Apex Locator User Manual



Display Unit User Manual



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Smart Wireless Apex Locator

User Manual



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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.

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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).

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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.



Pic. 1

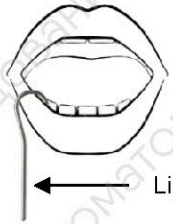
6.2 Getting Started

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).

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.



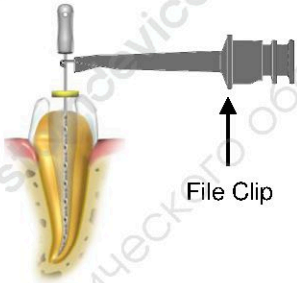


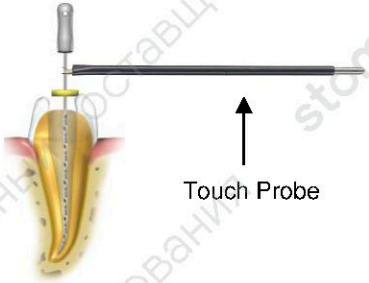
Pic. 2

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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).

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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

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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.

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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.



Pic. 8

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.

7.5 When the battery is charging, BAT LOW indicator will Blink red color.

7.6 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 distributer for battery replacement.

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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	- Follow instructions given by the disinfectant manufacturer (concentration, immersion time, etc.)

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#	Operation	Instructions	Details and Warnings
		proteolytic enzyme if possible. - Rinse well the accessories in flowing water	- Do not use disinfectant solution containing aldehyde, phenol or any products which may damage the accessories
6	Drying	No particular requirements	
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 temperature of 141°C (286°F)
9	Sterilization	- Steam sterilization at 135°C (275°F) during 10 minutes in gravity type autoclave (Tabletop, 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)

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9. Troubleshooting

Please review the suggested solutions before calling customer service.

#	Problem	Possible Cause	Solution
1	The device does not turn on by pressing ⏻ button	1. Malfunction of the button 2. The battery is depleted 3. Battery is completely flat 4. Electronic malfunction	1. Press ⏻ 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
3	The device does not show file advance inside the canal	1. Bad electrical contact 2. Electronic malfunction	1. Perform cable connection test as described in section 6.1 2. Contact your customer service
4	Incorrect measurements	1. 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)

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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 discovery.

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

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 is covered by the "CE Marking of Conformity" certificate. The device bears the following CE identification mark:

CE
0344

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13. European Authorized Representative

European Authorized Representative who has been empowered to enter into commitments in our behalf:

CEpartner4U B.V.
ESDOORNLAAN 13, 3951 DB MAARN, THE NETHERLANDS.
Contact Person: Mr. Ton Pennings
Tel. +31 343 442 524, Fax +31 343 442 162
Email: office@cepartner4u.com

14. Technical Specifications

Wirele-X electronic apex locator is a programmable electrical medical device

- 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
- Ingress of liquids – not protected
- The device is intended for indoor use only
- Environmental conditions during storage/transportation:
  - Temperature: –20 ºC to +60 ºC (-4 ºF to 140 ºF)
  - Relative humidity: 10% to 90%, non-condensing
  - Atmospheric pressure: 106 kPa to 19 kPa
- Environmental conditions during device usage:
  - Temperature: +10 ºC to +40 ºC (50 ºF to 104 ºF)
  - Relative humidity: 10% to 90%, non-condensing
  - Atmospheric pressure: 106 kPa to 70 kPa

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

Specifications:

Dimensions:	66 x 32 x 22 mm
Weight:	20 gr.
Type of display:	LEDs
Power source:	3.7V Lithium-ion polymer battery
External charger:	Input: 230V / 50-60 Hz or 120 V / 50-60 Hz
	Output: 5V DC

Information about radio communications

- Bluetooth® 5.0 Low Energy Communication.
- Frequency band: 2.402 to 2.480 GHz.
- The effective radiated power is below 5 mW.
- Europe: EU EN 300 328 V2.1.1.
- USA: Contains FCC ID: RYYEYSHJN.

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15. Standard symbols

Normative Symbols:


Class II equipment


Type BF Applied Parts


Direct current


Manufacturer


Consult instructions for use


Manufacturing date


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


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


Temperature limitation


Humidity limitation


Atmospheric pressure limitation

16. Packaging Box Content

Check the content of the packaging box before use:

- **Wirele-X** apex locator - 1 pc.
- Measurement cable - 1 pc.
- Lip clip - 2 pcs.
- File clip - 2 pcs.
- Touch probe - 1 pc.
- User Manual - 1 pc.
- Charger - 1 pc.

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

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ANNEX

Electromagnetic Compatibility

Notes:

- **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 of use.

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 re-orienting the equipment.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration:
electromagnetic emissions - Wirele-X</th></tr>
<tr><td colspan="3">Wirele-X is intended for use in professional healthcare facility electromagnetic environment specified below; The customer or the user of Wirele-X should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">Wirele-X is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Complies</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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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
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
Surges IEC 61000-4-5	±1 kV Line-to-line ±2 kV Line-to-ground	Not Applicable	Not Applicable
Voltage dips Voltage interruptions IEC 61000-4-11	0% UT; 0,5 cycle 0% UT; 1 cycle and 70% UT; 25/30 cycles 0% UT; 250/300 cycles	Not Applicable	Not Applicable

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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 IEC 61000-4-8	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 for domestic purposes, commercial or hospital, clinic environment.

Note:

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

Conducted disturbances inducted by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of **Wirele-X**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation 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
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	Where *P is* the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* i s the recommended separation distance in meters (m).

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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
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range .[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Notes:

- 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.

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**.

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

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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 interference by maintaining radiation levels of RF wireless communications equipment (emitters) within the compliance limits specified in the table below.

Recommended radiation levels of RF wireless Communications Equipment			
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 – 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 is affected by absorption and reflection from structures, objects, and people.

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wirelex

Smart Wireless Apex Locator

Display Unit User Manual



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FOR DENTAL USE ONLY

DIRECTIONS FOR USE

Introduction

Congratulations, you have made a good choice with **Wirele-X Display** Unit.
The display unit is used to display more comprehensively and more effectively measurements, system status, and additional information, which are of user interest.

Ergonomic user-friendly design of **Wirele-X Display** Unit makes it a choice of preference in modern dental clinic. Utilizing the advantages of well proven patented technology, Wirele-X, together with a state-of-the-art monitoring application **Wirele-X Display** Unit, helps to achieve optimal performance and sustainable use during working length determination.



Wirele-X Display

1. Indications for use

Wirele-X Display unit is a monitoring application that displays the progress of the Wirele-X apex locator measurements in a graphical presentation on its screen.

2. Contraindications

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

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3. Warnings

⚠ This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

⚠ 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.

⚠ Do not drop, bend, or puncture your device; do not insert foreign objects into or place heavy objects on your device. Sensitive components inside might become damaged.

⚠ Your device screen is made of glass. The glass might break if the device is dropped on a hard surface, is subjected to a high impact, or is crushed by a heavy object. If the glass chips or cracks, do not touch the broken glass or attempt to remove it from the device. Stop using the device immediately and contact your distributor for repair, replacement, or disposal information.

4. Precautions

- Do not use **Wirele-X Display** 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 Display** 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 Display** from occasional spillage of liquids.
- Do not use **Wirele-X Display** in presence of flammable materials.
- **Wirele-X Display** should be used with the manufacturer's original accessories only.
- For your own safety, please use personal protection gear (gloves, mask).

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5. Adverse Reactions

None.

6. Step-by-Step Instructions

Turn on the Display Unit by pressing the power button for a several seconds.



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After a short logo presentation, the home screen is displayed and includes the following indications:



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The Wirele-X apex locator and the Display communicate via Bluetooth.
Turn the Wirele-X device on and wait for Bluetooth connection to the Display.

When the Wirele-X is connected to the Display, the Blue LEDs around the power button of Wirele-X will stop blinking and the "Apex Locator Battery" symbol should appear on the status bar of the Display.



⚠ The Wirele-X will connect automatically to the display when Bluetooth of the Display is enabled.

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6.1 *Cable connection test*

Connection test feature is intended to check the integrity of the cables:

6.1.5 Insert the Measurement cable with attached Lip Clip and File Clip into the Wirele-X receptacle. "Cable Connection" symbol should appear on the status bar of the display, indicating proper connection.

6.1.6 Verify that the File Clip contact and the Lip Clip are clean and make connection between them.

6.1.7 "Cable Test" symbol should appear on the status bar of the display, indicating proper contact.

6.1.8 If the symbol does not appear, the Measurement cable or the File Clip should be replaced.



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6.2 Getting Started

The progression of the file inside the canal is presented on the **Wirele-X** device LEDs. In connected mode with the Display, the endodontic file progression is shown on the screen while the LEDs on the **Wirele-X** remains off.

The tooth image presented on the Display unit is only a representation of a root canal and may not coincide with its actual shape. As with all electronic length determination devices, the bars shown on the Display do not represent the distance in millimeters or any other linear scale.

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

⚠ Before connecting the Measurement cable with attached Lip Clip and File Clip to the patient, plug the Measurement cable into **Wirele-X** device receptacle.

6.3 Apex localization

6.3.1 Coronal and Medial Zone

The progression of the file inside the canal is shown inside the small tooth image on the right side of the display



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Along the pre-apical zone a zoomed view of file progression in the canal is shown on the enlarged root image by means of blue bars graduated from 2.0 to 1.0. The correspondent numerical value appears on the left side of the display under the zoomed tooth image.

Wirele-X Provides audio feedback of file progression as a series of progressive rate beeps.

6.3.2 Apical Zone

The apical zone is divided into **11** color bars graduated from 1.0 to 0 (Apex) serving as a visual indication of file progression. The numerical value appears on the left side of the display under the tooth image. File progression in the apical zone is accompanied by a series of beeps with variable rate. When the apex is reached (red bar at the mark "0" and reading "APEX"), solid tone is emitted.

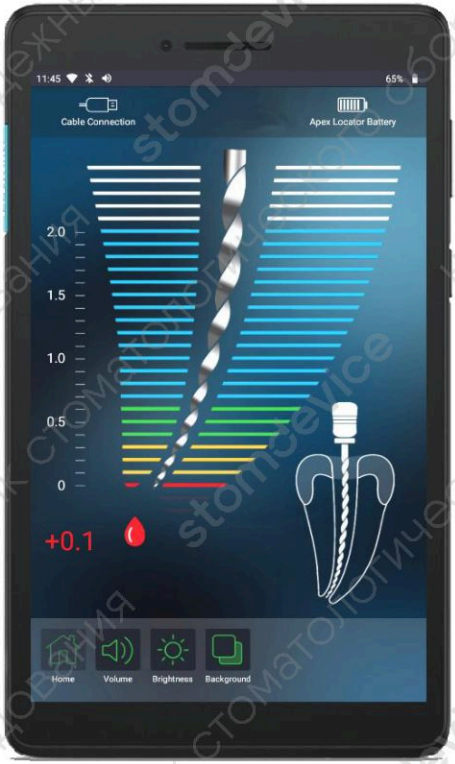
The apical position indicated by **Wirele-X** corresponds to file tip position at minor apical foramen.



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6.3.3 *Over-instrumentation*

A red “Blood drop” icon and warning sound indicate that the file has passed the Apex. Red numerical values changing from +0.1 to +0.5 indicate relative depth of over-instrumentation and may be helpful during determination of canal patency. After the value +0.5 the “OVER” reading appears.





To return to the apical position, gently retreat the file until the “Blood drop” disappears and “APEX” indication returns.

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6.4 Audio feedback

Wirele-X Display 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 display and enables monitoring of file advance in the apical zone, even without seeing the display. Pressing the volume key you may adjust the sound volume.

6.5 Automatic Sleep Mode

Wirele-X Display will automatically enter sleep mode after 5 minutes without use. In order to prolong the battery life, to resume the **Wirele-X Display** operation, touch the screen or press the On/Off button.

It is recommended to switch off the device after completing the measurements by pressing the On/Off button and selecting Power off.

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6.6 Settings menu

6.6.1 Activating the Wi-Fi

Wirele-X Display can be connected to Wi-Fi to download updates to the **Wirele-X** Display and apex locator.

- To activate the Wi-Fi, select Settings.
- Select the Wi-Fi tab.
- Set Wi-Fi to ON .
- Choose your network and enter the password.



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6.6.2 Activating the Bluetooth®

Bluetooth® must be activated to connect **Wirele-X** Display and the apex locator.

⚠ The apex locator has to be in a distance up to 5m in order to connect to Display.

- To activate the Bluetooth®, select Settings.
- Select the Bluetooth® tab.
- Set Bluetooth® to ON .
- The Display will recognize the apex locator automatically and will be displayed under "My device"



In case that the connection could not be established automatically.

- Press the "SCAN" button and wait until available devices are detected.
- Your apex locator device will be displayed under "Available devices".
- Select your device.

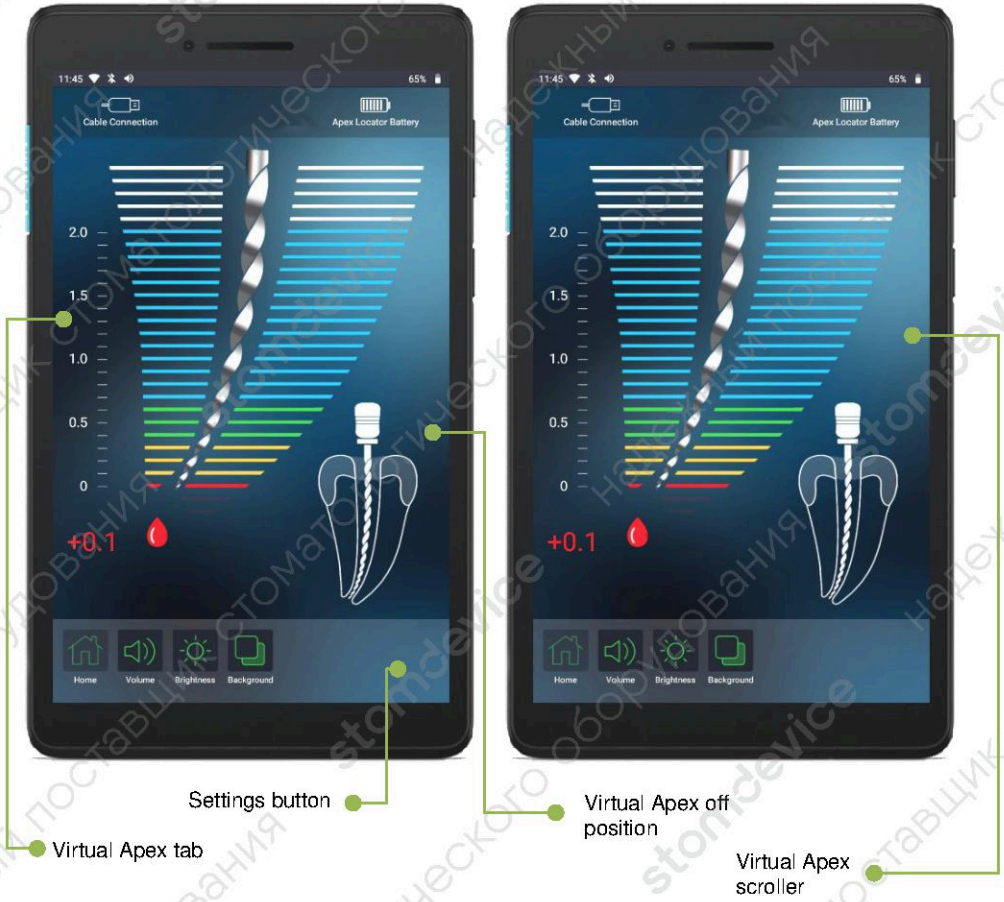
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6.6.3 *Virtual Apex function*

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

To activate Virtual Apex or to modify Virtual Apex mark position, follow the next steps:

- Press the "Settings" button and access the "Virtual Apex" tab on the settings menu.
- Use the scroller on the right side of the virtual apex setting screen, to set the Virtual Apex position (0.1 to 1.0 marks of the scale).



- To turn off Virtual Apex, place the scroller at position "0" mark of the scale (OFF).

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When Virtual Apex feature is enabled, Virtual Apex mark and position appears on the tooth image on the main screen.

When the file tip reaches the Virtual Apex position and during further advance of the file special “Virtual Apex” sound appear, clearly distinguished from regular audio feedback.

When the real “**APEX**” is reached, the solid tone is sounded, as usual. If the file overpasses the apex, “Blood Drop” appears and an audio warning signal is activated as described in the section 6.3.2 “Over-instrumentation”.



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6.6.4 User Manual Language selection

The **Wirele-X** user manual is provided in different languages. You can select your preferred language that the user manual will be displayed.

- To choose your preferred language, select Settings.
- Select the User Manual tab.
- Choose your preferred language.



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6.6.5 Changing the interface

The **Wirele-X** Display interface may be selected from different graphical options. To select your preferences

- Select Settings.
- Select the Change interface tab.
- Select your preferred graphical presentation.



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6.6.6 Updates

When the **Wirele-X** Display is connected to the Wi-Fi the device checks automatically for available updates. When software updates are available, Updates symbol will appear on the screen with number of available updates:

1 - one update available to the Display or to the Apex Locator.

2 - two updates available, one to the Display and another one to the Apex Locator

To perform software update

- Select Settings.
- Select the Updates tab.

⚠ During update of the Apex Locator or the Display base unit, charger has to be connected.

- Press the "Update Now" button to start the update. The progress of update will be displayed during the process.
- The update will be completed automatically, and the new software version will be presented.



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7. Battery Charging

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

The Battery level is displayed on the top right corner on the screen.



To charge the battery:

- Connect the charger to the mains.
- Plug charger cable into the charger receptacle.

⚠ Do not attempt to replace the internal rechargeable lithium ion battery. There is risk if the battery is replaced with an incorrect type. Contact your distributer for factory replacement.

⚠ Please only use original power adapter supplied with the Wirele-X device.

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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.

The **Wirele-X Display** should be cleaned using tissue or soft cloth impregnated with aldehyde free disinfecting and detergent solution (a bactericidal and fungicidal).

9. Troubleshooting

Please review the suggested solutions before calling customer service.

#	Problem	Solution
1	Device does not power on or system crashes	Please first charge the battery for half an hour, then press and hold the power button to force the power off. Finally, press the power button to boot normally.
2	The touch screen does not work or is not sensitive	Please press the power button first, forced shutdown. Then, press the power button to boot normally.
3	The device cannot access the internet via a wireless network	Restart the wireless router or go to Settings and restart Wi-Fi.
4	The device cannot wake up from sleep mode	Please press the power button first, forced shutdown. Then, press the power button to boot normally.

10. Warranty

Wirele-X Display is warranted for 12 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 discovery.

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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.

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12. Technical Specifications

- Internally powered equipment
- Not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide
- Continuous operation
- Ingress of liquids – not protected
- The device is intended for indoor use only
- Environmental conditions during storage/transportation:
  - Temperature: –20 ºC to +60 ºC (-4 ºF to 140 ºF)
  - Relative humidity: 10% to 90%, non-condensing
  - Atmospheric pressure: 106 kPa to 19 kPa
- Environmental conditions during device usage:
  - Temperature: +10 ºC to +40 ºC (50 ºF to 104 ºF)
  - Relative humidity: 10% to 90%, non-condensing
  - Atmospheric pressure: 106 kPa to 70 kPa

FCC Compliance Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult an authorized dealer or service representative for help.

Specifications:

Dimensions:	110 x 195 x 9 mm
Weight:	260 gr.
Type of display:	7" IPS 1024x600
Power source:	3450mAh Lithium-ion polymer battery
External charger:	Input: 230V / 50-60 Hz or 120 V / 50-60 Hz
	Output: 5V DC

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