Dentsply Sirona

Propex Pixi®

apex locator

User Manual

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For dental use only

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Electronic instructions for use
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Technical modifications on our product are not subject to notification.
Photos on our devices are not contractual.

Introduction

Congratulations on the purchase of **Propex Pixi®** apex locator. **Propex Pixi®** is a device aimed at detecting the minor apical foramen based on analysis of electrical properties of different tissues inside the root canal system. For optimal safety and performance, read this user manual carefully before use. Make sure you have understood and followed the clinical precautions - as well as the general warnings, precautions and contraindications - before proceeding to determining a working length. Keep this user manual for future reference.

1 Indication For Use

Propex Pixi® is an electronic device used for apex location during root canal treatment.
Propex Pixi® must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

2 Contraindications

Propex Pixi® is not recommended for use:

- In patients who have a pacemaker or other implanted electrical devices, or have been cautioned by their physicians against the use of small electric appliances such as shavers, hair dryers, etc;
- In patients allergic to metal;
- In children.

3 Warnings

- The scale indication on the **Propex Pixi®** screen does not represent a distinct length or distance in mm or other linear units. It simply indicates the file progression towards the apex;
- The following patient related factors may prevent accurate readings:
  - Blocked root canals;
  - Teeth with large apices;
  - Root fracture or perforation;
  - Metal crowns or bridges, if they come into contact with the file or the lip clip.

- Inaccurate or incorrect readings due to the environment are likely to occur in the following cases:
  - Presence of portable or movable radio frequency transmitters in the surroundings;
  - Film viewers or other Illumination devices which use an inverter may cause abnormal operation of the apex locator. Such devices should be turned off during use of the **Propex Pixi®**;
  - Electromagnetic interference could cause improper operation of the device. In such cases the device behaviour may become abnormal or random. Usage of any devices emitting electromagnetic radiation, such as cellular phones, remote controls, transceivers, etc., should be prohibited in the vicinity of **Propex Pixi®**.
- General safety warnings:
  - In order to prevent infectious agent transfer it is highly recommended to use a rubber dam system during the endodontic procedure.
  - Make sure that the lip clip, hook or fork does not come into contact with an electric power source such as an electrical socket. This could result in a severe electrical shock.
  - Do not use **Propex Pixi®** in the presence of flammable substances.
- Only use the original charger.
- Use AAA 1.2V 1000mAh NiMH rechargeable batteries only. Usage of non rechargeable batteries may cause device damage.
  Recommended battery type: Manufacturer – GP Batteries
  Model No.: GP100AAAHC.

4 Precautions

Important notice:

The use of apex locators alone without a preoperative and postoperative radiograph is not a recommended practice, since apex locators may not be able to work properly in all conditions.

It is mandatory to confirm radiographically the working length established using the apex locator.

It is important to follow the precautions below and pay close attention to any condition or situation that may influence the electrical conductivity during the procedure.

- Inaccurate or incorrect readings are likely to occur in the following cases, all procedure related:
  - Partially blocked canal.
  - Size of the measuring file differing significantly from the canal diameter. Ideally, the selected file should be the thickest one capable of reaching the apex.
  - Presence of liquids and/or tissue debris in the access cavity. Prior to the use of the device, the access cavity must be dried with a cotton pellet in order to prevent leaking current.
  - Contact of the file or the lip clip with metallic dental structures. Be particularly careful with patients fitted with metal crowns or bridges.
  - Contact of the file with another instrument.
  - Very dry canal, for instance in the presence of restoration. In this case the canal must be moistened with an irrigation solution, or with Glyde™ file prep.

- Contact between the file and the gums (this may cause a false reading indicating that the apex has been reached).
- Use of an ultrasonic scaler with the counter electrode attached to the patient (electrical noise from the scaler could interfere with the apex localization).
- Use of the apex locator in conjunction with an electric scalpel.
- Use of a damaged lip clip, hook or fork.

- For apex localization, concentrations of NaOCl higher than 5 % may result in reduced accuracy.
- As a safety precaution in order to avoid over-instrumentation, it is recommended to proceed as follows: place the file onto an endodontic ruler, where the **Propex Pixi®** indicates ‘0.0’. Subtract a minimum of 0.5 mm from the measured file length.
- Please also respect the following precautions:
  - For your own safety, be aware of wearing personal protective equipment (gloves, glasses, mask).
  - If the bar graph makes sudden large movements in the coronal part of the canal, slowly continue advancing the file toward the apex until the signal returns to normal.
  - This **Propex Pixi®** unit must not be connected to or used in combination with any other apparatus or system. It must not be used as an integral component of any other apparatus or system. Using replacement parts or accessories not supplied by the original manufacturer or vender could adversely affect the EMC performance of the **Propex Pixi®**.

- The device must be used with the manufacturer’s original accessories only.
- Unplug the device before replacing the battery.
- Never use batteries that are leaky, deformed, discolored or otherwise abnormal.
- In case of battery leakage, carefully dry the battery terminals and remove all of the leaked liquid. Then replace the battery with a new one.
- Dispose of old batteries according to local codes and regulations.
- Accessories including lip clips, hooks or forks should be clean and without residue of chemical disinfectants or other medicinal solutions such as sodium hypochlorite or formalin.
- Do not expose **Propex Pixi®** to any liquid.
- **Propex Pixi®** must be stored in normal temperature (< 60°C) and humidity conditions.

5 Adverse Reactions

If the apex locator provides an incorrect reading and there is no radiographic data (see “Important notice” in the “Precautions” section in chapter 4), the following adverse reactions may occur:

- Incomplete root canal treatment;
- Apex perforation.

6 Step-by-Step Instructions

6.1 Content

Check the content of the equipment before use:

1. **Propex Pixi®** apex locator;
2. Switching charger;
3. Measurement cable with clip;
4. Lip clip (2x);
5. Connection hook
   - User manual;
   - Product card.

Fig. 1

6.2 Connecting the AC Plug Adapter

Select the plug adapter that matches your electric power outlet.

Fig. 2 Plug adapters for power supply

Align and insert the plug adapter at the rounded edge and then snap it into place by inserting the opposite end (see Fig. 2). To remove, pull the locking button (1) and pull out the plug adapter.

6.3 Recharging the Battery

Propex Pixi® is equipped with a rechargeable battery.
When the battery is low, blinking battery icon appears on the status bar of the device indicating that the battery requires recharging.
When the battery icon is blinking, the battery requires recharging. However, it is still functional for several treatments before the device shuts down.

Procedure for recharging the battery:

1. Complete the measurements and disconnect the measurement cable from the patient;
2. Unplug the measurement cable from the device;
3. Connect the charger cable to **Propex Pixi®**;
4. Connect the charger to the mains. While charging, the charger and the device should be outside patient environment (at least 1.5 m from the patient).

During battery charging the battery symbol will first blink (see Fig. 3), then will remain steady when charging is completed (see Fig. 4).

Fig. 3 Charging

Fig. 4 Full

Duration of charging: Approximately 12 hours (24 hours after long period of non-use).

Note

Propex Pixi® cannot be used while charging.

6.4 Replacement of the Rechargeable Battery

Propex Pixi® is powered by one 1.2V AAA NiMH rechargeable battery.

If a fully charged battery is not sufficient for normal device operation during at least one working day, the battery should be replaced by a new one at your earliest convenience.

Please note that a new battery should be charged for 24 hours prior to the first use of the device.

Warning
Use GP100AAAHC or compatible NiMH rechargeable battery only.
Usage of non-rechargeable batteries may cause device damage.

The battery compartment is located at the rear side of **Propex Pixi®**.

1. Carefully lift and tilt back the silicon cover to expose the screw. Release the screw.

Fig. 5

2. Remove the battery compartment cover and the old battery.

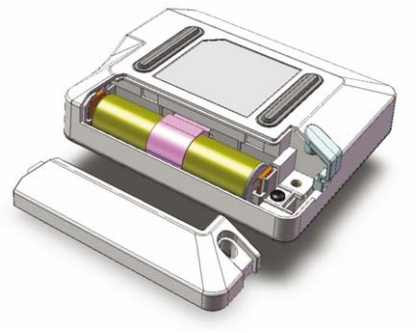

Fig. 6

3. Insert a new battery into the battery compartment according to polarity marking.
4. Close the battery compartment, secure the cover with the screw and adjust the silicon screw cover.

The new battery should be charged for 24 hours prior to the first use of the device.

6.5 Cable Connection Test

A connection test feature is included in **Propex Pixi®** in order to check the cables:

1. Connect the measurement cable and turn on the device.
2. Connect the metal part of the connection hook to the lip clip. Make sure that the accessories are cleaned properly before the test.
3. “Connection test” icon should appear on the status bar - see Fig. 7.
4. If no icon appears, the connection hook or the measurement cable should be replaced.

Fig. 7

Note
Measurement cable with attached lip clip and connection hook constitute Applied Parts of the device.

6.6 Apex Localization

6.6.1 Getting Started

Disconnect the charger from the device if connected.

1. Before connecting the measurement cable with attached lip clip and connection hook to the patient, plug measurement cable into the device and turn on the device by pressing the ⏻ “ON / OFF” button on the top of the device. The first bar will start blinking.
2. Attach the lip clip to the patient.
3. Gently insert the file into the canal.

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

4. Connect the connection hook to the metal shaft of the file.

The first bar will stop blinking accompanied by a double beep signal – see Fig. 8.

Fig. 8

Note
A blinking bar indicates faulty connection. Disconnect the measurement cable from the patient and check cable connections, clean the connection hook and the lip clip, moisten the canal if necessary and start again.

No other adjustments are required before starting apex localization.

6.6.2 Apex Localization

Advance the file with slow clockwise turns. In the pre-apical zone bar 2.0 turns on – see Fig. 9 and an audio signal sounds. As the file progresses in the canal, subsequent bars turn on gradually (Fig. 10) and the interval between the audio signals becomes shorter. If the bar graph suddenly makes a large movement in the upper part of the canal, continue slightly towards the apex so the signal returns to normal.

Warning

The scale indication on the **Propex Pixi®** screen does not represent a distinct length or distance in mm or other linear units. It simply indicates the file progression towards the apex.

Fig. 9

Fig. 10

6.6.3 Apical Zone

The apical zone is divided into 3 bars graduated from 1.0 to 0.0 (apex) – see Fig. 11.

Beginning of apical zone | Middle of apical zone | Apical position

Fig. 11

When the apex is reached, a solid tone is emitted.

The indication 0.0 on the **Propex Pixi®** screen relates to the minor apical foramen file position (the apical length).

6.6.4 Over-Instrumentation

A red “OVER” segment and an audio warning signal (rapid intermittent signal) indicate that the file has passed the apex – Fig. 12.

Fig. 12

6.6.5 Completion of the measurements

- Before unplugging the measurement cable from the device receptacle disconnect the lip clip and the connection hook 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.

Note

As a safety precaution in order to avoid over-instrumentation, it is recommended to proceed as follows: stop file progression in the canal at the point where the **Propex Pixi®** indicates '0.0'.
Place the file onto an endodontic ruler and measure the apical length.
Subtract a minimum of 0.5 mm from the measured file length.

6.7 Sound Adjustment

Propex Pixi® is equipped with an audio indicator which enables monitoring of the progression of the file within the canal in addition to visual monitoring.

The volume can be adjusted to four different levels: mute, low, normal and high, by successively pressing the "VOLUME" button.
When sound level is muted the icon is turned off. At other sound levels the icon remains turned on.

6.8 Demo Mode

The built-in demo mode is available to become acquainted with the device and to demonstrate its operation.

1. Disconnect the measuring cable or the charger from the device, if connected, and turn the device off.
2. To start the demo mode, press and hold the ⏻ “ON / OFF” button for about 2 seconds. until the whole display turns on (Fig. 13) and immediately turns off again accompanied by two beeps.

Fig. 13

3. During the demo cycle the device operating sequence is shown on the screen.
4. Demo cycles are repeated automatically until interrupted by the operator.
5. To exit the demo mode press the ⏻ ”ON / OFF” button and hold for about 1 second until a beep sounds. The device shuts down.

Note

If the measurement cable is connected to **Propex Pixi®** during the demo cycle, the device switches automatically to normal operation mode.

6.9 Automatic Shutdown

Propex Pixi® automatically shuts down after 3 minutes of non-use. In order to prolong battery life, it is recommended to switch the device off after usage by pressing the ⏻ “ON / OFF” button.

7 Cleaning, Disinfection and Sterilization

7.1 General Recommendations

- The device does not contain user serviceable parts. The service and repair should be provided by factory trained service personnel only.
- After each use, all objects that were in contact with infectious agents should be cleaned using towels impregnated with a disinfecting and detergent solution (a bactericidal, fungicidal and aldehyde free solution). Use of chemical agents may cause damage to the equipment. We recommend to use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval).
- The lip clip and the hook must be sterilized between treatments. Please note that the measuring cable cannot be autoclaved.
- In addition, a fork is not included in the **Propex Pixi®** but it can be used and should follow the same procedure as the lip clip and hook.
- Follow the “Disinfection and sterilization procedure” described in section 7.2.
- The user is responsible for the sterility of the lip clip, the connection hook and the fork for the first cycle and each further usage.
- All damaged accessories should be discarded and dirty accessories should be cleaned and sterilized per the procedure described in section 7.2.

7.2 Disinfection and Sterilization Procedure for Lip Clip, Connection Hook and Fork

Foreword

For hygiene and sanitary safety purposes, the lip clip, the connection hook and the fork must be cleaned, disinfected and sterilized before each usage to prevent any cross-contamination between patients. This concerns the first use as well as the subsequent uses.

General recommendations

- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer. For all metal instruments, it is recommended to use anticorrosion disinfecting and cleaning agents;
- For your own safety, please wear personal protective equipment (gloves, glasses, mask).
- The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments where applicable after sterility.
- Limitations and restrictions on reprocessing:
  the appearance of defects such as cracks, deformations (bent, twisted), corrosion, loss of colour coding or marking, are indications that the devices are not able to fulfil the intended use with the required safety level.
- Use only clean water in all cleaning and rinsing steps.

Step-by-step procedure

	Operation	Operating mode	Warning
1	Disassembling	• Disassemble the device.	

	Operation	Operating mode	Warning
2	Pre-Disinfection	• Pulp and dentine remnants must be removed from the accessories immediately. • After using the accessories on the patient, place them directly into a dish filled with a suitable cleaning and disinfection solution (e.g. CIDEZYME®, ENZOL® Enzymatic Detergent Solutions, Johnson & Johnson Medical, 0.8% for between 1 minute and 2 hours) for cleaning, pre-disinfection and interim storage. • Wash the accessories under flowing sterile, deionized water or in a disinfection solution at least three times for a minute each time, in order to remove all visible traces of contamination and remnants.	• Do not allow remnants to dry on. Clean no later than 2 hours. For visible impurities that are observed on instruments, a pre- cleaning is recommended by brushing them manually with soft material. Only use clean, soft brushes to manually remove contamination and remnants, or a clean, soft cloth or wipe that is only used for this purpose. Do not use metal brushes or wire wool. Check that no visible contamination or remnants remain, and repeat the pre-cleaning process if necessary. • Make sure that the products are fully immersed. • The disinfectant solution should be aldehyde free (to avoid blood impurities fixation), suitable for disinfecting the accessories, and compatible with the accessories. • Disinfectant used for pre-treatment is only for personal protection and does not obviate the need for disinfection once cleaning has been completed. Pre-treatment should never be omitted.
3	Rinsing	• Abundant rinsing (at least 1 min).	• Use clean water. • If a pre-disinfectant solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before the cleaning.

	Operation	Operating mode	Warning
4	Manual Cleaning or assisted by an ultrasonic device	• Place the pre-cleaned accessories into the cleaning bath for the prescribed contact time (e.g. CIDEZYME®, ENZOL® Enzymatic Detergent Solutions, Johnson & Johnson Medical, 0.8% for 1 minute); make sure that the products are fully immersed (if necessary, use a soft brush to carefully brush them down). • Remove the accessories from the cleaning bath and rinse them off thoroughly at least three times for a minute each time with sterile, deionized water. • Next, place the accessories in an ultrasonic bath with a cleaning agent (e.g. CIDEZYME®, ENZOL® Enzymatic Detergent Solutions, Johnson & Johnson Medical, 0.8% for 20 minutes).	• When choosing cleaning agents and disinfectants, make sure that:They are suitable for cleaning or disinfecting instruments You use a disinfectant with proven efficacy (e.g. with VAH/DGHM or FDA certification or CE mark) and that the disinfectant is compatible with the cleaning agent The chemicals used are compatible with the accessories. • Combined cleaning/ disinfection products should only be used if the instruments are only slightly contaminated (no visible contamination/remnants). Comply with the concentrations and contact times specified by the manufacturers of the cleaning agents and disinfectants, as well as their instructions regarding the intensity of subsequent rinsing. • Use only freshly prepared solutions, water that is sterile or has a low microbe content (< 10 cfu/ml) and a low endotoxin content (< 0.25 EU/ml, e.g. purified water (PW/HPW)), and filtered, oil-free air for drying.

	Operation	Operating mode	Warning
4	Manual Cleaning or assisted by an ultrasonic device	• Place the pre-cleaned accessories into the cleaning bath for the prescribed contact time (e.g. CIDEZYME®, ENZOL® Enzymatic Detergent Solutions, Johnson & Johnson Medical, 0.8% for 1 minute); make sure that the products are fully immersed (if necessary, use a soft brush to carefully brush them down). • Remove the accessories from the cleaning bath and rinse them off thoroughly at least three times for a minute each time with sterile, deionized water. • Next, place the accessories in an ultrasonic bath with a cleaning agent (e.g. CIDEZYME®, ENZOL® Enzymatic Detergent Solutions, Johnson & Johnson Medical, 0.8% for 20 minutes).	• Make sure that the accessories are not in direct contact with one another. • The hook mechanism has to be activated during the cleaning process, the rinsing process and the ultrasonic bath cleaning (press several times the push button) to allow the inner parts to be cleaned more effectively. • Make sure that the products are fully immersed (if necessary, use a soft brush to carefully brush them down). • No visible impurities should be observed on the accessories.

	Operation	Operating mode	Warning
5	Disinfection	• Once the accessories have been cleaned and inspected, place them into the disinfection bath for the prescribed contact time (e.g. Cidex OPA, Johnson & Johnson Medical, 100% for 20 minutes); the accessories must be sufficiently immersed in the solution. • Remove the accessories from the disinfection bath and rinse them off thoroughly at least five times for a minute each time with water. • Dry the accessories by blowing them down fully.	• The hook mechanism has to be activated several times during disinfection and the rinse to allow the inner parts to be disinfected more effectively. • To dry use oil-free, filtered compressed air and then leave the accessories to dry further in a clean place for at least 20 minutes. • Once the accessories are dry, inspect and pack them as soon as possible.
6	Rinsing	• Abundant rinsing (at least 1 min).	• Use quality water in accordance with local regulations. • If a disinfecting solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before the autoclaving. • Dry on a single use non-weaved cloth, or with a drying machine or filtered compressed air.

	Operation	Operating mode	Warning
7	Inspection	• Inspect devices and sort out those with defects. • Assemble the devices (stops).	• Dirty instruments must be cleaned and disinfected again. • Discard instruments which show any deformations (bent, twisted), damages (broken, corroded) or defects (loss of colour coding or marking) affecting the resistance, the safety or the performance of the instrument. • Do not use instrument lubricants.
8	Packaging	• Place the devices in a support or container to avoid any contact between instruments or posts and pack the devices in “Sterilization pouches”.	• Avoid any contact between instruments during sterilization. Use supports or containers. • Check the validity period of the pouch given by the manufacturer to determine the shelf life. • Use packaging which are resistant up to a temperature of 141°C (286°F) and in accordance with EN ISO 11607.

	Operation	Operating mode	Warning
9	Sterilization	• Steam sterilization at: 134 °C / 273°F, 3 min.	• The accessories (lip clip, hook and fork) must be sterilized according to the packaging labelling. • Use only autoclaves that match the requirements of EN 13060, EN 285. • Respect the maintenance procedure of the autoclave device given by the manufacturer. • Use only this recommended sterilization procedure. • Control the efficiency (packaging integrity, no humidity, colour change of sterilization indicators, physico-chemical integrators, digital records of cycles parameters).
10	Storage	• Keep devices in sterilization packaging in a dry and clean environment.	• Sterility cannot be guaranteed if packaging is open, damaged or wet. • Check the packaging and the medical devices before using them (packaging integrity, no humidity and validity period).

8 Technical Characteristics

Propex Pixi® complies with IEC 60601-1 Safety and IEC 60601-1-2 EMC (Electromagnetic compatibility) standards.

Propex Pixi® electronic apex locator belongs to the following category of medical devices:

- Internally powered equipment (AAA 1.2V 1000mAh NiMH rechargeable battery);
- 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;
- 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.

Specifications:

Dimensions	66 x 55 x 18 mm
Weight	55 gr.
Type of screen	Color LEDs
Supply	AAA 1.2V 1000mAh NiMH rechargeable battery
Switching charger	Input: 100-240 V AC ~ 50-60 Hz Output: 6V DC ± 5%, 1000 mA

9 Error Code

None.

10 Troubleshooting

Please review the checklist below should you experience a problem with your **Propex Pixi®**. If the problem persists after following the proposed solutions, please contact your distributor.

Warning

The following patient related factors may prevent accurate readings:

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

#	Problem	Possible cause	Solution
1	During battery charging the battery symbol blinks at a fast rate. 	The battery is not connected.	Open the battery compartment, and connect the battery as described in the User Manual, section 6.4.
		The battery is not rechargeable.	Replace the battery with a rechargeable type as described in the user manual, section 6.4.

#	Problem	Possible cause	Solution
2	The device does not turn on by pressing the “ON / OFF” button.	The button is functioning incorrectly.	Try pressing the ”ON/ OFF” button several times. If the device still does not turn on, please contact your distributor.
		The battery is discharged.	Charge the battery.
		Electronic malfunction.	Contact your distributor.
3	The device shuts off during the procedure.	The battery is low.	Charge the battery.
4	No sound during the procedure.	The sound control is set at “Mute” level.	Adjust the sound level by pressing the “VOLUME” button.
5	Display is not steady during the procedure.	There is not a good contact between the lip clip and the oral mucosa.	Ensure a good contact between the mucosa and lip clip (Place the lip clip in the labial angle opposite the tooth to be treated).
		The connection hook is soiled.	Clean the connection hook (with Ethanol).
		Deep caries provides a conductive path outside the canal.	Block the external conductive path.
		Perforation.	Remove the file, close the perforation and repeat the apex detection procedure, carefully inserting the file into canal.
		Large lateral canal.	Try continuing the procedure by gently advancing the file.

#	Problem	Possible cause	Solution
6	The transmission of the electric signal is interrupted. The device does not show file progression inside the canal.	Bad electrical contact.	Perform the cable connection test as described in the user manual, section 6.5.
		The connection hook is not properly connected to the file.	Place the connection hook on the metal part of the file below the plastic handle.
		The root canal is obliterated.	Check the comparative X-ray image for hints.
		In the case of retreatment: old filling material residues may block the root canal.	Remove old root filling material residues prior to use.
		The root canal may be blocked by the remnants of a medication (e.g. calcium hydroxide).	Completely remove the remnants prior to use.
		Root canal is extremely dry.	Rinse the root canal with **NaCl solution**. Dry the access cavity with a cotton pellet/ air-blower.
		The selected file is too small for a large root canal.	If there is no parietal contact use larger ISO size file. Important: exactly fitting files lead to precise results.
		Electronic malfunction.	Contact your distributor.

#	Problem	Possible cause	Solution
7	Display reaction is erratic: “0.0’’ or “OVER’’ appear on the screen before the apical constriction is reached.	Short circuit due to excess liquid (irrigation solution, saliva, blood) in the pulp chamber.	Dry the access cavity with a cotton pellet / air-blower. In case of excess bleeding wait until it has stops.
		A direct contact of the file with the gingiva or gingival proliferations, e.g. a fractured metal crown.	For isolation: • adequate preparation filling of access cavity; • use a rubber dam.
		A direct contact of the file with metal restorations (crown, parapulpal post, amalgam filling).	Isolate the file by inserting it into a small polyvinyl tube before use.

11 Warranty

Propex Pixi® is warranted for 12 months from the date of purchase. The accessories (cables, etc.) are warranted for 6 months from the date of purchase.

The warranty is valid for normal usage conditions. Any modification or accidental damage will void the warranty.

12 Disposal of the Product

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

13 Identification of Symbols

On the device label appear standard symbols as follows:

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

Symbol	Identification
	Humidity limitation
	Atmospheric pressure limitation
	Opened packages are not replaced
	Cannot be sold separately
	This product meets UL safety standard requirements
	Additional information, explanation on operation and performance
	INMETRO (National Institute of Metrology Standardization and Industrial Quality)
	GOST marking
	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Do not sterilize
	Accessory
	Plastic
	Carbon steel

Appendix

ELECTROMAGNETIC COMPATIBILITY (EMC)

The Product is intended for use in professional healthcare facility or home healthcare electromagnetic environment specified in this Appendix. The customer or the user of the Product should assure that it is used in such an environment.

Changes or modifications to this Product not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the Product and could cause EMC issues with this or other equipment. This Product is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

Warning

Use of portable phones or other radio frequency (RF) emitting equipment near the Product may cause unexpected or adverse operation.

Warning

The Product must not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the Product must be tested to verify normal operation in the configuration in which it is being used.

Compliant Cables and Accessories

Warning

Use of non-original cables or accessories may result in increased emissions or decreased immunity performance of the Product.

The table below lists cables and accessories for which the manufacturer claims EMC compliance:

Description	*Details*
Measurement Cable	Original only
Accessories:	
Lip Clip	Original only
Connection Hook	Original only
Charger	Original Switching charger only: Input: 100-240 V AC ~ 50-60 Hz Output: 6V DC ± 5%, 1000 mA

The recommended radiation levels of RF wireless communication equipment specified in this paragraph must be complied with.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Product is intended for use in professional healthcare facility or home healthcare electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.		
Emissions test	***Compliance***	***Electromagnetic environment - guidance***
RF emissions CISPR 11	Group 1	The Product 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	The Product is suitable for use in professional healthcare facilities or domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product 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	± 2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
Surges IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground	± 1 kV Line-to-line ± 2 kV Line-to-ground	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.

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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	0% UT; 0.5 cycle 0% UT; 1 cycle and 70% UT; 25/30 cycles 0% UT; 250/300 cycles	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinical environment. If the user of the Product requires battery charging during power mains interruptions, it is recommended that the Product charger be powered from a separate power supply (UPS, etc.).
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 for domestic purposes, commercial or hospital, clinic environment.
	Note UT is the a.c. mains voltage prior to application of the test level.		

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Immunity test	***IEC 60601-1-2 Test level***	***Compliance level***	***Electromagnetic environment - guidance***
Conducted disturbances induced by RF fields IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz 10 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.17 \times \sqrt{P}$ from 150 kHz to 80 MHz $d = 1.17 \times \sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ from 800 MHz to 2.7 GHz Where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m).

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Immunity test	***IEC 60601-1-2 Test level***	***Compliance level***	***Electromagnetic environment - guidance***
			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: 
	**Note** At 80 MHz and 800 MHz, the higher frequency range applies.		
	**Note** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.		

a
Field strengths 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 the Product is used exceeds the applicable RF compliance level above, the Product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Product.

b
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			
The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product can help prevent electromagnetic interference by maintaining radiation levels of RF wireless communications equipment (emitters) within the compliance limits specified below.			
Recommended radiation levels of RF wireless Communications Equipment			
Frequency band	**IEC 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

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