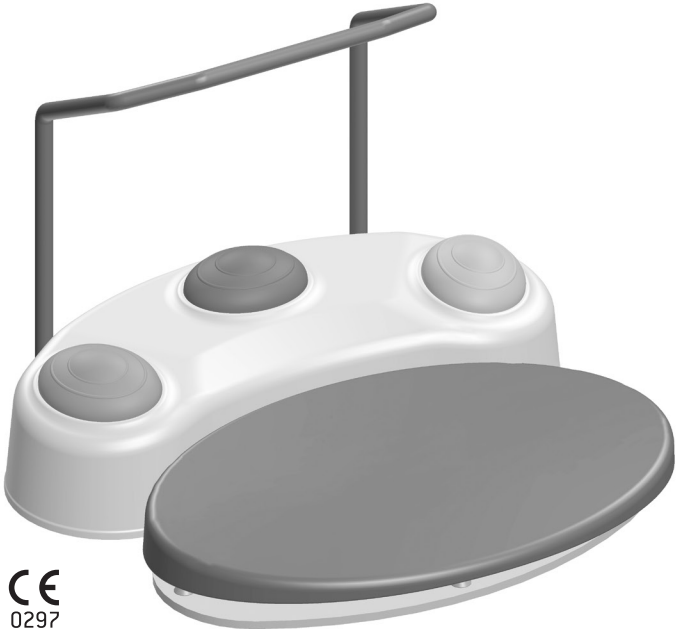
# Instructions for Use



CE
0297

## Foot control

## S-NW, S-N2, S-N1

# Contents

## 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

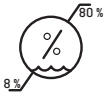

Medical Device


Serial number

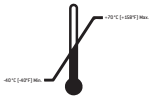

UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements

## Symbols

Non-ionizing electromagnetic radiation




Humidity limitation



Temperature limitation

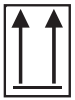
Battery compartment closed

"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

# Symbols


GITEKI (MIC) – Japan

S-NW: CCAH19LP2780T2
CAN dongle: CCAH19LP2790T5
SPI dongle: CCAH19LP2800T8

NCC – Taiwan

IC – South Korea

KCC-CRM-BGT-BLE113


01237-16-03402

ANATEL – Brazil

Complies with
IMDA Standards
DA103787

*Symbol only in IFU

IMDA – Singapur*

RCM – Australian / New Zealand

Contains FCC ID: QOQBLE113
Contains IC: 5123A-BGTBLE113

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 33).
> 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-NW, REF 30264000<br>S-NW, REF 30264003 | REF 07759700 | SI-1010/SI-1015/SI-1023, M-UK1010/ M-UK1015/M-UK1023, SA-430 M/SA-435 M<br>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<br>S-N2, REF 30285002 | | SI-1010/SI-1015/SI-1023, SI-915/SI-923 (REF 30286xxx, 30287xxx)<br>M-UK1010/M-UK1015/M-UK1023, SA-430 M/SA-435 M<br>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<br>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 |

| Foot control S-NW |
|---|
| 3 disposable batteries AA / Mignon / LR6 / 1.5V |

* Not included

> 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).

**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.

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.

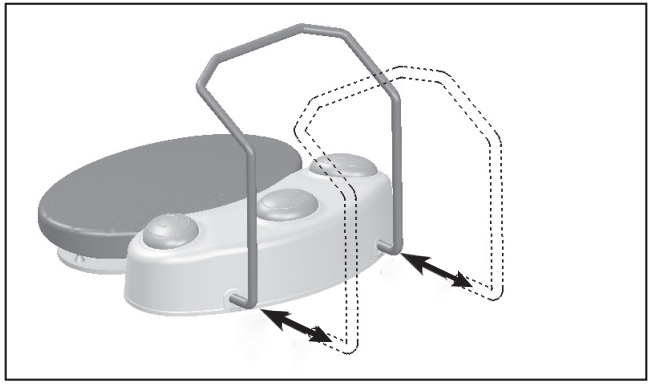
> Dispose faulty or flat batteries immediately and correctly via recycling systems. Do not dispose batteries in domestic waste.

> 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. Attaching - detaching the locator

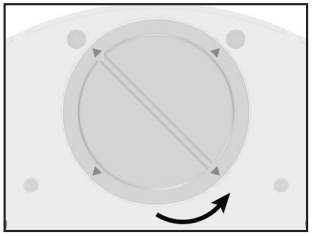


**Attaching and detaching the locator**

> Push it right in until the locator reaches the stop.
> Pull the locator out.

# Inserting and replacing batteries

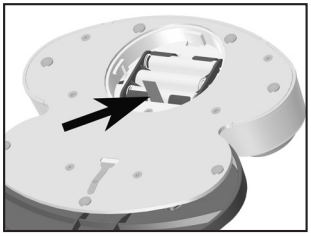
### Open battery compartment



❶ Open the battery compartment.

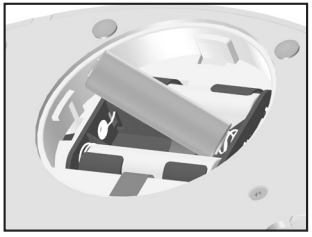
Note the symbols!

### Remove batteries



❷ Pull the red thread to remove the batteries.

### Insert batteries

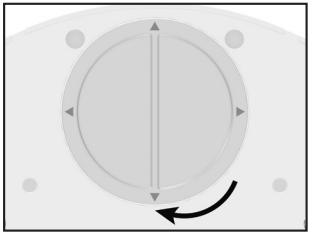


Reposition the red thread before inserting batteries.

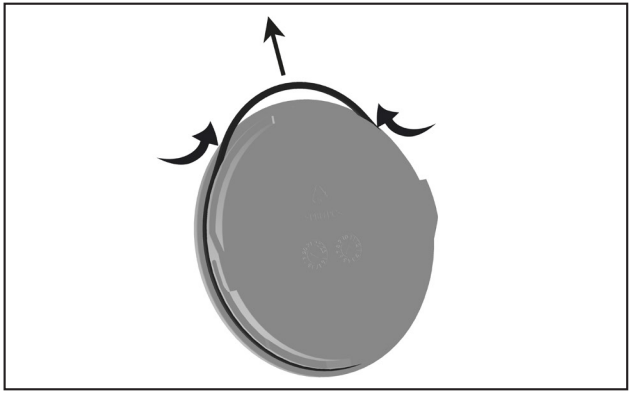
❸ Insert the batteries.

Pay attention to the positioning!

### Lock battery compartment



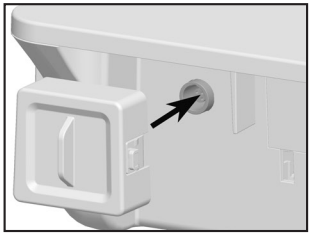
❹ Lock the battery compartment.



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.

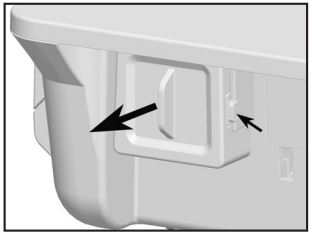
### Connecting CAN dongle



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

**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 Instructions for Use Implantmed/system assembler) and follow the directions.
> Press and hold the green/left and orange/middle buttons simultaneously on the S-NW foot control for at least 3 seconds.

**Disable pairing**

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

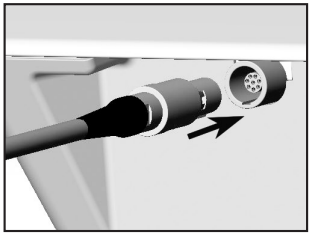
**Switching between multiple control units**

Press the orange/middle button for 3 seconds.

**Change application**

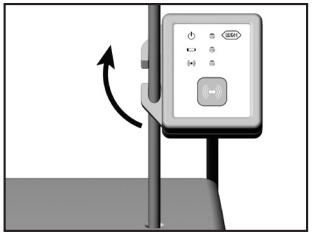
Press the orange/middle button for 3 seconds until an acoustic signal sounds.

## 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.

**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:

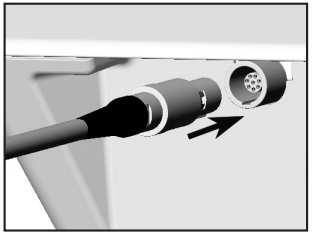
1. Press and hold the button on the SPI dongle for 4 seconds.
2. LED indicator flashes. SPI dongle is in pairing mode for 30 seconds.
3. Press and hold the green and orange buttons simultaneously on the S-NW foot control.
4. LED flashes three times when pairing is successful.

**Disable pairing**
Press and hold the green, orange and yellow buttons simultaneously on the foot control S-NW 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, ...).
> Replace 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.



Pay attention to the positioning!

❶ Plug in the foot control S-N2 / S-N1 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 processing in a washer-disinfector and sterilization.

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

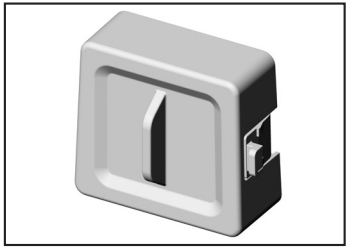
**Periodic inspection**
Regular periodic inspection of the function and safety of the medical device is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law.
The periodic inspection covers the complete medical device and must only be performed 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.

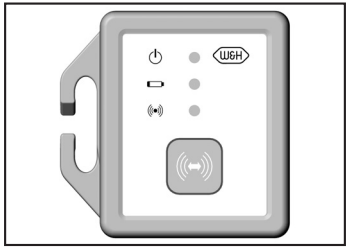
> Always return equipment in the original packaging
> Foot control S-NW: Remove the batteries.

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

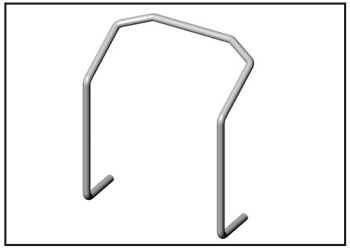
Use only original W&H accessories and spare parts or accessories approved by W&H.
**Suppliers:** W&H partners (Link: https://www.wh.com)



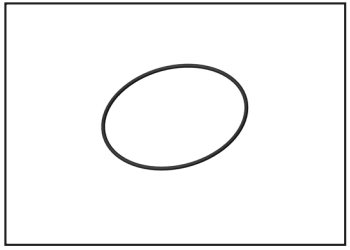
**07759700**
CAN dongle



**07795800**
SPI dongle



**04653500**
Locator for foot control



**07823400**
O-ring

# 10. Technical data

| **Foot control** | **S-NW** | **S-N2 / S-N1** |
|---|---|---|
| Power supply: | 3 disposable batteries<br>AA / Mignon / LR6 / 1,5V | – |
| Dimensions in mm (height x width x depth): | 154 x 202 x 210 | 156 x 207 x 206 |
| Weight in kg: | 1.2 | 1.3 |

| | |
|---|---|
| Freuquency band: | 2.4 GHz ISM band (2.402 – 2.480 GHz) |
| Transmitting power: | Class 3:1 mW (0 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: | +10 °C to +40 °C (+50°F to +104°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**


S-NW / S-N2 / S-N1 are approved for operation in potentially explosive atmospheres.

S-NW / S-N2 / S-N1 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)<br>CISPR 11/EN 55011 [150 kHz – 30 MHz] | Group 1<br>Class B | | |
| Electromagnetic radiation disturbance (Radiated Emissions)<br>CISPR 11/EN 55011 [30 MHz – 1000 MHz] | Group 1<br>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)<br>IEC/EN 61000-4-2 | Contact discharge: ±2 kV, ±4 kV, ±6 kV, ±8 kV<br>Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV | | |
| Radiated RF electromagnetic fields<br>IEC/EN 61000-4-3 [80 MHz – 2,7 GHz] | 10 V/m | | |
| Proximity fields from RF wireless communications equipment<br>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<br>IEC/EN 61000-4-4 | Mains supply: ±2 kV<br>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<br>IEC/EN 61000-4-6 | 3 V<br>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<br>IEC/EN 61000-4-11 | 0% for 0.5 cycle at 45° steps from 0°-315°<br>0% for 1 cycle<br>70% for 25/30 cycles<br>0% for 250/300 cycles | | |
| Proximity magnetic fields<br>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.

Software version S-NW:
CAN Dongle: 01.03.00
S-NW: 01.04.00
Software version S-N2:
S-N2: 01.00.00

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office@wh.com **wh.com**

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Rev. 009 / 10.06.2024
Subject to alterations