reddot award 2014
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“plusoptiX S12R”

User Manual
Plusoptix “Vision Screener”

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English

CE 0123

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.

Table of contents

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.

The short manuals are available in the area “Support” on our homepage (plusoptix.com). In addition to the short manuals, you will also find training videos there. To download short manuals or watch training videos, simply visit following website or scan the QR code with your smartphone:

plusoptix.com/support-S12R	

1. Intended use

The used symbols have the following meaning:

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

The Plusoptix Vision Screener is used for the early detection of vision disorders (preventive eye care). These vision disorders can cause permanent loss of vision (amblyopia) if they are not detected and treated in the early years of a child's life.

To detect vision disorders, the Plusoptix Vision Screener measures the sphere, cylinder, axis, line of vision and pupil size of both eyes at the same time. Using these measurement values, the spherical equivalent, gaze symmetry and interpupillary distance are calculated. All measurement values are compared with age-based referral criteria. "Refer" is automatically displayed as a precautionary result for every patient requiring an ophthalmologist appointment.

Note:
False-positive and false-negative results can occur in any type of preventive examination.

Note:
Preventive eye care with the Plusoptix Vision Screener does not replace the eye examination carried out by an eye care professional. An eye care professional remains the only person qualified to interpret the measurement values and establish a diagnosis. The measurement values must not be used directly to prescribe glasses or contact lenses.

All patients who are not already being treated by an eye care professional should undergo a preventive eye care examination. The first preventive eye care examination should be performed before the child's first birthday. In the event of a family history of visual disorders, an earlier preventive eye care examination at ages between 5 and 8 months is recommended. The examination should then be repeated regularly, as the eyes can change during growth and new visual disorders can manifest at any time.

2. Responsibility of the operator

The operator is responsible for ensuring that only trained users work with the Plusoptix Vision Screener.

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.

Attention:
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.

Attention:
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:

Attention:
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.

Attention:
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 Vision Screener

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.

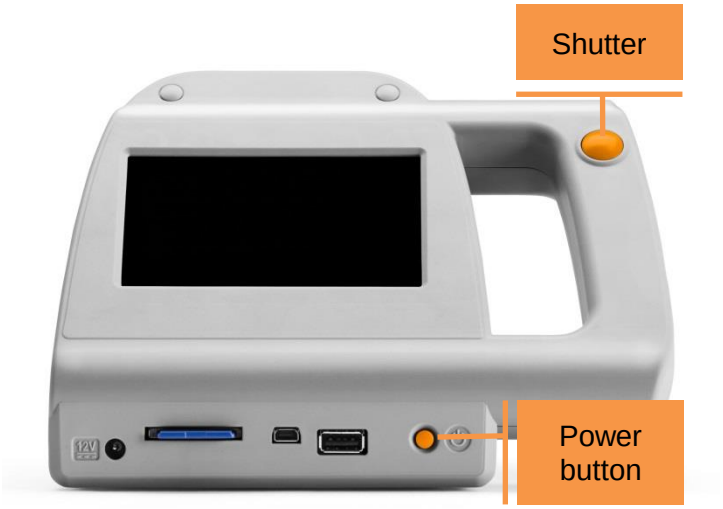


Figure 1: “plusoptiX S12R” rear view with touchscreen

Scope of delivery:

- 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)

Interfaces:

- 12V connection for medical power adapter
- USB interface
- Infrared interface (IR)
- SD card
- Mini USB interface

Turning the device on and off:

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.

Note:
If necessary, press and hold the power button to force the device to shut down.

For more information on the devices and their interfaces, refer to Short Manuals 1 and 2.

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.

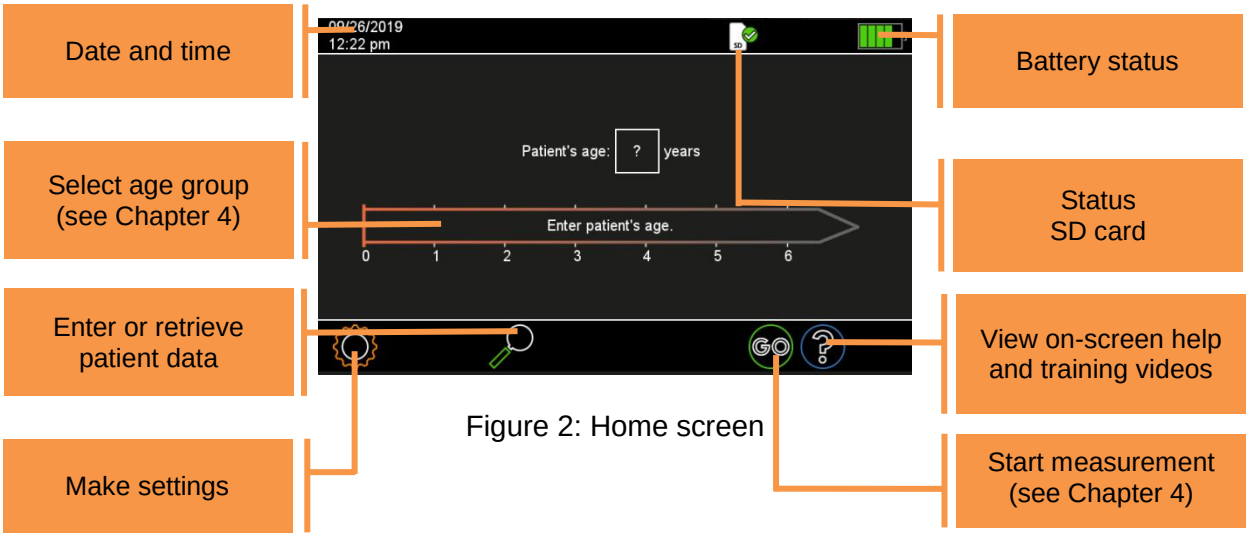


Figure 2: Home screen

4. Starting a measurement and aligning the device

- Select an age group by touching the appropriate age range on the time bar. You must select the age group in order to ensure that the measurement values of the patient are compared with the correct age-specific referral criteria.
- 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.

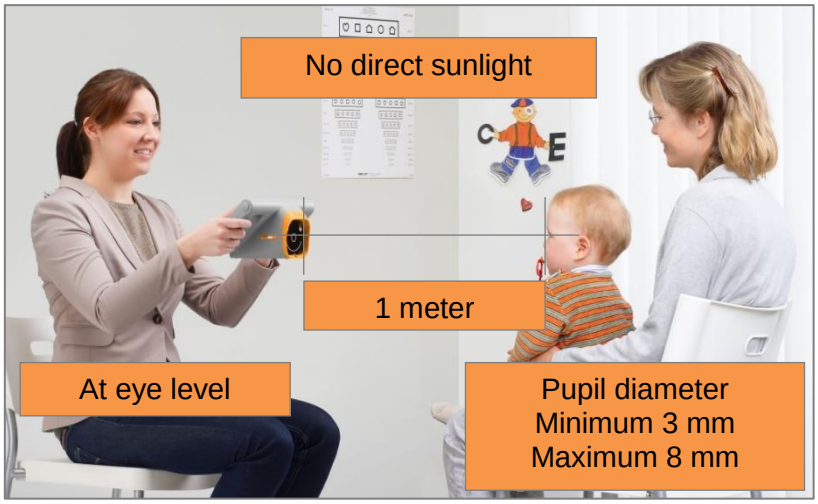


Figure 3: Measuring environment

- 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 S12R is fixed at a 45° angle to the camera axis. Tilt your wrists downwards to align the device.

Figure 4: Aligning the plusoptiX S12R

- 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).

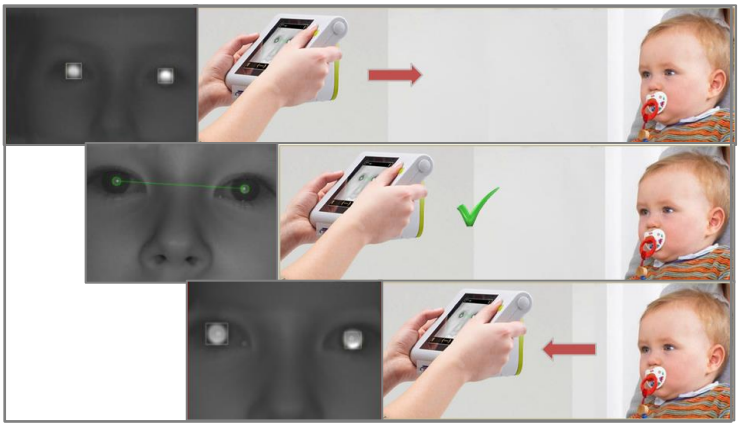


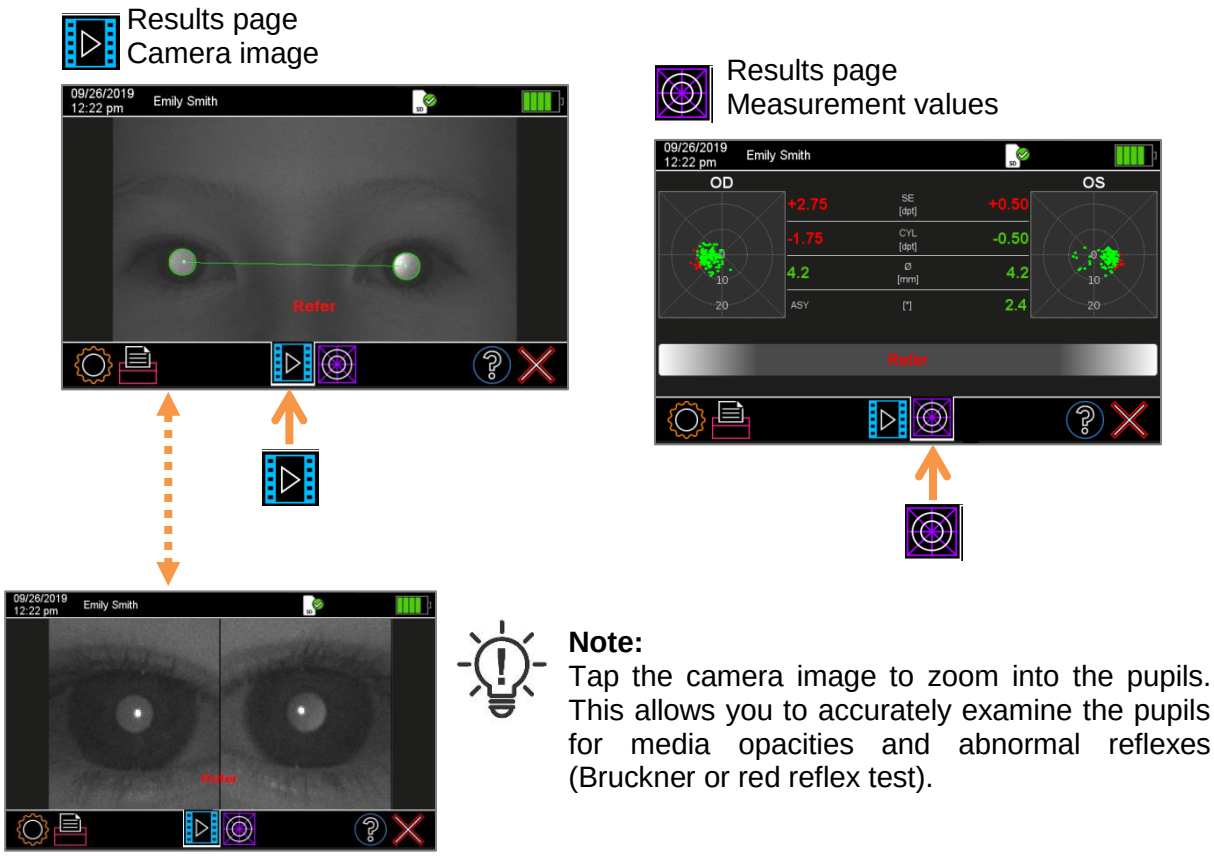
Figure 5: Detecting the correct measuring distance

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.

1) 

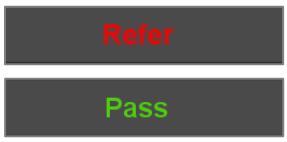
- The end of the measurement is confirmed by a “PING” sound. After the measurement, you will first see the “camera image” results page.
- Touch the appropriate icon in the middle of the navigation bar to access each of the three results pages:

Figure 6: Overview of the results pages



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 screening result is displayed:



The measurement has been successfully completed and the “Refer” or “Pass” screening result is displayed. “Refer” is automatically displayed as a preAttentionary result for every patient requiring an eye care professional appointment.

The measurement concluded without result and a “Try again” or “Refer or Try again” status is displayed. In this case, check the measuring environment (see figure 2).

Was the measurement discontinued due to direct sunlight, an incorrect measuring distance or a too small or too large pupil size? For more information on measurements without result, 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.

Our address is:

in Europe:
Plusoptix GmbH
Nordostpark 21
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

CE 0123	The device meets the requirements of Medical Devices Directive 2007/47/EC.
SGS c US 800693	The device has been tested and certified for compliance with applicable US American and Canadian standards by the Nationally Recognized Test Laboratory (NRTL).
Segurança SGS OCP 0040	The device has been certified according to Brazilian requirements and may therefore bear the INMETRO certification mark.
	The device meets the requirements for a Type B application part as per IEC 60601-1.
0°C +50°C	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).
	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.

Measurement values

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

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

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 S12R without cardboard box	Dimensions (LWH)	5.90 x 7.87 x 5.31 in (150 x 200 x 135 mm)
	Weight	38.80 oz (1,1 kg)
plusoptiX S12R in cardboard box	Dimensions (LWH)	10.63 x 16.54 x 8.27 in (270 x 420 x 210 mm)
	Weight	67.02 oz (1,9 kg)

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	

Attention:
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 recommenced 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	
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