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Product name: Electrocardiograph

Product model: H3

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After-sales Service Unit

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II

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.

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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Chapter 1 Safety Guidance

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.

 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 Warnings and Cautions

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.
- The use of this equipment is restricted to one patient at a time.
- 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.
- Do not posit the equipment to make it difficult to operate the power plug which uses to isolate the equipment circuits electrically from the supply mains.
- The housing of the equipment should be grounded well. Use the three-wirereceptacle 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. 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. 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.

ACaution

- Avoid liquid splashed on the equipment.
- Avoid high temperature and the equipment should be used within $+5^{\circ}\text{C}\sim+40^{\circ}\text{C}$.
- 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.

- The service life of this equipment is 5 years.
- 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.

Note

- 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 45 °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.

- 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

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.
- 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	
- ● 	Defibrillation-proof type CF applied part	~	AC indicator	
\triangle	Caution	(+/←	Battery charge and discharge indicator	
\Rightarrow	Equipotential grounding	0	Working status indicator	
용	Network connector	•~	USB connector	
SN	Serial Number	(3)	Refer to instruction manual/booklet	
EC REP	Authorised representative in the European Community	C € ₁₆₃₉	Conformit é Europ éenne Complies with medical device directive 93/42/EEC	
The symbol indicates the separate collection for electrical and electronic equipment.		<u> </u>	Warning: Only use the ECG cable provided by Comen. Other types of ECG cable may decrease the defibrillation energy delivered to the patient.	

(2) Symbols of Packing

Symbol	Description	Symbol	Description
<u>11</u>	Up		Stacking layers limit
<u> </u>	Fragile	*	Keep dry

Chapter 2 General Introduction

2.1 Production Composition

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

2.2 Intended Application

This instrument is applicable to clinic units to detect and record people's routine ECG signals.

2.3 Contraindications

None

2.4 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:

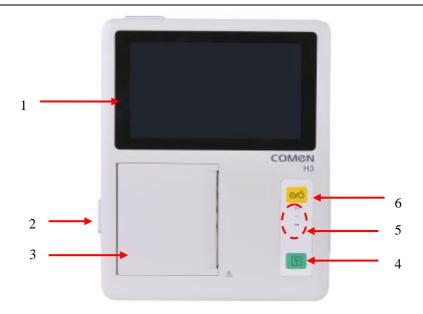
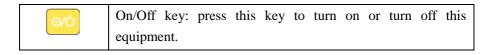


Figure 2-1 Top panel of main unit

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

2.5 Functions of Keys and Indicators



<u>্</u>	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 AC power supply is connected, this indicator is light until the battery is fully charged.
0	Working status indicator: after this equipment is switched on and not connected AC power, this indicator is light;
~	AC indicator: when connected to AC power supply, this indicator is light.

2.6 External Connectors

2.6.1 Left panel

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



Figure 2-2 Left panel

2.6.2 Right panel

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

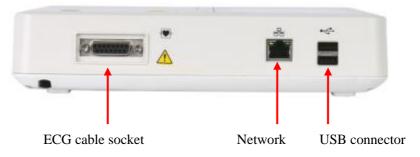


Figure 2-3 Right panel



 Currently our ECG machine H3 supports such external printers as PANTUM P3255DN.

Warning

- The accessories connected to the analog and digital interfaces should be validated according to the respective IEC standards. Furthermore all configurations should comply with the valid version of the IEC 60601-1. Therefore anybody, who connects additional equipment to the signal input connector or signal output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC60601-1. If there is any problem, consult us or your local agent.
- The sum of electric leakage should never exceed the electric leakage limits while patient cable interface, external input and output interface and net interface are connected with other equipments at the same time.

2.6.3 Back panel

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

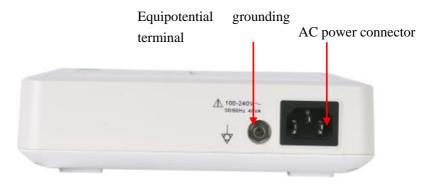


Figure 2-4 Back panel

2.7 Bottom panel

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

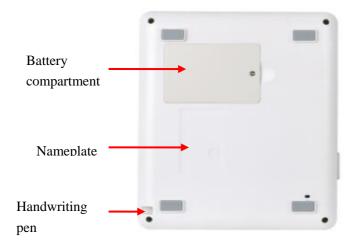


Figure 2-5 Bottom panel

2.8 Screen Display

The main screen is shown as follows:



Figure 2-6 Main screen

NO.	Definition	Name	Description		
	Patient and system information (from left to right)			Patient information	Display patient ID, sex, name and age, click here to enter the [Register] settings
		Measurement mode	Auto/manual/ rhythm, click here to change measurement mode circularly.		
1		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 supported.		
		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.
		Lowpass Filter	Click here to enter [Lowpass Filter], 75Hz, 100Hz, 150Hz and off are supported.
		Real-time heart rate value	Display the real-time heart rate value of current patient
		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 area		Display prompt message such as [paper?], [Lead off], "printing" and so on.
4	Lagragara	Time	Display current time. Click here to enter the" System time" setting screen.
4	Icons area	Battery information	Display the fuel gauge of the battery.
		Review key	Click here to enter [Review] screen.
5	Hotkey area (from top to bottom)	Copy key or lead switch key	Under auto mode, copy key is displayed here and click it to reprint the latest ECG report. Under rhythm mode, copy key is unavailable.
			Under manual mode, lead switch key is displayed here and click it to switch

General Introduction

	leads manually.
File	Click here to enter [File List] screen.
Config.	Click here to enter configuration screen.

Chapter 3 Operation Preparation



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



- Use the three-wirereceptacle 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.

Note

- If the use of the instrument is affected by equipotential grounding, contact the Company's After-sales Service Department or agents.
- 1) Use the AC Power Supply

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

■ Voltage: 100-240V~

■ Frequency: 50Hz/60Hz

■ 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-wirereceptacle.

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 80mm×20mm rolled thermosensitive record paper or 80mm×70mm 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

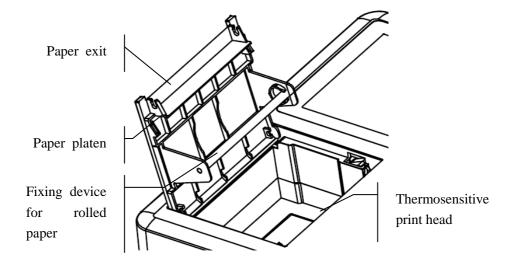


Figure 3-1 Inner structure of recorder

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.
- 4) 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



 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/blue
Chest 5	C5	White/black	V5	Brown/orange

Chest 6	C6	White/violet	V6	Brown/violet
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3.4.1 Positions of Limb Electrodes

1) Limb Electrode (Clamp type):

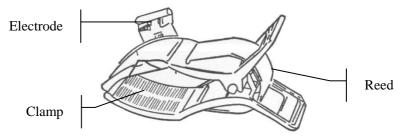


Figure 3-3Limb electrode

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~C6 chest electrode connected as figure 3-6

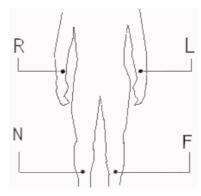


Figure 3-4Positions of four limb electrodes

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:

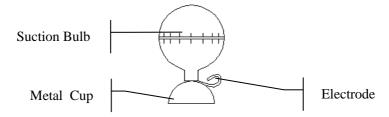


Figure 3-5 chest electrodes

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: Middle of 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

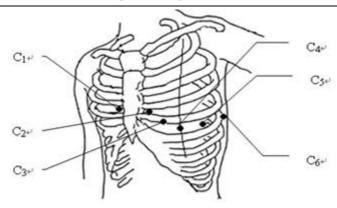


Figure 3-6Positions of chest electrodes

- 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.



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

Before using this electrocardiograph please read the user manual carefully to be

familiar with the performance of the equipment and the operation methods must be mastered and the cautions and warnings; 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-wirereceptacle.

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.

Chapter 4 System Settings

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 (\sim) key to switch on the equipment, then the equipment enters the working status.

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 () and battery charge and discharge indicator () are both light.

When the built-in rechargeable battery is used, press the () key to switch on the equipment directly. Then the equipment enters the working status and the battery working indicator lamp () turn light.

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 time 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.



- 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 "On", the ECG waveform and data printed under auto mode can be saved in [File List] screen, or it can not be saved.

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 key again to stop recording;



- 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. When the [Rhythm Lead Type]is set as [1 Channel],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.



- The ECG waveform and data will not be saved as patient case under rhythm mode.
- When [Print Select] is [Internal], [Rhythm Lead Style] can only be set as [1 Channel], when [Print Select] is [External] and [close], [Rhythm Lead Style] can be set as [1 Channel] and [3 Channel].

4.5 System Settings

4.5.1 Patient Information

Click [Config.] to enter the setting screen select [Patient Info], shown as the following figure:



Figure 4-1 Patient information screen



- 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 Option] is set as [On].
- [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 patientand 0045 represents the 45th patient being examined at this day.
- [Patient name]: entering patient's name within 20 characters
- [Sex]: male/ female
- [Age]: range 0~120
- [Height (cm)]: range 0~999
- [Weight (kg)]: range 0~999
- [SYS (mmHg)]: systolic pressure (range 0~999)
- [DIA (mmHg)]: diastolic pressure (range 0~999)

- [Doctor]: entering doctor's name within 20 characters
- [Technician]: entering technician's name within 20 characters
- [Bed NO].: entering the bed number within 20 characters
- [Hospital NO.]: entering hospital number within 10 characters
- [Update patient information]: click to delete the patient information of last patient. Select "yes" to confirm updating patient information.
- [Divisions]: entering division's name within 20 characters
- [Hospital]: entering hospital name within 40 characters
- [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], shown as the following figure:



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], [0.50Hz] and [OFF]

 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]: [75Hz], [100Hz], [150Hz] and [OFF]
 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 75Hz, 100Hz, 150Hz and OFF.



 When [EMG Filter], [DFT Filter] and [Lowpass Filter] are set to [OFF] and [AC Filter] is enabled, the waveform can be displayed without distortion.

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

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]: 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

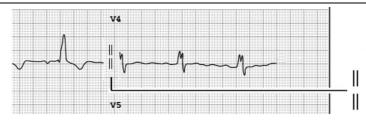


Figure 4-4 Simultaneous Sampling of Each Group

• [ECG Criteria]: select the naming criteria of lead wires (IEC and AHA)

[IEC]: When this standard is set, then the lead on the lead map will be named as: C1, C2, C3, C4, C5, C6, R, L, N, F.

[AHA]: When this standard is set, then the lead on the lead map will be named as: V1, V2, V3, V4, V5, V6, RA, LA, RL, LL.

- [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.



When [Printer Select] is set as [Internal], only [1 Channel] is available
in [Rhythm Lead Type] option; when [Printer Select] is set as
[External] and [Close], [1 Channel] and [3 Channel] are available in
[Rhythm Lead Type] option

4.5.3 Print Settings

mode.

Click [Config.] to enter setting screen, and select the [Printer], shown as following figure:

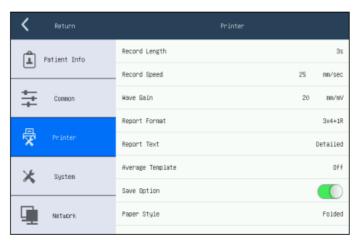


Figure 4-5 Print settings screen

- [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
- [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, [AGC] means auto gain control.
- [Report Format]: when [Printer Select] is set as [External] or [Close], the available report formats include [3×4], [3×4+1R], [3×4+3R], [6×2], [6×2+1R], [12×1] and [12×1+1T]; when [Printer Select] is set as [Internal], available report formats include [3×4] and [3×4+1R].
 - ➤ [3×4]: 12 leads are recorded in 3 channels and 4 sequences, when "Printer Select" is set as "External" or "Close", record 2.5s for each sequence, when "Printer Select" is set as "Internal", the recoding length of each sequence is decided by printing length.
 - > [3×4+1R]: 12 leads are recorded in 3 channels and 4 sequences, when "Printer Select" is set as "External" or "Close", record 2.5s for each sequence, when "Printer Select" is set as "Internal", the recoding length of each sequence is decided by printing length. And add 1 channel of rhythm lead waveform.
 - > [3×4+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.
 - ➤ [6×2+1R]: 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.
 - ➤ [12×1+1T]: 12 leads are recorded in 12 channels, in which there is 1 channel of rhythm lead waveform identified with "Rhy."

• [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:

ID : 14	08190001		
NAME :		BP :	/ mmHg
AGE :	yr	SEX :	
HEIGHT :	cm	WEIGHT :	kg
HR	: 60 bpm		
P Dur	89 ms		
PR int	: 166 ms		
QRS Dur	: 87 ms		
at/atc int	: 353/353 ms		
P/QRS/T axis	: 49/44/50 "		
RV5/SV1 amp	1 085/0 549	mV	
RV5+SV1 amp	1 634	mV	
RV6/SV2 amp	0. 770/0. 905	5 mV	

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:

ID	: 140	8190002				Minnesota Code
NAME			BP	1	mmHg	9-4-1 (V3)
AGE		yr	SEX :			
HEIGHT	2	cm	WEIGHT :	k	g	
HR		60 bpm				Diagnosis Info
P Dur		89 ms				800: Sinus Rhyt
PR int		169 ms				
QRS Dur	l i	84 ms				***Normal ECG**
QT/QTC	int	350/350 ms				
P/QRS/T	axis:	50/44/50 *				
RV5/SV1	amp :	1. 050/0. 522	m∨			
RV5+SV1	amp :	1. 572	mV			0.00
RV6/SV2	amp	0.742/0.86	8 mV			Confirmed By:

Figure 4-7 Detailed information

• [Average Template]: when [Printer Select] is set as [Internal], available average template includes [3×4+1R], [2×6+1R] and [Off]; when [Printer

Select] is set as [External] or [Close], available average template includes $[3\times4+1R]$, $[6\times2+1R]$ and [Off].

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

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

 $[6\times2+1R]$: 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]: [On] and [Off];

[On]: 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.



- 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], available paper style includes [(A4) Folded 295×210mm], [(16K) Folded 195×271mm]and [(B5) Folded 182×257mm].

This recorder adopts 80mm×20mm rolled thermosensitive record paper or 80mm×70mmfolded 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.



- If incorrect paper type is selected, the equipment may not print normally.
- [Pacing Logo]: [OFF],[I],[II],[V1],[V2],[V3],[V4],[V5],[V6].

 If [Pacing Logo] is set to lead, there will be pacing marks displayed above ECG

waveform when pacing pulse is detected.

• [Measurement Matrix]: [On] and [Off], it is only associate auto mode.
When this function is enabled, and the [Report Text] is set as [Detailed,] 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), ST40 (μV_S), ST60 (μV), ST80 (μV), nRNotch and Delta.

 (μV) , $Ua(\mu V)$, STj (μV) , ST1 (μV) , ST2 (μV) , ST3 (μV) , ST20

When [Measurement Matrix] is set to [OFF], 32 measurement values of each lead of 12 leads won't be output.

$riangle ext{Note}$

- When the [Report Text] is set as [Basic] or [Off], the [Measurement Matrix] is [off], and when the [Report Text] is set as [Detailed],the [Measurement Matrix] can be set as [on].
- [Printer select]: [Close], [Internal], [External];
- Save Fromt: Close, [BMP],[JPG],[PDF],[SCP],[XML],[DICOM] Close: the files of dat format can be saved only when [Save Option] is on.

[BMP],[JPG],[PDF],[SCP],[XML] or [DICOM]: The corresponding files of this format can be saved only when [Printer Select] is set to [Close], and [Save Option] is on.

• [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 measurement finishes, a rhythm recording will be added automatically.

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

- [Rhythm R-R 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

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



Figure 4-8 System Settings Screen

- [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.
- [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. Click the touch screen to exit the standby status.
- [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.
- [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.
- [Date Format]: [YY-MM-DD], [MM/DD/YY], [DD/MM/YY]

- [Time Format]: [12-Hour] and [24-Hour]
- [System Time]: set the system time of the electrocardiograph according to local time.
- [Language]: you can select a language for ECG displaying and recording
- [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 electrocardiographed patient waveform and parameters, which may affect the patient care and delay the diagnosis and treatment of the disease.
- [Version information]: view the version information of software installed in this instrument.
- [Default Config.]: click it to restore the default configuration.

4.6 Network Settings

Click the [Config.] to enter the setting screen and select [Network], shown as the following figure:



Figure 4-9 Network Settings Screen

- [IP address]: 255.255.255.217, the IP address of this electrocardiograph.
- [Remote IPaddr]: 200.200.200.99, 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
- [Network Type]: [Close], [Line], [WIFI] (It is necessary to set the WIFI account number and password if selecting this function only).
 - [Wifi ID]: view the ID of the wireless network of this electrocardiograph.
 - [Wifi Password]: view the password of the wireless of this electrocardiograph.
- [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.

• [Transfer Type]: [Close], [FTP Transfer], [DICOM Transfer], [Ecg Network].

[FTP Transfer]: It can transfer the case files to the specified folder via the FTP server. In the main interface, the [Printer Select] is set to [Close], and it will transfer the stored files of picture format to the specified folder when the storage is picture format; in [File] interface, all the selected files can be transferred.

[DICOM Transfer]: After the DICOM server is activated on the computer, only the files of DICOM format can be transferred in the main interface.

[Ecg Network]: After the software of ECG Network is activated on the computer, the waveforms on the instrument can be synchronized to the ECG Network.

[Close]: Files cannot be transferred.

• [Obtain Method]: [Close],[HL7], [DICOM Worklist].

[HL7]: When the transfer mode is not the ECG Network, enter the soft keyboard of the second ID, input the corresponding second ID, and click the extraction key on the soft keyboard to obtain the patient information. After the extraction succeeds, the corresponding information will be automatically inputted to the relevant options in the patient information page.

[DICOM Worklist]: When the transfer mode is not the ECG Network, set the DICOM AE to obtain the folder name of patient information, enter the soft

keyboard of the second ID, input the corresponding second ID, and click the extraction key on the soft keyboard to obtain the patient information. After the extraction succeeds, the corresponding information will be automatically inputted to the relevant options in the patient information page.

[Close]: It fails to obtain the patient information by the extraction key.

- [DICOM AE]: It defaults to ACME_STORE. It can change according to the server side folder name with the patient information.
- [FTP User]: When selecting the [FTP transfer], it is necessary to set this option. The system sets this option as TEST by default. User can also set as required. The set FTP user name needs to be consistent with the relevant setting of the FTP receiving software.
- [FTP Password]: When selecting the [FTP transfer], it is necessary to set this option. The system sets this option as COMEN by default. User can also set as required. The set FTP Password needs to be consistent with the relevant setting of the FTP receiving software.
- [FTP Port]: When selecting the [FTP transfer], it is necessary to set this option. The system sets this option as 21 by default. User can also set as required. The set FTP port value must be more than 20, and the set FTP Port needs to be consistent with the relevant setting of the FTP receiving software.

- The FTP receiving software includes two types, i.e., 32-bit and 64-bit. User can select a suitable server according to their computers.
- Steps of FTP transferring files: Under the condition that the instrument is connected to the network normally, select the [Printer]to [Close], the [Save Option] is on, select the [Transfer Type] to [FTP Transfer], and meanwhile keep the server port, user and password of the FTP receiving software consistent with the setting of these three options on the instrument. User can transfer files after setting the

transfer file directory as required.

4.7 ECG Recording

Take the ECG recording under auto mode with 3×4 display format, $3\times4+1R$ average template and detailed report information as an example, and the output ECG report includes part (a) and part (b), shown as the follows:

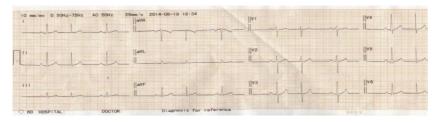


Figure 4-9 (a) Report format 3×4

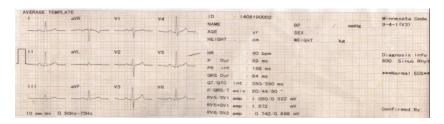


Figure 4-9 (b) Average template 3×4 and detailed report information

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), 3×4Average 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

• 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

4.8 Switch Off

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

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

Chapter 5 File Management

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.

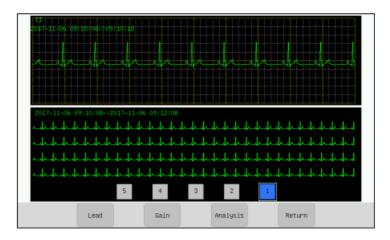


Figure 5-1 Review screen

In review screen, the default waveform displayed is II lead waveform. In compressed waveform area, the waveforms of the patient electrocardiographed 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]: [I], [II], [III], [aVR], [aVL], [aVF], [V1], [V2], [V3], [V4], [V5], [V6], switch ECG waveform of 12 leads to display, then click [OFF] to finish switching.

- [Gain]: 10mm/mV \, 20mm/mV. Set the waveform gain in the uncompressed waveform area and click the option of [Off] to complete the setting.
- [Analysis]: Select [Analysis] and prompt message [Analysis] will be displayed until analysis result. Click [Print] to print the selected 12-lead ECG waveform of 10 seconds and analysis report simultaneously. Click [OFF] to return review screen.
- [Return]: click to exit review screen and return to main screen.

5.2 Copy

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 [On], 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 standard8G SD card. The picture saved is maximum 8M. Click [File"]hotkey to enter [File List"] screen as shown below:

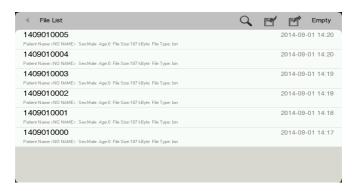


Figure 5-2 File list screen

Every patient file in file list screen displays the patient's information including: ID, name, file type and time of recording. File list screen supports the functions of selection all patient cases, search, import/export patient cases, and print or delete the patient cases.

- Selection all patient cases: Click icon, it can select/cancel selecting all
 the patient cases.;
- Search patient cases: click icon, enter the search condition such as patient ID, name, etc. and click the "Enter" to enter the search result screen.
- Import of patient cases:: Click icon, and import patient cases from the USB.
- Set patient cases: select the patient cases on the [File List], Click icon, the dialog box of "Please select your operation" appears, it can execute the recording (printing and transfer), export, deletion and cancel operation to the patient file.

$ilde{ ext{$igwedge}}_{ ext{Note}}$

- Only under auto mode and [Save Option] is set as [On], 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.



- 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
- \longrightarrow 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 200.200.200.100 and subnet mask 250.250.250.0 on your computer as below:

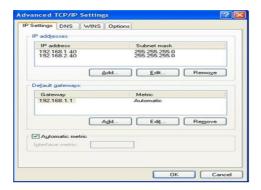


Figure 5-3 Computer IP Setup

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 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) → Tools → Internet Options → Advanced → Browse → uncheck "Use Passive FTP (Compatibility of the Firewall and DSL Modem)" → check "Enable Folder View for FTP Websites" (Figure 5-5 in red) → Save.

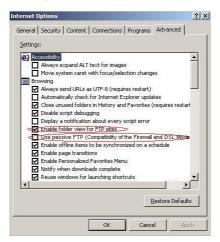




Figure 5-4 IE Browser

Figure 5-5 FTP protocol option

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

<u>∕!\</u>Note

- The IP address in ftp://root:comen@200.200.2017 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

File Management

Chapter 6 Prompt Message

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	
[Copy]	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 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]	
[Overload]	The electrodes are not connected correctly	

Chapter 7 Cleaning and Maintenance

7.1 Cleaning



 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°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.

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.



Caution

- 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.

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:

: Full capacity.

: Capacity is not full.

: The capacity is low.

Capacity is too low, it should be recharged immediately.

Absence or damage of the battery.

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 (\checkmark) are both light, which shows that 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.

extstyle ext

- 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.

Note

 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.
- 2) Check whether there is damage for the safety marks;
- 3) Validate the functions of the equipment as described in the user manual;
- 4) Conduct the following safety test according to IEC 60601-1.
 - lacktriangle Test the protective ground resistance, Limit:0.1 Ω
 - 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.

Appendix I Accessories

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.	PN.	Model	Туре	Name
1	040-000688-00	TD-15PK-J/IEC10/Q	Banana	12-lead; IEC
1	040-000008-00	TD-13PK-J/IEC10/Q	Daniana	Standard;Φ4.0
2	040-000151-00	TD-15PK-B/IEC10/Q	Banana	12-lead; IEC
2	040-000131-00	1D-13FK-D/IEC10/Q	Daniana	Standard;Φ3.0
3	040-000682-00	TD 15Dl: 1/AHA10/0	Banana	12-lead; AHA
3	040-000082-00	TD-15Pk-J/AHA10/Q	Danana	Standard;Φ4.0
4	040-000683-00	TD 15Dk I/O/AHA10/O	Donono	12-lead; AHA
-	040-000083-00	TD-15Pk-I/O/AHA10/Q	Banana	Standard;Φ3.0

Appendix II Technical Specifications

Safety	IEC60601-1	Medical Electrical
Standards		Equipment-Part 1: General
		Requirements for Safety and
		essential performance
	IEC60601-2-25	Medical Electrical
		Equipment-Part 2-25: Particular
		requirements for the basic safety
		and essential performance of
		electrocardiographs
	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
	EC11	Diagnostic electrocardiographic
		devices

	Anti-electric-shock type	Class I with internal power supply
Classification	Anti-electric-shock degree	ECG: Type CF
	in the presence of flammable	Equipment not suitable for use in the presence of flammable gas

Working mode	Continuous operation	
--------------	----------------------	--

Dimension	235mm×190mm×52.6mm
Weight	1.18kg (including main unit, recorder and battery, not including accessories)
Display	6.2 inch LCD color touch screen with resolution of 800×480 pixels

	Work Temperature	5℃~40℃
Work Environment	Relative Humidity	≤93%
	Atmospheric Pressure	700hPa~1060hPa

	Temperature	-20°C ∼+60°C
	Relative Humidity	≤93%
storage environment	Atmospheric Pressure	700hPa∼1060hPa
	Must avoid severe shock ,vibration, rain and snow during transpor	

	Rated voltage	100-240V∼
AC Power Supply	Rated frequency	50Hz/60Hz
	Rated input power	40VA

	Specifications	11.1V == 2600mAh
	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.
Battery	Discharge time	For a fully charged battery under ambient temperature of $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$, 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.

	Recording Method	Thermal dot-matrix printing
	Record Paper	80mm×70mmFolded thermosensitive paper 80mm×20mRolled thermosensitive paper
Recorder	Width of Record Paper 80mm	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%

	HR calculation	Peak detection
	Input Method	With defibrillator-proof protection
	Leads	Standard 12 leads and switching leads automatically
	Heart rate measurement range and accuracy	30~300bpm; ±1% or ±1bpm ,whichever is greater
	Sampling Mode	12 channels simultaneously
	Time Constant	≥5s
Main Unit	Frequency Characteristics	0.05Hz ~ 150Hz (+0.4dB)
	Sensitivity	2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 20/10mm/mV, 10/5 mm/mV and AGC. The default sensitivity is 10mm/mV. Error: ±2%
	Input Impedance	≥50M Ω
	Stand Voltage	Applying \pm 650mV d.c. polarization voltage, the range of sensitivity is \pm 5%.
	Input Circuit Current	≤50nA
	Calibration Voltage	1mV ±1%
	Noise Level	<15 μ Vp-p

	Multichannel crosstalk	≤0.5mm
	The skew between channels	<100μs
		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	≥110dB
Standby Functi	on	The response time of exiting standby status is less than 10s.

Appendix III EMC

ACaution

- H3 meets the requirement of electromagnetic compatibility in IEC60601-1-2.
- H3 meets the requirement of Group I Class A in 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.

Table 1

	Tab	ole I		
	declaration - elect	romagnetic emission		
H3 is intended for u	H3 is intended for use in the electromagnetic environment specified below. The			
customer or the user	of H3 should assur	e that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance		
RF emissions	Group 1	H3 uses RF energy only for its internal		
CISPR 11		function. Therefore, its RF emissions are		
		very low and are not likely to cause any		
		interference in nearby electronic		
		equipment.		
RF emissions	Class A	H3 is suitable for use in all		
CISPR 11		establishments other than domestic and		
Harmonic	Not Applicable	those directly connected to the public		
emissions	rvotrippiicuoic	low-voltage power supply network that		
IEC 61000-3-2		supplies buildings used for domestic		
Voltage	Not Applicable	purposes.		
fluctuations/	rvotrippheuoie			
flicker emissions				
IEC 61000-3-3				

Table 2

declaration - electromagnetic immunity

H3 is intended for use in the electromagnetic environment specified below. The customer or the user of H3 should assure that it is used in such an environment.

customer or th	e user of H3 should as	sure that it is use	d in such an environment.
Immunity	IEC 60601 test	Compliance	Electromagnetic
test	level	level	environment - guidance
Electrostatic	±8 kV contact	±8 kV contact	Floors should be wood,
discharge	±15 kV air	±15 kV air	concrete or ceramic tie. If
(ESD)			floors are covered with
IEC			synthetic material, the
61000-4-2			relative humidity should be
			at least 30 %. If ESD
			interfere with the operation
			of equipment, counter
			measurements such as wrist
			strap, grounding shall be
			considered.
Electrical	± 2 kV for power	± 2 kV for	Mains power quality should
fast	supply lines	power supply	be that of a typical
transient/bur		lines	commercial or hospital
st			environment.
IEC			
61000-4-4			
Surge	±1 kV differential	\pm 1 kV	Mains power quality should
IEC	mode	differential	be that of a typical
61000-4-5		mode	commercial or hospital
	±2 kV common		environment.
	mode	\pm 2 kV	
		common	
		mode	
Voltage dips,	0 % UT	0 % UT	Mains power quality should
	(100 % dip in UT)	(100 % dip in	ivianis power quanty snound

short interruptions and voltage variations on power supply input lines IEC 61000-4-11	for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300 cycles	UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300	be that of a typical commercial or hospital environment. If the user of the H3 requires continued operation during power mains interruptions, it is recommended that the H3 be powered from an uninterruptible power supply or a battery.
		cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is	the a.c. mains voltage	prior to application	on of the test level.

Table 3

declaration - electromagnetic immunity

H3 is intended for use in the electromagnetic environment specified below. The customer or the user of H3 should assure that it is used in such an environment.

Immunity	IEC 60601	Compliance	Electromagnetic
test	test level	level	environment - guidance
Conducted	3 V	3 V	Portable and mobile RF
RF	0.15 MHz to	0.15 MHz to	communications equipment should
IEC	80 MHz	80 MHz	be used no closer to any part of H3,
61000-4-6	(6V in ISM and amateur radio bands between 0.15MHz and 80MHz)	(6V in ISM and amateur radio bands between 0.15MHz and 80MHz)	than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 150 KHz to 80 MHz

Radiated	3V/m	3V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800
RF	80 MHz to		
IEC	2.7 GHz		MHz
61000-4-3			$d = 2.3\sqrt{P}$ 800 MHz to 2.7
			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:
			(((0)))
			0-0

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 whichH3 is used exceeds the applicable RF compliance level above, H3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating H3.
- b Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and H3

H3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of H3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and H3, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation dista	nce according to freque	ency of transmitter
output power of	-	m	•
transmitter	0.15 MHz to 80	80 MHz to 800	800 MHz to 2.7
W	MHz	MHz	GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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 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.

Table 5

declaration - IMMUNITY to proximity fields from RF wireless communications equipment

H3 is intended for use in an electromagnetic environment in which RF wireless communications equipment are controlled.

Immunit	ations equipi	IEC60601 t			Complia	Electromagne
y test	Test frequency	Modulat ion	Maxim um power	Immuni ty level	nce level	tic environment - guidance
Radiated	385 MHz	**Pulse	1.8W	27 V/m	27 V/m	
RF		Modulat				
IEC		ion:				
61000-4-		18Hz				
3	450 MHz	*FM+	2 W	28 V/m	28 V/m	
		5Hz				
		deviatio				
		n: 1kHz				
		sine				
	710 MHz	**Pulse	0.2 W	9 V/m	9 V/m	
	745 MHz	Modulat				
	780 MHz	ion:				
		217Hz				
	810 MHz	**Pulse	2 W	28 V/m	28 V/m	
	870 MHz	Modulat				
	930 MHz	ion:				
		18Hz				
	1720 MHz	**Pulse	2 W	28 V/m	28 V/m	
	1845 MHz	Modulat				
	1970 MHz	ion:				
		217Hz				

2450 MHz	**Pulse	2 W	28 V/m	28 V/m
	Modulat			
	ion:			
	217Hz			
5240 MHz	**Pulse	0.2 W	9 V/m	9 V/m
5500 MHz	Modulat			
5785 MHz	ion:			
	217Hz			

Note \ast - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.