

# Instructions for Use

Edition USA



CE  
0297

amadeo

M-MH40

M-UK1023, M-UK1015, M-UK1010

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# Symbols



**WARNING!**  
(if persons could be injured)



Sterilizable up to the stated  
temperature



Do not dispose of with  
domestic waste



**ATTENTION!**  
(if property could be damaged)



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 property



Manufacturer



Serial number



Medical Device



Date of manufacture



Type B applied part (not  
suitable for intracardiac  
application)



Thermo washer disinfectable



Catalogue number



Not for re-use

# Symbols



Follow Instructions for Use

**VA**

Power consumption  
(volt-ampere)

**A**

Electric current (ampere)



Class II equipment



Electric fuse

**Hz**

Frequency (hertz)



Foot control



Earth



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. 25UX – Control No.



Off

**V**

Electric voltage (volt)



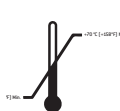
On

**AC**

Alternating current

# Symbols

**rpm** Revolutions per minute  
(= rpm)



Temperature limitation

**R<sub>x</sub>**<sub>only</sub>

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.



This way up



Humidity limitation



Fragile, handle with care



Data structure in accordance with Health Industry Bar Code



Keep dry



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



“Der Grüne Punkt” The Green Dot) trademark of Duales System Deutschland GmbH

# 1. Introduction

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## **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.

## **Indications for use**

The drive unit for surgical transmission instruments is indicated for: drilling, milling, cutting, sawing; screwing (for positioning) of osteosynthesis screws, implants and plate systems in soft and hard tissue.

Including: ENT surgery and Maxillofacial surgery, Spine surgery, Orthopaedic and General surgical procedures.



Misuse may damage the medical device and hence cause risks and hazards for patients, users 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

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## Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when compliance with the following instructions is ensured:

- > 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 68).
- > 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 device invalidates all claims under warranty and any other claims.

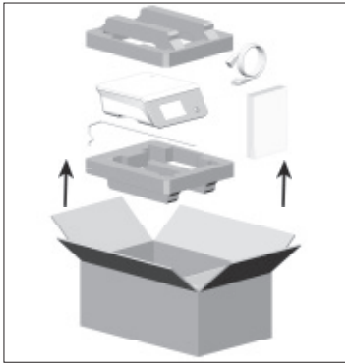
Improper use, unauthorized assembly, modification or repair to the medical device, non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.



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



## 2. Unpacking



Lift out the insert with the control unit. Remove the mains cable, irrigant support and Instructions for Use.

W&H packaging is environmentally friendly and can be disposed of by industrial recycling companies. However, we recommend that you keep the original packaging.

### 3. Scope of delivery

Control unit		M-UK1023 30387000	M-UK1015 30388000	M-UK1010 30389000
REF 04005900	Irrigant support		X	
Mains cable country-specific			X	

#### Optional included in set

REF 30264000	Foot control S-NW
REF 30285000	Foot control S-N2
REF 08174800	Irrigation tubing set 3,8 m MED (6 pcs, disposable)
REF 30393000	Motor M-MH40 with 3,5 m cable
REF 04006800	Locking pin (2 pcs)

## 4. Safety notes

## Control unit / Motor



- > Before using the medical device for the first time, store it at room temperature for 24 hours
- > Check the medical device and the motor with cable for damage and loose parts every time before use.
- > Do not operate the medical device and the motor with cable if it is damaged.
- > Check the parameter settings every time the device is restarted.
- > Perform a test run prior to every treatment.
- > 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.



- > Do not twist or kink the motor cable! Do not coil it too tightly!
- > Moisture in the motor with cable may cause a malfunction! (Risk of short circuit)
- > The motor with cable is lubricated for life and therefore should not be lubricated.



- > The medical device is not approved for operation in potentially explosive atmospheres.
- > The medical device is not approved for operation in oxygen rich Environment.



- > Use only original W&H fuses.
- > Never touch the patient and the electrical connections on the control unit simultaneously.



The control unit is classed as “conventional equipment” (closed equipment without protection against the ingress of water).



Use the control unit in the WS-75 (20:1) ratios exclusively with the contra-angle handpieces approved by W&H. 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.



### **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.



### **Mains cable / Power switch**

- > Only use the mains cable supplied.
- > Plug the mains cable only into an earthed power socket.
- > 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.



### **Rotational energy**

Deceleration of the bur can, cause the selected torque to be temporarily exceeded, compared to the value set, as a result of the rotational energy stored in the drive system.



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.

Note that when using or setting low speeds, the operation or run-down of rotary instruments is more difficult to detect.



### Control unit

#### 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.



### Motor with cable

#### Risks due to electromagnetic fields

This medical device is suitable for use on patients with cardiac pacemakers, if a safety distance between the medical device and the cardiac pacemaker of at least 15 cm (5,9 inch) is maintained.

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

- > Find out if the patient has other active implantable medical devices (AIMD) before using the medical device and inform about the risks.
- > Do not place the applied part on the patient's body



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

## Safety notes

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### Coolant supply



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



- > Always ensure correct operating conditions and that sufficient and adequate coolant is delivered.
- > Always provide sufficient coolant and ensure the appropriate 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.

### Irrigation tubing set



- > Note the expiration date and only use disposable irrigation tubing with undamaged packaging.
- > Replace the disposable irrigation tubing immediately after every treatment.
- > Follow your local and country-specific laws, directives, standards and guidelines for disposal.

## Safety notes

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### **Intermittent periodic duty S3 (3 min ON / 5 min OFF)**



The medical device is designed for intermittent periodic duty S3 with 3 minutes ON and 5 minutes OFF. If the specified operating mode is observed no overheating of the system and therefore no injury to the patients, users or third parties arises. The responsibility for the use and timely shutdown of the system lies with the user.

### **Transmission instrument**



- > Follow the directions and safety notes in the Instructions for Use of the transmission instrument.
- > Only use transmission instruments with an ISO 3964 (DIN 13940) compatible coupling system and manufacturer approved transmission instruments.
- > Follow the directions of the manufacturer of transmission instrument with reference to transmission ratio, maximum speed and maximum torque.

### **Hygiene and maintenance prior to initial use**



- > Clean and disinfect the control unit, the motor with cable and the irrigant support.
- > Sterilize the motor with cable.



## Safety notes

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### Test run



Do not hold the motor with transmission instrument at eye level.

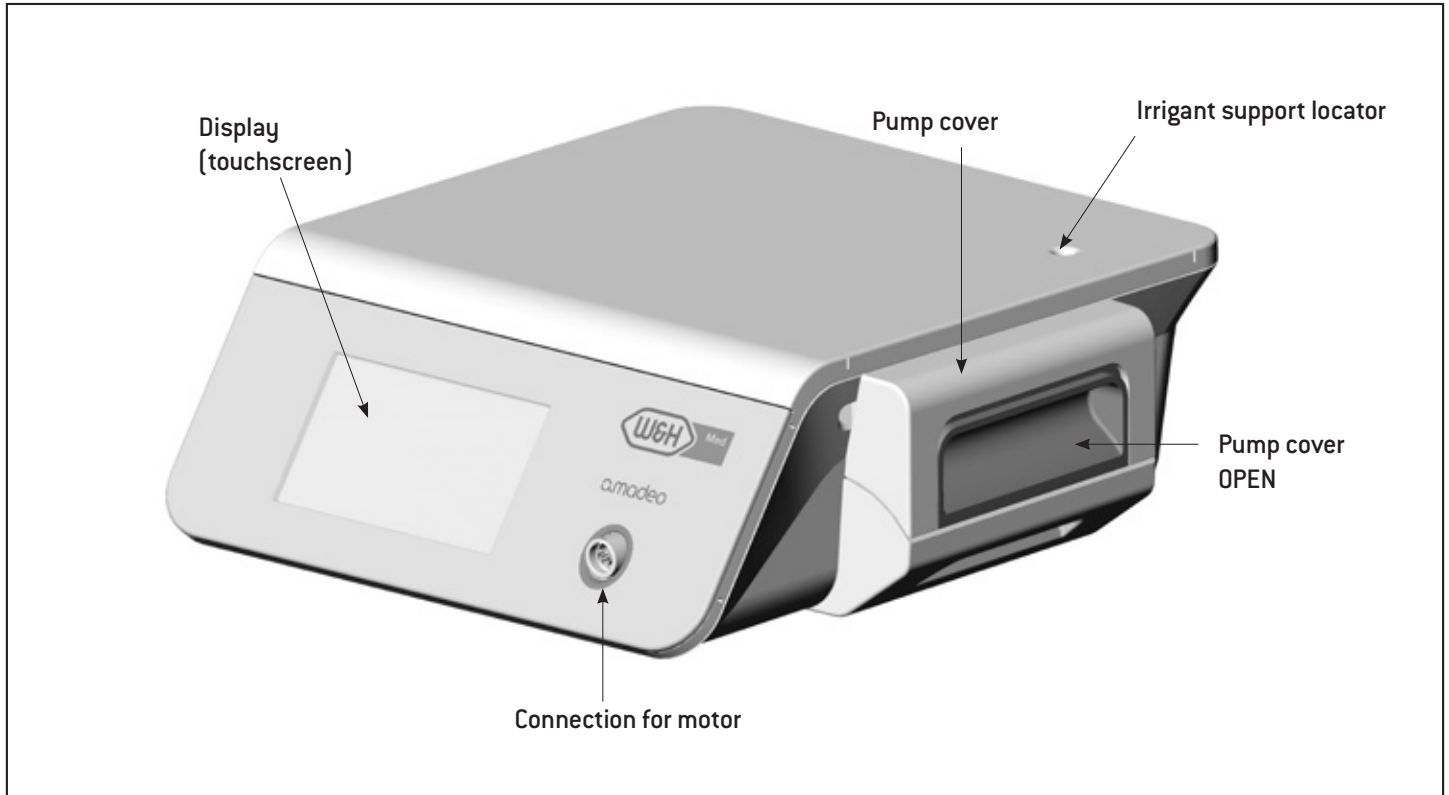
- > Connect the transmission instrument to the motor. Point the transmission instrument with the head facing downwards.
- > Operate the motor with the foot control.

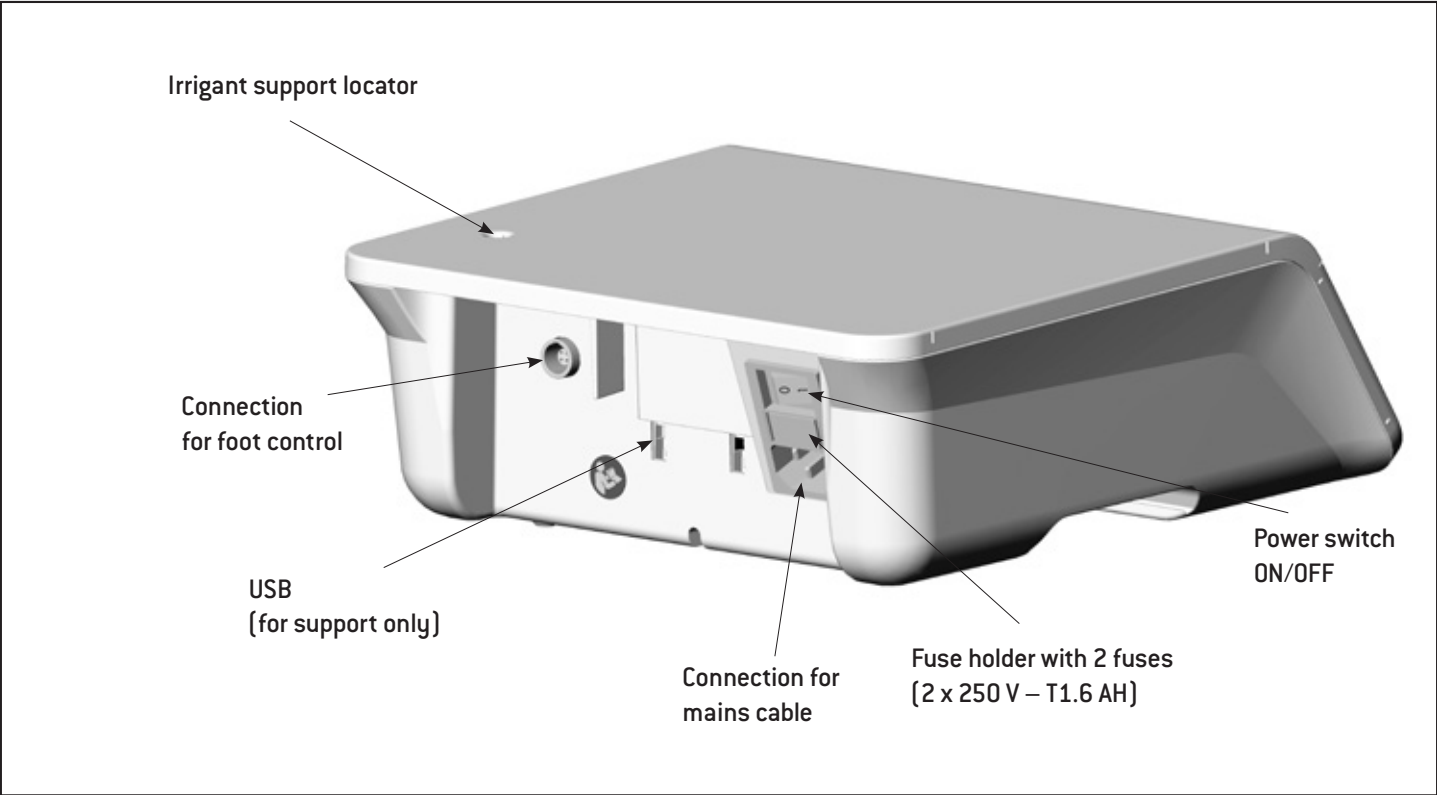


In the event of operating malfunctions (e.g., vibrations, unusual noise, resp. overheating) stop the medical device immediately and contact an authorized W&H service partner.

## 5. Description

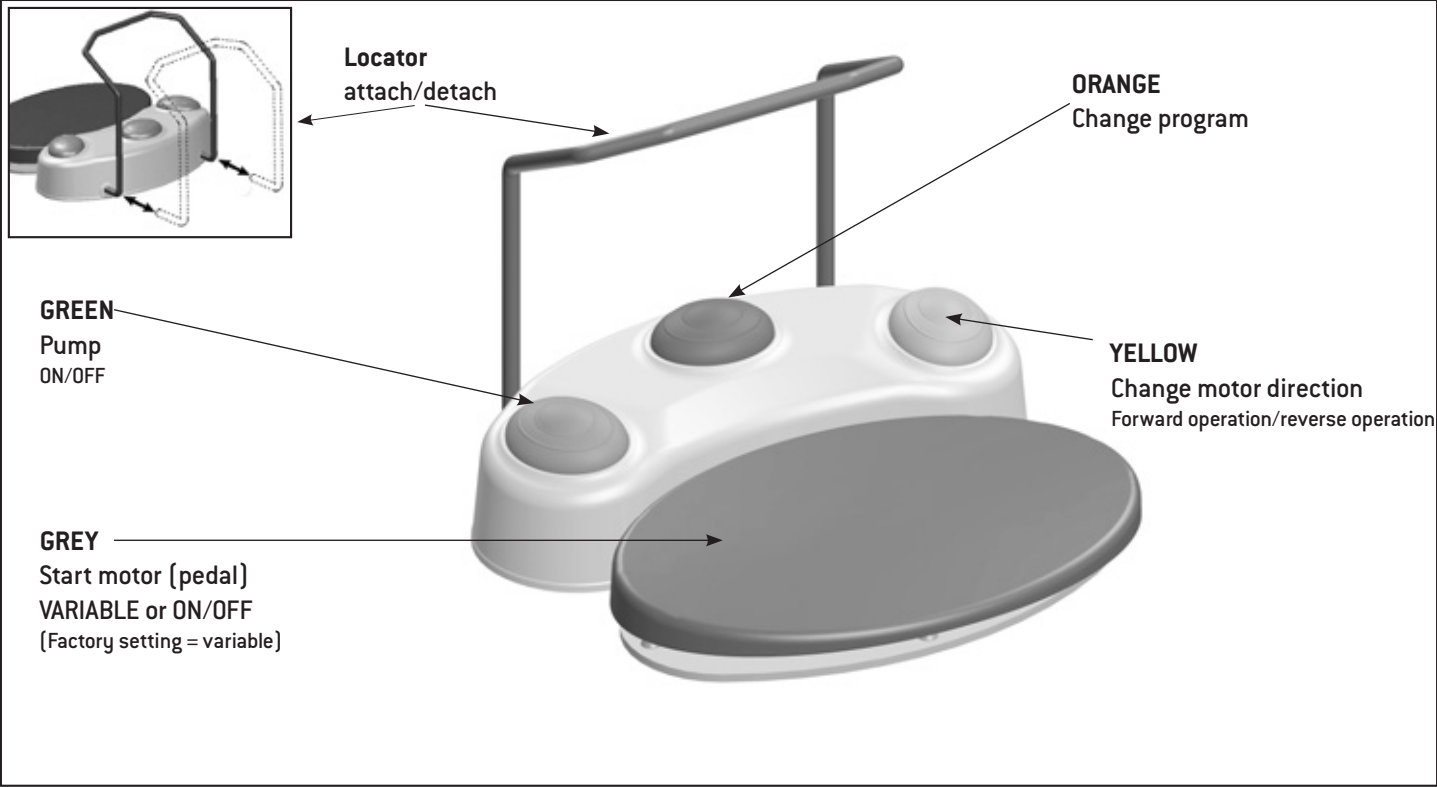
of front panel





# Description

# of foot control S-N2/S-NW



## **ORANGE**

### **S-N2 / S-NW: Change program**

Press the ORANGE button to change programs in ascending order. The motor direction is automatically set to forward operation every time the program is changed.



When changing to a program with drilling or sawing function, a longer acoustic signal sounds (risk of injury).

## **GREEN – pump ON/OFF**

Only when the motor is stationary can the pump be switched on or off by pressing the GREEN button of the foot control.

## **YELLOW – change motor direction**

### **Forward operation/reverse operation**

Press the YELLOW button to change from forward operation to reverse operation. A signal sounds on selection and the “Forward/reverse operation mode” symbol flashes. Before the motor starts in reverse operation, 3 audible signals are given.

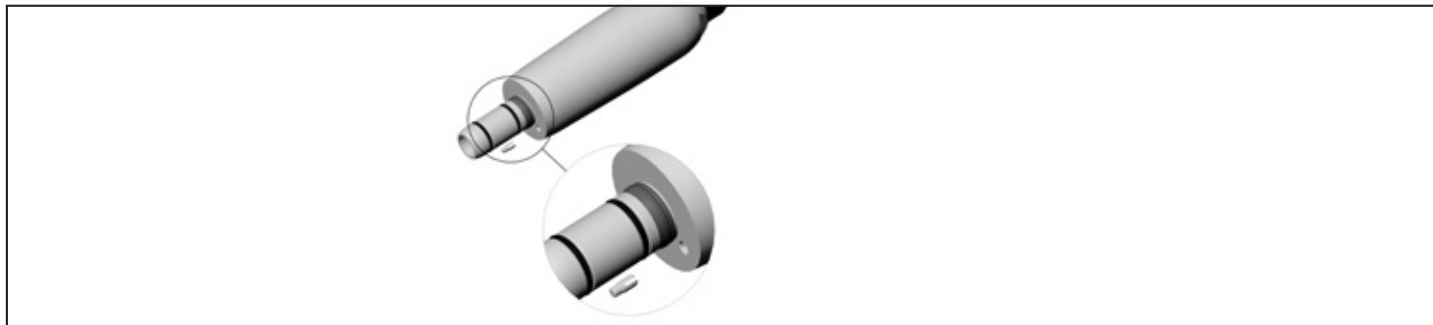
## Description

## of motor with cable



The motor with cable must not be disassembled.

The motor with cable must not be oiled (pre-oiled for entire service life).



To prevent the instrument on the motor attachment from turning during transmission of high torques, the locking pin supplied can be pushed into the designated hole (see illustration). The locking pin can only be used in combination with straight and contra-angle handpieces that have corresponding holes.



The motor with cable is a type B applied part (not suitable for intracardiac application).

### Temperature information



Temperature of the medical device on the operator side:

maximum 48°C (118.4°F)

Temperature of the medical device on the patient side (metal):

maximum 51°C (123.8°F)

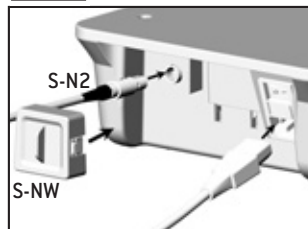
## 6. Start-up




Place the medical device on a flat level surface.



Ensure that the medical device can be disconnected from the power supply at any time.




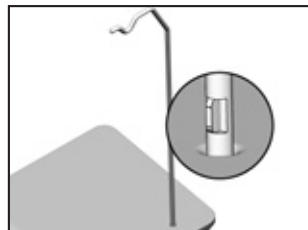
- 1** Connect the mains cable and foot control.

 Pay attention to the positioning!




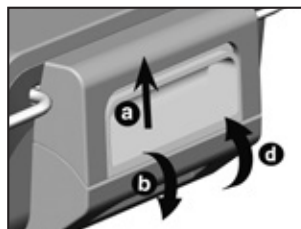
- 2** Connect motor cable.

 Pay attention to the positioning!



- 3** Insert the irrigant support.

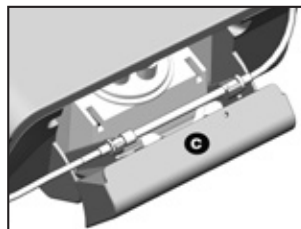
 Pay attention to the positioning!  
(Maximum load capacity 1.5 kg)



- 4** Insert the irrigation tubing.

> Open the pump cover [a,b].

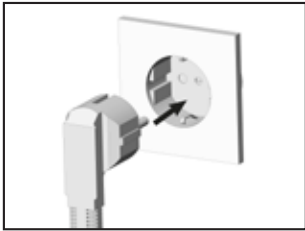
> Insert the irrigation tubing [c].



> Close the pump cover [d].

## 7. Control unit

## switching on and off



### Switching on the control unit

- 1 Plug the mains cable into an earthed power socket.

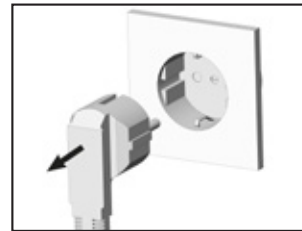


- 2 Switch on the control unit at the power switch.



### Switching off the control unit

- 1 Switch off the control unit at the power switch.



- 2 Pull the power plug out of the socket.





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 on your control unit and follow the directions of the setup wizard.

The set-up wizard guides you through the various set-up stages up to the main menu:

> Language selection

> Set Up Medical Device

Customized:

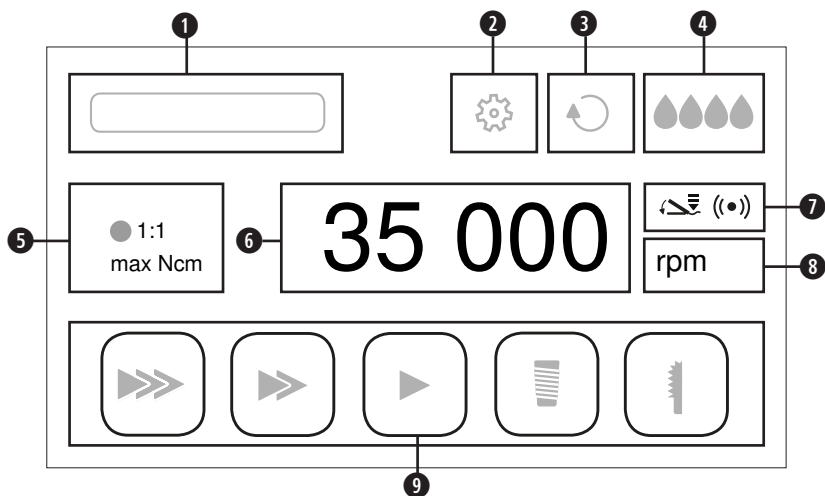
Create a user

Standard:

Default settings

## 9. Control unit operation

Main menu



<b>1</b>	Application area	<b>6</b>	Set speed / torque
<b>2</b>	Setup	<b>7</b>	Foot control
<b>3</b>	Forward/reverse operation mode	<b>8</b>	Progress display mode
<b>4</b>	Set coolant volume	<b>9</b>	Programs
<b>5</b>	Set program		

# Control unit operation

---

## My favorites



### Select drill protocol group

An activated drill protocol cannot be deleted



### Edit

> Adjust factory setting of drill protocol groups.

> Create drill protocol



### Copy



### Rename



### Activate



### Delete

# Control unit operation

16  
● 1:1  
max. 50 Ncm

## Set program



### Transmission

### rpm Speed

At 40,000 rpm the accuracy of the set speed is  $\pm 10\%$ .

### Ncm Torque

Adjustment range 5 – 80 Ncm with WS-75 only.

The motor switches off automatically when the set torque is reached in forward and reverse operation modes.

The accuracy of the set torque during the P4 (screw function) and P6 (thread cutting function) programs in the 20 – 50 Ncm range for the W&H WS-75 contra-angle handpiece is  $\pm 10\%$ . Greater deviations may be encountered with other contra-angle handpieces.

rpm  
(Ncm)

## Progress display mode



### Bar



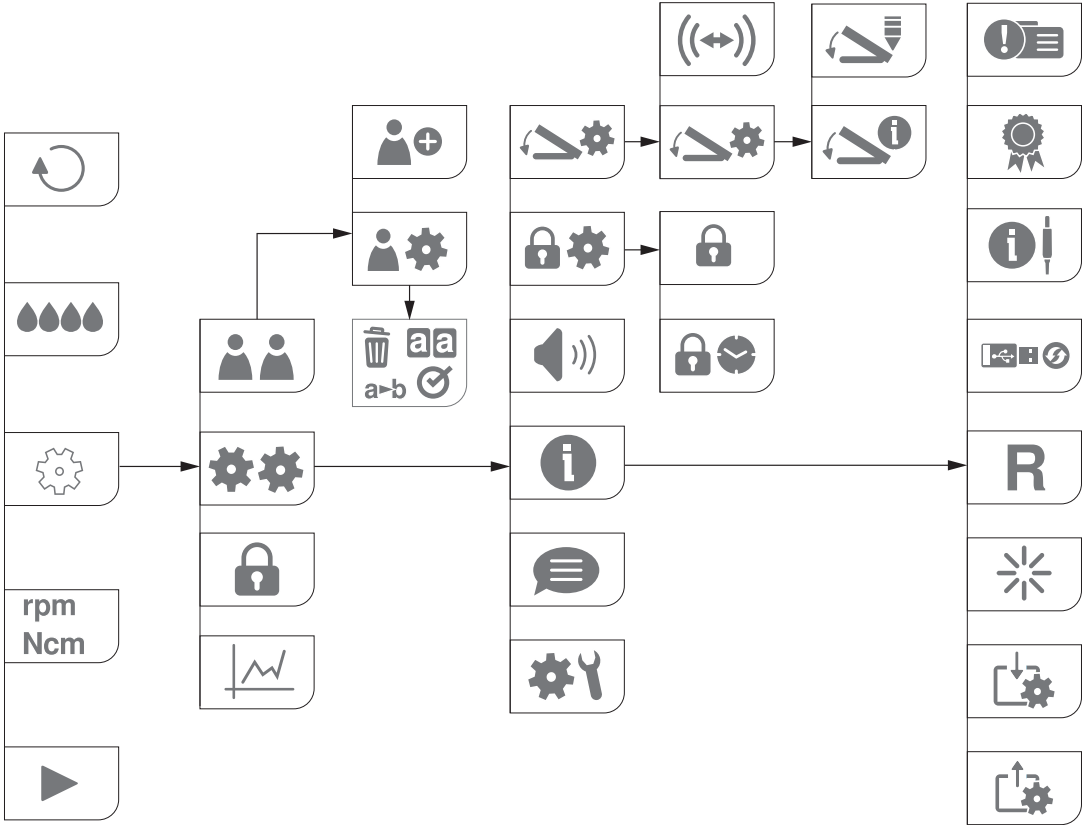
### Percent

100

### Total

Control unit operation

Menu Navigation



# Control unit operation



## User

An activated user cannot be deleted



## Add user



## Manage user

User settings: Copy, Rename, Activate, Delete



## Foot control



## Pairing – S-NW



## Properties



## Variable



## ON/OFF



## System



## Set screen lock

Activating / deactivating screen lock



## Screen lock



## Interval

Interval: Select time



## Sound

Activating/deactivating



## Language

Select language



## System check

Test run



## Torque curve

# Control unit operation

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**Device info**



**Service**



**Licenes**

GPL: GNU General Public License

LGPL: GNU Lesser General Public License



**Module info**



**User interface**



**Motor control unit**



**Foot control**



**Software update**



**Reset**

Restore factory settings



**Restart**

Control unit restarts automatically



**Import user settings**



**Export user settings**

# Control unit operation



Confirm/save



Favorite selected



black = information  
green = Information with selection option



red = error message, work cannot be continued  
orange = error message, work can be continued



red = replace batteries



Foot control S-NW



Foot control S-N2



Drill function



Drill function



Drill function



Screw function



Saw function



Thread cutting function






Fast screw function





## Control unit operation

## Factory settings

ENT Surgery			
Transmission	1:2	WS-75 (20:1)	WS-75 (20:1)
Speed rpm	80,000	2,000	15
Setting range rpm	400 – 80,000	10 – 2,000	10 – 50
Motor direction of rotation	forward	forward	forward
Pump	on	on	off
Torque Ncm (Setting range Ncm)	max	max	40 (5-80)





## Control unit operation

## Factory settings

<b>ENT Surgery 2</b>		
<b>Transmission</b>	1:1	1:1
<b>Speed rpm</b>	20,000	10,000
<b>Setting range rpm</b>	200 – 40,000	200 – 40,000
<b>Motor direction of rotation</b>	forward	forward
<b>Pump</b>	on	on
<b>Torque Ncm (Setting range Ncm)</b>	max	max




## Control unit operation

## Factory settings

<b>Maxillofacial Surgery</b>				
<b>Transmission</b>	1:1	1:1	1:2	S-8
<b>Speed rpm</b>	10,000	40,000	80,000	40,000
<b>Setting range rpm</b>	200 - 40,000	200 - 40,000	400 - 80,000	200 - 40,000
<b>Motor direction of rotation</b>	forward	forward	forward	forward
<b>Pump</b>	on	on	on	on
<b>Torque Ncm</b>	max	max	max	max




## Control unit operation

## Factory settings

General Surgical Procedures			
Transmission	WS-75 (20:1)	WS-75 (20:1)	WS-75 (20:1)
Speed rpm	15	1,000	150
Setting range rpm	10 – 50	10 – 2,000	10 – 200
Motor direction of rotation	forward	forward	forward
Pump	off	off	off
Torque Ncm (Setting range Ncm)	30 (5-80)	max	70 (5-80)



## Control unit operation

## Factory settings

<b>Orthopedics</b>			
<b>Transmission</b>	1:1	1:1	1:1
<b>Speed rpm</b>	40,000	5,000	8,000
<b>Setting range rpm</b>	200 – 40,000	200 – 40,000	200 – 40,000
<b>Motor direction of rotation</b>	forward	forward	forward
<b>Pump</b>	on	on	on
<b>Torque Ncm</b>	max	max	max

## Control unit operation

## Factory settings

<b>Spine Surgery</b>		
<b>Transmission</b>	1:1	1:2
<b>Speed rpm</b>	40,000	80,000
<b>Setting range rpm</b>	200 – 40,000	400 – 80,000
<b>Motor direction of rotation</b>	forward	forward
<b>Pump</b>	on	on
<b>Torque Ncm</b>	max	max



The thread cutter function can be selected when creating a new drill protocol.

### Thread-cutter function (chip breaker mode)



When the pedal (grey) on the foot control 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.

## 10. Error messages






The error message disappears when it is clocked or when the pedal (grey) on the foot control is released.

Icon	Description of error	Solution
	WARNING FOOT CONTROL	<ul style="list-style-type: none"><li>&gt; Check plug contacts of foot control</li><li>&gt; Check the plug contacts of the dongle</li></ul>
	WARNING MOTOR	<ul style="list-style-type: none"><li>&gt; Check the plug contacts of the motor</li><li>&gt; Allow motor to cool for at least 10 minutes</li></ul>
	WARNING STORAGE DEVICE <ul style="list-style-type: none"><li>&gt; Insufficient memory available</li><li>&gt; Unknown file system</li><li>&gt; The write protection is active</li><li>&gt; Unknown storage device</li></ul>	<ul style="list-style-type: none"><li>&gt; Plug in a USB stick with sufficient memory</li></ul>
	WARNING OVERHEATING	<ul style="list-style-type: none"><li>&gt; Switch off the control unit</li><li>&gt; Allow the control unit to cool for at least 10 minutes</li><li>&gt; Switch on the control unit</li></ul>



## Error messages

Icon	Description of error	Solution
	WARNING TIME-OUT	<ul style="list-style-type: none"><li>&gt; Release the pedal (grey) on the foot control</li><li>&gt; Allow motor to cool for at least 10 minutes</li></ul>
	SYSTEM ERROR	<ul style="list-style-type: none"><li>&gt; Switch the control unit off and back on again</li></ul> <p> If the error message appears again, contact an authorized W&amp;H service partner immediately.</p>

- > If the described problem cannot be resolved, the unit will need to be inspected by an authorized W&H service partner.
- > 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 the Food and Drug Administration (FDA) and 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 motor with cable after 500 processing cycles or one year.



Clean the medical device immediately after every treatment.

- ❶ Disconnect the motor with cable, foot control and power supply from the control unit.  
Check for any damage on the outer surface of each component.
- ❷ Lightly wipe all external surfaces of the control unit and foot control with a soft, lint-free cloth moistened with a neutral detergent for medical devices according to the manufacturer's instruction
- ❸ Use a clean cloth moistened with disinfectant and wipe all surfaces. Make sure all surfaces remain visibly wet at room temperature for at least the minimum time specified in the instructions for use supplied by the disinfectant manufacturer.



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

### Motor with cable / Irrigant support



Do not immerse the motor with cable or the irrigant support in liquid disinfectant or in an ultrasonic bath.

### Motor with cable / Irrigant support

- > Clean the motor with cable and the irrigant support under running tap water [ $< 35^{\circ}\text{C}$  /  $< 95^{\circ}\text{F}$ ].
- > Rinse and brush off all internal and external surfaces.
- > Remove liquid residues using compressed air.

### Control unit



Do not immerse the control unit in water or clean it under running water.

- > Lightly wipe all external surfaces of the control unit and foot control with a soft, lint-free cloth moistened with a neutral detergent for medical devices. Clean surfaces until all visible soil is removed.
- > Remove the detergent from all surfaces using a lint-free cloth moistened with distilled water, deionized water, or demineralized water.



Evidence of the medical device's basic suitability for effective manual cleaning was provided by an independent test laboratory using the cleaning agent "LUMINOX<sup>®</sup>" (Alconox).



Evidence of the medical device's basic suitability for effective manual cleaning was provided by an independent test laboratory using tap water  $< 35^{\circ}\text{C}$  and towels/cloth "WIPEX<sup>®</sup> WET DESI premium" (NORDVLIES GmbH, Bargteheide).

## Control unit / Motor with cable / Irrigant support



W&H recommends wipe-down disinfection.



Evidence of the basic suitability of the control unit, motor with cable and the irrigant support for effective manual disinfection (intermediate level) was provided by an independent test laboratory using the disinfectant “CaviWipes™” (Metrex).

## Control unit



W&H recommends wipe-down disinfection.



After removing all visible soil, use a clean cloth moistened with disinfectant and wipe all surfaces. Make sure all surfaces remain visibly wet at room temperature for at least the minimum time specified in the instructions for use supplied by the disinfectant manufacturer.

### Motor with cable / Irrigant support



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.



The control unit is not approved for automated cleaning and disinfection.



Evidence of the basic suitability of the motor with cable and irrigant support 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



## **Motor with cable / Irrigant support**

- > Ensure that the motor with cable and the irrigant support are completely dry internally and externally after cleaning and disinfection.
- > Remove liquid residues using compressed air.



### Inspection – Motor with cable / Irrigant support



- > Check the motor with cable and the irrigant support after cleaning and disinfection for damage, visible residual soiling and surface changes.
- > Reprocess any motor with cable and irrigant support that are still soiled.
- > Sterilize the motor with cable following cleaning and disinfection.

## Motor with cable



Pack the motor with cable in FDA cleared 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 filled sterilization package must not be under tension.

## Motor with cable



W&H recommends sterilization according to ANSI/AAMI ST55 or ANSI/AAMI ST79.



- > 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 motor with cable.

## Recommended sterilization procedures

- > “Dynamic-air-removal cycle”  
132°C (270°F) for at least 4 minutes
- > “Gravity-displacement cycle”  
121°C (250°F) for at least 30 minutes
- > Maximum sterilization temperature 135°C (275°F)

## Motor with cable



Evidence of the medical device's basic suitability 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)) and the CertoClav MultiControl MC2-S09S273\*\* steam sterilizer (CertoClav GmbH, Traun).

“Dynamic-air-removal cycle”:	132°C (270°F) – 4 minutes*/**
“Gravity-displacement cycle”:	121°C (250°F) – 30 minutes**

Minimum drying times:

“Dynamic-air-removal cycle”:	132°C (270°F) – 30 minutes**
“Gravity-displacement cycle”:	121°C (250°F) – 30 minutes**

\* EN 13060, EN 285, ISO 17665

\*\* ANSI/AAMI ST55 , ANSI/AAMI ST79

## Motor with cable



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

## 12. Servicing

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### **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

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## 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.

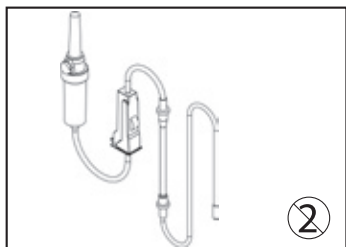
> Do not coil the cable around the motor and do not twist or kink the motor cable. (Risk of damage)

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



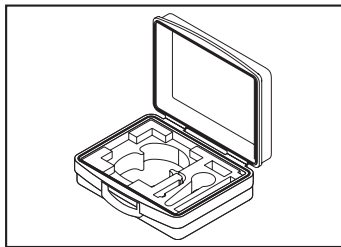
Use only original W&H accessories and spare parts or accessories approved by W&H.

Suppliers: W&H partners



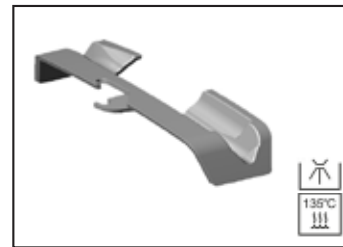
**08174800**

Irrigation tubing set 3,8 m MED  
(6 pcs)



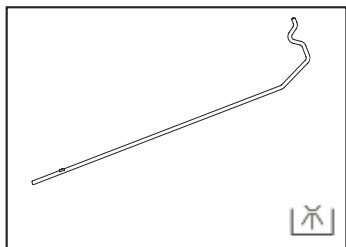
**07962790**

Transportation case



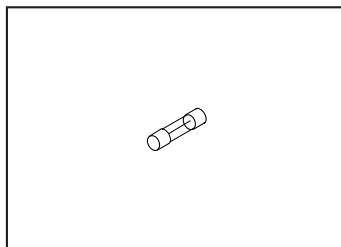
**07721800**

Universal support



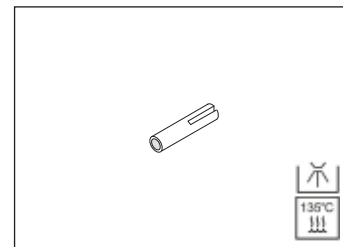
**04005900**

Irrigant support



**06352200**

Fuse (250 V - T1.6AH)

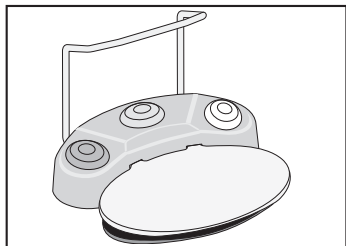


**04006800**

Locking pin



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

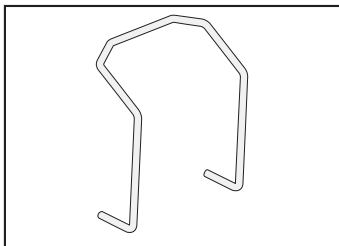


**30285000**

Foot control S-N2

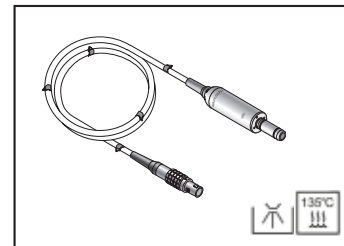
**30264000**

Foot control S-NW



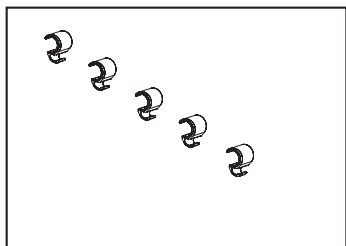
**04653500**

Locator for foot control



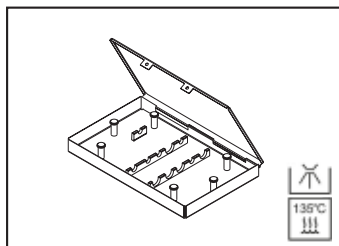
**30393000**

Motor M-MH40 with 3,5 m cable



**06290600**

Hose clips (5 pcs)



**08174810**

Cassette Amadeo

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



## 14. Technical data

Control unit	M-UK1023	M-UK1015	M-UK1010
Mains voltage:	230 V	120 V	100 V
Permissible voltage fluctuation:	220 – 240 V	110 – 130 V	90 – 110 V
Rated current:	0.3 – 0.8 A	0.3 – 1.6 A	0.3 – 1.4 A
Frequency:	50 – 60 Hz		
Mains fuse (2 pcs):	250 V – T1.6 AH		
Maximum power consumption:	170 VA	170 VA	140 VA
Maximum power output:	80 W		
Maximum torque at motor:	6.2 Ncm		
Motor speed range in the rated voltage range:	200 – 40,000 rpm		
Coolant flow rate at 100%:	min. 90 ml/min		
Operating mode	S3 (3 min ON / 5 min OFF)		
Dimensions in mm (height x width x depth):	100 x 262 x 291		
Weight in kg:	3.5		

### Ambient conditions

Temperature during storage and transport:

-40°C to +70°C (-40°F to +158°F)

Humidity for storage and transport:

8 % to 80 % (relative), non-condensing

Temperature in operation:

+10°C to +30°C (+50°F to +86°F)

Humidity in operation:

15 % to 80 % (relative), non-condensing

## Technical data

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**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 device (protective earth conductor used for functional earth connection only!)



Type B applied part (not suitable for intracardiac application)

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

## 15. Data on electromagnetic compatibility according to IEC/EN 60601-1-2

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### **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

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### **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*	
<b>Electromagnetic emissions</b>		
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	–	
<b>Immunity to electromagnetic interference</b>		
Electrostatic discharge (ESD) IEC/EN 61000-4-2	Contact discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 6$ kV, $\pm 8$ kV Air discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ 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: $\pm 2$ kV Input and output ports: $\pm 1$ kV	
Surges IEC/EN 61000-4-5	$\pm 1$ kV L – N	$\pm 2$ kV L – PE $\pm 2$ 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.

## 16. Disposal

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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

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Find your nearest authorized W&H service partner at <https://wh.com>  
Simply go to the menu option “Service” for full details.

Or simply scan the QR code.







**W&H Dentalwerk Bürmoos GmbH**  
**Ignaz-Glaser-Straße 53, 5111 Bürmoos, Austria**

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**Software version 1.X.X.**  
**Subject to alterations**