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Version: 001
Doc. Number: DFM 600 800 UM-001-12-2019-EN
Product Name: Defibrillator/Monitor
Product Model: DFM 600 DFM 800

Digitally signed by Bolea Petru
Date: 2023.07.03 15:11:45 EEST
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Location: Moldova

About Manufacturer

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Preface

This user manual introduces the performance, operating instruction and safety information regarding DFM 600/DFM800 defibrillator/monitor and can serve as the start guide of new users.

Target Audiences

This user manual is applicable to the professional clinical medical staff or the persons who are experienced in using the monitoring equipment for reading. The readers shall have the knowledge and working experience in medical procedure, practice and terms necessary for monitoring the patients.

Figures

All the figures provided in this user manual shall be for your reference only. The menus, options, values and functions in the figures may be not entirely consistent with what you see from the monitor.

Conventions

- →: This symbol is used to indicate the operating step.
- **[Character]**: is used to indicate the character string in the software.
- ***Italic text*** is used in this user manual to quote the referenced chapters or sections.

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Contents

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Chapter 1 Safety

1.1 Safety Information

⚠Danger

- **To indicate the dangers which would result in death or severe personal injury.**

⚠Warning

- **To warn you of the conditions where serious consequence, disadvantageous matters or danger may occur. Failure to comply with the warning will result in severe personal injury or death of the user or the patient.**

⚠Caution

- **To indicate potential danger or unsafe operation. If not avoided, it may lead to mild personal injury, product malfunction, damages or property loss. It may also give rise to more severe harm.**

⚠Attention

- **It emphasizes primary warnings or provides descriptions or explanations so that this product can be used in a better way.**

⚠Danger

- **The defilibrillator/monitor will cause high voltage during defibrillation, which will result in severe injury and death. Therefore this defibrillator/monitor should be operated by or under the guidance of professional clinic doctors. Only the trained and authorized personnel can operate the defibrillator/monitor.**
- **Don’t open the housing of this equipment to avoid potential electric shock. Any maintenance and upgrading operation must be conducted by the personnel trained and authorized by Okuman.**
- **Don’t use this equipment in the presence of flammable gases or anesthetics or in an oxygen-enriched atmosphere to avoid explosion and fire.**

⚠Warning

- **Check whether the defibrillator/monitor and its accessories can work nomally and safely prior to use.**
- **The alarm volume and alarm limits shall be set for different patients. Don’t rely merely on the audible alarm to monitor the patients; alarm volume too low or totally off will result in invalid**

alarm and endanger patient safety. The most reliable patient monitoring method shall be keeping the patient under close surveillance.

- **This equipment can only be connected to the sockets with protective grounding. If there is no such sockets, please operate it on battery power.**
- **The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. Keep the packaging material out of the reach of children.**
- **Please install the power cord and cables of various accessories carefully to avoid entanglement, potential strangulation or electrical interference.**
- **Don't use mobile phones near the equipment because the mobile phones will generate a strong radiation field.**
- **For the patient with pacemaker, cardiotachometer might measure the pacing pulsein case of cardiac arrest or arrhythmia. Do not completely rely on the alarm of cardiotachometer. The patient with pacemaker shall be closely monitored.**
- **During defilibration, operators shall not contact patients, tales and equipments. Before using these cables again, please check whether they can work properly.**
- **The equipments connected with the defibrillator/monitor shall form an equipotential body(the protective grounding is connected effectively).**
- **When the defibrillator/monitor is used in conjunction with electrosurgery units, the operator (doctor or nurse) shall ensure the patient safety.**
- **The physiological waveforms, physiological parameters and alarm message displayed by the monitor shall be for doctors' reference only and can not be used as the basis for clinic therapy.**
- **The electromagnetic field will affect the performance of this defibrillator/monitor. So the use of the other equipment, for examplemobile phone, X-ray or MRI equipment, near this defibrillator/monitor must meet corresponding EMC requirements, because they will emit high-strength electromagnetic radiation.**
- **Do not conduct therapy on patients lying on wet ground.**
- **When conducting therapy on patients with pacemaker, the pads or paddles should be placed away from the pacemaker.**
- **The equipment withoutdefibrillation protection shall be disconnected from the patient during defibrillation.**
- **The operator should verify that the synchronous input equipmentisapplicable to this defibrillator/monitor and the input signals are valid.**
- **Do not contact the device interfaces, thermal head of the recorder or other live equipment while contact the patient to prevent the patient form injury.**
- **Keep patient under close surveillence when using this defibrillator/monitor to conduct therapy. If the shock is delayed, the shockable rhythm may change to nonshockable rhythm, leading to delivering wrong shock.**
- **Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact any other conductive parts including earth.**
- **Do not posit the equipment to make it difficult to operate the power plug which uses to isolate the equipment circuits electrically from the supply mains.**
- **The installation and replacement of fuse should be performed by trained and qualified serviceman.**
- **The use of this monitor is restricted to one patient at a time.**
- **When the defibrillator/monitor is used with HF surgical equipment, the transducerand the**

cables must be avoided conductive connection to HFequipment to protect against burns to the patient.

- **After defibrillation, the ECG wave will recover within 5s, others will recover within 10s.**

⚠Caution

- **In order to avoid damage to this equipment and ensure patient safety, please use accessories specified in the user manual.**
- **Please install or move this equipment properly to prevent it from being damaged due to fall, collision, strong vibration or other external mechanical forces.**
- **Before this equipment is connected to the mains supply, please make sure that the mains supply meets the requirements for voltage and frequency specified on the nameplate or in this user manual.**
- **At the end of its service life, the equipment, as well as its accessories, must be disposed of according to local relevant laws and regulations or the rules and regulations of the hospital.**
- **Dry the equipment immediately in case of rain or water spray.**
- **Check the cables, paddle handles and functional accessories periodically for possible defects.**

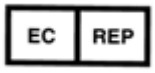
⚠Attention

- **Please install the equipment at the place that is convenient for observation, operation and maintenance.**
- **This user manual introduces the product according to the most complete configurations. The product you have purchased may not possess some configurations or functions.**
- **Please place this user manual near the equipment for easy and timely reference.**
- **This equipment is not intended for home use.**
- **The service life of the monitor is 5 years.**

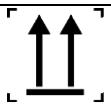
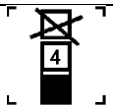
1.2 Symbols

(1) Equipment symbols

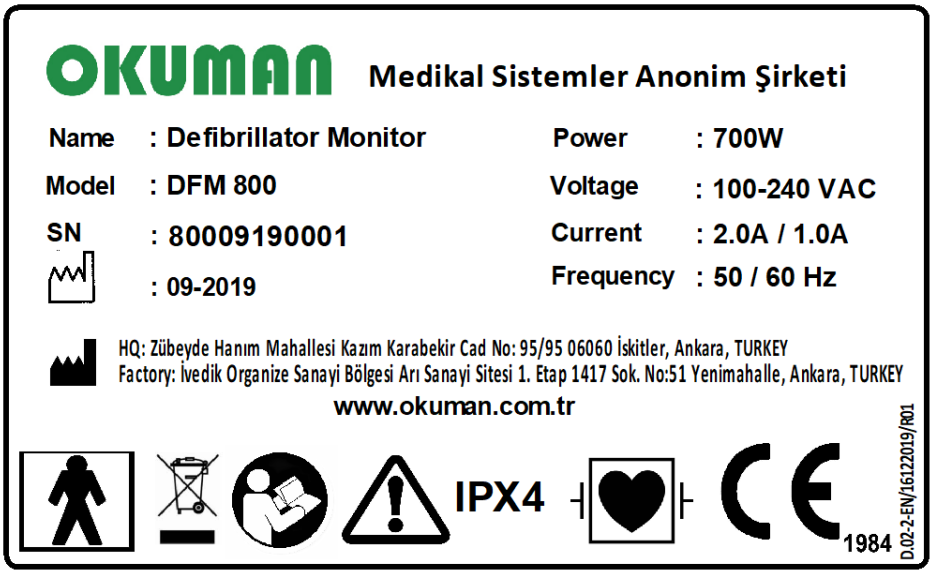
	Caution		Date of manufacture
	CF applied part with defibrillator-proof protection		Serial number
	BF applied part with defibrillator-proof protection		Equipotential grounding
	AC indicator		Network
	Battery indicator		USB
	Service indicator		Data input/output
	Main menu		DVI

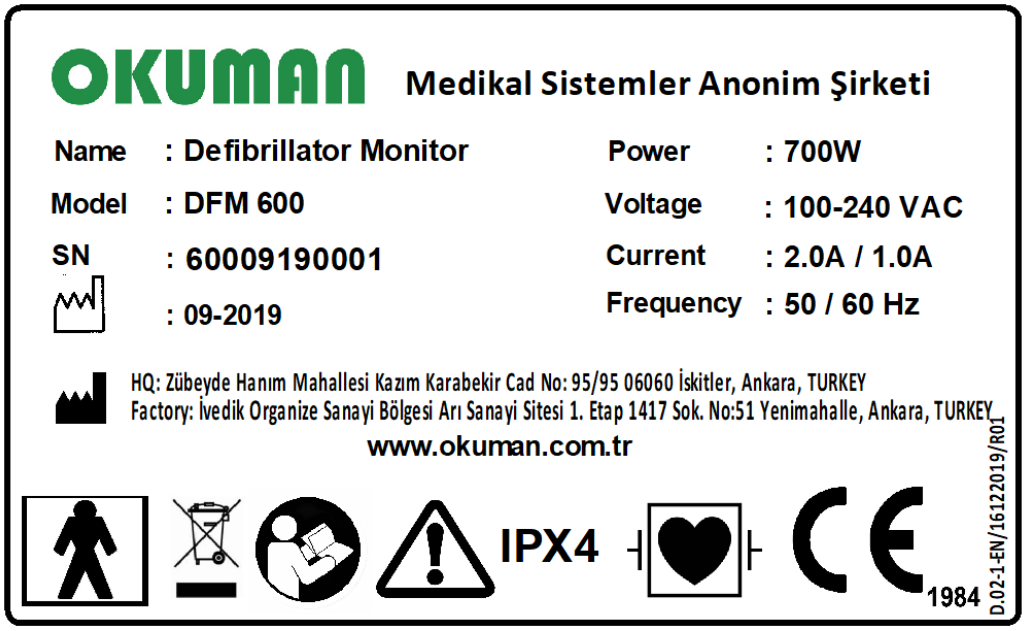
	Event		Shock button
	Lead select		Warning, high voltage
	12-lead ECG		Protective grounding
	Static-sensitive device	IP44	Degree of protection against harmful ingress of water and Degree of protection against harmful ingress of solid particle are 4, respectively.
	Refer to instruction manual/booklet		Record key
	NIBP Start key		Alarm pause key
	European community representative	CE1984	**Conformité Européenne** Complies with medical device directive 93/42/EEC

(2) Packaging symbols

	Up		The maximum stacking layers are 4.
	Fragile		Key dry

1.3 Label




OKUMAN
Medikal Sistemler Anonim Şirketi
Name : Defibrillator Monitor
Model : DFM 600
SN : 60009190001
: 09-2019
Power : 700W
Voltage : 100-240 VAC
Current : 2.0A / 1.0A
Frequency : 50 / 60 Hz
HQ: Zübeyde Hanım Mahallesi Kazım Karabekir Cad No: 95/95 06060 İskitler, Ankara, TURKEY
Factory: İvedik Organize Sanayi Bölgesi Arı Sanayi Sitesi 1. Etap 1417 Sok. No:51 Yenimahalle, Ankara, TURKEY
www.okuman.com.tr
IPX4
1984
D.02-1-EN/16122019/R01

Chapter 2 Overview

2.1 Intended Use

The defibrillator/monitor is applicable to manual defibrillation, AED defibrillation, pace-making and vital sign monitoring on patients.
The expected operator position is about one meter around the monitor in normal use.

2.2 Components

The defibrillator/monitor is composed of main unit, battery, paddles (external defibrillation paddles, internal defibrillation paddles), pads and other functional accessories.

2.3 Appearance Introduction

2.3.1 Front View

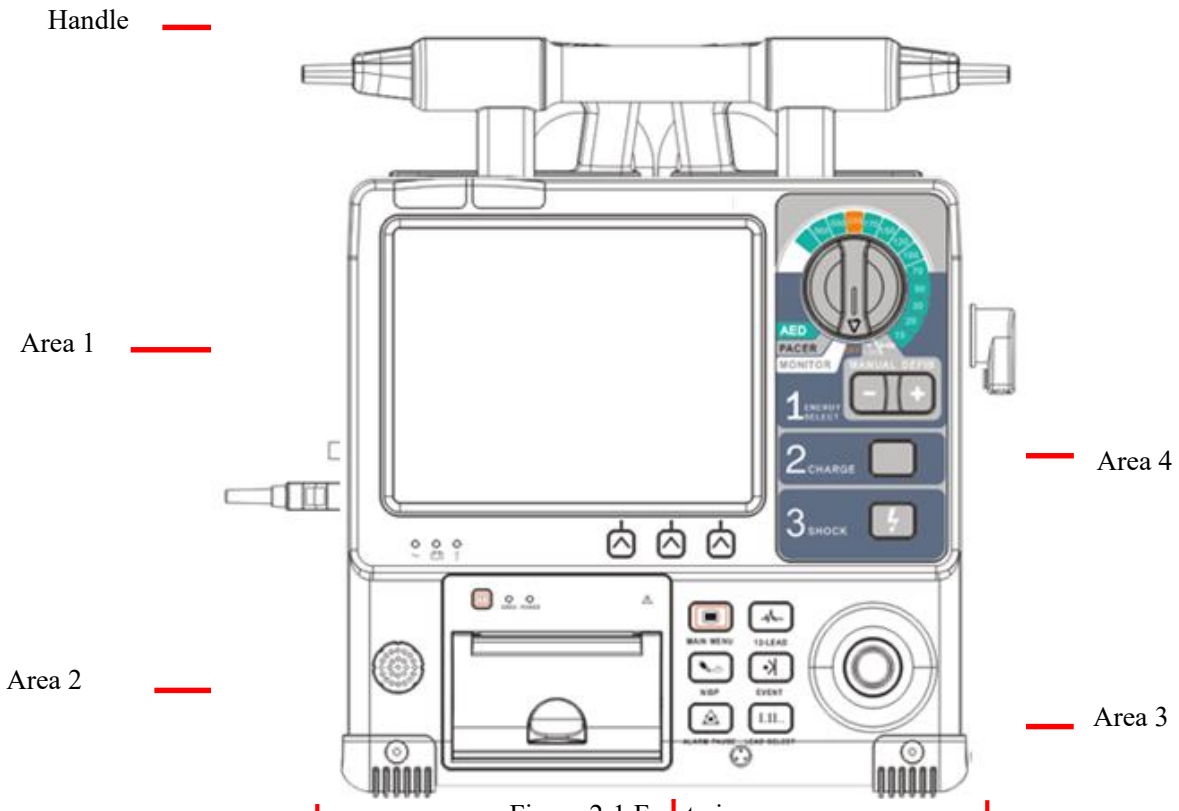


Figure 2-1 Front view

2.3.1.1 Area 1

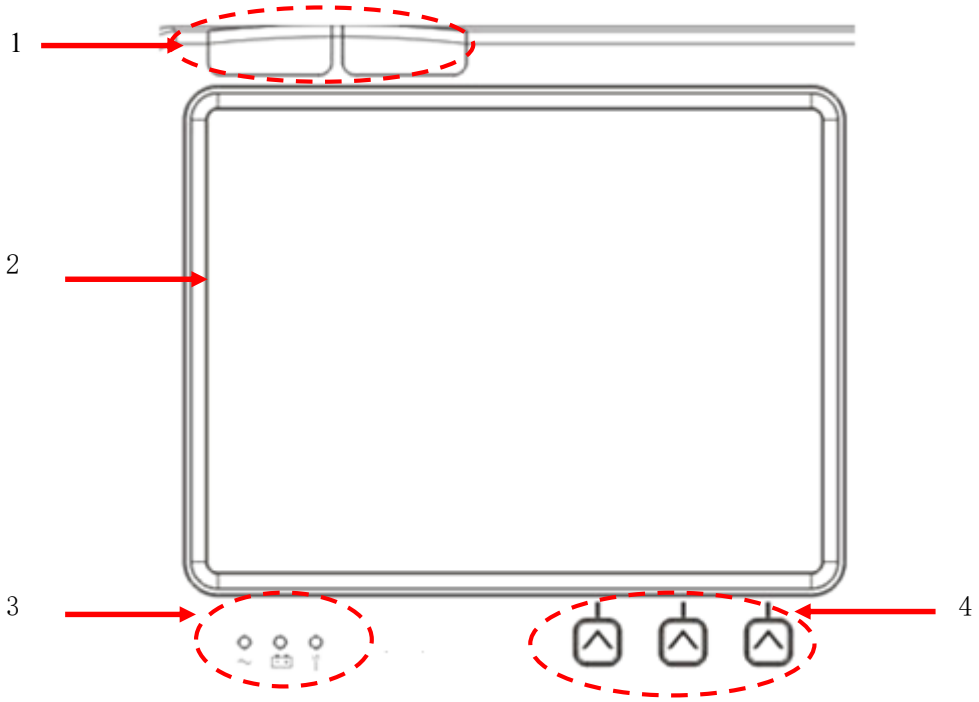


Figure 2-2 Area1

1	Alarm lamp (left: physiological alarm lamp; right: technical alarm lamp)		
2	Display screen		
3	~	AC indicator	Green: When connected with AC power supply
			Off: When disconnected with AC power supply
	- +	Battery indicator	Yellow: When battery is being charged
			Green: When battery is fully charged or operate on battery power
			Off: When no battery is installed or battery malfunctions
		Service indicator	Flash: When auto test or user test fails
			Off: When the unit operates properly
4	Soft buttons: one-to-one correspondence to the soft button labels on display screen. The buttons have different functions under different operating mode.		

2.3.1.2 Area 2

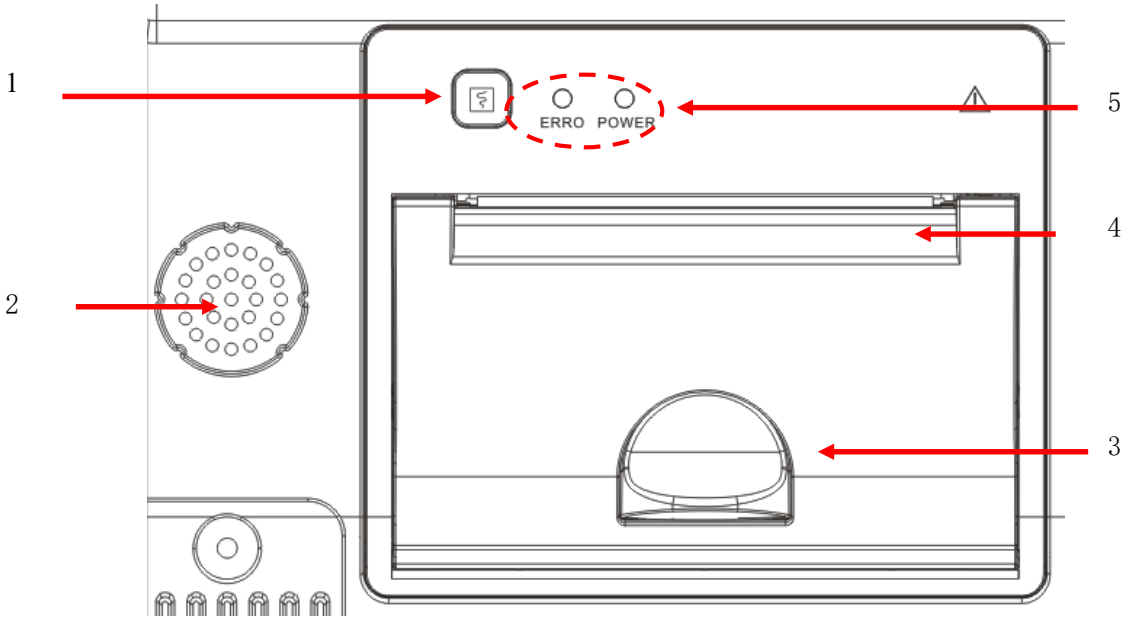


Figure2-3 Area 2

1	Record button: Press to start or stop recording.	
2	Loud speaker: Give out alarm sounds and voice prompt	
3	Latch: Press to open the recorder door	
4	Paper exit	
5	Error indicator	Red: Recorder error, for example, No paper, Recorder door open, etc.
		Green: Recorder operates properly
	Power indicator	Green: Recorder is powered on
		Off: An error occurred to the recorder or the recorder is not installed correctly

2.3.1.3 Area 3

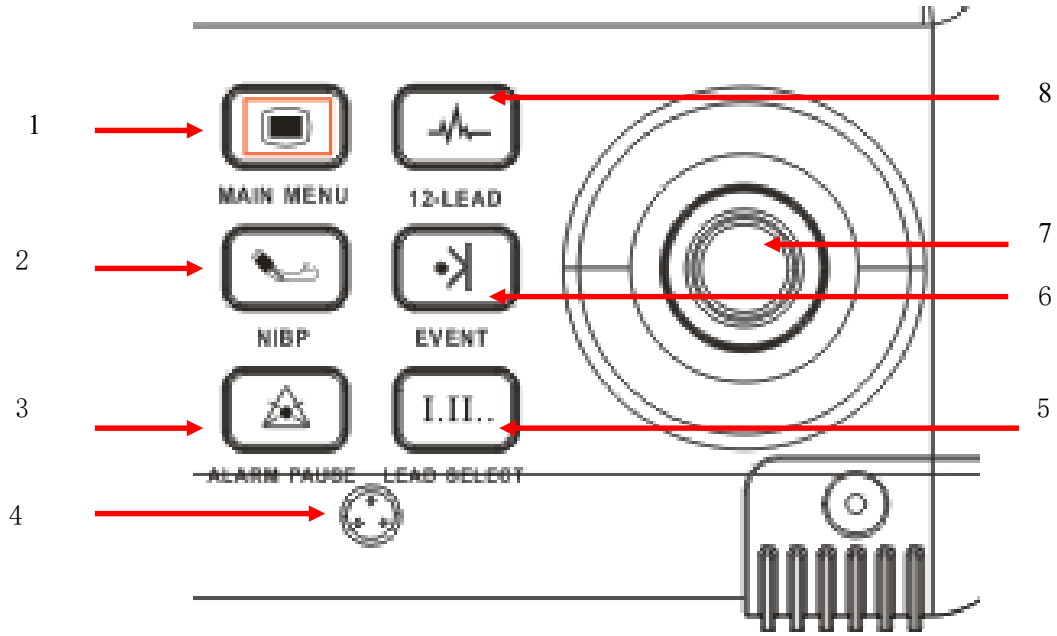


Figure2-4Area 3

1		Main Menu	Press to pop up or exit the main menu.
2		NIBP Start	Press to start or stop NIBP measurement.
3		Alarm Pause	Press to pause alarms
4	/	Loud Speaker	Used to record voices in AED mode
5	I.II..	Lead Select	Press to select lead for the first ECG waveform.
6		Event	Press to mark some specific events, or to pop up or exit [MARK EVENT SETUP] menu.
7	/	Rotary Knob	Used to select menus and confirm settings; rotate it right or left to move the cursor and press it to select.
8		12-lead	Press to enter or exit 12-lead screen in monitor mode.

2.3.1.4 Area 4

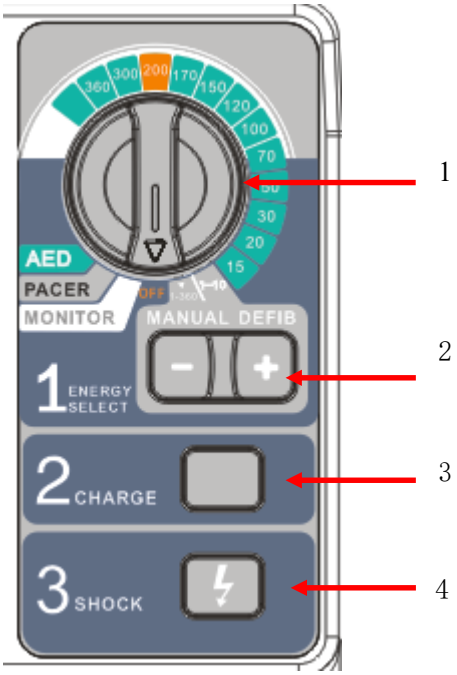


Figure2-5 Area 4

1	Mode Selector: Rotate to switch operating mode, including AED, Pacer, Monitor, Manual defibrillation and OFF mode, and select energy level in Manual defibrillation mode. The defibrillator/monitor will shut down when in OFF position for more than 10s.
2	Energy Select button: Press “-” and “+” to decrease and increase energy level respectively in manual defibrillation mode.
3	Charge button: Press to charge the defibrillator.
4	Shock button: Press to deliver defibrillator energy to patients

2.3.2 Right View

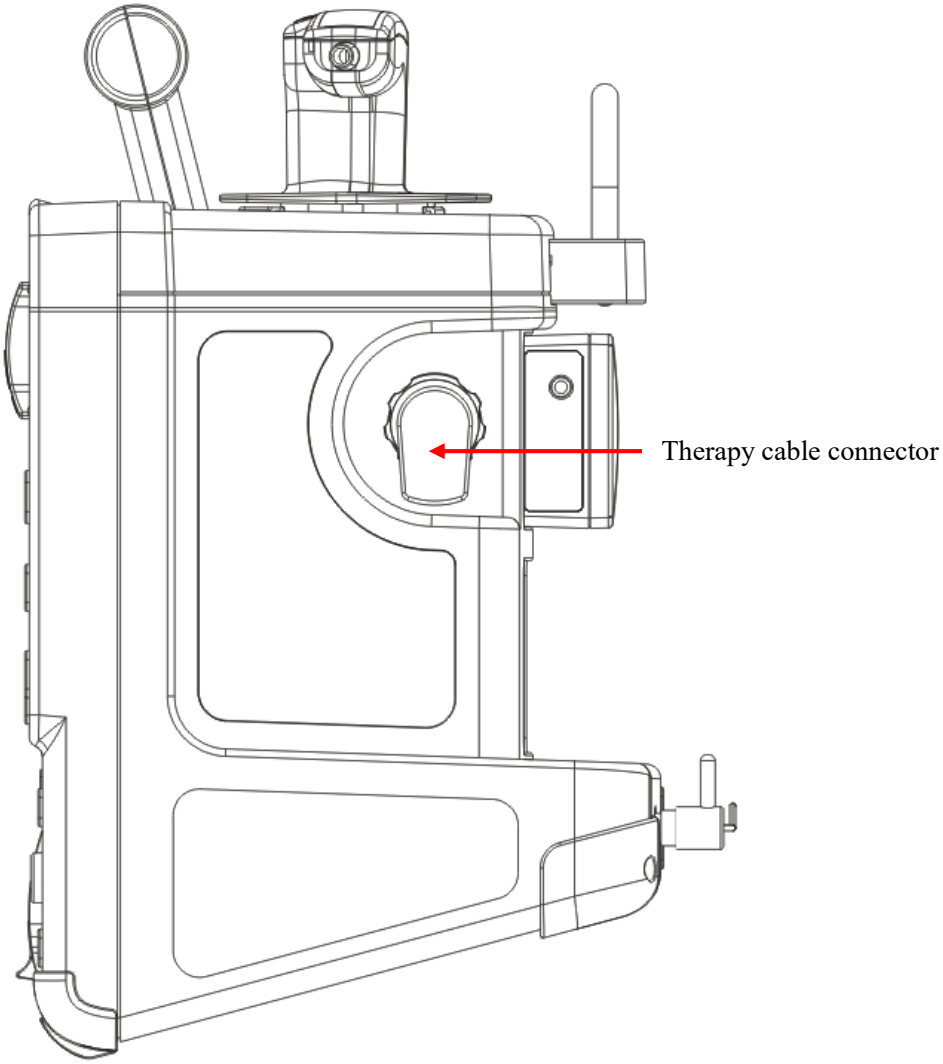


Figure 2-6 Right view

2.3.3 Left View

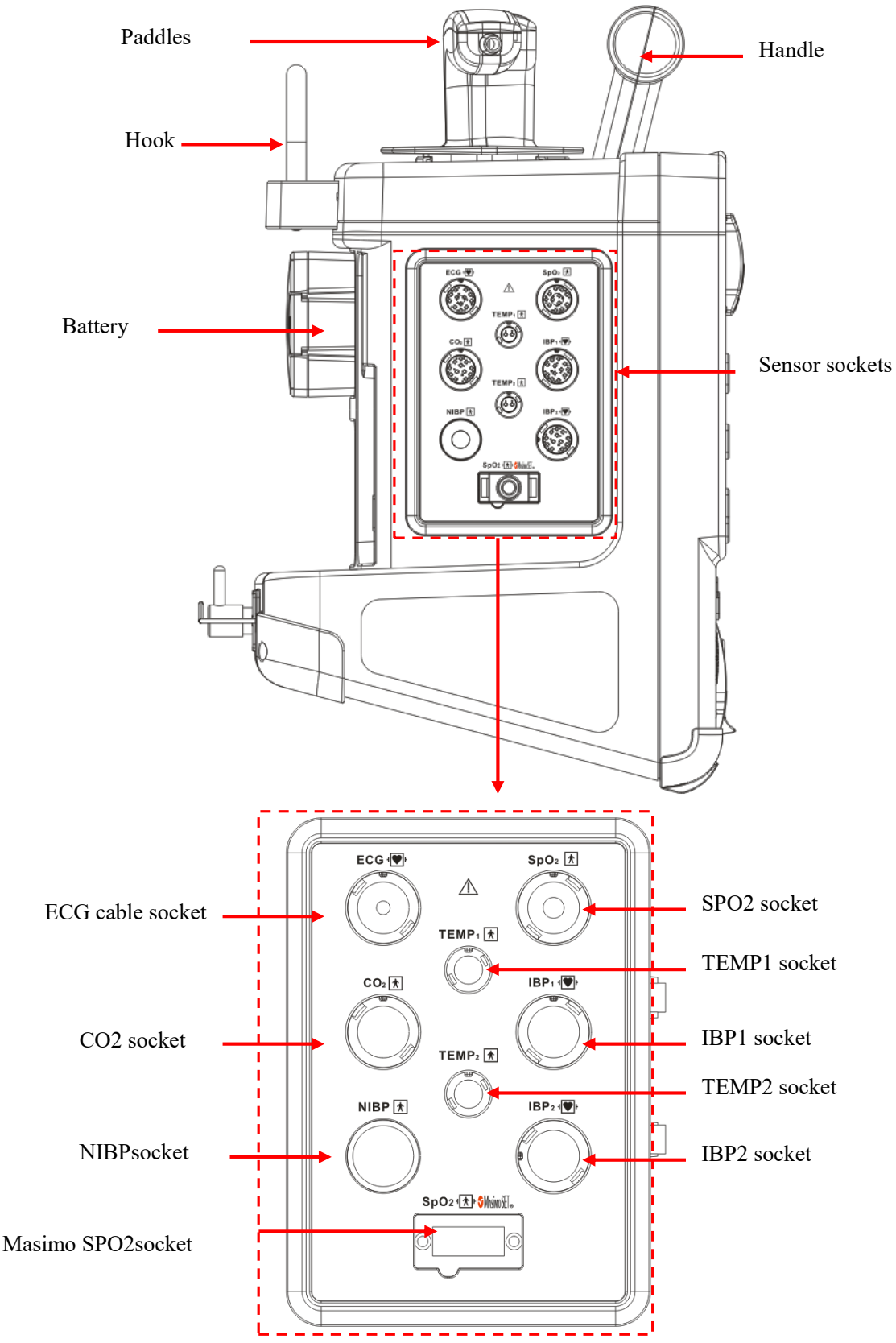


Figure 2-7 Left view

2.3.4 Rear View

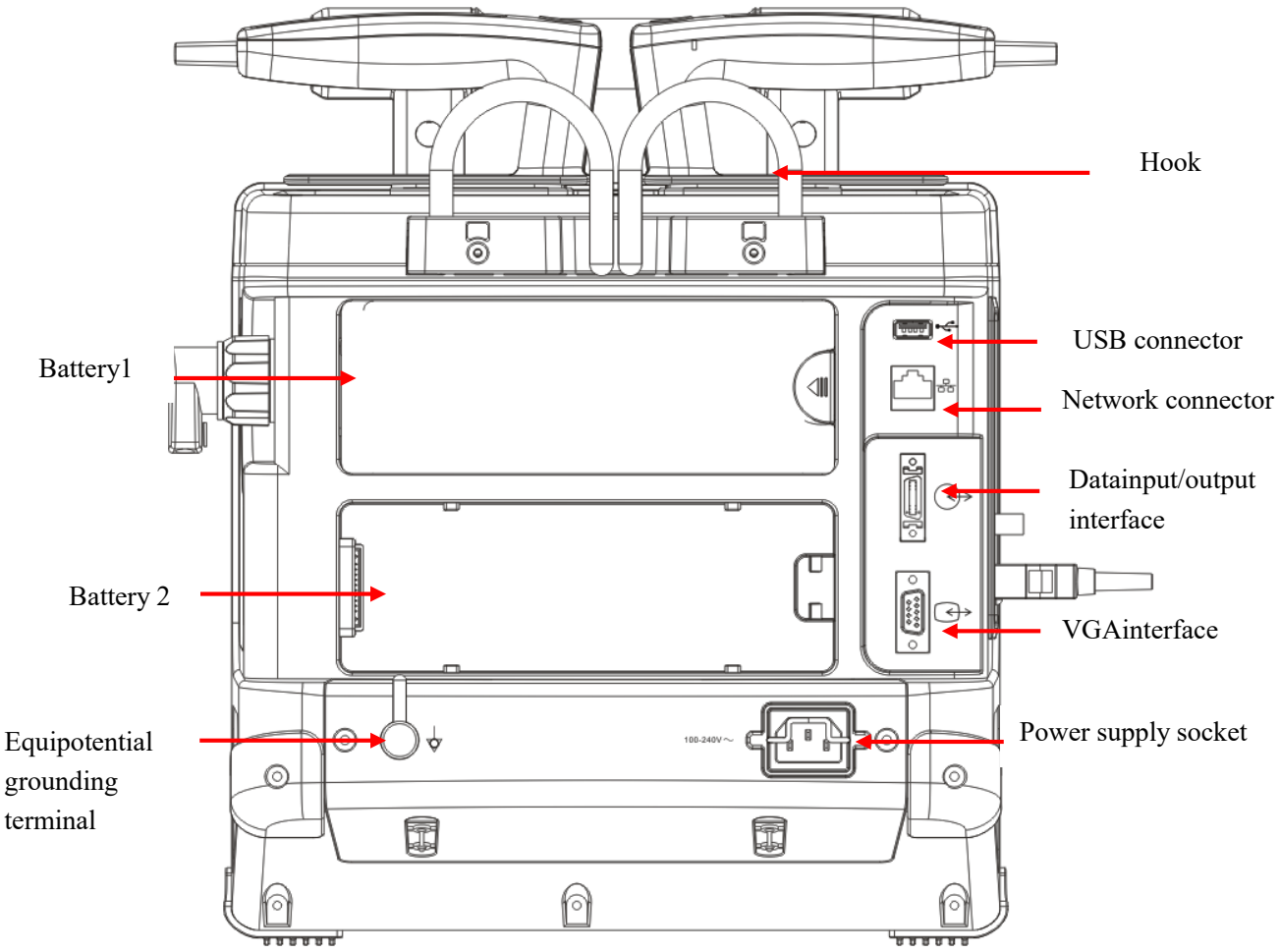
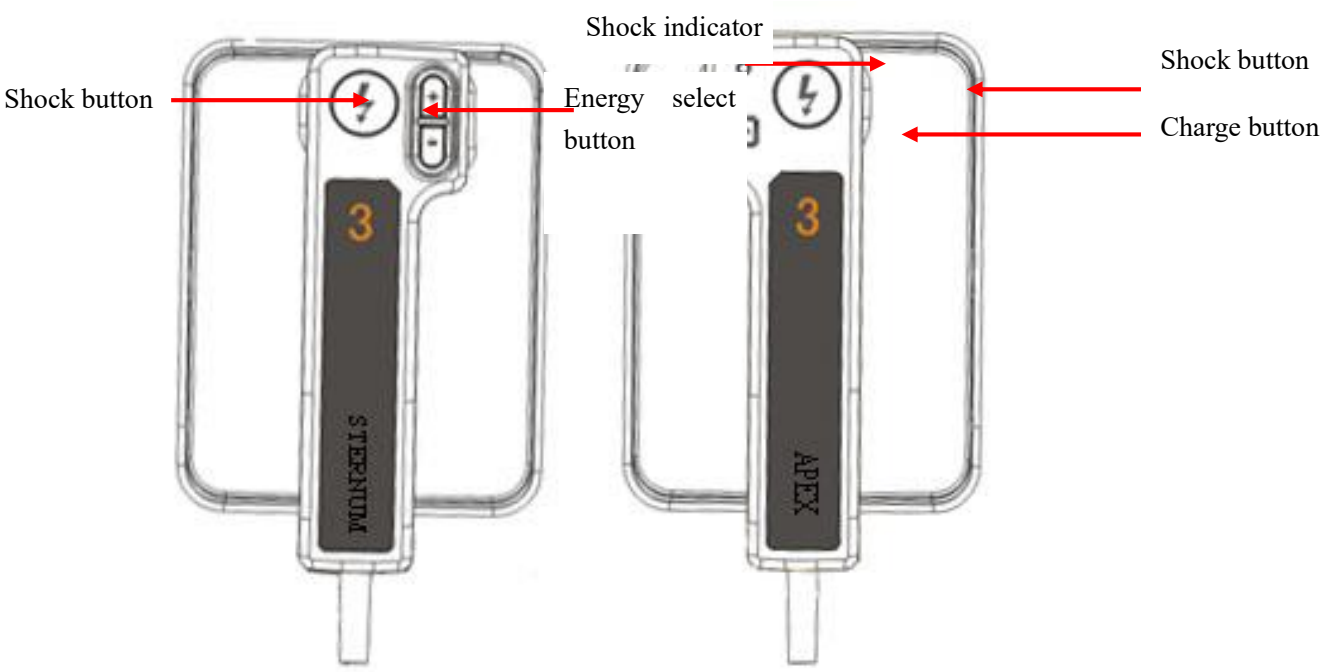


Figure 2-8Rear view

⚠Warning

- **Only the analog or digital equipment compliant with the specified IEC standards (like IEC 60950 standard for data processing equipment, IEC 60601-1 standard for medical equipment, etc.) are allowed to be connected to the defibrillator/monitor. The configuration of these equipment should comply with the valid version of IEC 60601-1 standard. The person who connects external equipment to the signal I/O interface should configure the medical system and ensure the medical system complies with IEC 60601-1 standard. If you have any question, please contact Okuman.**
- **When therapy cable socket, network connector and other connectors are connected to different equipment, the leakage current should not exceed the limit.**

2.3.5 External Defibrillation Paddles



Sternum Paddle Apex Paddle

2.4 Screen Display

The defibrillator/monitor is equipped with TFT LCD and can display parameter values, waveforms, alarm message, system time, network connection status, battery status and other status messages. Take the display screen in manual defibrillation mode as an example:

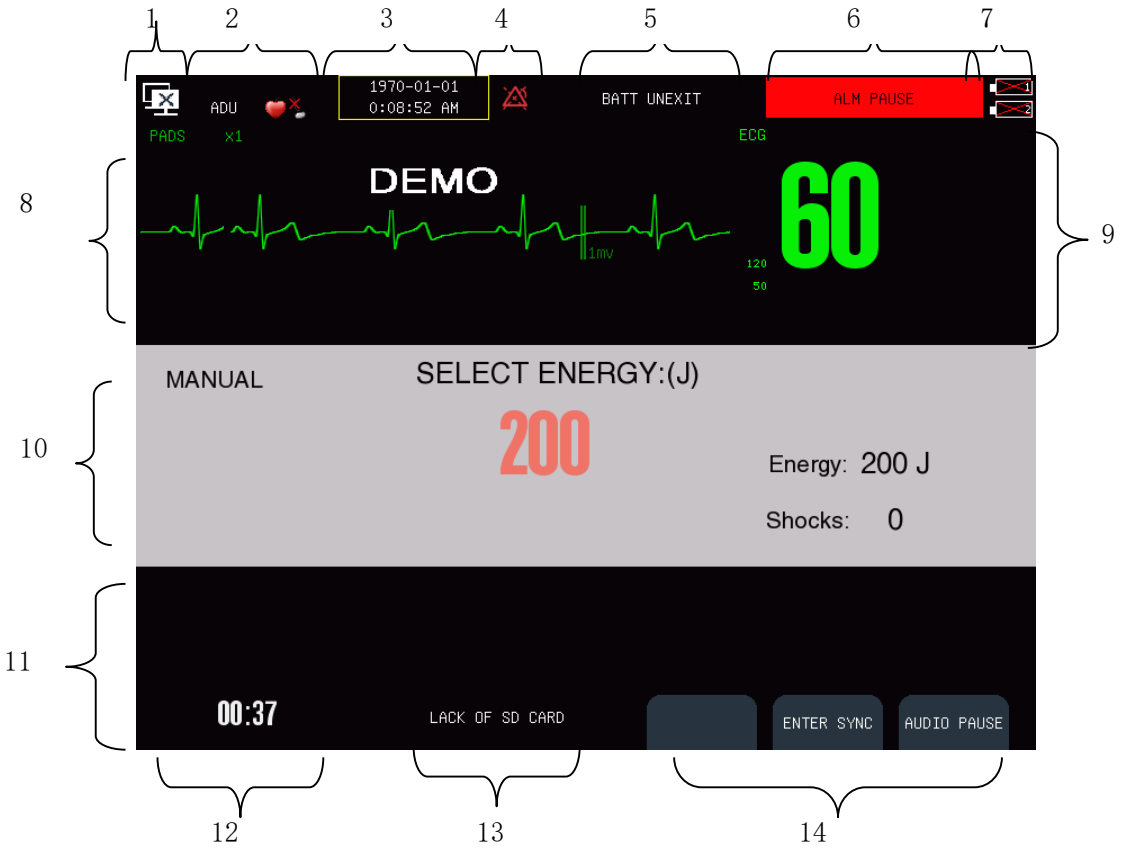


Figure 2-11 Main screen

1. **Network Connection Icon**
   - Show the network connection status between defibrillation/monitor and central monitoring system.
   - indicating that the network has not been connected successfully;
   - indicating that the network has been connected successfully;
   - Select the network connection icon to directly access [NETWORK SET] menu.
2. **Patient Information Area**
   - Display patient name, patient type, bed number, pacemaker status and so on.
   - indicates patient with pacemaker; indicates patient without pacemaker.
   - Select here to directly access [Patient Info] menu.
3. **System Time**
   - Display the system time
   - Select here to directly access [TIME SETUP] menu.
4. **IconsArea**

   indicates alarm pause.

   indicates alarms off.
5. **Technical alarm message area**
   - Display technical alarm message. When there are multiple messages, they will be displayed circularly.
   - Select here to directly access [TECHNICAL ALARMS] window.
6. **Physiological alarm message area**
   - Display physiological alarm message. When there are multiple messages, they will be displayed circularly.

- Select here to directly access [ALARM EVENT REIVEW] window.

7. **Battery Status Icon**
   - Indicate the status of two batteries. Refer to ***Battery*** for detail.
8. **Waveform Area**
   - Display the measurement waveforms with the waveform name at the left top corner.
9. **Parameter Area**
   - Display the measured value and the set alarm limit of each physiological parameter.
   - The color of a certain parameter is the same as that of its waveform.
   - Select each parameter area and the corresponding setup menu will be displayed.
10. **Manual Defibrillation Message Area**:
    - Display the energy selected, shock times and relative prompt message.
11. **Auxiliary Parameter Area**
    - Display measured value of other parameters except for ECG.
12. **Elapsed Time**
    - Display the operating time after this starting up
13. **Status Message Area**
    - Display status message and prompt message.
14. **Soft Button Labels**
    - These three labels are one-to-one corresponding to the three soft buttons below them. They will vary with different operating modes and display screens. Blank label indicates the corresponding soft button is invalid.

2.5 Operating Mode

The defibrillator/monitor is applicable to pre-hospital and in-hospital use and must only be used by qualified medical personnel who have received enough operation training, basic life support training and advance cardiac life support training.

The defibrillator /monitor supports four operating modes, including manual defibrillation mode, monitor mode, pacer mode and AED mode.

2.5.1 Manual Defibrillation Mode

In manual defibrillationmode, operators analyze patient’s cardiacrhythm and operatefollowing the steps below according to needs:

1. Select manual defibrillation mode and adjust energy level if necessary;
2. Charge the defibrillator;
3. Shock.

Synchronized cardioversionis also provided in manual defibrillation mode.

Manual defibrillation is applicable to patients suffering from ventricular fibrillation and ventricular tachycardia and without respiration and pulse; synchronized cardioversion is used to stop atrial fibrillation.

Contraindications

Do not conduct manual defibrillation on patients of any kind below:

- With response
- With autonomous respiration
- Can touch the pulse

2.5.2 Monitor Mode

In monitor mode, the defibrillator/monitor is applicable to adult, pediatric and neonate bedside monitoring and can be used to monitor, display, store, review and transfer multiple physiological parameters including ECG, RESP, TEMP, SpO_2, NIBP, IBP and CO_2.

⚠Attention

- **12-lead ECG cable is optional for DFM 600, while 5-lead ECG cable for DFM 800.**

2.5.3 Pacer Mode

Pacer mode provides noninvasive pacing therapy. Noninvasive pacing is used to conduct therapy for bradycardia patients.

Contraindications

Noninvasive pacing cannot be used for ventricular fibrillation therapy. Noninvasive pacing should be used with cause in case of hypothermia.

2.5.4 AED Mode

In AED mode, the defibrillator/monitor analyzes patient's cardiac rhythm automatically and gives "Shock Advised" or "No Shock Advised" prompts. What's more, the defibrillator/monitor can guide operators to conduct defibrillation through voice prompt and display prompt message on the screen as well.

AED is applicable to sudden cardiac arrest patients of the following kinds:

- Without response
- Without respiration or Not breathing properly

Only conduct defibrillation on children below 8 years old in manual defibrillation mode.

Contraindications

Do not conduct AED on patients of any kind below:

- With response
- With normal respiration

Chapter 3 Installation

⚠Warning

- **The defibrillator/monitor must be installed by the personnel specified by Okuamn.**
- **With copyright reserved, any person shall not falsify, photocopy or exchange the software in any manner whatsoever without prior written permission of Okuman.**
- **When the defibrillator/monitor is connected with other electrical equipment as a combination with specific function, if users could not confirm the combination has no danger (for example, the electric shock hazard caused by the accumulated leakage current) from the specifications of each equipment, please contact the specialist of Okuman or the hospital to ensure the combination is safe.**
- **Only the analog or digital equipments compliant with the specified IEC standards (like IEC 60950 standardfor data processing equipment, IEC 60601-1 standardfor medical equipment, etc.) are allowed to be connected to the defibrillator/monitor. The configuration of these equipment should comply with the valid version of IEC 60601-1 standard. The person who connects external equipment to the signal I/O interface should configure the medical system and ensure the medical system complies with IEC 60601-1 standard. If you have any question, please contact Okuman.**

3.1 Unpack and Check

Carefully unpack the equipement and accessories from the packaging box, and properly keep the packing materials for future transport or storage. Please check the accessories according to the package list.

- Check whether there is any mechanical damage;
- Check all the exposed cables and plug in some accessories for test.

Any problems should be immediately reported to the Service Department of our company or our agents.

⚠Warning

- **This equipment may suffer from microbial contamination during transport, storage or use. Please check whether the packaging is intact, especially for the disposable accessories, and do not use those with any damage.**
- **The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. Keep the packaging material out of the reach of children.**

3.2 Connect AC Power Cord

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

Use the power cord provided along with the equipment. Connect the power plug to the grounded three-wiresocket.

⚠Attention

- **Plug the power cord into the dedicated hospital socket.**
- **If battery is provided, you must charge the battery after the transport or storage of the monitor. If you directly turn on the monitor without connecting the AC power, itmay not work because of low battery. Connect the monitor to AC power supply and the battery will be charged whether the monitor is turned on or not.**

3.3 Power on

1. Before power on, please check whether there is mechanical damage on the defibrillator/monitor and whether the external cables and accessories are connected correctly.
2. Insert the power cord into AC power supply socket. If battery is used to supply power, make sure that there is adequate battery power.
3. Rotate the mode selector to the desired operating mode and the system performs self-test. First the left alarm lampturns red and right turns blue, and then left turns yellow and right turns blue.
4. After self-test, startup picture disappears and the defibrillator/monitor enters the selected operating mode.

⚠Warning

- **If any damage to the equipment or any error message is found, do not use the equipment for patient monitoring. Please contact the biomedical engineer of your hospital or maintenance engineer of Okuman.**

⚠Attention

- **If there is significant error in the self-test process, the system will give an alarm.**
- **Check all the available monitoring functions and make sure they work properly.**

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Chapter 4 Basic Operation

4.1 Using the Main Menu

How to access main menu:

In pacer, monitor and manual defibrillation mode, press button on the front panel to access [MAIN MENU] and perform operations and settings.In AED mode, the button is unavailable.

Figure 4-1 Main menu

⚠Attention

- **All settings you've made will be saved and memorized by the system without being changed due to power failure or power interruption, unless you restore the factory default settings manually.In case of power interruption, the mointor will save all the settings and saved patient data; when restarting the monitor, the monitor will restore to the settings before power interruption.**

4.2 General Settings

4.2.1 Setting the System Time

1. Access [MAIN MENU]→[CONFIG SETUP]→enter the password→[GENERAL SETUP];
2. Select [DATE FORMART] and select[yyyy-mm-dd] or [[dd-mm-yyy];
3. Select [TIME FORMAT] and select [12 HOURS] or [24 HOURS];
4. Select [TIME SETUP] and adjust the system according to your local time;
5. Or select the system time area on the main screen to enter [TIME SETUP] menu and adjust the system

according to your local time;

6. Select [UPDATE SYSTEM TIME] to save the system time.

4.2.2 Changing System Language

1. Access [MAIN MENU] →[CONFIG SETUP]→enter the password→[GENERAL SETUP];
2. Select [LANGUAGE SELECT] and select there quired system language.

4.2.3 High Contrast Display

High contrast display is helpful for operators to view the contents displayed on the screen in the environment with strong light.

In pacer, monitor and manual defibrillation mode, access [MAIN MENU], select [HIGH CONTRAST] and enter high contrast display with [HIGH CONTRAST] turning to [GENERAL DISPLAY]simultaneous sly.Select [GERNERAL DISPLAY] to exit high contrast display.

In AED mode, press [HIGH CONTRAST] soft button to enter high contrast display and press [NORMAL] soft button to exit the high contrast display.

4.2.4 Adjusting Screen Brightness

1. Access [MAIN MENU]→[MAINTENANCE]→[BRIGHTNESS];
2. Select the screen brightness level from 1 to 10. 1 is the darkest and 10 is the brightest.

4.2.5 Adjusting Key Volume

1. Access [MAIN MENU]→[MAINTENANCE]→[KEY VOL];
2. Select the key volume from 0 to 9. 0 means off and there is no sound when pressing buttons.

4.3 User Maintenance

Access [MAIN MENU]→[MAINTENANCE]→[USER MAINTAIN]→enter the password.

- Select [WAVE LINE] and select the wave line size from [BOLD], [MED] and [FINE].
- Select [WAVE DARW] and select the draw wave mode from [COLOR] and [MONO].

4.4 View Monitor Information

Monitor information is mainly for viewing the software and hardware version operated by the defibrillator/monitor, so as to facilitate the manufacturer to maintain and trace the monitor.

1. Access [MAIN MENU] →[MAINTENANCE] →[MONITOR INFO];
2. Select [SOFTWARE VERSION] and [HARDWARE VERSION] and view the software version and hardware version of the defibrillator/monitor respectively.

4.5 Module Setup

To switch parameter modules on or off:
Access [MAIN MENU] →[MAINTENANCE] → [MODULE SETUP] and select a certain parameter module to switch it on or off as needed.
If a parameter module is switched off, it stops working and its parameter value and waveform will not be displayed on the screen.

4.6 Demo Function

To enable Demo function:
Access [MAIN MENU], select [DEMO] and enter the password.

⚠Warning

- **Demo waveform is a kind of simulation of waveforms, which is made by the manufacturer only to demonstrate the machine performanceand help users to conduct training.In actual clinical use, the demo function should be disabled, because the medical staff may mistake it as the monitoring waveforms and parameters of the patient, which affects monitoring and delays diagnosis and treatment.**

4.7 Indication and Contraindication

Indication

- Pulse-free VT: High frequency depolarization of a focus in the ventricular muscle. Stimulation passes through abnormal ventricles. The absence of the P wave is characteristic of a large QRS complex.
- Ventricular fibrillation (VF)

Contraindication

- Digital toxicity and arrhythmia triggered by catecholamine (homogeneous depolarization in these rhythms)
- Multifocal atrial tachycardia

4.8 Side Effects and Patient Population

Side Effect

- May cause unwanted side effects such as skin burns.

Patient Population

- Infant, Pediatric, Adult

Chapter 5 Patient Manage

5.1 Quick Admitting Patient

If there is no time to enter patient information in detail under emergency, you can select the [QUICK ADMIT] to admit the patient quickly and only enter patient type and pacemaker status.

Specific steps:

Access [MAIN MENU]→[PAT FILE MANAGE]→[PATIENTMANAGE]→[QUICKADMIT].

- If no patient is admitted, dialog box [Whether to apply the monitor data to the patient to be admitted?] will be displayed. Select [YES], the existing monitor data will be applied to the patient to be admitted and the [Patient Info] menu will be displayed for entering patient type and pacemaker status. Select [NO], the existingmonitor data will not be saved and the [Patient Info] menu will be displayed for entering patient type and pacemaker status.
- If a patient has been admitted, dialog box [Discharge Current Patient and Admit New Patient?] will be displayed. Select [YES], the admitted patient will be discharged and the [Patient Info] menu will be displayed for entering patient type and pacemaker status. Select [NO] to cancel admitting patient.

5.2 Admitting Patient

1. Access [MAIN MENU] →[PAT FILE MANAGE] →[PATIENTMANAGE] →[Admit]
2. If no patient is admitted, dialog box [Whether to apply the monitor data to the patient to be admitted?] will be displayed. Select [YES], the existing monitor data will be applied to the patient to be admitted and the [Patient Info] menu will be displayed for entering patient information in detail. Select [NO], the existingmonitor data will not be saved and the [Patient Info] menu will be displayed for entering patient information in detail.
3. If a patient has been admitted, dialog box [Discharge Current Patient and Admit New Patient?] will be displayed. Select [YES], the admitted patient will be discharged and the [Patient Info] menu will be displayed for entering patient information in detail. Select [NO] to cancel admitting patient.
4. Enter patient information in detail in [Patient Info] menu, especially entering [PAT TYPE] and [PACE] correctly.
   - [PAT TYPE]: it is important to select correct patient type. It decides the measurement algorithm of the defibrillator/monitor and the range of alarm limits and safety limits.
   - [PACE]: if it is set to [ON], when pacemaker signal is detected, it will be indicated by " ' " above the ECG wave formand symbol will be displayed beside patient type; when it is set to [OFF], symbol will be displayed.

⚠Warning

- **When the patient type changes or admit a new patient, the system will load the default configuration. Usually, the alarm limits should be verified before patient monitoring to ensure that these alarm limits suit your patient.**
- **For patients without pacemaker, you should set [PACE] to [OFF]; otherwise, the system cannot detect arrhythmias associated with ventricular premature beats (including PVCs count)as well as perform ST segment analysis.**

- **For patients with pacemaker, you should set [PACE] to [ON]; otherwise, pacing pulse may be counted into normal QRS waves, causing the alarm "ECG signal is too weak" cannot be detected.**

5.3 Patient Information

The patient information can be edited or changed after a patient has been admitted or when the patient information is incomplete in monitor, manual defibrillation and pacer mode.

1. Access [MAIN MENU] → [PAT FILE MANAGE] →[PATIENT MANAGE] →[Patient Info];
2. Or select patient information area and enter [Patient Info] menu;
3. In the pop-up menu, edit or change patient information.

5.4 Discharging Patient

How to discharge a patient:

1. Access [MAIN MENU]→[PAT FILE MANAGE]→[PATIENT MANAGE]→[DISCHARGE];
2. Dialog box [Discharge Current Patient. Whether to Archive Patient Data?] will be displayed, select [YES] or [NO].
   - [YES]: discharge the patient successfully and the patient data are saved and can be reviewed in [PATIENT FILE] window.
   - [NO]: cancel patient discharging.

⚠Attention

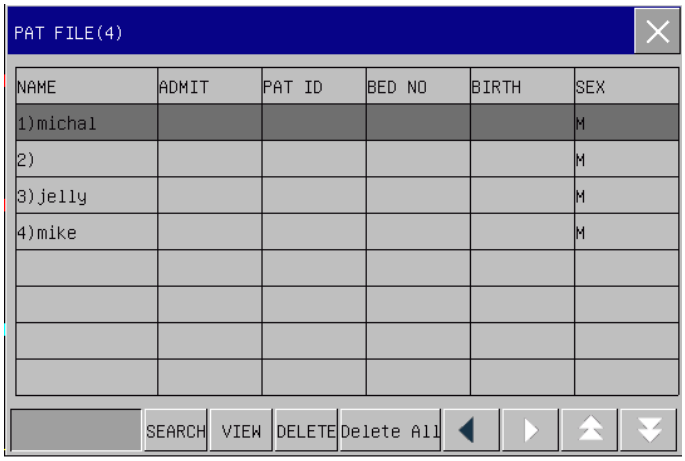
- **After discharging the patient, the [PACE] defaults to [OFF].**

5.5 Patient File

After discharging the patient, the patient data will be stored and can be reviewed in patient file window.

How to enter patient file window:

Access [MAIN MENU]→[PAT FILE MANAGE]→[PATIENT FILE] and enter patient file window, as shown below:



The following operations can be performed in the patient file window:

(1) View how many patient files has stored. For example, [PATIENT FILE (4)] means there are 4 patient files listed in patient file window.

(2) Search the patient file

Select the blank box before [SEARCH], enter the search criteria in the pop-up keyboard and select enter key. Then Select [SEARCH] and all the patient files that meet the search criteria will be displayed in the patient file window.

(3) View patient file

- Select ◀ or ▶ and press the knob to show more patient information not in current view.
- Select ⏫ or ⏬ and press the knob to show more patient files not in current view.
- Select a certain patient file, press the knob and then rotate the knob to select [VIEW], and the [REVIEW] window will be displayed, as shown below:

What can be viewed about this patient includes patient information, patient event, physiological alarm event, 12-lead diagnosis report, NIBP measurement result,trend graph and parameter waveforms.

⚠Warning

- **The physiological alarm events will be maintained when the alarm system is powered down.**

(4) Delete patient file

- Select a certain patient file, press the knob, rotate the knob to select [DELETE], select [YES] and this patient file will be deleted.
- Select [Delete All] and select [YES], all the patient files will be deleted.

5.6 Transferring Patient Data

How to transfer the patient data to USB storage device:

Access [MAIN MENU]→[PAT FILE MANAGE]→[TRANSFER PATIENT DATA]. In the pop-up dialog box “Transfer Current Patient Data to USB?”, select [YES]; select [NO] to cancel the transferring.

Chapter 6 Configuration Settings

How to access configuration setup menu:
Access [MAIN MENU]→[CONFIG SETUP]→enter the password and configuration setup menu will be displayed.

6.1 Factory Settings

Select [FACTORY DEFAULT] and select [OK] in the pop-up dialog box, the factory default settings will be restored.

6.2 General Settings

General settings include the following items:

- [DEPARTMENT]: enter the department name, up to 50 characters.
- [PAT TYPE]: select patient type from[ADU](adult), [PED](pediatric) and[NEO](neonate)
- [LANGUAGE SELECT]: select the system language.
- [DATE FORMAT]: select data format from [YEAR-MON-DATE] and [DATE-MON-YEAR].
- [TIME FORMAT]: select time format from [12HOURS] and [24HOURS].
- [TIME SETUP]: set the system time according to local time, and then select [UPDATE SYSTEM TIME] to save the settings.

6.3 Manual Defibrillation Settings

Manual defibrillation settings include the following items:

- [EXTERNAL DEFIB ENERGY]: select the default energy for external manual defibrillation. The available energy level includes 2J,5J, 10J, 50J, 100J, 150J, 170J, 200J and 300J.
- [INTERNAL DEFIB ENERGY]:select the default energy for internal manual defibrillation. The available energy level includes 2J,5J, 10J, 20J, 30J and 50J.
- [AUTO DISARM TIME]:select the time to energy auto disarm, including 30s, 60s, 90s and 120s.
- [SYNC KEEP]: toggle between [ON] and[OFF]. [ON] means the defibrillator/monitor is still in synchronized cardioversion mode after a synchronized shock. [OFF] means the defibrillator/monitor will auto exit synchronized cardioversion mode after a synchronized shock.
- [REMOTE SYNC INPUT]: select [ON] or[OFF] to activate or deactivate the remote synchronized cardioversion function respectively.
- [MONI PARAM.1]: select a parameter except for ECG for monitoring in manual defibrillation mode. Available parameter includes [SPO2], [NIBP], [CO2], [IBP1], [IBP2], [TEMP] and [RESP]. [OFF] means no parameter other than ECG will be monitored.
- [CHARGE TONE VOL]: select the battery charge tone volume. Available volume level includes [HIGH], [MED]and[LOW];
- [CONTACT IMPEDANCE INDICATOR]: toggle between[ON] and[OFF].[ON] means there will be contact impedance indicator displayed in manual defibrillation mode.

6.4 AED Settings

AED settings include the following items:

- [SERIAL SHOCK TIMES]: set the serial shock times, including 1,2 and 3.
- [FIRST SHOCK ENERGY]: select the energy for the first shock. Available energy level includes 100J, 150J, 170J, 200J, 300J and 360J.
- [SECOND SHOCK ENERGY]: select the energy for the second shock. Available energy level includes 100J, 150J, 170J, 200J, 300J and 360J. Not lower than the first shock energy.
- [THIRD SHOCK ENERGY]: select the energy for the third shock. Available energy level includes 100J, 150J, 170J, 200J, 300J and 360J. Not lower than the second shock energy.
- [AUTO DISARM TIME]: select the time to energy auto disarm, including 30s, 60s, 90s and 120s.
- [PRE-SHOCK CPR TIME]: select the pre-shock CPR time, including OFF, 30s, 60s, 90s, 120s, 150s and 180s.
- [CPR TIME]: select the CPR duration, including 30s, 60s, 90s, 120s, 150s and 180s.
- [CPR METRONOME]: select [ON] or[OFF] to activate or deactivate the CPR metronome function respectively.
- [CPR MODE]: select the CPR mode, including[30: 2], [15:2] and [ONLY PRESS].
- [NSA PROCESS MODE]: select the NSA process mode, including [CONTINUE ANALYZE] and [CPR].
- [VOICE PROMPT]: toggle [ON] and [OFF]. [ON] means there will be voice prompt to guide defibrillation in AED mode.
- [VOICE VOLUME]: select the volume of voice prompt in AED mode, including [HIGH], [MED] and[LOW].
- [VOICE INTERVAL]: select the interval of voice prompt in AED mode, including close, 30s, 60s, 90s, 120s, 150s and 180s.
- [AUDIO RECORDING]: select [ON] or [OFF] to activate or deactivate the audio recording function in AED mode respectively.

6.5 Pacer Settings

Pacer settings include the following items:

- [PACER RATE]: select the default pacing rate efrom 40ppm to 170ppm.
- [PACERCURRENT]: select the default pacing current from 0mA to 200mA.
- [DEFAULT PACERMODE]: select the default pacing mode from [DEMAND PACING], [FIXED PACING].

6.6 12-Lead Settings

- [REPROT FORMAT]: select the report format of 12-lead ECG, including 3×4 and 4×3.

6.7 MarkEvent Settings

Mark event settings include the following items:

- [EVENT WAVE 1]: select waveform from [CLOSE], [II], [I], [III], [PLETH] and so on.
- [EVENT WAVE 2]: select waveform from [CLOSE], [II], [I], [III], [PLETH] and so on.

- [EVENT WAVE 3]: select waveform from [CLOSE], [II], [I], [III], [PLETH] and so on.
- [EVENT A] defaults to [GENERIC].
- [EVENTB], [EVENTC], [EVENTD], [EVENTE], [EVENT F], [EVENT G], [EVENTH]: the following events can be selected: [ENINEPHRINE], [LIDOCAINE], [ATROPINE], [NITROGLYCERIN], [MORPHINE], [CANNULA], [VENOUS TRANSFUSION], [ADENOSINE], [AMIODARONE], [VASOPRESSIN], [ISUPREL], [DOPAMINE], [ASPININ], [OXYGEN] and [CPR].
- [CUSTOM EVENT 1], [CUSTOM EVENT 2], [CUSTOM EVENT 3], [CUSTOM EVENT 4]: The users can define the events by themselves, up to 20 characters.

6.8 Record Settings

Record settings include the following items:

- [RT RECORD TIME]:select the real-time record time, including 8s, 16s and 32s.
- [PAPER SPEED]: select the paper speed, including 12.5mm/s, 25mm/sand50mm/s.
- [ACTUAL ENERGY OUTPUT]: toggle between [ON] and[OFF]. [ON] means the actual delivered energy will be recorded on record paper when recording shock events.
- [GRID]: toggle between [ON] and[OFF]. [ON] means recording with grid.
- [AUTO RECORD]: the following reports and events will be recorded automatically when they are triggered if they are set to [ON]: [CHARGE EVENT], [SHOCK EVENT], [Mark Event], [12-LEAD REPORT] and [AUTO TEST REPORT].

6.9 Test Settings

- [USER TEST PROMPT]: toggle between [ON] and[OFF]. [ON] means the defibrillator/monitor will give a prompt when the user test is overdue.
- [AUTO TEST TIME]: set the time when the defibrillator/monitor conduct daily auto test. Available test time includes 0:00, 1:00, 2:00, 3:00, 4:00 and5:00.

6.10 Network Settings

In this menu, users can set the network bed number, local IP, subnet mask, server IP and MAC address.

When  is displayed, it means the defibrillator/monitor has been connected to central monitoring system successfully; however, when  is displayed, it means the defibrillator/monitor has not been connected to central monitoring system.

⚠Attention

- **The network bed number must be unique and cannot be the same as that of any other monitor connected to the central monitoring system, or it will cause signal deadlock because of the preemption of the central monitoring system channel.**
- **If the monitor system halted due to network bed number repetition, remove the network cable, turn off the monitor and restart. Reset the networks and then reconnect the network.**

Chapter 7 User Screen

This monitor provides two user screens in monitor mode: standard screen and 12-lead screen. User can get different screen messages from different screens.

7.1 Standard Screen

Standard screen can display waveforms of up to 4 channels with separate parameter display area based on the maximum configuration. The waveform on each channel is not fixedand you can change the position of each waveform as needed.

Switch to monitor modeand open the standard screen as shown below:

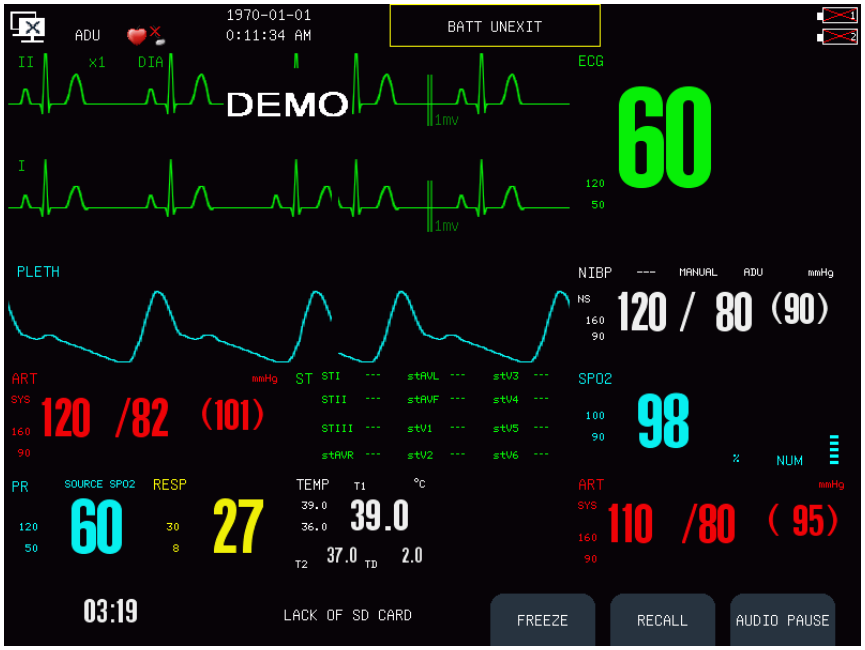


Figure7-1Standard Screen

On standard screen, the three soft button labels are [FREEZE], [REVIEW] and [ALARM RESET].

7.1.1 Freeze

You can freeze the displayed waveforms on the screen during patient monitoring and view the waveforms in detail. Totally 300 second frozen waveforms can be viewed.

Press [FREEZE] soft button and the [FREEZE] window will pop up as shown below:

Figure7-2Freeze window

In [FREEZE] window, select [REVIEW] and rotate the rotary knob to review the 300s frozen waveform on the screen. Select the [RECORD] and the waveforms selected in [WAVE 1], [WAVE 2], [WAVE 3] and [WAVE 4] and all parameter values at the frozen moment will be printed out by the recorder.
Press [FREEZE] soft buttonagain to exit frozen status.

7.2 12-lead Screen

12-lead screen can display ECG waveforms of 12 leads, including I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5 and V6, applicable to comprehensive observation of ECG waveforms when the lead type is 12-lead.

In monitor mode, press the button on the front panel to enter the 12-lead screen, as shown below:

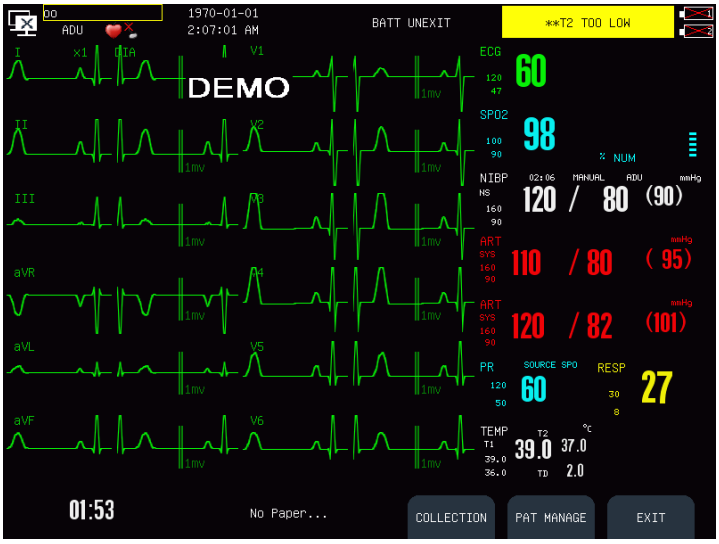


Figure7-312-lead Screen

The following operations can be performed on 12-lead screen:

1. Acquire and analyze ECG data
   Press [ACQUIRE] soft button to acquire and analyze 10 seconds ECG data of the patient and prompt message “Acquiring ECG…..” will pop up. After analysis, the diagnosis report will be displayed, and you can select [DIAG WAVE] to view the 10s ECG wave of 12 leads acquired and select [RECORD] to record this diagnosis report. While acquiring ECG data, please keep the patient still.
   All diagnosis reports are saved in the [12-LEAD REPORT REVIEW] window. Refer to ***12-lead Report Review***for detail.
2. Modify patient information

Press [PATIENT INFO] soft button to enter [Patient Info] menu and modify patient information.

Warning

- **Keep patient still while acquiring 12-lead ECG data, or the accuracy of ECG data will be affected.**
- **If the defibrillator/monitor is put in a mobile vehicle, please stop the vehicle when acquiring12-lead ECG data.**

⚠Attention

- **The LEAD SELECT button on front panel is unavailable after entering 12-lead screen.**
- **The ECG filter mode is fixed to diagnosis and cannot be changed while acquiring 12-lead ECG data.**
- **The MAIN MENU and EVENT button on front panel are unavailablewhile acquiring 12-lead ECG data.**

7.3 Tailoring Your Screens

You can tailor your monitor's screen by setting:

- Waveform sweep speed;
- Waveform display style;
- Parameter and waveform display color;
- Waveform exchange;
- Gain.

Here we take ECG as an example.

7.3.1 AdjustingWaveform Sequence

Adjusting waveform sequence means to arrange the waveform display order on the screen.
Access [MAIN MENU]→[WAVE SEQUENCE] and set [WAVE 1], [WAVE 2],[WAVE 3] and [WAVE 4].
[WAVE 1] is always ECG waveform with different sources under different operating modes. The source is lead"II"in pacer and monitormode and "Paddle"in manual defibrillation mode.

7.3.2 Changing the Waveform Sweep Speed

(a) Select ECG parameter and [ECG SETUP] menu will be displayed.
(b) Set [SWEEP] to 6.25mm/s, 12.5mm/s, 25mm/s or 50 mm/s;

7.3.3 Setting the Waveform Display Style

(a) Access [MAIN MENU]→[MAINTENANCE]→[USER MAINTAIN]→enter the password.
(b) Set [WAVE LINE] to [FINE], [MED](medium) or [BOLD] ;
(c) Set [WAVE DRAW] to [COLOR] or [MONO];

7.3.4 Setting the Display Color

(a) Select ECG parameter and [ECG SETUP] menu will be displayed;
(b) Set [DISPLAY COLOR] to [GREEN], [YELLOW], [CYAN], [WHITE], [RED], [BLUE], [PURPLE] or [ORANGE];

7.3.5 Setting Waveform Gain

(a) Select ECG parameter and [ECG SETUP] menu will be displayed;
(b) Set [GAIN] to [×0.25], [×0.5], [×1], [×2], [×4] or [AUTO].

Chapter 8 Alarm

8.1 Alarm Type

The monitor can give an alarm of two types, physiological alarm and technical alarm.

(1) Physiological alarm

Physiological alarm is usually caused by a certain physiological parameter of the patient which exceeds the set upper/lower limit scope or by the physiological abnormality of the patient. The alarm message of the physiological alarm will appear in the physiological alarm message area.

(2) Technical alarm

The technical alarm is also referred to as a system error message, indicating the alarm is caused by a misoperation or system malfunction thereby causing improper operation of a system function or distortion of monitored results. The alarm message of the technical alarm will appear in the technical alarm message area.

Prompt message is to display the information relative to the system conditions themselves, which have nothing to do with the patient's vital sign.Prompt message will appear in the prompt message area.

8.2 Alarm Level

The monitor can give an alarm in three levels:high, medium and low, based on the severity.

	Physiological alarm	Technical alarm
High level	The patient is in a critical condition, endangering the patient's life, emergent attention required.	Indicate a severe device malfunction or an improper operation, which could make it possible that the monitor cannot detect critical patient status and thus threaten the patient's life, such as low battery and so forth.
Medium level	The patient's vital signs are abnormal, relevant measures and treatment are immediately required.	Indicate a device malfunction or an improper operation, which may not threaten the patient's life but may compromise the monitoring of vital physiological parameters.
Low level	The patient's vital signs are abnormal and relevant measures and treatment may be required.	Indicate a device malfunction or an improper operation, which may compromise a certain monitoring function but will not threaten the patient's life.

All alarm levels for technical alarms and some physiological alarms have be set before the monitors are delivered, and the users are not allowed to change them. But the level of some physiological alarms can be modified.

8.3 Alarm Mode

When giving an alarm, the monitor will prompt the users in both audio and visual modes:

- Visual alarm
- Audio Alarm
- Alarm Message
- Parameter's flashing

In which light signal, audio signal and alarm message are differentiated with those in different alarm levels.

8.3.1 Visual Alarm

The alarm lamp will flash at different frequencies and in different colors for different alarm levels.
Physiological alarm:

- High level alarm : the left alarm lamp flashes twice every second in red ;
- Medium level alarm : the left alarm lamp flashes once every two second in yellow ;
- Low level alarm : the left alarm lamp turns yellow without flashing.

Technical alarm :

- High level alarm : the left alarm lamp flashes twice every second in red ;
- Medium level alarm : the left alarm lamp flashes once every two second in yellow ;
- Low level alarm : the right alarm lamp turns cyan without flashing.

When physiological alarm and technical alarm are triggered simultaneously, the flashing frequency and color of alarm lamp are based on the highest alarm level. If only low level physiological alarm and technical alarm are triggered simultaneously, the left alarm lamp turns yellow without flashing and also the right alarm lamp turns cyan without flashing.

8.3.2 Audio Alarm

The audio alarm is to prompt the alarm in different levels of severity with different sounds.

- High level alarm: Do-Do-Do--Do-Do----Do-Do-Do--Do-Do.
- Medium level alarm: Do-Do-Do.
- Low level alarm: Do.

⚠Warning

- **Both beside monitor and central monitoring systems have audio alarm function.**
- **The bedside monitor connected to a central monitoring system may not give alarms at the same time with the central monitoring system despite the same alarm limits, becasue bedside monitor has the alarm delay function.**
- **When alarms of multiple alarm level are triggered simultaneously, the defibrillator/monitor will give the alarm in audio and visual mode based on highest alarm level.**

8.3.3 Alarm Message

When there is a technical or physiological alarm, you will find a technical or physiological alarm message in the technical alarm message area or physiological alarm message area respectively. Physiological alarm messages for different levels of alarms are displayed in different background colors:

- High level alarm: red
- Medium level alarm: yellow
- Low level alarm: yellow (Physiological alarm), Cyan (Technical alarm)

Messages for different levels starting with different marks:

- High level alarm: ***

- Medium level alarm:**
- Low level alarm: *

8.3.4 Alarm Parameter Flashing

When a parameter is alarming, the parameter will flash once every second.The upper alarm limit or lower alarm limit will also flash in the same frequency indicating the parameter has violated the upper limit or lower limit repectively.

8.4 Adjusting the Alarm Volume

8.4.1 Adjusting the Minimum Alarm Volume

The minimum alarm volume is set to avoid the situation that the alarm cannot be heard due to the alarm volume being set too low. It decides the minimum alarm volume which can be set by users.
How to adjust the minimum alarm volume:

1. Access [MAIN MENU] →[CONFIG SETUP]→enter the password →[ALARM SETUP]→[Min. Alm Volume];
2. Adjust the minimum alarm volume from 0 to 10.

8.4.2 Adjusting the Alarm Volume

How to adjust the alarm volume:

1. Access [MAIN MENU] →[ALARM SETUP]→[ALM VOL];
2. Adjust the alarm volume from X to 10. X is the set minimum alarm volume.

When alarm volume is 0, there will be  displayed in the icon area indicating the alarm volume is 0.
The alarm signal sound pressure level from level 0 to level 10 of this monitor is between 40 dB to 60dB.

Warning

- **If alarm volume is 0, you will not hear the alarm sound when there is an alarm. Please set the alarm volume with caution.**
- **Auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm conditions.**

8.4.3 Setting the Reminder Tone

When the alarm volume is 0, the alarm is paused, or the alarm is switched off, the monitor will give periodic reminder signal: Ting---Ting---Ting---.
How to set reminder tone:

1. Access [MAIN MENU] →[CONFIG SETUP]→enter the password →[ALARM SETUP]→[Alarm Reminder];
2. Select [Alarm Reminder] and select [ON] or [OFF] to activate or deactivate the reminder tone

functionrespectively.

3. Select [Reminder Interval] to adjust the reminder interval. Available options include 1min, 2min and 3min;
4. Select [Reminder Volume] and adjust the reminder volume from [HIGH], [MED]and [LOW].

8.5 Alarm Settings

8.5.1 Setting the Alarm Level

Here we take RESP as an example to introduce how to set alarm level:

1 Select RESP parameter area;

2 Select [ALARM LEVEL];

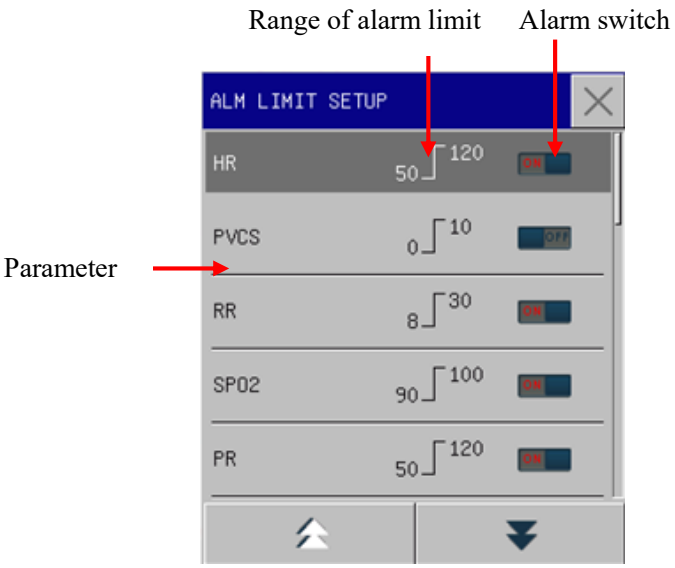
3 Select [HIGH] or [MED].

8.5.2 Setting the Alarm Limit

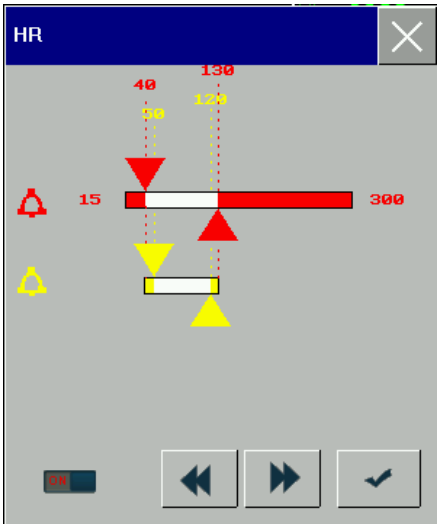
The smart alarm system is the feature of our company. For smart alarm parameter, the users can set the upper and lower limit of the high level alarm, medium level alarm and low level alarm together with no need to set the alarm level. When the measured value of a certain parameter violates the alarm limits, the monitor will auto give a corresponding alarm according to the alarm limits of which alarm level having been violated.For normal alarm parameter, the users need to set the alarm level and only the alarm limits of the selected alarm level can be set. When the measured value violates the alarm limits, the monitor will only give alarms of the selected alarm level. Except for TEMP, IBP and RESP parameter, the alarm of ECG, CO2, PR, NIBP and SpO2 parameter is smart alarm.

The methods to set the alarm limits for all smart alarm parameters are similar, and here we take ECG as an example:

1. Access [MAIN MENU]→[ALARM SETUP]→[ALM LIMIT SETUP];
2. Or select ECG parameter area, in the pop-up [ECG SETUP] menu, select [ALARM SETUP] and enter the alarm limit setup menu, as shown below:



3. Select HR parameter to enter HR alarm limit setup menu, as shown below:



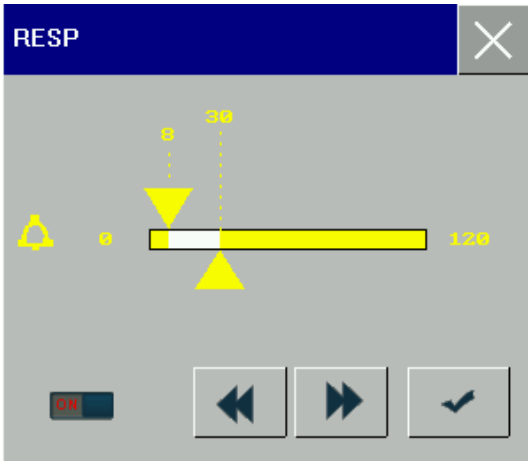
Here the users can set the alarm limits of high level alarm and medium level alarm together and can differentiate the alarm level by different colors:

- Red stands for high level;
- Yellow stands for medium level;

4. Select the triangle of each alarm level and select  or  to adjust the range of alarm limit.
5. Select  to save the alarm limit.

The methods to set the alarm limits for all normal alarm parameters are similar, and here we take RESP as an example:

1. Select RESP parameter area and the [RESP SETUP] menu will be displayed;
2. Select [ALARM LEVEL] and select [HIGH] or [MED];
3. Select [ALARM SETUP] and enter the alarm limit setup menu;
4. Select RESP and the RESP alarm limit setup menu will be displayed:



Here only the alarm limit of the selected alarm level can be set.

5. Select the triangle of each alarm level and select  or  to adjust the range of alarm limit.
6. Select  to save the alarm limit.

⚠ Warning

- **Setting alarm limits to extreme values will render the alarm system useless.**
- **It is very important to set the high limit for HR alarm to an appropriate value. Do not set it to**

be 20bpm higher than the patient's HR.

⚠Attention

- **The monitor will always save the alarm settings in case of power interruption and the alarm settings are restored automatically after power interruption.**

8.5.3 Alarm Recording

The monitor can record alarm events automatically when the alarms are triggered if the parameter alarm function and alarm recording function are activated.

How to activate or deactivate the alarm recording function:

1. Access [MAIN MENU] →[ALARM SETUP] →[ALM RECORD SETUP];
2. Select [ALL ALM RECORD ON] and the alarm recording function of all parameters will be activated;
3. Select [ALL ALM RECORD OFF] and the alarm recording function of all parameters will be deactivated;
4. Or select the separate parameter to activate or deactivate its alarm recording function;
5. Or select a certain parameter area to enter its setup menu andset [ALM RECORD] to [ON].
6. When the measured parameter value violates the alarm limit, the monitor will auto record the alarm events according to the recording time set in [ALM RECORD TIME].

8.5.4 Setting the Alarm Recording Time

The monitor provides three kinds of alarm recording time: 8s, 16s and 32s. 8s means the alarm recording time is 4 seconds before and after the alarm moment; and so forth.

How to set the alarm recording time:

Access [MAIN MENU] →[ALARM SETUP] →[ALM RECORDTIME] and select the required alarm recording time.

8.5.5 Setting the Alarm Delay Time

The alarm system provides five kinds of alarm delay time: [NOT ALLOWED], [5S],[10S], [15S] and [20S]. [NOT ALLOWED] indicates that the monitor will give alarms immediately once the measured parameter value violated the alarm limit; [5S] indicates the monitor will give alarms only when the measured parameter value exceeds the alarm limit for continual 5 seconds; and so forth.

How to set the alarm delay time:

1. Access [MAIN MENU] →[CONFIG SETUP]→enter the password →[ALARM SETUP]→[Alarm Delay];
2. Select the required alarm delay time.

8.6 Pausing Alarms

You can press  key on the front panel to pause the alarm triggered and put the alarm system into alarm paused status:

- Stop all the indications of physiological alarms and no new physiological alarm will be triggered.
- For technical alarm, the audio and visual alarm indicationwill be paused but alarm message still appears in technical alarm message area. If new technical alarm is triggered during alarm pause, only the alarm message of this technical alarm will be displayed without audio and visual alarm indication.
- The remaining pause time “ALM PAUSE xx” will appear at the physiological alarm message area.
- The  key on the front panel turns red.
- There will be  icon displayed in the icons area.

When the remaining alarm pause time ends, the alarm paused status will be automatically cancelled. You can also cancel the alarm paused status by pressing the  key on the front panel manually.

8.6.1 Setting the Alarm Pause Time

1. Access [MAIN MENU] —>[CONFIG SETUP] —>enter the password—>[ALARM SETUP] —>[ALM PAUSE TIME];
2. Select the alarm pause time. Available options include 1 min, 2 min, 3 min, 5 min, 10 min and15 min.

8.7 Switching off Alarms

8.7.1 Switching off Individual Parameter Alarm

Users can manually activate or deactivate the alarm function of individual parameter. If the alarm function of a certain parameter is activated, when the measured value of this parameter violates the alarm limit, the monitor will give an alarm immediately. If the alarm function of a certain parameter is deactivated, the monitor will not give any alarm about this parameter.

How to switch off individual parameter alarm, here we take ECG as an example:

1. Access [MAIN MENU]→[ALARM SETUP]→[ALARM LIMIT SETUP], select [HR] to switch off ECG alarm function;
2. You can also select [ALL ALM OFF] to switch off the physiological alarm function of all parameters simultaneously.

When the alarm function of an individual parameter is deactivated, the icon  will appear in corresponding parameter area.

8.7.2 Switching off All Parameter Alarms

Switching off all parameter alarms is password protected and can only be operated by the authorized personnel.

How to switch off all parameter alarms:

Access [MAIN MENU] —>[CONFIG SETUP] —>enter the password—>[ALARM SETUP] —>[ALARM OFF] and select [ON], and then press the  key on the front panel.

⚠Attention

- **The alarm system will be auto switched off once entering manual defibrillation mode.**

When all parameter alarms are switched off, the system will give reminder tone periodically as the interval set in [Reminder Interval].

During alarms off status:

- For physiological alarms, no alarm lamp flashes, no alarms are sounded and no measured parameter value and alarm limit flash. Physiological alarm message are not be displayed.
- Prompt message "ALARM OFF" will be displayed in the physiological alarm message area with red background.
- Alarm off icon  will be displayed in the icons area.
- For technical alarms, no alarms are sounded and no alarm lamp flashes, but alarm message remains unchanged.

The alarm system will exit the alarm off status under the circumstances:

- Press the  on the front panel;
- Enter the synchronized defibrillation in manual defibrillation mode;

⚠ Warning

- **When alarms are switched off or paused, the monitor will not give alarm signals. Therefore, the patient should be kept under close surveillance.**

8.8 Alarm Reset

By pressing the [ALARM RESET] soft button, the following operations can be conducted:

1. Cease the audio alarm indication of all physiological alarms and technical alarms.
2. Clear the alarm indications for which no associated alarm condition currently exist, thus re-enabling the alarm system to respond to future alarm conditions.
3. For lead off and sensor off technical alarm condition,clear the alarm lamp flashing and audio alarm indication and the alarm messages turn to prompt messages displayed in the technical alarm message area.

8.9 Alarm Presets

This defibrillator/monitor has only one alarm preset: the factory default settings. Refer to ***Appendix IV*** for the factory alarm default settings.

Once the alarm settings have been modified, the defibrillator/monitor will always save the modified alarm settings. In case of power interruption, the defibrillator/monitor will restore the alarm settings set before power interruption. When the patient type changes or admit a new patient, the system will load the default configuration. Usually, the alarm limits should be verified before patient monitoring to ensure that these alarm limits suit your patient.

How to use the factory default settings:

Access [MAIN MENU]→[CONFIG SETUP]→enter the password→[FACTORY DEFAULT], select [YES] in

the pop-up dialog box and the factory default settings will be restored.

When restarting the defibrillator/monitor, the alarm system will restore the alarm settings set before turning off the defibrillator/monitor.

8.10 Check the Alarm System

How to check the alarm system:

1. Connect the SpO2 cable with the monitor;
2. Access [MAIN MENU] →[ALARM SETUP] →[ALM LIMIT SETUP];
3. Enable the SpO2 alarm function;
4. Enter SpO2 alarm limit setup menu and set the upper alarm limit of high level to 97 and lower alarm limit of high level to 90.
5. When the measured SpO2 value exceeds the alarm limits, please observe the audio and visual alarm and check whether the alarm indications complies with what introduced in this chapter.
6. Disconnect the SpO2 sensor from the monitor, and you will find the technical alarm message “SPO2 SENSOR OFF” in the technical alarm message area.

Chapter 9 Battery

9.1 General Introduction

This monitor is equipped with twolithium rechargeable batteries with number “1” and “2” on the battery icon to identify. The batteries will be charged automatically once the monitor is connected to the AC power supply, no matter whether the monitor is turned on or turned off. Under the circumstance of sudden power failure, this monitor will automatically operate onbatteries without any operation interruption. The battery indicator will turn green after cutting off AC power supply.

 Stands for battery 1

 Stands for battery 2

When the battery is being charged, the battery bar is moving and the battery indicator turns yellow.

The battery bar displayed on the upper right corner of the screen indicates the battery’s charge level, here taken battery 1 as an example:

 indicates the charge level of battery 1 iDFM 8000%～100%

 indicates the charge level of battery 1 iDFM 6000%～80%

 indicates the charge level of battery 1 is40%□60%

 indicates the charge level of battery 1 is20%□40%

 indicates the battery is low and charge level of battery 1 is0%～20%

 indicates the battery is critically low and needs to be charged immediately.

 indicates no battery 1 or damaged battery 1.

There aremultiple LEDs on the battery to indicate its approximate battery level. Press the button beside the LEDs and the LEDs will be illuminated to show the battery level.

⚠Attention

- **Remove the battery if the monitor is not likely to be used for some time.Charge the battery once every two months to avoidover discharge.**
- **Connect the monitor with AC power supply as far as possible to ensure the battery is always being charged.**
- **The monitor should always be installed with at least one fully charged battery.**

⚠Warning

- **Check the battery periodically to ensure there is adequate battery power.**
- **The battery solution is harmful. In case battery solution splashes onto skin or into eyes, rinse the skin and eyes with clean water at once and then ask the doctors for help.**
- **Keep the battery out of reach of children.**
- **Only use the battery specified by the manufacturer.**

9.2 Battery Alarms

9.2.1 Low Battery Alarms

When the battery level is lower than 20%, a low level technical alarm “Low Battery” will be triggered. At this moment, replace the battery or connect the monitor with AC power supply in order not to affect the therapy and monitoring on patients. When the battery level is lower than 5%, a high level technical alarm “Battery Too Low, Shutting Down…..” and the monitor will shut down after about 60 seconds if not replace the battery or connect AC power supply.

⚠Attention

- **After the alarm “Low Battery” is triggered, this defibrillator/monitor can at least conduct vital signs monitoring for 20 minutes and 6 maximum energy deliveries.**

9.2.2 Battery Aging Alarms

If the operation time of battery is obviously shorter than the time declared in battery specification, the system will trigger a technical alarm “BATTERY 1(2) AGING”. Under such circumstance, contact the manufacturer to replace the battery.

9.2.3 Battery Fault Alarms

When there is any battery fault, the system will trigger a technical alarm “BATTERY 1 (2) FAULT”.Under such circumstance, replace battery or contact the maintenance personnel.

9.3 Battery Installation

1. Turn off the monitor and disconnect power cord and other connecting cables.
2. Put the back panel of the monitor upwards.
3. Align the battery connector with battery pin.
4. Press the battery into the battery pin until it clicks into place.
5. To replace a battery, press the latch on the right end of the battery with right hand and push the battery to the right with left hand; reinsert a new battery.

⚠Warning

- **Only the battery specified by the manufacturer can be used.**
- **The installation of the battery should be performed by the personnel authorized by the manufacturer.**
- **Watch your hand when installing the battery.**

9.4 Optimization and Check of Battery Performance

(1) To optimize the battery performance

When the battery is used for the first time at least two complete cycles of optimization of the battery should be carried out. A complete optimization cycle should be:uninterrupted charging battery until the power is full, followed by use until the battery is fully discharged and monitor automatically shuts down.

Ensure thesewhen the battery is in optimization process:

(a) Disconnect the monitor from the patient and suspend all monitoring and measuring procedures.

(b) The optimized battery should be kept in the battery holder of the unit.

(c) When charging the battery, at least six hours of charging should be ensured until it is fully charged.

(d) Disconnect the AC power supply and the monitor is powered with the battery until the battery runs out and the monitor automatically shuts down.

(e) A battery optimization process is done.

(2) To check the battery performance

The service life of battery is changeable along with its storage, working environment, charge cycles and service time. Even though battery is out of service its performance will gradually deteriorate.

Procedure for checking the battery is as follows:

(a) Confirm whether the battery is damaged. When the battery shows the symbol "  ", it indicates the battery is damaged or not in the battery holder.

(b) Checkwhether the battery can be normally charged when the battery is connected to alternating current;

(c) Disconnect the monitor from the patient and suspend all monitoring and measuring procedures.

(d) When charging the battery, at least six hours of charging should be ensured until it is fully charged.

(e) Disconnect the AC power supply, power on the monitor with the battery until it is fully discharged and the monitor shuts down automatically. Record the start and stop time.

(f) The duration of battery discharge will reflect the battery performance.

(g) Once the discharge duration is down to 50% of the original time, it requires changing the battery.

⚠Attention

- **In order to extend the service life of the battery, it is recommended to charge it every three months after a long dormant period so as to prevent overdischarge.**
- **Battery power supply loss depends on the configuration and operation of the monitor; for example, the unit will have a big loss of battery power if it is used to measure NIBP parameter often.**

9.5 Battery Recycle

If the battery shows apparent damage or low capacity, it should be exchanged immediately, and the old battery should be recycled and properly disposed of in accordance with relevant laws or rules and regulations for hospitals.

⚠Warning

- **Do not remove the battery or make it short-circuiting or put it into fire; otherwise, it would cause battery on fire, explosion, harmful gas leakage or other dangers.**

Chapter 10 Review

What can be reviewed on the defibrillator/monitor are the alarm events, trend graph, trend table, 12-lead diagnosis report, NIBP measurementand parameter waveform.

The monitor can save 120h trend data, 2,000 groups of NIBP data and 200 parameter alarm events, 48h parameter waveform, 5 ECG diagnosis reports for each patient and maximum storage of 480min audio recording (maximum 60min for each patient).

10.1 Alarm Event Review

Reviewing physiological alarm events

Maximum 200 physiological alarm events can be reviewed in the alarm event review window.

How to enter the physiological alarm event review window:

1. Select the physiological alarm message area;
2. Or in monitor mode, press [REVIEW] soft button→[ALARM EVENT REVIEW];
3. Or access [MAIN MENU]→[REVIEW]→[ALARM EVENT REVIEW];
4. The physiological alarm event review window will be displayed as shown below:

The following operations can be performed in the physiological alarm event review window:

1. **Set the end time**

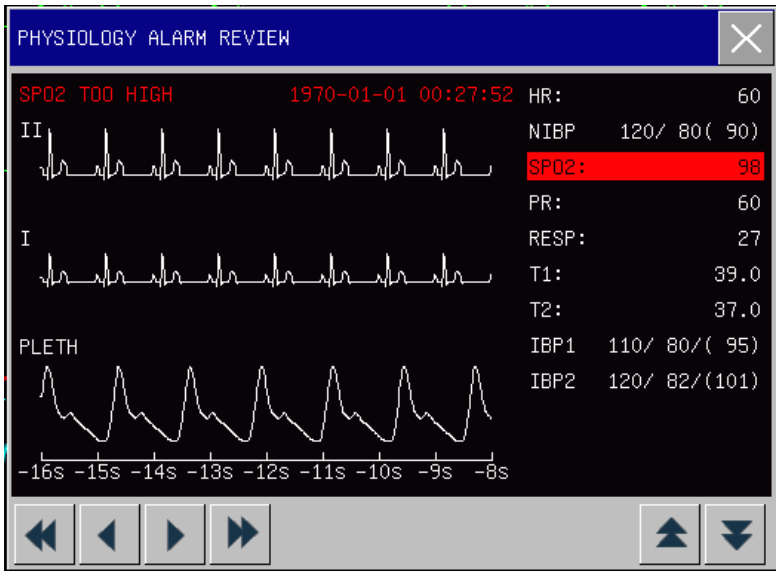
   Select [END TIME] and set the end time in the pop-up menu. All the physiological alarm events occurred before the end time will be displayed in this windowin chronological order.

2. **Select the alarm event**

   Select [EVENT] and select the alarm event in the pop-up list box.Available options include [ALL] andsperate parameter [ECG], [SpO_2], [RESP], [NIBP], [TEMP], [CO2], [ARR], [IBP<1,2>] and [USER EVENT].

3. **View a certain alarm event**

   Select a certain alarm event in this window, for example “SpO2 TOO HIGH” and enter the review window of this alarm event, as shown below:

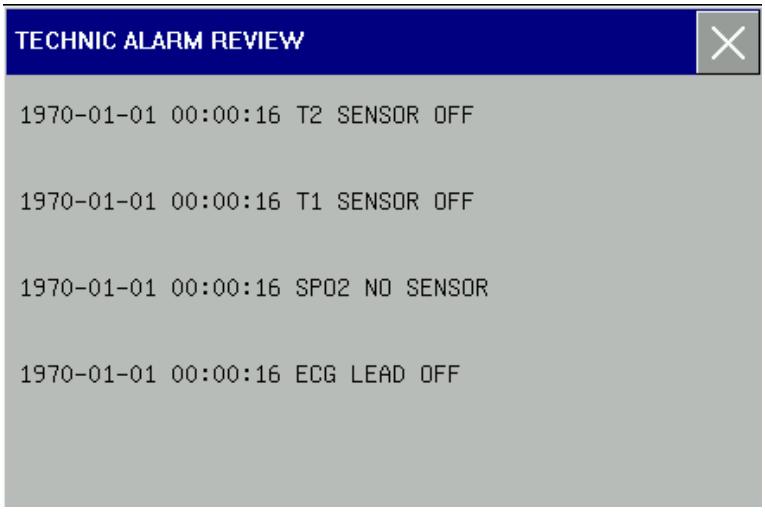


What displayed in this window are follows:

- Alarm Time
- Alarm event
- Alarm level
- 16s waveform before and after the alarm moment and parameter value at the alarm moment.

Viewing technical alarm events:

Select technical alarm message area and the [TECHNICAL ALARMS] window will be displayed, as shown below. All the technical alarm events are shown in chronological order.



Attention

- **When the stored physiological alarm events are more than 200, the defibrillator/monitor will only store the latest 200 events and the earlier ones will be overwritten.**
- **When the stored technical alarm events are more than 200, the defibrillator/monitor will only store the latest 200 events and the earlier ones will be overwritten.**
- **The alarm log will not maintain all the alarm events when the alarm system is powered down and the time of powering down is not captured in the alarm log, neither.**

10.2 Trend Review

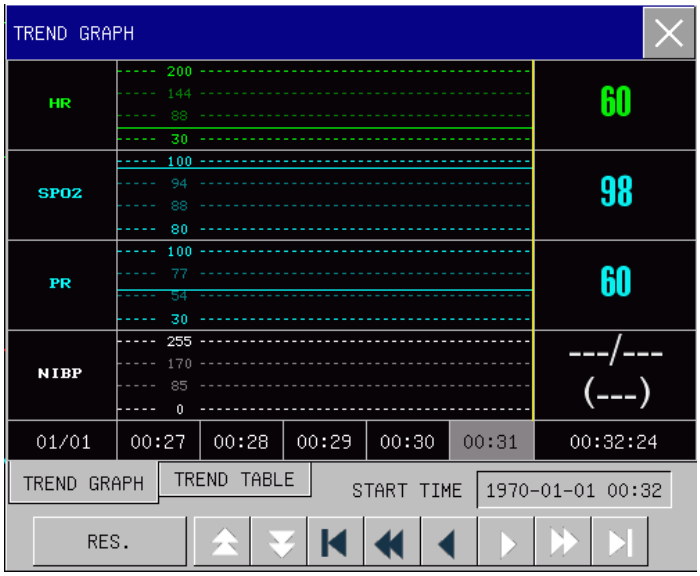
Trend review consists of trend graph review and trend table review. Users can select the trend graph or trend table label to switch trend review.

10.2.1 Trend Graph Review

The trend graph in the latest 1 hour can be displayed with the resolution of one data every second or every 5 seconds; and the trend graph in the latest 150 hours can be displayed with the resolution of one data every minute, or every 5 or 10 minutes.

How to enter trend graph review window:

1. Press the [REVIEW] soft button→[TRENDS REVIEW];
2. Or access[MAIN MENU]→[REVIEW]→[TRENDS REVIEW];
3. The trend graph review window will be displayed as shown below:



The vertical and horizontal axis respectively represents the measured value and the measuring time.

The following operations can be performed in the trend graph review window:

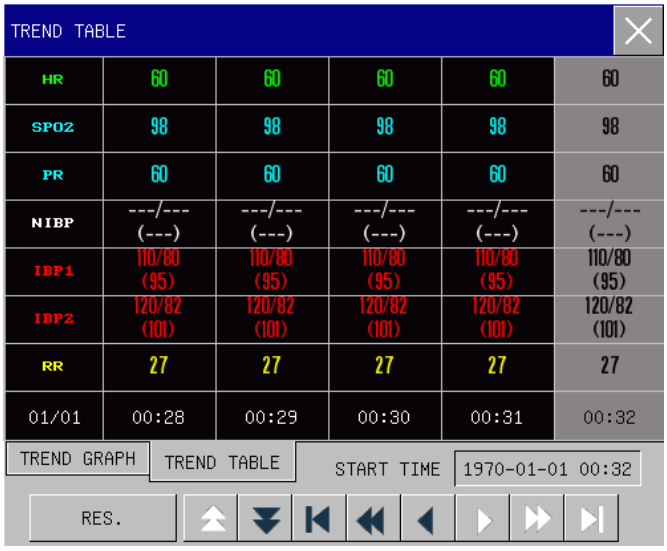
1. **Set the start time**
   Select[START TIME] and set the start time in the pop-up menu. The trend graph from the start time will be displayed.
2. **Display the trend graph of different parameters**
   Press the key ⏫ or ⏬ to show the trend graph of the parameters not in current view;
   Or select any parameter name and select the parameter in the pop-up list box, and the trend graph of the selected parameter will be displayed.
3. **Display 1h or 150h trend graph**
   Select[RES.], in the pop-up list box, select 1 or 5 seconds to review thetrend graph in the latestone hour and select 1, 5 or 10 minutes to review thetrend graph in the lastest 150 hours.
4. **Observethe earlier or latertrend curves**
   Press ⏪ or⏩ to observe the earlier trend curves or thelater trend curves respectively.Press ⏮ or ⏭ to observe the earliest or latest trend curve respectively.

5. **Obtain trend data at a certain moment**
   Press ◀ or ▶to move cursorand the selected moment will change when the cursor moves. The measured parameter values at the selected moment will be displayed at the right of the window.

10.2.2 Trend Table Review

The trend table data in the latest 120 hours can be displayed with the resolution of one data every minute, every 5minutes, 10minutes, 30minutes or 60minutes.
How to enter trend table review window:

1. Press the [REVIEW] soft button→[TRENDSREVIEW];
2. Or access[MAIN MENU]→[REVIEW]→[TRENDSREVEIW];
3. The trend graph review window will be displayed;
4. Select [TREND TABLE] to enter the trend table review window, as shown below:



The following operations can be performed in the trend table review window:

1. **Set the start time**
   Select [START TIME] and set the start time in the pop-up menu, and the trend table data from the start time will be displayed.
2. **Display thetrend tables of different resolutions**
   Select [RES.] and select the resolution in the pop-up list box. Available resolutions includes 1 minute, 5minutes, 10minutes, 30minutesand 60minutes
3. **Display trend data of different parameters**
   Press ⏫ or ⏬ to show the trend data of the parameters not in current view.
4. **Observe earlier or later trend data**
   Press⏪ or ⏩ to observe the earlier or later trend data respectively.Press ⏮ or ⏭ to observe the earliest or latest trend data respectively.

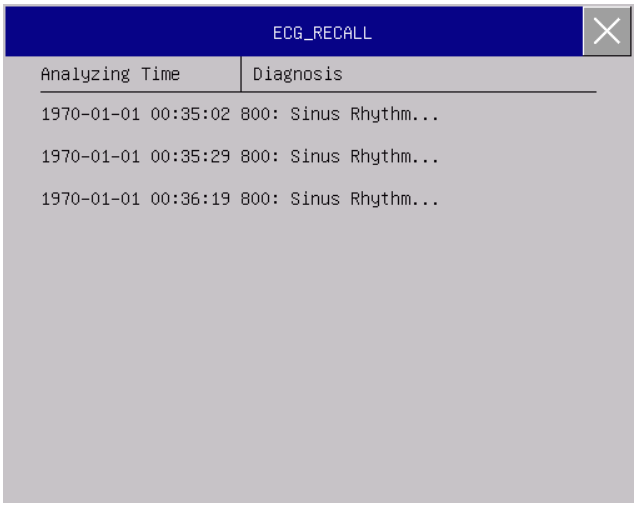
10.3 12-lead ECG Report Review

12-lead ECG report review is to review 12-lead ECG diagnosis report. At most 5 ECG diagnosis reports for

every patient can be stored.

How to enter the 12-lead ECG report review window:

1. Press the [REVIEW] soft button→[12-LEAD REPORT REVIEW];
2. Or access[MAIN MENU]→[REVIEW]→[12-LEAD REPORT REVIEW];
3. The 12-lead ECG report review window will be displayed, as shown below:



In the 12-lead ECG report review window, the diagnosis reports are listed in chorological order. Select a certain report to view it in detail, as shown below:

The following operations can be performed for this diagnosis report:

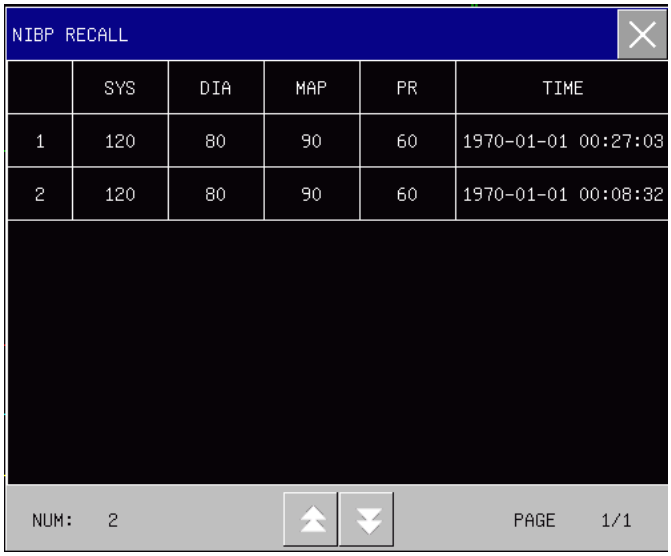
1. Select [REC] and this diagnosis report will be recorded;
2. Select [DIAG WAVE] to view the acquired 10s 12-lead ECG waveform of this diagnosis report.

10.4 NIBP Measurement Review

This defibrillator/monitor can display the latest 2000 groups of NIBP measurement data in the NIBP measurement review window.

How to enter NIBP measurement review window:

1. Press the [REVIEW] soft button→[NIBP REVIEW];
2. Or access[MAIN MENU]→[REVIEW]→[NIBP REVIEW];
3. The NIBP measurement review window will be displayed, as shown below:

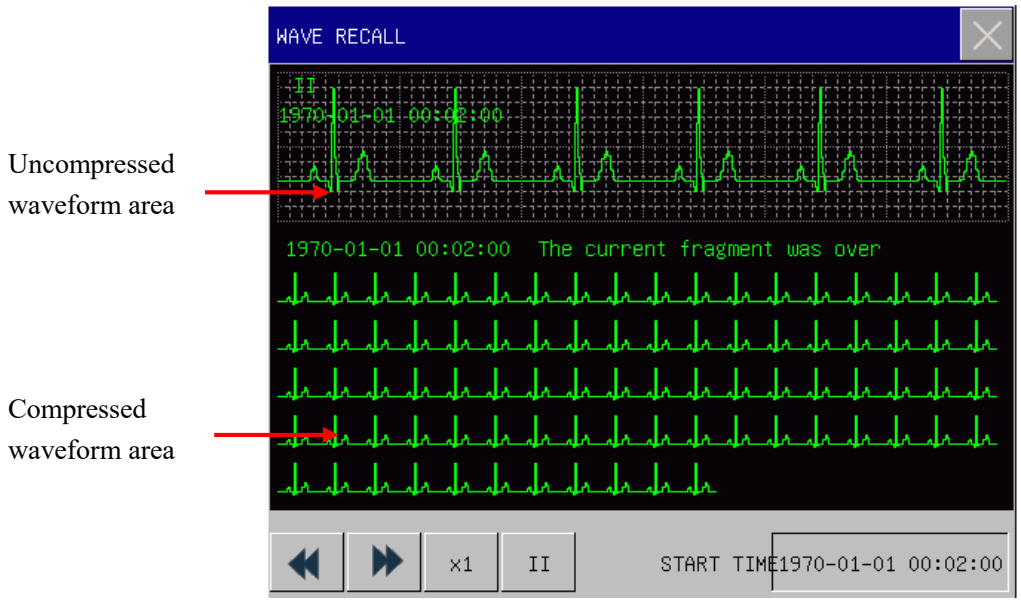


Data is displayed in the sequence of time from earlier to later. Each screen can display 7groups of NIBP measurement data. Select ⏫or⏬ to view the later or earlier data respectively. Maximum data of2000 groups can be displayed. But if NIBP measurement data are more than2000 groups,the monitor will only save the latest 2000 groups and theearlier ones will be overwritten. In this window, measured PR data can be review as well.

10.5 Waveform Review

This defibrillator/monitor can display parameter waveforms of 120 hours in the waveform review window. The waveforms of any parameter monitored can be reviewed.
How to enter waveform review window:

1. Press the [REVIEW] soft button→[WAVE REVIEW];
2. Or access [MAIN MENU]→[REVIEW]→[WAVE REVIEW];
3. The waveform review window will be displayed, as shown below:



The following operations can be performed in the waveform review window:

1) Set the start time

Select [STARTAT] and set the start time in the pop-up menu, and the parameter waveform from the start time will be dispalyed.

2) Change the gain

Select [×1] and select the gain for the uncompressed ECG waveforms.

3) Review different waveforms

Select [II] and select the lead name or parameter name in the pop-up list, and the waveform of the selected lead or parameter will be displayed.

4) Obeserve the amplified waveform

Click anywhere in the compressed waveform area and the 6-second amplified waveform will be displayed in the uncompressed waveform area.

5) Observe the earlier or later ECG waveform

Select ◀◀ or ▶▶ to observe earlier or later waveform respectively.

Chapter 11 Recording

11.1 Overview

This defibrillator/monitor applies a thermos sensitive recorder with recording paper width of 80mm.

11.2 Recording Types

According to the way recordings are triggered, the recordings can be classified into the following categories:

- Real-time recording triggered manually;
- Frozen waveform recording triggered manually;
- Recording triggered by events like charge event, shock event, mark event, 12-lead ECG report and auto test report;
- Recording triggered by alarm events.

11.3 Starting Recording

How to start recording manually:

- Press  on the front panel and the real-time recording will be started;
- Select [RECORD] in frozen waveform window and the frozen waveform recording will be started.

How to start recording automatically:

- If the alarm function and alarm recording function of a certain parameter are activated, once this parameter triggers an alarm, the defibrillator/monitor will start alarm recording automatically;
- When the corresponding events are triggered, the defibrillator/monitor will start recording automatically.

During the process of recording, you can press  on the front panel to stop recording

11.4 Record Settings

Access [MAIN MENU], select [RECORD SETUP] and the record setup window will be displayed.

11.4.1 Selecting the Recording Waveform

The recorder can print out waveforms of up to 4 channels.

1. Access [RECORD SETUP] menu;
2. Select [WAVE 1], [WAVE 2], [WAVE 3] and [WAVE 4] respectively and select the waveform label in the pop-up list box.[CLOSE] means there will be no waveform printed on this channel.

11.4.2 Adjusting the Recording Speed

1. Access [RECORD SETUP] menu;
2. Select [PAPER SPEED];
3. Select 12.5mm/s, 25mm/sor50 mm/s.

11.4.3 Setting the Recording Time

1. Access [RECORD SETUP] menu;
2. Select [RT RECORD TIME];
3. Select the real-time recording time from 8s, 16s and 32s.

11.5 Loading Recording Paper

1. Press the recorder door release to open the recorder door;
2. Take out the no-paper rod
3. Put the new recording paper inand tip of paper should be out from the paper exit.
4. At least 1 inch paper must be out of recorder door, and close the door.
5. Press  to check if the recordingpaper has been loaded well.If no printing, please re-load the recordingpaper.

⚠Attention

- **Don't touch the thermosensitive head when loading recording paper. Unless during paper loading or trouble shooting, the recorder door must be kept closed.**
- **During recording, do not pull the recording paper forcefully, or the recorder may be damaged. Never use the recorder without recording paper loaded.**

11.6 Clearing Paper Jam

If there is any unusual noise when the recorder is operating or if the paper advance is improper, users should open the recorder door to check whether there is paper jam.

Procedures to clear paper jam:

a) Cut the recording paper from the paper exit side;
b) Open the recorder door;
c) Take out the recording paper from the recorder;
d) Re-load recording paper.

Chapter 12 Cleaning and Disinfection

Use only the substances approved by Okuman and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover the damage caused by unapproved substances or methods.
Okuman make no claims regarding the effectiveness of the listed chemicals or methods as a means for controlling infection. For the method to control infection, please consult the Infection Control Officer or Epidemiologist in your hospital and also refer to the local policies.

12.1 Overview

Keep your equipment and accessories free of dust and dirt. After cleaning and disinfection, please check the equipment and if any damage is found, stop use it. To avoid damage to the equipment, please follow the rules below:

- Always dilute the cleaning agents and disinfectants following the manufacturer's instructions or use the lowest possible concentration.
- Do not allow liquid to enter the enclosure.
- Do not pour liquid onto any part of the equipment or accessories.
- Do not immerse any part of the equipment into liquid;
- Do not use abrasive materials, bleaching powder or erosive cleaners (such as acetone or acetone-based cleaners).
- Keep the paddles clean. The paddles and paddle holders should be cleaned comprehensively after each use and before user test.

12.2 Cleaning and Disinfection of the Monitor and Accessories

To avoid cross infection, please clean the monitor and accessories after each use. Please understand the relevant regulations about equipment cleaning in your hospital before cleaning.
Steps of cleaning:

1. Turn off the monitor,
2. Disconnect the power cord and accessory cable from the monitor;
3. Clean the display screen and the enclosure of the monitor and plug-in modules with a soft cloth moistened (not wet) with cleaning agents;
4. Clean the external defibrillation paddles, accessory cable and sensor with a soft cloth moistened (not wet) with cleaning agents;
5. After cleaning, wipe off the cleaning agent with a dry soft cloth;
6. Allow the monitor, accessory cable and sensor to air dry.

To avoid damage to the monitor and accessories, disinfection is recommended only when regulated as necessary in the Hospital Maintenance Schedule. Please clean the monitor and accessories first before disinfection.
The recommended cleaning agents and disinfectants for the monitor and accessories are listed in the following table:

Components	Selectable Cleaning Agents	Selectable Disinfectants
Monitor enclosure	Isopropyl alcohol(70%), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite

Power cord	Isopropyl alcohol(70%), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
External paddles	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
ECG cable	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
ECG electrode	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
Temperature probe	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
SpO2 sensor	Isopropyl alcohol(70%)	Glutaraldehyde solution(2%), Sodium hypochlorite
IBP cable	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
Mainstream CO2 module	Ethanol (70%), Isopropyl alcohol(70%)	Glutaraldehyde solution(2%), Sodium hypochlorite
Sidestream CO2 module	Ethanol (70%), Isopropyl alcohol(70%)	Glutaraldehyde solution(2%), Sodium hypochlorite

⚠Warning

- **Do not use the cleaning agents and disinfectants other than those recommended in this user manual, because permanent damage to the monitor or accessories may occur, or safety hazards may be caused.**
- **Before cleaning the monitor, make sure that it is switched off and disconnected from AC power.**
- **Never use acetone on any part of the monitor.**
- **Never pour or spray liquid on the monitor.**
- **Use a cloth to wipe off any cleaning agent remaining on the monitor or accessories.**
- **Do not mix the cleaning agents, or dangerous gas will be produced.**
- **Do not clean or disinfect the disposable accessories. Do not reuse the disposable accessories to avoid cross infection.**
- **To protect environment, the disposable accessories must be disposed of properly according to local regulations and requirements.**
- **After cleaning, inspect the sensor cable for damage or aging. If any damage or aging is found, please replace the sensor cable.**
- **Do not sterilize the monitor and accessories by autoclave.**
- **Do not use ETO gas to disinfect the monitor or accessories.**
- **Do not immerse the sensor or connector into any cleaning agent or disinfectant.**
- **To prevent cleaning liquids and dust from entering the ISA analyzer through its LEGI connector,**

keep the Nomoline Family sampling line connected while cleaning the analyzer. Never sterilize or immerse the ISA sidestream gas analyzer in liquid.

- **The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.**
- **Remove the disposable IRMA airway adapter prior to cleaning the IRMA probe. Never sterilize or immerse the IRMA probe in liquid**
- **The IRMA oxygen sensor cell and IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.**

⚠ **Caution**

- **If you accidently pour liquid onto the monitor or accessories, please contact the customer service immediately.**

12.3 Cleaning and Disinfection of the Internal Defibrillation Paddles

The recommended cleaning agents for internal defibrillation paddles are clean water, alcohol-free soap, sodium hypochlorite (with chlorine bleaching powder and 3% water) and hydrogen peroxide. The specific cleaning steps are as follows:

1. Clean the internal defibrillation paddles, handles, cables and connectors with a soft cloth moistened (not wet) with cleaning agents;
2. Allow the internal defibrillation paddles, handles, cables and connectors to air dry;
3. Examine the internal defibrillation paddles. If any sign of damage or wear is found, do not use the internal paddles again;
4. Individually place the internal paddles to avoid damage to electrode surfaces.

After cleaning the internal defibrillation paddles, it is recommended to disinfect them by high pressure steam, specific methods are as follows:

Adjust the pressure and temperature of the high-pressure steam sterilizer to 130 kPa and 135℃ respectively, and then sterilize the internal defibrillation paddles for 5 minutes.

⚠ **Caution**

- **Only use the cleaning agents and disinfectants recommended in this user manual.**
- **Do not immerse the internal defibrillation paddles during cleaning.**
- **The internal defibrillation paddles must be hand washed. Do not clean them by ultrasonic or mechanical washing machines.**

12.4 Cleaning and Disinfection of the Cuff

Take out the rubber bag before cleaning the cuff.

The cuff can be hand washed or machine washed in warm water or with mild detergent. Hand wash can extend the service life of the cuff. Air dries the cuff after cleaning.

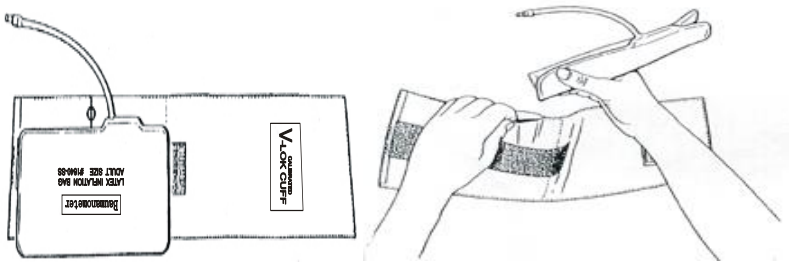
The cuff may be disinfected with a cloth moistened with 70% ethanol or 70% isopropanol. Prolonged use of disinfectant may cause discoloration of the cuff.

⚠Warning

- **Don’t compress the rubber pipe on a cuff.**
- **Do not allow the liquid to enter the rubber bag when cleaning it.**
- **Do not dry clean the cuff.**
- **The disposable cuff must be disposed of according to the local laws and regulations.**

After cleaning, put the rubber bag into the cuff as following steps:

1. Place the rubber bag on the top of the cuff.
2. Roll the rubber bag lengthwise and insert it into the large opening;
3. Hold the hose and the cuff and shake the complete cuff until the rubber is in position.
4. Thread the hose from inside the cuff and out through the small hole under the internal flap, as shown below:



Chapter 13 Maintenance

13.1 Maintenance Check

A comprehensive maintenance check including safety check should be conducted by the qualified maintenance personnel before using, after 6-12 continuous operation or after each maintenance and upgrading.
Check items including:

- Self-test
- Shift exchange check
- User test
- Recorder test
- Manual defibrillation test
- Pacing test
- Functional module test
- NIBP overpressure protection test
- Electrical safety test

Cables and paddleswhich can be abraded easily are key accessories for this defibrillator/monitor. Daily inspection and test is recommended. What's more, it is recommendedto replace cables and paddles every three years.
If you find any damage on the defibrillator/monitor, stop using it on patient,and contact the biomedical engineer of the hospital or our customer service immediately.
All the safety and maintenance checks that need to dismantle the monitor should be performed by a qualified customer service technician. Non-professional operation can cause the monitor damage or cause a security risk, and human health may be endangered.
The circuit diagrams of the defibrillator/monitor can be provided by Okuman as per customer demands. Qualified technicians can use it to help the user repair some apparatus that Okuman classifies as "can be maintained by the user".

⚠Warning

- **If the hospital or agency who uses thisdefibrillator/monitor does not follow a satisfactory maintenance schedule, the defibrillator/monitor may become damaged and personal safety may be endangered.**

13.2 Maintenance and Test Schedule

The following maintenance and test items can only be conducted by the maintenance personnel approved by Okuman. Please clean and disinfect this defibrillator/monitor before maintenance and test.

Maintenance and test items	**Schedule**
Clean this equipment and accessories	After use
User test (Routinetest, Energy Delivery test, Controlstest)	Once a week or as required. Controls test is once a year.
Recorder test	Once a year or as required

ECG cable test	Once a year or as required
Manual defibrillation test (charge and shock function, disarming energy, synchronized defibrillation)	Once a year or as required
Pacing test	Once a year or as required
ECG calibration	Once a year or as required
NIBP test (pressure verification, air leakage test)	Once every two years or as required.
NIBP overpressure protection test	Once a year or as required
IBP calibration	Once a year or as required
Functional test	Once a year or as required
Electrical safety test (Housing leakage current test, Earth leakage current earth test, Patient leakage current test, Patient auxiliary current test)	Once every two years, after defibrillator/monitor falling off and replacing power supply or as required.

13.3 Self-test

Each time you turn on the defibrillator/monitor, it performs internal self-test. If any error is found during self-test, service indicator will be illuminated and alarm message will be displayed in technical alarm message area.
Self-test contains the following test items:

- Power module test
- Therapy module test

Self-test should be performed every day or after initial installation and replacing components for the main unit to make sure that the defibrillator/monitor can work properly.
Specific steps are as follows:

1. Put paddles into the paddle tray and make them contact well. Install the defibrillator/monitor with battery (install two batteries if equipped) and connect AC power supply. Check whether AC indicator and battery indicator are illuminated.
2. Rotate mode selector to monitor mode. Check whether the defibrillator/monitor can be turned on.
3. Observetechnical alarm message area, status message area and battery icon for error message.

13.4 Shift Exchange Check

In order to ensure that your defibrillator/monitor is available at any time, it is recommended to perform checks according to the “Shift Exchange Checklist” in Appendix V.

13.5 Auto Test

As long as the defibrillator/monitor is connected to AC power supply, it will perform routine test and energy delivery test daily at the specified time and remind the users of the error found.
How to set auto test time:

Access [MAIN MENU]→[CONFIG SETUP]→enter password→[TEST SETUP]→[AUTO TEST TIME] and select auto test time. Available options include 0:00, 1:00, 2:00, 3:00, 4:00 and 5:00.
Auto test item and schedule are listed below:

Test item	Description	Schedule
Routine test	Test battery and therapy modules	Once a day from 0:00 to 5:00
Energy delivery test	Deliver 200J energy	Once a week after routine test.

There is no prompt message on the screen of defibrillator/monitor during auto test. If auto test fails, after turning on the defibrillator/monitor, a low level technical alarm “Last Auto Test Failed”will be triggered. If the next auto test passes, or the routine test or energy delivery test which fails in auto test passes during user test, the “Last Auto Test Failed”alarm will be cleared.
It is recommended to perform user test if the auto test fails.
The defibrillator/monitor will save an auto test report after each auto test. You can choose whether to print auto test report after each auto test. Specific steps are: Access [MAIN MENU]→[CONFIG SETUP]→enter password→[RECORD SETUP]→[AUTO RECORD] →[AUTO TEST REPORT] and select [ON] or [OFF].
You can select [HISTORY] in user test interface to view the auto test results.

⚠Attention

- **If the defibrillator/monitor is switched off, it will perform auto test daily at the specified time only when it is connected to AC power supply.**
- **Install the defibrillator/monitor with at least one battery, place the paddles in the paddle tray correctly or connect electrode cable and 50Ω test load, or the auto test will not pass.**
- **Clean the paddles and place them into paddle tray correctly after each use. Only when the paddles contact well with the metal parts of paddle tray, will the auto test pass.**

13.6 User Test

User test performs routine test, energy delivery test and controls test.

⚠Warning

- **Make sure that patient is not connected to the defibrillator/monitor when conducting user test.**

⚠Attention

- **Install the defibrillator/monitor with at least one battery, place the paddles in the paddle tray correctly or connect electrode cable and 50Ω test load, or the auto test will not pass.**
- **Clean the paddles and place them into paddle tray correctly after each use. Only when the paddles contact well with the metal parts of paddle tray, will the auto test pass.**

13.6.1 User Test Interface

Access [MAIN MENU]→[USER TEST] to enter user test interface.

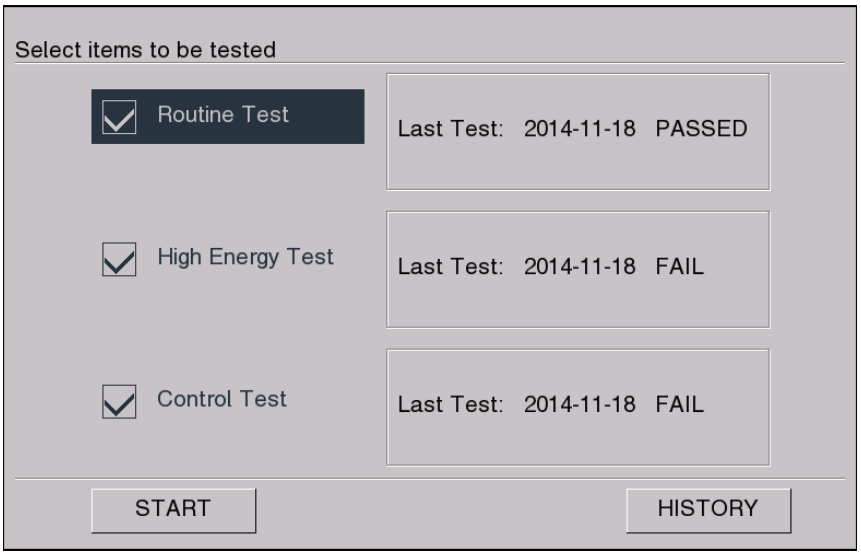


Figure13-1User test interface

Select items to be tested and select [START] to start test. Perform the test following what indicated on the screen. After test, the"Test completed" prompt message will be displayed. Press [RECORD] to print the test result. Press [BACK]soft button to return to user test interface.

13.6.2 Routine Test

Routine test includes the following test items:

- Battery 1, battery 2
- Main board
- Defibrillation/pacer function
- Monitor function

Perform the test following what indicated on the screen.

If any test item of routine test fails, the service indicator will be illuminated. The test result of each test item will be displayed on the screen. If the defibrillation/pacer function test fails, the system will give low leveltechnical alarm "Last User Test Failed" when switching on the defibrillator/monitor next time and it is suggested to perform a successful user test to clear this alarm.

⚠Attention

- **It is recommended to perform user test when changing shift.**

13.6.3 Energy Delivery Test

Energy delivery test includes 200J charge and shock test and charge and shockcircuit function test. Perform the energy delivery test following what indicated on the screen.

If energy delivery test fails, the service indicator will be illuminated and the system will give low leveltechnical alarm "Last User Test Failed" when switching on the defibrillator/monitor next time. It is suggested to perform a successful user test to clear this alarm.

13.6.4 Controls Test

Controls test includes the following test items:

- Controls (all the buttons on front panel and mode selector)
- Audio test
- Display test

Perform the controls test following what indicated on the screen.

If any test item of controls test fails, the service indicator will be illuminated and the system will give low leveltechnical alarm "Last User Test Failed" when switching on the defibrillator/monitor next time It is suggested to perform a successful user test to clear this alarm.

⚠Attention

- **During controls test, the controls have been tested turn green.**
- **Controls test doesn't test the OFF mode. If you rotate the mode selector to OFF for more than 4s, the defibrillator/monitor will shut down.**

13.6.5 Test Result Review

The defibrillator/monitor could save the test results of routine test, energy delivery test and controls test. Press [HISTORY] in user test interface to view the test results.

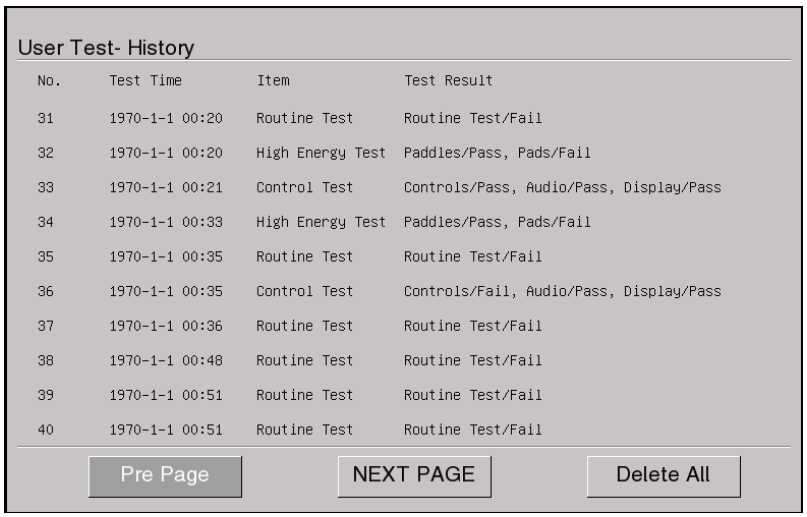


Figure13-2 Testresult review

The defibrillator/monitor could save up to 300 test reports which are listed in chronological order. Select a certain test report to view it in detail.

Press [PRE PAGE] and [NEXT PAGE] to view the test reports not on current page. Press [DELETE ALL] to delete all the test reports. Press [BACK] soft button to return to user test interface.

13.6.6 User Test Prompt

It is recommended to perform routine test and energy delivery test once a week and controls test once a year.

Each time you turn on the defibrillator/monitor, the system will check the time period from last routine test, energy delivery test and controls test automatically. If user test prompt function is activated and you do not perform corresponding test within the suggested time period,the system will give technical alarm “USER TEST OVERDUE”. If user test prompt function is deactivated and there will be no prompt even when user test is overdue.

How to activate or deactivate user test prompt function:

Access [MAIN MENU]→[CONFIG SETUP]→enter password→[TEST SETUP]→[USER TEST PROMPT] and select [ON] or [OFF].

13.7 Recorder Test

1. Start the defibrillator/monitor and switch to monitor mode.
2. Print ECG waveforms. Verify that the recorder can print normally and what printed is clear.
3. Simulate such troubles as no recording paper and recorder door open, and check whether there is corresponding prompt message on the screen. After clearing all these troubles, check whether the recorder can work properly.

13.8 ECG Cable Test

It is recommended to conduct ECG cable test once a year.

Test tool: ECG simulator

Specific test steps are as follows:

1. Switch to monitor mode. If 12-lead ECG cable is being test, enter 12-lead screen.
2. Connect the ECG cable to the defibrillator/monitor and connect the ECG lead wire to ECG simulator.
3. Start ECG simulator and select a normal ECG rhythm
4. After several seconds, check that there is normal ECG waveform displayed and there is no “ECG LEAD OFF”technical alarm. For 12-lead ECG cable, press button to print 12-lead real-time waveform and confirm the output waveforms of all leads are normal.

13.9 Manual Defibrillation Test

Test tool: Defibrillator/Pacer analyzer

13.9.1 Charge/ Shock Function

1. Remove two batteries, connect the defibrillator/monitor to AC power supply only, switch on the defibrillator/monitor and switch to manual defibrillation mode.
2. Connect paddle cable with the therapy cable connector on the defibrillator/monitor. Place the paddles on the defibrillator/pacer analyzer correctly.
3. Access[MAIN MENU]→[CONFIG SETUP]→[RECORD SETUP]→[AUTO RECORD] and set [SHOCK EVENT] to [ON].
4. Set the operating mode of defibrillator/pacer analyzer as energy measurement mode (the displayed energy is 0 or blank this moment).
5. Select 1J energy for the defibrillator/monitor.

6. Charge the defibrillator and deliver the energy to verify whether the value measured by the defibrillator/pacer analyzer meets the accuracy requirements shown in the following table.

Energy select (J)	Measured value (J)
1	0～3
100	85～115
360	306～414

7. Adjust energy level to 100J and 360J respectively and repeat step 6.
8. Operate the defibrillator/monitoron fully charged battery, switch on it and switch to manual defibrillation mode. Repeat step2 through step 7.
9. Check whether the shock event has been recorded automatically and what has been recorded is correct.
10. Use the pads and repeat step 3 through step 9.

13.9.2 Disarming Energy

1. Operate the defibrillator/monitoron fully charged battery, switch it onand switch to manual defibrillation mode.
2. Connect paddle cable with the therapy cable connector on defibrillator/monitor. Place paddles on the defibrillator/pacer analyzer correctly.
3. Set the operating mode of defibrillator/pacer analyzer as energy measurement mode (the displayed energy should be 0 or blank at this moment).
4. Select 360J energy for the defibrillator/monitor.
5. Charge the defibrillator/monitor.
6. Check whether there is charge tone during charge.
7. After charge, press [DISARM] soft button to disarm the energy.
8. Check there is “SHOCK CANCELED” prompt message and the charge completed prompt tone stops.
9. Check that the measured energy value on defibrillator/pacer analyzer is 0J or blank.
10. Access [CONFIG SETUP]→[MANUAL DEFIB SETUP]and set [AUTO DISARM TIME] to 60s.
11. Exit [CONFIG SETUP] menu.
12. Set the operating mode of defibrillator/pacer analyzer as energy measurement mode (the displayed energy should be 0 or blank at this moment). Select 360J energy for the defibrillator/monitor and charge.
13. Form the moment charge completes, check whether there is “SHOCK CANCELED” prompt message after 60s and whether the measured energy value on defibrillator/pacer analyzer is 0J or blank.
14. Use pads and repeat step3 through step 13.

13.9.3 Synchronized Defibrillation

1. Connect paddle cable with the therapy cable connector on defibrillator/monitor.Place paddles on the defibrillator/pacer analyzer correctly.Connect ECG cable with the defibrillator/monitor and connect the lead wires to the defibrillator/pacer analyzer.
2. Set the operating mode of defibrillator/pacer analyzer as synchronized defibrillation time measurement mode and output normal sinus rhythm (for example: amplitude 1mV, heart rate 60bpm).
3. Access [CONFIG SETUP]→[MANUAL DEFIB SETUP]and set [SYNC KEEP] to [ON].
4. Select 10J for the defibrillator/monitor.
5. Press [ENTER SYNC] soft button to enter synchronized defibrillation mode. If remote synchronization input function is activated, after pressing [ENTER SYNC] soft button, select [LOCAL] in the pop-up

dialog box to enter synchronized defibrillation mode.

6. Press LEAD SELECT button on the front panel to select [PADDLE] as ECG source and charge the defibrillator.
7. After charge, press both shock buttons on paddles to deliver the energy synchronously.
8. Check whether the system can deliver the energy synchronously. The delivered energy measured by the defibrillator/pacer analyzer should meet the requirement of 10J±2J.
9. Check that the delay of defibrillation synchronization measured by the defibrillator/pacer analyzer is less than 60ms.
10. Check that the synchronized shock marker is above R wave.
11. Check that the prompt messages are correct during the test.
12. Select lead II as ECG source. Charge the defibrillator and repeat step 7 through step 11.
13. Use pads and repeat step 2 through step 12.

13.10 Pacing Test

Test tool: defibrillator/ pacer analyzer

1. Operate the defibrillator/monitor on fully charged battery, switch it on and switch to pacer mode. Set the pacing mode to [DEMAND PACING].
2. Connect pads cable to the defibrillator/monitor and place pads on defibrillator/pacer analyzer correctly.
3. Set the operating mode of defibrillator/pacer analyzer as pacing measurement mode and set test load as 50Ω.
4. Set the [PACR RATE] to [70ppm] and [PACR CURRENT] to [30mA].
5. Press [BEGAIN PACING] soft button. Verify whether the pacing rate measured by the defibrillator/pacer analyzer meets the requirement of 70 ppm±1ppm and pacing current meets the requirement of 30 mA±5mA.
6. Press [STOP PACING] soft button. Set the [PACR RATE] to [170ppm] and [PACR CURRENT] to [200mA].
7. Press [BEGAIN PACING] soft button. Verify whether the pacing rate measured by the defibrillator/pacer analyzer meets the requirement of 170 ppm±2ppm and pacing current meets the requirement of 200 mA±10mA.

13.11 ECG Calibration

During the use of monitor, ECG calibration is required when the ECG signal is inaccurate. ECG calibration should be conducted by the serviceman approved by Okuman at least once a year or when you doubt the measured value.

Specific steps are as follows:

1. Press ECG parameter area;
2. Press [ECG CALIBRATE]. Then the screen displays square wave signal and displays prompt message “ECG CAL, CAN’T MONITOR”.
3. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%.
4. After calibrating, press [STOP ECG CALIBRATE].

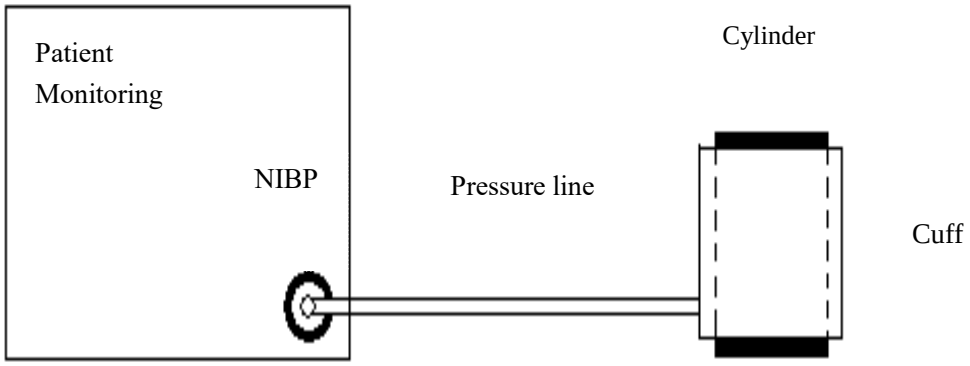
13.12 NIBP Air Leakage Test

It is used to check if the NIBP measuring pump has a leak. If the leakage test is passed, the system will not give any prompt; if not, there will be a corresponding error message in the NIBP parameter area.NIBP air leakage test should be conducted by the serviceman approved by Okuman at least once a year or when you doubt the measured value.

Leakage test process:

(1) Connect the cuff to the NIBP socket on the monitor.

(2) Wrap the cuff around a cylinder with proper size, as the figure shows.



(3) Enter [NIBP SETUP] menu.

(4) Select [LEAKAGE TEST] and the monitor starts to perform NIBP air leakage test with “Leakage Testing…” status message displayedin NIBP parameters area.

(5) System automatically inflates to the pressure of 180mmHg.

(6) After about 20 seconds, the system will automatically open the valve, which means leakage measurement is complete.

(7) If there is no error message in the NIBP parameter area, it means that the system has no sign of air leakage. If error message [Pump Leaking…] is displayed, it means that the air circuit may have an air leakage fault. Under such a circumstance, the operator should check the entire connection for loosening, and run the leakage test again after having made sure that the connection is errorless.

(8) If the error message still appears, please contact the manufacturer for repair.

⚠Warning

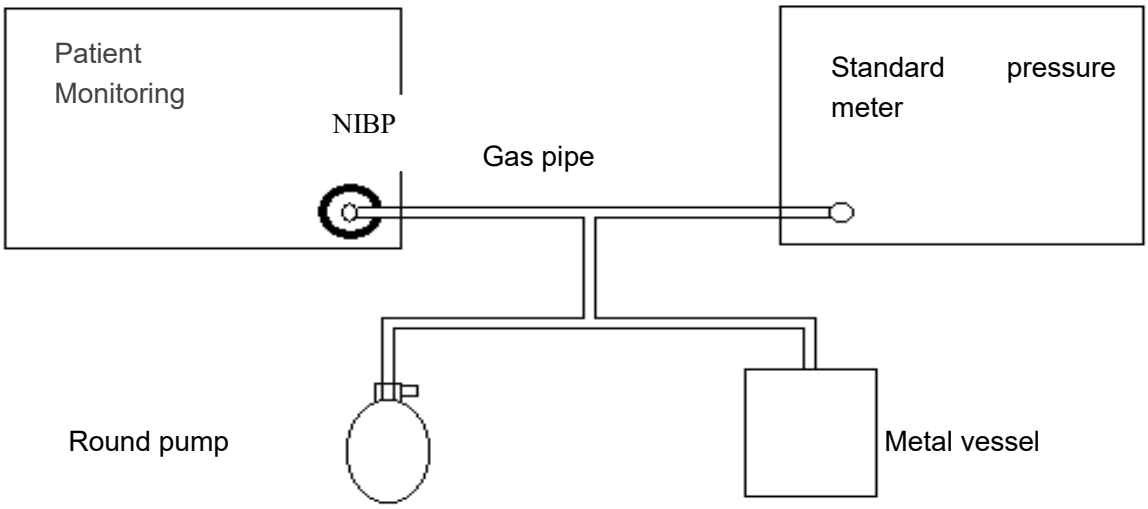
- **This air leakage test, different from those described in the standard EN 1060-1, is for users to simply test air leakage in NIBP inflation. If the system displays an error message [Pump Leaking…] at the end of testing, please contact the Okuman maintenance engineers.**

13.13 NIBP Pressure Verification

NIBP pressure verification should be carried out once a year or when you doubt the measured NIBP by the serviceman approved by Okuman.

Manufacturers recommend a calibrated pressure gauge (or mercury sphygmomanometers) with a precision more than 1mmHg to be used for NIBP pressure verification. Specific steps are as follows:

1. Set measure mode to adult mode and select a metal container with a volume of 500ml ± 5% to replace cuff.
2. Connect a calibrated standard gauge with measurement error of less than 0.8mmHg, a spherical air pumps with a t-interface and inflatable tubes with NIBP socket on the monitor as the figure shown below:



3. Access [MAIN MENU]→[MAINTENANCE] →[USER MANTIAN] →enter password→[NIBP VERIFY].
4. Inflate the metal container with spherical air pump to pressure of 100 and 200 mmHg respectively. The difference of pressure value between standard pressure gauge and monitor should be within 3mmHg. Otherwise, please contact the Okuman maintenance engineers.

13.14 NIBPOverpressure Protection Test

It is recommended to conduct NIBP overpressure protection test once a year. The specific steps are as follows:

1. Open the housing of the defibrillator/monitor, take out the multi-parameter module, remove the gas tube connected with NIBP measuring transducer and block it up.
2. Connect NIBP cuff.
3. Start NIBP measurement. When the pressure rises to the overpressure protection point (300～330mmHg), the valve will open and the sound of deflation will be heard, and the prompt message “OVERPRESSURE PROTECTION” will be displayed on the screen.

If the system can give an alarm and deflate normally, the overpressure protection function is normal.
Otherwise, please contact the service technician of our company.

13.15 IBP Calibration

IBP calibration can only be performed by the manufacturer at least once a year or as required. When IBP calibration is needed, please contact the manufacturer.

13.16 Electric Safety Test

The users can not conduct the electric safety test including ground impedance test, leakage current test and so on. Please contact the service technician for the electric safety test when necessaryy.

Chapter 14 Patient Safety

14.1 General Introduction

The design of the defibrillator/monitor complies with the international safety standard regarding medical electrical equipment. The defibrillator/monitorhasthe functions of defibrillation protection with floating input and surgical electrotome protection.

14.2 Environment Requirements

Users should follow the following guides to ensure absolute safety of electricity installation.
Vibration, dust, corrosives or explosive gas, extreme temperature and humidity should be avoided in the environment where the defibrillator/monitor is used.
If the defibrillator/monitor is installed in an instrument cabinet, please ensure good ventilation and enough space in the front to operation and at back for maintenance, when the cabinet door is open. A clear space of at least 2 inches or 5 centimeters should be cleared around the defibrillator/monitor for ventilation.
The monitoring system should be in the ambient temperature -20℃□+70℃(storage), 0℃□45℃(running) to meet the requirements. An ambient environment out of this range may affect the accuracy of the defibrillator/monitor and cause damages to its components and circuits.

14.3 Grounding Protection

To protect the patients and operation staff, the housing of thedefibrillator/monitor must be grounded. So the defibrillator/monitor is equipped withthree-wirecable. When pluging the cable into a matching connector, the defibrillator/monitor is grounded through the grounding lineinside the power line. In case no three-plug connector is available, please consult the electrical operating staff in the hospital.

⚠Warning

- **Replacement of the three-plug connector with a two-plug connector is strictly prohibited.**

The grounding wire should be connected with the equipotential grounding terminal of the defibrillator/monitor. The users, who do not know whether a given combination of instruments may invite dangers, e.g. due to accumulations of leakage currents, should consult relevant manufactures or experts in this field so as to guarantee that the required safety of the combined instruments are not damaged when the given combination is in use.

14.4 Equipotential Grounding Connection

The first-class protection of the defibrillator/monitor is embodied in the protective grounding (protective ground) system of the building by means of power plugs grounding. The defibrillator/monitor should be separately connected to the equipotential grounding system for examinations of hearts or skulls. One end of the euquipotential grounding line (potential equalization conductor)should be connected to the equipotential grounding terminals on the rear panel of the defibrillator/monitor and the other end should be connected to one

connector of the equipotential grounding system. The equipotential grounding system should be in place for safety functions of the protective grounding line in case of any damage to the protective grounding system. Cardiac or brain examinations should be conducted only in the rooms equipped with protective grounding systems. A check of the defibrillator/monitor should be conducted to guarantee it is in good condition before each use. The cables connecting with patients and defibrillator/monitor should be guaranteed not having been subjected to electrolytic pollution.

⚠Warning

- **Battery should be used to power the monitor in case of unstable protective grounding system.**

14.5 Condensation

The working instruments should be guaranteed not to form any condensation. Transferring of the instrument from one room to another may cause condensation on the instrument. This is attributed to its exposure to humid air at different temperatures. Unnecessary problems can be avoided by placing the instrument in a dry place before using it.

Note: Condensation is defined as coagulation of gases or liquids when cooled, e.g. water vapor when cooled is transformed into water and water when cooled into ice. The lower the temperature is, the faster condensation is formed.

⚠Warning

- **The defibrillator/monitoris prohibited to use in the presence of flammable anesthetic agents so as to avoid any risk of explosions.**

Chapter 15 ECG Monitoring

15.1 Overview

The ECG measures the electrical activity of the patients' heart and displays it on the monitor in the form of waveform and valueso as to accurately assess the physiological status of the patient. To get accurate measured value, the ECG lead wired should be placed correctly.

This defibrillator/monitor is applicable tomonitoring ECG by using 3-lead, 5-lead and 12-lead wires as well as paddles and pads. Different waveformscan be displayed according to different lead wires.

15.2 ECG Display

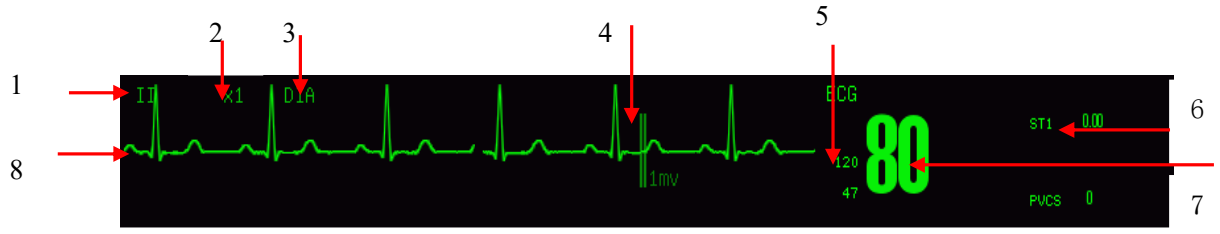


Figure 15-1 ECGDisplay

⚠Attention

- **The pacing sign aldetected will be shown as " ' "above the ECG waveform**

1. ECG lead name
   Select the lead name and rotate the knob to switch ECG lead name.
2. ECG wave gain
   Select the gain and rotate the knob to switch ECG wave gain.
3. Filter mode
   Select the filter mode and rotate the knob to switch the filter mode.
4. 1 mV Scale
5. ECG alarm limit
6. PVCs and ST-I analysis
   Display the current analysis state of PVCs and ST segment with the refresh rate of once per second.
7. ECG measured value
8. ECG waveform.

15.3 Safety Information

⚠Warning

- **The operators shall not touch the patients, tables and instruments during defibrillation.**
- **Only use the ECG lead wire specified by OKuman.**
- **When connecting the electrodes or patient cable, make sure that the conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact any other conductive parts including earth and make sure that all the electrodes are placed on the patient to prevent them from contacting the conductive parts or earth.**
- **The ECG cable with defibrillation-proof protection should be used when conducting defibrillation.**
- **After defibrillation, the ECG waveform will recover within 5 seconds without losing any stored data.**
- **This monitor is protected from electrosurgical interference.**
- **Inspect the electrode application site for skin irritation daily. If there is sign of allergy, replace the electrodes or change the application site.**
- **The pacemaker state should be set properly for the patients. For the patients with pacemaker, the pacing pulse will be counted when sudden cardiac arrest and some arrhythmia happen. Keep close surveillance on the patients with pacemaker and do not rely merely on heart rate alarms and heart rate value displayed.**
- **Before ECG monitoring, check that the function of ECG cable is normal. After disconnecting the ECG cable, the monitor will trigger an audible alarm anddisplayalarm message "ECG LEAD OFF".**
- **Never expose the equipment under x-ray or strong magnetic field (MRI).**
- **During defibrillation, the ECG cable connected with patient may be damaged. Before reusing these cables, check whether its function is normal.**

⚠Attention

- **Interference from ungrounded equipment near the patient and ESU interference may cause waveform problems.**
- **If ECG electrodes are placed correctly, but the ECG waveform is not accurate, please replace lead wires.**
- **In order to protect the environment, the electrodes used should be recycled or be disposed of properly.**
- **Try not to use external paddles to conduct ECG monitoring.**

15.4 Steps of ECG Monitoring

15.4.1 Placement of ECG Electrodes

15.4.1.1 Preparation

Take patient skin preparation beforeapplying ECG electrodes:

1. As skin is poor conductor of electricity, to get a good contact of the electrode and the skin, it is important to make preparation for the patients' skin.
2. If necessary, shave the area for the electrode.
3. Thoroughly clean the skin with soap and water.(Do not use ether or pure alcohol, because they will increase the resistance of the skin).
4. Dry and rub the skin in order to increase the capillary blood flow and remove skin debris and oil.
5. Attach the connector of ECG cable prior to placement of the electrode.
6. Place electrodes on the patient. If the electrodes used do not have conductive gel, apply the conductive gel before placement.
7. Connect the electrode lead and the patient cable.
8. Check whether the defibrillator/monitor is turned on and rotate the mode selector to monitor mode.

15.4.1.2 Identifiers and Color Code of ECG Electrodes

The tables below list the identifiers and color codes of ECG electrodes in American standard and European standard.

Identifiers and color codes of 3-lead and 5-lead ECG electrodes

American standard		**European standard**	
Identifier	**Color**	**Identifier**	**Color**
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White

Identifiers and color codes of 12-lead ECG electrodes

American standard		**European standard**	
Identifier	**Color**	**Identifier**	**Color**
RA	White	R	Red
LA	Black	L	Yellow
RL	green	N or RF	Black
LL	Red	(f)	Green
V1	Red	C1	Red

V2	Yellow	C2	Yellow
V3	Green	C3	Green
V4	Blue	C4	Brown
V5	Orange	C5	Black
V6	Purple	C6	Purple

15.4.1.3 Placement of 3-lead ECG Electrodes

The position of electrode of 3-lead ECGcable is divided into American standard and European standardsee the figure below:
White/red (right arm) electrodes - placed under the clavicle, near the right shoulder.
Black/yellow (left arm) electrodes - placed under the clavicle, near the left shoulder.
Red/green (left leg) electrodes - placed in the left lower abdomen.

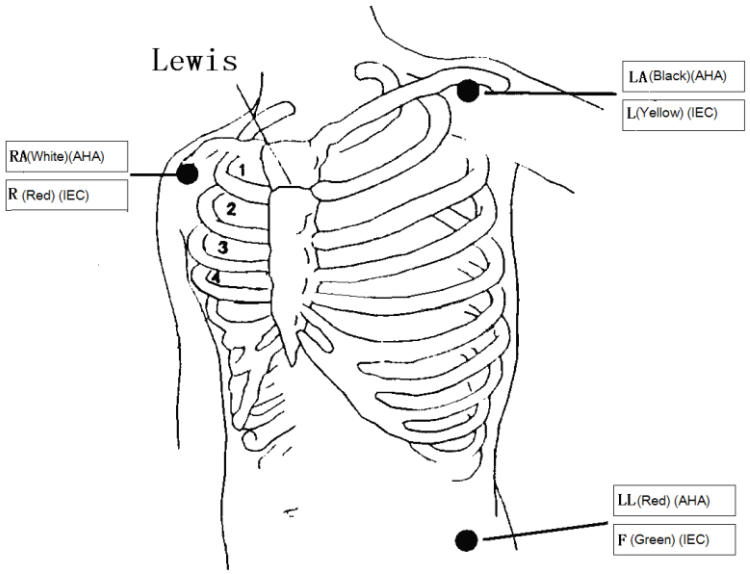


Figure15-2 Positions of electrodes of 3-lead ECG cable

15.4.1.4 Placement of 5-lead ECG Electrodes

The position of electrode of 5-lead ECG cable is divided into American standard and European standard (see the figure below):

- White/red (right arm) electrodes - placed under the clavicle, near the right shoulder.
- Black/yellow (left arm) electrodes - placed under the clavicle, near the left shoulder.
- Green/black (right leg) electrodes – placed at the right lower quadrant.
- Red/green (left leg) electrodes - placed in the left lower abdomen.
- Brown/white (chest) electrode- on the chest wall

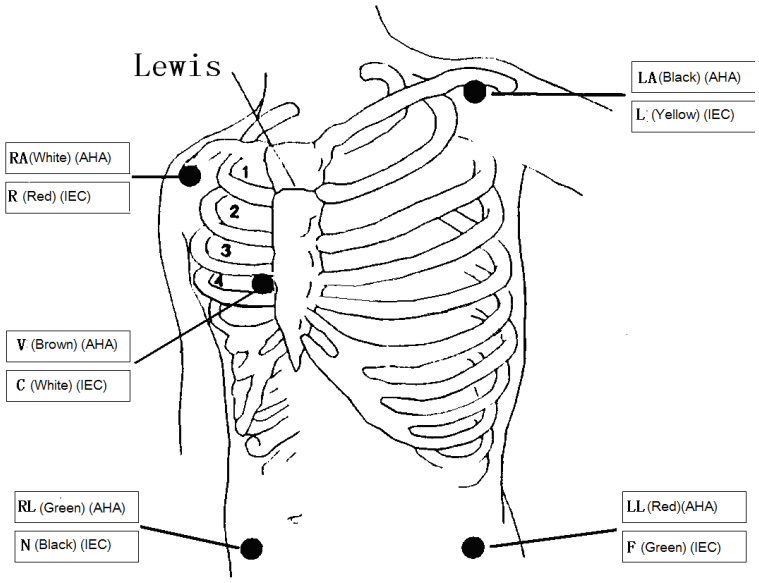


Figure15-3 Positions of electrodes of 5-lead ECG cable

15.4.1.5 Placement of Reformed 12-lead ECG Electrodes

The position of electrode of 12-lead ECG cable is divided into American standard and European standard, see the figure below

White/red (right arm) electrodes - placed under the clavicle, near the right shoulder.

Black/yellow (left arm) electrodes - placed under the clavicle, near the left shoulder.

Green/black (right leg) electrodes – placed at the right lower abdomen.

Red/green (left leg) electrodes - placed in the left lower abdomen.

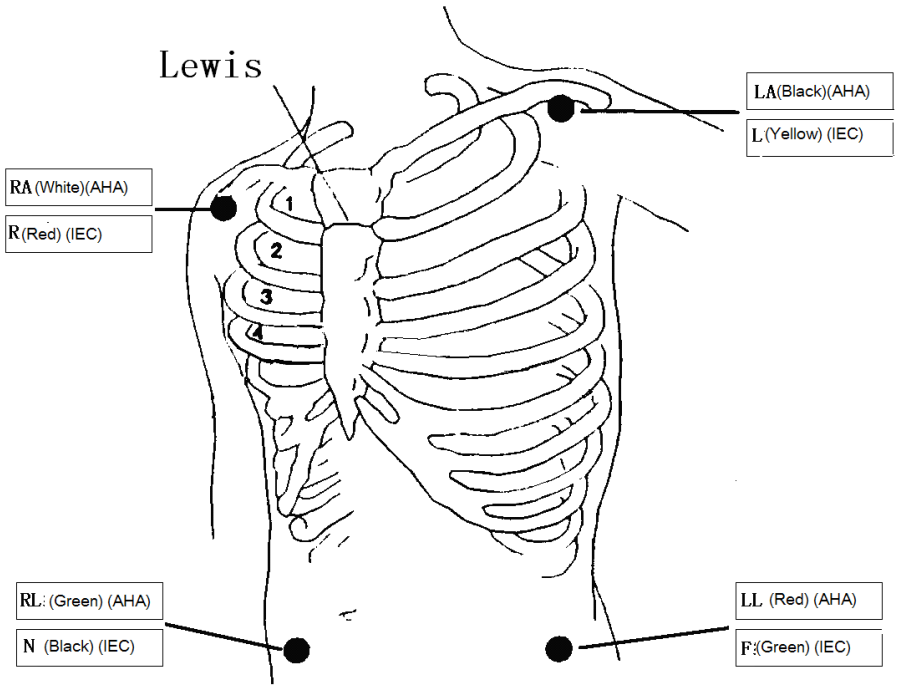


Figure 15-4Positions of limb electrodes of 12-lead ECG cable

There are generally six electrode positions on the chest, using intercostal gap to pinpoint the positions, V1 ~ V6:

V1/C1: in the fourth intercostal space on the right edge of the sternum

V2/C2: in the fourth intercostal space on the left edge of the sternum

V3/C3: at the midpoint of the C2 and C4

V4/C4: at the intersection of the fifth intercostal space on the left edge of the sternum and the midline of left clavicular

V5/C5: at the left anterior axillary line, with horizontal position the same as the C4

V6/C6: at the parallel median axillary line of C4 level on the leftat the left median axillary line, with horizontal position the same as the C4

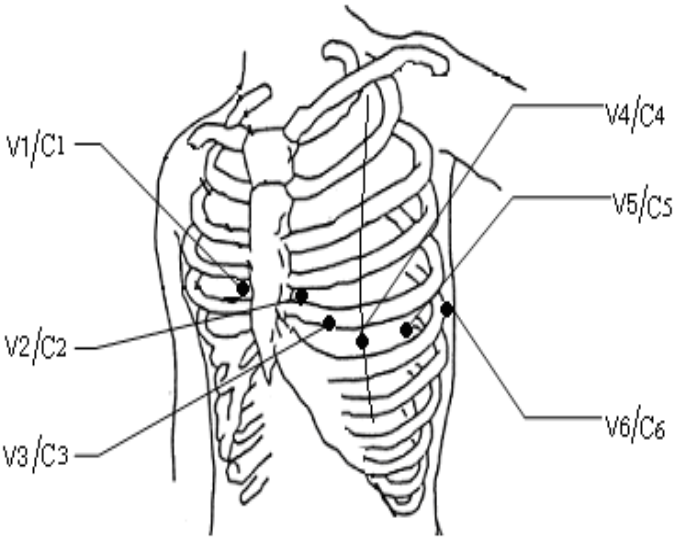


Figure 15-5Position of chest electrodes of 12-lead ECG cable

15.4.1.6 ECG Lead Connection Recommended for Surgical Patients

⚠Warning

- **When using electricity surgical unit (ESU), put the ECG electrode at the middle position between ESU earth plate and electrosurgical knife to avoid burn. The cable of electricity surgical unit and the ECG cable can't be entangled.**
- **In the use of electricity surgical unit (ESU), never allow the electrodes to be close to the earth plate of electricity surgical unit, or ECG signal would be interfered seriously.**

The position of ECG lead depends on the type of surgery. For example, for the thoracotomy, electrode can be put on the chest or the back. In the operating room, because of using electrosurgical knife equipment, sometimes artifact may affect ECG waveform, in order to cut the artifact, you can put the electrode on left and right shoulder, near the abdomen of left or right side, and the breast lead can be put on the left side of chest quiet near the center. To avoid the electrode being put on the upper arm, or ECG wave will become very small.

15.4.2 Placement of Pads or External Paddles

15.4.2.1 Preparation

1) Do skin preparation
2) Place external paddles or pads
   - For pads: place pads on patient in the anterior-lateral position according to the indication on the packaging.
   - For external paddles: hold the handle of paddles with two hands and take the paddles out form the paddle tray. Apply some conductive gel to the paddles and place them on patient in the anterior-lateral position.
3) For pads: connect pads with pads cable.
4) Connect paddles cable or pads cable to the defibrillator/monitor until the “click” is heard.

15.4.2.2 Anterior-Lateral Placement

1. Place the RA pad or Sternum paddle on the patient’s upper right torso, lateral to the sternum and below the clavicle, as shown below:
2. Place either the LL pad or Apex paddle lateral to the patient’s left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, as shown below:

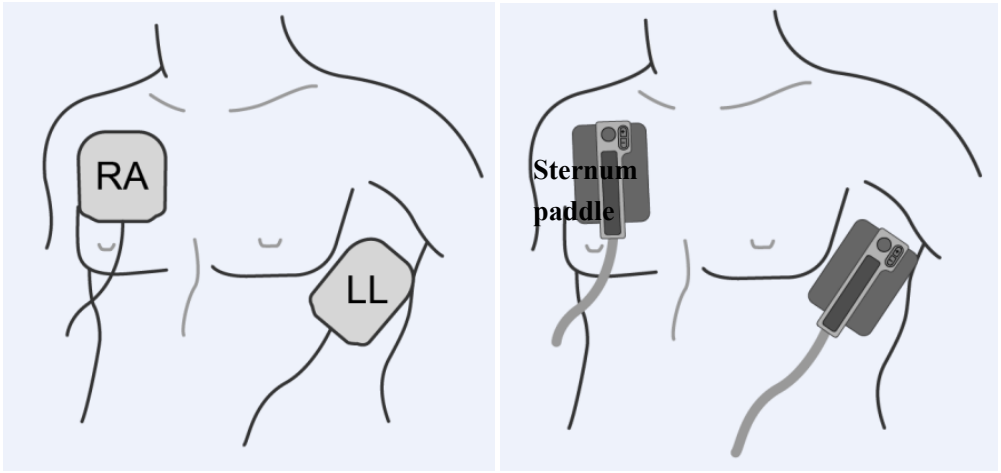


Figure15-6Anterior-lateral Placement

⚠Attention

- **When conducting ECG monitoring, the external paddles and pads can only be placed in the anterior-lateral position.**

15.5 Waveform Quality

Feature of a good signal:

- Tall, narrow and without notch.
- R wave tall, completely above or below the baseline.

- T waves less than 1/3 height of the R wave.
- P wave should be much smaller than the T wave

In order to obtain 1 mV calibration ECG wave, ECG should be calibrated, at the same time,the screen displays the prompt: CAL,CAN'T MONITOR! (cannot monitor the patient during calibration).

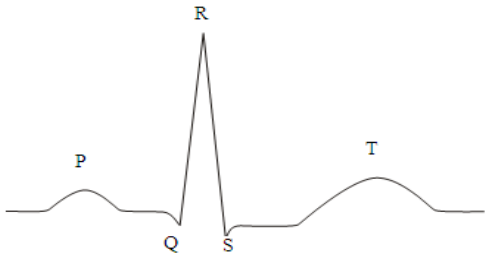


Figure 15-7Standard ECG Waveform

15.6 ECG Settings

15.6.1 Setting the Lead Type

This monitor is applicable to the 3-lead, 5-lead and 12-lead ECG monitoring. When ECG cables of different leads are used, the ECG leads that can be monitored are different.

When using 3-lead ECG lead wire, the leadscan be monitored include I, II and III.

When using 5-lead ECG lead wire, the leadscan be monitored include I, II, III, aVR, aVL, aVF and V1.

When using 12-lead ECG lead wire, the leadscan be monitored include I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5and V6.

When using the 3-lead ECG lead wire, only one channel ECG waveform can be displayed on the screen; while when using the 5-lead or 12-lead ECG lead wire, ECG waveforms of two channels can be displayed on the screen.

Steps for setting the lead type:

1. Select ECG parameter area and [ECG SETUP] menu will be displayed;
2. Select[LEAD TYPE] and select [3 LEADS], [5 LEADS] or [12 LEADS]

15.6.2 Setting the Lead Name

Method1: only valid for the first ECG waveform

1. Select the lead name of ECG waveform of the first channel;
2. Rotate the knob to change the lead name.

Method 2: valid for two ECG waveforms

1. Select ECG parameter area and the [ECG SETUP] menu will be displayed;
2. Select[ECG 1]and select the lead name, for example, lead II.
3. When using 5-lead ECG cable and 12-lead ECG cable, select [ECG 2] and select the lead name, for example, lead I.

15.6.3 Setting the Gain

Gain is used to adjust the size of ECG waveform. Available gains include× 0.25 × 0.5 × 1, × 2, × 4 and auto. Auto mode automatically adjusts the gain by the monitor. The right side of each ECG waveform channel has given 1mv scale. The height of the 1mv scale is proportional to the amplitude.

1. Select ECG parameter area and the [ECG SETUP] menu will be displayed;
2. Select[GAIN] and select [× 0.25],[× 0.5],[× 1], [× 2], [× 4] or[AUTO]

⚠Attention

- **When the input signal is too large, the peak may be truncated. The user can refer to the actual waveform to manually change the gain of the ECG waveform in order to avoid the incomplete waveform display.**

15.6.4 Setting the Filter Mode

There are four filter modes: diagnostic mode, monitor mode, therapy mode and ST mode. The diagnosis mode shows unfiltered ECG wave; the monitor mode can filter out the artifacts which may lead to false alarms. The therapy mode in the operating room can reduce the artifact and interference from electrical surgical unit. Filter mode is displayed above the first ECG waveform.

ST filter mode is user-friendly to conduct more accurate ST segment measurements. Frequency response range of this mode is 0.05Hz-40Hz.The good scalability of low frequency ensures undistorted interpretation of patient's ST segment, and can effectively filter high-frequency interference signals over 40Hzincluding power frequency interference. In this mode the user can more accurately acquire the measured ST segment value by adjusting the position of the ST segment analysis points.

1. Select ECG parameter area and the [ECG SETUP] menu will be displayed;
2. Select[FILTER]and select [Diagnosis], [Monitor], [Therapy] or [ST];
3. Or select the filter mode above the first ECG waveform and rotate the knob to switch the filter mode.

⚠Warning

- **Only under diagnostic mode will the actual ECG signal will be provided. ECG waveforms have varying degrees of distortion under monitor mode and therapy mode. At this time, the system can only provide the basic status of the ECG signal, which may have a great impact on the result of the ST segment analysis and arrhythmia analysis. So we recommended that when the interference is small, try to use the diagnostic mode to monitor the patient.**

15.6.5 Setting the Notch

Notch inhibits the 50Hz or 60Hz frequency components of signals collected. When the filter mode is not the diagnostic mode, the system automatically enables the notch; while when filter mode is the diagnostic mode, the user should select to enable or disable the notch function according to the need.

1. Select ECG parameter areaand the [ECG SETUP] menu will be displayed;
2. Select [NOTCH];
3. Select [50Hz] or [60Hz] according to the frequency of the power supply;
4. Or select [OFF] to deactivate the notch function.

15.6.6 Setting the Heart Rate Source

1. Select ECG parameter area and the [ECG SETUP] menu will be displayed
2. Set [HR SOURCE] and select [ECG], [SpO_2] or [AUTO];
   - [ECG] means the heart rate is calculated based on the ECG waveform and HR value will be the alarm source;
   - [SPO2] means the heart rate is calculated based on the PLETH waveform and SpO2 value will be the alarm source;
   - [AUTO] means the defibrillator/monitor would decide the HR source based on the signal quality.

15.6.7 Setting the Calculation Lead

1. Select ECG parameter areaand the [ECG SETUP] menu will be displayed;
2. Select [CALCULATE LEAD] and select the lead to calculate heart rate in the pop-up list box.

Available calculation leads vary will different lead wires:

- When using 3-lead ECG lead wire, the calculation lead is fixed to lead II.
- When using 5-lead ECG lead wire, the available calculation leads include I, III and V.
- When using 12-lead ECG lead wire, the available calculation leads include I, II, V1,V2, V3, V4, V5and V6.

15.7 ST Segment Analysis

15.7.1 About ST Segment Analysis

The normal heart beat and atrioventricular pacing are used for ST segment analysis. The defibrillator/monitor analyzes these heart beats and calculates the elevation and depression of the ST segment. The DFM 800/DFM 600 defibrillator/monitor can display the information in ST numerical form. It can continuously monitor all available leads. For ST-segment analysis, the ECG waveform is not required to be displayed on the screen. For ST analysis,it usually uses a special filter which ensures diagnostic quality. If you use the "diagnosis" filter mode to monitoring ECG, the ST segment of the ECG wave will be slightly different from the ST segment in the ST fragment with the same waveform. In order to diagnostically assess the ST-segment, please always switch to filter mode of "ST". You can also select the "monitor" or "therapy" mode, but ST-segment data will have a serious distortion.

ST segment analysis can measure the elevation or depression of the specified ST-segment of a lead.

Meaning of ST-segment measurement: A positive number indicates the elevation, a negative number indicates depression

Measuring range of the ST segment: -2.0 ~ +2.0 mV.

15.7.2 Impact on ST Segment

Some clinical conditions make it difficult to get reliable ST monitoring, such as:

- Unable to obtain the leads with low noise;
- The irregular baseline resulting from arrhythmia such as atrial fibrillation / atrial flutter;

- The patient is continuous ventricular pacing
- Patients have left bundle branch block

When these things happen, you should consider disabling ST monitoring

⚠Warning

- **The clinical significance of the ST change information provided by the defibrillator/monitor should be decided by the doctors.**

15.7.3 Enabling ST Segment Analysis

1. Select ECG parameter area;
2. Enter the menu [ST ANALYSIS];
3. Set [ST ANALYSIS] to[ON] or [OFF].

When it is set to [ON], ST value would be displayed in the ECG parameter area;

15.7.4 Adjusting the ST Segment Analysis Point

Set the ST measurement point as R peak point.The ST measured values of every cardiac integrated wave is the vertical distance between the peak point and the two measurement points, as shown below:

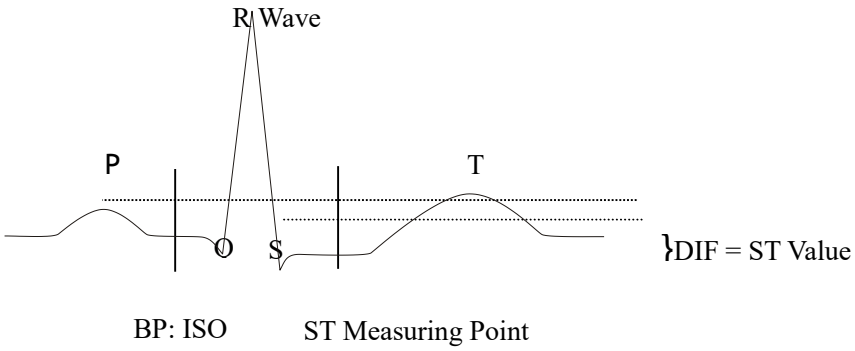


Figure 15-8 ST Analysis point

⚠Attention

- **If the patient's heart rate or ECG waveform changes obviously, you need to adjust the location of ISO and ST point. The abnormal QRS complex are not considered when the ST analysis is made.**

Method to adjust the ISO and ST point:

1. Select ECG parameter area, in the pop-up [ECGSETUP] menu, enter the menu[ST ANALYSIS];
2. Set [ST ANALYSIS] to[ON];
3. Select the [DEF POINT] to enter the [DEF POINT] window; the three vertical lines in the window stand for the position of ISO, J, and ST respectively.
   - The ISO point is to decide the position of equipotential point against R peak point. Locate the ISO point in the middle of the flattest part (between P wave and Q wave or before P wave) in the baseline.
   - The J point is to decide the position of J point against R peak point, which is conducive to correctly locating ST point. Locate the J point at the end of QRS complex and the start point of ST.

- ST point is located in a certain position with a fixed distance from J point—J+40, J+60 or J+80.Move the J cursor to locate the ST point in the middle of the ST.

4. Select [ST] and press the knob to choose an ECG lead whose J point and P wave are obvious. Press once, name of ST would change from ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-V1, ST-V2, ST-V3, ST-V4, ST-V5, ST-V6 circularly.
5. Select [ISO (ms)],[ST (ms)] point. Press ⬅and ➡to make adjustment. Select [J] to decide position of each point.

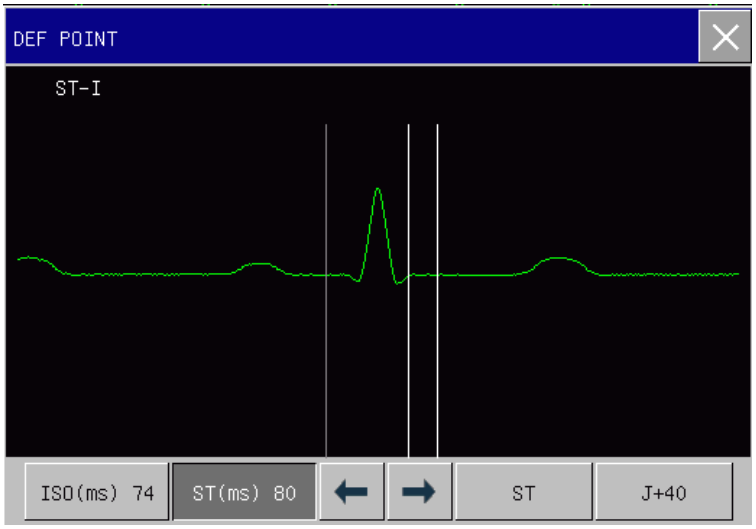


Figure15-9Adjustthe ST Segment Analysis Point

⚠Warning

- **Please ensure that the location of the ST measurement points suitable for the patients.**

15.8 Arrhythmia Analysis

Arrhythmia analysis is used for the clinical monitoring of patients' ECG to detect changes in heart rate and ventricular premature beat, to save the arrhythmic events and to generate alarm information. Arrhythmia analysis can be used to monitor pacemaker and non-pacemaker patients. Doctors may, based on the arrhythmia analysis, evaluate the patient's condition (such as heart rate, the PVCs (premature ventricular contraction) frequency, rhythm, and abnormal heartbeat) and give the appropriate diagnosis and treatment. In addition to the detection of ECG changes, the arrhythmia analysis can also be used to monitor patients and give appropriate alarms.

The arrhythmia monitoring is disabled by default. Users can turn on this function according to your need.

The function of arrhythmia monitoring can, by testing and classification of arrhythmias and heart abnormalities, remind doctors to pay attention to the heart beat rhythm of the patient, and then give alarm.

The monitor can make 19 kinds of arrhythmia analysis.

Arrhythmia analysis system will store 200 alarm events and the operator can edit the arrhythmic events in the menu.

15.8.1 Enabling Arrhythmia Analysis

1. Select ECG parameter area;
2. Enter the [ARR ANALYSIS]menu;
3. Select [ARR ANALYSIS] and toggle between[ON] and [OFF];

15.8.2 Arrhythmia Alarm Settings

1. Select ECG parameter area
2. Enter [ARR ANALYSIS] menu;
3. Select [ARR ALM SETUP];
4. Select [ARR TYPE] and select [ALL] or separate arrhythmia [ASYSTOLE], [VFIB], [R ON T], [VT> 2], [COUPLET], [PVC], [BIGEMINY], [TRIGEMINY], [SVT], [BRADY], [PNC], [PNP], [MISSED BEATS],[IHB], [VTAC], [TACHY],[PVCs TOO HIGH], [EXTREME TACHY], [EXTREME BRADY].

15.8.3 Setting the Arrhythmia Threshold

You can set the threshold for tachycardia, extreme tachycardia and extreme bradycardia. When HR value exceeds the threshold, the defibrillator/monitor will give corresponding alarms.
Specific steps are as follows:

1. Select ECG parameter area and the [ECG SETUP] menu will be displayed;
2. Select [ARR ANALYSIS] and then select [ARRH THRESHOLD]
3. Select [TACHY] to adjust the tachycardia threshold with valid range of 120～350;
4. Similarly, select [EXTREME TACHY] to adjust the extreme tachycardia threshold with valid range of 60～350;
5. Similarly, select [EXTREME BRADY] to adjust the extreme bradycardia threshold with valid range of 15～120;

15.8.4 ArrhythmiaRelearning

During ECG monitoring, when great changes of patient’s ECG template takes place, the users should start the arrhythmia relearning process, which can help the monitor learn new ECG template to correct arrhythmia alarm and HR value sander store ST measurement.
Particular procedures are:

1. Select ECG parameter area;
2. Enter [ARR ANALYSIS]menu;
3. Select [ARR RELEARN].

Chapter 16 Manual Defibrillation and Synchronized Cardioversion

16.1 Overview

This chapter introduces how to conduct manual defibrillation and synchronized cardioversion by using pads, external paddles and internal paddles.

It is necessary to assess patient's cardiac rhythm correctly and decide whether to conduct synchronized defibrillation or synchronized cardioversion before manual defibrillation. Select proper energy level to charge the defibrillator. During defibrillation, the screen will display text message to indicate the users how to operate.

In manual defibrillation mode, beside ECG, the defibrillator/monitor can monitor one more physiological parameter. Enter [CONFIG SETUP]→[MANUAL DEFIB SETUP]→[MONITOR PARAM.1] and select the parameter to be monitored.

In manual defibrillation mode, if NIBP measurement is being conducted when charging the defibrillator, NIBP measurement will stop. After shock or disarming the defibrillator, NIBP measurement will auto start if NIBP measure mode is auto, while NIBP measurement can be started manually if the measure mode is manual.

The alarm is disabled by default when entering the manual defibrillation mode and you can press  key to enable the alarms.

16.2 Safety Information

⚠Danger

- **Do not conduct defibrillation in the presence of oxygen-rich atmospheres. When conducting defibrillation on the patient with oxygen catheter, place the oxygen catheter properly. Do not put it near the pads to avoid fire and explosion.**
- **During defibrillation, do not allow pads to touch each other or touch ECG electrodes, lead wires, dressings, etc. Otherwise electrical arcing and patient skin burns could be caused.**
- **During defibrillation, do not touch patient and conductive material (including bed and stretcher) connected with the patient to avoid potential injury and death.**
- **During defibrillation, do not allow the patient touch conductive liquid like saline solution, blood and conductive gel and conductive material like bed and stretcher to avoid forming current path.**
- **Do not use wet hands or the hands with conductive gel to handle the paddles, or the operators may be shocked.**

⚠Warning

- **Do not use liquid conductive agent. Only the conductive gel specified by Okuman can be used.**
- **Do not attach the paddles to your body to verify whether the paddles are connected well.**
- **When using the paddles, put the paddles on patient flatly and push them with equal strength. Do not push the paddles with too much strength, or patient could be injured.**
- **Select appropriate defibrillation energy level for children.**

- **During synchronizedcardioversion, if ECG waveform is obtained through external paddles, the artifacts caused by paddles' movement may be similar to R wave and trigger defibrillation shock.**

⚠Caution

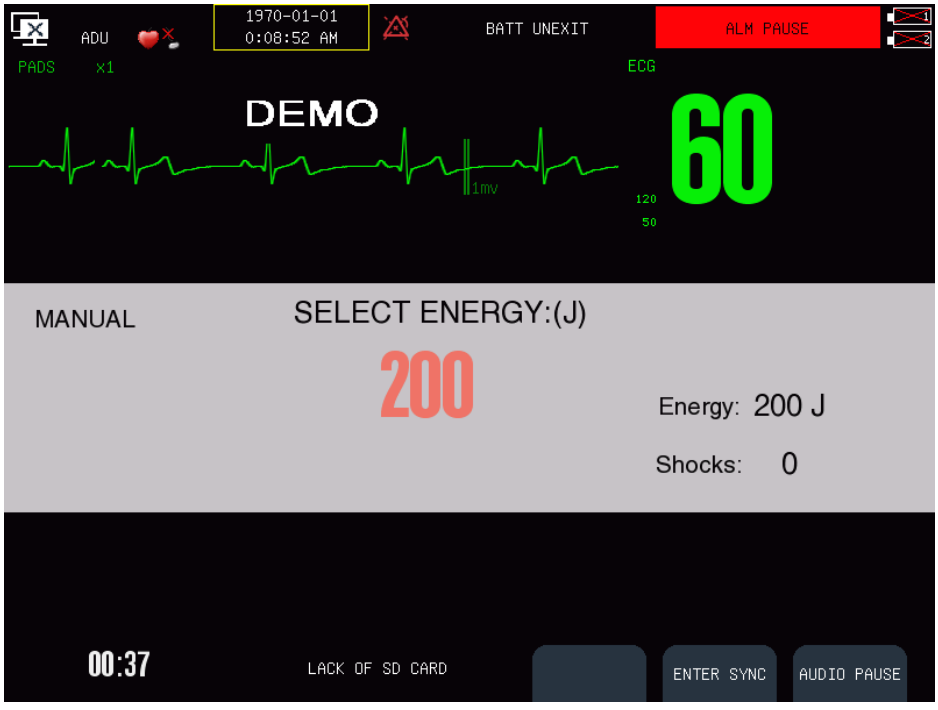
- **After therapy, the conductive gel on the paddles should be cleaned immediately to prevent the paddles from corrosion.**
- **The medical device which has no defibrillation protection shall be disconnected from the patient during defibrillation.**

⚠Attention

- **Too high impedance could have a great impact on patient's therapy. Reduce the impact caused by high impedance to the utmost. When prompt message "IMPEDANCE TOO HIGH, SHOCK CANCELED" appears, please check whether patient skin is clean and dry and whether chest hair has been shaved. If the prompt message is still there, please replace pads or pads cable.**
- **Alarms are disabled by default when entering manual defibrillation mode with text message"ALARM OFF" displayed in physiological alarm message area. You can enable alarms by pressing alarm pause key, entering synchronizedcardioversion mode or switching to monitor mode or pacer mode.**

16.3 Manual Defibrillation Interface

The manual defibrillation interface is shown as follows:



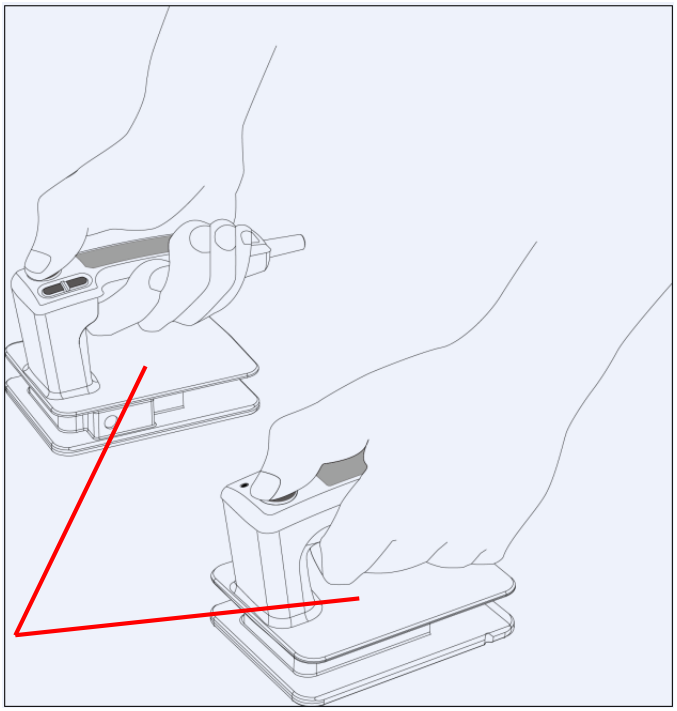
In manual defibrillation mode, only one ECG waveform and relevant parameters can be displayed. In

defibrillation message area at the middle of manual defibrillation interface, such information about manual defibrillation as defibrillation mode, synchronized status, energy level, impedance indicator, defibrillation prompt message, shock times and so on will be displayed.

16.4 Steps of Manual Defibrillation

1. Remove all clothing from patient's chest. Dry patient's chest and do skin preparation if necessary.
2. Choose proper therapy cable and insert it into the therapy cable connector on the right panel of the defibrillator/monitor until a "click" is heard.
3. Place pads or paddles.
   - **Pads**: place pads to the patient in the anterior-lateral position or anterior-posterior position according to the indication on the packaging.
   - **Paddles**: hold the handle of paddles with two hands and take the paddles out form the paddle tray. Apply some conductive gel to the paddles and place them on the patient in the anterior-lateral position.

Do not contact this surface and the parts below it.



4. Rotate the mode selector to manual defibrillation mode.
5. Select energy level and the energy level selected will be displayed in defibrillation message area.
   - Turn the mode selector to the desired energy level;
   - Turn the mode selector to 1-360 position and press "+" and "—" to adjust energy level.
6. Charge the defibrillator
   - Press **CHARGE** button on the front panel. If external paddles are used, you can also press the **CHARGE** button on the paddles. When the defibrillator is being charged, the progress bar will be displayed in defibrillation message area and charge tonewill be given out. When the defibrillator is charged well, charge completed prompt tone will be given out.

   If you want to increase or reduce the selected energy level during charge or after charge completed, change the energy level directly and recharge the defibrillator.
7. Shock

   Make sure the patient needs to be shocked and the charge has been completed. Make sure no one

contactswith the patient and on one contacts with the accessories and equipment connected with the patient. Shout out “STAND CLEAR” loudly and clearly.

- For pads: press the **SHOCK** button on the front panel
- For external paddles: press the both shock buttons on the paddles simultaneously.

⚠Attention

- **200J energy level is recommended for defibrillation.**
- **When using external paddles, the SHOCK button on the front panel is not available.**
- **Usually, defibrillation is conducted by using paddles or pads. But you can choose ECG lead wires to conduct ECG monitoring during defibrillation and any available lead can be selected to display.**

16.4.1 Using Child Paddles

Child paddles are installed inside the external paddles. To use child paddles, press the latch in the front end of external paddles and pull the electrodes of external paddles.
For other operating steps, please refer to ***16.3 Steps of Manual Defibrillation***.

16.4.2 Using Internal Paddles

Use internal paddles to conduct defibrillation following the steps below:

1. Start the defibrillator/monitor and rotate the mode selector to manual defibrillation mode.
2. Select proper internal paddles according to patient’s condition. Insert the cable of internal paddles into the therapy cable connector on the defibrillator/monitor until a “click” is heard.
3. Select energy level.
4. Hold the handle of the two internal electrodes and place the internal paddles at right atrium and left ventricular as shown below:

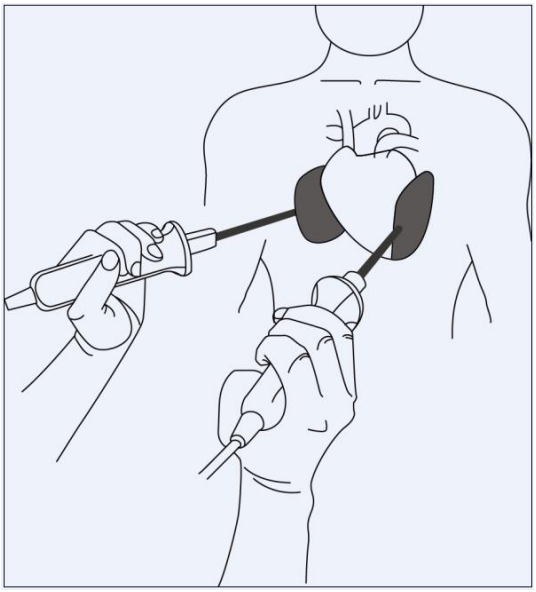


Figure16-1Placement of internal paddles

5. Press the **CHARGE** button to charge the defibrillator
6. Make sure no one contacts with the patient and on one contacts with the accessories and equipment connected with the patient. Shout out “STAND CLEAR” loudly and clearly.
7. Press the **SHOCK** button to deliver energy to the patient.

⚠Attention

- **Clean the internal paddles after each use.**
- **Sterilize the internal paddles before use, or serious infection will be caused.**
- **When using internal paddles, the maximum selectable energy level is 50J. Higher energy will damage the heart.**

16.5 Synchronized Cardioversion

In manual defibrillation mode, press [ENTER SYNC]soft button to enter the synchronized cardioversion mode. The synchronized state will be displayed in defibrillation message area and an R wave mark will be displayed above each R wave detected as shown below:

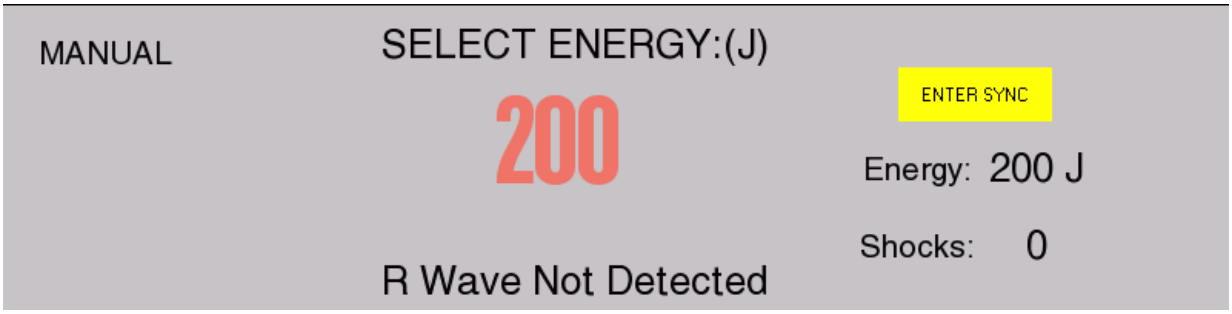


Figure16-2Synchronized Cardioversion

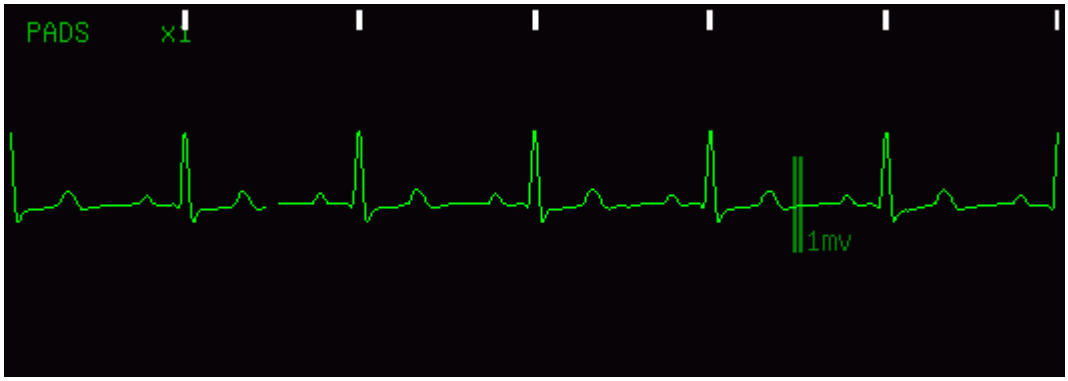


Figure16-3 R wave mark

ECG monitoring can be conducted by pads, paddles and also 3-lead ECG cable, 5-lead ECG cable and 12-lead ECG cable. Use pads and paddles to give shock.

When conducting synchronized cardioversion, it is recommended to monitor ECG by using 3-lead ECG cable, 5-lead ECG cable or 12-lead ECG cable and give shock by pads and paddles.

When using internal paddles to conduct synchronized cardioversion, it is required to use ECG lead to obtain ECG signal. Because ECG signal obtained by internal paddles has too much noise, which will result in that

correct R wave cannot be detected. Therefore, ECG signal obtained by internal paddles is not reliable for synchronized cardioversion.

16.5.1 Steps of Synchronized Cardioversion

1. Connect therapy cable and place pads or paddles; if using ECG lead to monitor ECG, connect ECG lead wire and place ECG electrodes.
2. In manual defibrillation mode, press [ENTER SYNC] soft button and select [OK] in the pop-up dialog box to enter the synchronized cardioversion mode.
3. Select the lead. The selected lead must has clear signal and large QRS complex.
4. Make sure the R wave mark appears above the R wave. If the R wave mark doesn't appear or appear at the wrong position (like above T wave), select another lead.
5. Make sure the defibrillator/monitor has entered synchronized cardioversion mode with text message [SYNC] displayed in defibrillation message area.
6. Select energy level.
7. Charge the defibrillator.
8. Make sure the patient needs to be shocked and the charge has been completed. Make sure no one contacts with the patient and on one contacts with the accessories and equipment connected with the patient. Shout out "STAND CLEAR" loudly and clearly.
9. Press **SHOCK** button. If the external paddles are used, press both shock buttons on the paddles simultaneously. When the next R wave is detected, the defibrillator/monitor will give a shock.

⚠Attention

- **The alarms will auto be enabled after enter synchronizedcardioversion.**
- **When giving a shock, you should press and hold the shock button (or shock buttons on external paddles) until the shock is delivered. The defibrillator/monitor will deliverthe shock when the next R wave is detected.**

16.5.2 Giving Another Shock

If another synchronized cardioversion is required after giving a shock, please do the following steps:

1. Make sure that the defibrillator/monitor is still in synchronized cardioversion mode.
2. Repeat the steps of synchronized cardioversion introduced above.

If [SYNC KEEP] is set to [ON], the defibrillator/monitor will still be in synchronized cardioversion mode after giving a shock; while if it is set to [OFF], the defibrillator/monitor will auto exit synchronized cardioversion mode after giving a shock.

16.5.3 Exit Synchronized CardioversionMode

Press [EXIT SYNC] soft button to exit the synchronized cardioversion mode.

16.6 Remote Synchronized Cardioversion

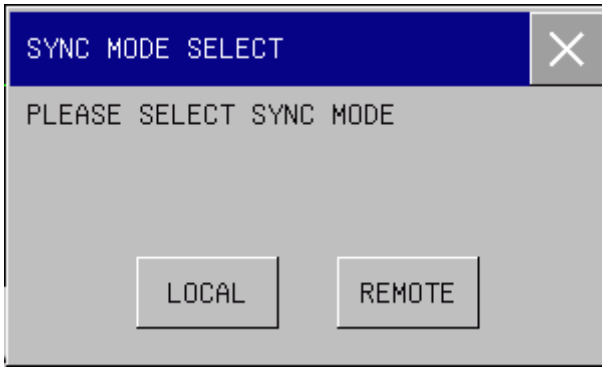
The defibrillator/monitor can realize remote synchronized cardioversion by connecting with the bedside

monitor. The bedside monitor providing ECG signal must have a synchronized defibrillation connector and must be connected with the data input/output interface of the defibrillator/monitor through the synchronized cable.

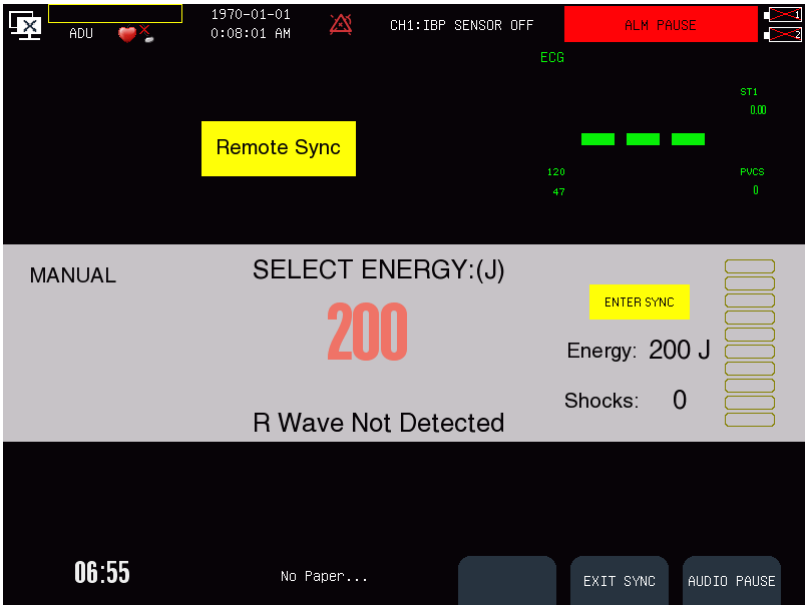
Access [MAIN MENU]→[CONFIG SETUP]→enter password→[MANUAL DEFIB SETUP] →[REMOTE SYNC INPUT] and select [ON] to enable remote synchronized cardioversion function.

Conduct remote synchronized cardioversion following the steps below:

1. Connect the bedside monitor with the defibrillator/monitor through the synchronized cable.
2. Start the defibrillator/monitor and enter manual defibrillation mode.
3. Press [ENTER SYNC] soft button and the [SYNC MODE SELECT] menu will be displayed as shown below:



4. Select [REMOTE] to enter remote synchronized cardioversion mode and the text message [Remote Sync] with yellow background will appear on the screen.
5. Make sure that each time the bedside monitor detects an R wave, the mark on the defibrillator/monitor will flash once, which indicates that the synchronized signal has been received once.
6. Connect the therapy cable with the defibrillator/monitor until a “click” is heard.
7. Place pads or paddles.
8. Conduct the remote synchronized cardioversion following the step 6 through step 9 introduced in ***16.5.1 Steps of Synchronized Cardioversion***.

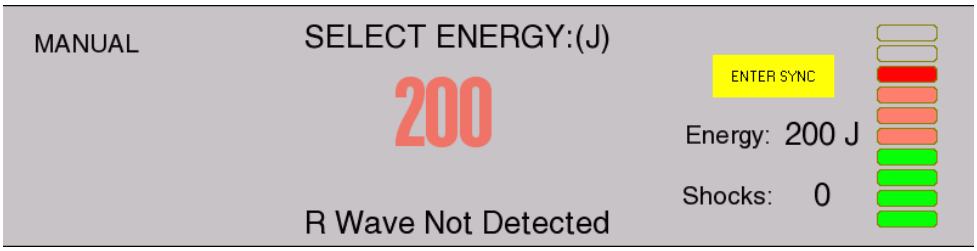


⚠Attention

- **After entering remote synchronized cardioversion mode, the defibrillator/monitor will not display ECG waveform and parameter values of the patient. Please view the ECG waveform of the patient on bedside monitor.**
- **Make sure that the bedside monitor being used has such performance that when performing remote synchronized cardioversion, the bedside monitor and defibrillator/monitor used together can deliver shock synchronously within 60ms of detecting the next R wave peak.**

16.7 Contact Impedance Indicator

The contact impedance indicator is used to indicate the contact impedance of the patient, as shown in the figure below:



In which

 : The contact impedance is too high.

 : The contact impedance is high.

 : The contact impedance is normal.

 : The therapy cable is not connected well.

To open the contact impedance indicator, please follow the steps below:

Access [MAIN MENU]→[CONFIG SETUP]→enter password→[MANUAL DEFIB SETUP] →[CONTACT IMPEDANCE INDICATOR] and select [ON] to open the contact impedance indicator.

⚠Attention

- **It is recommended to conduct defibrillation when the contact impedance is normal. The defibrillation can also be conducted when the contact impedance is high.**

Chapter 17 Noninvasive Pacing

17.1 Overview

Noninvasive pacing therapy is used to deliver rhythmical pulse to patient's heart through the pads. When delivering the pacing pulse once, a white pacing mark will appear on ECG waveform. In the demand pacing mode, the white R wave mark will appear above ECG waveform untilelectrical capture occurs.
In pacer mode, the physiological parameters except RESP can be monitored and trigger alarms.
During demand pacing, ECG monitoring should be performed by using ECG electrodes and 3-lead, 5-lead or 12-lead ECG cable. Pacing pulse is delivered throughpads, but pads are not capable of monitoring ECG and delivering pacing pulse at the same time.

17.2 Safety Information

⚠Attention

- **Pacer mode supports arrhythmia analysis and give arrhythmia alarms includingAsystole, Ventricular Fibrillation and Ventricular Tachycardia.**
- **If pacing is interrupted for some reason, press [BEGAIN PACING] soft button to continue pacing.**
- **In pacer mode, the pacing state of the patient cannot be changed.**
- **If pads do not contact well, prompt message "PACING STOPPED" and "PADS OFF" will be displayed.**
- **In pacer mode, pads cannot be used to monitor ECG waveform.**

⚠Caution

- **If pacing needs to be conducted for a long period, you should check the skin in touch with ECG electrodes and pads and replace ECG electrodes and pads periodically.**
- **For conducting therapy on the patient with implanted device(like permanent pacemaker or cardioverter-defibrillator), please consult the doctors or refer to the user manual of the implanted device.**

⚠Warning

- **For conducting paicng therapy on the patient with oxygen catheter, please place the oxygen catheter properly and do not put it near the pads to avoid fire and explosion.**
- **During pacing, the heart rate and alarms given by the defibrillator/monitor may be inaccurate. Keep the patient under close surveillance and do not rely entirely on the heart rate displayed on the screen.**

17.3 Pacing Interface

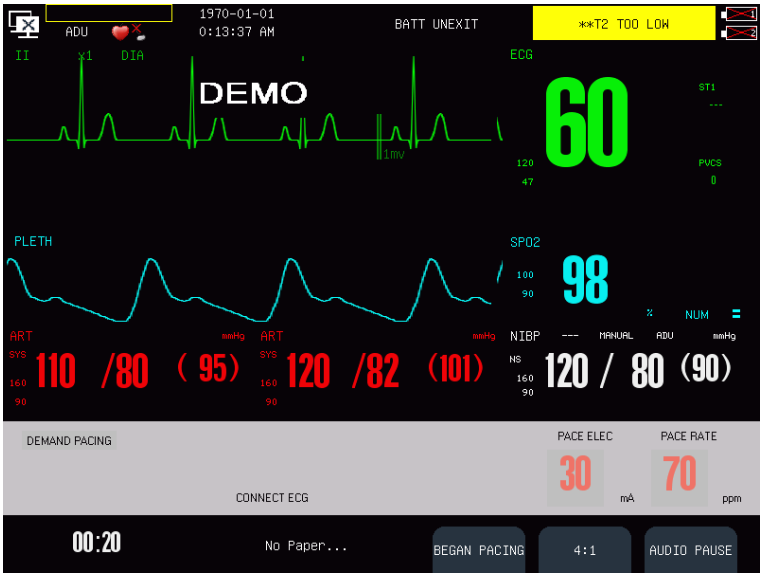


Figure17-1Pacing interface

In pacer mode, the defibrillator/monitor can display one ECG waveform and other physiological parameters monitored. In the pacing message area, such information related to pacing as pacing mode shortcut key, pacing message, pacing alarm, pacing current and pacing rate will be displayed.

17.4 Pacing Mode

Two pacing modes are provided by the defibrillator/monitor: demand pacing and fixed pacing.

- Demand pacing: the defibrillator/monitor will deliver pacing pulse only when patient's heart rate is lower than the set pacing rate.
- Fixed pacing: the defibrillator/monitor will deliver pacing pulse at the set pacing rate.

During pacing, you can change the pacing mode through the pacing mode shortcut key. The pacing will not stop when changing the pacing mode and will continue to deliver pacing pulse at the set pacing rate and as the set pacing current.

⚠Attention

- **Use demand pacing for most patients. Use fixed pacing only when there is no reliable R wave detected or there is no available monitoring shock due to interference.**
- **In fixed pacing mode, there is no R wave mark above the pacing QRS complex.**
- **In demand pacing mode, if patient's heart rate is higher than the pacing rate, the defibrillator/monitor will not deliver pacing pulse and there will be no pacing mark either.**

17.5 Preparation for Noninvasive Pacing

1. Connect pads cable with the therapy cable connector on the defibrillator/monitor right panel.
2. Make sure that the packaging of pads is intact and pads are not expired.

3. Connect pads with pads cable.
4. Place pads on the patient in the anterior-lateral or anterior-posterior position.
5. For demand pacing mode, use ECG lead cable to monitor ECG. Connect the ECG lead cable and place ECG electrodes. To receive the best ECG monitoring signal, make sure there is adequate space between the ECG electrodes and pads.

17.5.1 Steps of Demand Pacing

After finishing the preparation, follow the steps below:

1. Switch to pacer mode**.**Demand pacing is enabled automatically and ECG waveform from lead II will be displayed by default.
2. Select the lead with R wave easy to recognize
3. Make sure that the R wave mark appears above R wave, as shown below. If the R wave mark doesn't appear or appear at the wrong position (like above T wave), select another lead.

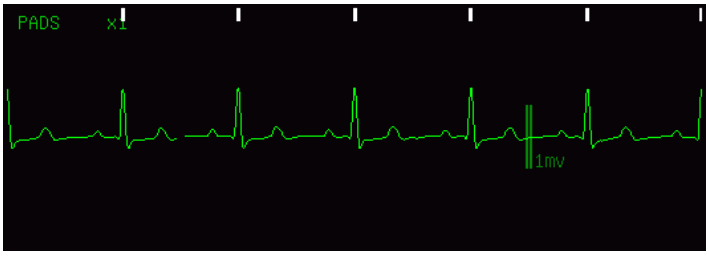


Figure17-2 R wave marker

4. Set the pacing rate. If necessary, set the initial pacing current. Rotate the knob to outline the pacing rate or pacing current hotkey and press the knob,then rotate the knob to change the pacing rate or initial pacing current and press the knob to confirm the change.
5. Press [BEGAIN PACING] soft buttonto start pacing and the pacing message "PACING…." will appear.

⚠Attention

- **In demand pacing mode, the defibrillator/monitor will detect the connection of pads cable, pads, ECG cable and ECG electrodes. If any connectionerror is detected, the pacing will stop and relevant prompt message will appear in the pacing message area until the connection is good.**

6. Make sure the white pacing marker appears on the ECG waveform, as shown in the figure below:

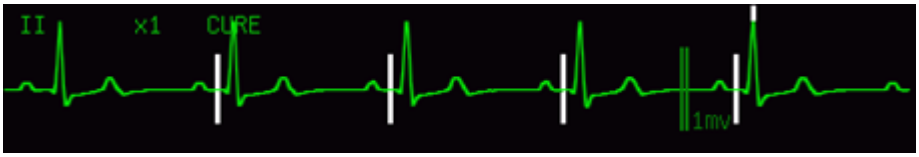


Figure17-3Pacing mark

7. Adjust pacing current: increase the pacing current until electrical capture occurs (Electrical capture is indicated by a QRS complex following each pacing mark), then adjust pacing current to the lowest level

which can maintain the electrical capture.

8. Confirm the peripheral circulation has a pulse.

To interrupt pacing and view patient's pulse rate, please press [4:1]soft button. The defibrillator/monitor will deliver the pacing pulse at one fourth of the set pacing rate.

Press [STOP PACING]soft button to stop pacing. Press [BEGIAN PACING] soft button to restart delivering pacing pulse after pacing stops.

17.5.2 Steps of Fixed Pacing

1. Enter pacer mode.
2. Select the pacing mode hotkey and switch to fixed pacing mode.
3. If ECG lead is used, press **LEAD SELECT** button to select the desired lead.
4. Set pacing rate. If necessary, set the initial pacing current.
5. Press [BEGAIN PACING]soft button to start pacing and the pacing message "PACING…." will appear.
6. Make sure the white pacing marker appears on the ECG waveform, as shown in the figure below:

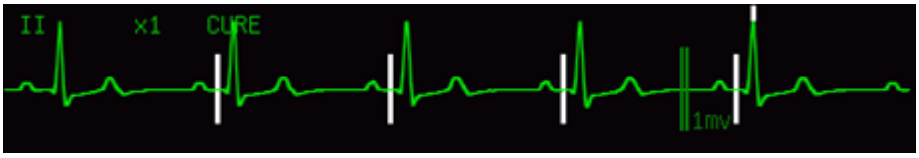


Figure17-3Pacing mark

7. Adjust pacing current: increase the pacing current until electrical capture occurs (Electrical capture is indicated by a QRS complex following every pacing mark), then adjust pacing current to the lowest level which can maintain the electrical capture.
8. Confirm the peripheral circulation has a pulse.

To interrupt pacing and view patient's pulse rate, please press [4:1] soft button. The defibrillator/monitor will deliver the pacing pulse at one fourth of the set pacing rate.

Press [STOP PACING]soft button to stop pacing. Press [BEGIAN PACING] soft button to restart delivering pacing pulse after pacing stops.

⚠Attention

- **The monitor or pacer mode may be instable when electrotome and other electronic equipment are used.**

⚠Warning

- **Use pads on patient carefully to avoid shock during pacing.**
- **When operaing the defibrillator/monitor on battery in pacer mode, if " LOWBATTERY"alarm triggered, please connect the defibrillator/monitor to AC power supply or replace the battery with a fully charged one immediately.**

Chapter 18 AED

18.1 Overview

In AED (Automatic External Defibrillation) mode, the defibrillator/monitor will analyze patient's ECG waveform automatically and indicate the users to operate according to the cardiac rhythm monitored. The defibrillator/monitor starts to perform intelligent analysis after entering AED mode. When a shockable rhythm is detected, the defibrillator/monitor will give "shock advised" prompt and start to auto charge immediately.

18.2 Safety Information

⚠Danger

- **Do not conduct defibrillation in the presence of oxygen-rich atmospheres. When conducting defibrillation on the patient with oxygen catheter, place the oxygen catheter properly. Do not put it near the pads to avoid fire and explosion.**
- **During defibrillation, do not allow pads to touch each other or touch ECG electrodes, lead wires, dressings, etc. Otherwise electrical arcing and patient skin burns could be caused.**
- **During defibrillation, do not touch patient and conductive material (including bed and stretcher) connected with the patient to avoid potential injury and death.**
- **During defibrillation, do not allow the patient touch conductive liquid like saline solution, blood and conductive gel and conductive material like bed and stretcher to avoid forming current path.**

⚠Warning

- **During defibrillation, the bubble between pads and patient skin will cause patient skin burns. Make sure that pads are placed to patient skin tightly to avoid bubbles.**
- **Do not use dry pads. Use the pads immediately after unpacking them.**
- **AED is only applicable to the patients more than eight years old.**

⚠Caution

- **For the patients with pacemaker, the sensitivity and specificity of AED analysis may decline.**
- **Improper operation on pads during storage or before use will damage the pads. Do not use the damaged pads.**

18.3 AED Interface

AED interface is shown as the figure below:

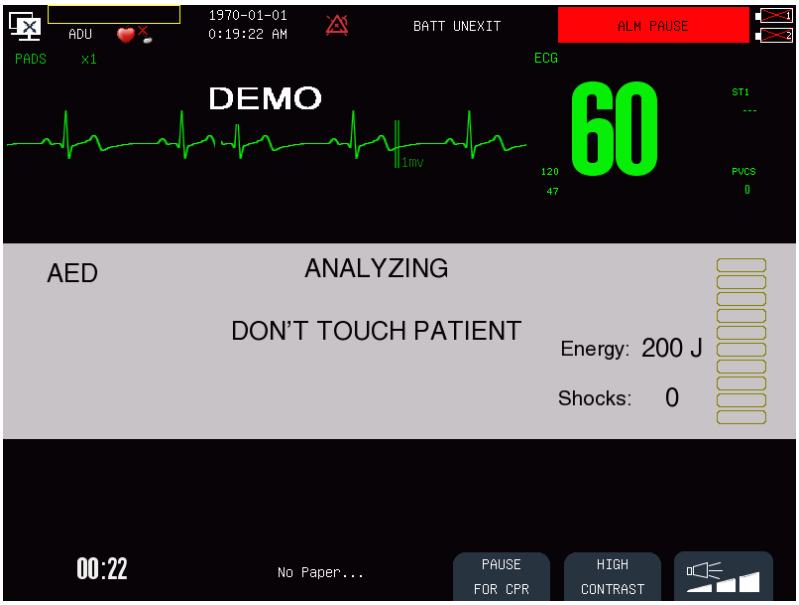


Figure18-1 AED interface

In AED mode, the defibrillator/monitor will only display one ECG waveform detected by pads and HR value calculated from this displayed waveform. The AED message area at the middle of AED interface will display AED prompt message, contact impedance indicator (settable), shock times and so on.

For the introduction to contact impedance indicator and its setting method, please refer to section ***16.7 Contact Impedance Indicator*** for detail.

There are there soft buttons at the lower right corner of AED interface.

- When the defibrillator/monitor is used outdoors, press [HIGH CONTRAST] soft button to view the display screen clearly.
- Press  to adjust voice volume.

18.4 AED Procedure

Verify that the patient is in cardiac arrest without consciousness, pulse or normal breathing.

1. Remove all clothing from patient's chest. Dry patient's chest and do skin preparation if necessary.
2. Place pads on patient in the anterior-lateral position according to the indication on packaging.
3. Connect pads with pads cable. Connect pads cable with the therapy cable connector on the defibrillator/monitor right panel until a "click" is heard.
4. Rotate the mode selector to AED.
   In AED mode, the defibrillator/monitor will detect the connection of pads cable and pads. If any connection error is detected, relevant prompt message will appear in the AED message area until the connection is good.
5. Perform AED following the voice prompt and prompt message.
   The defibrillator/monitor will analyze patient's cardiac rhythm based on the ECG waveform detected by pads and give a warning of "Not Contact Patient". When a shockable rhythm is detected, the defibrillator/monitor will start to auto charge immediately.
   The voice prompt can be enabled or disabled in [CONFIG SETUP] menu or by pressing the soft button below  .

6. If there is a shock advised, press the **SHOCK** button on the front panel.
   After charge completes, the defibrillator/monitor will give out “Do not touch patient! Press shock button” voice prompt. At this moment, check that no one touches the patient and accessories or equipment connected with the patient and shout out “STAND CLEAR” loudly and clearly. Then press the **SHOCK** button on the front panel to deliver a shock.

After shock, the defibrillator/monitor will give “Energy Delivered” voice prompt and textmessage. The shock times on the screen will update to indicate the number of shocks has been delivered. If the [SERIAL SHOCK NUM] is set as more than one, the defibrillator/monitor will restart to analyze patient’s cardiac rhythm after a shock being delivered and estimate whether the shock is successful. There will be voice prompt and text message for indicating the users to perform more shocks.

⚠Attention

- **Do not place pads in the anterior-posterior position. The AED algorithmof this defibrillator/monitor has not been verified under the anterior-positerior placement.**
- **Keep patient still during cardiac rhythm analysis in order to prevent misdiagnosis and delayed diagnosis.**
- **The defibrillator/monitor will not deliver shocks automatically. Shocks will only be delivered by pressing SHOCK button.**
- **Too high impedance could have a great impact on patient’s therapy. Reduce the impact caused by high impedance to the utmost. When prompt message “IMPEDANCE TOO HIGH, SHOCK CANCELED” appears, please check whether patient skin is clean and dry and whether chest hair has been shaved. If the prompt message is still there, please replace pads or pads cable.**

18.5 Shock Advised

If the shockable cardiac rhythm is detected, the defibrillator will be auto charged to the set energy level and charge tone will be given out. The **SHOCK** button will flash after charge completes.

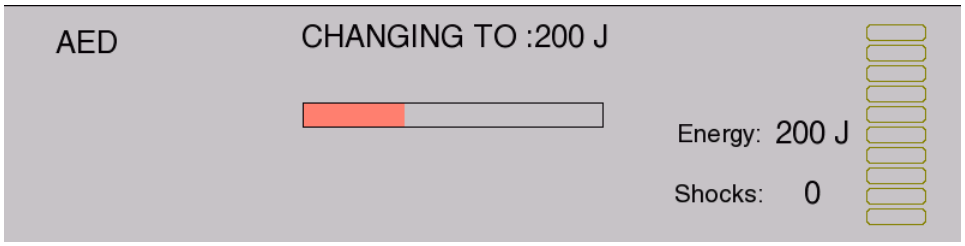


Figure18-2Charge state

The cardiac rhythm analysis will continue during charge. Ifthe situation that the cardiac rhythm has changed and is not suitable for shock before delivering a shock is detected, the defibrillator will disarm the energy automatically.

After the defibrillator/monitor gives out voice prompt“Do not touch patient, Press shock button”, if the users do not press **SHOCK** button during the interval set in [AUTO BREAK TIME], the defibrillator will disarm the energy automatically and restart cardiac rhythm analysis.

Press [PAUSE FOR CPR]soft button to disarm the defibrillator at any time during charge or after charge completes.

Initial shock energy recommended for adult patient is 200J.

18.6 No Shock Advised

When there is no shockable rhythm detected, the defibrillator/monitor will give “NO SHOCK ADVISED” prompt message.

If NSA process mode is set as:

- [CPR]: Enter CPR, the defibrillator/monitor will give out voice prompt “No shock advised, Pause, if needed, start CPR”and display text prompt “IF NEEDED, START CPR” in AED message area. CPR countdown will also appear.
- [CONTINUE ANALYSIS]: The defibrillator/monitor will continue to monitor patient’s ECG and analyze the potentially shockablecardiac rhythm. Before shockablecardiac rhythm being detected, the defibrillator/monitor will give out voice prompt “No shock advised. If needed, pause analysis for CPR” repeatedly and display “NO SHOCK ADVISED” and “MONITORING…” text prompt circularly.

You can press [PAUSE FOR CPR] soft button to stop analysis and start CPR. [CPR TIME] can be set in [AED SETUP].

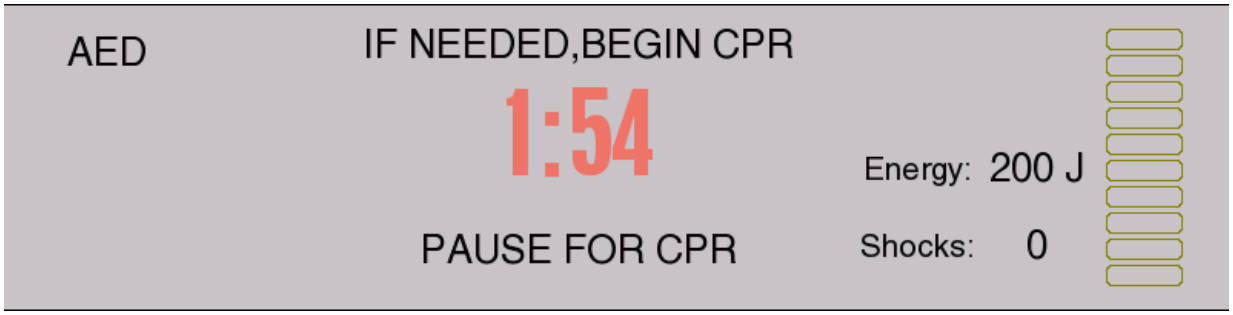


Figure18-3 CPR prompt

After CPR, the defibrillator/monitor will resume analysis, or during CPR, you can press [RESUME ANALYSIS]soft button to resume cardiac rhythm analysis.

18.7 CPR

If the [PRE-SHOCK CPR TIME] isn’t set to [OFF], the system will enter initial CPR after entering AED mode. The users can set the pre-shock CPR time or disable the initial CPR function in [PRE-SHOCK CPR TIME].

After finishing the serial shocks, the defibrillator/monitor will pauseanalysis and enter CPR. The CPR countdown will start and voice prompt “Pause, If needed, Start CPR” will be given out. After CPR, the defibrillator/monitor will resume analysis. During CPR, you can press[RESUME ANALYSIS]soft button to resume cardiac rhythm analysis.

During serial shocks, if you press [PAUSE FOR CPR] soft button after a shock delivered, the defibrillator/monitor will enter CPR. The CPR duration can be set in [CPR TIME] in [AED SETUP].

18.7.1 UsingCPR Metronome

After enter CPR, the defibrillator/monitor provides the CPR metronome function and indicates the operators to

press the patient's chest 120 times per minute which is recommended byAHA/ERC and perform ventilation. You can enable and disable the CPR metronome function in [CPR METRONOME] in [AED SETUP].

⚠Warning

- **CPR metronome doesn't prompt the current condition of the patient. The operators should assess patient's condition constantlybecause patient's condition may vary in a very short period. Do not perform CPR on the patients with response and normal breathing.**

⚠Attention

- **CPR metronome can be affected by the on/off state of AED voice prompt and the settings of voice volume.**

18.8 AEDAudio Recording

In AED mode, the system can tape the whole therapy process.

You can enable the audio recording function by accessing [MAIN MENU]→[CONFIG SETUP]→enter password→[AED SETUP]→[AUDIO RECORDING]and select [ON].

After audio recording function is enabled,  symbol will appear at the upper right corner of the AED message area.

The system can store audio recording up to 480 min and store audio recording of 60 min for each patient.

Chapter 19 RESP Monitoring

19.1 Overview

The monitor measures respiration according to the thoracic impedance values between two electrodes and display a channel of RESP waveform on the screen.

19.2 RESP Display

Figure 19-1 RESP display

19.3 Placing Electrodes for RESP Measurement

RESP measurement applies the same electrodes and placement methods as that of ECG monitoring. For example, if the 5-lead ECG cable is applied, the placement method is shown on the figure below (for the placement methods of the ECG cable of other lead types, please refer to ***ECG Monitoring***):

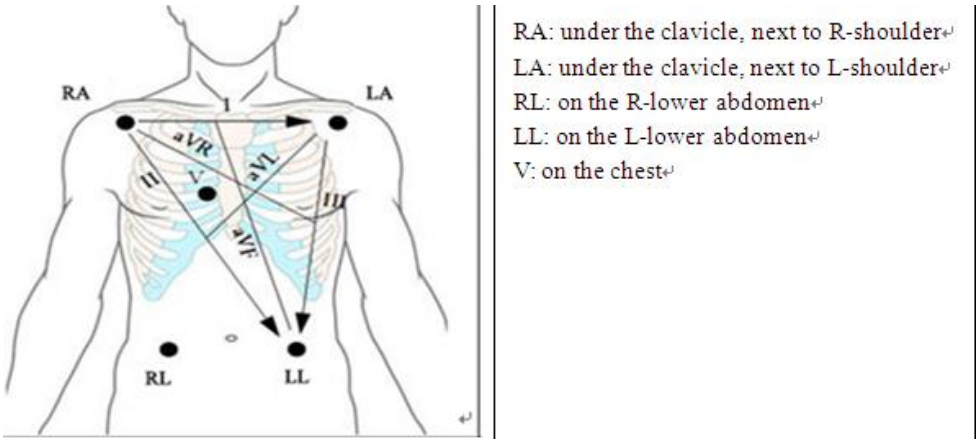


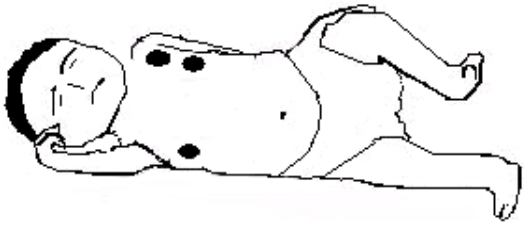
Figure 19-2 Positions of electrodes of 5-lead ECG cable

⚠Attention

- **Put the green and the red electrodes at opposite angle so as to get the best respiration wave. You should avoid putting the electrodes over the liver area and the ventricle of the heart in the line between the respiratory electrodes, which can help to avoid cardiac overlay or artifacts from the pulsing blood flow. This is particularly important for neonates.**

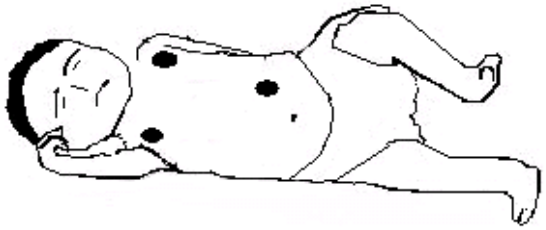
Lateral thoracic expansion

Some patients' thorax may expand laterally, especially for the neonates. Two RESP electrodes shall be placed on the right mid-axillary line and the left lateral thorax where the patient has the maximum breathing movement to make sure that the RESP waveform is distinct. See the following figure:



Abdominal respiration

For some patients the chest movement is limited so they primarily conduct abdominal respiration You shall remove the electrode which was placed on the left leg to the left abdomen where there is maximum expansion to make sure the RESP waveform is clear. See the following figure:



⚠Attention

- **RESP monitoring cannot be applied to the patient who moves frequently, because it may lead to wrong alarms.**

19.4 RESP Settings

19.4.1 Setting the RESP Lead

RESP lead is where the current respiratory waveform comes from. There are leadIand lead II to choose.

1. Select RESP parameter area andthe [RESP SETUP]menu will be displayed;
2. Select [Lead Selection] and select [I] or[II].

19.4.2 Setting the Gain

Gain is used to adjust the size of RESP waveform. The alternative gains are×0.25, ×0.5, ×1, ×2, ×3, ×4 and ×5.

1. Select RESP parameter area and the [RESP SETUP]menu will be displayed;
2. Select [GAIN];
3. Select [×0.25], [×0.5], [×1], [×2], [×3], [×4] or [×5].

19.4.3 Setting Apnea Alarm Time

1. Select RESP parameter area and the [RESP SETUP]menu will be displayed;
2. Select [RESP APNEA]and then select [10s], [15s], [20s], [25s], [30s], [35s], [40s], [45s], [50s], [55s], [1min] or [NO] for adult; select [10s], [15s], [20s] or [NO] for pediatric or neonate.
   - [10s]meansthat if apnea lasts for more than 10s and RESP alarm function is enabled, the monitor will give an apnea alarm.
   - [NO] means the apnea alarm function is disabled.

19.4.4 Setting the RESP Filter

Enhancing filter is to enhance filtering the interference of heart beat.

1. Select RESP parameter area and he [RESP SETUP]menu will be displayed;
2. Select [ENHANCE FILTER] to enable or disable the RESP filter function.

Chapter 20 SpO2 Monitoring

20.1 Overview

SpO_2monitoring measures blood-oxygen saturation, that is, the percentage of the total oxyhemoglobin. For example, when 97% of the total number of hemoglobin molecules combines with oxygen in the arterial blood's red blood cells, this blood will have 97% SpO_2, and the SpO2 reading displayed on the defibrillator/monitor is 97%. This value shows the percentage of oxygen-carrying hemoglobin molecules, constituting oxyhemoglobin. Furthermore SpO_2 can also provide pulse rate signal and plethysmography wave (PLETH).

20.1.1 Principle of Measuring SpO_2

Pulse oximetry is a measurement of oxygen saturation. It is a continuous, non-invasive way of measuring the hemoglobin oxygenation saturation. It is involved in measuring how much light emitting from the sensor side passes through the patient's tissue (such as a finger or ear) and then reaches the other side of the receiver.
Though the amount of light passing through depends on many factors, most of them are constant. However, one of the factors is that blood flow in the arteries changes with time, since it is pulsatile. It is possible to obtain arterial blood oxygen saturation by measuring the amount of light absorbed during the pulse. And measuring SpO2 can provide a "PLETH" waveform and pulse rate signal.
The display screen can display "SpO2" value and "PLETH" waveform.

⚠Warning

- **If there is carbonyl hemoglobin, methemoglobin, or dye dilution chemical present, the SpO2 value will deviate.**

20.1.2 Recognition of the Type of SpO2

The types of SpO2 have been configured when the equipment is delivered from the factory, which is recognizable by the SpO2 socket on the defibrillator/monitor:

- Digital SPO2: SpO2 logo marked on the left side of the defibrillator/monitor.
- Nellcor SPO2: SpO2 logo and NELLCOR logo marked on the left side of the defibrillator/monitor.
- Masimo SPO2: SpO2 logo and Masimo SET logo marked on the left side of the defibrillator/monitor.

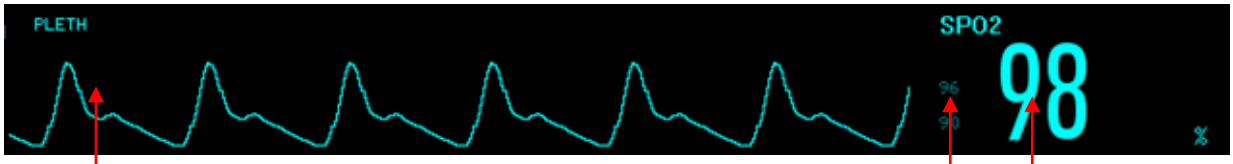
The wavelength range and maximum light output power of different sensors are very important information to clinical doctors, such as, when conduting photodynamic therapy

- Measurable wavelength of SpO2 module sensor: red light 660nm, infraredlight 905nm.
- Measurable wavelength of Masimo SpO2 module sensor: red light 660nm, infraredlight 940nm.
- Measurable wavelength of Nellor SpO2 module sensor: red light 660nm, infraredlight 890nm.
- Sensor s' maximum output light power is less than 18mW.

⚠Warning

- **This defibrillator/monitor can automatically identify the SpO2 sensor. Therefore, as the internal hardware has been fixed before delivery from factory, improper SpO2 sensor can not measure the SpO2 value.**

20.2 SpO2 Display



PLETH Waveform

Alarm limit SpO2 value Measured

Figure 20-1 SpO2 Display

20.3 Safety Information

⚠Warning

- **Check whether the sensor cable is in good condition prior to monitoring. When you discennect the SpO_2 sensor cable from the monitor, the monitor will trigger a technical alarm and display alarm message "SpO_2 NO SENSOR" on the screen.**
- **If the sensor or its packaging has signs of damage, do not use it and return to the factory.**
- **Continuous and prolonged monitoring may increase the risk of undesirable changes in skin characteristics, such as irratation, reddenning, blistering, or even pressure necrosis etc, especially for the neonates or patients with perfusion disorders and varying or immature forms of skin. Check thesesor application site every two hours and move the sensor if the skin quality changes.More frequent checkis required due to different status of individual patents.**
- **High oxygen levels will have premature children been in danger of infecting the crystal-like fibrous tissue disease. Therefore, the SpO_2 alarm limit must be set carefully based on generally accepted clinical practice.**
- **Do not entangle the cable of the sensor and electrical surgical unit.**
- **Do not placethe sensor on limbs with an arterial catheter or intravenous tube.**
- **Do not place the sensor and the cuff on the same limb while measuring, because the NIBP measurement may occlude the blood flow and affect the readings of SpO_2.**
- **A functional tester or SpO_2 simulator cannot be used to access the accuracy of a pulse oximeter probe or a pulse oximeter monitor.**
- **The pulse oximeter monitor is calibrated to display functional oxygen saturation.**

⚠Attention

- **Make sure that the nail covers the light inside the sensor. The sensor cable should be placed on the back of hands.**
- **SpO_2 waveform and pulse volume are out of proportion.**
- **There is a signal indicator in SpO_2 parameter area to indicating the pulse signal strength.**
- **The SpO_2 waveform is normalized.**

20.4 Steps of Monitoring

⚠Warning

- **Select the appropriate placement according to the instrument and its supporting probe, which is fundamentally vital to neonates.**

1. Rotate the mode selector to monitor mode;
2. Insert the connector of the sensor cable into the SpO_2socket.
3. Attach the sensor to the appropriate position on the patient.

Placement of finger adult/pediatric SpO2 sensor:

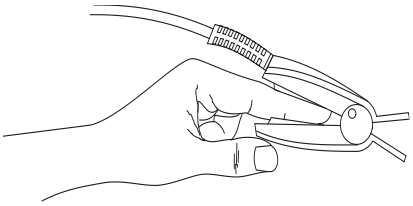


Figure20-2Placement of finger adult/pediatric SpO2 sensor

Placement of neonate SpO2 sensor:

NeonateSpO2sensor consists of the Y-shaped SpO2sensor and sensor jacket. Insert the LED side of the Y-shaped sensor in the upper groove of the sensor jacket, and respectively the PD side of the sensor in the lower (See Figure 20-3), then the neonateSpO2sensor is shown in Figure 20-4.

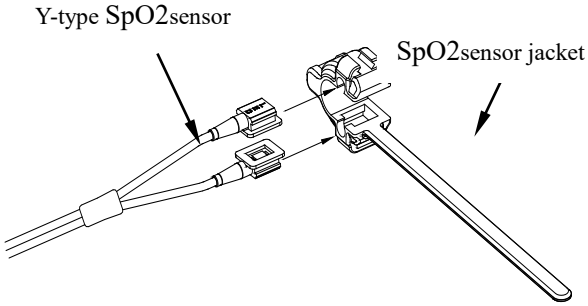


Figure20-3NeonatalSpO2sensor (1)

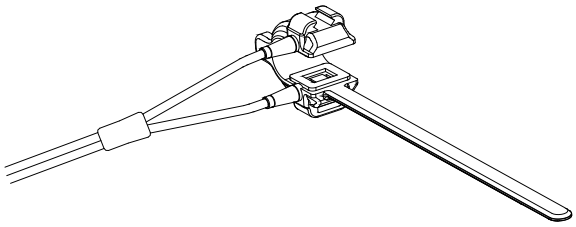


Figure20-4NeonatalSpO2sensor (2)

Attach the sensor to the neonatal hand or foot as shown below.

Figure 20-5Placement of the neonatal SpO2sensor

⚠Attention

- **When the accurate positioning between the test site and the probe fails, it may result in wrong readings of SpO2, and even stop monitoring because of the failure of searching pulse. In this case you should re-position these two.**
- **Excessive movement of measured sites may affect the accuracy of the measurement, therefore, you should calm the patient or replace sites in order to reduce the impact of excessive movement.**

⚠Warning

- **The maximum measuring time of SpO2 sensor on a single measuring site is 2 hours.**
- **In a long and continuous monitoring process, it is advisable to check periodically the positioning of the sensor to avoid inaccurate measurement due to changing in the positioning because of moving or other factors.**

20.5 Measurement Limitations

During operation, the following factors can affect the accuracy of SpO2 measurement :

- High-frequency radio interference, for instance, interference self-generated from the host system or from ESU connected to the system.
- During magnetic resonance imaging scanning (MRI), do not use the photoelectric oximeter and SpO2 sensor, since induced currents may cause burning.
- Intravenous dye.
- Patient's excessive movement.
- External ray radiation.
- Improper placement of sensor or improper contact position with the object .
- Sensor's temperature (optimal temperature should be among 28 ℃ - 42 ℃) .
- The sensor is placed on the limbs with a blood pressure cuff, arterial catheter, or the pipeline of body cavity.
- The concentrations of non-functional hemoglobin such as carboxyhemoglobin (COHb) and methemoglobin (MetHb) etc.
- Extremely low SpO2.
- The measured area has poor circulation.
- Syndromes such as shock, anemia or low temperature etc and application of vasoconstriction drugs can

reduce blood flow to the level of not being able to be measured.

- Measurement also depends on both the oxyhemoglobin and deoxyhemoglobin's absorption of specific wavelengths of light. If any other substances absorb the same wavelength, they will generate false measurement or lower SpO_2 values. These substances are as follows: COHb, MetHb, methylene blue , indigo rouge.
- It is recommended to use only the SpO_2sensor described in the accessories.

20.6 SPO2 Settings

20.6.1 Setting the Intelligent Alarm

1. Select SpO2 parameterand the [SpO2 SETUP] menu will be displayed;
2. Select [SatSecond];
3. Select [10], [25], [50], [100] or [NOT ALLOWED]

NOTE: This feature is only available on NELLCOR SpO2.

Intelligent alarm is designed to reduce false alarms, help the doctor grasp more accurate and timely changes in SpO2. For example, set the intelligent alarm range as 50, the upper limit of NELLCOR SpO2 alarm as 97%, and lower limit as 90%, the measured SpO2 value turns out to be 80% and remains for 3 seconds, then, it decreases to 78% and remains for 2 seconds, so calculating from the time the alarm limit is exceeded, the sound-light alarm will initialize instantly only when the SpO2 value is out of the alarm range for 5 seconds. Meanwhile , the circle beside the SpO2 value returns to origin. Its calculation is as follow:

Minus percentage points x seconds = SatSeconds integer

values of the calculated SatSeconds are shown:

%SpO2	second	SatSeconds
(90%-80%) x	3 =	30
(90%-78%) x	2 =	24
Total SatSeconds	=	54

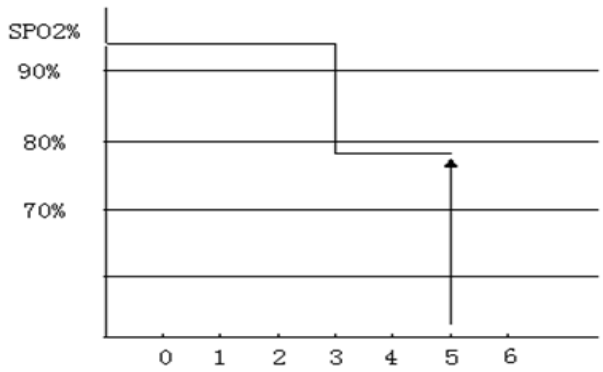


Figure20-6 Example figure

SatSeconds Example:

After about 4.9 seconds, the instrument will report SatSeconds alarm, because 54 is beyond the intelligent alarm range 50 SatSeconds.

Within a few seconds , saturation will fluctuate a bit, and not be stable. Generally, the patient's SpO2 value may fluctuate between the upper and lower limits of the alarm, and may re-enter to non-alarm range several times. In this volatile period, the system will store the positive and negative points of the SpO2, till it reaches the SatSeconds limit or patient's SpO2 values returned to and remains in the non-alarmrange.

20.6.2 Setting the Average Time

The average time, SpO2 value displayed on the monitor, is the result of averaged data collected during a period of time. The shorter (or longer) the average time is, the faster (or more slowly) the monitor will respondto the patient's SpO2 value changes, but with lower (or higher) measurement accuracy. Please set a shorter average time for critically ill patients so as to analyze the disease in time.

1. Select SpO2 parameterand the [SpO2 SETUP] menu will be displayed;
2. Select [AVERAGE TIME], and then select [2-4s], [4-6s], [8s], [10s], [12s], [14s] or [16s].

NOTE: This feature is only available onMasimo SpO_2.

20.6.3 Setting the Calculation Sensitivity

There are three kinds of calculation sensitivities, including normal, sensitive and APOD. For typical patient monitoring, use "normal" sensitivity. As for those patients who have moist skin, active exercise, or for other reasons, the sensor may be dropped off a patient's body, then use the "sensitive" sensitivity. If the patient has very low perfusion levels and wants to improve the sensitivity performance, please use the "APOD" sensitivity.

1. Select SpO2 parameterand the [SpO2 SETUP] menu will be displayed;
2. Select [SENSITIVITY], and then select [NORMAL], [MAXIMUM] or [APOD].

NOTE: This feature is only available onMasimo SpO_2.

20.6.4 Setting the Signal IQ

When it is turned on, below the PLETH waveform, there is signal collection indication, which is mainly reflecting the quality of the signal during the acquisition process. This signal indication disappears as it is turned off.

1. Select SpO2 parameterand the [SpO2 SETUP] menu will be displayed;
2. Select [SIGNAL IQ];
3. Select [ON] or [OFF].

NOTE: This feature is only available onMasimo SpO_2.

20.6.5 Setting the Pulse Sound

1. Select PR parameter area and the [PR SETUP] menu will be displayed;
2. Select [BEAT VOL] and adjust the beat volume from 0 to 10. 0 means off and 10 means the maximum volume.

20.7 SPO2 Accuracy Test

The recommended method of determining the SpO2 accuracy of the monitor is to compare its SpO2 readings with the readings of a CO-oximeter.

⚠Warning

- **A functional tester or SpO2 simulator cannot be used to access the accuracy of a pulse oximeter probe or a pulse oximeter monitor.**

⚠Note

- **Confirmation about SpO2 measurement accuracy: accuracy of SpO2has been confirmed in the comparison between experiment on human being and referential value of arterial blood measured by CO-oxygen pressure gauge. Measurement results of Pulse Oxygen Meter are subject to statistical distributions, which are, compared to measurement results by CO-oxygen pressure gauge, expected to fall in designated accuracy range with 2/3 results.**
- **Masimo SpO2 has passed the non-movement accuracy verification by compared to the laboratory joint photoelectric oximeterand monitor in the human blood research where healthy adult volunteers' SpO2 value are at 70% to 100% under the inducible hypoxic condition. This difference equals to ± one standard deviation, which contains 68% of the sample.**
- **Masimo SpO2 has passed the non-movement accuracy verification in the human blood research where healthy adult volunteers conduct friction motion or tapping motion at 2 to 4 Hz to induce a hypoxic condition. There is no repeated movement at range from 1 to 2 cm and frequency from 1 to 5 Hz. When set at inducible hypoxic condition (SpO2 70% ~100%) with range from 2 to 3 cm, the results should compare those of laboratory joint photoelectric oximeterand monitor. This difference equals to ± one standard deviation, which contains 68% of the sample.**

20.8 Low Perfusion Accuracy Test

This monitor can measure low perfusion and the recommended method of determining the low perfusion accuracy of the monitor is to compare its low perfusion readings with the readings of a simulator.

20.9 PR Accuracy Test

The recommended method of determining the PR accuracy of the monitor is to compare its PR readings with the readings of ECG from the same time.

20.10 Masimo Information

- Masimo Patent

  It contains one or more of the following U.S. patents: RE38,492, RE38,476, 6,850, 787, 6,826,419, 6,816,741, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,584,336, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,206,830, 6,157,830, 6,067, 462, 6,011,986, 6,002,952, 5,919,134, 5,823,950, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international patents or a item or a number of patents referred to in the www.masimo.com/patents. Including functions from products of Satshare ® and the U.S. Patent 6,770,028. Other patents are under application.

- Other Information

Chapter 21 NIBP Monitoring

21.1 Overview

The non-invasive blood pressure (NIBP) measurement uses oscillation method and is available for adults, pediatric, neonates, pregnant and pre-eclamptic patient.

In order to understand how the oscillation method works, you can compare it to the auscultatorymethod.

- Auscultatorymethod: doctors listen to the blood pressure through stethoscope and know the systolic pressure and diastolic pressure. As long as the arterial pressure curve is normal, then mean blood pressure can be calculated through systolic pressure and diastolic pressure.
- Oscillation method: the monitor cannot hear the blood pressure but only measure the vibration scope of pressure in cuff. The changes of blood pressure cause the vibration of the cuff and cuff pressure at the maximum scope is the mean blood pressure. The systolic pressure and diastolic pressure can be calculated after measuring the mean blood pressure.

Generally speaking, invasive measure the systolic pressure and diastolic pressure to calculate the mean blood pressure. Invasive measures mean brachial arterial pressure to calculate systolic pressure and diastolic pressure.

When perfoming NIBP measurement on a pediatric and neonate, you must ensure that the correct measure mode is selected. Wrong measure mode could jeopardize patient safety, because high blood pressure of adults is not suitable forpediatric and neonates.

According to the IEC601-2-30/EN60601-2-30 standard, NIBP measurement can be conducted during electrosurgical operation and during the discharging period of defibrillator.

21.2 NIBP Display

NIBP values are displayed in the parameter area; the following figure is for reference only; what displayed on your monitor might be different:

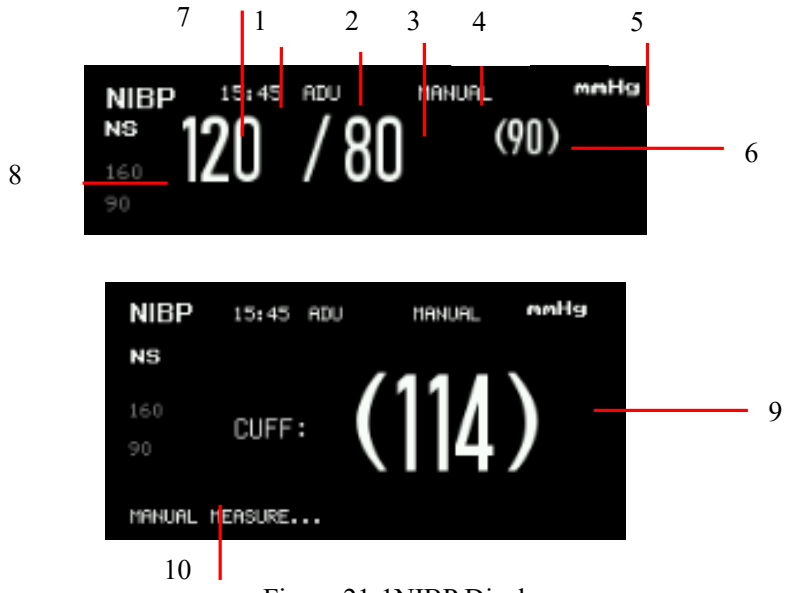


Figure 21-1NIBP Display

1	Time of last measurement	2	Measure mode: adult, pediatric and neonate
3	Diastolic pressure	4	Interval
5	Pressure unit: mmHg or kPa	6	Mean arterial pressure
7	Systolic pressure	8	Alarm limit for systolic pressure
9	Cuff pressure	10	Prompt message

21.3 Safety Information

⚠Warning

- **Before starting the measurements, make sure the selected measure mode applies to your patients. Using other than the neonatal mode on a neonatal patient may put the patient in danger.**
- **Do not install the cuff on a limb with an intravenous infusion tube or a catheter. During cuff inflation, if infusion is lowed down or clogged, the area around the tube may be damaged.**
- **Ensure theconnection tubing that attached blood pressure cuff and monitor is with no kinking.**
- **Too frequent measurements can cause injury to the patient due to bloodflow interference.**
- **Do not place the cuff over a wound, as this can cause further injury.**
- **Do not place the cuff on any limb whereintravascular access or therapy, or an arterio-venous (A-V) shunt is present, as thiscould cause temporary interference to blood flow and result in injury to the patient.**
- **Do not place the cuff on the arm on the side of a mastectomy.**
- **Pressurization of the cuff can temporarily cause loss offunction of simultaneously used monitoring equipment on the same limb.**
- **NIBP measurement cannot be performed onthose patients suffering from sickle-cell disease or skin damage or any anticipated damage.**
- **For a patient suffering from serious disturbance of blood coagulation, the decision to operate automatic blood pressure measurement must be made according to the clinical evaluation, because the friction area between body and sleeves has the risk of hematoma.**

21.4 NIBP Measurement

21.4.1 Measurement Steps

1. Conenct the NIBP cuff to the monitor and swtich to monitor mode.
2. Verify that the cuff is completely deflated.
3. Use a cuff with suitable size on the patient. Be sure that the cuff is not too tightly wrapped around the limb, otherwise it may cause discoloration or even ischemia to the far end of the limb.

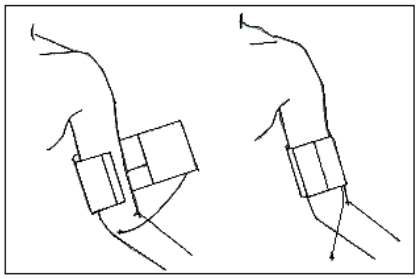


Figure 21-2 Usage of cuff

⚠Attention

- **The width of the cuff should be 40％ (or 50% for neonates) of the circumference of the limb, or 2/3 of the length of the upper arm. The length of the inflated part of the cuff should be long enough to wrap 50 ~ 80% of the limb; a cuff of wrong size will produce a wrong reading. If you have a problem about the size of the cuff, use a larger cuff in order to reduce errors.**

Adult/pediatric/neonateresuable cuff

Patient type	Limb Circumference	Cuff width	Gastube length
Neonate	10□19 cm	8 cm	2m
Pediatric	18□26 cm	10.6 cm	
Adult 1	25□35 cm	14 cm	
Adult2	33□47 cm	17 cm	
Leg	46□66 cm	21 cm	

Pediatric/neonate disposable cuff

Size	Limb Circumference	Cuff width	Gastube length
Neonate1	3.0 ～ 5.5 cm	2.6cm	2 m
Neonate 2	4.0 ～ 7.6 cm	3.7 cm	
Neonate 3	5.6 ～ 10.6 cm	4.5 cm	
Neonate 4	7.0 ～ 12.8 cm	5.3 cm	
Neonate 5	8.9 ～ 15.0 cm	6.0 cm	

4. Check if the edges of the cuff are located inside the range marked by < - >. If not, replace the cuff with a more suitable one.
5. Check whether the measure mode is correct. To change the measure mode, please enter the menu [NIBP SETUP] to change [MEASURE MODE].
6. Press the button to inflate the NIBP cuff.

Body parts used for pressure-measuring should be in the same horizontal location with patient's heart. If unable

to do so, it is necessary to use the following correction method to modify the measurement results:

- If cuff is above the heart level location, 0.75mmHg (0.10kPa) should be added to the displayed value for per centimeter gap.
- If cuff is below the heart level location, the displayed value should minus 0.75mmHg (0.10kPa) for per centimeter gap.

In order to obtain accurate blood pressure measurement for the hypertension patient, the patient position should be as follows:

a) Comfortably seated
b) Legs uncrossed
c) Feet flat on the floor
d) Back and arm supported
e) Middle of the cuff at the level of the right atrium of the heart.

What's more, the hypertension patient should relax as much as possible and not talk during the measurement procedure. 5 minutes should elapse before the first reading is taken.

21.4.2 Operation Prompt

(1) Start an auto measurement:
Enter [NIBP SETUP] → [INTERVAL]to select time interval for auto measurement, and then press button to auto inflate the NIBP cuff and measure the NIBP as the set interval.

(2) Start a manual measurement:
- Enter [NIBP SETUP], set [INTERVAL]to[MANUAL] and then press button to start a manual measurement.
- Press button to start a manual measurement after the auto measurement stops. If you press button again, the manual measurement will be stopped and the interval countdown starts.

(3) Start a continuous measurement:
Enter [NIBP SETUP]and select[CONTINUAL MEASURE] to start a continuous measurement lasting for 5 minutes.

(4) Stop the measurement:
In the measurement process, press button to stop at any time.

⚠Warning

- **If the NIBP measurement under the auto or continuous measure mode lasts too long, the limb with the cuff may suffer from purpura, ischemia or nerve damage. During patient monitoring, you should check the color, warmness and sensitivity of the far end of the limb from time to time. Once you observe any anomaly, place the cuff on another place or stop measurement immediately.**

⚠Attention

- **If unexpected readings are obtained, first the operator should use the same method to take measurement and then check the functions of the defibrillator/monitor.**

21.4.3 Measurement Limitations

According to the patient's condition, oscillatory measurement has some restrictions. Such measurements are

looking for regular impulse waves produced by arterial pressure. In case the patients' condition makes this kind of detection difficult, measurement values will become unreliable and load time will increase. Users should be aware that the following conditions will interfere with the measurement method, so that pressure is not reliable or load time increases. In this case, the patient's condition will make measurement impossible.

(1) Patient Movement

If patient is moving, shaking or in spasms, measurement will be unreliable or even impossible, as these may interfere with the detection of the arterial pressure pulse and measurement time will be extended.

(2) Arrhythmia

If patient has shown arrhythmia caused by irregular heart beats, measurements are unreliable or even impossible and load time will be extended.

(3) Heart-Lung Machine

If patient is connected to an artificial heart-lung machine, measure cannot be conducted.

(4) Pressure Change

If within a certain time, arterial pulse pressure is being analyzed to get the measurements, when blood pressure in patients is rapidly changing, measurement will be unreliable or even impossible.

(5) Severe Shock

If a patient is in serious shock or hypothermia, the pressure will be unreliable. The reducing blood flowing to periphery would cause a decline in arterial pulse.

(6) Heart Rate Limitation

Blood pressure measurement cannot be performed when heart rate is lower than 40bpm (beats per minute) or higher than 240bpm (beats per minute).

(7) Obese Patients

A thick layer of fat around a limb damps oscillations from the artery, thus preventing them from reaching the cuff. The accuracy is lower than the normal one.

21.5 NIBP Settings

21.5.1 Setting the Measure Mode

Measure mode includes adult, child and neonate, which is the same as the patient type.

1. Select NIBP parameter area and the [NIBP SETUP]menuwill be displayed;
2. Select [MEASURE MODE]
3. Select[ADU], [PED] or[NEO] ;

21.5.2 Setting the Interval Time

1. Select NIBP parameter area and the [NIBP SETUP]menuwill be displayed;
2. Select [INTERVAL];
3. Select [MANUAL] to conduct a manual measurement;
4. Select [1min], [2min], [2.5min], [3min], [4min], [5min], [10min], [15min], [30min], [60min], [90min], [120min], [180min], [240min] or [480min] for auto measurement;

21.5.3 Setting the Pressure Unit

1. Select NIBP parameter area and the [NIBP SETUP] menuwill be displayed;
2. Select [UNIT];
3. Select [mmHg] or [kPa];

21.5.4 Setting the Initial Pressure

1. Select NIBP parameter area and the [NIBP SETUP] menuwill be displayed;
2. Select [INFLATION] and select the suitable initial pressure value;

- Neonates: The range of the initial pressure value is 60-120 mmHg, the default value is 100mmHg
- Pediatric: The range of the initial pressure value is 80-200 mmHg, the default value is 140mmHg
- Adults: The range of the initial pressure value is 80-240 mmHg, the default value is 160mmHg;

21.6 NIBP Reset

Select NIBP parameter to enter [NIBP SETUP], and then select [RESET]. Reset can restore the inflation value of the blood pressure pump to the initial setting.If the blood pressure pump is working abnormally, it can be checked by means of reset, and will restore from any abnormality caused by an accidental reason.

Chapter 22 TEMP Monitoring

22.1 Overview

This defibrillator/monitor has two temperature measurement channels; body temperature can be measured by temperature probes.The probe should be applied to skin surface or rectum according to the type of the probe you bought. The recommended minimum measuring time is 1 mimute, or the measured value will not be accurate.

22.2 TEMP Display

The parameter area can display the values and units of two channels of body temperatures ([T1] and [T2]), as well as the temperature difference ([TD]). By selecting TEMP parameter area, you can open the[TEMP SETUP]menu.

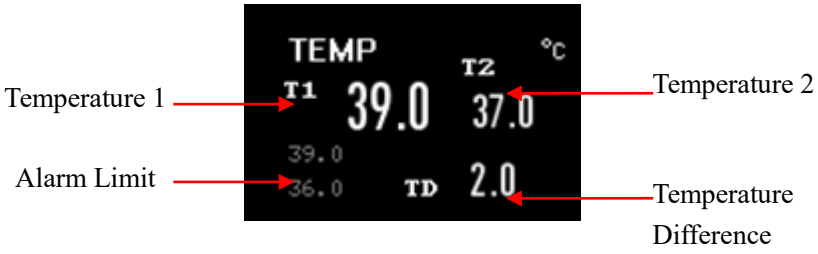


Figure 22-1 TEMP display

22.3 Safety Information

⚠Warning

- **Check whether the TEMP probe cable is in good condition prior to monitoring. When you discennect the TEMP probe cable from the monitor, the monitor will trigger a technical alarm and display alarm message "T1 SENSOR OFF" or "T2 SENSOR OFF" on the screen.**
- **Be careful in handling the TEMP probe and cable, when not in use, the probe and cable should be pulled into the loose ring. If the wire is pulled too tight, it will lead to mechanical damage.**
- **Calibrate the temperature measuring instrument at least once every two years (or according to the required time in the hospital directive rules). Please contact the manufacturer when calibration is needed.**

⚠Attention

- **Disposable temperature probe can only be used once.**
- **During the monitoring process, the temperature measuring instrument will automatically check itself once per hour. Self-checking will last 2 seconds and will not affect the temperature monitoring.**

22.4 Steps of TEMP Monitoring

1. If you are using a disposable temperature probe, first connect the temperature probe to the cable first and then connect the cable to the TEMP socket on the defibrillator/monitor. For reusable temperature probe, it can be directly connected to the TEMP socket.
2. Securely attach the temperature probe onto the patient's body.
3. Switchon the defibrillator/monitor.

22.5 Setting the Temperature Unit

1. Select TEMP parameter and the [TEMP SETUP] menu will be displayed;
2. Select [TEMP UNIT];
3. Select [℃] (Celsius degree) or [℉] (Fahrenheit degree) according to your habit.

Chapter 23 CO2 Monitoring

23.1 Overview

What described in this chapter is the way of CO2 measurement by sidestream and mainstream CO_2 modules, which is different from the way of CO_2 measurement in anesthetic gas. Please note their differences.

CO_2 measurement modes are divided into sidestream and mainstream.

- For sidestream measurement mode, the respiratory gases inside patient airways are sampled with a constant sampling flow and analyzed by remote CO_2 sensor built in the measurement system.
- For mainstream measurement mode, CO_2 sensors are mounted on an airway joint that is directly inserted into the respiratory system of a patient.

CO_2 measurement provides:

- CO_2 waveform.
- End-tidal CO_2 ($EtCO_2$):CO_2 value measured at the end-tidal of respiration.
- Minimum inspiratory CO_2 (Ins CO_2):The minimum value measured during respiration.
- Airway Respiration Rate (AwRR):respiration rate per minute derived from CO_2 waveform.

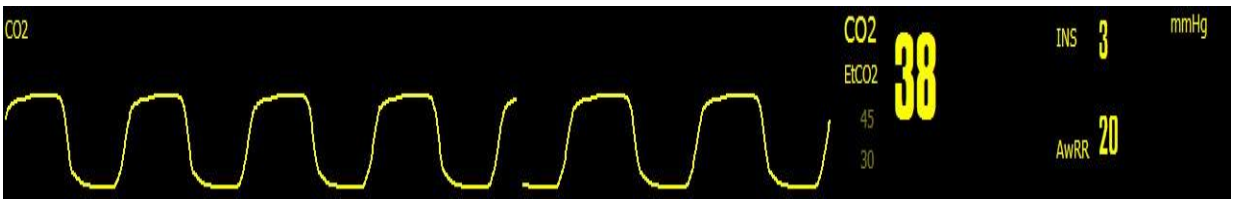


Figure 23-1 CO_2waveform and parameter display

⚠Warning

- **The bumping and shaking of the CO_2 module should be avoided whenever possible.**

⚠Attention

- **Do not use this defibrillator/monitor in the presence of anesthetic gas.**
- **This defibrillator/monitor can only be operated by professionals who are well trained and familiar with this user manual.**

23.2 Measuring Principle and Working Process

The CO2 measuring principle is mainly based on the characteristic that CO2 can absorb the infrared rays with a wavelength of 4. 3um. The measuring method works as follows: CO2 is introduced to a measuring chamber of which one side is irradiated by infrared rays, and sensors are employed to measure the attenuation degrees of received infrared rays at the other side of the measuring chamber, and the attenuation degree is directly proportional to the CO2 concentrations.

The conversion between CO2 partial pressure and CO2 concentration is:

CO2 Partial Pressure (mmHg)= CO2 Concentration (%)×Pamp (Ambient Pressure)

For example:5% CO2 = 38mmHg at 760mmHg

5% CO2 = 35mmHg at 700mmHg

CO2 Module:adopting Autorun instruction measurement mode, and the waveform is sampled once every 31 milliseconds.

23.3 Operating Instructionfor CO_2 Connection

(1) The connection schematic of the mainstream module produced by the RESPIRONICS company is shown in the figure below:

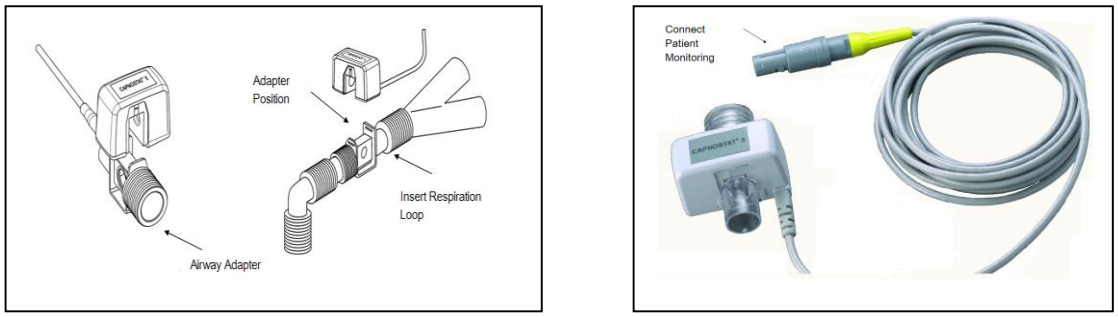
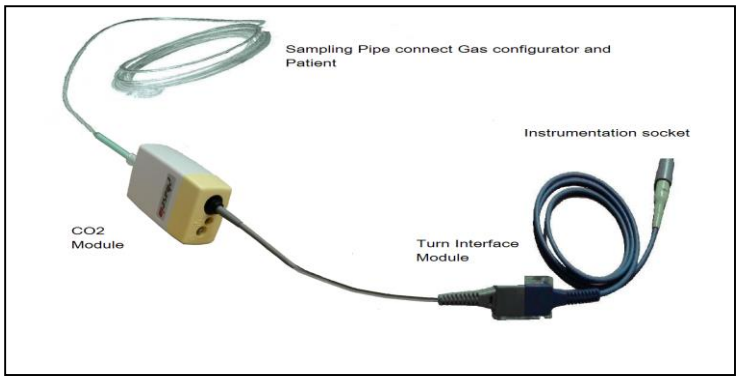


Figure 23-2 Mainstream CO2 module connection schematic

(2) The connection schematic of the sidestream module produced by the RESPIRONICS company is shown in the figure below:

Figure 23-3 Sidestream CO2 module connection schematic

(3) The connection schematic of the ISA™ sidestream analyzer produced by the Masimo company is shown in the figure below:



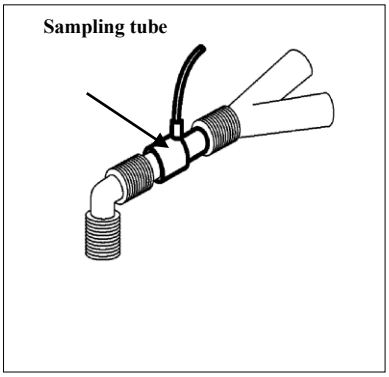
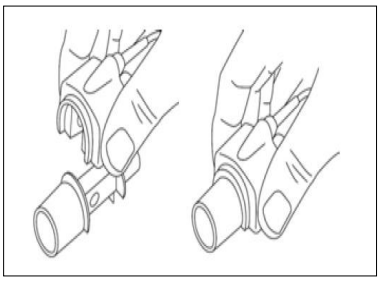


Figure 23-4ISA™ Sidestream Analyzer (ISA CO_2) CO_2 Connection Schematic

(4)The connection schematic of the IRMA™ mainstream analyzer produced by the Masimo company is shown in the figure below:



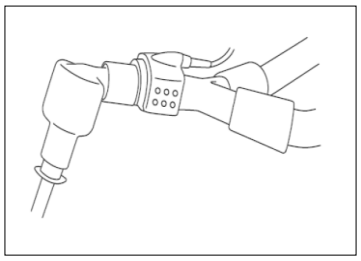


Figure 23-5IRMA™ Mainstream Analyzer (IRMA CO_2) CO_2 Connection Schematic

⚠Warning

- **Before use, please check airway joints. Do not use when visible damage or breaks are found on the airway adapter.**
- **When CO_2module is not used, it must be turned off, otherwise the CO2 module will be in a working condition all the time.**

23.4 Measuring Procedure of RESPIRONICS Mainstream and Sidestream Modules

The RESPIRONICS sidestream analyzer operating procedure is roughly the same as the mainstream analyzer operating procedure; please refer to the sidestream analyzer operating procedure for the mainstream analyzer operating procedure.

1. Switch to monitor mode;
2. Connect CO2 module cable with CO2 socket;
3. Make connections according to the CO2 module type as Figure 23-2 or Figure 23-3;
4. Access [MAIN MENU]→[MAINTENANCE]→[MODULE SETUP] and set [CO2] module switch to [ON].
5. In the [CO2 SETUP] menu, set [O2 COMPENSATE] to 21 (usually it is 21, in order to make sure that its data is in an activated state, the users still needs to reselect it);
6. In the [CO2 SETUP] menu, select an appropriate [BALANCE GAS]: room air, N2O or helium (usually if

there is no N2O or helium indoors, you can just select room air);

7. In the [CO2 SETUP] menu, select a correct [ALTITUDE(m)]:0□5029.2m andthe default is 0m. When the CO2 value is higher or lower than the normal value, users should choose appropriate atmospheric pressure based on the local condition (the atmospheric pressure is corresponding to the altitude, so it can only be adjusted via altitude). Mainly refer to the following table for its standard:

Air Pressure Conversion Table – EtCO_2Reading Based on Altitude

Altitude		**Atmospheric Pressure**	**5%CO2**
Inch	**m**	**mmHg**	**ETCO2 mmHg**
Sea Level (0)	Sea Level (0)	760	38
500	152. 4	745	37
750	228. 6	738	37
1, 000	304. 8	731	37
1, 500	457. 2	717	36
2, 000	609. 6	704	35
2, 500	762	690	35
3, 000	914. 9	677	34
3, 500	1066. 8	665	33
4, 000	1219. 2	652	33
4, 500	1371. 6	640	32
5, 000	1524	628	31
5, 500	1676. 4	616	31
6, 000	1828. 8	604	30
6, 500	1981. 2	593	30
7, 000	2133. 6	581	29
7, 500	2286	570	29
8, 000	2438. 4	560	28
8, 500	2590. 8	549	27
9, 000	2743. 2	539	27
10, 000	3048	518	26
10, 500	3200. 4	509	25
11, 000	3352. 8	499	25
11, 500	3505. 2	490	24
12, 000	3657. 6	480	24
12, 500	3810	471	24
13, 000	3962. 4	462	23
13, 500	4114. 8	454	23
14, 000	4267. 2	445	22
14, 500	4419. 6	437	22
15, 000	4572	428	21
15, 500	4724. 4	420	21
16, 000	4876. 8	412	21
16, 500	5029. 2	405	20
16, 800	5120. 6	400	20

Note: It is assumed that the atmospheric pressure is 760mmHg and the ambient temperature is 0℃ at the sea level. Calculation of Atmospheric Pressure:the sea-level based ambient temperature is assumed as 0℃. Refer to the above Table.

⚠Warning

- **The defibrillator/monitor does not compensate the pressure automatically. Therefore, correct altitude must be set when measuring CO2 for the first time. Improper setting of altitude will result in incorrect CO2 readings. A 5% CO2 deviation is generally generated corresponding to difference of each 1000m height.**

8. In the [CO2 SETUP] menu, select [ZERO], then prompt message "Zero in Progress, Please Wait" will be displayed. You can start measuring CO_2 only after zeroing CO_2.

23.5 Measuring Procedure of Masimo Sidestream and Mainstream Analyzers

The Masimo sidestream analyzer operating procedure is roughly the same as the mainstream analyzer operating procedure; please refer to the sidestream analyzer operating procedure for the mainstream analyzer operating procedure.

23.5.1 MeasurementSteps

1. Switch to monitor mode;
2. Connect the Nomoline sampling line to the interface socket of the ISA analyzer (CO2 module).
3. Connect the interface cable of the ISA analyzer to the CO2 socket.
4. Access [MAIN MENU]→[MAINTENANCE]→[MODULE SETUP] to set [CO2] module switch to [ON].
5. Enter [CO2 SETUP] menu and set [WORK MODE] to [MEASURE];
6. Set appropriate [O2 COMPENSATE], [N2O COMPENSATE].
7. Connect the outlet of the sample gas to the discharge systemor make the gas flow back to the patient's circuit.
8. If the LED is green, ISA Analyzer is available.
9. Carry out pre-use check.
10. If there is nothing wrong, start to monitor the CO2 Gas.

23.5.2 Pre-use Check

Before connecting the Nomoline sampling line to the breathing circuit, carry out the following steps:

1. Connect the sampling line to the gas entrance interface (LEGI) of the ISA CO_2 module.
2. Check whether the green light of LEGI is steadily on or not (indicating the system is normal).
3. Breathe to the sampling line, check if valid CO_2 waveforms and values are displayed on the host monitoring equipment.
4. Use the fingertip to occlude the sampling line and wait for 10 seconds.
5. Check that an occlusion alarm is displayed and that the LEGI shows a flashing red light.
6. If applicable: perform a tightness check of the patient circuit with the sampling line attached.

⚠Attention

- **The end of the gas circuit adapter which connects the gas sampling tube should point upward so as to prevent the condensing water drops entering the gas sampling tube and blocking it up.**

⚠Warning

- **Hang the external CO2 analyzer onto the CO2 bracket on the rear housing of the defibrillator/monitor to prevent the dropping damage of the CO2 module.**
- **Unless HME is used to protect the IRMA probe, the state indicating LED should face upward all the time during IRMA probe placement.**
- **Do not pull the cable of ISA sidestream Gas Analyzer.**
- **Do not operate the ISA sidestream Gas Analyzer in the environment beyond the designated working temperature.**
- **Make sure all connections are firm and reliable. Any leakage will result in the inclusion of ambient air in the patients respiratory gas, which leads to a wrong reading.**

23.6 CO2 Settings

23.6.1 Setting the Pressure Unit

1. Select CO2 parameter area and [CO2 SETUP] menu will be displayed;
2. Select [UNIT];
3. Select [mmHg] or [kPa];

23.6.2 Setting the Apnea Alarm Time

1. Select CO2 parameter area and [CO2 SETUP] menu will be displayed;
2. Select [APNEA TIME];
3. Select [10s], [15s], [20s], [25s], [30s], [35s], [40s],[45s], [50s], [55s], [1min]or [NO] for adults and select [10s], [15s], [20s]or [NO] for pediatric/neonates.
   - [10s] means when the time for the patient to have apnea exceeds 10 seconds, and the CO2 alarm function is enabled, the defibrillator/monitor will trigger an alarm; and so on.
   - [NO]: means apnea alarm function is disabled.

23.6.3 Setting the Gas Compensation

1. Select CO2 parameter area and [CO2 SETUP] menu will be displayed;
2. Select [O2 COMPENSATE]and select [HIGH], [MED] or [LOW];
3. Select [N2O COMPENSATE]and select [ON] or [OFF].

NOTE: This feature isonly available on Masimo CO2.

Gas compensation setting varies with different CO2 modules;

1. Select CO2 parameter area and [CO2 SETUP] menu will be displayed;
2. Select [O2 COMPENSATE] and set the value;

NOTE: This feature is only available on RESPIRONICS CO2.

⚠Warning

- **Please set the compensation of various gases based on actual circumstances; otherwise the measured result may seriously deviate from the actual value, which will result in misdiagnosis.**

23.6.4 Setting the Altitude

1. Select CO2 parameter area and [CO2 SETUP] menu will be displayed;
2. Select [ALTITUDE (m)];
3. Select the altitude in the pop-up list box.

NOTE: This feature is only available on RESPIRONICS CO2.

23.6.5 Setting the Balance Gas

1. Select CO2 parameter area and [CO2 SETUP] menu will be displayed
2. Select [BALANCE GAS];
3. Select [ROOM AIR], [N2O] or [HELIUM];

NOTE: This feature is only available on RESPIRONICS CO2.

23.6.6 Setting the Work Mode

1. Select CO2 parameter area and [CO2 SETUP] menu will be displayed
2. Select [WORK MODE];
3. Select [MEASURE] or [SLEEP].

NOTE: This feature is only available on Masimo CO2.

23.7 Zeroing of RESPIRONICS Mainstream and Sidestream Module

Please zero before monitoring CO2; zeroing is to eliminate the effect of baseline drifting on the results during measurement, thus ensuring the correctness of measured results.

Usually, the module will zero itself automatically when necessary. The user can zero the module manually when the user considers it necessary:Select CO2 parameter to enter [CO2 SETUP], select [ZERO] to zero the CO2 module. During zeroing, make sure that the patient circuit is exposed to the ambient air (21% oxygen and 0% CO2) for approximately 30 seconds; when the 30s zeroing prompt on the screen ends, it means zeroing is completed.

23.8 Masimo Mainstream and Sidestream Analyzer RelatedInformation

23.8.1 Zeroing

An infrared gas analyzer needs to determine the zero reference level for CO_2 measurement.

Automatic Zeroing

The ISA sidestream gas analyzer performs zeroing automatically by switching the gas sampling from the respiratory circuit to the ambient air. The automatic zeroing is performed every 24 hours and takes less than 3 seconds for ISA CO2 gas analyzers and less than 10 seconds for ISA multigas analyzers. If the ISA sidestream gas analyzer is equipped with an oxygen sensor, automatic zeroing also includes the room air calibration of the oxygen sensor.

Manual Zeroing

Select CO2 parameter to enter [CO2 SETUP] andselect [ZERO] to zero the CO2 module. During zeroing, make sure that the patient circuit is exposed to the ambient air (21% oxygen and 0% CO_2) for approximately 30 seconds; when this menu is in a non default (settable) condition, zeroing can be executed.

⚠Warning

- **Since successful zeroing requires the presence of ambient air (21% oxygen and 0% CO_2) in the gas analyzer, ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.**

23.8.2 CO2 Module Indicator Status

Overview of States Indicated by LEGI:

Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady red light	Sensor error
Blinking red light	Check sampling tube

23.8.3 Adverse Effects on Performance

(1) The following circumstances can cause known adverse effects on indicated performance:

- Quantitative effects of humidity or condensate.
- Quantitative effects of barametric pressure.
- Interfering gases or vapors.
- Other sources of interference.

(2) Gas measurement unit

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

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

The total pressure of gas mixtureis measured by a cuvette pressure sensor in the ISA gas analyzer.

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

CO_2 (mmHg) = (CO_2concentration) x (atmospheric pressure (kPa) from the ISA) x (750 / 100)。

For example: 5.0 vol% CO_2 @ 101.3 kPa 0.05 x 101.3 x 750 / 100 = 38 mmHg

(3) Effects of Humidity

The partial pressure and volume percentage of CO_2, N_2O, oxygen or an anesthetic gas depend on the amount of water vapor in the measured gas. O2 measurement will be calibrated to show 20.8 vol%, at actual ambient temperature and humidity level, instead of showing actual partial pressure 20.8 vol% O2 corresponds to the actural O2 concentration in room air with 0.7 vol% H2O concentration (at 1013hPa 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 a patient, the breathing gas is saturated with water vapor at body temperature (BPTS).

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

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

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

Where:

Et CO_2 = Et CO_2 value sent from ISA [vol %]

Pamb = Ambient pressure sent from ISA [kPa]

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

Et CO_2 (BTPS) = Et CO_2 gas concentration at BTPS[vol%]

O2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H2O

23.8.4 ISA Sidestream Gas Analyzer Safety Information

⚠Warning

- **The ISA sidestream gas analyzer is designed to be used by authorized or trained medical personnel.**
- **Use only Nomoline sampling lines produced by PHASEIN.**
- **The ISA sidestream gas analyzer shall not be used with inflammable anesthetic agents.**
- **Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.**
- **Do not reuse disposable sampling lines.**
- **Do not lift the ISA/host equipment by the sampling line as it could disconnect from the ISA/host equipment, causing the the ISA/host equipment to fall on the patient.**
- **Used disposable sampling lines should be disposed of according to local regulations for medical waste.**
- **Do not use adult/pediatric type sampling line configurations with infants, as this may add dead space to the patient circuit.**
- **Do notuse infant type sampling line configurations with adults, as this may case excessive flow resistance.**
- **Do not use the ISA sidestream gas analyzer with metered-dose inhalers or nebulized medications**

as this may clog the bacteria filter.

- **Check that the gas sample flow is not too high for the present patient type.**
- **Since successful zeroing requires the presence of ambient air (21% oxygen and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.**
- **The Nomoline sampling line and its interfaces are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.**
- **Never sterilize or immerse the ISA sidestream gas analyzer in liquid.**
- **Measurements can be affected by mobile and RF communications equipment. Make sure that the ISA gas analyzer is used in the electromagnetic environment specified in this user manual.**
- **ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjuction with other assessments of clinical signs and symptoms.**
- **Replace the sampling line if the sampling line input connector starts flashing red, or a Nomoline occlusion message is displayed on the host equipment.**
- **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 contuinued safe operation.**
- **ISAsidestream gas analyzersare not designed for MRI environments.**
- **During MRI scanning, the host equipment must be placed outside the MRI suite.**
- **Use of high frequency electrosurgical equipment in the vicinity of the ISA/host equipment may produce interference and cause incorrect measurements.**
- **Do not use external ambient cooling of the ISA equipment.**
- **Do not apply negative pressure to the Nomoline (i.e. by a syringe) to remove condensed water.**
- **Too strong positive or negative pressure in the patient circuit might affect the sample flow.**
- **Strong scavenging suction pressure might affect the sample flow.**
- **Exhaust gases should be returned to the patient circuitor a scavenging system.**
- **Always use a bacteria filter on the evac side if sampled gas is intended to be re-breathed.**
- **Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.**

23.8.5 IRMA Mainstream Gas Analyzer Safety Information

⚠Warning

- **Do not use IRMA adult/pediatric airway adapter with infants as the adapter adds 6ml space to the patient circuit.**
- **Replace the adapter if rainout/condensation occurs inside the airway adapter.**
- **Use only IRMA airway adapters made by PHASEIN.**
- **Do not use the IRMA infant airway adapter withadults as this may cause excessive flow resistance.**
- **The host equipment shall have adequate protection against contact with live parts.**
- **Only adapter cables approved by PHASEIN AB can be used.**
- **There must be a warning implemented in the host equipment to indicate when demo data is being displayed.**
- **The host equipment should be equipped with appropriate alarm systems to remind the user of situations which could lead to death or serious deterioration of the patient's state of health.**
- **Alarm message corresponding to each bit in the IRMA statussummary field must be**

implemented in the host equipment.

- **The IRMA probe is not intended to be in patient contact.**
- **Incorrect probe zeroing will result in false gas readings.**
- **The IRMA probe is intended for use by authorized or trained medical personnel only.**
- **The IRMA probe must not be used with inflammable anesthetic agents.**
- **Disposable IRMA airway adapters shall not be reused. Reuse of the disposable adapter can cause cross infection.**
- **Used airway adapters should be disposed of according to local regualtions for medical waste.**
- **Use only PHASEIN manufactured oxygen sensor cells. Depleted oxygen sensors shall be disposed of in accordance with local regualtions for batteries**
- **Never try to open the oxygen sensor assembly. The oxygen sensor in the IRMA probe is a disposable product and contains a caustic electrolyte and lead.**
- **The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may alllow patient secretions to block the adapter windows and result in incorrect operation.**
- **Tokeep secretions and moisture from poolingon the windowsor oxygen sensor port, always place the IRMA probe in a vertical position with the LED pointing upwards.**
- **Do not use the IRMA airway adapter with metered-dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.**
- **Incorrect agent selection by the user for IRMA OR (no automatic anesthetic agent identification) will result in false anesthetic agent readings.**
- **Using IRMA OR (no automatic anesthetic agent identification) with gas mixtures containing more than one agent will result in false anesthetic agent readings.**
- **Measurements can be affected by mobile and RF communications equipment. Make sure that the ISA gas analyzer is used in the electromagnetic environment specified in this user manual.**
- **Never sterilize or immerse the IRMA probe in liquid.**
- **The IRMA oxygen cell and the IRMA airway adapter are non-sterile devices. Do not autoclave the devices as this will damage them.**
- **Do not leave depleted oxygen sensors mounted in the IRMA probe, even if the probe is not in use.**
- **Do not apply tension to the sensor cable.**
- **Do not operate the device outside the temperature environment specified in this user manual.**
- **(U.S.): Federal law restricts this device to sale by or on the order of a physician.**

23.8.6 Airway Obstruction

When the anesthetic gas airway is obstructed, on the screen there will be such analarm message as[AIRWAY OCCLUSION]; under such a circumstance, replace the Nomoline sampling line.

⚠**Warning**

- **Do not use the ISA sidestream gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.**

23.8.7 Discharging Waste Gases

When nitrous oxide and/or an anesthetic gas is used, you should prevent these gases from polluting the operating room. Usually the gas outlet should be connected to (via the gas discharging tube connected to the sample gas outlet of the host equipment) a discharging system (used for discharging collected gases) or the patient circuit (used for the back flow of collected gases).

⚠Warning

- **Anesthetics:when perform measurement on the patients who are receiving or have recently received anesthetics, connect the outlet on the module to a waste gas processing system, anesthesia machine or ventilator, so as to prevent medical staff from inhaling the anesthetic.**

23.8.8 Consumables

The Nomoline sampling is non-reusable.
Every two weeks or whenever [SAMPLING LINE CLOGGED] alarm message appears, whichever comes first, the Nomoline sampling line should be replaced.

23.8.9 Safety Symbol Information

Symbol	Title	Explanation
	Instructions for use	Consult instructions for use
	Instructions for use	Refer to instruction manual/booklet
	Catalog number	
	Serial number	
	Batch code	
	Year of manufacture	
	Use by date [YYYY-MM-DD]	The device should not be taken into operation after the date accompanying the symbol.
	Temperature limitation	
	Pressure limitation	

Symbol	Title	Explanation
	Humidity limitation	
	Do not re-use	Nomoline and Nomoline Airway Adapter Set are intended for single patient use
	Biohazardous waste	Nomoline Family sampling lines shall be disposed as biohazardous waste
	For EU only: Waste Electrical and Electronic Equipment (WEEE)	For EU only: Electrical and electric equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)
	ETL Listing Mark	Conforms to ANSI/AAMI 60601-1:2005 Cert. to CAN/CSA-C22.2 No.60601.1:2008.
CE **1984**	ConformitéEuropéenne	Complies with 93/42/EEC Medical Device Directive
IPX4	IP classification indicating level of water protection	“Splash-proof”
Rx ONLY	Rx only	(US Only) Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
CO_2	CO_2	ISA equipped to measure CO_2 only
CO_2	Multigas (AX+ or OR+)	ISA equipped to measure multiple gases
	Sigma Multigas Technology	The product is fitted with PHASEIN Sigma Multigas Technology
	Gas Inlet	
	Gas Outlet	
	Defibrillation-proof type BF applied part	The applied part of ISA is the Nomoline Family sampling line
IP44	IP classification indicating level of protection against ingress of water and	Protected against tools and small wires (>1mm). Protected against water spray from any direction.

Symbol	Title	Explanation
	solid foreign parts	
	Limited temperature rise	The maximum probe surface temperature at room temperature (23°C) is for IRMA AX+ 50°C / 122°F.
	Warning: Supplementary text.	"Warning" refers to a dangerous situation which may cause personal injury or death. A warning symbol should be in conformity with: ISO 7010-W001.

23.8.10Maintenance

The user should verify gas readings regularly; If finding any problem, please contact an engineer of the manufacturer for maintenance.

23.8.11Patents and Trademarks

(1) Patent Statement

Masimo owns the following patents for relevant products described in this operating instruction manual: SE519766; SE519779; SE523461; SE524086. Other patents are being applied.

(2) Trademark

Masimo IRMA™, Masimo ISA™, Masimo XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, PHASEIN GasMaster™ and ISA MaintenanceMaster™ are trademarks ofMasimo. Tygothane® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

Chapter 24 IBP Monitoring

24.1 Overview

The invasive blood pressure(IBP) monitoring can usually monitor arterial blood pressure, central venous pressure, pulmonary arterial pressure, left atrial pressure, right atrial pressure and intracranial pressure.
The defibrillator/monitor can be directly used for measuring blood vessel pressure (diastolic pressure, systolic pressure, mean pressure).

24.2 IBP display

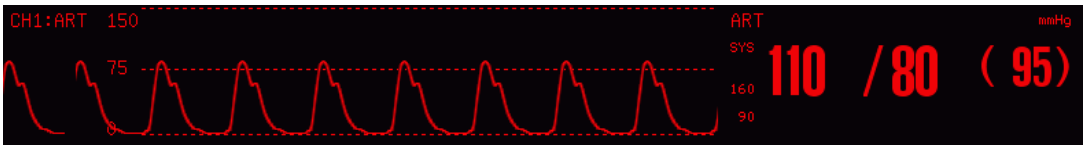


Figure24-1 IBP display

24.3 Safety Information

⚠Warning

- **Make sure that the accessory to be used meets medical instrument safety requirements.**
- **When connecting or using an accessory, you should avoid touching any metal part connected to an electric appliance.**
- **When the monitor is used with HF surgical equipment, the transducerand the cables must be avoided conductive connection to the HFequipment to protect against burns to the patient.**
- **Do not repeatedly use a disposable pressure transducer.**
- **Check whether the IBP cable is in good condition prior to monitoring. When you discennect the IBP cable from the monitor, the monitor will trigger a technical alarm and display alarm message "IBP SENSOR OFF" on the screen.**
- **If liquid (not the solution used for filling the pressure tube and transducer) is spattered onto the monitor or accessory, especially when the liquid may enter the transducer or monitor, please contact the maintenance department of the hospital.**
- **If any damage or aging sign is found on transducer, cable and pressure tubing, replace them immediately.**

⚠Attention

- **No matter a new sensor or a used sensor, it should be calibrated regularly in accordance with hospital regulations.**
- **The user should zero the transducer before monitoring. During monitoring, the user should maintain the pressure transducer and the heart at the same level all the time; in order to**

prevent tube clogging, the user should keep injecting heparin saline to wash the tube and maintain the unobstructed condition of the pressure measurement path, and securely fixed the tube in order to prevent it from moving or falling off, which will affect invasive blood pressure measurement.

- **Only pressure transducers designated in this user manual can be used.**

24.4 Steps of IBP Monitoring

1. Connect the IBP cable to the IBPsocket and switch to monitor mode.
2. Prepare the pressure tube and transducer.The method is to fill up the system with normal saline and make sure that there is no bubble in the tube system.
3. Connect the patient tube to the pressure tube and make sure that there is no air in the tube and the pressure tube or the transducer.

⚠Warning

- **If there are bubbles in the pressure tube or the transducer, wash the system again with the filled liquid.**

4. Place the transducer at the same level as the heart, approximately at middle axillary line.
5. Select thepressure label;
6. Zero the sensor.

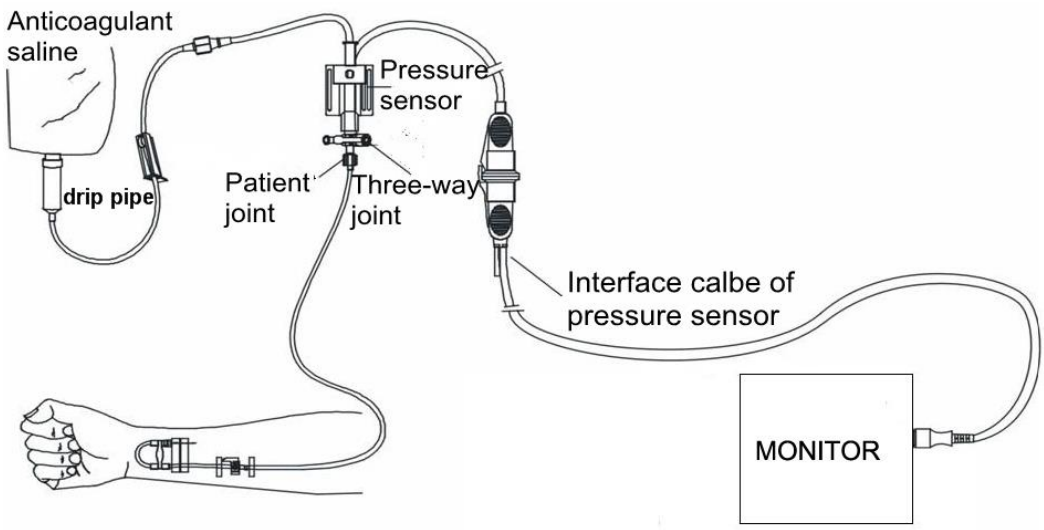


Figure 24-2 IBP Monitoring

24.5 IBP Pressure Zeroing

It is required to perform IBP pressure zeroing when the IBP cable is connect to IBP socket and before IBP monitoring.

⚠Attention

- **The user should ensure that the pressure transducer has been zeroed before measurement; otherwise the instrument will not have an effective zero value, which will result in inaccurate measured data.**

1. Select IBP parameter area and [IBP<1,2> SETUP] menu will be displayed;
2. Select [ZERO];

Keys to IBP pressure zeroing:

1. Before starting zeroing, turn off the 3-way stop cock at the patient side.
2. Before starting zeroing, the pressure transducer must be exposed to the atmosphere.
3. The sensor must be placed at the same level as the heart, approximately at the middle axillary line.
4. Zeroing should be carried prior to IBP monitoring, and at least once a day (zeroing must be carried out every time the cable is pulled out).

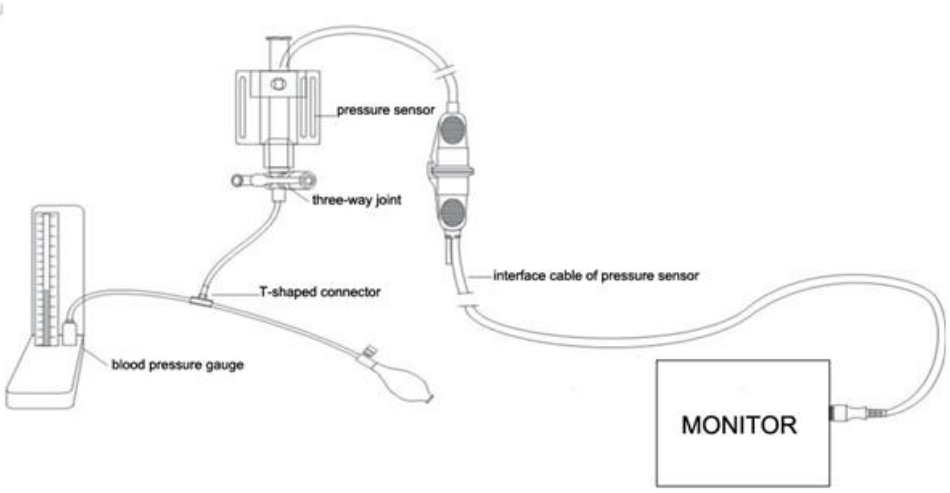


Figure 23-1IBP zeroing connection schematic

24.6 IBP Settings

24.6.1 Changing the Pressure Label

1. Select IBP parameter area and the [IBP<1,2> SETUP] menu will be displayed;
2. Select [CH1 LABEL] or [CH2 LABEL];
3. Select a suitable pressure label in the pop-up list box.

Pressure Label	Description
ART	Arterial pressure
PA	Pulmonary arterial pressure
CVP	Central venous pressure
RAP	Right atrial pressure
LAP	Left atrial pressure
ICP	Intracranial pressure
P1/P2	Expansion pressure

24.6.2 Setting the Filter Mode

1. Select IBP parameter area and the [IBP<1,2> SETUP]menu will be displayed;
2. Select [FILTER];
3. Select [SMOOTH],[NORMAL] or [NO FILTER].
   - [SMOOTH] means the smoothest waveforms can be acquired.
   - [NORMAL] means relatively smooth waveforms can be acquired.
   - [NO FILTER] means the filter fucntion is deactivated and the origial waveform will be displayed.

24.6.3 Adjusting the Pressure Scale

The user can adjust the upper scale and lower scale to change the size of IBP waveform.

1. Select IBPparameter area andthe [IBP<1,2> SETUP]menu will be displayed;
2. Select [CH1:ART RULER SETUP] for example, here “CH1:ART” means the pressure label on the first IBP channel is ART. ;
3. Select [UPPER SCALE] and [LOWER SCALE]and adjust the upper scale and lower scale respectively;

24.6.4 Setting the Pressure Unit

1. Select IBPparameter area and the [IBP<1,2> SETUP]menu will be displayed;
2. Select [UNIT];
3. Select [mmHg] or [kPa].

24.6.5 Setting the Calibration Pressure Value

1. Select the IBP parameter area and the [IBP<1,2> SETUP]menu will be displayed;
2. Select[CALIBRATION VALUE] and adjust the calibration pressure value. The valid range is 80～300;

Appendix I Accessories

⚠Warning

- **Only use the accessories specifiedin this user manual, or the defibrillator/monitor could be damaged.**
- **To avoid cross infection, do not reuse any disposable accessory.**
- **The unit package shall not be opened until immediately prior to use. If any damage is found on accessory and its packaging, please do not use it.**
- **The expired and damaged accessories would cause environmental pollution and they should be disposed of according to relevant local laws and regulations or hospital regulations.**
- **When using accessories, please refer to the user manual accompanied with the accessories for temperature requirements.**

- Defibrillation accessories

Accessory	Patient type	Model	Part No.
External paddles	Adult, pediatric	CM3901	040-000660-00
Pads	Adult	DF20N	040-000665-00
	pediatric	DF31L	040-000666-00
Pads cable	/	CM3905	040-000664-00

- ECG accessories

Accessory	Lead type	Compatible with	Type	Model	Part No.
ECG lead wire	12-lead	AHA	Clip	98ME01AB076	040-000481-00
	12-lead	IEC		98ME01EB075	040-000487-00
	5-lead	AHA		98ME01AC457	040-000480-00
	5-lead	IEC		98ME01EC680	040-000486-00
	3-lead	AHA		98ME01AC458	040-000479-00
	3-lead	IEC		98ME01EC681	040-000485-00

- SpO2 accessories

Accessory	Patient type	Type	Model	Part No.
SpO2 sensor	Adult	Reusable, finger	DS-100A	040-000010-00
	Adult	Reusable, finger	DURA-Y®D-YS	040-000075-00
	Pediatric	Reusable, finger	OXI-P/I	040-000086-00
	Neonate	Reusable, foot	OXIBAND®OXI-A/N	040-000087-00
	Adult	Reusable, finger		
	Pediatric	Disposable, finger	MAX-P	040-000004-00
	Neonate	Disposable, foot	OXIMAXMAX-N	040-000223-00

	Adult	Disposable, finger		
	Neonate	Disposable, foot	M-LNCS NEO-3	040-000200-00
	Adult	Disposable, finger		
	Neonate	Disposable, foot	M-LNCS NEO	040-000232-00
	Adult	Disposable, finger		
	Infant	Disposable, foot	M-LNCS INF-3	040-000198-00
	Pediatric	Reusable, finger	M-LNCS DCIP	040-000373-00
	Neonate	Reusable, finger	M-LNCS YI	040-000361-00
	Adult	Reusable, finger	M-LNCS DCI	040-000203-00
	Pediatric	Reusable, finger	A1418-SP203PV	040-000034-00
	Adult	Reusable, finger	A0916-SA203MV	040-000646-00
	Neonate	Reusable, Bundle	A1418-SW203MU	040-000334-00
	Neonate	Reusable, Bundle	A0816-SW106PU	040-000715-00
	Adult	Finger	SAL001	040-000726-00
	Pediatric	Finger	SCL001	040-000727-00
	Adult	Finger	SAS001	040-000728-00
	Pediatric	Finger	SCS001	040-000729-00
	Neonate	Foot	SES001	040-000730-00
SpO2 sensor belt	/	Reusable	M-LNCS YI	040-000362-00

- NIBP accessories

Accessory	Type	Model	Part No.
NIBP cuff	Adult, Reusable	U1880S	040-000583-00
	Pediatric, Reusable	U1881S	040-000584-00
	Infant, Reusable	U1882S	040-000585-00
	Pediatric, Reusable	U1883S	040-000586-00
	Reusable, adult, thigh	U1884S	040-000587-00
	Reusable, small adult	U1885S	040-000588-00
	Reusable, large adult	U1869S	040-000589-00
	Reusable, small adult, extension	U1889S	040-000590-00
	Adult, thigh	CK-XT-78243-001	040-000091-00
	Adult	CK-XT-78243-003	040-000092-00
	Infant	CK-XT-78243-008	040-000120-00
	Pediatric	CK-XT-78243-007	040-000140-00
	Neonate	CK-XT-78243-000	040-000141-00

- TEMP accessories

Accessory	Patient type	Application site	Model	Part No.
Temperature probe	Adult	Skin surface	TAS03-04	040-000246-00
	Neonate	Skin surface	TPS03-03	040-000387-00

	/	Rectum	TAE03-03	040-000385-00
	Neonate	Rectum	TPE03-04	040-000386-00
	Adult 2.25K	Skin surface	TPS03-07	040-000534-00
	Pediatric 2.25K	Skin surface	TPS03-06	040-000650-00
	Adult 2.25K	Rectum	TAE03-08	046-000652-00
	Pediatric/ neonate 2.25K	Rectum	TPE03-07	040-000651-00
● CO2 accessories				
Type	Accessory	Patient type	Model	Part No.
RESPIRONIC sidestream	LOFLO™ CO2 module	/	1022054	099-000004-00
	CO2 nasal tube	Adult	3468ADU-00	040-000027-00
	CO2 nasal tube	Infant	3468INF-00	040-000028-00
	CO2oral/ nasal tube	Adult	3470ADU-00	040-000029-00
	CO2oral/ nasal tube	Pediatric	3470PED-00	040-000030-00
	Airway adapter (with dryer line)	Pediatric/adult	3473ADU-00	040-000024-00
	Airway adapter (with dryer line)	Infant/Neonate	3473INF-00	040-000026-00
	Airway adapter (without dryer line)	Adult/pediatric	3472ADU-00	040-000316-00
	Sampling line (with dryer line)	/	3475-00	040-000399-00
MASIMOsidestream	ISA™ CO2 module	/	CAT.NO.800101	099-000007-00
	NOMOLINE sampling line	/	CAT.NO.108210	040-000017-00
Sidestream	CO2 module	/	C300	099-000021-00
	T-type airway adapter	/	L	040-000408-00
	Dryer line	/	ME-050-12ML	040-000405-00
	Disposable nasal sampling line	/	DM3100	040-000407-00
	Disposable extension sampling line	/	MM	040-000406-00
IBP accessories				
Accessory		Type	Model	Part No.
IBP transducer		Disposable	PX260	040-000673-00
		Disposable	42584-05	040-000674-00
		Disposable	5202620	040-000675-00
		Disposable	DPT-248	040-000633-00
		Disposable	DT-4812	040-000634-00
		Disposable	DP-248	040-000013-00

Appendix IIProduct Specifications

1. Classifications

Item	Classification	
Type of protection against electrical shock	ClassIwith internal power supply	
Classification of protection against electrical shock	BF applied parts	SpO_2,NIBP, TEMP, CO_2
	CF applied parts	ECG, IBP
Classification by medical device directive	Class III	
Safety standard	EN 60601-1,EN 60601-1-8,EN 60601-2-49,EN 60601-2-4,EN 60601-2-27, IEC 80601-2-30,EN 60601-2-34,ISO 80601-2-56, ISO 80601-2-61, EN ISO 81060-1, EN 1060-3,EN 60601-1-4,	
Degree of protection against harmful ingress of water	IPX4	
Degree of protection against harmful ingress of solid particle	IP4X	
Safety degree of use in the environment with flammable anesthesia gas or nitrous oxide (Not applicable)	This device cannot be used in the environment with flammable anesthesia gas or nitrous oxide.	
Operating mode	Continuous operation	

2. Specifications

(1) Size and weight

Item	Specifications
Size and weight	Size:324mm(L)×220mm(W)×345mm(H)(Including external paddles) Size:301mm(L)×220mm(W)×345mm(H)(Not including external paddles)
	Weight: 7.5Kg(not including batteries) Weight of one battery: 0.7Kg

(2) EnvironmentRequirements

Item	Specifications	
Work environment	Ambient temperature	0℃～45℃
	Relative humidity	10%～95%, no condensation
	Atmospheric pressure	700hPa～1060hPa
Transport and storage temperature	Ambient temperature	-20℃～70℃
	Relative humidity	10%～95%, no condensation
	Atmospheric pressure	700hPa～1060hPa
	Please protect the Monitor against violent impact, vibration and water in transport.	

(3) Power supply

Item	Specifications
Voltage	100−240V～
Frequency	50Hz/60Hz±1Hz
Rated power	200VA

(4) Display

Item	Specifications
Screen size	8.4 inch color TFT display screen
Displayed information	Up to 4 waveforms can be displayed.
Resolution	800×600 pixels

(5) Recorder

Item	Specifications
Paper width	80mm
Paper speed	12.5 mm/s, 25 mm/s, 50 mm/s
Real-time recording time	8s,16s,32s
Number of waveform channels	Up to four channels of waveform can be recorded.
Recording triggered by alarms	With alarm recording function

(6) Battery

Item	Specifications
Battery	Two rechargeable lithium-ion battery, 4500mAh, d.c.14.8V
Charge time	Charge time to 80% charge levelin less than 2 hours; Charge time to 100% charge levelin less than 3 hours
Running time	Running time of one battery in the environmental temperature of 20□ is as follows: (Running time of two batteries is twice of that of one battery) 1. Monitormode: more than 5 hours(interval of NIBP measurement is 15 minutes and no printing); 2. Defibrillation mode: more than 100 shocks(maximum energy level, charge interval more than 1 minute and no printing) 3. Pacer mode: more than 3 hours (50Ω load, frequency 80bpm, current 60mA and no printing); more than 2.5hours (50Ω load, frequency 170bpm, current 200mA and no printing); more than3 hours (50Ω load, frequency 40bpm, current 200mA and no printing)
Battery level indicator	There aremultiple LEDs on the battery to indicate itsapproximate battery level.
Low battery alarm	After low battery alarm, 20 minutes vital sign monitoring and at least 6 maximum energy deliveries can be conducted at the same time.

(7) Data storage

Item	Specifications	
Trend data	Short trend	1 hour with resolution of 1 second
	Long trend	120 hours with resolution of 1 minute
Trendgraph and trend table	120 hours	

Alarm events	200 alarm events with relevant parameter values at alarm moment and waveforms of 16s before and after the alarm moment.
NIBP measurement data	2000 groups
12-lead diagnosis report	5 12-lead diagnosis reports for each patient
Audio recording	Store up to 480minaudio recording (up to 60min for each patient)
Parameter waveforms	120 hours

(8) Defibrillation

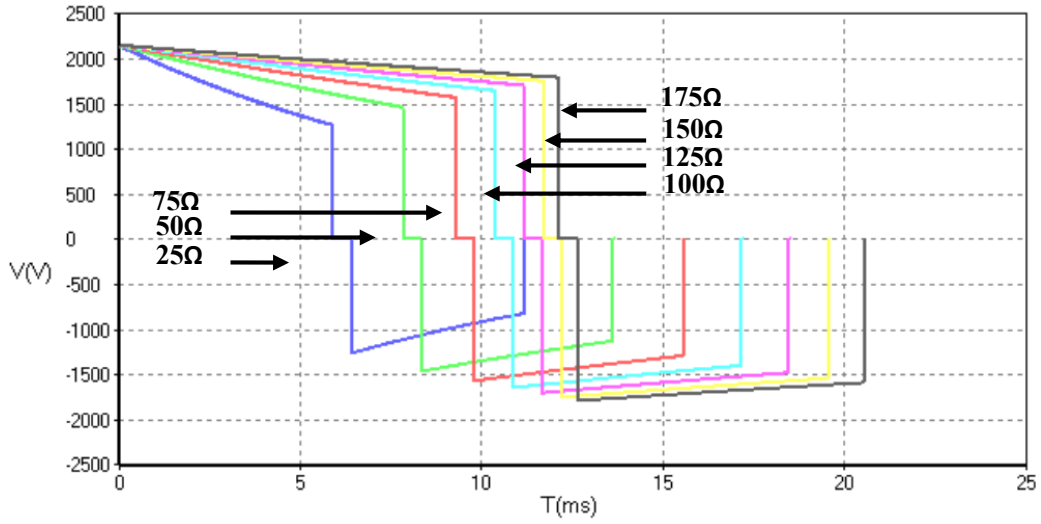
Item	**Specifications**
Defibrillation mode	Manual defibrillation, synchronized defibrillation and AED
Defibrillation waveform	BTE waveform. The waveform parameters are compensated automatically according to patient impedance.
Defibrillation electrode	External paddles, pads and internal paddles; child external paddles are inside adult external paddles
Controls and indicators of external paddles	There are charge button, shock button and energy select button on external paddles and there is shock indicator to indicate charge has completed.

Energy select	
External defibrillation	1/2/3/4/5/6/7/8/9/10/15/20/30/50/70/100/120/150/170/200/220/250/270/300/360J
Internal defibrillation	1/2/3/4/5/6/7/8/9/10/15/20/30/50J

Range of patient impedance	
External defibrillation	20Ω~250Ω
Internal defibrillation	15Ω~250Ω

Energy Delivery Accuracy
For 25Ω, 75Ω, 100Ω, 125Ω, 150Ω, 175Ωload, energy delivery accuracy is lower than ±2J or ±15％, whichever is the larger.
For 50Ωload, energy delivery accuracy is lower than ±1.5J or ±10％, whichever is the larger.

360J defibrillation waveform (Load impedance 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω and 175Ω)



Energy accuracy								
Energy Impedance	**25Ω**	**50Ω**	**75Ω**	**100Ω**	**125Ω**	**150Ω**	**175Ω**	**Accuracy**
1J	1.0	1.0	1.0	0.9	0.9	0.9	0.8	±2J
2J	1.9	2.0	1.9	1.9	1.8	1.7	1.6	±2J
3J	2.9	3.0	2.9	2.8	2.7	2.5	2.4	±2J
4J	3.9	4.0	3.9	3.7	3.6	3.4	3.2	±2J
5J	4.8	5.0	4.8	4.6	4.4	4.2	4.0	±2J
6J	5.8	6.0	5.8	5.6	5.3	5.1	4.9	±2J
7J	6.8	7.0	6.8	6.5	6.2	5.9	5.7	±2J
8J	7.8	8.0	7.8	7.4	7.1	6.8	6.5	±2J
9J	8.8	9.0	8.8	8.4	8.0	7.7	7.3	±2J
10J	9.7	10.0	9.7	9.3	8.9	8.5	8.1	±2J
15J	14.6	15.1	14.6	14.0	13.4	12.8	12.2	±15%
20J	19.5	20.1	19.5	18.7	17.8	17.0	16.3	±15%
30J	29.2	30.1	29.2	28.0	26.7	25.5	24.4	±15%
50J	48.7	50.1	48.7	46.6	44.5	42.5	40.6	±15%
70J	68.1	70.2	68.1	65.2	62.3	59.5	56.9	±15%
100J	97.2	100.2	97.2	93.1	88.9	84.9	81.2	±15%
120J	117.0	120.5	117.0	112.1	107.0	102.1	97.7	±15%
150J	146.0	150.4	146.0	139.9	133.5	127.5	121.9	±15%
170J	165.3	170.3	165.3	158.4	151.2	144.3	138.0	±15%
200J	194.7	200.5	194.6	186.5	178.0	169.9	162.5	±15%
220J	214.3	220.8	214.2	205.3	196.0	187.1	178.9	±15%
250J	243.5	250.8	243.4	233.2	222.6	212.5	203.3	±15%
270J	262.8	270.7	262.7	251.7	240.3	229.4	219.4	±15%
300J	292.0	300.8	292.0	279.7	267.1	254.9	243.8	±15%
360J	350.5	361.1	350.4	335.7	320.5	306.0	292.6	±15%

Charge time	
With a new fully charged	Charge time to 200J in less than 5s; charge time to 360J in less

battery(at20℃environmental temperature)	than 8s
With AC power supply	Charge time to 200J in less than 8s; charge time to 360J in less than 11s

For AEDs,the maximum time from the initiation of rhythm analysis with a clear ECG signal to readiness for discharge	
With anew fully charged battery	18s
With AC power supply	21s

Synchronized defibrillation delay	
Local synchronized defibrillation delay	Less than 60ms
Remote synchronized defibrillation delay	Less than 25ms(from synchronized signal rising edge)
AED	
Serial shock	Shock energy: 100～360J Shock times: 1, 2,3
Shockable rhythm	VF, VT

AED algorithm performance		
Cardiac rhythm	Performance requirements	Remark
A（true positive）	612	/
B（false positive）	2	/
C（false negative）	11	/
D（true negative）	531	/
A/(A+C)（Sensitivity of the device for shockable rhythms）	98.23%	/
A/(A+B)（True predictive value）	99.67%	/
D/(B+D)（Specificity of device for non-shockable rhythms）	99.62%	/
B/(B+D)（False positive rate）	0.38%	/
Shockable rhythm-VF	Sensitivity>90%	Comply with AAMI DF80and AHA (sensitivity>90%)
Shockable rhythm- VT	Sensitivity>75%	Comply with AAMI DF80and AHA (sensitivity>75%)
Nonshockable rhythm- NSR	Specificity >99%	Comply with AAMI DF80and AHA (specificity >99%)
Nonshockablerhythm-asystole	Specificity >95%	Comply with AAMI DF80and AHA (specificity >95%)
All other nonshockable rhythms	Specificity >95%	Comply with AAMI DF80and AHA (specificity >95%)
The adopted databases are based on the databases of MIT, CUDB, AHA and VFDB involved in the standard ANSI/AAMI EC57 and the adopted Okuman database of our company.		

(9) Noninvasive pacing

Pacing	
Pacing mode	Fixed pacing and demand pacing
Pacing waveform	Square signal with Rising Egde less than 40us, Falling Edge less than 40us, Voltage amplitude ranging from 0 to 150 V and Voltage fluctuation range of ±5% or ±0.25 V (Use the lager value).The one-way square-wave pulse with pulse width of 20ms±1.5ms
Pacing rate	40bpm~170bpm with accuracy of ±1.5%
Pacing current	0mA~200mA with accuracy of ±5% or5mA (larger one)
Pacing with decreased speed	When this function is enabled, pacing rate decreases to one fourth of original rate.
Output protection	The output end can stand 360J energy delivery without any damage.
Pads:DF20N(Adult)/ DF31L(pediatric)	Lasting Time: 1 hour for 200mA/170bpm and 4 hours for 200mA/40bpm.

(10) ECG

Item	Specifications	
ECG input	ECG input source can be 3-lead ECG cable, 5-lead ECG cable, 12-lead ECG cable, paddles and pads	
Sensitivity (Gain) and error	2.5 mm/mV（×0.25）, 5 mm/mV（×0.5）, 10 mm/mV（×1）20 mm/mV（×2）,40 mm/mV（×4）and auto; Error: less than ±5%	
Sweep	50mm/s, 25mm/s, 12.5mm/s with error less than ±10%	
Range of ECG signal	±0.2~±8mV	
Overload protection	Load 1V, power frequency, differential-mode AC voltage for 10s without damage (p-v).	
Respiration, lead off detection and active noise suppression	Measuring electrode <0.1μA Drive electrode<1μA	
QRS wave amplitude and interval	Amplitude (p-v RTI)	0.2mV～8mV
	Width (adult)	70ms～120ms
	Width(pediatric/neonate)	40ms～120ms
	No response to the signals:	a) with amplitude not exceeding 0.15mV (p-v RTI) (except for pediatric/neonate mode); or b)with 10ms width (except for pediatric/neonate mode) in case of 1mV amplitude.
Voltage tolerance	＞100μV（p-v）	
Notch filter	Monitor,Therapyand ST mode: the 50/60Hz notch function is auto activated; Diagnostic mode: the 50/60Hz notch function can be select to activate or deactivate manually. Power frequency interference rejection capability≥20dB	
Drifttolerance	Triangular wave amplitude (p-v RTI)	4mV
	QRS wave amplitude (p-v RTI)	0.5 mV

	QRS wave width			100ms
	QRS wave recurrence frequency			80bpm
HR measurement range and accuracy	Adult	15～300bpm		
	Pediatric/neonate	15～350bpm		
	Accuracy	±1% or ±1 bpm, whichever is the larger		
Alarm range	Adult	Upper limit: (lower limit＋2)～300bpm Lower limit: 15bpm～（upper limit－2）bpm		
	Pediatric/neonate	Upper limit: (lower limit＋2)～350bpm Lower limit: 15bpm～（upper limit－2）bpm		
Alarm error	±1 bpm			
Alarm start time for asystole	11s			
Alarm start time for heart rate too low or too high	10s			
Frequency characteristic	Therapy mode : 1 Hz～20 Hz (-3.0dB～+0. 4 dB); Monitor mode: 0.5 Hz～40 Hz (-3.0dB～+0. 4 dB); Diagnostic mode: 0.05Hz～150 Hz (-3.0dB～+0. 4 dB); ST mode: 0.05 Hz～40 Hz (-3.0dB～+0. 4 dB);			
Auxiliary output	Bandwidth	0.5-40Hz		
	Gain	Amplify the signal to the 1000 times of the original.		
	Propagation delay time	<35ms		
	The original pacing pulses are summarized up with the ECG signal.			
Input dynamic range	Input signal amplitude	±5mV		
	Rate (RTI)	320mV/s		
	DC offset voltage	-650～+650mV		
	Output signal change	±10％		
	Failure display (attenuation prior to display)	No declining below 50%		
Input impedance	No less than 5MΩ			
System noise (p-v RTI)	＜25μV			
Multichannel crosstalk	＜5％			
Time reference selection and accuracy	Time reference selection	Permanent display		25mm/s
		Impermanent display		12.5 mm/s, 25 mm/s, 50 mm/s
	Accuracy	±10％。		
Output display	Width of channels	30mm		
	Aspect rate	0.4s/mV		
Input signals reconstruction accuracy	Total system error	±20％ or ±100μV, the larger one		
	Frequency response	Sinusoidalinput		0.67～40Hz(attenuation -3dB)
		Response to 20ms (width) triangular wave		0~25Hz attenuation in amplitude of wave peak

	Response to the 0.3 mVs shock in its range	Deviation(RTI)	≤0.1mV
		Slop (RTI)	≤0.30mV/s
	Electrode weighting factor	≥±5%	
	Hysteresis effect of 15 mmoffset	≤0.5mm	
Calibrationvoltage	1mV; Error: ±5%		
CMRR	Diagnostic mode	＞90dB	
	Monitor mode	＞105dB	
	Therapy mode	＞105dB	
	ST mode	＞105dB	
Baseline control and stability	Reset time	3s	
	Drift rate within 10s	10μV/s	
	Baseline drift within 1h	≤500μV	
	Baseline driftunder work temperature	≤50μV/℃	
Pulse inhibition of non-overshoot pacemaker	Amplitude: ±2mV~±700mV; width: 0.1ms~2.0ms (method A).		
Pulse inhibition of overshoot pacemaker	Can not inhibit		
Inhibition of pacemaker pulse detector on quick ECG signals	Minimum input slew rate: 830mV/s		
Display capabilities of pacing pulses	Amplitude: ±2mV~±700mV; width: 0.5ms~2ms; maximum rise time: 100μS; the ECG display when the pacemaker pulse appears at 100 per minute.		≥0.2mV
ST measurement	Range	-2.0mV-+2.0mV	
	Accuracy	±0.02mV or ±10%, whichever is the larger within the measurement range of -0.8mV～+0.8mV; Not specified within other measurement range.	
ST Resolution	0.01 mV		
ST alarm range and error	Upper limit: (lower limit +0.2)～2.0 mV; Lower limit: -2.0～(upper limit -0.2 mV) Error:±0.1 mV		
Arrhythmia type	ASYSTOLE, VTAC, VFIB, R ON T, VT>2, COUPLET, PVC, BIGEMINY, TRIGEMINY, Supraventricular Tachycardia, BRADY, PNC, PNP, IHB, EXTREME TACHY, EXTREME BRADY, MISSED BEATS, TACHY, PVCs TOO HIGH		
PVCs alarm range	1～31/minute		
Leakage current	< 10 uA		
Electrosurgical	The change of HR is not more than ±10% compared with the HR without		

interference inhibition	interference
Electrotome protection	Cut mode: 300W; condense mode: 100W, recovery time:≤10s

HR Calculation	
Tall T-wave rejection capability	1.2mV
Heart rateaveraging	Meet the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 3). The HR is computed like this: If the last 3 continuous RR intervals are greater than 1200ms, thelast 4 RR intervals are averaged to compute the HR. Otherwise, the last 12 RR intervals with the longest interval and shortest interval excluded are averaged to compute the HR.
Heart ratemeter accuracy and response to irregular rhythm	Meet the requirementsofIEC 60601-2-27: Clause 201.7.9.2.9.101 b) 4), the HR is displayed as follows after the 20s stable segment: Figure A1, Ventricular bigeminy: 80±1bpm Figure A2, Slow alternating ventricular bigeminy: 60±1bpm Figure A3, Rapid alternating ventricular bigeminy: 120±1bpm Figure A4, Bidirectional systoles: 90±2bpm
Response time of heart rate meterto change in heart rate	Meet the requirementsofIEC 60601-2-27: Clause 201.7.9.2.9.101b)5): the response time to HR change from 80bpm to 120bpm or from 80bpm to 40bpm is less than 11s.
Time to alarm for tachycardia	Meet the requirementsofIEC 60601-2-27: Clause 201.7.9.2.9.101 b) 6), the waveform: Figure B1 1 - range: 11s Figure B1 0.5 - range: 11s Figure B1 2 - range: 11s Figure B2 1 - range: 11s Figure B2 0.5 - range: 11s Figure B2 2 - range: 11s

Pacing pulse	
Pacing mark	There will be pacing mark for the pacing pulse that meets the following conditions: Amplitude: ±2～±700mV Width: 0.1～2ms Uprising time: 10～100μs
Pacing inhibition	In accordance with the requirements in IEC 60601-2-27, the pulse meets the following conditions will be inhibited. Amplitude: ±2～±700mV Width: 0.1～2ms Uprising time: 10～100μs Minimum input slew rate: 10V/s RTI

(11) RESP

Item	Specifications
Technique	Thoracic impedance
RESP lead	Lead I and II available

Measurement range and accuracy	Range	Adult	0rpm-120brpm
		Pediatric/neonate	0rpm-150rpm
	Accuracy	7rpm ～ 150rpm: ±2rpmor ±2%, whichever is the larger0rpm~6rpm: not specified.	
Alarm range and error	Adult	Upper limit	(Lower limit＋2)～120rpm
		Lower limit	1rpm～(Upper limit－2)rpm
	Pediatric/neonate	Upper limit	(Lower limit＋2)～150rpm
		Lower limit	1rpm～(Upper limit－2)rpm
	Error	±1rpm	
Apnea alarm time and error	Apnea alarm time	Adult:10s ~ 60s Pediatric/neonate: 10s~ 20s	
	Error	±5s	
CVA recognition function	Alarm will be triggered in the event of the same HR and RR		

(12) NIBP

Item	Specifications		
Measurement technique	Oscillometric method		
Measurement range and accuracy	Adult	Systolic pressure	5.3～36kPa（40～270mmHg）
		Diastolic pressure	1.3～28.7kPa（10～215mmHg）
		Mean arterial pressure	2.7～31.3kPa（20～235mmHg）
	Pediatric	Systolic pressure	5.3～26.7kPa（40～200mmHg）
		Diastolic pressure	1.3～20kPa（10～150mmHg）
		Mean arterial pressure	2.7～22kPa（20～165mmHg）
	Neonate	Systolic pressure	5.3～20kPa（40～135mmHg）
		Diastolic pressure	1.3～13.3kPa（10～100mmHg）
		Mean arterial pressure	2.7～14.7kPa（20～110mmHg）
	Accuracy	±5mmHg; when the measured NIBP exceeds the ranges described above, there is still reading on the screen but the accuracy is not specified.	
Static pressure measurement	Measurement range: 0 mmHg（0 kPa）～300 mmHg（40.0 kPa）;		
	Accuracy: ±3 mmHg（±0.4 kPa）		
Overpressure protection	Adult	300mmHg	
	Pediatric	240mmHg	
	Neonate	150mmHg	
	Error	±3mmHg	
Alarm range and error	Adult	SYS	Upper limit:5.6kPa～36kPa(42mmHg～270mmHg); Lower limit:5.3kPa～35.7kPa（40mmHg～268mmHg）
		DIA	Upper limit:1.6kPa～28kPa（12 mmHg～210mmHg）; Lower limit:1.3kPa～27.7kPa（10 mmHg～208mmHg）

		MAP	Upper limit:2.9kPa～30.6kPa（22 mmHg～230mmHg） Lower limit:2.6kPa～30.3（20 mmHg～228mmHg）
	Pediatric	SYS	Upper limit:5.6kPa～26.6kPa（42mmHg～200mmHg） Lower limit:5.3kPa～26.3kPa（40mmHg～198mmHg）
		DIA	Upper limit:1.6kPa～22kPa（22mmHg～165mmHg） Lower limit:1.3kPa～21.7kPa（20 mmHg～163mmHg）
		MAP	Upper limit:2.9kPa～22kPa（22mmHg～165mmHg） Lower limit:2.6kPa～21.7kPa（20mmHg～163mmHg）
	Neonate	SYS	Upper limit:5.6kPa～18kPa（42mmHg～135mmHg） Lower limit:5.3kPa～17.7kPa（40mmHg～133mmHg）
		DIA	Upper limit:1.6kPa～12.6kPa（12 mmHg～95mmHg） Lower limit:1.3kPa～12.3kPa（10 mmHg～93mmHg）
		MAP	Upper limit:2.9kPa～14.6kPa(22mmHg～110mmHg) Lower limit:2.6kPa～14.3kPa(20 mmHg～108mmHg）
	Error	±0.1kPa or ±1mmHg, whichever is the larger	
Measure mode	Manual, auto and continuous		
	Interval of auto mode		1、2、3、4、5、10、15、30、60、90、120、180、240、480min
	Continuous		5min

(13) SPO2

Item	Specifications
Display range	1%□100%
Display resolution	1%
Measurement accuracy	SpO2: Measurement range: 0%～100%; Accuracy: ±2% (measured without motion in adult/pediatric mode) or ±3% (measured without motion in neonate mode) in the range of 70%～100%; (1) Masimo SpO2: Measurement range: 1%～100%; Accuracy: ±2% (measured without motion in adult/pediatric mode), ±3% (measured with motion in adult/pediatric mode) or ±3%(measured without motion and with motion in neonate mode) in the range of 70%～100% (2) Nellcor SpO2: Measurement range: 0%～100% Accuracy: ±2% (measured without motion in adult/pediatric mode) or ±3% (measured without motion in neonate mode) in the range of 70%～100% (3) Accuracy is not specified in other ranges.

Alarm range and accuracy	Upper limit	(lower limit ＋1)%～100%
	Lower limit	1□□(upper limit □1)□
	Accuracy	±1%
Data and other signal processing time	8 seconds	
Data update period	2 seconds	
Perfusion Index(PI) (Only available on Masimo SpO_2)		
Measurement range	0.02 % ~20 %, accuracy not specified.	
Resolution	0.02%~9.99%: 0.01%; 10.0% ~20.0%: 0.1%.	
Low perfusion		
Conditions	Pulse amplitude: > 0.2%	
SpO2 Accuracy	±3%	

(14) PR

Item	Specifications
Measurement range and error	(1) SpO2 module Measurement range: 25bpm～254bpm; resolution: 1bpm; error: ±2bpm (without motion) (2) MasimoSpO2 module Measurement range: 25bpm～240bpm; resolution: 1bpm; error: ±3bpm (without motion) and ±5bpm (with motion) (3) Nellcor SpO2 module Measurement range: 20bpm～300bpm; resolution: 1bpm; error: ±3bpm in the range of 20bpm～250bpm, no specified in the range of 251bom～300bpm (4) NIBP module Measurement range: 40bpm～240bpm; resolution: 1bpm; error: ±3bpm or ±3%, whichever is the larger.
Alarm range and accuracy	Upper limit: (lower limit □1)□350bmp Lower limit: 1～(upper limit －1)bpm
	±1 bpm

(15) TEMP

Item	Specifications	
Measurement range and accuracy	Range	0℃～50℃
	Accuracy	±0.1℃ (not include sensor error)
Alarm range and error	Upper limit: (lower limit □0.1)～50.0˚C Lower limit: 0℃～(upper limit －0.1)˚C	
	Error: ±0.1℃	
Display resolution	0.1°C	
Number of channels	Two channels	
Operating mode	Direct mode	
Transient response	No less than 20 seconds	

(16) CO2

Item	Specifications	
Measurement range	a) Respironics CO2 module Range: 0mmHg～150mmHg,0%～19.7%, 0kPa～20kPa;	
	b) Masimo CO2 module Range: 0mmHg～190mmHg, 0%～25%, 0kPa～25.3kPa;	
	c) CO2 module Range: 0mmHg～150mmHg, 0%～19.7%, 0kPa～20kPa	
CO2 resolution	1mmHg/0.1kPa/0.1%	
CO2 accuracy	a)Respironics CO2 module 1)0mmHg～40mmHg:±2mmHg; 2)41mmHg～70mmHg: ±5%; 3)71mmHg～100mmHg: ±8%; 4)101mmHg～150mmHg:±10%.	
	b)Masimo CO2 module 1)0mmHg～114mmHg:±1.52mmHg+2%; 2)114mmHg～190mmHg: not specified.	
	c) CO2 module 1) 0mmHg～40mmHg:±2mmHg; 2) 41mmHg～70mmHg:±5%; 3) 71mmHg～100mmHg:±8%; 4) 101mmHg～150mmHg:±10%.	
AwRR measurement range and accuracy	a)Respironics CO2 module Adult measurement range: 2rpm～150rpm; Accuracy: ±1rpm	
	b) Masimo CO2 module Adult measurement range: 0rpm～150rpm; Accuracy: ±1rpm	
	c) CO2 module Adult measurement range: 2rpm～150rpm; Accuracy: ±1rpm	
Alarm range	Respironics and CO2 module	0 mmHg～150mmHg or 0 kPa～20kPa
	Masimo CO2 module	0 mmHg～190mmHg or 0 kPa～25.3kPa
Alarm error	±0.1kPa/±1mmHg	

(17) Masimo CO2Gas Analyzer

Name	Specifications
ISA™Sidestream analyzer	
Measurement method	infrared gas measurement
Apnea alarm time	10s, 15s, 20s, 25s, 30s, 35s, 40s.

General specification	
Instruction	Ultra-compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Operating temperature	ISA AX+: 0~50°C（32~122°F）, ISA OR+: 5~50°C（41~122°F）
Storage temperature	-40~70°C（-40~158°F）
Operating humidity	< 4kPa H2O（non-condensing）（95% RH，30°C）
Operating atmospheric pressure	52.5~120kPa (corresponding to max altitude at 4572m/15000 feet)
Water treatment	Sampling tubes are patented waterproof tubes
Flow rate of sampling	50w rate of
Data output	
Fi/ET value	CO2、O2、N2O、anesthetic gases（halothane, enflurane, isoflurane, sevoflurane, desflurane）
Waveform	Displaying four waveforms of gas concentration at most
Diagnosis parameters	Atmospheric pressure
Mark	RESP detected, no RESP detected, replace O2 transducer, check sampling tubes, accuracy undesignated and wrong transducer
Gas analyzer	
ISA transducer	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 μm
Compensation	CO_2 broadening effect
Calibration	No need for calibration. There is an auto zeroing each time the machine is started and then auto zeroing every 24 hours after that (ISA CO2) and every 8 hours (ISA AX+/OR+).
Reheating time	ISA CO_2: < 10s, ISA AX+/OR+: <20s
Gas	
Measurement range and accuracy under standard condition	Accuracy of all measured values is subject to standards of EN ISO 21647:2004 and EN 864:1996. CO_2 0-15vol% ±(0.2vol% + 2 % of the reading) N2O 0-100vol%±(2vol% + 2 % of the reading) HAL, ISO, ENF 0-8vol%±(0.15vol% + 5 % of the reading) SEV 0-10vol%±(0.15vol% + 5 % of the reading) DES 0-22vol%±(0.15vol% + 5% of the reading) O2 0-100vol%±(1vol% + 2 % of the reading)
Up-going time	CO_2≤ 250ms, N2O≤ 350ms, AG≤ 350ms, O2≤ 450ms
System overall response time	< 3s（2 meters sampling tube）
Respiratory detection	Adaptive threshold, minimum 1vol% change in CO2 concentration
Respiratory frequency	0-150 times respiration/minute
Anesthetic gas threshold	Main AG threshold (ISA OR+/AX+): 0.15vol%. When detecting one kind of AG, though its concentration is less than 0.15vol%, the monitor would still report its concentration.

Interfering gas and vapor effects				
Gas or vapour	Gas level	CO_2	AG	N_2O

		ISA CO_2	ISA AX+		
N2O 4)	60 vol%	–[2)]	–[1)]	–[1)]	–[1)]
HAL 4)	4 vol%	–[1)]	–[1)]	–[1)]	–[1)]
ENF, ISO, SEV 4)	5 vol%	Reading+8%[3)]	–[1)]	–[1)]	–[1)]
DES 4)	15 vol%	Reading+12%[3)]	–[1)]	–[1)]	–[1)]
Xe (Xenon) 4)	80 vol%	Reading-10%[3)]		–[1)]	–[1)]
He (Helium) 4)	50 vol%	Reading-6%[3)]		–[1)]	–[1)]
Metered dose inhaler propellants		Metered dose inhaler propellants			
C2H5OH (Ethanol) 4)	0.3 VOI%	–[1)]	–[1)]	–[1)]	–[1)]
C3H7OH(Isopropanol) 4)	0.5 VOI%	–[1)]	–[1)]	–[1)]	–[1)]
CH3COCH3 (Acetone) 4)	1 vol%	–[1)]	–[1)]	–[1)]	–[1)]
CH4 (Methane) 4)	3 vol%	–[1)]	–[1)]	–[1)]	–[1)]
CO(Carbon monoxide) 5)	1 vol%	–[1)]	–[1)]	–[1)]	–[1)]
NO(Nitrogen monoxide) 5)	0.02 vol%	–[1)]	–[1)]	–[1)]	–[1)]
O2 5)	100 vol%	–[2)]	–[2)]	–[2)]	–[2)]

Note 1:Negligible interference, effect included in the specification “Accuracy, all conditions” above.
Note 2:Negligible interference with N2O / O2 concentrations correctly set, effect included in the specification “Accuracy, all conditions” above.
Note 3:Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO2 and 50 vol% Helium, the actual measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.
Note 4:According to the EN ISO 21647:2004 standard.
Note 5:In addition to the EN ISO 21647:2004 standard.

Item	**Specifications**
IRMA™（AG）maintream gas analyzer	
Measurement method	infrared gas mesurement
Apnea alarm time	10s, 15s, 20s, 25s, 30s, 35s, 40s.
General specification	
Description	Ultra-compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Operating condition	IRMACO2+: 0~40°C（32~104°F）; IRMA AX+: 10~40°C（50~104°F） IRMA OR+: 10~35°C（50~95°F）
Storage condition	-20~50°C（-4~122°F）
Humidity	10~95%（non-condensing）
Barometric pressure	IRMA CO2/AX+: 52,5-120kPa (4572m); IRMA OR: 70-120kPa (3048m)

Data output	
Fi/ET	CO2, O2, N2O, anesthetic gases（halothane, enflurane, isoflurane, sevoflurane, desflurane）
Waveforms	Displaying four waveforms of gas concentration at most
Diagnostic parameters	Atmospheric pressure
Flags	RESP detected, no breaths detected, replace O2 sensor, check sampling line, unspecified accuracy and sensor error
Gas analyzer	
ISA sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 μm
Compensations	Broadening effects of CO_2.
Calibration	No need for calibration. Room air calibration for O2 sensor when replacing air adapter (less than 5s).
Warm-up time	<20s (usually <10s)
Airway adapter	
Adult/child	6ml ineffective volum
Infant	1ml ineffective volum
Gas	
Measurement range and accuracy under standard condition	Accuracy of all measured values is subject to standards of EN ISO 21647:2004 and EN 864:1996. Range （IRMACO2） CO2 0-15 vol% （IRMA OR） （IRMA AX+） CO2 0-10 vol% 0-10 vol% 0-15 vol% O2 0-100vol% N2O 0-100 vol% 0-100 vol% HAL, ISO, ENF 0-5vol% 0-8 vol% SEV 0-8 vol% 0-10 vol% DES 0-18 vol% 0-22 vol%
Up-going time	CO_2≤90ms ; N_2O, AG≤300ms; O_2≤300ms
System overall response time	<1s
Respiratory detection	Adaptive threshold, minimum 1vol% CO2 change of concentration
Respiratory frequency	0-150 times respiration/minute
Anesthetic gas threshold	Main AG threshold: 0.15vol%, subordinate AG: 0.2vol%+10% of the main AG concentration, IRMA OR: 0.3vol%. when the concentration exceeds the threshold, though lower than the threshold, the monitor would still report its concentration.

Interfering gas and vapor effects					
Gas or vapour	Gas level	CO2		AG	N2O
		ISA CO2	ISA AX+		
N2O 4)	60 vol%	–[1&2]	–[1&2]	–[1]	–[1]

HAL 4)	4 vol%	–[1)]	–[1)]	–[1)]	–[1)]
ENF, ISO, SEV 4)	5 vol%	reading+8%[5)]	–[1)]	–[1)]	–[1)]
DES 4)	15 vol%	reading+12%[5)]	–[1)]	–[1)]	–[1)]
Xe (Xenon) 4)	80 vol%	reading-10%[5)]		–[1)]	–[1)]
He (Helium) 4)	50 vol%	reading-6%[5)]		–[1)]	–[1)]
Metered dose inhaler propellants 4)	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol) 4)	0.3 VOI%	–[1)]	–[1)]	–[1)]	–[1)]
C3H7OH(Isopropanol) 4)	0.5 VOI%	–[1)]	–[1)]	–[1)]	–[1)]
CH3COCH3 (Acetone) 4)	1 vol%	–[1)]	–[1)]	–[1)]	–[1)]
CH4 (Methane) 4)	3 vol%	–[1)]	–[1)]	–[1)]	–[1)]
CO(Carbon monoxide) 5)	1 vol%	–[1)]	–[1)]	–[1)]	–[1)]
NO(Nitrogen monoxide) 5)	0.02 vol%	–[1)]	–[1)]	–[1)]	–[1)]
O2 5)	100 vol%	–[1&2)]	–[1&2)]	–[2)]	–[2)]

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.
Note 2: For probes not measuring N_2O andO_2, the concentrations shall be set from host according to the instructions in chapter 4.2 (SetN2O / SetO2), please refer to appendix B.(IRMA CO2 measures neither N_2O, nor O_2. IRMA AX+ does not measure O_2.)
Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO2 and 50 vol% Helium, the measured CO2 concentration will typically be
(1-0.06) * 5.0 vol% = 4.7 vol% CO2.
Note 3: According to the EN ISO 21647:2004 standard.
Note 4: In addition to the EN ISO 21647:2004 standard.

(18) IBP

Item	Specifications	
Number of IBP channels	Two channels	
IBP label	ART, PA, CVP, RAP, LAP, ICP, P1, P2	
Measurement range	ART	0□40kPa(0□300mmHg)
	PA	-0.8□16kPa(-6□120 mmHg)
	CVP	-1.3□5.3kPa(-10□40mmHg)
	RAP	-1.3□5.3kPa(-10□40mmHg□
	LAP	-1.3□5.3kPa(-10□40mmHg)
	ICP	-1.3□5.3kPa (-10□40mmHg)
	P1, P2	-6.6□40kPa(-50□300mmHg)
Accuracy	±1mmHg or ±2%, whichever is the larger (not including transducer error)	
Static pressuremeasurement	Range	-1.3kPa～+40kPa(-50mmHg～+300mmHg)
	Display resolution	0.1kPa or 1mmHg
	Error	±1mmHg or ±2%, whichever is the larger (not including transducer error)

IBP alarm range	ART	Upper limit: (Lower limit□2)-300 mmHg Lower limit: 0□(Upper limit□2)mmHg
	PA	Upper limit: (Lower limit□2)□120mmHg Lower limit: -6□(Upper limit□2)mmHg
	CVP	Upper limit: □Lower limit□2)□40mmHg Lower limit:-10□(Upper limit□2)mmHg
	RAP	Upper limit: □Lower limit□2)□40mmHg Lower limit:-10□(Upper limit□2)mmHg
	LAP	Upper limit: □Lower limit□2)□40mmHg Lower limit:-10□(Upper limit□2)mmHg
	ICP	Upper limit: □Lower limit□2)□40mmHg Lower limit:-10□(Upper limit□2)mmHg
	P1	Upper limit: □Lower limit□2)□300 mmHg Lower limit:-50□(Upper limit□2)mmHg
	P2	Upper limit: (Lower limit□2)□300 mmHg Lower limit:-50□(Upper limit□2)mmHg
IBP alarm error	±0.1 or ±1mmHg	
Pressure transducer	Sensitivity : 5μV/V/mmHg	
	Impedance: 300□3000Ω	

Appendix III Alarm Message

1. Physiological alarm

Alarm message	Default alarm level	Causes	Solutions
ECG			
HRTOO HIGH	High, medium	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.	Check the patient's condition and check if the alarm limit is suitable for the patient type.
HR TOO LOW	High, medium		
SPO2			
SPO2TOO HIGH	High, medium	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.	Check the patient's condition and check if the alarm limit is suitable for the patient type.
SPO2 TOO LOW	High, medium		
PRTOO HIGH	High, medium		
PR TOO LOW	High, medium		
NIBP			
NSTOO HIGH	High, medium	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.
NS TOO LOW	High, medium		
NMTOO HIGH	High, medium		
NM TOO LOW	High, medium		
NDTOO HIGH	High, medium		
ND TOO LOW	High, medium		
CO2			
CO2 TOO HIGH	Medium	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.
CO2 TOO LOW	Medium		
AwRRTOO HIGH	Medium		
AwRR TOO LOW	Medium		
INS TOO HIGH	Medium		
INS TOO LOW	Medium		

Alarm message	Default alarm level	Selectable level	Causes	Solutions
ECG				
XXTOO HIGH	Medium	High, medium, low	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.
XX TOO LOW	Medium	High, medium, low		
Here XX stands for ST-I, ST-II, ST-III, ST-AVR, ST-AVL, ST-AVF, ST-V1, ST-V2, ST-V3, ST-V4, ST-V5 and ST-V6.				
PVCsTOO HIGH	Medium	High, medium, low		
PVCs TOO LOW	Medium	High, medium, low		
ECG LOST	High	High	The ECG signal is so weak that the monitor cannot perform ECG analysis.	Check the patient's condition and check the connection of lead wires.
ASYSTOLE	High	High	Arrhythmia has occurred to the patient.	Check the patient's condition and check the connection of lead wires and electrodes.
VFIB	High	High		
R ON T	Medium	High, medium, low		
VT > 2	Medium	High, medium, low		
COUPLET	Medium	High, medium, low		
PVC	Medium	High, medium, low		
BIGEMINY	Medium	High, medium, low		
TRIGEMINY	Medium	High, medium, low		
Supraventricular Tachycardia	Medium	High, medium, low		
BRADY	Medium	High, medium, low		
PNC	Medium	High, medium, low		
PNP	Medium	High, medium, low		
MISSED BEATS	Medium	High, medium, low		

IHB	Medium	High, medium, low		
VTAC	Medium	High		
TACHY	Medium	High, medium, low		
PVCs TOO HIGH	Medium	High, medium, low		
EXTREME TACHY	High	High		
EXTREME BRADY	High	High		
SPO2				
NO PULSE	High	High	The pulse signal is so weak that the monitor cannot perform pulse analysis.	Check the patient's condition and check the connection of SpO_2 sensor.
RESP				
RRTOO HIGH	Medium	High, medium	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.
RR TOO LOW	Medium	High, medium		
RESP APNEA	High	High	The respiration signal is so weak that the monitor cannot perform respiration analysis.	Check the patient's condition and check the connection of lead wires.
RESP ARTIFACT	High	High	The patient's heartbeat has interfered with his respiration.	
IBP				
IBP1 Asystole	High	High	Sharp Falling of Blood Pressure	Check the patient's condition and check the connection of sensor.
IBP2 Asystole				
ZZ TOO HIGH	Medium	High, medium	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.
ZZ TOO LOW	Medium	High, medium		
Here ZZ stands for IS1, ID1, IM1, IS2, IM2 and ID2.				
TEMP				
T1 TOO HIGH	Medium	High, medium	The measured parameter value is higher than the upper alarm limit or lower than the lower alarm limit.	The measured parameter value is higher than the upper alarm limit or
T1 TOO LOW	Medium	High, medium		
T2TOO HIGH	Medium	High, medium		

T2 TOO LOW	Medium	High, medium		lower than the lower alarm limit.
TDTOO HIGH	Medium	High, medium		

2. Technical alarm

Alarm message	Default alarm level	Selectable level	Causes	Solutions
ECG				
ECG LEAD OFF	Low	Low	ECG electrode has fallen off the patient.	Check the connection of lead wires and electrodes.
ECG XX LEAD OFF	Low	Low		
Here XX stands for LL, LA, RA, V, V1, V2, V3, V4, V5 and V6.				
ECG XX OVER LOAD	Low	Low	ECG signal has exceeded the measurement range.	Check the connection of electrodes and lead wires and clean the patient's skin if necessary.
Here XX stands for I, II, III, RA, LA, LL, V1, V2, V3, V4, V5 and V6.				
ECG COMM STOP	High	High	There is a problem with the communication between the ECG module and the monitor.	Restart the monitor. If the problem is still there, please contact the serviceman.
ECG COMM ERR	High	High		
HR ALM LMT ERR	Low	Low	The parameter alarm limit has been accidentally changed.	Please contact the serviceman.
PVCs ALM LMT ERR	Low	Low		
ST ALM LMT ERR	Low	Low		
HR EXCEED	Low	Low	The measured value has exceeded the measurement range.	
ST1 EXCEED	Low	Low		
ST2 EXCEED	Low	Low		
ST3 EXCEED	Low	Low		
ST4 EXCEED	Low	Low		
ST5 EXCEED	Low	Low		
ST6 EXCEED	Low	Low		
ST7 EXCEED	Low	Low		
RESP				
RR ALM LMT ERR	Low	Low	The parameter alarm limit has been accidentally changed.	Please contact the serviceman.
RR EXCEED	Low	Low	The measured value has exceeded the measurement range.	

SPO2				
SPO2 FINGER OFF	Low	Low	SpO2 sensor has fallen off the patient's finger, or SpO_2 sensor has not been connected well.	Check the connection of SpO2 sensor.
SPO2 NO SENSOR	Low	Low		
SPO2 SENSOR OFF	Low	Low		
NELLC ERR,Reseting	Low	Low	An error occurred to Nellcor module and the system is resetting.	If the system failed to reset or if the error is there after restarting the monitor, please contact the serviceman.
SEARCH PULSE	Low	Low	The system is searching pulse.	
SPO2 LOST	Low	Low	The SpO2 signal is too low or too weak.	Check the patient's condition, or apply the SpO2 sensor to a suitable measuring site. If the fault is still there, please change the SpO2 sensor.
SPO2 INIT ERR	Low	Low	An error occurred to the SpO2 module in the initialization progress.	Restart the monitor. If the problem is still there, please contact the serviceman.
SPO2 COMM STOP	Low	Low	The SpO2 module failed to communicate with the system.	
SPO2 COMM ERR	Low	Low		
SPO2ALM LMT ERR	Low	Low	The parameter alarm limit has been accidentally changed.	Please contact the serviceman.
PRALM LMT ERR	Low	Low		
SPO2EXCEED	Low	Low	The measured parameter value has exceeded the measurement range.	
PREXCEED	Low	Low		
NIBP				
NS ALM LMT ERR	Low	Low	The parameter alarm limit has been accidentally changed.	Please contact the serviceman.
NM ALM LMT ERR	Low	Low		
ND ALM LMT ERR	Low	Low		
NS EXCEED	Low	Low	The measured NIBP value has exceeded the measurement range.	
NM EXCEED	Low	Low		
ND EXCEED	Low	Low		
TEMP				
T1 SENSOR OFF	Low	Low	TEMP probe has not connected well.	Check the connection of TEMP probe.
T2 SENSOR OFF	Low	Low		

T1 ALM LMT ERR	Low	Low	The parameter alarm limit has been accidentally changed.	Please contact the serviceman.
T2 ALM LMT ERR	Low	Low		
TD ALM LMT ERR	Low	Low		
TEMP1 EXCEED	Low	Low	The measured TEMP value has exceeded the measurement range.	
TEMP2 EXCEED	Low	Low		
IBP				
CH1:IBP SENSOR OFF	High	High	The IBP transducer has not connected well.	Check the connection of IBP transducer.
CH2:IBP SENSOR OFF	High	High		
IBP1 SENSOR FAULT	High	High	The single fault has occurred to the IBP transducer.	Replace a new transducer.
IBP1 SENSOR FAULT	High	High		
IBP<1,2> COMM ERR	High	High	There is a problem with the communication between the IBP module and the monitor.	Restart the monitor. If the problem is still there, please contact the serviceman.
IBP<1,2> COMM STOP	High	High		
IBP1 ALM LMT ERR	Low	Low	The parameter alarm limit has been accidentally changed.	Please contact the serviceman.
IBP2 ALM LMT ERR	Low	Low		
IBP1 SYS EXCEED	Low	Low	The measured IBP value has exceeded the measurement range.	
IBP1 DIA EXCEED	Low	Low		
IBP1 MEAN EXCEED	Low	Low		
IBP2 SYS EXCEED	Low	Low		
IBP2 DIA EXCEED	Low	Low		
IBP2 MEAN EXCEED	Low	Low		
IBP1 ZEROING	Low	Low	IBP pressure zeroing is in progress.	
IBP2 ZEROING	Low	Low		
IBP1 ZERO FAIL	Low	Low	IBP pressure zeroing failed. Check the connection of the IBP transducer and conduct zeroing again.	
IBP2 ZERO FAIL	Low	Low		
IBP1 ZERO SUCCESS	Low	Low	IBP pressure zeroing succeeded.	
IBP2 ZERO SUCCESS	Low	Low		
IBP1 NEED ZERO-	Low	Low	Please conduct IBP pressure zeroing.	

CAL				
IBP2 NEED ZERO-CAL	Low	Low		
CO2				
CO2 COMM STOP	High	High	There is a problem with the communication between the IBP module and the monitor.	Restart the monitor. If the problem is still there, please contact the serviceman.
CO2 IS SLEEPING	Low	Low	CO2 module is in standby mode.	
CO2 IS ZEROING	Low	Low	CO2 zeroing is in progress.	
CO2ALM LMT ERR	Low	Low	The parameter alarm limit has been accidentally changed.	Please contact the serviceman.
INS ALM LMT ERR	Low	Low		
AWRR ALM LMT ERR	Low	Low		
CO2SPAN CAL ERROR	Low	Low	Please conduct CO2 span calibration again.	
CO2SPAN CALIBRATING...	Low	Low	CO2 span calibration is in progress.	
CO2SAMPLING LINE CLOGGED	Low	Low	Sampling line is clogged.	Check the airway for clogging. If the problem is still there, please replace the sampling line.
CO2REPLACE ADPTER	Medium	Medium	An error occurredto the adapter. Replace the adapter.	
CO2NO SAMPLING LINE	Low	Low	Check if the sampling line is connected well.	
CO2NO ADPTER	Low	Low	Check if the adapter is connected well.	
CO2OUT OF RANGE	Low	Low	CO2 outside the specified accuracy range.	
CO2TEMP OUT OF RANGE	Low	Low	Internal temperature outside the operating range.	Stop measurement and measure again when the internal temperature is inside the operating range, or contact the serviceman.
CO2ZERO REQUIRED	Low	Low	Please conduct the zeroing.	
CO2SOFTWARE ERROR	Low	Low	Restart the monitor. If the problem is still there, please contact the serviceman.	
CO2HARDWARE ERROR	High	High	Replace the sensor. If the problem is still there, please contact the serviceman.	
CO2SPEED OUT OF BOUNDS	Low	Low	An error occurred to the CO2 module.	

CO2FACTORY CALIBRATION LOST	Low	Low		Restart the monitor. If the problem is still there, please contact the serviceman.
CO2 PRESSURE OUT OF RANGE	Low	Low	Ambient pressure outside the operating range.	Contact the serviceman.
Battery				
Low Battery	High	High	Low battery, please charge the battery immediately.	
Low Battery 1	Low	Low		
Low Battery 2	Low	Low		
BATTERY 1 AGING	High	High	The battery is aging, please replace the battery.	
BATTERY 2 AGING	High	High		
BATTERY 1 MALF	High	High	The battery malfunctions. Please check if the correct battery is being used and check the battery for damage, or replace the battery.	
BATTERY 2 MALF	High	High		
Paddles				
PADDLE OVER LOAD	High	High	The input signal is out of the measurement range.	Reconnect the electrodes or paddles. If necessary, clean the patient's skin.
PAD OVER LOAD	High	High		

3. Prompt message

Prompt message	Causes
LOOSE CUFF	NIBP cuff is too loose or has not connected with the monitor.
AIR LEAK	There is a leak in NIBP airway.
AIR LEAKAGE	
AIR PRESSURE ERROR	An error occurred to the air pressure when measuring NIBP.
WEAK SIGNAL	The patient's pulse is too weak or the cuff is too loose when measuring NIBP.
RANGE EXCEEDED	The NIBP measured value has exceeded the measurement range.
EXCESSIVE MOTION	There is too much patient motion.
OVER PRESSURE	NIBP airway may be occluded.
SIGNAL SATUATED	The NIBP signal is saturated due to excess motion or other sources.
NIBP SYSTEM FAILURE	An error occurred during NIBP measurement and the monitor cannot perform analysis correctly.
NIBP TIME OUT	
MEASURE FAIL	
CUFF TYPE ERR	Wrong type of NIBP cuff is being used.
NIBP RESET ERR	An improper reset occurred during NIBP measurement.
ARR LEARNING	Arrhythmia is learning.
ECG Calibrating	ECG calibration is in progress.
MANUAL MEASURE...	Manual NIBP measurement is in progress.

LEAK DETECTING...	Pneumatic test is in progress.
RESETTING...	Manual reset is being performed.
CONT MEASURING…	Continual NIBP measurement is in progress.
PLEASE START	Please press NIBP start key to start NIBP measurement.
AUTO MEASURING	Auto NIBP measurement is in progress.
No Paper...	No recording paper, please load new recording paper.
Paper Door Open.	The paper door is open.
RECORDER COMM ERR	There is a problem with the communication between the recorder and the monitor.
NO BATTERY	No battery is installed.
NO BATTERY 1	Battery 1 is not installed.
NO BATTERY 2	Battery 2 is not installed.

Appendix IV Factory Default Settings

1. General settings

Items	Factory Default	Remarks
Patient type	Adult	
Language	English	
Date format	YEAR-MON-DAY	
Time format	12 hours	

2. Manual Defibrillation Settings

Items	Factory Default	Remarks
External defibrillation default energy	200J	
Internal defibrillation default energy	10J	
Auto disarm time	60s	
Synchronization keep	Off	
Remote synchronization	Off	
Monitor parameter 1	Off	
Charge volume	Medium	
Contact impedance indicator	Off	

3. AED Settings

Items	Factory Default	Remarks
Shock series	1	
First shock energy	200J	
Second shock energy	300J	
Third shock energy	360J	
Auto disarm time	30s	
Pre-shock CPR time	Off	
CPR time	120s	
CPR metronome	On	
CPR mode	30:2	
NSA process	CPR	
Voice prompt	On	
Voice volume	High	
Voice interval	30s	
Audio recording	Off	

4. Pacer Settings

Items	Factory Default	Remarks
Pacing rate	70ppm	
Pacing current	30mA	
Pacing mode	Demand pacing	

5. Mark Event Settings

Items	Factory Default	Remarks
Event wave 1	II	
Event wave 2	I	
Event wave 3	PLETH	
Event A	Simple	
Event B	Lidocaine	
Event C	Atropine	
Event D	Nitroglycerin	
Event E	Morphine	
Event F	Cannula	
Event G	Venous transfusion	
Event H	Adenosine	

6. Record Settings

Items	Factory Default	Remarks
Energy delivered	Off	
Grid	Off	
Charger event	Off	
Shock event	Off	
Marked event	Off	
12-lead report	Off	
Auto test report	Off	
Real-time recording time	32s	
Recording speed	25 mm/s	

7. Alarm Settings

Items	Factory Default	Remarks
Alarm volume	7	
Alarm recording time	8s	
Alarm pause time	2min	
Alarm delay time	Disabled	
Minimum alarm volume	0	
Reminder tone	Off	
Reminder interval	1min	
Reminder volume	Medium	

8. 12-lead Settings

Items	Factory Default	Remarks
Report format	3×4	

9. Network Settings

Items	Factory Default	Remarks
Network bed number	1	
Local IP	200.200.200.10	
Sub mask	255.255.255.0	
Server IP	200.200.200.100	

10. Test Settings

Items	Factory Default	Remarks
User test prompt	Off	
Auto test time	3:00	

11. ECG Settings

Items			Factory Default				Remarks
Alarm recording			Off				
Display color			Green				
Sweep			25mm/s				
Lead type			3 leads				
ECG cascade			On				
Gain			×1				
Calculation lead			II				
Filter mode			Diagnosis				
Notch			50Hz				
HR source			ECG				
Pace			Off				
QRS volume			1				
Arrhythmia analysis			Off				
ST analysis			Off				
HR alarm limits		High level		Adult	Pediatric	Neonate	
			Upper limit	130	170	200	
			Lower limit	40	60	100	
		Medium level	Upper limit	125	165	180	
			Lower limit	45	70	110	
PVCs	Alarm level		Medium				
	Alarm recording		On				
	Alarm limit			Adult	Pediatric	Neonate	
			Upper limit	4	4	4	
			Lower limit	0	0	0	

ST	Alarm level		Medium			
	Alarm recording		Off			
	Alarm limit		Upper limit	0.2	0.2	0.2
			Lower limit	-0.2	-0.2	-0.2
Arrhythmia threshold		Tachy	160			
		Extreme tachy	180			
		Extreme brady	50			

12. RESP Settings

Items	Factory Default				Remarks
Alarm level	Medium				
Alarm recording	Off				
Display color	Yellow				
Lead selection	II				
Sweep	12.5mm/s				
Gain	X1				
RESP apnea	20s				
Enhance filter	Off				
RESP alarm limit		Adult	Pediatric	Neonate	
	Upper limit	30	30	100	
	Lower limit	8	8	30	

13. SPO2 Settings

Items		Factory Default				Remarks
Alarm recording		Off				
Display color		Cyan				
Sweep		25mm/s				
Sensitivity		Normal				Masimo
Signal indication		On				Masimo
Average time		8s				Masimo
Intelligent alarm		/				Nellcor
SPO2 alarm limit	High level		Adult	Pediatric	Neonate	
		Upper limit	100	100	99	
		Lower limit	86	86	76	
	Medium level	Upper limit	100	100	97	
		Lower limit	88	88	78	

14. PR Settings

Items	Factory Default	Remarks
Alarm source	SPO2	/
Alarm recording	Off	/
Pulse volume	2	/

PR alarm limit	High level		Adult	Pediatric	Neonate	
		Upper limit	130	170	160	
		Lower limit	40	65	110	
	Medium level	Upper limit	125	165	165	
		Lower limit	45	70	115	

15. NIBP Settings

Items		Factory Default				Remarks
Alarm recording		Off				/
Display color		White				/
Unit		mmHg				/
Pre-inflation value		160				/
Interval		Manual				
SYS alarm limit	High level		Adult	Pediatric	Neonate	/
		Upper limit	180	140	100	
		Lower limit	70	50	40	
	Medium level	Upper limit	170	130	95	
		Lower limit	80	60	45	
Meanalarm limit	High level	Upper limit	130	110	80	/
		Lower limit	50	30	20	
	Medium level	Upper limit	120	100	75	
		Lower limit	55	40	25	
DIAalarm limit	High level	Upper limit	110	80	70	/
		Lower limit	40	30	10	
	Medium level	Upper limit	100	75	65	
		Lower limit	45	35	15	

16. CO2 Settings

Items		Factory Default				Remarks
Alarm recording		Off				/
Display color		Yellow				/
Sweep		6.25				/
Gain		X1				/
Unit		mmHg				/
Apnea time		20s				/
O2 compensation		0				/
Balance gas		Indoor air				/
Altitude		0.0				/
CO2 alarm limit	Medium level		Adult	Pediatric	Neonate	/
		Upper limit	55	55	50	
		Lower limit	10	10	25	
INS alarm limit	Medium level	Upper limit	5	5	5	
		Lower limit	0	0	0	
AwRRalar	Medium level	Upper limit	35	35	100	

m limit		Lower limit	25	25	25	

17. IBP Settings

Items		Factory Default				Remarks
Alarm level		Medium				/
Alarm recording		Off				/
Display color		Red				/
Sweep		25mm/s				/
Channel 1 label		ART				/
Channel 2 label		ART				/
Unit		mmHg				/
Calibration pressure value		200				/
Filter		Normal				/
Upper scale		150				/
Lower scale		0				/
IBP alarm limit	SYS		Adult	Pediatric	Neonate	/
		Upper limit	160	120	90	
		Lower limit	90	70	55	
	MEAN	Upper limit	110	90	70	
		Lower limit	70	50	35	
	DIA	Upper limit	90	70	60	
		Lower limit	50	40	20	

18. TEMP Settings

Items		Factory Default				Remarks
Alarm level		Medium				/
Alarm recording		Off				/
Display color		White				
Unit		℃				
TEMP alarm limit	T1		Adult	Pediatric	Neonate	/
		Upper limit	39.0	39.0	39.0	
		Lower limit	36.0	36.0	36.0	
	T2	Upper limit	39.0	39.0	39.0	
		Lower limit	36.0	36.0	36.0	
	TD	Upper limit	2.0	2.0	2.0	
		Lower limit	0	0	0	

19. Maintenance

Items	Factory Default	Remarks
Screen brightness	2	/
Key volume	5	

20. User Maintenance

Items	Factory Default	Remarks
Wave line	Thin	/
Draw wave	Color	

Appendix V EMC

⚠Attention

- **DFM 600/DFM 800meets the requirement of electromagnetic compatibility in IEC60601-1-2.**
- **The user needs to install and use according to electromagnetism compatibility information which is attached with it.**
- **Portable and mobile RF communicationdevices may influenceDFM 600/DFM 800performance, so DFM 600/DFM 800 should be kept away from them during using.**
- **Guidance and manufacturer's declaration stated in the appendix.**

⚠Warning

- **DFM 600/DFM 800should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, theDFM 600/DFM 800 should be observed to verify normal operation in the configuration in which it will be used.**
- **Use accessories and cables other than those sold by DFM 600/DFM 800 manufacturer as replacement parts of internal components and parts may cause DFM 600/DFM 800 increase of transmission or reduction of immunity.**

Guidance and manufacturer's declaration - electromagnetic emissions		
This device is intended for use in the electromagnetic environment specified below. The user or customer of this device must guarantee the use in such environments.		
Emission test	**Compatibility**	**Electromagnetic environment - guide**
RF transmissions CISPR 11	Group 1	This device uses RF energy only for its internal functions. Therefore, RF transmissions are very low and unlikely to cause interference in nearby electronic equipment.
RF transmissions CISPR 11	Class B	This device is suitable for use in all installations, including local installations and those directly connected to the Low Voltage power supply network that supplies buildings used for local purposes
Harmonic emissions IEC 61000-3-2	To class	
Voltage fluctuations / flicker propagation IEC 61000-3-3	Compatible	

Guidance and manufacturer's declaration-electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The user or customer of this device must ensure that it is used in such environments.			
Immunity Test	**IEC 60601 Test Level**	**Compatibility Level**	**Electromagnetic environment - guide**
Electrostatic Discharge IEC 61000-4-2	+ 8 kV contact + 15 kV weather	+ 8 kV contact + 15 kV weather	Floors must be wood, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient regime / burst IEC 61000-4-4	± 2KV 100 KHZ	± 2KV 100 KHZ	City grid power quality should be the same as that of a typical commercial or hospital environment.
Shock wave IEC 61000-4-5	0,5-1 kV phase (s) to phase (s) 0,5-1-2 kV	0,5-1 kV phase (s) to phase (s) 0,5-1-2 kV	City network power quality should be the same as in a typical commercial or hospital setting.

	phase (s) to earth	phase (s) to earth	
Voltage pits, short interruptions and voltage changes in the power supply input lines IEC 61000-4-11	%0 UT; 0.5 per at 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0, and 335^0, %70 UT; 25 per %0 UT; 1 per %0 UT; 250 per	%0 UT; 0.5 per at 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0, and 335^0, %70 UT; 25 per %0 UT; 1 per %0 UT; 250 per	City grid power quality should be the same as that of a typical commercial or hospital environment.
Güç frekansı (50/60Hz) manyetik alanı IEC 61000-4-8	30 A/m, 50Hz	30 A/m, 50Hz	The magnetic fields of the power frequency should be at levels typical of a typical location in a typical commercial or hospital setting.
NOTE: Ut is the mains voltage a.a before the test level is applied.			

Guidance and manufacturer's declaration electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device must guarantee the use in such an electromagnetic environment.

Immunity Test	**IEC 60601 Experiment Level**	**IEC 60601 Experiment Level**	**IEC 60601 Experiment Level**
Transmitted RF IEC 61000-4-6	150kHz-80MHz, 3V rms, 80% AM (1kHz) (6Vrms for ISM bands)	3 V_{rms} 3 V_{rms}	Portable and mobile RF communications equipment, including cables, should not be used closer to any part of Model 005 than the separation distance calculated by the equation appropriate for the transmitter frequency. **Recommended separation distance** $\boldsymbol{d = 1.16\sqrt{P}}$ $\boldsymbol{d = 1.2\sqrt{P}}$ 0,15 MHz ila 80 MHz
Radiated RF IEC 61000-4-3	80MHz - 2700MHz, 3V/m, 80% AM (1kHz)	3 V/m	$\boldsymbol{d = 2.3\sqrt{P}}$ 80 MHz ila 2.7 GHz Where P is the maximum rated output power of the transmitter specified by the transmitter manufacturer in watts (W), d is the recommended separation distance in meters (m). b Field strength emitted from fixed RF transmitters determined by an electromagnetic site discovery should be less than the Compatibility Level in each frequency range. D Interference may occur due to proximity to 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 to all situations. Electromagnetic propagation is affected by absorption and reflection in structures, objects and people.

a EBT (Industrial, scientific and medical) bands between 150 KHz and 80 MHz are 6.765 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.

[b] Compliance levels in the EBT frequency band in the 150 KHz and 80 MHz frequency range and in the frequency range of 80 MHz to 2.5 Ghz are intended to reduce the likelihood of interference caused by unintentional transport of mobile / portable communications equipment to patients. Therefore, in these frequency ranges, an additional factor 10/3 is taken into account in the formula used to calculate the recommended separation distance for transmitters.

[c] The intensity of the area emitted by fixed transmitters, such as base stations and mobile ground radios of radio telephones (cellular / wireless), amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically accurately. For the evaluation of the electromagnetic environment due to fixed RF transmitters, the discovery of the electromagnetic site should be considered. If the measured field strength where Model 005 is used exceeds the applicable RF compliance level specified above, [ET Equipment or ET System] should be observed to operate normally. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 005.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V / m.

Appendix VI Shift Checklist

It is recommended to check the defibrillator/monitor every day when exchanging shift as the checklist shown as follows:

Unit name: Serial Number: Department:

Check item	Description	Pass/fail	Remarks
Appearance	Clean, intact, no spills and objects on the unit		
Battery	With battery installed; battery indicator is illuminated; battery charge level is more than 60%.		
AC power supply	Connect AC power supply and AC indicator is illuminated.		
Record paper	With adequate record paper in unit		
Cables, connectors	Cablesare intact, connectors without loosening and bending		
ECG cable and electrodes (nocheck when not used)	ECG cable and electrodes are ready; ECG cable is intact; cable connector without loosening and bending; electrodes are not expired.		
Paddles (nocheck when not used)	Paddle cable is intact, cable connector without loosening and bending; paddles are correctly placed in the paddle tray.		
Therapy cable and pads(no check when not used)	Therapy cable and pads are ready; therapy cable is intact; cable connector without loosening and bending; pads are not expired.		
Shock test for therapy cable * (no test when not used)	Switch to manual defibrillation mode; connect therapy cable and test load; charge to 200J and press SHOCK button. Check the energy is delivered normally. Disconnect the test load after test.		
Shock test for paddles* * (no test when not used)	Switch to manual defibrillation mode; connect paddles, put paddles in paddle trayproperly; charge to 10J and press SHOCK button. Check the energy is delivered normally.		
Service indicator	Service indicator is off.		
Checked by:	Date:		

*: perform this test only when therapy cable is not used in auto test or when auto test fails.

**: perform this test only when paddles are not used in auto test or when auto test fails.