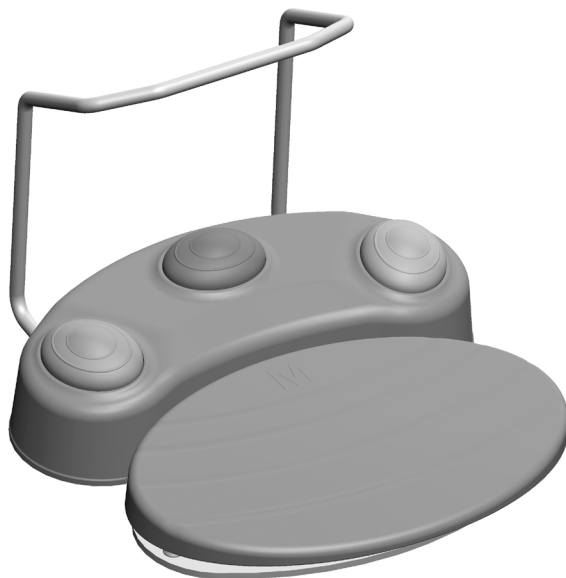


Instructions for Use



CE
0297

Foot control

**S-NW, S-N2, S-N1
S-NW3, S-N3**

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Symbols



WARNING!
(if persons could be injured)



CE marking with identification
number of the Notified Body



Consult Instructions for Use



ATTENTION!
(if property could be damaged)



Manufacturer



Do not dispose of with
domestic waste



General explanations, without
risk to persons or property



Date of manufacture



DataMatrix code for product
information including UDI
(Unique Device Identification)



Foot control



Catalogue number



Category AP equipment



Medical Device



Serial number



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

Symbols

	Non-ionizing electromagnetic radiation		Humidity limitation		Temperature limitation
	Battery compartment closed		“Der Grüne Punkt” (The Green Dot) trademark of Duales System Deutschland GmbH		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.
	Battery compartment open		Data structure in accordance with Health Industry Bar Code		
	This way up		Keep dry		
	Fragile, handle with care		Trademark of RESY OfW GmbH for identification of recyclable transport and outer packaging of paper and cardboard		RCM – Australian / New Zealand

Symbols

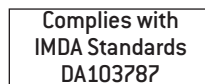
S-NW:



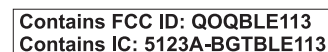
NCC – Taiwan



ANATEL – Brazil



IMDA – Singapur**



FCC / IC – USA / Canada*

**Symbol only in IFU

S-NW3:



FCC / IC – USA / Canada*

* This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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.

1. Introduction

For your safety and the safety of your patients

These Instructions for use explain how to use your medical device. 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

Foot control for operation of medical electrical equipment.



Misuse may damage the foot control 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 foot control for the physician, dental hygienists, dental employees (prophylaxis) and dental assistants target group.

Introduction

Hereby, W&H declares that the medical product is in compliance with Directive 2014/53/EU (RED).
The full text of the EU declaration of conformity is available at the following internet address <https://wh.com>

Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the foot control when it is used in compliance with the following directions:

- > The foot control must be used in accordance with these Instructions for Use and with the Instructions for Use of the drive unit.
- > The foot control 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 32).
- > Unauthorized opening of the foot control invalidates all claims under warranty and any other claims.

The respective foot control may only be used with the control unit listed in the scope of delivery.

Improper use, unauthorized assembly, modification or repair to the medical device, non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.



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

Foot control	Incl. dongle	Compatible with control unit*
S-NW3, REF 30495000	REF 08165950	SI-1010/SI-1015/SI-1023, M-UK1010/ M-UK1015/M-UK1023, SA-430 M/SA-435 M
S-NW3, REF 30495001		SI-2101/SI-2102
S-N3, REF 30497000		SI-2100
S-NW, REF 30264000	REF 07759700	SI-1010/SI-1015/SI-1023, M-UK1010/ M-UK1015/M-UK1023, SA-430 M/SA-435 M
S-NW, REF 30264003	REF 07759700	Built-In Solution (to be agreed with the system assembler)
S-NW, REF 30264001	REF 07795800	SA-320, SA-310, SI-915/SI-923 (REF 16929000/16929001)
S-N2, REF 30285000		SI-1010/SI-1015/SI-1023, SI-915/SI-923 (REF 30286xxx, 30287xxx) M-UK1010/M-UK1015/M-UK1023, SA-430 M/SA-435 M
S-N2, REF 30285002		Built-In Solution (to be agreed with the system assembler)
S-N1, REF 05046200		SI-915/SI-923 (REF 009001xx)
S-N1, REF 06202400		SA-310 SI-915/SI-923 (REF 16929000/16929001)
S-N1, REF 07004400		SA-320
S-N1, REF 06382200		PA-123, PA-115
Locator, REF 04653500		For all listed foot controls
Wireless foot control		
3 disposable batteries AA / Mignon / LR6 / 1.5V		

* Not included in the scope of delivery

3. Safety notes

General



- > Before using the foot control for the first time, store it at room temperature for 24 hours.
- > Check the foot control for damage and loose parts each time before using.
- > Do not operate the foot control if it is damaged.
- > Replace the foot control as soon as the resistance is noticeably reduced.
- > Never touch the patient and the electrical contacts on the medical device simultaneously.
- > The ESD spring contact on the bottom of the foot control must be in contact with the ground during operation.



ESD is the abbreviation for “electrostatic discharge”.



The foot control is approved for use in explosive areas (AP).

The foot control is approved for operation in oxygen rich environment.



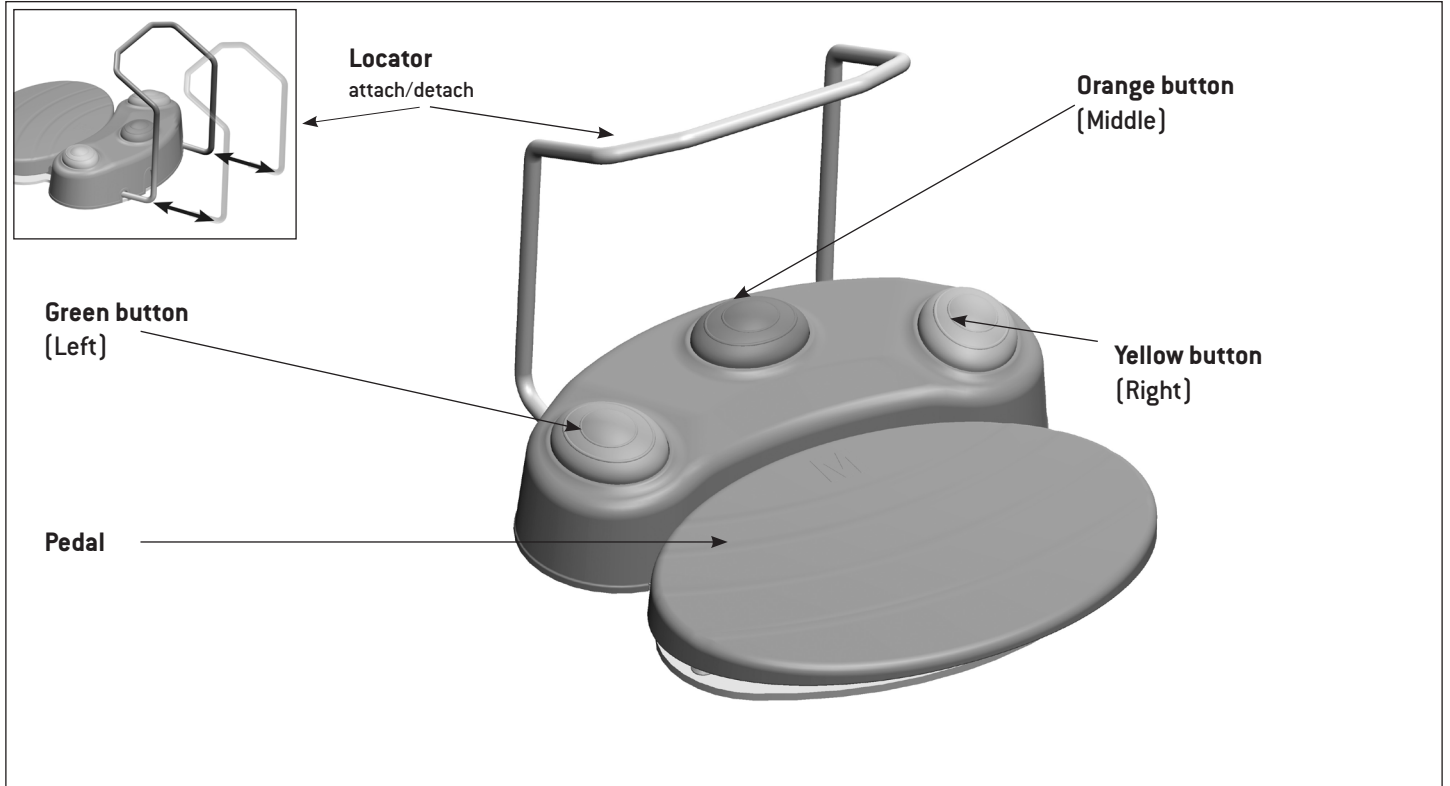
Risks due to electromagnetic fields

The functionality of active implantable medical devices (AIMD) (e.g. cardiac pacemaker, ICD) can be affected by electric, magnetic and electromagnetic fields.

Find out if the patient has active implantable medical devices (AIMD) before using the medical device and inform about the risks.

-  S-NW: Keep the orange/middle button pressed and switch between the control units/applications.
-  **Disposable batteries**
- > Replace the disposable batteries at the first prompt (battery icon on display or LED on dongle).
 - > Replace batteries outside explosive atmospheres only.
 - > Pay attention to the battery icon on the display before and after each treatment.
-  Dispose faulty or flat batteries immediately and correctly via recycling systems. Do not dispose batteries in domestic waste.
-  > Use only high-quality disposable alkaline AA / Mignon / LR6 / 1.5 V batteries. Risk of explosion if the wrong type of battery is used.
- > Do not mix new, old or different types of disposable batteries.
 - > Do not use rechargeable batteries.
 - > When inserting disposable batteries make sure that they are correctly oriented.
 - > Check the O-ring of the battery cover for damage. Replace a faulty or leaking O-ring immediately.
 - > Always keep spare batteries on hand.
-  Disposable batteries may cause damage due to leakage or corrosion.
- > Remove the disposable batteries if you are not going to use the foot control for a longer period.
 - > See the safety notes of the battery manufacturer.

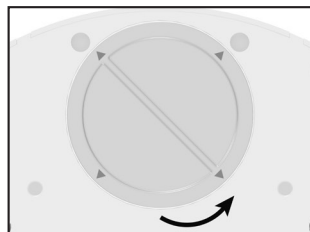
4. Product description



5. Wireless foot control

Inserting and replacing batteries

Open battery compartment

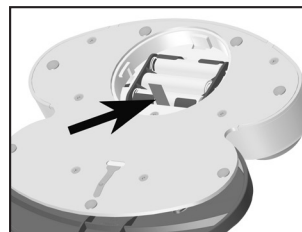


- ❶ Open the battery compartment.



Note the symbols!

Remove batteries



- ❷ Pull the red thread to remove the batteries.

Insert batteries



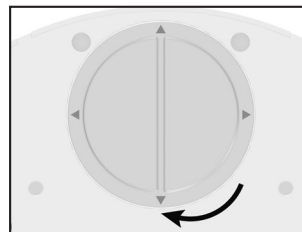
Reposition the red thread before inserting batteries.

- ❸ Insert the batteries.

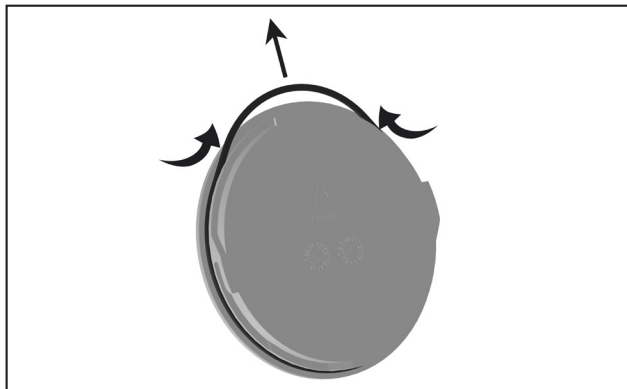


Pay attention to the positioning!

Lock battery compartment



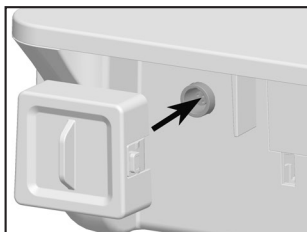
- ❹ Lock the battery compartment.



Do not use sharp tools!

- 1 Firmly squeeze the O-ring between your thumb and index finger so that it forms a loop.
- 2 Pull off the O-ring.
- 3 Push the new O-ring on in its place.

Connecting CAN dongle

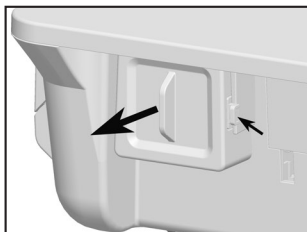


❶ Plug in the CAN dongle.



Pay attention to the positioning!

Removing CAN dongle



❷ Press the side lock and remove the CAN dongle.

CAN dongle activated



Icon visible on display

- > CAN dongle inserted
- > Control unit switched on
- > Foot control actuated

Connection



- > The wireless foot control and the CAN dongle are paired by default.
- > If the connection is inactive, you can activate pairing on the control unit (see Instructions for Use control unit/system assembler) and follow the directions.
- > Press and hold the green/left and orange/middle buttons simultaneously on the wireless foot control for at least 3 seconds.

Delete connection

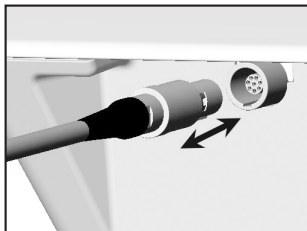
Press and hold all three buttons simultaneously on the foot control S-NW for at least three seconds.

Switching between multiple control units

Press the orange/middle button for 3 seconds.

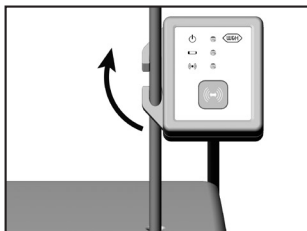
Change application

Press the orange/middle button for 3 seconds until an acoustic signal sounds.



 Pay attention to the positioning!

- 1 Plug in the SPI dongle or disconnect the SPI dongle from the control unit.



- 2 Attach the SPI dongle to the irrigant support or remove the SPI dongle from the irrigant support.

Green – SPI dongle activated

LED on if the SPI dongle is connected and the control unit is switched on.

Orange – battery

LED flashes if the batteries on the foot control need to be replaced.

Blue – Connection



The foot control S-NW and the SPI dongle are paired in default status.

Active connection: LED indicator flashes

Inactive connection:

- ❶ Press and hold the button on the SPI dongle for 4 seconds.
- ❷ LED indicator flashes. SPI dongle is in connection mode for 30 seconds.
- ❸ Press and hold the green and orange buttons simultaneously on the S-NW foot control.
- ❹ LED flashes three times when pairing is successful.

Delete connection

Press and hold the green, orange and yellow buttons simultaneously on the foot control S-NW for at least three seconds.

Switching between multiple control units

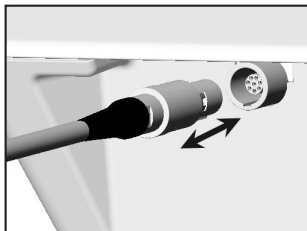
Press the orange/middle button for 3 seconds.

- > Check the plug-in connection of the dongle.
- > Remove metallic objects between foot control, control unit and dongle.
- > Change the position of the foot control.
- > Eliminate any sources of interference (e.g. brush motors, mobile telephones, radios, WLAN, ...).
- > Disconnect the existing connection and reconnect.
- > Remove and replace the batteries.

If the connection problem cannot be remedied using the steps described above, the unit will need to be inspected by an authorized W&H service partner.

6. Wired foot control

Connecting / disconnecting



 Pay attention to the positioning!

- ❶ Plug in the wired foot control or disconnect the foot control from the control unit.



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



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



- > The foot control is sealed and may be wiped clean.
- > The foot control is not approved for automated cleaning and disinfection.



The ESD spring contact on the bottom of the foot control must be cleaned regularly.



Do not immerse the medical device in water or clean it under running water.



Evidence of the medical device's basic suitability for effective manual cleaning was provided by an independent test laboratory using tap water < 35°C and towels/cloth »WIPEX® WET DESI premium« (NORDVLIES GmbH, Bargteheide).



W&H recommends wipe-down disinfection.



Evidence of the medical device's basic suitability for effective manual disinfection was provided by an independent test laboratory using the disinfectants "mikrozid® AF wipes" (Schülke & Mayr GmbH, Norderstedt) and "CaviWipes™" (Metrex).

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.

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.

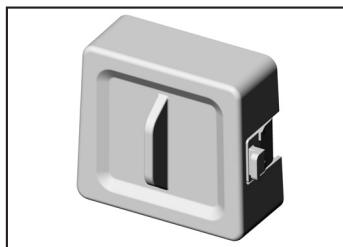


- > Always return equipment in the original packaging
- > Wireless foot control: Remove the batteries.

9. Accessories, consumables, spare parts and other recommended medical devices by W&H

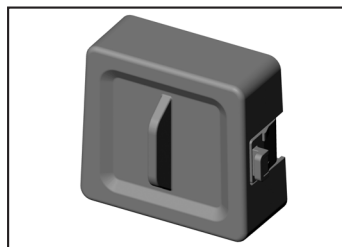


Use only original W&H accessories and spare parts or accessories approved by W&H.
Suppliers: W&H partners [Link: <https://www.wh.com>]



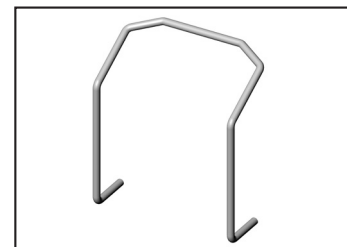
07759700*

Dongle S-NW CAN-Bus



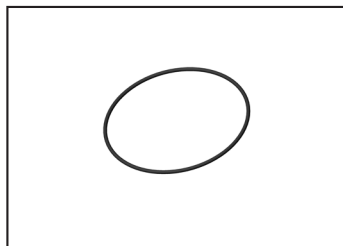
08165950*

Dongle S-NW3 CAN-Bus



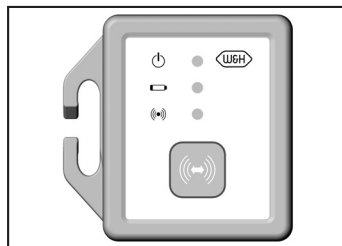
04653500

Locator for foot control



07823400

O-ring



07795800*

SPI dongle

Scan the QR code to find accessories, consumables and spare parts for this medical device.



* An overview of which dongle is compatible with which foot control can be found in the chapter 'Scope of delivery'.

10. Technical data

Foot control	S-N1 / S-N2	S-N3	S-NW / S-NW3
Power supply:	–	–	3 disposable batteries Typ AA / Mignon / LR6 / 1.5 V
Dimensions in mm (height x width x depth):	156 x 207 x 206	154 x 202 x 210	154 x 202 x 210
Weight in kg:	1.3	1.3	1.2

Frequency band:	2.4 GHz ISM band (2.402 – 2.480 GHz)
Transmitting power:	S-NW: Class 3:1 mW (0 dBm) S-NW3: Class 2:2.5 mW (+4 dBm)
Modulation:	GFSK
Channels:	40 channels with 2 MHz spacing

Ambient conditions

Temperature during storage and transport:	-40 °C to +70 °C (-40°F to +158°F)
Humidity during storage and transport:	8 % to 80 % (relative), non-condensing
Temperature during operation (S-N1, S-N2, S-NW, Dongle S-NW CAN-Bus):	+10 °C to +40 °C (+50°F to +104°F)
Temperature during operation (S-N3, S-NW3, Dongle S-NW3 CAN-Bus):	+10 °C to +30 °C (+50°F to +86°F)
Humidity during 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

 Foot controls are waterproof according to IPX8, 1 m depth of immersion, 1 hour (water-tight in accordance with IEC 60529)

Pollution level:	2
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 high-intensity 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



RF communication equipment

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.



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

Results of the electromagnetic tests

Requirement	Class / Test Level*		
Electromagnetic emissions			
Mains terminal disturbance voltage [Conducted Emissions] CISPR 11/EN 55011 [150 kHz – 30 MHz]	Group 1 Class B		
Electromagnetic radiation disturbance [Radiated Emissions] CISPR 11/EN 55011 [30 MHz – 1000 MHz]	Group 1 Class B		
Harmonic distortion IEC/EN 61000-3-2	Class A		
Voltage fluctuations and flicker IEC/EN 61000-3-3	–		
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 fields 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	710 / 745 / 780 / 5240 / 5500 / 5785 MHz		9 V/m
	385 MHz		27 V/m
	450 / 810 / 870 / 930 / 1720 / 1845 / 1970 / 2450 MHz		28 V/m
Electrical fast transients / bursts IEC/EN 61000-4-4	Mains supply: ±2 kV Input and output ports: ±1 kV		
Surges IEC/EN 61000-4-5	±1 kV L – N	±2 kV L – PE	±2 kV N – PE
Conducted disturbances induced by RF fields IEC/EN 61000-4-6	3 V 6 V in ISM bands and in amateur radio bands		
Power frequency magnetic fields IEC/EN 61000-4-8	30 A/m		
Voltage dips, short interruptions and voltage variations IEC/EN 61000-4-11	0% for 0.5 cycle at 45° steps from 0°-315° 0% for 1 cycle 70% for 25/30 cycles 0% for 250/300 cycles		
Proximity magnetic fields IEC/EN 61000-4-39	30 kHz		8 A/m
	134.2 kHz		65 A/m
	13.56 MHz		7.5 A/m

* There are no deviations or simplifications to IEC/EN 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 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 twenty-four months from the date of purchase. Accessories and consumables are not covered by the warranty.

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 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.





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Software version: 01.XXX
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