DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

CE 0483

DIXION

Patient Monitors

Storm DS7

Storm DS5

Storm DS3

User Manual

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Product Information

- Product Model: STORM DS3/STORM DS5/STORM DS7
- Product Name: Patient monitor
- Manufacturer Name: DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH
- After Service Contact Information:

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This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

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CE mark

Statement

Manufacturer holds the copyright of this manual, and we are also entitled to deal with this manual as confidential files. This manual is only used for operation, maintenance and service of product, someone else can not publish the manual.

This manual contains exclusive information protected by copyright laws and we reserve its copyright. Without written approval of manufacturer no parts of this manual shall be photocopied, Xeroxed or translated into other languages.

The contents contained in this manual are subject to amendments without notification.

Manufacturer's Responsibility

Only under the following circumstances will manufacturer be responsible for the safety, reliability and performance of the instrument:

All the installation, expansion, readjustment, renovation or repairs are conducted by the personnel certified by manufacturer.

The storage condition, operation condition and electrical status of the instrument conform to the product specification.

The instrument is used in accordance with the user’s manual.

About this manual

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question,

please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

The manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practiced and terminology as required for monitoring patients.

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your product.

Conventions:

Bold Italic text is used in this manual to quote the referenced chapter or sections.

【】is used to enclose screen texts.

→ is used to indicate operational procedures.

Signs in this manual：

Warning: Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.

Caution: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

Note: Provides application tips or other useful information to ensure that you get the most from your product.

Contents

Chapter 1 General Introduction

1.1 Intended Use

The monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including ECG, Heart Rate (HR), Respiration Rate (RR), Temperature(Temp), Pulse Oxygen Saturation(SpO_2), Pulse Rate(PR), Carbon dioxide(CO_2), Anesthetic Gas(AG), Non-invasive Blood Pressure(NIBP), Invasive Blood Pressure(IBP), Cardiac output (C.O.) , TotalHemoglobin(SpHb),Carboxyhemoglobin(SpCO),Methemoglobin(SpMet).

Cardiac output(C.O.)monitoring are for adults only.

The following functions are not applicable to neonates: ST segment monitoring, Total Hemoglobin (SpHb), Carboxyhemoglobin (SpCO), and Methemoglobin (SpMet).

Warning: The monitor is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operations on it.

1.2 Contraindications

- **When conducting defibrillation, it is imperative to only use the ECG electrodes and ECG cables specified by manufacturer.**
- **To avoid burning, when the electrotome operation is performed, the electrodes should be placed near the middle between ESU grounding pad and electrotome and the electrotome should be applied as far as possible from all other electrodes, a distance of at least 15 cm/6 in is recommended.**
- **When using the ESU device, avoid placing the electrodes near**

the ESU grounding pad, otherwise, grate deal interference will influence the ECG signals. The monitor should be placed far from the operating table. Power wires and the ECG cables should be partitioned and should not be in parallel.

- **The measurement of Resp is not applicable for patient with excessive motion, otherwise it may cause the mistake of Resp alarm.**
- **Do not use the monitor and the SpO2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.**
- **Do not use the SpO2 sensor on a limb where the NIBP cuff is applied. This may result in inaccurate SpO2 reading due to blocked blood flow during cuff inflation.**
- **Do not conduct SpO2 measurement on the finger smeared with nail polish, otherwise unreliable measurement results might be produced.**
- **The following factors may influence the accuracy of measurements:**
  - **——Incorrect sensor application or use;**
  - **——Significant levels of dysfunctional hemoglobins.(such as carboxyhemoglobin or methemoglobin);**
  - **——Intravascular dyes such as indocyanine green or methylene blue;**
  - **——Exposure to excessive illumination,**
  - **——Excessive patient movement;**
  - **——Low perfusion;**
  - **——Electromagnetic interference, such as MRI device;**
  - **——Electrosurgical units.**
  - **——The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;**
- **Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.**
- **Use clinical judgement to decide whether to perform frequent Auto BP measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**

- **Use clinical judgement to decide whether to perform Auto BP measurement on the patients of thrombasthemia.**
- **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 cuff inflation.**
- **NIBP measurements are impossible with heart rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.**

  The measurement may be inaccurate or impossible:

  ——with excessive and continuous patient movement such as shivering or convulsions;

  ——if a regular arterial pressure pulse is hard to detect;

  ——with cardiac arrhythmias;

  ——with rapid blood pressure changes;

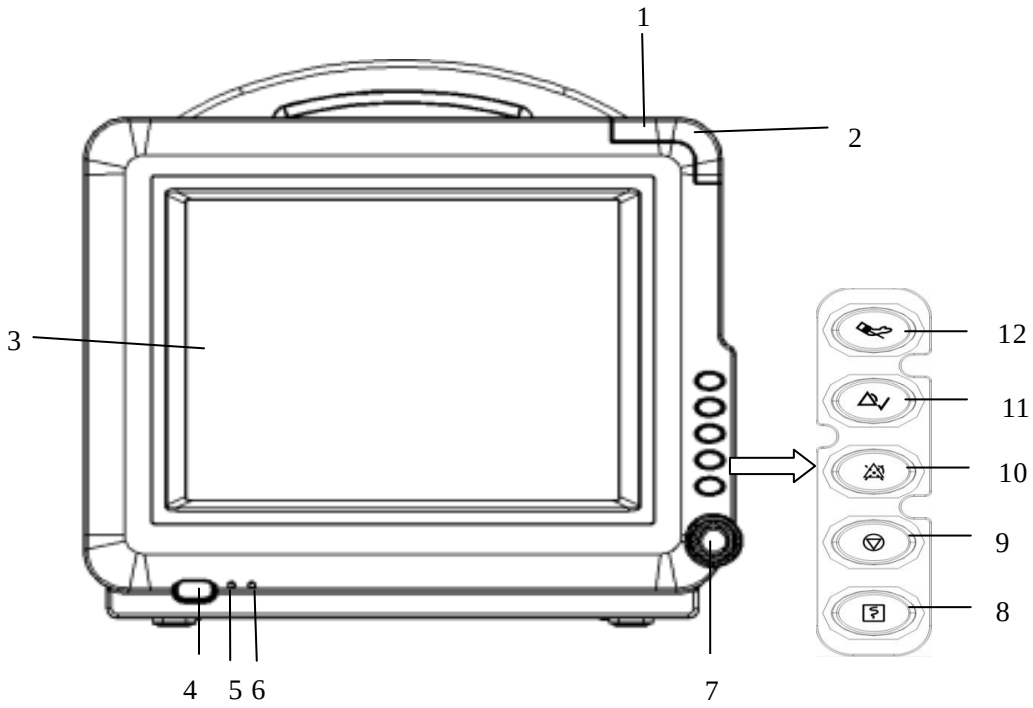
  ——with severe shock or hypothermia that reduces blood flow to the peripheries;

  ——on a edematous extremity.
- **Do not use device on patients that can not tolerate the withdrawal of 50 ml/min±10 ml/min from the airway or patients that can not tolerate the added dead space to the airway.**
- **The sidestream AG module must not be used with flammable anesthetic agents.**
- **Operating high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.**

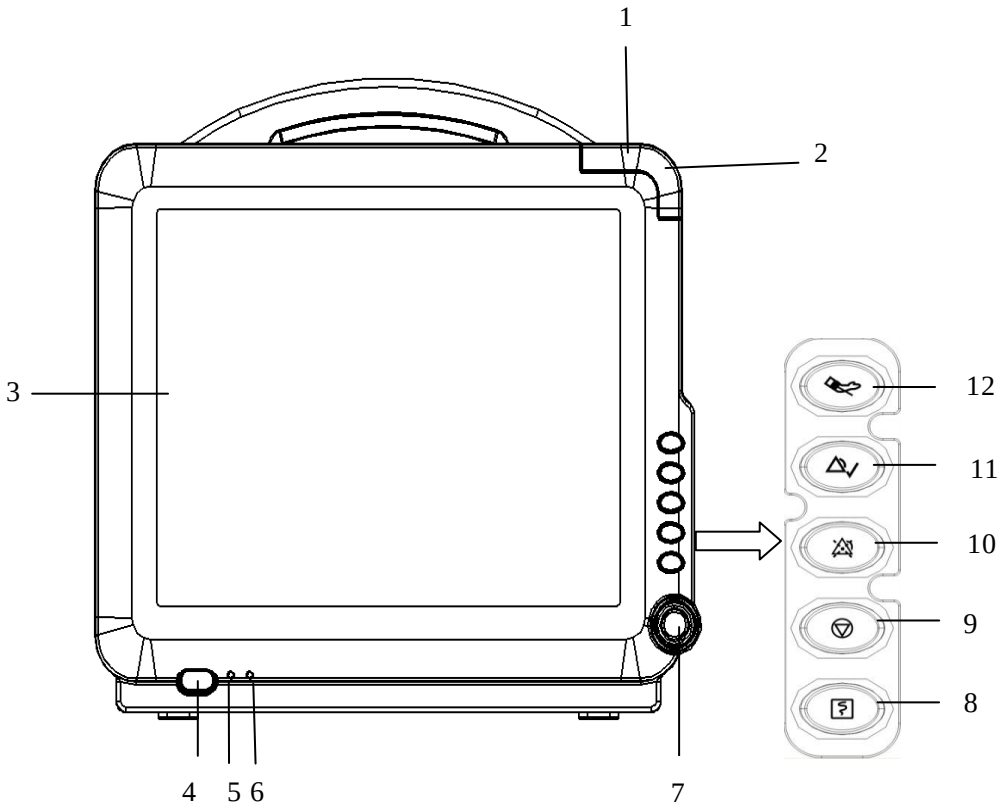
1.3 Main Unit

1.3.1 Front View

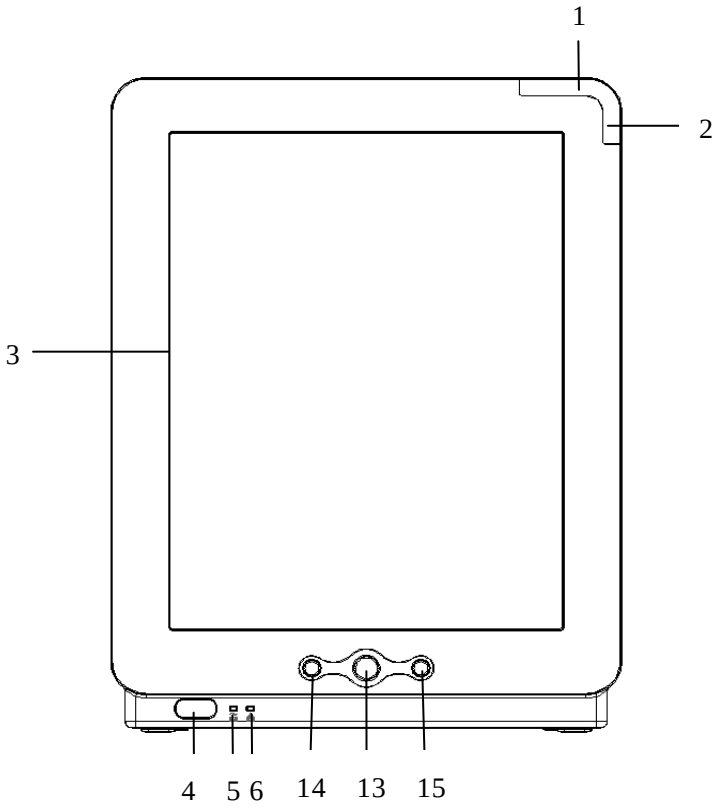
◆ **STORM DS3** Patient monitor:



◆ **STORM DS5** Patient monitor:



◆ **STORM DS7** Patient monitor:



1. Alarm indicating lamp

When a physiological alarm occurs, this lamp will light up as defined below:

- ◆ High level alarm: the lamp quickly flashes red.
- ◆ Medium level alarm: the lamp slowly flashes yellow.
- ◆ Low level alarm: the lamp lights yellow without flashing.

When a technical alarm occurs, this lamp will light up as defined below:

- ◆ High level alarm: the lamp quickly flashes red.
- ◆ Medium level alarm: the lamp slowly flashes yellow

2. Low technical alarm indicating lamp

When a technical alarm occurs, and the technical alarm level is low, this lamp will light cyan without flashing.

3. Display screen

4. Ö/⊙ Power button

5. Power indicating lamp

It is a LED that lights green and orange, the status of the LED is specified as follows:

- ◆ Green: When the AC mains is connected.
- ◆ Orange: When the AC mains is not connected and monitor is powered by battery.
- ◆ Off: When the AC mains is not connected.

6. Battery charging indicating lamp

- ◆ Light up: When the battery is being charged.
- ◆ Off: When the battery is fully charged or no battery in monitor.

7. Trim Knob

The Trim Knob is used for:

- ◆ Turn left or turn right to move the cursor.
- ◆ Press down to perform an operation, such as open a menu dialog or select one option.

8.  Press this button to start or stop recording.

9.  Press this button to freeze or defreeze waveform.

10.  Press this button to pause or reactive the alarms.

11.  Press this button to reset all the alarms.This switches off the audible alarm indicators. (Details refer to ***Alarm*** chapter)

12.  Press this button to start or stop NIBP measurement.

13.  Confirm button:Press this button to confirm the current operation

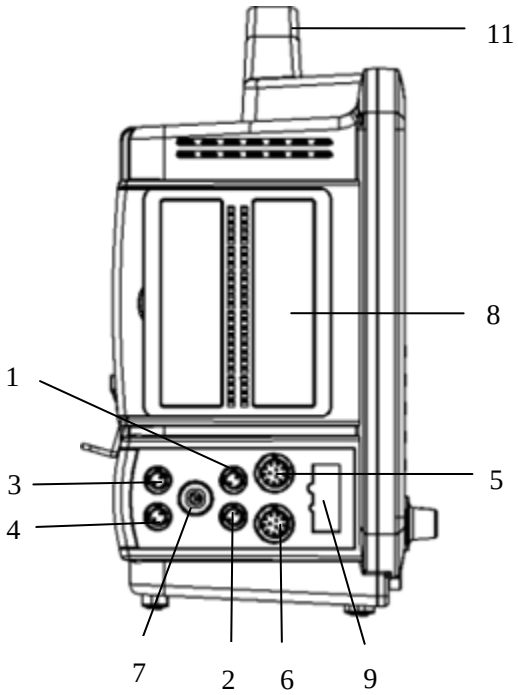
14.  Press this button to move the cursor left.

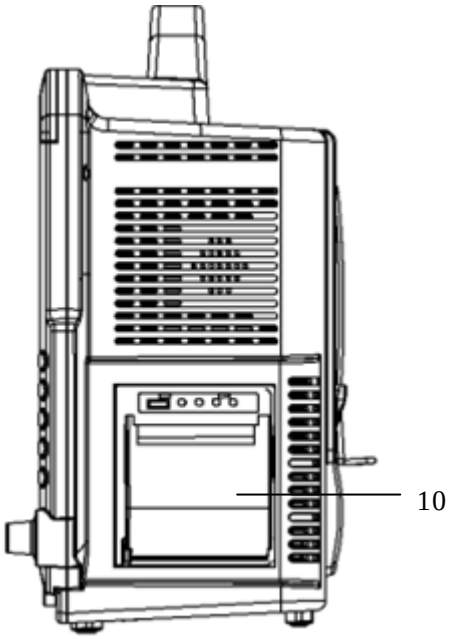
15. > Press this button to move the cursor right.

1.3.2 Side View

◆ **STORM DS3/ STORM DS5** Patient monitor:

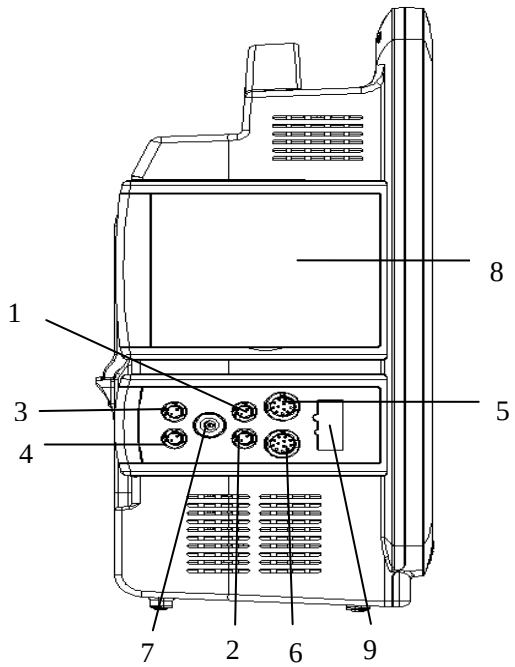
Left side: Right side:

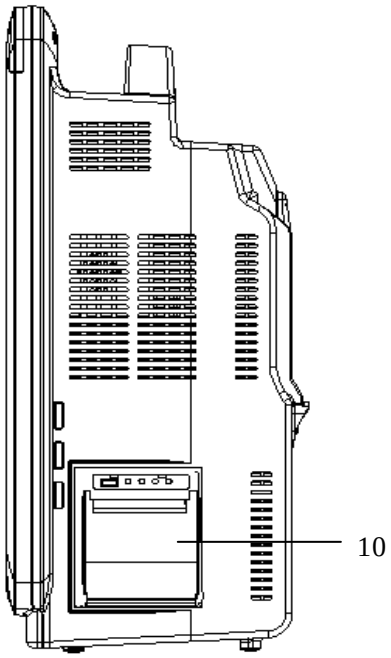




◆ **/STORM DS7** Patient monitor:

Left side: Right side:



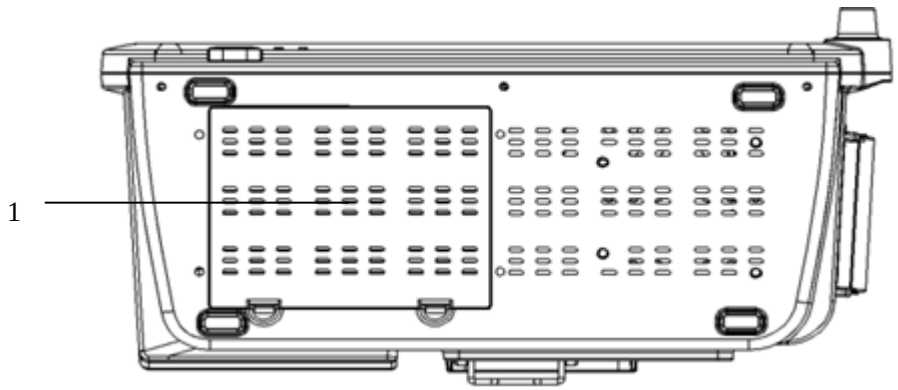


1.TEMP1 connector
2. TEMP2 connector
3.IBP1 connector
4. IBP2 connector
5.SpO_2 connector (BLT)
6. ECG connector
7.NIBP connector
8. Module slots
9. SpO_2 connector（specially for Nellocor SpO_2）
10.Recorder
11. Handle

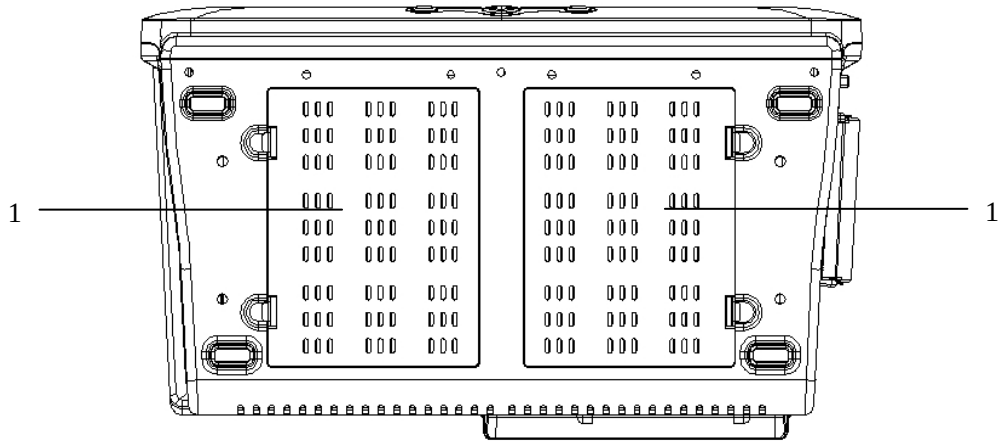
Caution: In order to prevent poor contact due to dust accumulated, please regularly clean the contact point according to actual application condition. Before cleaning, the monitor must be powered off. When cleaning, please wipe the point with medical cotton dipped into medicinal alcohol by use of a nipper.

1.3.3 Bottom View

◆ **STORM DS3/ STORM DS5** Patient monitor:



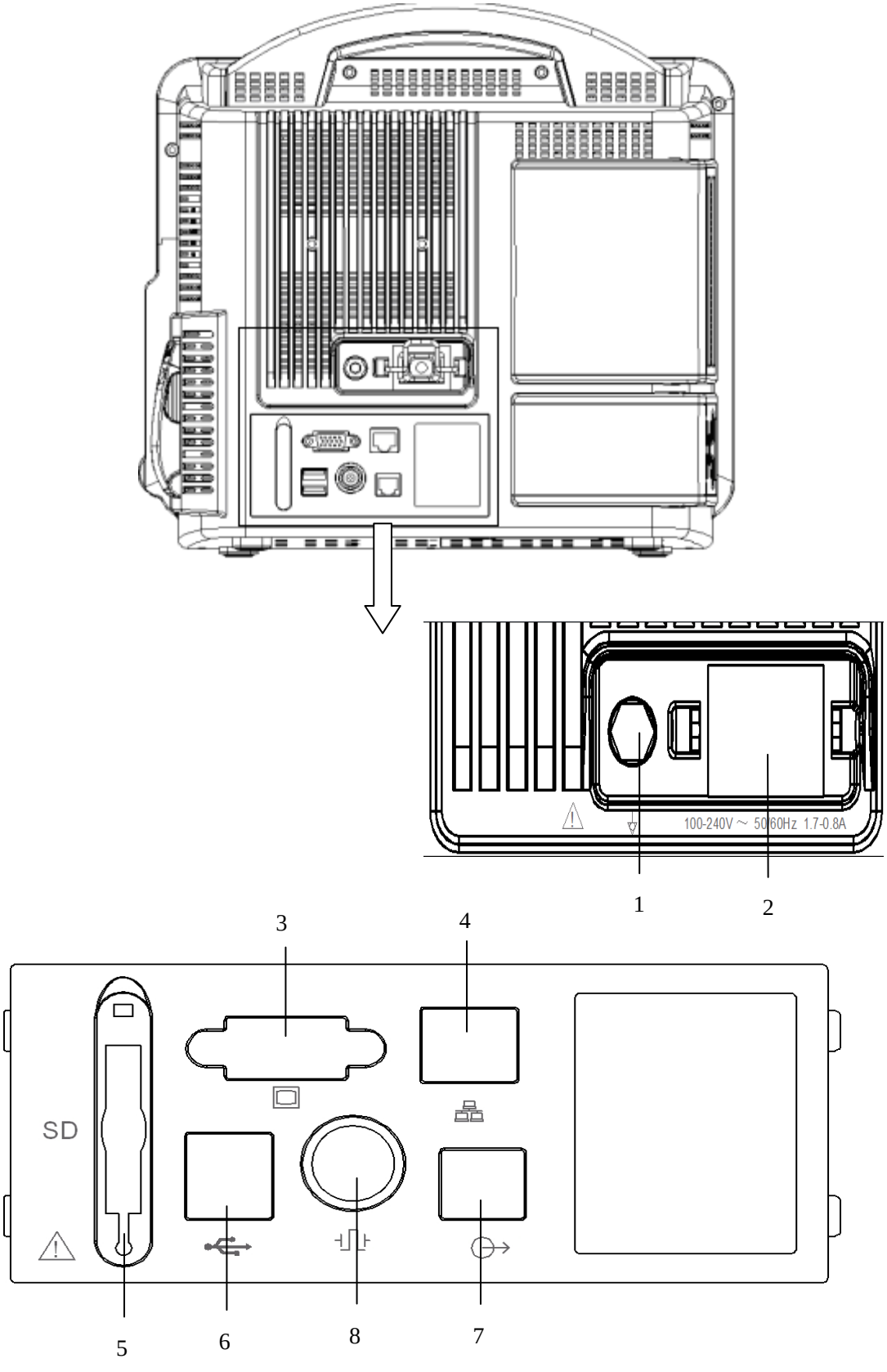
◆ **STORM DS7** Patient monitor:



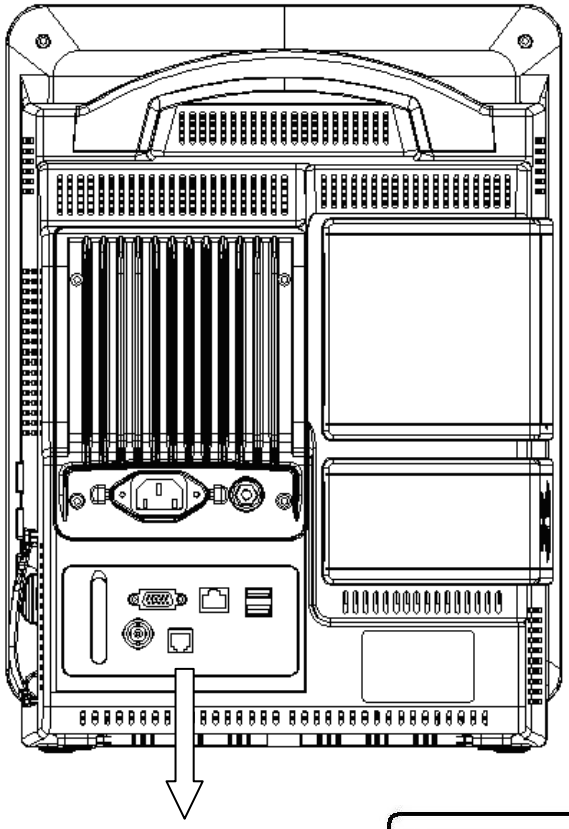
1. Battery compartment

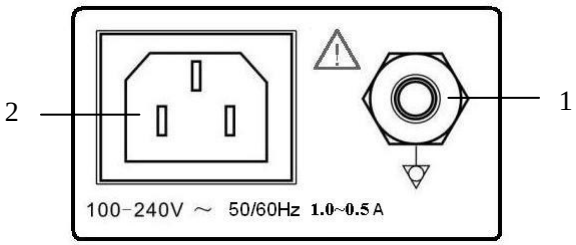
1.3.4 Rear View

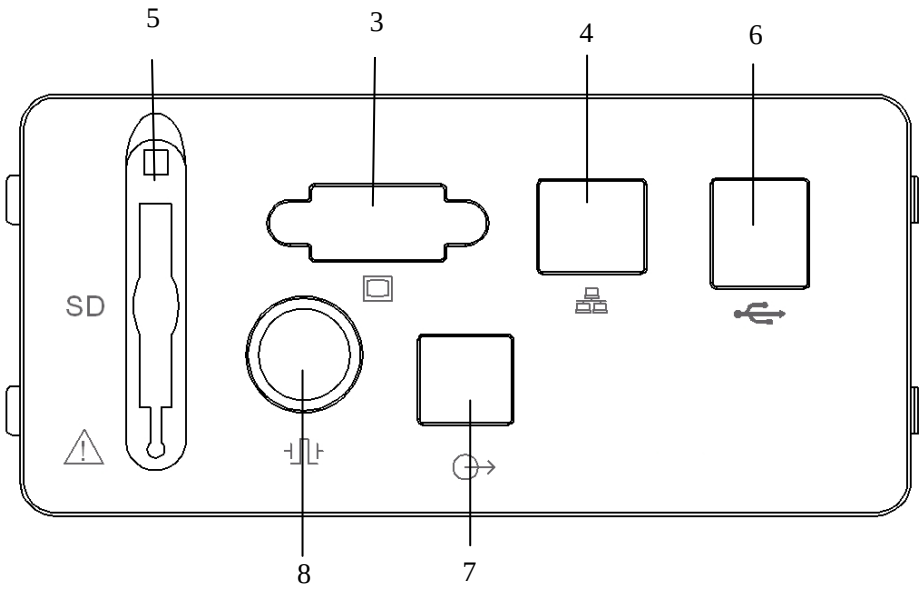
◆ **STORM DS3/ STORM DS5** Patient monitor:



◆ **STORM DS7** Patient monitor:







1. Equipotentiality terminal

Base on the requirements of safety and anti-interference, the monitor must be connected with equipotentiality system individual. When connected together, the various parts of an equipment or of a system will be brought to the same potential, not necessarily being the earth (ground) potential.

Connected method: Use the green/yellow equipotential grounding cable and connect it to the euipotentiality terminal of the monitor and the equipotential grounding system.

2. AC power input connector

3. VGA display connector

Connect to standard VGA display for secondary displaying.

4. Wired network connector

Standard RJ45 socket. It is used for connection with the central monitoring system provided by manufacturer.

5. SD Memory card slot

6. USB socket

Connect to USB device, such as mouse.

7. Nurse call connector

Connect to nurse call system in hospital. When an alarm occurs, outputting the nurse call signal to remind nurse.

8. Auxiliary output / Defibrillator synchronization connector

Connect to the device, such as oscillograph to output analog signals. It also can be connected to defibrillator for output defibrillator synchronization signal.

Caution: The VGA，USB and SD interface can only connected to the equipment with standard interface.

Warning:

- **Additional equipment connected to the medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.**
- **The operator could not touch these ports and the patient simultaneously.**

1.4 Measurement Modules

The monitor can support the following modules:

- IBP module: Invasive Blood Pressure module.
- Temp module: Temperature module.
- SpO_2 module: Nellcor SpO_2 module, Masimo SpO_2 module.
- CO_2 module: Mainstream CO_2 module, sidestream CO_2 module and LoFlo CO_2 module.
- AG module: Mainstream AG module and sidestream AG module.
- C.O. module: Cardiac output module.

  Under the condition of maximum configuration, the monitor is equipped with one 2-slot plug-in box box. Because different measurement modules occupy different amount of slots, hence the amount of plug-in modules on the monitor may vary.

1.4.1 Plug and unplug module

The monitor supports hot plug of all modules. That is, you can plug in or pull out a module when the power of the monitor has not been shut off.

◆ Plug in and pull out of modules

——Plug in module: make a module point to the position of the slot and push it into the slot until the buckle at bottom of the module clicks into place.

——Pull out module: lift up the buckle at bottom of the module, and pull out the module and remove it.

——After plugging in a module, please make sure whether the indicating lamp on the module lights up. If not, please pull out and plug in the module once more.

Note: If you want to replace the modules of the monitor, refer to the methods as Chapter 1.4.1. The measurement modules should be replaced by service personnel specified by manufacturer.

1.5 Equipment Symbols

Symbol	Symbol Note	Symbol	Symbol Note
	Attention: Consult accompanying documents (this manual).	**ECG**	Short for "Electrocardiogram"
	Dangerous voltage	**SpO_2**	Short for "Pulse Oxygen Saturation"
	Equipotentiality	**TEMP**	Short for "Temperature"
	Alternating current	**IBP**	Short for "Invasive Blood Pressure"
	Output	**NIBP**	Short for "Non-invasive Blood Pressure"
	VGA display connector	**CO_2**	Short for "Carbon dioxide"
	USB socket	**AG**	Short for "Anesthetic gas"

Symbol	Symbol Note	Symbol	Symbol Note
	Gas outlet	**C.O.**	Short for "Cardio Output"
	Gas inlet		Computer network
	Manufacture date		Defibrillator synchronization output connector
	Manufacturer		Auxiliary plug-in box connector
SN	Serial number	**IPX1**	Degree of protection against ingress of liquid
LOT	Batch code	REF	Catalog number
	Do not re-use		Use by date [YYYY-MM-DD]
	Temperature limitation		Pressure limitation
	Humidity limitation		Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.
CE 0483	CE mark		Refer to this user's manual.
Hospital Only	Symbol marked on a tag attached to the supply cord of the monitor to warn that the supply cord should be connected to the sockets which are Hospital Only to achieve grounding reliability.		
	Defibrillation-proof Type CF applied part		
	Defibrillation-proof Type BF applied part		

Symbol	Symbol Note	Symbol	Symbol Note
	Warnning：the protection against the effects of the discharge of a cardiac defibrillator is dependent upon the appropriated cable		

Chapter 2 Safety

2.1 Safety Information

Warning:

- **No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.**
- **Before putting the system into operation, verify that the monitor, connecting cables and accessories are in correct working order and operating condition.**
- **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth**
- **Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its intenral electrical power source**
- **To avoid explosion hazard, do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.**
- **Do not open the monitor housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by manufactureronly.**
- **When using the monitor with electrosurgical units (ESU), make sure the patient is safe.**
- **Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.**
- **Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**

- **The physiological data and alarm messages displayed on the monitor are for reference only and cannot be directly used for diagnostic interpretation.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patient or personnel.**

Caution：

- **To ensure patient safety, use only parts and accessories specified in this manual.**
- **At the end of its service life, the monitor, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the monitor, please contact us.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the monitor. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Before connecting the monitor to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the monitor's label or in this manual.**
- **Always install or carry the monitor properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
- **The American mains plug whose ground is in the same plug with its other two cords is Hospital Only. The supply cord should be connected to the sockets which are Hospital Only to achieve grounding reliability.**

Note:

- **Put the monitor in a location where you can easily see the screen and access the operating controls.**
- **Keep this manual in the vicinity of the monitor so that it can be obtained conveniently when needed.**
- **The software was developed in compliance with IEC 60601-1. The possibility of hazards arising from software errors is minimized.**
- **This manual describes all features and options. Your monitor may not have all of them.**

2.2 General Safety

Warning: The monitor is neither a therapeutic instrument nor a device that can be used at home.

1. Safety precautions for installation

- Connect the power cord to a properly earthing socket. Avoid putting the socket used for it in the same loop of such devices as the air conditioners, which regularly switch between on and off.
- Avoid putting the monitor in the locations where it easily shakes or wobbles.
- Enough space shall be left around the monitor so as to guarantee normal ventilation.
- Make sure the ambient temperature and humidity are stable and avoid the occurrence of condensation in the operation process of the monitor.

Warning: Never install the monitor in an environment where flammable anesthetic gas is present.

2. Monitor conforms to the safety requirements of IEC 60601-1. This monitor is protected against defibrillation effects.

3. Notes on symbols related to safety

Type BF applied part, defibrillation protected

The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.

Type CF applied part, defibrillation protected

The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.

The type CF applied parts provide a higher degree of protection against electric shock than that provided by type BF applied parts.

Warnning：The protection against the effects of the discharge of a cardiac defibrillator is dependent upon the appropriated cable

4. When a defibrillator is applied on a patient, the monitor may have transient disorders in the display of waveforms. If the electrodes are used and placed properly, the display of the monitor will be restored within 10s. During defibrillation, please note to remove the electrode of chest lead and move the electrode of limb lead to the side of the limb. The electrode of the defibrillator should not come into direct contact with the monitoring electrodes. Please ensure the monitor is reliably grounded and the electrodes used repeatedly should be kept clean.

Warning: When conducting defibrillation, do not come into contact with the patient, the bed and the monitor. Otherwise erious injury or death could be resulted in.

5. To guarantee the safe operation of the monitor, the monitor is provided with various replaceable parts, accessories and consuming materials (such as sensors and their cables, electrode pads). Please use the products provided or designated by the manufacturer.

6. Monitor only guarantees its safety and accuracy under the condition that it is connected to the devices provided or designated by manufacturer. If the monitor is connected to other undesignated

electrical equipment or devices, safety hazards may occur for causes such as the cumulating of the leakage current.

7. To guarantee the normal and safe operation of the monitor, a preventive check and maintenance should be conducted for the monitor and its parts every 6-12 months (including performance check and safety check) to verify the instrument can work in a safe and proper condition and it is safe to the medical personnel and the patient and has met the accuracy required by clinical use.

Caution: The monitor does not contain any parts for self-repair by users. The repair of the instrument must be conducted by the technical personnel authorized by manufacturer.

2.3 Important Notes for Safety

- **Patient Number**

The monitor can only be applied to one patient at one time.

- **Interference**

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

- **Protection against ingress of liquid**

To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered the device, take it out of service and have it checked by a service technician before it is used again.

- **Accuracy**

If the accuracy of any value displayed on the monitor or printed on a printout paper is questionable, determine the patient's vital signs by alternative means. Verify that the equipment is working correctly.

- **Alarm**

Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal

surveillance and correct operation of monitor.

The functions of the alarm system for monitoring the patient must be verified at regular intervals.

- **Before Use**

Before putting the system into operation, please visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately.

Before using the system, the operator must verify that it is in correct working order and operating condition.

Periodically, and whenever the integrity of the product is in doubt, test all functions.

- **Cables**

Route all cables away from patient's throat to avoid possible strangulation.

- **Disposal of package**

Dispose of the packaging materials, please observe the applicable waste control regulations and keeping it out of children's reach.

- **Explosion hazard**

Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.

- **Leakage current test**

When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.

- **Battery**

The device is equipped with a battery. The battery discharges even when the device is not in use. If you do not use the battery for a long time, store the device with a fully charged battery and take out the battery, so that the service life of the battery will not be shortened.

- **Disposal of accessories and device**

Disposable accessories are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

The service life of this monitor is 5 years. At the end of its service life,

the monitor, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact manufacturer or its representatives.

- **EMC**

Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason, make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Also, keep mobile phones or other telecommunication equipment away from the monitor.

- **Instruction for use**

For continuous safe use of the monitor, it is necessary that listed instructions were followed. However, instructions listed in this manual in no way can supersede established medical practices concerning patient care.

- **Loss of data**

Should the monitor at any time temporarily lose patient data, close patient observation or alternative monitoring devices should be used until monitor function is restored.

When the AC power supply has been interrupted of the monitor, the monitor can change to use the battery supply DC power.

When the monitor lost of power and has been powered off, if the monitor does not automatically resume operation within 60s, restart the monitor using the power switch. Once monitoring is restored, you should verify correct monitoring state and alarm function.

- **Intended for use in conjunction with other medical devices**

The monitor can be used together with high-frequency electrotomes and defibrillators.

2.4 Safe Operation Conditions

Methods of sterilization or disinfection recommended by the manufacturer	Sterilization: not applicable Disinfection: Refer to ***Maintenance and Cleaning*** Chapter
Electromagnetic interference	No mobile telephone nearby
Electrosurgical interference damage	No damage
Diathermy instruments influence	Displayed values and prints may be disturbed or erroneous during diathermy
Defibrillation shocks	The monitor specifications fulfill the requirements of IEC 60601-1, IEC 60601-2-27, IEC 60601-2-49, IEC 60601-2-34
Auxiliary outputs	The monitor must fulfill the requirements of standard IEC 60601-1
Applied parts	ECG electrode, ECG lead wires, SpO2 sensor, Temperature probe, NIBP cuff, IBP transducer(including catheter and fluid-filled system), CO_2 sampling tube, AG sampling tube, C.O. floating catheter.

Chapter 3 Basic Operations

3.1 Unpacking and Checking

1. Unpacking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier. If the packing case is intact, open the package.

2. Remove the monitor and accessories carefully.

3. Keep all the packaging materials for future use in transportation or storage.

4. Check the monitor and accessories

Check the monitor and its accessories one by one in accordance with the packing list. Check to see if the parts have any mechanical damages. In case of problems, please contact us or our agent.

Warning:

- **Keep the packing materials out of children's reach. Disposal of the packing materials should observer the applicable waste control regulations.**
- **The monitor might be contaminated during storage and transport. Before use, please verify whether the packages, especially the package of disposable accessories, are intact. In case of any damage, do not apply it to the patient.**

Caution: Please put a monitor onto a horizontal and stable supporting plane. Avoid putting the monitor in the locations where it easily shakes or wobbles. Enough space shall be left around the monitor so as to guarantee normal ventilation.

Warning: Please ensure the monitor is working under specified conditions; otherwise, the technical specifications

mentioned in this manual will not be met, thus possibly leading to damage of equipment and other unexpected results.

3.2 Getting Started

3.2.1 Inspecting the Monitor

1. Before you start to make measurements, carry out the following checks on the monitor including all connected modules.

——Check for any mechanical damage, including the power cables，lead wires and so on.

——Check for the oxide of the ports.

——Check for any incorrect connection of all the external cables and accessories.

2. Plug the power cord into the AC power source. If you are using battery power, ensure that the battery has sufficient power for monitoring. When you use a battery for the first time, you must charge it, following the instructions given in ***Battery*** chapter.

3. Press the power switch, check the physiology alarm lamp lights up in yellow, the technical alarm lamp will light up in cyan in turn, and goes out, afterwards the startup screen will display.

3.2.2 Starting the Monitor

1. Press the power switch, physiology alarm lamp lights up in red and yellow, the technical alarm lamp will light up in cyan in turn, and goes out, afterwards the startup screen will display.

2. After the startup screen disappears, the system clanks and enters main screen and meanwhile the technical alarm lamp goes out.

Warning: If the monitor is mechanically damaged, or if it is not orking properly, do not use it for any monitoring procedure on a patient. Contact your service personnel.

Caution:

- **The monitor does not have mains switch. The monitor is switched completely only by unplugging the power cable from the AC power source.**
- **For measurements in or near the heart we recommend connecting the monitor to the equipotential grounding system. Use the green/yellow equipotential grounding cable and connect it to the terminal labeled with the ⏚ symbol.**

Warning: Mains plug is intended to be used as isolation device from the supply mains. Please always make mains plug easily to operate.

3.3 Starting Monitoring

1. Decide what parameters should be monitored or measured.
2. Install required modules or sensors.
3. Check whether the installation of modules or sensors is correct.
4. Check whether all kinds of settings are correct.
5. Start monitoring on a patient. Detailed information refers to the related chapters.

3.4 Shutting off the Monitor

Please follow the below steps to shut off the monitor:

1. Confirm that the patient monitoring is finished.
2. Disconnect the cables and sensors form the monitor.
3. Confirm that the monitoring data is stored or cleared.
4. Press the power switch, then pop up the dialog box'Do you want to shutdown the machine?', click【**Yes**】to turn off the monitor. If the monitor can't be switched off normally, forced close the monitor by pressing and holding the power switch for more than 5s. This may cause some damages to the device.

3.5 Standby Mode

Standby mode can be used when you want to temporarily interrupt monitoring.

◆ To enter standby mode:

Select【**Main Menu**】smartkey→【**Standby**】, then select【**Yes**】to enter the standby mode. Under standby mode, the monitor will suspend alarm for patient, and all waves and numerics will disappear but all the settings and patient data will be retained.

◆ To resume monitoring:

Press any intelligent smartkey on the screen or trim knob, and you can exit standby mode and resume monitoring.

Note: Press any smartkey on the screen or trim knob, and the monitor will exit standby mode.

3.6 Networked Monitoring

If the user intends to connect the monitor to the central monitoring system, there are two ways for connection:

1) Plug its connecting electrical cable into the network connector at the back of the monitor.
2) Connect the central monitoring system by WIFI.

Note: This monitor can only be connected to the central monitoring system provided by manufacturer, do not attempt to connect this monitor to other central monitoring system.

3.7 Operation Mode

Press the power switch after the monitor connecting to the power supply and the monitor will switch on in the "monitor mode".

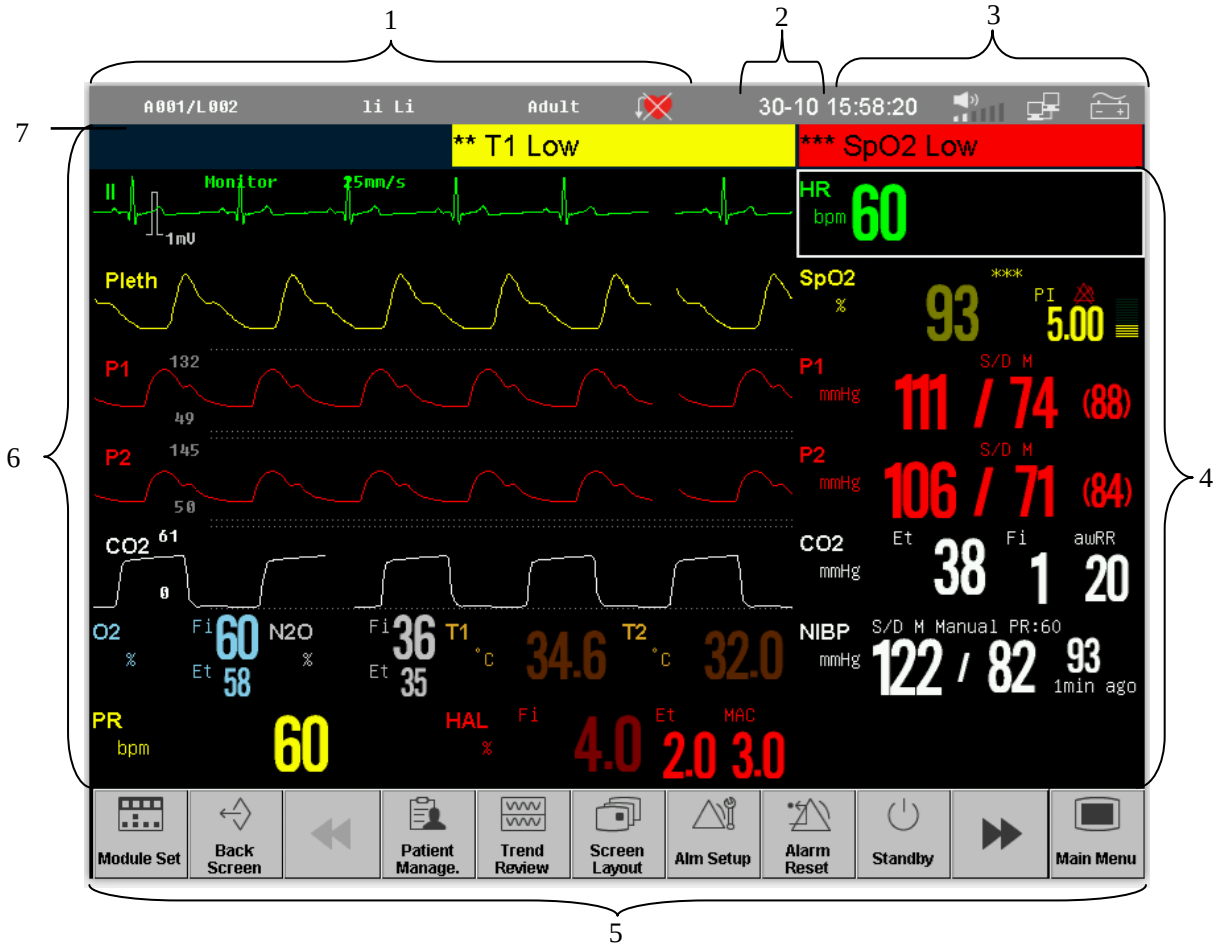
If you want to change the operation mode, you can select【**Main Menu**】smartkey→【**Work Mode**】. Then select the operation mode you need.

There are four kinds of operation mode for this monitor:

- Monitor Mode (Monitor): The normally operation mode to monitor the patient.
- Demo Mode (Demo): To give some demo screens. You should input the password to enter the mode.
- Configuration Mode(Config): You need to input password to enter the mode. The mode is for the special configuration personnel in hospital or the senior users to configure the monitor.
- Maintenance Mode (Mainten.): You need to input password to enter the mode. This mode is only for the service personnel. (The setting information under the config mode and service mode refer to ***Service manual***)

3.8 Screen Display

The monitor adopts a display screen of high-resolution TFT LCD. Measurement numerics, waveforms, patient info, alarm area and menu can be displayed on the screen. Standard screen is shown as follows:



1. Patient info area

Shows the room number, bed number, patient name, patient category and paced status of patient.

2. Physiological alarm area

Shows the physiological alarm messages, medium-level and low-level alarm messages display on the left, while the high-level alarm messages display on the right.

3. Alarm status area

 The alarm is suspended.

 Press this button to reset all the alarms.This switches off the audible alarm indicators.

4. Parameter area

It consists of various parameter areas, and shows measurement numerics for each parameter module. Label displays on the top left corner of each parameter area. When you close or open some parameter module, the parameter area on the screen will be rearranged automatically.

5. Area of smartkeys

Shows smartkeys, these smartkeys are used to conduct some common operations.

6. Waveform area

Shows the waveforms of each physiological parameter. Label displays on the top left corner of each waveform area. When you close or open some waveform, the waveform area on the screen will be rearranged automatically.

7. Technical alarm area

Shows technical alarm messages and prompt messages.

3.9 Using the Smartkeys

The position on the screen where a focus may stay is referred to as the smartkey. Through a smartkey, you may quickly enter some menus or execute some operations. The smartkeys of the monitor may be divided into the following types:

Waveform smartkey

An area where any waveform stays is the smartkey; you may select a waveform area to enter a setting menu of the corresponding waveform.

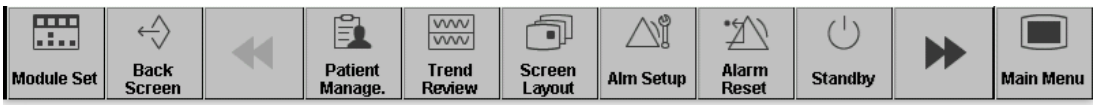
Parameter smartkey

An area where any parameter stays is the smartkey; you may select a parameter area to enter a setting menu of the corresponding parameter.

Smartkeys

Smartkeys at the bottom of the screen may be configured, through which some functions may be quickly executed. These smartkeys vary with different configurations.

For example, if you want to enter【**Module Set**】menu, you shall touch the position shown as follows:

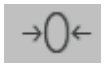


To configure the smartkeys on the screen by the following ways:

Select【**Main menu**】smartkey→【**Smartkey Define**】, select the smartkeys you want to display on the screen.

The symbols on the smartkeys are shown as follows:

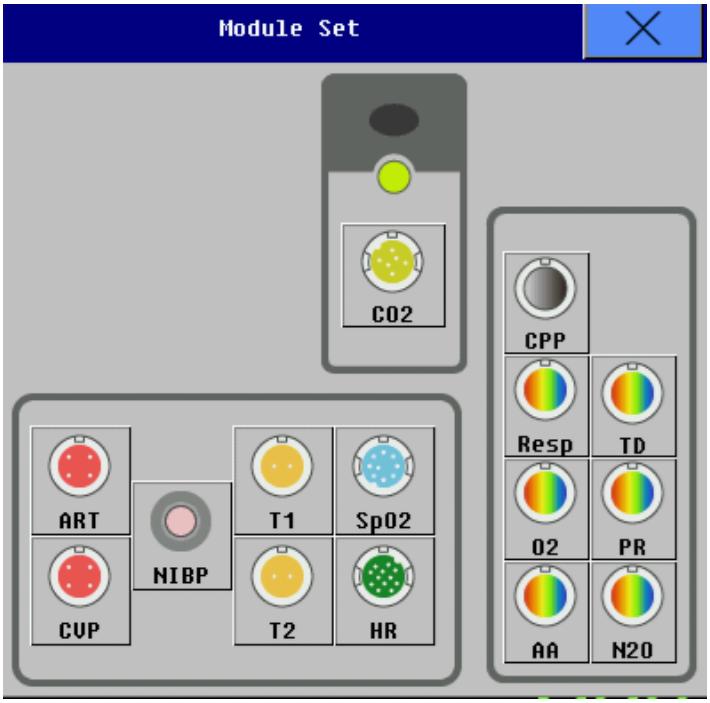
Smartkey	Smartkey Note	Smartkey	Smartkey Note
	Module Set		Back screen
	Previous page		Next page

	Patient Manage		Trend review
	Screen Layout		Alarm Setup
	Alarm Reset		Standby
	Enter NIBP menu		Stop NIBP measurement
	Start NIBP STAT measurement		Freeze waves
	Lock screen or Unlock screen		Wireless Setup
	NIBP review measurement		Adjust volume
	Adjust brightness		Zero
	C.O. measure		Tabular trends
	Discharge patient		Calculation
	Recorder		

3.10 Setting Measurement Modules

3.10.1 Setting Measurement Modules

Select【**Module Set**】smartkey to enter the module config window, shown as follows. Depending on different configuration, your monitor will display different contents.



Parameter measurement modules which are configured by user are displayed in above window, and label displays near the corresponding connector of module.

◆ **Open or close some parameter**

To open or close some parameter, take T1 for example:

——To open T1 measurement: select T1 module in【**Module Set**】menu , from the menu that appears, select【**Actived**】.

——To close T1 measurement: select T1 module in【**Module Set**】menu, from the menu that appears, select【**Closed**】.

3.10.2 Using Labels

Depending on the configuration of your monitor, you can measure ECG, Resp, SpO_2, PR, NIBP, multiple Temp, multiple IBP, CO_2, AGand C.O.simultaneously. The monitor uses labels to distinguish between them. All setting contents related to the parameter (such as parameter color, waveform color, wave scale and alarm setting) are stored in each label. You can alter the label of IBP and Temp parameters. Detail operations are as follows:

◆ **Changing Temp Label**

1. Select【**Module Set**】smartkey to enter the Module config window in which you can select the Temp label you want to alter. Then, there is

a module config window popping up.

2. Select【**Change Label**】to rename the temp. Options are as follows:

Label	Description	Label	Description
Tesoph	Esophageal temperature	Trect	Rectal temperature
Tnaso	Nasopharyngeal temperature	Tblad	Bladder temperature
Ttymp	Tympanic temperature	Tskin	Skin temperature
T1	Non-specific temperature	T2	Non-specific temperature

◆ **Changing IBP Label**

1. Select【**Module Set**】smartkey to enter the Module config window in which you can select the IBP label you want to alter. Then, there is a module config window popping up.

2. Select【**Change Label**】to rename the IBP. Options are as follows:

Label	Description	Label	Description
ART	Arterial blood pressure	ICP	Intracranial pressure
PA	Pulmonary artery	RAP	Right atrial pressure
CVP	Central venous pressure	LAP	Left atrial pressure
P1	Non-specific pressure	P2	Non-specific pressure

3.10.3 Resolving Label Conflicts

Each label must be unique, that is, it can only be assigned once. You can't monitor two pressures labeled "Tskin" at the same time. If you need to use two identical temperatures, you must assign different labels to them.

Measurement labels are stored in the measurement module. If you try to use two measurement modules with identical labels, the monitor will close the second module automatically.

◆ **IBP and Temp module**

Take the Temp module for example, when your monitor has been equipped with a Temp module (module A), and the module uses the

label Tskin, then if you plug in another Temp module (module B) with the label Tskin, thus the monitor will close the module B automatically.

To resolve conflict of labels:

—— You can keep on using module A to measure Tskin;

—— If you decide to measure Tskin with module B, you need to modify the label Tskin with the module A first, and activate the module B once again.

◆ **Other modules**

The monitor can simultaneously support three independent IBP modules and IBP module in EMS, also support three independent Temp modules and the Temp module in EMS, but only support one measurement module of other type, otherwise the monitor will close the second module automatically.

Take the CO_2 module as an example: a monitor has been equipped with one CO_2 module (module A), furthermore, the module A is active, and at that time, if you plug in another CO_2 module (module B), the monitor will close the module B automatically.

To resolve the conflict:

——You can keep on using module A;

——If you need to use the module B, you must pull out both module A and B, then plug in the module B. Or you can close the module A and activate the module B in the【**Module Set**】window.

3.11 Using Mouse

The monitor supports USB-interface mouse and allows hot plugging and plug & play.

While using mouse, you should take care of the following:

The left key of a mouse is the major key, and the right key of the mouse is the secondary key.

To click the major key of a mouse is equivalent to the operation of pressing trim knob.

3.12 Using Soft Keyboard

The software of the monitor can provide soft keyboard to input data and support entering in Chinese and English.

3.13 Using SD Memory Card

In order to avoid patient's data loss as the power of a monitor suddenly fails, the monitor can be fitted with SD memory card that can provide the data saving function while power failure or power off. In the process of monitoring, patients' trend data and related waveform etc. are saved in the SD memory card. In case the power of the monitor suddenly fails and the monitor is restarted, the monitoring data of the patient will be consistent with those before power failure or power off.

■ Plug in SD memory card:

1. Switch off the power of the monitor;
2. Plug in a SD memory card into the slot for SD memory card;

■ Remove SD memory card:

1. Switch off the power of the monitor;
2. Press the SD memory card;
3. After the SD memory card popping up, you can remove it.

■ Review data in SD memory card:

1. Before operation, please be sure there is a SD memory card in the monitor. Select【Main menu】smartkey→【History Data】, a patient data list will pop up.(In the list, the patient with"*"is the current patient.)
2. Select a patient in the list, then select【View】, a review menu will pop up.
3. In the menu, select the option you need to review. You can select: 【Pat. Infomation】, 【Tabular Trends】, 【NIBP Review】, 【ARR Review】, 【Alm Review】 or 【Full Disclosure】 .

Review history data is something like review the current patient data. For more details please refer to ***Review*** chapter.

Caution:

- **Please make sure that the SD memory card is unlocked before using it.**
- **Please do not plug in and pull out SD memory card while the monitor has been turned on.**
- **Within the short time after starting monitor, data probably cannot be stored in a SD memory card.**
- **Please do not use the SD memory card in any equipment other**

than the monitor.

- **While the available space of a SD memory card is little, the monitor will display "space of memory card is insufficient", at that time, user should delete some data in the SD memory card or replace a new SD memory card to ensure sufficient memory of the SD memory card.**

3.14 General Setting

3.14.1 Adjusting the screen brightness

1. Select【**Brightness**】or select【**Main menu**】→【**Brightness**】.
2. You can set the screen brightness to a value between 1 and 10. 1 is the minimum brightness and 10 is the maximum.

If the monitor runs on batteries, choose a lower level brightness to save the power. When the monitor enters standby mode, the screen brightness is automatically set to the lowest level.

3.14.2 Adjusting the volume

1. Setting the QRS volume

Select【**Volume**】smartkey→【**QRS Volume**】, or select【**QRS Volume**】in ECG or SpO_2 parameter area. The QRS volume can be set to silence or a value between 1 and 6. Silence means the QRS volume is turned off and 6 is the maximum volume.

2. Setting the alarm volume

Select【**Volume**】smartkey→【**Alm Volume**】, or select【**Main Menu**】→【**Alm Setup**】→【**Alm Volume**】. The volume can be set to a value between X and 6. X is the minimum alarm volume and 6 is the maximum volume. Alarm silence is invalid.

3.14.3 Setting the Date and Time

User can configure the system date and time. The user is advised to set system time before implementing monitoring. If the configuration is to be conducted during the process of monitoring, the user is advised to switch off the monitor after exiting the current window and then restart it.

The time for the revision takes effect after the current window is exited.

To set the date and time:

1. Select【**Main Menu**】smartkey→【**System Time Setup**】.
2. Select【**Date Format**】, it can be set to【**Month Day**】 or 【**Month Day**】.
3. Select【**Time Format**】, it can be set to【**24h**】or【**12h**】.
4. Set the current date and time and select【**OK**】to confirm it.

Caution: Changing the date or time will affect the storage of trends and events, it may result in data loss.

Chapter 4 User Interface

4.1 Display Style

Display style of user interface can be set according to your need. Including:

——Sweep mode of wave;

——Screen brightness:

——Display color of wave and parameter:

——Parameter and wave to be monitored.

4.1.1 Screen Brightness

1. Select【**Main Menu**】smartkey→【**Brightness**】or select【**Brightness**】smartkey;
2. You can set the screen brightness to a value between 1 and 10. 1 is the minimum brightness and 10 is the maximum.

4.1.2 Parameter Color

1. Select【**Main Menu**】smartkey→【**Screen Setup**】;
2. Select【**Parameter Color Setup**】, click the color block of corresponding parameter, and then select the color according to your need from the popped menu.

4.1.3 Selecting Parameter

You can select the parameters to be displayed according to the requirement of monitoring and measurement.

1. Select【**Module Set**】smartkey.
2. From the popped menu, you can select the parameter to be displayed according to your need.

Besides, you can close a waveform display by below methods:Select a wave area, and select【**Close Wave**】in the menu.

4.1.4 Changing Waveform

You can exchange the positions of some waveform A for the other waveform B, and also can add the display of some waveform C under the waveform A. The setting method is as follows:

1. Select the waveform A and enter the setting menu of the waveform A.
2. Select **【Exchange Wave】**, and select the label of the waveform B from the options, then it will exchange position with waveform A.
3. Select **【Add Wave】**, and select the label of the waveform C from the options. The screen will be rearranged automatically, and the selected waveform C will be inserted under the waveform A.

4.2 Screen Layout

You can set the screen layout as required. The setting method is as follows:

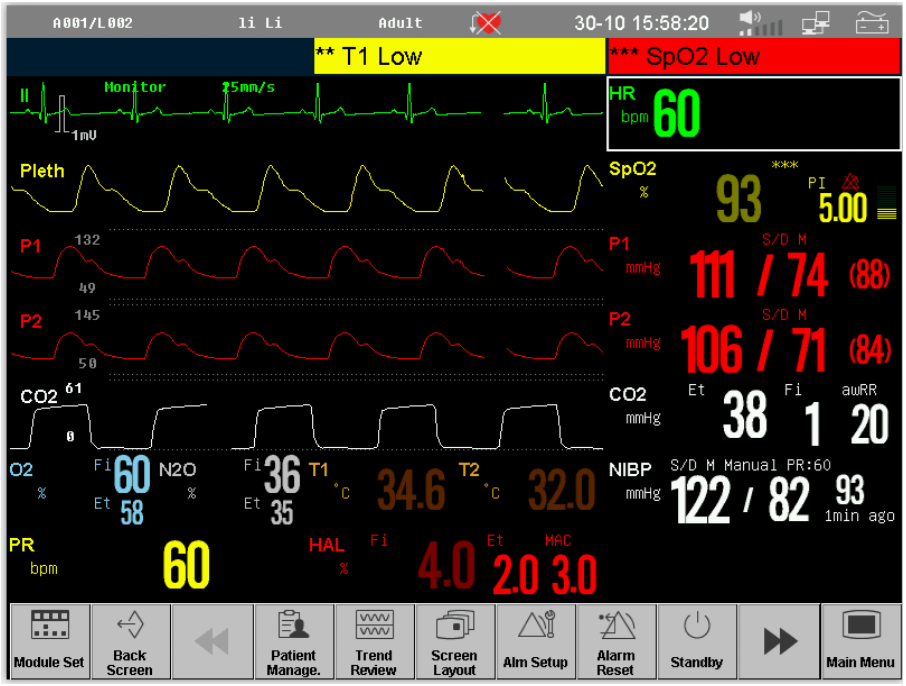
1. Select the **【Main Menu】** smartkey→**【Screen Layout】** or select **【Screen Layout】** smartkey.
2. Select one screen according to your need.

The following are the display interface of screens, which may differ from those on your monitor.

■ **Standard Screen**

To enter standard screen:

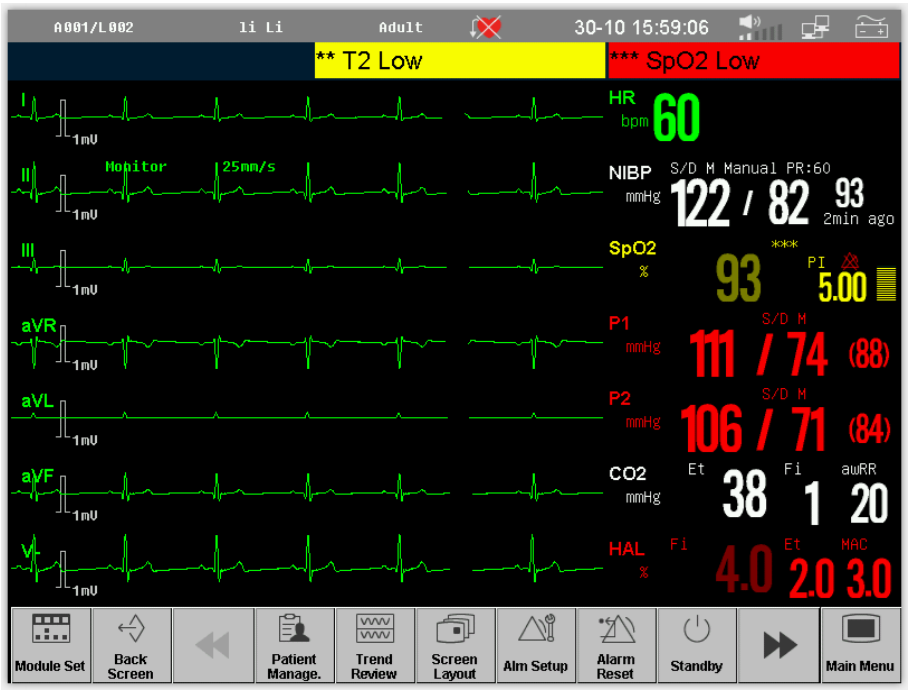
- Select **【Main Menu】** smartkey→**【Screen Layout】**→**【Standard】**.
- Or select **【Screen Layout】** smartkey→**【Standard】**.



■ 7-lead

To enter 7-lead screen:

- Select【**Main Menu**】smartkey→【**Screen Layout**】→【**7-lead**】.
- Or select【**Screen Layout**】smartkey→【**7-lead**】.

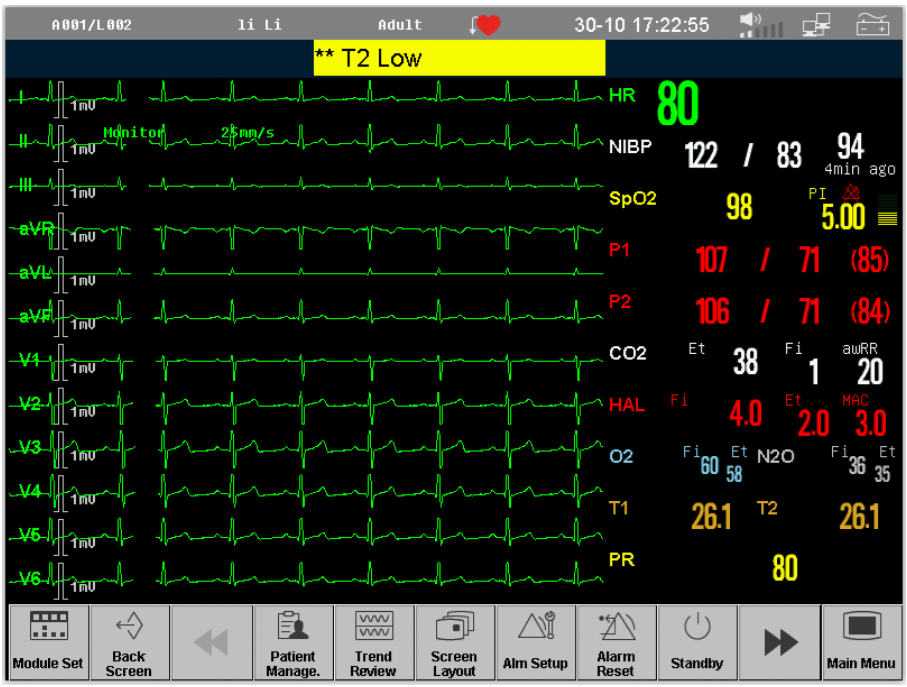


The ECG waveforms of 7-lead are displayed in the waveform display area, they are I, II, III, aVR, aVL, aVF, and V- respectively.

■ 12-lead

To enter 12-lead screen:

- Select【**Main Menu**】smartkey→【**Screen Layout**】→【**12-lead**】.
- Or select【**Screen Layout**】smartkey→【**12-lead**】.

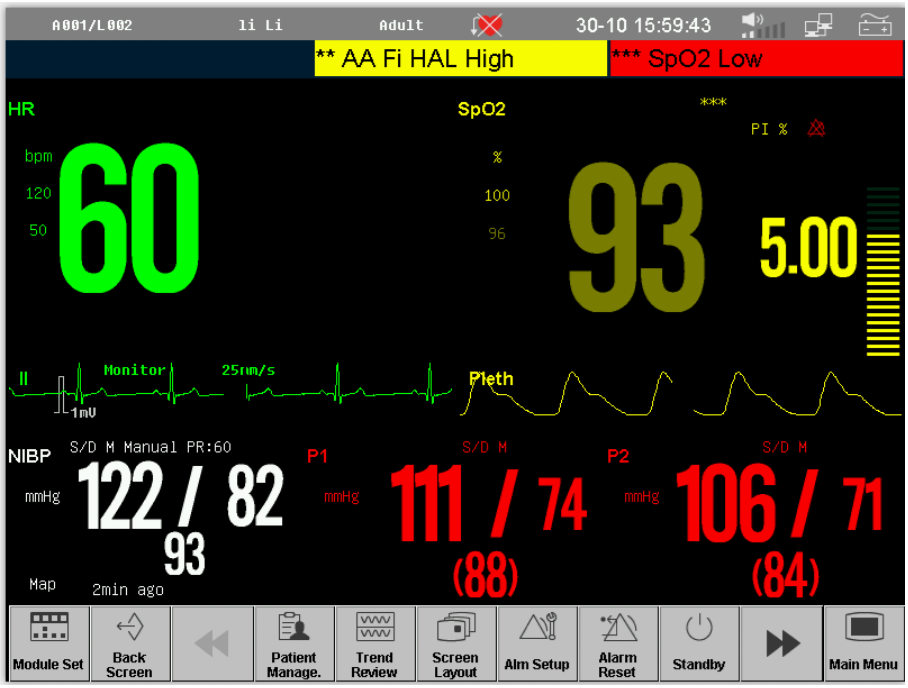


The 12-lead ECG waveforms are displayed in the waveform display area, they are I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 and V6.

■ Big Numerics

To enter big numerics screen:

- Select【**Main Menu**】smartkey→【**Screen Layout**】→【**Big Numerics**】.
- Or select【**Screen Layout**】smartkey→【**Big Numerics**】.



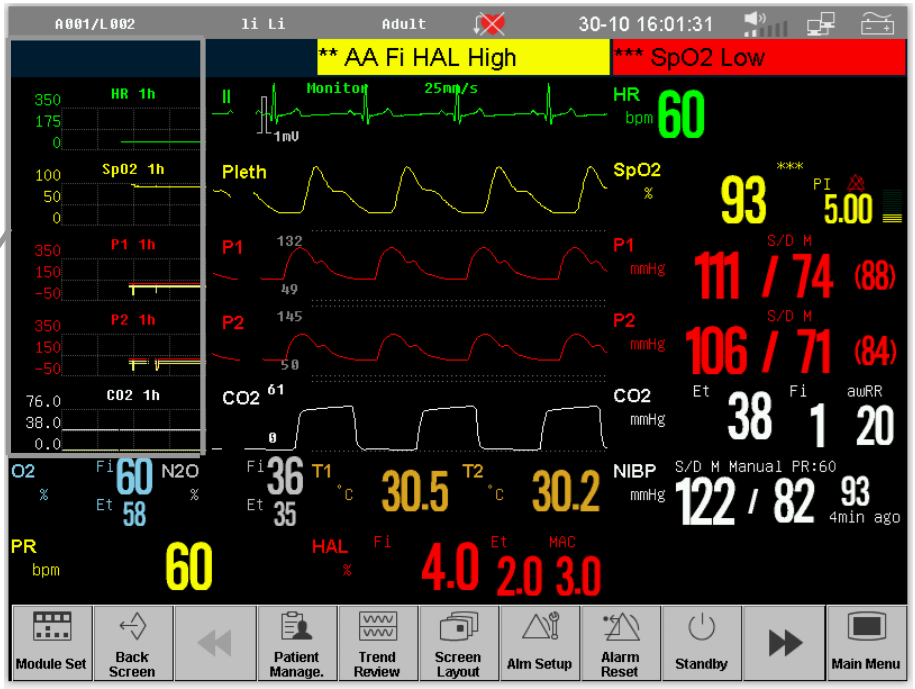
On big numerics screen, you can select any parameters on screen, conduct some parameter settings and observe the parameter as required.

At the same time, a waveform will be displayed under the parameter area if the monitor can measure a waveform for the parameter.

■ HI RES Trend

To enter high resolution trend screen:

- Select【**Main Menu**】smartkey→【**Screen Layout**】→【**HI RES Trend**】.
- Or select【**Screen Layout**】smartkey→【**HI RES Trend**】.



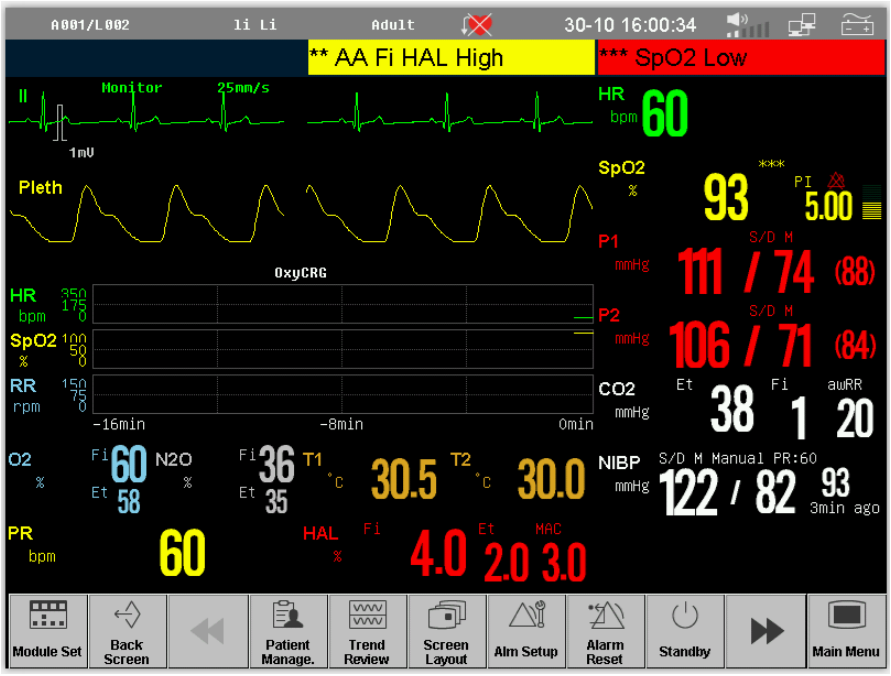
The HI RES Trend graph relevant to the parameters is displayed on the left corner of the waveform, it shows the graphic trend for some time of each parameter. Label and duration of trend display above the each trend, while scale display on the left.

Select a HI RES Trend of parameter to enter the setting menu, and select【**Time length**】to select the trend time length of the HI RES Trend.

■ OxyCRG

To enter OxyCRG screen:

- Select【**Main Menu**】smartkey→【**Screen Layout**】→【**OxyCRG**】.
- Or select【**Screen Layout**】smartkey→【**OxyCRG**】.

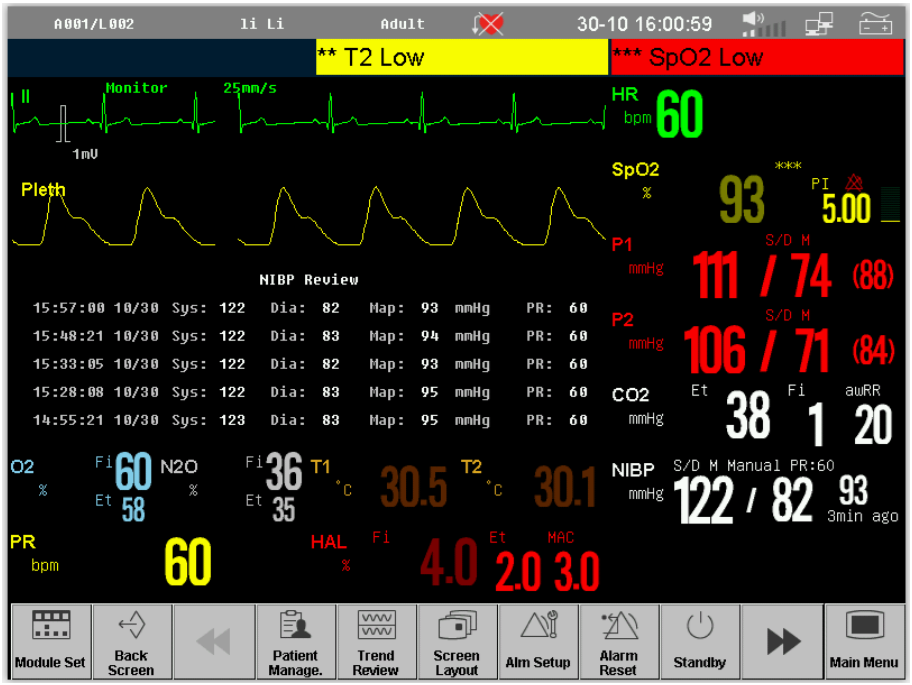


The graphic trend of HR, SpO_2 and Resp within 16 minutes are displayed under the waveforms.

■ NIBP Review

To enter NIBP review screen:

- Select【**Main Menu**】smartkey→【**Screen Layout**】→【**NIBP Review**】.
- Or select【**Screen Layout**】smartkey→【**NIBP Review**】.

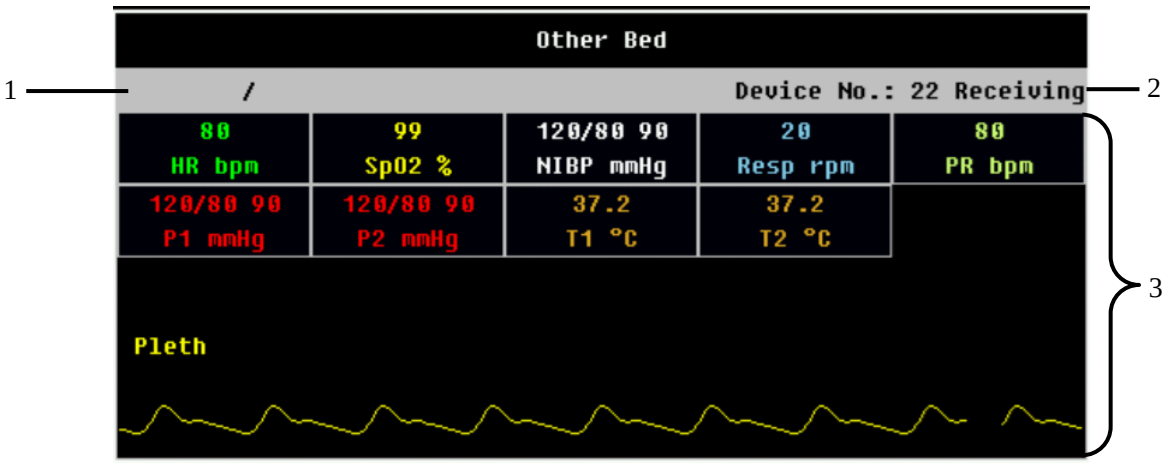


The recent groups of NIBP measurement results are displayed below the waveforms.

■ **Other Bed screen**

To enter other bed screen:

- Select【**Main Menu**】smartkey→【**Screen Layout**】→【**Other Bed**】.
- Or select【**Screen Layout**】smartkey→【**Other Bed**】.



After your monitor is connected to the central monitoring system, you can realize other bed monitoring by selecting the monitors for other beds in the same network. The other-bed-monitoring screen can display all the parameter data of other bed and a certain physiological parameter waveform. You can select at most 10 other-bed monitors to constitute "another-beds-monitoring group".

The other-beds-monitoring screen in the above figure consists of the following parts:

1. **Patient's information region:** Display patient's room number, bed number, and other information;
2. **Information display setting region:** Display the device numbers of the set other-bed monitors and whether they are receiving data.
3. **Other-bed-monitoring region:** Display all the physiological parameter data and a certain physiological parameter waveform.

To perform other-bed monitoring, you can do the following:

1) Select the Other-Bed-Monitoring window, and then choose the device number you need in the ejected list;
2) Select【**Select Wave**】to display a certain physiological parameter

waveform of the selected other-bed monitor in the other-bed-monitoring window; and

3) Lastly, select【**Start/Stop**】to receive data and start other-bed monitoring to stop other-bed monitoring, select【**Start/Stop**】 again. After that, data receiving will be stopped, and so will the current monitoring.

Chapter 5 Alarm

Alarm refers to a prompt that is given by the monitor for medical personnel through visual, audible and other means when a vital sign appears abnormal or the monitor occurs technical problem.

Note: The monitor generates all the audible and visual alarms through speaker, alarm lamp and screen. When the monitor powers on, the alarm lamp will be lighted one time and the speaker will give a beep voice, which indicates the alarm system of the monitor is working order.

5.1 Alarm Category

According to character of alarm, the monitor's alarms can be classified into three categories: physiological alarms, technical alarms and prompt messages.

■ Physiological alarms

Physiological alarms are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition. Physiological alarm message are displayed in the physiological alarm area.

■ Technical alarms

Technical alarms are triggered by a device malfunction due to improper operation or system problems. The problems may result in system abnormal operation or irresponsible monitoring parameters. Technical alarm message are displayed in the technical alarm area.

■ Prompt messages

As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the monitor will show some message to indicate the system status.

5.2 Alarm Level

According to severity of alarm, the monitor's physiological alarms are classified into three categories: high level alarms, medium level alarms and low level alarms.

- High level alarms: Indicate that the patient is in a life threatening situation and an emergency treatment is necessary. This is the highest level alarm.
- Medium level alarms: Indicate that the patient's vital signs appear abnormal and an immediate treatment is required.
- Low level alarm: Indicate that the patient's vital signs appear abnormal and an immediate treatment may be required.

The levels of some physiological alarms are predefined before the monitor leaves the factory and can not be changed by users. While some levels of physiological alarms can be changed by users.

The monitor's technical alarms are classified into two categories: medium level and low level.

The levels of technical alarms are predefined before the monitor leaves the factory and can not be changed by users.

5.3 Alarm Indicators

When an alarm occurs, the monitor will indicate it through the following means:

- Alarm tone: According to alarm level, speaker in the monitor gives alarm sound in different tone.
- Alarm lamp: According to alarm level, alarm lamp on monitor flashes in different color and speed.
- Alarm message: Alarm messages are displayed on the screen.
- Flashing numeric: The numeric of parameter in alarm flashes.

Caution: The concrete presentation of each alarm prompt is related to the alarm level.

5.3.1 Alarm Tone

The different level alarms are indicated by the system in following different audio ways:

Alarm level	Audible prompt
High	"DO-DO-DO------DO-DO, DO-DO-DO------DO-DO"
Medium	"DO-DO-DO"
Low	"DO-"

The interburst interval for all auditory alarm signals can be set in the **【System Alm Setup】**,but this must be the maintainer can operate.

Select**【Main Menu】**smartkey→**【Work Mode】**→**【Mainten.】**,enter into the **【Mainten.】** mode need the password.

Then Select**【Main Menu】**smartkey→**【Mainten.】**→**【System Alm Setup】**→**【Alm Sound Type】**,you can select types of **【ISO】**

When the type is select as**【ISO】**, the interval cannot be set, it was defaulted as follows:

1. **【(Low) Alm Sound Inter.】**: **25s**
2. **【(Med) Alm Sound Inter.】**: **15s**
3. **【(High) Alm Sound Inter.】**: **10s**

5.3.2 Alarm Lamp

When a physiological alarm occurs, the alarm levels are indicated in the following different visual ways:

Alarm level	Visual prompt
High	Alarm lamp flashes in red with 2 Hz.
Medium	Alarm lamp flashes in yellow with 0.5 Hz.
Low	Alarm lamp lights on in yellow without flashing.

When a technical alarm occurs, the alarm levels are indicated in following different visual ways:

Alarm level	Visual prompt
High	Alarm lamp flashes in red with 2 Hz.
Medium	Alarm lamp flashes in yellow with 0.5 Hz.
Low	Alarm lamp lights on in cyan without flashing.

Caution: When multiple alarms of different levels occur at the same time, the monitor will select the alarm of the highest level and give visual and audible alarm indications.

5.3.3 Alarm Message

◆ **Physiological alarm**

1) Physiological alarm messages are displayed in the physiological alarm area.

2) The "*" symbol before the alarm message match the alarm level as follows:

High level alarms: ***

Medium level alarms: **

Low level alarms: *

3) The system uses different background colors for the alarm message to match the alarm level:

High level alarms: red

Medium level alarms: yellow

Low level alarms: yellow

◆ **Technical alarm**

1) Technical alarm messages are displayed in the technical alarm area.

2) The "*" symbol before the alarm message match the alarm level as follows:

High level alarms: ***

Medium level alarms: **

Low level alarms: *

3) The system uses different background colors for the alarm message to match the alarm level:

High level alarms: red

Medium level alarms: yellow

Low level alarms: cyan

◆ **Prompt messages**

1) Prompt messages are displayed in technical alarm area or the corresponding parameter area.

2) Prompt messages have no color and visual and audible alarm indication.

- When multiple alarms occur at the same time, the alarm messages will be displayed in the alarm area in turn.
- Select the physiological alarm or technical area, an alarm message window will pop up, you can observe the alarm message from it.

5.3.4 Flashing Numeric

When a physiological alarm occurs, the numeric of parameter flashes.

5.4 Alarm Status Symbol

 The alarm sound is off.

 The alarm is suspended.

 The parameter alarm is off.

5.5 Setting Alarm Volume

Select【**Main Menu**】smartkey→【**Alm Setup**】→【**Alm Volume**】, you can set the alarm volume of system. The volume can not to be set【**Silence**】. You can set the alarm volume values between X and 6. X can be set as 1, 2, 3, 4, 5, 6. X is the minimum alarm volume and 6 is the maximum volume.（The minimum alarm volume X can be set in the Maintenance Mode with password, the password can only be get from the factory.）

When the volume set to 1~6, the volume symbol is displayed as "  "in the middle of the screen.Or select 【**Volume**】smartkey→【**Alm Volume**】to set the alarm volume.

Warning: The auditory alarm signal sound pressure levels can not be set to less than ambient levels, this may impede operator recognition of alarm conditions and the alarm system provides.

5.6 Parameter Alarm

The setup for parameter alarm is in their setting menus. In the menu for a specific parameter, you can view and set the alarm limit, alarm status. The alarm setting of parameter is independent from each other. Or you can select **【Main Menu】** smartkey→ **【Alm Setup】** to set the parameter alarm.

For the parameters whose alarm switch is set to ON, the alarm will be triggered when at least one of them exceeds alarm limit. The following actions take place:

1. Trigger audible and visual alarm according to alarm level;
2. Alarm message is displayed in the physiological alarm area;
3. The numeric of parameter in alarm flashes.
4. If alarm recording is on, the recorder starts alarm recording at set interval.

When a parameter alarm is off, a symbol "  " will be displayed near the parameter. If the alarms are turned off individually, they must be turned on individually.

5.6.1 Alarm Switch

Select **【Alm Switch】** in each parameter setting menu to set the alarm switch of them. You can select **【On】** or **【Off】**. When a parameter alarm is off, a symbol "  " will be displayed near the parameter. If the alarms are turned off individually, they must be turned on individually.

5.6.2 Alarm Level

Select **【Alm Level】** in the setting menu of each parameter, you can view and set the alarm levels of present parameters. The level can be set to **【Low】**, **【Med】** or **【High】**.

5.6.3 Alarm Limit

■ Setting Individual Alarm Limits

The alarm limit can be set in each parameter setting menu, you can select **【Hi Lmt】**, **【Lo Lmt】** to set the alarm limit for each parameter. The alarm limit is adjustable, Physiological alarm will be triggered when the measuring value exceeds the set limit.

■ **Setting All Alarm Limits**

Select【**Main Menu**】smartkey→【**Alm Setup**】→【**Alm Limit**】to set the alarm limits of all present parameters.

Warning:

- **Medical personnel should set the alarm limits of parameters in line with the clinical environment and existing clinical experience. Before monitoring, please confirm whether the alarm setting is suitable for the monitored patient.**
- **The users can not set the alarm limit over the exteme values, that will render the alarm system useless.**
- **If different alarm presets are used for the same or similar equipment in any single area, a potential hazard may exist.**

5.7 Pausing Alarms

Press the button on the front panel of monitor, you can suspend all alarm indicators of the monitor:

——The alarm lamp and alarm sounds are all suspended.

——The parameters of physiological alarm stop flashing.

——The alarm message in the physiological alarm area will not be displayed.

——The remaining time and the icon will be shown in the physiological alarm area.

——The technical alarm message will still be shown in the technical alarm area.

The default duration of alarm paused is 2 min,and the duration time can be select as 【**1min**】, 【**2min**】,【**3min**】,【**5min**】in the maintenance mode with password. After the alarm paused time，the monitor will automatically cancel the alarm pausing. Press again the button , the alarm pausing can be cancelled by manual operation.

After returning to the normal status, whether the alarm still exists is dependent on whether the alarm condition is met. But when pressing the button , the alarm of lead-off/sensor-off/module-off are cease.

5.8 Alarm Reset

Press the button on the front panel of the monitor; you can acknowledge all active physiological and technical alarms:

——The auditory alarms are all shut off.

——Visual alarm signals for latching alarm conditions that no longer exist are cease.

——The visual alarm signals for any existing alarm conditions will continue as long as those alarm conditions exist.

——The parameters of physiological alarm keep on flashing.

——The alarm of lead-off/sensor-off/module-off are cease.

After acknowledging the alarms, if a new technical alarm or physiological alarm occurs, the monitor will enable the audible alarm once again.

5.9 Latching Alarms

The physiological alarms are classified into **Latching** and **Non-latching**.

- Latching alarms: Even if the alarm cause has been cleared, the system still prompts the alarm of the parameter until you acknowledging the alarm.
- Non-latching alarms: After clearing the cause of parameter alarm, the system will not prompt the alarm of the parameter.

All the technical alarms are non-latching alarm, and all the physiological alarms are non-latching alarm except the Arrhythmia alarm, the Arrhythmia alarm can be set to non-latching alarm or latching alarm only in the Maintenance Mode or Service Mode with password.

5.10 When an Alarm Occurs

Note: When an alarm occurs, you should always check the patient's condition first.

Check the alarm message appeared on the screen. It is needed to identify the alarm and action appropriately, according to the cause of the

alarm.

1. Check the patient's condition.
2. Identify alarming parameter and alarm category.
3. Identify the cause of the alarm.
4. Silence the alarm, if necessary.
5. When cause of alarm has been over, check that the alarm system is working properly.

You will find the alarm messages for the individual parameter in ***Appendix C Alarm message***.

5.11 Alarm when power is lost

After a loss of power, the alarm settings prior to the power loss are restored.

If you want to restore either the alarm settings from the default settings, please enter the alarm setting menu to select the setting.

Chapter 6 Patient Management

6.1 Admitting a Patient

The monitor displays physiological data and stores it in the trends as soon as a patient is connected. This lets you monitor a patient who is not yet admitted. However, it is very important to admit patients properly. If a patient is admitted in the monitor, it is advised to discharge the current patient before admitting a new patient. Or else, the data of next patient will be stored in the current patient's data.

To admit a patient,

1. Select【**Patient Manage.**】smartkey→【**Admit Patient**】,and then select【**Yes**】to discharge the current patient and admit a new patient. The patient info window will be popped up.

2. Enter or select the patient information:

——MRN: Enter the patient's medical record number (MRN);

——Last Name: Enter the patient's last name (family name);

——First Name: Enter the patient's first name;

——Gender: Choose【**Male**】or【**Female**】;

——Patient Type: Choose the patient category, either【**Adult**】, 【**Pediatric**】or【**Neonate**】;

(The patient category setting determines the algorithm the monitor uses to process and calculate some measurements, the safety limits that apply for some measurements, and the alarm limit ranges.)

——Paced: Choose【**Yes**】or【**No**】. An icon will be displayed in the patient info area on the screen when choosing【**Yes**】, if not, will be displayed. (You must choose【**Yes**】if your patient has a pacemaker. The monitor will detect the paced status of patient if choose【**Auto**】, when pacemaker is detected, there are prompt information'ECG Pacing Detected' display in the screen and icon will be displayed in the patient info area.)

——Room No.: Enter the patient's room number;

——Bed No.: Enter the patient's bed number;

——Age: Enter the patient's age;

——Height: Enter the patient's height;

——Weight: Enter the patient's weight;

——Blood Type: Enter the patient's blood type.

Warning:

- **【Patient Type】and【Paced】status will always contain a default value, regardless of whether the patient is admitted or not. Users must confirm whether the default value is suitable for the monitored patient.**
- **For paced patients, you must set【Paced】to【Yes】. If it is incorrectly set to【No】, the monitor could mistake pace pulses for regular QRS complexes and fail to alarm during asystole.**
- **For non-paced patients, you must set【Paced】to【No】, otherwise, the system can not detect the arrhythmia related to Ventricular Premature, and will not conduct ST analysis.**

6.2 Quick Admitting a Patient

Use"Quick Admit"only if you do not have the time or information to fully admit a patient. Complete the rest of the patient information details later.

To quick admit a patient,

1. Select【**Patient Manage.**】smartkey→【**Quick Admit**】, and select【**Yes**】in the window popped up to discharge the previous patient and admit a new patient.
2. Set【**Patient Type**】and【**Paced**】, the patient status changes to admitted.

6.3 Edit Patient Information

After a patient has been admitted, you can edit the patient information in following ways:

1. Select【**Patient Manage.**】smartkey→【**Pat. Information**】.
2. Edit the patient information in the popped up menu.

6.4 Discharging a Patient

You should always perform a discharge before starting monitoring for a new patient, even if your previous patient was not admitted.

To discharge a patient,

1. Select【**Patient Manage.**】smartkey→【**Discharge Pat.**】.
2. In the popped up menu, you can:

——Do not choose【**Standby**】, and select【**OK**】, the monitor will return main screen after discharging the patient.

——Choose【**Standby**】, and select【**OK**】, the monitor will enter standby mode after discharging the patient.

——Select【**Cancel**】to cancel the discharge operation and return main screen.

Chapter 7ECG

7.1 Introduction

Before mechanical systole, the heart firstly produces electrical excitement, which results in biological current, and conducts the current to the body surface through tissue and humour. Different potential changes take place at various parts of the body, thus body-surface potential differences are formed. Record the changing potential differences to form the dynamic curve, i.e. ECG, also called body-surface ECG or regular ECG.

Through many electrodes connected with ECG cables, the monitor examines the changes of body-surface potential caused by the heart of patient, observes the ECG activities, records the ECG waveform, and calculates the HR. The monitor can achieve 3-lead, 5-lead and 12-lead monitoring, and has the function of ST-segment monitoring and arrhythmia analysis.

7.2 Safety Information

Warning:

- **It is imperative to only use the ECG electrodes and cables provided by manufacturer or specified in this manual. Users shall use the electrode which has little polarization voltage and little contact resistance.**
- **When the electrode polarized voltage is too high, the monitor will indicate the abnormal state by alarm system.**
- **Before connecting the ECG cables to the monitor, please check if the lead wires and cables have been worn out or cracked. If so, they should be replaced.**
- **When you are connecting the electrodes or the patient cable, make sure that the connectors never come into contact with**

other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are attached to the patient, to prevent them from contacting conductive parts or earth.

- **Please check the skin where the electrodes are placed, replace the electrodes or relocate the electrodes in case of skin allergy occurs.**
- **When conducting defibrillation, it is imperative to only use the ECG electrodes and cables specified by manufacturer.**
- **Do not touch the patient, bed or the monitor during defibrillation.**
- **The monitor is protected against defibrillation effect. When applying defibrillator to the patient, the monitor will experience transient disorderly waveforms. If the electrodes are used and placed correctly, the display of the monitor will be restored within 10s. During defibrillation, the chest leads such as V_1~V_6 should be removed and such limb electrodes as RA, LA, RL, LL should be moved to the side of the limbs.**
- **Interference from instruments near the patient and ESU interference can cause problems with the ECG wave.**
- **The monitor cannot be directly applied to heart and cannot be used for the measurement of endocardio ECG.**

7.3 Monitoring Procedure

7.3.1 Skin Preparation for Electrode Placement

Good electrode-to-skin contact is important for a good ECG signal, as the skin is a poor conductor of electricity. It is necessary to deal with the skin properly before placing the electrodes. The steps are shown as follows:

1. Select sites with intact skin, without impairment of any kind.
2. Clip or shave hair from sites as necessary.
3. Gently abrade the skin to remove dead skin cells to improve the conductivity of the electrode site.
4. Wash sites thoroughly with soap and water, leaving no soap residue.

(We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.)

6. Dry skin thoroughly.

7.3.2 Placing Electrode

1. Preparation before electrode placement

1) Skin preparation (refers to ***Chapter 7.3.1***);

2) Check if the buttons on the electrodes are clean and free of damage;

3) Place the electrodes on the body of patient. Before attaching, smear some conducting cream on the electrodes if the electrodes are not electrolyte self-supplied;

4) Connect the cable leads to the electrodes through the buttons of the electrodes.

Note:

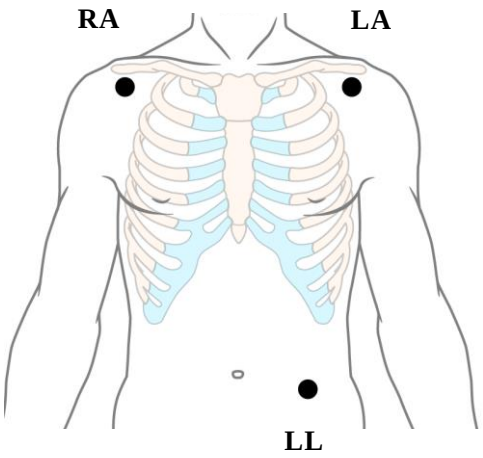
- **For patients who tremble a lot or patients with especially weak ECG signals, it might be difficult to extract the ECG signals, and it is even more difficult to conduct HR count. For severely burnt patients, it may be impossible to stick the electrodes on and it may be necessary to use the special pin-shape electrodes. In case of bad signals, care should be taken to place the electrodes on the soft portions of the muscle.**
- **Check the irritation caused by each electrode to the skin, and in case of any inflammations or allergies, the electrodes should be replaced and the user should relocate the electrodes every 24h or at a shorter interval.**
- **When the electrotome operation is performed, the ECG leadwires should be intertwisted as much as possible. The monitor should be placed far from the operating table. Power wires and the ECG lead cables should be partitioned and should not be in parallel.**

---

2. Electrode Placement

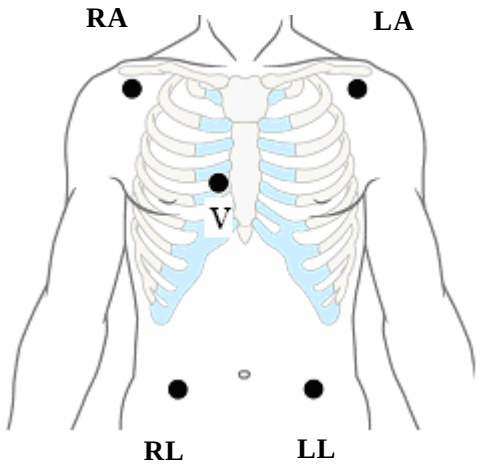
■ 3-Lead

Take the AHA standard as an example, when conducting 3-lead ECG monitoring, use 3-lead ECG cable. The three limb-leads of RA, LA and LL as shown in below figure, will be placed on the relevant locations. This connection can establish the lead of I, II, III.



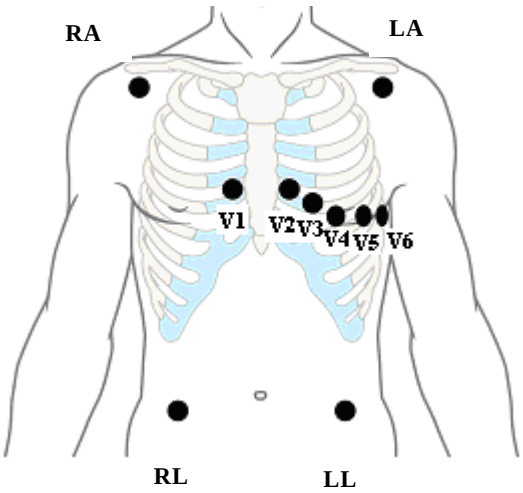
■ 5-Lead

Take the AHA standard for example, when conducting 7-lead ECG monitoring, use 5-lead ECG cable. The four limb-leads of RA, LA, RL and LL as shown in below figure, will be placed on the relevant locations. This connection can establish the lead of I, II, III, aVR, aVL, aVF; according to actual needs, chest lead V can be placed on any of the locations between V_1~V_6, respectively making one lead of V_1~V_6 established.



■ **12-Lead**

Take the AHA standard as an example, when conducting 12-lead ECG monitoring, use 12-lead ECG cable, and all the leads are placed on the relevant locations respectively as shown in the below figure. This kind of connection realizes the establishment of such 12 leads as I, II, III, aVR, aVL, aVF, V_1~V_6.



■ **Place electrodes for a surgical patient**

While placing electrodes for a surgical patient, the type of surgery should be considered, for instance, as to a chest surgery, the chest lead electrodes can be placed at sides or backside of chest. Moreover, while using a surgical electrotome, in order to reduce the influence of artifacts to ECG waveform, the electrodes can be placed at left and right shoulders, close to left and right sides of abdomen; the chest lead electrodes can be placed at left side of chest midst. Please avoid placing the electrode at the upper arms, otherwise the ECG waveform will become very small.

Warning:

- **To avoid burning, when the electrotome operation is performed, the electrodes should be placed near the middle between ESU grounding pad and electrotome and the electrotome should be applied as far as possible from all other electrodes, a distance of at least 15 cm/6 in is recommended.**
- **When using the ESU device, avoid placing the electrodes near**

the ESU grounding pad, otherwise, grate deal interference will influence the ECG signals. The monitor should be placed far from the operating table. Power wires and the ECG cables should be partitioned and should not be in parallel.

The following table shows the ECG electrode label to identify each electrode and its associated color of AHA and IEC standards.

Electrode labels (IEC)	Electrode colors (IEC)	Electrode labels (AHA)	Electrode colors (AHA)	Placement
R	Red	RA	White	Directly below the clavicle and near the
L	Yellow	LA	Black	Directly below the clavicle and near the left
N	Black	RL	Green	On the right lower
F	Green	LL	Red	On the left lower
C1	Red	V1	Red	On the fourth intercostal space at the right sternal border
C2	Yellow	V2	Yellow	On the fourth intercostal space at the left sternal border
C3	Green	V3	Green	Midway between the V2 and V4 electrode positions
C4	Brown	V4	Blue	On the fifth intercostal space at the left midclavicular line
C5	Black	V5	Orange	On the left anterior axillary line, horizontal with the V4 electrode position
C6	Violet	V6	Violet	On the left midaxillary line, horizontal with the V4 electrode position

7.3.3 Connecting ECG Cable

Plug the ECG cable into the ECG connector. An ECG waveform and numeric appears on the monitor display.

7.3.4 Selecting Leads

Depending on the patient to be monitored, you shall select the proper leads as required.

1. Select ECG parameter area, enter ECG parameter setup menu, select【**Lead Type**】.
2. You can select【**3 lead**】,【**5 lead**】or【**12 lead**】.

7.3.5 Checking Paced Status

It is important to set the paced status correctly when you start monitoring ECG.

If the【**Paced**】status has been set to【**Yes**】, the icon will be shown on the screen. If the system detects paced signal, the symbol "|" will be marked on the ECG wave.

To change the paced status, you can select【**Patient Manage.**】smartkey→【**Pat. Information**】, and set the【**Paced**】status in the popped up menu.

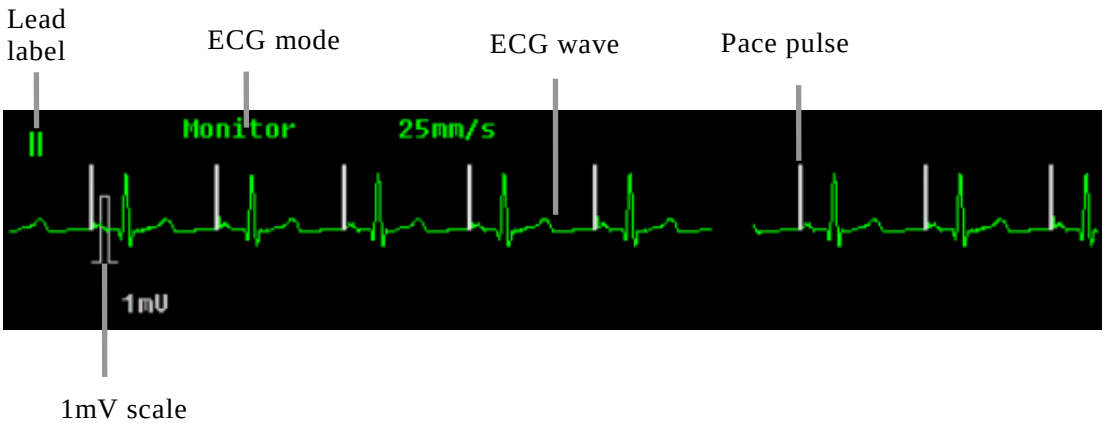
Warning:

- **For paced patients, you must set【Paced】to【Yes】. If it is incorrectly set to【No】, the monitor could mistake pace pulses for regular QRS complexes and fail to alarm during asystole.**
- **Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Keep pacemaker patients under close observation.**
- **For non-paced patients, you must set【Paced】to【No】, otherwise, the system can not detect the arrhythmia related to Ventricular Premature(including PVCs count), and will not conduct ST analysis.**

7.4 ECG Display

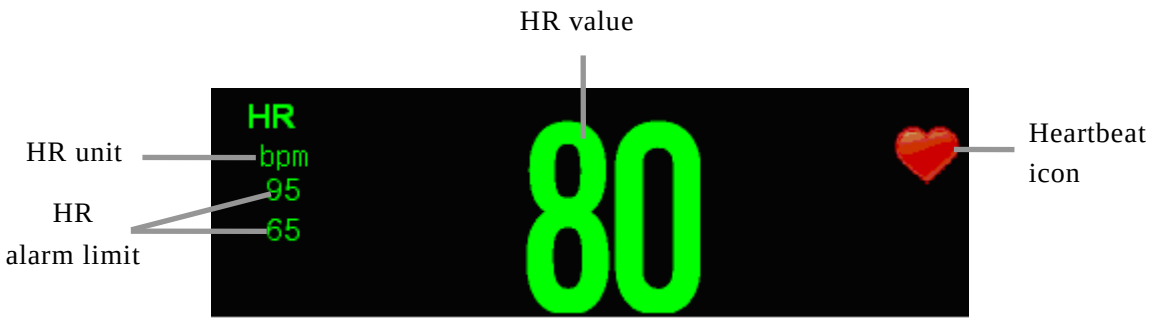
The following figure shows the ECG display screen, the display on your monitor may be looked slightly different.

◆ **Waveform Display**



If the【**Paced**】status has been set to【**Yes**】and the system detects paced signal, the paced pulse "|" will be marked on the ECG wave.（As it shown above）

◆ **Parameter Display**



If the monitor doesn't obtain an effective HR value by ECG measuring, the PR value will be displayed instead here.

7.5 Setting ECG

7.5.1 Setting ECG Parameter

Select the ECG parameter area to enter the ECG parameter setting menu.

◆ **Setting ECG Mode**

The ECG mode can be selected as required, including【**User**】, 【**Diagnosis**】,【**Monitor**】and【**Surgery**】.

【**Monitor**】: Use under the normal measurement.

【**Diagnosis**】: Use when diagnostic quality is required. The unfiltered ECG wave is displayed so that changes of waveform are visible.

【**Surgery**】:Use while the signal is distorted by high-frequency or low-frequency interference. During a surgery, selecting the mode【**Surgery**】 can reduce artifacts and the interference from electro-surgical units. Under normal measurement conditions, selecting【**Surgery**】may suppress the QRS complexes too much so as to interfere the ECG analysis.

【**User**】: Users can manually set the switches of various filters as required.

■ **The states of the filter under various ECG modes**

Filter / ECG mode	Drift filter	HUM filter	EMG filter
Diagnosis	Off	Optional	Off
Surgery	Intense	On	Intense
Monitor	Mild	On	Mild
User	Optional	Optional	Optional

Note:Under the mode of【Surgery】and【Monitor】, the state of the filter cannot be regulated. Only under the state【Diagnosis】of【User】can the state be regulated. Please select【Monitor】during monitoring a patient, select【Surgery】under the state of great interference.

◆ **Setting QRS Volume**

The monitor will give out QRS sound according to HR value. Select【**QRS Volume**】in the ECG setting menu to change the QRS volume. The volume can be set to a value between 1 and 6, and also can be silenced.

◆ **Setting the Primary Lead**

Select【**Primary Lead**】in ECG parameter setting menu, and you can

set the primary lead as required, the wave of primary lead will be displayed on the top of the screen.

7.5.2 Setting ECG Waveform

Select one ECG waveform to enter the ECG wave setting menu.

◆ **Setting Wave Gain**

If ECG wave on the screen is too small or be cut much, you shall select**【Wave Gain】**in the ECG setting menu to change the amplitude of ECG wave respectively. The options are**【Auto】**,**【0.25×】**,**【0.50×】**, **【1.00×】**,**【2.00×】** and **【4.00×】**.When selecting**【Auto】**, the monitor will adjust the amplitude of ECG wave automatically.

◆ **Setting Wave Speed**

Select**【Wave Speed】**in the ECG setting menu, and select proper sweep speed in the options.

◆ **Setting Wave Cascade**

Select**【Wave Cascade】**in the ECG setting menu, you can set this wave as cascade display or not.

7.6 ST Monitoring

The monitor performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations and depressions.

ST segment monitoring fuction is not applicable to neonates.

The clinical significance of the ST segment analysis should be determined by a physician.

Warning: Some clinical conditions may make it difficult to achieve reliable ST monitoring, for example:

——If you are unable to get a lead that is not noisy;

——If the patient is continuously ventricularly paced;

——If the patient has left bundle branch block;

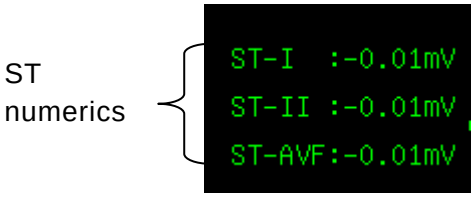
——If arrhythmias such as atrial fib/flutter are present, which may cause an irregular baseline;

You should consider switching ST monitoring off if these conditions are present.

7.6.1 Switching ST On and Off

Select【**ST Setup**】in the ECG setting menu, from the popped up window select【**ST Analsis. Switch**】, it can be set to【**On**】or【**Off**】.

7.6.2 ST Display



ST segment are displayed on the right of ECG parameter area of screen. The quantity for ST segments displaying on the screen depends on the current lead type, and it also depends on the quantity of parameters displaying on the screen. Up to 12 ST segment numerics of 12 leads can be displayed on the screen.

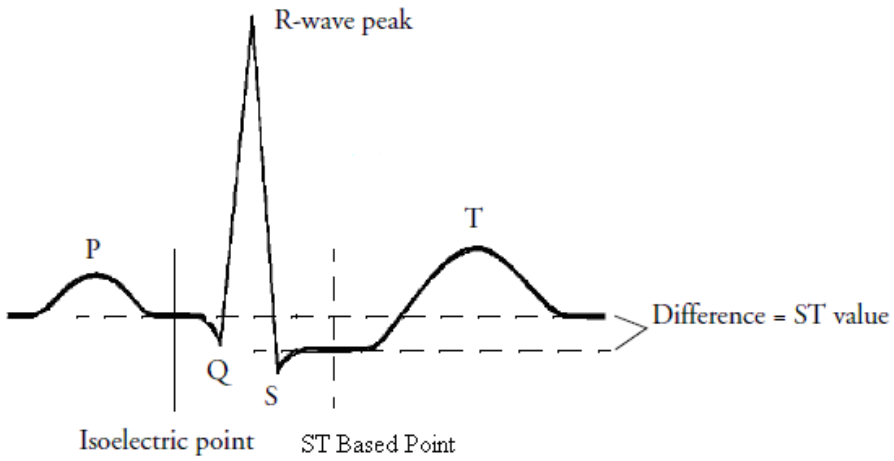
A positive ST value indicates ST segment elevation; a negative value indicates depression.

7.6.3 Setting ST Alarm

The ST alarm limit of each lead can be set in ST analysis setting menu, and in this menu, you can also set alarm switch, alarm level and alarm print switch.

7.6.4 Adjust ST point

The ST value for each beat complex is the vertical difference between the ISO point and the ST point, as shown in the figure below. The isoelectric (ISO) point provides the baseline, the ST point is at the midpoint of the ST segment.



In the ST analysis menu, select【**Adjust ST point**】, the QRS complex will be displayed on the popped up window, the two vertical lines indicate the position of ISO point and ST point. Set the R wave peak as the reference point for ST measurement.

The ST measurement points and ISO point need to be adjusted when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly.

You can select【**ISO**】or【**ST**】and then adjust the point right and left.

Caution: When conducting ST analysis, the system will not consider abnormal QRS complex.

7.7 Arrhythmia Monitoring

Arrhythmia analysis provides information on your patient's condition, including heart rate, PVC rate, rhythm, and ectopics.

7.7.1 Switching Arrhythmia Analysis On and Off

Select【**ARR Analysis**】in ECG setting menu, and set【**ARR Analysis**】to【**On**】or【**Off**】.

7.7.2 PVCs Display

PVC Count 

PVC count indicates the quantity of PVC occurring within 1 minute.

When the PVC quantity in 1minute exceeds the set alarm limit, the monitor will indicate alarm message "Multi PVCs".

7.7.3 Setting Arrhythmia Alarm

Select 【**ARR Analysis**】→【**ARR Alm Setup**】in the ECG setting menu, in the popped up menu, you can set the alarm status for each Arrhythmia, including alarm switch, alarm level and alarm print switch. You can select【**ALL ARR Alm-Resume Default**】,【**All ARR Alm-Alm Switch**】,【**ALL ARR Alm-Alm Level**】and【**All ARR Alm-Alm Print**】to set the alarm status for all arrhythmia.

Arrhythmia can be analyzed by the monitor is shown in the following table:

Arrhythmia Type	**Abbreviation**	**Applicable Patient Type**	**Alarm Level**
ASYSTOLE	ASY	All	Default High
VENT FIB/TACH	VF/VT	All	Default High
PAC	PAC	Non-paced	Default medium,User selectable
RUN PVCs	RUN	Non-paced	Default medium,User selectable
COUPLET	CPT	Non-paced	Default low,User selectable
BIGEMINY	BGM	Non-paced	Default low,User selectable
TRIGEMINY	TGM	Non-paced	Default low,User selectable
R ON T	ROT	Non-paced	Default low,User selectable
TACHY	TAC	All	Default medium,User selectable
BRADY	BRD	All	Default medium,User selectable
MISSED BEAT	MIS	Non-paced	Default low,User selectable
ST Elevation	STH	Non-paced	Default low,User selectable
ST Depression	STL	Non-paced	Default low,User selectable
PNP	PNP	Paced	Default medium,User selectable

Arrhythmia Type	Abbreviation	Applicable Patient Type	Alarm Level
PNC	PNC	Paced	Default medium,User selectable
NOISE	NOS	All	Default low,User selectable
V-TACH	VT	Non-paced	Default High
VPB	VPB	Non-paced	Default low,User selectable
Frequent PVCs	PVCH	Non-paced	Default low,User selectable

7.7.4 Arrhythmia Relearning

◆ **Initiating Arrhythmia Relearning Manually**

During monitoring, if you have any question on the analysis result of arrhythmia, you can start the arrhythmia relearning manually. Select **【ARR Analysis】** in the ECG setting menu, and select **【Arr. Relearning】**. Then, a prompt message of "ARR is relearning" will be displayed in the technical alarm area.

◆ **Automatic Arrhythmia Relearn**

The arrhythmia relearning can be automatically started in the following cases:

1. The arrhythmia function is switched on;
2. The lead type is changed manually;
3. After lead-off, reconnect the lead;
4. The primary lead is changed.

7.7.5 Arrhythmia Review

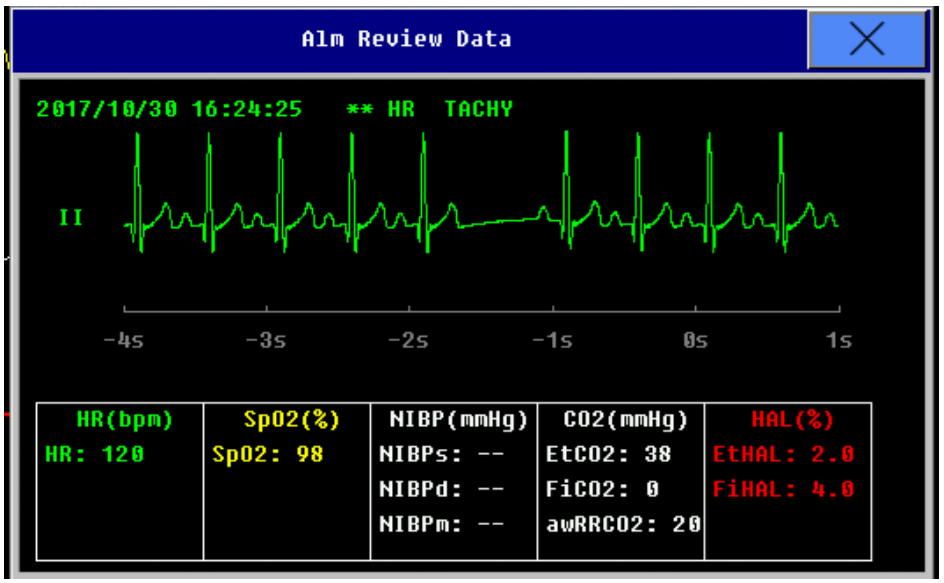
Select **【ARR Analysis】** in the ECG setting menu, and then select **【ARR Review】**to view the Arrhythmia events happened before. Shown as follows:

In the ARR Review window, you can:

——Select an ARR event and then select【**Delete**】to delete the event.

——Select ▲▲ or ▼▼ to turn up or turn down the displaying window.

——Select an ARR event and then select【**Wave**】to enter the ARR Wave window which is as follows:



In the area of smartkeys which is under the the ARR Wave window, you can:

——Select 【**Record**】to record the current displaying ARR waveform and parameter values.

——Select ◀ or ▶ to shift ARR waveform leftwards or rightwards.

——Select ▲▲ or ▼▼ to turn page up or down.

——Select ⏮ or ⏭ to shift ARR waveform to the first or last page.

Chapter 8 Respiration Rate (Resp)

8.1 Introduction

For the respiratory measurement (Resp), the monitor measures the thoracic impedance between two ECG electrodes on the patient's chest. Changes in the impedance due to thoracic movement produce the Resp waveform on the monitor screen. The monitor counts the waveform cycles to calculate the respiration rate (RR).

8.2 Safety Information

Warning:

- **For the sake of safety, all the leads on the ECG cable must be connected to patient.**
- **When monitoring Resp, the ECG cable with electrotome-proof must not be used.**
- **The measurement of Resp is not applicable for patient with excessive motion, otherwise it may cause the mistake of Resp alarm.**

8.3 Monitoring Procedure

1. Connecting ECG Cable

To monitor Resp parameters, it is unnecessary to use other cables and it is only necessary to use the ECG cable.

2. Placing Resp Electrodes

Skin preparation for electrode placement refers to ***chapter 7.3.1***. It is unnecessary to use other electrodes for monitoring Resp, but it is very important to place the electrodes. The Resp signal is always measured between two of the ECG electrodes. If you are using standard ECG electrode placement, Resp is measured between the RA and LL electrodes or between the RA and LA electrodes.

Caution: In order to get the best Resp waveforms, when using RA and LA electrodes for measuring Resp, it is advised to place them horizontally; when using RA and LL electrodes, it is advised to place them cornerways.

◆ **Optimizing Lead Placement for Resp**

If you want to measure Resp and you are already measuring ECG, you may need to optimize placement of the two electrodes between which Resp will be measured for some patients. Repositioning ECG electrodes from standard positions, results in changes in the ECG waveform and may influence ST monitoring.

◆ **Cardiac Overlay**

Cardiac activity that affects the Resp waveform is called cardiac overlay. It happens when the Resp electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrode placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the Resp electrodes. This is particularly important for neonates

◆ **Lateral Chest Expansion**

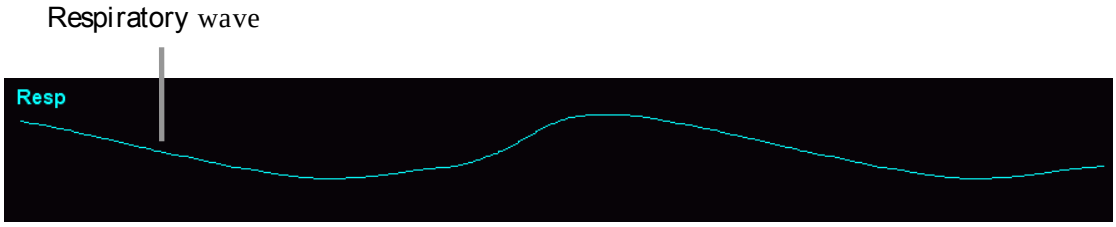
Some patients, especially neonates, expand their chests laterally. In these cases it is best to place the two Resp electrodes in the right midaxillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the Resp wave.

◆ **Abdominal Breathing**

Some patients with restricted chest movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the Resp wave.

8.4 Resp Display

◆ **Waveform Display**



◆ **Parameter Display**

8.5 Setting Resp

8.5.1 Setting Resp Parameter

Select Resp parameter area to enter Resp parameter setting menu.

◆ **Setting Resp Lead**

In the Resp setting menu, select【**Resp Lead**】, and you can select【**RA-LA**】or【**RA-LL**】.

◆ **Setting Apnea Alarm Time**

In the Resp setting menu, select【**Apnea Alm**】, and select the apnea time as required in the options. The monitor indicates an alarm when a pre-adjusted time has elapsed since the last detected breath.

◆ **Resp Anti-Drift**

In the Resp setting menu, select【**Resp Anti-Drift**】, and you can select【**Close**】or【**Open**】.

8.5.2 Setting Resp Waveform

Select Resp waveform area, and then enter the Resp waveform setting menu.

◆ **Setting Wave Gain**

If Resp wave on the screen is too small or be cut much, you shall select【**Wave Gain**】in the Resp setting menu to change the amplitude of Resp wave. The options are【**0.25×**】,【**1×**】,【**2×**】and【**4×**】.

◆ **Setting Wave Speed**

In the Resp setting menu, select【**Wave Speed**】, and select proper sweep speed in the options.

Chapter 9 SpO2

9.1 Introduction

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, usually shortened as SpO_2) adopts the principles of light spectra and volume tracing. The LED emits lights with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.

$$SpO_2\ \% = \frac{\text{oxygenated hemoglobin}}{\text{oxyhemoglobin + deoxyhemoglobin}} \times 100\%$$

The SpO_2 sensor measurement wavelengths are nominally 660nm for the Red LED and 905 nm for infrared LED

9.2 Safety Information

Warning:

- **Use only SpO2 sensors specified in this manual. Follow the SpO2 sensor's instructions for use and adhere to all warnings and cautions.**
- **When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's conditions.**
- **Do not use the monitor and the SpO2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.**
- **Prolonged continuous monitoring may increase the risk of unexpected changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. For neonates, or patients with poor peripheral blood circulation or**

sensitive skin, inspect the sensor site more frequently.

Warning:

- **Check the SpO2 sensor and its package for any sign of damage before use. Do not use the sensor if any damage is detected.**
- **Before use, the operator must ensure the compatibilityies of the monitor, SpO_2 sensor and extension cables; otherwise, this may lead to the burning of patients; do not use damaged sensor or extension cable. Do not soak the sensor into water or make it wet, otherwise it may be damaged.**
- **When disposing the disposable SpO_2 probe or useless SpO_2 probe, please observe all local, state, and federal regulations that relate to the disposal of this products or similar products.**
- **Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.**

Caution:

- **In case it is necessary to add a clip to fix the fingertip sensor, the cable instead of the sensor itself should be clipped. Please note that the cable of sensor should not be pulled with force.**
- **A function tester cannot be used to assess the accuracy of the SpO2.**

Note:

- **The pleth wave is not equal to the intensity of PR signal.**
- **The production divergence and drive current of LED influence the range of the peak wavelength of the emitted light by the oxygen probe.**
- **The monitor does not provide automatic self-examination alarm signal and the operator has to use SpO_2 simulator for self-examination.**
- **To validate the PR accuracy, we reference to the electronic**

pulse simulator the computation the PR accuracy.

9.3 Monitoring Procedure

1. Selecting SpO2 Sensor

Depending on the patient category, weight and application site, you can select the SpO2 sensor as required.

2. Connecting SpO2 Sensor

Plug the SpO_2 sensor cable into the SpO_2 connector on the measurement module.

3. Applying SpO2 Sensor

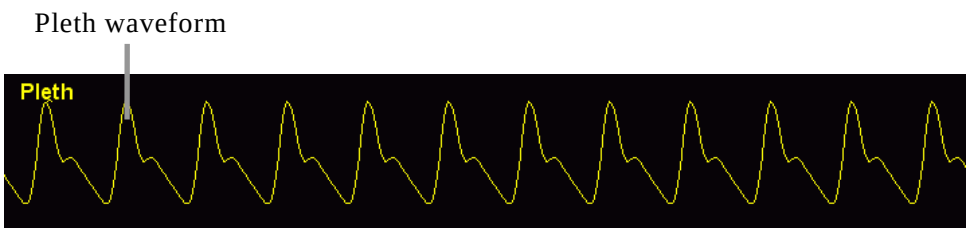
Clean the application site, such as colored nail polish, and apply the sensor to the patient.

Warning:

- **Do not use the SpO_2 sensor on a limb where the NIBP cuff is applied. This may result in inaccurate SpO_2 reading due to blocked blood flow during cuff inflation.**
- **Do not conduct SpO_2 measurement on the finger smeared with nail polish, otherwise unreliable measurement results might be produced.**
- **When using finger sensor, make sure the nail faces to the light window.**

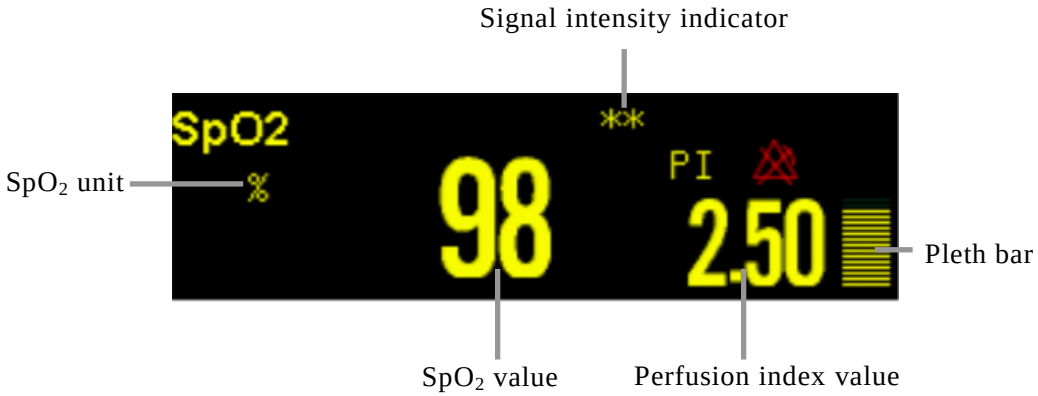
9.4 SpO_2 Display

9.4.1 Waveform Display



9.4.2 Parameter Display

➢ **For BLT SpO_2 and Nellcor SpO_2**



Indicator of signal intensity	Description
"Weak Signal"	The signal strength is too weak to measure.
"*"	The signal strength is low.
"**"	The signal strength is good.
"***"	The signal strength is best.

Warning:

- **When the "Weak Signal" is indicated, it means the signal obtained by the SpO2 probe is too bad. User should check the patient's condition and move the probe to other appropriate position.**

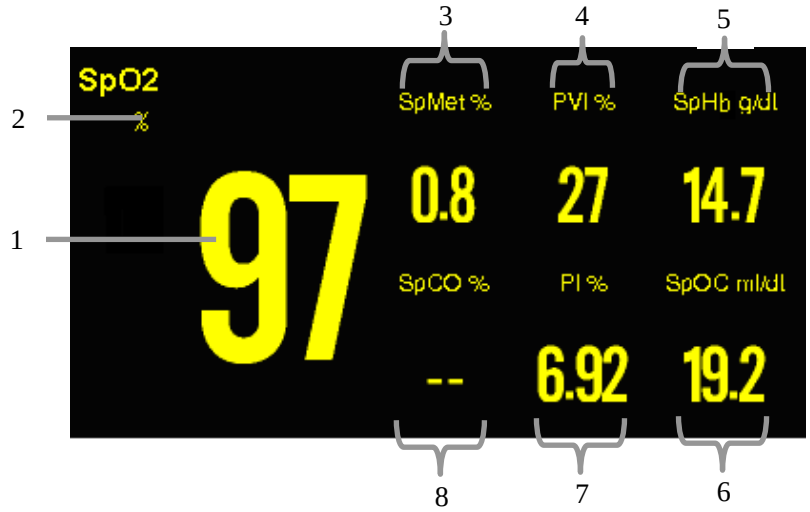
Note:

- **When the SpO2 value is low confidence, the measuring value and "?" will display in turn.**
- **The monitor can support the function of dual SpO2 modules. Furthermore, two SpO2 modules can be accessed simultaneously, and the waveform and values of two modules can be displayed in real time.**

➢ **For Masimo SpO_2**

The Masimo module is intended to monitor the SpO_2, SpMet, PVI, SpHb, SpOC, PI, SpCO of patients.

The following figure shows the SpO2 display screen, the display on your monitor may be looked slightly different.



1. SpO_2 value;
2. SpO_2 unit;
3. SpMet(Methemoglobin Saturation) value and unit;
4. PVI(Pleth Variability Index) value and unit;
5. SpHb(Total Hemoglobin) value and unit;
6. SpOC(Oxygen Content) value and unit;
7. PI(Perfusion Index) value and unit;
8. SpCO(Carboxyhemoglobin Saturation) value and unit.

■ **Parameters Description**

a) Perfusion index(PI) : PI is a value that indicates arterial pulse signal strength as the percentage of pulsatile signal to non-pulsatile signal. The perfusion index allows clinicians to place sensors on optimal sites.

b) Carboxyhemoglobin Saturation(SpCO): SpCO is a value that represents the percentage of carboxyhemoglobin saturation within the blood.

c) Methemoglobin Saturation(SpMet): SpMet is a value that represents the percentage of methemoglobin saturation within the blood.

d) Pleth Variability Index(PVI): PVI is a measure of peripheral

perfusion changes secondary to respiration, or the PI amplitude modulation over a respiration, and can be closely related to intrathoracic pressure changes.

e) Total Hemoglobin(SpHb): SpHb is a measure of the total hemoglobin concentration in arterial blood.

f) Oxygen Content(SpOC): SpOC is a measure of the total oxygen content present in the blood.

9.5 Setting SpO_2

9.5.1 Setting SpO_2 Parameter

Select SpO_2 parameter area to enter SpO_2 parameter setting.

◆ **Setting NIBP measurement on the same limb**

When NIBP and SpO_2 are simultaneously measured to the same limb of patient, the operator shall enter the SpO_2 parameter setting menu and set **【NIBP Same Side】** to **【On】** in order to ensure that the SpO_2 alarm status will keep constant during the NIBP measurement until the completion of NIBP measurement. If **【NIBP Same Side】** is set to **【Off】**, the low perfusion will result in the SpO_2 measurement inaccuracy during the NIBP measurement and trigger the physiological alarm of SpO_2.

◆ **Setting QRS Volume**

Select **【QRS Volume】** in the SpO_2 setting menu to change the QRS volume. The volume can be set to a value between 1 and 6, and also can be silenced.

◆ **Setting Average Time**

The SpO_2 reading shown on the monitor is the average of data collected within a specific time. The shorter the averaging time is, the quicker the monitor responds to the change in the patient's oxygen saturation level. Contrarily, the longer the averaging time is, the slower the monitor responds to the change in the patient's oxygen saturation level, but the measurement accuracy will be improved. When a critical

patient is monitored, selecting shorter averaging time will help understanding the patient's state.

You can select【**Average Time**】in the SpO_2 setting menu, and select a proper time as required.

◆ **Setting PR Source**

To set the PR source, you can select the PR parameter area, then select【**PR Source**】. The options of【**ART**】, 【**SpO_2**】,【**SpO_2L**】, 【**HR**】 and【**Auto**】are available.

【**ART**】: The monitor takes ART as the PR source.

【**SpO_2**】: The monitor takes SpO_2 as the PR source.

【**SpO_2L**】: The monitor takes SpO_2L as the PR source.

【**HR**】: The monitor takes HR as the PR source.

【**Auto**】: When the monitor can detect ART signal, the monitor will automatically take the ART as the PR source. If failing to detect the ART signal, the monitor will automatically take SpO_2 as the PR source.

➢ **For Masimo module:**

◆ **Setting Sensitivity mode**

You can set sensitivity mode of Masimo SpO_2 module according to use condition. Select【**Sensitiv.**】in the SpO_2 setting menu with the options of【**Max**】,【**Normal**】or【**APOD**】.

【**Max**】: This mode should be used for the sickest patients, where obtaining a reading is most difficult. The mode is recommended during procedures and when clinician and patient contact is continuous.

【**Normal**】: This mode provides the best combination of sensitivity and probe-off detection performance. The mode is recommended for the majority of patients.

【**APOD**】: This mode is the least sensitive in picking up a reading on patients with low perfusion but has the best detection for probe-off conditions. The mode is useful for patients that are at particular risk of the sensor becoming detached (pediatric, combative, etc.)

◆ **Setting Alarm Delay Period**

In the SpO2 setting menu, select【**Alarm Delay Period**】, and you can select the delay time in the alarms as required in the options.

The delay time can be set in the Maintenance Mode with password, the password can only be get from the factory.

◆ **Setting FastSat mode**

The FastSat mode is clinically applicable during procedures when detecting rapid changes in oxygen saturation is paramount such as induction, intubation and sleep studies.

Select【**FastSat**】in the SpO_2 parameter setting menu, you can select【**On**】or【**Off**】to enable or disable the FastSat mode.

◆ **Setting SmartTone**

【**SmartTone**】is a feature that affects pulse beep and can be selected in the SpO_2 parameter setting menu. When you set it to【**On**】, it will allow the audible pulse beep to beep when the pleth shows signs of motion. The pulse beep is suppressed during signs of motion when SmartTone is set to【**Off**】.

◆ **Setting SpHb mode**

While monitoring Hemoglobin levels, there are two blood sample sources from which Hemoglobin readings can be obtained: arterial and venous. You can select【**SpHb mode**】in the SpO_2 parameter setting menu, and you can select【**Arterial**】or【**Venous**】.

◆ **Setting SpHb Average**

You can select the averaging mode for SpHb value, select【**SpHb average**】in the SpO2 parameter setting menu, and you can select【**Short**】,【**Medium**】or【**Long**】.

◆ **Setting SpHb Precision**

You can select the SpHb precision to be displayed on the screen, select【**SpHb Precision**】in the SpO2 parameter setting menu, and select a proper time as required.

◆ **Setting SpHb Unit**

You can select【**SpHb Unit**】in the SpO_2 parameter setting menu, and select the unit as required. The options are【**g/dL**】and【**mmol/L**】.

◆ **Setting Waveform Mode**

You can select【**Wave Mode**】in the SpO_2 parameter setting menu, and select【**Resp. out**】or【**Resp. in**】.

◆ **View the Version of Firmware**

You can select【**Version**】in the SpO_2 parameter setting menu, and you can view the version of firmware.

9.5.2 Setting SpO_2 Waveform

◆ **Setting Wave Speed**

Select【**Wave Speed**】in the SpO_2 wave setting menu, and select the wave speed in the options as required.

9.5.3 Sat. Alarm (Nellcor SpO2)

With traditional alarm management, high and low alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated, an audible alarm immediately sounds. When the patient % SpO2 fluctuates near an alarm limit, the alarm sounds each time the limit is violated. Such frequent alarms can be distracting.

Nellcor's Sat-Seconds alarm management technique is used to reduce these nuisance alarms.

The Sat-Seconds feature is available with the Nellcor SpO2 module to decrease the likelihood of false alarms caused by motion artifacts. To set the Sat-Seconds limit, select【**Sat.Alm**】in the【**SpO2 Setup**】menu and then select the appropriate setting.

With Sat-Seconds alarm management, high and low alarm limits are set in the same way as traditional alarm management. A Sat-Seconds limit is also set. The Sat-Seconds limit controls the amount of time that SpO2 saturation may be outside the set limits before an alarm sounds.

The method of calculation is as follows: the number of percentage points that the SpO2 saturation falls outside the alarm limit is multiplied by the number of seconds that it remains outside the limit. This can be stated as the equation:

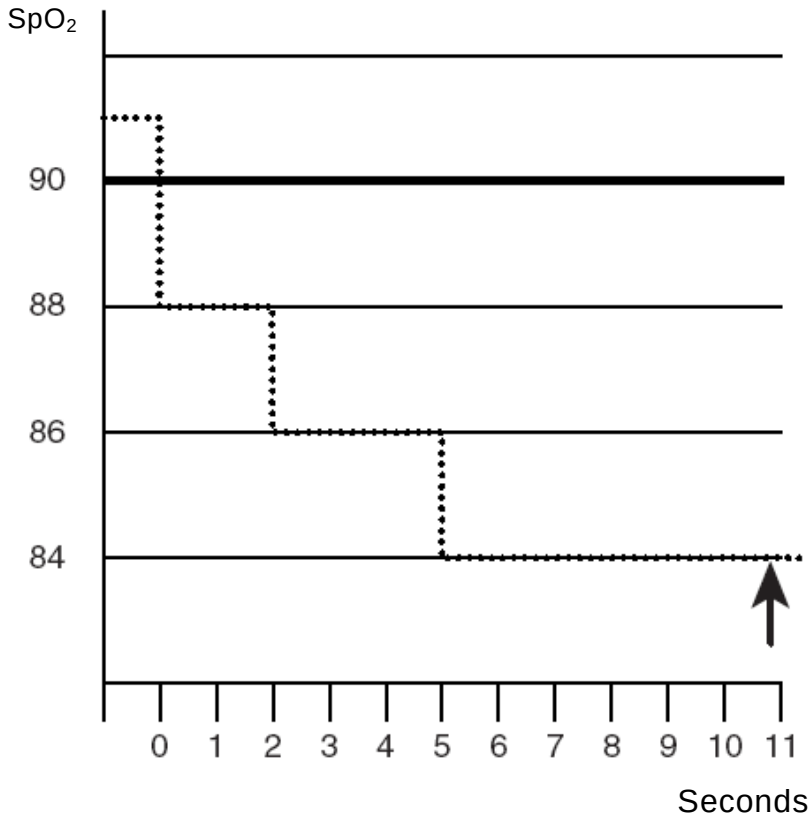
Sat-Seconds= Points × Seconds

Only when the Sat-Seconds limit is reached, the monitor gives a Sat.alarm. For example, the figure below demonstrates the alarm

response time with a Sat-Seconds limit set at 50 and a low SpO2 limit set at 90%. In this example, the patient % SpO2 drops to 88% (2 points) and remains there for 2 seconds. Then it drops to 86% (4 points) for 3 seconds, and then to 84% (6 points) for 6 seconds. The resulting Sat-Seconds are:

%SpO_2	Seconds	Sat-Seconds
2x	2=	4
4x	3=	12
6x	6=	36
Total Sat-Seconds		52

After approximately 10.9 seconds, a Sat-Second alarm would sound, because the limit of 50 Sat-Seconds would have sbeen exceeded.



Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Often, the patient % SpO2 may fluctuate above and below an alarm limit, re-entering the non-alarm range several times. During such fluctuation, the monitor integrates the number of %SpO2 points, both positive and negative, until either the

Sat-Seconds limit is reached, or the patient %SpO2 re-enters the non-alarm range and remains there.

◆ **Setting Sat. Alm**

You can select 【**Sat. Alm**】 and 【**Normal Alm**】.

◆ **Setting Sat. Alm Limit**

After selecting【**Sat. Alm**】,you can select 【**Sat. Alm Limit**】 to set set Sat. Alm Limit to be 10, 25, 50 or 100(system default is 10), this Limit should be matched with the clinical environment and patient conditions.

9.6 Measurement Limitations

If you doubt the SpO_2 measurements, check the patient's vital signs first, then check the monitor and SpO_2 sensor. The following factors may influence the accuracy of measurements:

——Incorrect sensor application or use;

——Significant levels of dysfunctional hemoglobins.(such as carboxyhemoglobin or methemoglobin);

——Intravascular dyes such as indocyanine green or methylene blue;

——Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material)

——Excessive patient movement;

——Venous pulsations;

——Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

——Low perfusion;

——Electromagnetic interference, such as MRI device;

——Electrosurgical units.

The monitor can be used during defibrillation, but the readings may be inaccurate for a short time

Loss of pulse signal can occur in any of the following situation:

——The sensor is too tight;

——There is excessive illumination from light sources such as a surgical lamp, a brilirubin lamp, or sunlight;

——A blood pressure cuff is inflated on the same extremity as the one with a SpO2 sensor attached;

——The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;

——There is arterial occlusion proximal to the sensor.

——The patient is in cardiac arrest or is in shock.

Chapter 10 Temperature (Temp)

10.1 Introduction

The monitor measures Temperature with Temperature sensors. The type of the temperature sensors are surface and coelom. The surface sensor is use to measuring body surface temperature, such as axilla and forehead skin. The coelom sensor is use to measuring the rectum temperature.

The monitor has maximum eight channels for Temp measurement option, and can display the temperature of eight channels and temperature difference (TD) at the same time.

10.2 Safety Information

Warning:

- **Disposable Temp probes must not be re-sterilized or reused.**
- **Should the Temp probe become damaged beyond repair, or for some reason its useful life is considered to be at an end, please observe all local, state, and federal regulations that relate to the disposal of this products or similar products.**

Caution:

- **The self-test of the temperature measurement is performed automatically termly during the monitoring. The test procedure lasts about 1s and does not affect the normal measurement of the Temp monitoring.**
- **The Temp sensors and cables should be handled with care. When not in use, the sensor and the cable should be rounded into loose ring shape.**
- **If the ambient temperature is over 15-35℃, the temperature measurement may be inaccurate.**

Note:

- **If Temp to be measured beyond probe's measuring range, over measuring range alarm will be displayed on the screen. Check if probe is on the corresponding patient body site, or change it to other site on the patient.**
- **If "Temp self-check error" is displayed on the screen, it is possibly that something is wrong with the temperature module, the operator should stop using the module and contact the manufacturer.**
- **The minimum measuring time of TEMP recommend to 15min.**
- **The mode of operation of our TEMP is direct mode.**

10.3 Monitoring Procedure

1. **Selecting Temp probe**

   Select the correct type and size of probe for your patient.

2. **Connecting Temp probe to monitor**

   Plug the Temp cable into the Temp connector on monitor.

3. **Applying the probe to patient**

   Apply the probe to the patient correctly.

4. **Selecting Label**

   Select an appropriate temperature label.

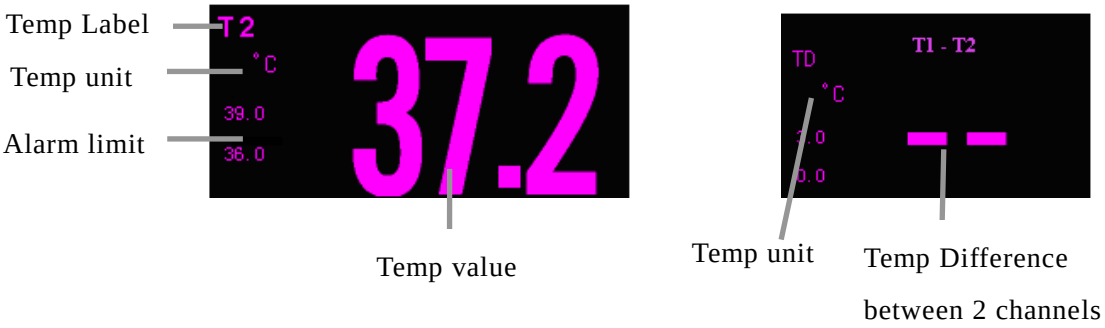
5. **Checking the Alarm Setting**

   Check that the alarm settings are appropriate for this patient and this type of Temp measurement.

Warning: Make sure you set alarm limits for the correct label. The alarm limits you set are stored for that particular label only. Changing the label may change the alarm limits.

10.4 Temp Display

The monitor can display Temp of each channel (such as T1 and T2) and the Temp difference between two channels (TD).



10.5 Setting TD

◆ Selecting Param A and Param B

TD is the difference between two channels of Temp, i.e.the difference between Param A and Param B. You can select【**Parameter A**】and 【**Parameter B**】in the TD parameter setting menu, and select the temp label displayed on the screen as required.

Chapter 11 NIBP

11.1 Introduction

The monitor uses the oscillometric method for measuring NIBP. It is applicable for adult, pediatric and neonatal patients. The method of oscillometric indirectly estimates the systolic and diastolic pressures within the blood vessels by measuring the change of the pressure within blood pressure cuff along with the volume of the arteries and calculates the average pressure.

The NIBP measurement is suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator according to IEC 80601-2-30.

A physician must determine the clinical significance of the NIBP measurement.

11.2 Safety Information

Warning:

- **Check the patient category before monitoring. Incorrect settings may result in some risk for patient safety. Higher adult setting is not suitable for pediatric and neonatal patients.**
- **Do not use the NIBP with pregnant or pre-eclamptic patient Do not use the NIBP cuff on the arm of a mastectomy patient, we suggest measuring blood pressure on their legs.**
- **Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.**
- **Use clinical judgement to decide whether to perform frequent Auto BP measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
- **Use clinical judgement to decide whether to perform Auto BP measurement on the patients of thrombasthemia.**
- **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 cuff inflation.

- **If you doubt the NIBP measurements, check the patient's vital signs by other device, and then check the monitor.**
- **The continuous cuff pressure due to connection tubing kinking may cause the effect of blood flow interference and resulting harmful injury to the patient.**
- **Do not use the cuff over a wound, as this can cause further injury.**
- **That pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.**

11.3 Measurement Limitations

NIBP measurements are impossible with heart rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

——with excessive and continuous patient movement such as shivering or convulsions;

——if a regular arterial pressure pulse is hard to detect;

——with cardiac arrhythmias;

——with rapid blood pressure changes;

——with severe shock or hypothermia that reduces blood flow to the peripheries;

——on an edematous extremity.

11.4 Measurement Mode

There are three modes of measuring NIBP:

- **Manual**: measurement on demand.
- **Auto:** continually repeated measurements in the set interval.
- **STAT:** rapid series of measurements over a five minutes period, then the monitor returns to the previous mode. Use only on supervised patients.

■ **Sequence**: up to four measurement cycles which will run consecutively, with number of measurements and interval between them configurable for each cycle.

11.5 Monitoring Procedure

11.5.1 Preparing to Measure NIBP

1. Check the patient category, if you want to change the patient category, select【**Main menu**】smartkey→【**Patient Manage.**】→【**Admit Patient**】and select the patient type as required.

Note:

To obtain accurate routine resting blood pressure measurements for the condition hypertension including as following steps:

- **Keep the patient in a suitable position, including**
  - **1) comfortably seated;**
  - **2) legs uncrossed;**
  - **3) feet flat on the floor;**
  - **4) back and arm supported;**
  - **5) middle of the cuff at the level of the right atrium of the heart;**
- **Suggest the patient to be relax as much as possible and not talk during the measurement procedure,**
- **Suggest that 5 min should elapse before the first reading is taken;**
- **Suggest that operator position on the right side of the monitor in normal use.**

---

2. Select the appropriate cuff according to patient category.

——Check the limb circumference of patient.

——Select the appropriate cuff (The applicable limb circumference for cuff is marked on the cuff). The width of the cuff should be about 40% of the limb circumference (50% for neonate) or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle 50%~80% of the limb.

Note: The accuracy of measurement of BP depends on the suitability of the cuff.

---

3. Confirm the cuff has been entirely deflated.

4. Plug the air pipe plug of cuff into the connector (NIBP) of monitor until the plug and socket contact well. (Attention: you shall nip the part of air pipe plug of cuff close to socket with fingers before pulling it out.)

5. Tie the cuff to the upper arm or thigh of the patient.

Ensure the mark "Φ" on the cuff shall lie above artery while the air pipe shall be under the cuff, ensuring the air pipe outside the cuff does not knot and the white line on the cuff shall be within the range " ⟺ ", otherwise the cuff shall be replaced.

The monitor is applicable for standard neonatal cuff, pediatric cuff and adult cuff. (Including arm cuff and thigh cuff).

Note:

- **While measuring blood pressure, the patient must keep calm without any talk.**
- **The cuff tied on the limb shall be on the same level as the patient's heart so as to avoid the reading error resulting from the hydrostatics effect of the blood flow between the heart and cuff. If the cuff position is higher than heart level, the BP reading will be lower, the measured result shall be added 0.75mmHg (0.1kPa) for each centimeter higher; in case the cuff position is lower than heart level, the BP reading will be higher, the measured result shall be deducted 0.75mmHg (0.1kPa) for each centimeter lower.**
- **The environmental or operational factors which can affect the performance of the NIBP module and its BP reading :**
  1) **Avoid compression or restriction of pressure tubes.Air must pass unrestricted through the tubing.**
  2) **The bladder of the cuff is not folded or twisted.**
  3) **A wrong cuff size, and a folded or twisted bladder, can cause inaccurate measurements**
  4) **Do not wrap the cuff too tightly around the limb.**

6. Connect the cuff with the air-inflating pipe and ensure the pipe connecting cuff is not knotted or tangled while placing pipe naturally without any press or force.

11.5.2 Starting and Stopping Measurements

Use the  button or  smartkey to start or stop measurements.

11.5.3 Auto Measurement

1. Select NIBP parameter area, and enter NIBP setting menu.
2. Set【**Measure Mode**】to【**Auto**】.
3. Set【**Interval**】in the options as required.
4. Start the Auto measurement manually for the first time, and then enter the Auto mode, the first auto measurement will be started within 5min, and then the monitor will start the measurement continually repeated in the set interval after the first measurement.

Warning: Prolonged NIBP measurements in Auto mode are associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the NIBP measurements.

11.5.4 STAT Measurement

Select  smartkey, or select NIBP parameter area, and select【**STAT**】to start STAT measurement. The measurement will last 5min.

11.5.5 Sequence Measurement

1. Select NIBP parameter area, and enter NIBP setting menu.
2. Set【**Measure Mode**】to【**Sequence**】.
3. Select【**Set Sequence**】to enter the Setup NBP Sequence window.

Up to four measurement cycles can be setup which will run consecutively. For each cycle you can set the number of measurements and the interval between them.

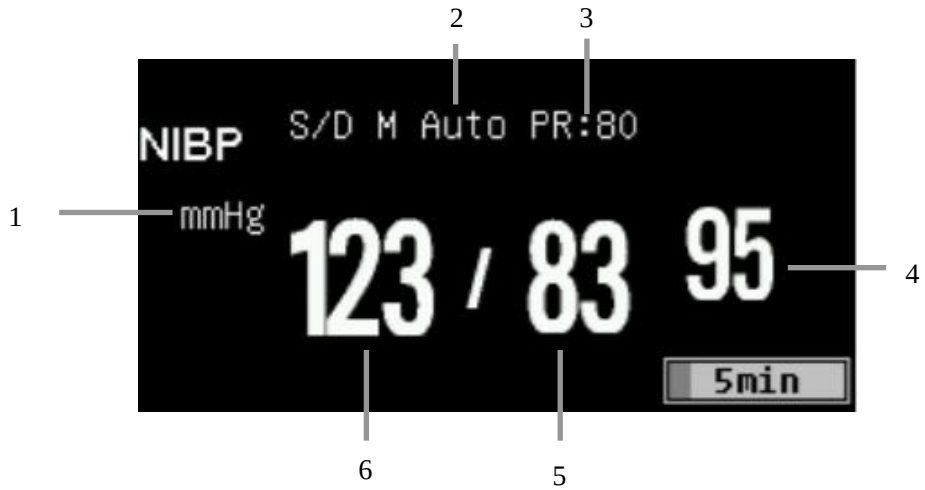
4.Select each sequence in turn and select the number of measurements and the time interval between the measurements.

5.NBP monitoring will end after the last measurement of the cycle.

When the NBP measurement mode is set to Sequence, the repetition time for Auto mode cannot be changed.

11.6 NIBP Display

There is no waveform displayed for NIBP measurement, the NIBP readings are displayed in the parameter area. The following figure shows the NIBP display screen, the display on your monitor may be looked slightly different.



1. Pressure unit
2. Measurement mode
3. PR value
4. Mean arterial blood pressure
5. Diastolic blood pressure
6. Systolic blood pressure

11.7 Setting NIBP

11.7.1 Setting Unit

Select NIBP parameter area, and select【**Unit**】in the NIBP setting menu, and the options are【**mmHg**】or【**kPa**】.

11.7.2 Setting Initial Cuff Inflation Pressure

Select NIBP parameter area, and select【**Inflation**】in the NIBP setting menu, set the initial cuff inflation pressure according to patient type and requirement.

11.7.3 Setting Assisting Venous Puncture

You can use the NIBP cuff to cause sub-diastolic pressure, and block the venous blood vessel to assist venous puncture.

1. Select the NIBP parameter area, and enter the NIBP parameter setting menu.
2. Select【**Venipunc. Press**】, and set to a proper value.
3. Select【**Stat/Stop Assist Venipunc.**】to start it.
4. Puncture vein and draw blood sample.
5. Select【**Stat/Stop Assist Venipunc.**】again to deflate the cuff. The cuff deflates automatically after a set time if you do not deflate it.

11.7.4 NIBP Resetting

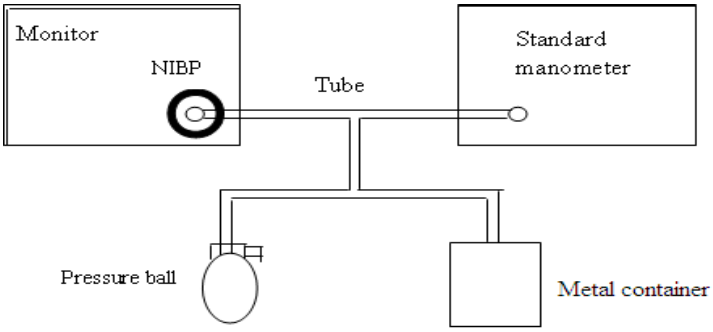
Select NIBP parameter area, and select【**Reset**】, then the inflation value of blood pressure pump restores to the initial value. In case the blood pressure pump doesn't work as normal but without any prompt, the blood pressure pump can be checked by reset, thus the blood pressure pump in abnormal condition due to unexpected reason will automatically restore.

11.8 NIBP Calibration

The maintenance and calibration of NIBP measurement is necessary for every year. If you need to maintain NIBP, please contact the professional service personnel.

Calibration tools: 3 way connector, pipe, roundness pump, metal container (500±25 ml), standard manometer (Calibration already, precision over 1 mmHg)

1. Connect monitor, manometer, roundness pump and metal container as follows.



2. Reading of manometer should be 0 before deflate, if not, cut the connection until it return to zero.

3. Select【**Maintenance**】→input password→【**Main Menu**】→【**Maintenance**】→【**Machine Maintenance**】→【**NIBP Maintenance**】→【**Adult**】→【**NIBP Calibration**】.

4. Turn up pump output pressure to 150 mmHg,the pressure showed by monitor and consult manometer can't be over 3 mmHg,if not, setting【**Press Calibration**】for 150 mmHg,select【Ok】key in right of the menu.

Chapter 12 IBP

12.1 Introduction

The method of IBP measurement is direct measuring the BP of artery or veins on the pressure sensor mainly through liquid coupling so as to obtain the pressure curve of the continuous BP.

12.2 Safety Information

Warning:

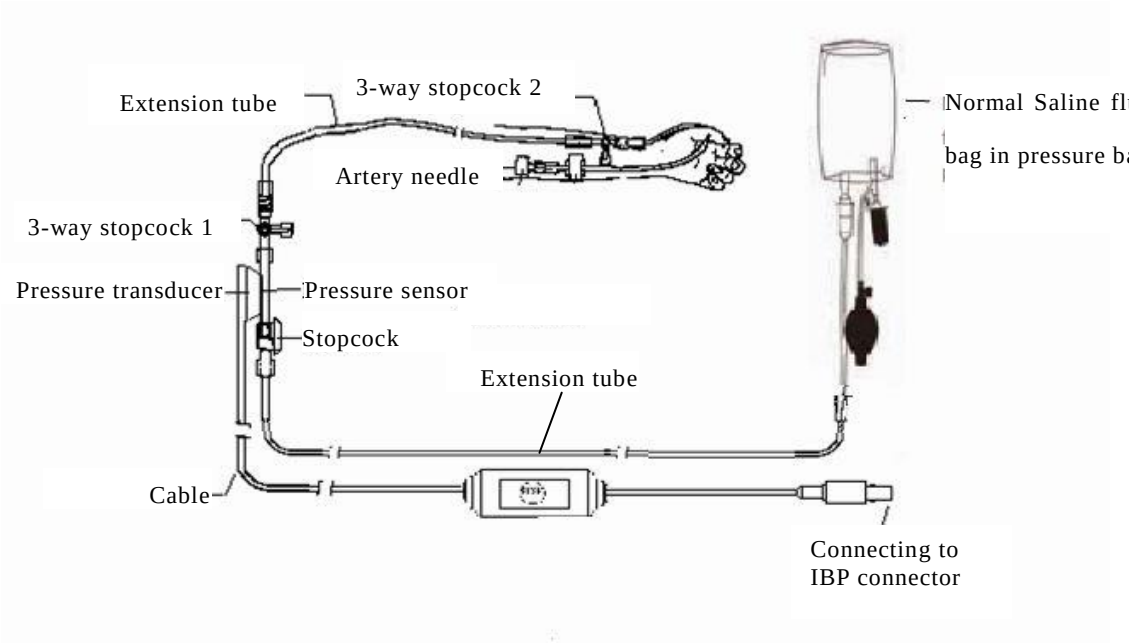
- **It is imperative to only use the IBP transducer provided by manufacturer or specified in this manual. Disposable pressure transducer should not be reused.**
- **The operator should avoid contact with the conductive parts of the accessories when being connected or applied.**
- **When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided conductive connection to the HF equipment to protect against burns to the patient.**

12.3 Monitoring Procedure

1. Plug the IBP cable into the IBP connector on the monitor.
2. Connect IBP cable to the disposable pressure transducer.
3. Fill the transducer and extension tube with saline water mixed with heparin. Press the stopcock to expel the saline water from the air outlet to exhaust all air from the tubing. Ensure that the transducer and stopcocks are free of air bubbles.
4. Select a proper pressure label.
5. Zero the pressure transducer. (Please refer to ***chapter 12.7***)
6. Connect the extension tube of the transducer and blood vessel with the

artery needles and secure them, then make sure 3-way stopcock 1 and 3-way stopcock 2 (See the following figure) are in a state of ON. At this moment, BP waveforms should appear on the screen of the monitor.

7. Flush the system once with saline water mixed with heparin every 15min, this will keep the tubing without jam.



Warning:

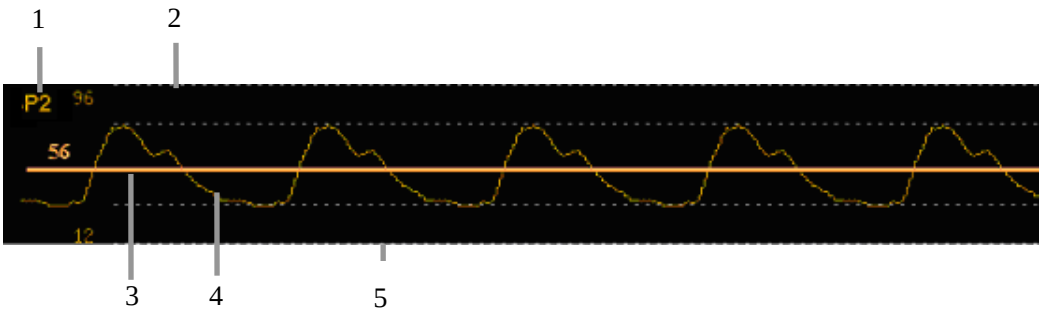
- **The pressure measuring side of the transducer should be on the same level as the heart of the patient in the process of zero-setting and measurement.**
- **If air bubbles appear in the tubing system, flush the system with the infusion solution again. Air bubbles may lead to a wrong pressure reading.**
- **If measuring intracranial pressure with a sitting patient, level the transducer with the top of the patient's ear. Incorrect leveling may give incorrect values.**

Caution: The monitoring procedure may be different depending on the different IBP accessories, please conduct the IBP measurement as actual status.

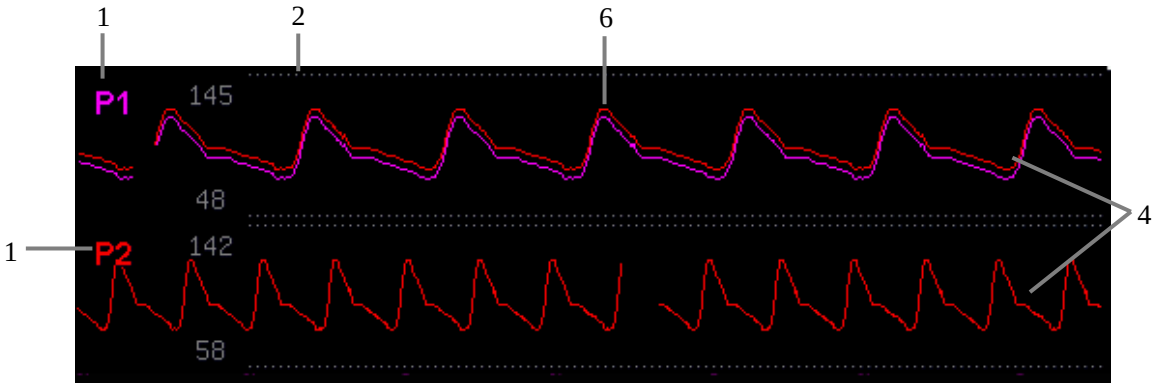
12.4 IBP Display

◆ **Waveform Display**

One channel:

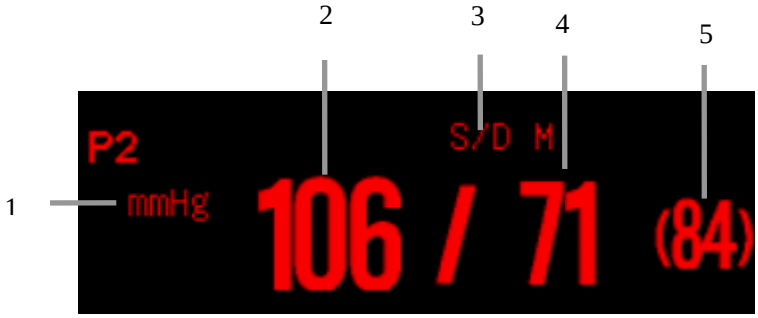


Double channels:



1. IBP label
2. Upper scale of pressure
3. High resolution cursor
4. IBP waveform
5. Lower scale of pressure
6. Interposition of IBP curves

◆ **Parameter Display**



1. Pressure unit: mmHg，kPa or cmH_2O
2. Systolic blood pressure
3. Display format
4. Diastolic blood pressure
5. Mean arterial blood pressure

12.5 Setting IBP

12.5.1 Setting IBP Parameter

Select IBP parameter area to enter IBP parameter setting menu.

◆ **Setting Unit**

Select IBP parameter area, and select【**Unit**】in the IBP setting menu, and the options are【**mmHg**】,【**kPa**】or【**cmH_2O**】.

◆ **Setting Display Format**

Select【**Display Format**】in the IBP setting menu, and the options are【**S/D M**】,【**S/D**】,【**Mean**】or【**M S/D**】.

12.5.2 Setting IBP Waveform

Select IBP waveform area, and enter the IBP waveform setting menu.

◆ **Setting Wave Speed**

Select【**Wave Speed**】in the IBP waveform setting menu, and select the wave speed in the options as required.

◆ **Setting Wave Scale**

Select【**Wave Scale**】in the IBP waveform setting menu, and you can select【**Auto**】or【**Manual**】. When selecting【**Manual**】, you can adjust the position of upper scale and lower scale manually. While selecting【**Auto**】, the monitor will adjust the wave scale according to actual IBP waveform range automatically.

◆ **Setting overlap IBP**

Select【**IBP overlap**】in the IBP waveform setting menu, you can select the IBP waveform that need to overlap. The overlap IBP waveforms will be displayed on IBP waveform area at the same time.

◆ **Setting High Resolution Cursor**

It is suggested to use the high resolution cursor when you want to scale the IBP waveform more accuracy. Select【**High Res. Cursor**】in the IBP waveform setting menu, and adjust the position of high resolution cursor as required. The high resolution cursor will be displayed on IBP waveform at the same time.

12.6 Calculating Cerebral Perfusion Pressure

The monitor can calculate the difference between mean arterial pressure(ART) and the intracranial pressure(ICP). The difference is cerebral perfusion pressure , which is labeled CPP. Therefore, the CPP value will be displayed on the screen only when the ART and ICP are displayed at the same time.

12.7 Zeroing the Pressure Transducer

To avoid inaccurate pressure readings, the monitor requires a valid zero. Zero the transducer in accordance with your hospital policy (at least once per day). You must perform a zero:

——when you use a new transducer or tubing；

——every time you reconnect the transducer cable to the monitor；

——if you think the monitor's pressure readings are not correct；

——when the monitor is restarted.

Procedure of the IBP Transducer Zero:

1. Turn off patient stopcock (3-way stopcock 2) before you start zeroing.
2. The transducer must be vented to atmospheric pressure before zeroing.
3. The transducer should be placed at the same level with the patient

heart, approximately mid-axially line.

4. Select【**Zero**】smartkey, or press the button on the IBP module, and select the IBP label to be zeroed from the options. Select【**Zero**】in the IBP parameter setting menu to start zeroing.
5. Wait 3s for the zeroing procedure end and the pressure value that is displayed on screen will approximately return to zero.
6. After completing zero, close the stopcock to atmospheric pressure, and open the stopcock to the patient.

Caution: During zeroing, the 3-way stopcock near artery needle shall be closed and avoid connecting the artery needle to patient. Ensure that the tubing is free of air.

12.8 Pressure Calibration

The purpose of the calibration is to ensure that the system gives you accurate measurements. Calibration should be performed whenever a new transducer is used or as frequently as dictated by your Hospital Procedures Policy.

IBP pressure calibration should be done by the professional service personnel who you should contact if you need to maintenance IBP.

The Calibration Procedure:

1) Close the stopcock that was open to atmospheric pressure for the zero calibration.
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) Inflate to make the mercury bar rise to 0, 50 and 200 mmHg separately. The difference between the indicated pressure of the sphygmomanometer and the indicated pressure of the monitor will not exceed ±4% or ±4 mmHg, whichever is greater. Otherwise, please contact the manufacturer.

After calibration, disassemble the blood pressure tubing and the

attached 3-way valve.

Warning: You must never perform this procedure while patient is being monitored.

Chapter 13 Carbon Dioxide (CO2)

13.1 Introduction

The monitor adopts infrared absorption technology to measure the carbon dioxide (CO_2) concentration in the breathing airway of patient. Because CO_2 molecule can absorb infrared light of special wavelength, and the amount of absorbed infrared light directly relates to the concentration of CO_2, therefore while the infrared light radiated from the infrared light source passing through the gas sample containing CO_2, part of energy will be absorbed by CO_2 in the gas. At another side of infrared light source, a photodetector is used to measure the remaining infrared energy and convert it to electric signal, which will be compared with the energy of infrared light source and adjusted so as to correctly reflect the CO_2 concentration in the gas sample.

There are two methods for measuring carbon dioxide in the patient's airway:

1. Mainstream: Uses a CO_2 sensor attached to an airway adapter directly inserted into the patient's breathing system.
2. Sidestream: Takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with the CO_2 sensor.

If you use AG module to measure CO_2 parameter, the details refer to ***chapter 14 AG*.**

13.2 Monitoring Procedure

13.2.1 Mainstream CO_2 Module

1. Attaching the CO_2 sensor cable

Plug the cable of CO_2 sensor into CO_2 connector on the monitor.

2. Selecting a proper airway adapter

Select an airway adapter based on the patient's size, ET tube diameter and monitoring situation. For more information refer to the following table

or contact manufacturer.

Airway Adapter Type	ET Tube Diameter
SPU* Pediatric/Adult	＞4.0mm
Adult (Reusable)	＞4.0mm
SPU* Neonatal/Pediatric	≤4.0mm
Neonatal (Reusable)	≤4.0mm

*SPU= Single Patient Use

3. Attaching the airway adapter to the CO_2 sensor

Before attaching the airway adapter to the CO_2 sensor, verify that the airway adapter windows are clean and dry. Clean or replace the adapter if necessary.

Follow these steps:

1) Align the arrow on the bottom of the airway adapter with the arrow on the bottom of the sensor.

2) Press the sensor and airway adapter together until they click.

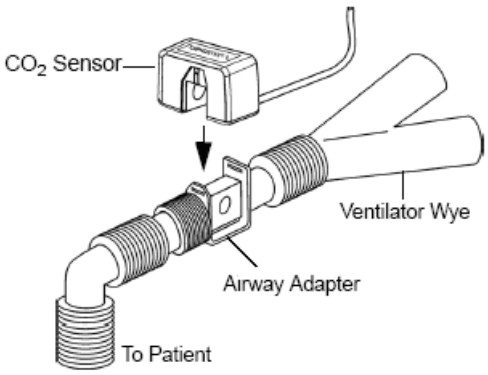
3) Wait for the airway adapter and sensor to warm up.

The monitor will display the "Sensor Warm Up" message for approximately 1 minute while the sensor and adapter warm to operating temperature. The message disappears when the sensor is ready for use.

Caution: Warm up time varies with ambient temperature of the CO_2 sensor.

4. Perform a zero, the details refer to ***chapter 13.5 Zeroing***.

5. After zeroing, attach the airway adapter to the airway circuit as follows:

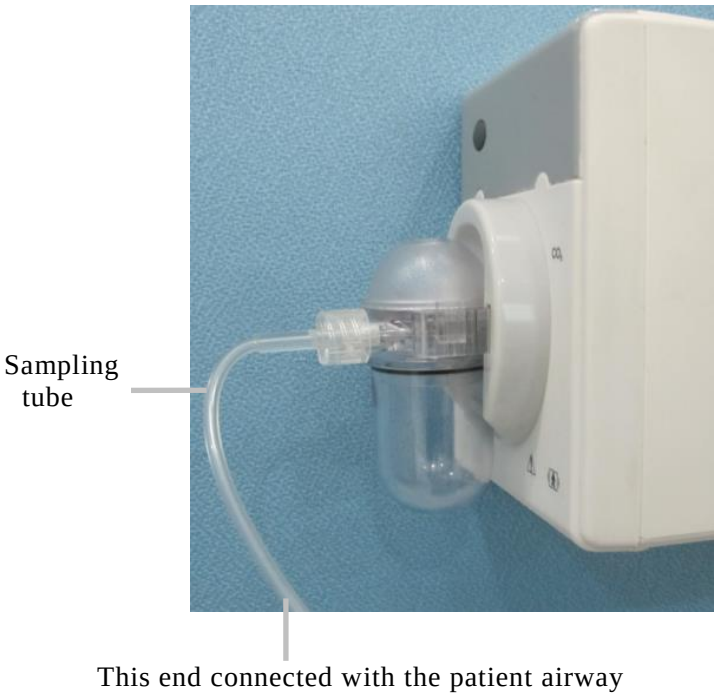


6. Ensure the airway air-proof and ready to measure.

13.2.2 Sidestream CO_2 Module

■ Sidestream CO_2 module with dehydration flask:

1. Fix the dehydration flask to the receptacle on the monitor, and connect the CO_2 measurement components as follows:



Note: Inserting the CO_2 module into slot automatically starts the sampling pump. Removal of the CO_2 module turns the sample pump off.

Caution:

- **Pay attention to the water level of dehydration flask. If the highest water level reaches, please replace the dehydration flask in time to prevent the module from soaking by water.**
- **Please keep the sampling tube clean, and prevent the tube from clogging by dust.**

Note: Dehydration flasks and sampling tubes are disposable, please use products provided or designated by manufacturer.

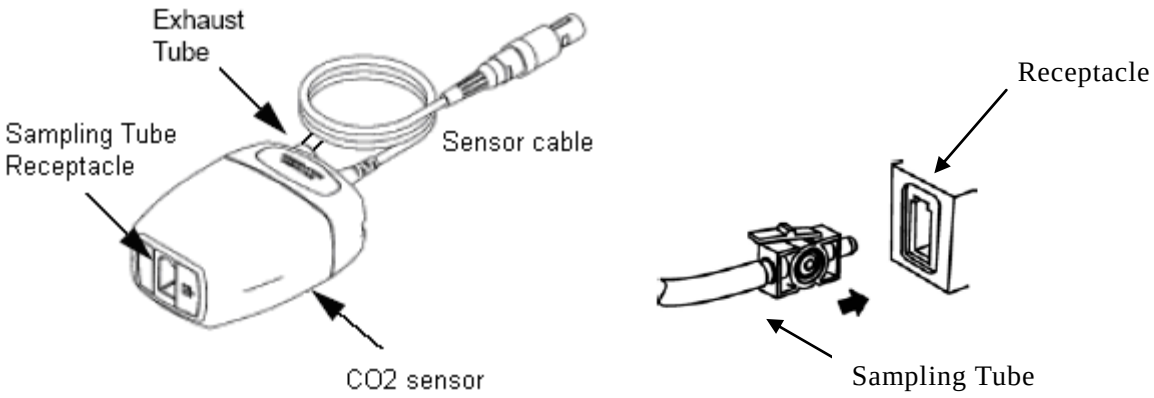
13.2.3 LoFlo CO_2 Module

1. Attaching the CO_2 sensor Cable

   Plug the sensor cable into the CO_2 connector on the monitor.

2. Attaching the Sampling Tube

   Insert the sampling tube into the sampling tube receptacle. Shown as follows:



Note:

- **Inserting the sampling tube into the receptacle automatically starts the sampling pump. Removal of the sampling tube turns the sample pump off.**
- **To remove the sampling tube from the sampling tube receptacle, press down on the locking tab and pull the sampling tube from the receptacle.**

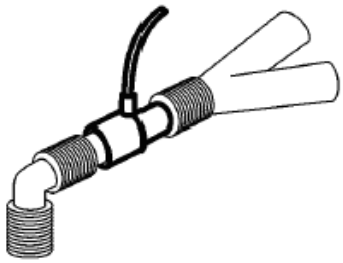
3. If the sampling pump fails to turn on, or runs intermittently, perform a "Zero" procedure. (Refer to the ***chapter 13.5 Zeroing***)

4. Ensure that the CO_2 sensor exhaust tube vents gases away from the sensor environment.

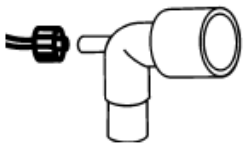
5. Wait for the CO_2 sensor to warm up. The monitor will display the **"**Sensor Warm Up**"** message for approximately 1minute while the sensor warms up to operating temperature. The message disappears when the sensor is ready for use.

6. Applying airway adapter or cannula

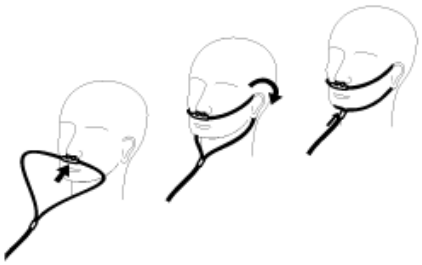
1) For intubated patients requiring an airway adapter: Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y section. Shown as follows:



2) For intubated patients with an integrated airway adapter in the breathing circuit: Connect the male connector on the straight sample line to the female port on the airway adapter. Shown as follows:

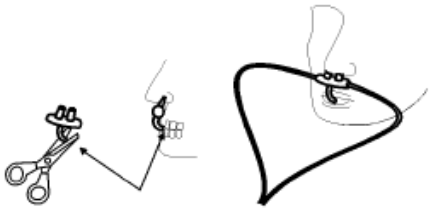


3) For non-intubated patients: Place the nasal cannula onto the patient. Shown as follows:



4) For patients prone to mouth breathing use an oral-nasal cannula. Trim

the oral sampling tip if necessary to fit the patient. It should extend down past the teeth and be positioned in the mouth opening. Remove the cannula from the patient if the tip needs to be trimmed. Shown as follows:



5) For nasal or oral-nasal cannulas with oxygen delivery, place the cannula on the patient as shown then attach the oxygen supply tubing to the oxygen delivery system and set the prescribed oxygen flow.

Caution:

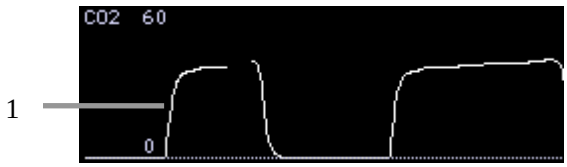
- **Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.**
- **Always disconnect the cannula, airway adapter or sampling tube from the CO_2 sensor when not in use.**

Caution:

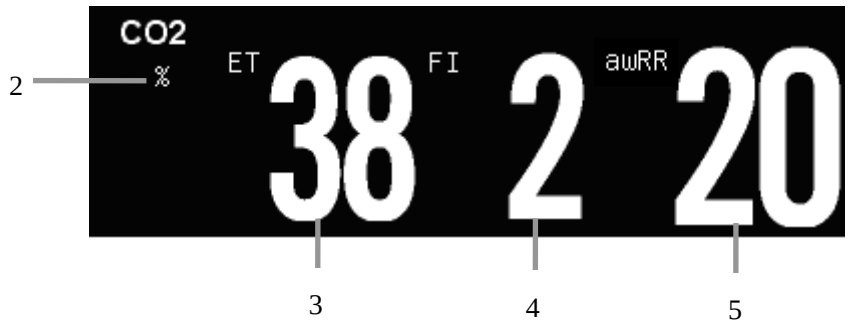
- **Do not insert the things other than sampling tube into receptacle of sampling tube.**
- **The sampling tubes are disposable. Please keep the sampling tube clean, and prevent the tube from clogging by dust. It is advised to replace the sampling tube every 12h (up to 120h of use with filter tip), the sampling tube leaks or has been damaged and contaminated.**

13.3 CO_2 Display

◆ **Waveform Display**



◆ **Parameter Display**



1. CO_2 waveform
2. Unit of CO_2
3. End-tidal CO_2 value ($EtCO_2$)
4. Inspired minimum CO_2 ($FiCO_2$)
5. Airway respiration rate (awRR)

13.4 Setting CO_2

13.4.1 Setting CO2 Parameter

Select the CO_2 parameter area to enter CO_2 parameter setting menu.

◆ **Setting Unit**

Select【**Unit**】in the CO_2 parameter setting menu, and the options are【**mmHg**】,【**kPa**】or【**%**】.

◆ **Setting Apnea Alarm Time**

For mainstream CO2 and LoFlo CO2 module, select【Apnea Alm】in the CO2 parameter setting menu, you can select the apnea time as required in the options. The monitor indicates an alarm when a

pre-adjusted time has elapsed since the last detected breath.

◆ Setting Expiring Cycle

The value of $EtCO_2$ and $FiCO_2$ in the CO_2 parameter area will be refreshed in real-time. As for the mainstream CO_2 module and LoFlo CO_2 module, you can set the method to calculate $EtCO_2$ and $FiCO_2$.

The【**Et Cycle**】can be set in the CO_2 parameter setting menu in maintance mode:

【**One Breath**】: calculate the $EtCO_2$ and $FiCO_2$ by every respiratory wave.

【**10s**】or【**20s**】: a time interval, during which the maximum CO_2 concentration is $EtCO_2$, and the minimum CO_2 concentration is $FiCO_2$.

◆ Setting Alarm Switch

In maintance mode:Select【**Alarm Switch**】in CO_2 parameter setting. Alarm ON or OFF can be set.

◆ Setting CO_2 Corrections

Temperature, water vapor in the patient's breath, barometric pressure, and the proportions of O_2, N_2O and Helium in the mixture all influence CO_2 absorption.

In maintance mode:For mainstream CO_2 module and LoFlo CO_2 module, select【**Set CO_2 Calibra.**】in the CO_2 parameter setting menu, set these options as required before zeroing:

——【**Gas Temp**】:Set the temperature of gas.

——【**Barometric**】:Set the atmospheric pressure.

——【**Calibrate Gas**】:Select the gas type of zeroing, the options are【**Air**】and【**N_2**】.

——【**O_2 Compens**】:Select the concentration of oxygen. It can be set to a value between 0% and 100%. The default value is 16%.

——【**AGT**】:Select the concentration of anesthetic agent. It can be set to a value between 0.0% and 20.0%. The default value is 0.0%.

——【**Balance Gas**】:Select the type of balance gas, the options are【**Air**】,【**N_2O**】and【**HELIUM**】. When the most proportions of the

mixture is air, select【**Air**】;When the most proportions of the mixture is N_2O, select【**N_2O**】. When the most proportions of the mixture is Helium, select【**HELIUM**】.

Warning: Please set the CO2 corrections according to actual situation, otherwise, the measured value may be inaccurate and away from actual value

13.4.2 Setting CO_2 Waveform

◆ **Setting Wave Scale**

Select【**Wave Scale**】in the CO_2 waveform setting menu, and you can adjust the position of wave scale manually, and the waveform amplitude will vary along with it.

◆ **Setting Wave Speed**

Select【**Wave Speed**】in the CO_2 waveform setting menu, and select the wave speed in the options as required.

13.5 Zeroing

Mainstream CO_2 module and LoFlo CO_2 module

Zeroing allows the CO_2 sensor to adjust to the optical characteristics, in order to obtain accurate readings. While zeroing is recommended the first time a CO_2 sensor is connected to the monitor, it is only absolutely necessary when the message"Zero Required"is displayed.

Follow these steps:

1. Ensure that the nasal cannula or airway adapter is not connected to the patient or close to any source of CO_2 (including the patient's, your own, exhaled breath and ventilator exhaust valves).
2. Select【Zero】in the CO2 parameter setting menu, this will start zeroing. The monitor zeroes the sensor and displays the message "Zero In Progress" for about 15-20s on the screen. The message disappears upon completion of the zeroing.

Caution:

- **Always ensure that the sampling tube is properly connected to the LoFlo CO_2 sensor before zeroing.**
- **Always ensure that the mainstream CO_2 sensor is properly connected to the airway adapter before zeroing.**
- **Do not attempt zeroing for 20s after removing the adapter or cannula from the patient's airway. This time allows any CO_2 remaining in the adapter or cannula to dissipate before zeroing.**
- **Do not attempt to zero the sensor while the adapter or cannula is in the patient's airway.**
- **Do not attempt zeroing if the temperature is not stable.**
- **Zeroing with CO_2 in the adapter or cannula can lead to inaccurate measurements or other error conditions. If you attempt zeroing while CO_2 remains in the adapter or cannula, the time required to zero the sensor may be increased.**

13.6 Calibration

The monitor has already been calibrated before leaving factory. User can directly apply it to measuring in normal conditions, to the exclusion of the below conditions.

For Sidestream CO_2 module, please carry out gain calibration and manual offset calibration, when the following conditions happened:

——The module has been used for between half a year and one year.

——The accuracy of CO_2 reading has been doubted by clinical physician.

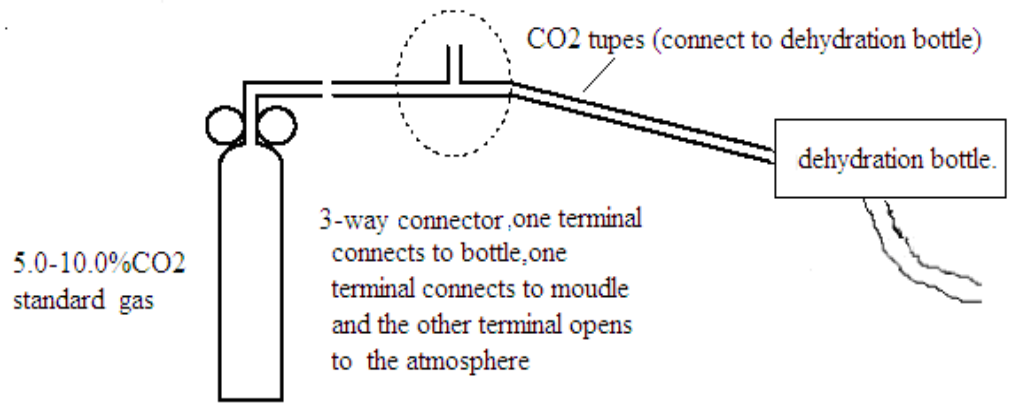
——After the latest calibration, atmospheric pressure or height above sea level varies evidently.

1. Preparation of calibration instruments:

CO2 standard gas (with a concentration of about 5%, and a variety of concentrations can also be prepared), 3-way connector (used for connecting the gas bottles, CO2 tubes and open to air. The 3-way connector mentioned here is not the one in the appendix when our

Company sells the modules, and the 3-way connector in the appendix is used for connecting the respirator or the anesthesia machine), dehydration bottle and CO2 tubes.

2. Make connections in accordance with the following figure:



A. Connect the air outlet tubes of standard gas bottle to one terminal of the 3-way connector, and the middle terminal of the 3-way connector opens to the atmosphere; connect the gas sampling tube provided by our Company to the remaining terminal of the 3-way connector (see the circle part of the above figure), connect the other terminal of the sampling tube to the dehydration bottle and the dehydration bottle is inserted into the bracket of the dehydration bottle.

B. After the airway is connected, start the sampling pump (i.e. start up the CO2 module), warm up the monitor for 30 minutes, and during the warming up, it is allowed to press the sampling tube with a hand for a short time, and as a result, the pump on the module will increase in speed quickly and it can be heard that the sound is markedly increased; in case the pump does not speed up when the sampling tube is pressed by hand, or the pump has only small increase in speed-up, it is due to the improper connections of the dehydration bottle and the bracket and there is a leakage, or at a certain location of the tube from the bracket to the module there is phenomenon of air leakage, at this time, it is inappropriate to conduct calibration, and it is necessary to check out the leaking point and eliminate the leaking point before conducting calibration, otherwise, due to air leakage, it will lead to the lowering of

the measured values. After monitor warm-up, switch on the standard gas, observe the rotation speed of the pump on the module; if the pump rotates very slowly, it indicates the air flow of the standard gas output is too big, leading to the fact that high pressure is exerted on the module. At this time, it is necessary to adjust the volume of the standard gas output, until the pump on the module rotates at a normal speed.

3. Gain calibration:

A. Turn the trim knob, and after moving the cursor to the CO2 menu, press the key and change the unit to "%";

B. Turn the trim knob, and after moving the cursor to the main menu, press the key to enter **【Main Menu】→【Maintenance】→【Machine Maintenance】→【CO2 Module Calibration】**, select **【Offset Calibration】** as "manual";

C. Enter CO2 menu, select **【Zero】**, and enter relevant value according to the concentration of the CO2 standard gas and then press **【Ok】**;

D. Observe whether the value displayed by "FiCO2"is consistent with the concentration of the standard gas, and the error shall be ±0.1, and the observation time shall be no less than 1 minute.

Attention:

Within one or two minutes after the standard gas passes through the module, it is necessary to enter the calibration value, and in case the standard gas passes for a long time (for example exceeding 5 minutes) without entering the calibration value, the display value will be slightly lower.

E. Stop sampling pump;

F. Turn the trim knob and after moving the cursor to the CO2 menu, press the key, change the popped-up **【Offset Calibration】** to "Automation", and the unit is set as "mmHg".

◆CO2 Wave value: Hide or show the CO2 wave value

◆Wave Fill Type: Select **【Normal】** or **【Fill】** type of the Wave Fill way.

Caution: User may only calibrate the device under the instruction of the technical personnel authorized by manufacturer. Moreover, incorrect calibrating procedure may result in incorrect reading.

13.7 Removing Exhaust Gases from the System

Warning: When using the LoFlo CO2 measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, or to the anesthesia machine/ventilator, to avoid exposing medical staff to anesthetics.

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the outlet connector of LoFlo CO_2 sensor.

13.8 Safety Information

Warning:

- **Do not position the sensor cables or tubing in any manner that may cause entanglement or strangulation.**
- **Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use cannula kits and on-airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.**
- **Inspect the LoFlo on-airway adapters, LoFlo sampling kits and CO2 airway adapters for damage prior to use. Do not use the LoFlo on-airway adapters, LoFlo sampling kits and CO2 airway adapters if they appear to be damaged or broken.**
- **Replace the LoFlo on-airway adapters, LoFlo sampling kits and CO2 airway adapters if excessive secretions are observed.**

- **Monitor the CO_2 waveform (Capnogram). If you see changes or abnormal appearance check the airway adapters and the sampling tube. Replace it if needed.**
- **Monitor the CO_2 waveform (Capnogram) for elevated baseline. Elevated baseline can be caused by sensor or patient problems.**
- **Do not operate the CO_2 module when it is wet or has exterior condensation.**
- **Do not use device on patients that can not tolerate the withdrawal of 50 ml/min±10 ml/min from the airway or patients that can not tolerate the added dead space to the airway.**
- **Do not connect the exhaust tube to the ventilator circuit.**

Caution:

- **Use only accessories provided by manufacturer**
- **Do not sterilize or immerse the CO_2 sensor in liquids.**
- **Clean the CO_2 sensor and accessories as directed in this manual.**
- **Do not apply excessive tension to the CO_2 sensor cable.**
- **It is recommended that the CO_2 sensor be removed from the circuit whenever an aerosolized medication is delivered. This is due to the increased viscosity of the medications which may contaminate the sensor windows, causing the sensor to fail prematurely.**

Note:

- **This product and its accessories are latex free.**
- **After the life cycles of the CO_2 module and its accessories have been met, disposal should be accomplished following national and local requirements.**
- **Nitrous oxide, elevated levels of oxygen and helium can influence the CO_2 measurement. Please setup gas compensation according to actual state.**
- **Barometric pressure compensation is required to meet the stated accuracy of the CO2 module.**

- **Do not place the airway adapter between the ET tube and the elbow, as this may allow patient secretions to block the adapter windows.**
- **Position the airway adapter with its windows in a vertical and not a horizontal position, this helps keep patient secretions from pooling on the windows.**

Chapter 14 Anesthetic Gas (AG)

14.1 Introduction

AG module is used to measure respiratory and anesthetic gases of a patient during anesthesia, including CO2, N2O, O2 (Only sidestream AG module can measure O2), Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane.

AG module is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room and for applicable versions emergency medicine/emergency transport settings for adult, pediatric and infant patients.

AG module is not intended to be used as the only means of monitoring a patient. They shall always be used in combination with other vital signs monitoring devices and/or professional human judgments of patient condition.

The measuring principle is that anesthetic gas can absorb infrared light. Gases that can be measured by AG module are able to absorb infrared light. Besides, each gas has its own absorption characteristic. First the gas is driven into a sample cell. Then the optic infrared filter selects the infrared light with special wavelength to penetrate this gas. For a given volume, the higher the gas concentration is, the more infrared light is absorbed. We may measure the quantity of the infrared light that have penetrated the gas and then calculate the gas concentration via specialized formula. If you desire to measure multiple gases, you should install various infrared filters in the AG module.

There are two methods for measuring anesthetic gas in the patient's airway:

1. Mainstream: Uses an AG sensor attached to an airway adapter directly inserted into the patient's breathing system.
2. Sidestream: Takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with the AG

module.

Note:

- **This chapter describes the operation of IRMA multi-gas sensor and ISA multi-gas module, if you use the IRMA CO2 or ISA CO2 sensor, please refer to this chapter.**
- **For the operation and technical specification of IRMA CO2 sensor and ISA CO2 sensor, please refer to the IRMA User's Guide and ISA User's Guide, which are delivred to the end-user together with the IRMA and ISA sensor.**

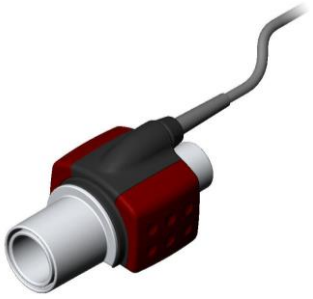
14.2 Monitoring Procedure

14.2.1 Mainstream AG module

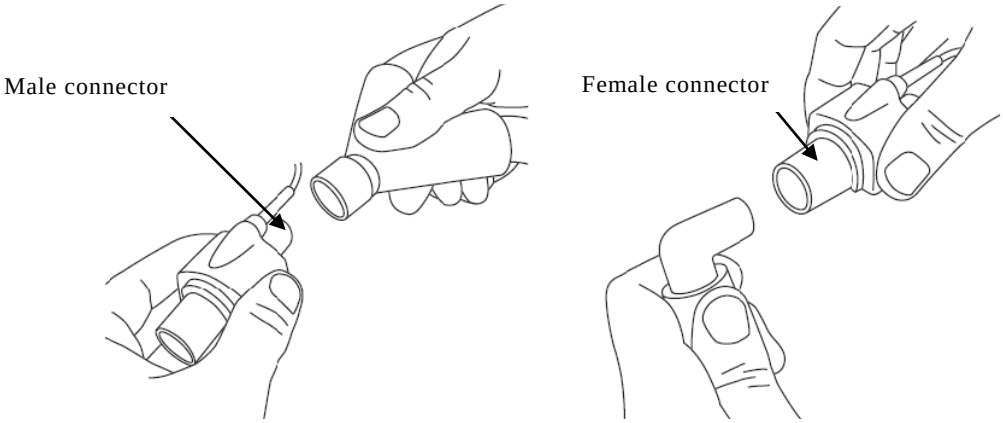
◆ **Preparation for Monitoring:**

1. Plug the AG sensor connector into the AG connector on the monitor.
2. Attach AG sensor on the AG airway adapter. Shown as follows:

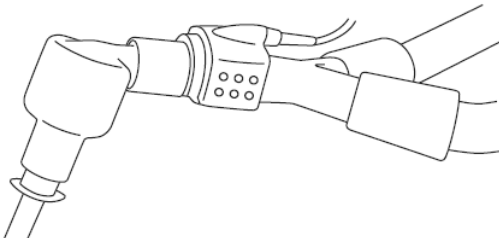
3. A green LED indicates that the AG sensor is ready for use. A blue LED indicates that may measurement of anesthetic gases.



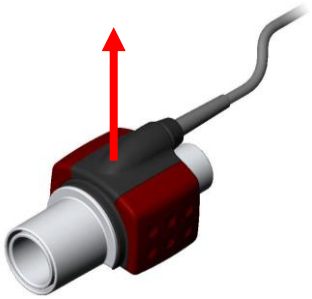
4. Connect the 15 mm male connector of AG airway adapter to the breathing circuit Y-piece, and connect the 15mm female connector of AG airway adapter to the patient's endotracheal tube.



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



5. Unless the AG sensor is protected with an HME always position the AG sensor with the indicating LED pointing upwards



◆Pre-use Check

1. Always verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.
2. Perform the tightness check of the patient circuit with the AG sensor snapped on the AG airway adapter.

The state of the LED on the AG sensor:

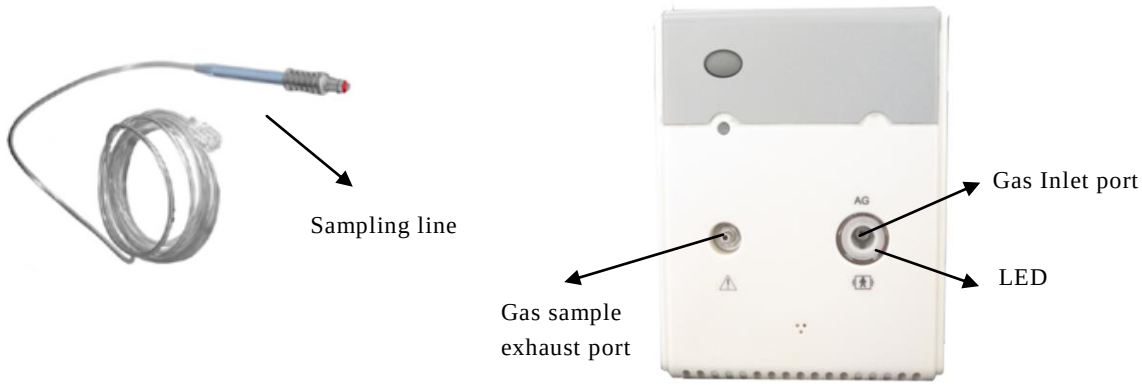
Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light [1)]	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check airway adapter

Note 1: Valid for IRMA multi-gas sensors only.

14.2.2 Sidestream AG module

◆ **Preparation for Monitoring:**

1. Connect a Nomoline sampling line to the inlet port of the AG module.



2. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit.
3. Power up the patient monitor.
4. A green LED indicates that the AG module is ready for use.
5. Perform a pre-use check.

◆ **Nomoline Family sampling lines**

ISA sidestream module 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 (NOMO is ture) section, which removes condensed water. The NOMO section is also fitted with a bacteria filter that protects the ISA

module from water intrusion and cross contamination.

As long as no sampling line is connected, the ISA module remains in a low-power sleep mode. Once the sampling line is connected, the ISA module 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 Airway adapter Set or a com-bination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter. Spontaneously breathing patients could similarly be monitored using a 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.

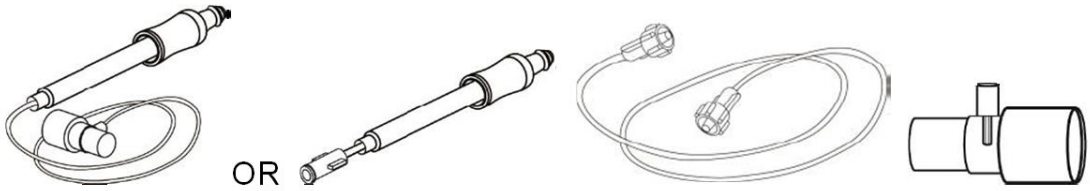


Figure 1.The disposable Nomoline Airway Adapter Set is an alternative to using a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter.

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 measure-ment fidelity when used with the ISA module. 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)

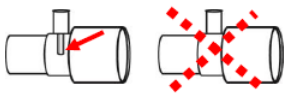


Figure 2. For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left above.

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

◆ **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 module is ready for use.

◆ **Pre-use Check**

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

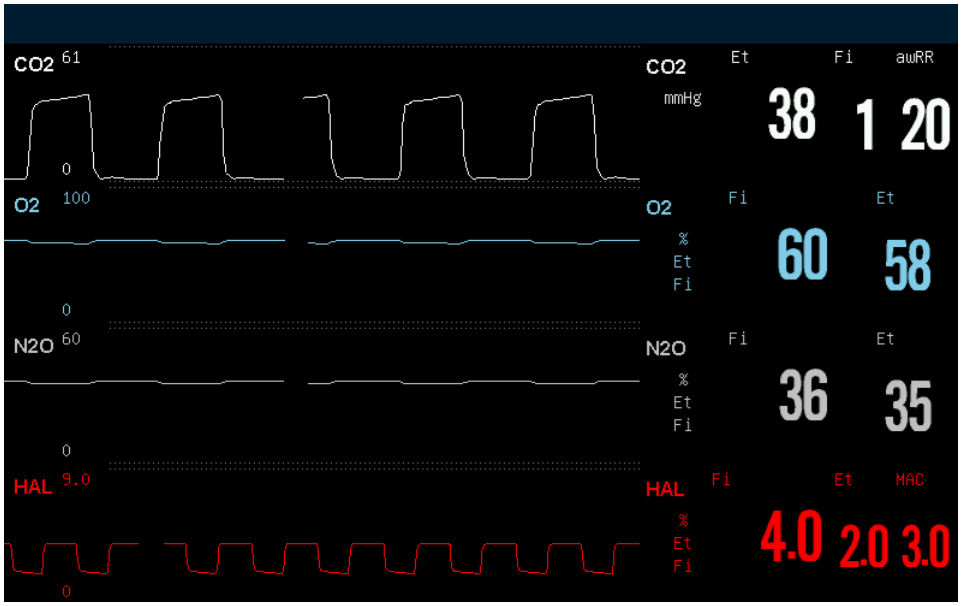
1. Connect the sampling line to the inlet port of the AG module.
2. Check that the AG module shows a steady green light (indicating that the system is OK)
3. For AG module with O_2 option fitted: Check that the O_2 reading on the monitor is correct (21%).
4. Breathe into the sampling line and check that valid CO_2 waveforms and values are displayed on the monitor.
5. Occlude the sampling line with a fingertip and wait for 10 seconds.
6. Check that an occlusion alarm is displayed and that the AG module shows a flashing red light.
7. If applicable: Perform a tightness check of the patient circuit with the sampling line attached.

The state of the LED on the AG module：

Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error

Blinking red light	Check sampling line

14.3 AG Display



AG module can send waves and numerics for all measured gases for display on the monitor screen. Including:

1. Waveform of CO_2, O_2, N_2O and AA*;
2. Et and Fi Value of CO_2, O_2, N_2O and AA;

(It should maked with O2 option fitted)

3. MAC: MAC is defined as the minimum alveolar concentration at steady-state that prevents reaction to a standard surgical stimulus (skin incision) in 50% of patients at 1 atmosphere (i.e. sea level);
4. Gas Unit;
5. Alarm limit of gas;

*AA means a kind of anesthetic agent among the Desflurane (DES), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV) and Halothane (HAL)

The mainstream AG module does not have the function of O2 measurement.

14.4 Setting Gas

14.4.1 Setting Gas Parameter

Select the parameter area of CO_2, O_2, N_2O and AA, to enter the setting menu of each gas.

◆ **Setting Alarm Switch**

Select 【**Alarm Switch**】in the parameter area of CO_2, O_2, N_2O and AA. Alarm ON or OFF can be set.

◆ **AG Type**

All anesthetic agents will be automatically identified.

AG Type	Description	AG Type	Description
HAL	Halothane	ISO	Isoflurane
ENF	Enflurane	SEV	Sevoflurane
DES	Desflurane		

14.4.2 Setting Gas Waveform

Select the waveform area of CO_2, O_2, N_2O and AA, and enter the setting menu of each gas.

◆ **Setting Wave Scale**

Select【**Wave Scale**】in the gas waveform setting menu, and you can select the wave scale in the options as required, and the waveform amplitude will vary along with it.

◆ **Setting Wave Speed**

Select【**Wave Speed**】in the gas waveform setting menu, and select the wave speed in the options as required.

14.5 MAC Calculation

Minimum alveolar concentration (MAC) is a standard for comparing the potency of inhalation anesthetics. The MAC value represents the alveolar concentration of an anesthetic (at one atmosphere) that, in 50 percent of a tested population, prevents gross muscular movement in response to a

painful, standardized stimulus.

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

$$MAC = \frac{\%Et(AA1)}{X(AA1)} + \frac{\%Et(AA2)}{X(AA2)} + \frac{\%Et(N2O)}{100}$$

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

Note:

- **Altitude, patient age and other individual factors are not considered in the formula above.**

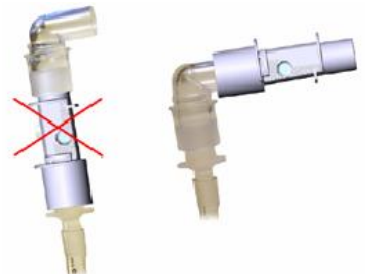
14.6 Safety Information

14.6.1 Mainstream AG module

Warning:

- **The IRMA probe is intended for use by qualified medical personnel only.**
- **Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.**
- **The IRMA probe is not designed for MRI-environments.**
- **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.**
- **No modification of this equipment is allowed.**
- **Disposable IRMA 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 medical waste.**
- **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.**

- **Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.**
- **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. Shown as follows:**



- **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 use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.**
- **The IRMA sensor is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Replace the adapter if rainout/condensation occurs inside the airway adapter.**
- **Use only Masimo manufactured IRMA airway adapters.**
- **The IRMA sensor is not intended to be in patient contact.**

Caution:

- **Do not apply tension to the sensor cable.**
- **Do not operate the IRMA sensor outside the specified operating temperature environment.**
- **Always disconnect the IRMA sensor from the monitor when not in use to prolong the lifetime of IRMA sensor.**

- **The materials of patient breath tubing which is connected to the gas adapter, can't be anti-static and electric ones. Or it will be more dangerous when using HF electrosurgical equipments.**

14.6.2 Sidestream AG module

Warning:

- **The sidestream AG module is intended for use by authorized healthcare professionals only.**
- **Use only airway T-adapters with the sampling point in the center of the adapter.**
- **Do only use sample lines intended for anesthetic agents if N2O and/or anesthetic agents are being used.**
- **Do not operate the ISA sidestream module if the enclosure is damaged.**
- **Use only Nomoline sampling lines manufactured by Masimo.**
- **The sidestream AG module must not be used with flammable anesthetic agents.**
- **Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.**
- **Do not re-use disposable sampling lines.**
- **Do not lift the monitor by the sampling line as it could disconnect from the monitor, casing the monitor to fall on the patient.**
- **Used disposable sampling lines shall be disposed of in accordance with local regulations for medical waste.**
- **Do not use the Nomoline Airway Adapter Set Infant with adult/ pediatric patients**
- **Do not use the sidestream AG module with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.**
- **Check that the gas sample flow is not too high for the present patient category.**
- **Measurements can be affected by mobile and RF communications equipment. Make sure that the sidestream AG module is used in the electromagnetic environment specified in this manual.**

- **The sidestream AG module is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Replace the sampling line if the sampling line input connector starts flashing red, or a Nomoline occlusion message is displayed on the host monitor.**
- **No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.**
- **The sidestream AG module is not designed for MRI environments.**
- **During MRI scanning, the monitor must be placed outside the MRI suite.**
- **Operating high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.**
- **Do not use external ambient cooling of the ISA device.**
- **Do not apply negative pressure to the Nomoline (i.e. by a syringe) to remove condensed water.**
- **Too strong positive or negative pressure in the patient circuit might cause incorrect readings and internal damage.**
- **Strong scavenging suction pressure might cause incorrect readings and internal damage.**
- **Exhaust gases should be returned to the patient circuit or a scavenging system.**
- **Always use a bacteria filter on the evac side if sampled gas is intended to be re-breathed.**
- **Do not place the sidestream AG module in any position that might cause it to fall on the patient.**

Caution:

- **Do not operate the sidestream AG module outside the specified operating temperature environment.**

Caution:

- **Federal law restricts this device to sale by or on the order of a physician. (US Only)**
- **For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**

14.7 AG Maintenance

14.7.1 Zeroing

◆ **Mainstream AG module:**

In order to ensure the accuracy of gas measurement, zero reference calibration should be performed at regular intervals.

Under the following conditions, it is necessary to perform zero reference calibration:

——The measured reading occurs error;

——A"Zero Required" alarm message is displayed;

——When "unspecified accuracy" alarm message is displayed.

——Airway adapter is replaced.

As following procedures:

1. Snap a new AG airway adapter onto the AG sensor. Ensure that the airway adapter is not connected to the breath circuit of patient.
2. Wait for the sensor to warm up:

——For IRMA CO_2 sensor: Allow 10s for warm up of the sensor after power on and after changing the IRMA airway adapter;

——For IRMA AX+ sensor: Allow 30s for warm up of the sensor after power on and after changing the IRMA airway adapter.

3. Select【**Zeroing**】in the AG parameter setting menu, this will start zeroing. The monitor zeroes the module and displays the"Zeroing"message for about 5s.
4. There will be a blinking green light on the AG sensor LED during 5s while Zero Reference calibration is in progress. Wait until the AG indicating lamp light on green (When using CO_2 module, the reading of CO_2 on the screen is"0".) The message disappears upon completion of the zeroing.

Warning: Incorrect zero reference calibration will result in false gas readings.

◆ **Sidestream AG module:**

The sidestream AG module needs to establish a zero reference level for the CO_2, N_2O and anesthetic agent gas measurement. This zero calibration is here referred to as "zeroing".

The sidestream AG module performs zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. An automatic zeroing is performed 1 to 3 times per day, and takes less than 3s for CO_2 module and less than 10s for AG module.

If the sidestream AG module is fitted with an oxygen sensor, the automatic zeroing will also include room air calibration of the oxygen sensor.

Warning: Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO2) in the AG module, ensure that the AG module is placed in a well ventilated place. Avoid breathing near the sidestream AG module before or during the zeroing procedure.

14.7.2 Preventive maintenance

Maintenance for IRMA sensor

The IRMA sensor can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA Airway Adapter prior to cleaning the IRMA sensor.

Maintenance for sidestream AG module

Once every year, or whenever gas readings are questionable, perform a leakage check according to below steps and verify gas readings with a reference instrument or with calibration gas.

Leakage check:

1. Connect a new Nomoline sampling line with male Luer lock to the ISA gas inlet connector and check that the gas inlet connector shows a steady green light.

2. Connect a short silicon tubing with an inner diameter of 3/32" (2.4 mm) to the Nomoline male Luer.
3. Exhale a long breath into the silicon tubing until the CO2 concentration is greater than 4.5 vol% or 34 mmHg.
4. Quickly connect the silicon tubing tightly to the exhaust port.
5. Wait 1 minute until the CO2 concentration has stabilized. Note the value.
6. Wait 1 minute and check that the CO2 concentration has not decreased more than 0.4 vol% or 3 mmHg. If it has decreased more there is a major leakage in the ISA unit or in the Nomoline. Do not operate the ISA if there is a major leakage in the unit.

14.8 Adverse effects on Performance

—Quantitative effects of humidity or condensate;
—Quantitative effects of barometric pressure;
—Interfering gases or vapors; (Refer to chapter A.6.8)
—Other sources of interference. (Refer to Appendix D)

Gas measurement units

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 measured by a cuvette pressure sensor in the ISA sidestream module.

For conversion to other units, the actual atmospheric pressure sent from the ISA sidestream analyzer may be used, e.g.

CO2 in mmHg = (CO2 concentration)×(atm. pressure value in kPa from ISA) ×(750/100).

Example: 5.0% CO2 @ 101.3 kP ⇨ 0.05×101.3×750 / 100 = 38 mmHg

Effects of humidity

The partial pressure and the volume percentage of CO_2, N_2O, O_2 and anesthetic agents depend on the amount of water vapor in the measured gas. The O_2 measurement will be calibrated to show 20.8% at actual

ambient temperature and humidity level, instead of showing actual partial pressure. 20.8% O_2 corresponds to the actual O_2 concentration in room air with 0.7% H_2O concentration (at 1013 hPa this equals for example 25℃ and 23% RH). The measurement of CO_2, N_2O, and anesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS).

When the breathing gas is sampled, and passing the sampling line, the gas temperature will get close to the ambient temperature before reaching the ISA sidestream gas analyzer. As the Nomoline removed all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.

If CO_2 values at BTPS are required, the following equation can be used:

$$EtCO2(BTPS) = EtCO2 * \left(1 - \left(\frac{3.8}{Pamb}\right)\right)$$

where:

EtCO₂ = $EtCO_2$ value sent from ISA [%]

Pamb = Ambient pressure sent from ISA [kPa]

3.8 = Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa]

$EtCO_2$(BTPS) = $EtCO_2$ gas concentration at BTPS [%]

O_2 is assumed to be room air calibrated at a humidity level of 0.7% H_2O.

14.9 Masimo Information

14.9.1 Patents

Masimo holds the following patents regarding products: SE519766; SE519779; SE523461; SE524086. Other patents pending.

14.9.2 Trademarks

Masimo IRMA™, Masimo ISA™, Masimo XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, Masimo GasMaster™ are trademarks of Masimo.

Chapter 15 C.O.

15.1 Overview

Cardiac output (C.O.) module is inserted into the plug-in slot of the monitor for C.O. measurement. C.O. measurement adopts the thermodilution method to invasively measure the cardiac output and other hemodynamic parameters in order to determine the flow rate of the blood circulation system.

As for the thermal dilution method, the cold solution is introduced into the blood circulation system, and measuring the resulting drop in temperature at a downstream site. In the window of the C.O. measurement, the temperature change is shown as a curve, and the monitor will calculate the C.O. value according to this curve. The C.O. value is inversely proportional to the area under this curve. Cardiac output is a continuous variable; therefore, to obtain a reliable C.O. average value, a series of measurements must be carried out. Generally, the average value of multiple thermal dilution measurements is used for therapy decision.

15.2 Safety Information

Warning:

- **Never reuse the disposable accessories.**
- **Never touch the C.O. connecting cable when defibrillation is carried out during the C.O. monitoring period. Otherwise, electric injury, electric shock or other damages might be caused.**
- **Do not soak or wet the connector.**
- **Do not soak the C.O. connecting cable in alcohol; otherwise, the connecting cable might be hardened or damaged.**
- **Never sterilize the C.O. connecting cable at high pressure.**

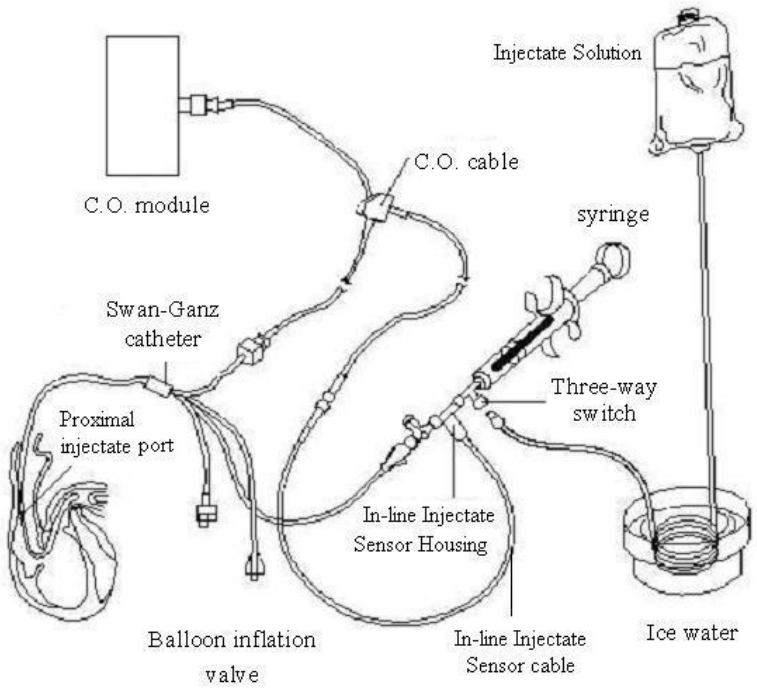
15.3 C.O. Display

There is no waveform display of C.O. measurement on the main interface, only the value of C.O., TB (temperature of blood), TI (injectate temperature), C.I.(cardiac index) and the prompt info can displayed in the parameter zone. See the interface in the following figure:

15.4 Measurement of C.O.

1） Insert the C.O. interface cable to the C.O. module.

2） As shown in the following figure, insert the thermistor connecting cable of the Swan-Ganz catheter into the thermistor connector, and connect the In-line Injectate sensor cable to the In-line Injectate Sensor Housing.



3）Select the C.O. parameter zone to enter into the menu of **【C.O. Setup】**, and select the **【C.O. Measure】** to enter into the measurement window.

4）If the **【Measure Mode】** in the **【Setup C.O. 】** is set as single, when the words "Ready for New measurement" are displayed on the screen, select the **【Start】** to start the C.O. measurement. When there is prompt information "Inject now…" on the screen, please inject the solution to the right atrium port of the Swan-Ganz catheter. The optimal injection rate is 2.5ml/s. The cardiac output, cardiac index and corresponding curve will display in the measurement window in real time.

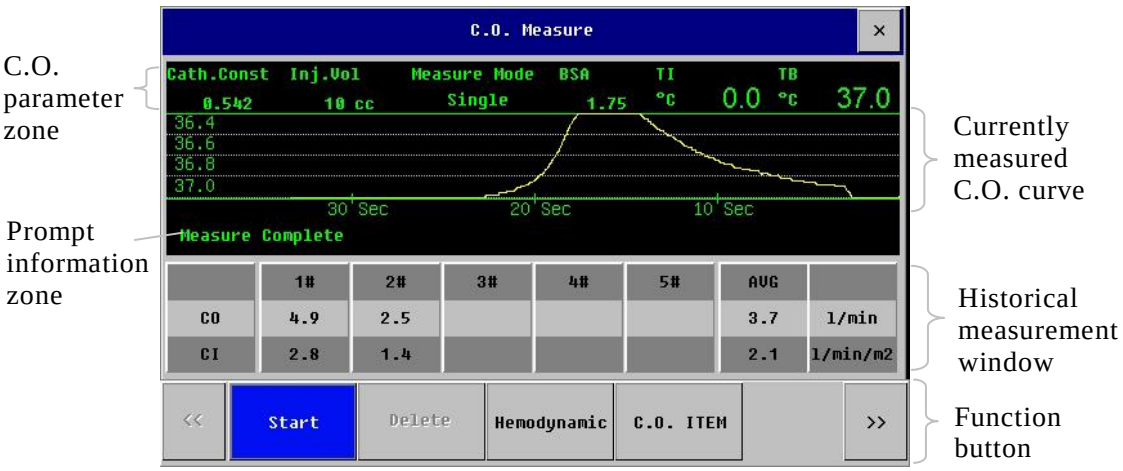
5) If the **【Measure Mode】** in the**【Setup C.O.】** is set as continuous, select the **【Start】** to automatically enter into the continuous measure mode. When there is prompt information "Inject now…" on the screen, please inject the solution to the right atrium port of the Swan-Ganz catheter. The optimal injection rate is 2.5ml/s. The cardiac output, cardiac index and corresponding curve will display in the measurement window in real time. When the first measurement ends, the words "Ready for New measurement, please wait…." are displayed on the screen, and then a new measurement can be started. When there is prompt information "Inject now…"on the screen, please repeat the injection process. When the number of measurements meets the demand, select the **【Stop】** to stop the measurement.

15.5 C.O. Setting

Select the C.O. parameter zone to open the menu of **【C.O. Setup】**, and set the items in the menu.

15.5.1 C.O. Measurement

Select the **【C.O. Measure】** to open the C.O. measurement window as shown in the following figure, please pay attention that whether the TB cable is well connected and the value of C.O. setting is correspond with actual value before C.O. measurement.



Below the C.O. measurement window, the following function buttons are included:

1) **【Start】:** Start a C.O. measurement.
2) **【Delete】:** Selectively delete the measured values in the historical measurement window.
3) **【Hemodynamic】**: Open the menu of **【Hemodynamic】**. See ***1.5.4*** of this chapter for the detailed content of the menu.
4) **【C.O. ITEM】:** Open the C.O. item to browse the measurement results.
5) **【Setup Scale】:** Open the menu of scale setting to adjust the scale range.
6) **【Setup C.O.】:** Open the menu of **【Setup C.O.】**. See ***1.5.2*** of this chapter for the detailed content of the menu.
7) **【Record】:** Record the latest measurement curve and measurement result.

15.5.2 C.O. Setting

Select the **【Setup C.O.】** to set the items in the C.O. setting window in proper order.

1） 【Measure Mode】: Single mode or continuous mode is optional.

2） **【TI Source】:** The temperature source of injectate can be input by the user or measured by the injectate temperature probe. The options include manual and auto. When **【Auto】** is set, the temperature of

injectate can be obtained through the In-line Injectate sensor cable in real time.

3）**【Setup TI】:** When the **【TI Source】** is automatic, the TI is unadjustable; when the **【TI Source】** is manual, the TI is adjustable.

4）**【Inj.Vol】:** 3cc, 5cc or 10cc is optional.

5）**【Cath.Const】**: The set value of the constant can be obtained in the document attached to the Swan-Ganz catheter, which depends on the injectate volume, temperature and the catheter type. To change this value, please select the catheter constant in the window of **【Setup C.O.】**, and input the correct value.

6）**【Weight】**: Set the correct patient's body weight, which is used to calculate the hemodynamic and other parameters.

7）**【Height】:** Set the correct patient's height, which is used to calculate the hemodynamic and other parameters.

8）**【TEMP Unit】**: ℃ or ℉ is optional.

15.5.3 Alarm-related Settings

Select the **【Alm Switch】** in the menu of **【C.O. Setup】** to open or close the alarm.

Select the **【Alm Level】** in the menu of **【C.O. Setup】**; the alarm is divided into low, med and high according to the severity of the alarm.

Select the **【TB Hi Lmt】** in the menu of **【C.O. Setup】** to set the alarm upper limit of the blood temperature.

Select the **【TB Lo Lmt】** in the menu of **【C.O. Setup】** to set the alarm lower limit of the blood temperature.

15.5.4 Hemodynamic

Select the **【C.O. Measure】** in the menu of **【C.O. Setup】**, and select the **【Hemodynamic】** in the menu bar below the C.O. measurement window to open the hemodynamic window.

Important hemodynamic parameter values are displayed in the hemodynamic window. These parameters consist of parameters for monitoring and parameters for calculation. Select the **【Calculation】** to switch the display of parameters for monitoring and parameters for

calculation.

Parameters for monitoring refer to the input values which can be obtained from the patient monitoring data and the values which are inputted manually. The parameters for monitoring, the identifications and the corresponding measurement units are as shown in the following figure:

Parameter	**Abbreviation**	**Unit**
Cardiac output	C.O.	L/min
Heart rate	HR	bpm
Pulmonary artery wedge pressure	PAWP	mmHg
Mean artery pressure	MAP	mmHg
Mean pulmonary artery pressure	MPAP	mmHg
Central venous pressure	CVP	mmHg
End diastolic volume	EDV	mL
Height	Height	cm
Weight	Weight	kg

Parameters for calculation refer to the parameter values automatically calculated by the selection of **【Calculation】**. The parameters for calculation, the identifications and the corresponding measurement units are as shown in the following figure:

Paramete	**Full Name**	**Unit**
C.I.	Cardiac index	$L/min/m^2$
BSA	Body surface area	m^2
SV	Stroke volume	mL
SVI	Stroke index	mL/m^2
SVR	Systemic vascular resistance	$dyn·s/cm^5$
SVRI	Systemic vascular resistance index	$dyn·s·m^2/cm^5$
PVR	Pulmonary vascular resistance	$dyn·s/cm^5$
PVRI	Pulmonary vascular resistance index	$dyn·s·m^2/cm^5$
LCW	Left ventricular work	kg·m
LCWI	Left ventricular work index	$kg·m/m^2$
RCW	Right ventricular work	kg·m
RCWI	Right ventricular work index	$kg·m/m^2$

Paramete	Full Name	Unit
LVSW	Left ventricular stroke work	g·m
LVSWI	Left ventricular stroke work index	g·m/m^2
RVSW	Right ventricular stroke work	g·m
RVSWI	Right ventricular stroke work index	g·m/m^2
EF	Ejection fraction	%

The functions of the buttons below the display window of parameters for calculation are as follows:

【<<*/*】 and **【>>*/*】:** Display the historical input values and the calculation results.

【Range】: Display the normal range or the unit.

【Record】: Print the calculation results.

【Show Input】: Switch the display of the input values and the calculation results.

15.6 Measurement Restrictions

C.O. measurement has its restrictions. It is inadvisable to carry out C.O. measurement when the patient is under one or more of the following circumstances:

- Patient with poor immune system
- Patient with right heart valve disease
- Patient with blood coagulation disorder
- Patient with vessel disease
- Patient with thrombolytic therapy
- Patient with pulmonary hyperpiesia
- Patient with pacemaker
- Patient with systemic hypotension

15.7 Influencing Factors

Some factors influencing the cardiac output include:

1） The temperature and volume of Injectate solution

2） The injection rate, the frequency and the interval

3） The position of catheter relative to the lung

The injection technique of the operator

Chapter 16 Freezing

While monitoring a patient, you can freeze the waveform on the screen, and then you can carefully survey the condition of the patient during this time interval through reviewing the frozen waveform. Meanwhile, you can output the frozen waveform by recorder or printer.

16.1 Freezing Waveform

Under the non-freezing condition, select【**Wave Freeze**】smartkey on lower monitor screen or press the button on the front monitor panel, then you can get the waveform enter freezing condition.

All waveform will be frozen without any more refreshing or roll. The data displayed in the parameter area will normally be refreshed.

The freezing condition will not influence the following functions:

—— Display and refreshing of dynamic short-time graphic trends.

——Display and refreshing of respiration oxygen chart.

——Display and refreshing of the monitoring screen of other sickbeds.

16.2 Reviewing Waveform

Under the freezing condition, you can browse frozen waveform for careful survey through the following methods:

Select ◀◀ or ▶▶ , ◀ or ▶ in the freezing setting, then by turning the trim knob right or left to make the waveform move right or left accordingly. Meanwhile, one downward arrow and time scale will be showed at the lower right corner of each waveform. The initial freezing time is recorded as【**0s**】.

Select ◀◀ or ▶▶ ,the time interval of the waveform moving is 4s.For example,when the initial freezing time is recorded as【**0s**】, select ▶▶, time scale will gradually changes into【**-4s**】,【**-8s**】,【**-12s**】… along with the waveform moving rightwards.

Select ◀ or ▶,the time interval of the waveform moving is 1s.For example,when the initial freezing time is recorded as【**0s**】, select ▶,

time scale will gradually changes into【**-1s**】,【**-2s**】,【**-3s**】… along with the waveform moving rightwards.

16.3 Releasing Freezing

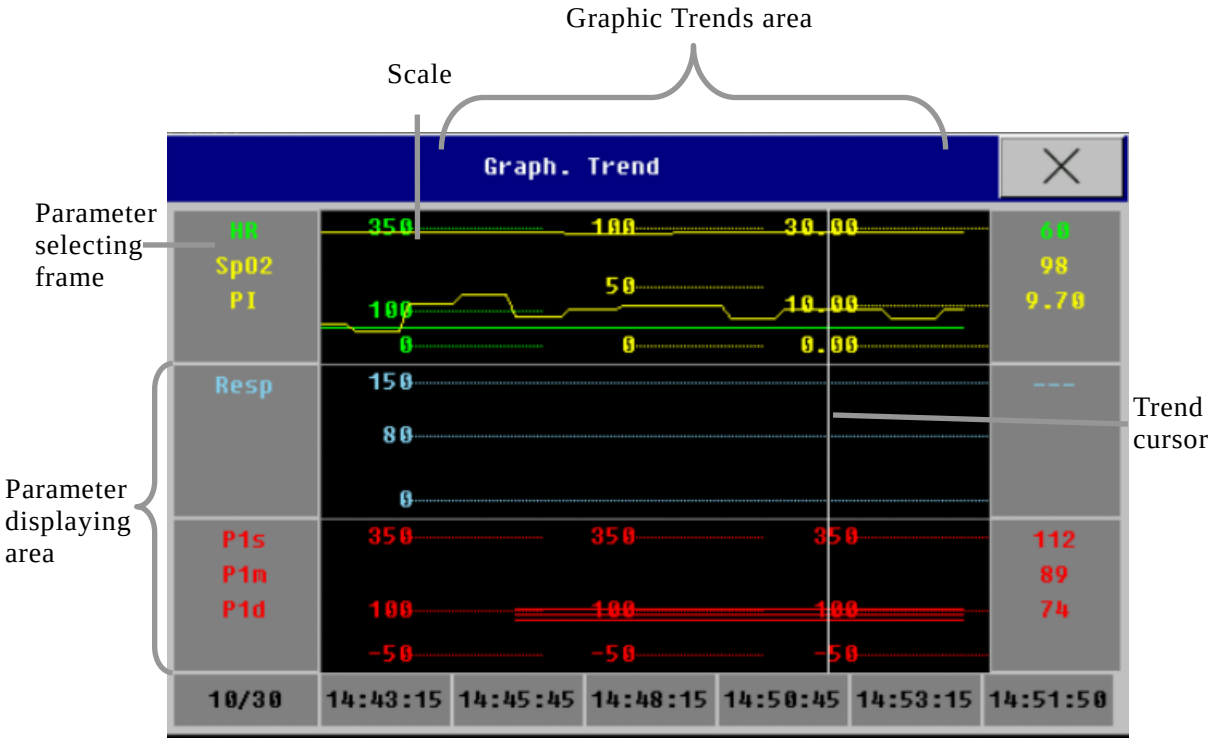
Under freezing condition, you can select the【**Defreeze**】smartkey on lower monitor screen, or press the button ⊽ on the front monitor panel to release the freezing condition.

Chapter 17 Reviewing

Select【**Main Menu**】 smartkey→【**Review**】to enter the review function. Select【**Pat. Information**】, 【**Tabular Trends**】, 【**NIBP Review**】, 【**ARR Review**】,【**Alm Review**】or【**Full Disclosure**】to open the relevant reviewing windows.

17.1 Reviewing Graphic Trends

Select【**Main Menu**】 or 【**Trend Review**】smartkey→【**Review**】→【**Tabular Trends**】→【**Graph. Trend**】to open the graphic trends review window which is as follows.



17.1.1 Selecting Review Parameter

You can select reviewing parameters by the following way:

——Select one parameter label in the parameter selecting frame.

——Select【**Trend Group**】and select the parameter combination required to display from the pull-down menu.

If you want to add a trend group defined by user as required, the

following way is available:

Select 【**Trend Group Set**】in the graphic trends window and enter the Trend Group Setup menu. You can define the name of trend group as required and add the parameter label requiring displayed.

17.1.2 Selecting Time interval

Select【**Time interval**】in the menu which is under the graphic trends window, and then select an appropriate resolution according to your need.

17.1.3 Browsing Graphic Trends

If needing to browse the graphic trends of this parameter in more time intervals:

——Select ◀◀ or ▶▶ and shift time scale axis leftwards or rightwards to browse the graphic trends of this parameter in more time intervals.

——Selecting ⏮ or ⏭ and shift time scale axis to the first or last page, you can browse the graphic trends in the first or the last time interval

——Selecting ◀ or ▶, you can shift the trend cursor. The corresponding time of current cursor position will display above the cursor, and the parameter value will display left to the graphic trends window. The value will vary with the shift of trend cursor.

——Select ⏫ or ⏬ and turn page up or down to browse the graphic trends with more parameters within this time interval.

17.1.4 Recording Graphic Trends

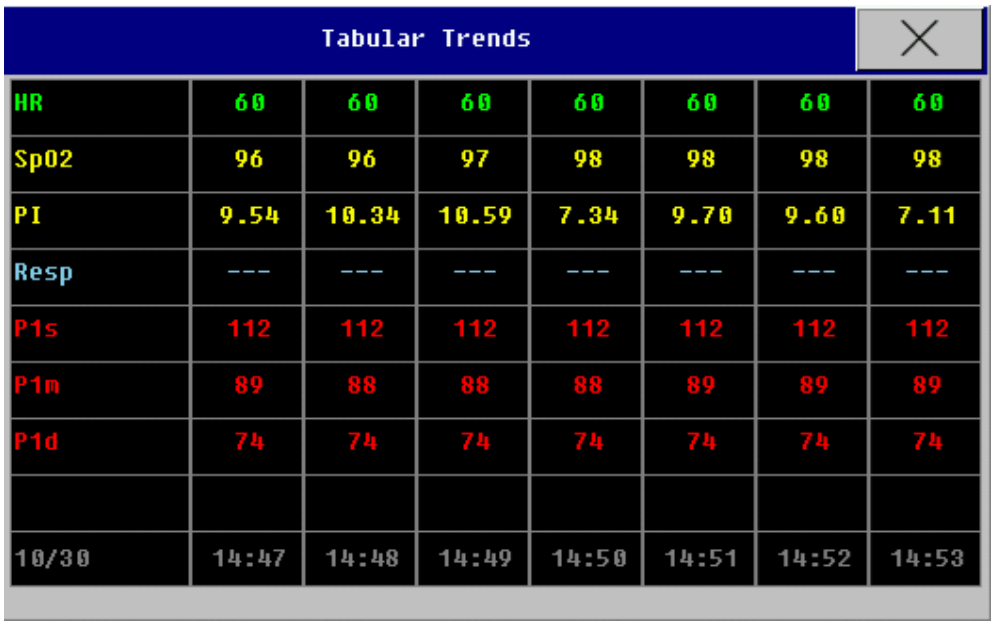
Select【**Record**】in the graphic trends window to record the graphic trends displaying in the current window.

17.1.5 Print Graphic Trends

Select【**USB print**】in the graphic trends window to print the graphic trends displaying in the current window. Details on print please refer to chapter 21.

17.2 Reviewing Tabular Trends

Select the【**Main Menu**】smartkey→【**Review**】→【**Tabular Trends**】to open the Tabular Trends review window as follows.



HR	60	60	60	60	60	60	60
SpO2	96	96	97	98	98	98	98
PI	9.54	10.34	10.59	7.34	9.70	9.60	7.11
Resp	---	---	---	---	---	---	---
P1s	112	112	112	112	112	112	112
P1m	89	88	88	88	89	89	89
P1d	74	74	74	74	74	74	74
10/30	14:47	14:48	14:49	14:50	14:51	14:52	14:53

17.2.1 Selecting Review Parameter

——Select【**Select Trend Group**】in the menu which is under the tabular trends window, then select the parameter group in the pull-down menu. If needing to add trend groups defined by the user, the following way is available:

——Select【**Trend Group Setup**】in the menu which is under the tabular trends window to enter the Trend Group Setup menu. You can define the trend group name by yourself based on your need, and then add the parameter label needing displaying.

17.2.2 Selecting Time interval

Select【**Interval**】in the menu which is under the graphic trends window, select an appropriate resolution according to your need.

17.2.3 Browsing Tabular Trends

- Select ◀◀ or ▶▶ and shift time scale axis leftwards or rightwards to browse the trends data of this parameter in the previous or the next page.
- Selecting ⏮ or ⏭ and shifting time scale axis to the first or last page, you can browse the trends data in the first or the last time interval.
- Select ◀ or ▶ and shift time scale axis leftwards or rightwards to browse the trends data in the previous or the next time interval.
- If needing to browse the trend data of this parameter in more time intervals, please select ⏫ or ⏬ and turn page up or down to browse the trends data of more parameters in this time interval.

17.2.4 Recording Tabular Trends

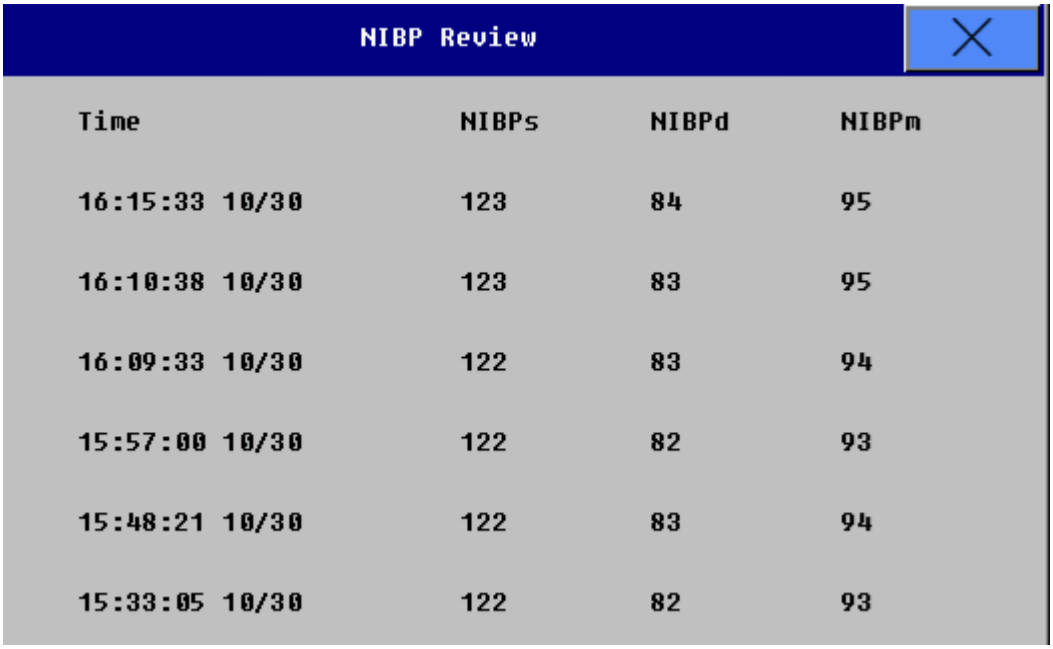
Select【**Record**】in the tabular trends window, you can record tabular trends of all the parameters in the current interval displayed in the window.

17.2.5 Printing Tabular Trends

Select【**USB print**】in the tabular trends window to print the tabular trends displaying in the current window. Details on print please refer to chapter 21.

17.3 Reviewing NIBP Measurement Results

Select【**Main Menu**】smartkey→【**Review**】→【**NIBP Review**】, then you can open NIBP review window as follows.



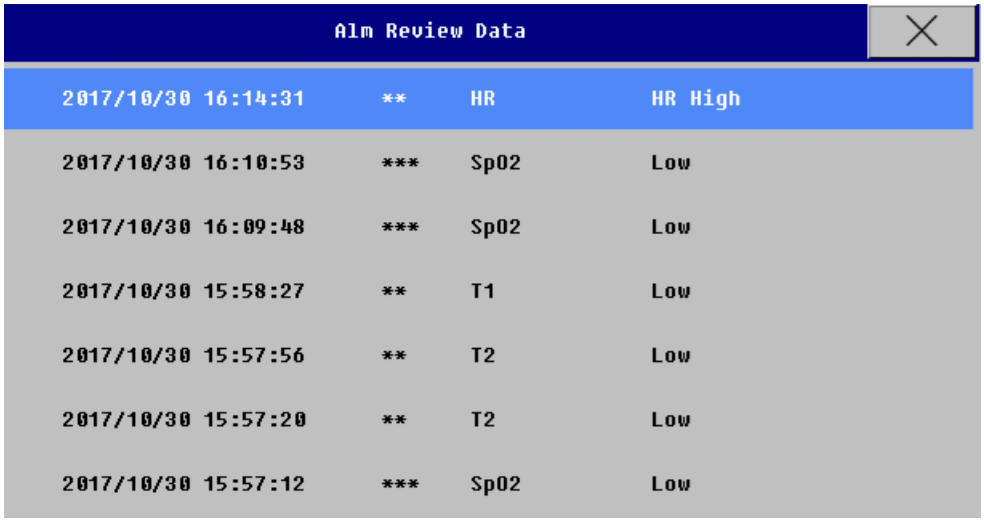
In the window, there are【**NIBPs**】,【**NIBPd**】,【**NIBPm**】and【**Time**】. You can select or to browse NIBP measurement results.

17.4 Reviewing Parameter Alarm

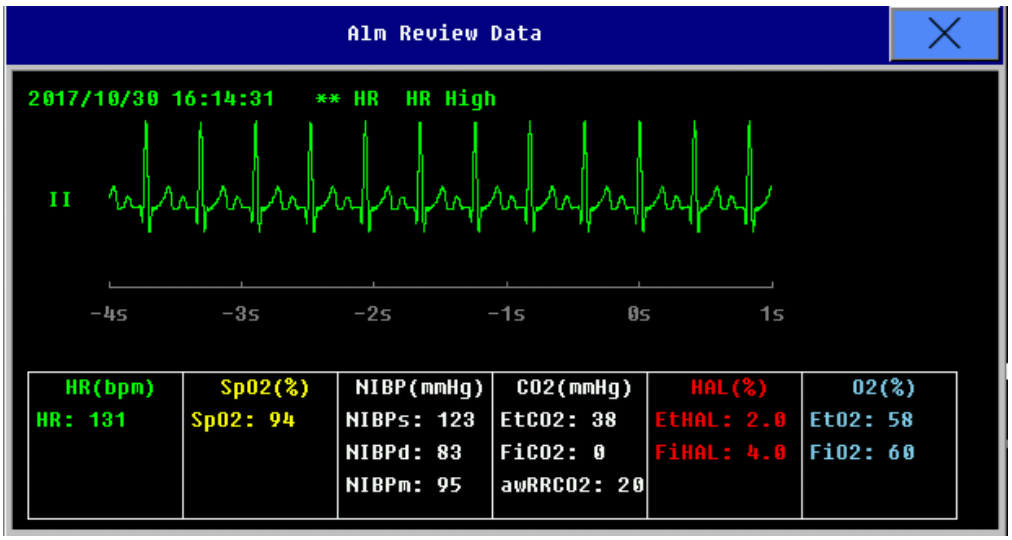
When a parameter alarm occurs, the monitor can store all the parameters' value at the alarm time and the associated waveform during 16 seconds before or after the alarm. So that you can review the alarm events.

When the alarm system is powered down or experienced a total loss of power for a finite duration, the contents of the alarm events will not be lost.

Select【**Main Menu**】→【**Review**】→【**Alm Review**】, you can open the list of parameter alarm events.



Select one of the events and then select 【**Wave**】to open its parameter review window as follows.



Note:

- **Once the alarm events storaged were reached the capacity, when a new event occurs, it will be saved and coverd the data of the oldest event.**
- **The alarm system closed and the close time will not log in the Alarm log.**

17.4.1 Browsing

In the menu which is under the parameter review window, select ◀ or ▶ to shift the waveform left and right.

In the menu which is under the parameter review window, select ⏫ or ⏬ to turn page up or down.

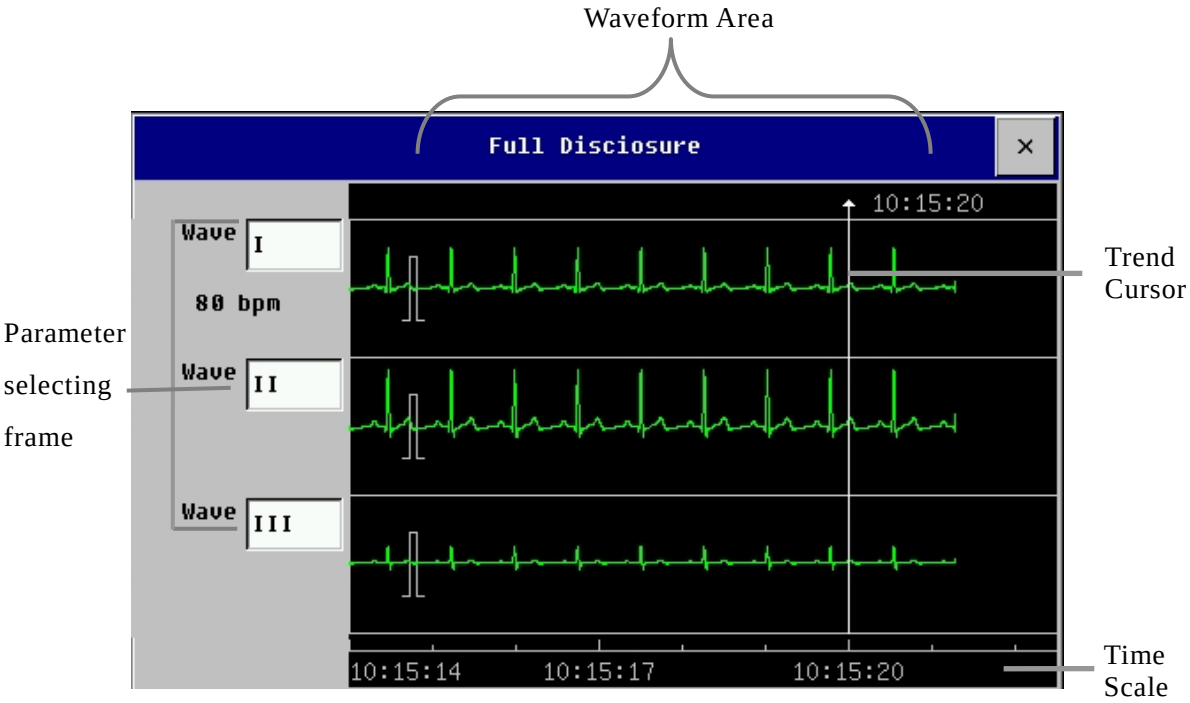
17.4.2 Recording Parameter Alarm

Select【**Record**】in the above window, you can record the current selected alarm event through the recorder.

17.5 Reviewing Holographic Waveform

Note: Only when the monitor has been configured with SD memory card, can the function of reviewing and recording holographic waveform be available.

Select【**Main Menu**】smartkey→【**Review**】→【**Full Disclosure**】to enter holographic waveform window shown as follows:



Note: If you want to review holographic waveform, please store the waveform before review. You can select【Waveform Storage】then select the parameter needing to store.

In the holographic waveform review window, you can:

——Select【**Start time**】to set the beginning time of review.

——You can select the waveform label needing to review in the parameter selecting frame.

——Select ◀◀ or ▶▶ , shift the time cursor left or right to browse waveform in more time.

——Select ◀ or ▶ to shift the trend cursor. Time above the cursor is the time when the cursor is in the current location.

——Select 【**ECG Wave Gain**】to change the amplitude of ECG wave. The options are【**0.25×**】,【**1×**】,【**2×**】and【**4×**】.

——Select【**Wave Speed**】to set the reviewing wave speed. The width of the waveform will change accordingly at different waveform speed.

Chapter 18 Calculations

The calculation result isn't the direct measurement patient data, but that the monitor gets according to the data you have offered. This monitor has the function of drug dose calculation, hemodynamic, nephridium, ventilation and oxygenation calculation.

18.1 Drug Dose Calculation

This calculation of drug concentration is mainly aimed at facilitating the work of physicians. It conducts concentration calculation on some commonly used drugs. A content of titration table can be output through recorder.

18.1.1 Calculation Step

1. Select【**Main Menu**】smartkey→【**Calculation**】→【**Drug Calc**】.
2. Select【**Drug Name**】, the following categories of drugs can be calculated by the monitor: AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN and PITOCIN. In addition, it provides DRUG_A, DRUG_B, DRUG_C, DRUG_D and DRUG_E to displace any other drugs flexibly.
3. Input【**Patient Weight**】, as independent information the weight is only used in the function of the calculation of drug concentration.
4. After finishing the above operation, in the system, the values that are given initially are only a group of random initial values and the operator shall not take this value as the calculation standard and a group of values appropriate to the patient must be reentered according to the physicians' comments.
5. Affirm that the inputting parameter values are correct.
6. Affirm that the calculation results are correct.

18.1.2 Calculation Unit

Drug A, drug B, drug C, drug D, drug E are not the real name of drugs, but only code name of drugs. The five kinds of drugs' units are fixed. You can select the appropriate units according to the physicians' comments. The rules of unit displaying are as follows:

- Drug A, drug B and drug C are fixed to "g" series units: g, mg and mcg.
- Drug D is fixed to "unit" series units: unit, k unit and m unit.
- Drug E is fixed to "mEq" unit.

When define some kind of drug by yourself, you should select drug A, drug B, drug C, drug D, drug E according to the unit series.

Caution: Drip speed and volume per drip are invalid for neonatal.

18.1.3 Titration Table

After finishing the calculation of drug dose calculation, select **【Titration】** in the interface of drug dose calculation to enter the interface of titration table.

You can rejigger the following options in the titration table:

- **Reference**：You can select from **【Dose】**, **【INF Rate】** and **【Drip Rate】**.
- **Dose Type**: Select the dose unit according to your need.
- **Step:** You can select from 1～10.

The data in the titration table will have some change after finishing the above options.

You can also select ⏫ or ⏬ and turn page up and down to browse more data. Select button **【Record】**, it will output the titration table data in the current screen. DOSAGE means dose while SPEED means transfusion speed**.**

18.2 Hemodynamic Calculation

18.2.1 Calculation Step

1. Select【**Main Menu**】smartkey→【**Calculation**】, then select【**Hemodynamic**】.
2. Input each parameter's value correctly:
   a) If you are calculating the current patient, the monitor can get C.O., HR, Height and Weight automatically. And you need to put in the other parameters' value by yourself.
   b) If you are not calculating the current patient, you need to input all of the parameters' value by yourself.
3. After you have finished the data input, please make sure they are correct. Then you can press the button【**Calculation**】to get all the output parameters' value.
4. In the Calculation Step window, you can:
   a) Select【**Range**】, the unit of each parameter disappears, and the unit of the parameter in red word will be changed into the logical range of them. The option has been changed into【**Unit**】, select【**Unit**】to redisplay the unit of each parameter.
   b) Select【**Record**】to print the current page out.
   c) Select【**Show Input**】to display the corresponding input value of the current calculation result.

Note:

- **If there is a sign of "---" in the output parameter, it means the parameter is invalid in this calculation.**
- **If the output parameter is red, it means the parameter is beyond the logical range.**

18.2.2 Input Parameters

Abbreviation	Unit	Full Name
C.O.	L/min	cardiac output
HR	bpm	heart rate
PAWP	mmHg	pulmonary artery wedge pressure
Art Mean	mmHg	mean artery pressure
PA Mean	mmHg	mean pulmonary artery pressure
CVP	mmHg	central venous pressure
EDV	ml	end diastolic volume
Height	cm	height
Weight	kg	weight

18.2.3 Output Parameters

Abbreviation	Unit	Full Name
C.I.	$L/min/m^2$	cardiac index
BSA	m^2	body surface area
SV	ml	stroke volume
SI	ml/m^2	stroke index
SVR	DS/cm^5	systemic vascular resistance
SVRI	$DS{\cdot}m^2/cm^5$	systemic vascular resistance index
PVR	DS/cm^5	pulmonary vascular resistance
PVRI	$DS{\cdot}m^2/cm^5$	pulmonary vascular resistance index
LCW	kg·m	left cardiac work
LCWI	$kg{\cdot}m/m^2$	left cardiac work index
LVSW	g·m	left ventricular stroke work
LVSWI	$g{\cdot}m/m^2$	left ventricular stroke work index
RCW	kg·m	right cardiac work
RCWI	$kg{\cdot}m/m^2$	right cardiac work index
RVSW	g·m	right ventricular stroke work
RVSWI	$g{\cdot}m/m^2$	right ventricular stroke work index
EF	%	ejection fraction

18.3 Nephridium Calculation

18.3.1 Calculation Step

1. Select【**Main Menu**】smartkey→【**Calculation**】, then select【**Nephridium**】.
2. Input each parameter's value correctly.
3. After you have finished the data input, please make sure they are correct. Then you can press the button【**Calculation**】to get all the output parameters' value.
4. In the Calculation Step window, you can:

a) Select【**Range**】, the unit of each parameter disappears, and the unit of the parameter in red word will be changed into the logical range of them. The option has been changed into【**Unit**】, select【**Unit**】 to redisplay the unit of each parameter.

b) Select【**Record**】to print the current page out.

c) Select【**Show Input**】to display the corresponding input value of the current calculation result.

Note:

- **If there is a sign of "---" in the output parameter, it means the parameter is invalid in this calculation.**
- **If the output parameter is in red word, it means the parameter is beyond the logical range.**

18.3.2 Input Parameters

Abbreviation	Unit	Full Name
URK	mmol/L	urine pstassium
URNa	mmol/L	urinary sodium
Urine	ml/24h	urine
Posm	mOsm/kgH2O	plasm osmolality
Uosm	mOsm/kgH2O	urine osmolality
SerNa	mmol/L	serum sodium
Cr	umol/L	creatinine
UCr	umol/L	urine creatinine

Abbreviation	Unit	Full Name
BUN	mmol/L	blood urea nitrogen
Height	cm	height
Weight	kg	weight

18.3.3 Output Parameters

Abbreviation	Unit	Full Name
URNaEx	mmol/24h	urine sodium excretion
URKEx	mmol/24h	urine potassium excretion
Na/K	%	sodium potassium ratio
CNa	ml/24h	clearance of sodium
Clcr	ml/min	creatinine clearance rate
FENa	%	fractional excretion of sodium
Cosm	ml/min	osmolar clearance
CH2O	ml/h	free water clearance
U/P osm	\	urine to plasma osmolality ratio
BUN/Cr	mmol/L	blood urea nitrogen creatinine ratio
U/Cr	\	urine-serum creatinine ratio

18.4 Ventilation Calculation

18.4.1 Calculation Step

1. Select【**Main Menu**】smartkey→【**Calculation**】, then select【**Ventilation**】.
2. Input each parameter's value correctly:
3. After you have finished the data input, please make sure they are correct. Then you can press the button【**Calculation**】to get all the output parameters' value.
4. In the Calculation Step window, you can:

a) Select 【**Unit of Pressure**】 to change the unit of pressure. And its value will convert and renovate automatically at the same time.

b) Select【**Range**】, the unit of each parameter disappears, and the unit of the parameter in red word will be changed into the logical range

of them. The option has been changed into【**Unit**】, select【**Unit**】to redisplay the unit of each parameter.

c) Select【**Record**】to print the current page out.

d) Select【**Show Input**】to display the corresponding input value of the current calculation result.

Note:

- **If there is a sign of "---" in the output parameter, it means the parameter is invalid in this calculation.**
- **If the output parameter is in red word, it means the parameter is beyond the logical range.**

18.4.2 Input Parameters

Abbreviation	Unit	Full Name
FiO2	%	percentage fraction of inspired oxygen
RR	rpm	respiration rate
PeCO2	mmHg	partial pressure of mixed expiratory CO2
PaCO2	mmHg	partial pressure of carbon dioxide in the arteries
PaO2	mmHg	partial pressure of oxygen in the arteries
TV	ml	tidal volume
RQ	\	respiratory quotient
ATMP	mmHg	atmospheric pressure

18.4.3 Output Parameters

Abbreviation	Unit	Full Name
PAO2	mmHg	partial pressure of oxygen in the alveoli
AaDO2	mmHg	alveolar-arterrial oxygen difference
Pa/FiO2	mmHg	oxygenation ratio
a/AO2	%	arterial to alveolar oxygen ratio
MV	L/min	minute volume
Vd	ml	volume of physiological dead space

Abbreviation	Unit	Full Name
Vd/Vt	%	physiologic dead space in percent of tidal volume
VA	L	alveolar volume

18.5 Oxygenation Calculation

18.5.1 Calculation Step

1. Select【**Main Menu**】smartkey→【**Calculation**】, then select【**Oxygenation**】.
2. Input each parameter's value correctly:
3. After you have finished the data input, please make sure they are correct. Then you can press the button【**Calculation**】to get all the output parameters' value.
4. In the Calculation Step window, you can:

a) Select 【**Unit of Pressure**】 【**Unit of Hb**】and 【**Unit of Oxygen Content**】 to change the unit of pressure. And its value will convert and renovate automatically at the same time.

b) Select【**Range**】, the unit of each parameter disappears, and the unit of the parameter in red word will be changed into the logical range of them. The option has been changed into【**Unit**】, select 【**Unit**】to redisplay the unit of each parameter.

c) Select【**Record**】to print the current page out.

d) Select【**Show Input**】to display the corresponding input value of the current calculation result.

Note:

- **If there is a sign of "---" in the output parameter, it means the parameter is invalid in this calculation.**
- **If the output parameter is in red word, it means the parameter is beyond the logical range.**

18.5.2 Input Parameters

Abbreviation	Unit	Full Name
C.O.	L/min	cardiac output
FiO2	%	percentage fraction of inspired oxygen
PaO2	mmHg	partial pressure of oxygen in the arteries
PaCO2	mmHg	partial pressure of carbon dioxide in the arteries
SaO2	%	arterial oxygen saturation
PvO2	mmHg	partial pressure of oxygen in venous blood
SvO2	%	venous oxygen saturation
Hb	g/L	hemoglobin
CaO2	ml/L	arterial oxygen content
CvO2	ml/L	venous oxygen content
VO2	ml/min	oxygen consumption
RQ	without	respiratory quotient
ATMP	mmHg	atmospheric pressure
Height	cm	height
Weight	kg	weight

18.5.3 Output Parameters

Abbreviation	Unit	Full Name
BSA	m^2	body surface area
VO2 calc	ml/min	oxygen consumption
C(a-v)O2	ml/L	arteriovenous oxygen content difference
O2ER	%	oxygen extraction ratio
DO2	ml/min	oxygen transport
PAO2	mmHg	partial pressure of oxygen in the alveoli
AaDO2	mmHg	alveolar-arterial oxygen difference
CcO2	ml/l	capillary oxygen content
Qs/Qt	%	venous admixture
C.O.calc	L/min	calculated cardiac output

Chapter 19 Other Functions

19.1 Nurse Call

Nurse Call is a function that the monitor will send signal to call nurse when the alarm conditions destined are occurred.

The monitor has a nurse call output connector, connect the connector to the nurse call system of the hospital by the nurse-call cable provided along with the monitor, the nurse call function can be realized.

The nurse call function is valid when the following conditions are concurrent:

——The nurse call function is open.

——An alarm condition destined is occurred.

——The monitor is not in the state of alarm paused or system silence.

The setting way of nurse call, please refer to ***Service Manual.***

Warning: The nurse call function should not be used as the primary patient alarm inform source. It is necessary for combining the auditory and visual alarm signal and the patient clinical feature and symptom as the primary information to medical and nursing staff about the physiological condition of the patient.

19.2 Analog Signal Output

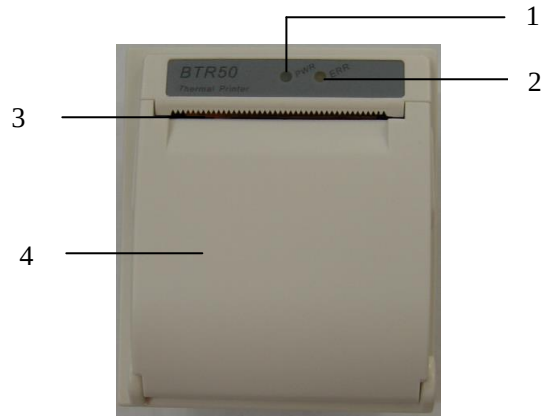
The monitor has an auxiliary output port that can provide "analog signal output". Connect the monitor to an equipment such as an oscillograph, and then do some associated setup, after that you can output the analog signal to the oscillograph through the port.

The setting way of analog signal output, please refer to ***Service Manual***.

Chapter 20 Recording

20.1 Recorder

This monitor uses the thermal recorder which supports various record types. It can output the patient information, measurement data, review data and three waveforms at best.



1. Power indicator lamp

——ON: The recorder works well.

——OFF: The monitor is powered off.

2. Trouble indicator lamp

——ON: There is something wrong with the recorder, such as short of paper, door of the recorder not fasten up and something like that.

——OFF: The recorder goes well.

3. Paper out port
4. Recorder door

20.2 Recording Type

The records can be divided into the following types according to trigger modes:

1. Real-time record of manual startup;
2. The circular record of automatic startup of the recording meter in line with the given time interval;

3. The alarm record triggered by out-of-limit parameter and so on;
4. Record started by manual operation and related to special function.

Note:

- **If you want to know the introduction about alarm record, please turn to Alarm chapter.**
- **If you want detail information of record about the special function, please turn to the corresponding chapters.**

20.3 Setting Recorder

Select the【**Main Menu**】smartkey→【**Recorder Setup**】, you can set the recorder.

Selecting The Record Waveform

The recorder can output three waveforms at one time at best. During the setup of recorder, you can select【**Waveform 1**】,【**Waveform 2**】and【**Waveform 3**】in turn, then select waveform label in each option. Select【**NULL**】to close output of the waveform. These setup are suitable for real time record and cycle record.

Setting The Record Speed

Select【**Record Speed**】in the setup of recorder, select an appropriate record speed according to your need.

Setting Periodic Recording Interval

You can set a certain time interval, and the recorder will automatically start recording in line with the given time interval with the time span of 8 seconds. Select【**Record Interval**】in the recorder setting and select the time interval as required. After setting, the recorder will start recording in line with the given time interval.

◆ **Setting Alarm Record**

Select【**Alm Trigger**】in the setup of recorder to record the alarm or not when an alarm is happening. You can select off or on.

20.4 Starting and Stopping Recording

1. You can start recording by manual way through the following means:

——Press the button on the front panel of the monitor to start real time recording.

——Select the button 【**Record**】in the current window or above the menu to start the associated record of the special function.

2. The recorder can start recording automatically in the following situation:

——If the periodic recording has been started, the recorder will start recording in the set time interval.

——When the【**Alm Trigger**】in the setup of recorder is set to【**On**】, and the【**Alm Trigger**】of some parameter is set to【**On**】, once the parameter happens to alarm, it will trigger the recorder to start a alarm recording.

3. You can stop by pressing the button on the front panel of the monitor.

4. The recorder will stop recording automatically in the following situation:

——The recorder has finished its task.

——The recorder is short of paper.

——There is something wrong with the recorder.

20.5 Installing Recording Paper

If the record paper runs out, please install the record paper as the following step:

1. Press both sides of the recorder door with one hand and pull outwards to open the recorder door.
2. Put the recording paper into the recorder with the thermal side which is smoother up.
3. Close the door of the recorder, and pull some recording paper outside of the paper out port.

Caution:

- **Must use the thermo-sensitive recording paper; otherwise, it will lead to recording failure, bad-quality record or damage of thermo-sensitive printing head.**
- **Do not pull out the recording paper during recorder printing, otherwise the recording meter may be damaged.**
- **Unless for paper replacement or fault remedy, don't keep the recorder door open.**

20.6 Clearing Jam Paper

While the sound of recorder operation or printing of recording meter is abnormal, please first check whether there is paper jam in the recording meter.

If so, please clear it as per following steps:

1. Open the recorder door;
2. Pull out the recording paper, and cut off the wrinkle part;
3. Load recording paper once again and close the recording meter door.

20.7 Cleaning Recorder

After long-time service, some paper scrap and impurity will accumulate on the printing head, and affect printing quality as well as the service life of printing head and roll shaft. The recorder can be cleaned according to the following methods:

1. Before cleaning, the measures such as wearing anti-static wrist strap shall be adopted to avoid the damage to recording meter resulting from static;
2. Open the recorder door and pull out recording paper;
3. Use a tampon with some alcohol to sweep slightly the surface of thermo-sensitive parts of printing head;
4. After the alcohol entirely vaporizes, load recording paper once again and close the recorder's door.

Caution:

- **Don't use any article that can damage the thermo-sensitive parts of recorder during cleaning.**
- **Don't heavily press the printing head of recorder.**

Chapter 21Print

21.1 Printer

The monitor uses the laser printer through USB port. It can print the patient information, measurement data, review data and waveforms at best. The printer types are as below:

- Brother-HL2250DN
- HP LaserJet P2055dn

Besides, the size of print paper is A4.

Note:

- **The supported printer is updated due to software or technical specification change. Contents of printer are subject to change without prior notice. If you have question about printer, please contact with the manufacture.**

21.2 Setting the printed report

21.2.1 Setting the Tabular Trends report

Select【**Select Trend Group**】in the menu which is under the tabular trends window, then select the parameter group in the pull-down menu. If needing to add trend groups defined by the user, the following way is available:

Select【**Trend Group Setup**】in the menu which is under the tabular trends window to enter the Trend Group Setup menu. You can define the trend group name by yourself based on your need, and then add the parameter label needing displaying.

Select【**Interval**】in the menu which is under the graphic trends window, select an appropriate resolution according to your need.

Then click【**USB print**】to print the Tabular Trends report per your need.

21.2.2 Setting the Graph Trend report

You can select reviewing parameters by the following way:

——Select one parameter label in the parameter selecting frame.

——Select【**Trend Group**】and select the parameter combination required to display from the pull-down menu.

If you want to add a trend group defined by user as required, the following way is available:

Select 【**Trend Group Set**】in the graphic trends window and enter the Trend Group Setup menu. You can define the name of trend group as required and add the parameter label requiring displayed.

Select【**Interval**】in the menu which is under the graphic trends window, and then select an appropriate resolution according to your need.

Then press【**USB print**】to print the Graph Trends report.

21.2.3 Print the current display screen

Press this button  to freeze current display waveform, then press【**USB print**】to print the current display screen.

21.3 Installing printing Paper

If the printing paper runs out, please install the printing paper as the following step:

1. Open the door of the printer.
2. Put the printing paper into the printer.
3. Close the door of the printer.

Caution:

- **Before printing, please check and close the door of printer, otherwise, no report will be printed.**

21.4 Clearing Jam Paper

If there is paper jam in the printer, please clear it as per following steps:

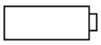
1. Open the printer door;
2. Pull out the printing paper;
3. Load printing paper once again and close the door of the printer.

Chapter 22 Battery

22.1 Introduction

The monitor can be fitted with rechargeable battery to ensure its continuous work after the failure of alternating current power supply, and it needs no special maintenance under the normal condition. While the monitor connecting with alternating current power, no matter whether the monitor is operating or not, the battery always can be charged. In the event of sudden being powered off, the monitor will automatically get power supply from battery without interruption of monitoring work.

Indicative message under the screen will display battery states:

 Indicates that the battery is fully charged.

 Indicates that the battery is half charged.

 Indicates that the battery is almost depleted and need to be charged immediately.

 Indicates that the battery is being charged.

 Indicates that the AC mains is connected.

The power supply of battery can only function for a certain period. Excessively low voltage of battery will trigger a technical alarm and the "Battery Low" message will be displayed. At this moment, the monitor shall immediately connect with alternating current power supply to charge the battery.

Caution:

- **Remove the batteries prior to shipping or if the monitor is not likely to be used for an extended period of time.**
- **Disconnect the AC supply mains plug when the battery is fully charged.**

Warning:

- **Use only batteries specified in this manual.**
- **Keep the batteries out of children's reach.**
- **The batteries should be installed or replaced by service personnel specified by manufacturer. The batteries replacement by inadequately trained personnel could result in a hazard.**

22.2 Installing a Battery

The battery compartment is in the bottom part of the monitor, please refer to the following steps when installing or charging the batteries.

1. Turn off power of the monitor, and disconnect the power wire and other connected wires.
2. Open the battery door towards the direction labeled on it.
3. Take out the old battery.
4. Insert the new battery towards the direction labeled.
5. Close the battery door.

22.3 Optimizing Battery Performance

A battery needs at least two optimizing cycles when it is put into use for the first time. A battery cycle is one complete, uninterrupted charge of the battery, followed by a complete, uninterrupted discharge of the battery. A battery should be conditioned regularly to maintain its useful life. Condition a battery once when it is used or stored for two months, or when its run time becomes noticeably shorter.

To optimize a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the battery in need of optimizing into the battery compartment to the monitor.
3. Place the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
4. Remove the AC mains and allow the monitor to run from the battery until it shuts off.

5. Replace the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
6. The optimizing of the battery is over.

22.4 Checking Battery Performance

The performance of a battery may deteriorate over time. To check the performance of a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
3. Disconnect AC mains and allow the monitor to run on the battery until it shuts off.
4. The operating time of a battery reflects its performance directly.

Caution:

- **The operating time of a battery depends on the configuration and operation of the monitor. NIBP measurement, SpO2measurement and using of recorder will deplete the battery faster than other parameters' measurement.**
- **Check the performance of the batteries regularly to see if there are any problems.**

22.5 Disposing Batteries

Warning: Batteries that are damaged or depleted should be replaced and discarded properly. Dispose of used batteries according to local regulations.

Caution: The service life of battery depends on the service time and frequency. This monitor battery can be charged and discharged for 300 times generally.

Warning: Do not disassemble batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, or leak, causing personal injury.

Chapter 23Maintenance and Cleaning

23.1 Equipment Maintenance

Warning: For optimal performance, product service should be performed only by qualified service personnel.

Note: To ensure the performance and safety of equipment, it must be checked after using 1 year. When check the equipment, please contact professional technology engineers.

The service personnel can provide servicing only when they have passed the profession trainning, and acquired the work license.

Seasonal Safety Check:

Please clean the plug of power cord at least once a year. Too much dust on plug may cause the fire.

The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the following tests, the device has to be repaired.

① Inspect the equipment and accessories for mechanical and functional damage.

② Inspect the safety relevant labels for legibility.

③ Inspect the fuse to verify compliance with rated current and breaking characteristics.

④ Verify that the device functions properly as described in the instructions for use.

⑤ Test the protection earth resistance according IEC 60601-1:0.1Ω.

⑥ Test the earth leakage current according IEC 60601-1: Limit: NC

500μA, SFC: 1000μA.

⑦ Test the enclosure leakage current according to IEC 60601-1:Limit: NC 100μA, SFC: 500μA.

⑧ Test the patient leakage current (normal operation) according IEC 60601-1:

Limit: type BF: for a.c.: 100μA, for d.c.: 10μA.

type CF: for a.c.: 10μA, for d.c.: 10μA.

⑨ Test the patient leakage current under single fault condition according IEC 60601-1:

Limit: type BF: for a.c.: 500μA, for d.c.: 50μA.

type CF: for a.c.: 50μA, for d.c.: 50μA.

⑩ Test the patient leakage current Mains voltage on applied part: According IEC 60601-1:

Limit: type BF: for a.c.: 5mA**.**

type CF: for a.c.: 50uA

Warning: No use-serviceable parts inside, before servicing to authorized representative or manufacturer.

Note: We will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.

23.2 Equipment Cleaning

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

1. Always dilute according the manufacturer's instructions or use lowest possible concentration.
2. Do not immerse part of the equipment in the liquid.
3. Do not pour liquid onto the equipment or accessories.

4. Do not allow liquid to enter the case.
5. Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

Warning: Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.

Caution: If you spill liquid onto the equipment or accessories, contact us or your service personnel.

23.3 Cleaning of the Monitor

- Common detergent and non-corrosive disinfectant used in hospital can be applied to clean monitor, however you must be aware that many kinds of detergents must be diluted prior to utilization, and please use it according to the instruction of detergent manufacturer.
- Avoid the use of alcohols, amino or acetonyl detergent.
- The enclosure and screen of monitor shall be free of dust, and they can be wiped with lint-free soft cloth or sponge soaked in detergent. While cleaning, be careful and do not spill liquid onto the instrument and keep any liquid out of it. When wiping the side panel of monitor, you must be especially careful to keep water out of all kinds of cable and outlet on the panel.
- Do not use abrasive material including wire brush or metal brightener during cleaning because this material will damage the panel and monitor screen.
- Do not submerge the monitor in liquid.
- While cable or plug of attachment accidentally gets wet, please rinse it with distilled water or deionized water and dry it in the environment of temperature 40℃ to 80℃ for at least one hour.

23.4 Cleaning and Sterilizing of Accessories

1. ECG cable

The recommended disinfectors include glutaric dialdehyde solution and 10% decolourant solution.

a) Please clean cable prior to sterilization.
b) Clean the cable surface with soft cloth bedewed with some fresh water or neutral soapy water.
c) Scrub cable with soft cloth bedewed with some disinfector.
d) Wipe off the disinfector remaining on cable by soft cloth bedewed withfresh water.
e) Put cable in a shady and cool environment for airing.

Attention:

- Do not sterilize lead wire with high-pressure, radioactive or steam device.
- Do not directly submerge lead wire in liquid.
- To avoid long-time harm to cable, it is suggested that sterilization to the product be conducted only when necessary according to the regulation of your hospital.
- Do not clean and reuse disposable electrode.

2. SpO2 Sensor

The recommended disinfector include: isopropyl alcohol 70%, 10% decolourant solution can be used for sterilization at lower standard. Don't use undiluted decolourant (5%～5.25% sodium hypochlorite) or other non-recommended disinfector in order to avoid damage to sensor.

The method of cleaning and sterilization can refer to the corresponding method of ECG cable.

Attention:

- Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof).
- Do not sterilize by irradiation, steam, or ethylene oxide.
- Do not directly submerge sensor in any liquid.
- To avoid long-time harm to sensor, it is suggested that sterilization to

the product is conducted only when necessary according to the regulation of your hospital.

3. Temp Sensor

The recommended disinfector: 70% isopropyl alcohol solution, glutaric dialdehyde solution and 10% decolourant solution.

The method of cleaning and sterilization can refer to the corresponding method of ECG cable.

Attention:

- Do not repeatedly sterilize and use disposal temperature sensor.
- To avoid long-time harm to sensor, it is suggested that sterilization to the product be conducted only when necessary according to the regulation of your hospital.
- Temp sensor can only withstand 80～100℃ temperature for a short time and the heating temperature is not allowed to surpass 100℃.

4. NIBP Cuff

a) Please regularly clean the product;

b) Remove cuff from connector and pull out airbag from sheath;

c) Submerge clean and soft medical gauze pad or other soft cleaning tools into fresh water or neutral soapy water, and wring out surplus water from the submerged gauze then wipe airbag and pipe;

d) Wash the cuff sheath in the clean neutral soapy water;

e) After the sheath and airbag intensive drying, enclose airbag with cuff sheath and put into operation.

Attention:

- Excessive or frequent cleaning may damage airbag, so don't clean airbag unless necessary.
- Do not dry airbag and sheath in high temperature.
- If higher sterilization level is required, please choose disposal cuff.
- One disposal cuff can only be used for one patient.
- Carefully keep water and cleaning solution out of the connecting parts of cuff and monitor.

5. CO2 Sensor and Reusable Airway Adapter

▭ The outside of the module or sensor may be cleaned and disinfected by wiping with 70% isopropyl alcohol, a 10% bleach solution, or mild soap. After cleaning, wipe with a clean, water-dampened cloth to rinse. Dry before use.

▭ Reusable airway adapters may be cleaned by rinsing in a warm soapy solution, followed by soaking in a liquid disinfectant such as 70% isopropyl alcohol, a 10% bleach solution, Cidex® or System 1® (refer to the disinfectant manufacturer's instructions for use). Adapters should then be rinsed with sterile water and dried.

▭ Reusable airway adapters may also be pasteurized or autoclaved. Autoclave at 121℃ (250℉) for 20 minutes, unwrapped.

▭ Before reusing the adapter, ensure the windows are dry and residue-free, and that the adapter has not been damaged during handling or by the cleaning process.

6. Mainstream AG Sensor

The IRMA sensor can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA Airway Adapter prior to cleaning the IRMA sensor.

Caution:

- **The IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.**
- **Never sterilize or immerse the IRMA sensor in liquid.**

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7. Sidestream AG module

The ISA sidestream module should be cleaned on a regular basis.

Use a cloth moistened with max 70% ethanol or isopropyl alcohol to clean the module.

To prevent cleaning liquids and dust from entering the ISA sidestream module through its inlet port, keep the Nomoline sampling line connected while cleaning the module.

Warning:

■ **The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.**

■ **Never sterilize or immerse the ISA sidestream module in liquid.**

8. C. O. Interface Cable and Injection Temperature Probe.

The method for the maintenance, please refer to that of ECG cable.

Warning: Never use EtO or formaldehyde for disinfection.

Caution: Sterilization maybe do some harm to monitor, it is suggested that the sterilization be performed only when your hospital considers it necessary in line with maintenance plan. Clean equipment before sterilization.

Note: The electric schematic and element list can only be offered to the eligible service center or personnel.

Chapter 24 Accessories

Warning:

- **Use only accessories specified in this manual. Using other accessories may cause damage to the monitor and we cannot ensure the measuring accuracy which are same as we specified.**
- **Disposable accessories are designed for single-patient use only. Reuse of them may cause a risk of contamination and affect the measurement accuracy.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **To avoid losing the efficacy or comtaminate the accessory, please don't open the disposable or sterile accesssory packages untimely.**
- **If the sterile accesssory package have damaged, please do not use it.**

1. ECG

ECG Cable

Type	Description	Standard	PN
Snap	12-lead	IEC	15-031-0001
Snap	5-lead	IEC	15-031-0002
Snap	3-lead	IEC	15-031-0013
Snap	12-lead	AHA	15-031-0003
Snap	5-lead	AHA	15-031-0004
Snap	3-lead	AHA	15-031-0014
Clip	5-lead	AHA	15-031-0021
Clip	5-lead	IEC	15-031-0022

2. SpO_2

Nellcor SpO2 sensor

Type	Model	Patient category
Disposable	MAX-A	Adult finger (patient size>30kg)
	MAX-P	Pediatric foot/hand (patient size 10-50kg)
	MAX-I	Infant foot/hand (patient size 3-20kg)
	MAX-N	Adult finger or neonatal foot/hand (patient size >40 kg or <3 kg)
Reusable	DS-100A	Adult
	15-100-0018	Nellcor Reusable dura-Y multi-site sensor

Nellcor SpO2 Extension cable

Accessories	Model / PN
Extension cable	15-100-0144

BLT SpO2 sensor

Type	Patient category	PN
Reusable	Adult	15-100-0013
	Pediatric	15-100-0014
	Neonatal	15-100-0015

SpO2 Extension cable

Accessories	PN
Extension cable	15-031-0007

Masimo SpO2 Sensor

Type	Model / PN	Patient category
Reusable	M-LNCS DCI	Adult finger
	M-LNCS DCIP	Pediatric finger
	M-LNCS YI	Neonatal
	Rainbow DCI	Adult finger
	Rainbow DCIP	Pediatric finger
	Rainbow R2-25a, R2-25r, R2-20a, R2-20r	Multi-site
Disposable	M-LNCS Neo	Neonatal foot

	M-LNCS Inf	Infant toe

Masimo SpO2 Extension cable

Accessories	Model / PN
Extension cable	15-100-0186

3. Temp

Temp probe

Type	Applied site	PN
Reusable	Surface	15-031-0005
	Coelom	15-031-0012

4. NIBP

Disposable cuffs

Patient category	Limb circumference (cm)	PN
Neonatal	3-5.5	15-100-0104
	4-8	15-100-0105
	6-11	15-100-0106
	7-13	15-100-0107

Reusable cuffs

Patient category	Limb circumference (cm)	PN
Adult	25-35cm	15-100-0118
Adult thigh	44－53cm	15-100-0142
Large adult	33-47cm	15-100-0120
Pediatric	18-26cm	15-100-0121
Neonatal	6-11cm	15-100-0122

5. IBP

Accessories	Material	PN
IBP kits (UTAH)	PT-01 pressure transducer （sterilized:EO）	15-100-0053
	Extension cable	15-031-0029
IBP kits(BD)	4Pin to 6 Pin cable	15-100-0023
/	Extension cable	15-031-0032

6. CO_2

Sidestream CO2 (CPT)

Accessories	PN
CO_2 sampling tube	15-100-0035
CO_2 dehydration flash	15-100-0036
CO_2 3-way stopcock	15-100-0037

Mainstream CO2 (C5)

Accessories	PN
CO_2 sensor	16-100-0015
Airway adapter (adult)	15-100-0042
Airway adapter(neonatal)	15-100-0043
Extension cable	15-031-0011

LoFlo CO2

Accessories	PN
CO_2 sensor	16-100-0016
Airway adapter (adult)	15-100-0045
CO_2 nasal cannula (adult)	15-100-0044
CO_2 /O_2 nasal cannula	15-100-0046
CO_2 nasal cannula	15-100-0048
CO_2 nasal cannula (infant)	15-100-0049
Extension cable	15-031-0011

7. AG

Mainstream AG (IRMA)

Accessories	Model	PN
Gas sensor	IRMA AX+	16-100-0019
Airway adapter		15-100-0039
Airway adapter (infant)		15-100-0040
Extension cable		15-031-0010

Sidestream AG (ISA)

Accessories	PN
Nomoline Sampling line	15-100-0089

8. C.O.

Accessories	Model	PN
C.O. Interface cable	COC-001-SL	15-100-0148
Injection temperature sensor	SP4042	15-100-0147
Injection temperature sensor cap	SP4045 （ sterilized: EO）	15-100-0146
Floating catheter	131F7（sterilized:EO）	15-100-0179
Syringe for anesthesia 12mL	833703（sterilized:EO）	15-100-0169

Appendix A Product Specifications

A.1 Safety Specifications

According to the MDD 93/42/EEC, the monitor is Type Ⅱb equipment. Classified according to the IEC60601-1 is as follows:

Parts	Classification of protection against electric shock	Degree of protection against electric shock	Degree of protection against ingress of liquid	Degree of protection against hazards of explosion	Mode of operation
Mainframe	I	No mark	IPX1	Not suitable	Continuous
Secondary display		No mark			
Temp Module	NA	Type CF applied part defibrillation proof			
IBP Module					
SpO_2 Module					
C.O. Module					
CO_2 Module		Type BF applied part defibrillation proof			
AG Module					

Note:

I: Class I, internally and externally powered equipment.

When you doubt about the protecting earth integrality or protecting earth lead of the equipment, you'd better change the equipment to internally powered equipment.

CF: Type CF applied part.

BF: Type BF applied part.

NA: Not applicable

Not suitable: Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

A.2 Environmental Specifications

Operating temperature	+5℃ to +40℃ (IRMA AX+ sensor: +10℃ to +40℃ ISA OR+/AX+ sensor: +5℃ to +50℃)
Operating humidity	15% to 85%（non condensing）
Operating atmospheric pressure	700hPa to 1060hPa
Transportation and storage temperature	-20℃ to +55℃
Transportation and storage humidity	≤ 93%（non condensing）
Transportation and storage atmospheric pressure	500hPa to 1060hPa

A.3 Physical Specifications

Parts	**Weight（kg）**	**Size(W×H×D)(mm)**	**Remark**
Mainframe	STORM DS3/ STORM DS5:<4.5 STORM DS7: 6	STORM DS3/ STORM DS5: 318×264×152 STORM DS7: 335× 366× 172	Including screen, stationary parameter module, a lithium battery, a recorder, without accessories.
Sidestream CO_2 module	<0.35	136.6×102×80.5	
LoFlo CO_2 module	<0.4	136.6×102×40	
Mainstream CO_2 module	<0.5	136.6×102×40	
Mainstream AG module	<0.8	136.6×102×40	
Sidestream AG module	<0.8	136.6×102×80.5	Including oxygen module
IBP module	<0.3	136.6×102×40	
Temp module	<0.3	136.6×102×40	
BLT-SpO_2 module	<0.3	136.6×102×40	

Nellcor SpO_2 module	<0.3	136.6×102×40	
Masimo SpO_2 module	<0.3	136.6×102×40	
C.O. module	<0.3	136.6×102×40	

A.4 Power Specifications

Input voltage	100V-240V AC
Frequency	50Hz/60Hz
Earth leakage current	<0.3 mA
Input current	1.7A -0.8A
Standard requirement	According to IEC 60601-1 and IEC 60601-1-2
Fuse	T 2A/250V, integrated in the power module

A.5 Hardware Specifications

A.5.1 Display

Mainframe display	
Type	Color TFT LCD
Size（diagonal）	STORM DS3: 10.4 inch STORM DS5: 12.1 inch, STORM DS7: 15 inch
Resolution	STORM DS3/STORM DS5: 800×600 pixels STORM DS7: 1024×768 pixels
External display	
Type	Medical-Grade TFT display
Size	15inch, 17inch, bigger size
Resolution	STORM DS3/STORM DS5: 800×600 pixels STORM DS7: 1024×768 pixels
EMC	MPR II, CISPR 11B
Third party certificate	UL, C-UL, TUV, CE, FCC

A.5.2 Recorder

Model	BTR50
Type	Thermal dot array
Horizontal	16 dots/mm（at 25 mm/s paper speed）
Vertical resolution	8 dots/mm
Paper width	50 mm
Paper length	15 m
Recording speed	12.5 mm/s, 25 mm/s, 50 mm/s
Recording waveform	Maximum 3 tracks
Recording way	Real-time recording, periodic recording, alarm recording

A.5.3 Battery

Type	Rechargeable lithium ion battery
Model	LB-08
Size	105mm×78mm×20mm
Weight	<360 g
Quantity	STORM DS3/STORM DS5:1 STORM DS7: 1 or 2
Rated voltage	11.1 VDC
Capability	4000 mAh
Operating time	One new and fully charged battery at 25℃ ambient temperature, connecting SpO_2 , ECG, Temp, IBPsensor and NIBP work on AUTO mode for 15 minutes interval. STORM DS3/STORM DS5:3.5 hours STORM DS7:2 hours
Charge time	6h to 100%（Standby）
Turn off delay	5 min -15 min after the low battery alarm first
Indicator of battery capability	With

A.5.4 Mainframe LED

Physiological alarm indicating	1 (Yellow/Red)
Technical alarm indicating lamp	1 (Red /Yellow/Cyan)
Power indicating lamp	1 (Green/Orange) When powered with AC, it lights green while turn on and off the monitor. When powered with battery, it lights orange only while turn on the monitor.
Battery charging indicating lamp	1 (Orange)

A.5.5 Audio indicating

Speaker	Gives audible alarm, QRS tone; Supports Pitch Tone and multi-level volume; Alarm tones meet the requirement of IEC 60601-1-8.
Alarm pressure	45 dB to 85 dB. Testing place is 1 meter from the tone.

A.5.6 Input device

STORM DS3/STORM DS5:

Keys	
Key Numbers	1 power button, 5 shortcut keys (NIBP measurement, alarm acknowledge, alarm pause, waveform freezing, and record):
Touch screen	
Touch screen input	With
Others	
Mouse input	Support
Knob input	Support

STORM DS7:

Keys	
Key Numbers	1 power button and 3 navigation keys. 3 shortcut keys (NIBP measurement, alarm pause, and record)
Touch screen	
Touch screen input	With
Others	
Mouse input	Support

A.5.7 Connectors

Power	1 AC power inlet
Wired network	1, standard RJ45 interfaces.100 BASE-TX, IEEE 802.3
USB	2, standard USB1.1 socket(for the connections to a mouse, printer, U disk, and so on)
Video output	1 standard VGA connector (PS: To get the equivalent of the same monitor LCD display, STORM DS7 should have vertical installation of the screen)
Auxiliary output Defibrillation synchronization	One standard BNC connector with software configuration function for analog and synchronization output
Equipotential grounding point	1
Nurse call	1 RJ11 connector for nurse call
SD card	Optional

A.5.8 Signal Output

Auxiliary output interface	
Standard	EN 60601-1 about short circuit protection and leakage current request
Output impedance	Rated 50Ω

ECG analog signals output	
Bandwidth （-3dB refer to 10Hz）	Diagnosis mode: 0.05 Hz to 120 Hz Monitor mode: 0.5 Hz to 40Hz Surgery mode: 1 Hz to 25Hz
Signal range	-11V to +11V
Signal delay	25 ms（in diagnosis mode, filter off）
Sensitivity	1V/mV±5%
PACE rejection/ strengthener	Non
Nurse call output	
Drive mode	Relay
Electric specification	≤60W, ≤2A, ≤36VDC, ≤25VAC
Isolated voltage	1500 VAC
Signal type	N.C., N.O.
Defibrillator synchronization signal output	
Output impedance	50Ω±10%
Delay	≤35 ms（from R wave crest to pulse raise）
Amplitude	High level : 3.5 V to 5 V, the maximal output current 1mA. Low level: < 0.5V, the maximal input current 5mA.
Pulse width	100ms±10%
Rise and drop time	< 1ms

A.5.9 Data Storage

Trend data	Long trend: 168h，minimum resolution is 1min （store when power goes off）
	High resolution trend: 2h, minimum resolution is 5s
Parameter alarm event	128 groups of parameter alarm events and associated parameter waveform at the alarm moment. Waveform length is selected among 8s, 16s and 32s.
ARR event	128 groups of ARR event and the associated

	waveform for each waveform. The waveform length is selected among 8s, 16s and 32s.
NIBP measurement result	1000 groups
Holographic waveform	The storage time depends on the stored waveforms and the quantity of them.

A.5.10 Alarm

Level	Low, medium and high
Indication	Sound and light indication
Setup	Default and custom
Silence	All alarms can be silenced
Volume	45~85 dB measured at 1 meter

A.6 Measurement Specifications

A.6.1 ECG

Standard	EN 60601-2-27 / IEC 60601-2-27, ANSI/AAMI EC 13 :2002
Lead type	3 lead: I, II, III 5 lead: I, II, III, aVR, aVL, aVF, Vx 12 lead: I, II, III, aVR, aVL, aVF, V1-V6
Lead standard	AHA, IEC
Gain	1.25 mm/mV(×0.125), 2.5 mm/mV（×0.25）, 5 mm/mV（×0.5）, 10 mm/mV（×1）, 20 mm/mV（×2）, 40 mm/mV（×4）, Auto
CMRR	Diagnostic mode ≥ 89 dB Monitor mode ≥ 105 dB Surgery mode ≥ 105 dB
Bandwidth (-3d B)	Diagnostic mode: 0.05 Hz to 150 Hz Monitor mode: 0.5 Hz to 40 Hz Surgery mode: 1 Hz to 25Hz

Input impedance	≥ 5.0 MΩ
ECG signal range	± 10.0 mV
Electrode offset potential	± 500 mV
Patient leakage current	< 10 uA
System noise	≤ 30 μVpp (RTI)
AC filter (50/60 Hz line frequency)	Monitor, Surgery mode: AC filter turns on. Diagnostic, User mode: AC filter turns on or off.
Standardizing signal	1 mV ± 5%
Baseline recovery	Monitor mode: ≤ 3 s; Surgery mode: ≤ 1 s
Indication of electrode separation	Every electrode (exclusive of RL)
Sweep speed	12.5 mm/s, 25 mm/s, 50 mm/s
Protection	Breakdown Voltage 4000VAC 50Hz/60Hz. 60S Anti-interference of electrocautery unit Anti-protection of defibrillation
Baseline recovery	<5s after Defibrillation. (Mon or Surg mode)
Recovery time of electrodes after defibrillation	ECG waveform will recover to the baseline in 10 s.
Pacer pulse mark	With pacer pulse detector, complies with IEC 60601-2-27: 2005, 50.102.12. For the pacer pulse in compliance with following conditions, pacer mark will be signed on the screen(≥ 2 mm): Pacing pulse amplitudes: ±2 mV to ±700mV Pacing pulse widths: 0.1 ms to 2ms Rise time: 10 us to 100us

HR	
Measurement range	Adult: 10 bpm to 300 bpm Pediatric and Neonatal: 10 bpm to 350 bpm
Resolution	1 bpm

Accuracy	±1% or ±1 bpm, whichever is greater
Detecting sensitivity (II lead)	≥0.20mVpp
Response time of HR meter to change in HR	<12s
Response of HR to QRS amplitude is 1mVp-p, width is 10ms	Adult: without response Adult:without response
Alarm range	0 bpm to 300 bpm, high/low limit can be adjusted continuously.

ST segment	
Measurement Channels	Calculating I, II, V- lead etc. at the same time Default : II lead
Measurement range	-2.0 mV to +2.0 mV
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or ±10%, whichever is greater; Over ±0.8mV: unspecified
Resolution	0.01mV
Alarm range	-2.0 mV to +2.0 mV, high/low limit can be adjusted continuously.
Arrhythmia analysis	
Kinds	ASYSTOLE, VENT FIB, VPB, COUPLET, MULTI PVCS, BIGEMINY, TRIGEMINY, R ONT, MISSED BEATS, ST HIGHER, ST LOWER,TACHY, BRADY, PNC, PNP, NOISE, VTACHY, PVCS HIGHER

ECG/ST/arrhythmia supplemental information as required by AAMI EC11/13	
Electrosurgery protection （electrocautery	Cut mode: 300W Coag mode: 100W HR change: ≤10%

unit protection）	Resuming time: ≤10s Complies with ANSI/AAMI EC 13:2002, 4.2.9.14
Input circuit current	< 0.1uA
Tall T-Wave rejection capability	Minimum recommended 1.2 mV T-Wave amplitude Complies with ANSI/AAMI EC 13:2002, 4.1.2.1 c)
Heart rate averaging	≤ 50 bpm, once every two beats; 50 bpm to 120 bpm, once every four beats; > 120 bpm, once every six beats.
HR meter accuracy and response to irregular rhythm	Ventricular bigeminy: 80 bpm Slow alternating ventricular bigeminy: 60 bpm Rapid alternating ventricular bigeminy: 120 bpm Bidirectional systoles: 90 bpm
Response time of HR meter to change in HR	HR change from 80 bpm to 120 bpm: less than 10s HR change from 80 bpm to 40 bpm: less than 10s Complies with ANSI/AAMI EC13-2002: 4.1.2.1 f
Time to alarm for Tachycardia	Vent Tachycardia 1mVp-p, 206bpm: Gain 0.5, Range 6.5s to 8.4s, Average 7.2s Gain 1.0 Range 6.1s to 6.9s, Average 6.5s Gain 2.0, Range 5.9s to 6.7s, Average 6.3s
	Vent Tachycardia 2mVp-p, 195bpm: Gain 0.5, Range 5.4s to 6.2s, Average 5.8s Gain 1.0, Range 5.7s to 6.5s, Average 6.1s Gain 2.0, Range 5.3s to 6.1s, Average 5.7s
Indicator for ECG working abnormally	Each amplificatory channel has ECG abnormal operation indicating. It complies with EC13 2002, 4.2.9.1.
Pacemaker pulse rejection capability without overshoot	Rejection of pacemaker pulses with amplitudes from ±2 mV to±700 mV and widths from 0.1 ms to 2.0 ms (Method A)

A.6.2 Resp

Measurement method	Thoracic impedance
Lead	Selected from: Ⅰ (RA-LA) or Ⅱ (RA-LL); Default: Ⅱ

Excitation frequency	Sine wave: 64.8 kHz
Excitation current	≤ 0.3mA
Excitation current	≤ 500 μA RMS max.
Measuring impedance range	0.2Ω to 3Ω
Baseline impedance range	500 Ω to 2000Ω(using defibrillator proof cable with resistance of 1kΩ)
Gain	×0.25, ×1，×2，×4
Bandwidth	0.25 Hz to 2.0Hz（-3dB）
Sweep speed	6.25mm/s, 12.5mm/s, 25mm/s
Measurement range	0 rpm to 150 rpm
Resolution	1 rpm
Accuracy	±2 rpm
Alarm range	0 rpm to 150 rpm, high/low limit can be adjusted continuously.
Delay of apnea alarm	10s, 15s, 20s, 25s, 30s, 35s, 40s, 45s, 50s, 55s, 60s
Alarm Indication	Blinking display of the data and parameters, text prompts, Three levels of alarming: sound-light alarming, alarming with blinked data and parameters, and that with text prompts.

A.6.3 NIBP

Standard	IEC 80601-2-30		
Measurement way	Automatic oscillometry		
Measurement kinds	Sys, Dia, Map,PR		
Measurement range（mmHg）	Adult	Sys	30~270 mmHg
		Dia	10~220 mmHg
		Map	20~235 mmHg
	Pediatric	Sys	30~235 mmHg
		Dia	10~220 mmHg

		Map	20~225 mmHg
	Neonatal	Sys	30~135 mmHg
		Dia	10~110 mmHg
		Map	20~125 mmHg
Cuff pressure range	0 mmHg to 280 mmHg		
Resolution	1 mmHg		
Pressure accuracy Static: Clinic:	±3 mmHg Average error: ±5 mmHg, standard deviation: ≤8 mmHg		
Unit	mmHg, kPa		
Cuff auto deflation	The cuff will deflate automatically when power is off or time of measurement is beyond 120 seconds(90 seconds for neonate) or the cuff pressure is beyond the overpressure protection set by software and hardware.		
Measurement time	Normally, it is 20s to 45s (depending on HR and moving interference typically) Maximal measurement time: 120s（adult / pediatric）, 90s（neonate）		
Initial inflation pressure	Adult default: 160 mmHg Pediatric default: 130 mmHg Neonatal default: 75 mmHg		
Software overpressure protection	Double hardware,software overpressure protection Adult: (297±3) mmHg Pediatric: (147±3) mmHg Neonatal: (252±3) mmHg		
Assistant venipuncture inflation mode	Inflation pressure（should be close to diastolic pressure）: Adult : 20 mmHg to 120 mmHg (normally 80 mmHg); Pediatric: 20 mmHg to 80 mmHg (normally 60mmHg); Neonatal: 20 mmHg to 50 mmHg (normally 40mmHg).		

Intervals for periodic measurement time	1min, 2min, 2.5min, 3min, 4min, 10min, 15min, 30min, 45min,60min, 90min, 120min,240min, 480min.	
Alarm range	Sys	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
	Dia	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
	Map	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
Alarm Indication	Blinking display of the data and parameters, text prompts, Three levels of alarming: sound-light alarming, alarming with blinked data and parameters, and that with text prompts.	
Work mode	Adult	Single, Cycle, STAT, Sequence
	Pediatric	Single, Cycle, STAT, Sequence
	Neonatal:	Single, Cycle, Sequence
PR		
PR range	40 bpm to 240 bpm	
Resolution	1 bpm	

A.6.4 SpO2

■ **BLT SpO_2**

SpO_2	
Measurement technic	Digital SpO_2 technic
Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2% 0% to 69%: unspecified
Alarm range	0% to 100%, high/low limit can be adjusted continuously.
Average time	Normal:8s, slow: 16s，fast: 4s

Anti-interference ability	Anti-interference of movement Anti-interference of electrocautery unit
Resisting low perfusion ability	With powerful ability of resisting low perfusion, PR amplitude can reach to 0.2% with value of SpO_2 displaying
PR modulation tone（Pitch Tone）	With
SpO_2 alarm range	0% to 100%, high/low limit can be adjusted continuously.
Sensor	Pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 905 nm. The total optical output power of the sensor LEDs is less than 15 mW. This information may be useful to clinicians, such as those performing photodynamic therapy.
PR	
Measurement range	20 bpm to 250 bpm
Resolution	1 bpm
Average time	8s
Accuracy	±1% or ±1 bpm, whichever is the greater
Alarm range	0bpm ～ 300bpm, high/low limit can be adjusted continuously.
PR alarm range	0 bpm to 300 bpm, high/low limit can be adjusted continuously.
Perfusion index	
Measurement range	0.05% to 20%

■ **Nellcor SpO_2**

SpO_2	
Measurement range	0% to 100%

Resolution	1%
Accuracy	70% to 100%: ±2%（adult/pediatric） 70% to 100%: ±3%（neonate） 0% to 69%, unspecified
Alarm range	0% to 100%, high/low limit can be adjusted continuously.
Average time	8s, 16s
PR	
Measurement range	20 bpm to 300 bpm
Accuracy	20 bpm to 250 bpm: ±3 bpm 251 bpm to 300 bpm: unspecified
Resolution	1 bpm
Alarm range	0bpm ～ 300bpm, high/low limit can be adjusted continuously.
Perfusion index	
Measurement range	0.05% to 20%

■ **Masimo SpO_2**

SpO_2	
Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%:±2%（adult/pediatric, non-motion conditions） 70% to 100%:±3%（neonate, non-motion conditions） 70% to 100%:±3%（motion conditions） 0% to 69%,unspecified
Average time	2-4s, 4-6s, 8s, 10s, 12s, 14s, 16s
PR	
Measurement range	25 bpm to 240 bpm
Accuracy	±3 bpm（non-motion conditions） ±5 bpm（motion conditions）

Resolution	1 bpm
SpCO	
Measurement range	0% to 100%
Accuracy	0% to 40%：±3%（non-motion conditions） ＞40%，unspecified
Resolution	1%
SpMet	
Measurement range	0% to 100%
Accuracy	0% to 15%:±1%（non-motion conditions） ＞15%，unspecified
Resolution	0.1%
PI	
Measurement range	0.05% to 20%
SpHb	
Measurement range	0 g/dl to 25 g/dl
Accuracy	8 g/dl to 17 g/dl: ±1 g/dl（non-motion conditions） ＜8 g/dl or ＞17 g/dl，unspecified
Resolution	0.1g/dl
SpOC	
Measurement range	0 ml/dl to 35 ml/dl
PVI	
Measurement range	0% to 100%
Resolution	≤1%

Note 1: The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult volunteers 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 plus or minus one standard deviation, which encompasses 68% of the population

A.6.5 Temp

Standard	ISO80601-2-56
Measurement way	Thermal resistance way
No. of channels	8
Measurement Range	0.0℃~50.0℃ (32℉~122℉)
Measurement Accuracy	0.0℃-50.0℃: ±0.1℃ (not including the probe) 25.0℃-45.0℃: ±0.2℃ (including the probe)
Resolution	0.1℃
Temperature unit	Centigrade (℃), Fahrenheit (℉)
Updated time	Every 1~2 s
Self-test	About every 5~10 mins
Temperature probe nominal resistance	2522Ω@25℃
Temperature probe type	YSI400 series probes or other compatible probes (accuracy ± 0.1℃)
Alarm Range	0.0~50.0 ℃ , with upper and lower limits continuously adjustable
Alarm Indication	Blinking display of the data and parameters, text prompts, Three levels of alarming: sound-light alarming, alarming with blinked data and parameters, and that with text prompts.
The transient response time	≤30s

A.6.6 IBP

No. of channels	8
Sensitivity of transducer	5uV/V/ mmHg, ±2%
Impedance of transducer	300Ω to 3000Ω

Static pressure measurement range	-50 mmHg to +300 mmHg	
Static pressure measurement accuracy	±4 mmHg or ±4% of the reading, whichever is the greater (inclusion of transducer)	
Dynamic pressure measurement range	-50 mmHg to +300mmHg	
Dynamic pressure measurement accuracy	±4mmHg or ±4% of the reading, whichever is the greater	
Resolution	1 mmHg	
Unit	mmHg, kPa, cmH_2O	
Frequency Response	d.c.～20Hz	
Zero calibration of pressure	With	
Kinds of Measurement	ART, PA, CVP, RAP, LAP, ICP	
Options of range	ART	0～50 mmHg 50～150 mmHg 100～240 mmHg 0～300 mmHg AUTO
	PA CVP LAP RAP ICP	0～20 mmHg 0～30 mmHg 0～50 mmHg 0～80 mmHg AUTO
	(The AUTO changes automatically by the interval time of 10mmHg to ensure the most suitable status for observing.)	

Alarm range	Sys	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
	Dia	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
	Map	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
Alarm Indication	Blinking display of the data and parameters, text prompts, Three levels of alarming: sound-light alarming, alarming with blinked data and parameters, and that with text prompts.	
Recovery time after defibrillation	<5s	

A.6.7 CO2

■ **Sidestream CO_2 module (CPT)**

Measurement way	Infrared spectrum
Measurement mode	Sidestream
Measurement range	0.0 % to 13.1 % (0 mmHg to 99.6 mmHg)
Resolution	1mmHg
Unit	%, mmHg
Accuracy	<5.0 %, ±0.3 % (±2.0 mmHg) ≥5.0 %, <±10 % of the reading
Measurement range of awRR	0 rpm to 150 rpm
Calibration	Offset calibration, auto/ manual; gain calibration
Alarm range	0.0～13.1%(0～99.6mmHg) , high/low limit can be adjusted continuously.
Alarm Indication	Blinking display of the data and parameters, text prompts, Three levels of alarming: sound-light alarming, alarming with blinked data and parameters, and that with text prompts.

■ Mainstream CO_2 module (CAPNOSTAT5)

Warm up time	Capnogram displayed in less than 15 s, at an ambient temperature of 25℃, full specifications within 2 minutes.
Measurement range	0% to 19.7 %（0 mmHg to 150 mmHg）
Resolution	0.1% or 1mmHg
Stability	Accuracy specification will be maintained over a 120 hour period.
Rise time	＜60ms
Unit	%, mmHg, kPa
Accuracy	0 mmHg to 40 mmHg, ±2 mmHg 41 mmHg to 70 mmHg, ±5% of reading 71 mmHg to 100 mmHg, ±8% of reading 101 mmHg to 150 mmHg, ±10% of reading The temperature is 35℃

■ LoFlo CO_2 module

Warm up time	Capnogram displayed in less than 20 s, At an ambient temperature of 25℃, full specifications within 2 minutes.
Measurement range	0% to 19.7 %（0 mmHg to 150 mmHg）
Resolution	0.1% or 1 mmHg
Stability	Accuracy specification will be maintained over a 120 hour period.
Unit	%, mmHg, kPa
Accuracy (760mmHg， temperature is 25℃)	0 mmHg to 40 mmHg, ±2 mmHg 41 mmHg to 70 mmHg, ±5% of reading 71 mmHg to 100 mmHg, ±8% of reading 101 mmHg to 150 mmHg, ±10% of reading (when RR ＞80 rpm, all the range is ±12% of reading) Gas temperature at 25℃
Total time of system response	＜3s
Sampling frequency and accuracy of gas	Sampling frequency: 50mL/min Accuracy: -7.5mL/min～+15mL/min

A.6.8 AG

■ Mainstream AG module (IRMA)

Measurement way	Infrared spectrum	
Measurement mode	Mainstream	
Measurement parameters	CO_2, N_2O, agent（ISO, ENF, SEV, HAL, DES）	
Resolution	0.1%	
Warm up time	IRMA CO2: < 10s (concentrations reported and full accuracy) IRMA AX+: < 20s (concentrations reported, automatic agent identification enabled and full accuracy).	
Rise time (When the flowing speed is 10 L/min)	CO_2 ≤ 90 ms N_2O ≤ 300 ms ISO, ENF, SEV,HAL,DES ≤ 300 ms	
Total system Response Time	＜1s	
Primary agent threshold	0.15%. When an agent is identified, concentrations will be reported even below 0.15% as long as apnea is not detected.	
Secondary agent threshold	0.2%+10% of total agent concentration	
Agent identification time	< 20s (typically < 10s)	
Measurement range and accuracy of gas		
Gas	Range (%)	Accuracy[1)]
CO_2	0 to 15	± (0.2% + 2% of reading)
N_2O	0 to 100	± (2% + 2% of reading)
ISO，ENF，HAL	0 to 8	± (0.15% + 5% of reading)
SEV	0 to 10	± (0.15% + 5% of reading)
DES	0 to 22	± (0.15% + 5% of reading)
Accuracy-All conditions		
Gas	Accuracy[2)]	

CO_2	±(0.3 kPa + 4% of reading)
N_2O	±(2 kPa + 5% of reading)
ISO，ENF，HAL，SEV，DES	±(0.2 kPa + 10% of reading)
awRR measurement range	0 rpm to 150 rpm
awRR measurement accuracy	±1 rpm
Alarm range	
SEV，ISO，ENF，HAL，DES	0% to 30%, high/low limit can be adjusted continuously.
CO_2	0% to 10%, high/low limit can be adjusted continuously.
N_2O	0% to 82%, high/low limit can be adjusted continuously.
awRR	0 rpm to 150 rpm high/low limit can be adjusted continuously.

Note1: The accuracy specification is valid for the operating temperature and humidity conditions specified（22±5℃and 1013±40 hPa）, except for interference specified in the table "Interfering gas and vapor effects" below.

The accuracy specification for IRMA AX+ is not valid if more than two agents are present in the gas mixture.

Note2： 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".3）

Note3： Effects from water vapor partial pressure on gas readings：

The effects of water vapor are illustrated in the table section 2.7 of Masimo IRMA user guide. 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 and vapor effects

Gas or vapor	Gas level	Effect (CO_2)		Effect (Agents)	Effect (N_2O)
		IRMA CO2	IRMA AX+		
N_2O	60%	—		—	—
HAL	4%	—		—	—
ENF, ISO, SEV	5%	+8% of reading [1)]	—	—	—
DES	15%	+12% of reading [1)]	—	—	—
Xe (Xenon)	80%	-10% of reading [1)]		—	—
He (Helium)	50%	-6% of reading [1)]		—	—
Metered dose inhaler Propellants	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol)	0.3%	—		—	—
C_3H_7OH (Isopropanol)	0.5%	—		—	—
CH_3COCH_3 (Acetone)	1%	—		—	—
CH_4 (Methane)	3%	—		—	—
CO (Carbon monoxide)	1%	—		—	—
NO (Nitrogen monoxide)	0.02%	—		—	—
O_2	100%	—		—	—

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

■ Sidestream AG module (ISA)

Measurement mode	Sidestream
Sampling flow rate	50ml/min ± 10ml/min
Measurement parameters	CO_2, N_2O, O_2, agent (ISO, ENF, SEV, HAL, DES)

Compensations	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.
Calibration	No span calibration is required for the IR bench. An automatic zeroing is performed 1 to 3 times per day.
Warm-up time	ISA CO2: < 10s (Concentrations reported and full accuracy) ISA OR+/AX+: <20s (Concentrations reported, automatic agent identification enabled and full accuracy)
Typical rise time at 50 ml/min sample flow	ISA CO2: CO2≤200ms ISA OR＋/AX+： CO2≤300ms N_2O, O_2,ISO, ENF, SEV, DES ≤ 400 ms HAL≤ 500 ms
Total system response time	ISA CO2: < 3s ISA OR+/AX+: < 4s (with 2m Nomoline Airway Adapter Set sampling line)
Primary agent threshold	0.15%. When an agent is identified, concentrations will be reported even below 0.15%.
Secondary agent threshold	0.2 % +10% of total agent concentration
Agent identification time	<20s (typically <10s)

Measurement range and accuracy of gas:

Gas	Range	Accuracy[1)]
CO_2	0 to 25%	0 to 15% ： ±(0.2% + 2% of reading) 15 to 25%：Unspecified
N_2O	0 to 100%	±(2% + 2% of reading)
HAL, ENF, ISO	0 to 25%	0 to 8%：±(0.15% + 5% of reading) 8 to 25%：Unspecified
SEV	0 to 25%	0 to 10%：±(0.15% + 5% of reading)

		10 to 25%：Unspecified
DES	0 to 25%	0 to 22%：±(0.15% + 5% of reading) 22 to 25%：Unspecified
O_2	0 to 100%	±(1% + 2% of reading)
Accuracy-All conditions		
Gas	Accuracy[2)]	
CO_2	±(0.3 kPa + 4% of reading)	
N_2O	±(2 kPa + 5% of reading)	
ISO，ENF，HAL，SEV，DES	±(0.2 kPa + 10% of reading)	
O_2	±(2 kPa + 2% of reading)	
awRR measurement range		0 rpm to 150 rpm
awRR measurement accuracy		±1 rpm
Alarm range		
SEV，ISO，ENF，HAL，DES		0% to 30%, high/low limit can be adjusted continuously.
CO_2		0% to 10%, high/low limit can be adjusted continuously.
N_2O		0% to 82%, high/low limit can be adjusted continuously.
O_2		18% to 100%, high/low limit can be adjusted continuously.
awRR		0 rpm to 150 rpm high/low limit can be adjusted continuously.

Note 1: The accuracy specification is valid for the operating temperature and humidity conditions specified（22±5℃and 1013±40 hPa）, except for interference specified in the table "Interfering gas and vapor effects" below.

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.

Note2：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".

Interfering gas and vapor effects

Gas or vapor	Gas level	Effect (CO_2)		Effect (Agents)	Effect (N_2O)
		ISA CO_2	ISA AX+ ISA OR+		
N_2O	60%	—		—	—
HAL	4%	—		—	—
ENF, ISO, SEV	5%	+8% of reading [1)]	—	—	—
DES	15%	+12% of reading [1)]	—	—	—
Xe (Xenon)	80%	-10% of reading [1)]		—	—
He (Helium)	50%	-6% of reading [1)]		—	—
Metered dose inhaler Propellants	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol)	0.3%	—		—	—
C_3H_7OH (Isopropanol)	0.5%	—		—	—
CH_3COCH_3 (Acetone)	1%	—		—	—
CH_4 (Methane)	3%	—		—	—
CO (Carbon monoxide)	1%	—		—	—
NO (Nitrogen monoxide)	0.02%	—		—	—
O_2	100%	—		—	—

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

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.

A.6.9 C.O.

Measurement Mode	Thermal dilution method
Measurement Wave	Thermal dilution curve
Measurement parameters	C.O.,TB, TI, C.I.
Measurement Range	C.O. : 0.1 L/min ~ 20 L/min TB: 23.0 ~ 43.0℃ TI: -1.0 ~ 27.0℃
Resolution	C.O.: 0.1 L/min TB: 0.1℃ TI: 0.1℃
Precision	C.O.: 2% SD TB.TI: ±0.1℃
TB Alarm range	23.0~43.0 ℃ , high/low limit can be adjusted continuously

Appendix B Factory Defaults

This section lists the most important factory default settings. These settings are not user-adjustable. However, you can restore the factory default settings of the monitor if necessary.

Note: The items with ★ can be only displayed in the configuration mode while others can be displayed in all modes.

B.1 Monitor Defaults

◆ System

Patient messages

Patient messages	Factory Defaults
Category	Adult
Paced	No

Interface Setup

Interface setup	Factory defaults
Scan Mode★	Refresh
Brightness	7

Alarm

Alarm setup	Factory defaults
ALM Volume	2
LO ALM Volume★	2
Alarm paused time★	2min
High ALM Volume★	ALM Volume +2
Med ALM Volume★	ALM Volume +2
High Alm Sound interval★	10s
Med Alm Sound interval★	15s
Low Alm Sound interval★	25s
ALM Sound type★	ISO

Recorder

Recorder setup	Factory defaults
Waveform 1	II
Waveform 2	Pleth
Waveform 3	Resp
Record speed	25mm/s
Record Interval	Off
Cycle record duration	8s
Manual record duration	10s

Rec Delay★	8s
Grid★	On
Alm trigger	Off

◆ **ECG**

ECG setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Printing Switch★	Off		
Limit Display★	Off		
High limit of HR alarm (bpm)	120	160	200
Low limit of HR alarm (bpm)	50	75	100
QRS Volume	2		
Lead Type	5 Lead		
ECG Mode	Monitor		
Wave Gain	1		
Wave Speed	25 mm/s		
Primary Lead Select	Ⅱ		
Leads Off Alarm Lev.★	Medium		
Color	Green		

◆ **ST segment**

ST setup	**Adult**	**Pediatric**	**Neonatal**
ST Analysis Switch	Off		
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Print★	Off		
ST-X high alarm limit (mV)	+0.2		
ST-X low alarm limit (mV)	-0.2		
Note : X stands for Ⅰ，Ⅱ，Ⅲ，aVR, aVL, aVF, V1, V2, V3, V4, V5 or V6.			

◆ **Arrhythmia**

Arrhythmia setup	**Adult**	**Pediatric**	**Neonatal**
ARR Analysis Switch	Off		
PVCs Alarm	Off		
PVCs Alarm Lev.	Medium		
High Alarm Limit of PVCs	10		
ARR ALM Setup	**Alarm**	**Alarm Lev**	**Alarm Print★**
ASYSTOLE	On	High	Off
VENT FIB/TACH	On	High	Off

RUN PVCs	On	Medium	Off
COUPLET	On	Low	Off
BIGEMINY	On	Low	Off
TRIEMINY	On	Low	Off
R ON T	On	Low	Off
VPB	On	Low	Off
TACHY	On	Medium	Off
BRADY	On	Medium	Off
MISSED BEAT	On	Low	Off
ST Elevation	On	Low	Off
ST Depression	On	Low	Off
PNP	On	Medium	Off
PNC	On	Medium	Off
NOISE	On	Low	Off
V-TACH	On	High	Off
Frequent PVCs	On	Low	Off

◆ **Resp**

Resp setup	**Adult**	**Pediatric**	**Neonatal**
Resp Lead	RA-LL		
Alarm Switch★	On		
Alarm Lev.	Medium		
Alarm Print★	Off		
Limit Display★	Off		
High limit of RR (rpm)	30	30	100
Low limit of RR (rpm)	8	8	30
Apnea Time	20s		
Apnea Alarm Level★	High		
Resp Anti-Drift	Open		
Wave Gain	2		
Wave Speed	12.5 mm/s		
Color	Azure		

◆ **SpO_2**

SpO_2 setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
HI Limit Alarm Lev.	Medium		
LO Limit Alarm Lev.	Medium		
Alarm Print★	Off		

Limit Display★	Off		
High alarm limit of SpO_2 (%)	100	100	95
Low alarm limit of SpO_2 (%)	90	90	85
Desat Limit (%)	85	85	85
PI Alm Switch	Off		
PI Alm Level	Medium		
Low alarm limit of PI (%)	0.5	0.5	0.3
QRS Volume	2		
NIBP same side	On		
Average Time	4 s		
Sensitiv. (Masimo)	Normal		
Wave Speed	25 mm/s		
Color	Yellow		

◆ **Temp**

Temp setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Print	Off		
Limit Display	Off		
High alarm limit（℃）	39.0		
Low alarm limit（℃）	36.0		
Unit	℃		
Color	Yellow		

◆ **TD**

TD setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Print	Off		
Limit Display	Off		
High alarm limit（℃）	3.0		
Low alarm limit（℃）	0.0		
Unit	℃		
Color	Yellow		
Param A	T1		
Param B	T2		

◆ **NIBP**

NIBP setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Print★	Off		
Limit Display★	Off		
ALM Source	Sys &Map&Dia		
Alarm Limit (mmHg)			
High alarm limit of Sys	160	120	90
Low alarm limit of Sys	90	70	40
High alarm limit of Dia	90	70	60
Low alarm limit of Dia	50	40	20
High alarm limit of Map	110	90	70
Low alarm limit of Map	60	50	25
Measure Mode	Manual		
Unit	mmHg		
Inflation（mmHg）	160	130	75
Venipuncture Press （mmHg）	80	60	40
Interval	5 min		
Color	White		

◆ **IBP**

ART/P1/P2 setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Show Value When Need Zero★	Yes		
Alarm Lev.★	Medium		
Alarm Print★	Off		
Limit Display	Off		
High alarm limit (mmHg)	160/90 (110)	120/70 (90)	90/60 (70)
Low alarm limit (mmHg)	90/50 (70)	70/40 (50)	55/20 (36)
Unit	mmHg		
Display Format	S/D(M)		
Wave Speed	25 mm/s		
Scale	Manual		
Color	Red		
PA setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Show Value When Need Zero★	Yes		

Alarm Lev.	Medium		
Alarm Print★	Off		
Limit Display★	Off		
High alarm limit (mmHg)	34/16 (20)	60/4 (26)	60/4 (26)
Low alarm limit (mmHg)	10/0 (0)	24/-4 (12)	24/-4 (12)
Unit	mmHg		
Display Format	S/D(M)		
Wave Speed	25 mm/s		
Scale	Manual		
Color	Red		
CVP/RAP/LAP/ICP setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Show Value When Need Zero★	Yes		
Alarm Lev.	Medium		
Alarm Print★	Off		
Limit Display★	Off		
High alarm limit (mmHg)	14/6 (10)	10/2 (4)	10/2 (4)
Low alarm limit (mmHg)	6/-4 (0)	2/-4 (0)	2/-4 (0)
Unit	mmHg		
Unit (CVP)	cmH_2O		
Display Format	M		
Wave Speed	25 mm/s		
Scale	Manual		
Color	Wine		

◆ **CO_2**

CO_2 setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Print★	Off		
Limit Display★	Off		
Unit	mmHg		
High alarm limit of $EtCO_2$	65 mmHg	65 mmHg	45 mmHg
Low alarm limit of $EtCO_2$	26mmHg	26mmHg	30 mmHg
High alarm limit of $FiCO_2$	5mmHg	5mmHg	4 mmHg
High alarm limit of awRR	30 rpm	30 rpm	100 rpm
Low alarm limit of awRR	8 rpm	8 rpm	30 rpm
Scale（mmHg）	61		
Wave Speed	12.5 mm/s		
Color	White		

Apnea alarm time	20s

◆ **AG**

AA setup	**Adult**	**Pediatric**	**Neonatal**
AA Type	Auto		
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Print★	Off		
Limit Display★	Off		
Scale(%)	9		
Wave Speed	6.25 mm/s		
AA Color	Dark Green		
ENF Color	Dark Yellow		
SEV Color	Yellow		
DES Color	Green		
ISO Color	Dark Red		
HAL Color	Red		

Alarm limit（%）	**Adult/Pediatric/Neonatal**		
	ENF	**SEV**	**DES**
High limit of Et	3.0	6.0	8.0
Low limit of Et	0.0	0.0	0.0
High limit of Fi	2.0	5.0	6.0
Low limit of Fi	0.0	0.0	0.0
Alarm limit（%）	**Adult/Pediatric/Neonatal**		
	ISO	**HAL**	
High limit of Et	3.0	3.0	
Low limit of Et	0.0	0.0	
High limit of Fi	2.0	2.0	
Low limit of Fi	0.0	0.0	

N_2O setup	**Adult**	**Pediatric**	**Neonatal**
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Print★	Off		
Limit Display★	Off		
High alarm limit of Et (%)	82		
Low alarm limit of Et (%)	0		
High alarm limit of Fi (%)	82		
Low alarm limit of Fi (%)	0		
Scale(%)	80		
Wave Speed	12.5 mm/s		
Color	White		

O_2 setup	Adult	Pediatric	Neonatal
Alarm Switch	On		
Alarm Lev.	Medium		
Alarm Print★	Off		
Limit Display★	Off		
High alarm limit of Et (%)	100		
Low alarm limit of Et (%)	10		
High alarm limit of Fi (%)	100		
Low alarm limit of Fi (%)	18		
Scale(%)	100		
Wave Speed	12.5 mm/s		
Color	Azure		

◆ **C.O.**

C.O. setup	Adult
Alarm Switch	On
Alarm Lev.	Medium
Alarm Print★	Off
Limit Display★	Off
Measurement mode	Single
TI Source	Manual
TI setup	0℃
Volume of injecta	10CC
Confficient of duct	0.542
High limit of TB	43℃
Low limit of TB	23℃
Unit of TEMP	℃

Appendix C Alarm messages

C.1 Monitor Alarm Messages

◆ System

Technical alarm:

Alarm messages	Cause	Level
Battery low	Voltage of battery is too low	Medium
Recorder Out of Paper	Recorder Out of Paper	Low
XX Unusual Unplugged	Unplug XX module from the monitor	Medium
SD Card Full	SD Card Full	Low
SD Card R/W Error	SD Card read/write error	Low

Prompt messages:

Messages	Cause	Level
Unknown Module	Plug in the unknown module	No alarm
SD be about to full	SD Card storage is about to full	No alarm

◆ ECG

Physiological alarm:

Alarm messages	Cause	Level
HR high	HR measuring value is above the high alarm limit	Medium (User-Selectable Medium or High)
HR low	HR measuring value is below the low alarm limit	
ST-X high	ST-X measuring value is above the high alarm limit	Medium (User-Selectable)
ST-X low	ST-X measuring value is below the low alarm limit	
QTc High	QTc measuring value is above the high alarm limit	Medium
DQTc High	DQTc measuring value is above the high alarm limit	Medium
Note: X stands for I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 or V6.		

Technical alarm:

Alarm messages	Cause	Level
RA, LA, LL, V1, V2,V3, V4, V5,V6 leads off	ECG electrode fall off the skin or ECG cables fall off the monitor	Medium
ECG leads off	Key-leads are disconnected, so it can't measure normal ECG waveform.	
Ⅰ, Ⅱ,Ⅲ, V1, V2, V3, V4, V5, V6 polarized	ECG electrode polarized	Low
ECG communicating error	ECG measurement failure or communication failure	Medium
ECG noise	ECG noise is too much.	Low
Can't analyse QT	QT measuring value can't analyse	Low

◆ Resp

Physiological alarm:

Alarm messages	Cause	Level
RR high	RR measuring value is above the high alarm limit	Medium (User-Selectable Medium or High)
RR low	RR measuring value is below the low alarm limit	
Resp apnea	No signal for breath in specific interval	High
Resp Artifact	Heartbeat disturb the resp	High

Technical alarm:

Alarm messages	Cause	Level
Resp communicating error	Resp measurement failure or communication failure	Medium

◆ SpO_2

Physiological alarm:

Alarm messages	Cause	Level
SpO_2 high	SpO_2 measuring value is above the high alarm limit	Medium (User can select Medium or High)
SpO_2 low	SpO_2 measuring value is below the low alarm limit	Medium (User can

		select Medium or High)
PI low	PI value is too low	Medium (User can select Medium or High)
Desat limit	SpO_2 measuring value is too low.	High
PR high	PR measuring value is above the high alarm limit	Medium (User can select Medium or High)
PR low	PR measuring value is below the low alarm limit	
SpO_2 pulse timeout	SpO_2 signal is predominantly invalid and therefore cannot be analyzed	High

Technical alarm:

Alarm messages	**Cause**	**Level**
SpO_2 sensor off	SpO_2 sensor may be disconnected from the patient or the monitor	Medium
SpO_2 communicating error	SpO_2 measurement failure or communication error	Medium
SpO_2 Low Confidence	No measuring data update during 25s or low perfusion	Low
SpO_2 Motion Interference	Patient movement too much	Low
SpO_2 Sensor Failure	SpO2 Sensor Failure	Medium
SpO_2 Interference	SpO2signal Interference	Low

Prompt messages:

Messages	**Cause**	**Level**
Search pulse	SpO_2 module is searching for pulse	No alarm
Sensor disconnected	SpO_2 probe isn't connected to the monitor	No alarm

Masimo SpO2 module:

Alarm messages	**Cause**	**Level**
No cable	No cable connected	No alarm
Replace cable	Cable life expired; Cable is defective	No alarm

Alarm messages	Cause	Level
Incompatible cable	Cable is incompatible	No alarm
Unrecognized cable	Cable is unrecognized	No alarm
Only mode	Only mode is detected	No alarm
No sensor	No sensor connected	No alarm
Replace sensor	Sensor life expired, Sensor is defective	No alarm
Invalid sensor	Sensor is incompatible; Sensor is unrecognized	No alarm
No Adhesive	No adhesive sensor connected	No alarm
Invalid Adhesive	Incompatible adhesive sensor	No alarm
Replace Adhesive	Defective adhesive sensor	No alarm
Sensor Initializing	Sensor is initializing	No alarm
Low perfusion	Low perfusion index	No alarm
Demo tool	The monitor is at demo mode	No alarm
Check sensor	Check sensor is connecting	No alarm
LOW SIQ	SpO2 Signal IQ is low	No alarm
Module Failure	SpO2 module failure	No alarm
PI Low Confidence	PI confidence is low	No alarm
SpCO Low Confidence	SpCO confidence is low	No alarm
SpMet Low Confidence	SpMet confidence is low	No alarm
SpHb Low Confidence	SpHb confidence is low	No alarm
SpOC Low Confidence	SpOC confidence is low	No alarm
PVI Low Confidence	PVI confidence is low	No alarm
PR Low Confidence	PR confidence is low	No alarm

◆ Temp

Physiological alarm:

Alarm messages	Cause	Level
〈Temp label〉high	〈Temp label〉 measuring value is above high alarm limit	Medium (User can select Medium or High)
〈Temp label〉low	〈Temp label〉measuring value is below low alarm limit	
TD High	TD measuring value is above high alarm limit	

Technical alarm:

Alarm messages	Cause	Level
〈Temp label〉Sensor off	〈Temp label〉sensor may be disconnected from user or monitor	Medium

〈Temp label〉over High range	〈Temp label〉 over measuring range	Low
〈Temp label〉below low range	〈Temp label〉 below measuring range	
TEMP lev.1 self test failure	Temp self checking error	
TEMP lev.2 self test failure	Temp self checking error	
Temp communicating error	Temp measurement error or communication error	Medium

◆ NIBP

Physiological alarm:

Alarm messages	Cause	Level
NIBP Sys high	NIBP Sys measuring value is above high alarm limit	sMedium (User-Selectable Medium or High)
NIBP Sys low	NIBP Sys measuring value is below low alarm limit	
NIBP Dia high	NIBP Dia measuring value is above high alarm limit	
NIBP Dia low	NIBP Dia measuring value is below low alarm limit	Medium (User-Selectable Medium or High)
NIBP Map high	NIBP Map measuring value is above high alarm limit	
NIBP Map low	NIBP Map measuring value is below low alarm limit	

Technical alarm（displayed in the indicating area under NIBP MAP）:

Alarm messages	Cause	Level
Loose Cuff	1. Cuff is completely unwrapped. 2. The cuff is not connected. 3. Adult cuff used in neonate mode.	Low
Air Leak	Air leak in pneumatics, hose, or cuff.	
Air Pressure Error	Unable to maintain stable cuff pressure, e.g. kinked hose.	
Weak Signal	Very weak patient signal due to a loosely wrapped cuff. The pulse of patient is too weak.	
Range Exceeded	Measurement range exceeds module specification.	

Excessive Motion	1.Too many retries due to interference of motion artifact. 2.Signal is too noisy during measurement, e.g. patient has severe tremor. 3.Irregular pulse rate, e.g. arrhythmia.	Low
Overpressure Sensed	Cuff pressure exceeds the specified high safety limit. Could be due to rapid squeezing or bumping of cuff.	Medium
Signal Saturated	Large motion artifact that saturates the BP amplifier's amplitude handing capability.	Low
Air System Leak	Module reports Air Leakage failure while in the Pneumatic Test mode.	
System Failure	Module occurs abnormal processor event.	
Time Out	Measurement took more than 120 seconds in adult, 90 seconds in neonate mode.	
Cuff Type Error	Neonate cuff used in adult mode.	
Unspecified accuracy	Exceed the measuring rage.	
Cycle mode abort	Power off unexpectedly during cycle mode measuring.	
Zero Calibrate Failure	Zero calibrate failure	Medium
Calibrate Failure	NIBP pressure calibration failed	
Overpress Zero Failure	Overpress zero failure	
Overpress Cal. Failure	Overpress calibrationfailure	

Prompt messages（displayed in NIBP parameter area）:

Messages	**Cause**	**Level**
NIBP Resetting	NIBP measurement module is resetting	Prompt message
Overpress Testing	NIBP is testing Over-Pressure	
Manometer Testing	NIBP is testing Manometer	
Air Leakage Testing	NIBP is testing Air Leakage	

◆ **IBP**

Physiological alarm:

Alarm messages	**Cause**	**Level**
〈IBP label〉 Sys high	Sys measuring value of 〈IBP label〉 is above high alarm limit	Medium (User-Selectable Medium or High)
〈IBP label〉 Sys low	Sys measuring value of 〈IBP label〉 is below low alarm limit	
〈IBP label〉 Dia high	Dia measuring value of 〈IBP label〉 is above high alarm limit	
〈IBP label〉 Dia low	Dia measuring value of 〈IBP label〉 is below low alarm limit	
〈IBP label〉 Mean high	Mean measuring value of 〈IBP label〉 is above high alarm limit	
〈IBP label〉 Mean low	Mean measuring value of 〈IBP label〉 is below low alarm limit	

Technical alarm:

Alarm messages	**Cause**	**Level**
〈IBP label〉 sensor off	〈IBP label〉 sensor disconnect from the monitor.	Medium
Catheter off	Detection of disconnected catheter	High
IBP Communicating Error	IBP communication is error	Medium
Zero Fail.	Zero failure	Medium

Prompt messages:

Messages	**Cause**	**Level**
〈IBP label〉 zeroing	〈IBP label〉 is zero calibrating	No alarm
〈IBP label〉 Zero Succ.	〈IBP label〉 zero is successful	
〈IBP label〉 Zero Requ.	〈IBP label〉 zero is required.	

◆ CO_2

Physiological alarm:

Alarm messages	Cause	Level
$EtCO_2$ high	$EtCO_2$ measuring value is above high alarm limit	Medium (User can select Medium or High)
$EtCO_2$ low	$EtCO_2$ measuring value is below low alarm limit	
$FiCO_2$ high	$FiCO_2$ measuring value is above high alarm limit	
aWRR high	aWRR measuring value is above the high alarm limit	
aWRR low	aWRR measuring value is below the low alarm limit	
Apnea	No signal for breath in specific interval	High

Technical alarm:

Alarm messages	Cause	Level
Sensor Off	CO2 sensor off patient or off the monitor	Medium
Unspecified accuracy	Measurement of GAS module over range	Low
Zero Required	The sensor needs verify zero	Medium
Sensor Over Temp	Temperature of the sensor is over the normal working temperature.	Low
Sensor Failure	Sensor failure	Low
Sensor Not Initialized	Sensor or module is not initialized	Low
Sensor in Sleep Mode	Sensor is in sleep mode	Low
Check Sampling Tube	Sampling tube is occluded or damaged; Sampling tube is kinked or pinched； Exhaust tube is blocked or no sampling line connnected	Low
Check Adapter	CO2 airway adapter disconnected with CO2 sensor	Low
Replace Airway Adapter	The adapter is blocking, and should replaced by a new one	Low
Motor Overspeed	The unstable pressure of motor makes the speed exceed limit; motor is breakdown	Low
Default Lost	Factory default setting lost	Low

Software Error	The module software is running wrongly	Low
Hardware Error	The module hardware is breakdown	Low
Sensor Error	Sensor is breakdown	Medium
No adapter	The module is not connected to the adapter	Low
Sampling line clogged	Sampling line is blocking, or the sampling line can't inlet gas normally for the pressure.	Low
Latest span cal. failed	The latest calibration is failed	Low
Factory calibration lost/missing	FLASH breakdown leads to the loss of factory standard information	Low

Prompt messages:

Messages	Cause	Level
Zero in Progress	Zeroing is in progress.	No alarm
Sensor Warm Up	Module is warming up.	

◆ AG

Physiological alarm:

Alarm messages	Cause	Level
〈AG label〉Et High	Et〈AG label〉is above high alarm limit	Medium (User can select Medium or High)
〈AG label〉Et Low	Et〈AG label〉is below low alarm limit	
〈AG label〉Fi High	Fi〈AG label〉is above high alarm limit	Medium (User can select Medium or High)
〈AG label〉Fi Low	Fi〈AG label〉 is below low alarm limit	
AA MAC Low	Two kinds of AG gas have been detected simultaneously,the MAC value is below low alarm limit	Medium (User can select Medium or High)
AA MAC High	Two kinds of AG gas have been detected simultaneously,the MAC value is above high alarm limit	
N_2O Et High	EtN_2O is above high alarm limit	Medium (User can select Medium or High)
N_2O Et Low	EtN_2O is below low alarm limit	
N_2O Fi High	FiN_2O is above high alarm limit	Medium (User can select
N_2O Fi Low	FiN_2O is below low alarm limit	

		Medium or High)
O_2 Et High	EtO_2 is above high alarm limit	Medium (User can select Medium or High)
O_2 Et Low	EtO_2 is below low alarm limit	
O_2 Fi High	FiO_2 is above high alarm limit	Medium (User can select Medium or High)
O_2 Fi Low	FiO_2 is below low alarm limit	
O_2 Fi Low	FiO_2 measurement value is below 18%	High

Technical alarm:

Alarm messages	**Cause**	**Level**
Sensor off	Airway adaptor of GAS module disconnected with sensor	Medium
Unspecified accuracy	Measurement of GAS module over range	Low
Sensor error	Sensor is breakdown	Medium
Software Error	Software error.	Low
Hardware Error	Hardware error.	Low
Default Lost	Factory default setting lost	Low
Motor Overspeed	Motor speed out of bounds	Low
Replace Adapter	Please replace the adapter	Low
Zero Required	Zero calibration is required.	Medium
Check Sampling Tube	Sampling tube is occluded or damaged; Sampling tube is kinked or pinched； Exhaust tube is blocked or no sampling line connnected	Low
Mix Agents	Mix anaesthesia gas	Medium
Room Air O_2 Cal. Required	Room Air O_2 calibration is required	Low
O_2 Measure Failed	O_2 measure is failed	Medium
O_2 latest span cal. failed	The latest calibration is failed	Low
O_2 span Cal. Required	O_2 span calibration is required	Low

O_2 Replaced Sensor	O_2 sensor needs to be replaced	Medium
O_2 Sensor Low	O_2 Sensor signal is Low	Low
O2 Span cal. In progress	O2 Span calibration is in progress	Low
No adapter	AG module is not connected to the adapter	Low

Prompt messages:

Messages	Cause	Level
Zeroing	Zeroing is in progress.	No alarm

◆ C.O.

Physiological alarm:

Prompt	Cause	Level
TB High	TB is above high alarm limit	Medium (User can select Medium or High)
TB Low	TB is below low alarm limit	

Technical alarm:

Prompt	Cause	Level
TB Sensor Off	TB sensor may be disconnected from the patient or the monitor	Medium
TI Sensor Off	TI sensor may be disconnected from the patient or the monitor	Medium
TI Over High Range	Measurement of TI over high range	Medium
TI Below Low Range	Measurement of TI below low range	Medium
TB Over High Range	Measurement of TB over high range	Medium
TB Below Low Range	Measurement of TB below low range	Medium
TB Self-test failure	TB self testing error	Low
TI Self-test failure	TI self test error	Low
Measure Time Out	Injection is not performed over 30 sec during manual measuring	Low
Sensor error	The sensor is inconsistent with the actual	Low
Module failure	The C.O. module sheds off the monitor.	Medium

Appendix D Guidance and Manufacturer's Declaration of EMC

Guidance and manufacturer's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The *monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of the *monitor* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *monitor* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The *monitor* is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *monitor* 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	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment. Make sure there is not impulse interference >1kV in use environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *monitor* requires continued operation during power mains interruptions, it is recommended that the *monitor* be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	If image distortion occurs, it may be necessary to position the *monitor* further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity

The *monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *monitor* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the *monitor* including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 metres (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 *monitor* is used exceeds the applicable RF compliance level above, the *monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *monitor*

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *monitor*			
The *monitor* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *monitor* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *monitor* 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.74**
1	**1.17**	**1.17**	**2.33**
10	**3.69**	**3.69**	**7.38**
100	**11.67**	**11.67**	**23.33**
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.			

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