



GIMA

ARTICOLI & APPARECCHI PER MEDICINA

ECG TASCABILE CARDIO-C - 3 DERIVAZIONI
CARDIO-C POCKET ECG - 3-LEAD
ECG PORTABLE CARDIO-C - 3 DÉRIVATIONS
CARDIO-C ECG DE BOLSILLO - 3 DERIVACIONES
ECG DE BOLSO CARDIO-C - 3 DERIVAÇÕES
CARDIO-C POCKET EKG - 3 AVLEDNINGAR

REF PC-80D (GIMA 33245)



Shenzhen Creative Industry Co.,Ltd.
 Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park,
 Songbai Road, Xili Street, Nanshan District, 518110
 Shenzhen, R.P.C. Cina
 Made in China



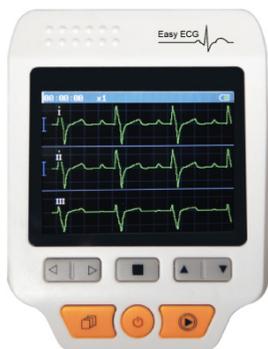
Shanghai International Holding Corp. GmbH (Europe)
 Eiffestrasse 80, 20537 Hamburg - Germany



Gima S.p.A.
 Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



User Manual



Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the manual very carefully before using this device.

These instructions describe the operating procedures to be followed strictly. Failure to follow these instructions may cause measuring abnormality, device damage, or personal injury.

The Manual is published in English and Shenzhen Creative Industry Co., Ltd. (Creative) has the ultimate right to explain the Manual. No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent. Creative reserves the right to improve and amend it at any time without prior notice.

Version of This Manual: Ver 1.8

Advised Date: June 2, 2023

All rights reserved.

For user's convenience, we share the latest version analysis software of this device on our website, the user can enter into our website (www.creative-sz.com) to download the corresponding latest version data manager software. Please contact the manufacturer or your local distributor if anything about software downloading.

3502-2430011

WARNING

1. Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. Stop using the unit, when there is obvious damage.
2. Stop using the ECG cable if it is damaged, please change a new one.
3. Do NOT make diagnosis oneself by the measurement and measurement results, always consult the doctor if

abnormal information is presented frequently.

4. It is NOT designed or intended for medical diagnosis.
5. It is NOT designed or intended for therapy purpose.
6. WARNING for PACEMAKER PATIENTS

Heart rate calculation may also count the pacemaker pulse for the patient who carries a cardiac pacemaker because of no pacemaker pulse rejection capability for this device. Do not rely entirely upon the heart rate reading of this device for pacemaker patients.

7. Do NOT use the device in the bathroom or moist circumstance.

8. Do NOT operate it in the environment where strong electro-magnetic interference exists.

9. Necessary service must be performed by qualified service engineers ONLY.

10. Clinical ECG examination is suggested for normal examination of your heart condition.

11. Connect/Disconnect data cable to the monitor gently and carefully, do NOT twist or shake the data cable plug with force to insert into or unplug from data interface port, or the data interface port may be damaged.

12. When the ECG amplifier is overload or saturation due to lead off or poor contacts between electrode and the skin, the monitor will prompt "Contact?" to remind the operator.

13. Do not touch the metal electrodes or place the electrodes of lead wire on patient for ECG measurement while the USB cable is connected to PC, electrical hazard will be caused by the leakage current.

14. ECG electrodes, lead wires and cable are not allowed to contact any other conductive parts.

15. It is strongly recommended to use Ag /AgCl (Silver Chloride) electrode to make sure the ECG signal quality is good.

16. Dispose of the expired device and its accessories according to applicable local regulations.

Summary

Dear Users,.....	1
WARNING.....	1
1 OVERVIEW.....	4
1.1 Appearance	4
1.2 Name and Model	4
1.3 Structure	4
1.4 Features.....	4
1.5 Intended Use	4
1.6 Operating Environment	4
2 INSTALLATION	4
2.1. Device check up	4
2.2 Power supply	5
2.2.1 When powered by AC mains power supply:	5
2.2.2 Batteries installation	5
2.3 Starting the ECG monitor	5
3 DEFAULT MENU SCREEN	5
3.1 Menu screen.....	5
4 ECG MEASUREMENTS	6
4.1 Methods of ECG measurement	6
4.2 Measuring procedure	8
4.2.1 Preparing Phase.....	8
4.2.2 Quick measurement by built-in electrodes.....	8
4.2.3 Long term measurement by external lead wires.....	8
4.3 Measurement Result Interpreting and Description.....	9
5 WAVEFORM REVIEW.....	10
5.1 Record list.....	10
5.2 Waveform Review.....	11
6 DATA MANAGEMENT	12
6.1 Storage status	12
6.2 Delete ID.....	12
6.3 Delete all	12
6.4 Upload Data	12
7 MEASUREMENT OPTION SETTING	13
7.1 Creating new ID	13
8 SYSTEM SETUP	13
8.1 Sound setting	13
8.2 Brightness Setting	13
8.3 Time/Date Setting.....	14
8.4 Auto power off	14

8.5 Power saving	14
8.6 Language	14
9 HELP	14
10 TECHNICAL SPECIFICATIONS.....	14
10.1 ECG measurement	14
10.2 Power supply	14
10.3 Classification.....	15
10.4 Display.....	15
10.5 Data Memory	15
10.6 Overall Dimension and Weight	15
10.7 Additional declaration	15
6) BATTERY LIFE: FOUR AA ALKALINE BATTERIES CAN BE USED FOR MORE THAN 8 HOURS MEASUREMENT.	15
MAXIMAL INPUT DC OFFSET VOLTAGE: $\pm 300\text{MV}$	15
11 MAINTENANCE.....	15
12. TROUBLESHOOTING.....	15
13 KEY OF SYMBOLS	16

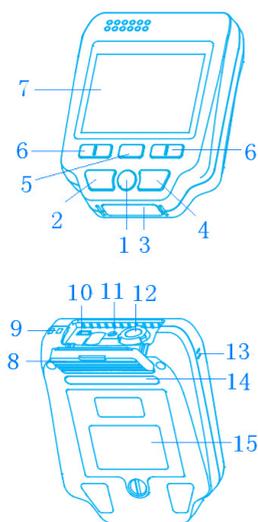


Figure 1-1.

13. Speaker
14. Metal electrode II and III
15. Battery cover, nameplate

1.2 Name and Model

Name: Easy ECG Monitor

Model: PC-80D

1.3 Structure

PC-80D Easy ECG Monitor mainly consists of circuit boards, display screen and metal electrodes/lead wires.

1.4 Features

1. Small in size, light in weight, and easy to carry.
2. One-key measurement, easy to operate.
3. ECG waveform and interpretation of results are displayed clearly on color dot-matrix LCD screen.
4. UP to 19 types of measurement results can be presented.
5. High capacity of built-in memory, up to 24 hours records storage and review for single channel ECG waveform; or 8 hours for 3 channels.
6. Quick measurement by built-in metal electrodes or long term measurement by external lead wires for recording 3 channels of ECG signals.
7. Voice prompt is available with data management function, data records can be reviewed and deleted locally, uploaded to PC as well.
8. Auto power off time can be set.
9. With power saving feature.

1.5 Intended Use

This Easy ECG Monitor is intended for measuring and recording the ECG signal and calculating the average heart rate for adult patients. It is applicable for use in clinics and homes, and convenient to operate by the patients themselves.

⚠ This device is not an ECG monitor used in clinical institution or hospital, but is used for spot-check purpose ONLY. It can not be used to substitute the normal ECG examination or real time monitoring. The measurement results are useful reference for doctor, but do not make direct diagnostic or analytical decision based on the information provided by this device.

1.6 Operating Environment

Operating temperature	5°C~40°C
Operating humidity	30%~80%
Atmospheric pressure	70 kPa ~106kPa

2 INSTALLATION

2.1. Device check up

1. Open the packing box and take out the device and accessories carefully. Place the device to a position of safe, stable and easy-checking.

1 OVERVIEW

1.1 Appearance

1.  Power: Long time press (about 2 seconds) makes the device power on or off; short time press turns on/off the backlight.
2.  Back: back to upper level of menu.
3. Metal Electrode I
4.  Measurement: shortcut button for built-in electrodes measuring, press this button to start measuring.
5.  OK: confirm selection or modification.
6. Navigation key:
 -  Left: move the cursor forwards/to the left, or adjust parameter values.
 -  Right: move the cursor backwards/to the right, or adjust parameter values.
 -  ▲: move the cursor upward/forward, or adjust parameter values.
 -  ▼Down: move the cursor downwards /backward, or adjust parameter values.
7. Display screen: display ECG waveforms and data.
8. I/O cover
9. Lanyard hole
10. USB interface: USB data socket.
11. DC input socket
12.  Lead wire socket: for connecting to lead wire.

2. Check up the number of accessories according to the packing list.

- Check up that the device without any visible or obvious damage.
- Check up that the accessories without any deformity or defect, including the plugs, lead wires and sensors.
- Check up there is no potential danger or abnormality existing in the device and accessories. If existing, stop using it.

Any quality problem, please contract us or our sale agent. We will offer the solution to satisfy our customer as soon as possible.

2.2 Power supply

2.2.1 When powered by AC mains power supply:

- Make sure that the input of the power adapter is within 100~240VAC with 50/60Hz, and the output is specified to be 5VA.
- Use the power cord and power adapter provided by the manufacturer. Insert the DC output of the power adapter to the DC input port of the device and the other end to the AC power cord, then plug the AC power cord to the mains power outlet with protected earth.

Caution: To eliminate potential serious danger and damage, please DO NOT use other type of power adapter or AC power cord than those provided by the manufacturer.

2.2.2 Batteries installation



Figura 2-1.

1. Open the battery cover by a screwdriver or a coin.
2. Insert four AA size batteries into the battery compartment with correct polarity as directed (as shown in figure 2-1).
3. Close the battery cover and fasten it.

➤ Once the AC power supply has been interrupted, the device will turn to use the built-in batteries automatically to make the device continuous working. The device will send a reminder if battery voltage is low while using built-in batteries and it will power off automatically when the batteries are exhausted to the level that can not sustain normal working.

⚠ DO NOT insert batteries with their polarities reversed. Dispose of the used batteries according to appli-

cable local regulations

2.3 Starting the ECG monitor

Long time press the “⏻” Power key (lasting for 2 seconds) until a beep sound is heard to indicate the device is turned on, then the booting screen will appear, as shown in the figure 3-1, after that the device enters into the default menu screen, as shown in figure 3-2. At this time, the user can begin operating it.

- Before measurement, please check all the applicable functions to make sure that the monitor works normally.
- Do not use this device to monitor the patient if there is any indication of damage or prompt of error message. Please contact the local dealer or the manufacturer.

3 DEFAULT MENU SCREEN

3.1 Menu screen

Long time press the “⏻” Power key (lasting for 2 seconds) until a beep sound is heard to indicate the unit is turned on, then the booting screen will appear, as shown in the figure 3-1, after that the device enters into the default menu screen, as shown in figure 3-2.

There are 6 entries, press navigation key to shift focus on them and press “■” OK key to go into the selected entry. Each entry has an icon and it is defined as following:

-  Measure: Detect ECG signal, mean while, display waveform, HR value, and analyze the ECG waveform to prompt necessary information.
-  Review: Recall and view the ECG records stored in this device (including waveform data and measurement result).
-  Memory: ECG records management including storage status check and record deletion.
-  Option: Measurement related setup including signal input selection, measuring time, bandwidth, HR alarm limit setting and user ID (ID number).
-  Setup: System setup including date/time, language, sound and display etc.
-  Help: Provide on-line information about measuring methods and general knowledge of ECG.

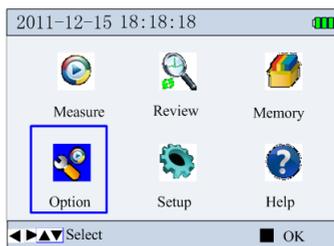


Figure 3-1.

4 ECG MEASUREMENTS

There are 2 measuring modes for the ECG measurement, which includes quick measurement by built-in electrodes and long term measurement by external lead wires.

- Quick measurement: press “” measure key to enter into the quick measurement directly; it can display single channel ECG signal measured by built-in electrodes, the signal can be lead I, lead II or chest lead according to the electrode placement.
- Long term measurement: after selecting the signal input option in the measuring option menu, move the cursor to the “” measure icon, then press the “” OK key to start the long term measurement.

For long term measurement, the external lead wires will be used in stead of built-in electrodes; there are two options for signal input.

Limb lead measurement: it measures 3 channels ECG signal for lead I, lead II, and lead III simultaneously and displays them;

Chest lead measurement: it measures single channel ECG signal for lead I or lead II or lead III or lead V according to the electrode placement. It is suitable for long term measurement.

4.1 Methods of ECG measurement

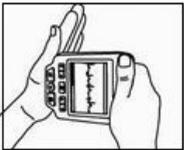


Figure 4-1 palm placement

It is recommended to clean your skin with SOAP and water to keep it moist without oily.

1. Measurement by built-in electrodes:

Easy and quick ECG measurement by built-in electrodes can be done by putting electrodes on hand, leg and chest respectively.

1). Hand measurement

It is convenient to take ECG measurement by hands or palms. The ECG waveform detected by this method is equivalent to Lead I of regular ECG examination.



Figure 4-2 wrist placement

A. Palm placement: Hold the device with right hand; make sure that the fingers touch the metal electrode II and III reliably. Press the electrode I on the left palm, as shown in figure 4-1.

B. Wrist placement: Hold the device with right hand; make sure that the fingers touch the metal electrode II and III reliably. Press the electrode I below the left wrist about 1 inch, as shown in figure 4-2. When the

ECG signal at palm placement is not good, try to measure with wrist placement.

Note: Keep at ease and make sure the skin contact well with the electrodes during ECG measurement. Please place the device on correct position, do not shake it during the measurement. Dirty skin may cause poor signal quality, so clean your skin before measuring.

2). Leg Measurement

The ECG waveform detected by Leg Measurement is equivalent to Lead II of regular ECG examination. Keep at ease when seating down, and then lift your left leg on a bench (figure 4-3A) or on the right knee (figure 4-3B). Hold the device with the right hand when measuring and make sure that the fingers touch the metal electrode II and III reliably, place the electrode I on the left leg above the ankle, as shown in figure 4-3A and 4-3B.

Note: Keep at ease and make sure the skin is clean and moist before measuring. Do not make your hands or feet too stiff and trembling when measuring.

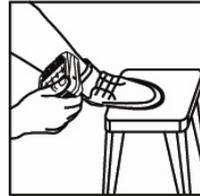


Figure 4-3A Leg measurement

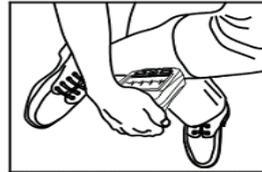


Figure 4-3B Leg measurement

3). Chest Measurement



Figure 4-4 Chest measurement

It is recommended to take ECG measurement on chest, since the signal detected by this way is stronger and with less interference. The ECG waveform detected by Chest Measurement is similar to the Lead V4 or V5 of regular ECG examination. Hold

the device with the right hand, make sure that the fingers touch the metal electrode II and III reliably, as shown in figure 4-4, place the electrode I on the left chest align with the midclavicular line (V4 position) or the anterior axillary line (V5 position) and on the level of the 5th intercostal space.

Note: keep at ease and clean the electrode I by using the wet cloth before measuring. If the waveform baseline wanders or noisy waveform appears, hold your breath for a moment to get stable and clean signal.

2. Measurement by external lead wires

The ECG signal which is detected by external lead wires is more stable than that by hand measurement. ECG measurement by external lead wires can be done by placing the electrodes on limbs or chest respectively.

1). Electrodes placement on limbs (paste on chest)

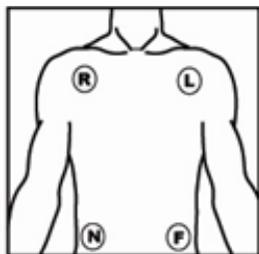


Figure 4-5 the location of electrodes on limbs

On default menu screen enter “ ” option setup menu to select “limb lead” for signal input. By this way, the 3 channels of limb lead I, II and III can be measured and displayed simultaneously and continuously. The electrodes are adhesive ECG electrodes. The location of the electrode is shown in figure 4-5.

Figure 4-5 the location of electrodes on limbs

R (red): on the 2nd intercostal space at the right mid-clavicular line;

L (yellow): on the 2nd intercostal space at the left mid-clavicular line;

F (green): on the left upper abdomen

N (black): on the right upper abdomen

Operation: Connecting the lead wires after placing the electrodes well and then insert the connector onto the device; Power on the device to select the “limb lead” for signal input and set the measuring time on option setup menu, then press “■” OK key to start the measurement.

Note: keep at ease when seating or lying down.

2). Electrodes placement for “Single Lead” setting

① Lead I, II, or III measurement

On default menu screen enter “ ” option setup menu to select “Single Lead” for signal input, and place the electrodes to obtain the signal for lead I, or lead II or lead III (as shown in form 4-1). By this way, the ECG signal of lead I or II or III can be measured and displayed as a single channel. Either adhesive electrodes or limb clip type electrodes (optional) can be used to do this measurement. The location of electrodes placement refers to form 4-1.

	ECG Lead Electrode Label (color) (IEC standard / AHA standard)		
Electrodes Placement	Lead I	Lead II	Lead III
place on interior of right arm (between the wrist and the elbow). Refers to R in figure 4-5.	R(Red) / RA(White)	R(Red) / RA(White)	L(Yellow) / LA(Black)
place on interior of the left leg (between the knee and the ankle). Refers to F in figure 4-5.	L(Yellow) / LA(Black)	F(Green) / LL(Red)	F(Green) / LL(Red)
place on interior of the left arm (between the wrist and the elbow). Refers to L in figure 4-5.	F(Green) / LL(Red)	L(Yellow) / LA(Black)	R(Red) / RA(White)

Form 4-1

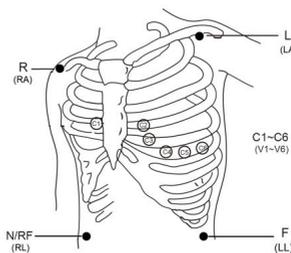


Figure 4-6 the location of chest lead measurement

Note: It’s recommended to place the electrodes on chest for long term measurement of ECG signal for lead I or II or III. Please refer to appendix I for more details about measuring methods.

② Lead V (chest lead) measurement

On default menu screen enter “ ” option setup menu to select “Single Lead” for signal input, and place the electrodes to the position of V₁/2/3/4/5/6. ECG signal detected by this method is single channel measurement, which is equivalent to the waveform of regular chest lead. It is intended for professional use (i.e. by doctor). The location of the electrodes is shown in figure 4-6.

R (red): place on interior of left arm (between the wrist and the elbow);

L (yellow): place on interior of the right arm (between the wrist and the elbow);

F (green): on the 5th intercostal space at the left anterior axillary line;

N (black): unused.

Operation: Connecting the lead wires after placing the electrodes well and then insert the connector onto the device; Power on the device to select the “single lead” for signal input and to set the measuring time on option setup menu, then press “■” OK key to start the measurement.

Note:

1. The lead V (chest lead) Measurement can obtain the ECG signal of Chest Lead (V1-V6). Please refer to appendix I to select the location of F (green) electrode when you want to get the different chest lead. At the same time, you should set the lead information (V1-V6) that you want on the option setup menu.

2. Either adhesive electrode or sucking bulb electrode (optional) can be used to Chest Lead Measurement. Please refer to appendix I for more details about measuring methods.

4.2 Measuring procedure

4.2.1 Preparing Phase

The quick measurement is as following for details:

At default menu screen, press “▶” measure key to enter into the quick measuring screen directly, as shown in figure 4-7, in addition, at the beginning of measurement (including quick and long term measurement), the preparing phase shows on the screen with a heart beat icon and counting down seconds, the beeper will sound with the counting down at the interval of one second.

During this period the device will check the signal quality and auto scale the display. Please adjust your holding position if the detected waveform is not smooth or poor signal and it may prompt: “Check well-connection with lead wires.”



Figure 4-7 Preparing phase (quick measurement)

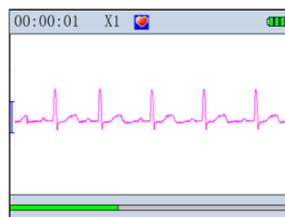


Figure 4-8 After preparing (quick measurement)

4.2.2 Quick measurement by built-in electrodes

Please refer to the section 4.1 “Hand measurement” to make the electrodes well-connection with skin. At default menu screen, press “▶” measure key can enter into quick measurement preparing screen directly, after 10 seconds, it will enter into the measuring screen, as shown in Figure 4-8. The measuring time lasts for about 30 seconds.

4.2.3 Long term measurement by external lead wires

There are 2 options (Limb lead and Single lead) for long term measurement by external electrodes. The detail information about the electrodes placement is described in section 4.1.

4.2.3.1 Single lead setting

Please refer to the section 4.1 “Single lead measurement” to connect the lead wires; enter “▶” option setup menu to select “Single lead” for signal input; return to default menu screen, move the cursor to the “▶” measure icon, press the “■” OK key to enter into external electrodes measurement (3 lead wires) preparing screen. During the 10 seconds preparing period, press “▲▼” to select II or I or III or V or V1/2/3/4/5/6 for option. After the preparing period, it will enter into the single lead measuring screen, as shown in Figure 4-9. In this measuring mode, it can measure and display the ECG signal of lead I or lead II or lead III or lead V or lead V1/2/3/4/5/6 respectively according to your settings.



Figure 4-9 Misurazione con derivazione singola

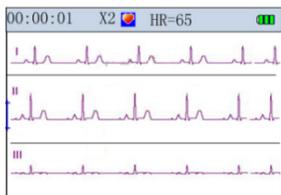


Figure 4-10 measuring (limb lead)

4.2.3.2 Limb lead setting

Please refer to the section 4.1 “Limb lead measurement” to connect the lead wires; enter “” option setup menu to select “limb lead” for signal input; return to default menu screen, move the cursor to the “” icon, press the “” OK key to enter into external electrodes measurement (4 lead wires) preparing screen. After 10 seconds, it will enter into the limb lead measuring screen, as shown in Figure 4-10.

On-screen display:

- (1) “00: 00: 01”: Measuring time
- (2) “X1”:“X1”: ECG waveform amplitude scale; “X2”: twice size of the nominal scale; “X4”: four times size of the nominal scale.
- (3) “”: Heart beat indicator. It flashes while heart beats.
- (4) “HR=65”: Current HR value. It is displayed during measurement only when external lead wires are used, if the ECG signal is poor, this value could become “---”.
- (5) : Enhanced filter mode indication. It shows up only when the bandwidth is set to enhanced mode.
- (6) : Status of battery capacity
- (7) “”: ECG waveform
- (8) “”: Bar whose height is corresponding to 1mV amplitude
- (9) “”: Status bar for measurement progress.

Operation:

When in the quick measurement by built-in electrodes:

- ① Press “” key, the screen display direction will be rotated in counterclockwise;
- ② Press the “” OK key or “” return key to stop measuring and return to the default menu screen directly, the measuring data won’t be saved.

When in the external electrodes lead wire measurement:

- ① The device will stop measuring automatically if the measuring time is over;
- ② Press the “” OK key or “” return key to stop me-

asuring and return to the default menu screen directly, the measuring data would be saved.

Note:

- ① If the storage is full, the device will stop to measure and it prompts “Fail to save this record because of full data memory”, at this moment, you should delete some records to make sure enough storage space, then measuring again.
- ② If the battery is low, the battery icon “” flashes red, the device stop to measure and it prompts “low battery voltage, measuring is interrupted, press return key to exit! ”, at this time, connect to external power can continue to measure, or replacing a new battery to measure again.
- ③ During measurement, the pulse beep sound could be heard.
- ④ During the measurement by external lead wires, if “HR alarm” option is set to “On” and the HR value is out of the alarm limits, the alarm sounds will occur with 3 short beeps, and the HR value is reversely displayed.
- ⑤ During the quick measurement, if the device does not well contact with the electrodes or the signal is poor, it can not calculate the HR value, the measuring result will be “poor signal, measure again”, and the data will not be saved.
- ⑥ During the measurement, if the electrodes have loose contact with the skin, it will prompt “poor signal”. If it is external lead wire measurement, the HR value shows “_”.

4.3 Measurement Result Interpreting and Description

When the measuring is finished, the device will interpret the measurement result, as shown in figure 4-11/4-12/4-13; the measurement result description refers to the index 2.

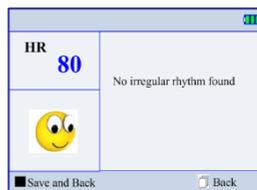


Figure4-11 (no irregularity found Quick measurement)

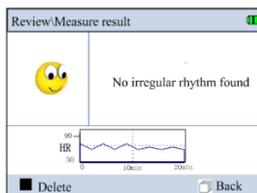


Figure 4-12 (no irregularity found in Ext.)

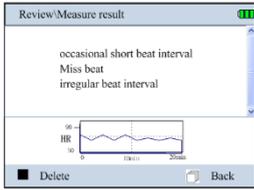


Figure 4-13 (irregularity found in Ext.)

1. In the external lead wire measuring mode, the current measurement result will be saved by default, as shown in figure 4-12/4-13. Press the “■” OK key or “⏪” back to return the default menu screen after reviewing the result.

2. After the quick measurement by built-in electrodes, the device will save the data automatically, and it prompts “The result is saved successfully, as shown in figure 4-14. Press the “■” OK key or “⏪” back to return the default menu screen. If the “⏪” back key is pressed or no key operation after 6 seconds, return to default menu screen directly and the current measurement data won't be saved

Notes:

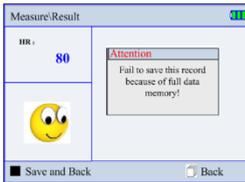


Figure 4-14.

1. It is capable of voice prompt for working status and measurement result.
2. The device provides the ECG measurement result with 19 types of interpretation after the quick measurement, please refer to the appendix 2 for detail.
3. Up to 8 hours ECG records can be stored in built-in memory, when the memory is full, the device will prompt that “Memory full”.
4. During the ECG measurement by external lead wires for long term measuring, if you interrupt the measuring manually then no result interpreting will be displayed.

5 WAVEFORM REVIEW

5.1 Record list

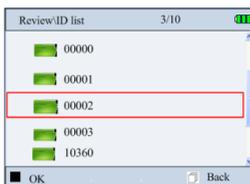


Figure 5-1 waveform review/ID list



Figure 5-2 waveform review/record list



Figure 5-3 Review (Quick measurement)

Select “⏪” review key on the default menu screen, then press “■” OK key to enter into the user ID list screen, as shown in Figure 5-1. Selecting a folder which contains the data for a given ID, then press OK key, the display screen is as shown in Figure 5-2.



Figure 5-4 Review (External electrodes)

Legend of icons:

😊: Indicates the measured result without irregularity found.

😬: Indicates the measured result with some irregularity found.

😱: Indicates that the waveform has much noise or lead off during measurement.

|||: Indicates the 3 leads measurement by external electrodes (with 4 lead wires)

||: Indicates the single lead measurement by external electrodes (with 3 lead wires)

|: Indicates the quick measurement (30 seconds by built-in electrodes)



Figura 5-5

Note: the ID list only display the ID which contains data.

5.2 Waveform Review

In the record list, selecting a record, then press “n” OK key, the quick measurement record is shown in the figure 5-3; the external lead wire measuring records is shown in figure 5-4.

On-screen display:

- (1) “”: Measured ECG waveform
- (2) “”: Mark corresponding to 1mV amplitude
- (3) “”: ECG waveform snap-shot
- (4) “”: Zooming box for ECG waveform
- (5) “”: Mark of irregular segment of waveform. Please refer to appendix 2 for detailed information.

Notes: The Zooming box contains ECG waveform measured in about 3~4 seconds.

1. For quick measurement by built-in electrodes, the display will review this record automatically, press “” OK key, the display will browse the recorded waveform automatically, Press it again to stop the browsing operation; Press the “” can scroll the waveform manually. When the review is finished, press “” OK key to bring the measurement result, as shown in figure 5-5, in the measuring result screen, press “” OK key, it prompts “Are you sure to delete this record?”, as shown in figure 5-6 screen. You can delete this record according to the prompts.

2. For external lead wires measurement (limb lead and single lead), the display shows 5 lines of compressed waveform, every line contains 30 seconds of waveform data as shown in figure 5-4. Press the “” key to move the grey zooming box pane, press “” OK key to zoom in the waveform display within the grey zooming box.

The single lead review screen is shown in figure 5-7; the limb lead review screen is shown in figure 5-8.



Figure 5-7 Single lead (the Chest lead) review screen

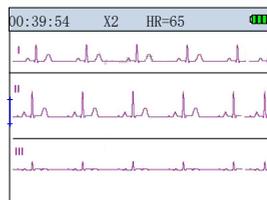


Figure 5-8 (no irregular found in Limb lead)

In the figure 5-7/5-8/5-9 screen, press the “” OK key can review the result description for this ID record, as shown in figure 5-10/5-11. In the measure result screen, press the “” OK key can delete this record. Note:

When in limb lead review screen, press “” key can switch the three and single signal channel on screen display; and if there is any irregular found in the review screen, it will display the measuring HR value instantaneously, and there is an inverted triangle shown on the irregular segment, as shown in figure 5-9.

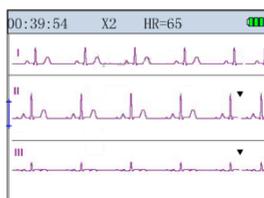


Figure 5-9 (irregular found in Limb lead)

For the external lead wire measurement record description, if there is no irregular found, it will display a smile face and prompts “No irregularity found”. HR trend graph which shown below displays the HR record in length of 20 minutes in one page, press “” to review next page, as shown in figure 5-10; if there is any irregularity found, the result is as shown in the figure 5-11, it will display the statistical result of irregularity.

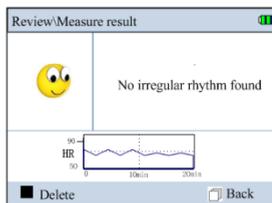


Figure 5-10 No irregularity found (Ext.)

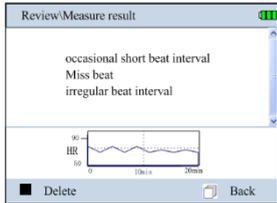


Figure 5-11 (irregularity found in Ext.)

6 DATA MANAGEMENT

Select “Memory” icon on the default menu, then press “**■** OK” button to enter into data management screen, as shown in Figure 6-1.

6.1 Storage status

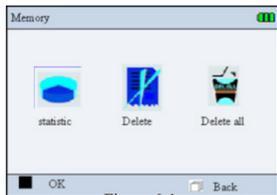


Figure 6-1.

On data management screen, select “Statistic”, then press “**■** OK” key to enter into the Storage status screen, as shown in Figure 6-2.

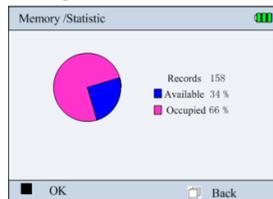


Figure 6-2.

6.2 Delete ID

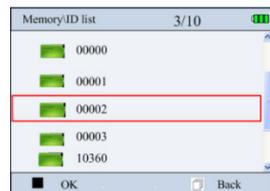


Figure 6-3.

1. On data management screen, select “Delete” with Navigation Key, then press “**■** OK” key to enter into the ID list screen, as shown in figure 6-3.

2. Press the Navigation Key “<”, “>”, “▲” or “▼” to select the ID; when pressing “**■** OK” key, there are two diffe-

rent prompts for two different situations:

Situation 1: this ID does not contain any data record.

The ID number of “00000” ~ “00004” is reserved, when pressing “**■** OK” key, the device prompts “This ID can’t be removed”.

If it is a new ID, press the “**■** OK” key to delete the selected record according to the prompt: “Are you sure to delete this ID”.

Situation 2: there are data records under this ID. Pressing “**■** OK” key to enter into the record list screen, as shown in figure 6-4. The record list screen display the date and time of all records for this ID.

Press the Navigation Key “<” key to perform select this ID (press it again to cancel selection), the selected record will be labeled “v”;

Press the Navigation Key “>” key to select all the data records under this ID (press it again to cancel selection), the selected record will be labeled “v”;

Press “**■** OK” key: delete the selected record according to the prompt.

Note: the ID list display the all ID numbers, even if there is no record under this ID number.

6.3 Delete all

On data management screen, select “Delete all” with Navigation Key, then press “**■** OK” key, at this time it prompts that “Delete all?”. You can delete all data records stored in the device according to the prompt.

6.4 Upload Data

When measuring is finished, on data management screen, select “Upload data” to enter into upload data screen, as shown in figure 6-5. On this screen, you can transmit data to PC for data management, and interpretation through PC-80D data cable. Please refer to the ECG Viewer Manager for detailed operation.



Figure 6-4.

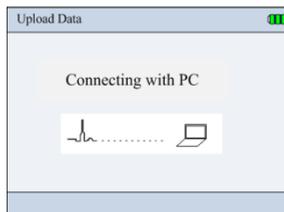


Figure 6-5

7 MEASUREMENT OPTION SETTING

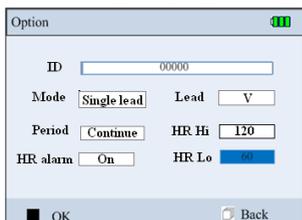


Figure 7-1

On the default menu, select the “Option”, then press the “■” OK key to enter into the optional parameters setting for measurement, as shown in figure 7-1..

On-screen display:

User ID: Displaying the last created ID No. or “New ID”. At most 100 ID can be created. When creating a new ID, at most 30 characters can be entered; the default ID is “00000”, the number of “00000” ~ “00004” is reserved (already created at factory) and can not be deleted.

Mode: It is valid only for external lead wires with two options of “Limb lead” and “Single lead”. The “Limb lead” is for the measurement by external 4 lead wires; the “Single lead” is for the measurement by external 3 lead wires, it is intended for professional user (i.e. doctor). The “Limb lead” by external lead wires or the “Quick measurement” by built-in electrodes is recommended for ordinary users. The default setting is “Limb lead”.

Lead: when the measuring mode is set to “Single lead”, lead V is the default label. If you want to specify other labels such as lead I/II/III/V/V1/V2/V3/V4/V5/V6, select the lead label from the pull-down menu.

Period: “30S”, “1min”, “5min”, “10min”, “30min”, “continue” are optional. The default measuring time is “Continue”.

HR alarm: “On” and “Off” are optional. The default setting is “On”.

HR Hi: the high alarm limit with setting range of 35~240bpm, the default value is 120bpm;

HR Lo: the low alarm limit with setting range of 30~115bpm, the default value is 60bpm.

Operation:

1. Press the navigation key “<, >, ▼ or ▲”: Move the cursor upwards/backwards.
2. Press “■” OK key: Conform to option and enter into the corresponding parameter setting.
3. Press the navigation key “▼ or ▲”: Adjust parameter values.
4. Press “■” OK key: Conform the selection, if you do not want to adjust parameter values, or the setting is accomplished, please enter the “⏪ Back” button.

7.1 Creating new ID

On the “Option” setup menu, selecting “New ID” item

from the ID pull-down menu, as shown in figure7-2.

Operation:

1. Press the navigation key “<, >, ▼ or ▲”: Move the cursor upwards/backwards.
2. Press the “■” OK key: Conform to select the corresponding numbers or letters.
3. Press the navigation key “<, >, ▼ or ▲”: Move the cursor to “Enter” key ,press the OK key “■” to accomplish the operation.

During entering the ID number, you can move the cursor to the “Del” button to correct the numbers or letters input error. When the entering number exceeds 30 characters, the cursor would move to the “Enter” button to prompt the user that the entering is finished.

8 SYSTEM SETUP

On the default menu screen, select “Setup” with Navigation Key, then press “n”OK key button to enter into system setup screen, as shown in Figure 8-1.

1. Press the navigation key “<, >, ▼ or ▲”: Move the cursor upwards/backwards.
2. Press “■” OK key: Conform to option and enter into the corresponding parameter setting.
3. Press the navigation key “<, >, ▼ or ▲”: Adjust parameter values.
4. Press “■” OK key: Conform to option, if you do not want to adjust parameter values, or the setting is accomplished, please enter the “⏪ Back” button.

8.1 Sound setting

On system setting screen, select “Volume” to enter into the sound setting screen, as shown in figure 8-2.

Beep: Setting the beeper and voice Open/Close. Move the slide icon to left means the beeper is disabled; Move the slide icon to right means the beep is enabled.

Speech: Adjust the volume with the navigation key. Move the slide icon to left means the speech volume is minimal; Move the slide icon to right means the speech volume is maximal.

8.2 Brightness Setting

On system setting screen, select “Display” to enter into the brightness setting screen, as shown in figure8-3. Adjust brightness with Navigation Key.

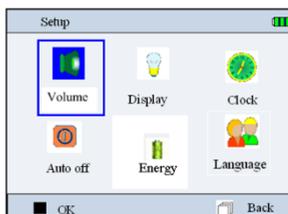


Figure 8-1

8.3 Time/Date Setting

On system setting screen, select “Clock” to enter into the date and time setting screen, as figure 8-4.

1. press navigation key “ \leftarrow , \rightarrow , \blacktriangledown or \blacktriangle ” and “ \blacksquare ” OK key to select the date and time you need.
2. press navigation key “ \blacktriangledown , \blacktriangle ” to adjust the time value.
3. Press “ \blacksquare ” OK key confirm the date and time setting value. If you do not want to adjust the parameter value or the setting is finished, please press the “ \square ” back button.

8.4 Auto power off

On system setting screen, select “Auto off” to enter into the timeout setting for auto power off, as shown in the figure 8-5. Press navigation key “ \leftarrow , \rightarrow , \blacktriangledown or \blacktriangle ” to set the timeout time. Press the “ \square ” back button when setting is done.

8.5 Power saving

On system setting screen, select “Energy” to enter into the power saving setting, as shown in figure 8-6. Press navigation key “ \leftarrow , \rightarrow , \blacktriangledown or \blacktriangle ” to set the timeout time for power saving. Press the “ \square ” back button when setting is done. The display screen will be dark when the device works in power saving mode.

Exit from power saving mode:

- ① Press any key to exit from power saving mode.
- ② Power saving mode terminates automatically when lead off.

8.6 Language

Press navigation key “ \leftarrow , \rightarrow , \blacktriangledown or \blacktriangle ” in the system setup screen shown in the figure 8-1 to select language icon, press “ \blacksquare ” OK key to change the language, as shown in the figure 8-7.

It has “简体中文(Chinese)”, “English” and “繁体中文(Traditional Chinese)” language modes.



Figure 8-4

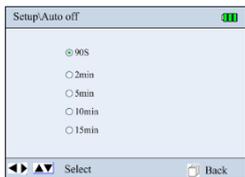


Figure 8-5

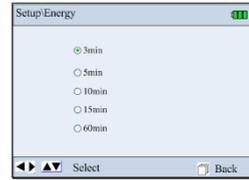


Figure 8-6



Figure 8-7

9 HELP

On default menu screen, select “Help”, then press “ \blacksquare ” OK key to enter into help info screen. In the info screen, you can browse the “FAQ”, “How to”, “ECG info” and software version information. As shown in 9-1.

10 TECHNICAL SPECIFICATIONS

10.1 ECG measurement

1. Amplification channels: 3.
2. Signal input: 3 embedded metal electrodes or external lead wire cable (with 3/4 lead wires).
3. Lead selections and measuring methods: Quick measurement by embedded electrodes; measurement by external electrodes with 3 lead wires (single channel for Lead I, II, or III) or 4 lead wires (3 simultaneous channels for Lead I, II and III)
4. ECG bandwidth: 0.05Hz~40Hz (Enhanced mode), 0.5Hz~40Hz (Normal mode).
5. Internal noise level: 30 μ Vp-p
6. Heart rate measurement range: 30bpm~240bpm
7. Heart rate measurement accuracy: ± 2 bpm or $\pm 2\%$, whichever is greater
8. Display scale: 5.0mm/mV $\pm 10\%$
9. Common-Mode Rejection Ratio (CMRR): ≥ 60 dB
10. Waveform scan speed: 20mm/s $\pm 10\%$
11. Input current: 0.1uA
12. Input Impedance: ≥ 5 M Ω (single ended)
13. Maximum input DC offset voltage: ± 300 mV

10.2 Power supply

Battery: 4 \times AA alkaline batteries

Input power: 5.0V/1.0A; provided AC adapter input voltage: a.c. 100~240V, 50/60Hz.

Auto power-off: timeout setting from 90s to 15 mi-

nutes

Threshold of low battery voltage indication: 4.4V
+/-0.2V.

10.3 Classification

1. The type of protection against electric shock: Internally powered equipment
2. The degree of protection against electric shock: Type BF applied part
3. The degree of protection against harmful ingress of liquid: Ordinary equipment without protection against ingress of liquid.
4. Electro-magnetic Compatibility: Group I, Class B

10.4 Display

1. LCD type: Color LCD
2. Display area: 70.08mm x 52.56mm.

10.5 Data Memory

Stored data records can be uploaded to the computer by data cable provided by the manufacturer.

10.6 Overall Dimension and Weight

Dimension: (L)130mm×(W) 98mm× (H) 36 mm

Weight: 210g (not including batteries)

10.7 Additional declaration

- 1) Electro-surgical interference suppression: Without the function of Electro-surgical interference suppression.
- 2) Defibrillator discharge protection: Without protection against defibrillator discharge.
- 3) Respiration or lead off detector and active noise suppressor: The auxiliary leakage current is less than 0.1uA.
- 4) Per minutes HR average calculation: the latest 8 times R-R intervals falling on the range of heartbeat average.
- 5) Display updates speed: 1 time/ second.

6) BATTERY LIFE: FOUR AA ALKALINE BATTERIES CAN BE USED FOR MORE THAN 8 HOURS MEASUREMENT.

**MAXIMAL INPUT DC OFFSET VOLTAGE:
±300MV**

12. TROUBLESHOOTING

Trouble

The device can not turn on.

Possible Reason	Solution
1. The batteries are drained or almost drained.	1. Change batteries.
2. The batteries are not inserted properly.	2. Reinstall batteries.
3. The device is broken out.	3. Please contact the local service center.

11 MAINTENANCE

1. Please change the batteries, when appears low-voltage icon.
2. It is recommended to wipe the metal electrode with medical alcohol, when the measuring signal is too weak.
3. Please wipe the surface of the unit with clean cloth or let it dry in air.
4. Please take out the batteries if the unit will not be used for a long time.

5. Storage and Transportation

Ambient temperature: -20 to 60°C

Relative humidity: 10~ 95%

Atmospheric pressure: 50~107.4KPa

6. In case any indication of damage about the function of the monitor, it is not allowed to apply it to the patient for any monitoring. Please contact the local dealer or our company in case of any problems. We are to offer you the best solution for your satisfaction.
7. The maintenance is to extend the life of the electrodes; on the surface of the electrodes you should clean it by wet cloth or medical alcohol if necessary. It is recommended to protect the electrodes from ultraviolet radiation; do not wipe the electrodes with hard and rough things.

Notes:

1. Keep it away from corrosive substances, explosive substances, high/low temperature and moisture.
2. If the device gets wet or has water steam, please stop operating it.
3. When it is taken from cold environment to warm and humid environment, please do not use it immediately.
4. DO NOT operate the button on front panel with sharp materials.
5. DO NOT immerse the device into liquid. Do NOT spray any liquid on it directly.
6. The life of this unit is 5 years. In order to ensure its long service life, please pay attention to the use of maintenance.

Trouble

The device is failure in measuring heart rate.

Possible Reason	Solution
1. Electrode and body does not contact well.	1. Place the electrode correctly.
2. Moved when measuring.	2. When measuring, please keep quiet and avoid moving.
3. Electromagnetic interference.	3. Keep away from interference source.
4. Weak signal.	4. Change a place (chest) to measure.

Trouble

ECG waveform excursion, strong irrelevant waveform or the ECG waveform displays on the screen, but the prompt info is "Contact?"

Possible Reason	Solution
1. Skin is dry or oily.	1. Clean skin with soap and water and eliminate skin crumb and grease to make the skin wet and free of grease.
2. Electrode and body does not contact tightly.	2. Press the electrode with a certain force.
3. Muscle strain.	3. Keep hand relax while measuring.

13 KEY OF SYMBOLS

Symbol	Description	Symbol	Description
	Battery indicator		Heart Rate (Unit: beats per minutes)
	Power button		shortcut button for ECG measuring
	Confirmation button		Back button
	Navigation key		USB Port
	Lead wire socket		Type BF applied part
SN	Serial number		DC power supply port
	Medical Device complies with Directive 93/42/EEC		Manufacturer
	Authorized representative in the European community		WEEE disposal
	Non-ionizing radiation		Follow instructions for use
	Atmospheric pressure limit		Temperature limit
	Humidity limit		Keep in a cool, dry place
	Keep away from sunlight		Caution: read instructions (warnings) carefully
	Product code		Lot number
			Imported by

Appendix 1 Measurement Result Description

No.	ECG Measurement Result Descriptions	Notes: (bpm, time/minute)
1	No irregularity found.	60 bpm \leq HR \leq 100 bpm, No irregular HR found.
2	Suspected a little fast beat	100 bpm < HR \leq 110 bpm
3	Suspected fast beat	HR > 110 bpm
4	Suspected missing Beat	No heart beat is detected within the period of twice of average R-R interval
5	Suspected arrest	No heartbeat is detected within 4 seconds
6	Suspected short run of fast beat	More than 3 consecutive premature beats are found
7	Suspected a little slow beat	50 bpm \leq HR < 60 bpm
8	Suspected slow beat	HR < 50 bpm
9	Suspected occasional short beat interval	Premature beat
10	Suspected occasional irregular beat interval	Bigeminy and Trigeminy.
11	Suspected a little fast and interval with occasional short beat interval	A little fast beat and suspected Premature beat.
12	Suspected a little slow and interval with occasional short beat interval	A little slow beat and suspected Premature beat.
13	Suspected a little slow beat and interval with occasional irregular beat	A little slow beat and suspected Bigeminy /Trigeminy.
14	Waveform baseline wander	Signal saturation or lead wire off during measuring, but the average HR still be calculated.
15	Suspected fast beat with baseline wander	Fast beat and interval with waveform baseline wander.
16	Suspected slow beat with baseline wander	A little slow beat and interval with waveform baseline wander.
17	Suspected occasional short beat interval with baseline wander	Premature beat with waveform baseline wander
18	Suspected occasional irregular beat interval with baseline wander	Bigeminy /Trigeminy with baseline wander
19	Poor Signal, measure again	Small waveform or baseline wander is larger, average HR can not be measured.

Appendix 2 General Knowledge of ECG

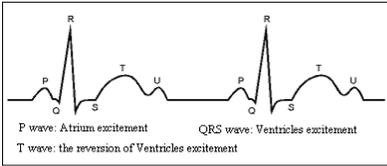


Figure 1 Normal ECG Waveform

● **Normal sinus rhythm:** In sinus conditions, SA node paces the heart with the regularly rate and the normal rhythm. The heart rate is in the range of 60 to 100 times per minute and the rhythm is regular. P wave is normal and each one is followed by a QRS wave. P-R interval: $0.12 \sim 0.20s$; QRS wave: $0.06 \sim 0.10s$; No ectopic ECG activity.
Symptom: Sinus rhythm, heart rate: $60 \sim 100bpm$
Indication: Normal

● Several abnormal ECG waveforms



Figure 2 Tachycardia Waveform

1) Tachycardia: The heartbeat becomes faster. Tachycardia is determined by the rhythm of the heart, the average rhythm beats faster than 100 times a minute is considered as Tachycardia. The result description "Suspected fast beat" in this device may be doubted as Tachycardia.

Symptom: heart rate $>100bpm$

Indication: It may occur with the normal people who have these physiology conditions: rage, fatigue, smoking, drinking too much wine, excessive coffee and strong tea, etc.

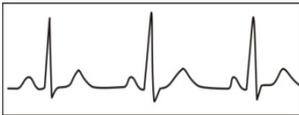


Figure 3 Bradycardia Waveform

Pathology: anemia, Hyperthyroidism, blood hypoxia, myocarditis, hypokalemia, fever, influence of some medication (such as atropine, epinephrine etc.).

Suggestion: If it belongs to pathology condition, please go to hospital.

2) **Bradycardia:** The heartbeat becomes more slowly. It is determined by the rhythm of the heart, the average rhythm is less than 60 beats per minute is considered as Bradycardia. The result description "Suspected slow beat" in this device may be doubted as Bradycardia.

Symptom: heart rate $<60bpm$

Indication: It occurs when healthy people fall asleep, and it can be found in athlete (or those who love doing sports frequently), old people, or vagus excitement person.

Pathology: Sick sinus syndrome, Ischemic heart disease, Cardiomyopathy, intracranial hypertension, increased hypokalemia, Low temperature, period of convalescence of acute infectious disease or after use some medicines such as digitalis.

Suggestion: If it belongs to the pathology condition, please see the doctor.

Premature beat: In a normal beat a QRS waveform appears prematurely and is followed by a comeback pause. The result description "Suspected occasional short beat interval" in this device may be doubted as Premature beat.

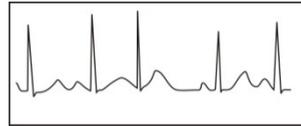


Figure 4 Premature Beat

What is premature beats? It is premature contraction. The normal heart beat is always regularly, and each beat interval is also symmetrically; Premature beat is out of this general regulation, the heart beats prematurely and followed by a long time interval; the phenomena of a premature beat between two heart beats is called inserting premature beat. The display of "early beat" may be suspected Premature beat. According to different original positions, it can be divided into Premature atrial Contraction, Premature Nodal Contraction and Premature Ventricular Contraction (PVC), which needed to be judged by experts.
Symptom: The heart beat is arrhythmic, it occurs as the phenomenon that the heart suddenly beats and then stops for a while. Some people have palpitation or have no symptom.

Indication: The premature beat can be found occasionally in healthy people, with no distinct symptom or sometimes with palpitation. This may be caused by fatigue, anxiety, insomnia, smoking too much, or drinking too much wine, coffee, strong tea etc. It can be recovered without treatment. However, if premature beat occurs frequently, continuously or in multi-focus, it will indicate functional cardiovascular disease. Please see a doctor as soon as possible.

Suggestion: The character of premature beat needs professional to confirm, so please save the temporal figure in time. When seeing a doctor, you can recall it to doctor to judge the character of premature (Premature atrial Contraction, Premature Nodal Contraction, Premature Ventricular Contraction or multi-focus premature beat) and help cure.

Testee's Symptom: Normal heart beat is followed by a premature beat.



Figure 5 Bigeminy

3) Bigeminy: It is a type of PVC in which a normal beat is coupled with a premature beat.

Because of its trigger cardiac abnormal pacemaker in different position, it divided into arial, ventricular and node. In the clinic medically, the ventricular is the most common, aria is more common, but the node is rarely found.

Indication: PVC occurs frequently.

Suggestion: Please see the doctor



Figure 6 Trigeminy

5) Trigeminy: It is a type of PVC in which two normal beats are coupled with a premature beat. Because of its trigger cardiac abnormal pacemaker in different position, it divided into Arial, ventricular and node. If ventricular trigeminy occurs 3 times continuously, please see a doctor as soon as possible.

Indication: PVC occurs frequently.

Suggestion: Please see the doctor.

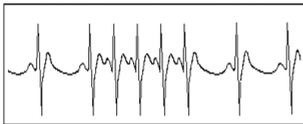


Figure 7 Tachycardia

6) Short run of tachycardia: PVC (Premature Ventricular Contraction) occurs more than 3 times continuously.

Testee's Symptom: PVC occurs More than 3 times continuously.

The heart beat is fast and regularly, but starts and stops suddenly.

According to the different of active original position, it can be divided into: Paroxysmal ventricular tachycardia, Paroxysmal supraventricular tachycardia (Needing professional to judge).

1) Paroxysmal supraventricular tachycardia: By atrial and nodal extrasystole cause to happen, frequency >180Dpm (time/minute).

Indication: Most commonly found in healthy people, it causes by deep respiration, tachypnea, positional changes, swallow, rage etc. It also appears in functional cardiac disease, such as Wolff - Parkinson-White Syndrome, rheumatic heart disease, coronary heart disease, Cardiomyopathy, Congenital heart disease, medicinal reaction (digitalis toxicosis) etc.

Suggestion: If it occurs time after time, please see the doctor as soon as possible.

2) **Paroxysmal ventricular tachycardia:** Caused by Premature Ventricular Contraction, Heart Rate >140bpm.

Indication: Most commonly found in heart disease patient, it can cause ventricle fibrillation if it's serious, so the tester needs to see a doctor immediately.

Suggestion: The character of short run needs professional to confirm, so please save the temporal figure in time. And you can provide it to doctor as a reference.

Appendix 3 EMC

The equipment meets the requirements of IEC 60601-1-2:2014.

Table 1

Guidance and manufacturer's declaration-electromagnetic emission		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Pulse Oximeter suitable for use in all establishments, including domestic establishments and those directly network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC61000-3-3	N/A	

Table 2

Guidance and manufacturer's declaration-electromagnetic emission			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge(ESD) IEC61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	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 IEC61000-4-4	±2kV for power Supply lines ±1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	±1kV line (s) to line(s) ±2kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycles <70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	N/A	N/A
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity

The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Pulse Oximeter should assure that it is used in such an electromagnetic environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	N/A 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of The Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2 d=1.2 80MHz to 800MHz d=2.3 800MHz to 2.5GHz 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 metres (m). b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ,a should be less than the compliance level in each frequency range .b Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 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 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, and electromagnetic site survey should be considered. If the measured field strength in the location in which The Pulse Oximeter is used exceeds the applicable RF compliance level above, The Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The Pulse Oximeter. b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Table 4

Recommended separation distances between portable and mobile RF communication the equipment			
The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W(Watts)	Separation distance according to frequency of transmitter M(Meters)		
	150kHz to 80MHz $d=1.2 \sqrt{P}$	80MHz to 800MHz $d=1.2 \sqrt{P}$	80MHz to 2,5GHz $d=2.3 \sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.38	0.73

1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be determined 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 absorption and reflection from structures, objects and people.

Quality Certificate

Name: Easy ECG Monitor

Model: PC-80D

Date: _____

QA: _____

This product has been inspected in accordance with
the standards specified in the User Manual.

Shenzhen Creative Industry Co., Ltd



Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.