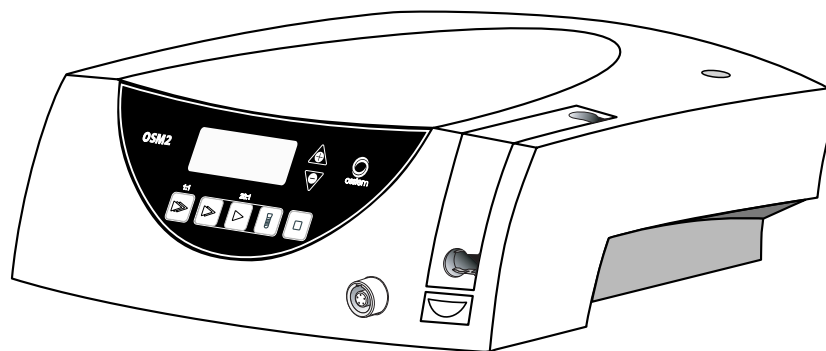


Instructions for use



OSM2

SI-923 / SI-915

W&H Symbols



WARNING!
(Risk of injury)



ATTENTION!
Important notes!
(to prevent damage occurring)



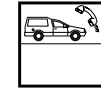
General explanations,
without risk to
persons or objects



Thermo washer disinfectable



Sterilizable
up to the stated temperature



W&H Service

Only for USA

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.

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1. Introduction



For your safety and the safety of your patients

These Instructions for Use 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 to read the safety notes on Pages 8 to 10.

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.

Qualifications of the user


Only suitably qualified medical, technical and specialist trained staff may use the dental surgical unit OSM2 from OSSTEM. We have based our development and design of the OSM2 on the "physician" target group.

Introduction

 **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 product and this applies to the dental surgical units

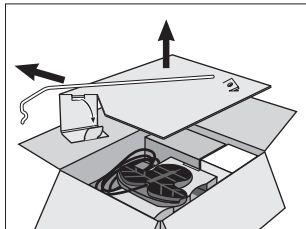
- OSM2 SI-915 and
- OSM2 SI-923

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

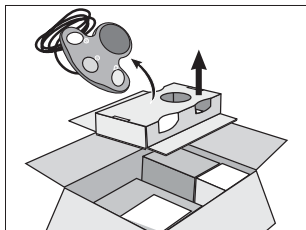
 **Responsibility of the manufacturer**
The manufacturer can only accept responsibility for the safety, reliability and performance of the OSM2 when there is compliance with the following directions:

- OSM2 must be used in accordance with these Instructions for Use.
- OSM2 has no components which can be repaired by the user. Assembly, modifications or repairs must only be undertaken by skilled personnel authorized by W&H.
- The electrical installation at the premises must comply with the regulations of ÖVE-EN 7 ("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.

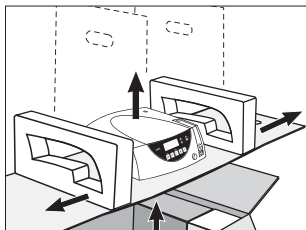
2. Unpacking



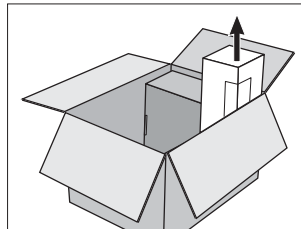
❶ Lift out insert with stand.



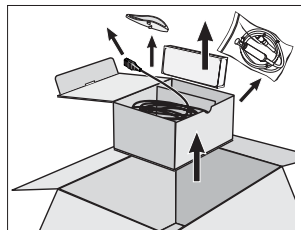
❷ Remove foot control and insert.



❸ Lift out insert with control unit.



❹ Remove irrigation tubing set.



❺ Remove carton containing motor, mains cable, motor support and instruments (optional).

The packaging is environmentally friendly and can be disposed of by industrial recycling companies.

However, we recommend that you keep the original packaging.

3. Equipment supplied

- Control unit REF 05191900 (230 V)
- Foot control REF 04785700
- Motor with 1.8 m cable including 5 clips, REF 04720024
- Mains cable REF 01343700 (Europe)
- Motor support REF 04735700
- Stand REF 04005900
- Locking pins REF 04006800 (2 pcs)
- Irrigation tubing set REF 436360 (3 pcs, disposable)

Alternative specification:

- Control unit REF 05192000 (115 V)
- Mains cable REF 02821400 (USA, CAN, J) / REF 03212700 (UK, IRL) / REF 02909300 (AUS, NZ)

Optional accessories:

- Motor protective cover REF 04032600
- Sterilization cassette REF 04013500
- Transportation case REF 04013600
- Trolley white REF 04541900 / 04542100
- Trolley, stainless steel, REF 04042600

4. Safety notes



Please ensure that you carry out the following instructions

- Only fit the handpieces when the motor is at a complete standstill.
- Never touch rotary instruments which are still rotating.
- Never touch the chuck mechanism of straight and contra-angle handpieces while they are still running.
- Always ensure correct operating conditions and that sufficient and adequate cooling is delivered.
- Avoid overheating at the treatment site.



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 OSM2 or non-compliance with our instructions invalidates all claims under warranty and any other claims.

Cardiac pacemaker function

Use of the OSM2 involves the generation of magnetic fields, which are below the interference threshold limit according to EN 50061 Ad1. Even under adverse conditions, there is no likelihood of serious harm to the patient. The OSM2 is designed for the intermittent operating mode S3 with an operating time of 4 minutes and a pause time of 10 minutes.

Safety notes



Danger zones M and G

In accordance with IEC 60601-1 / UL 60601-1, the control unit is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.

Control unit

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



The OSM2 Program 4 is only designed to be used with the contra-angle handpieces WS-75 E/KM and WI-75 E/KM approved by W&H. Use of other contra-angle handpieces may result in deviation from the indicated torques and is under the user's responsibility. The specified transmission ratios for the Programs 1 to 5 must always be considered.



Motor and foot control

The motor and foot control are approved for use in zone M (AP).
Please note that at low speeds, it is more difficult to determine that the motor is running.

Mains cable

Only connect to an earthed socket outlet.

Power failure

In the event of a power failure, if the OSM2 is switched off, or when alternating between programs, the last values set are saved and re-activated on power-up.

Safety notes

System failure

A total system failure of the OSM2 does not constitute a critical fault.

Intermittent operating mode S3 (4min/10min)

When there is a current consumption of max. 0.8 A for SI-923 and 1.6 A for SI-915 (with pump switched on), the permissible relative load time is 4 minutes to 10 minutes pause time.



Coolant

The OSM2 is designed for use with physiological saline solution. Use only suitable irrigation fluids and comply with the medical data and instructions from the manufacturer. Use the W&H irrigation tubing set or accessories approved by W&H. Coolant bottle or coolant bag can be obtained from a pharmacist.



Sterility of irrigation tubing set

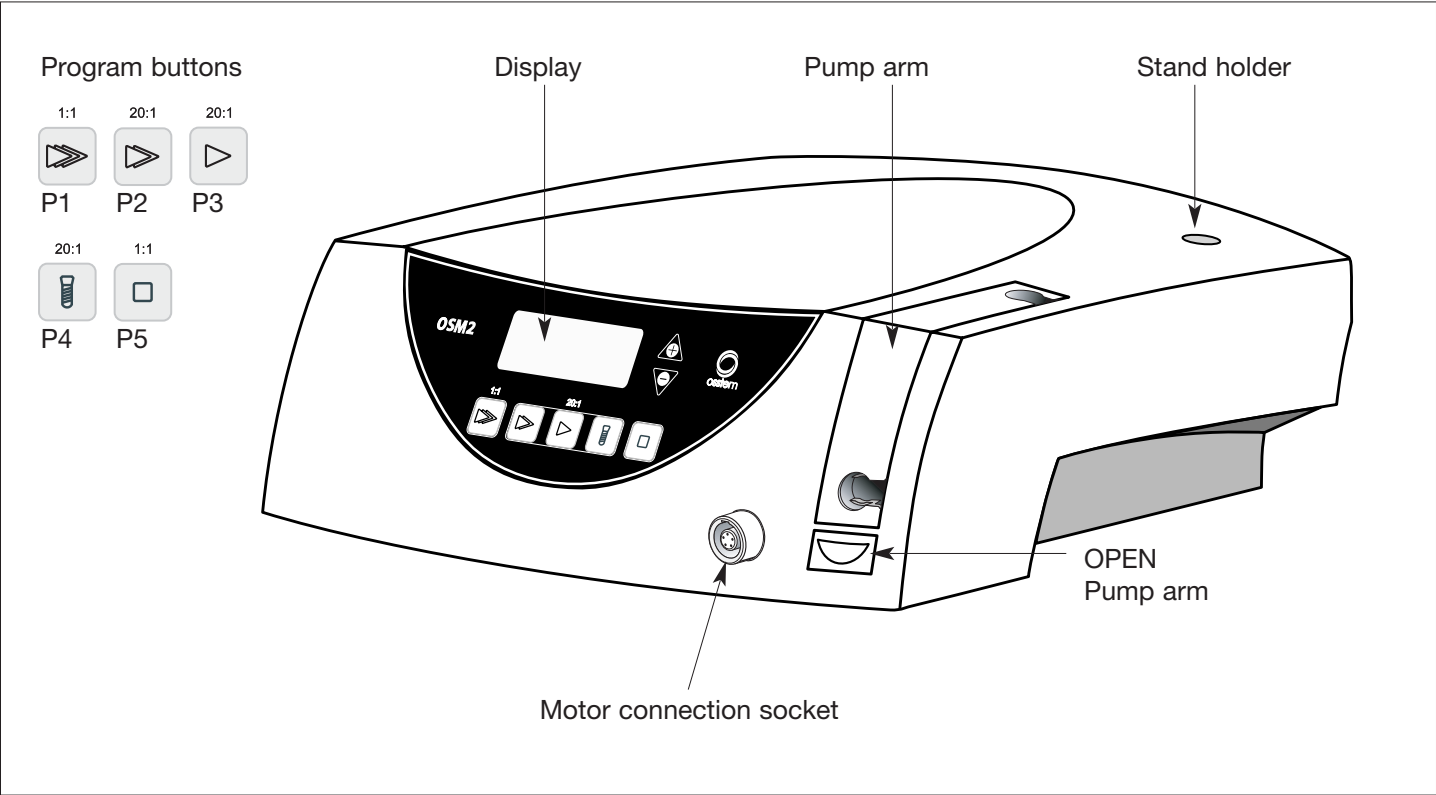
Sterile irrigation tubing sets are supplied with the equipment. These irrigation tubings are disposable articles and must be thrown away after each treatment! Please note the expiry date and the relevant regulations for disposal of irrigation tubing.



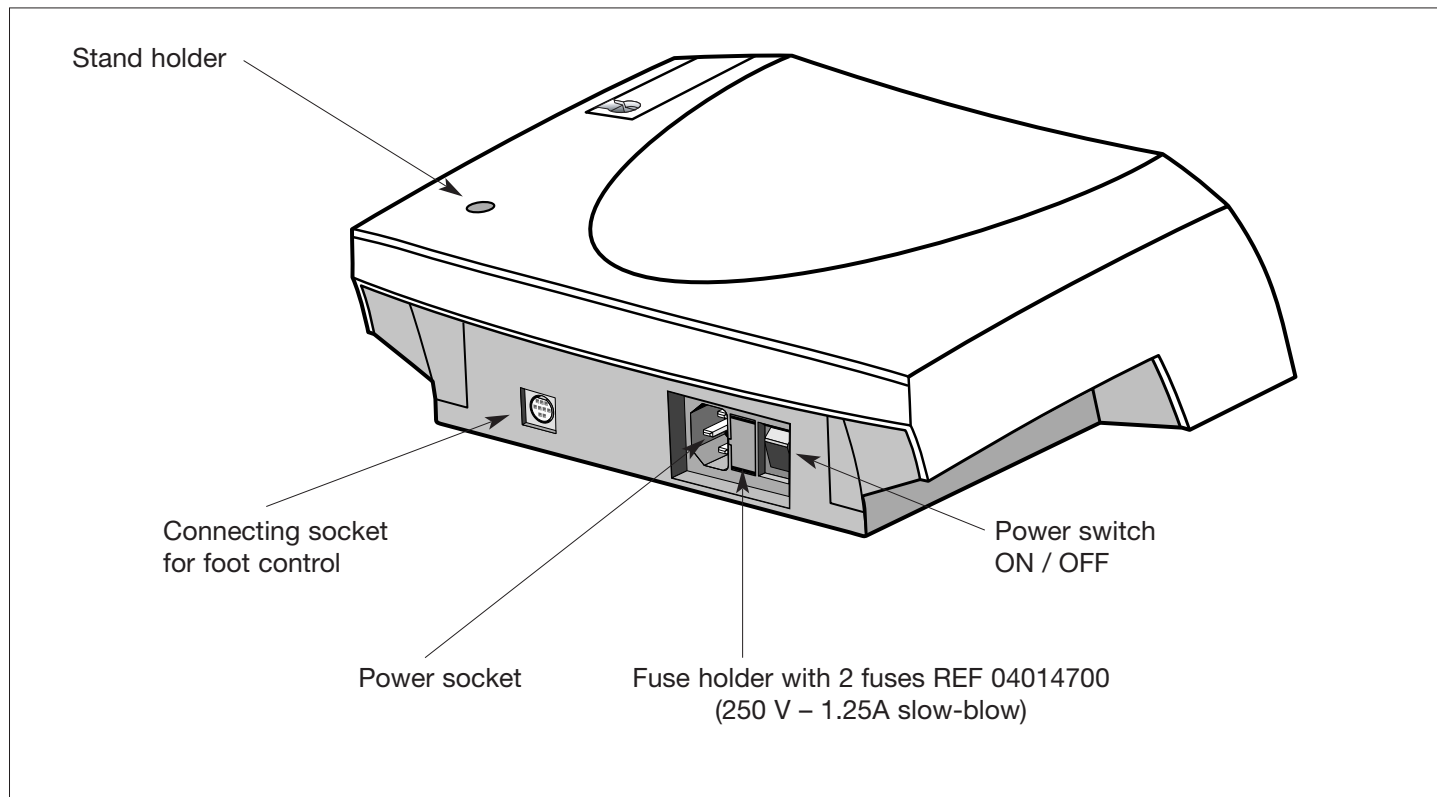
Rotational energy

Fast deceleration of the bur can, at times, cause the selected torque to be overloaded as a result of the rotational energy stored in the drive system. We therefore advise compliance with the individual manufacturer's instructions for use, particularly when adjusting superstructure screws. For safety reasons, these should be screwed in very carefully by hand, or by using a torque wrench. We would point out that adjusting these screws with an electric motor represents a potential risk as described above.

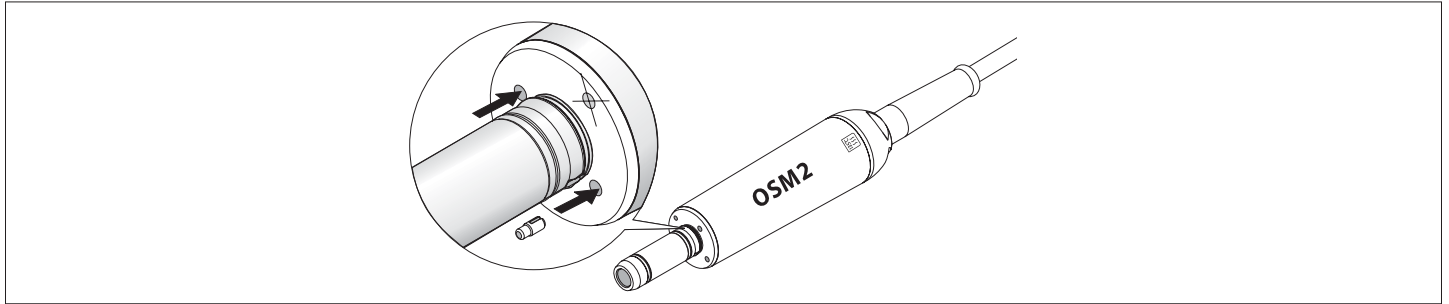
5. Description of front panel



6. Description of rear panel



7. Description of motor with cable



The motor may not be dismantled!

The motor bearings are lubricated for life. No oil lubrication or other maintenance is necessary.

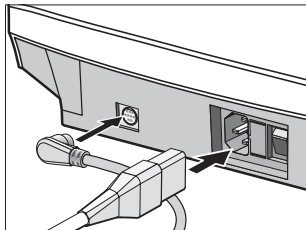


To prevent the instrument on the motor attachment from turning during the transmission, the locking pin supplied can be pushed into one of the two holes (see illustration). The locking pins can only be used in combination with straight and contra-angle handpieces that have corresponding holes.

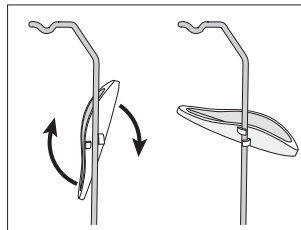
Test run

- Start the motor.
- If you observe dysfunctions (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) contact your authorized service organization (see Page 41 – 43).

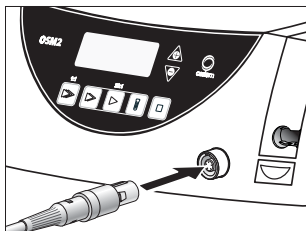
8. Starting operation – General



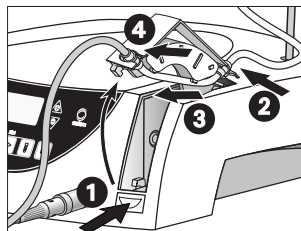
- 1** Connect the mains cable and foot control.



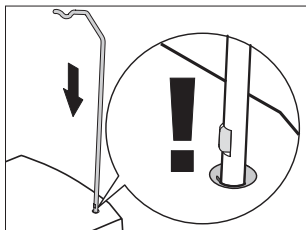
- 4** Place the motor support on the stand and rotate it to fix in place.



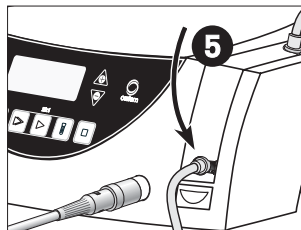
- 2** Connect the motor cable.
Note the positioning!



- 5** Fit the irrigation tubing set.

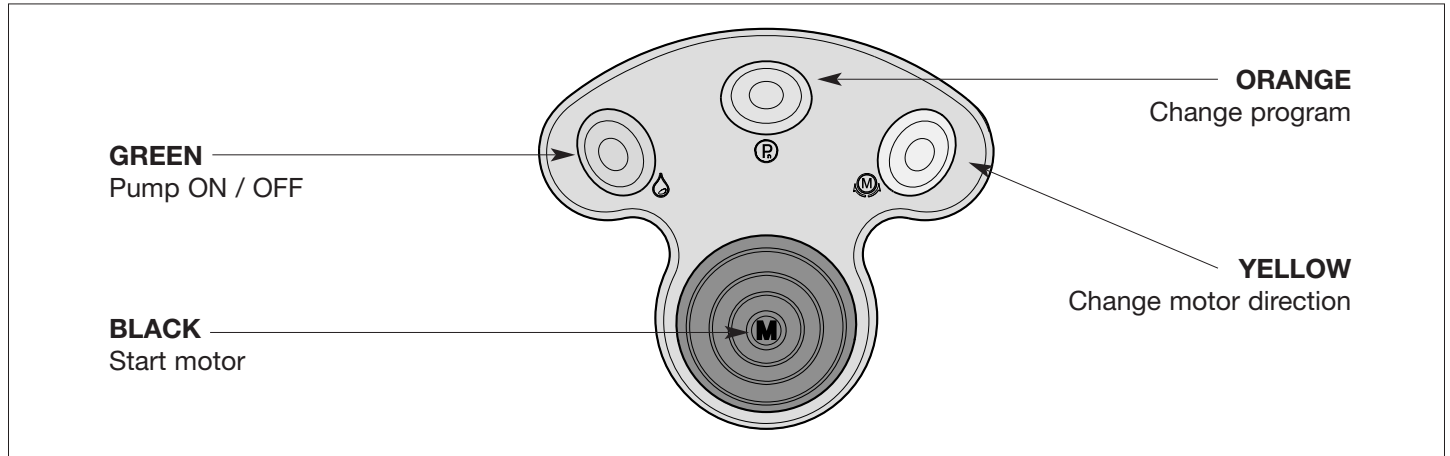


- 3** Insert the stand.
Note the positioning!



- 6** Close pump arm.

9. Starting operation – Foot control



Operation

- BLACK = VARIABLE or ON / OFF (Factory setting = variable)
- GREEN = Pump ON / OFF
- ORANGE = Program 1 to 5
- YELLOW = Motor forward / reverse drive

Starting operation – Foot control

Changing program

The Programs 1 – 5 can be selected in ascending sequence by operating the ORANGE button.

When changing from Program 5 to Program 1, a longer confirmation signal is heard.

With each program change, the speed is automatically set to forward operation.

Pump ON / OFF

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

When pump operation is active, the pump symbol appears on the display.

Reverse operation

You can switch between forward and reverse operation by pressing the YELLOW button. 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.

Starting operation – Foot control

To change from **VARIABLE** to **ON / OFF**



Keep Program button P3 depressed throughout this procedure!



❶ Press P3 for approx. 4 seconds



❷ Keep P3 depressed and simultaneously press PLUS and MINUS



❸ Keep P3 depressed and carry out adjustment.

01 = VARIABLE (factory setting) – Press PLUS button



00 = ON / OFF – Press MINUS button



After changeover the Program button P3 illuminates and is active!

10. Reset factory settings



Factory setting always starts with Program 1 (P1).




❶ Switch off the control unit






❷ Keep P1 depressed and simultaneously switch on the control unit


❸ Keep P1 depressed as long as on the display the adjustment “DE FAU” appears

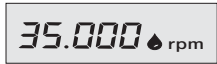
Factory settings (P1 – P5)

	P1 <small>1:1</small> 	P2 <small>20:1</small> 	P3 <small>20:1</small> 	
Transmission ratio	1:1	20:1	20:1	
Factory setting 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	
Factory setting Ncm	max.	max.	max.	
Adjustable range Ncm	–	–	–	
Intermediate stage Ncm	–	–	–	

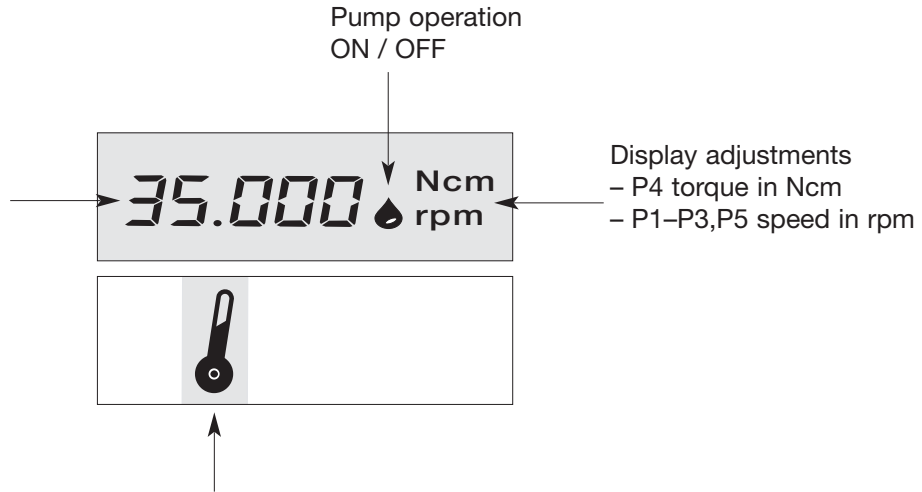
	P4 forward <small>20:1</small> 	P4 reverse <small>20:1</small> 	P5 <small>1:1</small> 	
Transmission ratio	20:1	20:1	1:1	
Factory setting rpm	15	30	35 000	
Adjustable range rpm	–	–	300 – 40 000	
Motor direction	forward	reverse	forward	
Pump	on	off	on	
Factory setting Ncm	20	50	max.	
Adjustable range Ncm	5 – 50	5 – 50	–	
Intermediate stage Ncm	32	32	–	

11. Control unit operation – Changing the program (P1 – P5)

 Activate the required Program (P1 – P5) by pressing the corresponding Program button. During selection an audible signal can be heard and the Program button is illuminated. On the display the selected Program appears with the adjusted range in rpm, e.g. for P1:



Display adjustments
– P1–P3,P5 speed
– P4 torque



Error messages
– Motor temperature too high
– Motor connection

Control unit operation – Changing the speed (P1 – P3, P5)



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

① Press Program button (P1–P3, P5)




② Increase speed



② Decrease speed

Control unit operation – Changing the torque (P4)

 Adjustable range from 5 up to 50 Ncm, intermediate stage 32 Ncm. Keeping PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.

When changing from 5 to 50 Ncm and 50 to 5 Ncm, a longer confirmation signal is heard.

When the adjustable torque in the forward/reverse drive mode is reached, the motor switches off automatically.



❶ Press Program button P4



❷ Increase torque in 5-Ncm-steps



❷ Decrease torque in 5-Ncm-steps

Control unit operation – Changing the coolant flow (P1 – P5)



Factory setting 100 %. Adjustable range 65 %, 80 % and 100 %.
Depressing PLUS / MINUS the values are continuously increased / decreased.



Keep Program button P2 depressed throughout this procedure!



❶ Keep P2 depressed for approx. 4 seconds
(the adjusted coolant flow rate appears)



❷ Keep P2 depressed and press PLUS button
to increase flow rate





❷ Keep P2 depressed and press MINUS button
to decrease flow rate



After adjustment, the Program button P2 illuminates and is active!


12. Error messages

Error No.	Description	Remedy
00	Electronics overheating – safety shutdown	Switch off the equipment, allow to cool for at least 10 minutes, then re-start
01	Electronics overloaded	Switch off the equipment and then re-start
07	Foot control error – initializing	Switch off the equipment, re-start, do not actuate foot control when switching on
09	Foot control error	Switch off the equipment, check connection of the foot control, then re-start
19	Run limiting control	Switch off the equipment and re-start
99	System failure	Switch off the equipment and re-start
	Motor temperature too high	Switch off the equipment, allow motor to cool for at least 10 minutes, then re-start
	Motor connection – safety shutdown	Switch off the equipment, check motor connection, then re-start



If one of the error messages described above cannot be rectified by switching off the OSM2 and then switching it on again, the equipment must be checked by a service and repair organization authorized by W&H (see Page 41 – 43). If a total failure of the equipment occurs caused by external circumstances, the equipment must be switched off and then on again.

13. Disinfection, Cleaning, Sterilization

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



- Wear protective [clothing](#).
- Disinfect and clean the motor **immediately after every treatment!**
- Sterilize the motor following disinfection and cleaning.
- Sterilize motor with cable and motor support prior to every use.

Control unit, foot control

Pre-disinfection

- If heavily soiled: Clean first with disinfectant cloths.

Manual cleaning and disinfection





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

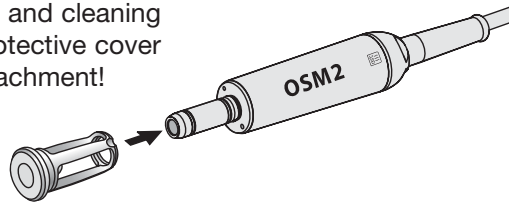
- Disinfection with surface disinfectants, [wiping](#) disinfection is recommended.
- [Use only surface disinfectants which do not contain chlorine and which are certified by officially recognized institutes.](#)
- For USA:** Use EPA registered surface disinfectants.
- Note the dosage and the action time of the [surface disinfectants used!](#)

Disinfection, Cleaning, Sterilization

Motor with cable

 Do not twist and kink the motor cable! Do not coil it too tightly! This instruction is not necessary when a sterilization cassette is utilized (optional accessory).

 Before disinfection and cleaning push the motor protective cover onto the motor attachment!



Pre-disinfection

– If heavily soiled: Clean first with disinfectant cloths.

Manual cleaning

– Rinse under demineralized water (< 38 °C) with the aid of a brush (not recommended in U.K.)
– Then remove any liquid residues (absorbent cloth, blow dry with compressed air)

Disinfection


– Disinfection with surface disinfectants, [wiping](#) disinfection is recommended.
– [Use only surface disinfectants which do not contain chlorine and which are certified by officially recognized institutes.](#)
 For USA: Use EPA registered surface disinfectants.
– Note the dosage and the action time of the [surface disinfectants used!](#)

Disinfection, Cleaning, Sterilization


Sterilization and storage

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

- Note the instructions of the unit manufacturer.
- Clean before sterilizing.
- Wrap motor and accessories in sterile goods packing according to EN 868-5.
- Make sure that you only remove dry sterile goods.
- Store sterile goods dust-free and dry.

 For sterilization with a drying program: Remove the motor protective cover.
For sterilization without a drying program: Use the motor protective cover (see Page 26).

Approved sterilization procedures

 Follow your country-specific directives, standards and guidelines.

Steam vacuum sterilization according to EN 13060, using a sterilization holding time of a minimum of 3 minutes at 134 (+ 3) °C (273.2 + 5.4 °F)

or

Steam gravity sterilization using a sterilization holding time of a minimum of 3 minutes at 134 (+ 3) °C (273.2 + 5.4 °F)



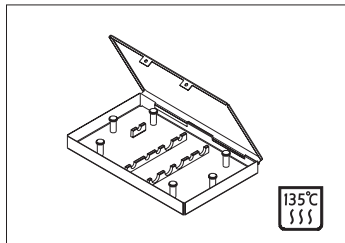
Before starting operation again

Wait until the motor and cable are completely dry.

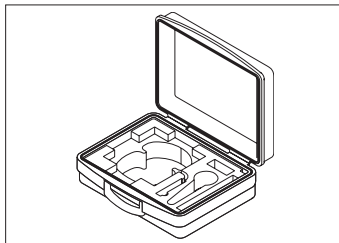
Moisture in the plug or motor can lead to a malfunction! (Risk of short circuit)

14. W&H Accessories

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



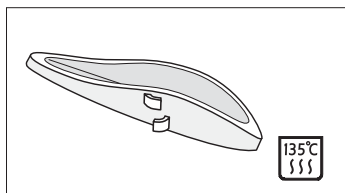
04013500
Sterilization cassette



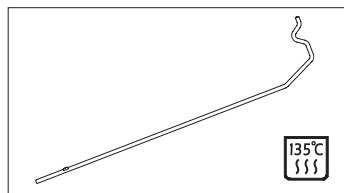
04013600
Transportation case



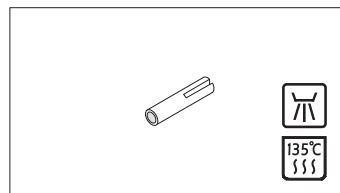
04541900 / 04542100
Trolley white
04042600
Trolley, stainless steel



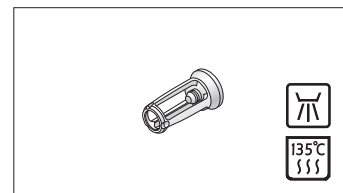
04735700
Motor support



04005900
Stand

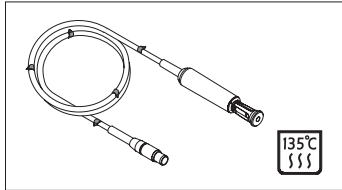


04006800
Locking pin



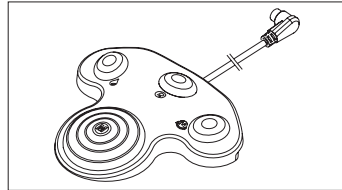
04032600
Motor protective cover

W&H Accessories



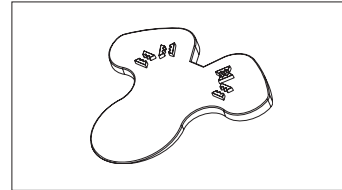
04720024

Motor with 1.8 m cable



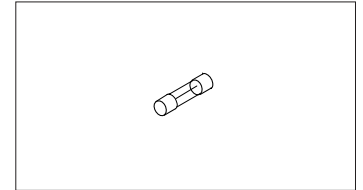
04785700

Foot control



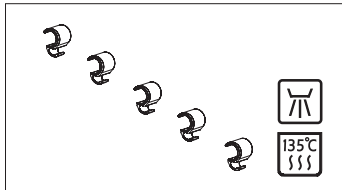
04308700

Step wedge for foot control



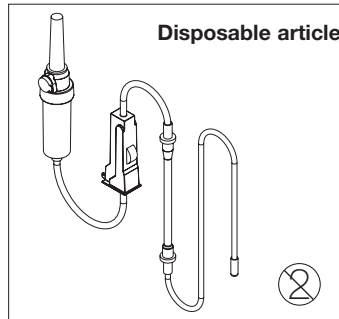
04014700

Fuse 1.25A slow-blow



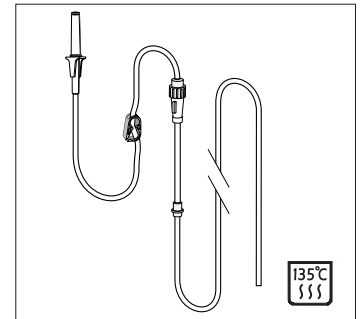
04019000

Clips (5 pcs)



04363600

Irrigation tubing set 2.2 m (6 pcs)



04719400

Irrigation tubing set 2.2 m

15. Servicing



Regular checking of OSM2 and accessories

Regular servicing of function and safety of the OSM2 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 needs to include the following procedures:

- visual inspection for outside damage
- measurement of enclosure leakage current
- measurement of patient leakage current
- visual inspection of internal components and electronic boards on suspicion of safety interference,
e. g. mechanical damage of the enclosure or indicators for overheated or burned (electronic) components

We recommend that only skilled personnel authorized by W&H should undertake this servicing and checking.

Servicing

Motor and cable

The standard ISO 11498 stipulates a durability of at least 250 sterilization cycles. In the case of the motor and cable from W&H, regular servicing is specified only after 500 sterilization cycles, or one year.

Repairs

If a defect occurs, always return all the equipment, due to the fact that with motor malfunctions, an inspection of the electronic controls is also necessary!

Returns

- Refer all questions to your authorized dental dealer or to one of our service organizations (see Page 41 – 43).
- 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)

16. Technical data

OSM2	SI-923	SI-915
Supply voltage:	220 – 240 V	100 – 130 V
Rated current:	0.1 – 0.8 A	0.2 – 1.6 A
Permitted voltage fluctuation:	± 10 %	± 10 %
Frequency:	50 – 60 Hz	50 – 60 Hz
Max. mechanical output power:	70 W	70 W
Max. torque on the motor:	5.5 Ncm	5.5 Ncm
Max. coolant in ml (with hose ø 6/4):	approx. 100 ml/min	approx. 100 ml/min
Fuses:	2x 250 V – 1.25A slow-blow	2x 250 V – 1.25A slow-blow
Operating mode:	S3 (4min/10min)	S3 (4min/10min)
Dimensions in mm (WxDxH):	252 x 254 x 90	252 x 254 x 90
Weight in kg:	3.30	3.30

Classification according to § 5 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1 / UL 60601-1



Equipment of Protective Class II (type of protection against electric shock)



Type BF appliance (not suitable for intracardiac application)



Motor REF 04720024 and foot control REF 04785700 conform to Class AP according to IEC 60601-1 / UL 60601-1 in danger zone M.



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

Technical data

Physical characteristics

Temperature in storage:	-40 °C (-40 °F) to +70 °C (+158 °F)
Air humidity in storage:	8 % to 80 % (relative), non-condensing at +40 °C (+104 °F)
Temperature in operation:	+10 °C (+50 °F) to +40 °C (+104 °F)
Air humidity in operation:	15 % to 80 % (relative), non-condensing at +40 °C (+104 °F)

Recycling

W&H considers that it has a special duty towards the environment. The OSM2 equipment along with its packaging has been designed to be as environmentally friendly as possible.

Disposal of the OSM2 (control unit), foot control and motor

[Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.](#)

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. In this way, you will contribute to the recycling of raw materials and the avoidance of waste.



Letter of indemnity

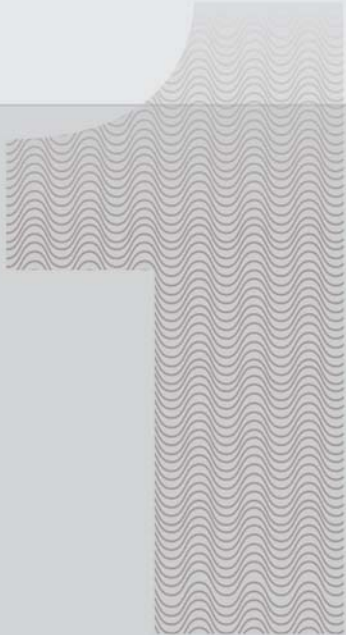
This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the instructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects within a warranty period of one year 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! High-pressure bulbs are excluded from the warranty.

Claims under warranty – accompanied by proof of purchase – must be sent to the vendor or to an authorized W&H service point. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

year warranty



CERTIFICATION OF TRAINING

essential for EU user / customer

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



CERTIFICATION OF TRAINING

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W&H Surgical unit _____

Type _____ SN _____

Name of the user / customer _____

Clinic, Department _____

Address _____

Signature _____

Name of the instructor _____

Address _____

Date _____ Signature _____



Authorized W&H Service organizations

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