

USER MANUAL



BRASSELER
USA®

Wirele-X Brasseler Rev. 01 - 2023-09-26
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Manufactured For:
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FOR DENTAL USE ONLY

DIRECTIONS FOR USE

Introduction

Congratulations, you have made a good choice with **Wirele-X**. Ergonomic user-friendly design of **Wirele-X** makes it a choice of preference in modern dental clinic. Utilizing the advantages of well proven patented technology, **Wirele-X** is a precise, user-friendly, apex locator intended for use either by skilled endodontic experts or by qualified dental practitioners performing root canal treatments. Custom color graphic display of **Wirele-X** helps to achieve optimal performance during working length determination.



Wirele-X Apex Locator

1. Indications for use

Wirele-X is an electronic device used for apex localization and working length determination during root canal treatment. The device enables to obtain correct results in canals with various conditions – dry and wet.

2. Contraindications

Wirele-X is not recommended for use in patients that have a pacemaker or other implanted electrical devices.

3. Warnings

- ⚠ This product 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 Wirele-X, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4. Precautions

- Do not use **Wirele-X** in the vicinity of devices emitting electromagnetic noise such as x-ray viewer with fluorescent lamps, film viewers, ultrasonic devices, etc.
- Cellular wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations etc. can affect **Wirele-X** and should be kept at least at a distance of 30 cm (12 inches) to any part of the device.
- During device operation protect **Wirele-X** from occasional spillage of liquids.
- Do not use **Wirele-X** in presence of flammable materials.
- Wirele-X** should be used with the manufacturer's original accessories only.
- In order 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 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 measurements. For working length determination, we recommend to use sodium hypochlorite solution at maximum 3% concentration.
- Make sure that the canal is wet enough to ensure reliability of the measurement.
- Ensure that the file does not touch other instruments.
- Avoid excessive liquids inside the tooth cavity to prevent overflow and incorrect measurements.
- Teeth with open apices may give imprecise results.
- Apex locator may not be able to provide correct measurements in all conditions. In any case, it is recommended to take an X-Ray prior to device use and to compare the results obtained by both methods.
- For your own safety, please use personal protection gear (gloves, mask).

5. Adverse Reactions

None

6. Step-by-Step Instructions

6.1 Cable connection test

Connection test feature is included in **Wirele-X** in order to check the cables:

- 6.1.1 Insert the Measurement cable with attached Lip Clip and File Clip into the device receptacle.
- 6.1.2 Verify that the File Clip contact and the Lip Clip are clean and make connection between them.
- 6.1.3 LEDs of all bars will turn on indicating proper connection of cables (Pic. 1).
- 6.1.4 If LEDs on the bars does not appear, the Measurement cable or the File Clip should be replaced.

6.2 Getting Started

Prior the first use, it is recommended to sterilize the Lip Clip, the File Clip and the Touch Probe. Please refer to section 8 for further information regarding **Wirele-X** maintenance.

- 6.2.1 Disconnect the charger from the device if connected and turn the device on by pressing the On/Off button. Blinking blue color LEDs around the On/Off button indicating the device is On (Pic. 2).

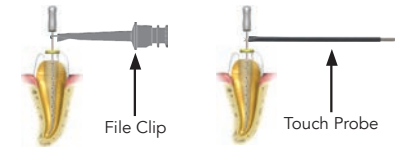


Pic. 1



Pic. 2

- 6.2.2 Before connecting the Measurement cable with attached Lip Clip and File Clip to the patient, plug the Measurement cable into the device receptacle.
- 6.2.3 Attach the Lip Clip to the patient lip.
- 6.2.4 Gently insert endodontic file into the root canal and connect the File Clip to the file (to ensure precise measurements the file size should be adjusted to the canal diameter). Alternatively, use the Touch Probe to provide electrical contact with the endodontic file.



- 6.2.5 The first green bar will turn on accompanied by a double beep signal (Pic. 3). Absence of first green bar and of audio signal indicates a faulty connection. In such case disconnect the Measurement cable from the patient, check cable connections, clean File Clip/Touch Probe contact, moisten the canal, if necessary, and start again. No other adjustments are necessary before starting measurements.



Pic. 3

6.3 Apex localization

6.3.1 Apical Zone

Introduce the endodontic file slowly into the canal, file position in the Apical Zone is indicated by 3 bars: 1.0, 0.5, and 0.0 (Pic. 4, Pic. 5 and Pic. 6). File progression in the apical zone is accompanied by a series of beeps with variable rate. When the apical position is reached (orange bar at the mark "0.0"), solid tone is emitted (Pic. 6). The apical position indicated by Wirele-X corresponds to file tip position at minor apical foramen.

Beginning of the Apical Zone



Pic. 4

Mid-Apical Zone



Pic. 5

Apical position



Pic. 6

6.3.2 Over-instrumentation

The last red bar and warning sound indicate that the file has passed the apex. (Pic. 7).

To return to the apical position, gently retreat the file until the last red bar disappears and "0.0" indication returns.

Note: Values shown in the pre-apical and apical zones serve as a convenient reference to judge the file tip position in relation to the apex, but they do not represent the actual distance from the apex in mm.



Pic. 7

6.3.3 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.
- 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 apical length provides clinically acceptable working length. Nevertheless, in each case the dentist should define proper working length basing on his experience, apex locator readings, radiographs and other available data.

6.4 Audio feedback

- Wirele-X** is equipped with an audio indicator which accompanies file progression within the canal in the pre-apical and apical zones. This function is activated in parallel with the LEDs and enables monitoring of file advance in the apical zone, even without seeing the device.

6.5 Automatic Shutdown

Wirele-X automatically shuts down after 5 minutes without use. In order to prolong the battery life, it is recommended to switch off the device after completing the measurements by pressing the On/Off button.

7. Battery Charging

Wirele-X a battery-operated portable device which is powered by a lithium-ion rechargeable battery.

When the battery is depleted BAT LOW indicator will start blinking (Pic. 8). **Wirele-X** will continue normal operation even with low battery for several treatments before the device shuts down.

To charge the battery:

- 7.1 Complete the measurements and disconnect the Measurement cable from the patient.
- 7.2 Unplug the Measurement cable from the device.
- 7.3 Connect the charger to the mains.
- 7.4 Plug charger cable into the device receptacle.
- 7.6 When the battery is charging, BAT LOW indicator will Blink red color.
- 7.7 When charging is completed BAT LOW indicator will turn off and blue color LED around the on/off button will turn on.

⚠ **While charging, the charger and the device should be outside patient environment (at least 1.5 m from the patient).**

If the battery is completely flat and the device would not turn on, contact your local distributor for battery replacement.

8. Maintenance, cleaning and sterilization

8.1 General

- The device does not contain user serviceable parts. The service and repair should be provided by factory trained service personnel only.
- All objects that were in contact with potentially infectious agents should be cleaned after each use:
Lip Clip, File Clip and Touch Probe should be disinfected and sterilized by autoclaving between treatments. Please follow "Disinfection and sterilization procedure" described in section 8.2. The maximum number of sterilization cycles is:
 - File clip: 120.
 - Lip clip: 120.
 - Touch Probe: 120.

Measurement cable and the device should be cleaned using tissue or soft cloth impregnated with aldehyde free disinfecting and detergent solution (a bactericidal and fungicidal).

⚠ **The Measurement cable cannot be autoclaved.**

⚠ **Use of agents other than specified above may cause damage to the equipment and its accessories.**

8.2 Disinfection and sterilization procedure

#	Operation	Instructions	Details and Warnings
1	Preparation at the point of use prior to processing	No particular requirements	
2	Preparation for decontamination / preparation before cleaning	No particular requirements	
3	Cleaning: Automated	The accessories are not intended for automated cleaning	
4	Cleaning: Manual	Clean the accessories with an adequate brush or towel soaked in a disinfectant solution	- The File Clip should be activated during cleaning process (pressed and released several times) - After cleaning no visible impurities should remain on the accessories
5	Disinfection	- Soak the required accessories in a disinfectant solution combined with proteolytic enzyme if possible. - Rinse well the accessories in flowing water	- Follow instructions given by the disinfectant manufacturer (concentration, immersion time, etc.) - Do not use disinfectant solution containing aldehyde, phenol or any products which may damage the accessories
6	Drying	No particular requirements	

Pic. 8

