ETROG®Care PLATFORM

INSTRUCTIONS FOR USE
MULTIVS ES008 A

Wireless Wearable Health monitor
Patch and Chest Belt.

℞ only

Device Description

The ETROG® Care Platform is a wireless physiological monitoring system. The Platform was developed with an Application Programming Interface intended to allow development of user interface applications enabling health care professionals to access collected vital information. The platform consists of:

- Wearable Biosensor – MULTIVS ES008A
- Adhesive patch
- Chest Belt
- Gateway Software
- Server Software

MULTIVS ES008A is an integrated Bio-Sensors and wireless transceiver, rechargeable battery-operated device that can be worn on the body torso via adhesive patch or chest belt, Enabling recording of heart rate, electrocardiography (ECG), Photoplethysmogram (PPG), Pulse Wave Transit time (PWTT), Changes in Blood Pressure, heart rate variability(HRV) , R-R interval, respiratory rate, skin temperature, activity (including step count) and posture (body position relative to gravity).

MULTIVS ES008A operates at spot or continues measurements mode to gather physiological data from the person being monitored and transmit the data via encrypted bi-directional communication to the gateway (smart phone / mobile device) when in range of the Gateway that in turn will transmit the data to the server platform storage for real-time monitoring and or future analysis.
Collected data by MULTIVS ES008A device is transmitted to the gateway immediately. A continuous connection is needed between the sensor device and the gateway in order to facilitate continuous data transmission. The wireless transmission of the data occurs continuously with a delay or latency of 100 millisecond between continuous data collection and transmission. Gateway data will be uploaded immediately after receiving full measurement data to secure platform server. Authorized healthcare professionals can configure the system parameters via the secure server platform to generate notifications and alerts based on changes in measured data. The secure server platform will trigger a notification when configured physiologic data parameters are exceeded.
In the event that MULTIVS ES008A device is NOT in range to communicate with gateway, the measurement data will be stored in local device memory and will be transmitted when communication is reestablished.

The gateway will pair automatically with device once in range.

The MULTIVS ES008A can operate as standalone device and collect measurement data per pre-scheduled program, this data will be sent to gateway once it comes into range – automatically.
In addition, the healthcare professionals can configure the type, mode (spot or continues), Duration and Interval of measurements done by the sensor device.

Indications for Use

MULTIVS ES008A is an integrated Bio-Sensors and wireless transceiver, rechargeable battery-operated device that can be worn on the body torso via adhesive patch or chest belt, Enabling recording of heart rate, electrocardiography (ECG), Photoplethysmogram (PPG), Pulse Wave Transit time (PWTT), Changes in Blood Pressure, heart rate variability (HRV) , R-R interval, respiratory rate, skin temperature, activity (including step count) and posture (body position relative to gravity). MULTIVS ES008A operates at spot or continues measurements mode to gather physiological data from the person being monitored and transmit the data via encrypted bi-directional communication to the gateway (smart phone / mobile device) when in range of the gateway that in turn will transmit the data to the server platform storage for real-time monitoring or future analysis. The ETROG®Care platform can be configured by authorized persons to notify healthcare professionals when physiologic data falls outside selected parameters.

The ETROG® Care Platform MULTIVS ES008A is intended for use on adult patients who are 18 years of age and above.

The ETROG®Care platform is not intended for use on critical care in-patients or as a diagnostic or alarm device

Contraindications:

The device is not intended for use on patients who have implanted defibrillator or pacemaker.

The device is not intended as a stand-alone diagnostic monitor, but the data can be used to diagnose health status.

Warnings:

Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact continuous or real-time monitoring. Data will be stored on sensor device or gateway for transfer once connectivity is reestablished.

The nature of hydro-gel silicone or hydrocolloid adhesives may cause adverse skin reactions. Healthcare providers should advise patients to seek medical attention if either of the following occurs:

- Allergic reaction that persisting beyond 24 Hours

Relative contraindications:

- Histories of skin allergic reactions irritations should be considered before placing the patch on a patient.
- Do not place device on broken skin.
- This device is not intended to replace appropriate medical supervision and safe practices.
- Clinical validation has not been performed on patients who are pregnant or breastfeeding.

Warnings:

- This device is not intended to replace appropriate medical supervision and safe practices.
- Do not use this device during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.

Precautions:

• For data to be sent to a healthcare professional for review: The device battery must have adequate power for data transmission. Red flashing LED on device will indicate that the battery power is low. Low power device notification will be passed to gateway and server too.

- The patch must be attached to the patient. Notification will indicate if the patch is off the body or not properly attached.
- The patient must remain in range of their gateway (i.e. smartphone, PC, tablet, body worn cellular modem or wall mount device). Notification will indicate that the sensor has disconnected from the gateway.
- The gateway must remain charged and functional for data transmission. Wireless connectivity must be active for transmission of data from the gateway to the server.
- Healthcare providers must be aware if uninterrupted continuous data monitoring is necessary for patient safety, treatment in home setting may not be appropriate. If there is a clinical need, additional measures may be taken to ensure appropriate care.
- Data collected by MULTIVS ES008A for patients experiencing cardiac arrhythmia may indicate slightly elevated respiratory rate values, compared to visual observation, for the duration of the active arrhythmic episode.
- The gateway device must operate and connected ONLY to MULTIVS ES008A during active monitoring. please note that performance of either or both Bluetooth connected devices/system could potentially be affected if gateway is used for other purpose.
- Similar devices may cause signal interference during data transmission. If you experience this affect, steer clear of interfering devices.
- Do not use the device if the package has been opened, or appears used, damaged, or expired.
- Do not wear device over excessive body hair in the torso area. Excessive body hair should be removed several hours before application.
- Do not use the patch when showering or bathing.
- if discomfort or irritation occurs to the patient, device should be removed.
- If the patient experience mild soreness or redness after removing the patch, a new patch should not be placed in the same location.
- Incorrect handling, excessive force, or dropping the device may cause malfunction or permanent damage.
- The device must be kept away from children and pets. The device may be a choking hazard, and may be harmful if swallowed.
- If any component of the MULTIVS ES008A ETROG® Care Platform fails to operate after attempting all suggested troubleshooting methods, the patient should contact his healthcare provider as soon as possible..
- Clinical validation performed in mixed age population, including elderly subjects (Age 59 to 86) with a BMI (Body Mass Index) range of 13.5-59.5 kg/m2.
- Dispose of MULTIVS ES008A per local laws, care facility laws or hospital laws for routine/non- hazardous electronic waste.

Storage and Handling

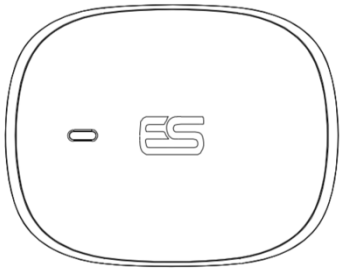
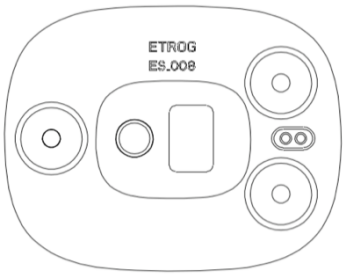
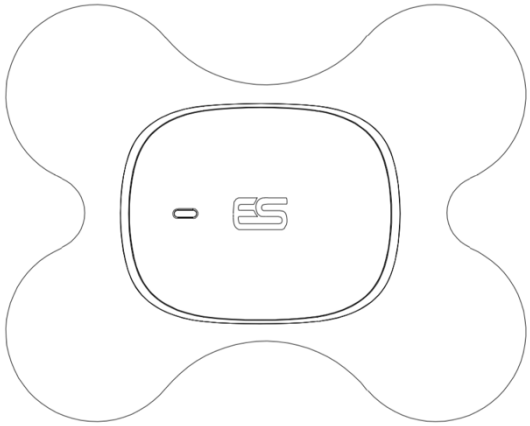
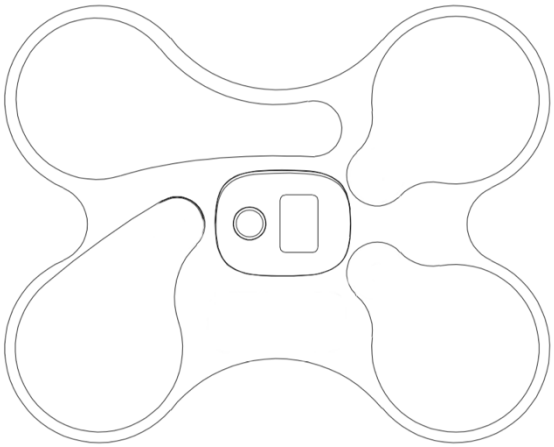
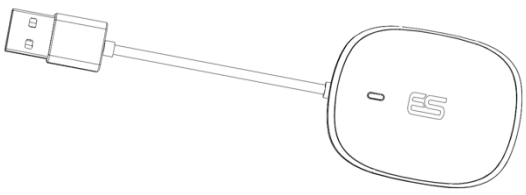
- Storage temperature range: 0 – 40o C
- Storage relative humidity range: 10 – 95% RH
- The patient hands must be clean and dry before handling MULTIVS ES008A. Gloves are recommended for healthcare professionals when handling the Device.

System Interoperability

The ETROG® Care Platform is a wireless physiological monitoring system. The Platform was developed with an Application Programming Interface intended to allow development of user interface applications enabling health care professionals to access collected vital information. Please contact ETROG SYSTEMS LTD., to obtain implementation information.

MULTIVS ES008A Operating Instructions

MULTIVS ES008A Overview

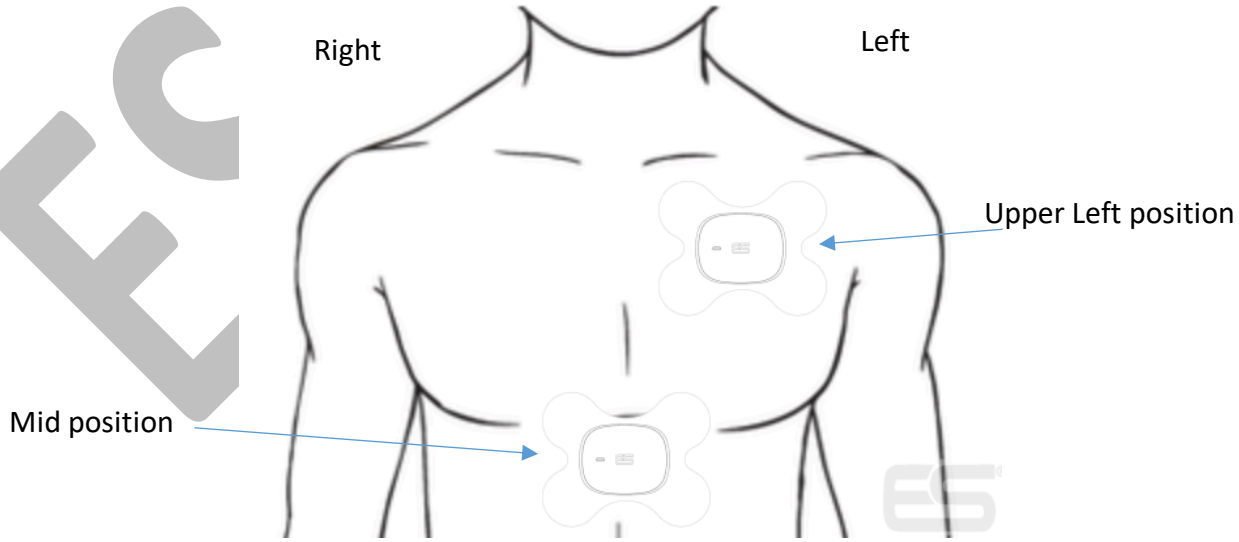
Top View - Device	Bottom View - Device
	
Top View - Device with Patch	**Bottom View - Device with Patch**
	
Charger Cabel	**Device Charging**
	

Preparation and Application

Note: Please fully charge the device before start of use.

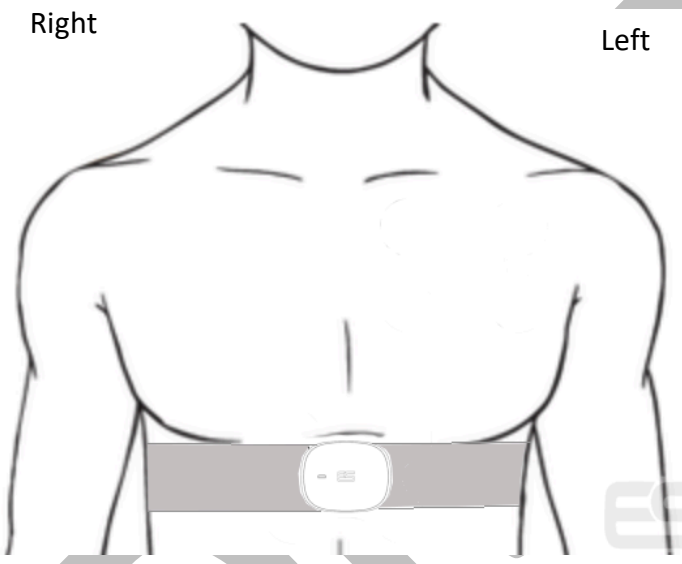
MULTIVS ES008 Patch

1. Take device and attach to patch via magnetic connectors. Retain the adhesive backing of patch.
2. Select the location for patch placement on body as per the diagram below. ensure it is free from hair and skin is intact.
3. Use isopropyl alcohol to clean the skin area where the patch is intended to be placed and allow site to fully dry.
4. Remove the adhesive backing from the patch and apply to prepared skin. Press down on patch ends to ensure it is well adhered to skin. Note: keep the adhesive backing in a clean place for later use.



ES-Chest Belt

1. Take device and attach to chest belt via magnetic connectors.
2. Use isopropyl alcohol to clean the skin area where the belt is intended to be placed and allow site to fully dry.
3. Strap the belt around chest as per the diagram below and adjust size. the feel should be firm yet comfortable.



Connect to Gateway

Please refer to the Gateway application's user manual for more instructions on how to connect to the MULTIVS ES008A. During first time connection a calibration and data measurement control test will be done – to ensure proper placement and compatibility.

Removal and Re-application

ES-Patch

Grip the Device and gently pull away from patch magnets. Place Device in original box or soft material. Keep away from reach of children, pets, direct sunlight, and AC/fans.

Grip one end of the patch and peal gently away from skin. Place the patch adhesive side on the original adhesive backings away from reach of children, pets, direct sunlight, and AC/fans. Remove the patch prior to showers and baths.

The patch can be re-applied. Re-apply used patch follow instruction above.

ES-Chest Belt

Open belt hook and place in a dry clean area. Keep away from reach of children, pets, direct sunlight, and AC/fans.

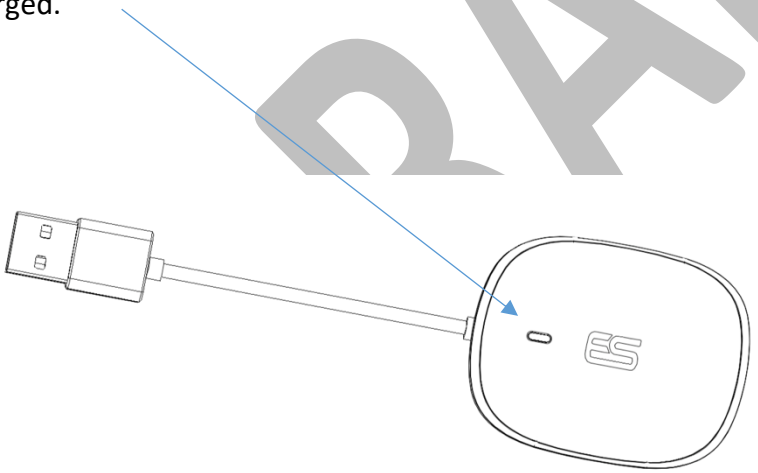
The chest belt can be re-used. follow instruction above.

Charging

Place device on provided cradle or connect to charging cable as per diagram.
The charging connector is magnetic and will align automatically to the right position.
Connect the USB plug to available charger. (not provided).

Led indicator

During charging the Device led indication will flash slowly RED and will be steady GREEN when device is fully charged.



Disposal

Disposal of a battery into fire or a hot oven, or mechanically crushing or cutting of a battery can result in an explosion.
Leaving a battery in an extremely high temperature surrounding environment that can result in an explosion or the leakage of flammable liquid or gas.
A battery subjected to extremely low air pressure may result in an explosion or leakage of flammable liquid or gas.
Please observe local laws for disposal of battery-operated electronic products.

Additional notes:
It is recommended that continues wearing of patch on single position will be for up to 48 hours at a time. Allow 4 hours of rest to skin before re-applying on same position.

Troubleshooting

Device Not Charging -
No led light -
Connectivity -
Make sure all magnets contacts are connected
Belt – clean electrode area
For additional information regarding the proper use of the MULTIVS ES008A Platform please contact the prescribing physician, caregiver, or healthcare provider.

ETROG SYSTEMS Contact Information:

HQ
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7/9 Derech HaDarom Road, Kiryat Gat , **ISRAEL**
Phone: +972 86665042
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ETROG Systems Ltd.
750 Chestnut Ridge Rd.
Chestnut Ridge, NY 10977
Phone: +1 347 434 9204

Product Specifications:

Measurements	Specifications
ECG Dynamic Range	-10mV to +10mV
Heart Rate (at rest and or physical activity)	30 – 200 Beats per Minute (<±5 or 10% Beats per Minute, whichever is greater)
Photoplethysmogram (PPG)	RED, Infra RED, Green
Respiration Rate (RR)	6 – 30 BPM
Skin Temperature	15^0C – 47^0C (≤± 0.30^0C)
Step Count	Re-set after upload to server / every 24 HRs.
Posture Detection (relative to gravity)	Upright, Lying down, Lying Right, Lying Left, Lying front, Upside-down, Moving.

System Specifications

Communications	
Bluetooth (BT4.2)	Max. 10 Meters (30 Feet Line of Sight)
Radio Modulation	GFSK
Radio Frequency	2.402 – 2.48 GHz
Transmit power	≤0dBm
Security	AES-CCM 128 Bit Encryption (Advanced Encryption Standard-CCM mode)
Battery	
Battery Type	Polymer Li-Ion
Battery Voltage	DC 3.7 V (0.45W)
Battery Life	300 Charge cycles

Operating Conditions

Ambient Temperature	10–40^0 C
Humidity	10 – 95% RH
Altitude	<3000 m
Barometric Pressure	70 kPa to 102 kPa

Electromagnetic Emission Declaration		
MULTIVS ES008A is intended for use in the electromagnetic environment specified below. The end user of ES008A should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	ES008A 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	ES008A 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.

FCC Compliance

•FCC ID: 2ATHK-ES008A

- . The MULTIVS ES008A Platform 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 (FCC Title 47, Subpart A, Part 15.19(3)).

- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21)

  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 (FCC Title 47, Subpart B, Part 15.105(b)):
  - 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.

Canada License-exempt

•IC ID:

- This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
- Le present appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisee aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioelectrique subi, meme si le brouillage est susceptible d'en compromettre le fonctionnement.

Guidance and declaration – electromagnetic immunity (For ME equipment ME system that are not life-supporting)			
MULTIVS ES008A is intended for use in the electromagnetic environment specified below. The end user of the MULTIVS ES008A Platform should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance
Radiated RF IEC 61000-4- 3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the MULTIVS ES008A Platform than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.17√P 80 MHz to 800 MHz d = 2.33√P 800MHz to 2.5 GHz 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 transmitters, as determined by an electromagnetic site surveya 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 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 MULTIVS ES008A Platform is used exceeds the applicable RF compliance level above, the MULTIVS ES008A Platform should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MULTIVS ES008A Platform.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and declaration – electromagnetic immunity
(For ME equipment ME system that are not life-supporting)

MULTIVS ES008A is intended for use in the electromagnetic environment specified below. The end user of the MULTIVS ES008A Platform 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 ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Recommended separation distance between portable and mobile RF communications equipment and MULTIVS ES008A Platform
(For ME equipment ME system that are not life-supporting)

MULTIVS ES008A is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the MULTIVS ES008A Platform can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MULTIVS ES008A 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	
	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.17	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

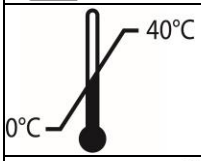
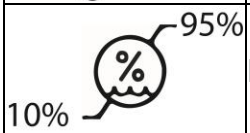
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
ES008A complies with the applicable requirements and relevant provisions of the Radio Equipment Directive 2014/53/EU (RED).
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

General symbols

Symbol	Title
IP24	Protected against splashing water
IP67	Protected against submerging in water (up to 1 meter for 30 minutes)
	Re-use is not allowed

Symbol	Title
	Read usage instructions
	Properly dispose of EEE (Electrical and Electronic Equipment)
	Non-ionizing radiation
	Defibrillation proof type CF applied part
	MR Unsafe
	Underwriters Laboratories MEDICAL — PATIENT MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; CAN/CSA-C22.2 No. 60601-1:08; ANSI/AAMI/IEC 60601-2-25, "Medical Electrical Equipment - Part 2-25: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographs" E358758
 0843	CE Marking conformity
	Manufacturer
	Caution, consult documents

	Not to be used in case package is damaged
	Prescription only
EC REP	Authorized Representative in the European Community

Symbol	Title
REF	Catalogue number
LOT	Batch code
	Use by date
	Temperature limits (Storage)
	Humidity limits (Storage)
	Contents (Numeral represents quantity of units inside)