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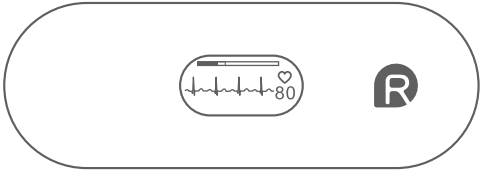


ECG Recorder

User Manual

Table of Contents

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 (eg. 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 pets, 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℃, 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.
- Report to the manufacturer and the competent authority of the Member State in which you're established for any serious incident that has occurred in relation to the device.

2. Introduction

2.1 Name and Model

Name: ECG recorder

Model: ER2-S

2.2 Intended Use

The ECG recorder is intended to record, display, store and transfer single-channel electrocardiogram(ECG) rhythms at home or in healthcare environment.
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 is intended for use by adults' health-conscious individuals.
The product does not include analysis and diagnosis functions.
The product has not been tested and it is not intended for pediatric use.

2.2.1 Contraindications:

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

2.3 About ECG recorder

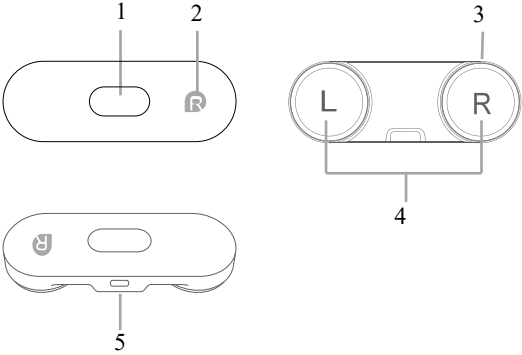


Figure 1

1. Display screen

   It can display time, power, waveform and heart rate when measuring.

2. Logo on the right

   When measuring, the R mark is located on the right side of the user.

3. LED indicator

Indicator	Status	Description
/	OFF	• Not activated • Out of battery
Green light	Flashing with the rhythm of the heartbeat	• Recording your ECG
	Flashing every 5 seconds	• Fully charged • In standby mode
Orange light	Flashing with the rhythm of the heartbeat	• Recording your ECG
	On	• Charging
	Flashing every 5 seconds	• Low Battery • In standby mode
Blue light	On	• Connected to the App and ready to start recording
	Flashing with the rhythm of the heartbeat	• Connected to the App and recording your ECG

4. ECG electrodes

   Used to connect the body surface and receive the human body ECG signal.

5. Charging interface

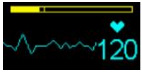
   Used to connect the charging cable.

2.4 Symbols

	Symbol	Significance
Symbols on the device		Type CF-Applied Part
		Manufacturer
		Date of manufacture
		Authorized representative in the European Community
		This product complies with the European Council EU 2017/745 (MDR)
		Authorized Representative in the United Kingdom
		UKCA marking
		Caution, incorrect use may cause personal injury and damages of goods. Refer to the instruction manual.
	IP22	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.
		Follow Instructions for Use.
		This product complies with the rules and regulations of the Federal Communication Commission.
		Non-ionizing radiation

		Indicate separate collection for electrical and electronic equipment (WEEE).
		MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
		Medical device
		Unique device identifier
		Use-by date
		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).
		Temperature limit
		Humidity limitation
		Atmospheric pressure limitation

	Symbol	Significance
Symbols on the screen		Hold still
		Complete thirty-second measurement

		Complete five-minute measurement
		Saving data
		Data saved, view the results in the App
		Measuring time less than 30s
		Battery status reminder
		Heart rate and waveform
		Indicate the state where measurement is stopped without data saving after 6 consecutive detection of non-human body measurement
		Low battery
		Power off
		Charging
		Charge complete

2.5 Product structure and composition

This product is mainly composed of ECG recorder main unit, charging base, and charging cable.

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

1) Lead I

Hold onto the device with both hands.

Note: If the EKG quality is poor with Lead I, please try to use Lead II.

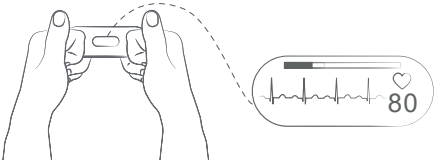


Figure 2

Wrong way of operation:

a. Shake your hands at will

b. Loose fingers during measurement

2) Lead II

For a Lead II EKG, the left knee should contact one electrode and the right hand should contact the other electrode.

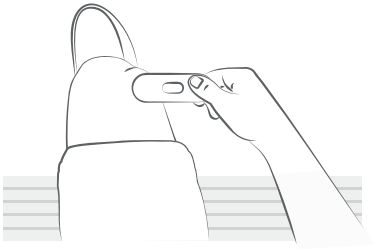


Figure 3

3) Anterior Precordial Lead

For an Anterior Precordial Lead, the device can be placed on the lower left side of the chest, just below the pectoral muscle.

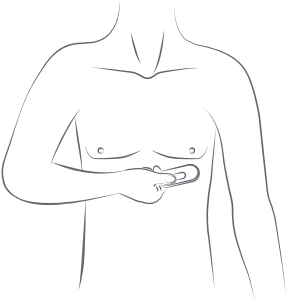


Figure 4

Note:

- Moisten hands and measuring area before measurement.
- Please make sure that the “R” symbol is always on the right hand side.
- DO NOT use the electrodes on a portion of the body with too much body fat, body hair or very dry skin; otherwise, a successful recording may not be possible.

3.4.2 Measuring step

1) After selecting a measurement method, the device automatically turns on when it detects the ECG signal. The signal light turns green and flashes, the device starts measuring and emits a "ticking" heartbeat sound.

2) Hold still for at least 30 seconds, the device will emit a short beep, at which point the measurement can be ended and the device will complete the data saving for 30 seconds to 5 minutes.

3) When the continuous contact exceeds 5 minutes, the device stops measuring and switches off automatically. The signal light turns green and flashes (at 5 seconds intervals) and the device completes 5 minutes of data saving.

3.5 Data export function

After 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 for up to 20 minutes each. 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 power adapter by the charging cable.
2. Connect the charging cable to the USB port with 5V output voltage. While charging, the indicator light will remain orange; when the charging is completed, the indicator light will turn green and flash every 5 seconds.

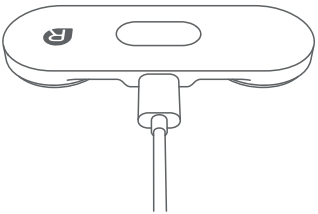


Figure 5

Note:

- The power adapter is NOT included in the package.
- Compatible power adapter output: DC 5V, 1A
- **DO NOT** use the device while charging.

⚠ 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 orange 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

The ECG recorder needs 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.

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 send it to the appropriate facility for recovery and recycling.

4.5 Problem solving

Problem	Possible Cause	Recommended Action
The device cannot perform normal acquisition	1. The battery is low 2. Equipment damage	1. Please charge the device 2. Please contact your local agent

ECG waveform is disordered with large clutter	1. Measurement method is incorrect 2. Poor contact of ECG electrode	1. Please re-measure according to the instructions in the manual 2. Please clean the ECG electrode according to the method described in the manual.

5. Accessories

Serial number	Accessory name	Quantity
1	Charging cable	1

⚠ Warnings and Cautionary Advice

- Use only the accessories specified in this manual, otherwise the device may be damaged.

6. Specifications

Classification		
EC Directive	EU 2017/745 (MDR)	
	RED, 2014/53/EU	
Degree protection against electrical shock	Type CF	
Environmental		
Item	**Operating**	**Storage**

Temperature	5 ~ 45°C	-25 ~ 70°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	3.7Vd.c., 90mAh	
Battery run time	Not less than 24 hours (full state)	
Charging input voltage range	4.5 ~ 5.5V DC voltage	
Charging time	2 hours (to 90% power)	
ECG		
Lead type	Integrated ECG electrodes	
Lead	Lead I	
Input impendence	≥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	94mm×34mm×12 mm	
Packing size	172mm×113mm×59mm	
weight	<30 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-3623

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 ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 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 ECG recorder 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 ECG recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The ECG recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The 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 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 $E = \frac{6}{d}\sqrt{P}$ equation applicable to the frequency of the transmitter. **Recommended separation**
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	
5240	0.2	0.3	9	9	
5500					

5785					**distance** 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, 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.					

Guidance and manufacturer's declaration – electromagnetic immunity			
The ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The ECG recorder should assure that it is used in such an environment.			
Immunity test	IEC 60601	Compliance level	Electromagnetic environment – guidance

	test level		
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 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 whichThe ECG recorder is used exceeds the applicable RF compliance level above, The 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 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 ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The 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% 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.			

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PN: 255-07195-00 Version: C
Model: ER2-S Date: Mar. 2024

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