

Instructions for Use



CE
0297

**Foot control
variable**

S-NW, S-N2, S-N1

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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

Symbols on the foot control S-NW



CE mark
with identification number
of the Notified Body



Non-ionizing electromagnetic
radiation



Article number



Do not dispose of with
domestic waste



Battery compartment closed



Serial number



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



Battery compartment open



Date of manufacture



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



Regulatory Compliance Mark (RCM)
indicates compliance with the
Australian and New Zealand
electrical safety, EMC, EME and
telecommunications requirements

Symbols on the foot control S-N2 / S-N1



CE mark
with identification number
of the Notified Body



Article number



Do not dispose of with
domestic waste



Serial number



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



Date of manufacture



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

Symbols on the packaging



CE mark
with identification number
of the Notified Body



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



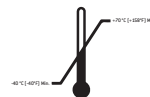
This way up



Data structure in accordance with
Health Industry Bar Code



Fragile, handle with care



Permitted temperature range



Keep dry



Humidity,
Limitation



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



Caution! Federal law restricts this device to sale
by or on the order of a dentist, physician or any
other practitioner licensed by the law of the state
in which he or she 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

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.



It is therefore essential that you observe the safety notes on pages 13 to 15.

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 dentists, dental hygienists, dental employees (prophylaxis) and dental assistants target group.

Introduction



Production according to EU Directive

The foot control S-N1 and S-N2 is a medical device as defined by EU Directive 93/42/EEC.

The foot control S-NW is a medical device as defined by EU Directive 93/42/EEC and R&TTE Directive 99/5/EC.



Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the foot control if 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 drill unit.
- > The foot control 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 32).
- > Unauthorized opening of the foot control invalidates all claims under warranty and any other claims.



The foot control must be used only with the control unit listed in the equipment supplied.

Introduction



See the chapter below in the Instructions for Use for the drill unit:

- > Symbols
- > Introduction
- > Safety notes
- > Start-up
- > Description and operation of foot control
- > Hygiene and maintenance
- > Accessories and spare parts
- > Servicing
- > Technical data
- > Recycling and disposal

2. Electromagnetic compatibility (EMC)



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

W&H only guarantees compliance of the control unit with the EMC Directives when it is used with original W&H accessories and spare parts. The use of accessories and spare parts that have not been approved by W&H may lead to increased emission of electromagnetic interference or to reduced resistance to electromagnetic interference.



You can find the current EMC manufacturer's declaration on our website at <http://wh.com> or, alternatively, you can also request a copy directly from the manufacturer.



HF communication equipment

Do not use any portable and mobile HF communication equipment (e.g., mobile telephones) during operation of the foot control. These may affect medical electrical equipment.

3. Scope of delivery

Foot control	Incl. dongle	Compatible with control unit*
S-NW, REF 30264000	REF 07759700	Implantmed SI-1010, Implantmed SI-1015, Implantmed SI-1023
S-NW, REF 30264001	REF 07795800	Piezomed, Elcomed, Implantmed REF 16929000 / 16929001
S-N2, REF 30285000		Implantmed SI-1010, Implantmed SI-1015, Implantmed SI-1023
S-N1, REF 05083300		SI-95 (Implantmed, DU900, OsseoSet™ 100, Frios® Unit S) SA-200, SA-200 C (Elcomed)
S-N1, REF 05046200		SI-923, SI-915 (Implantmed REF 00900100 / 00900101 / 00900102 / 00900103 / 00900104 / 00900105 / 00900106 / 00900107), BTI DrillTech®, Implant Unit, Ism, Surgical Motor System, OSM2, MIS MCU, DU1000, Frios® Unit S/i, OsseoSet 200, Osscora instrument set)
S-N1, REF 06202400		SA-310 (Elcomed) SI-923, SI-915 (Implantmed REF 16929000 / 16929001)
S-N1, REF 07004400		SA-320 (Piezomed)
S-N1, REF 06382200		PA-123, PA-115 (Tigon+)
Locator, REF 04653500		For all listed foot controls
Foot control S-NW		
3 disposable batteries AA / Mignon / LR6 / 1.5V		

* Not included

4. 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 before every use.
- > Do not use the foot control if it is damaged.
- > Replace the foot control if the resistance of the pedal is noticeably reduced.
- > Never touch the patient and the connections for the foot control on the control unit 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”.



Danger zones M

The foot control is approved as per IEC 60601-1 / ANSI/AAMI ES 60601-1 for use in zone M (AP).

Zone M, also referred to as the “medical environment”, includes the part of a room in which potentially explosive atmospheres may occur as a result of the use of analgesics or medical skin cleaning or disinfectants, but only in small quantities and only for a short time.

Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.

Safety notes – general



Risks due to electromagnetic fields

The functionality of implantable systems, such as cardiac pacemakers and ICD (implantable cardioverter defibrillator) can be affected by electric, magnetic and electromagnetic fields.

- > Find out if patients and users have an implanted device before using the product and test the possible applications.
- > Assess the risks and benefits.
- > Keep the product away from implanted devices.
- > Take appropriate emergency precautions and take immediate action on any signs of changes to health.
- > Symptoms such as increased heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD (implantable cardioverter defibrillator).



Improper use

In addition to unauthorized assembly, installation, modification of or repairs to the foot control or non-compliance with our instructions, improper use will invalidate all claims made under warranty or otherwise.

Safety notes – foot control S-NW



Keep the ORANGE button depressed and switch between the control units.
Programs cannot be changed in descending order using the foot control S-NW.

Disposable batteries

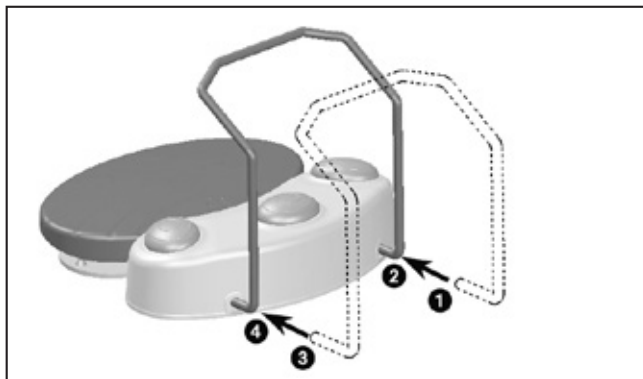
- > Replace the disposable batteries at the first prompt (battery icon on display or LED on dongle).
- > Replace batteries outside zone M only.
- > Use only high-quality disposable alkaline AA / Mignon / LR6 / 1,5 V batteries. Risk of explosion if the wrong type of battery is used.
- > Do not mix new, 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.
- > Pay attention to the battery icon on the display before and after each treatment.
- > Always keep spare batteries on hand.
- > Dispose of faulty or flat batteries immediately and correctly via recycling systems. Do not dispose of batteries in domestic waste.



Disposable batteries may cause damage due to leakage or corrosion.

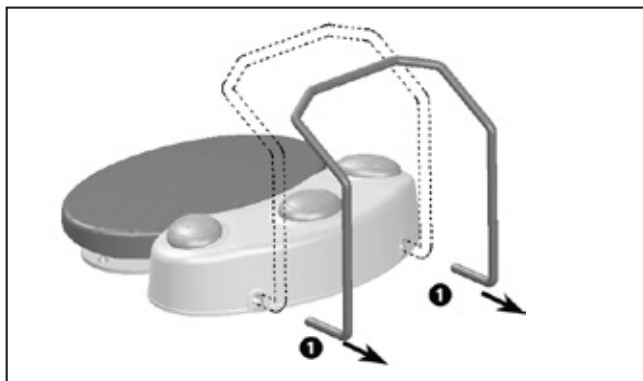
- > Remove the disposable batteries if you are not going to use the foot control for a longer period.
- > See the safety notes of the battery manufacturer.

5. Attaching / detaching the locator



Attaching the locator

- ❶ Insert one of the guides on the locator into one of the holes on the foot control.
- ❷ Push it right in until the locator reaches the stop.
- ❸ Insert the other guide on the locator into the other hole on the foot control.
- ❹ Push it right in until the locator reaches the stop.



Detaching the locator

- ❶ Pull the locator out.

6. Foot control S-NW – Inserting and replacing batteries

Open battery compartment



❶ Open the battery compartment.



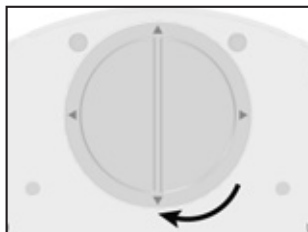
Note the symbols!

Remove batteries



❶ Pull the red thread to remove the batteries.

Lock battery compartment



❷ Lock the battery compartment.

Insert batteries

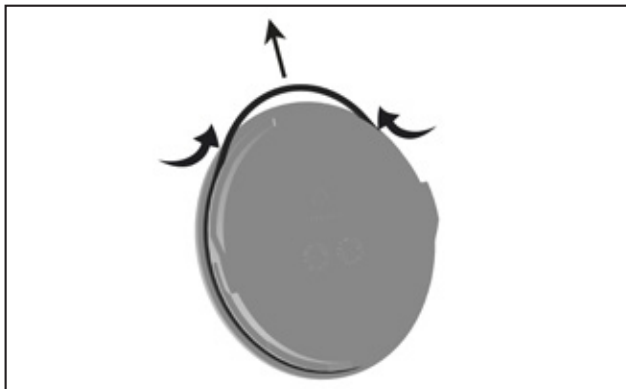


❷ Insert the batteries.



Pay attention to the positioning!

Foot control S-NW – replacing the O-ring



Do not use sharp tools!

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

Foot control S-NW – connecting and disconnecting the CAN dongle

Connecting CAN dongle

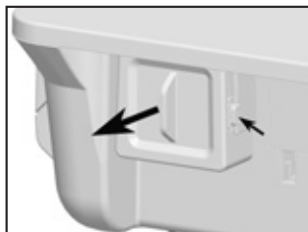


❶ Plug in the CAN dongle.



Pay attention to the positioning!

Removing CAN dongle



❷ Press the side lock and remove the CAN dongle.

Foot control S-NW – Description of CAN dongle

CAN dongle activated



Icon am Display sichtbar

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



Pairing

The foot control S-NW and the CAN dongle are paired by default.

If pairing is inactive, you can activate pairing on the control unit (see Implantmed instructions for use) and follow the directions.

Disable pairing

Press and hold the green, orange and yellow buttons simultaneously on the foot control S-NW.


Using multiple W&H control units simultaneously

Press and hold the orange button on the foot control S-NW for 3 seconds to switch between the various control units.

Foot control S-NW – connecting and disconnecting the SPI dongle

Connecting and disconnecting the SPI dongle



 Pay attention to the positioning!

❶ Plug in the SPI dongle or disconnect the SPI dongle from the control unit.



❷ Attach the SPI dongle to the irrigant support or remove the SPI dongle from the irrigant support.

Foot control S-NW – description of SPI dongle

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 – pairing



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

If pairing is active: LED indicator flashes

If pairing is inactive:

- ❶ Press and hold the button on the SPI dongle for 4 seconds.
- ❷ LED indicator flashes. SPI dongle is in pairing 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.

Disable pairing

Press and hold the green, orange and yellow buttons simultaneously on the foot control S-NW.

Using multiple W&H control units simultaneously

Press and hold the orange button on the foot control S-NW for 3 seconds to switch between the various control units.

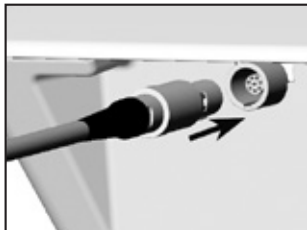
Foot control S-NW – assistance with pairing problems

- > 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, ...)
- > Delete the pairing and repeat the pairing process.
- > Remove and replace the batteries.



If the pairing problem cannot be remedied using the steps described above, the unit will need to be inspected by an authorized W&H service partner (see page 32).


7. Connecting and disconnecting foot control S-N2 / S-N1



Pay attention to the positioning!

- 1 Plug in the foot control S-N2 / S-N1 or disconnect the foot control from the control unit.

8. Hygiene and maintenance

 Follow your local and country-specific laws, directives, standards and guidelines for cleaning, disinfection and sterilization.



- > Wear protective clothing.
- > Clean and disinfect the foot control **immediately after every treatment!**



- > The foot control is sealed and may be wiped clean.
- > The foot control is not approved for mechanical cleaning (thermo washer disinfectant) and sterilization.
- > Do not immerse the foot control or clean it under running water.

Pre-disinfection

- > If heavily soiled, clean first with disinfectant cloths.



Only use disinfectants which have no protein-fixing effect.

Manual cleaning

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

Manual disinfection



W&H recommends wipe disinfection.

- > Use only disinfectants which do not contain chlorine and which are certified by officially accredited institutes.
- > Note the manufacturer's specifications for the use of the disinfectant.

9. W&H accessories and spare parts



Use only original W&H accessories/spare parts or accessories approved by W&H.

Reference source: W&H Partner



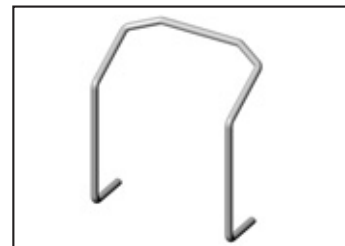
07759700

CAN dongle



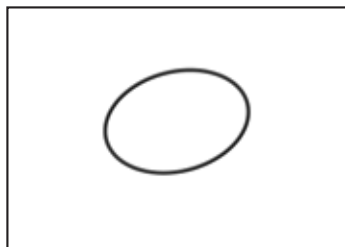
07795800

SPI dongle



04653500

Locator



07823400

O-ring

10. Servicing



Regular checks

Regular servicing of function and safety including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The inspection must be undertaken by a qualified organization and must include the following procedures:

- > External visual inspection
- > Measurement of device leakage current
- > Measurement of ESD capacity
- > Visual inspection of the ESD spring contact on the bottom of the foot control (electrostatic discharge)
- > Function test with check to see if the maximum speed can be reached



The regular inspection must only be performed by an authorized W&H service partner (see page 32).

Repairs and returns

In case of a fault or malfunction, send the control unit, the foot control and the motor with cable for repair to an authorized W&H service partner (see page 32).



- > Always return equipment in the original packaging.
- > Do not coil the cable around the motor and do not twist or kink the motor cable. (Risk of damage)
- > Remove the foot control batteries.

11. Technical data

Foot control	S-NW	S-N2 / S-N1
Power supply:	3 disposable batteries AA / Mignon / LR6 / 1.5V	—
Dimensions in mm (height x width x depth):	154x202x210	156x207x206
Weight in kg:	1.2	1.3

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



The foot control S-NW / S-N2 / S-N1 conforms to Class AP according to IEC 60601-1 / ANSI/AAMI ES 60601-1 in danger zone M



The foot control S-NW / S-N2 / S-N1 is 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

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 twenty-four months from the date of purchase. Accessories and consumables (batteries, O-ring, locator for foot control) 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-month warranty

Authorized W&H service partners

Visit W&H on the Internet at <http://wh.com>

You can find your nearest W&H service partner under “Service” in the menu.

If you do not have Internet access, please contact:

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