patient monitor

PM4010

User Manual – V3

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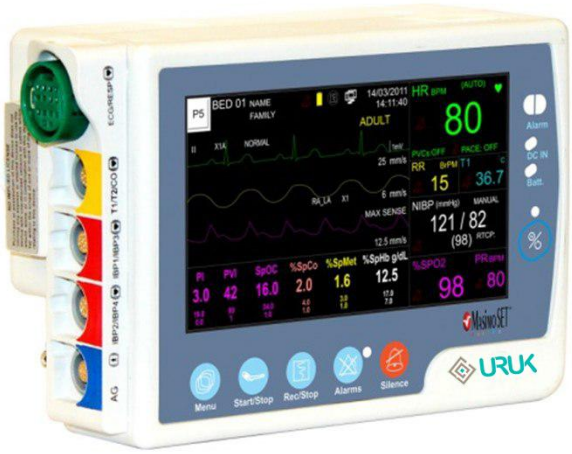
URUK Medical Equipment Co.

User manual

PM4010
patient monitors



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Manual Purpose

This manual is for PM4010 patient monitor and its accessories

Observance of this manual is a prerequisite for proper operation and ensures patient and operator safety. If you have any question about the device, please contact our customer service.

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 device operation.

Explanations of the used expressions in this manual

Warning

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

Note

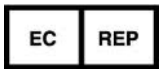
A NOTE symbol provides useful information and recommendations about device function.

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
August 2025	D00010-V3

Symbols

Symbol	Description
	Consult user manual of the monitor and pay attention to the warnings and cautions.
	The device is IEC60601-1 type CF (Defibrillation proof applied part) equipment. The units displaying this symbol provide an F-type isolated (floating) patient applied part with a high degree of protection against shock and is suitable to use with defibrillator simultaneously.
	This sign is according to the requirements of the IEC60601-1 standard for functional parts connected to the patient of type BF and protected against the effects of simultaneous use with electroshock.
	This sign is according to the requirements of the IEC60601-1 standard for functional parts connected to the patient of type BF.
	The presence of this symbol next to the patient connector shows that a part of the patient's protection against the effects of using a defibrillator is considered in the accessory connected to the patient, and therefore, only approved accessories should be used.
	The equipment shall be disposed of in an environmentally-friendly manner.
100-240 VAC 120 VA 50/60 Hz	AC power supply
	3A fast fuse
S/N	Serial number
	Manufacture date
	Manufacturer information
	Equipotential ground
	European community representative
	Using the MASIMO PulseOximeter module

تحذيرات عامة

- مراقبة علامات الحيوية من خلال شاشة مراقبة المريض يجب أن تُجرى عن طريق محترفي الرعاية الصحية المؤهلين.
- قبل البدء في عملية المراقبة، يرجى قراءة هذا الدليل وتعليمات استخدام الملحقات بعناية.
- جهاز مراقبة العلامات الحيوية مخصص للاستخدام فقط كعامل مساعد في تقييم المريض. ويجب استخدامه بالتزامن مع العلامات والأعراض السريرية.
- قبل المراقبة، يجب على المشغل التأكد من أن الجهاز والملحقات تعمل بأمان وأنها في حالة عمل مناسبة.
- لتجنب خطر التعرض لصدمة كهربائية، يجب توصيل هذا الجهاز فقط بمصدر تيار كهربائي مزود بتأريض واقي.
- إذا كانت دقة القياسات موضع شك، فتحقق أولاً من العلامات الحيوية للمريض بوسائل بديلة ثم افحص جهاز المراقبة للتأكد من أنه يعمل بشكل سليم.
- لا تستخدم جهاز مراقبة المريض أثناء التصوير بالرنين المغناطيسي (MRI). من المحتمل أن تسبب التيارات المستحثة حروقًا. قد يؤثر جهاز مراقبة على صورة التصوير بالرنين المغناطيسي، وقد تؤثر وحدة التصوير بالرنين المغناطيسي على دقة قياسات الشاشة.
- تأكد من عدم تعرض الكابلات والملحقات للتوتر أثناء المراقبة.
- يجب ضبط المنبه حسب حالة المريض. قبل المراقبة، تأكد من أن نظام الإنذار الصوتي يعمل بشكل صحيح.
- المعدات غير مناسبة للاستخدام في وجود خليط مخدر قابل للاشتعال مع الهواء أو الأكسجين.
- قد يكون هناك خطر التعرض لصدمة كهربائية عند فتح غطاء جهاز المراقبة. يجب أن يتم تنفيذ جميع أعمال الصيانة والتحديث المستقبلي لهذا الجهاز بواسطة موظفين مدربين ومعتمدين من قبل الشركة المصنعة.
- لمنع تأثيرات التوافق الكهرومغناطيسي (EMC)، لا ينبغي استخدام النظام بالقرب من أجهزة أخرى أو مكدسة معها، وإذا كان الاستخدام المجاور أو المكدس ضروريًا، فيجب التحقق من التشغيل العادي لجهاز مراقبة المريض في ظل ظروف الاستخدام.
- لا تلمس المريض أو الطاولة القريبة أو الجهاز أثناء إزالة الرجفان.
- لا تستخدم الهاتف الخلوي بالقرب من هذا الجهاز. قد يؤدي المستوى العالي من الإشعاع الكهرومغناطيسي المنبعث من هذه الأجهزة إلى حدوث تداخل قوي مع أداء جهاز مراقبة المريض.
- يجب على الطبيب أن يأخذ في الاعتبار جميع الآثار الجانبية المعروفة عند استخدام جهاز مراقبة المريض.
- عند استخدام مزيل الرجفان، سيتم مقاطعة المتغيرات والإشارات مؤقتًا حتى بضع ثوانٍ بعد إزالة الرجفان.
- لا تعرض الجهاز لأي مصدر حرارة محلي مثل أشعة الشمس المباشرة.
- ستكون هناك بعض مخاطر تلويث البيئة المرتبطة بالتخلص من الملحقات ذات الاستخدام الواحد وأجزاء معينة من النظام (مثل البطارية المعيبة والتي تم إيقاف تشغيلها). يجب التخلص من الجهاز وملحقاته وفقًا للقوانين الوطنية بعد انتهاء صلاحيتها. اتصل ببلديتك للتحقق من المكان الذي يمكنك فيه التخلص من البطاريات القديمة بأمان.
- من الممكن زيادة تسرب التيار عندما يتم توصيل عدة أنظمة بالمريض في وقت واحد.
- لا تستخدم شاشة واحدة لمريضين أو أكثر في نفس الوقت.
- لا تقم بتوصيل العناصر غير المحددة كجزء من جهاز المراقبة. يجب تثبيت النظام ووضعه في الخدمة وفقًا لمعلومات التوافق الكهرومغناطيسي (EMC) الواردة في الملحق الرابع.
- في حالة تناثر الماء على النظام أو الملحقات، يرجى إيقاف تشغيل الشاشة ومسحها بقطعة قماش ناعمة ثم تشغيلها.
- تم تصميم برنامج جهاز المراقبة بطريقة تقلل من المخاطر الناجمة عن أخطاء البرنامج.
- لتجنب خطر التعرض لصدمة كهربائية، يجب توصيل هذا الجهاز فقط بمحول طبي موصى به.
- إذا كان يجب استخدام النظام في الهواء الطلق أو في حالة ممطرة، استخدم كيسًا خاصًا موصى به من قبل الشركة المصنعة.
- قبل استخدام النظام، تحقق من حالة شحن البطارية.
- لا تلمس الشاشة بأشياء حادة.
- يصف هذا الدليل جميع ميزات ووظائف الجهاز. جهازك قابل للتخصيص بدرجة كبيرة وقد لا يحتوي على بعض هذه الميزات.
- إذا تم إيقاف تشغيل الشاشة بسبب انقطاع التيار الكهربائي أو تفريغ البطارية، فسيتم الاحتفاظ بجميع الإعدادات الحالية.

General Warnings

Patient's Safety

The patient monitor is designed to comply with the international safety standards requirements for medical electrical equipment. This device has floating inputs and is protected against the effects of defibrillation and ESU. If the correct electrodes are used in accordance with the manufacturer instructions, the display screen will recover within 10 seconds after defibrillation.

Grounding the patient monitor

To protect the patient and hospital personnel, the case of patient monitor must be grounded. The patient monitor is equipped with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3- wire receptacle is not available, consult the hospital electricians. If there is any doubt regarding the completeness of the protective grounding wire, the equipment must be operated with internal battery or DC input.
Protection class I instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, the portable Patient Monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the rear panel of the monitor and the other end to one point of the equipotential grounding system.
The equipotential grounding system is for the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in medically used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order.

Warning

- Vital signs monitoring through the patient monitor should be performed by qualified health care professionals.
- 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, carefully read this manual and directions for use of accessories.
- Before monitoring, the operator must check that the device and accessories function safely and are in proper working condition.
- 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
- To protect against the risk of electric shock, the system must be connected to a power source with a suitable protective ground.
- Make sure that cables and accessories are not under tension during monitoring.
- Equipment is not designed for use in the presence of a flammable anesthetic mixture with air or oxygen. In case of using under these conditions, an explosion may occure.
- 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.
- Alarm should be set according to patient condition. Before monitoring, make sure that the audio alarm system functions correctly.

- 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.
- 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 appendix.
- 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.
- If the system should be used outdoor or in rainy condition, use special bag recommended by the manufacturer.
- 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.
- Do not touch the screen with sharp objects.
- The environment in which the system is used must be free from vibration, dust, corrosive and flammable gases, high temperature and humidity.

Note

- 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.
- Before working with the system, make sure of the battery charge level.
- The system is designed to work well in temperatures between 0 and 40 degrees Celsius. When the ambient temperature exceeds these limits, it has an adverse effect on the measurement accuracy of the monitor and may damage the electrical circuits and modules.

- For the safety of the patient and personnel, it is better to ground the system. If there is no earth connection, it is better to disconnect the device adapter and use the internal battery when connecting the device to the patient.

1) Introduction

Device Description

PM4010 vital signs monitoring system is designed and built with the aim of complete and continuous monitoring of the patient's vital signs from the moment of the accident to full recovery and improving access and medical care. PM4010 portable monitor is compatible with neonates, children and adults and can be used in medical care centers and can monitor vital signs including cardiac signal, respiratory signal, respiratory gases, blood pressure, temperature and blood oxygen and anesthesia indicators.

PM4010 patient monitor can be used alone as a complete monitor. The advantages of this system are its small size, light weight, internal battery and portability. In addition, by connecting some peripherals designed for it, it can easily and in the shortest possible time become a suitable monitor for different departments. There is no need to separate the monitor from the patient in order to connect the monitor to peripheral devices and change its usage, so there will be no interruption in monitoring the patient's vital signs and recording and storing vital information in its memory.

If used with the F1 or F1R station, it is possible to connect to the CS110 central system (for monitoring data on the network via Wi-Fi). With the help of this feature, it is possible to view the information of several monitor devices that are connected to a number of patients in the same ward at the nursing station and remotely.

Also, PM4010 has the possibility of establishing two-way communication with the VIEWER display system (showing signals and parameters on a larger screen and applying settings by the VIEWER system remotely). This feature can be useful in infectious departments where the monitor is connected to the patient and remote monitoring is a priority. In addition, if the PM4010 system is connected to the VIEWER, both of these systems can be connected to the central system together.

Equipped with a recorder, the F1R station have also provided the possibility of recording the heart signal and vital parameters.

Intended Use

The monitoring system is intended to be used by trained healthcare professionals to effectively and safely care for an adult, child or infant patient.

The PM4010 monitoring system can be installed in all medical rooms that meet the requirements of the medical location, such as emergency departments, ICU, CCU, NICU, general operating room, open heart operating room, recovery, etc.

Contraindications

- The monitoring system is not intended for use in a helicopter or at home or in MRI environment or in an oxygen-enriched environment.
- The monitor device is not a treatment device.

Operating Environment

The operating environment of the equipment must comply with the requirements specified in this manual. This system must be completely free of noise, vibration, dust, corrosive, flammable and explosive substances in the environment where it is used.

Features

Continuous monitoring of vital signs, including:

- ECG: ECG waveform, Heart Rate (HR), ST segment, PVCs/min and Arrhythmias.
- RESP: Respiration waveform, Respiratory rate (RR).
- SpO2(Rainbow*): SpO2 waveform, Percentage of pulse oximetry Saturation (SpO2), Pulse Rate (PR), and if the specific software is installed, PI, PVI, SpHb, SpOC, SpCO, SpMet.
- NIBP: Systolic pressure, Diastolic pressure and pressure with maximum fluctuation amplitude (MAP)
- IBP*: Invasive blood pressure measurement (up to 4 channels)
- TEMP: 2 channels of temperature.
- CO2*: EtCo2, FiCo2, AWRR.
- BFA*: Anesthetic depth index (BFI), Percentage of Burst Suppression (BS%), Signal Quality Index (SQI), Electromyogram index (EMG%).

PM4010 has also these capabilities:

- Alarm system (visual and audible)
- Storing data (TREND and SIGMA)
- Storing 80 arrhythmias.
- Remote monitoring – connecting to VIEWER and central systems (with F1 or F1R stations)
- Recording the ECG (F1R station)

Some features are optional and are indicated with (*).

Note

- PM4010 vital signs monitor system is designed in such a way that the operator can work with it easily by using several keys and touch screen.

Getting started

Note

- Due to the dimensions and weight of the PM4010, it can be used mobile or placed next to the patient's bed.

1- 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.

2- Insert the battery

When you use the system for the first time, you should insert the battery into the monitor. (More information in “Getting to know PM4010” section)

3- Place the monitor in the station station

Put the monitor in the station. (More information in “Getting to know PM4010” section)

4- 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 station and the other end to a grounded power receptacle.

5- 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.

Warning

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

Note

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

Getting to know PM4010

Front panel

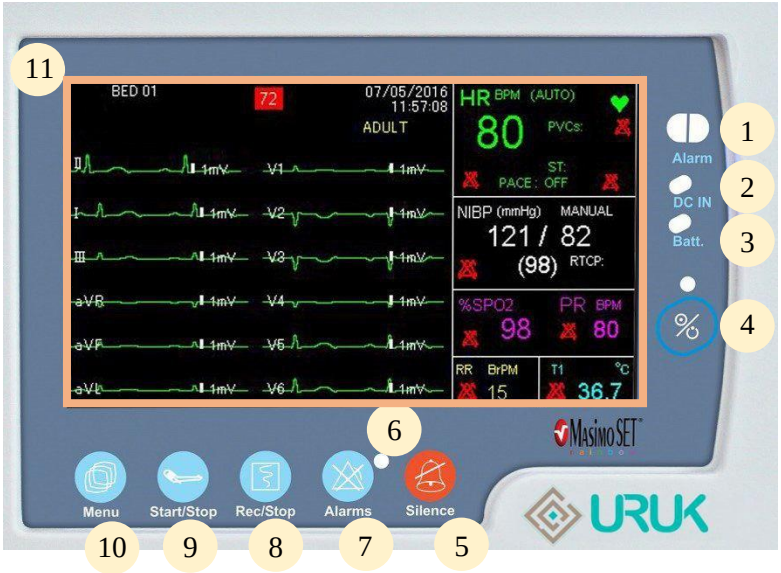


Figure 1-1 Front panel

1	Alarm	Alarm indicator
2	DC IN	Indicator for placing the PM4010 on a powered station
3	Batt.	Battery indicator lights in green when it is fully charged, and otherwise, lights in orange.
4	Power	Power On/Off key and indicator
5	Silence	By pressing this key, the audible alarm can be disabled for 120 seconds, and the countdown timer and the Silence symbol in the Header Area will be displayed in a flashing manner every 5 seconds. By pressing this key again, the system will come out of the temporary silence mode and the audible alarms will be allowed to be activated again.
6		Alarm silence indicator
7	Alarms	By pressing this key, alarms can be disabled indefinitely, and until this key is pressed again, even if a new alarm occurs, the alarm signs (indicator and alarm sound) will remain disabled. Due to standard compliance, it is currently not possible to use this key for the operator. But in the future, the user can access it.
8	Rec/Stop	By pressing this key, you can record the ECG signal and all numerical parameters with the recorder in the station, and pressing this key again will stop the recording.
9	Start/Stop	By pressing this key, the blood pressure measurement starts, if this key is pressed again during the blood pressure measurement, the measurement will stop.
10	Menu	Opens the HOME MENU window or returns to the main page of monitoring.
11	Display screen	All the waveforms and parameters are displayed in this area. More description is as follows.

Display screen

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

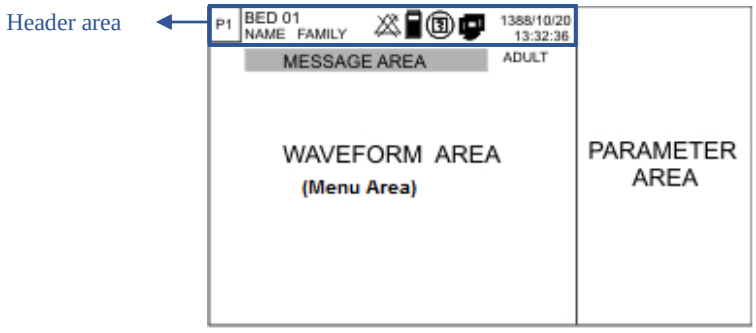


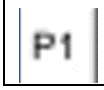
Figure 1-2 display screen

Note

- In case of direct sunlight on the monitor screen, the reflection of direct light will cause the screen to not be seen properly.
- In order to see the monitor screen properly, it is better to have the monitor device in an environment darker than the environment of the observer.
- If the monitor is used in an open environment, adjust the location of the monitor so that it is not exposed to direct light.

- Header area

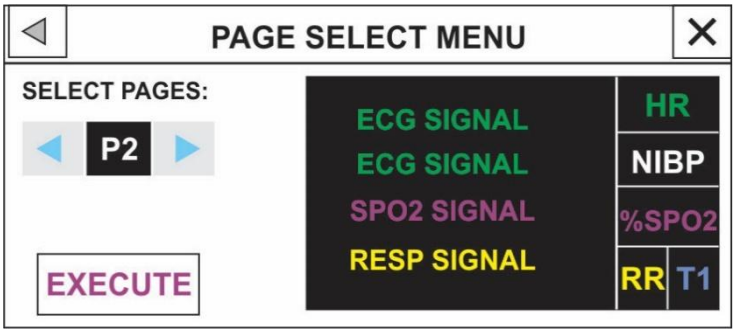
The header area of the screen displays operating status of the monitor and patient information. Bed number, patient mode (adult, pediatric or neonatal), patient name, date & time and page number are displayed in this area. This information is displayed on the screen during monitoring:

	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.
	Page number. Touching this section changes the form of view.

Note

- 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.
- By pressing the touch screen on the left side of the first trace, Freeze mode will be activated, and all the waveforms on the screen will remain in a fixed state, and the message “FROZEN” will be displayed in white in the signal section, and with Pressing this area again, drawing the signals will be continued and a white line is created on the signals where the signals were frozen.
- There are 2 ways to change the page:
  1- Touching the PAGE button on the top left corner of the screen will show the next page.

2- By pressing and holding the PAGE button (for less than 2 seconds), the PAGE SELECT window opens and provides quick selection of desired page. Pressing the EXECUTE button shows the selected page.



- There are 23 pages in PM4010 by default, providing wide variety of formats for viewing signals and parameters. More information in "Page Setup" section.
- At first time, the monitor turns on with P1 page. But after that, when the monitor is turned on, the page that was set on it before turning off the system 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.

- Parameters 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 (levels I, II and III). When there is no alarm, the message is displayed on gray background.

Warning

- The alarm indicator in normal condition is off. It flashes when an alarm occurs.
- To verify proper function of indicators, they all light when the monitor is powered on.
- Before monitoring the patient, check the keys' function and make sure that they are in proper working condition.

Note

- 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 (×) is pressed, the menu will be closed and setting will not change.
- If you press Start/Stop key in pages which do not include NIBP parameter, the measurement will not be done. If you enter these pages during the measurement and press Start/Stop key, the measurement will be stopped.
- If a new alarm occurs in the silence mode, the monitor will exit from this mode. This event will not happen within 120 sec after the monitor is turned on.

Interfaces

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

Figure 1-3 PM4010 interfaces

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

Note

- Some connections and modules may be disabled in your device.
- In order to properly connect the cables, the grooves and protrusions should be opposite each other.

PM4010 Stations

F1 station

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

In the F1 station, the adapter connector and digital data output (RS422) is located on the right side of the station.

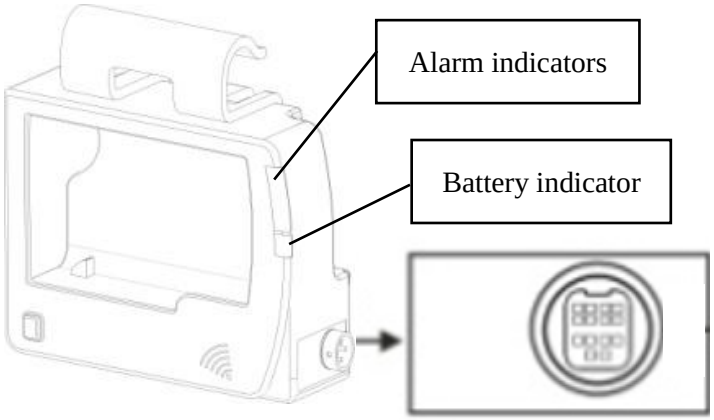


Figure 1-4 F1 station and its power/output socket

F1R station

The only difference between this station and the F1 station is the addition of a recorder module to record signals and numerical parameters.

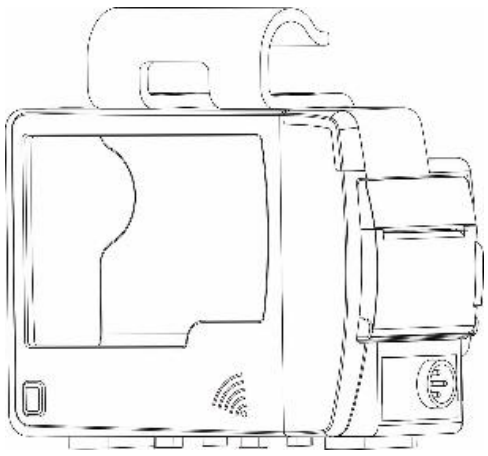


Figure 1-5 F1R station

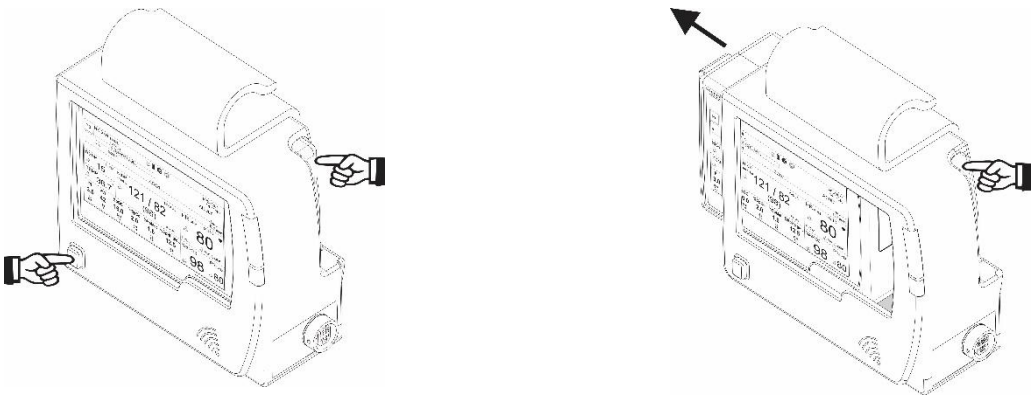
The use of F1 and F1R station also provides the possibility of connecting to the Central and Viewer systems.

Note

- Alarm indicators and a speaker are embedded in the station so that visual and auditory alarms can be seen and heard more clearly when PM4010 is placed in the station. The station alarm indicators are bigger than the PM4010 indicators, and when an alarm occurs, these indicators are activated in the station, corresponding to the PM4010 indicators. The sound of alarm or heart beat is also cut off from the monitor side when PM4010 is placed in the station, and they are strengthened and activated in the station.
- By placing the PM4010 monitor inside its station and connecting the power cable to the station, the following items will be provided:
  1. The possibility of charging the auxiliary battery inside the station and charging the internal battery of PM4010
  2. Hanging on the side of the stretcher rail during patient transfer
  3. The possibility of installation on the serum stands, on the table and hanging on the edge of the bed
- Only URUK monitors can be connected to URUK central network.
- Before connecting the PM4010 monitor to the network, the operator shall perform relevant settings such as AP Index and Bed Number.
- WIFI connection in the PM4010 monitor is done by connecting to the access point and exchanging information with the central system.

Removing the PM4010 monitor from the station

Press and hold the eject button in lower left corner of the station and simultaneously push out the monitor (figure 1-6 a). When the monitor moves in its position, release the eject button and remove the monitor (figure 1-6 b).



(a) (b)

Figure 1-6 Removing PM4010 from the station

Battery

PM4010 has two rechargeable batteries. One is placed in the right side of the monitor and the other is inside the stand. If you place the monitor in the station and connect the station to AC power adaptor, the internal monitor battery will recharge automatically. When the battery is depleted, it takes at least 3 hours to be fully charged. 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.

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

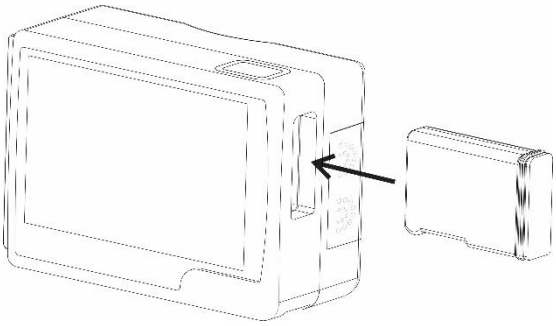


Figure 1-7 Battery insertion

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

(b) (a)

Figure 1-8 Removing internal battery

Warning

- The battery should not be opened, thrown into fire, or short-circuited. These actions may cause ignition and explosion. Leakage or overheating may cause injury.
- 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

Note

- Information about the battery and adapter is included in the technical specifications chapter.
- 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.
- For best battery performance, use only the recommended charger.

Using the PM4010 monitor in different environments

This monitor can be used from the moment of the accident with the arrival of the ambulance, in such a way that the monitor is installed on the station and connected to the stands according to the figures below, so that the patient's vital signs can be evaluated.

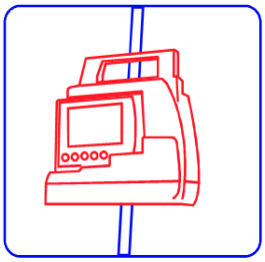


Figure 1-9 Hanging on serum stand

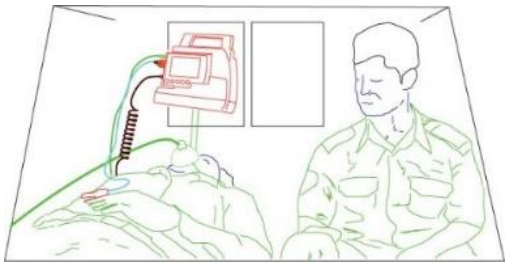


Figure 1-10 PM4010 in ambulance

After transferring the patient to the treatment center, while transferring the person to the operating room or to the ward, the monitor along with its station can be connected to the edge of the bed as shown in the figure below in order to be informed about possible changes in the patient's vital signs.

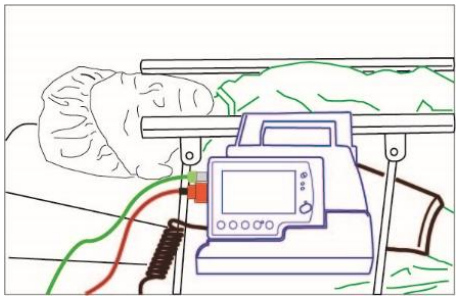


Figure 1-11 PM4010 connected to the edge of bed

To convert the PM4010 monitor into a portable monitor by the patient, just put the PM4010 monitor inside a special bag. In this case, it can be carried by the patient due to its light weight.

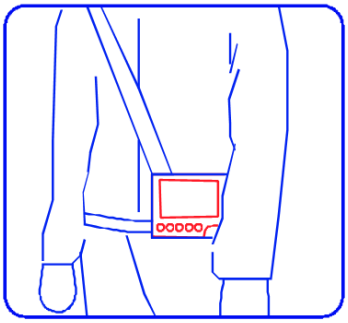


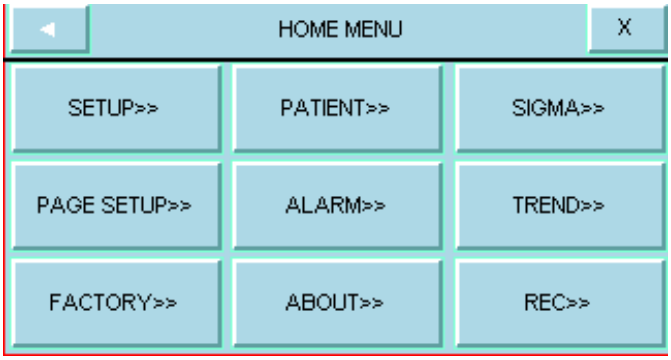
Figure 1-12 Portable PM4010 inside the bag

2) System Configuration

HOME MENU

Patient monitor contains a flexible configuration. The configuration setting is done through HOME MENU.

You can access this menu by pressing the MENU key on the front panel or touching middle part of the header area on the screen.



(a)

Figure 2-1 HOME menu

a) PM4010 with F1 and F1R stands

SETUP

By pressing SETUP, you can access the following menu:

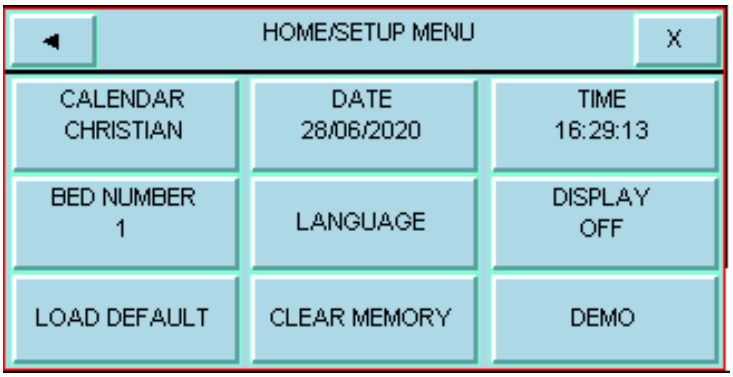


Figure 2-2 setup window

The below settings can be performed in this menu:

- **CALENDER**: Available options are "SOLAR" and "CHRISTIAN"
- **DATE**: Press this item to set date in the following window:
- **TIME**: Press this item to set time in the following window:
- **BED NUMBER**: Press this item to set bed number in the following window (from 1 to 99).
- **LANGUAGE**: Press this item to select the desired language in the following window. Available options are ENGLISH, ITALIAN, SPANISH POLISH, RUSSIAN, TURKISH, GERMAN and FRENCH, PORTUGUESE.

- **DISPLAY OFF**: Select this item to turn off the display screen until a key is pressed or an alarm occurs. When the monitor is in the Silent mode, this item becomes inactive.
- **LOAD DEFAULT**: Select this item to access SETUP/ DEFAULT MENU and to load the manufacturer default settings for the desired parameter. (Refer to default settings chapter). Because all your previous settings will be missed by selecting this item, the system asks for your confirmation before changing settings.
- **CLEAR MEMORY**: You can clear the stored parameters in the system such as TREND, NIBP LIST data and ARR. Press this item to call up the following menu:

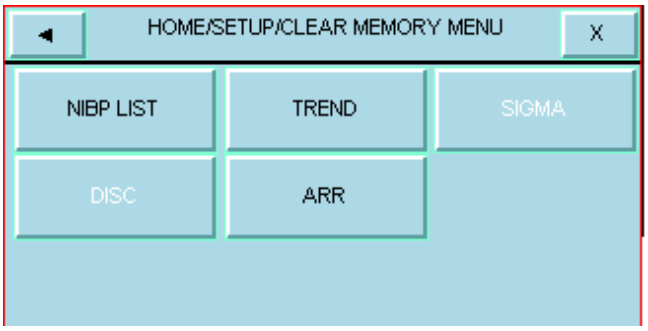


Figure 2-3 Clear memory menu

- **DEMO**: For displaying demo waveforms and parameters. In this mode, “Demo” is displayed on the ECG waveform. The operator cannot access this menu because it is password protected.

Note

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

The page number is shown on the left side of header area and each time it is touched, the next page will be displayed.

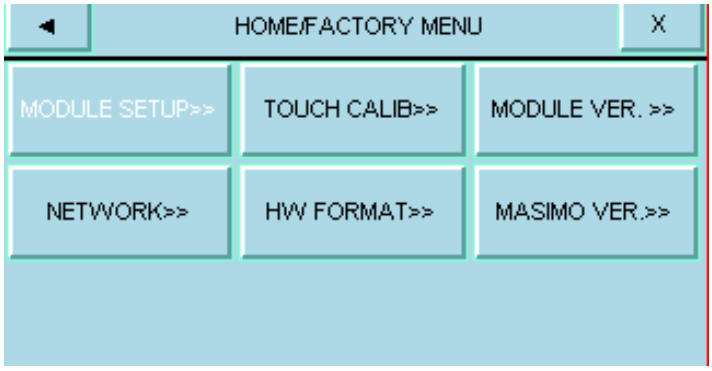
Table 2-1 Different pages of PM4010

Displayed Signals	Displayed Parameters	Page Number
RR‹SpO2‹ECG	NIBP‹T1‹ RR‹ SpO2‹HR	P1
RR‹ECG 2Trace, SpO2	NIBP‹T1‹RR‹SpO2‹HR	P2
ECG 4Trace	NIBP‹T1‹RR‹SpO2‹HR	P3
ECG 7Trace	NIBP‹T1‹RR‹SpO2‹HR	P4
ECG 12Trace	NIBP‹T1‹RR‹SpO2‹HR	P5
SpO2	NIBP‹SpO2(PI, PR), T1 T2	P6
SpO2	SpO2(PI, PR)	P7
ECG, IBP, SpO2	HR, IBP, SpO2, NIBP	P8
ECG, IBP	HR, IBP, RR, T1, NIBP	P9
ECG, IBP1, IBP2	HR, IBP1, IBP2, SpO2, NIBP	P10

ECG, IBP1, IBP2	HR, IBP1, IBP2, SpO2 (PI, PVI, SpOC, SpCO, SpMet, SpHb)	P11
ECG	HR, IBP1, IBP2, SpO2, NIBP	P12
ECG, SpO2, CO2	HR, SpO2, NIBP, T1, Et CO2, Fi CO2, AWRR	P13
ECG, SpO2, IBP	HR, SpO2, IBP1, IBP2, T1, Et CO2, Fi CO2, AWRR	P14
ECG	HR, IBP1, IBP2, SpO2, NIBP, Et CO2, Fi CO2, AWRR	P15
ECG, BFA	HR, BFI (BS, SQI, EMG)	P16
CO2	Et CO2, Fi CO2, AWRR	P17
SpO2, CO2	SpO2 (PI, PR), Et CO2, Fi CO2, AWRR	P18
IBP, CO2	SpO2 (PI, PR), Et CO2, Fi CO2, AWRR, IBP	P19
SpO2, Multi-Gas	SpO2 (PI, PR), Et (CO2, AA, N2O), Fi (CO2, N2O, AA), MAC, AWRR	P20

FACTORY

Pressing this button, opens this menu:



(a)

Figure 2-4 Factory window

a) PM4010 with F1 and F1R stands

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:** Settings related to activating or deactivating different modules are done in this section.
- **TOUCH CALIB.:** In this section, the touch screen can be calibrated in the four corners and center of the screen. Only people approved by the manufacturer with a password will have access to this menu.
- **MODULE VERSION:** This item opens a window containing information about software version of different modules.
- **NETWORK:** In this window, by pressing either AP INDEX or WARD INDEX key, a window will open where you can select AP (access point - name of the central network) and WARD (hospital unit name). Pressing the EXECUTE key will apply the changes.

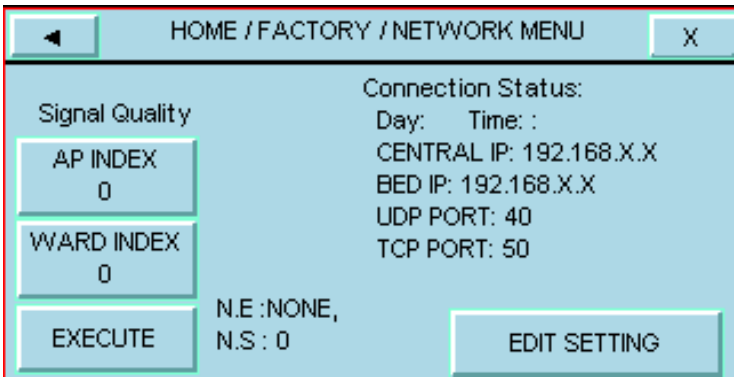


Figure 2-5 Network window

The operator does not have access to more network settings that are done by pressing EDIT SETTING.

- **HW FORMAT:** The operator does not have access to this item.
- **MASIMO VERSION:** 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.

PATIENT

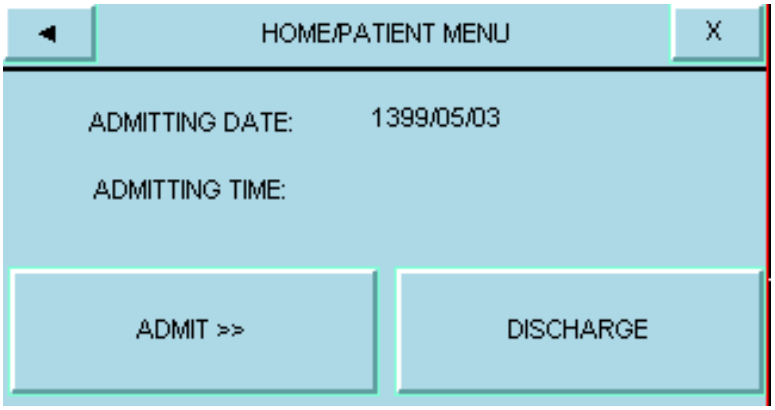


Figure 2-6 Patient window

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

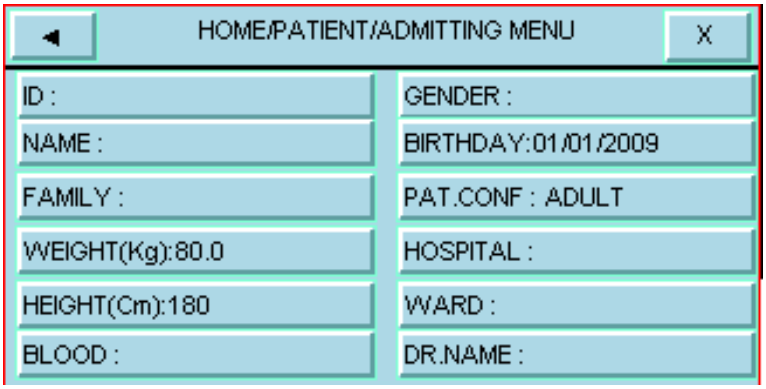


Figure 2-7 Patient admit window

- ID: Patient code in hospital
- NAME: Patient's name
- FAMILY: Patient's family name
- WEIGHT: Patient's weight from 0.5 to 300 Kg
- HEIGHT: Patient's height from 20 to 250 cm
- BLOOD TYPE: patient's blood type. Options are A+, A-, B+, B-, AB+, AB-, O+ and O-.
- GENDER: Patient's gender. Available options are Female and Male
- BIRTHDAY: patient's date of the birth
- PAT. CONF.: Patient configuration. Options are Neonate, Pediatric and Adult
- HOSPITAL: Hospital name.
- WARD: Ward name.
- Dr.NAME: Physician name.

Note

- An artificial keyboard will be opened for entering textual data.
- A maximum of 15 characters can be entered in text information.
- 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.

ALARM

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

All alarm messages are displayed in the Message Area.

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

PM4010 Patient Monitor offers three levels of alarm.

- Level I alarm indicates the patient's life is in danger or the monitor under use has serious problems. It is the most serious alarm.
- Level II alarm means serious warning.
- Level III alarm is a general warning.

The patient monitor has preset the alarm level for the parameters. You can also modify alarm level of each module in its own window. Alarm settings, including priorities, ranges, alarm sound, etc., should be done in such a way that repeated alarms are prevented and the patient is not put in danger, considering the absence of a caregiver, the patient's condition, and the environment.

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

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

- Level I alarm message: Red background – Black text

- Level II alarm message: Yellow background – Black text
- Level III alarm message: Cyan background – Black text
- Messages: Gray background _ Black text

The alarm sound is activated in three levels:

- Level I alarm sounds "DO-DO-DO--DO-DO" every 10 seconds;
- Level II alarm sounds "DO- DO-DO" every 20 seconds;
- Level III alarm sounds "DO-" every 30 seconds.
- The sound intensity of the audible alarm at a distance of one meter from the front of the device is between 50 dB(A) and 66 dB(A) for gains 1 to 8.

Warning

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

Note

- During the monitor is being powered on, audible and visible (yellow and red indicators) alarms will be self-tested. The monitor beeps every time it is powered on and yellow and red indicators light concurrently. The indicators turn off after the monitor is powered on. If no beep sound is heard or no alarm indicator lights, do not use the monitoring system on any patient and notify After Sales Service.
- When alarms of different levels occur at the same time, the alarm LED prompts the alarm of the highest level (red color) and the other alarms are displayed alternately in a background color corresponding to their levels.
- If two or more alarms of the same level occur simultaneously, the alarm messages will be displayed alternately.
- The alarms are triggered by a parameter or by technical problems of the patient monitor. The delay time from an alarm occurrence to alarm manifestation (parameter blinking, alarm message, alarm sound) is less than 1 second (Delay time of APNEA alarm is corresponding to APNEA LIMIT setting in RESP menu).

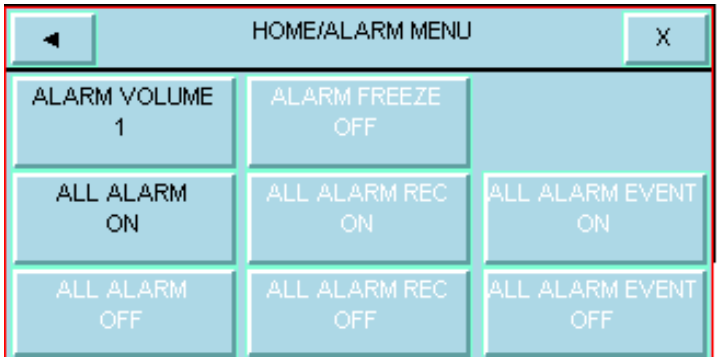


Figure 2-8 Alarm window

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

- **ALL ALARM ON.OFF**: By pressing the ALL ALARM ON/OFF keys, the ALERT window opens, and by selecting YES or NO, it is possible to turn ON or OFF all monitor alarms.

Note

- 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.
- • ALL ALARM EVENT, ALL ALARM REC, ALARM FREEZE menus are inactive.
- If the monitor detects situations like ASYSTOLE or APNEA, alarm will be activated even when it is in "OFF" mode.
- When a technical alarm occurs, you can press Alarm Silence key to disable the alarm.
- Alarm settings for each parameter are available in the window corresponding to that parameter. In each window, you can see the alarm ranges and its features for a specific parameter. Refer to each module's section for details.
- When the parameter alarm is "OFF", the sign is displayed next to that parameter. For a parameter whose alarm is set to "ON", the alarm range is displayed next to the parameter, and when the value of the desired parameter exceeds the set range, the alarm is activated and the following events occur:
  1- The message related to the alarm is displayed with a background color corresponding to the level of that alarm.
  2- The monitor beeps with the set alarm level and sound level.
  3- The alarm indicator flashes.

The Alarm Silence key

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

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

Note

- User should identify the alarm causes. You will find the alarm messages of each module in its own chapter. When an alarm occurs, take the actions below:
  1. Check the patient's condition.
  2. Know each module's alarms and their causes.
  3. Press Silence button, if necessary.
  4. After removing the alarm cause, enable the alarm sound check its functionality.
- The alarm messages related to each module are listed in the section related to that module.

ABOUT

Information about the manufacturer is mentioned here.

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:

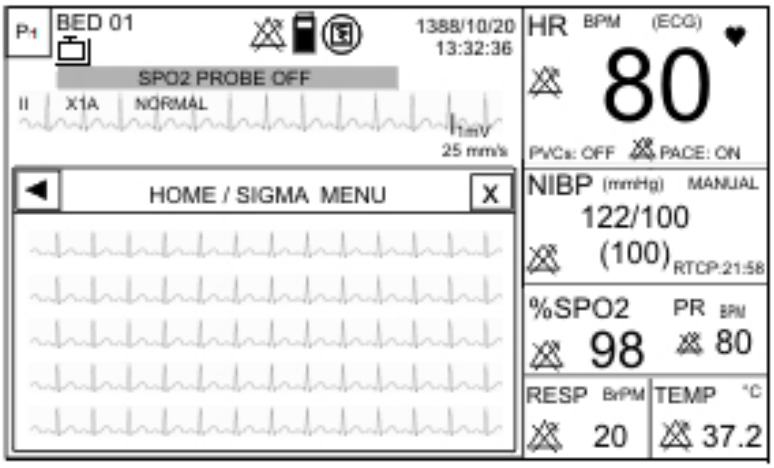


Figure 2-9 SIGMA window

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.

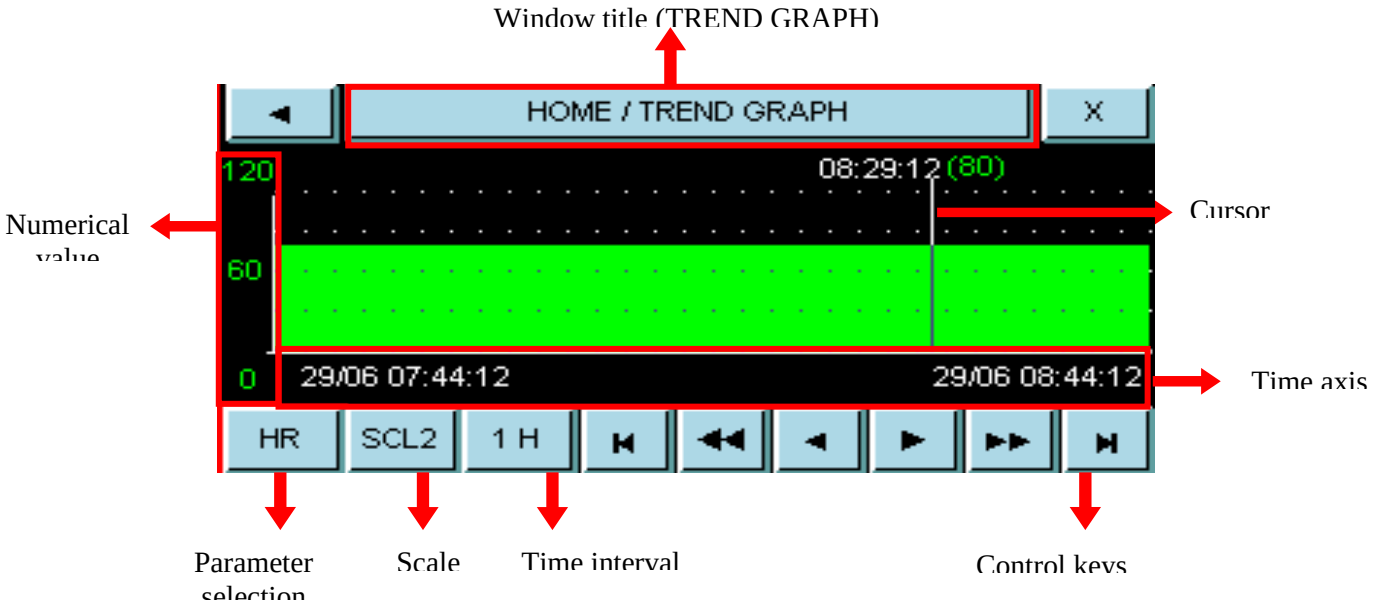


Figure 2-10 TREND GRAPH window

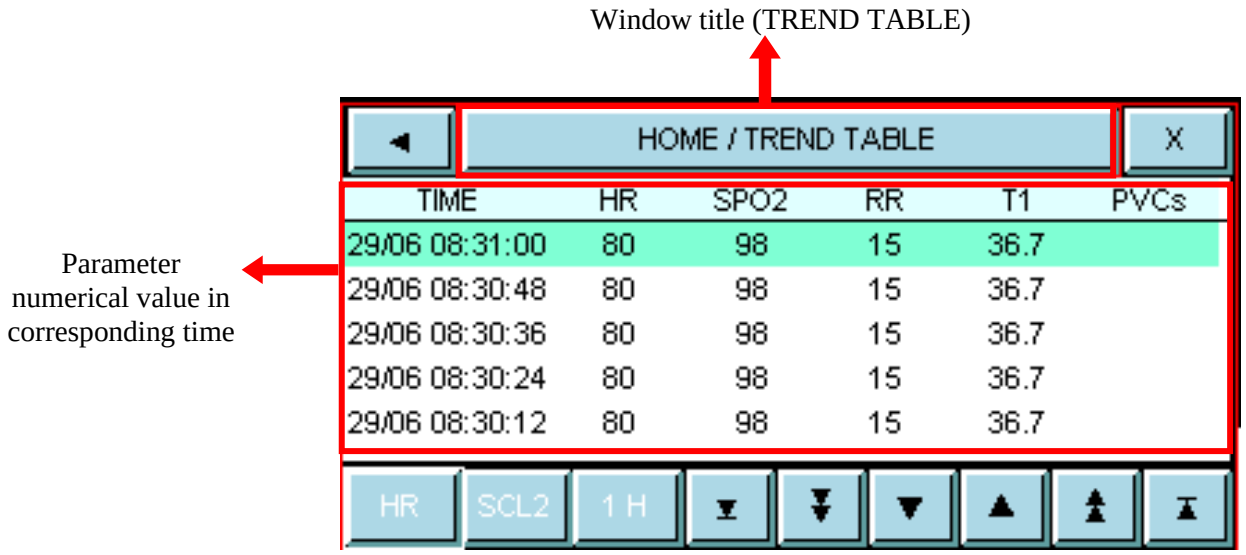


Figure 2-11 TREND TABLE window

- Parameter selection in TREND GRAPH: By touching the parameter field, a window will open to select the desired parameter. The available options are:
  HR, SpO2, PR, T1, T2, IBP1, IBP2, EtCO2, FiCO2, AWRR, PVCs, ST, AFIB, SpHb, PI, SpCo, SpOc, SpMet, PVI, IBP, IBP4.
  This item is inactive in the Trend Table and only the selected parameter can be seen in the graph.

Note

- Only available parameters in each page can be selected.
- If Masimo Rainbow set is used, you will see one of the selected Rainbow parameters instead of TEMP parameter in the trend table.
- If any physiological module is inactive, the corresponding parameter will not be displayed in the trend.

- Scale: Each time you touch this part, you can adjust the parameter display range on the vertical axis. According to the limits set in the table below, you can choose SCALE from 1 to 6 for each parameter.

PARAMETER	SCALE1		SCALE2		SCALE3		SCALE4		SCALE5		SCALE6	
	MIN	MAX	MIN	MIN	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX
HR	0	60	0	120	0	240	-	-	-	-	-	-
SPO2	80	100	60	100	0	100	-	-	-	-	-	-
T1/ T2	30	42	24	48	0	48	-	-	-	-	-	-
IBP1/IBP2/ IBP3/IBP4	-20	50	-20	100	-20	200	-50	300	50	250	-	-
RESP	0	60	0	120	0	240	-	-	-	-	-	-
AWRR	0	60	0	120	0	240	-	-	-	-	-	-
CO2/ ETCO2/ FICO2	0	50	0	100	-	-	-	-	-	-	-	-
O2/ ETO2/ FIO2	0	50	0	100	-	-	-	-	-	-	-	-

N2O/ ETN2O/ FIN2O	0	50	0	100	-	-	-	-	-	-	-	-
AA/ ETAA/ FIAA	0	1.0	0	2.0	0	3.0	0	5.0	0	10.0	0	20.0
PVCS	0	20	0	50	0	100	-	-	-	-	-	-
ST	-0.2	0.2	-0.5	0.5	-1	+1	-2	2	-	-	-	-
AFIB	0	1	-	-	-	-	-	-	-	-	-	-
PR	0	60	0	120	0	240	-	-	-	-	-	-
PI	0	20	0	10	0	5	-	-	-	-	-	-
PVI	0	30	0	100	-	-	-	-	-	-	-	-
SPOC	0	36	6	20	-	-	-	-	-	-	-	-
SPCO	0	12	0	24	0	50	-	-	-	-	-	-
SPMET	0	6	0	20	-	-	-	-	-	-	-	-
SPHB	6	20	2	14	0	25	-	-	-	-	-	-

- Time interval selection: 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.

REC.

PM4010 has the ability to record signals and parameters using URUK thermal recorder in F1R station.

Recording capabilities in the system:

- Recording speed is adjustable to 6, 12.5 and 25 mm/s.
- Up to 2 selectable waveforms recording.
- The automatic recording with selectable time intervals
- The real time and continuous recording
- 10, 20 and 30 second real times recording of the waveform
- Recording parameters when alarms occur
- Recording of fixed waveform (Freeze)
- Recording of numerical parameters
- Recording from TREND
- Recording from NIBP LIST
- Recording from ARR LIST
- Recording from ARR WAVE

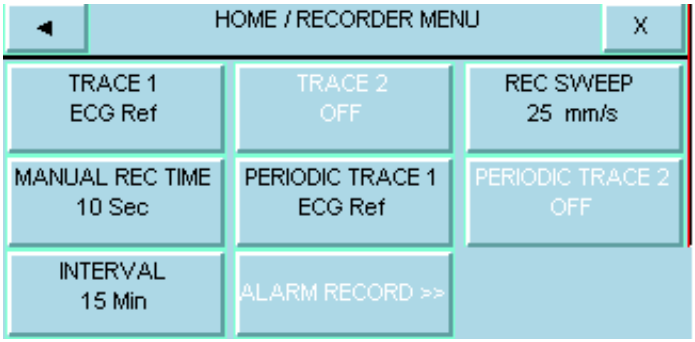


Figure 2-12 Recorder window

- Record channel waveform selection: In general, 2 waveforms can be selected for recording (TRACE 1, 2). Each record channel can be adjusted separately. Available choices for determining the waveform of channels one and two in the PM4010 system are: ECG, SpO2, IBP1, IBP2, RESP, GAS and OFF. By setting TRACE 1, 2 to "OFF", recording of numerical parameters is done only. By setting other options, the system recorder is activated and recording is done through it.
- RECORDER SWEEP: Available options are 6, 12.5 and 25 mm/s.
- Manual REC. time: Available options are MANUAL, 10 sec, 20 sec, 30 sec and CONTINUOUS.
    - By setting it to 10, 20 or 30 seconds, by pressing the "REC/STOP" key on the front panel of the system, real time recording starts from 5 seconds before, and after 10, 20 or 30 seconds, recording is automatically ended.
    - In CONTINUOUS mode, by pressing the "REC/STOP" key on the front panel of the system, recording starts from 5 seconds before and continues until the "REC/STOP" key is pressed again.
- Periodic recording: The PERIODIC INTERVAL item is used to select the time interval between automatic records.
  Available choices are 15 minutes, 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, 24 hours and OFF.
  In automatic recording, it is also possible to select the waveform of each channel separately through PERIODIC TRACE1, 2 items.
  The monitor records for 10 seconds at the time intervals set in this section.
- Parametric Recording: Parametric recording starts when you press “Rec/Stop” key if both traces in RECORDER WINDOW are set to “OFF”.
- Alarm Recording: If “ALARM REC” is set ON in each parameter’s window, the system automatically starts recording when an alarm occurs. Alarm recording is activated when the numeric parameters violate adjusted alarm limits or when an arrhythmia event occurs.
  When an alarm of parameters has occurred, only numeric parameters will be recorded and parameter’s value that triggered the alarm record is marked with an arrow.
  During HR alarm recording, the monitor also records 20 seconds of ECG waveform.
  You can “ON” or “OFF” alarm recording in HOME /RECORDERWINDOW and also it can be set in each parameter menu.
- Freeze Recording: The monitor prints out 20 seconds of the selected waveforms and numeric parameters in FROZEN mode. So, you can freeze abnormal waveforms on the screen and record them.
- TREND Recording: The monitor can print out the trend graph and numeric parameters in the current TREND WINDOW. Select "RECORD" in TREND WINDOW to start recording.
- ARR EVENT LIST Recording: The monitor can print out ARR EVENT LIST. Select "RECORD" in ARR EVENT LIST WINDOW to start recording.
- ARR WAVEFORM Recording: The monitor can print out stored arrhythmia waveforms in ARR WAVEFORM LIST WINDOW. Select "RECORD" in ARR EVENT RECAL/WAVE WINDOW to start recording.

- NIBP LIST Recording: The monitor can print out NIBP LIST. Select "RECORD" in NIBP LIST WINDOW to start recording.

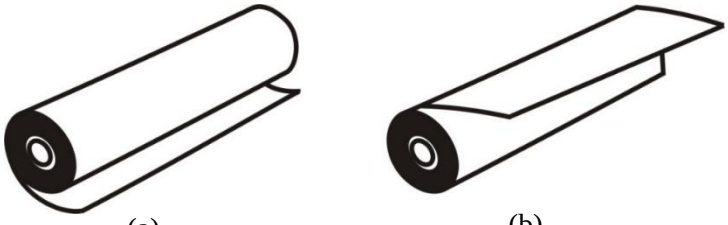
Recorder paper

Warning

- Do not touch the recorder head while recording and immediately after recording because it is so hot and may lead to personal injury including burns.
- While the recorder is working, the record paper goes out steadily. By pulling the paper, the recorder will be damaged.

Note

- Use only manufacturer recommended white thermosensitive record paper, otherwise the recording quality may be poor and the thermosensitive printhead may be damaged.
- Do not use grid paper.
- Do not use paper with edges that are pasted or have turnups at the start of the roll. If they need to be used unavoidably, replace with new paper roll as soon as possible before entire roll is used up.
- Thermosensitive surface of paper should be placed facing the head. Make sure to place the paper correctly.



(a) (b)

Figure 2-13 Paper placement a) incorrect, b) correct

- The paper detector may not operate properly if covered with foreign matter. Therefore, if you find foreign matter on the sensor, remove it and clean the sensor.
- If the paper is jammed, open the recorder door and remove the paper. Do not pull the paper by force.
- Be careful when inserting paper. Avoid damaging the thermosensitive printhead. Do not touch thermosensitive print head.
- It is recommended to use the paper with colored marks intended to aware that the paper is near to finish. Otherwise, the operator should be sure about sufficient paper for recording.

Data printed on recorder paper

- Recording Type (MANUAL, PERIODIC, ALARM, FREEZE, (Parameter) TREND, NIBP, ARR)
- Recording Date and Time
- Bed number
- Patient name, Patient ID, Gender, Height, Weight, Date of birth
- Parameter name and value
- Sweep Speed

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

Recorder Technical Alarms

Message	Cause	Solution	Explanation
Rec. Software Error	Software error	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
Recorder Fault	Hardware error	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	
Rec Door Open	The recorder door is open	Close the recorder door.	
Rec Paper Out	Recorder paper has been used up.	Insert a new paper roll.	
Print head High Temp	The thermal head is too hot.	Stop operation for a few minutes.	
Print head High Vol.	Print head voltage is high.	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	
Print head Low Vol.	Print head voltage is low.	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	
Time out Error	The recorder could not record.	Turn the system off and then on. If the problem persists, contact after sales service of the manufacturer.	

3) System Functions

Introduction

In this chapter, the function of modules and various capabilities of the PM4010 monitoring system will be explained. This system is equipped with various modules for vital signs monitoring. Cardiac signal monitoring and arrhythmia detection, breathing monitoring, blood oxygen, invasive and non-invasive blood pressure, temperature, respiratory gases and depth of anesthesia are among the functions of the PM4010 system.

Note

- Depending on the device model, some features may be disabled in your system.

ECG

General information

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

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

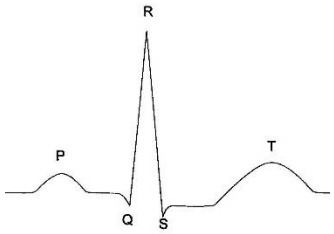


Figure 3-1 Standard ECG waveform

Warning

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

Patient Preparation

1. Prepare the patient's skin prior to the electrode placement.

- The skin is a poor conductor of electricity; therefore, preparation of the patient's skin is important to facilitate good electrode contact to skin.
- Shave hair from the selected sites, if necessary.
- Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because increases skin impedance).

- Rub the skin gently to increase the capillary blood flow in the tissues.

2. Put the electrodes on the patient body. Before attachment, apply some conductive gel on the electrodes if the electrodes are not self-supplied with electrolyte.

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

ECG Lead Wire Placement

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

Electrode placement for 3-Wire cable

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

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

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

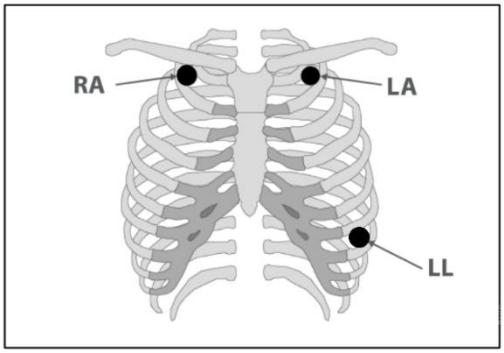


Figure 3-2 Electrodes' locations for 3-wire ECG cable

Electrode placement for 5-Wire cable
Right Arm (RA): red electrode, be placed near the right shoulder, directly below the clavicle.
Left Arm (LA): yellow electrode, be placed near the left shoulder, directly below the clavicle.
Chest (C): white electrode, be placed on the chest as illustrated in figure 4-2
Right Leg (RL): black electrode, be placed on the right hypogastrium.
Left Leg (LL): green electrode, be placed on the left hypogastrium.

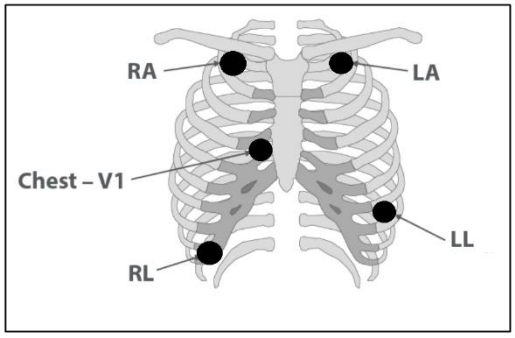


Figure 3-3 Electrodes' locations for 5-wire ECG cable

Note

- Depending on the type of cable (3-wire or 5-wire), the different leads I, II, III, aVR, aVL, aVF and V can be chosen.
- Electrode C in the 5-wire ECG cable can be placed in different places on the chest (according to the description mentioned for the 10-wire cable).

C or V Electrodes placement for 5- and 10-Wire cable

The electrodes of the main leads (left and right hand and left and right foot) should be placed similarly to the 3 and 5 wires.

Other electrodes should be placed as follows:

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

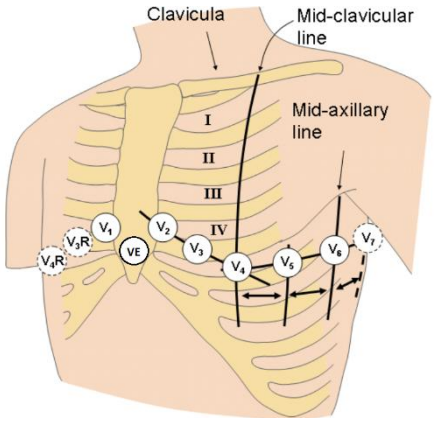
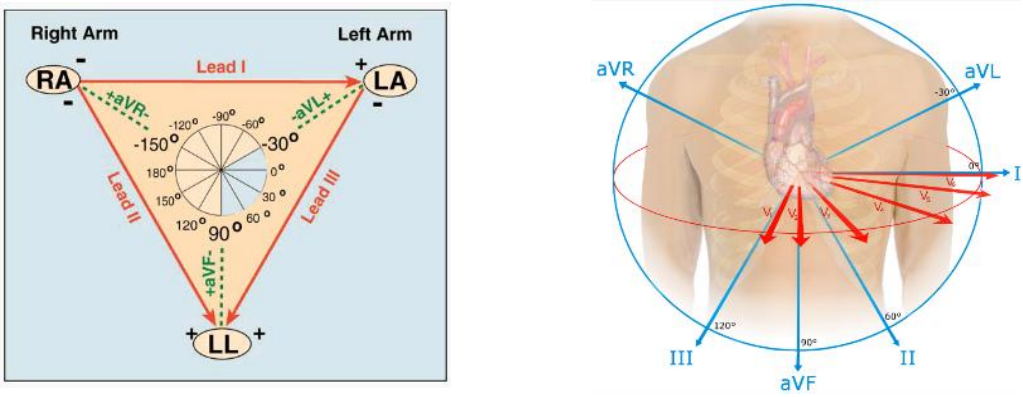


Figure 3-4 C or V electrodes' locations for 5/10-wire ECG cable

ECG leads and how they are calculated



(a) (b)

Figure 3-5 a) and b) Electrodes locations and ECG leads

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

Warning

- Unplug the ECG cable from the socket, the error message "ECG NO CABLE" should be displayed on screen.
- Before monitoring, check ECG cable safety and replace cables that are damaged, scratched, torn, or their distorted lead-wires.
- Pay attention that ECG cable is not subjected to tension during connection.
- ECG cable may be damaged if they are connected to a patient during defibrillation. Cables that have been connected to a patient during defibrillation should be checked for functionality before being used again.

- To ensure patient safety, all leads must be attached to the patient. Make sure that there is no contact between the conductive parts of electrodes, including the neutral electrode and any other conductive parts including earth.
- Use only one type of electrode on the same patient to avoid variations in electrical resistance. For ECG monitoring, it is recommended to use silver/silver chloride electrode. When dissimilar metals are used for different electrodes, the electrodes may cause large offset potentials due to polarization, which may be severe enough to prevent obtaining an ECG trace. Using dissimilar metals may also increase recovery time after defibrillation.
- Check once a day whether there is any skin irritation resulted from the ECG electrodes. If so, replace electrodes or change their sites.
- Line Isolation Monitor (LIM) fluctuations may resemble actual cardiac waveforms and thus activate heart rate alarms. Such fluctuations may be minimized by proper electrode and cable placement, as specified in this manual.
- When using Electro surgery equipment, leads should be placed in the furthest possible distance from Electro surgery electrodes and its grounding plate to avoid burning.
- The placing of the ECG leads will depend on the type of surgery that is being performed. For example, with open heart surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artefacts can sometimes affect the ECG waveform due to the use of ESU (Electro Surgical Unit). To reduce this effect, you can place the electrodes on the right or left side of shoulders and on the top side of the stomach. Avoid placing the electrodes on the upper arms (except when the ECG waveform is too weak).
- Improper connection of the ESU return electrode might lead to patient severe burn.
- When using ESU, never place an electrode near the grounding plate of the Electro surgery device, otherwise there will be a great deal of interference with the ECG signal.
- Do not immerse ECG leads completely in water, solvents or cleaning solutions because the connectors are not waterproof.
- Do not sterilize ECG cable by irradiation, steam or ethylene oxide.
- Use only the ECG cable introduced by the manufacturer. The use of other ECG cables may cause malfunction of the system and reduce its safety during the use of electroshock.

ECG parameter and its settings

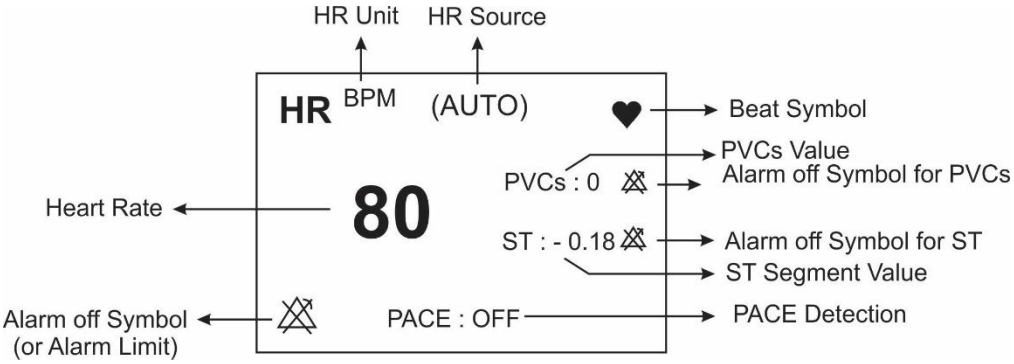


Figure 3-6 ECG parameter area

Note

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

- Both or one of the electrodes of reference lead are disconnected or not connected properly.
- The RL electrode is disconnected or not connected properly.

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

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

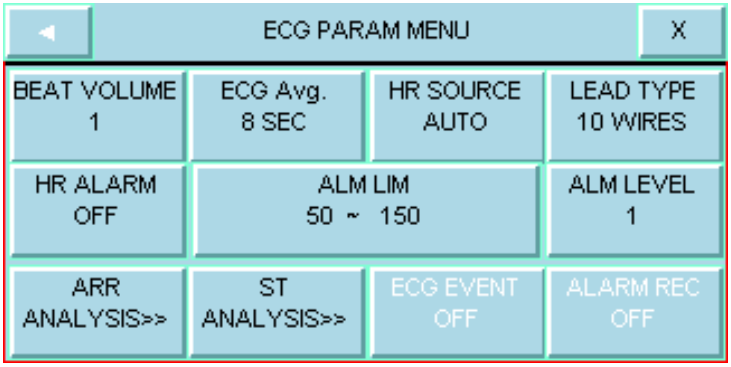


Figure 3-7 ECG window

BEAT VOLUME

It can be set between “1” to “7” and “OFF”; "OFF" indicates silence, while 7 indicates maximum volume.

ECG Avg.

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

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

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

By selecting any of these options, HR number changes will be applied up to the set time. For example, by selecting HR AVERAGE: 8, if HR changes from 90 to 200, it will take a maximum of 8 seconds to show the changes in HR.

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

** The above results are for lead II as reference lead.*

Note

- When HR is high (for instance when HR reaches to 120 bpm - tachycardia), the alarm is activated after 6 seconds. (by setting HR alarm limits between 60 bpm and 100 bpm).
- In case of cardiac Asystole, the alarm is activated after 10 seconds (from 80 bpm to 0 bpm).

- The ECG module is able to reject TALL-T pulses greater than 1.2 mv.
- The maximum amount of current that is delivered to the patient to detect the presence of leads is 90 nA.
- Specifications of the noise elimination circuit: the common noise signal with a current range of 10 μA is applied inversely to the main lead.
- The ECG cable consists of two parts, one end is the connector that connects to the monitor, and the other end is the leadwire that connects to the patient's body.
- Heart rates measured for 4 irregular rhythms according to IEC 60601-2-27:2011 are as follows:

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

HR Source

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

Note

- In AUTO mode, the heart rate is calculated from the module that its accessory is connected to the monitor.
- If two or more signals are being monitored simultaneously, the heart rate calculation will be done based on the signals priority, i.e., ECG, IBP1, IBP2, IBP3, IBP4 and SPO2 signals respectively.
- If the heart rate is calculated from any signal except ECG, PR alarms will be enabled based on HR alarm settings (Alarm Level and Alarm Limit).
- If HR SOURCE is set to any module except ECG, HR will change to PR and its features (e.g., unit) will change corresponding to the selected module for HR SOURCE.
- If HR SOURCE is set to any signal except ECG, beat symbol and sound will be according to the selected signal.
- If “HR SOURCE” is set to any module and cable of the module is not connected to the system, HR value will not be displayed.
- Calculating HR from IBP signal is possible just from ART, PAP, RVP, LVP and IBP labelled signal.
- HR value measurement range is 25~240 bpm, when the HR is calculated from IBP signal.
- Calculating HR value from IBP signal is not possible in the following conditions and the HR value will be displayed "---":
  - “IBP1/IBP2 STATIC PRESSURE” message on the screen
  - “IBP1/IBP2 SEARCH” message on the screen
  - HR value less than 25
  - Selecting CVP, LAP and RAP labels.

LEAD TYPE

To adjust ECG measurement mode to 3 WIRES, 5 WIRES and 10 WIRES.

HR ALARM

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

ALARM LIMIT

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

ALARM LEVEL

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

ECG EVENT

This item is inactive.

ALARM REC.

By activating this feature, when ECG alarms occur, a record is taken of the signal and its parameter.

ECG Alarms

Physiological Alarms

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

Technical Alarms

Alarm	Cause	Solution	Explanation
ECG NO CABLE	ECG cable is not connected to the system.	Connect ECG cable.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

ECG CHECK LA،RA،LL	The leads are not properly connected.	Make sure that the mentioned leads are properly connected to patient.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
ECG DEFECT	ECG module failure	Turn off and on the system. If this message is displayed again, contact local After Sale Service.	
ECG CHECK RL OR ALL	RL or other leads are not properly connected.	Make sure that all leads (esp. RL) and patient cable are properly connected to patient.	
ECG CHECK LL OR ALL	LL or other leads are not properly connected.	Make sure that all leads (esp. LL) and patient cable are properly connected to patient.	
ECG CHECK LA OR ALL	LA or other leads are not properly connected.	Make sure that all leads (esp. LA) and patient cable are properly connected to patient.	
ECG CHECK RA OR ALL	RA or other leads are not properly connected.	Make sure that all leads (esp. RA) and patient cable are properly connected to patient.	
ECG CHECK C (C2، C3، C4، C5، C6)	C lead is not properly connected to the patient.	Make sure that C lead and ECG cable are properly connected to patient.	

Note

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

Arrhythmia Analysis

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

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

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

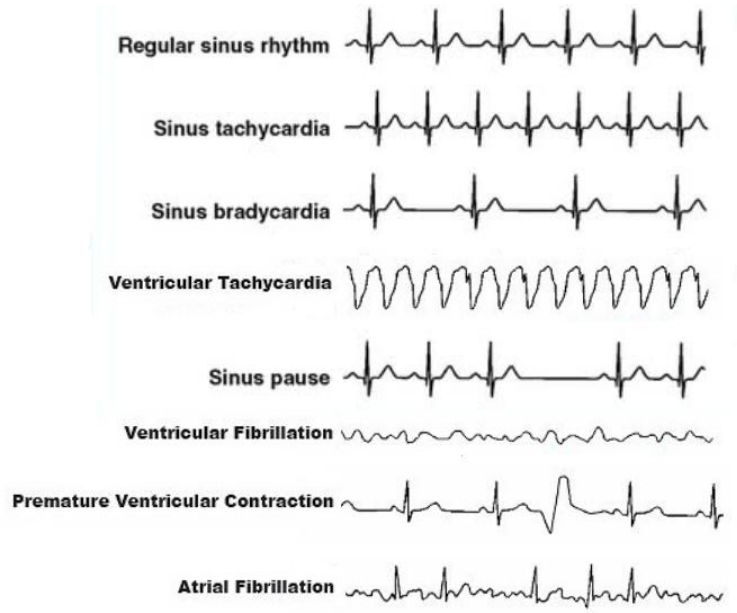


Figure 3-8 ECG signal; normal and some arrhythmias

Warning

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

Note

- When the arrhythmia monitoring is active, the heart rate (HR) 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.
- ST, ARR, Pace and HR are calculated from main lead that is displayed on the first trace and can be adjusted in ECG menu.
- It is recommended to use ECG lead I or II to have the best accuracy of ARR software.

Arrhythmia detection algorithm principle

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

- **Detection algorithm**: detects waves in ECG signal that could be QRS complexes.
- **Feature extraction** algorithm: During the learning phase an initial set of QRS templates or complexes is built. Beats that have a similar shape are placed in the same pattern. Then the monitor creates a reference template based on its identification of the patient's dominant QRS pattern. When a new true QRS complex is detected, it is compared with the existing templates. If no match is found, a new QRS template is added to the template set.
- **Labelling algorithm**: analyses all templates. Each template and the beats belonging to it are labelled with one of the following names: normal beats, premature ventricular beats (PVC: Premature Ventricular Contraction) and unknown beats. Premature Ventricular Contraction

(PVC) is ectopic impulse originating from ventricles, before the normal electrical activation sequence of the heart has occurred.

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

Note

- Parallel to this process there is an algorithm for detection of ventricular fibrillation and atrial fibrillation are based on waveform analysis and R-R intervals analysis.
- If two or more arrhythmias are detected simultaneously, the monitor alarms in order of event priority.
- When PACE is turned ON, for patient with pacemaker, the system will not detect the arrhythmia relating to premature ventricular beats.
- At most one minute after AFIB (atrial fibrillation) occurs, the corresponding alarm is announced and the time of its occurrence is stored in Trend.
- When ARR analysis is enabled, current PVC values are trended every 20 seconds and can be reviewed on the TREND window.
- When arrhythmia monitoring is active, the PVC value is shown in ECG parameter window in the following figure and updated every 5 seconds.
- The classification of each beat (Beat Classification) is based on the analysis of individual beats. If the characteristics of the new beat do not match the normal patterns, this beat is classified as premature or unknown. The monitor uses all beats to calculate the HR number and excludes unknown beats in the classification of arrhythmias.

Arrhythmia window

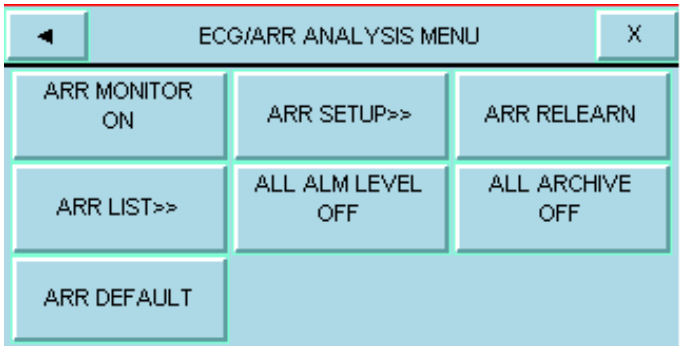


Figure 3-9 ARR analysis window

- ARR MONITOR: This item is used to enable or disable arrhythmia monitoring. The default is "OFF". When the Arrhythmia monitoring is disabled "PVCs OFF" is displayed in ECG parameters area.
- ARR SETUP: 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.

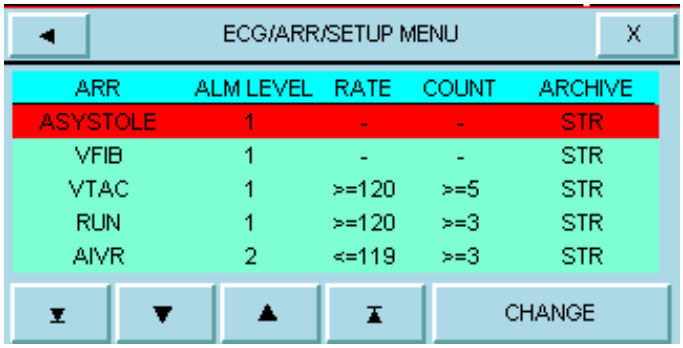


Figure 3-10 ARR setup window

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.

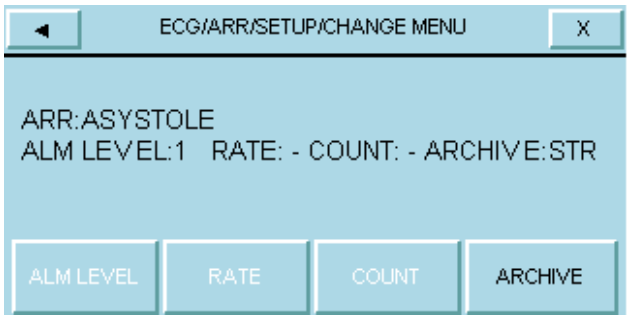


Figure 3-11 CHANGE window (sample)

- ALM LEVEL: This item is used to set the alarm level of each arrhythmia event. Available options are 1, 2 and OFF.

Note

- Alarm level for “ASYSTOLE”, “VFIB” and “VTAC” cannot be set and always is level 1.

- RATE: This parameter determines the heart rate in each arrhythmia. By setting this parameter as well as Count, you can determine the point at which an event call is triggered. You cannot modify the rate for “ASYSTOLE”, “VFIB”, “COUPLET”, “BIGEMINY”, “TRIGEMINY”, “PAUS”, “AFIB” and “FREQUENT PVCs”.
  “RUN” and “AIVR” derive their rate settings from “VTAC” and cannot be modified.

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

- COUNT: This parameter specifies the number of PVCs in each arrhythmia. By setting this parameter and rate, you can determine the point at which an event call is triggered.
  You can't modify the count for "ASYSTOLE", "VFIB", "COUPLET", "BIGEMINY", "TRIGEMINY", "TACHY", "BRADY", "AFIB" and "PAUS".
  Count of "AIVR" is ≥3 and it cannot be modified. Count setting for other arrhythmias is as the table below:

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

- ARCHIVE: You can determine whether the selected event and its information are stored and recorded automatically or both.
  STR: Stores the selected arrhythmia event.
  REC: Automatically records the selected event.
  STR/REC: Stores and records the selected event simultaneously.
  OFF: No action if arrhythmia event activates.

Note

- You can view the stored events in ARR EVENT RECALL Window.
- You can use "ALL ARCHIVE" in SETUP window to set all arrhythmias ARCHIVE condition to the same state.

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

Note

- In most situations the learning procedure takes about 20 seconds.
- If the monitor couldn't find 6 matching beats after 20 seconds, the relearn procedure continues and the "RELEARN" message remains on the screen till acceptable condition happens.
- Before starting learning procedure, verify quality of the ECG signal and ensure that it displays a normal reference pattern.
- While the monitor is in learning phase, all arrhythmia alarms and trend collection are suspended.
- 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: You can review any stored arrhythmia event (maximum 80 events) in this menu.

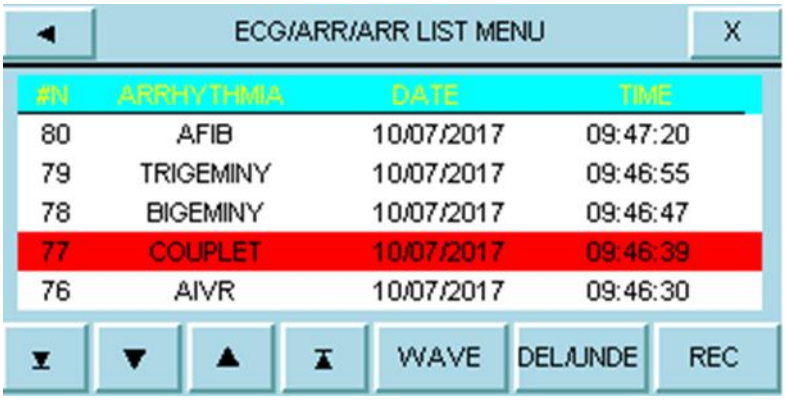


Figure 3-12 ARR LIST window

REC 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.
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.

Select WAVE to see detailed information of an arrhythmia event:

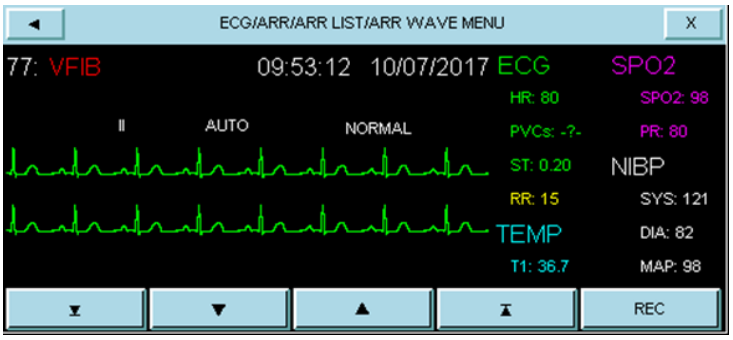


Figure 3-13 WAVE window

With the control keys bottom of the page, the waveform and parameters related to different arrhythmias can be viewed and recorded.

- ALL ALM 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 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

Arrhythmia Alarm Messages

(Arrhythmias are in order of priority):

Arrhythmia	Time of occurrence & Cause

ECG ASYSTOLE	5 seconds pass without the detection of valid QRS complex.
VFIB ARRHYTHMIA	Ventricular Fibrillation: The monitor identifies a sinusoidal waveform with fibrillation characteristics. (Certain ventricular tachycardias have sinusoidal waveforms closely resembling those of ventricular fibrillation. Because of the similarity of these waveforms, the monitor may classify such types of ventricular tachycardia as ventricular fibrillation) .
VTAC ARRHYTHMIA	Ventricular Tachycardia: N or more PVC's are detected in a time interval T= (60*(N-1))/R, where N is defined as the VTAC count and R is defined as the VTAC rate.
RUN ARRHYTHMIA	Ventricular Run: Series of 3 to N-1 consecutive PVCs with a beat to beat rate ≥ the VTAC rate.
AIVR ARRHYTHMIA	Accelerated Idioventricular Rhythm: Series of 3 or more PVCs with a beat rate less than the VTAC rate.
BIGEMINY ARRHYTHMIA	Ventricular Bigeminy: Sequence of beats with the pattern : normal, PVC, normal, PVC, normal, PVC
TRIGEMINYARRHYTHMIA	Ventricular Trigeminy: Sequence of beats with the pattern : normal, normal, PVC, normal, normal, PVC
COUPLET ARRHYTHMIA	Ventricular Couplet: Sequence of beats with the pattern : normal, PVC, PVC, normal, PVC, PVC
TACHY ARRHYTHMIA	Sinus Tachycardia: HR ≥ TACHY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.
BRADY ARRHYTHMIA	Sinus Bradycardia: HR≤ BRADY rate setting. A PVC or other abnormal beat breaks the analysis sequence and restarts analysis.
AFIB ARRHYTHMIA	Atrial Fibrillation: Formation of QRS complexes in irregular intervals
PAUS ARRHYTHMIA	Actual R-R interval more than 2.1 times of the average R-R interval.
FREQUENT PVCs	More than N (event count set in the ARR SETUP WINDOW) PVC per minute.

ST ANALYSIS

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

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

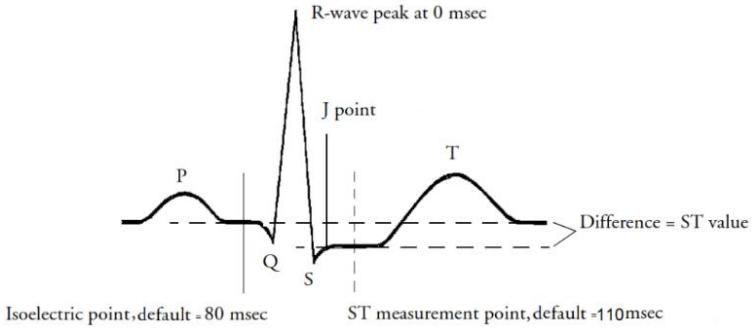


Figure 3-14 ST segment

The ST algorithm examines QRS complexes that are classified as normal beats (detection and classification of beats is provided by the arrhythmia detection algorithm) and deletes beats that have a ventricular origin. By combining the characteristics of normal beats, it creates an averaged QRS complex. ST segment deviation is calculated in this way.

Note

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

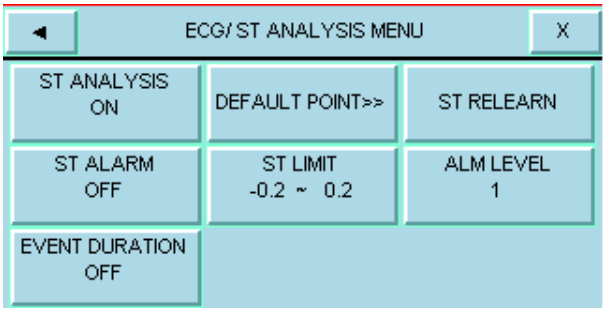


Figure 3-15 ST Analysis window

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.

DEFAULT POINT

This window is used to adjust the position of both ISO and ST measurement points. When you change the ST and ISO measuring points on the DEFAULT POINT window, the monitor recomputes the ST deviation value accordingly.

As shown above, the DEFAULT POINT WINDOW shows the dominant QRS complex template. If the template is not established, a horizontal line will be displayed and if the ST ANALYSIS is "OFF", the message "ST ANALYSIS KEY IS OFF" will appear in this window.

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.

Two vertical lines indicate the positions of the ISO and ST points.

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

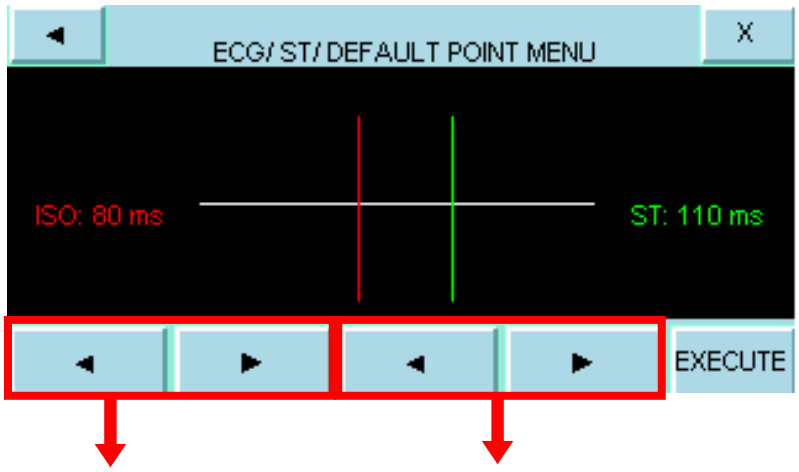


Figure 3-16 Default point window

Note

- Peak of R-wave is the reference point for ST calculation and changing range of ST and ISO are 5 to 400ms by step of 5ms.
- It is good clinical practice to check the position of ISO and ST measuring points before starting ST monitoring and completing learning procedure.
- In practice, accurate determination of ISO and ST measuring points requires careful clinical evaluation.
- The ST measurement point should be adjusted if patient's HR or ECG morphology changes significantly.
- If pace is ON (for patient with pacemaker) or during learning procedure, there is no waveform in DEFAULT POINT Window and you can see just ISO and ST lines. In this condition, ST value will not be measured.

- A red vertical marker with “CHG” label on ST in TREND window shows the time in which the measuring point has been changed.
- Abnormal QRS complex is not considered in ST segment analysis.

ST RELEARN

Click on ST RELEARN in the ST ANALYSIS window to start learning procedure. The message “RELEARN” is displayed in the message area. The procedure will take about 20 seconds.

During the learning procedure, the following actions will be taken:

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

Note

- The monitor automatically begins to learn a reference template whenever you execute any of the following tasks (If ST ANALYSIS is ON):
  - Turning on the monitor
  - Connecting ECG cable.
  - Changing an ECG lead configuration.
  - Choosing “NEW” from HOME / PATIENT INFORMATION
- A yellow vertical marker with “LRN” label On ST in TREND window shows the time in which the learning procedure has been done.

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.

Note

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

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.

ALM LEVEL

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

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 Physiological alarms

The alarm occurs when ST value of reference lead (by default: lead II) exceeds the adjusted alarm limits:

Alarm	Cause
ST- II HIGH	ST segment value violates adjusted high limit.
ST-II LOW	ST segment value violates adjusted low limit.

ST Technical alarms

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

ECG Trace menu

Touch the ECG waveform area to access the below menu:

Figure 3-17 ECG Trace window

ECG LEAD

You can choose the desired lead for the desired TRACE.

Note

- 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.
- ST, ARR, Pace and HR are calculated from main lead that is displayed on the first trace and can be adjusted in ECG menu.
- Due to higher amplitude of signal voltage in leads II and V, it is recommended to select one of these leads as main lead.
- If an ECG waveform is not accurate while the electrodes are properly attached, try to change the lead.
- In any situation that causes circuit saturation (such as Discharge of defibrillator), the constant signal will be displayed, which usually does not last more than 5 seconds.

ECG SIZE

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

ECG SWEEP

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

ECG FILTER

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

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

PACE DETECT

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

Warning

- For patients with pacemaker, PACE DETECT must be switched "ON", otherwise, the pace pulses may affect HR counting and result in low precision of HR value.
- For the patients with pacemaker, the monitor may continue to count the pacemaker rate as heart rate during the occurrence of cardiac arrest or some arrhythmias. Do not rely entirely upon monitor alarms. Keep the patients with pacemaker under close surveillance.

Note

- ECG signals with the slope of up to 1 V/s will not be counted as Pace signal.
- Monitoring of patients with pacemaker is not generally affected when PACE DETECT is enabled.
- In addition to normal paces, the pace detector detects ineffective paces and atrial paces that occur between 150 and 250 milliseconds before ventricular paces.

ECG CALIB

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

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.

RESP

General Information

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

place of electrodes is important. Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of chest movement to optimize the respiratory waveform.

Note

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

ESP parameter and its settings

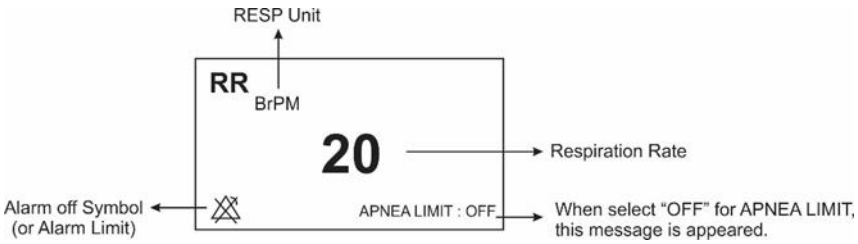


Figure 3-18 RESP parameter area

Touch RESP parameter area to access the below menu:

Figure 3-19 RESP window

RR ALARM

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

ALM LIMIT

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

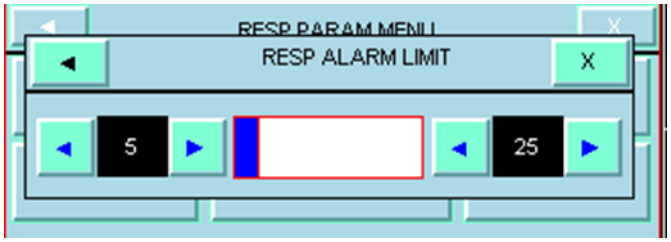


Figure 3-20 RESP alarm limit adjustment

ALM LEVEL

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

APNEA LIMIT

To set the standard of judging an apnea case. It can be set to 10 – 40 seconds and OFF and increases/decreases by 10s. When you select OFF, the message “APPNEA LIMIT: OFF”.

Note

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

EVENT MARK

This item is inactive.

ALARM REC

By activating this feature, when RESP alarms occur, a record is taken of the signal and its parameter.

RESP Trace menu

Touch RESP waveform area to access the below menu:

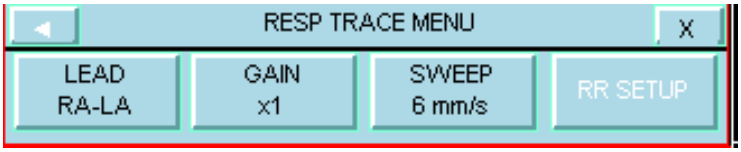


Figure 3-21 RESP Trace window

- **LEAD**: Available options for RESP LEAD are "RA-LA" and "RA-LL".
- **GAIN**: To adjust the size of RESP waveforms, select gain value for each channel from ×0.25, ×0.5, ×1, ×2 and ×4.
- **SWEEP**: Available options for RESP SWEEP are 3, 6, 12/5, and 25 mm/s.
- **RR SETUP**: This item is inactive.

RESP physiological alarms

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

RESP technical alarms

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

SpO2

General Information

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

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

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

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

1. Sensor (probe)
2. Patient cable (Extensor)

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

(a) (b)

Figure 3-22 a) sensor, b) patient cable.

Masimo Technology

Signal Extraction Technology ® (SET ®)

Signal Extraction Technology® (SET®) signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional

pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise).

Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform (DST), readily identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

Rainbow Pulse CO-Oximetry Technology®

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

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxhygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).
2. The amount of arterial blood in the tissues changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

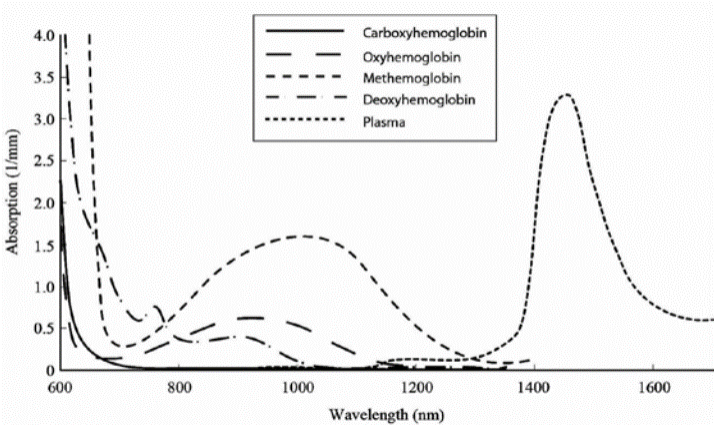


Figure 3-23 Absorption spectra

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

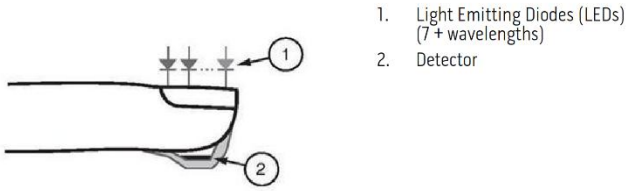


Figure 3-24 Light Emitting Diodes and Detector

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)).

SpO2 monitoring parameters

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

Note

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

Rainbow monitoring parameters

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

- **SpHb** measures the level of total hemoglobin in arterial blood.
- **SpOC** calculates the levels of total oxygen content in the arterial blood. Neither SpO2 nor Hb parameter by itself can indicate the actual amount of oxygen in the blood. A patient with normal SpO2 or Hb may have low levels of oxygen. In fact, both SpO2 and Hb are considered by SpOC parameter.
- **SpCO** measures the levels of carboxyhemoglobin saturation (reflecting the blood levels of carbon monoxide bound to hemoglobin) in arterial blood.
- **SpMet** measures the levels of oxidized form of haemoglobin.

Successful Monitoring for rainbow parameters

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

Warning

- The Pulse CO-Oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.
- 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.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse co-oximeter unless the setup was verified to be correct.
- Do not use pulse co-oximeter during magnetic resonance imaging (MRI) or in an MRI environment. Induced current could potentially cause burns.
- Do not use the Pulse CO-Oximeter if it appears or is suspected to be damaged.
- ***Explosion hazard***: Do not use the pulse co-oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To protect against injury, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Do not attempt to sterilize the device.
  - Use cleaning solutions only as instructed in this operator's manual.
  - Do not attempt to clean the device while monitoring a patient.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.
- 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 accuracy of SpCO and SpMet parameters measurement can be affected by:
  - Improper sensor application
  - Intravascular dyes such as indocyanine green or methylene blue
  - Abnormal hemoglobin levels
  - Low arterial perfusion
  - Low arterial oxygen saturation levels including altitude induced hypoxemia
  - Elevated total bilirubin levels
  - Motion artifact
- The accuracy of SpHb and SpOC parameters measurement can be affected by:
  - Improper sensor application
  - Intravascular dyes such as indocyanine green or methylene blue
  - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
  - Elevated PaO2 levels
  - Elevated levels of bilirubin
  - Low arterial perfusion
  - Motion artefact
  - Low arterial oxygen saturation levels
  - Elevated carboxyhemoglobin levels
  - Elevated methemoglobin levels
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Vasospastic disease such as Raynaud's
  - Elevated altitude
  - Peripheral vascular disease
  - Liver disease
  - EMI radiation interference
- The following factors may influence the accuracy of SpO2 measurement:

  - Improper sensor application and placement
  - Elevated levels of COHb or MetHb : High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed
  - Elevated levels of bilirubin
  - Elevated levels of dyshemoglobin
  - Vasospastic disease, such as Raynaud's , and peripheral vascular disease
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Severe anemia
  - Very low arterial perfusion
  - Extreme motion artifact
  - Abnormal venous pulsation or venous constriction
  - Severe vasoconstriction or hypothermia
  - Arterial catheters and intra-aortic balloon
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
  - Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
  - Skin color disorders
- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- The Pulse CO-Oximeter should not be used as the sole basis for diagnosis or therapy decisions (related to suspected carbon monoxide poisoning, for example). It must be used in conjunction with clinical signs and symptoms.
- The pulse co-oximeter is not an apnea monitor.
- The Pulse CO-Oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The Pulse CO-Oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse co-oximeter should not be used for arrhythmia analysis.
- SpCO measurement may not be possible due to insufficient arterial saturation level or high MetHb level.
- SpO2, SpCO, SpMet, and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion. See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.
- Tissue damage or inaccurate measurement can be caused by incorrect application or use of an SpO2 sensor, for example by wrapping the sensor too tightly or by applying supplemental tape.
- Shortness of the pulse signal may happen for the following reasons:
  - When the patient has a cardiac arrest.
  - The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
  - There is arterial occlusion proximal to the sensor.
- Do not adjust, repair, open, disassemble, or modify the Pulse CO-Oximeter or accessories. Injury to personnel or equipment damage could occur. Return the Pulse CO-Oximeter for servicing if necessary.
- Do not place the monitoring system where the controls can be changed by the patient.
- ***Electrical shock and flammability hazard***: Before cleaning, always turn off the device and disconnect it from any power source.

- When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the Pulse CO-Oximeter on electrical equipment that may affect the device, preventing it from working properly.
- If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If "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.
- If you use pulse oximetry during whole body irradiation, place the pulse oximetry sensors outside the radiation area. If pulse oximetry sensors are exposed to radiation, numerical parameters may be displayed incorrectly or zero.
- The device must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.
- 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 devices prior to clinical decision making to completely understand the patient's condition.
- Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
- ***Electrical shock hazard***: Perform periodic tests in accordance with safety standards to ensure that leakage current is allowed in the system and the circuits of the applied parts. The sum of the leakage currents should be in accordance with IEC60601-1 and UL60601-1. When connecting the external device to the system, the leakage current should be checked. When something happens, such as falling from a height of more than one meter or spilling blood or other liquids on the device, it needs to be tested again before using the device again. There is a possibility of damage to the user.
- ***Product Disposal***: Follow local regulations regarding disposal of this device and/or accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the Pulse CO-Oximeter.
- Do not perform SpO2 and NIBP measuring in same arm simultaneously; because obstruction of blood flow during NIBP measuring may adversely affect the SpO2 value.
- Before using the sensor, pay attention to the description of the sensor, such as the patient's age, weight, and whether it is disposable or not, which is written in its packaging.
- Do not use the SpO2 sensor whose packaging or the sensor itself is damaged and return it to the supplier.
- Electrocautery cable and SpO2 cable should not be twisted together.
- Avoid using the SpO2 sensor in that hand where there is an arterial catheter or a venous syringe.
- Before starting to monitor the pulse oximeter, make sure its settings are 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"
- The pulse oximetry system may estimate the SpO2 number higher than usual in the vicinity of Hb-Co and Met-Hb and colored chemical liquids.
- Change the application site or replace the sensor and/or patient cable when a "SPO2 REPLACE SENSOR" and/or "SPO2 REPLACE CABLE", or a persistent poor signal quality message (such as "SPO2 LOW SIGNAL IQ") is displayed. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.

- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor and result in inaccurate measurements. To prevent interference from ambient light, cover the rainbow sensor with an ambient light shield.

Note

- For Masimo patent information, please refer to the following address: www.masimo.com/patents.htm
- No Implied License Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.
- A functional tester cannot be used to assess the accuracy of the Pulse CO-Oximeter.
- 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.
- Changes or modifications shall void the guaranty for the pulse co-oximeter accessories.
- SpO2 value is always displayed in a fixed position of SpO2 window and Pulse Rate is displayed beside it, but if "HR SOURCE" is set to "SpO2", PR value will be eliminated from SpO2 window and displayed instead of HR value in the ECG WINDOW.
- The Pleth waveform is displayed as normalized waveform and its amplitude does not comply with real blood volume variations.
- User can be informed of inadequacy of signal and physiological parameters values by various messages and alarms in necessary situations.
- Make sure the nail covers the light window.
- The sensor wire should always be placed above the finger.
- To select the appropriate sensor, refer to the accessories chapter.
- To roll up the accessory cable, do not wrap it tightly around the accessory or the device, this may cause damage to the cable.
- Pulse oximetry system is a quick warning system. Laboratory oximeters should be used as an aid to fully understand the patient's condition.
- SpO2 module updates SpO2 and pulse rate values every 1 sec.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Cables and sensors are provided with X-Cal technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.
- Materials used in our SpO2 sensors are innoxious.

SpO2 parameter and its settings

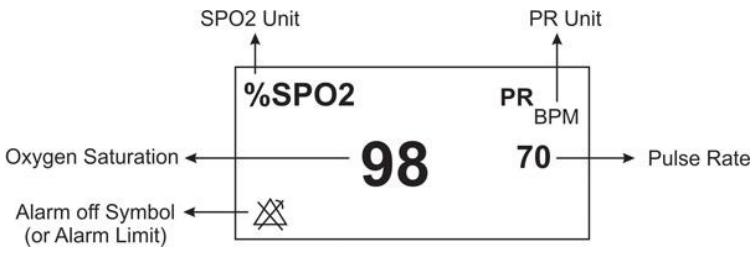


Figure 3-25 SpO2 parameter area

To monitor SpO2, follow this procedure:

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

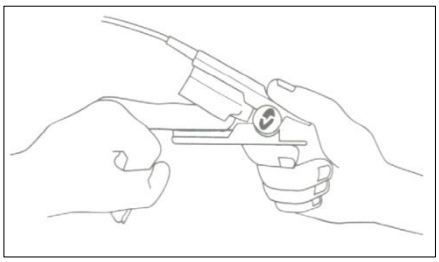


Figure 3-26 SpO2 sensor placement

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

Touch SPO2 parameter area to access the below menu:

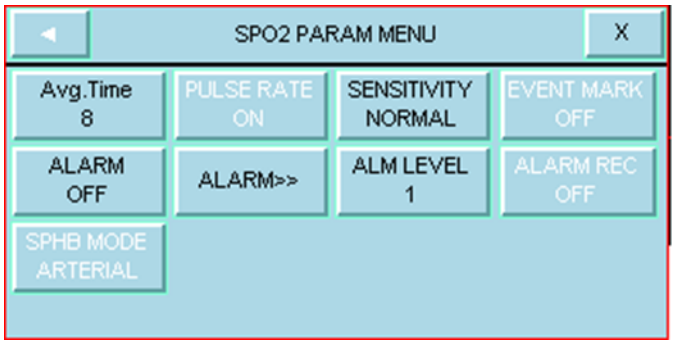


Figure 3-27 SpO2 window

Avg. Time

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

Available options are 2, 4, 8, 10, 12, 14 and 16.

PULSE RATE

This item is always ON.

SENSITIVITY

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

- **NORM** (Normal Sensitivity): NORM is the recommended for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).
- **APOD** (Adaptive Probe Off Detection® Sensitivity): APOD is the recommended where there is a high probability of the sensor becoming detached due to excessive movement. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings. By selecting this mode, “SPO2 APOD MODE” appears on the screen with yellow color.
- **MAX** (maximum sensitivity): MAX is recommended sensitivity mode for patients with low perfusion or when a low perfusion message displays in APOD or NORM mode. MAX mode is not recommended for care areas where patients are not monitored visually, such as general wards. In MAX mode, the message "SpO2 MAX SENS." displays on the screen with yellow color.

Warning

- APOD mode is not advisable for patients with low perfusion because the system has the least sensitivity to signal changes in this mode.

EVENT MARK

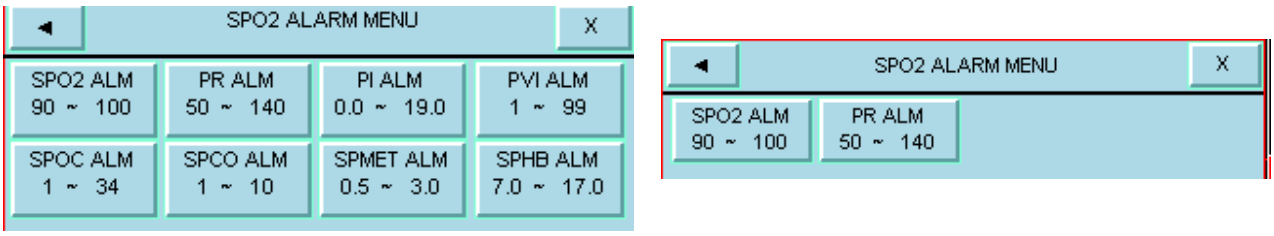
This item is inactive.

ALARM activation

Pick "ON" to switch on SpO2 alarm functions such as parameters blinking, audio alarm, and light indicator. Pick "OFF" to switch off the alarm functions and there will be a  symbol in the Parameter Area.

ALARM menu

By clicking on this option, the SpO2 ALARM MENU window will open, where you can change SpO2 and PR alarm ranges (and rainbow parameters, if enabled).



(a) (b)

Figure 3-28 SpO2 alarm menu a) without rainbow parameters, b) with rainbow parameters

By clicking on any of the options in the SpO2 ALARM MEN window, a window for setting the alarm range corresponding to the same parameter will open as shown in the figure below, where the upper limit and lower limit can be set:

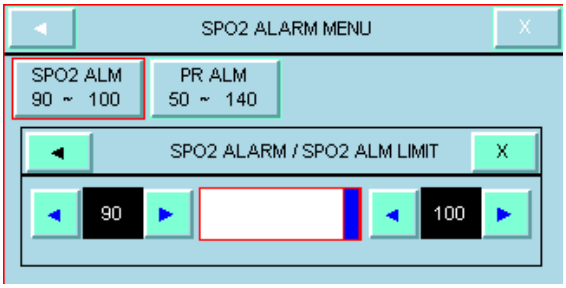


Figure 3-29 SpO2 alarm limit window

Parameter	Alarm limits	
SpO2	Lower limit	1 ~ (upper limit - 1)
	Upper limit	(lower limit + 1) ~ 100
PR	Lower limit	20 ~ (upper limit - 5)
	Upper limit	(lower limit + 5) ~ 235
PI	Lower limit	0.0 ~ (upper limit – 0.1)
	Upper limit	(lower limit + 0.1) ~ 19.0
PVI	Lower limit	1 ~ (upper limit - 1)
	Upper limit	(lower limit + 1) ~ 99
SpCO	Lower limit	1.0 ~ (upper limit - 1)
	Upper limit	(lower limit + 1) ~ 99
SpMet	Lower limit	0.5 ~ (upper limit – 0.5)
	Upper limit	(lower limit + 0.5) ~ 99.5
SpHb	Lower limit	0.5 ~ (upper limit – 0.1)
	Upper limit	(lower limit + 0.1) ~ 24.5
SpOC	Lower limit	1.0 ~ (upper limit – 1)
	Upper limit	(lower limit + 1) ~ 34.0

ALM LEVEL
Available options are 1 and 2 that level 1 represents the high level alarm.

ALARM REC.
By activating this feature, when SpO2 alarms occur, a record is taken of the signal and its parameter.

SpHb MODE
Setting the measurement mode of VENOUS or ARTERIAL saturation hemoglobin.

Monitoring Rainbow Parameters

The rainbow parameters are displayed on a special page designed for SpO2 and rainbow parameters:

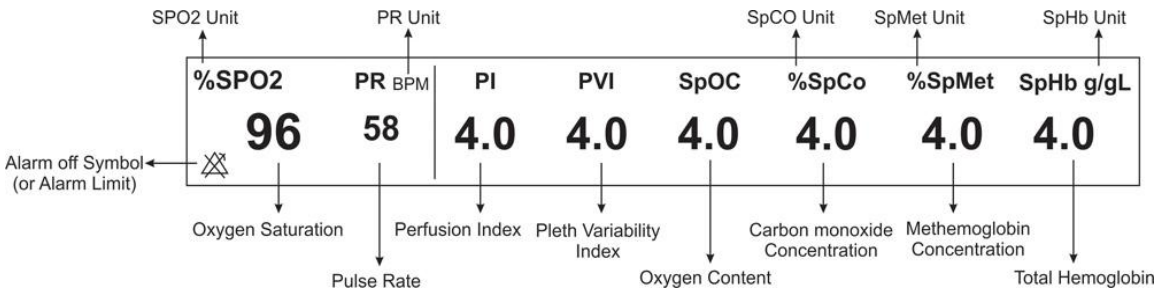


Figure 3-30 Rainbow parameters display

SpO2 and Rainbow Trace menu

By clicking on the SPO2 waveform area, a window will open to set its plotting speed (SPO2 TRACE MENU). Selectable options for signal drawing speed (PLETH SWEEP) are 12.5 and 25 mm/s.

SpO2 and Rainbow physiological alarms

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

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

SpO2 technical alarms

Alarm	Cause	Solution	Description
SPO2 NO CABLE	SpO2 cable is not properly connected to the patient monitor.	Make sure that the SpO2 cable is correctly connected to the monitor.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 NO AD* SENSOR	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	Ensure that the adhesive portion is firmly connected to the sensor.	
SPO2 NO SENSOR	SpO2 Sensor is not fully inserted into the connector.	Make sure that SpO2 sensor is correctly connected to the patient cable connector.	
	SpO2 measurement does not have	1-Assess the patient.	

Alarm	Cause	Solution	Description
SPO2 LOW SIGNAL IQ**	confidence due to poor signal quality caused by excessive motion or other signal interference.	2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	
SPO2 LOW PR CONFIDENCE	Pulse rate measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	
SPO2 LOW PI CONFIDENCE	PI measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	
SPO2 LOW PVI CONFIDENCE	PVI measurement does not have confidence due to poor signal quality caused by excessive motion or other signal interference.	1-Assess the patient. 2-Check the sensor and ensure proper sensor application. 3-Change the sensor site.	
SPO2 REPLACE CABLE	The life of the SpO2 cable has expired.	Replace the SpO2 cable.	
SPO2 CABLE DEFECT	1. The SpO2 cable is damaged. 2. SpO2 cable is not compatible.	1. Make sure that the Masimo SpO2 cable is correctly connected to the monitor. 2.Turn the device on and off. If this message is displayed again, replace the cable.	Alarm level 2- the message is displayed in

Alarm	Cause	Solution	Description
SPO2 REPLACE SENSOR	SpO2 sensor has used all its available monitoring time.	Replace the SpO2 sensor.	yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 SENSOR DEFECT	1. The SpO2 sensor is damaged. 2. SpO2 sensor is not compatible.	1. Make sure that SpO2 sensor is properly attached to the cable connector. 2. Turn the device on and off. If this message is displayed again, replace sensor.	
SPO2 SENSOR OFF	1-SpO2 Sensor may be detached from the patient. 2-The sensor is not connected to patient properly. 3-The sensor is damaged.	1-Disconnect and reconnect the sensor to the patient. 2-Properly reapply the sensor on the patient and reconnect the sensor to the monitor or patient cable. 3-Replace the sensor.	
SPO2 REPLACE AD* SENSOR	When a single-patient-use sensor is used, the life of the adhesive portion of the sensor has expired.	Replace the adhesive portion of the sensor.	
SPO2 AMBIENT LIGHT	This may be caused by excessive ambient light sources such as surgical lights or direct sunlight, or other.	In the case of using rainbow sensor, place a Masimo Optical Light Shield over the sensor.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled and ignores this fault.
SPO2 RAINBOW HARDWARE FAIL	SpO2 hardware error	Restore power to the instrument. If this message is displayed again, contact After sales service of the manufacturer.	
SPO2 PROBE DEFECT	Failure to properly operate the sensor or cable or both of them.	Check the function of the sensor and the cable separately and replace the defective part.	

Alarm	Cause	Solution	Description
SPO2 SENSOR CHECK CONNECTION	The sensor connection to the system is not correct.	Check the sensor connection and, if necessary, replace the sensor and/or cable.	

SpO2 messages

Message	Cause	Solution
SpO2 CABLE NEAR EXP	The SpO2 cable is near expiration.	-
SpO2 SENSOR NEAR EXP	The SpO2 sensor is near expiration.	-
SpO2 AD* SENSOR NEAR EXP	The SpO2 adhesive sensor is near expiration.	-
SpO2 SEARCH	The instrument is searching for pulse.	If instrument fails to display within 30 seconds, disconnect and reconnect the sensor. If pulse search continues, move the sensor to better perfused site.
SpO2 SIGNAL WEAK	The SPO2 signal amplitude is too weak or undetectable.	Change the place of the probe.
SpO2 DEMO MODE RUN	The SpO2 measurement is in demo mode.	-
SpO2 ONLY MODE	Measuring rainbow parameters is not possible (due to the ambient light or the dark skin pigmentation).	Use a Masimo light shield to cover the sensor and adjust the sensor.
* AD SENSOR stands for Adhesive Sensor. * SIGNAL IQ stands for Signal Identification and Quality Indicator.		

NIBP

General Information

The monitor uses the oscillometric method for measuring Non-Invasive Blood Pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall.

In this method, the cuff is pumped to a pressure higher than the systolic pressure, and then the pressure starts to decrease gradually. During pressure reduction, amplitude and pressure fluctuations are revealed. The amplitude of fluctuations initially has an upward trend. As the pressure decreases further, the fluctuation amplitude increases and reaches its maximum value at one point, which is considered as MAP pressure (pressure with maximum fluctuation amplitude). In the following, the amplitude of fluctuations decreases and eventually the fluctuations disappear. In the oscillometric method, the MAP pressure is detected and the systolic and diastolic pressures are revealed based on the MAP pressure.

NIBP monitoring is intended for adult, pediatric, and neonatal patients.

Note

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

NIBP Safety Information

Warning

- Make sure to select the correct patient category setting for your patient before NIBP measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise, it may lead to a safety hazard.
- **If the neonate mode is used for adult or pediatric, the pressure measurement will be impossible because of the limitation of pumping in the neonate's mode.**
- Do not measure NIBP on patients with inflammation or on the limb where skin damage has occurred or is expected.
- **Do not measure NIBP if the tissue is damaged or is likely to be damaged.**
- Use clinical judgment to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- The monitor may not operate correctly if used or stored outside the relevant temperature, altitude or humidity ranges described in the Performance Specifications.
- Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during the cuff inflation.
- Do not apply cuff on the arm on the side of a mastectomy.
- Continuous cuff pressure measurement due to connection tubing kinking may cause blood flow interference and result in harmful injury to the patient.
- NIBP reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition. If you doubt the NIBP measurements, determine the patient’s vital signs by alternative means, and then verify that the monitor is working correctly.
- There is a possibility of purpura, ischemia, and neuropathy when the cuff is closed continuously on the tissue. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site or stop the blood pressure measurements immediately. Check more frequently when making automatic or STAT measurements. Auto NIBP measurements with one- and two-minute intervals are not recommended for extended periods of time.
- Do not modify or replace connectors of the NIBP air hose except with URUK -approved connectors. Use only recommended manufacturer Blood Pressure Cuffs and Hose. The use of other cuffs and hoses has a negative effect on the accuracy of the measurement.
- Never connect intra-arterial or intra-venous lines, or any other incompatible connectors to the NIBP hose. This can cause serious injury or death.
- NIBP diagnostic significance must be decided by the hospital’s clinician staff.
- Accuracy of NIBP measurement depends on using proper size of the cuff. It is essential to measure limb circumference and choose a cuff with proper size.
  - Selecting a very small size will increase the measured pressure.
  - Selecting a very large size will reduce the measured pressure.

Note

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

NIBP Measurement Limitations

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

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

Note

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

Measurement modes

There are three NIBP measurement modes are:

- **MANUAL**: measurement on demand.
- **AUTO**: repeated measurements at set intervals.
- **STAT**: continual rapid series of measurements over a five minute period.

NIBP Window

The NIBP window shows only numeric parameter.

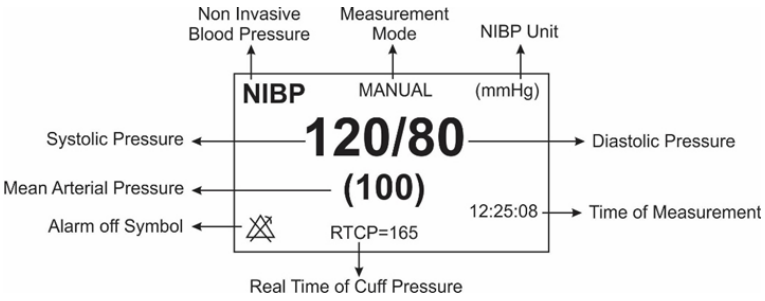


Figure 3-31 NIBP parameter area

Note

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

Preparing For NIBP Measurements

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

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

Note

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

Placing the NIBP Cuff

To place the NIBP cuff, follow this procedure:

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

    a. Measure the patient's limb circumference.

    b. Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the length of the upper arm or the thigh. The inflatable part of the cuff should be long enough to encircle to overlap at least 50% to 80% of the limb.

    c. Apply the cuff to the patient's upper arm or leg and make sure the cuff and artery are aligned.

    d. The cuff should fit snugly, but with enough room for two fingers to be placed between the cuff and the patient's arm (on adults), and loosely on neonates with little or no air present within the cuff. Otherwise, it may cause discoloration and ischemia of the extremities. Make sure that the cuff index line falls within the range markings on the cuff. If it does not, use a cuff that fits better.

    e. Middle of the cuff should be at the level of the right atrium of the heart. If it is not, use the measurement correction formula to correct the measurement.

    f. Connect the cuff to the air tubing. Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.

Warning

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

Starting and Stopping NIBP Measurements

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

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

Changing NIBP settings

Touch the NIBP parameter area and the setting window will be opened:

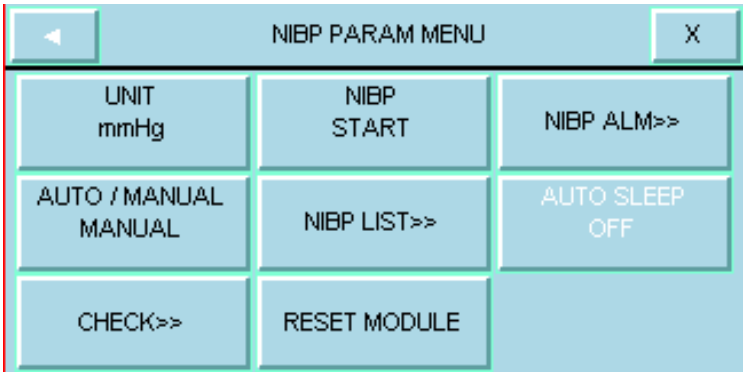


Figure 3-32 NIBP window

NIBP UNIT

To set NIBP UNIT, follow this procedure:

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

NIBP START/STOP

Select this item to start or stop NIBP measurement:

- Enter the NIBP setting window.
- Select NIBP START/STOP.

NIBP Alarm

To set the NIBP alarm, follow this procedure:

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

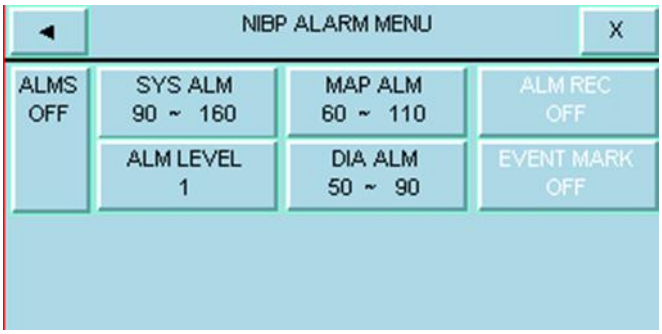


Figure 3-33 NIBP alarm menu

NIBP Alarm level

To set NIBP alarm level, follow this procedure:

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

NIBP SYS LIMIT

To set NIBP SYS alarm limit, follow this procedure:

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

NIBP DIA LIMIT

To set NIBP DIA alarm limit, follow this procedure:

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

NIBP MAP LIMIT

To set NIBP map alarm limit, follow this procedure:

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

NIBP Alarm Record

By enabling this option, NIBP alarms will be recorded when they occur.

EVENT MARK

this item is inactive.

NIBP mode

To set NIBP mode, follow this procedure:

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

Note

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

RESET MODULE

To reset the module, follow this procedure:

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

Warning

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

Note

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

NIBP LIST

To view NIBP list:

- Enter the NIBP setting window.
- Select NIBP LIST. You can view the result and time of the latest NIBP measurements. The patient monitor can store the latest 100 NIBP measurements data.

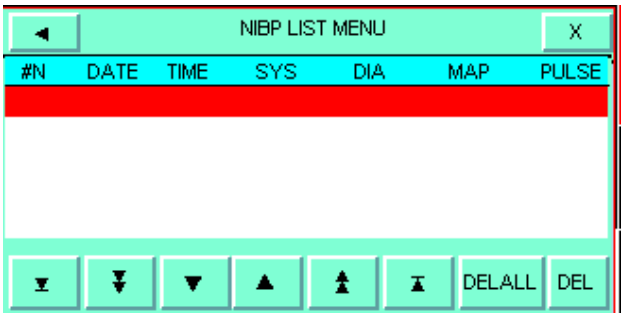


Figure 3-34 NIBP list window

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.

Press DEL to remove the highlighted record.

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

Pressing the RECORD button prints the NIBP list.

AUTO SLEEP

This item is inactive.

NIBP TESTS

To perform the NIBP module tests, follow this procedure:

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

Warning

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

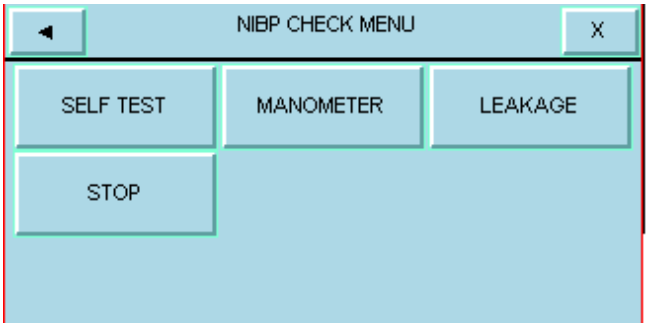


Figure 3-35 NIBP check menu

Note

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

TEMP

General Information

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

Two TEMP probes can be used together to obtain 2 temperature data and compare them to determine the temperature difference.

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

Specifications

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

TEMP monitoring setup:

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

TEMP parameter and its settings

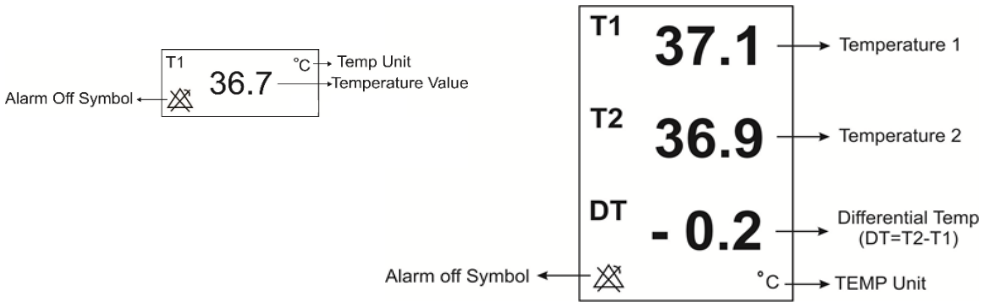


Figure 3-36 TEMP parameter area

Touch the TEMP parameter area to access the below menu:

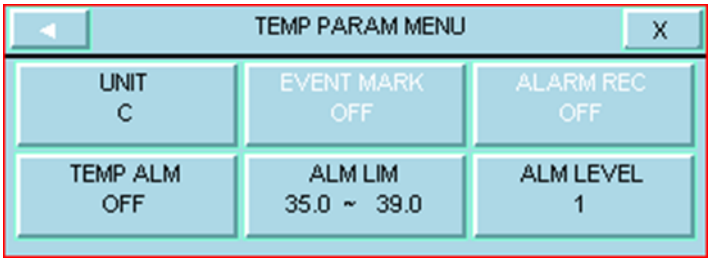


Figure 3-37 TEMP window

UNIT

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

EVENT MARK

This item is inactive.

ALARM REC

By enabling this option, TEMP alarms will be recorded when they occur.

TEMP ALM

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

ALM LIMIT

By pressing this item, you can access TEMP ALARM LIMIT window. The TEMP alarm is activated when the temperature value violates adjusted ALARM HIGH and LOW limits.

LOW limit: 0 ~ (HIGH limit – 0.5) °C

HIGH limit: (LOW limit + 0.5) ~ 50 °C

ALM LEVEL

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

TEMP ALARM MESSAGES

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

Inspection and recalibration

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

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

Warning

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

Note

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

IBP

General Information

In Invasive Blood Pressure (IBP), blood pressure pulses are transmitted through a cannula needle and sterile fluid to a sensor (elastic diaphragm) and converted into an electrical signal. Blood pressure has a maximum value (Systole: SYS) and a minimum value (Diastole: DIA).

The patient monitor measures direct blood pressure (Systolic, Diastolic and Mean) of the selected blood vessel through two channels, and displays two IBP waveforms. It has the ability of measuring four channels and displaying changes in these pressures.

Warning

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

Note

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

IBP equipment connection

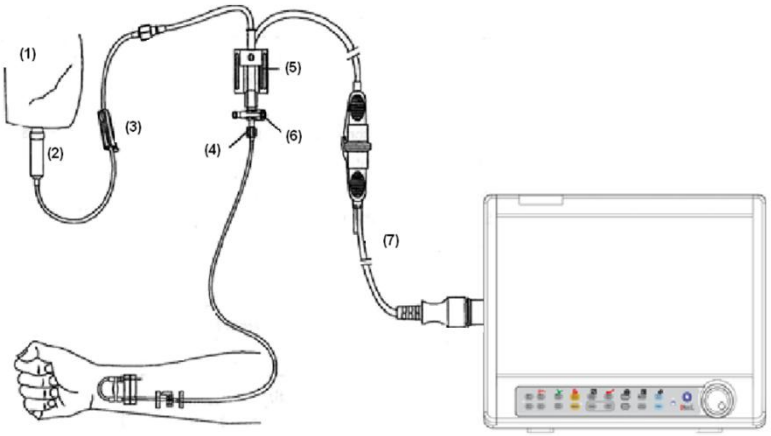


Figure 3-38 IBP connections

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

Preparatory steps for IBP measurement

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

Warning

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

IBP parameter and its settings

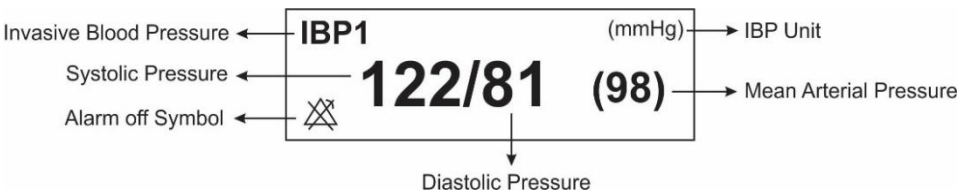


Figure 3-39 IBP parameter area

Touch the IBP parameter area and the setting window will be opened.

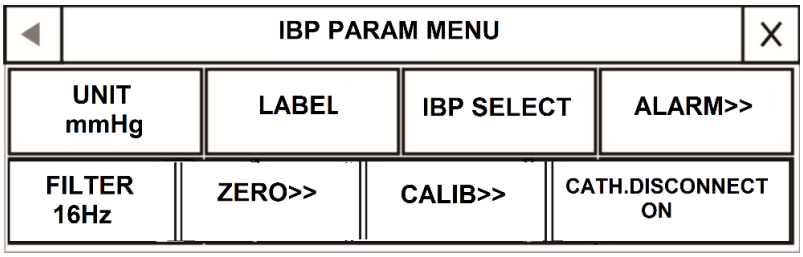


Figure 3-40 IBP settings window

UNIT

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

LABEL

Suitable label should be selected, regarding the place of measurement.

The available pressure labels are

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

Warning

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

Note

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

IBP SELECT

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

ALARM

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

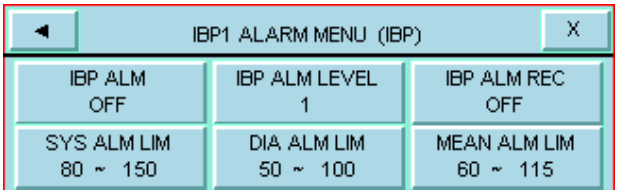


Figure 3-41 IBP alarm window

- **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**: Select this item to set the alarm level for each label. Available options are 1 and 2. Level "1" is the most serious alarm.
- **IBP ALM REC**: Enable this item to record signal upon an alarm occurrence.
- **SYS ALM LIM**: Select this item to set the upper and lower alarm limits of the systolic pressure.
- **DIA ALM LIM**: Select this item to set the upper and lower alarm limits of the diastolic pressure.
- **MEAN ALM LIM**: Select this item to set the upper and lower alarm limits of the mean pressure.
- The upper and lower limits of systolic, diastolic and mean alarms for ART, LVP, PAP, RVP, CVP, LAP, RAP, ICP are listed in the table below. Note that CVP, LAP, RAP and ICP are applied only for the Mean pressure. Therefore, alarm ranges can only be set for MEAN.

Lable	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

Filters are used to have a clearer and more detailed waveform. Available options are 22Hz, 16Hz, and 8Hz.

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

ZERO

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

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

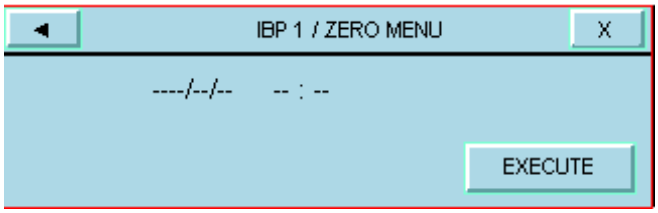


Figure 3-42 IBP zeroing window

6. In this window select < IBP ZERO > to start zeroing procedure.
   The message "PLEASE WAIT" will be displayed during the procedure. When the procedure is completed successfully, the message "IBP1/IBP2 ZERO OK" appears.
   The last zeroing time will be saved and displayed in the window .
7. After successful zeroing, you can turn stopcock to patient on and the other stopcock to atmospheric pressure off.

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

CALIB

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

Warning

- The calibration should be performed by hospital medical engineers.

The calibration equipment is connected as follows:

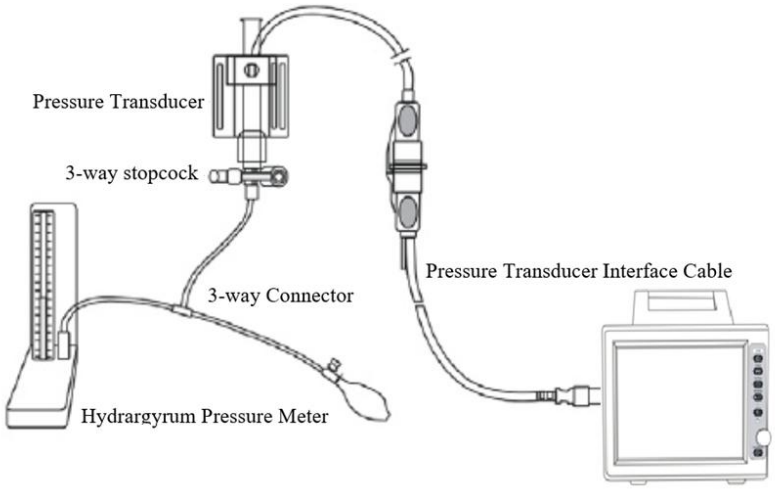


Figure 3-43 calibration equipment connection

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

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

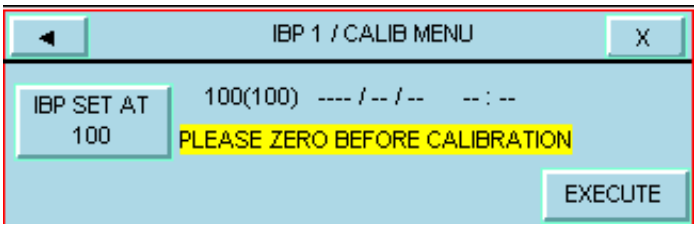


Figure 3-44 IBP calibration window

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

Warning

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

- Troubleshooting the Calibration

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

Message	Corrective action
IBP1/ IBP2 NO SENSOR , UNABLE TO CALIBRATE	Make sure that the transducer is connected, then start calibration procedure.
IBP1/IBP2 OVERANGE, UNABLE TO CALIBRATE	Verify that adjusted pressure in the menu and sphygmomanometer pressure are equal. If the problem still exists, contact after sales services.

IBP1/IBP2 UNSTABLE PRESSURE, UNABLE TO CALIBRATE	Make sure that the transducer is attached to the patient or perhaps the tubing system or other connections are damaged accidentally and should be checked. If the problem still exists, contact after sales services.

Note

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

CATH. DISCONNECT

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

Symptoms of the catheter disconnection are as follows:

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

Note

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

Enabling PPV parameter

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

Pulse pressure is the difference between the systolic and the diastolic pressure values for a single beat. Pulse pressure variation is defined as the maximum pulse pressure less the minimum pulse pressure divided by the average of the two. The average variation in pulse pressure is calculated over periods of 30 seconds.

Activating PPV feature is carried out through connecting to the Viewer.

Warning

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

IBP Trace menu

Touch the IBP waveform area to access the below menu:

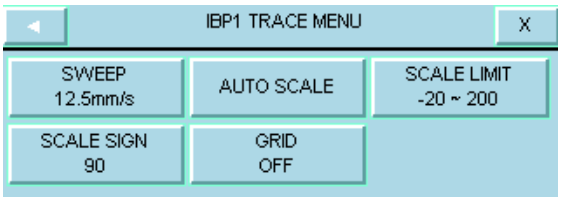


Figure 3-45 IBP Trace menu

SWEEP
Available options are 3, 6, 12.5 and 25 mm/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
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
SCALE SIGN of all IBP, ART, LVP, PAP, RVP, CVP, LAP, RAP and ICP labels can be changed by step of one.

Warning

- Since the scale is not displayed in this mode, if the doctor does not pay attention to the values of SYS, DIA, MEAN numbers, she/he may not notice the decrease or increase in pressure from the shape of the signal and may have an error in diagnosis.
- Ensure that the alarm ranges are correctly set for the label. Because these ranges are saved only for that particular label. Changing the label changes the alarm ranges.

GRID

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

IBP physiological alarms

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

IBP technical alarms

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

IBP messages

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

GAS (Main Stream)

General Information

Patient Monitor provides mainstream method for Gas measurement.

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

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

It is available in various parameter configurations as follows:

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

The combination of IRMA and base monitor considered a ME SYSTEM and all ME SYSTEM requirements were complied with.

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

Warning

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

Note

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

Measurement principle

The IRMA sensor head snaps in place on the top of the airway adapter that includes the optical components for measuring all gases. The IRMA airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained by continuously measuring the infrared gas absorption through the XTP windows in the gas flow through the adapter. The XTP windows are transparent to light in the wavelength ranges of interest and they are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission.

Identifying Gases

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

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

Measured parameters

The measured parameters are EtCo2, EtN2O, EtAA (End Tidal CO2/N2O, Anesthesia Agent), FiCo2, FiN2O, FiAA (Fraction Inspiratory CO2/N2O/Anesthesia Agent), AWRR (Air Way Respiratory Rate) and MAC.
Fi and Et values are displayed after a breath and average of RESP value is updated regularly. If the respiration rate (RR) violates 80 bpm, Et value for Anesthesia agent and N2O will fall below nominal value (Etnom) according to below formula:
Et = 80*Etnom /RR
EtCO2 value for the respiration rate below 150 bpm will be in the specified range (IRMA CO2 and IRMA AX+).

MAC (Minimum alveolar concentration)

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

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

MAC = %ET(AA1)/X(AA1) + %ET(AA2)/X(AA2) + %ET(N2O)/100

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

Note

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

Airway adapter

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

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

Figure 3-46 IRMA airway adapters: Adult/ Pediatric and infant

Warning

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

Preparatory steps for gas measurement

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

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

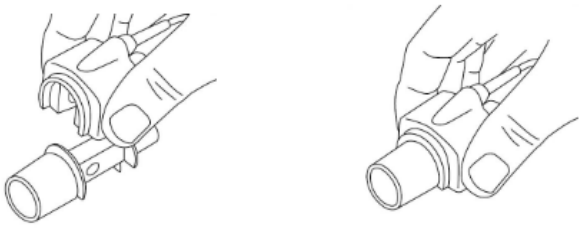


Figure 3-47 Adapter connection to probe

3. Depending on IRMA model, perform the following:

- IRMA AX+:
  - Wait minimum 30 seconds
  - Perform zeroing

- CO2:
  - Wait minimum 10 seconds
  - Perform zeroing, if gas readings does not show 0% or if an unspecified accuracy message is displayed.

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

Figure 3-48 Green indicator

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

Figure 3-49 Adapter connection to Y-piece

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

Figure 3-50 Adapter connection to tracheal tube

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.

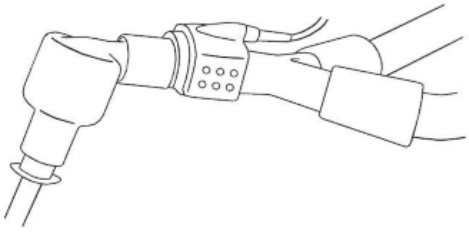


Figure 3-51 Using HME

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

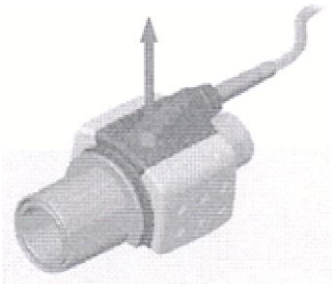


Figure 3-52 Correct position of indicator (upward)

Placement of IRMA Probe

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

Gas span check

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

Pre-use check

Always verify gas readings and waveforms on the patient monitor before connecting the IRMA airway adapter to the patient circuit. Perform the tightness check of the patient circuit according to the User Manual for the monitor with the IRMA probe snapped on the IRMA airway adapter.

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

Verify that there has not been any accumulation of gas between the IRMA sensor head and the XTP windows by checking that the CO2 readings on the monitor are correct before connecting a patient to the breathing circuit.

Check that the connections have been made correctly by verifying an actual CO2 waveform on the monitor display

Warning

- To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.
- Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.
- Disposable airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.
- Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.
- The IRMA probe is not intended to be in patient contact.
- If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA sensor is used in the electromagnetic environment specified in this manual.
- The IRMA probe is not designed for MRI-environments.
- Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.
- Don’t use the device in the environment which contains flammable anesthetic gas.
- Before any interpretations are made of parameters readings and waveforms one, assure that the multi-gas probe is functioning correctly. Partial obstruction of airway with water can result in distorted waveforms. A leak in the airway may result in low parameters measurements. Check the monitor to see if it is functioning properly.
- Verify sensor detection before starting GAS monitoring. Unplug the sensor from IRMA connector to verify that the error message "CO2 NO SENSOR "is displayed.

Note

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

GAS parameter and its settings

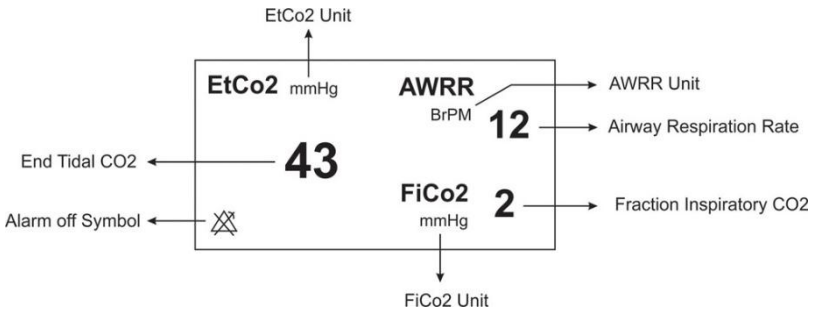


Figure 3-53 GAS parameter area

If using the Multi-Gas sensor, the GAS parameter area in its special page is as follows:

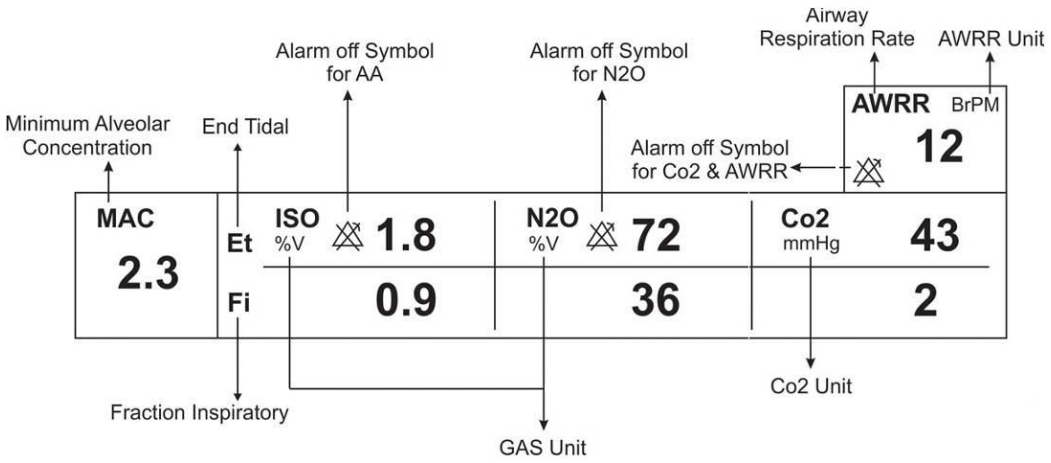


Figure 3-54 GAS parameter area with multi-gas sensor

Touch CO2 parameter area to access the below menu:

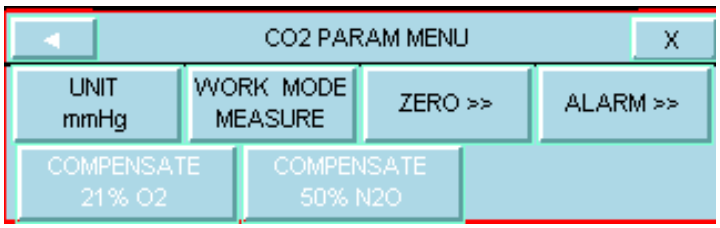


Figure 3-55 CO2 settings window (CO2 senor)

Note

- After capnography probe is connected to the monitor, at first sensor type 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.

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

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

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.

Note

- 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” manually.

ZERO

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

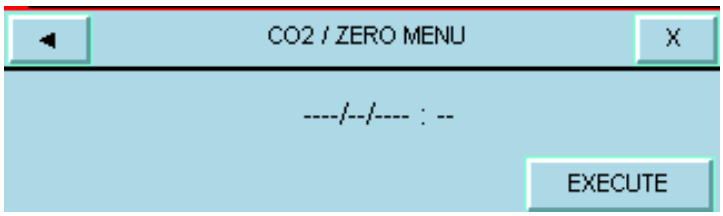


Figure 3-56 ZEROING window

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.

- 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.

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.

In order to measure with high accuracy, it is necessary to observe the following points for IRMA probe:

- The ZEROING operation is performed by replacing the IRMA adapter without connecting it to the patient's breathing circuit and with the help of a monitor. To perform this operation, you must select <ZERO> from the GAS window.
- Pay attention to avoid any breathing near the adapter before or during the Zeroing operation. For the successful operation of Zeroing, the presence of ambient air in the adapter is very important.
- If the "CO2 ZERO REFERENCE CALIB REQUIRED" alarm is observed, the Zeroing operation must be repeated.

Warning

- For accurate measurements, IRMA sensor should be set zero to room air.
- Incorrect zeroing will result in false gas readings.

Note

- Zero reference calibration should only be performed by qualified service technicians, and should NOT be a part of normal operating procedures.
- Always perform a pre-use check after performing zero reference calibration.
- If the adapter is separated from the GAS probe, zeroing is not possible and the CO2 NO ADAPTER message is displayed in the relevant menu.

ALARM

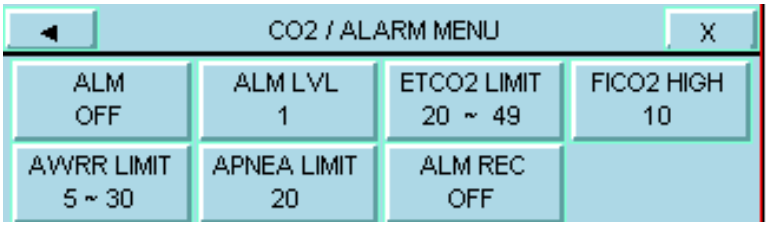


Figure 3-57 CO2 alarm window

- **ALM**: Select "ON" to enable all alarm indications such as parameters blinking, audio alarm, and light indicator. Select "OFF" to disable the alarm indications and call up symbol in the multi-gas parameter area.
- **ALM LVL**: Selectable between 1 and 2. Level 1 represents the most serious case.
- **ETCO2 LIMIT**: The alarm is activated when the EtCo2 exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit (Range: 0.4~13.0%V , step 0.1%V).
  Default for upper limit is 6.5%V and for lower limit is 2.6%V.
- **FICO2 HIGH**: The alarm is activated when the FiCo2 exceeds adjusted ALARM HIGH limit. (Range: 0.1~13.0%V, step 0.1%V), Default for upper limit is 1.3%V.
- **AWRR LIMIT**: The alarm is activated when the AWRR value exceeds adjusted ALARM HIGH limit or falls below adjusted ALARM LOW limit. (Range :1-120BrPM)
  Default for upper limit:
  Adult/Pediatric: 30BrPM
  Neonate: 60BrPM
  Default for lower limit:
  Adult/ Pediatric: 5BrPM
  Neonate: 15BrPM

- **APNEA LIMIT**: Pick it to set the standard of judging an apnea case. It sets to 10 - 40 seconds and "OFF", increases/decreases by 5s. Select OFF to disable the alarm.
- **ALM REC**: By activating this feature, when GAS alarms occur, a record is taken of the signal and its parameter.

COMPENSATE O2/N2O

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:

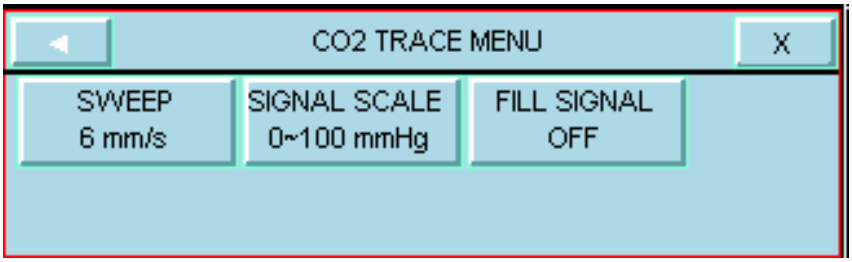


Figure 3-58 CO2 trace menu

- 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:

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

AUTOSCALE is an 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.

Status of LED on the IRMA probe

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

GAS Alarm Messages

Physiological alarms

Alarm	Situation	Visual prompt	Audio sound
AWRR HIGH	Respiration rate violates adjusted high limit	●AWRR value blinks. ●The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
AWRR LOW	Respiration rate violates adjusted low limit	●AWRR value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 HIGH	End Tidal Co2 violates adjusted high limit	●EtCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
EtCo2 LOW	End Tidal Co2 violates adjusted low limit	●EtCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
FiCo2 HIGH	FiCo2 violates adjusted high limit	●FiCo2 value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated
CO2 RESP APNEA	Non-respiration condition overruns adjusted time	● The alarm indicator flashes. ●The message "CO2 RESP APNEA" blinks in red background.	Activated
EtN2O HIGH	End Tidal N2O violates adjusted high limit	●EtN2O value blinks. ● The alarm indicator flashes. ● The alarm message is displayed in a background corresponding to its level.	Activated

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

Technical alarms

Alarm	Cause	Solution	Explanation
CO2 SYSTEM FAULT # 1,2,3,4	Sensor error	Turn the system off and on and if problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

CO2 REPLACE ADAPTER	IR signal low	Change adapter	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO ADAPTER	There is no adaptor connected to the sensor.	Connect adapter	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 INVALID	CO2 outside specified accuracy range.	Zero the sensor, if the problem still exists, contact after sales service of the manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
N2O INVALID	N2O outside specified accuracy range.	Zero the sensor, if the problem still exists, turn off and on the system and if again this message appears contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
AGENT INVALID	Agent outside specified accuracy range.	Zero the sensor, if the problem still exists, turn off and on the system and if again this message appears contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
AGENT MIXTURE	In IRMA AX+ mode, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds.		Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.

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

Messages

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

GAS (Side Stream)

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.

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

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

Different types of the sensor are as follows:

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

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances.

The intended patient population is adult, pediatric and infant patients.The Nomoline Product Family is intended to be used with systems that include the Masimo ISA gas measurement technology (ISA). The Nomoline Product Family is indicated for the measurement of respiratory rate and respiratory and anesthetic gases in adult, pediatric and infant patients. The Nomoline Product Family includes single use and multi-use devices for gas sampling and/or oxygen delivery. The Nomoline Product Family is indicated for use by clinical professionals in healthcare environments, including mobile environments.

Warning

- The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals only.
- The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Do not make any changes in the GAS system.
- An ISA sidestream gas analyzer shall only be connected to medical devices approved by Masimo Sweden AB .

Note

- The combination of ISA and monitor shall be considered a ME (medical electrical) SYSTEM.
- (U.S. Only): Federal law restricts this device to sale by or on the order of a physician.

Measurement principle

Gas monitoring uses infrared (IR) spectroscopy method to measure and identify different gases.

Infrared spectroscopy is used to measure the concentration of molecules that absorb infrared light. Since the absorption is proportional to the concentration of gas molecule, the concentration can be determined by comparing its absorption.

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

The measurement of CO2, N2O and anaesthetic agents in the breathing gas mixture is based on the fact that the different gases absorb infrared light at specific wavelengths. Since ISA analyzer analyzes the breathing gas mixture, the amount of infrared light absorbed by the gases is measured continuously by the infrared spectrometer.

A microprocessor continuously calculates the CO2, N2O and anesthetic agent concentrations from the infrared light absorption measurements using matrix calculations to identify which anesthetic agents are present in the gas mixture.

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

Measurable parameters by ISA sensor are:

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

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

For more details, please refer to Technical Specification section.

Note

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

MAC (Minimum alveolar concentration)

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

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

MAC = %ET (AA1)/X (AA1) + %ET (AA2)/X (AA2) + %ET (N2O)/100

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

NOMOLINE Family sampling lines

ISA samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO2 possible for adult, pediatric and infant patients.

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

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

The Nomoline Family sampling lines are available in a wide variety of versions for both intubated and spontaneously breathing patients and in both disposable and re-sposable configurations – intubated patients can for instance be monitored using the disposable Nomoline Nasal CO2 Cannula or a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Nasal CO2 Cannula with Luer Connector.

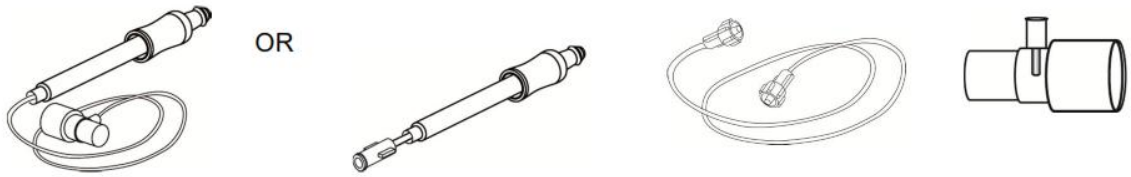


Figure 3-59 The disposable Nomoline Airway Adapter Set is an alternative to using a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter.

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

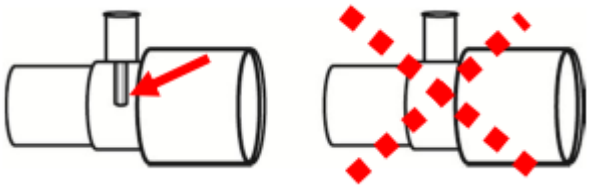


Figure 3-60 For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left above.

Warning

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

Note

- Using sample tubes or cannulas with larger inner diameter than 1 mm will increase ISA's total system response time.
- The patient age as well as other individual factors is not taken into account in the above-described formula. Et gas concentrations for secondary agent (AA2) are only available for ISA (Multi-gas) probe.
- GAS system is not designed for use with water trap. The Nomoline adapter (CAT no. 108220) is designed for the use of several patients and can replace the Water trap.

Nomoline Family sampling line replacement

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

Neonatal sampling hoses are designed to minimize the volume of dead space and can be used even for very small patients.

Warning

- Replace the sampling line if the sampling line input connector starts flashing red, or the Monitor displays a "Check sampling line" message.
- Do not use sampling line if it or its package is damaged and return it to the vendor.
- Use only the recommended ISA sampling line by the manufacturer. Other sampling lines may cause sensor improper performance. (Refer to Accessories chapter for more detail)
- If the sampling hose was connected to the patient for a long time, it should be replaced once every two weeks or whenever the Sampling line clogged message is observed. (Each was occurred earlier).
- Do not use infant sampling hoses for adults, because infant sampling hoses add a lot of resistance to air flow to the patient's respiratory circuit.

Preparatory steps for Multi-gas monitoring

To set up ISA analyzer, follow these steps:

1. Securely mount the ISA analyzer.
2. Connect the ISA analyzer interface cable into corresponding connector on the side panel of patient monitor.
3. Connect a Nomoline Family sampling line to the ISA analyzer input connector. It will click into place when properly seated.
4. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit to prevent pollution of the operation room when N2O and/or anesthetic agents are being used.

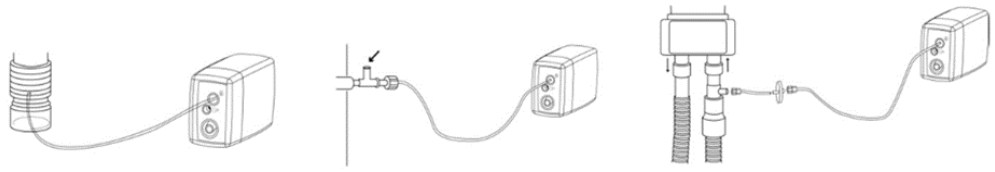


Figure 3-61 Analyzer placement in respiratory circuit

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

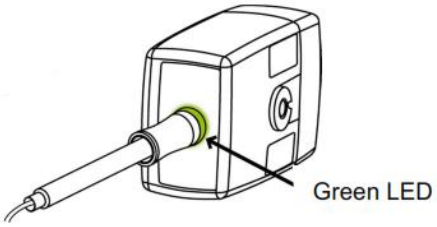


Figure 3-62 Green indicator

7. Perform a pre-use check as mentioned in its section (following section).

Warning

- Do not operate the ISA sidestream gas analyzer if the enclosure is damaged.
- Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.
- Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
- Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
- Measurements can be affected by mobile and portable RF communications equipment. It should be assured Make sure that the ISA gas analyzer is used in the electromagnetic environment specified in EMC section of this manual.
- The ISA sidestream gas analyzers are not designed for MRI (magnetic resonance imaging) environments. During (MRI) scanning, ISA must be placed outside the MIR suite.
- Use of high frequency electrosurgical equipment in the vicinity of the ISA/monitor may produce interference and cause incorrect measurements.
- Do not use the Nomoline Airway Adapter Set Infant with adult/pediatric patients.
- Do only use sample lines intended for anesthetic agents if N2O and/or anesthetic agents are being used.
- Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination.
- Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.
- Exhaust gases should be returned to the patient circuit or to a scavenging system.

Note

- The ISA analyzer should be securely mounted in order to avoid the risk of damage to the ISA.
- Do not operate the ISA side stream gas analyzer outside the specified operating environment.
- Returning the ISA's exhaust gas to the patient circuit is not allowed in the USA.

Pre-use check

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

1. Connect the sampling line to the ISA gas inlet connector.
2. Check that the gas inlet connector is lit with a steady green light.
3. For ISA OR+: Check that the O2 reading on the monitor is correct (21 vol%).

4. Breathe briefly into the sampling line and check that monitor displays a valid CO2 waveform and valid values.
5. Occlude the sampling line with a fingertip and wait for 10 seconds.
6. Check that occlusion alarm is displayed on the monitor and that the gas inlet connector shows a flashing red light.
7. If applicable: Perform a tightness check of the patient circuit with the sampling line attached.

Warning

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

Note

- 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.
- Do not apply tension to the ISA sensor cable.

GAS parameter and its settings

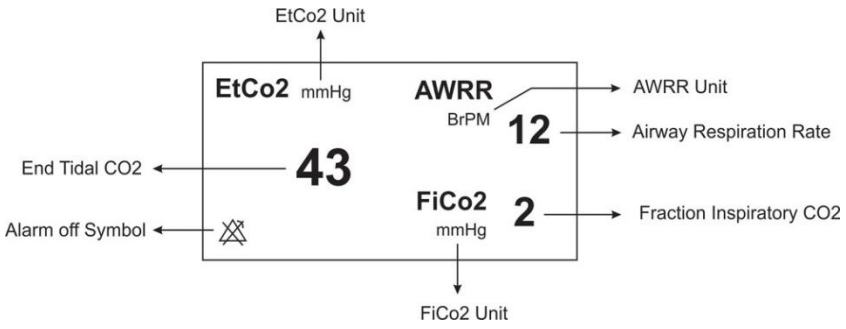


Figure 3-63 CO2 parameter area

If using the Multi-Gas sensor, the GAS parameter area in its special page is as follows:

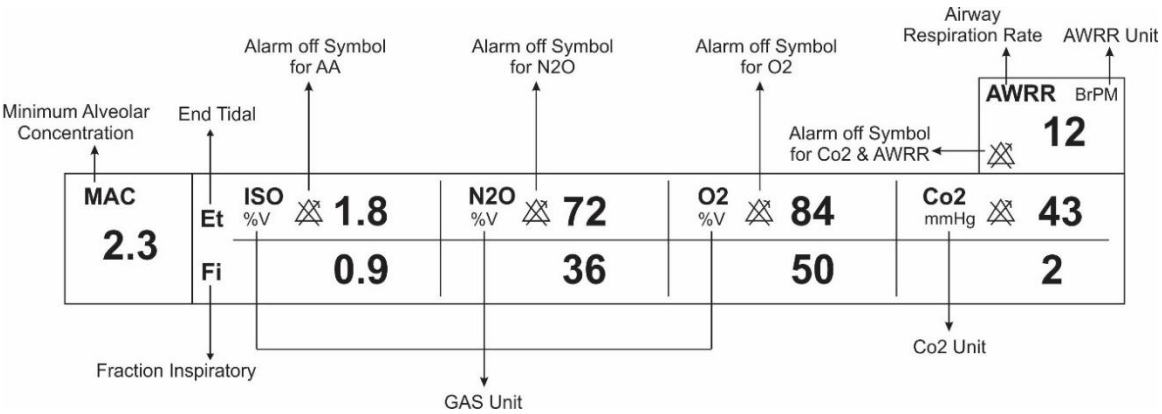
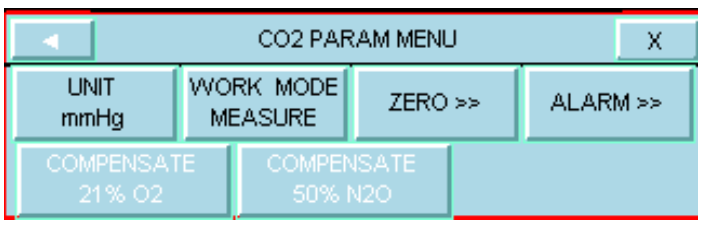


Figure 3-64 GAS parameter area using Multi-gas sensor

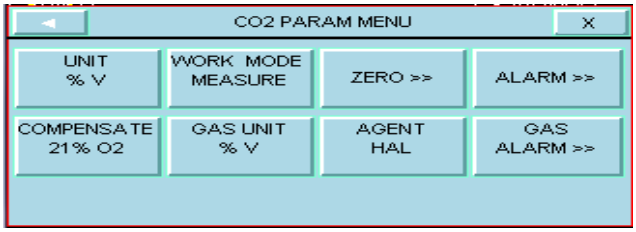
Note

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

Touch CO2 parameter area to access the below menu:



(b)



(a)

Figure 3-65 a) GAS settings window, b) CO2 settings window

UNIT (CO2/GAS)

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.

Note

- If the monitor doesn't detect any CO2 signal for 30 minutes after connecting ISA sensor, the sensor is automatically disabled and goes to "standby" mode to decrease the power consumption and extend the life cycle of IR source and ISA sensor.
- When not using gas monitoring functions, it is suggested to disconnect the sensor. When gas monitoring is not used, it is suggested to disconnect the sensor.
- For enabling ISA sensor, you can enter Gas window and set the monitor to Measure mode.
- ISA sensor remains in standby mode until the sampling line is connected to it. As soon as the sampling line is connected, the sensor switches on and starts measurement.

ZERO

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

ISA performs zeroing by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed 1 to 3 times per day, and takes less than 3 seconds for ISA CO2 gas analyzers and less than 10 seconds for ISA Multigas analyzers.

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

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

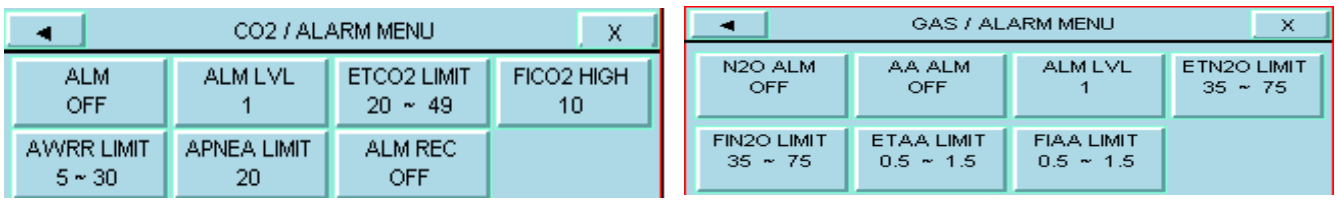
Warning

- Since a successful zeroing requires the presence of ambient air (21% O2 and 0% CO2), ensure that the ISA is placed in a well-ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.

Note

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

ALARM (CO2 and GAS)



(b) (a)

Figure 3-66 a) GAS alarm window, b) CO2 alarm window

CO2 Alarms:

- **ALM**: elect "ON" to enable all alarm indications such as parameters blinking, audio alarm, and light indicator. Select "OFF" to disable the alarm indications and call up  symbol in the GAS parameter area.
- **ALM LVL**: Selectable between 1 and 2. Level 1 represents the most serious case.
- **ETCO2 LIMIT**: The alarm is activated when the EtCo2 exceeds adjusted ALARM HIGH or LOW limit (Range: 0.4~13.0 %, step 0.1%) Default for upper limit is 6.5%V and for lower limit is 2.6%V.
- **FICO2 HIGH**: The alarm is activated when the FiCo2 exceeds adjusted ALARM HIGH limit (Range: 0.4~13 %V, step 0.1%V). Default for upper limit is 1.3%V.
- **AWRR LIMIT**: The alarm is activated when the AWRR exceeds adjusted ALARM HIGH or LOW limit. (Range: 1-120BrPM)
  Default for upper limit:
  Adult/Pediatric: 30BrPM
  Neonate: 60BrPM
  Default for lower limit:
  Adult/Pediatric: 5BrPM
  Neonate: 15BrPM
- **APNEA LIMIT**: Pick it to set the standard of judging an apnea case. It sets to 10 - 40 seconds and "OFF" and increases/decreases by 5s.
- **ALM REC**: By activating this option, if an alarm occurs, a record will be taken from it.

GAS Alarms:

- N2O and anesthetic gas alarms (AA ALARM): By selecting "ON" for each of the above options, all the signs of alarm occurrence such as blinking parameters, alarm sound and alarm indicator are activated. By selecting "OFF", all the signs of alarm occurrence are deactivated and the sign is displayed in the section related to the Multi-gas parameter.
- Alarm level (ALM LVL): Setting the sensitivity level for alarms. Level 1 or 2 can be selected for all gas parameters equally.
- EtN2O alarm limit: The EtN2O alarm is activated when the N2O value at the end of exhalation exceeds the set upper or lower limit. (Range 1~100% V and step: 1% V) The default value for the upper limit is 75% V and for the lower limit is 35% V.
- FiN2O alarm limit: The FiN2O alarm is activated when the inspiratory N2O value exceeds the set upper or lower limit. (Range 1~82%V and step: 1%V) The default value for the upper limit is 75%V and for the lower limit is 35%V.
- EtAA alarm limit: The EtAA alarm is activated when the amount of anesthetic gas at the end of exhalation exceeds the set upper or lower limit.
- FiAA alarm limit: FiAA alarm is activated when the amount of inspiratory anesthetic gas exceeds the set upper or lower limit. Each anesthetic gas has a different alarm and default range, which consists of:

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

COMPENSATE (O2 and N2O)

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.

Note

- This option is displayed in the corresponding menu only when the GAS (CO2) sensor is connected to the system. And in GAS AX+/OR+ modes, this option is removed from the menu.

AGENT (anesthetic agent)

Types of anesthetic gases including DES, SEV, ISO, ENF, HAL can be selected. By setting this option to AUTO, the detection of anesthetic gas will be done automatically.

GAS Trace menu

Touch the CO2 waveform area to access the below menu:

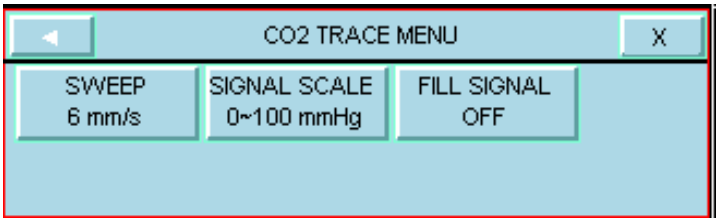


Figure 3-67 CO2 trace menu

- SWEEP: Select this item to adjust speed of the Multi-Gas signals 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:

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

AUTOSCALE is an 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.

Status of LED on the ISA probe

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

Note

- In GAS OR+ mode, if the anesthetic gas concentration does not exceed the detection threshold of the sensor, the statement "AA?" Instead of the anesthetic gas name, it is displayed in the Multi-gas window.
- In GAS OR+ mode, if there is a mixture of two anesthetic gases in the patient's airways and the concentration of these gases is higher than the detectable threshold limits of the sensor, the message "AGENT MIXTURE" will be displayed in the error message area.

GAS Alarms

Physiological alarms

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

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

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

		●The alarm Level 1- the message is displayed in red background.	

Technical alarms

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

Alarm	Cause	Solution	Explanation
AGENT INVALID	Agent outside specified accuracy range.	Zero the sensor. If the problem still exists, contact After sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
AGENT MIXTURE	In ISA AX+, if there is two anesthesia agents mixture in patient airway and their concentration exceed agent detection thresholds		Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and the alarm is disabled for 120 sec.
AGENT UNRELIABLE	- The accuracy of the agent identification and measurement could not be guaranteed. - More than 2 anesthetic agents are present in the breathing circuit - High concentrations of solvents, cleaning agents or other interfering gases are present in the breathing circuit		Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
CO2 INVALID AMBIENT PRESSURE	Ambient pressure outside operating range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 INVALID AMBIENT TEMPERATURE	Internal temperature outside operation range.	Turn the system off and on. If the problem still exists, contact after sales service of manufacturer.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
O2 SENSOR ERROR	Sensor failure	Please contact after sales service of manufacturer	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.

Alarm	Cause	Solution	Explanation
CO2 ZERO REFERENCE CALIB REQUIRED	CO2 value is more than 800 PPM (0.80%V) and measurement accuracy is low.	Perform automatic zeroing procedure in an environment with CO2 less than 0.80%V.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled for 120 sec.
CO2 NO SENSOR	Sensor is disconnected from the system	Connect the sensor to the system. If the problem still exists, contact after sales service of manufacturer.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.

Messages

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

Brain Function Assessment (BFA) Monitoring

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%.

Signal Quality Index (SQI)

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

Warning

- The monitor will not render accurate readings when used on patients with severe neurological disorders and patients under 2 years of age.
- The monitor will not render accurate readings when used on patients weight less than 70% or more than 130% of ideal body weight and recent use of psycho-active medication, including alcohol
- The use of pacemakers might cause either long periods of artifacts or elevated BFI values.
- The displayed EEG signal has no diagnostic aspect cannot be used to evaluate the patient's clinical condition. it is only used to evaluate the quality of connecting the electrodes to the patient.
- Do not use the monitor when cardiac defibrillator is used. Patient cables are not protected against defibrillation.
- When used with electro surgical unit please note the positioning of the neuro sensors. In order to reduce the hazard of burns, the neuro sensors should not be located between the surgical site and the electro surgical unit return electrode.

- Not to be used in the presence of flammable gases; explosion risk.
- Pay attention if the BFA monitor is connected to a patient connected to other equipment. The total of leakage current may exceed the allowable limit and cause a possible hazard to the patient.
- The conductive parts of neuro sensor should not contact other conductive parts including earth.
- The monitor should be used in conjunction with other patient monitoring parameters and clinical signs. This will ensure the optimum balance of the anesthesia/sedation administration.
- Do not open the BFA case. There are no user-serviceable parts inside. The case should only be opened by qualified service personnel using proper grounding techniques. When the case is opened, an electrical shock hazard exists which can result in serious injury to persons and instrument component damage.
- Neuro sensors are disposable and should not be reused. Before use pay attention to the expiry date.

Note

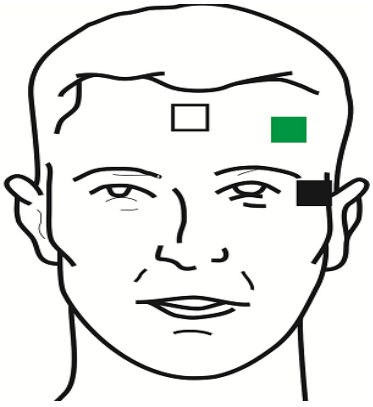
- Operating the monitor close to equipment radiating high-energy radio frequencies (electrosurgical/cauterizing equipment, portable radios, cellular telephones, etc.) may cause signal disturbance. If this happens, reposition the monitor away from the source of interference.

Skin Preparation and Placement of Sensors

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

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

Position of the three neuro sensors is shown in 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.



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

Figure 3-68 Neurosensor placement

Note

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

Picture below shows how to use neuro sensor.

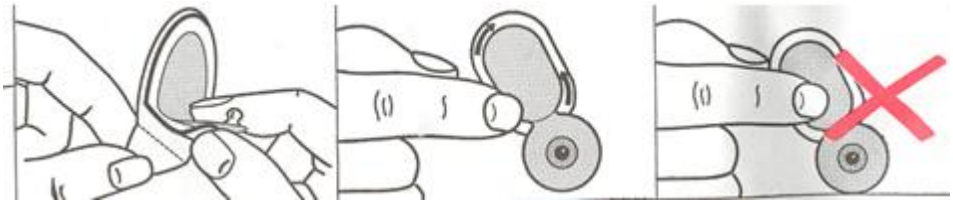


Figure 3-69 Correct use of neuro Sensors

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

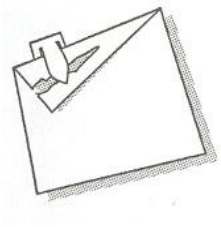


Figure 3-70 Correct maintenance of neuro sensors in its package

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.

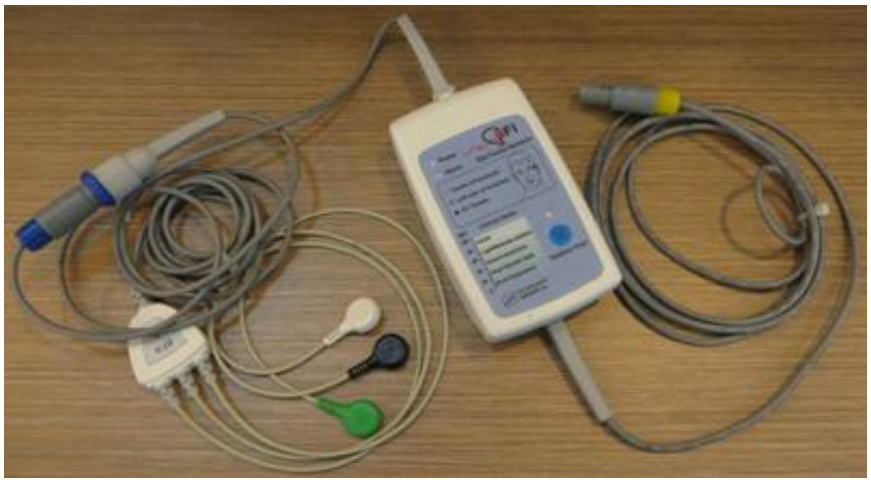


Figure 3-71 BFA module

BFA module keys and indicators

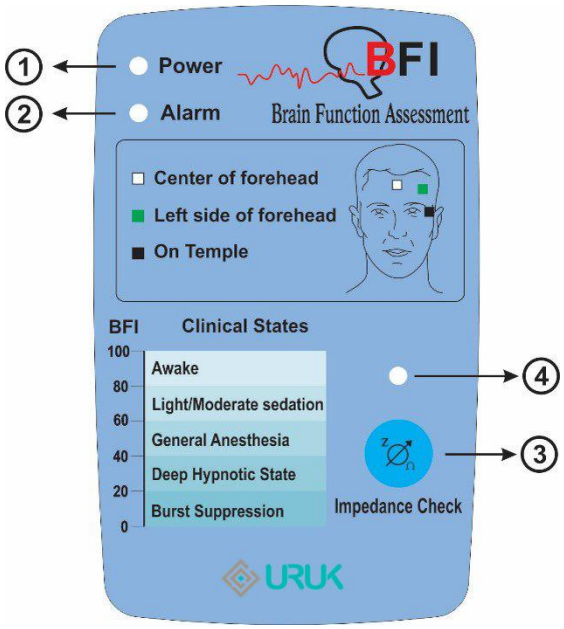


Figure 3-72 BFA module keys and indicators

- Power Indicator: This indicator is turned on as BFA module is connected to the monitor and remains ON until the module is disconnected (①).
- Alarm Indicator: If "BFA ELECTRODE ALARM" occurs (resulting from inappropriate connection of neuro sensors), this indicator will flash with frequency of 1 Hz (②).
- Impedance key: Impedance measurement is initiated by pressing this key (③) and its indicator (④) flashes on the module for one second.

BFA Module Setup

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

Warning

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

BFA parameter and its settings

BFA parameter window is as below:

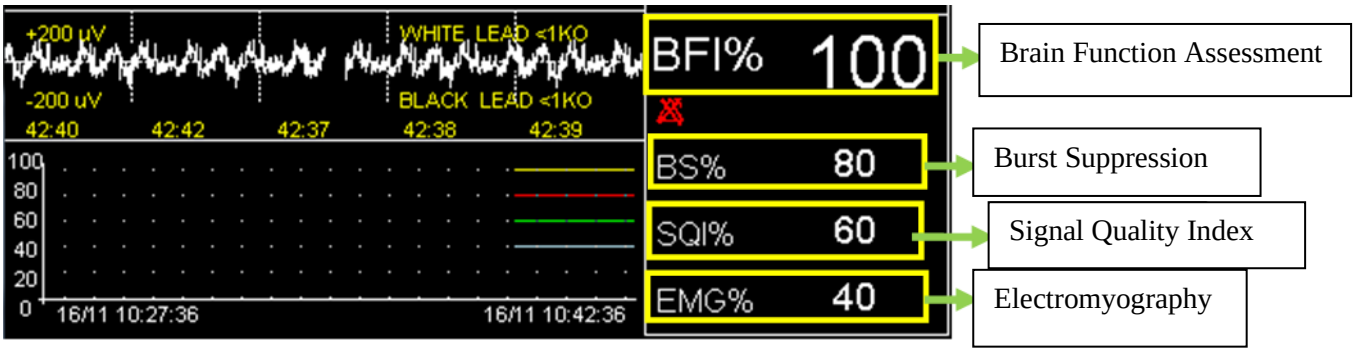


Figure 3-73 BFA parameter area

Touch BFA parameter area to access the below menu:

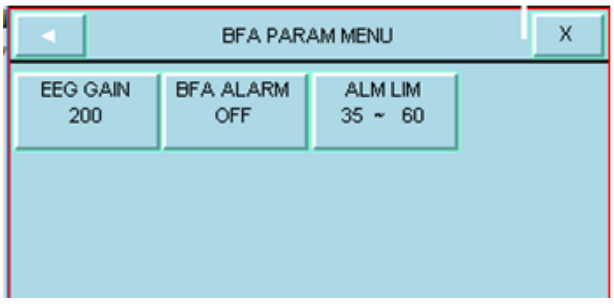


Figure 3-74 BFA parameter menu

- 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.

- 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.
- 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).

BFA TREND MENU

Touch EEG signal area to access the below menu:

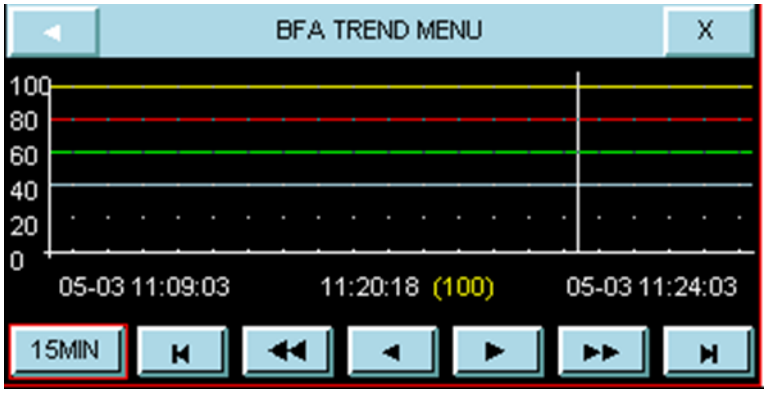


Figure 3-75 BFA trend window

- 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.

Note

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

BFA Alarms

Physiological alarms

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

Technical alarms

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

Note

- 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.

4) Viewer

General Information

The Viewer system is a 24-inch touch screen designed to make connection with PACS, Central system, PM4010 monitor or Ventilator system and to save vital signs data (as tabular and graphic trends) for a duration of 96 hours.

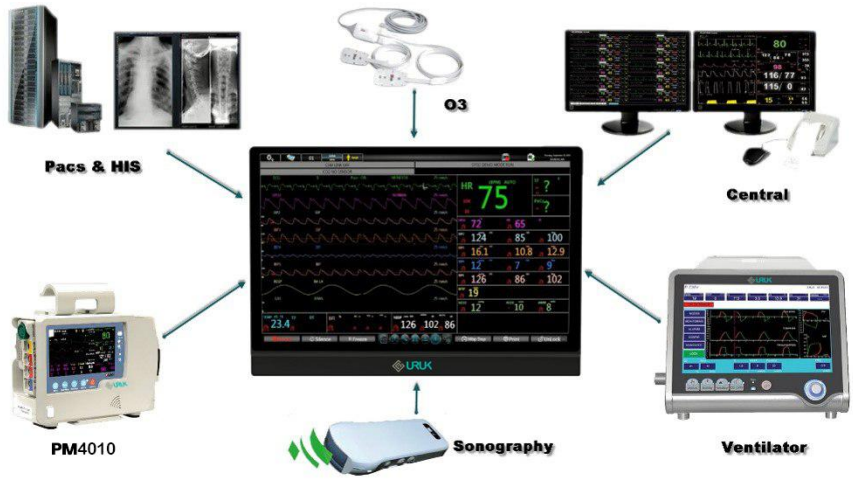


Figure 4-1 Viewer communication with other devices

Warning

- Do not touch the screen with sharp objects.
- 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.
- Do not use the Viewer system during magnetic resonance imaging (MRI) scanning. Induced currents could potentially cause burns. The system may affect the MRI image, and the MRI unit may affect the accuracy of the measurements.
- To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective earth.
- In case of sudden power failure, patient data will be saved in the History for 96 hours. If the system remains off for more than 96 hours, the data will be lost. (If the monitor turns off due to power failure or battery discharging, all current settings will be restored.)
- Audible alarm of the Viewer system sounds via speaker of the PM4010 monitor station.
- Check the PM4010 monitor charge status before disconnecting it from the Viewer system.

Note

- This guide describes all features and functions of the device. Your device is highly customizable and may not have some of these features.
- For more information about different menus, refer to each module's chapter in the PM4010 monitor ‘s Operator Manual.
- If interface cable between the PM4010 monitor and the Viewer system is not connected, the message “PM4010 Disconnect” will appear on the Viewer screen.
- Touch Parameter area on the Viewer screen to open the parameter menu and touch Waveform area to access the signal settings. Any change in the settings will be applied to both PM4010 monitor and Viewer system.
- If the Ventilator system makes a connection to the Viewer, the Viewer settings will not be applied to the Ventilator.

- If interface cable between the Ventilator system and the Viewer is not connected, the message “Ventilator Disconnect” will appear on the Viewer screen.
- Once connection between the PM4010 monitor and the Viewer system is established, all parameters’ settings except Sweep Speed setting will be transferred to the Viewer.
- The signal sweep speed setting is distinct for each system and cannot be transferred or applied to other system.
- For more information about the system cleaning, please refer to Care and Cleaning chapter of the PM4010’s Operator Manual.

Environmental conditions

Storage and transportation temperature	-25 ~ 60 ◦c
Operating humidity	20 ~ 90 %
Storage and transportation humidity	10 ~ 100 %
Altitude (sea level)	-200 ~ 3000 m
Power supply	50 Hz/60 Vac,100 ~240 P max= 72 W

Get to know the Viewer

Display screen

The Viewer system has a color TFT screen. The patient parameters, waveforms, alarm messages, bed number, date, time, system status and error messages are displayed on the screen.

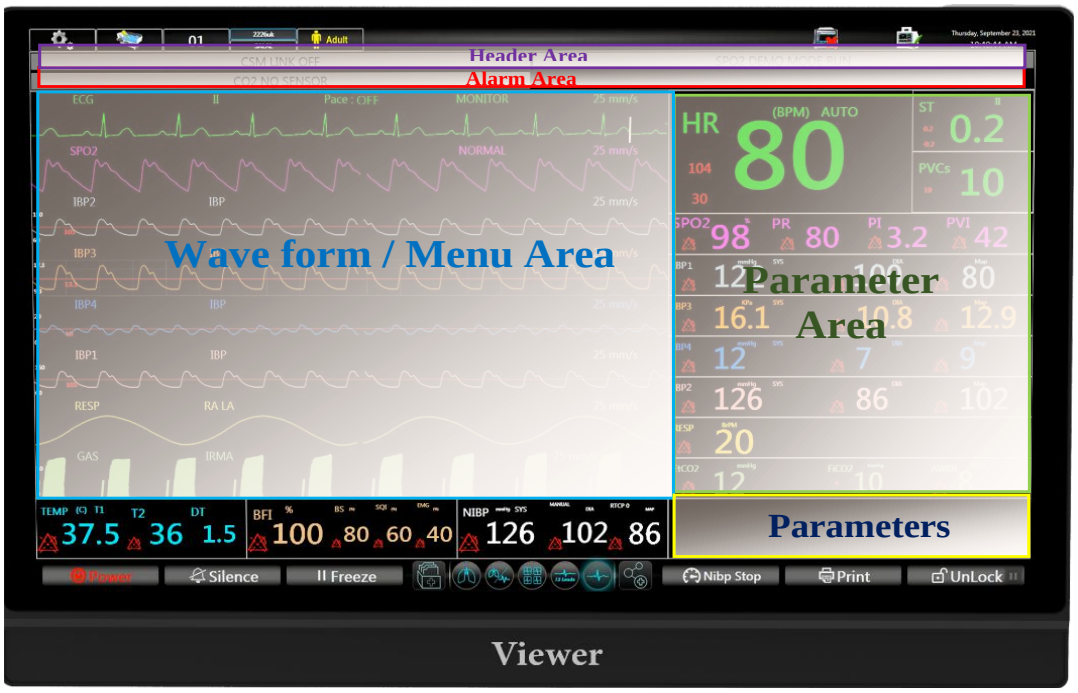


Figure 4-2 Display screen of Viewer

Header Area

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

No.	Icon	Explanation
1		**Bed icon**: Choose this icon to select the patient bed from 1 to 99. If the patient is not admitted, this icon will be displayed.
		This icon will be available only if the patient is admitted.
2		This icon will appear if Adult mode is selected in Patient Parameters Menu (Selecting this icon will open Patient Parameters Menu).
		This icon will appear if Pediatric mode is selected in Patient Parameters Menu.
		This icon will appear if Neonate mode is selected in Patient Parameters Menu.
3		If the alarm silence is activated, this icon along with a 120 sec countdown timer will be displayed.
4		If the Central system makes a connection with the Viewer, this icon will appear.
		If no connection is made between the Central system and the Viewer, this icon will appear.
5		If the PM4010 monitor makes a connection with the Viewer, this icon will appear.
		If no connection is made between the PM4010 monitor and the Viewer, this icon will appear.
6		If the Ventilator system makes a connection with the Viewer, this icon will appear.
		If no connection is made between the Ventilator system and the Viewer, this icon will appear.
7		This icon will appear if O3 module makes a connection with the Viewer.
		This icon will appear if O3 module fails to connect to the Viewer.
8		Select this icon to access the system setup menu (See Configuration chapter for details).

Alarm Area

Different alarm 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.

8 alarm messages with the highest level are displayed in this area.

Waveform / Menu Area

All waveforms can be displayed simultaneously in this area.

Parameter Area

Numeric values of each parameter are displayed in the same color as their corresponding waveforms on a certain area of the screen. The parameters values are measured and refreshed every second. (Except NIBP values which are refreshed after each measurement).

Page Configuration

The Viewer system has multiple pages that you can configure these pages by dragging and dropping your desired parameters in each page.

Interfaces and Keys

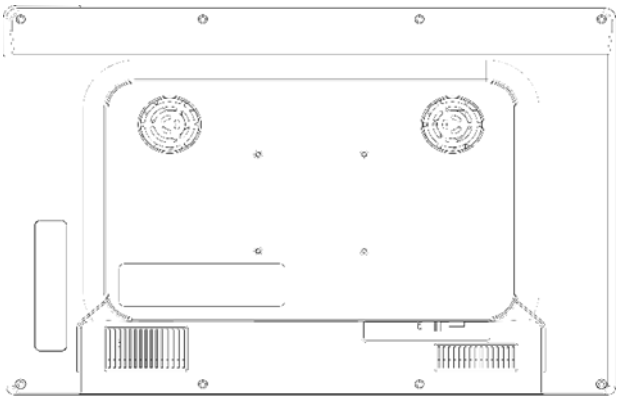


Figure 4-3 Rear view

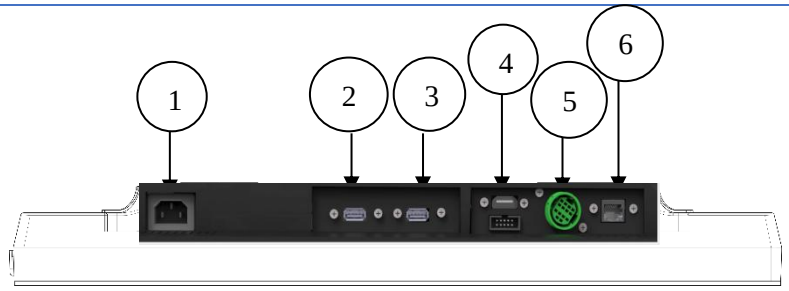


Figure 4-4 Bottom view

1	Power supply 100 ~ 240 VAC, 50/60Hz, MAX:1A
2	USB port
3	Connector of the Ventilator's cable
4	VGA or HDMI output for connection to slave monitor
5	Connector of the PM4010's cable
6	LAN socket for the Central system connection
	Power key

Soft keys

There are soft keys at the bottom of the screen.

Figure 4-5 Soft key bottom of the screen

Taskbar keys		
1-		Three options **Display Off**, **Shut Down** and **Restart** are available for this key.
2-		Press this key to silence alarm for 120 seconds.
3-		Press this key to freeze dynamic signals. Press again to unfreeze the signals.
4-		Press this key to start Non-invasive blood pressure (NIBP) measurement. Press again to stop Non-invasive blood pressure (NIBP) measurement.
5-		Press this key to take screenshot of the screen. You can save the captured image as PDF file or print it.
6-		Select Unlock key to drag & drop parameters. Select Lock key to disable drag& drop function.

Viewer Pages

You can configure different pages of the Viewer system using Drag & Drop item. There are five main pages to display numeric parameters and signals.

Figure 4-6 Pages control keys (soft keys)

To display the PM4010 parameters and signals (dynamically)

To display 12 traces of ECG signal

To display parameters and signals in grid form

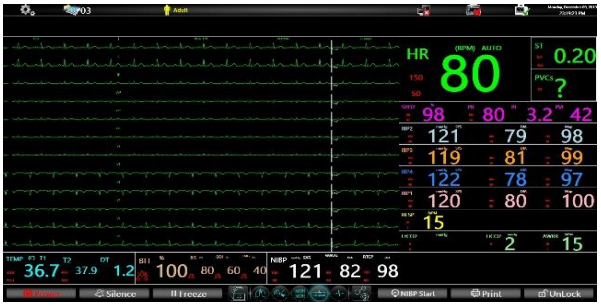
To display the PM4010 and Ventilator data

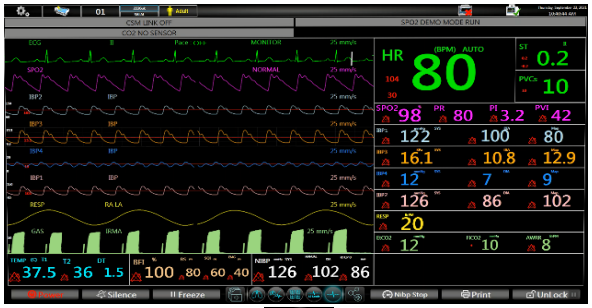
To display the Ventilator data

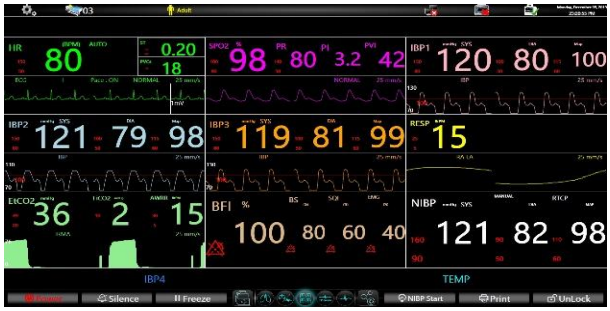
Screenshots page

History page

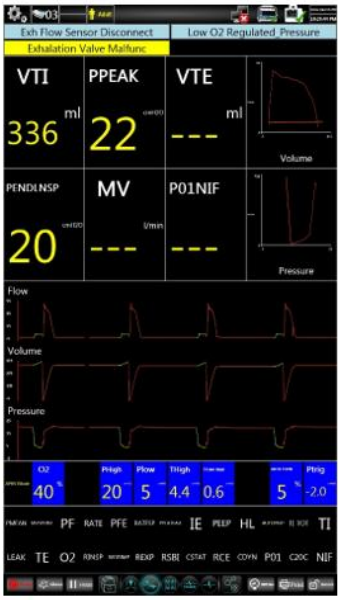
Landscape pages







Vertical pages



Screenshot

A list of taken screenshots is available in this page. You can copy screenshot files from this page to a USB flash. Select your desired files and press Copy. The selected files will be copied to “Viewer Screenshots” folder in the connected USB flash.

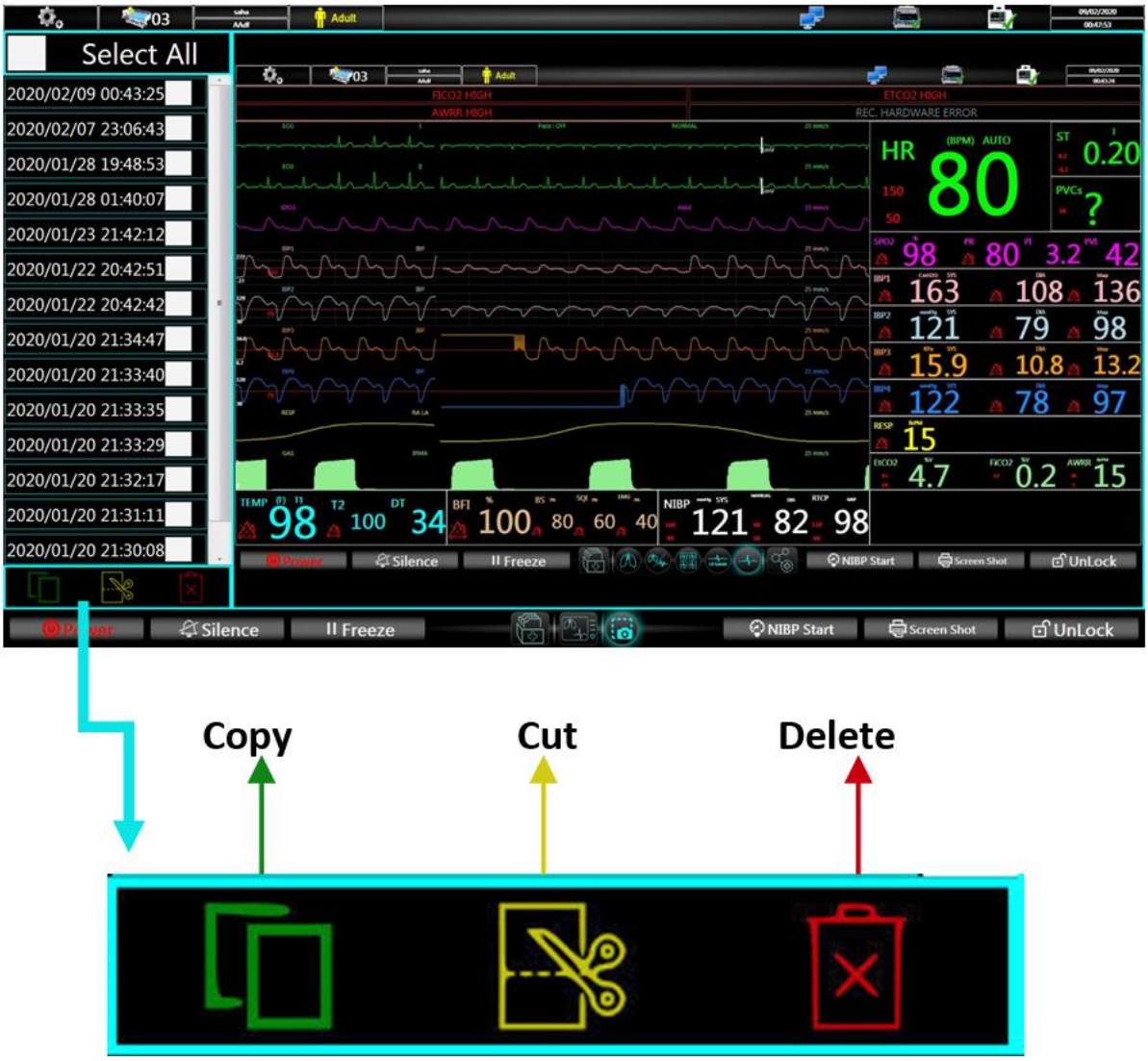


Figure 4-7 Screenshot management

History

96 hours of patient data before discharge time is saved in this page and can be reviewed in two sections: PM4010 History and Ventilator History. You can also monitor current parameters of PM4010 monitor in this page.

By entering this page, the below icons will be shown at the bottom of the page:

Figure 4-8 Control items in History page

- PM4010 history: The PM4010 History contains the below information: Disclosure, Tabular Trends, NIBP List, ARR List, Alarm List
- Ventilator history: The Ventilator History contains the below information: Disclosure, Tabular Trends, Alarm List
- Back to monitoring page:

The items mentioned above, are described below:

Disclosure

96 hours of patient data before discharge time is saved in this page and can be reviewed in two sections: PM4010 History and Ventilator History. You can also monitor current parameters of PM4010 monitor in this page You can review 96 hours of patient data in form of signal (1-19 signals) in this page. The items Go to, Sweep, Signals and Navigation keys are available in this page. Date of the latest signals and numeric parameters is shown in this page.

The signals of 30 sec before the current time are displayed on the screen. If no search is done in this page, data will be updated per 30 seconds. If any search is done in the signals, user should press the key ⏯ to update the disclosure data per 30 sec.

In Disclosure, in addition to the possibility of moving on the waveform itself through touch, keys for faster and easier use are built in, which function as follows:

⏮ : Access to the first time and stored information

⏯ : Access to the latest and most updated time and stored information

⏪ : Access to the information of older pages of the scrolling form of the time range of the X-axis

⏩ : Access to the information of newer pages by scrolling the time range of the X axis

⏵⏴ : Cursor movement and the possibility of scanning a point on the waveform

Figure 4-9 Disclosure

- Signals: Select different signals (up to 19 signals) to be displayed in the Disclosure page.

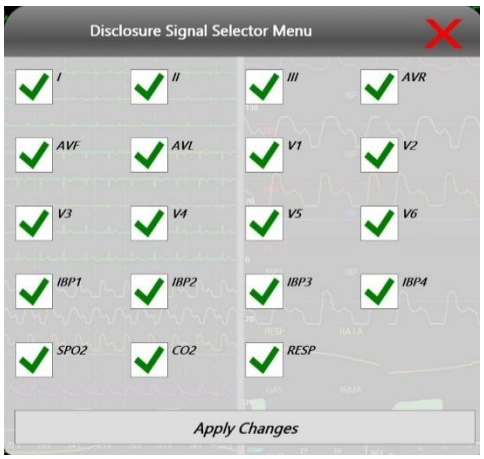


Figure4 4-10 Disclosure signal selection

- Sweep: Select sweep speed of the signals. Available options are 12.5, 25 and 50 mm/s.

Figure 4-11 Sweep menu

- Go to: Select this item to enter Tabular Trend, Graphical Trend or Alarm List. Data of each menu will be displayed as long as the cursor is placed on the signal.

Figure 4-12 Go To menu

Tabular Trends

You can review up to 96 hours of the patient data as table in this page. Up to 6 parameters can be selected and monitored. The items Go to, Clear Filter, Parameters and Navigation keys are available in this page.

Figure 4-13 Tabular Trends display

- Parameters: Select this item to open Trend Select Menu and select up to 5 parameters to be monitored in the Tabular Trends. Available parameters are: HR, SPO2, RESP, IBP1, IBP2, IBP3, IBP4, T1, T2, Gas ،ST, PVCs.
- Go To: Select this item to enter Tabular Trend, Graphical Trend or Alarm List. Data of each menu will be displayed as long as the cursor is placed on the signal.
- Clear Filters: Use this item to filter and search data of each parameter column easily. Select Clear Filter to clear the filter from all columns.

NIBP list

All NIBP measurements of patient within the last 96 hours are saved and displayed in this section.

ARR list

All arrhythmia events of patient within the last 96 hours are saved and displayed in this section.

Alarm list

All alarm events (and their level) occurred within the last 96 hours are saved and displayed in this section.

Warning

- When the PM4010 monitor is not connected to the Viewer system, a blank space is created in history of the Viewer.
- The History window is updated every 30 seconds. If a menu is selected by the user or a search is made on the information, until the History window is closed, the selected part will be displayed, and the signal or the table will not move every 30 seconds to display the updated information.

Note

- When the PM4010 monitor is connected to the Viewer system, Trend setting and saved data of the PM4010 will not transfer to the Viewer system. In addition, History data of the Viewer system will not transfer to the PM4010 monitor.
- After connection between the PM4010 monitor and the Viewer system is established, Trend data of both systems will be saved.
- All items of Alarm List, ARR List and NIBP List are the same as Tabular Trend except "Parameters" which is not available in these pages.
- TREND or History settings in PM4010 and Viewer systems, are independent from each other.

System Configuration

Select the  icon to access the Setup menu. The following items can be set through this menu.

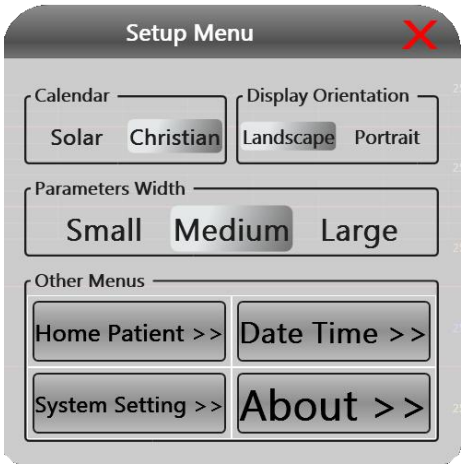


Figure 4-14 Setup menu

Calendar

Available options are SOLAR and CHRISTIAN.

Display Orientation

You can change orientation of the display screen based on your available space and desired view. Available options are Landscape and Portrait.

Parameters Width

Select Small, Medium or Large option to change width of Parameter area.

Other Menus

Home Patient

Select Patient to open Patient Menu and enter the patient demographic information.

- Select Admit to save information of a new patient or to edit information of the previous patient.
- Select Discharge to remove information of the previous patient.

By entering information of a new patient, date and time of admission will be displayed below the menu.

- ID: Patient code in hospital (Up to 15 characters)
- Name: Up to 15 characters
- Family: Up to 15 characters
- Ward: Up to 15 characters
- Doctor Name: Up to 15 characters
- Weight: Optional from 0.5 to 300 Kg
- Height: Optional from 20 to 250 cm
- PAT. Conf.: Available options are Neonate, Pediatric and Adult.
- Blood
- Gender
- Birthday

Warning

- If the PAT. Conf. (Neonate, Pediatric and Adult) is changed, HR value will disappear for a few seconds .

Date Time

You can set the system date and time.

Note

- If connection between the Central system and the Viewer is established, two systems will be synchronized and Date/Time setting will be disabled in the Setup menu of the Viewer system and the PM4010 monitor.
- If no connection is made between the Central system and the Viewer, Date/Time setting will be disabled in the Setup menu of the PM4010 monitor and the PM4010 will be synchronized to the Viewer system.
- When connection is made between the Central system and the Viewer, if time difference between these devices is more than 1 minute, the below message will appear:
  "Changing the date or time will affect the storage of HISTORY. Are you sure to connect with the central?"
  By selecting Yes:
  If the Viewer time is ahead of the Central time, a blank space will be displayed in the History to extent of time difference (if difference is more than 96 hours, the History will be totally blank).
  If the Viewer time is behind the Central time, the History data will be deleted to extent of time difference (if difference is more than 96 hours, the History will be totally blank).
  By selecting No:
  The Viewer will not connect to the Central system and its time will stay fixed.

System Settings

The operator cannot access this menu and only authorized personnel of the manufacturer can change the system setting.

About

Select this item to see the system version and manufacturer information in the About menu.

5) Care and Cleaning

System Check

Before using the monitor,

- Check if there is any mechanical damage in the system and accessories.
- Check if all the power cable and accessories are firmly connected.
- Check all the functions of keyboard and modules to make sure that the monitor is in proper condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or local After Sale Service.

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

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

Warning

- If user does not follow a satisfactory maintenance schedule, the monitor may become invalid, and human health may be endangered.

Note

- It is recommended that the system is calibrated by manufacturer every year, but it has to be calibrated once every 2 years. The medical canter can request the system calibration whenever the system accuracy is in doubt.
- System lifetime is 10 years.
- To ensure maximum battery life, it is recommended that, at least once a month, the monitor runs on battery until it turns itself off and then recharged.

Cleaning and Disinfection

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment.

Manufacturer makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. See also any local policies that apply within your hospital.

Warning

- Before cleaning the monitor 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.
- Do not use ETO gas to disinfect the monitor.

Note

- 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.

External surfaces

In-between patients and as required:

For cleaning: wipe gently using a moist cloth and warm soapy water or mild detergent and for disinfection use the following recommended agents:

- Alcohol 70%
- Isopropyl alcohol
- N-propanol

Note

- For cleaning and disinfection of BFA module must act as external surfaces of the device.

Display screen

In-between patients and as required use clean and soft cloth with screen cleaner or mild soapy water and with Isopropyl alcohol may be used for cleaning and disinfection.

Note

- 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.

Recorder

Accumulation of paper powder or foreign matter between the thermal head and platen roller deteriorates the print quality. Clean the head elements and platen roller surface using alcohol and a cotton swab. Wait until the alcohol dries then close the recorder door.

Warning

- Do not clean the recorder immediately after recording because thermal head and its surrounding area are hot during and after recording.

Accessories

To clean, disinfect and sterilize reusable transducers, sensors, cables, leads, and so forth, refer to the instructions delivered with the accessories.

Also, trolley/ wall stand, accessory holders and extension cables, NIBP Hose, CO2 Mainstream and Side Stream Analyzer (if applicable) should be cleaned and disinfected after each patient or when necessary, using a soft, clean cloth soaked in mild soapy water and, if necessary, Isopropyl alcohol, and then wiped with a soft and dry cloth.

Warning

- 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 accessories shall be done in accordance with the policies of the hospital.

The following table summarizes the methods of cleaning, disinfecting and sterilizing different parts of the device:

<table>
<tr><th>Device parts</th><th>Single-use</th><th>Cleaning</th><th>Disinfection</th><th>Sterilization</th></tr>
<tr><td>External surface of device</td><td>-</td><td rowspan="3">In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.</td><td>In-between patients and as required use
■ Alcohol 70%
■ Isopropyl alcohol
■ N-propanol</td><td rowspan="5">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.</td></tr>
<tr><td>BFA module</td><td>disposable electrodes</td></tr>
<tr><td>* Trolley/ Wall stand,
* Holders of accessory,
* Extension cables
* NIBP Hose,
* CO2 Mainstream and Sidestream Analyzer</td><td>-</td><td rowspan="2">In-between patients and as required use
■ Isopropyl alcohol</td></tr>
<tr><td>Display screen</td><td>-</td><td>In-between patients and as required:
Clean and soft cloth with screen cleaner or mild soapy water</td></tr>
<tr><td>Recorder (printhead)</td><td>-</td><td>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.</td><td>use as required
■ Isopropyl alcohol</td></tr>
<tr><td>ECG Accessory</td><td>disposable electrodes</td><td colspan="3" rowspan="6">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.</td></tr>
<tr><td>SpO2 Accessory</td><td>disposable sensor</td></tr>
<tr><td>NIBP Cuff</td><td>-</td></tr>
<tr><td>TEMP Accessory</td><td>-</td></tr>
<tr><td>IBP Accessory</td><td>disposable transducers and Domes</td></tr>
<tr><td>GAS Accessory (Main-stream/Side-stream)</td><td>disposable Airway Adapter, Nemoline family sampling lines</td></tr>
</table>

Device parts	Single-use	Cleaning	Disinfection	Sterilization
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.

Note

- If the monitor or equipment falls from a height and is damaged or in the vicinity of a very high temperature and high humidity, contact the company's after-sales service at the earliest opportunity to ensure the correct operation.
- Thoroughly clean the system before and after the system is not used for a while.

Weekly check of the following items is recommended:	**Monthly check of the following items is recommended:**
1. Device cleanness 2. Visual inspection of device (case, screen, keys and indicators) 3. Visual inspection of accessories 4. Function of accessories 5. Disposable accessories and accessories with limited time of use.	1. Calibration label (Sending the device to the manufacturer for calibration at the specified date). 2. Visual inspection of device 3. Device cleanness 4. Function of keys and indicators 5. Visual inspection of accessories

The preventive maintenance (PM) checklist #PL-F-68 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.

6) Accessories

General Information

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

Warning

- The accessories listed below are specified to be used for bedside monitor. Manufacturer does not take responsibility for any possible hazard to the patient or monitor if other accessories are used.
- Patient protection against defibrillator effects requires using accessories specified in this chapter.

ECG	**Part num.**
ECG patient cable, 3 leads	10003
ECG patient cable, 5 leads	10038
ECG patient cable 10 leads	10066
ECG Extension for Neonate ECG cable- FMT (E201-3000)	10055
ECG Lead Wire (single use)- Neonate-Fiab (F9058N) or Caremed (230601)	03122
SPO2	
Adult Digit Reusable Sensor - > 30 Kg (LNCS DCI)	18-045
SPO2 Probe , Y- Sensor - > 1 Kg (LNCS)-MASIMO	18-049
SPO2 Extension – Red LNC-10 – MASIMO	18-060
SPO2 Sensor , Reusable , Finger/Toe - Adult > 30 Kg, Red DCI-dc12	18-055
SPO2 Extension Cable	18-056
Rainbow R25 Sensor, Adult, Adhesive, >30Kg, (SPO2,SPCo,SPMet)	18-062
Rainbow Disposable R2-25a Sensor, Disposable, Adult, >30Kg, (SPO2,SPHb,SPMet)	18-063
Rainbow Disposable R2-25r Sensor, Reusable, Adult, >30Kg, (SPO2,SPHb,SPMet)	18-064
Rainbow Disposable R2-20a Sensor, Disposable, Pediatric, 10-50KG, (SPO2,SPHb,SPMet)	18-065
Rainbow Disposable R2-20r Sensor, Reusable, Pediatric, 10-50KG, (SPO2,SPHb,SPMet)	18-066
Rainbow DC-3 SC 360, Reusable, Adult, (SpO2,SpMet,SpHb)	18-068
Rainbow DCI, Reusable, Adult, SpO2,SpCO,SpMet)	18-069
M-LNCS DCI, Reusable, Adult, (SpO2)	18-070
Rainbow R1-20L Pulse Co-Oximeter Sensor, Disposable, Pediatric, (SPHb ,SPO2,SPMet)	18-072
SPO2 Probe, Disposable, Neonate, Adhesive , < 1 Kg ,LNCS,Masimo	18-046
SPO2 Probe, Disposable, Neonate, Adhesive , < 3 Kg or >40Kg,LNCS,Masimo	18-047
SPO2 SPO2 Disposable Sensor, 3-20 Kg, (LNCS Inf)	18-075
Ambient Shield Accessory for Rainbow Sensor	18-067
NIBP	
NIBP Child Cuff, Ultra Check (US1320)	13-052
NIBP Cuff Reusable , Neonate-Single M 5301 Bladderless, Tube length 20cm	13-077
NIBP Cuff Reusable , Infant , Single M5302 Bladderless Tube length 20cm -	13-078
NIBP Cuff Reusable , Pediatric , Single M5303 Bladderless Tube Length 20 cm	13-079
NIBP Cuff Reusable , Adult , Single M5304 Bladderless, Tube Length 20 cm	13-080
NIBP Cuff Reusable - Large Adult, Single M5305 Bladderless, Tube Length 20 cm	13-081
NIBP Cuff Reusable, Adult, Thigh, Single M5306 Bladderless, Tube Length 20 cm	13-082
NIBP Cuff Disposable, Neonate, Single M5541-1# with CT-167 Connector	13-085
NIBP Cuff Disposable, Neonate, Single M5541-2# with CT-167 Connector	13-086
NIBP Cuff Disposable, Neonate, Single M5541-3# with CT-167 Connector	13-087
NIBP Cuff Disposable, Neonate, Single M5541-4# with CT-167 Connector	13-088
PU Legthing Tube (Black)	13-097

NIBP Cuff Reusable – Adault – Single M5114PU, TPU Bladder, Tube Length 20 cm	13083
NIBP Cuff Reusable – Adult – Single M5104 Nylon, TPU Bladder, Tube Length 20 cm	13084
TEMP	
TEMP Probe, Skin ,LAUNCH (LNHmed) (98ME04GA634)	10-083
TEMP Probe,Rectal,LAUNCH (LNHmed) (98ME04GA635)	10-084
TEMP Interface Probe, Data Cable for Redel Connector to Temp Probe	24-073
IBP	
IBP Transducer, MEDEX , MX860/866 Novatrans	16-001
IBP Disposable Dome , MEDEX , MX860/866 Novatrans Dome	16-031
IBP Extension Cable , MEDEX , MX860/866 Novatrans Extension	16-042
IBP Transducer, MEDEX , MX960 Logical	16-002
IBP Disposable Dome, MEDEX , MX960 Logical Dome	16-033
IBP Extension Cable , MEDEX , MX960 Logical Extension	16-043
IBP Transducer Cable , TRUWAVE	16-037
IBP Transducer , Disposable ,RX only ,PX260	16-036
IBP Interface Probe, One channel IBP interface	16-051
IBP Interface Probe, Two channel IBP interface	16-052
IBP Transducer kit, Disposable, iPex, Ref BKT,164ET	16-046
IBP Cable, Ipex, P/N: BKT,164ET	16-053
IBP Bracket for iPex Transducer	16-047
CO2 (main stream)	
IRMA Disposable Airway Adapter without O2 port	20-025
IRMA Disposable Airway Adapter for infant	20-035
IRMA Adapter Cable	24-111
Probe Holder for IRMA sensor	20-043
CO2Airway daptor,Disposable,neonate/pediatric	20091
CO2Airway Adaptor,Disposable,Adult/pediatric	20092
CO2 (side stream)	
Nomoline with luer lock connector. 2 m. Box of 25	20-045
Clamp of ISA Module Holder	20-055
VersaStream,CO2/GasAirway,Adapter Sampling Line, Adult / Pediatric	20-077
VersaStream,CO2/GasAirway,Adapter Sampling Line, Infant	20-078
VersaStream, CO2/Gas Sampling Line with Luer Lock Male(it uses with Sidestream Airway Adapter-Adult/Pediatric, part number:4420531)	20-079
T4F Water Filter for Capno-S+	20-094
Sample line for Capno-S+	20-095
T Airway Adapter for Capno-S+	20-096
BFA	
BFA Accessory Patient Cable, URUK	22- 028
Adapter	
URUK Adaptor 60W, 15v for PM4010	09263

Note

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

ECG Electrodes	Part num.
Adults ECG Disposable Electrodes, FIAB Manufacturer	P28042 (REF: F9060)
Pediatric ECG Disposable Electrodes, FIAB Manufacturer	P28047 (REF: F9060P)
Arbo H124SG, COVIDIEN Manufacturer	P10079 (REF: 31.1245.21)
EEG Electrodes	
Neuroline 720, AMBU Manufacturer	P22009 (REF: Neuroline 720)

7) Technical Specifications

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” 5” Flexible display Configuration
Waveforms	ECG, SPO2, RESP/CO2, IBP1,IBP2,IBP3,IBP4. ,EEG(PM4010: Freezable)
Numeric Parameters	PM4010: HR, PVCs,ST, SPO2 (%SPO2, PR, PI), Rainbow (SpMet, SpCO, SpHb, SpOC, PVI), NIBP (SYS, DIA, MAP), RR, TEMP1,2, IBP1,2,3,4 (SYS, DIA, MAP), EtCo2, FiCo2, AWRR, BFI, BS%, EMG%, SQI%,
Operation Method	Membrane, Touch screen
AC Power(Adaptor)	100 - 240 VAC, 50/60 Hz , Ip: 1.4 – 0.7 A, Output:15VDC,4A
Application	Compact and Mobile Monitor.
Safety	Based on IEC 60601-1, Class I
Protection	Against Electro surgery and Defibrillator and EMC.

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

Input Impedance	> 5 MΩ	
QRS Detection	Duration	40 to 120 msec
		0.25 to 5 mV forAdult/Pediatric
	Amplitude	0.2 to 5 mV for Neonate
Heart Rate Range	15 - 300 BPM for adult/Pediatric	
	15 - 350 BPM for neonate	
Accuracy	±1% or 2 BPM	
Tall T-Wave	Reject up to 1.2 mV Amp.	
Pacer Detection/Rejection	Duration	0.1 - 2 msec
	Amp	±2 to ± 700 mV (Without over/undershoot)
	Reject from heart rate counter.	
	Re-insert into ECG to display on screen.	
	Ineffective pace rejection	HR:0, Pace: 60
		HR:60, Pace:60
		HR:30, Pace:80
	Beside rejection of atrial paces preceed ventricular paces by 150 or 250 ms	
Protection	Defibrillator and Electrosurgery	

ST ANALYSIS	
Display resolution	0.01 mV
Measurement Range	-2mv to +2mv
Alarm Range	-2mv to +2mv
Features	User Adjustable Isoelectric and ST point trending of ST values
Update period	5 Sec.

ARRHYTHMIA ANALYSIS	
Type	ASYS, VFIB, VTAC, RUN, AIVR, COUPLET, BIGEMINY, TRIGEMINY, TACHY, BRADY, AFIB, PAUS, FREQUENT PVCs
Learning	Rapid Learning: only 20 seconds required for recognition of dominant rhythm.
Method	Real time arrhythmia detection with innovative feature.
Memory	Capability of storing the latest 150 ARR event (waveform and Parameters)

NIBP			
Physical dimensions	Width: 2.52 in (64 mm) Length: 3.11 in (79 mm) Height: 0.96 in (24.5 mm) Weight: 0.25lbs (0.11kg)		
Operating voltage	5V DC ± 5% Input Voltage		
Current Consumption	Idle: 52mA Measurement: 190mA Inflation: 350 mA		
Communication Protocol	Serial RS232 or TTL		
Operating Conditions	Temperature: 50C to 400C Humidity: 20% to 90%		
Storage Conditions	Temperature: -250C to 600C Humidity: 10% to 100%		
Technique	Oscillometry		
Measurement time	20-25 sec (excluding cuff inflation time)		
Safety & Regulatory Standards	IEC 60601-1, AAMI SP10, EN1060-1, EN 1060-3, EN1060-4, IEC 80601-2-30, ISO 81060-2: 2014		
NIBP Accuracy	Meets BS EN ISO 81060-2:2014		
Measurement method	Oscillometric		
Mode of operation	Manual/Automatic/Stat		
Auto mode repetition intervals	1,2,3,5,10,15,20, 30, 45, 60, 90 minutes and 2, 4, 8,12,16,20 and 24 hours.		
STAT mode cycle time	5 min		
Max measurement time	Adult, pediatric: 180 s Neonate: 90 s		
Heart rate range	30 to 240 bpm		
Cuff pressure Rang	Adult		0-290 mmHg
	Neonate		0-145 mmHg
Measurement Range(mmHg)	Adult	SYS	30 ~ 255 mmHg
		DIA	15 ~ 220 mmHg
		MAP	20 ~ 235 mmHg
	Neonate	SYS	30 ~ 135 mmHg
		DIA	15 ~ 110 mmHg
		MAP	20 ~ 125 mmHg
	Pediatric	SYS	30 ~ 240mmHg
		DIA	15 ~ 220 mmHg
		MAP	20 ~ 230 mmHg
Software overpressure protection	Adult: 290 ± 3 mmHg Pediatric: 240 ± 3 mmHg Neonate: 145 ± 3 mmHg		
Resolution	1 mmHg		
Transducer accuracy	±3 mmHg over full range in operating conditions		

default initial cuff inflation pressure (mmHg)	Adult : 150 mmHg Pediatric: 140mmHg Neonate: 85 mmHg
Memory	100 Records

SpO2 (Masimo Rainbow Set)			
SpO2 Parameters	SpO2,PI,PR		
Method SpO2	2 Wavelengths of light used		
	SpOC		
	SpCO		
	SpMet		
	SpHb		
	PVI		
Method Rainbow	7+Wavelengths of light used		
Range	SpO2	0 – 100 %	
	PR	25 – 240 bpm	
	PI	0.02– 20.0 %	
	SpMet	0 – 99.9 %	
	SpCO	0 – 99 %	
	SpHb	0 – 25.0 g/dL	
	SpOC	0 – 35.0 ml/dL	
	PVI	0 – 100 %	
Accuracy	Oxygen Saturation		
	No motion conditions	Adult/Pediatric	±2% (SpO2 70 ~ 100%) Unspecified (SpO2 0 ~ 69%)
		Neonate	±3% (SpO2 70 ~ 100%) Unspecified (SpO2 0 ~ 69%)
	Motion conditions	Adult/Pediatric/Neonate	±3% (SpO2 70 ~ 100%) Unspecified (SpO2 0 ~ 69%)

	Low perfusion conditions	Adult/Pediatric/Neonate	±2% (SpO2 70 ~ 100%) Unspecified (SpO2 0 ~ 69%)
	Pulse Rate		
	No motion conditions	Adult/Pediatric/Neonate	±3bpm (PR 25 ~ 240)
	Motion conditions	Adult/Pediatric/Neonate	±5bpm (PR 25 ~ 240)
	Low perfusion conditions	Adult/Pediatric/Neonate	±5bpm (PR 25 ~ 240)
	Carboxyhemoglobin Saturation		
	Carboxyhemoglobin Saturation	Adult/Pediatric	±3% (1 - 40)
	Methemoglobin Saturation		
	Methemoglobin Saturation	Adult/Pediatric/Neonate	±1% (1 – 15)
	Total Hemoglobin		
	Total Hemoglobin	Adult/Pediatric	±1g/dL (8 – 17) g/dL
Resolution	SpO2	1%	
	PI	0.1%	
	PR	1 BPM	
	SpCO	1.0 %	
	SpMet	0.1 %	
	SpHb	0.1 g/dL	
	PVI	0-100%	
	SpOC	0.1 ml/dL	

1. The Masimo SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
2. The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population.
3. The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
4. The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.
5. The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
6. See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.
7. Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent A (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of $\pm A_{rms}$ compared to the reference value. Unless otherwise noted, SpO2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.
8. Masimo M-LNCS, LNOP, RD SET, and LNCS sensors types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8 pin modular plug, RD 15 pin modular plug, LNCS 9 pin, cable based, and M-LNCS 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.

TEMPERATURE	
Channel	PM4010: 2 Channel Monitoring 2 channel.
Probe Type	YSI 400 Compatible
Range	0 - 50 °C
Accuracy	± 0.2 °C

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

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

Multi-gas, Mainstream (MASIMO SWEDEN AB)		
IRMA CO2	CO2	
IRMA AX+	CO2, N2O, primary and secondary agents (HAL, ISO, ENF, SEV, DES)	
Gas /CO2 Interface	Connector and S/W Interface Driver, Applicable for All Gas and CO2 Modules.	
Description	Extremely compact infrared mainstream multigas probe available in two parameter configurations.	
Cable length	2.5 m ±0.1 m	
Recovery time after defibrillator test	Unaffected	
Drift of measurement accuracy	No drift	
Surface temperature (at ambient temp. 23°C)	IRMA CO2	Max 39°C / 102°F
	IRMA AX+	Max 46°C / 115°F
Interface	Modified RS-232 serial interface operating at 9600 bps.	
Airway adapters	Disposable adult/pediatric:	- Adds less than 6 ml deadspace.
		- Pressure drop less than 0.3 cm H2O @ 30 LPM.
	Disposable infant:	- Adds less than 1 ml deadspace.
		- Pressure drop less than 1.3 cm H2O @ 10 LPM.
	(Infant Airway Adapter recommended for Tracheal Tube ID size = 4 mm)	
Degree of protection against harmful ingress of water or particulate matter	IPX4	

Method of sterilization	The IRMA system contains no sterile parts.
Mode of operation	CONTINUOUS OPERATION
Data output	
Breath detection	Adaptive threshold, minimum 1 vol% change in CO2 concentration.
Respiration rate[1]	0–150 ±1 bpm. The respiration rate is displayed after three breaths and the average value is updated every breath.
Fi and ET[2] Fi and ET are displayed after one breath and have a continually updatedbreath average. The following methods are used to calculate end-tidal (ET) values: -CO2: The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end ofthe cycle. -N2O and anesthetic agents: The momentary gas concentration at the time point where ETCO2 is detected. ET-values for anaesthetic agents and N2O (IRMA AX+) will typically decrease below nominal value when respiration rate exceeds 80 bpm. The maximum decrease is described by the formula ET = 80*ETnom/RR. ETCO2 will be within specification for all respiration rates up to 150 bpm (IRMA AX+ and IRMA CO2)	
Automatic agent identification	IRMA AX+: Primary and secondary agent.
Gas Analyzer	
Probe	2-9 channel NDIR type gas analyzer measuring at 4-10 µm. Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing Airway adapter (IRMA AX+) No span calibration required for the IR bench.
Warm-up time	IRMA CO2: < 10 seconds (concentrations reported and full accuracy)
	IRMA AX+: < 20 seconds (concentrations reported, automatic agent identification enabled and full accuracy)
Rise time[3] (@10 l/min)	CO2 ≤ 90 ms
	N2O ≤ 300 ms
	HAL, ISO, ENF, SEV, DES ≤ 300ms
Primary agent threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.

Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.[1]
Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.[2]
Measured @ 10 l/min with gas concentration steps corresponding to 30% of total measuring range for each gas.[3]

Secondary agent threshold	0.2 vol% +10% of total agent concentration
Agent identification time	<20 seconds. (Typically < 10 seconds)
Total system response time[1]	< 1 second

Accuracy - standard conditions

The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa

Gas	Range	Accuracy
CO2	0 to 15 vol%	±(0.2 vol% +2% of reading)
N2O	0 to 100 vol%	±(2 vol% +2% of reading)
HAL,ISO,ENF	0 to 8 vol%	±(0.15 vol% +5% of reading)
SEV	0 to 10 vol%	±(0.15 vol% +5% of reading)
DES	0 to 22 vol%	±(0.15 vol% +5% of reading)

Accuracy - all condition

The following accuracy specifications are valid for all specified environmental conditions except for interference specified in the table “Interfering gas effects” and the section “Effects from water vapor partial pressure on gas readings” below.

Gas	Accuracy
CO2	±(0.3 kPa + 4% of reading)
N2O	±(2 kPa + 5% of reading)
Agents[2]	±(0.2 kPa + 10% of reading)

Gas concentration conversion

Gas concentration is reported in units of volume percent. The concentration is defined as:

$$\%\,gas = \frac{(Partial\ pressure\ of\ gas\ component)}{(Total\ pressure\ of\ gas\ mixture)} * 100$$

The total pressure of the gas mixture is estimated by measuring the actual atmospheric pressure in the IRMA probe.

Effects from water vapor partial pressure on gas readings

[1] Measured according to EN ISO 80601-2-55.

[2] The accuracy specification for IRMA AX+ is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

The effects of water vapor are illustrated by the examples in the following table. The two columns to the right show the relative error in displayed concentrations when adding or removing water vapor from the gas mixture, and referencing the measurement to dry gas conditions at actual temperature and pressure (ATPD) or saturated conditions at body temperature (BTPS).

Temp [C]	RH [%]	P [hPa]	H2O part.pres. [hPa]	errrel [%]	errrel ATPD [%]	errrel [%] BTPS
10	20	1013	2	0	-0.2	+6.0
20	20	1013	5	0	-0.5	+5.7
25	0	1013	0 (ATPD)	0	0	+6.2
25	23	1013	7.3	0	-0.7	+5.5
25	50	1013	16	0	-1.6	+4.6
30	80	1013	42	0	-4.1	+2.0
37	100	1013	63 (BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

The table illustrates that the gas concentrations in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

Interfering gas effects					
Gas or vapour	Gas level	CO2		Agents	N2O
		IRMA CO2	IRMA AX+		
N2O-note4)	60 vol%	- note1&2)	- note1&2)	- note1)	- note1)
HAL-note4)	4 vol%	- note1)	- note1)	- note1)	- note1)
ENF, ISO, SEV-note4)	5 vol%	+8% of reading-note3)	- note 1)	- note1)	- note1)
DES-note4)	15 vol%	+12% of reading-note3)	- note 1)	- note1)	- note1)
Xe (Xenon)-note4)	80 vol%	-10% of reading-note3)		- note1)	- note1)
He (Helium)-note4)	50 vol%	-6% of reading-note3)		- note1)	- note1)
Metered does inhaler propellants-note4)	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol)-note4)	0.3 vol%	- note1)	- note1)	- note1)	- note1)
C3H7OH (Isopropanol)-note4)	0.5 vol%	- note1)	- note1)	- note1)	- note1)
CH3COCH3 (Acetone)-note4)	1 vol%	- note1)	- note1)	- note1)	- note1)
CH4 (Methane) -note4)	3 vol%	- note1)	- note1)	- note1)	- note1)
CO (Carbon monoxide) -note5)	1 vol%	- note1)	- note1)	- note1)	- note1)
NO (Nitrogen monoxide)-note5)	0.02 vol%	- note1)	- note1)	- note1)	- note1)
O2-note 5)	100 vol%	- note1&2)	- note1&2)	- note1)	- note1)

Note 1 : Negligible interference, effect included in the specification " Accuracy all conditions" above.

Note 2 : For probes not measuring N2O and/or O2 the concentrations shall be set from host according to the instructions. (IRMA CO2 measures neither N2O, nor O2. IRMA AX+ dose not measure O2.)

Note 3 : Interference at indicated gas level. for example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture contaning 5.0 vol% CO2 and 50 vol% Helium, the measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.

Note 4 : According to the EN ISO 80601-2-55:2011 standard.

Note 5 : In addition to the EN ISO 80601-2-55:2011 standard.

Multi-gas, Sidestream (MASIMO SWEDEN AB)	
ISA CO2	CO2, CO2 waveform
ISA AX+	CO2, N2O, primary and secondary Agents (HAL, ISO, ENF, SEV, DES)
ISA OR+	CO2,O2, N2O, primary and secondary Agents (HAL, ISO, ENF, SEV, DES)
Gas /CO2 Interface	Connector and S/W Interface Driver, Applicable for All Gas and CO2 Modules.
Description	Compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Ambient CO2	≤ 800 ppm (0.08 vol%)
Recovery time after defibrillator test	Unaffected
Water handling	Nomoline Family sampling lines with proprietary water removal tubing.
Sampling flow rate	50 ± 10 sml/min[1]
Degree of protection against harmful ingress of water or particulate matter	IPX4
Method of sterilization	The ISA system contains no sterile parts.
Mode of operation	CONTINUOUS OPERATION
Degree of protection against electric shock	Nomoline Family sampling lines are classified as DEFIBRILLATION-PROOF TYPE BF APPLIED PART
Data output	
Breath detection	Adaptive threshold, minimum 1 vol% change in CO2concentration.
Respiration rate [2]	0 to150 ± 1 breaths/min (or BrPM)

[1] Volumetric flow rate of air corrected to standardized conditions of temperature and pressure.

[2] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

Fi and ET[1]

Fi and ET are displayed after one breath and have a continually updated breath average.

The following methods are used to calculate end-tidal (ET) values:

-CO2: The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle.

-O2: The highest/lowest concentration of O2during the expiratory phase (depending on whether ETO2 is higher or lower than FiO2

-N2O and anesthetic agents: The momentary gas concentration at the time point where ETCO2 is detected.

ET will typically decrease below nominal value (ETnom) when respiration rate (RR) exceeds the RR threshold (RRth) according to the following formulas:

ISA CO2	ET=ETnom×(125⁄RR)_for RRth >125	
CO2		
ISA OR+/AX+		
CO2	ET=ETnom×$\sqrt{(70 / RR)}$ for RRth >70	
N2O, O2, DES, ENF, ISO, SEV	ET=ETnom×$\sqrt{(50 / RR)}$ for RRth >50	
HAL	ET=ETnom×$\sqrt{(35 / RR)}$ for RRth >35	
Automatic agent identification	ISA OR+/AX+: primary and secondary agent.	
Gas analyzer		
Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 µm.	
	Data acquisition rate 10 kHz (sample rate 20 Hz / channel).	
	O2 measurements by Servomex's paramagnetic sensor.	
Calibration	No span calibration is required for the IR bench. An automatic zeroing is performed 1 to 3 times per day.	
Compensation	ISA CO2	Automatic compensation for pressure and temperature.
		Manual compensation for broadening effects on CO2.
	ISA OR+/AX+	Automatic compensation for pressure, temperature and broadening effects on CO2.
Warm-up time	ISA CO2:	<10 seconds (concentrations reported and full accuracy)
	ISA OR+/AX	+: <20 seconds (concentrations reported, automatic agent identification enabled and full accuracy

[1] Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

Rise time[1]	CO2		≤ 200 ms(≤ 300 ms for ISA OR+/AX+)
	N2O, O2, ENF, ISO, SEV, DES		≤ 400 ms
	HAL		≤ 500 ms
Primary agent threshold (ISA OR+/AX+)	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%		
Secondary agent threshold (ISA OR+/AX+)	0.2 vol% +10% of total agent concentration		
Agent identification time (ISA OR+/AX+)	<20 seconds (typically <10 seconds)		
Total system response time[2]	ISA CO2:	< 3 seconds	
	ISA OR+/AX+:	< 4 seconds (with 2m Nomoline Airway Adapter Set sampling line)	

Accuracy standard conditions		
The following accuracy specifications are valid with no drift for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:		
	Range[3]	Accuracy
CO2	0 to15 vol%	±(0.2 vol% +2% of reading)
N2O	0 to 100 vol%	±(2 vol% +2% of reading)
HAL, ENF, ISO	8 to 25 vol%	±(0.15 vol%+5% of reading)
SEV	0 to 10 vol%	±(0.15 vol% +5% of reading)
DES	0 to 22 vol%	±(0.15 vol% +5% of reading)
O2	0 to 100 vol%	±(1 vol% +2% of reading)
Accuracy - all conditions		

[1] Measured according to EN ISO 80601-2-55.

[2] Measured according to EN ISO 80601-2-55.

[3] All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

The following accuracy specifications are valid with no drift for all specified environmental conditions, except for interference from water vapor in the below section “Effects from water vapor partial pressure on gas readings”.

GAS	Accuracy
CO2	±(0.3 kPa + 4% of reading)
N2O	±(2 kPa + 5% of reading)
Agents[1]	±(0.2 kPa + 10% of reading)
O2	±(2 kPa + 2% of reading)

Effects from water vapor partial pressure on gas readings

When the breathing gas flows through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The measurement of all gases will always show the actual partial pressure at the current humidity level in the gas sample. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. However at an ambient temperature of 37 °C and a breathing gas with a relative humidity of 95% the gas reading will typically be 6% lower than corresponding partial pressure after removal of all water.

[1] The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

Interfering gas and vapor efects					
Gas or vapour	Gas level	CO2		Agents	N2O
		ISA CO2	ISA AX+/OR+		
N2O-note4)	60 vol%	- note2)	- note1)	- note1)	- note1)
HAL-note4)	4 vol%	- note1)	- note1)	- note1)	- note1)
ENF, ISO, SEV-note4)	5 vol%	+8% of reading-note3)	- note1)	- note1)	- note1)
DES-note4)	15 vol%	+12% of reading-note 3)	- note1)	- note1)	- note1)
Xe (Xenon)-note4)	80 vol%	-10% of reading-note3)		- note1)	- note1)
He (Helium)-note4)	50 vol%	-6% of reading-note3)		- note1)	- note1)
Metered does inhaler propellants-note4)	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol)-note4)	0.3 vol%	- note1)	- note1)	- note1)	- note1)
C3H7OH (Isopropanol)-note4)	0.5 vol%	- note1)	- note1)	- note1)	- note1)
CH3COCH3 (Acetone)-note4)	1 vol%	- note1)	- note1)	- note1)	- note1)
CH4 (Methane)-note4)	3 vol%	- note1)	- note1)	- note1)	- note1)
CO (Carbon monoxide)-note5)	1 vol%	- note1)	- note1)	- note1)	- note1)
NO (Nitrogen monoxide)-note5)	0.02 vol%	- note1)	- note1)	- note1)	- note1)
O2-note5)	100 vol%	- note2)	- note2)	- note1)	- note1)

Note 1 : Negligible interference, effect included in the specification " Accuracy all conditions" above.

Note 2 : Negligible interference with N2O/O2concentrations correctly set, effect included in the specification " Accuracy all conditions" above.

Note 3 : Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture contaning 5.0 vol% CO2and 50 vol% Helium, the actual measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.

Note 4 : According to the EN ISO 80601-2-55:2011 standard.

Note 5 : In addition to the EN ISO 80601-2-55:2011 standard.

BFA (Brain Function Assesment)		
BFA Interface	Required for Integratig BFA mdule and monitors	
EEG sensitivity	±450µV	
Noise	<2µVp-p <0.4µV RMS, 0.25-250 Hz	
CMRR	>140dB	
Input impedance	>50MΩ	
Sample rate	1000 samples/sec(16 bits equivalent)	
Brain Function Index (BFI)	0-100. Filter 1-47Hz, 1sec. update	
EMG	0-100. Filter 30-47 Hz,1 sec. update	
BSR	0-100. Filter 2-47 Hz, 1 sec. update	
Signal Quality Index (SQI)	0-100. 1 sec. update	
EEG Waveform	±250µV, user-adjustable, 5 sec	
Alarms	Auditory and visual, user-adjustable limits	
Artifact rejection	Automatic	
Sensor impedance measurement	0-30kOhm / Manual-Automatic/ measurement current 0.06µA	
Power supply	5 VDC	
Power Consumption	Less than 0.5 W	
Weight	100 gr	
Dimensions	111×64×25 mm	
Classification	Class I, type BF, continuous use	
Sensors	Ambu Neuro Sensors	
Cable length	195 cm/ 77” with 35 cm/ 14” split	
Memory	Data recording (96 hours)	
Trend	BFI/EMG/SQI/BS, 10 sec. update	
Environment - Operation	Temperature	5-40°C
	Rel humidity	20~96%
	Altitude	-200~3000m

Recorder	
Model	URUK Thermal Printer
Channel	PM4010: Up to 2 waveforms
Printing Speed	6, 12.5, 25 mm/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	PM4010: HR,ST,PVCs,AFIB, RESP, T1,T2, IBP1(SYS,DIA,MAP), IBP2(SYS,DIA,MAP) IBP3(SYS,DIA,MAP) IBP4(SYS,DIA,MAP) SPO2, PR,SpHb, PI, SpCo, SpMet, PVI, SpOc, EtCo2,FiCo2,AWRR
Trend Time Save	96 Hours
Trend Time Interval	5, 10, 15, 30, 45 Min, 1, 2, 4 Hours
Resolution	1 sec

INPUT/OUTPUT	
Network	PM4010: Digital, TCP/IP (Wi-Fi) and TCP/IP (Wire)
	GSM/GPRS/EDGE: 850/900/1800/1900MHz), GSM 0.9/1.8 GHz

Internal Battery		
Nickel-Metal Hybride 3.6V,2.5AH Lithium Polymer 11.1V,4.3AH (PM4010 only) Lithium ion 11.1V,3.3AH		
System Model	Nickel-Metal Hybride	
	Charge time	Usage
PM4010	~ 3hours	~ 2:30hours
F1		
F1R		
System Model	Lithium Polymer	
	Charge time	Usage
PM4010		
F1	~ 6hours	~ 5hours
F1R	~ 6hours	~ 4hours
System Model	Lithium ion	
	Charge time	Usage
PM4010		
F1	~ 6hours	~ 10hours
F1R	~ 6hours	~ 8hours

Physical Specification		
Model	Dimension (mm)	Weight (approximately)
PM4010 Monitor	155(W) × 107(H) × 65(D)	Less than 800g
F1 Station	190(W) × 155(H) × 80(D)	800g
F1R Station	220(W) × 155(H) × 90(D)	1100g

ENVIRONMENTAL		
Temperature	Operating:°C	PM4010: 5 to 40°C
	Storage & Transport:	-25 to 60 °C
Humidity	Operating: (Noncondensing)	20-90 % (Noncondensing)
	Storage & Transport: (Noncondensing)	10-100 %
Altitude	-200 to 3000 m	

Viewer Specification	
Storage	
12 Lead ECG Signal	1000 Records
Physician Measurement and Interpretation	1000 Records
Physiological Parameters	1000 Records
Print	
Laser Printer	Print in Any Size paper
File	PDF/ JPEG Format
Filters	
Notch Filter	50/60 Hz
Drift Filter	0.5 Hz
Display	

12 Lead ECG Signal	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
ECG Sample Rate	500
ECG Symbol Length	16 bit
ECG Signal Length	10 Sec
Physiological Parameters	Heart Rate, NIBP, SPO2, TEMP1, RR
Calibration Signal	1 mV, 200 ms
Manually Lead selection	Yes
Superimposition	Yes
Patient information	Name, Patient ID, Gender, Age
Sender Information	Ambulance ID
Time Sweep	(12.5/25/50) mm/Sec
Voltage Gain	(5/10/20/40) mm/mV
Physician information	Name, ID, Interpretation Note
Measurement	
Automatic Measurement	Optional
Manual Measurement	P and QRS Duration, PQ and QT Intervals
Heart Axis	P, QRS, T Axis
Other	
Portable Software	Yes
Touch Screen	Yes
Compatibility	Win XP/Vista/7/8/10
Upgrade Capability	Manual
Connection	
Connecting to Data Repository	Online/ Offline
Data Base	Costume Format

8) System Parameters

Menu item	selection	Default
The parameters in ECG menu		
ECG LEAD	I,II,III,aVR,aVF,aVL,V1,V2,V3,V4,V5,V6	II
CABLE TYPE	3 Wires,5 Wires, 10 Wires	3 Wires
DISPLAY FORMAT	Cascade, 2Traces, 4Traces, 7Traces, 12Traces	Cascade
ECG SIZE	CHANGE (×0.25,×0.5,×1,×2,×4),AUTO	AUTO
ECG SWEEP	12.5,25,50mm/s	25
ECG FILTER	MONITOR,NORMAL,EXTENDED	NORMAL
HR AVERAGE	4,8,16SEC	8SEC
HR SOURCE	ECG,SpO2,IBP1,IBP2,AUTO	AUTO
BEAT VOLUME	1,2,3,4,5,6,7,OFF	1
PACE DETECT	ON,OFF	OFF
ECG CALIB	ON,OFF	OFF
ALARM LEVEL	1,2	1
HR ALARM	ON,OFF	OFF
HR HIGH ALARM	HR LOW ALARM +5 to 250	150Bpm
HR LOW ALARM	30 to HR HIGH ALARM -5	50Bpm
The parameters in RESP menu		
Menu item	**selection**	**Default**
RESP LEAD.	RA-LA,RA-LL	RA-LA
RESP GAIN	×0.25,×0.5,×1,×2,×4	×1
RESP SWEEP	3,6,12.5,25mm/s	6mm/s
ALARM LEVEL	1,2	1
RR ALARM	ON ,OFF	OFF
RR HIGH ALARM	RR LOW ALARM +1 to 150	25Brpm
RR LOW ALARM	5 to RR HIGH ALARM -1	5Brpm
APNEA LIMIT	10 to 40S, OFF	10S
The parameters in SpO2 menu		
Menu item	**selection**	**Default**
AVERAGE TIME	2-4,4-6,8,10,12,14,16	8
SpO2 PLETH SWEEP	12.5,25mm/s	PM4010: 25 mm/s
ALARM LEVEL	1,2	1
SpO2 ALARM	ON,OFF	OFF
SpO2 HIGH ALARM	SpO2 LOW ALARM +1 to 100 (with step 1)	100
SpO2 LOW ALARM	1 to SpO2 HIGH ALARM -1 (with step 1)	90
PR HIGH ALARM	PR LOW ALARM +5 to 235	140
PR LOW ALARM	20 to PR HIGH ALARM -5	50
SpO2 SENSITVITY MODE	NORMAL , MAX , APOD	NORMAL
SPO2 PULSE RATE	ON, OFF	ON
PI HIGH ALARM	PI LOW ALARM +0.1 to 19.0 (with step 0.1)	19.0
PI LOW ALARM	0.0 to PI HIGH ALARM -0.1 (with step 0.1)	0.0
PVI HIGH ALARM	PVI LOW ALARM +1 to 99 (with step 1)	99
PVI LOW ALARM	1 to PVI HIGH ALARM -1 (with step 1)	1
SpOC HIGH ALARM	SpOC LOW ALARM +1 to 34.0 (with step 1)	34.0
SpOC LOW ALARM	1.0 to SpOC HIGH ALARM -1 (with step 1)	1.0

SpCO HIGH ALARM	SpCO LOW ALARM +1 to 99.0 (with step 1)	10.0
SpCO LOW ALARM	1.0 to SpCO HIGH ALARM -1 (with step 1)	1.0
SpMet HIGH ALARM	SpMet LOW ALARM +0.5 to 99.5 (with step 0.5)	3.0
SpMet LOW ALARM	0.5 to SpMet HIGH ALARM -0.5 (with step 0.5)	0.5
SpHb HIGH ALARM	SpHb LOW ALARM +0.1 to 24.5 (with step 0.1)	17.0
SpHb LOW ALARM	0.5 to SpHb HIGH ALARM -0.1 (with step 0.1)	7.0
The parameters in NIBP menu		
Menu item	**selection**	**Default**
NIBP UNIT	mmHg , KPa	mmHg
ALARM LEVEL	1,2	1
NIBP ALARM	ON,OFF	OFF
SYS HIGH ALARM	Adult: SYS LOW ALARM +5 to 255 Neonate: SYS LOW ALARM +5 to 135 Pediatric: SYS LOW ALARM +5 to 240 (with step 5)	Adult: 160mmHg Neonate: 90mmHg Pediatric: 120mmHg
SYS LOW ALARM	Adult: 30 to SYS HIGH ALARM -5 Neonate: 30 to SYS HIGH ALARM -5 Pediatric: 30 to SYS HIGH ALARM -5 (with step 5)	Adult: 90mmHg Neonate: 40mmHg Pediatric: 70mmHg
DIA HIGH ALARM	Adult: DIA LOW ALARM +5 to 220 Neonate: DIA LOW ALARM +5 to 110 Pediatric: DIA LOW ALARM +5 to 220 (with step 5)	Adult: 90mmHg Neonate: 60mmHg Pediatric: 70mmHg
DIA LOW ALARM	Adult: 15 to DIA HIGH ALARM -5 Neonate: 15 to DIA HIGH ALARM -5 Pediatric: 15 to DIA HIGH ALARM -5 (with step 5)	Adult: 50mmHg Neonate: 20mmHg Pediatric: 40mmHg
MAP HIGH ALARM	Adult: MAP LOW ALARM +5 to 235 Neonate: MAP LOW ALARM +5 to 125 Pediatric: MAP LOW ALARM +5 to 230 (with step 5)	Adult: 110mmHg Neonate: 70mmHg Pediatric: 90mmHg
MAP LOW ALARM	Adult: 20 to MAP HIGH ALARM -5 Neonate: 20 to MAP HIGH ALARM -5 Pediatric: 20 to MAP HIGH ALARM -5 (with step 5)	Adult: 60mmHg Neonate: 25mmHg Pediatric: 50mmHg
AUTO/MANUAL	1min, 2min, 3min,5min,10min,15min,20min, 30min,45min, 60min, 90min, 2hr,4hr, 8hr, 12hr, 16hr, 20hr, 24hr,MANUAL, STAT	MANUAL
The parameters in TEMP menu		
Menu item	selection	Default
TEMP UNIT	ºC,ºF	ºC
ALARM LEVEL	1,2	1
TEMP ALARM	ON ,OFF	OFF
T1 HIGH ALARM	T1 LOW ALARM +0.5 to 50	39
T1 LOW ALARM	0 to T1 HIGH ALARM -1	35
T2 HIGH ALARM	T2 LOW ALARM +0.5 to 50	40
T2 LOW ALARM	0 to T2 HIGH ALARM -1	36
DT HIGH ALARM	DT LOW ALARM +1 to 50	5
DT LOW ALARM	0 to DT HIGH ALARM -1	1.0
The parameters in IBP menu		
Menu item	**selection**	**Default**

IBP UNIT	mmHg , KPa,cmH2O	mmHg
IBP LABEL	IBP, ART, PAP, CVP, LAP, RAP, LVP, RVP,ICP	IBP
IBP SWEEP	3,6,12.5,25 mm/s	12.5 mm/s
IBP GRID	ON, OFF	OFF
IBP FILTER	8, 16, 22 Hz	16 Hz
ALWAYS AUTO SCALE	ON,OFF	OFF
IBP ALARM	ON,OFF	OFF
ART CATH. DISCONNECT ALM	ON , OFF	OFF
PPV MEASUREMENT	ON , OFF	OFF
ALARM LEVEL	1,2	1
IBP HIGH ALARM	IBP LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
IBP LOW ALARM	-50to IBP HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
ART HIGH ALARM	ART LOW ALARM +5 to 300	SYS: 150 mmHg DIA: 100 mmHg MEAN: 115 mmHg
ART LOW ALARM	-50to ART HIGH ALARM -5	SYS: 80 mmHg DIA: 50 mmHg MEAN: 60 mmHg
LVP HIGH ALARM	LVP LOW ALARM +5 to 300	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 HIGH ALARM	RAP LOW ALARM +1 to 100	15 mmHg
RAP LOW ALARM	-50 to RAP HIGH ALARM -1	-5 mmHg

ICP HIGH ALARM		ICP LOW ALARM +1 to 100	Adult: 10mmHg Neonate: 4mmHg Pediatric: 4mmHg
ICP LOW ALARM		-40 to ICP HIGH ALARM -1	0 mmHg
IBP SCALE			
IBP	**HIGH**	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	-20
	SIGN	(HIGH+LOW)/2	90
ART	**HIGH**	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	40
	SIGN	(HIGH+LOW)/2	120
PAP	**HIGH**	LOW +5 TO 300 (with step 5)	80
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	35
CVP	**HIGH**	LOW +5 TO 300 (with step 5)	30
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	10
LAP	**HIGH**	LOW +5 TO 300 (with step 5)	40
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	15
RAP	**HIGH**	LOW +5 TO 300 (with step 5)	30
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	10
LVP	**HIGH**	LOW +10 TO 300 (with step 10)	200
	LOW	-50 TO HIGH-10	-20
	SIGN	(HIGH+LOW)/2	90
RVP	**HIGH**	LOW +5 TO 300 (with step 5)	80
	LOW	-50 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	35
ICP	**HIGH**	LOW +5 TO 100 (with step 5)	40
	LOW	-40 TO HIGH-5	-10
	SIGN	(HIGH+LOW)/2	15

The parameters in ARR menu			
Menu item		**selection**	**Default**
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 $VTAC_{count}-1$ (with step 1)	>=3
	AIVR	-	>=3
	FREQUENT PVCs	1 to 15 (with step 5)	>=10
ARCHIVE	ASYSTOLE	STR, STR/REC, OFF, REC	STR
	VFIB	STR, STR/REC, OFF, REC	STR
	VTAC	STR, STR/REC, OFF, REC	STR
	RUN	STR, STR/REC, OFF, REC	STR
	AIVR	STR, STR/REC, OFF, REC	STR
	COUPLET	STR, STR/REC, OFF, REC	STR
	BIGEMINY	STR, STR/REC, OFF, REC	STR
	TRIGEMINY	STR, STR/REC, OFF, REC	STR
	TACHY	STR, STR/REC, OFF, REC	OFF
	BRADY	STR, STR/REC, OFF, REC	OFF
	AFIB	STR, STR/REC, OFF, REC	STR
	PAUS	STR, STR/REC, OFF, REC	OFF
	FREQUENT PVCs	-	-

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

The Parameters in GAS WINDOW(Mainstream & Sidestream)			
Menu item	**selection**		
CO2 UNIT	KPa ,%V ,mmHg		mmHg
SIGNAL SWEEP	3mm/s, 6mm/s, 12.5mm/s, 25mm/s		12.5mm/s
SIGNAL SCALE	**CO2**	6%,10%,Auto scale	10%
	O2/N2O	0-50%,0-100%, Auto scale	100%
	AA	1,2,3,5,10,20%, Auto scale	20%
WAVEFORM (Mainstream)	CO2, N2O, AA		CO2
WAVEFORM	CO2, O2, N2O, AA		CO2

(Sidestream)			
O2 COMPENSATE	1-100 vol%, OFF	21% , AUTO	
N2O COMPENSATE	0-100 vol% (ONLY FOR ISA CO2, IRMA2 CO2)	0%	
GAS UNIT	KPa ,%V	%V	
AGENT	ISO,ENF,HAL,DES,SEV	HAL AUTO (For IRMA(AX+) & ISA(OR+) & ISA(AX+))	
WORK MODE	MEASURE, STANDBY	MEASURE	
GAS/RESP	GAS, RESP	GAS	
FIIL SIGNAL	ON,OFF	OFF	
CO2 ALARM	ON,OFF	OFF	
N2O ALARM	ON,OFF	OFF	
AA ALARM	ON,OFF	OFF	
O2 ALARM	ON,OFF	OFF	
ALARM LEVEL	1,2	2	
APNEA ALARM	20s,25s,30s,35s,40s,45s,50s, 55s,60s, OFF	20s	
		ADULT/PED	NEONATE
AWRR LOW	1~(HIGH-1)	5 BrPM	15 BrPM
AWRR HIGH	(LOW+1) ~120	30 BrPM	60 BrPM
EtCo2 LOW	0.4~(HIGH-0.1) (%V)	2.6%V	
EtCo2 HIGH	(LOW+0.1)~13(%V)	6.5%V	
FiCo2 HIGH	0.4~ 13(%V)	1.3%V	
EtO2,FiO2 LOW (sidestream)	18~(HIGH-1) (%V)	50%	
EtO2,FiO2 HIGH (sidestream)	(LOW+1)~105(%V)	100%	
EtN2O ,FiN2O LOW	1~(HIGH-1) (%V)	35%	
EtN2O HIGH	(LOW+1)~100(%V)	75%	
FiN2O HIGH	(LOW+1)~82(%V)	75%	
EtDES ,FiDES LOW	0.1~(HIGH-0.1) (%V)	5%	
EtDES ,FiDES HIGH	(LOW+0.1)~18(%V)	10%	
EtISO ,FiISO LOW	0.1~(HIGH-0.1) (%V)	0.8%	
EtISO ,FiISO HIGH	(LOW+0.1)~5(%V)	2%	
EtENF ,FiENF LOW	0.1~(HIGH-0.1) (%V)	0.5%	
EtENF ,FiENF HIGH	(LOW+0.1)~5(%V)	1.5%	
EtSEV ,FiSEV LOW	0.1~(HIGH-0.1) (%V)	1%	
EtSEV ,FiSEV HIGH	(LOW+0.1)~8(%V)	3%	
EtHAL ,FiHAL LOW	0.1~(HIGH-0.1) (%V)	0.5%	
EtHAL ,FiHAL HIGH	(LOW+0.1)~5(%V)	1.5%	
ZERO	Only for Mainstream		

The Parameters in BFA WINDOW		
Menu item	**selection**	**Default**
EEG Gain	25uV,50-250uV	100uV
BFA ALARM	ON,OFF	OFF
BFI LOW	1~(HIGH-1)	35%
BFI HIGH	(LOW+1)~100	60%

The Parameters in Cardiac Output WINDOW		
Catheter Type	131HF7,139HF75P,Simulator	131HF7
Temp_Scale	1,2,4	1
SYSTEM DEFUALT		
ALARM VOLUME	1,2,3,4,5,6,7	1
CALENDAR	SOLAR, CHRISTIAN	CHRISTIAN
PATIENT CAT.	ADUL,NEONATE,PEDIATRIC	ADULT
BED NUMBER	1..150	01
TOUCH SOUND	1, 2, 3, OFF	1
BACK LIGHT	1 to 8	18.5” Monitor: 7
	1 to 6	12” Monitor: 5
		10” Monitor: 3
		15” Monitor: 2
BED TO BED	DURATION :1,2,3,4,5	1 Min
Module Color		
ECG COLOR	Green	GREEN
IBP1 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	LIGHT RED
IBP2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	LIGHT BLUE
IBP3 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	DARK ORANGE
IBP4 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	DARK CYAN
SpO2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	MAGENTA

CO2 COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	YELLOW
RESP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	YELLOW
NIBP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	WHITE
TEMP COLOR	White, Blue, Brown, Green, Red, Yellow, Cyan, Orange, Cream, Magenta, Light Brown, Light Green, Light Yellow, Light Red, Light Blue, Light Cyan, Light Orange, Light Magenta, Dark Orange, Dark Cyan	CYAN

9) Troubleshooting

General Information

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

Troubleshooting guide is intended to help users to solve minor problems caused by incorrect use of the monitor or failure of accessories.

When you face any problem, please be sure that you have followed all procedure mentioned in Correct Action column before you contact with After Sale Service.

System		
Fault Symptoms	**Possible Cause**	**Correct Action**
The monitor does not turn on		●Check POWER AC path. ●Call for service.
The monitor is unable to run on battery	●Battery is discharged. ●The battery fuse is faulty. ●etc.	●Charge the battery according to the specified charge time in the Technical Specification Chapter. ●Check fuse existence ●Call for service
ECG		
Fault Symptoms	**Possible Cause**	**Correct Action**
NO ECG waveform	●ECG cable is not connected correctly. ● ECG cable is faulty. ●Improper placement of leads and electrodes. ●etc.	●Connect ECG cable correctly ●Check leads and electrodes. ● Short-circuit all the leads, if the cable is perfect, no error message will be displayed. ●Don't use old and faulty electrodes ●Call for service
Noisy ECG waveform	●Loose connection of electrodes ●Earth connection failure ●Wrong ECG filter ●etc.	●Check electrodes and leads. ● Check applied gel on the chest lead or change the chest lead, if necessary. ●Check the earth. ●Set filter mode correctly ●Call for service
Spike on ECG waveform	●If "PACE: ON" is selected for patient without Pace marker, ECG signal will be received as PACE. ●etc.	●Turn OFF "Pace detection" in ECG menu.
Unstable HR	●ECG signal is noisy or isn't suitable ●etc.	●Check leads and electrodes. ●Change lead to display the best ECG signal. ●Call for service
RESP		
No "RESP" signal No good waveform Unstable RR	●Electrodes are not connected correctly. ●Patient moves during the measurement. ●etc.	●Check leads and electrodes. ●change RESP lead. ●Calm patient.

		●Call for service.
RESP APNEA	No respiration is detected for a specific time.	● Call the Customer service department.
TEMP		
Fault Symptoms	**Possible Cause**	**Correct Action**
Invalid T1/T2 value	●Location of the sensor isn't suitable. ●Faulty sensor. ●etc.	●Put the sensor in suitable position. ●Change the sensor. ●Call for service
SpO2		
Measurement failure	AC noise interferes with the signal.	● Set AC frequency through the below window (Chapter 2, Setting): HOME/MODULE SETUP/MASIMO VERSION WINDOW
	Inappropriate size of sensor	● Use appropriate sensor regarding patient weight and intended use.
	High ambient light sources	● Reduce ambient light.
Reading does not match clinical evaluation results or blood test	Low arterial perfusion or incorrect probe connection	● Check the relevant alarm message. ● Make sure that the sensor has not been connected too tight. ● Set Sensitivity on MAX and make sure that the sensor has been connected correctly to the patient. Refer to operating instructions of the sensor for correct usage.
Measurement results are in doubt	Low perfusion or low signal amplitude	● Place the sensor in a better perfused monitoring site. ● Place the sensor in three different sites and check measurement accuracy in these sites. ● Record the blood test results to make a comparison with the sensor readings.
	Inappropriate sensor size or incorrect sensor placement	● Check that the sensor has been selected correctly. Check that the sensor has been placed in appropriate site.
SpCO value is displayed blank.	SpO2 value is lower than 90%	● Evaluate the patient status.
	SpMet value is more than 2%	● Perform laboratory analysis of the blood sample.
	SpCO value is unstable.	● Use appropriate sensor regarding patient weight and intended use. ● Wait until the parameter value becomes stable.
No SpO2 waveform Noisy SpO2 waveform	● The SpO2 probe in an unsuitable place. ●Faulty sensor ●etc.	●Change the place of probe on patient ●Change the probe and check the waveform. Contact the manufacturer to replace the probe with a new one, if necessary. ●Call for service.

Invalid SpO2 value	●Patient movement during measurement ●Inappropriate placement of the probe. ●etc	●Calm the patient ●Change the place of the probe. ●Call for service.
Fault Symptoms	**Possible Cause**	**Correct Action**
NIBP		
Sometimes the monitor reinflate the cuff.	● The initial inflation pressure in the first measurement is 150 mmHg in adult mode. In the next measurements, inflation continues to 30 mmHg higher than the last successful measurement. If the first measurement is more than 150 mmHg or more than 30 mmHg in the next measurements, the monitor will reinflate the cuff. ● Patient movement during the measurement ● inappropriate cuff size ● Airway leakage ● Incorrect connection of air tubing to the rectus ● The monitor failure	● In case of changing the patient, be sure to select the module reset option in the settings window. ● Check connections. ● Check air tubing. ● Select appropriate cuff size. ● Check the patient status. Prevent the patient movement. ● Call for service.
NIBP START button does not function.	● The Start button is pressed immediately after turning on the monitor. ● The Start button is faulty. ● The battery charge is too low and the monitor is not plugged in.	● Turn the monitor off and on. Wait a minute until the monitor starts up. Now try the button function again. ● Open NIBP menu and click on MODULE START to check function of the NIBP Start button. ● Plug in the monitor. ● Call for service.
The module is not able to measure the blood pressure and ? appears on the screen.	● Inappropriate measurement mode. ● Improper cuff size ● Patient movement ● Some diseases such as cardiac arrhythmia cause conflict in patient pulses and consequently could result in measurement failure.	● Make sure that correct mode has been selected for the patient. For example, if neonate mode is selected for adult or pediatric patient, the module might not be able to measure. ● If the cuff size is not selected correctly, the module might not be able to measure. For example, if the selected cuff is larger than proper size, the patient's pulse becomes weak and the measurement failure occurs. ● Remain the patient calm and relaxed during the measurement and make sure that the patient does not talk or laugh. Any movement could affect the measurement accuracy and lead to measurement failure. ● Check the patient status. ● Call for service.
NIBP module low accuracy	● Incompatibility between the number measured by the monitor and the pressure set by the simulator ● Incompatibility of pressure measured by NIBP and pressure measured by IBP ● Inconsistency of the pressure measured by NIBP and the pressure measured by the doctor	● The simulator is not a suitable reference for evaluating the accuracy of the blood pressure monitor. Use alternative methods such as IBP or auscultatory to assess accuracy. ● The accuracy of blood pressure measurement in the IBP method depends on settings such as ZEROING, use of appropriate accessories, IBP calibration and catheter level. First, make sure the IBP settings are correct. ●The monitor may be out of calibration and needs calibration. Call after sales services for the module calibration.
IBP		

Fault Symptoms	Possible Cause	Correct Action
Invalid IBP value Noisy IBP signal	●No zeroing before use. ●Existence of air bubbles in tubing system or the transducer dome. ●Noisy source exists nearby the system or accessories ●Faulty sensor ●etc	●Perform zeroing ●Keep the system and cable away from noise source. ● Check that proper label with regard to place of measurement is selected. ● Wash up the tubing system and dome. ● Change the dome. ●Change the sensor. ●Call for service
C.O (Cardiac Output)		
After the catheter is inserted into the patient body, the message "ready for measurement" does not appear and the message "Noisy baseline" remains on the screen.	●The catheter is not placed in proper position. ●There is other noise source, for example Electrocautery.	● Make sure that the catheter is inserted properly. ●Turn off the device caused noise and then use C.O measuring module.
Inaccurate C.O value	● The manufacturer recommended accessories are not used. ● Catheter type is not selected properly in C.O Setup menu. ● Injectate solution temperature is not zero (the range of -5 to 5 0 °C)	● Use the manufacturer recommended accessories. ● Select the catheter type correctly in Setup menu. Make sure that the temperature of injectate solution is zero.
CO2 No Adapter/Sampling line	The sampling adapter/hose is not connected to the system.	• Connect the adapter/hose to the system. • Call for service.
SAMPLING LINE IS CLOGGED	Occlusion in sampling hose.	●Change the hose. ●Call for service
MULTIGAS		
Fault Symptoms	**Possible Cause**	**Corrective Action**
Problem in CO2 measurement	● Adaptor failure ●No zeroing before measurement.	●Replace adapter for each patient. ●Perform zeroing procedure according to instructions of this manual. ●If the problem is not resolved, contact after sale service of the manufacturer.

BFA		
BFA module does not turn on when it is connected to the monitor		● Check interface cable between the module and the monitor. ● Check proper attachment of neuro sensors. Clean the skin before attaching the sensor or use a new sensor, if necessary ● If the problem persists, contact after sale service of the manufacturer.
BFI is higher than expected range		● Check anesthetic delivery systems: IV lines and status of vaporizers. ● Some patients require more doses of drug to reach intended level of anesthesia. ● Drug dosage is not sufficient for Maintenance phase, so BFI increases during painful stimulations.
BFI rises along with EMG	●High levels of facial muscular or electromyographic (EMG) activity ●Attention must be paid to reactions of patient against the stimuli during surgery. ●When the patient is asleep, EMG activity may increase due to reactions to painful stimuli during surgery. ●Lack of muscular relaxation or muscular rigidity caused by some opioids (analgesics).	●In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent may decrease BFI.
Central		
Fault Symptoms	**Possible Cause**	**Corrective Action**
Problem in function of different parts of the central system such as touch screen, recorder and etc		●Turn off and on the system. ●If the problem is not resolved, contact after sale services.
No connection is made with the central system.	●Check proper connection of the cable between the central and bedside monitor.	●If the problem persists, contact after sale services.

Some advices to reduce measurement errors

NIBP

When NIBP measurement is made, it is an important factor to set the measurement unit on mmHg and connect the pressure cuff to the patient properly and according to instructions of this manual.

The most likely reason that the system doesn't display NIBP value is cuff failure or leakage, therefore when dealing with this problem, use an intact cuff to test the system and check air hose connection and other connections. If the problem is not removed, contact the manufacturer's customer service.

Note

- Adjust the system measuring mode (Adult, Pediatric and Neonate) and choose a proper size of cuff with regard to patient weight and age for NIBP measurement.
- It is recommended to reset the module after replacing each patient...
- Deflate the cuff completely by hand.
- It is recommended to take the pressure, the patient should sit in a comfortable position and the patient's legs should not be placed on the support. The back and arm of the patient should have proper support. Before taking the pressure, the patient should rest for 5 minutes. Remain quiet during measurement.
- Attach the cuff to patient arm and keep the arm in same level with the patient heart.
- The cuff should be placed on upper arm.
- The cuff should be properly closed and there should be enough space to place two fingers between the cuff and the patient's arm (for adults).
- Align the cuff and artery properly.
- Remove any tight fitting clothing before taking measurement.
- Apply proper size of cuff for the patient.
  - Too small size of the cuff results in too high pressure values.
  - Too large size of the cuff results in too low pressure values.

IBP

A very important point in the IBP parameter is the absence of bubbles in the path and also the DOME, check this matter first. In addition, in many cases, the problem is solved by replacing the DOME. It should be noted that, as you know, the DOME is disposable and must be replaced for every patient. It is also effective to choose the right label according to the area of vein detection. Please check this parameter as well. If the problem is not resolved, replace the device's transducer. (if available) If the problem is not resolved by checking all the above items, contact the after-sales service.

CO2

If there is a problem with the display of CO2 or anesthetic gases, the most important factor is the adapter, which must be replaced for each patient. If the problem is not solved after replacing the adapter, inform the company. In addition, zeroing is very important in the measurement accuracy. Please do zeroing according to the instructions of the manual so that the displayed number is accurate.

Appendix 1: Electro-Magnetic Compliance

Warning

- Use only the recommended manufacturer accessory. Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that the bedside monitor is used in the electromagnetic environment specified.
- To prevent EMC effect on the monitor, the system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the monitor performance.

PM4010 patient monitoring system

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, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	The **PM4010** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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 interruptions and voltage vPM4010tions on power supply input lines	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles	Complies	Mains power quality should be 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.

	<5% UT (>95% dip in UT) for 5 sec		
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** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 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.