STATERA Vi

Endo Motor

User Manual

For dental use only

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https://www.forumtec.net

Technical modifications on our product are not subject to notification.
Photos of our devices are not contractual.

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Introduction

Congratulations on the purchase of **STATERA vi** endo motor.

STATERA vi endo motor is indicated for root canal treatment, using endodontic instruments in torque-controlled continuous rotation and in reciprocating movement with embedded apex locator.

For optimal safety and performance, read this user manual carefully before use. Make sure you have understood and followed the clinical precautions - as well as the general warnings, precautions, and contraindications - before proceeding to root canal treatment. Keep this user manual for future reference.

1 Indication For Use

The **STATERA vi** is a cordless handpiece with apex localization capability, used for driving files in both continuous rotation and reciprocating mode during an endodontic procedure for enlargement of root canals, while monitoring the position of the endodontic file tip within the canal.

The intended patient population consists of patients who need to undergo root canal treatment.

1.1 Intended Purpose

The intended purpose of the device is: To assist dental professionals in performing canal enlargement and or apex localization and working length determination during root canal treatment.

1.2 Intended Use

The intended use of the device is to assist dental professionals in performing canal enlargement and or apex localization and working length determination during root canal treatment.

1.3 Patient Target Group

The intended patient population is patients who need to undergo root canal treatment

1.4 Intended Users

The device shall be used by skilled endodontic experts or by qualified dental practitioners performing root canal treatments.

2 Contraindications

STATERA vi endo motor is not recommended for use in patients that have a pacemaker or other implanted electrical devices.

3 Warnings

- **STATERA vi** endo motor must only be used in hospital environments, clinics, or dental offices either by skilled endodontic experts or by qualified dental practitioners performing root canal treatments.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of **STATERA vi** endo motor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4 Precautions

- Do not use **STATERA vi** endo motor in the vicinity of devices emitting electromagnetic noise such as x-ray viewer with fluorescent lamps, film viewers, ultrasonic devices, etc.
- During device operation protect **STATERA vi** endo motor from occasional spillage of liquids.
- Do not use **STATERA vi** endo motor in presence of flammable materials.
- **STATERA vi** endo motor should be used with the manufacturer's original accessories only.
- Do not press the contra-angle pushbutton when the motor handpiece is running or if it is coming to a stop. This will lead to detachment of the instrument or cause the pushbutton to overheat.
- Do not remove the contra-angle from the motor handpiece during operation.
- Only use undamaged root canal instruments. Please refer to the information provided by the manufacturer.
- Only insert the instrument when the contra-angle is stationary.

- Never place your fingers on the moving parts of the instrument while it is running or coming to a stop.
- Only use the original contra-angle
- To prevent infectious agent transmission, it is highly recommended to use a rubber dam system during the endodontic procedure.
- To ensure that short circuits do not impair the apex locator measurements, be particularly careful with patients fitted with metallic crowns, bridges, or large metallic fillings (avoid any contact of the file or the lip clip with metals).
- High concentrations of sodium hypochlorite may result in a lower accuracy of the apex locator measurements. For working length determination, we recommend using sodium hypochlorite solution at maximum 5% concentration.
- Make sure that the canal is wet enough to ensure reliability of the apex locator measurement.
- Ensure that the contra angle or the file does not touch other instruments.
- Avoid excessive liquids inside the tooth cavity to prevent overflow and incorrect apex locator measurements.
- Teeth with open apices may give imprecise apex locator results.
- The use of apex locators alone without a preoperative and postoperative radiograph is not a recommended practice since apexlocators may not be able to work properly in all conditions. It is mandatory to confirm radiographically the working length established using the apex locator.
- For your own safety, please use personal protection gear (gloves, mask).

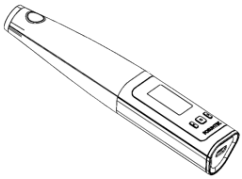
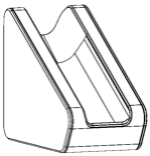
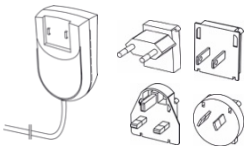
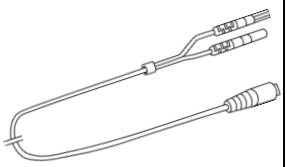
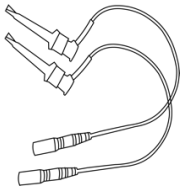
5 Adverse Reactions

None.

6 Step-by-Step Instructions

6.1 Content

Check the content of the equipment before use:

Handpiece 	Contra Angle 6:1 	Charging cradle 
AC/DC Adaptor 	Measurement cable 	Lip clip (2 pcs.) 
File Clip (2 pcs.) 	F type Spray Nozzle 	Protective Silicon Sleeve - Contra angle 
	Handpiece Protective Sleeve, replace for each patient.	

Note
Contra angle, measurement cable with attached lip clip and file clip constitutes Applied Parts of the device.

6.2 STATERA vi endo motor Overview

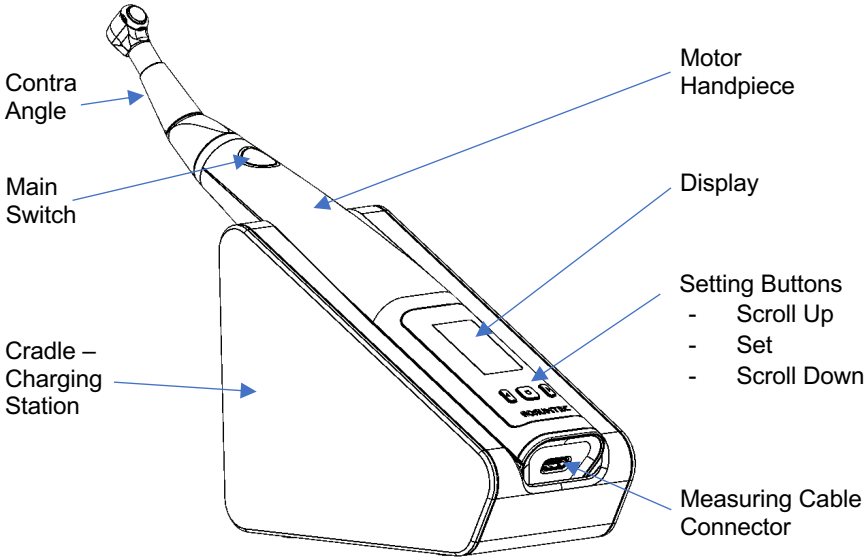


Fig. 1 Front view

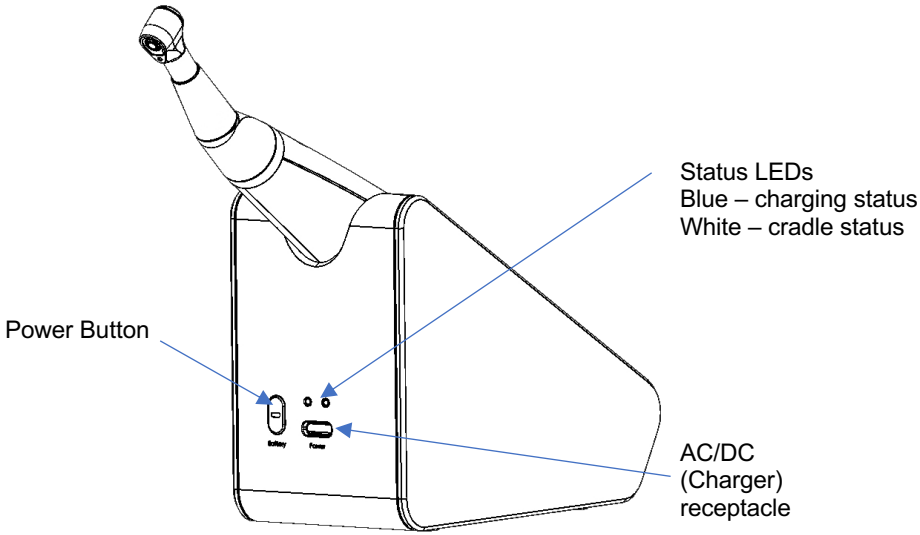


Fig. 2 Rear view

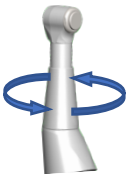
6.3 Setting up

6.3.1 Connect/Remove the Contra Angle

- Insert the contra angle into the motor handpiece – see Fig. 3. Push the contra angle all the way until a click sound is heard and the contra angle is secured.

Fig. 3 Contra Angle connection

- The contra angle rotates 360° so that the display can always be viewed easily.



- To remove the contra angle from the handpiece, pull out the contra angle horizontally when the motor handpiece does not run.

Fig. 4 Contra Angle removal

6.3.2 Put on the Handpiece Protective Sleeve

Put the protective sleeve on the handpiece.

Warning
To prevent cross contamination between patients, use a new sleeve for each patient. Never reuse the sleeves

After placement, make sure that the sleeve is not torn.

After use, remove the protective sleeve and throw it away.

6.3.3 Connecting the AC/DC Plug Adapter

Select the plug adapter that matches your electric power outlet.

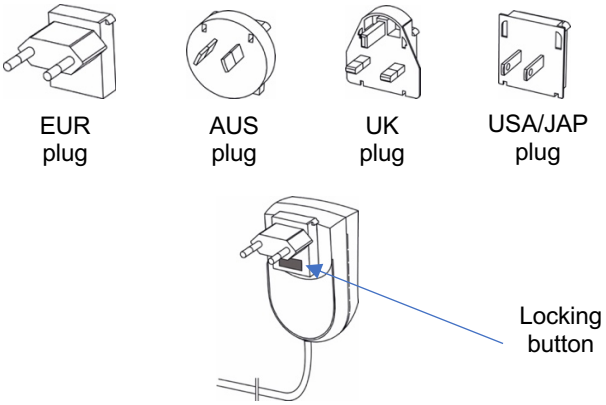


Fig. 3 Plug adapters for the charger

Slide the plug adapter downwards into the slots until it locks in place with a click. To remove, press the locking button (see Fig. 3) and pull out the plug adapter.

6.3.4 Recharging the Battery

STATERA vi endo motor is a battery-operated portable device powered by a lithium-ion rechargeable battery. The handpiece is being charged via inductive (wireless) charging while it is placed on its cradle. Battery status during the motor's operation is shown on the screen.

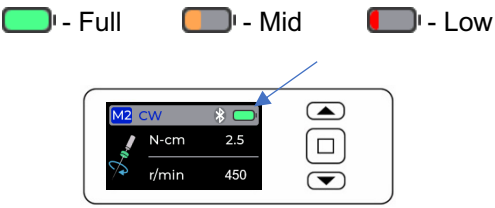


Fig. 4 Battery status indicator

When the motor battery is low, battery indicator on the screen will turn red, meaning that the battery requires recharging. However, the **STATERA vi** endo motor will continue normal operation even with low battery for several treatments before the device shuts down.

The cradle is also a battery-operated unit powered by internal lithium-ion rechargeable battery and serves as a charging station to charge the handpiece

via inductive (wireless) charging. Cradle's battery status during operation is shown on the status LEDs.

Warning
Replacement of the lithium-ion rechargeable batteries can be performed by a trained service personnel only.

6.3.5 Charging the Cradle

- Connect the charger cable to the charging receptacle on the cradle (see Fig. 2). Plug the charger into the power outlet.
- White color LED on the cradle will blink, indicating that the cradle battery is charging. When charging is completed, the white LED will stop blinking and turn steady white.

6.3.6 Charging the STATERA vi endo motor

- Place the **STATERA vi** endo motor on the cradle. Charging will begin automatically if the battery is low and needs to be recharged.
- A steady white LED on the cradle signifies that it is powered on, while a steady blue LED indicates that the motor is currently charging.
- While charging, the battery icon appears on the motor's screen (see Fig. 5). Once charging is complete, the motor's screen and the blue LED on the cradle will turn off.

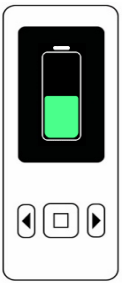


Fig. 5 **STATERA vi** endo motor is charging

Warning
While charging the cradle, the charger and the cradle should be outside patient environment (at least 1.5m from the patient).

Duration of charging when battery is depleted: Approximately 3 hours.

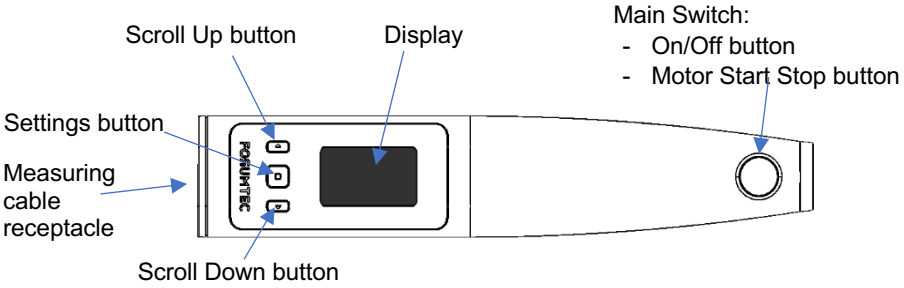
Notes

- Use only the original charger.
- **STATERA vi** endo motor cannot be operated while charging.

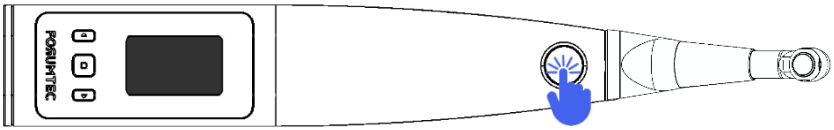
In case that the battery is completely flat, and the device would not turn on, contact your distributor for battery replacement by a service personnel.

6.4 Operation of the motor

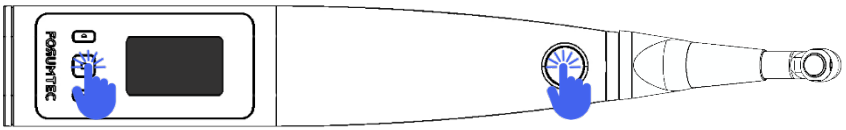
6.4.1 Motor handpiece description



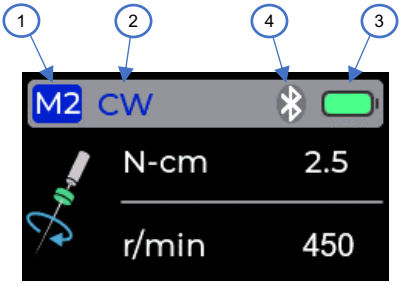
- Connect the contra angle to the handpiece and switch the device on by pressing the Main Switch button.



- To power the handpiece off, press the Main Settings button along with the Main Switch button.



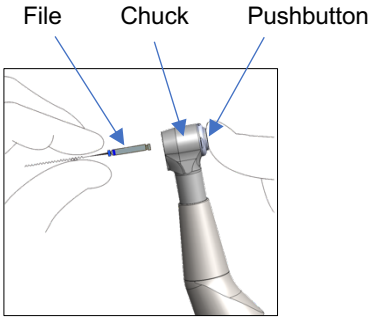
- After switching the device on, the main screen is displayed (after a short logo animation). Status bar is in the upper part of the display. The status bar consists of:



1 - Program memory slot number
2 - Program mode
3 - Battery level indicator
4 - Bluetooth connection indicator
- Bluetooth is disconnected
- Bluetooth is connected
- Bluetooth is disabled

6.4.2 Install file

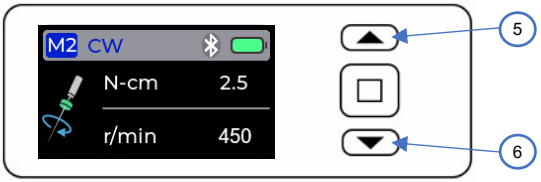
- Insert the file into the contra angle chuck until it stops.
- Press the pushbutton on the contra angle head and turn the file gently until it engages with the latch mechanism. Push inwards to click and release the pushbutton. Pull the file gently to make sure it is locked.
- To release the file, press the pushbutton on the contra angle head and pull out the file.



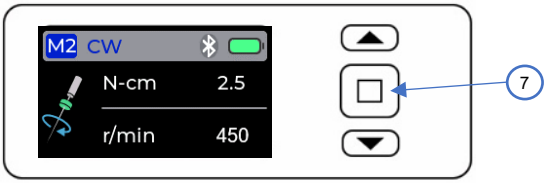
Warning
Before inserting and pulling out the file, the motor handpiece must be stopped.

6.4.3 Modes of operation and parameters setup

The **STATERA Vi** device contains 10 programable memory program slots – from M0 to M9. To scroll between the device memory programs, use the “Scroll up” (5) or “Scroll down” (6) buttons.



Press and hold the “Main Settings” (7) button to access and modify the parameters settings for the selected program.



To confirm your selection and to move to the next parameter, press the “Main Settings” button (7). To confirm your selection and exit, press the “Main Switch” button (8).

6.4.3.1 Mode

Select the operation mode of the motor by pressing the “Scroll up” or “Scroll down” buttons:

Mode	Description
CW	Clockwise rotation. Device running in continuous rotation.
CCW	Counterclockwise rotation. Device is rotating in reverse. ** When this mode is being used, an alert sound is activated.*
REC	Reciprocating rotation.
BLF	Balanced Force Adaptive Technique. The file performs a precise watch-winding motion, rotating back and forth with equal amplitudes, alternating between clockwise and counterclockwise rotations. This motion is repeated in several steps, increasing the amplitude with each cycle until the entire circumference of the canal is effectively covered. The system automatically adapts speed, torque, and the extent of the watch-winding rotation based on real-time canal anatomy and clinical conditions. This technique is particularly effective for navigating curved or narrow canals, significantly reducing the risk of iatrogenic damage. By employing a gentle, controlled motion, the technique minimizes the risk of file separation, ledge formation, canal transportation, or perforation, ensuring safer and more efficient root canal treatment.
AL	Electronic Measurement. Apex Locator mode without motor rotation.

6.4.3.2 Speed

Set the rotation speed of the instrument by pressing the “Scroll up” or “Scroll down” buttons (press and hold the scroll button for fast scrolling).

Speed	Description
50 – 3,200 r/min	Rotation speed of the endodontic instrument.

To confirm your selection and to move to the next parameter, press the “Main Settings” button.

6.4.3.3 Torque

Set the max torque value by pressing the “Scroll up” or “Scroll down” buttons (press and hold the scroll button for faster scrolling).

Torque	Description
0.4 – 6.0 N-cm	The Max torque that can be applied on the endodontic instrument.

Warning

Use the torque and speed settings recommended by the instrument manufacturer.

6.4.3.4 Torque Action

Select the action that the motor shall perform If the applied torque on the endodontic instrument reached the maximum defined torque.

Torque Action	Description
Torque Release	The file automatically reverses direction until the torque is released, then returns to normal rotation.
Reverse	The file continues to rotate in reverse until the Motor Start/Stop button is pressed.
Reciprocation	The file turns to reciprocating rotation until the applied torque is released, then returns to normal rotation.
- **REC CW**	When Reciprocation action is selected, set the Clockwise reciprocation angle.
- **REC CCW**	Set the Counter-Clockwise reciprocation angle.

6.4.3.5 Apical Action

Select the action that the motor shall perform when the tip of the endodontic instrument has reached to the Apical limit.

Apical Action	Description
Off	No action
Reverse	The file automatically reverses direction until withdrawn from the apical limit, then returns to normal rotation.
Stop	The file automatically stops until withdrawn from the apical limit, then returns to normal rotation.

6.4.3.6 Auto Rotate

When the Measuring cable is connected to the device, and the Lip Clip is attached to patient's mouth, the motor detects automatically when the endodontic instrument is inserted into or withdrawn from the canal and can start or stop the motor rotation automatically, without the need to press the Start/Stop button.

Apical Action	Description
Off	No action.
Start	The motor will start the rotation automatically.
Stop	The motor will stop the rotation automatically.
Start & Stop	The motor will start & stop the rotation automatically.

6.4.3.7 Virtual Apex

Virtual apex enables to mark a predetermined position from the apex. When Virtual Apex feature is enabled, the dentist gets clear visual and audio indication that the file tip has reached the selected position near the Apex.

Select the action that the motor shall perform when the tip of the endodontic instrument reaches to the defined Virtual Apex position.

Apical Action	Description
Off	Apex Position – "0.0" reading on the display will trigger the Apical Action (see 6.4.3.5).
"1.0" to "0.1" display reading	The selected position between "1.0" to "0.1" will trigger the Apical Action (see 6.4.3.5).

Note
When the apex position is reached (last red bar "0.0"), a solid tone is sounded, even if the Dr's Choice feature is activated.

6.4.3.8 Adaptive Speed (in CW, CWW modes only)

When this feature is activated, the endodontic instrument will adjust its speed as it nears the Apex (indicated by a "0.0" display reading) or as the torque increases.

Apical Action	Description
Off	No action
Apical	The endodontic instrument will adjust its speed as it approaches the Apex.
Torque	The endodontic instrument will adjust its speed as the torque increases.

6.4.3.9 Angle CW (in REC mode only)

In reciprocating mode, set the progression angle of the instrument in clockwise direction by pressing the “Scroll up” or “Scroll down” buttons (press and hold the scroll button for fast scrolling).

Angle	Description
5° - 400°	The progression angle of the instrument in clockwise direction.

6.4.3.10 Angle CCW (in REC mode only)

In reciprocating mode, set the progression angle of the instrument in counterclockwise direction by pressing the “Scroll up” or “Scroll down” buttons (press and hold the scroll button for fast scrolling).

Angle	Description
5° - 400°	The progression angle of the instrument in counterclockwise direction.

6.4.4 Device Settings

To enter the Settings Menu, use the “Scroll up” (1) or “Scroll down” (2) buttons to reach “Settings”.

Press and hold the “Main Settings” (3) button to access and modify the device settings.

Use the “Scroll up” (1) or “Scroll down” (2) buttons to modify device settings. Use the “Main Settings” (3) button to advance in the settings menu.

Press the Main Switch button to save your settings and exit.

The Settings menu features:

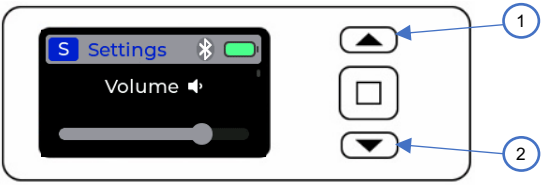
Volume	Set the volume level from Mute to High
Auto-Shutdown	Set the automatic shutdown timer
Dominant Hand	Rotate the user interface 180° degrees
Motor Calibration	Automatic calibration of the motor with the contra angle
Apex Locator Test	Automated self-test of the Apex Locator

Post-Charge Mode	Select whether the device powers off or stays on after being disconnected from the charging cradle.
CCW Alert Sound	Enable or disable the alert sound when CCW mode is running.
Apex Locator LEDs	Enable or disable the Main switch LEDs blinking according to apical position.
Bluetooth	Enable or disable the Bluetooth.
Set Factory Defaults	Reset the device to the factory default settings.
Version info	Device firmware information.

6.4.4.1 Volume - Sound Adjustment

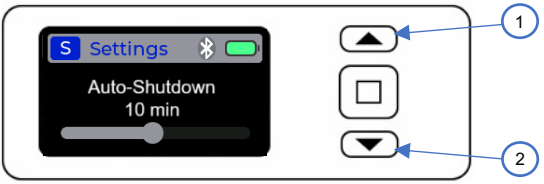
STATERA vi endo motor is equipped with an audio signal which enables monitoring of the torque and progression of the file within the canal in addition to visual monitoring.

The volume can be adjusted by pressing “Scroll up” (1) or “Scroll down” (2) buttons.



6.4.4.2 Automatic Shutdown

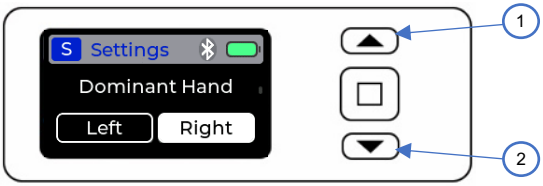
Automatic shutdown of the **STATERA vi** endo motor can be adjusted between 2 min to 20 min of device non-use. Simply adjust the Automatic Shutdown slider to your preferred time duration by pressing “Scroll up” (1) or “Scroll down” (2) buttons.



6.4.4.3 Dominant Hand

This feature will rotate the display direction 180°.

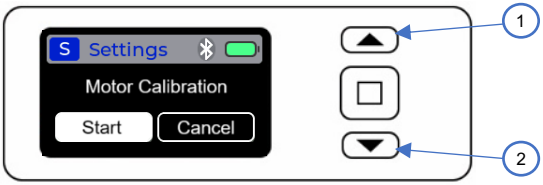
Use the “Scroll up” (1) or “Scroll down” (2) buttons for “Right” or “Left” depending on user’s dominant hand.



6.4.4.4 Motor Calibration

Calibrating the motor automatically sets the rotational speed to ensure torque precision. Always calibrate the motor handpiece after the contra-angle has been sterilized, lubricated, or exchanged.

- Remove the endodontic instrument from the contra angle prior performing the calibration.
- Make sure that the contra angle is properly attached to the handpiece.
- Use the “Scroll up” (1) or “Scroll down” (2) buttons to select “Start”.



- Press the “Main switch” button (3) to start the calibration process.

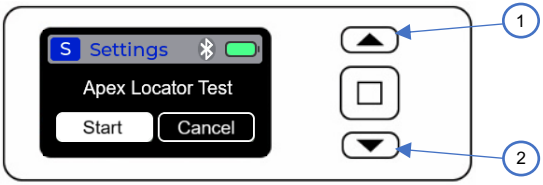
- Calibration will be performed automatically.

Warning
Do not insert any files during calibration. Risk of injury, as the motor changes rotational speed from the minimum to the maximum value during calibration.

6.4.4.5 Apex Locator Test

The automated self-test of the apex locator function verifies the device's accuracy and functionality before use. It conducts a series of internal checks to ensure the device is operating correctly.

- Use the “Scroll up” (1) or “Scroll down” (2) buttons to select “Start”.

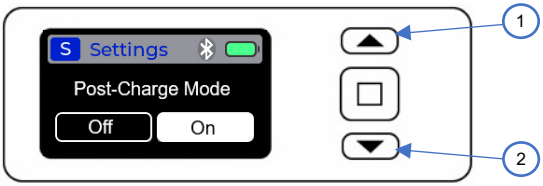


- Press the “Main switch” button (3) to start the self-test process.

6.4.4.6 Post-Charge Mode

Select whether the device powers off or stays on after being disconnected from the charging cradle.

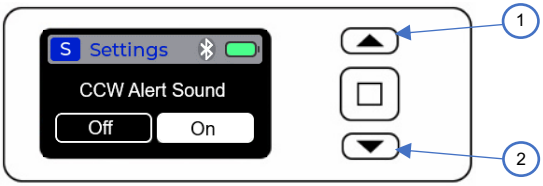
Use the “Scroll up” (1) or “Scroll down” (2) buttons to select if the endo motor device remains “On” or “Off” after being disconnected from the charging cradle.



6.4.4.7 CCW Alert Sound

Enable or disable the alert sound when CCW mode is running.

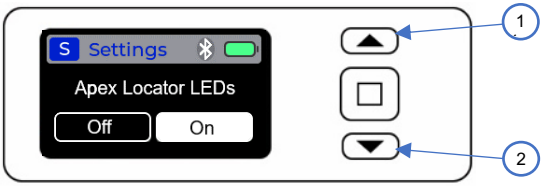
Use the “Scroll up” (1) or “Scroll down” (2) buttons to turn “On” or “Off” the alert sound during CCW mode rotation.



6.4.4.8 Apex Locator LEDs

Enable or disable the backlight LEDs on the main switch to blink based on the apical position.

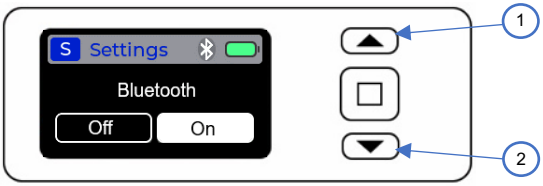
Use the “Scroll up” (1) or “Scroll down” (2) buttons to turn “On” or “Off” the LEDs blinking function.



6.4.4.9 Bluetooth

Enable or disable the Bluetooth feature on your endo motor device.

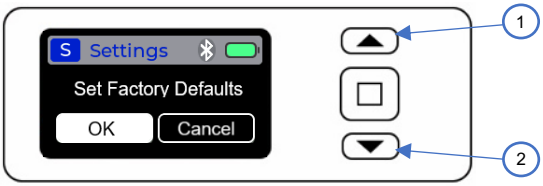
Use the “Scroll up” (1) or “Scroll down” (2) buttons to turn “On” or “Off” the Bluetooth function.



6.4.4.10 Set Factory Defaults

This option lets you reset all user-customized parameters to their original settings.

- Use the “Scroll up” (1) or “Scroll down” (2) buttons to select “OK”.



- Press the “Main switch” button (3) to restore defaults.

Note

Once user-edited parameters are reset, they cannot be recovered.

6.4.5 Canal Measurement

The **STATERA vi** features an integrated apex locator for length determination of the root canal.

The apex locator can be used in 2 ways:

Separate Length Determination: The working length is determined manually (without the motor) using the file clip and the lip clip.

Combined Length Determination (see 6.4.6.1): The working length is determined while the root canal is being prepared. The motor and the apex locator are thus active simultaneously using of the endodontic instrument inside the contra angle and the lip clip.

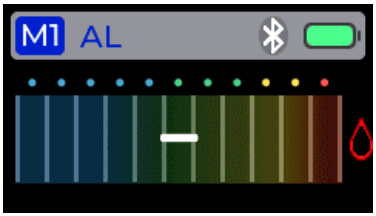
6.4.5.1 Separate Length Determination (with Hand Instrument)

Turn on the device and select AL mode (see 6.4.3) in one of the free memory programs (M0 is set to AL by default).

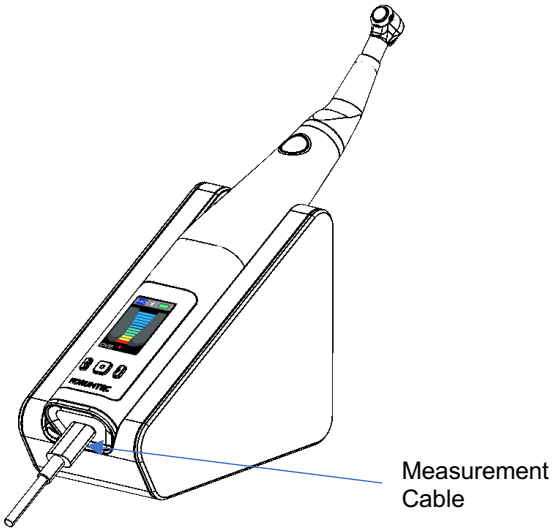
The Apex Locator can be configured for either a landscape or portrait interface.

Portrait interface

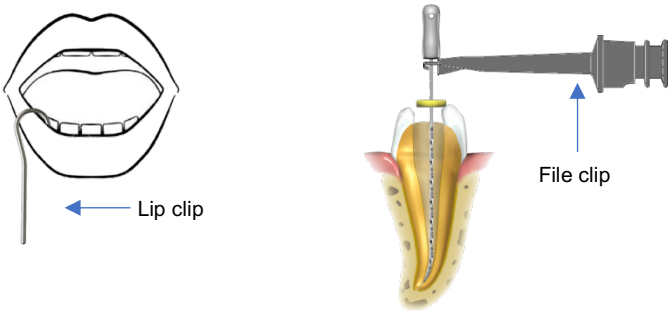
Landscape interface



Before connecting the measurement cable with attached lip clip and file clip to the patient, plug the measurement cable into the device receptacle. for optimal display viewing angle place the handpiece into the cradle.

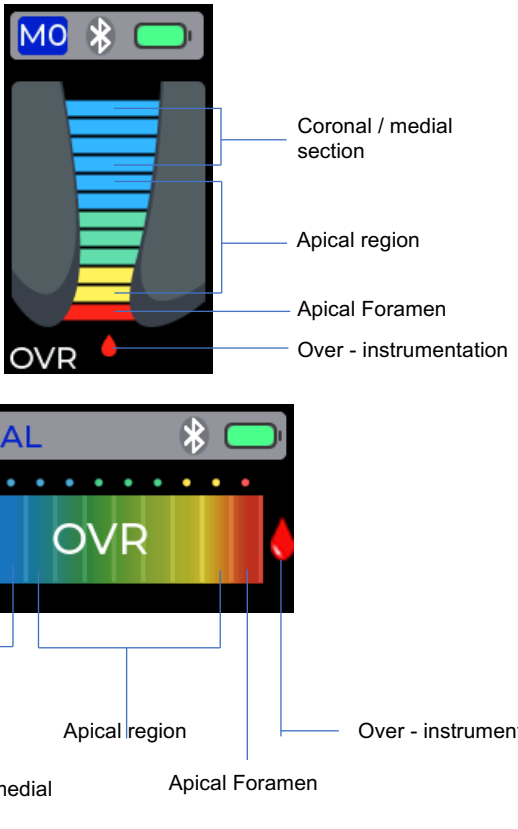


Attach the lip clip to the patient's lip and gently insert the file into the canal and connect the file clip to the metal shaft of the file.



Note
To ensure optimal performance the file size should be adjusted to the canal diameter.

Two initial beeps indicate closed measurement circuit and beginning of length determination. The file movement in the canal is shown on the screen.



Note

Absence of the two beeps audio signal indicates a faulty connection. Disconnect the measurement cable from the patient and check cable connections, clean the file clip and the lip clip, moisten the canal if necessary and start again.

No other adjustments are required before starting apex localization.

6.4.5.2 Apex Localization

Advance the endodontic file slowly into the canal. The first three blue bars correspond to the coronal/medial section. As the file progresses in the canal, subsequent green bars in the apical region turn on gradually and the interval between the audio signals becomes shorter.

Note

The bars indication on the **STATERA vi** endo motor screen does not represent a distinct length or distance in mm or other linear units. It simply indicates the file progression towards the apex.

When the last red bar is reached, a solid tone is emitted. The indication of the last red bar on the **STATERA vi** endo motor screen relates to the minor apical foramen file position.

6.4.5.3 Over-Instrumentation

A red drop segment and an audio warning signal (rapid intermittent signal) indicate that the file has passed the apex.

6.4.5.4 Completion of the measurements

- Before unplugging the measurement cable from the device receptacle, disconnect the lip clip and the file clip from the patient.
- Move the file stopper to the selected reference point on the tooth.
- Gently remove the file from the canal and measure the apical length between the stopper and the file tip.

Note

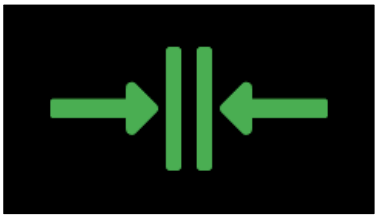
Determination of working length for canal shaping is a subject of dentist's professional judgment. In most cases subtraction of 0.5 mm from the measured "0.0" apical length provides clinically acceptable working length. Nevertheless, in each case the dentist should define proper working length based on his experience, apex locator readings, radiographs and other available data.

6.4.5.5 Cable Connection Test

In case measurement indication is not detected a cable connection test needs to be conducted. A connection test feature is included in **STATERA vi** endo motor to check the cables:

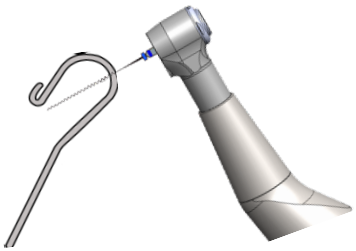
- Connect the measurement cable with attached file clip and lip clip and turn on the device.
- Connect the metal part of the file clip to the lip clip. Make sure that the accessories are cleaned properly before the test.

- "Cable connection test" icon  should appear on the screen.



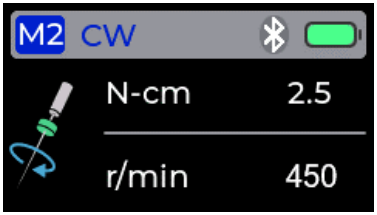
- If no icon appears, the file clip or the measurement cable should be replaced.

- Repeat the test also with the lip clip and the endodontic instrument connected to the contra angle.



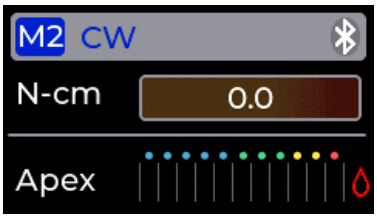
6.4.6 Operation

Select the memory program appropriate to the treatment to be performed. Insert the endodontic instrument into the contra angle, verify that the operating parameters such as: speed and torque are matching to the selected instrument.

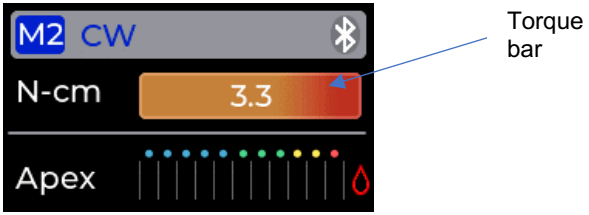


- Gently insert the endodontic instrument into the root canal and press the motor start/stop button (1) to start the motor operation.

- During the operation of the motor, the torque bar is displayed on the upper part of the screen and the apex locator scale is displayed on the lower part of the screen.

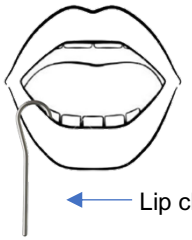


- As the torque level increases, the torque bar is filled from orange to red color and the torque numerical value changes accordingly.

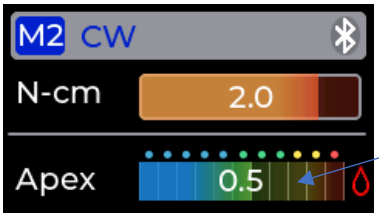


6.4.6.1 Combined Length Determination

In this mode the working length is determined while the root canal is being prepared. To use the apex locator simply connect the measuring cable to the handpiece and attach the lip clip on patient's lip (there is no need to connect the file clip).



- While the root canal is being prepared, the apex locator readings displayed on the lower scale on the screen.



Note

The apex locator bars/numerical values indication on the **STATERA vi** endo motor screen does not represent a distinct length or distance in mm or other linear units. It simply indicates the file progression towards the apex.

7 Maintenance and Reprocessing

7.1 General Recommendations

- The device does not contain user serviceable parts. The service and repair should be provided by factory trained service personnel only.
- After each use, all objects that were in contact with infectious agents should be cleaned using single-use wipes or a soft cloth impregnated with a disinfecting and detergent solution (a bactericidal, fungicidal and aldehyde free solution), according to manufacturer's directions. We recommend using only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval). Use of chemical agents may cause damage to the equipment. We recommend single-use wipes (e.g. CaviWipes™ or CaviCide™).
- In addition, the lip clip, the file clip, the contra angle and its protective sleeve must be sterilized before the first use and between treatments. Please note that the device housing, the cradle, and the measurement cable cannot be sterilized.
- The user is responsible for the sterility of the lip clip, the file clip, the contra angle and its protective sleeve for the first cycle and each further usage.
- All damaged accessories should be discarded, while dirty accessories should be cleaned and sterilized per the proceduredescribed in section 7.3.
- The maximum number of sterilization cycles is:
  - File clip: 200.
  - Lip clip: 200.
  - Contra angle: 200.
  - Silicon protective sleeve: 200.

7.2 Overview of the parts to be reprocessed

Part	Cleaning and disinfection			Steam-Sterilization
	Manual		Automated	
	Wipe	Brush (only cleaning)	Washer disinfector*	
Handpiece	X			
Cradle	X			
Measuring cable	X			
Charger	X			
Contra angle		X	X	X
Protective Silicon Sleeve		X	X	X
Lip Clip		X		X
File Clip		X		X

X: Required reprocessing step

*: Cleaning and disinfection equipment

7.3 Reprocessing methods

7.3.1 General reprocessing instructions

Reprocessing involves the following steps:

- Cleaning
- Disinfection
- Steam Sterilization as applicable

Perform reprocessing immediately after treatment, after 1 hour at the latest.

Detach the file and separate the contra angle from the motor handpiece. As applicable, detach the Silicon protective sleeve from the contra angle.

Disconnect the Measuring cable from the device and detach the Lip Clip and the File Clip from the Measuring cable.

For your own safety, please wear personal protective equipment (gloves, glasses, mask).

Note

Inappropriate care and cleaning of the unit can result in malfunction or damage. Use only care, cleaning, and disinfecting agents approved by the manufacturer.

Never clean in an ultrasonuc bath.

Never immerse in disinfectants.

7.3.2 Cleaning and disinfection

Manual wipe cleaning and disinfection

Note

Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.

Use of chemical agents may cause damage to the equipment. We recommend single-use wipes (e.g. CaviWipes™ or CaviCide™).

- For thorough wipe cleaning and disinfection, observe the disinfectant manufacturer's instructions.
- Clean surface with towelette to remove debris and bioburden.
- Check in good lighting (min. 500 lux) to see if the product is clean after reprocessing.
- If there is any contamination, repeat the process.
- Wipe off the disinfectant with a dry, clean, and lint-free cloth after it has taken effect.
- If necessary, sterilize afterwards.
- During each use, ensure that an cleared barrier sleeve covers the motor handpiece to maintain sterility and prevent cross-contamination.
- After each patient use, remove and discard the barrier sleeve.
- Clean and disinfect the motor handpiece, we recommend single-use wipes (e.g. CaviWipesTM or CaviCideTM). Follow the manufacturer's guidelines for effective use to ensure complete disinfection.
- Allow the motor handpiece to dry thoroughly before the next use or before reapplying a new barrier sleeve.

Manual cleaning with brush

- Pre-disinfect immediately after use with disinfection wipes (for at least 30 seconds) making sure the entire surface is wet (pay special attention to hard-to-reach areas: push button, chuck of the contra-angle and joint of the different parts). Follow instructions from the manufacturer of disinfection wipes.
- Abundant rinsing (for at least 1 minute) under running water (ambient temperature) including manual brushing for at least 15 seconds (pay special attention to hard-to-reach areas).

- Use a soft, clean and disinfected brush for thorough cleaning.
- Check in good lighting (min. 500 lux) if the product is clean after reprocessing.
- If there is any contamination, repeat the process.
- It is essential to lubricate the contra angle after cleaning.
- Subsequently, if applicable, disinfect/sterilize the product.

Automated reprocessing with a washer disinfector

The washer-disinfector must be approved by its manufacturer for cleaning and disinfecting these products and comply with ISO 15883-1/-2, e.g. 90 °C (194 °F) and 5 min holding time. Refer to the instructions for use of the device for the respective use.

- Place the contra angle in a kit, support, or container (made from stainless steel or titanium) to avoid any contact between devices.
- Place the contra angle in the washer disinfector and execute the defined cycle (Ao value >3000 or, a Cleaning at 55°C (131°F) holding time 10 min and disinfection at 90°C (194°F) holding time 5 min).
- Use a detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 0.4%).
- Make sure the contra-angle is completely dry after Automated cleaning. Remove any residual liquid with a single use non-woven cloth.
- After the process, check in good lighting (min. 500 lux) whether the product is clean. If there is any contamination, repeat the process. If necessary, sterilize afterwards.
- After doing automated cleaning: Lubricate the contra-angle immediately after thermal disinfection.

7.3.3 Steam Sterilization

Wrapped sterilization

- The product must be cleaned/disinfected according to the table "Overview of the parts to be reprocessed [paragraph 7.2]" prior to sterilization.
- The contra-angle is lubricated according to section "Lubrication of the Contra Angle [paragraph 7.4]".
- The product is packed in packaging suitable for sterilization and storage, e.g. paper/laminate packaging or ISO 11607 compliant container.
- Steam sterilizers that comply with the requirements of EN 13060, Class B or EN 13060 Class S and are also suitable for the sterilization of these products are approved.
- To ensure the device remains sterile, it is imperative to use FDA-cleared steam-sterilization wraps or pouches during the sterilization process.
- The following sterilization cycles can be used:

  Temperature: 135 °C (274 °F)
  Holding time: 10 min
  Minimum Drying time: 10 minutes

  or

  Temperature: 134 °C (274 °F)
  Holding time: 3 min
  Minimum Drying time: 20 minutes

Note

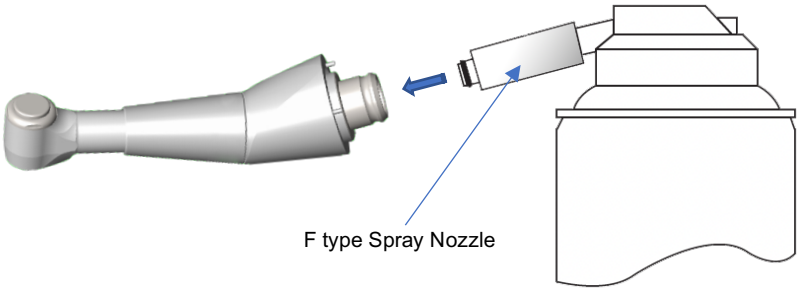
Do not exceed 140 °C (284 °F) even during the drying phase.

After sterilizing

- Remove the contra-angle handpiece and accessories from the steam sterilizer immediately.
- Store the contra-angle handpiece and accessories where they are protected against contamination.
- Keep the contra-angles and the accessories in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature (typically 15 - 25°C (59 - 77°F)).

7.4 Lubricating the Contra Angle

- Lubricate the contra angle only with dedicated spray. We recommend the use of the KaVo Spray or W&H Service Oil MD-400 for Lubrication.
- Lubricate after each use and before sterilization.
  - Screw the spray nozzle onto the spray with approx. 10 turns.



  - Insert the spray nozzle into the rear part of the contra-angle.
  - Hold the contra-angle securely to prevent it from detaching with the pressure of the spray and lubricate for 2-3 seconds until oil comes out from the contra-angle head.
  - Before attaching the lubricated contra-angle to the motor handpiece, wipe off excess oil. Place it on its end or lean it at an angle for gravity draining. Mount it after excess oil has been drained.

Warning
- Do not lubricate the motor handpiece.
- Never use a spray can upside down. Only spray gas, and no oil.

8 Troubleshooting

8.1 Troubleshooting

Please review the checklist below should you experience a problem with your **STATERA vi** endo motor. If the problem persists after following the proposed solutions, please contact your distributor.

Warning

The following patient related factors may prevent accurate apex locator readings:

- Blocked root canals;
- Teeth with large apices;
- Root fracture or perforation;
- Metal crowns or bridges if they come into contact with the file or the lip clip.

#	Problem	Possible cause	Solution
1	The device does not turn on by pressing the “Main Switch” button.	The button is functioning incorrectly.	Try pressing the ”Main Switch” button several times. If the device still does not turn on, please contact your distributor.
		The battery is discharged.	Charge the battery.
		Electronic malfunction.	Contact your distributor.
2	The device shuts off during the procedure.	The battery is low.	Charge the battery.
3	Motor handpiece does not run.	Probably the program is set to AL mode.	Change the mode of the programs from AL mode.
4	The device does not charge while placed on the Cradle	The Cradle battery is discharged.	Connect the charger to the Cradle.
5	No sound during the procedure.	The sound control is set at “Mute” level.	Adjust the sound level in the Settings menu.
6	Apex locator scale on the display is not steady during root	There is not a good contact between the lip clip and the oral	Ensure a good contact between the mucosa and lip clip (Place the

#	Problem	Possible cause	Solution
	canal measurements.	mucosa.	lip clip in the labial angle opposite the tooth to be treated).
		The file clip is soiled.	Clean the file clip with a single-use wipes.
		Deep caries provides a conductive path outside the canal.	Block the external conductive path.
		Perforation.	Remove the file, close the perforation and repeat the apex detection procedure, carefully inserting the file into canal.
		Large lateral canal.	Try continuing the procedure by gently advancing the file.
7	The transmission of the apex locator electric signal is interrupted. The device does not show file progression inside the canal.	Bad electrical contact.	Perform the Cable Connection Test sequence as described in the user manual, section 6.4.5.5
		The file clip is not properly connected to the file.	Place the file clip on the metal part of the file below the plastic handle.
		The root canal is obliterated.	Check the comparative X-ray image for hints.
		In the case of retreatment: old filling material residues may block the root canal.	Remove old root filling material residues prior to use.
		The root canal may be blocked by the remnants of a medication (e.g. calcium hydroxide).	Completely remove the remnants prior to use.

#	Problem	Possible cause	Solution
		Root canal is extremely dry.	Rinse the root canal with NaCl solution. Dry the access cavity with a cotton pellet/ air-blower.
		The selected file is too small for a large root canal.	If there is no parietal contact use larger ISO size file. Important: exactly fitting files lead to precise results.
		Electronic malfunction.	Contact your distributor.
8	Display reaction is erratic: apical foramen position or “Over” appear on the screen before the apical region is reached.	Short circuit due to excess liquid (irrigation solution, saliva, blood) in the pulp chamber.	Dry the access cavity with a cotton pellet / air-blower. In case of excess bleeding wait until it has stopped.
		A direct contact of the file with the gingiva or gingival proliferations, e.g. a fractured metal crown.	For isolation: adequate preparation filling of access cavity; use a rubber dam.
		A direct contact of the file with metal restorations (crown, parapulpal post, amalgam filling).	Isolate the file by inserting it into a small polyvinyl tube before use.

8.2 Abnormal Stop

The endo motor may stop working in the cases listed below:

#	Problem	Possible cause	Solution
1	Attention Motor Overload	The endo motor is continuously subjected to a heavy load, such as when the file becomes stuck in the canal and the motor is unable to rotate.	Press the press the motor start/stop button to start the motor operation.

2	Low Battery	The Battery power is too low, or the motor was subjected to a heavy load momentarily.	Press the motor start/stop button to start the motor operation. Charge the endo motor on its cradle.
3	E.7	Over current or motor high temperature detected	Let the motor to cool down
4	E.11	Max speed couldn't be reached during calibration	Restart the endo motor and try to perform calibration again Try without the contra angle
5	E.12	High torque level detected during calibration	Try without the contra angle, then lubricate the contra angle and try again.

8.3 Error Codes

In case an error or problem is detected, the endo motor will stop, and an error code will appear in the display. Restart the endo motor, if the error code appears again, stop using the endo motor and contact your local distributor. Please report the error code when requesting assistance.

Error code	Problem
E.1	Watch dog fault Main
E.2	Watch dog fault Drive
E.3	Drive version fault
E.4	Measure version fault
E.8	Lib Database fault
E.9	Drive connection fault
E.10	Phase init. failed
E.13	Apex locator internal test failed

9 Warranty

STATERA vi endo motor is warranted for 24 months from the date of purchase. The Contra Angle is warranted for 12 months from the date of purchase, and the device accessories (cables, battery) are warranted for 6 months from the date of purchase. Within the warranty period the manufacturer undertakes, at its sole discretion, to repair or replace the faulty item without charge.

This product has been developed specifically for use in dentistry and is intended to be operated only by qualified dental professionals in accordance with the instructions contained in this manual. However, notwithstanding anything contained herein, the user shall at all times be solely responsible for determining the suitability of the product for the intended purpose and the method of its use. Any guidance on technology application offered by or on behalf of the manufacturer, whether written, verbal or by demonstration, shall not relieve the dental professional from his/her obligation to control the product and to make all professional judgments regarding its use.

Except for the warranties specifically set forth in this manual, the manufacturer provides no warranties or guarantees of any kind covering the product, expressed or implied, including, without limitation, any warranties as to merchantability or fitness for a particular purpose. Any claim for damage or breakage to the product in transit should be made to the carrier promptly upon discovery.

The warranty is valid for normal usage conditions. Any damage caused by accident, abuse, misuse, or because of service or modification other than by a person authorized by the manufacturer will render the warranty void.

10 Disclaimer

The manufacturer, its representatives and its distributors shall have no liability or responsibility to customers or any other person or entity with respect to any liability, loss or damage caused or alleged to be caused directly or indirectly by equipment sold or furnished by us, including, but not limited to, any interruption of service, loss of business or anticipatory profits, or consequential damages resulting from the use or operation of the equipment.

The manufacturer reserves the right to implement changes and modifications of the product at any time, to revise this publication and to make changes in the contents hereof without obligation to notify any person of such changes, modifications, or revisions.

11 Certification

STATERA vi endo motor complies with the following standards: IEC 60601-1 (Safety) and IEC 60601-1-2 (Electromagnetic compatibility), including conducted and radiated immunity tests as specified for equipment of Group 1 Class B.

12 European Authorized Representative

13 Disposal of the Product

Recycling: PLEASE DO NOT THROW AWAY! This product and all its components must be recycled through your supplier.

14 Reporting of Incident to Manufacturer

Users shall report to the Manufacturer any serious incident related to the device, using this email: info@forumtec.net. Any personal information contained in this email is considered confidential and is accessible only by authorized personnel.

Any serious incident that has occurred in relation to the device should also be reported to the competent authority of the Member State in which the user and/or patient is established.

15 Technical Characteristics

STATERA vi endo motor electronic apex locator is a programmable electrical medical device, belongs to the following category of medical devices:

- Internally powered equipment
- Type BF Applied Parts
- Not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide
- Continuous operation
- Expected service life: 3 years
- Ingress of liquids – not protected
- The device is intended for indoor use only
- Environmental conditions during storage/transportation:
  - Temperature: –20°C to +60°C (-4°F to 140°F)
  - Relative humidity: 10% to 90%, non-condensing
  - Atmospheric pressure: 101.3 kPa to 50 kPa.
- Environmental conditions during device usage:
  - Temperature: 10°C to +40°C (50°F to 104°F)
  - Relative humidity: 10% to 90%, non-condensing
  - Atmospheric pressure: 101.3 kPa to 50 kPa.

STATERA vi endo motor is intended for use in electromagnetic environment specified for equipment of Group 1 Class B.

Specifications:

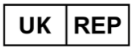
Dimensions Handpiece with Contra Angle (L x D x H)	210 x 26 x 28 mm
Dimensions Cradle (W x D x H)	55 x 111 x 90 mm
Weight Handpiece with Contra Angle	154 gr.
Type of screen	Color TFT display
Supply	3.6V Lithium-ion rechargeable battery (600 mAh – Handpiece) (3,200 mAh – Cradle)
Switching charger	Input: 100-240 V AC ~ 50-60 Hz Output: 5V DC, 2,000 mA
Contra Angle model	CA01

Contra Angle gear ratio	6:1
File shank attachment	Ø 2.35 mm ISO1797-1 Type1
Minimum fitting length of shank	11 mm
Maximum overall length of the rotary instrument	46 mm
Chuck type	Push-button

16 Identification of Symbols

Symbols used in these directions for use, packaging, device and parts.

Symbol	Identification
	Serial number
	Catalogue number
	Lot number
	Direct current (connection for power supply)
	Manufacturer
	Date of manufacture
	Class II equipment
	Type BF applied part
	Consult instructions for use
	Refer to instruction manual/booklet
	Recycling PLEASE DO NOT THROW AWAY! This product and all its components must absolutely be recycled through your distributor
	Temperature limitation

	Humidity limitation
	Atmospheric pressure limitation
	Additional information, explanation on operation and performance
	Warning
	Medical Device
	Authorized Representative in the European Community
	Authorized Representative in Switzerland
	Authorized Representative in the United Kingdom
	UK Conformity Assessed marking
	INMETRO marking
	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Non sterile
	Indicates the number of pieces in the package. “X” is replaced by the number of pieces in the package
	Keep Dry

Appendix

Electromagnetic Compatibility

Notes**:**

- **STATERA vi** endo motor requires special precautions regarding electromagnetic compatibility.
- It must be installed and prepared for use as described in section 6.3 “Getting Started”.
- Certain types of RF wireless communication equipment such as mobile telephones are likely to interfere with **STATERA vi** endo motor.
- The recommended radiation levels of RF wireless communication equipment specified in this paragraph must therefore be complied with.
- **STATERA vi** endo motor must not be used near or on top of another device. If this cannot be avoided, it is necessary – before clinical use – to check the equipment for correct operation under the conditions of use.

Electromagnetic Emissions

Notes:

- **STATERA vi** endo motor is intended for use in the professional healthcare facility electromagnetic environment specified in the tables below.
- The user and/or installer of the unit must ensure that it is used in such an environment.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Declaration - Electromagnetic Emissions		
Emissions test	***Compliance***	***Electromagnetic environment - guidance***
RF emissions CISPR 11	Group 1 Class A	The **STATERA vi** endo motor uses RF energy only for its internal function. Therefore, its RF emissions are extremely low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The **STATERA vi** endo motor is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the **STATERA vi** endo motor or shielding the location.
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	

Declaration – Electromagnetic Immunity			
Immunity test	***IEC 60601 Test level***	***Complianc elevel***	***Electromagnetic environment - guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15 kV air	8 kV contact 2, 4, 8, 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / bursts, IEC 61000-4-4	2 kV for power supply lines 1 kV for input/ output lines	2 kV for power supply lines Not Applicable	Mains quality of power should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	1 kV Line(s) to line(s) 2 kV Line(s) to earth 2kV Signal (input/output) to earth	1 kV Line(s) to line(s) 2 kV Line(s) to earth N/A	Mains quality of power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycles	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycles	Mains quality of power should be that of a typical commercial or hospital environment. If the user of the **STATERA vi** endo motor requires continued operation during power mains interruptions, it is recommended that the **STATERA vi** endo motor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration – Electromagnetic Immunity			
IMMUNITY *test*	*IEC 60601 TEST LEVEL*	*Compliance level*	*Electromagnetic environment - guidance*
Conducted RF IEC 61000-4-6	3 V, 6 V	3 Vrms, 6 V	Portable and mobile RF communications equipment should be used no closer to any part of the **STATERA Vi** endo motor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
	3 V/m	3 V/m	$d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m from 0.15 to 80 MHz; 6 V/m from 0.15 to 80 MHz and 80% AM at 1 kHz	3 V/m from 0.15 to 80 MHz; 6 V/m from 0.15 to 80 MHz and 80% AM at 1 kHz	$d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). 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: 
	3 V/m from 80 MHz to 2.7 GHz	3 V/m from 80 MHz to 2.7 GHz	

Recommended separation distances between portable and mobile RF communications equipment and the STATERA vi endo motor				
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter** (m)			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{12}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
5500							
5785							

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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