Vision Screener

„plusoptiX S16”

User Manual
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List of supplementary short manuals

These can be found in the “Support” section of our homepage (www.plusoptix.com).

1.  Adjusting settings and setting up WLAN
2.  Preparing and performing a measurement
3.  Viewing the measurement results
4.  Entering, retrieving or deleting patient data
5.  Documenting measurement results electronically
6.  Documenting measurement results on paper
7.  Exporting data
8.  Downloading software updates
9.  Troubleshooting malfunctions and measuring interruptions
1 Intended use and responsibility of the operator

Thank you for choosing to purchase the “plusoptiX S16”! Plusoptix is the global leader in the development, production and distribution of medical measuring devices for pediatric Vision Screening. If you have any further questions after reading this user manual, please do not hesitate to contact us. The symbols in this user manual have the following meanings:

Please read this user manual before using the “plusoptiX S16” for the first time! It explains the device’s functions. When the “plusoptiX S16” is switched on, additional training videos can be accessed by touching the blue “?”.

Warnings and tips are labelled with the Attention! symbol.

The “plusoptiX S16” fulfils the requirements of Medical Devices Directive 2007/47/EEC.

The “plusoptiX S16” fulfils the requirements for a Type B applied part of IEC 60601-1.

Only connect the “plusoptiX S16” to the enclosed GSM36P12-P1J medical power supply.

The “plusoptiX S16” can be stored and transported at a temperature between 0°C and +50°C (i.e. 32°F to 122°F). A temperature between +10°C and +40°C (i.e. 50°F to 104°F) with a non-condensing air humidity of 20% to 80% is required to operate the device.

Disposal

Do not dispose of the “plusoptiX S16” as domestic waste. Please send the “plusoptiX S16” to Plusoptix (Plusoptix GmbH, Neumeyerstrasse 46, 90411 Nürnberg, Germany) for environmentally friendly recycling. Plusoptix will reimburse you for the cost of the return.
Intended use

The “plusoptiX S16” is used for the early detection of visual disorders (preventative eye care). These visual disorders can cause permanent loss of vision in an eye (amblyopia) if they are not discovered and treated in the early years.

To detect visual disorders, the “plusoptiX S16” 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-dependent referral criteria. “Refer” is automatically displayed as a precautionary result for every patient requiring an ophthalmologist appointment.

Note:
Preventative eye care with the “plusoptiX S16” does not replace the eye examination carried out by an ophthalmologist. An ophthalmologist remains the only one who can interpret the measurement values and establish a diagnosis. The measurement values must not be used directly to prescribe glasses or contact lenses.

All children who are not already being treated by an ophthalmologist should undergo a preventative eye care examination. The first preventative eye care examination should be carried out at the age of one. They should then be repeated regularly, as the eyes can change during growth and new visual disorders can appear at any time. All children with a “Refer” result from the preventative eye care examination should be referred for an eye examination with an ophthalmologist.

Note:
False-positive and false-negative results can occur in any type of preventative examination.
Responsibility of the operator

- The operator is responsible for ensuring that only trained users handle the “plusoptiX S16”.

- Training must at least include reading the user manual and a briefing about the operation of the “plusoptiX S16”.
  The briefing about the operation of the “plusoptiX S16” can be carried out by a previously trained user. In addition to this, briefings are also provided by Plusoptix and by Plusoptix dealers authorised by Plusoptix.

- The operator is responsible for ensuring that external devices that are connected to the “plusoptiX S16” meet the standards of IEC 60601-1 and IEC 60601-1-1 when attached to the “plusoptiX S16”.

- The operator is informed that opening the “plusoptiX S16” runs the risk of receiving an (invisible) electric shock. The “plusoptiX S16” loses its approval as a medical product when it is opened. The operator is responsible for ensuring that the “plusoptiX S16” is only opened by Plusoptix or a dealer authorised by Plusoptix for service or warranty cases.

Warning:

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2 Checking the scope of delivery

The “plusoptiX S16” is delivered in a box with foam inserts, which protect the “plusoptiX S16” from damage. If the box shows any signs of damage upon delivery, please immediately inform the vendor of the “plusoptiX S16”.

On delivery, please check that the contents of the box are complete. The scope of delivery includes:

- User manual for the “plusoptiX S16”
- Vision Screener “plusoptiX S16”
- GSM36P12-P1J medical power supply
- Power cord (in the compartment under the device)

Optional accessories:

- Wireless “plusoptiX P12” label printer
- Self-adhesive labels for the “plusoptiX P12”

If the delivery is incomplete, please inform the seller of the “plusoptiX S16” immediately.
The “plusoptiX S16” is made up of the device with a smiley, which is connected to the cradle with the device cable.

![PlusoptiX S16 device](image)

During a measurement, the “plusoptiX S16” records a series of images. To ensure children look into the camera during the measurement, the “plusoptiX S16” plays a warble sound.

The speaker, the camera lens and the LEDs needed to light the images are located behind the black protective screen with the smiley. This smiley helps to keep the child’s attention.

**Attention:**
If a child is not looking at the camera lens in the middle behind the hexagon during the measurement, this can lead to a cancellation of the measurement or incorrect measured values of the visual symmetry. Therefore do not use any other external fixation aids!

**Note:**
So that the protective screen does not get dirty, we recommend you do not touch it. Should the protective screen get dirty, please heed the care instructions in Chapter 8.
There is a 4.3” screen (resistive touchscreen) on the back of the “plusoptiX S16”. To access a function displayed on the screen, simply tap the screen with your fingernail. The screen and contact sensor are protected behind a thin plastic cover.

![Image of the device with labels: On / off button, 4.3” screen (touchscreen), Trigger]

Figure 3: View of reverse side

The type plate with serial number (S/N 1601A-xxx-xxxx xxxx) can be found on the bottom of the cradle. If you contact us regarding ongoing service or guarantee issues, please make sure you always have the serial number of your “plusoptiX S16”. The serial number helps us to answer your question quickly.

![Image of the cradle's underside with the type plate]

Figure 4: Underside of the cradle with type plate

3.1 Connecting the „plusoptiX S16“

Connect the medical power supply to the power cord and then plug this in. The LED on the power supply lights up green for confirmation. Then connect the medical power supply to the “plusoptiX S16”.

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3.2 Integrated interfaces

The cradle has 4 connections:
- LAN connection (RJ45) for incorporation into the practice network
- 12V connection for the medical power supply
- 4 x USB interfaces
- DVI connection for optional connection of a monitor

The four USB interfaces can be used as follows:
- To save the screening reports and import an infographic
- To import patient data
- To export data
- Optional connection of a USB keyboard and USB mouse

3.3 Connecting an external monitor (optional)

The “plusoptiX S16” has a DVI interface to connect an external monitor. This enlarges the display of the results pages. This allows the results pages to be discussed easily with the patient.

Connect your monitor with the DVI interface in the cradle of the “plusoptiX S16”. When the device is mounted on the cradle, the image is shown on the external monitor and the screen of the “plusoptiX S16” is turned off.

Remove the device from the cradle before the measurement. The screen of the “plusoptiX S16” is now active and the external monitor is switched off. This avoids the child being distracted by the picture on the external monitor during the measurement.

After the measurement, replace the device on the cradle. The screen of the “plusoptiX S16” is now turned off again and the screen of the monitor shows an enlarged view of the results pages.

3.4 Connecting the USB keyboard and mouse (optional)

To enter data on the “plusoptiX S16”, it is necessary to connect a conventional USB keyboard. Connect your input device with the USB interface of the “plusoptiX S16”. You can also connect wireless input devices instead of cabled ones.

A USB keyboard is necessary for:
- inputting and selection of patient data
- entering the password in the WLAN settings
- configuring network settings to connect to the practice network

If a connected mouse or keyboard is not working, please check whether the USB keyboard or mouse is switched on, connected with the “plusoptiX S16” and whether the batteries are inserted. If your input device still doesn’t work, this means it is not supported by the drivers installed in the “plusoptiX S16”. Use input devices from another manufacturer instead in this case.

Note:
Non-functioning external input devices do not constitute a service or warranty case!
4 Switching the “plusoptiX S16” on and off and adjusting settings

Press the On / Off button briefly to turn the device on. The screen will come on immediately and the “plusoptiX S16” will start up. After approx. 30 seconds, the “plusoptiX S16” is ready to operate. The first time you start the device up, you will see the data and time settings page.

The selected time and date format is highlighted (1). Using the orange arrows (2), set the right date and current time. Confirm your entries with the green checkmark (3). The date, time and display format can be changed at a later date in the settings (4).


More information about adjusting the settings and implementing a WLAN connection can be found in short manual 1 on our homepage (www.plusoptix.com), under support.
5 Screen displays and training videos

All the screen displays of the “plusoptiX S16” are the same. The header is above, the information part in the middle and the navigation bar below. The button with the blue “?” (1) takes you to the help page, which explains the displayed buttons. The button with the blue “►” (2) takes you to the overview of available training videos. The red “X” (3) takes you back to the previous home page.

Note:
Watching training videos does not replace the need to read the user manual. They serve only to aid visualisation of what is written in the user manual.

The header shows the status. This includes, among other things:
- Date and time on the left side

The navigation bar operates the device. Among other things, you can select:
- the gear wheel (4) to access the settings
- the magnifier (5) to call up the database
- the “GO” button (6) to start a measurement (If the “GO” button is flashing, a measurement can be started by touching it)
- the blue “?” (1) to access the available training videos
- the red “X” (3) which interrupts without saving and returns you to the previous page.
6 Preparing the measurement area

The measurement is carried out using infrared light, which is also contained in sunlight and in the light of bulbs and halogen spotlights, for example. This infrared light is invisible to the human eye and completely safe.

To obtain correct measurement values, it is important to avoid disruptive sources of infrared light in the examination room. Close curtains, roller blinds and shutters to block out the sun’s rays.

Turn off all light sources that produce heat. This does not mean that the examination room should be dark. Cold light sources, such as energy saving bulbs and neon lights, do not affect the measurement values.

More information about preparing the measurement area can be found in short manual 2 on our homepage (www.plusoptix.com), under support.

7 Performing measurements

The “plusoptiX S16” measures both eyes at the same time (binocular) in 0.5 seconds from a distance of one meter. This means that even infants with a short attention span can be measured from the age of 5 months. The simultaneous measurement of both eyes also facilitates a reliable comparison of both eyes’ measurement values. More information about performing a measurement can be found in short manual 2 on our homepage (www.plusoptix.com), under support.

A measurement can be performed anonymously or by indicating patient data. More information about entering or retrieving patient data can be found in short manual 4 on our homepage (www.plusoptix.com), under support.
7.1 Preconditions for a successful measurement

a) The measuring distance is correct

The measuring distance must be between 95 cm and 105 cm. Check whether the camera image on the screen is in focus. You must be able to see the individual hairs on the eyelids or the eyelashes clearly on the camera image.

b) The patient is looking at the camera lens

The "plusoptiX S16" and the eyes of the patient must be aligned with one another. The patient must look at the nose of the smiley face. For this reason, an attention grabbing warble sound is emitted at the beginning of the measurement.

Note:
The attention span of toddlers is very short. Take advantage of the fact that the examination room is unknown to the toddler. The attention-grabbing "Warble" sound in this unknown environment always arouses interest. Avoid lengthy conversation with parents before the measurement.

Note:
If a child is not looking at the nose of the smiley face during the measurements, this can cause a termination of the measurement or inaccurate measurement values of the gaze symmetry. For this reason, do not use any other external fixation aids!

c) Both of the patient’s pupils should be completely visible

The pupils must not be covered by eyelids, eyelashes or hair, for example. Check whether both pupils can be seen completely on the screen and whether they are encircled in green.

d) Both pupil diameters must be between 4 and 8 mm

Note:
If a red error message is displayed, an action recommendation is also displayed below it. Please read short manual 9 on our homepage (www.plusoptix.com), under support.
7.2 Selecting the referral criteria

Touch the button to choose the referral criteria (1) in the settings. There are five validated groups of referral criteria to choose from (see figure 23).

These five groups are called ROC 1, ROC 2, ROC 3, ROC 4 and ROC 5. Each of these groups defines different, age-dependent thresholds, which lead to a “Refer” preventive test result. These five groups are shown along a schematic ROC (Receiver Operating Characteristic) curve. Select a group by touching the relevant button (2) and confirm by touching the green checkmark (3).

7.3 Starting the measurement and adjusting the “plusoptiX S16”

After you have set the time and date, the home page will be displayed every time you turn the “plusoptiX S16” on again.

Select an age group by touching the appropriate age range (see Figure 4). You must select the age group (4) in order to ensure the measurement values of the patient are compared with the correct age-specific referral criteria (see Chapter 7.2 “Selecting the referral criteria”).
- Hold the “plusoptiX S16” at eye level to the child, about 1.2 meters away. The measuring distance is one meter, but it requires practice to correctly estimate this measuring distance in one go. It is easier to hold the “plusoptiX S16” somewhat further away at the start of the measurement and then slowly move it towards the child.

- By touching the flashing “GO” button (1) or pressing the trigger, you will start the camera and a warble sound will be heard. You can now see the camera image on the screen.

**Note:**
A started measurement can be aborted by touching the screen.

- Adjust the “plusoptiX S16” so that both eyes can be seen on the screen and then slowly move the “plusoptiX S16” towards the patient until the camera image can be seen in high-definition on the screen. Firstly, the pupils will be surrounded by white squares (the image is still very blurred), then with red and finally with green circles (see Figure 11).
The image is blurry and two red bars will be displayed next to the camera image. As the measuring distance is too great, you can see the head of the patient virtually in its entirety. Move the “plusoptiX S16” towards the patient until the camera image can be seen in high-definition on the screen and both pupils are encircled in green.

The image can be seen in high-definition on the screen, the bars are green and both pupils are encircled in green. As soon as both pupils are surrounded by a green circle, the line between the pupils turns green and another warble sound can be heard. The “plusoptiX S16” is now a metre away from the child and the measurement begins automatically. A “ping” sound signalises the end of the measurement.

The image is blurry and two red bars will be displayed next to the camera image. As the measuring distance is too small, the eyes can be seen on the screen. Move the “plusoptiX S16” away from the patient until the camera image can be seen in high-definition on the screen and both pupils are encircled in green.

Figure 11: Detecting the correct measuring distance

7.4 Checking and documenting the measurement results

As space on the screen is limited, the measurement results are spread across a total of three results pages. After the measurement, you will first see the “camera image” results page. By touching the appropriate symbol in the middle of the navigation bar, you can access each of the three results pages. More information about checking and documenting the measurement results can be found in short manual 3, 5 and 6 on our homepage (www.plusoptix.com), under support.

Figure 12: Overview of the results pages
8 Maintenance, calibration, service and guarantee

The “plusoptiX S16” is an opto-electronic measuring device. The mechanical structure and functional principle is comparable to a video camera. If you handle the “plusoptiX S16” as carefully as you handle your own video camera, your “plusoptiX S16” will provide you with many years of problem-free, good service.

Maintenance and calibration
The “plusoptiX S16” is maintenance-free and does not need calibrating. If it is not being used, store it in the box for safekeeping. Only use a slightly damp microfibre cloth to clean the device.

Service
If the “plusoptiX S16” is not working perfectly, please read chapter Fehler! Verweisquelle konnte nicht gefunden werden. “Fehler! Verweisquelle konnte nicht gefunden werden.” or short manual 9 on our homepage (www.plusoptix.com), under support. Only contact Plusoptix if this is subsequently necessary.

Garantie

Serial number of the “plusoptiX S16”
The type plate with serial number (S/N 1601S-xxx-xxxx xxxx) can be found on the bottom of the cradle. If you contact us regarding ongoing service or guarantee issues, please make sure you always have the serial number of your “plusoptiX S16”. The serial number helps us to answer your question quickly.

Posting the “plusoptiX S16”
If case of a guarantee claim or service, please send to “plusoptiX S16” to us in its box at your expense. We will then return it to you at our expense after we have repaired it. If patient data is stored on the device, it must be removed from the device for data protection reasons. For this purpose, a copy of the database can be exported before shipping, and imported again after the receipt of the repaired device. For more information, refer to short manual 7 on our homepage (www.plusoptix.com), under support.

Our address is:

In Europe:
Plusoptix GmbH
Neumeyerstrasse 46
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
9 Technical details about the “plusoptiX S16”

Measurement values

<table>
<thead>
<tr>
<th>Metered value</th>
<th>Measurement range and tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphere</td>
<td>-7 to +5 dpt in 0.25 dpt steps ± 0.25 dpt</td>
</tr>
<tr>
<td>Cylinder</td>
<td>-7 to +5 dpt in 0.25 dpt steps ± 0.25 dpt</td>
</tr>
<tr>
<td>Axis</td>
<td>1 to 180° in 1° steps ± 15°</td>
</tr>
<tr>
<td>Spherical equivalent</td>
<td>-7 to +5 dpt in 0.25 dpt increments ± 0.25 dpt</td>
</tr>
<tr>
<td>Pupil diameter</td>
<td>3 to 8 mm in 0.1 mm steps ± 5%</td>
</tr>
<tr>
<td>Gaze asymmetry</td>
<td>0 to 25° in 0.1° steps ± 5%</td>
</tr>
<tr>
<td>Interpupillary distance</td>
<td>25 to 85 mm in 0.1 mm steps ± 5%</td>
</tr>
</tbody>
</table>

Interfaces and standards

<table>
<thead>
<tr>
<th>Interfaces</th>
<th>USB, DVI, IR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>WLAN, LAN (RJ-45)</td>
</tr>
<tr>
<td>“plusoptiX S16” screen</td>
<td>Diagonal 4.3”, aspect ratio 5:3 (800 x 480 pixels)</td>
</tr>
<tr>
<td></td>
<td>Resistive contact sensor</td>
</tr>
<tr>
<td>Standards</td>
<td>IEC 60601-1</td>
</tr>
<tr>
<td>IR</td>
<td>Plusoptix devices use infrared light with a wavelength of 870nm and a maximum intensity of 135mW/sr.</td>
</tr>
</tbody>
</table>

WLAN interface standards:

<table>
<thead>
<tr>
<th>Physical layer</th>
<th>Supports 802.11 b and g standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Network architecture types</td>
<td>Communication with cabled networks via access points</td>
</tr>
<tr>
<td>Security</td>
<td>WPA and WPA2</td>
</tr>
<tr>
<td>Transmit power</td>
<td>802.11b/g: 50 mW (+17 dBm) typically</td>
</tr>
<tr>
<td>Frequency range</td>
<td>2,400 - 2,4897 GHz</td>
</tr>
<tr>
<td>Operating channels</td>
<td>1-11 for North America and other, 1-13 for Europe and other</td>
</tr>
<tr>
<td>Channels</td>
<td>Supports all channels of 802.11d-APs.</td>
</tr>
<tr>
<td>RX sensitivity</td>
<td>-86 dBm typically @ 11 Mbps, -82 dBm @ 6 Mbps, -69 dBm @ 54 Mbps</td>
</tr>
<tr>
<td>Data rates</td>
<td>802.11g: 6, 9, 12, 18, 24, 36, 48, 54 Mbps</td>
</tr>
<tr>
<td></td>
<td>802.11b: 1, 2, 5.5, 11 Mbps</td>
</tr>
</tbody>
</table>

Power supply

Only use the GSM36P12-P1J power supply provided.

<table>
<thead>
<tr>
<th>Medical power adapter</th>
<th>Input</th>
<th>100 - 240 VAC, 50/60 Hz, 0.9 - 0.45 A</th>
</tr>
</thead>
<tbody>
<tr>
<td>(GSM36P12-P1J power supply)</td>
<td>Output</td>
<td>12 VDC, 3A, 36 W max.</td>
</tr>
</tbody>
</table>
Environmental conditions for operation and storage

The plusoptiX 16 has been designed for the environment category “Environment in areas of domestic health care, except for vehicles and planes”. “plusoptiX 12” can be stored in its box. Do not put the box near heat sources (radiators, fan heaters, etc.). When you remove the “plusoptiX 12” from its box for use, do not place it in the sunlight.

<table>
<thead>
<tr>
<th>Storage</th>
<th>Temperature</th>
<th>0 to +50°C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Humidity</td>
<td>10 to 80% non-condensing</td>
</tr>
<tr>
<td>Operation</td>
<td>Temperature</td>
<td>+10 to +40°C</td>
</tr>
<tr>
<td></td>
<td>Humidity</td>
<td>20 to 80% non-condensing</td>
</tr>
<tr>
<td>Max. Height</td>
<td>Max. storage height</td>
<td>&lt;2000m (78,740’’)</td>
</tr>
<tr>
<td></td>
<td>Max. operational height</td>
<td>&lt;2000m (78,740’’)</td>
</tr>
</tbody>
</table>

Dimensions and weight with and without the box

<table>
<thead>
<tr>
<th>plusoptiX S16 without cradle</th>
<th>Dimensions (HBD)</th>
<th>165 x 140 x 248 mm (6½ x 5½ x 9¾ in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>without box</td>
<td>Weight</td>
<td>0.7 kg (24.7 oz)</td>
</tr>
<tr>
<td>plusoptiX S16 without box</td>
<td>Dimensions (HBD)</td>
<td>190 x 155 x 265 mm (7½ x 6¼ x 10¾ in)</td>
</tr>
<tr>
<td></td>
<td>Weight</td>
<td>1.8 kg (52.9 oz)</td>
</tr>
<tr>
<td>plusoptiX S16 in the box</td>
<td>Dimensions (HBD)</td>
<td>270 x 420 x 210 mm (10¾ x 16½ x 8¼ in)</td>
</tr>
<tr>
<td></td>
<td>Weight</td>
<td>2.7 kg (93.5 oz)</td>
</tr>
</tbody>
</table>

Manufacturer’s declaration about electromagnetic compatibility (EMC)

The “plusoptiX 16” is intended for use in the electromagnetic environments listed below. Owners and holders of the “plusoptiX 16” are responsible for guaranteeing this environment.

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

Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help
### Emissions Test

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Conformity</th>
<th>Electromagnetic environment - Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emission CISPR 11</td>
<td>Group 1</td>
<td>The radiation is low and causes no interferences with electronic devices found nearby.</td>
</tr>
<tr>
<td>RF Emission CISPR 11</td>
<td>Category B</td>
<td></td>
</tr>
<tr>
<td>Harmonic Emissions IEC 61000-3-2</td>
<td>Category A</td>
<td>The “plusoptiX S16” can be used in all areas which are connected to the public mains supply.</td>
</tr>
<tr>
<td>Voltage fluctuations / Flicker IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

### Immunity Test

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 test values</th>
<th>Conformity values</th>
<th>Electromagnetic environment - Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESD IEC 61000-4-2</td>
<td>± 8 kV contact ± 2, 4, 8, 15 kV air</td>
<td>± 8 kV contact ± 2, 4, 8, 15 kV air</td>
<td>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%.</td>
</tr>
<tr>
<td>Electrical fast transient / burst IEC 61000-4-4</td>
<td>± 2 kV</td>
<td>± 2 kV</td>
<td>Only plugs that are usually available in domestic or clinical areas should be used.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>± 0.5 kV ± 1 kV ± 2 kV</td>
<td>± 0.5 kV ± 1 kV ± 2 kV</td>
<td>Only plugs that are usually available in domestic or clinical areas should be used.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions on power supply input lines IEC 61000-4-11</td>
<td>0% 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% 1 cycle 70% 25 cycles 0% 250 cycles</td>
<td>0% 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% 1 cycle 70% 25 cycles 0% 250 cycles</td>
<td>Only plugs that are usually available in domestic or clinical areas should be used.</td>
</tr>
<tr>
<td>Power frequencies and magnetic fields IEC 61000-4-8</td>
<td>30 A/m, 50/60Hz</td>
<td>30 A/m, 50/60Hz</td>
<td>Magnetic fields should not exceed the usual areas.</td>
</tr>
<tr>
<td>Immunity test</td>
<td>Testing level acc. to IEC 60601</td>
<td>Conformity results</td>
<td>Electromagnetic environment – Instructions</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Conduction RF disturbances</td>
<td>IEC 61000-4-6</td>
<td>3 V 0.15 MHz – 80 MHz 6 V 0.15 MHz and 0 MHz 80 % AM at 1 kHz 3 V 0.15 MHz – 80 MHz 6 V</td>
<td>Portable and mobile radio equipment must not be operated in a distance to „plusoptiX 16” (including the electrical lines) less than the recommended safe distance calculated using the appropriate equation for the transmission frequency. Recommended safe distance: $d = (3.5/10) \times \sqrt{P}$ 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 symbol shown.</td>
</tr>
<tr>
<td>Radio-frequency electromagn. fields</td>
<td>IEC 61000-4-3</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

COMMENT 1 At 80 MHz and 800 MHz, the higher frequency range applies.
COMMENT 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
**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 "plusoptiX 16", including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. The "plusoptiX 16" is not compatible to HF SURGICAL EQUIPMENT.

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**Recommended safety distances between portable and mobile HF telecommunication devices and the "plusoptiX 16"**

The "plusoptiX S16" is intended for use in an electromagnetic environment with controlled HF disturbance variables. The customer or user of the "plusoptiX S16" can contribute to avoiding electromagnetic disturbances, by complying with the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the "plusoptiX S16" – depending on the output power of the communication device, as stated below.

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

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. The distribution of electromagnetic quantities is influenced by absorption and reflections from buildings, objects and people.