CE 0197

CP Series Digital Holter Analysis system

User's Manual

Suzhou Beneware Medical Equipment Co., Ltd.

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BENEWARE

Revision History

Date	Version	Changes compared to previous issue
Aug. 2017	1.0	Base version

Statement

First of all, thank you for choosing this product. Before applying this instrument, please read this instruction manual carefully and make sure to observe safety precautions.

This manual is reference material for product operating, maintaining and repairing. Users should strictly observe its instructions, in case any loss be caused by incorrect installation or improper operation, Suzhou Beneware Medical Equipment Co., Ltd. (Beneware) will not shoulder any legal liability.

Suzhou Beneware Medical Equipment Co., Ltd. reserves revision right, updating right and final interpretation right of this manual.

Product Information

Product name : **CardioTrak Digital Holter Recorder**

Product type : CP-022, CP-025

Liability of the Manufacturer

Beneware is responsible for safety, reliability and performance of the instrument only under the following circumstances, namely: assembly operations, expansion, readjustment, improvement and maintenance are all conducted by personnel recognized by Beneware, electrical installation environment of corresponding rooms should be in accordance with national standards, and instruments are applied according to operating instructions.

If required by the user, Beneware will provide paid circuit diagram and other information to help the user resort to appropriate and qualified technical personnel to repair instrument parts provided by Beneware.

Contents

1 Brief Introduction

Ambulatory electrocardiogram (AECG) is a method to continuously record and analyze changes of human heart in active and static conditions for a long time. Holter is able to continuously record the whole process of electrocardiogram (ECG) activities for 24 hours, including ECG data in situations such as rest, activity, eating, work, study and sleep, and is able to find cardiac arrhythmia and myocardial ischemia that is out of normal ECG's reach. It is an important subjective evidence for clinical analysis of illness, determining diagnosis and judging healing effect.

The CP series digital Holter recorder is intended for patients（including infants weighing less than 10Kg）requiring ambulatory (Holter) monitoring. Such monitoring is most frequently used for the indications below:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Evaluation of patients for ST segment changes
- Evaluation of a patient's response after resuming occupational or recreational activities (for example, after myocardial infarction or cardiac surgery)
- Clinical and epidemiological research studies
- Evaluation of patients with pacemakers
- Reporting of time and frequency domain heart rate variability
- Reporting of QT interval
- Monitoring components

1.1 Functional Characteristics

The recorder has the following features:

- Mini-size and lightweight, easy to wear;
- 1-channel (CP-022), 1-channel/3-channel (CP-025) ECG record are available;
- Internal clock function supported;
- Up to 30 days long-term record supported;
- Built-in lithium battery can sustain at least 7 days continuous recording;
- Pacemaker pulse detection, accurately capture minor changes of signals;
- High capacity memory card storage, uncompressed synchronous recording.

Analysis software has the following features:

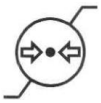
- International-advanced accuracy of analysis: detected by MIT-BIH and other authoritative databases;
- Fast analysis speed: parsing algorithm applies the advanced parallel analysis technique, significantly improve long range Holter data analysis speed;
- Flexible lead options: true three-channel intelligent analysis function, any one channel or two-channel could be analyzed independently. While the three channel are analyzed simultaneously, the channel with good signals is intelligently selected for the doctor to diagnose;
- Accurate template classification: apply the originally created MRC method to quickly and accurately classify about 100 thousand heart beats into several templates with different patterns, easy to quickly locate abnormal heart beat and improve analysis efficiency.
- Simple and efficient operation mode: batch editing method that is based on heart beat template, aided with plot, HR chart, event statistic of arrhythmia and other tools, the user could revise single or several heart beat or templates, add atrial fibrillation events and report forms, report and strips, as well as other operations quickly simply through limited mouse or keyboard operations;
- Accurate artifact identification: through the advanced Multi-RS artifact recognition algorithm, the program could effectively recognize artificial signals caused by electrode falling off, baseline drift, power frequency interference, electromyographical interference and so on, saving a lot tedious work and improving analysis speed;
- Complete intelligent analysis tool: except for the basic automatic detection and classification functions of the pacemaker, ventricular premature beat (VPB), atrial premature beat (APB), cardiac arrest, ST segment abnormal and other arrhythmia detection functions, the program also provides HRV time domain analysis, HRV frequency domain analysis, T wave alternans (TWA), heart rate turbulence (HRT) and automatic detection of atrial fibrillation, bringing significant convenience to doctors in their special medical record analysis and medical research;
- Rich configuration options: the program provides dozens of configuration options, the user could conveniently revise analysis parameters, report printing, channel data display, user interface and other configurations, as well as set single or multi channel arrhythmia analysis, flexibly set the analysis program;
- Friendly user interface: the user interface is based on the latest Ribbon style, which is able to respond to user's operation quickly so that the user could quickly position frequently used functions and also provides flexible interface configuration plan.

1.2 Safety Standard Requirements

- Safety category of this product is CF type applied part equipment of internal power supply, the ECG cable is the applied part.
- Power supply of this product is built-in rechargeable lithium battery.

1.3 Symbol Description

	Type CF applied part, suitable for direct cardiac application
	Refer to instruction manual/booklet
	WEEE information for the disposal or recycling of waste WEEE Check with your local Authority or retailer for recycling advice
	CE marking of conformity, and Notified Body Code
	Date of manufacture
	Manufacturer
	Serial number
	Batch code
	Catalogue number
	Model number
	Unique device identifier
	Medical device
	Date of manufacture; Country of manufacture

	Stacking limit by 2
	Authorised representative in the European Community
	Special cautious, one must refer to the instruction manual
IP67	N_1= 6 Dust-tight N_2= 7 Protected against the effects of temporary immersion in water
	Temperature limit (see Technical Specifications)
	Humidity limitation (see Technical Specifications)
	Atmospheric pressure limitation (see Technical Specifications)
	Fragile.
	Keep dry.
	Keep away from sunlight.
	This end up.

1.4 Environmental Requirements

Environmental test of the instrument should be in accordance with group II of climatical and mechanical environment tests of IEC 60601-1.

Please refer to "Appendix 1 Technical Specifications" for environmental requirements of operating, storage and transportation.

2 Application Cautions

This instrument can only be used by medical personnel with professional qualifications. For safe and effective use, and to avoid possible damages, please read the instruction manual before use, so as to get familiar with performance of the instrument and fully understand the correct operation method and cautions.

⚠ Caution ⚠:

This product is common equipment of inner power supply CF type application part, which is applicable to continuous operation and equipped with inner power supply, but can not be used in flammable and explosive environment, such as FLAMMABLE ANAESTHETIC MIXTURE WITH AIR and FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

⚠ Caution ⚠:

If the recoding time is shorter than the expected length, the user is advised to manually stop the recording operation; otherwise data in the latest 1 minutes will be missing.

⚠ Caution ⚠:

Only the specified ECG cable provided by the manufacture is applicable.

⚠ Caution ⚠:

Electrodes that are applicable to this product are to be used on body surface. Please correctively connect then while using. Application of other type Electrodes should be consulted with the relevant clinician.

⚠ Caution ⚠:

This product is directly applicable to the heart, but suitable electrodes should be used.

⚠ Caution ⚠:

This recorder could be used simultaneously with the pacemarker, no danger will occur.

⚠ Caution ⚠:

Before conducting defibrillation to patients, please firstly remove all electrodes of the ECG cable from the patient, to prevent defibrillation failure or damages to this product.

⚠ Caution ⚠:

Don't use in environment with explosive danger or contains anesthetic, volatile substance and other inflammable gas.

⚠ Caution ⚠:

When using this product, please avoid strong electromagnetic interference. Use mobile phone near this product may interfere with ECG records. In surrounding area of this product, there should be no high voltage cable, X-ray machine, ultrasonic instrument, electrotherapy machine, etc.

⚠ Caution ⚠:

Avoid contacting with water, don't use and store in places of abnormal temperature or humidity, poor ventilation, or with excessive dust or contain sulfur, saline and alkaline gases and chemical medicines.

⚠ Caution ⚠:

Disinfect the recorder and its accessories regularly with UV disinfection equipment.

⚠ Caution ⚠:

The operator should ensure safety operation of all parts, pay special attention to the LED indicator; in case accident occur, turn off the recorder and check it immediately.

⚠ Caution ⚠:

The recorder and its accessories should not be discarded casually when in discard processing, please let the qualified company or government department to handle after strict sterilization.

⚠ Caution ⚠:

No modification of this product is allowed.

⚠ Caution ⚠:

The PC or recharger connected to the recorder is required to meet the safety specifications prescribed by the standards EN60601-1:2005+A1:2012.

⚠ Caution ⚠:

Because of the risk of strangulation from the ECG or USB cable, the recorder may not be used for unattended children and nor for pets.

⚠ Caution ⚠:

The maximum temperature of the ECG cable is 46℃.

⚠ Caution ⚠:

The ECG cable may pose a risk of strangulation and asphyxiation. Do not allow children or pets to touch or play with the ECG cable that could cause strangulation.

⚠ Caution ⚠:

Please refrain from strenuous exercise while wearing the device, otherwise， it will affect ECG data acquisition.

⚠ Caution ⚠:

Please wait at least 4 hours before using after removing from minimum/maximum storage temperature/humidity.

⚠ Caution ⚠:

The ECG cable can be in contact with the human skin surface for 24 hours, Please note that may cause potential allergic reactions and Skin irritation due to prolonged exposure to ECG cable.

⚠ Caution ⚠:

Please refrain from strenuous exercise while wearing the device, otherwise， it will affect ECG data acquisition.

⚠ Caution ⚠:

Conductive parts of electrodes and associated connectors for CF applied parts, including neutral electrode, not contact other conductive parts including earth.

3 Structure Characteristics and Working Principle

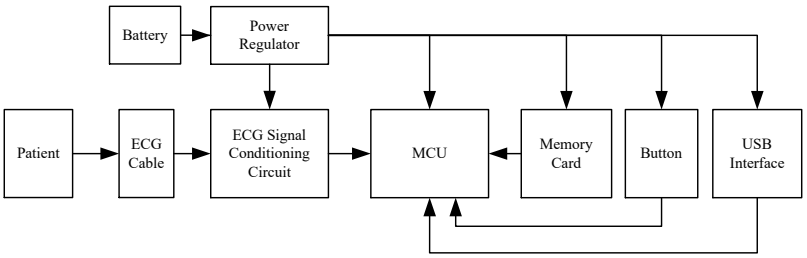
3.1 Electrical Schematic Diagram and Compendium of the Principle

3.1.1 Electrical Schematic Diagram and Parts List

Electrical schematic diagram and parts list is only for qualified maintenance station or personnel recognized by our company.

3.1.2 Compendium of the Principle

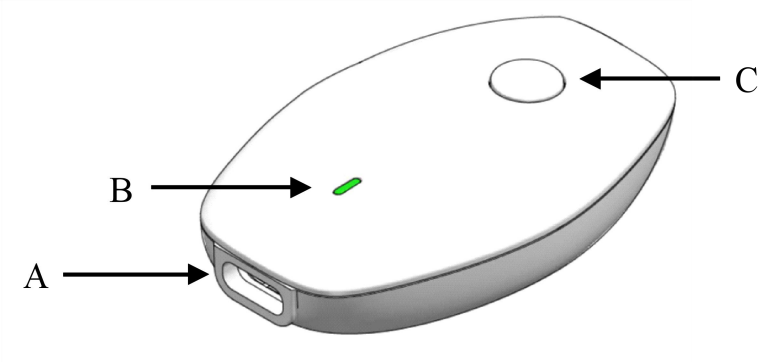
CP series digital Holter recorder includes ECG cable, ECG signal conditioning circuit, microprocessor (MCU), key, memory card, USB interface, battery and power regulator. The ECG cable is connected to ECG signal conditioning circuit, and the ECG signal conditioning circuit, key and memory card are connected to the MCU separately. Power regulator regulates battery power and supplies regulated power to the recorder. Body surface ECG potential is transferred to ECG signal conditioning circuit for amplification and filtering. The MCU samples output signals of ECG signal conditioning circuit, and stores them into the memory card after pre-processing.



Electrical Principle Block Diagram of the Recorder

3.2 Name and Function of Each Part

3.2.1 Structure Description of the Recorder



	Name	Instruction
A	Cable Connector	Used to connect ECG cable or USB cable
B	LED Indicator	Indicating the status of recorder
C	Button	Control button

3.2.2 Indicator Description and Function Summary

The statuses of the indicator are defined as followed:

Color	Status	Instruction
Green	Always Light	Ready for record
	Flashes every 4s	Recorder is now recording
	Flashes every 1s	Record ends
Orange	Always Light	Battery recharge finished
	Flashes every 1s	Battery low
	Flashes every 4s	Battery is recharging
Purple	Flashes every 2s	ECG signal abnormal
	Always Light	Memory error, unable to record
Blue	Always Light	Memory uninitialized
	Flashes every 1s	Data transmitting

3.3 Algorithms Instruction

3.3.1 Heart Rate Calculation

This product calculates the heart rate by using the analysis software installed in the computer. The heart rate shown in the analysis software is calculated by converting the average value between the current heartbeat's the first N and last N (the default N = 4) effective heartbeat in RR interval.

3.3.2 Pause Determination

This product determines a pause by using the analysis software installed in the computer. In the default settings, if two adjacent heartbeat RR interval ≥2.0s, it will be identified as a pause. The threshold parameter of pause time can be set via the computer software.

3.3.3 ST Segment Detection

This product detects ST segment by using the analysis software installed in the computer. Specific features are as follows:

The ST segment analysis is performed on all leads.

The operator can set detection criteria for ST segment shifts by setting the displacement parameter.

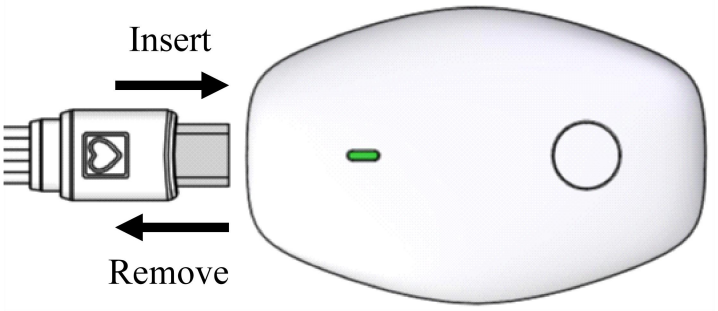
The numbers, types and durations of episodes are summarized in the clinical report by paragraph.

The ranges of displacements and slope values during each episode are reported.

4 Operating Instruction

4.1 Insert or remove ECG cable

The ECG cable can be inserted into or removed from the recorder as below. When the cable is completely inserted into the connector, a click will be felt. The ECG lead is fixed for CP-022 (1-channel). The ECG lead for CP-025 is automatically selected according to the type of ECG cable.



Insert / Remove ECG cable

4.2 Turn on the Recorder

The recorder will be turned on after the cable is inserted. If the recorder is in sleep mode, click the button will wake up the recorder.

4.3 Start Recording

Manual recoding: after the recorder is started up, press and hold the button for about 3 seconds, the recorder will send out 2 short and 1 long "Beep" sounds, the recorder starts recording.

Automatic recording: if all lead wires are in good connection for 3 minutes, the recorder will start recording automatically.

4.4 Mark a Patient Event

When the recorder is recording, click the button will mark a patient event.

4.5 Stop Recording

When the recording is finished, the recorder will stop recording automatically.

If the user needs to stop recording before recording is finished, remove the ECG cable to shut down the recorder and the record is stopped.

The recorder will automatically stop recording and power off after 1 minute if the

low battery is detected in the recording process.

4.6 Turn off the Recorder

The recorder can be turned off by removing the ECG cable. If the recorder is started up but keep idle for over 3 minutes, the recorder will turn to sleep mode automatically to save power.

4.7 Recharge the Battery

Connect the recorder to USB port with a USB cable, the recorder will recharge the battery from the USB port. When the battery is recharging, the LED will flash yellow every 4 seconds. When the recharge is finished, the LED will always light yellow.

FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

•Reorient or relocate the receiving antenna.

•Increase the separation between the equipment and receiver.

•Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

•Consult the dealer or an experienced radio/TV technician for help.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

RF Exposure Information

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

5 Use Step

5.1 Initialize the Recorder

Connect the recorder to PC with a USB cable, select "Initialize the memory card" in recording management interface of the analysis software for quick initialization, which applies the default recording configuration (default choice "three-channel and 24 hours" and turn off the pacemaker detection), no alteration is allowed; while selection of "Hookup" could configure channel duration, pacemaker detection, as well as edit patient information and recording information.

5.2 Patient Preparation

First clean the areas of the patient's skin with reference of 5.8 Reference Electrodes Placement, which is helpful in fixing the electrodes and the cuticular layer. First clean the skin with medical alcohol or alcohol cotton ball to eliminate greasiness; then use fine emery paper to clean skin gently, multiply enlarge contact area between the cuticular layer and the electrodes; when the skin processed is dry, paste the electrodes.

Then connect electordes to patient body according to 5.8 Reference Electrodes Placement.

5.3 Turn on the Recorder

Insert the ECG cable to turn on the recorder.

5.4 Start Recording

Press and hold the button for 3 seconds to start the record.

5.5 Stop Recording

When the record is finished, the recorder will stop recording automatically.

5.6 Remove the Electrodes

Remove the electrodes from the patient.

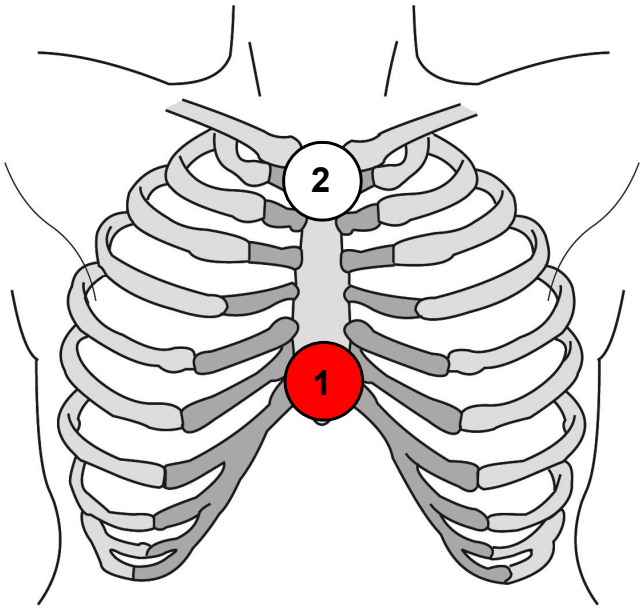
5.7 Data transmission

Connect the recorder to PC with a USB cable. Use the analysis program to setup the

recorder or transmit the off-line ECG data.

5.8 Reference Electrodes Placement

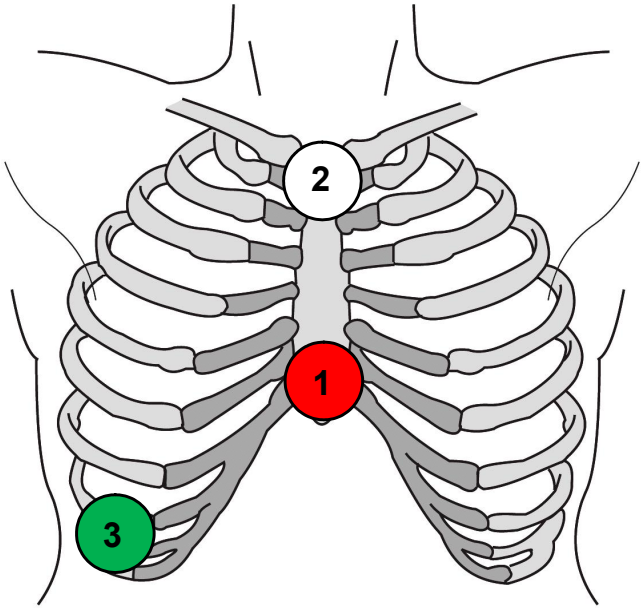
2-Electrode 1-Channel Placement



3

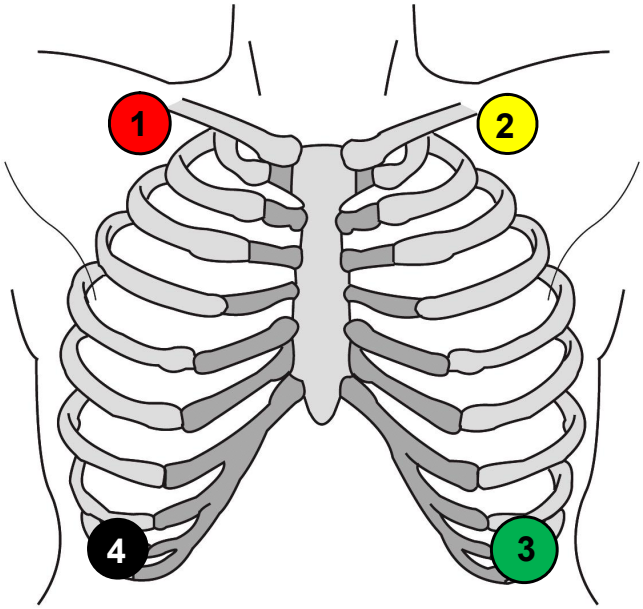
#	Electrode	Color	Position
1	**CH1+**	Red	Lower end of the sternum.
2	**CH1-**	White	Upper end of the sternum.

3-Electrode 1-Channel Placement



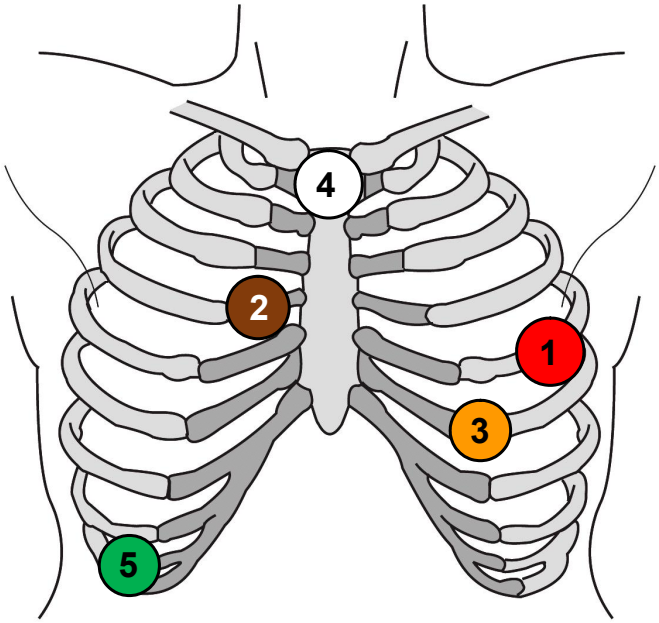
#	Electrode	Color	Position
1	**CH1+**	Red	Lower end of the sternum.
2	**CH1-**	White	Upper end of the sternum.
3	**RL**	Green	Lowest rib on right side of chest

4-Electrode 3-Channel Placement



#	Electrode	Color	Position
1	**R**	Red	Right clavicle, lateral of sternum border
2	**L**	Yellow	Left clavicle, lateral of sternum border
3	**F**	Green	Lowest rib on left side of chest
4	**N**	Black	Lowest rib on right side of chest
Channel 1: limb lead I, Channel 2: limb lead II, Channel 3: limb lead III			

5-Electrode 3-Channel Placement



#	Electrode	Color	Position
1	**CH1+**	**Red**	At the fifth rib on the anterior axillary line.
2	**CH2+**	**Brown**	At the fourth rib to the right of the sternal border.
3	**CH3+**	**Orange**	At the sixth rib on the midclavicular line.
4	**COM-**	**White**	At manubrium sternum.
5	**RL**	**Green**	Lowest rib on right side of chest
Channel 1: Mod V5 Channel 2: Mod V1, Channel 3: Mod V3			

6 Care and Daily Maintenance

6.1 Maintenance Cycle

For safety of the operator and the patients, it is recommended to conduct an overall maintenance and safety inspection to this product every quarter.

6.2 Maintenance Measures

6.2.1 Cautions and Maintenance of Battery

The ECG cable should be removed to turn off the recorder completely when the recorder is not used. Even the recorder turns into sleep mode without removing the ECG cable, the battery will discharge slowly. Overdischarge of the battery may cause damage. Put the recorder in dry and cool place along with the ECG cable.

Remove the recorder from the USB cable when the recharge is finished. Long term recharge of the battery may also cause damage.

6.2.2 Caution, Care and Maintenance of the ECG Cable

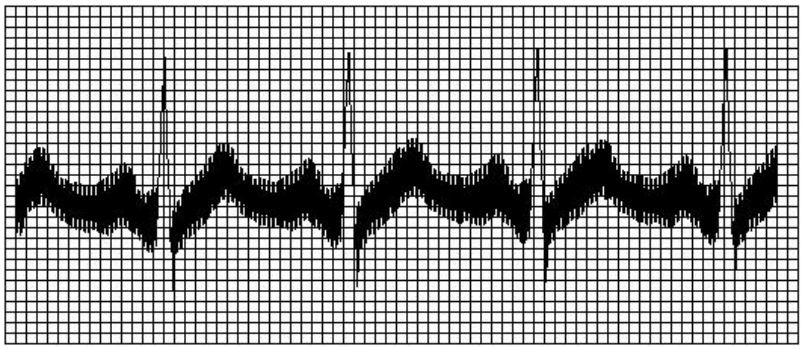
Check completeness of the cable regularly, damage of any single lead wire will cause interference to the corresponding signal. Use cotton dipped with 2% Glutaral solution or 10% Aqueous Sodium Hypochlorite solution to wipe the cable for sterilization, and then use cotton dipped with clean water to clean the disinfectant on the cable. The cable needs to be dried after cleaning. The insulation performance will still meet the usage requirement after cleaned in recommended ways.

- Do not clean the cable with detergent or disinfectant that contains Alcohol.
- Do not soak the cable and the recorder in liquid for sterilization.
- Do not sterilize the cable with high temperature.
- Serious folding or knotting the cable will reduce its service life, thus straightening out the cable while using.

Caution: Users shall not replace the ECG cable or other accessories, contact with relevant technical personnel to replace the damaged or malfunctioning accessories.

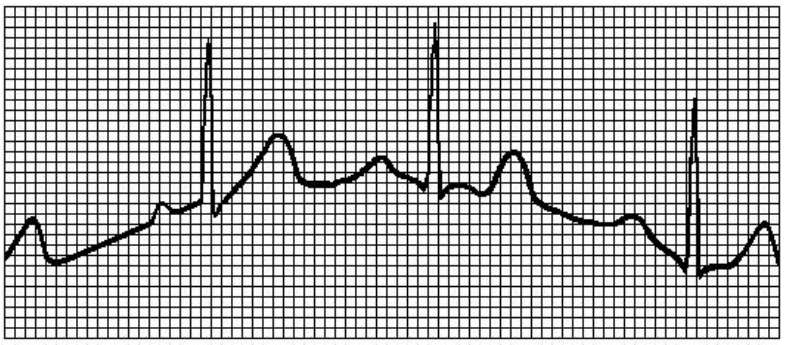
7 Normal Faults and Troubleshooting

7.1 AC Interference



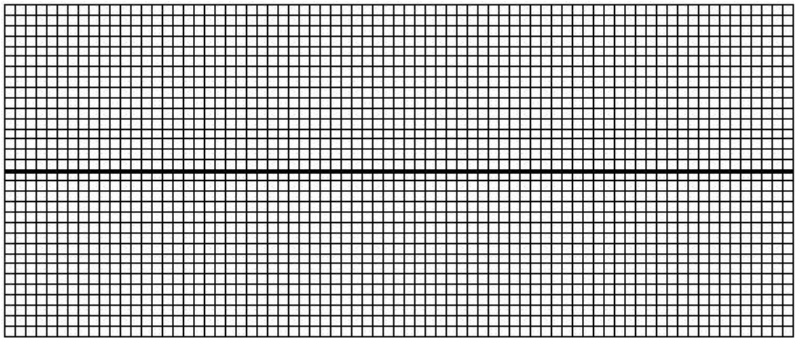
- Check if the ECG cable or the electrodes are correct.
- Check if the electrode plates are well connected to skin.
- Check if there is powerful electrical equipment in operation nearby. Such as X-ray machine or ultrasonic instrument, etc.

7.2 Unstable Baseline



- Check if the ECG cable or the electrodes are correct.
- Check if the patient's skin is well prepared.
- Check if the electrodes are connected well to skin.
- Check if it is caused by body movement of the patient or breathing.

7.3 No Signal



◆ Check if any electrode has dropped off from the patient.

8 Accessories and List

No.	Name	Qty.	Function and Instruction of Accessories
1	Recorder	1	Digital Holter recorder
2	ECG cable	1	Patient ECG cable
3	CD	1	Analysis program of the holter recorder
4	Silicon rubber case	1	Carrying the recorder
5	Instruction manual	1	Operating instructions of the instrument
6	Product certificate	1	Product quality certificate
7	Warranty card	1	Product warranty certificate
8	Packing list	1	Packing lists of accessories and auxiliaries

9 Warranty and After-sales Services

◆ When using the recorder, the user should fill out the *Warranty Card* according to the contents and send back to our company in time. On this basis, Our company will establish user archives and collect use information regularly, helpful in providing continuous and targeted high quality service to customers.

◆ No parts of this holter recorder or its accessories could be repaired by user, thus the user shouldn't dismount and repair it at will; Generally, our company

won't provide circuit, working principle or other technical materials, but if the user really needs these materials, please contact with our company's Technical Department. Damaged parts may cause danger, thus it needs to be repaired or replaced with new parts immediately, please contact with Technical Service Center of our company in time. The recorder and relevant accessories are warranted according to the following stipulated terms:

Part type	Warranty period
Recorder	Two years
ECG cable	One year
Silicon rubber case	One year

- Our company may fulfill the warranty commitment in the forms of door to door service, telephone guidance, and express delivery to the company.
- Even within the free warranty period, the following repair will be charged:
  1. Fault or damage caused by improper use of the user;
  2. Fault or damage caused by fall while moving after purchase;
  3. Fault or damage caused by repairing, transforming, dismounting that are conducted by personnel beyond our company;
  4. Fault or damage caused by fire, natural disasters, etc. after purchase;
  5. Fault or damage caused by connecting to other equipment;
  6. The warranty sealing tape is damaged;
  7. The user smears, alters equipment serial number, lead wire serial number without being authorized.
- Our company is irresponsible for other equipment faults caused directly or indirectly by faults of this product.
- In case the warranty tag be damaged, our company is entitled to be exempted from 12-month free maintenance services.
- For charged maintenance beyond the warranty period, it is advised to continuously apply the "Maintenance Contract System". Please refer to the Technical Service Center of our company for details.
- Please use the original factory accessories while changing auxiliaries of this product.
- The normal safety use term of the recorder is five years, no contraindication.

After-sales Services

If you have any problem in application, please contact the manufacturer or the local distributor immediately.

After-sale servicing unit (manufacturer):

Suzhou Beneware Medical Equipment Co., Ltd.

Address: 7F, No.8 Building, Software Park,

Suzhou Science and Technology Town,

Suzhou, China

Post Code: 215163

Tel: +86-512-66806855 **Fax: +86-512-66806855**

Website: www.beneware.net **E-mail: service@beneware.net**

Appendix 1 Product Specifications

Recorder Function	
Sample Rate	200Hz record sample rate, 3200Hz pacemaker sample rate
Resolution	12bits
Dynamic Range	10mV with ±300mV offset voltage
Frequency Response	≥-3dB and ≤0.83dB @ 0.05Hz to 60Hz
Input Impedance	≥10MΩ
Recording Time Limit	24-hour, 48-hour or 30 days for 1-channel record 24-hour, 48-hour or 14 days for 3-channel record
Pacemaker Detection	2~200mV, 0.1~2ms pacemaker pulse
Physical Specifications	
Dimension	57 x 37 x 13 mm
Weight	20g without ECG cable
Patient Cable	2 electrodes 1-channel cable 3 electrodes 1-channel cable 4 electrodes 3-channel cable (for CP-025 only) 5 electrodes 3-channel cable (for CP-025 only)
Ingress Protection	IP67
Collision	Still works in case fall on hard surface from 50mm height in any axial direction
Operating Environment	
Temperature	5 ~ 45°C
Humidity	10~95%, non-condensing
Pressure	700h ~ 1060hPa
Storage and Transport Environment	
Temperature	-40 ~ 55°C
Humidity	≤95%
Pressure	560h ~ 1060hPa
Battery	
Type	Built-in 300mAh 3.7V lithium polymer battery(Model no: 502035)
Recharge condition	5V DC, 100mA
Battery Capacity	CP-022: 30 days (pacemaker detection off) 14 days (pacemaker detection on) CP-025: 1-channel 30 days (pacemaker detection off) 1-channel 14 days (pacemaker detection on) 3-channel 14 days (pacemaker detection off) 3-channel 7 days (pacemaker detection on)
Life	Remain 80% of the nominal capacity after 300 full discharge and charge cycles

Appendix 2 Electromagnetic Compatibility

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the CP series Holter Recorder according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

<table>
<tr><th colspan="3">Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The CP series Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the CardioPatch Holter Recorder should assure that it is used in such an environment</td></tr>
<tr><td>Emission Test</td><td>Compliance</td><td>Electromagnetic Environment: Guidance</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>The CardioPatch recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The CardioPatch Holter Recorder is suitable for use in all establishments, including domestic establishments. The recorder has no connection to the public low-voltage power supply network.</td></tr>
<tr><td>Harmonic Emissions IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Electromagnetic Immunity			
The CP series Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Holter Recorder should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply line +/- 1 kV for input/ output lines	N/A	The CardioTrak Holter Recorder does not have AC or DC power lines.
Surge IEC 610004-5	+/- 1 kV differential mode +/- 2 kV common mode	N/A	The CardioTrak Holter Recorder does not have AC or DC power lines.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	N/A	The CardioTrak Holter Recorder does not have AC or DC power lines.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic Immunity			
The CP series Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioPatch Holter Recorder should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CardioPatch Holter Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $D = 1.2\sqrt{P}$ $D = 1.2\sqrt{P}$ 80 MHz to 800 MHz $D = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and D is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people. Additional notes are on following page.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the CardioPatch recorder: for equipment and systems that are not life-supporting

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

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 KHz to 80 MHz $D = 1.2\sqrt{P}$	80 MHz to 800 MHz $D = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $D = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12.0	12.0	23.0

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 separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

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EC REP

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