

Manufacturer's declaration
for W&H Osstell Classic ISQ measurement device

Electromagnetic compatibility (EMC)

- **WARNING:** The use of cables, accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity.

Cable / Accessories	Length	Reference
Charging cable –USB cable type C	1.0 m	Osstell USB Type A to C charging cable Ref. 100709

Electromagnetic compliance testing	
Standards	Titles
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

Manufacturer's declaration – Electromagnetic Emission

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 emissions 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. 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.
RF emissions CISPR 16-2-1:2014, Ed.3.0 CISPR 16-2-3:2014, Ed.3.2	Class B	
Harmonics EN 60601-1-2:2015	Class A ^(*) ^(**)	
Flicker EN 60601-1-2:2015	Complies ^(*) ^(**)	


^(*) Device is handheld and charged from a SELV via supplied USB cable. SELV charging adapter is not supplied, device intended to be charged from a computer or general USB charger. Device is tested with representable power adapters. (MEAN WELL GSM12E05

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

Manufacturer's declaration – Electromagnetic Immunity

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	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) EN 61000-4-2:2009, Ed.2.0	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	There are no specific limitations on floor materials or humidity in the environment in which the device is used.
Radiated RF Immunity EN 61000-4-3:2006+A1+A2, Ed.3.2	10 V/m, 80-2700 MHz 80% AM 1 kHz	10 V/m	<p>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.</p> <p>Typically, do not use wireless transmitters within the patient area, i.e. not closer than 1.5 m from the patient when the device is used to measure implant stability. Recommended minimum separation distance:</p> $d = 0.6\sqrt{P}$ <p>where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the absolute minimum recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p> 
Wireless Proximity Test EN 61000-4-3:2006+A1+A2, Ed.3.2	According to Table 9 in EN 60601-1-2:2015, 9 - 28 V/m	10 V/m	
Electric Fast Transients Immunity EN 61000-4-4:2012, Ed.3.0	+/- 2 kV, 100 kHz repetition rate	+/- 2 kV, 100 kHz repetition rate	Mains power quality should be that of a typical commercial and/or hospital environment. See (c) on previous page.
Surge Immunity EN 61000-4-5:2014, Ed.3.0	+/- 1 kV	+/- 1 kV	Mains power quality should be that of a typical commercial and/or hospital environment. See (c) on previous page.
Magnetic Fields Immunity EN 61000-4-8:2010, Ed.2.0	30 A/m	30 A/m 50Hz o 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity to Magnetic Fields immunity IEC 61000-4-39:2017	30 kHz 8A/m 134.2 kHz 65A/m 13.56 Mhz 7.5 A/m	30 kHz 8A/m 134.2 kHz 65A/m 13.56 Mhz 7.5 A/m	The product gives a warning when electromagnetic interference that may influence the measurement performance is encountered.


 Toyah Ohlson
 Director Supply Chain and Operations
 Osstell AB