

# Propex IQ<sup>®</sup> Apex Locator

## Directions for Use



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## Table of contents

	<b>Introduction</b>	<b>5</b>
<b>1</b>	<b>Indications for Use</b>	<b>6</b>
<b>2</b>	<b>Contraindications</b>	<b>6</b>
<b>3</b>	<b>Warnings</b>	<b>7</b>
<b>4</b>	<b>Precautions</b>	<b>14</b>
<b>5</b>	<b>Adverse Reactions</b>	<b>14</b>
<b>6</b>	<b>Step by Step Instructions</b>	<b>14</b>
6.1	Document Symbols	15
6.2	Device Compatibility	15
6.3	Package Contents	16
6.3.1	Assembling the charger	19
6.4	Modes of Operation	19
6.5	Description of the <b>Propex IQ®</b> Apex Locator	21
6.5.1	General overview	21
6.6	Description of the LED Colors	22
6.7	Description of the Sounds	24
6.8	Plugging in the <b>Propex IQ®</b> Measurement Cable	25
6.8.1	Plugging in the <b>Propex IQ®</b> Measurement Cable in uncombined mode	25
6.8.2	Plugging in the <b>X-Smart IQ®</b> Measurement Cable in combined mode	26
6.9	Testing <b>Propex IQ®</b> Apex Locator Functionality	27
6.9.1	Closed-loop test	27
6.9.2	Device test	28
6.10	Determining the Working Length	30
6.10.1	Definition	30
6.10.2	Start working length determination	31
6.10.3	Working length determination	31
6.10.4	Uncombined mode	33

6.10.5	Combined mode .....	36
6.10.6	Interruption of file progression indication .....	38
6.10.7	Tips for successful file progression indication .....	38
6.10.8	Comparison of electronic length determination versus radiography ..	39
6.11	Stand-by Mode .....	40
6.12	Battery Care .....	41
6.12.1	Battery Replacement .....	42
<b>7</b>	<b>Cleaning, Disinfection and Sterilization .....</b>	<b>43</b>
7.1	General .....	43
7.2	Cleaning Procedure .....	44
7.3	Disinfection .....	46
7.4	Sterilization of the File Clip and Lip Clip .....	47
<b>8</b>	<b>Technical Characteristics .....</b>	<b>48</b>
<b>9</b>	<b>Propex IQ® Apex Locator Error Codes .....</b>	<b>51</b>
<b>10</b>	<b>Troubleshooting .....</b>	<b>53</b>
<b>11</b>	<b>Warranty .....</b>	<b>60</b>
<b>12</b>	<b>Disposal of the Product .....</b>	<b>61</b>
<b>13</b>	<b>Identification of Symbols .....</b>	<b>61</b>
13.1	Normative Symbols .....	61
	<b>Appendix A: Electromagnetic Emissions and Immunity .....</b>	<b>63</b>



## FOR DENTAL USE ONLY

# Introduction

Dear Customer,

Congratulations on your purchase of **Propex IQ®** Apex Locator.

**Propex IQ®** Apex Locator is an electronic device for support in working length determination using endodontic instruments.

It can be used in:

- Uncombined mode (**Propex IQ®** Apex Locator only);
- Combined mode with **X-Smart IQ®** Handpiece;
- Connected mode (**Propex IQ®** Apex Locator in wireless communication with **Endo IQ®** App available for iPad®).

These Directions for Use (DFU) are kept up-to-date by Dentsply Sirona. The most current version can be accessed at [dentsplysirona.com](http://dentsplysirona.com) and is also available from **Endo IQ®** App. We strongly recommend that you periodically check this website for updates of this DFU.

The DFU is available in other languages upon request. If a printed version in your language is not enclosed, Dentsply Sirona will send a free copy to any address in Europe. To order a free copy of the DFU, send a request to [endo@dentsplysirona.com](mailto:endo@dentsplysirona.com).

Some images in the DFU may vary slightly from the actual device. We would appreciate your feedback. If any errors are noted, please contact Dentsply Sirona Endodontics Customer Service.



Maillefer Instruments Holding Sàrl  
Chemin du Verger 3  
CH-1338 Ballaigues  
Switzerland

Telephone +41 21 843 92 92  
Fax +41 21 843 92 93  
[endo@dentsplysirona.com](mailto:endo@dentsplysirona.com)  
[dentsplysirona.com](http://dentsplysirona.com)

# 1 INDICATIONS FOR USE

**Propex IQ®** Apex Locator supports the dentist in the determination of the working length during the endodontic treatment. The use of this product is destined exclusively to duly qualified dental practitioners.

The use of this product by unqualified, or untrained personnel can result in patient injury, personal injury and / or material damage.

Disposable Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. **Propex IQ®** Disposable Barrier Sleeve is non-sterile and intended for single patient use only.

To guarantee the safety, intended functionalities and good maintenance of **Propex IQ®** Apex Locator, follow the indications given in the present Directions for Use (DFU). Keep the DFU updated as per described in the Introduction section. Dentsply Sirona will not accept any liability if **Propex IQ®** Apex Locator is used, stored or manipulated outside of the indications given in the DFU.

# 2 CONTRAINDICATIONS

Read the following contraindications before use.

- Do not use **Propex IQ®** Apex Locator on patients wearing active implantable devices such as a heart pacemaker or defibrillator.
- The use of **Propex IQ®** Apex Locator is not recommended in patients allergic to metals. Check Section [8 Technical Characteristics](#) for a list of materials used.
- Do not use **Propex IQ®** Apex Locator for implants or any other dental procedure outside endodontics.
- Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.
- The end user of the device should use clinical judgment for its proper use.
- Color-blind users must ensure that they always operate the device with the sound ON, and that they are familiar with the various sound signals before using the device for the first time. Check section [6.7 Description of the Sounds](#) before using the device.
- Hearing-impaired users must ensure familiarity with the various visual signals before using the device for the first time. Check section [6.6 Description of the LED Colors](#) before using the device.
- The device is not indicated for users both color-blind and hearing-impaired unless they have these difficulties balanced out.

### 3 WARNINGS

Read the following warnings before use.



Some sections / texts of this DFU are dedicated uniquely to readers from a specific territory. When this happens the section / text will be clearly identified with a sentence similar to: For US / EU readers. If nothing is indicated, the text is applicable to all of the intended territories.



Dentsply Sirona accepts no liability in the event that any of these warnings are disregarded.

Check the outer packaging seal on reception. Do not use the device if the packaging seal has been broken. Contact customer service.

Report discrepancies between labeling and packaging, or issues with either, to customer service.

#### Dental Practitioner

- Read the full DFU before using **Propex IQ®** Apex Locator on a patient. Operate **Propex IQ®** Apex Locator only in accordance with this DFU to ensure safe and effective use.
- Ensure that you have a suitable working distance to see the display from your working position.
- **Propex IQ®** Apex Locator and the **Endo IQ®** App are intended for:
  - Endodontic treatment.
  - Use by trained and qualified professionals only, such as:
    - dentists in dental practice, and
    - dental assistants for cleaning and preparation of the device only, and in accordance with this DFU.

#### Environmental conditions

- Do not use **Propex IQ®** Apex Locator in the presence of free oxygen, anesthetics, flammable substances / gases or in a potentially explosive environment.
- **Propex IQ®** Apex Locator must be operated and stored in a safe, dry and clean environment.
- Place **Propex IQ®** Apex Locator on a flat and stable surface (if used without the clamp) or firmly attached to the lab coat (when used with the clamp).
- **Propex IQ®** Apex Locator must not be placed on damp surfaces, in damp locations or near liquids.
- Do not expose **Propex IQ®** Apex Locator to direct or indirect heat sources.
- Avoid collisions and falls. After a fall, please check that **Propex IQ®** Apex Locator works properly (refer to section [6.9 Testing Propex IQ® Apex Locator Functionality](#)).

- **Propex IQ®** Apex Locator contains a Bluetooth® module and may cause radio interference or disrupt the operation of equipment in its vicinity. If this happens, the interference should be reduced by reorienting or repositioning **Propex IQ®** Apex Locator or by screening off its immediate environment. For further information refer to [Appendix A: Electromagnetic Emissions and Immunity](#).
- **Propex IQ®** Apex Locator requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC Directive. In particular, **Propex IQ®** Apex Locator must not be used in the vicinity of fluorescent lamps, radio transmitters, remote controls or portable / mobile RF communication devices, even if they meet CISPR 11 requirements. See [Appendix A: Electromagnetic Emissions and Immunity](#).
- Make sure cables do not limit mobility during a procedure.
- Do not kink the cables or the charger.
- Do not pull directly on the cables when plugging in or unplugging components. Make sure the cables are not obstructed or have limited mobility.
- Refer also to section [8 Technical Characteristics](#) for general Environmental Conditions specifications.
- Use of **Propex IQ®** Apex Locator adjacent to, or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **Propex IQ®** Apex Locator and the other equipment should be observed to verify that they are operating normally.
- Do not expose **Propex IQ®** Apex Locator to infrasound or ultrasound sources.

#### During treatment

- Ensure that contact point between file and file clip are kept dry to avoid inaccurate readings.
- Make sure that the **Propex IQ®** Lip Clip and the **Propex IQ®** File Clip do not come into contact with an electric power source such as an electrical socket. This could result in severe electrical shock.
- The cable functionality must be checked with a closed-loop test before each use. See [6.9.1 Closed-loop test](#).
- If the **Propex IQ®** File Clip is not properly connected to the endodontic instrument, **Propex IQ®** Apex Locator will not provide correct information and the file clip could be damaged.
- Use of gloves and of a rubber dam are mandatory during treatment.
- Do not pour water or any other liquid over **Propex IQ®** Apex Locator.

- The use of Dentsply Sirona **Propex IQ®** Disposable Barrier Sleeves is required (see section **7 Cleaning, Disinfection and Sterilization**). Use only custom barriers provided by Dentsply Sirona made specifically for **Propex IQ®** Apex Locator.
- Always perform an X-ray and set the stopper to the determined working length before using **Propex IQ®** Apex Locator.
- Before starting the reading, dry the access cavity with a cotton pellet and ensure that there is no excess of liquid inside the root canal targeted for the treatment. An excess of liquid can hinder the reading process. Take into account that the canal should not be completely dry otherwise no reading will occur. Moisten an extremely dry canal with Glyde™ file prep to help provide a stable reading.
- Before starting the treatment, make sure that the device is in a stable position (over a flat surface or firmly attached to the lab coat if using the clamp) to ensure that the treatment can be done comfortably and that any visual / auditory signals emitted by **Propex IQ®** Apex Locator can be received.
- If any irregularities with **Propex IQ®** Apex Locator should occur during treatment, switch it off, consult Section **10 Troubleshooting** or Contact Dentsply Sirona Endodontics Customer Service.
- The scale indication on **Propex IQ®** Apex Locator and on **Endo IQ®** App does not represent a distinct length or distance in [mm] or other linear units. It only indicates an estimated proximity of the file tip to a reference point for working length determination.
- Make sure to use only fully metallic endodontic files whether in combined mode or in uncombined mode.
- Only use undamaged endodontic instruments, meaning the instruments shall be in good condition and within their useful life (as defined by the manufacturer). Please, refer to the information provided by the manufacturer of the instrument.
- An accurate working length determination cannot be made using a damaged **Propex IQ®** File Clip.
- Only use original cables and adaptors.
- The following patient-related factors may prevent accurate readings:
  - Blocked root canal.
  - Teeth with large apices.
  - Root fracture or perforation.
  - Metal crowns or bridges.
  - Endodontic file not matching canal size (canal size much larger than endodontic file size).

- If there is no audible sound or no visible flash of the LEDs when **Propex IQ®** Apex Locator is switched on, do not use it.
- Always switch off **Propex IQ®** Apex Locator before cleaning it.
- Dentsply Sirona cannot be held liable if **Propex IQ®** Apex Locator is not installed, operated and maintained in accordance with the instructions in this DFU. No modifications to **Propex IQ®** Apex Locator are allowed, except battery changes (see following Section).
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **Propex IQ®** Apex Locator (IEC 60601-1), including cables specified by Dentsply Sirona. Failure to observe this could result in a degradation of the performance of this equipment. For further information, refer to [Appendix A: Electromagnetic Emissions and Immunity](#).

#### After Treatment

- Never leave **Propex IQ®** Lip Clip or **Propex IQ®** File Clip in contact with a patient if either of them is not plugged into the measurement cable. This could result in severe electrical shock if they come into contact with an electrical source.
- Follow instructions given in section [7 Cleaning, Disinfection and Sterilization](#).

#### Battery

- Always use the original charger with the charging cable to charge **Propex IQ®** Apex Locator. Use of non-original chargers may result in serious risk for the safety of the user.
- Regularly check for signs of battery leakage.
- If fluid leaks from **Propex IQ®** Apex Locator, the battery may be damaged. Stop using the device immediately. If the leakage occurs while charging, disconnect the charger immediately. Avoid skin contact with the leaking fluid and contact the Dentsply Sirona Endodontics Customer Service as soon as possible.
- Do not recharge the battery in case of suspected faulty/ leaking battery.
- Do not use batteries past the expiry date (when provided).
- Never use a battery that is deformed, discolored or otherwise abnormal.
- If the batteries do not charge fully after 6 hours, they should be replaced.
- To charge the device, connect the charger to electrical mains compliant with the regulations in each country.
- Be sure to purchase and use only the original battery (part reference: for EU B00PPIQ2ACBAT, for US T00PPIQ2ACBAT).
- Only charge **Propex IQ®** Apex Locator out of patients reach.

- Only perform **Propex IQ®** Apex Locator test out of patients reach. Use new gloves to avoid contamination of the external tester.
- Only open **Propex IQ®** Apex Locator to change the batteries (see section [6.12.1 Battery Replacement](#)). Removing more than the bottom cover of **Propex IQ®** Apex Locator voids the warranty. Contact Dentsply Sirona Endodontics Customer Service for assistance.
- Fully charge **Propex IQ®** Apex Locator prior to its first use (6 hours charging time).
- Always ensure that both **Propex IQ®** Apex Locator and the iPad® have sufficient battery charge before starting treatment. At low battery level, **Propex IQ®** Apex Locator should not be used. See section [6.12 Battery Care](#).
- **Propex IQ®** Apex Locator must not be charged during treatment.
- **Propex IQ®** Apex Locator with an empty battery will not provide any audio or visual signals.

#### Combined mode

- **Propex IQ®** Apex Locator can be used in combined mode with **X-Smart IQ®** Handpiece.
- Only use **X-Smart IQ®** Handpiece for working in combined mode. Using **Propex IQ®** Apex Locator with another Handpiece can lead to severe electrical problems (including electrical shock).
- Only use Dentsply Sirona accessories and spare parts.
- Do not plug the **Propex IQ®** original cables into any other devices with compatible plugs.
- The use of the **X-Smart IQ®** Handpiece Sleeve is mandatory to ensure proper functioning of the system in combined mode. The barrier is designed for single use and must be disposed of and changed after each patient.
- Please ensure that you have the latest version of **X-Smart IQ®** Handpiece firmware and of **Propex IQ®** Apex Locator firmware to work in combined mode.



*For further information on **X-Smart IQ®** Handpiece Sleeve, please refer to **X-Smart IQ®** Handpiece Directions For Use.*



*Please read **X-Smart IQ®** Handpiece Directions For Use - **3 Warnings** before using **X-Smart IQ®** Handpiece.*



*Please read **Endo IQ®** App User Manual - **3 Warnings** before using **Endo IQ®** App.*

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### Accessories

- **Propex IQ®** Lip Clip and **Propex IQ®** File Clip are supplied unsterilized. You must reprocess them prior to first use and between patients (Follow instructions given in section [7 Cleaning, Disinfection and Sterilization](#)).
- Use Dentsply Sirona components / accessories and spare parts only. Using non-original accessories / spare parts can lead to increased emission of electromagnetic interferences or to reduced electromagnetic interference immunity.
- Examine the state of the connectors before use.
- Never leave **Propex IQ®** Lip Clip or **Propex IQ®** File Clip unplugged to the **Propex IQ®** Measurement Cable while in contact with a patient.

### Repairs and Defects

- Check if **Propex IQ®** Apex Locator works properly, if it has been subjected to mechanical shock or impact (e.g. if it has been dropped). Do not use it in case of malfunction, apparent breakage or cracks. The safety and effectiveness of the device can be seriously compromised. In cases of major shock, **Propex IQ®** Apex Locator needs to be inspected by authorized technical personnel. Contact Dentsply Sirona Endodontics Customer Service for assistance.
- **Propex IQ®** Apex Locator does not contain user serviceable parts (except batteries). The service and repair should be provided by factory trained service personnel only. Therefore, repairs, alterations and modifications to **Propex IQ®** Apex Locator are not permitted. Dentsply Sirona cannot be held liable if **Propex IQ®** Apex Locator has been altered or modified. If a defect should occur, contact Dentsply Sirona Endodontics Customer Service.
- It is mandatory to reprocess **Propex IQ®** Apex Locator and its accessories (including cables and tester) before shipping them to the service centre (follow instructions given in section [7 Cleaning, Disinfection and Sterilization](#)).
- Protect **Propex IQ®** Apex Locator with appropriate packaging when sending it for service.

### Transport

- Intact **Propex IQ®** Apex Locator can be transported by land freight or airfreight in the original packaging. The applicable requirements must be met (see table below).
- Defective **Propex IQ®** Apex Locator with intact battery can also be transported by airfreight or land freight in the original packaging.
- If the battery is defective (refer to Battery section above to identify defective batteries), **Propex IQ®** Apex Locator must not be transported by airfreight under any circumstances.



Applicable standards and regulations for the transport of **Propex IQ®** Apex Locator

	Air freight	Land freight
Intact <b>Propex IQ®</b> Apex Locator or defective <b>Propex IQ®</b> Apex Locator with intact battery.	<ul style="list-style-type: none"> <li>IATA: The batteries are considered "Not restricted" as long as they are shipped in compliance with SP A199.</li> <li>USA: 19 CR 172.102 Provisions 130 and 340.</li> </ul>	<ul style="list-style-type: none"> <li>UN 3496 NiMH (Nickel-metal hydride) batteries in equipment.</li> <li>EU (ADR / RID) Section 3.2 Table A: Batteries, nickel-metal hydride, "Not subject to ADR".</li> </ul>
<b>Propex IQ®</b> Apex Locator with defective battery.	Not possible.	<ul style="list-style-type: none"> <li>EU (ADR / RID) Identified damaged or defective batteries shall be carried in accordance with especial provision 376 and packaged in accordance with packaging instructions P908 of 4.1.4.1 or LP904 of 4.1.4.3 as applicable.</li> </ul>

Electromagnetic emissions and immunity

- HF (high-frequency) surgical equipment can influence the operation of the device and may not be operated in combination with **Propex IQ®** Apex Locator.
- Portable wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkie etc. can affect **Propex IQ®** Apex Locator and should be kept at least at a distance of 30 cm (12 inches) to any part of **Propex IQ®** Apex Locator.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the **Propex IQ®** Apex Locator or replacement parts for internal components, may result in increased emissions or decreased immunity of the **Propex IQ®** Apex Locator.
- Use of **Propex IQ®** Apex Locator adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **Propex IQ®** Apex Locator and the other equipment should be observed to verify that they are operating normally

## 4 PRECAUTIONS

Read the following precautions before use.

- The manufacturer declines any responsibility in the case of using **Propex IQ®** Apex Locator outside of its intended use or indications specified in this DFU. Please refer to sections **1 Indications for Use** and **3 Warnings** for further information on the indications for use.
- **Propex IQ®** Apex Locator may not be able to work properly in all conditions (see Sections **2 Contraindications** and **3 Warnings**).
- It is mandatory to take preoperative radiographs prior to using **Propex IQ®** Apex Locator and to compare the information given by both methods. In case of clinically relevant discrepancy, it is recommended to take a second radiograph with an endodontic file in place at the selected working length.

## 5 ADVERSE REACTIONS

The use of **Propex IQ®** Apex Locator is not recommended with patients allergic to metals (see Section **8 Technical Characteristics**).

If **Propex IQ®** Apex Locator provides an incorrect reading and there is no radiographic data to compare to, the following adverse reactions may occur:

- Inadequate root canal treatment due to under- or over-instrumentation.

## 6 STEP BY STEP INSTRUCTIONS

Refer to the section **3 Warnings** to verify any special care to exercise before starting to use the device.

Refer to the section **13 Identification of Symbols** to verify the description of all symbols before starting to use the device.







Refer to **Endo IQ®** App User Manual for all information regarding **Propex IQ®** Apex Locator connection with **Endo IQ®** App.

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Before use, check the exact contents of the package. See **6.3 Package Contents**.

## 6.1 Document Symbols

Symbol	Identification
	Consult <b>Endo IQ®</b> App User Manual or <b>Propex IQ®</b> Apex Locator Directions For Use
	If the instructions are not followed properly, operation may carry risks for the product or the user / patient
	Additional information, explanation on operation and performance
	Suggestion or advice





## 6.2 Device Compatibility

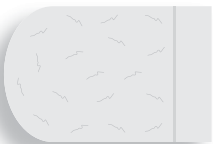



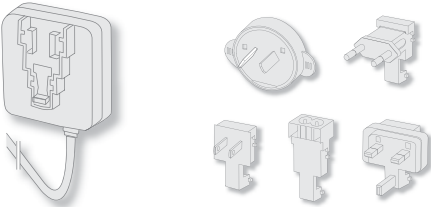
Specification	Description
iPad®	<ul style="list-style-type: none"> <li>• iPad Mini™ 2</li> <li>• iPad Mini™ 3</li> <li>• iPad Mini™ 4</li> <li>• iPad® (6<sup>th</sup> gen)</li> <li>• iPad Pro® 10.5"</li> <li>• iPad Pro® 12.9" (2<sup>nd</sup> gen)</li> </ul>
<b>Endo IQ®</b> App operating system	<ul style="list-style-type: none"> <li>• iOS</li> </ul>
<b>X-Smart IQ®</b> Handpiece	<ul style="list-style-type: none"> <li>• Original Dentsply Sirona <b>X-Smart IQ®</b> Handpiece</li> </ul>

\*Apple®, the Apple logo, iPad®, iPad Pro® and iPad Mini™ are trademarks of Apple Inc., registered in the U.S. and other countries. App Store® is a service mark of Apple Inc.

6.3 Package Contents

N°	Action
A	Remove carefully the device and the accessories from their packaging and place them on a flat surface.
B	Check that <b>Propex IQ®</b> Apex Locator is supplied with all the components shown below and that all components are in good condition.

List of components with Dentsply Sirona Stock Keeping Unit	
<b>Propex IQ®</b> Apex Locator B00PPIQ000000 (supplied with rechargeable battery B00PPIQ2ACBAT)	
<b>Propex IQ®</b> Measurement Cable B00PPIQ1ACCBL	
<b>X-Smart IQ®</b> Measurement Cable B00PPIQ1ACHPA	
<b>Propex IQ®</b> External Tester B00PPIQ1ACTST (There may be pins attached to the back of the tester depending on the tester version. These pins have no function)	

List of components with Dentsply Sirona Stock Keeping Unit	
<b>Propex IQ® Disposable Barrier Sleeve*</b> (x 100) B00PPIQ1ACBAR (replacement polyethylene sleeves are supplied separately)	
<b>Propex IQ® Lip Clip</b> (x 5) B00PPIQ5ACLCL	
<b>Propex IQ® File Clip</b> (x 2) B00PPIQ2ACFCL	
<b>Propex IQ® Clamp*</b> B00PPIQCLAMP0	
<b>AC Adapter Plugs</b> (*EU, *UK, US, *ANZ and universal adapter) B00PPIQ1ACCHG	
<b>Getting Started Guide(s) / DFU</b>	-

\*These components are not available in all kits

## Optional Propex IQ® Clamp

The device is delivered with an optional clamp (if available in your country), which can be installed on the back of the device with a screw (included in the package). The clamp can be installed with a standard flat / slot drive screwdriver (not included in the package). Remove the grub screw before attaching the clamp.














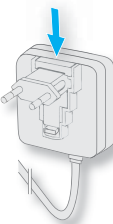
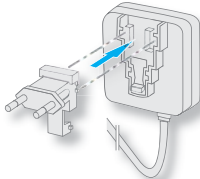
## Components not included

The following components are not included in the kit:




iPad® with iOS operating system.



6.3.1 Assembling the charger

N°	Action
A	Select the charger plug adapter that matches your power outlet.
B	Place the plug adapter into the slots and slide it downwards until it locks with a click.
<div><div></div><div></div><div></div></div>	

6.4 Modes of Operation

**Propex IQ®** Apex Locator can be used in 2 different modes:

Uncombined mode	Combined mode
Working only with <b>Propex IQ®</b> Apex Locator.	<div>Working with <b>Propex IQ®</b> Apex Locator plugged to <b>X-Smart IQ®</b> Handpiece for shaping towards the reference point while receiving endodontic file progression information.</div> <div><div><b>Propex IQ®</b> Apex Locator can be used while <b>X-Smart IQ®</b> Handpiece motor is rotating. The use of <b>X-Smart IQ®</b> Handpiece Sleeve is mandatory to ensure the proper functioning of the system in combined mode.</div></div>

Uncombined mode	Combined mode
	<p>The <b>X-Smart IQ®</b> Handpiece sleeve supplied in your country may look different from the <b>X-Smart IQ®</b> Handpiece sleeve shown on the illustration</p> 
For cable connection see <b>6.8.1 Plugging in the Propex IQ® Measurement Cable in uncombined mode.</b>	For cable connection see <b>6.8.2 Plugging in the X-Smart IQ® Measurement Cable in combined mode.</b>



On both operating modes, the device can be connected to the **Endo IQ®** App.

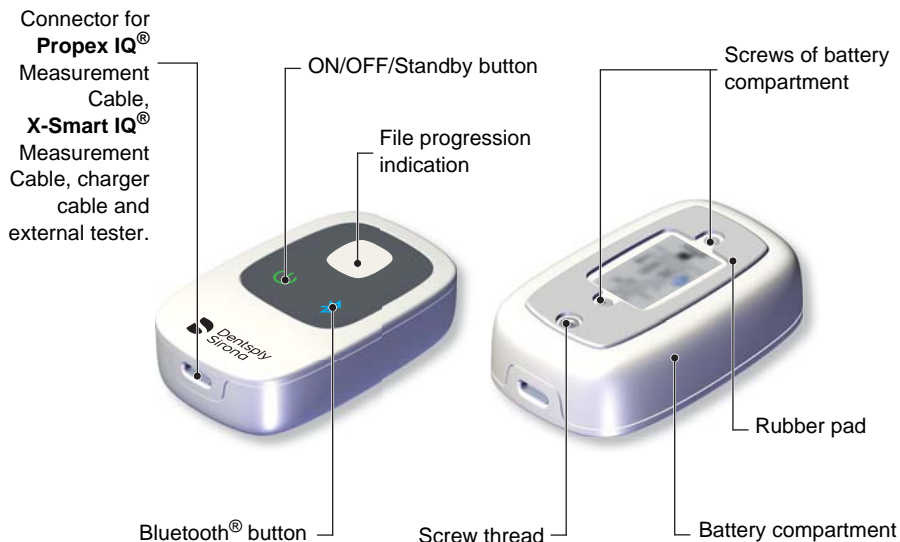


Refer to **Endo IQ®** App User Manual.














## 6.5 Description of the Propex IQ<sup>®</sup> Apex Locator



















### 6.5.1 General overview



The screw thread provides the ability to connect a **Propex IQ<sup>®</sup>** Clamp. Check with your distributor for more information about the clamp (if not included in the kit). The illustration above might slightly differ from the actual product.

## 6.6 Description of the LED Colors

Button / LED	Function	Status	Description
	All LEDs will light up white for a short period of time at the startup of <b>Propex IQ®</b> Apex Locator.		
	Power status		<b>Propex IQ®</b> Apex Locator is off.
			Device is powering on.
			Device is on.
			Stand-by. <i>LED flashing every 2.5 seconds, with a color corresponding to battery status.</i>
	Battery status		Device is charging. <i>LED flashing every second.</i>
			Device is sufficiently charged. <i>Enough autonomy for several procedures.</i>
			Low battery level. <i>Enough autonomy for approximately 15 minutes.</i>
			Very low battery level. <i>Enough autonomy for approximately 5 minutes. Do not start a new treatment at this battery level.</i>
			Critically low battery level. <i>There is no autonomy left. Please recharge your <b>Propex IQ®</b> Apex Locator.</i>

Button / LED	Function	Status	Description
	Connection of <b>Propex IQ®</b> Apex Locator with the <b>Endo IQ®</b> App		Bluetooth® not activated.
			Bluetooth® active but device not connected.
		 	Device connected to <b>Endo IQ®</b> App. See <b>Endo IQ® App User Manual - 6 Step by Step Instructions.</b>
		 	Connection lost. See <b>Endo IQ® App User Manual - 10 Troubleshooting.</b>
			Shaping target reverted to default setting 5 minutes after connection loss (if no file progress information was received during that time).
	Endodontic file progress information	   	File progress information. <i>The color (blue, green flashing, green, red flashing) varies according to the progression of the file in the root canal.</i> See <b>6.10.3 Working length determination.</b>
	Closed-loop test (See <b>6.9.1 Closed-loop test</b> )		Closed-loop test is successful. See <b>6.9.1 Closed-loop test.</b>
			Closed-loop-test failed. <i>Any indication other than white steady or no indication at all.</i> See <b>10 Troubleshooting.</b>
	Device test (see <b>6.9.2 Device test</b> )		Device test is on-going.
			Device test is successful. <i>The LED is ON until the <b>Propex IQ®</b> External Tester is unplugged.</i>
			Device test failed. <i>The LED is ON until the <b>Propex IQ®</b> External Tester is unplugged.</i>

## 6.7 Description of the Sounds



Sound volume can only be adjusted through the **Endo IQ®** App.



See **Endo IQ®** App User Manual - **6 Step by Step Instructions**.

Situation	Signal
<b>Any button pressed</b>	<ul style="list-style-type: none"> <li>One short beep.</li> </ul>
<b>Propex IQ® External Tester connected</b>	<ul style="list-style-type: none"> <li>Two short beeps</li> </ul>
<b>Combination of Propex IQ® Apex Locator with X-Smart IQ® Handpiece</b>	<ul style="list-style-type: none"> <li>Double beep if <b>Propex IQ®</b> Apex Locator is correctly combined with <b>X-Smart IQ®</b> Handpiece.</li> <li>No beep if an unknown cable is plugged or if <b>Propex IQ®</b> Apex Locator is incorrectly combined with <b>X-Smart IQ®</b> Handpiece.</li> <li>Three longer beeps if the combination is lost.</li> </ul> <p>See <b>6.10.5 Combined mode</b>.</p>
<b>Device test</b>	<ul style="list-style-type: none"> <li>Double beep when <b>Propex IQ®</b> Apex Locator device test is successful.</li> <li>Alternating beeps when <b>Propex IQ®</b> Apex Locator device test failed.</li> </ul> <p>See <b>6.9.2 Device test</b>.</p>
<b>Working length determination</b>	<ul style="list-style-type: none"> <li>Beeping intervals become shorter as endodontic file progresses towards reference point for working length determination.</li> <li>At reference point, continuous tone until apical foramen (major apical foramen/ diameter) is passed.</li> <li>Fast pulsating tones (alarm condition) when file passes the apical foramen.</li> </ul> <p>See <b>6.10.3 Working length determination</b>.</p>

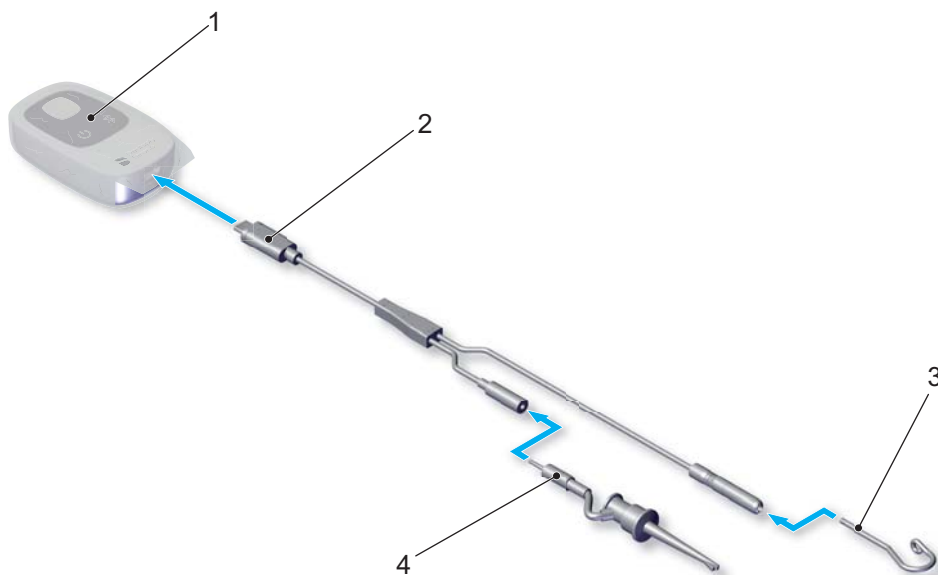


**X-Smart IQ®** Handpiece will rotate in reverse direction when **Propex IQ®** Apex Locator is uncombined during a treatment and the Apical Reverse function is activated.




## 6.8 Plugging in the Propex IQ® Measurement Cable

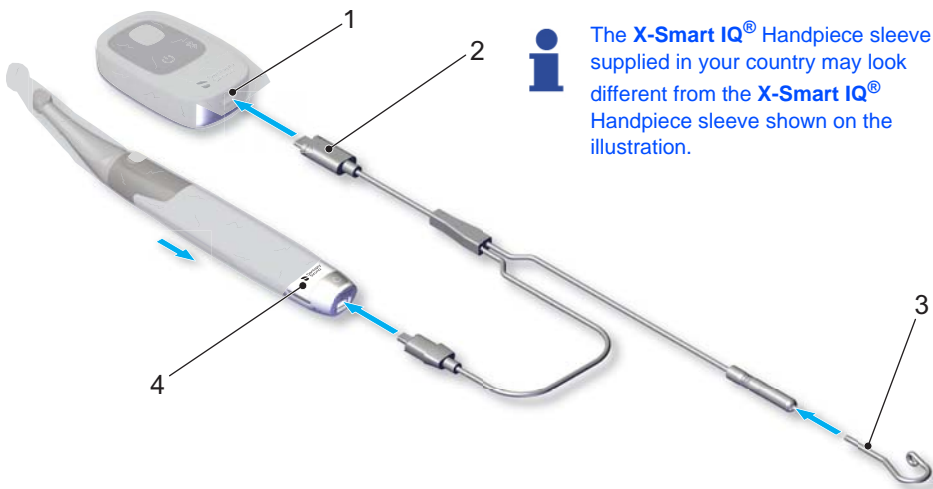
### 6.8.1 Plugging in the Propex IQ® Measurement Cable in uncombined mode

N°	Action
A	Insert <b>Propex IQ®</b> Apex Locator inside its proprietary single use protective sleeve.
B	Plug in the <b>Propex IQ®</b> Measurement Cable (2) to <b>Propex IQ®</b> Apex Locator (1).
C	Connect the <b>Propex IQ®</b> Lip Clip (3) to the <b>Propex IQ®</b> Measurement Cable (2).
D	Connect the <b>Propex IQ®</b> File Clip (4) to the <b>Propex IQ®</b> Measurement Cable (2).



6.8.2     **Plugging in the X-Smart IQ® Measurement Cable in combined mode**


N°	Action
	Only use <b>X-Smart IQ®</b> Handpiece for working in combined mode. Using <b>Propex IQ®</b> Apex Locator with another Handpiece can lead to severe electrical problems (including electrical shock).
A	Insert <b>X-Smart IQ®</b> Handpiece inside its proprietary single-use protective sleeve.
	The use of the <b>X-Smart IQ®</b> Handpiece Sleeve is mandatory to avoid contact between the contra-angle and the patient's mouth, which might cause wrong readings on <b>Propex IQ®</b> Apex Locator.
B	Insert <b>Propex IQ®</b> Apex Locator inside its proprietary single-use protective sleeve.
C	Plug in the <b>X-Smart IQ®</b> Measurement Cable (2) to <b>Propex IQ®</b> Apex Locator (1).
D	Connect the <b>Propex IQ®</b> Apex Locator Lip Clip (3) to the <b>X-Smart IQ®</b> Measurement Cable (2).
E	Plug in <b>X-Smart IQ®</b> Handpiece (4) to the <b>X-Smart IQ®</b> Measurement Cable (2).
	For further information on <b>X-Smart IQ®</b> Handpiece Sleeve, please refer to <b>X-Smart IQ®</b> Handpiece Directions For Use.

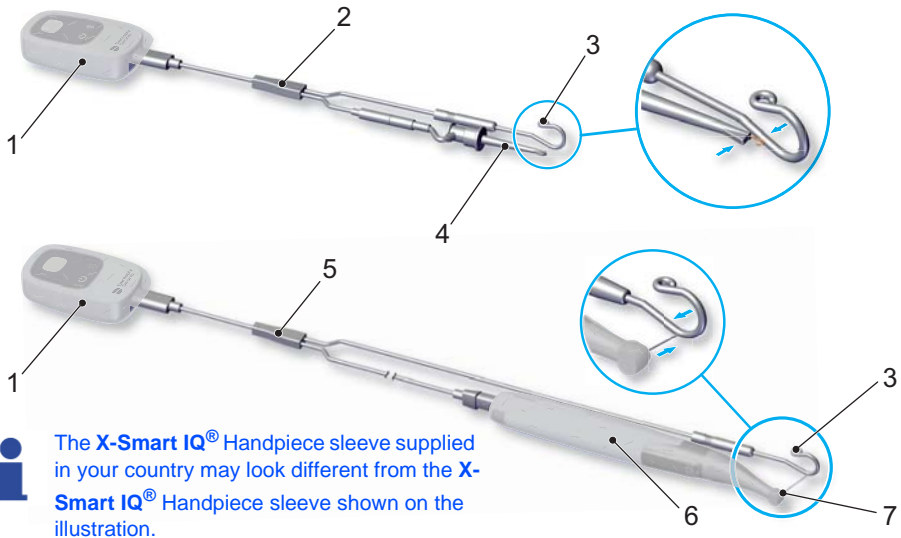


## 6.9 Testing Propex IQ® Apex Locator Functionality

### 6.9.1 Closed-loop test

This feature checks the cables. This test should be performed before each treatment.

N°	Action
A	Turn ON <b>Propex IQ®</b> Apex Locator (1). See <a href="#">6.6 Description of the LED Colors</a> .
B	Connect the <b>Propex IQ®</b> or <b>X-Smart IQ®</b> Measurement Cable (2 or 5) to <b>Propex IQ®</b> Apex Locator (1).
C	Connect the <b>Propex IQ®</b> Lip Clip (3) and the <b>Propex IQ®</b> File Clip (4) or <b>X-Smart IQ®</b> Handpiece (6) to the <b>Propex IQ®</b> or <b>X-Smart IQ®</b> Measurement Cable (2 or 5). Ensure that an endodontic file is inserted in the <b>X-Smart IQ®</b> Contra-angle.
D	Make a closed-loop circuit with the <b>Propex IQ®</b> or <b>X-Smart IQ®</b> Measurement Cable: Hook the <b>Propex IQ®</b> File Clip (4) to the lip clip (3) or put the lip clip (3) in contact with the endodontic file inserted in the <b>X-Smart IQ®</b> Contra-angle (7). <b>Propex IQ®</b> Apex Locator (1) central LED will turn white indicating that cables are functional. <i>Any result other than white indicates a test fail.</i>
 If the closed-loop test failed, please refer to <a href="#">10 Troubleshooting</a> .	



6.9.2 Device test

Use the **Propex IQ®** External Tester to test the basic functionality of the **Propex IQ®** Apex Locator. Run this test periodically (e.g. once a week), after the device has not been used for a long period of time or for troubleshooting reasons (as per Section [10 Troubleshooting](#)).



The **Endo IQ®** App will guide you through the different steps of the device test.





See **Endo IQ®** App User Manual - [6 Step by Step Instructions](#).

N°	Action
A	Turn ON <b>Propex IQ®</b> Apex Locator. See <a href="#">6.6 Description of the LED Colors</a> .
B	Plug the <b>Propex IQ®</b> External Tester (1) in the device (2). <i>The device test will automatically start. The central LED will flash white and a double beep will be emitted.</i>







### If device test is successful:

N°	Action
	Central LED will light up green and a double beep will be emitted simultaneously.
C	You can now unplug the <b>Propex IQ®</b> External Tester from <b>Propex IQ®</b> Apex Locator.
	

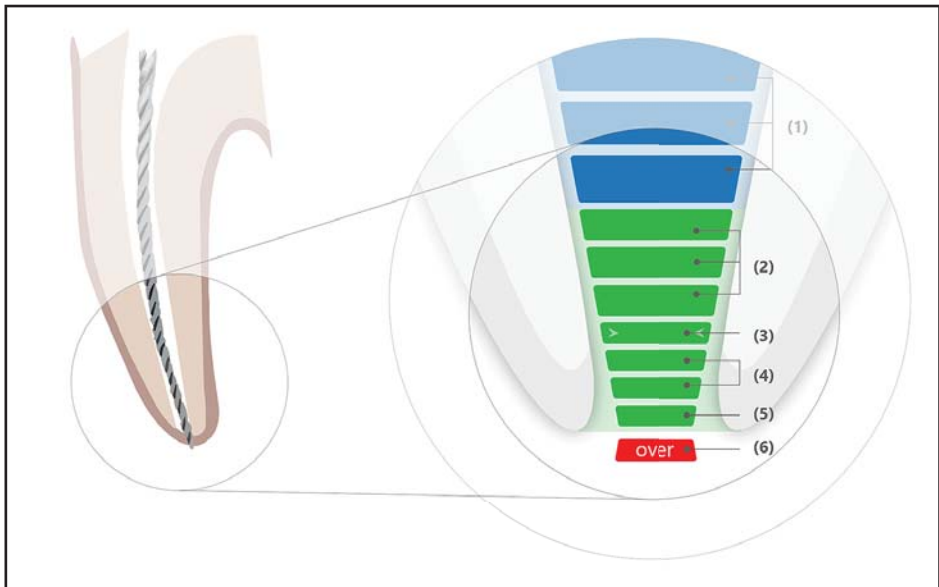
### If device test fails:

N°	Action
	Central LED will light up red and alternating beeps will be emitted simultaneously.
D	Unplug the <b>Propex IQ®</b> External Tester from <b>Propex IQ®</b> Apex Locator.
E	Repeat the above procedure (A to B one more time). <i>If the error persists DO NOT USE THE DEVICE and contact your Dentsply Sirona Endodontics Customer Service.</i>
	

## 6.10 Determining the Working Length

### 6.10.1 Definition

The anatomical terminology is defined as follows:



N°	Description
(1)	Coronal and medial regions.
(2)	Region coronal to the reference point for working length determination.
(3)	Reference point for working length determination.
(4)	Region beyond reference point.
(5)	Apical foramen.
(6)	Apical foramen (Major apical foramen or diameter) passed/over-instrumentation.

## 6.10.2 Start working length determination

As detailed in section **6.4 Modes of Operation**, **Propex IQ®** Apex Locator can work in different modes. Please also refer to Section **3 Warnings**.

Regardless of the mode of operation, the following steps and principles apply.



Prior to using **Propex IQ®** Apex Locator on a patient, the access cavity must be dried with a cotton pellet to prevent an electric short circuit through another canal. However, the canal being treated must be humid to allow electric conduction. Both conditions need to be met to ensure correct file progression information.

Moisten an extremely dry canal with Glyde™ file prep to help provide conditions for a stable reading.



Select the size of the file matching the root canal diameter.

Before starting to work with the **Propex IQ®** File Clip, check if corrosion is visible on the metal part of the hook. In case corrosion is present, use a new file clip (see Section **10 Troubleshooting**).

For detailed steps on how to work with **Propex IQ®** Apex Locator in uncombined and combined modes, refer to sections **6.10.4 Uncombined mode** and **6.10.5 Combined mode**.


## 6.10.3 Working length determination











It is mandatory to read carefully Section **3 Warnings** before reading this section. Important safety information is contained there.



*When working in connected mode, the working length is graphically illustrated in **Endo IQ®** App. Please refer to **Endo IQ®** App User Manual - **6 Step by Step Instructions**.*

Color indication on Propex IQ® Apex Locator	Endodontic file progression
	<p><b>Coronal and medial regions:</b></p> <p>Move the endodontic file apically.</p> <p>LED: Solid blue. Sound: Slow pulsating tone.</p>

Color indication on Propex IQ® Apex Locator	Endodontic file progression
	<p>Audio signals (from the device) serve as indication of the file tip progression towards reference point. The interval between the beeps becomes shorter when the endodontic file approaches the reference point for working length determination.</p>
	<p><b>Region coronal to the reference point for working length determination:</b></p> <p>The endodontic file can be moved further apically.</p> <p>LED: Flashing green. Sound: Fast pulsating tone.</p>
	<p><b>Reference point for working length determination:</b></p> <p>This is the relevant position to determine the working length.</p> <p>LED: Solid green. Sound: Solid tone.</p>
	<p>In combined mode, the Apical Reverse function can be activated. Refer to <b>Endo IQ® App User Manual – 6 Step by Step Instructions</b>.</p>
	<p>The position of the reference point can be adjusted with the “Shaping Target” function, which is only available when <b>Propex IQ® Apex Locator</b> is connected to the <b>Endo IQ® App</b>. Refer to the <b>Endo IQ® App User Manual</b> for instructions on that function.</p>
	<p><b>Region beyond reference point:</b></p> <p>Further file progression beyond the reference point is visualized.</p> <p>LED: Solid green. Sound: Solid tone.</p>

Color indication on Propex IQ® Apex Locator	Endodontic file progression
	<p><b>Apical foramen (Major apical foramen or diameter) passed / over-instrumentation.</b></p> <p>Alarm condition:</p> <p>LED: Flashing red. Sound: Fast pulsating tones.</p>
	<p>Potential harm to the patient can be caused when this region is reached.</p>

#### 6.10.4 Uncombined mode

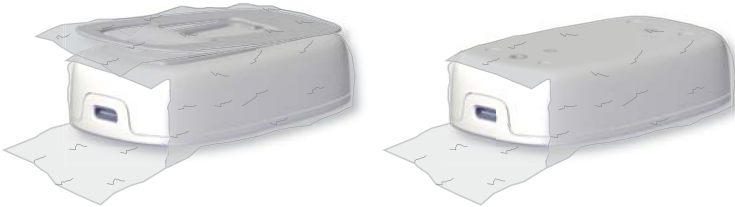


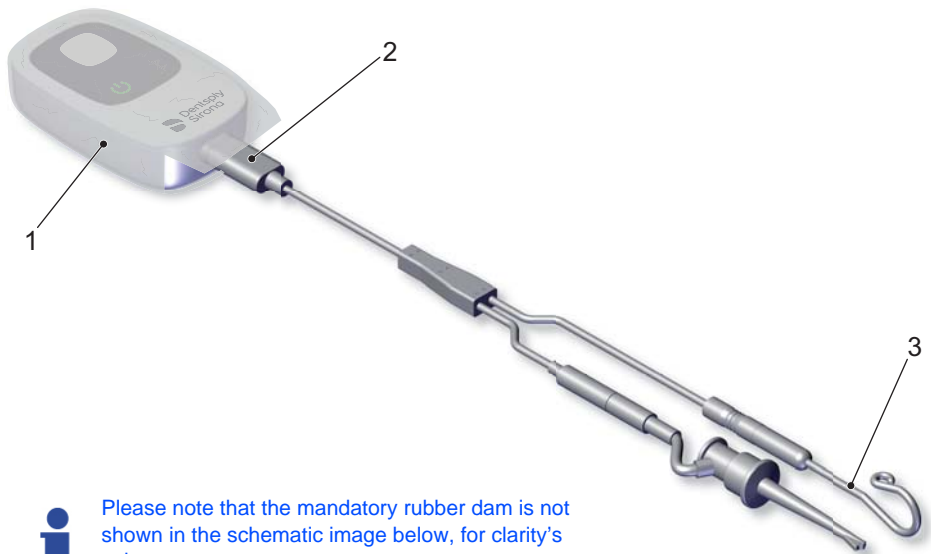
*If you have an iPad® and you prefer to work in connected mode, see **Endo IQ®** App User Manual.*

The following step-by-step instructions refer to the uncombined use (without **X-Smart IQ®** Handpiece).

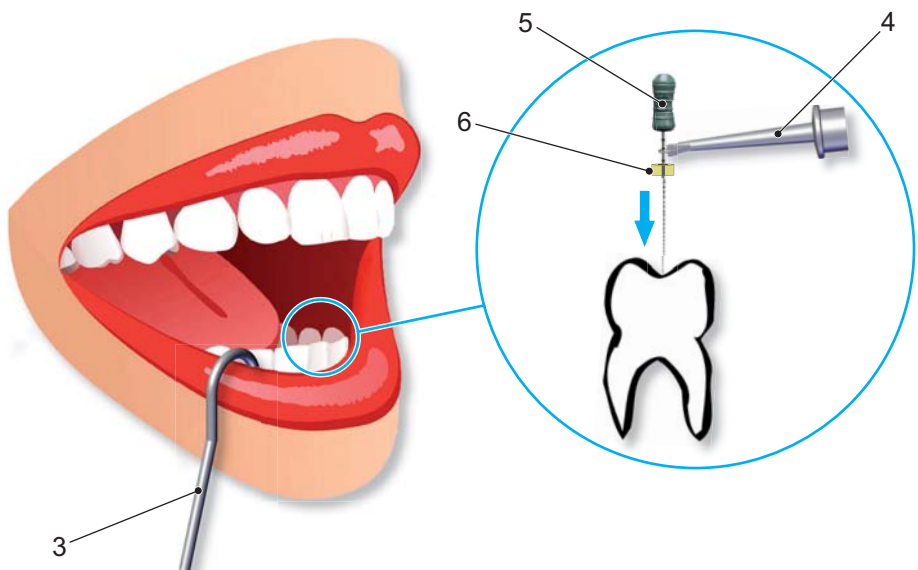
Ensure that a rubber dam/dental dam is securely placed before you start endodontic treatment.

Avoid touching the device with contaminated gloves to prevent contamination near the connector or underneath the clamp.

N°	Action
A	<p>After reprocessing of <b>Propex IQ®</b> Apex Locator and its accessories (see Section <a href="#">7 Cleaning, Disinfection and Sterilization</a>), place <b>Propex IQ®</b> Apex Locator in a single-use <b>Propex IQ®</b> Disposable Barrier Sleeve, with the long end of the barrier sleeve at the top. If you are using the optional <b>Propex IQ®</b> Clamp on the back of the device, pull a second sleeve over the clamp as follows:</p> 
B	Press the ON/OFF/Standby button on <b>Propex IQ®</b> Apex Locator (1).
C	Connect the <b>Propex IQ®</b> Measurement Cable (2) to the device (1).
D	Connect the <b>Propex IQ®</b> Lip Clip (3) to the <b>Propex IQ®</b> Measurement cable (2).
E	Connect the <b>Propex IQ®</b> File Clip (4) to the <b>Propex IQ®</b> Measurement Cable (2).
F	Perform a closed-loop test. See <a href="#">6.9.1 Closed-loop test</a> .
G	Put the lip clip (3) on the patient's lip on the opposite site of the tooth to be treated.
H	Insert the endodontic file (5) into the root canal and attach the file clip (4) to the metallic part of the endodontic file (5) directly below the plastic handle and above the stopper (6).
I	Move the endodontic file apically until reference point (default reference point or reference point defined as per Shaping Target function) is reached.
J	Set the silicon stopper at the coronal reference.
K	Remove the endodontic file from the root canal and use an external ruler to measure the distance between the tip of the endodontic file and the silicon stopper. This information will be relevant for subsequent files in your sequence.
L	Compare this distance information with the corresponding information given by pre-treatment radiographs.
M	Proceed with endodontic treatment. Carefully monitor file progression to avoid over-instrumentation.



Please note that the mandatory rubber dam is not shown in the schematic image below, for clarity's sake.



## 6.10.5 Combined mode

If you own an **X-Smart IQ®** Handpiece, you can operate **Propex IQ®** Apex Locator in combined mode for simultaneous canal shaping and file progression monitoring.

It is mandatory to read carefully Section **3 Warnings** before reading this section. Important safety information is contained there.

The use of **X-Smart IQ®** Handpiece Sleeve is mandatory to ensure the correct functioning of **Propex IQ®** Apex Locator in combined mode.


Ensure that a rubber dam/dental dam is securely placed before starting endodontic treatment.

Always establish the working length manually (radiographically and/or using uncombined mode) before starting an endodontic treatment in combined mode.

Avoid touching the device with contaminated gloves to prevent contamination near the connector or underneath the clamp.



*Please refer to **X-Smart IQ®** Handpiece Directions For Use for its use and specific hygiene measures.*

N°	Action
<b>A</b>	After reprocessing of <b>Propex IQ®</b> Apex Locator and its accessories (see Section <b>7 Cleaning, Disinfection and Sterilization</b> ), place <b>Propex IQ®</b> Apex Locator in a single-use <b>Propex IQ®</b> Disposable Barrier Sleeve, with the long end of the barrier sleeve at the top. If the optional <b>Propex IQ®</b> Clamp is used, pull a second <b>Propex IQ®</b> Disposable Barrier Sleeve over the clamp as illustrated in Section <b>6.10.4 Uncombined mode</b> .
<b>B</b>	Press the ON/OFF/Standby button on <b>Propex IQ®</b> Apex Locator (1).
<b>C</b>	Connect the <b>X-Smart IQ®</b> Measurement Cable (2) to the device (1).
<b>D</b>	Connect the <b>Propex IQ®</b> Lip Clip (3) to the <b>X-Smart IQ®</b> Measurement Cable (2).
<b>E</b>	Put a <b>X-Smart IQ®</b> Handpiece single-use barrier (4) over the Handpiece (5) to isolate it.
<b>F</b>	Plug the <b>X-Smart IQ®</b> Measurement Cable (2) into the Handpiece (5) and insert an endodontic file (6) into the <b>X-Smart IQ®</b> Contra-angle (7).
<b>G</b>	Perform a closed-loop test. See <b>6.9.1 Closed-loop test</b> .
<b>H</b>	Put the <b>Propex IQ®</b> Lip Clip (3) on the patient's lip on the opposite side of the tooth to be treated.
<b>I</b>	Move the endodontic file apically until reference point (default reference point or reference point defined as per Shaping Target function) is reached.
<b>J</b>	Proceed with endodontic treatment. Carefully monitor file progression to avoid over-instrumentation.
	In combined mode, you can use the Apical Reverse function. This function is only available when the <b>X-Smart IQ®</b> Handpiece is connected to the <b>Endo IQ®</b> App. Please refer to the <b>Endo IQ®</b> App User Manual for description of that function.





Please note that the mandatory rubber dam is not shown in the schematic image below, for clarity's sake.

The Handpiece sleeve supplied in your country may look different from the Handpiece sleeve shown on the illustration.



## 6.10.6 Interruption of file progression indication

During the treatment, the **Propex IQ®** File Clip may be disconnected from the endodontic file and reconnected at any time (e.g. when the file is changed to a larger size or when the length of another canal should be determined).

## 6.10.7 Tips for successful file progression indication

Implausible, rapidly changing indications from **Propex IQ®** Apex Locator may have various causes. Should you experience either situation, please review the below checklist to identify possible causes and take appropriate actions.

Issue	Solution
Excess liquid in the pulp chamber or root canal (i.e. rinsing solution, blood or saliva) creating wrong conductive path and incorrect length determination.	Dry the access cavity with a cotton pellet / air-blower. Wait until any bleeding has stopped.
Gingival proliferation can lead to direct contact with the endodontic file causing a short circuit and incorrect length determination.	Isolate the access cavity by: <ul style="list-style-type: none"> <li>• Adequate preparation filling;</li> <li>• Placing a dental dam;</li> <li>• Electro-cauterizing.</li> </ul>
The endodontic file contacting metallic dental restorations (crown, intracanal, amalgam filling) may cause a short circuit and incorrect length determination.	Carefully enlarge the access cavity and isolate with flow composite. Widen carefully the opening at the top of the crown.
No rubber dam and or <b>X-Smart IQ®</b> Handpiece Sleeve is used. This may cause a distortion of the electrical signal for the reading.	Use a rubber dam and the <b>X-Smart IQ®</b> Handpiece Sleeve.

If the device indications change too slowly, please review the following check-list:




Issue	Solution
Blocked root canal impeding the conductive path and preventing normal device functioning.	Check the comparative radiographs for support information on canal length; Catheterize with ISO 06 / 08 endodontic file until the working length is reached.
Retreatment: blockage by old canal filling material residue, impeding the conductive path and preventing normal device functioning.	Take a radiograph to re-check and try to completely remove the old canal filling material prior to determining length.
Blockage by remnants of a medicated substance (e.g. calcium hydroxide) impeding the conductive path and preventing normal device functioning.	Completely remove the remnants prior to determining length.
Extremely dry root canal impeding the conductive path and preventing normal device functioning.	Rinse root canal with irrigating solution such as NaCl or NaOCl and dry the access cavity with a cotton pellet / air- blower.
Special condition symptom: exceptionally large apical foramen due to lesion or incomplete formation.	May lead to incorrect feedback from <b>Propex IQ®</b> Apex Locator. Perform radiography.
Root fracture or perforation.	May lead to incorrect feedback from <b>Propex IQ®</b> Apex Locator. Perform radiography.

## 6.10.8 Comparison of electronic length determination versus radiography

Radiography represents a two-dimensional projection of a three-dimensional root canal system. There are some cases when the radiographic length and the electronic length do not match. In case of discrepancy, please refer to GCP standards applicable in your country as well as your clinical expertise.

## 6.11 Stand-by Mode

When **Propex IQ®** Apex Locator is not used for a certain period of time, it enters stand-by mode as described below.

Mode	LED description	Wake-up action
<b>Device active</b>	  ON/OFF/Standby LED emits a color corresponding to the battery status.	None.  <i>(Propex IQ® Apex Locator ready to be used).</i>
<b>Stand-by mode</b>	  ON/OFF/Standby LED flashes and emits a color corresponding to the battery status. Bluetooth® and Central LEDs are turned OFF.	Start using <b>Propex IQ®</b> Apex Locator.
<b>Shut-down</b> <i>(inactive for 20 min)</i>	  All LEDs are turned OFF.	Press the ON/OFF/ Standby button.

## 6.12 Battery Care



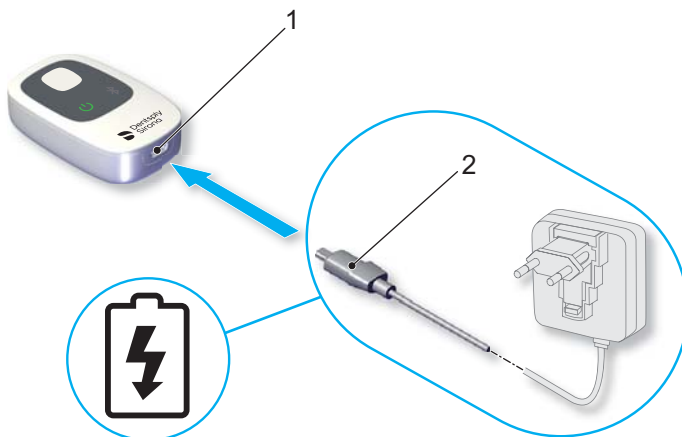
It is recommended to read Section **3 Warnings** (Battery) before reading this section. Important safety information is located there.

**Propex IQ®** Apex Locator is powered by two AAA (1.2 V) Ni-MH batteries. During the operation, the battery status is shown on the device front panel as the color of the ON/OFF/Standby button. See **6.6 Description of the LED Colors**.

The following notes will help you to ensure the battery provides a long service life:

- If the battery LED on the device flashes red, there is less than 5 min of device autonomy left. You must charge the device.
- Do not charge the battery more than once a day. It is recommended that you charge the device at the end of each day.
- Charge the battery overnight after using **Propex IQ®** Apex Locator. The battery is fully charged after up to 6 hours of charging.
- Always fully charge the battery, i.e. until the battery LED stops flashing green and turns steady green.
- When the charger is unplugged, the device will go in active mode.
- When the device is in standby mode and the charger is plugged, the device will start charging.
- When the device is turned off and the charger is plugged, the device will start charging.

N°	Action
A	Connect the charger (2) to the device (1) and plug it into the power outlet.



## 6.12.1 Battery Replacement



It is recommended to read section **3 Warnings** (Battery) before reading this section. Important safety information is located there.


Before replacing the battery, disconnect the charger from the device. Then switch the device OFF.

Always replace the batteries with two new batteries if they cannot be recharged correctly. The old batteries must be disposed of in accordance with local regulations.

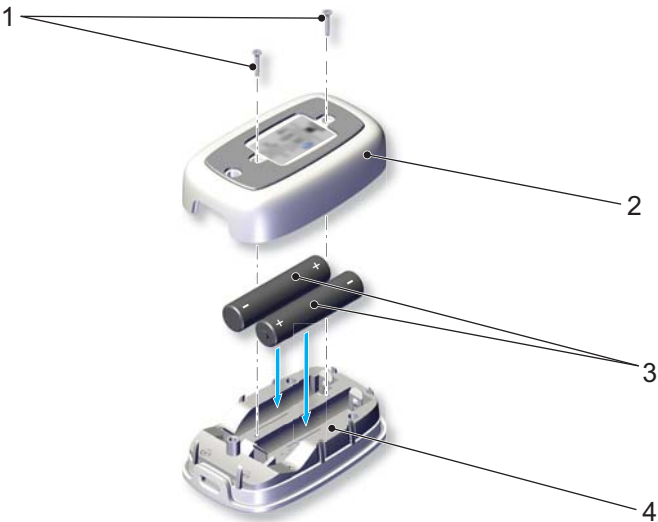
Fully charge the batteries before first use. Only use Dentsply Sirona batteries (part reference for EU: B00PPIQ2ACBAT, for US: T00PPIQ2ACBAT).

The battery compartment is located at the rear of **Propex IQ®** Apex Locator and its cover is secured by two 6-lobe screws (screw type: KN6041; screwdriver type: Torx T5).

N°	Action
A	Using an Torx T5 screwdriver, unscrew the two screws (1) and remove the battery cover (2).
B	Remove the two batteries (3) from the battery compartment (4).
C	Insert two new batteries, replace the battery cover (2) and screw the two screws (1).



In order to avoid ingress of liquids during reprocessing procedures, make sure that after closing the battery compartment no gaps are visible in the housing between the battery cover and the lower housing.



## 7 CLEANING, DISINFECTION AND STERILIZATION

### 7.1 General




You must consult the special **Propex IQ®** Cleaning, Disinfection and Sterilization Guide before proceeding with cleaning disinfection and sterilization.

Disposable (single-use) **Propex IQ®** Barrier Sleeves do not replace reprocessing of dental equipment / accessories or endodontic instruments. Always reprocess **Propex IQ®** Apex Locator.

The following parts shall be reprocessed before and after each treatment.

The reprocessing procedure might damage the (USB) plugs connected to the **Propex IQ®** Apex Locator / **X-Smart IQ®** Handpiece ports. They are unlikely to be contaminated during normal (plugged) use. Avoid reprocessing these plugs.

Part	Reprocessing steps
<ul style="list-style-type: none"> <li>• <b>Propex IQ®</b> Apex Locator</li> <li>• <b>Propex IQ®</b> Measurement Cable</li> <li>• <b>X-Smart IQ®</b> Measurement Cable</li> </ul>	Clean and disinfect.  <b>Do not sterilize.</b>
<ul style="list-style-type: none"> <li>• <b>Propex IQ®</b> File Clip</li> <li>• <b>Propex IQ®</b> Lip Clip</li> </ul>	Clean, Disinfect and Sterilize.



Dentsply Sirona accepts no liability in the event that these instructions are disregarded or unvalidated processes are used to reprocess the accessories.




Use only properly maintained equipment and approved materials according to national laws and/or regulations.



Always wear protective clothes for you own safety (gloves, mask, glasses and a waterproof gown) for the reprocessing process.

## 7.2 Cleaning Procedure

Cleaning is intended to remove all the visible soiling (e.g. organic and inorganic) from the surface of the device and accessories so that the subsequent disinfection process can be efficient.



N°	Cleaning steps
<b>Propex IQ® Apex Locator (and clamp, if used), Propex IQ® Measurement Cable and X-Smart IQ® Measurement Cable</b>	
<b>A</b>	Switch off <b>Propex IQ®</b> Apex Locator, then remove and discard the single-use <b>Propex IQ®</b> Disposable Barrier Sleeve (sleeves if the <b>Propex IQ®</b> clamp is used).
	Pay attention that no liquid enters the device connecting port, e.g. by keeping the cable plugged-in.
<b>B</b>	Clean the devices by using a single-use wipe or soft cloth soaked in cleaning fluid containing Alcohol Quaternary Ammonium active ingredients (e.g. CaviWipes™ or CaviCide™).
<b>C</b>	For the <b>Propex IQ®</b> Apex Locator, clean the grooves and device screws by using a clean brush with soft bristle (e.g. nylon) <u>slightly</u> soaked in cleaning solution containing Alcohol Quaternary Ammonium active ingredients (e.g. CaviWipes™ or CaviCides™).
<b>D</b>	Continue steps <b>B</b> and <b>C</b> until no debris appear on the wipe / brush. Replace the wipe and clean the brush as necessary.
<b>Propex IQ® File Clip and Lip Clip</b>	
<i>Pre-treatment of the file clip and lip clip – for personal protection</i>	
<b>E</b>	After use, place the file clip and lip clip directly into a dish filled with a suitable cleaning and disinfection solution (Cidezyme, Johnson & Johnson Medical, 0.8% for at least 1 minute, maximum 2 hours) for cleaning, pre-disinfection and interim storage. Make sure that the devices are fully immersed.



N°	Cleaning steps
<b>F</b>	Use clean, soft brushes or a clean, soft cloth or single-use wipe to remove contamination and remnants manually. Do not use metal brushes or wire wool.
<b>G</b>	Squeeze the <b>Propex IQ®</b> File Clip open and release it 5 times during cleaning to allow the inner parts to be cleaned effectively. Note that disinfectant used for pre-treatment is only <u>for personal protection</u> and does not obviate the need for disinfection once cleaning has been completed. Pre-treatment should never be omitted.
<b>H</b>	Rinse the devices under flowing sterile, deionized water at least 3 times for 1 minute each time, in order to remove all visible traces of contamination and remnants.
<b>I</b>	Check that no visible contamination or remnants remain, and repeat <b>E – H</b> if necessary. Replace the wipe and clean the brush when necessary.
<i>Cleaning of the file clip and lip clip – Cleaning and ultrasonic bath</i>	
<b>J</b>	Place the pre-treated <b>Propex IQ®</b> File Clip and Lip Clip 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 devices are fully immersed (if necessary, use a soft brush to make sure they remain fully immersed). Squeeze the file clip open and release it 5 times during cleaning to allow the inner parts to be cleaned effectively.
<b>K</b>	Remove the devices from the cleaning bath and rinse them thoroughly at least 3 times for 1 minute each time with sterile, deionized water; while rinsing, squeeze the file clip open and release it 5 times.
<b>L</b>	Place the devices 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 devices are fully immersed (if necessary, use a soft brush to make sure they remain fully immersed). Squeeze the file clip open and release it 5 times during cleaning to allow the inner parts to be cleaned effectively.
<b>M</b>	Then, remove the devices from the ultrasonic bath and rinse them thoroughly at least 3 times for 1 minute each time with sterile, deionized water; while rinsing, squeeze the file clip open and release it 5 times.

## 7.3 Disinfection

Disinfection shall be done immediately after cleaning using the following procedure:

N°	Disinfection steps
<b>Propex IQ® Apex Locator (and clamp, if used), Propex IQ® Measurement Cable and X-Smart IQ® Measurement Cable</b>	
<b>A</b>	Disinfect the surface of devices paying special attention to grooves and screws (and clamp, if used). Pay attention that no disinfectant enters the <b>Propex IQ®</b> Apex Locator connector, e.g. by having the cable plugged-in. Use a single-use wipe or soft clean cloth lightly soaked in disinfectant containing Alcohol Quaternary Ammonium active ingredients (e.g. CaviWipes™ or CaviCide™).
<b>B</b>	Remove all disinfectant residue. No visible impurities or liquid should remain on the devices after disinfection.
<b>C</b>	Insert <b>Propex IQ®</b> Apex Locator in a new and unused single-use <b>Propex IQ®</b> Disposable Barrier Sleeve before starting the next treatment.
<b>D</b>	If the device is not being used immediately after the reprocessing process, keep it in a safe and clean environment and follow the instructions for storage and transport.
<b>Propex IQ® File Clip and Lip Clip</b>	
<b>E</b>	Once the devices have been cleaned and inspected, place them into the disinfection bath for the prescribed contact time (Cidex OPA, Johnson & Johnson Medical, 100% for 20 minutes); the devices must be fully immersed in the solution. Squeeze the file clip open and release it 5 times during disinfection to allow the inner parts to be disinfected effectively.
<b>F</b>	Remove the devices from the disinfection bath and rinse them off thoroughly at least 5 times for 1 minute each time with water; when you rinse them, squeeze the file clip open and release it 5 times.
<b>G</b>	Dry the file clip and lip clip with oil-free, filtered compressed air and leave them to dry further in a clean place for at least 20 minutes.
<b>H</b>	Once the devices are dry, inspect them to ensure they are clean, dry and undamaged.
	Use only disinfectants with Alcohol Quaternary Ammonium active ingredients (e.g. CaviWipes™ or CaviCides™), except for the <b>Propex IQ®</b> File Clip and Lip Clip (see above). Use only disinfectants, which are EPA-approved and compatible with the device and accessories (see <a href="#">8 Technical Characteristics</a> ).
	Leave the disinfectant to act in accordance to manufacturer's instructions. Avoid leaving the disinfectant in contact with the device surfaces for a time longer than that recommended by the manufacturer of the disinfectant product. It can result in damage to the device.

## 7.4 Sterilization of the File Clip and Lip Clip

The sterilization process applies only to the lip clip and file clip. The maximum number of sterilization cycles is:

- File clip: 120;
- Lip clip: 120.

Proceed with the sterilization as follows:

N°	Sterilization steps for file clip and lip clip
<b>A</b>	Pack and seal accessories into single-use, undamaged sterilization packaging (single-layer packaging) that complies with the following requirements: <ul style="list-style-type: none"> <li>• DIN EN ISO / ANSI AAMI ISO 11607;</li> <li>• Suitable for steam sterilization (withstands temperatures of up to 142 °C (288 °F) or more, sufficient vapor permeability).</li> </ul>
<b>B</b>	Sterilize the file clip and lip clip by <b>Pre-Vacuum Displacement</b> (3 times pre-vacuum < 60 mbar). <ul style="list-style-type: none"> <li>• At 134 °C (273°F) for 3 minutes, drying time 20min (EU Market only);</li> <li>• at 132 °C (270 °F) for 4 minutes, drying time 20min (US Market only).</li> </ul> Please note: <ul style="list-style-type: none"> <li>• Do not exceed a sterilization temperature of 135°C (275°F) and a sterilization duration of 18min;</li> <li>• Always observe the operating instructions of the manufacturer for your sterilizer, especially about the loading weight, the operating time and functional testing;</li> <li>• Use steam sterilizers in accordance with DIN EN 13060 or DIN EN 285, ANSI / AAMI ST 79.</li> </ul>
<b>C</b>	Inspect the file clip and the lip clip before use after they have been reprocessed. If visible signs of moisture are present (damp spots on sterile packaging, pooled water in the load) at the end of the sterilization cycle, repackage and re-sterilize using a longer drying time. Dispose of any defective accessories immediately. If the press-release mechanism of the file clip does not function properly, repeat the complete reprocessing procedure. Discard the file clip if the press-release mechanism does not work properly.

The sterilization process must be validated in accordance with DIN EN ISO 17665 (valid installation and operational qualification (IQ and OQ) and product-specific performance qualification (PQ)).

## 8 TECHNICAL CHARACTERISTICS







Specification	Description
Manufacturer	<p>Maillefer Instruments Holding Sàrl Chemin du Verger 3 CH-1338 Ballaigues Switzerland</p> <p>Telephone +41 21 843 92 92 Fax +41 21 843 92 93 endo@dentsplysirona.com dentsplysirona.com</p>
Model	<b>Propex IQ®</b> Apex Locator
Dimensions	<p>Length: 75 mm Width: 46 mm Height: 20 mm</p>
Cable length	<ul style="list-style-type: none"> <li>Charger cable: 2 m</li> <li><b>Propex IQ®</b> and <b>X-Smart IQ®</b> Measurement cables: 1.3 m</li> <li><b>Propex IQ®</b> File clip FCA: 0.15 m</li> </ul>
Weight	80 g (0.18 lbs)
Material	User control panel: Polyester PVS-F
	Housing: ABS plastic
	Cables: TPE, silicone, TPV
	<b>Propex IQ®</b> File Clip: Glass filled nylon
	<b>Propex IQ®</b> Lip Clip: Stainless steel
	Screws: Stainless steel






Specification	Description
Material	Single use <b>Propex IQ®</b> Disposable Barrier Sleeve: Polyethylene
	<b>Propex IQ®</b> Clamp: Stainless steel
	Rubber pad: SEBS
	Threaded insert: brass
	Grub screw: stainless steel A1
Power supply	Rechargeable 2x AAA Ni-MH Batteries: Minimum capacity 750 mAh 1.2 VDC nominal; INTERNALLY POWERED DEVICE
Charger (type: FW7662M/05)	<ul style="list-style-type: none"> <li>Power supply: 100 - 240 VAC</li> <li>Frequency: 50 - 60 Hz</li> <li>Nominal power output: 5.5 VA</li> <li>Electrical safety class: Class II</li> </ul>
Applied part	BF ( <b>Propex IQ®</b> File Clip and <b>Propex IQ®</b> Lip Clip)
Protection against water ingress	IP 20
Safety level in the presence of flammable anesthetic gas mixtures or oxygen	Not suitable for use in the presence of flammable anesthetic gas mixtures or oxygen
Ambient conditions	<ul style="list-style-type: none"> <li>Use: in enclosed spaces</li> <li>Ambient temperature: 15°C - 35°C (59°F - 95°F)</li> <li>Relative humidity:&lt; 80%; non-condensing at 0°C (32°F)</li> <li>Operating altitude: &lt; 2 000 m (approximately 6561 ft) above sea level</li> <li>Maximum housing temperature according to IEC 60601-1/A1:2012</li> </ul>

Specification	Description
Conditions for transport and storage	<ul style="list-style-type: none"> <li>Ambient temperature: -20°C - +50°C (-4°F - 122°F)</li> <li>Relative humidity: 20% - 80%, non-condensing at &gt; 40°C (104°F)</li> <li>Pressure: 50 kPa - 106 kPa</li> <li>Do not subject <b>Propex IQ®</b> Apex Locator to temperature shock. Let it warm up to room temperature for 24h after bringing it from a cold to a warmer environment.</li> <li>Not to use or store system in a flammable environment</li> </ul>
iPad®	<ul style="list-style-type: none"> <li>iPad Mini™ 2</li> <li>iPad Mini™ 3</li> <li>iPad Mini™ 4</li> <li>iPad® (6th gen)</li> <li>iPad Pro® 10.5"</li> <li>iPad Pro® 12.9" (2nd gen)</li> </ul>
<b>Endo IQ®</b> App Operating System	<ul style="list-style-type: none"> <li>iOS</li> <li>Refer to <b>Endo IQ®</b> App User Manual</li> </ul>
EMC Tables	See <a href="#">Appendix A: Electromagnetic Emissions and Immunity</a>
Mode of Operation	Continuous (Ref. IEC 60601-1:2005 + A1:2012)
Expected Service Life	<b>Propex IQ®</b> Apex Locator Device: 3 years Measurement Cables: 6 months File Clip and Lip Clip: 120 sterilization cycles
Essential Performance	This equipment does not have Essential Performance (Ref. IEC 60601-1:2005 + A1:2012)
Medical Device Class	Class IIa, Rule 10, according to MDD 93/42/EEC (Annex IX)

## 9 PROPEX IQ® APEX LOCATOR ERROR CODES

If a failure occurs on **Propex IQ®** Apex Locator, the nature of the failure is given by a combination of colors and sounds as described in the following table.

State	Failure	Solution
 <b>Sound:</b> Audio signal	Critical / Device unrecoverable	Charge <b>Propex IQ®</b> Apex Locator (see <a href="#">6.12 Battery Care</a> ). <i>If the problem persists, return the instrument to your service center.</i>
 <b>Sound:</b> triple beep	Device warning - recoverable	Connect to <b>Endo IQ®</b> App for further information / instructions.  See <b>Endo IQ®</b> App User Manual - <a href="#">6 Step by Step Instructions</a> .
 <b>Sound:</b> off	Empty battery	Charge <b>Propex IQ®</b> Apex Locator (see <a href="#">6.12 Battery Care</a> ).
 <b>Sound:</b> triple beep	Bluetooth® module failure	Connect to <b>Endo IQ®</b> App for further information / instructions.  See <b>Endo IQ®</b> App User Manual - <a href="#">6 Step by Step Instructions</a> .

State	Failure	Solution
 <p><b>Sound:</b> triple beep</p>	Battery charge not sufficient to perform a firmware upgrade	<p>Connect to <b>Endo IQ®</b> App for further information / instructions.</p> <p> See <b>Endo IQ®</b> App User Manual - <b>6 Step by Step Instructions</b>.</p>
 <p><b>Sound:</b> triple beep</p>	General firmware failure	<p>Connect to <b>Endo IQ®</b> App for further information / instructions.</p> <p> See <b>Endo IQ®</b> App User Manual - <b>6 Step by Step Instructions</b>.</p>
 <p><b>Sound:</b> triple beep</p>	LED failure	<p>If <b>NONE</b> of the LEDs lights up in white color during boot-up and a triple beep sound is heard, there is a LED failure.</p> <p>Return the instrument to your service center.</p>



## 10 TROUBLESHOOTING

If **Propex IQ®** Apex Locator is not operating properly, check the possible cause using the following checklist. If you are unable to solve the problem by referring to the checklist, contact Dentsply Sirona Endodontics Customer Service.

Also refer to the error codes, which may be indicated on **Propex IQ®** Apex Locator, as described in section **9 Propex IQ® Apex Locator Error Codes**.



Refer to **X-Smart IQ®** Directions For Use for any troubleshooting related to **X-Smart IQ®** Handpiece in combined mode.



Refer to **Endo IQ®** App User Manual for any troubleshooting related to Bluetooth® connection.




Dentsply Sirona requires that you reprocess the product before shipping it to a service center.



To remedy certain problems, it is necessary to perform a factory reset (delete user settings and restore factory settings) on the device. In such case proceed as described below.

To perform a factory reset:

N°	Key	Action
A		Hold down the ON/OFF/Standby button for approximately 20 seconds. <i>The factory reset takes 20 seconds in total. After the first 10 seconds, there is a brief white flash of all LEDs. At the end of the process, another white flash and a long beep indicate a successful factory reset.</i>
B		Release the ON/OFF/Standby button.


<b>Propex IQ® Apex Locator does not switch on or it shuts off during treatment.</b>	
<b>Possible causes</b>	<b>Solutions</b>
<ul style="list-style-type: none"> <li>• The battery is completely empty (all LEDs are OFF).</li> </ul>	<ul style="list-style-type: none"> <li>• Connect the device to the charger and charge the device.</li> </ul>
<ul style="list-style-type: none"> <li>• The charger is not connected properly into the power socket.</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure that the charger is plugged in correctly and the power socket is under tension/switched ON (if applicable).</li> <li>• Ensure that the original adapter is being used.</li> </ul>
<ul style="list-style-type: none"> <li>• The battery is wrongly inserted.</li> <li>• The original battery has been replaced with a non-original one.</li> </ul>	<ul style="list-style-type: none"> <li>• Open the battery compartment and check the battery orientation.</li> </ul>
<ul style="list-style-type: none"> <li>• ON/OFF/Standby button malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Try pressing the ON/OFF/Standby button several times.</li> <li>• Replace the batteries with a new original battery.</li> </ul>
<ul style="list-style-type: none"> <li>• Electronic malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Perform a factory reset.</li> <li>• Contact Dentsply Sirona Endodontics Customer Service.</li> <li>• Send the device to Dentsply Sirona Endodontics Customer Service.</li> </ul>

No feedback from Propex IQ® Apex Locator during treatment.	
Possible causes	Solutions
<ul style="list-style-type: none"> <li>The battery is completely empty (all LEDs are OFF).</li> </ul>	<ul style="list-style-type: none"> <li>Connect the device to the charger and charge the device.</li> </ul>
<ul style="list-style-type: none"> <li>The cables are damaged or not connected correctly.</li> <li>Non-original cables are used.</li> </ul>	<ul style="list-style-type: none"> <li>Ensure that original cables have been used.</li> <li>Ensure that the cables are undamaged and connected correctly.</li> <li>Perform closed-loop to test to check functionality of cables and device test to check functionality of device.</li> <li>If in combined mode, ensure that the original <b>X-Smart IQ®</b> Contra-angle is being used.</li> <li>If in combined mode, ensure that the endodontic file has been correctly inserted into the <b>X-Smart IQ®</b> Contra-angle.</li> <li>Clean the lip clip and the file clip according to the procedure.</li> </ul>
<ul style="list-style-type: none"> <li>If all else fails.</li> </ul>	<ul style="list-style-type: none"> <li>Perform a factory reset.</li> </ul> <div data-bbox="602 817 680 890" data-label="Image"> </div> <p><b>If cables are damaged or if the Closed-Loop test fails after a second attempt, DO NOT USE Propex IQ® Apex Locator with the damaged cables and contact your Dentsply Sirona Endodontics Customer Service.</b></p> <ul style="list-style-type: none"> <li>If requested to send the device and/or components to Dentsply Sirona Endodontics Customer Service, reprocess the device, file clip, lip clip and cables before sending them back to customer services (Refer to Section <a href="#">7 Cleaning, Disinfection and Sterilization</a>).</li> </ul>

No sound or no light signal emitted during treatment.	
Possible causes	Solutions
<ul style="list-style-type: none"> <li>The battery is completely empty (all LEDs are OFF).</li> </ul>	<ul style="list-style-type: none"> <li>Connect the device to the charger and charge the device.</li> </ul>
<ul style="list-style-type: none"> <li>Electronic malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>Perform a factory reset.</li> <li>Send the device to Dentsply Sirona Endodontics Customer Service.</li> </ul>

Endodontic file progression indication is unstable or frozen.	
Possible causes	Solutions
<ul style="list-style-type: none"> <li>Calcified or obliterated root canal.</li> <li>Extremely dry root canal.</li> <li>Old root filling residues creating a blockage due to insufficient removal of intra-canal medicament (i.e. calcium hydroxide).</li> </ul>	<ul style="list-style-type: none"> <li>Check comparative X-rays for more information and repeat reading on <b>Propex IQ®</b> Apex Locator to verify the result.</li> <li>Rinse with NaOCl solution. Dry access cavity with cotton ball / air blow.</li> <li>Do a comparative X-ray, and fully remove old gutta-percha / intra-canal medicament.</li> </ul>
<ul style="list-style-type: none"> <li>Endodontic file too narrow for large root canal.</li> <li>Large lateral canal.</li> <li>Deep caries provide a conductive path outside the canal.</li> <li>Perforation.</li> </ul>	<ul style="list-style-type: none"> <li>Select a larger endodontic file.</li> <li>Block the external conductive path.</li> </ul>
<ul style="list-style-type: none"> <li><b>Propex IQ®</b> Lip Clip incorrectly attached to patient mouth. Insufficient contact between the lip clip and the oral mucosa.</li> <li>Endodontic file incorrectly connected to the file clip (i.e. connected to the metal shaft).</li> <li>Soiled <b>Propex IQ®</b> File Clip.</li> </ul>	<ul style="list-style-type: none"> <li>Place the lip clip in the patient mouth and ensure a good contact between the mucosa and lip clip (place the lip clip in the labial angle opposite to the tooth to be treated).</li> <li>Ensure that the endodontic file and the file clip are properly in contact with each other.</li> <li>Perform a closed-loop test.</li> <li>Clean the file clip according to the reprocessing instructions in <b>7 Cleaning, Disinfection and Sterilization</b>.</li> </ul>
<ul style="list-style-type: none"> <li>Defective connection cable.</li> </ul>	<ul style="list-style-type: none"> <li>Check cables and sockets for visible damage and ensure the connections are correct.</li> <li>Perform a closed-loop test to test cable functionality.</li> </ul>

Endodontic file progression indication is unstable or frozen.	
Possible causes	Solutions
<ul style="list-style-type: none"> <li>• LEDs damaged or not working properly.</li> <li>• Electronic malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Perform a factory reset.</li> <li>• Contact Dentsply Sirona Endodontics Customer Service.</li> </ul>

Endodontic file progression indication is too sensitive (i.e. it displays the relevant position for working length determination too quickly).	
Possible causes	Solutions
<ul style="list-style-type: none"> <li>• Short-circuit due to excess fluid in the pulp chamber (rinsing solution, saliva, blood).</li> </ul>	<ul style="list-style-type: none"> <li>• Dry the access cavity using an air blower or a cotton ball. In case of excess bleeding wait until it has stopped.</li> <li>• If heavy bleeding is observed, wait until bleeding has been successfully stopped.</li> </ul>
<ul style="list-style-type: none"> <li>• Direct contact between endodontic file and gingiva / gingival proliferation (i.e. in cases with fractured metal crowns).</li> <li>• Direct contact between endodontic file and metal restoration work (crowns, parapulpal pins; amalgam fillings).</li> </ul>	<ul style="list-style-type: none"> <li>• For isolation: <ul style="list-style-type: none"> <li>- Adequate tooth build-up;</li> <li>- Crown lengthening;</li> <li>- Electro-cauterisation.</li> </ul> </li> <li>• Use a dental dam. Isolate the endodontic file by placing 2-3 silicone stoppers on it or insert the endodontic file in a small polyvinyl tube before use.</li> <li>• Use the protective <b>X-Smart IQ®</b> Handpiece Sleeve on the <b>X-Smart IQ®</b> Handpiece (if in combined mode).</li> </ul> <div style="display: flex; align-items: center;">  <p><b>The use of X-Smart IQ® Handpiece Sleeve on the X-Smart IQ® Handpiece (when working in combined mode) is mandatory to ensure the correct functioning of the system in combined mode.</b></p> </div>
<ul style="list-style-type: none"> <li>• Lateral root canal.</li> <li>• Immature canal with large apex.</li> </ul>	<ul style="list-style-type: none"> <li>• Carefully widen the access cavity. If necessary add flow composites to isolate.</li> <li>• Repeat length determination process.</li> </ul>

<b>Battery does not recharge when the power supply is connected (the battery LED remains OFF when power supply is connected).</b>	
<b>Possible causes</b>	<b>Solutions</b>
<ul style="list-style-type: none"> <li>• Bad charger connection.</li> <li>• Power socket is not under tension/switched off (if applicable).</li> </ul>	<ul style="list-style-type: none"> <li>• Disconnect the charger from the device and reconnect it again.</li> </ul>
<ul style="list-style-type: none"> <li>• Charger malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Replace the charger with an original charger.</li> </ul>
<ul style="list-style-type: none"> <li>• Electronic malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Contact Dentsply Sirona Endodontics Customer Service.</li> </ul>

<b>Device test and quick closed-loop test do not start.</b>	
<b>Possible causes</b>	<b>Solutions</b>
<ul style="list-style-type: none"> <li>• <b>Propex IQ®</b> External tester is not working properly.</li> <li>• Electronic malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Perform a factory reset.</li> <li>• Contact Dentsply Sirona Endodontics Customer Service.</li> </ul>

<b>X-Smart IQ® Handpiece undetected in combined mode.</b>	
<b>Possible causes</b>	<b>Solutions</b>
<ul style="list-style-type: none"> <li>• <b>X-Smart IQ®</b> Measurement Cable or one of the connectors are damaged.</li> </ul>	<ul style="list-style-type: none"> <li>• Check the connection of the cable between <b>Propex IQ®</b> Apex Locator and the <b>X-Smart IQ®</b> Handpiece.</li> <li>• Perform a closed- loop test in combined mode.</li> </ul>
<ul style="list-style-type: none"> <li>• Firmware of the <b>X-Smart IQ®</b> Handpiece not up to date.</li> </ul>	<ul style="list-style-type: none"> <li>• Check if <b>X-Smart IQ®</b> Handpiece firmware is the latest version available (updated for <b>Propex IQ®</b> Apex Locator feature).</li> </ul>
<ul style="list-style-type: none"> <li>• Electronic malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Perform a factory reset.</li> <li>• Contact Dentsply Sirona Endodontics Customer Service.</li> </ul>

<b>Apical Reverse function cannot be switched on.</b>	
<b>Possible causes</b>	<b>Solutions</b>
<ul style="list-style-type: none"> <li>No connection between <b>Propex IQ®</b> Apex Locator and <b>X-Smart IQ®</b> Handpiece.</li> <li>Wrong cable connection.</li> <li>Cable or connector damaged.</li> <li><b>X-Smart IQ®</b> Handpiece not connected to <b>Endo IQ®</b> App.</li> </ul>	<ul style="list-style-type: none"> <li>Ensure proper connection of the cables between <b>Propex IQ®</b> Apex Locator and the <b>X-Smart IQ®</b> Handpiece.</li> <li>Ensure that all cables are original and undamaged.</li> <li>Connect <b>X-Smart IQ®</b> Handpiece to app to benefit from Apical Reverse function.</li> </ul>
<ul style="list-style-type: none"> <li>Firmware of <b>X-Smart IQ®</b> Handpiece not up to date.</li> </ul>	<ul style="list-style-type: none"> <li>Ensure that <b>X-Smart IQ®</b> Handpiece firmware is the latest version available (updated for <b>Propex IQ®</b> Apex Locator feature).</li> </ul>
<ul style="list-style-type: none"> <li>Apical Reverse setting on the <b>Endo IQ®</b> App accidentally set to OFF.</li> </ul>	<ul style="list-style-type: none"> <li>Switch ON the feature on the <b>Endo IQ®</b> App and retry.</li> </ul>
<ul style="list-style-type: none"> <li>Electronic malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>Perform a factory reset.</li> <li>Contact Dentsply Sirona Endodontics Customer Service.</li> </ul>

<b>Propex IQ® Apex Locator is overheating.</b>	
<b>Possible causes</b>	<b>Solutions</b>
<ul style="list-style-type: none"> <li>Electronic malfunction.</li> <li><b>Propex IQ®</b> Apex Locator has overheated and it has switched off.</li> </ul>	<ul style="list-style-type: none"> <li>Allow the device to cool down and start again.</li> <li>Check for possible leakage from <b>Propex IQ®</b> Apex Locator (liquids from defective battery). In case of suspected leakage, refer to Section <b>3 Warnings</b>.</li> </ul>

## 11 WARRANTY

Dentsply Sirona Endodontics offers customers the following product warranty:

- Dentsply Sirona Endodontics guarantees proper manufacturing of the product, the use of top quality materials, performance of all required tests and compliance with to all applicable relevant laws and regulations relating to the product. The full functionality of Propex IQ® Apex Locator is covered by a 12-month warranty. Cables, accessories and battery are covered by a 6 months warranty. Warranty period begins on the date of equipment purchase. The customer is only entitled to warranty services within the warranty period and under the condition that Dentsply Sirona has been informed of the defect within a one-month period from the date of discovery of the defect..

Component	Warranty period
<b>Propex IQ®</b> Apex Locator unit	12 months
<b>Propex IQ®</b> Charger	6 months
<b>Propex IQ®</b> Lip Clip	6 months
<b>Propex IQ®</b> File Clip	6 months
<b>Propex IQ®</b> External tester	6 months
<b>Propex IQ®</b> Measurement Cable <b>X-Smart IQ®</b> Measurement Cable	6 months
<b>Propex IQ®</b> Clamp	6 months

- This warranty covers only the exchange or repair of individual components or parts affected by manufacturing defects. The cost for personnel to be dispatched for purposes of technical assistance from the dealer to the customer, and /or packaging expenses of the customer will not be covered by Dentsply Sirona. Any customer claims beyond the realm of repair, such as claims for damages, will not be covered. This warranty does not include any compensation for direct or indirect personal injuries or material damage of any kind. The customer will not be entitled to damages covering downtime of the equipment.
- The warranty does not extend to damage for which evidence can be provided by Dentsply Sirona that such damage has been caused by negligence on the part of the user as related to Directions For Use, particularly during battery charging or battery replacement. The warranty explicitly excludes any defects arising on the basis of:
  - damage occurring during transportation to Dentsply Sirona for the purposes of repair;
  - damage occurring through environmental events such as lightning strikes, fire and / or humidity. This warranty shall automatically become cancelled and void if the product has been improperly repaired, modified or manipulated in any manner by the user, by non-authorized persons or by third party personnel.
- Legal claims, such as under product liability law remain unaffected.



## 12 DISPOSAL OF THE PRODUCT











Comply with your national and regional regulations, guidelines and requirements for the disposal of end-of-life electrical equipment and batteries.


















Make sure the product or battery are not mixed with other types of waste when being disposed of.

Prior to disassembly and disposal, your device must not be contaminated and must have been completely reprocessed (Refer to Section [7 Cleaning, Disinfection and Sterilization](#)).

## 13 IDENTIFICATION OF SYMBOLS

### 13.1 Normative Symbols

Symbol	Identification
	Serial number
	Lot number
	Catalogue number
	Refer to Instruction Manual / Booklet
	Consult Instructions for Use
	Electronic Instructions for Use (relevant information for use of the product is available in electronic format from <a href="https://dentsplysirona.com">dentsplysirona.com</a> ).
	Manufacturer
	Date of manufacture
	Class II equipment
	Type BF applied part

Symbol	Identification
	Direct current (connection for power supply)
	Alternating current
	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Opened packages are not replaced
	Temperature limit
	Humidity limitation
	Keep dry
	Fragile; handle with care
	Accessory
	Use by date
	Do not steam sterilize
	Do not re-use
	Caution
	Bluetooth®
	Non-sterile
	CE Mark
	Recycling: <b>PLEASE DO NOT THROW AWAY!</b> This product and all its components must absolutely be recycled through your distributor

## Appendix A: ELECTROMAGNETIC EMISSIONS AND IMMUNITY

Refer to the section **3 Warnings** to verify any special care to exercise before starting to use the device.

### EMC (general)

**Propex IQ®** Apex Locator is to be used in a dental practice, in a hospital or a private practice.

**Propex IQ®** Apex Locator is EMC-tested in conformity with the requirements of IEC 60601-1-2:2007 3<sup>rd</sup> (see the following tables) and IEC 60601-1-2:2014 4th Edition (according to clause 7 and 8.9, tables 4 to 9). **Propex IQ®** Apex Locator is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the below EMC information.

### Compliant Cables and Accessories



The use of accessories and cables other than specified by the manufacturer may result in increased emissions or decreased immunity of this product.

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### Information about charger

The charger must be used while the **Propex IQ®** Apex Locator is in charging mode only. **Propex IQ®** Apex Locator cannot be used for treatments when charging.

The charger for **Propex IQ®** Apex Locator complies with all relevant standards for battery charger devices.

### Information about radio communications

- Bluetooth® LE 4.0 Communication.
- Frequency band: 2.400 to 2.4835 GHz.
- The effective radiated power is below 10 mW.
- Europe: EU EN 300 328 V2.1.1.
- USA: Contains FCC ID: RFRMS42.
- Canada: Contains IC: 4957A-MS42.

This device complies with part 15C of the FCC:

Operation is subject to the following two conditions:

- This device may not cause harmful interference;
- This device must accept any interference received, including interference that may cause undesired operation of the device.

This Class B digital apparatus complies with Canadian ICES-0003.

## Compliance with Emission and Immunity Standard

This section provides guidance on compliance to Edition 3 (2007) and 4 (2014) of standard IEC 60601-1-2. Please refer to the relevant subsection according to the applicable regulation in your territory

### Compliance to IEC 60601-1-2:2007


Guidance and manufacturer's declaration - electromagnetic emissions		
<b>Propex IQ®</b> Apex Locator is intended for use in the electromagnetic environment specified below. The customer or the user of <b>Propex IQ®</b> Apex Locator should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	<b>Propex IQ®</b> Apex Locator 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.  <b>Propex IQ®</b> Apex Locator 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.
RF Emissions CISPR 11	Class B	
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	



The following tables are guidelines according to the 3<sup>rd</sup> edition of the medical standard IEC 60601-1-2.

Guidance and manufacturer's declaration - electromagnetic immunity			
<b>Propex IQ®</b> Apex Locator is intended for use in the electromagnetic environment specified below. The customer or the user of <b>Propex IQ®</b> Apex Locator should ensure that it is used in such an environment.			
Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines Not applicable (no input/output lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to Line(s)mode ± 2 kV line(s) to earth	± 1 kV differential mode Not applicable (no earth)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle  < 40% UT (60% dip in UT) for 5 cycles  70% UT (30% dip in UT) for 25 cycles.  < 5% UT (> 95% dip in UT) for 5 s	0% UT (> 95% dip in UT) for 0.5 cycle (at 0, 45, 90, 135, 180, 225 and 315° phase angle)  0% UT (> 95% dip in UT) for 1 cycle (at 0 phase angle)  70% UT (30% dip in UT) for 25/30 cycles (at 0 phase angle)  0% UT (> 95% dip in UT) for 250/300 cycles (at 0 phase angle)	Mains power quality should be that of a typical commercial or hospital environment.

Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <b>Propex IQ®</b> Apex Locator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = 1.2 \times \sqrt{P}$ <p>150 kHz to 80 MHz</p>

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5 GHz  Where <b>P</b> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  
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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.

<sup>a</sup>  
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 IQ®** Apex Locator is used exceeds the applicable RF compliance level above, the **Propex IQ®** Apex Locator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Propex IQ®** Apex Locator.

<sup>b</sup>  
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 <b>Propex IQ®</b> Apex Locator			
The <b>Propex IQ®</b> Apex Locator is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <b>Propex IQ®</b> Apex Locator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <b>Propex IQ®</b> Apex Locator as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \times \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12.0	12.0	23.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance <b>d</b> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <b>P</b> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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. Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile / portable communications equipment could cause interference if it is inadvertently brought into patient areas.			



## Compliance with IEC 60601-1-2:2014



Use of **Propex IQ®** Apex Locator adjacent to, or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **Propex IQ®** Apex Locator and the other equipment should be observed to verify that they are operating normally.



**WARNING:** Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of **Propex IQ®** Apex Locator. Otherwise, degradation of the performance of this equipment could result.

**Propex IQ®** Apex Locator does not have Essential Performance.

Guidance and manufacturer's declaration - electromagnetic emissions		
<b>Propex IQ®</b> Apex Locator is intended for use in the electromagnetic environment specified below. The customer or the user of <b>Propex IQ®</b> Apex Locator should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	<b>Propex IQ®</b> Apex Locator generates and uses conductively coupled radio-frequency 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	<b>Propex IQ®</b> Apex Locator is suitable for use in establishments directly connected to low voltage power supply network which supplies buildings used for domestic purposes.  Professional healthcare facility environment.
Harmonic Emissions IEC 61000-3-2	Not applicable	-
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	-

## Enclosure port

PHENOMENON	BASIC EMC STANDARD OR TEST METHOD	IMMUNITY TEST LEVELS	
		PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT	TEST RESULTS
Electrostatic Discharge	IEC 61000-4-2	± 8 kV CONTACT ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV AIR	<b>Pass</b>
Radiated RF EM fields <sup>a)</sup>	IEC 61000-4-3	3 V/m <sup>f)</sup> 80 MHz - 2,7 GHz <sup>b)</sup> 80% AM AT 1 KHz <sup>c)</sup>	<b>Pass</b>
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	SEE 8.10. OF REFERENCE STANDARD IEC 61000-4-3	<b>Pass</b>
RATED power frequency magnetic fields <sup>d) e)</sup>	IEC 61000-4-8	30 A/m <sup>g)</sup> 50 Hz OR 60 Hz	<b>Pass</b>

a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.

b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).

f) Before modulation is applied.

g) This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

## Input a.c. power port

PHENOMENON	BASIC EMC STANDARD OR TEST METHOD	IMMUNITY TEST LEVELS	
		PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT	TEST RESULTS
Electrical fast transients / bursts a) l) o)	IEC 61000-4-4	$\pm 2$ kV 100 kHz repetition frequency	Pass
Surges a) b) j) o) Line-to-line	IEC 61000-4-5	$\pm 0,5$ kV, $\pm 1$ kV	Pass
Surges a) b) j) k) o) Line-to-ground	IEC 61000-4-5	$\pm 0,5$ kV, $\pm 1$ kV, $\pm 2$ kV	Pass
Conducted disturbances induced by RF fields c) d) o)	IEC 61000-4-6	3 V <sup>m)</sup> 0,15 MHz - 80 MHz 6 V <sup>m)</sup> in ISM bands between 0,15 MHz and 80 MHz <sup>n)</sup> 80% AM at 1 kHz <sup>e)</sup>	Pass
Voltage dips <sup>f) p) r)</sup>	IEC 61000-4-11	0% UT; 0,5 cycle <sup>g)</sup> At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <sup>q)</sup>	Pass
		0% UT; 1 cycle and 70% UT; 25/30 cycles <sup>h)</sup> Single phase: at 0°	Pass
Voltage interruptions f) i) o) r)	IEC 61000-4-11		Pass

- a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.
- b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.
- c) Calibration for current injection clamps shall be performed in a 150  $\Omega$  system.
- d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.
- g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.
- h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
- i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.
- j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at  $\pm 2$  kV line(s) to earth and  $\pm 1$  kV line(s) to line(s).
- k) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.
- l) Direct coupling shall be used.
- m) r.m.s., before modulation is applied.
- n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

- o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.
- p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.
- q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
- r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range. See Table 1 Note c) for examples calculations.

**dentsplysirona.com**



**CE**  
0086



Mailefer Instruments Holding Sàrl  
Chemin du Verger 3  
CH-1338 Ballaigues  
Switzerland  
[endo@dentsplysirona.com](mailto:endo@dentsplysirona.com)  
[dentsplysirona.com](http://dentsplysirona.com)