

# LeECG & NeoECG Series Electrocardiograph

# Service Manual

# I Foreword

### Declaration

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### Description

This manual details the disassembly, safety, maintenance and common troubleshooting of LeECG & NeoECG Series Electrocardiograph. When using this service manual, please refer to the operator's manual for this product so that maintenance personnel can quickly eliminate common faults and use and maintain this product more efficiently.

This manual is intended for use only by authorized qualified service personnel.

Please read through the contents of this manual carefully to perform maintenance correctly. Please keep this manual in good condition after reading, so that it can be referred to at any time as needed.

### References

Operator's Manual of LeECG & NeoECG Series Electrocardiograph

# 11 Manufacturer Liability

Carewell assumes responsibility for the safety, reliability, and performance of the instrument in the event that:

- Assembly operations, expansions, re-adjustments, improvements and repairs of this device are performed by personnel authorized by Carewell;
- The electrical installation of the relevant room complies with the applicable national and local requirements;
- The device is used in accordance with the instructions in this manual.

Carewell is not responsible for direct, indirect or consequential damage or delays resulting from the following:

- the device is disassembled, stretched and re-adjusted;
- maintenance or modification of the device is conducted by unauthorized personnel;
- subsequent damage caused by improper use or maintenance;
- replacement or removal of serial number label and manufacture label.
- mis-operation caused by the neglect to the instructions in this manual.

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# Chapter 1 Safety

### 1.1 Safety Information

The following symbols are used in this manual to indicate hazards or information that requires special attention.

# \land Danger

A warning that an emergency hazard, if not avoided, could result in death, serious personal injury, or property damage.

# A warning

Potential hazards or unsafe service procedures not avoided could result in death, serious personal injury, product damage, or property damage.



Unsafe service operations not avoided may result in minor injuries, product failure, or property damage.

# Note

Important precautions, instructions provided and explanations to better repair this product must be followed.

#### 1.1.1 Danger

This manual does not address information and reminders about hazards.

### 1.1.2 Warning

# A warning

Do not open the case of the device while the power is connected.

# A warning

This device must be installed by qualified maintenance engineers.

# A Warning

Only qualified service personnel authorized by the company should disassemble this device.

# A warning

Remove batteries before disassembling this device.

# A Warning

This device must not be deformed or altered in any way.

# A warning

Maintenance and repair of device must be performed by professional personnel.

# \land Warning

When the device and its accessories (especially batteries) are disposed of, it is necessary to observe the relevant local and hospital waste disposal system regulations.

### 1.1.3 Caution

# A Caution

During maintenance, do not allow the device to be dropped or exposed to other mechanical damage such as impact or strong oscillation.

# A Caution

Improper servicing can damage the device. Service personnel must perform service according to the instructions in the service manual and perform adequate checks after service.

### 1.1.4 Note

# Note

Refer to the Operator's Manual for detailed instructions and other information on the device.

# Note

In case of device failure, it is recommended to immediately contact the after-sales service department of Carewell for consultation.

	MDD 93/42/EEC	Medical Device Directive
	IEC 60601-1: 2005+A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Standards	IEC 60601-2-25: 2011	Medical electrical equipment – Part 2–25: Particular requirements for the safety of electrocardiographs
	IEC 60601-1-2: 2014	Medical electrical equipment – Part 1–2: General requirements for basic safety and essential

# 1.2 Safety Specifications

		performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
	Anti electric-shock type:	Device: Class II with internal power supply Device equipped with recorder base: Class I with internal power supply
	Anti electric-shock degree:	Defibrillation proof Type CF applied part
Classifications	Degree of protection against harmful ingress of water:	7" device: IPX2 10.1" device: IPX0
	Installation and use:	Portable, not permanent installation device
	Working mode:	Continuous operation
	EMC:	Group I, Class B
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas

# 1.3 Symbol description

Symbol	Description	Symbol	Description
<b>I</b> €	Type CF defibrillation-proof applied part	Ċ	Power On/Off
♦€♦	Polarity of d.c. power connector	TYPE-C	USB connector
	Direct current indicator	<u>-</u> +	Battery indicator
$\sim$	Alternating current indicator	5	Print ready indicator
•	USB connector	1 <i>00-</i> 240V~	Power connector of recorder base
格	Network connector	$\triangleleft$	Equipotentiality
	For indoor use only		Class II equipment
	Manufacturer	$\sim$	Date of manufacture
<b>C€</b> 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.	EC REP	Authorised representative in the European Community

Symbol	Description	Symbol	Description
SN	Serial number	(((•)))	Non-ionizing electromagnetic radiation
$\triangle$	Caution! Consult accompanying documents	X	Dispose of in accordance to your country's requirements
	General warning sign (Background: yellow; Symbol and line: black)	<b>3</b>	Refer to Operator's Manual (Background: blue; Symbol: white)
IPX2	Degree of protection against harmful ingress of water	UK RP	UK Responsible Person

### Chapter 2 Product Introduction

### 2.1 Product Summary

### Product name: Electrocardiograph

Product model:

7-inch (7") screen model:	NeoECG S120, LeECG OS12
10.1-inch (10.1") screen	NeoECG T120, NeoECG T180,
model:	LEECG OT12

**Note:** The LeECG & NeoECG Series electrocardiographs include the above 5 models. The content in this manual, unless otherwise specified, is considered common to all models.

### Product description:

The electrocardiographs are divided into two screen sizes: 7" and 10.1". The 10.1" screen model device can be equipped with a removable recorder base. The electrocardiograph (hereinafter referred to as the "device") and the recorder base adopts a split design.

The device is intended to be used in medical institutions to acquire resting ECG signals from adult and pediatric patients through body surface with ECG electrodes, and analyze the ECG data for clinical diagnosis and research.

The device can print ECG reports through an external printer or an optional thermal recorder. It can be powered by an external DC power supply or a built-in rechargeable lithium battery, or a recorder base. It can transmit ECG data via a wired network, Wi-Fi or mobile network.

### Model difference:

The 7" screen devices all have the same electrical and structural composition of 12-lead synchronous acquisition board, the only difference is the housing color (black or white).

The 10.1" screen devices come in either an 18-lead simultaneous acquisition board or one with 12-lead. Electrical and structural composition of 18-lead synchronous acquisition board is different from that only supports 12-lead. It offers different ECG analysis functions and housing color (black or white).

Model	9-lead and 12-lead Synchronous Acquisition	15-lead and 18-lead Synchronous Acquisition	Screen Size & Device Color
NeoECG			7" Waita
S120		NA	7 WHILE
LeECG			7" block
0S12		NA	7 DIUCK
NeoECG			
T120*		NA	10.1"
NeoECG			white
T180			
LeECG			101" block
OT12			IU.I DIACK

Note

• indicates "default configuration", and N/A indicates "not applicable".

### 2.2 Product View

### 2.2.1 7" Device



No.	Name
1	Patient cable connector
2	Battery compartment
3	DC power supply connector, USB connector
4	Power-on indicator, DC power indicator, Battery indicator
5	Power switch key

**Note:** For the functions and usage of keys and connectors, see the Operator's Manual.

2.2.2 10.1" Device



No.	Name
1	DC power supply connector
2	Patient cable connector
3	Battery compartment
4	Camera
5	USB connector
6	Network connector

No.	Name
1	DC power supply connector
2	Patient cable connector
3	Battery compartment
7	Power switch key

### 2.2.3 Recorder Base







No.	Name
1	AC power socket
2	Equipotential grounding terminal
3	Battery compartment
4	Paper compartment cover open button

5	Device lock
6	Device connector
7	Recorder switch

# Chapter 3 Parts List

This chapter describes the device assembly and recorder base assembly.

Please consult Carewell for prices of all components.

### 3.1 7" Device



No.	Part Name	Material No.
1	Touch screen	SZ09.23300111
2	TP foam gum	SZ09.12300398
3	Smart-ECG 7-inch front case	SZ09.12300376
4	Smart-ECG 7-inch decorative lenses	SZ09.12300393
5	Smart-ECG 7-inch button	SZ09.12300386
6	Smart–ECG 7–inch button holder	SZ09.12300380
7	Adhesive for decorative parts	SZ09.12300399
8	Smart-ECG 7-inch acquisition board waterproof ring	SZ09.12300390
9	Smart-ECG 7-inch light sensor silicone sleeve	SZ09.12300392-01
10	Smart-ECG 7-inch light sensor FPC	SZ09.15300072-01
11	Smart-ECG 7-inch mic1	SZ09.11500015
12	Smart-ECG 7-inch mic	SZ09.11500014
13	PCBA of 7-inch acquisition board of Portable ECG Tablet (debugged)	SZ09.27300170
14	PCBA of 7-inch main control board of Portable ECG Tablet	SZ09.27300167
15	Smart-ECG 7-inch button silicone	SZ09.12300391-01
16	Smart-ECG 7-inch button – Master FPC	SZ09.15300073-01

No.	Part Name	Material No.
17	PCBA for 7-inch keypad of Portable ECG Tablet	SZ09.27300173
18	Smart-ECG 7-inch USB plug	SZ09.12300389-01
19	Smart-ECG 7-inch light transmitting column	SZ09.12300387-01
20	Smart-ECG 7-inch loudspeaker support lower cover	SZ09.12300382-01
21	Smart–ECG 7–inch loudspeaker	SZ09.11500013
22	Smart-ECG 7-inch loudspeaker support upper cover	SZ09.12300381-01
23	Loudspeaker waterproof sound transmission net	SZ09.12300401-01
24	Smart-ECG 7-inch battery compartment hardware	SZ09.13300207-01
25	Smart-ECG 7-inch flash lamp lens	SZ09.12300388-01
26	Camera lens back adhesive	SZ09.12300400-01
27	Smart–ECG 7–inch camera lens	SZ09.12300394-01
28	Smart-ECG 7-inch battery snap cover	SZ09.12300384-01
29	Smart-ECG 7-inch battery snap	SZ09.12300383-01
30	Smart-ECG 7-inch battery cover button	SZ09.12300385-01
31	Smart-ECG 7-inch rear housing	SZ09.12300377-01

No.	Part Name	Material No.
32	Lithium battery	SZ09.23300110
33	Smart-ECG 7-inch battery inner cover	SZ09.12300379-01
34	Smart–ECG 7–inch battery cover	SZ09.12300378-01



No.	Part name	Material No.
1	Touch screen	SZ09.23300112
2	Smart-ECG 10-inch display screen FPC	SZ09.15300075-01
3	TP foam gum	SZ09.12300447-01
4	Smart–ECG 10–inch front housing	SZ09.12300430-01
5	Smart-ECG 10-inch button spring	SZ09.13300222-01
6	Smart–ECG 10–inch button position	SZ09.12300433-01
7	Adhesive for decorative parts	SZ09.12300448-01
8	Smart-ECG 10 inch button	SZ09.12300437-01
9	Smart-ECG 10-inch decorative lenses	SZ09.12300439-01
10	Smart-ECG 7-inch light sensor silicone sleeve	SZ09.12300392-01
11	Smart-ECG 7-inch light sensor FPC	SZ09.15300072-01
12	Smart-ECG 10" shaft cover	SZ09.12300441-01
13	Smart-ECG 10-inch handle shaft	SZ09.13300225-01
14	PCBA of 10-inch main control board of Portable ECG Tablet	SZ09.27300184
15	Smart–ECG 7–inch mic	SZ09.11500014
16	Smart–ECG 10–inch light transmitting column	SZ09.12300438-01

No.	Part name	Material No.
17	Smart-ECG 10-inch antenna support	SZ09.12300444-01
18	10–inch pogopin plate PCBA of Portable ECG Tablet	SZ09.27300187
19	Smart-ECG 10-inch magnet	SZ09.13300220-01
20	Smart-ECG 10-inch rear housing	SZ09.12300431-01
21	Smart–ECG 10–inch footpad	SZ09.12300443-01
22	Smart-ECG 10-inch battery cover snap	SZ09.12300435-01
23	Smart-ECG 10-inch battery cover snap spring	SZ09.13300221-01
24	Smart-ECG 10-inch battery cover button	SZ09.12300436-01
25	Smart-ECG 10-inch handle	SZ09.13300223-01
26	Smart-ECG 10-inch handle footpad	SZ09.12300442-01
27	Smart-ECG 10-inch handle iron sheet	SZ09.13300224-01
28	Lithium battery	SZ09.23300110
29	Smart–ECG 10–inch battery cover	SZ09.12300432-01
30	Smart-ECG 10-inch flash lamp holder	SZ09.12300445-01
31	Smart-ECG 10-inch camera FPC	SZ09.15300076-01

No.	Part name	Material No.
32	Smart-ECG 7-inch flash lamp lens	SZ09.12300388-01
33	Camera lens back adhesive	SZ09.12300449-01
34	Smart-ECG 10-inch camera lens	SZ09.12300440-01
35	Smart-ECG 7-inch mic1	SZ09.11500015
36	Smart-ECG 10-inch loudspeaker	SZ09.11500016
37	Smart-ECG 10-inch loudspeaker support	SZ09.12300434-01
38	10" 18D kit PCBA (debugged)	SZ09.27300186



No.	Part name	Material No.
1	Recorder base front housing	SZ09.12300414-01
2	Device's indicator board PCBA	SZ09.27300190
3	Recorder base light transmitting column	SZ09.12300424-01
4	Recorder base paper compartment cover open button	SZ09.12300420-01
5	Recorder base shaft	SZ09.13300216-01
6	Recorder base shaft rubber stopper	SZ09.12300425-01
7	Recorder base paper compartment cover	SZ09.12300418-01
8	Recorder base toggle	SZ09.12300421-01
9	Recorder base snap	SZ09.12300422-01
10	Paper shaft body	SZ09.12300198-01
11	1112L Paper shaft spring	SZ09.24300103
12	Paper shaft movable sleeve	SZ09.12300199-01
13	Paper axle bushing	SZ09.12300200-01
14	Equipotential binding post	SZ09.13300227
15	Integrated thermal print head	SZ09.23300105
16	Recorder base printer retention spacer	SZ09.13300219-01
17	Recorder base rear housing	SZ09.12300415-01
18	Device's keypad PCBA	SZ09.27300188

No.	Part name	Material No.
19	Recorder base button	SZ09.12300419-01
20	Recorder base rear cover decoration	SZ09.12300417-01
21	Lithium battery	SZ09.23300083
22	Recorder base battery cover	SZ09.12300416-01
23	Fan	SZ09.11520010
24	Recorder base footpad	SZ09.12300426-01
25	Recorder base main board support	SZ09.13300217-01
26	Power insulated fish paper	SZ09.12300428-01
27	Delta Power PCBA	SZ09.27300192
28	SMART-ECG print power board (debugged)	SZ09.27300191
29	Recorder base small plate cover plate	SZ09.12300423-01
30	Device's adapter board PCBA	SZ09.27300189
31	Smart-ECG 10-inch magnet	SZ09.13300220-01

### Chapter 4 Disassembly and Installation

### 4.1 Tool

For disassembling or replacing parts and installation, a Phillips screwdriver is required.

### 4.2 Device Disassembly

Please follow the following principles and methods to disassemble the device and recorder base:

- The structure of the device and its components must be clearly understood before disassembly so that it can be disassembled and repaired before reassembly.
- Generally, disassembly should be carried out in the opposite order of assembly.
- During disassembly, the loosening direction, thickness end and large/small head of parts should be clearly identified.
- The disassembled parts should be placed in sequence in a regular manner so as to avoid clutter and disorder.
- The disassembled parts should be connected together according to the original structure as much as possible (such as screws, washers, etc.) so as to avoid errors during assembly.

### 4.3 Installing the 7" Device

#### 4.3.1 Installation Process


### 4.3.2 Installing the Acquisition Board

 Put mic1 into the corresponding slot on the front housing. Thread the mic1 line between the two studs.



2. Install mic into the corresponding slot on the front housing.



3. Snap the shielding cover over the slot position on the acquisition board.



Note: The edges of the shielding cover must snap into place.

4. Attach the acquisition board waterproof ring to the acquisition board and insert the acquisition board connection cable into the acquisition board socket.



5. Snap the acquisition board into the corresponding position on the front housing and fix it with five M2 \* 5 pan head non-tapping screws without any adverse phenomena such as slipping or loosening.



# 4.3.3 Installing the Main Control Board

1. Pass the Wi-Fi antenna through the notch under the acquisition board and snap it into the corresponding interface mount on the main control board.



2. Snap the main control board into the corresponding position on the front housing, and fix it with 3 M1.4 \* 5 pan head non-tapping screws without any adverse phenomena such as slipping or loosening.



- 4.3.4 Installing the Keypad
- 1. Place the button silicone at the corresponding position on the front housing.



2. Position the light transmitting column on the front housing.



3. Snap the keypad into place on the front housing, making sure that the threaded hole is aligned with the position of the lower stud.



- 4.3.5 Installing the Loudspeaker Support Assembly
- Install the loudspeaker waterproof sound transmission net to the corresponding position of the loudspeaker support upper cover.



2. Install the loudspeaker into the corresponding slot on the upper cover of the support, with the loudspeaker line leading out from the notch nearby.



3. Install the lower cover of the loudspeaker support to the upper cover of the loudspeaker support.



4. Solder the loudspeaker line to the corresponding position on the keypad, and then place the loudspeaker support assembly on the keypad, making sure that the loudspeaker support holes are aligned with the screw holes on the keypad, then fix it with two M1.4 \* 5 pan head non-tapping screws without any adverse phenomena such as slipping or loosening.



**Note:** The positive and negative electrodes of the loudspeaker line must be soldered correctly.

4.3.6 Installing the Front / Rear Housings Together Align the rear housing with the front housing and snap them together, and then lock the screws at the corresponding screw holes on the rear housing.



**Note:** There should be no gaps anywhere, and the snaps should be snapped properly into place.

4.3.7 Installing the Battery

Install the battery into the battery compartment.



4.3.8 Installing the Battery Inner Cover

Snap the battery inner cover onto the rear housing.

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- 4.3.9 Installing the Battery Cover
- 1. Align the battery cover with the rear housing and push the battery cover to the rear housing.



2. Flick the cover lock switch up to lock the battery cover.



# 4.4 Installing the 10.1" Device

#### 4.4.1 Installation Process





Note: The edges of the shielding cover must snap into place.

# 4.4.3 Installing the Buttons

1. Install the button spring in place into the spring slot.



2. Attach the double-sided glue for the button to the button position and stick the buttons to the button position.





3. Install the button holder into the button slot, and press gently so that it clicks into place.



**Note:** The snap on the back of the button holder should be attached onto the front housing.

4.4.4 Installing the Acquisition Board

1. Plug the acquisition board connection cable into the socket on the acquisition board.



2. Snap the acquisition board into the corresponding position on the front housing and fix it with five M2 \* 5 pan head non-tapping screws without any adverse phenomena such as slipping or loosening.



# 4.4.5 Installing the Light Sensor

1. Install the light sensor silicone sleeve on the light sensor head.



2. Attach the light sensor to the corresponding position on the front housing and glue it in place.



# 4.4.6 Installing the Display Screen FPC and mic

 Connect the display screen FPC (Flexible Printed Circuit Board) to the corresponding socket and snap it in place.



2. Install the mic cable to the corresponding position and fix it with silicone.



# 4.4.7 Installing the Main Control Board

- Connect the other end of the display screen FPC to the corresponding socket on the main control board and snap it in place.
- 2. Snap the main control board into the corresponding position on the front housing, and use three M3 \* 5 pan head non-tapping screws to lock it in place without any adverse phenomena such as slipping or loosening.



**Note:** The light sensor head FPC cannot be squashed under the main control board.

- 4.4.8 Installing the Loudspeaker
- Attach the loudspeaker anti-dust mesh to the loudspeaker and remove the protective paper from the surface.



2. Apply the loudspeaker sealing foam rubber to the loudspeaker holder and remove the protective paper from the surface.



3. Install the loudspeaker in place on the front housing.



**Note 1**: The loudspeaker should be fixed in the slot position of the loudspeaker, and the top of the loudspeaker should not exceed the edges of the sound chamber.

**Note 2**: The loudspeaker cable should be stuck in the outlet hole.

4. Install the loudspeaker holder into the corresponding position in the sound chamber.



**Note**: The foam on the loudspeaker holder must stick to the surrounding edge of the sound chamber.

- 4.4.9 Connecting and Sorting Cables
- 1. Connect all the cables to their corresponding positions, as shown in the following figure.
- 2. Secure the cables in place with acetic acid sticker at the locations shown below.



Note: The cables should not become loose.

4.4.10 Installing the Front / Rear Housings Together

1. Attach the other end of the pogopin connection cable from the rear housing to the main control board.



2. Align the rear housing with the front housing and press gently to bring the front and rear housing together.



**Note**: There should be no gap around the closed housing, and the snaps should fit into place.

# 4.4.11 Installing the Battery

Align the battery and place it in the battery compartment with the electrodes facing downwards.



 Screw seven M<sup>3</sup> \* 5 and two M<sup>2</sup> \* 5 pan head non-tapping screws in place without adverse phenomena such as slipping or loosening.



**Note**: Those marked with red circles are M3 \* 5 pan head non-tapping screws, yellow circles are M2 \* 5 pan head non-tapping screws.

2. Align the left side snap of the battery cover with the rear housing, push the battery cover to the left to push the snap into the rear housing, push the battery cover opening switch to the right, gently press the battery cover, and then loosen the battery cover switch to make the battery cover fit in place. Install foot pads at the four screw holes on the periphery.



# 4.5 Installing the Recorder Base

#### 4.5.1 Installation Process





2. Install the fan to the appropriate position on the main control board support and secure it with four M3 \* 14 pan head non-tapping screws.



3. Plug the fan cable through the slot in the main holder into the J4 socket on the printing power board, connect the AC-DC connection cable to the power board and the printing power board, and plug the keypad cable into the J12 socket on the printing power board; snap the magnetic loop into the printer cable, and then plug the printer cable into the J10 socket on the printing power board; and plug the POGO connection cable into the J9 socket on the printing power board.



4.5.3 Installing the AC Socket Connection Cable

 Install the AC socket in the appropriate position on the front housing and secure it with two M3 \* 5 pan head non-tapping screws.



**Note:** Install the AC socket with triangular pins facing downwards.

2. Place the terminal of the short green-yellow cable of the AC socket connection cables onto the equipotential terminal and fix it with one M6 nut.



- 4.5.4 Installing the Thermal Print Head
- 1. Install the integrated thermal print head into the appropriate position on the front housing, and pay attention not to install it in the opposite direction.



2. Flip the front housing over and secure the integrated thermal print head with three M3 \* 5 semi-adhesive containing pan head non-tapping screws.



3. Flip the front housing back, install the paper compartment cover open button to the left side of the front housing, align the hole of the paper compartment cover open button with the metal post of the integrated thermal print head, then push in the paper compartment cover open button and manually twist one M1.4 \* 5 pan head non-tapping screw in place.



4. Fix one printer fixing spacer to the corresponding position on the left side of the front housing with M3 \* 5 semi-adhesive-containing pan head non-tapping screws, fix the grounding post connection cable between the printer fixing spacer and the screw, fix another printer fixing spacer to the corresponding position on the right side of the front housing with M3 \* 5 semi-adhesive-containing pan head non-tapping screw, and lock the long yellow-green cable of the AC socket connection cables between the printer fixing spacer and the screw.



**Note:** Pay attention to the installation of the printer fixing spacer to ensure that the bent side is facing downwards; the fixing spacer should be pressed in place on the metal housing of the thermal print head.

# 4.5.5 Installing the Paper Compartment Cover

1. Insert a shaft into the right end of the printer shaft. Note that the grooved end of the shaft faces outward.



2. Align the shaft with the shaft hole at the right end of the front housing, and install the paper compartment cover on the front housing assembly.



3. Hold the groove of the other shaft with tweezers, and push the shaft in after aligning it with the shaft hole at the left end of the front housing.



4. Install the rubber plug of the shaft into the corresponding position of the front housing assembly, and then close the paper compartment cover. Note that the stepped end of the rubber plug of the shaft should be facing down.



- 4.5.6 Installing the Front / Rear Housings Together
- Plug the button connection cable from the front housing assembly into the keypad from the rear housing assembly.



2. Install the front and rear housings together.



# 4.5.7 Fixing the Rear Housing

Place the bottom of the recorder base upward, lock six M1.4 \* 5 pan head non-tapping screws at the yellow circle position, and tighten them with a screwdriver by hand; lock four M3 \* 5 semi-adhesive-containing pan head non-tapping screws at the blue circle position, and five M3 \* 10 pan head non-tapping screws at the red circle position.



**Note:** The M1.4 \* 5 pan head non-tapping screws shall be twisted manually with a screwdriver.

### 4.5.8 Installing the Battery

Install the lithium battery into the battery compartment, plug the battery cable into the battery compartment connector and connect the battery cable.



4.5.9 Installing the Battery Cover

Install the battery cover, fix it with two  $M3 \times 10$  pan head non-tapping screws, and lock the screws without any adverse phenomena such as slipping or loosening.



# 4.6 Inspection After Disassembly

After disassembly and reinstallation, the device should be thoroughly inspected.

### 4.6.1 Visual Inspection

There should be no physical damage to the device housing, display, buttons, power cables, the recorder base and accessories. Check that the device and the recorder base are visually clean and there are no missing parts. Check that all screws are tightened. Check for any unusual sound when shaking the device or the recorder base to prevent foreign matters from falling inside them. Check the labels (e.g., main unit label, warning labels.) provided by the manufacturer or the healthcare facility are present and legible.

#### 4.6.2 Power On Test

The power-on test is conducted to confirm whether the indicators can be lit up properly.

After installing the battery in the device or connecting the DC power supply, check whether the battery status indicator of the device is always on and whether the DC power indicator is always on.

After installing the battery in the recorder base or connecting the AC power supply, check whether the battery status indicator of the recorder base is always on and whether the AC power indicator is always on.

#### 4.6.3 Power On/Off Check

Press the power switch key of the device, the power-on indicator lights up, and the display screen turns on, then the device enters the start-up mode; after entering the main screen, press and hold the power switch key to turn off the device. The device should be able to be shut down normally, at the same time the power-on indicator goes out. Press the power switch key of the recorder base to turn on the thermal recorder, the power-on indicator of the recorder base lights up. Press the power switch again to turn off the recorder base, and the power-on indicator goes out.

### 4.6.4 Operation Check

After the device starts up and enters the main screen, check whether the screen display is normal: the text and symbols should be clear, and the LCD display content should be complete and clear; check whether the touch screen works normally and whether the screen response is normal during operation.

#### 4.6.5 Function Check

Insert the ECG cable plug into the patient cable connector of the device, tighten the knobs on both sides of the ECG cable plug, fix the ECG cable to the device, and connect all electrode plugs of the ECG cable to the signal end of the simulator. After starting up the device and the recorder base, carefully check whether all functions can be normally used, whether the waveform display is normal, and whether the device can display correctly after adjusting the relevant parameters; install the recording paper or connect the external printer, and test whether the ECG report can be normally printed. If necessary, it is recommended to conduct comprehensive performance and safety tests on the device and the recorder base again.

# Chapter 5 Hardware System

This chapter introduces the hardware system of the device, including the function of each circuit module and the overall structure diagram.

# 5.1 Overview

The hardware system of the 7" model device includes the ECG acquisition board, main control board, adapter board and 12V power adapter.

The hardware system of the 10.1" model device includes the ECG acquisition board, main control board, 12V power adapter, POGOPIN adapter board and recorder base.

# 5.2 ECG Acquisition Board

The ECG acquisition board is used to acquire ECG signals from human body and amplify the acquired ECG signals after smoothing and clamping, then perform digital-to-analog conversion of the amplified ECG signals, and then transmit them to the chip of the main control board for data processing.

The 7" model has a 12-lead configuration for the ECG acquisition board.

The 10.1" model has two kinds of lead configurations: 12-lead and 18-lead.
#### 5.3 Main Control Board

The main control board is used to process the ECG signal acquired by the ECG acquisition board and display the processed data as waveform on the display screen. The main control board also realizes a series of functions such as controlling peripherals, on/off management, charging management, networking, and indicator display.

### 5.4 Adapter Board

The adapter board of the 7" model device is mainly used to transfer signals from the input power supply, indicators, buttons etc.

The pogopin adapter board of the 10.1" model device is mainly used to connect the device to the recorder base for communication between them, and to charge the device via the recorder base.

#### 5.5 Power Adapter

The power adapter of the device converts 220V AC from the public mains power supply into 12V DC for use with the device.



#### 5.6 Hardware Architecture

Structure block diagram of 7" model device



Structure block diagram of 10.1" model device (with recorder base)

# Chapter 6 Upgrade

## 6.1 APP Upgrade

Currently, USB upgrade is supported. Create an Upgrade directory under the USB flash disk directory and put in the installation package (apk starting with SmartEcg) that needs to be upgraded.

## 6.2 System Software Upgrade

Follow the following steps to upgrade the system software:

 Double-click the DriverInstall.exe file in the Driver\_Auto\_Installer\_EXE\_v5.1524.03.zip folder to install the driver, and then restart the computer after the installation.

*Note*: If the driver is already installed, proceed directly to the next step.

2. Open the upgrade tool.

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#### 3. Click "Scatter-loading".

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- 4. Select "\*\_scatter.txt" file in the software package and then click "Open".
- 5. As for the upgrade mode, select "Firmware Upgrade", "Download Only", or "Format All + Download".



6. Click the "Download" button.



7. Turn off the device, connect one end of the USB cable to the device and plug the other end into the computer and wait for the upgrade to complete.

# Chapter 7 Troubleshooting

For more common faults, refer to the following table for troubleshooting. If the solution below still fails to recover, please contact our after-sale technical support personnel.

No.	Troubles	Possible Causes or Solutions
1	Startup screen crash	Press the power switch key and wait for the device to run internally. Do not turn on or turn off the device frequently, otherwise the chip will not reset normally.
2	Out of paper prompt when paper is available	Check that the recording paper is not covering the inner paper check switch, or that the spacing is too wide. Check for changes in the output of the receiver tube of the paper check switch.
3	Uneven paper travel, no paper travel, or uncontrolled speed	Check for mechanical faults for tight gears or inflexible rotation. Check that the recording paper is correctly placed and that the print head is not too tight. Check if the control drive chip is damaged. The step motor itself is damaged.

No.	Troubles	Possible Causes or Solutions
4	Paper travels fine but cannot print	Check the circuit of the print head on the control board. Check whether the socket has poor contact.
5	Printing not legible	Check whether the recording paper is correctly installed. Check the recording paper for moisture. If the thermal print head is too dirty, wipe it with a cotton cloth dampened with alcohol.
6	Printed content is missing or displayed intermittently.	The thermal print head is aged or burned out by overheating.
7	The device cannot be started up using only the internal battery.	The battery voltage is too low, charge the battery. If the battery voltage is normal, check the DC circuit in the power supply part.
8	The battery ran out quickly	Charge the battery before first use, self-discharge of the battery will reduce the power. If the battery voltage is too low, the automatic protection works, it should be charged immediately. The battery capacity may be

No.	Troubles	Possible Causes or Solutions
		insufficient. It is recommended to replace it with a new one.
9	The device shuts down soon after starting up when powered by the battery.	If the battery voltage is too low, the automatic protection will work and the battery should be charged as soon as possible.
10	Date/time will be in error	Check that the quartz crystal is normal. Check that the button cell voltage on the main board is greater than 2V.
11	Power switch key failure	Check the power switch key and that the on/off status is normal. Check if the battery voltage is too low.
12	Liquid crystal display is defective	The LCD module itself is damaged. Poor contact of the display screen FPC.
13	LCD display unclear or no display	LCD backlight abnormal. LCD power supply voltage is abnormal.
14	Some lead without waveform printout	If you acquire the ECG data immediately after the leadwires are applied to the patient, the

No.	Troubles	Possible Causes or Solutions
		ECG traces may not display because the ADS is not stable yet. Normally it is necessary to wait for the waveform of each lead to be stable if all leads are in good contact before ECG measurement.
15	Vertical broken track of printed waveform	This is usually caused by dirt on the print head surface and the print head needs to be cleaned. If this phenomenon persists after cleaning, it may be related to some heating units of the thermal print head that has been damaged. Please contact Customer Service Department of Carewell for a replacement.
16	AC interference. Symptom: There is an overlap of 50Hz sine wave with certain amplitude and regularity on the ECG traces, and obvious jitter appears on the ECG baseline.	<ul> <li>Check the following aspects of the device for solving problems:</li> <li>The device is properly grounded.</li> <li>The electrodes and leadwires are correctly connected.</li> <li>Enough conductive paste is applied to the electrodes and the patient's skin.</li> <li>Patient bed is properly</li> </ul>

No.	Troubles	Possible Causes or Solutions
		<ul> <li>grounded.</li> <li>Patient not come into contact with conducting objects such as metal parts of the patient bed.</li> <li>Nobody is touching the patient.</li> <li>There is no powerful electrical equipment operating nearby, such as X-ray machines or ultrasonic instruments.</li> <li>The patient is not wearing glass or diamond ornaments.</li> <li>AC filter frequency is properly set.</li> <li>If the interference cannot be cleared after the above measures, use an AC filter, and the recorded waveform is slightly attenuated.</li> </ul>
17	EMG interference. Symptom: The ECG has irregular fluctuation while the baseline demonstrates no change.	<ul> <li>Check the following aspects of the device for solving problems:</li> <li>The room is uncomfortable?</li> <li>The patient is nervous or feels cold?</li> <li>The bed is too narrow?</li> </ul>

No.	Troubles	Possible Causes or Solutions
		<ul> <li>The patient is talking?</li> <li>The limb electrode clamps are attached too tightly?</li> <li>If the interference cannot be cleared after the above measures, use an EMG filter, and the recorded waveform is slightly attenuated.</li> </ul>
18	The printed ECG waveform is out of the grid area of the printing paper.	It is caused by the great fluctuation of the waveform. Set the sensitivity to "Auto". The device will automatically adjust the sensitivity according to the amplitude of the ECG signal.
19	Baseline drift. Symptom: The printed ECG baseline irregularly moves up and down.	<ul> <li>Check the following aspects of the device for solving problems:</li> <li>The electrodes are firmly attached?</li> <li>The lead wires are properly connected to the electrodes?</li> <li>The electrodes and the patient's skin are clean?</li> <li>Whether enough conductive paste is applied to the electrodes and the patient's skin.</li> </ul>

No.	Troubles	Possible Causes or Solutions
		<ul> <li>During the recording, the patient moves or breathes.</li> <li>Mixed use of old and new electrodes.</li> </ul>
		If the interference cannot be cleared after the above measures, use an ADS filter.

## Chapter 8 Care and Maintenance

For the safety of the operator and the patient, as well as for the proper functioning of the device, it is necessary to pay attention to the care and maintenance of the product. The device is operated by a multifunctional capacitive touch screen, retaining only a few essential keys. The software/hardware interfaces have multiple functions. In order to make the most of the device's performance, carefully read the accompanying Operator's Manual before use. Because this device uses surface mount device (SMD) technology and large scale programmable logic units, the integration is high, the component density is large, the software/hardware functions are complex, and it may not be easy to identify faults in case of problems. When you encounter complex faults, it is necessary to use special detection instruments for debugging, or immediately contact the after-sales service personnel of the manufacturer. Do not disassemble and repair yourself to avoid making the faults worse.

In order to ensure that the performance of the device meets the requirements, regular maintenance and servicing of the device is required. Refer to the table below for maintenance.

Maintenance item	Maintenance frequency	Maintenance method
Touch screen	On demand	Clean according to the cleaning agent recommended in the

Maintenance item	Maintenance frequency	Maintenance method
		Operator's Manual.
Patient cable Chest electrodes Limb electrodes	On demand	For the cleaning, care, and maintenance of the patient cable and electrodes, refer to their instructions for use supplied with the accessories. Check the lead wires periodically for integrity and conductivity. If damage or deterioration is observed, replace it with a new one. After long-term use, if the surface of electrodes become oxidized and discolored, the electrodes should be replaced.
Battery	On demand	When the device is not used for a long time (more than 1 month), take out the battery from the device and store it in a cool dry place. To prevent the battery from becoming unusable due to over-discharge, charge the battery at least once every 6 months if it has not been used for a long time. If the battery is fully charged but a large amount of power has been consumed after only a few ECGs have been taken, consider replacing the

Maintenance item	Maintenance frequency	Maintenance method
		battery with a new one of the same model. When the battery reaches the service life, or it is found that the battery has an odor or leakage, replace it promptly with a new battery of the same model.
Recorder print head	1 time per month	Perform cleaning as described in the Operator's Manual.
Housings of the device and recorder base	1 time per month	Perform cleaning as described in the Operator's Manual.