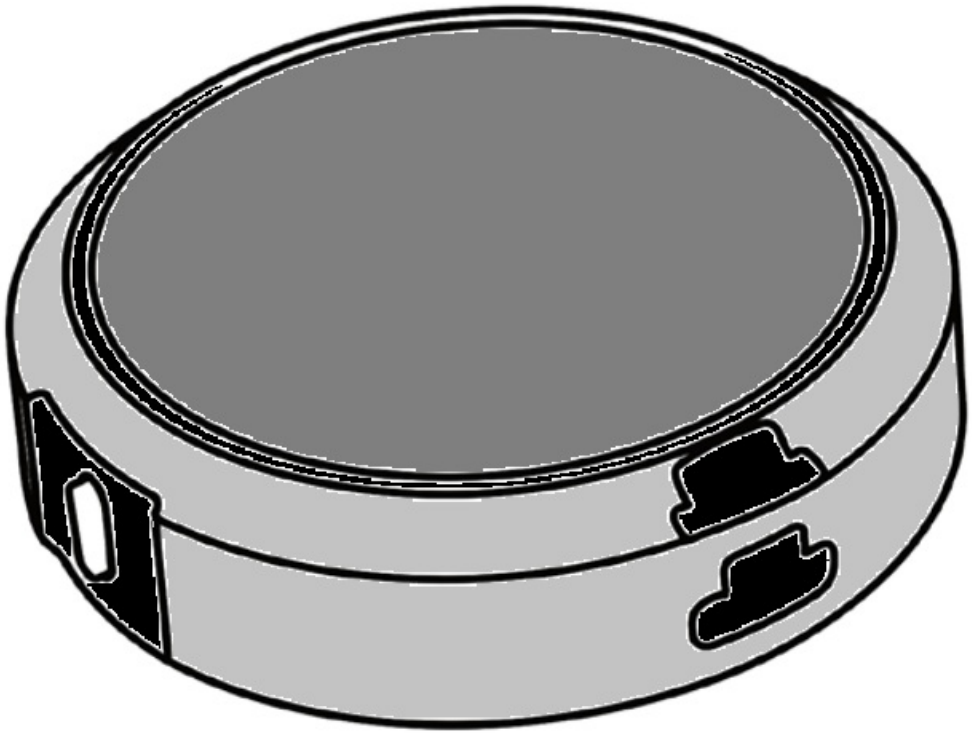
Viatom M54299EN Wireless Dynamic Multi Parameter Holter Instruction Manual

Contents

Viatom
Innovation Beyond Limitation

Viatom M54299EN Wireless Dynamic Multi Parameter Holter



Introduction

Thank you for purchasing a wireless dynamic multi-parameter holter (hereinafter referred to as the holter).

This manual describes the purpose, function and safe use of the device. Before using this device, please read carefully and fully understand the contents of this manual to ensure the proper use of this device 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 assist users in repairing equipment parts identified by the manufacturer as repairable.

This product does not have the function of detecting cardiac arrest and ST.
Software release version: V1

Safety information

Caution

- Before using this device, please read this manual carefully and fully understand the relevant warnings and risks.
- This device cannot replace the medical diagnosis results of professional physicians.
- The measurement results of this device are for reference only and cannot be directly used as a basis for clinical treatment.
- The disposable ECG electrodes used with this device are accessories purchased by the user and must be a regular device with a medical device registration certificate.
- Disposable ECG electrodes cannot be applied to the patient’s wounded or scarred skin.
- Disposable ECG electrodes should be in close contact with the skin. If itching, 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 physician’s advice if necessary.
- This device cannot be used simultaneously with defibrillators and electrosurgical equipment.

- This device cannot be used during CT or MRI.
- When using this device, 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 equipment or affect the operation of this device.
- This device cannot be used in a flammable environment (such as an oxygen-rich environment).
- This device cannot be used by infants weighing less than 10 kg.
- Do not swim or submerge the device in water. Do not immerse the device in water or other liquids. Keep the device waterproof and away from high temperature and humidity.
- Do not use acetone or other volatile solutions to clean the device.
- Do not violently bump or squeeze the device, if the case is broken, please stop using it.
- Do not place this device in a pressure vessel or gas sterilizer.
- Do not disassemble the device arbitrarily, as it will cause the device to malfunction or affect the normal operation of the device.
- Keep the device out of the reach of children.
- Be careful not to allow cables and hoses to become entangled due to excessive length.
- This device is not intended for use by persons with sensitive skin or allergies.
- Do not expose this device to direct sunlight, high temperature, high humidity, near water or fire, or to strong electromagnetic fields. Before using the device, make sure that the device 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.
- For proper monitoring, do not participate in strenuous or extensive physical activities.
- 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 device cannot distinguish all diseases. If you feel unwell, you should consult your physician immediately in addition to referring to the measurement results of this device.
- Do not perform self-diagnosis and take medication based on the measurement results of this device without consulting your physician. In particular, do not take any new medication without prior approval.
- This device cannot replace professional devices for measuring heart or other organ functions. Medical electrocardiogram measurement requires more professional and complete measurement.
- Do not use the information displayed by the host as the sole basis for clinical diagnosis. The host is used only as an auxiliary means in diagnosis. It must be used in conjunction with clinical manifestations and symptoms and the physician’s diagnosis.
- We recommend that you record your ECG waveform and measurement results, and provide them to your physician for reference if necessary.
- Although all parts of this device that come into contact with the human body have been tested for biocompatibility, a very small number of users may experience an allergic reaction, and should discontinue use if they experience an allergic reaction.
- Prolonged use 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 function holter cannot be used to evaluate the accuracy of devices 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 environment is too light
    - Incorrect sensor type
    - Excessive movement
    - Moisture in the sensor
    - High frequency electrosurgical interference
    - Improper use of sensors
    - Blood flow restriction
    - Weak pulse or poor signal
- Waste (including the discarded device itself) shall be handled in accordance with applicable laws and regulations.
- The validity period of this product is 5 years. Refer to the host nameplate for the product's manufacturing date.
- When multiple devices are used simultaneously on the same patient, the leakage current may overlap and cause a hazard. Prior to interconnection, it is recommended that a leakage current test be performed by a qualified technician to ensure that the leakage current is within the safe limits, i.e., will not cause harm to the patient, the operator, or the environment. If in doubt, the operator should consult the manufacturer for proper application.
- Do not expose the device to high temperatures, high pressure, gas fumigation, or liquid immersion disinfection. Please clean and disinfect the device and its accessories in accordance with the manufacturer's instructions. Power must be disconnected before cleaning or disinfecting the device.
- It is the operator's responsibility to check the compatibility of the holter, probes and cables prior to use and incompatible accessories may result in reduced performance of the device (including SpO2 probe).

Symbols

Symbols	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Consult instructions for use (Background: blue; Symbol: white)
	Caution, Incorrect use may cause personal injury and damages of goods. Refer to instruction manual.
	Type CF applied part
IP22	Dustproof and waterproof grade
	Non-ionizing electromagnetic radiation
	Indicates separate collection for electrical and electronic equipment (WEEE)
	Alarm free system
	Serial number
	Use-by date
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

CE 0197	Indicates that this device complies with the Medical Devices Regulation (EU) 2017/745 (MDR)
EC REP	Authorized representative in the European Community
UK REP	Authorized representative in the United Kingdom
UKCA	UKCA marking
UDI	Unique device identifier
MR	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
FC	This product complies with the rules and regulations of the Federal Communication Commission.
	Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).
	This product complies with verpackG

Product Introduction

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:

	M5	M12	Lepod	Lepod Pro	LMT- 5	LMT- 12
ECG (3 leads, 5 leads)	●	●	●	●	●	●
ECG (6 leads, 12 leads)	×	●	×	●	×	●
Blood oxygen*	●	●	●	●	●	●
Bluetooth	●	●	●	●	●	●
Software release version	V1	V1	V1	V1	V1	V1
Shell color	Black	Black	White	White	Blue	Blue

Note 1

- **●:** indicates that the corresponding model is configured with relevant functions and accessories.
- **×:** indicates that the corresponding model is not configured with relevant functions and accessories.
- ***:** The blood oxygen function is available when you purchased blood oxygen accessories.

Intended use

The Wireless dynamic multi-parameter holter is a small digital ambulatory ECG recorder. It is intended to record, store, display, transfer ECG data, receive and display blood oxygen (SpO2) and PR (pulse rate) data from the Pulse oximeter (SpO2 Probe); For routine checkups and/or self-monitoring of patients in the clinical setting and/or home settings under professional (e.g. doctor, nurse, family doctor) supervision.

Clinical setting is only applicable to the general medical clinical setting, not for ICU, Emergency, Intensive care, Surgery, and the clinical setting that must be specifically alarmed and analyzed.
The Wireless dynamic multi-parameter holter does not include analysis and diagnosis functions, does not include monitoring function. Data are given to the doctor or the user. The device no analysis by itself and is intended to be used with a compatible ambulatory ECG (Holter) analysis system (AI-ECG Tracker) which will analyze the recorded data. The device data and the data analysis are then reviewed by trained medical personnel for the purpose of forming a clinical diagnosis.

The device data are used as a base to establish a doctors' diagnosis, but the data cannot replace the diagnosis result given by a doctor.

Contraindication

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

Patient populations

- This product is suitable for adults (Over 18 years old).

About holter

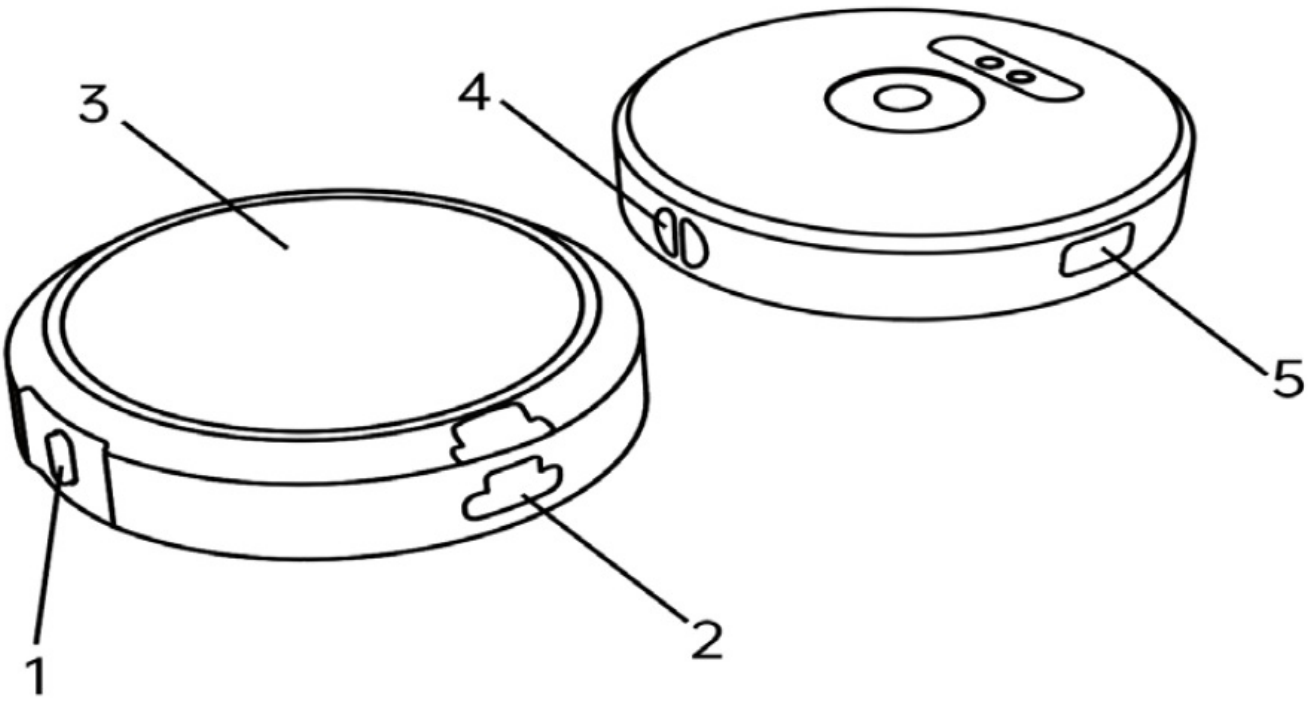


Figure 1

1. On/Off button:
    - Used to turn the device on and off. You can switch the ECG lead channel.
2. ECG interface/charging interface:
    - 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. blood oxygen interface:
    - Used to connect the SpO2 cable when measuring blood oxygen.

Note:

- If the device has been configured with the blood oxygen function, refer to the description of blood oxygen in this manual.

Product structure and composition

- It consists of a host, corresponding accessories (ECG cable, charging data cable, lanyard), and optional accessories (pulse oximeter).

Preparation before use

Unpacking inspection

Before unpacking, please check the packaging carefully. If you find any damage, please contact the carrier or our company immediately. If the packaging is complete, please unpack it properly, and carefully take out the device and other components from the packaging. Check that there is no mechanical damage to the device and that the items are complete. If you have any questions, please contact our company immediately.

Caution

- Please keep the packaging and packing materials for future shipping or storage.
- Please retain the warranty card for warranty service.
- When disposing of packaging materials, please comply with applicable local regulations or the hospital's waste disposal system and, keep the packaging materials out of reach of children.
- The device may become contaminated with microorganisms during storage, transportation and use. Before use, check that the packaging is intact, especially the disposable accessories. If any damage is found, please do not use the device.
- The production date and expiry date of the product are printed on the label.

Turn on and turn off

- The button screen lights up and the device turns on. When the measurement is finished, the device saves the data and automatically shuts down after a while without any operation.

Note:

- If the device has been stored for a long time, it should be charged before it is used again.

How to use

Before use

Caution

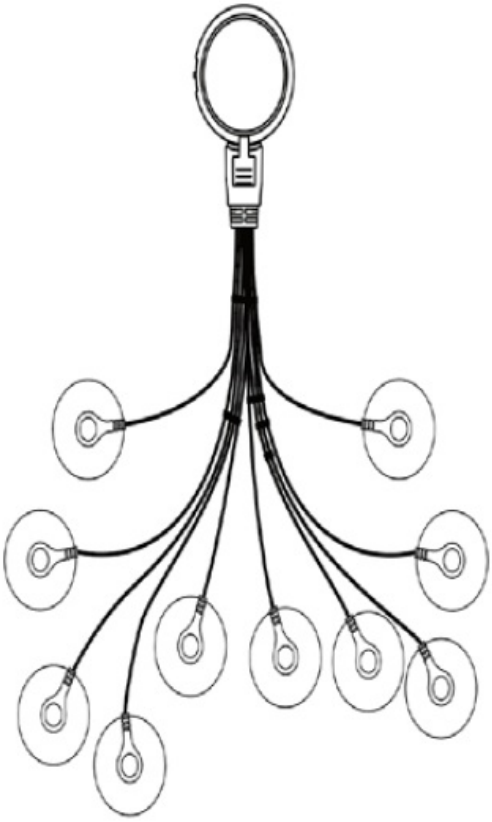
- Before taking the measurement, please observe the following points to ensure the accuracy of the measurement data.
- Use only the cables and other accessories specified in this manual.
- Check the integrity of the packaging of the purchased disposable ECG electrodes. If the packaging is damaged, please discard it immediately.
- Non-grounded equipment near 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.

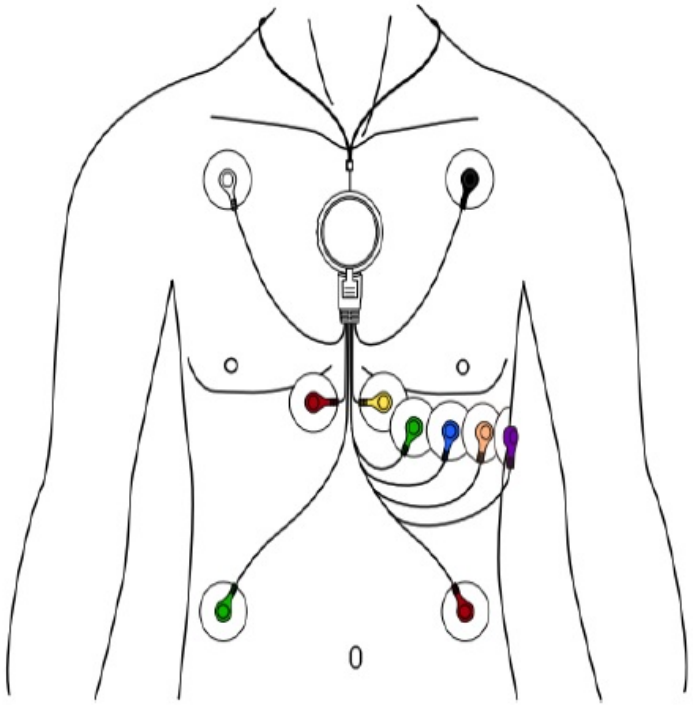
ECG lead wire and SpO2 probe placement

Use of ECG lead wire and SpO2 probe

1. Snap the disposable electrode pad into the electrode connector of the ECG lead wire.

2. Remove the protective packaging from the back of the disposable electrode pad.
3. Correctly place the ECG lead and SpO2 probe in accordance with the placement diagrams in the manual or the physician’s instructions. Make sure the electrode pads are in firm contact with the patient’s skin, the SpO2 probe is in direct contact with the finger skin.



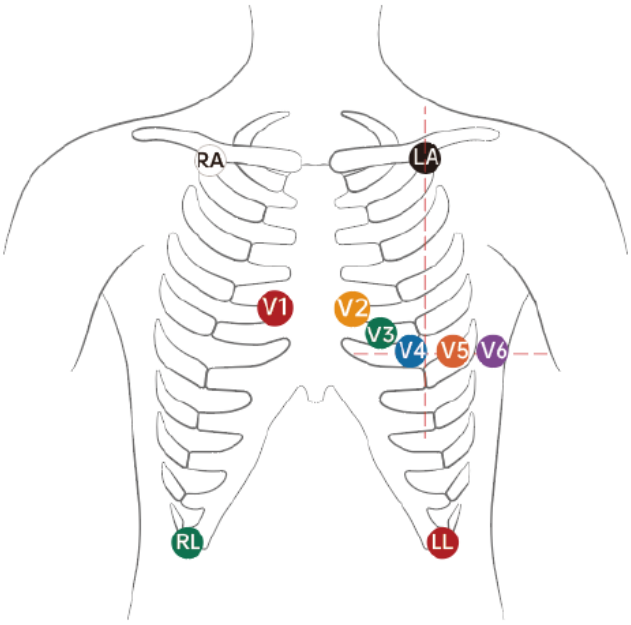


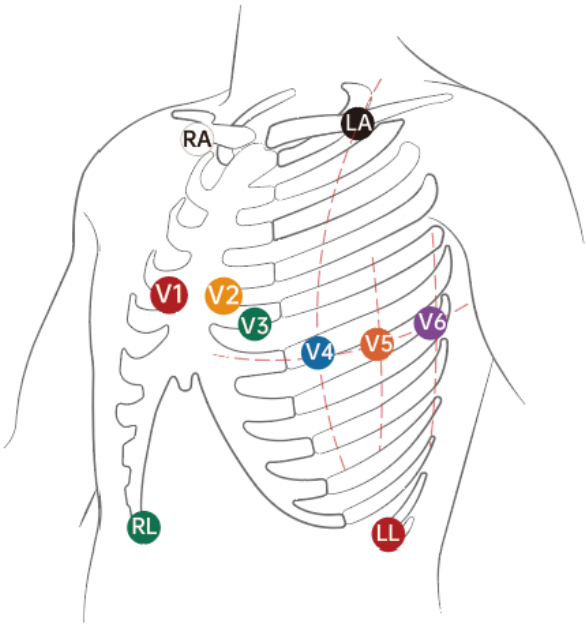
Caution

- It is recommended that it be used under the guidance of professional medical personnel. It is recommended that a person with professional medical training place the ECG lead and SpO2 probe.
- Proper pre-treatment of the patient’s skin is essential to obtain a good ECG record. Please refer to the electrode manufacturer’s instructions for skin pre-treatment techniques.
- Please be sure to use ECG electrodes specifically designed for long-term Holter monitoring, and the disposable electrode pads should have a valid medical device registration certificate (CE or FDA). All electrodes should be from the same manufacturer.
- If the circumference of the finger worn with the SpO2 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.

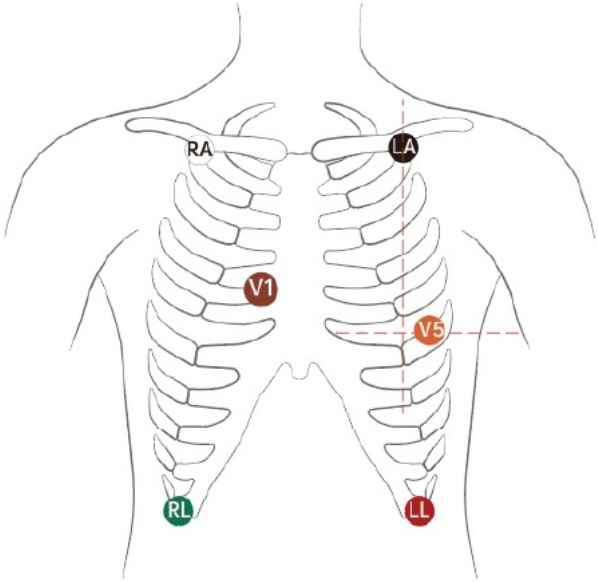
ECG lead wire placement

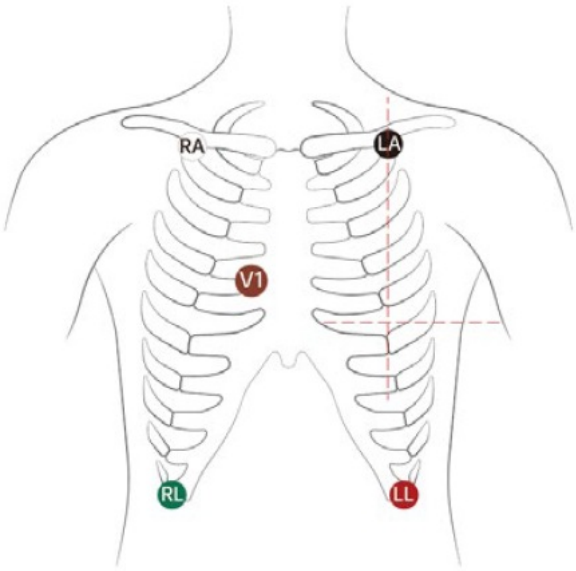
Place the lead wires marked in different colors on the human body according to the corresponding positions for ECG recording. The following figure shows the recommended placement on the body surface.



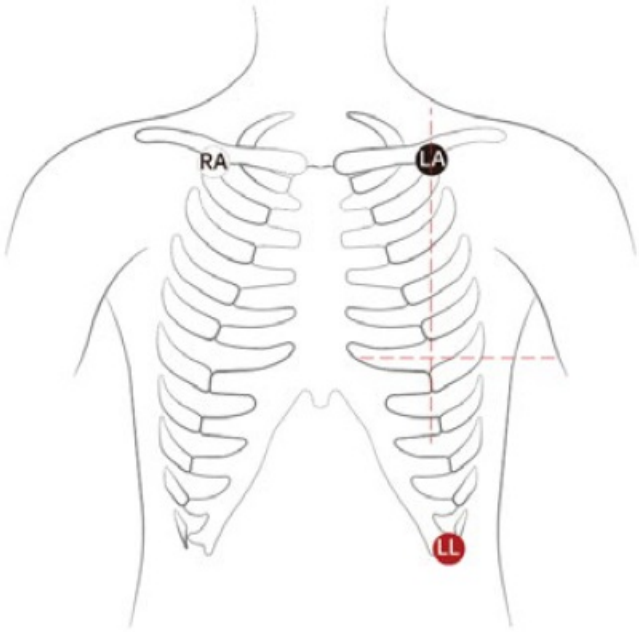


- Front reference diagram of twelve-lead placement
- Side reference diagram of twelve-lead placement





- Reference diagram of six-lead placement
- Reference diagram of five-lead placement



- Reference diagram of three-lead placement

Caution: The placement of electrodes is pivotal for right signal acquisition, SO must be supervised and/or assisted by a professional (e.g. doctor, nurse, family doctor) when the user performs electrode placement.

Table 1

AHA		IEC		Body surface position (common name)
Label	**Color**	**Label**	**Color**	
12-lead electrode cable				
RA	White	R	Red	Intersection point between the midline of the right clavicle and the second rib (right arm)
LA	Black	L	Yellow	The intersection of the left midline of the clavicle and the second rib (left arm)
RL	Green	N	Black	Right lower abdomen (right leg)
LL	Red	F	Green	Left lower abdomen (left leg)
V1	Red	C1	Red	The fourth intercostal space at the right edge of t he sternum
V2	Yellow	C2	Yellow	The fourth intercostal space at the left edge of th e sternum
V3	Green	C3	Green	Midway between V2(C2) and V4(C4)
V4	Blue	C4	Brown	Midclavicular line at the fifth intercostal space
V5	Orange	C5	Black	At the front axillary line, at the same level as V4(C4)
V6	Purple	C6	Purple	At the mid-axillary line, at the same level as V4(C4)

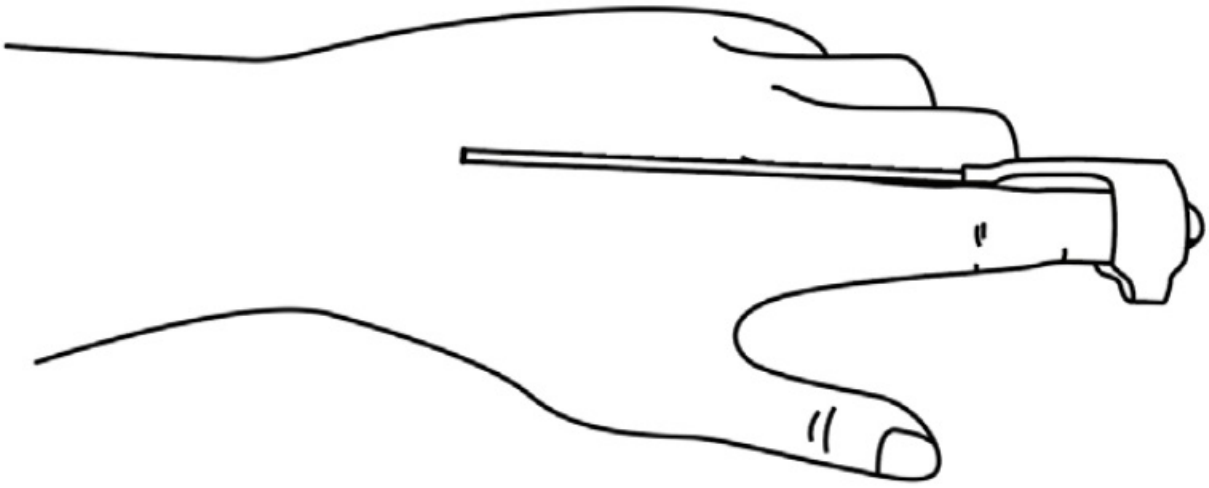
AHA		IEC		Body surface position (common name)
Label	**Color**	**Label**	**Color**	
				and V5(C5)
6-lead electrode cable				
RA	White	R	Red	Intersection point between the midline of the right clavicle and the second rib (right arm)
LA	Black	L	Yellow	The intersection of the left midline of the clavicle and the second rib (left arm)
RL	Green	N	Black	Right lower abdomen (right leg)
LL	Red	F	Green	Left lower abdomen (left leg)
V1	Brown	C1	Red	The fourth intercostal space at the right edge of t he sternum
V5	Orange	C5	Black	At the front axillary line, at the same level as V4(C4)
5-lead electrode cable				
RA	White	R	Red	Intersection point between the midline of the right clavicle and the second rib (right arm)
LA	Black	L	Yellow	The intersection of the left midline of the clavicle and the second rib (left arm)
RL	Green	N	Black	Right lower abdomen (right leg)
LL	Red	F	Green	Left lower abdomen (left leg)
V1	Brown	C1	Red	The fourth intercostal space at the right edge of t he sternum

3-lead electrode cable				
RA	White	R	Red	Intersection point between the midline of the right clavicle and the second rib (right arm)
LA	Black	L	Yellow	The intersection of the left midline of the clavicle and the second rib (left arm)
LL	Red	F	Green	Left lower abdomen (left leg)

SpO2 probe placement

The pulse oximetry probe is a precision measurement component, and its use must be measured in accordance with normal methods and procedures. If your method of operation is incorrect, the probe may be damaged. The function tester cannot be used to evaluate the accuracy of the SpO2 sensor or any device.

Put the index finger of the tested person into the probe for testing.



Reference diagram of SpO_2 probe placement

Caution

- The SpO2 probe is not suitable for use during motion, or when there is poor perfusion.

Measurement process

Start measurement

1. ECG measurement: Insert the ECG cable into the holter, attach the electrodes according to Table 1; after the

lead is successful, start the measurement and save the ECG data;
2. Blood oxygen measurement: when measuring ECG, the blood oxygen measurement can be started; after connecting the SpO2 cable, the holter will automatically save the data.
3. 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:

- The ECG electrode pads must adhere closely to the skin.
- 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 taking the measurement.
- When taking the measurement, try not to make large movements that may affect the ECG signal acquisition.

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.

Data view

During the test, you can view the real-time waveform by connecting to a Bluetooth device.
After the measurement is complete, the data from the holter can be transmitted to the PC or mobile device software for viewing via a USB data cable or Bluetooth connection.

To export data using a USB data cable, follow these steps:

1. Connect the holter to the PC via a USB data cable.
2. Open the supporting software on the PC.
3. Follow the prompts on the PC to export the data.

To export data in Bluetooth mode, follow these steps:

1. Turn on the Bluetooth function on your mobile device and make sure that it is paired with the holter.
2. Export the data according to the prompts on your mobile device.

Note:

- The holter has a maximum storage capacity (recording time) of 72 hours.

Charging

This device is powered by a rechargeable lithium battery. It can be charged by connecting it to a laptop or power adapter using a charging cable.
To charge the device, follow these steps:

1. Connect the device to the charging cable, as shown below.
2. Connect the charging cable to the USB interface with a 5V output voltage to begin charging. Once charging has started, the screen will display a charging icon.

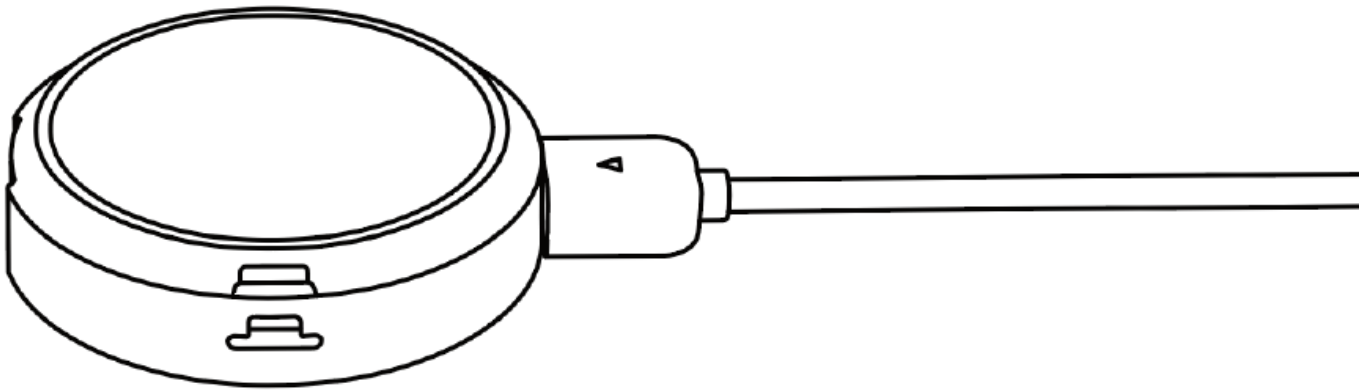


Figure 2

Caution

- The laptop used to charge the device should meet the requirements of IEC60950 and IEC60601 standards.
- A separate charging cable cannot be considered a medical device.
- For your safety, please follow the recommended steps to charge the device.
- Keep the device out of reach of children during the charging process.
- It is recommended to charge the device regularly during long-term storage to maintain battery performance.

Care And Maintenance

Repair

Caution

- This device must be repaired by a designated after-sales service center to enjoy warranty rights. Repairs made by unauthorized personnel may void the warranty.
- With proper maintenance, this device is expected to have a service life of 5 years. The ECG cable and the SpO2 probe are also expected to have a service life of 5 years.

Warranty

- During the warranty period, any device use problems caused by material defects will be covered by free warranty.
- The warranty is only valid for end users. If any issues arise during the warranty period, we will repair or replace the device free of charge.

Battery

- When the device’s remaining power is insufficient, a low battery icon will appear on the screen. At this point, the

device needs to be charged to ensure continued use.

Caution

- The built-in rechargeable lithium-ion battery is non-replaceable. 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. Overheating may cause the battery to explode.
- Do not contaminate or modify the battery, as this may cause leakage, overheating, fire or explosion.
- In the event of battery leakage, avoid skin and eye contact with the liquid. If contact occurs, please rinse the affected area immediately and go to the hospital for treatment.
- Do not dispose of the battery in fire, as this may cause an explosion.
- When the battery has exceeded its service life or no longer holds power, contact the manufacturer for proper handling. To dispose of the battery, please follow local laws for proper disposal.

Cleaning and disinfection

The holter and its accessories should be cleaned regularly, with a recommended cleaning frequency of once a week. To clean the device, please use a clean soft cloth, sponge or cotton ball soaked in a suitable cleaning agent.

The recommended cleaning agents are:

- Clear water
- Medical alcohol (75% concentration)

Caution

- Turn off the power before cleaning the holter.
- When cleaning the monitor, only wipe the outer periphery of the connector, not the inside.
- Do not use abrasive materials.
- Do not allow any liquid to 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 fully immerse the holter in water, solution or detergent.
- Do not use radiation or steam to sterilize product accessories.

Recycle

- Relevant wastes, residues, and end-of-life equipment and accessories should not be discarded arbitrarily, and should comply with local regulations.
- When you intend to dispose of this device, you must send it to an appropriate facility for recovery and recycling.

Troubleshooting Guide

Issue	Possible Cause	Solution
The device cannot perform normal collection	1. Low battery 2. Equipment damage	1. Charge the device 2. Contact local agent for repair
The ECG waveform is disordered and the clutter is large	1. Incorrect wearing style 2. Expired ECG electrodes	1. Re-wear according to instructions 2. Replace ECG electrodes
Failed to upload data	Low or dead holter battery	Charge the battery
	Incompatible operating system	Change the operating system
	Equipment damage	Contact supplier for repair
Blood oxygen cannot be read	1. Damaged SpO2 probe 2. Excessive finger movement	1. Contact local agent for repair 2. Keep the measuring part still
Pulse rate value is not displayed	1. Incorrect finger placement of fingers 2. Moving fingers or hands	1. Re-insert the finger 2. Try to keep calm and re-measure

Attachment list

No.	Accessory name	Quantity	Model	Code
1	Charging data cable	1	540-04525-00	
2	3-lead ECG lead wire	1	HA136S3A	540-05002-00
3	5-lead ECG lead wire	1	HA136S5A	540-04997-00
4	6-lead ECG lead wire (optional)	1	HA136S6A	540-04998-00
5	12-lead ECG lead wire (optional)	1	HA136S10A	540-05773-00
6	SpO2 probe (optional)	1	VTM01\VTM 01A\VTM01B	540-04521-00
7	Lanyard	1	560-05630-00	

When purchasing disposable ECG electrode pads, you should ensure that the product is suitable for long-term Holter use and has a medical device registration certificate (CE\FDA).
The above attachments are for reference only, and you should refer to the actual attachments for accurate information.

Caution

- Only use the accessories specified in this manual, as using other accessories may damage the device.
- Check the expiration date of the disposable ECG electrodes before use.
- Do not attach disposable ECG electrodes to wounded or scarred skin.
- Ensure that disposable ECG electrodes are in close contact with the skin. If itching, skin allergies or ulcers occur, stop using them immediately.
- The designated SpO2 probe with the device has passed the ISO80601-2-61 industry standard.

Appendix A

Appendix A Specifications

Classification		
Protection against electric shock	Internal power supply	
Application part protection against electric shoc k	CF type	
Environment		
	Work	**Transport and storage**
temperature	5 ~ 45°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 Li-ion 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 or ±2%, Whichever is larger
Resolution	1 bpm
	Heart rate = 60 divided by the mean time between RR or PP
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

Recommended maximum application time	24h
Wireless	Support Bluetooth connection
Bluetooth module	
Frequency	2360-2500MH
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

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

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

The 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 Wireless dynamic multi-parameter holter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Wireless dynamic multi-parameter holter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to the frequency of transmitter (m)**		
	150kHz to 80MHz $d = [\underline{3.5}]\ P\ V\ 1$	80MHz to 800MHz $d = [3.5]\ P\ E1$	800MHz to 2.7GHz $d = [\ 7\ ]\ P\ E1$
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** $E = \frac{6}{d}\sqrt{P}$
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	

870					Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					
NOTE 1 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					

Appendix B

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

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The 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 interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 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		

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	**IEC 60601 test leve l**	**Compliance level**	**Electromagnetic environment – g uidance**
Conducted RF IEC61000 -4-6	3Vrms 150kHz to 80MHz	N/A	Portable and mobile RF communica tions equipment should be used no closer to any part of the Wireless dy namic multi-parameter holter, includ ing cables, than the recommended separation distance calculated from the equation applicable to the frequ ency of the transmitter.
Radiated RF IEC61000-4 -3	10V/m 80MHz to 2.7GHz	10V/m	
			Recommended separation distan ce
			$d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80MHz to 800MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.7GHz Where P is the maximum output po wer rating of the transmitter in watts (W) according to the transmitter ma nufacturer and d is the recommended separation distance i n metres(m). Field strengths from fi xed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Int erference may occur in the vicinity o f equipment marked with the followi ng 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 the location in which the Wireless dynamic multi-parameter holter is used exceeds the applicable RF compliance level above, the Wireless dynamic multi-parameter holter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Wireless dynamic multi-parameter holter.

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

Guidance and manufacturer's declaration – electromagnetic immunity

The Wireless dynamic multi-parameter holter is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	0% U_T 0,5cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°, 0% U_T 1cycle	n.a.	n.a.
IEC 61000-4- 11	and 70% U_T 25/30 cycles Single phase: at 0°		
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.			

FCC STATEMENT

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.

CONTACTS

Wireless dynamic multi-parameter holter

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Documents / Resources

	Viatom M54299EN Wireless Dynamic Multi Parameter Holter [pdf] Instruction Manual M54299EN Wireless Dynamic Multi Parameter Holter, M54299EN, Wireless Dynamic Multi Parameter Holter, Dynamic Multi Parameter Holter, Multi Parameter Holter, Parameter Holter, Holter

References

- User Manual