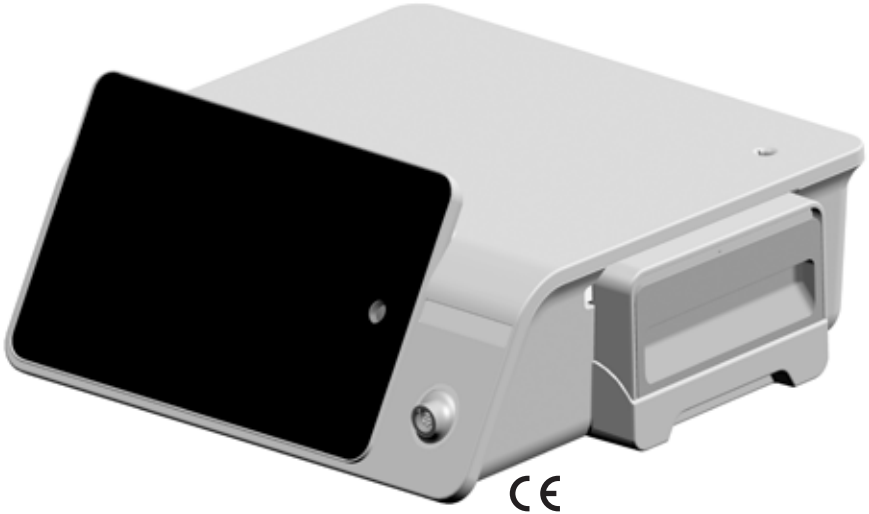
Instructions for Use



CE
0297

implantmed PLUS

SI-2100 / SI-2101 / SI-2102

Contents

Contents

Symbols

WARNING!
(risk of injury)

Sterilizable up to the stated temperature

Do not dispose of with domestic waste

ATTENTION!
(to prevent damage occurring)

CE marking with identification number of the Notified Body

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

General explanations, without risk to persons or objects

Manufacturer

Serial number

Medical device

Date of manufacture

Catalogue number

Thermo washer disinfectable

USB-C interface

Do not re-use

Symbols

Follow Instructions for Use

Class II equipment

Foot control

Off

On

VA Power consumption (volt-ampere)

Earth

V AC Volt alternating current

Hz Frequency (hertz)

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

MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005/(R)2012 + A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012, ANSI/AAMI ES60601-1:2005/A2:2021, CAN/CSA-C22.2 No. 60601-1:14, CAN/CSA-C22.2 No. 60601-1:14/A2:22, IEC 80601-2-60:2019. 25UX – Control No.

Symbols

This way up

Fragile, handle with care

Keep dry

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

Data structure in accordance with Health Industry Bar Code

Temperature limitation

Humidity limitation

RCM – Australian / New Zealand

Contains FCC ID: T7V9019
Contains IC:216Q-9019

FCC / IC – USA / Canada*

SI-2101 / SI-2102:

Contains FCC ID: R7T1101102
Contains IC: 5136A-1101102

FCC / IC – USA / Canada*

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.

Symbols

* 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
Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF).


Misuse may damage the medical device and hence cause risks and hazards for patient, user and third parties.


Qualifications of the user
Only suitably qualified medical, technical and specialist trained staff may use the medical device. We have based our development and design of the medical device on the physician target group.

Introduction

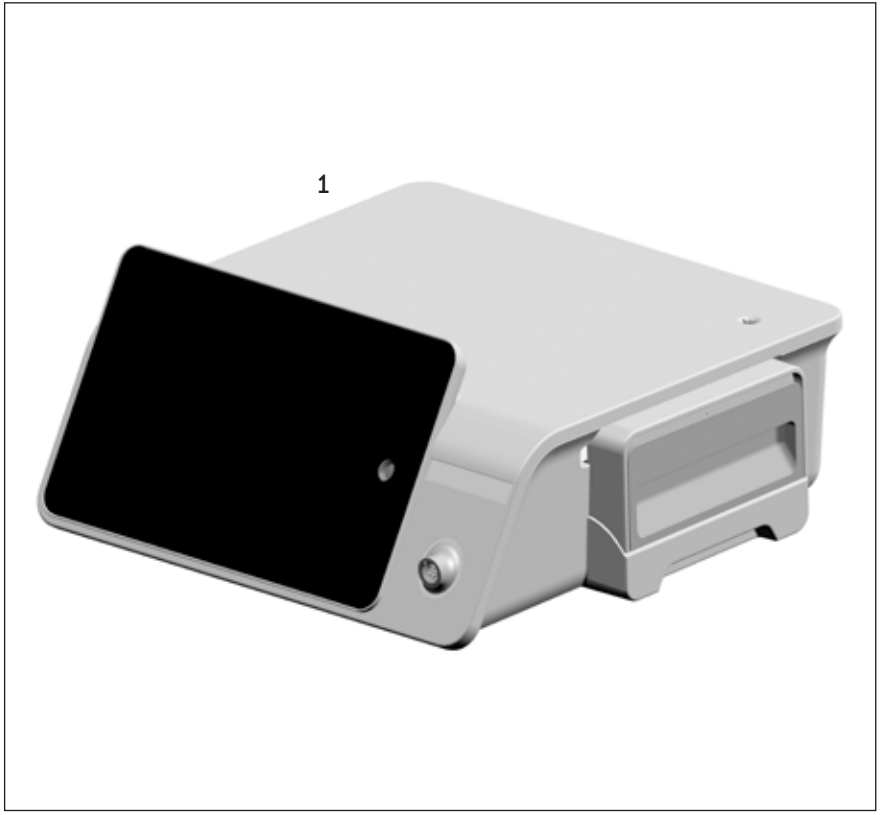
Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions

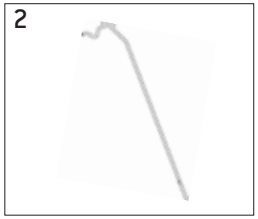
> The medical device must be used in accordance with these Instructions for Use.
> The medical device has no components that can be repaired by the user.
> Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 66).
> The electrical installation at the premises must comply with the regulations laid out in IEC 60364-7-710 ("Installation of electrical equipment in rooms used for medical purposes") or with the regulations applicable in your country.
> Unauthorized opening of the medical device invalidates all claims under warranty and any other claims.

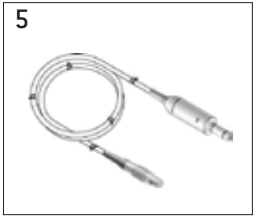
Improper use, unauthorized assembly, modification or repair to the medical device, non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

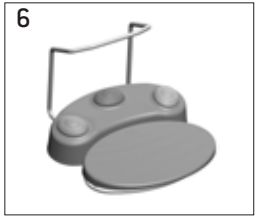
Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

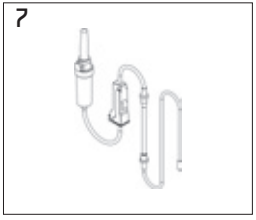
2. Scope of delivery











Scope of delivery

Nr.	REF	Description	Scope of delivery	Optional in the set
1	30504000	Control unit SI-2100*	X	
	30505000	Control unit SI-2101*	X	
	30506000	Control unit SI-2102*	X	
2	04005900	Stand	X	
3	07721800	Universal support	X	
4		Mains cable country-specific	X	
5	30281000	EM-19 LC motor with electrical contacts and 1.8 m cable		X
6	30497000	Foot control S-N3 (Compatible with SI-2100)		X
	30495001	Foot control S-NW3 (Compatible with SI-2101/SI-2102)		X
7	04363600	Irrigation tubing set 2.2 m (Disposable)		X

* Scope of delivery: 1 control unit according to order

Compatible with the Implantmed Plus II:

REF	Description
30507000	Piezomed Modul Plus II
08022260	Osstell Beacon

3. Safety notes

- > 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 each time before using.
- > Do not operate the medical device if it is damaged.
- > Check the parameter settings every time you restart.
- > Perform a test run each time before using.
- > 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.
- > The medical device is not approved for operation in oxygen rich environment.
- > Never touch the patient and the electrical contacts on the control unit simultaneously.
- > Make sure that no computer viruses are transferred to the control unit by an external data medium (USB stick).
- > Use the medical device in the 20:1 and SZ-75 (20:1) ratios exclusively with W&H contra-angle handpieces. Use of other contra-angle handpieces may result in deviation from the indicated torque. The user alone is therefore responsible for the above. The manufacturer does not accept any liability.

Observe the manufacturer's speed and torque specifications for retaining screws for superstructures. Adjusting these retaining screws with an electric motor presents a potential risk as described above.

Observe the manufacturer's speed and torque specifications for instruments, implants and osseodensification burs.

Safety notes

The connection of a USB hard drive with an external power source is not permitted.

Power failure

In the event of a power failure, if the control unit is switched off, or when switching between programs, the last values set are saved and re-activated on power-up.

System failure

A total system failure does not constitute a critical fault.

Software update

The control unit must be continuously supplied with power during the update. Interruptions may lead to data loss or device failure.

Mains cable / Power switch

> Only use the mains cable supplied.
> Plug the mains cable only into a power socket with protective contact.
> Set up the control unit so the power switch and the socket are easily accessible at all times.
> Disconnect the control unit from the power supply in case of danger.
> Turn off the control unit at the power switch.
> Pull the power plug out of the socket.

Safety notes

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.

Coolant supply

The medical device is designed for use with physiological saline solution.

> Always ensure the correct operating conditions and cooling function.
> Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction.
> Use only suitable coolants and follow the manufacturer's medical data and instructions.
> Only use an irrigation tubing set approved by W&H or accessories approved by W&H.

Follow the directions and safety notes in the Instructions for Use of the foot control, the electric motors and the transmission handpieces.

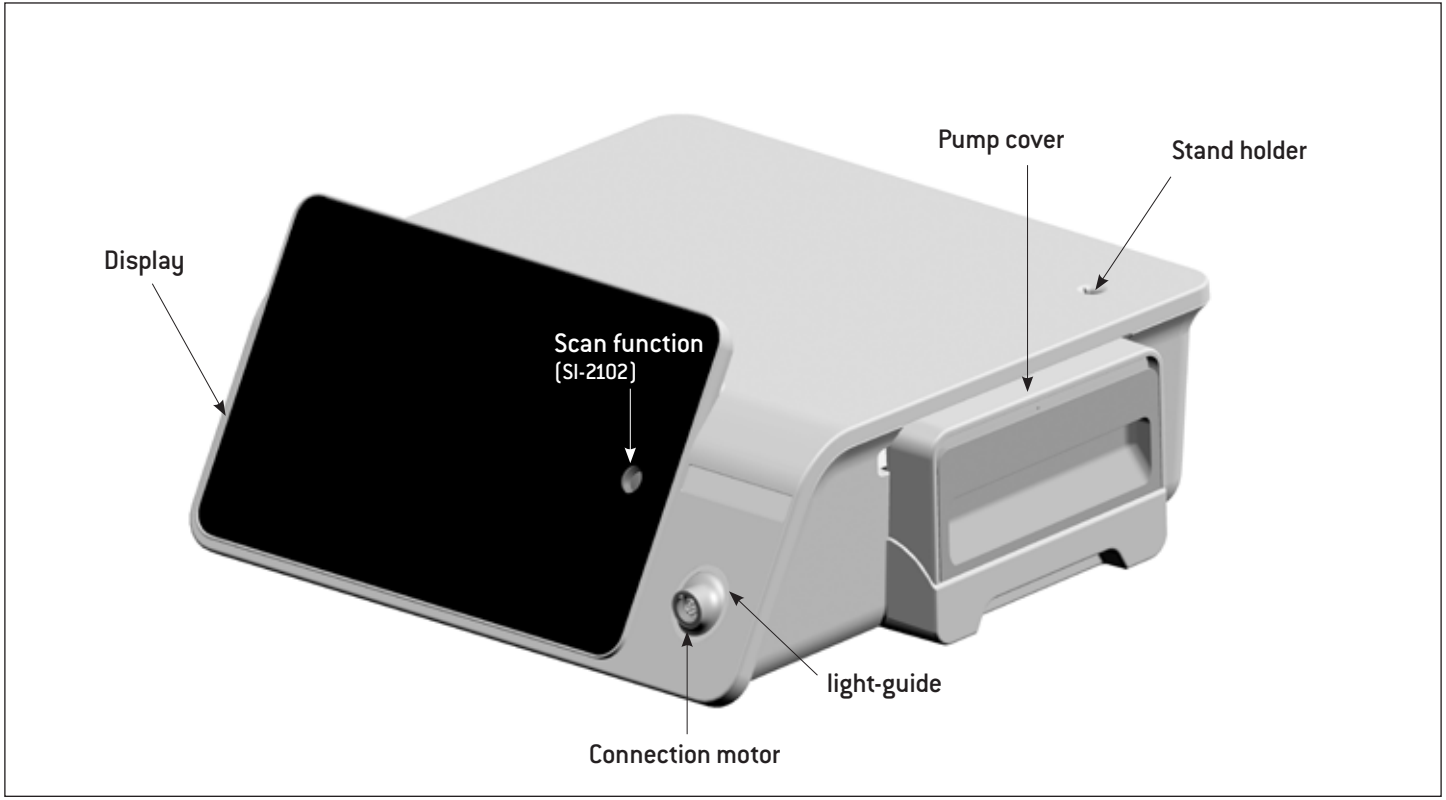
Safety notes

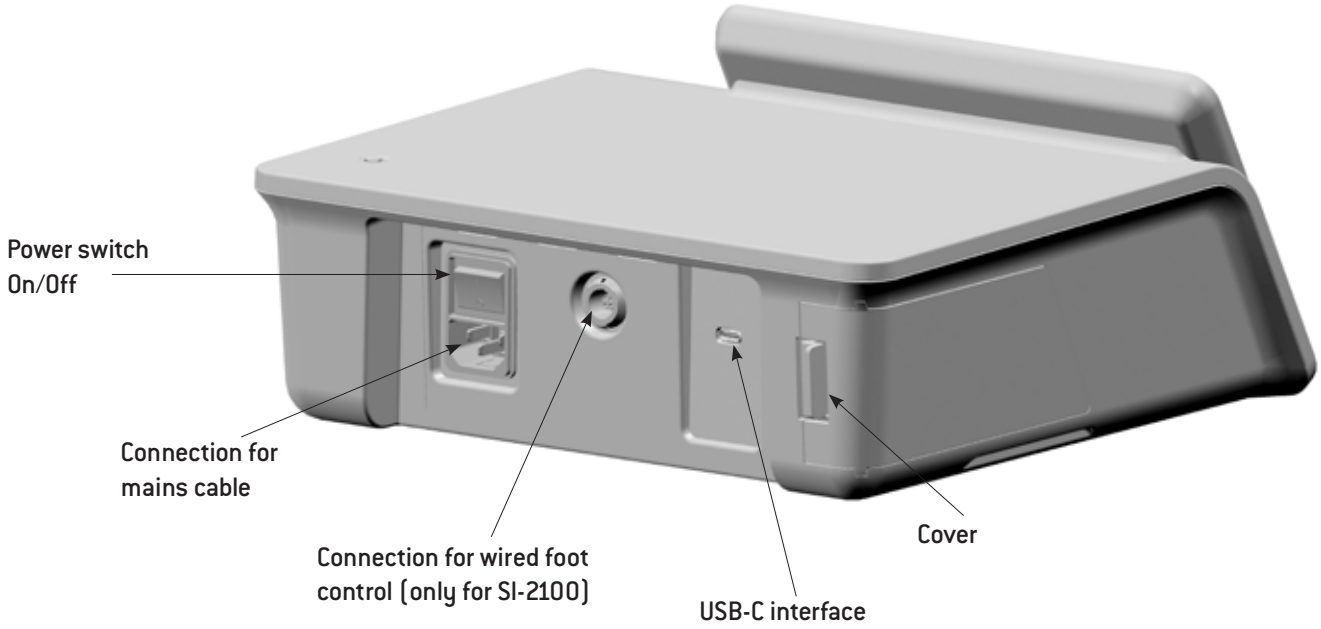
Sterile medical devices

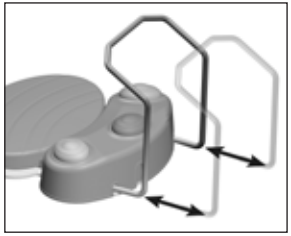
> Only use the medical device if the sterile packaging is undamaged and unopened.
> Note the expiration date.
> Replace the medical device immediately after every treatment.
> Dispose of the medical device in accordance with the applicable regulations.

Hygiene and maintenance prior to initial use

> Clean and disinfect the control unit, the universal support and the stand.
> Sterilize the universal support.


Pump cover
Stand holder
Display
Scan function
(SI-2102)
light-guide
Connection motor


Power switch
On/Off
Connection for
mains cable
Connection for wired foot
control (only for SI-2100)
USB-C interface
Cover



Locator
attach/detach

Orange button
(centre)

Green button
(Left)

Yellow button
(Right)

Pedal
Start motor
Variable or On/Off

Standard button configuration

Green button

Coolant volume ON/OFF: Only when the motor is at complete standstill can the coolant volume be switched on or off by operating the green button.

Orange button

> **Switch application:** Press the orange button for 3 seconds until an acoustic signal is emitted.

An acoustic signal sounds when switching application.

> **Switch program:** Press the orange button to switch programs in ascending order.

When switching from a torque or ISQ program to a speed program, a longer acoustic signal sounds.

Yellow button

Change motor direction: Press the yellow button to change the motor direction. An acoustic signal sounds and the forward/reverse operation icon lights up green for reverse operation. Three signal tones sound when the motor starts in reverse operation.

User-defined button configuration
The green and orange buttons can be configured individually under Settings, Button Configuration.


Check the selected profile and corresponding device settings before each application.

Green button
Coolant volume can now only be changed on the display.
> **Switch application:** Press the green button to switch application.


An acoustic signal sounds when switching application.

> **Switch tooth position:** Press the green button to switch tooth position.

Orange button
Switch program: Press the orange button to switch programs in ascending order.
The green button is configured automatically for switch application.

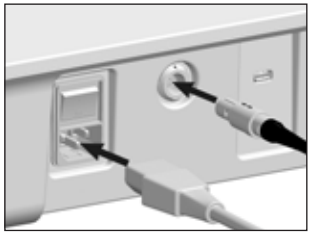

When switching from a torque or ISQ program to a speed program, a longer acoustic signal sounds.

The light-guide, an LED display around the motor connection, visually displays the following information to make use easier:

Colour	LED display	Information
White	Lights up	Active application
	Flashes	Cable connected successfully
–	Off	Inactive application
Red	Lights up	Warning / error (for details see System messages)

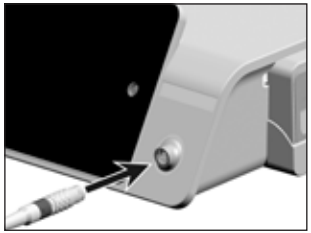
5. Start-up

Place the control unit on a flat, level surface.



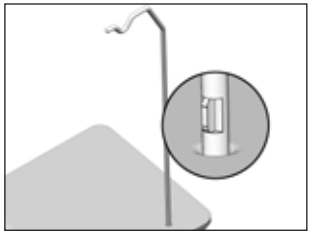
❶ Connect the mains cable and wired foot control (only for SI-2100).

Pay attention to the positioning!



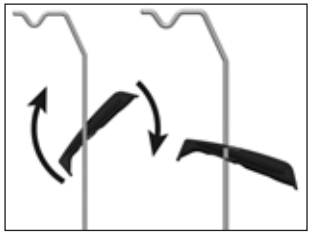
❷ Connect motor cable.

Pay attention to the positioning!

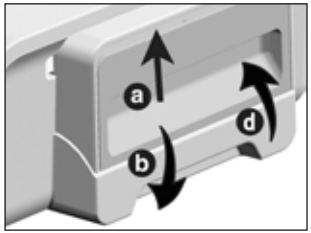


❸ Insert the stand.

Pay attention to the positioning! (Maximum load capacity 1.5 kg)



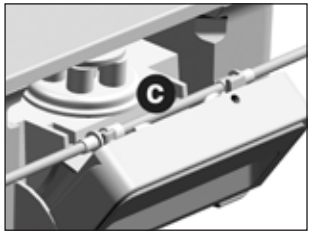
❹ Attach the universal support and lock it.



❺ Insert the irrigation tubing.

> Open the pump cover (a,b).

> Insert the irrigation tubing (c).

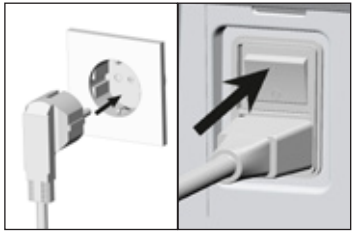


> Close the pump cover (d).

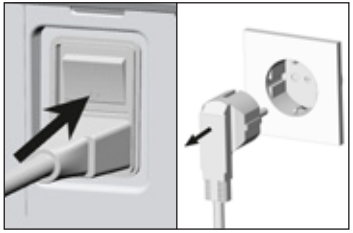
Start-up

Ensure that the control unit can be disconnected from the power supply at any time.

Before switching on the medical device with the power switch, the foot control (only for SI-2100) must be connected.



Switching ON
Plug the mains cable into a power socket with protective contact.
Switch the control unit on at the power switch.



Switching OFF
Switch the control unit off at the power switch.
Pull the power plug out of the socket.

Test run
Start up the medical device with the transmission instrument inserted.

In the event of operating malfunctions (e.g. vibrations, unusual noises or overheating) stop the medical device immediately and contact an authorized W&H service partner.

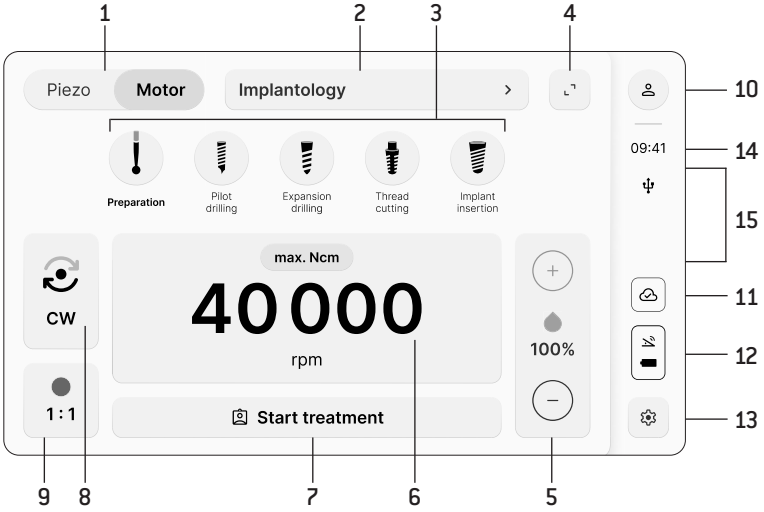
6. Setup wizard

The touch screen must only be touched using fingers.
Using hard objects on the touch screen may scratch or damage the surface.

Setting up control unit
Switch the control unit on and follow the instructions in the set-up wizard on the display.
The set-up wizard guides you through the various set-up stages up to the main menu:

> Select language
> Select continent and country
> Select timezone
> Connect foot control
> Connecting to WiFi
> Connecting to ioDent
> Confirm detailed diagnostic data

The user is responsible for selecting the correct country setting and complying with regulatory guidelines.



1	Application
2	Drill protocols
3	Programs
4	Show / hide sidebar
5	Coolant volume
6	Speed / torque setting
7	Start treatment
8	Forward / reverse operation
9	Transmission ratio

Sidebar display:	
10	User
11	ioDent connection
12	Foot control / battery state
13	Settings
Variable sidebar display:	
14	Time
15	Connected component

General

Device information
Information, software licence, certificate, logbook

Information
REF, serial number and software version

Legal and licences
Accept or decline detailed diagnostic data
Software licences

Certificate
Certificate renewal

Logbook
Device messages for service technicians

Language and region
Select language and timezone

Software update
Update software
Follow the directions on the display.
(Info about available software updates at ioDent.com)

General

Reset settings
Restore default settings, factory reset

Default settings
The following settings will be deleted in the selected profile:
> Display
> Sound
> Foot control
> Motor

Factory settings
All data and settings will be reset to factory settings.

Display

Screen lock
Activate/deactivate screen lock

Screen lock
Select a time between 1 - 30 minutes

Display

Appearance

Program icons
Select: Modern or classic

Progress display mode
Display speed and torque during operation
Select: Absolute value, bar or percentage display

Dental numbering system
Select: FDI or UNS
FDI (Féderation Dentaire Internationale = International dental numbering system I-IV)
UNS (Universal Numbering System = American dental numbering system 1-32)

Display

Time
Activate/deactivate time display

Torque curve
Activate/deactivate torque curve display after activating foot control

Sound

Activate/deactivate sound

Volume
Select: Standard or high

WiFi

Activate/deactivate WiFi
Update network, connect or disconnect encrypted WiFi
Open networks are not displayed.

Foot control

Characteristic (Motor)
Select: ON/OFF or variable
Variable: Motor regulation can be infinitely variable up to the maximum pre-set speed.
ON/OFF: Motor runs with maximum set speed.

Button configuration
Select button allocation: Standard or user-defined (see foot control product description for details)

Motor

Activate/deactivate motor LED

Fade-out time
Select: Between 1 - 30 seconds

Osstell Beacon

Select: Unrestricted connection or restricted connection with serial number
(see Osstell Beacon use for details)

Drill function

rpm **Speed**

The accuracy of the set speed is ±10% at a speed of 40,000 rpm.

Thread cutter function (chip breaker function)

When the pedal is pressed, the thread cutter rotates inwards until the set torque is reached. The control unit automatically switches to reverse operation when the set torque is reached. Disengaging and then re-engaging the pedal will switch the control unit back to forward operation.

If the thread cutter function is in reverse operation mode, the control unit can also start with the maximum torque.

Torque indicator function (reverse operation)

Three signal tones sound when the pedal is pressed. The function starts in reverse operation as standard. A signal tone sounds and the LED on the contra-angle handpiece flashes when the set torque is reached. The maximum torque that can be set varies depending on the speed selected.

Implant insertion

Ncm **Torque**

5 – 80 Ncm only for 20:1 / 5 – 70 Ncm only for SZ-75

When the pedal is pressed, the implant is inserted until the set torque is reached. When the set torque is reached in forward and reverse operation mode, the motor switches off automatically. The accuracy of the set torque is ±10% with W&H contra-angle handpieces (20:1) at a torque of 20 – 50 Ncm. Greater deviations are possible with different contra-angle handpieces.

User

Use the default profile or create an individual profile.
Changes will be synchronised automatically as soon as there is a connection to ioDent.

Creating users
A maximum of seven users can be created.

Check the selected profile and the associated device settings before each use.

Drill protocols

> Use a pre-defined drill protocol (Implantology / Oral surgery) or create a new drill protocol.
> Drill protocols can be edited at any time.

The order of the programs can be adapted.

User-generated drill protocols can be deleted, but pre-defined drill protocols can only be reset to W&H default settings.

Importing drill protocol default settings

> Import the drill protocol default settings for the patient ID via the planning software.
> The order of the programs cannot be adapted.
> The implant manufacturer and implant type are displayed in the 'Drill protocol' field.
> Speed, torque, coolant volume, direction of rotation and transmission ratio can be adapted at any time.

Treatment documentation is possible on the ioDent platform and a USB stick

> The treatment can either be imported via ioDent or created manually.
> Documentation is only possible if a patient ID has been selected.
> The documentation of drill protocols and torque curves is only possible in the thread cutter function, implant insertion and torque display function.
> The documentation of ISQ values is only possible with a connected Osstell Beacon.
> The torque curve will be displayed in the patient ID.
> A text file (csv) and a PDF will be saved on the USB stick.

Start treatment

> Create treatment.
> Enter patient ID manually.
> The treatment date is saved automatically.
> Select tooth position: One or more tooth positions can be created.

> Each created treatment can be changed at any time.
> The treatment date is saved automatically at the start.
> A maximum of 50 treatments can be created. The oldest treatment will be overwritten when a new one is created manually. During synchronisation via ioDent, the treatments to be deleted must be selected and deleted manually.

Ensure that the correct patient ID and the associated tooth position have been selected for the documentation.

Complete treatment

The patient ID must be completed after treatment has been carried out.

- > Created treatments can be deleted on the control unit.
- > The documentation remains on ioDent and the USB stick.
- > Final deletion can be carried out in ioDent or on the USB stick.

The patient ID and tooth position must be created.

Start scan function

> Tap on the Scan icon.
> Multiple materials can be recorded consecutively.
> Position the QR code 10-15 cm (4-5 inches) in front of the display, so that it is shown clearly.
> A green frame appears when the scan has been successful. The material data cannot be changed.
The QR code must be generated in line with ISO/IEC 15415, in order to be able to use the scan function.

The display brightness can be adapted in order to make the QR code easier to read.

If the QR code is not recognised, tap on the photo icon to initiate the scan manually.
The material number and material name can be entered manually.

> The scanned material can be allocated to one or more tooth positions.
> Additional photos may be taken for each material.
> The materials list will be displayed for the respective patient ID.

Check that the scanned code is correct.

> The treatment and all recorded materials can be deleted on the control unit.
> Final deletion can be carried out in ioDent.

Certificate renewal

> An active WiFi connection is required to renew the device certificate.
> The required one-time password must be requested from an authorized service partner.

Connecting to the ioDent platform

> An active WiFi connection is required to connect the control unit to ioDent.
> Generate the code to register the control unit.
> To connect the control unit permanently to your ioDent account, enter the registration code manually in your ioDent device management or scan the QR code on the display.

Check the transferred data for completeness and correctness.

Connecting the medical device to an IT network or changing an IT network can lead to previously unidentified risks to patients, operators or third parties. The operator of the IT network is responsible for identification, analyzing, evaluating and controlling these risks. Changes to the IT-Network include changes in the IT-network configuration, connection of additional items to the IT-Network, disconnecting items from the IT- Network, update of equipment connected to the IT-Network, and upgrade of equipment connected to the IT-Network.

Application layer protocols	HTTP, MQTT
Presentation and transport protocols	TLS >= 1.2, TCP
Port	443
Endpoints that must not be blocked by the firewall	*.azure-devices-provisioning.net (device provisioning) *.azure-devices.net (iot hub) *.blob.core.windows.net (file download) cert.iodent.com (certificate server) wh.com (internet status)

Follow the instructions and safety notes in the Osstell Beacon Instructions for Use.

Connecting to the Osstell Beacon

> Insert the Osstell dongle into the USB-C interface.
> ISQ values will be displayed in the patient ID.

Unrestricted connection

Each active Osstell Beacon connects automatically to the control unit.

Restricted connection with serial number

> Enter the serial number of the Osstell Beacon in the settings to establish a connection with the control unit.
> Delete the serial number in the settings to disconnect from the Osstell Beacon.

Check the transferred data for completeness and correctness.

9. System messages

System messages will be shown on the display and are divided into 4 categories:

Icon	Colour	System message
	Blue	Information
	Orange	Warning
	Red	Error
	Green	Update completed successfully

> A remedial measure is shown on the display for each system message.
> If the described system message cannot be resolved, the unit will need to be inspected by an authorized W&H service partner.
> The system message can be closed via the display or by pressing the pedal.
> In case of a total system failure, switch the control unit off and on again.

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, for example: 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) or 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 W&H universal support after 250 processing cycles.

> Clean the control unit immediately after every treatment.
> Wipe the control unit, the universal support and the stand with disinfectant.

Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step after cleaning.

Universal support / Stand

Do not place the universal support or the stand in liquid disinfectant or in an ultrasonic bath.

Universal support / Stand

> Clean the universal support and the stand under running tap water (< 35°C / < 95°F).
> Rinse and brush off all external surfaces.
> Remove any liquid residues using compressed air.

Control unit

Do not immerse the control unit 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).

Control unit / Universal support / Stand

W&H recommends wiping down with disinfectant.

Evidence of the basic suitability of the control unit, universal support and the stand for effective manual disinfection was provided by an independent test laboratory using the disinfectants “mikrozid® AF wipes“ (Schülke & Mayr GmbH, Norderstedt) and “CaviWipes™” (Metrex).

Universal support / Stand

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 and washer disinfector adaptors.

The control unit and foot control are not approved for automated cleaning and disinfection.

Evidence of the basic suitability the universal support and the stand 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

Universal support / Stand

> Ensure that the universal support and the stand are completely dry after cleaning and disinfection.
> Remove liquid residues using compressed air.

Universal support / Stand

> Check the universal support and the stand after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess the universal support and stand that are still soiled.
> Sterilize the universal support following cleaning and disinfection.

Universal support

Pack the universal support 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 method.
> The sterilization package must be large enough for the sterilization goods.
> The loading sterilization package must not be under tension.

Universal support

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 universal support.

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
> "Gravity-displacement cycle" (type N)**
  121°C (250°F) for at least 30 minutes
> Maximum sterilization temperature 135°C (275°F)

Evidence of the basic suitability of the universal support 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)), the Systec VE-150* steam sterilizer (Systec) and the CertoClav MultiControl MC2-S09S273** steam sterilizer (CertoClav GmbH, Traun).

"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*/**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 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**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

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

Universal support

> Store sterile goods dust-free and dry.
> The shelf life of the sterile goods depends on the storage conditions and type of packaging.

11. 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

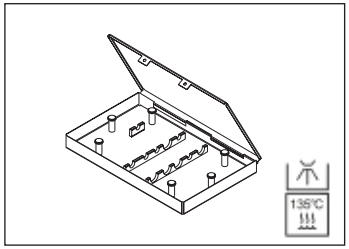
In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

Ensure that the medical device has been completely processed before returning it.

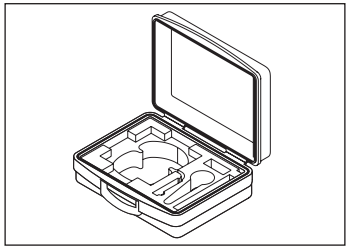
Always return equipment in the original packaging.

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

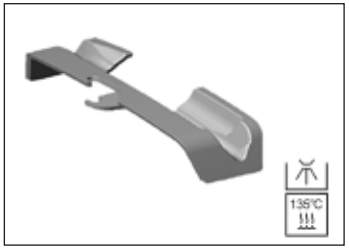
Use only original W&H accessories and spare parts or accessories approved by W&H.
Suppliers: W&H partners (Link: https://www.wh.com)



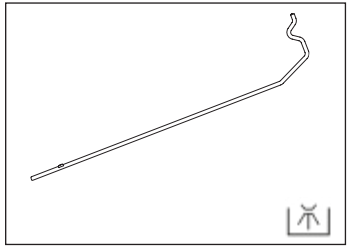
04013500
Cassette



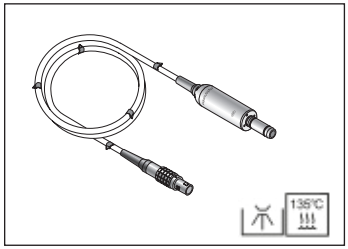
08237370
Transportation case



07721800
Universal support



04005900
Stand



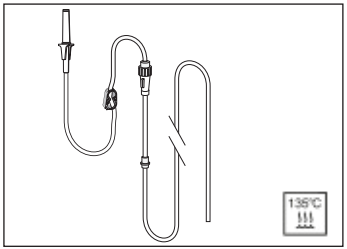
30281000
EM-19 LC motor with electrical contacts and 1.8 m cable

30497000*
Foot control S-N3

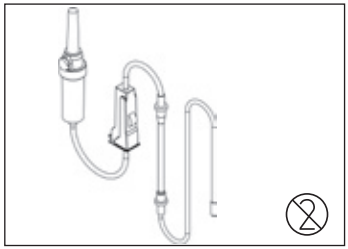
30495001*
Foot control S-NW3

* Information on the compatibility of the foot control with the relevant control unit can be found in the chapter 'Scope of delivery'.

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



04719400
Irrigation tubing set 2.2 m



04363600
Irrigation tubing set 2.2 m (6 pcs)

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

13. Technical data

Control unit	SI-2100	SI-2101	SI-2102
Mains voltage:	100 – 240 VAC		
Frequency:	50 – 60 Hz		
Maximum power consumption:	220 VA		
Maximum power output:	80 W		
Maximum torque at motor:	6.2 Ncm		
Speed range on the motor:	200 – 40,000 rpm		
Coolant flow rate at 100%:	at least 90 ml/min		
Dimensions in mm (height x width x depth):	130 x 293 x 283		
Weight in kg:	2.6		

Ambient conditions

Temperature during storage and transport:	-30°C to +70°C (-22°F to +158°F)
Humidity during storage and transport:	8 % to 80 % (relative), non-condensing
Temperature during operation:	+10°C to +30°C (+50°F to +86°F)
Humidity during operation:	15 % to 80 % (relative), non-condensing

Technical data

WIFI	
Frequency band:	2.4 GHz ISM Band (2.400 – 2.4835 GHz)
Transmitting power:	max. 20dBm
Modulation:	Single User / OFDMA Multi-User
Channels:	13 Channels with 20MHz spacing / 11 Channels with 40MHz spacing
Bluetooth Low Energy (SI-2101, SI-2102)	
Frequency band:	2.4 GHz ISM Band (2.402 – 2.480 GHz)
Transmitting power:	Class 2:2.5 mW (+4 dBm)
Modulation:	GFSK
Channels:	40 Channels with 2MHz spacing

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 equipment (protective earth conductor used for functional earth connection only!)

The medical device is classed as equipment without protection against the ingress of water (IPX0).

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

14. 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.

15. Disposal

Ensure that the parts are not contaminated on disposal.

Follow your local and country-specific laws, directives, standards and guidelines for disposal.

> Medical device
> Waste electrical equipment
> Packaging

W&H course certificate

for the user

The user has been trained to use the medical device correctly in accordance with the legal regulations (medical devices marketing regulations, medical devices act). Particular attention has been paid to the chapters on safety notes, start-up, operation, hygiene and maintenance, and service (regular inspections).

Product name	Serial number (SN)
Manufacturer with address	
Distributor with address	

Name of the user	Date of birth and/or personnel number
Hospital/dental practice/department with address	
Signature of the user	
The signature confirms that the user has been trained to use the medical device and has understood the content.	

Name of the instructor	Date of instruction
Address of the instructor	
Signature of the instructor	

W&H course certificate

for the instructor

The user has been trained to use the medical device correctly in accordance with the legal regulations (medical devices marketing regulations, medical devices act). Particular attention has been paid to the chapters on safety notes, start-up, operation, hygiene and maintenance, and service (regular inspections).

Product name	Serial number (SN)
Manufacturer with address	
Distributor with address	

Name of the user	Date of birth and/or personnel number
Hospital/dental practice/department with address	
Signature of the user	
The signature confirms that the user has been trained to use the medical device and has understood the content.	

Name of the instructor	Date of instruction
Address of the instructor	
Signature of the instructor	

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 12 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.

12 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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