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- The product is used in accordance with this Manual.
- The product is installed, maintained or upgraded by approved or authorized personnel by Comen.
- The storage and operating environments for the product shall comply with the recommended information and product specifications contained in this manual.
- The serial number label or manufacturing mark of the product is clearly legible.
- The damage is not caused by human factors.
- All replaceable components, accessories, and consumables for maintaining are originally supplied by Comen or recognized by Comen.

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Request for product return: Contact Comen’s after-sales service department and inform them of the product

serial number marked on the product's nameplate. If the product serial number is not clear and legible, product return will not be accepted. Please indicate the product serial number, manufacturing date, and a brief description of the reasons for returning.

After-sales Service Department

Name: After-sales Service Department of Shenzhen Comen Medical Instruments Co., Ltd.

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Preface

This user manual provides details on the performance, operations and safety instructions about the product. Please read carefully and understand the content of this manual so as to ensure the safety of the patients and operator.

This manual introduces the product of the most complete configurations. Some configurations or functions may not be available on the product you have purchased. If you have any questions, please contact us.

Please keep this manual near the device for easy and prompt access when needed.

Intended Users

This Manual is suitable for professional clinical personnel or those who are expected to have knowledge and work experience in medical procedures, practices, and terminology necessary to monitor patients.

Illustrations

All illustrations provided herein are for reference only. The menus, options, values and functions shown in the illustrations may be not exactly identical to those shown on the product.

Conventions

- →: This symbol is used to indicate operating steps.
- [**Character**]: This is used to represent character strings in the software.
- ***Bold and italic***: This is used to represent chapters quoted.

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Chapter 1 Safety

1.1 Safety Information

⚠WARNING

- **Alerts you to situations that may result in serious consequences, adverse events or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of the user or patient.**

⚠CAUTION

- **Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage, or cause more serious injury in the future.**

⚠NOTE

- **Emphasizes important precautions and provides instructions or explanations for better use of the product.**

1.2 Warnings and Cautions

In order to use the equipment effectively and avoid the possible damages, please read the user manual thoroughly before using.

1.2.1 Precautions for Operating the Equipment

⚠WARNING

- **Report any serious incident that has occurred in relation to the medical device to COMEN manufacturer and the competent authority of the Member State.**
- **This equipment cannot be used directly for the cardiac surgery, treatment and ECG monitoring.**
- **The use of this equipment is restricted to one patient at a time.**

- **This equipment is intended for use on adult and children.**
- **Do not place the power plug which connects the device and power supply on a position that difficult for users to reach.**
- **Before plugging and unplugging the power cord, please ensure the equipment has benn turned off and the power cord is not connected to an external AC socket. Failure to do so can cause electric shocks or other hazards to the patient or operator.**
- **Do not use this equipment in the presence of flammable anesthetics to avoid explosion.**
- **Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.**
- **To aviod shock hazard, the housing of the equipment should be grounded well. Use the three-wire socket with protective grounding and the grounding of the socket should be kept well.**
- **To aviod shock hazard, do not connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.**
- **This equipment should be installed by the qualified maintenance engineer. Only the authorized maintenance engineer can open the housing of the equipment.**
- **If there is any doubt for the integrality for the protective ground lead, please use the built-in battery for the power supply.**
- **Accessory devices connected to analog and digital interfaces should be verified according to IEC standards (e.g. IEC 60950 and IEC 60601-1). All the configurations should comply with the valid version of IEC 60601-1. Therefore, the personnel who connect the accessory equipment to signal input/output interfaces should confirm the whole system comply with the requirements in the valid version of IEC 60601-1 when configuring it. If there is any doubt, please contact Comen Company or local agents.**
- **When the electrocardiograph is used in conjunction with defibrillator or pacemaker, do not allow the patient to contact bed, table, metal or the equipment.**
- **This electrocardiograph cannot resist the interference from electrosurgery equipment, please keep it away form electrosurgical equipment.**
- **When using this equipment, please do not connect the equipment (including Electrosurgery equipment) that will impose high-frequency voltage on the patient's body to avoid interference. Before operating any high-frequency surgical equipment, please disconnect the lead from the electrocardiogram machine or remove the electrode from the patient.**
- **In order to ensure the patient safety, the summation of leakage current should never exceed leakage current limits in IEC 60601-1 when several other devices are connected with the patient at the same time, or damage will be occured.**
- **Only use the patient cable or other accessories provided by Comen. The accessories of other types may damage the equipment or affect the performance and safety of the equipment.**

- **Electrodes of dissimiliar metals should not be used.**
- **Please ensure that all the electrodes are attached to the correct positions on the patient body before use.**
- **Ensure that the electrodes (including neutral electrodes) and patient, do not come into contact with earth or any other conducting objects.**
- **The operator should be trained professionally and thoroughly understand the user manual before using.**
- **Any refit on this device is prohibited.**
- **The electrocardiograph shall not be serviced or maintained while in use with a patient.**
- **The patient's random movement during the test may lead to inaccurate measurement results. Do not let the patient move randomly during the test.**
- **Input signal reconstruction accuracy: Methods to test systematic error and frequency response, please refer to 4.2.7.2 and 5.2.7.2 description in ICS 11.040.50. Due to the sampling characteristics of the system and the asynchronicity of the sampling rate and the signal rate, the digital system may produce a perceptible modulation effect from one cycle to the next cycle, especially when measuring children's ECG. This non-physiological phenomenon should be noted when used.**
- **The electrodes nust not be placed on inflamed or ulcerated skin.**
- **People who are allergic to the electrode's conductive medium are prohibited to use this product.**
- **This device can not be used in an MRI environment.**

⚠CAUTION

- **Try to avoid liquid splashing on the equipment.**
- **Try to avoid high temperature emvironment and the equipment should be used within 0℃~40℃.**
- **Do not use this equipment in the environment with high pressure, bad ventilation, dust, sulfury gas and chemical medicines.**
- **Ensure that there is no strong electromagnetic interference source around the installation and operation environment of the equipment, such as radio transmitter, mobile phone etc. Large electrical equipment such as ESU, ultrasonic equipment, radioactive equipment and MRI equipment are likely to generate electromagnetic interference.**
- **Before using, the equipment, patient cable and electrodes should be checked to find whether there is damage which may affect the safety of the patient. If obvious damage or aging is found, the part should be replaced before using.**
- **Safety tests should be performed periodically for the equipment, at least once a year. The test should be performed by the trained and qualified personnel with safety test knowledge and**

experiences and the test results should be recorded. If there is any problem of the equipment in the above tests, it should be maintained.

- **When the service life is expired, the equipment and reusable accessories should be sent back to the manufacturer for recycling or disposed of them properly according to the local regulations.**

⚠**NOTE**

- **This equipment is not intended for home use.**
- **This equipment is responsible for iems specified in the relevant national standards only.**
- **In normal use, the distance between the operator and device shoul be within one meter.**

1.2.2 Precautions for Using of the Rechargeable Lithium Battery

⚠WARNING

- **Improper operation may cause the battery being hot, ignition, explosion or capacity declination. Read this user manual carefully before using the rechargeable lithium battery (hereinafter called "Battery").**
- **Do not reverse the anode and cathode when connecting the battery, otherwise explosion may be caused.**
- **Do not use the battery near the fire or in the environment with temperature higher than 45℃. Do not heat the battery or throw it into the fire. Avoid water splashing on the battery and do not throw the battery into water.**
- **Do not penetrate the battery with metal, hammer the battery or use other methods to damage the battery; otherwise battery heating, smoking, distortion or burning may be caused.**
- **As usage time increases, the battery's continuous power supply time will decrease to a certain extent. When leakage or foul smell is found, keep far away from the battery immediately. If your skin or clothes comes into contact with the leakage electrolyte, rinse it with clean water at once. If the electrolyte splashes into your eyes, do not rub them, irrigate them with clean water first and go to see a doctor immediately.**
- **Only authorized installation or maintenance engineer can open the battery compartment and replace the battery. And only the rechargeable lithium battery of the same mode provided by Comen can be used.**
- **When the service life of the battery is expired, or when there is peculiar smell, deformation, discoloration or distortion, stop using it immediately and disposing the battery according to the local regulations.**
- **Charge the battery after each use to ensure sufficient power reserve.**
- **Please remove the battery during storage, transportation or when it is not used for a long time.**
- **The battery is only for the use of this equipment and can only be charged in this equipment.**
- **Depleted lithium battery should be disposed of according to the local regulations.**

1.2.3 Precautions for Cleaning, Disinfection and Maintenance

⚠CAUTION

- **Turn off the equipment before cleaning. If the AC power supply is used, the AC power supply must be disconnected and the power cord and patient cable must be removed.**
- **Do not allow the liquid to enter the inner of the equipment during cleaning. Do not immerse the**

equipment and ECG cable into liquid in any case.

- **Do not use abrasive material to clean electrodes.**
- **Wipe off all the residual detergent on the equipment and on the surface of patient cable after cleaning.**
- **Do not disinfect the equipment by the way of high temperature, autoclaving or ionizing radiation. Do not use chloric disinfectants such as bleaching powder, sodium hypochlorite.**

1.3 Symbols

（1） **Device Symbols**

Symbol	Description	Symbol	Description
CE 1639	Complies with medical device Regulation (EU) 2017/745	EU REP	Authorized representative in the European Community
	Defibrillation-proof type CF applied part		Ionizing radiation
MD	Medical Device	UDI	Unique Device Identification
	Alternating current	SN	Serial Number
IPX0	Ingress Protection		Date of manufacturer
	Warning (Background: yellow; symbol and outline: black)		Manufacturer
	Consult instructions for use		Refer to operation manual (Background: blue; symbol: white)
	ON/OFF switch		Battery indicator light
	Equipotentiality		USB port
	Computer network		Waste electrical and electronic equipment sorting collection
	Print button		Menu
	TF card	/	/

(2) **Packaging Symbols**

Symbol	Description	Symbol	Description
	This way up		Stacking limit by number
	Fragile, handle with care		Keep dry
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation	/	/

Chapter 2 Overview

2.1 Product Composition

This equipment is mainly composed of the main unit, lead cable, limb electrode and chest electrode.

2.2 Intended Use

Electrocardiograph is intended to acquire, analyze, display, and record resting electrocardiographic information from adult, pediatric and neonate population by electrodes placing on the surface of body. The electrocardiograph is intended to be used by trained healthcare professionals. The electrocardiograph is intended to be used in professional healthcare facilities.

2.3 Contraindications

None

2.4 Appearance Introduction

2.4.1 Front View

The front view of this device is shown as the following figure:

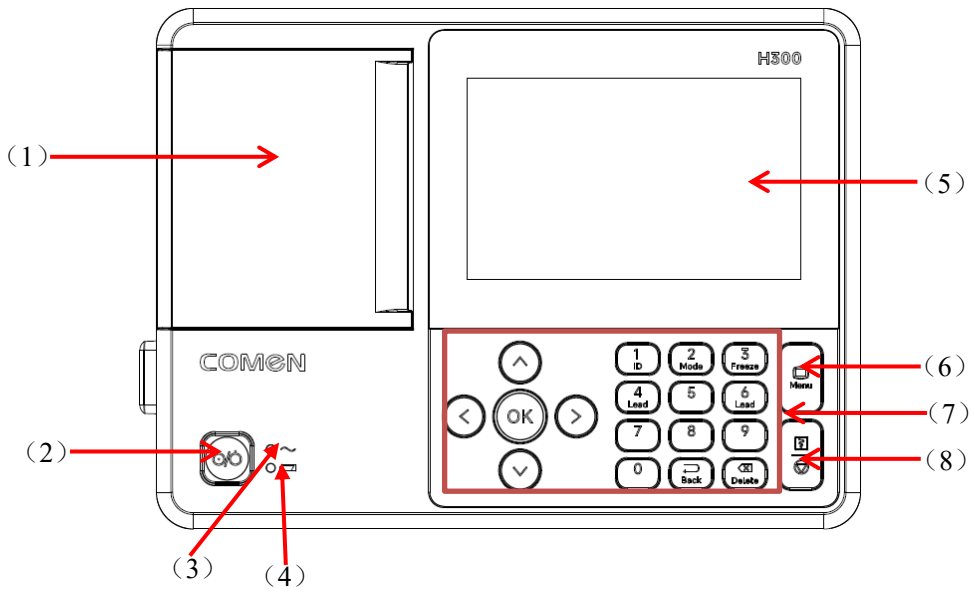


Figure 2-1 Front view

(1) Recorder

(2) ON/OFF switch: Press this button to turn on/off the ECG machine.

(3) AC power supply indicator:

- On: The electrocardiograph is connected with AC power supply.
- Off: The electrocardiograph is disconnected with AC power supply.

(4) Battery indicator light

- Remain on: the battery is being charged.
- Flash: the battery is supplying for the ECG machine.
- Off: the battery is fully charged, no battery is detected or the battery may malfunctioning.

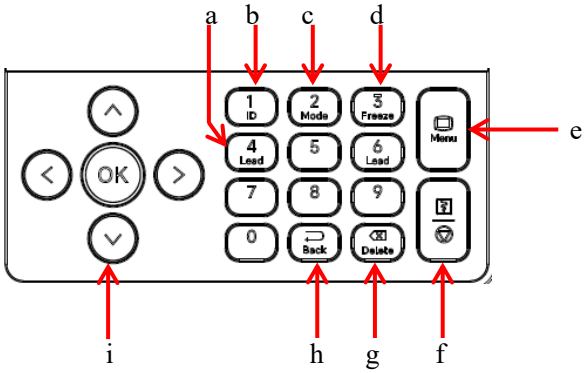
(5) Display screen: 5 inches, 800*480 (H300 with no touch screen, H301 with touch screen).

(6) Menu button: press this button to enter the main menu.

(7) Keyboard.

(8) Print key: press the key to start or stop recording ECG waveform.

Detailed introduction of keyboard:



No.	Description	No.	Description
a	Press to switch the lead group	f	Press to print the report.
b	Press to enter patient information screen.	g	Press to delete.
c	Press to switch measuring mode.	h	Press to back the previous step.
d	Press to freeze the ECG waveform.	i	The dorection key.
e	Press to enter setting menu.	/	/

2.4.2 Left View

The left view of this device is shown as the following figure:

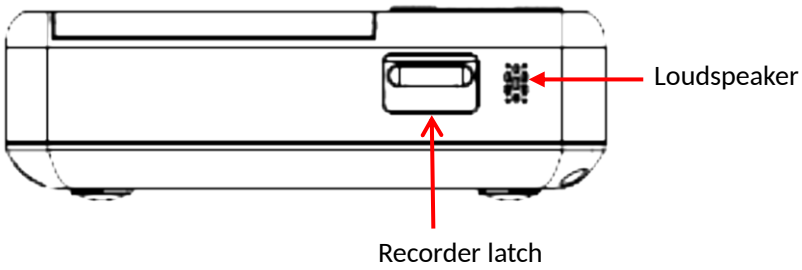


Figure 2-2 Left view

2.4.3 Right View

The right view of this device is shown as the following figure:

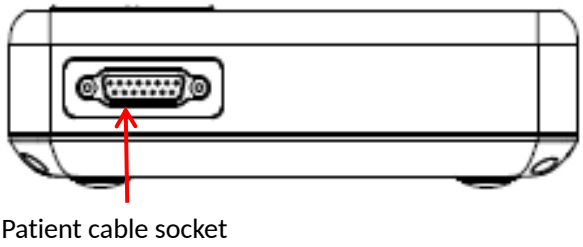


Figure 2-3 Right view

Patient cable socket: Connecting the patient cable for ECG waveform acquisition.

2.4.4 Bottom View

The rear view of this device is shown as the following figure:

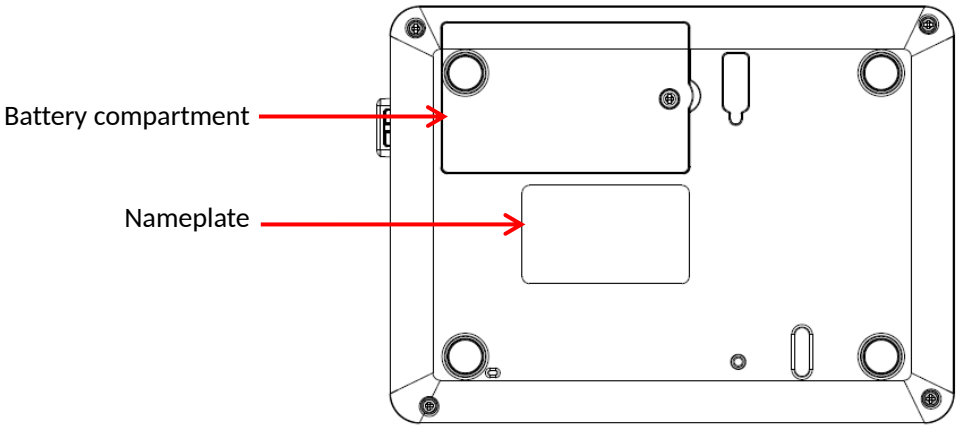


Figure 2-4 Botton View

2.4.5 Rear View

The rear view of this device is shown as the following figure:

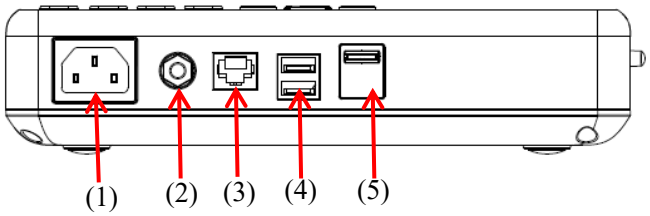


Figure 2-5 Rear View

(1) AC power supply port: Connect AC power supply to provide power for the ECG machine.

(2) Equipotential grounding terminal: Used for grounding or when other devices are used with this product, wires should be used to connect the equipotential terminals of this electrocardiogram and other devices to eliminate potential differences between different devices and ensure safety.

(3) Network port: Connecting to wired network, and it is suitable for HL7, DICOM, FTP and other network protocol to transfer patient files, obtain patient's information and transfer waveform data to ECG workstation.

(4) USB port: Connecting to a USB flash drive, mouse, keyboard, bar code reader recommended by Comen or other devices, and can also be used as software upgrading.

(5) Trans-flash Card port：Connecting the TF card.

2.5 Main Interface

The main interface of this device is shown as the following figure:

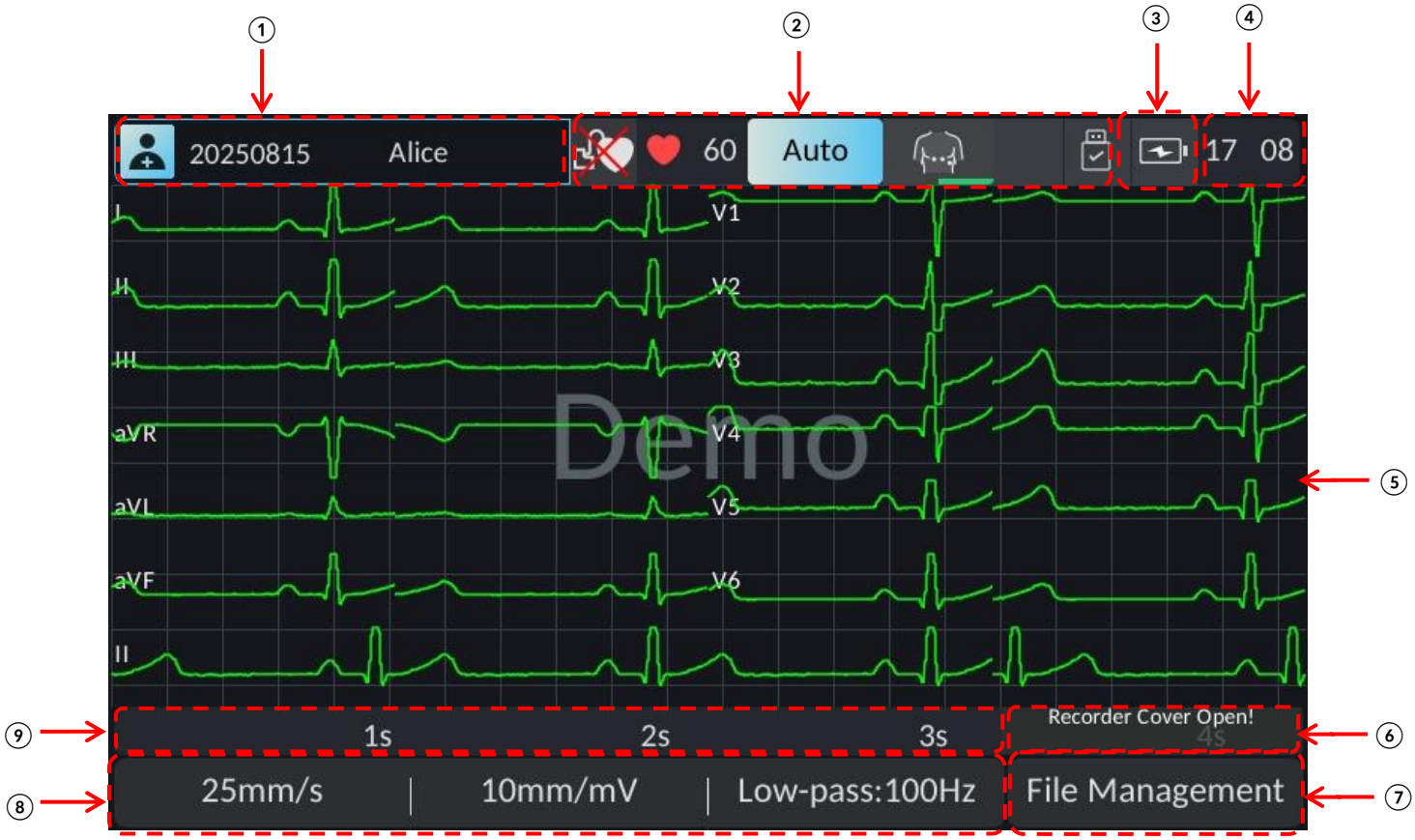


Figure 2-6 Main Interface

No.	Definition	Item	Description
①	Patient information	Patient information	Display patient ID and patient name.
②	System information (from left to right)	Pacemaker status icon	Display pacemaker status icon.
		Real-time heart rate value	Display the real-time heart rate value of current patient.
		Measuring mode	Manual/Auto/Rhythm/RR, tap on to switch measuring mode.
		Lead wire status map	It can be used as a reference diagram for connecting lead wires and can view the status of lead connection and detachment. Red indicates the lead is in a detached state, while green indicates that the lead is already connected.
		TF card status	Display TF card status.
		USB flash drive	Display USB flash drive status.

		status	
		WIFI status	Display WIFI status.
		4G/5G Network status	Display 4G/5G network status.
③	Icon area	Battery status icon	 Display battery level and charging status.
④	Time area	/	Display the current system time.
⑤	Waveform area	/	The ECG waveform will be displayed here.
⑥	Prompt message area	/	Such as recorder compartment door is open, low battery and so on.
⑦	Patient File Management shortcut key	/	Tap on to enter “File Management” interface.
⑧	System information (from left to right)	Paper speed	Tap on to change paper speed.
		Waveform gain	Tap on to change waveform gain.
		Filter	Click here to select Low pass filter, AC filter, Baseline Drift Filter and EMG filter.
⑨	Calibration area	/	Display waveform time axis.

2.6 Network Security

2.6.1 Network Security Guidance

⚠WARNING

- **Improper use may cause harm to the patient and the performance of the equipment.**
- **Unidentifiable or insecure networks are not allowed to connect.**
- **Please make sure that all softwares of connected devices are benign before the ECG machine is connected to them.**
- **Except for the planned connects, any other remote connection and remote operations are not allowed.**
- **For embedded devices, network security updates are integrated with software application updates, only allowing authorized users to update locally.**
- **When the ECG machine reaches the end of its service life, please empty the patient data and configuration data before disposing.**

⚠CAUTION

- **Before connect any USB flash drive, please scan it to protect the ECG machine from viruses or malware.**
- **When the network between the ECG workstation and the ECG machine is disconnected, a prompt of Connection Interrupted will be triggered.**
- **PEMS connecting with IT-network of other devices may cause risks that are not previously identified to patient, operator and the third party.**
- **Risks including machine modification, possible failure and electromagnetic interference should be identified, analyzed, evaluated and controlled by the responsible body.**
- **Subsequent modifications to the IT-network may cause new risks and require additional analysis; IT-network modifications include:**

  - Modification of the IT-network configuration;

  - New items connected to IT-network;

  - Interrupted Item connected to IT- network;

  - Update of the device connected to IT-network;

  - Upgrade of the device connected to IT-network.

⚠NOTE

- **ECG machine is intended to be operated by trained operators and professionals in professional medical institutions.**
- **Any medical institution that uses Comen ECG machines and ECG workstations must protect the patient's personal information in accordance with country specific regulations and comply with the medical institution management policies.**
- **When ECG machine is connected to Comen's specific ECG workstation, please install anti-virus softwares on the host server. For more information, please refer to the instructions of the ECG workstation.**
- **No software is required for embedded devices.**
- **Third party's Software Bills of Materials are available upon request.**

2.6.2 Connecting Guidance for Network Security

⚠ WARNING

- **Do not use this product in a patient environment if it does not comply with the requirement of IEC 60601-1.**
- **Medical electrical equipment used in the medical room must be connected to a potential equalization device (equipotential cable) to avoid potential differences.**

2.6.3 Recommendation for Network Security Defense

Following measures can be adopted to protect information assets and the safety of ECG machine：

- Physical Access: Only authorized users can operate the ECG machine and the equipment should be kept under control.
- Daily Use: Storage of patient data should be limited. The patient data should be exported from the ECG machine after use.
- Network Security: The responsible body and medical institution must adopt measures to assure the security of any shared network that ECG machine can be connected to.
- Device safety: Only connect the device to an IT network that is confirmed by compatible devices and specified by the manufacturer, and ensure that any connected devices are free of malware.
- Keep updating.
- Proper password.
- Take actions or follow up the alarm, inconformity and other anomalous of the equipment as well as report them to responsible body and professional technicians.

2.6.4 Exisiting Software Bills of Materials (SBOM)

Software	Description
Bootstrap	U-boot software, also referred as the first level boot software.
U-boot	Linux operating system boot software, also referred as the second level boot software.
Linux Kernel	Linux is an open source computer operating system kernel.

Software	Description
TSLib	To provide functions such as filtering, de-shaking, and calibration for the samples obtained by the touch screen drive.
libIconv	To realize the transform from a character encoding to the other.
libFreetype	To provide a unified, type-independent, simple and easy-to-use API to access TrueType, OpenType font files.
libJpeg	To provide codecs (encoding and decoding) for the JPEG picture format and interface functions for processing JPEG data.
libpng	To provide codecs (encoding and decoding) for the PNG picture format and interface functions for processing PNG data.

Chapter 3 Operation Preparation

3.1 Unpacking and Checking

Carefully take the device and its accessories out of the packing box, keep the packaging materials for future transportation or storage. Check the accessories against the Packing List and check the device for mechanical damage. In case of any problem, contact our Sales Department or the agency immediately.

3.2 Connect the Power Cable and Ground Wire

⚠ WARNING

- **Before connecting AC power, please ensure the voltage and frequency of the AC power supply is the same as that of the equipment label.**
- **To aviod electric shock, please use the three-wire power socket with protective grounding and the ground wire should be kept well. Do not open the housing of the equipment when the AC power supply is connected.**
- **If there is doubt for the integrality of protective ground wire, please use the built-in battery for the power supply.**

⚠NOTE

- **If the use of the instrument is affected by equipotential grounding, contact the Comen's After-sales Service Department or the agents.**

1) Use the AC Power Supply

First of all, check whether the AC power supply complies with the requirements, and then connect the power cord to the device and 3-prong power socket respectively. Finally, check the AC power indicator to ensure proper connection.

2) Use the Built-in Battery

When the ECG machine is delivered to users, it can be directly turned on because the built-in rechargeable lithium battery is installed. But the lithium battery capacity may be insufficient after storing and transporting, so it needs to be charged before use. When the battery reaches the end of the service year (300 times charging), or the service time is obviously shortened after being fully charged, please change the battery in time.

3) Connect the Ground Wire

Connect one end of the ground wire to the equipotential grounding terminal at the back panel of the equipment and connect another end to the public ground wire of the hospital.

⚠NOTE

- **Plug the power cord into hospital-specific socket.**
- **If the ECG machine is equipped with the battery, it should be charged after being transported or stored. If it is turned on without connecting alternating current, the ECG machine may not work normally because of the power failure. The battery can be charged no matter it is turned on or not only if it connects AC power supply.**

3.3 Install Record Paper

The equipment supports 80mmX70mm-200P black grid folded thermosensitive record paper and 80mmX20m rolled thermosensitive record paper. When the record paper is not loaded or it is used up, a prompt message will generate to remind the user of loading or replacing the record paper. When the record paper of a certain type is used, it should be set on the software of the ECG machine.

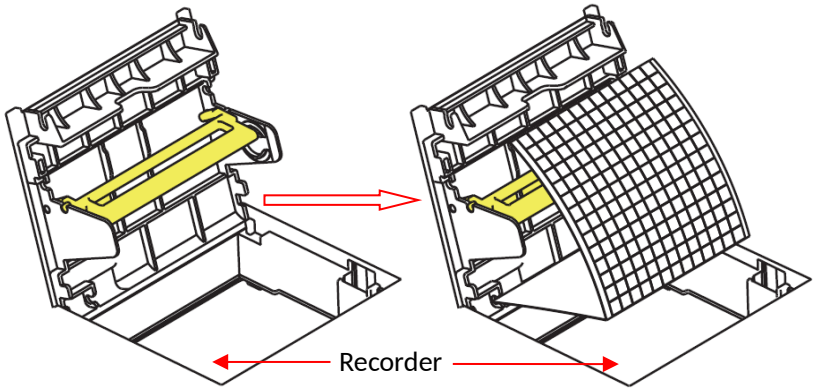


Figure 3-1 internal structure of recorder

3.3.1 Install Folded Thermosensitive Record Paper

(1) Press the latch on the left panel of the equipment with left hand, the recorder compartment will be released.

(2) Open the recorder compartment.

(3) Install the rod of folded paper on the roll fixing device to prevent paper jams during printing, as shown in the above figure;

(4) Remove the packaging of the new folded recording paper and place it in the paper slot. Pay attention that when the free end of the recording paper is upright, the grid surface of the recording paper should face the thermal printing head;

(5) Pull about 2cm paper out from the paper exit and close recorder cover.

3.3.2 Install Rolled Thermosensitive Record Paper

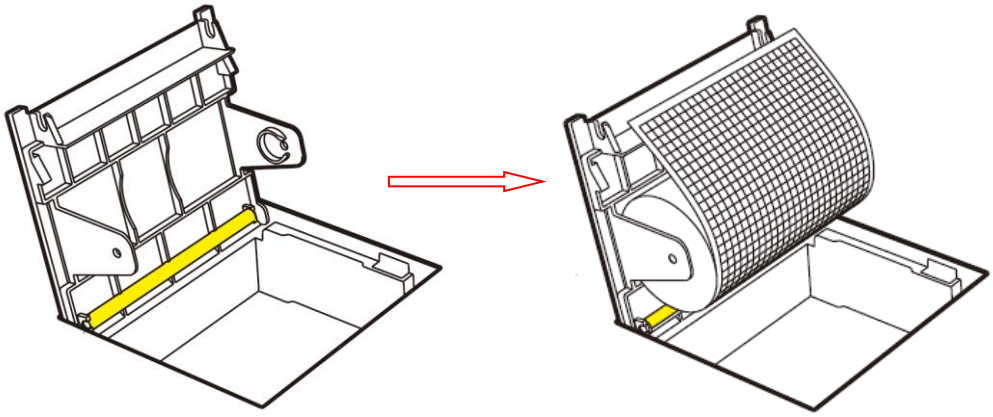


Figure 3-2 Installing Rolled Thermosensitive Record Paper

(1) Press the latch on the left panel of the equipment with left hand, the cover will be released.

(2) Open the paper compartment cover, pull the lever back to the front, and remove the roll from the roll holder.

(3) Peel off the adhesive tape from the seal of the new recording paper, insert the roll of paper into the roll holder on the recorder door (hold the recording paper in your right hand, press it against the upper holder, gently pull the lower holder outward with your left hand, and simultaneously push the roll of paper with your right hand until it is securely held in the holder and can rotate smoothly). Ensure that the printing side (grid side) of the paper faces the thermal print head.

(4) Pull the recording paper out of the paper outlet on the paper pressure roller, close the cover, and make sure that the recording paper is parallel to the paper outlet. .

3.4 Preparation for Patients

3.4.1 Instructions for Patients

1. Before connecting electrodes, please inform and explain to the patient about the process of ECG examination to help them relax and know what to do next so as to ease the patient’s nervousness and to be cooperative with inspection.
2. Protecting the privacy of patient is important for helping them relax, and the ECG examination should be performed in a quiet room; If there are other person in the room, and the curtain should be used during examination.
3. Inform the patient that the examination is painless.

4. Ensure the patient lie down comfortably and the limbs are relaxed.

After connecting the electrodes and lead wires, the patient should:

a) Keep still and do not talk.

b) Breathe naturally.

c) Try not to shake as far as possible.

d) Do not chew or clench the teeth.

The more relaxed the patient is, the less the interference the ECG waveform will be.

3.4.2 Cleaning the Skin

Skin is a poor conductor and may cause artifacts to distort ECG signals. There are dry and dead epidermal cells, oil and dirt on the skin, which will cause contact resistance.

Steps for cleaning skin:

1. When necessary, shave body hair at positions where electrodes will be placed.
2. Thoroughly clean the skin with soap water.
3. Wipe the skin hard to increase the capillary blood flow in the tissue and remove the dead dry cells and oil.

⚠ Note

- **If time is limit, the user can directly rub the positions where electrodes will be placed with gauze to remove dead cells and oil to increase the capillary blood flow.**

3.5 Connect ECG Cable

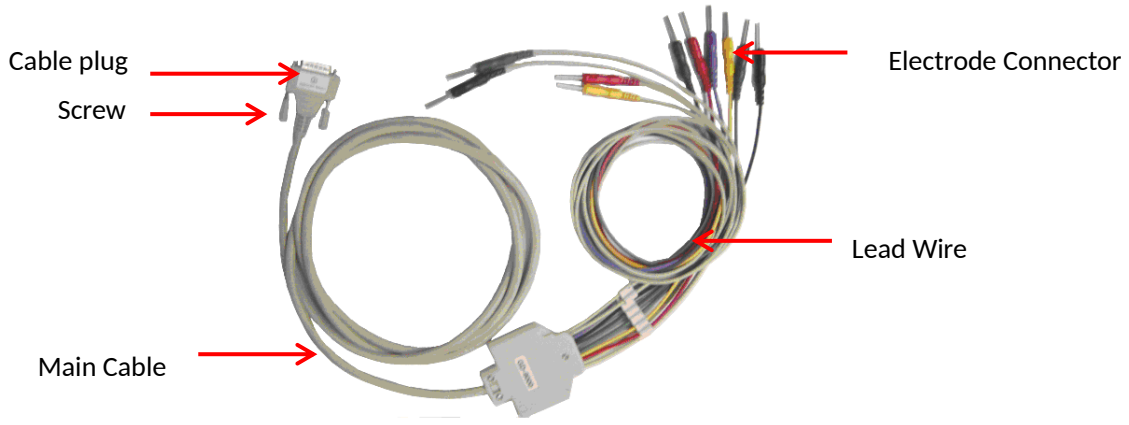


Figure 3-3 Patient Cable

Patient cable includes two parts: main cable which is connected to the electrocardiograph and the lead wires which are connected to the patient. There are 6 chest lead wires and 4 limb lead wires. The user can distinguish

the chest leads and limb leads from the color of the lead wires and the identifiers on the connector.

When connecting the patient cable, plug the patient cable into the cable socket on the electrocardiograph, and then tighten the screws on the two sides of the plug.

3.6 Connect Electrodes

Limb Electrode (Clamp type)

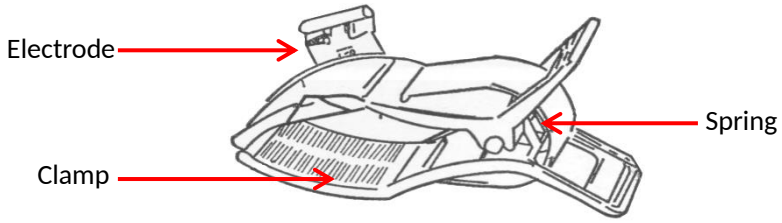


Figure 3-4 Limb Electrode

Chest Electrode Suction Bulb:

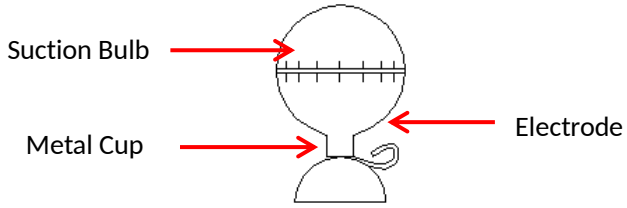


Figure 3-5 Chest Electrodes Bulb

⚠ WARNING

- **Please ensure that all the electrodes are attached to the correct positions on the patient body. Do not allow the electrodes (including neutral electrodes) and patient cables to contact any other conductive parts or the ground.**
- **Polarized electrode may cause residual charge after defibrillation, and it may affect the acquisition of ECG signal.**
- **Do not mix the electrodes of different types and brands, or large baseline drift or longer baseline drift recovery time after defibrillation may caused.**
- **Please use the patient cable with defibrillation protection and high-frequency cautery protection by our company. (refer to appendix I)**
- **Do not use electrodes which made from different metal materials.**

The contact resistance between the patient and electrodes exerts great influence on the quality of ECG,

therefore, the contact resistance should be minimized (conductive paste can be used) to obtain better ECG.

The identifiers and color codes are different according to different standards. The identifiers and color codes of European standard and American standard are shown in the table 3-1 below.

Table 3-1 Electrode Identifier and Color Code

Applied Part	European Standard (IEC)		American Standard (AHA)	
	Identifier	**Color**	**Identifier**	**Color**
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Left leg	F	Green	LL	Red
Right leg	N or RF	Black	RL	Green
Chest 1	C1	White/Red	V1	Brown/Red
Chest 2	C2	White/Yellow	V2	Brown/Yellow
Chest 3	C3	White/Green	V3	Brown/Green
Chest 4	C4	White/Brown	V4	Brown/Blue
Chest 5	C5	White/Black	V5	Brown/Orange
Chest 6	C6	White/Purple	V6	Brown/Purple

The following is the leads connection diagram according to European standard:

R electrode — Right arm

L electrode — Left arm

N electrode —Right leg

F electrode —Left leg

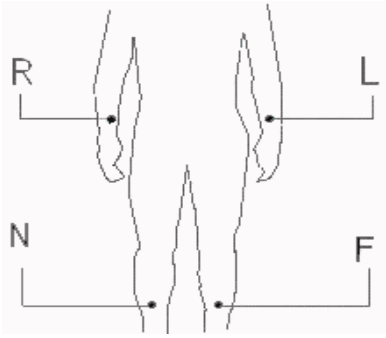


Figure 3-6 Placement of limb electrodes

The limb electrodes are placed above the wrist joint of the forearm and above the inner side of the ankle joint of the lower leg, on those parts the electrodes and skin contact tightly.

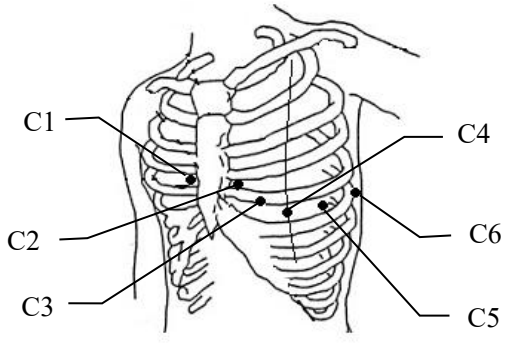


Figure 3-7 Placement of chest electrodes

C1: Fourth intercostals space on right border of sternum.

C2: Fourth intercostals space on left border of sternum.

C3: Midpoint of the line connecting C2 and C4.

C4: The intersection of the fifth intercostal space on the left sternal border and the midline of the left clavicle.

C5: Left anterior axillary line at the horizontal level of C4.

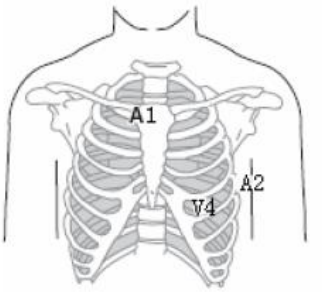
C6: Left midaxillary line at the horizontal level of C4.

■ NEHB Lead

Table 3-2 Electrode Identifier and Color Code

Applied part	European Standard (IEC)		American Standard (AHA)	
	Identifier	Color	Identifier	Color
Chest 1	N_{st}	White/ Pink	A1	Brown /Yellow
Chest 2	N_{ax}	White /Grey	A2	Brown /Red
Chest 3	N_{ap}	White / Brown	V4	Brown /Blue

The following is the leads connection diagram according to American standard:



A1: The point where the second rib joins the right edge of the sternum.

A2: Fifth intercostal space to the left of the posterior axillary line.

V4: Midclavicular line at the left fifth intercostal space.

Connect the limb electrodes:

1) Check if the electrodes are clean.
2) Connect four limb electrodes to the corresponding lead wires, straighten the lead wires to avoid twisting or tangling.
3) Roll up the cuff and trouser leg to expose the electrode placement.
4) Clean the skin where put the electrodes by wiping with alcohol.
5) Apply conductive paste on the skin where the electrodes are to be placed evenly.
6) Apply a thin layer of conductive paste to the metal electrode.

7) Use electrode clamps to secure the electrodes in place.

Connect the chest electrodes:

1) Check if the electrodes are clean.
2) Connect six chest electrodes to the corresponding lead wires, straighten the lead wires to avoid twisting or tangling.
3) Unbutton the front of the garment to expose the electrode placement.
4) Clean the skin where put the electrodes by wiping with alcohol.
5) Apply conductive paste on the skin where the electrodes are to be placed evenly.
6) Apply a thin layer of conductive paste evenly around the edge of the chest electrode suction bulb.
7) Squeeze the suction bulb of the chest electrode so that the lower edge of the metal electrode is tightly attached to the skin, and then release the suction bulb so that the electrode is attached to the patient's skin.

Connect electrode pads:

1) Roll up the patient cuff and trouser leg, unbutton the front of the garment to expose the electrode placement.
2) Clean the skin where put the electrodes by wiping with alcohol.
3) Place the electrode pads in the correct positions. Limb electrodes should be placed on the forearm above the wrist joint and on the inner side of the calf above the ankle joint, where the electrodes can make close contact with the skin, avoiding bony areas.
4) Align all lead wires to avoid twine and connect lead wire with electrode pads.

⚠**NOTE**

- **Do not apply too much conductive paste and the layer should be separated from each other. Otherwise it may cause short circuit between electrodes and the error of ECG signal recording.**

3.7 Inspection before Startup

Before using the electrocardiograph, please carefully read the user manual, familiarize yourself with the performance of the instrument, as well as the necessary operating methods and precautions.

Following inspection procedures are recommended before startup:

1) Environment

   Check whether there is other electric device around, such as ESU, ultrasonic equipment, radioactive equipment, which may generate interference. Switch off these devices when necessary.

   The room temperature is required to keep not lower than 18℃ to avoid the EMG interference caused by cold.

2) Power supply

When the AC power supply is connected, check whether the power cord has been connected well, and three-phase sockets with protective earth should be used.

3) Grounding

Check whether the grounding wire has been connected correctly and tightly;

4) Lead Wires

Check whether the lead wires have been connected well and avoid placing the lead wires near the AC power cord; check whether the lead wires have been connected with the corresponding electrodes correctly;

5) Electrodes

Check whether the electrodes have been attached well; check whether the electrodes, especially the chest electrodes, does not contact with each other.

6) Record Paper

Ensure that the record paper is adequate and is correctly installed;

7) Examinee

Check whether the hand and foot of the examinee are contact with the metal parts of the bed, whether the environment of the examination room is comfortable and whether the examinee is too nervous. Ask the examinee to relax the body and keep calm respiration.

3.8 Startup

When AC power supply is connected, the AC power indicator will light up, and press the ON/OFF button to turn on the equipment, and then the equipment enters the working status. When operating on AC power, If the built-in battery is low, the device will charge the battery simultaneously. In this case, both the AC power indicator and battery charging indicator light will remain on.

When built-in battery is used for power supply, press the ON/OFF button to turn on the equipment directly, the battery working indicator light will flash after the equipment enters the working status.

Chapter 4 Settings

Press [Menu] button during waveform acquisition, and you can access to menu setting interface.

4.1 Routine ECG Settings

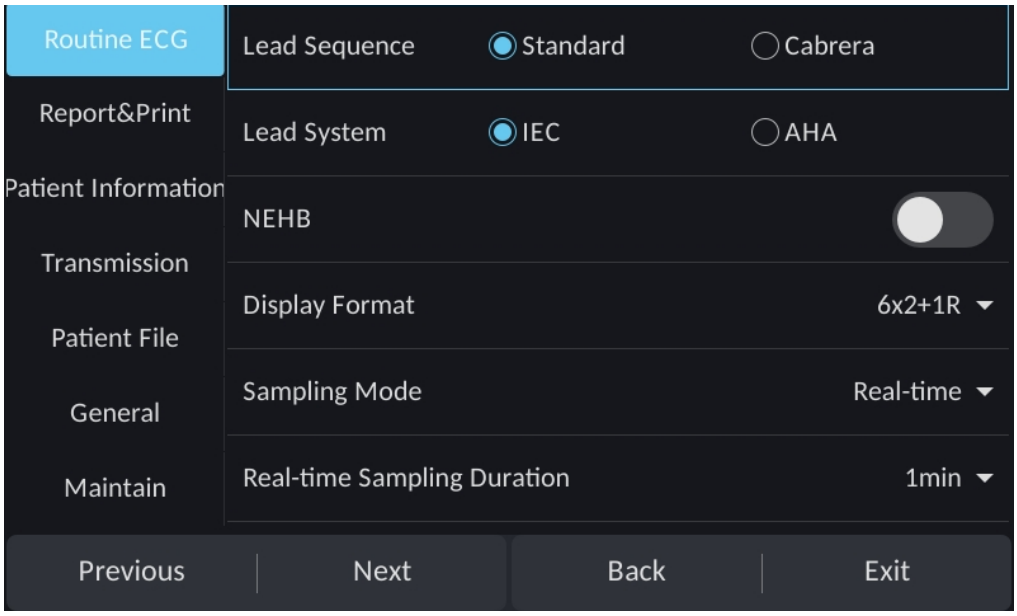


Figure 4-1 Routine ECG Setup

- **Lead Sequence**: choose from [**Standard**] and [**Cabrera**] to set the sequenceof displayed ECG waveforms.
  - ✧ [Standard]: The lead sequence for displaying the waveform is I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6.
  - ✧ [Cabrera]: The lead sequence for displaying the waveform is aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6.
- **Lead System**: select the naming criteria of lead wires: [IEC] and [AHA].
  - ✧ [IEC]: The lead will be named as: C1, C2, C3, C4, C5, C6, R, L, N, F.
  - ✧ [AHA]: The lead will be named as: V1, V2, V3, V4, V5, V6, RA, LA, RL, LL.
- **[NEHB]**: can set to ON or OFF. When it set to ON, the displayed waveform in manual mode are respectively from: I, II, III, ND, NA, NI.
- **Display Format**: the display formats of ECG waveform on the main screen include [3×4+1R], [6×2] and [6×2+1R]. This option is merely available under auto mode and manual mode.
  - ✧ [3×4+1R]: The ECG waveforms are arranged as per 3×4, adding a rhythm lead waveform.
  - ✧ [6×2]: The ECG waveforms are arranged as per 6×2.
  - ✧ [6×2+1R]: The ECG waveforms are arranged as per 6×2, adding a rhythm lead waveform.
- **Sampling Mode**: [Real-time], [Trigger], [Periodic] and [Pre-sampling]. This option is merely available

under auto mode.

- ✧ [Real-time]: Afetr pressing , 10-seconds data of ECG sampled from pressing the key will be recorded.
- ✧ [Trigger]: Afetr pressing , the recorder will be triggered to print if the patient experiences arrhythmias or other abnormalities.
- ✧ [Periodic]: After setting the [Periodic Sampling Duration] and [Periodic Sampling Interval], the recorder will print according to the set duration and interval after pressing .
- ✧ [Pre-sampling]: If there is a valid data over 10 seconds before pressing , the recorder will record 10- seconds data of ECG before pressing the button. If it is less than 10 seconds, the recorder will record 10- seconds data of ECG from pressing the button.

- ◆ **Real-time Sampling Duration**: Set data sampling duration. [10s], [20s], [30s], [1min], [5min], [10min] and [30min] are available.
- ◆ **Rhythm Type**: [1 Rhythm] and [3 Rhythms]
  - ✧ [1 Rhythm]: “Rhythm 1”, “Rhythm 2” and “Rhythm 3” can be set, and only one lead can be selected as the rhythm lead from [I], [II], [III], [aVR], [aVL], [aVF], [V1], [V2], [V3], [V4], [V5], [V6];
  - ✧ [3 Rhythms]: “Rhythm 1”, “Rhythm 2” and “Rhythm 3” can be set , any lead of [I], [II], [III], [aVR], [aVL], [aVF], [V1], [V2], [V3], [V4], [V5], [V6] can be selected as the rhythm lead of “Rhythm 1”, “Rhythm 2” and “Rhythm 3”.

  Under rhythm mode, when the [Rhythm Type] is set as [1 Rhythm], 60-second rhythm waveform of rhythm lead will be recorded and output; when the [Rhythm Type] is set as [3 Rhythms], 60-second rhythm waveform in total of three rhythm leads respectively selected for [Rhythm1], [Rhythm2] and [Rhythm3] will be recorded and output.
- ◆ **Rhythm 1/2/3**: The selected rhythm leads can be printed while recording ECG. Any lead of [I], [II], [III], [aVR], [aVL], [aVF], [V1], [V2], [V3], [V4], [V5], [V6] can be selected as the rhythm lead.

  Rhythm 1/2/3 must be different from each other.
- ◆ **Rhythm Sampling Duration**: [20s], [1 min], [3min], [5min], [10min], [15min] and [30min] are available.
- ◆ **Periodic Sampling Duration**: Periodic sampling duration can be set from 1min to 60min, defaulted by 60min.
- ◆ **Periodic Sampling Interval**: Periodic sampling interval must be less than or equal to periodic sampling duration.
- ◆ **AC Filter**: [50Hz], [60Hz] and [OFF]

  AC filter is used to filter the interference from AC power supply to avoid the reducing or distorting the ECG signal. When it is set OFF, filtering is disabled.
- ◆ **EMG Filter**: [25Hz], [35Hz], [45Hz] and [OFF].

EMG filter is low-pass filter, and is used to filter the interference on the ECG signal caused by strong muscle vibration. The smaller the setting value, the greater the resistance to myoelectric interference.

The EMG signal above the set value will be effectively attenuate, and the system will display the distortionless EMG signal of the set value or below the set value. When EMG Filter is set OFF, it is disabled and the device screen displays the frequency signals that can be detected.

- **Baseline Drift Filter**: [0.01Hz], [0.05Hz], [0.15Hz], [0.25Hz], [0.32Hz], [0.50Hz], [0.67Hz] and [OFF].

  Baseline drift filter is high-pass filter and is used to resist the drift of baseline and ensure the ECG signal is on the baseline during recording. The greater the setting value, the better ability to resist the drift of baseline.

  After setting, the signal below the set value will be effectively attenuate, and the distortionless signal of the set value or above the set value will be displayed. When set to OFF, the baseline drift filter is disabled.

- **Low-pass Filter**: [75Hz], [100Hz], [150Hz], [270Hz], [300Hz], [350Hz], [500Hz] and [OFF].

  Low pass filter is used to limit the bandwidth of the input signal and reduce the signal with the frequency higher than the set cutoff frequency. The smaller the setting value, the less interference there will be.

  The input signal above the set value will be effectively attenuate, and the system will display the distortionless signal of set value or below the set value. When it set OFF, Low-pass filter is disabled.

- **Wave Speed**: [5mm/s], [6.25mm/s], [10mm/s], [12.5mm/s], [25mm/s] and [50mm/s] are available.

- **Auto Arrhythmia Detection**: [On]/[Off]

  When it set on, under auto mode, if the recorded or saved ECG report contains arrhythmia data, there will pop up a prompt asking whether to automatically extend a rhythm report.

- **Electrode Reverse Prompt**: [On]/[Off]

  When it set on, if the electrodes are reversed, there will be a prompt.

- **Lead Off Prompt**: [On]/[Off]

  When it set on, if leads off in the 10-second waveform of pre-sampling, there will pop up a prompt of leads off.

4.2 Report&Print Settings

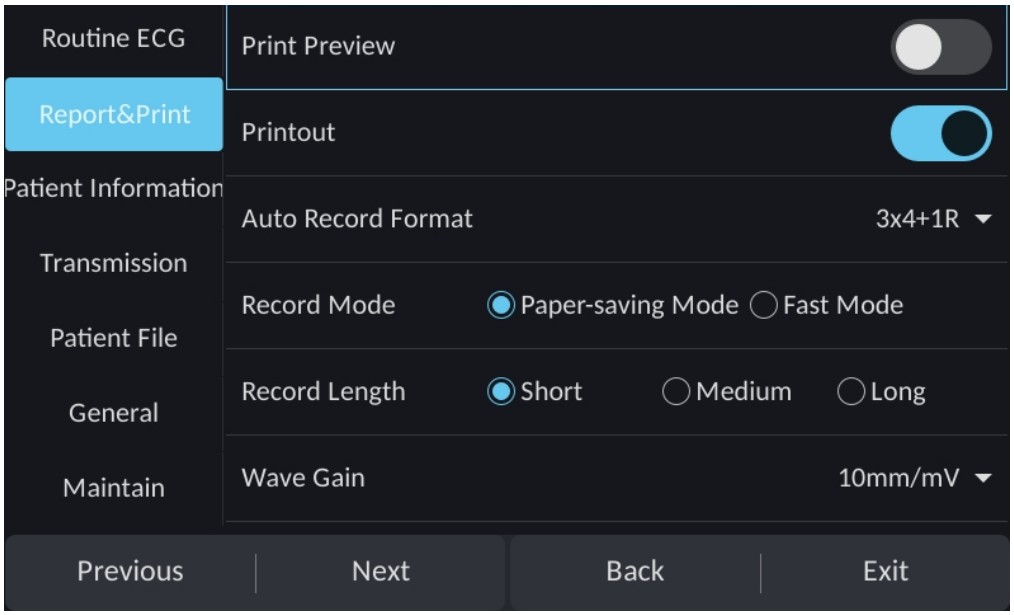


Figure 4-2 Report&Print Setup

- **Print Preview**: [On]/[Off]

  When it set on, the data can be previewed after sampling under the auto, rhythm and RR mode.

- **Printout** : [On]/[Off]

  When it set to off, the report won't be printed automatically.

- **Auto Record Format**: [3×4], [3×4+1R], [3×2+2×3] options are available.

- **Record Mode**: [Paper-saving Mode] and [Fast Mode].

  - [Paper-saving Mode]: Export rhythm report after sampling under auto mode.
  - [Fast Mode]: Export rhythm report at the while sampling under auto mode.

- **Record Length**: [Short], [Medium] and [Long] options are available.

- **Wave Gain**: Options are [1.25mm/mV], [2.5mm/mV], [5 mm/mV], [10mm/mV], [20mm/mV], [40mm/mV], [10/5 mm/mV], [20/10 mm/mV] and [AGC].

  Gain indicates the 1 mV scale height for recording ECG waveforms.

  In which:

  [10/5 mm/mV]: 10 represents the gain of limb leads, and 5 represents the gain of chest leads.

  [20/10mm/mV]: 20 represents the gain of limb leads, and 10 represents the gain of chest leads.

  [AGC]: The system will automatically choose the suitable gain according to ECG waveform height. This gain indicates that the 1 mV scale height for recording ECG waveforms is 10 mm.

- **Recording Speed**: the paper speed of recorder. [5mm/s], [6.25mm/s], [10mm/s], [12.5mm/s], [25mm/s] and [50mm/s] options are available.

- **Manually Channel**: [1 channel] and [3 channels]

- **Recording Sequence**: [Continuous] and [Simultaneous]
  - ✧ [Continuous]: The lead group will be sequentially sampled one after another. The recording start time of one group of leads is the recording end time of the previous group of leads.
  - ✧ [Simultaneous]: All leads are sampled synchronously. All lead groups start recording at the same time.
- **Average Template**: [On]/ [Off]
- **Feature Point Mark**: [On]/ [Off]
- **Minnesota Code**: [On]/ [Off]
- **Measure Info** (Measure Information): [On]/ [Off]
- **Measure Result:** [On]/ [Off]

  When it set to on, 32 measured items for each of the 12 leads can be output in the recording report. It is only available in auto mode.
- **Diagnosis**: [On]/[Off]
- **Device No.**: [On]/[Off]
- **Paper Type**: [Rolled Paper] and [Folded Paper].
- **Printer Type**: [Built-in Record] and [USB Printer].

⚠NOTE

- **Record mode can't be changed in the process of printing under any mode, which you must stop printing before you can re-select the record mode.**
- **If measurement and diagnosis are required in auto mode, the "Gender", "Age" and other detailed information of the patient should be entered, and the "Measure Result" and "Diagnosis" buttons in the "Report & Print" window should be turned on.**

4.3 Patient Information Settings

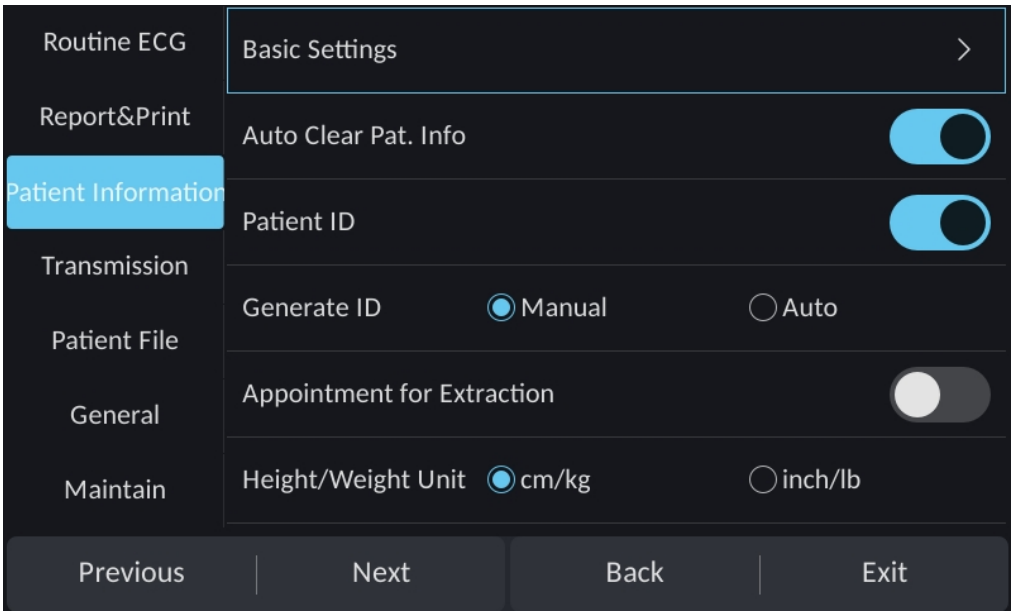


Figure 4-3 Patient Information

NOTE

- **Patient information can't be revised during recording.**
- **The equipment supports inputting English and pinyin (combine sounds into syllables).**

- **Basic Settings**: Selecte the required items, and once selected, users can enter the corresponding information.
- **Auto Clear Pat. Info** (Automatically Clear Patient Information): can be set to ON or OFF. When it set to ON, the patient information will be cleared if the leads fall off.
- **Patient ID**: [ON] or [OFF].

  When it set on, patint ID will be displayed on "patient information" screen.
- **Generate ID**: [Manual] or [Auto].
  - [Manual]: The patient ID will generate automatically based on the exam date.
  - [Auto]: The patient ID should be entered manually.
- **Appointment for Extraction**: [ON] or [OFF].

  When it set to ON, after pressing [Extract] in "Patient Information" window, the system will extractl patient information from the appointment server.
- **Height/Weight Unit**: [cm/kg] or [inch/lb].
- **Input Mode of Age**: [Age] or [Date of Birth].
- **BP Unit**: [mmHg] or [kPa].

- **Customized** : [ON] or [OFF].

  When the function is set to on, you can add customized settings.

- Customized Name : entering custom name.

4.4 Transmission Settings

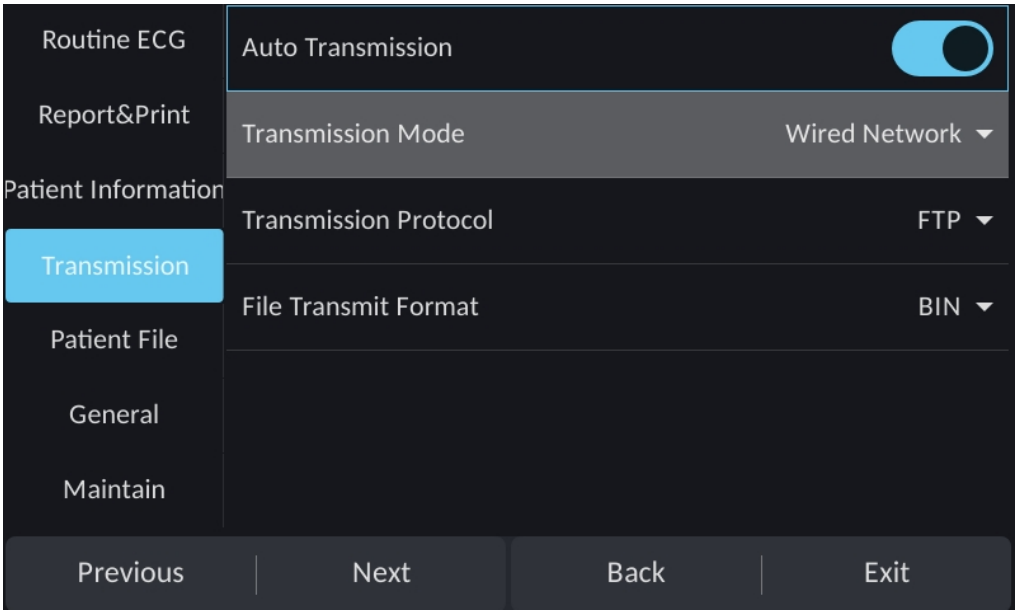


Figure 4-4Transfer Setup

- **Auto Transmission:** [ON] or [OFF].

  When it is set to ON, the ECG data recorded under the Auto, RR or Rhythm mode will be automatically transferred to the computer.

- **Transmission Mode**: [Wired Network], [WiFi] or [Mobile Network].

- **Transmission Protocol**: [FTP], [HL7] or [DICOM].

  - [FTP]: It can transfer the case files to the specified folder via the FTP server. In the main interface, when the file is saved as picture, and they will be transfered to the specified folder, all the selected files can be transferred in file interface.

  - [HL7]: When the transfer type is not ECG network system. After extracting the patient information, the corresponding information will be automatically input into the relevant options in the patient information page. Parameter data, waveform and report can be transferred via HL7 sever.

  - [DICOM]: When the transfer type is not the ECG network system, you can set the name of file folder that obtain patient information through DICOM, enter the soft keyboard and input the corresponding ID, and press “Extract” on the soft keyboard to obtain the patient information. After extracting, the corresponding information will be automatically input to the relevant options in the patient information page. After the DICOM server is started on the computer, files in DICOM format can be uploaded only on the main interface.

- **File Transmit Format**: BIN, PDF, JPG, BMP, DICOM_BMP, DICOM_ECG.

4.5 Patient File Settings

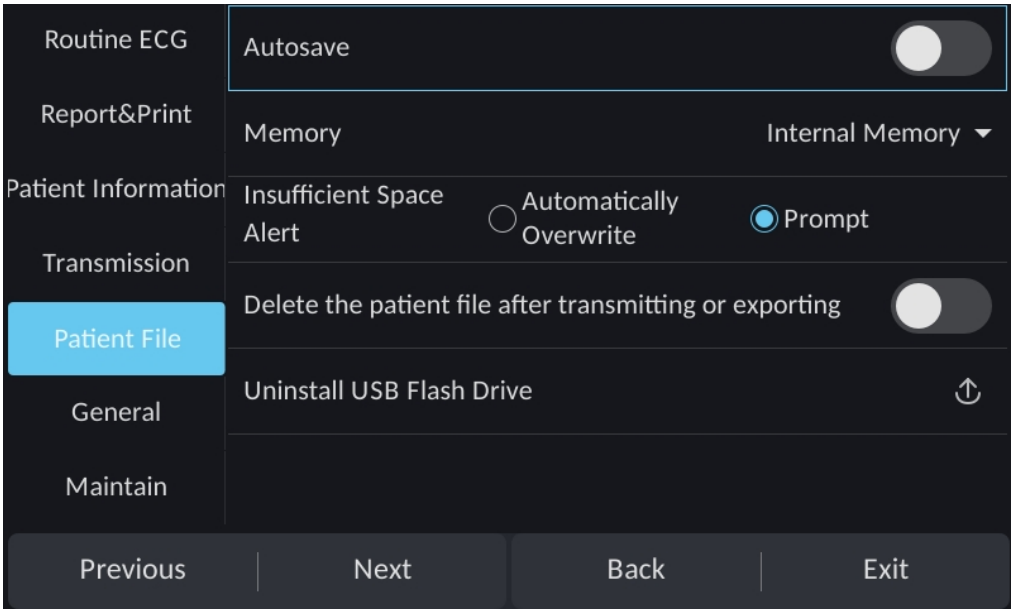


Figure 4-5 File

- **Autosave**: [ON] or [OFF].

  When it set on, the ECG data will be saved automatically; When it set off, an ask windown will pop up to confirm whether to save the ECG data.

- **Memory**: [Internal Memory], [TF Card] and [USB Flash Drive].

  When [Internal Memory] is selected, ECG data in auto, RR and rhythm modes are automatically saved in the ECG machine.

  When [TF Card] or [USB Flash Drive] is selected, ECG data in auto, RR and rhythm mode will automatically saved to TF Card or USB Flash Drive.

- **Insufficient Space Alert**: [Automatically Overwrite] and [Prompt]

  When [Automatically Overwrite] is selected, the new file will automatically overwrite the earliest file when the memory of the ECG machine is full.

  When [Prompt] is selected, a prompt will pop up when the memory of the memory is full.

- **Delete the patient file after transmitting or exporting**: [ON] or [OFF].

  When it set on, a prompt will pop up on file management interface to confirm whether to delete this file after transferring or exporting.

- **Uninstall USB Flash Drive**: Tap on to uninstall.

4.6 General Settings

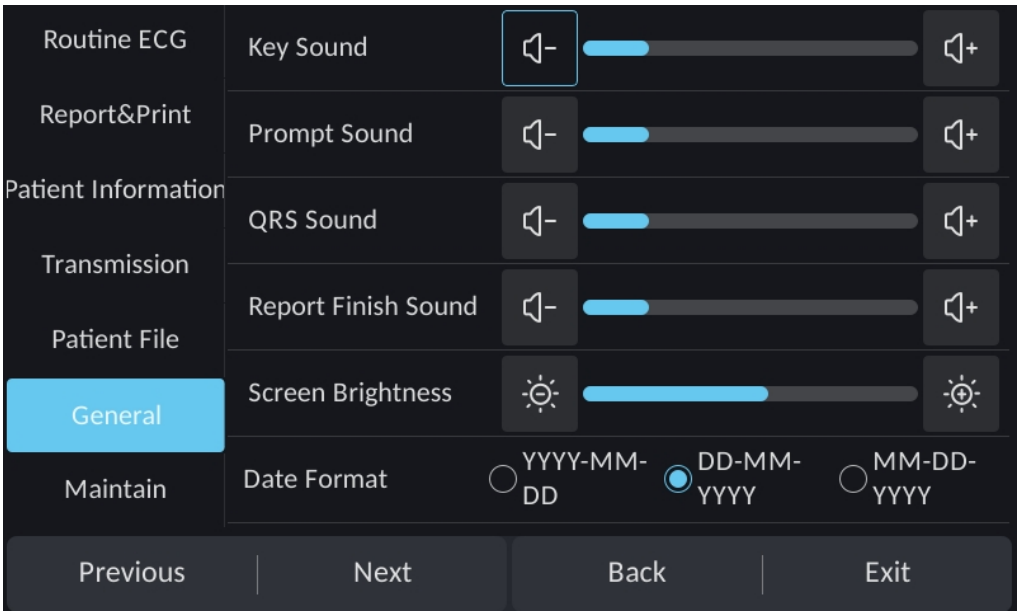


Figure 4-6 General Setup

- **Key Sound**: The device will make a short sound when a key is pressed. Tap on the volume adjustment icon to adjust the volume of the key sound.
- **Prompt Sound**: Except key sound and QRS sound, the other prompt sounds are also made by the ECG machine, such as leads off prompt sound and low battery prompt sound. Tap on the volume adjustment icon to adjust the volume of the prompt sound.
- **QRS Sound**: QRS sound is the brief “beep” coming from the equipment when the R wave is detected. Tap on the volume adjustment icon to adjust the volume of the QRS sound.
- **Report Finish Sound**: Report finish sound is the brief “beep” coming from the equipment when the report is printed. Tap on the volume adjustment icon to adjust the volume of the report completion tone.
- **Screen Brightness**: Tap on the brightness adjustment icon to adjust screen brightness.
- **Date Format**: [YYYY-MM-DD], [MM-DD-YYYY], [DD-MM-YYYY].
- **Date**: entering the current date, which will appear on the interface and ECG report.
- **Time Format**: [12-hour system] or [24-hour system].
- **Time**: Entering the current time, which will appear on the interface and ECG report.
- **Auto Standby**: [ON] or [OFF]. If there is no lead wire connected or no other operation within the set standby waiting time, the instrument will automatically enter the standby state, the display screen will turns black, and the instrument working indicator light will be on (when the battery is powered) or the AC indicator light will be on (when the AC is connected). In standby state, press anywhere on the screen or connect the lead wire, the system exit the standby state and back to the normal working state.

- **Standby Waiting Time**: Entering the time that ranges from 0 to 120min.
- **Auto Shutdown**: [ON] or [OFF].
- **Shutdown Waiting Time**: Entering the time that ranges from 0 to 120min.

4.7 Maintain Settings

Press [Menu] button, and choose [Maintain], then enter password to enter this menu.

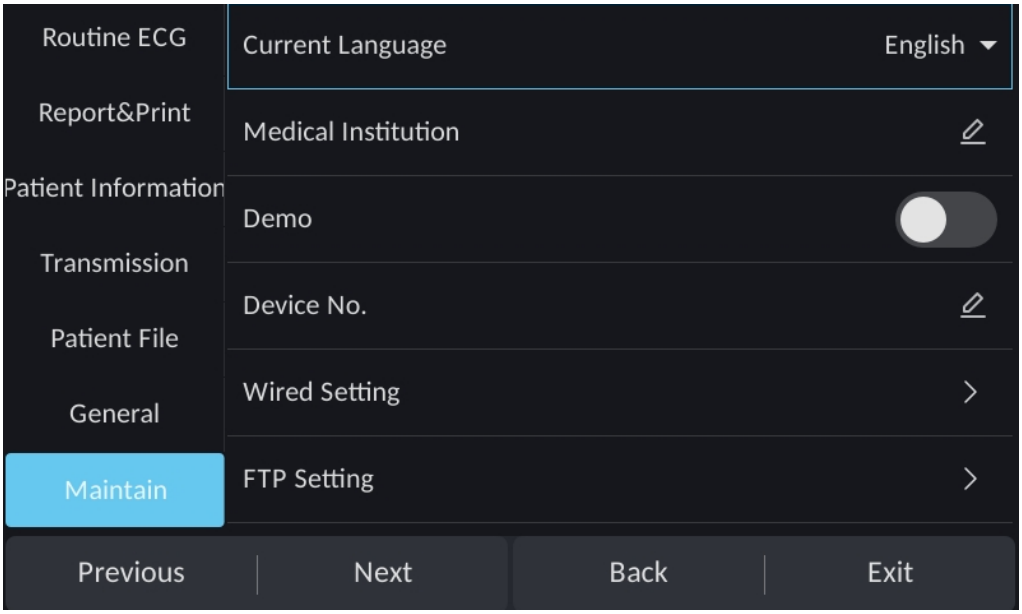


Figure 4-7 Maintain

- **Current Language**: Users can choose the language to be used on the ECG display screen and ECG recording.
- **Medical Institution**: entering the name of medical institution
- **Demo**: press it to activate or deactivate the Demo function.

> ⚠ **WARNING**
>
> - **Demonstration waveform is the simulated waveform set by the manufacturer to show the performance of the equipment and help the user to conduct training. In practical clinical application, demonstration waveform is forbidden to use, because it will mislead the medical personnel to consider it as the monitored patient waveform and parameters, which may affect the patient care and delay the diagnosis and treatment of the disease.**

- **Device No.**: Entering device number, up to 30 digits of English letters or numbers is allowed.
- **Wired Setting**:
  - Wired Auto-IP Acquisition: [ON] or [OFF]. When it set to ON, "Wired Static IP", "Wired Gateway ", "Wired Subnet Mask" and "Wired MAC Address" will be automatically filled. When it set to OFF,

"Wired Static IP", "Wired Gateway ", "Wired Subnet Mask" and "Wired MAC Address" can be manually set.

◆ **FTP Setting**: When "FTP" is selected for transmission, you should set the following items:

- ✧ FTP Username: It is set to Comen by default. The FTP user name should be consistent with the user name of FTP receiving software.
- ✧ FTP Password: It should be consistent with the password of FTP receiving software.
- ✧ FTP Path: Entering FTP path that can access to.
- ✧ FTP Server Address: It should be consistent with that of FTP receiving software.
- ✧ FTP Sever Port: It can be set as required, and it is 21 by default. It should be consistent with that of FTP receiving software.

Note:

FTP: Abbreviation of File Transfer Protocol which allows one computer to acquire files from or transfer files to another computer. While the connection mode of the ECG machine to the computer is the same as that to a computer. You can connect the ECG machine to a computer and designate a user name and password to use the computer in order to ensure safety. Whenever the computer accesses the files on the data management window of the ECG machine, FTP will be run and you can only copy the files to your computer for use.

⚠ **NOTE**

- **FTP receiving software is available in 32-bit and 64-bit versions, and users can choose suitable server according to their computers.**
- **Steps of FTP transferring files: Under the condition that the instrument is connected to the network normally, set the transfer protocol as FTP, in the same time, the server port, user name and password of the FTP receiving software consistent with the setting of these three options in the equipment. Users can set file content as required to upload files.**

◆ **HL7 Setting**: When "HL7" is selected for transmission, the following items should be set:

- ✧ HL7 Server IP: It can be set as required, and it is 200.200.200.100 by default.
- ✧ HL7 Server Port: It can be set as required, and it is 5000 by default.
- ✧ HL7 Send Parameter/ Report: [ON] or [OFF].
- ✧ HL7 Send Waveform: [ON] or [OFF].
- ✧ Interval Time: [ON] or [OFF].

◆ **DICOM Setting**: When "DICOM" is selected for transmission, the following items should be set:

- ✧ DICOM Server IP: It can be set as required, and it is 200.200.200.100 by default.
- ✧ DICOM Sever port: It can be set as required, and it is 5000 by default.
- ✧ DICOM AE: A terminal in DICOM communication that can enter a maximum of 16 letters or numbers.
- ✧ Worklist Server IP: It can be set as required, and it is 200.200.200.100 by default.

- ✧ Worklist Server Port: It can be set as required, and it is 5000 by default.
- ✧ Wolist AE: A terminal in DICOM communication that can enter a maximum of 16 letters or numbers.

- ◆ **Version Information**: To view the detailed information about version.
- ◆ **Battery Status**: To view the battery power and voltage.
- ◆ **QTc Formula**: [Hodges Format], [Bazett Format], [Fridericia Format] or [Framingham format], and they are displayed as QTcHd, QTcBz, QTcFd, QTcFm respectively on the printed report.
- ◆ **Tachycardia Criterion**: HR value can be entered and it is 100bpm by default.
- ◆ **Bradycardia Criterion**: HR value can be entered and it is 60bpm by default.
- ◆ **RR/PP**: [ON] or [OFF]. When it set to on, this parameter will contained in meastrement result and printed report.
- ◆ **Signal Quality**: [ON] or [OFF]. The red indicator light refers to bad signal quality, yellow means there in interference exists and green refers to goos signal quality.
- ◆ **User Password**: Consists of 6~16 bits including English upper and lower case and special characters.
- ◆ **Patient File Password Protection**: [ON] or [OFF]. When it set to on, password verification is required before viewing patient file.
- ◆ **Menu Password Protection**: [ON] or [OFF]. When it set to on, password verification is required before viewing menu.
- ◆ **Standby Password Protection**: [ON] or [OFF]. When it set to on, password verification is required before activating standby function.

⚠WARNING

- **This product can connect to the ECG workstation.**

4.8 Shutdown

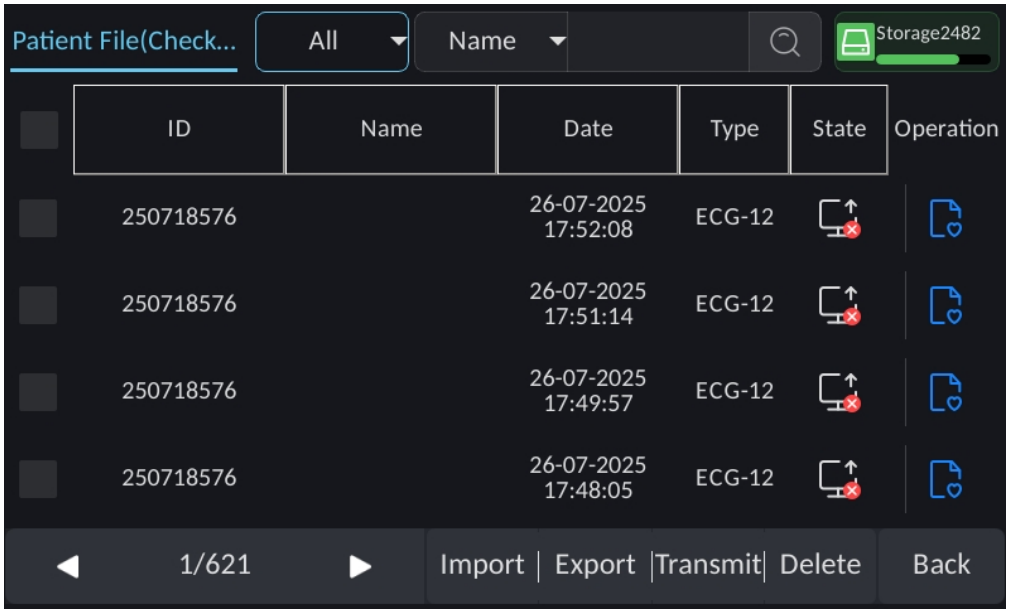
When the deveice is powered by built-in battery, press “” directly to shut down.

When the deveice is powered by AC power supply, press “” to shut down the device and then pull out the power plug.

Chapter 5 Patient File Management

Users need set the memory if they need to save the ECG data and please refer to ***4.5Patient File Settings*** for more details. Internal Memory is treated as default memorry and can save 2000 copies of 10s waveform data. External storage (USB flash drive, TF card), with a maximum total capacity of 32GB. ECG data recorded under auto mode will be automatically saved in internal memory.

Tap on "File Management" on the main interface to enter file management menu.



"File Management" interface displays the saved patient data. On this screen, users can record, delete the patient data, or transfer, copy the patient data to "External Memory". When the memory space is full, the prompt message "Memory is full, whether to overwrite the previous patient file?" will pop up if "Prompt" is selected under Insufficient Space Alert.

5.1 Transmit Files to Computer

Users need to install Comen ECG network system in advance and turn it on before transferring data.

5.1.1 Transmit Files via Wired Network

A dedicated network cable should be used to connect the computer network port and the ECG machine network port.

1. Auto Transmission

1) Press the menu button and tap on "Transmission" to enter setting screen.
2) Turn on "Auto Transmission", select "Wired Network" as "Transfer mode" and choose "Transmission Protocol".
3) Enter"Maintain" screen.

4) Turn on "Wired Auto-IP Acquisition", and then the “Wired Static IP”, “Wired Gateway”, “Wired Subnet Mask” and “Wired MAC Address” are automatically set done.
5) Setup the selected transmission protocol.
6) After completing the above settings, when a set of ECG data is recorded in auto, RR, or rhythm mode, the data will be automatically transmitted to the computer via the network.

2. Manual Transmission

1) Press the menu button and tap on "Transmission" to enter setting screen.
2) Turn off “Auto Transmission”, select "Wired Network" as "Transfer mode" and choose “Transmission Protocol”.
3) Enter"Maintain" screen.
4) Refer to step 4 and 5 of “Auto Transmit” for IP address setting.
5) Tap on "File Management", select the patient data to be transmitted, and tap on "Transmit" to transfer the patient data to the computer.

⚠NOTE

- **It takes time for ECG machine to transmit files, please be patient.**

5.1.2 Transmit Files via WIFI / Mobile Network

If WIFI or mobile communication function is equipped with the device you purchased, files can be transferred via WIFI or Mobile Network.

1. **WI-FI Network Transmission**

1) Press the menu button and tap on "Transmission" to enter setting screen.
2) Select "WI-FI" as "Transmission Mode".
3) Set to connect the wifi network.
4) The following steps can be found in ***5.1.1Transmit Files via Wired Network*** .

2. Mobile Network Transmission

1) Firstly, insert a SIM card.
2) Press the menu button and tap on "Transmission" to enter setting screen.
3) Select "Mobile Network" as "Transmission Mode".
4) Turn on “Auto Transmission”, select "Mobile Network" as "Transmission Mode".
5) The following steps can be found in ***5.1.1Transmit Files via Wired Network.***

⚠CAUTION

- **Do not insert or remove external memory or USB printer during file transmission.**

5.2 Transmit Files between Electrocardiograph and External Memory

1) Insert external memory into the electrocardiograph.
2) Tap on [File Management].
3) Tap on "Export" to copy the patient data into external memory folder; if you want to import patient data from the external memory folder into the electrocardiograph, tap on "Import".

⚠NOTE

- **To import data from external storage into the electrocardiograph, the external storage must contain a DataImport folder, and the DataImport folder must contain patient data. The folder name DataImport is case-sensitive, and the data placed in it is exported patient file bin data, which cannot be renamed.**
- **You are recommended to use the USB flash driver supplied or designated by Comen, like Kingston, PNY, ADATA or Apacer, or it may fail to be recognized by the electrocardiograph or reduce the performance and safety of the electrocardiograph.**
- **This electrocardiograph can only recognize the USB flash drive of FAT32 format. Please format USB flash drive to FAT32 format before using. The maximum total capacity of external storage is 32GB.**
- **Do not remove or insert the USB flash drive or TF card during file transmission, as this may result in file corruption. When you reinsert the USB flash drive or TF card, it will be restricted to read-only mode.**
- **Please do not frequently plug and unplug the USB flash drive while the device is running. Do not plug or unplug the TF card while the device is running.**

5.3 Delete Files

Tap on "File Management", select the patient data to be deleted and tap on "Delete" to delete patient data.

5.4 Print Files

Tap on "File Management", select the patient data to be printed and enter “Preview” interface, and then tap on "Print" to start printing.

Chapter 6 Acquiring and Printing

6.1 Input Patient Information

6.1.1 Manually Input Patient Information

1) Before manually inputting patient information, users can set related information in "Patient Info.". For more detail, please refer to 4.3 Patient Information Settings.
2) Tap on patient Information area on the main interface to fill the related patient information.

⚠ NOTE

- **When pacemaker is implanted and select “Yes” on patient information screen, the electrocardiograph can detect very small pacemaker pulses. However, the system will be very sensitive at this time and it should be placed far away from the equipment that emmitting high frequency radiation as it may interfere with pacemaker pulse detection and normal ECG acquisition.**
- **"Pacemaker" is recommended to be set “No” unless performing an electrocardiogram on patients with pacemakers.**

6.1.2 Download Patient Information from Appointment System

1) Connect the Electrocardiograph to the computer through network.
2) Activate the ECG network system on computer.
3) Press the menu button and tap on "Transmission" to enter setting screen. Select the “Transmission Protocol” that supports appointment-based access to patient information, such as HL7 or DICOM.
4) Enter “Maintain” interface.
5) Setup the IP address and port information for the appointment server, and then setup the IP address, gateway and subnet mask of device network.
6) Tap on patient information area on main interface, and then tap on "Appointment".
7) Tap on "Load" to download the appointment record from the server.

⚠ NOTE

- **To use the appointment function, you need to install the ECG network system with the appointment function.**

6.2 Print ECG Report

Procedures of ECG report printing are as follows:

1) Select work mode from "Manual", "Auto", "Rhythm" and "RR".
2) Setup system and print parameter as required.
3) Press "Print" button to start or stop recording.
4) If the "Manual" mode is selected, you need to manually switch the lead group, and press "Print" button to start or stop recording.

> ⚠ **Note**
>
> - **Users can not change record mode in the process of recording.**

6.3 ECG Report

Take the ECG recoding under auto mode with 3×4+1R display format, and average template, measure result and diagnosis are turned on as an example, and the output ECG report includes part (a) and part (b), shown as the follows:

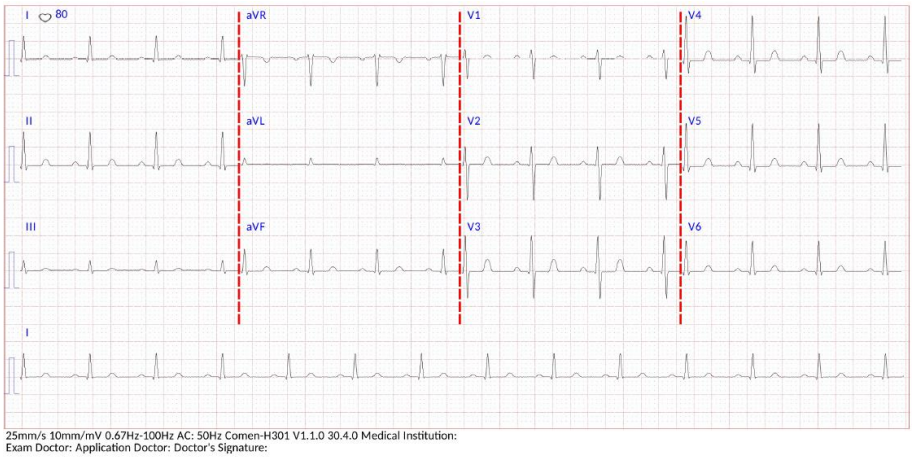


Figure 6-1（a） Report format 3×4+1R

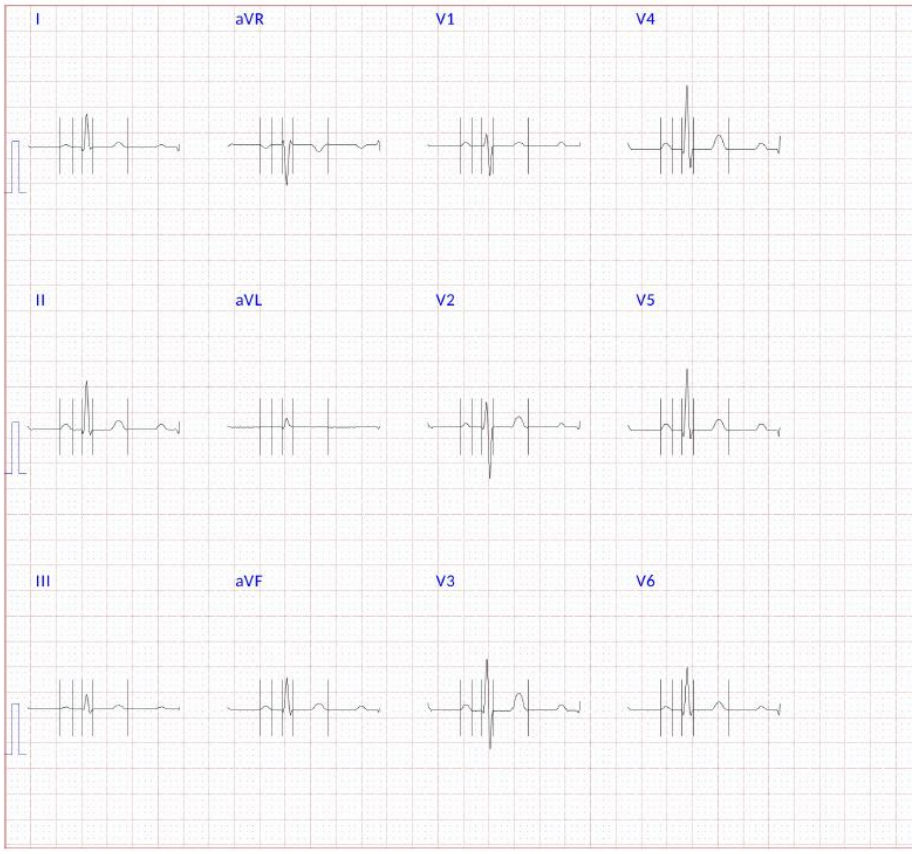


Figure 6-2（b） Average template 3×4+1R

Normal ECG Report

ID: 123456 Report Time: 21-08-2029 15:39:35 3x4+1R Simultaneous Device No.:

Name : Lisa
Gender : Unknown
Date of Birth:
Height :
Weight :
Blood Pressure(S/D) :
Pacemaker : No
Priority : Normal
Race : Unknown
Medication : Not Set
Medical History : Not Set
Room No. :

HR : 80 bpm
PDuration/PRInterval : 94/168 ms
QRSDuration : 90 ms
QT/QTc(Hd)Interval : 364/399 ms
P/QRS/TAxis : 57/44/56°
RV5/SV1Amplitude : 1.216/0.585 mV
RV5+SV1Amplitude : 1.801 mV
RV6/SV2 Amplitude : 0.864/1.011 mV

Sinus rhythm
--- Interpretation made without knowing patient's gender ---
Normal ECG

Figure 6-3（c） Measure Result

Information included are as follows:

- Detailed Information:
  - ⎍(Calibration Signal of the 1mV)
  - I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 (Identifiers of 12 Standard Lead and ECG waveforms)
  - Patient ID, display format, print speed, wave gain, baseline drift filter, low-pass filter, AC filter, model of device, software version, Glasgow algorithm version.
- Patient Information: Patient ID, name, gender, age, date of birth, height, pacemaker, blood pressure, race, medication, medical history, room No. and other basic information.
- Measure Result:
  - HR, P duration/PR interval, QRS interval, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude, RV5+SV1 amplitude and RV6/SV2 amplitude.
- Diagnosis: After entering the gender, age and other detailed information of patient, the diagnosis

information will be printed.

NOTE

- **Under manual mode, only patient information will be printed on the report.**
- **This equipment is for detecting, and it is only responsible for those items regulated by relevant national standards. The doctor should sign for the diagnosis based on the actual ECG waveform and is responsible for the report.**

Chapter 7 Prompt Message

There will be some prompt messages during operation, which are shown in the following table:

Prompt Message	Meaning	Cause
Signal overload!	The signal collected by the electrocardiogram parameter board is too large.	DC bias exceeding 970mv
Lead Off	ECG lead wire falls off.	Lead wire falls off.
Low Battery	Prompt the user that the battery is low and should be charged in a timely manner.	Battery power below 25%.
Low battery, the operation is cancelled!	Battery power insufficient for next print job.	Battery power below 25% and no AC power supply connected.
Printing…	The report is being printed.	Enter print status prompt
Recorder Cover Open!	The cover is not closed.	The cover is not closed.
No Recorder Paper!	There is no paper in recorder.	There is no paper in recorder.
Recorder Overheated!	The recorder is overheated.	The recorder is overheated.
Recorder Abnormal!	Recorder is in abnormal state.	Recorder is in abnormal state and printing is not available.
Paper type error!	Wrong paper type.	The black mark on the folded paper was not recognized properly.
USB Storage has been removed.	USB Storage has been removed.	USB Storage has been removed.
TF Card has been removed.	TF Card has been removed.	TF Card has been removed.
IP Conflict	IP Conflict	Wired network IP address conflict

Chapter 8 Cleaning, Disinfection and Maintenance

8.1 Cleaning

⚠ **CAUTION**

- **Turn off the device, and if the AC power supply is connected, disconnect the AC power supply and remove the power cord and patient cable before cleaning.**

(1) Cleaning of Main Unit and patient Cable

Wet a soft, clean lint-free cloth with mild soapsuds or a non-corrosive, diluted detergent solution, and then wipe the surface of the electrocardiograph and patient cable and dry them with clean and dry soft cloth.

(2) Cleaning of Electrodes

After using the electrodes, wipe off the conductive paste with a clean soft cloth. Seperate the suction bulb from metal cup of the chest electrode, and seperate the electrodes from the clamp and wash them in clean warm water (lower than 35℃). Make sure that there is no residual conductive paste. Naturally dry them or clean them with clean and dry soft cloth.

(3) Cleaning of Print Head

Soiled thermosensitive print head will affect the clarity of recording, therefore, the user should clean the surface of the print head periodically (at least once a month). The cleaning steps are as follows:
Open the recorder cover and remove record paper (if any). Wipe the print head gently with a clean soft cloth damped with a little 75% alcohol. For the stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth, after natural drying, install the record paper and close the recorder cover.

⚠ **CAUTION**

- **Do not allow the liquid to enter the inner of the equipment during cleaning. Do not immerse the equipment and patient cable into liquid in any case.**
- **Do not use abrasive material to clean electrodes.**
- **Wipe off all the residual detergent on the surface of equipment and patient cable after cleaning.**

8.2 Disinfection

To avoid long-term damage to the product, we recommend disinfecting it only when deemed necessary by your hospital's procedures. We also recommend cleaning the product before disinfecting it.

⚠ **CAUTION**

- **Do not disinfect the device by the way of high temperature, autoclaving or ionizing radiation.**
- **Do not use chloric disinfectants such as bleaching powder, sodium hypochlorite.**

8.3 Routine Inspection

Before daily initial use, it is necessary to inspect the equipment appearance. In case of electrocardiograph damage or fault, immediately stop using and contact the hospital's equipment engineer or maintenance personnel of Comen.

The inspection items include:

- The electrocardiograph housing shall be free of contamination, and the panel and display screen shall be free of fracture and damage.
- The buttons shall be in good condition.
- The ports, sockets and cables shall be free of damages and intertwining.
- The power cable and patient cable shall be connected to the electrocardiograph securely.
- The print paper should be sufficient and installed properly.
- The suction bulb of chest lead shall be free of cracks and the holding force of the limb electrode clamp shall be sufficient.

The electrocardiograph shall undergo a comprehensive inspection by the qualified maintenance personnel after being continuously used for 6-12 months, so as to ensure normal operation of the equipment.

The inspection items include:

- The environment and power supply shall meet the requirements.
- The equipment and accessories shall be free of mechanical damages.
- The power cable, patient cable and lead wire shall be free of wearing.
- The specified accessories are used.
- The battery performance is good.
- The recorder paper shall work normally and the printing shall be free of missing points.
- All functions shall be in good working condition.

8.4 Maintenance

8.4.1 Charge and Replace the Battery

⚠ WARNING

- **Improper operation may cause the battery being hot, ignition, explosion or capacity declination. Read this user manual carefully before using the rechargeable lithium battery (hereinafter called "Battery").**

(1) **Battery capacity display**:

Current capacity of the rechargeable battery can be identified according to the battery symbol at the top right corner on the screen:

: Full capacity.

: Capacity is not full.

: Capacity is low, it should be charged.

: Capacity is too low, it should be charged immediately.

: No battery installed.

(2) **Charge the battery**:

This electrocardiograph is equipped with built-in rechargeable lithium battery and its charge control circuit. For the power loss during storage and transportation process, the battery power may be inadequate and should be charged before first use. When connected to the AC power supply, the battery will be charged, and the AC power indicator（ ） and battery charge indicator（ ） flash, which shows the battery is being charged.

(3) **Replace the battery**:

When the service life of the battery is expired, or when there is peculiar smell, liquid leakage, please contact the local maintenance engineer or the manufacturer immediately to replace the battery.

⚠ WARNING

- **Only authorized engineer who is qualified to open the battery compartment and replace the battery. Only use the rechargeable lithium battery of the same model provided by Comen.**
- **Do not reverse the anode and cathode when installing the battery, otherwise explosion may be caused.**
- **The waste battery should be sent back to Comen or be disposed of according to the local regulations.**

⚠ **NOTE**

- **At present, Comen would conditionally provide circuit diagram, component list, figure captions, calibration methods in lists and other information to help users to authorize proper and qualified engineers to maintain those parts of instrument which can be maintained by users.**

8.4.2 Recoder and Recorder Paper

Storage requirements for record paper:

- Record paper should be stored in dry, dark and cool place, high temperature, damp and direct sunlight should be avoided.
- Do not place the paper under fluorescence for a long time.
- Be sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.
- Do not overlap the record paper with waveform for a long time, or else the ECG waveforms recorded may trans-print each other.

8.4.3 Maintenance of Main Unit, Patient Cable and Electrodes

⚠ **CAUTION**

- **Safety tests should be conducted periodically for the equipment at least once a year and the tests mainly include:**
  1) **Check whether there is mechanical and functional damage for the main unit and accessories.**
  2) **Check whether there is damage for the safety symbols;**
  3) **Validate the functions of the equipment as described in the user manual;**
  4) **Conduct the following safety test according to IEC 60601-1:2012.**
     - ✧ **Test the protective ground resistance, Limit: 0.1Ω.**
     - ✧ **Test the earth leakage current, Limit: Normal Condition 500μA, Single Fault Condition 1000μA.**
     - ✧ **Test the patient leakage current, Limit: Normal Condition 10μA, Single Fault Condition**

50μA (for CF type device).

Main unit:

- The main unit of the electrocardiograph should be protected from high temperature, sunlight, damp, dust or impact. The dust shied should be covered well if the equipment is not in use; when moving the electrocardiograph, intense vibration should be avoided.
- Liquid should be protected from entering the equipment, or the performance and safety of the equipment will be affected.
- The performance of the electrocardiograph should be tested periodically by the medical instrument maintenance department.

Lead wire:

- The integrality of the patient cable and lead wires should be examined periodically, and ensure the conduction is in good condition.
- The lead wires should be aligned to avoid knotting and blending.
- The core wire and shielding layer are easier to be damaged, especially the parts near the plug of the two ends, do not pull or wrest forcibly when using, nip the plug parts with hand.
- Cables and lead wires should be stored in large coils or hung up to avoid twisting or sharp angle folding.
- If the cables and lead wires are found to be damaged or aging, they must be replaced.

Electrode:

- After using the electrodes, the residual conductive paste should be cleaned.
- The suction bulb of the chest electrode should avoid the direct sunlight or being too hot.
- After prolonged use, the electrode surface may become oxidized and discolored due to corrosion or other factors. In such cases, the electrode should be replaced with a new one to ensure accurate electrocardiogram recording.

Discarding of the equipment and accessories:

Do not dispose of the waste electric or electronic equipment and its accessories as the unclassified civil waste. Collect them separately so as to reuse, recycle or dispose of safely and properly.

Appendix I Accessories

The accessories recommended by Comen and should be used when using this device.

⚠WARNING

- **Only use the patient cable or other accessories provided by Comen. The accessories of other types may damage the equipment or affect the performance and safety of the equipment.**
- **Reusable electrodes must be cleaned and disinfected before use.**
- **The following list of lead wires and electrodes recommended by our company have a service life of two years.**

Name	Model	Note	Manufacture
ECG Lead Cable	M0201183	American Standard + Adults+ Φ 4.0 Banana Insert Type	China Qingdao Bright Medical Manufacturing Co., Ltd.
	M0201085	European Standard+ Children/Adults+ Φ 4.0 Banana Insert Type	
Suction Bulb of Chest Lead	M0101074	Children + 4.0 Insert Type	
Limb Electrode Clamp	M0102087		
Suction Bulb of Chest Lead	M0101055	Adults + 4.0 Insert Type	
Limb Electrode Clamp	M0102057		

Appendix II Product Specification

Safety Standards	IEC60601-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
	IEC 60601-1-2	Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
	IEC60601-2-25	Medical electrical equipment-Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
	EC11	Diagnostic electrocardiographic devices

Classification	Medical device management	Class IIa per rule 10 of Annex VIII
	Type of protection against electric shock	Class I device, with internal power supply
	Level of protection against electric shock	Type CF, with defibrillation proof function
	Applied part	Patient cable
	Degree of safety of application in the presence of flammable gas	The equipment cannot be used in the presence of flammable gas.
	Ingress protection level	Main unit: IPX0;
	Electrical connection between equipment and patient	Non-electrical connection between equipment and patient
	Operation mode	Continuous operation
	EMC	CISPR 11 Group 1 Class A
	Explosion proof grade	Do not provide explosion protection (common equipment), and flammable RESP agents shall not be used.

Dimension	235mm×170.0mm×54mm (tolerance: ±2mm)
Weight	1.3kg (Full configuration, including battery)
Display	5-inch LCD color touch screen with resolution of 800*480 (H301); 5-inch display screen with resolution of 800*480 (H300)
Service life	10 years

Environment Requirement	Work Temperature	0℃～40℃
	Transport and storage Temperature	-20℃～60℃
	Relative Humidity (Non-condensing)	15% - 95 %
	Relative humidity range for transportation and storage (Non-condensing)	15% - 95 %
	Atmospheric Pressure (kPa)	Altitude 5000 m, 70.0 kPa~ 106 kPa
	Atmospheric pressure for Transportation and storage (kPa)	70.0 kPa~ 106 kPa
Transportation environment	Severe shock, rain and snow during transporting are prohibited.	
AC power requirement	Voltage	100-240V~
	Frequency	50Hz/60Hz;
	Input current	0.85A-0.45A
Battery Specification	Voltage	Battery a: 11.1V⎓; Battery b: 10.8V⎓
	Capacity	Battery a: 2200mAh; Battery b: 3350 mAh
	Charge time	**Battery a**: When the equipment turns off, it takes less than 3 hours to charge to 100% capacity under the temperature of 25℃±5. **Battery b**: When the equipment turns off, it takes less than 4 hours to charge to 100% capacity under the temperature of 25℃±5. **Battery a**: When the equipment turns off, it takes less than 2.2 hours

		to charge to 90% capacity from 0% under the temperature of 25℃±5. **Battery b**: When the equipment turns off, it takes less than 3 hours to charge to 90% capacity from 0% under the temperature of 25℃±5.
	Battery working time	**Battery a:** The battery can continuously work for at least 7 hours or continuously print for at least 3.5 hours (@5mm/s) with fully charged battery, 25 ℃ ±5 ℃ ambient temperature and brightness level 2; **Battery b:** The battery can continuously work for at least 9 hours or continuously print for at least 4.5 hours (@5mm/s) with fully charged battery, 25 ℃ ±5 ℃ ambient temperature and brightness level 2.

Recorder	Recording Method	Internal thermal printer and external laser printer
	Printing resolution ratio	8 dots/mm (Y axis)
		40 dots/mm (X axis, @25mm/s)
	Recorder paper	Folded paper: 80mm×70mm×200 pages(optional) Rolled paper: 80mm×20m
	Effective recording width	72mm
	Paper Speed	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50mm/s; Error: ±2%

Network Specification	**WI-FI**	
	Modulation Type	IEEE802.11 a/b/g/n
	Transmit frequency	IEEE 802.11b/g/n (2.4G): 2.412GHz~2.472GHz IEEE 802.11a (5G): 5.18GHz~5.24GHz, 5.745GHz~ 5.825GHz

	Frequency Characteristics	IEEE 802.11b/g/n (2.4G): 2400 MHz~2500 MHz IEEE 802.11a (5G): 4900 MHz~5845 MHz
	Cellular mobile network (4G)	
	Modulation Type	3GPP E-UTRA Release 11：LTE-FDD/LTE-TDD/WCDMA/TD-SCDMA/CDMA/GSM
	Transmit Frequency	LTE-FDD B1: 1920MHz~1980MHz, 2110MHz ~2170MHz LTE-FDD B3: 1710MHz~1785MHz, 1805MHz ~1880MHz LTE-FDD B5: 824MHz~849MHz, 869MHz~894MHz LTE-FDD B8: 880MHz~915MHz, 925MHz ~ 960MHz LTE-TDD B38: 2570MHz~2620MHz LTE-TDD B39: 1880MHz~ 1920MHz LTE-TDD B40: 2300MHz~2400MHz LTE-TDD B41: 2555MHz~2655MHz CDMA BC0: 824MHz~ 849MHz, 869MHz ~894MHz WCDMA B1: 1920MHz ~ 1980MHz, 2110MHz ~ 2170MHz WCDMA B8: 880MHz ~ 915MHz, 925MHz ~ 960MHz TD-SCDMA B34: 2010MHz ~ 2025MHz TD-SCDMA B39: 1880MHz ~ 1920MHz EGSM900: 880MHz ~ 915MHz, 925MHz ~ 960MHz DSC1800: 1710MHz ~ 1785MHz, 1805MHz ~ 1880MHz
	Frequency Characteristics	Bandwidth: 1.4/3/5/10/15/20MHz
	Radiant Power	Class 3 (23dBm±2dB) for LTE FDD Class 3 (23dBm±2dB) for LTE TDD Class 2 (24dBm+1/-3dB) for TD-SCDMA Class 3 (24dBm+1/-3dB) for WCDMA Class 3 (24dBm+2/-1dB) for CDMA BC0 Class E2 (27dBm±3dB) for EDGE 900MHz Class E2 (26dBm±3dB) for EDGE 1800MHz Class 4 (33dBm±2dB) for EGSM900

		Class 1 (30dBm±2dB) for DCS1800
	Cellular mobile network (5G)	
	Modulation Type	3GPP Release 13, 3GPP Release 14: LTE-Cat NB1
	Transmit Frequency	B1: 1920MHz ~ 1980MHz, 2110MHz ~ 2170MHz B3: 1710MHz ~ 1785MHz, 1805MHz ~ 1880MHz B5: 824MHz ~ 849MHz, 869MHz ~ 894MHz B8: 880MHz ~ 915MHz, 925MHz ~ 960MHz B20: 791MHz ~ 821MHz, 832MHz ~ 862MHz
	Radiant Power	23 dBm ±2 dB

	Input mode	With defibrillator-proof protection
	Lead wire	Standard 12-lead
	HR measurement range	30~350bpm
	Measurement Accuracy	±1bpm
	Sampling mode	12 leads simultaneous sampling
	Lead type	12-lead
	Sampling Rate	32kHz, 8 channels in total with ±1% deviation for each channel
	A/D convert	24 digits, deviation range ±1‰
	Resolution	0.1192μV/LSB, deviation range ±1‰
	Time constant	≥5s
	Frequency response	0.01Hz~500 Hz (-3dB~+0.4dB)
	Gain select	1.25mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV, 10/5 mm/mV, 20/10 mm/mV, AGC (Error: ±2%)
	Input impedance	≥100MΩ (10Hz)
	Input voltage range	≤±5 mVpp
	Calibration Voltage	1mV±1%
	Polarization Resistance Voltage	±970mV (Error: ±5%)

	Noise Level	≤12μVp-p
	Inter-channel Interference	≤0.5mm
	Common Mode Rejection Ratio (CMRR)	≥123dB (AC off) ≥140dB (AC on)
	Filter	AC Filter: 50 Hz, 60 Hz, OFF
		Baseline drift filter: 0.01 Hz, 0.05 Hz, 0.15 Hz, 0.25 Hz, 0.32 Hz, 0.5Hz , 0.67Hz, OFF
		EMG filter: 25 Hz, 35 Hz, 45 Hz, OFF
		Low-pass filter: 500 Hz, 350 Hz, 300 Hz, 270 Hz, 150 Hz, 100 Hz, 75 Hz, OFF
Pacemaker test	Amplitude	±1mV ~ ±700mV
	Width	0.1ms ~ 2.0ms
	Sampling Rate	48 kHz, deviation ±1%

Appendix III EMC

NOTE

- **H300/H301 meets the requirement of electromagnetic compatibility in IEC 60601-1-2.**
- **H300/H301 meets the requirement of Group I Class A in CISPR 11/EN 55011.**
- **Users should install and use the product in accordance with the electromagnetic compatibility information provided in the accompanying documentation.**
- **Portable and mobile RF communication devices may influence the performance of this device, so it should be kept away from them during using, such as mobile phones and microwaves.**
- **Refer to the annex for detailed guidance and declaration of manufacturer.**

WARNING

- **H300/H301 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the H300/H301 should be observed to verify normal operation in the configuration in which it will be used.**
- **The equipment is not intended for use in residential environment, which can not provide protection for radio reception.**
- **The operation of H300/H301 electrocardiographs with a minimum amplitude or value lower than the specified minimum (heart rate: 30bpm) may lead to inaccurate results.**
- **Except for cables sold as spare parts for internal components by Comen, using accessories and cables not specified may lead to an increase emission and a decrease immunity of H300/H301.**

Essential performance: Meet the requirement of IEC 60601-2-25.

Essential Performance
Defibrillation protection
Provides automatic measurement functions with accuracy that meets standard requirements.
The accuracy of amplitude measurement meets the requirements of the standard.
The accuracy of the absolute interval and waveform time limit measurements meets the requirements of the standard.
The accuracy of the inter-interval measurements in actual human electrocardiograms meets the requirements.
The printout information includes a label indicating the filter settings.
Anti-static discharge capability.
Capable of protecting against fast transient pulse groups.
Capable of resisting conducted interference.

Not resistant to electrosurgical interference.

Declaration—Electromagnetic emission		
H300/H301 is intended for use in the electromagnetic environment specified below. The customer or the user of H300/H301 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment--guidance**
RF emissions CISPR 11	Group 1	H300/H301 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 emissions CISPR 11	Class A	H300/H301 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Declaration—Electromagnetic immunity			
H300/H301 is intended for use in the electromagnetic environment specified below. The customer or the user of H300/H301 should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment--guidance**
Electrostatic (ESD) **IEC 61000-4-2**	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tie. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst **IEC 61000-4-4**	±2kV for power supply wires ±1kV for input/output wires	±2kV for power supply wires ±1kV for input/output wires	Mains power quality should be that of a typical commercial or hospital environment.

Surge **IEC 61000-4-5**	±1 kV line-to-line ±2 kV line-to-line	±1 kV line-to-line ±2 kV line-to-linee	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 for 0.5 cycle (>95% dip in U_T); 40 % U_T for 5 cycles (60 % dip in U_T); 70 % U_T for 25 cycles (30 % dip in U_T); <5 % U_T for 5s (>95% dip in U_T)	<5 % U_T for 0.5 cycle (>95% dip in U_T); 40 % U_T for 5 cycles (60 % dip in U_T); 70 % U_T for 25 cycles (30 % dip in U_T); <5 % U_T for 5s (>95% dip in U_T)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the H300/H301 requires continued operation during power mains interruptions, it is recommended that the H300/H301 be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field (50/60 Hz) **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 AC mains voltage prior to application of the test level.			

Declaration—Electromagnetic immunity			
H300/H301 is intended for use in the electromagnetic environment specified below. The customer or the user of H300/H301 should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment--guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of H300/H301, than the recommended separation distance calculated from the equation applicable to the frequency of the

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed RF 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 H300/H301 is used exceeds the applicable RF compliance level above, H300/H301 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating H300/H301.

b Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between
portable and mobile RF communications equipment and H300/H301

H300/H301 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of H300/H301 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and H300/H301, 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**		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	**80 MHz ～ 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz～ 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer

NOTE 1 At 80 MHz and 800 MHz, the 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.

Appendix IV List of Arrhythmia Information

Prompt Message	Meaning	Cause
R on T/R-on-T	R-on-T	Arrhythmia is detected during sampling.
Run PVCs	Multiple premature ventricular contractions	
Couplet	Paired premature ventricular contractions	
PVC	Single premature ventricular contraction	
Bigeminy	Premature ventricular contractions	
Trigeminy	Premature ventricular triad	
Tachy	Tachycardia	
Brady	Bradycardia	
Missed beats	Missed beats	
Non-sustain V-Tach	Non-sustained ventricular tachycardia	
Pause	Heart pause	
multiform PVC	polymorphic premature ventricular contractions	

Appendix V List of Critical Components

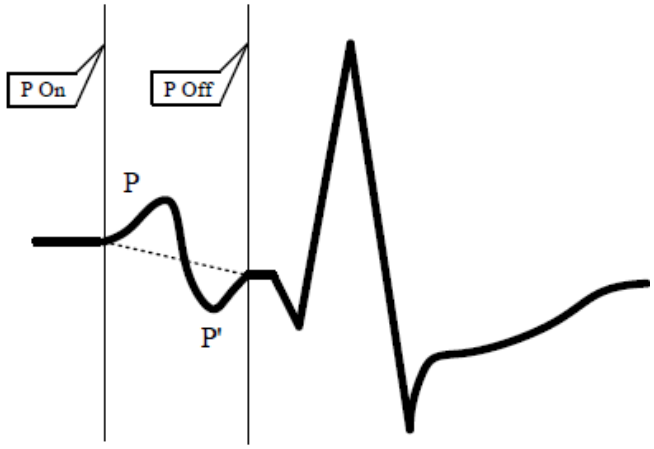
Object/ Part No.	Manufacturer / Trademark	Type/model	Technical data	Standard	Mark(s) of conformity
Switching Power Supply	DELTA ELECTRONICS,INC	MDS-040APS15B	Input: AC 100-240V, 50-60Hz, 1-0.5A Output: DC 15V, 2.67A	IEC 60601-1:2005 (Third Edition) + CORR.1:2006 +CORR. 2:2007 +A1:2012(or IEC 60601-1: 2012 reprint)	11042404003
Power inlet	RONGFENG INDUSTRIAL.CO.,LTD.	SS-120	250V; 10A;70 ^{0}C	EN 60320-1:2015+AC:2016+AC:2019+A1:2021; IEC 60320-1:2015/AMD1:2018 IEC 60320-1:2015	VDE:40028101
Plug (EU)	Dongguan Nan Ke Investment Co., LTD	XTH-005	AC 250V; 16A	DIN VDE 0620-2-1 (VDE 0620-2-1): 2016-01	VDE 40046047
Flexible cables (EU)		HO5VV-F	3 x 0.75 mm^2; 1.5 m	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE 40043002
Connector (EU)		XTH-021	AC 250V; 10A	DIN EN 60320-1 (VDE 0625-1):2016-04; EN 60320-1:2015+AC:2016; IEC 60320-1:2015	VDE 40049783
Plug (Brazil)	CHAO ZHOU NAN KE ELECTRONIC INDUSTRY LTD.	XD-016-A	Black non-rewirable plug 2P with earthing contact for class I equipment, 10A 250V~, Thermoplastic, crimped connections, IPX0, solid pins, provided with insulating sleeves, cable exit 180°, NBR 14136	ABNT NBR NM 60884-1:2010	TÜV 20.2173

Rechargeable Li-ion Battery	Shenzhen Comen Medical Instruments Co., Ltd.	CMLI1X3N002A	10.8 Vdc; 3350 mAh	IEC 62133-2:2017, IEC 62133-2:2017/AMD1:2021	4919143.50
Rechargeable Li-ion Battery	Shenzhen Comen Medical Instruments Co., Ltd.	CMLI1X3N001A	Rated Voltage: 11.1 V Rated Capacity: 2200 mAh	IEC 62133-2:2017	SZES190801522201

Appendix VI IEC 60601-2-25 Compliance Report On 12-lead Resting Analysis Algorithm

VI.1 Method for determining the amplitude of P, QRS, ST, and T waves

VI.1.1 Measuring method of amplitude of P Wave

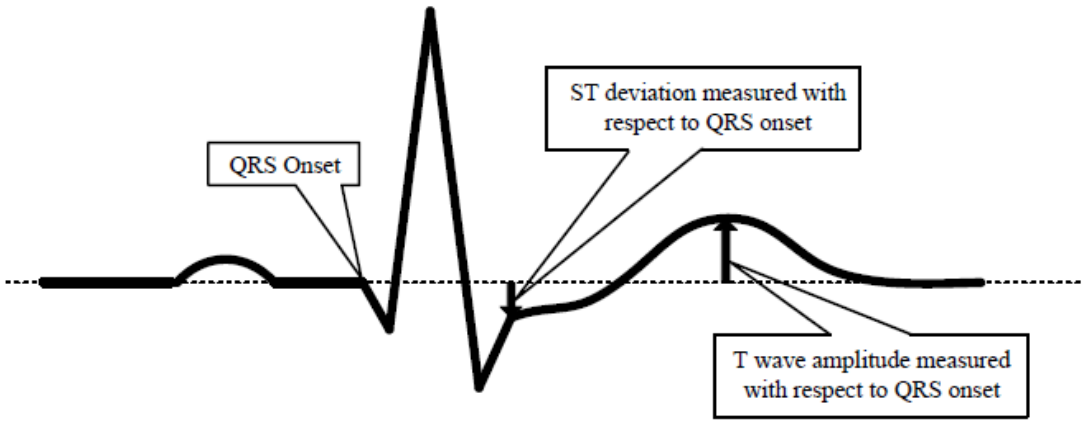


P On represents the starting point of P wave, P Off represents ending point of P wave, dashed line as reference baseline

The measurement method of P-wave amplitude: take the line connecting the starting point and ending point of P-wave as the reference baseline, as shown in the above figure. Positive amplitude from the reference baseline to the top edge of the P-wave; the negative amplitude is from the reference baseline to the bottom edge of the P-wave.

VI.1.2 Measuring Method of amplitude QRS complex, ST segment and T wave

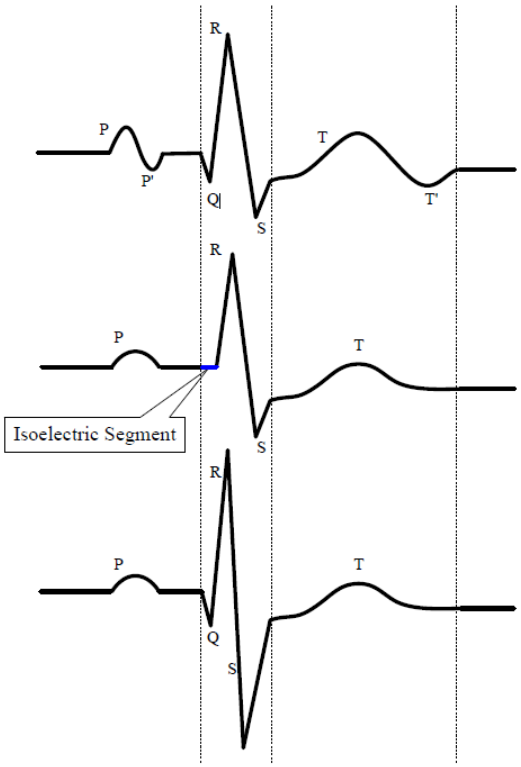
When measuring, taking the horizontal line at the beginning of the QRS complex as the reference baseline, as shown in the following figure:



The measurement of QRS complex, ST segment, and T-wave amplitude is based on the reference baseline of the horizontal segment at the beginning of the QRS complex. QRS Onset represents the starting position of the

QRS complex.

Ⅵ.2 Method for processing equipotential segments within the QRS complex



The Isoelectric Segment is an equipotential segment, which is located within the QRS complex within the dashed line

As shown in the above figure, the equipotential segment starting at the starting point of the QRS complex is processed as a part of the QRS complex. But it does not belong to the meaningful wave after (waveform area greater than 160 μ V Å ms).

Ⅵ.3 Distortion Testing

Tests with sinusoidal and impulse signals

1) High frequency response

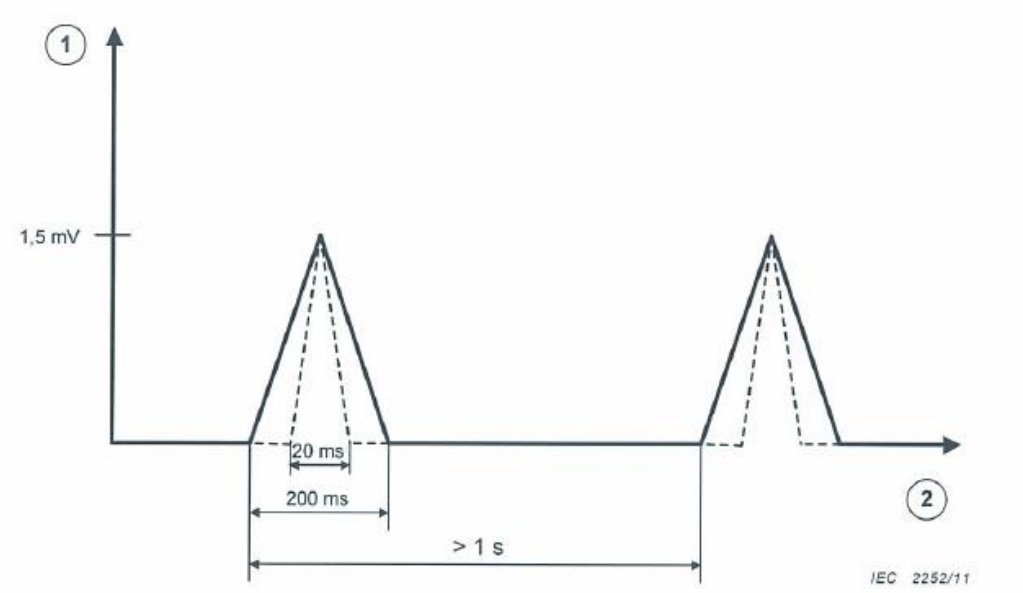
At normal gain electrocardiographs shall exhibit a high frequency response confirming to the specification of Table 201.107.

The electrocardiograph has to meet the requirements of method A and E or alternately methods A, B, C and D of Table 201.107.

Table 201.107-Frequency response

Test	Nominal input amplitude (Mv_{p-v})	Input signal frequency and waveform	Relative output amplitude response on ECG REPORT
A	1.0	0.67Hz to 40Hz, sinusoidal	±10% [a]
B	0.5	40Hz to 100Hz, sinusoidal	+10% /-30% [a]
C	0.25	100Hz to 150Hz, sinusoidal	+10% /-30% [a]

D	0.5	150Hz to 500Hz, sinusoidal	+10% /-100% [a]
E	1.5	⩽1Hz, triangular with 20ms base width	+0% /-10% [a]
a Output amplitude relative to that for a 10 Hz sinusoidal input signal. b Output amplitude relative to that for triangular input with 200 ms base width (see Figure 201.107)			



NOTE:

① Signal amplitude

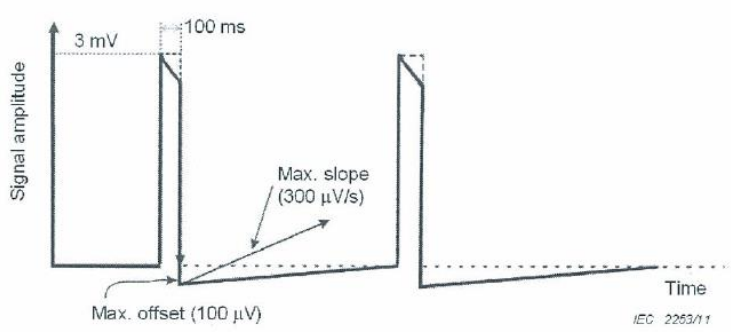
② Time

Figure 201.107-Triangular waveforms for test E of Table 201.107

2) Low frequency (impulse) response

A 0.3 mV ×s (3 mV for 100 ms) impulse input shall not produce a displacement greater than 0.1 mV outside the region of the impulse.

For a 0.3 mV ×s (3 mV for 100 ms) impulse input, the slope of the response must not exceed 0.3 mV/s following the end of the impulse. See Figure 201.108. In ME EQUIPMENT which changes the a.c coupling upon detection of a pacemaker pulse, disable the pacemaker pulse detection for this test.



NOTE:

----------(dashed trace) Input impulse signal

————(continuous trace) Electrocadiograph response

Figure 201.108-Input impulse signal and electrocaridiograph response

Appendix VII Minnesota Code

VI.I 1-type code

If there is a 6-4, 6-8, 7-1, 9-6-1, the code of 1 is not used.

Code	Description	Lead Wire
Anterior		
1-1-1	Ra>0 && |Qa|/Ra ≥ 1/3 && Qd ≥30mS	Either one of V2~V4
1-1-2	Qd≥44(42)40mS &&|Qa|≥0.12mV	Either one of V1~V4
1-1-6	In QS type, there is an R wave in the right lead.	Either one of V2~V6
1-1-7	QS type	V1~V4
1-2-1	Ra>0 && |Qa|/Ra>1/3 &&20mS≤Qd<30mS	Either one of V2~V4
1-2-2	34(32)30≤Qd<44(42)40ms&&|Qa|≥0.12mV	Either one of V2~V4
1-2-7	QS type	V1~V3
1-2-8	Ra≤0.2mV&&, no lead falls off	Either one of [V2, V3], [V3, V4] and [V4, V5]
1-3-1	Ra>0 && 1/5≤ |Qa|/Ra<1/3 &&Qd>20ms	Either one of V2~V4
1-3-2	QS type	V1, V2
Lateral		
1-1-1	|Qa|/Ra ≥ 1/3 && Qd ≥30mS	Either one of I,V5,V6
1-1-2	Qd≥44(42)40mS &&|Qa| ≥ 0.12mV	Either one of I,V5,V6
1-1-3	Qd≥44(42)40mS &&|Qa| ≥ 0.12mV &&Ra≥0.3(0.4)0.5mV	aVL
1-2-1	|Qa|/Ra>1/3 && 20mS≤Qd<30mS	Either one of I,V5,V6
1-2-2	34(32)30≤Qd<44(42)40ms&&|Qa|≥0.12mV	Either one of I,V5,V6
1-3-1	1/5≤ |Qa|/Ra<1/3 && 20mS≤Qd<30mS	Either one of I,V5,V6
1-3-2	QS type	I,V5,V6
1-3-3	34(32)30≤Qd<44(42)40mS&&Ra≥Ra≥0.3(0.4)0.5mV	aVL
Lower		
1-1-1	|Qa|/Ra ≥ 1/3 && Qd ≥30mS	II
1-1-2	Qd≥44(42)40mS &&|Qa| ≥ 0.12mV	II
1-1-4	Qd≥50mS(III) &&|Qa| ≥ 0.1mV(aVF)	III,aVF
1-1-5	Qd≥50mS(III) &&|Qa| ≥ 0.12mV	aVF
1-2-1	|Qa|/Ra≥1/3 && 20mS≤Qd<30mS	II
1-2-2	34(32)30≤Qd<44(42)40ms&&|Qa|≥0.12mV	II
1-2-3	QS type	II
1-2-4	44(42)40≤Qd<50mS(III)&&|Qa|≥0.1mV(aVF)	III,aVF
1-2-5	44(42)40≤Qd<50mS&&|Qa|≥0.12mV	aVF
1-2-6	|Qa|≥0.5mV	Either one of III,aVF
1-3-1	1/5≤ |Qa|/Ra<1/3 && Qd>20mS	II
1-3-4	30≤Qd<40mS(III)&&|Qa|≥0.1mV(aVF)	III,aVF
1-3-5	30≤Qd<40mS&&|Qa|≥0.12mV	II
1-3-6	QS type	III,aVF

VII.II 2-type code

If there is a 6-4, 6-8, 7-1, 9-1-1, 9-6-1, the code of 2 is not used.

2-1-1	Significant leftward deviation of the electrocardiographic axis-45° > axis->-90°

2-1-2	Moderate leftward deviation of the electrocardiographic axis-30° > axis >-45°
2-1-3	Mild leftward deviation of the electrocardiographic axis -5° > axis >-30° (group of 3~18 years old)
2-2	Significant rightward deviation of the electrocardiographic axis 120(130)140° ≤axis≤180° (210° for that under 16 yeas old)
2-3	Rightward deviation of the electrocardiographic axis 90(95)100° < axis <120(130)140°
2-4	Satisfy the following two conditions: 1.age≥16 && QRS<102 (114)120mS 2.|Sa|>0.2mV && R'a≤0 &&(|Sa|>Ra || |Sa|>0.4mV) For condition 2, it is required that any of lead I, II, and III should meet the requirements.

VII.III 3-type code

If there is a 6-4, 6-8, 7-1, 9-6-1, the code of 3 is not used.

Code	Description	Lead
3-1-1	Ra>2.6(3.0,2.5),3.0,2.5mV	V6
3-1-2	Ra>2.6(4.0,3.5),4.0,3.5mV	V5
3-1-3	Ra> 2.6(3.0,2.5),3.0,3.0mV	Either one of I,II,III,aVF
3-1-4	Ra>1.2(1.4,1.4),1.6,1.6mV	aVF
3-1-5	Ra(I)+|Sa(III)| >2.5mV	/
3-2	V1 lead with Ra≥|Sa|, Satisfy any of the following conditions: Ra(V1)>1.5(2.0,1.5)2.0,2.0mV R'a(V1)>1.0(1.0,1.0)1.0,1.5mV && R'a≥Ra Ra(V1)>1.0(1.5,1.0)1.5,1.5mV && Ra≥|Sa|	V1
3-3-1	Ra(V6)-Sa(V1)≥3.5(5.0,4.0)5.0,4.0mV	
3-3-2	Ra(V5)-Sa(V1)≥3.5(6.0,5.0)6.5,5.0mV	
3-3-3	Ra>1.5(2.0,2.0)2.5,2.5mV	I
3-3-4	Ra(V5)-Sa(V1)≥4.5(5.0,4.5)5.5,4.5mV&&Ra(V5)>3.0(3.5,3.0)3.5,3.5mV	
3-4-1	Ra-Sa>7.0mV&& age (3~18 years old)	V2
3-4-2	Ra-Sa>7.0mV&& age (3~18 years old)	V3
3-4-3	Ra-Sa>7.0mV&& age (3~18 years old)	V4

VII.IV 4-type code

If there is a 6-4, 6-8, 7-1, 9-6-1, the code of 4 is not used. There are 7-2,7-3,7-4,8-3-*, under 2 years old that are not categorized for the ST descending side of V4. Uncategorized ST descending sides for V1-V3 at less than 18 years of age.

Code	Description	Lead
Anterior		
4-1	ST1≤-0.1mV&&(ST2-ST1)≤0.02mV	Either one of V1~V4
4-2	ST1≤-0.05mV &&(ST2-ST1)≤0.02mV	Either one of V1~V4
4-3-1	ST1≤-0.01mV&&(ST2-ST1)≤-0.01mV && Ta≤-0.05mV	Either one of V2~V4
4-4-1	ST1≤-0.2mV	Either one of V2~V4
4-4-2	ST1≤-0.1mV	Either one of V2~V4
4-5	ST1≤0.03mV&&(ST2-ST1)≤0.02mV	Either one of V1~V4
Lateral		
4-1	ST1≤-0.1mV&&(ST2-ST1) ≤0.02mV	Either one of I,aVL,V5,V6
4-2	ST1≤-0.05mV&&(ST2-ST1)<0.02mV	Either one of I,aVL,V5,V6
4-3-1	ST1≤-0.01mV&&(ST2-ST1)≤-0.01mV && Ta≤-0.05mV	Either one of I,aVL,V5,V6
4-4-1	ST1≤-0.2mV	Either one of I,aVL,V5,V6

4-4-2	ST1≤-0.1mV	Either one of I,aVL,V5,V6
4-5	ST1≤0.03mV&&(ST2-ST1)≤0.02mV	Either one of I,aVL,V5,V6
Lower		
4-1	ST1<-0.1mV &&(ST2-ST1)≤0.02mV	Either one of I,I,aVF
4-2	ST1≤-0.05mV&&(ST2-ST1)≤0.02mV	Either one of ll,aVF
4-3-1	ST1≤-0.01mV&&(ST2-ST1)≤-0.01mV && Ta<-0.05mV	II
4-3-2	ST1<-0.03mV &&(ST2-ST1) ≤-0.01mV && Ta<-0.05mV	aVF
4-4-1	ST1≤-0.2mV	II
4-4-2	ST1≤-0.1mV	II
4-5	ST1≤0.03mV &&(ST2-ST1)≤0.02mV	II

VII.V 5-type code

If there is a 6-4, 6-8, 7-1, 9-6-1, the code of 5 is not used.

There are 7-2, 7-3, 7-4, 8-3-*, under 2 years old that are not categorized for the ST descending side of V2-V4.

Uncategorized T-wave abnormality for V2-V4 for man less than 18 years old and woman less than 30 years old.

Uncategorized T-wave abnormality for V2 for woman more than 30 years old.

Code	**Description**	**Lead**
Anterior		
5-1	T-a≤-0.5mV &&T-a≤STj	Either one of V2-V4
5-2-1	T-a≤-0.2mV &&T-a≤STj	Either one of V2-V4
5-2-2	T-a≤-0.1mV &&T-a≤STj	Either one of V2-V4
5-3	Ta<(STj-0.01mV)&&Ta<(ST1-0.01mV) ||(T+a<0.01mV&&Ra≥0.5mV)	Either one of V3 and V4
5-4	T-a=0 &&T+a/Ra<1/20 && Ra≥1.0 mV	Either one of V3 and V4
5-5	T-a=0&&T+a/Ra<1/10 &&Ra≥1.0mV	Either one of V3 and V4
5-6	No negative T-wave for that under 7 years old, T+a>0.3mV	V1
Lateral		
5-1	T-a≤-0.5mV &&T-a≤STj	Either one of l,aVL,V5,V6
5-2-1	T-a≤-0.2mV &&T-a≤STj	Either one of l,aVL,V5,V6
5-3	Ta<(STj-0.01mV)&&Ta<(ST1-0.01mV)||(T+a<0.01mV&&Ra≥0.5mV)	Either one of l,aVL,V5,V6
5-4	T-a=0 &&T+a/Ra<1/20 &&Ra≥1.0 mV	Either one of l,aVL,V5,V6
5-5	T-a=0&&T+a/Ra<1/10 &&Ra≥1.0mV	Either one of l,aVL,V5,V6
Lower		
5-1	T-a≤-0.5mV &&T-a≤STj	Either one of II,aVF
5-2-1	T-a≤-0.1mV && T-a≤STj	Either one of II,aVF
5-3	Ta<(ST1-0.01mV)&&Ta<(ST1-0.01mV)&&T+a<0.01mV && Ra≥0.5mV	II
5-4	T-a=0 &&T+a/Ra<1/20 && Ra≥1.0mV	II
5-5	T-a=0 &&T+a/Ra<1/10 && Ra≥1.0mV	II

VII.VI 6-type code

6-1	Complete atrioventricular block without artificial pacemaker (6-8)
6-2-1	2:1 atrioventricular block, no artificial pacemaker, no atrial fibrillation or fluttering
6-2-2	Atrioventricular block II degree (Mobitz), no artificial pacemaker (6-8), no atrial fibrillation, fluttering
6-2-3	Atrioventricular block II degree (Wenckebach) no artificial pacemaker (6-8), no atrial fibrillation, shaking
6-3	PR Prolonged, no artificial pacemakers (6-8), no atrial fibrillation, fluttering

6-4	Pre-excitation syndrome, no artificial pacemaker (6-8), no atrial fibrillation, shaking, no right-sided heart (9-6-1)
6-5	Shortened PR interval, no other codes for 6, no artificial pacemaker (6-8)
6-8	With cardiac pacemaker pulses. Note: Other Minnesota codes are not classified when an artificial pacemaker is available.

VII.VII 7-type code

If there is a 6-4, 6-8, 9-6-1, the code of 7 is not used.

7-1	Complete left bundle branch block
7-1-1	Incomplete left bundle branch block
7-2	Complete right bundle branch block
7-3	Incomplete right bundle branch block

VII.VIII 8-type code

If there is a 6-8, the code of 8 is not used.

8-1-1	Atrial pre-systole under 2 beats without atrial fibrillation
8-1-2	Ventricular pre-systole is under 2 beats
8-1-5	With atrial pre-systolic dystonic pattern (N-A,N-A)
8-1-6	With ventricular pre-systolic dystonic pattern (N-V,N-V)
8-1-7	Atrial pre-systole on more than 3 beats (frequent)
8-1-8	Ventricular preterm contractions over 3 beats (frequent)
8-3-1	Atrial fibrillation
8-3-2	Atrial flutter
8-4-2	Supraventricular tachycardia
8-6-3	Suspected left atrial rhythm
8-6-4	Coronary sinus rhythm
8-7-1	Atrioventricular dissociation
8-8-1	Sinus tachycardia
8-9-1	Sinus bradycardia

VII.IX 9-type code

If there is a 6-4, 6-8, 7-1, 9-6-1, the 9-1-* and 9-2-* are not used.

If there is a 6-4, 6-8, the 9-3-* is not used.

If there is a 6-4, 6-8, 7-1, 9-6-1, the 9-4-* and 9-5-* are not used.

If there is a 6-8, the 9-6-* is not used.

If there is a 6-4, 6-8, 7-1, 8-3-*, 9-6-1, the 9-7-*is not used.

Code	Description	Lead
Anterior (V1,V2,V3,V4)		
9-1-1	I,II,III, all QRS amplitude ≤0.5mV(≥3 years old), QRS amplitude <0.8mV(<3 years old)	/
9-1-2	V1~V6, all QRS amplitude ≤1.0mV	/
Lateral (I, aVL, V5, V6)		
9-2-1	For people less than 3 years old: when STj, ST1 and ST2≥0.3mV, STj×2>ST3; For people more than 3 years old: when STj, ST1 and ST2≥0.4mV, STj×2>ST3	Either one of V1~V4
9-2-2	When STj&&ST1&&ST2≥0.2mV, STj×2>ST3	Either one of V1~V4
Lower (II, III, aVF)		

9-2-1	For people less than 3 years old: When STj&& ST1&& ST2≥0.1mV, STj×2>ST3 For people more than 3 years old: When STj&& ST1&& ST2≥0.2mV, STj×2>ST3	Either one of II, III, aVF
9-2-2	When STj && ST1 && ST2≥0.1mV, STj×2>ST3	Either one of II, III, aVF
9-3-1	Either one of II, III, aVF, V1, V2, P+a≥0.25(0.25) 0.30mV	/
9-4-1	No 7-2(Complete right bundle branch block), V3: Ra≥|Sa|	/
9-4-2	V4: Ra≤|Sa|	/
9-5	Age<3:T>1.8mV; Age≥3: Limb lead T+a>1.8mV, chest lead T+a>1.5mV	/
9-6-1	right heart; I: P, QRS, T-wave is negative; V5,V6: QRS amplitude<1mV	/
9-6-2	Left and right upper extremity electrodes reversed; I: P, QRS, T-wave is negative; V5,V6: QRS amplitude≥1mV	/
9-7-1	QT extend: no 7-2(complete right bundle branch block), 8-3-*(Atrial fibrillation, shaking)	/
9-7-2	QTshortens: QT<QTc×0.8	/

Appendix VIII Consideration for Environmentally Conscious Design

1. Instructions for Minimizing Environmental Impact during Normal Use

This part is compiled based on the requirements of *Clause 4 Protection of Environment, 4.5.2 Instructions for minimizing environmental impact during normal use* of IEC 60601-1-9.

According to the requirements of this clause, the manufacturer shall provide instructions for minimizing the environmental impact of the ME equipment during normal use in the accompanying documents.

The instructions cover the following items (Table 1).

Table 1 The requirements of Clause 4.5.2 and Instructions provided by manufacturer

The requirements of Clause 4.5.2	Instructions provided by manufacturer
1) Instructions on how to install the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Try to keep the integrity of the non-disposable packing materials and put away the packing materials for future use or put into the specified location where complying with the rules and regulations of the local government and the hospital. Avoid overusing the cleaning reagents and other substances. For the reusable accessories, clean them with specified reagent and put away, and for the disposable ones, deal with them together and put into the specified location where complying with the rules and regulations of the local government and the hospital. If not specified, please follow the rules and regulations of the local government and the hospital.
2) Instructions on how to use and maintain the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Use the specified accessories and cleaning and disinfection reagent to avoid harm to the machine and accessories and reduction of the service life. Use the medical device strictly according to the instruction manual. And for maintaining the medical device, always dilute according to the manufacturer's instructions or use lowest possible concentration. Never use bleach. Do not mix disinfecting solutions (such as bleach and ammonia) as this may result in hazardous or poisonous gases or liquids. When there is a need to maintain, please follow the Instruction for Use or follow the rules and regulations of the Hospital.
3) Consumption during NORMAL USE (e.g. energy, consumable materials/parts, disposables, water, gasses,	During normal use of this device, it will consume electricity (alternate current and direct current-battery). The disposables are also consumed and shall be disposed

chemicals/reagents etc.);	according to the rules of the local government and the hospital. For cleaning or disinfection for the cables and machine, the water and ethanol or isopropanol will be used and the waste liquid shall be thrown according to the rules of the local government and the hospital.
4) Emissions during NORMAL USE (e.g. WASTE water, WASTE consumable materials, acoustic energy, heat, gasses, vapours, particulates, HAZARDOUS SUBSTANCES and other WASTE);	During normal use, it is expected there will be some consumption of the medical device. To avoid unnecessary consumption such as acoustic energy, heat, gases, hazardous substances, etc., it's recommended that on the premise of normal operation, turn off the unused functions to reduce the unnecessary heat emission and electricity consumption.
5) Information on the location within the ME EQUIPMENT of HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials.	The battery is located inside the table column. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

2. Information for End of Life Management

This part is compiled based on *Clause 4 Protection of Environment, 4.5.3 Information for end of life management* of IEC 60601-1-9.

According to the requirements of this clause, the manufacturer shall provide the responsible organization with information for the proper disposal of the ME equipment at *End of Life* (EOL). And the manufacturer shall make available information to waste treatment facilities necessary for the environmentally responsible management of end of life ME equipment.

The information shall contain the following items (Table 2).

Table 2 The requirements of Clause 4.5.3 and Instructions provided by manufacturer

The requirements of Clause 4.5.3	Instructions provided by manufacturer
1) The location of components and parts within the ME equipment that contain stored energy or pose other hazards that can result in an unacceptable risk to disassemblers or others and methods for controlling such risks.	The battery is located inside the table column. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.
2) The identity and location of hazardous substances requiring special handling and treatment	The battery is located inside the table column. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the

	device.
3) Disassembly instructions sufficient for the safe removal of these hazardous substances including radioactive sources and induced radioactive materials within the ME equipment.	For other hazards that may result in unacceptable risk, the main concern is the handling with battery: Risk of fire, explosion, or burns. Do not crush, puncture, disassemble or short circuit the battery. Do not dispose of the battery in fire or water. Do not place the battery in an environment whose temperature is above 60℃ (140℉). Store the battery in the -20℃ (-4℉) to 60℃ (140℉) environment. Use the specified charger only. Read instructions for use. Maximum Recommended Ambient temperature is 45℃ (125℉). Dispose of used batteries promptly and in an environmentally-responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements. As for disposing of the medical device, to avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the medical device appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories such as thermometers, where not otherwise specified, follow local regulations regarding disposal of hospital waste.