GIMA

PROFESSIONAL MEDICAL PRODUCTS

100G CONTEC ECG
1 CHANNEL WITH MONITOR

CE 0123

REF **33220**

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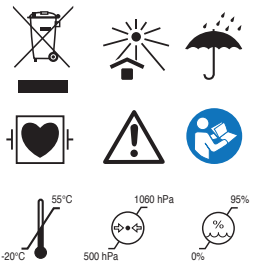

M33220-GB-Rev.2-12.20

Preface

Please read the User Manual carefully before using this product. The operating procedures specified in this User Manual should be followed strictly. This manual describes in detail the operation steps which must be noted, the procedures which may result in abnormality, and possible damage to the product or users. Refer to following chapters for details. Failed to follow the User Manual may cause measuring abnormality, device damage or personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues of such results due to user's negligence of this user manual for using, maintenance or storage. The free service s and repairs do not cover such faults either.

The content in this user manual complies with real product. For software upgrade and some modifications, the content in this user manual is subject to change without prior notice, and we sincerely apologize for that.

Attentions

Before using this product, the safety and effectiveness described in the following shall be considered:

- Type of protection against electric shock: class I (AC power supply), internal powered equipment (power supplied by battery)
- Degree of protection against electric shock: type CF, defibrillation-proof applied part
- Working mode: continuous running equipment
- Enclosure protection class: IPX0
- Measurement results shall be described by professional doctor combined with clinical symptoms.
- The using reliability depends on whether the operation guide and maintenance instructions in this user manual is followed.
- Service life: 5 years
- Date of manufacture: see the label
- Contraindications: none

⚠ **Warning: To ensure the device safety and effectiveness, please use the company recommended accessories. The maintenance and repair of the device should be done by professional personal specified by the company. It is forbidden to refit the device.**

Responsibility of the operator

- The device must be operated by a professionally trained medical staff, and kept by a special person.
- The operator should read the User Manual carefully before use, and strictly follow the operating procedure described in the User Manual.
- The safety requirements have been fully considered in product designing, but the operator can not ignore the observation of the patient and device.
- The operator is responsible for providing the information of product use to the company.

Responsibility of the company

- The company supplies qualified products to user in accordance with enterprise standard.

- The company installs and debugs the equipment and trains the physicians by contract.
- The company performs device repair in warranty period (a year) and maintenance service after warranty period.
- The company responds timely to the user's request.

Statement

Our company owns all rights to this unpublished work and intends to maintain it as confidential information. This user manual is used only for reference of operation, maintenance, or repair of our device. No part of this can be disseminated to others. And our company takes no responsibilities for any consequences and liabilities caused by using this user manual for other purposes.

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Contents

Chapter1 Overview

1.1 Overview

This product is a kind of electrocardiograph, which is able to sample 12 leads ECG signals and print out the ECG waveform with thermal printing system. Its functions are as follows: recording and displaying ECG waveform in auto/manual mode; prompt for electrode-off and out of paper; optional interface languages(Chinese/English, etc.); built-in lithium battery, powered either by AC or DC.

1.2 Intended use

This product is suitable for hospital, scientific research, wards, ambulances and carrying out medical consultations. It can be used by medical institutions to record human ECG signals, collect and extract the ECG waveform.

1.3 Main technical specifications

1.3.1 Environment conditions

Operation:

a). Environment temperature: 5℃~40℃

b). Relative humidity: 25%~95%(no condensation)

c). Atmospheric pressure: 700 hPa~1060 hPa

d). Power supply:

Voltage: 100-240 V～

Frequency: 50 Hz, 60 Hz

Input power: ≤150 VA

Battery:7.4 V, 2000 mAh rechargeable lithium battery

Transportation and Storage:

a). Environment temperature: -20 ℃～+55 ℃

b). Relative humidity: ≤95%

c). Atmospheric pressure: 500 hPa～1060 hPa

1.3.2 Input way: Floating and defibrillation protection

1.3.3 Lead: Standard 12 leads

1.3.4 Patient leakage current: <10μA

1.3.5 Input impedance: ≥2.5 MΩ

1.3.6 Frequency response:

Rated input amplitude	Input frequency and waveform	Relative output response
1.0	0.67Hz~40Hz, Sine wave	±10%[a]
0.5	40Hz~100Hz, Sine wave	+10 %, -30 %[a]
0.25	100Hz~150Hz, Sine wave	+10 %, -30 %[a]
0.5	150 Hz ~ 500 Hz, Sine wave	+10 %, -100 %[a]
1.5	≤1Hz,200ms, Triangle wave	+0 %, -10 %[b]
[a] relative to 10Hz [b] relative to 200 ms		

1.3.7 Time constant: ≥3.2s

1.3.8 CMRR: >105 dB

1.3.9 Filter: power frequency(AC50/60 Hz), myoelectricity(25 Hz/35 Hz (-3 dB)), baseline drift filter

1.3.10 Recording way: Thermal printing system

1.3.11 Specification of recording paper: 50 mm(W)×20 m(L) high-speed thermal paper

1.3.12 Time base selection(paper speed): 6.25, 12.5, 25, 50 mm/s, error: ±5%

1.3.13 Gain control(sensitivity): 2.5, 5, 10, 20 mm/mV, accuracy is ±2%,Standard sensitivity: 10 mm/mV±0.2 mm/mV

1.3.14 Auto record: record setup according to auto record format and mode, automatically change leads.

1.3.15 Manual record: record according to manual record format, and switch lead manually.

1.3.16 Product safety type: Class I type CF defibrillation-proof applied part

1.3.17 Polarization resistance voltage: ±610 mV

1.3.18 Noise level: ≤12 μVp-p

1.3.19 ECG signal input sampling frequency: 32 kHz

1.3.20 Waveform data processing sampling frequency: 1 kHz

1.3.21 Sampling precision: 24-bit

1.3.22 The minimum detection signal: 10 Hz, 20 μV(peak-peak value) deflected sinusoidal signal can be detected

1.3.23 Accuracy of input signal: ±5 %.

1.3.24 Amplitude quantization: ≤5μV/LSB

1.3.25 Fuse specification: 2 AC delay fuses (T2A/250VAC), rated current: 2A, rated voltage: 250V

1.3.26 Dimension: 315 mm(L)×215mm (W)×77 mm(H)

1.3.27 Net Weight: 1.5 kg

1.4 Main Characteristics

1.4.1 High resolution thermal-array output system(8 dots/mm), no adjustment required.

1.4.2 Record clear and exact single-channel ECG waveform and remarks in real-time and continuously. The remark includes: lead sign, sensitivity, paper speed, filter state, etc.

1.4.3 In auto mode, recording can be completed with one-button operation, which improves work efficiency.

1.4.4 Full touch keyboard, convenient to operate. TFT screen shows the working status, more clear for observation.

1.4.5 Both AC and DC power supply are supported. The device also has built-in rechargeable lithium battery.

1.4.6 Under optimal DC state, up to 7 hours standby time, print for 90 minutes, and record 160 pieces of ECG waveform.

1.4.7 Use digital signal processing technology to conduct AC filter, baseline filter and EMG filter on ECG signals, in order to get high-quality ECGs.

1.4.8 With multi-language interface, such as simplified Chinese and English.

1.5 Software overview

The ECG analysis program shows the results after analyzing the form of the electrocardiogram, providing auxiliary reference for doctors to make diagnosis. The analysis result cannot be used as the only standard for diagnosis. A comprehensive evaluation should be made by professional electrocardiogram technicians and physicians according to clinical experience and other test results.

The device is intended for use on all patient populations, which is decided by the clinical doctor. The analysis program only provides ECG analysis for patients above 3 years old (including 3 years).

Name of software: ECG100G embedded software

Software specification: none

Software version: Vx.x.x

Version naming rules: V<major version number>.<minor version number>.<revision version number>

The version of the software can be obtained in “About”.

Involved algorithm:

Name: ECG algorithm

Type: mature algorithm

Use: to convert ECG signals of human body into intuitive waveform images.

Clinical function: Electrocardiogram is an important method for clinical diagnosis of cardiovascular disease. How to use computer to quickly, automatically and accurately analyze ECG has been a hot topic for scholars at home and abroad. The ECG algorithm is the key to the analysis and diagnosis of ECG signals, and its accuracy and reliability determine the effectiveness of diagnosis and treatment of patients with heart disease.

Chapter2 Safety Precautions

2.1 Ensure that the device is placed on a flat level worktable. Avoid strong vibration or impact when moving it.

2.2 When working with AC power, the power cord must be 3-core, the frequency and voltage value of the AC power source must match the identification on the manual and have sufficient capacity. When the provided three-core power cord cannot be used, please use the built-in DC power supply or replace the three-core power cord that meets the standard requirements.

2.3 A perfect power supply system and grounding are necessary in the room.

⚠**Warning: To avoid the risk of electric shock, the device must be connected a power supply with protective grounding.**

2.4 If there are any questions for the integrality of protective grounding cable or the reliability of protective grounding cable connection can not be guaranteed, the device must be run with built-in DC power supply.

2.5 The safety requirements have been fully considered in product designing, but the operator can not ignore the observation of the patient and device. Cut off the power or take off the electrode when necessary to ensure patient's safety.

2.6 Please turn off the device and unplug the power cord before replacing the fuse or cleaning and disinfection. Don't rub the screen with sharp materials.

2.7 Keep the device from water, don't use or store it in places with high air pressure, humidity or temperature over the standard, bad ventilation, or too much dust.

2.8 Do not use the device in the place with flammable anesthetic gases or other flammable chemicals, otherwise there is a danger of explosion or fire.

2.9 Do not use the device in medical hyperbaric oxygen chamber, otherwise there is a danger of explosion or fire.

2.10 This device is not intended to act directly on the human heart. If this device is used with cardiac defibrillator or other electric stimulating devices at the same time, single-use chest electrodes and ECG lead cables with defibrillation function should be selected. 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, and the selected accessories should be designated by our company.

2.11 When the electrocardiograph is used together with a high-frequency electrosurgical knife, the ECG electrode should be kept away from the contact of the electrosurgical knife to prevent burns and burning of the electrode wires caused by high-frequency sparks.

2.12 When the electrocardiograph is used together with a defibrillator, the operator should avoid contact with the patient or the sickbed. The defibrillation electrode should not directly touch the ECG electrode to prevent sparks from burning the device and the patient.

2.13 Please do not use the electrocardiograph in the environment that is interfered by high-power device such as high-voltage cables, X-rays, ultrasonic machines and electrizer, keep the device away from emission sources such as mobile phones.

2.14 If other equipment is connected with this ECG device, it must be a Class I device that

complies with IEC60601-1.Because the total leakage current may hurt patient, the monitoring of leakage current is carried out and taken charge by the connected equipment.

2.15 Notes related to EMC

The device complies with the safety standards for medical electrical equipment or system electromagnetic compatibility in IEC60601-1-2. Electromagnetic environments exceeding the IEC60601-1-2 standard may cause harmful interference to the device or prevent the device from performing its intended function or degrade its performance. Therefore, if there is a phenomenon that does not match its function during use, be sure to confirm and eliminate adverse effects before continuing to use it. Corresponding precautions for this situation are given in this manual.

- The device or system should not be used near or stacked with other devices. If it must be used near or stacked with other devices, it should be observed and verified that the device is working normally under the configuration it is using.
- Use of accessories, transducers, and cables other than those specified by the manufacturer of the device or system as spare parts for internal components may result in increased emissions of the device or system and reduced immunity.

■ Effect from radiated electromagnetic waves:

The use of a mobile phone may affect the operation of the device. When installing medical electrical equipment, be sure to remind people around the device to turn off mobile phones and small radios.

■ Effect from shock and conduction electromagnetic waves:

High frequency noise from other equipment can enter the device through the AC socket. Please identify the source of noise, if possible, stop using the equipment. If the equipment can not be deactivated, use noise cancellation equipment or take other measures to reduce the impact.

■ Effect from static electricity:

Static electricity in a dry environment(indoor) may affect the operation of the device, especially in winter. Before using the device, humidify the indoor air or discharge the static electricity from the cable and operator.

■ Effect from thunder and lightning:

If there is thunder and lightning nearby, it may cause a voltage surge in the device. If you are concerned about danger, disconnect the AC power and use the internal power supply.

Chapter3 Warranty

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 free 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 door-to-door service, etc. to carry out warranty promise.

3.3 Even in warranty period, the following repairs are charged.

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

3.3.2 Faults or injuries caused by dropping accidentally after purchase.

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

3.3.4 Faults or injuries caused by improper storage or force majeure after purchase.

3.3.5 Faults or injuries caused by using 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 will be canceled if we find the protection label has been destroyed.

3.7 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 Working Principle and Structural Characteristics

4.1 Working principle and its block diagram

4.1.1 The power supply unit

Principle of power supply

After the AC power supply enters the switching power supply, it is converted to 9V DC voltage and supplied to the main board, it also provides constant voltage current limiting charging for the rechargeable lithium battery in the device through the DC-DC circuit, and generates +5V and +3.3V voltage through the power conversion to supply power to the corresponding modules. At the same time, the lithium battery in the device can independently satisfy working requirements of each module in the device through the buck-boost circuit.

⚠Note: The principle block diagram and component list are only available to service stations or maintenance personnel designated by our company.

4.1.2 Signal acquisition unit

The signal acquisition unit uses a floating setting, which is a signal acquisition and processing system, including analog circuit part and 24-bit A/D conversion and data processing part. The analog circuit consists of signal following, amplification, anti-aliasing low-pass filtering, lead-off detection and overload detection. CPU system is responsible for coordinating the work of each circuit such as the A/D converter, the lead-off detection circuit and the overload detection circuit, in order to achieve signal acquisition, processing, and lead-off detection. Control information and A/D conversion and data acquisition between the floating circuit and the solid circuit are transmitted through the optoelectronic coupler.

4.1.3 Control unit

（1）Principle of control unit

The control system consists of printing system, button system, liquid crystal display system, and signal acquisition system. The ECG signal sent from the signal acquisition system through the high-speed optoelectronic coupler is received by the CPU system, after digital filtering, gain adjustment and motor drive, it is sent to the printing system to print the ECG waveform. After the printing is completed, the CPU system processes waveform measurement and analysis. The CPU system also receives an interrupt signal and button code from the button system to complete the interrupt processing. In addition, the lead-off signal, paper out detection, battery voltage management, and automatic power-off are also managed by the CPU system. The liquid crystal controller receives data and commands from the CPU system to complete the display of the control state of the device.

（2）Principle block diagram is shown in Figure4-1.

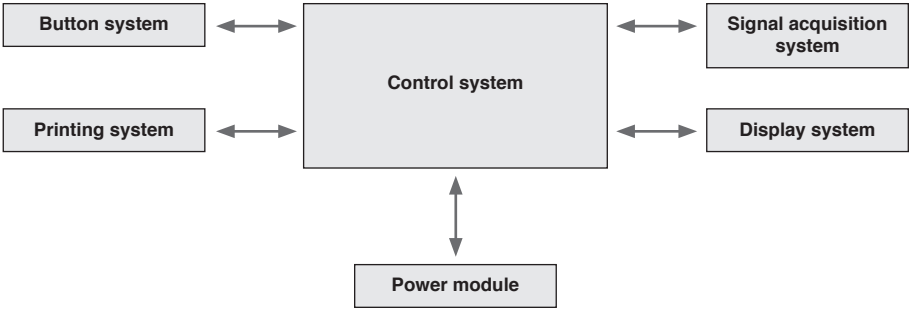


Figure 4-1 Block diagram of control unit

4.2 Name of each part and its function

4.2.1 Front view

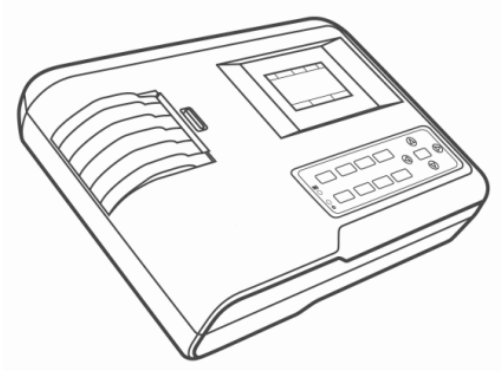


Figure 4-2 Front view

⚠Note

- **Do not put heavy objects on the screen or hit against it, otherwise the screen will be damaged.**
- **If the device is not in use, cover it to prevent liquid spills on the screen.**
- **Do not use sharp stuff to operate the buttons, otherwise it may case permanent damage to the buttons.**

4.2.2 Side view

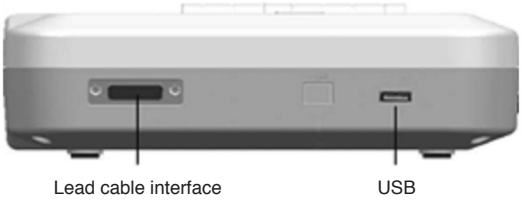


Figure 4-3 Side view

1、Lead cable interface：Connect with lead cables

2、USB interface: communicate with computers, convenient for program upgrade

Note

Operator must not touch the USB interface and patient at the same time.

3、Power socket

Connect with AC power cord  .

4、Grounding terminal (Equipotential terminal)

Connect with the potential equalization conductor  .

4.2.3 Buttons

 Function button: ON/OFF control

 Function button: gain adjusting

Function button: speed adjusting

 Function button: filter selection

 Function button: enter/exit the menu

 Function button: work mode selection

 Function button: calibration

 Function button: print

Function button: system menu

 Direction button: UP

 Direction button: DOWN

 Direction button: LEFT

 Direction button: RIGHT

4.2.4 Symbols

~AC	Alternating current
OFF	Power OFF
ON	Power ON
	Equipotentiality
◀ PAZIENTE	Lead cable socket
	Product code
	Lot number
	Manufacturer
	Date of manufacture
	Authorized representative in the European community
	Medical Device complies with Directive 93/42/EEC
	Keep in a cool, dry place
	Keep away from sunlight
	Follow instructions for use
	Temperature limit
	Atmospheric pressure limit
	Humidity limit
	Caution: read instructions (warnings) carefully

	WEEE disposal
	Defibrillation-proof type CF applied part
	This side up
	Fragile, handle with care
	Serial number
	USB interface
	Stacking limit by number

Chapter 5 Operation Precautions

5.1 Precautions before use

5.1.1 For safe and effective use, please read the user manual carefully before operation.

5.1.2 Check to ensure that the device is in good condition.

5.1.3 The device shall be placed on a flat surface, and moves gently to avoid strong vibration or shock.

5.1.4 Check to ensure that the lead cables are correctly connected, and the device grounding is correct.

5.1.5 The AC frequency and voltage should comply with the requirements, and enough current capacity should be guaranteed.

5.1.6 When using the battery for power supply, check to ensure that the battery voltage and battery status are in good condition, and the battery has enough power.

5.1.7 When the device is used together with other equipment, all devices and equipment should be equipotential grounded in order to protect the user and operator.

5.1.8 Install the device where easily grounded in the room. Do not allow the patient and patient-connected lead cables to come into contact with other conductor parts, including the earth or a hospital bed.

5.1.9 Clean the lead cable with neutral solvent. Do not use alcohol-based cleaners or gemicides.

5.1.10 Ensure that the device is running within the normal ambient temperature range of 5℃ to 40℃. If the device is stored at a higher or lower temperature, leave it in the operating environment for approximately 10 minutes before use in order to ensure the normal work.

5.2 Precautions during operating

5.2.1 The printing can be started after the ECG waveform is stable.

5.2.2 During using, the doctor should observe the patient carefully and cannot leave the operating site. If necessary, turn off the power or remove the electrode to ensure patient safety.

5.2.3 The patient and the device can only be connected via lead cables through the electrodes, in order to avoid patient touches other parts of device or conductors.

5.2.4 Patient can not move during operating.

5.2.5 Maintenance or repair to the device or accessory is not allowed during using.

5.3 Precautions after use

5.3.1 Set the states of all functions to initial states.

5.3.2 Cut off the power, gently remove the electrodes and limb clips, then remove the lead cables, do not pull with force.

5.3.3 Clean the device and all accessories, and store them for the next use.

Chapter 6 Preparations before Operation

6.1 Installation of recording paper

6.1.1 The device adopts high-speed recording paper, its specification is 50 mm(W)×20 m(L).

6.1.2 The installation method of recording paper is described as below:

(1) Slide the cover switch to the left to open the paper compartment cover. Take out the paper axis, insert it into the roll paper. The paper side with grids should be faced downwards, and then install it to proper position in the paper compartment.

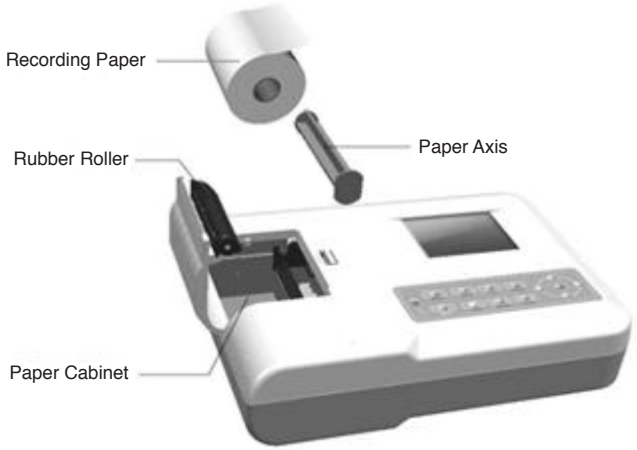


Figure 6-1 Installation of recording paper

(2) Pull out the recording paper from the slot of the paper compartment cover, and close the cover.

Note: The recording paper should be aligned with the slot of the paper compartment cover. It is recommended to leave 2cm paper outside.

6.1.3 If the recording paper runs out during recording, the device will stop printing automatically, and the screen will display a prompt of lack of paper.

6.2 Power supply connection

6.2.1 AC

Insert one end of the provided three-core power cord into the device's input socket, and insert the other end into a three-core power socket that meets the requirements. Ensure that the connection is secure and reliable, and the device is automatically grounded.

When the device is used in conjunction with other medical equipment, use the supplied potential equalization wire to connect the equipotential terminal of the device to the equipotential terminal of the connected equipment to prevent leakage current and protect the device.

6.2.2 Battery

The device has a built-in rechargeable lithium battery, which does not need to be re-installed by user. Check the battery's power and status before use.

⚠Note: Connect one end of the potential equalization wire to the equipotential terminal of the device, and connect the other end to the ground to enhance the reliability of the grounding. Do not use other pipes as ground wire, otherwise, the patient may be in danger of electric shock.

6.3 Lead cable connection

Connect the lead cable to the lead cable interface on the device, and fasten it to the device with the fixing knobs at both sides of the lead cable in order to prevent bad connection and affecting the detection.

⚠Note: The lead cable interface can not be used for other purposes except as the input interface of ECG signals.

6.4 Electrode installation

Proper installation of the electrodes is an important part of accurately recording the electrocardiogram. Make sure the electrodes are in good contact. Old and new electrodes or reusable electrodes and disposable electrodes cannot be used at the same time. If different types of electrodes are used together, some electrodes are subject to a large bias potential due to the polarization, which results in a longer polarization time and a longer recovery time after defibrillation. Squeezed spherical electrodes are commonly used in ECG recording and diagnosis, and especially cause this polarization voltage. Therefore, the ECG recording will be seriously affected. The electrode or lead plug must not touch other object surfaces or conductors, such as metal beds. Please replace them all when updating the electrodes.

6.4.1 Chest electrodes

As shown in Figure 6-2:

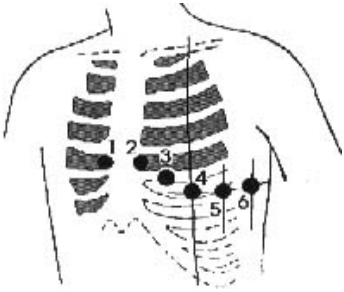


Figure 6-2 Installation of chest electrode

The chest electrodes should be installed to the following parts:

C1（Vl）: the fourth intercostal space at the right sternal margin

C2（V2）: the fourth intercostal space at the left sternal margin

C3（V3）: between C2 and C4

C4（V4）: the intersection between midclavicular line and the fifth intercostal space

C5（V5）: left anterior axillary line on the same plane as C4

C6（V6）: left midaxillary line on the same plane as C4

Clean the chest skin where the electrodes to be installed with alcohol, and apply some conductive pastes to these skin (about 25 mm-diameter range) and the edge of the chest electrode suction cup. Squeeze the suction ball to install the chest electrode at the positions of Cl-C6.

Note: The conductive paste coating should be separated from each other, and the chest electrodes should not touch each other to avoid short circuit.

6.4.2 Limb electrodes

The limb electrodes should be placed on the soft skin of both hands and feet. Before connecting, clean the skin of the electrode installation area with alcohol, and then apply a small amount of conductive paste on the cleaned skin. The electrode connection of the limbs is shown in Figure 6-3.

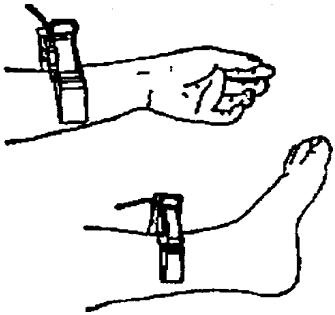


Figure 6-3 Installation of limb electrodes

6.4.3 Colors of lead cables

As shown in Table 6-1:

Table 6-1 Colors of lead cables

Electrode position	European standard		American standard	
	Mark	Color	Mark	Color
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Left leg	F	Green	LL	Red
Right leg	N/RF	Black	RL	Green
Chest 1	Cl	Red	Vl	Red
Chest 2	C2	Yellow	V2	Yellow
Chest 3	C3	Green	V3	Green
Chest 4	C4	Brown	V4	Blue
Chest 5	C5	Black	V5	Orange
Chest 6	C6	Purple	V6	Purple

Note

- **It is recommended to install the lead cables after turning off the device.**
- **Apply appropriate amount of conductive paste on the electrode when installing the electrode.**
- **If the ECG waveform does not appear for a long time, check if the electrode is in good contact with the skin.**

6.4.4 Lead method and system

As shown in Figure 6-4:

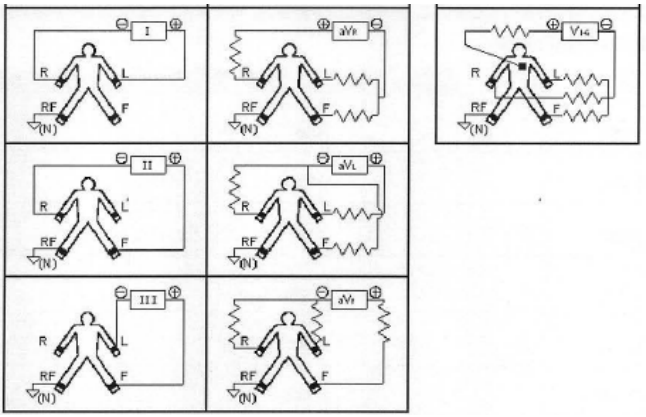


Figure 6-4 Lead system

6.4.5 Lead-off and overload indication

The device can check the connection status of the lead at any time. If lead-off or overload is detected, the screen will display corresponding lead code, as shown in Figure 7-2.

Note

- **In the lead-off prompt area, red font represents lead-off, yellow font represents overload.**
- **When the connection between lead cable and patient/the device is not reliable, and the ECG signal can not correctly transmitted, the device displays lead-off.**
- **In the printed report, lead-off is marked with "*", and lead overload is marked with "+".**

Chapter 7 Operation Guide

7.1 Main menu

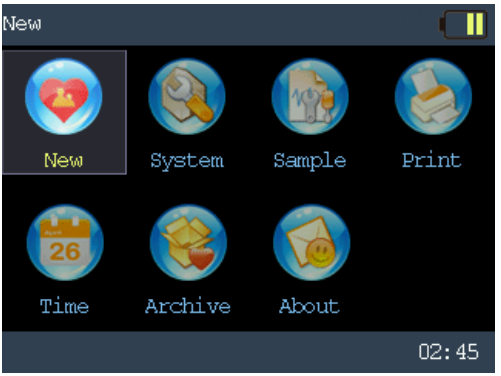


Figure 7-1

7.2 New

The sampling interface mainly displays the waveform, according to user's need, the settings of gain, speed, print mode, waveform display mode, printing, filter and other settings can be changed.

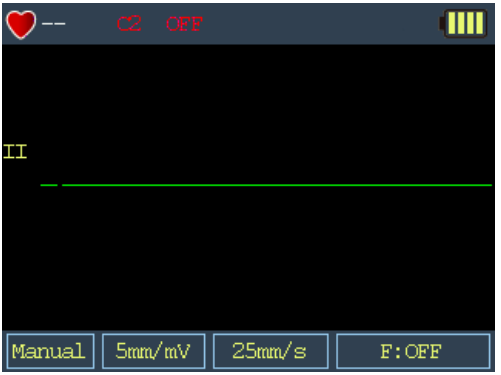


Figure 7-2

Status bar

1. Hear rate: indicating the heart rate of current sampling
2. Lead-off/ Information overload: under demonstration mode, this area displays "Demo"; under sampling mode, this area displays detected lead-off information.
3. Make sure there is enough printing paper before printing, or the device prompts for lacking of paper.

Display area

The sampled ECG waveform is displayed on the LCD screen, pressing UP/DOWN button

to display the previous or next lead.

Operation toolbar

1. Gain (sensitivity): use the SEN button  to switch the sensitivity between 2.5 mm/mV, 5 mm/mV, 10 mm/mV and 20 mm/mV. The gain (sensitivity) is checked by calibration function.

2. Speed: use the SPEED button 

to switch the speed between 6.25 mm/s, 12.5 mm/s, 25 mm/s and 50 mm/s.

3. Print mode: use the MODE button  to change the print mode, the selections are manual and auto.

4. Filter: use the FILTER button  to turn on or turn off the filter, which includes AC filter (AC), EMG filter (EMG) and baseline filter (DFT).

5. Display calibration signal: the screen shows 1mV signals every time after pressing the calibration button  on the front panel, which is convenient to view the current sensitivity.

Note: The calibration is a totally automatic process, user does not need to press any buttons.

6. Switch lead: use the UP/DOWN buttons  to change the lead.

7. Print: press the PRINT button  to print ECG waveform, press the button one more time to stop the printing.

7.3 System setup

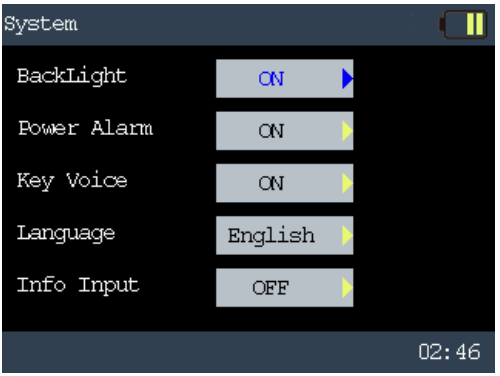


Figure 7-3

Operation instructions:

1. “BackLight”: ON and OFF of the backlight
2. “Power Alarm”: “ON”: the device makes sound prompt for low battery; “OFF”: no sound prompt
3. “Key Voice”: “ON”: the device has button operation sound; “OFF”: no sound prompt
4. “Language”: Language is switchable.
5. “Info Input”: “ON”: Patient’s name, age, sex and weight can be input before printing, press  button to confirm the input information. User can turn it to “OFF” if unnecessary.

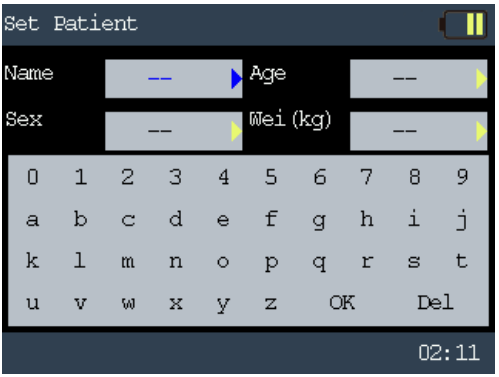


Figure 7-4

7.4 Sampling setup

Figure 7-5

Operation instructions:

1. “AC Filter”: 50 Hz or 60 Hz
2. “EMG Filter”: 35 Hz or 25 Hz
3. “Demo Mode”: “ON”: demo mode; “OFF”: real-time sampling mode

7.5 Print setup

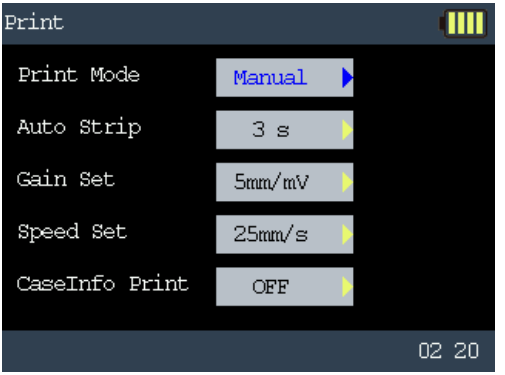


Figure 7-6

Operation instructions:

1. “Print Mode”: print mode, optional between manual and Auto
2. “Auto Strip”: automatic printing time, optional between 3s, 6s, 10s, 12s, 15s and 20s
3. “Gain Set”: gain setup, optional between 2.5 mm/mV, 5 mm/mV, 10 mm/mV and 20 mm/mV
4. “Speed Set”: speed setup, optional between 6.25 mm/s, 12.5 mm/s, 25 mm/s and 50 mm/s
5. “CaseInfo Print”: set it to on or off according to necessary.

7.6 Time setup

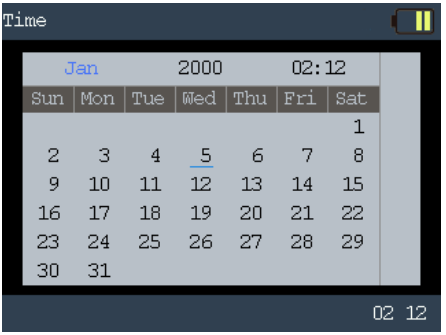


Figure 7-7

Operation instructions:

Date and time can be modified by user.

7.7 Case management

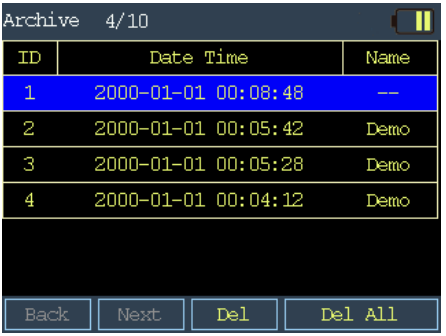


Figure 7-8

Operation instructions:

All saved cases can be checked by user, and case review and delete operations are also available. User is able to store cases only under auto mode, and there are 10 cases stored at most.

7.8 About

Figure 7-9

Operation instructions:

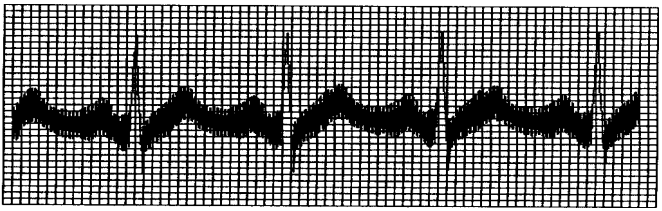
This interface shows the software version number of the device.

Chapter 8 Troubleshooting

8.1 Auto shutdown

- The battery is almost running out, which causes overdischarge protection circuit action.
- The voltage of AC power supply is too high, which causes overvoltage protection circuit action.

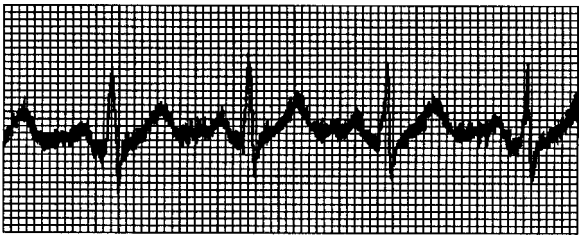
8.2 AC interference



- Whether the device is grounded reliably?
- Whether the electrode or lead cable is connected correctly?
- Whether the electrodes and skin are daubed with enough conductive paste?.
- Whether the metal bed is grounded reliably?
- Whether the patient is touching the wall or metal parts of the bed?
- Whether the patient touches other people?
- Whether there is high power electric equipment working nearby? Such as X-ray machine or ultrasonic device, etc.

Note: If the interference can not be removed after taking above measures, please use a AC filter.

8.3 EMG interference

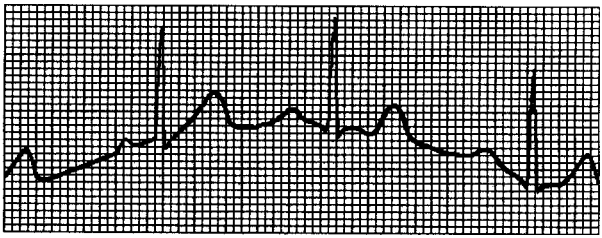


- Whether the room is comfortable?
- Whether the patient is nervous?
- Whether the bed space is narrow?
- Whether patient speaks during recording?
- Whether the limb electrode is too tight?

Note: If the interference can not be removed after taking above measures, please use a

EMG filter. The ECG waveform recorded at this time will be slightly attenuated.

8.4 Baseline drift



- Whether the electrode installation is stable?
- Whether the connection of lead cables or electrodes is reliable?
- Whether the electrodes and patient skin are cleaned and are daubed with enough conductive paste?
- Whether it is caused by patient's movement or breathing?
- Whether the electrodes or leads are in bad connection?

Note: If the interference can not be removed after taking above measures, please use a baseline filter.

8.5 Troubleshooting list

Phenomenon	Cause of failure	Solutions
Too large interference, disorderly waveform	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.	1. Check the power cord and lead cables. 2. Let the patient prepare for the measurement.
Baseline burr	1. AC interference is large. 2. Patient nervous, and EMG interference is large.	1. Improve 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	1. Bad electrode conductivity. 2. Low battery. 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.	1. Use alcohol of high quality. 2. Clean electrode slice and the skin under the electrode with alcohol. 3. Charge the battery.

Baseline draft	1. Low power. 2. Patient movement.	1. Charge the battery. 2. Keep patient still.
Unclear waveform	1. Low battery. 2. The printer head surface is dirty. 3. The thermal paper problem.	1. Charge the battery. 2. Cut off the power, clean the printer head with alcohol, air dry. 3. Replace the thermal print paper with specified one.

Chapter 9 Maintenance

9.1 Battery

9.1.1 The device is designed with built-in full-sealed and maintenance-free 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 in powering on state, as shown in Table 9-1. After absolutely discharged, the battery needs 3.5 hours to charge to 90%, and 4 hours to charge to full capacity.

Table 9-1 Battery status display

No.	Icon	Description
a		Using battery, and battery is full, or using AC power supply, and the battery is completely charged.
b		Using battery, and battery level is 3/4 of battery full
c		Using battery, and battery level is 1/2 of battery full
d		Using battery, and battery level is 1/4 of battery full
e		Using battery, and the battery is low. It is recommended to charge the battery before use or adopt AC power supply.

Note: When charging the battery, the displayed status of battery level switches between icon e to icon a.

9.1.2 The device can continuously print for 1.5 hours or work for more than 4 hours in standby mode when battery is completely charged. When the device is powered by battery, a battery icon will be displayed on the LCD screen, 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 permanent damage to the battery.

Note: The above data is obtained by printing demo waveform under the test environment of temperature 25℃, speed 25mm/s and gain 10mm/mV. In actual use, the operation time may be shorten due to operation condition and environment.

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

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

Note

- **Do not try to dismantle the sealed battery without permission.The replacement of battery shall be carried out by professional maintenance personal authorized by our company, and the same model of rechargeable battery provided by our company should be used.**
- **Do not touch the positive and negative terminals of the battery directly with wire, otherwise there is a danger of fire.**
- **Do not use the battery near fire sources or in environments where the temperature exceeds 60°C. Do not heat the battery or throw it into fire, water and avoid splashed**

by water.

- **Do not puncture, hammer or strike the battery or destroy it by other ways, otherwise it will cause battery overheat, smoke, deform or burn dangers.**
- **Keep away from the battery when it appears leakage or emitting unpleasant smell. If the battery electrolyte leaks onto the skin or clothes, clean with water immediately. If the electrolyte accidentally enters your eyes, do not rub your eyes, immediately clean with water and see a doctor.**
- **If the battery reaches its service life, or battery smell, deform, discolor or distorted appears, please stop using the battery and dispose it in accordance with local regulations.**

9.2 Recording paper

In order to ensure the quality of the ECG waveform, please use the high-speed thermal recording paper supplied or specified by the company. If you use unspecified recording paper, the recorded ECG waveform may be blurred, faded, and the paper feeding may not be smooth. This may even increase the wear of the device and shorten the service life of important parts such as the thermal print head. For information on how to purchase such recording paper, please contact your dealer or the company. Please be careful!

9.2.1 When using recording paper, it is absolutely not allowed to use recording paper with wax on the surface or in grayish/black color. Otherwise, the wax will stick to the heating part of the print head, resulting in abnormal work or damage of the print head.

9.2.2 High temperature, humidity and sunlight may cause the recording paper to change color. Please keep the recording paper in a dry and cool place.

9.2.3 Please do not place the recording paper under fluorescent light for a long time, otherwise it will affect the recording effect.

9.2.4 Please do not to put the recording paper together with the PVC plastic, otherwise the color of recording paper will change.

9.2.5 Please use the recording paper with specified dimension. Recording paper that does not meet the requirements may damage the thermal print head or silicone rubber roller.

9.3 Maintenance after use

9.3.1 Press 

button to shutdown the device.

9.3.2 Unplug the power cord and lead cables. Hold the header of plug to disconnect, and do not pull the cable with force directly.

9.3.3Clean the device and accessories, cover them up to against dust.

9.3.4 Store the device in a cool and dry place, avoid strong vibration when moving.

9.3.5 When cleaning the device, do not immerse it in the cleaner. Power supply must be cut off before cleaning. Use neutral detergents for cleaning. Do not use any detergent or disinfectant containing alcohol.

9.4 Lead cables and electrodes

9.4.1 The connectivity of the lead cable can be detected by the multimeter. Check whether each

wire of the lead cable is in good contact according to the following table. The resistance of each wire from the electrode plug to the corresponding pin in the lead cable plug should be less than 10Ω. The integrity of the lead cable must be checked regularly. Any lead wire damage will cause a false waveform of the corresponding lead or all leads on the ECG. The lead cable can be cleaned with neutral solvent. Do not use the detergent or germicide containing alcohol (Please do not immerse the lead cables in liquid for cleaning).

Note: The resistance of lead cable with defibrillation-proof protection function is about 10KΩ.

Table 9-2 Lead cable mark and pin position table

Mark	L	R	C1	C2	C3	C4	C5	C6	F	N
Pin position	10	9	12	1	2	3	4	5	11	14

9.4.2 Bending or knotting will shorten the service life of the lead cable. When using it, please straighten the lead cable first.

9.4.3 The electrode should be well stored. After long time use, the surface of the electrode may oxidize and discolor due to corrosion and other factors, which may affect the signal acquisition. In this case, the electrode must be replaced.

9.5 Silicone rubber roller

The silicone rubber roller should be smooth and free of stains, otherwise it will affect the ECG recording effect. In order to remove the stains on the roller, please use a clean soft cloth damped with a small amount of alcohol to wipe it along the longitudinal direction, and scroll the roller in the paper conveying direction while wiping until it is clean.

9.6 Cleaning of thermal print head

Dirt and dust on the surface of the TPH can affect the clarity of the waveform. To clean the print head surface, open the paper compartment cover after turning off the device, use a clean and soft cloth dampened with alcohol to wipe the surface gently. For the residual stains on print head, moist it with a little alcohol first, then wipe with a soft cloth. Never use hard objects to scratch the surface, otherwise the print head will be damaged. Wait until the alcohol has evaporated, then close the paper compartment cover. The print head should be cleaned at least once a month during normal use.

9.7 Fuse replacement

⚠ **Warning: To ensure the safety and effectiveness of the product, please use our company recommended accessories for replacement. The maintenance and repair to the device should be performed by professional maintenance personal specified by our company.**

9.8 Disposal of product scrap

The disposal of packaging materials, waste battery and end-of-life device should obey the local laws and regulations, and user should treat the scrapped products and materials properly according to the laws and regulations, and try to support the classification and recycling work.

9.9 Others

9.9.1 Do not open the device enclosure to avoid electric shock danger.

9.9.2 The device associated circuit schematics and critical parts list are only available to authorized service station or maintenance personnel, who is responsible for maintenance of the device.

9.9.3 The device belongs to measuring instrument. User should send the device to national designated inspection institution for inspection according to the requirements of the national metrological verification procedure. The device shall be inspected at least once per year, and all the accessories should be inspected and maintained regularly (at least once every six months).

Chapter 10 Packing List and Accessories

10.1 Accompanying accessories

When the device is shipped from the factory, the intact packaging should contain the following contents, as shown in Table 10-1:

Table 10-1 Packing list and accessories

Name	Quantity
Electrocardiograph	1 pc
Chest electrodes (suction cup/electrode slice)	1 set (6 pcs)
Limb electrodes (limb clip)	1 set (4 pcs)
ECG lead cable	1 pc
Potential equalization wire	1 pc
Power cord	1pc
User manual	1 pc
Recording paper	1 pc

10.2 Notes

10.2.1 Please follow the instructions on the package when opening the package.

10.2.2 After unpacking, please check the accessories and accompanying documents in accordance with the packing list, then start inspecting the device.

10.2.3 If the packaging content does not meet the requirement or the device does not work properly, please contact our company immediately.

10.2.4 Please use the accessories provided by our company, otherwise the performance and safety of the device may be affected. If accessories provided by other company need to be used, please first consult the after-sales service of our company, or we will not responsible for any caused damages.

10.2.5 The package shall be kept properly for future use in regular maintenance or device repair.

Appendix I EMC Guidance and Manufacturer Declaration

Table 1:

Guidance and manufacturer's declaration –electromagnetic emission	
The Infrared Thermometer is intended for use in the electromagnetic environment specified below. The purchaser or the user of the device should assure that it is used in such environment.	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable

Table 2:

Guidance and manufacturer's declaration-electromagnetic immunity		
The Infrared Thermometer is intended for use in the electromagnetic environment specified below. The purchaser or the user of the Infrared Thermometer should assure that it is used in such environment.		
Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ± 15 kV air	±8kV contact ±15kV air
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ± 1 kV for input/output line	±2kV for power supply lines Not Applicable
Surge IEC 61000-4-5	±1 kV lines to lines ±2 kV lines to earth	±1 kV lines to lines ±2 kV lines to earth
Voltage dips, short interruptions and voltage vatiations 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 cycle 70%UT(30%dip in UT) for 25 cycle <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 cycle 70%UT(30%dip in UT) for 25 cycle <5%UT(>95%dip in UT) for 5 sec
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m

Table 3:

Guidance and manufacturer's declaration – electromagnetic immunity		
The Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer the user of the Infrared Thermometer should assure that it is used in such environment.		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz- 2.7 GHz	3 V/m80 MHz- 2.7 GHz
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.		
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 Infrared Thermometer is used exceeds the applicable RF compliance level above, the Infrared Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Infrared Thermometer.		

Table 4：

Guidance and manufacturer's declaration - electromagnetic Immunity							
The [Code SI] is intended for use in the electromagnetic environment specified below. The customer or the user of the [Code SI] should assure that it is used in such an environment							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 –390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	745						
	780						

wireless communications equipment)	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	1845						
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
	5500						
	5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the
ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

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

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

⚠ **Warning**

- **Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.**
- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **Active medical devices are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.**

Note：

- **The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.**
- **When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.**

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.