

Product Information

- Product Model: E30
- Product Name: Digital Electrocardiograph
- Manufacturer Name: Guangdong Biolight Meditech Co., Ltd.
- Contact Information:
Address: No.2 Innovation First Road, Technical Innovation Coast,
Hi-Tech Zone Zhuhai, P.R. China
Post code: 519085
Fax: +86-756-339919
Toll-free consultation hot line: +86-400-8818-233

Revision History

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

- Document No.: J/E30-I-016
- Revision number: V1.0
- Release time: May.2015

Copyright © 2015 Guangdong Biolight Meditech Co., Ltd. All rights reserved.

CE mark



EC Representative Name:

Shanghai International Holding Corp. GmbH (Europe)

EC Representative Address:

Eiffestrasse 80, 20537 Hamburg Germany

Statement

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

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

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

Manufacturer's Responsibility

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

- All the installation, expansion, readjustment, renovation or repairs are conducted by the personnel certified by manufacturer.
- The storage condition, operation condition and electrical status of the instrument conform to the product specification.
- The instrument is used in accordance with the user's manual.

About this manual

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

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

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

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

required for monitoring patients.

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

Conventions:

- ***Bold Italic*** text is used in this manual to quote the referenced chapter or sections.
- **【 】** is used to enclose screen texts.
- → is used to indicate operational procedures.

Signs in this manual:



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



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



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

⟨This page is blank⟩

Content

| | |
|--|------------|
| Chapter 1 General Introduction | 1-1 |
| 1.1 Intended use | 1-1 |
| 1.2 Contraindications | 1-1 |
| 1.3 Manufacture Config | 1-1 |
| 1.4 Main Unit..... | 1-2 |
| 1.5 Screen Display | 1-4 |
| 1.6 Equipment Sign..... | 1-6 |
| Chapter 2 Safety | 2-1 |
| 2.1 Safety Information | 2-1 |
| 2.2 General Safety..... | 2-3 |
| 2.3 Important Notes for Safety | 2-5 |
| 2.4 Safe Operation Conditions..... | 2-7 |
| Chapter 3 Getting Started | 3-1 |
| 3.1 Unpacking and Checking..... | 3-1 |
| 3.2 Power Supply | 3-2 |
| 3.3 Placing Cables..... | 3-3 |
| 3.4 Placing Electrodes..... | 3-3 |
| 3.5 Install the chart paper..... | 3-6 |
| 3.6 Inspecting Before Starting | 3-7 |
| Chapter 4 Operation Instruction | 4-1 |
| 4.1 Turn On/Off | 4-1 |
| 4.2 Main Menu..... | 4-1 |
| 4.3 Patient Info Setup..... | 4-2 |
| 4.4 File Management..... | 4-3 |
| 4.5 Work Mode Setup..... | 4-5 |
| 4.6 Filter Setup | 4-7 |
| 4.7 Report Info Setup | 4-9 |
| 4.8 System Setup..... | 4-10 |
| Chapter 5 Read the Printed ECG Report | 5-1 |
| Chapter 6 Battery | 6-1 |

| | |
|---|------------|
| 6.1 Introduction | 6-1 |
| 6.2 Optimizing Battery Performance | 6-1 |
| 6.3 Checking Battery Performance | 6-2 |
| 6.4 Disposing Batteries | 6-2 |
| Chapter 7 Clean and Maintenance..... | 7-1 |
| 7.1 Summarize | 7-1 |
| 7.2 Cleaning of the Electrocardiograph | 7-2 |
| 7.3 Cleaning and Sterilizing of Accessories | 7-2 |
| 7.4 Cleaning and Maintenance of Recorder | 7-4 |
| Chapter 8 Accessories..... | 8-1 |
| Appendix A Product Specifications..... | 1 |
| A.1 Safety Specifications | 1 |
| A.2 Environmental Specifications | 1 |
| A.3 Physical Specifications | 2 |
| A.4 Power Specifications | 2 |
| A.5 Hardware Specifications | 3 |
| A.6 Measure of ECG Waveform | 3 |
| A.7 Display of ECG Collection | 4 |
| A.8 Input/Output Specification..... | 5 |
| A.9 Storage Specification..... | 5 |
| A.10 Function | 5 |
| Appendix B Factory Default Setting..... | 6 |
| Appendix C Prompt Information..... | 7 |
| Appendix D Measurement | 8 |
| D.1 The Waveform Boundaries of 12 Leads..... | 8 |
| D.2 Measurements of One Beat | 9 |
| D.3 Isoelectric Segments..... | 9 |
| D.4 Stability of Measurements against NOISE | 10 |
| D.4.1 Acceptance of minimum waves | 10 |
| D.4.2 Disclosed changes of measurments caused by NOISE on ECGs..... | 11 |
| Appendix E Guidance and Manufacturer's Declaration of EMC..... | 12 |

Chapter 1 General Introduction

1.1 Intended use

Digital Electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.



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

1.2 Contraindications

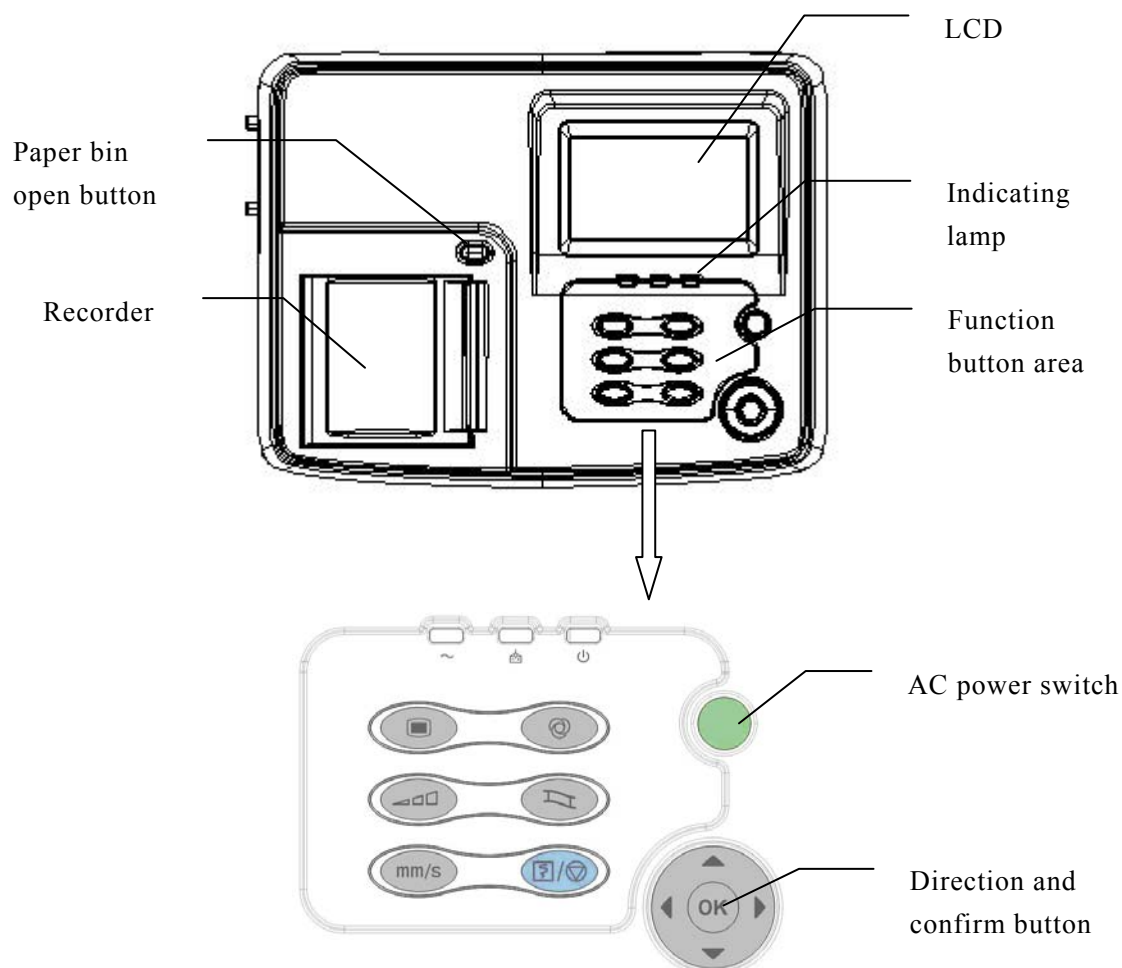
Temporary no found.

1.3 Manufacture Config




Electrocardiograph mainly consists of mainframe, ECG cables and electrodes.

1.4 Main Unit







1.4.1 Top View



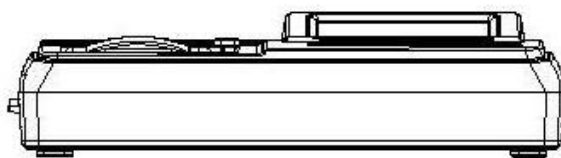
◆ Indicating lamp

| NO. | Name | Note |
|-----|---|--|
| 1 |  AC power indicating lamp | Green light turns on if with AC power. |
| 2 |  Battery status indicating lamp | Orange light turns on if battery is in process of recharging .The light will be off after recharging finished. |
| 3 |  Equipment operation indicating lamp | Green light turns on when equipment is running; Green light twinkling when equipment enters standby status. |

◆ Function button

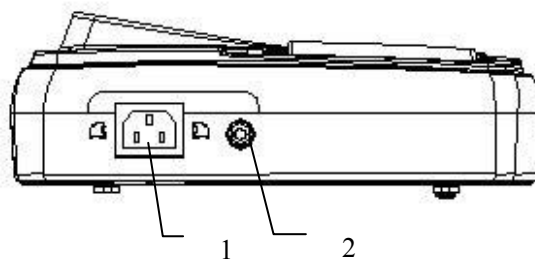
| NO. | Name | Note |
|-----|--|---|
| 1 |  Menu button | Press to enter the main menu interface. |
| 2 |  Working mode switch button | Press to switch the current working mode. |
| 3 |  Waveform gain select button | Press to adjust the ECG waveform gain. |
| 4 |  Filter bandwidth select button | Press to adjust the bandwidth of filter. |
| 5 |  Scan speed select button | Press to adjust the waveform scanning speed and the paper moving speed of recorder. |
| 6 |  Record button | Press to start or stop record. |

1.4.2 Front View

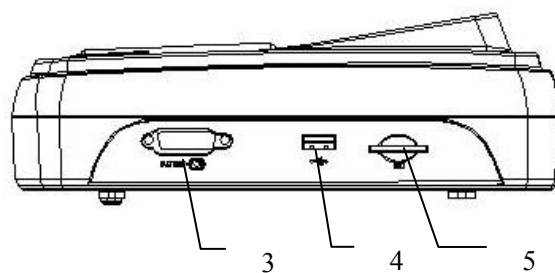


1.4.3 Side View

◆ Left side:

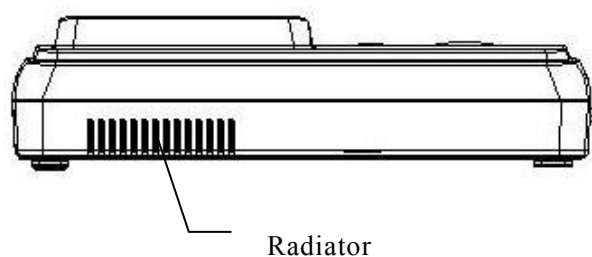


◆ Right side:

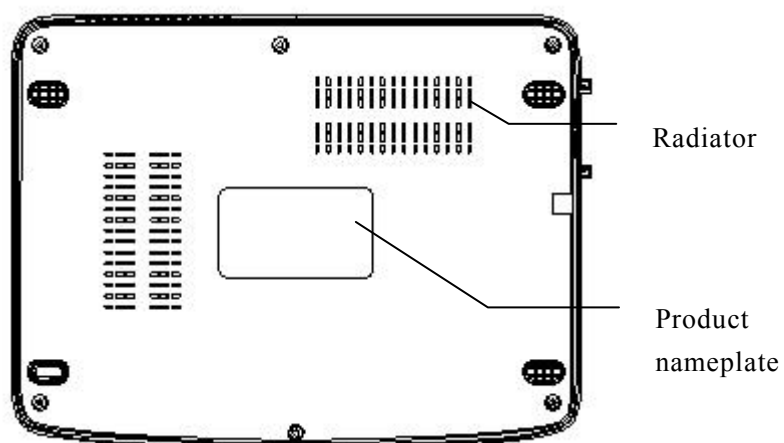


| NO. | Name | Note |
|-----|-------------------------------|---|
| 1 | AC mains socket | Connect to AC power |
| 2 | Equipotent grounding terminal | Connect to the Equipotential grounding system of hospital |
| 3 | Patient cable socket | Connect to patient cable |
| 4 | USB connector | Standard USB connector |
| 5 | SD memory card slot | Can be inserted SD memory card |

1.4.4 Back View

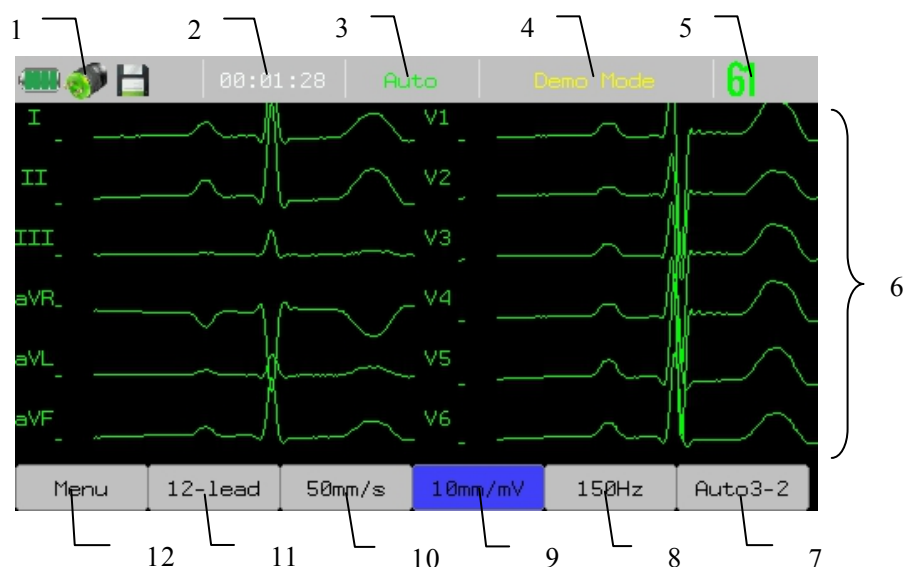


1.4.5 Bottom View



1.5 Screen Display























The following is the main interface of electrocardiograph:



| No. | Display | Note |
|-----|-----------------------------|---|
| 1 | System info area | Including: saving medium prompt, battery capability indicator, AC power on/off prompt and network access prompt. |
| 2 | Current time | The current time of the system is displayed. In the system setup, the current time and display format may be set. |
| 3 | Working mode | The current working mode is displayed, i.e. Auto, Manual, Rhythm. |
| 4 | Prompt info area /Demo mode | <ul style="list-style-type: none"> ◆ Under the normal working mode, systemic info is displayed, i.e. no paper, lead off, print head overheating etc. ◆ Under the Demonstration mode, “Demo” will be shown here. |
| 5 | ECG info | Heart beat and heart rate values are displayed. |
| 6 | Waveform display area | ECG waveform is displayed. |
| 7 | Auto3-2 | Press to select the format of record report. |
| 8 | 150Hz | Press to adjust the bandwidth of filter. 150Hz, 100Hz, 75Hz, 45Hz, 35Hz or 25Hz is optional. |
| 9 | 10mm/mV | Press to adjust the waveform gain. 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV is optional. |
| 10 | 50mm/s | Press to adjust the waveform scanning speed and the paper moving speed of recorder. 50mm/s, 25mm/s, 12.5mm/s, 10mm/s, 6.25mm/s or 5mm/s is optional. |

| No. | Display | Note |
|-----|---------|---|
| 11 | 12-Lead | Press to select the lead number on screen display. 3-Lead, 6-Lead, 12-Lead is optional. |
| 12 | Menu | Press to enter the main menu. |

1.6 Equipment Sign

| Sign | Note | Sign | Note |
|---|--|---|--|
|  | CE mark |  | Dangerous voltage |
|  | Attention: Consult accompanying documents (this manual). |  | Alternating current |
|  | Battery charging indicating lamp |  | Equipment running indicating lamp |
|  | Non-ionizing radiation |  | Equipotential grounding |
| PATIENT  | Patient Cable socket |  | Manufacture date |
|  | USB socket |  | Manufacturer |
| SD | SD Memory card slot | SN | Serial number |
|  | Frangibility, Be careful |  | Avoid drench, Keep dryness |
|  | limitation of heap |  | This end keep upward while moving or storing |
|  | Indicator of U flash disk |  | Indicator of SD card connect |
|  | Indicator of battery capability |  | Indicator of Alternating current |
|  | Type CF applied part, defibrillation protected The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof. | | |
|  | Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC. | | |

Chapter 2 Safety

2.1 Safety Information



Warning:

- Before putting the system into operation, verify that the Cardiograph, connecting cables and accessories are in correct working order and operating condition.
- Use only accessories specified by our company. Using other accessories may cause damage to the Cardiograph.
- Do not open the Cardiograph housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by manufacturer only.
- To avoid explosion hazard, do not use the Cardiograph in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Don't use this device where exists high voltage device or high static electricity, or else, there is fire because of spark.
- Please connect the Cardiograph to a socket with protective earth. If the socket does not have protective earth conductor, please do not use the socket and use battery to provide power to the Cardiograph.
- To avoid burning, when using the ESU device, make sure those electrodes is far away from electrotome.
- Do not let patient come into contact with the sickbed during defibrillation. Please use the ECG cable supplied by our company. It is not suggested to use it with other electrical stimulator device at the same time, if necessary to use at the same time, professional technicians must be present and disposable chest electrode is suggested to use in order to avoid burning skin caused by metal electrode.
- To insure patient safety, leakage current summation caused can't

exceed admit value.

- Please insure all electrodes connected and connect to the right position. Put electrodes and patient away from other electric parts and the earth.
 - To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patient or personnel.
 - Keep the packing materials out of children's reach. Disposal of the packing materials should observe the applicable waste control regulations.
 - Although safe request is considered during device design, but operator must not ignore device status and observing patient. Please especially notice device and patient can't be moved during device working.
 - Device connected to digital and stimulant connector must be validated with each IEC standards (e.g. data processing equipment standard: IEC950, Medical electrical equipment: IEC60601-1), and all the configurations must comply with availability version of IEC60601-1. So the medical system must comply with availability version of IEC60601-1.
 - The electrocardiograph can be directly applied to heart.
-



Caution:

- At the end of its service life, the cardiograph, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the cardiograph, please contact us.
- Magnetic and electrical fields are capable of interfering with the proper performance of the cardiograph. For this reason make sure that all external devices operated in the vicinity of the cardiograph comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
- Before connecting the cardiograph to the power cord, check that the

voltage and frequency ratings of the power cord are the same as those indicated on the cardiograph's label or in this manual.

- **Always install or carry the cardiograph properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
-



Note:

- **Put the cardiograph in a location where you can easily see the screen and access the operating controls.**
 - **Keep this manual in the vicinity of the cardiograph so that it can be obtained conveniently when needed.**
 - **The software was developed in compliance with IEC 60601-1-4. The possibility of hazards arising from software errors is minimized.**
 - **This manual describes all features and options. Your cardiograph may not have all of them.**
-

2.2 General Safety



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

1. Safety precautions for installation

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



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

2. Cardiograph conforms to the safety requirements of IEC 60601-1. This

cardiograph is protected against defibrillation effects.

3. Notes on symbols related to safety



Type CF applied part, defibrillation protected

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

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



Attention! Please refer to the documents accompanying this cardiograph (this manual)!

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

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

6. The device connected to cardiograph must comply with IEC 60601-1 and IEC950. If the cardiograph is connected to other undesignated electrical equipment or devices, safety hazards may occur for causes such as the cumulating of the leakage current.

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



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

2.3 Important Notes for Safety

■ Patient Number

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

■ Interference

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

■ Protection against ingress of liquid

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

■ Accuracy

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

■ Before Use

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

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

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

■ Cables

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

■ Disposal of package

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

■ Explosion hazard

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

or liquids.

■ **Leakage current test**

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

■ **Battery**

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

■ **Disposal of accessories and device**

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

When operating with defibrillator at the same time, cables with defibrillator-proof must be adopted in order to avoid any unwanted damage.

The service life of this electrocardiograph is 5 years. At the end of its service life, the electrocardiograph, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact manufacturer or its representatives.

■ **EMC**

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

■ **Instruction for use**

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

■ **Loss of data**

Should the electrocardiograph at any time temporarily lose patient data, close patient observation or alternative monitoring devices should be used

until electrocardiograph function is restored.

If the electrocardiograph does not automatically resume operation within 60s, restart the electrocardiograph using the power switch. Once monitoring is restored, you should verify correct monitoring state and alarm function.

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

The electrocardiograph can be used together with high-frequency electrotomes and defibrillators. Patient's safety must be ensured during the process.

■ **Prompt**

The machine can give prompts of abnormal status arising from excessive polarization voltage of ECG electrode.

For any question, contact us or native agent.

2.4 Safe Operation Conditions

| | |
|--|--|
| Methods of sterilization or disinfection recommended by the manufacturer | Sterilization: not applicable Disinfection: Refer to <i>Clean and Maintenance</i> Chapter |
| Electromagnetic interference | No mobile telephone nearby |
| Electrosurgical interference damage | No damage |
| Diathermy instruments influence | Displayed values and prints may be disturbed or erroneous during diathermy |
| Defibrillation shocks | The electrocardiograph specifications fulfill the requirements of IEC 60601-2-25. |

<This page is blank>

Chapter 3 Getting Started

3.1 Unpacking and Checking

1. Unpacking

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

2. Remove the electrocardiograph and accessories carefully.

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

4. Check the electrocardiograph and accessories

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



Warning:

- **Keep the packing materials out of children's reach. Disposal of the packing materials should observe the applicable waste control regulations.**
 - **The electrocardiograph might be contaminated during storage and transport. Before use, please verify whether the packages, especially the package of disposable accessories, are intact. In case of any damage, do not apply it to the patient.**
 - **Please ensure the electrocardiograph is working under specified Conditions; otherwise, the technical specifications mentioned in this manual will not be met, thus possibly leading to damage of equipment and other unexpected results.**
-



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


3.2 Power Supply

3.2.1 AC Power Supply

- ⇒ AC power: AC 100V-240V, 50Hz/60Hz.
- ⇒ Take out the accessory power cord, and insert the plug of output end into the AC power socket at back panel of Electrocardiograph, and insert the plug of input end into a grounded three-phase power socket (a specialized socket of hospital is required), and ground the machine via ground wire (protective grounding) of power cord.
- ⇒ If AC power is ON, the AC power indicator on Electrocardiograph will turn on, showing the status of AC power. If the battery status indicator is ON in orange, it shows that rechargeable battery is being recharged.
- ⇒ After turning on the machine startup button, the equipment running indicator on Electrocardiograph will turn on; indicator in green glitters in startup process or standby status; indicator in green will be always ON if the machine has started normal running.



Caution:

- **The electrocardiograph does not have mains switch. The electrocardiograph is switched completely only by unplugging the power cable from the AC power source.**
 - **Connect electrocardiograph to Equipotential grounding system. Use the green/yellow Equipotential grounding cable and connect it to the terminal labeled with the  symbol.**
-

3.2.2 Battery Power Supply

- ⇒ Electrocardiograph is equipped with recharge battery for power supply to Electrocardiograph in case of AC power interruption.
- ⇒ Please charge up battery before use. No external charger is provided. Rechargeable battery can be charged up when Electrocardiograph is connected to AC power. To ensure full charging of battery for use at any time, we suggest keeping Electrocardiograph connected to AC power socket at all times.
- ⇒ When many AC disturbances are found during test, the mode of battery

- power supply may be adopted to maintain the equipment operation. In this way, the impact of AC disturbances may be reduced.
- ☐ For the power supply period of battery, see the product specification.
- For battery maintenance, please refer to the section of **Battery**.

3.3 Placing Cables

Insert patient cable pin into patient cable socket on the right side, and tighten the screw.

3.4 Placing Electrodes

3.4.1 Skin Preparation for Electrode Placement

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

1. Select sites with intact skin, without impairment of any kind.
2. Clip or shave hair from sites as necessary.
3. Gently abrade the skin to remove dead skin cells to improve the conductivity of the electrode site.
4. Wash sites thoroughly with soap and water, leaving no soap residue.
(We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.)
5. Dry skin thoroughly.

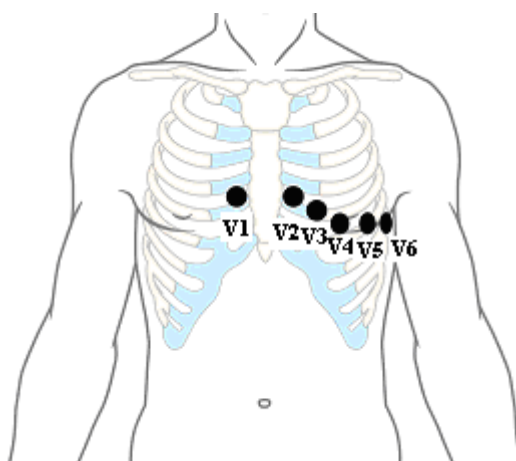
3.4.2 Placing Electrode

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

| Electrode labels (IEC) | Electrode colors (IEC) | Electrode Labels (AAMI) | Electrode colors (AAMI) | Position |
|------------------------|------------------------|-------------------------|-------------------------|---|
| R | Red | RA | White | sword arm (Inside) |
| L | Yellow | LA | Black | Left arm (Inside) |
| N | Black | RL | Green | Right leg (On crus, midpoint between knee and ankle.) |
| F | Green | LL | Red | Left leg (On crus, midpoint between knee and ankle) |
| C1 | Red | V1 | Red | On the fourth intercostal space at the right sternal border |
| C2 | Yellow | V2 | Yellow | On the fourth intercostal space at the left sternal border |
| C3 | Green | V3 | Green | Midway between the V2 and V4 electrode positions |
| C4 | Brown | V4 | Blue | On the fifth intercostal space at the left midclavicular line |
| C5 | Black | V5 | Orange | On the left anterior axillary line, horizontal with the V4 electrode position |
| C6 | Violet | V6 | Violet | On the left midaxillary line, horizontal with the V4 electrode position |

◆ Emplacing of chest electrodes

In general, 6 electrodes are placed on chest based on the intervals of ribs. Taking the American standard as an example, the emplacing positions of electrodes V1-V6 are shown in the figure below:



Please refer to the following steps at the time of connecting chest electrodes:

1. Check whether the electrodes are clean and intact;
2. Clear up lead wire to avoid twisting, and firmly connect the electrode connector to electrodes;
3. Wipe up with alcohol the skin where electrodes will be placed;
4. Evenly spread the conductive paste in a diameter of about 25mm at each position on chest where electrodes will be placed;
5. Evenly spread a thin layer of conductive paste at the edges of chest electrode suction balls;
6. Place the electrodes on skin and squeeze the rubber balls, and then loosen the rubber balls, so the electrodes will be adsorbed on the corresponding positions on chest.

◆ **Emplacing of electrodes on limbs**

Limb electrodes shall be placed at the positions with close contact with skin such as upper side of wrist and upper inner side of ankle. Please refer to the following steps at the time of connecting limb electrodes:

1. Check whether the electrodes are clean and intact;
2. Clear up lead wire to avoid twisting, and firmly connect the electrode connector to electrodes;
3. Wipe up with alcohol the skin where electrodes will be placed;
4. Evenly spread the conductive paste on skin;
5. Evenly spread a thin layer of conductive paste on the surface of limb electrodes;
6. Properly place the electrodes on skin.

! Caution:

- The conductive paste shall not be used excessively and the spreading layers shall be separated; otherwise, electrode short-circuit will be caused, resulting in ECG signal record error.
 - Patients and the machine can be connected via lead and electrode only.
 - If ECG waveform does not appear during long period, please confirm whether electrodes are in good contact with skin.
-

3.5 Install the chart paper

When the chart paper is not installed or is used up, “no paper” will be shown on the screen of Electrocardiograph to remind the users of installing or replacing the chart paper. Refer to the following steps during installation.

- 1) Press down the paper pin open button to open the paper pin:



- 2) Remove the packaging of new chart paper, and then place the chart paper into recorder box.



- 3) Pull out about 2cm chart paper from the paper outlet of recorder, keep the

thermosensitive side (printed with grids) downward.



- 4) Close the paper pin, you will hear a sound of “ka” which indicates the recorder box is well closed and the installation is completed.

! Caution: The storage of chart paper shall meet the following requirements:

- Chart paper shall be stored at a dry cool place to prevent from high temperature, humidity and direct sunlight.
 - Do not overlap for long period the chart paper with recorded waveform; otherwise, the recorded waveforms will blot each other.
 - Please use the chart paper provided by the manufacturer; otherwise, the lifespan of thermosensitive recording head of printer will be shortened.
-

3.6 Inspecting Before Starting

Please read the manual carefully before using the electrocardiograph, be familiar with the function, operations and notes. Check the following contents before starting up.

1. Environment

Make sure the electrocardiograph will not be interfered by electromagnetic radiation. Mobile phones, X-rays or MRI equipment are all possible interference sources, because they can produce high-intensity electromagnetic radiation. The room temperature should be kept warm (above 18°C) to avoid ECG interfere caused by cold.

2. Power supply

Please check whether power cord and device connect well before using AC power.

3. Earthing

Please check the earthing line connected well.

4. Cable

Please check the cable pin connected firmly, and avoid cable close to AC power cord. Check the cable connects to the corresponding electrodes.

5. Electrode

Please check electrode placed firmly. And insure the chest electrodes are not contact each other.

6. Recording paper

Please check the recording paper enough and be putted right.

7. Patient

Make sure patient doesn't contact the metal part of the bed, the room condition is comfortable and the patient is relaxed. Ask the patient to release body and breathe calmly.


Chapter 4 Operation Instruction

4.1 Turn On/Off

◆ Using AC power supply:

——Turn on: Press the power button after connecting the power cord, the screen displays the start interface, and then enter work mode.

——Turn off: Press power button, and screen will display “The device is shutting off...”, when the prompt info is over, the device is power off. Then unplug the power pin.

 **Note: When powering off is not work, pressing power button lasting 5s can force to turn off.**

◆ Using battery:


——Turn on: Press the power button, the screen displays the start interface, and then enter work mode.

——Turn off: Press power button, and screen will display “The device is shutting off...”, when the prompt info is over, the device is power off.

Warning:

- **Advert to status of patient and device at any moment;**
 - **If the electrocardiograph is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient. Contact your service personnel.**
-

4.2 Main Menu

Enter the monitor interface by press the power button of the Electrocardiograph, then press the “” button to enter the main menu. Shown as following chart:

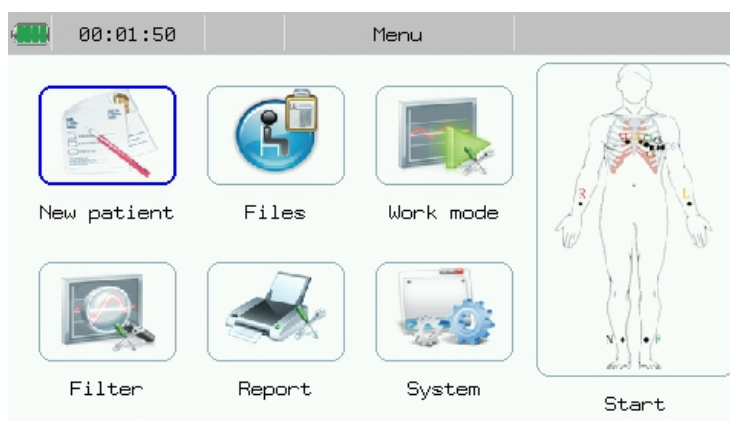


Fig.4-1: Main Menu

4.3 Patient Info Setup

Press **【New patient】** in main menu to enter patient info setup interface. Shown as following chart:

Fig.4-2: Patient info setting

In the interface, you may conduct the following operations:

- **【ID】** : Input patient ID.
- **【Race】** : Select patient race.
- **【Name】** : Input patient name.
- **【Gender】** : Select patient gender.
- **【Age】** : Input patient age. (Range: 0-200)
- **【Paced】** : Setting the paced status, if the patient is paced patient, you should set to **【Yes】** .
- **【Height】** : Input patient heights. Unit: “cm” or “inch”
- **【Weight】** : Input patient weight. Unit: “Kg” or “pound”
- **【Medicine】** : Input medicine patient taken.

After setting patient info, select **【OK】** .

Patient ID has a default value which indicates after the current case, the

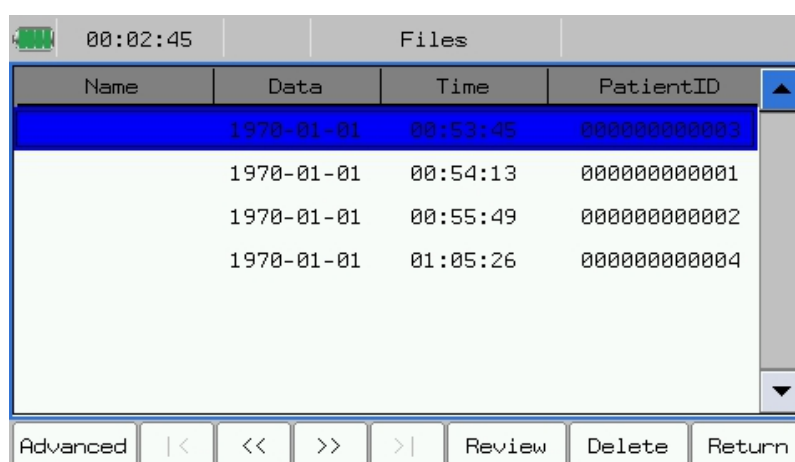
patient ID will plus one automatically.

4.4 File Management

4.4.1 File Management Interface

Electrocardiograph can store and manage more than 300 shares of patient data. It can review, edit, record, delete or transmit patient data in file management window. Data stored including the ECG waveform and ECG report with patient info.

Press **【Files】** in main menu to enter file management interface. Shown as follows:



| Name | Data | Time | PatientID |
|------------|----------|--------------|-----------|
| 1970-01-01 | 00:53:45 | 000000000003 | |
| 1970-01-01 | 00:54:13 | 000000000001 | |
| 1970-01-01 | 00:55:49 | 000000000002 | |
| 1970-01-01 | 01:05:26 | 000000000004 | |

Advanced |< << >> >| Review Delete Return

Fig.4-3: File management interface

In the interface, you may conduct the following operations:

- Select **【Advanced】** : Prompt the following sections, Turn up one page of contents displayed by interface. Includes: Query, List All, Delete All, File Transmit. (Select the **【File Transmit】** to transfer the selected patient data to the save medium such as SD card, U disk or Flash.)
- Select **【|<】** :Turn up one page of contents displayed by interface.
- Select **【>|】** :Turn down one page of contents displayed by interface.
- Select **【<<】** :Move the cursor to select the previous case.
- Select **【>>】** : Move the cursor to select the next case.
- Select **【Review】** :Enter the review interface.
- Select **【Delete】** :Can delete the selected content. After you choosing a patient data, press this key, the system can spring a dialog box, and then you can choose **【OK】** to delete the data.
- Select **【Return】** :Back to the main menu.

4.4.2 File Review

After choosing a patient data in file management interface, Press **【Review】** can enter the following file review interface.



Fig.4-4: File Review--Waveform

In the interface, you can select **【Wave】** or **【Text】** to review the waveform or text info. Shown as follows:



Fig.4-5: File Review--Text display (Patient Info)

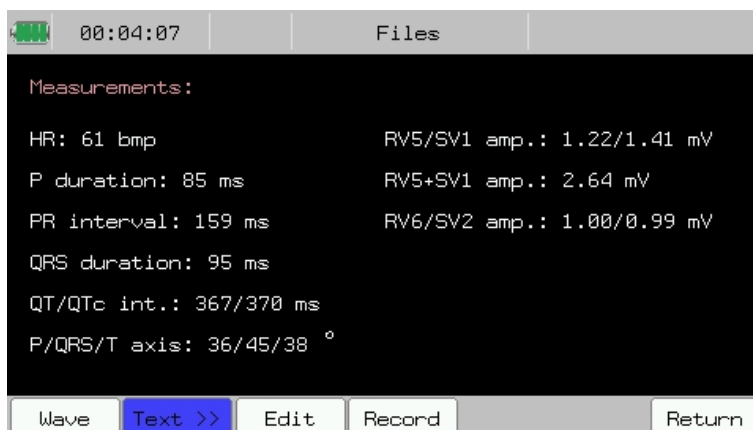


Fig.4-6: File Review--Text display (Measure Result)

In the figure4-4 to 4-6, you may conduct the following operations:

- Select **【Edit】** : Can change patient info saved in file.
- Select **【Record】** : Can record the current ECG report.
- Select **【Return】** :Back to the previous interface.

4.4.3 File Edit

Press **【Edit】** in file review interface to enter patient info edit interface. You can edit the patient info according to the following chart:

The screenshot shows a patient information editing screen titled 'New patient'. It contains several input fields: ID (000000000005), Race (Unknown), Name (cady), Height (170 cm), Gender (Male), Weight (60 Kg), Age, and Medicine. There are OK and Cancel buttons at the bottom.

Fig.4-7: Edit—Patient Info

This patient info inputting may only be effective on selected file.

4.5 Work Mode Setup

In main interface, you can switch electrocardiograph's work mode by pressing **【Work mode】**. Work mode contains: Auto mode, Manual mode and Rhythm mode. In this interface, you can set the parameters of Auto style, Manual style, Rhythm style and Rhythm leads. Shown as following chart:






The screenshot shows a work mode setup screen titled 'Work mode'. It contains settings for Auto style (Auto3-2), Manual style (Man1), Rhythm style (Rhy1), Rhy-lead1 (I), Rhy-lead2 (II), and Rhy-lead3 (III). There are Default, OK, and Cancel buttons at the bottom.

Fig.4-8: Work Mode Setup

4.5.1 Auto Mode

During ECG recording in Auto mode, the lead group will switch over automatically in order, i.e. after the recording of ECG signals of leads in a group is completed within the specified period, the machine will switch over automatically to the next lead group and begin to record the ECG signals of the next lead group. Before recording ECG signals, 1mV calibration is conducted automatically, and mark is added on chart paper.






Operating refers to the following steps:

1. Before recording, enter the patients' info.
2. Press “” on the panel to switch the working mode into Auto mode.
3. After select **【Work Mode】** in main interface, you can select **【Auto style】** according to actual needs, then press **【OK】** to complete the setup. Or you can just press **【Auto3-2】** to select the proper report format below the monitor interface directly.
4. Press “/” on the panel to start recording. The machine will stop automatically after a complete ECG diagram is recorded.
5. To stop recording in the course of recording, press “/” on the panel.

4.5.2 Manual Mode

In manual mode, users may select lead group according to actual needs, and conduct different setups of recording parameters or other parameters for different lead groups.






Operating refers to the following steps:

1. Before recording, enter the patients' info.
2. Press “” on the panel to switch the working mode into Manual mode.
3. After select **【Work Mode】** in main interface, you can select **【Manual style】** according to actual needs, then press **【OK】** to complete the setup. Or you can just press **【Man1】** to select the proper report format below the monitor interface directly.
4. Press “/” on the panel to start recording.
5. To stop recording in the course of recording, press “/” on the panel.

4.5.3 Rhythm Mode

In Rhythm mode, users may select lead according to actual needs, and record the rhythm waveform of single lead within 60s or rhythm waveforms of 3 leads within 20s each.

Operating refers to the following steps:

1. Before recording, enter the patients' info.
2. Press “” on the panel to switch the working mode into Rhythm mode.
3. After select **【Work Mode】** in main interface, you can select **【Rhythm style】** and **【Rhy-lead】** according to actual needs, then press **【OK】** to complete the setup. Or you can just press **【Rhy1】** to select the proper report format below the monitor interface directly.
4. Press “/” on the panel, the prompt info area will display “Sampling...”, and timing the sample time. It will start to draw when the time reaches 60s or 20s.
5. The machine will stop automatically after a complete rhythm diagram is recorded.
6. To stop recording in the course of recording, press “/” on the panel.

! Caution: Please check whether there is any error message shown on the screen before start recording. If electrodes fall off displayed, check whether the corresponding electrode is well connected with patient or the polarized voltage overtops. If unconnected electrodes displayed, check whether RA electrode is well connected with patient or the cables is well connected with machine. If message still exists, maybe there is a broken circuit within patient cable, please replace the cable with a new one.

4.6 Filter Setup

Set the filter parameters of Electrocardiograph in order to improve the ECG anti-disturbance performance. Filters include Power frequency filter, Baseline drift filter, EMG filter and Lowpass filter.

- ◆ AC filter: Resist interference of AC power to prevent attenuation or

distortion of ECG signal.

- ◆ DFT filter: Resist drift of baseline to ensure that ECG signal is on baseline at the time of recording.
- ◆ EMG filter: Resist interference to ECG signal caused by strong muscle fibrillation. When EMG filter is in use, lowpass is **【Off】**.
- ◆ Lowpass filter: Restrict the bandwidth of input signal and attenuate the signals higher than the cut-off frequency. When lowpass is in use, EMG filter is **【Off】**.

In main interface, press **【Filter】** to enter the filter setup interface. Shown as following chart:

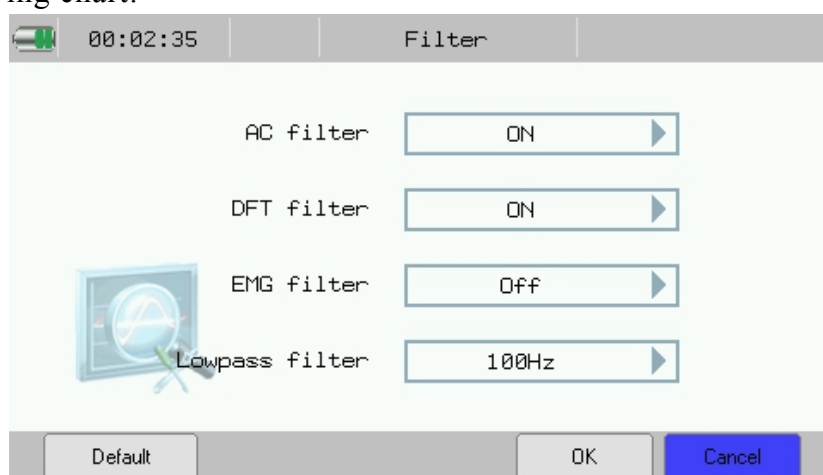


Fig.4-9: Filter Setup

In this interface, you may conduct the following operations:

- Select **【AC filter】**: Select **【On】** or **【Off】** to turn on/off the status of power frequency filter. According to the frequency of AC mains supply, the Factory Default Setting can be set to “50Hz” or “60Hz”.
- Select **【DFT filter】**: Select On/Off to turn on/off the baseline drift filter. When the unstability of baseline is found, it is suggested to open the baseline drift filter in order to eliminate the drift of baseline or the other interference without any distortion of ECG wave, greatly enhance the ability of resist the drift of baseline and also convenient for the interpretation of the waveform, DFT will shown in the chart paper when the baseline drift filter is on, the frequency of baseline drifter filter with the value of 0.05Hz will displayed when the baseline drift filter is off.
- Select **【EMG filter】**: Cut-off frequency is optional. Options: 25Hz, 35Hz or 45Hz.
- Select **【Lowpass filter】**: Cut-off frequency is optional. Options: 75Hz,

100Hz or 150Hz.

After setup of filter, select **【OK】**.

Caution: The setups of EMG filter and lowpass are mutually exclusive, i.e. only one setup is effective at the same time.

4.7 Report Info Setup

The users may set the relevant information of recorder. Press **【Report】** in main interface to enter report info setup interface. Shown as following chart:

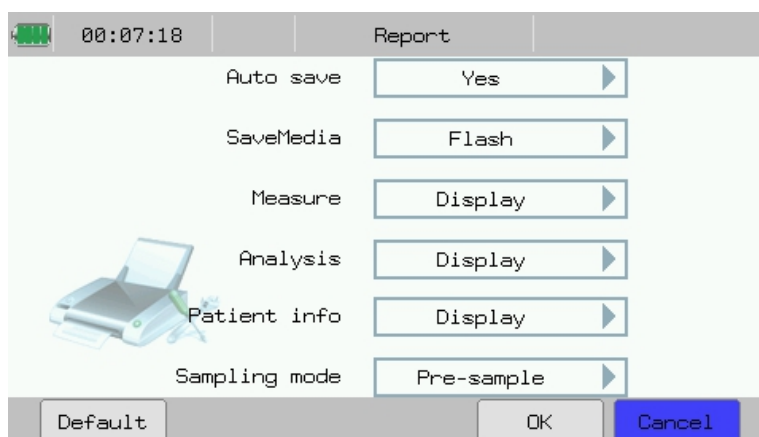


Fig.4-10: Report Info Setup

In the interface, you may conduct the following operations:

——Select **【Auto save】**: May select **【Yes】** or **【No】**. When **【Yes】** is selected, the relevant data may be automatically saved at designated location of system after recording of a patient.



——Select **【Default medium】**: May select one auto save medium according to actual needs, i.e. Flash, SD card or U disk.



——Select **【Measure】**: May select **【Display】** or **【Not display】**. Result of the ECG waveform measurement will be exported while selecting **【Display】**, otherwise, it will not.

——Select **【Patient info】**: May select **【Display】** or **【Not display】**. Record of the ECG data collected will be exported while selecting **【Display】**, otherwise, it will not.

——Select **【Sampling mode】**: Optional: Pre-sample, Real-time sample and Trigger sample.

1) When **【Pre-sample】** is selected, collection of ECG data begins as

soon as lead is connected to patient; it is unnecessary to wait for the user to press “/▽” before beginning collection of ECG data. When the user press “/▽”, record of the ECG data collected within 10s before pressing this key will be exported;

- 2) When **【Real-time sample】** is selected, if the user press “/▽”, record of the ECG data collected within 10s after pressing this key will be exported;
- 3) When **【Trigger sample】** is selected, if the user press “/▽”, Electrocardiograph will automatically trigger record once in case of arrhythmia.

After setup of report info, select **【OK】** . If **【Default】** is selected, the device will resume the default set of manufacturer.

4.8 System Setup

Press **【System】** in main interface to enter system setup interface. Shown as following chart:

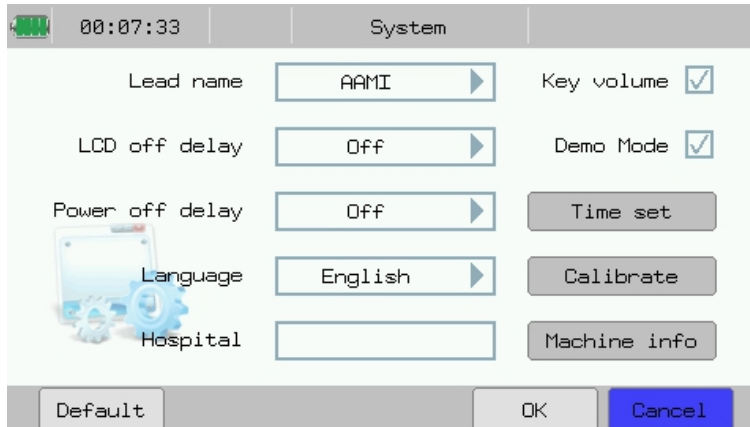


Fig.4-11: System Setup

In the interface, you may conduct the following operations:

- Select **【Lead name】** : May select lead name displayed. Optional: **【AAMI】** or **【IEC】** .
- Select **【LCD off delay】** : Set the automatic shut-off time of LCD of Electrocardiograph. After LCD shuts off automatically, press any key to reactivate LCD screen. Optional: 10 minutes, Half an hour, 1hour, 4hours, Off.

——Select **【Power off delay】** : Set the automatic shut-off time of the Electrocardiograph in case of power supply by built-in battery. Optional: 10 minutes, Half an hour, 1hour, 4hours, Off.

——Select **【Language】** : May select the language of electrocardiograph displaying or the language using for ECG recording according to actual needs.

——Select **【Hospital】** : May input hospital's name, it will be displayed in ECG report.


——Select **【Key volume】** : May open or close the volume of key sound.

——Select **【Demo Mode】** : May start or shut the demonstration mode according to actual needs.

——Select **【Time set】** : Enter into the time set interface, refer to **4.8.1** section for details.

——Select **【Calibrate】** : Calibrate the touch screen. Complete the calibration by following the prompt steps displayed on the screen.

——Select **【Machine info】** : See the version info of the device.

 **Note:** When **【Power off delay】** or **【LCD off delay】** is off, both of the functions are useless. The electrocardiograph will enter into the status of “standby” or “power off” if the device is not been used within the preset time of **【LCD off delay】** or **【Power off delay】** .

4.8.1 Time Setup

In the system setup interface, press **【Time set】** to enter the time set interface. Shown as following chart:

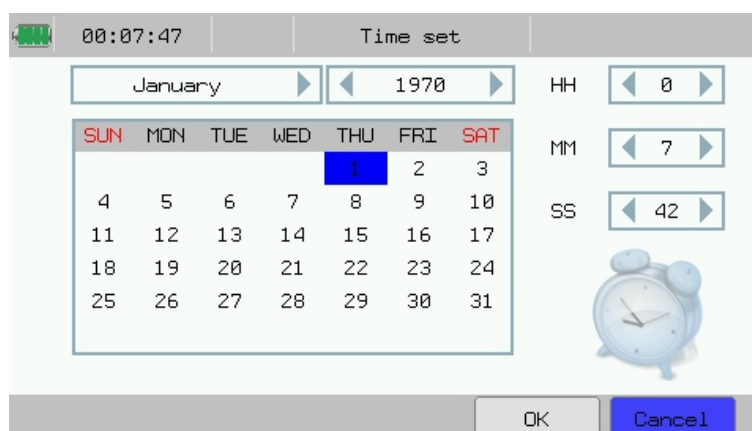


Fig.4-12: Time Setting

In the interface, you may conduct the following operations:

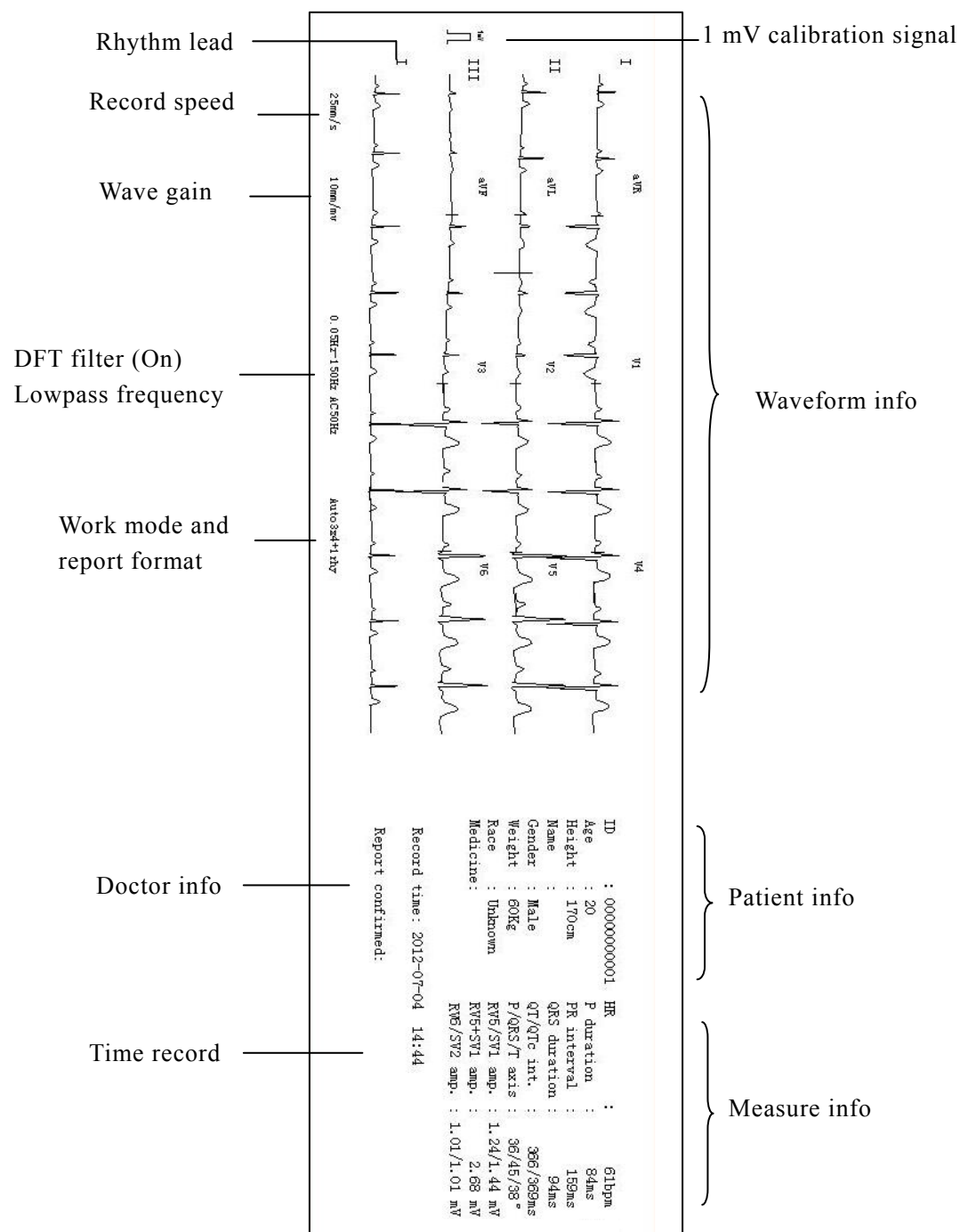
——Select respectively **【Year】** / **【Month】** / **【Day】** / **【HH】** / **【MM】** / **【SS】** : Users can set the current data and time.

After setup of Date-Time, select **【OK】** .

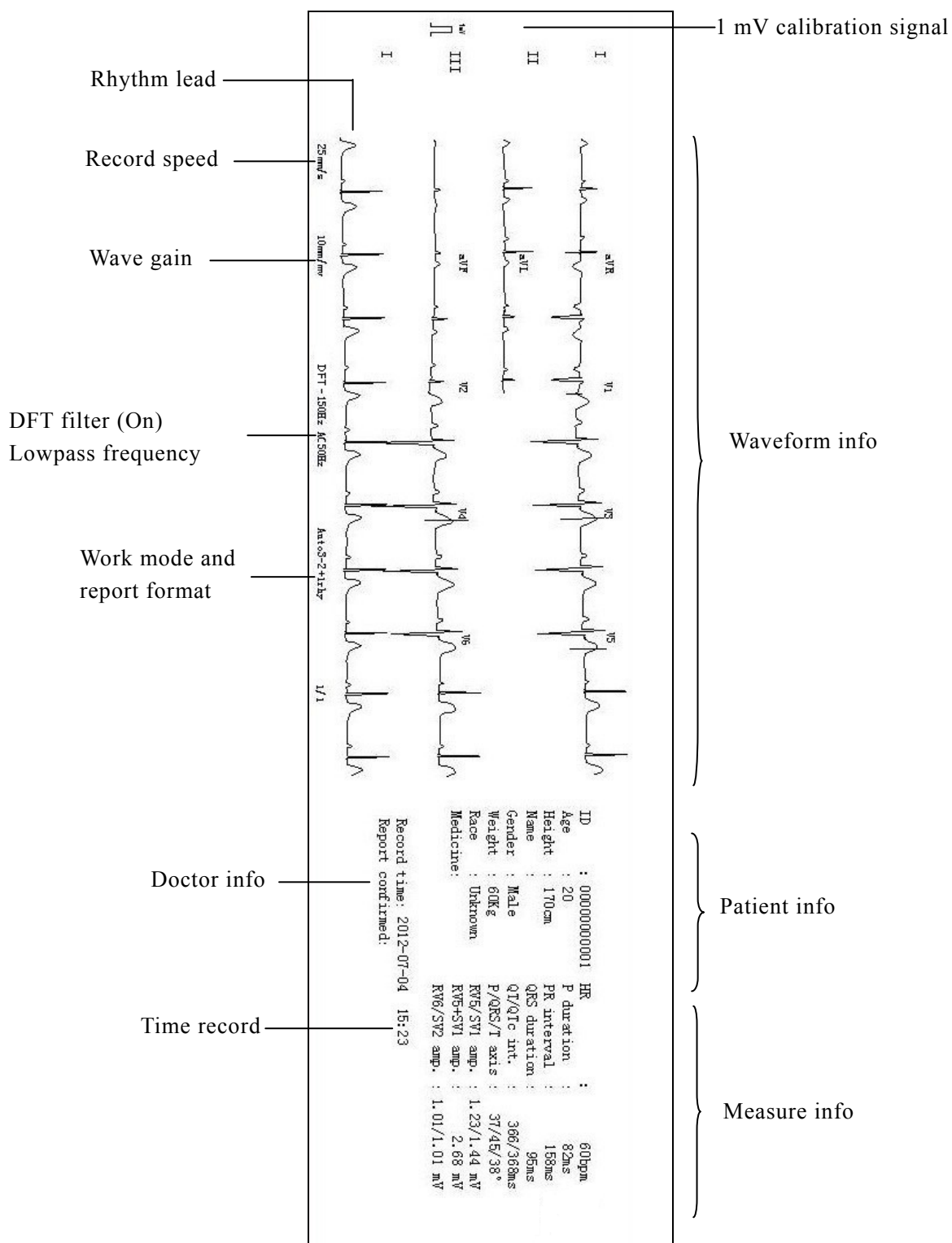
Chapter 5 Read the Printed ECG Report

This chapter describes the printed report of the Electrocardiograph in each mode.

◆ The chart below is the ECG report of Auto 3×4+1 in Auto mode:



◆ The chart below is the ECG report of Auto 3-2+1 in Auto mode:

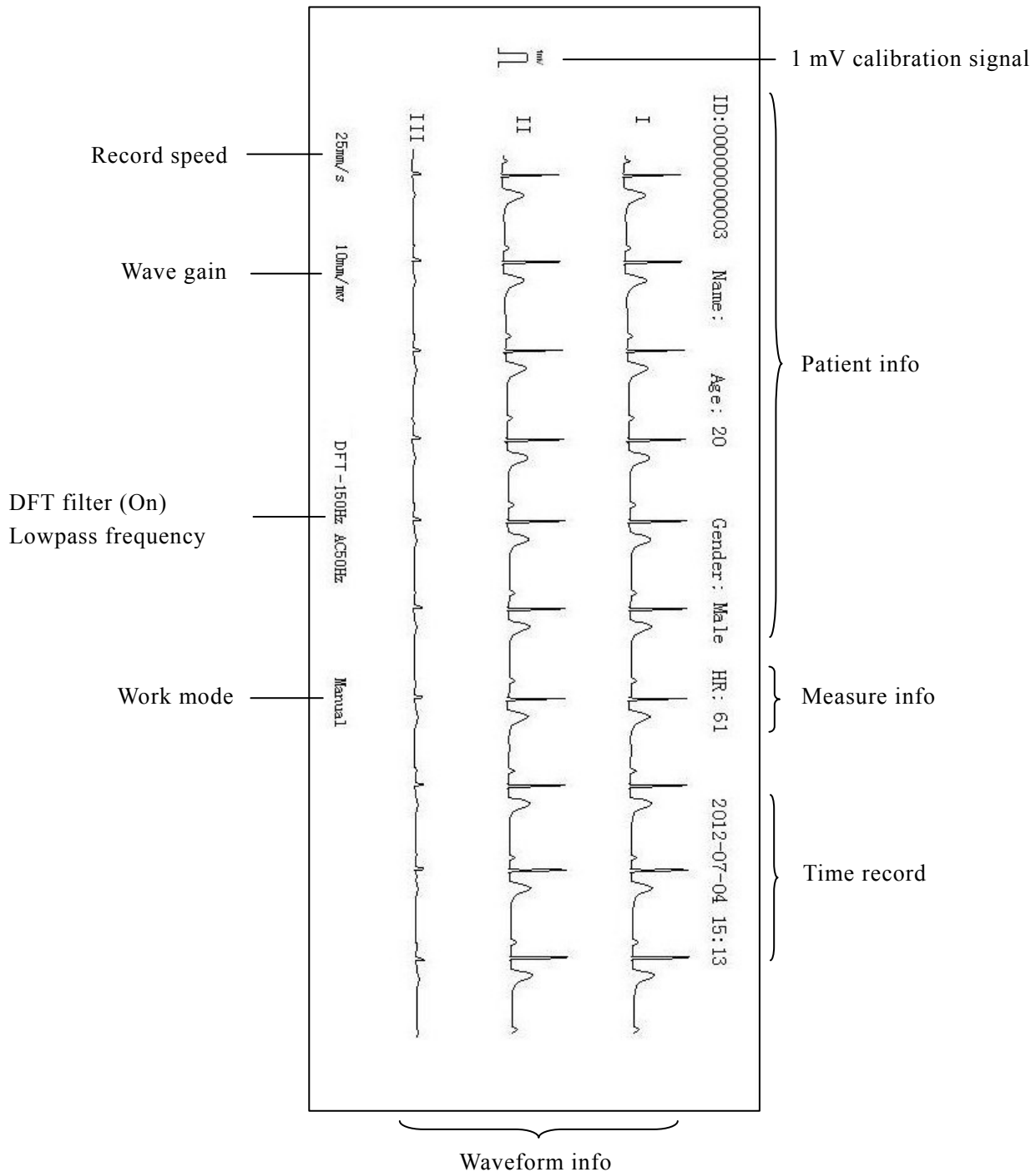


The “+1” in Auto mode indicates that one rhythm lead will be displayed.

In manual mode, real-time recording of ECG waveform is conducted manually according to the requirements of users, and start and stop of

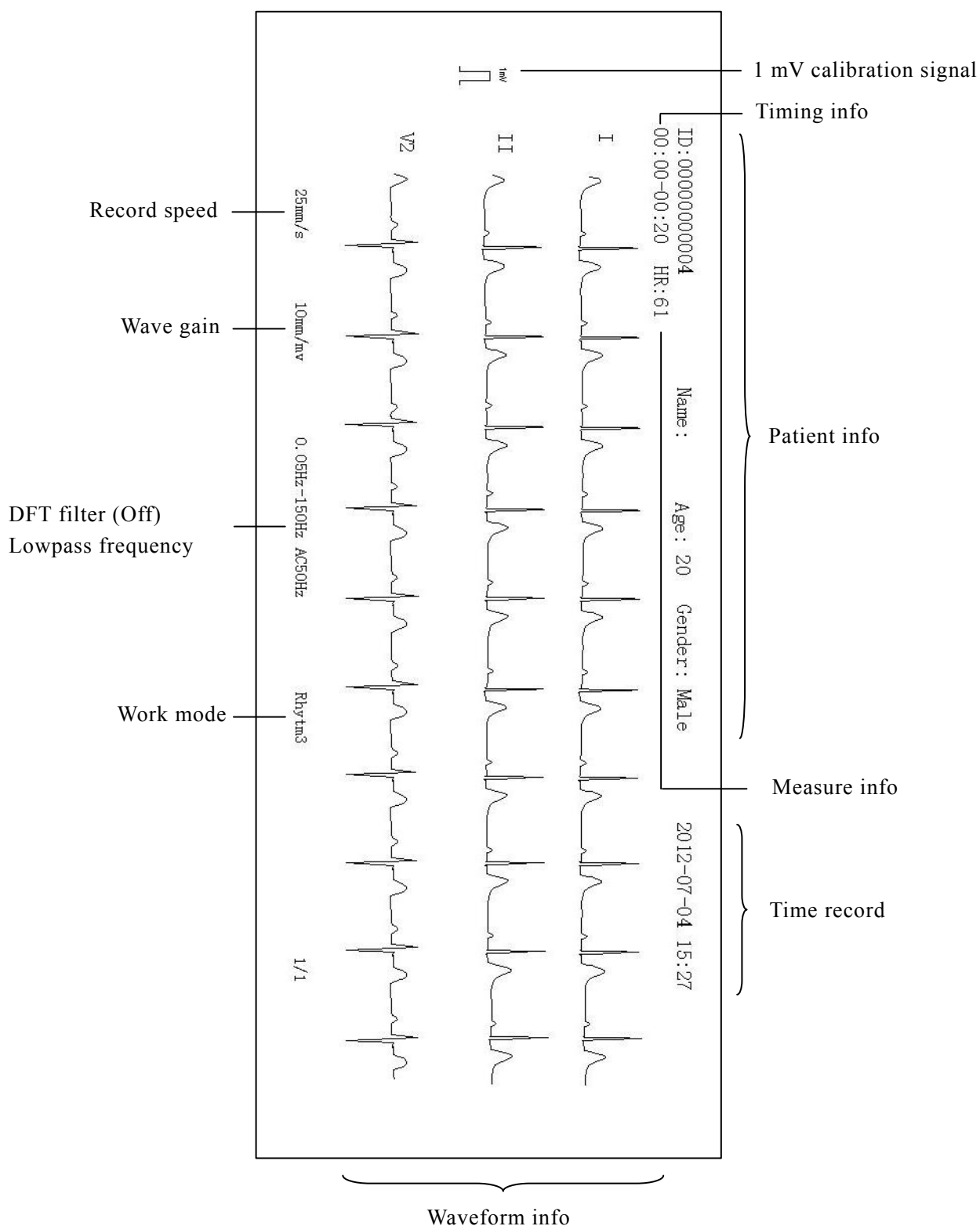
recording are controlled via keys. Optional: Manual 1(display waveform of lead I ~III), Manual 2(display waveform of lead aVR~aVF), Manual 3(display waveform of lead V1~V3), Manual 4(display waveform of lead V4~V6).

◆ The chart below is the ECG report of Manual 1 in Manual mode:



In Rhythm mode, specific lead rhythm is analyzed. Optional: single-rhythm lead mode and 3-rhythm lead mode.

◆ The chart below is the ECG report of 3-rhythm lead in Rhythm mode:



Report info in each mode is different, the description hereinafter is being written according to the most comprehensive info.

A. Patient info contains:

Patient number (ID), name, age, gender, height, weight, blood pressure, race, room number and medicine in use.

B. Measurement info includes:

——HR (heart rate);

——P time limit (average of P wave time limit of average heart beat of many leads);

——PR time limit (average of PR interphase of average heart beat of many leads);

——QRS time limit (average of QRS wave time limit of average heart beat of many leads);

——QT/QTc interphase (average of QT interphase of average heart beat of many leads/ normalized QT interphase);

——P/QRS/T ECG axis (ECG axis refers to the dominant direction of average integrated ECG vector on face);

——RV5/SV1 amplitude (maximum amplitude in R and R'waves of average heart beat of lead V5/ maximum of absolute amplitude value in S and S' waves of average heart beat of lead V1);

——RV5+SV1 amplitude (sum of RV5 and SV1);

——RV6/SV2 amplitude (maximum amplitude in R and R'waves of average heart beat of lead V6/ maximum of absolute amplitude value in S and S'waves of average heart beat of lead V2).

C. Diagnosis information: Result of automatic diagnosis is displayed.



Caution:

The users should pay attention to the following aspects during measurement of ECG waveform:

- When the interference of EMG or AC power is comparatively big, the identification of P wave and Q wave is unreliable sometimes; due to baseline drift, the identification of ST section and T wave is possibly unreliable.
- The terminal positions of S wave and T wave are curved and unclear, resulting in measurement errors sometimes.
- If missing of check of R wave is caused by some lead fall-off and QRS low voltage, the measurement of HR will possibly have big error.

- In case of QRS low voltage, the calculation of ECG axis and the dividing point identification of QRS wave are unreliable sometimes.
 - Frequent ventricular extrasystole is occasionally regarded as representative heart beat through checkup.
 - Identification of P wave is difficult in case of combined arrhythmia, and the relevant parameters are possibly unreliable.
-

Chapter 6 Battery

6.1 Introduction

The electrocardiograph can be fitted with rechargeable battery to ensure its continuous work after the failure of alternating current power supply, and the battery needs no special maintenance under the normal condition. While the electrocardiograph is connecting with alternating current power, no matter whether the electrocardiograph is operating or not, the battery always can be charged. In the event of sudden being powered off, the electrocardiograph will automatically get power supply from battery without interruption of monitoring work.

Indicative message on top left corner of the screen will display battery states:



Indicate that the battery is fully charged.



Indicate that the battery is half charged.



Indicate that the battery is low charged.



Indicate that the battery is almost depleted and need to be charged immediately.

The battery icon will flash while charging.

! Caution: The electrocardiograph is equipped with built-in battery, no special battery maintenance is needed by user, if there is any question, please contact manufacturer or its representatives.

6.2 Optimizing Battery Performance

A battery needs at least two optimizing cycles when it is put into use for the first time. A battery cycle is one complete, uninterrupted charge of the battery, followed by a complete, uninterrupted discharge of the battery. A battery should be conditioned regularly to maintain its useful life. Condition a battery

once when it is used or stored for two months, or when its run time becomes noticeably shorter.

To optimize a battery, follow this procedure:

1. Disconnect the electrocardiograph from the patient and stop all monitoring and measuring procedures.
2. Connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
3. Remove the AC mains and allow the electrocardiograph to run from the battery until it shuts off.
4. Replace the electrocardiograph in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
5. The optimizing of the battery is over.

6.3 Checking Battery Performance

The performance of a battery may deteriorate over time. To check the performance of a battery, follow this procedure:

1. Disconnect the electrocardiograph from the patient and stop all monitoring and measuring procedures.
2. Connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
3. Disconnect AC mains and allow the electrocardiograph to run on the battery until it shuts off.
4. The operating time of a battery reflects its performance directly.

6.4 Disposing Batteries

Batteries that are damaged or depleted should be replaced and discarded properly. Dispose of used batteries according to local regulations.

! **Caution: The service life of battery depends on the service time and frequency. This electrocardiograph battery can be charged and discharged for 300 times generally.**



Warning:

- **Do not random remove battery, place battery at a place with open flame or cause short circuit of battery. Combustion or explosion of battery or leak of battery electrolyte is possible to result in personal injuries.**
 - **In case built-in rechargeable battery reaches the time limit of service life or is damaged, the user shall timely contact the local maintenance engineer or manufacturer for replacing with new battery;**
 - **In case of leak of battery electrolyte or unpleasant smell, the user shall immediately go away from the battery; in case of battery electrolyte drips onto clothes or skin, the user shall immediately rinse with clean water; in case battery electrolyte enters into eye, the user shall immediately rinse with clean water and see a doctor instead of rubbing the eye.**
 - **Do not cut battery with metal chisel, hammer or knock battery or otherwise damage battery; otherwise, there will be risks due to heating, smoking, distortion or combustion of battery.**
-

<This page is blank>

Chapter 7 Clean and Maintenance

7.1 Summarize

☞ Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

1. Always dilute according the manufacturer's instructions or use lowest possible concentration.
2. Do not immerse part of the equipment in the liquid.
3. Do not pour liquid onto the equipment or accessories.
4. Do not allow liquid to enter the case.
5. Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

☞ In order to guarantee the normal operating life-span of the device, safety tests in a 6~12 month cycle should be taken. The main contents of test are shown as below:

1. Validating the functions of the electrocardiograph according to the user's manual.
2. Checking whether the electrocardiograph or the accessories is damaged.
3. Processing relevant safety tests according to IEC 60601-1.
4. User should processing a regular test for the sensitivity of device according to actual needs, the method of sensitivity regular testing is shown as below:

Put on a external pace voltage (risetime no greater than 5ms, amplitude of $1\text{mV} \pm 0.01\text{mV}$) to the I , II , V1~V6 leads of the electrocardiograph, in order to determine whether the calibration voltage error is within the range of 5% through the recorded waveform.



Warning: Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.



Caution: If you spill liquid onto the equipment or accessories, contact manufacturer or your service personnel.

7.2 Cleaning of the Electrocardiograph

- ⇒ Common detergent and non-corrosive disinfectant used in hospital can be applied to clean electrocardiograph, however you must be aware that many kinds of detergents must be diluted prior to utilization, and please use it according to the instruction of detergent manufacturer.
- ⇒ Avoid the use of alcohols, amino or acetonyl detergent.
- ⇒ The enclosure and screen of electrocardiograph shall be free of dust, and they can be wiped with lint-free soft cloth or sponge soaked in detergent. While cleaning, be careful and do not spill liquid onto the instrument and keep any liquid out of it. When wiping the side panel of electrocardiograph, you must be especially careful to keep water out of all kinds of cable and outlet on the panel.
- ⇒ Do not use abrasive material including wire brush or metal brightener during cleaning because this material will damage the panel and electrocardiograph screen.
- ⇒ Do not submerge the electrocardiograph in liquid.
- ⇒ While cable or plug of attachment accidentally gets wet, please rinse it with distilled water or deionized water and dry it in the environment of temperature 40℃ to 80℃ for at least one hour.



Caution:

- **Avoid the environment with high temperature and humidity**
 - **Avoid sunshine, dust or bump, and avoid shook acutely while moving.**
-

7.3 Cleaning and Sterilizing of Accessories

1. ECG cable

- a) Please clean cable before disinfection.
- b) Clean the surface of cable by use of soft cloth dipped with appropriate quantity of clean water or neutral soap water;
- c) Dip soft cloth with appropriate quantity of disinfectant, and wipe the cable;
- d) Clean the residual disinfectant on cable by use of soft cloth dipped with clean water;

e) Air dries the cable at a shady and cool place.



Caution:

- It is necessary to regularly check the cable and lead wire of the patient to ensure their completeness and good conduction;
 - Damaged or aging cable or wire shall be replaced timely;
 - In the course of use, tidy up the lead wire as much as possible, and do not pull it forcibly.
-

2. Chest electrode and limb electrode

- a) Please clean chest electrode and limb electrode before disinfection.
- b) Wipe off the conductive paste on surface of electrode with soft cloth;
- c) Take apart the electrode plate and clamp of limb electrode as well as rubber ball and metal cup of chest electrode;
- d) Put electrode into clean warm water (not higher than 35℃) and clean it to ensure no residue of conductive paste;
- e) Air dries the electrode at a shady and cool place.



Caution:

- Electrode shall be timely cleaned after use;
 - Rubber ball of chest electrode shall be prevented from direct sunlight; otherwise, aging will be caused;
 - Electrode with eroded surface shall be timely replaced with new electrode.
-

Caution:

- ☞ Do not disinfect cable and lead wire with high voltage, radial or steam.
- ☞ Do not dip cable or lead wire directly in liquid.
- ☞ To prevent long-term damage to cable, it is suggested that the product be disinfected only when your hospital regulation deems it as necessary.
- ☞ Do not clean or reuse disposable electrode.



Warning: Do not use EtO, phenyl, amido or iodo for disinfection of the machine.



Caution: Disinfection possibly causes damage to Electrocardiograph to some extent. It is suggested that disinfection be conducted only when your hospital maintenance plan deems it as necessary. The equipment shall be cleaned before disinfection.



Note: Electric schematic diagram and list of components are provided to the qualified maintenance station or personnel certified by the manufacturer only.

7.4 Cleaning and Maintenance of Recorder

To prevent stain on surface of thermosensitive printing head due to excessive long period of use of printer and clarity of recording is adversely affected, the users shall regularly (at least once every month) clean the surface of recording head:

- ⇒ Open the box cover of recorder;
- ⇒ Take out the remaining chart paper;
- ⇒ Gently wipe the surface of recording head by use of clean soft cloth dipped with small quantity of diluted alcohol;
- ⇒ Air dry the recorder at a cool and ventilated place;
- ⇒ Place the chart paper properly, and close the box cover of recorder.

Chapter 8 Accessories



Warning:

- Use only accessories specified in this manual. Using other accessories may cause damage to the electrocardiograph.
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.

Accessories list:

| NO. | Name | Specification | PN |
|-----|--|---|--------------------|
| 1. | Standard chest electrode | One set comprises 6 electrodes | 1.15.62-0001-01-00 |
| 2. | Enhanced chest electrode | One set comprises 6 electrodes | 1.15.62-0001-02-00 |
| 3. | Standard limb electrode(IEC) | One set comprises 4 electrodes(2 large and 2 small) | 1.15.61-0004-01-00 |
| 4. | Enhanced limb electrode(IEC) | One set comprises 4 electrodes(2 large and 2 small) | 1.15.61-0004-02-00 |
| 5. | Standard limb electrode (AAMI) | One set comprises 4 electrodes(2 large and 2 small) | 1.15.61-0004-03-00 |
| 6. | Enhanced limb electrode(AAMI) | One set comprises 4 electrodes(2 large and 2 small) | 1.15.61-0004-04-00 |
| 7. | Thermosensitive chart paper | 80mm*20m | 1.21.00-000024-006 |
| 8. | 15 PIN Type AAMI standard integrated 12-lead ECG cable | With 10K defibrillation resistance | 1.15.52-0035-01-00 |
| 9. | 15 PIN Type IEC standard integrated 12-lead ECG cable | With 10K defibrillation resistance | 1.15.52-0035-02-00 |

| NO. | Name | Specification | PN |
|-----|--|---------------------------------------|--------------------|
| 10. | 15 PIN Type AAMI enhanced integrated 12-lead ECG cable | With 10K defibrillation resistance | 1.15.52-0036-01-00 |
| 11. | 15 PIN Type IEC enhanced integrated 12-lead ECG cable | With 10K defibrillation resistance | 1.15.52-0036-02-00 |

Appendix A Product Specifications

A.1 Safety Specifications

According to the MDD 93/42/EEC, the electrocardiograph is Type II a equipment. Classified according to the IEC60601-1 is as follows:

| | |
|--|---|
| Classification of protection against electric shock | Class I, internally and externally powered equipment. |
| Degree of protection against electric shock | Type CF applied part, and is defibrillator-proof. |
| Degree of protection against ingress of liquid | Ordinary equipment |
| Degree of protection against hazards of explosion | Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide. |
| Mode of operation | Continuous |
| Electromagnetism compatible | Group I Class B |

A.2 Environmental Specifications

| | |
|-----------------------------------|-----------------------|
| Operating | |
| Temperature | 5℃～40℃ |
| Relative humidity | ≤85% (non condensing) |
| Atmospheric pressure | 700hPa～1060hPa |
| Transportation and storage | |
| Temperature | -20℃～+55℃ |
| Relative humidity | ≤93% (non condensing) |
| Atmospheric pressure | 500hPa～1060 hPa |

A.3 Physical Specifications

| | |
|---------------------|-----------------------|
| Size (W×H×D) | 315mm × 215mm × 75mm |
| Weight | 1.6 kg |
| Display | 4.3", 480×272 TFT LCD |

A.4 Power Specifications

A.4.1 AC Power

| | |
|------------------------|---|
| Rated Voltage | 100V-240V AC |
| Rated Frequency | 50Hz/60Hz |
| Rated Power | 80VA |
| Standard | Comply with IEC 60601-1 and IEC 60601-1-2 |

A.4.2 DC Power (Built-in battery)

| | |
|---|--|
| Type | Rechargeable lithium ion battery |
| Rated Voltage | 11.1V |
| Capability | 2000mAH |
| Operating time | Used continuously for 4 hours (print 150 shares of cardiogram) |
| Charge time | 4 hours |
| Charge flow | 0.5C ₅ A |
| Discharge stop Voltage | 9.5V±0.3V |
| Charge voltage | 12.6V±0.05V |
| Charge mode | Constant voltage/constant current charged |
| Circle times | ≥300 times, ≥80% leave |
| Indication of battery capability | With |

A.5 Hardware Specifications

A.5.1 Recorder

| | |
|------------------------------|---|
| Recording way | Thermal dot array |
| Horizontal resolution | 40 dots/mm (25mm/s) |
| Vertical resolution | 8 dots/mm |
| Recording speed | 5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s, error:±3%. |
| Recording linearity | ≤0.5mm/30M |
| Paper width | 72mm |
| Paper type | Reel thermosensitive printing paper |
| Recording precision | ±5% (X axes), ±5% (Y axes) |
| Recording type | Auto (4×3, 3×4+1, 3×4, 2×6+1, 2×6, 3-2+1, 3-2), Manual (Manual1, Manual 2, Manual 3, Manual 4), Rhythm (single-lead rhythm, three-lead rhythm). |

A.5.2 Mainframe LED

| | |
|---------------------------------------|--|
| AC Power indicating lamp | 1 (Green). It lights green when powered with AC. |
| Battery status indicating lamp | 1 (Orange) It lights orange while battery charging. |
| Device running indicating lamp | 1 (Green) It lights green when turn on the device. Green light twinkling when equipment enters standby status. |

A.6 Measure of ECG Waveform

| | |
|-------------------------------------|---|
| HR range | 30bpm -350bpm |
| HR precision | ±1bpm (10s average) |
| Coefficient error | ≤5%, 0.333 |
| Measure info of ECG waveform | P time limit, PR interphase, QRS time limit, QT interphase, QTC interphase, RR interphase, RV5swing, SV1swing, RV6swing, SV2swing, RV5+SV1swing, P axis, QRS axis , T axis. |

A.7 Display of ECG Collection

| | |
|--|---|
| Signal input | 12-Lead, defibrillator-proof, Pacemaker pulse rejection |
| Degree of protection against electric shock | 4000V, Type CF applied part |
| Electrode offset potential Range warp of Electrode offset potential allowed | $\pm 500\text{mV}$ $\leq 5\%$ |
| Response to frequency Baseline filter ECG filter Lowpass filter | 0.05Hz~150Hz (-3dB) On/Off (0.05Hz) 25Hz, 35Hz, 45Hz 75Hz, 100Hz, 150Hz |
| Gain selection | 2.5, 5, 10, 20 (mm/mV), Auto |
| Gain accuracy | $\leq 5\%$ |
| Time base selection | 5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25mm/s, 50mm/s |
| Input impedance | $\geq 50\text{M}\Omega$ (10Hz) |
| Current of input loop | $\leq 50\text{nA}$ |
| Patients leakage current | $\leq 10\mu\text{A}$ |
| CMRR | $\geq 110\text{dB}$ (with AC filter) |
| Time for response to wave displaying | $\leq 5\text{s}$ (after connected with electrodes, time interval of valid waveform displayed on the screen.) |
| Time for baseline recovered after switching leads | $\leq 1\text{s}$ |
| Defibrillator-proof | 5000V 360J Recovering time for defibrillator-proof $\leq 5\text{s}$ Recovering time for defibrillator electrode polarization $\leq 10\text{s}$ Energy reduced $\leq 10\%$ Voltage transfer $\leq 1\text{V}$ |

A.8 Input/Output Specification

| | |
|--------------------------|--|
| Keyboard | 6 function keys, 4 direction keys, 1confirm key, 1 power key |
| Touch screen | Standard touch-screen connector (4 lines) |
| Indicating lamp | Operation indicator (Green) AC power indicating lamp (Green) Charge indicator (Orange) |
| USB connector | USB Host (1) connects USB device |
| SD card connector | Standard SD card (1) |

A.9 Storage Specification

| | |
|------------------------|---|
| Fixed Memory | 50 groups of ECG data |
| Optional Memory | SD card or U disk |
| Storage mode | Background storage automatically SD-U disk-Fixed memory (optional) |

A.10 Function

| | |
|-----------------------------|--|
| Recording function | According to setup, the machine can complete reports of ECG, real-time waveform, rhythm waveform, saving review; It can provide reports in multiple formats such as Auto (4×3, 3×4+1, 3×4, 2×6+1, 2×6, 3-2+1, 3-2), Manual (manual1, manual2, manual3, manual4), Rhythm (single-lead rhythm and 3-lead rhythm). |
| Operation function | It can conduct recording, mode selection and shortcut function menu selection through shortcut keys; It supports operations on touch screen. |
| Maintenance function | Software can be upgraded by means of USB flash disk; Software function configuration is allowed. |
| Storage function | Data saving of SD card and USB flash disk is supported; Transfer, import and export of data are allowed. |

Appendix B Factory Default Setting

This chapter lists some important factory default settings of electrocardiograph. Users can not change them, but electrocardiograph can be recovered to factory default setting according to actual need.

| No. | Item | Factory Default Setting |
|-----|-----------------|-------------------------|
| 1 | Work Mode | Auto |
| 2 | Sample mode | Pre-sample |
| 3 | Measure | Display |
| 4 | AC filter | 50Hz |
| 5 | DFT filter | On |
| 6 | EMG filter | Off |
| 7 | Lowpass filter | 100Hz |
| 8 | Gain | 10mm/mV |
| 9 | Speed | 25mm/s |
| 10 | Rhythm style | Three lead |
| 11 | RHY lead CH 1 | II |
| 12 | RHY lead CH 2 | V1 |
| 13 | RHY lead CH 3 | V5 |
| 14 | Key volume | Off |
| 15 | Power off delay | Off |
| 16 | LCD delay | Off |
| 17 | Height unit | cm |
| 18 | Weight unit | kg |
| 19 | Auto save | No |
| 20 | Default medium | Flash |

Appendix C Prompt Information

| Prompt information | Cause |
|------------------------|---|
| No paper | Chart paper is not installed or chart paper is used up |
| Roller not in place | Rubber stick is not been well pressed |
| Print head overheating | Print head of recorder is overheating |
| Demo | The system is in demonstration status. |
| Lead missed | Electrode and lead wire fall off or are disconnected. |
| Lead fall-off | Electrode falls off from the patient. |
| Learning | The self-study process of arrhythmia algorithm in sampling mode is triggered. |
| Recording | ECG data are being recorded. |
| Sampling now | Data are being collected. |
| Error--1 | Failed to prepare data |
| Error --2 | Failed to analyze |
| Error --4 | Failed to turn on SPI |
| Error --5 | There is not enough SPI buffer |
| Error --6 | Failed to start SPI |
| Error --8 | Failed to pack data |
| Error --9 | Failed to stop SPI |
| Error --10 | Unknown cause |

Appendix D Measurement

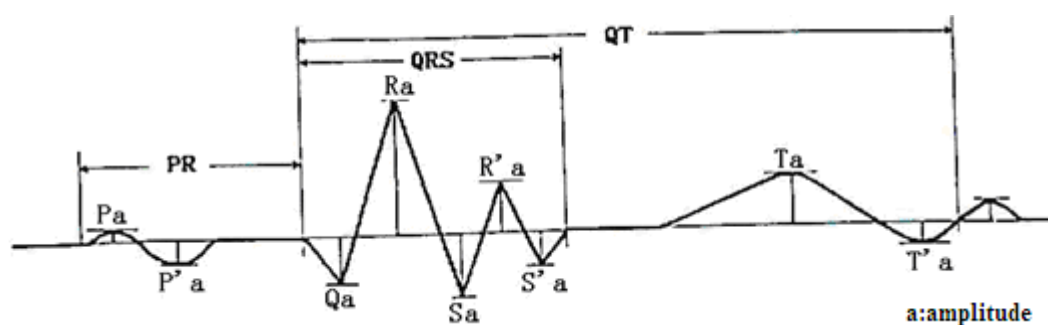
One predominant beat is selected from each 12 leads waveform. The 12 predominant beats are used to locate the waveform boundaries (the onsets and ends of P, QRS, T wave) in multilead ECG signal (the 12 standard leads) and measure features of clinical importance (such as the amplitude and duration of the Q, R, S, R' and S' waves, the QT interval, the PR interval).

D.1 The Waveform Boundaries of 12 Leads

We adopt some scientific methods to determine multilead wave onset and end as follows: Firstly, we detect and obtain, for each waveform boundary WB (including P end (Pe), P onset (Pb), QRS onset (QRSb), QRS end (QRSe), T end (Te)), a set of waveform boundary positions $WB_j(i)$ belonging to beat i of lead j (j can take values from 1 to 12 (12 leads), except for values corresponding to the leads where no detection was made). The next step is the selection, from these $WB_j(i)$ positions, of the one $WB(i)$ that will be considered as the real onset or end of waveform at the i th beat. Electrophysiologically, if all $WB_j(i)$ were correctly detected, we should select the earliest $WB_j(i)$ ($j=1,2,\dots,12$) for the waveform onset and the latest for the waveform end, in order to recover the boundary from that lead where the electrical activity of the heart has the longest temporal project. However, due to noise or errors, misestimations could have occurred in the determination of some $WB_j(i)$, that may lead to erroneous final $WB_j(i)$ position. To reduce the risk of this occurrence, we apply the following multilead wave boundary detection rule for each i th beat: we calculate the mean and the standard deviation of $WB_j(i)$ ($j=1,2,\dots,12$), and we search the minimum time position (for onsets) or maximum time position (for ends) of $WB_j(i)$ ($j=1,2,\dots,12$). If the difference between the minimum or maximum $WB_j(i)$ position and the mean is bigger than three times the standard deviation, the minimum or maximum $WB_j(i)$ point is rejected as a possible noisy detection. After that we take the wave onsets (ends) as the minimum (maximum) of the remaining $WB_j(i)$ positions, obtaining the final $WB(i)$.



D.2 Measurements of One Beat

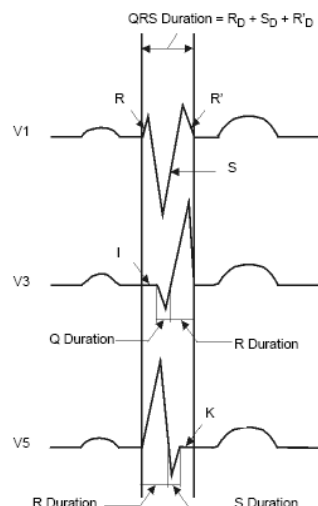


| Parameter | Description | Measurement unit |
|-----------|---|------------------|
| P_a | Amplitude of the P wave | mV |
| $P'a$ | Amplitude of the P' wave (in case of biphasic P wave) | mV |
| Q_a | Amplitude of the Q wave | mV |
| R_a | Amplitude of the R wave | mV |
| S_a | Amplitude of the S wave | mV |
| $R'a$ | Amplitude of the R' wave | mV |
| $S'a$ | Amplitude of the S' wave | mV |
| T_a | Amplitude of the T wave | mV |
| $T'a$ | Amplitude of the T' wave (in case of biphasic T wave) | mV |
| P_d | Duration of P wave | ms |
| $P'd$ | Duration of P' wave | ms |
| PR | PR interval | ms |
| QRS | Duration of QRS | ms |
| QT | QT interval | ms |

D.3 Isoelectric Segments

Between the global onset and offset of the QRS-complex, signal parts with a duration of more than 6 ms and amplitudes not exceeding $20\mu\text{V}$ for at least three samples should be defined as isoelectric segments – I-wave before the global QRS-ONSET and K-wave after the global QRS-OFFSET.

Isoelectric parts (I-wave) after global QRS-ONSET or before global QRS-OFFSET (K-wave) are excluded in the duration measurement of the respective adjacent waveform.



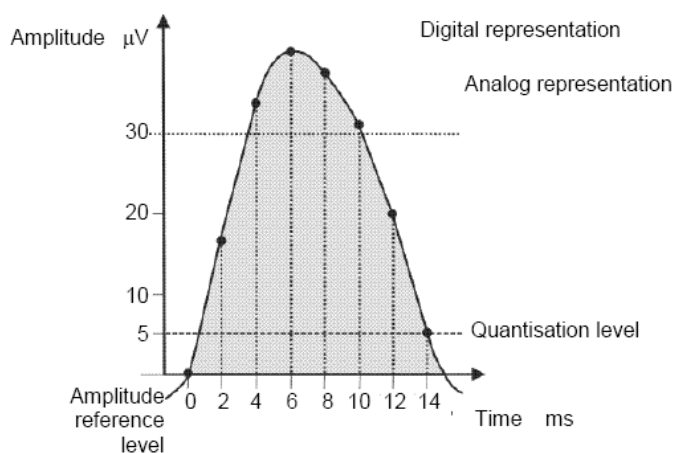
D.4 Stability of Measurements against NOISE

D.4.1 Acceptance of minimum waves

The labeling of the QRS waveforms depends by definition (since Einthoven) on the first detected wave. A tiny positive wave at QRS beginning is called r or R and may mask a true, following Q wave. Therefore the acceptance criteria of initial waveforms should be clearly defined and standardised.

The following rule for acceptance of minimum waves is used by wave detection:

- The signal part under consideration shows clearly two opposite slopes with at least one turning point in between;
- The signal part under consideration deviate at least $30\mu\text{V}$ from the reference level for duration of at least 6 ms.



IEC 551/03

To be accepted because
duration above $30\mu\text{V} \geq 6\text{ ms}$

D.4.2 Disclosed changes of measurements caused by NOISE on ECGs

| Global measurement | Type of added NOISE | Disclosed differences | | Remark |
|--------------------|---------------------|-----------------------|--------------------|--------|
| | | Mean (ms) | Standard deviation | |
| | | MA_ | MA_ | |
| P-duration | High | 5.8 | 8.4 | |
| | AC | 0.2 | 7.2 | 50Hz |
| | AC | 6.0 | 12.0 | 60Hz |
| | Baseline | 5.6 | 8.4 | |
| PR-interval | High | 2.4 | 8.2 | |
| | AC | -5.6 | 7.7 | 50Hz |
| | AC | 1.6 | 6.7 | 60Hz |
| | Baseline | 0.0 | 9.1 | |
| QRS-duration | High | 3.2 | 7.9 | |
| | AC | 2.2 | 6.4 | 50Hz |
| | AC | 2.0 | 10.2 | 60Hz |
| | Baseline | 2.2 | 9.5 | |
| QT-interval | High | 4.2 | 7.6 | |
| | AC | 7.4 | 7.9 | 50Hz |
| | AC | 5.0 | 6.9 | 60Hz |
| | Baseline | 3.6 | 8.7 | |

Appendix E Guidance and Manufacturer's Declaration of EMC

Guidance and manufacturer's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS


Row

| Guidance and manufacture's declaration – electromagnetic emission | | |
|---|------------|---|
| The E30 Digital Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of E30 Digital Electrocardiograph should assure that it is used in such an environment. | | |
| Emission test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The E30 Digital Electrocardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emission CISPR 11 | Class A | |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | The E30 Digital Electrocardiograph is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes, provided the following warning is heeded. |

**Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS**

| Guidance and manufacture's declaration – electromagnetic immunity | | | |
|---|---|---|--|
| The E30 Digital Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of E30 Digital Electrocardiograph should assure that it is used in such an environment. | | | |
| Immunity test | EN 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV air | Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines ±1 kV for input/output lines | ±2kV for power supply lines ±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | ±1 kV differential mode ±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec | <5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the E30 Digital Electrocardiograph requires continued operation during power mains interruptions, it is recommended that the E30 Digital Electrocardiograph be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE U_T is the a.c. mains voltage prior to application of the test level. | | | |

**Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

| Guidance and manufacture's declaration – electromagnetic immunity | | | |
|---|---|------------------|---|
| The E30 Digital Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of E30 Digital Electrocardiograph should assure that it is used in such an environment. | | | |
| Immunity test | EN 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Conducted RF IEC 61000-4-6 | 3 V _{rms} 150 kHz to 80 MHz | 3 V | <p>Portable and mobile RF communications equipment should be used no closer to any part of the E30 Digital Electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |
| <p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</p> <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the E30 Digital Electrocardiograph is used exceeds the applicable RF compliance level above, the E30 Digital Electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the E30 Digital Electrocardiograph.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |

**Recommended separation distances between portable and mobile
RF communications equipment and the EQUIPMENT or SYSTEM –
for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING**

| Recommended separation distances between portable and mobile RF communications equipment and the E30 Digital Electrocardiograph | | | |
|--|--|---|---|
| The E30 Digital Electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the E30 Digital Electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the E30 Digital Electrocardiograph as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) | | |
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz |
| | $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ | $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ | $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |
| For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. | | | |
| NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. | | | |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

<This page is blank>

Product name: Digital Electrocardiograph

Product type: E30

Manufacturer: Guangdong Biolight Meditech Co., Ltd.

Address: No.2 Innovation First Road, Technical Innovation Coast, Hi-Tech

Zone Zhuhai, P.R. China

Fax: +86-756-3399919

Post code: 519085

Toll-free consultation hot line: +86-400-8818-233

PN: 22-041-0039