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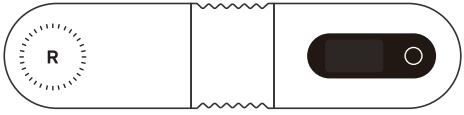

Dynamic ECG Recorder

User Manual

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1. The Basics

This manual contains the instructions necessary to operate the product safely in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

1.1 Safety

⚠ Warnings and Cautionary Advice

- Before using this equipment, please read this manual carefully and fully understand the warnings and risks.
- This device is not intended to replace the medical diagnosis of a professional doctor.
- The measurement results of this device are for reference only and cannot be directly used as a basis for clinical treatment.
- We do not recommend the use of this device if you have a pacemaker or other implantable device in your body. Please follow the doctor's advice if necessary.
- This device cannot be used with a defibrillator.
- This device cannot be used during ct or nuclear magnetic resonance (MRI) procedures.
- This equipment must not be used in a flammable environment (e.g. oxygen-rich environment).
- This device is not intended for use by infants weighing less than 10 kg.
- Do not swim or submerge the device in the water. Do not immerse the device in water or other liquids.
- Do not use acetone or other volatile solutions to clean the device.

- Do not strongly collide or crush the device. If the casing is broken, stop using it.
- This device cannot be placed in a pressure vessel or gas sterilization equipment.
- Do not disassemble or modify the device without authorization of the manufacturer, otherwise it may cause machine malfunction or affect the normal operation of the device.
- Keep this device out of the reach of children or pests.
- This device should not 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 sources, and high electromagnetic influence.
- Users should try to avoid sweating. The sweat will affect the contact between the electrodes and the skin, affecting the quality of the measurement.
- Users should inspect loosened electrodes, that can degrade performance or cause other problems.
- Do not participate in violent or extensive physical activity in order to make appropriate measurements.
- The measurement results of this device cannot distinguish all diseases. If your body feels unwell, you should consult your doctor immediately, in addition to the measurement results of this device.
- Do not self-diagnose and take medication based on the measurements of this device without consulting your doctor. In particular, do not take new medications without prior permission.
- This device is not a substitute for professional heart or other organ function measurement equipment. Medical

ECG measurement requires more professional and complete measurements.

- This device cannot be used to diagnose a disease directly. Please consult your doctor.
- We recommend that you record your ECG curve and the results of the measurements and provide them to your doctor if necessary.
- Waste (including the equipment itself is scrapped) is disposed of in accordance with relevant laws and regulations.
- When the ambient temperature is 20 °C, the minimum and maximum storage temperature from the product to ready for use is 2H (the time required).
- The patient is the expected user.
- Do not pile up the long tubing at the head of the bed, as it may wrap around the head or neck of the patient during sleep.
- Li batteries capacity will decrease after charge discharge for 300 times.
- The electrodes (Applied parts) should not contact other conductive parts including earth.
- The product should not be maintained while in use.
- The device shall only be maintained by qualified professionals.
- The manufacturer shall provide the service personnel with circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair the device.

2. Introduction

2.1 Name and Model

Name: Dynamic ECG recorder

Model: ER1-LB

2.2 Intended Use

The Dynamic ECG recorder is intended to measure, review and store adults' ECG data at home or in healthcare environment.

The device continuously records and stores ECG and activity data for at least 7 days at a time.

The device does 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 does not include analysis and diagnosis functions.

The device has not been tested and it is not intended for pediatric use.

2.3 Contraindications:

The product is not intended for use in patients with cardiac pacemakers or other implantable devices.

2.4 About ER1-LB

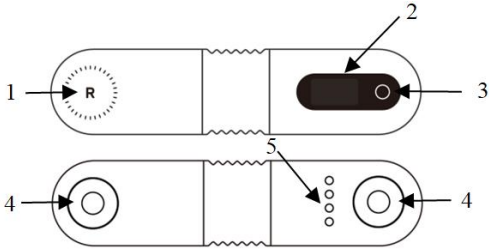

Figure 1

1. Right sign

   When wearing, the side marked "R" should be on the right hand side of the wearer.

2. Display screen

   The display screen demonstrates ECG waveform, and shows heart rate, battery power and charging status.

3. Touch key

   A. Long press 6s to turn off (In power-on non-measuring state)

   B. Long press 3s to turn on (In power-off state);

   C. Short press to lighten the screen and long press 1s to check device time (In standby state)

   D. Short press to lighten the screen, and switch pages displaying device ID and device time & battery status. (Not wearing the device)

   E. Short press to switch pages displaying ECG waveform, heart rate, device ID, and device time & battery status. (Wearing the device)

F. Press and hold for 3 seconds to mark ECG events accompanied by a vibration (Wearing the device)

Note: This function is off by default and can be turned on in the App.

4. Electrode buckle

For connecting chest strap, disposable electrocardiogram electrode or charging cable.

5. Charging contacts

For connecting the charging clip.

2.5 Symbols

	Symbol	Significance
Symbols on the device		Type BF-Applied Part
		Manufacturer
		Date of manufacture
		Authorized representative in the European Community
		Authorized Representative in the United Kingdom
		UKCA marking
		This product complies with the EU 2017/745 (MDR)
		Caution, Incorrect use may cause personal injury and damages of goods. Refer to instruction manual.

	IP22	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.
		MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
		Follow Instructions for Use.
		This product complies with the rules and regulations of the Federal Communication Commission.
		Non-ionizing radiation
	SN	Serial number
		Indicate separate collection for electrical and electronic equipment (WEEE).
		This product complies with verpackG
		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).
	MD	Medical device
	UDI	Unique device identifier

		Use-by date
		Temperature limit
		Humidity limitation
		Atmospheric pressure limitation

	Display	Indications
Symbols on the screen		Powering on
		Battery status reminder
		Device ID display
		Start measurement
		ECG waveform demonstration
		Heart rate measurement
		ECG Marker
		Lead off

		Invalid waveform
		Battery level below 15% or 5%
		Switch to home screen, low battery display
		Charging
		Charge complete
		Data upload reminder
		Data storage
		Data download via Bluetooth
		USB data transfer in progress
		Powering off
		Standby screen
		Lead off countdown

2.6 Product structure and composition

This product is mainly composed of Dynamic ECG recorder main unit, charging cable, chest strap (optional), and disposable ECG electrodes.

3. Using Instructions

3.1 Before use

⚠ Warnings and Cautionary Advice

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

- Use only the cables and accessories specified in this manual.
- This device has no alarm function and therefore does not generate an audible alarm for the result of the measurement.
- Ungrounded equipment next to the patient and interference from electrosurgery can cause waveform instability.

3.2 Open box to check

Please check the box carefully before unpacking. If you find any damage, please contact the carrier or the company immediately.

If the package is complete, unpack it in the correct way and carefully remove the device and other components from the box. Check the device for any mechanical damage and complete items.

If you have any questions, please contact us immediately.

⚠ **Warnings and Cautionary Advice**

- Please save the box and packing materials for future transportation or storage.
- When handling packaging materials, local regulations or the hospital's waste disposal system must be followed and the packaging materials should be kept out of the reach of children.
- The device may be contaminated by microorganisms during storage, transportation and use. Please confirm that the packaging is in good condition before use.
- The date of manufacture and the date of use of the product are listed on the label.

3.3 Boot

When the device is shipped from the factory, it is completely inactive by default. Activate the device by charging before it is used for the first time.

3.4 Measuring process

3.4.1 Measurement methods

ECG electrode wearing method:

Remove the packaging of the disposable ECG electrodes, install them on the device through the electrode buckle, and wear the Dynamic ECG recorder on the chest as shown in the figure.

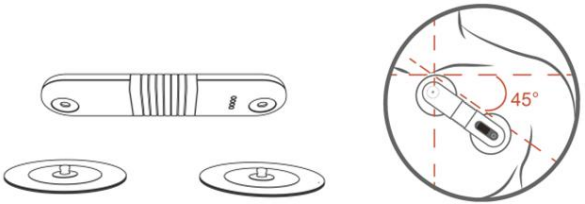

Figure 2

Chest Strap measurement method:

Attach the main unit to the strap and then wear them beneath the precordium with the R end on the right side.

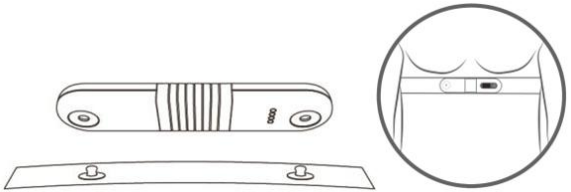

Figure 3

Precautions:

a. Before use, please check whether the single-use ECG electrode is within the validity period.

b. The ECG electrode must be in direct contact with the skin.

c. Before wearing, if necessary, remove the hair in the covered area, then clean the skin with clean water, and dry it before attaching the electrode pad or chest strap.

3.4.2 Measuring steps

1) Select a measurement method and wear the device according to the above instructions.
2) The device automatically turns on and starts recording when it detects the ECG signal. The screen displays the ECG waveform and heart rate.
3) Keep recording for at least 5 minutes.
4) To end the current recording, press and hold the touch key for 6 seconds or charge the device. The recording ends automatically when the time reaches the upper limit.

Note:

- If the device is accidentally taken off before the recording is ended, the data will be saved after 30 minutes, during which the recording can be resumed when the device is re-worn.
- The upper limit of a single recording depends on the version you select (24/72/168 hours).
- Recordings less than 5 minutes will not be saved.

3.5 Data export function

When the measurement is completed, the measured data can be transmitted to the mobile equipment for viewing via Bluetooth.

Steps for data export via Bluetooth:

1) Turn on the Bluetooth function of the mobile equipment.
2) Pairing via Bluetooth, the mobile equipment will receive data form the device.

Precautions:

The device can store up to 10 measurements or 168 hours of measurement data. To ensure that the data collected each time

can be viewed smoothly, please export the data in time after each measurement is completed.

3.6 Charging

This device uses a rechargeable lithium battery.

It is charged by connecting a laptop or a power adapter with the charging cable.

Charging steps:

1) Connect the device with the USB clip.
2) Connect the charging cable to the USB port with 5V output voltage. While charging, the screen displays the charging icon. When the charging is completed, the charge complete icon will be displayed.

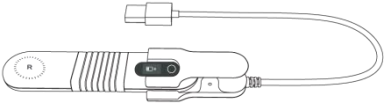

Figure 4

⚠ **Warnings and Cautionary Advice**

- The device cannot be used during charging. If a third party charging adaptor (Class II) is selected, choose one that complies with IEC60950 or IEC60601-1.
- Keep the device out of reach when charging.
- When the device is not in use for a long time, it is necessary to periodically charge the device to maintain battery performance.

4. Maintenance

⚠ Warnings and Cautionary Advice

Have the device repaired by authorized service centers only, otherwise its warranty is invalid.

4.1 Warranty

The product is warranted to be free from defects in materials and workmanship within warranty period when used in accordance with the provided instructions.

4.2 Battery

When the remaining battery power is low, the indicator light will turn yellow and flash, and the device needs to be charged.

⚠ Warnings and Cautionary Advice

- The built-in rechargeable lithium-ion battery cannot be replaced. Non-professionals cannot open the enclosure and modify or replace the battery.
- Do not expose the main unit to high temperatures such as ovens, water heaters and microwave ovens. Overheated batteries may explode.
- Do not contaminate or modify the battery, otherwise it may result in battery leakage, overheating, ignition or explosion.
- If the battery leaks, keep your skin and eyes away from the leaking fluid. If skin or eyes come into contact with leaking fluid, rinse your skin or eyes immediately and go to hospital for treatment.
- Do not throw the battery into fire, otherwise it may cause an explosion.

- When the battery exceeds the service life or no longer holds the power, contact the manufacturer for disposal. Follow local laws for proper disposal of the battery.

4.3 Cleaning

Dynamic ECG recorder and straps need to be cleaned regularly (once a week). Carefully swab the device with a clean, soft cloth or cotton ball with 70% medical alcohol or water.

Do not use petrol, thinners or similar solvents.

⚠ Warnings and Cautionary Advice

The device must be cleaned with 70% medical alcohol or water before being used by another patient. At the same time, disposable ECG pads cannot be mixed and must be replaced.

4.4 Recycling

Disposal of waste, residues, etc., as well as the device and accessories at the end of their useful life must comply with local regulations. If you intend to discard this device, please take it to the appropriate facility for recovery and recycling.

4.5 Trouble shooting

Problem	Possible Cause	Recommended Action
The device cannot perform normal acquisition	The battery is low	Please charge the device
	Equipment damage	Please contact your local agent

Problem	Possible Cause	Recommended Action
ECG waveform is disordered with large clutter	Measurement method is incorrect	Please re-measure according to the Instructions in the manual
	Poor contact of ECG electrode	Please clean the ECG electrode according to the method described in the manual

5. Accessories

Serial number	Accessory name	Quantity
1	Charging cable	1
2	Chest Strap (optional)	1
3	Disposable ECG electrodes	10

⚠ **Warnings and Cautionary Advice**

1. Use only the accessories specified in this manual, otherwise the device may be damaged.
2. Check if the disposable ECG electrode has expired before use.
3. The disposable ECG electrodes used with this device are user-purchased device, which must be a formal device with a medical device registration certificate.
4. Disposable ECG electrodes should not be attached to patients with traumatized or scarred skin.

5. Disposable ECG electrodes should be in close contact with the skin. If itching, skin irritation or ulceration occurs, stop using it immediately.
6. The device uses specialized disposable ECG electrodes, and is not compatible with those on the market. Please contact customer service or agent if you need to purchase.

6. Specifications

Classification		
EU Regulation	MDR, EU 2017/745	
EC Directive	RED, 2014/53/EU	
Degree protection against electrical shock	Type **BF**	
Environmental		
Item	**Operating**	**Storage**
Temperature	5 ~ 45°C	-25 ~ 60°C
Relative humidity (non-condensing)	10% ~ 95%	10% ~ 95%
Atmospheric pressure	700 ~ 1060 hPa	700 ~ 1060 hPa
Degree of dust & water resistance	IP22	
Drop test	1.0 m	
Power supply		
Type of battery	Rechargeable lithium polymer battery	
Battery specification	3.8V d.c., 240mAh	
Battery run time	168 hours (full state)	
Charging input voltage range	4.5 ~ 5.5V DC voltage	
Charging time	2 hours (to 90% power)	

ECG	
Lead type	Single-use ECG electrode
Lead	Lead I
Input impedance	≥10MΩ, 10Hz
Linearity and dynamic range	10mV (peak-to-valley)
Common mode rejection	≥60dB
Frequency response	0.67 ~ 40 Hz
Gain error	Maximum error ±10%
Physical	
Size	100mm×23mm×10 mm
Packing size	172mm×113mm×59mm
weight	<20 g (with battery)
Wireless connectivity	Bluetooth connection support Built-in Bluetooth 4.0 BLE
EXPECTED SERVICE LIFE	5 years
Bluetooth RF	
Frequency range	2.402 - 2.480 GHz
Max RF power	-10dBm

7. FCC Warning

FCC ID: 2ADXK-3614

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:

(1) This device may not cause harmful interference, and

(2) 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.

8. 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 Dynamic ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Dynamic ECG recorder should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Dynamic ECG recorder 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 Dynamic ECG recorder is suitable for use in all establishments, including domestic establishments and those directly connected to the
Harmonic emissions IEC 61000-3-2	n.a.	

Voltage fluctuations/ flicker emissions IEC 61000-3-3		public low-voltage power supply network that supplies buildings used for domestic purposes.

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

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800MHz to 2.7GHz $d=[\frac{7}{E_1}]\sqrt{P}$
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 meters (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**
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					
5240	0.2	0.3	9	9	
5500					

5785					$E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in 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: 
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					

The Dynamic ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The Dynamic ECG recorder should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 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 Dynamic ECG recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80MHz to 800MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.7GHz where P is the maximum output 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 the location in which The Dynamic ECG recorder is used exceeds the applicable RF compliance level above,

The Dynamic ECG recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The Dynamic ECG recorder

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 Dynamic ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The Dynamic ECG recorder 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% UT 0,5cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°, 0% UT 1cycle and 70% UT 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 : UT is the AC mains voltage prior to application of the test level.			

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