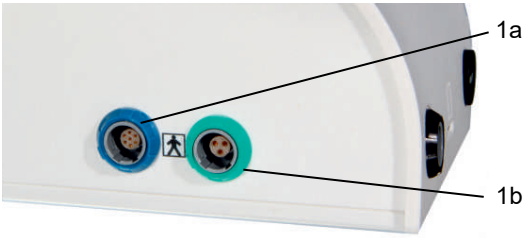
EndoPilot²

User manual

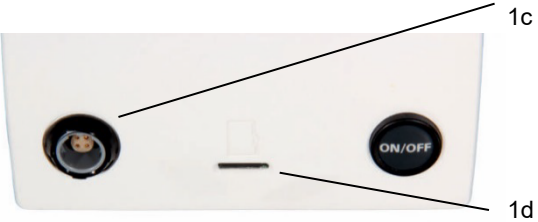
610 2221 v07- 25.01.2021

Schlumbohm

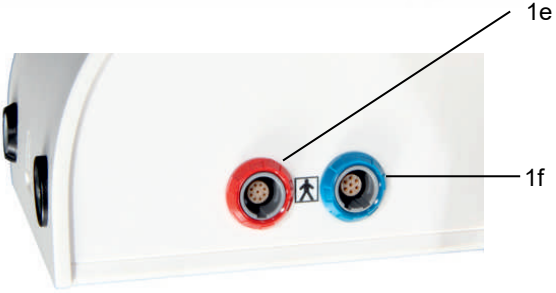
Illustration 1 Control unit Basic device



Right side of the device



Rear side with microSD card



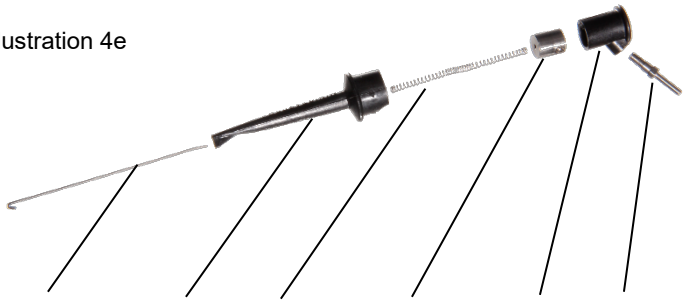
Left side of the device

Illustration 2

Illustration 3

Illustration 4

Illustration 4e



You can dismantle the patented file clamp (4e) for reprocessing (cleaning, disinfection and sterilization).
A universal key for ultrasonic-tools can be used as a tool for assembly (with a wrench size of 3.2 mm).

Illustration 5

Illustration 6

Illustration 7 7a 7b

Illustration 8

Illustration 9 Ill.10 Ill.11 Illustration 12 12a 12d 12b

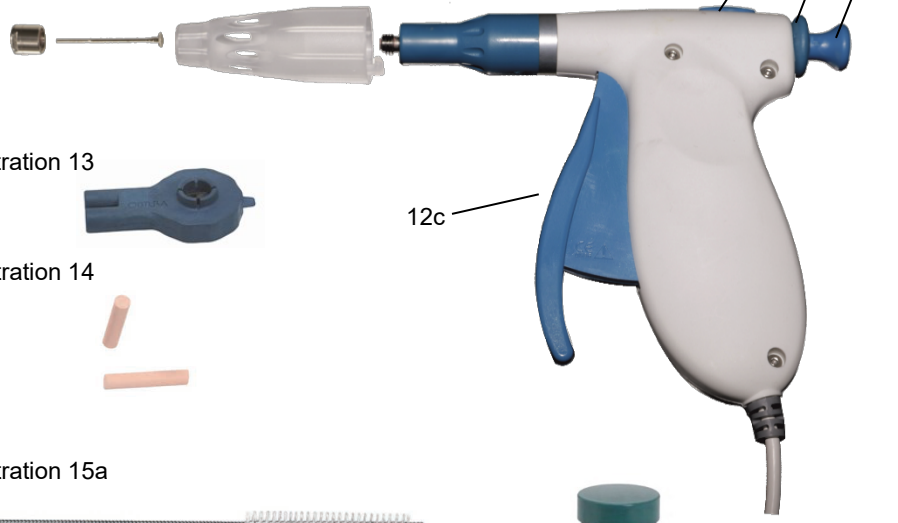


Illustration 13

Illustration 14

Illustration 15a

Illustration 15b

Description of the single parts

ill.	Ref. No.	Designation	#
1	110 2011	EndoPilot² Control unit with a touch screen, including 5 connecting sockets and a microSD slot (1a to 1f)	A2
2	109 2322 110 2203	Power supply with primary plug, 2 models available Input: 100 – 240 V AC Output: 12 V DC 1.25 A Input: 100 – 240 V AC Output: 12 V DC 1.50 A	 A2 A2
3	109 2361	Wireless foot switch, single pedal with Bluetooth	A2
4	109 2311 109 2312 109 2314 109 2318 109 2315 109 2316 110 2303	Apex cable set (from version v06 on) consisting of: 4a – Measuring cable with plug 4b – Lip-clip 4c – Cap for the plug socket (for Lip-clip) 4d – Cable for file clamp 4e – File clamp (can be dismantled) The file clamp can be dismantled (see ill. 4e). To dismantle, the contact is unscrewed and removed from the knob. You can clean all parts individually (see reprocessing instructions). At the end of assembly, firmly tighten the contact again. Caution: Check if the device is functioning properly! Loose parts may fall out and enter the patient's mouth. 4f - Retainer for apex cable (mounted on the device)	 A2 A1 A1 A1 A1 A1
5	109 0126	Contra-angle for apex measurement. Fully insulated, 1:1 gear, tools-coupling ISO 14457:2017 and ISO-E motor coupling ISO 3964:2016 + Amd. 1:2018	A3
6	109 0112	Motor with apex measuring contact, LED power indicator and ISO-E motor coupling ISO 3964:2016 + Amd. 1:2018	A2
7	109 0151 540 5173 364 2901	DownPack (D-Pack) handpiece with LED indicator for processing removable parts: 7a – Screw cap 7b – Blue O-ring	A2 A1 A1
8	109 0152 to ...56	D-Pack heating tips type E&Q standard Ø2,35mm Available in 5 different sizes: XF, F, FM, M and ML Accessories from Original manufacturer: Meta Biomed; Item: EQ0036XF, EQ0023F, EQ0032FM, EQ0034M a. EQ0035ML	A4
12	823-810	BackFill gun (Order-no.110 1041) 12a - Release knob, 12b - Piston, 12c - Lever and 12d – Guide-Cylinder with rotary knob	A5
9	823-616	Nut for BackFill-Needles (mounted on the back-fill gun)	A5

ill.	Ref. No.	Designation	#
		Accessories from original manufacturer: Obtura Spartan / Young innovations	
		BackFill Needles 20 ga (5 pcs) (Order-no.110 1044)	
	823-620	Obtura Spartan	A5
		BackFill Needles 23 ga (5 pcs) (Order-no.110 1045)	
10	823-623	Obtura Spartan	
		BackFill Needles 25 ga (5 pcs) (Order-no.110 1046)	
	823-635	Obtura Spartan	
		Thermal protector (4 pcs.) (Order-no.110 1043)	
11	823-815	Heat insulator protects against thermal damage Obtura Spartan	A5
13	822-613	Obtura Multi Tool for shaping and for screwing on and unscrewing the BackFill needles Obtura Spartan	(-)
		Not part of the Set :	
14	*822-602*	*Standard Gutta-percha pellets From the US market, see Obtura Spartan; (box with 100 pcs.)*	(-)
15a	*823-813*	*Obtura Cleaning brushes (2 brushes) to clean the BackFill gun Obtura Spartan*	(-)
15b	*822-609*	*Obtura Cleaning Solution Obtura Spartan*	(-)

(#) refers to the relevant processing instructions A1-A5, see chapter 18
(-) means: The manufacturer has not foreseen any preparation for the product.

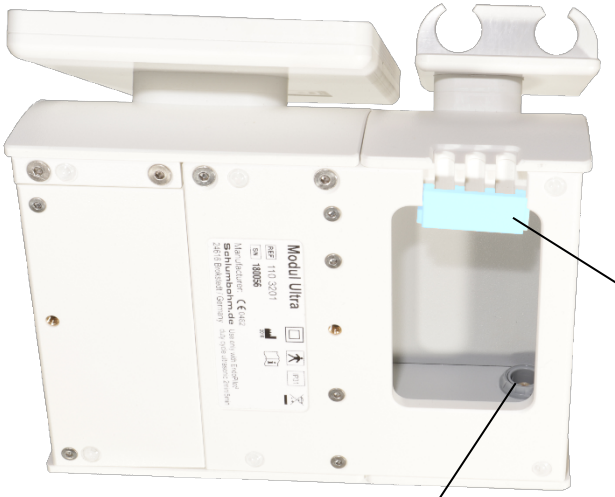
Ultrasonic module*

Illustration 16 EndoPilot² with ultrasonic module

Description of the single parts

ill.	Ref. No	Designation	#
16	110 3201	Ultrasonic module with 1 connecting socket (15a)	A2
17	X12282	Ultrasonic handpiece with Satelec® compatible screw thread Type: Acteon Satelec Suprasson (Order-no. 109 3102)	A6
18	109 3132	Rinsing adapter Attachment to a standard syringe for flushing the Acteon Satelec Suprasson handpiece	A1
19	F00406	Wrench (Order-no. 109 3113) Acteon Satelec universal wrench for ultrasonic tips	A6
20	109 3122	Ultrasonic handpiece cable Acteon Satelec highly flexible supply cable with plug	A6
21	109 2351 Optional	Twin wireless foot switch Pedal I = Start Pedal II = Select / to select the functions, including 2x 1.5 V batteries, type AA	A2

(#) refers to the relevant processing instructions A1-A6, see chapter 18



cable guide for
motor-, apex- and
ultrasonic-cable

(a locking clamp keeps
the cables in place)

Illustration 16a
Ultrasonic module
Bottom compartment with the connection for the ultrasonic cable

Illustration 17

Illustration 18
Rinsing sleeve
(for cleaning)

Illustration 19

Illustration 20

Illustration 21

Congratulations!

We are delighted you have decided to purchase the **EndoPilot²**. You have made a good choice. The family-owned company Schlumbohm® has been successful on the dental industry market for 50 years. These many years of experience, as well as excellent contacts to specialists, nationally and internationally, allow Schlumbohm® to design outstanding devices that enable both the patient and the dentist to achieve an optimal treatment result.
In addition to striving, of course, for an optimal treatment result, the focus for each development is on an easy and most convenient handling.
With **EndoPilot²**, you have acquired a product which has been developed and tested with the utmost care. The device meets the highest demands with regard to function and operation.

Caution! The device is available in various configuration levels

The EndoPilot² systems can be ordered in different configuration levels:

- EndoPilot ² comfort (REF 110 0607)
  Endo motor with apex locator
- EndoPilot ² plus (REF 110 0609)
  Endo motor with apex locator, DownPack and BackFill
- EndoPilot ² ultra: (REF 110 0610)
  Endo motor with apex locator and ultrasonic extension
- EndoPilot ² ultra plus: (REF 110 0611)
  Endo motor with apex locator, DownPack, BackFill, ultrasonic

This user manual describes the:
EndoPilot² comfort, EndoPilot² plus, EndoPilot² ultra and EndoPilot² ultra plus.
Devices with less function, as for example the model “EndoPilot² comfort” can be upgraded, the device must be returned to the manufacturer.

All chapters for the “ultrasonic-function” are marked with: *

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WEEE reg. no. DE 88116129

CE 0482

℞ only

The manufacturer reserves the right to change the information and data contained in this user manual without prior notice.
This user manual has been prepared with the greatest possible care. However, as errors can never be fully excluded, we would appreciate any information at any time so we can improve the documentation for you. Please contact us directly in such an event. Also, should you have any further questions, please do not hesitate to contact us.

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1. Notes

1.1. **Symbols used**

Symbol	Title, Description / Explanatory Text, Standard / Reference No. of Symbol
CE 0482	The product complies with the requirements of EU Regulations / No. of notified body
	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. ISO 15223-1:2016 / Ref. 5.5.4
	Type BF Applied Part To identify a type BF applied part complying with IEC 60601-1 IEC 60601-1: 2005+Cor.:2006+Cor.:2007+A1:2012 / Ref. Table D1 / 20
	Waste Collection Separate collection for waste of electrical and electronic equipment. EN 50419 - Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC
	Do not re-use Device intended for single use only and not to be re-used ISO 15223-1:2016 / Ref. 5.4.2
	Non-sterile A medical device not subjected to sterilization ISO 15223-1:2016 / Ref. 5.2.7
	UDI of the device, Data-Matrix-Code (GS1-Code)
	UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements
	EU representative EU authorised representative ISO 15223-1:2016 / Ref. 5.1.2
	automated processing in the thermal disinfector
	Steam sterilization up to the indicated temperature
	Batch Code Batch code so the lot or batch can be identified ISO 15223-1:2016 / Ref. 5
	Manufacturer/ Date of Manufacture Indicates the medical device manufacturer / Indicates Date of Manufacturer ISO 15223-1:2016 / Ref. 5.5.1 /5.1.3

Description of the symbols used.

IP31	Ingress protection code Protection against particles with 2.5 mm diameter and dripping water complying with IEC 60601-1 IEC 60601-1: 2005+Cor.:2006+Cor.:2007+A1:2012 / Ref. Table D3 / 2
	Catalogue Number Indicates catalogue number, part number of device ISO 15223-1:2016 / Ref. 5.1.6
	Serial Number Serial number so the device can be identified ISO 15223-1:2016 / Ref. 5.1.7
	Consult Instructions for Use Indicates the need for user to refer to instructions for use ISO 15223-1:2016 / Ref. 5.4.3
 48 Wh	The device contains a lithium-ion battery (power output 48 Wh) (The current shipping instructions must be followed during shipping!)
	Class II equipment To identify a class II insolation protection, complying with IEC 60601-1 IEC 60601-1: 2005+Cor.:2006+Cor.:2007+A1:2012 / Ref. Table D1 / 9
	Consult Instructions for Use Indicates the need for user to refer to instructions for use IEC 60601-1: 2005+Cor.:2006+Cor.:2007+A1:2012 / Ref. Table D2 / 10
	Wireless connection
	Fragile, handle with care Indicates a medical device that can be broken or damaged if not handled carefully. ISO 15223-1:2016 / Ref. 5.3.1
	Temperature Limit Indicates temperature the medical device can be exposed ISO 15223-1:2016 / Ref. 5.3.7 Different values on the outer package and on the device! Package: Note temperature during storage / transport (-15°C to +60°C) Device sticker: Note temperature during operation (+15°C to +40°C)
	Keep Dry Indicates a medical device that needs to be protected from moisture. ISO 15223-1:2016 / Ref. 5.3.4
	Humidity limitation Relative humidity range for storage (on package) or use (on device) ISO 15223-1:2016 / Ref. 5.3.8
	This side up ISO 7000:2008 / Ref. 0623
	Medical Device This item is a medical-device ISO 15223-1 draft

Description of the symbols used.

Rx only	Prescription Use Only Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician. No standard; designated by FDA per 21 CFR 801.109(b)(1)
2 °C 8 °C	Temperature Limit Indicates the temperature limits to which the medical device can be safely exposed. for storage (on package) or use (on device) ISO 15223-1:2016 / Ref. 5.3.7 (the values in this listing are examples)

1.2. **Intended use**

The EndoPilot² systems are dental devices, which combine in a single control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator which assists the operator to locate the file tip in the root canal and an ultrasonic-hand-piece for root-canal cleaning and preparation.
The EndoPilot² systems are intended solely for use by trained dental professionals in professional health care facilities for patients which needs root-canal-treatment.

1.3. **Device Description**

The EndoPilot² is a device that combines the functions:

1.3.1. Apex locator

The apex locator determines the file position in the root canal. This length determination can either be performed manually (without a motor) by using the file clamp, or during preparation using the contra-angle (integrated length determination with a motor).

1.3.2. Motor

Mechanical root canal preparation in combination with US registered Endo-File systems, optional with integrated length determination. The file manufacturer's current file-parameters has been integrated in the file database of the device.

1.3.3. DownPack hand-piece with heating tip

Vertical thermoplastic condensation of gutta-percha in the root canal and the cutting off of gutta-percha pins.

1.3.4. BackFill gun

Final thermoplastic filling of root canals with gutta-percha.

1.3.5. Ultrasonic handpiece*

*The Ultrasonic module has been developed to extend the EndoPilot². It supplements the device concept with the ultrasonic function for the execution of professional endodontic treatments in combination with US registered Endo-tools from Satelec Acteon.

Possible areas of application: Activation of a rinsing solution in the root canal, revisions, preparations of the canal with ultrasonic instruments and the removal of pins.

1.4. General precautions

Read through this user manual carefully and completely! This is the only way to guarantee maximum safety. The most common problems during operation and maintenance result from the fact that insufficient attention is paid to basic safety precautions and possible accident risks are not foreseen.
The user and team must be familiar with the device prior to the first usage.
Keep the user manual and the attachments (e.g. reprocessing instructions) on the device.
Always use a cofferdam to prevent the inhalation or swallowing of small parts and the transmission of germs! Also use rubber gloves.
Do not work on the bone with the device.
If you have any questions or information on any problems, please contact your dealer immediately. Do not use the device if the patient or the user has an active implant (pacemaker, etc.)!
*Ultrasonic module: Use safety goggles. The patient should also wear safety goggles. The use of ultrasound may release aerosols and germs into the air. You must therefore always use a surgical mask.

1.4.1. Contraindications

No contraindications have been identified.
The device must not be used on patients or by clinicians with an active implant (cardiac pacemaker etc.)!

1.4.2. Operating instructions

Use

- The EndoPilot² may only be used by licensed specialists.
- The applied parts must be used sterile. It is imperative that you follow the disinfection and reprocessing instructions (see chapter 18).
- Check the device for damage before use.
- Do not use the device if it is not working properly.
- Only use the device for its intended application.
- Do not combine the device with other devices, such as endo devices from other manufacturers.
- Do not modify the product's characteristics in any way. Schlumbohm® declines any and all responsibility in the event of device modification.
- The microSD card must be removed from the EndoPilot² when shipping! Removing this will switch off the power to the device.

Spatial conditions

- The device must not come into contact with liquids or be installed in damp places. Keep the foot switch away from spilled liquids.

- Do not expose the device to direct or indirect heat sources.
- The device may not be used in an environment with free oxygen, explosive or inflammable gases or flammable liquids.
- The EndoPilot² should not be installed near devices emitting electromagnetic radiation so as not influence the correct length determination. Switch off mobile phones in the immediate vicinity during treatment. (See chapter 17 EMC)
- Do not cover the device with cloths or foils. Flammable materials may be damaged or even ignited if the DownPack function is activated unintentionally.
- Ensure that the rooms in which the device is used are equipped with smoke detectors. National fire protection regulations must be adhered to.
- Never leave the appliance unattended when in use.
- Ensure that the foot switch cannot be pressed unintentionally, for example by a chair or trolley.
- The signal of the wireless foot switch is transmitted in an encrypted form. This technology ensures a secure connection between the foot switch and the device. This prevents unintentional operation of one device with the foot switch of another device. Do not operate mobile phones or devices with strong electromagnetic radiation in the immediate vicinity of the device. This may impair the wireless foot switch's function in individual cases.
- The device does not contain any life-supporting functions. The continued application in the event of device failure will likely be impossible. This failure will not endanger the patient's life. Make sure that the treatment can also be completed in the event of device failure.

Device components and accessories

- The power supply has a safety-relevant function. Only use the supplied, medically approved, original power supply unit!
- Follow the file manufacturer's instructions for use and disposal of the endodontic files.
- The accuracy of the length determination, the torque and the speed are only guaranteed when using the EndoPilot² 1:1 contra-angle.
- An exact length determination may not always be possible due to abnormal or unusual canal morphology (blocked or fractured canal).
- The tolerance for torque and speed is 10%.
- The DownPack handpiece and BackFill gun become hot. There is a risk of burning, damage to the environment and fire.
- Place the DownPack handpiece and the BackFill gun back into the holder immediately after use.
- Only place the BackFill gun's thermal protector on the gun immediately before use in the mouth, as this keeps it cool. Remove the thermal protector from the hot gun after use.
- To avoid the leading-in of external voltages, the hand-pieces and the lip clip must not be put down on electrically conductive surfaces.
- Always remove the lip clip from the patient's mouth when the apex measurement is not required. The lip clip must not be in the patient's mouth when using ultrasound, BackFill or DownPack. Never place the lip clip, file clamp and motor on conductive surfaces. Always return the motor to the handpiece holder. Always place the lip clip on the retaining provided for this purpose.

- Ensure that the file clamp of the apex cable has been put together correctly after preparation and that the contact has been screwed-in tightly.
- *Ultrasonic module: Do not use any deformed or worn instruments. At first, always choose a very low ultrasonic power output and only increase the energy when necessary. The ultrasonic device is intended for intermittent (interrupted) operation. To keep heating to a minimum, operation should be limited to 1 minute at maximum power and to 4 minutes at minimum power.
- *Ultrasonic module: Please note that the ultrasonic instruments heat up during operation. Make sure, therefore, that there is appropriate external cooling, if necessary.

Compatibility

- Endo files: You can use all US registered available nickel titanium files with a standard ISO shaft, tools-coupling ISO 14457:2017.
  Do not use instrument parameters out of file manufacturer's specifications.
- DownPack heating tips: Only use the original tips which are available from the manufacturer Meta Biomed.
- Backfill needles: Only use the original needles which are available from the manufacturer. Obtura, Young Innovations
- *Ultrasonic module: Ultrasonic tips: You can use all US registered endo instruments from Satelec Acteon
- Warning, do not use non-FDA-registered accessories

General information

- Keep this user manual and all information safe on the device.
- Keep the documents for the entire product life cycle.
- The operator is obliged to report all incidents within the meaning of the current regulations for medical devices, as well as any information on risks, to the manufacturer.

2. First steps

2.1. **Assembly**

Please first compare the components delivered with the enclosed shipping documents and the corresponding serial or LOT numbers. Check that the display glass is undamaged.
Please note that all components are supplied non-sterile and not disinfected (see chapter 18). Even the brand-new device needs to be processed before it is used for the first time.

The following conditions should be considered when installing the device:

- The support surface must be level and made of non-combustible material.
- The device must not be installed in damp places. Do not use the device in areas when liquids have been spilt on the floor.
- Do not expose the device to direct or indirect heat sources. (E.g. sun or radiator)
- Only charge or operate the device when it is at room temperature (do not exceed max. +40°C)!

- The ambient temperature must be within the prescribed limits. (See chapter 16). Avoid heating up to above 60°C in any case!
- The device must not be installed near free oxygen, flammable gas mixtures or liquids (e.g. in operating theatre or emergency areas).
- The EndoPilot² should not be installed near devices emitting electromagnetic radiation so as not influence the correct length determination.
- Place the foot switch in such a way that it will be easy to operate.
- Make sure that the foot switch cannot be activated unintentionally.
- Place the device in such a way that the power supply cable can be pulled out of the device when necessary.

2.2. **Holders for the handpieces**

The holders provide a safe position for the applied parts. Insert the retainer for the apex cable laterally into the hole at right handpiece holder.
You can upgrade the device with additional functions (example: left arm with a holder for DownPack and BackFill). For the assembly of additional holders as well as for the arrangement of the handpieces, please follow the assembly instructions provided separately.
*Ultrasonic module: A double holder is mounted on the extension module for the ultrasonic handpiece and the motor.

2.3. **Connection**

All connections are plugged in and must **not** be twisted! Care must be taken to ensure that the plug's groove fits into the socket's groove. The 'Push and Pull' connections for the handpieces are color-coded (the numbers refer to the illustrations on the inside cover page).

Figure	Connection	Use
1a	blue	Motor
1b	green	Apex cable, connection to the patient (lip clip)
1c	black	Power supply unit
1d	Slot	microSD card
1e	red	BackFill gun, optional
1f	blue	D-Pack, optional, please do not insert the motor here!

Insert the EndoPilot² microSD card into the SD slot before first use.
(Insert the card carefully, do not use sharp tools).

*Ultrasonic module: The 'Push and Pull' connections for the handpieces are color-coded as for the EndoPilot²:

Figure	Connection	Use
16a	grey	Ultrasonic handpiece cable and ultrasonic handpiece

When connecting the ultrasonic handpiece to the ultrasonic cable, ensure that the handpiece is not twisted during connection. If the EndoPilot² control unit is not already equipped with the ultrasonic module, it can be done later. The device can be upgraded in the factory. Your dealer will advise you how to reship the device.

2.4. **Touch display**

Remove the transport protective film before use. All functions of the EndoPilot² are called up using the convenient touch display. The touch display allows intuitive and self-explanatory operation. Operate the touch display with a light touch of the finger. Operation is of course possible when wearing gloves.
The display must not be operated with metallic objects under any circumstances (risk of glass breakage)!

With the  button, you will always return to the previous menu or back to the start menu.

2.5. **Foot switch**

Functions of the wireless foot switch (single-pedal type Single):
- Starting / Stopping the motor
- Saving the actual measured root length (see chapter 3.)
- Activating the EndoPilot² from sleep mode

Additional functions of the optional two-pedal wireless foot switch (type Twin):
- Tapping on the Select button briefly:
  Change to the next instrument.
- Pressing the Select button for a prolonged period:
  Moving between the functions: Ultrasonic and endo motor.

Low batteries may lead to interruption and a loss of function.
Replace low batteries immediately.
Low voltage of the batteries is displayed in the service menu (see chapter 11)
Spare batteries should always be available for uninterrupted operation.

Battery replacement: Please open the battery compartment under the foot switch's base plate. Remove the used batteries. Insert new batteries. Pay attention to the prescribed pole direction. Correctly dispose of the old batteries.

Model:	Location:	Battery type:
Single foot switch	Unscrew the base plate	2x 1.5 V, type AAA
Twin foot switch	Battery compartment	2x 1.5 V, type AA

Do not use rechargeable batteries; they have a lower nominal voltage! Only use brand name batteries and batteries of the same type.
Caution! If the wireless foot switch is not used for a long time, the batteries must be removed.

Bluetooth connection:
The wireless foot switch is already connected to the device on delivery.
If a new foot switch is supposed to be connected to the device, this is possible using the service menu (see chapter 11).

EMC from outside or other devices could lead to an interruption
Cellphones in the same room should be switched off during usage.
Devices with strong electromagnetic radiation should not stand directly side by side to the device. Distance between foot-switch and control-unit should be limited to 1,5m.
(for more details see chapter 17 EMC manufacturer`s declaration)

2.6. **Charging, switching-on, standby mode, switching-off**

Make sure to fully charge the device before first use. (The device can only be charged or switched on with the inserted microSD card.)
When charging, please ensure that the device has not been heated by sunlight. Charging is interrupted at a device temperature above 40°C.

To charge, plug the power supply unit into the socket (the green LED in the power supply unit must light up). The device plug of the power supply unit is plugged into the black socket (1c) on the rear of the device. The device is switched on automatically by connecting the power supply unit, the blue LED on the front of the device flashes during charging.
During charging, the display illumination can be switched off with the On/Off switch on the rear of the device, charging continues. When the battery is fully charged, the blue LED lights up continuously. The power supply can be disconnected.

The respective battery status is displayed at the bottom edge of the screen.
If the charge drops to 10% of the capacity, a warning message appears. In this case the battery must be charged immediately. If not charged, the device will switch off to avoid a total discharge of and damage to the battery.

Charge the battery regularly.

If the device is not used for a prolonged period of time, the device automatically switches to sleep mode and the display illumination switches off. The sleep mode is indicated by slow flashing of the blue LED in the display. By briefly pressing the foot switch or the touch display, the device switches on again. The last menu used is displayed again.

After a long waiting period, the device will switch off completely. This "Auto off" time can be set in the setup menu.

To avoid unnecessary power consumption in standby mode, the mains plug should be removed from the plug socket when the EndoPilot² is not in use for a longer period of time.

In case of malfunctions, you can completely switch off the device by removing the microSD card. The microSD card must be removed when the device is shipped.

2.7. **Preparation of the root canal - motor and contra-angle**

The EndoPilot² contra-angle (5) is attached to the motor (6). Only use contra-angles with a 1:1 ratio. The integrated apex length determination during preparation (see chapter 4.5.3) only works in conjunction with the original EndoPilot² contra-angle.

If the contra-angle was changed or sterilized, a calibration must be performed under the Calibration (motor menu) menu item. The calibration compensates the friction in the contra-angle. Contra-angles may only be changed when the motor is at a standstill.

Operating instructions:
Before operation, check that the motor is firmly locked in place in the contra-angle.

During operation of the contra-angle, never exert pressure on its push button, as this could lead to friction or incorrect measurements!

Due to the shape of the root canal, the endo files are bent and stressed during use. Although the device reduces the risk of file breakage, file breakage cannot be completely eliminated. Please make sure that you know the instruments' permissible torques. Choose the right file. Never use deformed or damaged files!
The menu offers a variety of setting options. All parameters such as speed, torque and operating mode etc. may be changed individually.
Parameters that deviate from the instrument manufacturer's specifications may lead to file breakage and other damage. Schlumbohm® is not liable for damage caused by operating the device in a way that deviates from the instrument manufacturer's specifications.

To avoid file breakage, please note the following points:

- Never apply pressure to insert the file or to move it forward.
- Even Nickel-titanium files break due to material fatigue. Only prepare as many canals as intended by the file manufacturer.
- Experience and practice are indispensable for the effective use of Nitti instruments.
- Practice handling extracted teeth or Endo plastic blocks.

LED motor: GREEN The torque is *below* 80% of the permissible load
RED The torque is *above* 80% of the permissible load

2.8. **Filling technique - DownPack (D-Pack)**

Connect the DownPack handpiece (7) to the blue socket (1f) on the left side of the EndoPilot². Only use the handpiece holder provided on the EndoPilot² for storage.
Note that the tip becomes very hot. It can reach a surface temperature of over 400°C without a thermal load (without heating up the gutta-percha).
Do not use the tip in the air, without thermal load (without cooling)
Do not press the foot-switch several times repeatedly (pumping).

Using the heating tip:
Open the chuck by two turns of the screw-cap and insert the heating tip (8) (always insert the shaft as far as possible). Fix the tip by tightening the screw-cap. Before use, check that the heating tip is fixed firmly in position. A twisting tip may lead to injuries. You can use the wrench (13) to loosen the screw-cap when necessary. Note the limited service life of the heating tip. This varies depending on the frequency of use, load and deformation in each case. Check the heating tip for function and mechanical integrity before each use. The use of excessive force may lead to breakage and to injuries due to slipping.

Never use heating tips from other manufacturers!
Do not use the DownPack handpiece with the apex cable at the same time.
It is possible to heat up the tooth and the adjacent tissue by continuously introducing heat into the treatment site. Ensure adequate waiting times and proceed with caution. Excessive heating may lead to changes in the filling material's properties.
LED DownPack:
Red light: DownPack is in operation, the heating process is running
(for application see chapter 5.1).

2.9. **Filling technique - BackFill**

Connect the BackFill gun (12) with the cable to the red socket (1f) of the device. The nut for BackFill needle (9) must be tightened with the wrench (13) to avoid leakage of gutta-percha at the thread. Form the needle with the tool's forming rollers. Always make sure that the needle is not bent or torn out of the connection base. Avoid bending back and forth. Press the release (12a) and pull the piston (12b) backwards a little. Then insert only 1 pellet of gutta-percha (14) into the upper opening of the gun for the time being. If the gun is already heated, this should be done quickly to prevent the inserted material from sticking. Use the lever (12c) to push the gutta-percha into the heating chamber with the help of the piston (12b) and later through the needle. Make sure that the small screw and the seal at the end of the piston (12b) are in place and firmly tightened. As long as the set temperature is not reached and the gutta-percha is still hard, you should not press too hard to avoid damaging the gun.

If the heating times are longer, the gun's outer parts will also be warmed up.
The bushing in the front area of the gun reaches temperatures of over 200°C. This is necessary as a matter of principle, but requires careful handling.
Always use a heat thermal protector (11) to avoid burns. Always put on the thermal protector shortly before application so that it does not heat up. Remove the thermal protector from the gun after applying the gutta-percha. If necessary, change the protector during work to have a cool thermal protector on the gun in each case. Check the heat of the thermal protector (11) with your fingers before the application.

Do not touch the patient's lips or mucous membrane with the needle. During the filling process, the needle should rise with the filling material.
Do not place the BackFill gun on electrically conductive surfaces. External voltages could be transferred. Do not use the BackFill gun with the apex cable at the same time. Only use the EndoPilot² holder for storage.
The use of excessive force may lead to breakage of the needle and to injuries. Always make sure that the gun has been cleaned and prepared before each treatment. Use a new needle in each case and a new gutta-percha pellet for each application.

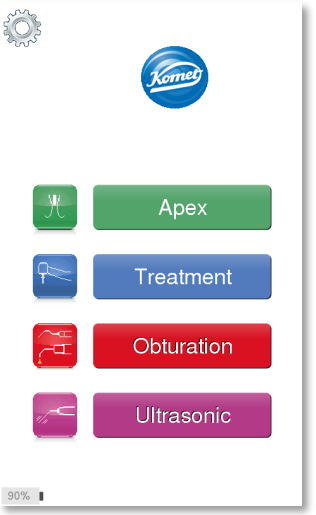
After application, squeeze out any gutta-percha residue from the gun while the handpiece is still hot. First unscrew the needle and pull the piston backwards out of the gun.
Only use original gutta-percha pellets. For information on dismantling, see the reprocessing instructions.

3. - 6. Functions Start menu

Setup button (see chapter 7)

3. Manual apex length determination
4. Motor system for NiTi files
5. BackFill gun DownPack handpiece
6. Ultrasonic function

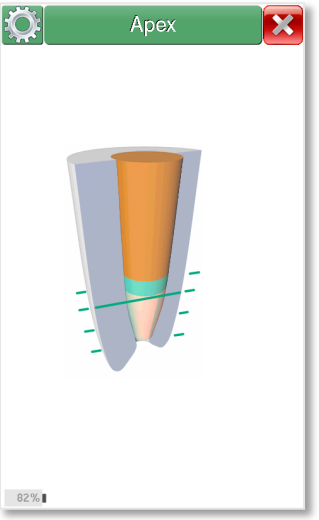
Battery status display



3. Manual apex length determination

In this menu you can pre-probe the canal manually, i.e. with a file guided by the hand. Use the lip clip (4b) and the file clamp (4e) for this.
The marker (horizontal line) determines the position in the root canal where the 'Auto-Stop' function is reached during mechanical preparation. The manufacturer has already set the marker. The user (if desired) can, however, change the setting directly on the display by moving the bar (by tapping on it with the finger). With this function it is possible to transfer the X-ray verified position of a pilot instrument to the display.
The marker's setting remains unchanged until the device is switched off. If the device is switched on again, the line is reset to the default value.

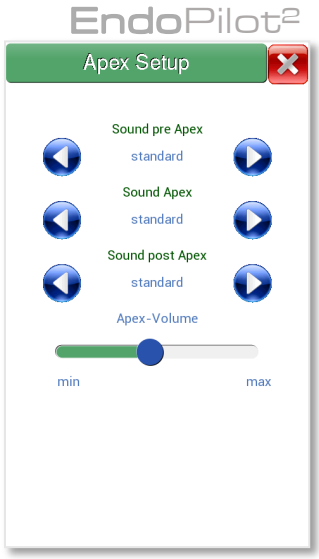
Do not place the measuring cables on electrically conductive surfaces, as external voltages could be transferred to the device.



Use the button to access the settings in the Apex setup menu.

You can configure the settings in this Setup menu:

For example, you can set different sounds and the volume.



Caution:
If you allow the file to touch the lip clip, this will cause a short circuit. With this short circuit you can test the correct operation of the display and apex locator.

3.1. **Tips for length determination**

Place the cap (4c) on the lip clip's socket before use; the cap protects the socket from contamination.
The lip clip (4b) is hung in the patient's cheek pouch on the opposite side of the tooth to be treated.
Remove the lip clip from the patient's mouth if you do not need the measurement (especially if you use other functions such as ultrasound or BackFill or DownPack).
Before you start the length determination, the canal should be rinsed briefly with physiological saline solution. The canal input must then be dried (e.g. with a cotton pellet) to avoid leakage current and, as a consequence, incorrect measurements. Protective gloves should be worn during the length determination so that the measuring current has no power dissipation. For the manual measurement, the file is connected to the file clamp below the shaft and slowly inserted into the root canal.
The file is automatically connected using the contra-angle for the integrated length determination during preparation. Here, the file clamp is not required.

Please keep in mind that incorrect measurements due to disturbances (conductive residual fillings, cracks, etc.) may occur during the electronic length determination as a matter of principle.
Chemicals in the canal can influence the measurement due to different conductivity. The ideal measuring medium is physiological saline solution.

The results should always be compared with an X-ray control image.

4. Motor system

4.1. Favorites

When you access the Preparation menu, the Favorites menu will appear.

The device has a large file database.
The values of many file systems are already stored in this database.

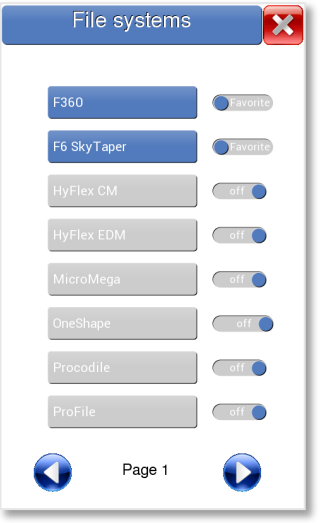
Use the File systems button to reach the Selection menu (see 4.2).
After activation, the file systems that are saved as favorites are displayed here. This will speed up the selection of the file system in the future.
This example shows F360 and F6 SkyTaper.

The MyFile system is initially an empty system.
Here, the user can create his or her own sequences by copying files. See chapter 4.4

4.2. Selection of the file systems

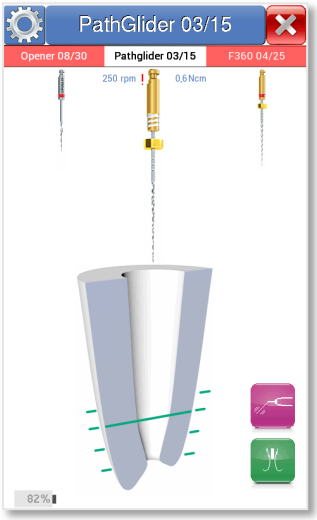
Select the file systems to be displayed in the Favorites menu. You can choose a maximum of 5 systems.

Here, you can find further file systems



4.3. **Preparation**

After selecting the file system and the desired file, the Endomotor is started up using the foot switch in the Preparation menu. The selected file appears in the upper line. The speed and torque values of the file are indicated below.
In addition to the currently selected file, further files are shown. You can select these by tapping on or swiping them directly.



Press the  button to call up ‘Setup Motor’ (see 4.5). Here, you can configure the settings for the motor drive. Changed values are displayed with a red exclamation mark.

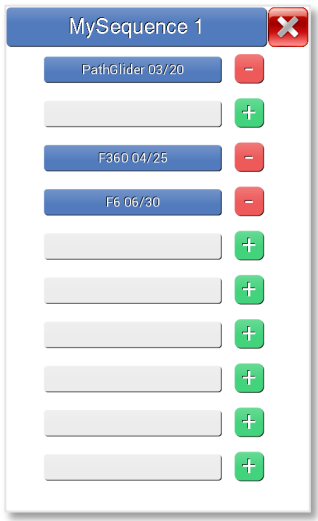
The apex display is always in operation and thus also allows manual probing with the help of the file clamp. Please note that the file clamp must be stored in an insulated place. Otherwise, incorrect measurements may occur during the length determination using the contra-angle.

*By pressing the ultrasonic- icon you can switch to the ultrasonic-menu
(if the ultrasonic-extension-module is mounted).

You can switch the integrated apex measurement off and on again during preparation by pressing the green apex icon at the right edge of the screen.

4.4. **MyFile file system**

The MyFile system offers 5 sequences for free configuration. Select one of the ‘MySequence’ sequences from the menu (sequence 1 has been chosen here). Sequences that have not yet been filled are displayed in grey.



Now copy up to 10 instruments from existing file systems into the sequence in any order.

To copy, press the green plus button at the desired position and select a file.
You can change the file parameters (speed, torque...) of the files copied into the MyFile file system as desired.
These changes have no repercussions on the data in the original file system.

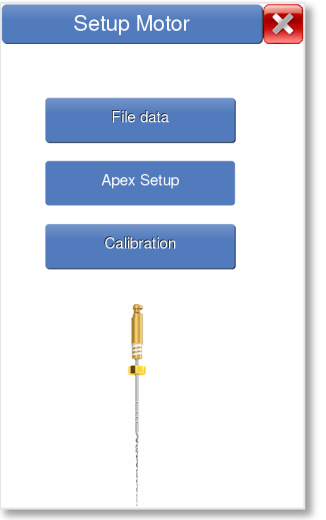
You can delete entries again with the Minus button

4.5. Setup motor

The settings that apply to the entire preparation are chosen under this menu.

It is possible to individually change the selected file's parameters. Select the File data. The File setup opens (see below).
You can configure further settings for the apex measurement during motor operation under Apex setup.

You can test the motor with the contra-angle handpiece under Calibrate. Leave the motor and the contra-angle handpiece in the holder and start the calibration.



4.5.1. File data

All US registered, pre-programmed nickel titanium files with a standard ISO shaft, tools-coupling ISO 14457:2017 can be used. The device offers pre-programmed standard settings, provided from the tool manufacturers.
The File setup menu offers a variety of setting options. The device allows all parameters such as speed, torque, operating mode, etc. to be changed individually. Please contact the file manufacturer first, if you want to change the Parameters. Parameters that differ from the instrument manufacturer's specifications may lead to file breakage and other damage.

Under the Movement menu item, you can select:

- Twist (right rotation with 'Shake loose' when jamming)
- Twist off (right movement, motor stops in the event of overload)
- Left rotation
- Reciprocal function

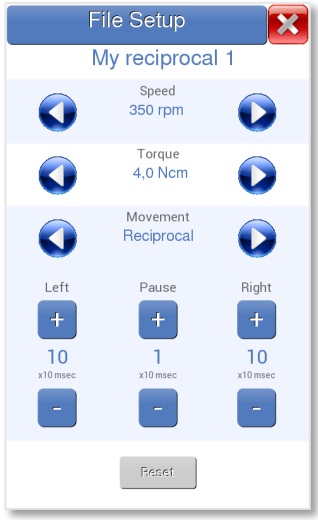
Note:
Please keep in mind that the file manufacturers reserve the right to make changes and customizations to the instrument's characteristic values. The data stored in this device has been defined with great care in accordance with manufacturer recommendations. The user can individually customize future changes or import such changes via an update.

4.5.2. Reciprocal function

General:
An Endo instrument is set into a cyclic right-left movement with the reciprocal technique. The user rhythmically pulls the instrument out of the canal to remove chips. The advantage of this technique is the significant saving of time.

Settings:

Under the File systems overview, the device offers the Reciprocal file system (see chapter 4.1). It is suitable for file systems that are to be operated in reciprocal mode. By using the setup menu, the user can check the pre-set values.



Select the function in the File Setup menu of the file under Movement.

The parameters are set using the - or + button and saved with Save.

During your work, please ensure a constant removal of chips.

Remark:

The torque is also monitored in this operating mode. However, since this technique does not have a distinct start-up phase when the motor is started, the torque control can already be triggered at high speed settings when the motor is started. In this case, a higher torque limit should be set.

The cyclic drive.

This function provides a step-by-step drive in the direction of rotation. To configure this function, a Left or Right parameter is set to zero. The other parameter indicates the length of the step. The pause between the movements allows the instrument to partially reset the torsion.

4.5.3. Apex functions during motor operation

You can select the settings that apply to the preparation under the Apex Setup menu.
(See also section chapter 3)

You can set various sounds and the apex signal's volume.

Here, you define how the motor reacts when reaching the apex position.
You can set the motor's stop time. You can also switch off the function for stopping the motor at the apex.
As Apex function you can select:

- Apex stop (stop time: 0.5 or 1 or 2 seconds)
- Apex stop off (the apex position is displayed, the motor does not stop automatically).

Check the apex cable and the correct connection by briefly touching the lip clip with the clamped file. The **Short circuit** error message must be displayed (see chapter 14). A convenient function of the EndoPilot² is the length determination during the mechanical preparation. In principle, all instructions already mentioned in chapter 3 (Manual apex length determination) apply. For the measurement during preparation, the contra-angle handpiece takes over the file clamp's task. The measuring signal is transferred to the file through the insulated contra-angle. The lip clip is still needed to close the electric circuit.

The results should always be compared with an X-ray control image.

You can select a total of two modes of operation:

1. Apex function Apex stop **0.5 seconds/ 1 second/ 2 seconds.**
The position or propulsion of the file in the root canal is displayed on the symbolized apex during preparation and the manual probing. It is not possible to enter or change the parameters while the motor is being started up using the foot switch.
1. If the horizontal line, which may have been set by manual probing, is reached, the motor stops for the selected time unit (0.5; 1 or 2 seconds).
2. An acoustic signal and flashing red LED on the motor signal that, with immediate effect, the file's maximum torque limit will be further reduced in the cutting direction.

2. Apex function Apex stop off
The position or propulsion of the file in the root canal is displayed on the apex image on the display during preparation and the manual probing.
An acoustic signal sounds when the horizontal line is crossed. The motor does not stop and the torque is not reduced either.

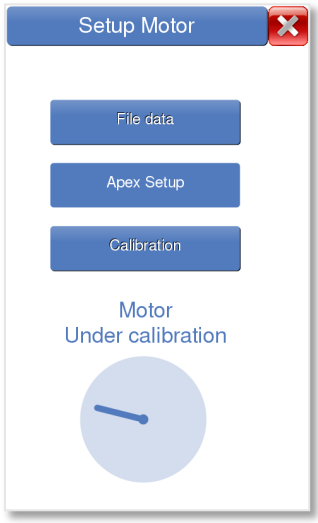
Note: An electronic length determination is only possible with conductive tool shafts. There are instruments with insulating shafts. It is therefore not possible to determine the length during preparation.

4.5.4. Calibrate

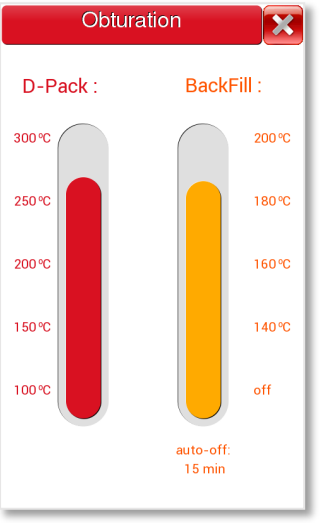
Always perform a calibration after each sterilization. The calibration compensates for the contra-angle's friction.

This calibration can compensate for small torque losses at the contra-angle. This function always allows safe operation at low torque limits.

If calibration is not possible, the contra-angle will be very dirty or damaged. In this case, please contact the manufacturer.



5. Obturation



5.1 Setting the DownPack temperature

5.2. Setting the BackFill temperature

The temperatures shown are only examples.

Here, the remaining run time of the BackFill gun is displayed.

5.1. **DownPack**

In this menu, you can select the temperature of the heating tip. The temperature column is set to the desired temperature (touch display). Start the heating process by pressing the foot switch. An acoustic signal sounds when the desired temperature is reached. Releasing the foot switch (after a few seconds) will stop the heating process (second acoustic signal).
If you press the foot switch for a longer time, the heating process is automatically stopped for safety reasons. The shut-off time depends on the chosen temperature. At maximum power, the device stops after 5 seconds. At low power, the device stops after 40 seconds at the latest.
Do not press several times in quick succession. This will make the needle hotter than desired.
During the heating process, the connected BackFill gun is switched off for a short time. Please also refer to chapter 5.2.

5.2. **BackFill**

You can select the temperature of the gun's heating in this menu. The BackFill gun must be connected. The temperature column is set to the desired temperature using the touch display. The device is heated as soon as a temperature has been chosen. The 'Heating up' message appears. When the temperature is reached, an acoustic signal sounds and the auto-off time of max. **15 minutes** is displayed. After the time has elapsed, the heating process is automatically switched off again (acoustic signal). You can switch off the heating process manually by pressing the OFF button at the bottom of the temperature column.
Do not leave the device unattended during the BackFill operation.

During obturation (D-Pack and BackFill), the patient must no longer be connected to the apex cable!

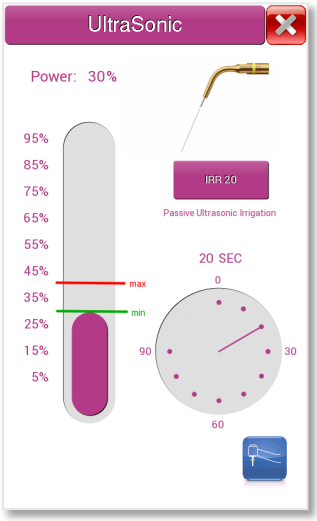
6. Ultrasonic function*

6.2 Setting of the ultrasonic power output
Select the power by pushing the bar graph

6.4 Ultrasonic instrument selection
Press the name of the tool to enter the tool-library

6.4 Setting of the run time
Select the run time directly at the clock

With the motor button you will return to the last used file system



6.1. **Operating instructions***

When inserting the instruments, make sure that only instruments with a suitable type of thread are used.
First tighten the selected instrument by hand and then with the wrench. When using fixed wrenches, take care not to overtighten the instruments. The handpiece and the instrument may be damaged. Only change the instruments when the ultrasonic handpiece is switched off. Do not twist the handpiece's cable connection. Do not use instruments that have been deformed or show wear. Pay attention to the product life cycle of the instruments. Work without exerting excessive pressure on the instruments. Instrument breakage may lead to injuries. Dispose of used instruments in an appropriate manner. Ensure that a contamination or an infection is prevented.
If possible, cool the instrument with external cooling to prevent it and the treatment site from heating up. Always use sterile water when working in the root canal.
Please note that freely vibrating, thin instruments may also break without an external load, which is solely due to the ultrasonic vibration. Flying splinters may lead to injuries. The device may only be operated when the ultrasonic handpiece is connected to the handpiece cable. Never touch the handpiece cable's contacts! Select only appropriate program parameters for the instrument. You must no longer used the device if malfunctions or disturbances occur. Contact the manufacturer immediately.
Ensure that the ultrasonic tips are used according to your field of application. Do not use any other ultrasonic handpieces or cables.

During the ultrasonic application, the patient must no longer be connected to the apex cable!

Place the handpieces back into the holder after use.
The handpiece connection of the ultrasonic handpiece to the cable and the internal contacts must be absolutely dry. Pay attention to damage to the insulation and the handpiece. Only use proper functioning handpieces and ultrasonic cables. Damaged insulation may lead to electric shocks.

Check the ultrasonic handpiece for damage before use and especially after each disinfection and sterilization. If there is any evidence of cracks, do not use the ultrasonic handpiece again. There is a risk of electric shock.
Use a cofferdam with each treatment. This prevents the inhalation or ingestion of small parts.
Do not leave the device unattended. Ensure that the foot switch is not pressed unintentionally.

6.2. **Setting the ultrasonic power output***

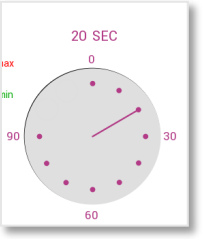
You can freely set the level of intensity on the touch display. Care must be taken to choose an appropriate level of intensity. Always choose a small power output at the beginning of the application and then increase it to the required power level. Do not activate instruments if they are still in the air (without contact with the tooth). The ultrasonic device is intended for intermittent (interrupted) operation. During operation, the handpieces axis can reach a temperature of up to 50°C. Physiological effects are not to be expected.
To keep heating to a minimum, operation should be limited to 1 minute at maximum power and to 4 minutes at minimum power.
Ensure adequate cooling times:
1 minute operation at maximum power, 3 minutes cooling time.
4 minutes operation at minimum power, 6 minutes cooling time
The instrument's working end may also heat up due to friction. Ensure adequate cooling of the treatment site.

6.3. **Ultrasonic instrument selection***

Use the instrument button to select one of the many ultrasonic instruments. The corresponding power output settings are already pre-programmed.
The instrument selection is saved and is retained, even if the ultrasonic extension module is switched off. The respective instrument is displayed in the upper right corner.

6.4. **Setting the run time***

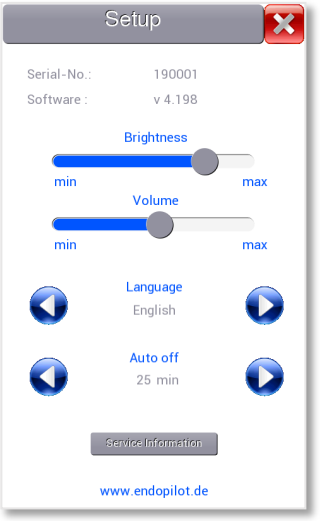
Rinsing liquids, as for example EDTA, often require pre-set exposure times.
Setting the run time allows defined activation times to be adhered to.
You can independently set the run time for the ultrasonic extension from 1 second to 90 seconds. After the countdown, it stops automatically with an acoustic signal!
Always ensure adequate cooling times (see above)



7. - 11. Setup functions

7. Software release and updates

You can find the device data and software release here.
Updates can be made using the microSD card.



8. Brightness / Volume

Setting the brightness

Setting the volume

9. Setting the language

Here, you can choose the language

10. Auto-off time

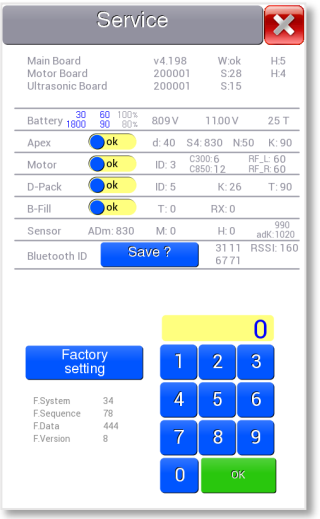
Setting the switch-off time

Open the service menu with further information (chapter 11)

11. Service information / Bluetooth

This data indicates the device state.
This data is helpful in the event of an error.

If you want to connect a new footswitch, press it.
The foot switch is added with the Save button. The green 'Detected' message appears when the added foot switch is pressed again.
On the right side you will find the battery voltage of the switch. Low voltage (under 1,4V) will lead to an interruption and a loss of function. Keep fresh batteries in stock and replace low batteries immediately.



You can use the keypad to activate further functions or query the settings.
By resetting, all file parameters are reset to the factory settings. Caution! Changes made by the user are deleted.

Software Updates:
Updates are easy to perform with the help of the microSD card. Software-updates are provided on company supplied microSD cards.
For details see Update Instruction document 610 2206
Caution! Never insert microSD cards with unknown contents into the device.

12. Maintenance, transport and disposal

12.1. **Periodical tests**

The national legislative authority requires the operator of certain electrical, medical equipment, in some countries, to perform regular tests.

In Germany the national legislative authority requires the operator of certain electrical, medical devices, in §11 of the “Medizin Produkte Betreiber Verordnung” (MP-BetreibV), to perform periodical tests
The appendix 1 of the “Medizin Produkte Betreiber Verordnung“ specifies the groups of devices for which safety checks are obligatory. The aim is to ensure operational safety and to avoid safety risks.

For the EndoPilot², the German legislative authority does not prescribe any safety checks.

However, as the manufacturer, we recommend an annual safety check of the device and particularly the power-supply in connection with the prescribed maintenance (§ 7 “Medizin Produkte Betreiber Verordnung“) in accordance with the international standard IEC 62353 “Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment” (resp. DIN EN 62353 / VDE 0751-1)

The scope of testing should include the following test steps:

- Is the power supply unit the original power supply unit?
  (REF. number matches the number in the user manual)?
  Caution, the power supply unit is relevant to safety. No other power supply units may be used!
- Measurement of the leakage current at the power supply.
- Visual inspection of the power supply and the entire device
  (special attention must be paid to the integrity of the cables, the plug connections and the insulation)!
- Functional test of all parts.

The device complies with protection class II, the applied parts with type BF
(see the user manual chapter 16 “Technical Data”).

The tests must comply with the international standard IEC 62353 (resp. DIN EN 62353 / VDE 0751-1). Persons and organizations with appropriate expertise (Germany: following § 7 Chapter.4 MP-BetreibV) must perform these tests.

12.2. **Maintenance**

You can find detailed information on the processing of individual components in chapter 18 (Cleaning, disinfection and sterilization) of the mentioned preparation instructions.
It is imperative that you follow the following instructions:
- Check the connection cable and plug connections every 6 months.
- If the wireless foot switch is not used for a long time, the batteries must be removed.
- Do not use rechargeable batteries for the foot switch (only batteries of type AAA with 1.5V).
- The EndoPilot² does not contain any components that can be repaired on the spot.
- Modifying or opening the device voids the warranty.
- Repairs may only be carried out by the manufacturer!
- Even for infrequent use, the device should be charged every 6 months.
- Only use the intended power supply unit!
- A battery change is planned after 4 years. Heavily aged batteries can pose a safety risk.
Caution: Only the manufacturer or an authorized partner may change the battery.

Caution! The motor must not be lubricated or oiled under any circumstances! When servicing the contra-angle, make sure that no lubricant or cleaning agents enter the motor! Allow excess oil to drip out of the contra-angle before operation. For this purpose, set the contra-angle down in a vertical position.
The contra-angle should be oiled with oil spray for contra-angles immediately after application (before reprocessing) to remove penetrated treatment fluids such as sodium hypochlorite.

Before operating the ultrasonic handpiece, check for damage to the insulation and check whether the oscillator's axis is firmly anchored in the housing before each application. Do not use any damaged ultrasonic handpieces or cables.
Make sure that the connectors are dry.

12.3. **Transport**

Prevent the device from falling. The device contains a lithium-ion battery (Li-Ion battery) Power output: 48 Wh. A hard fall may lead to mechanical damage to the device and the battery unit. The inserted battery may cause fires and injuries if handled incorrectly. The device must not be heated up to above 60°C, burned, immersed in liquids or dismantled.

If possible, please use the manufacturer's packaging or sufficiently strong packaging for shipping the device. Please follow the applicable shipping regulations.

Switch off the device prior to shipping and remove the microSD card. Enclose these in a clearly visible way. Pack the unit so that the on/off switch on the rear side of the device cannot be activated unintentionally during transport.

Ensure that all components are disinfected prior to shipping (see processing instructions in chapter 18).
Dirty and contaminated products must not be shipped.

For shipment please follow the current transport regulations for equipment with Lithium-Ion-Batteries (UN3481).

12.4. **Disposal**

Dispose of any waste and used disposables properly. National regulations must be observed.

The device is a high-quality medical product with a long service life. At the end of its product life cycle, the device must be disposed of correctly. Observe country-specific disposal regulations.
It must be assumed that the device is contaminated at the end of its life cycle. The device and accessories must be decontaminated before disposal; germs pose a hazard. Before disposing of or prior to transport, all parts that have come into contact with patients must be thoroughly cleaned, disinfected or sterilized. The device itself and the foot switch must be subjected to surface disinfection on all sides. Also spray plugs and sockets during this last preparation. Remove the batteries from the foot switch.

Please note that the device contains a high-output Li-Ion battery. This may lead to fires and injuries if handled incorrectly (e.g.: overheating, mechanical damage, use of liquids and short circuit). Please do not dismantle the control unit yourself. Avoid falls and unnecessary damage.

Disposal in the EU: Pursuant to EU directives (WEEE and RoHS), this device may not be disposed of along with general household waste. Please observe the applicable national laws and regulations concerning the disposal of waste equipment.

Disposal in Germany: In the Federal Republic of Germany, the Electrical Law (ElektroG) regulates the disposal of waste electronic equipment.

Since the device has been used in the medical field, it must be assumed that the waste equipment could be infected. For this reason, the rules of the EAR (national register for waste electric equipment: Stiftung EAR) exclude this type of device from the ElektroG.

The EndoPilot² is an exclusively commercially used product (B2B). The disposal takes place by return to the manufacturer. The sender bears all costs for the return shipment. For further details please contact your dealer.

13. Troubleshooting

If the EndoPilot² does not seem to work properly, it does not necessarily have to be a device malfunction! Please check the device first with the help of the following table to exclude any handling errors or disturbances (such as special anatomical peculiarities during the apex measurement).

Problem	Possible reason	Solution
Device in general		
The device does not show any function and the display remains switched off.	No power supply, battery may not be charged	Is the power supply plugged in correctly (the LED on the power supply must light up)?
Operation of the touch display is not possible; the device does not react.	Display damaged	Return to the manufacturer.
No acoustic signals	Sound is switched off	Turn on the sound again.
Endo motor		
The instrument does not turn.	Calibration not performed	Perform the calibration with the contra-angle on the motor.
	Motor damaged	Check the cable connection and the plugs for damage. Check whether the motor runs without the contra-angle.
	Contra-angle damaged	Check whether the axis can rotate freely.
Apex locator		
No measurement possible. Signal missing or weak and interrupted	Contact problems	Are the lip clip and the measuring cable connected correctly? Are the lip clip and the file clamp immaculately clean? Check if a short circuit is indicated on the display when the lip clip and file clamp or the instrument in the contra-angle are touching each other.
	Lip clip on the wrong plug	The lip clip must be plugged into the measuring cable not into the short cable for the file-clamp!
	wrong contra-angle	Check whether the EndoPilot² contra-angle is attached. Is it properly locked in place? Connect the lip clip and NiTi file. Is a short circuit displayed?
	Root canal calcified or obliterated	Check the X-ray, if necessary create a glide path to the working length with a suitable file.
	Root canal very dry	Intermediate rinsing with a saline solution. Dry the cavity with a cotton pellet
	Blocking due to old filling / medical inlay	X-ray for comparison! Complete removal of old gutta-percha residues, or residues from the medical inlay.

Apex locator (continuation of the table)		
Measurement tends to show apex too early or the signal is at a maximum	Subsidiary current or high conductivity	Remove moisture from the crown or the 'cavity bottom'. Are there side canals? If necessary, rinse with a saline solution.
Wireless foot switch		
No function	Batteries empty	Open the battery compartment under the switch's base plate and change the batteries. Do not use rechargeable batteries.
No function	Switch not recognized.	Connect the switch with the device / see Setup
No function	Signal interference due to strong electromagnetic radiation. (EMC)	Switch off other devices (such as mobile phones) in the vicinity. Check the environment. (A cable switch can be used in particularly exposed areas)
DownPack		
The instrument does not heat up	Instrument damaged	Insert new heating tips (no third-party products!)
	Instrument turns	Use a tool for firm clamping
BackFill		
No gutta-percha at the tip of the needle	Handpiece too cold	Has the waiting time been adhered to? Is the heating chamber perceptibly warm?
	Pellet is used up	Is the piston fully pressed in? Insert a new pellet
	Lock-in slips	Turn the rotary knob clockwise as far as possible (see 11d)
Piston is blocked (cannot be pulled back during cleaning)	Gutta-percha residues	The residues stick to the piston, the gun must be emptied completely while it is still warm
Ultrasound		
Poor power output	Tip not tightened, deformed or worn out. Thread may be wrong	Tighten the instrument with a wrench or replace the instrument. Caution Satelec (Acteon) and EMS threads are different. Damage to the handpiece is possible
No function	Tip not tightened, cable may be defective	Tighten the instrument with a wrench. Contact the service team

If the problem cannot be solved, please contact your dealer or Schlumbohm directly for advice.

If the device switches itself off, this may indicate a malfunction. Please contact the manufacturer. Avoid mechanical damage. Do not open the device yourself.

14. Error messages

For certain operating errors or malfunctions, the device will display explanatory texts.
The following malfunctions are, for example, automatically detected:

- Battery only has 10% charge.
  With Quit you confirm that you have read the message.
  The device must be charged immediately.

- External voltage on the apex cable or contra-angle. With this function, the device shows that an electrical voltage is applied at the apex connections. The external voltage can be caused by defective devices or electrical installations.

15. Warranty / Liability

Schlumbohm® warrants this product against defects in materials and workmanship for the period of one year from the date of the original invoice. The product warrant provided by Schlumbohm® includes the repair or the replacement of the entire device or individual parts. The decision whether to replace or repair is entirely up to the manufacturer.
In the event of an alleged defect during warranty, the customer has to inform the Schlumbohm® customer service immediately. The customer service will give further instructions. Normally you will be asked to return the complete unit. The costs of returning the product are at the sender's expense.

Application errors exclude a warranty.
Schlumbohm® does not warrant for wear and contamination of the handpieces and contra-angle. Schlumbohm® does not warrant for glass breakage on the display or damage to the battery.

Schlumbohm® declines all responsibility for any damage caused by unsupervised device operation.

Schlumbohm® declines all responsibility for any damage caused by improper packaging or when shipping the device.

Schlumbohm® declines all responsibility for any damage caused as a result of the clinical application of its products. Irrespective of whether or not such use is associated with other medical devices (e.g. pacemakers).

16. Technical Data

Type:	**EndoPilot²**
Power supply[1]:	Input: 100 - 240 V/AC (50-60 Hz) Output: 12 V DC / 1.5 A Power supply unit for medical devices according to: IEC 60601-1 and IEC 60601-1-2 (Only use the original EndoPilot² power supply unit) Charge the device regularly, at least every 6 months
Electrical protection class:	II
Bluetooth transmission:	2.402-2.480 GHz, TX Power: +7 dBm
FCC ID:	T9JRN4020
Output: Basic device	Max. 3 V / 5 A or 12 V / 1.25 A (direct current)
Use:	The device is intended for short-term operation Motor: 30 seconds full load / 1 minute rest Ultrasound: 1 minute operation at maximum power, 3 minutes cooling time 4 minutes operation at minimum power, 6 minutes cooling time (forced shutdown after 1 - 90 seconds depending on the selection) DownPack: 5 seconds operation at the maximum temperature, 5 seconds cooling time (forced shutdown after 5-30 seconds depending on the power setting) BackFill: 15 minutes operation at the maximum temperature, 5 minutes Cooling time (forced shutdown after 15 minutes of continuous operation)
Speed Endomotor:	200-1000 rpm +/- 10%
Torque:	Max. 5 Ncm +/- 10%
Device class:	Class according to EN 60601- 1: Type BF applied part The device must not be operated in potentially explosive atmospheres Keep the device away from combustible material.
IP protection class:	IP31 EndoPilot² and wireless foot switch IP31 ultrasonic extension IP40 power supply unit
MD / EU class:	IIa
Environmental conditions:	Air pressure 800 hPa to 1060 hPa
For the company:	+15°C to +40°C / air moisture: 20-80%, non-condensing
For the transport:	-15°C to +60°C / air moisture: 20-80%, non-condensing
Battery type:	Li-Ion battery, 7.2 V, power output: 48 Wh
Weight:	1450 g EndoPilot² control unit
Dimensions: height x width x depth	19 cm x 20.5 cm x 17.5 cm (basic device)

Subject to technical changes!

[1] No other power supply units may be used. The power supply unit is relevant to safety!

17. EMC manufacturer's declaration

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC instructions contained in the accompanying documents.
Portable and mobile RF communications equipment can affect medical electrical equipment.

Warning notice
The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emission or decreased immunity of the equipment or system.

Medical electrical equipment or systems must not be placed directly next to each other or stacked with other equipment and, if operation is necessary close to or stacked with other equipment, the medical electrical equipment or system should be observed to verify normal operation in the configuration in which it will be used. A minimum distance of 30 cm should be assumed.

This device is intended solely for use by medical specialized staff in professional health care facilities. This device may cause wireless interference or interfere with the operation of equipment in the immediate vicinity.

It may be necessary to take suitable remedial actions, such as a new orientation or a new arrangement of the device.
The EndoPilot² device may be impaired in its function due to interference from other devices. The device does not contain any life-supporting functions. The continued application in the event of device failure will likely be impossible. This failure will not endanger the patient's life.

This equipment (the used Bluetooth modules) has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

Guidelines and manufacturer's declaration Electromagnetic emissions		
The EndoPilot² device is intended for use in an environment specified below. The customer or user of the device should ensure that it is operated in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group **1**	The EndoPilot²-Device uses RF energy only for internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class **B**	The EndoPilot²-Device is suitable in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class **A**	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidelines and manufacturer's declaration Electromagnetic immunity			
The EndoPilot²-Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Device should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2:2014 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	**± 6 kV** contact discharge **± 8 kV** air discharge	**± 8 kV** contact discharge **± 15 kV** air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Fast transient electrical disturbances (bursts) IEC 61000-4-4	**± 2 kV** power supply lines **± 1 kV** input and output lines	**± 2 kV** power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	**± 1 kV** differential mode **± 2 kV** common mode	**± 1 kV** differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines	**>95%** dip / 0.5 cycles dip in U_T / 0.5 cycles **60%** dip / 5 cycles dip in U_T / 5 cycles **30%** dip / 25 cycles dip in U_T / 25 cycles **>95%** dip / 5 cycles. dip in U_T / 5 cycles	**>95%** dip / 0.5; 1 cycle dip in U_T / 0.5; 1 cycle **60%** dip / 5 cycles dip in U_T / 5 cycles **30%** dip / 25 cycles dip in U_T / 25 cycles **>95%** dip / 5 cycles. dip in U_T / 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EndoPilot²-Device requires continued operation during power mains interruption, it is recommended that the Device be powered from an UPS or a battery.
Magnetic field Power frequency (50/60) Hz Magnetic field according to IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
Conducted RF According to IEC 61000-4-6	V_1 = 3 V 150 kHz - 80 MHz	V_1 = 6 V 150 kHz - 80 MHz 80% AM, 1 kHz	Portable and mobile communications equipment should be used no closer to any part of the EndoPilot²Device (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.17 \sqrt{P}$ for V_1 = 3 V $d = 1.2 \sqrt{P}$ for V_1 =10 V
Radiated RF according to IEC 61000-4-3	E_1 = 3 V/m 80 MHz – 2.5 GHz	E_1 = 3 V/m 80 MHz – 2.7 GHz 80% AM, 1 kHz E_1 = 28 V/m 385; 450; 810; 870; 930 MHz 50% PM, 18 Hz E_1 = 28 V/m 1720; 1845; 1970; 2450 MHz 50% PM, 217 Hz E_1 = 9 V/m 710; 745; 780; 5240; 5500; 5785 MHz 50% PM, 217 Hz	$d = [12/E1] \sqrt{P}$ 80 MHz - 800 MHz $d = [12/E1] \sqrt{P}$ 800 MHz - 2.5 MHz Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

18. Cleaning, disinfection sterilization (Processing)

Reprocess the product immediately after each application or after each patient.
Even the brand-new device needs to be processed before it is used for the first time.

Information is provided in the enclosed reprocessing instructions.

Several reprocessing instructions apply to the individual components, depending on their design and resistance. The applicable instructions are specified in the list of components in the first part of this manual, see (# A1-A6).
 # (-) means: Reprocessing is not planned.

The following reprocessing instructions are delivered with the device:

(They comply with ISO 17664:2017)	Document no:
# A1. EndoPilot reprocessing instructions for thermostable components	610 2141 (chap.1)
# A2. EndoPilot reprocessing instructions for thermolabile components	610 2141 (chap. 2)
# A3. EndoPilot reprocessing instructions for the 1:1 contra-angle	609 2110
# A4. EndoPilot reprocessing instructions for DownPack heating-tips	609 2112

For Items from other original manufacturers look at the individual reprocessing instructions: These instructions are also delivered with the device (or could be downloaded from our website, see below). For direct information contact the original manufacturer

A4. DownPack E&Q heating-tips:
Meta Biomed: Homepage www.meta-biomed.com
or: http://www.endopilot.de/edp2/6102244v00.pdf 610 2244

A5. BackFill components
Obtura Spartan / Young Innovation:
www.obtura.com/UserFiles/Obtura/Instructions for se/Obtura_III_MAX_Cleaning_Instructions.pdf
or:
http://www.endopilot.de/edp2/6102242v00.pdf and 610 2242
http://www.endopilot.de/edp2/6102205v00.pdf 610 2205

A6. Ultrasonic hand-piece: See document
Satelec / ACTEON: At www.satelec.com/documents
http://satelecsupport.com/Documentation/STERILIZATION/STERILIZE.pdf
or: http://www.endopilot.de/edp2/6102243v00.pdf 610 2243

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