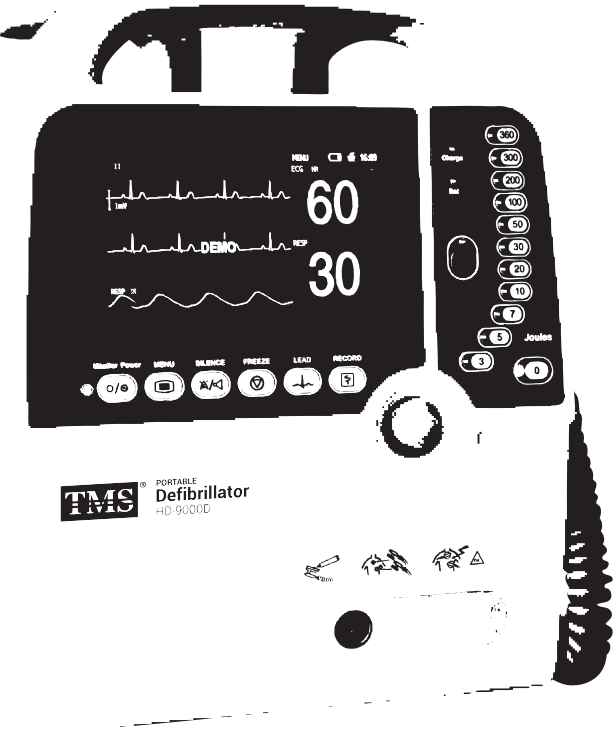
TMS

Portable
Defibrillator
HD-9000D



Operation Manual

Manual de Operación
Manuel d'utilisation
Bedienungsanleitung
操作手册
オペレーションマニュアル
사용 설명서

4-IC-TDF910

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PREFACE

Thank you for purchasing TMS Defi-Monitor.

This manual is intedted to guide the new users on how to effectively operate TMS Defibrillator. The objective of this manula is to provide a board overview of the function, major features and other supplimental information of TMS Defibrillator.

The TMS Defibrillator is under constant improvement to enhance its performance and reliability development continues after the documentation has gone to press so small inconsistencies may occur. We would appreciate any feedback on this manual.

STATEMENT

LIABILITIES OF THE MANUFACTURER

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

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

The electrical safety status at the installation site of the instrument conforms to the national standards:

The instrument is used in accordance with the operation procedures.

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CONTENTS

Chapter 1 General Introduction

1.1 Intended use

Defibrillator is used to monitor patient's physiological parameters such as ECG and RESP. It is intended to be used in various hospital rooms such as Coronary Care Unit, Intensive Care Unit, Neonatal Intensive Care Unit and Operating Room.

It is not intended to be used in outdoor transport applications.

1.2 About this Manual

This user's manual consists of the following chapters:

Chapter 1 gives an introduction on the content and signs/logo used in this manual, the main features and appearance of the monitor, the basic operations of various buttons and the meanings of the symbols on the monitor.

Chapter 2 gives important safety notes on how to carefully used the instrument. Please do read this chapter before using the monitor!

Chapter 3 gives an introduction to the preparatory steps before using the instrument.

Chapter 4 provides operation instructions of the instrument; including illustrations of the screen display, normal selection for soft button on screen, details for entry of patient data and trend maps.

Chapter 5 gives details of specific parameter measurement; which includes preparatory steps, cables or probes connection, setup of parameters, maintenance and cleaning of equipments and sensors.

Chapter 6 gives detailed description of system alarm, including level and mode of alarm, default setting and changing procedure of alarm parameters, prompt of specific alarms and the general operation to carry when an alarm occurs.

Chapter 7 gives detailed description of record function.

Chapter 8 gives general maintenance and cleaning methods of the instrument.

Signs in this manual:

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

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

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

NOTE:

This user manual introduced the product with full configuration. Some functions of the product you bought may be provided.

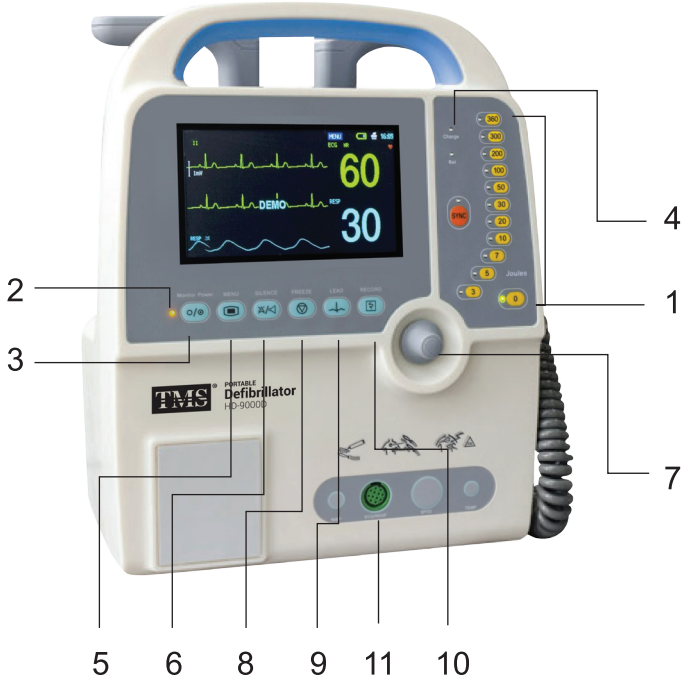
1.3 Brief Introduction to the Monitor Part

The monitor has features as follows:

- Multiple measuring functions include 3-lead, 7-lead ECG/HR, RESP.
- Complete built-in module design ensures stable and reliable performance
- Can store the trend data for 72 hours and has the function of displaying trend data and trend maps.
- Optional built-in recorder supports real time recording, present screen printout and trigger printout by alarm.
- Parameter display with big character.
- 7" high resolution true-color graphics
- Portable design, stylish and convenient.
- Rechargeable maintenance free battery, can continue working when AC power is off.
- Nurse call function guarantee patient alarm, draws enough attention.
- Can be connected with the central station for centralized monitoring.
- Is resistant to high-frequency electrotode and is protected against defribillation side effects.

1.4 Appearance and Structure of the Monitor Parts

1.4.1 The Front Appearance



1. Energy selector; energy selection used for heart defribrillating treatment.
2. AC power indicator lamp.
   Light is turned on when AC power is connected.
   Light is turned out when the AC power is not connected.
3. O/⊙ monitor Power switch.
4. Battery charging indicator lamp.
   Light is illuminated when the battery is being charged or using battery only.
   Light goes out when the battery is fully charged or there is no battery inside the monitor.
5. ▭ Press the key to (1) open the menu (when there is no dialog on the screen) or (2) close the dialog on the screen.

6. Pressing this key less than 2 seconds; can pause the monitor alarm paused or cancel the pause. Pressing this key for more than 2 seconds; can silence the monitor's audio system or cancel the silence.
7. Trim Knob
   The Trim Knob is used:
   To move the cursor to the left or right.
   To select one option or open the menu dialog by pressing the knob down.
8. Press this key to freeze or defreeze the wave display on screen.
9. Press this key to change the lead:
10. Press this key to start or stop the real-time recording.
11. ECG Socket

Warning: The sensor cable sockets on the monitor can only be connected with the sensor cables supplied with this instrument and no other cables shall be used.

1.4.2 The Back Appearance

1. AC Input Socket

CAUTION:

The AC input at the back panel of the Monitor should be connected with the 100V-240V AC power by electrical wires supplied with this instrument.

2. Potential Equalization Conductor Terminal

Based on the requirements of safety and anti-interference, the monitor must be connected with potential equalization system individual. Connect the Potential equalization conductor terminal to the potential equalization system with the green and yellow potential equalization cable. If the protection earth system is damaged, the potential equalization system can take on the safety function of protection earth conductor.

3. Fuse

Fuse specs: T3.0AL250V Φ5×20 mm

1.4.3 Notes on the symbol on the monitor

SYMBOLS	NOTES ON THE SYMBOLS
	Defibrillator-proof type CF equipment (Refer to IEC 60601-2-27) The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.
	Attention! Please refer to the document supplied with this instrument (this manual)!
	Potential equalization conductor terminal
	Dangerous voltage
	AC/Battery power indicator
	Battery charge indicator
	Non-ionizing radiation
	Auxiliary output

ECG	Short for “Electrocardiogram”.
RESP	Short for “Respiration”
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed of waste correctly after use. Please follow Local Ordinances or Regulations for disposal.

Chapter 2 Important Safety Notes

WARNING:

PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurences of cardiac arrest or some arrhytmias. Do not rely entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

Only trained doctors and nurses can use the device.

The monitor is not a therapeutic instrument nor a device that can be used at home.

2.1 General Safety

1. Safety precautions for safe installation

- The AC input socket of the monito should be connected to the electrical wires supplied with this instrument.
- Only AC power supply 100V~240V 50Hz/60Hz can be used.
- Connect the electrical wire to a properly grounded socket. Avoid connecting the socket in the same loop of such devices as the air conditioners, which regularly switch between ON and OFF.
- Avoid putting the monitor in the locations where it easily shakes or wobbles.
- Monitor should be placed in a room with normal ventilation.
- Make sure the ambient temperature and humidity are stable to avoid the occurrence of condensation.

WARNING:

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

2. The monitor conforms to the requirements of IEC 601-1:1988. The monitor is protected against defribillation side effects.

3. Notes on symbols related to Safety.

Defribillator-proof type CF equipmen (refer to IEC 60601-2-27). The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defribillator proof.

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

Attention! Please refer on the user's manual.

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

WARNING:

When conducting defribillation, do not come into contact with the patient, the bed and the monitor. Otherwise serious injury or death might occur.

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

6. The monitor guarantees safety and accuracy only if it is connected to the devices provided or designated by the manufacturer. If the monitor is connected to other undesignated electrical equipment or devices, observe safety hazards to avoid cumulating of the leakage current.

7. A preventive check and maintenance should be conducted every 6-12 months to:
   • Guarantee the normal and safe operation of the instrument.
   • Verufy the safety of its use among medical personnel & patient.
   • Check of the instrument conforms to the usage accuracy required by the clinicians.

CAUTION:

In case of instrument damage. Repair must be conducted by the technical personnel been authorized by manufacturer.

2.2 Some Important Notes for Safety

PATIENT NUMBER
The Monitor can only be used to one patient at one time.

INTERFERENCE
Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radio emitted from such devices may result in strong interference with the monitor performance.

ACCIDENTAL SPILLS
To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered the device, discontinue its use and have it checked by a service technician before using again.

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

ALARMS
Do not rely mainly on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance and correct operation of monitoring equipment. The functions of the alarm system for monitoring the patient must be verified at regular intervals.

BEFORE USE
Before starting the operation, please visually inspect all connecting cables. Damaged cables and connectors must be replaced immediately. The operator must verify correct working order and operating condition. Periodically, and whenever the integrity of the product is in doubt, test all the functions.

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

DISCHARGE TO CLEAR PATIENT DATA
When monitoring a new patient, you must clear all previous patient data from the system. To accomplish this; shut down the device, then turn on it.

DISPOSAL OF PACKAGE
Please observe the applicable waste control regulations and keep out of reach of children.

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

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

BATTERY POWER
The device is equipped with a battery pack. The battery discharges even when the device is not in use. Store the device with a fully charged battery and take out the battery, so that the service life of the battery will not be shortened.

DISPOSAL OF ACCESSORIES AND DEVICE
Disposable devices are intended for single use only. They should not be used as performance could degrade or contamination could occur. The service life of this monitor is five years. At the end of its service life, the product, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact us.

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

INSTRUCTION FOR USE
For continuous safe use of this equipment, it is necessary that listed instructions were followed. However, instructions listed in this manual in no way can supersede established medical practice concerning patient care.

LOSS OF DATA

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

If the monitor, does not resume its operation within 60 seconds, restart the monitor using the power on/off switch. Once monitoring is restored, you should verify correct monitoring state and alarm function.

2.3 Classifications

The Monitor is classified, according to IEC601-1: 1988 as:

Type of protection against electric shock:	I
Degree of protection against electric shock:	CF: ECG, RESP
Degree of protection against harmful ingress of water:	Ordinary Equipment (enclosed equipment without protection against ingress of water)
Degree of safety of application in the presence of a flammable anesthetic-mixture with air or with oxygen or nitrous oxide:	Not suitable
Mode of operation:	Continuous operation

I: Class I equipment
CF: Type CF applied part
Not suitable: Equipment not suitable for use in the presence flammable anesthetic mixture with air or with oxygen or nitrous oxide.

2.4 Safe Operating and Handling Conditions

Method(s) of sterilization or disinfection recommended by the manufacturer:	Sterilization: not applicable Disinfection: See "The Maintenance and Cleaning of the System->General Cleaning"
Electromagnetic interference	No cellular telephone nearby
Electro surgical interference damage	No damage
Diathermy instruments influence	Displayed values and prints may be disturbed or erroneous during diathermy.
Defibrillation shocks	The Monitor specifications fulfill the requirements of IEC 601-1, IEC 60601-2-27, IEC 60601-2-49.
Auxiliary outputs	The system must fulfill the requirements of standard IEC 60601-1-1.

Chapter 3 Getting Started

3.1 Open the Package and Check

- Unpack the packaging case
  Open the packaging case and the accessory box, accessories include electrical wire, various patient sensors and user's manual (this manual), warranty card, certificate and particular paper and the foam case contains the monitor.

- Remove the monitor and accessories

CAUTION:

Please place the monitor in a room with normal ventilation and in a stable supporting plane, not on the places that can easily shock or wake.

- Keep all the packaging materials for future use.
- Check the monitor and accessories.

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

3.2 Connect Power

3.2.1 AC Power

- Confirm the rated AC Current is: AC 100V~240V 50Hz/60Hz
- Use the electrical wires provided along with the instrument, put its output end plug (round headed) into the AC current socket on the back of the monitor, and the plug of input end into a grounded socket of the mains (It must be a special socket of the hospital), connect the monitor through the earth one of electrical wires.
- When the AC indicating light beside the power switch is green, it means the AC power is on. And when the monitor is not connected to AC power and the built-in DC battery is used as the power source, the indicating light is orange.

WARNING:

The monitor must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor , disconnect the monitor from the power line and operate it on battery power.

NOTE:

The equipment has no mains switch. The equipment is switched completely only by disconnecting the power supply from the wall socket. The wall socket has to be accessible.

NOTE:

For measurements in or near the heart we recommend connecting the monitor to the potential equalization system. Use the green and yellow potential equalization cable and connect it to the pin labeled with the symbol.

3.2.1 Battery Power

The Monitor has a battery pack to provide power to the monitor whenever AC power is interrupted. The battery is generally referred to as the "battery".

You must charge the battery before using it. There is no external charger. The battery is charged when the monitor is connected to AC power. A fully depleted battery will take about 6 ½ hours to fully charge. To assure a fully charged battery is ready for use, we recommend that the monitor be unplugged into AC power whenever it is not in use.

Depending on usage, you can get about 120 minutes of battery power with a, fully-charged battery on the monitor.

NOTE:

When the monitor is connected to AC current, the battery is in a state of being recharged. When it is unable to be connected to the AC current, the battery can be used to supply power, and at this time it is unnecessary to use the electrical wires, and the instrument can be switched on directly.

NOTE:

A "BATTERY LOW" message at the technical alarm information display area of the screen and an audible system alarm indicate approximate 5 minutes of battery life remaining. You should connect the monitor to an AC power source when the message is displayed.

NOTE:

This monitor contains a rechargeeable battery. The average life span of this type of battery is approximately three years. When replacement becomes necessary, contact a qualified service representative to perform the replacement.

Disposal Notice

Should this product become damaged beyond repair, or for some reason its useful life is considered to be at an end, please observe all local, state, and federal regulations that relate to the disposal of products that contain lead, batteries, plastics, etc.

Install Battery

The battery storage is located at the bottom of the monitor, following the steps to install a battery.

1. Open the battery gate according to the direction marked on the monitor.
2. Turn the baffle up clockwise.
3. Push the battery into the gate with the electrode point to the bottom of the monitor.
4. After pushing the battery inside the storage withdraw, turn the baffle back to the middle position.
5. Close the gate.

Uninstall Battery

1. Open the battery gate according to the direction marked on the monitor.
2. Turn the baffle up clockwise.
3. Take out the battery. Then close the gate.

3.3 Connect to the Central Monitor System

WARNING:

Accessory equipment connected to the analog and digital interface must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 601-1:1988 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

If the user intends to connect the monitor to the central monitoring system, plug its connecting electrical cable into the Network Connector interface at the back of the monitor.

NOTE:

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

3.4 Power on the Monitor

- Press the power switch on the front panel of the monitor.
- About 10 seconds after the monitor is switched on, after passing the self examination of the system, the monitor enters the monitoring screen.

WARNING:

In case the monitor is found to be working abnormally or indication of errors appears, discontinue its use and contact the after sale service center as soon as possible.

3.5 Connect Patient Sensors

Connect sensor cables to the relevant sockets of the monitor and put sensors on the monitored locations on the body of the patient. Refer to the relevant content of Chapter 5 for details.

WARNING:

For safety reasons, all connectors for patient cables and sensor leads (with the exception of temperature) are designed to prevent inadvertent disconnection. Should someone pull on the leads. Do not route cables in a way that they may present a stumbling hazard. Do not install the monitor in a location where it may drop on the patient. All consoles and brackets used must have a raised edge at the front.

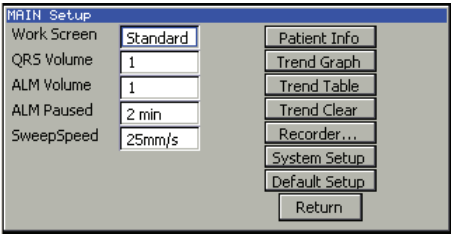
Chapter 4 Operation Instructions

NOTE:

For Concision, the following terms are used to describe one or more operations
Choose—Turn on the Trim Knob and move the cursor onto the item that needs to be changed.
Conform—press the Trim Knob.
Select—move the cursor onto the item and press the Trim Knob.

4.1 Main Menu

Press the key on front panel to open (Main Setup) dialogue window, press the key again to close the dialogue window

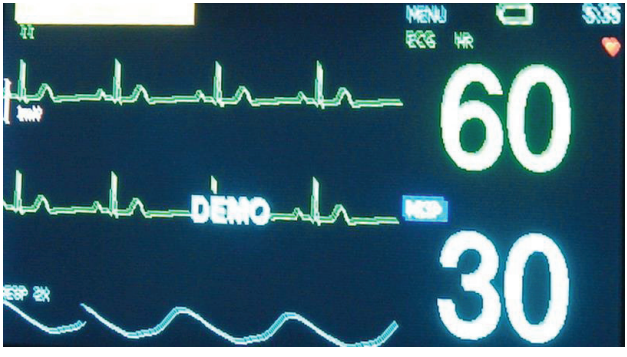


4.2 Work Screen

Select [Menu]-- Work Screen, can choose which work screen is used in patient monitoring.

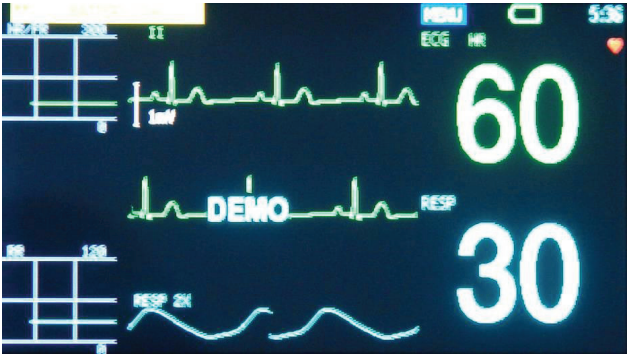
Standard

Standard display screen. Display one ECG wave, PLETH wave, RESP wave and all measurement parameters.



Short Trend

Standard display screen. Display one ECG wave, PLETH wave, RESP wave and all measurement parameters.



4.3 Setup Volume

QRS volume

Select **[MENU]** ---> **[QRS volume]**, options are 0~3. Select 0 to close the QRS volume, Select 3 to setup maximal QRS volume.

NOTE:

Alarm Volume

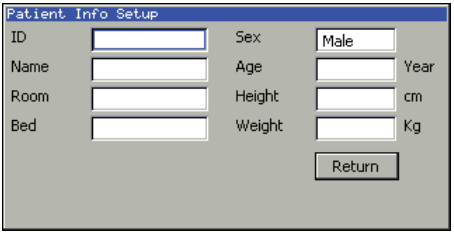
Select **[MENU]** ---> **[ALM volume]**, options are 0~3. Select 0 to close the alarm, Select 3 to setup maximal alarm volume.

4.4 Setup Wave Sweep Speed

Select **[MENU]** ---> **[Sweep Speed]**, options are 12.5 mm/s, 25 mm/s and 50 mm/s. This option influences ECG, PLETH waveform displays and recording speed of the recorder.

4.5 Setup Patient Information

Select **[MENU]** ---> **[Patient Info]** button, and a following patient information dialogue window will be displayed.

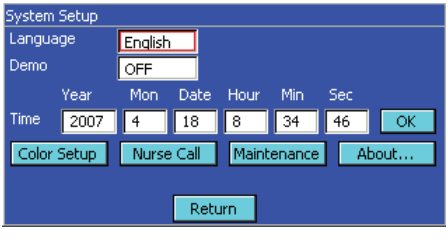


Patient information includes:

ID	The ID number of the patient (setup due to the actual condition of the hospital).
Name	The name of the patient. The length of the name are up to 10 characters only.
Room	The number of patient sickroom.
Bed	The bed number of patient.
Height	The height of patient.
Sex	The sex of patient (male/female).
Age	The age of patient.
Weight	The weight of patient.

4.6 System Setup

Select **[MENU]** ---> **[System Setup]** button, and a following system setup dialogue dialogue window will be displayed.



4.6.1 System Setup

1. Select **[MENU]** ---> **[System Setup]** ---> **[Language]**, select language which will be used in the system.
2. Exit the dialogue windows.

4.6.2 Setup Demo Function

■ **Enter demo mode**

Select (MENU) --> (System Setup) --> (Demo), select <ON> input the DEMO password and enter OK

■ **Exit demo mode**

Select (MENU) --> (System Setup) --> (Demo), select <OFF>.

NOTE:

The purpose of waveform demontration is only to demonstrate the machine performance and for training purposes. This function is not recommended for other purposes.

4.6.3 Setup system time

Select (MENU) --> (System Setup): setup <Year>, <Mon>, <Date>, <Hour>, <Min>, <Sec> and select (OK) to confirm.

CAUTION:

The change of time will influence the trend data saved or lose data. It is suggested to setup the time before using the monitor to patient; once time set-up is done, restart the monitor and is now ready for patient use. The changed time will be available after exit the current window.

4.6.4 Setup display color

Select (MENU) --> (System Setup) --> (Color Setup), and a following colorsetup window will be displayed.

User can change the display colors of waveforms and data displayed on screen freely.

4.6.5 Setup nurse call function

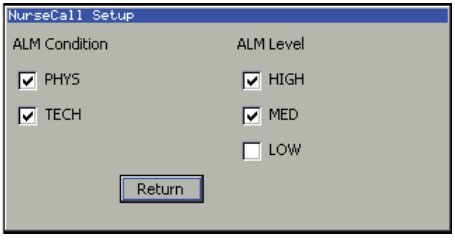
Nurse Call is a function of the monitor in which the monitor sends a signal to call a nurse when the alarm conditions destined are occurred.

The monitor has a nurse call output socket; to setup: connect the socket to the nurse call system of the hospital via nurse-call cable provided along with the monitor, the nurse call function will the be available.

The nurse call function is available when the following conditions are concurrent:

1. The nurse call function is open.
2. An alarm condition destined is occurred.
3. The monitor is not in the state of alarm paused or system silence.

Select 【MENU】 -- > 【System Setup】 -- > 【Nurse Call】, and a following nurse call setup window will be displayed.



ALM Condition	Select the alarm condition type. The options of alarm condition type includes physical alarm condition and technical alarm condition.
ALM Level	Select the alarm level. The options of alarm level include low, medium and high alarm levels.

Failure to select 【ALM Condition】and 【ALM Level】,will not trigger the nurse call action.

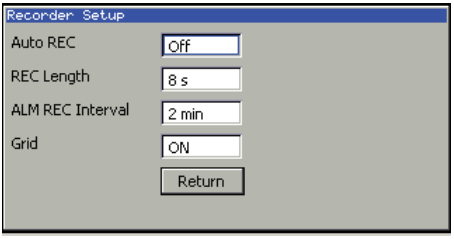
Warning: The nurse call function shall not be used as the primary patient alarm information source. It is necessary to monitor the auditory and visual alarm signal and the patient clinical feature and symptom as the primary information of the physiological condition of the patient.

4.6.6 System information

Select 【MENU】 -- >【System Setup】 -- >【About】, the system information window will be displayed, system information includes software version and manufacturer information.

4.7 Setup recorder

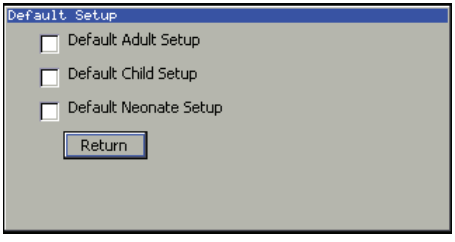
Select 【MENU】 -- > 【Recorder】, a following setup recorder window will be displayed.



Auto REC	For continuous recording; Turn On auto recording. For recording with time interval: Turn Off auto recording and select [ALM REC Interval]. Setup time interval. The content of auto recording includes one ECG waveform, PLETH waveform, respiration waveform and all parameters measured.
REC Length	Select the wave form recording length. The Options are 8s, 12s and 16s.
ALM REC Interval	Select the interval of alarm recording. Alarm recording function will be disabled when <OFF> is selected.
Grid	Select if the grid is recorded in the waveform recording area of the recording paper. Options are <OFF>, <ON>.

4.8 Restore default system setup

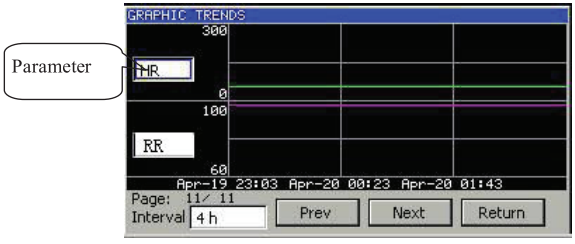
Select 【MENU】 -- >【Default Setup】, and a following default system setup window will be displayed, select one item in this window, choosen system setup will be used as default setup. There are three options: ADULT, CHILD, NEONATAL.



4.9 Display of trend

4.9.1 Display of trend map

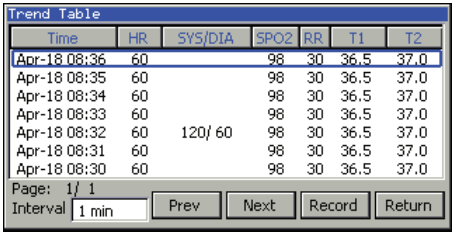
Select 【MENU】 -- > 【Trend Graph】,, and a following trend graph window will be displayed.



Parameter	The options are HR and RR. Choose one parameter option.
Interval	The option are 4, 8, 12, 16, 24, 48 and 72 hours. Choose one which will be the length of trend graph time in one page.
Prev	Turn to previous page.
Next	Turn to next page.
Return	Exit trend graph window.

4.9.2 Display of trend data

Select 【MENU】 -- > 【Trend Table】, and a following trend data window will be displayed.



Interval	User can choose from 1, 2, 3, 4, 5, 10, 15, 30, 60, 90

	minutes and 2, 4, 8 hours, which is the displayed interval between trend data item.
Prev	Turn to previous page.
Next	Turn to next page.
Record	Print the trend data in current screen through recorder.
Return	Exit trend table window.

4.9.3 Clear trend data

Select 【MENU】 -- > 【Trend Clear】, and a following trend clear prompt window will be displayed.

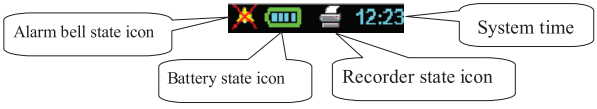
Selecting【YES】 will delete all data in trend graph, trend table and NIBP review table.

Note: The Monitor can store a maximum of 72 hours trend data and 600 items of NIBP measurement result. When the maximum trend data storage time is achieved, the monitor will not save new trend data unless the old trend data is cleared.

4.10 Display information on the screen

4.10.1 System state display area

The system state is displayed at the right top of the screen.



Auditory alarm signal is off; when an alarm occur, the monitor will not make any sound.

The recorder is ready. The icon will flicker when the recorder is working.

Recorder lacks of paper, the door is open or other errors.

The battery is full.


The battery is half-full.

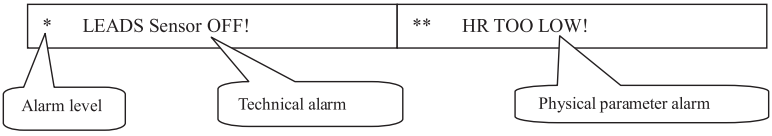

The battery is empty.

Note: When the battery is empty, the system will alarm, in order to remind the users to charge up. If the monitor has not been charged up right away, the monitor will shut down within 5 to 15 minutes use.

4.10.2 Alarm information display area

Alarm information is displayed at the top of the screen.

Alarm information region:



Alarm level:

* Low-level alarm
** Middle-level alarm
*** High-level alarm

Parameter alarm, the parameter will display flickeringly in order to warn.

Chapter 5 Parameters Measurement

5.1 Measurement of ECG/HR

5.1.1 Principles of Measuring

Before the mechanical contraction, the heart will firstly produce electrization and biological current, which will be conducted to body surface through tissue and humors. The current will present difference in potential in different locations of the body, forming potential difference ECG which is also known as body surface ECG or regular ECG. Boby surface ECG or regular ECG is obtained by recording this changing potential difference to form a dynamic curve. The Monitor measures the changes in the body surface potentials caused by the heart of the patient, observes the cardioelectric activities, records the cardioelectric waveforms and calculates the HR through the multiple electrodes connected to various cables. The measurement range of HR is 10~300 bpm.

5.1.2 Precautions during ECG Monitoring

Warning: Before connecting the ECG cables to the monitor, please check if the lead wires and cables is damage. If so, they should be replaced.

Warning: It is imperative to use only the ECG cables provided with the instrument by the manufacturer.

Warning: The equipment is capable of displaying the ECG signal in the presence of pacemaker pulses without rejecting pacemaker pulses.

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

When the electrotome operation is performed, electrodes should be placed on the circle which centre is the operation area, the ECG leadwires should be intertwisted as much as possible. The main unit of the instrument should be placed at a distance from the operation table. Electrical wires and the ECG lead cables should be partitioned and should not be in parallel.

Note: When several parts of equipment are interconnected, the total leakage current is limited to the safety range according to standards IEC 60601-2-27.

The monitor is protected against defribillation side effect. When applying defribillator to the patient, the monitor will experience transient disorderly waveforms. If the electrodes are used and placed correctly, the display of the monitor will be restored within 10 seconds. During defribillation, the chest leads such as V1~V6 shall be removed and such limb electrodes as RA, LA, RL, LL shall be moved to the side of the limbs.

Warning: All the electrodes and conducting part shall not be into contact with any other conductors including the ground. For the sake of patient safety, all the leads on the ECG cables must be attached to the patient.

Warning: When conducting defibrillation, it is imperative to use only the electrodes recommended by manufacturer.

Warning: Do not come into contact with the patient, bed and the monitor during defibrillation.

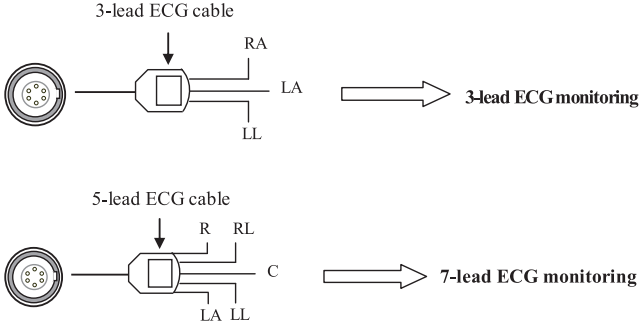
Warning: The Monitor cannot be directly applied to heart and cannot be used for the measurement of endocardio ECG.

5.1.3 Preparing the Measurement of ECG/HR

1) Plug the ECG cable into the ECG socket of the monitor.
2) Place the electrodes onto the body of the patient and connect them to the relevant lead wires of the ECG cables, and at this moment ECG waveforms will appear on the screen.
3) Set the parameters relevant to ECG monitoring.

5.1.4 Connecting the ECG Cables to the Monitor

The Monitor is provided with three different ECG cables relevant to 3-Lead or 7-Lead ECG monitoring:



1) **3-lead ECG cable**

- Including three limb leads: RA, LL, and LA.
- Realize 3-lead ECG monitoring.

2) **5-lead ECG cable**

- Including four limb leads: RA, RL, LL, LA and one chest-lead C.
- Realize 7-lead ECG monitoring.

5.1.5 Connecting the ECG Electrodes to the Patient

1) Connection steps

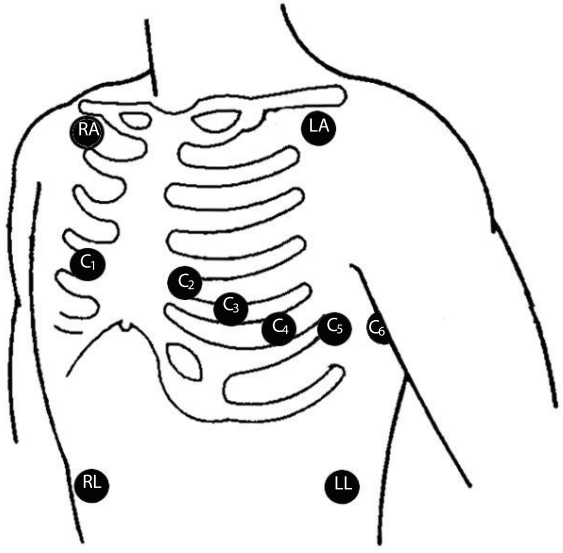
- Clean the patient's skin and remove the oil stains or sweat stains on the skin with alcohol. If necessary, remove the body hair at the locations where the electrodes are to be placed or grind off and clean it with alcohol.
- Check if the buttons on the electrodes are clean and free of damage.
- Place the electrodes on the body of patient. Before attaching, smears some conducting cream on the electrodes if the electrodes are not electrolyte self-supplied.
- Connect the cable leads to the electrodes through the buttons of the electrodes.

Note: For patients who tremble a lot or patients with especially weak ECG signals, it might be difficult to extract the ECG signals, and it is even more difficult to conduct HR calculation. For severely burnt patients, it may be impossible to stick the electrodes on and it may be necessary to use the special pin-shape electrodes. In case of bad signals, care should be observed while placing the electrodes on the soft portions of the muscle.

Note: Check if irritation occur in each electrode attached to the skin. In case of any inflammations or allergies, the electrodes should be replaced and the user should relocate the electrodes every 24 hours or at a shorter interval.

Note: When the amplifier is saturated or overloaded, the input signal is medically meaningless, then the equipment gives an indication on the screen.

2) Location for electrode placement



The following table shows the lead name to identify each lead wire and its corresponding color of AHA and IEC standards.

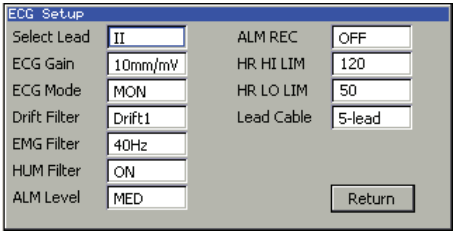
AHA Label	AHA Color	IEC Label	IEC Color	Location
RA	White	R	Red	Under the clavicle of the right shoulder.
LA	Black	L	Yellow	Under the clavicle of the left shoulder.
RL	Green	N	Black	Right lower abdomen.
LL	Red	F	Green	Left lower abdomen.
V_1	Brown	C1	White	4th intercostal space on the right sternum side.
V_2	Yellow	C2	Yellow	4th intercostal space on the left sternum side.
V_3	Green	C3	Green	Center of the line connecting V_2 and V_4.
V_4	Blue	C4	Brown	Node of the left 5th intercostal space and the mid-clavicular line.
V_5	Orange	C5	Black	Node with the left anterior axillary line at the same height with V_4.
V_6	Purple	C6	Purple	Node with the left mid-axillary line at the same height with V_4.

When conducting 3-leads ECG monitoring, use 3-lead ECG cable. The three limb-leads of RA, LA and LL should be placed on the relevant locations. This connection can established the lead of I, II, III

When conducting 7-leads ECG monitoring, use 5-lead ECG cable. The four limb-leads of RA, LA, RL and LL should be placed on the relevant locations. This connection can established the lead of I, II, III, aVR, aVL, aVF; according to actual needs, chest lead C can be placed on any of the locations between C_1~C_6, respectively making one lead of V_1~V_6 established.

5.1.6 ECG Setup menu

Select the <**ECG**> button on the screen, and a following ECG setup window will be displayed.



Select Lead	Select the monitoring lead, the selections: <I>, <II>, <III>, <aVR>, <aVL>, <aVF> and <V->.
ECG Gain	Select the gain of the ECG waveform, the selections: <**2.5mm/mV**>, <**5mm/mV**>, <**10mm/mV**>, <**20mm/mV**>, <**40mm/mV**> and <**AUTO**>.
ECG Mode	There are four operation modes, which are unfiltered, operation, monitoring and user. They are identified as: < **UNFI** >, <**OPS**>, <**MON**>, <**USER**> in the ECG menu.
Drift Filter	Drift filter. Three options are provided: <**OFF**> (time-constant > 3.2 seconds, the comeback time of ECG waveform is long, and the distortion of the waveform is little), <**Drift 1**> (time-constant > 0.3 second, the comeback time of ECG waveform is shorter), <**Drift 2**> (time-constant > 0.15 second, the comeback time of ECG waveform is shortest, and the distortion of the waveform is obvious).
EMG Filter	The low pass filter in order to filtrate the EMG noise, the selections: <**OFF**>, <**25Hz** > and <**40Hz** >.
HUM Filter	The notch filter in order to filtrate the HUM noise. Select <**ON**> open the filter, select <**OFF**> close the filter.
ALM Level	Set the alarm level of ECG parameter, the selections: <**OFF**>, <**LOW** >, <**MED** > and <**HIGH** >.
ALM REC	Select <**ON**>, the alarm of ECG/HR parameter will trigger alarm recording. Select <**OFF**>, the alarm of ECG/HR parameter will not trigger alarm recording.
HR HI LIM	Select the upper limit of HR alarm, adjustable range: **0～350**, adjust continuously, equal or above the lower limit.
HR LO LIM	Select the lower limit of HR alarm, adjustable range: **0～350**, adjust continuously, equal or below the upper limit.
LEAD Cable	Select the ECG input cable, the selections: <**3- lead**>, <**5-lead**>.

The states of the filter under various modes of ECG:

ECG mode \ Filter	Drift filter	HUM filter	EMG filter
UNFI	OFF	OFF	OFF
OPS	Drift 2	ON	25Hz
MON	Drift 1	ON	40Hz
USER	Optional	Optional	Optional

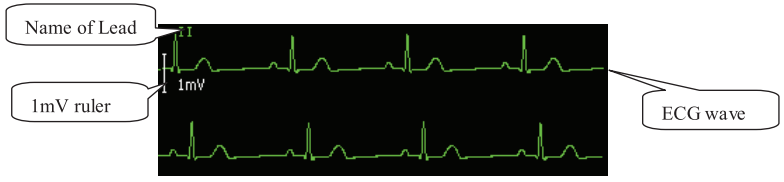
Note：Under the mode of UNFI, OPS and MON, the state of the filter cannot be regulated. Only under the state of USER can the state be regulated.

Caution:

- When "3 Lead" is selected as <Lead Cable>, **ECG is in 3-lead input mode, and only Lead I, II or III can be measured.**
  When "5 Lead" is selected as <Lead Cable>, **ECG is in 5-lead input mode, and Lead I, II, III, aVR, aVL and aVF and one chest lead can be measured.**

5.1.7 Display of ECG parameter

- Waveform display



- Data display

Caution: Whenever ECG leads are connected, heart rate measured by ECG will display on the position of heart rate parameter. When ECG leads are not connected, while SpO_2 sensor is connected, pulse rate will display on the position of heart rate parameter automatically.

5.1.8 Maintenance and Cleaning

If there are any sign that the ECG cable may be damaged or deteriorated, replace it with a new one before using it to patient.

Cleaning: Use fine-hair cloth moistened with mild soap or cleaning agent containing 70% ethanol to clean the equipment.

Sterilization: Sterilization is only recommended when stipulated as necessary in the hospital maintenance schedule, sterilization facilities should be cleaned first.

Recommended sterilization material:

- Ethylate: 70% alcohol, 70% isopropanol
- Acetaldehyde

Disinfection: Disinfection is only recommended when stipulated as necessary in the hospital maintenance schedule; disinfection should be cleaned first.

5.2 Measurement of RESP

5.2.1 Principles of Measuring

The Monitor measures RESP with the method of impedance. When a patient exhales and inhales, changes will take place in the size and shape of the thoracic cavity, causing consequent changes in the impedance between the two electrodes installed at the patient's chest. Based on the cycle of impedance changes, the respiration rate can be calculated. The measuring range of respiration rate is 0~120 times/min.

5.2.2 Preparing the Measurement of RESP

1) Plug the ECG cable into the ECG socket of the monitor.

2) Place the various pads of the electrodes onto the body of patient and connect them to the relevant lead cables. At this moment, the screen will show RESP waves and the RESP rate will be calculated.

3) Set the parameters relevant to RESP monitoring.

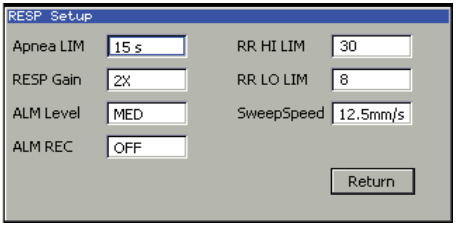
5.2.3 Connect the ECG Cable with Patient and the Monitor

To measure RESP parameters, it is unnecessary to use other cables and it is only necessary to use the two: RA and LL leads in the ECG cable.

Warning: For safetypurposes, all the leads on the ECG cable must be connected to the body of patient.

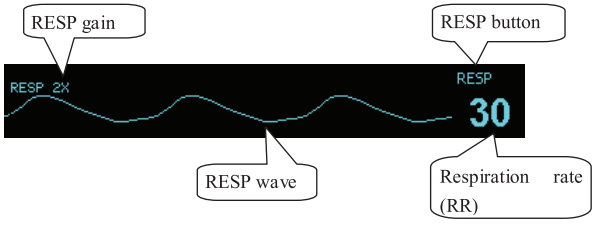
5.2.4 RESP Setup menu

Select the <**RESP**> button on the screen, and a following RESP setup window will be displayed.



Apnea LIM	Define the concept of choke. When the duration of no RESP reach this limit, apnea alarm will be triggered. Range: 10~60s.
RESP Gain	Select the magnify times of RESP gain. Options: <**1x**>, <**2x**>, <**4x**>.
ALM Level	Setup alarm level of RESP parameters, the selections: <**OFF**>, <**LOW**>, <**MED**> and <**HIGH**>.
ALM REC	Select <**ON**>, the alarm of RESP parameter will trigger alarm recording. Select <**OFF**>, the alarm of RESP parameter will not trigger alarm recording.
RR HI LIM	Select the alarm upper limit of RESP rate. Range: **0～120,** adjust continuously, equal or above the lower limit.
RR LO LIM	Select the alarm lower limit of RESP rate. Range: **0～120,** adjust continuously, equal or below the upper limit.
Sweep Speed	Set the sweep speed of RESP waveform. Options are <**25mm/s**>, <**12.5mm/s**> and <**6.25mm/s**>.

5.2.5 Display of RESP parameter



5.2.6 Maintenance and Cleaning

Please refer to 5. 1.8 of chapter 5.

Chapter 6 Alarm

This chapter gives general information about the alarm and corresponding remedies.

Note: The equipment generates all the auditory and visual alarms through speaker, LED and screen.

6.1 Alarm Priority

There are two kinds of alarms, defined as physiological alarm and technical alarm. Physiological alarms refer to those alarms triggered by patient′s physiological situation that could be considered dangerous to his or her life. Technical alarms refer to system failure, which can make certain monitoring process technically impossible or make monitoring result unbelievable. Each alarm, either technical or physiological, has it′s own priority.

Alarms in the monitor are divided into three priorities, that is: high priority, medium priority and low priority.

- High priority alarm indicates the patient′s life is in danger. It is the most serious alarm.
- Medium priority alarm means serious warning.
- Low priority alarm is a general warning.

Only alarm priority of parameters exceeding limits alarm can be modified by the user, the other alarm priorities of physiological and technical alarms are preset by the system and they can not be changed by the user.

6.2 Alarm Modes

When alarm occurs, the monitor may catch the user's attention in two ways, which are auditory prompt, visual prompt and description. Visual prompt is given by alarm indicator lamp of the monitor and auditory prompt is given by speaker in the device. Physiological alarm information is displayed in the Physiological Alarm area. Most of technical alarm information is displayed in the Technical Alarm area.

The alarm sound and visual display complies with of the standard IEC 601-1-8 clause 201.3.2.

Note: The concrete presentation of each alarm prompt is related to the alarm priority.

■ **Alarm sound**

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

Alarm level	Audio prompt
High	Mode is "DO-DO-DO------DO-DO, DO-DO-DO------DO-DO", which is triggered once every 10 seconds.
Medium	Mode is "DO-DO-DO", which is triggered once every 25 seconds.
Low	Mode is "DO-", which is triggered once every 25 seconds.

■ **Lamp light**

Alarm level	Visual prompt
High	Alarm indicator flashes in red with 2Hz.
Medium	Alarm indicator flashes in yellow with 0.5Hz.
Low	Alarm indicator lights on in yellow.

■ **Screen Display**

Physiological alarm: The parameter which triggers the alarm, flashes in the frequency of 2Hz on the screen. The physiological alarm area displays alarm message and red "***" indicates high priority alarm, yellow "**" indicates medium priority alarm and yellow "*" indicates low priority alarm.

Technical alarm or general message: The technical alarm area provides text prompt and red "***" indicates high priority alarm, yellow "**" indicates medium priority alarm, yellow "*" indicates low priority alarm and cyan indicates general message.

Note: When alarms of different priorities occur at the same time, the monitor prompts the one of the highest priority.

6.3 Alarm Setup

■ **Set Alarm volume**

Select 【MENU】 -- > 【ALM volume】, options are 0~3. Select 0 to close the alarm sound, Select 3 to setup maximal alarm volume.

The alarm sound is closed, when an alarm takes place, the monitor will

not make any sound.

■ **Set alarm limits of physiological parameters**

The alarm limit of each physiological parameter can be set in its menu, and they are continuous in alarm range. For example:

ECG alarm setup:

1. Select <ECG> button
2. Configure the following parameters related to ECG alarm, <ALM Level>, <ALM REC>, <HR LO LIM> and <HR HI LIM>.

Please refer to above operation for Methods of Alarm setup of the other parameters

It is important to set physiological alarm limits properly. The monitor can't give medicinal alarm prompt in clinical application with improper setting of physiological alarm limit.

The physiological alarm occurs when the measurement exceeds the set parameter limits.

Please refer to above operation for Methods of alarm setup of the other parameters.

■ **Alarm indication of physiological parameters**

Auditory: when alarm occurs, the system generates alarm sound to catch the user's attention (auditory alarm can be disabled).

Visual: The parameter flashes on the display area of the screen and alarm indicator lights.

Warning：The lower limit and the upper limit of parameter must be set based on clinical practices and general clinical experiences.

Note：When parameter alarm level is off, alarm will be disabled, even if the measurement results exceed the limits.

6.4 Alarm state icon

According to alarm setup of the monitor, the following icons will be displayed on screen.


The alarm is suspended.


The system sound is silenced.


The alarm sound is off.


The parameter alarm is off.

The system sound includes alarm sound and QRS sound.

6.5 SILENCE/ALARM PAUSED

■ **SILENCE**

Press the key on the front panel for more than 2 seconds to shut off all sounds. When the system is in SILENCE status, any newly generated alarm will cancel the SILENCE status and make the system back to normal status giving auditory alarm prompt.

When in the SILENCE status, the icon will be displayed in the right upper portion of the screen.

■ **ALARM PAUSED**

Press the key on the front panel for less than 2 seconds to close all auditory and visual prompt and description of all the physiological alarms The rest seconds for ALARM PAUSED is displayed in the Physiological Alarm area. And the icon will be displayed in the physiological alarm area.

The user may set up the time for ALARM PAUSED. Select 【MENU】 -- > 【ALM Paused】, two selections are available: 1 and 2 minutes.

When in the ALARM PAUSED status, press the key again to restore the normal alarm status. Besides, during ALARM PAUSED status, newly occurring technical alarm will cancel the ALARM PAUSED status and the system will come back to the normal alarm status.

Note: Whether an alarm will be reset depends on the status of the alarm cause. But by pressing key can permanently shut off audio sound of Lead Off/Sensor Off alarms.

6.6 Parameter Alarm

The setup for parameter alarm is in each of their menus. In the menu for a specific parameter, you can check and set the alarm limit, alarm and status. The setup is isolated from each other. When a parameter alarm level is off, the icon displays near the parameter.

For the parameters whose alarm level is not off, the alarm will be triggered when at

least one of them exceeds alarm limit. The following actions take place:

1. Alarm message displays on the screen as described in alarm mode;
2. The monitor beeps in its corresponding alarm level and volume;
3. If alarm recording is on, the recorder starts alarm recording at set interval.

6.7 When an Alarm Occurs

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

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

1. Check the patient's condition.
2. Identify which parameter is alarming or which kind of alarm it is.
3. Identify the cause of the alarm.
4. Silence the alarm, if necessary.
5. You will find the alarm messages for each parameter in their correrponding parameter chapters of this manual.

6.8 Alarm Description and Prompt

6.8.1 ECG alarm information

Physiological Alarm Information:

Message	Cause	Alarm Level
HR too high	HR measuring value is above the upper alarm limit	User-Selectable
HR too low	HR measuring value is below the lower alarm limit	

Technical Alarm Information：

Message	Cause	Alarm Level
RA/LA/LL/V- OFF LEADS OFF	ECG electrode fall off the patient's skin or ECG cables fall off the monitor	Low
ECG Signal Saturated	ECG electrode polarized	Low

6.8.2 RESP alarm information

Physiological Alarm Information：

Message	Cause	Alarm Level
RR too high	RR measuring value is above the upper alarm limit	User-Selectable
RR too low	RR measuring value is below the lower alarm limit	
RESP Apnea	No signal for breath in specific interval	

6.8.3 System Alarm and Prompt

Technical Alarm Information:

Message	Cause	Alarm Level
Battery failure	Battery failure	Low
BATTERY LOW	Energy of battery is exhausted.	Medium
KB ERR	Keyboard error	Low
REC ERR	No paper in the recorder or the recorder door is open.	Low
RTC RESET	System time error, user should reset the system time.	Low
RTC USELESS	System time failure.	Low
ECG communication error	ECG module failure or communication failure	Low

Prompt Information

Message	Cause	Alarm Level
Wave Frozen	The waveform display on the screen is frozen.	No alarm

Chapter 7 Recording

■ **The monitor carries out the recording function by a built-in recorder optional.**

This icon will be displayed in the system information area of the screen when the monitor has been equipped with a recorder.

This icon will be displayed in the system information area of the screen when the recorder lacks of paper, the door is not closed or other errors.

■ **Alarm recording**

The monitor has the function of alarm trigger recording.

- Select 【MENU】 --> 【Recorder…】 --> 【ALM REC Interval】, setup the alarm recording interval when alarm is occurring continuous. Alarm recording function will be disabled when <OFF> is selected.
- Access the parameter setup windows and set the 【ALM REC 】 to <ON>, and setup the parameter alarm level and alarm limit correctly.
- When the parameter alarm occurs and the 【ALM REC 】 is <ON>, all the parameter values during the alarm will be printed out. And the parameter value which trigger the alarm recording will be marked with "*".
- If duration of the parameter alarm is over alarm recording interval, the monitor will print out all the parameter values again.

Note：The <ALM REC> is included in any parameter setup menu. If the option is at <OFF>, the parameter alarm cannot trigger the alarm recording.

■ **Auto recording**

The monitor has the function of auto recording.

- Select 【MENU】 --> 【Recorder…】 --> 【Auto REC】, setup interval time of auto recording.
- Select 【MENU】 --> 【Recorder…】 --> 【REC Length】, setup the recording length of waveform in auto recording.
- The monitor prints out waveforms and parameter values according to interval time set in 【Auto REC】.

■ **Real-Time Recording**

The monitor has the function of real time recording. Press the  key on front panel to start the real-time recording of waveforms and parameter values, press the key again to end the real-time recording. The ECG waveform recorded is selected by 【Select Lead】 in ECG Setup window.

Chapter 8 The Maintenance and Cleaning

8.1 System Check

An effective maintenance schedule should be established for your monitoring equipment and reusable supplies. This should include inspection as well as general cleaning on a regular basis. The maintenance schedule must comply with the policies of your institution′s infection control unit and/or biomedical department.

Check with your Biomedical department to be sure preventive maintenance and calibration has been done. The User Maintenance Instruction contains detailed information.

Before using the monitor, check the equipment following these guidelines:

- Check the equipment for only mechanical damage.
- Check all the outer cables, inserted modules and accessories for fraying or other damage. Qualified service personnel should repair or replace damaged or deteriorated cables.
- Check all the functions relevant to patient monitoring, make sure that the monitor is in good condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or Manufacturer′s Customer Service immediately.

Note: Refer to the User Maintenance Instruction for more comprehensive checkout procedures.

The overall check of the monitor, including the safety check, should be performed only by qualified personnel once every 6 to 12 month, and whenever the monitor need to be fixed up.

- Inspect the safety relevant labels for legibility.
- Verify that the device functions properly as described in the instructions for use.
- Test the protection earth resistance according IEC 601-1:1988, Limit 0.1Ω.
- Test the earth leakage current according IEC 601-1:1988, Limit: NC 500uA, SFC 1000uA.
- Test the patient leakage current according IEC 601-1:1988, Limit: 100uA(BF), 10uA(CF).
- Test the patient leakage current under single fault condition with mains voltage on the applied part according IEC 601-1:1988, Limit: 5mA(BF), 50uA(CF).

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

The synchronism of the defibrillator should be checked in the frequency required by the hospital regulations. At least every 3 months, it should be checked by the biomedical engineer of the hospital or qualified service technician.

All the tests that requires opening the monitor should be performed by qualified service technician. The safety and maintenance check can be conducted by a personnel from the manufacturer. You can obtain the material about the customer service contract from the local office.

The circuit diagrams, parts lists and calibration instructions of the patient monitor can be provided by the manufacturer.

Warning: If the hospital or agency using the monitor does not follow a satisfactory maintenance schedule. Monitor malfunction might occur and patient's safety is compromised.

Note: To ensure maximum battery life; please ensure that the battery is always fully charged when you are keeping the device in storage for an extended period of time, and check the battery status at least once every month and recharge the battery if necessary.

Warning: For battery replacement, contact the manufacturer's service technician.

8.2 Battery Maintenance

A built-in rechargeable battery is designed for the patient monitor, which enables continuous working when AC power not avaiable. Special maintenance is not necessary in the normal situation. Please pay attention to the following usage instruction:

- Operate the patient monitor in the environment according to the specification of this manual.
- Use AC power for the patient monitor when available.
- Recharge the battery sooner when it is off. The volume of battery will not be charged to what it should be, when the battery has not been charged for a long time.

- Recharge the battery every 6 months even if the patient monitor is not actively used.
- Avoid sun expolsure.
- Avoid infrared and ultraviolet radiation.
- Avoid moist, dust and erosion from acid gas.

8.3 General Cleaning

Warning: Before cleaning the monitor or the sensors, make sure that the equipment is switched off and disconnected from the power line.

The Patient Monitor must be kept dust-free.

Regular cleaning of the monitor shell and the screen is strongly recommended. Use only non-caustic detergents such as soap and water to clean the monitor shell.

Please pay special attention to the following items:

1. Avoid using ammonia-based or acetone-based cleaners such as acetone.
2. Most cleaning agents must be diluted before use. Follow the manufacturer′s directions carefully to avoid monitor damage.
3. Don′t use the sharp cleaning material, such as steel wool etc.
4. Don′t let the cleaning agent enter into the chassis of the system.
5. Don′t leave the cleaning agents in any part of the equipment.

8.4 Cleaning Agents

Examples of disinfectants that can be used on the instrument casing are listed below:

- Diluted Ammonia Water
- Diluted Sodium Hypochlorite (Bleaching agent).

Note: The diluted sodium hypochlorite from 500ppm (1:100 diluted bleaching agent) to 5000ppm (1:10 bleaching agents) is very effective. The concentration of the diluted sodium hypochlorite depends on how many organisms (blood, mucus) on the surface of the chassis to be cleaned.

- Diluted Formaldehyde 35%--37%
- Hydrogen Peroxide 3%

- Alcohol 75%
- Isopropanol 70%

The patient monitor and sensor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.

The manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts.

8.5 Sterilization

Sterilization is needed for the following parts

- **For ECG/RESP cable**

Sterilization is only recommended when stipulated as necessary in the hospital maintenance schedule. Sterilization facilities should be cleaned first.

Recommended sterilization material:
Ethylate: 70% alcohol, 70% isopropanol
Acetaldehyde
No sterilization needed for ECG electrodes and other disposable parts.
Please pay special attention to the following items:

- **Do not let liquid enter the monitor.**
- **Do not pour liquid onto the monitor during sterilization.**
- **Use a moistened cloth to wipe up any agent spilled on the monitor.**

8.6 Disinfection

Disinfection is only recommended when stipulated as necessary in the hospital maintenance schedule. Disinfection facilities should be cleaned first.

Warning: Do not use ETO gas or formaldehyde to disinfect the monitor.

Brief Introduction to the Defibrillator Part

1. SAFETY INSTRUCTION

Before you use defibrillator , read the following tips carefully for safety use and to avoid possible damage to patient/user:

1. Please read the entire manual carefully to understand its proper operation before use.

2. The unit can be only applied to the specified use in the manual. No other using ways to avoid possible danger.

3. Like other defibrillators, the unit should keep away from explosive and dangerous places.

4. Any alterations or modifications to the unit should be done by the qualified and trained person from the manufacturer.

5. The unit could adapt with the parts which are approved by the legal quality department. All the original parts are checked before leaving the factory.

6. Check the unit whether in normal and safe condition before use. For example, don't use the defibrillator if the wire is damaged or other parts are not in good condition.

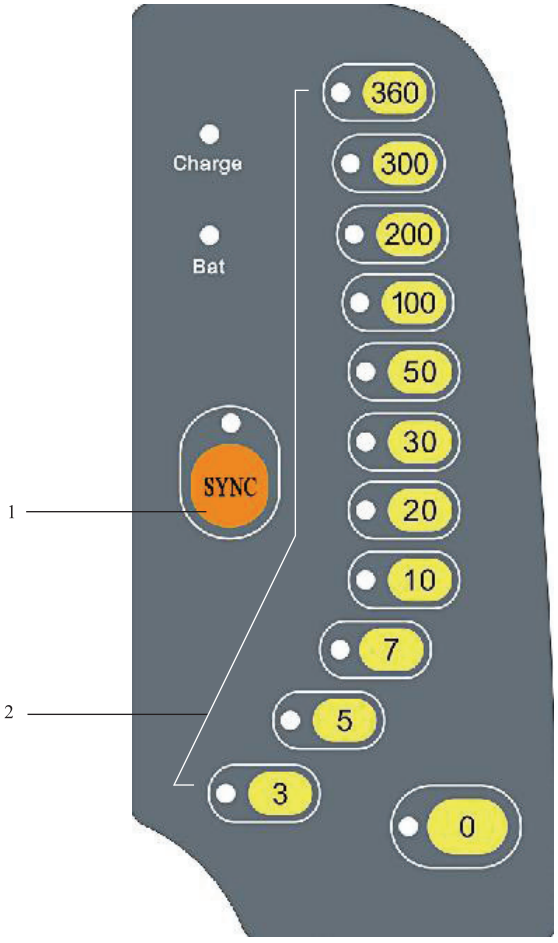
7. Special notice to the instructions in appendix A1 during operation.

8. When using the defibrillator, be sure that no instrument sensitive to the magnetic field or possible disturbance sources is near to the area where defibrillator is placed.

9. The maximum energy charging time is 15 seconds. The discharge should not be over three times per minutes. The unit is OK for a certain cooling time.

Besides, our unit conforms to the requirements of general provisi ons for Medical Equipment

2. BOARD DISPLAY



(1) SYNC or NON SYNC mode

(2) ENERGY SELECTOR To select the energy of the heart defibrillating treatment.

3. OPERATION INSTRUCTION

(1) First plug the power cord into the outlet well.

(2) Put the ON/OFF defibrillator power switch to "1" place. Then the indicating lamp in top of energy selector "0" step will light.

NOTE:

If the buzzer beeps 4 short, that is the failure warning of the batteries or power supply.

(3) Energy selector：Press the button (2) to choose an energy step. If the lamp on top of the button lights, it indicates that the energy of selected step is full and is ready to do defibrillating discharge. If with full energy, but no discharge or use, press "0" step selector to do inner discharge and zeroing the energy.

(4) Electrode position: Hold the hand of the electrode and get them from the block on the unit. The electrode pad should be placed along with the hear axis. APEX pad should be placed on the patient's left heart, above auxiliary line of apex cords. The other should be at the right chest, below the clavicle.

NOTE:

- **To protect the skin from burning, put enough conductive gel on the pad surface.**
- **The two electrode pads should be pressed firmly with 10 kilograms force to make the safe energy transfers and prevent skin burning.**
- **Make sure that there are no connecting and transferring gel between the two electrodes.**

(5) Energy discharge: Press the release key on two pads at the same time for discharge.

NOTE:

- **Note: The buzzer will beep shortly once the discharge is finished.**
- **Before and during the discharge, all the participants of revival treatment should keep distance from the conductive onjects (such as stretcher) ones All other instrument connected to the patient should be removed from the patient before discharge.**
- **Note: Avoid the connection of two pads to discharge. This will cause short circuit.**
- **Note: After full charge of the energy, please press "0" key for internal discharge if not use.**

4. Maintenance

Put off the power plug when surely the unit is closed.

It is OK to clean with the home detergent and use the clean cloth.

It is also OK to sterilize the electrode pads with hospital-grade ethanol or disinfectant.

NOTE:

Don't use the cloth of water dropping for cleaning. The dropping water may affect the performance of the unit. Also don't put the unit into the water.

the performance of the unit. Also don't put the unit into the water.

No matter use or not of the unit, we recommend the operator to check and maintain the defibrillator and its parts. Please notice the following tips for maintain

1. Check whether the outer case is OK or damaged

2. Check the conducting wire of electrodes is OK or insulation damage

3. Clean all the conductive gel and dirty on the two pads and other electrodes, so as to make sure the good connection and avoid the electric spark.

In order to make the good function of defibrillator, the unit should equip with a charging battery that can work well. The battery of the unit can support 10 times discharge.
The operator can full charge of the electricity and then discharge to verify the times.
Note: The unit should be repaired directly damage of outer case or loss of electricity.

5. Technical features

Defibrillation

Driving terms：monophasic, synchronous/asynchronous， external defibrillating treatment
Energy steps：0、3、5、7、10、20、30、50、100、200、300、360 joule（50ohm）twelve steps available
Charging time：＜10 seconds（360joule）
Pad electrode：Adult type(pediatric integrated)

Safety：

Series：Protect step II，type：electrocardiogram C F，Others is B F， 25th group of Medical instrument manufacture

Others：

Working power：AC/DC：AC 220V/50Hz or 110V/60Hz(*)； 12Vchargable battery for DC
Battery capacity：+10timesreserve（360joule）
Normal working condition：
Working temperature：5~40℃
Relative temperature：≤80%
Atmospheric pressure：86kpa~106kpa
*Before connect the power cord to the outlet, please check the power supply condition matched in the label located in the back of this equipment's shell.

6. Warranty Terms

Our company will support a one-year warranty against the purchasing date (consumables and attached excluded). During the warranty, the company will remove all problems and it will detect the caused of the materials that is made by the manufacturer. We will repair and change if the procedure of the machine runs by default. The implement of responsibility will not prolong the original warranty time.

The requirements of all other contracts' terms or beyond this contract will be excluded. Otherwise these terms are specified, oversighted, or subject to the obligatory legal regulations or laws.

Regarding the damage caused by the wrong operation not according to the instruction, violent action, illegal repairing not done by the authorized person, our company will be not responsible. The warranty requirements from distributors(agents) to purchaser is beyond this regulation.

If warranty is needed, please contact with your distributors(agents). Or Deliver all the purchasing documents of our machine, such as invoice, your name, address to our technical department. Even beyond the warranty time, our company will try our best to serve you.

Appendix

A1 General instructions and regulation of operating the defibrillator.
What is cardiac defibrillation ?

Cardiac defibrillation is to release the current to the electrical muscle, so as to cause contracting, and the myocardial depolarization. So that this can remove the abnormal heart's rhythmic patterns, which will is dangerous to the life. The abnormal heart's rhythm is the incompatible between the heart muscle and the physical action.

Abnormal heart's r hythm	Possible treatment
1. Incompatibly of active parts of heart muscle (e.g. quivering of the heart)	1. Synchronous DC defibrillation
2. Complete abnormal of heart muscle beat (Ventricular flutter)	2. Asynchronous DC defibrillation (heart defibrillate)

The above table offers two common abnormal heart's rhythm case s and the related possible treatments for that. Actually the cardiac defibrillator is designed especially for asynchronous defibrillation, so this is not available in the synchronous one.

Also the above DC defibrillations are different. Here we briefly discuss about it.

(1)Asynchronous DC defibrillation (heart defibrillate)

No prolong when using this way. Just release the energy immediately press the "discharge" switch. The precondition is the correctness of cardiac fibrillation diagnosis and pulse Defects.

If the defibrillator's energy asynchronously releases to the heart rhythm, this will damage the heart. If the energy affects to the heart muscle at heart refractory Period(around half of T-wave), it will aggravate the heart quivering.

(2). Synchronous DC defibrillation

The precondition of this defibrillation is that the victims have distinguished heart rhythm. As to the synchronous discharge, the Electrocardiogram will have clear QRC Composite wave. Some millisecond(about 10-60) after R-wave detection, the synchronous mechanical system from ECG part will control to discharge.
The ECG parts will indicate "SYNC" to show the detection of QRS composite wave for doctors' easy operation.

When using, the discharge doctor should carefully note of the signal and make sure that each QRS composite waves are legible. Also they are not interfered by others or cardiac pulse synchronization

Steps for the heart defibrillation(Asynchronous DC defibrillation)

The following treatment steps only applies to the heart defibrillator. This does not apply to the machinery, cardiopulmonary or pharmacological recovery fields. The basic premise of synchronous DC defibrillation is ventricular fibrillation, which means that in the victims' electrocardiogram have P-QRS wave or T wave defects.

1. **Open the defibrillator**

2. **Put the conductive gel on the two electrode pads.**
   Remember enough gel on the pads in order to reduce transmission resistance and more energy into the victims. Too little gel possibly causes the skin burning under the pads.

Note: No gel to the hand of the electrode pads. Otherwise, it is dangerous to transfer the electric spark to the operator or doctor.

3. **Energy selection**
   The discharging energy confirms with the victims' height and weight. It is around 2 joule/kgs. Also it is according to experiences and the specific aid situation.

4. **Position of electrode pads**
   The pads should be firmly pressed on the victims' naked chest. Also for the safe energy transmission, it is necessary to press with around 10kilograms force. Too small force will also cause the skin burning. It is necessary to do practice on the training instrument for the correct position.

The pads position is crucial to the successful recovery. So the current between the electrodes should transfer the chest to myocardial tissue. Only when 80% heart being defibrillating, and get to "critical mass", possibly the fibrillation can be over.

Wrong position of electrode pads will cause large loss of current from the heart side without any effect.

Correct position of sternum electrode: — Right Chest
— Right side of sternum
— Beneath the clavicle

Correct position of pole electrode — Beneath the left chest
— Above apex
— Center of axillary line

Note: Don't put the conductive gel on the ele ctrodes on the victims' chest. If not, the current will only flow through the electrode surface. The gel also could not be on the hand of electrode pads. If not, it may form electric spark and danger to the doctor.

5. Protection before electrode discharge

Before the defibrillation, the doctor in charge should very clearly tell all the participants for recovery aid away from the victim, the bed and the connected instrument. All other instrument that is not used to defibrillation treat should remove from the victim. If not, it is possible to cause spark on other participants

6. Discharge the energy

Press the release key on the pads at the same time. The defibrillator will do the discharge.

7. Observe the result

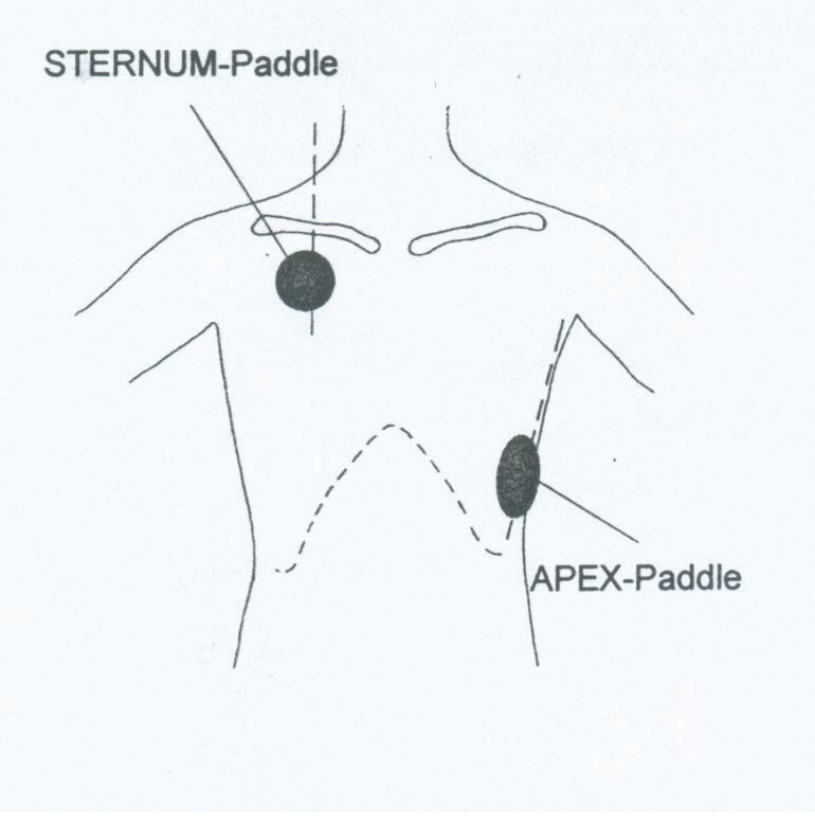
After defibrillation, it is necessary to diagnose the victim situation and the patient monitor. According to the observing result, if necessary, more defibrillation will be done for the treatment(Repeat steps 3-7 again)

If using artificial or pharmacological measures for assistant, the emergency doctor should do the guarantee and be responsible for that.

8. Make sure that the defibrillator in good condition

After the treatment, you should clean the electrode pads, electrodes and wires for next good use.

A1: The placing position of paddles



A2:The use of paddles

Our company's defibrillator use the composite paddles, an external paddle for adults, built-in paddles for children. If you need to use the children's paddle, the adult's paddle should be spun. After used, if you need to resume the paddle, please first clean up the electrode of the children paddle, then spin again. Must be tightened up and good in keep in touch.

TMS®

Product Warranty Card

Name: _____

Address: _____

_____

Product Name: _____

Model: _____

Date of Purchase: _____

Purchased From: _____

Inmed Corporation warrants this product to be free from defects in material or workmanship within 1 year from date of purchase under normal use. If fault is found, please return the equipment, freight prepaid, in its original packaging along with the purchase receipt to the address below. Inmed Corporation will repair or replace any defective parts free of charge subject to the terms and conditions stated herein.

For service, the unit is to be returned freight prepaid to:

Inmed Corporation
5 Calle Industria, Bagumbayan,
Quezon City 1110, Philippines
Tel: +63.2.5711888 | Fax: +63.2.5719912

Please register your unit online at www.inmed.com.ph