

Electrocardiograph

H3

User Manual

Shenzhen Comen Medical Instruments Co., Ltd

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Version: A Part No.: 046-000653-00 Product name: Electrocardiograph Product model: H3

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Preface

This user manual provides the performance, operation instructions and safety information regarding the H3 Electrocardiograph and can serve as the start guide for new users.

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

Performance, Structure and Composition

H3 Electrocardiograph is mainly composed of main unit, lead wires, limb electrodes and chest electrodes.

Applicable Scope

H3 Electrocardiograph is applicable to capturing ECG wave complex for waveform and rhythm analysis in medical units.

Illustrations

All the illustrations provided in this User Manual are for your reference only. The menus, options, values and functions in the illustrations may not be entirely consistent with what you see from the electrocardiograph.

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1.1 Safety Information

Warning

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

Caution

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

Note

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

1.2 Safety Information

In order to use the equipment effectively and avoid the possible damages, please read the user manual in detail before using and be familiar with the equipment to know the correct operation methods and safety information thoroughly.

1.2.1 Precautions for Operating the Equipment

Warning This equipment is not intended for treatment. This equipment can not be used directly for the cardiac surgery.

- Do not use this equipment in the presence of flammable anesthetics to avoid explosion.
- Do not use this equipment in the presence of high-voltage equipment or high electrostatic quantity.
- The housing of the equipment should be grounded well. Use the three-wire receptacle with protective grounding and the grounding of the receptacle should be kept well.
- 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 doubt for the integrality for the protective ground lead, please use the built-in battery for the power supply.
- The accessory equipments connected with the analog and digital interfaces of H3 Electrocardiograph should be verified according to IEC standards. All the configurations should comply with the valid version of IEC 60601-1-1. Therefore, the personnel who connect the accessory equipments to signal input/output interfaces should confirm the whole system comply with the requirements in the valid version of IEC 60601-1-1. If there is any doubt, please contact Comen Company or local agents.
- In order to ensure the patient safety, the summation of leakage current should never exceed leakage current limits when several other equipments are connected with the patient at the same time.
- When the H3 electrocardiograph is used in conjunction with defibrillator or pacemaker, do not allow the patient to contact bed, table, metal or equipment.
- In order to avoid burns, keep the electrodes far away from the electrosurgical generator while using an ESU at the same time.
- Only use the ECG 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.
- 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 patients to contact any other conductive parts or the ground.
- The operator should be trained professionally and thoroughly understand the user manual before using.

Caution

- Avoid liquid splashed on the equipment.
- Avoid high temperature and the equipment should be used within $+5^{\circ}C \rightarrow +40^{\circ}C$.
- 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 etc. are likely to generate electromagnetic interference.
- Confirm that there is no mechanical damage on the equipment, ECG cable and electrodes before using the equipments. If obvious damage or aging is found on a certain part, replace this part before using.
- Safety tests should be conducted periodically for the equipment, at least once a year. The test should be conducted 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 properly according to the local regulations.

MNote

- This equipment is not intended for home use.
- This equipment is for examine use instead of diagnosis use. It is only responsible for indicators regulated by relevant national standards.

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 60 °C. Do not heat the battery or throw it into the fire. Avoid water splashed 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.

Warning(Continued)

- 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. Only use the rechargeable lithium battery of the same mode provided by Comen.
- When the service life of the battery is expired, or when there is peculiar smell, deformation, discoloration or distortion, stop using it immediately and dispose the battery 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, disconnect the AC power supply and remove the power cord and ECG cable before cleaning.
- 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 ECG 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 etc.

1.3 Symbol Description

(1) Symbols of Instruments

Symbol	Description	Symbol	Description
ł	CF applied parts, with defibrillation-proof protection	ζ	AC indicator
\wedge	Attention! Please refer to the accompanying document.	(+/<-	Battery charge and discharge indicator

\forall	Equipotential grounding	\odot	Working status indicator
- 2 -	Network connector	•	USB connector
SN	Serial Number	~	Date of manufacture

(2) Symbols of Packing

Symbol	Description	Symbol	Description
[11]	Up		Stacking layers limit
[¶]	Fragile	()	Keep dry

2.1 Intended Application

H3 Electrocardiograph is intended to capture the patient's ECG wave complex to conduct waveform analysis and rhythm analysis for clinic diagnosis and research use.

2.2 Contraindications

None

2.3 Top Panel of the Main Unit

H3 electrocardiograph applies 6.2 inch color LCD. The top panel of the main unit is shown as follows:



Figure 2-1 Top panel of main unit

Chapter 2-1

1	Display screen
2	Recorder latch
3	Recorder
4	Print key
5	Indicators(from top to bottom: working status indicator, AC indicator and battery charge and discharge indicator)
6	On / Off key

2.4 Functions of Keys and Indicators

0/0	On/Off key: press this key to turn on or turn off this equipment.
হ	Print key: press this key to record ECG waveform; press this key for 3s and release this key to enter touch screen calibration interface.
(+/<	Battery charge and discharge indicator: when the battery is used to supply power, this indicator is light; when AC power supply is connected, this indicator is light until the battery is fully charged.
\odot	Working status indicator: this indicator is light after this equipment is switched on; this indicator is flashing when the equipment is under standby status
\sim	AC indicator: when connected to AC power supply, this indicator is light.

2.5 Screen Display

The main screen is shown as follows:



Figure 2-2 Main screen

NO.	Definition	Name	Description
1	Patient and	Patient information	Display patient ID, name and age
	system	Sex	Display patient sex
	information	Measurement mode	Auto/manual/ rhythm, click here to change measurement mode
	(from left to		circularly.
	right)	Recording speed	Click here to change recording speed circularly. Under manual
			mode, recording speeds of 5mm/s, 6.25mm/s, 10mm/s,
			12.5mm/s, 25mm/s and 50mm/s are supported; under auto and
			rhythm mode, recording speeds of 25mm/s and 50mm/s are
	ż		supported. Please refer to 4.5.3 Print Settings for detail.
		Wave gain	Click here to change wave gain circularly. 2.5mm/mV, 5
			mm/mV, 10mm/mV, 20mm/mV, 10/5mm/mV, 20/10 mm/mV
			and AGC are supported. Please refer to 4.5.3 Print Settings for
			detail.
		EMG Filter	Click here to enter "EMG Filter" setting screen. Please refer to
	9	2	4.5.2 Common Settings for detail.
		Real-time heart rate	Display the real-time heart rate value of current patient
		value	

		Leads status map	It can be used as the reference for the connection status of all
			leads. The connection and falling off status of all leads can be
			observed. Red represents leads falling off; green represents
			leads connected well.
2	Waveform area		Display ECG waveform
3	Prompt message		Display prompt message such as "paper?", "Lead off",
	area		"printing" and so on. Please refer to Chapter 6 for detail.
4	Icons area	Time	Display current time. Click here to enter the "System time"
			setting screen.
		USB 🗲	Display this icon only when USB flash disk is connected
		Connected to PCECG	Display this icon only when this equipment has connected to
		workstation	PCECG workstation successfully.
		Battery information	Display the fuel gauge of the battery.
5	Hotkey area	Review key	Click here to enter "Review" screen. Please refer to 5.1
	(from top to		Review for detail.
	bottom)	Copy key or lead	Under auto and rhythm mode, copy key is displayed here and
		switch key	click it to reprint the latest ECG report.
			Under manual mode, lead switch key is displayed here and
			click it to switch leads manually.
		File	Click here to enter "File List" screen. Please refer to 5.3 Files
			for detail.
		Config.	Click here to enter "Configuration" screen. Please refer to
			Chapter 4.5 for detail.

2.6 External Connectors

2.6.1 Left panel

The left panel of this equipment is shown as the following figure:



Figure 2-3 Left panel

2.6.2 Right panel



The right panel of this equipment is shown as the following figure:

2.6.3 Back panel

The back panel of this equipment is shown as the following figure:



Figure 2-5 Back panel

Chapter 2-5

2.7 Bottom panel

The bottom panel of this equipment is shown as the following figure:



Figure 2-6 Bottom panel

Warning

Only use the ECG 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.

3.1 Connect the Power Cord and Ground Lead

Warning

- Use the three-wire receptacle with protective grounding and the grounding of the receptacle 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 for the protective ground lead, please use the built-in battery for the power supply.

1) Use the AC Power Supply

First check whether the AC power supply complies with the requirements:

- Voltage: 100-240V~
- Frequency: 50Hz/60Hz±1 Hz
- Power: 40VA

Then plug the power cord into the AC power supply socket on the back panel of the equipment, and insert the power cord plug into the three-wire receptacle.

2) Use the Built-in Battery

When this equipment is delivered to the user, the built-in rechargeable lithium battery has been installed which can be used directly. Because of the power loss in the storage and transportation, for the initial use, the battery power may be inadequate and at this time the battery should be charged. When the service life of the battery is expired (cycle life \geq 300 times) or the running duration of a fully charged battery shortens obviously, the battery should be replaced in time. The detailed instruction of the charging and replacing battery, please refer to section 7.3.1.

3) Connect the Ground Lead

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

3.2 Loading Record Paper

This equipment adopts $80 \text{mm} \times 20 \text{mm}$ rolled thermosensitive record paper or $80 \text{mm} \times 70 \text{mm}$ folded thermosensitive record paper. When the record paper is not loaded or it is used up, "Paper?" will display in prompt message area to remind the user of loading or replacing the record paper. When the record paper of a certain type is used, the paper style should be set the same as the corresponding paper style.

3.2.1 Recorder Inner Structure



Figure 3-1 Inner structure of recorder

3.2.2 Loading Rolled Thermosensitive Record Paper

- 1) Press the latch on the left panel of this equipment to open the recorder cover
- 2) Take out the paper roller from the fixing device
- 3) Unwrap the new record paper and load it into the fixing device. Pay attention to that the grid surface should face the thermosensitive print head.
- Pull out the record paper from the paper exit, close the recorder cover and keep the record paper parallel with paper exit.
- 5) Select [Config.] \rightarrow [Print Settings] \rightarrow [Paper Style] \rightarrow [Rolled]

3.2.3 Loading Folded Thermosensitive Record Paper

- 1) Press the latch on the left panel of this equipment to open the recorder cover
- 2) Unwrap the new folded record paper and place it into the paper tray. Pay attention to that when the free end of the record paper is vertical, the grid surface of the record paper should face the thermosensitive print head;
- 3) Pull about 2cm of paper out from the paper exit and close recorder cover.
- 4) Select [Config.] \rightarrow [Print Settings] \rightarrow [Paper Style] \rightarrow [Folded]

3.3 Connect ECG Cable



Figure 3-2 ECG cable

ECG cable includes two parts: main cable which is connected to the electrocardiograph and the lead wires which are connected to the patient. Lead wires have 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.

ECG Cable Connection: Plug the ECG cable into the ECG cable socket on the right panel of the electrocardiograph; secure the screws at the two sides of the plug.

3.4 Electrodes Connection

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 patients to contact any other conductive parts or the ground.

The contact resistance between the patient and electrodes exerts great influence on the quality of ECG; therefore the contact resistance should be minimized 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 below.

	European Standard		American Standard	
Electrodes	Identifier	Color	Identifier	Color
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	RF	Black	RL	Green
Left leg	F	Green	LL	Red
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/orange
Chest 5	C5	White/black	V5	Brown/orange
Chest 6	C6	White/violet	V6	Brown/violet

3.4.1 Positions of Limb Electrodes

1) Limb Electrode (Clamp type):



Figure 3-3 Limb electrode

2) Connect limb electrode:

R electrode — Right limb connected as figure 3-4

L electrode — Left limb

N electrode — Right leg

F electrode —Left leg

C1 \sim C6 chest electrode connected as figure 3-6



Figure 3-4 Positions of four 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.

Connect the limb electrodes:

- 1) Check that the electrodes are clean;
- 2) Align all lead wires and connect the electrode connectors to electrode well;
- 3) Clean electrode area on limb surface with alcohol;
- 4) Daub conductive gel on the skin evenly;
- 5) Daub a thin layer of conductive gel on the surface of the limb electrode
- 6) Connect the electrodes to skin surface correctly.

3.4.2 Positions of Chest Electrodes

1) Chest Electrode:



Figure 3-5 chest electrodes

2) Chest electrodes connection:

As the following figure shows, the chest electrodes' position on body surface is

- C1: Fourth intercostals space at right border of sternum
- C2: Fourth intercostals space at left border of sternum
- C3: Fifth rib between C2 and C4
- C4: Fifth intercostals space on left midclavicular line
- C5: Left anterior axillary line at the horizontal level of C4
- C6: Left midaxillary line at the horizontal level of C4



Figure 3-6 Positions of chest electrodes

- a) Check that the electrodes are clean firstly;
- b) Align all lead wires and connect the electrode connectors to electrodes well;
- c) Clean electrode area on chest surface with alcohol;
- d) Daub the round area of 25mm diameter on each electrode site with conductive gel evenly;
- e) Place a small amount of conductive gel on the brim of chest electrode's metal cup;
- f) Place the electrode on chest electrode site and squeeze the suction bulb. Unclench it and then the

electrode is adsorbed on chest. Attach all chest electrodes in the same way.

MNote

• Do not daub too much conductive gel and the layer should be separated. Otherwise it may cause short circuit between electrodes and the error of ECG signal recording.

3.5 Inspection before Power on

Following inspection procedures are recommended before power on.

1) Environment

Check whether there is other electric equipment in the surrounding environment, such as ESU, ultrasonic equipment, radioactive equipment etc, which may generate interference. Switch off these equipments when necessary;

The room is required to keep warm (not lower than -20° C) to avoid the EMG interference caused by cold.

2) Power Supply

When the AC power supply is used, check whether the power cord has been connected well, and the receptacle used should be grounded three-wire receptacle.

3) Grounding

Check whether the ground lead has been connected correctly and tightly;

4) Lead Wires

Check whether the lead wires have been connected well and avoid the lead wires to be close to 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 connected well; check whether the electrodes and particular the chest electrodes contact with each other;

6) Record Paper

Ensure that the record paper is adequate and the loading is correct.

7) Examinee

Check whether the hand and foot of the examinee 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 quiet respiration.

4.1 Switch on

When AC power supply is used, first connect the power cord and the AC indicator \sim turns light. Then press the key to switch on the equipment, after some information is displayed on the screen, the equipment enters the working status and the working status indicator is illuminated. When AC power supply is used, if the battery power is insufficient, the battery will be charged at the same time and the AC power indicator \sim and battery charge and discharge indicator is are both light. When the built-in rechargeable battery is used, press the key to switch on the equipment directly. After some information is displayed on the screen, the equipment enters the working status and both the battery charge and discharge indicator is displayed on the screen, the equipment enters the working status and both the battery charge and discharge indicator and work status indicator turn light.

WARNING

• When AC power supply is connected, the battery is fully charged and electrocardiograph is power off the charging indicator lamp is light, but in fact, there is no charging current. When electrocardiograph is power on, charging indicator lamp will go off automatically.

4.2 Auto mode

Under auto mode, 10s ECG waveforms of 12 leads will be gathered automatically. Leads will be switched in order automatically while recording ECG and at the same tine 1mV calibration pulse will be printed on the record paper automatically.

Specific operations steps:

- 1) Click Auto/ Manual/ Rhythm mode hotkey to switch to Auto mode
- 2) Press key to sample ECG waveforms. Then the ECG waveforms will be analyzed automatically after sampling. After analyzing, ECG waveforms will be printed according to the settings of "Print Settings".
- 3) If necessary, click the "Copy" key to reprint the waveform.

MNOTE

- Recording mode can not be changed during the course of printing. Stop printing before changing the recording mode.
- Only when "Save Option" is set as "Save Data", the ECG waveform and data printed under auto mode can be saved in "File List" screen, or it can not be saved.
- Under auto mode, if measurement and diagnosis information are needed to output, the detailed patient information should be input and "Report Text" should be set as "detailed".

4.3 Manual Mode

Under Manual mode, users can determine which lead to be recorded. Click the "Lead" hotkey to sequentially switch the leads need to be recorded.

Specific operation steps:

- 1) Click Auto/ Manual/ Rhythm mode hotkey to switch to Manual mode;
- 2) Press key to conduct recording, and click the "Lead" hotkey to select the leads to be recorded;
- 3) Press **I** key again to stop recording;

MNOTE

- The ECG waveform and data will not be saved as patient case under manual mode.
- Under manual mode, only the ECG waveform will be printed without patient information, measurement information and diagnosis information

4.4 Rhythm Mode

Under Rhythm mode, 60s ECG waveform of 12 leads will be gathered and 60s ECG waveform of "Rhythm Lead 1" will be recorded. The lead displayed on the screen under rhythm mode is determined by the settings of "Rhythm Lead 1", "Rhythm Lead 2", "Rhythm Lead 3" and "Rhythm Lead Type".

Specific operation steps:

- 1) Click Auto/ Manual/ Rhythm mode hotkey to switch to Rhythm mode;
- 2) Press key to sample ECG waveform automatically and "Sampling" prompt message will appear in the prompt message area. After sampling, ECG waveforms will be printed until the printing ends

automatically.

NOTE

- The ECG waveform and data will not be saved as patient case under rhythm mode.
- Under rhythm mode, only the ECG waveform will be printed without patient information, measurement information and diagnosis information.

4.5 System Settings

4.5.1 Patient Information

Click "Config." to enter the setting screen, shown as the following figure:

< Config	Patient Info	
Patient Info	Second id	
	Patient Name	
Common settings	Sex	Male
	Agə	
Print Settings	Height(cm)	
"X"	Weight(kg)	
System Settings	SYS(mmHg)	
50 A	DIA(mmHg)	

Figure 4-1 Patient information screen

<u>М</u>поте

- Patient information can't be changed during the process of recording.
- Under auto mode, a new patient case will be formed after every printing when "Save Pption" is set as "Save Data".

- Second ID: supporting entering 20 numbers. It can be entered by hand or by scanning, but it will not be displayed on main screen. The first ID, generated by system automatically, will be displayed in patient information area on main screen, and it can't be changed. For example, in the first ID 0902190045, 090219 represents the arrival date of a patient and 0045 represents the 45th patient being examined at this day.
- Patient name: entering patient's name within 20 characters
- Sex: male/ female
- Age: range 0 ~999
- Height (cm): range 0 ~999
- Weight (kg): range 0~999
- SYS (mmHg): systolic pressure (range 0 ~999)
- DIA (mmHg): diastolic pressure (range 0 ~999)
- Hospital: entering hospital name within 40 characters
- Doctor: entering doctor's name within 20 characters
- Technician: entering technician's name within 20 characters
- Divisions: entering division's name within 20 characters
- Bed NO.: entering the bed number within 20 characters
- Hospital NO.: entering hospital number within 20 characters
- Update patient information: click to delete the patient information of last patient. Select "yes" to confirm updating patient information.
- Patient details: click to show/hide the following information.
 - Medication: select the medicine used by patient (Digitalis, Diuretics, β-blockers, Quinidine, Procainamide, Amiodarone, Disopyramide, Lidocaine, Other antiarrhythmic drugs, Mental therapy, Steroid, Other drugs, Untreated and Unknown drugs.)
 - Type: select the disease type of the patient. (Normal, Unknown, Myocardial infarction, Myocardial ischemia, Hypertension, Congenital heart disease, Valvular heart disease, Pericarditis, Respiratory diseases, Endocrine diseases, Implantable pacemakers, Pulmonary embolism, After cardiac surgery, Cardiomyopathy and Other)
 - V3 electrode Pos.: select the position of V3 electrode (standard position and V4R position)

4.5.2 Common Settings

Click "Config." to enter the setting screen and select "Common settings", shown as the following figure:

< Config	Common settings	
-	AC Filter	50Hz
Patient Info	EMG Filter	OFF
Common settings	DFT Filter	0.50Hz
	Lowpass Filter	75Hz
Print Settings	Display Format	3x4
×	Lead Sequence	Standard
System Settings	Sample Mode	Real time
122	Sample Order	Simultaneous

Figure 4-2 Common Settings screen

• AC Filter: 50Hz, 60Hz and OFF

AC filter is used to resist the interference of the AC power supply to avoid the reducing or distortion of the ECG signal.

- EMG Filter: 25HZ, 35HZ, 45HZ and OFF
 EMG filter is used to resist the interference on the ECG signal caused by strong muscle vibration.
- DFT Filter: 0.05Hz, 0.10Hz, 0.20Hz and 0.50Hz
 Drift filter is used to resist the drift of baseline and ensure the ECG signal is on the baseline in the recording process.
- Lowpass Filter: 70HZ, 100Hz and 150Hz

Lowpass 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 cutoff frequencies the user can select are 70Hz, 100Hz and 150Hz.

- Display Format: the display formats of ECG waveform on the main screen include 3×4 and 6×2. This option is merely available under autoc mode and manual mode.
- Lead Sequence: Standard and Cabrera.

System Settings

Lead Order	Lead Group 1	Lead Group 2	Lead Group 3	Lead Group 4
Standard	I, II, III	aVR, aVL, aVF	V1, V2, V3	V4, V5, V6
Cabrera	aVL, I, -aVR	II, aVF, Ш	V1, V2, V3	V4, V5, V6

• Sample Mode: Real time and Pre-sampling

Real-time sampling: ECG data of 10 seconds after pressing key will be sampled and output. Pre-sampling: Once the lead wires are connected with the patient, the Electrocardiograph starts to sample ECG data automatically. ECG data of 10 seconds before pressing key will be output.

Sample Order: Sequential and Simultaneous
 In the sequential sampling of each group, "[]" shows in the place of printing lead waveform; and in the Simultaneous sampling of each group, "[]" shows in the place of the printing lead waveform. As shown in the following figure:



Figure 4-3 Sequential Sampling of Each Group



Figure 4-4 Simultaneous Sampling of Each Group

- ECG Criteria: select the naming criteria of lead wires (IEC and AHA)
- Rhythm Lead 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 of "Rhythm Lead 1", "Rhythm Lead 2" and "Rhythm Lead 3".
- Rhythm Lead Type: 1 Channel and 3 Channel
 When select "1 Channel", only the lead of "Rhythm Lead 1" can be set and any lead of "I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6" can be selected as the rhythm lead; when select "3 Channel", any lead of "I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6" can be selected as the rhythm lead of "Rhythm Lead 1", "Rhythm Lead 2" and "Rhythm Lead 3".
 Under rhythm mode, when the "Rhythm Lead Type" is set as "1 Channel", 60s rhythm waveform of

rhythm lead selected in "Rhythm Lead 1" will be recorded and output; when the "Rhythm Lead Type" is set as "3 Channel", total 60s rhythm waveform of three rhythm leads respectively selected in "Rhythm Lead 1", "Rhythm Lead 2" and "Rhythm Lead 3" will be recorded and output.

ANote

• When "Printer Select" is set as "Internal" or "Close", only "1 Channel" is available in "Rhythm Lead Type" option.

4.5.3 Print Settings

Click "Config." to enter setting screen, and select the "Print Settings", shown as following figure:

< Config	Print Settings	
<u>ക</u>	Record Length	Эs
Patient Info	Record Speed	25 mm/sec
Common settings	Wave Gain	10 mm/mV
	Report Format	3x4+1R
Print Settings	Report Text	Off
"X"	Average Template	3x4
System Settings	Save Option	Save Data
60.9	Paper Style	Rolled

Figure 4-5 Print settings screen

• Record Length: 3s, 6s and 10s.

3s, 6s and 10s can be selected as the recording time of each waveform group under auto mode; this option is not available under manual and rhythm mode.

- Record Speed: the paper speed of recorder. Under manual mode, five kinds of speed 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s and 50mm/s are available; under auto and rhythm mode, only two kinds of speed 25mm/s and 50mm/s are available.
- Wave Gain: there are seven wave gains including AGC, 2.5mm/mV, 5 mm/mV, 10mm/mV, 20mm/mV, 10/5 mm/mV and 20/10 mm/mV. In 20/10 mm/mV, 20 represents the sensitivity of limb leads, and 10 represents the sensitivity of chest leads.
- Report Format: when "Printer Select" is set as "External" or "Picture", the available report formats

include 3×4 , $3 \times 4+1R$, $3 \times 4+3R$, 6×2 , $6 \times 2+1R$, 12×1 and $12 \times 1+1T$; when "Printer Select" is set

as "Internal" or "Close", available report formats include 1×12 , $1 \times 12+1R$, 3×4 and $3 \times 4+1R$.

 3×4 : 12 leads are recorded in 3 channels and 4 sequences, and record 2.5s for each sequence.

 $3 \times 4+1$ R: 12 leads are recorded in 3 channels and 4 sequences, record 2.5 seconds for each sequence and add 1 channel of rhythm lead waveform.

 $3 \times 4+3R$: 12 leads are recorded in 3 channels and 4 sequences, record 2.5 seconds for each sequence

and add 3 channels of rhythm lead waveform.

 6×2 : 12 leads are recorded in 6 channels and 2 sequences, and record 5 seconds for each sequence.

 $6 \times 2+1$ R: 12 leads are recorded in 6 channels and 2 sequences, record 5 seconds for each sequence and add 1 channel of rhythm lead waveform.

 12×1 : 12 leads are recorded in 12 channels and record 10 seconds all together.

 $12 \times 1+1$ T: 12 leads are recorded in 12 channels, in which there is 1 channel of rhythm lead waveform identified with "Rhy." and record 10 seconds all together.

 1×12 : 12 leads are recorded in 1 channel and 12 sequences, and the recording time is determined by the setting of "Record Length".

 $1 \times 12+1$ R: 12 leads are recorded in 1 channel and 12 sequences and add 1 channel of rhythm lead waveform. The recording time is determined by the setting of "Record Length".

• Report Text: Off, Basic and Detailed;

Off: only ECG waveforms are output.

Basic: what output includes ECG waveforms, patient information, intervals, axis, amplitude and so on, shown as the following figure:



Figure 4-6 Basic information

Detailed: what output includes ECG waveforms, patient information, intervals, axis, amplitude, Minnesota Code, diagnosis information and so on, shown as the following figure:



1D	: 140	8190002			Minnesota	Code
NAME	1.		BP	/ meHg	9-4-1 (V3)	
AGE	5	yr	SEX			
HEIGHT	14	om	WEIGHT	٨g		
HR	1	60 bpm			Diagnosis	Info
P Du	r ;	89 ms	=		800 Sinu	s Rhyt
PR in	t i	169 ms				
GRS DU	e ;	84 ms			***Normal	ECG**
OTO TO	int	350/350 ms				
P/QRS/	axis:	50/44/50 *				
RV5/SV	amp :	1 050/0 522	mV			
RV5+SV	amp :	1.572	rs∨		Conf. man	0
RV8/SV:	2 amp	0. 742/0. 86	9 mV		CONTITMES	BY

Figure 4-7 Detailed information

Average Template: when "Printer Select" is set as "Internal" or "Close", available average template includes 3 × 4 、 2 × 6+1R and Off; when "Printer Select" is set as "External" or "Picture", available average template includes 3×4+1R, 6×2+1R and Off.

 3×4 : 12 leads of average template waveform are recorded in 3 channels and 4 sequences;

 $3 \times 4+1$ R: 12 leads of average template waveform are recorded in 3 channels and 4 sequences and add one average template waveform of the rhythm lead.

 $2 \times 6+1$ R: 12 leads of average template waveform are recorded in 2 channels and 6 sequences and add one average template waveform of the rhythm lead.

 $6 \times 2 + 1$ R: 12 leads of average template waveform are recorded in 6 channels and 2 sequences and add one average template waveform of the rhythm lead;

Off: there is no average template waveform output.

• Save Option: Off and Save Data;

Save Data: under auto mode, all the recorded ECG data will be saved in the "File List" screen automatically.

Off: all the recorded ECG data will not be saved.

NOTE

- When the storage is full, the prompt message "MEM FULL" will appear in the promt message area to remind the user.
- Paper Style: when "Printer Select" is set as "Internal" or "Close", available paper style includes "Rolled" and "Folded"; when "Printer Select" is set as "External" or "Picture", available paper style includes "(A4) Folded 295×210mm", "(16K) Folded 195×271mm" and "(B5) Folded 182×257mm".

This recorder adopts $80 \text{mm} \times 20 \text{mm}$ rolled thermosensitive record paper or $80 \text{mm} \times 70 \text{mm}$ folded thermosensitive record paper. When no record paper is loaded or it is used up, "Paper?" prompt

message will be displayed to remind the user of loading or replacing the record paper.

MOTE If incorrect paper type is selected, the equipment may not print normally.

- Pacing Logo: the pacing logo will be printed on the record paper when pacing pulse is detected. (This function is not supported at present.)
- Measurement Matrix: when this function is enabled, under auto mode, 32 measurement values of each lead of 12 leads will be output on record paper. The 32 measurements values include Pd(ms), Qd (ms), Rd1(ms), Rd (ms), Sd1 (ms), Sd2 (ms), Td (ms), Ud(ms), PR (ms), QT (ms), QRS (ms), VAT (ms), Pa1 (µV), Pa2 (µV), Qa (µV), Ra1 (µV), Ra2 (µV), Sa1 (µV), Sa2 (µV), Ta1 (µV), Ta2 (µV), Ua(µV), STj (µV), ST1 (µV), ST2 (µV), ST3 (µV), ST20 (µV), ST40 (µVs), ST60 (µV), ST80 (µV), nRNot and Delta.
- Printer select: Close, Internal, External and Picture;
- Print function selection: One key print, Extend the record and Normal print;

One key print: under auto mode, press key to print the ECG waveform and report, and after this a rhythm waveform report will be printed;

Extend the record: under auto mode, if any of the following emergencies, including extreme tachycardia, extreme bradycardia, tachycardia and bradycardia, occurs in the diagnosis result after analysis calculation finishes, a rhythm recording will be added automatically.

Normal print: under auto mode, only output an ECG report.

- RR Analysis: click it to activate or deactivate the function of RR interval analysis.
- Printer Test: click it to start or stop printer test.

The printer test can detect whether the print head works normally. After loading record paper, click "Printer

Test" option to start printer test, and at this time the recorder starts to output record paper and print triangle wave in valid 72mm printing range. The integrality and clarity can be used to judge whether the thermosensitive print head works normally.

WARNING

• When the recorder is abnormal, it must be maintained or modified by the qualified engineer designated by Comen Company, otherwise Comen company shall not be responsible for the safety, reliability and performance of the instrument.

4.5.4 System Settings

< Config	System Settings	
Patient Inco	Language	English
La Padent injo	Demo Mode	
Common settings	Кеу Веер	
-I-	QRS Beep	
Print Settings	Default Config	Restore the default Settings
"ד	System time	2014-09-01 14:17:00
System Settings	Auto Standby	o _{ff}
473	Date Format	YY-MM-DD

Click the "Config." to enter the setting screen and select "System Settings", shown as the following figure:

Figure 4-8 System Settings Screen

- Language: Chinese and English can be chosen as the language displayed on the screen and printed on the record paper.
- Demo Mode: click 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.
- Key Beep: click it to activate or deactivate the touch sound.
- QRS Beep: click it to activate or deactivate the heart beat sound. Heartbeat sound is the brief "beep…beep" send out by the equipment when the R wave is detected.
- Default Config.: click it to restore the default configuration.
- System Time: set the system time of the electrocardiograph according to local time.
- Auto Standby: off, 5min, 10min, 15min, 20min, 25min and 30min. If there is no operation during the set period, the electrocardiograph will enter standby status automatically, screen turns black and

working status indicator flashes. Click the touch screen to exit the standby status.

- Date Format: YY-MM-DD, MM-DD-YY, DD-MM-YY
- Time Format: 12-Hour and 24-Hour
- Timing shutdown: set the time of shutdown. Available options include Off, 10min, 30min, 1Hour, 2 Hour, 3 Hour, 5 Hour. When the equipment has worked for the set time, it will shut down automatically.
- Version information: view the version information of software installed in this instrument.
- Screen Brightness: screen brightness can be adjusted automatically by the equipment itself according to environment light and it can also be adjusted manually with ten brightness levels from 1 to 10.
- IP address: enter the IP address of this electrocardiograph.
- Remote IPaddr: enter the IP address of the computer connected with this electrocardiograph.
- Remote Port: 5065, the remote port number connected with PCECG workstation.
- Sub Net Mask: 255.255.255.0, the sub net mask of the computer connected with this electrocardiograph
- Gate Way: 200.200.200.1, the default gateway of the computer connected with this electrocardiograph
- TCP Function: click it to activate or deactivate the TCP function. When the TCP function is activated, this electrocardiograph can be connected to PCECG workstation.

TCP (Transmission Control Protocol) is a connection-oriented reliable transport layer communication protocol based on bytes stream.

• FTP Function: click it to activate or deactivate the FTP function. When the FTP function is activated, this electrocardiograph can be connected with computer and the patient cases saved in "File List" screen can be viewed on the computer connected. Please refer to Chapter 5.4 for detail.

FTP (File Transfer Protocol) allows one computer to acquire files from or transfer files to another computer. You can connect the ECG machine to a computer and designate a user name and password to use the computer in a safe way. 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 to use.

- WIFI-ON/OFF: click it to activate or deactivate the WIFI function.
- WIFI-SSID: view the ID of the WIFI of this electrocardiograph.
- WIFI-PWD: view the password of the WIFI of this electrocardiograph.

Warning

Only connect this electrocardiograph to the PCECG workstation system of Comen Company. Please refer to "User manual of PCECG workstation" for detailed connection methods.

- Maintenance functions: the function of software upgrade. Insert the USB flash disk into the USB connector, click this option and the software upgrade will be conducted automatically.
- Battery Information: click here to display relevant information of the battery, such as: Battery status, Charging time, Discharging time and Battery temperature.

4.6 ECG Recording

Take the ECG recording under auto mode with 3×4 display format, 3×4 average template and detailed report information as an example, and the output ECG report includes part (a) and part (b), shown as the follows:



Figure 4-9 (a) Report format 3×4

AVERAGE TE	MPLATE						THE HOUSE H	Internet in the later of the la
1	aVR	VI	94	10 14	68100002			Minnesota Code
				NAME		BP	/ mella	9-4-14V30
				ABE	47	SEX		
				HEIGHT	Ç.M	WEIGHT	he	
П 11 +	aVL	V2	vs	- HR	60 bos			Diagnonis Info
				P Dur	89 ms			800 Sirwas Rhy
				PR int	169 me			
				GRS Dur	84 ms			###Normal ECG#
				DT DTO INE	360 350 mm			
		*** I	va (P/GRS/T axis	50 44 50 *			
				RV5-SV1 amp	1 050 0.522	ww		
				RV5+SV1 amp	1 572	Web		Daniel Lower L. D.
ID mm/mv	Q. SOHE-70HE			RV0/SV2 amp	0 742 0 868	1974		NORTHING BY



Part (a) and part (b) include the following contents:

- Display information
 - Π (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)
 - 0.15~100Hz (0.15Hz Baseline Drift Filter, 100Hz Lowpass Filter), AC 50Hz (AC Filter), 25mm/s (Print Speed), 10mm/mV (Gain), 3×4 Average Templates and confirmed by.
- Patient information: Second ID, name, age, height, sex and weight.
- Measurement information
 - Heart Rate
 - P Time Limit (Average Value of the Average Cardiac Beat P Wave Time Limits of Many Leads)
 - PR Interval (Average Value of the Average Cardiac Beat PR Intervals of Many Leads);
 - QRS Time Limit (Average Value of the Average Cardiac Beat QRS Wave Time Limits of Many Leads);
 - QT/QTC Interval (Average Value of the Average Cardiac Beat QT Intervals of Many Leads/Normalized QT Intervals);

- P/QRS/T Electric Axis (ECG Axis is the Main Direction of the Average Synthetic Vector on the Frontal Plane);
- RV5/SV1 Amplitude (Maximum Amplitude in the Average Cardiac Beat R and R' Waves of the Lead V5/Maximum Amplitude Absolute Value in the Average Cardiac Beat S and S' Waves of Lead V1);
- RV5+SV1Amplitude (Sum of RV5 and SV1);
- RV6/SV2 Amplitude (Maximum Amplitude in the Average Cardiac Beat R and R' Waves of the Lead V6/Maximum Amplitude Absolute Value in the Average Cardiac Beat S and S' Waves of Lead V2);

Minnesota Code

• Diagnosis information

MNOTE

• This equipment is detecting equipment instead of diagnosis equipment, and it is only responsible for those indicators regulated by relevant national standards. The diagnosis information selected and printed by doctors is the adjunctive and optional software function of this equipment, and can only be the reference for diagnosis use. The doctor should sign after diagnosis and confirmation according to actual ECG waveform. The doctor should be responsible for printed reports

4.7 Switch Off

When using built-in battery, press "²"key to shut down this instrument;

When using AC supply power, press "²"key to shut down this instrument and then pull out the plug.

5.1 Review

Review function means the ECG waveform of previous 10 minutes can be viewed in the review screen. The 12-lead ECG can be reviewed, analyzed and printed in the review screen. Click "Review" hotkey to enter the review screen, shown as the following figure.



Figure 5-1 Review screen

In review screen, the default waveform displayed is "II" lead waveform. In compressed waveform area, the waveforms of the patient monitored are displayed, and click any compressed waveform area, the selected

10s waveform will be displayed in the uncompressed waveform area which is convenient for doctors to

observe the waveform.

- "Lead": switch ECG waveform of 12 leads to display, and the default one is the waveform of "II" lead;
- "Gain": choose one gain from ×1 and ×2 as the gain of ECG waveform in compressed area and uncompressed area;
- "Analysis": click to analyze the ECG waveform in compressed area;
- "Print": click to print the ECG waveform in compressed area;
- "Return": click to exit review screen and return to main screen.

Chapter 5-1

This electrocardiograph has the function of copying the latest recording under auto mode, that is, click the "copy" hotkey, the latest report can be reprinted.

5.3 Patient Files

A file can be formed only under auto mode. Set "Save Option" as "Save Data", then conduct a recording under auto mode, and then a new file forms. This electrocardiograph can save binary 200 patient files in the Flash, and 40,000 binary patient files in the standard 8G SD card. The picture saved is maximum 8M. Click "File" hotkey to enter "File List" screen as shown below:

< File List	Q 🛃 🛃 Empty
1409010005	2014-09-01 14:20
Patient Name KNO NAME> Sex Male Age:0 File Size:187 kByte File Type: bin	
1409010004	2014-09-01 14:20
Patient Name (NO NAME) Sex: Mala Age:0 File Size:187 kByte File Type: bin	
1409010003	2014-09-01 14:19
Patiert Name; <no name="">_Sex.Male_Age.0_File Size;187kByte_File Type; bin</no>	
1409010002	2014-09-01 14 18
Patient Name <no name="">. Sex:Male: Age 0. File Size:187 kByte: File Type: bin</no>	
1409010001	2014-09-01 14:18
Palient Name <nd name="">. Sex Male: Age:0. File Size 187 kByte. File Type: bin</nd>	
1409010000	2014-09-01 14 17
Patient Name <no name="">. Sex Male: Age: 0. File Size:187.kByte: File Type: bin</no>	

Figure 5-2 File list screen

Every patient file in file list screen displays the patient's information including: name, sex, age, file size, file type and time of recording. File list screen supports the functions of search, import/export patient files, and print or delete the patient files.

- Search patient file: click icon, enter the search condition such as patient ID, name, etc. and click the "Enter" to enter the search result screen.
- Click a certain patient file to print, export or delete it.
- Click *limes to import patient files from USB flash disk;*
- Click to export patient files into USB flash disk.

Chapter 5-2

MNOTE

- Only under auto mode and "Save Option" is set as "Save Data", the printed waveform and data can be saved in file list screen for review. The waveforms and data printed under manual and rhythm mode will not be saved.
- You are recommended to use the USB flash disk 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 disk of FAT or FAT32 format. Please format it to FAT or FAT32 before using your USB flash disk. FAT and FAT32 are respectively available for the USB flash disk in a capacity of 0~2G and 2G~8G.

5.4 Transfer Files to Computer

1) Use the network cable to connect the electrocardiograph to your computer.

Mote

• If the electrocardiograph is connected to your computer via a switch, please use the straight network cable; if it is directly connected to your computer, please use the cross network cable.

2) Disable the Windows firewall

3) Set the TCP/IP address of your computer: click the local connection icon " \square " \rightarrow Attributes \rightarrow Internet Protocol (TCP/IP) (double click) \rightarrow Advanced \rightarrow Advanced TCP/IP Setup \rightarrow IP Setup \rightarrow IP Address \rightarrow Add \rightarrow input the IP address. If the remote address of the electrocardiograph is 192.168.2.40, please input the IP address 200.200.100 and subnet mask 250.250.250.0 on your computer as below:

IP address 192 168 1.40 192 168 2.40		Subret mask 358,358,358,358,8	
	Add	Edit.	Remove
Vejault galeways:			
Gateway 192.168 1.1		Metric Automatic	
	[Agd	Edt.	[Remove
Automatic metric			
Statistics evenue			

Figure 5-3 Computer IP Setup

If your computer is connected to WAN or LAN, please set the IP address as shown in the figure above. Either IP number should not conflict with that of any other computer. If the electrocardiograph is connected Chapter 5-3 to an off-line computer, they can share the same IP number.

4) Set the FTP view protocol: Internet Explorer (double click, Figure 5-4) \rightarrow Tools \rightarrow Internet Options \rightarrow Advanced \rightarrow Browse \rightarrow uncheck "Use Passive FTP (Compatibility of the Firewall and DSL Modem)" \rightarrow check "Enable Folder View for FTP Websites" (Figure 5-5 in red) \rightarrow Save.



Figure 5-4 IE Browser

Internet Explorer

Figure 5-5 FTP protocol option

5) Double click "My Computer", input ftp://root:comen@200.200.200.217 and press [Enter] to view the patient files displayed in file list screen.

Note

- The IP address in ftp://root:comen@200.200.200.217 is the same as the local IP address of the electrocardiograph. If the local IP address of the electrocardiograph is 200.200.200.217, please input ftp://root:comen@192.168.2.217 in "My Computer". This IP address should not be the same as that of any other computer connected to LAN or WAN, or the system could be halted.
- The patient files copied from the USB flash disk and from computer should be stored in two files with different file names, or there could be ID confusion, resulting in failure to be recognized by the electrocardiograph.

The prompt message during operation is shown in the following table

Prompt message	Causes
Lead off	Leads fall off form patient's body
Low Battery	Low battery
Sampling / printing	The data is being sampled or printed
Сору	Remind the users of reviewing patient's ECG data
Process	The ECG data is being processed
MEM FULL	The storage of files is full, no more patient's files can be saved
Paper?	Record paper is used up or the position of record paper is wrong
Demo	Demo function is enabled
USB printer?	USB printer is not connected or is not connected correctly
USB printer paper?	The record paper has not been loaded in USB printer or it has been used
	up
Printer close	the "Printer Select" is set as "Close"
Signal overload	The electrodes are not connected correctly

7.1 Cleaning

ACaution

Turn off the equipment before cleaning. If the AC power supply is used, disconnect the AC power supply and remove the power cord and ECG cable before cleaning.

1) Cleaning of Main Unit and ECG Cable:

Soak the soft and clean lint free cloth in mild soapsuds or in the non-corrosive washing solution after dilution, wipe the surface of the electrocardiograph and ECG cable and use the clean and dry soft cloth to clean.

2) Cleaning of Electrodes:

After the using of electrodes, clean the conductive gel with the clean soft cloth. Disconnect the suction bulb and metal cup of the chest electrode, disconnect the electrodes and the clamp and wash them with clean warm water (lower than 35 $^{\circ}$ C). Make sure that there is no residual conductive gel. Naturally dry them or clean them with clean and dry soft cloth.

3) Cleaning of Print Head:

Dirty and 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):

Open the recorder cover and remove record paper. Wipe the print head gently with a clean soft cloth damped with a little75% alcohol. For the stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth; after natural drying, load 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 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 ECG cable after cleaning.

Chapter 7-1

7.2 Disinfection

In order to avoid permanent damage to the equipment, we suggest you should only perform the disinfection when necessary according to the regulations of your hospital; we also suggest that you clean the product first before disinfection.



7.3 Maintenance

7.3.1 Charge and Replace 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 identification:

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

- : indicates that battery capacity is above 70% and the battery charge and discharge indicator is green.
- : indicates that battery capacity is between 10% and 70% and the battery charge and discharge indicator is yellow.
- Indicates that battery capacity is lower than 10%. The battery charge and discharge indicator is red and "Low Battery" appears in the prompt message area.

2) Charge the battery

This electrocardiograph is equipped with built-in rechargeable lithium battery and its charge control circuit. Because of the power loss in the storage and transportation, for the initial use, the battery power may be inadequate and at this time the battery should be charged.

When connect with the AC power supply, the battery will be charged. And then the AC power indicator \sim

and battery charge and discharge indicator are both light, which shows that the battery is being charged. Chapter 7-2

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 installation or maintenance engineer can open the battery compartment and replace the battery. Only use the rechargeable lithium battery of the same mode provided by Comen.
- Do not reverse the anode and cathode when connecting the battery, otherwise explosion may be caused.
- The waste battery should be sent back to Comen Company or disposed of according to the local regulations.

MNote

• At present, Comen Company would conditionally provide curcuit diagram, 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.

7.3.2 Record Paper

Storage requirements of record paper:

- Record paper should be stored in dry, dark and cool area, avoiding high temperature, humidity and sunshine.
- Do not put 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 recorded paper for a long time, or else the ECG waveforms recorded may trans-print each other.

7.3.3 Maintenance of Main Unit, ECG Cable and Electrodes

Caution Safety tests should be conducted periodically for the equipment at least once every two years and the test mainly includes: 1) Check whether there is mechanical and functional damage for the main unit and accessories.

Chapter 7-3

Cleaning and Maintenance

- 2) Check whether there is damage for the safety marks;
- 3) Check whether the fuse complies with the rated current and breaking characteristics;
- 4) Validate the functions of the equipment as described in the user manual;
- 5) Conduct the following safety test according to GB9706.1-2007
 - Test the protective ground resistance, Limit: 0.1Ω .
 - Test the earth leakage current, Limit: NC 500µA, SFC 1000µA.
 - Test the patient leakage current, Limit: NC 10µA, SFC 50µA (CF).

Main Unit:

- The main unit of the electrocardiograph should be protected from high temperature, sunshine, humidity 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:

- The integrality of the ECG cable and lead wires should be examined periodically;
- The lead wires should be aligned to avoid knotting and blending;
- The core wire and shielding layer are easier to be damaged, especially the places near the plug of the two ends, do not pull or wrest forcibly when using, nip the plug parts with hand;
- The cables and leads should be coiled into a disk with larger diameter in storage or be hung, wresting or sharp angle folding should be avoided;
- If the cables and lead wires are found to be damaged or aging, new cable and lead wires should be replaced.

Electrode:

- After using the electrodes, the residual conductive gel should be cleaned;
- The suction bulb of the chest electrode should avoid the direct sunlight or too hot;
- After long time of using and for the reasons of corrosion and so on, the surface of the electrodes may be oxidated and the color will change, then new electrode should be replaced to obtain good ECG recording.

Discarding of the equipment and Accessories:

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

•

Only use the ECG 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.

No.	Name	Model	Manufacturer
1	12-lead plug-type ECG cable of European Standard	A3003-EE0	APK
2	12-lead pin-type ECG cable of European Standard	TD-15PK-B	Qingdao Bright
3	12-lead pin-type ECG cable of European Standard	98ME02EA668	Launch Medical
4	12-lead plug-type ECG cable of American Standard	A3012-EE1	APK
5	12-lead banana-plug-type ECG cable of European Standard	A4012-EE0	APK
	12-lead banana-plug-type ECG cable of American		
6	Standard	A4012-EE1	APK
7	Suction chest electrodes	P26-ST30-21	Qingdao Bright
8	Suction chest electrodes	P28-H30	Qingdao Bright
9	Child suction chest electrodes	B23-B30-17	Qingdao Bright
10	Suction chest electrodes	98ME02AA644	Launch Medical
11	Adult suction chest electrodes	G32-G40-24	Qingdao Bright
12	Suction chest electrodes	A30-G26-21	Qingdao Bright
13	Limb clamp electrodes	B30-(RY)-GND	Qingdao Bright
14	Child limb clamp electrodes	D40-89	Qingdao Bright
15	Adult limb clamp electrodes	BD-15PB	Qingdao Bright
16	Limb clamp electrodes	98ME02GA704	
17	Limb clamp electrodes	B30	Qingdao Bright

Safety	IEC60601-1	Medical Electrical Equipment Part 1: General
Standards	GB9706.1	Requirements for Safety
	IEC60601-2-25	Medical Electrical Equipment Part 2: Special
	GB10793	Requirements for Safety of Electrocardiograph
	EN 60601-1-4	Medical Electrical Equipment Part 1-4: General
		Requirements for Safety Supplement Standard:
		Programmable Electrical Medical System
	EN 60601-2-51	Medical Electrical Equipment Part 2-51: Special
		Requirements for Safety Basic Performance,
		Record and Analysis of the Single Channel and
		Multi-channel Electrocardiograph
	EN ISO14971	Medical Device Application of the Risk
		Management on the Medical Devices
	YY1139	Single-channel and multi-channel
		electrocardiograph
Classification	Anti-electric-shock type	Class I with internal power supply
	Anti-electric-shock degree	Type CF
	Degree of protection again	nst Ordinary equipment (Sealed equipment without
	harmful ingress of water	liquid proof)
	Degree of safety of application	in Equipment not suitable for use in the presence
	the presence of flammable gas	of flammable gas
	Working mode	Continuous operation
Dimension	235mm×190mm×52.6mm	
Weight	1.18kg (including main unit, record	rder and battery, not including accessories)
Display	6.2 inch LCD color touch screen w	with resolution of 600×480 pixels
Work	Work temperature	5℃~40℃
Environment	Transport and storage temperature	-20℃~55℃
	Relative Humidity	15%~80% (No condensation)

Appendix II-1

Technical Specifications

Atmospheric Pressure	$700hP_{2} \sim 1060hP_{2}$

AC Power	Rated voltage	100-240V~	
Supply	Rated frequency	50Hz/60Hz±1Hz	
	Rated input power	40VA	
Battery	Rated voltage	11.1V ===	
	Charge time	Under ambient temperature of $25 ^{\circ}\text{C} \pm 5 ^{\circ}\text{C}$, charge to 90% for less than 3 hours and charge to 100% for less than 3.4 hours.	
	Discharge time	For a fully charged battery under ambient temperature of $25 \degree C \pm 5 \degree C$, the electrocardiograph should print at least 500 ECG reports, or conduct continuous recording for at least 2 hours, or conduct recording with no record paper for at least 7 hours.	
Fuse	T315mAL 250V、T500mAL 110V φ5×20		
HR calculation	Calculation method	Peak detection	
Recorder	Recording Method	Thermal dot-matrix printing	
	Record Paper	80mm×70mm Folded thermosensitive paper 80mm×20mm Rolled thermosensitive paper	
Width of Record Paper		80mm	
	Valid Recording Width	72mm	
	Paper Speed	5 mm/s, 6.25 mm/s, 10mm/s, 12.5 mm/s, 25mm/s, 50mm/s; Error:±2%	
Main Unit	Input Method	With defibrillator-proof protection	
	Leads	Standard 12 leads and switching leads automatically	
	Sampling Mode	12 channels simultaneously	
	A/D Sampling	24 bits	
	Time Constant	≥5s	
	Frequency Characteristics	$0.05Hz \sim 150Hz \ (^{+0.4dB}_{-3.0dB})$	
	Sensitivity	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 20/10 mm/mV, 10/5 mm/mV and AGC. The default sensitivity is 10 mm/mV. Error: $\pm 2\%$	

Appendix II-2

Technical Specifications

Input Impedance	>50M O

	Stand Volta	ge	Applying \pm 650mV d.c. polarization voltage, the range of sensitivity is \pm 5%.	
Input Circuit		Current	≤50 mA	
	Calibration Voltage		1 mV±1%	
	Noise Level Multichannel crosstalk Filter		<15 µ Vp-p	
			≤0.5mm	
			AC Filter: 50Hz, 60Hz, OFF	
			DFT Filter: OFF, 0.05Hz, 0.10Hz, 0.20Hz, 0.50Hz	
			EMG Filter: 25Hz, 35Hz, 45Hz, OFF	
			LOWPASS Filter: OFF, 75Hz, 100Hz, 150Hz	
	CMRR		≥100dB	
Communication Interface RS232 con		RS232 com	munication interface	
Standby Function The re		The response	nse time of exiting standby status is less than 10s.	

Attention

- H3 meets the requirement of electromagnetic compatibility in IEC60601-1-2. 0
- H3 meets the requirement of Group I Class Ain CISPR 11/EN 55011.
- The user needs to install and use according to electromagnetism compatibility information which is • attached with it.
- Portable and mobile RF communication devices may influence H3 performance, so H3 should be kept away from them during using.
- Guidance and manufacturer's declaration stated in the appendix.

Warning

- H3 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the H3 should be observed to verify normal operation in the configuration in which it will be used.
- Class A equipment is intended for use in an industrial environment. The H3 may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.

Guianne and manufacturer 5 declaration - electromagnetic emissions			
The H3 is intended for use in the electromagnetic environment specified below. The customer or the user of the			
SECP-II should assure that it is used in such an environment.			
Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions		The H3 uses RF energy only for its internal function.	
CISPR 11	Group 1	Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions		The H3 is suitable for use in all establishments other than	
CISPR 11	Class A	domestic and those directly connected to the public	
Harmonic emissions	Notomicable	low-voltage power supply network that supplies building	
IEC 61000-3-2	Not applicable	used for domestic purposes.	
Voltage fluctuations / flicker			
emissions	Not applicable		
IEC 61000-3-3			

Table 1

Guidance and manufacturer's declaration –electromagnetic emissions

Gui	Guidance and manufacturer's declaration – electromagnetic immunity			
The H3 is intended for u	ise in the electromagne	etic environment specifi	ed below.	
The customer or the use	r of the H3 should ass	ure that it is used in such	n an environment.	
T	IEC 60601 test	Compliance level	Electromagnetic environment –	
	level	Compliance level	guidance	
Electrostatic discharge (ESD)	±6 kV contact ±8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with	
			synthetic material, the relative humidity	
IEC 61000-4-2			should be at least 30 %.	
Electrical fast	±2 kV for power	$\pm 2 \mathrm{kV}$ for power	Mains power quality should be that of a	
transient/burst	supply lines	supply lines	typical commercial or hospital	
IEC 61000-4-4			environment.	
Surge	± 1 kV line(s) to	± 1 kV line(s) to	Mains power quality should be that of a	
	line(s)	line(s)	typical commercial or hospital	
IEC 61000-4-5	\pm 2 kV line(s) to	\pm 2 kV line(s) to	environment.	
	earth	earth		
Voltage dips, short	<5 % <i>U</i> T	<5 % <i>U</i> T	Mains power quality should be that of a	
interruptions and	(>95 % dip in <i>U</i> T)	(>95 % dip in UT)	typical commercial or hospital	
voltage variations	for 0,5 cycle	for 0,5 cycle	environment. If the user of the H3 requires	
on power supply	40 % <i>U</i> T	40% <i>U</i> T	continued operation during power mains	
input lines	(60 % dip in <i>U</i> T)	(60 % dip in <i>U</i> T)	interruptions, it is recommended that the	
	for 5 cycles	for 5 cycles	H3 be powered from an uninterruptible	
IEC 61000-4-11	70 % <i>U</i> T	70% <i>U</i> T	power supply or a battery.	
	(30 % dip in <i>U</i> T)	(30 % dip in <i>U</i> T)		
	for 25 cycles <5 % <i>U</i> T	for 25 cycles <5 % <i>U</i> T		
	(>95 % dip in <i>U</i> T)	(>95 % dip in <i>U</i> T)		
	for 5 s	for 5 s		
Power frequency	3 A/m	3 A/m	Power frequency magnetic fields should be	
(50/60 Hz)			at levels characteristic of a typical location	
magnetic field			in a typical commercial or hospital	
IFC 61000-4-8			environment.	

Guidance and manufacturer's declaration – electromagnetic immunity					
The H3 is intended f	for use in the electror	nagnetic environ	ment specified below.		
The customer or the	user of the H3 shoul	d assure that it is	used in such an environment.		
Immunity test	IEC 60601 test	Compliance	Electromagnetic		
	level	level	environment – guidance		
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz and 800MHz, the hi	3Vrms 3V/m gher frequency ra	Portable and mobile RF communications equipment should be used no closer to any part of the H3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in 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. ^b Interference may occur in the vicinity of equipment marked with the following symbol:		

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 transmitters, such as base stations for radio (cellular/cordless) telephones and land

mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the H3 is used exceeds the applicable RF compliance level above, the H3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the H3.

Table 4

Recommended separation distances between					
portable and mobile RF communications equipment and the H3					
The H3 is intended for use in a	The H3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The				
customer or the user of the H3	3 can help prevent electrom	agnetic interference by mai	ntaining a minimum distance		
between portable and mobile	between portable and mobile RF communications equipment (transmitters) and the H3 as recommended below,				
according to the maximum output power of the communications equipment.					
Rated maximum output	Separation distance according to frequency of transmitter				
power of transmitter	m				
W	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz		
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$		
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 distance d 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 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

COMEN

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EC REP

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