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

Type B applied part (not suitable for
intracardiac application)

Symbols

on the Osstell ISQ module

Follow Instructions for Use

Manufacture

Date of manufacture

Do not dispose of with domestic waste

CE marking
with identification number
of the Notified Body

Medical Device

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

Catalogue number

Serial number

DC – direct current

Symbols on the packaging

CE XXXX — CE marking with identification number of the Notified Body

Consult Instructions for Use

This way up

Fragile, handle with care

Keep dry

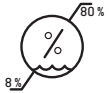
"Der Grüne Punkt" (The Green Dot) trademark of Duales System Deutschland GmbH

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

MD — Medical Device

HIBC — Data structure in accordance with Health Industry Bar Code

c UL us — UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements



Humidity limitation

℞ only — Caution! 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.

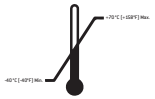
Trademark of RESY OfW GmbH for identification of recyclable transport and outer packaging of paper and cardboard

Manufacturer

Date of manufacture

REF — Catalogue number

SN — Serial number



Temperature limitation

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.

Indications for 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 medical device 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 medical device on the »physician« target group.

Introduction

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.
> Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 37).
> Unauthorized opening of the unit 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. 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 medical device for the first time, store it at room temperature for 24 hours
> Check the medical device for damage and loose parts every time before use.
> Do not operate the medical device 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.

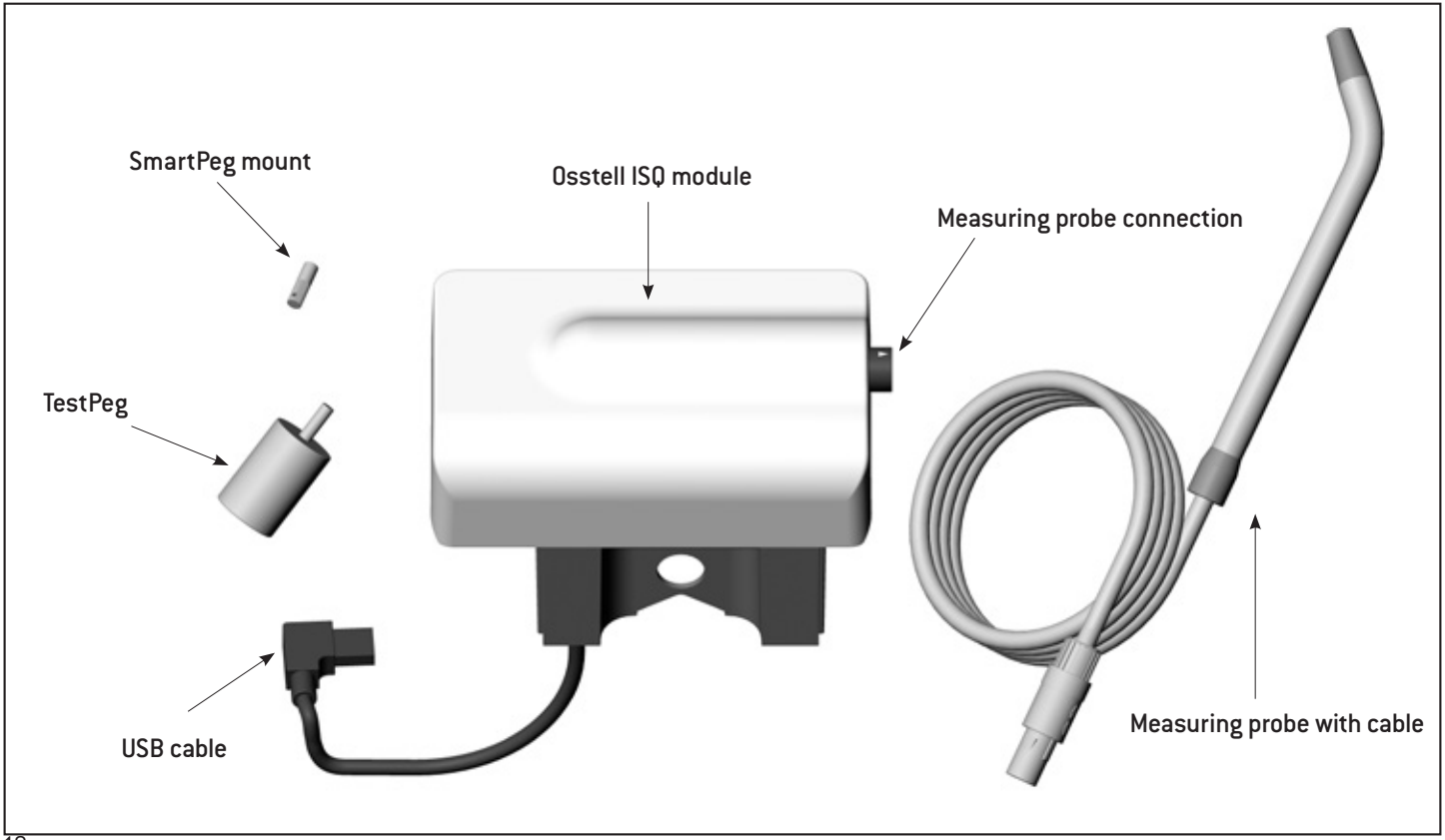
> The medical device is not approved for operation in potentially explosive atmospheres.

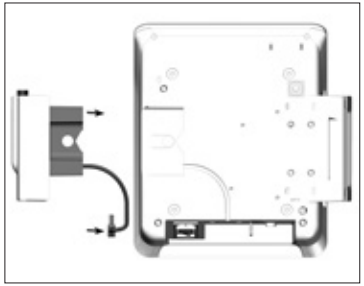
Do not twist or kink the cable! Do not coil it too tightly!

The medical device 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.

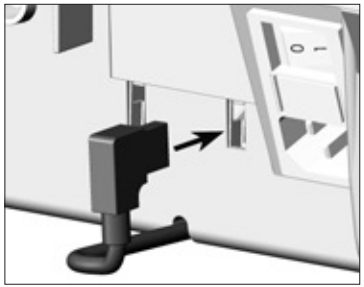
4. Description



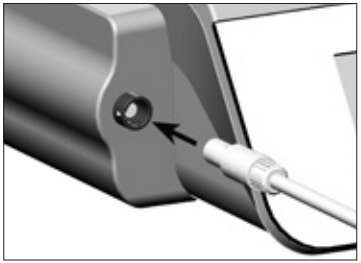


❶ Push in the Osstell ISQ module until it engages audibly.

Pay attention to the positioning of the USB cable!



❷ Connect USB.



❸ Connect measuring probe.

Pay attention to the positioning!

6. 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.

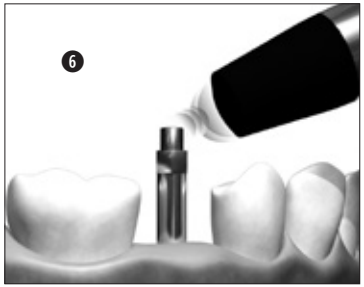
❸ Insert the SmartPeg into the SmartPeg mount.
The SmartPeg is magnetic and is held in place by SmartPeg mount. Check that it is retained secure hold.

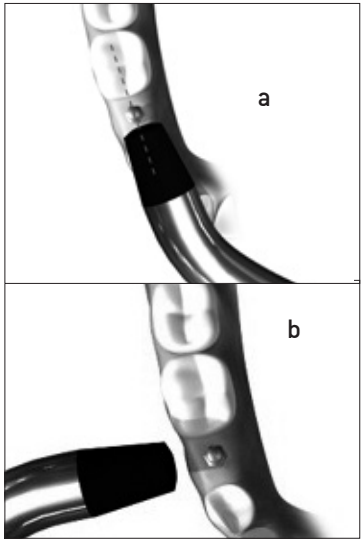
❹ Attach the SmartPeg to the implant or abutment by screwing the SmartPeg mount using finger force of approximately 4-6 Ncm.

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.

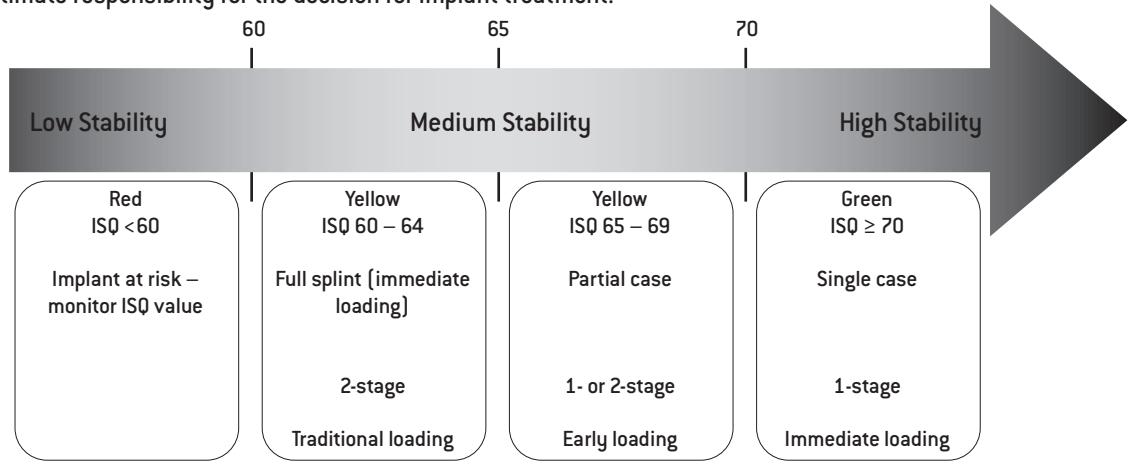
❼ Remove the SmartPeg with the SmartPeg mount.

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 response signal 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 them 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 / SmartPeg mount

Pack the medical device 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 / SmartPeg mount

W&H recommends sterilization according to EN 13060, EN 285 or ANSI/AAMI ST55

> 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 medical device.

Recommended sterilization procedures

> "Dynamic-air-removal prevacuum cycle" (type B) / "Steam-flush pressure-pulse cycle" (type S)*/**
134°C (273°F) for at least 3 minutes, 132°C (270°F) for at least 4 minutes

> Maximum sterilization temperature 135°C (275°F)

Evidence of the medical device's 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): 134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/**
"Steam-flush pressure-pulse cycle" (type S): 134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/**

Drying times:
"Dynamic-air-removal prevacuum cycle" (type B): 132°C (270°F) – 30 minutes**
"Steam-flush pressure-pulse cycle" (type S): 132°C (270°F) – 30 minutes**

* EN 13060, EN 285, ISO 17665
** ANSI/AAMI ST55 , ANSI/AAMI ST79

Measuring probe with cable / Universal support / SmartPeg mount

> Store sterile goods dust-free and dry.

> The shelf life of the sterile goods depends on the storage conditions and type of packaging.

8. Servicing

Periodic inspection

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

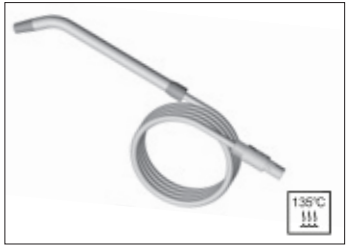
In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

> 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)

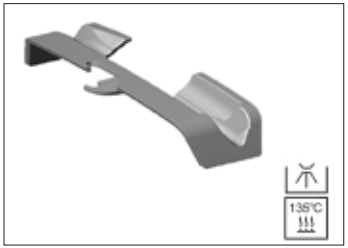
9. W&H accessories and spare parts

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

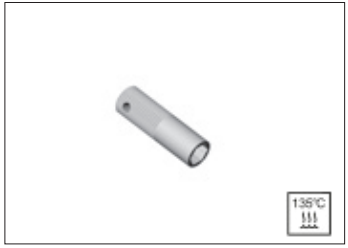


07721100
Measuring probe with cable*

07849900
TestPeg



07721800
Universal support



07460300
SmartPeg mount

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

10. 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)
Air Humidity for storage and transport:	8 % to 80 % (relative), non-condensing
Temperature in operation:	+10°C to +35°C (+50°F to +95°F)
Air 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 Device according to IEC 60601-1/ANSI/AAMI ES 60601-1

Class II medical electrical device (protective earth conductor used for functional earth connection only!)

Type B applied part (not suitable for intracardiac application)

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

11. Data on electromagnetic compatibility according to IEC/EN 60601-1-2

Operating environment and EMC warning notes
This medical device is neither life-sustaining nor coupled to the patient. It is suitable for operation both in domestic healthcare and in facilities used for medical purposes except rooms/areas, in which EMC interference of highintensity may occur. The customer and/or the user should assure that this medical device is set up and used in an environment of the specified type and/or in accordance with the specifications of the manufacturer.
This medical device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.

No special precautions are necessary to maintain the basic safety and essential performance of this medical device.

Essential performance
This medical device has no critical functions and therefore does not have any essential performance features.

Data on electromagnetic compatibility according to IEC/EN 60601-1-2

Portable RF communication devices
Portable RF 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.

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.

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.

Results of the electromagnetic tests

Requirement	Class / Test Level*	
Electromagnetic emissions		
Electromagnetic radiation disturbance (Radiated Emissions) CISPR 11/EN 55011 [30 MHz – 1000 MHz]	Group 1 Class B	
Immunity to electromagnetic interference		
Electrostatic discharge (ESD) IEC/EN 61000-4-2	Contact discharge: ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV Air discharge: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	
Radiated RF electromagnetic field IEC/EN 61000-4-3 [80 MHz - 2,7 GHz]	10 V/m	
Proximity fields from RF wireless communications equipment IEC/EN 61000-4-3	385 MHz	27 V/m
	450 MHz	28 V/m
	710 / 745 / 780 MHz	9 V/m
	810 / 870 / 930 MHz	28 V/m
	1720 / 1845 / 1970 MHz	28 V/m
	2450 MHz	28 V/m
	5240 / 5500 / 5785 MHz	9 V/m

Results of the electromagnetic tests

Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV
Conducted disturbances induced by RF fields IEC/EN 61000-4-6	3 V 6 V in ISM bands 6 V in amateur radio bands
Power frequency magnetic field IEC/EN 61000-4-8	30 A/m
Surges IEC/EN 61000-4-5	–
Voltage dips, voltage interruptions IEC/EN 61000-4-11	–

* There are no deviations or simplifications to IEC 60601-1-2.

12. Disposal

Ensure that the parts are not contaminated on disposal.

Follow your local and national laws, directives, standards and guidelines for disposal.

> Medical device
> Waste electrical equipment
> Packaging

Explanation of warranty terms

This W&H medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee 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 manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 12/24 months from the date of purchase.

12 months: Measuring probe with cable
24 months: Osstell ISQ module

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.

12/24 months 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

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