IMPLANTEST

Operating Instructions

Medizintechnik Gulden

Manufacturer of the Periotest

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Manufacturer of the Periotest

IMPLANTEST

An electrical measuring instrument for dentistry and dental implantology

Operating Instructions

Symbols used in these Operating Instructions as well as on the product and the package

VAC	(volts alternating current): Alternating current in volts.
VDC	(volts direct current): Direct current (DC) in volts.
f	Serial number of the unit
	Electrical protection class: II (double insulation, complies with the requirements of IEC 60601-1.
	Part applied to patient: Type B.
N	Date of manufacture (YYYY-MM)
M	Name and address of the manufacturer.
	Disposal: Please recycle.
h	Order number / item number

Storage and transport conditions

Temperature: The product must be stored and transported at temperatures ranging -4 °F and +122 °F.

Air pressure: Permissible atmospheric pressure is 500 to 1060 hPa.

Humidity: Permissible relative humidity is 20 to 90 %.

Observe information in accompanying documents.

Fragile; handle with care.

p

Protect from moisture.

CE 0366

This product bears the CE mark in accordance with the provisions of Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

Item number and Version of Operating Instructions

REF 8920165
Version 2015-06-24

Contents

1 Warning and safety information

1.1 General safety information

This device is subject to a notification of the risk of electrical shock, fire, or mechanical hazards, according to the IEC 60601-1.

Intended use

The Implantest is an electrical measuring instrument for dentistry and dental implantology. It may be used only by licensed dentists or those working under the direct guidance of a licensed dentist.

Modification of the device

Do not make modifications to this device. Attempts could result in injury and will void warranty.

Disclaimer

The manufacturer or distributor assumes no liability in cases involving:

- Work or repairs performed by any personnel not authorized by the manufacturer, importer or distributor
- Use other than intended use, as described in this manual
- The use of non-OEM components or any components not listed in the section entitled "Supplies" of this manual

Electromagnetic compatibility

To prevent potential risks from electromagnetic interference, no medical devices or other electronic devices may be operated in the immediate vicinity of the Implantest (see chapter 12 for recommended working clearances between Implantest and portable and mobile RF communication devices).

The device meets the current applicable guidelines for electromagnetic compatibility (IEC 60601-1-2). This unit does not cause any harmful interference. This device can receive interference from other devices, such as wireless transmitters, mobile communication devices, and other household appliances, including interference that may lead to undesired functions. Special EMC precautions are required for the installation and operation of the Implantest. These Operating Instructions contain the corresponding EMC information.

Operating environment	Never use this unit in the presence of flammable gasses.
Malfunction or damage	In case of malfunction or damage of the unit, stop using it immediately. Damaged instruments can cause injuries. Contact the distributor or the manufacturer.
Connected devices	The Implantest may be used only with the supplied probe. The use of non OEM-probes may lead to incorrect readings.
Sterilization	Maximum sterilization temperature for the probe is 273 °F.
Power supply	The Implantest is powered by a rechargeable battery. The supplied power supply unit and the charging unit are used only to charge the battery, not to operate the Implantest. Do not use any charging devices other than the supplied power supply unit and the supplied battery charger.
Battery	The Implantest is equipped with a built-in rechargeable battery. Do not try to open the Implantest casing and change the battery. The battery may be replaced only by an authorized dealer or the manufacturer.
Side effects	No known side effects.
Return for repair	Please disinfect or sterilize all parts being returned for repair or evaluation.
Disposal 	Any disposal of this product must comply with relevant national regulations; please observe the regulations applicable in your country. Your product is marked with the symbol on the left. Disposing of your product in the trash is not allowed.

2 Technical information

2.1 Technical description

The Implantest is an electrical measuring instrument for use in dental practices. It is designed for the following range of applications:
- Assessment of the osseointegration of dental implants
- Diagnosis and assessment of periodontal desease and tooth mobility.

The instrument‘s scale ranges from +0.1 to +10.0. The unit of measure is „Implantest values“ which correspond to the contact time of the probe with the measured object (tooth, implant). A short contact time corresponds to a high Implantest value; a long contact time corresponds to a low Implantest value.

Contraindications

The Implantest should not be applied in the following cases:
- All types of acute apical periodontitis
- Acute trauma such as dislocation, root fracture, and alveolar process fracture.

2.2 Service life of Implantest instruments

With proper use, the non-moving parts of the Implantest instrument have a typical service life of five years. The moving parts of the Implantest instrument have a typical service life of three years. However, this is not indicative of a warranty as wear may occur earlier or later than indicated above depending on use, frequency of sterilization and frequency of maintenance.

If your Implantest (the unit as a whole, or in parts) or the accessories shall not be used any more, do not dispose the product or the parts with household garbage. They can be posing a risk to the environment. Please return these parts to the manufacturer. Alternatively, there may be local recycling or collection points.

3 Supplies

- Implantest including probe REF 8917140
- Lithium-ion polymer battery (built-in) REF 8917025
- Switch mode power supply unit REF 8919610
- Battery charger REF 8916793
- Test sleeve REF 5950027
- Cleaning brush REF 5245758
- Operating Instructions REF 8920165

4 Setting up the Implantest

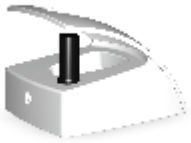
Remove the Implantest and its accessories from the box. Before installing, inspect everything for damage. Report any visible damage immediately. Check the contents of the box for all items as described in chapter 3 (“Supplies“).

CAUTION

- Do not install the Implantest near direct or indirect heat sources.

- Prior to initial use, all components of the Implantest must be disinfected (see chapter 9).

The charger should be placed on a sturdy, level surface. Ensure that the charger is in a secure position. Plug the supplied test sleeve into its holder on the rear side of the charger. Connect the charger with the power supply unit. Then plug the power supply unit into a mains socket. The LEDs on the charger and on the power supply unit will both light up green.



Place the Implantest into the charger to charge the battery. The green LED on the charger will begin to blink. Once the battery is fully charged, the LED will stop blinking and remain solid green

5 Controls and functional elements

1 - Power supply unit
2 - Battery charger
3 - Implantest hand unit
4 - Test sleeve
5 - Cleaning brush
6 - Tip of the probe
7 - Mounting ring
8 - Start button
9 - LCD

6 Operation

6.1 Operating the unit

Remove the Implantest from the charger. Press the start button to turn on the unit. All segments of the display will light up for approximately two seconds. A short sound confirms the device is ready for use and the display will show - - . -.

NOTE
The Implantest does not have a button to turn the power off. The device switches off automatically after approximately three minutes of being idle.
Once you have completed taking your measurements, put the Implantest back on the charger.

6.2 Functional test

Prior to each use of the Implantest confirm functionality. Visually inspect the device. If you observe damage, do not use the device. Contact your supplier or the manufacturer immediately.

The functional test is performed by measuring the supplied test sleeve. Remove the Implantest from the charger. Fit the test sleeve onto the tip of the probe. Press the start button to turn on the unit. After two seconds, a sound indicates the unit is ready to measure. Hold the Implantest horizontally and press the start button again. The measuring process will start.

A sound signifies the measuring cycle (approx. 3 seconds – 10 impulses) is finished, and the reading is indicated on the display. The reading should match the value indicated on the test sleeve. A deviation of +/- 1.0 Implantest values is acceptable. In case of a higher deviation, or no reading at all, the Implantest is not measuring properly. Please observe the instructions in section 9.1 (Care and cleaning). The probe must be clean and dry, which enables the tapping head to move easily. If cleaning the probe does not solve the problem, please contact your dealer.

Remove the test sleeve from the tip of the probe and plug it into the holder on the rear side of the charger.

7 Conducting Measurements with the Implantest

7.1 Positioning the patient

The preferable position of the patient is sitting upright. But it is also possible to conduct measurements on the patient in a lying or reclined position.

When taking a measurement, teeth of the maxilla and the mandible must not have contact with each other.

7.2 Point of application at the tooth / implant

The tapping head of the Implantest should hit the center of the vestibular (buccal / labial) surface of the tooth.

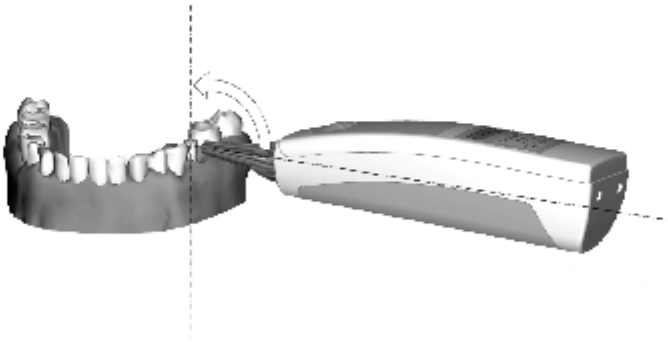
To measure dental implants, two measuring directions are relevant:

1. Accordingly to the measurement of natural teeth: Position of the Implantest from vestibularly in a lingual / palatial direction. Mainly the lingual wall is measured.

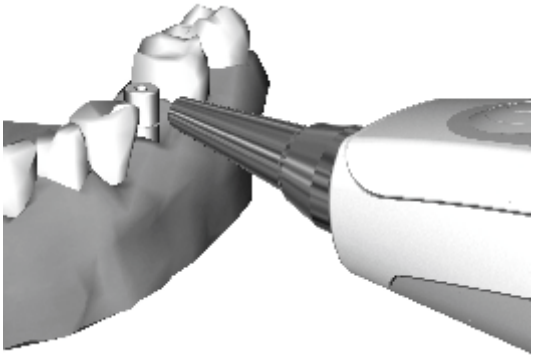
2. Alternatively, if anatomically possible and accessible: Position of the Implantest from a lingual / palatial direction, in direction of vestibularly. Mainly the vestibular wall is measured.The measuring point for implants is at the implant abutment, the gingiva former or the final crown.

7.3 Positioning the Implantest

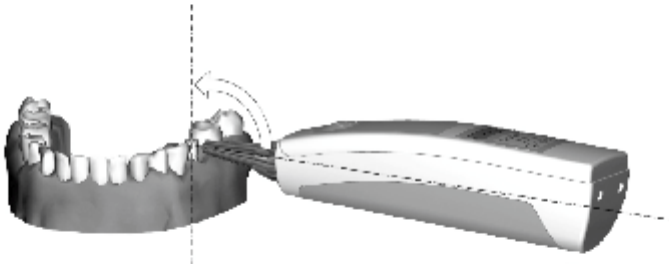
1. Horizontal positioning: Valid readings are only received if the Implantest is held horizontally (+/- 25°).

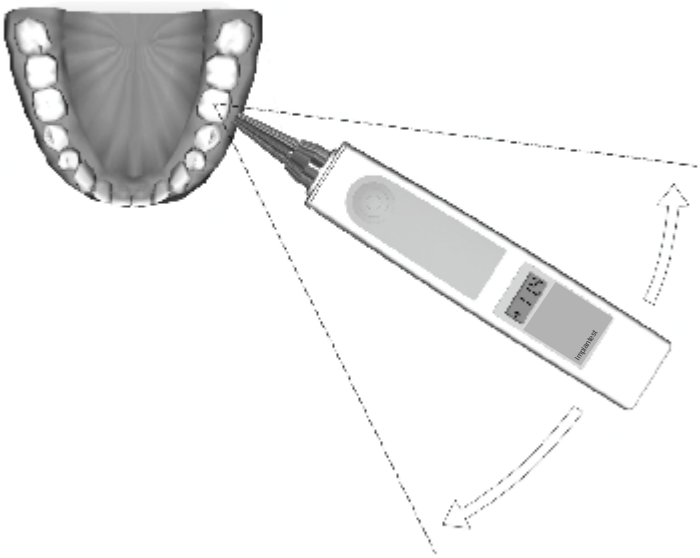


2. The tip of the device should be positioned at a distance of 0.6 and 2.5 millimeters from the measuring surface. If the device is held closer than 0.6 mm or further away than 2.5 mm, there will be no valid reading. In the beginning it requires a little practice to meet the correct distance. Practice test measurements are recommended before actual use on patients.



3. Right angle between the Implantest and the tooth / implant: In order to get readings with the highest accuracy, place the Implantest in a right angle (Implantest horizontally, tooth / implant axis vertically). In the molar area, this is not always possible. Deviations up to 45° are acceptable but can lead to slightly different readings (+/- 1.0 Implantest value).



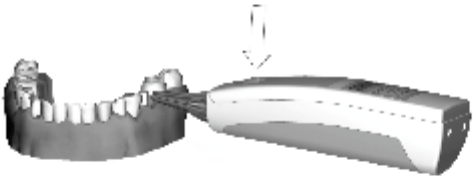


7.4 Measuring procedure

To turn the unit on press the start button. All segments on the display light up for approximately two seconds. Then a short melody plays, the display shows - - . - and the Implantest is ready to conduct measurements.

Press the start button again to start the measuring process. The measuring cycle consists of 10 impulses of the pressure sensitive measuring head against the measuring object (tooth, implant). For each valid impulse, a low tone will be emitted. Invalid impulses, for example due to a too high deviations from correct posturing of the Implantest, will be followed by a high tone. You can make corrections to the posture of the Implantest during the measuring process.

A short sound signifies the measuring cycle (approximately four seconds) is finished. At least 4 of 10 impulses must be accepted in order to get a valid reading. A valid reading is shown on the display. If less than 4 impulses were valid, no reading will be indicated on the display. The display will show - - . - .



To start a new measurement, press the start button again. The preceding reading will be erased.

When finished taking measurements, place the Implantest back into the charger. The Implantest does not have an off button. It turns off automatically after three minutes.

7.5 Measuring times for dental implants

You can take measurements in each stage of the implant treatment process. Typical points in time are

- Directly after implant insertion (measuring the primary stability)
- After the healing phase
- After the final crown is installed
- At follow-up appointments

7.6 Measuring the occlusal load

To measure occlusal load, the patient should press his teeth together as if swallowing. The measurement can be taken on the upper jaw with the teeth closed. To check occlusal adjustment, it is also possible to take measurements on the lower jaw.

8 Interpreting Implantest values

The Implantest scale ranges from +0.1 to +10.0. The higher the Implantest value, the higher the stability and damping degree of the tooth / implant.

ATTENTION

The device can generate in certain rare circumstances too low or too high readings and treatment decisions should not be based solely on Implantest values. The values in this section of the manual are for reference only and should be evaluated in correlation with other clinical observations.

Measurement of natural teeth

Clinical degree of tooth loosening	Implantest value range
0	**+5.0 to +10.0**
I	**+3.5 to +4.9**
II	**+1.7 to +3.4**
III	**+0.1 to +1.6**

Measurement of dental implants

There are a large number of implant systems available on the market and each one has unique mechanical properties. The Implantest can be used to measure stability of all implant systems, however the Implantest values can give only reference values. Interpretation of these values is dependent on the implant system, measured component (e.g. healing abutment or impression transfer etc.), distance from the alveolar crest and other variables. Comparison of multiple measurements over a period of time is more indicative than an absolute value of a one time measurements.

Implantest value range	Interpretation
+7.0 to +10.0	Good implant stability
+5.0 to +6.9	Clinical examination is required; loading of the implant is dependant on implant type and clinical situation
+4.9 or lower	Osseointegration is insufficient, the implant cannot be loaded

It is not uncommon to observe a temporary decrease in stability after two to three weeks following implantation. Persistent and significant lower Implantest values may suggest either a lack of integration of the implant, a screw loosening, an overloading of the implant, or an infection (e.g. peri-implantitis).

Correlation between Periotest values and Implantest values

Periotest value	Implantest value
-8	+10.0
-7	+9.7
-6	+9.4
-5	+9.1
-4	+8.8
-3	+8.5
-2	+8.2
-1	+7.9
0	+7.6
+1	+7.3
+2	+7.0
+3	+6.7
+4	+6.4
+5	+6.1
+6	+5.8
+7	+5.6
+8	+5.3
+9	+5.1
+10	+4.9
+11	+4.8
+12	+4.6
+13	+4.4
+14	+4.3
+15	+4.1
+16	+4.0
+17	+3.8
+18	+3.7
+19	+3.6
+20	+3.4
+21	+3.3
+22	+3.2
+23	+3.0
+24	+2.9
+25	+2.7

9 Care and cleaning

ATTENTION
Only the Implantest probe coming in contact with the patient can be sterilized. All other parts cannot be sterilized and should be disinfected with an appropriate germicidal agent. Do NOT put the entire unit in an autoclave.

9.1 Cleaning and disinfecting

Cleaning and disinfecting the surfaces

The Implantest must be disinfected or sterilized after every use.

Wipe off surfaces with surface disinfectants with validated germicidal properties. Disinfectants should comply with the requirements of the respective national regulatory body.

Disinfecting the measuring head

To disinfect the measuring head, unscrew the tip of the probe and wipe off the head with alcohol wipes. Do not use soaking wet wipes. It is very important to avoid any liquid penetrating the inner parts of the probe. If you use disinfection sprays, only spray from the side. Do not spray inside the probe (use a side angle as illustrated below). Never use oil or lubricants.

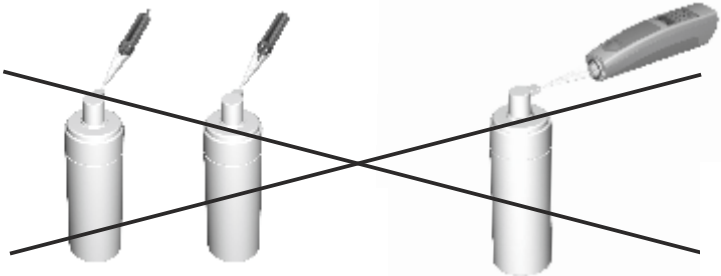
Cleaning the tip of the probe

The tip of the probe must always be clean inside. To clean it, unscrew the tip from the probe. Look inside. If you observe impurities, please use the supplied cleaning brush to remove it. After each use of the brush, it must be cleaned, too. Use disinfection foam or spray. The brush will wear out over time. After 10 applications, the brush should not be used any more. A new brush can be ordered, item number 5245758. If the impurities inside the tip of the probe are not too adhesive, you can use cotton buds instead of the brush.

ATTENTION

During cleaning do not allow liquids or oil to enter the inner parts of the probe. Do not spray liquids or oil into the probe. Such liquids can leave residues or cause internal corrosion interfering with the movement of the measuring head resulting in malfunction.

Also ensure that no cleaning agents penetrate the Implantest charger or the power supply unit.



9.2 Sterilization of the Implantest probe

The Implantest probe can be autoclaved at 273°F, 2.1 bar, 3 minutes holding time. The probe withstands a minimum of 250 sterilization cycles. You can sterilize the probe wrapped or unwrapped. After sterilization let the probe dry for one hour to ensure the probe is completely dry before use. Remaining humidity can cause malfunction.

Once the sterilization procedure is complete, the probe is inserted into the Implantest housing. Push the probe into the housing as far as it will go. Turn the probe until it slides a little bit more inside. Screw the mounting ring on. This is illustrated below:

Please screw and unscrew the mounting ring only by hand. Do not use tools.

10 Battery

10.1 Charging the battery

The Implantest is equipped with a lithium-ion polymer (li-ion) storage battery.

WARNINGS

- Only use the supplied battery charging equipment to charge the battery (battery charger REF 8916793 and switch mode power supply unit FRIWO FW7660M/12 REF 8919610). If you use a different charging equipment, the Implantest and its battery can be damaged.
- The Implantest battery is built-in and can be replaced only by the manufacturer or an authorized service partner. Do not attempt to open the Implantest casing and change the battery. There is a risk of injury.
- If, after fully charging the battery, it discharges quickly and LOBAT is shown on the display, or the unit turns off suddenly during a measuring process, the battery has reached its life cycle and needs to be replaced.
- If the Implantest has not been in use for a long period of time, it may not turn on and it may not be possible to charge the battery. In this case please send the Implantest to the manufacturer or your dental dealer for inspection, or for battery replacement.

When the display shows LOBAT the battery must be recharged. The battery does not have a "memory effect” therefore the frequency or length of time of charging is not important.

Insert the Implantest into the charger to charge its battery. The unit can be inserted into the charger, on or off. A flashing green LED indicates the unit is charging. A solid green LED indicates a fully charged battery. It takes approximately one hour to fully charge an empty battery. A fully charged battery can take approximately 100 measurements.

11 Maintenance

The Implantest is basically maintenance-free. There is no need for recalibration or readjustment. If errors occur during the functional test, a thorough cleaning of the device, namely the probe, might be necessary. Furthermore, the battery must be replaced, depending on the frequency of use, after two to six years.

12 Technical data

Manufacturer	Medizintechnik Gulden e.K.
Model	Implantest type 3218
Implantest hand unit data	
Dimensions	Approx. 180 x 31 x 40 mm
Material	
Housing (white parts)	ABS (Flammability HB)
Housing (blue parts)	TPE (Flammability HB)
Probe sleeve	Brass, nickel and chrome plated
Measuring head	Stainless steel X8CrNiS18-9
Weight incl. battery	Approx. 153 g
Noise level	< 65 dBA
Power supply	Battery driven device
Power consumption from battery charger during charging	max. 225 mA
Battery	
type	Lithium-ion polymer
Voltage nominal	7.4 VDC
Capacity typical	250 mAh
Protection against electrical shock	
Protection class	Internal power supply
Degree of protection against electrical shock	Applied part: type B 
Operating mode	Intermittent operation: ON 4 sec. / OFF until next measurement
Housing IP class	IP20

12 (continued): Technical data

Energy transfer from the measuring head to the measured object (tooth, implant)	Max. 0.00018 Joule
Weight of the tapping head	Approx. 9 g
Range of the Periotest value scale	+0.1 to +10.0
Unit of measure	Implantest values
Accuracy of measure	+/- 0.3 Implantest value
Display resolution	0.1 Implantest value

Operating conditions	Temperature: 59 to 86 °F Relative humidity: 20 to 90 % Air pressure: 700 to 1060 hPa
Transport and storage conditions	Temperature: -4 to 122 °F Relative humidity: 20 to 90 % Air pressure: 500 to 1100 hPa

Implantest battery charger data

Input voltage	12 VDC
Housing IP class	IP20
Protection class	II
Item number / order number	REF 8916793

Switch mode power supply unit data

Manufacturer	Friwo
Type	FW7660M/12
Input voltage	100 to 240 VAC
Mains frequency	50 to 60 Hz
Output voltage	12 VDC
Output current	800 mA
Housing IP class	IP40
Item number / order number	REF 8919610

13 Electromagnetic compatibility

13.1 Electromagnetic emission

The UNIT is intended for operation in the electromagnetic environment specified below. The customer or user of the UNIT should make sure that it is used in such an environment.

Emission measurement	Conformity	Electromagnetic environment guidelines
RF emissions according to **CISPR 11**	Group 1	The **UNIT** 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 according to **CISPR 11**	Class B	The **UNIT** is intended for use in all facilities, including residential areas and in any facilities connected directly to a public power supply providing electricity to buildings used for residential purposes.
Harmonics according to **IEC 61000-3-2**	not applicable Power output < 50 W	
Voltage fluctuations/Flicker according to **IEC 61000-3-3**	not applicable no significant flicker	

13.2 Working clearances

Recommended working clearances between portable and mobile HF communication devices and the UNIT

The UNIT is intended for operation in an electromagnetic environment where radiated HF interference is checked. The customer or the user of the UNIT can help prevent electromagnetic interference by duly observing the minimum distances between portable and/or mobile HF communication devices (transmitters) and the UNIT. These values may vary according to the output power of the relevant communication device as specified below.

Nominal transmitter output [W]	Working clearance according to transmission frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = [1, 2]\sqrt{P}$	$d = [1, 2]\sqrt{P}$	$d = [2, 3]\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance d in meters (m) can be determined using the equation in the corresponding column, where P is the maximum nominal output of the transmitter in watts (W) specified by the transmitter manufacturer.

Remark 1
The higher frequency range applies at 80 MHz and 800 MHz.

Remark 2
These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.

13.3 Interference immunity

The UNIT is intended for operation in the electromagnetic environment specified below. The customer or user of the UNIT should make sure that it is used in such an environment.

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidelines
Electrostatic discharge (ESD) according to IEC - 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors 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 according to **IEC 61000-4-4**	± 1 kV for input and output lines ± 2 kV for power cables	± 1 kV for input and output lines ± 2 kV for power cables	The quality of the line power supply should be that of a typical commercial or hospital environment.
Surge voltages according to **IEC 61000-4-5**	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the line power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and variations of the power supply according to **IEC 61000-4-11**	< 5 % U_T for ½ period (> 95 % dip of U_T) 40 % U_T for 5 periods (60 % dip of U_T) 70 % U_T for 25 periods (30 % dip of U_T) < 5 % U_T for 5 sec. (> 95 % dip of U_T)	< 5 % U_T for ½ period (> 95 % dip of U_T) 40 % U_T for 5 periods (60 % dip of U_T) 70 % U_T for 25 periods (30 % dip of U_T) < 5 % U_T for 5 sec. (> 95 % dip of U_T)	The quality of the line power supply should be that of a typical commercial or hospital environment. If the user of the **UNIT** requires it to continue functioning following interruptions of the power supply, it is recommended to have the **UNIT** powered by an uninterrupted power supply or a battery.
Magnetic field of power frequencies (50/60 Hz) according to **IEC 61000-4-8**	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Remarks: U_T is the AC supply voltage prior to application of the test level.			

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidelines
			Portable and mobile radio equipment must not be used within the recommended working clearance from the **UNIT** and its cables, which is calculated based on the equation suitable for the relevant transmission frequency. Recommended working clearance:
Conducted HF interference **IEC 61000-4-6**	$3V_{eff}$ 150 kHz to 80 MHz[1]	$3V_{eff}$	$d = [1, 2]\sqrt{P}$
Radiated HF interference **IEC 61000-4-3**	3V/m 80MHz to 800MHz[1] 3V/m 800MHz to 2.5GHz[1]	$3V_{eff}$ $3V_{eff}$	$d = [1, 2]\sqrt{P}$ at 80 MHz to 800 MHz $d = [2, 3]\sqrt{P}$ at 800 MHz to 2.5 GHz
			Where **P** is the nominal transmitter output in watts (W) specified by the transmitter manufacturer and **d** is the recommended working clearance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[2], should be less than the compliance level[3] in each frequency range. Interference is possible in the vicinity of equipment bearing the following graphic symbol.

1. The higher frequency range applies at 80 MHz and 800 MHz.

2. 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. An investigation of the location is recommended to determine the electromagnetic environment resulting from stationary HF transmitters. If the measured field strength in the location in which the UNIT is used exceeds the applicable RF compliance level above, the UNIT should be observed to verify normal operation. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the UNIT.

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

We reserve the right to make any alterations which may be required due to technical improvements.

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