

## **USER MANUAL**





Wirele-X Brasseler Rev. 01 - 2023-09-26

## **Manufactured For:**

Brasseler U.S.A. Dental, LLC One Brasseler Blvd Savannah, GA 31419 U.S.A.



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## **FOR DENTAL USE ONLY**

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## **DIRECTIONS FOR USE**

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## 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.

- ⚠ 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
- 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
- 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

### 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

# 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.

patient.

## **6.5 Automatic Shutdown**

6.4 Audio feedback

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.

**6.2.2** Before connecting the Measurement cable with attached Lip Clip and File Clip to the patient, plug

6.2.4 Gently insert endodontic file into the root canal

**6.2.5** The first green bar will turn on accompanied by a double beep signal (Pic. 3).

indicates a faulty connection.

starting measurements.

position at minor apical foramen.

6.3 Apex localization

6.3.1 Apical Zone

4. Pic. 5 and Pic. 6).

Apical Zone

Pic. 4

6.3.2 Over-instrumentation

file has passed the apex. (Pic. 7).

The last red bar and warning sound indicate that the

To return to the apical position, gently retreat the file

until the last red bar disappears and "0.0" indication

zones serve as a convenient reference to

judge the file tip position in relation to the

apex, but they do not represent the actual

• Before unplugging the Measurement cable from the device

receptacle, disconnect the Lip Clip and the File Clip from the

• Move the file stopper to the selected reference point on the tooth. • Gently remove the file from the canal and measure the apical

• Determination of working length for canal shaping is a subject of

dentist's professional judgment. In most cases subtraction of 0.5

working length. Nevertheless, in each case the dentist should

define proper working length basing on his experience, apex

• Wirele-X is equipped with an audio indicator which accompanies

file progression within the canal in the pre-apical and apical

locator readings, radiographs and other available data.

mm from the measured apical length provides clinically acceptable

**Note:** Values shown in the pre-apical and apical

distance from the apex in mm.

6.3.3 Completion of the measurements

length between the stopper and the file tip.

Absence of first green bar and of audio signal

from the patient, check cable connections,

No other adjustments are necessary before

the canal, if necessary, and start again.

clean File Clip/Touch Probe contact, moisten

In such case disconnect the Measurement cable

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.

File progression in the apical zone is accompanied by a series

(orange bar at the mark "0.0"), solid tone is emitted (Pic. 6).

of beeps with variable rate. When the apical position is reached

The apical position indicated by Wirele-X corresponds to file tip

Beginning of the Mid-Apical Zone Apical position

6.2.3 Attach the Lip Clip to the patient lip.

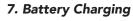
the Measurement cable into the device receptacle.

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

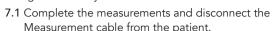
provide electrical contact with the endodontic file.



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:



7.2 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
- 7.7 When charging is completed BAT LOW indicator will turn off and blue color LED around the on/off button will turn on.

## Mhile 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 distributer for battery replacement.

## 8. Maintenance, cleaning and sterilization

Pic. 3

Pic. 6

Pic. 7

- 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 Inst		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 accesso- ries are not intended for automated cleaning	
4	Cleaning: Manual	Clean the accessories with an adequate brush or towel soaked in a disinfectant	- The File Clip should be activated during cleaning process (pressed and released several times) - After cleaning no visible impurities should remain on

solution the accessories - Follow instructions given by the disinfectant Disinfection Soak the reauired accessories in a disinfectant (concentration, immersion solution time, etc.) - Do not use disinfectant combined with solution containing aldehyde, phenol or proteolytic enzyme if any products which may possible. - Rinse well the damage the accessories accessories in flowing water

6 Drying No particular

#	Operation	Instructions	Details and Warnings
7	Maintenance, inspection and testing of the accessories	No particular requirements	
8	Packaging	Pack the accessories in sterilization pouches	- Check the validity period of the pouch given by the manufacturer to determine the shelf life of the sterilized items - Use packaging which is resistant up to a tempera- ture of 141°C (286°F)
9	Sterilization	- Steam sterilization at 135°C (275°F) during 10 minutes in gravity type autoclave (Table Top, N type) - Drying time after sterilization - 30 minutes	- Follow maintenance and operation procedures of the autoclave provided by the manufacturer - The only sterilization parameters to be used are those that have been validated and provided to the user in this User Manual
10	Storage	Keep sterilized accessories in sterilization pouches in a dry and clean environment	Sterility cannot be guaranteed if packaging is open or damaged (check the packaging before using the accessories)

#### 9. Troubleshooting

Please review the suggested solutions before calling customer service.

#	Problem	Possible Cause	Solution
1	The device does not turn on by pressing  (t) button	1. Malfunction of the button 2. The battery is depleted 3. Battery is completely flat 4. Electronic malfunaction	1. Press (b) button several times 2. Recharge the battery 3. Contact your customer service 4. Contact your customer service
2	The device shuts off while measuring	The battery is depleted	Recharge the battery

#	Problem	Possible Cause	Solution
3	not show file advance inside the canal contact contact de de 2. Electronic 2.		Perform cable connection test as described in section 6.1     Contact your customer service
4	Incorrect measurements	1. Extremely dry / calcified canal 2. Restoration treatment, conductive pass is blocked 3. Blood or irrigation liquid overflow provides conductive path outside the canal 4. Deep caries provides conductive path outside the canal 5. Metal crown or metal filling provide conductive path outside the canal 6. Perforation 7. Large lateral canal	1. Irrigate the canal 2. Remove old canal filling to open the path, irrigate the canal 3. Dry the excessive liquid 4. Block the external conductive path 5. Avoid contact between the file and metal crown/ filling 6. Remove the file, close the perforation and repeat the measurement, carefully inserting the file into canal 7. Try to continue the measurements (gently advance the file towards apex until regular readings appear)

## 10. Warranty

**Wirele-X** is warranted for 24 months from the date of purchase. The accessories (cables, batteries, etc.) 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

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

## 11. Disclaimer

The manufacturer, its representatives and its dealers 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.

### 12. Certification

13. Technical Specifications

Ingress of liquids – not protected
The device is intended for indoor use only

• Atmospheric pressure: 106 kPa to 19 kPa

• Atmospheric pressure: 106 kPa to 70 kPa

Information about radio communications

• Bluetooth® 5.0 Low Energy Communication

• The effective radiated power is below 5 mW.

• Frequency band: 2.402 to 2.480 GHz.

• USA: Contains FCC ID: RYYEYSHJN.

• Europe: EU EN 300 328 V2.1.1.

Environmental conditions during storage/transportation
 Temperature: -20 °C to+60 °C (-4 °F to 140 °F)

• Relative humidity: 10% to 90%, non-condensing

Environmental conditions during device usage:
Temperature: +10 °C to +40 °C (50 °F to 104 °F)

• Relative humidity: 10% to 90%, non-condensing

66 x 32 x 22 mm

Internally powered equipment

Type BF Applied Parts

Specifications:

Type of display:

Power source:

air, oxygen or nitrous oxide
• Continuous operation

Wirele-X 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.

Wirele-X electronic apex locator is a programmable electrical medical

• Not suitable for use in the presence of flammable anesthetic mixtures with

**Wirele-X** is intended for use in electromagnetic environment specified for equipment of Group 1 Class B.

3.7V Lithium-ion polymer battery

Input: 230V / 50-60 Hz or 120 V / 50-60 Hz

## 14. Standard symbols

Normative Symbols:

Direct current

Class II equipment Type BF Applied Parts

Consult instructions for use Manufacturing date

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

R Caution: Federal law restricts this device physician or licensed dental practitioner. Caution: Federal law restricts this device to sale by on the order of a

(+•4) Atmospheric pressure limitation

## 15. Packaging Box Content

Check the content of the packaging box before use:

• Wirele-X apex locator 1 pc. Display Unit 1 pc. • Measurement cable 1 pc. Lip clip 2 pcs. • File clip 2 pcs. • Touch probe 1 pc. • User Manual 1 pc. Quickguide 1 pc. Charger 1 pc. Stand 1 pc.

Note: Measurement cable with attached Lip Clip and File Clip constitute Applied Parts of the device.

## **ANNEX**

## **Electromagnetic Compatibility**

- Wirele-X requires special precautions with regard to 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 interfere to with Wirele-X
- The recommended radiation levels of RF wireless communication equipment specified in this paragraph must therefore be complied with
- Wirele-X 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

### **Electromagnetic Emissions**

#### Notes:

- Wirele-X 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 reorienting the equipment.

## Guidance and manufacturer's declaration electromagnetic emissions - Wirele-X

Wirele-X is intended for use in professional healthcare facility electronagnetic environment specified below; The customer or the user of Wirele-X should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions Group 1 CISPR 11		Wirele-X uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	- Wirele-X is suitable for use in all	
Harmonic emissions IEC 61000-3-2	Complies	establishments, including domestic establishments and those directly connected to the public low	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	voltage power supply network that supplies buildings used for domestic purposes.	

#### Guidance and manufacturer's declaration: electromagnetic immunity - Wirele-X

Wirele-X is intended for use in the electromagnetic environment speci-

The customer or the user of **Wirele-X** should assure that it is used in such

Immunity test	IEC 60601- 1-2 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±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	Not Applicable	Not Applicable

#### MHz МН cables, than the recommended separation distance calculated 6 Vrms om the equation applicable to n ISM in ISM the frequency of the transmitter. IEC 61000bands bands Recommended separation 150 kHz 150 kHz distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,7 GHz 08 ot to 80 MHz MHz 80% AM 80% AM Where P is the maximum output at 1 kHz at 1 kHz power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation

10 V/m

Guidance and manufacturer's declaration

electromagnetic immunity - Wirele-X

specified below; The customer or the user of **Wirele-X** should assure that

Immunity test

Portable and mobile RF

mmunications equipment

any part of **Wirele-X**, including

should be used no closer to

distance in meters (m). Field strengths from fixed RF

transmitters, as determined

by an electromagnetic site survey, a should be less than

the compliance level in each

Interference may occur in the

vicinity of equipment marked

with the following symbol: ((•))

frequency range .b

Wirele-X is intended for use in the electromagnetic environment

test

• UT is the a.c. mains voltage prior to application of the test level.

150 kHz

t is used in such an environment.

Conducted

disturbances

inducted by

RF fields

test

3 Vrms

150 kHz

10 V/m

80 MHz

to 80

Radiated RF

IEC 61000-

1 At 80 MHz and 800 MHz, the higher frequency range applies.
These guidelines may not apply in all situations .Electromagnetic

propagation is affected by absorption and reflection from structures objects and people.

#### Guidance and manufacturer's declaration electromagnetic immunity - Wirele-X

Wirele-X is intended for use in the electromagnetic environment specified below; The customer or the user of Wirele-X should assure that it is used in such an environment.

Immunity test	IEC 60601- 1-2 Test level	Compliance level	Electromagnetic environment - guidance	
Surges	±1 kV Line-to-line	Not Applicable	Not Applicable	
EC 61000-4-5	±2 kV Line-to- ground			
Voltage dips	0% UT; 0,5 cycle	Not Applicable	Not Applicable	
	0% UT; 1 cycle			
	and			
Voltage interruptions	70% UT; 25/30 cycles			
IEC 61000- 4-11	0% UT; 250/300 cycles			

#### Guidance and manufacturer's declaration electromagnetic immunity - Wirele-X

Wirele-X is intended for use in the electromagnetic environment specified below; The customer or the user of Wirele-X should assure that it is used in such an environment.

Immunity test	Immunity test	Immunity test	Immunity test
Rated power frequency magnetic fields	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used
IEC 61000-4-8			for domestic purposes, commercial or hospital, clinic environment.

#### Guidance and manufacturer's declarations electromagnetic immunity - Wirele-X

a. Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Wirele-X is used exceeds the applicable RF compliance level above, Wirele-X should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Wirele-X.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

### Specifications for enclosure port immunity to RF wireless communications equipment

Wirele-X is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled. The user and/or installer of the unit can help prevent electromagnetic

equipment (emitters) within the compliance limits specified in the table b				
Recommended radiation levels of RF wireless Communications Equipment				
Frequency band	EC 60601-1-2	Compliance	Minimum separation	

Frequency band	EC 60601-1-2 Test level	Compliance level	Minimum separation distance
380 – 390 MHz	27 V/m	27 V/m	0.3 m
430 – 470 MHz	28 V/m	28 V/m	0.3 m
704 <b>–</b> 787 MHz	9 V/m	9 V/m	0.3 m
800 – 960 MHz	28 V/m	28 V/m	0.3 m
1,700 – 1,990 MHz	28 V/m	28 V/m	0.3 m
2,400 – 2,570 MHz	28 V/m	28 V/m	0.3 m
5,100 – 5,800 MHz	9 V/m	9 V/m	0.3 m

Note: These guidelines may not apply in all situations. Electromagnetic propagation s affected by absorption and reflection from structures, objects, and people