



User Manual

Plusoptix “Binocular autorefractor”

06.05.2020 / CMD

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Thank you for choosing to purchase this device!



Please read this user manual before using the device for the first time!
It contains important information.



According to EU Medical Device Regulation 2017/745 concerning medical devices, we are required to inform you of the duty to report serious adverse events. These must be reported to the competent national authorities for medical devices and to the manufacturer.





















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Additional short manuals and training videos




In addition to this User Manual, you may access the short manuals available on our homepage. These contain detailed descriptions of the additional functions of the device.

Simply scan one of the QR codes on the next page, or go to “Support” on our homepage (plusoptix.com) to download the corresponding short manual. In addition to the short manuals, you will also find training videos there.

QR codes plusoptiX A12C	Short manuals www.plusoptix.com/user-manuals	QR Codes plusoptiX A16
 A12C 1	<p align="center">Short manual 1</p> <p align="center">Checking the scope of delivery and getting to know the device</p>	 A16 1
 A12C 2	<p align="center">Short manual 2</p> <p align="center">Adjusting settings and setting up WLAN</p>	 A16 2
 A12C 3	<p align="center">Short manual 3</p> <p align="center">Preparing and performing a measurement</p>	 A16 3
 A12C 4	<p align="center">Short manual 4</p> <p align="center">Viewing the measurement results</p>	 A16 4
 A12C 5	<p align="center">Short manual 5</p> <p align="center">Entering, retrieving or deleting patient data</p>	 A16 5
 A12C 6	<p align="center">Short manual 6</p> <p align="center">Documenting measurement results electronically</p>	 A16 6
 A12C 7	<p align="center">Short manual 7</p> <p align="center">Documenting measurement results on paper</p>	 A16 7
 A12C 8	<p align="center">Short manual 8</p> <p align="center">Exporting back-ups and reports (only plusoptiX A12C and A16)</p>	 A16 8
 A12C 9	<p align="center">Short manual 9</p> <p align="center">Downloading software updates</p>	 A16 9
 A12C 10	<p align="center">Short manual 10</p> <p align="center">Troubleshooting malfunctions and measurement interruptions</p>	 A16 10

1. Intended use

The used symbols have the following meaning:

	<p>Warnings are identified by this caution symbol.</p>
	<p>Tips & tricks are identified by this light bulb icon.</p>
	<p>Only the included medical power adapter GSM36B12-P1J may be connected to the device for power supply.</p>

The “plusoptiX A12” measures the sphere, cylinder, axis, gaze and pupil diameter in both eyes simultaneously (binocular) in a non-dilated pupil (miosis). These measurement values are used to calculate gaze asymmetry and inter pupillary distance.

With a binocular refraction measurement, spherical anisometropias can also be reliably detected in miosis, since the refraction difference of both eyes always remains the same despite accommodation. The height of the accommodation can be determined in a second measurement by +3 dpt correction glasses. If the spherical measurement values change by -3 dpt, the patient has not accommodated in the first measurement. All other measurement values (cylinder, axis, line of sight, and pupil diameter) are unaffected by accommodation and can therefore be accurately determined at the first measurement in miosis.



Note:

The interpretation of the measurement values for recommending therapy is reserved exclusively for the eye care professional. The measurement values may not be used directly for the prescription of glasses or contact lenses.

2. Responsibility of the operator

The operator is responsible for ensuring that only trained users work with the Plusoptix Binocular autorefractor.

Training

Training must at least include reading the user manual and a briefing on the operation of the device. The briefing on the operation of the device is provided by Plusoptix, by Plusoptix authorised dealers, or can be carried out by a previously trained user.

Electrical safety and electromagnetic compatibility

The operator is responsible for ensuring that external equipment connected to the device meets the standards IEC 60601-1 and IEC 60601-1-2 in respect to electrical safety and electromagnetic compatibility together with the equipment.



Caution:

The device may not be opened. Opening the device runs the risk of receiving an (invisible) electric shock, and it will invalidate its approval as a medical device. The operator is responsible for ensuring that the device is sent to Plusoptix or an authorised Plusoptix dealer for service or warranty cases.



Caution (only A12C):

If you insert batteries other than the supplied rechargeable batteries, only use rechargeable Nickel Metal Hydride NiMH/AA HR6 batteries with a capacity of 1,900 to 2,100 mAh and a quick-charge rate of at least 1 A. When inserting the batteries, check for the correct polarity.

In accordance with Standard IEC 60601-1-2, we are required to provide the following warnings:



Caution:

The use of accessories, transducers and cables that have not been approved or provided by the manufacturer may result in increased electromagnetic emission or reduced electromagnetic immunity of the device resulting in faulty operation.



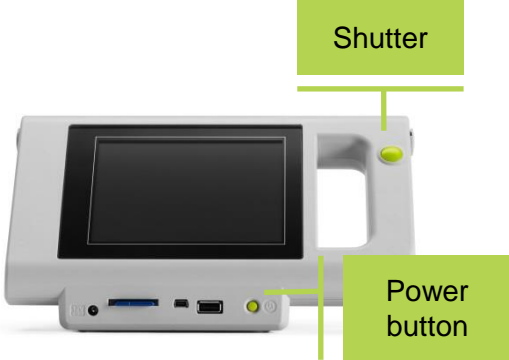


Caution:

Avoid use of the device next to or in conjunction with other equipment, as this could result in faulty operation. If such a use is required, the devices should be monitored to ensure correct function.

3. Initial operation of the Plusoptix Binocular autorefractor

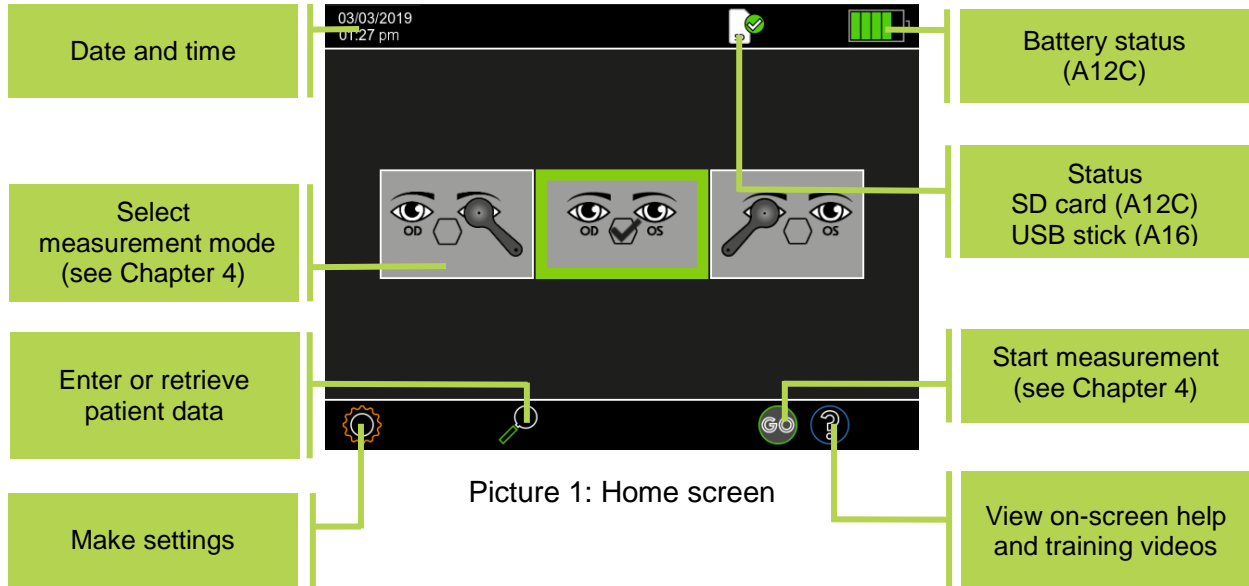
3.1. Checking the scope of delivery and getting to know the device

Upon delivery, please check that the contents of the packaging are complete. If any parts are missing, please notify the dealer immediately.

plusoptiX A12C	plusoptiX A16
	
Scope of delivery	
<ul style="list-style-type: none"> - This User Manual - Medical power adapter for power supply (GSM36B12-P1J) - Power cord (in the compartment under the device) - 6 x rechargeable AA batteries - SD card (inserted into device) 	<ul style="list-style-type: none"> - This User Manual - Medical power adapter for power supply (GSM36B12-P1J) - Power cord (in the compartment above the device)
Interfaces	
<ul style="list-style-type: none"> - 12V connection for medical power adapter - USB interface - Infrared interface (IR) - WLAN interface - SD card - Mini USB interface 	<ul style="list-style-type: none"> - 12V connection for medical power adapter - 4 x USB interface - Infrared interface (IR) - WLAN interface - LAN connection (RJ45) - DVI connection
<p style="text-align: center;">Turning the device on and off</p> <p>Briefly press the power button on the handle to turn the device on. The screen will come on immediately and the device will start up. After approx. 1 minute, the device is ready for use. Briefly press the power button to turn the device off. The device will shut down.</p> <p> Note: If necessary, press and hold the power button to force the device to shut down.</p>	
<p>For more information on the devices and their interfaces, refer to Short Manuals 1 and 2.</p>	

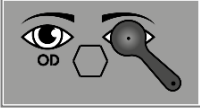

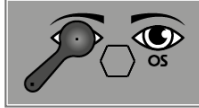
3.2. The home screen

After the start up, you will see the start screen. Similarly to all the screen displays of the device, it has the following structure: the header is arranged at the top, the information part in the middle, and the navigation bar at the bottom.

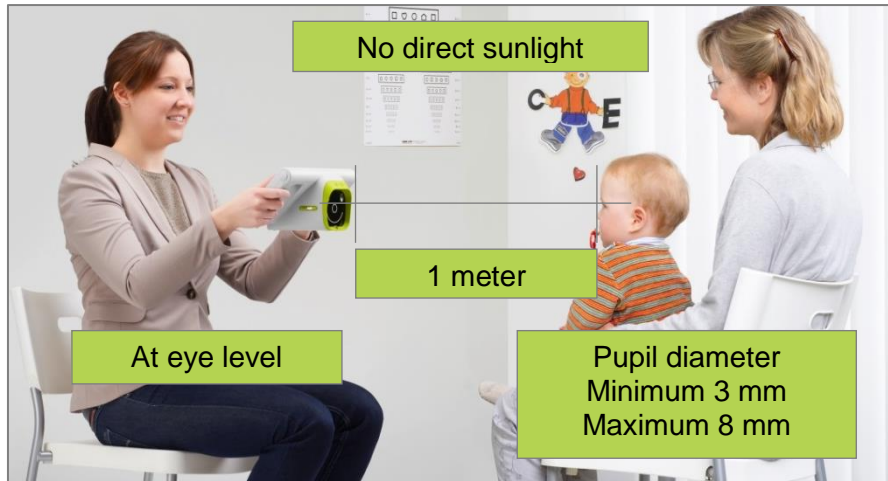


4. Starting a measurement and aligning the device

- Chose the measuring mode by touching one of the following buttons:

 <p>Monocular measurement: Measurement of the right eye (OD)</p>	 <p>Binocular measurement: Measurement of the left (OS) and right eye (OD) simultaneously</p>	 <p>Monocular measurement: Measurement of the left eye (OS)</p>
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- Start the measurement directly after selecting the measuring mode.
- Hold the device at eye level to the patient, about 1.2 meters away. The measuring distance is one meter, but it requires practice to correctly estimate this measuring distance. It is easier to hold the device further away when starting the measurement and then slowly move it towards the patient.



Picture 2: Measuring environment

- Press the shutter on the handle or touch the flashing "GO" button (1) on the screen to start the measurement; you will hear a warble sound. Instead of the start screen, you will now see the camera image.



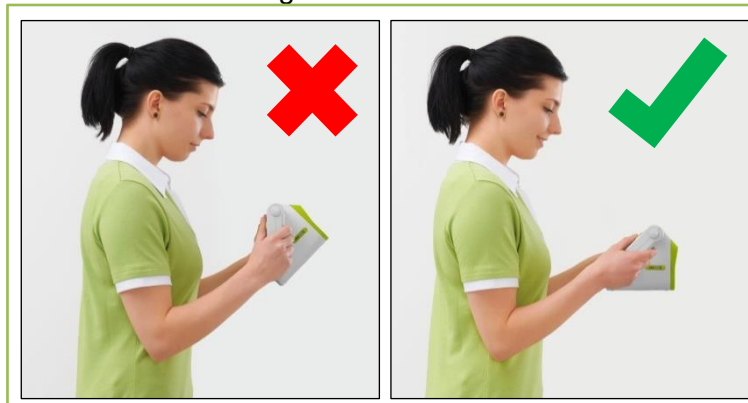
Note:

Touch the camera image if you wish to discontinue a started measurement.



Note:

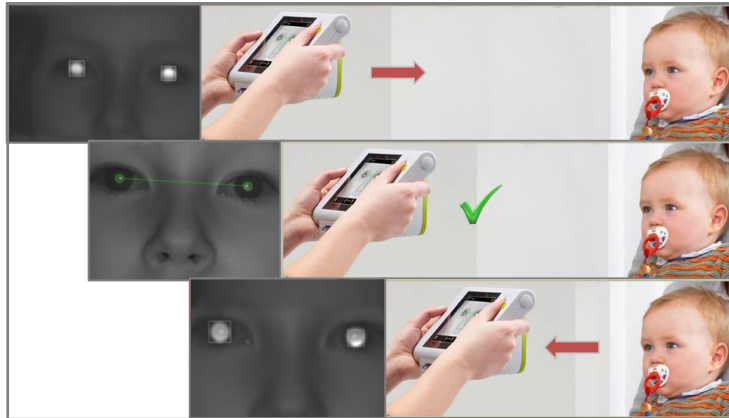
The screen of the plusoptix A12C is fixed at a 45° angle to the camera axis. Tilt your wrists downwards to align the device.



Picture 3: Aligning the plusoptix A12C

- Align the device so that both eyes can be seen on the screen, and then slowly move the device towards the patient until the camera image can be seen in high-definition on the screen (individual hairs of the eyebrows and the eyelashes must be visible).





Picture 4: Detecting the correct measuring distance



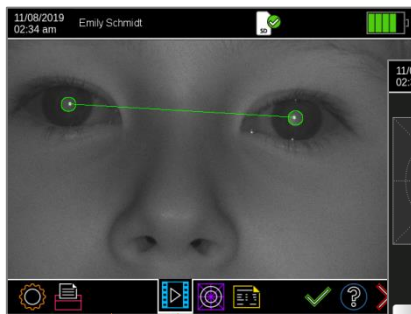
Note:

If a patient is not looking at the nose of the smiley face during the measurement, this can cause a termination of the measurement. The nose and the knees of the patient must always be directed towards the device.

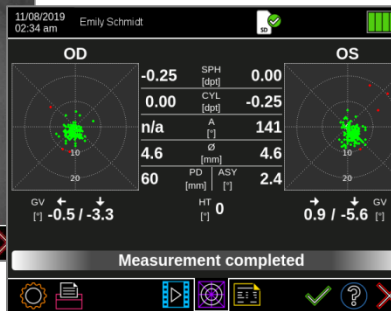
- The end of the measurement is confirmed by a “PING” sound. After the measurement, you will first see the “camera image” results page.
- Touch the appropriate icon in the middle of the navigation bar to access each of the three results pages:

Picture 5: Overview of the results pages

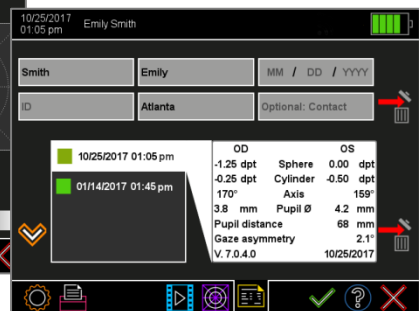
Results page
Camera image



Results page
Measurement values



Results page
Database



Note:

Tap the camera image to zoom into the pupils. This allows you to accurately examine the pupils for media opacities and abnormal reflexes (Bruckner or red reflex test).

In addition to the measurement values, a measurement result is displayed:

Measurement completed!

The measurement has been successfully completed.

Measurement inconclusive

The measurement has been stopped inconclusively.

Pupils not found!

If applicable, a red error message is also displayed:
If a red error message is displayed above the screening result, please refer to short manual 10.

For more information on performing a measurement and on viewing as well as documenting the measurement results, refer to Short Manuals 3 to 7.

5. Maintenance, service and warranty

This device is an opto-electronic measuring device. The mechanical structure and functional principle is comparable to a video camera. If you handle the device as carefully as you handle your own video camera, your device will provide you with many years of problem-free, good service.

Maintenance and calibration

The device is maintenance-free and does not need calibrating. When it is not being used, store it in the original packaging for safekeeping.

Cleaning

Use a slightly damp microfiber cloth for cleaning the device. Should it be necessary to disinfect the device, use Bacillol 30 Tissues, Clorox Healthcare Bleach Wipes or Teccare Control Tissues. These are approved for cleaning the device.

Service

If your device is not working correctly, please read the information on troubleshooting in Short Manual 10 first. Please contact Plusoptix or a Plusoptix authorized dealer only if you fail to find a solution in the manual.

Free software updates

Please check every 12 months to determine whether a new software version is available for download. To access the free download of our latest software version, please go to "Support" on our homepage.

Warranty

The device is supplied with a 12-month warranty from initial purchase. You may purchase an extended warranty. Please contact Plusoptix should you wish to do so. The warranty is invalidated in the case of external damage, improper use, incorrect cleaning or transportation without the original packaging (device cardboard box or Plusoptix carrier bag). The warranty is also invalidated if the device has been opened. External devices such as the SD card, USB memory stick, keypad and mouse are not covered by the warranty.

Shipping the device

In the case of a warranty claim or required service, please send us the device in its original packaging at your expense. After the repair, we will return it to you at our expense.



Note:

If patient data is stored on the device, it must be removed from the device for data privacy reasons. Export a copy of your database prior to shipping, and re-import it once you have received the repaired device. For more information on importing and exporting patient data, refer to Short Manual 8.





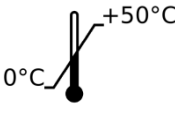

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in Europe:
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90411 Nuremberg
Germany
Tel: +49-911-59 83 99-20

in North and South America:
Plusoptix Service & Warranty
Attn: Richard Christensen
8736 SE 165th Mulberry Lane
Suite 220
Lady Lake, FL 32162

6. Technical specifications

Requirements & directives

	<p>The device meets the requirements of Medical Devices Directive 2007/47/EC.</p>
	<p>The device has been tested and certified for compliance with applicable US American and Canadian standards by the Nationally Recognized Test Laboratory (NRTL).</p>
	<p>The device has been certified according to Brazilian requirements and may therefore bear the INMETRO certification mark.</p>
	<p>The device meets the requirements for a Type B application part as per IEC 60601-1.</p>
	<p>The device can be stored and transported at temperatures between 0°C to +50°C (i.e 32°F to 122°F). Operation requires a temperature between +10°C and +40°C (i.e. 50°F to 104°F) at 20% to 80% relative humidity (non-condensing).</p>
	<p>Disposal Do not dispose of the device as domestic waste. Please send the device to Plusoptix for environmentally sound disposal. We will reimburse you for the cost of the return.</p>

Measurement values

Measurement value	Measuring range and tolerance
Sphere	-7 to +5 dpt in 0.25 dpt steps \pm 0.25 dpt
Cylinder	-7 to +5 dpt in 0.25 dpt steps \pm 0.25 dpt
Axis	1 to 180° in 1° steps \pm 15°
Pupil diameter	3 to 8 mm in 0.1 mm steps \pm 5%
Interpupillary distance	25 to 85 mm in 0.1 mm steps \pm 5%
Gaze asymmetry	0 to 25° in 0.1° steps \pm 2.62°
Head angle	-71 to +71° in 1° steps \pm 0.75°
Gaze direction	-30 to +30° for 5 mm pupil size; in 0.1° steps \pm 1,85°

Power supply

Power supply (medical power adapter GSM36B12-P1J)	Input	100–240 V AC, 50/60 Hz, 0.9–0.45 A
	Output	12 V DC, 3A, 36 W max.
Rechargeable batteries	Type / size	Nickel metal hydride NiMH / AA HR6
	Electric charge / number	1,900 to 2,100 mAh / 6 pieces

Operation, interfaces and standards

	A12C	A16
Touch screen operation	5.7 inch (capacitive) Aspect ratio 4:3 (640 x 480 pixels)	4.3 inch (resistive) Aspect ratio 5:3 (800 x 480 pixels)
Interfaces	12V, USB, IR, Mini-USB, SD WLAN	12V, 4 x USB, IR, DVI WLAN, LAN (RJ-45)
Standards	EN 60601-1	
IR	Devices use infrared light with a wavelength of 870nm and a maximum intensity of 135mW/sr.	

WLAN interface standards:

Physical layer	Supports 802.11 b and g standards
Network architecture types	Communication with wired networks via access points
Security	WPA and WPA2
Transmit power	802.11b/g: 50 mW (+17 dBm) typically
Frequency range	2,400 - 2.4897 GHz
Operating channels	1-11 for North America and others, 1-13 for Europe and others
Channels	Supports all channels of 802.11d-APs.
RX sensitivity	-86 dBm typically @ 11 Mbps, -82 dBm @ 6 Mbps, -69 dBm @ 54 Mbps
Data rates	802.11g: 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11b: 1, 2, 5.5, 11 Mbps

Environmental conditions for operation and storage

According to standard IEC 60601-1-2, we are required to inform you that the device has been designed for the environment category "Environment in areas of domestic health care, except for vehicles and planes". It must be stored in its original packaging. Do not place the original packaging near heat sources (radiators, fan heaters, etc.). When you remove the device from its original packaging, do not expose it to sunlight.

Storage	Temperature	0 to +50 °C (+32 to +122 °F)
	Humidity	10 to 80 % non-condensing
Operation	Temperature	+10 to +40 °C (+50 to +104 °F)
	Humidity	20 to 80 % non-condensing
Max. height	Max. storage height	<2000 m (6,560 ft)
	Max. operating height	<2000 m (6,560 ft)

Dimensions and weight with and without cardboard box

plusoptiX A12C without cardboard box	Dimensions (LWH)	150 x 260 x 135 mm (5 ⁷ / ₈ x 10 ¹ / ₄ x 5 ¹ / ₃ in)
	Weight	1.4 kg (49.38 oz)
plusoptiX A12C in cardboard box	Dimensions (LWH)	270 x 420 x 210 mm (10 ³ / ₈ x 16 ¹ / ₂ x 8 ¹ / ₄ in)
	Weight	2.2 kg (77.60 oz)
plusoptiX A16 without cardboard box	Dimensions (LWH)	190 x 155 x 265 mm (7 ¹ / ₂ x 6 ¹ / ₈ x 10 ³ / ₄ in)
	Weight	1.8 kg (52.9 oz)
plusoptiX A16 in cardboard box	Dimensions (LWH)	270 x 420 x 210 mm (10 ³ / ₈ x 16 ¹ / ₂ x 8 ¹ / ₄ in)
	Weight	2.7 kg (93.5 oz)

Manufacturer's declaration on electromagnetic compatibility (EMC)

The device is intended for use in the electromagnetic environments listed below. Owners and users of the device are responsible for ensuring that these environment conditions are met.

This product conforms to the EMC standard (IEC 60601-1-2).

Emissions test	Conformity	Electromagnetic environment – Instructions
RF Emission CISPR 11	Group 1	The radiation is low and causes no interferences with electronic devices found nearby.
RF Emission CISPR 11	Category B	The device can be used in all areas which are connected to the public electricity supply.
Harmonic Emissions IEC 61000-3-2	Category A	
Voltage fluctuations / flicker IEC 61000-3-3	Compliant	



Caution:

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. Otherwise, degradation of the performance of this equipment could result.

Recommended safety distances between portable and mobile RF telecommunication devices and the device

The device is intended for use in an electromagnetic environment with controlled HF disturbance variables. The customer or user of the device can contribute to avoiding electromagnetic disturbances by complying with the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device – depending on the output power of the communication device, as stated below.

Maximum output power of the transmitter (in W)	Safety distance depending on the transmission frequency (in meters)		
	150kHz - 80MHz $d = 0.35 \sqrt{P}$	80MHz - 800MHz $d = 0.35 \sqrt{P}$	800MHz - 2.7GHz $d = 0.7 \sqrt{P}$
0.01	0.035	0.035	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.11	1.11	2.21
100	3.5	3.5	7

For transmitters, whose maximum nominal output is not stated in the above table, the recommended safety distance in meters (m) can be calculated using the equation from the relevant column, wherein P equals the maximum nominal output of the transmitter in watts (W) as per information by the transmitter's manufacturer.

COMMENT 1 At 80 MHz and 800 MHz, the higher frequency range applies.

COMMENT 2 These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity test	IEC 60601 test values	Conformity values	Electromagnetic environment – Instructions
ESD IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air	The floor should be made of wood, ceramic or stone. If the floor is covered with a synthetic material, the relative air humidity should not be less than 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV	± 2 kV	Only outlets that are usually available in domestic or clinical areas should be used.
Surge IEC 61000-4-5	± 0.5 kV ± 1 kV ± 2 kV	± 0.5 kV ± 1 kV ± 2 kV	
Voltage dips, short interruptions on power supply input lines IEC 61000-4-11	0% 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% 1 cycle 70% 25 cycles 0% 250 cycles	0% 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% 1 cycle 70% 25 cycles 0% 250 cycles	
Power frequencies (50/60 Hz) and magnetic fields IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Magnetic fields should not exceed the usual ranges.
Conducted RF disturbances IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 120V / 60 Hz 230V / 50 Hz	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 120V / 60 Hz 230V / 50 Hz	Portable and mobile radio equipment must not be operated in a distance to the device (including the electrical lines) less than the recommended safe distance calculated using the appropriate equation for the transmission frequency. Recommended safe distance: $d=(3.5/10) \times \sqrt{P}$ $d=(3.5/10) \times \sqrt{P}$ 80MHz - 800MHz $d=(7/10) \times \sqrt{P}$ 800MHz - 2,7GHz where P is the maximum output power rating of the transmitter in watts (W) as indicated by the transmitter manufacturer and d is the recommended safe distance in metres (m). The field strength of fixed RF transmitters as determined by a site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked by the pictogram shown.
Radio-frequency electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz - 2.7GHz 80% AM, 1KHz 27 V/m 385 MHz PM 50%, 18 Hz 28 V/m 450 MHz PM 50%, 18 Hz 9 V/m 710,745,780 MHz PM 50%, 217 Hz 28 V/m 810, 870, 930 MHz PM 50%, 18 Hz 28 V/m 1720, 1845, 1970 MHz PM 50%, 217 Hz 28 V/m 2450 MHz PM 50%, 217 Hz 9 V/m 5240, 5500, 5785 MHz PM 50%, 217 Hz	10 V/m 80 MHz - 2.7GHz 80% AM, 1KHz 27 V/m 385 MHz PM 50%, 18 Hz 28 V/m 450 MHz PM 50%, 18 Hz 9 V/m 710,745,780 MHz PM 50%, 217 Hz 28 V/m 810, 870, 930 MHz PM 50%, 18 Hz 28 V/m 1720, 1845, 1970 MHz PM 50%, 217 Hz 28 V/m 2450 MHz PM 50%, 217 Hz 9 V/m 5240, 5500, 5785 MHz PM 50%, 217 Hz	
<p>COMMENT 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>COMMENT 2 These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			