

## Instructions for use



CE  
0297

implantmed

SI-923 / SI-915

# Contents

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# W&H Symbols

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Symbols in the instructions for use



**WARNING!**  
[risk of injury]



**ATTENTION!**  
[to prevent damage occurring]



General explanations,  
without risk to persons  
or objects



Thermo washer disinfectable



Sterilizable  
up to the stated temperature



W&H Service

## For USA and Canada:

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

# W&H Symbols

## Symbols on the control unit

	Follow instructions for use		Do not dispose of with domestic waste	<b>REF</b>	Catalogue number
	Consult instructions for use		Foot switch	<b>SN</b>	Serial number
	Class II equipment		On / Off	<b>V</b>	Supply voltage of the unit
	Date of manufacture		Data matrix code for product identification e.g. for hygiene / maintenance processes	<b>AC</b>	Alternating current
	Electric fuse		MEDICAL – GENERAL MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1:2006, CAN/CSA-C22.2 No. 601.1-M90, CAN/CSA-C22.2-No. 60601-1:08, ANSI/AAMI ES 60601-1:2005 25UX (Control No.)	<b>VA</b>	Electric power input of the unit
	Not suitable for intracardiac application – Type B applied part			<b>A</b>	Supply current
				<b>Hz</b>	Frequency of the alternating current
				<b>rpm</b>	Revolutions per minute (rpm = min <sup>-1</sup> )

# W&H Symbols

## Symbols on the packaging



This way up



Temperature limit



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



Fragile, handle with care



Humidity limitation



Keep away from rain



CE 0297 from manufacturer



Der Grüne Punkt  
Identification mark of Duales  
System Deutschland AG



General symbol for  
recovery/recyclable

# Symbols

## Symbols on the irrigation tubing



Sterilization with ethylene oxide



Consult instructions for use



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



Not for re-use



CE 0481 from manufacturer



Latex-free



Not sterile



Use by



Sterilizable at the stated temperature



Batch ID



Caution, please observe accompanying documents

# 1. Introduction

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## **For your safety and the safety of your patients**

These instructions explain how to use your product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team and, of course, the safety of your patients, are of paramount importance to us.



It is therefore essential that you observe the safety notes on pages 12 to 16.

## **Intended use**

Mechanical drive unit with coolant supply for transmission instruments with coupling system according to ISO 3964 (DIN 13.940). The equipment is a drive unit for use in dental surgery, implantology and maxillo-facial surgery for treatment of dental hard tissue.

Misuse may damage the Implantmed 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 dental surgical unit Implantmed. We have based our development and design of the Implantmed on the »physician« target group.

# Introduction

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**CE** **Production according to EU Directive**  
0297 EU Directive 93/42/EEC has been used as a basis in the design and manufacture of this medical device and it applies to the dental surgical units

- > Implantmed SI-915 and
- > Implantmed SI-923

in the condition as supplied by us. This declaration does not apply to non-specified fittings, mountings etc.



## **Responsibility of the manufacturer**

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

- > The Implantmed must be used in accordance with these Instructions for use.
- > The Implantmed has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 52).
- > The electrical installation at the premises must comply with the regulations of 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 equipment invalidates all claims under warranty and any other claims.

## 2. Electromagnetic compatibility (EMC)

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### Notes on electromagnetic compatibility (EMC)

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

W&H guarantees the compliance of the device with the EMC requirements only when used with original W&H accessories and spare parts. The use of other accessories/other spare parts can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.



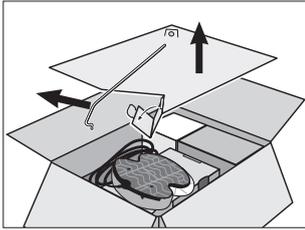
You can find the current EMC manufacturer's declaration on our website at [http://wh.com/en\\_global/emc](http://wh.com/en_global/emc) alternatively, you can obtain it directly from the manufacturer.



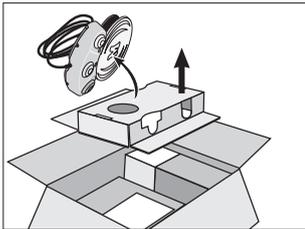
### HF communication equipment

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

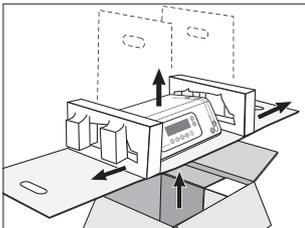
### 3. Unpacking



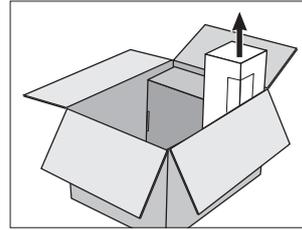
- ❶ Lift out the insert with the stand.



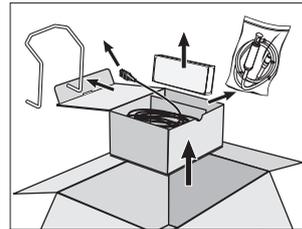
- ❷ Lift out the insert with the foot control.



- ❸ Lift out the insert with the control unit.



- ❹ Remove the irrigation tubing.



- ❺ Remove the carton with motor, accessories and instruments (optional).

W&H packaging is environmentally friendly and can be disposed of by industrial recycling companies.

However, we recommend that you keep the original packaging.

## 4. Scope of delivery

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### Control unit

- SI-923 REF 16929000 (230 V)
- SI-915 REF 16929001 (115 V)

### Mains cable

- REF 01343700 (EU)
- REF 02821400 (USA, CAN, J) / REF 03212700 (UK, IRL) / REF 02909300 (AUS, NZ) / REF 04280600 (CH) / REF 05901800 (DK)
  
- Foot control S-N1 REF 06202400
- Handle for foot control REF 04653500
- Motor with 1.8 m cable REF 06631600 incl. 5 clips REF 04019000
- Motor support REF 06177800
- Stand REF 04005900
- Locking pins REF 04006800 (2 pcs)
- Irrigation tubing REF 436360 (3 pcs, disposable)

## 5. Safety notes

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### **Please observe the following instructions under all circumstances**

- > Before using the Implantmed for the first time, store it at room temperature for 24 hours.
- > Only fit the straight and contra-angle handpieces when the motor is at a complete standstill.
- > Never touch rotary instruments that are still rotating.
- > Never touch the chuck mechanism of straight and contra-angle handpieces during operation or while they are still running down.
- > Make sure that the operation can be completed safely even if a device or instrument malfunctions.
- > Always ensure correct operating conditions and that sufficient and adequate cooling is delivered.
- > Avoid overheating at the treatment site.
- > Check the Implantmed, the straight or contra-angle handpiece and the motor with cable for damage and loose parts each time before using. Correct any faults or refer to an authorized W&H service partner (see page 52). Do not operate the Implantmed if it is damaged.
- > When changing the fuse, disconnect the unit from the power supply and only use W&H original fuses.
- > Perform a test run prior to each treatment.
- > Never touch the patient and the connections for the foot control simultaneously.
- > Check the parameter settings every time the device is restarted.
- > The ESD spring contact on the underside of the foot control must touch the floor during operation.



### **Use only suitable and serviceable tools**

Ensure that you comply with the manufacturer's instructions for surgical straight and contra-angle handpieces with respect to maximum speed, maximum torque, forward and reverse movement.



### **Inappropriate use**

Improper use, in addition to incorrect assembly, installation, modification or repairs of the Implantmed or failure to comply with our instructions invalidates all claims under warranty and any other claims.

## Safety notes

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### **Risks due to electromagnetic fields**

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

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

## Safety notes

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### **Danger zones M and G**

In accordance with IEC 60601-1/ANSI/AAMI ES 60601-1, the control unit and the motor with cable are not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.



Implantmed is not suitable for use in oxygen-enriched atmospheres.



### **Foot control**

is in accordance with IEC 60601-1/ANSI/AAMI ES 60601-1 approved for use in zone M (AP). Zone M is defined as a »medical environment« and constitutes the part of a room in which potentially explosive atmospheres may form due to the use of anaesthesia or medical antiseptics and antibacterial soaps; such atmospheres are limited and only occur very briefly.



Please note that at low speeds, it is more difficult to determine that the motor is running.

### **Control unit**

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



When using the transmission settings 20:1, Implantmed must only be employed with the following W&H-approved surgical contra-angle handpieces: WS-75 E/KM, WS-75 LED G, WI-75 E/KM and WI-75 LED G. Use of other contra-angle handpieces may result in deviation from the indicated torques and is the user's responsibility. The specified transmission ratios for the programs 1 to 5 must always be taken into consideration.

## Safety notes

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### Mains cable

Only use the mains cable supplied.

Only connect to a grounded socket outlet.



Set up the device so that the power switch is easily accessible.

In dangerous situations, the device can be disconnected from the power supply using the power switch or power cable.

The power switch can also be used to safely stop the device.

### Power failure

In the event of a power failure, if the Implantmed 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.

### Intermittent operating mode S3 (3 min/10 min)

The Implantmed is designed for intermittent operating mode S3 with an operating time of 3 minutes and an idle time of 10 minutes. If the operating mode specified is observed no overheating of the system and therefore no injury to the patient, user or third persons arises. The responsibility for the use and timely shutdown of the system lies with the user.

## Safety notes

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### Coolant

The Implantmed is designed for use with physiological saline solution. Use only suitable irrigation fluids and follow the manufacturer's medical data and instructions. Use the W&H irrigation tubing set or accessories approved by W&H.



You can purchase the coolant bottle or the coolant bag at a drugstore.



### Sterility of irrigation tubing set

Sterile irrigation tubing sets are supplied with the equipment. The irrigation tubing is a disposable article and must be discarded after each treatment. Please note the expiry date and the relevant regulations for disposal of irrigation tubing. Only use disposable irrigation tubing with undamaged packaging.



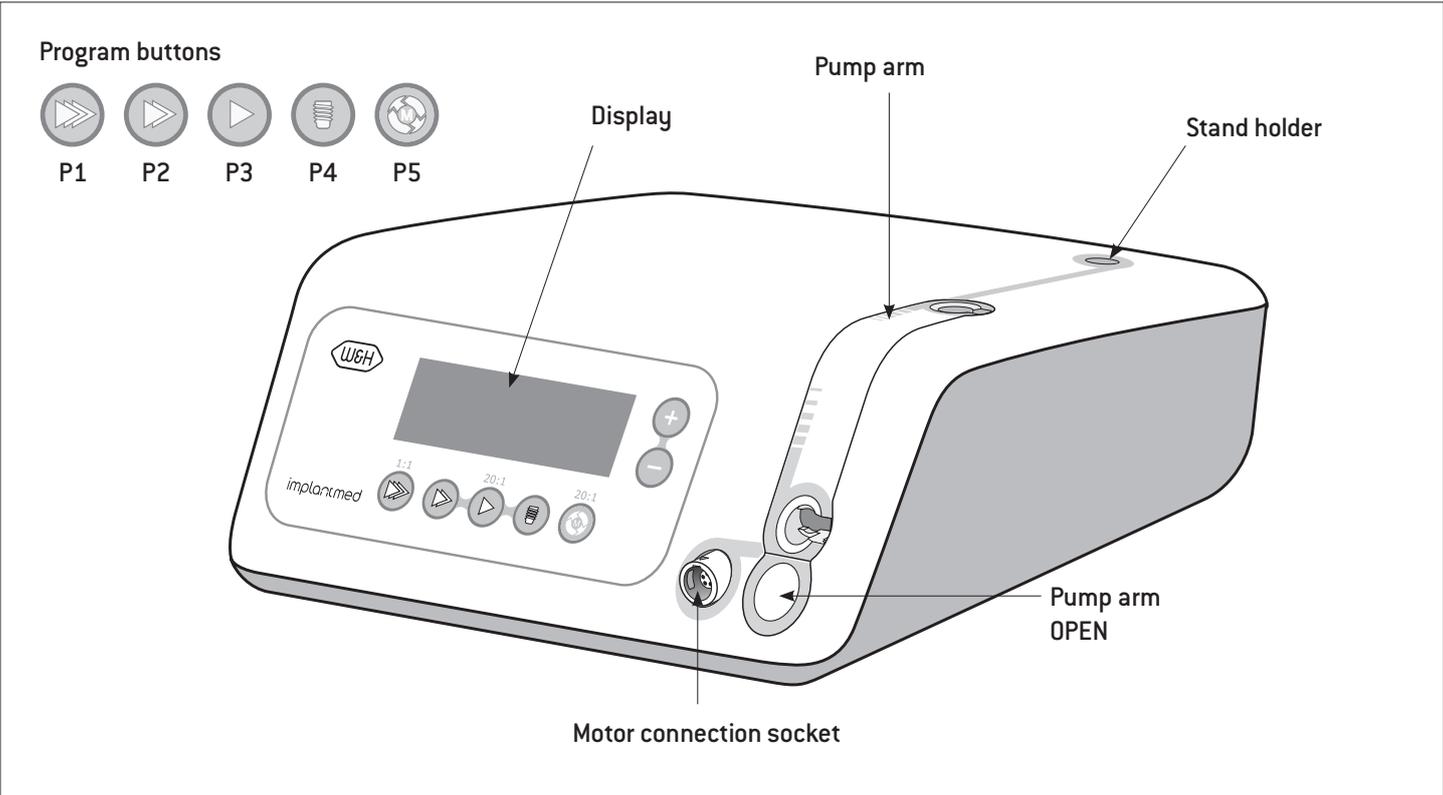
### Rotational energy

As a result of the rotational energy stored in the drive system – compared to the value set – fast deceleration of the bur can cause the selected torque to be significantly overloaded, at times.

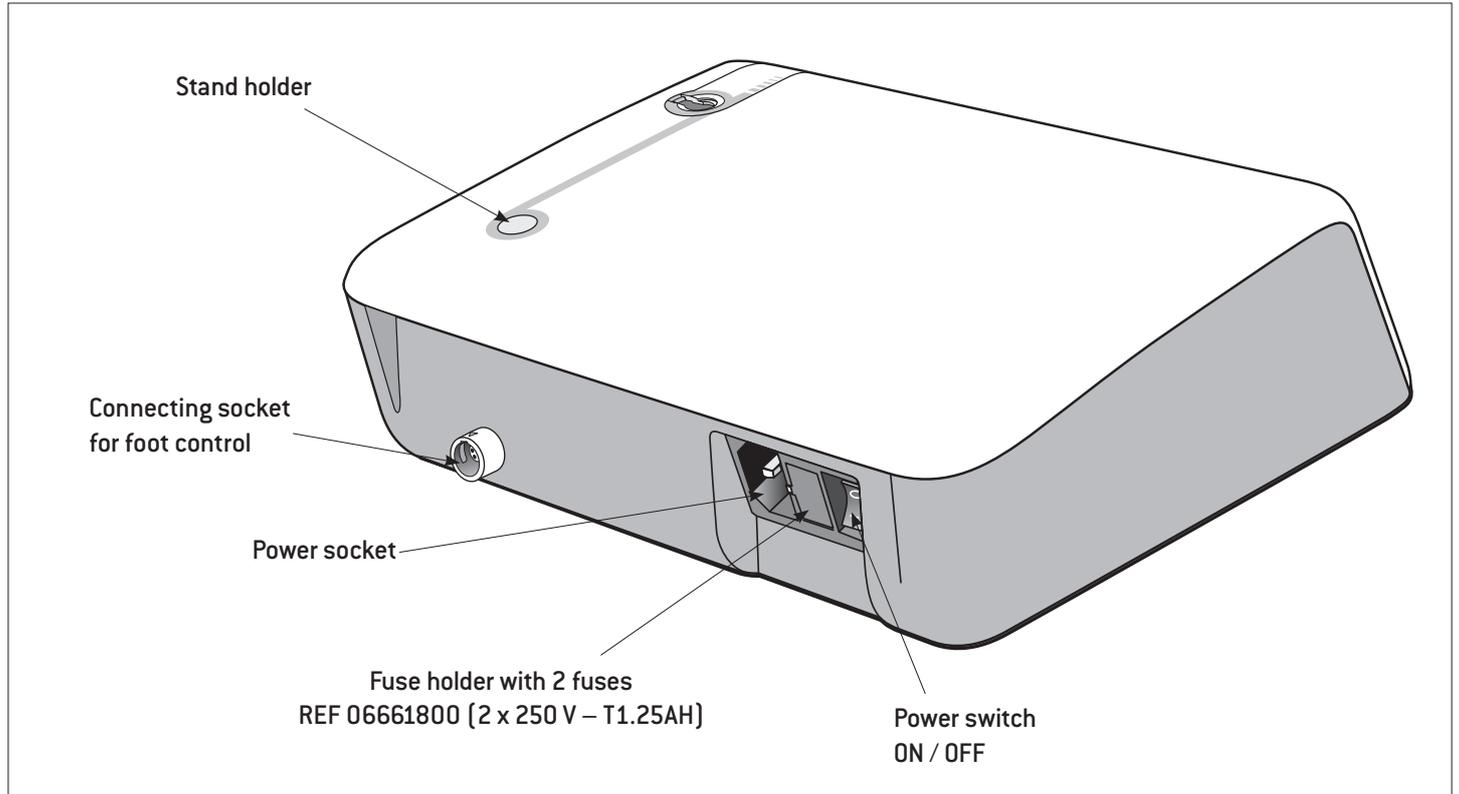


Observe the individual manufacturer's instructions for use when adjusting superstructure screws. We would point out that adjusting these screws with an electric motor presents a potential risk as described above.

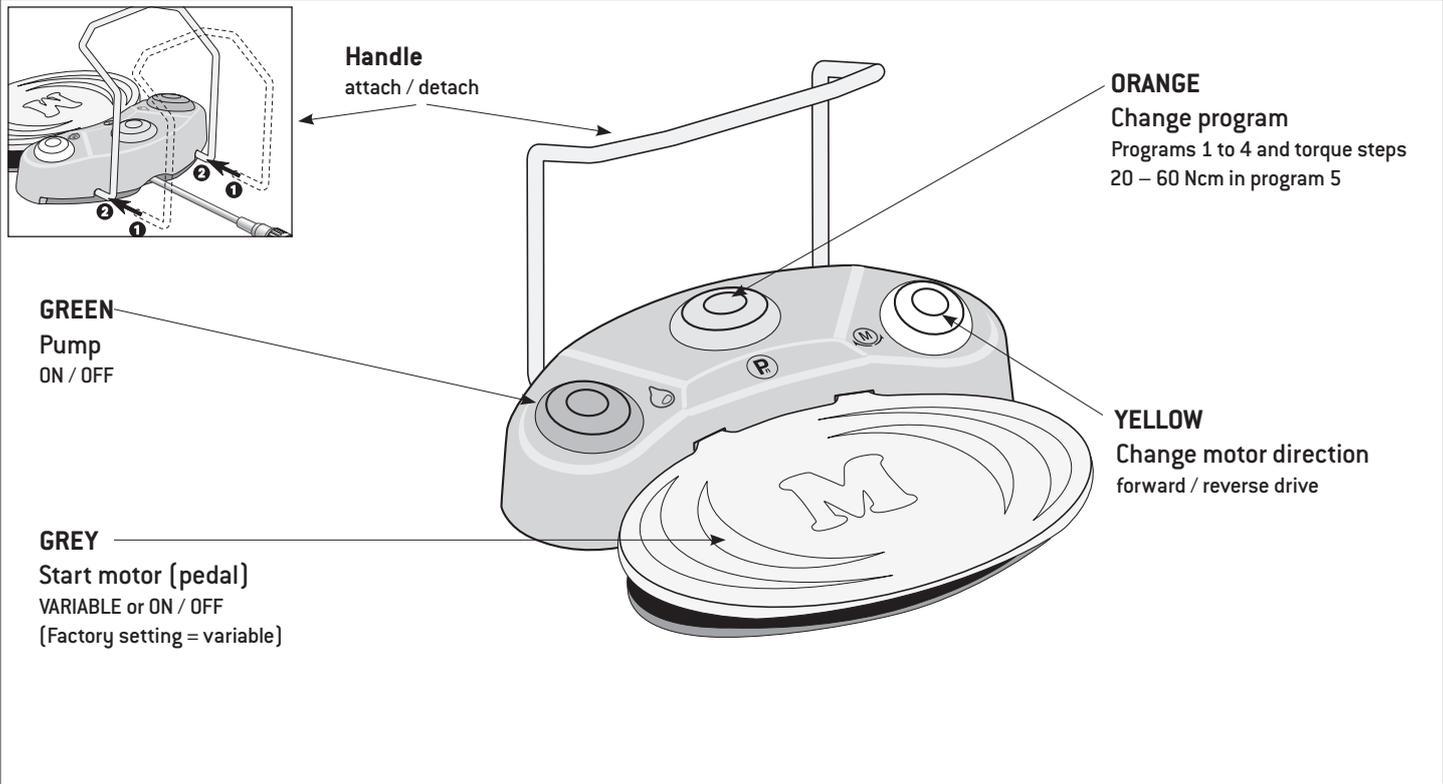
# 6. Description of front panel



## 7. Description of rear panel



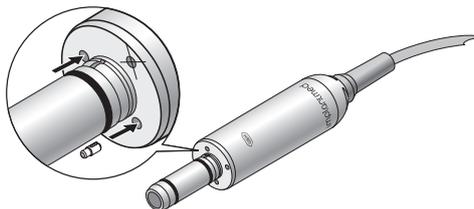
# 8. Description of foot control



## 9. Description of motor with cable



The motor with cable must not be disassembled.  
The motor with cable must not be oiled (lubricated for 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 defined as a type B applied part.

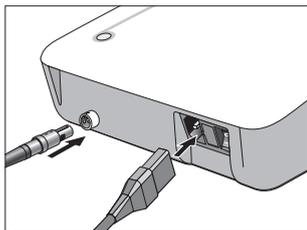
 Temperature information:  
Applied part – dental instrument with cooling: max. 40 °C  
Applied part motor: max. 55 °C

## 10. Starting operation – General



Always place the Implantmed on a flat level surface.

Ensure that the Implantmed can be disconnected easily from the power supply.

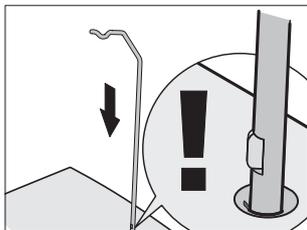


- 1** Connect the mains cable and foot control.

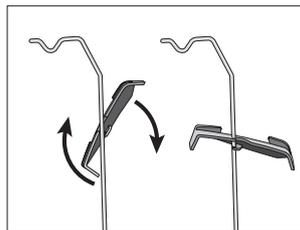
 Pay attention to the positioning!



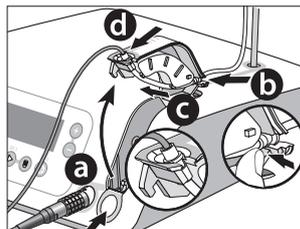
- 2** Insert the motor cable.
-  Pay attention to the positioning!



- 3** Insert the stand.
-  Pay attention to the positioning!  
[maximum load capacity 1.5 kg]

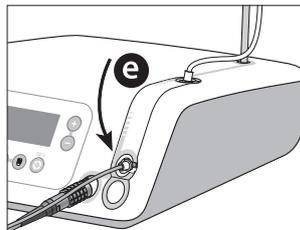


- 4** Attach the motor support and lock it.



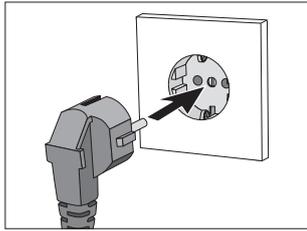
- 5** Insert the irrigation tubing.
- > Open the pump arm [a].
  - > Fit the irrigation tubing set [b, c, d].

 Follow the same sequence when removing the irrigation tubing.



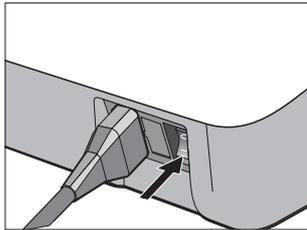
- > Close the pump arm [e].

# 11. Switch on / switch off Implantmed

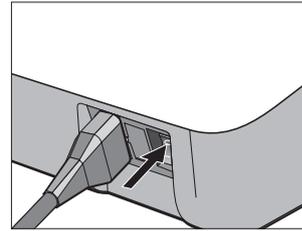


## Switch on Implantmed

- 1 Connect the Implantmed to the power supply.

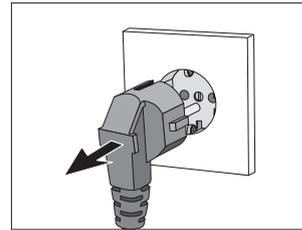


- 2 Turn the Implantmed on at the power switch.



## Switch off Implantmed

- 1 Turn the Implantmed off at the power switch.



- 2 Disconnect the Implantmed from the power supply.

## Test run

- > Start the motor.
- > In the event of malfunctions (e.g. vibrations, unusual noises, overheating, coolant failure or leakage), **stop the motor immediately** and contact an authorized W&H service partner (see page 52).

## 12. Control unit operation – Changing program (P1 – P5)

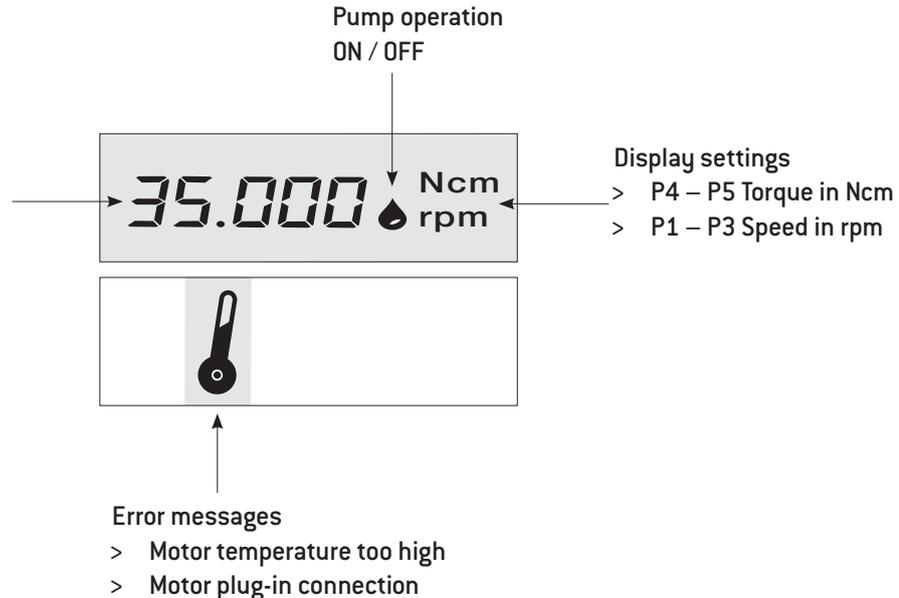


Activate the desired program (P1 – P5) by pressing the corresponding program button. During selection an audible signal can be heard and the Program button lights up. The selected program appears on the display with the adjusted range in rpm, e.g. for P1:



Display settings

- > P1 – P3 Speed
- > P4 – P5 Torque



Ensure when switching on the Implantmed that the LED displays on the buttons and the display itself are all on.

## Control unit operation – Changing speed (P1 – P3)

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Pressing and holding PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.

❶ Press program button (P1 – P3)



❷ Increase speed



❸ Decrease speed



The accuracy of the set speed in the range 300 – 40,000 rpm is  $\pm 10\%$ .

## Control unit operation – change torque (P4 – P5)



Program P4: range from 5 – 70 Ncm, intermediate stage 32 Ncm.  
Program P5: range from 20 – 60 Ncm.

Pressing and holding PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.

A longer confirmation signal is heard on changing from 5 to 70 Ncm (20 to 60) and 70 to 5 Ncm (60 to 20).

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



❶ Press program button P4 or P5



❷ P4: Increase torque in 5-Ncm steps  
P5: Increase torque in 10-Ncm steps



❸ P4: Decrease torque in 5-Ncm steps  
P5: Decrease torque in 10-Ncm steps



The accuracy of the set torque at 50 Ncm is  $\pm 10\%$  with the WI-75 and WS-75 contra-angle handpieces. Greater deviations are possible with other instruments.

## Control unit operation – change coolant flow rate (P1 – P5)

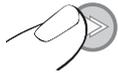


Factory setting 100 %. Adjustable range 65 %, 80 % and 100 %.

Press and hold the PLUS / MINUS button to continuously increase or decrease the values.



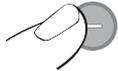
Keep program button P2 depressed throughout this procedure.



- 1 Keep P2 depressed for approx. 4 seconds  
(the set coolant flow rate will appear)



- 2 Continue to keep P2 depressed and increase the flow rate using the PLUS button



- 3 Continue to keep P2 depressed and decrease the flow rate using the MINUS button



After adjusting, program button P2 is illuminated and active.

## 13. Foot control operation

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### Change program

Press the ORANGE button to select programs 1 – 4 and torque steps (20 – 60 Ncm) in program 5 in ascending order. A longer confirmation signal is heard on changing from program 4 to program 1 or 60 Ncm to 20 Ncm setting in program 5. With each program change, the motor direction is automatically set to forward operation.

### 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. The pump symbol appears on the display if the pump function is activated.

### Reverse operation

Press the YELLOW button to change from forward operation to reverse operation.

On selecting reverse operation, an audible signal can be heard and the selected program button flashes.

Before the motor starts in reverse operation, 3 audible warning signals are given.

# Foot control operation

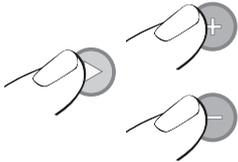
To change from VARIABLE to ON / OFF



Keep program button P3 depressed throughout this procedure.



① Keep P3 depressed for approx. 4 seconds



② Continue to keep P3 depressed and simultaneously press the PLUS and MINUS buttons



Continue to keep P3 depressed and set the adjusting.



01 = VARIABLE (factory setting) – Press PLUS button



00 = ON/OFF – Press MINUS button



After adjusting, program button P3 is illuminated and active.

## 14. Reset factory settings

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The factory setting always starts with program 1 (P1).

❶ Switch off control unit



❷ Keep P1 depressed and simultaneously switch on the control unit

❸ Keep P1 depressed until the setting  
»DE FAU« appears on the display

## Factory settings (P1 – P3)

	<b>P1</b> 	<b>P2</b> 	<b>P3</b> 
<b>Transmission ratio</b>	1:1	20:1	20:1
<b>Speed rpm</b>	35,000	1,200	800
<b>Adjustable range rpm</b>	300 – 40,000	15 – 2,000	15 – 2,000
<b>Motor direction</b>	forward	forward	forward
<b>Pump</b>	on	on	on
<b>Torque Ncm</b>	100%	100%	100%

## Factory settings (P4 – P5)

	<b>P4 forward</b> 	<b>P4 reverse</b> 	<b>P5 forward</b> 	<b>P5 reverse</b> 
<b>Transmission ratio</b>	20:1	20:1	20:1	20:1
<b>Speed rpm</b>	15	30	20	20
<b>Motor direction</b>	forward	reverse	forward	reverse
<b>Pump</b>	on	off	on	on
<b>Torque Ncm</b>	20	60	20	20
<b>Adjustable range Ncm</b>	5 – 70	5 – 70	20 – 60	20 – 60
<b>Intermediate stage Ncm</b>	32	32	–	–

## 15. Thread cutter function (chip breaker mode)



When the thread cutter function (P5) is activated, the speed in both forward and reverse operation modes is 20 rpm and can no longer be changed. When the foot pedal (grey) on the foot control is pressed, the thread cutter rotates inwards until the set torque is reached. When the set torque is reached, the device automatically switches to reverse operation. Disengaging and then re-engaging the foot pedal will switch the device back to forward operation.



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



❶ Press program button P5.



❷ Use Plus/Minus to increase or decrease the torque.

## 16. Error messages

Error no.	Description	Solution
00	Electronics overheating–Safety shutdown	Switch off device, allow device to cool for at least 10 minutes, re-start
01	Electronics overloaded	Switch off device, allow device to cool for at least 10 minutes, re-start
07	Foot control error – initializing	Switch off device, re-start, do not actuate foot control when switching on
09	Foot control error	Switch off device, check plug-in connection of foot control, re-start
19	Running time limiter	Switch off device and re-start
99	System failure	Switch off device, allow motor to cool for at least 10 minutes, re-start
	Motor temperature too high Motor plug-in connection	Switch off device, check plug-in motor connection, allow motor to cool for at least 10 minutes, re-start



If one of the error messages described above cannot be rectified by switching off the Implantmed and then switching it on again, the equipment must be checked by an authorized W&H service partner (see Page 52). If a total failure of the equipment occurs caused by external circumstances, the equipment must be switched off and then on again.

# 17. Hygiene and maintenance

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



- > Wear protective clothing.
- > Clean and disinfect the motor **immediately after every treatment!**
- > Sterilize the motor following cleaning and disinfection.
- > Sterilize motor with cable and motor support prior to every use.
- > The control unit is not approved for mechanical cleaning (thermo washer disinfectant) and sterilization.
- > Do not immerse the control unit or clean it under running water.

## Control unit, foot control

### Pre-disinfection

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



Only use disinfectants that have no protein-fixing effects.

### Manual cleaning and disinfection



The front panel of the control unit and the foot control are sealed and may be wiped clean.

- > Disinfection with disinfectants, wiping disinfection is recommended.
- > Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.  
**For USA and Canada:** Use EPA registered surface disinfectants.
- > Note the manufacturer's specifications for the use of the disinfectants.
- > Clean and inspect the ESD spring contact on the underside of the foot control on a regular basis.

# Hygiene and maintenance

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## Motor with cable



Do not twist or kink the motor cable! Do not coil it too tightly!

## Pre-disinfection

> If heavily soiled, clean first with disinfectant cloths.



Only use disinfectants that have no protein-fixing effects.

# Hygiene and maintenance

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## Motor with cable

### Manual cleaning

- > Rinse and brush off under demineralized water (< 38 °C / < 100 °F)
- > Remove any liquid residues (absorbent cloth, blow dry with compressed air).



Do not place the motor with cable in liquid disinfectant or in an ultrasonic bath.

### Manual disinfection

- > Disinfection with disinfectants, wiping disinfection is recommended.
- > Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.
- > Note the manufacturer's specifications for the use of the disinfectants.  
**For USA and Canada:** Use EPA registered surface disinfectants.



After manual cleaning and disinfection, you must carry out a final sterilization (wrapped) in a class B or S steam sterilizer (as per EN 13060).

**For USA and Canada:** Hospital grade sterilization with pre and post vacuum cycle.

# Hygiene and maintenance

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## Motor with cable

### Mechanical cleaning and disinfection internal and external



The motor with cable can be cleaned and disinfected in a thermo washer disinfector.



W&H permits preparation in a thermo washer disinfector with a drying program.

> Follow the manufacturer's recommendations for devices, cleaning and rinsing agents.



Ensure that the motor with cable is completely dry internally and externally after thermo washer disinfection.

# Hygiene and maintenance

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## Motor with cable

### Sterilization and storage



W&H recommends sterilization according to EN 13060, class B

Other sterilization methods may reduce the life span of your motor.

**For USA and Canada:** Hospital grade sterilization with pre and post vacuum cycle.

- > Observe the device manufacturer's instructions.
- > Clean and disinfect prior to sterilization.
- > Wrap the motor with cable and accessories in sterile goods packaging according to EN 868-5.  
**For USA and Canada:** Place the motor and the accessory in a standard handpiece sterilization pouch.
- > Make sure that you only remove dry sterile goods from the sterilizer.
- > Store sterile goods dust-free and dry.

# Hygiene and maintenance

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## Approved sterilization procedures



Follow your country-specific directives, standards and guidelines.

- > Steam sterilization class B with sterilizers in accordance with EN 13060.  
Sterilization holding time a minimum of 3 minutes at 134 °C.

or

- > Steam sterilization class S with sterilizers including drying program in accordance with EN 13060.  
The sterilizer manufacturer must give its express approval for the sterilization of motors.  
Sterilization holding time a minimum of 3 minutes at 134 °C.

### For USA and Canada:

- > Steam vacuum sterilization (hospital grade sterilization), 4 minutes at  $134 \pm 2$  °C ( $273 \pm 4$  °F)

or

- > Gravity displacement sterilization, 6 minutes at  $134 \pm 2$  °C ( $273 \pm 4$  °F)
- > All other sterilization methods are not approved and must not be used.

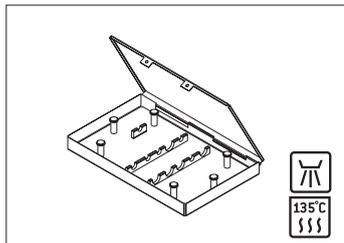


### Before restart operation

Wait until the motor and the cable have cooled down and are completely dry.  
Moisture in the plug or motor can lead to a malfunction. (Risk of short circuit)

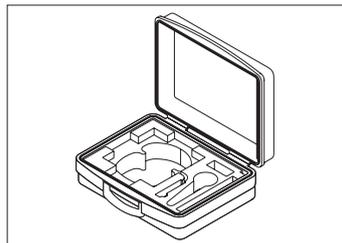
## 18. W&H Accessories

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



**04013500**

Sterilization cassette



**04013600**

Transportation case

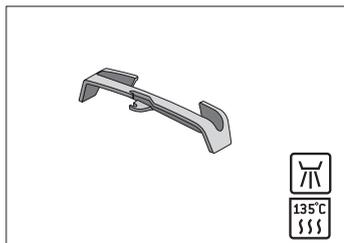


**04541900**

Trolley, white

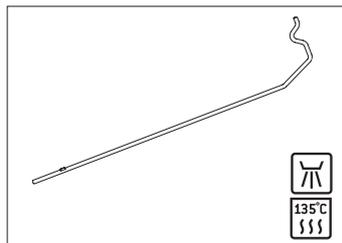
**04542100**

Trolley, white with power sockets



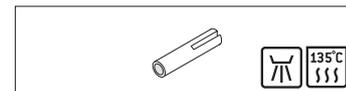
**06177800**

Motor support



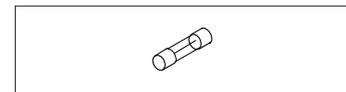
**04005900**

Stand



**04006800**

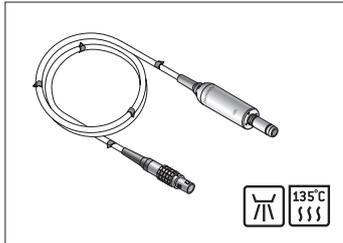
Locking pin



**06661800**

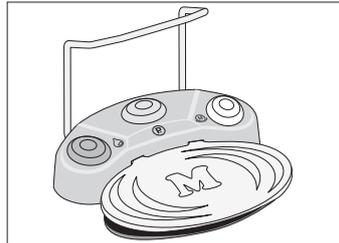
Fuse (250 V - T1.25AH)

## W&H Accessories



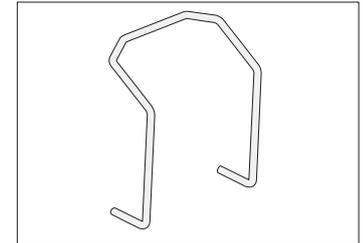
**06631600**

Motor with 1.8 m cable  
incl. 5 clips



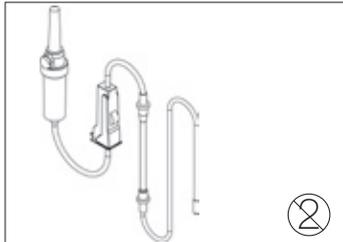
**06202400**

Foot control S-N1



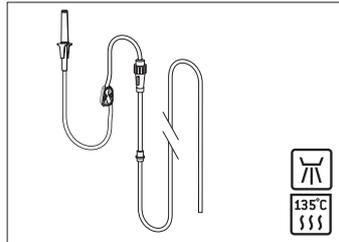
**04653500**

Handle  
for foot control S-N1



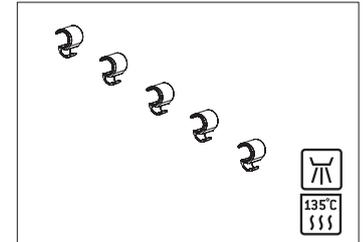
**04363600**

Irrigation tubing 2.2 m (6 pcs)



**04719400**

Irrigation tubing 2.2 m



**04019000**

Clips (5 pcs)

## 19. Servicing

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### **Regular checking of Implantmed and accessories**

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

- > Visual inspection for outside damage
- > Measurement of device leakage current
- > Measurement of patient leakage current
- > Visual inspection of internal components on suspicion of safety interference,  
e. g. mechanical damage of the enclosure or indications of overheating
- > Visually inspecting the ESD spring contact on the underside of the foot control (electrostatic discharge)
- > Function test with check to see if the maximum speed can be reached

We recommend that only an authorized W&H service partner (see page 52) should undertake this servicing and checking.

# Servicing

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## Motor with cable

The standard ISO 11498 stipulates a durability of at least 250 sterilization cycles. In the case of the motor with cable from W&H, we recommend you to have a regular service carried out after 500 sterilization cycles or one year.

## Repairs

If a defect occurs, always return all the equipment, because motor malfunctions an inspection of the electronic controls is also necessary.

## Returns

- > Refer all questions to an authorized W&H service partner (see page 52).
- > 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)

## 20. Technical data

Implantmed	SI-923	SI-915
Supply voltage:	220 – 240 V	100 – 130 V
Permitted voltage fluctuation:	± 10 %	± 10 %
Nominal current:	0.1 – 0.8 A	0.2 – 1.7 A
Frequency:	50 – 60 Hz	50 – 60 Hz
Mains fuse:	2x 250 V – T1.25AH	2x 250 V – T1.25AH
Max. power consumption:	170 VA	170 VA
Max. mechanical output power:	70 W	70 W
Max. torque on the motor:	5.5 Ncm	5.5 Ncm
Motor speed range in the nominal voltage range:	300 – 40,000 min. <sup>-1</sup>	300 – 40,000 min. <sup>-1</sup>
Coolant flow rate at 100%:	at least 90 ml/min	at least 90 ml/min
Operating mode:	S3 (3min / 10min)	S3 (3min / 10min)
Dimensions in mm (WxDxH):	235 x 240 x 100	235 x 240 x 100
weight control-unit with motor in kg:	2.7	2.7

### Physical characteristics

Temperature for storage and transport:	-40 °C to +70 °C
Humidity for storage:	8 % to 80 % (relative), non-condensing at +40 °C
Temperature during operation:	+10 °C to +40 °C
Humidity during operation:	15 % to 80 % (relative), non-condensing at +40 °C

# Technical data

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**Classification according to Paragraph 5 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1 / ANSI/AAMI ES 60601-1**



Class II equipment



Type B applied part (not suitable for intracardiac application)



The foot control REF 06202400 conforms to Class AP according to IEC 60601-1 / ANSI/AAMI ES 60601-1 in danger zone M



The foot control is water-tight according to IPX8, 1 m depth of immersion, 1 hour (water-tight in accordance with IEC 60529)

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

## 21. Recycling and disposal

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### Recycling

W&H considers that it has a special duty towards the environment. Implantmed along with its packaging has been designed to be as environmentally friendly as possible.



### **Disposal of Implantmed (control unit), foot control and motor**

Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.

Ensure that the parts are not contaminated on disposal.

### **Disposal of the packaging material**

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. This way, you will contribute to the recycling of raw materials and the avoidance of waste.



**Copy for the user / customer**

# **CERTIFICATION OF TRAINING**

essential for EU user / customer

The user / customer has been trained in all functions of the surgical unit  
in accordance with the current Instructions for Use.  
Particular attention was paid to Safety notes,  
Cleaning, Disinfecting, Sterilization and Servicing.

W&H Surgical Unit \_\_\_\_\_  
Type \_\_\_\_\_ SN \_\_\_\_\_

Name of the user / customer \_\_\_\_\_  
Clinic, department \_\_\_\_\_  
Address \_\_\_\_\_  
Signature \_\_\_\_\_

Name of the instructor \_\_\_\_\_  
Address \_\_\_\_\_  
Date \_\_\_\_\_ Signature \_\_\_\_\_





**Copy for the medical device consultant**

## **CERTIFICATION OF TRAINING**

essential for EU user / customer

The user / customer has been trained in all functions of the surgical unit  
in accordance with the current Instructions for Use.  
Particular attention was paid to Safety notes,  
Cleaning, Disinfecting, Sterilization and Servicing.

W&H Surgical Unit \_\_\_\_\_

Type \_\_\_\_\_

SN \_\_\_\_\_

Name of the user / customer \_\_\_\_\_

Clinic, department \_\_\_\_\_

Address \_\_\_\_\_

Signature \_\_\_\_\_

Name of the instructor \_\_\_\_\_

Address \_\_\_\_\_

Date \_\_\_\_\_

Signature \_\_\_\_\_



# Explanation of warranty terms

This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee 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.

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 W&H service partner at <http://wh.com>

Simply go to the menu option »Service« for full details. Alternatively please contact:

**W&H (UK) LIMITED**, Unit 6, Stroud Wood Business Centre, Park Street, St Albans, Hertfordshire AL2 2NJ, United Kingdom  
t + 44 1727 874990, f + 44 1727 872254, E-Mail: [technical.uk@wh.com](mailto:technical.uk@wh.com)

**W&H Impex Inc.**, 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada  
t + 1 800 2656277, + 1 519 9446739, f + 1 519 9746121, E-Mail: [service.ca@wh.com](mailto:service.ca@wh.com)

**W&H Impex Inc.**, 14300 Henn Rd., Dearborn, MI 48126, USA  
t + 1 800 2656277, + 1 519 9446739, f + 1 519 9746121, E-Mail: [service.us@wh.com](mailto:service.us@wh.com)

**A-DEC AUSTRALIA CO. INC.**, Unit 8, 5-9 Ricketty Street, Mascot NWS 2020, Australia  
t + 61 2 83324000, f + 61 2 83324099, E-Mail: [a-dec@a-dec.com.au](mailto:a-dec@a-dec.com.au)



**Manufacturer**

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