Dentsply Sirona

ProPex® II

apex locator

User Manual



For dental use only

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Electronic instructions for use
For additional languages, visit our website: dentsplysirona.com

Technical modifications on our product are not subject to notification.
Photos on our devices are not contractual.

Introduction

Congratulations on the purchase of **ProPex ® II**.

ProPex ® II 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 INDICATIONS FOR USE

ProPex ® II is an electronic device used to indicate the location of the apex and the working length. This product must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

2 CONTRAINDICATIONS

The **ProPex ® II** 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 metals;
- in children.

3 WARNINGS

- The scale indication on the **ProPex ® II** 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's 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 ® II**.
- Electromagnetic interference could cause improper operation of the device. In such cases the device behavior 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 ® II**.
- 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 ® II** in the presence of flammable substances.
- Only use the original battery pack from your supplier.
- Only use the original charger.

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 at the point where the **ProPex ® II** indicates 'APEX'. 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 ® II** 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 ® II**;
  - 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 ® II** to any liquid;
  - **ProPex ® II** must be stored in normal temperature (< 60°C) and humidity conditions.

5 ADVERSE REACTIONS

If the apex locator provides 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:

- one **ProPex ® II** apex locator;
- one charger;
- one measurement cable;
- two lip clips;
- two connection hooks;
- two connection forks;
- one user manual.

6.2 Recharging the Battery

The **ProPex ® II** is delivered with a rechargeable battery.

On **ProPex ® II** a screen indicator shows the level of the battery charge. When this is flashing, the battery requires recharging. However, it is still functional for several treatments before the battery shuts down.

Procedure for recharging the battery:

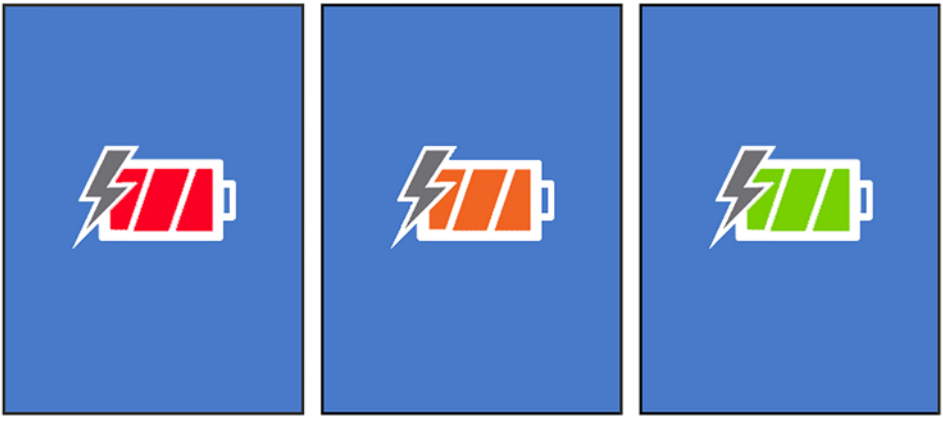
(1) Complete the measurements and disconnect the measurement cable from the patient.

(2) Unplug the measurement cable from the device.

(3) Connect the charger cable to the **ProPex ® II**.

(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).

Charging screen will appear during battery charging. When the battery image on the screen stops blinking and turns green, the charging is complete.



Low Mid Full

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

ProPex ® II cannot be used while charging.

6.3 Replacement of the Rechargeable Battery

The battery compartment is located at the bottom of **ProPex ® II** and its cover is secured by a screw.

(1) Release the screw and remove the battery compartment cover.

(2) Remove the battery and disconnect the battery cable from the connector.

(3) Insert the new battery cable into the connector.

(4) Insert the battery into the battery compartment.

(5) Close the battery compartment and secure it with the screw.







Use only original battery pack from your supplier!

6.4 Getting Started

(1) Disconnect the charger from the device if connected.

(2) Before connecting the measurement cable with attached lip clip and connection hook to the patient, plug measurement cable into the device receptacle and switch the device On – after a short logo presentation, the main screen is displayed and the cursor on the tooth image will start blinking.

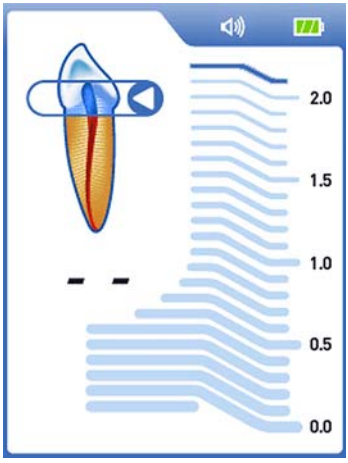
(While turning the device On without the measurement cable – the main screen will be displayed without cursor on the tooth image).

(3) Attach the lip clip to the patient.

(4) Gently insert the file into the canal – (to ensure precise measurements the file size should be adjusted to the canal diameter).

(5) Connect the hook to the file.

The cursor on the tooth will stop blinking (accompanied by a double beep signal).

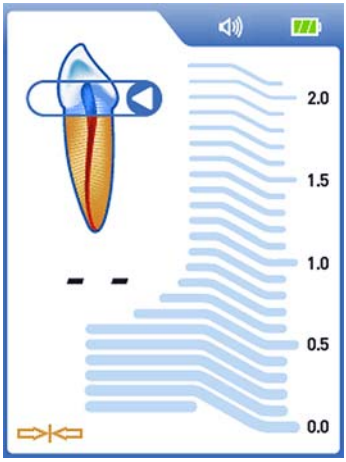


A blinking cursor and no sound signal indicates a faulty connection. Disconnect the measurement cable from the patient and check your connections, clean your hook connection, moisten the canal, if necessary, and start again.

No other adjustments are necessary before starting measurement.

Connection test feature is included in **ProPex® II** in order to check the cables:
- Connect metal part of the connection hook to the lip clip.
- "Connection test" icon should appear in the bottom left corner of the display, indicating proper connection.
- If no icon appears, the connection hook or the measurement cable should be replaced.

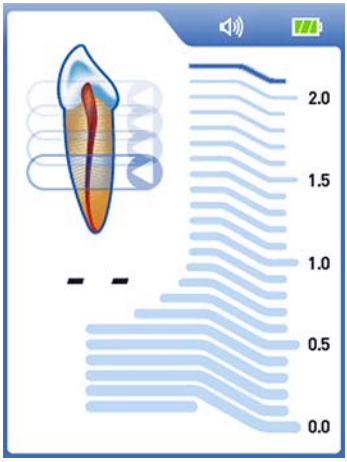
Measurement cable with attached lip clip and connection hook constitute Applied Parts of the device.



6.5 Searching for the Apex

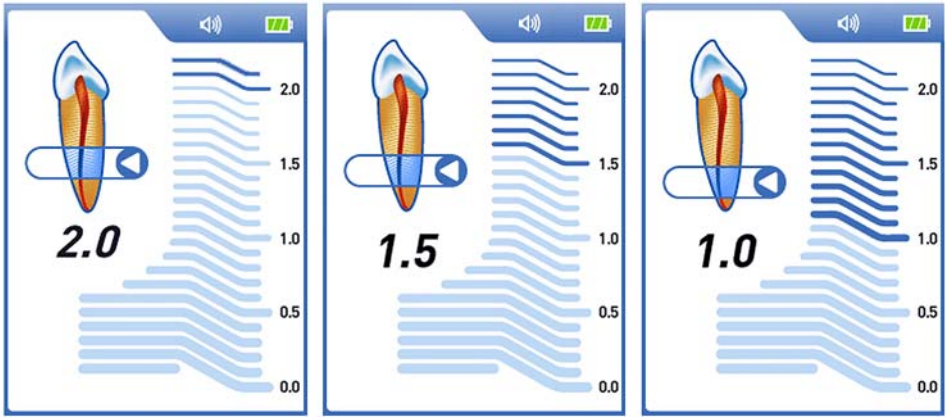
6.5.1 Coronal and Medial Zone

Slowly introduce the file into the canal and advance the file with slow clockwise turns. The cursor on the tooth icon indicates the progression of the file inside the canal.



Further progression of the file in the canal is shown both by the cursor on the tooth icon and by numerical value on the graphical scale. **ProPex® II** emits audible information of file progression via a series of progressive rate beeps. If the bar graph makes sudden large movements in the upper part of the canal, continue slightly towards the apex so the signal returns to normal.

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



6.5.2 Apical Zone

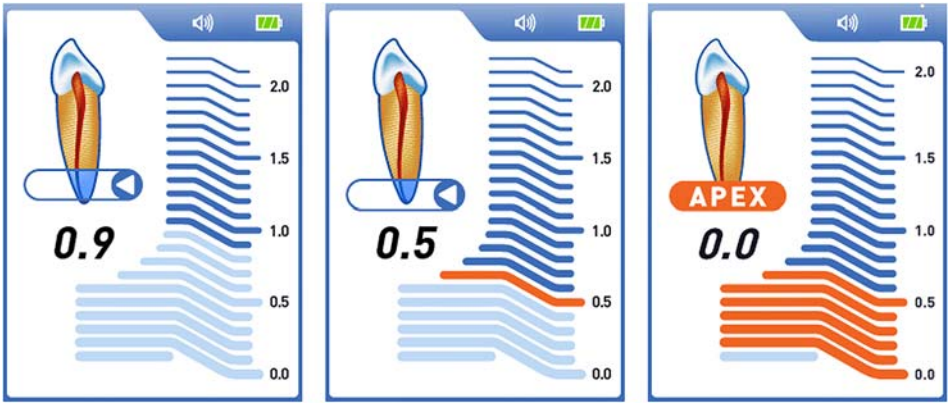
The apical zone is divided into 10 segments graduated from 0.9 to 0.0 (apex) as visual information of file progression.

When the apex is reached, the cursor shows “APEX” and a solid tone is emitted.

Beginning of Apical Zone

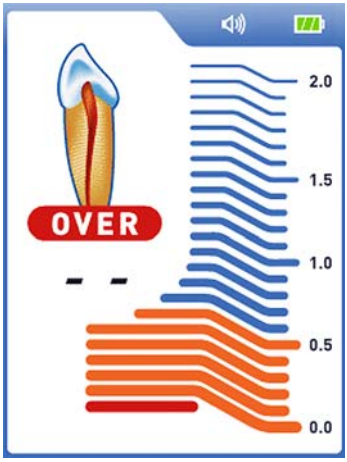
Middle of Apical Zone

Apical position



6.5.3 Over-Instrumentation

A red segment and a warning signal indicate that the file has passed the Apex. The cursor on the tooth icon shows “OVER”.



6.5.4 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 tip.

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 ® II** indicates ‘APEX’;
- place the file onto an endodontic ruler and measure the apical length;
- subtract a minimum of 0.5 mm from the measured file length.

6.6 Sound Adjustment

ProPex ® II is equipped with a sonic indicator which enables monitoring of the progression of the file within the canal.

This function, in conjunction with the display of progression, enables working "blind" while still monitoring the progression of the file.

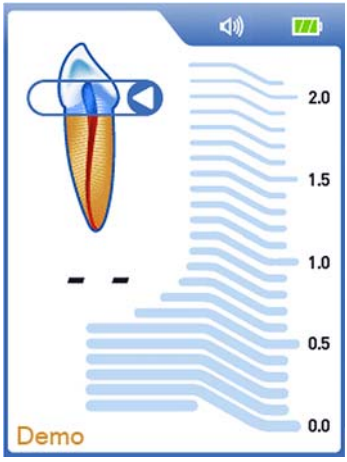
The volume can be adjusted to one of four levels: mute, low, normal and high, by successive presses on the volume key.

6.7 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 Off the device.

(2) To start Demo Mode, press and hold the (On/Off) button for about 2 seconds until the second beep sounds and “Demo” indication appears in the bottom left corner of the display.



(3) During Demo cycle device operating sequence is shown on the screen. Press ⏻ button to pause the simulation; press ⏻ button again to resume.

(4) When Demo cycle is completed, it is repeated automatically until interrupted by the operator.

(5) To exit Demo mode press ⏻ button and hold it for about 2 seconds until a beep sounds.



If measurement cable is connected to **ProPex ® II** during Demo cycle, the device switches automatically to normal operation mode.

6.8 Automatic Shutdown

ProPex ® II automatically shuts down after 5 minutes without use. It is advisable, however, to manually switch off equipment after measurement by simply pressing the ⏻ key (On/Off).

6.9 Maintenance of your ProPex ® II

- 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 the 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).
- Other recommendations:
  - do not expose **ProPex ® II** to any liquid. In particular, avoid spilling with chemical solutions used for treatment. These chemicals could cause damage, deform or discolor the device. Be especially careful to avoid spilling formalin cresol (FC) and sodium hypochlorite as they are quite aggressive. Wipe up any chemical spills immediately (some chemicals may leave discoloration and spots even if they are immediately wiped up);
  - handle the device carefully; do not drop, bump or expose the unit to any kind of impact or shock. Rough handling could cause significant damage;
  - do not drop anything on or bang the measuring cable plug after it has been inserted into the connector;
  - **ProPex ® II** must be stored in normal temperature (< 60°C) and humidity conditions.
- Reprocessing procedure:
  - the lip clip, the hook and the fork must be sterilized between treatments by autoclaving at 134°C;
  - the measuring cable cannot be autoclaved.

See the section **7 Cleaning, Disinfection and sterilization** for the detailed procedure.

7 CLEANING, DISINFECTION AND STERILIZATION

7.1 General Information

The measurement cable and the surface of the equipment should be cleaned with a paper towel or soft cloth or wipe that has been wetted with aldehyde-free disinfection and cleaning solution (bactericidal and fungicidal).

The lip clip, the hook and the fork must be cleaned, disinfected and sterilized before each use to prevent any contamination. This concerns the first use as well as the subsequent uses. The only way to ensure that these accessories are effectively sterilized is to thoroughly clean and disinfect them. When doing this, follow the instructions set out in this chapter.

When you use any of the other equipment that you have in your practice, make sure you follow the directions for use for this equipment. As part of your responsibility for ensuring that the accessories are sterile, always make sure that only validated cleaning, disinfection and sterilization methods are used, that the equipment (sterilizer) is regularly maintained and inspected, and that the validated parameters are adhered to each time.

In addition, ensure that you always comply with the applicable statutory rules and regulations with regard to hygiene in your practice or clinic. In particular, this applies to the directives on effective prion inactivation.

We accept no liability in the event that these instructions are disregarded or processes that have not been validated are used to prepare the accessories for reuse.

7.2 General Recommendations

- 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.
- For your own safety, please wear personal protective equipment (gloves, glasses, mask).
- Use only disinfecting solution which is approved for their efficacy (VAH/DGHM-listing, CE marking, FDA approval).

The cleaning, disinfection and sterilization process applies only to the lip clip, the hook and the fork. As long as they are treated with due care and are not damaged or contaminated, these accessories can be reused multiple times.

Make sure undamaged sterile packaging is used.

7.3 Procedure for Lip Clip, Hook and Fork

N°	Operation	Operating mode	Warning
1.	Pre-Disinfection or Decontamination	1. Pulp and dentine remnants must be removed from the accessories immediately. 2. 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. 3. 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.	1. 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. 2. Make sure that the products are fully immersed. 3. The disinfectant solution should be aldehyde free (to avoid blood impurities fixation), suitable for disinfecting the accessories, and compatible with the accessories. Note that 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.
2.	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.

N°	Operation	Operating mode	Warning
3.	Manual Cleaning	1. 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). 2. 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. 3. 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. 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

N°	Operation	Operating mode	Warning
4.	Disinfection	1. 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. 2. Remove the accessories from the disinfection bath and rinse them off thoroughly at least five times for a minute each time with water. 3. 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.
5.	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.
6.	Inspection	Inspect devices and sort out those with defects.	Defects include: - deformation of the plastic; - corrosion; - discoloration of the plastic. Dirty instruments must be cleaned and disinfected again. Maintenance is not required. Do not use instrument lubricant.

N°	Operation	Operating mode	Warning
7.	Packaging	Pack the devices in “Sterilization pouches”.	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.
8.	Sterilization	Steam sterilization at: 134°C (237°F) during 3 min.	The accessories (lip clip, hook and fork) must be sterilized according to the packaging labelling. Use fractionated vacuum or gravity (less preferred) autoclaves (according to EN 13060, EN 285). Use validated sterilization procedure according to ISO 17665-1. Respect maintenance procedure of the autoclave device given by the manufacturer. Use only the listed sterilization procedures.
9.	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 before using the instruments).

8 TECHNICAL CHARACTERISTICS

ProPex ® II complies to IEC60601-1 safety standard and the requirement of CE Marking of Conformity.

CE
0086

ProPex ® II electronic apex locator belongs to the following category of medical devices:

Specification	Description
Manufacturer	Maillefer Instruments Holding Sàrl Chemin du Verger 3 CH-1338 Ballaigues Switzerland endo@dentsplysirona.com
Model	**ProPex ® II** apex locator
Dimensions (Length x Height x Width)	130 x 80 x 63 mm
Weight	360 g
Type of screen	Color Graphic TFT
Screen dimensions	3.5“
Power supply	Rechargeable battery: 2.4 V NiMH
Charger power supply (input)	120 V or 230 V
Charger power supply (output)	6 VDC
Frequency	50 - 60 Hz
Type of protection against electrical shock	Internally powered equipment
Applied part	BF

Specification	Description
Safety level in the presence of flammable anesthetic gas mixtures or oxygen	Not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide
Mode of operation	Continuous operation
Ingress of liquids	Not protected
Ambient conditions	• Use: in enclosed spaces • Ambient temperature: 10°C - 40°C (50°F - 104°F) • Relative humidity: 10% - 90%, non-condensing • Operating altitude: 106 kPa to 70 kPa
Conditions for transport and storage	• Ambient temperature: -20°C - +60°C (-4°F - 140°F) • Relative humidity: 10% - 90%, non-condensing • Operating altitude: 106 kPa to 19 kPa
EMC Tables	See **Appendix 1** (page 34) and/or **Appendix 2** (page 41)

9 PROPEX ® II APEX LOCATOR ERROR CODE

None.

10 TROUBLESHOOTING

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



The following patient's 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.

N°	Problem	Possible cause	Solution
1.	Triple beep signal during battery charging.	The battery is not connected.	Open the battery compartment, and connect the battery as described in the User Manual.
		The battery is not a rechargeable type.	Replace the battery with a rechargeable type as described in the User Manual.
		Bad battery.	Replace the battery with a new one.
2.	The device does not turn on by pressing the “ON / OFF” button.	The battery is discharged.	Charge the battery.
		Button malfunction.	Try pressing the “ON/OFF” button several times.
		Electronic malfunction.	Contact your distributor.
3.	When the charger is connected, the battery charging screen does not appear.	Bad charger connection.	Disconnect the charger from the device and reconnect it again.
		Charger malfunction.	Replace the charger.
		Electronic malfunction.	Contact your distributor.
4.	The device shuts off during the procedure.	The battery is low.	Charge the battery.

N°	Problem	Possible cause	Solution
5.	No sound during the procedure.	The sound control is set at “Mute” level.	Adjust the sound level as described in the User Manual.
6.	Indication of file position 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.
7.	The device does not show file progression inside the canal.	Bad electrical contact.	Perform the cable connection test as described in the User Manual.
		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 re-treatment: 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.

N°	Problem	Possible cause	Solution
8.	Display reaction is over-sensitive: apex/over is activated before it 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 stopped.
		A direct contact of the file with the gingiva or gingival proliferations, e.g. a fractured metal crown.	For isolation: - adequate preparation filling; - use a rubber dam.
		A direct contact of the file with metal restorations (crown, parapulpal post, amalgam filling).	Isolate the file by placing 2-3 silicone stoppers on it or insert the file in a small polyvinyl tube before use.

11 WARRANTY

ProPex ® II 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.

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

12 DISPOSAL OF THE PRODUCT



PLEASE DO NOT THROW AWAY !

This product and all its components must absolutely be recycled through your supplier.

13 IDENTIFICATION OF SYMBOLS

On the device label appear standard symbols as follows:

Symbol	Identification
	Serial number
	Catalogue number
	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
	CE marking
	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Do not sterilize
	Accessory
	Plastic
	Carbon steel

Appendix 1

ELECTROMAGNETIC COMPATIBILITY
EMC according to IEC 60601-1-2 ed.3

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.



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



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



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.
Connection Fork	Original only.
Charger	Original charger only: Input: 120 V / 50 - 60 Hz or 230 V / 50 - 60 Hz Output: 6 VDC.

Guidance and manufacturer's declaration - electromagnetic emissions		
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.		
Emission 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 all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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 tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity for not life support equipment			
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 tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	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: $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). 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 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a Fixed 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 access the electromagnetic environment due to fixed RF transmitters, and 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 b observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Product. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the not life support 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 electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Product as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 0.35 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.1	1.1	2.2
100	3.5	3.5	7
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the higher frequency range applies. NOTE 1: At 80 MHz and 800 MHz, the separation distance fort the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix 2

ELECTROMAGNETIC COMPATIBILITY
EMC according to IEC 60601-1-2 ed.4

The **ProPex ® II** is intended for use in professional healthcare facility or home healthcare electromagnetic environment specified in this chapter.

The customer or the user of the **ProPex ® II** should assure that it is used in such an environment.

Changes or modifications to this **ProPex ® II** not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the **ProPex ® II** and could cause EMC issues with this or other equipment. This **ProPex ® II** 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.



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



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

Compliant Cables and Accessories



Use of non-original cables or accessories may result in increased emissions or decreased immunity performance of the **ProPex ® II**.

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.
Connection Fork	Original only.
Charger	Original charger only: Input: 120 V / 50 - 60 Hz or 230 V / 50 - 60 Hz Output: 6 VDC.

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 **ProPex ® II** is intended for use in professional healthcare facility or home healthcare electromagnetic environment specified below. The customer or the user or the **ProPex ® II** should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The **ProPex ® II** 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 **ProPex ® II** 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 **ProPex ® II** is intended for use in the electromagnetic environment specified below. The customer or the user of the **ProPex ® II** 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

Voltage dips Voltage interruptions IEC 61000-4-11	0% U_T; 0.5 cycle 0% U_T; 1 cycle and 70% U_T; 25/30 cycles 0% U_T; 250/300 cycles	0% U_T; 0.5 cycle 0% U_T; 1 cycle and 70% U_T; 25/30 cycles 0% U_T; 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 **ProPex ® II** requires battery charging during power mains interruptions it is recommended that the **ProPex ® II** 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 of domestic purposes, commercial or hospital, clinic environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **ProPex ® II** is intended for use in the electromagnetic environment specified below. The customer or the user of the **ProPex ® II** should ensure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced 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 the **ProPex ® II**, 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 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). 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: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: 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 **ProPex ® II** is used exceeds the applicable RF compliance level above, the **ProPex ® II** should be observed to verity normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **ProPex ® II**.

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 **ProPex ® II** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **ProPex ® II** 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	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

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CE
0086

Maillefer Instruments Holding Sàrl
Chemin du Verger 3
CH-1338 Ballaigues
Switzerland
email: endo@dentsplysirona.com