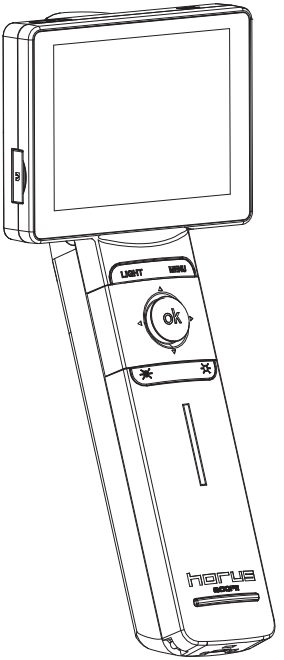
Horus Scope

E–Series Digital Otoscope

User Manual



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pmnl 173 rev 0 8-22

Contents

1. Category

Model Name Horus Scope E-Series

Product Name Digital Otoscope

Accessory 1. Battery

2. Disposable Specula

a.) adult x 8

b.) pediatric x 8

3. Power Adapter 5V,1.2A

4. USB Cable 1.8M with double core

2. Symbols

	CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.
	Operating Instructions for Use.
	Manufacturer.
	Date of Manufacturing.
	Type BF indicates that the device is classified as a device with an applied part that is Type BF.

REF	Catalogue Number.
GTIN	Global Trade Item Number
LOT	Lot number
SN	Serial Number
	GS1 Data Matrix
MD	Medical Device
R_x ONLY	Medical Prescription only
	Direct current
	Power button
	Recycling lithium-ion batteries
	Specific Battery Recycling
	Disposal of non-contaminated electrical and electronic equipment
	This product had an internal rechargeable battery with a Class II power supply.
	Keep away from sunlight

	Hand with care
	Fragile
	This side up
	Fragile, handle carefully
	Lithium-ion battery
	Flammable material
	Follow instructions for use
EC REP	European Authorized Representative
CE	CE-mark

3. Before Use

Prior to installation and start-up of the Horus Scope E-Series, carefully read the user manual. As with all technical devices, the proper function and safety operation of this device depend on the user complying with the safety recommendations described in these operating instructions. In addition, please make sure that it does not appear damaged or broken. If there are breaks on the outer casing or other visual defects, please contact the manufacturer or a certified service facility.

⚠ Caution: Federal law restricts this device to sale by or on the order of a healthcare professionals, and other countries shall be follow.

Indication for use

Intended for qualified healthcare professionals who trained in its use.

The device is intended to be used in hospital or clinic.

The device may be used on any human group.

The device does not provide a diagnosis or therapy.

The clinical benefit is for healthcare professionals, helping deliver state-of-the-art care to their patients.

Contraindications

⚠ This instrument must not be used for the following patients:

- Patients who are hypersensitive to light.
- Patients who recently underwent photodynamic therapy (PDT).
- Patients taking medication that causes photosensitivity.

- Patients with a history of migraines.
- Patients with a history of photosensitive epilepsy.
- Patients with any kind of disease which could be induced by flash or strong light.

Camera handling

Protect the camera from excessive vibration, force, or pressure.

⚠ Avoid using the camera under the following conditions, which may damage the lens, the monitor, or the control unit and may also cause the camera to malfunction or prevent recording:
- Dropping or hitting the camera against a hard surface.
- Exerting excessive force on the lens or the monitor.

The camera is not dust resistant, splash resistant, or waterproof. Avoid using the camera in places with excessive dust or sand, or where water can come into contact with the camera.

⚠ Avoid using the camera under the following conditions, which present the risk that sand, water, or foreign material may enter the camera through the lens or gaps around buttons. Be especially careful because these condition may damage the camera, and such damage may not be repairable:
- Operate in extremely dusty or sandy places
- Exposing the camera to rain or moisture

Condensation (When the lens or the monitor is fogged up)

⚠ Condensation may occur when the camera is exposed to sudden changes of temperature or humidity. Avoid these

conditions because they may soil the lens or the monitor, cause mold, or damage the camera.

⚠ If condensation does occur, turn off the camera and wait for about two hours before using it. Once the camera adjusts to the surrounding temperature, the fogging will clear naturally.

No compensation for missed shots

⚠ We cannot compensate for missed shots if technical problems with the camera or card prevent recording.

4. Usage cautions and notes

When in use

⚠ The camera may become warm if used for long periods of time, but this is not its fault.

⚠ Keep the camera as far away as possible from electromagnetic equipment (such as microwave ovens, TVs, video games, etc.).

⚠ Do not use the camera near radio transmitters or high-voltage lines.

⚠ Never leave the camera and the battery in a car or on a car hood in the summer. Doing so may cause leakage of the battery electrolyte, overheating, fire, or a battery explosion due to the high temperature.

⚠ If the camera gets wet, do not attempt to dry with a heater, microwave, autoclave, or UV light.

⚠ Do not extend the supplied cables. Do not keep the power

cord near any heat source.

⚠ Plug of the power adapter is the disconnect device from the Mains power source. When the camera is not in use, please disconnect the power plug and keep it in a safe place.

⚠ The eye cannot be exposed to the illumination light at operation.

⚠ Please remove the battery if the device is not in use for a long time.

⚠ Before use the device, please make sure that the voltage of the power supply meets the product specifications.

⚠ The product needs to be installed in a location where it can be easily unplugged its power.

⚠ The performance criteria of the following description are accepted when operating the device: short-term function abnormal but can be resumed without operator intervention. Unless basic safety can not be achieved.

⚠ In any operating conditions, the camera can be returned to the photo mode is regarded as the normal state.

⚠ E-Series does not apply CATEGORY AP or CATEGORY APG which is defined in the standard IEC 60601-1.

⚠ When E-Series is connected to computer as a storage device, the user can not operate the device to take pictures or record videos.

⚠ Caution – Do not stare at operating lamp. May be harmful to the eyes.

Charging the battery

⚠ The time required for charging varies depending on the

conditions of battery usage. Charging takes longer at high or low temperatures and when the battery has not been used for some time.

⚠ The battery will get warm during charging and for some time thereafter.

⚠ The battery will be drained completely if not used for long periods of time, even after being charged.

⚠ Only use Li-ion Battery 3.6V / Capacity 3350mAh which shall be provided by the manufacturer or distributors. The battery has designed the protection circuit. To ensure the safety of the product operation, if the battery reaches its life time, please contact the manufacturer or distributor to buy the spare battery.

NOTE

The battery cannot be affected by external force impact. Its appearance cannot be damaged. If the battery is broken or damaged by external force, DO NOT USE to avoid dangerous.

Memory cards

⚠ If you purchase different memory capacity of memory card, must be preceded format to FAT32.

⚠ To prevent damage to cards and data:

- Avoid high temperatures, direct sunlight, electromagnetic fields, and static electricity.
- Do not bend, drop, or expose to strong impacts.
- Do not touch the terminals or allow them to become dirty or wet.
- When operating this device, please do not remove or

insert the memory card.

When disposing of/transferring memory cards:

⚠ If using the “format” or “delete” functions on your camera or computer, this only changes the file management information and does not completely delete the data from the memory card. When disposing of or transferring your memory cards, we recommend physically destroying them or using commercially available computer data erasing software to completely delete the data from the card. Data on memory cards should be managed responsibly.

Protection

⚠ Do not attempt to remove the cover from the product to prevent the product from malfunctioning.

⚠ No modification of this device is allowed. The performance would be subject to any modification and may cause hazardous radiation exposure.

EMC (electromagnetic compatibility)

During installation and operation of the device, observe the following instructions:

⚠ When operating the device simultaneously with other electronic equipment, please make sure the distance between the device and other electronic equipment is no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer.

⚠ Do not use or stack the device near, on, or under other electronic equipment to avoid electromagnetic interference with the operation of the device.

⚠ Do not use the system with portable and mobile radio frequency communication systems because that may have an adverse effect on the operation of the device.

⚠ Do not use cables or accessories that are not specified for the device because that may increase the emission of electromagnetic waves from the device and decrease the immunity of the device to electromagnetic disturbance.

⚠ The product is not an RF electromagnetic energy medical product for the purpose of transmitting or receiving.

Cleaning and disinfection

The device is a precision photo electronic instrument that shall be handled with specific care. Please note the following cleaning instructions:

⚠ Turn off the device before cleaning it.

⚠ Disinfect the camera with CaviWipes and maintain 3~5 mins. Wait for the cleaning liquid to dissolve before turning the power on and connecting USB cable or other device to the camera.

⚠ It is recommended to clean the device with a clean cloth and solvent (clean water with 75% alcohol)

⚠ Clean the specula before each use.

NOTE

⚠ *The device is not intended to be sterilized. Disinfect the device with CaviWipes that is a commercial product and be manufactured by THORLABS Inc. (www.thorlabs.com).*

Maintenance Please check E-Series once every 3 months.

Operating Environment

- Ambient temperature: 10°C to +35°C
- Relative humidity: 30% to 90%
- Atmospheric pressure: 800hPa to 1013hPa
- Shock (without packing): 10G, duration 6ms

Environment for Storage

- Ambient temperature: −10°C to +55°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 700hPa to 1013hPa

Environment for Transportation

- Ambient temperature: −40°C to +70°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 500hPa to 1013hPa
- Vibration, sinusoidal: 10Hz to 500 Hz: 0.5G
- Shock: 30G, duration 6ms
- Bump: 10G, duration 6ms

NOTE

It is recommended to remove the battery if the device is stored over two weeks.

Regulations

⚠ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user

It is the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on E-Series may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

Please note that the actual controls and components, menu items, and other information of your camera may differ from those in the illustrations provided in these instructions.

and/or patient is established.

⚠ This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2: 2014. These limits are designed to provide reasonable protection against harmful interference in a standard medical installation. If this device does cause harmful interference to other devices, which can be determined by turning the system off and on, the user is encouraged to try to correct the interference through one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the system and other devices.
- Connect the device to an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

⚠ The International Electrotechnical Commission sets the

essential requirements for electrical and electronic equipment that may disturb or be disturbed by other equipment. The device complies with these requirements as shown in the tables in “Standards: EMC”. Follow the guidance in the tables for use of the device in an electromagnetic environment.

⚠ External equipment intended for connection to signal inputs, signal outputs or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 or IEC 62368-1 for IT-equipment and the IEC 60601-series for Medical Electrical Equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated in the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents.

⚠ Any person who connects external equipment to signal inputs, signal outputs or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.

IT Network Security

Computers used to connect to the device should be note the following security instructions:

⚠ Make sure anti-virus software is installed in personnel computer before connecting the device to it and keep the latest version.

⚠ Recommended anti-virus software,

- Android: Norton Mobile Security
- Windows: Norton™ Internet Security

⚠ The device can only be updated or processed by original factory or a legally authorized distributor. Do not allow unauthorized persons or users to update or process the software with any memory card.

⚠ Users must keep patient information in a safe place.

⚠ Physically destroyed the memory card when abandoned.

⚠ Connection of E-Series to an IT-Network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.

⚠ The responsible organization which operates E-Series should identify, analyze, evaluate and control the risks when the devices connect to an IT-Network.

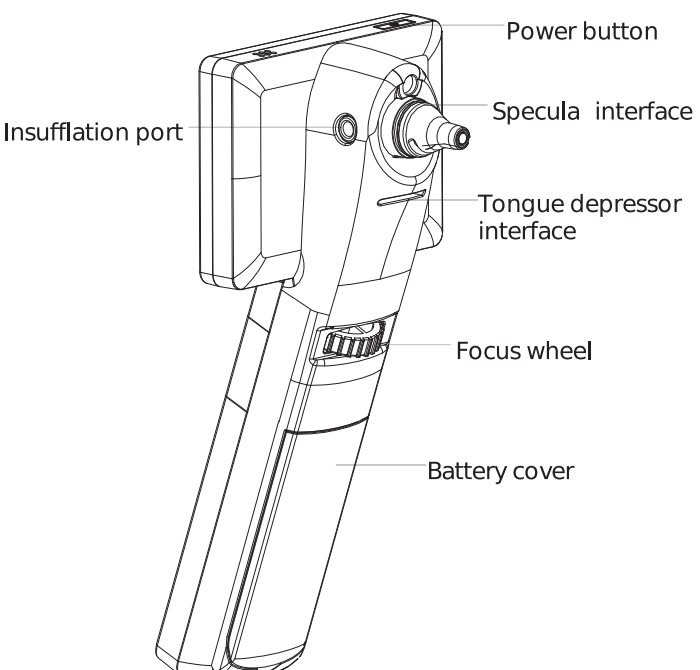
⚠ Subsequent changes to the IT -NETWORK could introduce new RISKS and require additional analysis. These changes include:

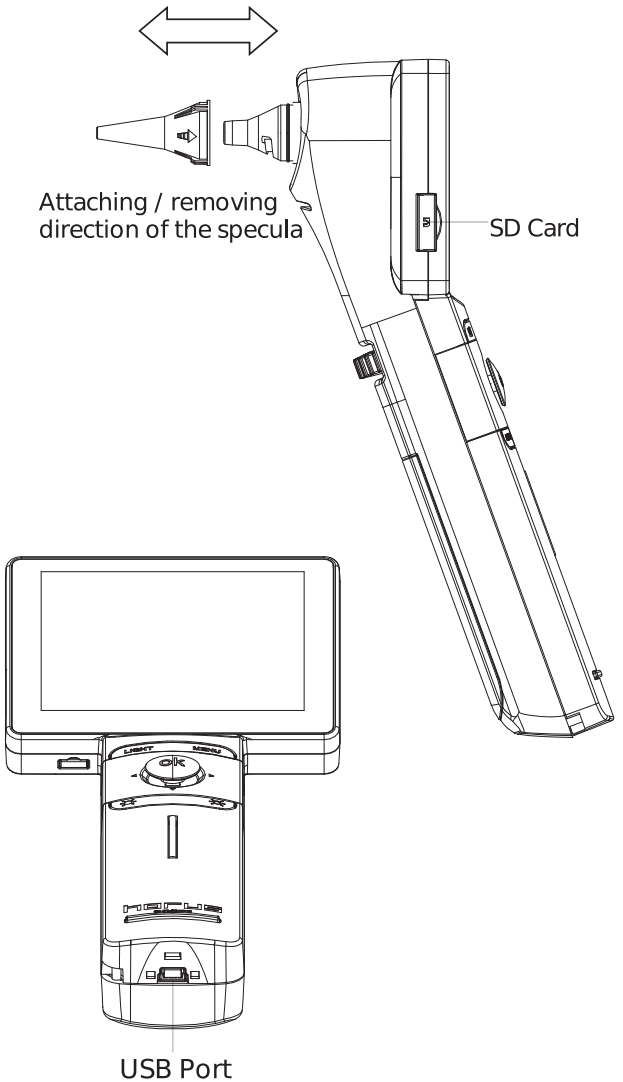
- Changes in the IT-Network configuration.
- Connection of additional items to the IT-Network.
- Update of equipment connected to the IT-Network
- Upgrade of equipment connected to the IT-Network.

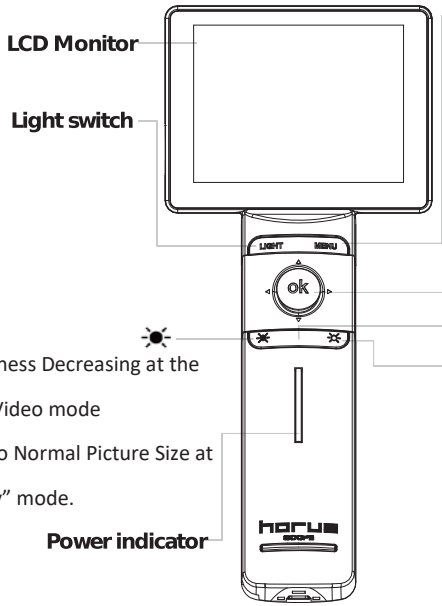
5. Intended Uses

The E-Series is a digital hand-held otoscope used to record digital photographs and video of the human ear canal and tympanic membrane and pharyngitis. The E-Series can also be used for the general inspection of the throat and nasal cavity and capture photographs and video of those areas.

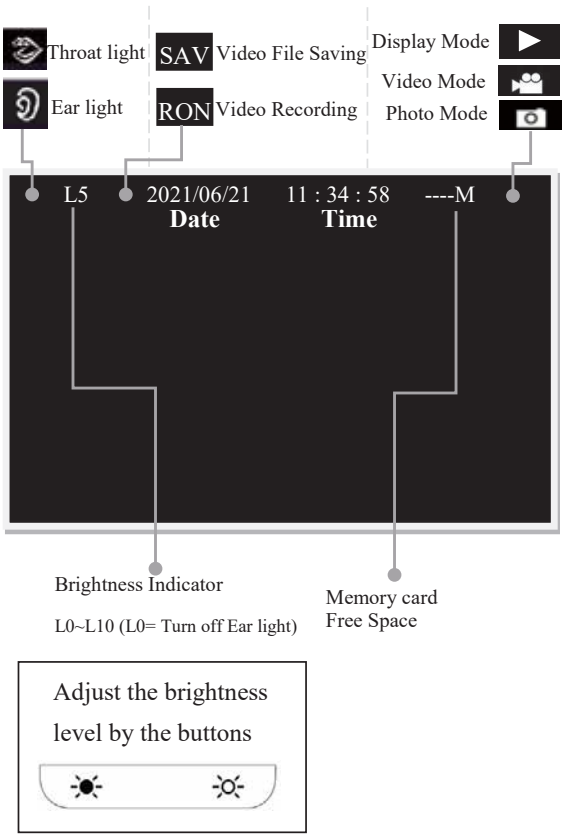
6. User Interface




Attaching / removing
direction of the specula
SD Card
USB Port


LCD Monitor
Light switch
Menu
ok button
●Capture image at the Photo/Video Mode
●Enter key function at “menu” mode
LIGHT
MENU
ok
Brightness
●Brightness Decreasing at the Photo/Video mode
●Back to Normal Picture Size at “Display” mode.
Power indicator
ightness
Increasing at the Photo/Video mode
●Zoom In Picture at “Display mode”. (Move the picture by moving the arrow button.)

7.Operating Screen Instructions



NOTE

Without touching any buttons, the system automatically enters standby mode after 2 minutes, and turn off the system after 30 minutes.

Press the “OK” button to wake up the device if device is in the “standby mode”.

8. Charging the Battery and Transferring Photos

Charging the Battery:

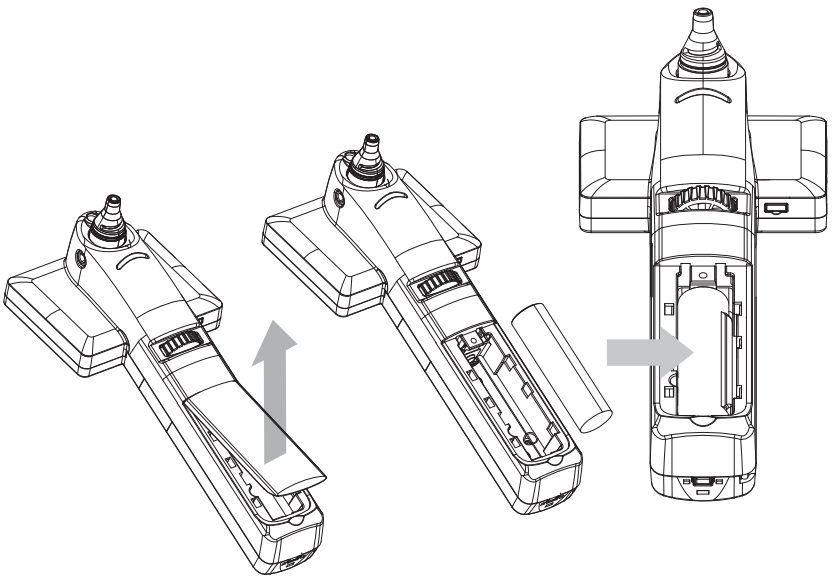
Step 1. Connect the E-Series and power adapter via a USB cable.
Step 2. Insert the power adapter into the wall plug to charge the device.

Transferring Photos:

Connect the E-Series to the computer via USB cable. In normal situations, the E-Series becomes a standard storage device, and the user can review or copy the photos from this device to the computer.

9. Battery Replacement

Battery Replacement



- Open the battery cover by digging out the gap at the bottom of the battery cover with a finger or pointed object.
- Tilt the battery cover and remove by lifting it up.
- Remove the original battery and replace it with a new battery, placed in the correct direction.
- Return the battery cover and secure it in place.

10. Technical Description

. Focus Range > 6.5 mm (Typical)

. Dimension 199.5 x 114 x 90mm^3 (Typical)

. Weight 200 Grams without battery (Typical)

. Illumination Natural White LED

Focus:	Manual Focus
Image Resolution:	1920 x 1080 pixels
Screen:	TFT-LCD
Image Format:	JPEG (Photo graph) and H.264 (Video)
Interface:	Mini USB
File Transfer:	Mini USB Port to PC
File storage:	Memory card, Supports 8GB to 32GB by FAT32 Format.
Power Source:	Rechargeable Lithium Battery 3.6V/3350mAh The battery is in compliance with IEC 62133-2:2017.
External Power:	Source: 100~240 VAC , 50/60 Hz
Power adapter spec:	Brand Name: Good Opportunity Electronic Co., Ltd. Model Name: GS2U-006-050-A Input Spec.: 100-240 Vac, 50/60Hz, 0.2A Output Spec.: 5V DC, 1.2A
Operating time:	3 hours
Charging time:	5 hours
Expected service life:	5 years from the date of initial

(defined by manufacturer)	operation *Proper maintenance is necessary
Intermittent operation of throat light	≤ 3 minutes on, ≥ 10 minutes off between uses

11. Liability

Manufacturer considers itself responsible for the effects on safety reliability and performance of the device only if:

- ⚠ The device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.
- ⚠ Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized.
- ⚠ The electrical installation of the relevant room complies the requirements.
- ⚠ The equipment is used in accordance with these instructions for use.

12. Disposition

- ⚠ Follow the local governing ordinances and recycling plans regarding disposal or recycling of device components, especially when disposing of the lithium ion battery, circuit board, plastic parts that contain brominated flame retardant, LCD, or power cord.

⚠ Follow the local governing ordinances and recycling plans when disposing of the circuit board with the lithium battery. Inappropriate disposal may contaminate the environment.

⚠ When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.

⚠ Inappropriate disposal may contaminate the environment.

⚠ When disposing of specula, follow the disposal procedures for medical waste such as needles, infusion tubes, and metal instruments for surgery as specified by your medical facility to avoid infection outside the facility and environmental pollution

13. Standards

Electrical safety	IEC 60601-1:2005+A1:2012 (EN 60601-1:2006+A1:2013)
EMC and regulatory compliance	IEC 60601-1-2:2014 (EN 60601-1-2:2015)
Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments	ISO 15004-1:2020

⚠ Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and

IEC 60601-1). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output-part configures a medical system and is therefore responsible for the system complying with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.

EMC (Electromagnetic Compatibility)

The device complies with the International Electrotechnical Commission standards (IEC 60601-1-2: 2014) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the device in a Professional Healthcare Environment.

EMC (IEC 60601-1-2: 2014)

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in professional healthcare establishments and those directly connected to the public low voltage power supply network that supplies buildings used for professional healthcare purposes.
Harmonic emissions IEC 61000-3-2	Class A *1	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	*2	

*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floor 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	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2 kV Line to ground	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2 kV Line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC	0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycles 70% U_T for 25/30 cycles	0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycles 70% U_T for 25/30 cycles (50/60 Hz) 0% U_T for	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is

61000-4-11	(50/60 Hz) 0% U_T for 250/300 cycles (50/60Hz)	250/300 cycles (50/60Hz)	recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 or 60 Hz)	30 A/m at 50 Hz	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 a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	3 Vrms (V1=3) at 0.15 – 80 MHz & 6V at ISM Frequency	Portable and mobile RF 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** $E = \frac{6}{d}\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m (E1=3) 80 MHz to 2.7 GHz 80% AM at 1kHz	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 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] 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 device is used exceeds the applicable RF compliance level above 3V/m, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Test specifications for enclosure port immunity to RF wireless communications equipment						
Test frequency (MHz)	Band[a] MHz	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380–390	TETRA400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430–470	GMRS460, FRS460	FM[c] ±5kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE band 13,17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA800, i DEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
970						
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100–5800	WLAN 802.11 a/ n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 percent duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 percent pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The minimum separation distance for higher immunity test levels shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$, where P is the maximum power in watts (W), d is the minimum separation distance in meters [m), and F is the immunity test level in V/m.

EC REP MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

horus

SCOPE