Instructions for Use
Edition USA

CE
0297

OSSTELL isq
module

SI-SQ

Contents

Symbols in the Instructions for Use

WARNING!
(if persons could be injured)

ATTENTION!
(if property could be damaged)

General explanations,
without risk to persons or property

Sterilizable
up to the stated temperature

Thermo washer disinfectable

Call customer service

Symbols

on the Osstell ISQ module

Follow Instructions for Use

Date of manufacture

Do not dispose of with domestic waste

Type B applied part (not suitable for intracardiac application)

CE mark
with identification number
of the Notified Body

Data Matrix code
for product information
including UDI (Unique Device Identification)

Catalogue number

Serial number

DC – direct current

Symbols

on the packaging

CE mark
with identification number
of the Notified Body

This way up

Fragile, handle with care

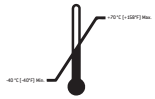
Keep dry

»Der Grüne Punkt« (The Green Dot)
trademark of Duales System
Deutschland GmbH

Trademark of RESY OfW GmbH
for identification of recyclable
transport and outer packaging
of paper and cardboard

Data Matrix code
for product information including UDI (Unique
Device Identification)

Data structure in accordance with
Health Industry Bar Code



Permitted temperature range

Humidity,
Limitation

Caution! According to Federal law restricts this device to sale by or on the order of a physician, dentist, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

1. Introduction

For your safety and the safety of your patients
These Instructions for Use explain how to use your product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team and, of course, the safety of your patients, are of paramount importance to us.

Observe the safety notes.

Intended use
Osstell ISQ is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region Osstell ISQ can add important information to the evaluation of implant stability and can be used as part of an overall treatment evaluation program. The final implant treatment decisions are the responsibility of the user.

Misuse may damage the Osstell ISQ module and hence cause risks and hazards for patients, users and third parties.

Qualifications of the user
We have based our development and design of the Osstell unit for Implantmed on the “physician” target group.

Introduction

CE 0297

Production according to EU Directive
The medical device complies with the regulations of Directive 93/42/EEC.

Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the Osstell ISQ module when compliance with the following instructions is ensured:

> The Osstell ISQ module must be used in accordance with these Instructions for Use.
> The Osstell ISQ module has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 35).
> Unauthorized opening of the equipment invalidates all claims under warranty and any other claims.

In addition to unauthorized assembly, installation, modification of or repairs to the Osstell ISQ module and measuring probe with cable, transmission instrument and non-compliance with our instructions, improper use will invalidate all claims made under warranty or otherwise.

Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

2. Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to particular precautions in regard to EMC and must be installed and put into operation in accordance with the EMC notes included.

W&H guarantees the compliance of the device with the EMC requirements only when used with original W&H accessories and spare parts. The use of accessories and spare parts not approved by W&H can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

HF communication equipment
Portable HF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the medical device. Otherwise, degradation of the performance of this medical device could result.

The medical device may be interfered by other equipment, even if these other devices comply with CISPR (International special committee on radio interference) emission requirements.

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

The medical device is not intended for use in the vicinity of HF surgical devices.

3. Scope of delivery

	Osstell ISQ module	30210000
07849900	TestPeg	x
07721800	Universal support	x
07460300	SmartPeg mount	x
07721100	Measuring probe with cable	x

> Before using the Osstell ISQ module for the first time, store it at room temperature for 24 hours.
> Check the Osstell ISQ module and the measuring probe with cable for damage and loose parts every time before use.
> Do not operate the Osstell ISQ module and the measuring probe with cable if it is damaged.
> Perform a test measurement with the TestPeg prior to every use.
> The responsibility for the use and timely shutdown of the system lies with the user.
> Ensure that it is possible to complete the operation safely should the units or instruments fail.

> The Osstell ISQ module is not approved for operation in potentially explosive atmospheres.

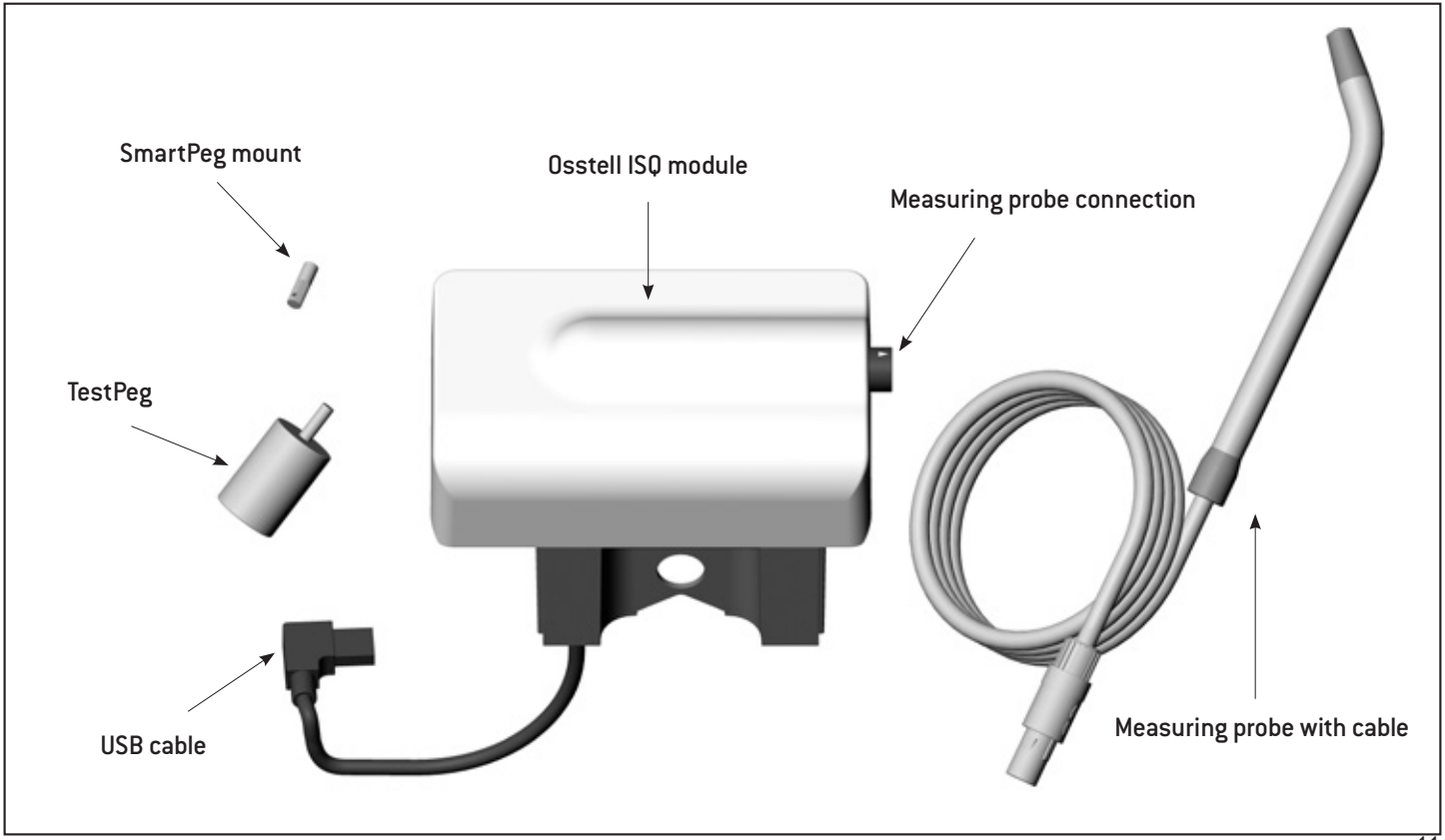
Do not twist or kink the cable! Do not coil it too tightly!

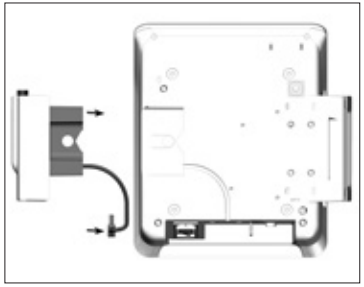
The Osstell ISQ module is classed as “conventional equipment” (closed equipment without protection against the ingress of water).

Hygiene and maintenance prior to initial use

> Clean and disinfect the Osstell ISQ module and the measuring probe with cable.
> Sterilize the measuring probe with cable.

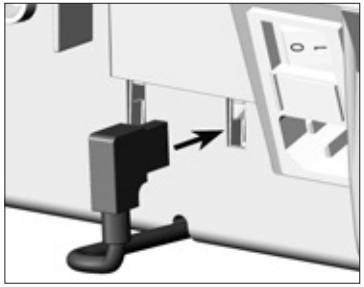
5. Description



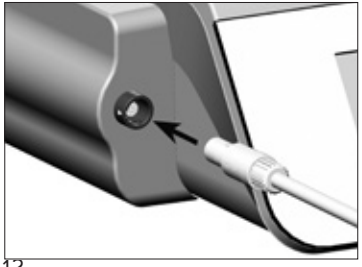


❶ Push in the Osstell ISQ module until it locks audibly.

Pay attention to the positioning of the USB cable!



❷ Connect USB.



❸ Connect measuring probe.

Pay attention to the positioning!

7. Operation

> The TestPeg is for testing only and for teaching in the function.
> You can purchase SmartPegs from smartpegs.wh.com or osstell.com.
> SmartPegs are for single use only.
> SmartPegs are available for a range of different implant systems and can be used in combination with all conventionally available implants.*
> Ensure that the sterile chain is not broken.
> Only use SmartPegs with intact packaging.

ISQ

❶ Select ISQ program.
The ISQ program always appears after the last program.

❷ Pull a thread through the SmartPeg mount.
Tie the thread to your wrist to prevent loss.

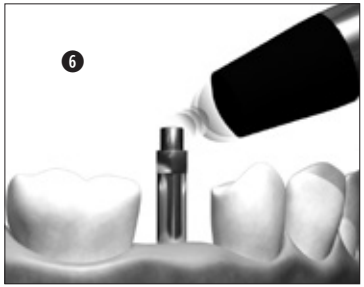
❸ Insert the SmartPeg into the SmartPeg mount.
The SmartPeg is magnetic and is held in place by SmartPeg mount. Check that it is retained secure hold.

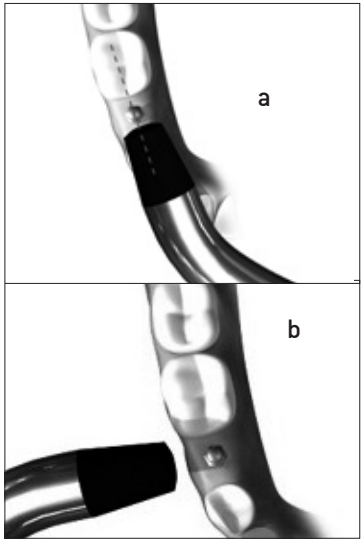
❹ Attach the SmartPeg to the implant or abutment by screwing the SmartPeg mount using finger force of approximately 4-6 Ncm.

Do not overtighten the SmartPeg or the SmartPeg thread may be damage

* For further information, please contact an authorized W&H service partner or visit osstell.com

Operation





❺ Press the foot control pedal once to start the measurement.

Press the foot control pedal again to stop the measurement early.

❻ Hold the measuring probe about 3 to 5 mm from the tip of the SmartPeg until the measured value is displayed.

Measure in both the mesiodistal direction (a) and the buccolingual direction (b).
Do not measure from above.
Repeat 5 and 6 to perform multiple measurements.

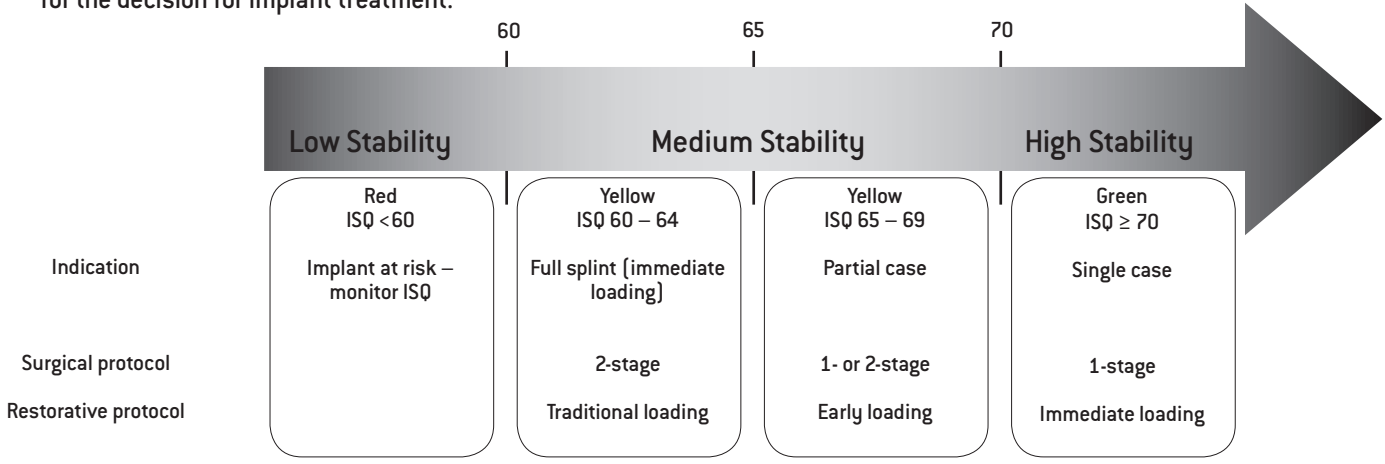
The measured value is underlined in colour and confirmed by a signal tone.

❼ Remove the SmartPeg with the SmartPeg mount.

Operation

Measurement result*

The measurement result can be used as part of a general assessment program. The user bears the ultimate responsibility for the decision for implant treatment.



This is a summary of scientific data and therefore does not represent an official recommendation.
To monitor osseointegration, measurements should be taken after implant insertion and before restoration of the implant.
Scientific studies can be found here www.osstell.com

ISQ value

The resonance frequency as a measure of implant stability is calculated from the oscillation frequency of the SmartPeg.
The results of this calculation are displayed as the ISQ value. The scale from the ISQ value ranges from 1 to 100.

* For further information, please contact an authorized W&H service partner or visit osstell.com

Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.

> Wear protective clothing, safety glasses, face mask and gloves.

> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.

Cleaning agents and disinfectants

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
> Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
> Use disinfectants which have been tested and found effective by the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichischen Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).

> The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.

The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

> Send worn or damaged medical devices and/or medical devices with material changes to an authorized W&H service partner.

Processing cycles

> We recommend a regular service for the measuring probe with cable after 250 processing cycles or one year.

> We recommend a regular service for the W&H universal support after 250 processing cycles.

Wipe the Osstell ISQ module, the measuring probe with cable and the universal support and the irrigant support with disinfectant.

Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfectant step after cleaning.

Measuring probe with cable / Universal support

Do not immerse the measuring probe with cable and the universal support in liquid disinfectant or in an ultrasonic bath.

Measuring probe with cable / Universal support

> Clean the measuring probe with cable and the universal support under running tap water (< 35°C / < 95°F).
> Rinse and brush off all internal and external surfaces.
> Remove liquid residues using compressed air.

Osstell ISQ module

> Do not immerse the Osstell ISQ module in water or clean under running water.

Measuring probe with cable / Universal support

> W&H recommends wipe-down disinfection.

Evidence of the basic suitability measuring probe with cable and the universal support for effective manual disinfection was provided by an independent test laboratory using the »mikrozid® AF wipes« disinfectant (Schülke & Mayr GmbH, Norderstedt).

Universal support

W&H recommends automated cleaning and disinfection using a washer-disinfector (WD).
Read the notes, follow the instructions and heed the warnings provided by the manufacturers of washer-disinfectors, cleaning agents and/or disinfectants.

Evidence of the universal support basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer-disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) according to ISO 15883.
> Cleaning at 55°C (131°F) – 5 minutes
> Disinfection at 93°C (200°F) – 5 minutes

Osstell ISQ module / Measuring probe with cable

The Osstell ISQ module and the measuring probe with cable are not approved for automated cleaning and disinfection.

Measuring probe with cable / Universal support

> Ensure that the measuring probe with cable and the universal support are completely dry internally and externally after cleaning and disinfection.

> Remove liquid residues using compressed air.

Inspection – Measuring probe with cable / Universal support

> Check the measuring probe with cable and the universal support after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess any measuring probe with cable and the universal support that are still soiled.
> Sterilize the measuring probe with cable and the universal support following cleaning and disinfection.

Measuring probe with cable / Universal support

Wrap the measuring probe with cable and the universal support in sterilization packages that meet the following requirements:

> The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization procedure.
> The sterilization package must be large enough for the sterilization goods.
> The loading sterilization package must not be under tension.

Measuring probe with cable / Universal support

W&H recommends sterilization according to EN 13060, EN 285.

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
> The program selected must be suitable for the measuring probe with cable and the universal support.

Recommended sterilization cycles

> Steam sterilization (type B, S)
> Sterilization time at 3 minutes at 134°C (273°F), 4 minutes at 132°C (270°F)
> Maximum sterilization temperature 135°C (275°F)

Evidence of the measuring probe with cable and the universal support basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)) and the Systec VE-150 steam sterilizer (Systec).

> »Dynamic-air-removal prevacuum cycle« (type B): temperature 134°C (273°F) – 3 minutes*
> temperature 132°C (270°F) – 4 minutes*
> »Steam-flush pressure-pulse cycle« (type S): temperature 134°C (273°F) – 3 minutes*

* EN 13060, EN 285, ISO 17665

Measuring probe with cable / Universal support

> Store sterile goods dust-free and dry.
> The shelf life of the sterile goods depends on the storage conditions and type of packaging.

9. Servicing

Regular checks
Regular periodic inspection of the function and safety of the medical device is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law.

The periodic inspection covers the complete medical device and must only be performed by an authorized service partner.

Servicing

Repairs and returns

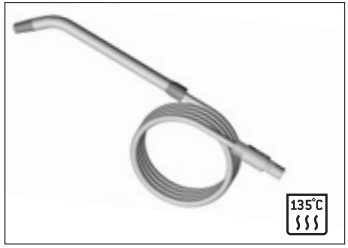
In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

> Ensure that the medical device has been completely processed before returning it.

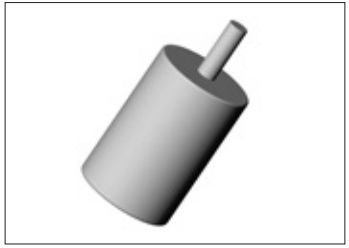
> Always return equipment in the original packaging!
> Do not coil the cable around the measuring probe and do not twist or kink the cable. (Risk of damage)

10. W&H accessories and spare parts

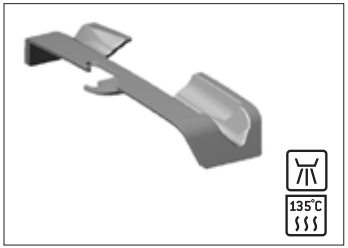
Use only original W&H accessories and spare parts or accessories approved by W&H.
Suppliers: W&H partners



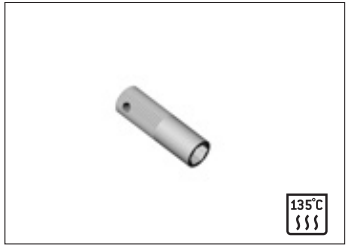
07721100
Measuring probe with cable*



07849900
TestPeg



07721800
Universal support



07460300
SmartPeg mount

* The measuring probe with cable from Osstell is compatible with the W&H Osstell ISQ module.

11. Technical data

Osstell ISQ module	**SI-SQ**
Voltage from Implantmed:	5.5 V
Dimensions in mm (height x width x depth):	79 x 138 x 88
Weight in kg:	0.210 kg
TestPeg measured value tolerance:	55 +/-5
SmartPeg measured value tolerance:	+/-1

Ambient conditions	
Temperature during storage and transport:	-40°C to +70°C (-40°F to +158°F)
Humidity for storage and transport:	8% to 80% (relative), non-condensing
Temperature in operation:	+10°C to +35°C (+50°F to +95°F)
Humidity in operation:	15% to 80% (relative), non-condensing

Technical data

Classification according to Paragraph 6 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1/ANSI/AAMI ES 60601-1

Class II medical electrical equipment

Type B applied part (not suitable for intracardiac application)

Pollution level:	2
Overvoltage category:	II
Altitude:	up to 3,000 m above sea level

12. Disposal

Ensure that the parts are not contaminated on disposal.

Follow your local and country-specific laws, directives, standards and guidelines for disposal.

> Waste electrical equipment
> Accessories and spare parts
> Packaging

Explanation of warranty terms

This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for Use have been followed.

As the manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty – accompanied by proof of purchase, must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

24 - month warranty

Authorized W&H service partners

Find your nearest authorized W&H service partner at http://wh.com
Simply go to the menu option »Service« for full details.

Or simply scan the QR code.

Manufacturer's declaration

Electromagnetic compatibility (EMC)
WARNING: The use of cables, power supplies, accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity. Only use original W&H accessories.

cables and accessories	length	reference
Osstell ISQ module SI-SQ	0.17 m	Manufacturer: W&H REF 30210xxx
Probe ISQ	1.3 m	Manufacturer: W&H REF 07721100

Operate the product in a place with a maximum distance to electrical and magnetic interfering transmitters. If operation of the product close to other devices or together in a stack is necessary, observe the correct function of the system.

Electromagnetic Immunity I (Table 2, IEC 60601-1-2:2007)
The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level (3rd Ed.)	IEC 60601-Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines 5kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines 100kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines Both repetition rates	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	0% U_T 0.5 cycle @ 0°,45°,90°,135°,180°,225°,270° & 315° 0% U_T 1 cycle and 70% U_T 25/30* cycles @ 0° 0% U_T 250/300* cycle	Complies to both editions requirements	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3A/m	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the mains (AC) voltage before apply test levels
* 25/30 (250/300) means cycles at 50/60Hz

Manufacturer's declaration

Electromagnetic Immunity II (Table 4, IEC 60601-1-2:2007)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level (3rd Ed.)	IEC 60601-Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
				Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} in ISM and amateur radio bands* between 0,15 MHz and 80 MHz	6 V_{rms}	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the re-commended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ª, should be less than the compliance level ᵇ in each frequency range Interference may occur in the vicinity of equipment marked with the symbol described lateral.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

* The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

ª Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.

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

Manufacturer's declaration

Immunity level of RF fields from wireless communication devices (Table 9, IEC 60601-1-2:2014)

Test frequency	Band[a]	Service[a]	Modulation[b]	Maximum power	Distance	IMMUNITY TEST LEVEL
(MHz)	(MHz)			(W)	(m)	(V/m)
385	380 –390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM[c] ± 5 kH deviation 1 kHz sine	2	0.3	28
710						
745	704 – 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
780						
810						
870	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
930						
1720						
1845	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240						
5500	5100 – 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the product may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended Separation Distances between portable and mobile HF- communications equipment and the product (Table 6, IEC 60601-1-2:2007)

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product – according on output power and frequency of the communications equipment – as recommended in the following table.

Rated maximum output power of transmitter in watts (W)	Separation distance according to the frequency of transmitter in meter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
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 rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

Electromagnetic Emission (Table 1, IEC 60601-1-2:2007)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF-emission CISPR 11	Group 1	The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF-emission CISPR 11	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2 (*)	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 (*)	complies	

(*) Remark: for devices with power consumption of 75 W to 1000 W only

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Form no. 50875 AAE
Rev. 004 / 11.12.2020
Subject to alterations