

BINGO PRO

APEX LOCATOR

User Manual



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FOR DENTAL USE ONLY

DIRECTIONS FOR USE

Introduction

You have made a good choice with **BINGO PRO** – the most innovative apex locator on the market. This apex locator has been optimized inheriting proven technology and measurement precision of well-known Bingo line of electronic apex locators and implementing unique full color 3D user interface.

Ergonomic user-friendly design of **BINGO PRO** makes it a choice of preference for modern dental clinic.



1. **Indications for use**

BINGO PRO 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 different conditions (dry, wet, blood, etc.).

2. **Contraindications**

BINGO PRO 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 by qualified dental personnel.**
-  **Use only the original charger.**

4. **Precautions**

- Do not use **BINGO PRO** near devices emitting electromagnetic noise such as fluorescent lamps, film viewers, ultrasonic devices, etc. Cellular phones, remote controls or other devices generating electromagnetic waves may cause abnormal operation of **BINGO PRO**. Such devices should be turned off.
- During device operation protect **BINGO PRO** from occasional liquid spillage.
- Do not use **BINGO PRO** in the presence of flammable materials.
- **BINGO PRO** device 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 metal crowns or bridges (avoid any metallic contact with the file or the Lip Clip).
- 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 another instrument.
- 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 means (gloves, mask).

5. **Adverse Reactions:**

None.

6. **Step-by-Step Instructions**

6.1 *Recharging the Battery*

Before the first use or after prolonged storage **BINGO PRO** battery should be recharged. Refer to the section 7 for battery recharging instructions.

6.2 *Cable connection test*

Connection test feature is included in **BINGO PRO** in order to check the cables:

- Plug the Measurement cable with attached Lip Clip and File Clip into the device receptacle.
- Verify that the file clip contact and the lip clip are clean and make connection between them.
- “**Connection**” symbol  should appear on the status bar of the display, indicating proper connection (Pic. 1).
- If the symbol  does not appear, the Measurement cable or the File Clip should be replaced.

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

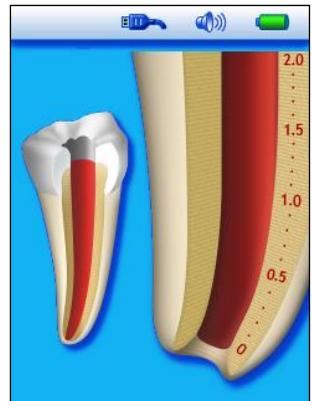


Pic. 1

6.3 *Getting Started*

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

- 6.3.1 Disconnect the charger from the device, if connected.
- 6.3.2 Turn the device on by pressing  (On/Off) button. After a short logo presentation, the main screen is displayed. Status bar with battery and sound level indicators is located in the upper part of the display.
- 6.3.3 Before connecting the Measurement cable with attached Lip Clip and File Clip to the patient, plug Measurement cable into the device receptacle and make sure that the cable icon appears on the status bar (Pic. 2).
- 6.3.4 Attach the Lip Clip to the patient.
- 6.3.5 Gently insert endodontic file into the root canal and connect the File Clip to the file (to ensure



Pic. 2

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.

- 6.3.6 The file image inside the tooth will appear accompanied by a double beep signal (Pic. 3). Absence of file image 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.

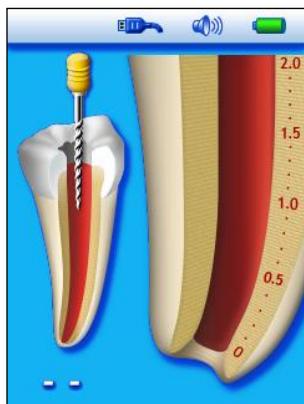


Pic. 3

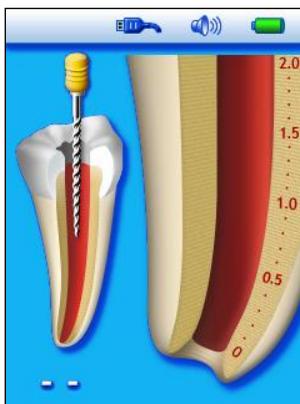
6.4 Apex localization

6.4.1 Coronal and Medial Zone

Slowly move the file forward inside the root canal. The progression of the file inside the canal is shown inside the tooth image on the left part of the display (Pic. 4 to Pic. 6).



Pic. 4



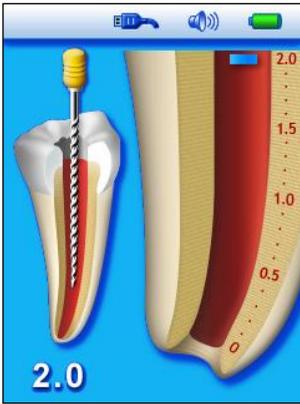
Pic. 5



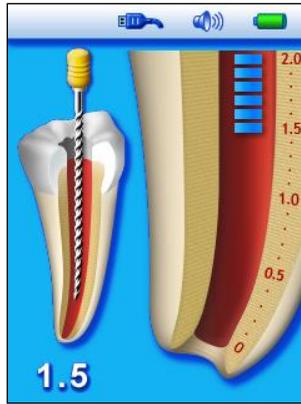
Pic. 6

Along the pre-apical zone a zoomed view of file progression in the canal is shown on the enlarged root image on the right side of the display by means of blue bars graduated from 2.0 to 1.0 (Apical Zoom). The correspondent numerical value appears on the left side of the display under the tooth image (Pic. 7 to Pic. 9).

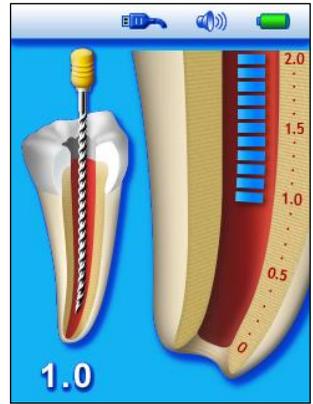
BINGO PRO provides audio feedback of file progression as a series of progressive rate beeps.



Pic. 7



Pic. 8



Pic. 9

6.4.2 Apical Zone

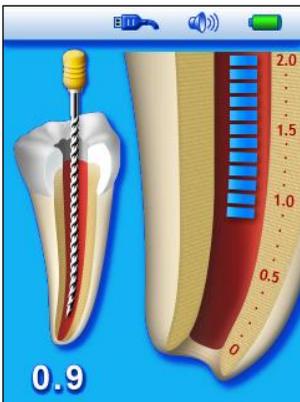
The apical zone is divided into 11 color bars graduated from 1.0 to 0 (Apex) serving as a visual indication of file progression (Pic. 10 and Pic. 11). The numerical value appears on the left side of the display under the tooth image. File progression in the apical zone is accompanied by a series of beeps with variable rate. When the apex is reached (red bar at the mark "0" and reading "APEX"), solid tone is emitted (Pic. 12).

The apical position indicated by **BINGO PRO** corresponds to file tip position at minor apical foramen.

Beginning of the Apical Zone

Middle of the Apical Zone

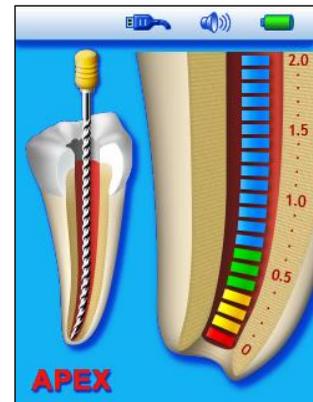
Apical position



Pic. 10



Pic. 11

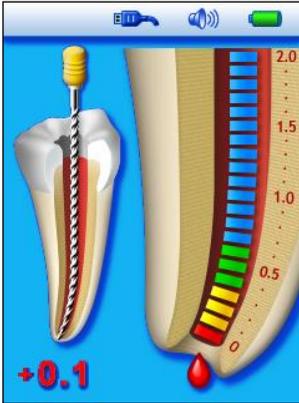


Pic. 12

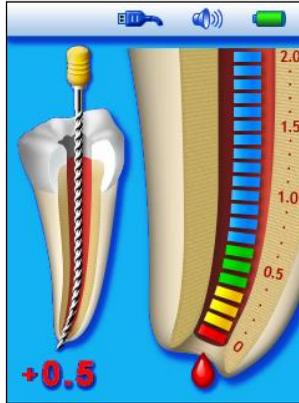
6.4.3 Over-instrumentation

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

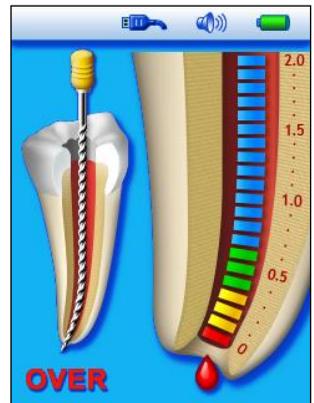
and may be helpful during determination of canal patency (Pic. 13 and Pic. 14). After the value **+0.5** the “**OVER**” reading appears. (Pic. 15).



Pic. 13



Pic. 14



Pic. 15

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

Note: Numerical 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.

6.4.4 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.
- 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.

6.5 Audio feedback

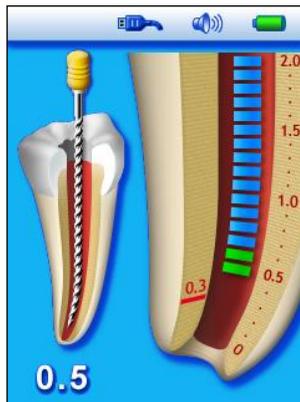
BINGO PRO is equipped with an audio indicator which accompanies file progression within the canal in the pre-apical and apical zones. This function, is activated in parallel with Apical Zoom display and enables monitoring of file advance in the apical zone, even without seeing the display. Successively pressing the volume key  you may adjust the sound volume to one of four levels: Mute, Low, Normal and High.

6.6 Virtual Apex

Virtual apex enables to mark a predetermined position at the required distance 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.

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

- 6.6.1 Press and hold the MODE button for about 1 sec. until the beep sounds and Virtual Apex mark is blinking on the screen. (Blinking "0" mark with adjacent red line inside the canal indicates that Virtual Apex was previously disabled).
- 6.6.2 Press the MODE button to select Virtual Apex position (0.1 to 1.0 marks of the scale). To confirm your selection press and hold the MODE button for about 1 sec. until beep sounds and the Virtual Apex mark stops blinking.



Pic. 16

If Virtual Apex feature is enabled, Virtual Apex mark appears on the left side of the Apical Zoom image (Pic. 16).

When the file tip reaches the Virtual Apex position and during further advance of the file special "Virtual Apex" beeps 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 6.4.3 "Over-instrumentation".

- 6.6.3 To disable Virtual Apex feature, Press and hold the MODE button for about 1 sec, proceed to the mark "0", press and hold the MODE button again. The Virtual Apex mark disappears.

6.7 Demo mode

The built-in Demo mode is available to demonstrate operation of the device and to improve the learning curve of the operator.

- 6.7.1 Disconnect the Measurement cable or the charger from the device, if connected, and turn the device Off.
- 6.7.2 To start Demo Mode, press and hold the  button for about 1 sec. until the second beep sounds and "Demo" indication appears on the status bar (Pic. 17).
- 6.7.3 During Demo cycle the operating sequence of the device is shown on the screen. Press  button to pause the simulation; press  button again to resume.
- 6.7.4 When Demo cycle is completed, it is repeated automatically until interrupted by the operator.
- 6.7.5 To exit Demo mode press  button and hold it for about 1 sec. until a beep sounds.



Pic. 17

Note: If Measurement cable is plugged into device receptacle during Demo cycle, BINGO PRO switches automatically to regular operation mode.

6.8 Automatic Shutdown

BINGO PRO 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  button.

7. Rechargeable Battery

7.1 Battery Charging

BINGO PRO is delivered with a rechargeable battery.

Battery indicator on the status bar shows the battery charge level. When the icon is flashing, the battery requires recharging, however, it is still functional for several treatments before the device shuts down.

To charge the battery:

- Complete the measurements and disconnect the Measurement cable from the patient.
- Unplug the Measurement cable from the device.
- Connect the charger to the mains.
- Plug charger cable into the device receptacle. While charging, the charger and the device should be outside patient environment (at least 1.5 m from the patient).

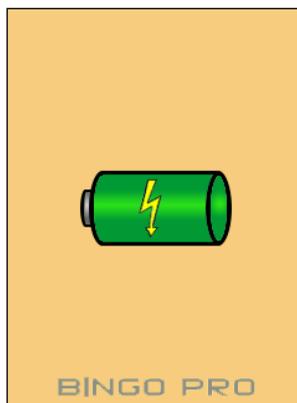
Charging screen will appear during battery charging. Running battery icon animation indicates charging in process (Pic. 18). When the animation on the screen stops and the battery image turns fully green, the charging is complete (Pic. 19).

Charging



Pic. 18

Charging is completed



Pic. 19

Duration of charging: About 12 hours (24 hours after long periods without use).

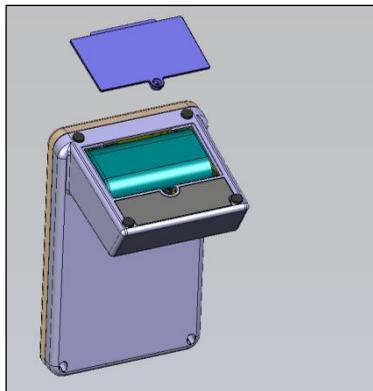
Note: **BINGO PRO** cannot be used while charging.

 **Warning:** Use only original battery pack from your supplier!

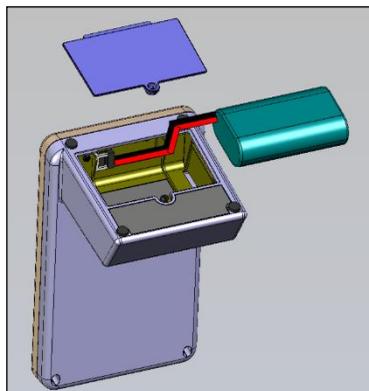
7.2 Battery Replacement

The battery compartment is located at the bottom of **BINGO PRO** and its cover is secured by a screw.

- Release the screw and remove the battery compartment cover (Pic. 20).
- Remove the battery from battery compartment and disconnect the battery cable jack from the battery connector of **BINGO PRO** (Pic. 21).
- Insert the cable jack of the new battery into the battery connector.
- Insert the battery into the battery compartment.
- Close the battery compartment and secure the cover with the screw.



Pic. 20



Pic.21

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.

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.

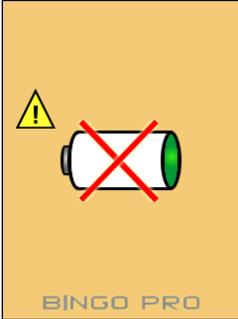
8.2 Disinfection and sterilization procedure

#	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	<ul style="list-style-type: none"> - Clean the accessories with an adequate brush or towel soaked in a disinfectant solution 	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Soak the required accessories in a disinfectant solution combined with proteolytic enzyme if possible - Rinse well the accessories in flowing water 	<ul style="list-style-type: none"> - 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 items
6	Drying	No particular requirements	
7	Maintenance, inspection and testing of the accessories	No particular requirements	
8	Packaging	Pack the devices in sterilization pouches	<ul style="list-style-type: none"> - Check the validity period of the pouch given by the manufacturer to determine the shelf life - 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. (Table Top, N type)	<ul style="list-style-type: none"> - Follow maintenance and operation procedures of the autoclave provided by the manufacturer -The only sterilization parameters to be used are those that have

#	Operation	Instructions	Details and Warnings
		- Drying time after sterilization – 30 minutes	been validated and provided to the user in this User Manual
10	Storage	Keep devices in sterilization packaging in a dry and clean environment	Sterility cannot be guaranteed if packaging is open or damaged (check the packaging before using the instruments)

9. Troubleshooting

Please review the suggested solutions before calling customer service.

#	Problem	Possible Cause	Solution
1	<p>The device shows the following picture during charging</p> 	The battery is not connected	<p>Open the battery compartment, and connect the battery as described in the User Manual, section 7.2</p> <p>Warning: Use only the original battery pack from your supplier!</p>
2	The device does not turn on by pressing  button	<ol style="list-style-type: none"> 1. Malfunction of the button 2. The battery is flat 3. Electronic malfunction 	<ol style="list-style-type: none"> 1. Press  button for several times 2. Charge the battery 3. Contact your customer service
3	The device shuts off while measuring	The battery is flat	Charge the battery
4	No sound while measuring	“Sound control” set at “Mute” level	Adjust the sound level by pressing  button
5	The device does not show file advance inside the canal	<ol style="list-style-type: none"> 1. Bad electrical contact Electronic malfunction 	<ol style="list-style-type: none"> 1. Perform cable connection test as described in section 6.2 2. Contact your customer service
6	Incorrect measurements	1. Dry/calcified canal	1. Irrigate the canal

#	<i>Problem</i>	<i>Possible Cause</i>	<i>Solution</i>
		<ol style="list-style-type: none"> 2. Restoration treatment, conductive pass is blocked 3. Blood or irrigating 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 	<ol style="list-style-type: none"> 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 measurements, carefully inserting the file into canal 7. Try to continue the measurements (gently advance the file towards apex until regular readings appear)

10. *Warranty*

BINGO PRO is warranted for 24 months from the date of purchase. The accessories (cables, battery 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*

BINGO PRO 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.

BINGO PRO is covered by the “CE Marking of Conformity” certificate. The device bears the following CE identification mark:



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*

BINGO PRO 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 °C to +60 °C (0 °F to 140 °F)
 - Relative humidity: 10% to 90%, non-condensing
 - Atmospheric pressure: 106 kPa to 19 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: 106 kPa to 70 kPa

BINGO PRO is intended for use in electromagnetic environment specified for equipment of Group 1 Class B.

Specifications:

Dimensions: 122 x 74 x 70 mm
 Weight: 300 gr.
 Type of screen: Color Graphic TFT
 Screen dimensions: 3.5"
 Power source: 2.4V NiMH rechargeable battery
 External charger: Input: 230V / 50-60 Hz or 120 V / 50-60 Hz
 Output: 6V DC

15. Standard symbols

On the device label appear standard symbols as follows:



Class II equipment



Type BF applied part



Direct current



Manufacturer



Consult instructions for use



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 or on the order of a physician or licensed dental practitioner.

16. Packaging Box Content

- **BINGO PRO** apex locator - 1 pc.
- Charger - 1 pc.
- Measurement cable - 1 pc.
- Lip Clip - 5 pcs.
- File Clip - 2 pcs.
- Touch Probe - 1 pc.
- User Manual - 1 pc.

Forum Engineering Technologies (96) Ltd.
40 Hutsot Hayotser St.,
Ashkelon 7878563, Israel.
P. O. Box 3095
Tel : +972-8-6788217 Fax : +972-8-6788218
www.forumtec.net E-mail :info@forumtec.net