# Instructions for use

# MASTERsurg LUX Wireless REF 1.009.1200





Distributed by:

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#### 1 User instructions

# 1.1 User guide

#### 1.1.1 Symbols



Refer to the chapter on Safety/Warning symbol



Important information for users and service technicians



Thermodisinfectable



Sterilisable up to 135 °C



CE mark (European Community). A product bearing this mark meets the requirements of the pertinent EC directives, i.e. the standards applicable in Europe.

#### 1.2 Target group

This document is for dentists and dental office staff.

#### 1.3 Service



Please direct all questions regarding the product, service and maintenance to the KaVo Technical Service:

Toll-free: 1-888-ASK-KAVO (888-275-5286)

Email: customerservice@kavo.com

Please refer to the serial number of the product in all inquiries!

#### 1.3.1 Repair Service

KaVo offers a fixed-price service check for the original factory maintenance. You can use a loaner device for the time of the service check.

For repairs, please contact KaVo Repair Service.

For scheduling or if you have any questions, please contact:

KaVo Repair Service

KaVo Dental Corporation

11729 Fruehauf Drive

Charlotte, NC 28273 USA

Toll-free Direct Customer Service: 1-888-ASK-KAVO (888-275-5286)

Email: techservice@kavo.com

www.kavousa.com

# 1.4 Terms and conditions of warranty

KaVo provides the final customer with a warranty that the product cited in the handover certificate will function properly and guarantees zero defects in the material or processing for a period of 12 months from data of purchase, subject to the following conditions:

Upon justified complaints of flaws or a short delivery, KaVo will make good its warranty by replacing the product free of cost or repairing it according to the customer's wishes. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default and gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.

KaVo cannot be held liable for defects and their consequences due to natural wear, improper cleaning or servicing, non-compliance with operating, servicing or connection instructions, calcification or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with factory specifications.

The warranty does not usually cover bulbs, glassware, rubber parts and the colour-fastness of plastics.

Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party are excluded from the warranty. Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party are excluded from the warranty.

# 1.5 Transportation and storage

# 1.5.1 Currently valid packaging regulations



#### Note

Only valid for the Federal Republic of Germany.

Dispose of and recycle the sales packaging appropriately in accordance with current packaging regulations, employing waste management or recycling companies. Comply with the comprehensive return system. KaVo has had its sales packaging licensed for this purpose. Please comply with the regional public waste-disposal system.

#### 1.5.2 Damage in transit

#### In Germany

If the packaging is visibly damaged on delivery, please proceed as follows:

- The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
- 2. Leave the product and packaging in the condition in which you received it.
- 3. Do not use the product.
- 4. Report the damage to the shipping company.
- 5. Report the damage to KaVo.
- 6. Consult with KaVo first, before returning a damaged product.
- 7. Send the signed delivery receipt to KaVo.

1 User instructions | 1.5 Transportation and storage

If the product is damaged but there was no discernable damage to the packaging on delivery, proceed as follows:

- 1. Report the damage to the shipping company immediately and no later than 7 days after delivery.
- 2. Report the damage to KaVo.
- 3. Leave the product and packaging in the condition in which you received it.
- 4. Do not use a damaged product.

#### **Note**



Failure on the part of the recipient to comply with any of the above-mentioned obligations will mean that the damage will be considered to have arisen following delivery (in accordance with the General German Freight Forwarders' Terms and Conditions, Art. 28).

#### **Outside Germany**

# i

#### Note

KaVo shall not be held liable for damage arising from transportation. The shipment must be checked on arrival.

If the packaging is visibly damaged on delivery, please proceed as follows:

- The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
  - Without this evidence, the recipient will not be able to assert a claim for damages against the shipping company.
- 2. Leave the product and packaging in the condition in which you received it.
- 3. Do not use the product.

If the product is damaged but there was no discernable damage to the packaging on delivery, proceed as follows:

- 1. Report any damage to the shipping company either immediately or no later than 7 days after delivery.
- 2. Leave the product and packaging in the condition in which you received it.
- 3. Do not use a damaged product.

# i

#### **Note**

If the recipient fails to comply with any of the above-mentioned obligations, the damage will be considered to have arisen following delivery (in accordance with CMR law, Chapter 5, Art. 30).

#### 1.5.3 Information on the packaging: Storage and transportation



#### **Note**

Please keep the packaging in case you need to return the product for servicing or repair.

The symbols printed on the outside are for transportation and storage, and have the following meaning:

<u> </u>	Transport upright with the arrows pointing upwards!
T	Fragile - protect against impact!
	Protect from moisture!

1 User instructions | 1.5 Transportation and storage

kg max	Permissible stacking load
ç	Temperature range
<u>%</u>	Humidity
hPa	Air pressure

2 Safety | 2.1 Description of safety instructions

# 2 Safety

#### 2.1 Description of safety instructions

#### 2.1.1 Warning symbol



Warning symbol

#### 2.1.2 Structure



# **⚠** DANGER

The introduction describes the type and source of the hazard.

This section describes potential consequences of non-compliance.

► The optional step includes necessary measures for hazard prevention.

# 2.1.3 Description of hazard levels

Safety instructions distinguishing between three hazard levels are used in this document to prevent personal and property damage.



# **⚠** CAUTION

#### **CAUTION**

indicates a hazardous situation that can cause damage to property or mild to moderate injuries.



# **MARNING**

#### **WARNING**

indicates a hazardous situation that can lead to serious or fatal injury.



#### ⚠ DANGER

#### **DANGER**

indicates a maximal hazard due to a situation that can directly cause death or fatal injury.

# 2.2 Information about electromagnetic compatibility

#### **Note**



Based on IEC 60601-1-2 (DIN EN 60601-1-2) concerning the electromagnetic compatibility of electrical medical devices, we must draw your attention to the following points:

- Medical electrical devices are subject to special precautions concerning the electromagnetic compatibility and must be installed and operated in accordance with the KaVo assembly instructions.
- High-frequency communications devices may interfere with electrical medical devices.

#### See also:

12 Information about electromagnetic compatibility, Page 71



#### Note

KaVo cannot guarantee the compliance of accessories, cables, and other components not supplied by KaVo with the EMC requirements of IEC 60601-1-2 (DIN EN 60601-1-2).

# 2.3 Disposal of electronic and electrical devices

# Note



According to EC directive 2012/19 concerning used electrical and electronic devices, this product is subject to the cited directive and must be disposed of accordingly within Europe.

For more information, please visit www.kavo.com or contact your specialised dental supplier.

For final disposal:

#### In Germany

To return an electrical device, you need to proceed as follows:

- On the homepage www.enretec.de of enretec GmbH, you can download a form for a disposal order under the menu item eom. Download the disposal order or complete it as an online order.
- 2. Enter the corresponding information to complete the order, and submit it as an online order or by fax +49 (0)3304 3919 590 to enretec GmbH.

The following contact options are also available for questions and for initiating a disposal order:

Phone: +49 (0) 3304 3919-500 Email: eom@enretec.de and

Postal address: enretec GmbH, Geschäftsbereich eomRECYCLING®

Kanalstraße 17 D-16727 Velten

3. A unit that is not permanently installed will be picked up at the office.

A permanently installed unit will be picked up at the curb at your address on the agreed date.

The owner or user of the device will have to bear the cost of disassembly, transportation and packaging.

#### International

For country-specific information on disposal, contact your dental supplier.

# 2.4 Safety instructions

#### **MARNING**

Application of un-authorised accessories or un-authorised modifications of the product.



Accessories that have not been approved and/or inadmissible modifications of the product could lead to hazards and/or personal injury or property damage.

- Only use accessories that have been approved for combination with the product by the manufacturer or are equipped with standardised interfaces (e. g. MULTIflex couplings, INTRAmatic).
- ▶ Do not make any modifications to the device unless these have been approved by the manufacturer of the product.

2 Safety | 2.4 Safety instructions



#### **⚠** CAUTION

#### Electrical sparks in the product.

Explosion and/or fire.

- ▶ Do not use product in areas subject to an explosion hazard.
- ▶ Do not operate the product in an oxygen-enriched atmosphere.



# **⚠** CAUTION

Damaged mains cable / missing protective conductor.

Electrical shock.

Check the mains cable before use. The socket outlet must have a protective contact and meet the respective national guidelines.



# **⚠** CAUTION

#### Damage by liquids.

Faults on electrical components.

Protect openings of the product from any ingress of liquids.



#### Inadvertent penetration of liquids.

Electrical shock.

- ▶ Do not place the product in a tub-like container.
- Check the coolant containers and lines for absence of leakage. If any liquid is detected on the device, do not touch the device and disconnect the device from the mains supply without delay. Make sure that the surface of the device is completely dry before plugging the main plug back in the socket.



#### **A** CAUTION

#### Rotating parts while the pump is operating

Injuries

▶ Do not stick anything in the pump. Turn off the device when the pump is open.

# **⚠** CAUTION



#### Risks from electromagnetic fields.

Electromagnetic fields might interfere with the functions of implanted systems (such as pacemakers).

Ask patients if they have a cardiac pacemaker or other system implanted before you start the treatment!



# **⚠** CAUTION

#### Impact of power failure.

Failure of the voltage supply or other errors can cause the surgical motor to come to a standstill.

Make sure that the power supply is working.

# 3 Description of the product

The MASTERsurg LUX Wireless is a surgical controller according to 21 CFR § 872.4200 (dental handpiece and accessories). The device consists of a surgical control unit, a foot controller, a surgical motor (separate IFU) + motor cable, an instruments tray, a holder and a tube set. As a functional principle the software-based surgical control unit controls the speed and torque of a dental micro motor. The unit is equipped with a pump for the use with external irrigation tubing allowing irrigation of the working area. The surgical control unit is operated through the buttons on the tabletop console or via foot control. The device is intended to be used with the INTRA LUX S600 LED (separate IFU) motor. Straight or contra-angle handpieces with a handpiece connection according to ISO 3964 can be equipped. The instrument tray allows the dentist to deposit the handpieces in a safe position. The holder is intended to be used for general storage of the bottle. The tube set is needed to deliver the external irrigation from the bottle to the different handpieces. A power cord provides electric power to the unit. The MASTERsurg LUX Wireless will be delivered with software on the surgical control unit.

#### 3.1 Intended use

#### Indications for use

This KaVo product is intended for surgery to expose and dissect oral tissue structures or endodontic treatments (e.g. periodontal gap, gingiva, bone, jaw, extractions and implantations).



#### **⚠** CAUTION

US Federal law restricts this device to sale by or on the order of a health care professional / dentist.

For dental use only.





#### Note

The MASTERsurg LUX Wireless is approved for use in surgical theatres.

The overarching guidelines and/or national laws, national regulations and the rules of technology applicable to medical devices for start-up and use of the KaVo product for the intended purpose must be applied and followed.

The user must ensure that the unit works properly and is in satisfactory condition before each use.

The applicable national legal regulations must be observed during the use of the device, in particular the following:

- Applicable regulations governing the connection and start-up of medical devices.
- Current occupational safety regulations.
- Current accident prevention regulations.

It is a responsibility of the user:

to only use equipment that is operating correctly,

#### 3 Description of the product | 3.1 Intended use

- to protect him or herself, the patient and third parties from hazards, and
- to prevent contamination from the product

To guarantee the consistent readiness for use and to preserve the value of the KaVo product, the recommended maintenance services must be carried out in 2 year intervals.

The following persons are authorised to repair and service the KaVo product:

- Technicians of KaVo branch offices after appropriate product training.
- Specifically KaVo-trained technicians of KaVo franchised dealers.



#### **Note**

The permitted work is described in the Technician's Instructions available to the trained service staff.

In Germany, operators, equipment managers and users are obliged to operate their equipment in accordance with the MPG regulations.

The services encompass all the test tasks required in accordance with § 6 of the medical devices operator ordinance (Medizinprodukte-Betreiberverordnung, MPBetreibV).

After servicing, interventions, and repairs of the device, the device must be tested according to IEC 62353 (according to the state of the art) before re-use.



#### Note

The product must be cleaned and serviced according to instructions if it is not to be used for an extended period of time.





Any waste which is generated must be recycled or disposed of in strict compliance with all applicable national regulations in a manner which is safe both for people and the environment.

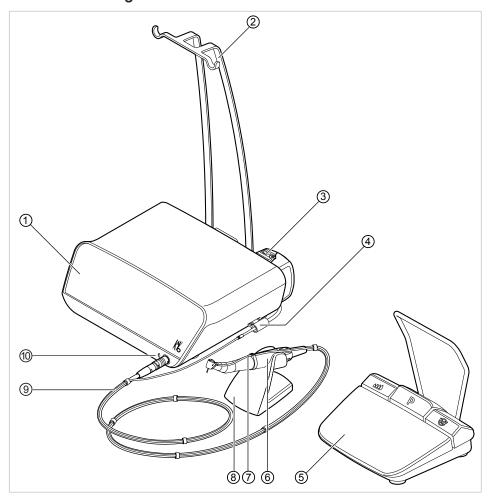
If you have any questions regarding proper disposal of the KaVo product, please contact the KaVo branch.



#### **Note**

A recycling pass can be downloaded from www.kavo.com.

# 3.2 MASTERsurg LUX Wireless

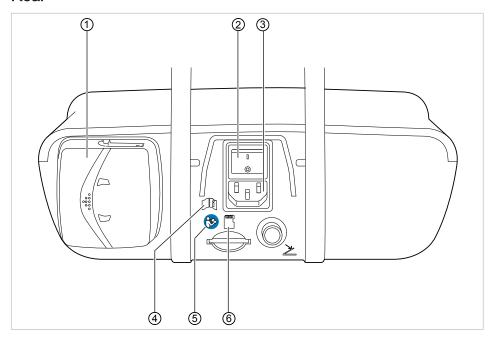


- ① Hand-held control panel
- 3 Hose pump
- ⑤ Wireless foot control
- ⑦ Coolant hose
- Motor cable

- ② Bottle holder
- 4 Hose fixation
- ⑤ Surgical motor
- 8 Handpiece tray
- Symbol of type B applied part

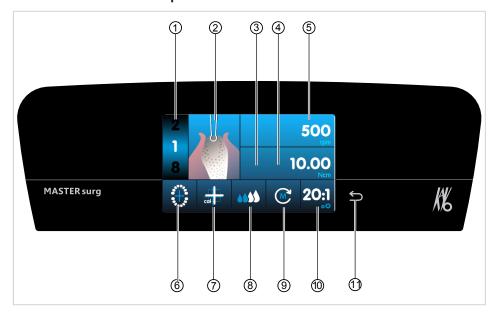
# 3 Description of the product | 3.2 MASTERsurg LUX Wireless

# Rear



- ① Hose pump locking mechanism
- 3 Power plug
- ⑤ Follow the instructions for use
- ② On-button
- 4 Please note the instructions for use
- ⑥ SD card slot

# 3.3 Hand-held control panel



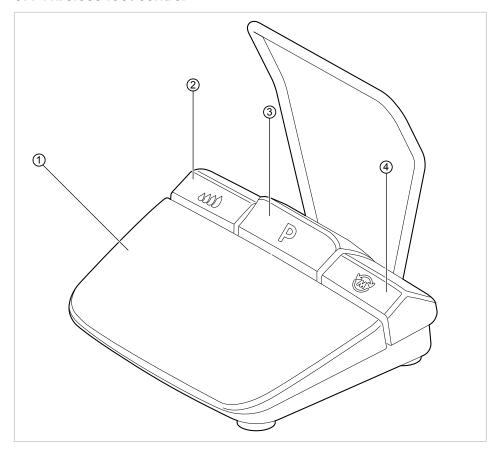
- ① Program step
- 3 Maximal torque reached
- ⑤ Speed
- Activation of one-touch calibration
- Direction of motor rotation
- Back key

- ② Display of the activity
- 4 Torque limit
- ⑥ Wireless foot control status indicator / input implant position
- ® Coolant pump settings
- Transmission ratio



The back key has two functions. Pressing the back key briefly returns you to the previous step. Pressing the back key long opens the device settings.

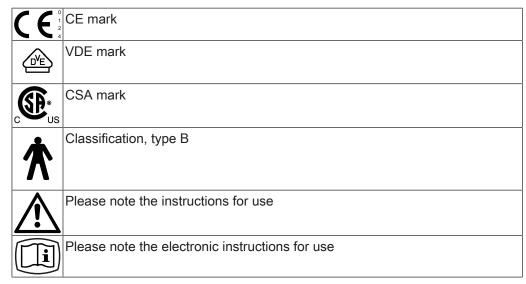
#### 3.4 Wireless foot control



- ① Speed key (grey)
- ③ Programme key (grey)
- ② Pump key (blue)
- ④ Direction of motor rotation key (yellow)

# 3.5 Rating plates of MASTERsurg LUX Wireless and wireless foot control

The rating plates of MASTERsurg LUX Wireless and wireless foot control are affixed on the underside of the housing and include the following symbols:



3 Description of the product | 3.5 Rating plates of MASTERsurg LUX Wireless and wireless foot control

	<u></u>
	Follow the instructions for use
П	Operating mode: continuous operation with intermittent load
$\sim$	Alternating current (AC)
V	Supply voltage
	Protection class II
	Manufacturer
SN	YYYY = Year manufactured XXXXXXX = Serial number
REF	Material number
Type:	Device type
X	For disposal information, see Intended use
	GOST R certification
× 10	HIBC Code
((( <u>*</u> )))	Product includes HF emitter

3 Description of the product | 3.6 Technical Specifications MASTERsurg LUX Wireless

# 3.6 Technical Specifications MASTERsurg LUX Wireless

Width	265 mm
Depth	255 mm
Height	100 mm
Weight	approx. 2.0 kg
Weight of wireless foot control	approx. 1.1 kg
Weight of motor	approx. 125 g
Input voltage	100 - 240 V ~
Input frequency	50/60 Hz
Rated power	max. 150 W
Speed	300 – 40,000 rpm
Max. torque on the motor	5.5 Ncm
Pump delivery rate	30 - 110 ml/min
Wireless foot control: Class of protection	IPX8
Wireless foot control: Emitted power	max. 3 dBm (e.i.r.p.)
Wireless foot control: Frequency band	ISM 2.4 GHz
Length of motor cable	6.5 ft (2 m)
Operating mode Continuous operation with intermittent load	30 sec. of operation/ 9 min. pause



# **Note**

The maximal motor load is 30 seconds operating time / 9 minutes pause (full load at maximal speed).

# Transportation and storage conditions

Ambient temperature	-20 °C - +50 °C
Relative humidity	5% - 95%
Air pressure	700 hPa - 1,060 hPa

# Operating environment



# **MARNING**

# Inappropriate operating conditions.

Impairment of the electrical safety of the device.

It is essential to comply with the operating conditions specified in the "Technical Specifications" chapter.

3 Description of the product | 3.7 Scope of delivery

Ambient temperature	+10 °C - +35 °C
Relative humidity	15% - 80%
Air pressure	700 hPa - 1,060 hPa
Max. elevation for operation	up to 3,000 m

# 3.7 Scope of delivery

The scope of delivery of the MASTERsurg LUX Wireless includes the following:

- MASTERsurg LUX Wireless unit
- Wireless foot control
- Surgical motor INTRA LUX S600 LED
- Motor cable S600
- Instrument tray
- Hose set sterile S600 (5 units)
- Bottle holder
- Batteries, alkaline type AA/ LR6 (3 pcs.)
- SD memory card (with sample programme)
- Instructions for use MASTERsurg LUX Wireless
- Brief instructions for use MASTERsurg LUX Wireless
- Instructions for use INTRA LUX S600 LED

# 4 Commissioning

# 4.1 Unpacking

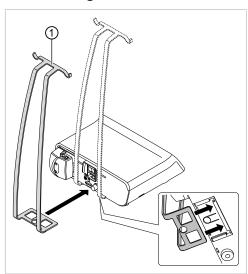


#### **Note**

You need to keep the cardboard box and all packaging materials to be able to safely ship the unit in the future.

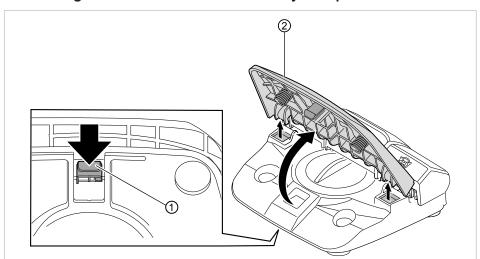
- ► Open the cardboard box.
- ▶ Remove the hose boxes.
- Take out the wireless foot control and additional equipment.
- ► To take out the unit, pull it vertically upward and place it on a level surface.

# 4.2 Installing the bottle holder



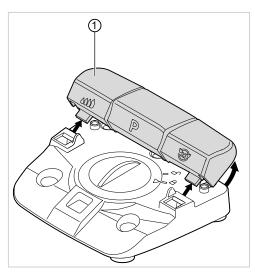
- ▶ Slide the bottle holder ① in the guide on the underside of the unit.
- ⇒ The bottle holder ① snaps into place audibly and is then affixed.

#### 4.3 Getting the wireless foot control ready for operation

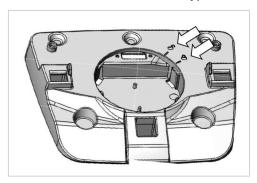


▶ On the underside of the wireless foot control, press down the snap-in lug ① of the speed button ② and take the speed button ② off the wireless foot control.

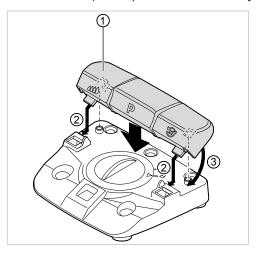
4 Commissioning | 4.3 Getting the wireless foot control ready for operation



- ▶ Pull the button bar ① including the pump button, program button, and motor direction button slightly upwards and take it off the wireless foot control.
- ► To open the lid, turn it to the left and take it off.
- ► Insert 3 batteries, alkaline type AA/ LR6.

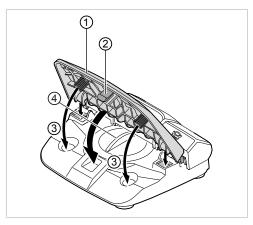


► Place the lid on the unit (arrow points at "Open" symbol) and close it by turning it clockwise (arrow points at "Closed" symbol).

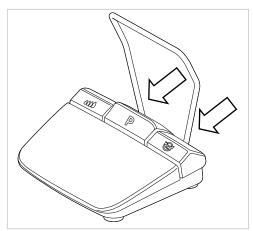


4 Commissioning | 4.3 Getting the wireless foot control ready for operation

▶ Plug the button bar ① onto the wireless foot control ② and press it on lightly until the button bar ① snaps into place ③.



▶ Plug the speed button ① onto the wireless foot control and press it on lightly until the snap-in lug ② snaps in. Make sure that the foot pedal springs are situated in the recesses of the housing ③.



Slide the bracket into the designated recesses.

The wireless foot control is now ready for operation and can be used. The initial connection is done at the factory.

#### **Note**



#### Stand-by mode

The wireless foot control does not need to be switched on and off. It switches into stand-by mode automatically after a certain period of rest or once the MASTERsurg LUX Wireless is switched off. To start the wireless foot control, briefly press the pedal once.



#### Note

If the wireless foot control is not connected or if it is in stand-by mode, a yellow warning symbol of the wireless foot control is shown on the display of the MASTER-surg LUX Wireless.

► To solve the problem:

#### See also:

# 4.4 Connecting the surgical motor

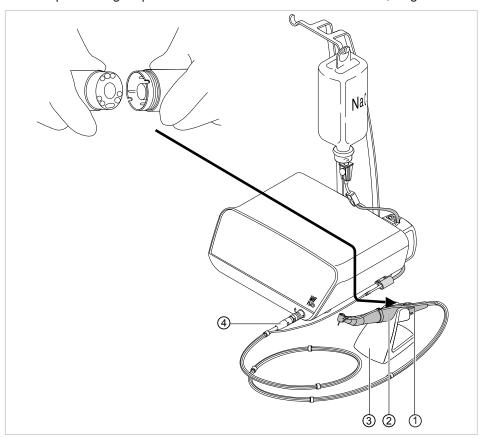


#### Note

The delivered parts are not sterile (except for the coolant hose). Before the first treatment of a patient, the surgical motor, motor cable, and the handpiece tray need to be reprocessed.

#### See also:

7 Reprocessing steps in accordance with DIN EN ISO 17664, Page 59



- Motor coupling
- 3 Handpiece tray

- ② Surgical motor
- 4 Plug of motor cable
- ▶ Plug the surgical motor ② into the motor coupling ① and secure it with a union nut. Please note the separate instructions for use of the motor.
- ▶ Place the surgical motor on the handpiece tray ③.
- ▶ Insert the plug of the motor cable ④ into the connector on the device, align the marker points, and insert the plug until it snaps into place.

# 4.5 Connecting the coolant container and hose set



# **A** CAUTION

Running, open hose pump.

Risk of injury.

► Turn off the device before opening the hose pump.



#### **⚠** CAUTION

Danger of tipping due to the coolant containers being too heavy.

Malfunctions

- ▶ Use coolant containers with a maximal volume of 1 litre only.
- ► Check the stability.



#### **Note**

The coolant must be selected to suit the planned application. The flow rate of the coolant is dependent on the instrument used. The user must set an adequate flow of coolant and check this.



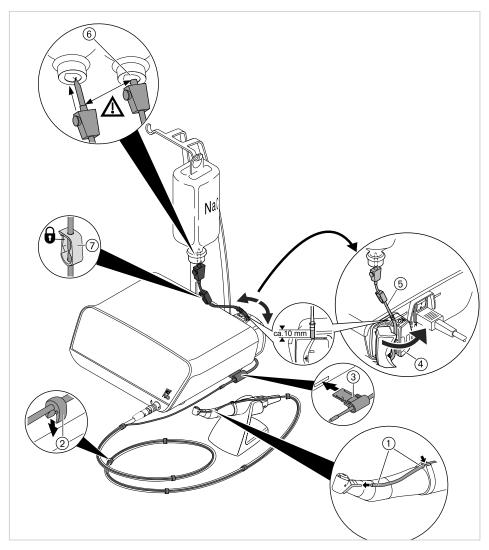
#### Note

The hose set sterile S 600 (10 pcs.) (**Mat. no. 1.009.8757**) must be changed after each application.



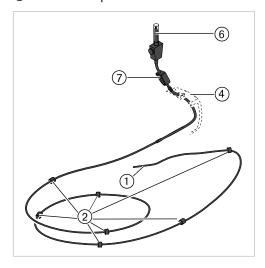
#### **Note**

Check the integrity of the hose set before use. If product or packaging are damaged, the product needs to be discarded.



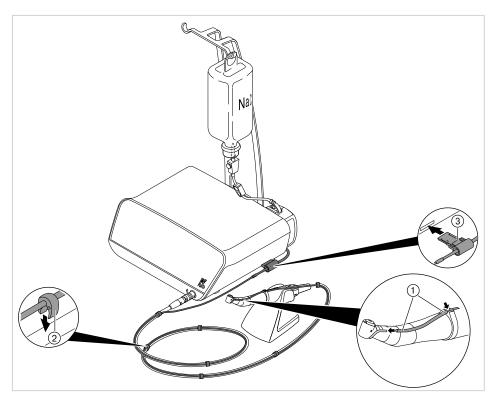
- ① Coolant hose
- 3 Hose fixation
- ⑤ Pump hose
- ⑦ Hose clamp

- 2 Clips
- 4 Lock
- 6 Insertion needle



- ① Coolant hose
- 3 Hose fixation
- ⑤ Insertion needle

- ② Clip
- 4 Lock
- ⑦ Hose clamp

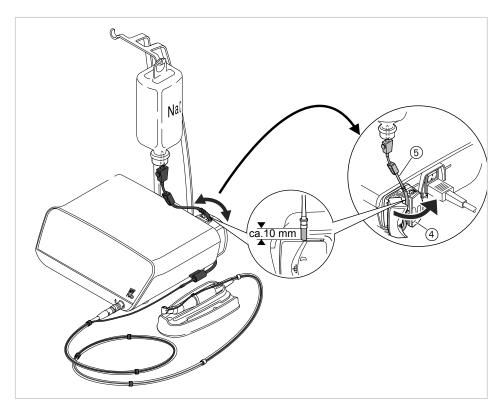


- ► Close the hose clamp ⑦ of the hose set.
- ► Attach the coolant hose ① to the straight or contra-angle handpiece.
- ▶ Place the coolant hose ① tightly, without loops or kinks, against the outside of the motor cable and attach it in regular intervals using the enclosed clips ②.
- ▶ Plug the hose fixation ③ into the opening of the device with the blue border until the hose fixation ③ snaps in.



# Note

The unit recognises the hose fixation. If the unit fails to recognise the hose fixation or if it is not plugged in, the coolant supply symbol is shown with a yellow background.



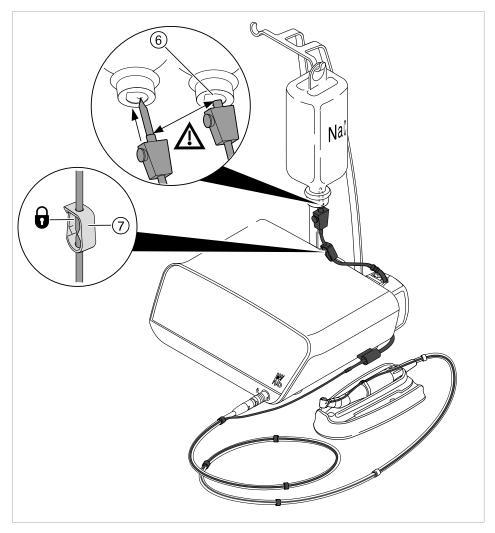
- ► Open the lock ④ and insert the pump hose ⑤.
- ► Close the lock ④.



#### **Note**

Make sure to place the pump hose in the pump appropriately such that the pump hose does not get clamped or pinched by the lock. Route all hoses relaxed and without tension.

#### 4 Commissioning | 4.6 Electrical connection



- ► Stick the puncture needle ⑥ into the coolant container and hook-in the coolant container on the bottle holder.
- ► Check the sealing and firm seating of the puncture needle ⑥. Prevent fluid from leaking above the device.
- ▶ If you use a glass bottle, open the ventilation on the puncture needle ⑥.
- ▶ If you use a bag, keep the ventilation on the puncture needle ⑥ closed.
- ▶ Open the hose clamp ⑦ before startup.



#### **Note**

Using a new hose, it may take up to approx. 10 seconds for the coolant to exit on the handpiece, depending on the feed rate.

#### 4.6 Electrical connection



# **⚠** CAUTION

Damaged mains cable / missing protective conductor.

Electrical shock

► Check the mains cable before use. The socket outlet must have a protective contact and meet the respective national guidelines.

4 Commissioning | 4.6 Electrical connection



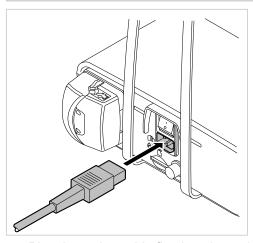
# **Note**

The unit must be set-up appropriately such that the mains plug and the electrical outlet are easily accessible.



#### **Note**

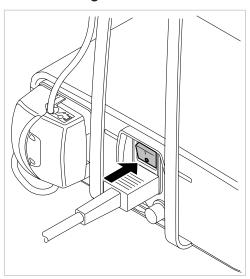
The protective earth conductor is used as functional earthing (FE) rather than as protective earthing (PE).



▶ Plug the mains cable first into the mains socket on the device and then the other end of the mains cable into the electrical outlet of the supply network.

# 5 Operation

# 5.1 Switching the device on



- ► Turn the device on.
- ⇒ The device runs a self test.



#### **Note**

Unless the unit is monitored, KaVo recommends turning it off for safety and energy-saving reasons.



#### **Note**

#### **Auto-Off function**

After 10 minutes of inactivity, the light on the handpiece, the pump and the motor on the unit are turned off.

# 5.2 Device settings

The following device settings can be made or displayed:

- Setting the language
- Setting the documentation
- Setting the LUX brightness
- Setting the LUX afterglow time
- Setting the operating mode of the foot pedal
- Setting the pump key operating mode of the foot control
- Connect the wireless foot control
- Adjusting the clock time
- Setting the date
- Setting the LCD brightness
- Setting the volume
- Setting the key sound volume
- Multi-programme mode
- Exporting settings

- Importing settings
- Factory settings
- Version



Press the back key for a long time in order to access the device settings.

# 5.2.1 Setting the language



▶ Press the plus and minus keys to change the language.

# 5.2.2 Setting the documentation

Three modes are available:

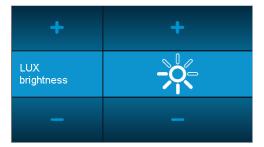
- Implant: Documentation during implant insertion
- Permanent: Documentation of entire treatment process on SD card
- Off: Documentation disabled



► Touch the plus and minus keys to set the documentation mode.

# 5.2.3 Setting the LUX brightness

The LUX brightness determines the brightness of the LEDs on the handpiece. The brightness can be set in 4 steps ranging from off to maximal brightness.



Press the plus and minus keys to change the LUX brightness.

# 5.2.4 Setting the LUX afterglow time

The LUX afterglow time determines how long the handpiece LEDs afterglow after each motor stop. The afterglow time can be set from 0 to 10 seconds.



Press the plus and minus keys to change the LUX afterglow.

# 5.2.5 Setting the operating mode of the foot pedal

The motor can be triggered in either of two operating modes:

The motor starts at full speed when the foot pedal is actuated.



The motor speed can be adjusted continuously up to the maximal level using the foot pedal



► Touch the symbol to change the operating mode of the foot pedal.

# 5.2.6 Setting the pump key operating mode of the foot control

The pump can be triggered in either of two operating modes:

Actuating the pump key switches the coolant flow on or off.



Actuating the pump key gradually increases the coolant flow up to its maximum value.



Touch the symbol to change the operating mode of the pump key on the foot control.

#### 5.2.7 Connect the wireless foot control

The wireless foot control can control all functions of the surgical unit to which it is connected.



#### Note

In order to ensure that only a combination of control unit and wireless foot control communicate, these need to be connected.

The wireless foot control can be connected in three steps:

- 1. Touch the symbol to start the connection process.
- 2. Press and hold down the speed button of the wireless foot control for at least 1 second.
- Release the speed button and then press both the left and the right button of the
  wireless foot control concurrently until the confirmation of connection "Successfully
  connected to wireless foot control" is displayed. This process can take up to 15
  seconds.



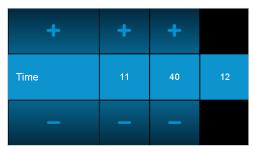


Press the back key to return to the selection of device settings.

# 5.2.8 Adjusting the time of day

The time of day can be set as hours, minutes and seconds:

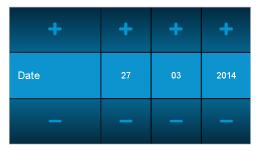
#### 5 Operation | 5.2 Device settings



Press the plus and minus keys to change the time of day.

# 5.2.9 Setting the date

The date can be set as day, month and year:



Press the plus and minus keys to change the date.

# 5.2.10 Setting the LCD brightness

The LCD brightness determines the brightness of the display. The brightness can be set in 3 steps ranging from dark to maximal brightness.



▶ Press the plus and minus keys to change the LCD brightness.

# 5.2.11 Setting the volume

The volume level determines the volume of signal sounds. The volume can be set in 3 steps ranging from quiet to maximal volume. The volume cannot be turned off for safety reasons.



▶ Press the plus and minus keys to change the volume.

## 5.2.12 Setting the key sound volume

The key sound determines the volume of the sound made when a key is pressed. The volume can be set in three steps or switched off.



Press the plus and minus keys to change the volume of button sounds.

## 5.2.13 Multi-program mode

- One program: One program with up to 4 to 10 program steps and/or activities is available. After start-up, you can start immediately with the first step of treatment.
- Multiple programs: After start-up, an overview of the 10 programs is displayed. For each program, up to 4 to 10 program steps and/or activities are available.



## 5.2.14 Exporting settings

The export of settings allows the user to export all device settings in a <SURG\_MA.SET> file to the SD card. KaVo recommends exporting the settings as soon as the individual basic settings have been made.



### 5.2.15 Importing settings

The import of settings allows the user to import all device settings in a <SURG\_MA.SET> file from the SD card. This allows a defined status to be restored, e.g. if settings were changed or deleted inadvertently.

#### 5 Operation | 5.3 Surgical Motor INTRA LUX S600 LED



## 5.2.16 Factory settings

Factory settings can be used to re-set the unit to its condition at the time of delivery. All program steps and device settings are re-set to their default values.



► Touch the symbol to restore the factory settings.

In the window, you will be asked whether or not you wish to carry out the action.



- ► Touch "Yes" to carry out the action.
- ▶ Press "No" or the back key to discontinue the action.

## **5.2.17 Version**



Display of software version (presently: 01.10)



▶ Press the back key for a long time in order to exit from the device settings.

## 5.3 Surgical Motor INTRA LUX S600 LED



#### **Note**

Following instructions for use, service instructions and installation instructions in the motor, handpiece and contra-angle handpiece packaging.

#### See also:

Instructions for use INTRA LUX S600 LED

## 5.3.1 Attaching the straight or contra-angle handpiece

## **⚠** CAUTION



Damage from changing the straight and contra-angle handpieces during operation. Wear to the catch on the straight and contra-angle handpiece and motor. Unbalanced motor axis.

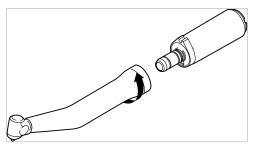
Change the straight and contra-angle handpieces only when the motor is not running.



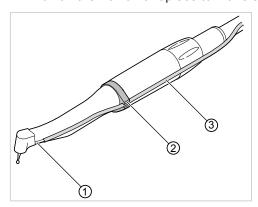
#### **Note**

Following instructions for use, service instructions and installation instructions in the motor, handpiece and contra-angle handpiece packaging.

All straight and contra-angle handpieces with INTRAmatic connection ISO 3964 can be attached.



- ▶ Place the KaVo handpiece on the motor, lightly press it against the motor while turning it slightly in the direction of the arrow until the guide stud can be heard to lock into place.
- ▶ Pull on the KaVo handpiece to make sure that it is securely attached to the motor.



▶ Route the coolant hose ③ from the unit along the motor cable (clips) and connect it to the straight or contra-angle handpiece ①. Place the coolant hose ③ into the holding ring ② for this purpose.

## 5.3.2 Removing the straight or contra-angle handpiece

#### **A** CAUTION



Damage from changing the straight and contra-angle handpieces during operation. Wear to the catch on the straight and contra-angle handpiece and motor. Unbalanced motor axis.

- Change the straight and contra-angle handpieces only when the motor is not running.
- ▶ Pull the coolant hose off the straight or contra-angle handpiece.
- ► Twist the straight or contra-angle handpiece slightly to pull it off.

## 5.4 Setting-up multi-program mode

A total of 10 programs are available to the user. These can be assigned, e.g., to various users or implant systems. Each program includes 4 to 10 program steps and/or activities.

After start-up, an overview of the 10 programs is displayed.





► Changing page. Programs 1 to 5 on page 1; programs 6 to 10 on page 2



► Changing the name of the selected program.



Deleting a program and/or resetting program settings and name to factory settings.



Run selected program.

Multi-program mode can be disabled in the device settings here.

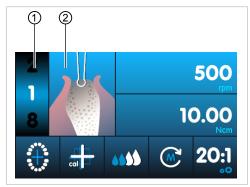


#### Note

In One-program mode, changes to settings become effective in program 1 (topmost program on page 1).

## 5.5 Setting and executing program steps

The MASTERsurg LUX Wireless is based on program steps and associated activities and can be operated intuitively using the graphical user interface.



Program step 1: Marking

The current program step is shown on the display as number ① and the corresponding activity is shown as symbol ②. Each program step can be assigned to any activity by selecting the corresponding symbol.

Visualising the activity is an easy means for checking if the activity set on the device is the same as the current treatment step. Maloperation can thus be largely prevented.

Default values have been set at the factory for the parameters, speeds, torques, transmission ratios and coolant flow rate for every activity according to application. The parameters can be changed only within a reasonable range for the specific activity. In the activity, "Free application", all available values can be set. The table below lists the ranges of values and factory settings.

A treatment sequence can consist of 4 to 10 program steps and/or activities. The treatment sequence can be designed individually through any arrangement of the activities. During the sequence, the wireless foot control is used for navigation such that the device does not have to be touched again during the intervention. Changed values are saved automatically and are then available for the next use.

### 5.5.1 Factory settings

The following program steps are pre-set at the factory:

Programme step	Icon	Activity	Speed [rpm]	Torque [Ncm]	Transmission ratio	Coolant flow
1		Marking	200 – 2,000 500 (D)	5 – 20 10 (D)	16:1 27:1 20:1 (D)	0 – 4 2 (D)
2		Pilot drilling	200 – 2,000 500 (D)	5 – 20 10 (D)	16:1 27:1 20:1 (D)	0 – 4 2 (D)

## 5 Operation | 5.5 Setting and executing program steps

Programme step	Icon	Activity	Speed [rpm]	Torque [Ncm]	Transmission ratio	Coolant flow
3		Template drilling	200 – 2,000 500 (D)	5 – 20 10 (D)	16:1 27:1 20:1 (D)	0 – 4 2 (D)
4		Tapping	15 – 50 20 (D)	5 – 80 25 (D)	16:1 27:1 20:1 (D)	0 – 4 2 (D)
5		Placing im- plant	15 – 50 20 (D)	5 – 80 25 (D)	16:1 27:1 20:1 (D)	0 – 4 0 (D)
6		Setting a closure cap	15 – 50 20 (D)	5 – 15 8 (D)	16:1 27:1 20:1 (D)	0 – 4 0 (D)
7	$\Lambda \mathcal{D}$	Free use	300 – 40,000 40,000 (D)	0.15 – 5.5 3 (D)	1:1	0 – 4 2 (D)
	1-14/		20 – 2,000	5 – 80	16:1	
			15 – 2,000	5 – 80	20:1	
	'Ru   H.		15 – 1,200	5 – 80	27:1	
8		Rinsing function	_	_	-	_
9	A	Treatment completed (can be set from programme step 4)	_	_	_	_

(D) = factory setting (default setup)



## **Note**

The listed indications are only examples. In order to prevent risks, it is essential to comply with the manufacturer recommendations concerning implants, handpieces, and tools.

## 5.5.2 Exemplary programme step sequences

**Example 1: Factory setting** 

Step	1	2	3	4	5	6	7	8
Activity	Marking	Pilot drilling		Thread cut- ting	Placing implant	Setting closure cap		Treatment completed (can be set from pro- gram step 4)
Symbol	7			4				A

Example 2: Program steps that do not include the activity, "Cut thread", and include the "Rinsing function" activity

Step	1	2	3	5	4	5	7
Activity	Marking	Pilot drilling	Template drilling	Rinsing function	Placing implant		Treatment completed (can be set from program step 4)
Symbol							

Example 3: Activity "Free use" as step 1, screw implant in manually

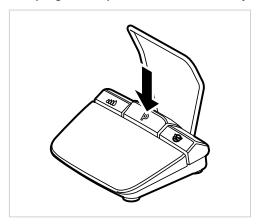
Step	1	2	3	4	5
Activity	Free use	Marking	Pilot drilling		Treatment completed (can be set from program step 4)
Symbol					

## 5.5.3 Selecting the program steps



Select step by touching the program step display.

The program step is saved automatically.



The program steps can be selected during the treatment using the program key of the wireless foot control. After the last program step follows the first step again. Press the program key long to select the previous program step.

### See also:

## 5.5.4 Selecting activities



► Touch the symbol. This opens a window that shows all activities.

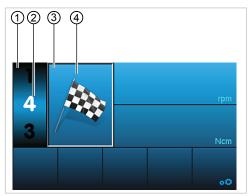


Select the desired activity.

The activity is saved automatically.

## 5.5.5 Limiting the program steps

The number of program steps can be limited. Program steps that are not needed are deleted from the display.



- ► Touch the upper or lower black program step on the display to select program step ②, which terminates the treatment (can be set from program step 4).
- ► Touch the activity display.
- Select the flag symbol.

The settings are saved automatically and the treatment is terminated with the selected program step.

Navigating through the program steps with the wireless foot control, the step with the flag symbol is skipped.

## Undo the limitation of program steps

Select the program step with the flag symbol and assign different activity.

## 5.6 Changing default values

The default values set at the factory can be changed within a given range. If the selected activity is Free use, the values can be set freely.

The following values can be changed:

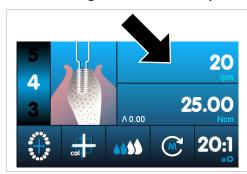
- Maximal speed
- Torque limit
- Coolant flow
- Direction of motor rotation
- Transmission ratio

#### 5 Operation | 5.6 Changing default values

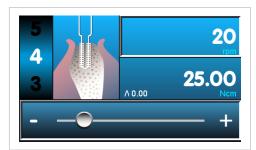
- ► Select the desired value by touching it.
- ► To set the desired value, proceed as shown on the display.

The value is saved automatically.

## 5.6.1 Setting the maximum speed



Select speed display.



Slide the slider to the desired value or touch the plus or minus area.

The value is saved automatically.



Press the back key to close the speed setting.

## 5.6.2 Setting the torque limit



## Note

The MASTERsurg LUX Wireless reduces the power to prevent the maximal torque setting from being exceeded. This may lead to the motor coming to a standstill if the rotating handpiece is blocked.

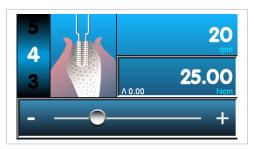


Select the torque display.



#### **Note**

The torque values can deviate by max.  $\pm$  10 % with the KaVo contra-angle hand-pieces SURGmatic S201. Larger deviations are possible with other contra-angle handpieces.



Slide the slider to the desired value or touch the plus or minus area.

The value is saved automatically.

Press the back key to close the speed setting.

The maximal torque value reached is displayed during the treatment in the activities "Cut thread", "Place implant" and "Set closure cap". The value is re-set as soon as the motor starts again.



## 5.6.3 Setting the coolant flow

## **⚠** CAUTION



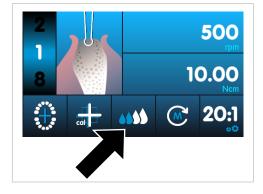
#### Coolant dosed incorrectly.

Tissue damage.

- Please note the instructions for use of the attachment tool.
- ► Set the coolant flow sufficiently high.

The coolant flow rate can be set to 4 levels or switched off:

- Off
- Level 1 = approx. 32 ml/min
- Level 2 = approx. 50 ml/min
- Level 3 = approx. 76 ml/min
- Level 4 = approx. 110 ml/min





### 5 Operation | 5.6 Changing default values

► Touch the coolant display until the supply rate is set as desired.

The value is saved automatically.



The coolant flow can be set and switched on or off during the treatment using the pump key of the wireless foot control. The pump key has two operating modes.

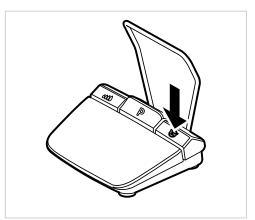
#### See also:

#### See also:

## 5.6.4 Changing the direction of motor rotation



► Touch Direction of motor rotation in order to change the direction of motor rotation.



The direction of motor rotation can be changed during the treatment using the direction of motor rotation key of the wireless foot control. The changed direction of motor rotation is shown on the display. For safety reasons, running in counterclockwise direction is not saved.

#### See also:



Three audible signals indicate counterclockwise rotation. When the motor starts up, 3 more audible signals are issued.



#### **Note**

The set torque automatically increases by 5 Ncm. The maximum torque of the selected activity cannot be exceeded.

## 5.6.5 Setting the transmission ratio



Touch the transmission ratio display to set the value as desired.

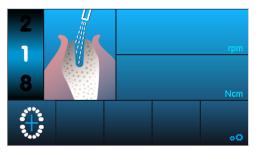
The value is saved automatically.

#### See also:

Example 2: Program steps that do not include the activity, "Cut thread", and include the "Rinsing function" activity, Page 43

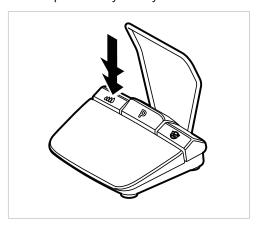
### 5.7 Rinsing function

## 5.7.1 Manual rinsing function

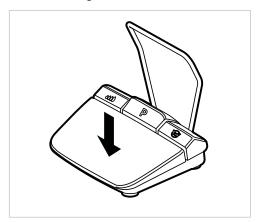


#### 5 Operation | 5.7 Rinsing function

The rinsing function serves to feed liquid and to start-up the illumination on the handpiece. The motor is not activated during this process. The rinsing function can be called up manually at any time.



Press the pump key on the wireless foot control for an extended time to activate the rinsing function.



Press the speed key on the wireless foot control to start the rinsing function and control the coolant flow.



► To terminate the rinsing function, press the back key or the pump key.

## 5.7.2 Program activity rinsing function

The rinsing function serves to feed liquid and to start-up the illumination on the handpiece. The motor is not activated during this process. The rinsing function can be defined as an activity in the course of the program.

Defining and executing program steps.

#### See also:

Example 2: Program steps that do not include the activity, "Cut thread", and include the "Rinsing function" activity, Page 43

## 5.8 Activating the one-touch calibration

The one-touch calibration automatically compensates for torque deviations of the motor that may be caused, e.g., by aging processes. When the handpiece is attached, the unit detects if the handpiece runs sluggish or is defective. The one-touch calibration thus provides for a more accurate torque on the contra-angle handpiece.

#### **Note**

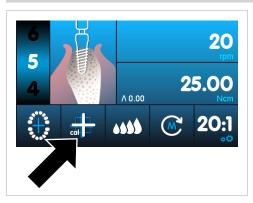


The handpiece must be attached for calibration.

One-touch calibration should be carried out only with KaVo surgical handpieces with a transmission ratio of 16:1, 20:1 or 27:1.

The one-touch calibration cannot be carried out with third-party handpieces or handpieces with different transmission ratios.

The calibration must be repeated whenever the handpiece is changed.



► Touch the calibration symbol in order to start the One-Touch calibration.

The display shows "Press wireless foot control".



## **A** CAUTION

#### The motor starts at full speed.

Risk of injury.

- ▶ Hold the motor firmly or put it in a safe holder during the calibration.
- Press the wireless foot control and hold it down until the display shows that "Calibration was successful".
- ▶ If you release the wireless foot control before the display shows that the calibration was successful, press the wireless foot control again until the display shows that the calibration was successful.
- Press the back key to terminate the calibration and to return to the selection of device settings.

If an unsuitable or defective handpiece was used in the calibration, the calibration is discontinued and the error message, "Measurement failed undefined error", is shown.

▶ Press the back key to terminate the failed calibration.

#### See also:

8 Troubleshooting, Page 65

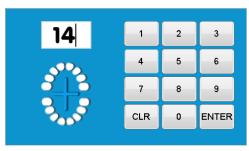
## 5.9 Implant position



The implant position can be entered as a two-digit number. The entry can be made either in the FDI (ISO system) or in the Universal Numbering System (American System).

The implant position can be entered in any step of the program and is recorded if documentation is enabled.

#### See also:

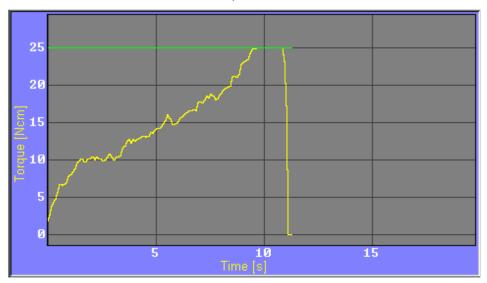


#### 5.10 Documentation

The documentation function of the MASTERsurg LUX Wireless allows the date, time, torque, speed, direction of rotation, program name, implant position, activity, transmission ratio, pump level, software version and serial number of the unit to be recorded.

Three modes are available:

• Implant: A torque plot is shown in the "Set implant" activity after each motor stop. The plot visualises the torque profile applied during insertion of the implant (yellow line). The green line describes the maximum torque reached. The torque plot is also stored in the <IMPxxxxx.BMP> file on the SD card. All other data are recorded as numerical values in the file, <IMPxxxxx.CSV>.



- Permanent: Documentation of the entire treatment process as numerical values in the <REC000xx.CSV> file on SD card without BMP
- Off: Documentation disabled. No recording or output of the treatment data.



#### **Note**

In the modes, "Implant" and "Permanent", please make sure that an SD card is inserted on the back of the unit.



#### **Note**

Please make sure that the proper implant position is selected.

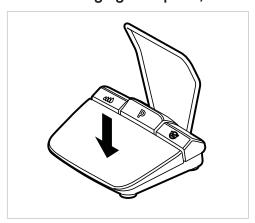


#### **Note**

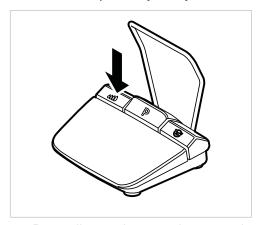
The torque plot can be closed by pressing one of the keys on the wireless foot control or by touching the back key on the unit. The updated torque plot is displayed again after each motor stop.

### 5.11 Wireless foot control

## 5.11.1 Changing the speed, coolant flow, and direction of motor rotation

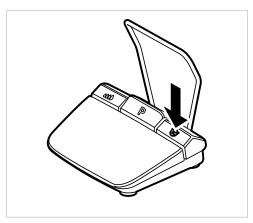


Press the speed key with your foot to start the motor and increase the speed.



- ▶ Depending on the pump key operating mode of the wireless foot control, press the pump key to set the coolant flow or to switch it on or off.
- Press the pump key of the foot control for an extended time to activate the rinsing function.

#### 5 Operation | 5.12 Changing the coolant container



Press the direction of motor rotation key of the wireless foot control to set the direction of motor rotation.

## 5.11.2 Selecting the program steps

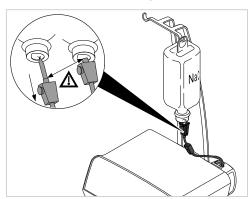
Program steps can be selected during the treatment using the program key of the wireless foot control.

- Press the program key of the wireless foot control **briefly** to select the next program step.
- Press the program key of the wireless foot control long to select the previous program step.

## 5.12 Changing the coolant container

The coolant container can be changed as follows:

► Close the hose clamp.



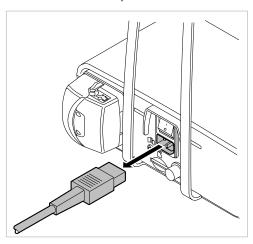
- Pull the hose and puncture needle out of the empty coolant container.
- ▶ Replace the empty coolant container by a full coolant container.

#### See also:

## 6 Decommissioning

## 6.1 Disconnecting the electrical connection

- ► Turn the device off.
- ▶ Disconnect the power cable the socket of the supply mains.
- ▶ Disconnect the power cable from the device.

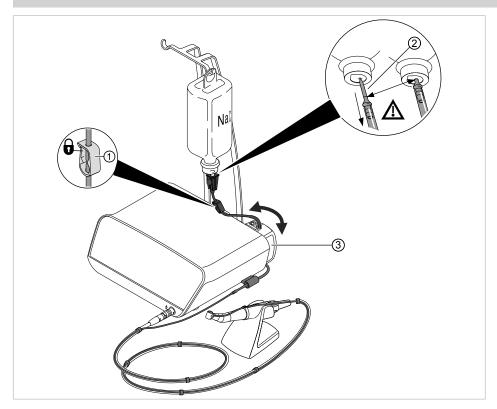


## 6.2 Disposal of the coolant hose



### Note

The coolant hose with accessories needs to be exchanged and discarded after each treatment.

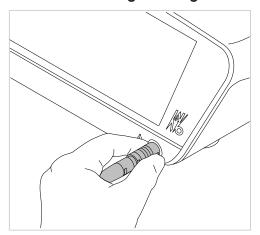


- ► Close the hose clamp ①.
- ▶ Pull the puncture needle ② out of the coolant container.
- ► Open the lock ③ and remove the hose.

6 Decommissioning | 6.3 Disconnecting the surgical motor

Remove the hose set from the unit and discard it.

## 6.3 Disconnecting the surgical motor



▶ Disconnect the plug of the motor cable from the connector on the device. Make sure to grasp the plug as close to the device as possible.

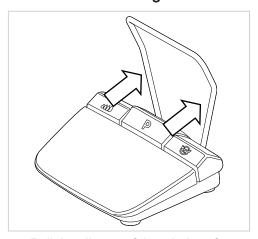


#### Note

Cleaning and disinfecting the motor connected with the motor lead.

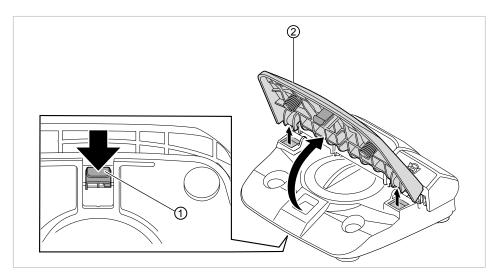
#### See also:

## 6.4 Decommissioning the wireless foot control

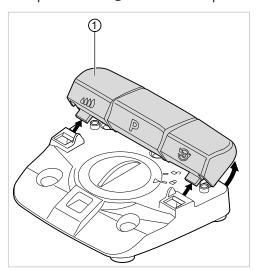


► Pull the clip out of the wireless foot control.

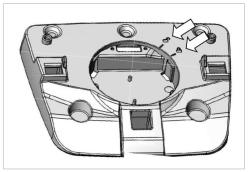
6 Decommissioning | 6.4 Decommissioning the wireless foot control



▶ On the underside of the wireless foot control, press down the snap-in lug ① of the speed button ② and take the speed button ② off the wireless foot control.

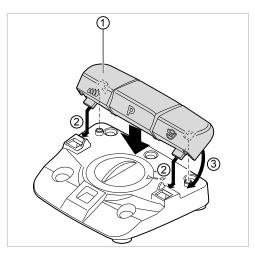


- ▶ Pull the button bar ① including the pump button, program button, and motor direction button slightly upwards and take it off the wireless foot control.
- ► Turn the lid to the left and take it off.
- ► Take out 3 alkaline type AA/ LR6 batteries and disposed them properly, if applicable.

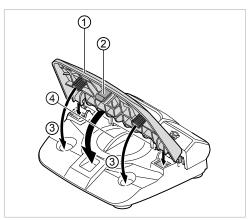


Place the lid on the unit (arrow points at "Open" symbol) and close it by turning it clockwise (arrow points at "Closed" symbol).

6 Decommissioning | 6.5 Dismantling the bottle holder



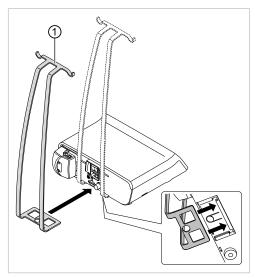
▶ Plug the button bar ① onto the wireless foot control ② and press it on lightly until the button bar ① snaps into place ③.



▶ Plug the speed button ① onto the wireless foot control and press it on lightly until the snap-in lug ② snaps in. Make sure that the foot pedal springs are situated in the recesses of the housing ③.

## 6.5 Dismantling the bottle holder

The bottle holder can be disassembled if the device is to be stored, shipped or disposed in space-saving manner.



▶ Press down the click-stop knob on the bottom side of the unit and pull off the bottle holder ① towards the back.

## 7 Reprocessing steps in accordance with DIN EN ISO 17664



#### **Note**

The reprocessing steps for surgical motors with motor cable and for the straight and contra-angle handpieces are described in the corresponding Instructions for use.



#### Note

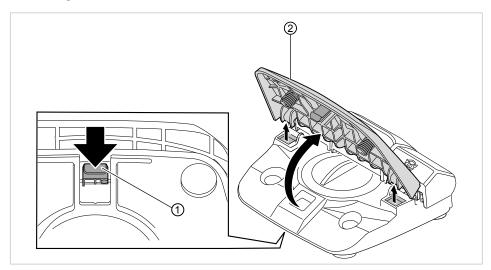
The instructions for cleaning and sterilisation have been validated by the manufacturer. Any departure from the instructions provided must be checked by the user for efficacy and possible detrimental consequences.

## 7.1 Cleaning

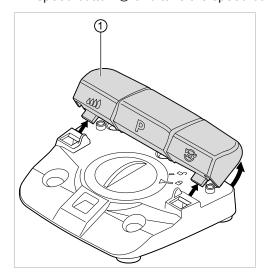
## 7.1.1 Manual cleaning

▶ Use a moist disposable cloth to wipe down all visible surfaces of the unit, bottle holder, wireless foot control surfaces, and connecting cables.

## Cleaning the wireless foot control



▶ On the underside of the wireless foot control, press down the snap-in lug ① of the speed button ② and take the speed button ② off the wireless foot control.

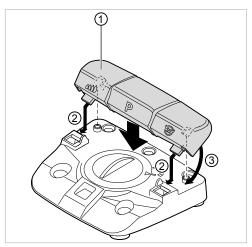


7 Reprocessing steps in accordance with DIN EN ISO 17664 | 7.1 Cleaning

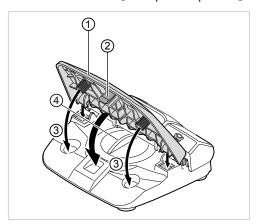
▶ Pull the button bar ① including the pump button, program button, and motor direction button slightly upwards and take it off the wireless foot control.



Clean the individual parts of the wireless foot control under running water and then dry them.



▶ Plug the button bar ① onto the wireless foot control ② and press it on lightly until the button bar ① snaps into place ③.



▶ Plug the speed button ① onto the wireless foot control and press it on lightly until the snap-in lug ② snaps in. Make sure that the foot pedal springs are situated in the recesses of the housing ③.



#### Note

The lid ④ needs to stay closed while the wireless foot control is being cleaned.

## 7.1.2 Machine cleaning



## **⚠** CAUTION

## Damage by liquids.

Faults on electrical components.

Do not machine-clean the device.

The following parts of the unit are released for machine-based cleaning:

- Handpiece tray
- Motor and motor cable



#### Note

Please comply with the corresponding Instructions for use when you re-process the motor and motor cable.

The re-processing steps for the handpiece tray are as follows:



KaVo recommends washer disinfectors in compliance with ISO 15883-1, which are operated using alkaline cleaning agents.

► For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector.

## 7.2 Disinfection



#### **Note**

After each treatment of a patient, the surfaces near the patient that may have been contaminated by contact or aerosol need to be disinfected. All disinfection measures need to be carried out by wipe disinfection.



#### Note

Please comply with the corresponding Instructions for use when you re-process the motor and motor cable.

#### 7.2.1 Manual disinfection

- Use a soft disposable cloth and an approved disinfectant for disinfection by wiping down all visible surfaces of the unit, bottle holder, wireless foot control surfaces, and connecting cables. Make sure that all surfaces are wetted.
- Let the disinfectant act for the prescribed time.
- Dry the surfaces.

Permissible disinfectants (application range in accordance with the available manufacturer's instructions and national guidelines. Please note material safety data sheets.) KaVo recommends the following products based on the compatibility of the materials. The microbiological efficacy must be confirmed by the disinfectant manufacturer.

- FD 322 Dürr
- Microcide AF Liquid (Schülke & Mayr)
- CaviCide made by Metrex

#### 7.2.2 Automated disinfection

The following parts of the unit are released for machine-based disinfection:

7 Reprocessing steps in accordance with DIN EN ISO 17664 | 7.3 Packaging

- Handpiece tray
- Motor and motor cable



#### **Note**

Please comply with the corresponding Instructions for use when you re-process the motor and motor cable.

The re-processing steps for the handpiece tray are as follows:



KaVo recommends washer disinfectors in compliance with ISO 15883-1, which are operated using alkaline cleaning agents.

► For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector.

## **7.2.3 Drying**



#### **Note**

Coolant hose with accessories is intended for single use only and is not to be disinfected and sterilised. No drying required.

Allow all disinfected and and sterilised parts to dry fully on room air before using them again.

## **Automatic Drying**

The drying procedure is usually part of the cleaning programme of the washer disinfector.

▶ Follow the instructions for use of the thermodisinfector.

## 7.2.4 Service, inspection and testing after preparation



## Note

It is essential to comply with the hygiene requirements (sterility) during the test after reprocessing. If sites of fracture and clear changes of the surface are visible, the parts need to be checked by the Service.

Check for cleanliness, intactness, servicing, and repair as described in the following:

- ► Check the adjustable functions of the unit and the motor function.
- Check the hose pump for sufficient coolant flow rate.
- ► Check the control commands on the wireless foot control.

### 7.3 Packaging



#### **Note**

The quality and use of the sterilisation packaging must comply with applicable standards and be suitable for the sterilisation procedure!



#### **Note**

If potentially infectious liquids and particles can contact the products, it is recommendable to cover and protect these areas with sterile disposable products.

Seal the handpiece tray and motor cable in a sterilisation pouch.

7 Reprocessing steps in accordance with DIN EN ISO 17664 | 7.4 Sterilisation

#### 7.4 Sterilisation



#### Note

Please comply with the corresponding Instructions for use when you re-process the motor and motor cable.

Sterilisation by moist heat in accordance with ISO 17665-1 in a steam steriliser (autoclave)





Damage to device due to improper sterilisation.

Damage to the sterile device.

No hot air sterilisation, no chemical cold sterilisation, do not sterilise with ethylene oxide!





#### Product damage

Contact corrosion

Remove the sterilised item from the autoclave immediately after sterilising and drying.

#### Note



Treating patients who are possibly afflicted by an acute, critical infectious disease, be sure to comply with the hygienic measures cited in applicable publications and reports. If possible, use suitable disposable devices to avoid the transmission of critical pathogens. This concerns the protection of the user, patients and all participants in the surgery.

All dental and medical materials considered to be contaminated must be suitably processed and sufficiently identified after cleaning and sterilisation before returning them.



#### Note

The user is responsible for observing the regulations and conditions for sterility. The coolant container needs to be disposed and the hoses need to be changed after each patient.



KaVo medical devices released for sterilisation are temperature-resistant up to 138 °C (280.4 °F).

The following parts are released for sterilisation:

- Motor cable
- Handpiece tray
- Autoclave with 3-fold fractionated pre-vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Drying time: 20 min.
- Autoclave using the gravitation method
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Drying time: 30 min.



#### Note

Allow the sterilised items to cool to room temperature before using them again.

7 Reprocessing steps in accordance with DIN EN ISO 17664 | 7.4 Sterilisation

## 7.4.1 Storage

Observe all necessary measures for hygiene when storing sterile goods. Store protected from dust and in a dry place, release with identification on the packaging. Evaluate the duration of storage.

## 8 Troubleshooting



### Note

If malfunctions cannot be located or eliminated using this troubleshooting guide, a technician trained by KaVo must be commissioned to eliminate the problem.



### **Note**

The permitted work is described in the Technician's Instructions available to the trained service staff.

In case of malfunction, the display names the malfunction directly or shows an error number.

Malfunction	Cause	Remedy
Non-functional device.	The unit is switched off.	► Switch-on the mains switch on the rear of the unit.
	Neither end of the power cable is plugged in.	► Plug in the power input cable.
	Unknown.	► Turn the unit off and on.
	Blown fuse.	► Contact customer service.
No coolant in the hand- piece.	No coolant flow pre-selected. Pump is off.	<ul> <li>▶ Pre-select coolant flow.</li> <li>See also:</li> <li></li></ul>
	Hose fixation is not plugged in.	<ul> <li>▶ Plug in the hose fixation.</li> <li>See also:</li> <li></li></ul>
	Bottle is empty.	► Connect new bottle.
	Hose clamp is closed.	► Open the hose clamp.
	Pump locking mechanism is not closed.	► Check and close, if needed, the closing mechanism.
	Hose is kinked.	► Check hose and remove the kink, if any.
	Glass bottle containing the coolant is not ventilated.	Open the cap on the ventilation valve of the puncture needle.
Insufficient coolant flow in the instrument.	Spray nozzles are crusty or soiled.	Clean the spray nozzles with the nozzle needle or re-process the part.
		See also:  SURGmatic Instructions for use
	Glass bottle containing the coolant is not ventilated.	Open the cap on the ventilation valve of the puncture needle.
The motor makes a grinding noise or does not run smoothly.	The motor is not correctly plugged on or screwed on.	<ul> <li>Firmly insert the motor hose into the housing.</li> <li>Firmly screw on the motor hose to the motor.</li> <li>Check if all the connections and couplings are firmly seated.</li> </ul>

## 8 Troubleshooting

Malfunction	Cause	Remedy
No light on the straight or contra-angle handpiece	The light is not turned on.	► Turn on the light.  See also:  ■ 5.2.3 Setting the LUX brightness, Page 33
	The straight and contra- angle handpiece is improp- erly attached.	Attach the straight and contra-angle handpiece until the catch audibly locks.
	Defective LED.	➤ Replace the LED.  See also:  Instructions for use INTRA LUX S600 LED
	Not a suitable straight and contra-angle handpiece.	Use a suitable light, straight and contra-angle handpiece.

## Error message from software

	_	_
Malfunction	Cause	Remedy
Event E3: Release the foot pedal	Wireless foot control was actuated while the unit started up.	► Release the wireless foot control.
Event E4: Data initialisation	Setting data newly initialised.	<ul> <li>Confirm message and check or correct the program settings.</li> <li>If the problem persists, notify service engineer</li> </ul>
Event E6: Internal communication error	Internal system error.	Turn the unit off and on. If the problem persists, notify service engineer.
Event E9:	Time was not reset after	► Setting the date and time.
Setting the time and date	re-start.	► If the problem persists, have a service engineer replace the battery of the real-time clock.
Event E14: Is shown at start-up if the battery level is low	Battery level low.	► Batteries (alkaline type AA/ LR6) must be supplied and replaced soon. Confirm the message to be able to continue working.
Event E14: Is shown approximately every 10 min if battery level is low	Battery level critical.	► Batteries (alkaline type AA/ LR6) must be replaced instantaneously to be able to continue working.
Event E29: SD card write protection	SD memory card is write- protected or defective.	<ul> <li>Switch the write-protect switch on the left side of the card upwards to "unlock", "write" or the like.</li> <li>If the problem persists, use a new SD memory card.</li> <li>If the problem persists, notify service engineer.</li> </ul>
All events > 30: Hardware error	Internal system error.	Turn the unit off and on. If the problem persists, notify service engineer.

Malfunction	Cause	Remedy
Events E36 and E37: Motor overload	Overtemperature on stator. Over-current > nominal current.	► Let the motor rest. If the problem persists, notify service engineer.
Event E47	Residual moisture in the plug of the motor cable can lead to false recognition of an E47 error during the start-up test of the device.	<ul> <li>Turn the device off.</li> <li>Disconnect the motor cable from the device.</li> <li>Turn the device on.</li> <li>Connect the motor cable.</li> <li>Make sure that water cable and motor plug are absolutely dry.</li> <li>Do not drive with compressed air as this may drive liquid into the plug.</li> <li>If the problem persists, notify service engineer.</li> </ul>
Wireless foot control symbol has a yellow background	Wireless foot control mal- function.	<ul> <li>▶ Reconnect the wireless foot control.</li> <li>See also:</li> <li>⑤ 5.2.7 Connect the wireless foot control, Page 35</li> <li>▶ Check if the wireless foot control is installed correctly.</li> <li>▶ If the problem persists, notify service engineer.</li> </ul>
One-touch calibration failed.	Straight or contra-angle handpiece is too sluggish.	<ul> <li>▶ Perform a run in the absence of the straight or contra-angle handpiece.</li> <li>⇒ If no error message is displayed, the handpiece runs too sluggish.</li> <li>▶ Use a different straight or contra-angle handpiece.</li> </ul>
	If the run in the absence of the straight or contra-angle handpiece again produces an error message, the mo- tor torque is too low.	Use a different motor; possibly return the motor for repair.
Motor symbol has a yellow background.	No motor attached.	► Connect the motor.
Pump symbol has a yellow background.	Hose fixation is not plugged in.	► Plug in the coolant hose.
Service symbol is green	Service is due soon.	<ul> <li>Arrange a precautionary appointment at a KaVo subsidiary or with a KaVo authorised dealer.</li> </ul>
Service symbol is yellow	Service period is expired.	Arrange an appointment at a KaVo subsidiary or with a KaVo authorised dealer.
Service symbol is red	Service overdue: > 4 months	Arrange an appointment immediately at a KaVo subsidiary or with a KaVo authorised dealer.
Error message "SD card defective" during software update	SD card is formatted incorrectly or SD card is defective.	► Format SD card in FAT16 or FAT32 format or use new CD card. Then repeat the updating process.
Hardware error	Internal system error.	Turn the unit off and on. If the problem persists, have the service staff repair the unit.

9 Run a software update

## 9 Run a software update

Please proceed as follows to update the software:

- Download the current firmware file from www.kavo.de/produkte.
- Copy the firmware file to an SD card (storage capacity 1 32 GB, FAT format).
- ► Turn the device off.
- ► Insert the SD card with the new firmware file into the unit. Make sure that only a single firmware file with the .bin file extension (the downloaded current file) is stored on the SD card.
- ► Turn the device on.
- ⇒ The update process starts automatically.



#### **Note**

The unit must not be turned off during the update process.

After the update process, the unit starts using the updated software.



## **MARNING**

#### Malfunctions of the unit.

The software version displayed on the start screen or in the version display must coincide with the software version that was downloaded. If these do not coincide or if there is any other error, please contact Customer Service.

#### See also:



#### **Note**

All program and device settings remain unchanged.

## 10 Safety checks ("STK")

The MASTERsurg LUX Wireless must be subjected to a service check including safety check ("STK") every 2 years. The safety check may only be done by a professional trained by KaVo or in a shop trained by KaVo. Perform the safety check ("STK") as described in the KaVo technician's instructions.

The urgency of the service check is indicated on the display by a symbol in "traffic light colours".

Symbol	Description
green	<ul> <li>Service check is soon due.</li> <li>Arrange a precautionary appointment at a KaVo subsidiary or with a KaVo-authorised dealer.</li> </ul>
yellow	<ul><li>Service check is due.</li><li>Arrange an appointment at a KaVo subsidiary or with a KaVo-authorised dealer.</li></ul>
red	Service check is over-due.  Arrange an appointment immediately at a KaVo subsidiary or with a KaVo-authorised dealer.

## Repair Service

KaVo offers a fixed-price service check for the original factory maintenance. You can use a loaner device for the time of the service check.

For repairs, please contact KaVo Repair Service.

For scheduling or if you have any questions, please contact:

KaVo Repair Service

KaVo Dental Corporation

11729 Fruehauf Drive

Charlotte, NC 28273 USA

Toll-free Direct Customer Service: 1-888-ASK-KAVO (888-275-5286)

Email: techservice@kavo.com

www.kavousa.com

#### 11 Accessories

#### 11 Accessories

The following accessories are approved for the MASTERsurg LUX Wireless:

- Hose set sterile S600 (10 pcs.) (Mat. no. 1.009.8757)
- Hose set sterilisable S600 (Mat. no. 1.011.0633)
- Handpiece tray (Mat. no. 1.009.3411)
- Motor INTRA LUX S600 LED (Mat. no. 1.008.8000)
- Motor cable S600 (Mat. no. 1.009.1700)
- Wireless foot control (Mat. no. 1.010.0289)
- Cable-type foot control (Mat. no. 1.010.0288)
- KaVo SURGmatic straight and contra-angle handpieces

12 Information about electromagnetic compatibility | 12.1 Guidelines and manufacturer's declaration - electromagnetic emission

## 12 Information about electromagnetic compatibility

## 12.1 Guidelines and manufacturer's declaration - electromagnetic emission

The MASTERsurg LUX Wireless is intended for use in an environment as specified below. The MASTERsurg LUX Wireless customer or user must ensure that the unit is used in an environment matching the description.

Measurements of emitted interference	Conformance	Electromagnetic environment - Guidelines
HF emissions according to CISPR 11	Group 1	The MASTERsurg LUX Wireless uses HF energy exclusively for its internal operation. Therefore, the HF emission of the device is very low and interference with adjacent electronic devices is unlikely.
HF emissions according to CISPR 11	Class B	The MASTERsurg LUX Wireless is intended for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.
Emission of harmonics according to IEC 61000-3-2	Class A	The MASTERsurg LUX Wireless is intended for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.
Emission of voltage fluctuations/ flicker according to IEC 61000-3-3	complies	The MASTERsurg LUX Wireless is intended for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.



## Note

The device or system may not be used or stacked directly next to other devices. If it has to be used close to or stacked next to other devices, the device or system must be monitored to ensure that it is used properly in the existing arrangement.



#### Note

The immunity test levels required in IEC 60601-1-2 (DIN EN 60601-1-2) are met.

## 12.2 Guidelines and manufacturer's statement - Electromagnetic immunity

The MASTERsurg LUX Wireless is intended for use in an environment as specified below. The MASTERsurg LUX Wireless customer or user should ensure that the unit is used in an environment matching the description.

12 Information about electromagnetic compatibility | 12.3 Guidelines and manufacturer's statement - Electromagnetic immunity

Interference immunity tests	IEC 60601 test levels	Compliance level	Electromagnetic environ- ment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV atmospheric dis- charge	± 6 kV contact discharge ± 8 kV atmospheric dis- charge	Floors should be made of wood or concrete or be fitted with ceramic tiles. If the floor is fitted with synthetic material, the relative humidity must be at least 30 %.
Fast transient electrical interference / bursts according to IEC 61000-4-4	± 2 kV for power lines	± 2 kV for power lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV push-pull voltage (symmetrical) ± 2 kV common mode voltage (unsymmetrical)	± 1 kV push-pull voltage (symmetrical) ± 2 kV common mode voltage (unsymmetrical)	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage interruptions, short-term interruptions, and fluctuations of the sup- ply voltage according to IEC 61000-4-11	< 5 % $U_T$ for 1/2 period (> 95 % interruption) 40 % $U_T$ for 5 periods (60 % interruption) 70 % $U_T$ for 25 periods (30 % interruption) < 5 % $U_T$ for 5 s (> 95 % interruption)	< 5 % $U_T$ for ½ period (> 95 % interruption) 40 % $U_T$ for 5 periods (60 % interruption) 70 % $U_T$ for 25 periods (30 % interruption) < 5 % $U_T$ for 5 s (> 95 % interruption)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the MASTER-surg LUX Wireless needs uninterrupted function of the unit even when the power supply is interrupted, it is recommended to supply the MASTERsurg LUX Wireless from an uninterruptible power system or a battery.
Magnetic field at a supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to typical values in a business and hospital environment.

Note: U  $_{\scriptscriptstyle T}$  is the alternating mains voltage before the application of the test level.

# 12.3 Guidelines and manufacturer's statement - Electromagnetic immunity

The MASTERsurg LUX Wireless is intended for use in an environment as specified below. The MASTERsurg LUX Wireless customer or user should ensure that the unit is used in an environment matching the description.

12 Information about electromagnetic compatibility | 12.4 Recommended safe distances between portable and mobile HF telecommunications equipment and the MASTERsurg LUX Wireless

Interference immunity tests	IEC 60601 test levels	Compliance level	Electromagnetic environment - Guidelines
Wire-based HF interference according to IEC 61000-4-6 Wireless HF interference according to IEC 61000-4-3	3 V <sub>eff</sub> 150 kHz to 80 MHz 3 V/m 800 MHz to 2.5 GHz	3 V <sub>eff</sub> 3 V/m	Portable and mobile radio devices should not be used closer to the MASTERsurg LUX Wireless including the cables than the recommended safe distance calculated using the equation for the transmission frequency. Recommended safe distance: $d = [3.5/3]^{\sqrt{P}} = 1.17^{\sqrt{P}}$ $d = [3.5/3]^{\sqrt{P}} = 1.17^{\sqrt{P}}$ for 80 MHz to 800 MHz $d = [7.0/3]^{\sqrt{P}} = 2.33^{\sqrt{P}}$ for 800 MHz to 2.5 GHz where P is the maximal nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and d is the recommended safe clearance in metres (m). The field strength of stationary wireless radio transmitters as measured locally should be lower than the conformance level at all frequencies. Interference is possible in the vicinity of devices that bear the following symbol.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not be applicable in every case. The propagation of electromagnetic waves is subject to absorption and reflection by buildings, objects, and people.

The field strength of stationary transmitters such as base stations of mobile telephones and land mobile radio devices, amateur radio stations, AM and FM radio and television broadcasting stations cannot be determined based on theoretical considerations. A site study should be considered to determine the electromagnetic environment in terms of stationary transmitters. If the field strength measured at the location at which the MASTERsurg LUX Wireless is used exceeds the conformity levels specified above, the MASTERsurg LUX Wireless should be monitored to confirm that it is functioning as intended. Should unusual performance features be observed, additional measures may be required, such as, e.g., a different alignment or another location for the MASTERsurg LUX Wireless.

 $^{\rm b}$  In the frequency range of 150 kHz to 80 MHz, the field strength should be less than  $3V_{\rm eff}$  V/m.

# 12.4 Recommended safe distances between portable and mobile HF telecommunications equipment and the MASTERsurg LUX Wireless

The MASTERsurg LUX Wireless is intended for use in an electromagnetic environment like the one specified below. The customer or user of the MASTERsurg LUX Wireless can help to avoid electromagnetic interference by complying with the min-

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imum safe distance between portable and mobile HF-telecommunication devices (transmitters) and the MASTERsurg LUX Wireless - dependent on the output power of the communication device - as given below.

Rated power of the trans- mitter in W			800 MHz to 2.5 GHz d=2.33 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters whose maximum rated power is not included in the above table, the recommended safe distance d in metres (m) can be calculated using the equation for the respective column, where P is the maximum rated power of the transmitter in Watts (W) as specified by the manufacturer.

Note 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

Comment 1: To calculate the recommended safe distance from transmitters with a frequency range of 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to reduce the probability that a mobile/portable communication unit that is inadvertently brought into the patient area would cause malfunction.

