spike on ECG waveform	• If PACE is "ON" for patient without Pace marker, ECG noise will be counted as PACE pulse. • etc	• Set OFF “Pace detection” in ECG window.
Unstable HR	• ECG signal is noisy or is not suitable. • etc	• Check leads and electrodes. • Change leads to monitor the best ECG signal. • Call the Customer service department.
Problem	**Possible Cause**	**Correct Actions**
RESP		
- No “RESP” signal -No good waveform -Unstable RR	• The electrodes are not connected properly. • The patient moves extremely during measurement. • etc	• Check leads and electrodes. • Change RESP lead. • Calm the patient. • Call the Customer service department.
	No respiration is	• Call the Customer

RESP APNEA	detected for a specific time.	service department.

Problem	Possible Cause	Correct Actions
TEMP		
Strange T1	• Improper placement of the probe. • Faulty sensor • etc	• Place the probe in appropriate location. • Replace the probe. • Call the Customer service department.
Problem	**Possible Cause**	**Correct Actions**
SPO2		
-No SPO_2 waveform -Noisy waveform	• SPO_2 probe is not placed in appropriate location. • Faulty sensor • etc	• Check the probe placement. • Change the probe and check the waveform. Contact the manufacturer to replace the probe ,if necessary. • Call the Customer service department.
-No SPO2 value -Strange SPO2 value	• Patient movement during measurement • Improper placement of the probe. • etc	• Calm the patient. • Change the probe position. • Call the Customer service department.

Problem	Possible Cause	Correct Actions
NIBP		
NIBP cuff cannot inflate	• Improper connection of air hose. • The air hose has been occluded or tangled. • Leakage of the air hose or cuff. • etc	• Check connections. • Check the air hose. • Replace the hose and the cuff, if necessary. • Call the Customer service department.
-NIBP cannot be measured -Strange NIBP value	• The cuff or air hose is not connected to the system. • Improper cuff placement • Patient movement during the measurement • Low battery power • etc	• Check the cuff and the air hose • Change the cuff position • Calm the patient • Connect the monitor to the mains power. • Call the Customer service department.

Problem	Possible Cause	Correct Actions
IBP		
Strange IBP value Noisy IBP signal	● Zeroing has not been performed before measurement. ● Noisy source nearby the system or accessories. ● Faulty sensor ● etc	● Perform zeroing ● Keep the system and cable away from any noise source. ● Replace the sensor. ● Call the Customer service department.

Problem	Possible Cause	Correct Actions
CO2		
CO2 System fault #01	Software error	Call the Customer service department.
CO2 System Fault#02	Hardware error	Call the Customer service department.
CO2 System Fault#03	The engine speed is out of range.	Call the Customer service department.
CO2 System fault#04	The device is out of calibration.	Call the Customer service department.
CO2 No Adapter/Sampling line	There is no adaptor/ sampling line connected to the system.	● Connect adaptor/sampling line. ● Call the Customer service department.
SAMPLING LINE IS CLOGGED	Sampling line occlusion	● Replace the sampling line with a correct one. ● Call the Customer service department.
RESP APNEA	Non-respiration condition overruns the specified time	Call the Customer service department.
CO2 NO SENSOR	The sensor is not connected or there	● Connect CO2 sensor. ● Call the Customer

	is not CO2 module.	service department.

Some advices to reduce measurement errors:

- **NIBP**

When NIBP measurement is made, it is an important factor to set the measurement unit on mmHg and connect the pressure cuff to the patient properly and according to instructions of this manual.

The most likely reason that the system doesn't display NIBP value is cuff failure or leakage, therefore when dealing with this problem, use an intact cuff to test the system and check air hose connection and other connections. If the problem is not removed, contact the manufacturer's customer service.

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

Please observe the following instructions for pressure measurement:

1- Delete information of discharged patients and prepare the system for monitoring of new patient. You may turn off the system in the meantime and relax new patient in a comfortable position.

2- Deflate the cuff completely by hand.

3- The patient should sit quietly in a comfortable place with good back support to lean and the feet resting on the floor.

4- Relax patient in a comfortable position for 2-3 minutes before measurement.

5- Remain quiet during measurement.

6- Attach the cuff to patient arm and keep the arm in same level with the patient heart.

7- The cuff should be placed on upper arm.

8- Place the cuff tight enough so that you can only slip two fingertips under it.

9- Align the cuff and artery properly.

10- Remove any tight fitting clothing before taking measurement.

11- Apply proper size of cuff for the patient.

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

Chapter 21 BFA Monitoring

Contents

General Information

Anesthesiologists have been using hemodynamic and clinical characteristics such as heart rate, blood pressure, tears, facial variations, pupil diameter and perspiration as well as different stimulations and personal experiences to measure the level of patient consciousness for many years. They also use devices such as Capnography and pulse oximetry in this regard. Since none of these parameters is directly associated with the level of consciousness, Physicians must use indirect measurement methods to apply appropriate dosage for each patient in order to make the patient feel no pain during surgery.

There are some standards to determine required dosage for each patient, for example one standard is based on needs of a middle-aged man. This standard is certainly not suitable for females, patients of different ages or patients with dangerous and unknown diseases.

There are common cases in which the patient is overdosed (receives excessive amount of drug) and this results in long wake-up time after anesthesia, prolonged recovery accompanied by nausea as well as economic loss.

A rare and chronic condition is when the patient receives low amount of drug and does not lose his consciousness completely (subconsciousness level), but due to the injection of muscle relaxant drugs he is unable to react during surgery and has a vague picture of what is going on around him. This can cause long-term emotional consequences and subsequent psychological traumas. The most of these patients suffer nightmare during few days after surgery.

A lot of attempts were made to measure the level of consciousness using patient vital signs signals, a method through which the required dosage of drug for each patient can be estimated without considering physiological factors such as weight, age, etc.

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

The monitor is intended for use in monitoring the hypnotic state of the brain by data acquisition of EEG signals of the anesthetized or sedated patient in all areas of the hospital.

Measurement principle

An instrumentation amplifier collects ongoing EEG with a high Common Mode Rejection Ratio (CMRR) ensuring a high-quality EEG acquisition.

Special algorithms that eliminate their effects on subsequent BFI calculations detect artefacts.

The performance of the BFI is based on the analysis of the frequency content and phase of the EEG signals.

The monitor also evaluates the amount of burst suppression (BS) in each fifty-second period of the EEG. This measurement quantifies the amount of "silent" or "flat" EEG periods characteristic of the deepest levels of hypnosis.

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

BFA Index (BFI)

The BFI is a unit-less index from 0 to 100, where 0 indicates a flat EEG and 100 indicates EEG activity in awake state. BFI range in adequate anaesthesia is designed to be between 40 and 60. All values in the table are

approximate values based on the mean values of the patient behaviour.

The relationship between BFI and the clinical state of patient is shown in the table below:

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

EMG

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

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

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

The EMG bar should be checked frequently, especially in case of a sudden increase in the BFI. If BFI increases

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

Burst Suppression Indicator (BS)

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

SQI: Signal Quality Index

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

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.

Do not use the monitor when cardiac defibrillator is used. Patient cables are not protected against defibrillation.

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

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.

Skin Preparation and Placement of Sensors

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

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

 The performance of the BFA module is only guaranteed by the manufacture when the BFA Procedure Pack is used.

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

Position of the three neuro sensors is shown in figure8-1. The advanced signal processing of the monitor ensures that a deviation in the positioning of the sensors up to 2 cm (0.78 in) has no significant influence on the index. However, it is recommended to place the sensors on an area of the skull where only a few muscle fibres are present in order to achieve the best quality signal.

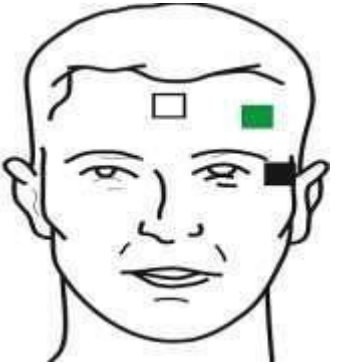


Figure 21-1 Neuro Sensor Placement

White electrode (1): middle of forehead

Green electrode (2): left side of forehead

Black electrode (3): on temple

●Make sure no part of the neuro sensors is in contact with any other conductive parts including earth/ground

●If skin rash or other unusual symptoms develop, remove sensors from patient.

●Change neuro sensors every 24 hours to check skin integrity.

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

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

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

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

Picture below shows how to use neuro sensor.

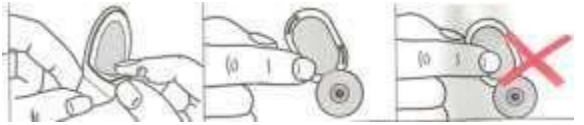


Figure 21-2 Correct use of neuro Sensors

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

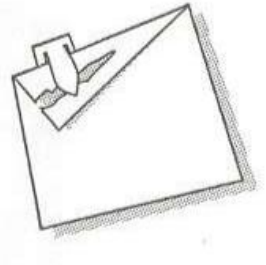


Figure 21-3 Correct maintenance of neuro sensors in its package

BFA monitoring system

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

a) BFA module

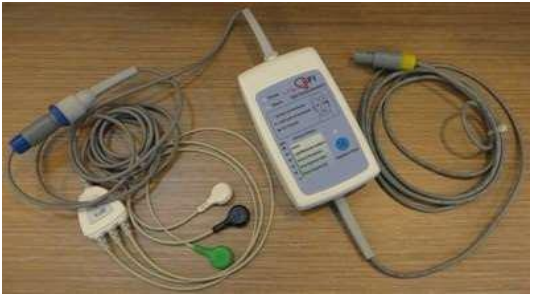


Figure 21-4 BFA module

BFA module keys and indicators

Power Indicator: This indicator is turned on as BFA module is connected to the monitor and remains ON until the module is disconnected (21-5①).

Alarm Indicator: If "BFA ELECTRODE ALARM" occurs (resulting from inappropriate connection of neuro sensors), this indicator will flash with frequency of 1 Hz (Figure 21-5②).

Impedance key: Impedance measurement is initiated by pressing this key (Figure 21-5③) and its indicator (Figure 21-5④) flashes on the module for one second.

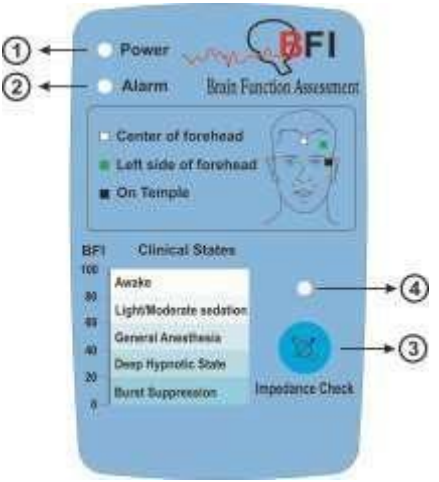


Figure 21-5 BFA module keys and indictors

b) BFA on patient monitor

BFA Module Setup

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

2- Connect the patient cable to BFA module.

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.

3- After communication is established, you can monitor different BFA parameters such as BFI%, BS%, SQI%, EMG% and also EEG signal on the patient monitor. (At

first only EEG signal can be monitored and after 20 seconds, other parameters appear on the monitor).

BFA PARAM MENU

BFA parameter window is as below:

Figure 21-6 BFA Window

Touch EEG parameter area to access the below menu:

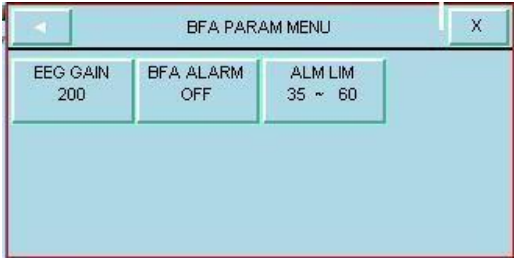


Figure 21-7 BFA PARAM MENU

■ **To change EEG gain:**

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

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

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

■ **To set the BFI alarm limit:**

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

Figure 21-8 BFA ALARM LIMIT

BFI alarm level is always II.

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

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

BFA TREND MENU

Touch EEG area to access the below menu:

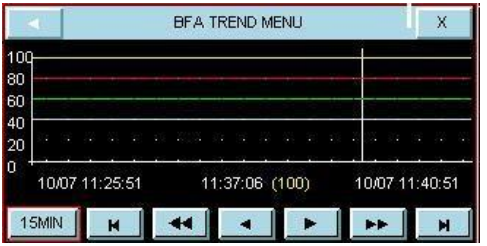


Figure 21-9 BFA TREND MENU

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

- As long as the cursor line is not moved in TREND menu, every click on the first left item will change the x -axis based on the selected interval.Moving the cursor to choose a specific time and pressing trend time interval item (the first left item), x -axis will be

zoomed in and zoomed out equal to the trend interval according to the specific time the cursor line shows.

- The cursor line in trend graph shows specific time. Click on the fourth and fifth left items to set the interval on 15, 30 min and 1 and 2 H. The specific time to which the cursor points will change and numeric parameters of this time will be displayed on the right side of the TREND menu.

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

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

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

BFA Alarm Messages and Troubleshooting

Alarm limit is activated as a follow:

Alarm	Situation	Visual prompt	Audio sound
BFI HIGH	Cerebral state index violates adjusted high limit	●BFI value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in yellow background.	Activated
BFI LOW	Cerebral state index violates adjusted low limit	●BFI value blinks. ● Alarm indicator flashes.	Activated

		• Alarm message is displayed in yellow background.	

BFA messages on patient monitor include:

Message	**Cause**	Solution
BFA ELECTRODE ALARM	Placement of neuro sensors or their connections might be faulty or the impedance of the sensors may exceed 10k Ω. This alarm can also be caused by high frequency instrument.	• Check all neuro sensors and their connections. • Check the patient cable. If it is not connected or is faulty, please connect it or replace it. • Check if either of the neuro sensors are disconnected or badly connected. • Replace faulty sensor. • Follow the procedure explained in the section

		"Skin Preparation and Sensor Placement" to clean the skin.
BFA SQI LOW	If sensor impedance is more than 5kΩ, the %BFI, %BS, %EMG and %SQI will be blanked.	●Check that neuro sensors are not dry. ●Check that the skin hasbeen cleaned properly. ●Follow the procedure explained in the section "Skin Preparation and Sensor Placement" to clean the skin.
BFA LINK OFF	BFA module is off.	Establish the connection between the module and the monitor via interface cable.

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

Troubleshooting

- **BFA module does not turn on when it is connected to the monitor.**

  - Check interface cable between the module and the monitor.

  - If the problem persists, contact after sale service of manufacturer.

- **BFI is higher than expected range**

  - Check anesthetic delivery systems: IV lines and status of vaporizers.

  - Some patients require more doses of drug to reach intended level of anesthesia.

  - Drug dosage is not sufficient for Maintenance phase, so BFI increases during painful stimulations.

- **BFI rises along with EMG**

  High levels of facial muscular or electromyographic (EMG) activity can elevate the BFI under certain circumstances. When this happens, attention must be paid to reactions of patient against the stimuli during surgery. When the patient is asleep, EMG activity may increase due to reactions to painful stimuli during surgery, lack of muscular relaxation or muscular rigidity caused by some opioids (analgesics). In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent may decrease BFI.

BFA module cleaning and maintenance

Cleaning

Please pay special attention to the following items for cleaning BFA module and patient cable:

1. Don't use strong solvents such as acetone or ammonia.
2. Most cleaning agents must be diluted before use.
3. Don't use rough material, such as steel wool etc.
4. Don't leave the cleaning agents on any part of the equipment

 The BFA module should be cleaned with hospital-grade ethanol and then dried by a clean cloth.

Storage

Store in a clean, dry atmosphere at room temperature and, if available, use the original packaging for protection.

 The BFA module should be disposed of taking into consideration environmental factors, local laws and regulations. All components can be safely disposed of in the approved manner as per hospital or locally regulated guidelines.

Maintenance

To ensure the monitor remains in good operating condition, it is important to keep it clean and carry out the routine maintenance procedures. There are no serviceable parts in this instrument and all service is to be carried out by the manufacturer.

 If the monitor is dropped, damaged or subjected to excessive moisture or high temperature, immediately be taken out of service for examination by qualified service personnel.

 As required clean the external surfaces of the monitor thoroughly before and after a prolonged period of storage.

 If the module is dropped or severely shaken, it should immediately be taken out of service and inspected by qualified service personnel to ensure its proper function prior to use.

Chapter 22, ARR Monitoring

Contents

General Information

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

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

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

 This monitor can detect up to 13 types of arrhythmias.

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

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

ARR Analysis

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

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

It is recommended to use ECG lead I or II to have the best accuracy of ARR software.

Arrhythmia detection algorithm principle

The arrhythmia algorithm is based on template matching. (A template is a group of beats matching the same morphology). The algorithm detects QRS complexes, generates QRS templates and performs beat labelling. This algorithm is divided into three parts: detector, classifier and labelling.

The detector algorithm detects waves in ECG signal that could be QRS complexes.

The classifier algorithm forms templates of similar QRS complexes. During the learning phase an initial set of QRS template is built. Then the monitor creates a reference template based on its identification of the patient's dominant QRS pattern. When a new true QRS complex is detected, it is compared with the existing templates. If no match is found, a new QRS template is added to the template set.

The labelling algorithm analyses all templates. Each template and the beats belonging to it are labelled with

one of the following names: normal beats, ventricular beats and questionable beats.

Through this process, the monitor can verify an arrhythmia event's occurrence.

Parallel to this process there is an algorithm for detection of ventricular fibrillation.

Detection of ventricular fibrillation is based on waveform analysis. AFIB arrhythmia is detected through obtained parameters in the previous parts and analysis of R-R intervals. Maximum one minute after occurring AFIB arrhythmia, related alarm will be activated and time of arrhythmia occurrence will be recorded in the Trend window.

Beat and rhythm classification

Beat classification refers to the analysis of individual beats. If the new beat's features do not match those of the normal template, the new beat is classified as premature or questionable.

The monitor uses all detected beats to calculate the heart rate, eliminating questionable beats from arrhythmia classification.

Rhythm classification refers to analysis of sequences of beats. The monitor compares the sequence of the last twelve beats with the sequences stored in the monitor's memory. If it detects two or more events simultaneously, the monitor alarms in order of event priority.

The following table describes detectable arrhythmias by the monitor:

Arrhythmia	Event and Beat Classification
ECG ASYSTOLE	5 seconds pass without the detection of valid QRS complex.
VFIB ARRHYTHMIA	Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics.)Certain ventricular tachycardias have sinusoidal waveforms closely resembling those of ventricular fibrillation. Because of the similarity of these waveforms, the monitor may classify such types of ventricular tachycardia as ventricular fibrillation(.
VTAC ARRHYTHMIA	Ventricular Tachycardia: N or more PVC's are detected in a time interval T= (60*(N-1))/R, where N is defined as the VTAC count and R is defined as the VTAC rate.
RUN ARRHYTHMIA	Ventricular Run: Series of 3 to N-1 consecutive PVCs with a beat to beat rate ≥ the VTAC rate.
AIVR ARRHYTHMIA	Accelerated Idioventricular Rhythm: Series of 3 or more PVCs with a beat rate less than the VTAC rate.
BIGEMINY ARRHYTHMIA	Ventricular Bigeminy: Sequence of beats with the pattern : normal, PVC, normal, PVC, normal, PVC

ARR Analysis

TRIGEMINYARRHYTHMIA	Ventricular Trigeminy: Sequence of beats with the pattern : normal, normal, PVC, normal, normal, PVC
COUPLET ARRHYTHMIA	Ventricular Couplet: Sequence of beats with the pattern : normal, PVC, PVC, normal, PVC, PVC
TACHY ARRHYTHMIA	Sinus Tachycardia: HR ≥ TACHY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.
BRADY ARRHYTHMIA	Sinus Bradycardia: HR≤ BRADY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.
AFIB ARRHYTHMIA	Atrial Fibrillation: Formation of QRS complexes in irregular intervals
PAUS ARRHYTHMIA	Actual R-R interval more than 2.1 times of the average R-R interval.
FREQUENT PVCs	More than N (event count set in the ARR SETUP WINDOW) PVC per minute.

Premature Ventricular Contraction (PVC) is ectopic impulse originating from ventricles, before the normal electrical activation sequence of the heart has occurred.

The PVC value is shown in ECG parameter window and updated every 5 seconds.

When ARR analysis is enabled, current PVC values are trended every 20 seconds and can be reviewed on the TREND window.

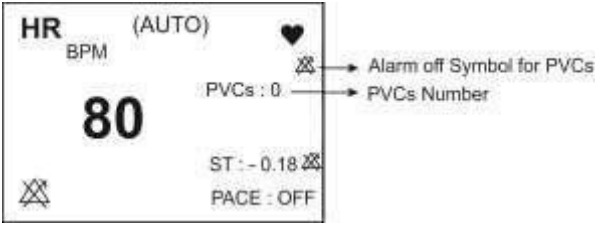


Figure 22-1 PVC value in ECG parameter area

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

ARR ANALYSIS

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

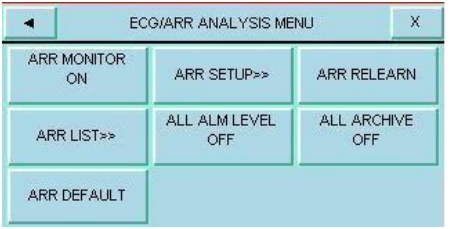


Figure 22-2 ECG/ARR ANALYSIS MENU

■ **ARR MONITOR**

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

■ ARR SETUP

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

Figure 22-3 ECG/ARR/ SETUP MENU

The ARR SETUP table allows you to configure arrhythmia monitoring accordingly to your patient’s needs. All detectable arrhythmia events listed in the first column of the table .Using the remaining columns, you can modify the attributes of each event. Fields that are not applicable for certain event category are shown with dash symbol, while those that cannot be modified are ghosted. Arrhythmia default settings are shown in the figure 22-3.

ARR Analysis

1. Press ▲ ▼ to scroll up or down and select your desired arrhythmia event to configure.
2. Press ▲▲ ▼▼ _ to scroll through pages.
3. Press CHANGE to access settings of the selected arrhythmia event in the below menu.

Figure 22-4 ECG/ARR/ SETUP/CHANGE MENU

■ **ALM LEVEL**

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

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

ARR Analysis

- **RATE**

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

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

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

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

- **COUNT**

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

ARR Analysis

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

Count of “AIVR” is ≥3 and cannot be modified.

Arrhythmia event	Count setting
VTAC	5-12 step by 1
RUN	(VTACcount -1) ~3 step by 1
FREQUENT PVCs	1-15 step by 1

- **ARCHIVE**

You can determine whether the selected event is stored, recorded automatically or both. You can view stored events on ARR EVENT RECALL Window. **STR**: Stores selected arrhythmia event.

REC: Automatically generates a recording of selected event.

STR/REC: Event is stored and recorded simultaneously.

OFF: No action if arrhythmia event occurs.

- **ALL ALARM LEVEL**

Press to set the level of all arrhythmia alarms to the same value or to disable all of them.

- **ALL ARCHIVE**

Press to set all arrhythmia ARCHIVE condition to the same state.

■ **ARR RELEARN**

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

 In most situations the learning procedure takes about 20 seconds.

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

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

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

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

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

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 LIST

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

Figure 22-5 ECG/ARR/ ARR LIST MENU

ARR Analysis

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

■ **To review different pages of ARR list:**

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

Press ▲ ▼ _ to review different pages.

Press ▲ ▼ to select an arrhythmia event.

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

Select WAVE to access the below menu.

Figure 22-6 ECG/ARR LIST/ ARR WAVE MENU

ARR Analysis

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

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

■ **REC in ARR WAVE Menu**

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

■ **To delete/undelete an arrhythmia event:**

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

■ **REC in ARR LIST Menu**

This item allows you to record the arrhythmias list.

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

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

■ **ARR DEFAULT**

Select this item to load the manufacturer default settings for ARR parameter. Because all your previous settings will be missed by selecting this item, the system asks for your confirmation before changing settings (figure 22-7).

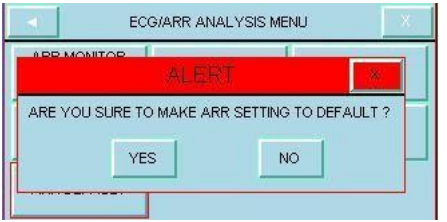


Figure 22-7 Alert message

Chapter 23, ST Monitoring

Contents

General Information

ST segment deviation is defined as the displacement above or below the isoelectric level. The measurement of deviation compares the isoelectric point to the ST measurement point.

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

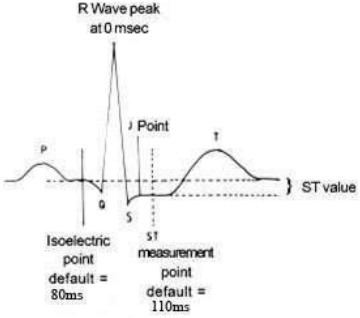


Figure 23-1 ST Measurement Algorithm

The ST measurement for each beat complex is vertical difference between the two measurement points, ST and ISO.

The ST analysis examines QRS complexes classified as normal beats (beat detection and classification information provided by the arrhythmia algorithm are used to eliminate beat that are ventricular in origin). The monitor combines the measurements and features of normal beats into a composite (or average) QRS complex. It derives the ST segment deviation from this average.

ST Analysis

The ST segment algorithm documents changes in ST segment in adult patients that can be indicative of the severity and duration of myocardial ischemia. Since many ischemic episodes are silent or painless, continuous monitoring of ST segment changes can provide the earliest warning of ischemic events.

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

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

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

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

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

 Measurement unit of ST segment is “mV”.

ST monitoring function is “OFF” as a default. You can switch it “ON”, when this monitoring is necessary. When ST monitoring is enabled, current ST values are trended and can be reviewed on the TREND window.

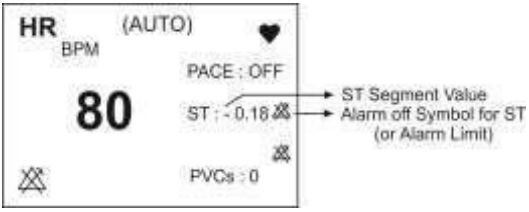


Figure 23-2 ST value in ECG parameter area

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

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

ST ANALYSIS

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

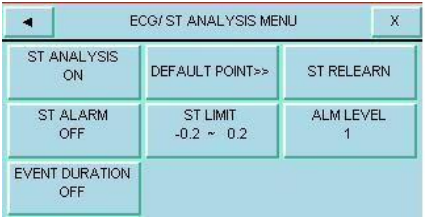


Figure 23-3 ECG/ST ANALYSIS MENU

■ **ST ANALYSIS**

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

■ **ST ALARM**

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

" " symbol in the ST parameter area.

■ **ALM LEVEL**

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

■ **ST LIMIT**

ST alarm is activated when the ST segment value exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (Range: -2.0 ~ +2.0 step 0.1) Default for upper limit is +0.2 and for lower limit is -0.2.

■ **EVENT DURATION**

Select this item to determine the time that a potential ST alarm condition must persist on ECG waveform before the monitor classifies it as a valid alarm condition.

Available options for EVENT DURATION are OFF, 15s, 30s, 45s and 60s.The default is OFF and alarm will be activated immediately if alarm condition happens.

■ **ST REALERN**

Select to start a learning procedure. The message "RELEARN" is displayed in the message area. The procedure will take about 20 seconds.

During the learning procedure the following actions will be taken:

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

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

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

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

A yellow vertical marker with “LRN” label on ST in TREND window shows the time in which the learning procedure has been done.

■ DEFAULT POINT

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

Figure 23-4 ECG/ST ANALYSIS/DEFAULT MENU

As shown above, the DEFAULT POINT MENU shows the dominant QRS complex template. Two vertical lines indicate the positions of the ISO and ST points.

ISO: It is the base point, used to indicate the baseline point of the ST analysis. The default is 80ms.

ST Analysis

ST: It is the ST measurement point. The default is 110ms. (Selectable between 5 to 400 ms by step of 5ms) The reference point is the position where the peak of R-wave locates.

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

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

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

If the template is not established, a horizontal line will be displayed and if the ST ANALYSIS is “OFF”, the message “ST ANALYSIS KEY IS OFF” appears in this window.

You may select ISO or ST, and then switch the knob left or right to move the cursor line. When the cursor is at the intended position, you may select the base point or the measurement point.

 Abnormal QRS complex is not considered in ST segment analysis.

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

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

APPENDIX I

LIST OF MONITOR PARAMETERS

(SELECTIONS AND DEFAULTS)

Menu item	Selection	Default
The parameters in ECG menu		
ECG LEAD	I,II,III,aVR,aVF,aVL,V1,V2,V3,V4,V5,V6	II
ECG SIZE	CHANGE,AUTO	AUTO
ECG SWEEP	12.5,25,50mm/s	25
ALARM LEVEL	1,2	1
HR ALARM	ON,OFF	OFF

HR HIGH ALARM	HR LOW ALARM +5 to 250	150Bpm
HR LOW ALARM	30 to HR HIGH ALARM -5	50Bpm
ECG FILTER	MONITOR,NORMAL, EXTENDED	NORMAL
HR SOURCE	ECG,SPO2, IBP1,IBP3, IBP2,IBP4, AUTO	AUTO
BEAT VOLUME	1,2,3,4,5,6,7,8.OFF	1
PACE DETECT	ON,OFF	OFF
ECG CALIB	ON,OFF	OFF

ECG AVERAGE	4,8,16SEC	8SEC
LEAD TYPE	3 Wires,5 Wires, 10 Wires	3 Wires
The parameters in RESP menu		
RESP LEAD.	RA-LA,RA-LL	RA-LA
RESP GAIN	×0.25,×0.5,×1,×2,×4	×1
RESP SWEEP	3,6,12.5,25mm/s	6mm/s
ALARM LEVEL	1,2	1
RR ALARM	ON ,OFF	OFF

RR HIGH ALARM	RR LOW ALARM +1 to 150	25Brpm
RR LOW ALARM	5 to RR HIGH ALARM -1	5Brpm
APNEA LIMIT	10,15,20,25,30,35, 40S , OFF	10S
The parameters in SPO2 menu		
Avg. Time	2~4, 4~6, 8, 10, 12, 14, 16	8
SPO2 PLETH SWEEP	12.5,25mm/s	12.5mm/s
ALARM LEVEL	1,2	1
ALARM	ON,OFF	OFF

SPO2 HIGH ALARM	SPO2 LOW ALARM +1 to 100	100
SPO2 LOW ALARM	1 to SPO2 HIGH ALARM -1	90
PR HIGH ALARM	PR LOW ALARM +5 to 235	140
PR LOW ALARM	20 to PR HIGH ALARM -5	50
SpMet HIGH ALARM	SpMet LOW ALARM +0.5 to 99.5	3.0
SpMet LOW ALARM	0.5 to SpMet HIGH ALARM -0.5	0.5

SpCO HIGH ALARM	SpCO LOW ALARM +1 to 99.0	10.0
SpCO LOW ALARM	1.0 to SpCO HIGH ALARM -1	1.0
SpHb HIGH ALARM	SpHb LOW ALARM +0.1 to 24.5	17.0
SpHb LOW ALARM	0.5 to SpHb HIGH ALARM -0.1	7.0
PI HIGH ALARM	PI LOW ALARM +0.1 to 19.0	19.0
PI LOW ALARM	0.0 to PI HIGH ALARM -0.1	0.0

PVI HIGH ALARM	PVI LOW ALARM +1 to 99	99
PVI LOW ALARM	1 to PVI HIGH ALARM -1	1
SpOC HIGH ALARM	SpOC LOW ALARM +1 to 34.0	34.0
SpOC LOW ALARM	1.0 to SpOCI HIGH ALARM -1	1.0
SPO2 SENSITVITY	NORMAL , APOD,MAX SENS	NORMAL

SPO2 PULSE RATE	ON,OFF			OFF		
The parameters in NIBP menu						
NIBP UNIT	**mmHg , KPa**			**mmHg**		
ALARM LEVEL	**1,2**			**1**		
NIBP ALARM	**ON,OFF**			**OFF**		
	Adult	Neonate	Pediatric	Adult	Neinate	Pediatric
SYS HIGH ALARM	SYS LOW ALM +5 to 255	SYS LOW ALM +5 to 135	SYS LOW ALM +5 to 240	160 mmHg	90 mmHg	120 mmHg
SYS	30 to	30 to SYS	30 to	90	40	70

LOW ALARM	SYS HIGH ALM -5	HIGH ALM -5	SYS HIGH ALM -5	mmHg	mmHg	mmHg
DIA HIGH ALARM	DIA LOW ALM +5 to 220	DIA LOW ALM +5 to 110	DIA LOW ALM +5 to 220	90 mmHg	60 mmHg	70 mmHg
DIA LOW ALARM	15 to DIA HIGH ALM -5	15 to DIA HIGH ALM -5	15 to DIA HIGH ALM -5	50 mmHg	20 mmHg	40 mmHg
MAP HIGH ALARM	MAP LOW ALM +5 to 235	MAP LOW ALM +5 to 125	MAP LOW ALM +5 to 230	110 mmHg	70 mmHg	90 mmHg
MAP LOW	20 to MAP	20 to MAP	20 to MAP	60 mmHg	25 mmHg	50 mmHg

ALARM	HIGH ALM -5	HIGH ALM -5	HIGH ALM -5			
AUTO/ Manual/ STAT	MANUAL, STAT ,AUTO 1min, 2min, 3min,5min,10min,15min, 20min, 30min,45min,60min,90 min,2H,4H, 8H, 12H, 16H, 20H, 24H.			MANUAL		
AUTO SLEEP	ON,OFF			OFF		
The parameters in TEMP menu						
TEMP UNIT	ºC,ºF			ºC		
ALARM LEVEL	1,2			1		
TEMP	ON ,OFF			OFF		

ALARM		
TEMP HIGH ALARM	T1 LOW ALARM +0.5 to 50.0	39.0
TEMP LOW ALARM	0.0 to T1 HIGH ALARM -0.5	35.0
The parameters in IBP menu		
IBP UNIT	mmHg , KPa,cmH2O	mmHg
IBP LABEL	IBP,ART,PAP,CVP,LAP, RAP,LVP,RVP,ICP	IBP
ALARM LEVEL	1,2	1
IBP ALARM	ON,OFF	OFF

IBP HIGH ALARM	IBP LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
IBP LOW ALARM	-50to IBP HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
ART HIGH ALARM	ART LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
ART LOW ALARM	-50to ART HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg

LVP HIGH ALARM	LVP LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 20 mmHg MEAN: 80 mmHg
LVP LOW ALARM	-50 to LVP HIGH ALARM -5	SYS: 80 mmHg DIA: -5 mmHg MEAN: 20 mmHg
PAP HIGH ALARM	PAP LOW ALARM +1 to 120	SYS: 40 mmHg DIA: 20 mmHg MEAN: 30 mmHg
PAP LOW ALARM	-50 to PAP HIGH ALARM -1	SYS: 5 mmHg DIA: -5 mmHg MEAN: 0 mmHg
RVP HIGH ALARM	RVP LOW ALARM +1 to 100	SYS: 40 mmHg DIA: 15 mmHg MEAN: 30 mmHg

RVP LOW ALARM	-50 to RVP HIGH ALARM -1	SYS: 5mmHg DIA: -5 mmHg MEAN: 0 mmHg
CVP HIGH ALARM	CVP LOW ALARM +1 to 100	15 mmHg
CVP LOW ALARM	-50 to CVP HIGH ALARM -1	-5 mmHg
LAP HIGH ALARM	LAP LOW ALARM +1 to 100	20 mmHg
LAP LOW ALARM	-50 to LAP HIGH ALARM -1	-5 mmHg
RAP	RAP LOW ALARM +1 to 100	15 mmHg

HIGH ALARM		
RAP LOW ALARM	-40 to RAP HIGH ALARM -1	-10 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 FILTER	22Hz,16Hz,8Hz	16Hz
IBP SWEEP	3mm/s,6mm/s,12.5mm/s,25m m/s	12.5mm/s

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
IBP GRID		ON,OFF	OFF

The parameters in ARR menu			
ARR MONITOR	ON, OFF		OFF
ALARM LEVEL	ASYSTOLE	1	1
	VFIB	1	1
	VTAC	1	1
	RUN	1, 2, OFF	1
	AIVR	1, 2, OFF	2
	COUPLET	1, 2, OFF	2
	BIGEMINY	1, 2, OFF	2
	TRIGEMINY	1, 2, OFF	2
	TACHY	1, 2, OFF	2
	BRADY	1, 2, OFF	2
	AFIB	1, 2, OFF	1

	PAUS	1, 2, OFF	2
	FREQUENT PVCs	1, 2, OFF	OFF
RATE	VTAC	100 to 200 (with step 10)	>=120
	RUN	VTAC rate	>=120
	AIVR	<VTAC rate-1	>=119
	TACHY	100 to 200 (with step 10)	>=120
	BRADY	30 to 105 (with step 5)	<=50
COUNT	VTAC	5 to 12 (with step 1)	>=5
	RUN	3 to VTAC -1 count	>=3

		(with step 1)	
	AIVR	-	>=3
	FREQUENT PVCs	1 to 15 (with step 5)	>=10
ARCHIVE	ASYSTOLE	STR, STR/REC, OFF, REC	STR
	VFIB	STR, STR/REC, OFF, REC	STR
	VTAC	STR, STR/REC, OFF, REC	STR
	RUN	STR, STR/REC, OFF, REC	STR

	AIVR	STR, STR/REC, OFF, REC	STR
	COUPLET	STR, STR/REC, OFF, REC	STR
	BIGEMINY	STR, STR/REC, OFF, REC	STR
	TRIGEMINY	STR, STR/REC, OFF, REC	STR
	TACHY	STR, STR/REC, OFF, REC	OFF
	BRADY	STR,	OFF

		STR/REC, OFF, REC	
	AFIB	STR, STR/REC, OFF, REC	STR
	PAUS	STR, STR/REC, OFF, REC	OFF
	FREQUENT PVCs	-	-

The parameters in ST menu		
ST ANALYSIS	ON, OFF	OFF
ST ALARM	ON, OFF	OFF
ALARM LEVEL	1, 2	1
ST LOW ALARM	-2 to ST HIGH ALARM -0.1	-0.2

ST HIGH ALARM	ST LOW ALARM +0.1 to 2	0.2
EVENT DURATION	15S, 30S, 45S, 60S, OFF	OFF

The Parameters in BFA WINDOW		
EEG Gain	25uV,50-250uV	100uV
BFA ALARM	ON,OFF	OFF
BFI LOW	1~(HIGH-1)	35%
BFI HIGH	(LOW+1)~100	60%

The Parameters in GAS WINDOW(Mainstream & Sidestream)		
CO2 UNIT	KPa ,%V ,mmHg	mmHg
WORK MODE	MEASURE, STANDBY	MEASURE
ZERO	Only for Mainstream	
ALARM	ON,OFF	OFF
ALARM LEVEL	1,2	2
EtCo2 LOW	0.4~(HIGH-0.1) (%V)	2.6%V

EtCo2 HIGH	)LOW+0.1)~13(%V)	6.5%V	
FiCo2 HIGH	0.4~ 13(%V)	1.3%V	
EtO2,FiO2 LOW	18~(HIGH-1) (%V)	50% - (For IRMA ICU: 25)	
EtO2,FiO2 HIGH	)LOW+1)~105(%V)	100%	
AWRR LOW	1~(HIGH-1)	ADULT	NEONATE
		5 BrPM	15 BrPM
AWRR HIGH	)LOW+1) ~120	30 BrPM	60 BrPM
APNEA LIMIT	10s,15s,20s,25s,30s,35s,40s, OFF	30S	15S
O2 COMPENSATE	1-100 vol%, OFF	21% , AUTO	
N2O COMPENSATE	0-100 vol% (ONLY FOR ISA CO2, IRMA2 CO2)	0%	
SWEEP	3mm/s, 6mm/s, 12.5mm/s, 25mm/s	12.5mm/s	

SIGNAL SCALE	CO2	6%,10%,Auto scale	10%
	O2	0-50%,0-100%, Auto scale	100%
FIIL SIGNAL	ON,OFF		OFF
WAVE FORM	CO2, O2		CO2
GAS UNIT	KPa ,%V		%V

SYSTEM DEFUALT			
PAGE	PM4010	P1 … P23	P1
ALARM VOLUME	1,2,3,4,5,6,7,8		1
CALENDAR	SOLAR, CHRISTIAN		CHRISTIAN
PAT. CONF	ADUL,NEONATE,		ADULT

	PEDIATRIC	
BED NUMBER	1…99	01
Module Color		
ECG	-----	Green
SPO2	-----	Magenta
RESP	-----	Yellow
TEMP1,2	-----	Cyan
IBP1	-----	Light Red
IBP2	-----	Light Blue
IBP3	-----	Light Orange
IBP4	-----	Cyan
NIBP	-----	White
CO2	-----	Yellow
BFA	-----	White

Contents

APPENDIX II
Technical Alarms

Message	Cause	Solution	Explanation
SYSTEM Error Messages			
LOW BATTERY	Insufficient battery charge	Place the monitor on the station and connect the power cable to the station.	When the battery is running out of power, level III alarm is activated. If user does not apply AC power to the monitor, level II and I alarms are displayed respectively as the charge level decreases.
SYSTEM HARDWARE ERROR	Data storage failure	Contact the Customer Services department.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
ECG Error Messages			
ECG NO CABLE	ECG cable is not connected to the system.	Connect ECG cable.	Level 3 alarm. The message is displayed in the cyan background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
ECG CHECK LA,RA,LL	The mentioned lead is not properly connected.	Ensure that mentioned lead is connected properly.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
ECG DEFECT	ECG module failure	Turn off and on the monitor. If the message is displayed again, contact the Customer Services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.

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

Message	Cause	Solution	Explanation
CHECK LA OR ALL	LA or other leads are not properly connected to the patient.	Make sure that all electrodes especially LA and also ECG cable are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
CHECK RA OR ALL	RA or other leads are not properly connected to the patient.	Make sure that all electrodes especially RA and also ECG cable are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
ECG CHECK C (C2, C3, C4, C5, C6)	C lead is not properly connected to the patient.	Make sure that all mentioned electrodes and ECG cable are properly connected.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

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

Message	Cause	Solution	Explanation
SPO2 PROBE DEFECT	The SPO2 probe is damaged	Replace SPO2 probe by a correct one.	Level 2 alarm. The message is displayed in yellow background. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
SPO2 PROBE OFF	SPO2 probe may be detached from the patient finger.	Ensure that the probe is connected properly to the patient.	Level 3 alarm. The message is displayed in the cyan background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
SPO2 CHECK PROBE	SPO2 probe is not properly positioned to the patient	Make sure that the probe is attached properly to the patient. (Refer to Fig. 6-1)	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and alarm is disabled for at least 120s.

Message	Cause	Solution	Explanation
SPO2 HIGH AMBIENT LIGHT	This may be caused by entering environmental light into the probe	Make sure that SPO2 probe is properly connected to the patient (Refer to figure 7-4).	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and alarm is disabled for at least 120s.
SPO2 DEFECT	SPO2 module failure	Turn the system off and on. If the message persists, contact the Customer services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

Message	Cause	Solution	Explanation
SPO2 SEARCH	SPO2 is not calculable due to some reasons such as long time motions.	Attach the sensor to the other finger, provoke blood cycle, and calm the patient.	In this condition SPO2 value is not displayed.
SPO2 SIGNAL WEAK	The SPO2 signal amplitude is too weak or undetectable.	Change the probe position.	

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

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

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

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

Message	Cause	Solution	Explanation
SYSTEM FAILURE	Error occurs in pump, A/D sampling, pressure transducer or software.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
NIBP LOW BATTERY	The charge of the battery is low so NIBP measurement is not possible.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
NIBP MODULE ERROR	Failure during measurement	Wait for 10 seconds, then measure.	Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to gray and the system will ignore this fault.
NIBP NO MODULE	No NIBP module is installed.		Alarm level is set in NIBP alarm menu. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

NIBP Messages		
Message	**Cause**	**Solution**
NIBP STOP PRESSED	NIBP stop key has been pressed during measurement	
NIBP LEAKAGE O.K	Successful leakage test	

Message	Cause	Solution	Explanation
IBP Error Messages			
IBP1/IBP2 NO SENSOR	Channel 1 or 2 transducer is not connected.	Check the transducer connection.	Level 3 alarm. The message blinks and by pressing Alarm Silence key, alarm is disabled and the system ignores this fault.
IBP1/IBP2 ADJUST SCALE	IBP1 or IBP2 signal is out of display range for about 5 seconds.	Press <AUTO SCALE> in IBP WINDOW.	Level 3 alarm. The message blinks and by pressing Alarm Silence key, alarm is disabled and the system ignores this fault.
IBP1/IBP2 STATIC PRESSURE	This condition occurs when the maximum and minimum values of a pulsatile pressure signal (Just for IBP, ART, PAP, RVP and LVP labels) differ by less than 3mmHg.In this condition, only Mean		

	pressure is displayed. This message can be caused by the following reasons: - A physiological condition e.g. asystole - Transducer stopcock is closed to the patient. - A catheter tip lodged against a vessel wall. - A clot on the catheter tip.		
IBP1/IBP2 SEARCH	IBP signal can't be processed by the software because the signal is weak or less pulsatile.	- Check that all IBP measurement setup is suitable or not. - Check patient status and treat him, if necessary.	

GAS (Mainstream) Error Messages			
Alarm	**Cause**	**Solution**	**Explanation**
CO2 SYSTEM FAULT # 1,2,3,4	Sensor failure	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 REPLACE ADAPTOR	IR signal low	Change adapter	Level 2 alarm. the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO ADAPTOR	There is no adaptor connected to the sensor.	Connect adapter	Level 2 alarm. The message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

Alarm	Cause	Solution	Explanation
CO2 INVALID.	CO2 outside specified accuracy range.	Zero the sensor, if the problem still exists, contact after sales service of the manufacturer.	Level 2 alarm. 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, turn off and on the system and if again this message appears contact after sales service of manufacturer.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 INVALID PRESSURE	Ambient pressure outside operating range.	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

Alarm	Cause	Solution	Explanation
CO2 INVALID TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
O2 PORT FAILURE	Adapter O2 port Clogged or plugged.	Change the adapter.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
REPLACE O2 SENSOR	O2 sensor lifetime is finished.	Place new O2 sensor	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

Alarm	Cause	Solution	Explanation
ROOM AIR O2 CALIB REQUIRED	If the sensor operate for a long time period without being disconnected from the adapter or the operating temperature for oxygen sensor changes significantly.	Perform room air calibration.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 ZERO CALIB REQUIRED	Ambient Co2 is more than 800 PPM (0.08% V). In this condition measurement accuracy is low.	Automatic zeroing shall be performed in an environment with CO2 level less than 0.08% V.	Level 2 alarm. The message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

Alarm	Cause	Solution	Explanation
CO2 NO SENSOR	The sensor is disconnected from the system	Connect sensor if problem exist again, Contact after sales service of manufacturer.	Level 3 alarm. The message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
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.	

GAS (Sidestream) Error Messages			
Alarm	**Cause**	**Solution**	**Explanation**
CO2 SYSTEM FAULT # 1,2,3,4	Sensor failure	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.
CHECK SAMPLING LINE	IR signal low	Change sampling line	Level 3 alarm. The message is displayed in the cyan background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.

Alarm	Cause	Solution	Explanation
SAMPLING LINE CLOGGED	Sampling line occlusion	Remove obstruction otherwise change the sampling line by a correct one.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the 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 the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.
O2 INVALID.	O2 outside specified accuracy range.	Zero the system. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.

Alarm	Cause	Solution	Explanation
CO2 INVALID PRESSURE	Ambient pressure outside operating range.	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID TEMPERATURE	Internal temperature is outside operating range.	Turn the system off and on. If the problem still exists, contact the Customer services of the manufacturer.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.
REPLACE O2 SENSOR	O2 sensor lifetime is finished.	Replace O2 sensor with a new one.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.

Alarm	Cause	Solution	Explanation
O2 SENSOR ERROR	The Sensor failure	Replace O2 sensor by a new one.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.
O2 SPAN CALIB REQUIRED	If the sensor operate for a long time period without being disconnected from the sampling line or the operating temperature for oxygen sensor changes significantly	Perform room air calibration.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.

Alarm	Cause	Solution	Explanation
CO2 ZERO CALIB REQUIRED	Ambient Co2 is more than 800 PPM (0.08% V). In this condition measurement accuracy is low.	Automatic zeroing shall be performed in an environment with CO2 level less than 0.08% V.	Level 2 alarm. The message is displayed in the yellow background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled for 120 sec.
CO2 NO SENSOR	The sensor is disconnected from the system	Connect the sensor. If the problem still exists, contact the Customer services of the manufacturer.	Level 3 alarm. The message is displayed in the cyan background. By pressing ALARM SILENCE, the background becomes gray and alarm is disabled and ignores this fault.

Alarm	Cause	Solution	Explanation
CO2 SENSOR STANDBY MODE	Manual setting. No breath is detected for 30 min and ETCO2 is less than 4 mmHg for more than 30 min. The monitor does not detect the sampling line.	Enter GAS window and set WORK MODE on MEASURE.	
Recorder Error Messages			
Alarm	**Cause**	**Solution**	**Explanation**
Rec. Software Error	Software error	Turn the system off and on. If the problem persists, contact the Customer services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

Alarm	Cause	Solution	Explanation
Recorder Fault	Hardware error	Turn the system off and on. If the problem persists, contact the Customer services.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Rec Door Open	The recorder door is open	Close the recorder door.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.
Rec Paper Out	Recorder paper has been finished	Insert a new paper roll.	Level 2 alarm. The message is displayed in the yellow background. By pressing Silence key, the message background will change to the gray and the system will ignore this fault.

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

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

Physiological Alarms

Alarm	Situation	Visual Alarm	Audio Alarm
ECG Alarms			
HR HIGH	Heart rate violates adjusted high alarm limit.	• HR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background color corresponding to its level.	Activated
HR LOW	Heart rate violates adjusted low alarm limit.	• HR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background color corresponding to its level.	Activated
ECG ASYSTOLE	Heart beat is not detected in last 10 seconds.	• HR is "00" and blinks • "ECG ASYSTOLE" is displayed. • Alarm indicator flashes. • Alarm message is displayed in a background color corresponding to its level.	Activated

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

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

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

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

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

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

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

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

	alarm limit.	background color corresponding to its level.	

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

	limit.	corresponding to its level.	

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

		its level.	

GAS (Mainstream & Sidestream) Alarms			
Alarm	**Situation**	**Visual Alarm**	**Audio Alarm**
AWRR HIGH	Respiration rate violates adjusted high limit	• AWRR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
AWRR LOW	Respiration rate violates adjusted low limit	• AWRR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 HIGH	End Tidal Co2 violates adjusted high limit	• EtCo2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated

Alarm	Situation	Visual Alarm	Audio Alarm
EtCo2 LOW	End Tidal Co2 violates adjusted low limit	• EtCo2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
FiCo2 HIGH	FiCo2 violates adjusted high limit	• FiCo2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
CO2 RESP APNEA	Non-respiration condition overruns adjusted time	• Alarm indicator flashes. • Message "CO2 RESP APNEA" blinks in red background.	Activated
EtO2 HIGH	End Tidal O2 violates adjusted high limit	• EtO2 value blinks. • Alarm indicator flashes. • Alarm message	Activated

		is displayed in a background corresponding to its level.	
EtO2 LOW	End Tidal O2 violates adjusted low limit	● EtO2value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
FiO2 HIGH	FiO2 violates adjusted high limit	● FiO2 value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated
FiO2 LOW	FiO2 violates adjusted low limit	● FiO2 value blinks. ● Alarm indicator flashes. ● Alarm message is displayed in a background corresponding to its level.	Activated

Alarm	Situation	Visual Alarm	Audio Alarm
FiO2 Too LOW	FiO2 falls below 18%.	• FiO2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
ST Alarms			
ST HIGH	ST segment value violates adjusted high limit	• ST value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
ST LOW	ST segment value violates adjusted low limit	• ST value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated

Arrhythmia Alarms			
Alarm	**Situation**	**Visual Alarm**	**Audio Alarm**
ASYSTOLE ARRHYTHMIA	5 seconds pass without the detection of valid QRS complex.	• Alarm indicator flashes. • Alarm message is displayed in red background.	Activated
VFIB ARRHYTHMIA	Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics.)Certain ventricular tachycardias have sinusoidal waveforms closely resembling those of ventricular fibrillation. Because of the similarity of these	• Alarm indicator flashes. • Alarm message is displayed in red background.	Activated (If ARR Monitoring is ON)

	waveforms, the monitor may classify such types of ventricular tachycardia as ventricular fibrillation(.		
VTAC ARRHYTHMIA	Ventricular Tachycardia: N or more PVC's are detected in a time interval T= (60*(N-1))/R, where N is defined as the VTAC count and R is defined as the VTAC rate.	• Alarm indicator flashes. • Alarm message is displayed in red background.	Activated (If ARR Monitoring is ON)
RUN ARRHYTHMIA	Ventricular Run: Series of 3 to N-1 consecutive PVCs with a beat to beat rate ≥ the VTAC rate.	• Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated (If ARR Monitoring and Alarm indications are ON)

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

	PVC, PVC		are ON)

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

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

APPENDIX III
MASIMO MODULE

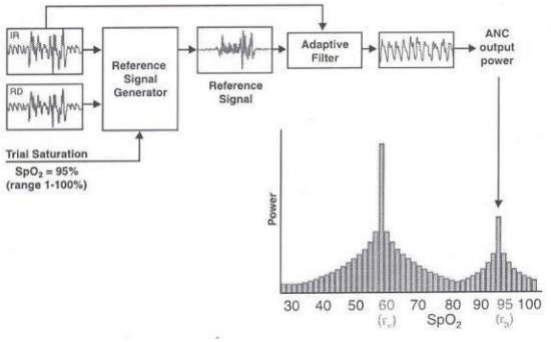
Signal Extraction Technology

INTRODUCTION

Masimo SET® pulse oximetry is a new and fundamentally distinct method of acquiring, processing and reporting arterial oxygen saturation and pulse rate. As illustrated below, Masimo SET technology enables the power of adaptive filters to be applied to real-time physiologic monitoring by utilizing proprietary techniques to accurately establish a “noise reference” in the detected physiologic signal, thus enabling the direct calculation of arterial oxygen saturation and pulse rate. Because it is not bound by a conventional “red over infrared” ratio

approach, the Masimo SET system substantially eliminates the problems of motion artifact, low peripheral perfusion and most low signal-to-noise situations. This greatly extends the utility of SpO2 in high motion, low signal and n o i s e i n t e n s i v e e n v i r o n m e n t s .

Discrete Saturation Transformation (DST®) Algorithm

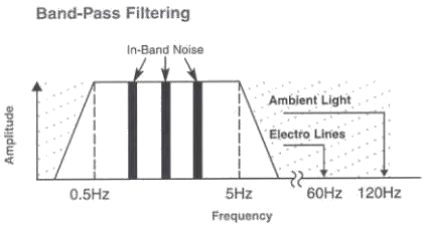


Masimo SET's most powerful algorithm is DST. All algorithms depend upon assumptions. The more assumptions, the weaker the algorithm. DST makes only one assumption - that arterial blood has a higher oxygenation than venous – making it the most powerful pulse oximetry algorithm.

CONVENTIONAL FILTERS

While pulse oximetry is readily accepted as a standard of care in the Operating Room, Recovery Room and most Intensive Care Units, its performance in high motion environments or in patients with low perfusion is substantially less than ideal. The reported high incidence of false alarms due to motion artifact and the inability of conventional pulse oximetry systems to provide information during times of crisis have led to its

characterization as a “fair weather friend.” Confronted with the problem of motion artifact, false alarms and poor "signal to noise" environments, medical equipment manufacturers have utilized band-pass filtering in an attempt to address these confounding clinical problems. Band-pass filters, whether in analog or digital form, are designed to allow only a physiologic window of interest to pass while rejecting frequencies outside the desired frequency band. With the advent of Digital Signal Processing (Digital Filtering), the performance of band-pass filtering was improved, but was still unable to address the problem of noise occurring within the bandwidth of interest.



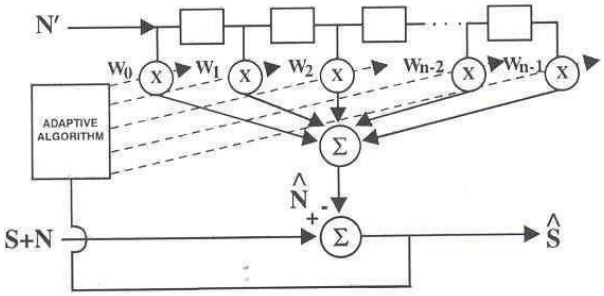
ADAPTIVE FILTERS

To address the confounding issue of "in-band" noise, a class of filters known as adaptive digital filters has evolved. These filters take advantage of the fact that the construction of the filter itself is contained within the memory of the microprocessor, allowing its multiplication coefficients, symbolized as W0, W1,...Wn-1, to be changed in real time, hence altering the filter's characteristic. Thus, the filter can be tuned “on the fly.” The multiplication coefficients determine whether the frequency components

of an input signal should be cancelled (e.g., multiplied by zero) or allowed to pass (e.g., multiplied by one). Given that the filter's coefficients can be rapidly changed, adaptive filters derive their name in their ability to change their filtering characteristics in response to changing in-band noise.

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

the desired signal portion (S^). The combination comprising the adaptive filter and the subtracter is commonly called an adaptive noise canceller (ANC).



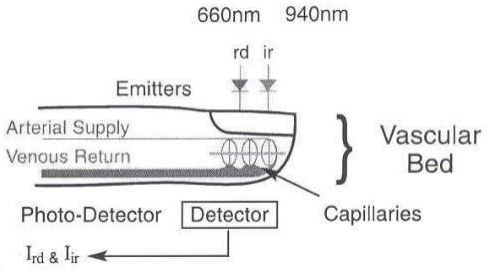
Adaptive Noise Canceller (ANC) block diagram

This approach has been widely used in the telecommunications and aerospace industries where a

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

CONVENTIONAL PULSE OXIMETRY

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



Basis For Measurement:

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

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

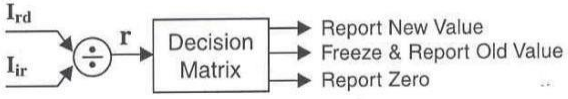
In a large noise environment, conventional wisdom holds that pulse oximetry will yield an optical density ratio

substantially equivalent to "noise over noise" or a ratio of one . This is eq uivalent to a saturatio n value o f approximately 82% in most conventional systems.

If: $N >> S$,

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

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



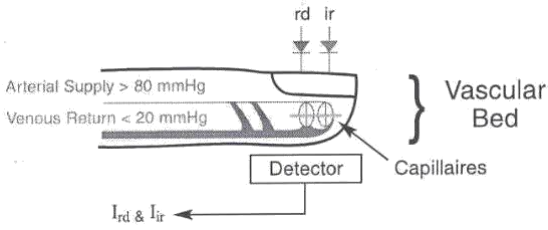
The attempt to treat the "symptom" rather than the “core problem” does not provide clinicians with continuous real-time information and can be unreliable in critical medical situations.

MASIMO SET® PULSE OXIMETRY

Masimo Signal Extraction Technology rejects the conventional wisdom and begins with an understanding that during patient motion the venous blood, being at a relatively low pressure, is quite susceptible to the local effects of perturbation during motion. Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion, representing a significant source of in-band noise within the frequency bandwidth of interest. In addition, the venous blood is a strong absorber of light. Hence, it can represent a

significant contributor to the total optical density during motion episodes. Furthermore, the venous blood saturation is normally lower than the arterial blood saturation. This explains why saturation values tend to drop in conventional pulse oximeter systems during episodes of patient motion.

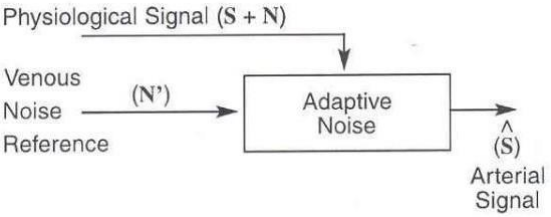
During routine patient motions (shivering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio based oximetry system. Having identified the venous blood as a significant contributor to noise during motion, it follows that if the noise reference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



GENERATING A NOISE REFERENCE

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

light. The resultant is a reference signal that contains only noise portions. This is the noise reference signal (N')



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

DISCRETE SATURATION TRANSFORM®

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

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

If:

① $I_{rd} = S_{rd} + N_{rd}$

② $I_{ir} = S_{ir} + N_{ir}$

③ $r_a = \frac{S_{rd}}{S_{ir}}$

$S_{rd} = r_a \cdot S_{ir}$

Then:

$I_{rd} - [I_{ir} \cdot r_a] = [S_{rd} + N_{rd}] - [S_{ir} r_a + N_{ir} r_a]$

Substituting $S_{ir} r_a$ for S_{rd}, we get:

$= [S_{ir} r_a + N_{rd}] - [S_{ir} r_a + N_{ir} r_a]$

$= N_{rd} - N_{ir} r_a$

$= N'$ **(Noise Reference)**

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

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

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

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

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

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

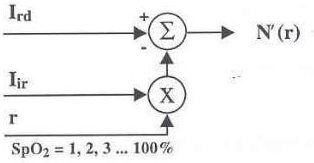
Case I: $r \neq r_a, r_v$ $\quad N'(r) = (r_a - r) S_{ir} + (r_v - r) N_{ir}$

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

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

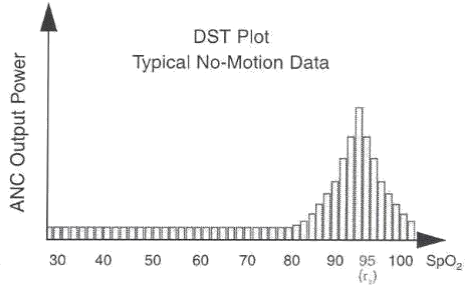
For each selected value of the optical density ratio, the corresponding reference signal is calculated and subsequently processed through an adaptive noise canceller.

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



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

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



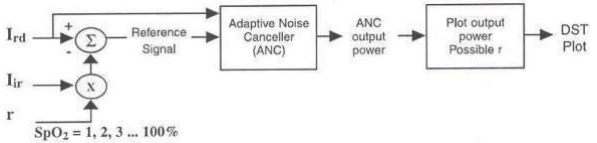
In summary, the procedure for determining the arterial oxygen saturation utilizing Masimo SET processing is as follows:

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

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

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

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



The procedure demonstrates another important feature of Masimo SET pulse oximetry. It is able to calculate the arterial oxygen saturation without first extracting or determining discrete pulses in the physiologic data. For Masimo SET processing, the saturation algorithm is independent of the pulse rate algorithm. This is a

significant distinction between Masimo SET systems and conventional pulse oximetry systems where the recognition of a clean pulse is a prerequisite for the calculation of accurate arterial oxygen saturation. Another advantage of Masimo SET technology is that it can monitor arterial oxygen saturation and pulse rate even if the motion starts before the pulse oximeter is turned on. It does not require clean data during instrument start-up.

Results of clinical research and evaluation performed for determining Rainbow measurement accuracy

1. SPO2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SPO2, 0-40% SpCO, and 0-15% SpMet against a laboratory CO-Oximeter. SPO2 and SpMet accuracy was determined on 16 neonatal NICU

patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SPO2 and 0.9% SpMet.

2. The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SPO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
3. The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range

of 70-100% SPO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

4. The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
5. The Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation wich encompasses 68% of the population.

6. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8-17 g/dl SpHb against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.
7. The following substances may interfere with pulse CO-Oximetry measurements:

- Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SPO2 and SpCO measurements.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SPO2 measurements.
- Very low arterial Oxygen Saturation (SPO2) levels may cause inaccurate SpCO and SpMet measurements.

- Severe anemia may cause erroneous SPO2 readings.
- Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Elevated levels of total bilirubin may lead to inaccurate SPO2, SpMet, SpCO and SpHb readings.

APPENDIX IV

EMC

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

Measurements can be affected by mobile and RF communications equipment. It should be assured that the bedside monitor is used in the electromagnetic environment specified.

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

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The ***PM4010*** Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ***PM4010*** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **PM4010** 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 **PM4010** is suitable for use in all establishments,

Harmonic emissions IEC 61000-3-2	Complies	including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ***PM4010*** Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ***PM4010*** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least

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

interruptions and voltage variations on power supply input lines IEC 61000-4-11	for 0.5 cycle 40% U_T (>60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec		that of a typical commercial or hospital environment. If the user of the **PM4010** requires continued operation, it is recommended that the ***PM4010*** be powered from an uninterruptible power supply or a battery.

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The **PM4010** Patient Care Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the ***PM4010*** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ***PM4010***, including cables, than the recommended separation distance

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

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

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

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

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

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

electromagnetic site survey should be considered. If the measured field strength in the location in which the ***PM4010*** is used exceeds the applicable RF compliance level above, the ***PM4010*** should be observed to verify normal operation. If abnormal performance is observed, additional measures may necessary, such as reorienting or relocating the ***PM4010.***

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

Recommended separation distances between

Portable and mobile RF communications equipment and the

Vital Sign Monitor

The ***PM4010*** Patient Care Monitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***PM4010*** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***PM4010*** as recommended below, according to the maximum output power of the communications equipment.

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

APPENDIX V
IRMA Design and Theory

This section describes the basic concepts used in PHASEIN IRMA in terms of design, technical solutions and gas measurement.

1. Basic design features

PHASEIN IRMA mainstream multi-gas probe consists of an IRMA sensor head, an oxygen sensor cell (optional) and an airway adapter. As all necessary calibration constants are stored within each IRMA sensor head, the probes can be replaced without the need for recalibration.

Figure 1. *PHASEIN probe with airway adapter.*

The IRMA sensor head includes a multi-channel IR bench, a barometric pressure sensor, a signal processor, a power regulator, and a RS-232 digital interface.

Figure2. *PHASEIN probe with airway adapter and O2 sensor –XL.*

The ultra compact multi-channel IR micro bench comprises a high reliability infrared source, an infrared chopper wheel with an integrated brush less DC micro motor, an infrared detector and all necessary components for processing the infrared measurement signal.

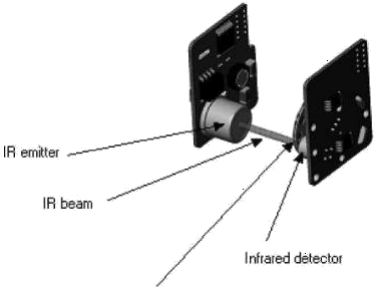


***Figure3.IRMA** multi-channel IR micro bench*

The airway adapter, with or without an oxygen port (optional), includes the optical components for measuring gases - the XTP™ windows that are transparent to light in the wavelength ranges of interest.

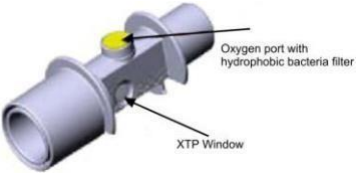


***Figure 4.** IRMA airway adapter with oxygen port.*

Figure 5. *IRMA airway adapter without an oxygen port.*

The ultra fast response time oxygen sensor is normally integrated in the IRMA probes OR/OR+ allowing proximal measurement of INSP/EXP oxygen concentrations.

Figure 6. *IRMA ultra fast response time oxygen sensor.*

2. Gas measurement and identification

The IRMA probe snaps in place on the top of the airway adapter. The IRMA airway adapter is, for example inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained by continuously measuring the infrared light absorption, through the XTP windows in the gas flow through the adapter.

To measure the concentrations and identify the gases, absorption of up to nine different wavelengths of infrared light is measured.

Figure 7. *PHASEIN IRMA IR light path through the IRMA airway adapter.*

The measurement of CO2, N2O and anesthetic agents in the breathing gas mixture is based on the fact that the different gas components absorb infrared light at specific wavelengths.

A microprocessor continuously calculates the CO2, N2O and anesthetic agent concentrations from the infrared light absorption measurements, using matrix calculations to automatically identify which anesthetic agents are present in the gas mixture. Mixtures of maximum two anesthetic agents are automatically identified and both agents are measured. If more than two agenets are present simultaneously in a gas mixture, an alarm will be set.

Oxygen does not absorb infrared light to the same extent as other breathing gases and is therefore measured using an ultra rapid response time oxygen sensor (see Section 2.2 Oxygen measurement).

2.1 Infrared measurement technology

The absorption spectra for CO2, N2O and the five anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane are shown in the figure below.

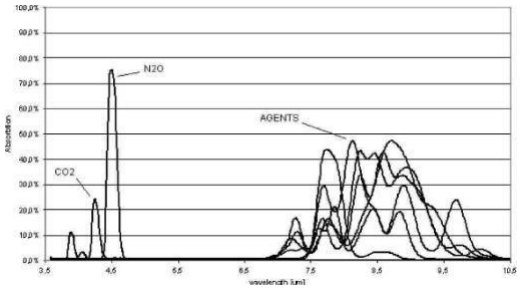


***Figure* 8.** *Absorption spectra*.

PHASEIN IRMA uses the absorption peaks at 4.2 and 3.9 µm for the measurement of CO2 and N2O respectively, and five different wavelengths in the 8-12 µm range for anesthetic agent measurements. Two additional wavelengths beside the absorption peaks are used as references. To measure the absorption of light at these

wavelengths, a broadband infrared radiation source is used. The light transmitted from the infrared source passes through the XTP windows in the airway adapter and is then filtered using a set of narrow optical band pass filters. The individual filters are mounted in a rapidly rotating filter wheel that intersects the light path before the light reaches the infrared detector.

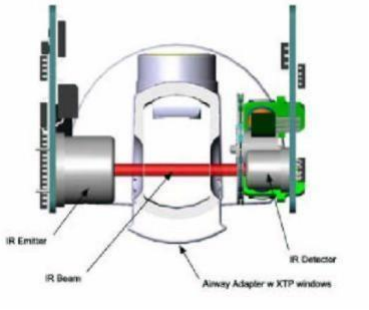


Figure 9. *Optical path*

No radiation will be absorbed if the airway adapter is empty. The output signal from the detector will thus have its maximum amplitude at a concentration of zero, with lower amplitudes at higher concentrations.

2.2 Oxygen measurement

A fuel cell oxygen sensor uses a membrane that allows diffusion of O2 into the sensor. Inside the sensor, there is a sensing electrode (cathode) made of a noble metal such as gold or platinum, and a working electrode made of a base metal such as lead or zinc. The electrodes are immersed in an electrolyte. Fuel cell oxygen sensors are current generators and do not require any external power supply. By connecting a resistor between the anode and the cathode, a voltage proportional to the 02 concentration is generated. Since the measurement involves a chemical reaction, the fuel cell is gradually consumed during the process (also when the equipment is not in use), and requires replacement at regular intervals.

PHASEIN's oxygen sensor is specially designed to provide an ultra fast response time, thus allowing a breath-by-breath analysis of the oxygen waveform at a proximal location (i.e. between the patient's endotracheal tube and the Y-piece of the breathing circuit). The vast majority of oxygen sensors available on the market are normally too slow for a breath-to-breath gas analysis.

For monitors, anesthesia machines and ventilators already equipped with oxygen measuring devices, the IRMA probe is available with an O2 sensor dummy instead of thenormal oxygen sensor. Figure 11 shows an IRMA with theoxygen sensor dummy and figure 2 shows an IRMA with oxygen sensor installed.

3. PHASEIN XTP™ airway adapter

The IRMA disposable airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing

circuit. The respiratory gas measurements are obtained through the XTP windows in the sides of the adapter.

As the airway adapter is positioned directly in the airway, its performance can be affected by water vapor, patient secretions or nebulized medications that can accumulate on the adapter's windows. The use of metered does inhalers can also affect the adapter.The water vapor can condense on the surface of the adapter windows in the format of small discrete water droplets. This condensation can affect the light absorption through the windows thus affecting the precision of the measurement.

The design and material technology of the XTP windows have special features that prevent a decrease in performance when water vapor is present.

The root cause of water droplet formation is the difference in surface tension between the plastic and water. This mismatch means that the water condenses into discrete droplets with a high contact angle. Figure 10

illustrates a water droplet with various contact angles showing the effects of condensed water on light transmission.

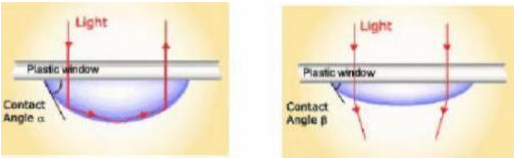


Figure 10. *Effect of condensed water on light transmission.*

The XTP windows are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission. Figure 11 illustrates the light transmission in a XTP window.

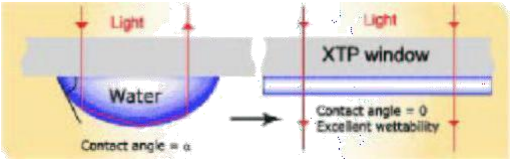


Figure11. *Light transmission through a XTP window*

For optimal results, the airway adapter shall not be placed between an endotracheal tube and an elbow, as this may allow patient secretions to block the adapter windows. The IRMA airway adapter shall be positioned with its windows in a vertical position to help keep patient secretions from pooling on the windows.

The airway adapter is designed as a disposable for both adult/pediatric and infant applications. The adult/pediatric adapter is available with or without an oxygen port, Fig. 12.

Figure 12. *IRMA airway adapters: Adult/pediatric with and without an oxygen port and infant adapter.*

The airway adapter with an oxygen port is equipped with a hydrophobic bacteria filter to protect the oxygen sensor from contamination. Figure.13 illustrates the flow of gases in the adapter and the location of the hydrophobic bacteria filter.

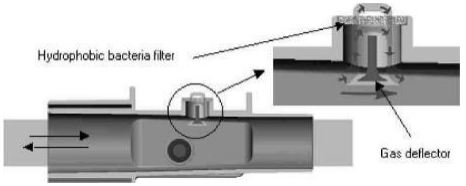


Figure13. *Flow of gases through an IRMA airway adapter with an oxygen port.*

For monitors, anesthesia machines and ventilators already equipped with oxygen measuring devices, the airway adapter is available without an oxygen sensor port (see Fig.13).

Do not use the IRMA adult/pediatric airway adapter with infants as the adapter add 6 ml dead space to the patient circuit.

The IRMA infant airway adapter has specially designed connectors for minimizing the dead space (see fig. 12) and can be used even for very small patients. The infant adapter is available without an oxygen port only.

Effect of water vapor

The total pressure of the gas mixture is estimated by measuring the actual barometric pressure in the IRMA sensor .The partial pressure and the volume percentage of CO2 ,N2O ,O2 and anaesthetic agents depend on the

amount of water vapor in the breathing gas. The O2 measurement will be calibrated to show 20.8% at actual ambient temperature and humidity level, instead of showing actual partial pressure.

20.8 vol % O2 corresponds to the actual O2 concentration in room air with 0.7 vol% H2O concentration (at 1013hPa this equals for example at 25°C and 23% RH). The measurement of CO2, N2O and anaesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

The effects of water vapor are illustrated by the examples in the following table.O2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H2O. The two columns to the right show the relative error in displayed concentrations when adding or removing water vapor from the gas mixture, and referencing the measurement to dry gas conditions at actual temperature and pressure (ATPD) or saturated conditions at body temperature (BTPS).

Temp [C]	RH [%]	P [[hPa]	H2O part. pres. [[hPa]	Err(rel) [%]	err(rel) ATPD[%]	err(rel)[%] BTPS
10	20	1013	2	0	-0.2	+6.0
20	20	1013	5	0	-0.5	+5.7
25	0	1013	0(ATPD)	0	0	+6.2
25	23	1013	7.3	0	-0.7	+5.5
25	50	1013	16	0	-1.6	+4.6
30	80	1013	42	0	-4.1	+2.0
37	100	1013	63(BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

The table above illustrates that the gas concentrations in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

If calibration of O2 is not performed with room air humidity equal to 0.7 vol% H2O ,the difference between

the O2 concentration delivered by IRMA and the actual partial pressure of O2 will be equal to the concentration of ambient water vapor -0.7%(O2 diff [%] = Conc H2O[%]-0.7%.

For example, if a room air calibration of O2 is performed at a humidity of 1.6 vol% H2O (corresponding to 50% RH at 25°C and 1013 hPa) the standard calibration value of 20.8 vol% O2 will be 1.6%-0.7%=0.9% too large. The correct O2 concentration (actual partial pressure of O2) at theses conditions is (1-0.009)*20.8=20.6 vol%O2.

APPENDIX VI
ISA Design and Theory

1. Gas measurements

The measurement of CO2, N2O and anesthetic agents is based on the fact that different gases absorb infrared light at specific wavelengths. The analysis of respiratory gases by the ISA gas analyzers are therefore performed by continuously measuring the infrared light absorption in the gas flow through an infrared spectrometer. Oxygen, on the other hand, does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods.

The gas analysis

At the heart of an ISA gas analyzer, the SIGMA spectrometer is seated. The SIGMA spectrometer uses a proprietary broadband infrared radiation source to transmit light through the gas sample. Before reaching the gas sample, the light path is intersected by narrowband optical filters that only let through light corresponding to selected wavelength peaks of the measured gases. At the other end of the light path, a sensor detects the portion of the light that is not absorbed by the gas. The amplitude of the detector output is an inverse function of the gas

concentration. Thus, at a concentration of zero, the amplitude is at its maximum.

If the gas sample is a mixture of several components that absorb light at the same wavelength, such as a mixture of two anesthetic agents, the absorbed radiation will be the sum of the absorption of the agents. To determine the concentration of each of the individual gases, several filters have to be used. The ISA gas analyzers therefore uses the SIGMA spectrometer, which contains up to nine different narrowband filters to facilitate simultaneous measurement of CO2, N2O and a mixture of any two of the five anesthetic agents.

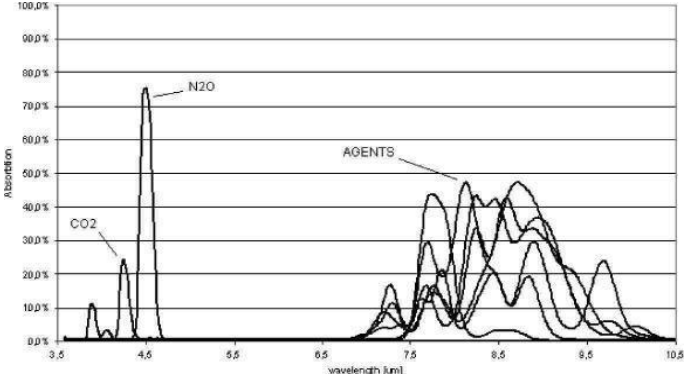


Figure 1. *Gas absorption spectra*

The selection of the optical filters within the spectrometer is crucial to the characteristics and performance of the gas analyzers. The SIGMA spectrometer uses the strong absorption peaks at 4.2 and 4.5 µm for CO2 and N2O measurements and five wavelengths in the 8 to 10 µm long wave infrared range (LWIR) for the anesthetic agent calculations. The LWIR contains strong absorption peaks for the anesthetic agents and negligible interference from other common respiratory gases, such as alcohol and acetone, that could degrade measurement accuracy.

In addition to the measurement filters, two optical filters appropriately located within the 4 to 10 µm range are used as references.

2. Oxygen measurement

Oxygen does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods. The ISA OR+ analyzer is fitted with a paramagnetic oxygen sensor, and the ISA AX+ module is designed be fitted with either a paramagnetic or a galvanic (fuel-cell) oxygen sensor.

Paramagnetic oxygen analysis

Paramagnetic oxygen analyses are based on measurements of the attractive force exerted by a strong magnetic field applied to the oxygen molecules in a gas mixture. The paramagnetic analyzer distinguishes oxygen from other gases as a function of their magnetic susceptibility. Due to its paramagnetic nature, oxygen is attracted into the magnetic field, while most other gases are not. On a scale, where oxygen is assigned the value 100, most other gases have a magnetic susceptibility of close to zero.

The Servomex sensor

An oxygen sensor well suited for the ISA gas analyzer is the PM1116 paramagnetic oxygen sensor from Servomex. In this sensor, a symmetrical non-uniform magnetic field is created. If oxygen is present, it will be attracted into the strongest part of this field. Two nitrogen-filled glass spheres are mounted on a rotating suspension within the magnetic field. Centrally on this suspension, a mirror is mounted. A light beam projected on the mirror is reflected onto a pair of photocells. Oxygen attracted into the magnetic field will push the glass spheres from the strongest part of the magnetic field, causing the suspension to rotate. When this rotation is detected by the photocells, a signal is generated and passed to a feedback

system. The feedback system will pass a current around a wire mounted on the suspension, causing a restoring torque that keeps the suspension in its original position. The current flowing around the wire is measured. This current is directly proportional to the oxygen concentration.

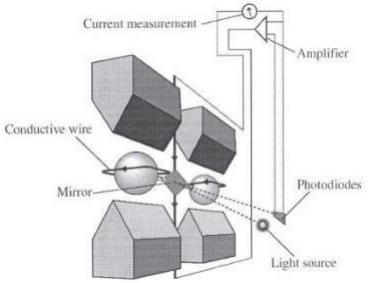


Figure 2. *Oxygem measurement with Servomex PM1116 paramagnetic oxygen sensor.*

The most important benefits of the paramagnetic oxygen sensor are:

•Fast rise time

•High stability and accuracy

•No chemicals to replace or renew

•Low maintenance requirements

Galvanic oxygen analysis

As an alternative to the paramagnetic sensor, the ISA gas analyzer is designed be fitted with a galvanic oxygen sensor. A galvanic fuel-cell oxygen sensor uses a membrane that allows diffusion of O2 into the sensor. Inside the sensor, there is a sensing electrode (cathode) made of a noble metal such as gold or platinum, and a working electrode made of a base metal such as lead or zinc. The electrodes are immersed in an electrolyte. Fuel-cell oxygen sensors are current generators and do not require any external power supply. By connecting a resistor between the anode and the cathode, a voltage proportional to the O2 concentration is generated.

Since the measurement involves a chemical reaction, the fuel cell is gradually consumed during the process (also when the equipment is not in use), and requires replacement at regular intervals.

3. Sampling

A sidestream gas analyzer continuously removes a gas sample flow from the respiratory circuit, for example a nasal cannula, a respiratory mask or the Y-piece of an intubated patient. The gas sample is fed through a sampling line to the gas analyzer. The sampled gas is usually warm and humid, and cools down in contact with the wall of the sampling line. Water therefore condenses in form of droplets on the inner wall of the sampling line. These droplets could potentially occlude the sampling line and interfere with the gas measurement.

The Nomoline

To overcome the shortfalls of current gas sampling solutions, the Nomoline sampling line has been developed for the ISA sidestream gas analyzers.

Warning: Use only Nomoline sampling lines manufactured by PHASEIN.

Unlike traditional solutions that remove water vapor and collect water in a container, the Nomoline sampling line incorporates a unique water separation section, the NOMO section. This section is made of a special polymer and a hydrophobic bacteria filter that removes water

vapor and aspired or condensed water. Water and water vapor passes through the membrane-like surface of the sampling line and evaporates into the surrounding air,while leaving O2, CO2 and anesthetic gases unaffected.

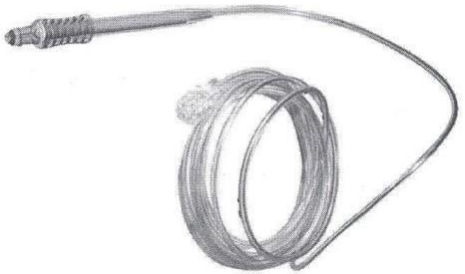


Figure 3. *The Nomoline (no moisture) sampling line.*

To protect the ISA analyzer, the Nomoline includes a filter with the bacterial filter efficiency of
$\geq$ 99.9980 %. It is important to be aware that secretions and nebulized medications may attach to the surface of the bacteria filter, and may cause clogging.

Warning: Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

The Nomoline sampling lines are specially designed for 50 ml/min low sample flow applications. The Nomoline has a very low dead space that results in an ultra-fast rise time, making measurements of CO2, N2O and anesthetic agents possible even at high respiratory rates. ISA sidestream gas analyzers are therefore suitable for adult, pediatric and infant patients.

The Nomoline sampling line is available in 2 and 3 meter versions and comes with a male Luer Lock type connector to work with different kinds of third-party sampling equipment, including patient interfaces for intubated, nasal and oral sampling. Although the selection of optimal patient interfaces is crucial, the Nomoline sampling line fits in any normal configuration.

Flow control

During normal operation, a sidestream gas analyzer is continuously fed with a small sample gas flow. To pull the gas through the sampling line and maintain a steady flow, a high-precision flow control system is required. In ISA sidestream gas analyzers, the flow control system

consists of an integrated micro pump, a zero valve and a flow controller. The pump is fitted with a low-power brushless motor having three miniature ball bearings to ensure trouble free operation without regular maintenance. Its balanced shaft design and integrated pneumatic filter virtually eliminate pressure and flow variations.

System response

In any sidestream gas monitoring system, there are three major time parameters involved:

•Total system response time

•Delay time

•Rise time

When designing a sidestream gas monitoring system, the physical characteristics of several components have to be considered. Parameters such as sampling volume, tubing material, tubing diameter and the physical design of the sampling interfaces play decisive roles in determining the responsiveness of the system.

Generally, the total system response time equals the delay time plus the rise time.

The delay time is defined as the time required for a step function change at the sampling site to result in 10% of the final value. Parameters affecting the delay time are the sample flow rate, tubing length and tubing inner diameter. In mainstream gas monitoring, where no tubing exist, the delay time is virtually zero, whereas a sidestream system has a sample delay time of a few seconds.

The rise time is defined as the time required for a step function change at the sampling site to bring about a rise from 10% to 90% of the final gas concentration value.

4. Gas data concentration

Gas measurement units

Gas concentration is reported in units of volume percent. The concentration is defined as:

$$\% \text{ gas} = \frac{\text{Partial pressure of gas component}}{\text{Total pressure of gas mixture}} * 100$$

The total pressure of the gas mixture is measured by a cuvette pressure sensor in the ISA gas analyzer.

For conversion to other units, the actual atmospheric pressure sent from the ISA sidestream analyzer may be used, e.g.

CO2 in mmHg = (CO2 concentration) x (atm. pressure value in kPa from ISA) x (750 / 100).

Example: 5.0 vol% CO2 @ 101.3 kPa Ö 0.05 x 101.3 x 750 / 100 = 38 mmHg

Effects of humidity

The partial pressure and the volume percentage of CO2, N2O, O2 and anesthetic agents depend on the amount of water vapor in the measured gas. The O2 measurement will be calibrated to show 20.8 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure. 20.8 vol% O2 corresponds to the actual O2 concentration in room air with 0.7 vol % H2O concentration (at 1013 hPa this equals for example 25°C and 23% RH). The measurement of CO2, N2O, and anesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS).

When the breathing gas is sampled, and passing the sampling line, the gas temperature will get close to the ambient temperature before reaching the ISA sidestream gas analyzer. As the Nomoline removed all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.

If CO2 values at BTPS are required, the following equation can be used:

EtCO2 (BTPS) = EtCO2 * (1 – (3.8 / Pamb))

where:

EtCO2 = EtCO2 value sent from ISA [vol %] Pamb = Ambient pressure sent from ISA [kPa]

3.8 = Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa] EtCO2(BTPS) = EtCO2 gas concentration at BTPS [vol%]

O2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H2O.

Spectral broadening

The presence of oxygen and nitrous oxide can cause some interference in the CO2 measurement. This is known as spectral broadening.

Nitrous oxide, N2O:

ISA sidestream analyzers capable of N2O measurements automatically compensates for spectral broadening caused by nitrous oxide.

When using an ISA sidestream gas analyzer without this capability, the current nitrous oxide concentration should be transmitted to the ISA Gas analyzer using the SetN2O command.

For most applications, sufficient accuracy in CO2 measurement will be achieved by setting N2O to one standard concentration used always with N2O in use, as recommendation 50 vol%, SetN2O 50 for actual concentrations in the span 30 – 70 vol% N2O. When N2O is not in use send SetN2O 0. The default value is 0.

By using this range, see table below, the maximum CO2 error with N2O compensation on (30-70%) will be limited to 3.2 % relative.

N2O range	N2O parameter
0-30 vol%	0
30-70 vol%	50

Oxygen, O2:

ISA sidestream analyzers capable of O2 measurements automatically compensates for spectral broadening caused by nitrous oxide.

When using an ISA sidestream gas analyzer without this capability, the current nitrous oxide concentration should be transmitted to the ISA Gas analyzer using the SetO2 command.

For most applications, sufficient accuracy in CO2 measurement will be achieved by dividing the oxygen concentration into three ranges: “high”, “medium” and “low”. By using these ranges, along with the SetO2 values in the table below, the maximal relative CO2 error will be limited to 1.2%.

O2 range	O2 parameter
0-30 vol%	0
30-70 vol%	50
70-100 vol%	85

5. Interfering gas and vapor effects

Gas or vapor	Gas level	CO2		Agents	N2O
		ISA CO2	ISA AX+	- 1)	- 1)
N2O 4)	60 V%	- 2)		- 1)	- 1)
HAL 4)	4 V%	- 1)		- 1)	- 1)
ENF , ISO , SEV 4)	5 V%	+8 % of reading 3)		- 1)	- 1)
DES 4)	15 V%	+12 % of reading 3)		- 1)	- 1)
Xe (Xenon) 4)	80 V%	-10 % of reading 3)		- 1)	- 1)
He (Helium) 4)	50 V%	-6 % of reading 3)		- 1)	- 1)
Metered dose inhaler propellants 4)	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol) 4)	0.3 V%	- 1)	- 1)	- 1)	- 1)
C_3H_7OH (Isopropanol) 4)	0.5 V%	- 1)	- 1)	- 1)	- 1)
CH_3COCH_3 (Acetone) 4)	1 V%	- 1)	- 1)	- 1)	- 1)
CH_4 (Methane) 4)	3 V%	- 1)	- 1)	- 1)	- 1)
CO (Carbon monoxide) 5)	1 V%	- 1)	- 1)	- 1)	- 1)

NO (Nitrogen monoxide) [5]	0.02 V%	- [1]	- [1]	- [1]	- [1]
O2 [5]	100 V%	- [2]	- [2]	- [1]	- [1]

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions”

above.

Note 2: Negligible interference with N2O / O2 concentrations 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 containing

5.0 vol% CO2 and 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 21647:2004 standard.

Note 5: In addition to the EN ISO 21647:2004 standard.