DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

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DIXION

Patient monitor

Storm 5500, Storm 5800

User Manual

Version No.: V1.4
Release Date: March 2018
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About this Manual

P/N: UM05-05-08-V1.4

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH (hereinafter called DIXION) cannot be held liable.

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The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of DIXION.

DIXION holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

DIXION only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by DIXION, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

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Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use/Indications for Use

The monitors are intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The STORM 5500 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO$_2$), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO$_2$ and Quick Temperature (Quick TEMP).

The STORM 5800 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO$_2$), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO$_2$ and Anesthetic gas (AG).

The arrhythmia detection and ST Segment analysis are intended for adult and pediatric patients.

The monitors are not intended for MRI environments.

1.2 Safety Guidance

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

WARNING

1   Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defect or signs of aging which may impair the safety or performance.

2   Medical technical equipment such as these monitor/monitoring systems must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.

3   EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

4   SHOCK HAZARD-To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.

5   Do not come into contact with the patient, table, or the monitor during defibrillation.

6   The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.

7   Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

8   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.

9   Route all cables carefully to avoid possible entanglement, apnea, or electrical interference. For the device mounted over the patient, sufficient precautionary measures should be taken to prevent it from falling on the patient.

10 Devices connecting with monitor should be equipotential.

11 If the earth protection system is not stable, use the battery for power supply.

12 Do not rely exclusively on the auditory 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 with correct operation of monitoring equipment.

WARNING

13 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.

14 The monitor is equipped with Wi-Fi to receive RF electromagnetic energy. Therefore, any other equipment complying with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.

15 Only patient cable and other accessories supplied by DIXION can be used. The performance and electric shock protection cannot be guaranteed, and the patient may be injured otherwise. Prior to use, check if the casing of a disposable or sterilized accessory is intact. Do not use it if its casing is damaged.

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

17 If several medical equipments are connected to a patient, the sum of the leakage currents shouldn't exceed the limits, otherwise it may cause shock hazard.

18 During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off. The settings configured by the user can be stored, and settings not configured by user keep no change. That is, the last settings used will be recovered when the power is restored.

19 If leakage or foul odor is detected, ensure that there's no fire around.

20 Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices. Be sure to perform the electromagnetic compatibility test, as described in the Wireless LAN System Installation, before installation and any time new medical equipment is added to the Wireless LAN coverage area.

21 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

22 The packaging is to be disposed of according to local or hospital's regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.

WARNING

23 After defibrillation, the ECG display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers' instructions.

24 Clinical decision making based on the output of the device is left to the discretion of the provider.

25 This equipment is not intended for home usage.

26 Do not service or maintain the monitor or any accessory which is in use with the patient.

27 The appliance coupler or mains plug is used as isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.

28 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

29 The monitors are MR Unsafe. The monitors are not intended for use in an MRI environment.

30 Only recommended batteries can be used for the monitor.

31 Without use of data store function, all data measured (including trend data, review data, alarm events and so on) are cleared either when the monitor is turned off or when the monitor is powered down in the process of monitoring.

32 Additional multiple socket-outlets or extension cords can't be connected to the system.

33 Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.

34 Connecting any accessory (such as external printer) or other device (such as the computer) to this monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:

a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and

b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

35 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

36 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.

37 Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in this user manual.

WARNING

38 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

39 The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.

40 Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously, such as USB connector, VGA connector or other signal input/output connectors.

41 SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.

42 SHOCK HAZARD - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.

43 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.

44 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. The equipment can protect against the effects of the discharge of a defibrillator. Use only DIXION-approved accessories.

45 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.

46 To protect the monitor from damage during defibrillation, for accurate measurement information and to protect against noise and other interference, use only accessories specified by DIXION.

47 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.

48 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION

1 Electromagnetic Interference - Ensure that the environment in which the patient monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, etc.

CAUTION

2   Keep the environment clean. Avoid vibration. Keep it far away from corrosive medicine, dust area, high temperature and humid environment.

3   Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.

4   Do not use autoclave or gas to sterilize the monitor, recorder or any accessories.

5   The device and reusable accessories may be sent back to the manufacturer for recycling or proper disposal after their useful lives.

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

7   Remove a battery whose life cycle has expired from the monitor immediately.

8   Avoid liquid splashing on the device.

9   To ensure patient safety, use only parts and accessories manufactured or recommended by DIXION.

10 Before connecting the monitor to the AC power, make sure the voltage and the power frequency are consistent with the requirements indicated on the device label or in this user manual.

11 Protect the device against mechanical damage resulting from falls, impacts, and vibration.

12 Do not touch the touch screen with a sharp object.

13 A ventilated environment is required for monitor installation. Do not block up the ventilation grille at the back of the device.

14 The device must be connected to the ground to avoid the signal interference.

15 Poor connection might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it in time.

16 To protect eyes from damage, don't look directly at supplementary LED for long time.
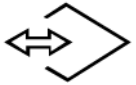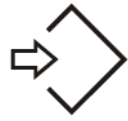
NOTE:

1   Position the device in a location where the operator can easily see the screen and access the operating controls.

2   The monitor can only be used on one patient at a time.

3   If the monitor gets damp or liquid pours on the monitor, please contact the service personnel of DIXION.

4   This monitor is not a device for treatment purposes.

5   The pictures and interfaces in this manual are for reference only.

6   Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.

7 It is recommended to format the USB flash drive to the FAT file type via PC prior to use.

1.3 Explanation of Symbols on the Monitor

1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
3		Caution
4		MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
5		Equipotential grounding
6		Alternating Current
7		Power Supply switch
8		SERIAL NUMBER
9		Network port
10		USB (Universal Serial Bus) Connection

11		Bell cancel – AUDIO PAUSED
12		NIBP measurement
13		Trend
14		Picture freeze
15		Graphical recorder
16		Menu
17		Video output
18		RS-232 port
19		Nurse call port
20		Write data into store
21		Defibrillator synchronization/Signal output port

22	⊖→	Output
23	CE 0483	CE marking
24	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
25	⚒	Date of manufacture
26	🏭	MANUFACTURER
27	P/N	Part Number
28	♲	General symbol for recovery/recyclable
29	🗑	Disposal method
30	📖	Operating instructions
31	👁	Refer to User Manual (Background: Blue; Symbol: White)
32	⚠	Warning (Background: Yellow; Symbol & outline: black)

33		Anti-theft lock
34		Gas inlet
35		Gas outlet (evac)
36	CO_2	ISA equipped to measure CO_2 only.
37	CO_2	ISA equipped to measure multiple gases.
38	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
39	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
40		Non-ionizing electromagnetic radiation
41	**FCC ID**	Federal Communications Commission: Contains FCC ID: SMQV1102DIXION
42		DO NOT REUSE

NOTE:

The user manual is printed in black and white.

Chapter 2 Installation

NOTE:

1 The monitor settings must be configured by the authorized hospital personnel.

2 To ensure that the monitor works properly, please read the user manual and follow the steps before using the monitor.

2.1 Initial Inspection

Before unpacking, check the packaging and ensure that there are no signs of mishandling or damage. If the shipping cartons are damaged, contact the carrier for compensation and package them again.

Open the package carefully and remove the monitor and accessories. Check that the contents are complete and that the correct options and accessories have been delivered.

If you have any question, please contact your local supplier.

2.2 Mounting the Monitor

Place the monitor on a flat, level surface, hang it on the bed rail, or mount it on a wall. For detailed information about how to install the wall mount for the monitor, please refer to the *Wall Mounting Bracket Assembly Instruction*.

WARNING

1 The wall mounting bracket can be fixed only on a concrete wall.

2 The safe load of the wall mounting bracket is 7.5 kg. Exceeding the safe load may cause bracket to fail and the device to fall.

2.3 Connecting the Power Cable

Connection procedure of the AC power line is listed below:

1. Make sure the AC power supply complies with the following specifications: 100 V-240 V~, 50 Hz/60 Hz.

2. Connect the power cord provided with the monitor. Connect the power cord to connector of the monitor. Connect the other end of the power cord to a grounded power outlet.

NOTE:

1 Connect the power cable to the socket specialized for hospital use.

2 Only use the power cable supplied by DIXION.

2.4 Checking the Monitor

Make sure there is no damage on the measurement accessories and cables. Then turn on the monitor, check whether the monitor can start normally. Make sure all alarm lamps light up and the alarm sound is heard when turning on the monitor.

WARNING

If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact Customer Service Center immediately.

NOTE:

1 Check all the functions of the monitor and make sure that the monitor is in good status.

2 If rechargeable batteries are provided, charge them after using the device every time, to ensure the electric power is enough.

3 The interval between double pressing of POWER switch should be longer than 1 minute.

4 After long-time continuous running, please restart the monitor to ensure the monitor's steady performance and long lifespan.

2.5 Checking the Recorder

If your monitor is equipped with a recorder, open the recorder's door to check if paper is properly installed in the slot. If no paper exists, refer to Chapter *Recording* for details.

2.6 Setting Date and Time

To set the date and time:

1. Select **Menu** > **Maintenance** > **User Maintain** > **Date/Time Setup**.

2. Adjust the date display format based on the user's habit.

3. Set the correct time of year, month, day, hour, min and sec.

2.7 Handing Over the Monitor

If you are handing over the monitor to the end-users directly after configuration, make sure that it is in the monitoring mode.

The users must be adequately trained to use the monitor before monitoring a patient. To achieve this, they should have access to, and read, the following documentation delivered with the monitor:

● User Manual (this book) - for full operating instructions.

● Quick Reference Card - for quick reminders during use.

2.8 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that

interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.

2. Increase the separation between the equipment and receiver.

3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

4. Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE:

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.

2.9 FCC RF Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

Chapter 3 Basic Operation

This manual is for clinical professionals using the STORM 5500/STORM 5800 patient monitors. Unless otherwise specified, the information here is valid for all the above products.

This user manual describes all features and options. Your monitor may not have all of them; they are not all available in all geographies. Your monitor is highly configurable. What you see on the screen, how the menus appear and so forth, depend on the way it has been tailored for your hospital and may not be exactly as shown here.

You may frequently use the follow functions:

◆ ECG monitoring (Refer to *Monitoring ECG* for more information.)

◆ SpO$_2$ monitoring (Refer to *Monitoring SpO$_2$* for more information.)

◆ PR monitoring (Refer to *Monitoring PR* for more information.)

◆ NIBP monitoring (Refer to *Monitoring NIBP* for more information.)

◆ Alarm (Refer to *Alarms* for more information.)

3.1 Overview

3.1.1 Front View
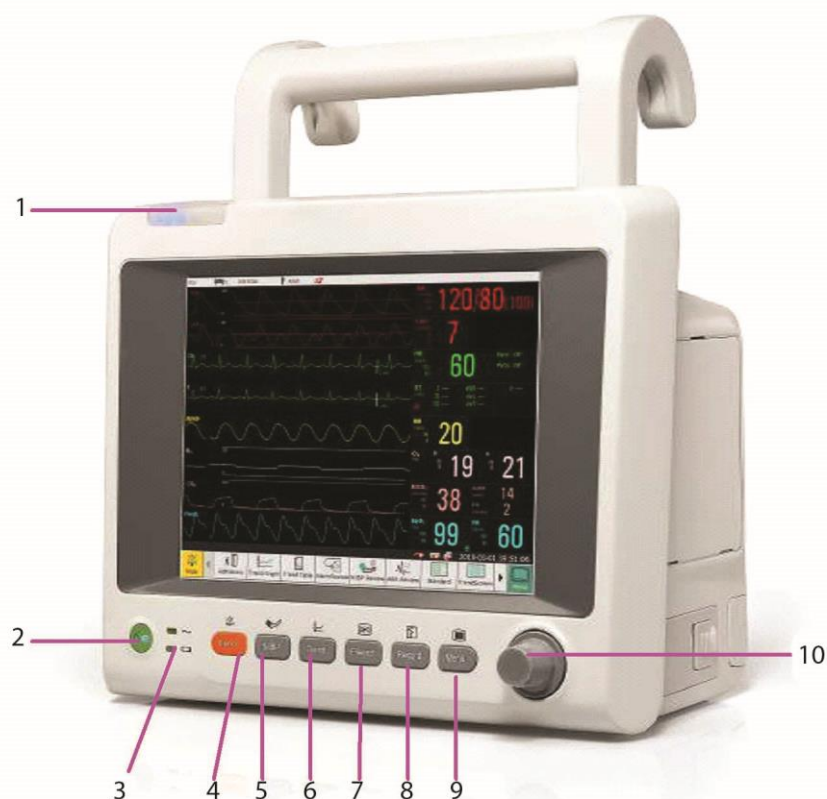
STORM 5500
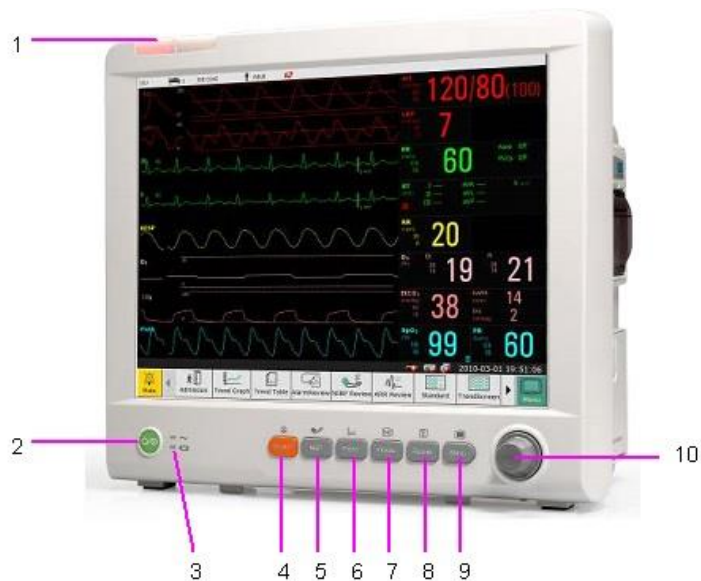
STORM 5800

1	Alarm indicator — when an alarm occurs, the alarm indicator will light or flash. The color of light represents the alarm level.
2	Power supply switch — when the monitor is connected to the AC power supply, press the key to turn the monitor on. When the monitor is turned on, press the key to turn the monitor off.
3	Battery indicator, refer to Section *Battery Power Indicator* for details.
4	Mute —Press it to suspend the output of all audible alarm signals. Upon the configuration, pressing this button to pause or turn off the audio alarm. Further information can be found in the section *Audio Alarm Paused* and section *Audio Alarm Off*.
5	Start / Stop NIBP measurement — Press this button to inflate the cuff and start blood pressure measurement. During the measurement, press the button to stop the measurement.
6	Trend Key — Press this button to enter trend table review interface.
7	Freeze /Unfreeze — In normal mode, press this button to freeze all the waveforms on the screen. In **Freeze** mode, press this button to restore the waveform refreshing.
8	Start / Stop Recording — Press this button to start a real-time recording. During the recording, press this button again to stop recording.
9	Menu — Press this button to return to the main interface when there is no menu open.
10	Rotary Knob (hereinafter called knob) — The user can rotate the knob clockwise or anticlockwise. This operation can make the highlighted item shift up, down, left or right to choose the desired item. Remember, when using the knob, rotate this button to highlight, and press it to select the

	item.

3.1.2 Rear View

STORM 5500

1	Speaker
2	Equipotential grounding terminal, if the monitor or other processing unit are used in internal examinations on the heart, ensure that the room incorporates an equipotential grounding system to which the monitor and other processing unit have separate connection.
3	Anti-theft lock interface
4	Security lock, used to prevent the power supply cord from falling.
5	Power supply interface
6	Network interface. It connects the monitor to the central monitoring system via standard network cable.
7	Nurse call port/ analog output/ defibrillator synchronization. Nurse call port: it connects the monitor to the hospital's nurse call system. Alarms indications are alerted through the nurse call system if configured to do so. Analog output: the monitor outputs the waveform through the port. Defibrillator synchronization: the monitor outputs the defibrillator synchronization signal through the port.

8	USB interfaces. They are used to connect the USB device.
9	VGA output

STORM 5800

1	VGA output
2	USB interfaces. They are used to connect the USB device.
3	Nurse call port/ analog output/ defibrillator synchronization. Nurse call port: it connects the monitor to the hospital's nurse call system. Alarms indications are alerted through the nurse call system if configured to do so. Analog output: the monitor outputs the waveform through the port. Defibrillator synchronization: the monitor outputs the defibrillator synchronization signal through the port.
4	Network interface. It connects the monitor to the central monitoring system via standard network cable.
5	RS232 interface. Connect it to communicate with other devices.
6	Anti-theft lock interface

7	Heat sink
8	Power supply interface
9	Security lock, used to prevent the power supply cord from falling.
10	Equipotential grounding terminal, if the monitor or other processing unit are used in internal examinations on the heart, ensure that the room incorporates an equipotential grounding system to which the monitor and other processing unit have separate connection.
11	Speaker

3.1.3 Side View

STORM 5500

1	Sensor interface
2	CO$_2$ module holder
3	Recorder door
4	Battery door

STORM 5800

1	Sensor port
2	AG module holder
3	Recorder door
4	Battery door

3.1.4 Configuration

Model	Size (W×H×D)	Function Configuration
STORM 5500	261 mm (W) ×215 mm (H) ×198 mm (D)	ECG (3-lead, 5-lead, 12-lead), RESP, SpO$_2$, NIBP, IBP (2 channels),TEMP, Quick TEMP, CO$_2$
STORM 5800	370 mm (W)× 320 mm (H) × 175 mm (D)	ECG (3-lead, 5-lead, 12-lead), RESP, SpO$_2$, NIBP, TEMP, IBP (4 channels), C.O., CO$_2$, AG

3.2 Operating and Navigating

Everything you need to operate the monitor is contained on its screen. Almost every element on the screen is interactive. Screen elements include measurement data, waveforms, screen keys, information fields, alarms fields and menus. The configurability of the monitor means that often you can access the same element in different ways. For example, you might be able to access an

item through its on-screen setup menu, via a hard key, or via a shortcut key. The User Manual always describes how to access items via an on-screen menu. You may use whichever way you find most convenient.
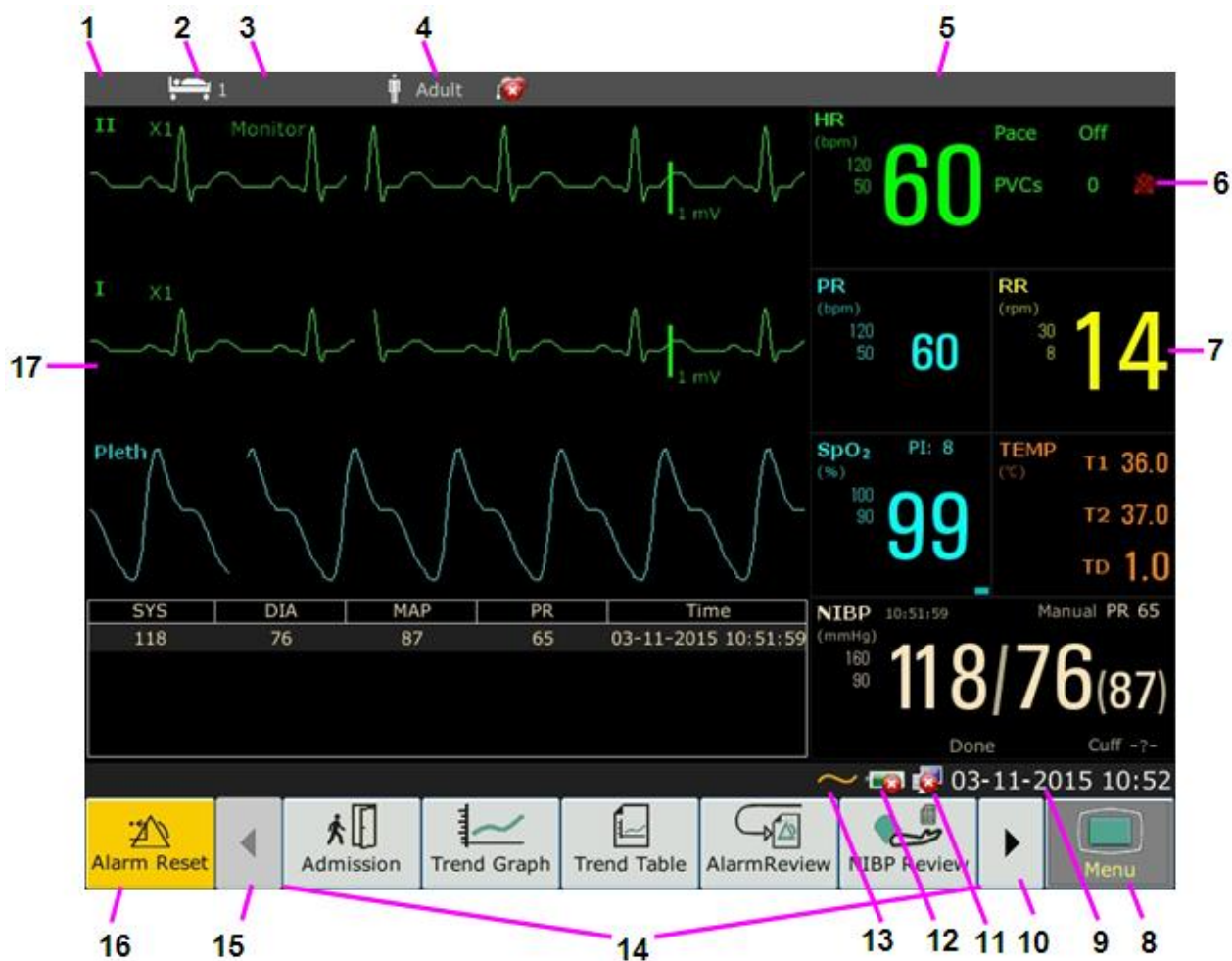
1	Department
2	Bed number
3	Patient name
4	Patient type
5	Alarm area
6	Alarm off
7	Measurement value
8	Menu
9	Date and time
10	Scroll right to display more shortcut keys
11	Networking symbol
12	Battery status symbol

13	AC power supply symbol
14	Shortcut key area
15	Scroll left to display more shortcut keys
16	Alarm reset key
17	Parameter waveform

3.2.1 Using Keys

The monitor has four different types of keys. If the key sound is enabled, the monitor gives a normal key sound when the operation is valid.

3.2.1.1 Permanent Keys

A permanent key is a graphical key that remains on the screen all the time to give you fast access to functions.

Menu   To display the main setup menu.

Alarm Reset   To reset the alarm.

3.2.1.2 Shortcut Keys

A shortcut key is a configurable graphical key, located at the bottom of the main screen. It gives you fast access to functions. The selection of shortcut keys available on your monitor depends on your monitor configuration and on the options purchased. You can adjust the shortcut key sequence as need.

	Perform a 12-lead analysis		Switch to the standard screen
	Exit from 12-lead analysis		Switch to the OxyCRG screen
	Access the 12-lead review		Switch to the large font screen
	Perform 12-lead record		Set the module switch
	Admit a patient		Change the key volume
	Review the trend graph		Adjust the screen brightness
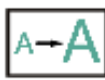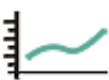
	Review the trend table		Zero the IBP sensor
	Review the alarm event		Alarm setup
	Access the NIBP review		Change the beat volume
	Access the ARR review		Enter standby mode
	Switch to the trend screen		Enter night mode
	Switch to the vital screen		Select this item by the trim knob to enable the touch screen operation
	Printer Setup		Enter MEWS interface
	Enter privacy mode		

3.2.1.3 Hardkeys

A hardkey is a physical key on a monitoring device, such as the recording key on the front panel. Refer to the illustration in *Main Unit* for more information.

3.2.1.4 Pop-up Keys

Pop-up keys are task-related graphical keys that appear automatically on the screen when required. For example, the confirmation pop-up key appears only when you need to confirm a change.

3.3 Operating Mode

3.3.1 Demo Mode

To change the operating mode into the demo mode, please refer to the following procedure:

Select **Menu** > **Common Function**, then choose **Demo Mode** from the popup interface and input password **3045**.

To exit **Demo Mode**, select **Menu** > **Common Function** > **Demo Mode**.

WARNING

Demo Mode is for demonstration purposes only. You must not change into Demo Mode

during monitoring. In Demo Mode, all stored trend information is deleted from the monitor's memory.

3.3.2 Standby Mode

To enter into standby mode, select **Menu** > **Common Function** > **Standby**, or press the shortcut key ⏻ on the screen directly, the monitor enters into standby mode after user's confirmation.

In standby mode:

1. The monitor stops monitoring patients and stores previous monitoring data.

2. The monitor won't respond to all alarms and prompts, except Battery Low alarm.

3. Audio alarm paused status discontinues. Audio alarm off, alarm off, alarm reset and alarm latch status are not influenced.

4. Continuous real-time recording will stop immediately, and other recording task will stop after current recording finishes.

5. MFM-CMS won't update monitoring data, and will display monitor's standby mode. If network is disconnected, monitor will make request for connection.

The monitor exits standby mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key (except Power ON/OFF key).

2. Battery Low alarm occurs.

After exiting standby mode, the monitor resumes monitoring, including parameter monitoring, storage and alarm; users need to press Recorder key to restart recording.

NOTE:

The monitor is unable to enter into standby mode when exporting data.

3.3.3 Night Mode

To switch to night mode, you may:

●   Select the shortcut key ☾ on the main screen, or

●   Select **Menu** > **Common Function** > **Night Mode**.

NOTE:

In night mode, the sound of key, heart beat and pulse is muted; the alarm volume and screen brightness are down to their minimum; the settings including key volume, beat volume, PR volume, alarm volume and screen brightness are unavailable.

3.3.4 Privacy Mode

Only if the monitor is connected and admitted by MFM-CMS, the privacy mode can be activated.

To enter into privacy mode, you can select **Menu** > **Maintenance** > **User Maintain** > **Shortcut**

Setup > **Privacy Mode** (it is defaulted to be off). Press the shortcut key on the screen, the monitor enters into privacy mode after user's confirmation.

In privacy mode:

1. The screen displays message: **Privacy mode** and **Patient is in monitoring without audio alarm and alarm indicator lighting. Please click screen or hard key to exit**.

2. Monitoring data, alarm information, stored data and monitor status are transmitted to MFM-CMS.

3. Audio alarm paused status discontinues. Audio alarm off, alarm off, alarm reset and alarm latch status are not influenced.

The monitor exits privacy mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key (except Power ON/OFF key).

2. Battery Low alarm occurs.

3. The monitor is disconnected with MFM-CMS.

NOTE:

The monitor is unable to enter into privacy mode when exporting data.

3.4 Changing Monitor Settings

3.4.1 Adjusting Screen Brightness

To change the screen brightness:

1. Select the shortcut key on the screen directly, or

2. Select **Menu > Common Function > Brightness**, and select the appropriate setting for the screen brightness. **10** is the brightest, **1** is the least bright.

3.4.2 Changing Date and Time

To change the date and time, please refer to Section *Setting Date and Time*.

WARNING
Change to date and time will influence the storage of trend data.

3.5 Adjusting Volume

3.5.1 Adjusting Key Volume

The key volume is the volume you hear when you select any field on the monitor screen or when

you turn the knob. To adjust the key volume:

1.   Select the shortcut key ![icon] on the screen directly, or

2.   Select **Menu** > **System Setup** > **Key Volume**, then select the appropriate setting for the key volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the key volume will be off.

3.5.2 Adjusting Alarm Volume

To change the alarm volume:

1.   Select the shortcut key ![icon] on the screen directly, or

2.   Select **Menu** > **Alarm Setup** and select the desired setting for the **AlarmVolume** item: five bars represent the maximum volume and one bar represents the minimum volume.

3.5.3 Adjusting Beat Volume

Beat volume is from HR or PR, depending on your setting of the beat source. To change the beat volume:

1.   Select the shortcut key ![icon] on the screen directly, or

2.   Select **ECG Setup** > **Beat Volume**, then select the appropriate setting for the beat volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the beat volume will be off.

3.6 Checking Your Monitor Version

To check the monitor version, please select **Menu** > **Common Function** > **About** to check the monitor software revision.

3.7 Networked Monitoring

Your monitor can be connected to the wired network and the wireless network. If the monitor is networked, a network symbol is displayed on the screen.

NOTE:
1   Be aware that some network-based functions may be limited for monitors on wireless networks in comparison to those on wired networks.

2   When selecting dynamic IP mode, please check the IP address from MFM-CMS.

3.8 Setting Languages

To change the language, please:

1.   Select **Menu** > **Maintenance** > **User Maintain**, then type the correct password **ABC** into the

displayed interface.

2. Select the **Language** option on the popup interface to open the language list.

3. Select the desired language from the list. To make the change validate, please restart the monitor.

3.9 Calibrating Screens

To calibrate the screen, please refer to the following steps:

1. Select **Menu** > **Maintenance** > **User Maintain**, input the user password **ABC**, and select **TouchScr Calibration** on the **User Maintain** menu. User can also enter into calibration interface through pressing shortcut key F9 in connected keyboard.

2. The symbol appears on the screen.

3. Click on the central point of the symbol .

NOTE:

1 If calibration file is lost or damaged, the monitor will automatically enter into screen calibration interface.

2 In the screen calibration interface, the screen turns gray and no measurement data can be displayed.

3.10 Disabling the Touch Screen

The user can disable touch screen operation by selecting and holding the permanent key for three seconds. A message of **Screen Locked** and the symbol will be displayed at the bottom of screen. To enable the touch screen operation, select the symbol by using the knob**.**

3.11 Using the Barcode Scanner

To enter the barcode setup menu, please select **Menu > Maintenance > User Maintain**. After entering the required password **ABC**, select **Other Setups > BarCode Setup**. Then the user can set serial No, last Name, first Name and so on.

NOTE:

While using keyboard, please set "Capslock" as "lower case" before using Bar Code Scanner.

3.12 Resolving IBP Label Conflicts

Each label must be unique and can only be assigned once. The measurement labels are stored in the measurement modules. If you try to use two IBP channels that have identical labels, this causes a label conflict in the monitor.

For example, an IBP channel (channel A) has already been loaded and the label Art is used for channel A. Then another IBP channel (channel B) is loaded and the label Art is also used for

channel B. In this case, a label conflict will be triggered. A prompt indicating IBP label conflict will appear on the left of the screen. Additionally, at the corresponding measurements area, a label flickers to indicate a label conflict. The flickering label is the default one assigned by the system.

The IBP channel with a label conflict will not provide any measurement data; besides, the functions of setup, zeroing and calibrating are unavailable. To resolve the label conflict, you have to change the conflicting label into a non-conflicting one via the following method:

1. Select the IBP channel with a label conflict on the screen and open the **Options** menu.

2. Choose another label among the options from the **Alias** pull-down list to resolve the label conflict.

Chapter 4 Alarms

The alarm information here applies to all measurements. Measurement-specific alarm information is discussed in the sections of individual measurements.

WARNING

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.

4.1 Alarm Category

The monitor provides two types of alarms: physiological alarms and technical alarms. Also, the monitor provides prompts.

4.1.1 Physiological alarms

If one or several physiological parameters of the currently monitored patient exceed the predefined alarm limit, the monitor will give an alarm, and this type of alarm is called physiological alarms. About the detailed alarm information, please refer to the Section *Physiological Alarm Information*.

4.1.2 Technical Alarms

If one or several technical status of the device is in abnormal status, the monitor will give an alarm. And this type of alarm is called technical alarms. Technical alarms can't be disabled. About the detailed alarm information, please refer to Section *Technical Alarm Information*.

4.1.3 Prompts

The monitor can give the character indication of monitoring process or other functions. And this character is called prompts. About the detailed alarm information, please refer to Section *Prompts*.

4.2 Selecting Alarm Tone Type

The user can select the alarm tone type as desired.

1.   Select **Menu** > **Maintenance** > **User Maintain**, and enter the required password **ABC**.

2.   If configured, select **Alarm Setup**, and set **Alarm Tone** to **Standard** or **Mode 1**.

   ◆   **Standard**: Standard alarm sound according to IEC 60601-1-8.

   ◆   **Mode 1**: User customized alarm sound according to clinical applications.

4.3 Alarm Levels

In terms of severity, the device's alarm levels can be classified into three categories: high level alarms, medium level alarms and low level alarms.

1. High level alarms

   A high level alarm intensively warns the operator of a high priority alarm condition which requires immediate operator response. Failure to respond to the cause of the alarm condition is likely to result in death or irreversible injury of the patient.

2. Medium level alarms

   A medium level alarm warns the operator of a medium priority alarm condition which requires prompt operator response. Failure to respond to the cause of the alarm condition is likely to result in reversible injury of the patient.

3. Low level alarms

   A low level alarm reminds the operator of a low priority alarm condition which requires response. And the response time for a low priority alarm condition can be greater than that for a medium priority alarm condition. Failure to respond to the cause of the alarm condition is likely to result in discomfort or reversible minor injury of the patient.

The high/medium/low-level alarms are indicated by the system in following different ways:

Standard

Alarm level	Prompt
High	Mode is "DO-DO-DO------DO-DO, DO-DO-DO------DO-DO", which is triggered once every 10 seconds. The alarm indicator flashes in red, with frequency of 1.4 Hz～2.8 Hz. The alarm message flashes with red background, and the symbol *** is displayed at the alarm area.
Medium	Mode is "DO-DO-DO", which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz～0.8 Hz. The alarm message flashes with yellow background, and the symbol ** is displayed at the alarm area.
Low	Mode is "DO-", which is triggered once every 30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly blue. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

Mode 1

Alarm level	Prompt
High	Mode is "Di-Di-Di-Di-Di-Di", which is triggered once every 10 seconds. The alarm indicator flashes in red, with frequency of 1.4 Hz～2.8 Hz. The alarm message flashes with red background, and the symbol *** is displayed at the alarm area.

Medium	Mode is "Di-Di-Di", which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz~0.8 Hz. The alarm message flashes with yellow background, and the symbol ** is displayed at the alarm area.
Low	Mode is "Di-", which is triggered once every 30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly blue. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

The sound pressure range for standard audible alarm signals is from 45 dB to 85 dB, and for Mode 1 is from 30 dB to 85 dB.

When different level alarms occur at the same time, alarm sound and alarm indicator prompt the highest level alarm, alarm messages display in turn.

The parameter area has two flash methods to prompt alarms: background flash and text flash. User can select one method from **Menu** > **Alarm Setup** > **Visual Effect**:

1. **Text Flash**: text flashes with frequency of 1 Hz.

2. **Background Flash**: background flashes with frequency of 1 Hz.

WARNING

1   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 patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

2   Ensure the volume is properly set up. When the sound pressure of audible alarm is below or equivalent to the ambient noise, it may be difficult for the operator to distinguish the audio alarm.

4.4 Controlling Alarm

4.4.1 Setting Parameter Alarm

Parameter alarm settings including alarm switch, alarm record, alarm level and alarm limit are available on the respective alarm setup menu for each parameter. To access the menu for parameter alarm settings, use the shortcut key ⚠ or select **Menu** > **Alarm Setup**, and then click **Alarm Options** to open the menu shown below for alarm settings of each parameter. Also, you can access this menu via the respective parameter setup menu.

Upper arrow or lower arrow to increase or decrease the alarm limit

High Alarm Limit

Setting value of high alarm limit

Setting value of low alarm limit
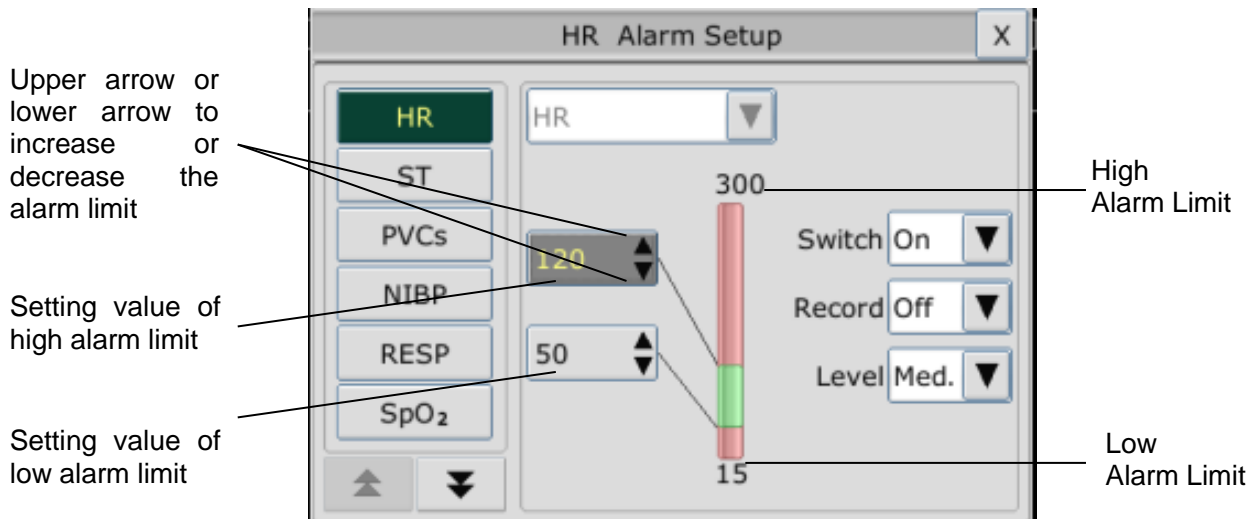
Low Alarm Limit

WARNING

1   When the alarm is set to **Off**, the monitor won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.

2   Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.

3   Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.

4.4.2 Audio Alarm Paused

You can temporarily prevent alarms from sounding by pressing the hardkey ⍻ on the front panel.

You can set the alarm pause time as desired. The default alarm pause time is 120 s.

1.   Select **Menu** > **Maintenance > User Maintain**, and enter the required password **ABC**.

2.   Select **Alarm Setup**, and set **Pause Time** to **60 s**, **120 s**, or **180 s**.

When alarms are paused,

◆   The audio alarm is turned off, and no alarms are sounding.

◆   The visual alarm indications are still displayed.

◆   The monitor displays the audio alarm paused icon .

◆   The monitor displays the remaining pause time in seconds with red background.

◆   The hardkey ⍻ on the front panel flashes in yellow.

When the alarm pause time expires, the audio alarm paused status is automatically terminated and

alarm is sounding. You can also terminate the alarm paused status by pressing the hardkey ⍺.

NOTE:

If a new alarm occurs during the audio alarm paused period, the new alarm will not be sounding.

4.4.3 Audio Alarm off

Set **Pause Time** to **Permanent**, press hardkey ⍺, the monitor displays information: **please confirm whether to activate audio alarm off function?** Click **Yes**, the monitor will enter into audio alarm off status. Click **No**, the monitor will keep current status.

- The audio alarm is turned off, and no alarms are sounding.

- The visual alarm indications are still displayed.

- The hardkey ⍺ on the front panel flashes in yellow.

Remind signal: Audio alarm off symbol and **Audio Alarm off** on a red colored background are displayed with an interval of 2s during the audio alarm off status.

Pressing the hardkey ⍺ again can resume the audio alarm.

NOTE:

If a new alarm occurs during the audio alarm off period, the new alarm will not be sounding.

4.4.4 Alarm Reset

Select the shortcut key **Alarm Reset** on the screen directly. When the alarm is reset,

◆ No alarms are sounding until a new alarm occurs.

◆ As for the active alarms, the visual alarm indications are still displayed.

◆ All latching alarms are cleared. If the alarm condition is no longer present, all alarm indications stop and the alarm is reset.

◆ It will not influence the configuration of physiological alarm off, audio paused, and audio off status.

NOTE:

If a new alarm occurs after the alarm is reset, the new alarm will be sounding.

4.5 Latching Alarms

To configure the alarm latching setting, select **Menu** > **Maintenance** > **User Maintain** > **Alarm Setup** and choose **Alarm Latch** which can be set to **On** or **Off**. When it is set to **Off**, alarm indications end when the alarm condition ends. When it is set to **On**, the visual alarm indication is still displayed after the alarm condition ends; meanwhile, the alarm time is also displayed for

the latched alarm for your reference. The indication lasts until you acknowledge the alarm.

You can use the permanent key [Alarm Reset] on the screen to acknowledge the latched alarm.

4.6 Disabling Sensor Off Alarms

To set sensor off alarm, please select **Menu** > **Maintenance** > **User Maintain** and enter the required password **ABC**. Then select **Alarm Setup** and set **Sensor Off Alm** from the pull-down list. If it is set to **On**, and a sensor off alarm occurs, after pressing the hardkey ⌷⃠ or permanent key [Alarm Reset] the user can disable the audio alarm signal, however, the visual alarm indications are still displayed. If it is set to **Off**, and a sensor off alarm occurs, after pressing the hardkey ⌷⃠ or permanent key [Alarm Reset], sensor-off status will be announced with a prompt message. It means there's no audio alarm signal and alarm indicator, but prompt information displayed.

In **Menu** > **Maintenance** > **User Maintain > Alarm Setup**, **SpO$_2$ Sensor Off** and **ECG Lead Off** alarm level can be adjusted as **High**, **Med.** or **Low**. These alarm levels are set to **Low** by default.

4.7 Network Disconnected Alarms

To configure the network disconnected alarms, select **Menu** > **Maintenance** > **User Maintain** > **Alarm Setup** and choose **Disconnect Alarm** which can be set to **On** or **Off**. The alarm is off by default.

NOTE:

1. When the monitor is connected with the central monitoring system, you must set **Disconnect Alarm** to **On**.

2. If **Disconnect Alarm** occurs during audio alarm paused or audio alarm off status, the monitor will prompt a sounding alarm with information of **NetWork Disconnect**. During the network disconnected status, activating audio alarm paused or audio alarm off function can disable the audio alarm signal of **Disconnect Alarm**.

4.8 Testing Alarms

When you switch the monitor on, a self test is started with a "Di" tone. You must check that the alarm indicator lights and that you hear a single tone. This indicates that the visible and auditory alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

NOTE:

The patient monitor will reboot in 3 seconds due to self-test failure.

Chapter 5 Alarm Information

5.1 Physiological Alarm Information

WARNING

During monitoring, the physiological alarms including ASYSTOLE, VFIB/VTAC, RESP APNEA, SpO$_2$ No Pulse, CO$_2$ APNEA, AG FiO$_2$ Low, and AG APNEA are preset to be on. ASYSTOLE, RESP APNEA, SpO$_2$ No Pulse, CO$_2$ APNEA, AG FiO$_2$ Low, and AG APNEA cannot be turned off.

Message	Cause	Alarm level
ECG		
HR High	HR measuring value is above the upper alarm limit.	User-selectable
HR Low	HR measuring value is below the lower alarm limit.	User-selectable
ST-X High	ST measuring value is above the upper alarm limit. (X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
ST-X Low	ST measuring value is below the lower alarm limit.(X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
PVCs High	PVCs measuring value is above the upper alarm limit.	User-selectable
ASYSTOLE	No QRS is detected for 4 consecutive seconds	High
VFIB/VTAC	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.	High
VT > 2	$3 \leq$ the number of consecutive PVCs < 5	User-selectable
COUPLET	2 consecutive PVCs	User-selectable
BIGEMINY	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.	User-selectable
TRIGEMINY	A dominant rhythm of N, N, V, N, N,V	User-selectable
R ON T	A type of single PVC under the condition that HR < 100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Single PVC detected in normal heartbeats.	User-selectable

Message	Cause	Alarm level
TACHY	Adult: RR interval for 5 consecutive QRS complex $\leq$ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\leq$ 0.375 s.	User-selectable
BRADY	Adult: RR interval for 5 consecutive QRS complex $\geq$ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\geq$ 1 s.	User-selectable
MISSED BEATS	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR $\geq$ 120 bpm, no beats are detected for one second.	User-selectable
IRR	Consistently irregular heart rhythm	User-selectable
PNC	PACER NOT CAPTURE: no QRS complex detected in 300ms after a pace pulse.	User-selectable
PNP	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.	User-selectable
VBRADY	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.	User-selectable
VENT	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.	User-selectable
RESP		
RESP APNEA	RESP can not be measured within the set apnea alarm delay time.	High
RR High	RR measuring value is above upper alarm limit.	User-selectable
RR Low	RR measuring value is below lower alarm limit.	User-selectable
SpO$_2$		
SpO$_2$ High	SpO$_2$ measuring value is above upper alarm limit.	User-selectable
SpO$_2$ Low	SpO$_2$ measuring value is below lower alarm limit.	User-selectable
SpO$_2$ No Pulse	The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor can't detect the pulse signal.	High
PR High	PR measuring value is above upper alarm limit.	User-selectable
PR Low	PR measuring value is below lower alarm limit.	User-selectable

Message	Cause	Alarm level
TEMP		
T1 High	Measuring value of T1 channel is above upper alarm limit.	User-selectable
T1 Low	Measuring value of T1 channel is below lower alarm limit.	User-selectable
T2 High	Measuring value of T2 channel is above upper alarm limit.	User-selectable
T2 Low	Measuring value of T2 channel is below lower alarm limit.	User-selectable
TD High	Measuring value of TD channel is above upper alarm limit.	User-selectable
NIBP		
SYS High	SYS measuring value is above upper alarm limit.	User-selectable
SYS Low	SYS measuring value is below lower alarm limit.	User-selectable
DIA High	DIA measuring value is above upper alarm limit.	User-selectable
DIA Low	DIA measuring value is below lower alarm limit.	User-selectable
MAP High	MAP measuring value is above upper alarm limit.	User-selectable
MAP Low	MAP measuring value is below lower alarm limit.	User-selectable
PR (NIBP) High	PR measuring value from the NIBP module is above upper alarm limit.	User-selectable
PR (NIBP) Low	PR measuring value from the NIBP module is below lower alarm limit.	User-selectable
IBP		
Art SYS High	Art SYS measuring value is above upper alarm limit.	User-selectable
Art SYS Low	Art SYS measuring value is below lower alarm limit.	User-selectable
Art DIA High	Art DIA measuring value is above upper alarm limit.	User-selectable
Art DIA Low	Art DIA measuring value is below lower alarm limit.	User-selectable
Art MAP High	Art MAP measuring value is above upper alarm limit.	User-selectable
Art MAP Low	Art MAP measuring value is below lower alarm limit.	User-selectable
PA SYS High	PA SYS measuring value is above upper alarm limit.	User-selectable
PA SYS Low	PA SYS measuring value is below lower alarm limit.	User-selectable
PA DIA High	PA DIA measuring value is above upper alarm limit.	User-selectable
PA DIA Low	PA DIA measuring value is below lower alarm limit.	User-selectable
PA MAP High	PA MAP measuring value is above upper alarm limit.	User-selectable

Message	Cause	Alarm level
PA MAP Low	PA MAP measuring value is below lower alarm limit.	User-selectable
CVP MAP High	CVP MAP measuring value is above upper alarm limit.	User-selectable
CVP MAP Low	CVP MAP measuring value is below lower alarm limit.	User-selectable
ICP MAP High	ICP MAP measuring value is above upper alarm limit.	User-selectable
ICP MAP Low	ICP MAP measuring value is below lower alarm limit.	User-selectable
LAP MAP High	LAP MAP measuring value is above upper alarm limit.	User-selectable
LAP MAP Low	LAP MAP measuring value is below lower alarm limit.	User-selectable
RAP MAP High	RAP MAP measuring value is above upper alarm limit.	User-selectable
RAP MAP Low	RAP MAP measuring value is below lower alarm limit.	User-selectable
P1 SYS High	P1 SYS measuring value is above upper alarm limit.	User-selectable
P1 SYS Low	P1 SYS measuring value is below lower alarm limit.	User-selectable
P1 DIA High	P1 DIA measuring value is above upper alarm limit.	User-selectable
P1 DIA Low	P1 DIA measuring value is below lower alarm limit.	User-selectable
P1 MAP High	P1 MAP measuring value is above upper alarm limit.	User-selectable
P1 MAP Low	P1 MAP measuring value is below lower alarm limit.	User-selectable
P2 SYS High	P2 SYS measuring value is above upper alarm limit.	User-selectable
P2 SYS Low	P2 SYS measuring value is below lower alarm limit.	User-selectable
P2 DIA High	P2 DIA measuring value is above upper alarm limit.	User-selectable
P2 DIA Low	P2 DIA measuring value is below lower alarm limit.	User-selectable
P2 MAP High	P2 MAP measuring value is above upper alarm limit.	User-selectable
P2 MAP Low	P2 MAP measuring value is below lower alarm limit.	User-selectable
CO_2		
$EtCO_2$ High	$EtCO_2$ measuring value is above upper alarm limit.	User-selectable
$EtCO_2$ Low	$EtCO_2$ measuring value is below lower alarm limit.	User-selectable
$FiCO_2$ High	$FiCO_2$ measuring value is above alarm limits.	User-selectable
CO_2 APNEA	In the set apnea alarm delay time interval, no RESP can be detected using CO_2 module.	High
AwRR High	AwRR measuring value is above upper alarm limit.	User-selectable
AwRR Low	AwRR measuring value is below lower alarm limit.	User-selectable
AG		
$EtCO_2$ (AG) High	$EtCO_2$ (AG) measuring value is above upper alarm limit.	User-selectable

Message	Cause	Alarm level
EtCO$_2$ (AG) Low	EtCO$_2$ (AG) measuring value is below lower alarm limit.	User-selectable
FiCO$_2$ (AG) High	FiCO$_2$ (AG) measuring value is above alarm limits.	User-selectable
AwRR (AG) High	AwRR (AG) measuring value is above upper alarm limit.	User-selectable
AwRR (AG) Low	AwRR (AG) measuring value is below lower alarm limit.	User-selectable
EtO$_2$ High	EtO$_2$ measuring value is above upper alarm limit.	User-selectable
EtO$_2$ Low	EtO$_2$ measuring value is below lower alarm limit.	User-selectable
FiO$_2$ High	FiO$_2$ measuring value is above upper alarm limit.	User-selectable
FiO$_2$ Low	FiO$_2$ measuring value is below lower alarm limit.	User-selectable
EtN$_2$O High	EtN$_2$O measuring value is above upper alarm limit.	User-selectable
EtN$_2$O Low	EtN$_2$O measuring value is below lower alarm limit.	User-selectable
FiN$_2$O High	FiN$_2$O measuring value is above upper alarm limit.	User-selectable
FiN$_2$O Low	FiN$_2$O measuring value is below lower alarm limit.	User-selectable
EtHAL High	EtHAL measuring value is above upper alarm limit.	User-selectable
EtHAL Low	EtHAL measuring value is below lower alarm limit.	User-selectable
FiHAL High	FiHAL measuring value is above upper alarm limit.	User-selectable
FiHAL Low	FiHAL measuring value is below lower alarm limit.	User-selectable
EtENF High	EtENF measuring value is above upper alarm limit.	User-selectable
EtENF Low	EtENF measuring value is below lower alarm limit.	User-selectable
FiENF High	FiENF measuring value is above upper alarm limit.	User-selectable
FiENF Low	FiENF measuring value is below lower alarm limit.	User-selectable
EtISO High	EtISO measuring value is above upper alarm limit.	User-selectable
EtISO Low	EtISO measuring value is below lower alarm limit.	User-selectable
FiISO High	FiISO measuring value is above upper alarm limit.	User-selectable
FiISO Low	FiISO measuring value is below lower alarm limit.	User-selectable
EtSEV High	EtSEV measuring value is above upper alarm limit.	User-selectable
EtSEV Low	EtSEV measuring value is below lower alarm limit.	User-selectable
FiSEV High	FiSEV measuring value is above upper alarm limit.	User-selectable
FiSEV Low	FiSEV measuring value is below lower alarm limit.	User-selectable
EtDES High	EtDES measuring value is above upper alarm limit.	User-selectable
EtDES Low	EtDES measuring value is below lower alarm limit.	User-selectable

Message	Cause	Alarm level
FiDES High	FiDES measuring value is above upper alarm limit.	User-selectable
FiDES Low	FiDES measuring value is below lower alarm limit.	User-selectable
AG FiO₂ Low	FiO_2 measure value is extremely low.	High
AG APNEA	In the set apnea alarm delay time interval, no RESP can be detected using AG module.	High
C.O.		
TB High	TB measuring value is above upper alarm.	User-selectable
TB Low	TB measuring value is below lower alarm.	User-selectable

5.2 Technical Alarm Information

NOTE:

The ECG alarm information listed in the below table describes the lead names in America. For the corresponding lead names in Europe, please refer to the section *Installing Electrodes*.

Message	Cause	Alarm Level	Action Taken
ECG			
ECG Lead Off	1) The drive electrode or more than one ECG limb electrode falls off the skin; 2) ECG cables fall off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG LL Lead Off	ECG electrode LL falls off the skin or the ECG cable LL falls off the monitor.	Low	
ECG LA Lead Off	ECG electrode LA falls off the skin or the ECG cable LA falls off the monitor.	Low	
ECG RA Lead Off	ECG electrode RA falls off the skin or the ECG cable RA falls off the monitor.	Low	
ECG V Lead Off	ECG electrode V falls off the skin or the ECG cable V falls off the monitor.	Low	
ECG V1 Lead Off	ECG electrode V1 falls off the skin or the ECG cable V1 falls off.	Low	Make sure that all electrodes, leads and patient cables are

Message	Cause	Alarm Level	Action Taken
ECG V2 Lead Off	ECG electrode V2 falls off the skin or the ECG cable V2 falls off.	Low	properly connected.
ECG V3 Lead Off	ECG electrode V3 falls off the skin or the ECG cable V3 falls off.	Low	
ECG V4 Lead Off	ECG electrode V4 falls off the skin or the ECG cable V4 falls off.	Low	
ECG V5 Lead Off	ECG electrode V5 falls off the skin or the ECG cable V5 falls off.	Low	
ECG V6 Lead Off	ECG electrode V6 falls off the skin or the ECG cable V6 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG Signal Exceeded	ECG measuring signal is beyond measuring range.	Low	Check lead connection and patient condition
ECG Comm Fail	ECG module failure or communication failure	High	Stop measuring function of ECG module, and notify biomedical engineer or manufacturer's service staff.
ECG Noise	ECG measuring signal is greatly interrupted.	Low	Check lead connection and patient condition
RESP			
RESP Comm Fail	RESP module failure or communication failure	High	Stop measuring function of RESP module, and notify biomedical engineer or the manufacturer's service staff.

Message	Cause	Alarm Level	Action Taken
RESP Cardiac Artifact	No RESP waveform can be detected due to apnea or shallow breathing of the patient.	High	Check whether the patient is breathing normally. Take measures to help the patient breathe normally when necessary. If the patient is breathing normally, try to adjust the electrode position on the patient in order to reduce the interference of cardiogenic artifact.
RESP Noise	RR cannot be measured due to patient movement.	Low	Check whether the RESP leads are well connected. Keep the patient calm for better monitoring.
RR Exceed	RR measuring value is out of the measure range.	Medium	Check whether interference to the respiratory signal exists. And check whether the patient is breathing normally; breathing too rapidly or too slowly may endanger patient's life.
SpO$_2$			
SpO$_2$ Sensor Off	SpO$_2$ sensor may be disconnected from the patient or the monitor.	Low	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the monitor and cables are well connected.

Message	Cause	Alarm Level	Action Taken
SpO$_2$ Comm Fail	SpO$_2$ module failure or communication failure	High	Stop using measuring function of SpO$_2$ module, and notify biomedical engineer or manufacturer's service staff.
SpO$_2$ Sensor Err	Malfunction in the SpO$_2$ sensor or in the extension cable.	Low	Replace the SpO$_2$ sensor or the extension cable.
SpO$_2$ No Sensor	SpO$_2$ sensor was not connected well or connected to the monitor, or the connection is loose.	Low	Make sure the monitor and sensor are well connected, reconnect the sensor.
SpO$_2$ Low Perfusion	The pulse signal is too weak or the perfusion of the measurement site is too low. The SpO$_2$ value and PR value might be inaccurate then.	Low	Reconnect the SpO$_2$ sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO$_2$ Noisy Signal	There is interference with SpO$_2$ measurement signals due to patient movement, ambient light, electrical interference or else.	Low (DIXION SpO$_2$ module)	Check the condition of patient and avoid patient movement; make sure the cable is well connected.
SpO$_2$ Light Interference	Ambient light around the sensor is too strong.	Low	Reduce interference of the ambient light and avoid sensor's exposure to strong light.

Message	Cause	Alarm Level	Action Taken
NIBP			
NIBP Comm Fail	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, and notify biomedical engineer or manufacturer's service staff.
NIBP Leak	NIBP pump, valve, cuff or tube has a leakage.	Low	Check the connections and the wrapped cuff to see whether they are all prepared well.
NIBP Excessive Pressure	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Init Pressure High	The initial pressure is too high during measuring	Low	
NIBP Aux Excessive Pressure	Pressure has exceeded the second safety limit as specified.	High	Notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm Level	Action Taken
NIBP Time Out	Measuring time has exceeded the specified time.	Low	Measure again or use other measuring method.
NIBP Self Test Error	Sensor or other hardware errors.	Low	If failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Cuff Type Error	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
NIBP System Pressure Abnormality	Atmospheric pressure or system pressure is abnormal. The valve is occluded so that deflation is failed.	Low	Check whether the airway is occluded or pressure sensor works properly. If the problem still exists, contact your service personnel.
NIBP System Failure	NIBP is not calibrated.	High	Contact your service personnel.

Message	Cause	Alarm Level	Action Taken
NIBP Weak Signal	Cuff is too loose or patient pulse is too weak.	Low	Use other methods to measure blood pressure.
NIBP Range Exceeded	Maybe the patient blood pressure value is beyond the measurement range.	High	Use other methods to measure blood pressure.
NIBP Loose Cuff	Cuff is not properly wrapped or no cuff is connected.	Low	Properly wrap the cuff.
NIBP Interference	Signal noise is too large or pulse rate is not regular due to the patient movement.	Low	Make sure that the patient under monitoring is motionless.
NIBP Leak Test Error	Fail to deflate normally during the leak test, so NIBP leak test cannot be finished.	Low	Test again. If the problem still exists, contact your service personnel.
NIBP Pressure Low	Maybe pre-inflation pressure can't block the vessel.	Low	Check if the cuff leak or cuff is properly wrapped.
NIBP Pulse Abnormal	Arrhythmia is serious or pulse rate is not regular due to the patient movement.	Low	Make sure that the patient under monitoring is motionless.
NIBP Pulse Signal Weak	Pulse is too weak, and the detected signal is too weak.	Low	Check if the cuff leak or cuff is properly wrapped.

Message	Cause	Alarm Level	Action Taken
TEMP			
TEMP T1 Sensor Off	Temperature cable of TEMP channe1 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected
TEMP T2 Sensor Off	Temperature cable of TEMP channe2 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected.
Excessive T1	TEMP1 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
Excessive T2	TEMP2 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
TEMP Comm Fail	TEMP module failure or communication failure.	High	Stop measuring function of TEMP module, and notify biomedical engineer or Manufacturer's service staff.
T1 Calibration Failed	T1 calibration failed.	High	Please check whether the module works properly.
T2 Calibration Failed	T2 calibration failed	High	Please check whether the module works properly.
IBP			
YY Sensor Off (YY stands for the IBP label name: Art, PA, CVP, RAP, LAP, ICP, P1 and P2)	IBP sensor falls off.	Medium	Check the sensor connection and reconnect the sensor.
IBP Catheter Off	IBP catheter falls off due to patient movement.	High	Check the catheter connection and reconnect it.

Message	Cause	Alarm Level	Action Taken
IBP Sensor Err	Malfunction in the IBP sensor or in the extension cable.	Medium	Replace the IBP sensor or the extension cable.
YY Comm Fail (YY stands for the IBP label name: Art, PA, CVP, RAP, LAP, ICP, P1 and P2)	IBP module failure or communication failure	High	Stop measuring function of IBP module, and notify biomedical engineer or Manufacturer's service staff.
C.O.			
C.O. Comm Fail	C.O. module failure or communication failure	High	Stop measuring of C.O. module, or notify biomedical engineer or Manufacturer's service staff.
C.O. TI Sensor Off	C.O. TI sensor not connected	Low	Insert injective temperature sensor.
C.O. TB Sensor Off	C.O. TB sensor not connected	Low	Insert TB sensor.
C.O. TEMP Out Of Range	TI/TB measuring value is beyond measuring range.	High	Please check TI/TB sensor.
AG			
AG Comm Fail	AG module failure or communication failure.	High	Stop measuring function of AG module, and notify biomedical engineer or Manufacturer's service staff.
CO_2 Out Of Range	The CO_2 concentration exceeds the accuracy range of AG module.	High	
N_2O Out Of Range	The N_2O concentration exceeds the accuracy range of AG module.	High	
AA Out Of Range	The anesthesia gas concentration exceeds the accuracy range of AG module.	High	

Message	Cause	Alarm Level	Action Taken
O$_2$ Out Of Range	The O$_2$ concentration exceeds the accuracy range of AG module.	High	
AG Baro Press Out Of Range	The barometric pressure exceeds the specified working barometric pressure range.	High	Make sure the AG module is used within the specified barometric pressure range.
AG Mixed Agents MAC<3	Two types of anesthetic agents are present in the gas mixture, and the concentration is low.	Low	Adjust the concentration of the anesthetic agents if necessary.
AG Mixed Agents MAC≥3	Two types of anesthetic agents are present in the gas mixture, and the concentration is high.	Medium	Adjust the concentration of the anesthetic agents if necessary.
AG AA Id Unreliable	1) Mainstream: The airway adapter was replaced without a zeroing. 2) More than 2 anesthetic agents are present in the breathing circuit. 3) High concentrations of solvents, cleaning agents or other interfering gases are present in the breathing circuit.	Medium	1) Perform a zeroing after replacing the adapter. 2) Reduce the number of anesthetic agent types. 3) Replace the sampling tube or reduce the interfering gases.
AG Zero Required	Zeroing of AG module is required.	Medium	Perform zero calibration.
AG Replace O$_2$ Sensor	Replacement of the O$_2$ sensor is required.	Medium	Stop measuring function of AG module, and notify biomedical engineer or Manufacturer's service staff.
AG Motor Error	Malfunction in the AG motor.	High	
O$_2$ Cali Required	O$_2$ sensor requires calibration.	Low	
AG Software Error	Malfunction in the AG software.	High	

Message	Cause	Alarm Level	Action Taken
AG Hardware Error	Malfunction in the AG hardware.	High	
AG Uncalibrated	AG module calibration is not completed.	High	
AG Calibration Fail	Calibration of the sidestream AG module fails.	Medium	
AG Replace Adapter	Replacement of the adapter is required.	Medium	Replace the adapter.
AG TEMP Out Of Range	The temperature of the AG module exceeds the specified working temperature range.	High	Make sure the AG module is used within the specified temperature range.
Sample Line Occluded	The sampling tube is occluded.	Medium	Replace the sampling tube.
O_2 Sensor Error	Malfunction in the O_2 sensor inside the sidestream AG module.	High	Stop measuring function of AG module, and notify biomedical engineer or Manufacturer's service staff.
O_2 Port Clogged	AG module O_2 Port is occluded.	Medium	
AG No Adapter	No adapter is connected.	Medium	Connect the adapter correctly.
No Sample Line	No sampling tube is connected.	Medium	Connect the sampling tube correctly.
AG Occlusion	AG module sample line occluded	High	Replace the sampling line.
Check Watertrap/Sample Line	Watertrap or sample line falls off.	Low	1) Check whether water trap is installed normally. 2) Check whether sample line is installed normally.
AG Change Watertrap	Malfunction in watertap	Medium	Replace the watertrap.
Watertrap will be full	Watertrap will be full.	Medium	Replace the watertrap.

Message	Cause	Alarm Level	Action Taken
AG Agent Mixture	Mixture agents are detected, but the monitor cannot calculate MAC because of low concentration.	Medium	Check agents' concentration ratio.
CO_2			
CO_2 Comm Fail	CO_2 module failure or communication failure	High	Check if the water tray has been fixed.
CO_2 Zero Required	Zero calibration failure	Low	Disconnect the sampling cannula or adapter from the airway; initiate the zeroing before making sure that no expired air is inside the sampling cannula and adapter.
CO_2 Check Adapter	1) For the Respironics CO_2 module: The cannula is off or disconnected. 2) For the DIXION CO_2 module: The water trap is disconnected or not properly connected.	Low	1) For the Respironics CO_2 module: Check whether the adapter is properly connected or replace the adapter. 2) For the DIXION CO_2 module: Properly connect the water trap.
CO_2 Sensor Over Temp	CO_2 sensor temperature exceeds +40 °C.	High	Stop using measuring function of CO_2 module, notify biomedical engineer.
CO_2 Out Of Range	The CO_2 concentration exceeds the accuracy range of CO_2 module.	High	Reduce CO_2 concentration.

Message	Cause	Alarm Level	Action Taken
CO$_2$ Sensor Faulty	CO$_2$ module failure	High	Stop measuring function of CO$_2$ module, notify biomedical engineer.
CO$_2$ Occlude	Water trap of SideStream is occluded.	High	Make sure the gas exhaust works well
QuickTemp			
QuickTemp Comm Fail	TEMP module failure or communication failure.	High	Stop measuring function of TEMP module, and notify biomedical engineer or manufacturer's service staff.
Temp exceed limit	The TEMP value is beyond the range of +25 °C ~ +45 °C.	Med	Put the sensor into the sensor bracket, take it out and measure again.
No Temp Sensor	TEMP sensor is not connected to the TEMP module.	Low	Connect the sensor and the monitor well, and measure again.
Ambient temp too high	The Sensor temperature is higher than +40 °C.	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.
Ambient temp too low	The Sensor temperature is lower than +10 °C.	Low	
Probe temp too high	The original temperature of sensor >+33 °C & ≤+40 °C.	Low	
Probe data error	Offline: NTC resistance >R 0 °C; Short: NTC resistance <R+100 °C.	Med	Put the sensor into the sensor bracket, take it out and

Message	Cause	Alarm Level	Action Taken
Probe heater error	Single failure	Med	measure again. If the problem persists, stop using measuring function of TEMP module, and notify biomedical engineer or manufacturer's service staff.
Temp Sensor Off	After the sensor temperature reaches Predict value, it descends to the value lower than Predict value.	Med	Reconnect the sensor and make sure that the cable is properly connected.
Others			
Battery Low	Battery Low	High	Please change the battery or charging.
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper
Recorder setup needed	The user presses the **RECORD** button when the monitor is not installed with a recorder.	Low	Notify the manufacturer's service staff to install and set the recorder.
Printer Unavailable	The selected printer is not available.	Low	Check whether the network connection is in good condition and whether the printer is malfunctioning.
Removable device is full	Less than 10M space is left in the removable device.	Low	Delete some data in the removable device or use another removable device.
Removable dev read-only	The removable device is read-only.	Low	Repair the removable device or replace it with a new one.

Message	Cause	Alarm Level	Action Taken
Network Disconnect	In distributed alarm system, the monitor's network is disconnected.	Low	1) Check if the network cable is well connected. 2) Check if the CMS is turned on. 3) Check if the IP of bedside monitor and CMS are on the same network segment.

5.3 Prompts

Message	Cause
ECG ARR Learning	The QRS template building required for Arr. Analysis is in process.
VFIB/VTAC Off	VFIB/VTAC alarm is set to **Off**.
SpO$_2$ Search Pulse	SpO$_2$ module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
Manual Measuring	In manual measuring mode
Continual Measuring	In continuous measuring mode
Auto Measuring	In automatic measuring mode
Measurem. Canceled	Press the "Start/stop NIBP measurement" button to stop the measurement.
Calibrating	During calibrating
Calibrat. Canceled	Calibration is over.
Leak. Test Running	The leakage test is in process.
Leak.Test Canceled	Pneumatic test over
Module Self Test	The module is self-testing.
STAT Measuring	Block vessel to puncture in this mode.
Manometer Mode	Calibrate in this mode.
Please Switch To Maintain Mode	Need to calibrate in this mode.
Please Switch To Normal Mode	Need to measure in normal mode.
Leakage Test Ok	There is no leak.
Resetting	NIBP module in resetting

Message	Cause
Please Start	NIBP module is in idle status.
Done	NIBP measurement is completed.
Quick TEMP Is Warming Up	Quick TEMP Is Warming Up.
Place Probe On Measure Place	Probe isn't placed on the measurement site.
CO_2 Standby	Turn from measuring mode to standby mode, making the module in energy-saving status.
CO_2 Sensor Warms Up	The CO_2 module is in warm-up state.
CO_2 Zero Start	CO_2 module starts zero calibration.
CO_2 Zero OK	CO_2 module completes zero calibration.
Please Press 'Zero'.	Enter the IBP zeroing menu, and zeroing is not performed yet.
Zero OK	IBP completes zeroing.
Pulsatile Pressure Zero Fail.	During the zeroing process, pressure fluctuation is excessive.
Pressure out of normal range,Fail.	During the zeroing process, pressure value is beyond the zeroing range.
Sensor Off, Fail!	Perform zeroing when the sensor is off.
Invalid Time,Zero Fail.	Time is not set up prior zeroing.
Unable to Calibrate in Demo Mode	Perform zeroing in Demo Mode.
Zeroing...	Zeroing is in progress.
Please Press 'Calibrate'.	Enter the Calibration menu, and Calibration is not performed yet.
Calibration OK	Calibration is completed.
Pulse Pressure Calibration Failed	During the Calibration process, pressure fluctuation is excessive.
Pressure out of range	During the Calibration process, pressure value is beyond the Calibration range.
Zeroing and Calibration Failed	Zeroing is not performed prior calibration.
Sensor Off,Fail.	Perform calibration when the sensor is off.
Invalid Time,Calibration Fail.	Time is not set up prior calibration.
Unable to Calibrate in Demo Mode	Perform calibration in Demo Mode.
Calibrating...	Calibration is in progress.

Message	Cause
IBP alias collision	The same IBP label appears.
C.O. Lack Param	Parameter is not configured for C.O. measurement.
AG Self-Testing......	AG module is performing a power-on self-test.
AG Span Calib In Progress	The calibration of AG module is in progress.
MultiGas Zero in Progress	The zeroing of AG module is in progress.
Warm-up over	The monitor displays this message after taking the sensor out of the bracket and warm-up is over.
Measure over	After the Predict measuring is over, the data and message display on the interface.
Measure time out	No measuring result after the module entering Predict state for 30 s.
Printer Busy	The monitor is performing a print job.
No Default Printer	No default printer has been set.
Incomplete parameter input, unable to score	In MEWS interface, parameters are not completely input.
No WIFI module detected	No Wi-Fi module is detected.
SpO$_2$ Noisy Signal	There is interference with SpO$_2$ measurement signals due to patient movement, ambient light, electrical interference or else. (Nellcor SpO$_2$ module)

5.4 Adjustable Range of Alarm Limits

ECG alarm limits are listed as follows: unit (bpm)

	Patient Type	ALM HI	ALM LO
HR	ADU	300	15
	PED	350	15
	NEO	350	15

ST analysis alarm limits are listed as follows: unit (mV)

	ALM HI	ALM LO
ST	2.0	-2.0

PVCs alarm upper limits are listed as follows:

	ALM HI	ALM LO
PVCs	100	1

RESP alarm limits are listed as follows: unit (rpm)

Patient Type	ALM HI	ALM LO
ADU	120	6
PED	150	6
NEO	150	6

SpO_2 alarm limits are listed as follows (unit %):

	ALM HI	ALM LO
SpO_2	100	20

PR alarm limits is listed as follows: unit (bpm)

	ALM HI	ALM LO
PR	300	30

NIBP alarm limits are listed as follows: unit (mmHg, kPa, 1 mmHg=0.133 kPa)

DIXION module:

Patient Type		ALM HI	ALM LO
ADU	SYS	270	40
	DIA	215	10
	MAP	235	20
	PR (NIBP)	240	40
PED	SYS	230	40
	DIA	180	10
	MAP	195	20
	PR (NIBP)	240	40
NEO	SYS	135	40
	DIA	100	10
	MAP	110	20
	PR (NIBP)	240	40

Omron module:

Patient Type		ALM HI	ALM LO
ADU/ PED	SYS	250	60
	DIA	200	40
	MAP	235	45
	PR (NIBP)	200	40
NEO	SYS	120	40
	DIA	90	20
	MAP	100	30
	PR (NIBP)	240	40

SunTech module:

Patient Type		ALM HI	ALM LO
ADU	SYS	260	40
	DIA	200	20
	MAP	220	26
	PR (NIBP)	220	30
PED	SYS	230	40
	DIA	160	20
	MAP	183	26
	PR (NIBP)	220	30
NEO	SYS	130	40
	DIA	100	20
	MAP	110	26
	PR (NIBP)	220	30

TEMP alarm limits are listed as follows:

	ALM HI	ALM LO
T1	50°C (122 ºF)	0°C (32 ºF)
T2	50°C (122 ºF)	0°C (32 ºF)
TD	50°C (122 ºF)	/

IBP alarm limits are listed as follows: unit (mmHg)

	ALM HI	ALM LO
Art	300	0
RAP	40	-10
LAP	40	-10
CVP	40	-10
PA	120	-6
ICP	40	-10
P1	300	-50
P2	300	-50

CO_2 alarm limits are listed as follows:

	ALM HI	ALM LO
$EtCO_2$	150 mmHg	0 mmHg
$FiCO_2$	50 mmHg	/
AwRR	150 rpm	2 rpm

C.O. alarm limits are listed as follows:

	ALM HI	ALM LO
TB	43 °C (109.4 ºF)	23 °C(73.4 ºF)

Quick Temp alarm limits are listed as follows:

Patient Type	ALM HI	ALM LO
ADU	42 °C (107.6 ºF)	35.5 °C (95.9 ºF)
PED	42 °C (107.6 ºF)	35.5 °C (95.9 ºF)

AG alarm limits are listed as follows:

Masimo Module

	ALM HI	ALM LO
$FiCO_2$	25.0%	0.1%
$EtCO_2$	25.0%	0%
FiO_2	100.0%	18.0%
EtO_2	100.0%	0%
FiN_2O	100.0%	0%
EtN_2O	100.0%	0%
EtDes	18.0%	0%
FiDes	18.0%	0%
EtIso	5.0%	0%
FiIso	5.0%	0%
EtHal	5.0%	0%
FiHal	5.0%	0%
EtSev	8.0%	0%
FiSev	8.0%	0%
EtEnf	5.0%	0%
FiEnf	5.0%	0%
awRR	150 rpm	0 rpm
Apnea Time	40s	20s

Dräger Minimodule

	ALM HI	ALM LO
$FiCO_2$	13.6%	0%
$EtCO_2$	13.6%	0%
FiO_2	100.0%	18.0%
EtO_2	100.0%	0%
FiN_2O	100.0%	0%
EtN_2O	100.0%	0%
EtDes	20.0%	0%
FiDes	20.0%	0%
EtIso	8.5%	0%
FiIso	8.5%	0%
EtHal	8.5%	0%
FiHal	8.5%	0%
EtSev	10.0%	0%
FiSev	10.0%	0%
EtEnf	10.0%	0%
FiEnf	10.0%	0%
awRR	100 rpm	0 rpm

Chapter 6 Managing Patients

6.1 Admitting a Patient

The monitor displays physiological data and stores it in the trends as soon as a patient is connected. This allows you to monitor a patient who is not yet admitted. It is however important to admit patients properly so that you can identify your patient on recordings, reports, and networked devices.

During admission you enter data that the monitor needs for safe and accurate operation. For example, the patient category setting determines the algorithm the monitor uses to process and calculate some measurements, the safety limits that are applied for some measurements, and the alarm limit ranges.

To admit a patient, please:

1. Select the **Admission** key on the screen or.

2. Select **Menu** > **Patient Setup** > **New Patient**, then a message is displayed to ask the user to confirm to update patient.

3. Click on **No** to cancel this operation; click on **Yes**, the **Patient Info** window is displayed.

4. Enter the patient information:

    ● **MRN**: Enter the patient's medical record number.

    ● **Last Name**: Enter the patient's last name (family name).

    ● **First Name**: Enter the patient's first name.

    ● **Bed No.**: Select a bed No. from 1 to 254.

    ● **Doctor**: Enter the attending doctor for the patient.

    ● **Gender**: **Male**, **Female** and **N/A**.

    ● **Type**: Choose the patient type, either **Adult**, **Pediat**, or **Neonat**.

    ● **BloodType**: **N/A**, **A**, **B**, **AB** and **O**.

    ● **Pace**: Choose **On** or **Off** (You must select **On** if your patient has a pacemaker).

    ● **Date of Birth**: Enter the patient's date of birth.

    ● **Date of Admission**: Enter the patient's date of admission.

    ● **Height**: Enter the patient's height.

    ● **Weight**: Enter the patient's weight.

NOTE:

Updating patient will clear the history data in the monitor associated with the patient.

6.1.1 Patient Category and Paced Status

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

The paced setting determines whether the monitor shows pacemaker pulses or not. When **Pace** is set to **Off**, pace pulses are filtered and therefore do not show in the ECG wave.

WARNING

1   Changing the patient category may change the arrhythmia and NIBP alarm limits. Always check alarm limits to make sure that they are appropriate for your patient.

2   For paced patients, you must set Paced to **On**. If it is incorrectly set to **Off**, the monitor could mistake a pace pulse for a QRS and fail to give an alarm during asystole.

6.2 Quick Admit

If you do not have the time or information to fully admit a patient, you can use Quick Admit to quickly admit a patient and complete the rest of the patient information later. To quickly admit a patient, please:

1.   Select the shortcut key on the screen directly, or

2.   Select **Menu** > **Patient Setup** > **Quick Admit**, then a message is displayed to ask the user to confirm to update patient.

3.   Click on **No** to cancel this operation; click on **Yes** to continue and the **Quick Admit** window is displayed.

4.   Configure **Type** and **Pace** to the correct setting and click **Yes** to finish the quick patient admission operation. If you want to quit the operation, click **No**.

6.3 Barcode Admit

Barcode scanner can recognize patient information directly and quickly, which can provide convenience and reduce mistakes for users. To admit a patient by barcode, please:

Select **Menu** > **Patient Setup** > **Barcode Admit**, in **Barcode** interface, user can scan the barcode through scanner or input the barcode through keyboard, then the patient information will be stored in monitor.

NOTE:

1   Caps Lock is unavailable, user can input capitals and symbols through switching Shift key.

2   The start and end code should be set before using scanner to update patient, otherwise the barcode can't be recognized normally.

6.4 Editing Patient Information

To edit the patient information after a patient has been admitted, select **Menu** > **Patient Setup** > **Patient Info.**, and make the required changes on the popup interface.

6.5 Central Monitoring System

The monitor can be connected to the central monitoring system. Through the network:

1. The monitor sends patient information, real-time monitoring or measurement data to the central monitoring system.

2. The real-time monitoring information is displayed on the central monitoring system as the same to the monitor, and the central monitoring system can perform some bilateral control. For example: changing patient information, receiving patient, discharging patient and so forth.

For detailed information, please refer to *MFM-CMS Central Monitoring System User Manual*.

And the monitor supports HL 7 protocol.

NOTE:

1   Use wired instead of wireless networking when connecting the monitor to central monitoring system in the operating room because the ESU will interfere with a wireless network, which may cause networking failure.

2   Make sure the network connection between the monitor and the central monitoring system is in good condition when the time synchronization function on the monitor is active.

3   The time synchronization function might not be available to all software versions of MFM-CMS. Consult our technical service department or your local distributor for more information.

Chapter 7 User Interface

7.1 Setting Interface Style

The user can set the interface based on the requirement, and the set options include the following:

- Sweep of the waveform.

- Parameters needing to be monitored.

Changing some settings may have the risk, so only the authorized person can change them. After changing the settings, please notify the operator.

7.2 Selecting Display Parameters

The user can select the display parameters based on the monitoring and measurement requirements. To select the parameter, please:

1. Select the shortcut key [icon] on the screen directly, or

2. Select **Menu** > **System Setup** > **Module Switch**.

3. Select the required parameters from the popup interface.

4. Exit the menu and the screen will adjust the parameters automatically.

7.3 Changing Waveform Position

The user can exchange the waveform positions of parameter A and parameter B with the following method:
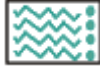
1. Select waveform A and open the setup menu of waveform A.

2. Select **Change** from the popup menu and select the desired label name of waveform B from the pull-down list.

7.4 Changing Interface Layout

Select **Menu** > **Display Setup** to open the **Display Setup** menu on which you can

- Select a function screen based on the clinical requirements by configuring **View Selection**.

- Select the maximum number of waveforms displayed on the screen by configuring **Wave. Num.**

- Decide whether the control bar is displayed or not displayed on the screen by setting **Control Bar** to **On** or **Off**.

7.5 Viewing Trend Screen

To view the trend screen, the user can press the shortcut key ▨▨ on the screen directly or select **Menu** > **Display Setup > View Selection > TrendScreen**.

7.6 Viewing OxyCRG Screen
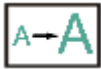
To view the OxyCRG screen, the user can press the shortcut key 👶 on the screen directly or select **Menu** > **Display Setup > View Selection > OxyCRG**. This interface is always used in NICU because the SpO_2, HR and Resp of the neonate are different from those of adults. OxyCRG is in the bottom half part of wave area; it consists of HR trend, SpO_2 trend and RR trend or compressed respiration waveform.

Select OxyCRG waveform to open **OxyCRG Setup** menu, you can set:

1. **Interval**: set the interval to **1 min**, **2 min** and **4 min**.

2. **Parameter**: to select **RESP** or **RR**.

7.7 Viewing Large Font Screen

To open the large font screen, please refer to the following steps:

1. Select the shortcut key [A→A] on the screen directly or.

2. Select **Menu** > **Display Setup** > **View Selection > Large Font** to open this interface.

You can view any available parameter by selecting the parameter from the pull-down list on each section.
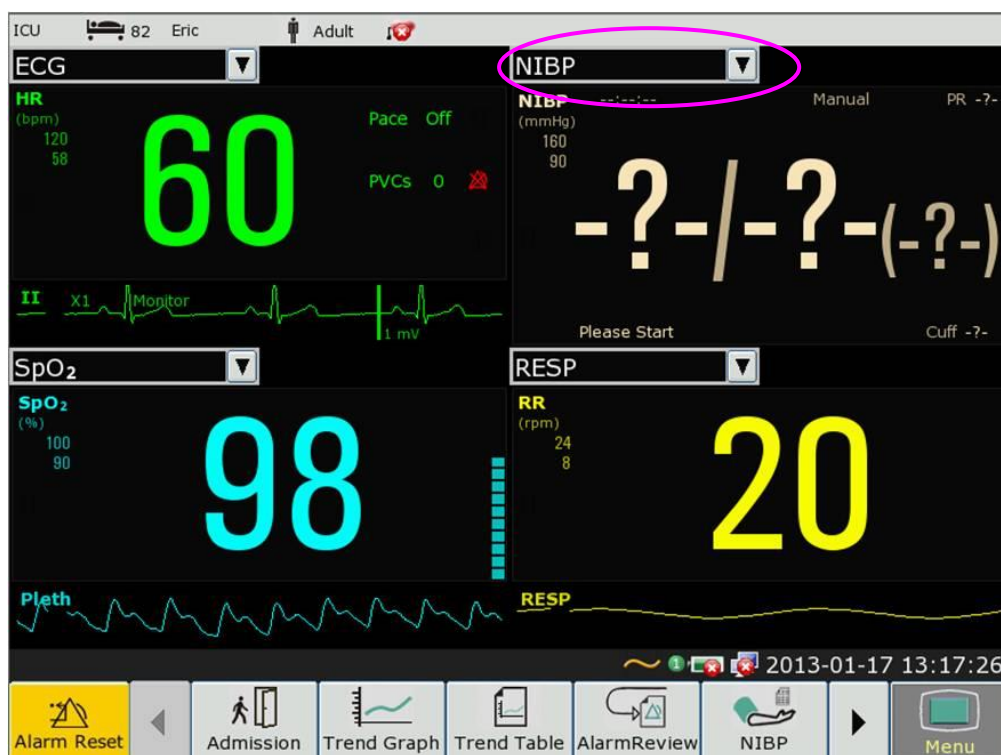
7.8 Viewing the Vital Screen

To view the vital screen, the user can press the shortcut key [icon] on the screen directly or select **Menu** > **Display Setup > View Selection > Vital**.

7.9 Viewing the Bed View Window

The **Bed View** window allows you to view one waveform, numeric information of all parameters and alarm information from another bed on the same network. The monitor enables a maximum of eight beds to be viewed.

NOTE:

1   The IP addresses of the monitors configured with bed view function should share the same network segment. The IP addresses of the monitors on the same LAN should be unique from each other; you cannot use the bed view function in the monitors in which an IP address conflict exists.

2   In order to use the bed view function without impediment, you need to restart the monitor after you change its IP address.

3   To use the bed view function smoothly, make sure the network connection is in good condition.

4   In the **Bed View** window, you cannot view the over-limit alarms of physiological parameters occurring on other beds. Besides, arrhythmia alarms and vital alarms will be indicated only by alarm icons.

7.9.1 Opening the Bed View Window

Before opening the **Bed View** window, make sure the bed view function is configured on your monitor. To open the **Bed View** window, select **Menu** > **Display Setup** and choose **Bed View** in the **View Selection** list.

7.9.2 Settings of the Bed View Window

Click on the **Bed View** window to open the **ViewBed Setup** menu on which you can

● Assign a bed to be viewed by selecting the bed No. in the **Bed No.** list.

● Select the waveform to be displayed on the window in the **Wave Type** list.

● Use the buttons [icon] and [icon] to view more numeric information of parameters in the window.

7.10 Changing Parameter and Waveform Colors

The user can set the display colors of parameter and waveform as desire. To change the display color, please select **Menu > Maintenance > User Maintain**, enter the required password **ABC**. Then select **Color Setup** to make color changes on parameter and waveform.

7.11 User Configuration

Users can save the current monitor's configuration, delete the saved user configuration and rename it. Three pieces of user configuration can be saved in the monitor.

To save the user configuration:

1. Select **Menu > Maintenance > User Maintain**, enter the required password **ABC** and then select **User Configure**.

2. Click on **Save**, enter a file name for the configuration and confirm it. A message will display after the operation.

To delete the user configuration:

1. Select **Menu > Maintenance > User Maintain**, enter the required password **ABC** and then select **User Configure**.

2. Select the configuration file needed to delete from the list, click on **Delete** and confirm the operation. A message will display after the operation.

To rename the user configuration:

1. Select **Menu > Maintenance > User Maintain**, enter the required password **ABC** and then select **User Configure**.

2. Select a configuration file needed to rename from the list and click on **Rename**.

3. Enter a name for the configuration file and confirm it.

7.12 Default Configuration

To set default configuration, select **Menu > Default**. On the **Default** menu, users can choose a factory configuration (adult, pediatric or neonate) based on the patient category. Also, users can choose a user configuration saved in the monitor if it is available. For more information about user configuration, refer to *User Configuration*.

To check the configuration currently used, select **Menu > Default**. The one labeled with ● is current configuration. If there's no labeled configuration, it means the currently used configuration is not one of them.

7.13 Neonatal Configuration

Neonatal configuration is exclusively designed for neonate. When it is set to **On**, the patient type is defaulted to be neonate and cannot be changed.

Neonatal configuration is not set by user. Contact the professionals authorized by the manufacturer if needed.

Chapter 8 Monitoring ECG

8.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the monitor as a waveform and a numeric. This chapter also tells you about arrhythmia monitoring and ST monitoring.

8.2 ECG Safety Information

WARNING

1 Only use the ECG leads supplied by the manufacturer when using the monitor for ECG monitoring.

2 When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient but not the conductive part or ground.

3 Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.

4 Place the electrode carefully and ensure a good contact.

5 Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the auditory alarm is activated.

6 If the ECG signal exceeds the measuring range, the monitor will indicates it by a message "ECG Signal Exceeded".

7 ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

8 In order to avoid being burnt, please keep the electrodes far away from the radio knife while using electrosurgical equipment.

9 When using Electrosurgery (ES) equipment, do not place an electrode near the grounding plate of the Electrosurgery device: otherwise there will be a great deal of interference with the ECG signal.

10 For patients with pacemakers, the pacing impulse analysis function must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected.

11 The electrodes should be made of the same metal materials.

WARNING

12 According to AAMI specifications the peak of the synchronized defibrillator discharge should be delivered within 60 ms of the peak of the R wave. The synchronization pulse output on the patient monitors is delayed by a maximum of 35 ms from the R wave peak. Your biomedical engineer should verify that your ECG/Defibrillator combination does not exceed the recommended maximum delay of 60 ms.

13 Before outputting signals with defibrillator synchronization or ECG, check if the output is functioning normally.

14 ECG accessories are not suitable for DIRECT CARDIAC APPLICATION. (Refer to IEC60601-1 for more information about the definition of DIRECT CARDIAC APPLICATION.)

15 Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. Check lead wires for damage and ensure good skin contact prior to and during use. Always use fresh electrodes and follow proper skin preparation techniques.

NOTE:

1 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

2 IEC/EN60601-1-2 (protection against radiation is 3 v/m) specifies that the electrical field density exceeding 3 v/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.

3 If the pacemaker signals are beyond the claimed range, the heart rate may be calculated incorrectly.

4 In the default settings of the monitor, the ECG waveforms are the first two waveforms from top in the waveform area.

5 For measurements in or near the heart we recommend connecting the monitor to the potential equalization system.

6 For protecting environment, the used electrodes must be recycled or disposed of properly.

8.3 ECG Display

The figure below is for reference only.
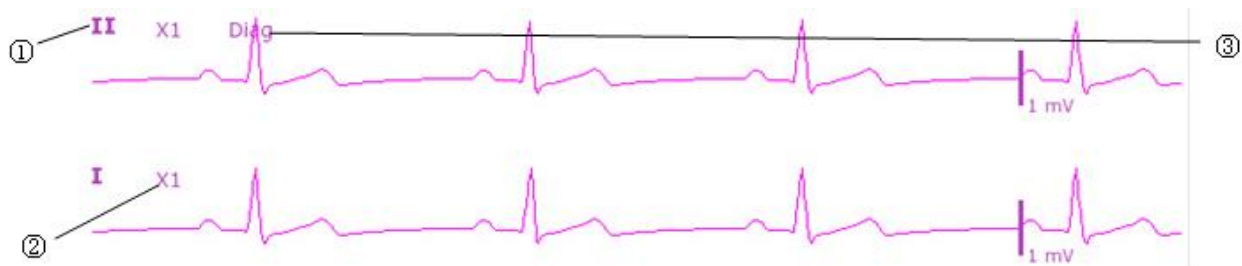
The symbol "①"indicates lead name of display waveform: there are other leads for selection, such as I, II, III, aVR, aVF, aVL, V (for 5 Leads). If you want to change the lead, please refer to section *Selecting Calculation Lead*.

The symbol "②" indicates waveform gain: there are several options, such as X0.125, X0.25, X0.5, X1, X2 and Auto. If you want to change it, please refer to section *Changing the Size of the ECG Wave*.

The symbol "③" indicates Filter setting, there are three options: monitoring, surgery, diagnosis. If you want to change it, please refer to section *Changing the ECG Filter Setting*.

8.3.1 Changing the Size of the ECG Wave

If any of the displayed ECG waveform is too small or clipped, you can change the size of it on the screen. First select **ECG Waveform Setup** > **ECG Gain**, then select an appropriate factor from the pop-up box to adjust the ECG waveform.

X0.125 to make strength of ECG signal waveform of 1mV become 1.25 mm;

X0.25 to make strength of ECG signal waveform of 1mV become 2.5 mm;

X0.5 to make strength of ECG signal waveform of 1mV become 5 mm;

X1 to make strength of ECG signal waveform of 1mV become 10 mm;

X2 to make strength of ECG signal waveform of 1mV become 20 mm;

X4 to make strength of ECG signal waveform of 1mV become 40 mm;

AUTO let the monitor choose the optimal adjustment factor for all the ECG waves.

NOTE:

The effect of ECG wave gain is subject to the size of the wave area. Whichever wave gain is chosen, the ECG wave has to be displayed within the wave area.

8.3.2 Changing the ECG Filter Settings

The ECG filter setting defines how ECG waves are smoothed. An abbreviation indicating the filter type is shown underneath the lead label on the monitor display. Filter settings do not affect ST measurement.

To change the filter setting, in the **ECG Setup** menu, select **Filter** and then select the appropriate setting.

– **Monitor**: Use this mode under normal measurement conditions.

– **Surgery**: The filter reduces interference to the signal. It should be used if the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to a wandering or rough baseline. In the operating room, the Filter reduces artifacts and interference from electro-surgical units. Under normal measurement conditions, selecting **Surgery** may suppress the QRS complexes too much and thus interfere with the clinical evaluation of the ECG displayed on the monitor.

– **Diagnosis**: Use when diagnostic quality is required. The unfiltered ECG wave is displayed so that changes such as R-wave notching or discrete elevation or depression of the ST segments are visible.

8.4 Selecting Calculation Lead

To set the calculation lead, select **ECG Setup** > **Calc. Lead**, or on the **Normal** display interface, click on the calculation lead waveform area, select **Calc. Lead** from the popup interface to make the appropriate setting. For 3 Leads, II, I, and III are selectable; For 5 Leads, II, I, III, aVR, aVL, aVF, and V are selectable; For 12 Leads, II, I, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6 are selectable. Normal QRS complex should be:

■ The normal QRS should be either completely above or below the baseline and it should not be biphasic. For paced patients, the QRS complexes should be at least twice the height of pace pulses.

■ The QRS should be tall and narrow.

■ The P-waves and the T-waves should be less than 0.2 mV.

8.5 Monitoring Procedure

8.5.1 Preparation

The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

■ Select sites with intact skin, without impairment of any kind.

■ Shave hair from sites, if necessary.

■ Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).

■ Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

8.5.2 Connecting ECG Cables

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

2. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.

3. Connect the electrode lead to the patient's cable.

<div style="text-align:center">**CAUTION**</div>

To protect the monitor from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by DIXION.

8.5.3 Selecting Lead Type

To change the lead type, please:

1. Select the ECG parameter area, open the **ECG Setup** menu;

2. Set **Lead Type** to **3 Leads**, **5 Leads** or **12 Leads** based on the lead used.

8.5.4 Installing Electrodes

NOTE:

The following table gives the corresponding lead names used in Europe and America respectively. (Lead names are represented by R, L, F, N, C, C1-C6 in Europe, whose corresponding lead names in America are RA, LA, LL, RL, V, V1-V6.)

AHA (American Standard)		IEC (Europe Standard)	
Electrode Labels	Color	Electrode Labels	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green
V4	Brown/Blue	C4	White/ Brown
V5	Brown/Orange	C5	White/ Black
V6	Brown/Purple	C6	White/ Purple

8.5.4.1 Electrode Placement for 3-Lead

Take the American standard for example, see the following figure:

■   RA placement - directly below the clavicle and near the right shoulder.

■   LA placement: directly below the clavicle and near the left shoulder.

■   LL placement - on the left hypogastrium.
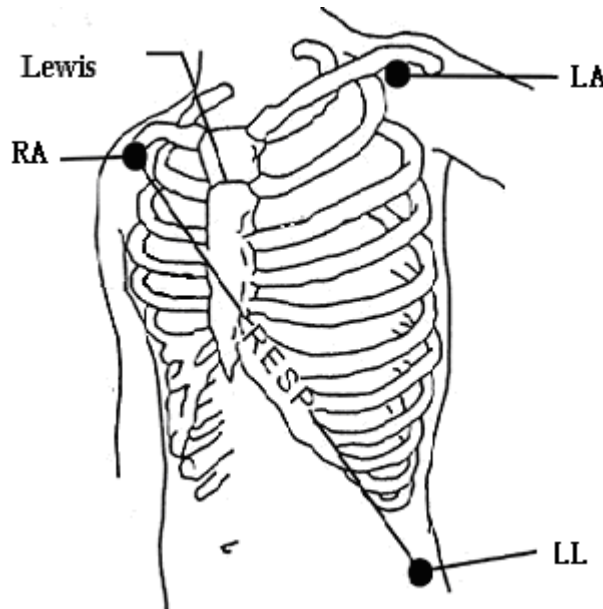
Electrode Placement for 3-Lead

8.5.4.2 Electrode Placement for 5-Lead

Take the American standard for example, see the following figure:

■   RA placement: directly below the clavicle and near the right shoulder.

■   LA placement: directly below the clavicle and near the left shoulder.

■   RL placement: on the right hypogastrium.

■   LL placement: on the left hypogastrium.

■   V placement: on the chest, the position depends on your required lead selection.
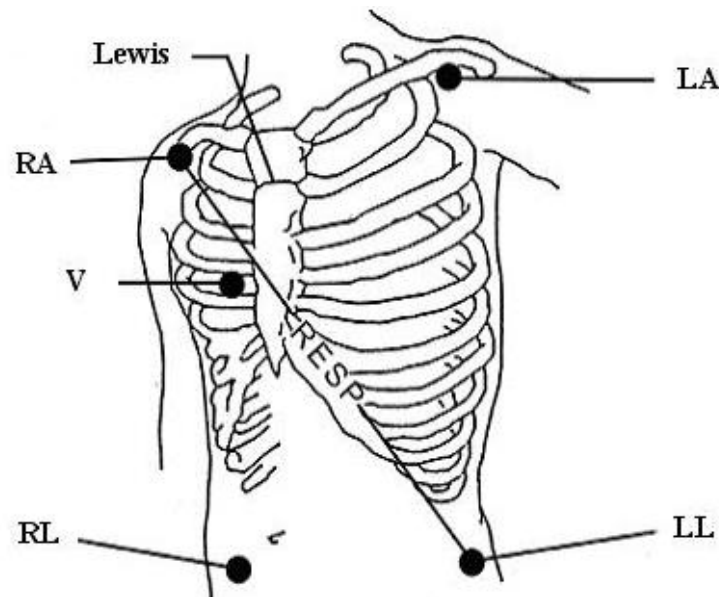
Electrode Placement for 5-Lead

NOTE:

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

For 5-lead, attach the V electrode to one of the indicated positions as below:

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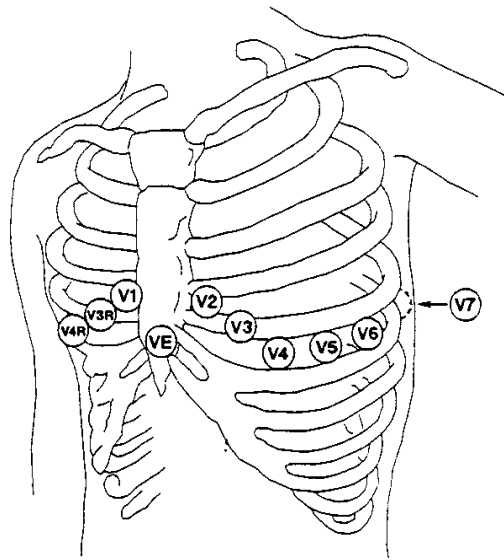
V-Electrode Placement for 5-Lead

8.5.4.3 Electrode Placement for 12-Lead

Take the American standard for example; the 12-lead electrodes should be placed as follows:

The limb electrodes are placed in the same position as the 3-lead placement.

■   RL placement: on the right hypogastrium.

■   V1: On the 4th intercostal space at the right sterna margin.

■   V2: On the 4th intercostal space at the left sterna margin.

■   V3: Midway between V2 and V4 electrodes.

■   V4: On the 5th intercostal space at the left clavicular line.

■   V5: On the left anterior axillary line, horizontal with V4 electrode.

■   V6: On the left middle axillary line, horizontal with V4 electrode.

Electrode Placement for 12-Lead
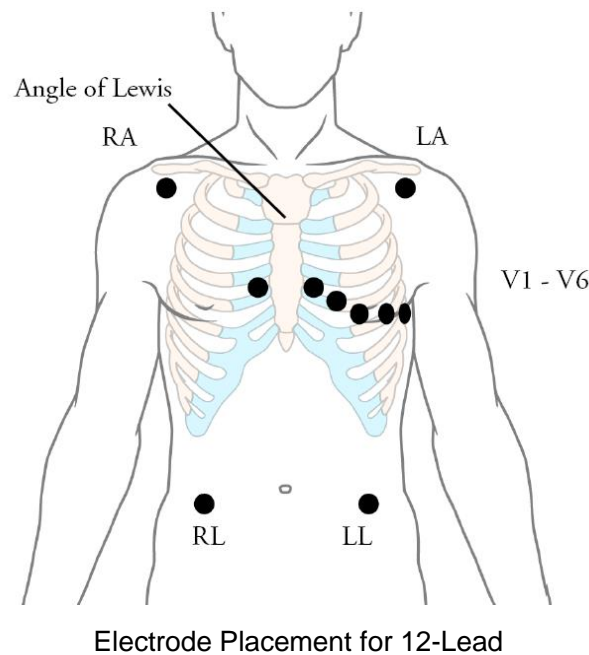
8.5.4.4 Recommended ECG Lead Placement for Surgical Patients

WARNING

When using Electrosurgery (ES) equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the ES grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the patient monitor with other electrosurgery equipment, it is advised to use the counteracting defibrillation ECG lead.

The placement of the ECG leads will depend on the type of surgery that is being performed. For example, in an open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts may affect the ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms. Otherwise the ECG waveform will be too small.

WARNING

When using electrosurgical (ES) equipment, never place ECG electrodes near to the grounding plate of the ES device, as this can cause a lot of interference on the ECG signal.

NOTE:

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

2 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

8.6 ECG Menu Setup

8.6.1 Setting Alarm Source

To change the alarm source, please select **ECG Setup** > **Alarm Source**, then a pop-up box is displayed:

HR: the monitor considers the HR as HR/PR alarm source;

PR: the monitor considers the PR as HR/PR alarm source;

AUTO: If the Alarm Source is set to **AUTO**, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and at least one ECG lead can be measured without a technical condition. The monitor will automatically switch to Pulse as the alarm source if:

    –a valid ECG lead can no longer be measured and

    –a pulse source is switched on and available.

The monitor then uses the pulse rate from the measurement currently active as system pulse. While PR is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the monitor automatically uses HR as alarm source.

8.6.2 Setting Beat Source

To change the beat source, select either **ECG Setup** > **Beat Source** or **PR Setup** > **Beat Source**. Select from the following options:

HR: HR is HR/PR beat source;

PR: PR is HR/PR beat source;

AUTO: If the Beat Source is set to **AUTO**, the monitor will use HR as the beat source whenever the ECG measurement is switched on, and at least one ECG lead can be measured. The monitor will automatically switch to PR as the beat source if:

- a valid ECG lead can no longer be measured and

- a Pulse source is switched on and available.

If an ECG lead becomes available again, the monitor automatically uses HR as beat source and the monitor gives a "Di" tone with a blinking heart ♥ displaying in the HR parameter box when one heartbeat is detected. While a pulse is detected, the monitor gives a "Da" tone.

8.6.3 Smart Lead Off

When **Lead Type** is **5 Leads** or **12 Leads** and **Smart LeadOff** is set to **On**, if the selected ECG waveform cannot be measured because of lead-off or other reasons, it will automatically switch to another available lead channel via which a waveform can be measured. And the lead name above the display ECG waveform also automatically turns into the current one.

To change the smart lead off setting, select **ECG Setup** > **Smart LeadOff**, and select the desired setting.

8.6.4 ECG Display

It varies with **Lead Type**. When **Lead Type** is set to **3 Leads**, **Display** can be set to **Normal**, and it can display one ECG waveform on the main screen.

When **Lead Type** is set to **5 Leads**, **Display** can be set to **Normal**, **Full-Scr** and **Half-Scr**. Select **Normal** to display two ECG waveforms on the main screen; select **Full-Scr** to display seven ECG waveforms which occupy the area of seven waveforms on the main screen; Select **Half-Scr** to display seven ECG waveforms on the screen, occupying the area of four waveforms.

NOTE:

If **3 Leads** is selected in the **ECG Setup** menu, only **Normal** can be selected for **Display** in the sub-menu.

8.6.5 Setting Pace Status

It is important to set the paced status correctly when you start monitoring ECG. To change the paced status in the ECG Setup menu, select **Pace** to toggle between **On** or **Off**. When **Pace** is set to **On**:

 - Pace Pulse Rejection is switched on. This means that pacemaker pulses are not counted as extra QRS complexes.

 - Paced symbol is displayed as $^|$ on the main screen.

NOTE:

1   When monitoring a patient with a pacemaker, set **Pace** to **On**. If monitoring a patient without a pacemaker, set **Pace** to **Off**.

2   If **Pace** is set to **On**, the system will not perform some types of ARR analysis.

<div align="center"><u>WARNING</u></div>

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.

8.6.6 ECG Calibration

This item is used to calibrate ECG waveform. When you select this item from ECG Setup menu again, the ECG waveform calibration ends.

NOTE:

The device can't be monitored during ECG calibration.

8.6.7 ECG Waveform Settings

To change this speed, select **ECG Waveform Setup** > **Sweep**, then select an appropriate setting from the pop-up list. The bigger the value is, the wider the waveform is.

8.7 12-Lead ECG Monitoring

In 12-lead display mode, 12 ECG waveforms and one rhythm lead waveform will be shown at the waveform area on the screen. The rhythm lead is for ECG calculation before entering 12-lead display mode. Also, in this mode, the filter mode is set to **Diagnosis** and cannot be changed.

8.7.1 Diagnosis Function

If your monitor is configured with the 12-lead ECG monitoring function, the monitor can perform automatic diagnosis function. To perform 12-lead diagnosis analysis:

1. In the **ECG Setup** menu, set **Lead Type** to **12 Leads** and set **Display** to **12 Leads**.

2. Select the shortcut key on the screen directly.

3. The diagnosis results will be provided in the **Diagnosis Review** window after approximately 10 seconds.

The measurement function provides the automatic measurement of the common parameters, such as heart rate, PR interval, QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude and RV5+SV1 amplitude. The interpretation function provides the automatic diagnosis of hundreds of abnormal cases, such as arrhythmia, AV block, IVCD (Intraventricular Conduction Block), myocardial infarction, ventricular hypertrophy and atrial enlargement, ST-T abnormality and electrical axis deviation.

8.7.2 Waveform Durations and Isoelectric Segments

Between the global onset and offset of the QRS-complex, signal parts with a duration of more than 6 ms and amplitude not exceeding 20 µV should be defined as isoelectric segments.

Because the duration of the Q-, R- or S-wave of 12 leads is respectively detected by the ECG algorithm, isoelectric parts (I-waves) after global QRS-onset or before global QRS-offset (K-wave) are excluded in the measurement duration of the respective adjacent waveform.
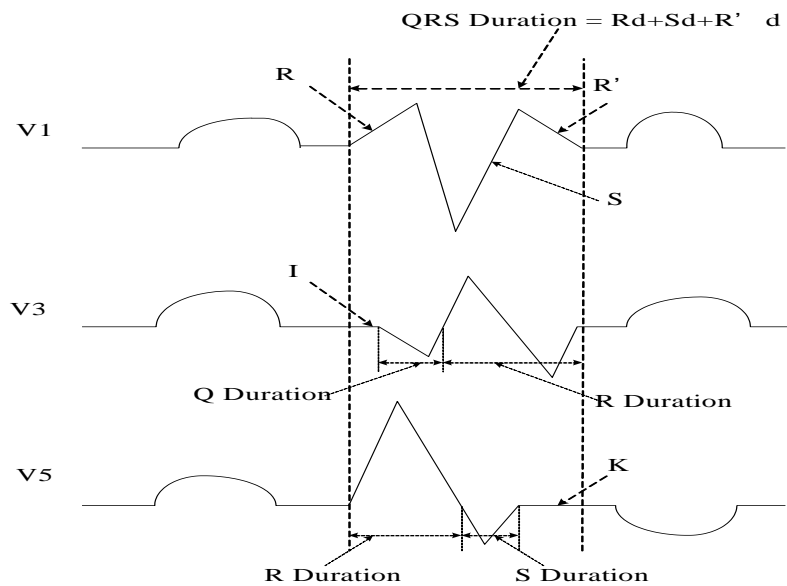
8.8 ST Segment Monitoring

The monitor performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics and snippets on the monitor.

ST segment monitoring function is shut off by default. You can switch it to **On** when necessary. When using the ST analysis function, the ST analysis results will be displayed on the right of the main screen, please refer to the following figure.

NOTE:

1   ST-segment analysis is intended for use with adult and pediatric patients and is not clinically validated for use with neonatal patients.

2   ST analysis is always performed using a dedicated filter which ensures diagnostic quality. If you are monitoring ECG using an ECG filter mode other than **Diagnosis**, the ST segment of the ECG wave may look different from the ST segment of the ST template for the same wave. For diagnostic evaluation of the ST segment, always set the filter to **Diagnosis** or use the ST template.

3   The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.

8.8.1 Setting ST Analysis

To change ST analysis, please select **ECG Setup** > **ST Analysis**, then select **On** or **Off** from the pop-up list.

8.8.2 ST Display

Your monitor screen may be configured to look slightly different from the illustrations.

ST	I 0.08	aVR -0.09	V 0.04
	II 0.10	aVL 0.03	
	III 0.02	aVF 0.06	

8.8.3 About ST Measurement Points

The ST value for each beat complex is the vertical difference between the ISO point and the ST point, as shown in the diagram below. The isoelectric (ISO) point provides the baseline, and the ST point is at the midpoint of the ST segment. The J point is where the QRS complex changes its slope; as it is a fixed distance away from the ST point, it can be useful to help you position the ST point correctly.
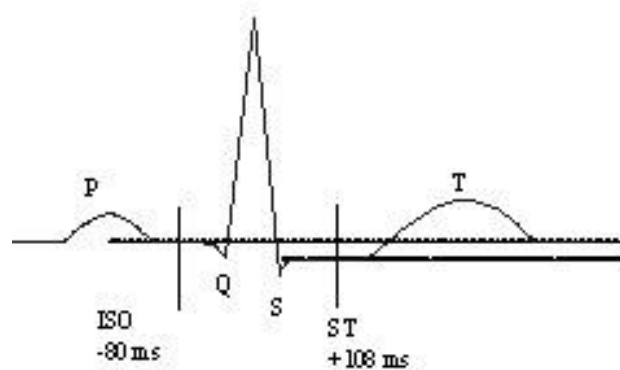
DEF POINT

The ST and ISO measurement points need to be adjusted when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly. Always ensure that ST measurement points are appropriate for your patient. Abnormal QRS complex is not considered in ST segment analysis.

8.8.4 Adjusting ST and ISO Measurement Points

Depending on your monitor's configuration, the ST point can be positioned, too.

These two points can be adjusted by turning the knob. When adjusting ST measurement point, the system will show the ST Measurement Point Window. The system displays the QRS complex template in the window. It is adjustable for the highlight bar in the window. You may select ISO or ST, switch the knob left or right to move the cursor line. When the cursor is at the required position, you may select the base point or the measurement point.

8.9 Arr. Monitoring

8.9.1 Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of adult and pediatric patients in clinics, and detect the changes of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarming information. The arrhythmia analysis is not clinically validated for use with neonatal patients. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

The monitor can support up to 16 different arrhythmia analyses.

ARR Types	Occurring Condition
ASYSTOLE	No QRS is detected for 4 consecutive seconds
VFIB/VTAC	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.
VT > 2	$3 \leq$ the number of consecutive PVCs < 5
COUPLET	2 consecutive PVCs
BIGEMINY	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.
TRIGEMINY	A dominant rhythm of N, N, V, N, N,V
R ON T	A type of single PVC under the condition that HR < 100，R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).
PVC	Single PVC detected in normal heartbeats.
TACHY	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
BRADY	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.
MISSED BEATS	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR $\geq$ 120 bpm, no beats are detected for one second.
IRR	Consistently irregular heart rhythm
PNC	PACER NOT CAPTURE: no QRS complex detected in 300 ms after a pace pulse.
PNP	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.

ARR Types	Occurring Condition
VBRADY	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.
VENT	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.

8.9.2 ARR Analysis Menu

8.9.2.1 Switching ARR Analysis On and Off

To switch ARR Analysis on or off, in the **ECG Setup** menu, select **ARR Analysis** to toggle between **On** and **Off** from the popup interface.

8.9.2.2 PVCs Alarm

Select **On** in the menu to enable prompt message when an alarm occurs; select **Off** to disable the alarm function, and there will be a symbol beside **PVCs**.

WARNING

When the PVCs Alarm is set to **Off**, the monitor won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.

8.9.2.3 ARR Relearning

Pick this item to start a learning procedure, and **ECG ARR LEARNING** is displayed on the screen. The ECG ARR LEARNING will start automatically in the following status:

- Connecting leads;
- Starting ARR learning manually;
- Switching calculation leads.

8.9.2.4 ARR Alarm

By selecting **ECG Setup > ARR Analysis > ARR Alarm Setup**, the arrhythmia alarms can be individually switched on or off. They are: **R-ON-T**, **VT > 2**, **COUPLET**, **PVC**, **BIGEMINY**, **TRIGEMINY**, **TACHY**, **BRADY**, **MISSED BEATS**, **IRR**, **PNC**, **PNP**, **VBRADY** and **VENT**.

VFIB/VTAC alarm is preset to be on. To switch it on or off, select **Menu** > **Maintenance > User Maintain**, and enter the required password **ABC**. Select **Alarm Setup > VFIB/VTAC** from the popup list to toggle between **On** and **Off**. When **VFIB/VTAC** is set to **Off**, the monitor displays the alarm off symbol , and **VFIB/VTAC Off** is displayed on a red colored background.

ASYSTOLE alarm is preset to be on and cannot be turned off.

Chapter 9 Monitoring RESP

9.1 Overview

The monitor measures respiration from the amount of thoracic impDIXIONce between two ECG electrodes. The change of impDIXIONce between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

9.2 RESP Safety Information

WARNING

1   If you do not set the detection level for the respiration correctly in manual detection mode, it may not be possible for the monitor to detect apnea. If you set the detection level too low, the monitor is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.

2   The respiration measurement does not recognize obstructive and mixed apneas - it only indicates an alarm when a pre-adjusted time has elapsed since the last detected breath.

3   If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3 V/m), field strengths above 3 V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.

4   Cardiogenic artifact in impDIXIONce respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as $etCO_2$ and SpO_2.

NOTE:

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

9.3 Electrode Placement for Monitoring Resp

Correct patient skin preparation techniques for electrode placement are important for Resp measurement: you will find this information in the chapter on ECG.

The Resp signal is always measured between two of the ECG electrodes. There are two standard ECG leads for selection: I lead (RA and LA) and II lead (RA and LL).
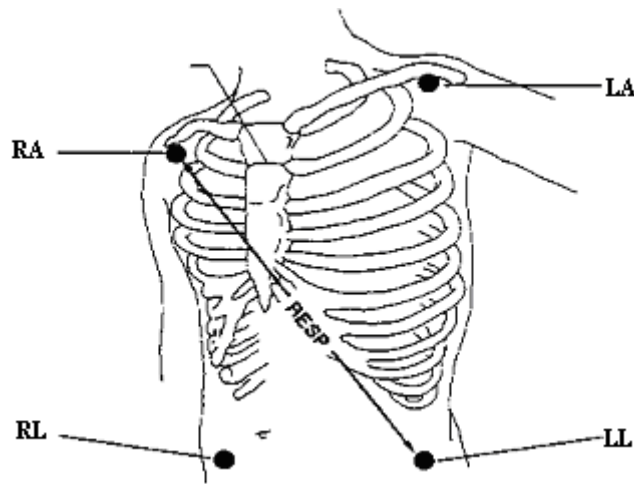
Electrodes Placement for 5-Lead

9.4 Cardiac Overlay

Cardiac activity that affects the RESP waveform is called cardiac overlay. It happens when the RESP electrodes pick up impDIXIONce 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 respiratory electrodes. This is particularly important for neonates.

9.5 Chest Expansion

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

9.6 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 respiratory wave.

NOTE:

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

9.7 Selecting Resp Lead

To change Resp lead, in the **RESP Setup** menu, select **RESP Lead** to pick up the appropriate lead from the pop-up list.

9.8 Changing Hold Type

To change the calculation mode, in the **RESP Setup** menu, set **Hold Type** to **Manual** or **AUTO**. When it is set to the **AUTO** mode, **Hold High** and **Hold Low** are unavailable, and the monitor can calculate the respiration rate automatically. When it is set to the **Manual** mode, you can adjust the broken lines in RESP area by the **Hold High** and **Hold Low** items.

9.9 Changing the Size of the Respiration Wave

Select the Resp waveform area to open the **RESP Waveform Setup** menu:

● Select **AMP**, and choose an appropriate value. The bigger the value is, the higher the waveform amplitude will be.

● Select **Sweep**: select an appropriate setting from the pop-up list.

9.10 Changing the Apnea Time

The apnea alarm is a high priority red alarm used to detect apneas. The apnea alarm delay time defines the time period between the point where the monitor cannot detect any respiration activity and the indication of the apnea alarm.

1. In the **RESP Setup** menu, select **Apnea Alm**.

2. Select the appropriate setting from the popup list.

Chapter 10 Monitoring SpO$_2$

10.1 Overview

SpO$_2$ is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO$_2$ measuring unit. SpO$_2$ Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% of the hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO$_2$ oxygen saturation of 97%. The SpO$_2$ numeric on the monitor will read 97%. The SpO$_2$ numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO$_2$/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

10.2 SpO$_2$ Safety Information

WARNING

1   If the SpO$_2$ sensor cannot work properly, please reconnect the sensor or change a new one.

2   Do not use the SpO$_2$ sensors if the packaging or the sensor is damaged and return them to the vendor.

3   Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. More frequent examinations may be required for different patients.

4   Tissue damage may be caused by incorrect application or prolonged measurement duration using the sensor (more than 4 hours). Inspect the sensor periodically according to the sensor user manual.

5   Use only DIXION permitted sensors and extension cables with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.

6   High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off.

7   When serious arrhythmia is present, the SpO$_2$ pulse rate may differ from ECG heart rate but this does not indicate an inaccurate SpO$_2$ value.

NOTE:

1   Make sure the nail covers the light window. The wire should be on the backside of the hand.

2   SpO$_2$ waveform is not proportional to the pulse volume.

3   Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line.

4   Don't use the functional simulator to assess the SpO$_2$ accuracy.

5   The device is calibrated to display functional oxygen saturation.

6   The materials with which the patient or any other person can come into contact conform with the standard of EN ISO 10993-1: 2009.

7   When the SpO$_2$ value is potentially incorrect, it will display "-?-".

10.3 Measuring SpO$_2$

1.   Select the correct patient category setting (adult/pediatric and neonatal), as this is used to optimize the calculation of the SpO$_2$ and pulse numerics.

2.   During measurement, ensure that the application site:

   – has a pulsatile flow, ideally with a good circulation perfusion.

   – has not changed in its thickness, causing an improper fit of the sensor.

Measurement Procedure

1.   Switch on the monitor.

2.   Attach the sensor to the appropriate site of the patient finger.

3.   Plug the connector of the sensor extension cable into the SpO$_2$ socket.
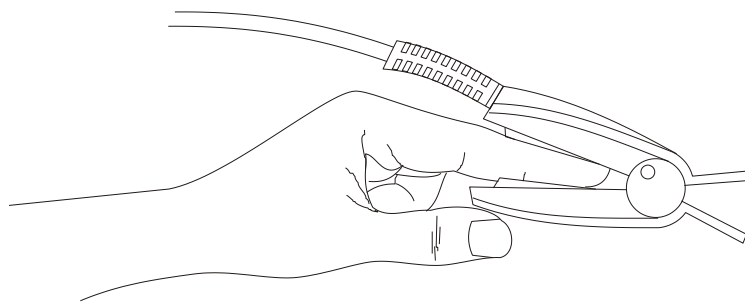
Mounting of the Sensor

WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours. For neonate, change the measuring site every 20 minutes.

NOTE:

Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

10.4 Measurement Limitations

Certain patient conditions can affect the measurements and cause the loss of the pulse signal.

Inaccurate measurements can be caused by:

- incorrect sensor application

- high levels of ambient light sources, such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight

- failure to cover the sensor with opaque material in high levels of ambient light conditions

- dysfunctional hemoglobins

- poor peripheral perfusion

- excessive patient movement

- venous pulsations

- intravascular dyes, such as indocyanine green or methylene blue

- externally applied coloring agents (nail polish, dye, pigmented cream)

- defibrillation

- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

- electromagnetic interference

- low perfusion

Loss of pulse signal can occur for the following reasons:

- the sensor is applied too tightly

- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached

- there is arterial occlusion proximal to the sensor

- poor peripheral perfusion

NOTE:

1   Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

2   To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

3   Move the sensor to a less active site, and keep the patient still, if possible.

4   For Nellcor SpO₂ module, the algorithm automatically extends the amount of data

required for measuring SpO₂ and PR depending on the measurement conditions. During normal measurement conditions the averaging time is 6 to 7 seconds. During conditions such as those caused by low perfusion, interference (e.g., external interference such as ambient light or patient movement), or a combination of these, the algorithm automatically extends the amount of data required beyond 7 seconds. If the resulting dynamic averaging time exceeds 20 seconds, the screen will display prompt message "SpO₂ Search Pulse" and SpO₂ and PR will continue to be updated every second. As these conditions extend, the amount of data required continues to increase. If the dynamic averaging time reaches 40 seconds, the screen will display high-level alarm message "SpO₂ No Pulse" indicating a loss-of-pulse condition.

10.5 Assessing the Validity of a SpO₂ Reading

You can check the quality of the pleth wave and the stability of the SpO₂ values to assess whether the sensor functions properly and whether the SpO₂ readings are valid. Always use these two indications simultaneously to assess the validity of a SpO₂ reading.

Generally, the quality of the SpO₂ pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO₂ values also reflects the signal quality. Different from varying SpO₂ readings caused by physiological factors, unstable SpO₂ readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO₂ readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

1   The SpO₂ accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies are composed of local healthy men and women from age 19 to 37 (for DIXION SpO₂ module), from 18 to 50 (for Nellcor SpO₂ module), with various skin pigmentations. Note that the study population was healthy adults and not in the actual intended use population.

2   The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).

10.6 SpO$_2$ Alarm Delay

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity setting. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.

2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

10.7 Perfusion Index (PI)*

* Only applicable to the SpO$_2$ module.

PI is a numeric value indicating perfusion level. It reflects the perfusion level at the monitoring site.

As the measurement of SpO$_2$ is based on the pulsation caused by the blood flow through the vessel, PI is in relation to the strength of the pulse. Also, you can use PI as a signal quality indicator for the measurement of SpO$_2$.

PI is indicated by a value ranging from 0 to 10. The bigger the value is, the better the perfusion and the signal quality will be. The perfusion level and the signal quality are at their maximum when the value reaches 10. When PI is below 2, it indicates the low perfusion and the poor signal quality at the monitoring site; you need to reposition the sensor or find a better site.

The PI value will be displayed in the SpO$_2$ parameter area.

10.8 Setting Pitch Tone

If tone modulation is on, the PR sound lowers when the SpO$_2$ level drops. In the **SpO$_2$ Setup** menu, select pitch tone to toggle between **On** and **Off**.

10.9 Setting Sensitivity

The different sensitivity indicates different refresh frequency. **High** indicates the refresh frequency of SpO$_2$ value is the most frequent. To change the sensitivity, please follow the steps:

1 Select the **SpO$_2$ Setup** menu;

2 Select **Sensitivity** on the interface and select the desired sensitivity from the popup list.

10.10 SatSeconds Alarm Management*

* Only applicable to the Nellcor SpO$_2$ module.

* Not applicable to MFM-CMS.

10.10.1 Describing SatSeconds

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an alarm is immediately triggered. When the SpO$_2$ level fluctuates near an alarm limit, the alarm is triggered each time the limit is violated. Such frequent alarms can be distracting.

With the SatSeconds technique, upper and lower SpO$_2$ alarm limits are set in the same way as traditional alarm management. However, you can also set a SatSeconds limit that allows monitoring of SpO$_2$ below the selected lower alarm limit and above the selected upper alarm limit for a period of time before an alarm is triggered.

The method of calculation is as follows:

The number of percentage points that the SpO$_2$ falls outside the alarm limit is multiplied by the number of seconds that the SpO$_2$ level remains outside that limit. This can be stated as an equation:

Points $\times$ Seconds = SatSeconds

Where:

Points = SpO$_2$ percentage points outside of the limit

Seconds = number of seconds that SpO$_2$ remains at that point outside of the limit

The alarm response time, assuming a SatSeconds limit set at 50 and a lower alarm limit set at 90, is described and illustrated below.

In this example, the SpO$_2$ level drops to 88 (2 points below the limit) and remains there for a period of 2 seconds (2 points × 2 seconds = 4 SatSeconds). The SpO$_2$ then drops to 86 for 3 seconds and then to 84 for 6 seconds. The resulting SatSeconds values are shown below:

SpO$_2$		Seconds		SatSeconds
2	$\times$	2	=	4
4	$\times$	3	=	12
6	$\times$	6	=	36
Total SatSeconds			=	52

After approximately 10.7 seconds, a SatSeconds alarm will be triggered, because the limit of 50 SatSeconds has been exceeded. See arrow (↑) in the following figure.
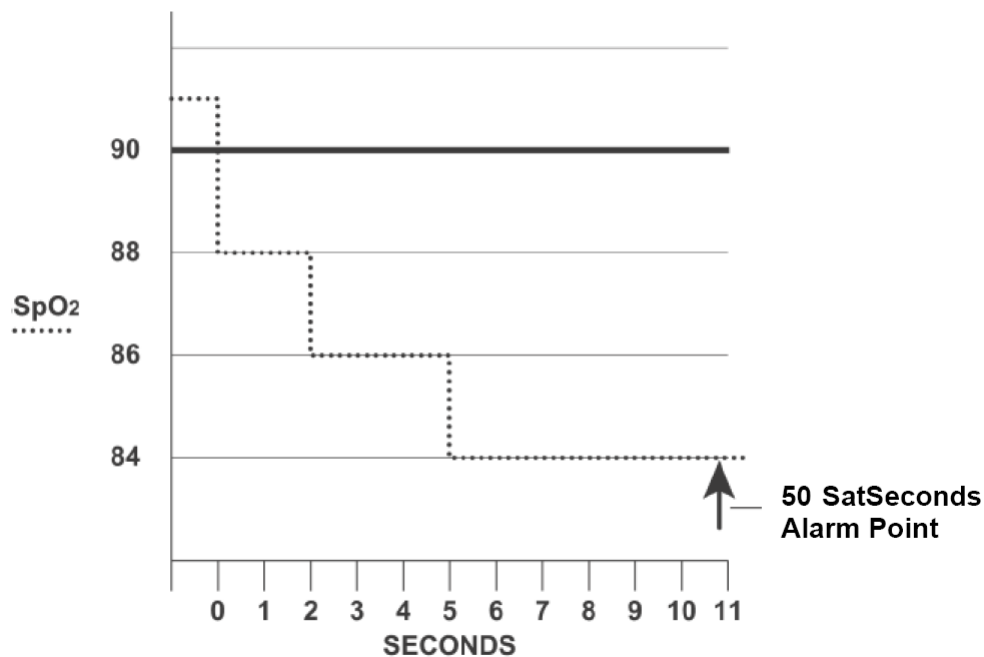
Alarm Response with SatSeconds

Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Often, the patient SpO$_2$ may fluctuate above and below the alarm limit, re-entering the non-alarm range several times. During such fluctuation, the monitor integrates the number of SpO$_2$ points, both positive and negative, until either the SatSeconds limit is reached, or the patient SpO$_2$ returns within a normal range and remains there.

10.10.2 SatSeconds "Safety Net"

The SatSeconds "Safety Net" is for patients whose saturation makes frequent excursions below or above the SpO$_2$ limit but does not remain in violation long enough for the SatSeconds limit to be reached. If three or more SpO$_2$ alarm limit violations occur within a 60-second period, an alarm will be triggered even if the SatSeconds limit has not been reached.

10.10.3 Setting SatSeconds Duration

You can set **SatSeconds** to **Off** or to the duration among **10**, **25**, **50** and **100**. To configure the SatSeconds settings, enter the **SpO$_2$ Setup** menu and select the desired SatSeconds setting from the **SatSeconds** list.

Chapter 11 Monitoring PR

11.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). You can display a pulse from any measured SpO_2 signal or any arterial pressure.

11.2 Setting PR Source

The monitor provides PR source options. You can select SpO_2 or arterial pressure labels as the PR source in the **PR Source** list on the **PR Setup** menu.

NOTE:

In the **PR Source** list, an arterial pressure label accompanied with a label with brackets indicates this label is in conflict. Do not select a conflicting label as the PR source.

11.3 Setting PR Volume

Select **PR Setup** > **PR Volume**, then select the appropriate setting for the PR volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the PR volume will be off.

11.4 Selecting the Active Alarm Source

In most cases, the HR and Pulse numerics are identical. In order to avoid simultaneous alarms on HR and Pulse, the monitor uses either HR or Pulse as its active alarm source. To change the alarm source, select **PR Setup** > **Alarm Source**, then a pop-up box is displayed:

● **HR**: if you want HR to be the alarm source for HR/Pulse.

● **PR**: if you select Pulse as the active alarm source, the monitor will prompt you to confirm your choice. Be aware that if you select Pulse as the alarm source, ECG HR alarms are switched off.

● **AUTO**: If the Alarm Source is set to Auto, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and at least one ECG lead can be measured without a technical alarm condition. The monitor will automatically switch to Pulse for the alarm source if:

  • a valid ECG lead can no longer be measured and

  • a Pulse source is switched on and available.

The monitor uses the pulse rate from the currently active measurement as system pulse. While PR is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the monitor automatically uses HR as alarm source.

NOTE:

Pulse alarms are only generated when the active alarm source is set to **PR**, a pulse source is set as system pulse and pulse alarms are switched on.

Chapter 12 Monitoring NIBP

12.1 Overview

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients. It is also intended for use with pregnant, including pre-eclamptic patients.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI/ISO 81060-2:2013) in relation to mean error and standard deviation.

12.2 NIBP Safety Information

<table>
<tr><td align="center"><u>WARNING</u></td></tr>
</table>

1 Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.

2 Do not measure NIBP on the arm of the same side with a mastectomy.

3 Use clinical judgement to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.

4 Ensure that the correct setting is selected when performing measurements. It may be dangerous for the neonate to use an over pressure level. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.

5 The equipment is suitable for use in the presence of electrosurgery.

6 Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, child or neonate.)

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

8 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.

9 Do not attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to patient.

10 Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.

WARNING

11 Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.

12 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.

13 Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.

14 Verifying the calibration is only applicable for adults, and it cannot be operated in automatic measuring interval. Continuous measuring cannot be operated in automatic measuring interval either.

NOTE:

1   It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.

2   If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.

3   Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of patient. Continuous measuring and automatic measuring in neonatal or pediatric mode may result in tissue damage or ischemia to the patient.

4   NIBP measurement can be affected by extremes of temperature, humidity and altitude.

5   NIBP measurement value should be explained by qualified professionals.

12.3 Measurement Limitations

Measurements are impossible with pulse 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 in the following situations:

● A regular arterial pressure pulse is hard to detect.

● Patients with cardiac arrhythmias.

● Patients with excessive and continuous movement such as shivering or convulsions.

● Patients with rapid blood pressure changes.

● Patients with severe shock or hypothermia that reduces blood flow to the peripheries.

● Patients with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.

● Patients on an edematous extremity.

12.4 Measurement Methods

There are three methods of measuring NIBP:

● Manual - measurement on demand.

● Auto - continually repeated measurements (between 1 and 480 minute adjustable interval).

● Continual- the measurement will run consecutively in five minutes, then the monitor enters manual mode.

WARNING

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purpura, 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 blood pressure measurements.

12.5 Measurement Procedures

To obtain accurate measurements, the following operating steps need to be observed:

1. Ensure the patient position in normal use, including

◆ Comfortably seated

◆ Legs uncrossed

◆ Feet flat on the floor

◆ Back and arm supported

◆ Middle of the cuff at the level of the right atrium of the heart

2. Relax as much as possible and do not talk during the measurement.

3. Wait for five minutes until the first reading is taken.

NOTE:

If an NIBP measurement is suspect, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.

To start the measurement:

1. Connect the air hose and switch on the monitor.

2. Apply the blood pressure cuff to the patient's arm or leg and follow the instructions below. Ensure that the cuff is completely deflated.

   Apply the appropriate size cuff to the patient (About the cuff size selection, please refer to Section *NIBP accessories*), and make sure that the symbol "Φ" is over the artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.

NOTE:

The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.
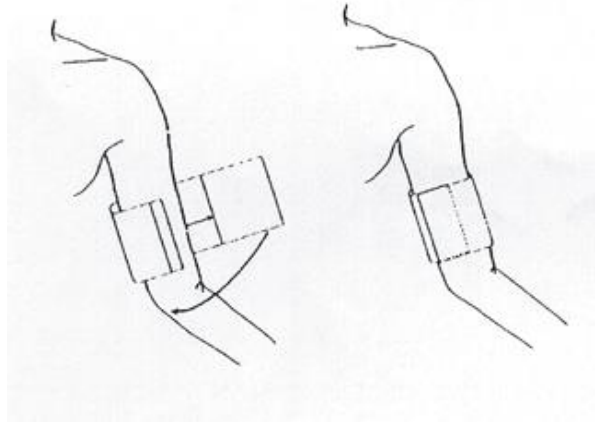
Cuff Usage

3. Connect the cuff to the air tubing.

4. Check whether the patient mode is appropriately selected. Access the **Patient Setup** menu from **Menu**. Turn the knob to select the required patient **Type** in the **Patient Info.** menu.

5. Select a measurement mode in the **NIBP Setup** menu. Refer to section *Operation Prompts* for details.

6. Press the ![button] button on the front panel to start a measurement.

NOTE:

1   Please make sure the cuff is well connected. A leak of air may cause measurement error.

2   Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.

3   Do not disinfect the cuff with radiation or gas, or the cuff will be deteriorated.

4   Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.

12.5.1 Operation Prompts

1. Manual Measuring

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Manual**. Then press the ![button] button on the front panel to start a manual measurement.

2. Automatical Measurement

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Auto**, then press the ![button] button on the front panel to start the automatical measurement according to the selected time interval.

During the idle period of measurement process, press the button on the front panel at any time to start a manual measurement. Then press the button on the front panel to stop manual measurement and the system continues to execute auto measurement program according to the selected time interval.

3. Continuous measurement

Access the **NIBP Setup** menu and pick the **Continual** item to start a continuous measurement. The continuous measurement will last 5 minutes.

4. Stopping continuous measurement

During continuous measurement, press the button on the front panel at any time to stop continuous measurement.

12.5.2 Correcting the Measurement if Limb is not at Heart Level

To correct the measurement if the limb is not at heart level to the displayed value:

Add 0.75 mmHg (0.10 kPa) for each centimeter higher or	Deduct 0.75 mmHg (0.10 kPa) for each centimeter lower or
Add 1.9 mmHg (0.25 kPa) for each inch higher	Deduct 1.9 mmHg (0.25 kPa) for each inch lower

12.6 NIBP Multi-Review Window

To set the display of NIBP measurements, select **NIBP Setup** > **Review**:

* When it is set to **On**, a window for NIBP measurements will be displayed at the waveform area on the main interface, and the size of this window varies depending on the numbers of displayed waveforms.

* When it is set to **Off**, the window is unavailable on the screen.

12.7 Resetting NIBP

When the pressure does not work properly and the system fails to give a message for the problem, pick **Reset** in the **User Maintain > NIBP Maintain** menu to activate self-test procedure, and thus restore the system from abnormal performance.

12.8 Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure transducers must be verified and calibrated, if necessary, at least once every two years by a qualified service professional. See the Service Manual for details.

12.9 Leakage Test

<table>
<tr><td align="center"><u>WARNING</u></td></tr>
</table>

This leakage test other than being specified in the EN 1060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

Procedure of Leakage Test

1.   Connect the cuff securely with the socket for NIBP air hole.

2.   Wrap the cuff around the cylinder of an appropriate size.

3.   Make sure the patient type has been set to **Adult**.

4.   Access **User Maintain > NIBP Maintain**.

5.   Select **Leakage Test**. Then the prompt **Leak. Test Running** will appear indicating that the system has started the leakage test.

For STORM 5800 with the Omron module:

The system will automatically inflate the pneumatic system to 285 mmHg. After 4 minutes, the system will automatically open the deflating valve, which marks the completion of a pneumatic measurement.

For STORM 5500/STORM 5800 with the module:

The system will automatically inflate the pneumatic system to about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system will automatically open the deflating valve to stop the leak test and indicates **NIBP Leak**. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.

For STORM 5800 with the SunTech module:

NOTE:

When applying high pressures; take special care to increase the pressure at a rate that will not cause unwanted overpressure errors (300mmHg).

Manually inflate the pneumatic system to approximately 250 mmHg. Start the timer and wait 60 seconds for the pneumatic system to reach its pressure equilibrium point. After the waiting period, record the pneumatic pressure level (P1) and wait another 60 seconds and record the pneumatic pressure level again (P2). Safety circuitry on the module only allows the pressure in the pneumatic system to remain above 10mmHg for 180 seconds. When this safety time limit is exceeded, the valves will open releasing the pressure. Subtract P2 from P1 and this is the leak rate per minute.

6. If the alarm information **NIBP Leak** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the leakage test. If the failure prompt still appears, please contact the manufacturer for repair.
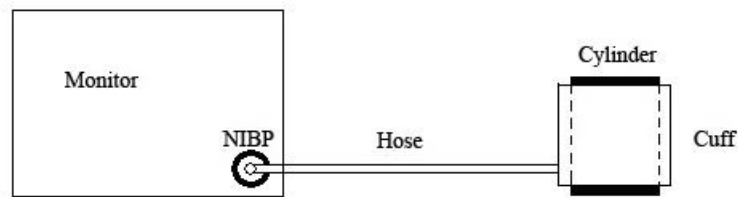
Diagram of NIBP Air Leakage Test

12.10 Setting Inflation Mode

To change the inflation mode:

1. Select **NIBP Setup** > **Inflation Mode**;

2. Choose **Manual** or **AUTO** from the pull-down list.

    ◆ If **Manual** is chosen, the preset value by users will be adopted as the inflation value when measuring blood pressure.

    ◆ If **AUTO** is chosen, the default value will be adopted as the inflation value when measuring blood pressure.

Chapter 13 Monitoring TEMP

13.1 Overview

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is applied to the skin or to the rectum.

Two TEMP probes can be used simultaneously to measure two TEMP values and get the temperature difference. The standard configuration is skin probe for adult.

13.2 TEMP Safety Information

WARNING

1 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable of the channe1 from the socket, and then the screen will display the error message **TEMP T1 Sensor Off** and the auditory alarm is activated. It is the same to the other channel.

2 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.

NOTE:

1 The materials with which the patient or any other person can come into contact conform with the standard of EN ISO 10993-1: 2009.

2 The reference body site temperature is the same as the temperature of the measuring site.

13.3 TEMP Monitoring Setup

With a reusable TEMP probe you can plug the probe directly into the monitor. Apply the TEMP probes securely to the patient. Switch on the monitor.

It takes 5 minutes for the body temperature to stabilize.

13.4 Calculating Temp Difference

The monitor can calculate and display the difference between two temperature values by subtracting the second value from the first. The difference is labeled TD.

Chapter 14 Monitoring Quick TEMP*

*not available in the U.S.A., Canada, UK and Germany

14.1 Overview

Quick temperature measurement is to establish thermal balance between probe and human body. When the probe is placed on the measurement site until a steady reading is available - after approximately three minutes for oral and rectal measurements and five minutes for axillary measurements. And the measurement temperature is the monitoring temperature. The temperature curve in this process has a certain discipline. The approximatively actual temperature curve can be simulated by temperature data sampled earlier. The temperature at thermal balance is calculated through the specific algorithm based on the curve.

The monitor can only measure temperature of adult and pediatric patients. If the user measures temperature of neonatal patient, the monitor will not display data. The oral/axillary sensor and rectal sensor are of standard configuration.

14.2 Quick TEMP Safety Information

<div align="center"><u>WARNING</u></div>

1 To ensure optimal accuracy, always confirm that the correct mode and alarm limit are selected. Changing the measure position may lead to the change of alarm limit.

2 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable from the socket, and then the screen will display the error message TEMP SENSOR OFF and the auditory alarm is activated.

3 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.

4 Verification of the temperature module is necessary as frequently as dictated by your Hospital Procedures Policy. When you need to calibrate the temperature measurement, please contact the manufacturer.

5 Patient actions may interfere with accurate oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum or mints, brushing teeth, smoking or performing strenuous activity may affect temperature readings for up to 20 min after activity has ended.

6 Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

7 Biting the sensor tip while taking a temperature may result in damage to the sensor.

WARNING

8   Make sure disposable TEMP sensor covers are used to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.

9   Quick Temp measurement isn't suitable for use during defibrillation.

14.3 Measuring Procedure

14.3.1 Measurement for Oral Temperature

1. Ensure the oral probe (white probe) and probe are well installed.

2. Remove the probe from the probe well.

3. Observe the oral mode indicator on the screen (flashing head icon).

If this icon is not flashing, press the **Measure Pos** button and set it to **Oral** until the head icon appears.

4. Load the probe cover.

5. Place the probe tip deep into the patient's sublingual pocket as shown in the following figure.

Sublingual Pocket
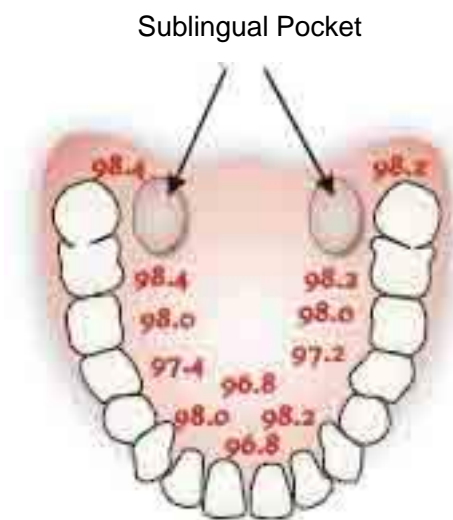
Measuring Position in Mouth

6. Do not hand the probe to the patient to place in his or her own mouth.

7. Always hold the probe in place, maintaining tissue contact until temperature is complete.

If necessary, repeat the measurement procedure shown above.

When the monitor enters prediction mode, "- - -" will display in the TEMP parameter area. After prediction measuring is over, the measuring value displays on the interface.

If the prediction measuring is successfully finished, the monitor enters **Monitor Mode** after 30s; otherwise the monitor enters **Monitor Mode** immediately after the prediction measuring. The monitoring state lasts for 10 min, and then the monitor enters waiting state. "-?-" displays in the TEMP parameter area. Or you can directly enter **Monitor Mode** by selecting **TEMP Setup** > **Monitor Mode**.

NOTE:

1   After one measurement, the user should put the sensor well to the sensor bracket and then take it out for starting a new measurement.

2   To ensure optimal accuracy, always confirm that the correct measurement position is selected.

3   The reference body site temperature is the same as the temperature of the measuring site.

14.3.2 Measurements for Rectal Temperatures

1. Ensure that the rectal probe (red probe) and probe well are installed.

2. Remove the red probe from the probe well.

3. Observe the Rectal Mode indicator on the display (flashing lower body icon).

4. Load a probe cover. Apply lubricant if desired.

5. Separate the buttocks and gently insert the probe only 1.5cm (5/8 inch), less for infants and children.
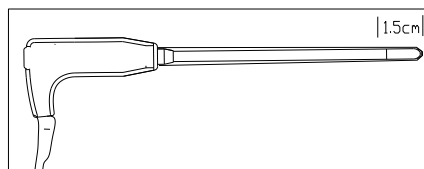
Measuring Position in Rectal

WARNING

Incorrect insertion can cause bowel perforation.

14.3.3 Measurements for Axillary Temperatures

1. Ensure that the white probe and probe well are installed.

2. Remove the probe from the probe well.

3. Press **TEMP Setup > Measure Pos** and select the Axillary mode.

4. Observe the axillary mode indicator on the display (flashing axillary icon).

5. Load a probe cover.

6. Adjust clothing to visualize the axilla.

7. Avoid folds in the axilla and place the probe tip vertically as high as you can as shown.

8. Place the arm at the patient's side. Hold in this position without movement of the arm or probe during the measurement cycle.
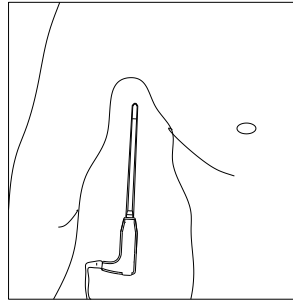
Measuring Position in Axillary

NOTE:

Do not take an axilliary temperature through the patient's clothing. Direct contact between the patient's skin and the probe is required.

To obtain accurate rectal temperature, use the white temperature probe.

14.4 Changing Temp Unit

To change **Temp Unit**, please:

1 Select the **TEMP Setup** menu to open it and select **Unit** on the interface.

2 Select the appropriate unit from the popup list.

Chapter 15 Monitoring IBP

15.1 Overview

IBP is measured by means of a catheter inserted directly into the circulatory system. A pressure transducer connected to the catheter converts the mechanical force exerted by the blood into an electrical signal, which is displayed graphically as pressure versus time on a monitor screen or numerically on digital display.

The monitor measures direct blood pressure of one selected blood vessel through two channels or four channels, and displays waveforms and pressure of measured direct blood pressure (SYS, DIA and MAP).

15.2 IBP Safety Information

WARNING

1   The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.

2   Disposable IBP transducer or domes should not be reused.

3   If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.

NOTE:

1   Use only the pressure transducer listed in the IBP Accessories

2   Calibrate the instrument as frequently as dictated by your Hospital Procedures Policy.

15.3 Monitoring Procedures

Preparatory steps for IBP measurement:

1.   Plug the pressure cable into the corresponding socket and switch on the monitor.

2.   Flushing through the system with normal saline solution. Ensure that the system is free of air bubbles.

3.   Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.

4.   Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.

5.   For the label name selection, please refer to Selecting a Pressure for Monitoring.

6.   To zero the transducer, please refer to Zeroing the Pressure Transducer.

WARNING

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

15.3.1 Selecting a Pressure for Monitoring

Tell the monitor which pressure you want to monitor by selecting its pressure label. The label is a unique identifier for each type of pressure. When you choose a label, the monitor uses that label's stored settings, for example color, wave scale and alarm settings. The label also determines which algorithm is used to process the pressure signal, so an incorrect label can lead to incorrect pressure values. To select the label, please refer to the following table:

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

15.3.2 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 using a pressure module, the zero information is stored in the module.

15.3.3 Zeroing a Pressure Measurement

The zeroing procedure is listed as below:

1. Turn off the stopcock to the patient.

2. Vent the transducer to atmospheric pressure, to compensate for the static and atmospheric pressure exerted on the transducer.

3. In the setup menu for the pressure, select **Zero**.

4. When you see the message **Zero Ok**, please close the stopcock to atmospheric pressure, and open the stopcock to the patient.

15.3.4 Troubleshooting the Pressure Zeroing (Taking Art for Example)

The status message lists the probable cause of an unsuccessful calibration.

Message	Corrective Action
Art ZERO FAIL	Make sure that the transducer is not attached to the patient
Art SENSOR OFF, FAIL	Make sure that transducer is not off, and then proceed zeroing
IN DEMO, FAIL	Make sure that the monitor is not in DEMO mode. Contact service technician if necessary
PRESSURE OVER RANGE, FAIL	Make sure that the stopcock is vented to atmosphere. If the problem persists, please contact service technician
PULSATILE PRESSURE ZERO FAIL	Make sure that the transducer is vented to air, not connected to a patient, and try again.

15.3.5 IBP Pressure Calibration

IBP is not user-calibrated. Calibration should be performed by a qualified service professional as frequently as dictated by your Hospital Procedures Policy.

15.4 Changing the IBP Waveform Ruler

The top, middle and bottom rulers are available for each channel of IBP waveform. Users can adjust the top, middle or bottom rulers manually:

1.   Open the menu **Wave Setup** of IBP by clicking on the IBP waveform area.

2.   Select a suitable ruler from the options **TopRuler**, **MidRuler** and **BotRuler**.

15.5 Measuring PAWP

PAWP, Pulmonary Artery Wedge Pressure, used to assess the cardiac function, is obtained by introducing a balloon-tipped pulmonary artery flotation catheter into the pulmonary artery. When the catheter is in one of the smaller pulmonary arteries, the inflated balloon occludes the artery allowing the monitor to record changes in the intrathoracic pressures that occur throughout the respiration cycle. The user can view the PAWP measurement result via connected CMS.

15.5.1 Measurement Procedures

Pulmonary Artery Wedge Pressure (PAWP) values are affected by fluid status, myocardial contractility, valve and pulmonary circulation integrity. The most accurate PAWP values are obtained at the end of the respiration cycle when the intrathoracic pressure is fairly constant. You can use the respiration waveform as a reference when assessing the PAWP waveform, to ensure constant measurement timing relative to the respiratory cycle.

To start the measurement:

1.   On the standard screen interface, select the PA parameter window to enter its setup menu.

Then, select **Setup** > **PAWP Activate** to open the PAWP measurement window.

2. Prepare and check the accessories according to your hospital policy.

3. Wedge the flotation catheter into the pulmonary artery. Then inflate the balloon and pay attention to PA waveform changes on the screen.

4. After obtaining a stable PAWP waveform, press **Freeze** to freeze the waveform. In freeze status, you can adjust the PAWP scale to an appropriate position by selecting **Measure** and moving the cursors up and down according to the clinical experience. Select **Confirm** to store the PAWP, CVP, HR values. To review the frozen waveform, press **s Browse** and rotate the trim knob clockwise or counter-clockwise as desired. If you need to review the stored PAWP, CVP, HR values, select **PAWP Review**.

5. Deflate the balloon when the monitor prompts you "**Please deflate the balloon!**".

6. If you need to start a new measurement, select **Remeasure**.

7. Click on **Exit** or select **Setup** > **PAWP Exit** to exit.

WARNING
1   Prolonged inflation can cause pulmonary hemorrhage, infarction or both. Inflate the balloon for the minimum time necessary to get an accurate measurement.
2   If the PAWP (mean) is greater than the PA (systolic), deflate the balloon and report the incident in accordance with hospital policy, because the pulmonary artery could be accidently ruptured, and the PAWP value derived will not reflect the patient's hemodynamic state, but will merely reflect the pressure in the catheter or balloon.

15.6 Measuring CPP

CPP is calculated by subtracting MAP and ICP, it means: CPP=MAP-ICP.

15.6.1 Measurement Procedures

To start CPP measurement:

1. Click the ICP parameter area to enter into **ICP Options** interface, select **Setup** to enter into **ICP Setup > CPP Source**; CPP source is defaulted as the currently opened artery, it can be selected as **Art**, **P1** or **P2**. If there is more than one arterial pressure at the same time, the priority level should be: Art > P1 > P2.

2. Take P1 as example: if P1 is selected as CPP Source, when MAP and ICP are both measured, ICP area will display CPP and its value as below picture, unit is same as ICP. Invalid CPP will display "-?-". CPP will be closed if exit ICP parameter.
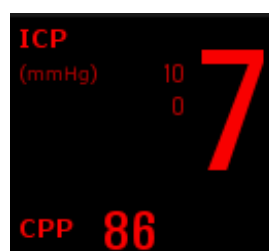
15.7 Calculating PPV

Pulse Pressure Variation (PPV) is calculated from the specific arterial pressure values, which reflects the variation between the maximal pulse pressure and the minimum pulse pressure in 30 seconds. Pulse pressure is affected by left ventricular-stroke volume, arterial resistance and arterial compliance.

PPV is calculated according to the following equation:

PPV= (PPmax – PPmin)/(PPmax + PPmin)/2) * 100%

To select an arterial pressure as PPV source:

1.   Click the PPV parameter area to enter **PPV Setup** menu.

2.   Select **Art**, **P1**, **P2**, or **AUTO** as **PPV Source**.

Only when P1 and P2 are arterial pressure can they be selected as PPV source. When it is set to **AUTO** and if there is more than one arterial pressure at the same time, the priority level should be: Art > P1 > P2.

Chapter 16 Monitoring CO$_2$

16.1 Overview

The monitor provides the sidestream and mainstream methods for CO$_2$ monitoring. Module and Respironics Sidestream CO$_2$ module are used for sidestream measuring, and Respironics Mainstream CO$_2$ module is used for mainstream measuring.

The principle of CO$_2$ measurement is primarily based on the fact that CO$_2$ molecule can absorb 4.3μm infrared ray. Absorption intensity is proportional to CO$_2$ concentration of patient sample, the CO$_2$ concentration will compute according to the detecting CO$_2$ absorption intensity of patient sample.

● Sidestream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a remote CO$_2$ sensor. You can measure Sidestream CO$_2$ using the monitor's built-in CO$_2$ measurement.

● Mainstream measurement uses a CO$_2$ sensor attached to an airway adapter directly inserted into the patient's breathing system.

16.2 CO$_2$ Safety Information

<div align="center">

WARNING

</div>

1 Do not use the device in the environment with flammable anesthetic gas.

2 The device should be used by trained and qualified medical personnel authorized by DIXION.

3 Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the CO$_2$ measurement.

4 The monitor will be damaged if any pipeline from the CO$_2$ module is disconnected, or the air tube /the air inlet /the air outlet are plugged by water or other materials.

5 The accuracy of the CO$_2$ measurement will be affected by the following reasons: the airway was highly obstructed; the leakage of air way connection or quick variation of environment temperature.

6 Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.

7 In the presence of electromagnetic devices (i.e., electrocautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20V/m will not adversely affect module performance.

8 Do not place the sensor cables or tubing in any manner that may cause entanglement or strangulation.

9 When using with mask, the measurement result may be relatively low due to O$_2$ supply.

10 When using mechanical ventilation, gas compensation should be well set. Inappropriate setting may cause low measurement result.

NOTE:

1   After the low battery alarm appears, please do not start the CO_2 measurement, or the monitor may turn off for the low capacity of battery.

2   For disposal of hospital waste such as accumulated fluids, calibration gases, sampled gases, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

16.3 Monitoring Procedures

16.3.1 Zeroing the sensor

You must perform zeroing following the steps when using the new airway adapter.

1.   Expose the sensor to room air and keep it away from all sources of CO_2 including the ventilator, the patient's breath and the operator's.

2.   In the **CO₂ Setup** menu, please set the **Work Mode** to **Measure**.

3.   For DIXION module, select **User Maintain** > **CO₂ Maintain**, and click **Zero**. For Respironics modules, click **Zero** in the **CO₂ Setup** menu.

4.   If the system briefly displays **Zero In Progress**, the process is successful. After the zeroing calibration is finished, you can start CO_2 Monitoring. If the system displays **Breath detected** or **Zero required**, zeroing has failed. Zero calibration must be performed again.

16.3.2 Sidestream CO₂ Module

16.3.2.1 Measurement Steps

DIXION EtCO₂ Module

1.   Fix the water trap to the water trap holder on the left side of the monitor.

2.   Connect the sampling cannula or the sampling line to the water trap.

3.   Set **Work Mode** to **Measure**.

4.   For intubated patients, an airway adapter is required. For non-intubated patients, place the nasal cannula or the sampling mask onto the patient.

CAUTION
1 The water trap collects water drops condensed in the sampling line and therefore prevents them from entering the module. If the water trap is nearly filled, you should replace it to avoid blocking the airway.
2 Based on a sample gas temperature of 37 °C, a room temperature of 23 °C and sample relative humidity of 100%, the water trap will be filled after approximately 90 hours with the flowrate of 100ml/min and approximately 130 hours with the flowrate of 70 ml/min. In clinical practice, the water trap can be used for a longer time before it is filled. It is recommended to replace the water trap once every month.
3 When replacing the water trap or suspecting the measurement value, please check if the O-rings of the water trap holder are normal and well installed. If the O-rings get damaged or loose, contact DIXION's service staff.

NOTE:

1   Disconnect the water trap from the holder or set **Work Mode** to **Standby** when the module is not in use.

2   To avoid patient cross infection, do not connect the exhaust tube to the ventilator circuit. If the sampled gas is returned to the breathing system, always use the bacterial filter of the sample gas return kit.

Respironics Sidestream Module

1. Plug the sensor cable into the monitor's CO$_2$ input connector. Allow the sensor two minutes for warm-up.

2. Appropriately connect the cannula, airway adapter or sample line to the sensor. It will click into place when seated correctly.

Connecting Respironics Sidestream Module

3. To zero the sensor, please refer to zeroing the sensor.

4. For intubated patients, an airway adapter is required;
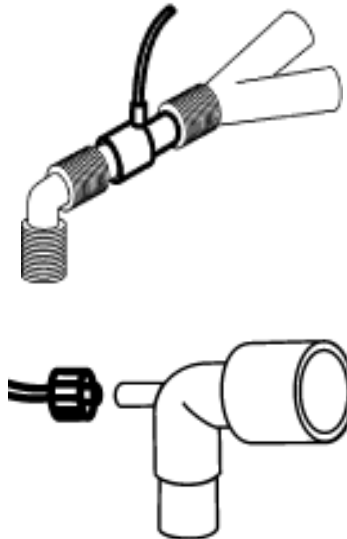
Air adapter

For non-intubated patients: Place the nasal cannula onto the patient.

Place the nasal cannula

NOTE:

1   You must perform a zero calibration as described in this procedure each time the ambient temperature changes more than 10°C (for example during transport).

2   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.

3   Always disconnect the cannula, airway adapter or sample line from the sensor when the sensor is not in use.

4   Do not connect the exhaust tube to the ventilator circuit. Cross infection can occur if sampling gas is returned to the breathing system.

16.3.2.2 Removing Exhaust Gases from the System

WARNING

Anesthetics: When using the sidestream CO$_2$ measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, to avoid exposing medical staff to anesthetics.

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the sidestream sensor at the outlet connector.

16.3.3 Mainstream CO$_2$ Module

NOTE:

You must perform a zero calibration as described in this procedure each time you use a new airway adapter.

Respironics Mainstream CO$_2$ Module

16.3.3.1 Measurement Steps

1   Attach the sensor connector to the CO$_2$ connector on the monitor.

2   Wait two minutes, allowing the sensor to reach its operating temperature and a stable thermal condition.

3   Choose the appropriate airway adapter and connect it to the sensor head. The airway adapter clicks into place when seated correctly.
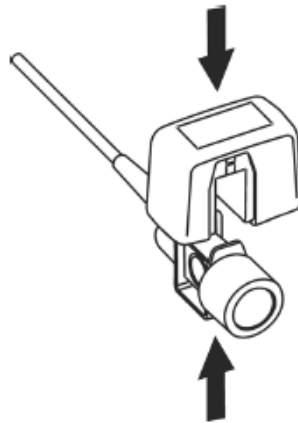
Connecting Sensor

4   To zero the sensor, please refer to zeroing the sensor.

5   Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y-section.
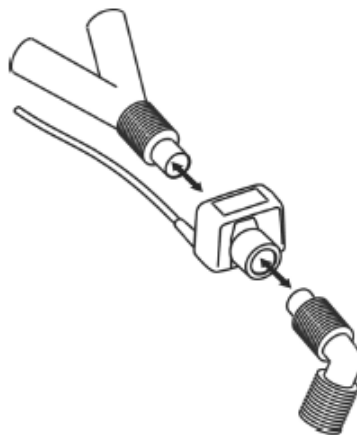
Connecting Airway Adapter

WARNING

1   No routine user calibration required.

2   Accuracy is affected by temperature and barometric pressure.

NOTE:

1   Replace the airway adapter, if excessive moisture or secretions are observed in the tubing or if the CO_2 waveform changes unexpectedly without a change in patient status.

2   To avoid infection, use only sterilized, disinfected or disposable airway adapters.

3   Inspect the airway adapters prior to use. Do not use it if airway adapter appears damaged or broken. Observe airway adapter color coding for patient population.

4   Periodically check the flow sensor and tubing for excessive moisture or secretion buildup.

16.4 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. If values seem inaccurately high or low, check that the monitor is using the appropriate corrections.

For the sidestream module, the following items are available in the **CO_2 Other Setup** menu: **N_2O Compen.**, **O_2 Compens.**, **Anest. Agent, Vapor Compen.** and **Pump Rate**. The concentration of compensated gas should be set based on the current gas concentration which is supplied for patient. As for O_2 and N_2O, make the supplied gas concentration multiply to its volume to get the concentration. For instance, supply 100% O_2, and its volume is 60%, then O_2 compensation is: 100%*60%=60%. AG concentration is decided by anaesthesia apparatus.

For the Respironics CO_2 modules, there are **Baro Press**, **O_2 Compens**, **Anes Agent** and **Balance Gas** in the **CO_2 Other Setup** menu. The concentration of compensated gas (including O_2 and AG) should be set based on the current gas concentration which is supplied for patient. The selection of balance gas depends on actual situation. For instance, N_2O should be selected as balance gas if the real balance gas is N_2O.

16.5 Changing Apnea Alarm

This determines the time limit after which the monitor gives an alarm if the patient stops breathing.

1. Select the **CO_2 Setup** menu to open it;

2. Select **Apnea Alm** from the menu;

3. Choose the apnea alarm time from the pop-up list.

<div style="text-align:center"><u>WARNING</u></div>

Safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

16.6 Setting CO_2 Waveform

Open the menu **CO_2 Waveform Setup** by clicking on the CO_2 waveform area:

◆ Choose **Mode** and set it to **Curve** or **Filled** from the pop-up list;

◆ Choose **Sweep** and select a suitable setting from the pop-up list. The bigger the value is, the wider the waveform will be.

Chapter 17 Monitoring C.O.

17.1 Overview

The Cardiac Output (C.O.) measurement is performed by using Thermodilution method. The monitor can determine blood temperature, measure cardiac output, and perform hemodynamic calculations. You can have iced injecta using either the flow through system or individual syringes of injecta. You can perform up to 6 measurements before editing the average Cardiac Output. The prompt message on the screen will tell you when to inject.

17.2 C.O. Safety Information

WARNING
1   Make sure that appurtenance applied is in conformity with relevant Medical Device Safety Requirements.
2   Appurtenance should be avoided from contact with conductive metal body when being connected or applied.

NOTE:

To replace the catheter thermistor, please enter the catheter computation coefficient into the **Constant** item according to the instruction.

17.3 C.O. Monitoring Procedures

1. Plug the C.O. interface cable into the C.O. socket and turn on the monitor.

2. Attach the injective probe connector and catheter thermistor connector to the appropriate parts of the cardiac output interface cable. And open the patient information window to confirm the patients' height and weight.

3. Pick the **C.O. Measure** item in the **C.O. Option** menu.

4. You can perform more than one measurement as required.

5. After the completion of the measurement, access the **C.O. Measure** window for **Review** to edit the measured data.
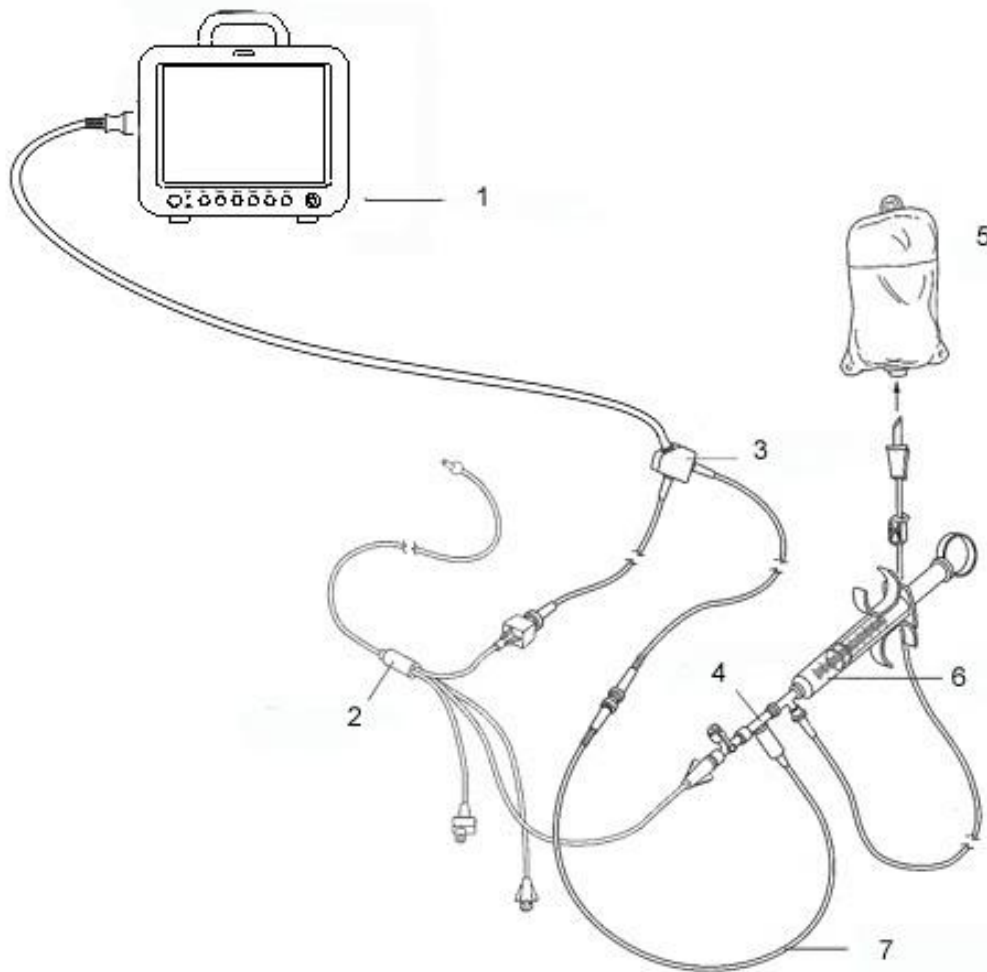
1: Monitor; 2: Thermodilution Catheter; 3: Cardiac Output Cable; 4: Injectate Sensor Housing;
5: Injectate; 6: Delivery System; 7: In-line injectate Temperature probe.

C.O. Sensor Connection

WARNING

1   Make sure that the computational constant for the measurement is appropriate to the
     catheter used.

2   Before a C.O. measurement is initiated, check the accuracy of patient setup. The
     calculation of C.O. is related to the patient height, weight, and catheter computation
     coefficient; therefore, incorrect input will lead to error in calculation.

NOTE:

The blood temperature alarm will not function during C.O. measurement. It will resume
automatically when the measurement is over.

17.4 C.O. Measurement Window

Select the **C.O. Option** menu to enter the **C.O. Measure** window and start C.O. measurement. If C.O. transducer is not connected, the monitor will display **No Sensor** on the screen.
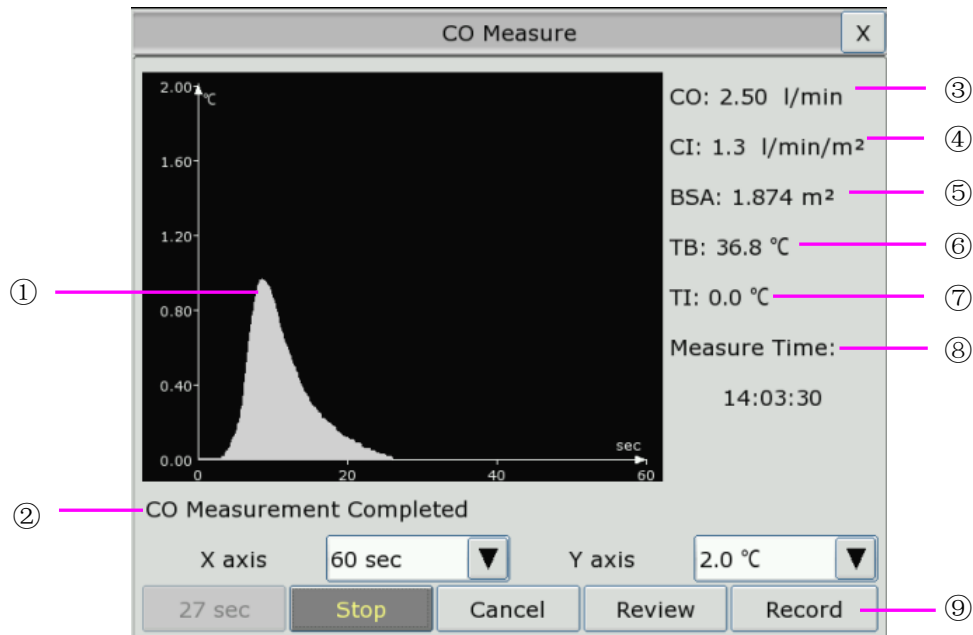
C.O. Measure Window

①	Measurement curve
②	Prompt message area
③	Cardiac Output
④	Cardiac Index
⑤	Body Surface Area
⑥	Blood Temperature
⑦	Injectate Temperature
⑧	Start time of the measurement
⑨	Function keys

The functional keys on the C.O. measure window are explained in the following table:

Start	Start a measurement
Stop	If the blood temperature cannot resume in a considerably long time, the measurement could not stop automatically. Use this button to stop the measurement and display the C.O., CI calculation result.
Cancel	Cancel the processing measurement or cancel the result after measurement.

Record	Print out the curve.
Y axis	Change the scale Y (temperature) value. Three models are available: 0 °C ~0.5 °C, 0 °C ~1 °C, 0 °C ~2.0 °C. Adjust the scale by the temperature differences. A smaller scale results in a larger curve.
X axis	Change the Scale X (time) value. Two modes are available: 0~30s, 0~60s. If you start measurement in the 0~30s mode, it will be switched to 0~60s mode automatically if the measurement cannot finish within 30 seconds. After the switch, no further adjustment can be made to the Scale X.
Review	Enter the **Review** window

17.5 Measurement Process

Measurement should be taken when the message "**Ready for new measurement**" appears on the screen. Press the **Start** button, and then start injection. The thermodilution curve, current blood temperature and the injective temperature are displayed during the measurement. Curve drawing will stop automatically when the measurement finishes, and the C.O. and CI (③ and ④ in the above figure) will be calculated and displayed on the screen. The monitor will display C.O. in the parameter area and the start measurement time (⑧ in the above figure).

To ensure the accuracy of the measurement, it is suggested that a reasonable interval should take place between two consecutive measurements. The length of the interval can be set in the C.O. Setup menu (Time unit: second). The interval time counter is displayed on the screen. The next measurement cannot be performed until the time reduces to zero and a message **Ready for new measurement** appears.

NOTE:

1 It is strongly recommended that the user must push the injector within four seconds after pressing the **Start** button.

2 It is strongly recommended that you wait at least 1 minute (or longer depending on the patient's clinical condition) before starting the next measurement.

Repeat this procedure until you have completed the measurements you want.

You can perform a maximum of six measurement editing. If you perform additional measurements the earliest measurement each time will be deleted. If any of the curves in the editing window is not selected for calculation (excluded from the averaging calculations), the place will be taken by the new measurement.

17.6 Editing C.O.

Pick the **Review** button on the **C.O. Measure** menu to access the **Review** as shown below:
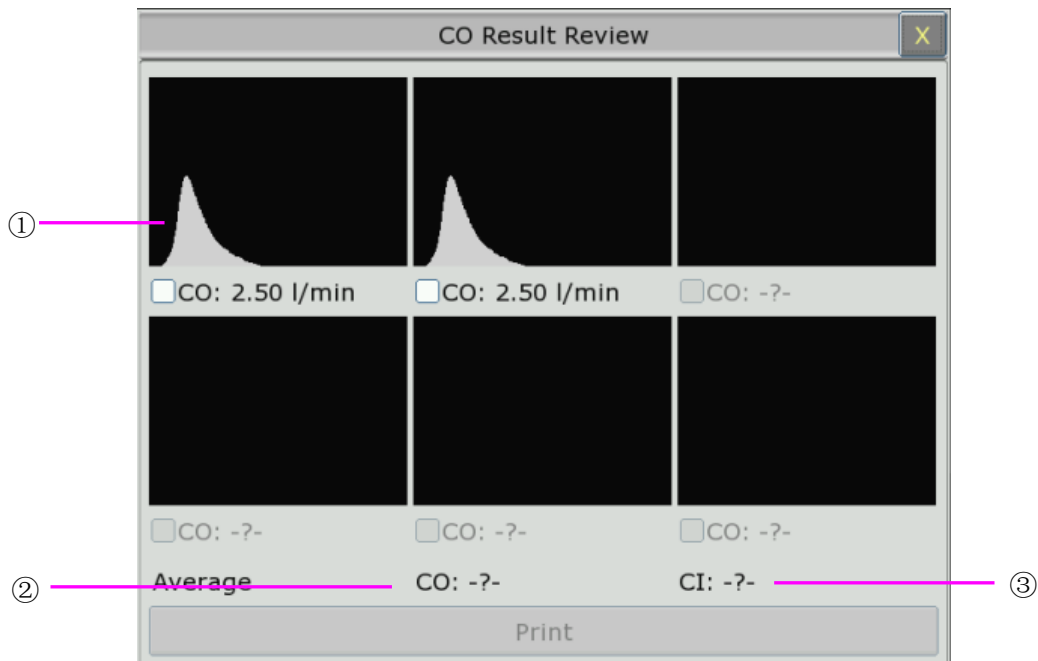
Window for C.O. Edit

◆ Contents displayed in the window:

①	Six curves of the six measurements and C.O. value
②	Average value of C.O.
③	Average value of CI

Values of selected measurements can be averaged and stored in the C.O. item in the HEMOD menu as the basis for Hemodynamic calculations.

17.7 Blood Temperature Monitoring

Blood temperature monitoring can function when C.O. measurement is not taken. The blood temperature is measured by the thermistor situated in the distal end of the flotation catheter in the pulmonary artery.

The blood temperature alarm function will not work during the C.O. measurement. When the measurement ends, the function will automatically resume.

The current blood temperature is displayed in the C.O. parameter area.

Thermodilution Catheter Site
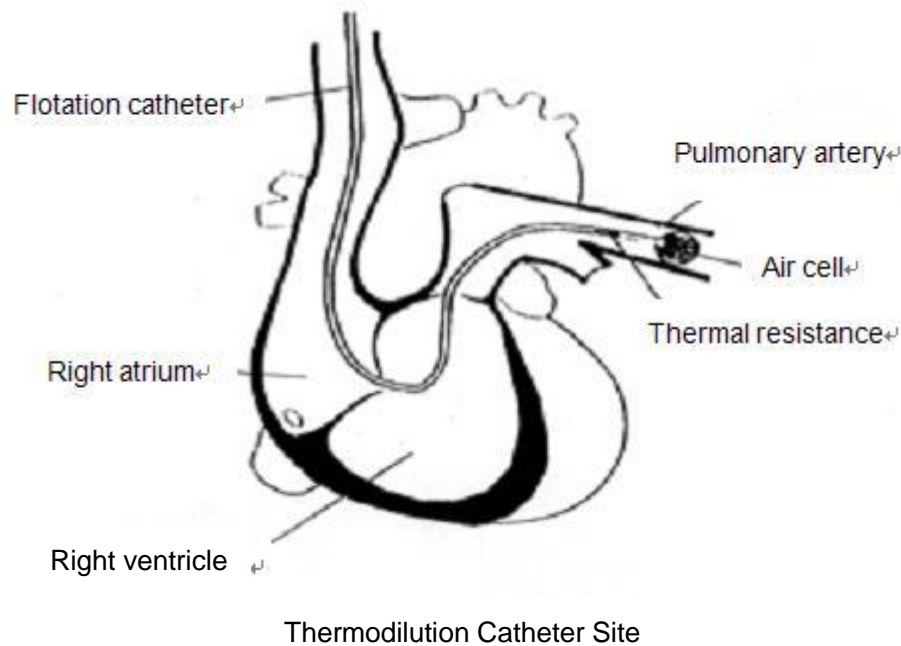
17.8 Setting the Computation Constant

The computation constant is associated with catheter and injective volume. When the catheter is changed, please adjust **Constant** in the **C.O. Setup** menu based on product description provided by the manufacturer.

17.9 Recording C.O. Measurements

C.O. measurement can be recorded by the recorder. To record the C.O. measurement, please select **Record** in the **C.O. Measure** menu.

17.10 Setting INJ. TEMP Source

To change the INJ Temp Source, please:

1   Select **Inj Temp Source** in the **C.O. Setup** menu;

2   Select **Auto** or **Manual** from the list;

●   **Manual**: directly displaying the injective temperature from INJ. TEMP.

●   **Auto**: indicating the system obtains the injective temperature through sampling.

17.11 Setting the Interval

You can set the minimum interval between two measurements in sequence by selecting **C.O. Option** > **C.O. Setup** > **Interval** and configuring **Interval** to a certain value by the second. No C.O. measurement can be taken during the interval.

The adjustable range of **Interval** is: 5 to 300 seconds.

Chapter 18 Monitoring AG

18.1 Overview

The monitor uses ISA sidestreasm gas analyzer (hereinafter called ISA analyzer), Dräger AG sidestream Minimodule (hereinafter called Dräger Minimodule), and and IRMA mainstream module (hereinafter called IRMA module) to monitor the anesthetic gas which can be used to measure the gases of adult, pediatric and neonatal patients during anesthesia, recovery and respiratory care. And the anesthetic gas includes Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), CO_2 and N_2O. The user can view the AG measurement result via connected CMS.

18.2 Safety Information

18.2.1 Safety Information for ISA Analyzer

<div align="center">

<u>WARNING</u>

</div>

1 The ISA analyzer is intended for use by authorized and trained medical personnel only.

2 Use only Nomoline sampling lines manufactured by Masimo.

3 The ISA analyzer must not be used with flammable anesthetic agents.

4 Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.

5 Do not re-use disposable sampling line.

6 Do not lift the monitor by the sampling line as it could disconnect from the monitor, causing the monitor to fall on the patient.

7 Used disposable sampling lines shall be disposed of in accordance with local regulations for medical waste.

8 Do not use adult/pediatric type sampling line configurations with infants, as this may add dead space to the patient circuit.

9 Do not use infant type sampling line configurations with adults, as this may cause excessive flow resistance.

10 Do not use the ISA analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

11 Check that the gas sample flow is not too high for the present patient category.

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

WARNING

13 The Nomoline sampling line and its interfaces are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.

14 Never sterilize or immerse the ISA analyzer in liquid.

15 Measurements can be affected by mobile and RF communications equipment. Make sure that the ISA analyzer is used in the electromagnetic environment specified in this manual.

16 ISA analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

17 Replace the sampling line if the sampling line input connector starts flashing red, or a Nomoline occlusion message is displayed on the host.

18 ISA analyzers are not designed for MRI environments.

19 Use of high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.

20 Do not use external ambient cooling of the ISA device.

21 Do not apply negative pressure to the Nomoline to remove condensed water.

22 Too strong positive or negative pressure in the patient circuit might affect the sample flow.

23 Exhaust gases should be returned to the patient circuit or a scavenging system.

24 Always use a bacteria filter on the evac side if sampled gas is intended to be re-breathed.

25 Do not place the ISA analyzer in any position that might cause it to fall on the patient.

CAUTION

1 The ISA analyzers should be securely mounted in order to avoid the risk of damage to the ISA.

2 Do not apply tension to the ISA analyzer cable.

3 Do not operate the ISA analyzer outside the specified operating temperature environment.

18.2.2 Safety Information for Dräger Minimodule

WARNING

1 Dräger Minimodule is intended to be used by trained and authorized health care professionals only.

2 Dräger Minimodule must not be used in areas where combustible or explosive gas mixtures are likely to occur.

3 Modifications to the module may lead to malfunctions.

4 It's recommended to use accessories approved by Dräger. If other, incompatible accessories are used, there is a risk of patient injury due to module failure.

5 Do not use the module near magnetic resonance imagers (MRI, NMR, NMI).

6 During warm-up, reported values may not be accurate.

7 If the gas sensors are not ready for operation, the patient will not be adequately monitored. Before using the medical device, ensure a suitable substitute monitoring.

8 Misdiagnosis or misinterpretation of the measured values or other parameters can endanger the patient. Do not make therapeutic decisions based solely on individual measured values and monitoring parameters. Therapeutic decisions must be made solely by qualified users.

9 When using three anesthetic agents, the oxygen measurement may be inaccurate. Only use two agents at a time.

10 The use of authentic Dräger sample lines is strongly recommended, as other sample lines with an incorrect length and/or diameter may lead to erroneous agent concentration readings and waveforms or water trap/sample line alarms.

11 Never use standard pressure-sensor tubing or IV lines (PVC) because it absorbs anesthetic agents, which are released later (degassing) resulting in erroneous agent concentration readings.

12 The sample flow diverted by the module may reduce the breathing system volume in case of low-flow anesthesia. Compensate by increasing the fresh-gas flow of the anesthesia machine accordingly. In some anesthesia systems, the sample flow may influence the measurement of the expiratory minute volume.

13 The liquid in the water trap could be contaminated and must be handled and disposed of with care. Dispose of the liquid in an adequate way and in compliance with local regulations.

14 Disconnect sample line before removing the water trap from the medical device. Contaminated liquid could be pushed out of the water trap when removing it without disconnecting the sample line.

15 Do not spray the O-rings of the water trap holder with silicon spray. Silicon can get into the measuring cuvette and influence the gas measurement permanently.

WARNING

16 Connect the sample line properly, otherwise faulty gas measurements may result.

17 Used sample lines may be infectious due to the breathing gases that passed through them. Sampling lines are not reusable and must be replaced after each patient unless a bacterial filter is in place between sample line and patient.

18 Always connect the gas exhaust of the medical device and anesthesia machine to the scavenging system.

19 Ensure proper ventilation of the place where the medical device is located.

20 Negligent placement of sample line, cables, and similar device components can endanger the patient. Use particular diligence when establishing connections to the patient.

21 To avoid temporary influence on the gas measurement and prevent damage to the water trap and measuring system do not use nebulizers/aerosols in the breathing system, when the medical device is connected.

22 Do not wash or disinfect the inside of the sample line or water trap to avoid temporary influence on the gas measurement and prevent damage to the water trap and measuring system. Do not sterilize the sample line or water trap.

CAUTION

1 Strictly observe the requirements in the user manual while using the module.

2 Do not operate the medical device without water trap.

3 If the water trap is nearly filled, you should replace it to avoid blocking the airway.

4 Do not apply excessive pressure (e.g., syringe, or compressed air) to the inlet, exhaust port, or the water trap of the medical device.

5 To avoid temporary influence on the gas measurement and prevent condensation and resulting failure of electrical components, do not switch on the medical device after significant temperature changes for 1 to 2 hours (e.g., after storage in unheated rooms).

18.2.3 Safety Information for IRMA Module

WARNING

1 The IRMA probe is intended for use by authorized and trained medical personnel only.

2 The IRMA probe must not be used with flammable anesthetic agents.

3 Disposable IRMA airway adapters shall not be reused. Used disposable airway adapters shall be disposed of in accordance with local regulations for medical wastes.

4 Use only Masimo manufactured oxygen sensor cells. Depleted oxygen sensors shall be disposed of in accordance with local regulations for batteries.

5 Do not use the IRMA Adult/Pediatric adapter with infants as the adapter adds 6 ml dead space to the patient circuit.

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

7 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.

8 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.
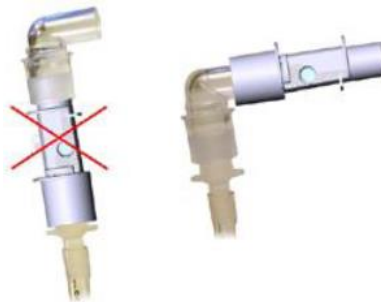
9 To keep secretions and moisture from pooling on the windows or oxygen sensor port, always position the IRMA probe in a vertical position with the LED pointing upwards.

10 Do not use the IRMA airway adapter with metered dose inhalsers or nebulized medications as this may affect the light transmission of the airway adapter windows.

11 The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessment of clinical signs and symptoms.

12 Incorrect probe zeroing will result in false gas readings.

13 Incorrect agent selection by the user for IRMA AX (no automatic agent identification) will result in false agent readings.

14 Using IRMA AX (no automatic identification) with gas mixtures containing more than one agent will result in false agent readings.

15 Use only Masimo manufactured IRMA airway adapters.

CAUTION

1   Do not apply tension to the probe cable.

2   Do not operate the IRMA probe outside the specified operating temperature environment.

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

NOTE:

For disposal of hospital waste such as accumulated fluids, calibration gases, sampled gases, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

18.3 Monitoring Steps

18.3.1 Monitoring Steps for ISA Analyzer

18.3.1.1 Performing a Pre-use Check

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

1. Connect the sampling line to the ISA gas inlet connector (LEGI).

2. Check that the LEGI shows a steady green light (indicating that the system is OK).

3. For ISA OR+ and ISA AX+ 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 LEGI shows a flashing red light.

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

18.3.1.2 Leakage Check

1. Connect a new Nomoline sampling line with male luer lock to the ISA LEGI and check that the LEGI 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 CO_2 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 CO_2 concentration has stabilized. Note the value.

6. Wait 1 minute and check that the CO_2 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.

18.3.1.3 System Setup for Analyzer

If your system is using the plug-in and measure ISA analyzer, please follow the setup instructions below:

1. Connect the ISA analyzer interface cable to the monitor.

2. Connect a Nomoline sampling line to the ISA analyzer input connector.

3. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit.

4. Power up the monitor.

5. A green LED indicates that the ISA analyzer is ready for use.

6. Perform a pre-use check as described in section Perform a pre-use Check.

18.3.1.4 Zeroing

The infrared 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".

ISA analyzer performs zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed every 24 hours, and takes less than 3 seconds for ISA CO_2 module and less than 10 seconds for ISA analyzer.

If the ISA analyzer 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% CO_2), ensure that the ISA analyzer is placed in a well ventilated place. Avoid breathing near the ISA analyzer before or during the zeroing procedure.

18.3.1.5 Cleaning

The ISA sidestream gas analyzers and Nomoline Adapter can be cleaned using a cloth moistened (not wet) with max 70% ethanol or isopropyl alcohol.

To prevent cleaning liquids and dust from entering the ISA gas analyzer through its LEGI connector, keep the Nomoline Family sampling line connected while cleaning the analyzer.

CAUTION

Never immerse the ISA sidestream gas analyzer in liquid.

18.3.1.6 Maintenance

Once every year, or whenever gas readings are questionable, perform a leakage check according to section *18.3.1.2* and verify gas readings with a reference instrument or with calibration gas.

WARNING

The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any parts of the sampling line.

18.3.1.7 Replacement of Consumables

The Nomoline and Nomoline Airway Adapter Set are single-patient use products.

The Nomoline Adapter is a multiple-patient use product.

The T-adapter and Nomo Extension are single-patient use products.

Nomoline Family sampling lines and all consumables mentioned above 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 ml/min sample flow. This situation is indicated by a red flashing gas inlet connector and an alarm message; Replace the Nomoline and wait until the gas inlet connector switches to green indicating that the ISA gas analyzer is ready for use.

18.3.1.8 MAC Calculation

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

$$MAC = \frac{\% Et(AA1)}{X(AA1)} + \frac{\% Et(AA2)}{X(AA2)} + \frac{\% Et(N_2O)}{100}$$

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.

18.3.2 Monitoring Steps for Dräger Minimodule

1. Fix the water trap to the water trap holder.

2. Connect the sampling cannula or the sampling line to the water trap.

3. Set **Work Mode** to **Measure**.

4. For intubated patients, an airway adapter is required. For non-intubated patients, place the nasal cannula or the sampling mask onto the patient.

Upon start-up, the module passes through an initialization (status message ***MultiGas Initialization*** appears) and warm-up period (status message ***MultiGas Warming Up*** appears). During this time, concentrations for certain gases may not be available and the anesthetic agent may not be identified. After the warm-up period, the module will have achieved full ISO-accuracy.

18.3.2.1 Zeroing

The module purges and zeroes itself and does not need any interaction by the user. Waveforms flatline and parameter box values blank from the screen during this cycle.

18.3.2.2 MAC Calculation

Standard MAC values
1 standard MAC is equal to the alveolar anesthetic concentration at one atmosphere (760 mmHg) at which 50% of all patients no longer respond to noxious stimuli. The integrated MAC algorithm is based on the MAC values shown in the following table. The values specified in the table apply to a patient age of 40 years and are guiding values only.

	1 MAC corresponds to: (in 100 % O2)
Halothane	0.77 Vol%
Enflurane	1.7 Vol%
Isoflurane	1.15 Vol%
Desflurane	6.65 Vol%
Sevoflurane	2.10 Vol%
N2O	105 Vol%

For gas mixtures, the respective multiples for N_2O and anesthetic agents are added according to the following equation.

$$MAC_{standard,total} = \frac{\text{exp. conc. Anesth.}_1}{MAC_{standard} \text{ Anesth.}_1} + \frac{\text{exp. conc. Anesth.}_2}{MAC_{standard} \text{ Anesth.}_2} + \frac{\text{exp. conc. N}_2O}{MAC_{standard} \text{ N}_2O}$$

NOTE :
Age and other factors are not taken into account for standard MAC value calculation.

Age-corrected MAC values

The equation applies to patients older than 1 year.

$MAC_{age\ corrected} = \text{standard MAC x } 10^{(-0.00269 \text{ x (age } -40))}$

For gas mixtures, the respective multiples for N_2O and anesthetic agents are added according to the following equation.

$$MAC_{age\ corrected,total} = \frac{\text{exp. conc. Anesth.}_1}{MAC_{age\ corrected} \text{ Anesth.}_1} + \frac{\text{exp. conc. Anesth.}_2}{MAC_{age\ corrected} \text{ Anesth.}_2} + \frac{\text{exp. conc. N}_2O}{MAC_{age\ corrected} \text{ N}_2O}$$

CAUTION

1   Always set patient age correctly. Incorrect settings can lead to inappropriate MAC values and therefore to inappropriate anesthetic gas delivery.

2   Age-based MAC values only apply if the patient's age is $\geq$ 1 year. An aged-based MAC of 1 year is used if the patient's age is $<$ 1 year.

3   If patient age is not entered, the default age-based MAC of 40 years is used.

18.3.3 Monitoring Steps for IRMA Module

1   Plug the IRMA connector into the IRMA input and switch the power on.

2   Snap the IRMA sensor head on the top of the IRMA airway adapter. It will click into place when properly seated.
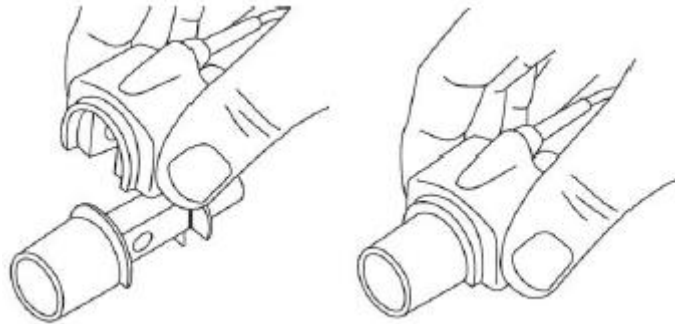
3   A green LED indicates that the IRMA probe is ready for use.

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

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

Alternatively, connect an HME (Heat Moisture Exchanger) between the patient's endotracheal
tube and the IPMA probe. Placing an HME in front of the IRMA probe 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 IRMA probe as well.
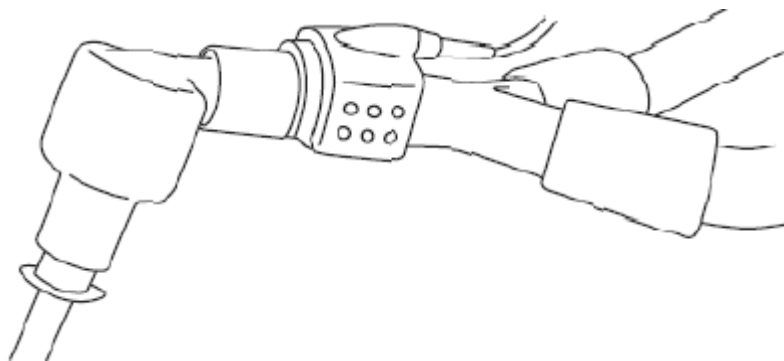
6   Unless the IRMA probe is protected with an HME always position the IRMA probe with the
    status LED pointing upwards.

18.3.3.1 Placement of IRMA Probe

When connecting IRMA probe to an infant patient circuit, it is important to avoid a direct contact
between the IRMA probe and the infant's body. 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.

WARNING

The IRMA probe is not intended to be in long term skin contact.

18.3.3.2 Performing a Pre-use Check

Prior to connecting the IRMA airway adapter to the breathing circuit, verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.

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

18.3.3.3 Zeroing

WARNING

Incorrect probe zeroing will result in false gas readings.

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

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the host instrument to transmit a zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the zeroing procedure. The presence of ambient air (21% O_2 and 0% CO_2) in the IRMA airway adapter is of crucial importance for a successful zeroing. If a "ZERO-REQ" alarm should appear directly after a zeroing procedure, the procedure has to be repeated.

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

Zeroing for IRMA AX+ probes:

Zeroing should be performed every time the IRMA airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy message is displayed.

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

18.3.3.4 Cleaning

The IRMA probe 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 probe.

CAUTION
1 The IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
2 Never immerse the IRMA probe in liquid.

18.3.3.5 Maintenance

Gas readings should be verified at regular intervals with a reference instrument or by conducting the gas check. The suggested interval is once every year.

18.3.3.6 MAC Calculation

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

$MAC=\%ET(AA_1)/X(AA_1)+\%ET(AA_2)/X(AA_2)+\%ET(N_2O)/100$

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

18.4 Setting Apnea Alarm Time

This determines the time limit after which the monitor gives an alarm if the patient stops breathing.

1 Select the **CO$_2$ (AG) Setup** > **Apnea Alm**;

2 Choose the apnea alarm time from the pull-down list.

18.5 Working Status of ISA analyzer

Working status of the ISA analyzer can be indicated by the indicator. For the detailed information, please refer to the following table.

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

18.6 Working Status of IRMA Module

The working status of the IRMA module can be transmitted by the IRMA probe. For the detailed information, please refer to the following table.

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 adapter

18.7 O_2 Compensations

The following models need O_2 compensation: IRMA AX+, ISA AX+. For the compensation details, please refer to the following table.

O_2 Range	Set O_2 Range
0 to 30 vol%	Low
30 to 70 vol%	Med.
70 to 100 vol%	High

18.8 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 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure. 20.8 vol% O_2 corresponds to the actual O_2 concentration in room air with 0.7 vol% H_2O concentration (at 1013 hPa this equals for example 25°C 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 flows through the sampling line, the gas temperature will adapt to ambient before reaching the gas analyzer. As the NOMO section removes 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:

$EtCO_2$ = EtCO$_2$ value sent from ISA [vol %]

$Pamb$ = Ambient pressure sent from ISA [kPa]

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

$EtCO_2(BTPS)$ = EtCO$_2$ gas concentration at BTPS [vol%]

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

Chapter 19 Freeze

When monitoring a patient, the user may freeze the waveforms and examine them. Generally, the user can review a frozen waveform of a maximum of 120 seconds. The freeze function of this monitor has the following features:

■ Freeze status can be activated on any operating screen.

■ Once entering the Freeze status, the system exits all other operating menus. Besides, the system freezes all waveforms in the Waveform area of the Basic Screen, and also freezes Full Lead ECG waveforms and extra waveforms on the Full Lead ECG interface (if any). Nevertheless the Parameter area refreshes normally.

■ The frozen waveforms can be reviewed and recorded.

19.1 Entering/Exiting Freeze Status

19.1.1 Entering Freeze Status

In the Non-Freeze status, press the ⧖ button on the control panel of the monitor to exit the current menu. Press the ⧖ button again, freeze status is entered and the popup **Freeze** menu is displayed. In Freeze status, all waveforms are frozen and will no longer be refreshed.

19.1.2 Exiting Freeze Status

In the Freeze status, executing any of the following operations will command the system to exit the Freeze status:

● Exit the **Freeze** menu;

● Press the ⧖ button on the control panel again;

● Execute any operation that may trigger the adjustment of the screen or the display of a new menu.

After exiting Freeze status, the system will clear screen waveforms and resume displaying real-time waveforms. In the Screen Refresh mode, the system will sweep the waveforms from left to right in the Waveform Area.

Press the ⧖ button on the control panel, and the **Freeze** menu will appear on the bottom part of the screen. At the same time, the system freezes the waveforms.

NOTE:

Pressing the ⧖ button repeatedly over a short period of time may result in discontinuous waveforms on the screen.

19.2 Reviewing Frozen Waveform

By moving the frozen waveform, you may review a waveform of 120 seconds before it is frozen. For a waveform of less than 120 seconds, the remaining part is displayed as a straight line. Select **Time** on the **Freeze** menu and use the up/down arrow keys to move the frozen waves so that you can review the other parts of the frozen waves not displayed on the current screen.

Chapter 20 Review

The monitor provides 120-hour trend data of all parameters, storage of 1200 NIBP measurement results and 200 alarm events. This chapter gives detailed instruction for review of all data.

20.1 Trend Graph Review

■   The latest 1-hour trend is displayed every 1 or 5 seconds.

■   The latest 120-hour trend is displayed every 1, 5 or 10 minutes.

To review Trend Graph, please press the **Trend Graph** key 〰️ on the screen or select **Menu** > **Review** > **Trend Graph**, then the trend graph interface is displayed.

In the trend graph, the y-axis stands for the measurement value and x-axis stands for the time.
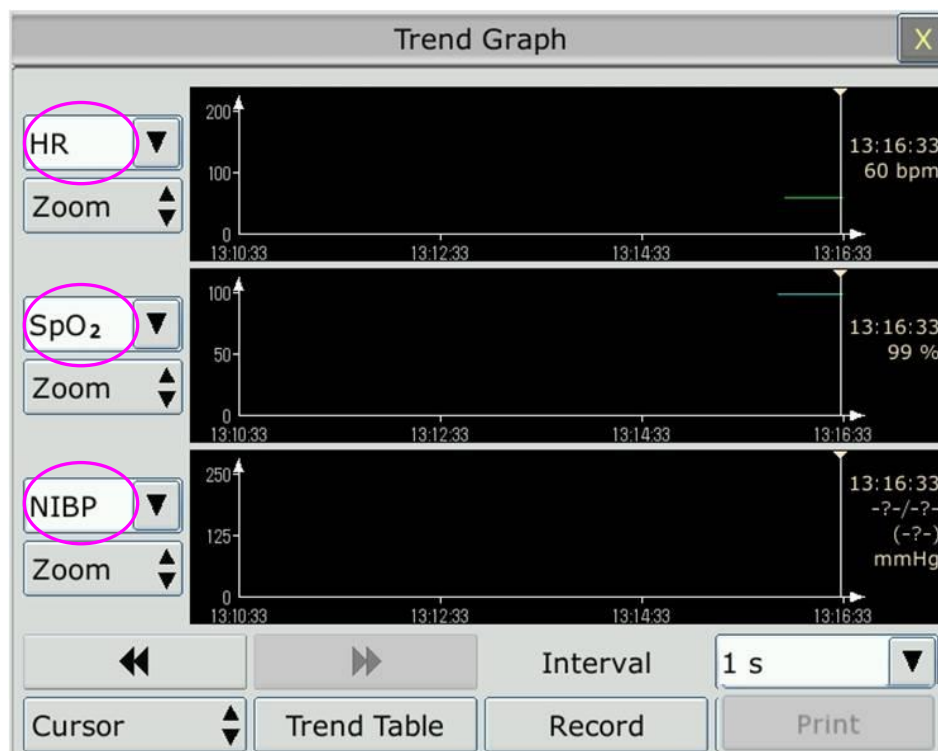
20.1.1 Selecting Trend Graph of Specific Parameter

The monitor can review trend graph of different parameters. To change the existing trend graph, please select **Menu** > **Review** > **Trend Graph** and select a required parameter name from the popup list.

20.1.2 Adjusting Trend Scale

You can use **Zoom** on the trend graph review interface to adjust the trend scale. Once you adjust the trend scale on the trend graph review interface, you also change the trend scale of the related parameters for the screen trend displayed on the main screen.

20.1.3 Setting Interval

The monitor can support five kinds of interval. To set an appropriate interval, please select **Menu** > **Review** > **Trend Graph** and an interface is displayed. Choose **Interval** on the interface to open the list and select an appropriate resolution among **1 s**, **5 s**, **1 min**, **5 min** and **10 min**.

NOTE:

Please select 1 sec interval if completed NIBP data is expected to display on the screen.

20.1.4 Scrolling Left and Right the Screen

All trend graphs can't be displayed on the current screen due to the screen limitation. The user can scroll left and right the screen manually to see measurement trends that do not fit in the current view by selecting and pressing the symbol ◄◄ and ►► displayed on the trend graph.

20.1.5 Switching to the Trend Table

The user can switch to the trend table interface on the **Trend Graph** interface. To do so, please select **Menu** > **Review** > **Trend Graph** and select the **Trend Table** option from the popup interface.

20.2 Trend Table Review

To review the trend table, please press the **Trend Table** key ▦ on the screen or select **Menu** > **Review** > **Trend Table**, then the trend table is displayed.

NOTE:

The CO_2 module and AG module cannot be measured at the same time, so their trend graph cannot be displayed at the same time.

20.2.1 Setting Interval

The monitor can support eleven kinds of interval. To set an appropriate interval, please select **Menu** > **Review** > **Trend Table** and an interface is displayed. Choose **Interval** on the interface to open the list and select an appropriate interval among **1 s**, **5 s**, **30 s**, **1 min**, **3 min**, **5 min**, **10 min**, **15 min**, **30 min**, **60 min** and **NIBP**.

20.2.2 Scrolling the Screen

All trend tables can't be displayed on the current screen due to the screen limitation. The user can scroll left, right, up and down the screen manually to see measurement trend tables that do not fit in the current view by selecting and pressing the symbol ◄◄ , ►► , ▼ and ▲ displayed on the trend graph.

20.2.3 Switching to Trend Graph

The user can switch to the trend graph on the **Trend Table** interface. To do so, please select **Menu** > **Review** > **Trend Table** and select the **Trend Graph** option from the popup interface.

20.3 NIBP Review

To review the NIBP measurement data, select the **NIBP Review** key on the screen or select **Menu** > **Review** > **NIBP Review**, then the **NIBP Review** window is displayed.

20.3.1 Scrolling the Screen

All measurement data can't be displayed on the current screen due to the screen limitation. The user can scroll up and down the screen manually to see measurement data that doesn't fit in the current view by selecting and pressing the symbol ▼ and ▲ displayed on the **NIBP Review** interface.

20.4 Alarm Review

To review the alarm event, select the **Alarm Review** key on the screen or select **Menu** > **Review** > **Alarm Review**, then the **Alarm Review** Window is displayed.

NOTE:

The monitor can store a maximum of 200 alarm events. As soon as the alarm event storage is full, the earliest alarm event will be replaced by the latest one.

20.4.1 Scrolling the Screen

All alarm events can't be displayed on the current screen due to the screen limitation. The user can scroll up and down the screen manually to see alarm events that don't fit in the current view by selecting and pressing the symbol ▼ and ▲ displayed on the **Alarm Review** interface.

20.4.2 Selecting Alarm Event of Specific Parameter

The monitor can review alarm event of the specific parameters. To view the alarm event of the specific parameter, please select **Menu** > **Review** > **Alarm Review** and choose **Event Type** to select the required parameter name from the popup list.

20.4.3 Setting Time Index

The user can set end time of alarm review by selecting the **Time Index** option displayed on the alarm review interface.

If the user selects **Current Time** on the popup interface, the alarm events occurring before the current time are displayed on the alarm event review interface.

If the user selects **User Define**, he can define the review time by setting time box displayed on the interface**.** The alarm events occurring before the **User Define** option are displayed on the alarm event review interface.

20.5 Arr Review

Select the **ARR Review** key ⎍⎍⎍ on the screen or select **ECG Setup** > **ARR Analysis** > **ARR Review** or **Menu > Review > ARR Review** to open the Arr review interface**.** The interface displays the latest arrhythmia events.

20.5.1 Scrolling the Screen

All arrhythmia events can't be displayed on the current screen due to the screen limitation. The user can scroll up and down the screen manually to see the other arrhythmia events that do not fit in the current view by selecting and pressing the symbol ▼ and ▲ displayed on the **Arrhythmia Review** interface.

20.5.2 Arrhythmia Alarm Review

You may select an alarm event by the knob and access the alarm review interface to get more information. On the alarm review interface, you can:
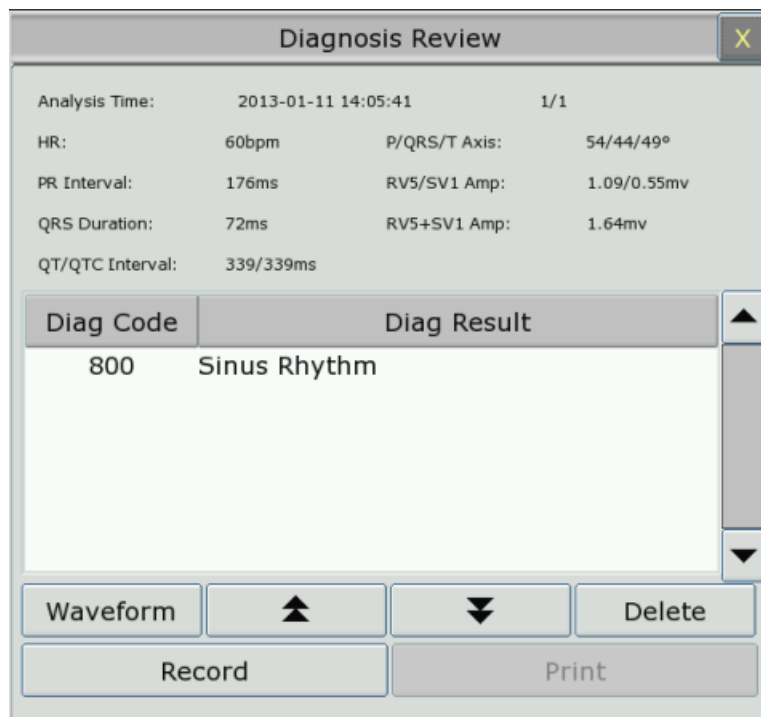
◆ Right or left shift the waveform to review the complete 8-scecond waveform.

◆ Select **Record** and output the arrhythmia waveform by the recorder.

◆ Select another name from the pull-down list of **Rename** for the arrhythmia event to change its name.

◆ Select **Delete** to remove a specific arrhythmia event.

◆ Select **Alarm List** or exit the menu to get back to the arrhythmia review interface.

NOTE:

1   If there are more than 200 arrhythmia events, the monitor will only keep the recent ones.

2   The name of arrhythmia event will be shown on the alarm status area.

20.6 12-lead Diagnosis Review

Select the **Analysis Review** key ⤵▤ on the screen or select **Menu** > **Review** > **Analysis Review** to open the 12-lead analysis review interface.

20.6.1 Scrolling the Screen

All analysis results or waveforms can't be displayed on the current screen due to the screen limitation. The user can scroll up and down the screen manually to see the analysis results or waveforms that do not fit in the current view by selecting and pressing the symbol ▼ and ▲ displayed on the 12-lead analysis review interface.

20.6.2 Deleting Diagnosis Results

The user can delete the analysis results displayed on the current screen by selecting **Delete** on the interface.

20.6.3 Switching Between Waveforms and Results

The user can review the analysis waveforms on the analysis result interface by selecting the **Wave** option and review the analysis results on the analysis waveform interface by selecting the **Result** option.

Chapter 21 Calculation and Titration Table

The monitor provides calculation and record function and titration table. Calculations are patient data that are not directly measured but calculated by the monitor.

The monitor can perform drug calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation and renal function calculation, and also support record function.

NOTE:
The drug calculation function acts only as a calculator. The patient weights in Drug Calculation menu and in Patient Information menu are independent of each other. Therefore changing the Weight in Drug Calculation menu will not change the weight in the Patient Information menu.

21.1 Drug Calculation

21.1.1 Calculation Procedures

1. The drug calculation window is displayed by selecting **Menu** > **Common Function** > **Calculation** > **Drug Dose**.

2. Select the right pull-down box of the **Drug** option and select the required drug name among the 15 drugs which are listed as follows. And the drug name of **Drug A**, **Drug B**, **Drug C**, **Drug D** and **Drug E** can be defined by the user.

    - Drug A, Drug B, Drug C, Drug D and Drug E
    - AMINOPHYLLINE
    - DOBUTAMINE
    - DOPAMINE
    - EPINEPHRINE
    - HEPARIN
    - ISUPREL
    - LIDOCAINE
    - NIPRIDE
    - NITROGLYCERIN
    - PITOCIN

3. The system generates values that can't be treated the calculation results. The user must enter the correct parameter value based on the doctor's instruction.

4. Manually enter the value of patient weight or directly obtain the value from the monitor by selecting **Get Info**.

5. Enter the correct parameter value.

6. Confirm whether the calculation result is correct.

The following formulas are applied to dose calculation:

Concentrate   = Amount / Volume

INF Rate   = DOSE / Concentrate

Duration   = Amount / Dose

Dose   = Rate × Concentrate

DRIP Rate   = INF Rate / 60 × DROP Size

21.1.2 Calculation Unit

Each drug has the fixed unit or unit series to calculate. Among the same unit series, the unit binary varies with the entered parameter value.

The calculation units of the drugs are listed as follows:

Drug	Unit
DRUG A, DRUG B, DRUG C, AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN	g, mg, mcg
DRUG D, PITOCIN, HEPARIN	Ku, mu, Unit
DRUG E	mEq

When defining a drug, select Drug A, Drug B, Drug C, Drug D, and Drug E based on the unit series.

NOTE:

1 The drug calculation is displayed as invalid value before the user edits the drug name and patient weight, and the user can't enter any value.

2 Drip Rate and Drop Size are invalid in the neonatal mode.

21.1.3 Titration Table

After completing the drug calculation, the user can open the **Titration** on the **Drug Dose** interface.

The user can change the following items in the titration table:

- Basic
- Step
- Dose Type

The data in the trend table will vary with the changes above. And the user can perform the following:

- Scroll up and down the screen by selecting and pressing the symbol ▼ and ▲ displayed on the trend graph.

- Record the data displayed in the current window by selecting **Record**.

21.2 Hemodynamic Calculation

21.2.1 Calculation Procedure

1. The hemodynamic calculation interface is displayed by selecting **Menu** > **Common Function** > **Calculation** > **Hemodynamics**.

2. Manually enter the values required on this interface. You can also directly obtain the values of HR, C.O., PA MAP, CVP, and PAWP if they are available from the monitor by selecting **Get Info**.

3. Select **Calculate** to output parameter value.

21.2.2 Input Parameters

Items	English Full Name/Description
PAWP	Pulmonary artery wedge pressure
CVP	Central venous pressure
C.O.	Cardiac output
HR	Heart rate
EDV	End-diastolic volume
AP MAP	Mean Artery Pressure
PA MAP	Pulmonary artery mean pressure
Height	/
Weight	/

21.2.3 Output Parameters

Items	English Full Name/Description
CI	Cardiac index
BSA	Body surface area
SV	Stroke volume
SVI	Stroke volume index
SVR	Systemic vascular resistance
SVRI	Systemic vascular resistance index
PVR	Pulmonary vascular resistance
PVRI	Pulmonary vascular resistance index
LCW	Left cardiac work
LCWI	Left cardiac work index

Items	English Full Name/Description
RCW	Right cardiac work
RCWI	Right cardiac work index
LVSW	Left ventricular stroke work
LVSWI	Left ventricular stroke work index
RVSW	Right ventricular stroke work
RVSWI	Right ventricular stroke work index
EF	Ejection fraction

21.3 Oxygenation Calculation

21.3.1 Calculation Procedure

1.   Select **Menu** > **Common Function** > **Calculation** > **Oxygenation**.

2.   Manually enter the values required on this interface. You can also directly obtain the values of patient height, patient weight, C.O. and FiO_2 if they are available from the monitor by selecting **Get Info**.

3.   Select **Calculate** to output parameter value.

21.3.2 Input Parameters

Items	English Full Name/Description
C.O.	Cardiac output
FiO_2	Percentage fraction of inspired oxygen
PaO_2	Partial pressure of oxygen in the arteries
$PaCO_2$	Partial pressure of carbon dioxide in the arteries
SaO_2	Arterial oxygen saturation
PvO_2	Partial pressure of oxygen in venous blood
SvO_2	Venous oxygen saturation
Hb	Hemoglobin
CaO_2	Arterial oxygen content
CvO_2	Venous oxygen content
VO_2	Oxygen consumption
RQ	Respiratory quotient
ATMP	Atmospheric pressure
Height	/
Weight	/

21.3.3 Output Parameters

Items	English Full Name/Description
BSA	Body surface area
VO_2 calc	Calculated oxygen consumption
C (a-v) O_2	Arterial venous oxygen content difference
O_2ER	Oxygen extraction ratio
DO_2	Oxygen transport
PAO_2	Partial pressure of oxygen in the alveoli
$AaDO_2$	Alveolar-arterial oxygen difference
CcO_2	Capillary oxygen content
Qs/Qt	Venous admixture
C.O. calc	Calculated cardiac output
PaO_2/FiO_2	PaO_2/FiO_2
PaO_2/PAO_2	PaO_2/PAO_2
$AaDO_2/PaO_2$	$AaDO_2/PaO_2$
DO_2I	Oxygen delivery index
VO_2I	Oxygen consumption index
CaO_2 calc	Calculated arterial oxygen content
CvO_2 calc	Calculated venous oxygen content

21.4 Ventilation Calculation

21.4.1 Calculation Procedure

1. Select **Menu** > **Common Function** > **Calculation** > **Ventilation**.

2. Manually enter the values required on this interface. You can also directly obtain the values of FiO_2, RR, PIP and PEEP if they are available from the monitor by selecting **Get Info**.

3. Select **Calculate** to output parameter value.

21.4.2 Input Parameters

Items	English Full Name/Description
FiO_2	Percentage fraction of inspired oxygen
RR	Respiration rate
$PeCO_2$	Partial pressure of mixed expiratory CO_2
$PaCO_2$	Partial pressure of carbon dioxide in the arteries

PaO$_2$	Partial pressure of oxygen in the arteries
VT	Tidal volume
RQ	Respiratory quotient
ATMP	Atmospheric pressure
PIP	Peak inspiratory pressure
PEEP	Positive end-expiratory pressure

21.4.3 Output Parameters

Items	English Full Name/Description
PAO$_2$	Partial pressure of oxygen in the alveoli
AaDO$_2$	Alveolar-arterial oxygen difference
PaO$_2$/FiO$_2$	PaO$_2$/FiO$_2$
PaO$_2$/PAO$_2$	PaO$_2$/PAO$_2$
AaDO$_2$/PaO$_2$	AaDO$_2$/PaO$_2$
MV	Minute volume
VD	Volume of physiological dead space
VD/VT	Physiological dead space in percent of tidal volume
VA	Alveolar volume
Cdyn	Compliance dynamic

21.5 Renal Function Calculation

21.5.1 Calculation Procedure

1. Select **Menu** > **Common Function** > **Calculation** > **Renal Function**.

2. Manually enter the values required on this interface.

3. Select **Calculate** to output parameter value.

21.5.2 Input Parameters

Items	English Full Name/Description
URK	Urine potassium
URNa	Urinary sodium
Urine	Urine
Posm	Plasm osmolality
Uosm	Urine osmolality
SerNa	Serum sodium

SCr	Serum creatinine
UCr	Urine creatinine
BUN	Blood urea nitrogen
UUN	Urine urea nitrogen
Height	/
Weight	/
Type	Patient type: Adult, Pediat, Neonat
Gender	Male, Female, N/A.

21.5.3 Output Parameters

Items	English Full Name/Description
URNaEx	Urine sodium excretion
URKEx	Urine potassium excretion
Na/K	Sodium potassium ratio
CNa	Clearance of sodium
CCr	Creatinine clearance rate
CUUN	Urine urea nitrogen clearance rate
FENa	Fractional excretion of sodium
FEUr	Fractional Excretion of Urea
Cosm	Osmolar clearance
CH_2O	Free water clearance
U/P osm	Urine to plasma osmolality ratio
BUN/SCr	Blood urea nitrogen creatinine ratio
U/SCr	Urine-serum creatinine ratio

Chapter 22 Recording

A thermal dot matrix recorder is used for the monitor and can support many recording types and output patient information, measurement data, review data waveform and so forth.

1	Recording indicator
2	Paper feeding key: press this key to start or stop feeding recording paper without outputting anything on the paper
3	Paper outlet
4	Recorder door

22.1 Performance of the Recorder

- Waveform record is printed at the rate of 25 mm/s or 50 mm/s.
- 48mm wide printout paper.
- It can record up to three waveforms.
- User-selectable real-time recording time and waveform.
- Auto recording interval is set by the user, and the waveform is in accordance with the real time recording.

NOTE:

It is suggested that the user should not use the recorder when the low battery displays, or the monitor may be turned off automatically.

22.2 Starting and Stopping Recording

The monitor provides several types of stripe recording. You can start recording following the procedure below:

Recording Type	Description/ Procedure
Continual real-time recording	Select at least one Rec waveform in **Recorder Setup** (A maximum of three waveforms can be selected), select **Continual** in **R-T Rec Time**. Press the **Record** button on the front panel to start the recording. Press the button again to stop recording.
8-second real-time recording	Select at least one Rec waveform in **Recorder Setup** (A maximum of three waveforms can be selected), select **8 s** in **R-T Rec Time**, set **Record Interval** as needed, press the **Record** button on the front panel to start the recording. Press the button again to stop recording or when R-T Rec time ends, the monitor stops recording automatically. The runtime for each wave is 8 seconds. The record Interval can be set as: **Off**, **10 min**, **20 min**, **30 min**, **40 min**, **50 min**, **1 h**, **2 h**, **3 h**, **4 h**.
Trend graph recording	Select **Menu > Review > Trend Graph**, click **Record** to start recording.
Trend table recording	Select **Menu > Review > Trend Table**, click **Record** to start recording.
NIBP review recording	Select **Menu > Review > NIBP Review**, click **Record** to start recording.
Arrhythmia review recording	Select **Menu > Review > ARR Review**, select one arrhythmia alarm and click **Record** to start recording.
Alarm review recording	Select **Menu > Review > Alarm Review**, select one alarm and click **Record** to start recording.
Drug calculation titration recording	Select **Menu > Common Function > Calculation > Drug Dose > Titration**, click **Record** to start recording.
Hemodynamic Calculation result recording	Select **Menu > Common Function > Calculation > Hemodynamics**, click **Record** to start recording.
Oxygenation Calculation result recording	Select **Menu > Common Function > Calculation > Oxygenation**, click **Record** to start recording.
Ventilation Calculation result recording	Select **Menu > Common Function Calculation > Ventilation**, click **Record** to start recording.
Renal Function Calculation result recording	Select **Menu > Common Function > Calculation > Renal Function**, click **Record** to start recording.
12-lead diagnosis recording	Select **ECG Setup > 12-L Review**, click **Record** to start recording.

Recording Type	Description/ Procedure
C.O. measurement recording	Select **C.O. Option** > **C.O. Measure**, click **Record** to start recording.
Frozen waveform recording	In the **Freeze** window, click **Record** to start recording.

To manually stop recording, click **Record** again in the related windows.

The recorder will stop recording in the following situations:

● The recording task is finished.

● No paper in the recorder.

● Malfunction stops the recorder from running properly.

NOTE:

You can also use the button ⌇ on the front panel to manually start or stop recording.

22.3 Recorder Operations and Status Messages

22.3.1 Record Paper Requirement

Only standard thermosensitive record paper can be used: otherwise the recorder may not function, the recording quality may be poor, and the thermosensitive printhead may be damaged.

22.3.2 Proper Operation

■ When the recorder is working, the record paper goes out steadily. Do not pull the paper outward with force: otherwise the recorder may be damaged.

■ Do not operate the recorder without record paper.

22.3.3 Paper Out

When the **Recorder Out OF Paper** alarm is displayed, the recorder cannot start. Please insert record paper properly.

22.3.4 Replacing Paper

1. Pull outwards the upper arc part of the recorder casing to release the casing, shown in the following figure.

2.   Insert a new roll of paper into the paper cassette, printing side facing upwards.

3.   Ensure proper position and tidy margin.

4.   Pull about 2 cm of the paper out, and close the recorder casing.

NOTE:

Be careful when inserting papers. Avoid damaging the thermo-sensitive print head. Unless when inserting papers or shooting troubles, do not leave the recorder catch open.

22.3.5 Removing Paper Jam

When the recorder functions or sounds improperly, you should open the recorder casing to check for a paper jam. Remove the paper jam in the following way:

■   Cut the record paper from the feeding edge.

■   Open the recorder casing.

■   Re-insert the paper.

NOTE:

1   If the monitor is not installed with a recorder, it will indicate **RECORDER SETUP NEEDED** after pressing the **Record** button.

2   Do not touch the thermo-sensitive print head when performing continuous recording.

Chapter 23 Printing Patient Reports

Patient reports can be printed out by an HP series laser printer connected with the monitor.

NOTE:

Use the printer HP Laser Jet P2055dn which is tested to be compatible with the monitor.

23.1 Printer Settings

You can configure the printer settings on the monitor before printing out patient reports. Click the

shortcut key   or select **Menu** > **System Setup** > **Printer Setup**, and you can

● Assign a locally networked printer by selecting it from the **Printer** list.

● Search all available printers networked with the monitor by clicking **Search Printer**.

● Enable or disable double side printing by setting **DoubleSide Print** to **On** or **Off**.

The reports will be printed out on A4 paper and with single side by default.

NOTE:

1   You need to search all available printers on the local network for the first time you use a networked printer.

2   Make sure the IP of the printer and the IP of the monitor share the same network segment.

3   Do not click **Search Printer** during printing patient reports, or the printer might stop the current print job.

4   When a printer simultaneously received print jobs from several networked monitors, a print job conflict may occur. Check the use status of the monitors and the printers on the same network prior to use and avoid print job conflicts.

5   Make sure there is no lack of paper before printing patient reports, or the alarm **Printer Unavailable** will be triggered.

23.2 Starting and Stopping Report Printing

You can print out ten types of patient reports following the procedure below:

Report Type	Procedure
Trend graph report	In the **Trend Graph** window, click **Print** to start printing.
Trend table report	In the **Trend Table** window, click **Print** to start printing.
Alarm waveform report	In the **Alarm Review** window, click **Print** to start printing.
NIBP review report	In the **NIBP Review** window, click **Print** to start printing.
Arrhythmia review report	In the **ARR Review** window, click **Print** to start printing.

Report Type	Procedure
12-lead diagnosis report	In the **Diagnosis Review** window, click **Print** to start printing.
12-lead diagnosis waveform report	In the **12-Lead Diagnosis Waveform Review** window, click **Print** to start printing.
Drug calculation titration report	In the **Titration** window, click **Print** to start printing.
Oxygenation calculation report	In the **Oxygenation** window, click **Print** to start printing.
Ventilation calculation report	In the **Ventilation** window, click **Print** to start printing.
Renal function calculation report	In the **Renal Function** window, click **Print** to start printing.
C.O. measurement report	In the **C.O. Measure** window, click **Print** to start printing.
Hemodynamics report	In the **Hemodynamics** window, click **Print** to start printing.

To stop the current print job, click **Stop Printing** in the windows mentioned above.

NOTE:

You can only start one print job at a time. Before starting a new print job, you have to stop the current print job or wait until the current print job is completed.

Chapter 24 Other Functions

24.1 Nurse Call

The monitor provides dedicated nurse call port which is connected to nurse call system through the nurse call cable to perform the nurse call function. You should activate the function following the steps below:

1. Select **Menu** > **Maintenance** > **User Maintain**, and input the password **ABC**;

2. Select **Other Setups** > **Aux Output**;

3. Choose **On** in the **Nurse Call** list.

24.2 Analog Output and Defibrillator Synchronization

The monitor provides analog output signals to accessory equipment. Also, if a defibrillator is connected to the monitor, a defibrillator synchronization pulse can be output. You should activate the function following the steps below:

1. Select **Menu** > **Maintenance** > **User Maintain**, and input the password **ABC**;

2. Select **Other Setups** > **Aux Output**;

3. Choose **Analog Output** or **Defibrillation** in the **Aux Output** list.

24.3 Wi-Fi

Wi-Fi modules are optional to be configured in the monitors. And you should configure the settings on the monitor following the steps below before connecting the monitor to a wireless network:

1. Select **Menu** > **Maintenance** > **User Maintain**, and input the password **ABC**.

2. In the **User Maintain** menu, select **Network Maintain**.

3. In the **Network Maintain** menu, select **Wi-Fi** from the **Network Type** list. And click **Config** to open the **Wi-Fi Setup** window. The available networks will be listed in this window.

4. Choose a network from the window. You will be prompted to enter the password of that network if a password is required.

If the monitor is successfully connected to the selected network, it will be indicated by the message **Connected**, and the local IP address of the monitor will be displayed in the **Wi-Fi Setup** window. Also, a symbol indicating the networking state will be displayed on the lower portion of the main screen. The meanings of the networking state symbols are explained below:

Wi-Fi signal intensity: Level 4

Wi-Fi signal intensity: Level 3

Wi-Fi signal intensity: Level 2

Wi-Fi signal intensity: Level 1

NOTE:

1 Be aware that some network-based functions may be limited for monitors on wireless networks in comparison with those on wired networks.

2 The obstacle may interfere with data transmission and even cause data loss.

3 To make the change of the Bed No. effective when the monitor has been connected to a wireless network, you need to disconnect the wireless connection and then connect it again or reboot the monitor.

4 If the monitor fails to connect to any wireless network or no available wireless network is in the Wireless Setup window, switch the Network Type from Wireless to Wired and then to Wireless again. Then retry to connect to a wireless network.

5 Use the wireless device recommended by DIXION, otherwise some exceptional situations such as frequent network disconnection may occur on the monitor.

6 The wireless driver is compatible with channels 1-11 only.

24.4 Storing Data in the Storage Device

24.4.1 Data Stored in the Storage Device

A single piece of patient data maximally contains the following information:

Patient information	MRN, name, date of birth, date of admission, gender, type, height, weight, blood type, pace, doctor, bed No., department
Trend graph and trend table	240 hours
NIBP measurement review	1200 sets
Alarm review	200 sets
Arrhythmia event	200 sets
12-lead diagnosis review	50 sets
Waveforms	3-lead/5-lead:48 hours 12-lead: 35 hours

When the single patient data reach the maximum, you can choose to **Keep storing** or **Stop storing** by selecting **Menu** > **Common Function** > **Data Store** > **if one patient data full**.

If you choose **Keep storing**, as soon as the single patient data is full, the earliest data will be replaced by the latest one.

If you choose **Stop storing**, the monitor will stop data storing and the latest data cannot be stored when the single patient data reach the maximum. For instance, if all the patient data (such as the trend graph, trend table, NIBP measurements, arrhythmia event, alarm event and 12-lead diagnosis) except waveforms reach the maximum, the monitor will stop storing, while only the waveforms keep storing until they are full.

NOTE:

When store time for single patient data reaches 240 hours, the monitor will create a new folder for continuous data store.

24.4.2 Activating/ Deactivating Data Storing

To activate/ deactivate the data storing function, select **Menu** > **Maintenance** > **User Maintain** > **Other Setups**, and set **Data Store** to **On** or **Off**.

The monitor will stop storing data in the storage device under the following circumstances:

● No storage devices are selected.

● There is no enough space in the storage device for storing data.

● The removable device is read-only.

● The data storing function is deactivated.

● The monitor is switched off.

● The power supply is off.

24.4.3 Selecting a Storage Device

To configure the storage device, select **Menu** > **Common Function** > **Data Store** > **Storage Medium**, and choose the storage medium from the pop-up list as desired. **Internal Storage Device** and **Removable Device** can be selected.

When you choose **Internal Storage Device** as the storage medium, if configured, the storage device name will automatically become **Internal Storage Device**. You may plug several removable devices into the monitor at the same time, but only one is operative. You can select a removable device as a working one among the plugging devices by selecting **Menu** > **Common Function** > **Data Store** > **Storage Device** and choosing the device name from the list. By default, the first plugged removable device is the working one.

After you configure the appropriate storage device, click exit. If the storage device is successfully starting data storing, the monitor will be indicated by the symbol 🖫. If there is no enough space in storage device, or the storage device is read-only/damaged, the symbol 🖫 will be displayed.

CAUTION

1   Not all the removable devices are compatible with the monitor, Use the removable devices recommended by DIXION.

CAUTION

2   Do not set the read-only switch on the removable device to on when the removable device is inserted in the monitor.

24.4.4 Reviewing Data Stored in the Storage Device

To review data stored in the storage device, select **Menu** > **Review** > **History Patient**. You can choose to review the storage device as desired from the pop-up list. Choose a patient from the list to review the data including patient information, trend graph, trend table, NIBP measurements, arrhythmia event, alarm event, 12-lead diagnosis and waveform.

24.4.5 Deleting Data Stored in the Storage Device

To delete data of one patient, choose the patient from the list after selecting **Menu** > **Review** > **History Patient**, and then click **Delete data** on the **Review** menu. Further confirmation of deletion is required.

To delete data of all patients, select **Menu** > **Review** > **History Patient** and click **Delete all data** on the **History Patient Review** menu. Further confirmation is required.

24.4.6 Exporting Data Stored in the Internal Storage Device

To export data of one patient from the internal storage device to the removable device, choose the patient from the list after selecting **Menu**> **Review**> **History Patient**, and then click **Export Current Data** on the **Review** menu.

To export data of all patients, select **Menu**> **Review**> **History Patient** and click **Export all data** on the **History Patient Review** menu.

24.4.7 Formatting the Internal Storage Device

To format the internal storage device, select **Menu**> **Maintenance**> **User Maintain** > **Other Setups** > **Format internal storage device**. Further confirmation is required.

NOTE:

1   As soon as the internal storage device is formatted, all the data will be cleared.

2   You have no need to restart the monitor after formatting is successful. The internal storage device can be identified and loaded automatically.

3   If formatting is failed, try again. Restart the monitor and retry the formatting if formatting is failed repeatedly.

24.4.8 Ejecting a Removable Device

Before unplugging a removable device from the monitor, you need to select **Menu** > **Removable Device** and click **Eject** to uninstall the removable device. In this menu, you can also check the

remaining capacity of the storage device.

<div align="center"><u>CAUTION</u></div>

Do not remove the removable device without ejecting it during data storing, or the removable device might be damaged.

24.5 MEWS*

*Not available in USA.
You can use Modified Early Warning System to get an early warning score based on measurement value or input value of each vital sign. Depending on the score calculated, an action list with appropriate recommendations is displayed.

24.5.1 MEWS Score Interface

There are three methods as following to enter into MEWS score system interface:

1. Click shortcut icon [MEWS] to enter into MEWS interface.

2. In **Menu** > **Common Function**, click **MEWS** to enter into MEWS interface.

3. Click MEWS parameter area in main interface to enter into MEWS interface.

24.5.2 MEWS Score Criteria

In MEWS interface, select **Criteria** to check score criteria as following:

Value							
	3	2	1	0	1	2	3
HR(bmp)		≤40	41~50	51~100	101~110	111~129	≥130
SYS(mmhg)	≤70	71~80	81~100	101~109		≥200	
RESP(rpm)		<9		9~14	15~20	21~29	≥30
TEMP(℃)		<35.0		35.0~38.4		≥38.5	
Consciousness				A	V	P	U
Age				<50	50~70		>70

The relationship between consciousness level and its display result is as below:

Consciousness	**Displayed Result**
Sober	A
Responsive to Voice	V
Responsive to Pain	P
Unresponsive	U

24.5.3 MEWS Score Method

MEWS includes two methods: MEWS Score Calculator and Auto MEWS Score.

1. **MEWS Score Calculator**. If you choose MEWS Score Calculator, it is required to manually input **HR/PR**, **TEMP**, **RR**, **SYS**, **Age**, **Consciousness**, and then click **Start to Score**, the monitor will calculate and then display score result.

NOTE:

If any of above information is not completely input, the monitor will prompt information: **Incomplete parameter input, unable to score**.

2. **Auto MEWS Score**. If you choose Auto MEWS, it is required to manually input **Age** and **Consciousness**. After clicking **Start to Score**, the monitor will display MEWS result that will be refreshed with the same interval as NIBP measurements. Clicking **Stop to Score** could exit MEWS score.

24.5.4 MEWS Score Result

MEWS results include MEWS, time and severity level. The relation for value and severity level is as following:

MEWS	Severity Level	Color	Symbol
MEWS<5	Non-urgent	Green	3
MEWS=5	Observing	Yellow	5
5<MEWS≤9	Warning	Orange	7
MEWS>9	Critical	Red	10

24.5.5 MEWS Trend Table

Trend table provides the monitored patient's MEWS scores during a period of time; it includes score time, score parameters and value, MEWS score. To check the trend table, click **Trend Table** button in **MEWS** interface.

NOTE:

Trend table is cleared after admitting new patients.

Chapter 25 Using Battery

This monitor can run on battery power, which ensures its uninterrupted operation even when AC power supply is interrupted. The battery recharges whenever the monitor is connected to the AC power source. During monitoring, if the AC power is interrupted, the monitor will take power from the internal battery. If the monitor is powered by battery, the monitor will switch off automatically before the battery is completely depleted.

25.1 Battery Safety Information

WARNING

1   Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.

2   The service life of the battery depends on the service frequency and time. The service life of the battery is about three years if the battery is well maintained and stored. The service life of the battery may shorten if it is used inappropriately.

3   Periodic checks on the battery performance are required. Change the battery if necessary.

4   Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the battery together with metal objects, which can result in short circuits.

5   Do not unplug the battery when monitoring.

6   Do not heat or throw the battery into a fire.

7   Do not use, leave the battery close to fire or other places where temperature may be above 60°C.

8   Do not immerse, throw, or wet the battery in water/seawater.

9   Do not destroy the battery: do not pierce the battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.

10 Use the battery only in the monitor. Do not solder the leading wire and the battery terminal directly.

11 If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately. If liquid leaks of the battery splash onto your skin or clothes, wash well with fresh water immediately.

12 Keep away from fire immediately when leakage or foul odor is detected.

13 Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.

14 Do not use a battery with serious scratch or deformation.

WARNING

15 Use the battery with similar performance, which can extend the service life of the battery.

16 When the monitor is running on battery power, do not replace the battery during monitoring patients; or the monitor will be powered off, which may result in patient injury.

17 Do not place battery in the monitor with the (+) and (-) in the wrong way.

25.2 Battery Power Indicator

The indicator labeled Battery on the front panel of the monitor illuminates in green when the monitor is battery powered and illuminates in yellow when battery is being charged. The indicator is not illuminated when the monitor is not powered or when AC power is applied.

25.3 Battery Status on the Main Screen

Battery status symbols show the status of each battery detected and the combined battery power remaining.

Remaining battery power: 100%.

Remaining battery power: 75%

Remaining battery power: 50%

Remaining battery power: 25%

Batteries are almost depleted and need to recharge immediately.

No battery is installed.

25.4 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as recommended here can help to slow down this process.

1.   Disconnect the patient from the monitor and stop all monitoring and measurement.

2.   Switch the monitor power on and charge the battery for more than 6 hours continuously.

3.   Disconnect monitor from mains power and let the monitor run until there is no battery power left and the monitor shuts off.

4. The running time of the battery reflects the battery performance.

If the running time is obviously less than the specified time in the specification, please change the battery or contact the service personnel.

25.5 Replacing the Battery

To install or replace the battery, please follow the procedure:
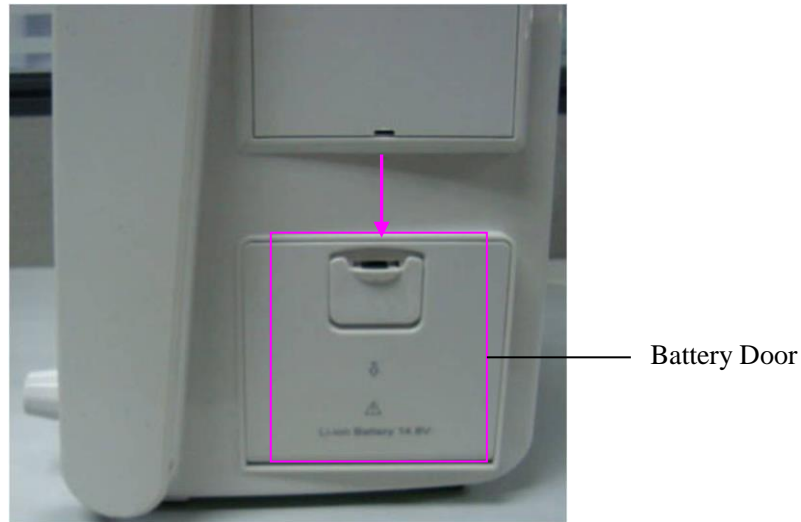
Battery Door

1. Pull the battery door according to indication on it to open it.

2. Pull the plastic retainer until the battery can be removed.

3. Insert the new battery into the battery compartment.

4. Pull the metal retainer downward to fix the battery and close the battery door.

25.6 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

WARNING
Do not disassemble batteries, put them into fire or cause them to short circuit. They may ignite, explode or leak, causing personal injury.

25.7 Maintaining the Battery

Batteries should be conditioned regularly to maintain their useful life.

Remove the batteries from the monitor if they are not used for a longer period of time. And recharge the batteries at a minimum of every 6 months when they are stored.

Discharge the battery completely once every month.

Chapter 26 Care and Cleaning

Use only the DIXION-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

DIXION Instruments has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

26.1 General Points

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

● Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.

● Always dilute according to the manufacturer's instructions.

● Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.

● Do not pour liquid onto the system.

● Do not allow liquid to enter the case.

● Never use abrasive material (such as steel wool or silver polish).

● Inspect the monitor and reusable accessories after they are cleaned and disinfected.

CAUTION

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or DIXION service engineer.

26.2 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

● Mild near neutral detergent

● Ethanol (75%)

● Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

26.2.1 Cleaning the Monitor

WARNING

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

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.

2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain.

3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

4. Dry the monitor in a ventilated and cool place.

26.2.2 Cleaning the Reusable Accessories

26.2.2.1 Cleaning the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

3. Wipe off residual moisture with a dry cloth.

4. Leave the cable assembly to air dry.

26.2.2.2 Cleaning the Blood Pressure Cuff

Cleaning the Cuff:

1. Take out the air bladder before cleaning.

2. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution until no visible contaminants remain.

3. Rinse the cuff and after cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

4. Wipe off residual moisture with a dry cloth.

5. Air dry the cuff thoroughly after cleaning.

Replacing the Air Bladder:

After cleaning, replace the air bladder into the cuff following the steps below:

1. Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.

2.   Thread the hose from within the cuff and out through the small hole at the top of the cuff.

3.   Adjust the bladder until it is in position.

26.2.2.3 Cleaning the SpO₂ Sensor

1.   Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2.   Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution until no visible contaminants remain.

3.   After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

4.   Wipe off residual moisture with a dry cloth.

5.   Leave the sensor to air dry.

26.2.2.4 Cleaning the IBP/C.O. Cables

1.   Wipe the cables with a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2.   After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

3.   Wipe off residual moisture with a dry cloth.

4.   Leave the cables to air dry.

26.2.2.5 Cleaning the TEMP Sensor/Quick TEMP Probe

1.   Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2.   After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

3.   Wipe off residual moisture with a dry cloth.

4.   Leave the sensor/probe to air dry.

26.3 Disinfection

For devices or accessories that have been in contact mucosal surface, High Level disinfection must occur, for all other accessories, low level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected. The validated disinfectants for cleaning the monitor and reusable accessories are:

●   Ethanol (75%)

●   Isopropanol (70%)

●   Cidex OPA (High level disinfection of intracavitary temperature probe only)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

The monitor and reusable accessories shall be disinfected to avoid patient cross infection.

26.3.1 Disinfecting the Monitor

Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

To disinfect the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.

2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.

3. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.

4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.

5. Dry the monitor for at least 30 minutes in a ventilated and cool place.

26.3.2 Disinfecting the Reusable Accessories

26.3.2.1 Disinfecting the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution.

2. Wipe off the disinfectant solution with a dry cloth after disinfection.

3. Leave the cable assembly to air dry for at least 30 minutes.

26.3.2.2 Disinfecting the Blood Pressure Cuff

Disinfecting the Cuff:

1. Take out the air bladder before disinfection.

2. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.

3. Leave the cuff and air bladder to air dry for at least 30 minutes.

Replacing the Air Bladder:

After disinfection, replace the air bladder into the cuff. Refer to Section *26.2.2.2* for more information.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

26.3.2.3 Disinfecting the SpO$_2$ Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.

2. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.

3. Wipe off the disinfection solution with a dry cloth after disinfection.

4. Leave the sensor to air dry for at least 30 minutes.

26.3.2.4 Disinfecting the IBP/C.O. Cables

1. Wipe the cables with a soft cloth dampened with the disinfectant solution.

2. Wipe off the disinfectant solution with a dry cloth after disinfection.

3. Leave the cables to air dry for at least 30 minutes.

26.3.2.5 Disinfecting the TEMP sensor

The intracavitary TEMP sensors should be reprocessed by high-level disinfection before and after use on each new patient. Cidex OPA is the validated agent for high level disinfection. Refer to the instructions of the disinfectant for the methods of disinfection. High level disinfection has been validated with a 12 minute soak. Rinse and dry according to the labeled instructions of Cidex OPA. Do not dampen the sensor connector.

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

1. Wipe the patient contact area with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).

2. Wipe off the disinfectant solution with a dry cloth after disinfection.

3. Leave the sensor to air dry.

26.4 Cleaning and Disinfecting Other Accessories

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for the methods of cleaning and disinfecting the monitor.

Chapter 27 Maintenance

WARNING

1   Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

2   If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.

27.1 Inspecting

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

● If the environment condition and power supply meet requirement.

● If the power supply cord has damage and insulativity meets requirement.

● If the device and accessories have damage.

● Specified accessories.

● If the alarm system can work properly.

● If the recorder can work properly and the paper meets the requirement.

● Battery performance

● If all monitoring functions are in good conditions.

● If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please don't use the monitor and contact local Customer Service Center.

27.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local regulations. The following tasks are for DIXION-qualified service professionals only. Contact an DIXION-qualified service provider if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	Frequency
Safety checks. Selected tests on the basis of IEC60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped.
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

Chapter 28 Warranty and Service

28.1 Warranty

DIXION warrants that DIXION's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) damage caused by mishandling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by DIXION.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, DIXION will, at its discretion, repair or replace the defective part(s) free of charge. DIXION will not provide a substitute product for use when the defective product is being repaired.

28.2 Contact information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor or

DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

Couvenstraße 6, 40211, Dusseldorf, Germany
Tel: +4921138838868, Fax: +4921138838697

Chapter 29 Accessories

You can order accessories from DIXION supplies or consult your local DIXION representative for details.

WARNING

1. Never reuse disposable transducers, sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard.

2. Use only DIXION-approved accessories. Using non-DIXION-approved accessories may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by DIXION with patient monitors by other manufacturers.

3. IBP and C.O. sterilized accessories are already sterilized, refer to the package labeling for detailed method. Do not use a sterilized accessory if its packaging is damaged.

NOTE:

Transducers and sensors have a limited shelf life. Refer to the package labeling.

The following cables may not all be available in all countries. Please check availability with your local DIXION supplier.

29.1 ECG Accessories

Part Number	Accessories
01.57.471381	3-lead, 6-pin, Defib, IEC, Clip
01.57.471382	3-lead, 6-pin, Defib, AHA, Clip
01.57.471383	3-lead, 6-pin, Defib, IEC, Snap
01.57.471384	3-lead, 6-pin, Defib, AHA, Snap
01.57.471389	3-lead, 6-pin, ESU, IEC, Clip
01.57.471390	3-lead, 6-pin, ESU, AHA, Clip
01.57.471391	3-lead, 6-pin, ESU, IEC, Snap
01.57.471392	3-lead, 6-pin, ESU, AHA, Snap
01.57.471380	3-lead, 12-pin, Defib, AHA, Snap
01.57.471388	3-lead, 12-pin, ESU, AHA, Snap

Part Number	Accessories
01.57.471378	3-lead, 12-pin, Defib, AHA, Clip
01.57.471386	3-lead, 12-pin, ESU, AHA, Clip
01.57.471379	3-lead, 12-pin, Defib, IEC, Snap
01.57.471387	3-lead, 12-pin, ESU, IEC, Snap
01.57.471377	3-lead, 12-pin, Defib, IEC, Clip
01.57.471385	3-lead, 12-pin, ESU, IEC, Clip
01.57.471230	5-lead, 6-pin, ESU, Adult/pediatric
01.57.471231	5-lead, 6-pin, ESU, Adult/pediatric, Extended
01.57.471232	5-lead, 6-pin, Defib, Adult/pediatric
01.57.471233	5-lead, 6-pin, Defib, Adult/pediatric, Extended
01.57.471226	5-lead, 12-pin, ESU, Adult/pediatric
01.57.471227	5-lead, 12-pin, ESU, Adult/pediatric, Extended
01.57.471228	5-lead, 12-pin, Defib, Adult/pediatric
01.57.471229	5-lead, 12-pin, Defib, Adult/pediatric, Extended
01.13.036620	5-lead, Clip, AHA, Adult/pediatric, Extended
01.13.036621	5-lead, Clip, AHA, Adult/pediatric
01.13.036622	5-lead, Snap, AHA, Adult/pediatric, Extended
01.13.036623	5-lead, Snap, AHA, Adult/pediatric
01.13.036624	5-lead, Clip, IEC, Adult/pediatric, Extended
01.13.036625	5-lead, Clip, IEC, Adult/pediatric
01.13.036626	5-lead, Snap, IEC, Adult/pediatric, Extended
01.13.036627	5-lead, Snap, IEC, Adult/pediatric
01.57.040203	12-lead, Snap, IEC, Adult/pediatric
01.57.471163	12-lead, Clip, IEC, Adult/pediatric
01.57.109101	12-lead, Snap, AHA, Adult/pediatric

Part Number	Accessories
01.57.471169	12-lead, Clip, AHA, Adult/pediatric
01.57.471072	12-lead, 12-pin, Defib, AHA, Adult/pediatric
01.57.471168	12-lead, 12-pin, Defib, IEC, Adult/pediatric
01.57.471461	3-lead, Clip, IEC, 1.0m, Reusable
01.57.471462	3-lead, Snap, IEC, 1.0m, Reusable
01.57.471463	3-lead, Clip, AHA, 1.0m, Reusable
01.57.471464	3-lead, Snap, AHA, 1.0m, Reusable
01.57.471465	5-lead, 12-pin, Defib, Clip, IEC, 3.4m, Reusable
01.57.471466	5-lead, 12-pin, Defib, Clip, AHA, 3.4m, Reusable
01.57.471467	5-lead, 12-pin, Defib, Snap, IEC, 3.4m, Reusable
01.57.471468	5-lead, 12-pin, Defib, Snap, AHA, 3.4m, Reusable
01.57.471469	5-Lead, 6-pin, Defib, Clip, IEC, 3.4m, Reusable
01.57.471470	5-lead, 6-pin, Defib, Clip, AHA, 3.4m, Reusable
01.57.471471	5-Lead, 6-pin, Defib, Snap, IEC, 3.4m, Reusable
01.57.471472	5-Lead, 6-pin, Defib, Snap, AHA, 3.4m, Reusable
01.57.471473	5-lead, 12-pin, ESU, Clip, IEC, 3.4m, Reusable
01.57.471474	5-Lead, 12-pin, ESU, Clip, AHA, 3.4m, Reusable
01.57.471475	5-Lead, 12-pin, ESU, Snap, IEC, 3.4m, Reusable
01.57.471476	5-lead, 12-pin, ESU, Snap, AHA, 3.4m, Reusable
01.57.471477	5-lead, 6-pin, ESU, Clip, IEC, 3.4m, Reusable
01.57.471478	5-lead, 6-pin, ESU, Clip, AHA, 3.4m, Reusable
01.57.471479	5-lead, 6-pin, ESU, Snap, IEC, 3.4m, Reusable
01.57.471480	5-lead, 6-pin, ESU, Snap, AHA, 3.4m, Reusable
01.57.471481	3-lead, 12-pin, ESU, AHA/IEC, 2.7m, Reusable
01.57.471482	3-lead, 12-pin, ESU, AHA/IEC, 5.0m, Reusable

Part Number	Accessories
01.57.471483	3-lead, 12-pin, Defib, AHA/IEC, 2.7m, Reusable
01.57.471484	3-lead, 12-pin, Defib, AHA/IEC, 5.0m, Reusable
01.57.471485	3-lead, 6-pin, ESU, AHA/IEC, 2.7m, Reusable
01.57.471486	3-lead, 6-pin, ESU, AHA/IEC, 5.0m, Reusable
01.57.471487	3-lead, 6-pin, Defib, AHA/IEC, 2.7m, Reusable
01.57.471488	3-lead, 6-pin, Defib, AHA/IEC, 5.0m, Reusable
01.57.471196	3-lead, Snap, AHA, Neonate
01.57.471198	3-lead, Clip, AHA, Neonate
01.57.471195	3-lead, Snap, IEC, Neonate
01.57.471197	3-lead, Clip, IEC, Neonate
01.57.471193	3-lead, 6-pin, Defib, Neonate
01.57.471194	3-lead, 12-pin, Defib, Neonate
01.57.471276	ECG CONDUCTIVE ADHESIVE ELECTRODES
01.57.471056	ECG Electrodes, adult, disposable, 30 pieces
01.57.471060	ECG Electrodes, adult, disposable, 100 pieces
01.57.471057	ECG Electrodes, child, neo disposable, 50 pieces

29.2 SpO$_2$ Accessories

Part Number	Accessories
For DIXION Module	
02.01.210119	SH1 Adult Reusable SpO$_2$ Sensor (Lemo)
02.01.210120	SH1 Adult Reusable SpO$_2$ Sensor (DB9)
02.01.210673	SH3 Neonate Warp SpO$_2$ Sensor
02.01.210122	SH4 Adult Silicone Soft-tip SpO$_2$ Sensor
02.01.210121	SH5 pediatric Silicone Soft-tip SpO$_2$ Sensor
01.13.210001	SpO$_2$ adapter cable, standard (Lemo to DB9)

Part Number	Accessories
02.57.225000	SpO$_2$ Sensor, Ear Clip, Adult/Pediatric, 1m, reusable
01.13.036336	SpO2 adapter cable, standard (Lemo to DB9) 4.0m
01.57.471235	SHD-A SpO$_2$ Sensor, adult, disposable
01.57.471236	SHD-P SpO$_2$ Sensor, pediatric, disposable
01.57.471237	SHD-I SpO$_2$ Sensor, Infant, disposable
01.57.471238	SHD-N SpO$_2$ Sensor, Neonate, disposable
For Nellcor Module	
01.15.30043	Nellcor Reusable Adult SpO$_2$ Sensor (DS-100A OxiMax)
01.15.40096	Nellcor Reusable Adult/Neonate SpO$_2$ Sensor (OXI-A/N OxiMax)
01.13.30131	Nellcor SpO$_2$ Extension cable (Compatible with Nellcor OXI-Max SpO$_2$ module and Nellcor sensor)
01.57.471069	Nellcor SpO$_2$ Extension cable (Compatible with Nellcor OXI-Max SpO$_2$ module and Nellcor sensor)

29.3 NIBP Accessories

Part Number	Accessories
For DIXION Module	
01.57.471326	NIBP Cuff, E5, Infant,10-15cm, reusable
01.57.471327	NIBP Cuff, E6, Small child,13-17cm, reusable
01.57.471328	NIBP Cuff, E7, Child,16-21.5cm, reusable
01.57.471329	NIBP Cuff, E8, Small adult,20.5-28cm, reusable
01.57.471330	NIBP Cuff, E9, Adult,27-35cm, reusable
01.57.471331	NIBP Cuff, E10, Large adult,34-43cm, reusable
01.57.471005	NIBP Hose, Quick Connect to Quick Connect
01.57.471323	NIBP Cuff, Neonate, 10cm-15cm, reusable
01.57.471324	NIBP Cuff, Neonate, 6cm-11cm, reusable
01.57.471157	NIBP Cuff, neonatal #1, 3-6cm,disposable

Part Number	Accessories
01.57.471158	NIBP Cuff, neonatal #2, 4-8cm,disposable
01.57.471159	NIBP Cuff, neonatal #3, 6-11cm,disposable
01.57.471160	NIBP Cuff, neonatal #4, 7-13cm,disposable
01.57.471161	NIBP Cuff, neonatal #5, 8-15cm,disposable
01.57.471303	NIBP Tube, 3m
01.57.471291	NIBP Tube, 3m
For Omron Module	
01.59.102099	OMRON NIBP Tube (3.5 m) /CUFF HOSE(NO.1) length3.5 m
01.57.471457	HXA-GCUFF-SSLA,REF 9520668-3,SS 12 cm -18 cm, reusable, Omron
01.57.471458	HXA-GCUFF-SLA,REF 9520669-1,S 17 cm -22 cm, reusable, Omron
01.57.471459	HXA-GCUFF-MLA,REF 9520670-5,M 22 cm -32 cm, reusable, Omron
01.57.471460	HXA-GCUFF-LLA,REF 9520671-3,L 32 cm-42 cm,reusable, Omron
01.57.471081	OMRON Neonatal disposable cuff/CUFF(NO.10) arm 3.5 cm -6cm,width 2.5 cm
01.57.471082	OMRON Neonatal disposable cuff/CUFF(NO.11) arm 5 cm-7.5 cm, width 3 cm
01.57.471083	OMRON Neonatal disposable cuff/CUFF(NO.12) arm7.5 cm -10.5 cm，width 4 cm
01.57.471084	OMRON Neonatal disposable cuff/CUFF(NO.13) arm8.5 cm -13 cm, width 5 cm
01.59.473003	OMRON NIBP Tube (3.5 m) /CUFF HOSE(NO.3) length3.5 m (Only compatible with Neonatal Disposable and NIBP Tube)
For SunTech Module	
01.57.471157	NIBP Cuff, neonatal #1, 3 cm -6 cm, disposable
01.57.471158	NIBP Cuff, neonatal #2, 4 cm -8 cm, disposable
01.57.471159	NIBP Cuff, neonatal #3, 6 cm -11cm,disposable
01.57.471160	NIBP Cuff, neonatal #4, 7 cm -13cm,disposable
01.57.471161	NIBP Cuff, neonatal #5, 8 cm -15cm,disposable

Part Number	Accessories
01.57.471494	APC Cuff, Child (Green), Range: 12 cm– 19 cm
01.57.471495	APC Cuff, Small Adult (Royal Blue), Range: 17 cm – 25 cm
01.57.471496	APC Cuff, Adult (Navy Blue), Range: 23 cm – 33 cm
01.57.471497	APC Cuff, Large Adult (Burgundy), Range: 31 cm – 40 cm
01.57.000974	OPC Cuff, Child, rang: 12 cm -19cm
01.57.000976	OPC Cuff, Small Adult, rang: 17 cm -25cm
01.57.000977	OPC Cuff, Adult, rang: 23 cm -33cm
01.57.000978	OPC Cuff, Large Adult, rang: 31 cm -40cm

29.4 TEMP Accessories

Part Number	Accessories
01.15.040257	Temperature Probe, Skin, Neonate/Infant, 6.3 mm plug (2.252K/25 ℃)
01.15.040258	Temperature Probe, rectal/oral, Neonate/Infant, 6.3 mm plug (2.252K/25 ℃)
01.15.040422	Neonatal/pediatric Skin Temperature Probe (10K)
01.15.040423	Neonatal/pediatric Rectal/Oral Temperature Probe (10K)
01.15.040185	Temperature Probe, Skin, adult, 6.3 mm plug (2.252K/25 ℃)
01.15.040184	Temperature Probe, rectal/oral, adult, 6.3 mm plug (2.252K/25 ℃)
01.15.040420	Skin Temperature Probe (10K)
01.15.040421	Rectal/Oral Temperature Probe (10K)

29.5 Quick Temp Accessories*

Part Number	Accessories
02.04.110140	Oral/Axillary Probe
02.04.110139	Rectal Probe
01.57.110159	Probe Covers

* Only applicable to STORM 5500.

* Not available in the U.S.A., Canada, UK and Germany

29.6 IBP Accessories

Part Number	Accessories
02.57.471280	ICP transfer cable
01.57.471014	Pressure transducer interface cable,BD
01.57.471013	Pressure transducer interface cable,EDWARD
01.57.471027	Pressure transducer interface cable,Hospira
01.57.471028	Pressure transducer interface cable,Utah
01.57.471835	IBP Pressure transducer interface cable/6pin, B.Braun type interface
01.57.40121	IBP Pressure transducer kit, BD, disposable(BD DT-4812)
01.57.471664	Disposable Pressure transducer PT161103, compatible with BD
01.57.471665	Disposable Pressure transducer PT151103, compatible with Edward
01.57.471666	Disposable Pressure transducer PT141103, compatible with Abbott

29.7 CO_2 Accessories

Part Number	Accessories
For DIXION Module	
02.01.210520	Dewatering Cup(Single Patient Use, Adult/Pediatric 10 ml)
01.57.471275	CO_2 Sampling Line with Male Luer Lock, 2.0 m
01.57.471282	All Purpose Sampling Cannula without filter (Non Sterile). Size: Adult
01.57.471283	All Purpose Sampling Cannula without filter (Non Sterile). Size: Infant
01.57.471284	All Purpose Sampling Cannula without filter (Non Sterile). Size: Neonate
01.57.471285	Duo Flow O_2+CO_2 Sampling Cannula (Non Sterile). Size: Adult
01.57.471286	Duo Flow O_2+CO_2 Sampling Cannula (Non Sterile). Size: Child
01.57.471287	Capnomask O_2+CO_2 Sampling Cannula (Non Sterile). Size: Adult
01.57.471288	Capnomask O_2+CO_2 Sampling Cannula (Non Sterile). Size: Child
For Respironics Module	
02.08.078137	Respironics EtCO$_2$ module/(Side-stream) 1022054
01.15.040143	Respironics CAPNOSTAT 5 EtCO$_2$ (Main-stream) Module 1015928
01.57.078139	Disposable CO_2 Nasal Cannula - Adult (Respironics 3468ADU-00)

Part Number	Accessories
01.57.078151	Adult/Pediatric Airway adapter kit with dehumidification tubing(Respironics 3473ADU-00)
01.57.078154	Disposable Sampling Line Kit with Dehumidification Tubing (Respironics 3475-00)
01.57.471019	Reusable Adult/Pediatric Airway Adapter (7007-01)
01.57.471020	Reusable Neonate/Infant Airway Adapter (7053-01)
01.59.078155	CO_2 Airway Adapter, Adult, disposable (6063-00)
01.59.078156	CO_2 Airway Adapter, Neonatal (infant/pediatric)(6312-00)
01.57.078142	Adult Nasal CO_2 with O_2 delivery sampling cannula(Respironics 3469ADU-00)
01.57.078143	Pediatric Nasal CO_2 with O_2 delivery sampling cannula(Respironics 3469PED-00)
01.57.078144	Infant Nasal CO_2 with O_2 delivery sampling cannula(Respironics 3469INF-00)
01.57.101019	Adult Nasal/Oral CO_2 sampling cannula(Respironics 3470ADU-00)
01.57.101020	Pediatric Nasal/Oral CO_2 sampling cannula(Respironics 3470PED-00)
01.57.101021	Adult Nasal/Oral CO_2 with O_2 delivery sampling cannula(Respironics 3471ADU-00)
01.12.031598	Adult/Pediatric Airway adapter kit(Respironics 3472ADU-00)
01.57.078140	Disposable CO_2 Nasal Cannula - Pediatric (Respironics 3468PED-00)
01.57.078141	Disposable CO_2 Nasal Cannula - Infant (Respironics 3468INF-00)
01.57.078152	Pediatric/Infant Airway adapter kit with dehumidification tubing(Respironics 3473INF-00)
01.57.078158	Pediatric mask/mainstream 9960PED-00
01.57.078159	Adult standard mask /mainstream 9960STD-00
01.57.078160	Adult large mask /mainstream 9960LGE-00
01.57.078161	Band/mainstream 8751-00
01.12.078162	Card Slot /Mainstream 6934-00

29.8 C.O. Accessories*

Part Number	Accessories
01.57.471663	C.O. cable, 3.0 m
01.13.40119	In-line Injection temperature probe (BD 684056-SP4042)

| 01.57.40120 | In-line Injection temperature probe housing (BD 680006-SP5045) |
| 01.57.100175 | Control Syringe (Medex MX387) |

*Not applicable to STORM 5500.

The Thermodilution Catheter is required when measuring C.O.. Swan-Ganz catheter (Type 131HF7 and 741HF7), manufactured by Edwards Lifesciences Corporation, has been validated to be compatible with the monitor. Refer to Edwards for more details.

29.9 AG Accessories*

Part Number	Accessories
For Masimo Module	
01.57.471043	Nomoline with Luer Lock connector,Box of 25,CAT.NO. 108210
01.57.471042	IRMA Airway Adapter, Adult/Pediatric, Box of 25, CAT.NO. 106220
01.57.471189	Nomoline Adapter
01.57.471190	Nomoline Airway Adapter Set
01.57.471191	Nomo Extension
01.57.471192	T-adapter
02.08.208005	ISA™ Sidestream Analyzers, ISA AX+, CAT.NO.800601 (CO_2, N_2O, 5AA, AAID)
02.08.208006	IRMA™ Mainstream Analyzers, IRMA AX+,CAT.NO.200601 (CO_2, N_2O, 5AA, AAID)
02.08.208007	ISA™ Sidestream Analyzers, ISAOR+, CAT.NO.800401 (CO_2, O_2,N_2O, 5AA, AAID)
01.13.113617	GAS Module Extension cable
For Dräger Minimodule (*not available in U.S.A.)	
01.57.471489	Water trap
01.57.471492	Sample line

* Masimo module is applicable to STORM 5800. Dräger Minimodule is only applicable to STORM 5800.

29.10 Other Accessories

Part Number	Accessories
01.57.471048	Assembly board for gas module
01.21.064142	Rechargeable Lithium-Ion Battery/TWSLB-002
01.21.064143	Rechargeable Lithium-Ion Battery/TWSLB-003
02.04.241047	EPRT-48mm recorder, Serial/parallel port

Part Number	Accessories
02.01.109592	Pole clamp, 1 set /package
02.01.109636	Pole clamp, 4 sets/package
01.57.78035	Recorder paper
01.18.052245	Netac USB flash disk (U208, 4G, USB2.0)
01.23.068023	Linear Barcode Scanner
02.04.241690	Patient monitor mounting arm assembly kit (Storm 5300)
02.04.241688	Patient monitor mounting arm assembly kit
02.04.241689	Patient monitor mounting arm assembly kit
83.60.360181	MT-207 Trolley
02.04.101976	Rolling Stand Basket (in the bottom)
83.60.101950	MT-206 Trolley
83.60.101952	MT-207 Trolley
01.13.037122	Power cable, length 1.8 m, American standard, medical grade
21.13.036384	Power cable, length 1.8 m, American standard
01.13.036638	Power cable, length 1.8 m, VDE
01.13.114214	Ground Cable
01.17.052452	SD Memory Card (8GB, Class4)

NOTE:
The part name may vary depending on context, but the part number is constant.

A Product Specification

NOTE:

The performance of the equipment with ☆ mark is determined to be essential performance.

A.1 Classification

Anti-electroshock type	Class I equipment and internal powered equipment
Anti-electroshock degree	ECG (RESP), TEMP, IBP, C.O., Quick Temp CF SpO$_2$, NIBP, CO$_2$, AG BF
Ingress Protection	IPX1
Disinfection/sterilization method	Refer to Chapter Care and Cleaning for details.
Working system	Continuous operation equipment
Compliant with Standards	IEC 60601-1: 2005+A1 :2012; IEC 60601-1-2: 2014; EN 60601-1: 2006+A1 :2013; EN 60601-1-2: 2007; IEC 60601-2-49: 2011

A.2 Physical Specifications

A.2.1 Size and Weight

Product	Size	Weight (standard configuration, without battery)
STORM 5500 8,4'	261 mm (W) × 215 mm (H) ×198 mm (D)	< 3.6 kg
STORM 5500 10,4'	303 mm (W) × 254 mm (H) ×161 mm (D)	< 3.8 kg
STORM 5500 12,1'	328 mm (W) × 285 mm (H) ×158 mm (D)	< 4.5 kg
STORM 5800	370 mm (W)× 320 mm (H) × 175 mm (D)	< 7 kg

A.2.2 Environment Specification

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Temperature		
Working	+0 °C to +40 °C(32 ℉~104 ℉)	
Transport and Storage	-20 °C to +55 °C(-4 ℉~131 ℉)	
Humidity		
Working	15%RH ~ 95%RH (non-condensing)	
Transport and Storage	15%RH ~ 95%RH (non-condensing)	
Altitude		
Working	86 kPa ~ 106 kPa	
Transport and Storage	70 kPa ~ 106 kPa	
Power Supply	100 V-240 V~,50 Hz/60 Hz	
	STORM 5500 8,4'	Current=1.0 A-0.5 A; Fuse: T3.15AH, 250VP
	STORM 5500 10,4', 12,1'	Current=1.4 A-0.7 A; Fuse: T3.15AH, 250VP
	STORM 5800	Current=1.4 A-0.7 A; Fuse: T3.15AH, 250VP

A.2.3 Display

Product	Display	Messages
STORM 5500	Display screen: 8.4, 10,4, 12,1 inch color TFT, supporting touch screen Resolution: 800×600	A maximum of 11 waveforms One power LED Two alarm LED One charge LED
STORM 5800	Display screen: 15 inch color TFT, supporting touch screen Resolution: 1024 × 768	A maximum of 13 waveforms One power LED Two alarm LED One charge LED

A.2.4 Battery Specification

Operating Time	STORM	2500 mAh	≥ 3.5 h

	5500	5000 mAh	≥ 7 h
	STORM 5800	One battery (5000 mAh)	≥ 6 h
		Two batteries (2*5000 mAh)	≥ 12 h
Condition	At 25±2 °C, with (a) new fully charged battery/batteries, DIXION module in use, continuous SpO$_2$ measurement and NIBP automatic measurement mode at interval of 15 minutes, ECG/TEMP module connected, recording at interval of 10 minutes, brightness set to "1".		
Charge Time	STORM 5500	2500 mAh	≤ 3.5 h, 100% charge ≤ 3.15 h, 90% charge
		5000 mAh	≤ 6.5 h, 100% charge ≤ 5.85 h, 90% charge
	STORM 5800	One battery (5000 mAh)	≤ 6.5 h, 100% charge ≤ 5.85 h, 90% charge
		Two batteries (2*5000 mAh)	≤ 13 h, 100% charge ≤ 11.7 h, 90% charge
Condition	Environment temperature: 25±2 °C. STORM 5500 is powered off.		

A.2.5 Recorder

Record Width	48 mm
Paper Speed	12.5 mm/s, 25 mm/s, 50 mm/s
Trace	3
Recording types	Continuous real-time recording 8 seconds real-time recording Time recording Alarm recording Trend graph recording Trend table recording NIBP review recording Arrhythmia review recording Alarm review recording Drug calculation titration recording Hemodynamic Calculation result recording 12-lead analysis recording

	C.O. measurement recording

A.2.6 Data Storage

Trend graph/trend table review	1 hour, at 1 Second Resolution by default
	120 hrs, at 1 min. Resolution by default
Alarm/Monitoring Event data	Up to 200 sets
NIBP Measurement Review	1200 sets
Arrhythmia events	Up to 200 sets
12-lead Diagnosis Review	Up to 50 sets

A.3 Wi-Fi

IEEE	802.11b/g/n
Frequency Band	2.4 GHz ISM band
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM
	802.11b with CCK and DSSS
Typical Transmit Power ($\pm$2 dBm)	17 dBm for 802.11b DSSS
	17 dBm for 802.11b CCK
	15 dBm for 802.11g/n OFDM

A.4 ECG

Complies with IEC 60601-2-25: 2011, IEC 60601-2-27: 2011.

Lead Mode	3-Lead: I, II, III
	5-Lead: I, II, III, aVR, aVL, aVF, V
	12-Lead: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Lead Naming Style	AHA, IEC
☆Display Sensitivity (Gain Selection)	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 gain
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s

Bandwidth (-3dB)	Diagnosis: 0.05 Hz to 150 Hz
	Monitor: 0.5 Hz to 40 Hz
	Surgery: 1 Hz to 20 Hz
☆CMRR (Common Mode Rejection Ratio)	Diagnosis: > 95 dB
	Monitor: > 105 dB
	Surgery: > 105 dB
Notch	In diagnosis, monitor and surgery modes: 50 Hz/60 Hz (Notch filter can be turned on or off manually)
☆ Differential Input Impedance	> 5 MΩ
☆Input Signal Range	±10 mV PP
☆ Accuracy of Signal Reproduction	An error of ≤ ±20 % of the nominal value of the output or ±100 μV, whichever is greater. The total error and frequency response comply with IEC 60601-2-27: 2011, Sect. 201.12.1.101.1.
☆ Electrode Offset Potential Tolerance	±800 mV
Auxiliary Current (Leads off detection)	Active electrode: < 100 nA
	Reference electrode: < 900 nA
☆ Recovery Time After Defibrillation	< 5 s (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)
Leakage Current of Patient	< 10 μA
Scale Signal	1 mV PP, accuracy is ±5%
☆System Noise	< 30 μVPP
☆Multichannel Crosstalk	≤ 5% of the input signal Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.5.
☆Frequency and Impulse Response	Frequency response: Input a 5 Hz, 1 mV sine wave signal, and the output signal amplitude remains within the range of 71 % to 110 % at 0.67 Hz and 40 Hz. Input a 1 Hz, 1.5 mV 200 ms triangular wave input signal, and the output shall be within 11.25 mm~15 mm. Impulse response: Displacement value: ≤ 0.1 mV Slope: ≤ 0.3 mV/s following the end of the pulse. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.8.

Sampling Frequency	1000 Hz
Sampling Channel Switch Time	< 80 μS
A/D Precision	24 Bits (Minimum resolution: 0.077uV/LSB)
☆ESU Protection	Cut mode: 300 W Coagulation mode: 100 W Restore time: ≤ 10 s
Electrosurgical Interference Suppression	Test according to ANSI/AAMI EC13:2002, Sect. 5.2.9.14. Complied with ANSI/AAMI EC13:2002, Sect. 4.2.9.14.
Minimum Input Slew Rate (Lead II)	> 2.5 V/s
☆Baseline Reset Time	< 3 s
Pace Pulse	
☆Pulse Indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to2.0 ms Ascending time: 10 μs to 100 μs
☆Pulse Rejection	Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs
Pace Pulse Detecting Lead: one among I, II, III, AVR, AVL, AVF, V1, V2, V3,V4, V5, V6	
Heart Rate	
HR Calculation	
☆Range	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm
☆Accuracy	±1% or 1 bpm, whichever is greater
Resolution	1 bpm
Sensitivity	≥ 300 μVPP

☆QRS Detection Range	The detection range has exceeded the requirement described in the standard: Width: 70 ms~120 ms for adult, 40 ms~120 ms for Pediatric/neonate. Amplitude: 0.5 mv~5 mv In adult mode, these two signals are not responded: 1. when QRS amplitude of 0.15 mV or less is applied; 2. when QRS duration of 10 ms and QRS amplitude of 1 mV or less is applied. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.15.
PVC	
Range	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min
Resolution	1 PVCs/min
ST value	
Range	-2.0 mV to +2.0 mV
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV
HR Averaging Method	
Method 1	Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.
Method 2	If each of three consecutive RR intervals is greater than 1200 ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	Adult: RR interval for 5 consecutive QRS complex $\leq$ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\leq$ 0.375 s.
Normal	Adult: 0.5 s < RR interval for 5 consecutive QRS complex < 1.5 s. Pediatric/neonatal: 0.375 s < RR interval for 5 consecutive QRS complex < 1 s.
Brady	Adult: RR interval for 5 consecutive QRS complex $\geq$ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\geq$ 1 s.

Range of Ventricular Rhythm			
Ventricular Tachycardia	The interval of 5 consecutive ventricular beats is less than 600 ms		
Ventricular Rhythm	The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms		
Ventricular Bradycardia	The interval of 5 consecutive ventricular beats is more than 1000 ms		
Maximum Start-up Alarm Time for Tachycardia			
Ventricular Tachycardia 1 mV 206 bpm	Gain 0.5: 10 s Gain 1.0: 10 s Gain 2.0: 10 s		
Ventricular Tachycardia 2 mV 195 bpm	Gain 0.5: 10 s Gain 1.0: 10 s Gain 2.0: 10 s		
Response Time of Heart Rate Meter to Change in HR	HR range: 80 bpm to 120 bpm Range : Within 11 s HR range: 80 bpm to 40 bpm Range : Within 11 s		
☆Tall T-wave Rejection	Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude		
Accuracy of Heart Rate Meter and Response to Irregular Rhythm	Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy: 80 bpm±1 bpm Slow alternating ventricular bigeminy: 60 bpm±1 bpm Rapid alternating ventricular bigeminy: 120 bpm±1 bpm Bidirectional systoles: 91 bpm±1 bpm		
Time to Alarm for Heart Rate alarm conditions	Asystole alarm: ≤ 10 s HR low alarm: ≤ 10 s HR high alarm: ≤ 10 s		
Arrhythmia analyses	ASYSTOLE	VFIB/VTAC	COUPLET
	VT>2	BIGEMINY	TRIGEMINY
	VENT	R on T	PVC
	TACHY	BRADY	MISSED BEATS
	IRR	VBRADY	PNC

	PNP	
12-Lead ECG Synchronization Analysis	Average parameters of heart beat	
	Heart rate (bpm)	
	Time limit of P wave (ms)	
	PR interval (ms)	
	QRS interval (ms)	
	QT/QTC (ms)	
	P-QRS-T AXIS	

A.5 RESP

Method	ImpDIXIONce between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is lead II.
Calculation Type	Manual, Automatic
Baseline ImpDIXIONce Range	200 Ω to 2500 Ω(with ECG cables of 1 KΩ resistance)
Measuring Sensitivity	Within the baseline impDIXIONce range: 0.3 Ω
Waveform Bandwidth	0.2 Hz to 2.5 Hz (-3 dB)
Respiration Excitation Waveform	Sinusoid, 45.6 kHz($\pm$ 10%), < 350 µA
☆RR Measuring Range	
☆Adult	0 rpm to120 rpm
☆Neo/Ped	0 rpm to150 rpm
Resolution	1 rpm
☆Accuracy	
☆Adult	6 rpm to 120 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
☆Neo/Ped	6 rpm to 150 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
☆Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s

☆Apnea Alarm Time Setup	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.

A.6 NIBP

Complies with IEC 80601-2-30: 2009.

DIXION Module

Technique	Oscillometry
Mode	Manual, Auto, Continuous
Measuring Interval in AUTO Mode (unit: minutes)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480
Continuous	5 min, interval is 5 s
Measuring Type	SYS, DIA, MAP, PR
☆Measuring Range	
☆Adult Mode	SYS: 40 mmHg to 270 mmHg DIA: 10 mmHg to 215 mmHg MAP: 20 mmHg to 235 mmHg
☆Pediatric Mode	SYS: 40 mmHg to 230 mmHg DIA: 10 mmHg to 180 mmHg MAP: 20 mmHg to 195 mmHg
☆Neonatal Mode	SYS: 40 mmHg to 135 mmHg DIA: 10 mmHg to 100 mmHg MAP: 20 mmHg to 110 mmHg
☆Alarm Type	SYS, DIA, MAP
☆ Cuff Pressure Measuring Range	0 mmHg to 300 mmHg
Pressure Resolution	1 mmHg
☆Maximum Mean Error	±5 mmHg
☆Maximum Standard Deviation	8 mmHg
Maximum Measuring Period	
Adult/Pediatric	120 s
Neonate	90 s
Typical Measuring Period	20 s to 35 s (depend on HR/motion disturbance)

Dual Independent Channel Overpressure Protection	
Adult	(297±3) mmHg
Pediatric	(245±3) mmHg
Neonatal	(147±3) mmHg
PR	
☆Measuring Range	40 bpm to 240 bpm
☆Accuracy	±3 bpm or 3.5%, whichever is greater
Pre-inflation Pressure	
Adult Mode	Default: 160 mmHg Range: 80/100/120/140/150/160/180/200/220/240 mmHg
Pediatric Mode	Default: 140 mmHg Range: 80/100/120/140/150/160/180/200 mmHg
Neonatal Mode	Default: 100 mmHg Range: 60/70/80/100/120 mmHg

Omron Module

Not applicable to STORM 5500.

Method	Oscillometric
Mode	Manual, Auto, Continuous
Measuring Interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90 min, 2/4/8 h
Continuous	5 min, interval is 5 s
☆PR Range	Adult/ Pediatric mode: 40 bpm to 200 bpm
	Neonatal mode: 40 bpm to 240 bpm
☆PR Accuracy	± 2 bpm or 2% of the readings
☆Measuring Type	SYS, DIA, MAP
☆Measuring Range	
☆Adult/ Pediatric Mode	SYS: 60 mmHg to 250 mmHg DIA: 40 mmHg to 200 mmHg MAP: 45 mmHg to 235 mmHg

☆Neonatal Mode	SYS: 40 mmHg to 120 mmHg
	DIA: 20 mmHg to 90 mmHg
	MAP: 30 mmHg to 100 mmHg
Alarm Type	SYS, DIA, MAP
Cuff pressure Measuring Range	0 mmHg to 300 mmHg
Pressure Resolution	1 mmHg

Measuring Accuracy				
☆ Maximum Mean Error	±5 mmHg			
☆ Maximum Standard Deviation	8 mmHg			
	Adult/Pediatric		Neonate	
	Normal Condition	Single Fault Condition	Normal Condition	Single fault Condition
Maximum Cuff Pressure	300 mmHg	330 mmHg	150 mmHg	165 mmHg
Maximum Measuring Period	Less than 160 s	Less than 180 s	Less than 80 s	Less than 90 s

Pre-inflation Pressure	
Adult/ Pediatric Mode	Default: 180 mmHg
	Range: 120/140/150/160/180/200/220/240/260/280 mmHg
Neonatal Mode	Default: 120 mmHg
	Range: 80/100/120/140 mmHg

Dual Independent Channel Overpressure Protection	
Adult/Pediatric	< 300 mmHg
Neonatal	< 150 mmHg

SunTech Module

Not applicable to STORM 5500.

Method	Oscillometric
Mode	Manual, Auto, Continuous
Measuring Interval in AUTO Mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/240

PR	
☆Measuring range	30 bpm to 220 bpm
☆Accuracy	±3 bpm or ±2%, whichever is greater
☆Measuring Type	SYS, DIA, MAP, PR
☆Measuring Range	
☆Adult Mode	SYS: 40 mmHg ~ 260 mmHg DIA: 20 mmHg ~ 200 mmHg MAP: 26 mmHg– 220 mmHg
☆Pediatric Mode	SYS: 40 mmHg– 230 mmHg DIA: 20 mmHg– 160 mmHg MAP: 26 mmHg– 183 mmHg
☆Neonatal Mode	SYS: 40 mmHg – 130 mmHg DIA: 20 mmHg– 100 mmHg MAP: 26 mmHg – 110 mmHg
☆Alarm Type	SYS, DIA, MAP
Pressure Resolution	1 mmHg
☆Maximum mean error	±5 mmHg
☆Maximum standard deviation	8 mmHg
Maximum measuring period	
Adult/Pediatric	130 s
Neonate	75 s
Overpressure protection	
Adult/Pediatric	< 300 mmHg
Neonate	< 150 mmHg
Pre-inflation Pressure	
Adult Mode	120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 240 mmHg, 260 mmHg, 280 mmHg Default: 160 mmHg
Pediatric Mode	80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 250 mmHg Default: 140 mmHg

Neonatal Mode	60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 120 mmHg, 140 mmHg Default: 90 mmHg

A.7 SpO$_2$

Complies with ISO 80601-2-61: 2011.

DIXION Module

Measuring Range	0% to 100%
Resolution	1%
☆Data Update Period	1 s
☆Accuracy	
☆Adult /Pediatric	±2% (70% to 100% SpO$_2$)
	Undefined (0% to 69% SpO$_2$)
☆Neonate	±3% (70% to 100% SpO$_2$)
	Undefined (0% to 69% SpO$_2$)
Pulse Rate	
Measuring Range	25 bpm to 300 bpm
☆ Adjustable Range of Alarm Limits	30 bpm to 300 bpm
Resolution	1 bpm
☆Accuracy	±2 bpm
Sensor	
Red Light	(660±3) nm
Infrared Light	(905±10) nm
Emitted Light Energy	< 15 mW
PI	
Measuring Range	0-10, invalid PI value is 0.
Resolution	1

Nellcor Module

Measuring Range	1% to 100%
Resolution	1%
☆Data Update Period	1 s

| ☆Accuracy | DS-100A, OXI-A/N(Adult): $\pm$ 3% (70% to 100% SpO_2) |
| | OXI-A/N(Neonate): $\pm$ 4% (70% to 100% SpO_2) |

Pulse Rate	
Measuring Range	20 bpm to 300 bpm
Resolution	1 bpm
☆Accuracy	$\pm$ 3 bpm (20 bpm to 250 bpm)
Sensor	Wave length: approximately 660 nm and 900 nm
	Emitted light energy: < 15 mW

NOTE:

The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A.8 TEMP

Complies with EN 12470-4: 2000+ A1: 2009 and ISO 80601-2-56: 2009.

Technique	Thermal resistance
Position	Skin, oral cavity, rectum
Measure Parameter	T1, T2, TD(the absolute value of T2 minus T1)
Channel	2
Sensor Type	YSI-10K and YSI-2.252K
Unit	°C, °F
Measuring Range	0 °C to 50 °C(32 ºF to 122 ºF)
Resolution	0.1 °C (0.1 ºF)
☆Accuracy[1]	$\pm$0.3 °C
Refresh Time	Every 1 s to 2 s
Temperature Calibration	At an interval of 5 to 10 minutes
Measuring Mode	Direct Mode
Transient Response Time	$\leq$ 30 s

Note 1: The accuracy consists of two parts, as following:

● Accuracy (not including sensor): $\pm$ 0.1 °C

● Sensor accuracy: $\leq$ $\pm$0.2 °C

A.9 Quick TEMP

Only applicable to STORM 5500.

Measuring Range	25 °C ~ 45 °C(monitoring mode)
	35.5 °C～42 °C (prediction mode)
Operating Temp	10 °C ~ 40 °C
Sensor Type	Oral/Axillary sensor, Rectal sensor
Resolution	0.1 °C
Accuracy[1]	±0.3 °C
Response time	< 60 s
Update time	1 s ~ 2 s
Warm-up time	Less than 10 seconds
Prediction time	Less than 30 seconds
Measuring Mode	Direct Mode/Adjusted Mode
Transient Response Time	≤ 30 s
Clinical Bias	(-0.2 to -0.4)°C
Limits of Agreement	0.49
Repeatability	0.14 °C

Note 1: The accuracy consists of two parts, as following:

● Accuracy (not including sensor): ± 0.1 °C (25 °C ~ 45 °C) (monitoring mode)

● Sensor accuracy: ≤ ±0.2 °C

NOTE:

The direct mode refers to monitor mode, while adjusted mode refers to predict mode.

A.10 IBP

Complies with IEC 60601-2-34: 2011.

Technique			Direct invasive measurement
Channel			STORM 5800: 4 channels
			STORM 5500: 2 channels
IBP Measure	☆Measuring Range	Art	(0 to +300) mmHg
		PA	(-6 to +120) mmHg

		CVP/RAP/LAP/ICP	(-10 to +40) mmHg
		P1/P2	(-50 to +300) mmHg
	Resolution		1 mmHg
	☆Accuracy (not including sensor)		± 2 % or ±1 mmHg, whichever is greater ICP: 0 mmHg to 40 mmHg: ± 2 % or ±1 mmHg, whichever is greater; -10 mmHg to 0 mmHg: undefined
PR Measure	☆Measuring Range		20 bpm to 300 bpm
	Resolution		1 bpm
	☆Accuracy		30 bpm to 300 bpm: ± 2 bpm or ± 2%,whichever is greater; 20 bpm to 29 bpm: undefined
Pressure Unit			kPa, mmHg, cmH$_2$O
Pressure sensor			
Sensitivity			5 μV/V/mmHg
ImpDIXIONce Range			300 Ω to 3000 Ω
Filter			DC~ 12.5 Hz; DC~ 40 Hz
Zero			Range: ±200 mmHg
Pressure Calibration Range	IBP (excluding ICP)		80 mmHg to 300 mmHg
	ICP		10 mmHg to 40 mmHg
Volume Displacement			4.5 x 10^{-4} in^3 / 100 mmHg

A.11 CO$_2$

Complies with ISO 80601-2-55: 2011.

DIXION Module

Intended Patient	Adult, pediatric, neonatal	
Measure Parameters	EtCO$_2$, FiCO$_2$, AwRR	
Unit	mmHg, %, kPa	
☆ Measuring Range	CO$_2$	0 mmHg to 150 mmHg (0 % to 20%)
	AwRR	2 rpm to 150 rpm

Resolution	EtCO$_2$	1 mmHg		
	FiCO$_2$	1 mmHg		
	AwRR	1 rpm		
☆Accuracy	EtCO$_2$	± 2 mmHg, 0 mmHg to 40 mmHg	Respiratory rate ≤ 60 rpm	Typical conditions: Ambient temperature: (25± 3) ℃ Barometric pressure: (760± 10) mmHg Balance gas: N$_2$ Sample gas flowrate: 100 ml/min
		± 5% of reading, 41 mmHg to 70 mmHg		
		± 8% of reading, 71 mmHg to 100 mmHg		
		± 10% of reading, 101 mmHg to 150 mmHg		
		±12% or ± 4 mmHg of reading, whichever is greater	Respiratory rate > 60 rpm	All conditions
	AwRR	± 1 rpm		
Drift of Measure Accuracy	Meets the requirements of the measure accuracy			
Sample Gas Flowrate	70 ml/min or 100 ml/min(default), accuracy: ±15 ml/min			
Warm-upTime	Display reading within 20 s; reach to the designed accuracy within 2 minutes.			
Rise Time	< 400 ms (water trap with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)			
Response Time	< 4 s (water trap with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)			
Work Mode	Standby, measure			
O$_2$ Compensation	Range: 0% to 100% Resolution: 1% Default: 16%			
N$_2$O Compensation	Range: 0% to 100% Resolution: 1% Default: 0%			

AG Compensation	Range: 0% to 20% Resolution: 0.1% Default: 0%
Humidity Compensation Method	ATPD(default), BTPS
Barometric Pressure Compensation	Automatic (The change of barometric pressure will not add additional errors to the measurement values.)
Zero Calibration	Support
Calibration	Support
☆Alarm	$EtCO_2$, $FiCO_2$, AwRR
☆ Apnea Alarm Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s, 60s; default value is 20 s.
Data Sample Rate	100 Hz
$EtCO_2$ Change[1]	AwRR > 80 rpm, $EtCO_2$ descending 8% AwRR > 120 rpm, $EtCO_2$ descending 10%

Note 1: Use a test device equivalent to EN ISO 80601-2-55 fig 201.101 to measure at 1:2 I/E ratio. Respiration rate accuracy is determined by frequency of device, and ET READING change refers to the nominal value.

Interfering Gas Effects:

Gas	Gas Level (%)	Quantitative Effect/Comments
Nitrous oxide	60	The interfering gas will have no effect on the measurement value if compensation of O_2, N_2O, anesthetic agents has been correctly set.
Halothane	4	
Enflurane	5	
Isoflurane	5	
Sevoflurane	5	
Desflurane	15	

Respironics Module

Applicable Patient Type	Adult, pediatric and neonatal patients
Technique	Infra-red Absorption Technique
Measure Parameters	$EtCO_2$, $FiCO_2$, AwRR
Unit	mmHg, %, Kpa

☆Measuring Range		
☆EtCO$_2$	0 mmHg to 150 mmHg	
☆FiCO$_2$	3 mmHg to 50 mmHg	
☆AwRR	0 rpm to 150 rpm (Mainstream) 2 rpm to 150 rpm (Sidestream)	
Resolution	EtCO$_2$	1 mmHg
	FiCO$_2$	1 mmHg
	AwRR	1 rpm
☆EtCO$_2$ Accuracy	± 2 mmHg, 0 mmHg to 40 mmHg	
	± 5 % of reading, 41 mmHg to 70 mmHg	
	± 8 % of reading, 71 mmHg to 100 mmHg	
	± 10 % of reading, 101 mmHg to 150 mmHg	
	± 12% of reading, RR is over 80 rpm (sidestream) There will be no degradation in performance due to Respiration Rate. (mainstream)	
☆AwRR Accuracy	± 1 rpm	
Operation Mode	Measure, standby	
Sample Gas Flowrate (sidestream)	(50 ±10) ml/min	
O$_2$ Compensation		
Range	0% to 100%	
Resolution	1%	
Default	16%	
Barometric Pressure Compensation	User setup	
Anesthetic Gas Compensation		
Range	0% to 20%	
Resolution	0.1%	
Default	0.0%	
Balance Gas Compensation	Room air, N$_2$O, helium	
Stability		

Short Term Drift	Drift over 4 hours < 0.8 mmHg
Long Term Drift	120 hours
Zero Calibration	Support
☆Alarm Type	$EtCO_2$, $FiCO_2$, AwRR
☆Apnea Alarm Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.
Data Sample Rate	100 Hz
CO_2 Rise Time/Response Time (mainstream)	Less than 60 ms
Sensor Response Time (sidestream)	< 3 seconds, including transport time and rise time

Interfering Gas and Vapor Effects on $EtCO_2$ Measurement Values:

Gas or Vapor	Gas Level (%)	Quantitative Effect/Comments
Nitrous oxide	60	Dry and Saturated Gas
Halothane	4	(0 – 40) mmHg: ± 1 mmHg additional error
Enflurane	5	(41 – 70) mmHg: ± 2.5% additional error
Isoflurane	5	(71 – 100) mmHg: ± 4% additional error
Sevoflurane	5	(101 – 150) mmHg: ± 5% additional error
Xenon	80	*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.
Helium	50	
Desflurane	15	
		Desflurane:
		The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.
		Xenon:
		The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg.

Barometric Pressure on $EtCO_2$ Measurement Values:

Quantitative Effect
Ambient Barometric, Operational
(0 – 40) mmHg: ± 1 mmHg additional error
(41 – 70) mmHg: ± 2.5% additional error

(71 – 100) mmHg: ± 4% additional error
(101 – 150) mmHg: ± 5% additional error
*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.

NOTE:

Respiration Rate accuracy was verified by using a solenoid test setup to deliver a square wave of known CO_2 concentration to the device. 5% and 10% CO_2 concentrations were used. Respiration rate was varied over the range of the device. Pass/Fail criteria was comparison of the respiratory rate output from the sensor to the frequency of the square wave.

A.12 C.O.

Not applicable to STORM 5500.

Technique	Thermodilution Technique
Measure Parameters	C.O., TB, TI
Measuring Range	
C.O.	0.1 L/min to 20 L/min
TB	23 °C to 43 °C(73.4 ºF to 109.4 ºF)
TI	-1 °C to 27 °C(30.2 ºF to 80.6 ºF)
Resolution	
C.O.	0.1 L/min
TB, TI	0.1 °C (+0.1 ºF)
Accuracy	
C.O.	±5% or ± 0.2 L/min, whichever is greater
TB	±0.1 °C (not including sensor)
TI	±0.1 °C (not including sensor)

NOTE：

At least 90% of the C.O. data should reside inside the bounded region, and the lower 95% confidence interval should not exceed 85%.

A.13 AG

Complies with ISO 80601-2-55: 2011.

Masimo module is applicable to STORM 5800. Dräger Minimodule is only applicable to STORM 5800.

A.13.1 Sidestream

ISA analyzer

Module Type	ISA AX+	Displaying the concentration of CO_2, N_2O, and two anaesthesia agent and identifying the anaesthesia agent automatically (built-in module)
	ISA OR+	Displaying the concentration of CO_2, O_2, N_2O, and two anaesthesia agent and identifying the anaesthesia agent automatically (built-in module)
Measurement Parameters	CO_2 , N_2O , O_2, Halothane (HAL), Isoflurane(ISO), Enflurane(ENF), Sevoflurane(SEV) , Desflurane(DES), awRR, MAC	
Measurement Principle	CO_2, N_2O, Anaesthesia Agent: infra-red absorption characteristic; O_2: Paramagnetic method	
Sampling Flow Rate	(50±10) ml/min	
Work Mode	Measure	
Compensations	Automatic compensation for pressure, temperature and broadening effects on CO_2.	
Warm-up Time	< 20 s	
Rise Time at 50 ml/min sample flow	$CO_2 \leq 300$ ms N_2O, O_2, ENF, ISO , SEV, DES ≤ 400 ms HAL ≤ 500 ms	
Primary Anaesthesia Agent Threshold	≤ 0.15 vol%	
Second Anaesthesia Agent Threshold	0.2 vol% + 10%	
Agent Identification Time	< 20 seconds (typically < 10 seconds)	

Total System Response Time	< 4 seconds (with 2 m Nomoline Airway Adapter Set sampling line)		
Data Update Period	1 s		
Data Sample Rate	20 data frames, 420 bytes, per second		
Respiration Rate	(0 to 150) $\pm$ 1 breaths/min		
Fi and ET	Fi and ET are displayed after one breath and have a continuously updated breath average. ET will typically decrease below nominal value (ET_{nom}) when respiration rate (RR) exceeds the RR threshold (RR_{th}) according to the following formulas: CO_2 $\quad$ $ET=ET_{nom}\times\sqrt{(70/RR)}$ for $RR_{th}>70$ N_2O, O_2, DES, ENF, ISO , SEV $\quad$ $ET=ET_{nom}\times\sqrt{(50/RR)}$ for $RR_{th}>50$ HAL $\quad$ $ET=ET_{nom}\times\sqrt{(35/RR)}$ for $RR_{th}>35$ NOTE: Measured at I/E ratio 1:1 using breath simualtor according to EN ISO 80601-2-55 fig. 201.101		
Measurement Range	CO_2: 0 to 25 vol% O_2: 0 to 100 vol% N_2O: 0 to 100 vol% HAL, ENF, ISO, SEV, DES: 0-25 vol% AwRR: 0 rpm to 150 rpm		
Resolution	CO_2: 0.1% HAL, ENF, ISO, SEV, DES: 0.1% N_2O: 1% O_2:1% AwRR: 1 rpm		
☆ Accuracy- Standard Conditions	Gas	Range	Accuracy
	CO_2	0 to 15 vol%	$\pm$(0.2 vol% + 2% of reading)
		15 to 25 vol%	Unspecified
	N_2O	0 to 100 vol%	$\pm$(2 vol% + 2% of reading)
	HAL, ENF, ISO	0 to 8 vol %	$\pm$(0.15 vol% + 5% of reading)
		8 to 25 vol %	Unspecified
	SEV	0 to 10 vol %	$\pm$(0.15 vol% + 5% of reading)
		10 to 25 vol %	Unspecified

	DES	0 to 22 vol %	±(0.15 vol% + 5% of reading)
		22 to 25 vol %	Unspecified
	O_2	0 to 100 vol %	±(1 vol% + 2% of reading)
☆ Accuracy-All Conditions	Gas	Accuracy	
	CO_2	±(0.3 kPa + 4% of reading)	
	N_2O	±(2 kPa + 5% of reading)	
	Agents	±(0.2 kPa + 10% of reading)	
	O_2	±(2 kPa + 2% of reading)	
☆AwRR Accuracy	±1 rpm		
☆Apnea Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.		
☆Alarm	Providing alarms of $EtCO_2$, $FiCO_2$, EtO_2 , FiO_2 , EtN_2O , FiN_2O , $EtAA$, $FiAA$, AwRR		
Exhaust Emission	Interface for exhaust collection is available		
Support: ◆ Zero calibration ◆ O_2 compensation ◆ N_2O compensation			

Interfering Gas and Vapor Effects:

Gas or Vapour	Gas Level	CO_2 ISA AX+ ISA OR+	Agents	N_2O
N_2O [4]	60 vol%	– [1]	– [1]	– [1]
HAL [4]	4 vol%	– [1]	– [1]	– [1]
ENF, ISO, SEV [4]	5 vol%	– [1]	– [1]	– [1]
DES [4]	15 vol%	– [1]	– [1]	– [1]
Xe(Xenon) [4]	80 vol%	-10% of reading [3]	– [1]	– [1]
He(Helium) [4]	50 vol%	-6% of reading [3]	– [1]	– [1]
Metered Dose Inhaler Propellants [4]	Not for use with metered dose inhaler propellants			
C_2H_5OH(Ethanol) [4]	0.3 vol%	– [1]	– [1]	– [1]
C_3H_7OH	0.5 vol%	– [1]	– [1]	– [1]

(Isopropanol) [4]				
CH_3COCH_3 (Acetone) [4]	1 vol%	– [1]	– [1]	– [1]
CH_4(Methane) [4]	3 vol%	– [1]	– [1]	– [1]
CO(Carbon monoxide) [5]	1 vol%	– [1]	– [1]	– [1]
NO(Nitrogen monoxide)	0.02 vol%	– [1]	– [1]	– [1]
O_2 [5]	100 vol%	– [2]	– [1]	– [1]

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

Note 2: Negligible interference with N_2O / O_2 concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0vol% CO_2 and 50vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06) * 5.0vol% = 4.7vol% CO_2.

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

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

Dräger Minimodule

Method	Sidestream gas measurement
	Infrared measurement: CO_2, N_2O, anesthetic agents
	Paramagnetic measurement: O_2
Barometric Pressure Compensation	Automated compensation
Gas Sampling Rate	200 mL/min ±20 mL/min
Maximum time until water trap requires draining	41 hrs (sample gas under BTPS conditions, ambient air 23 °C)
Total System Response Time	< 3 s
Drift Compensation (zeroing)	Automated cyclical zeroing, once per day (in error-free operation)
Zeroing Duration	< 20 s
Cross Sensitivity	None concerning alcohol (< 3000 ppm blood conc.), acetone (< 1000 ppm), methane, water vapor, NO, and CO
☆O_2	
☆Range	(0 to 100) Vol%

☆Accuracy [1]	±(2.5 Vol% + 2.5 % rel.)
Rise Time (t10…90) [4]	< 500 ms
Time to Specified Accuracy [3]	< 450 s
☆CO_2	
☆Range	(0 to 13.6) Vol%
☆Accuracy [1]	±(0.43 Vol% + 8% rel.)
Rise Time (t10…90) [4]	< 350 ms
Time to availability [2]	< 60 s
Time to Specified Accuracy [3]	< 450 s
☆N_2O	
☆Range	(0 to 100) Vol%
☆Accuracy [1]	±(2 Vol% + 8% rel.)
Rise Time (t10…90) [4]	< 350 ms
Time to Specified Accuracy [3]	< 450 s
☆Anesthetic Gases Range	
☆Halothane	(0 to 8.5) Vol%
☆Isoflurane	(0 to 8.5) Vol%
☆Enflurane	(0 to 10) Vol%
☆Sevoflurane	(0 to 10) Vol%
☆Desflurane	(0 to 20) Vol%
☆Accuracy [1]	±(0.2 Vol% + 15 % rel.)
Rise Time (t10…90) [4]	< 450 ms
Time to Specified Accuracy [3]	< 450 s
Automatic Detection	
Primary Gas	At the latest at 0.3 Vol%
Secondary Gas	At the latest at 0.4 Vol% With a Desflurane concentration greater than 4 Vol%, mixture detection occurs at the latest when the concentration of the second anesthetic gas rises above 10% of the Desflurane concentration.
☆Respiratory Rate	

☆Range	0/min to 100/min (Respiratory rate is derived from the CO_2 value)
☆Accuracy	0/min to 60/min: ± 1 /min > 60 /min: not specified
Resolution	1 /min

Note 1: In accordance to ISO 21647:2004 and ISO 80601‑2‑55:2011, for respiratory rates from 0…60 [1]/min with I:E ratio of 1:1.

Note 2: Duration from power on at 10 °C module temperature to transmission of measurements with unspecified accuracy

Note 3: Duration from power on at 10 °C module temperature to transmission of measurements with specified accuracy

Note 4: With Dräger sample line and water trap

A.13.2 Mainstream

IRMA module

Module Type	IRMA AX+	Displaying the concentration of CO_2, N_2O and two anaesthesia agent and indentifying two anaesthesia agent
Measurement Parameters	CO_2, N_2O, HAL, Isoflurane(ISO), Enflurane(ENF), Sevoflurane(SEV), Desflurane(DES), awRR, MAC	
Measurement Principle	CO_2, N_2O, anaesthesia agent: infra-red absorption characteristic	
Barometric Pressure Compensation	Automatic	
Data Sample Rate	20 data frames, 420 bytes, per second	
Warm-up Time	IRMA AX+: < 20 seconds (Concentrations reported, automatic agent identification enabled and full accuracy)	
Rise Time	$CO_2 \leq 90$ ms $N_2O \leq 300$ ms HAL, ISO, ENF, SEV, DES ≤ 300 ms (Measured at 10 l/min with gas concentration steps corresponding to 30% of total measuring range for each gas.)	
Primary Agent Threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.	

Secondary Agent Threshold	0.2 vol% + 10% of total agent concentration
Agent Identification Time	< 20 seconds (typically < 10 seconds)
Total System Response Time	< 1 second (Measured at 10 l/min with gas concentrations according to table 201.103 in EN ISO 80601-2-55:2011.)
Respiration Rate	$(0-150) \pm 1$ bpm. The respiration rate is displayed after three breaths and the average value is updated every breath.
Fi and ET	IRMA AX+: CO_2, N_2O, primary and secondary agents (HAL, ENF, ISO, SEV, DES) Fi and ET are displayed after one breath and have a continually updated breath average. ET-values for anathesthetic agents and N_2O (IRMA AX+) will typically decrease below nominal value when respiration rate exceeds 80 bpm according to the formula $ET = 80*ET_{nom}/RR$ (tested at I/E ratio 1:1 using breath simualtor according to EN ISO 80601-2-55 fig. 201.101). $ETCO_2$ will be within specification for all respiration rates up to 150 bpm (IRMA AX+).
Data Update Period	1 s
Measurement Range	CO_2: 0 to 25 vol% N_2O: 0 to 100 vol% HAL, ENF, ISO, SEV, DES: 0-25 vol% AwRR: 0 to 150 rpm
Resolution	CO_2: 0.1% HAL, ENF, ISO, SEV, DES: 0.1% N_2O: 1% AwRR: 1 rpm

☆Accuracy- Standard Conditions	Gas	Range	Accuracy
	CO_2	0 to 15 vol%	$\pm(0.2$ vol% + 2% of reading$)$
	N_2O	0 to 100 vol%	$\pm(2$ vol% + 2% of reading$)$
	HAL ISO ENF	0 to 8 vol%	$\pm(0.15$ vol% + 5% of reading$)$
	SEV	0 to 10 vol%	$\pm(0.15$ vol% + 5% of reading$)$

	DES	0 to 22 vol%		$\pm$(0.15 vol% + 5% of reading)
☆Accuracy- All Conditions	Gas	Accuracy		
	CO_2	$\pm$(0.3 kPa + 4% of reading)		
	N_2O	$\pm$(2 kPa + 5% of reading)		
	Agents	$\pm$(0.2 kPa + 10% of reading)		
☆AwRR Accuracy	$\pm$1 rpm			
☆Apnea Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.			
Work Mode	Measure			
☆Alarm	Providing alarms of $EtCO_2$, $FiCO_2$, EtN_2O , FiN_2O , EtAA, FiAA, AwRR			
Support: ◆ Real-time gas concentration monitoring ◆ Zero calibration				

Interfering Gas and Vapour Effects:

Gas or Vapour	Gas Level	CO_2 IRMA AX+	Agents	N_2O
N_2O[4]	60 vol%	_ [1&2]	_ [1]	_ [1]
HAL[4]	4 vol%	_ [1]	_ [1]	_ [1]
ENF, ISO, SEV[4]	5 vol%	_ [1]	_ [1]	_ [1]
DES[4]	15 vol%	_ [1]	_ [1]	_ [1]
Xe(Xenon)[4]	80 vol%	-10% of reading [3]	_ [1]	_ [1]
He(Helium) [4]	50 vol%	-6% of reading [3]	_ [1]	_ [1]
Metered Dose Inhaler Propellants[4]	Not for use with metered dose inhaler propellants			
C_2H_5OH(Ethanol) [4]	0.3 vol%	_ [1]	_ [1]	_ [1]
C_3H_7OH (Isopropanol) [4]	0.5 vol%	_ [1]	_ [1]	_ [1]
CH_3COCH_3 (Acetone) [4]	1 vol%	_ [1]	_ [1]	_ [1]
CH_4(Methane) [4]	3 vol%	_ [1]	_ [1]	_ [1]

CO(Carbon monoxide) [5]	1 vol%	_[1]	_[1]	_[1]
NO(Nitrogen monoxide) [5]	0.02 vol%	_[1]	_[1]	_[1]
O_2 [5]	100 vol%	_[1&2]	_[1]	_[1]

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

Note 2: IRMA AX+ does not measure O_2.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0vol% CO_2 and 50vol% Helium, the measured CO_2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7vol% CO_2.

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

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

A.14 Interfaces

A.14.1 Analog Output

Bandwidth (-3 dB; reference frequency: 10 Hz)	Diagnosis/Monitor: 0.5 Hz to 40 Hz Surgery: 1 Hz to 20 Hz
Maximum Transmission Delay (Diagnosis Mode)	500 ms
Sensitivity	1 V/1 mV ±10%
PACE Rejection/ Enhancement	Not applicable.
Waveform Display	Consistent with the calculation leads.
Compliant with Standard and Directive	Complies with the requirements in terms of short circuit protection and leakage current in EN60601-1.
Output ImpDIXIONce	< 500 Ω
Interface Type	PS2 connector

NOTE:

While using analog output, set the calculation lead to Lead I, Lead II, or Lead III.

A.14.2 Defibrillator Synchronization

Output Impedance	< 500 Ω
Maximum Time Delay	35 ms (R-wave peak to leading edge of pulse)
Waveform	Rectangular wave
Amplitude	High level: 3.5 V to 5.5 V, providing a maximum of 1 mA output current; Low level: < 0.5 V, receiving a maximum of 5 mA input current
Minimum Required R-wave Amplitude	0.3 mV
Pulse Width	100 ms±10%
Limited Current	15 mA rating
Rising and Falling Time	< 1 ms
Interface Type	PS2 connector

A.14.3 Nurse Call

Drive Mode	Voltage output
Power Supply	≤ 12.6 VDC, 200 mA Max.
Interface Signal	12 V power supply and PWM waveform
Interface Type	PS2 connector

A 14.4 USB Interfaces

Number of USB Interfaces	Standard:2
Drive Mode	HOST interface, USB1.0/2.0 protocol
Power Supply	5 VDC±5%, 500 mA Max.
Interface Type	USB A-type port

A.14.5 VGA Interface

Number of VGA Interface	1
Horizontal Refreshing Rate	(30-94) KHZ
Video Signal	0.7 Vpp @ 75 Ohm, HSYNC/VSYNC signal TTL
Interface Type	DB-15 female receptacle

A.14.6 RS232 Interface

Applicable to STORM 5800.

Level	RS232
Output Voltage Range	-13.2 V~+13.2 V
Interface Type	DB-9 female receptacle

A.14.7 Network Interface

Bandwidth	10 Mbps
Interface Type	Standard RJ-45 network interface

B EMC Information

- Guidance and Manufacture's Declaration

B.1 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
STORM 5500 and STORM 5800 are intended for use in the electromagnetic environment specified below. The customer or the user of STORM 5500 and STORM 5800 should assure that they are used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	STORM 5500 and STORM 5800 use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	STORM 5500 and STORM 5800 are suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

NOTE:

The EMISSIONS characteristics of STORM 5500/STORM 5800 make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) STORM 5500/STORM 5800 might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

B.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
STORM 5500 and STORM 5800 are intended for use in the electromagnetic environment specified below. The customer or the user of STORM 5500 and STORM 5800 should assure that they are used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV for line to line ±2 kV for line to ground	±1 kV for line to line ±2 kV for line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of STORM 5500 and STORM 5800 requires continued operation during power mains interruptions, it is recommended that STORM 5500 and STORM 5800 be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

B.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
STORM 5500 and STORM 5800 are intended for use in the electromagnetic environment specified below. The customer or the user of STORM 5500 and STORM 5800 should assure that they are used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 V$_{rms}$ 150 kHz to 80 MHz 6Vrms[c] in ISM bands between 0,15 MHz and 80 MHz	3 V$_{rms}$ 150 kHz to 80 MHz 6Vrms[c] in ISM bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of STORM 5500 and STORM 5800, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150KHz to 80MHz
	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz
	See Table 1	Comply with Table 1	$d = 6\sqrt{P}\,/\,E$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer). Where P is the maximum output

			power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
			Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which STORM 5500 and STORM 5800 are used exceeds the applicable RF compliance level above, STORM 5500 and STORM 5800 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating STORM 5500 and STORM 5800.

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

[c] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies are included.							
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.							
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							

B.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and STORM 5500 STORM 5800		
STORM 5500 and STORM 5800 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of STORM 5500 and STORM 5800 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and STORM 5500 and STORM 5800 as recommended below, according to the maximum output power of the communications equipment.		

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

C Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory.

Note: If your monitor has been ordered preconfigured to your requirements, the settings at delivery will be different from those listed here.

C.1 Patient Information Default Settings

Patient Information Settings	
Patient Type	Adult
Pace	Off

C.2 Alarm Default Settings

Alarm Settings	
Pause Time	120 s
Sensor Off Alarm	Off
Alarm Latch	Off

C.3 ECG Default Settings

ECG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
Pace	Off		
Lead Type	5 Leads		
Display	Normal		
Filter	Monitor		
Smart Lead Off	Off		
Heart Volume	3		
ST Analysis	ADU	PED	NEO
ST Analysis	Off		

Alarm Switch	Off
Alarm Level	Medium
Alarm Record	Off
Alarm High Limit (ST-X)	0.2
Alarm Low Limit (ST-X)	-0.2

X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6.

ARR Analysis			
ARR Analysis	On		
PVCs Alarm Level	Medium		
PVCs Alarm Switch	Off		
PVCs Alarm Record	Off		
ARR Alarm Settings	Alarm Switch	Alarm Level	Alarm Record
ASYSTOLE	On	High	Off
VFIB/VTAC	On	High	Off
R ON T	On	Medium	Off
VT > 2	On	Medium	Off
COUPLET	On	Medium	Off
PVC	On	Medium	Off
BIGEMINY	On	Medium	Off
TRIGEMINY	On	Medium	Off
TACHY	On	Medium	Off
BRADY	On	Medium	Off
MISSEDBEATS	On	Medium	Off
IRR	On	Medium	Off
PNC	On	Medium	Off
PNP	On	Medium	Off
VBRADY	On	Medium	Off
VENT	On	Medium	Off

C.4 RESP Default Settings

RESP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	30	30	100
Alarm Low Limit	8	8	30
Apnea Time	20 s		
Calculation Type	Auto		
Resp Type	II		
Sweep	12.5 mm/s		
Amplitude	1		

C.5 SpO$_2$ Default Settings

SpO$_2$ Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	100	100	95
Alarm Low Limit	90	90	88
Pitch Tone	On		
Sweep	12.5 mm/s		

C.6 PR Default Settings

PR Settings	ADU	PED	NEO
PR Source	SpO$_2$		
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100

Pulse Volume	3
Alarm Source	Auto

C.7 NIBP Default Settings

NIBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (SYS)	160	120	90
Alarm Low Limit (SYS)	90	70	40
Alarm High Limit (Map)	110	90	70
Alarm Low Limit (Map)	60	50	30
Alarm High Limit (Dia)	90	70	60
Alarm Low Limit (Dia)	50	40	20
DIXION Module			
Inflation value	160	140	100
Omron Module			
Inflation value	180	180	120
SunTech Module			
Inflation value	160	140	90
Unit	mmHg		
Interval	Manual		

C.8 TEMP Default Settings

TEMP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (T1)	39.0	39.0	39.0
Alarm Low Limit (T1)	36.0	36.0	36.0
Alarm High Limit (T2)	39.0	39.0	39.0
Alarm Low Limit (T2)	36.0	36.0	36.0

Alarm High Limit (TD)	2.0	2.0	2.0
Unit	°C		

C.9 Quick TEMP Default Settings

Quick TEMP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (T1)	39.0	39.0	/
Alarm Low Limit (T1)	36.0	36.0	/
Unit	°C		

C.10 IBP Default Settings

IBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Unit	mmHg		
Filter	12.5 Hz		
	SYS, DIA, MAP	SYS, DIA, MAP	SYS, DIA, MAP
Alarm High Limit (ART, P1, P2)	160, 90, 110	120, 70, 90	90, 60, 70
Alarm Low Limit (ART, P1, P2)	90, 50, 70	70, 40, 50	55, 20, 35
Alarm High Limit (PA)	35, 16, 20	60, 4, 26	60, 4, 26
Alarm Low Limit (PA)	10, 0, 0	24, -4, 12	24, -4, 12
	MAP	MAP	MAP
Alarm High Limit (CVP, RAP, LAP, ICP)	10	4	4
Alarm Low Limit (CVP, RAP, LAP, ICP)	0	0	0

C.11 CO$_2$ Default Settings

CO$_2$ Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Standby		
Unit	mmHg		
Apnea Time	20 s		
O$_2$ Compensate	16%		
Anes Agent	0%		
Alarm High Limit (EtCO$_2$)	50	50	45
Alarm Low Limit (EtCO$_2$)	25	25	30
Alarm High Limit (FiCO$_2$)	4	4	4
Alarm High Limit (AWRR)	30	30	100
Alarm Low Limit (AWRR)	8	8	30
Sweep	12.5 mm/s		
Amplitude	Low		

C.12 C.O. Default Settings

C.O. Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (TB)	43.0	43.0	43.0
Alarm Low Limit (TB)	23.0	23.0	23.0
Injective Temperature Source	Auto		
Temperature Unit	°C		
Interval	30		
Constant	0.542		

C.13 AG Default Settings

AG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Measure (Masimo Module) Standby (Dräger Minimodule)		
Apnea Time	20s		
Unit	%		
O_2 Compensate	OFF		
Anes Agent	HAL		
Alarm High Limit (EtAA)	8.0	8.0	8.0
Alarm Low Limit (EtAA)	0.0	0.0	0.0
Alarm High Limit (FiAA)	6.0	6.0	6.0
Alarm Low Limit (FiAA)	0.0	0.0	0.0
Alarm High Limit (EtN$_2$O)	55	55	55
Alarm Low Limit (EtN$_2$O)	0	0	0
Alarm High Limit (FiN$_2$O)	53	53	53
Alarm Low Limit (FiN$_2$O)	0	0	0
Alarm High Limit (EtO$_2$)	90.0	90.0	90.0
Alarm Low Limit (EtO$_2$)	18.0	18.0	18.0
Alarm High Limit (FiO$_2$)	88.0	88.0	88.0
Alarm Low Limit (FiO$_2$)	18.0	18.0	18.0
Sweep	12.5 mm/s		
Amplitude	2		

D Abbreviations

Abbr	English Full Name/Description
AC	Alternating current
Adu	Adult
AG	Anaesthesia gas
Art	Arterial
aVF	Left foot augmented lead
aVL	Left arm augmented lead
aVR	Right arm augmented lead
awRR	Airway respiration rate
BP	Blood pressure
BTPS	Body temperature and pressure, saturated
CI	Cardiac index
C.O.	Cardiac output
CISPR	International Special Committee on Radio Interference
CMS	Central monitoring system
CO_2	Carbon dioxide
COHb	Carboxyhemoglobin
CVP	Central venous pressure
DC	Direct current
Des	Desflurane
Dia	Diastolic
ECG	Electrocardiogram
EEC	European Economic Community
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
Enf	Enflurane
ESU	Electrosurgical unit
Et	End-tidal
$EtCO_2$	End-tidal carbon dioxide
EtN_2O	End-tidal nitrous oxide

Eto	Ethylene oxide
EtO_2	End-tidal oxygen
Fi	Fraction of inspired
$FiCO_2$	Fraction of inspired carbon dioxide
FiN_2O	Fraction of inspired nitrous oxide
FiO_2	Fraction of inspired oxygen
Hal	Halothane
Hb	Hemoglobin
Hb-CO	Carbon mono-xide hemoglobin
HR	Heart rate
IBP	Invasive blood pressure
ICP	Intracranial pressure
ICU	Intensive care unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
Iso	Isoflurane
LA	Left arm
LAP	Left atrial pressure
LCD	Liquid crystal display
LED	Light emitting diode
LL	Left leg
MAP	Mean arterial pressure
MDD	Medical Device Directive
MetHb	Methemoglobin
MRI	Magnetic resonance imaging
N/A	Not applied
N_2	Nitrogen
N_2O	Nitrous oxide
Neo	Neonate
NIBP	Non-invasive blood pressure
O_2	Oxygen

oxyCRG	Oxygen cardio-respirogram
PA	Pulmonary artery
PAWP	Pulmonary artery wedge pressure
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse rate
PVC	Premature ventricular complex
R	Right
RA	Right arm
RAP	Right atrial pressure
Resp	Respiration
RHb	Reduced hemoglobin
RL	Right leg
RR	Respiration Rate
Sev	Sevoflurane
SpO$_2$	Pulse Oxygen Saturation
SYS	Systolic pressure
TB	Blood Temperature
TD	Temperature difference
TEMP	Temperature
USB	Universal serial bus

DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

Couvenstraße 6, 40211, Dusseldorf, Germany
Tel: +4921138838868, Fax: +4921138838697