

EDAN

iM50/iM60/iM70/iM80

Patient Monitor

Version 1.201

CE₀₁₂₃

About this Manual

P/N: 01.54.455711-1201

Release Date: August 2013

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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 EDAN INSTRUMENTS, INC. (hereinafter called EDAN) cannot be held liable.

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

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

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

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

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

The iM50 patient monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO₂), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO₂) and quick temperature (Quick TEMP). This monitor is suitable for use in intra-hospital transport and hospital environments including clinic, emergency department, wards, PACU and NICU.

The iM60 patient monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO₂), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO₂) and cardiac output (C.O.). This monitor is suitable for use in hospital environments including OR, ICU, NICU, PACU and wards.

The iM70 patient monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO₂), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO₂), cardiac output (C.O.) and anesthetic gas (AG). This monitor is suitable for use in hospital environments including OR, ICU, NICU, PACU and wards.

The iM80 patient monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO₂), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO₂), cardiac output (C.O.) and anesthetic gas (AG). This monitor is suitable for use in hospital environments including OR, ICU, NICU, PACU and wards.

The arrhythmia detection and ST Segment analysis are not intended for neonatal patients.

1.2 Safety Guidance

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 system 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**-The power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.
 - 5 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.
 - 6 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.
 - 7 Route all cables away from patient's throat to avoid possible strangulation.
 - 8 Devices connecting with monitor should be equipotential.
 - 9 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 60601-1-1. 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/EN60601-1-1. If in doubt, consult our technical service department or your local distributor.
 - 10 Only patient cable and other accessories supplied by EDAN can be used. Or else, the performance and electric shock protection cannot be guaranteed, and the patient may be injured.
-

WARNING

- 11 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
 - 12 When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.
 - 13 During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off, and only the patient information and alarm settings can be saved. After reconnecting the power supply, the user should turn on the monitor for monitoring.
 - 14 Keep away from fire immediately when leakage or foul odor is detected.
 - 15 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.
 - 16 Dispose of the package material, observing the waste control regulations and keeping it out of children's reach.
 - 17 After defibrillation, the screen display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers' instructions.
 - 18 This equipment is not intended for family usage.
-
-

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, etc.
 - 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 could 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.
-
-




CAUTION














- 7 Remove a battery whose life cycle has expired from the monitor immediately.
 - 8 Avoid liquid splash on the device. The temperature must be kept between 5°C and 40°C while working. And it should be kept between -20°C and 55°C during transportation and storage.
 - 9 To ensure patient safety, use only parts and accessories manufactured or recommended by EDAN.
 - 10 Federal (U.S.) law restricts this device to sale by or on the order of a physician.
-













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 EDAN.
- 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 The monitor may not be compatible with all models of USB flash drives. Use the USB flash drives that are recommended by EDAN.
- 8 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

	This symbol indicates that the equipment is IEC/EN60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.
	This symbol indicates that the instrument is IEC/EN 60601-1 Type BF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.
	Symbol for “Caution”

	Equipotential grounding terminal
	Alternating Current
	Power Supply switch
	Serial number
	Network port
	USB (Universal Serial Bus) Connection
	Audio alarm is off
	NIBP measurement
	Trend graph
	Freeze
	Record
	Menu
	VGA output, External Monitor

	RS-232 port
	Nurse call port
	SD Card port
	Signal output port
	Signal output
	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
	Authorized representative in the European community
	Date of manufacture
	Manufacturer
P/N	Part Number
	Recycle
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
	Consult Instructions For Use

	Locked position
	Gas inlet
	Gas outlet (evac)
	ISA equipped to measure CO ₂ only.
	ISA equipped to measure multiple gases.
Rx only (U.S.)	Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
	(Only applicable to iM50 and iM80) With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1, IEC 60601-2-25*, IEC 60601-2-27, IEC 60601-2-30, IEC 60601-2-34, IEC 60601-2-49, IEC 60601-2-51* (Symbol * means this standard only applicable to iM80)

Chapter 2 Installation

NOTE:

- 1 The monitor settings must be specified 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

If all situations are normal, please place the monitor on a flat, level surface, hung on the bed rail, or mounted on a wall. About how to install the wall mount for the monitor, please refer to the following content.

2.2.1 Installing Wall Mount for the Monitor

For how to install wall mount for the monitor, please refer to *Wall Mounting Bracket Assembly Instruction*.

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: 100V-240V~, 50Hz/60Hz.
- 2 Apply the power line provided with the monitor. Plug the power line to inlet interface of the monitor. Connect the other end of the power line to a grounded 3-phase power output.

NOTE:

Connect the power line to the jack special for hospital usage.

2.4 Checking Out 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 continuous 360-hour runtime, 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 the 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*

*The statement is not applicable to iM50 or iM80.

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. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

2.9 FCC RF Radiation Exposure Statement*

*The statement is not applicable to iM50 or iM80.

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.

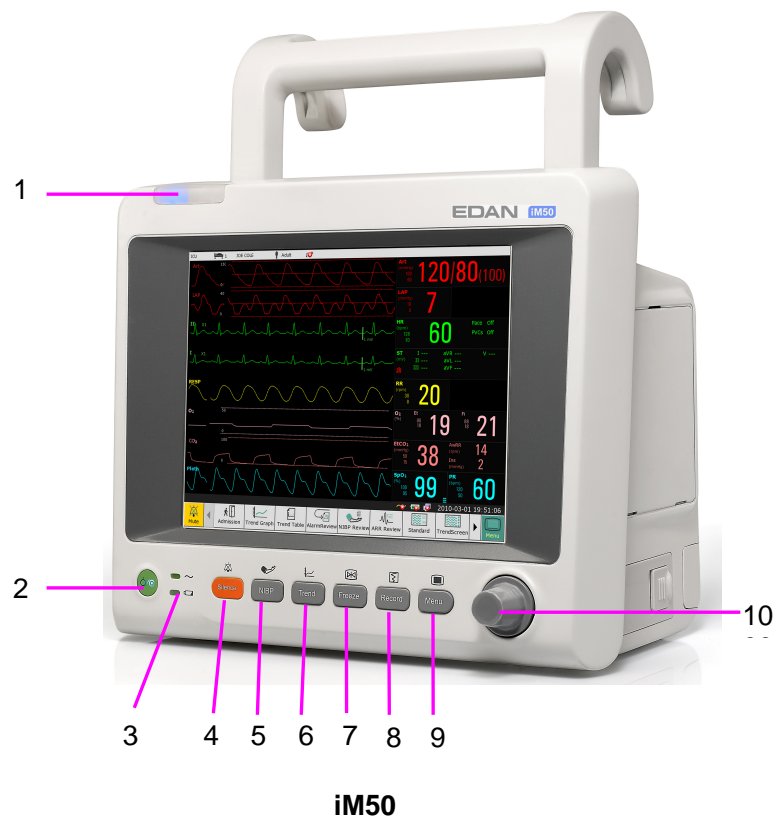
Chapter 3 Basic Operation

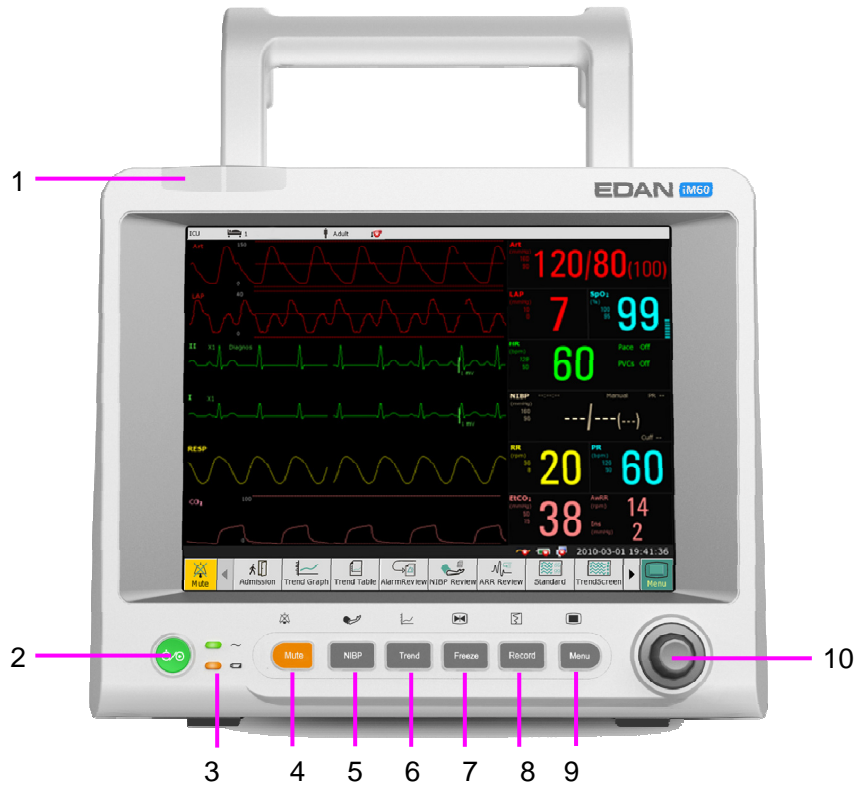
This manual is for clinical professionals using the iM50/iM60/iM70/iM80 patient monitors. Unless otherwise specified, the information here is valid for all the above products.

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.

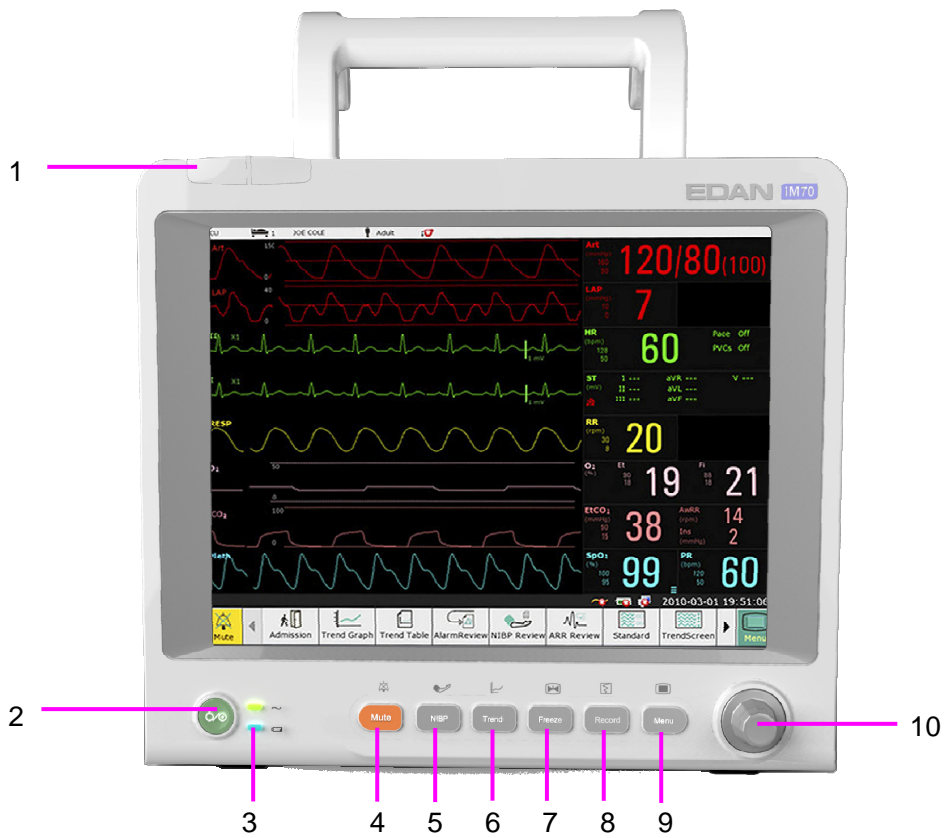
3.1 Overview

3.1.1 Front View

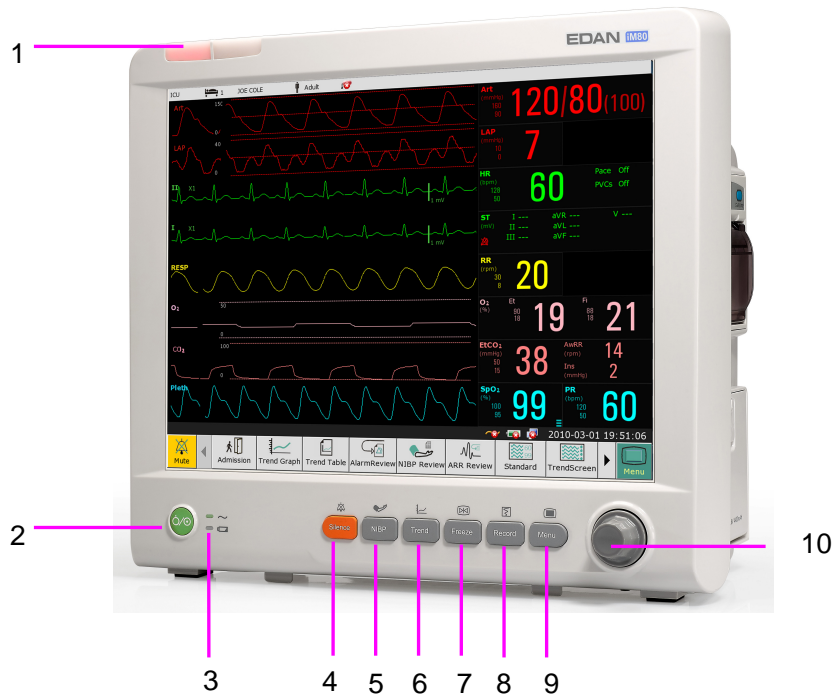






iM60



iM70



iM80

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 <i>Battery Indicator</i> for details.
4	Mute — Press this button to pause the alarm. All the audio alarm will be closed. At the same time, the message of Temporary Alarm Mute **s and the symbol  will be displayed in the information area. When you repress it or the pause time is over, the system will resume the normal monitoring status and the message of Temporary Alarm Mute **s and icon will vanish. Symbol  is shown in the information area. Pressing or holding the button again can resume the alarm. Further Alarm Mute information can be found in the chapter Alarm Mute.
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.