

X-Smart IQ[®] Handpiece

Directions for Use



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RX ONLY

Introduction

Congratulations on your purchase of the **X-Smart IQ®** Handpiece.

These Directions for Use (DFU) are kept up-to-date by Dentsply Sirona. The most current version can be accessed at dentsplysirona.com and is also available in the **Endo IQ®** App.

For environmental reasons, a printed version of the DFU is not available in certain counties. However, a printed version is available upon request (free of charge within 7 calendar days to any address in North America). For a free copy of the DFU send your request to tulsacustserv@dentsplysirona.com. The DFU is available in other languages upon request.

The DFU has been compiled with the utmost care.

Nevertheless, it is not always possible to completely rule out the risk of error, despite all our efforts. Some images in the DFU may vary slightly from the actual device. We would appreciate your feedback in this area. If any errors are noted, please contact Dentsply Sirona.

Dentsply Sirona reserves the right to change the information and data contained in the DFU without prior notice.

Repairs, alterations and modifications to the device are not permitted unless the manufacturer's prior written consent has been obtained. Dentsply Sirona cannot be held liable if the device has been altered or modified.

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1 INDICATIONS FOR USE

The **X-Smart IQ**[®] Handpiece is a cordless motor handpiece with torque control used to operate endodontic files in both reciprocating and continuous rotation mode during an endodontic procedure.

The device must only be used in hospital environments, clinics or dental offices by qualified persons.

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

2 CONTRAINDICATIONS

Read the following contraindications before use.

- The **X-Smart IQ**[®] Handpiece must not be used in patients fitted with an implanted heart pacemaker (or other electrical equipment) or cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.).
- Safety and effectiveness have not been established in pregnant and breastfeeding women or in children.
- Clinical judgment needs to be exercised by the end user of the **X-Smart IQ**[®] Handpiece.

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.

Dentist

- The **X-Smart IQ**[®] Handpiece is intended for endodontic treatment and shall only be used by trained and qualified dentists.
- Do not use the **X-Smart IQ**[®] Handpiece for implants or any other dental procedure outside endodontics.

Environmental conditions

- The **X-Smart IQ**[®] Handpiece is intended for use in professional healthcare facility environments: physician offices, dental offices, clinics and hospitals (except near HF surgical equipment, outside of RF shield room of an ME system for magnetic resonance imaging).
- The device must not be used in home healthcare environments or in special environments.
- The device must not be placed in moist surroundings or in contact with liquids.
- Do not expose the device to direct or indirect heat sources.
- The device must be operated and stored in a safe environment (follow labeling indications).
- The device can be operated to a maximum ambient temperature of 35°C (95°F) and up to an altitude of 2 000 m (approximately 6561 ft) above sea level.
- Do not use the device in the presence of free oxygen, anesthetics or flammable substances.
- The device can cause radio interference or disrupt the operation of equipment in its vicinity. If this happens, the interference should be reduced by reorienting or repositioning the device or by screening off its immediate environment. The electromagnetic radiations emitted by the **X-Smart IQ**[®] Handpiece are below the recommended limits specified by the applicable relevant provisions (ref. IEC 60601-1-2, EN 60601-1-2). For more details, refer to applicable standards IEC 60601-1-2, EN 60601-1-2.
- Use of the **X-Smart IQ**[®] Handpiece adjacent to, or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the proper functioning of the devices shall be checked before use.
- The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC Directive.
- The use of any accessories or components other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity and in improper operation. Refer to sections [6.2](#), [6.3](#) and [Appendix A: Electromagnetic Emissions and Immunity](#) for further details.
- The **X-Smart IQ**[®] Handpiece Case contains permanent magnets. Magnets could affect the normal functioning of pacemakers, implanted heart defibrillators and hearing aid devices. Do not place the accessories or any other object sensitive to static magnetic fields near the **X-Smart IQ**[®] Handpiece Case.
- Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

During treatment

- If any irregularities with the device should occur during treatment, switch it off. Contact Dentsply Sirona or your Dentsply Sirona authorized service partner.
- No thermal hazard risk exists for patients.

Battery

- If liquid should emerge from the **X-Smart IQ®** Handpiece, the battery may be leaking. Stop using the device immediately and contact Dentsply Sirona or your Dentsply Sirona authorized service partner.
- Never open the **X-Smart IQ®** Handpiece yourself. Opening the device voids the warranty. Contact Dentsply Sirona or your Dentsply Sirona authorized service partner.
- Follow all local laws and regulations regarding the storage and shipment of lithium-ion batteries. (See transport section below).
- Always check to ensure the **X-Smart IQ®** Handpiece has a sufficient battery charge before starting treatment.

Consumables

- Use of gloves, of the Custom Polyethylene Barrier (**X-Smart IQ®** Handpiece Sleeve) placed over the **X-Smart IQ®** Handpiece (use exclusively Custom Polyethylene Barriers provided by Dentsply Sirona and made specifically for this handpiece), and of a rubber dam are mandatory during treatment.
- The battery charging port on the **X-Smart IQ®** Handpiece is a proprietary connection. Only use the original charger and cable supplied with the handpiece. Use of non-original chargers jeopardizes the safety of the patient and user.

Transport

- Clean / disinfect the **X-Smart IQ®** Handpiece Support, **X-Smart IQ®** Handpiece Case and **X-Smart IQ®** Handpiece before shipping them back to the service center.
- Intact devices can be transported by land freight or airfreight in the original packaging.
- Defective devices with intact battery can also be transported by airfreight or land freight in the original packaging.
- If the battery is defective, the device must not be transported by airfreight under any circumstances.
- All applicable requirements must be met (see next page).

Applicable standards and regulations for the transport of the **X-Smart IQ®** Handpiece:

	Airfreight	Land freight
Intact X-Smart IQ® Handpiece or defective X-Smart IQ® Handpiece with intact battery.	<ul style="list-style-type: none"> For international shipping of lithium-ion batteries, refer to the International Air Transport Association (IATA) guidelines, available under: http://www.iata.org/lithiumbatteries Applicable regulations: Lithium batteries are classified in Class 9 – Miscellaneous dangerous goods as: - UN 3481, Lithium ion batteries contained in equipment or packed with equipment; For shipping of lithium-ion batteries within the United States, refer to the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) site under: http://www.phmsa.dot.gov/hazmat/guidance 	ADR/RID Class 9 M4 plus UN 3481 Packing group II, tunnel category E ADR/RID-Labels 9. Proper shipping name Lithium-Ion batteries, UN 3480. ADR Special Provisions 188, 230,310, 636 will apply and Packing Instruction P903, P903a and P903b. Damaged and defective batteries: contact your National Competent Authority. Waste batteries: Note: For ADR, see the following address: www.unece.org/trans/danger/publi/adr/adr2011/11contentse.html
X-Smart IQ® Handpiece with defective battery	Not possible.	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.

X-Smart IQ® Contra-angle

- Only use the original Dentsply Sirona **X-Smart IQ®** Contra-angle.
- **X-Smart IQ®** Contra-angle must be checked for damage before reuse. Damaged products must be replaced.
- Never press the **X-Smart IQ®** Contra-angle pushbutton when the motor is running or coming to a stop. This may cause detachment of the endodontic instrument or overheating of the pushbutton.
- Never remove the **X-Smart IQ®** Contra-angle from the **X-Smart IQ®** Handpiece during operation.
- Only insert the endodontic instrument when the **X-Smart IQ®** Contra-angle is properly attached to **X-Smart IQ®** Handpiece.
- Never place your fingers on the moving parts of the endodontic instrument while it is running or coming to a stop.

Endodontic instruments

- Before use, ensure the endodontic instrument is securely locked in place.
- Use the torque and speed settings recommended by the endodontic instrument manufacturer. Preset values in the library must be checked prior to use. Torque values shown on the **Endo IQ®** App are accurate and reliable only if **X-Smart IQ®** 6:1 Contra-angle is properly maintained and lubricated.
- Use only undamaged endodontic instruments. Please refer to information provided by the manufacturer.
- Follow the file manufacturer's instructions for use of endodontic files.
- The endodontic file shown on the display must always match the file in use. This is of utmost importance to avoid misusing reciprocating endodontic files and continuous rotary endodontic files.
- Never use continuous rotary endodontic files in reciprocating mode.
- Never use reciprocating endodontic files in continuous rotary mode.

Cleaning, disinfection and sterilization

See Section **7 Cleaning, Disinfection and Sterilization**.

Repairs and Defects

- Do not use the **X-Smart IQ®** Handpiece if you suspect damage or a defect.
- If a defect should occur, contact Dentsply Sirona or your Dentsply Sirona authorized service partner ([voice 1-800-662-1202](tel:1-800-662-1202) or [fax 1-800-597-2779](tel:1-800-597-2779)).

4 PRECAUTIONS

Read the following precautions before use:

The manufacturer declines any responsibility in the case of using **X-Smart IQ®** Handpiece (including accessories) for applications other than those specified in this DFU and following intended use.

5 ADVERSE REACTIONS





There are no known adverse reactions.

6 STEP BY STEP INSTRUCTIONS

Refer to section [3 Warnings](#) to reference any special care needed before using the **X-Smart IQ®** Handpiece.

Before use, please check the exact contents of the package. See section [6.3 Package Contents](#).

6.1 Document Symbols



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





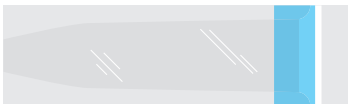
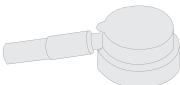
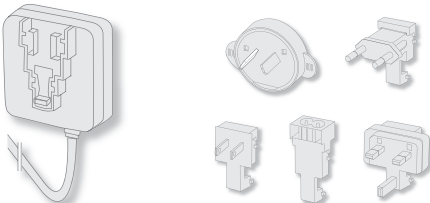
6.2 Device Compatibility

Specification	Description
iPad® requirements	<ul style="list-style-type: none"> • iPad Mini™ 2 • iPad Mini™ 3 • iPad Mini™ 4 • iPad® (6th gen) • iPad Pro® 10.5" • iPad Pro® 12.9" (2nd gen)
Endo IQ® App operating system	<ul style="list-style-type: none"> • iOS
Propex IQ® Apex Locator	<ul style="list-style-type: none"> • Original Dentsply Sirona Propex IQ® Apex Locator

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	Carefully remove the X-Smart IQ® Handpiece and the accessories from their packaging and place them on a flat surface.
B	Check that the X-Smart IQ® Handpiece is supplied with all the components and accessories shown below.
	Neither X-Smart IQ® Handpiece nor its accessories are supplied disinfected or sterilized.
	The X-Smart IQ® Handpiece, X-Smart IQ® Handpiece Support and X-Smart IQ® Handpiece Case are available in X-Smart IQ® kit or you can buy them from your dealer or Dentsply Sirona Endodontics customer service.

List of components	
X-Smart IQ® Handpiece	
X-Smart IQ® Handpiece Support	
X-Smart IQ® Handpiece Case	
X-Smart IQ® Contra-angle	
X-Smart IQ® Handpiece Sleeve	
X-Smart IQ® Spray Nozzle (used for lubrication)	
AC Adapter and plugs (*EU, *UK, US, *ANZ and universal adapter)	
Getting Started Guide / DFU	-

*These components are not available in all kits

Components not included

The following components are not included in the kit:



iPad® with iOS.

6.4 System Setup

6.4.1 First use of X-Smart IQ® Handpiece



The use of **Endo IQ®** App is required to set up the default settings of **X-Smart IQ®** Handpiece.

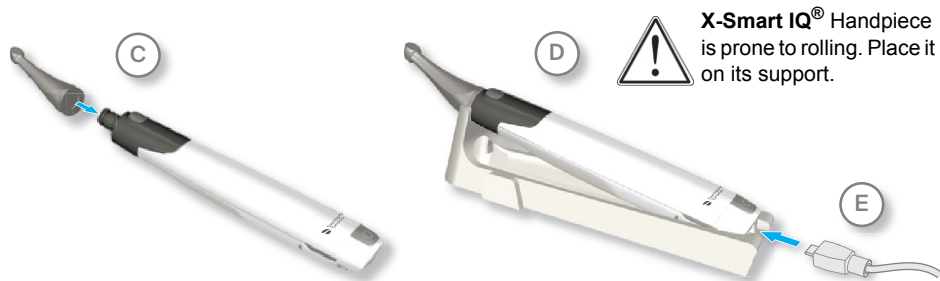



Refer to **Endo IQ®** App User Manual - **3 Warnings** to verify any special care to exercise before starting to use **Endo IQ®** App.



For more detailed setting-up instructions, refer to **Endo IQ®** App User Manual - **6 Step by Step Instructions**.

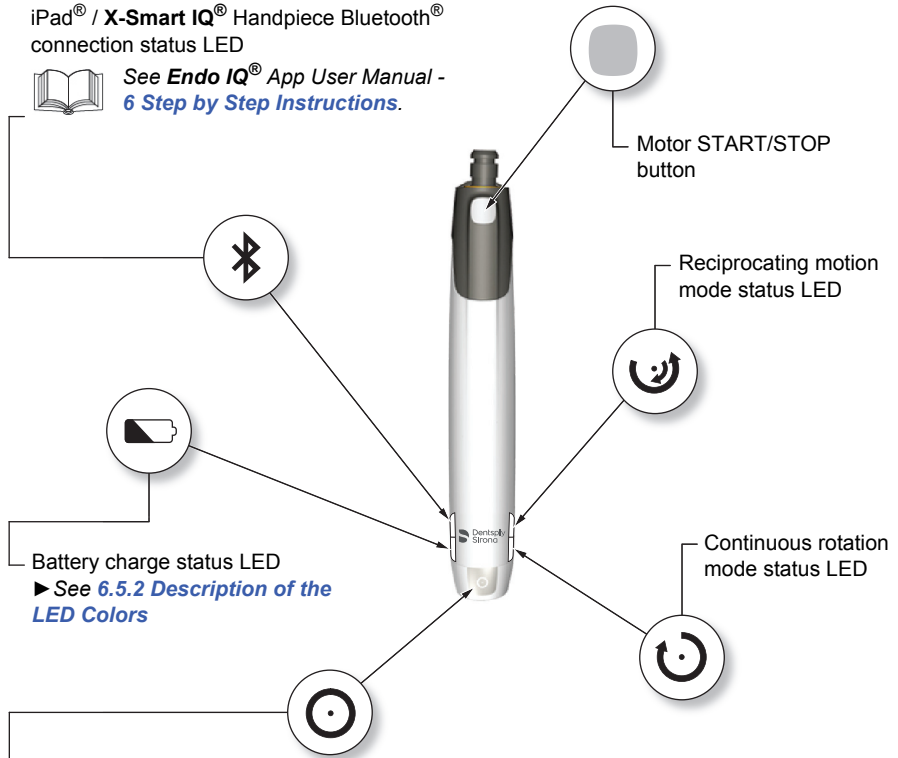
N°	Action
A	Activate the Wifi and Bluetooth® of the iPad® and set up the volume.
B	Install and update Endo IQ® App.
	Ensure the motor is not running before connecting or disconnecting the X-Smart IQ® Contra-angle.
C	Insert the X-Smart IQ® Contra-angle on X-Smart IQ® Handpiece.
D	Separate X-Smart IQ® Handpiece Case from X-Smart IQ® Handpiece Support. Place X-Smart IQ® Handpiece on its support.
E	Connect X-Smart IQ® Handpiece to the AC adapter before its first use.
	The battery has been electronically disconnected for transport. Charge the battery completely prior to first use. The X-Smart IQ® Handpiece will then be ready for operation.



N°	Action
F	Connect X-Smart IQ[®] Handpiece to Endo IQ[®] App . The application will automatically check the X-Smart IQ[®] Handpiece firmware and suggest a firmware update if needed.
G	Choose and activate X-Smart IQ[®] Handpiece motor settings.
	When the initial settings are fixed X-Smart IQ[®] Handpiece can also work in unconnected mode without Endo IQ[®] App . See 6.5.5 Unconnected mode .

6.5 Description of X-Smart IQ[®] Handpiece

6.5.1 General Overview



iPad[®] / X-Smart IQ[®] Handpiece Bluetooth[®] connection status LED



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

Battery charge status LED

► See **6.5.2 Description of the LED Colors**



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













• Activates X-Smart IQ[®] Handpiece.








X-Smart IQ[®] Handpiece does not turn off, it automatically switches to Stand-by mode.

► See **6.5.8 Stand-by Mode.**

- Advance to the next endodontic file during a treatment.
- Go back to the previous file during a treatment.
- To reset X-Smart IQ[®] Handpiece press for 10 seconds.
- To reset X-Smart IQ[®] Handpiece to factory settings press for 20 seconds.

6.5.2 Description of the LED Colors





Button/ LED	State	Description
		X-Smart IQ® Handpiece ready.
		X-Smart IQ® Handpiece in energy-saving mode.
		X-Smart IQ® Handpiece rotating.
		X-Smart IQ® Handpiece ready for calibration.
		X-Smart IQ® Handpiece turning in reverse direction / X-Smart IQ® Handpiece locked.
		Error detected. See 10 Troubleshooting for errors concerning the X-Smart IQ® Handpiece.  See <i>Endo IQ® App User Manual - 10 Troubleshooting</i> for errors regarding the application connection.
		Reciprocating motion mode active.
		Continuous rotation mode active.

Button/ LED	State	Description
		<p>X-Smart IQ® Handpiece completely charged / Enough battery available to complete the treatment.</p>
		<p>X-Smart IQ® Handpiece charging.</p>
		<p>Low battery level. Connect X-Smart IQ® Handpiece to the AC-adapter. See 6.7.1 Battery charge and storage.</p>
		<p>Very low battery level. Do not use on patient until charged. 3 short beeps are emitted by the X-Smart IQ® Handpiece. Immediately connect X-Smart IQ® Handpiece to the AC-adapter. See 6.7.1 Battery charge and storage.</p>
		<p>X-Smart IQ® Handpiece in unconnected mode. See 6.5.5 Unconnected mode.</p> <p>Use Endo IQ® App for initial set-up.</p>

6.5.2.1 X-Smart IQ[®] Handpiece connected with Endo IQ[®] App



See also **Endo IQ[®] App User Manual - 6 Step by Step Instructions** and **10 Troubleshooting**.

Button/ LED	State	Description
		Bluetooth [®] ON, X-Smart IQ [®] Handpiece is connecting to Endo IQ [®] App.
✖		When the Bluetooth [®] LED is flashing blue during the connection with the iPad [®] , X-Smart IQ [®] Handpiece is locked (Motor START / STOP button LED is yellow).
		X-Smart IQ [®] Handpiece connected to Endo IQ [®] App.
		X-Smart IQ [®] Handpiece has lost connection with Endo IQ [®] App.

6.5.3 Description of the Sounds

Mode	Description
Device running in continuous rotation	Intermittent sound when: <ul style="list-style-type: none"> • The device is rotating in reverse direction. • The torque measured is about 75% over the defined torque.
Device running in reciprocating motion	Intermittent sound when: <ul style="list-style-type: none"> • The endodontic instrument is subject to increased friction. • The device is rotating in continuous forward rotation.
Battery charge level	Three short beeps when the battery charge level is critically low.
Motor START/STOP button	A short beep when pressing the button.
Multifunction button	A short beep when pressing the button.

6.5.4 X-Smart IQ[®] Handpiece connected with Propex IQ[®] Apex Locator



X-Smart IQ[®] Handpiece can work in combined mode with Propex IQ[®] Apex Locator.



See *Propex IQ[®] Apex Locator Directions for Use - 6 Step by Step Instructions*.



Ensure that you have the latest version of X-Smart IQ[®] Handpiece and Propex IQ[®] Apex Locator firmware to work in combined mode.



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

6.5.5 Unconnected mode

X-Smart IQ[®] Handpiece can be used without connection to the iPad[®] or Endo IQ[®] App. This mode is called unconnected mode. Initial set-up requires the connection of X-Smart IQ[®] Handpiece to the iPad[®] and Endo IQ[®] App. Once the X-Smart IQ[®] Handpiece is set-up with Endo IQ[®] App, the user can specify the unconnected motor settings (i.e. RPM and Torque). See [6.4.1 First use of X-Smart IQ[®] Handpiece](#). This default setting defines the parameters used in unconnected mode until the next time the handpiece is connected to Endo IQ[®] App.

See [6.5.2 Description of the LED Colors](#) for X-Smart IQ[®] Handpiece LED status in unconnected mode.



Check the current settings of the unconnected mode before using **X-Smart IQ®** Handpiece.



The user will be unable to change settings without connecting to the **Endo IQ®** App.



The user will be unable to perform the **X-Smart IQ®** Contra-angle calibration without connecting to the **Endo IQ®** App.

6.5.6 Torque Reverse Functionality

The Torque Reverse function allows the **X-Smart IQ®** Handpiece to automatically reverse rotation direction when the applied torque is higher than the maximum defined torque. The Torque Reverse function can only be enabled or disabled when **X-Smart IQ®** Handpiece is connected with **Endo IQ®** App.



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

Mode	Explanation – Continuous Rotation	Explanation – Reciprocating Rotation
Torque Reverse OFF	If the applied torque on X-Smart IQ® Handpiece is higher than the maximum defined torque, X-Smart IQ® Handpiece stops. The user must press the Motor START/STOP button to restart the motor.	
Torque Reverse ON	If the applied torque on X-Smart IQ® Handpiece is higher than the maximum defined torque, X-Smart IQ® Handpiece automatically rotates in reverse direction until the applied torque is lower than a pre-defined threshold.	If the applied torque on X-Smart IQ® Handpiece is higher than the maximum defined torque, X-Smart IQ® Handpiece automatically rotates in reverse direction until the Motor START/STOP button is pressed.

6.5.7 Apical Reverse Functionality

Apical Reverse function allows the **X-Smart IQ®** Handpiece to automatically rotate in the opposite direction, when the relevant position for working length determination is reached.



Apical Reverse function is not activated by default in the **X-Smart IQ®** Handpiece. The function is only available when the **X-Smart IQ®** Handpiece is connected to **Endo IQ®** App and only works in combined mode with **Propex IQ®** Apex Locator. Activation or deactivation of Apical Reverse function is described in detail in the **Endo IQ®** App User Manual.



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

6.5.8 Stand-by Mode

X-Smart IQ® Handpiece enters stand-by mode when it is not used for a certain period of time.

Mode	LED description	Endo IQ® App display (if applicable)	Wake-up action
Device active	All LEDs are active.	Bluetooth® ON, device visible on status bar.	None. (X-Smart IQ® Handpiece ready for use).
Stand-by mode 1 <i>(inactive for 5 min)</i>	X-Smart IQ® Handpiece START/ STOP button flashing blue every 3 s. All other LEDs are OFF.	Bluetooth® ON, device visible on status bar.	Pick-up X-Smart IQ® Handpiece.
Stand-by mode 2 <i>(inactive for 35 min)</i>	All LEDs OFF.	Bluetooth® OFF, device not visible on status bar.	Press the multifunction button.

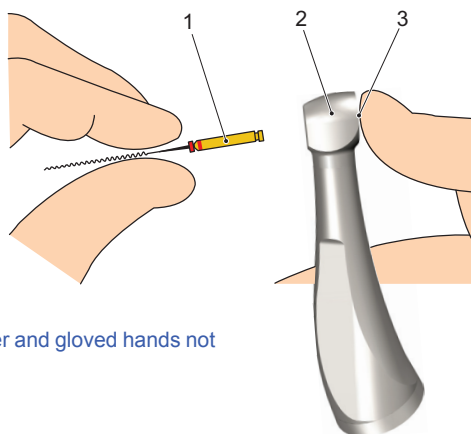
6.6 Endodontic file insertion and removal

6.6.1 Endodontic file insertion

N°	Action
A	Insert the file (1) into the chuck (2) until it stops.
B	Turn the file (1) gently until it engages with the latch mechanism. Push inwards to click.
C	Pull on the file (1) gently to make sure it is locked.

6.6.2 Endodontic file removal

N°	Action
A	Press the pushbutton (3) and pull out the file (1).



Custom barrier and gloved hands not shown.

6.7 Battery Care



Follow the charging instructions in section **6.7.1 Battery charge and storage** and read the warnings in the battery section in section **3 Warnings**.



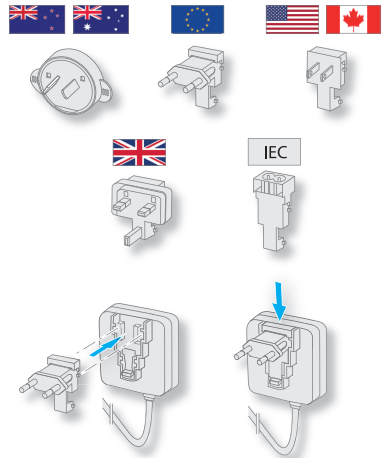
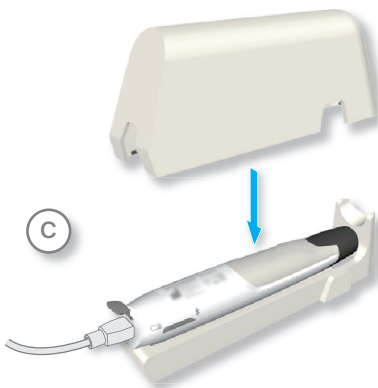
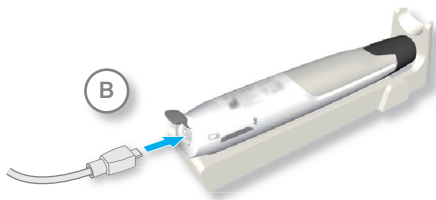
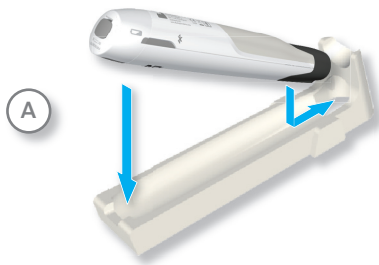
Charge **X-Smart IQ®** Handpiece fully before using it for the first time (about 6 hours) to optimize battery life.

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

- If the battery LED on **X-Smart IQ®** Handpiece lights up red, charge the battery. You can continue treatment while it is charging.
- Continuous operation with the charger connected shortens the lifetime of the battery. It is recommended to work without the charging cable connected.
- Charge the battery no more than once a day.
- Charge the battery as soon as the battery LED turns red, at the latest when the LED starts flashing red.
- Always fully charge the battery, i.e. until the battery LED turns green.
- Charging the battery can take up to six hours, if it is completely empty.
- Autonomy: Two days with 8 treatments per day or 16 total treatments.

6.7.1 Battery charge and storage

N°	Action
A	When storing X-Smart IQ® Handpiece inside its support, the motor shall be placed with the On/Off button facing down.
B	Plug-in the AC adapter.
C	Place X-Smart IQ® Handpiece Case over X-Smart IQ® Handpiece and X-Smart IQ® Handpiece Support.



Charging time: maximum 6 hours

7 CLEANING, DISINFECTION AND STERILIZATION

7.1 Foreword

Regular maintenance of the **X-Smart IQ®** Handpiece is essential to ensure that treatments are completely hygienic and that the device's service life is maximized.

The **X-Smart IQ®** Handpiece, the **X-Smart IQ®** Handpiece Support and **X-Smart IQ®** Handpiece Case and the **X-Smart IQ®** Contra-angle are not disinfected or sterilized. The user must perform the necessary reprocessing steps prior to the first use.

The user is responsible for the sterility of accessories. Always ensure that only validated methods of cleaning, disinfection and sterilization are used; that regular maintenance and inspections are performed on the equipment used (disinfection, sterilizer); that the validated parameters are maintained in every sterilization cycle.

Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

Refer to section **3 Warnings** to reference any special care needed before using the device.

7.2 Single Use of X-Smart IQ® Handpiece Sleeves

The use of the Custom Polyethylene Barrier over **X-Smart IQ®** Handpiece is mandatory. The barrier is designed for single use and must be disposed of after use.



The **X-Smart IQ®** Handpiece Sleeve does not replace cleaning and disinfection of dental instruments. Please clean and disinfect dental instruments after each treatment as described by the device manufacturer.



Please refer to the instructions for use on the **X-Smart IQ®** Handpiece sleeve box and to this DFU Section **3 Warnings** (important information contained there).

7.3 Cleaning and Disinfection of Components

The components of the kit (listed in table below) must be cleaned and wiped-down with a disinfection wipe before and after each treatment. They are not approved for machine-based cleaning (i.e. thermal disinfection, washer disinfectors) or sterilization



Please refer to the manufacturer's information on use of the disinfectant and to Section **3 Warnings**.





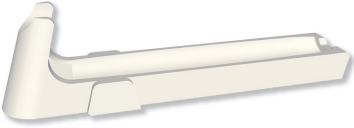


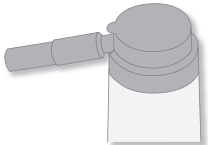
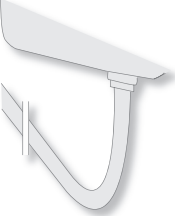
- Do not place the **X-Smart IQ®** Handpiece in an autoclave unit or washer-disinfector.
- Wear protective clothing during all cleaning, disinfection and sterilization processes.
- Do not apply fast sterilization or sterilization procedures with non-packaged accessories. In addition, do not use hot-air sterilization, radiation sterilization or sterilization with formaldehyde, ethylene oxide or plasma.
- Never place the components of the kit (listed in table below) in a washer-disinfector, autoclave or ultrasonic bath.
- If you use a disinfecting spray, never spray the devices and accessories directly. Instead, spray a paper towel or use a pre-moistened disinfectant towelette (wipe).
- Only use surface disinfectants that are certified by officially recognized institutes, and are chlorine-free and aldehyde-free.
- In addition to using the **X-Smart IQ®** Handpiece Sleeve, clean and disinfect the **X-Smart IQ®** Handpiece regularly. When subjecting **X-Smart IQ®** Handpiece to wipe-down disinfection ensure that the charging cable is not connected and that the charging port is closed.
- Do not use CaviCide1™ or CaviWipes1™ on any items shown or listed in table below.



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

For wipe-down disinfection of components proceed as follows:

N°	Action
A	After any pre-cleaning, lightly soak a paper tissue or soft cloth in a mild, aldehyde-free disinfection and cleaning solution (bactericidal and fungicidal) and use it to clean / disinfect all components. Dentsply Sirona recommends the use of Dentsply VoloWipes™.
B	Thoroughly disinfect surfaces with a lightly soaked wipe (min. 30 seconds), making sure the entire surface is wet. Allow contact time > 30 minutes. If large surfaces have to be treated, use more than one wipe where necessary.

Name	Image	VoloWipes™	No spray
X-Smart IQ® Handpiece			
X-Smart IQ® Handpiece Case			
X-Smart IQ® Handpiece Support			
X-Smart IQ® Spray Nozzle			
Charging cable			

7.4 Lubrication of the X-Smart IQ[®] Contra-angle

It is essential to lubricate the **X-Smart IQ[®] Contra-angle** at least once a day, or after every internal cleaning procedure, before every sterilization or after 30 minutes of use. It is recommended to use W&H Service Oil F1 MD-400 Oil Spray Can, 400 ml.

- When lubricating the **X-Smart IQ[®] Contra-angle**, ensure that no oil contaminates the **X-Smart IQ[®] Handpiece**. This could damage it and negatively impact safety during operation.
- Do not place the **X-Smart IQ[®] Contra-angle** in a disinfectant solution or in an ultrasonic bath.
- Wear protective gloves during preparation and transportation of the **X-Smart IQ[®] Contra-angle**.
- Use only cleaning agents that do not have protein-binding effect.

Always calibrate the **X-Smart IQ[®] Handpiece** after the **X-Smart IQ[®] Contra-angle** has been sterilized or exchanged. The calibration function is available in the **Endo IQ[®] App**.



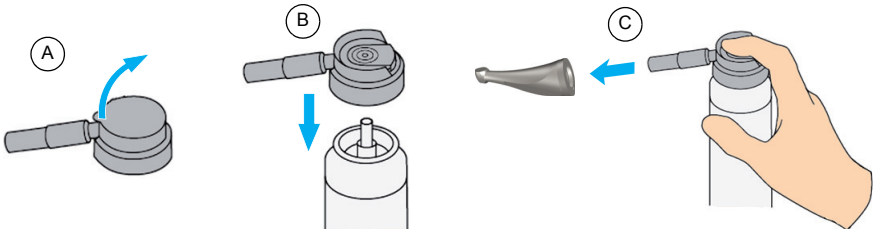
Lubricate the **X-Smart IQ[®] Contra-angle** immediately after thermal disinfection. Use the included **X-Smart IQ[®] Spray Nozzle** to lubricate the **X-Smart IQ[®] Contra-angle**.



Dentsply Sirona recommends reprocessing the **X-Smart IQ[®] Contra-angle** using a fully automatic reprocessing device, e.g. the adapter available from Dentsply Sirona.

Please perform the following steps to lubricate the **X-Smart IQ[®] Contra-angle**:

N°	Action
A	Remove the X-Smart IQ[®] Spray Nozzle cap.
B	Attach the X-Smart IQ[®] Spray Nozzle to the oil can (e.g. W&H Service Oil F1 MD-400).
C	Lubricate the X-Smart IQ[®] contra-angle according to the information in the Instructions for Use of the oil spray can.



7.5 Cleaning, Disinfection and Sterilization of the X-Smart IQ[®] Contra-angle

The X-Smart IQ[®] Contra-angle must be pre-cleaned, thermally disinfected (if applicable) and sterilized before and after every treatment.



Always start with preparation at the point of use and manual pre-cleaning in accordance with section 7.5.1 Pre-Treatment of the X-Smart IQ[®] Contra-angle.



Frequent reprocessing has minimal effects on the service life of X-Smart IQ[®] Contra-angles. The end of the product service life is normally dependent on wear and tear, or damage caused by use.



Please refer to the manufacturer's information regarding equipment, cleaning agents and rinsing agents.

Overview of X-Smart IQ[®] Contra-angle cleaning, disinfection and sterilization

X-Smart IQ [®] Contra-angle cleaning and disinfection parameters					
Method	Pre-Clean/ Wipe down	Lubricate (for complete instructions, see Section 7.4)	(Minimum): Temp / Time	Drying Time	DFU Section/ Page
Thermal disinfection (if applicable). Sterilization required following this step	Yes	After	Cleaning at 65°C (149°F) / 5 min. Disinfection at 90°C (194°F) / 5 min	Drying performed automatically during the drying cycle in the washer-disinfector	For complete instructions, see Section 7.5.2
X-Smart IQ [®] Contra-angle sterilization and drying time with Dynamic Air Removal Prevacuum cycle					
Dynamic air removal (pre-vacuum) sterilization	Yes	Before	Sterilize at 132°C (270°F) / 4 min	Drying time is 30 min	For complete instructions, see Section 7.5.3
Dynamic air removal (steam flush pressure pulse) sterilization	Yes	Before	Sterilize at 132°C (270°F) / 4 min	Drying time is 30 min	For complete instructions, see Section 7.5.3

X-Smart IQ® Contra-angle cleaning and disinfection parameters					
Method	Pre-Clean/ Wipe down	Lubricate (for complete instructions, see Section 7.4)	(Minimum): Temp / Time	Drying Time	DFU Section/ Page
X-Smart IQ® Contra-angle sterilization and drying time with Gravity-Displacement Steam					
Gravity – Displacement Steam	Yes	Before	Sterilize at 121°C (250°F) / 30 min	Drying time is 30 min	For complete instructions, see Section 7.5.3
Gravity – Displacement Steam (EU Market Only)	Yes	Before	Sterilize at 134°C / 10 min	Drying time is 30 min	For complete instructions, see Section 7.5.3
Gravity – Displacement Steam	Yes	Before	Sterilize at 132°C (270°F) / 15 min	Drying time is 30 min	For complete instructions, see Section 7.5.3




7.5.1 Pre-Treatment of the X-Smart IQ® Contra-angle

- Detach the used endodontic file and separate the **X-Smart IQ®** Contra-angle from the **X-Smart IQ®** Handpiece, prior to any manual pre-treatment.
- No special transport container is required for the **X-Smart IQ®** Contra-angle. Transportation is not subject to any special requirements.
- Rinse the **X-Smart IQ®** Contra-angle under running water in order to remove any coarse soiling if necessary.



Manual pre-cleaning is required for an efficient cleaning procedure, used in conjunction with machine-based reprocessing or sterilization.

7.5.2 Machine-based Reprocessing of the X-Smart IQ[®] Contra-angle (Thermal-Disinfection)

N°	Operation	Remarks
A	<p>Automatic cleaning / disinfection Cleaning at 65°C (149°F) holding time 5 min. Disinfection at 90°C (194°F) holding time 5 min.</p>	<p><i>Use washer-disinfector conforming to EN ISO 15883, e.g. Belimed WD, programme: neutral.</i></p> <p><i>Use an authorized and suitable cleaning solution for initial removal of organic and inorganic soils: (recommended 0.5% (v/v) deconex 24 LIQ, Borer Chemie or similar).</i></p> <p><i>Use authorized and suitable neutralizing solution: (recommended 0.25% (v/v) deconex 26 plus, Borer Chemie or similar).</i></p> <p><i>Deionized water (DI) or water that has this degree of purity is recommended for cleaning.</i></p>
	<p>Ensure the X-Smart IQ[®] Contra-angle attachment is completely dry after thermal disinfection. Remove any residual liquid with particle-free compressed air.</p>	
	<p>Drying is performed automatically during the drying cycle in the washer-disinfector.</p>	
	<p>Sterilization is required after Machine-based Reprocessing of the X-Smart IQ[®] Contra-angle.</p>	

7.5.3 Sterilization of the X-Smart IQ[®] Contra-angle (Autoclaving)



For the calibration function refer to **Endo IQ[®] App User Manual - 6 Step by Step Instructions**.



Contra-angles must be checked for damage before they are reused. Damaged products must be replaced.



If you only use **X-Smart IQ[®]** Handpiece in unconnected mode (without the **Endo IQ[®]** App), no calibration is required.

7.5.3.1 Approved Sterilization Procedure of the X-Smart IQ® Contra-angle

N°	Operation	Remarks
A	<p>Packaging Place the X-Smart IQ® Contra-angle in sterile barrier packages compliant with EN 868-5.</p>	<p><i>Clean and disinfect before sterilization.</i> <i>The X-Smart IQ® Contra-angle should also be lubricated before sterilization.</i> <i>Make sure to use only dry sterile items.</i> <i>Use a sterilization temperature with tolerance in compliance with ISO 17665.</i></p>
B	<p>Sterilization</p> <p>Dynamic Air Removal (pre-vacuum) Sterilization Sterilize at 132°C (270°F) for 4 min.</p> <p>Dynamic Air Removal (steam pulse pressure pulse) Sterilization Sterilize at 132°C (270°F) for 4 min.</p> <p>Gravity-Displacement Steam Sterilize at 121°C (250°F) for 30 min.</p> <p>Gravity-Displacement Steam Sterilize at 134°C for 3 min (EU Market Only).</p> <p>Gravity-Displacement Steam Sterilize at 132°C (270°F) for 15 min.</p>	<p><i>Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.</i> <i>Steam sterilization in accordance with ANSI/AAMI ST79.</i></p>
C	<p>Drying / Storage Drying time for all methods is 30 minutes.</p>	<p><i>Before resuming operation: wait until the X-Smart IQ® Contra- angle has cooled down and is completely dry.</i> <i>Store sterile X-Smart IQ® Contra-angles in a dry, dust-free place at room temperature.</i></p>

8 TECHNICAL CHARACTERISTICS


Specification	Description
Manufacturer	<p>Dentsply Tulsa Dental Specialties 608 Rolling Hills Drive Johnson City, Tennessee 37604 USA</p> <p>Phone: 1-800-662-1202 Fax: 1-800-597-2779 tulsacustserv@dentsplysirona.com dentsplysirona.com</p>
Model	X-Smart IQ® Handpiece
Dimensions (Length x Height x Width)	<p>X-Smart IQ® Handpiece: 206 mm x 24.6 mm x 24.8 mm</p> <p>X-Smart IQ® Handpiece Case and X-Smart IQ® Handpiece Support: 181 mm x 66 mm x 41 mm</p>
Material	<p>X-Smart IQ® Handpiece: PBT / PET Stainless steel TPE (thermoplastic elastomer) Silicone</p> <p>X-Smart IQ® Handpiece Case and X-Smart IQ® Handpiece Support: PC/ABS Somalac VP290</p>
Weight	<p>X-Smart IQ® Handpiece: 180 g (0.4 lbs)</p> <p>X-Smart IQ® Handpiece Case and X-Smart IQ® Handpiece Support: 120 g (0.26 lbs)</p>
X-Smart IQ® Contra-angle	<p>X-Smart IQ® Contra-angle compatible with rotary and reciprocating endodontic files, with a 2.35 mm shaft conforming to ISO 1797-1:2011, Type 1</p>








Specification	Description
Power supply	Lithium ion battery: 3.6 V, 2,000 mAh
Charger power supply	100 - 240 VAC
Frequency	50 - 60 Hz
Charger nominal power input	5.5 VA
Torque range	5 mNm – 50 mNm (0.5 Ncm – 5 Ncm) Dependent on motor speed
Speed range of the micromotor shaft	1 200 – 5 100 rpm (in rotary mode) Independent of contra-angle reduction
Type of protection against electrical shock	Class II and internally powered equipment
Applied part	BF (contra-angle)
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
Mode of operation	Non Continuous Operation Duty Cycle: ON (Maximum activation time): 3 mins; OFF (minimum deactivation time): 1 min
Ambient conditions	<ul style="list-style-type: none"> • Use: in enclosed spaces • Ambient temperature: 15°C - 35°C (59°F - 95°F) • Relative humidity: < 80%; non-condensing at 0°C (32°F) • Operating altitude: < 2 000 m (approximately 6561 ft) above sea level • Maximum housing temperature according to IEC 60601-1:2006
Medical device class	Class I / regulation: 872.4200
Conditions for transport and storage	<ul style="list-style-type: none"> • Ambient temperature: -20°C - +50°C (-4°F - 122°F) • Relative humidity: 20% - 80%, non-condensing at > 40°C (104°F) • Atmospheric pressure: 50 kPa – 106 kPa





Specification	Description
Bluetooth®	<ul style="list-style-type: none"> • Bluetooth 4.0 low energy • Device contains transmitter with: <ul style="list-style-type: none"> - FCC ID: RFRMSR - IC-ID: 4957A-MSR • Working distance: 25 m • Output Power: 6 mW • Frequency Range: 2400.0 - 2483.5 MHz
iPad® requirements	<ul style="list-style-type: none"> • iPad Mini™ 2 • iPad Mini™ 3 • iPad Mini™ 4 • iPad® (6th gen) • iPad Pro® 10.5" • iPad Pro® 12.9" (2nd gen)
Endo IQ® App Operating System	iOS
EMC Tables	See Appendix A: Electromagnetic Emissions and Immunity
Expected Service Life	Motor: 3 years Contra-angle: 3 years
Essential Performance	This equipment does not have Essential Performance (Ref. IEC 80601-2-60)

9 X-SMART IQ® HANDPIECE ERROR CODES

If a failure occurs on X-Smart IQ® Handpiece, the nature of the failure is given by a combination of colors as described in the following table.

State	Failure	Solution
	Total system failure	<i>Re-initialize X-Smart IQ® Handpiece with a Factory Reset (see 6.5.1 General Overview).</i>

State	Failure	Solution
	Battery empty	<p><i>Charge the battery (see 6.7.1 Battery charge and storage).</i></p>
	Motor overheating	<p><i>Wait for a few minutes and press the multifunction button to reactivate X-Smart IQ® Handpiece.</i></p>
	Motor hardware failure	<p><i>Reset the device by holding the multifunction button for 10 seconds (see 6.5.1 General Overview).</i></p>
	Battery failure	<p><i>Return the X-Smart IQ® Handpiece to your service center.</i></p>
	General hardware failure	<p><i>Reset the device by holding the multifunction button for 10 seconds (see 6.5.1 General Overview).</i></p>
	X-Smart IQ® Handpiece START/STOP button sensor is not working properly	<p><i>Reset the device by holding the multifunction button for 10 seconds (see 6.5.1 General Overview).</i></p>
	Bluetooth radio module failure	<p><i>Reset the device by holding the multifunction button for 10 seconds (see 6.5.1 General Overview).</i></p>

State	Failure	Solution
	<p>Calibration failed</p>	<p>Lubricate the X-Smart IQ® Contra-angle (see 7.5.3 Sterilization of the X-Smart IQ® Contra-angle (Autoclaving)) and perform the calibration again.</p> <p>If the error persists, try to replace the X-Smart IQ® Contra-angle and perform the calibration again.</p>
	<p>General firmware failure</p>	<p>Reset the device by holding the multifunction button for 10 seconds (see 6.5.1 General Overview).</p>
	<p>Wireless connection loss (unintended) when motor was unlocked</p>	<p>Reconnect your X-Smart IQ® Handpiece.</p>
	<p>Wireless connection loss (unintended) when motor was locked - reconnect timeout</p>	<p>Reconnect your X-Smart IQ® Handpiece.</p>

10 TROUBLESHOOTING

If the device is not operating properly, read the following checklist. If you are unable to solve the problem by referring to the checklist, contact your customer service.

Also refer to any error codes that may be indicated on the device, as described in section [9 X-Smart IQ® Handpiece Error Codes](#).



Refer to **Endo IQ®** App User Manual - [10 Troubleshooting](#) for errors related to the **X-Smart IQ®** Handpiece connection with **Endo IQ®** App.

Problem	Cause / Solution
<p>Running X-Smart IQ® Handpiece cannot be stopped during preparation.</p>	<p>The ON/OFF button is blocked or faulty.</p> <p><i>Briefly press the multifunction button once to stop the X-Smart IQ® Handpiece. Start and stop X-Smart IQ® Handpiece again. If the error has not been remedied, contact your service center.</i></p>
<p>X-Smart IQ® Handpiece cannot be switched on.</p>	<p>The battery is completely empty (all LEDs off).</p> <p><i>Connect X-Smart IQ® Handpiece to charger (see 6.7.1 Battery charge and storage).</i></p> <p>The X-Smart IQ® Handpiece no longer responds (the LEDs are lit but X-Smart IQ® Handpiece does not respond when the button is pressed).</p> <p><i>Perform a reset (see 6.5.1 General Overview).</i></p> <p><i>The multifunction button is faulty. Contact your service center.</i></p>
<p>The X-Smart IQ® Contra-angle cannot be calibrated.</p>	<p>The calibration procedure may have been interrupted by increased resistance in the X-Smart IQ® Contra-angle.</p> <ol style="list-style-type: none"> <i>1. If calibration has been interrupted, calibrate X-Smart IQ® Handpiece again to rule out the possibility of a motor fault.</i> <i>2. Clean and lubricate the X-Smart IQ® Contra-angle (see 7.5 Cleaning, Disinfection and Sterilization of the X-Smart IQ® Contra-angle). Start the calibration procedure again.</i>
<p>X-Smart IQ® Handpiece is getting hot.</p>	<p>Overheating.</p> <p><i>The device switches off automatically if it overheats. Allow the device to cool down and start again X-Smart IQ® Handpiece.</i></p>
<p>A reciprocating endodontic instrument has become jammed in the root canal.</p>	<p>Treatment was not performed properly.</p> <p><i>Remove the reciprocating endodontic instrument with pliers by rotating clockwise carefully.</i></p>
<p>A rotary endodontic instrument has become jammed in the root canal.</p>	<p>Treatment was not performed properly.</p> <p><i>Select reverse rotation, start X-Smart IQ® Handpiece and rotate the endodontic instrument out of the root canal carefully.</i></p>
<p>All LEDs are OFF and motor will not switch ON when pressing the multifunction button.</p>	<p>Battery was electronically disconnected. X-Smart IQ® Handpiece motor was blocked.</p> <p><i>Plug-in the power cable.</i></p>

11 WARRANTY

Dentsply Sirona warrants **X-Smart IQ®** Handpiece Support, **X-Smart IQ®** Handpiece Case and **X-Smart IQ®** Handpiece against defects in material and workmanship under normal practices of installation, use, and servicing.

- **X-Smart IQ®** Handpiece is guaranteed for 36 months from date of purchase (see terms and conditions below).
- **X-Smart IQ®** Handpiece Support and **X-Smart IQ®** Handpiece Case are guaranteed for 12 months from date of purchase.
- **X-Smart IQ®** 6:1 Contra-angle is guaranteed for 24 months from date of purchase.
- Never open the **X-Smart IQ®** Handpiece yourself. Opening the device voids the warranty. Contact Dentsply Sirona or your Dentsply Sirona authorized service partner.
- If the product fails within 30 days from the date of purchase, please contact the Technical Service Department at 1-800- 662-1202.

Component	Warranty Period
X-Smart IQ® Handpiece	36 months
X-Smart IQ® Handpiece Support	12 months
X-Smart IQ® Handpiece Case	12 months
Charger	12 months
X-Smart IQ® Contra-angle	24 months

11.1 Exclusion of Liability

In the following cases the manufacturer declines all liability:

- Use of **X-Smart IQ®** Handpiece Support, **X-Smart IQ®** Handpiece Case and **X-Smart IQ®** Handpiece for purposes and applications that differ from the specific requirements made in this Directions For Use.
- Cleaning, disinfection and sterilization methods contrary to the directions in this Directions For Use.
- Contra-angle maintenance contrary to the directions in this Directions For Use.
- Work or repairs performed by unauthorized persons.
- Damage caused to or by the iPad®.
- Rights under the warranty or statutory guarantee are rendered void if the device is opened without permission.
- Electrical installations in the room must meet the provisions of IEC 60364-7-710 (Installation of electrical equipment in rooms used for medical purposes) and the regulations applicable in your territory.

If you have any questions, contact your dealer or Dentsply Sirona.

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 its battery are not mixed with other types of waste when they are being disposed of.

Prior to disassembly and disposal ensure that the device is not contaminated. Prior to total or partial disposal of the device (parts), the device or relevant part must have been completely reprocessed (consult 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. It means that relevant information for use of the product is available in electronic form (dentsplysirona.com)
	Date of manufacture
	Class II equipment
	Type BF applied part
	Direct current (connection for power supply)
	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Opened packages are not replaced
	Alternating current
	Temperature limit

Symbol	Identification
	Humidity limitation
	Atmospheric pressure limitation
	Keep dry
	Fragile; handle with care
	Accessory
	Use by date
	Do not steam sterilize
	Do not re-use
	Caution
	Plastic

Appendix A: Electromagnetic Emissions and Immunity

Compliant Cables and Accessories



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

Description	Part Number	Type	Length
AC Adapter	A105300000000	X-Smart IQ® Handpiece Universal Charger	2050 mm

Instructions for Maintaining BASIC Safety for the Expected Service Life

Do not open or alter the device or its components and accessories to ensure safety and performance. Store and transport the device in the conditions indicated in the labeling and this DFU. The environmental conditions should correspond to the conditions listed in section [Compliance with Emission and Immunity standard](#).

Certain environmental conditions could affect the life of critical components of the product. See also Section [3 Warnings](#).

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 country or territory.

Compliance to IEC 60601-1-2:2007

Guidance and manufacturer's declaration - electromagnetic emissions		
<p>X-Smart IQ® Handpiece is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.</p>		
Emission test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	<p>X-Smart IQ® Handpiece 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.</p>
RF Emissions CISPR 11	Class B	<p>X-Smart IQ® Handpiece is suitable for use in establishments directly connected to low voltage power supply network which supplies buildings used for domestic purposes.</p>
Harmonic Emissions IEC 61000-3-2	Not applicable	-
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	-

Guidance and manufacturer's declaration - electromagnetic immunity			
<p>X-Smart IQ® Handpiece is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.</p>			
Immunity test	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	<p>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</p>
Electrostatic transient / burst IEC 61000-4-4	± 1 kV line(s) to line(s) mode ± 2 kV line(s) to earth	± 2 kV for power supply lines ± 1 kV for input / output lines	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>

Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<p>< 5% U_T (> 95% dip in U_T) for 0.5 cycle</p> <p>< 40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p>< 5% U_T (> 95% dip in U_T) for 5 s</p>	<p>0% U_T (> 95% dip in U_T) for 0.5 cycle (at 0, 45, 90, 135, 180, 225 and 315° phase angle)</p> <p>0% U_T (> 95% dip in U_T) for 1 cycle (at 0 phase angle)</p> <p>70% U_T (30% dip in U_T) for 25/30 cycles (at 0 phase angle)</p> <p>0% U_T (> 95% dip in U_T) for 250/300 cycles (at 0 phase angle)</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p> <p>If the user of X-Smart IQ® Handpiece requires continued operation during power mains interruptions, it is recommended that X-Smart IQ® Handpiece be powered from an uninterruptible power supply or a battery.</p>
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.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration electromagnetic immunity			
<p>X-Smart IQ® Handpiece is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz outside ISM and amateur radio bands	10 Vrms	<p>Portable and mobile RF communications equipment should be used at a minimal distance from any part of X-Smart IQ® Handpiece, including cables. The recommended separation distance can be calculated from the equation applicable to the frequency of the transmitter.</p> $d = 0.35 \times \sqrt{P}$
	10 Vrms 150 kHz - 80 MHz in ISM and amateur radio bands	10 Vrms	$d = 0.35 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35 \times \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = 0.7 \times \sqrt{P}$ <p>800 MHz to 2.7 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
 NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a
 Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobiles 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 **X-Smart IQ®** Handpiece is used exceeds the applicable RF compliance level above, **X-Smart IQ®** Handpiece should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating **X-Smart IQ®** Handpiece or the **ME EQUIPMENT** in its vicinity.

b
 Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and **X-Smart IQ®** Handpiece

X-Smart IQ® Handpiece is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and **X-Smart IQ®** Handpiece as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 0.35 \times \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \times \sqrt{P}$	800 MHz to 2.7 GHz $d = 0.7 \times \sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.13	0.11	0.22
1	0.4	0.35	0.7
10	1.3	1.1	2.2
100	4.0	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the 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.

Compliance with IEC 60601-1-2:2014



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



X-Smart IQ® Handpiece is a portable RF communication equipment which includes peripherals such as antenna cables and external antennas and it should be used at a minimal distance of 30 cm (12 inches) from any part of the **X-Smart IQ®** Handpiece. These include cables specified by the manufacturer. Failure to observe this may result in the degradation of the performance of **X-Smart IQ®** Handpiece.



This equipment does not have Essential Performance (Ref. IEC 80601-2-60).

Guidance and manufacturer's declaration - electromagnetic emissions		
X-Smart IQ® Handpiece is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	X-Smart IQ® Handpiece 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	X-Smart IQ® Handpiece 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	Pass
Radiated RF EM fields ^{a)}	IEC 61000-4-3	3 V/m ^{F)} 80 MHz – 2.7 GHz ^{B)} 80% AM at 1 KHz ^{C)}	Pass
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10. of reference standard IEC 61000-4-3	Pass
RATED power frequency magnetic fields ^{d) e)}	IEC 61000-4-8	30 A/m ^{G)} 50 Hz or 60 Hz	Pass

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	± 2 kV 100 kHz repetition frequency	Pass
Surges a) b) j) o) Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV	Pass
Surges a) b) j) k) o) Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV	Pass
Conducted disturbances induced by RF fields c) d) o)	IEC 61000-4-6	3 V ^m) 0.15 MHz – 80 MHz 6 V ^m) in ISM bands between 0.15 MHz and 80 MHz ⁿ) 80% AM at 1 kHz ^e)	10 Vrms
Voltage dips f) p) r)	IEC 61000-4-11	0% U _T ; 0.5 cycle ^g) at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° ^q)	Pass
		0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles ^h) Single phase: at 0°	Pass
Voltage interruptions f) i) o) r)	IEC 61000-4-11	0% U _T ; 250/300 cycle ^h)	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 Ω 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 **X-Smart IQ®** Handpiece 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 ± 2 kV line(s) to earth and ± 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 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2 MHz, 3.5 MHz to 4 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 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28 MHz to 29.7 MHz and 50 MHz to 54 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.

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