



Instructions for use



CE
0297

elcomed
SA-310

Contents

Symbols	4
1. Introduction	8
2. Electromagnetic compatibility (EMC)	10
3. Unpacking	11
4. Scope of delivery	12
5. Safety notes	13
6. Description of front panel	18
7. Description of rear panel	19
8. Description of foot control	20
9. Description of motor with cable	21
10. Starting operation – General	22
11. Switch on / switch off Elcomed	23
12. Control unit operation – Setup settings	24
13. Control unit operation – General settings	25
14. Control unit operation – Elcomed settings	32
15. Control unit operation – Main menu settings	38
16. Foot control operation	44
17. Error messages	45
18. Hygiene and maintenance	47
18. Servicing	58
19. W&H Accessories	60

Contents

20. Technical data	63
21. Disposal	65
Explanation of warranty terms	71
Authorized W&H service partners	72

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

W&H Symbols

Symbols on the control unit



Follow instructions for use



Consult instructions for use



Class II equipment



Date of manufacture



Not suitable for intracardiac application – Type BF applied part



MEDICAL – GENERAL MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
UL 60601-1:2006,
CAN/CSA-C22.2 No. 601.1-M90:2005,
CAN/CSA-C22.2 No. 60601-1:2008,
ANSI/AAMI ES 60601-1:2005.
25UX (Control No.)



Do not dispose of with domestic waste



Foot switch



On / Off



Electric fuse



USB connection



Data Matrix Code for product identification, e.g. in hygiene / maintenance process

REF Catalogue number

SN Serial number

V Supply voltage of the control unit

AC Alternating current

VA Electric power input of the control 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



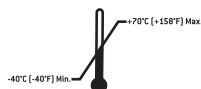
Keep away from rain



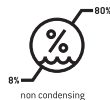
»Der Grüne Punkt«
Identification mark of
Duales System Deutschland AG



General symbol for
recovery / recyclable



Temperature limits



Humidity limitation



CE 0297
from the manufacturer



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 irrigation tubing set



Sterilized using 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



Do not reuse



CE 0481
from the manufacturer



Latex free



Non-sterile



Use by



Sterilizable up to the
stated temperature



Batch code



Caution, consult
accompanying documents

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 13 to 17.

Intended use

Drive unit for surgical transmission instruments with coupling system according to ISO 3964 (DIN 13.940) with the functions »mechanical drive« and »supply with coolant«. It is indicated for use in dental, surgical procedures.

Misuse may damage the Elcomed and hence cause risks and hazards for patients, users and third parties.

Qualifications of the user

The W&H Elcomed dental surgical unit is intended for use by suitably qualified and trained medical, technical and specialist staff only. We have based our development and design of the Elcomed on the »physician« target group.

Introduction



Production according to EU Directive

EU Directive 93/42/EEC has been used as a basis in the design and manufacture of this medical product and it applies to the dental surgical unit

> Elcomed SA-310

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 Elcomed when it is used in compliance with the following directions:

- > The Elcomed must be used in accordance with these Instructions for use.
- > The Elcomed 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 72).
- > 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 device 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

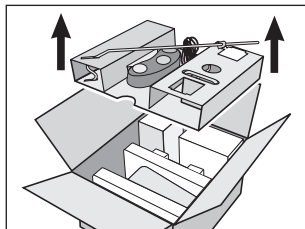
Alternatively, you can obtain it directly from the manufacturer.



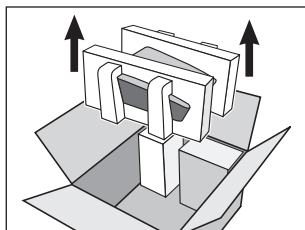
HF communication equipment

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

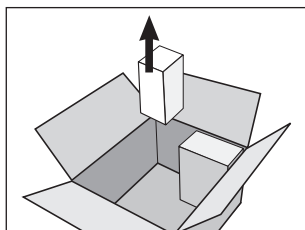
3. Unpacking



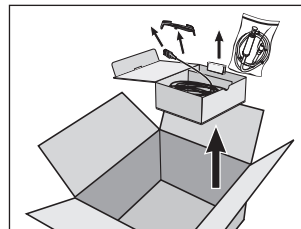
- ❶ Lift out the insert with the stand and the foot control.



- ❷ Lift out the insert with the control unit.



- ❸ Remove the irrigation tubing set.



- ❹ 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

REF 15933100	Control unit with documentation	REF 15933101	Control unit with documentation
REF 05513400	Motor with 1.8 m cable incl. 5 clips	REF 06205800	Motor with 3.5 m cable incl. 10 clips
REF 436360	Irrigation tubing set 2.2 m (3 pcs, disposable)	REF 436410	Irrigation tubing set 3.8 m (3 pcs, disposable)
REF 06290700	USB flash drive	REF 06290700	USB flash drive
REF 15933102	Control unit without documentation	REF 15933103	Control unit without documentation
REF 05513400	Motor with 1.8 m cable incl. 5 clips	REF 06205800	Motor with 3.5 m cable incl. 10 clips
REF 436360	Irrigation tubing set 2.2 m (3 pcs, disposable)	REF 436410	Irrigation tubing set 3.8 m (3 pcs, disposable)
Accessories		Mains cable	
REF 06202400	Foot control S-N1	REF 01343700	(EU)
REF 04653500	Handle for foot control S-N1	REF 04280600	(CH)
REF 06177800	Motor support	REF 05901800	(DK)
REF 04005900	Stand	REF 02821400	(USA, CAN, J)
REF 04006800	Locking pin (2 pcs)	REF 03212700	(UK, IRL)
		REF 02909300	(AUS, NZ)

5. Safety notes



Please observe the following instructions under all circumstances

- > Before using the Elcomed for the first time, store it at room temperature for 24 hours.
- > Check the Elcomed, 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 72). Do not operate the Elcomed if it is damaged.
- > Check the parameter settings every time the device is restarted.
- > Perform a test run each time before using.
- > Make sure that the operation can be completed safely even if a device or instrument malfunctions.
- > Never touch the chuck mechanism of the straight or contra-angle handpiece during operation or while they are still running down.
- > Only fit the straight or contra-angle handpiece onto the motor, when the motor is at a complete standstill.
- > Never touch the rotary instrument which is still rotating.
- > Always ensure correct operating conditions and that sufficient and adequate cooling is delivered.
- > Avoid overheating at the treatment site.
- > When changing the fuse, disconnect the device from the power supply and only use W&H original fuses.
- > Never touch the patient and the connection for the foot control simultaneously.
- > The ESD spring contact on the underside of the foot control must touch the floor during operation.
- > Moisture in the plug or motor can lead to a malfunction. (Risk of short circuit)



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, clockwise and anticlockwise rotation.



Inappropriate use

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

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.



Elcomed is not suitable for use in oxygen enriched atmospheres.



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 anaesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary. Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.



Zone G, also known as an »enclosed medical gas system«, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.



Foot control

The foot control is in accordance with IEC 60601-1 / ANSI/AAMI ES 60601-1 approved for use in zone M (AP).



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

Safety notes

Control unit

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



When using transmission settings 975, WS-75 and WI-75, Elcomed must be used exclusively with the following W&H-approved surgical contra-angle handpieces: 975 AE, 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 6 must always be considered.

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 mains cable.

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

Power failure

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

System failure

A total system failure does not constitute a critical fault.

Safety notes

Intermittent operating mode S3 (2min/10min)

The Elcomed is designed for intermittent operating mode S3 with an operating time of 2 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 patients, users or third parties arises. The responsibility for the use and timely shutdown of the system lies with the user.



Coolant

The Elcomed 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 tubings are supplied with the equipment. These irrigation tubings are disposable articles and must be discarded after each treatment! Please note the expiry date and the relevant regulations for disposal of irrigation tubings. Only use disposable irrigation tubings 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.

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.

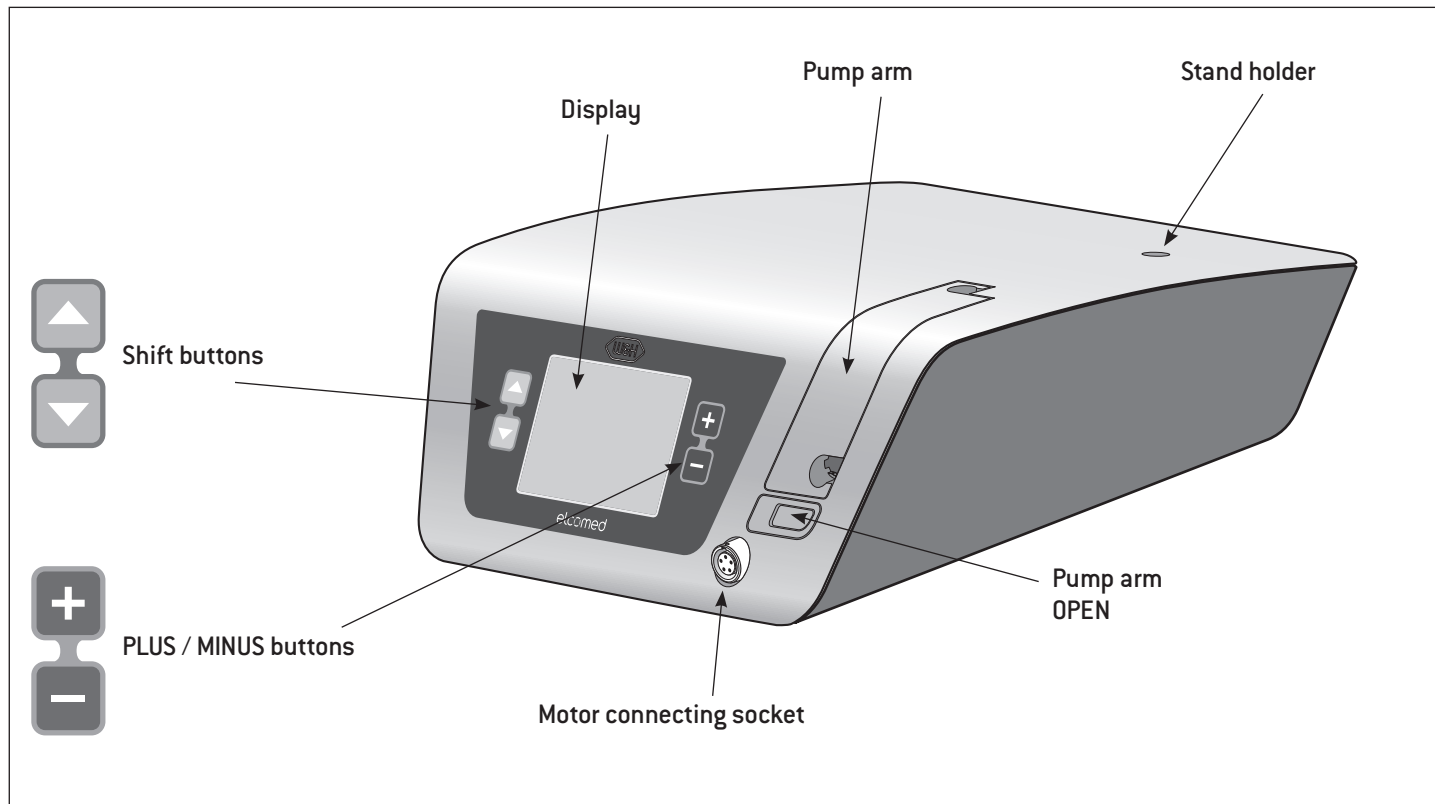
- > Find out if patient and user have implanted systems before using the product and consider the application.
- > Weigh the risks and benefits.
- > Keep the product away from implanted systems.
- > Make appropriate emergency provisions and take immediate action on any signs of ill-health.
- > Symptoms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



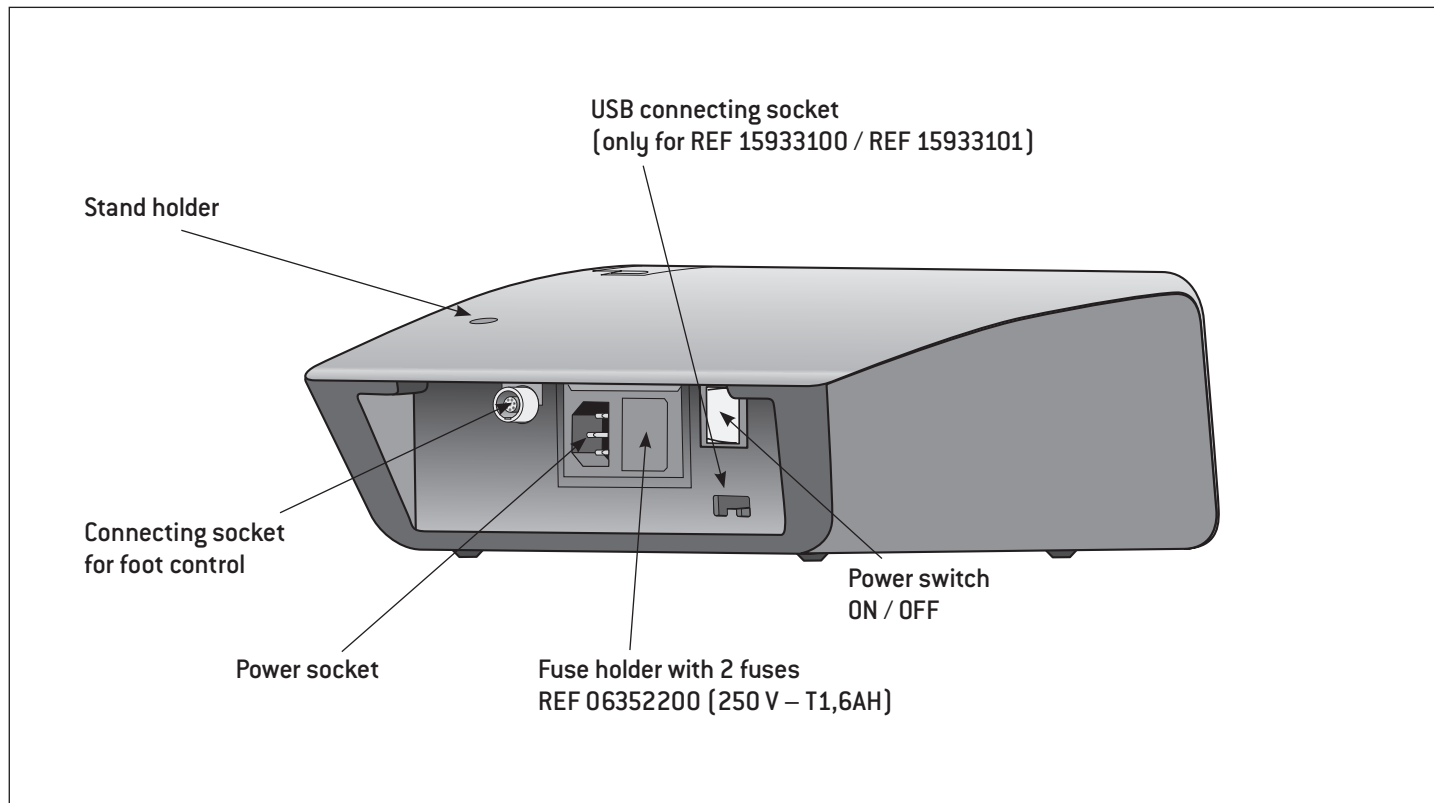
Hygiene and maintenance prior to initial use

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

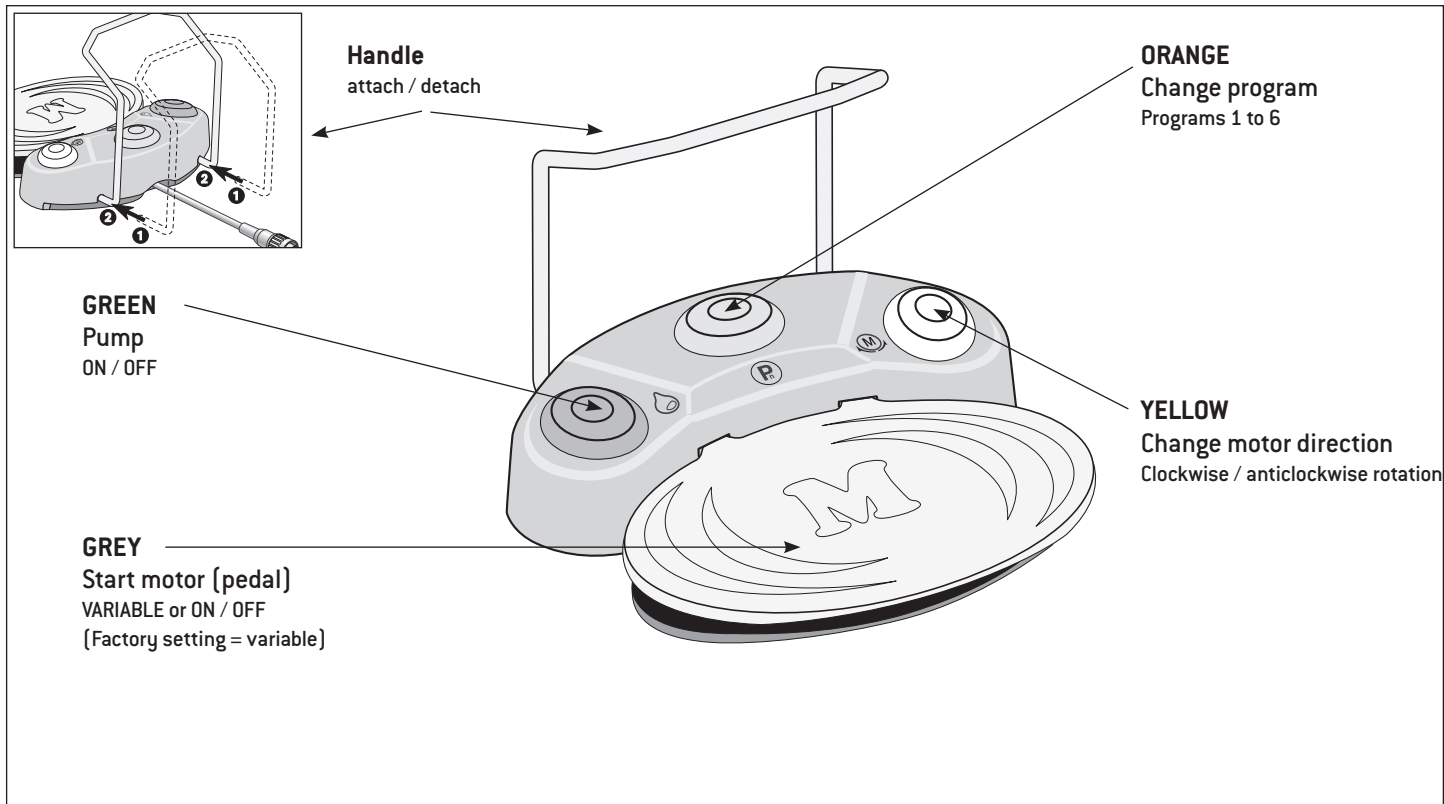
6. Description of front panel



7. Description of rear panel



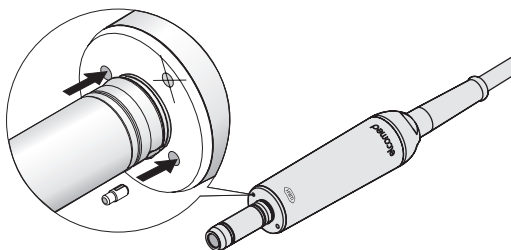
8. Description of foot control



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 BF applied part.



Temperature information

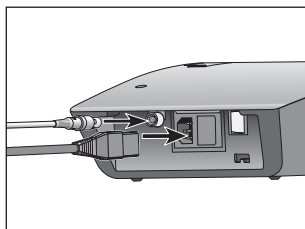
Applied part motor: max. 55°C (131°F)

10. Starting operation – General



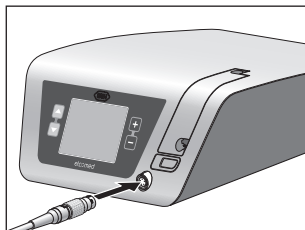
Always place the Elcomed on a flat level surface.

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



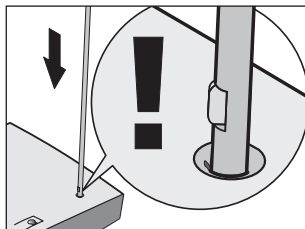
- 1** Connect the mains cable and the foot control.

Pay attention to the positioning!



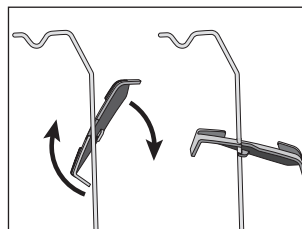
- 2** Insert the motor cable.

Pay attention to the positioning!

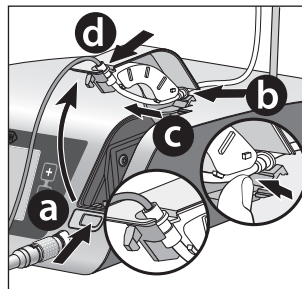


- 3** Insert the stand.

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



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

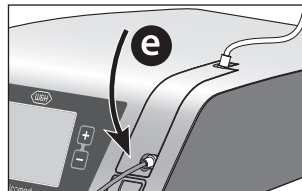


- 5** Insert the irrigation tubing.

a Open the pump arm.

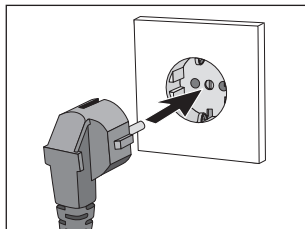
b c d Fit the irrigation tubing.

Follow the same sequence when removing the irrigation tubing.



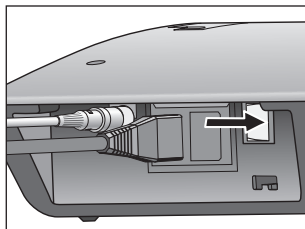
e Close the pump arm.

11. Switch on / switch off Elcomed

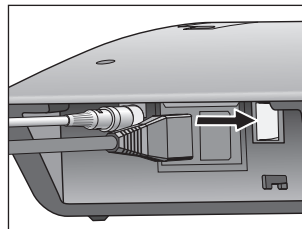


Switch on Elcomed

- 1 Connect the Elcomed to the power supply.

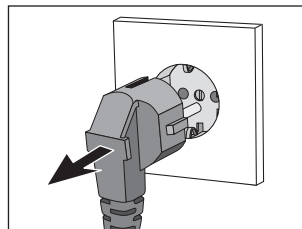


- 2 Turn the Elcomed on at the power switch.



Switch off Elcomed

- 1 Turn the Elcomed off at the power switch.



- 2 Disconnect the Elcomed 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 72).

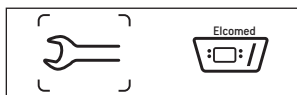
12. Control unit operation – Setup settings

Calling up the setup settings

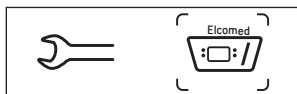
 Simultaneously press shift buttons ▲ and ▼ for 2 seconds.



- 1 Select General settings or Elcomed settings



- 2 General settings are active
Confirm with the PLUS button
For a description of the General settings see pages 25 – 31



- 3 Elcomed settings are active
Confirm with the PLUS button
For a description of the Elcomed settings see pages 32 – 37

 Press the MINUS button to move from the setup settings to the main menu.
Ensure when switching on the Elcomed that the LED display of the buttons and the display itself fully lights up.

13. Control unit operation – General settings



Press shift button ▲ or ▼ to select the desired menu. Press the PLUS / MINUS button to set the menu functions.
The selected functions light up in green.

Date →	 26	06.04.2009	← Date settings
Time →		PM 03:57:12	← Time settings
Contrast →			← Contrast display
Volume →			← Volume display
Reset →	Res		← Return



To exit the general settings, select Return with shift button ▼.
Confirm with the PLUS / MINUS button.

General settings – Date



① Date



② Activate date settings



③ Select the day, month or year,
or exit the date settings



④ Adjust settings for day, month or year

General settings – Time



The clock stops while the settings are being adjusted.



① Time



② Activate time settings



③ Select time format (am, pm, 24h),
select hours, minutes or seconds
or exit the time settings



④ Adjust the settings for time format, hours,
minutes, seconds

General settings – Contrast



① Contrast



② Increase contrast



③ Decrease contrast

General settings – Volume



① Volume



② Increase volume



③ Decrease volume



Mute

General settings – Reset factory settings

 The device will restart after the factory settings have been reset.



① Reset



② Start reset countdown



③ The reset countdown can be interrupted within 5 seconds

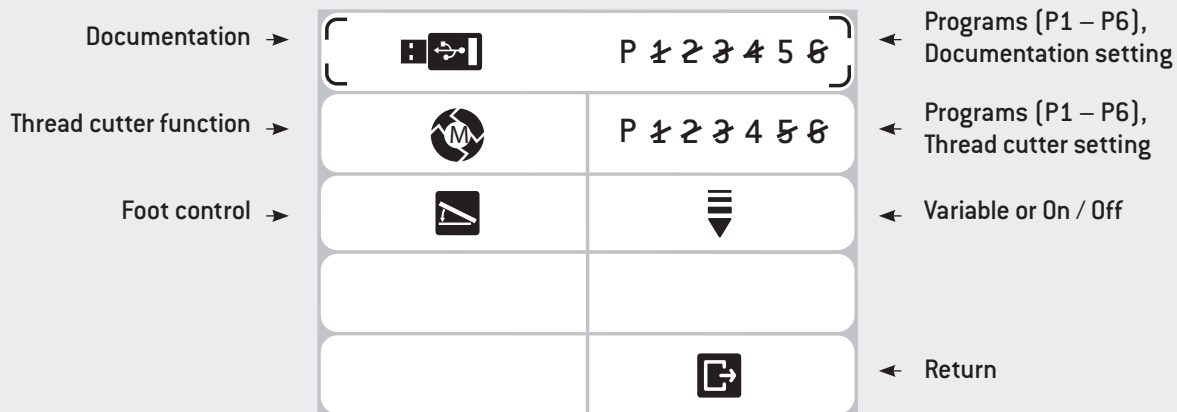
General settings – Factory settings (P1 – P6)

	P1	P2	P3	P4	P5	P6
Speed (rpm)	35,000	1,200	800	20	20	40,000
Torque (Ncm)	100 %	100 %	100 %	50	35	100 %
Coolant supply volume	100 %	100 %	100 %	100 %	60 %	100 %
Coolant	active	active	active	active	active	active
Transmission ratio	1:1	WS-75 (20:1)	WS-75 (20:1)	WS-75 (20:1)	WS-75 (20:1)	1:1
Motor direction	clockwise	clockwise	clockwise	clockwise	clockwise	clockwise
Thread cutter function	not active	not active	not active	active	not active	not active
Documentation function only for REF 15933100 / REF 15933101	not active	not active	not active	not active	active	not active

14. Control unit operation – Elcomed settings



Press shift button ▲ or ▼ to select the desired menu. Press the PLUS / MINUS button to set the menu functions. The selected functions light up in green.



To exit the Elcomed settings, select Return with shift button ▼. Confirm with the PLUS / MINUS button.

Elcomed settings – Documentation (only for REF 15933100 / REF 15933101)

Documentation On / Off

 The documentation for each program must be activated or deactivated. The On / Off documentation applies to both directions of rotation. Insert a USB flash drive to save the documentation.

 Never connect or disconnect the USB flash drive when the motor is running.



① Documentation



② Activate documentation setting



③ Activate or deactivate documentation



④ Switch between programs (P 1, 2, 3, 4, 5, 6)
or exit the documentation setting

Elcomed settings – Documentation

 Documentation is only possible at a preselected speed ≤ 50 rpm and only with transmission settings 975, WS-75 and WI-75. Speed, torque and coolant can be changed during documentation.

Recording starts after a minimum torque of 1 Ncm is reached and ends 10 seconds after the motor is switched off. If the motor is restarted within 10 seconds, recording will continue even if the minimum torque of 1 Ncm has not yet been reached.

A picture file [bmp] and a text file [csv] are saved on the USB flash drive. The text file can be imported into Microsoft® Office Excel®** for further processing. The csv file can be opened either by double-clicking or by right-clicking on the file and selecting »Open with...«.

- > bmp file {torque progression, date, time, display screenshot}
- > csv file {torque data}



Do not use the saved bmp file and the csv file for diagnostic purposes.



Make absolutely sure that the USB flash drive is plugged into your computer correctly.

* Microsoft® is a registered trademark. All rights reserved by Microsoft Corporation.

** Office Excel® is a registered trademark of Microsoft®. All rights reserved by Microsoft Corporation.

Elcomed settings – Documentation

Symbol	Description	Solution
	Documentation active	
	Documentation not active	
	Documentation not possible	Adjust W&H contra-angle handpiece, connect USB flash drive, replace faulty USB flash drive, connect USB flash drive with sufficient memory space
	Storage device not recognized	Connect USB flash drive, replace faulty USB flash drive (the symbol will disappear in 3 seconds if no action is taken)
	Insufficient memory	Connect USB flash drive with sufficient memory space (the symbol will disappear in 3 seconds if no action is taken)
	Storage device recognized	Disappears after 1 second
	Saving process active	Disappears once documentation is saved
	Saving process finished	Disappears after 1 second

Elcomed settings – Thread cutter function (chip breaker mode)

 Activating the thread cutter function is only possible with transmission settings WS-75 and WI-75. When the thread cutter function is activated, the speed in both clockwise and anticlockwise rotations is 20 rpm and can no longer be changed. When the 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 anticlockwise rotation. Disengaging and then reengaging the pedal will switch the device back to clockwise rotation.

 If the thread cutter function is in anticlockwise rotation, the device can also start with the maximum torque.



❶ Thread cutter function



❷ Activate thread cutter setting



❸ Activate or deactivate thread cutter function



❹ Switch between programs (P 1, 2, 3, 4, 5, 6) or exit the thread cutter setting

 The thread cutter symbol, instead of the clockwise or anticlockwise rotation symbol, appears on the display in the main menu. The torque and coolant supply volume can be changed in the main menu.

Elcomed settings – Foot control

To change from VARIABLE to ON / OFF

 Switching between variable and On / Off is only possible in this menu.



① Foot control



② Select setting



= VARIABLE (factory setting)
Continuously variable motor control



= ON / OFF

15. Control unit operation – Main menu settings



Press shift button ▲ or ▼ to select the desired menu. Press the PLUS / MINUS button to set the menu functions.
The selected functions light up in green.

Programs [P1 – P6] →	[(P) 1]			← Documentation On / Off
Speed →	rpm	35.000		← Speed display
Torque →	Ncm	100%		← Torque display
Coolant →		100%	15:52 15.05.2008	← Time / Date
Transmission →		1:1		← Clockwise / anticlockwise rotation Thread cutter function

Main menu settings – Changing the program



❶ Program



❷ Next program



❸ Previous program

Main menu settings – Changing the speed



When the safety speed (40,000 rpm) is reached, an audible signal (safety stop) sounds.
To exceed the safety speed press the PLUS button once again or hold the PLUS button down (repeat function).

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

rpm ❶ Speed



❷ Increase speed



❸ Decrease speed



rpm 40.000 = the set maximum speed in rpm



= current speed display



At 50,000 rpm the accuracy of the speed displayed is $\pm 10\%$.

Main menu settings – Changing the torque



Settings range from 10 % to 100 % or 5 Ncm to 80 Ncm.

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

When the set torque in clockwise or anticlockwise rotation is reached, the motor automatically switches off.

Ncm ① Torque



② Increase torque in 10 % or 1 Ncm steps



③ Decrease torque in 10 % or 1 Ncm steps



With W&H surgical contra-angle handpieces WS-75, WI-75 and 975, if the speed is less than exactly 50 rpm, the torque is displayed in Ncm and can be adjusted in 1 Ncm increments. Above 50 rpm, the torque is displayed in 10 % increments.



With the contra-angle handpieces WS-75 and WI-75 in the range from 15 – 50 Ncm, the accuracy of the set torque achieved is $\pm 12\%$.

Main menu settings – Changing the coolant flow



Adjustable range: 0 % – 100 %.

By keeping PLUS / MINUS depressed the values are continuously increased / decreased.



❶ Coolant



❷ Increase flow rate in 20 % steps



❸ Decrease flow rate in 20 % steps

Main menu settings – Changing the transmission ratio



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

The transmission ratio can be adjusted only in clockwise rotation.



① Transmission ratio



② Select next transmission ratio



③ Select previous transmission ratio

16. Foot control operation

Changing the program

- > Press the ORANGE button to select programs 1 to 6 in ascending order.
- > Hold the ORANGE button down to select programs 6 to 1 in descending order.



With each program change, the motor direction is automatically set to clockwise rotation.

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 the pump is switched off, the pump symbol on the display is crossed out.

Anticlockwise rotation

- > Press the YELLOW button to change from clockwise rotation to anticlockwise rotation.



On selecting anticlockwise rotation, an audible signal can be heard and the anticlockwise symbol flashes.
Before the motor starts in anticlockwise rotation, an audible warning signal is given.

17. Error messages

Error	Description	Solution
	Foot control not recognized	Connect foot control
	Foot control error	Connect a functioning foot control or release the engaged button on the foot control
	Motor not recognized	Connect motor
	Motor error	Connect a functioning motor
	Motor faulty	Connect a functioning motor
	Shift buttons or PLUS / MINUS buttons activated when switching on the device	Release the activated button, switch off the device and restart

Error messages

Error	Description	Solution
	Electronics overheating Safety shutdown	Switch off the device, allow to cool for at least 10 minutes, then restart
	Electronics overloaded	Switch off the device and restart
	Call service centre	Switch off the device and restart. If the error message appears again, contact an authorized W&H service partner.



If one of the error messages described above cannot be rectified by switching off Elcomed and then switching it on again, the device must be checked by an authorized W&H service partner (see page 72).

If a total failure of the device occurs caused by external circumstances, the device must be switched off and then on again.



Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.



> Wear protective clothing, safety glasses, face mask and gloves.



> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.



Cleaning agents and disinfectants

- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
- > Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
- > It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
- > Use disinfectants which have been tested and found effective by the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).
- > The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.



The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

- > Send worn or damaged medical devices and/or medical devices with material changes to an authorized W&H service partner.



Processing cycles

- > We recommend a regular service for the W&H motor with cable after 500 processing cycles or one year.
- > W&H recommends that the motor support and the stand is replaced after 250 processing cycles.



- > Clean and disinfect the medical device immediately after every treatment.
- > Wipe the control unit, the motor with cable, the motor support and the stand with disinfectant.



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

Motor with cable / Motor support / Stand



- > Do not immerse the motor with cable, the motor support or the stand in liquid disinfectant or in an ultrasonic bath.

Motor with cable / Motor support / Stand

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



Control unit

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



Foot control

- > The ESD spring contact on the bottom of the foot control must be cleaned regularly.

Motor with cable / Motor support / Stand

-  > W&H recommends wiping down with disinfectant.
-  Evidence of the basic suitability of the motor with cable, the motor support and the stand for effective manual disinfection was provided by an independent test laboratory using the »mikrocid® AF wipes« disinfectant (Schülke & Mayr GmbH, Norderstedt).

Motor with cable / Motor support / Stand



W&H recommends automated cleaning and disinfection using a washer-disinfector (WD).

Read the notes, follow the instructions and heed the warnings provided by the manufacturers of washer-disinfectors, cleaning agents and/or disinfectants.



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



Evidence of the basic suitability of the motor with cable, the motor support and the stand for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer-disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg).

- > Cleaning at 55°C (131°F) – 5 minutes
- > Disinfection at 93°C (200°F) – 5 minutes

Motor with cable / Motor support / Stand



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

Inspection – Motor with cable / Motor support / Stand



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

Motor with cable / Motor support



Pack the motor with cable and the motor support in sterilization packages that meet the following requirements:

- > The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization method.
- > The sterilization package must be large enough for the sterilization goods.
- > The filled sterilization package must not be under tension.

Motor with cable / Motor support



W&H recommends sterilization according to EN 13060, EN 285 or ANSI/AAMI ST79.



- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
- > The program selected must be suitable for the motor with cable and the motor support.

Recommended sterilization cycles

- > Steam sterilization (type B, S, N)
- > Sterilization time at least 3 minutes at 134°C (273°F), 30 minutes at 121°C (250°F)
- > Maximum sterilization temperature 135°C (275°F)



Evidence of the motor with cable and the motor support basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)), the Systec VE-150 steam sterilizer (Systec) and the CertoClav MultiControl MC2-S09S273 steam sterilizer (CertoClav GmbH, Traun).

“Dynamic-air-removal prevacuum cycle” (type B): temperature 134°C (273°F) – 3 minutes*

“Steam-flush pressure-pulse cycle” (type S): temperature 134°C (273°F) – 3 minutes*

“Gravity-displacement cycle” (type N): temperature 121°C (250°F) – 30 minutes**

* according to EN 13060, EN 285, ISO 17665

** according to ANSI/AAMI ST55, ANSI/AAMI ST79

Motor with cable / Motor support



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

18. Servicing



Regular checks

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:



Control unit

- > External visual inspection
- > 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 indicators of overheating



Foot control

- > External visual inspection
- > Measurement of device leakage current
- > Measurement of ESD capacity
- > Visual inspection of the ESD spring contact on the bottom of the foot control (electrostatic discharge)
- > Function test with check to see if the maximum speed can be reached

The regular inspection must only be performed by an authorized W&H service partner.

Servicing

Repairs and returns

In the event of operating malfunctions immediately contact an authorized W&H service partner.

Repairs and maintenance work must only be undertaken by an authorized W&H service partner.



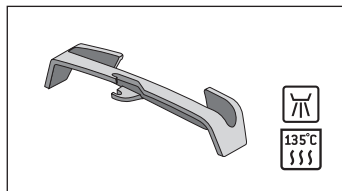
- > Ensure that the medical device has been completely processed before returning it.



- > Always return equipment in the original packaging.
- > Do not coil the cable around the motor and do not twist or kink the motor cable. (Risk of damage)

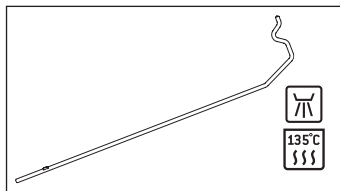
19. W&H Accessories

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



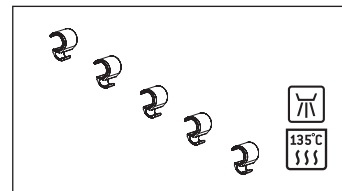
06177800

Motor support



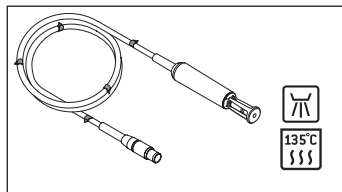
04005900

Stand



06290600

Clips (5 pcs)

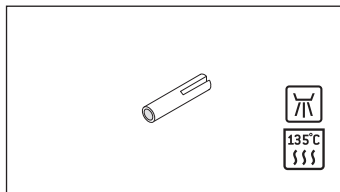


05513400

Motor with 1.8 m cable
incl. 5 clips

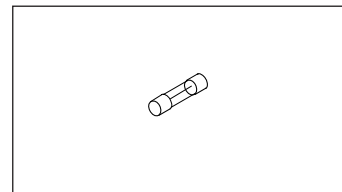
06205800

Motor with 3.5 m cable
incl. 10 clips



04006800

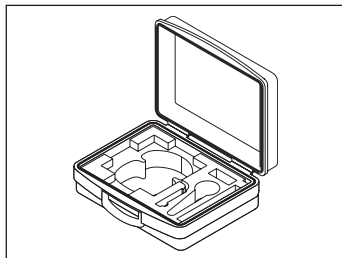
Locking pin



06352200

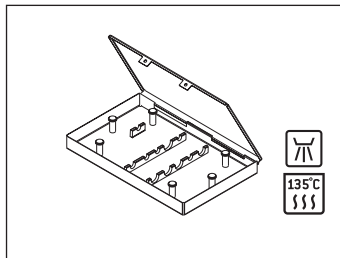
Fuse (250 V – T1.6AH)

W&H Accessories



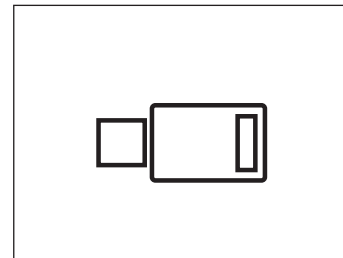
07945930

Transportation case



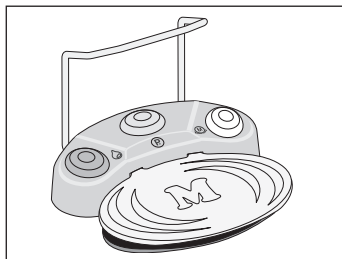
04013500

Sterilization cassette



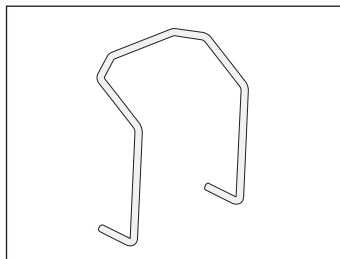
06290700

USB flash drive



06202400

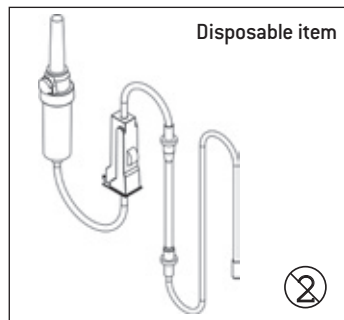
Foot control S-N1



04653500

Handle for foot control S-N1

W&H Accessories

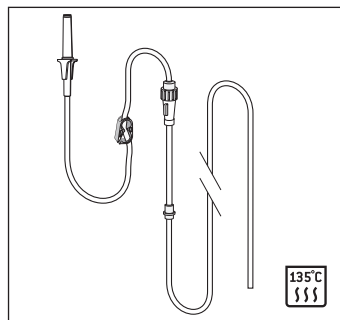


04363600

Irrigation tubing set 2.2 m (6 pcs)

04364100

Irrigation tubing set 3.8 m (6 pcs)



04719400

Irrigation tubing set 2.2 m

20. Technical data

Elcomed

SA-310

Supply voltage:	110 – 130 V / 220 – 240 V
Permitted voltage fluctuation:	±10 %
Nominal current:	0.1 – 1.8 A / 0.1 – 0.9 A
Mains fuse:	2 x 250 V – T1.6AH
Frequency:	50 – 60 Hz
Max. power consumption:	180 VA
Max. mechanical output power:	100 W
Max. torque on the motor:	7 Ncm
Motor speed range in the nominal voltage range:	300 min ⁻¹ – max. 50,000 min ⁻¹
Coolant flow rate at 100 %:	at least 90 ml/min
Operating mode:	S3 (2min/10min)
Dimensions in mm (WxDxH):	256 x 305 x 109
Weight in kg:	7

Physical characteristics

Temperature for storage and transport:	-40°C to +70°C [-40°F to +158°F]
Air humidity for storage and transport:	8 % to 80 % (relative), non condensing
Ambient temperature during operation:	+10°C to +40°C [+50°F to +104°F]
Air humidity during operation:	15 % to 80 % (relative), non condensing

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



Type BF 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. Disposal



Ensure that the parts are not contaminated on disposal.



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

- > Medical device
- > Waste electrical equipment
- > Packaging

W&H course certificate for the user

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

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

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

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



W&H course certificate for the instructor

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

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



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



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

Explanation of warranty terms

This W&H 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 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, 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

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

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

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