PEOPLE HAVE PRIORITY

Instructions for use



CE
0297

implantmed

SI-923 / SI-915

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W&H Symbols

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


Consult instructions for use


Class II equipment


Date of manufacture


Electric fuse


Not suitable for intracardiac application – Type B applied part


Do not dispose of with domestic waste


Foot switch


On / Off


Data matrix code for product identification e.g. for hygiene / maintenance processes


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.)

REF Catalogue number

SN Serial number

V Supply voltage of the unit

AC Alternating current

VA Electric power input of the unit

A Supply current

Hz Frequency of the alternating current

rpm Revolutions per minute (rpm = min^{-1})

W&H Symbols

Symbols on the packaging

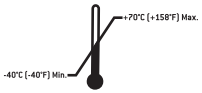
This way up

Fragile, handle with care

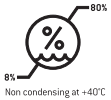
Keep away from rain

Der Grüne Punkt
Identification mark of Duales System Deutschland AG

General symbol for recovery/recyclable



Temperature limit



Humidity limitation

CE 0297 from manufacturer

Rx only

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

Symbols

Symbols on the irrigation tubing



Sterilization with ethylene oxide



Not for re-use



Latex-free



Use by



Batch ID



Caution, please observe accompanying documents



Consult instructions for use



CE 0481 from manufacturer



Not sterile



Sterilizable at the stated temperature



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

1. Introduction

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

CE 0297

Production according to EU Directive
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)

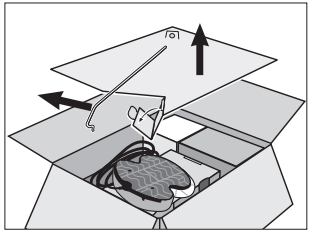
Notes on electromagnetic compatibility (EMC)
Medical electrical equipment is subject to particular precautions with regards to EMC and must be installed and put into operation in accordance with the EMC notes included.

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.

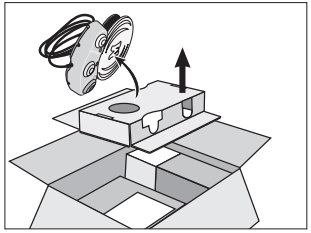
You can find the current EMC manufacturer's declaration on our website at
http://wh.com/en_global/emc
alternatively, you can obtain it directly from the manufacturer.

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.

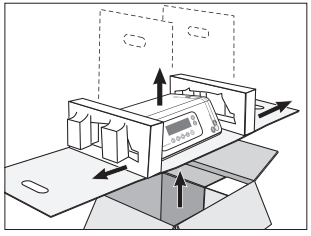
3. Unpacking



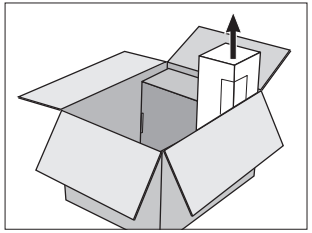
❶ Lift out the insert with the stand.



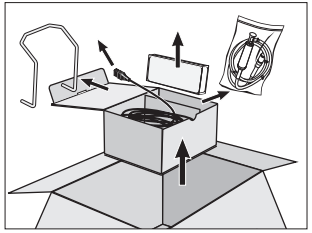
❷ Lift out the insert with the foot control.



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

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

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.
> 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

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

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

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.
Simply switch the unit off and then on again.

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

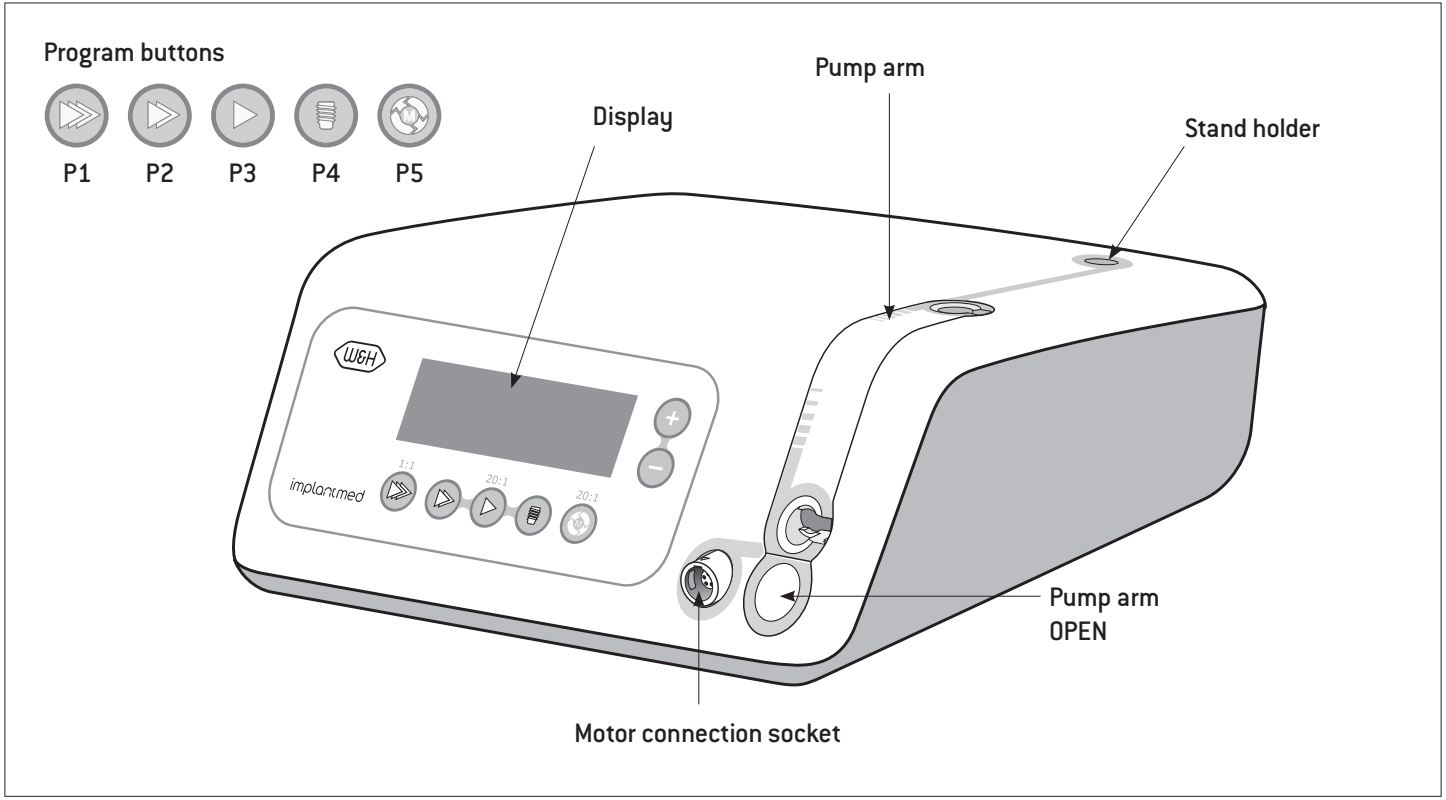
Coolant
The Implantmed is designed for use with physiological saline solution. Use only suitable irrigation fluids and follow the manufacturer's medical data and instructions. Use the W&H irrigation tubing set or accessories approved by W&H.
You can purchase the coolant bottle or the coolant bag at a 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.

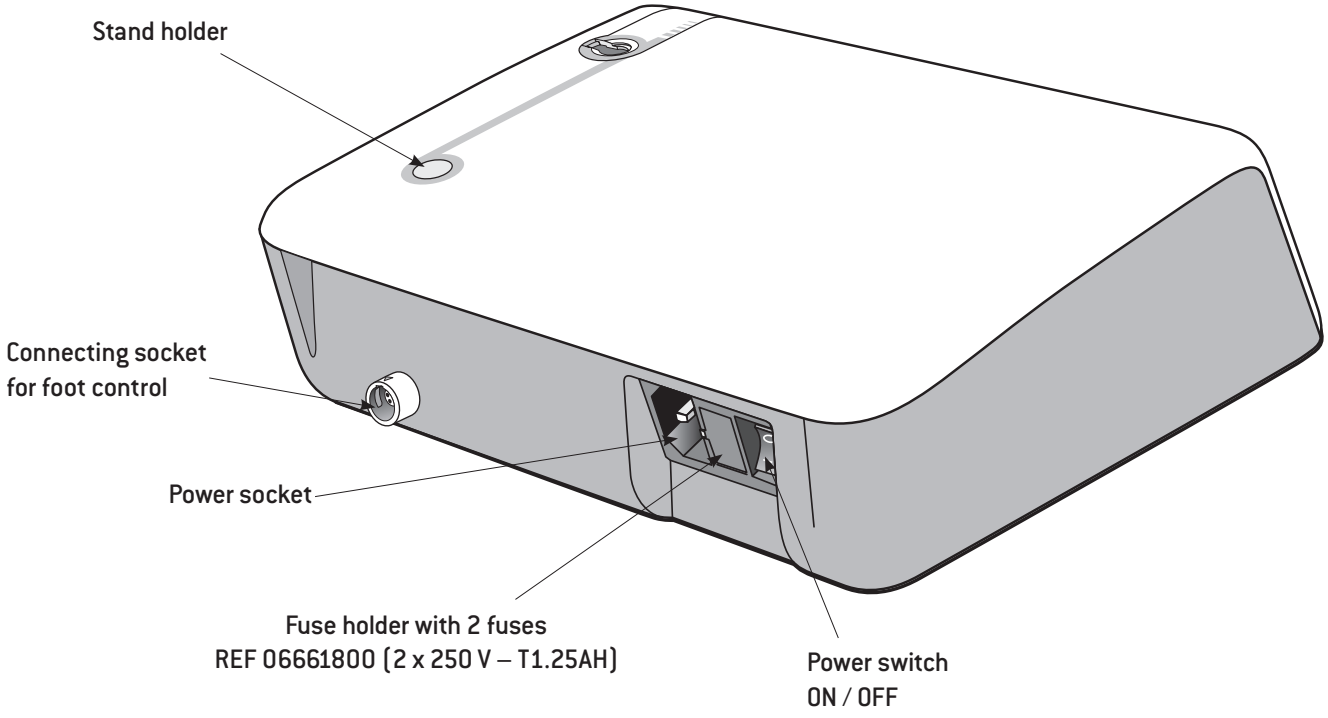
Rotational energy
As a result of the rotational energy stored in the drive system – compared to the value set – fast deceleration of the bur can cause the selected torque to be significantly overloaded, at times.

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.

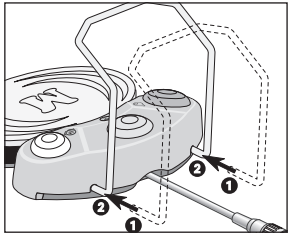
6. Description of front panel



7. Description of rear panel



8. Description of foot control



Handle
attach / detach

ORANGE
Change program
Programs 1 to 4 and torque steps
20 – 60 Ncm in program 5

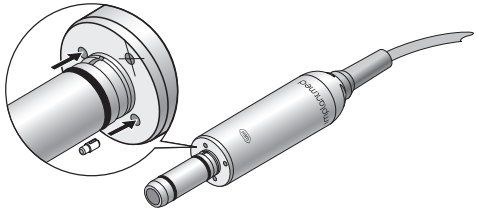
GREEN
Pump
ON / OFF

YELLOW
Change motor direction
forward / reverse drive

GREY
Start motor (pedal)
VARIABLE or ON / OFF
(Factory setting = variable)

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).



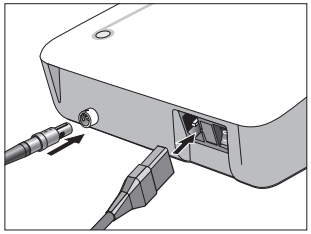
To prevent the instrument on the motor attachment from turning during transmission of high torques, the locking pin supplied can be pushed into the designated hole (see illustration). The locking pin can only be used in combination with straight and contra-angle handpieces that have corresponding holes.

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

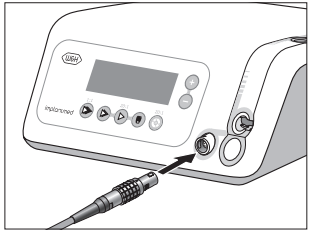
10. Starting operation – General

Always place the Implantmed on a flat level surface.
Ensure that the Implantmed can be disconnected easily from the power supply.



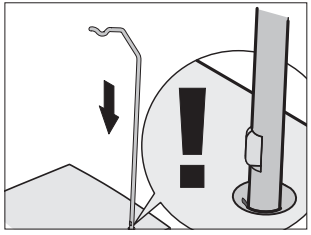
❶ Connect the mains cable and foot control.

Pay attention to the positioning!



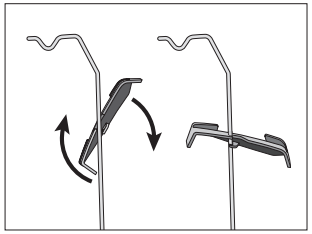
❷ Insert the motor cable.

Pay attention to the positioning!

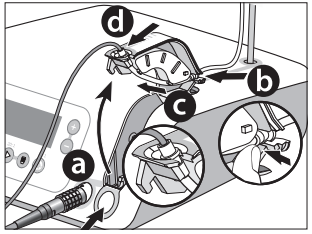


❸ Insert the stand.

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



❹ Attach the motor support and lock it.

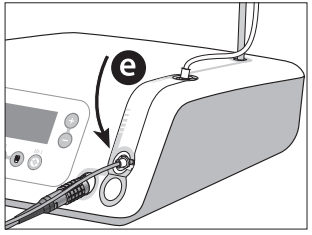


❺ Insert the irrigation tubing.

> Open the pump arm (a).

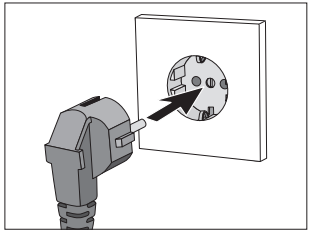
> Fit the irrigation tubing set (b, c, d).

Follow the same sequence when removing the irrigation tubing.



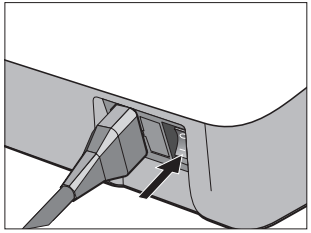
> Close the pump arm (e).

11. Switch on / switch off Implantmed

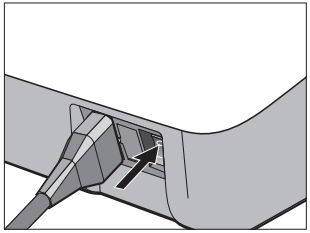


Switch on Implantmed

❶ Connect the Implantmed to the power supply.

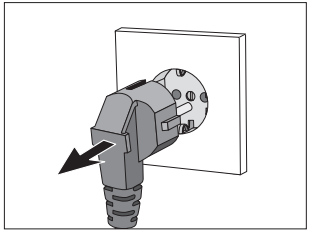


❷ Turn the Implantmed on at the power switch.



Switch off Implantmed

❶ Turn the Implantmed off at the power switch.



❷ 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:

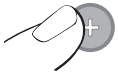


Ensure when switching on the Implantmed that the LED displays on the buttons and the display itself are all on.

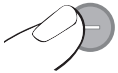
Control unit operation – Changing speed (P1 – P3)

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 ± 10%.

Control unit operation – change torque (P4 – P5)

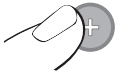
Program P4: range from 5 – 70 Ncm, intermediate stage 32 Ncm.
Program P5: range from 20 – 60 Ncm.

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).

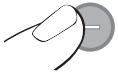
The motor switches off automatically when the set torque is reached in forward and reverse operation modes.



❶ Press program button P4 or P5



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

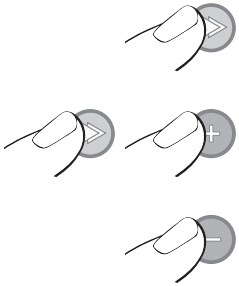


❸ P4: Decrease torque in 5-Ncm steps
P5: Decrease torque in 10-Ncm steps

The accuracy of the set torque at 50 Ncm is ± 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.

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

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

❸ 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

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.

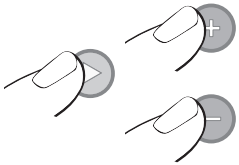
Foot control operation

To change from VARIABLE to ON / OFF

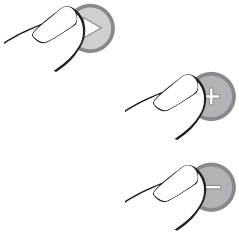
Keep program button P3 depressed throughout this procedure.



❶ Keep P3 depressed for approx. 4 seconds



❷ 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

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)

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

Factory settings (P4 – P5)

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

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 disinfector) 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

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

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

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

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

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 ± 2 °C (273 ± 4 °F)

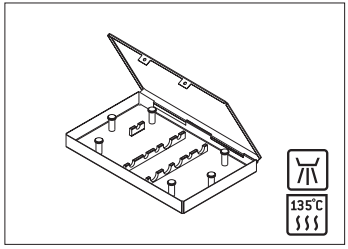
or

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

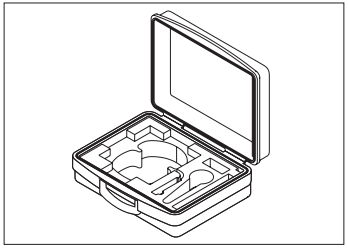
Before restart operation
Wait until the motor and the cable have cooled down and are completely dry.
Moisture in the plug or motor can lead to a malfunction. (Risk of short circuit)

18. W&H Accessories

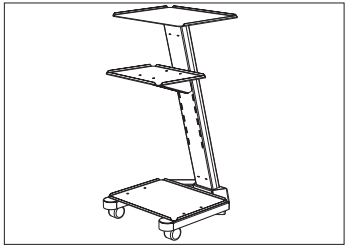
Use only original W&H accessories/spare parts or accessories approved by W&H



04013500
Sterilization cassette

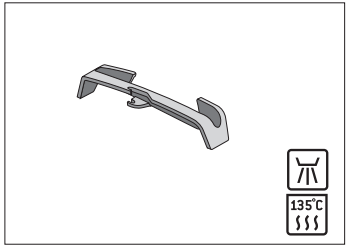


04013600
Transportation case

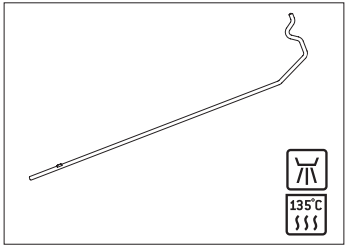


04541900
Trolley, white

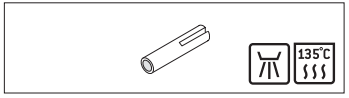
04542100
Trolley, white with power sockets



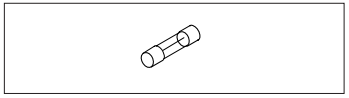
06177800
Motor support



04005900
Stand

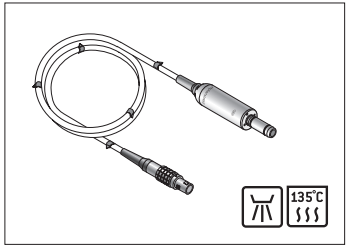


04006800
Locking pin

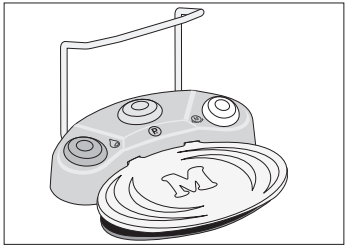


06661800
Fuse (250 V - T1.25AH)

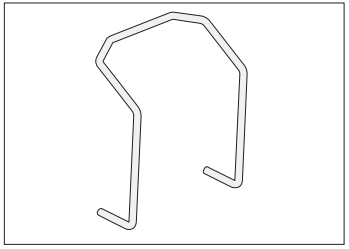
W&H Accessories



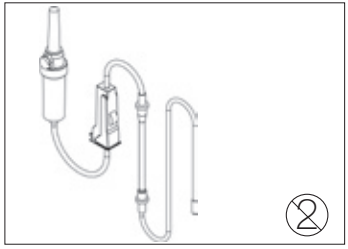
06631600
Motor with 1.8 m cable
incl. 5 clips



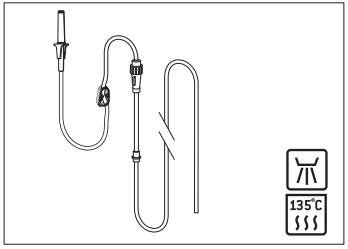
06202400
Foot control S-N1



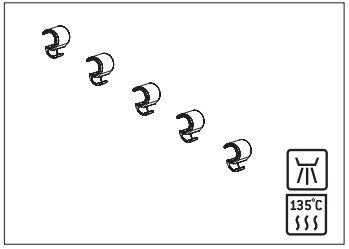
04653500
Handle
for foot control S-N1



04363600
Irrigation tubing 2.2 m (6 pcs)



04719400
Irrigation tubing 2.2 m



04019000
Clips (5 pcs)

19. Servicing

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

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 $min.^{-1}$	300 – 40,000 $min.^{-1}$
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

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

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.

PEOPLE HAVE PRIORITY

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 _____

PEOPLE HAVE PRIORITY

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

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, 6 Stroud Wood Business Centre, Park Street, St Albans, Herts AL2 2NJ, United Kingdom
t + 44 1727 874990, f + 44 1727 874628, E-Mail: 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

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

W&H DENTAL-MECHANIK (ASIA) PTE-LTD., 18 Boon Lay Way, #10-94 Tradehub 21, 609966 Singapore
t + 65 63168370, f + 65 63168371, E-Mail: service.sg@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

Manufacturer

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