Instruction for Use

Wireless dynamic multi-parameter holter

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Content

1. Introduction

Thank you for purchasing a wireless dynamic multi-parameter holter (hereinafter referred to as: holter). This manual describes the purpose, function and safe use of the equipment. Before using this equipment, please read carefully and fully understand the contents of this manual to ensure the correct use of this equipment and the safety of patients and operators. Our company can provide circuit diagrams, component lists, legends, calibration rules, or other information necessary for qualified technicians to help users repair equipment parts designated by the manufacturer as repairable.
This product does not have the function of identifying stop blog and ST.
Software release version: V1

1.1 Safety information

⚠ **Caution**

- Before using this equipment, please read this manual carefully and fully understand the relevant warnings and risks.
- This device cannot replace the medical diagnosis results of professional doctors.
- The measurement results of this equipment are for reference only and cannot be directly used as a basis for clinical treatment.
- The disposable ECG electrodes used in conjunction with this device are accessories purchased by the user and must be a regular device with a medical device registration certificate.
- Single-use ECG electrodes cannot be attached to the patient's wounded or scarred skin.
- Single-use ECG electrodes should be in close contact with the skin. If itching or skin allergies or ulcers occur, stop using them

immediately.

- If you have a pacemaker in your body, we do not recommend that you use this device. Follow your doctor's advice if necessary.
- This equipment cannot be used simultaneously with defibrillators and electrosurgical equipment.
- This equipment cannot be used during CT or MRI.
- When using this equipment, please stay away from equipment that generates strong electric and magnetic fields. Using this device in an inappropriate environment may cause interference to surrounding radio devices or affect the operation of this device.
- This equipment cannot be used in a flammable environment (such as an oxygen-rich environment).
- This device cannot be used by babies weighing less than 10 kg.
- Do not swim or submerge the device in water. Do not immerse the device in water or other liquids. Please pay attention to waterproofing and keep it away from high temperature and humidity.
- Do not use acetone or other volatile solutions to clean the equipment.
- Do not violently bump or squeeze the device, if the shell is broken, please stop using it.
- Do not place this equipment in a pressure vessel or gas sterilization equipment.
- Do not disassemble the equipment at will, otherwise it will cause the machine to malfunction or affect the normal operation of the equipment.
- Please place the device out of the reach of children.
- Be careful of strangulation of cables and hoses due to excessive length.
- This device cannot be used on people with sensitive skin or allergies.
- This equipment cannot be placed in the following environments: direct sunlight, high temperature, high humidity, close to water or fire, high electromagnetic influence. Before using the equipment, you must ensure that the equipment is in a normal working condition and operating environment.

- The user should try to avoid sweating, as sweat will affect the contact between the ECG electrodes and the skin and affect the quality of the measurement.
- Do not participate in strenuous or extensive physical activities in order to conduct proper monitoring.
- In order to measure pulse oximetry and pulse rate more accurately, the device should be used in a quiet and comfortable environment.
- The measurement results of this equipment cannot distinguish all diseases. If you feel unwell, you should consult your doctor immediately in addition to referring to the measurement results of this device.
- Do not conduct self-diagnosis and medication based on the measurement results of this device without consulting your doctor. Especially do not take new drugs without prior permission.
- This equipment cannot replace professional heart or other organ function measurement equipment. Medical electrocardiogram measurement requires more professional and complete measurement.
- Do not use the information displayed by the host as the only basis for clinical diagnosis. The host is only used as an auxiliary means in diagnosis. It must be used in conjunction with clinical manifestations and symptoms and the doctor's diagnosis.
- We recommend that you record your ECG curve and measurement results, and provide them to your doctor for reference if necessary.
- Although all parts of this equipment in contact with the human body have been tested for biocompatibility, a very small number of users may have allergic reactions, and should stop using them if they have allergic reactions.
- Continuous use for too long may increase the risk of undesirable changes in cortical properties, such as allergies, redness, blistering or burns. Check the wearing position every 6-8 hours.
- The device is calibrated to display functional blood oxygen saturation. The instrument should be calibrated and maintained regularly by qualified professionals.
- The function holter cannot be used to evaluate the accuracy of equipment and sensors.
- The device is used to determine the percentage of arterial oxygen

saturation of functional hemoglobin. The following factors may reduce performance or affect the accuracy of pulse oximetry measurements:

-The surrounding environment is too light

-The sensor type is incorrect

-Excessive movement

-Moisture in the sensor

-High frequency electrosurgical interference

-Improper use of sensors

-Blood flow restrictor

-Weak pulse or poor signal

- Waste (including the scrapped equipment itself) shall be treated in accordance with relevant laws and regulations.
- The validity period of this product is 5 years. For the production date of the product, please refer to the nameplate of the host.
- When several devices are used on the same patient at the same time, the leakage current may overlap and cause danger. Before connecting to each other, it is recommended that a qualified professional perform a leakage current test to ensure that the leakage current is within the safe allowable range, that is, it will not cause harm to the patient, the operator and the surrounding environment. If there is still any doubt, the user should consult the manufacturer for the correct method of use.
- Do not perform high temperature, high pressure, gas fumigation, or liquid immersion disinfection of the equipment. Please clean and disinfect the equipment and its accessories according to the manufacturer's requirements. The power must be cut off before cleaning or disinfecting the equipment.
- It is the operator's responsibility to check the compatibility of the monitor, probes and cables prior to use and incompatible accessories can result in reduced performance of the instrument. (including blood oxygen probe and temperature probe).

1.2 Symbols

Symbols	Meaning

	Indicates the item is a medical device
	Follow Instructions for Use.
	Type CF applied part
IP22	Dustproof and waterproof grade
	Non-Ionizing Radiation
	Indicate separate collection for electrical and electronic device (WEEE).
	Alarm free system
	Serial Number
	Indicates the date after which the medical device is not to be used
	This product complies with the Europea Council EU 2017/745 (MDR)

EC REP	Authorized representative in the European Community

2. Product introduction

2.1 Product name and model

Product name：Wireless dynamic multi-parameter holter

Product model： M5, M12, Lepod, Lepod Pro, LMT-5 and LMT-12.

Model difference：

Function	M5	M12	Lepod	Lepod Pro	LMT-5	LMT-12
ECG (3 leads, 5 leads)	●	●	●	●	●	●
ECG (6 leads, 12 leads)	×	△	×	△	×	△
Body temperature	△	△	△	△	△	△
Blood oxygen	△	△	△	△	△	△
Respiration rate	△	△	△	△	△	△
Blueototh	●	●	●	●	●	●

Software release version	V1	V1	V1	V1	V1	V1
Shell color	Black	Black	White	White	Blue	Blue

Note 1: ● indicates that this function is available, × indicates that this function is not available, and △ indicates optional function.

Note 2: The model you purchased may not have all the above functions, please refer to the actual model purchased.

2.2 Intended Use

It is used for wireless real-time monitoring of human body sign information, including dynamic ECG, respiration rate, body temperature, and blood oxygen. Does not include automatic analysis and diagnosis functions.

2.2.1Contraindication

This product is not suitable for patients who have a pacemaker in their body.

2.3 About holter

Figure 1

1. On/Off button:

Used to turn on and turn off the device.

You can switch the ECG lead channel.

2.ECG interface/charging interfacev:

Used to connect the ECG cable, and used to connect the charging cable.

3. Display:

Used to display information such as time, battery and ECG waveform.

4. Lanyard hole:

Used to install the lanyard.

5. Body temperature/blood oxygen interface:

When measuring body temperature, it is used to connect body temperature cable.

When measuring blood oxygen, it is used to connect the blood oxygen cable.

6. Electrode buckle:
When wearing measurement, the device can be fixed.

2.4 Product structure and composition

It consists of a host, corresponding accessories (cardiog cable, charging data cable), multi-parameter data management software and optional accessories (blood oxygen probe, body temperature probe, chest strap).

3. Preparation before use

3.1 Unpacking inspection

Before unpacking, please check the packing box carefully. If you find any damage, please contact the carrier or our company immediately. If the package is complete, please unpack it in the correct way, and carefully take out the device and other components from the box. Check whether there is any mechanical damage to the equipment and whether the items are complete. If you have any questions, please contact our company immediately.

Caution

- Please keep the packing box and packing materials for future transportation or storage.
- Please keep the warranty card for warranty use.
- When disposing of packaging materials, you must abide by relevant local regulations or the hospital's waste

disposal system and place the packaging materials out of the reach of children.

- The equipment may be contaminated by microorganisms during storage, transportation and use. Please confirm whether the packaging is intact before use, especially the disposable accessories. If any damage is found, please do not use it.
- The production date and expiration date of the product are shown on the label.

3.2 Turn on and turn off

The button screen lights up and the device turns on.

When the measurement is over, the device saves the data and will automatically shut down after a while without any operation.

Note: If the device has been stored for a long time, the device should be charged before using the device again.

4. How to use

4.1 Before use

⚠ **Caution**

- Before taking the measurement, please pay attention to the following points to ensure the accuracy of the measurement data.

- Use only the cables and other accessories specified in this manual.
- Ensure the integrity of the packaging of the purchased disposable ECG electrodes. If the packaging is damaged, please discard it directly.
- Non-grounded equipment next to the patient and interference from electrosurgery can cause waveform instability.
- If the ECG electrodes are dirty, please clean them with a soft cloth or cotton swab moistened with alcohol.

4.2 ECG lead wire, temperature probe and blood oxygen probe placement

A.Use of ECG lead wire, body temperature probe and blood oxygen probe

1. Snap the disposable electrode pad into the electrode connection of the ECG lead wire.
2. Remove the protective packaging on the back of the disposable electrode pad.
3. Correctly place the ECG lead, chest strap, temperature probe and blood oxygen probe in accordance with the electrode placement diagram in the manual or the doctor's guidance. Ensure that the electrode pads are firmly in contact with the patient's skin,

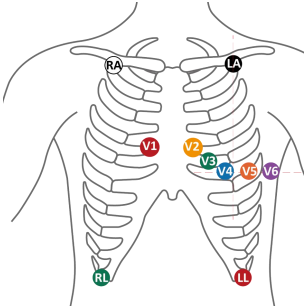
the blood oxygen probe must be in direct contact with the finger skin, and the temperature probe In close contact with the underarm skin.

⚠ **Caution:**

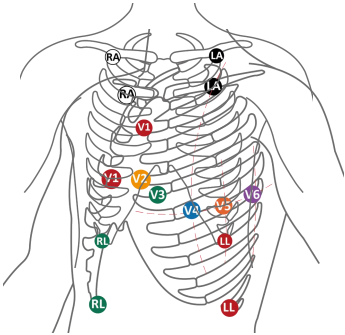
- It is recommended to use it under the guidance of professional medical staff. It is recommended that a person with professional medical training place the ECG lead, chest strap, temperature probe and blood oxygen probe.
- The correct pretreatment of the patient's skin is essential to obtain a good ECG record. Please refer to the electrode manufacturer's instructions for skin pretreatment techniques.
- Please be sure to use ECG electrodes specially used for long-term monitoring of Holter, and the disposable electrode pads should have a valid medical device registration certificate. All electrodes must be from the same manufacturer.
- If the circumference of the finger worn by the blood oxygen probe is too small or too large, the measurement may be inaccurate. Please choose a suitable finger to wear according to the circumference of your finger.

B.ECG lead wire placement

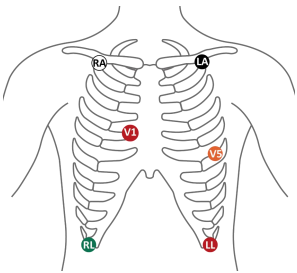
Place the lead wires marked in different colors on the human body according to the corresponding positions for ECG recording. The following figure shows the recommended body surface placement.



Front reference image for twelve-lead placement

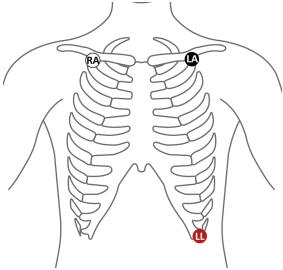


Side reference image for twelve-lead placement



Six-lead placement reference diagram

Five-lead placement reference diagram



Three-lead placement reference diagram

Table 1

Lead	Color	Body surface position (common name)
12-lead electrode cable		
RA	White	Intersection point between the midline of the right clavicle and the second rib (right arm)
LA	Black	The intersection of the left midline of the clavicle and the second rib (left arm)
RL	Green	Right lower abdomen (right leg)
LL	Red	Left lower abdomen (left leg)
V1	Red	Thoracic lead V1: the fourth

		intercostal space at the right edge of the sternum
V2	Yellow	Thoracic lead V2: the fourth intercostal space at the left edge of the sternum
V3	Green	Chest lead V3: midway between V2 and V4
V4	Blue	Thoracic lead V4: midclavicular line at the fifth intercostal space
V5	Orange	Chest lead V5: at the front axillary line, at the same level as V4
V6	Purple	Chest lead V6: at the mid-axillary line, at the same level as V4 and V5
6 lead electrode cable		
RA	White	Intersection point between the midline of the right clavicle and the second rib (right arm)
LA	Black	The intersection of the left midline of the clavicle and the second rib (left arm)
RL	Green	Right lower abdomen (right leg)
LL	Red	Left lower abdomen (left leg)

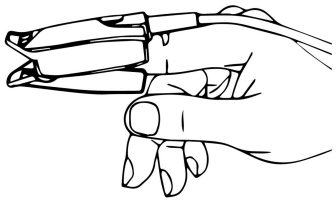
V1	Red	Thoracic lead V1: the fourth intercostal space at the right edge of the sternum
V5	Orange	Chest lead V5: at the front axillary line, at the same level as V4
5 lead electrode cable		
RA	White	Intersection point between the midline of the right clavicle and the second rib (right arm)
LA	Black	The intersection of the left midline of the clavicle and the second rib (left arm)
RL	Green	Right lower abdomen (right leg)
LL	Red	Left lower abdomen (left leg)
V1	Red	Thoracic lead V1: the fourth intercostal space at the right edge of the sternum
3 lead electrode cable		
RA	White	Intersection point between the midline of the right clavicle and the second rib (right arm)

LA	Black	The intersection of the left midline of the clavicle and the second rib (left arm)
LL	Red	Left lower abdomen (left leg)

The user can use the chest strap to fix the holter to record ECG, respiration rate and body temperature.

C.Spo2 probe placement

The pulse oximetry probe is a precision measurement component, and its use must be measured in accordance with the regular methods and procedures. If your operation method is wrong, the probe may be damaged. The functional tester cannot be used to assess the accuracy of the SpO2 sensor or a device.
Put the index finger or middle finger or ring finger of the tested person into the probe for testing.

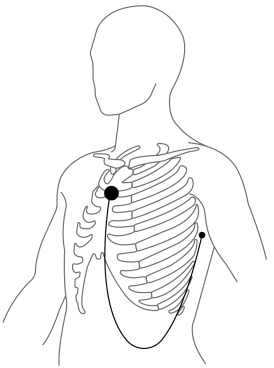


Reference diagram for placement of blood oxygen probe

D.Temperature probe placement

The temperature probe provided is a body surface probe. When using it, please stick the metal patch part of the body surface probe on the patient's body surface, such as the armpit.
If you need to detect the patient's temperature, please attach the temperature probe to the corresponding measurement site of the patient, and connect the other end to the temperature/blood oxygen interface.

- When plugging and unplugging the temperature probe plug, hold the front of the plug with your hand to perform plugging and unplugging actions.



Temperature probe placement reference diagram

4.3 Measurement process

4.3.1 Start of measurement

1）ECG measurement: insert the ECG cable into the

ECG holter, paste the electrodes according to Table 1, after the lead is successful, start the measurement and save the ECG data;

2）Body temperature measurement: When measuring the ECG, the body temperature can be measured; after connecting the body temperature cable, the holter will automatically save the body temperature data.

3）Blood oxygen measurement: when measuring the ECG, the blood oxygen measurement can be started; after connecting the blood oxygen cable, the holter will automatically save the data.

4）Respiration rate measurement: When measuring ECG, the respiration rate can be measured and displayed at the same time, without the need for a separate interface to connect accessories for measurement. The breathing rate measurement principle of this product is the chest impedance method, which collects data and waveforms of heart rate and respiratory parameters simultaneously through the ECG lead wire.

Note: In the process of measuring 12-lead ECG, there is no function to measure respiration rate.

5）After the ECG lead is successfully connected, the ECG waveform will be displayed on the screen. Press

the power button to switch the ECG waveform of different lead types.

Note:

a. The ECG electrode pads must be adhered closely to the skin.

b. If the skin where the electrode pads are applied is dry or hairy, please wipe the skin with a damp cloth or clean the hair before the measurement.

c. When measuring, try not to make large movements, which may affect the ECG signal acquisition.

4.3.2 Leads fall off

1）During the measurement process, if a lead falls off, there will be an indicator of the off state;

2）When all the leads fall off, the measurement will end after a period of time and the data will be saved; during the fall off process, the holter is charged or connected to a PC or mobile device to conduct data, and the measurement will end.

4.4 Data view

During the test, you can view the real-time waveform by connecting to a Bluetooth device.

After the measurement is over, the data measured in the holter can be transmitted to the PC or mobile device software for viewing via USB data cable or Bluetooth.

USB data cable to achieve data export steps:

1) Connect the holter to the PC via a USB data cable

2) Open the supporting software on the PC side

3) According to the PC terminal prompt, realize the export data

Steps to realize data export in Bluetooth mode:

1) Turn on the Bluetooth function of the mobile device and make sure that the Bluetooth function of the mobile device is turned on.

2) Through pairing on the mobile device, after the pairing is successful, the data is exported according to the prompt of the mobile device.

Note:

The maximum storage capacity (recording time) of the holter data is 72 hours.

4.5 Charging

This device uses a rechargeable lithium battery. It can be charged by connecting a laptop or power adapter with a

charging cable.

The specific steps of charging are as follows:

1. Connect the host through the charging cable. As shown below.

2. Connect the charging cable to the USB interface with 5V output voltage for charging. After entering the charging state, the screen displays the charging icon.

Figure 2

Caution:

- The laptop should meet the requirements of IEC60950 and IEC60601 standards.
- A separate charging cable cannot constitute a medical device.
- For your safety, please follow the steps to charge.
- Keep out of children's reach when charging.
- It is necessary to charge the device regularly when it is not in use for long-term storage to maintain battery performance.

5. Care and maintenance

5.1 Repair

⚠ **Caution**

- This equipment must be repaired by a designated after-sales service center, otherwise the warranty rights will not be enjoyed.
- Under the premise of proper maintenance, the expected service life of this equipment is 5 years.

5.2 Warranty

During the warranty period, equipment use problems caused by product material defects can provide free warranty. The warranty is only for end users. During the warranty period, we will repair or replace the equipment free of charge.

5.3 Battery

When the remaining power is insufficient, a low battery icon will appear on the screen, and the device needs to be charged at this time.

⚠ **Caution**

- The built-in rechargeable lithium-ion battery cannot be replaced. Non-professionals cannot open the case, modify or replace the battery without authorization.

- Do not expose the host to high temperature environments, such as ovens, water heaters and microwave ovens. The battery may explode if overheated.
- Do not contaminate or modify the battery. Otherwise, it may cause battery leakage, overheating, fire or explosion.
- If the battery leaks, please keep your skin and eyes free from the leakage of the liquid. If your skin or eyes come into contact with the leaked liquid, please rinse your skin or eyes immediately and go to the hospital for treatment.
- Do not throw the battery into fire. Otherwise, it may cause an explosion.
- When the battery has exceeded its service life or no longer holds power, contact the manufacturer for handling. To dispose of the battery, please follow local laws for proper disposal.

5.4 Cleaning and disinfection

The holter and its accessories need to be cleaned regularly. It is recommended to clean the device once a week. Please use a clean soft cloth, sponge or cotton ball to absorb detergent to clean the device.

The recommended cleaning agents are:

- Clear water

- Medical alcohol (75% concentration)

⚠ **Caution**

- The power must be turned off before cleaning the holter.
- When cleaning the monitor, only wipe the outer periphery of the connector, not the inside.
- Never use abrasive materials.
- Do not let any liquid enter the case, and never immerse any part of the holter in the liquid.
- Do not leave any cleaning fluid on any part of the surface of the holter.
- Do not autoclave the accessories.
- Do not use a damaged holter.
- Do not immerse the holter completely in water, solution or detergent.
- Do not use radiation or steam to sterilize product accessories.

5.5 Recycle

Relevant wastes, residues, etc., as well as equipment and accessories at the end of their service life should not be discarded at will, and should comply with local regulations. When you intend to discard this equipment, you must send it to an appropriate facility for recovery and recycling.

5.6 Question answer

Question	Cause	Solution
The device cannot perform normal collection	1. Low battery 2. Equipment damage	1. Please charge the device 2. Please contact your local agent
The ECG waveform is disordered and the clutter is large	1. Incorrect wearing style 2. Expired ECG electrodes	1. Please re-wear according to the instructions 2. Please replace the ECG electrodes
Failed to upload data	Possibly the holter battery is low or dead	Charge
	Operating system does not support	Please change the operating system
	The holter may be damaged	Contact supplier for repair
Blood oxygen cannot be read	1. The blood oxygen probe is damaged	1. Please contact your local agent

	2. Excessive finger movement	2. Keep the measuring part still
Pulse rate value is not displayed	1.Incorrect placement of fingers 2. Fingers or hands are moving	1. Re-insert the finger 2. Try to keep calm and re-measure

6. Attachment list

No.	Accessory name	Quantity
1	Charging data cable	1
2	3-lead ECG lead wire	1
3	5-lead ECG lead wire	1
4	6-lead ECG cable (optional)	1
5	12-lead ECG lead wire (optional)	1
6	Spo2 probe (optional)	1
7	Body temperature probe (optional)	1

8	Chest strap (optional)	1

* If the user purchases disposable ECG electrode pads, he must purchase a product that meets the long-term Holter use and has a medical device registration certificate.
* The above attachments are for reference only, please refer to the actual attachments.

Caution

- Only use the accessories specified in this manual, using other accessories may damage the device.
- Check whether the single-use ECG electrodes are expired before use.
- Single-use ECG electrodes cannot be attached to the patient's wounded or scarred skin.
- Single-use ECG electrodes should be in close contact with the skin. If itching or skin allergies or ulcers occur, stop using them immediately.
- The designated blood oxygen probe with the host has passed the YY0784 industry standard.

Appendix A Specifications

Classification		
Protection against electric shock	Internal power supply	
Application part protection against electric shock	CF type	
Environment		
	Work	**Transport and storage**
temperature	5 ~ 40°C	-25 ~ 55°C
Relative humidity (non-condensing)	10% ~ 95%	10% ~ 95%
Atmospheric pressure	700 ~ 1060 hPa	700 ~ 1060 hPa

Waterproof and dustproof	IP22
Power supply	
Battery Type	Rechargeable lithium polymer battery
Battery specifications	3.8Vdc, 400mAh
Battery runtime	72 hours (under full state)
Charging input voltage range	4.5 ~ 5.5V DC voltage
Charging time	2 hours (to over 90% battery)
ECG	
Lead	3 leads, 5 leads, 6 leads, 12 leads
input resistance	≥50MΩ，10Hz
Input signal range	10mV（p-v）
Common mode rejection ratio	≥120dB
Bandwidth	0.05 ~ 40 Hz
Gain accuracy	Maximum error ±10%

Heart rate	
Measuring range	30 ~ 250 bpm
Measurement error	±2bpm ， ±2%，Whichever is larger
Resolution	1 bpm
Body temperature	
Mode	Direct mode
Measurement site	Axilla
REFERENCE BODY SITE	Axilla
Display range	25.0℃ ~ 45.0℃
Resolution	0.1℃
Maximum allowable error	±0.1℃
At the measurement site (underarm), the minimum measurement time required to obtain an accurate reading	20s
Respiration rate	

Measuring range	0rpm～150rpm
measurement accuracy	±2rpm or ±2% of the measured value, whichever is greater.
Blood oxygen	
Blood oxygen range	70%～100%
Blood oxygen accuracy	Within the range of 70%～100%, the accuracy should be ±2%.
Pulse rate range	30bpm～250bpm
Pulse rate accuracy	±2bpm or ±2%, whichever is greater
Wavelength	Red light: 600nm, infrared light: 940nm
Maximum optical output power	0.8mW/1.2mW
Data update cycle	4s
Wireless	Support Bluetooth connection
Bluetooth module	
Frequency	2402-2480MH

Modulation type	GFSK modulation
Effective radiated power	-20dBm-+8dBm
Dimensions	48.2mm×48.2mm×15.2mm
Host weight	<50 g (including battery)
Period of use	5 years
Production Date	See the nameplate for details

Appendix B Electromagnetic compatibility

The device meets the requirements of IEC 60601-1-2.

⚠ **Warnings and Cautions**

- This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

- The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

Guidance and manufacturer's declaration – electromagnetic emissions		
The model Wireless dynamic multi-parameter holter is intended for use in t electromagnetic environment specified below. The customer or the user of t model Wireless dynamic multi-parameter holter should assure that it is used such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The model Wireless dynamic multi-parameter holter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interferenc in nearby electronic equipment.
RF emissions CISPR 11	Class B	The model Wireless dynamic multi-parameter holter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	n.a.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Recommended separation distances between portable and mobile RF communications equipment and the A&D unit

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d = [\frac{3.5}{P}]_{V_1}$	80MHz to 800MHz $d = [\frac{3.5}{P}]_{E_1}$	800MHz to 2.7GHz $d = [\frac{7}{P}]_{E_1}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.70
10	3.70	1.11	2.22
100	11.70	3.50	7.00

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.

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey,
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					

2450	2	0.3	28	28	should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
5240					
5500	0.2	0.3	9	9	
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity

The model Wireless dynamic multi-parameter holter is intended for use in the electromagnetic environment specified below. The customer or the user of The model Wireless dynamic multi-parameter holter should assure

Immunity test	**IEC 60601 test level**	**Compli ance level**	**Electromagnetic environment – guidance**

Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	$3V_{rms}$ 150kHz to 80MHz 10V/m 80MHz to 2.7GHz	N/A 10V/m	Portable and mobile RF communications equipment should be used no closer to any part of The model Dynamic ECG recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz

			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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and

40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1

MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4

MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c 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

Guidance and manufacturer's declaration – electromagnetic immunity			
The model Dynamic ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The model Wireless dynamic multi-parameter holter 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	± 8 kV contact ± 2 kV,± 4 kV,± 8 kV，± 15kV air	± 8 kV contact ± 2 kV,± 4 kV, ± 8 kV，± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	n.a.	n.a.
Surge IEC61000-4-5	± 1 kV line to line ±2 kV line to earth	n.a.	n.a.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T 0,5cycle At 0°,45°,90°,135°,180°,225°,270°and 315°, 0% U_T 1cycle and 70% U_T 25/30 cycles Single phase:at 0°	n.a.	n.a.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m, 50/60Hz	30A/m,50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE : U_T is the AC mains voltage prior to application of the test level.			

Wireless dynamic multi-parameter holter

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CE 0197

Version: A

Contents of this manual are subject to changes without prior notice.

Revision date: December 2021

FCC Warnning:

FCC ID:2ADXK-8100

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

This device may not cause harmful interference, and this device must accept any interference received, including interference that may cause undesired operation.

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

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

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

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

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