
New Whittemore Enterprises digital touch screen 12-channel 12-lead ECG EKG



Statement

Our company owns all rights to this unpublished work and intends to maintain it as confidential information. This publication is used only for reference of operation, maintenance, or repair of our device. No part of this can be disseminated to others.

This document contains proprietary information, which is protected by copyright. All rights reserved. Photocopy, reproduction or translation of any part in the manual without our company's written permission is prohibited.

All information contained in this publication is believed to be correct. Our company shall not be liable for incidental and consequential damages in connection with the furnishing, performance, or use of this material. This publication may refer to information and protected by copyrights or patents and does not convey any license under the patent rights of our company, nor the rights of others. Our company does not assume any liability for arising out of any infringements of patents or other rights of the third parties.

Content of this manual is subject to change without prior notice.

Contents

| | |
|----------------------------------------------------------|----|
| Chapter1 Overview | 1 |
| 1.1 Overview | 1 |
| 1.2 Main Technical Specifications | 1 |
| Chapter2 Safety Notes | 2 |
| Chapter3 Warranty Regulation..... | 3 |
| Chapter4 Product Main Characteristics | 4 |
| Chapter5 Electrocardiograph Panel Sketch Map | 6 |
| 5.1 Each Panel View and its Components..... | 6 |
| 5.2 Key Definition..... | 7 |
| 5.3 Indicator Light Definition | 9 |
| Chapter6 Notes Before Operating | 10 |
| Chapter7 Preparations Before Operation | 11 |
| Chapter8 Notes During Operation | 12 |
| Chapter9 Usage of Recording Paper..... | 13 |
| Chapter10 Electrode Placement | 14 |
| 10.1 Chest Electrode Placement..... | 14 |
| 10.2 Limb Electrode Attachment | 14 |
| 10.3 Check-List for Electrodes and ECG cables..... | 15 |
| Chapter11 Grounding and Power Connection of Device | 16 |
| Chapter12 Battery Operation Notes..... | 17 |
| Chapter13 Control Panels and Key Instructions | 18 |
| 13.1 Main Interface | 18 |
| 13.2 Sampling Interface | 19 |
| 13.3 Case Information Inputting | 20 |
| 13.4 Case Management | 22 |
| 13.5 Case Querying..... | 22 |
| 13.6 Case Review..... | 23 |
| 13.7 Time and Data Settings | 24 |
| 13.8 System Settings | 25 |
| 13.9 Sampling Settings | 27 |
| 13.10 Print Settings..... | 28 |

| | |
|-------------------------------------------|----|
| 13.11 Checking Electrodes Placement | 30 |
| 13.12 About Us | 31 |
| Chapter 14 Troubleshooting | 33 |
| 14.1 Powering off Automatically | 33 |
| 14.2 AC Interference | 33 |
| 14.3 EMG Interference | 33 |
| 14.4 Baseline Drift | 33 |
| 14.5 Troubleshooting List | 34 |
| Chapter 15 Maintenance | 36 |
| Appendix | 37 |

Chapter1 Overview

1.1 Overview

12-channel Electrocardiograph is such a kind of electrocardiograph, which gathers 12-lead ECG signals simultaneously and prints out the ECG waveforms with thermal printing system. It's major functions are as follows: recording and displaying ECG waveforms in manual/auto ways; measuring and diagnosing ECG waveform parameters automatically; electrode-off and paper lack prompt; optional interface languages (Chinese/English); powered either by AC or DC; selectable rhythm lead to detect abnormal heart rate conveniently ;case database management, etc.

800*600 dots high resolution LCD screen; 1728 dot wide, it can print 12-channel ECG waveforms. You can operate either by buttons or touch screen, which is convenient and quick.

1.2 Main Technical Specifications

1.2.1 Environment conditions

Operation

- a) Environment temperature: +5℃~+35℃
- b) Relative humidity: ≤80%
- c) Power supply: AC:100V~240V,50/60Hz
DC:14.8V, 3700 mAh rechargeable lithium battery
- d) Atmospheric pressure: 86kPa~106kPa

Transportation and Storage

- a) Environment temperature: -10℃~55℃
- b) Relative humidity: ≤95%
- c) Atmospheric pressure: 50kPa~106kPa

1.2.2 Input way: Floating and defibrillation protection

1.2.3 Lead: Standard 12 leads(model:BIP0057)

1.2.4 Patient leak current: <10μA

1.2.5 Input impedance: ≥50MΩ

1.2.6 Frequency response: 0.05Hz~150Hz(-3dB~+0.4dB)

1.2.7 Time constant: Time constant ≥3.2s

1.2.8 CMRR: >60dB, >100dB(Adding filter)

1.2.9 EMG interference filter: 25Hz/35Hz(-3dB)

1.2.10 Recording way: Thermal printing system

1.2.11 Specification of recording paper: 210mm(W)*20m(L) high-speed thermal paper

1.2.12 Paper speed:

Auto record: 25mm/s, 50mm/s, error:±5%

Rhythm record: 25mm/s, 50mm/s, error:±5%

Manual record:5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s, error:±5%

1.2.13 Sensitivity selections: 2.5,5,10,20,40mm/mV, error:±5%. Standard sensitivity is 10mm/mV±0.2mm/mV.

1.2.14 Auto record: Record setup according to auto record format and mode, automatically changing leads, measuring and analysing.

1.2.15 Rhythm record: record setup according to rhythm record format and mode, automatically measuring and analysing.

1.2.16 Manual record: record setup according to manual record format, manually changing leads.

1.2.17 Measurement parameters: HR, P-R interval, P Duration, QRS Duration, T Duration, Q-T interval, Q-Tc, P Axis, QRS Axis, T Axis, R(V5), S(V1), R(V5)+S(V1).

1.2.18 Product safety type: Class I CF applied part; there is defibrillation and pacing protection circuit in it.

1.2.19 Enduring polarization voltage: ±500mV

1.2.20 Noise level: ≤15μVp-p

1.2.21 Fuse specification: 2 pcs φ5*20mm AC time lag; T1.6A/250V(Power supply 220V)

1.2.22 Size: 340mm(L)*320mm(W)*85mm(H)

1.2.23 Net Weight: 3.2Kg

Chapter2 Safety Notes

- 2.1 The power supply should be grounded properly before operation.
- 2.2 If there are any questions for the integrality of protective grounding cable, the device must be run with built-in power supply.
- 2.3 Please pull out power supply plug before changing the fuse.
- 2.4 This device must be operated by medical staff trained technically and professionally, preserved by special person.
- 2.5 The operator must read this instruction manual carefully before operation, and operate the device according to operation regulations strictly.
- 2.6 The design of this device has mature consideration of security, but operator should never neglect attention to device state and patient's observation.
- 2.7 Please turn off the device and pull out power supply plug before cleaning and disinfection .
- 2.8 Please don't use this device in the presence of flammable anaesthesia gas.
- 2.9 Don't rub the screen with edge tools or sharp materials.
- 2.10 If this device is used with cardiac defibrillator or other electric stimulating devices at the same time, please choose Ag/AgCl chloride chest electrode and ECG lead cables with defibrillation function. To prevent the metal electrode from burning patients' skin, the disposable chest electrode should be used if the defibrillation time is over 5seconds. It is better not to use this device with other electric stimulating devices at the same time. If it is necessary, there must be professional technician guiding on the scene.
- 2.11 When connected with this ECG device, others must be Type I equipment complied with IEC60601-1. Because the total leakage current may injure patient, the monitoring of leakage current shall be carried out and taken charge by the connected devices.
- 2.12 Notes concerning ECG waveform measurement and analysis
 - (1) P wave and Q wave identify are not always reliable with intensive EMG or AC interference. Neither are the ST segment and T wave with baseline drift.
 - (2) Winding and unclear end position of S wave and T wave may cause error in measurement.
 - (3) When R wave is uninspected caused by some leads off or QRS wave low voltage, the heart rate measurement may deviate greatly from the correct.
 - (4) In case of QRS low voltage, ECG axis calculation and border-point identify of QRS wave are not always reliable.
 - (5) Occasionally, frequent ventricular premature complexes may be identified as dominant beat.
 - (6) Merging of versatile arrhythmias may result in unreliable measurement because of the difficulty in distinguishing P wave in such situation.
 - (7) This device is designed with auto analysis function, which only analyses the ECG waveforms it gathers and does not reflect all patient's states. Its analysis results may be not in accordance with doctor's diagnoses. Therefore, the final conclusion concerning each patient is up to the doctor basing on analysis results , patient symptoms, and other examinations together.

Chapter3 Warranty Regulation

3.1 In normal use, under strict observance of user manual and operation notes, in case of failure, please contact with our customer service department. Our company has the sales record and customer archives for each device. The customer has one year's warranty service from the date of shipping according to the following conditions. To supply all-around and quick maintenance service for you, please mail the maintenance card to us in time.

3.2 Our company may adopt such ways as guidance, express to company or calling in, etc to carry out warranty promise.

3.3 Even in warranty period , the following repairs are charged in principle:

3.3.1 Faults or injuries caused by misuse not according to user manual and operation notes.

3.3.2 Faults or injuries caused by dropping accidentally when moving after purchasing.

3.3.3 Faults or injuries caused by repair, reconstruction, decomposition, etc not in our company.

3.3.4 Faults or injuries caused by natural disasters such as fire, flood, earthquake, etc.

3.3.5 Faults or injuries caused by improper thermal recording paper.

3.4 The warranty period for accessories and fray parts is half a year. Power cable, recording paper, operation manual and packing material are excluded.

3.5 Our company is not responsible for the faults of other connected devices caused by the faults of this device directly or indirectly.

3.6 The warranty regulations are effective only in Chinese Mainland.






3.7 The warranty will be canceled if we find the protection label has been destroyed.

3.8 For charged maintenance beyond warranty period, our company advises to continue using "Maintenance contract regulation". Please refer to our customer service department for details.

Chapter4 Product Main Characteristics

- 4.1 Display with 800*600 dots color LCD, operate either by buttons or touch screen, which is convenient and quick.
- 4.2 With high resolution thermal print system (8 dots/mm), it needs no adjustment, and the record frequency is up to 150Hz.
- 4.3 Real-time and continuously record clear and exact 12 channel ECG waveforms and remarks. The remarks include lead sign, sensitivity, paper speed and filter state,etc.
- 4.4 In auto mode, one button operation to complete record, which will improve work efficiency.
- 4.5 Full digital filter design, against baseline draft, AC and EMG interference.
- 4.6 Baseline auto adjusted, optimized print setup, selectable rhythm lead.
- 4.7 Full touch keyboard control makes operations more convenient and the device status are clear and easily read through LCD screen.
- 4.8 The device can be powered either by AC or DC, with built-in lithium rechargeable battery and auto protection circuit, without operation, auto powering off time can be set up.
- 4.9 This device can record 300 pieces of ECG and print 180 minutes continually in the best DC state.
- 4.10 This device can store more than 1000 cases, more convenient for data review and statistic.
- 4.11 The figure of whole device is elegant and gliding.
- 4.12 One button operation to complete printing and storing.
- 4.13 The device adopts digital signal processor, through AC, DFT and EMG filters to obtain electrocardiogram of high quality.
- 4.14 The device has such functions as measuring, analysing and diagnosing conventional ECG parameters automatically to reduce doctor's burden and improve work efficiency.
- 4.15 The device gathers 12-channel ECG signals synchronously and then analyses record modes of such channels as 12*1, 6*2+1, 6*2, rhythm row12, row10, row8, row6,etc, with multiply report formats.
- 4.16 With multiply lead display modes, the device can observe 3,6,or 12 lead real-time waveforms, and display such information as lead-off and printer paper lack, etc, also with ECG parameter auto-detected and analysis reports, and record waveforms in auto/manual mode, with database to store patient information.
- 4.17 Safety Classification: Class I, defibrillator-proof type CF applied part .
- 4.18 The degree of protection against entry liquids: IPX0.
- 4.19 According to the degree of safety of application in the presence of a flammable anaesthetic mixture with air: Equipment not suitable for use in the presence of the gas above.
- 4.20 According to the mode of operation: Continuous operation.

4.21 Explanation of some symbols in this device:

| | |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------|
| ~AC | AC work mode |
| OFF | Power supply is disconnected |
| ON | Power supply is connected |
|  | Equipotential grounding post |
|  | Refer to instruction manual/booklet |
|  | Type CF applied part with defibrillation protection function |
|  | RS232 I/O |
|  | USB port |



Lead connector

WEEE (2002/96/EC)



This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.

Chapter5 Electrocardiograph Panel Sketch Map

5.1 Each Panel View and its Components

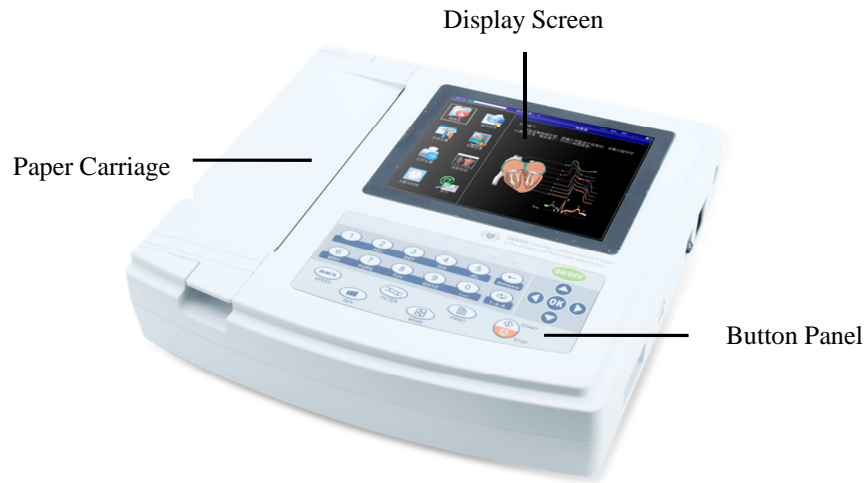


Figure 5-1 Front view

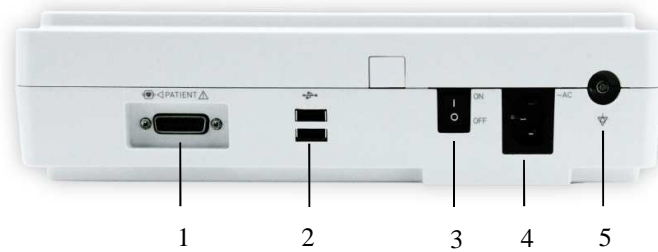


Figure 5-2 Side view

- 1、Lead Connector
- 2、USB Port

- 3、 Power Switch
- 4、 AC Input
- 5、 Grounding Post



Figure 5-3 Bottom view

5.2 Key Definition



Function key: This key is used to turn the device on or off.

Function key: This key is used to begin or stop sampling.

Function key: This key is used to select filter function.

Function key: This key is used to adjust paper speed.

Function key: This key is used to adjust gain.

Function key: This key is used to switch printing modes.

Function key: This key is used to start printing.



Function key: This key is used to confirm the operation you have done.



Function key: This key is backspace.



Function key: This key is used to switch input methods.



Direction key: Up



Direction key: Down



Direction key: Left



Direction key: Right



Number/Capital and Small letter/Character key: 0/Space/,



Number/Capital and Small letter/Character key: 1/.



Number/Capital and Small letter/Character key: 2/abc/ABC/:



Number/Capital and Small letter/Character key: 3/def/DEF/;



Number/Capital and Small letter/Character key: 4/ghi/GHI/*



Number/Capital and Small letter/Character key: 5/jkl/JKL/%



Number/Capital and Small letter/Character key: 6/mno/MNO/'



Number/Capital and Small letter/Character key: 7/pqrs/PQRS/#



Number/Capital and Small letter/Character key: 8/tuv/TUV/(



Number/Capital and Small letter/Character key: 9/wxyz/WXYZ)

5.3 Indicator Light Definition



When green, the light indicates that the device is powered by AC supply; while red and green, it indicates the battery is charging.



Powering on indicator light.

Chapter6 Notes Before Operating

6.1 To use the device safely and effectively, you should read the user manual carefully before operation.

6.2 Notes for installation and storage:

6.2.1 The device shall be keep away from high voltage cable, X-ray equipment, ultrasound device or electrotherapeutics machine, etc.

6.2.2 Avoid using and storing the device in the places with high air pressure, temperature and humidity beyond common standard, bad ventilation, excessive dust or salt-alkali gas and chemical medicine.

6.3 The device should be put on flat place and taken and put lightly when moved. Avoid too strong vibration and shock.

6.4 AC frequency and voltage value should be in accordance with the requirements to ensure enough current capacity.

6.5 Please place the device indoor where is easy to be grounded. Do not connect the patient and his connected cables with other conductors, including ground or beds which can be conducted well with ground.

Chapter7 Preparations Before Operation

- 7.1 Ensure the device is grounded and all the cables are connected reliably.
- 7.2 Ensure the electrodes, directly connected with patient, are placed correct and reliable.
- 7.3 If you have selected to purchase UPS, check whether the output voltage is normal or not.
- 7.4 Electric gel coats should be separated and chest electrodes should not connect with each other , so as to avoid short circuit.
- 7.5 AC power cable should not enlace with ECG lead cables.

Chapter8 Notes During Operation

- 8.1 Pay attention to the patient and device status at any moment.
- 8.2 Patient and device can only be connected through ECG lead cables.
- 8.3 Keep close observation of the patient and device to make sure they are still during operation.
- 8.4 Turn off the device after using.
- 8.5 Disconnect the power, and remove the ECG lead cables gently without strong force.
- 8.6 Properly keep the device and its accessories for operation next time.
- 8.7 Recording Paper Loading
 - 8.7.1 The device adopts high-speed thermal recording paper with the specification of 210mm(W)*20m(L).
 - 8.7.2 Open the cover of paper carriage, take out the paper roll and install it into recording paper then load them at the proper position inside the carriage.
 - 8.7.3 Close the cover of paper carriage. It's recommended to leave 2cm paper outside.

Chapter9 Usage of Recording Paper

9.1 When recording, the device will stop paper trace in case of paper lack, and the LCD screen will display as the figure below to prompt paper lack.(See Figure 9-1)

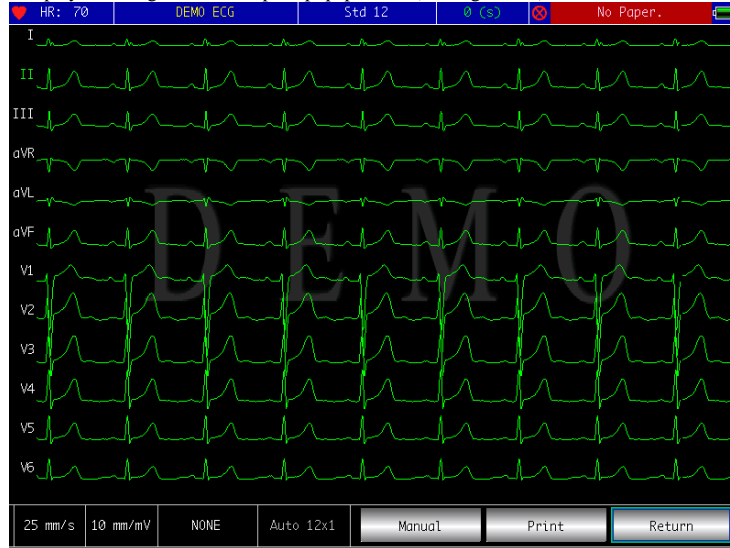


Figure 9-1

9.2 It is recommended to use the thermal recording paper specified by our company to ensure ECG waveforms of good effect. Bad recording paper will result in unclear ECG waveforms, fading or unsmooth paper trace, etc, even pricking up the device's worn up and shortening the service cycle of such important components as printer head. Please consult your manufacture or our company for purchasing this recording paper.

9.3 High temperature, humidity or direct sunniness may all be the causes for recording paper failure. The paper, which will not be used for long, shall be stored in place cool, dry and dark.

9.4 Substance may contaminate surface of the recording paper:

Gel, glue, and half-dry diazo compound copy paper, etc, including their organic solvent.

9.5 Substance may cause the waveforms to disappear:

Soft PVC folders, plastic, etc; demagnetization machine and tape containing plasticizer; Some fluorescence ink pen and stamp-pad ink, etc.

Chapter 10 Electrode Placement

It is better to attach chest electrodes first, then the limb electrodes.

10.1 Chest Electrode Placement

See Figure 10-1:

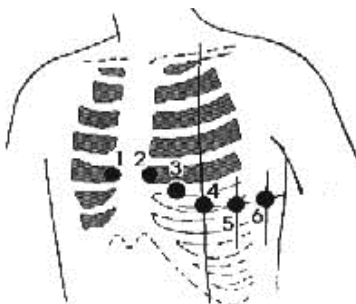


Figure 10-1

Attach the chest electrodes to the locations as following:

V1: Fourth inter-costal space at right border of sternum.

V2: Fourth inter-costal space at left border of sternum.

V3: Midway between V2 and V4.

V4: Fifth inter-costal space at left mid-clavicular line.

V5: Left anterior axillary line at the horizontal level of V4.

V6: Left mid-axillary line at the horizontal level of V4.

Clean the skin where chest electrodes are to be attached with alcohol, then apply ECG cream to here around 25mm in diameter and to the edge of chest electrodes, then press and attach the electrodes to the positions from V1-V6.

Note: Keep in mind that the electrodes' coming into contact with each other or cream's overlap from one position to another is not allowed to avoid short circuit.

10.2 Limb Electrode Attachment

Electrodes should be placed on the soft skin of hands and feet. Clean all the limb electrodes and the positions where limb electrodes are to be attached with alcohol before applying ECG cream to them, then firmly attach the electrodes to the positions. (See Figure 10-2)

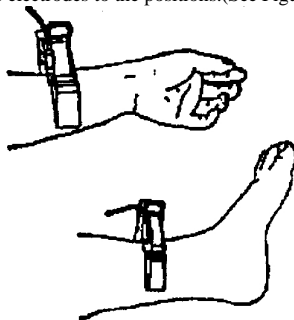


Figure 10-2

Note: Screw tightly the knob of ECG cable's plug after it is inserted to the ECG connector.

10.3 Check-List for Electrodes and ECG cables

| Electrode Location | Electrode Symbol | Plug No. |
|--------------------|------------------|----------|
| Right Arm | RA/R | 9 |
| Left Arm | LA/L | 10 |
| Left Leg | LL/F | 11 |
| Right Leg | RL/N | 14 |
| Chest 1 | V1/C1 | 12 |
| Chest 2 | V2/C2 | 1 |
| Chest 3 | V3/C3 | 2 |
| Chest 4 | V4/C4 | 3 |
| Chest 5 | V5/C5 | 4 |
| Chest 6 | V6/C6 | 5 |

Chapter11 Grounding and Power Connection of Device

Make sure power supply is off, plug the 3-line connector in the device, the other end into power receptacle which should be center grounded. It is prohibited to use water pipe or other pipeline as grounding cable. Properly grounded can ensure the safety and reduce the interference of AC and other electromagnetic wave.








Chapter12 Battery Operation Notes

12.1 The device is designed with built-in full-sealed and non-maintained rechargeable lithium battery, also equipped with perfect auto-charging-discharging monitor system. When the device is connected to AC power supply, the battery will be charged automatically. Battery status will be displayed on right edge of LCD screen(see 12.4) in powering on state. It needs about 4 hours to charge the battery full after absolute discharge.

12.2 The device can continuously print for 90 minutes and work for more than 10 hours in standby mode when battery is completely charged. When the device is powered by battery, there will be a battery indicator in LCD screen of the front panel, showing the battery capacity in 5 modes. When the battery capacity is too low for the device to operate, the device will turn off automatically to avoid forever damage to the battery.

12.3 The battery should be recharged in time after discharged completely. If not used for long, the battery should be recharged every 3 months, which can extend the life of the battery..

12.4 Seven power status displayed on LCD are showed in the table below:

| No. | Indicator | Description |
|-----|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| a |  | Unknown status, which is usually displayed within 1 minute after the device is turned on. |
| b |  | Using AC supply |
| c |  | Using battery, full power |
| d |  | Using battery, capacity : 3/4 |
| e |  | Using battery, capacity: 1/2 |
| f |  | Using battery, capacity : 1/4 |
| g |  | Using battery, low power, it is recommended to recharge the battery or use AC supply. |

Note: When charged, the battery icon shifts from f to c.

12.5 When the battery can not be recharged or works no more than 10 minutes after fully charged, please replace the battery.

Attention:

- Do not directly connect the battery polars "+" with "-" by wire, otherwise it might cause fire hazard.
- Avoid placing the battery where fire is present, or there will be explosion hazard.
- Please don't disassemble the sealed battery.

Chapter13 Control Panels and Key Instructions

13.1 Main Interface

See Figure 13-1:

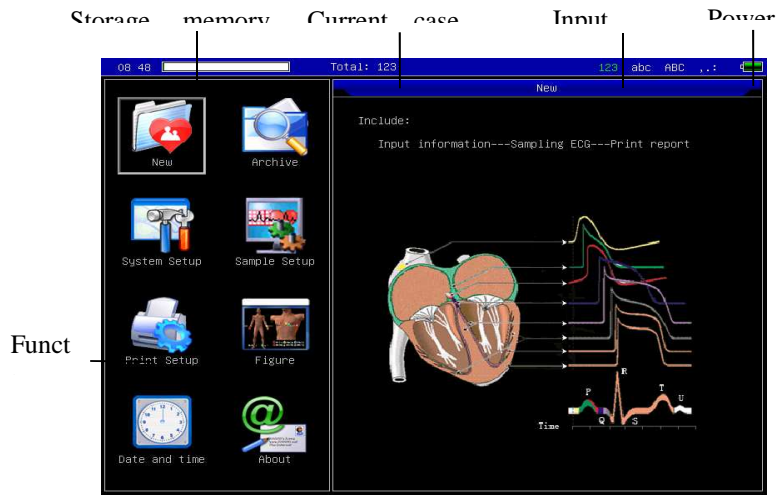


Figure 13-1

Power status:Please refer to 12.4

Function Buttons:



Click to Enter the sampling interface, when powered on, the device will automatically enter this interface.



Click to enter case management interface, where you can query , modify or delete case informations



Click to see the sketch map for electrode placement



Date and time settings



System settings







Sampling settings



Printing settings, including printing mode, style and content.





About us, displaying information about our company and software version, etc.

Quick switch: switch function from one to another quickly with these buttons    on the keyboard, and press  to set up the function selected.

13.2 Sampling Interface



Select  in the main interface or use shortcut key  on the keyboard to enter sampling interface.

Note: Because of the setup about information input time in system settings, it needs to input case information before sampling (refer to 13.3 Patient Information Input).

Sampling interface provides several lead display modes, including: 3 leads, 6 leads, and 12 leads, and the following interface displays 12 leads. (See Figure 13-2)

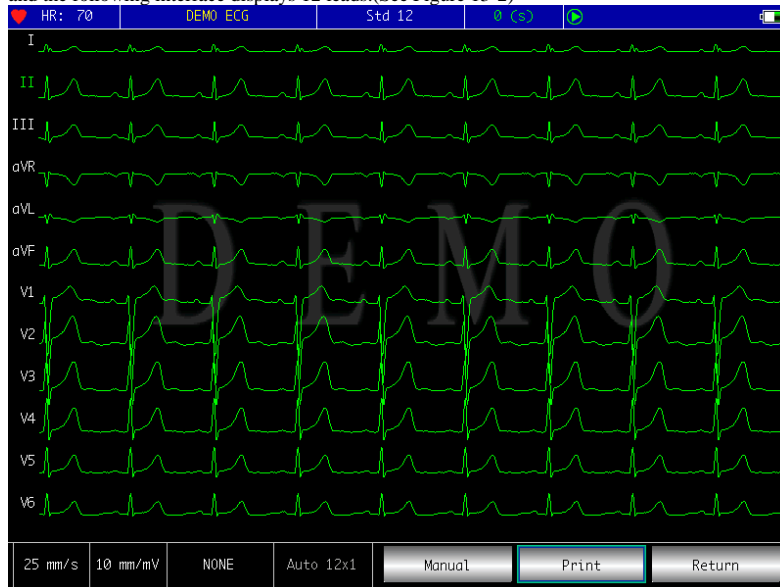




Figure 13-2


Stop sampling: when the device is sampling, you can click the menu button  on the keyboard panel to stop and return to the main interface.


Switch lead display mode: Double click the waveform on the screen to switch display mode


among 3 leads ,6 leads, and 12 leads.

Lead-off information: In Demo mode, it displays "DEMO ECG", while in sampling mode, it displays lead-off information detected.

Switch printing mode: when data mode is After Print, with the button  on the keyboard, you can change the printing mode among manual, auto 12*1, auto 6*2+1, auto 6*2, auto 3*4+2, rhythm 12, rhythm 10, rhythm 8, rhythm 6.

Adjust gain (Sensitivity): With the gain adjusting button  on the keyboard, you can switch among 2.5mm/mV , 5mm/mV , 10mm/mV , 20mm/mV, 40mm/mV .

Adjust paper speed:With the key of speed adjusting button  on the keyboard ,you can adjust paper speed among 5mm/s,6.25mm/s,10mm/s, 12.5mm/s, 25mm/s, 50mm/s.


Switch filter:With the key of filter selection button  on the keyboard ,you can switch filter among no filter, AC, EMG, DFT, AC+EMG, AC+DFT, EMG+DFT, AC+EMG+DFT.

- AC: AC Filter
- EMG: EMG Filter
- DFT: Baseline Filter

Print/Finish Printing: With the printing button  on the keyboard, you can begin or finish the printing operation.

Auto Mode: After starting printing, automatically the system prints and stores synchronous 12 leads waveforms, of which the length is according to related setup in printing settings, and also according to this to print analysis data and conclusion, then finish printing automatically.

Manual Mode: After starting printing, the user can print different lead instant waveforms by switching the lead displayed, namely the ECG printed in manual mode is not synchronous and

the data will not be saved. You need to stop printing by pressing  again.

During printing process, the printing state and display content mainly include:

| Display content | Explanation |
|-----------------|--------------------------------------------------------------------|
| Process... | It is printing. |
| Waiting... | It is finishing printing. |
| No Paper. | Paper lack, the user should restart printing after loading paper. |
| Print Timeout | Communication failure between this system and printing sub-system. |
| ECGTimeout | Communication failure between this system and sampling sub-system. |
| Low Power | Low power, it cannot start printing |

13.3 Case Information Inputting

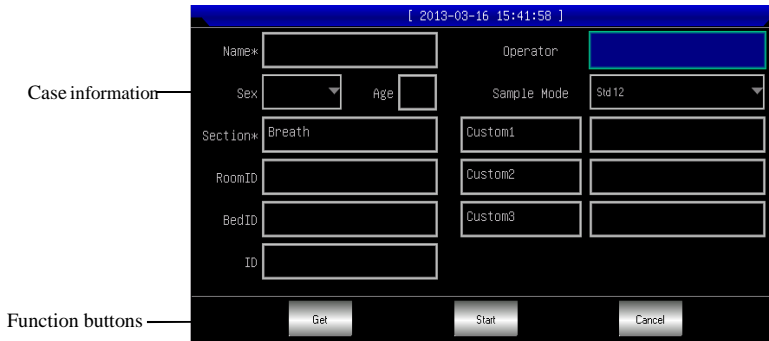



Figure 13-3

Select [Get] button, you can get the latest information of 10 patients, and the patient information will be automatically added to the corresponding edit box after selecting it.

Choose any item, by pressing  key, the screen keyboard will pop up as follows. Here click [Caps] button to switch between number/capital letter and number/small letter; press [Space] to input a space; press [Bkspace] to delete the character input last; press [OK] to confirm input and exit this interface. (See Figure 13-4)

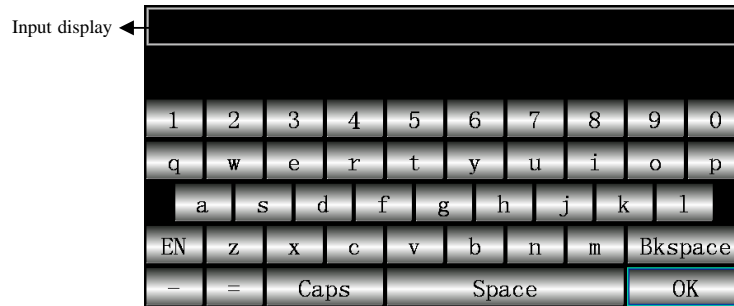


Figure 13-4

According to the limits of information, the screen keyboard has some character input limits, which will be showed in gray and are unavailable, as shown in the figure below (See Figure 13-5):

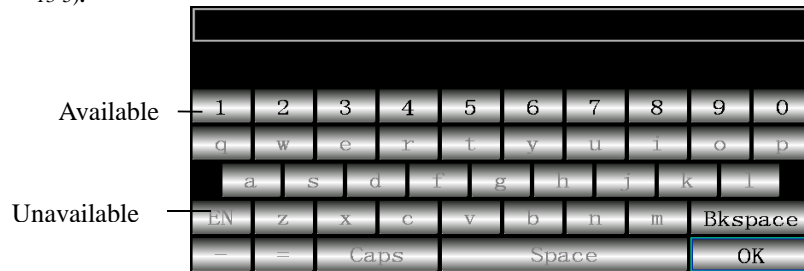




Figure 13-5

Besides, you can select the numbers in control panel to edit, press  to switch among numbers, small and capital letters or character input methods, and press  to delete the character last input. According to the limits to some information, when switching the input methods, the selected turns to be green and the limited gray and unavailable.

13.4 Case Management



Select the button in main interface to enter the case management interface, as shown below.(See Figure 13-6)

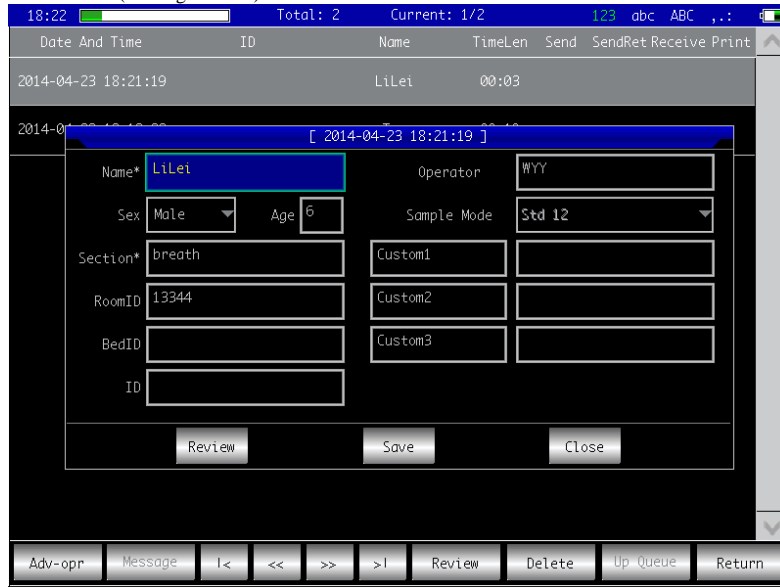






Figure 13-6

This interface displays all cases stored in the device. The user can select the case needed using the querying function (Refer to 13.5Case Querying); using editing function to edit and delete any case informations; besides, you can review the case informations stored(Refer to 13.6 Case Review).

-  : Select it, and the case list will turn to the first page .
-  : Select it, and the case list will turn to the last page .
-  : Select it, and the case list will turn to the former page .
-  : Select it, and the case list will turn to the later page .

13.5 Case Querying

Select [Query] in the[advanced] button and the case querying dialogue box shown below will

pop up. Input the query condition, click [Query], and the expected results will occur. Click [Clear], and the system will delete all the querying conditions input. (See Figure 13-7)

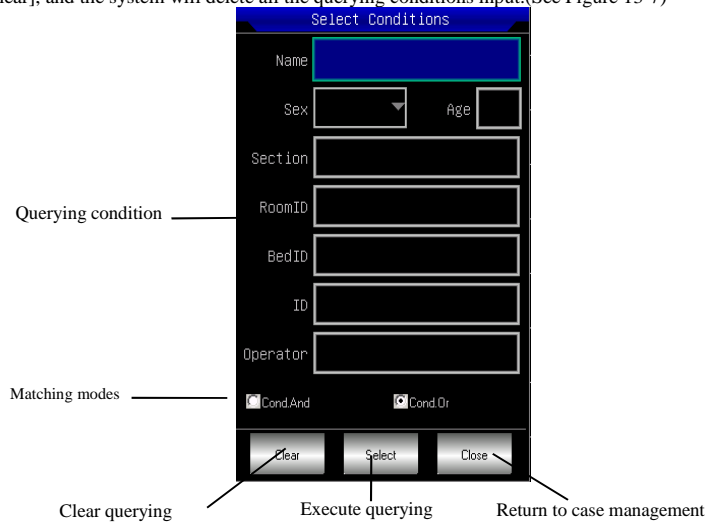


Figure 13-7

Here, [Cond.And] and [Cond.Or] are matching modes for querying condition, and only one can be selected. If you select [Cond.And], the displayed querying results have to satisfy all the conditions input; while for [Cond.Or], they only need to satisfy any conditions input.

Suggestion: In case of multiply cases, it is better to input all decided querying conditions, select [Cond.And] to find the corresponding case quickly.

13.6 Case Review

In case management interface, select the case you want to review, click [Review] to pop up the dialogue box shown below, which displays case information, here you can edit content, click [Save] to confirm modification and note it is not reversible. (See Figure 13-8)

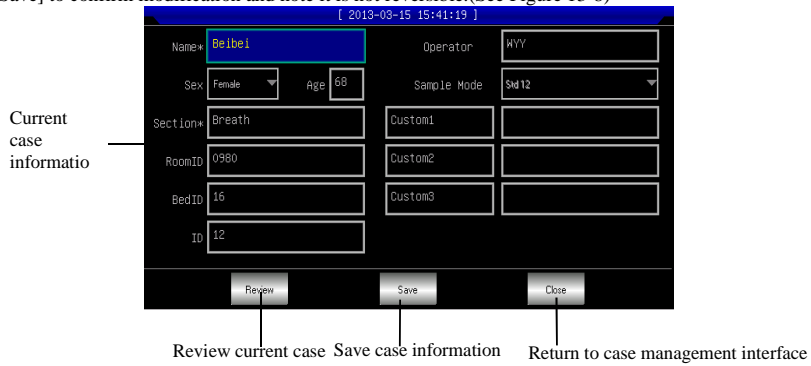


Figure 13-8

After ensure the selection, click [Review] to enter the review interface shown below, which is similar to the gathering interface. (See Figure 13-9)

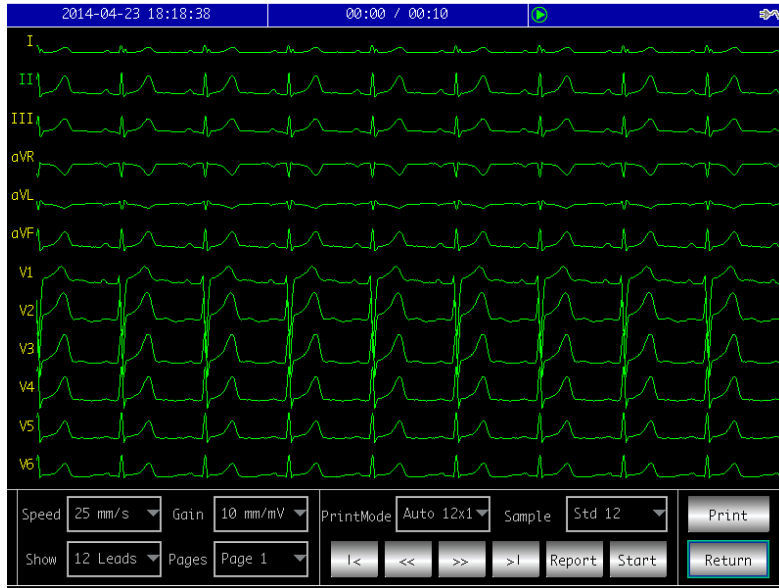





Figure 13-9

In this interface, user can switch printing modes by the button ; click  to begin printing.

13.7 Time and Data Settings



In the main interface, select  button, and data and time setting dialogue box shown below will pop up.(See Figure 13-10)

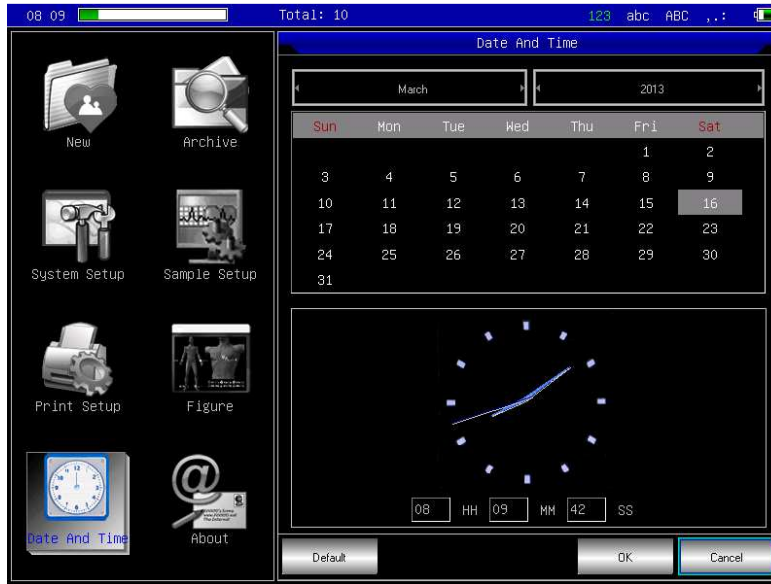



Figure 13-10

In this interface, user can switch options through  , and use   to edit option content.

13.8 System Settings



In the main interface, select  button, and system settings dialogue box shown below will pop up.(See Figure 13-11)

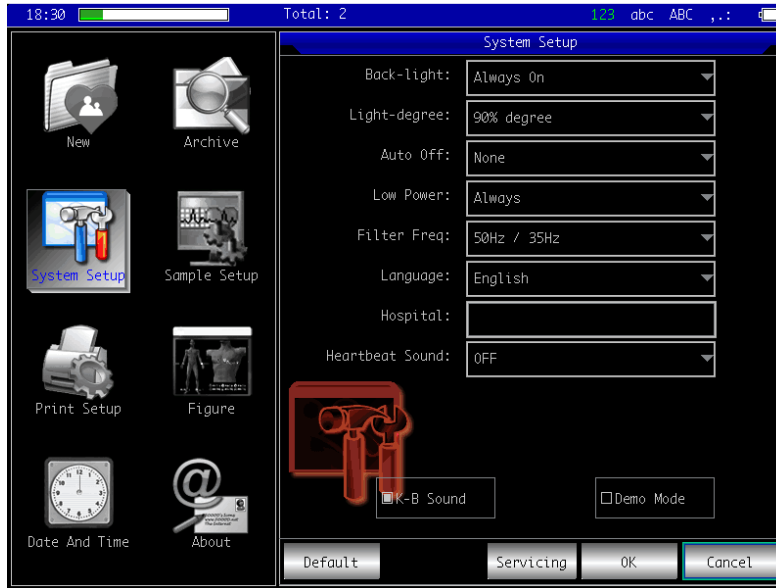


Figure 13-11

Here, click the button[Default], and the system settings will back to default. Each item, its options and explanation are shown in the table below.

| Item | Options | Explanation |
|-----------------|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| Back-light | 30Seconds/1Minute/ 2Minutes/5Minutes/ 10Minutes/Always On | If there is no operation for the time selected, screen backlight will be turned off. Select "Always On" to keep screen backlight on. |
| Light-degree | [90%degree]/[80%degree] /[70% degree]/[50% degree] | After setting light degree, the screen will display different backlight strength. |
| Auto off | [1 minute]/[3 minutes]/ [5 minutes]/[10 minutes]/ [15 minutes]/[30 minutes]/ [60 minutes]/[None] | If there is no operation for the time selected, the system will power off automatically. Select "None" and the system will not power off automatically. |
| Low Power | [Always]/[Only once]/[None] | When in low power, this can decide the alarm method. |
| Filter Freq | [50Hz/35Hz]/[50Hz/25Hz] /[60Hz/25Hz]/[60Hz/35Hz] | Set up the parameter compounding of AC Filter and EMG Filter. |
| Language | [English]/[Chinese] | Set up the language displayed. |
| Hospital | Custom | Custom the name of hospital |
| Heartbeat Sound | [ON]/[OFF] | Set the heartbeat sound |

| | | |
|-----------|--------|----------------------------------------------------------------------|
| K-B Sound | On/Off | Select to activate key-press sound, and not select to dumb it. |
| Demo Mode | On/Off | Select to make the system operate in demo mode, or in sampling mode. |

13.9 Sampling Settings



Select  in the main interface, the sampling setting dialogue box will pop up shown below.(See Figure 13-12)

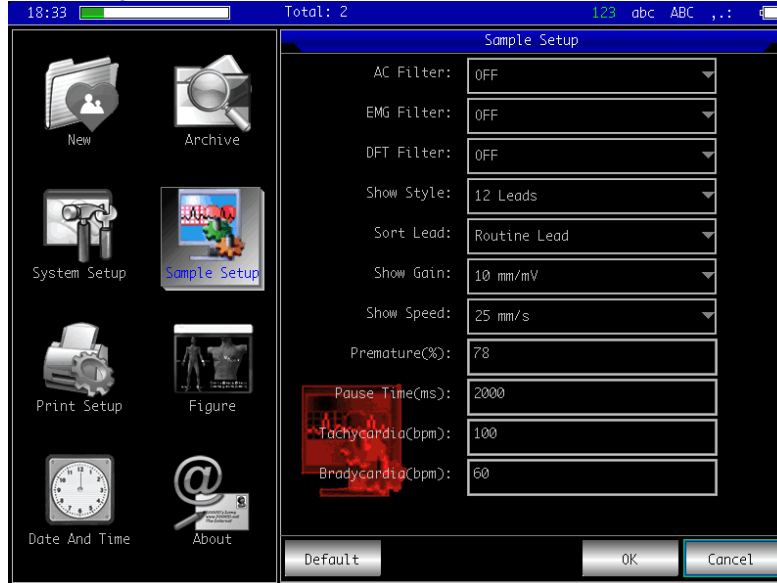


Figure 13-12

Here, select the button[Default], the sampling settings will go back to the default.
Each item, its options and explanation are shown in the table below.

| Item | Options | Explanation |
|-------------|--------------------------------------------------------------------------------------|--------------------------------------------------------|
| AC Filter | [ON]/[OFF] | Set up whether to use AC Filter or not. |
| EMG Filter | [ON]/[OFF] | Set up whether to use EMG Filter or not. |
| DFT Filter | [ON]/[OFF] | Set up whether to use DFT Filter or not. |
| Rhythm Lead | [I] / [II] / [III] / [avR] / [avL] / [avF] / [v1] / [v2] / [v3] / [v4] / [v5] / [v6] | Set up rhythm lead to use for printing in rhythm mode. |
| Show Style | [3 leads]/[6 leads]/[6*2 leads]/[12 leads] | Set up the ECG display mode in screen. |
| Sort lead | [Routine Lead]/[Cabrera Lead] | Switch mode between Routine Lead and Cabrera Lead |

| | | |
|----------------------|-------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Show Gain | [2.5mm/mV]/[5mm/mV]/[10m m/mV]/[20mm/mV] /[40mm/mV] | Set up the ECG gain in screen. |
| Show Speed | [5mm/s]/[6.25mm/s]/[10mm/s]/ 12.5mm/s]/[25mm/s]/[50mm/s] | Set up ECG sweep speed in screen, but when printing in auto and rhythm mode , it does not support 5mm/s, 10mm/s, 12.5mm/s. |
| Premature(%) | 0 ~ 100 | The system will use the input value as a standard of judging premature beat. |
| Pause Time(ms) | 1200 ~ 3000 | The system will use the input value as a standard of judging beat pause. |
| Tachycardia(bpm) | 0 ~ 250 | The system will use the input value as a standard of judging tachycardia. |
| Bradycardia(bpm) | 0~99 | The system will use the input value as a standard of judging bradycardia. |

13.10 Print Settings



Select the **Print Setup** button in the main interface, the printing setting dialogue box will pop up shown below.(See Figure 13-13)

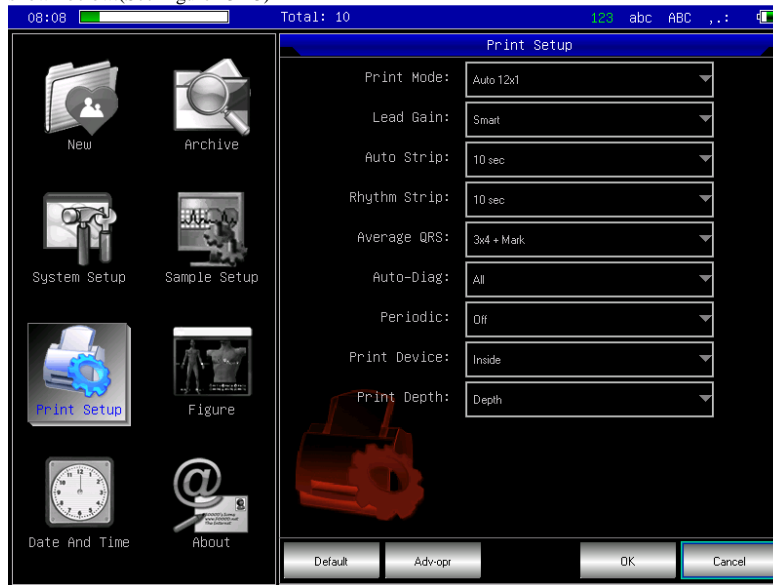


Figure 13-13

Click the button[Default], the print settings will go back to the default.
Each item, its options and explanation are shown in the table below.

| Item | Options | Explanation |
|--------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Print Mode | [Auto 12*1]/[Auto 6*2+1] /[Auto 6*2]/[Auto 3*4+2]/[Rhythm 12] /[Rhythm 10]/[Rhythm 8] /[Rhythm 6] | The selection will be used as the default printing mode. |
| Lead Gain | Smart/Current | The option selected will be used as printing gain mode. "Smart" means the system will adjust gain automatically to fit paper height; "Current" means it will use screen waveform gain as that of printing. |
| Auto Strip | 3Sec/4Sec/5Sec /6Sec/8Sec/10Sec/ 15Sec/20Sec/25Sec | The selection will be used as the time for printing each strip. |
| Rhythm Strip | 10Sec/15Sec/20Sec /25Sec/30Sec | In printing mode, when selecting rhythm 12, rhythm 10, rhythm 8, or rhythm 6, the system will use the time selected as the time for printing each row waveform. |
| Average QRS | [3*4+Mark]/[3*4]/ [None] | In printing mode, when selecting "Rhythm" Or "Auto", the system will use the format selected to print average QRS waveform. |
| Auto-Diag | All/Data /Conclusion/NonePrint | Printing diagnosis includes data and conclusion, you can select as your need. |
| Periodic | [per1Min]/[per 2 Min]/[per3Min] /[per5Min]/[per10Min]/[per20Min] /[per30Min]/[per 60 Min]/[off] | When gathering ECG, the system will activate printing according to the duration selected. When printing mode is manual, it will print in "Auto 12*1" mode, or in the mode currently set . |
| Print device | [Inside]/[Qoutside A4] | choose prints out the ECG waveforms with thermal printing system or USB external printer. |
| Print depth | [depth]/[shallow] | Choose wave print depth. |

Note: "Auto Strip", "Rhythm Strip", "Average QRS", "Auto-Diag", "Periodic" are only available in auto and rhythm printing mode.

In [the Print Setup] interface, click [Adv-opr] to enter the print settings advanced interface . as shown below:

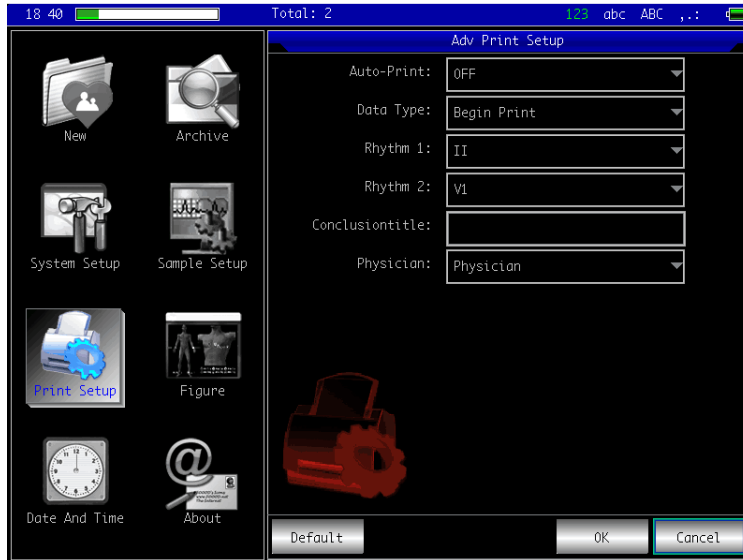


Figure 13-14

| Item | Options | Explanation |
|------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Auto Print | [ON]/[OFF] | Not support at present. |
| Data pattern | [Begin Print]/[After Print] | Set the print data to the data before pressing [Print] key or after pressing the key. |
| Rhythm 1 | [I] / [II] / [III] / [avR] / [avL] / [avF] / [v1] / [v2] / [v3] / [v4] / [v5] / [v6] | Set the rhythm lead, used for rhythm patterns lead print. |
| Rhythm 2 | [I] / [II] / [III] / [avR] / [avL] / [avF] / [v1] / [v2] / [v3] / [v4] / [v5] / [v6] | Set[Auto 3*4+2] , used for rhythm patterns lead print. |
| Conclusion title | Default is [Conclusions] words | Set print conclusion title. |
| Physician | [Physician]/[Specialist] | Set the default language of system. |

13.11 Checking Electrodes Placement

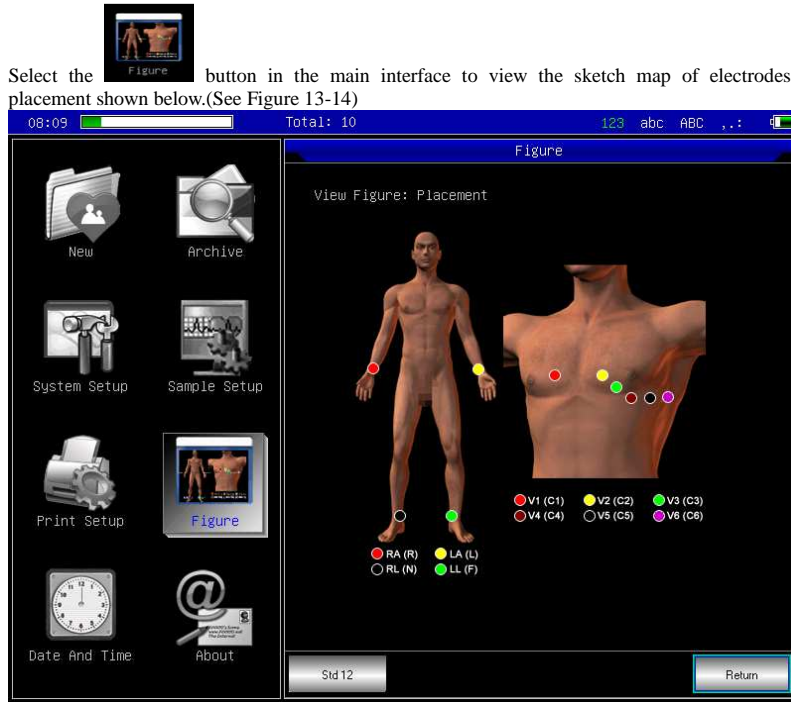



Figure 13-15

Click **【std 12】** to switch the placement sketch map about 12 leads and add 6leads
 Click **【return】** to exit interface.

13.12 About Us

Select the  button in the main interface, the interface shown below will pop up, which contains information related to this device.(See Figure 13-15)

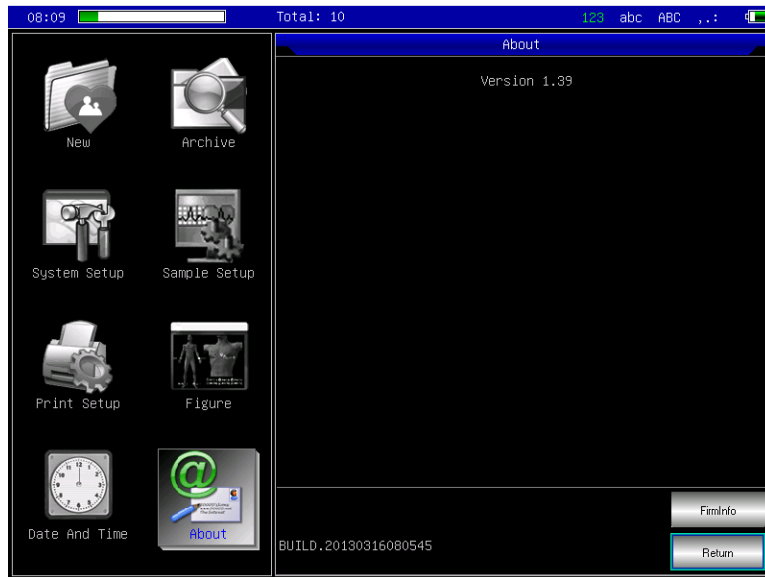


Figure 13-16

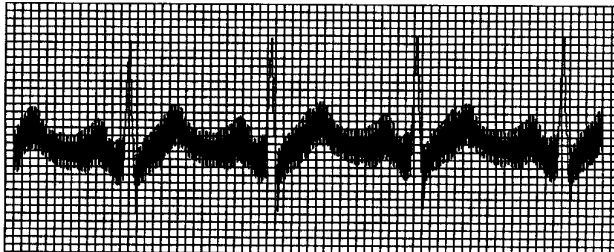
This interface shows the device name, version number, company name, copyright and our contact details.

Chapter 14 Troubleshooting

14.1 Powering off Automatically

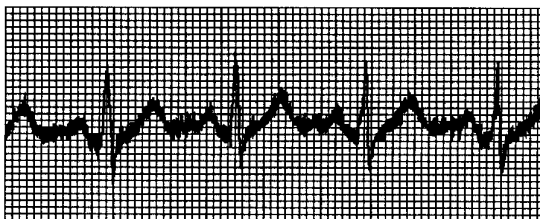
- ① Whether or not the battery capacity is nearly exhausted? Battery overdischarge protection circuit is activated.
- ② Whether or not AC supply voltage is too high? Overvoltage protection circuit is activated.
- ③ Whether or not AC interference is too large or fixed knob in lead cable socket is tightened? Overload protection circuit is activated.

14.2 AC Interference



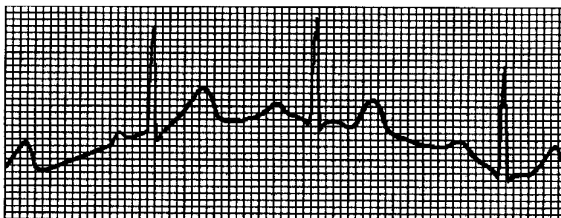
- ① Whether or not the device is grounded reliably?
- ② Whether or not the electrodes or lead cables are connected correctly?
- ③ Whether or not the electrodes and skin are smeared enough electric gel?
- ④ Whether or not the metal bed is grounded reliably?
- ⑤ Whether or not the patient has touched the wall or metal parts of the bed?
- ⑥ Whether or not the patient has touched other people?
- ⑦ Whether or not there is high-power electric equipment working nearby? Such as X-ray machine or ultrasonic device ,etc.

14.3 EMG Interference



- ① Whether or not the room is comfortable?
- ② Whether or not the patient is nervous?
- ③ Whether or not the bed space is narrow?

14.4 Baseline Drift



- ① Whether or not the electrode placement is instable?
 - ② Whether or not the electrodes or lead cables are connected reliably?
 - ③ Whether or not the electrodes and patient skin are cleaned and are smeared enough electric gel?
 - ④ Whether or not it is caused by patient's movement and breath?
 - ⑤ Whether or not the electrodes or leads are in bad connection?
- If you can not clear the interference after having taken all the measures above, use filter.

14.5 Troubleshooting List

| Phenomenon | Cause of failure | Remedy |
|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Too large interference, disorderly waveform | <ul style="list-style-type: none"> 1. Grounding cable is not connected reliably. 2. Lead cables are not connected reliably. 3. There is AC interference. 4. Patient is nervous and can not keep quiet. | <ul style="list-style-type: none"> 1. Check lead cables, grounding cable and power. 2. Do patient treatment well. |
| Baseline burr | <ul style="list-style-type: none"> 1. AC interference is large. 2. Patient nervous, and EMG interference is large. | <ul style="list-style-type: none"> 1. Amend the environment. 2. If the bed is made of steel, replace it. 3. The power cable and lead cables are not parallel or too close to each other. |
| Not regular waveform, large up-and-down, beeline figure | <ul style="list-style-type: none"> 1. Bad electrode conductivity. 2. Battery capacity lack. 3. Bad connection between electrodes and patient skin. 4. Loose connection between lead cables and the device's plug. 5. Bad connection between electrodes and lead cables. | <ul style="list-style-type: none"> 1. Use alcohol of high quality. 2. Clean electrode slices and the skin below them with alcohol. 3. Charge the battery. |
| Baseline draft | <ul style="list-style-type: none"> 1. Low power. 2. Patient movement. | <ul style="list-style-type: none"> 1. Charge the battery. 2. Keep patient still. |

| | | |
|------------------|-----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Unclear waveform | <ol style="list-style-type: none">1. The printer head surface is dirty.2. The thermal paper problem. | <ol style="list-style-type: none">1. In case of power cut, clean the printer head with alcohol, do not begin printing until the head is dry.2. Replace the thermal print paper with specified one. |
|------------------|-----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Chapter15 Maintenance

15.1 Do not open the enclosure of the device to avoid possible electric shock. Any maintenance and future upgrades to this device must be carried out by personnel trained and authorized by our company. The repair should be for our company's original components only.

15.2 Please pull out the power plug when it is power cut. When not used for a long period, the device should be placed where it is shady , cool, and dry, powered on every 3 months.

Appendix

EMC Information

Guidance and manufacturer's declaration – electromagnetic emission –
for all EQUIPMENT AND SYSTEMS


| | | | |
|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Guidance and manufacturer's declaration – electromagnetic emission | | |
| 2 | The model ECG1200G Electrocardiograph(ECG) is intended for use in the electromagnetic environment specified below. The customer or the user of the model ECG1200G Electrocardiograph(ECG) should assure that it is used in such an environment. | | |
| 3 | Emissions test | Compliance | Electromagnetic environment - guidance |
| 4 | RF emissions CISPR 11 | Group <input type="checkbox"/> | The model ECG1200G Electrocardiograph(ECG) 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. |
| 5 | RF emissions CISPR 11 | Class B | |
| 6 | Harmonic emissions IEC 61000-3-2 | Class A | |
| 7 | Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

| | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
| The model ECG1200G Electrocardiograph(ECG) is intended for use in the electromagnetic environment specified below. The customer or the user of the model ECG1200G Electrocardiograph(ECG) 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 | ± 6 kV contact ± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |

| | | | |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic transient / burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | ± 1 kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | < 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 sec | < 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 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the model ECG1200G Electrocardiograph(ECG) requires continued operation during power mains interruptions, it is recommended that the model ECG1200G Electrocardiograph(ECG) be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a. c. mains voltage prior to application of the test level. | | | |

**Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING**

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The model ECG1200G Electrocardiograph (ECG) is intended for use in the electromagnetic environment specified below. The customer or the user of the model ECG1200G Electrocardiograph (ECG) 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 | 3 Vrms 150 kHz to 80 MHz | 3 V | <p>Portable and mobile RF communications equipment should be used no closer to any part of the model ECG1200G Electrocardiograph (ECG) including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">80 MHz to 800 MHz</p> |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2,5 GHz | 3 V/m | $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">800 MHz to 2,5 GHz</p> <p>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</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model ECG1200G Electrocardiograph(ECG) is used exceeds the applicable RF compliance level above, the model ECG1200G Electrocardiograph(ECG) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model ECG1200G Electrocardiograph(ECG).

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the ECG-1101 Series ECG

The model ECG1200G Electrocardiograph(ECG) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model ECG1200G Electrocardiograph(ECG) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model ECG1200G Electrocardiograph(ECG) as recommended below, according to the maximum output power of the communications equipment

| Separation distance according to frequency of transmitter m | | | |
|----------------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| Rated maximum output of transmitter W | 150 kHz to 80 MHz $d = [\frac{3,5}{V_1}] \sqrt{P}$ | 80 MHz to 800 MHz $d = [\frac{3,5}{E_1}] \sqrt{P}$ | 800 MHz to 2,5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$ |
| 0,01 | 0.12 | 0.12 | 0.23 |
| 0,1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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.







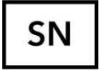
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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



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. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.



| Explanations of symbols on unit | |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Symbol for "applied parts" (the electrodes are type CF applied parts). |
|  | Symbol for "environment protection" - waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice. |
|  | Symbol for "manufacturer". |
|  | Symbol for "complies with MDD93/42/EEC requirements". |
|  | Symbol for "date of manufacture". |
|  | Symbol for "European representative". |
|  | Symbol for "serial number". |

Rev.0.10.14