

X-Smart IQ™

User Manual



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FOR DENTAL USE ONLY

Introduction

Congratulations on your purchase of the **X-Smart IQ™** endo motor.

The User Manual is always kept up to date by Maillefer Instruments Holding Sàrl (hereafter Dentsply Sirona) to bring it in line with the latest developments. You will find the current version on www.dentsplymaillefer.com and integrated into the **DENTSPLY ENDO IQ™** application.

In countries where the legal situation enables us to do so, we have decided not to produce a printed version of the User Manual, for environmental reasons.

If no printed version is enclosed in your national language and you wish to have a printed one, we will be happy to send you a copy (free of charge within 7 calendar days to any address in the EU). To order, simply send your request to info@dentsplymaillefer.com.

The User Manual is available in other languages on request.

This User Manual has been compiled with the utmost care. Nevertheless, it is not always possible to completely rule out the risk of error, despite all efforts to do so. Some pictures in this user manual with IQ-Device and iPad may vary slightly from the current device app. 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 User Manual without prior notice.



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1 INDICATIONS FOR USE

X-Smart IQ™ is a cordless motor handpiece with torque control used for driving 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 practitioners.

2 CONTRAINDICATIONS

Read the following contraindications before use.

- In cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.), **X-Smart IQ™** must not be used.
- Do not use **X-Smart IQ™** for implants or any other dental procedure outside endodontics.
- Safety and effectiveness have not been established in pregnant women and children.
- Clinical judgment needs to be applied by the end user of the device.

3 WARNINGS

Read the following warnings before use.

Dentist

- The motor handpiece is intended for endodontic treatment and may only be used by trained and qualified professionals such as dentists.

Suitable environments

- The device 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).

Non suitable environments

- The device must not be used neither in home healthcare environment nor in special environment. For more details, please refer to IEC 60601-1-2:2014, EN 60601-1-2:2015.

Ambient conditions

- The device must not be placed in humid surroundings or where it can come into 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.
- The device can be operated up to a maximum temperature of 35°C (95°F) and up to an altitude of 2 000 m (~ 6561ft 8in) above sea level.
- Do not use the device in the presence of free oxygen, anesthetics or flammable substances. The device must be operated and stored in a safe environment.

- The device can cause radio interference or disrupt the operation of equipment in the vicinity. If this happens, the interference should be reduced by reorienting or repositioning the device or by screening off the immediate environment. The electromagnetic radiations emitted by the **X-Smart IQ™** motor handpiece are below the recommended limits specified by the applicable relevant provisions (IEC 60601-1-2:2014, EN 60601-1-2:2015).
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC Directive. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls or portable or mobile RF communication devices, even if they meet CISPR 11 requirements.
- The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. (Refer to the chapter **14.2 Compliant Cables and Accessories**)
- 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 **X-Smart IQ™** motor handpiece, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The iPad® generates, uses and can radiate radio-frequency energy. The use of the iPad® in a medical environment requires particular care in regards to electromagnetic interference with other devices. Please refer to the Apple User Manual for more information about the iPad®'s electromagnetic compatibility.

- The iPad® protective case and the motor handpiece cover contain permanent magnets. Magnets could affect the normal functioning of pacemakers, implanted heart defibrillators and hearing aid devices. Do not place the accessories near these devices or any other object sensitive to static magnetic fields.
- Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

During treatment

- Gloves and a rubber dam are absolutely essential 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.

Battery

- Always use the original charger with the charging cable to charge the device. Use of non-original chargers jeopardizes the safety of the patient and user.
- If liquid should emerge from the motor handpiece, the batteries may be leaking. In this event, stop using the device immediately and contact Dentsply Sirona or your Dentsply Sirona authorized service partner.
- Never open the device yourself. Opening the device voids the warranty. Contact Dentsply Sirona or your Dentsply Sirona authorized service partner.
- A device with a faulty battery must not be sent by air freight.
- Always check to ensure that both the motor handpiece and the iPad® have a sufficient battery charge before starting treatment.

Contra-angle

- Never press the contra-angle pushbutton when the motor handpiece is running or if it is coming to a stop. This will lead to detachment of the instrument or cause the pushbutton to overheat.
- Never remove the contra-angle from the motor handpiece during operation.
- Only use undamaged root canal instruments. Please refer to the information provided by the manufacturer.
- Only insert the instrument when the contra-angle is stationary.
- Never place your fingers on the moving parts of the instrument while it is running or coming to a stop.
- Before treatment, check the contra-angle for any damage or loose parts.
- Only use the original Dentsply Sirona contra-angle.

Root canal instruments

- Before use, make sure the instrument is securely locked in place.
- Never use continuous rotary instruments in reciprocating mode.
- Never use reciprocating instruments in rotary mode.
- Use the torque and speed settings recommended by the instrument manufacturer.

iPad®, iPad® protective case and motor handpiece support/cover

- Hygiene measures to prevent cross-contamination are absolutely essential. Dentsply Sirona recommends using the iPad® protective case as indicated in [6.5.6 Setting up the Complete System](#) or any other hygienic sleeve/barrier for medical applications.
- The operating conditions and limitations specified by Apple® must be complied with.
- Ensure the iPad® and the accessories are in a stable position during the treatment.

- The motor handpiece cover can be magnetically attached to the iPad® protective case. The device can fall if subjected to abrupt movements.
- Do not disable the iPad® sound when using **X-Smart IQ™**.
- Do not disinfect the iPad® protective case if the protective plugs are not properly inserted.
- Apple®, the Apple logo and iPad® are trademarks of Apple Inc., registered in the U.S. and other countries. App Store® is a service mark of Apple Inc.

DENTSPLY ENDO IQ™ application

- Dentsply Sirona cannot be held liable for the developed application if unauthorized modifications have been made (e.g. jailbreaking...).
- Treatment notes linked to patients in the application are subject to the requirements of the applicable legislation on data privacy.
- User must take appropriate measures to protect any data associated with a patient such as activating the device master password, the encryption of the parameters for backup on iTunes® and avoiding using the iPad® outside the medical environment.
- It is strongly recommended to periodically transfer all treatment notes associated with a patient to your Dental Practice Management Software and back-up your iPad® using iTunes®.
- **DENTSPLY ENDO IQ™** does not replace your Dental Practice Management Software.
- It is strongly recommended that all open applications are closed before launching the **DENTSPLY ENDO IQ™** application.

Accessories

- The use of the handpiece sleeve is mandatory. This product is designed for single use and has to be disposed of and changed after every treatment.
- Only use Dentsply Sirona components/accessories and spare parts.
- Using other makes of accessories/spare parts can lead to increased emission of electromagnetic interferences or to reduced electromagnetic interference immunity.

Repairs and Defects

- Do not use the device if you suspect damage or a defect.
- Repairs, alterations and modifications to the device are not permitted unless the manufacturer's prior consent has been obtained. Dentsply Sirona cannot be held liable if the device has been altered or modified. If a defect should occur, contact Dentsply Sirona or your Dentsply Sirona authorized service partner.

Transport

- Intact devices can be transported by land freight or air freight in the original packaging. The applicable requirements must be met (see table below).
- Defective devices can also be transported by air freight or land freight in the original packaging. If the battery is defective, the device must not be transported by air freight under any circumstances.
- Leaking liquid can be an indicator of a defective battery.

Standards and regulations that apply to the transport of **X-Smart IQ™**

	Air freight	Land freight
Intact device or defective device with intact battery.	<ul style="list-style-type: none"> • UN 3481 Lithium batteries in equipment. • IATA Packing instruction 967 Part II. • Special regulations issued by airlines and national regulations must be complied with. 	<ul style="list-style-type: none"> • UN 3481 Lithium batteries in equipment. • ADR Special provisions 188 f) and g).
Device with defective battery.	Not possible.	<ul style="list-style-type: none"> • International, multilateral agreements M 228 and M 259. • ADR SV 661 (international, road). • Regulations issued by GRS (German Joint Battery Take-back System Foundation) for the transport of waste lithium batteries (FRG, road).

4 PRECAUTIONS

Read the following precautions before use.

- Please check the compatibility of your **DENTSPLY ENDO IQ™** application before updating the iPad® operating system.
- Always install the latest version of the **DENTSPLY ENDO IQ™** application. Regularly check for updates on the App Store®.

5 ADVERSE REACTIONS

There are no known adverse reactions.

Safety and effectiveness have not been established in pregnant women and children.





6 STEP BY STEP INSTRUCTIONS



Refer to the chapter [3 Warnings](#) to verify any special care to exercise before starting to use the complete device.

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


6.1 Document Symbols

Symbol	Identification
	Consult instructions 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

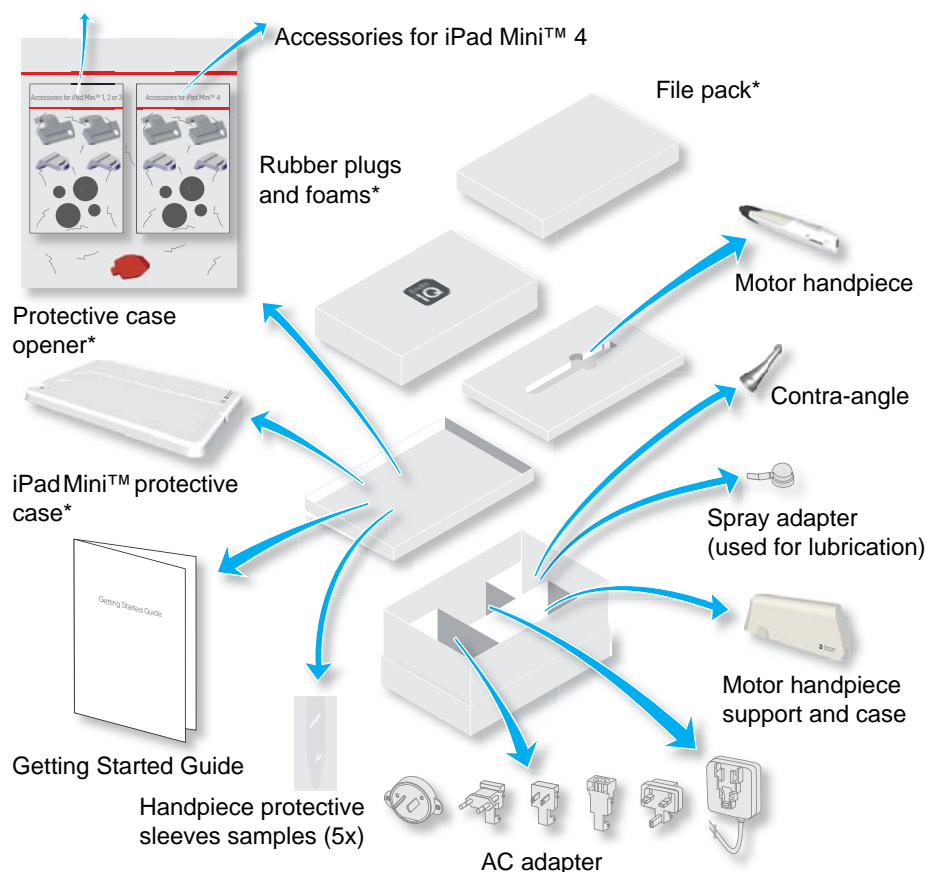
6.2 DENTSPLY ENDO IQ™ Application Compatibility

Specification	Description
iPad® requirement	<ul style="list-style-type: none">• iPad Mini™ 2• iPad Mini™ 3• iPad Mini™ 4
Operating System	<ul style="list-style-type: none">• iOS 11.x• iOS 12.x

6.3 Package Contents

N°	Action
A	Carefully remove the device and the accessories from their packaging and place them on a flat surface.
B	Check that the X-Smart IQ™ is supplied with all the components listed below.
 Not all components presented below are available in all kits.	

Accessories for iPad Mini™ 2 or 3



*These components are not available in all kits.

6.4 Components not included


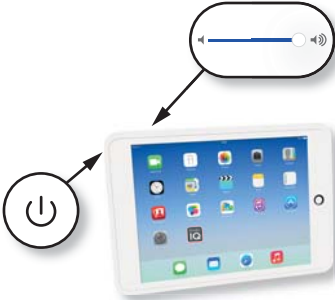
The following components are not included in the kit:



iPad® with iOS app (not part of the kit).

6.5 System Setup





6.5.1 Turning on the iPad® and setting the Volume

N°	Action
A	Turn on the iPad®.
B	Adjust the volume to maximum.
	The application uses sounds to give general information, see 6.6.1.3 Description of the Sounds.
	



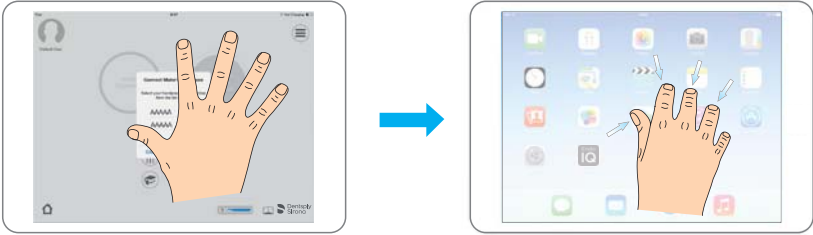
6.5.2 Activating the AssistiveTouch

The AssistiveTouch feature replaces the actions of the iPad® Home button which is not accessible when in the protective case.

To activate the AssistiveTouch




N°	Key	Action
A		Select Settings.
B		Select General.
C		Select Accessibility.
D		Select AssistiveTouch.
E		Set AssistiveTouch to ON.
 A virtual "Home" key is displayed.		

To press the Home button with AssistiveTouch

N°	Action
A	Tap on the virtual home button.
	
B	Select HOME .
	It is also possible to use the 5 fingers to swipe in and to return to the Home screen.
	





6.5.3 Activating the WiFi

You need to activate the WiFi to download the **DENTSPLY ENDO IQ™** application.

N°	Key	Action
A		Select Settings.
B		Select WiFi.
C		Set WiFi to ON.
D		Select your network and enter your password.

6.5.4 Activating the Bluetooth®

You need to activate Bluetooth® to connect the motor handpiece to the iPad®.






N°	Key	Action
A		Select Settings.
B		Select Bluetooth®.
C		Set Bluetooth® to ON.
 To connect the motor handpiece to the iPad®, see 6.7.3 Connecting the Motor Handpiece.		

6.5.5 Installing and Updating the DENTSPLY ENDO IQ™ Application



It is strongly recommended that data is backed up regularly by synchronizing with iTunes.

The **DENTSPLY ENDO IQ™** application is available in the App Store®.

N°	Key	Action
A		Connect to the App Store®.
B		Search and download the DENTSPLY ENDO IQ™ application.
	To download the DENTSPLY ENDO IQ™ application, you need an Apple ID. If you already have one, use it and log in. If you do not have one, follow the procedure on the Apple.com website to create an ID.	
	Regularly check for DENTSPLY ENDO IQ™ updates on the App Store®.	
	Always check Apple® is compatible with the application information (see 6.2 DENTSPLY ENDO IQ™ Application Compatibility) before updating your iPad®.	


6.5.5.1 Firmware update




The application checks the motor handpiece firmware version and, if the version is obsolete, **DENTSPLY ENDO IQ™** requests an update is performed.

Follow the instructions on the screen to execute the update.



Connect the motor handpiece to the AC adapter before starting the firmware update. See **6.8 Storing and charging the Motor Handpiece**.

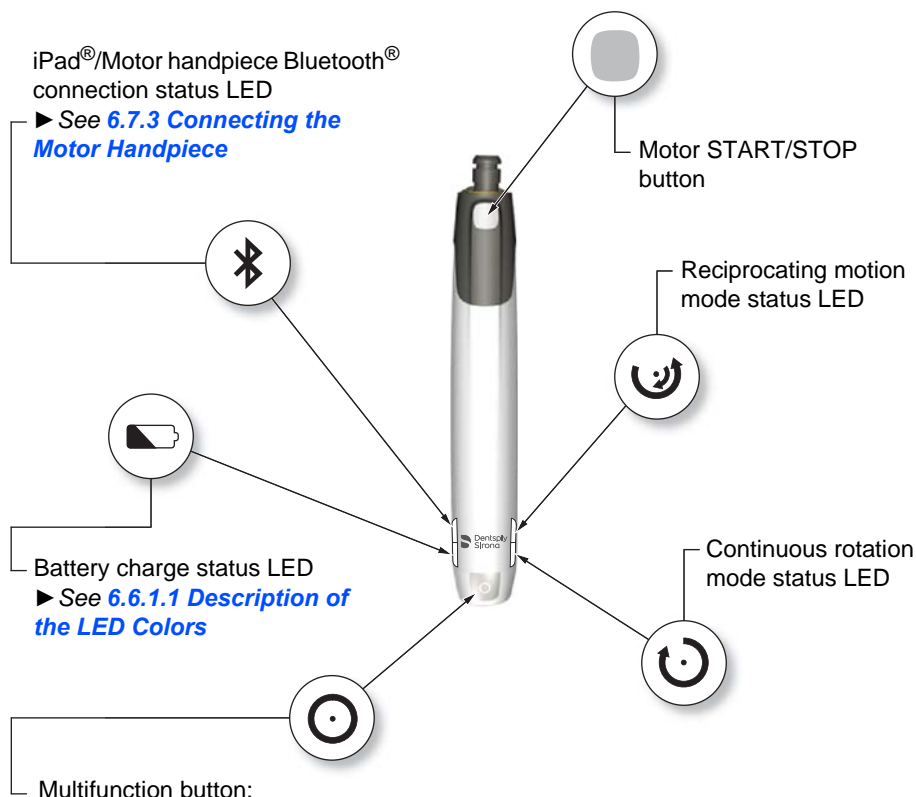
N°	Action
A	According to your iPad Mini™ model, use the suitable kit.
B	Stick the foams of your kit at the places indicated on the protective case.
C	Enclose and center the iPad Mini™ in the protective case. Place the corresponding plugs on the camera and the charging port.
	Pay attention to the iPad Mini™ orientation. In case of error, use the red key to open the protective case.
D	Separate the motor handpiece cover from the motor handpiece support.

N°	Action
E	Install the motor handpiece cover as a protective case holder.
	Place the assembly on a steady surface. Multiple configurations are possible.
F	Insert the contra-angle on the motor handpiece.
	Be sure the motor is always turned off when connecting or disconnecting the contra-angle.
G	Place the motor handpiece on its support.
H	Connect the motor handpiece to the AC adapter before its first use.
	The battery has been electronically disconnected for transport. Please charge the battery completely prior to initial use. Your motor handpiece will then be ready for operation














6.6 Motor Handpiece











6.6.1 Description of the Motor Handpiece






- Connects the motor handpiece to the application via Bluetooth®.
- See [6.7.3 Connecting the Motor Handpiece](#).
- Awakens the motor handpiece.
The motor handpiece does not turn off, it automatically switches to Stand-by mode.
- See [6.6.1.4 Stand-by Mode](#).
- Advance to the next file during a treatment.
- Go backwards to the previous file during a treatment.
- Reset the motor handpiece: press for 10 s.
- Factory reset of the motor handpiece: press for 20 s.

6.6.1.1 Description of the LED Colors

Button /LED	State	Description
		Motor handpiece ready.
		Motor handpiece ready for calibration. Or motor handpiece in energy-saving mode.
		Motor handpiece turning.
		Motor handpiece turning in reverse. Or motor handpiece locked.
		Error detected. See 10 Troubleshooting .
		Bluetooth® ON, motor handpiece ready to be connected. See 6.7.3 Connecting the Motor Handpiece .
		When the Bluetooth® LED is blinking blue during the connection with the iPad®, the motor handpiece is locked (Motor START/STOP button LED is yellow).
		Motor handpiece connected to the iPad®. See 6.7.3 Connecting the Motor Handpiece .
		Connection lost. See 10 Troubleshooting .

Button /LED	State	Description
		Second motor handpiece connected to the iPad®. See 6.7.3.1 Connecting a Second Motor Handpiece .
		Motor handpiece in stand-alone mode. See 6.6.3 Stand-alone mode: operation without the DENTSPLY ENDO IQ™ Application .
		Reciprocating motion mode active.
		Continuous rotation mode active.
		Device completely charged. Or enough battery available to complete the treatment.
		Device charging. For acoustic signals, see 6.6.1.3 Description of the Sounds .

Button /LED	State	Description
		Low battery level. Connect the motor handpiece to the AC-adapter. See 6.8 Storing and charging the Motor Handpiece . For acoustic signals, see 6.6.1.3 Description of the Sounds .
		Very low battery level. Immediately connect the motor handpiece to the AC-adapter. See 6.8 Storing and charging the Motor Handpiece . For acoustic signals, see 6.6.1.3 Description of the Sounds .

6.6.1.2 The Auto Reverse (AutoRev) Functionality

Mode	Explanation
AutoRev OFF	If the applied torque on the motor handpiece is higher than the maximum defined torque, the motor handpiece stops. The user must press the Motor START/STOP button to restart the motor.
AutoRev ON	If the applied torque on the motor handpiece is higher than the maximum defined torque, the motor handpiece automatically turns in reverse until the applied torque is lower than a pre-defined threshold (in continuous rotation), or until the Motor START/STOP button is pressed (in reciprocating rotation).

6.6.1.3 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. 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 instrument is subject to increased friction, After switching to forward rotation.
Battery charge level	<ul style="list-style-type: none"> One short beep when the battery charge level is low. Three-second beep when the battery charge level is critical.
Motor START/STOP button	A short beep when pressing the button.
Multifunction button	A short beep when pressing the button.

6.6.1.4 Stand-by Mode

When the motor handpiece is not used for a certain period of time, it enters stand-by mode as described below.

Mode	LED description	Application display	Wake-up action
Device active	All LEDs ON.	Bluetooth® ON, device visible on status bar.	None. (Device ready to be used).
Stand-by mode 1 <i>(inactive for 35 s)</i>	All LEDs ON. Motor START/ STOP button blinking blue every 3 s.	Bluetooth® ON, device visible on status bar.	Pick-up the motor handpiece.
Stand-by mode 2 <i>(inactive for 30 min)</i>	All LEDs OFF.	Bluetooth® OFF, device not visible on status bar.	Press the multifunction button.

6.6.1.5 Battery Care



Please also follow the charging instructions in the section **6.8 Storing and charging the Motor Handpiece** and heed the warnings in the Battery section in chapter **3 Warnings**.



Please charge the motor handpiece fully before using for the first time (about 6 hours) to optimize battery life.

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

- If the battery LED on the motor handpiece lights up red, charge the battery. You can continue treatment whilst it is charging.
- 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 blinking red.
- Always fully charge the battery, i.e until the battery LED turns green.
- If the battery is completely flat, charging can take up to six hours.
- Continuous operation with the charger connected shortens the lifetime of the battery. Dentsply Sirona recommends working without the charging cable connected.

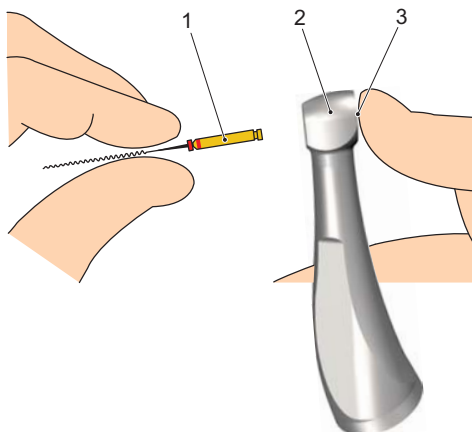
6.6.2 Inserting and removing the File

6.6.2.1 Inserting the File

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.

6.6.2.2 Removing the File

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



6.6.3 Stand-alone mode: operation without the DENTSPLY ENDO IQ™ Application

The motor handpiece can be used without the iPad® and the **DENTSPLY ENDO IQ™** application. This mode is called Stand-alone. Initial set-up requires the use of the **DENTSPLY ENDO IQ™** application, necessitating the motor handpiece being connected to the iPad Mini™ and the **DENTSPLY ENDO IQ™** application. Once the motor hand-piece is set-up with the **DENTSPLY ENDO IQ™** application, the user is able to specify the Stand-alone motor settings (i.e. RPM and Torque). This is the mode in which the motor handpiece will operate when it is not connected to the application, for example right after starting it or after a disconnection with the application.

To activate Stand-alone mode:

- Connect the motor handpiece to the **DENTSPLY ENDO IQ™** application.
See [6.7.3 Connecting the Motor Handpiece](#).
- Choose one of the available Stand-alone modes.
See [6.7.5.1 Motor Handpiece Information and Settings](#).



See [6.6.1.1](#) for motor handpiece LED status in Stand-alone mode.



The motor handpiece must be activated with the **DENTSPLY ENDO IQ™** application to be used in Stand-alone mode.



Check the current settings of the stand-alone mode before using the motor handpiece without the **DENTSPLY ENDO IQ™** application, see [6.7.5.1 Motor Handpiece Information and Settings](#).

6.7 DENTSPLY ENDO IQ™ Application

6.7.1 Starting the Application

DENTSPLY ENDO IQ™ is a multi-user iOS application for iPad® which includes the following features:

- A treatment log and reporting system (see [6.7.6.1 Treatment Details](#)).
- A file library (see [6.7.7 Customize File Sequences](#)).
- A user management (see [6.7.4 Interface Presentation](#)).
- Motor handpiece management via the Bluetooth® connection to the device.



The application is available in the App Store®.


See [6.5.5 Installing and Updating the DENTSPLY ENDO IQ™ Application](#) for instructions on installing the **DENTSPLY ENDO IQ™** application.

Application updates are also available in the App Store®.

Please check the compatibility of the application before updating.



Close all open applications before launching the **DENTSPLY ENDO IQ™** application.

N°	Key	Action
A		Start the application.






6.7.2 Editing or creating a User Profile

The first time you use the application, you will be requested to create an user profile.

You can edit the profile with your data.



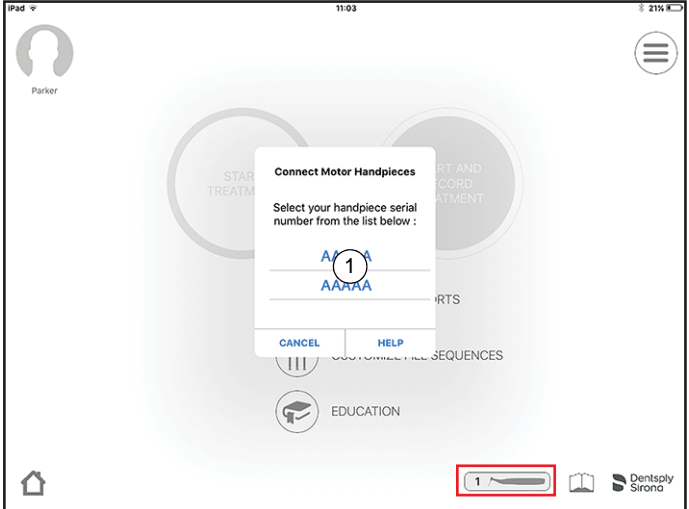







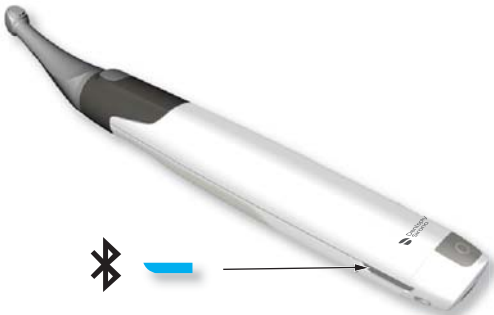
If there is only one user defined, you will be automatically connected as this user.

N°	Key	Action
A		Edit the profile. See 6.7.4 Interface Presentation . <i>Enter a user name and an email address.</i> <i>Email address is optional.</i>
 To add a new user, follow the steps below.		
B		Log out (see 6.7.4 Interface Presentation).
C		Create a user. <i>Enter a user name and a email address.</i> <i>Email address is optional.</i>
 The email address is used as the default recipient for treatment reports. To use this function, you must have an email address defined in the settings of the iPad® to send the treatment reports.		

6.7.3 Connecting the Motor Handpiece

The motor handpiece and the iPad® communicate via Bluetooth®.

N°	Action
A	<p>Press the multifunction button until the Bluetooth® LED blinks.</p> <p><i>Bluetooth® LED blinks blue, see 6.6.1.1 Description of the LED Colors.</i></p>
	
B	<p>Wait until the motor handpiece is visible on the DENTSPLY ENDO IQ™ application.</p> <p><i>See 10 Troubleshooting if the motor handpiece is not visible on the DENTSPLY ENDO IQ™ application after 10 s.</i></p>
	<p>When the motor handpiece is detected by the DENTSPLY ENDO IQ™ application, the pop-up (1) is displayed.</p>
	

N°	Action
C	Select the corresponding motor handpiece serial number from the pop-up.
	The serial number (2) can be found at the back of the motor handpiece.
	
	When the motor handpiece is connected : The icon (3) appears.
	
	The Bluetooth® LED on the motor handpiece is now blue.
	

6.7.3.1 Connecting a Second Motor Handpiece



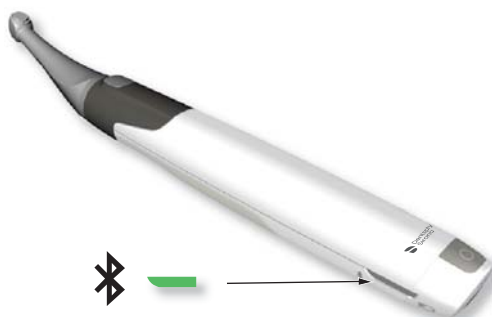
It is not possible to connect more than two motor handpieces to the **DENTSPLY ENDO IQ™** application.



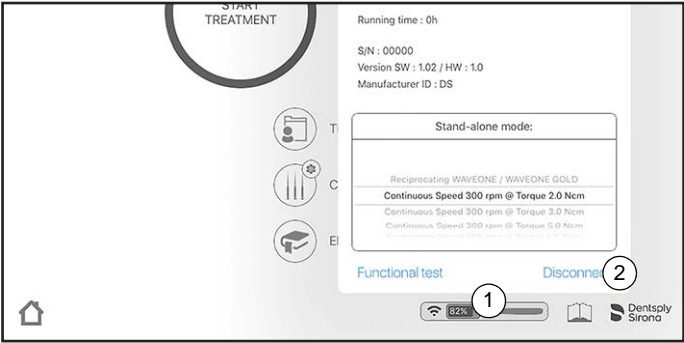



If two motor handpieces are connected to the **DENTSPLY ENDO IQ™** application, they have the same motor settings.

A second motor handpiece can be connected to the **DENTSPLY ENDO IQ™** application.

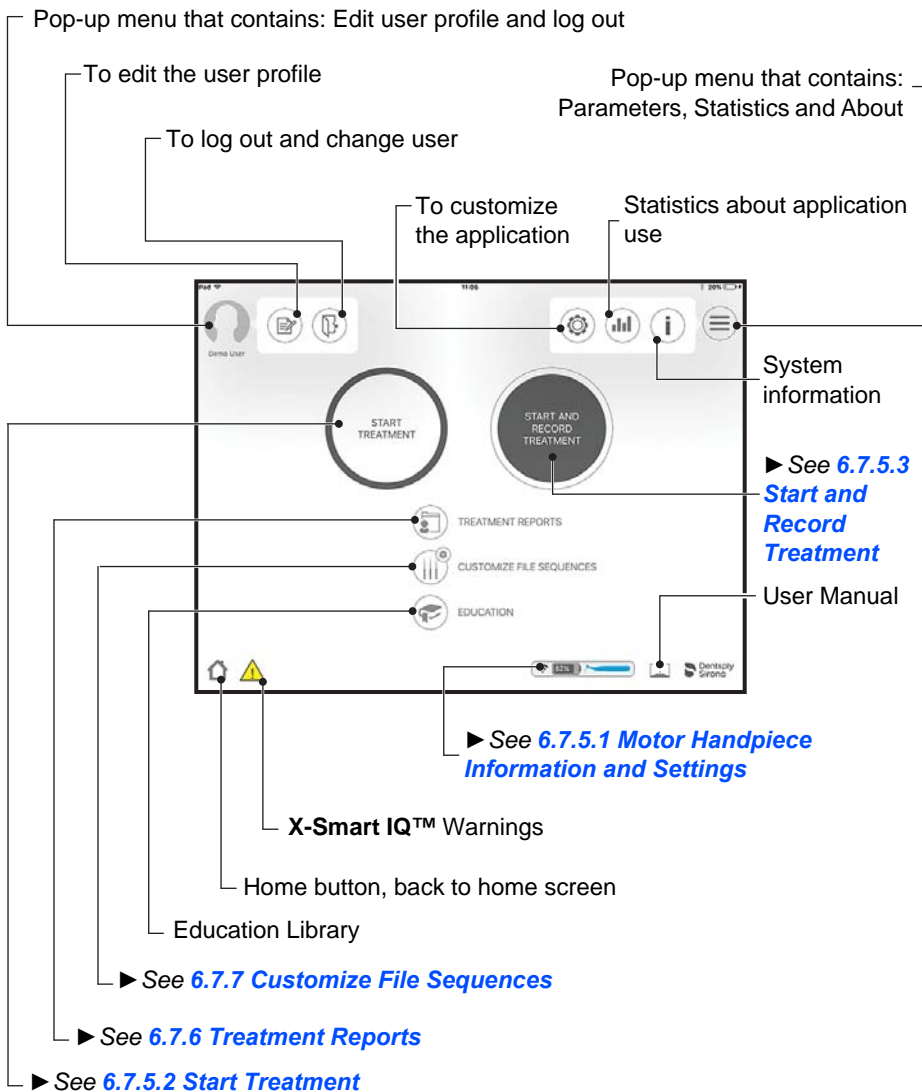
The second motor handpiece can be recognized by the green Bluetooth® LED and the following icon on the **DENTSPLY ENDO IQ™** application.


















6.7.3.2 Disconnecting the Motor Handpiece

N°	Action
A	Click on the icon (1).
B	Select Disconnect (2) and confirm the operation.
	
	The motor handpiece disappears from the status bar.
	The motor handpiece will use its stand-alone mode after a disconnection. See 6.6.3 Stand-alone mode: operation without the DENTSPLY ENDO IQ™ Application.
	If the motor handpiece is disconnected from the application (e.g. due to a communication issue), it will keep its last settings during 5 minutes, after that time it will fall into the stand-alone mode settings. See 6.6.3 Stand-alone mode: operation without the DENTSPLY ENDO IQ™ Application.






6.7.4 Interface Presentation



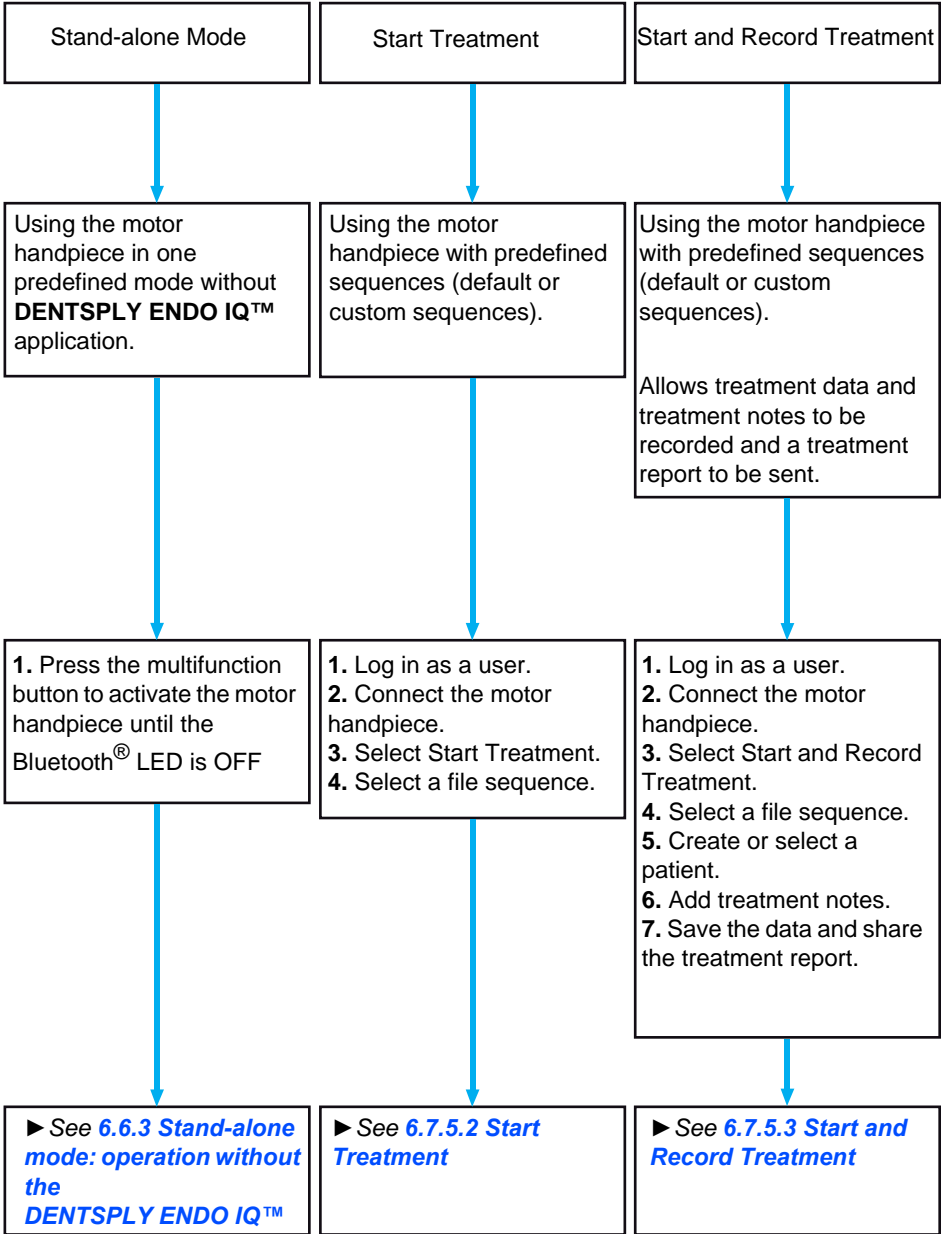
The following buttons are also present in the application:

Button	Action
	Takes you back to the previous page without saving.
	Save and leave the actual page.
	Patient information (see 6.7.6 Treatment Reports).
	Treatment notes (see 6.7.6.2 Treatment Notes).
	File library (see 6.7.7 Customize File Sequences).
	Torque recording graph (see 6.7.5.2 Start Treatment).
	Calibration (see 6.7.5.2 Start Treatment).
	Create and send a PDF report by email (see 6.7.6 Treatment Reports).
	Send multiple reports by email
	Edit (a file, a sequence, a patient, etc.).
	Delete (a file, a sequence, a patient, etc.).
	More information (see 6.7.6 Treatment Reports).
	All icons with a small < + > are used to create: new file, new sequence, new patient, etc.
	Draw
	Erase your drawings

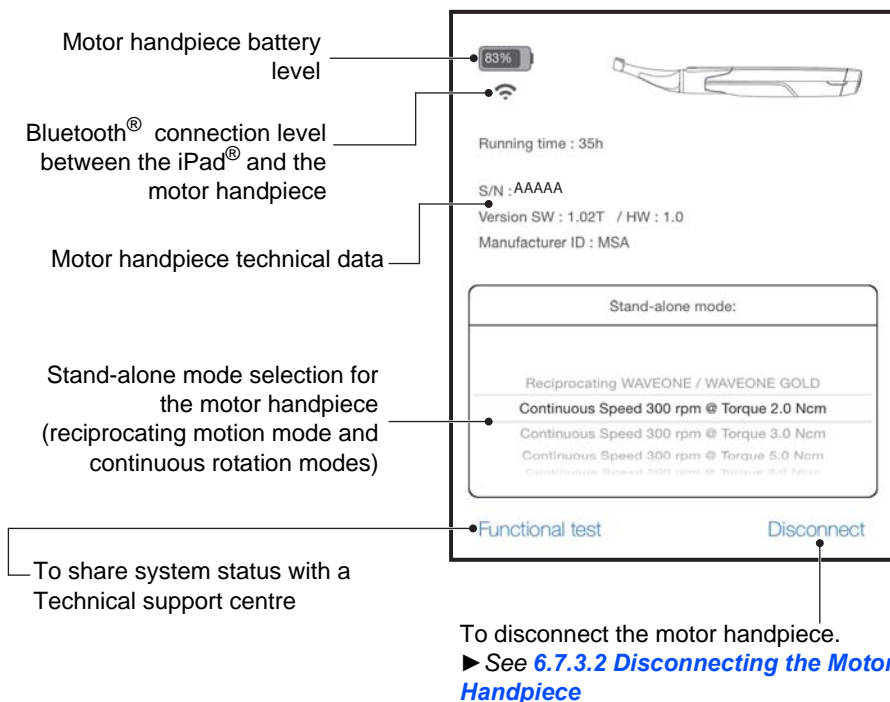
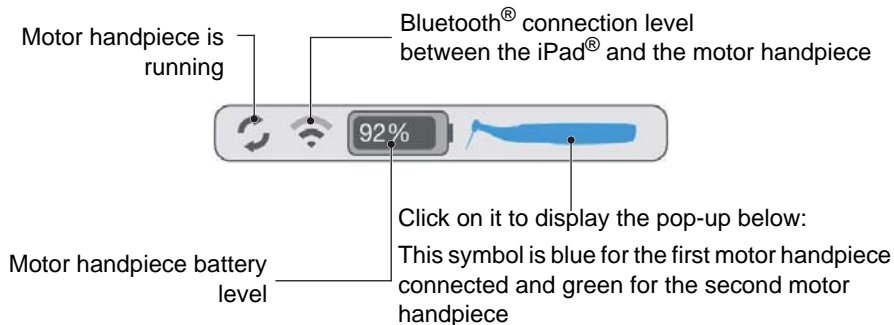
The following labels are also present in the application:

Button	Action
	Continuous rotation mode.
	Reciprocating motion mode.
	Bluetooth [®] connection level between the iPad [®] and the motor handpiece.
	Motor turning.
	Motor handpiece battery level.

6.7.5 Three Modes of Use



6.7.5.1 Motor Handpiece Information and Settings



6.7.5.2 Start Treatment

To adjust the torque and speed parameters

Click or swipe to move to next file or press the multifunction button. Double press the multifunction button to move to the previous file

Real time torque value (displayed in a circular bargraph)

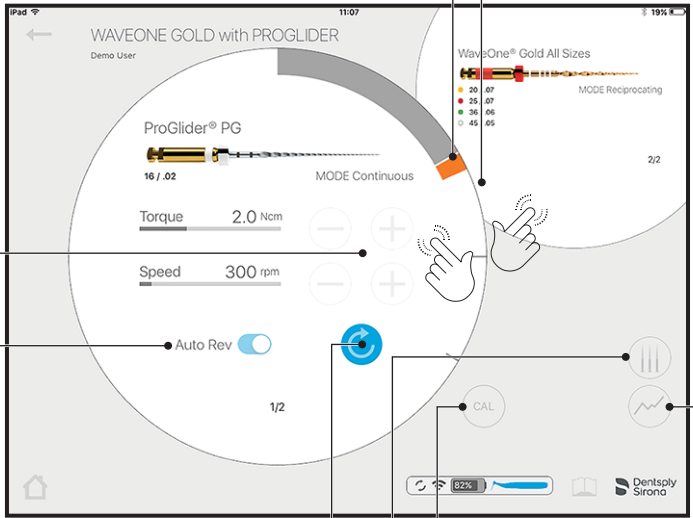
To display a torque graph in real time

To set auto reverse function.
► See [6.6.1.2 The Auto Reverse \(AutoRev\) Functionality](#)

Motor turns in reverse when activated

To calibrate the motor handpiece.
This is required to ensure the motor parameters are accurate. Calibration is recommended before each treatment. Follow the procedure on the screen

To select a file system or a file sequence.
► See [6.7.7 Customize File Sequences](#)




You can easily access "Start Treatment" by clicking on the Motor START/STOP button once the motor handpiece is connected to the X-Smart IQ™ application.



Press the multifunction button on the motor handpiece to move to the next file. Double press to move to the previous file.

6.7.5.3 Start and Record Treatment

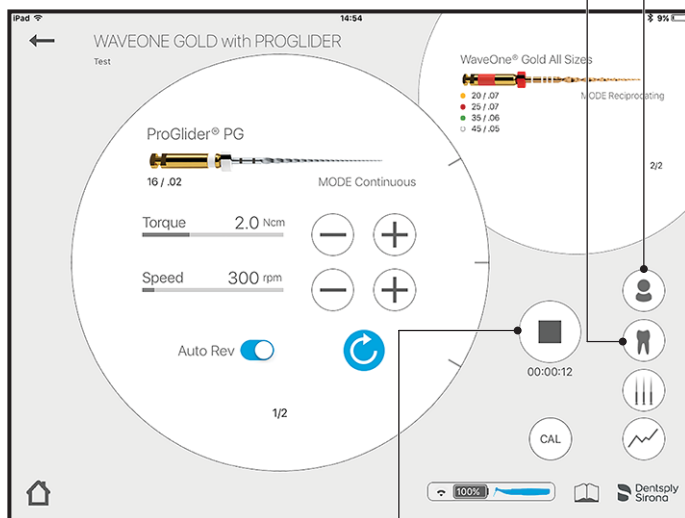


The buttons and functions described in "Start Treatment" are also applicable to "Start and Record Treatment".

To assign the current treatment to a patient

To select the tooth on which the treatment is being carried out and add treatment notes.

► See [6.7.6.2 Treatment Notes](#)



To stop recording the current treatment.

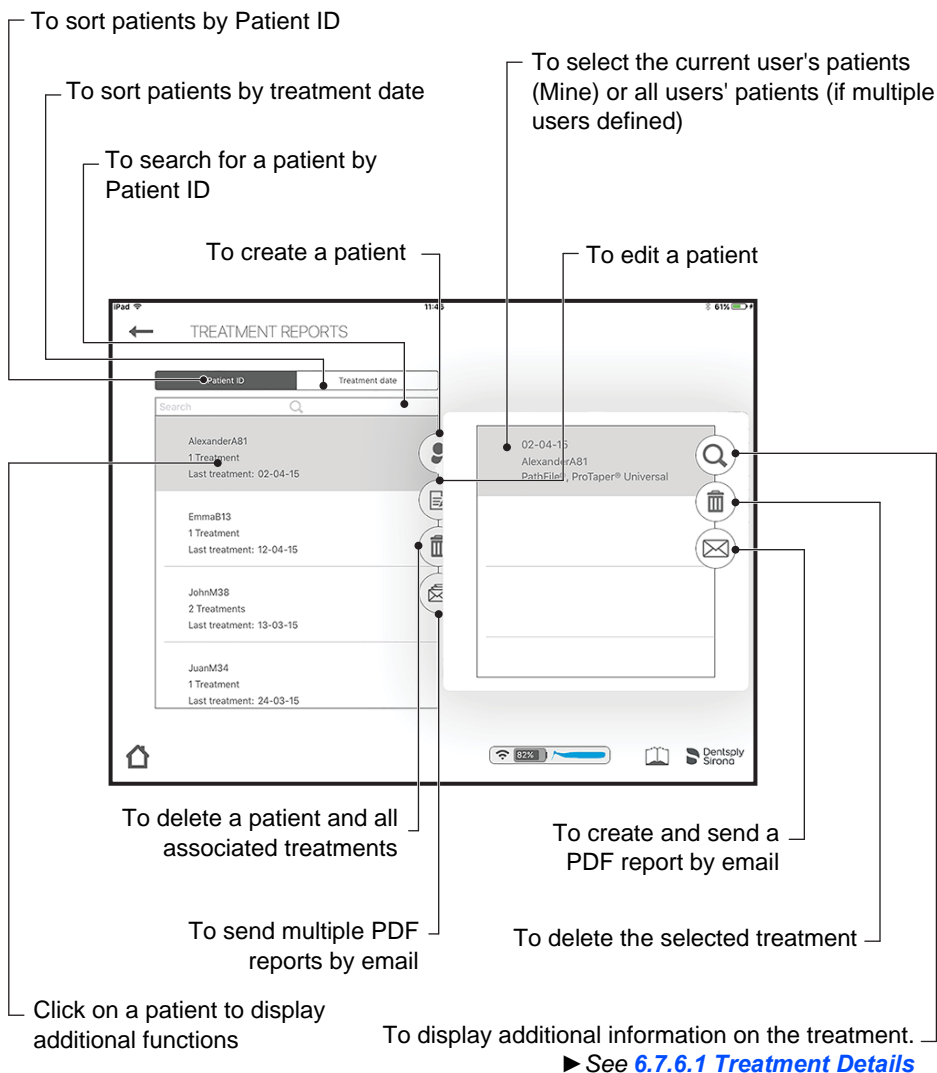
When you confirm, it opens the "Treatment Details" screen

► See [6.7.6.1 Treatment Details](#)

6.7.6 Treatment Reports

Treatment reports allow you to:

- Create, edit or delete a patient.
- View, edit or delete the treatments associated with the patients.

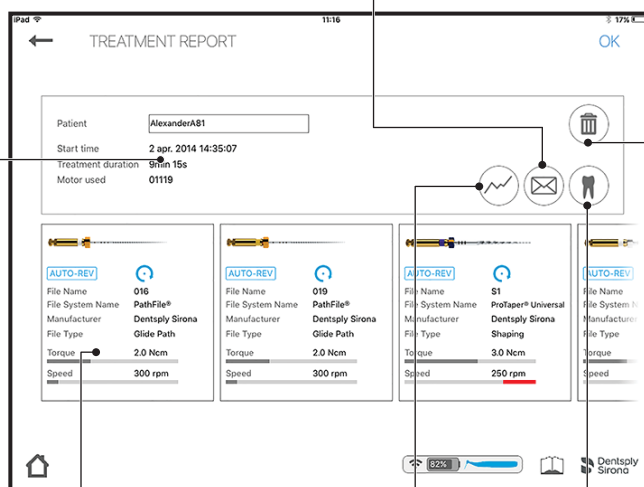


6.7.6.1 Treatment Details

Basic information for the patient and specific information for the associated treatment

To create and send a PDF report by email

To delete the treatment



To review your treatment notes.

► See [6.7.6.2 Treatment Notes](#)

To display a torque graph in real time

Technical data of the files used for the treatment

6.7.6.2 Treatment Notes

Treated tooth

Takes you back to the previous page without saving.

To save the treatments

To delete the treatment notes for the selected tooth

To add an extra canal

Information related to the treatments:
Canal type, Length, Last file used, GP Cone, Size, Other obturation, Size, Note

6.7.7 Customize File Sequences

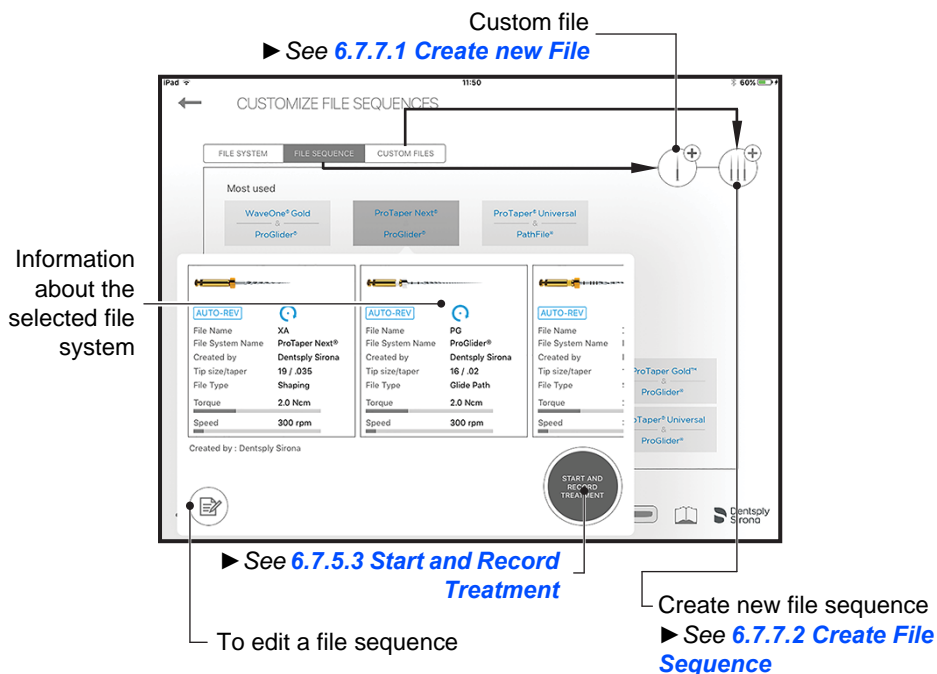
A file sequence is a collection of files that are used during a treatment. It is composed of files provided by Dentsply Sirona or a third-party manufacturer.

The file sequences are divided into 4 categories:

- Most frequently used sequences.
- Sequences created by the user.
- Standard file sequences provided by Dentsply Sirona.
- Standard file sequences provided by VDW.

The "Customize File Sequences" screen allows you to :

- Review all file systems and file sequences,
- Create, edit or delete file sequences (see [6.7.7.2 Create File Sequence](#)),
- Create and define custom files for third-party products,
- Start and record a treatment from the chosen file (see [6.7.5.3 Start and Record Treatment](#)).





Follow the file manufacturer's instructions for use of endodontic files.



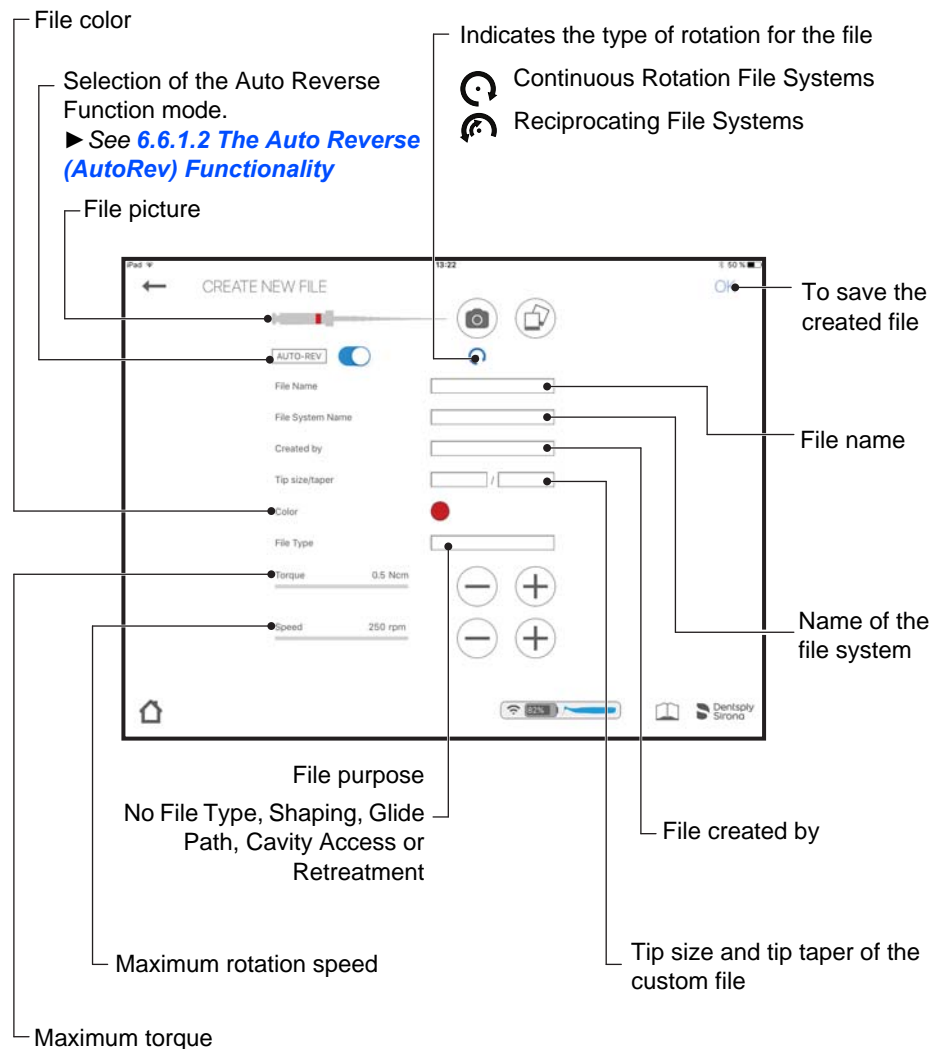
The file system shown on the display must always match the file in use. This is of the utmost importance in order to avoid misusing reciprocating files and continuous rotary files.



Torque and speed values are liable to modification by the file manufacturers without notice.

Therefore, the preset values in the library must be checked prior to use. Torque values shown on the application are accurate and reliable only if the **X-Smart IQ™** 6:1 contra-angle is properly maintained and lubricated.

6.7.7.1 Create new File



6.7.7.2 Create File Sequence



The standard file sequence can not be edited or deleted but it is possible to create a copy that can be edited.

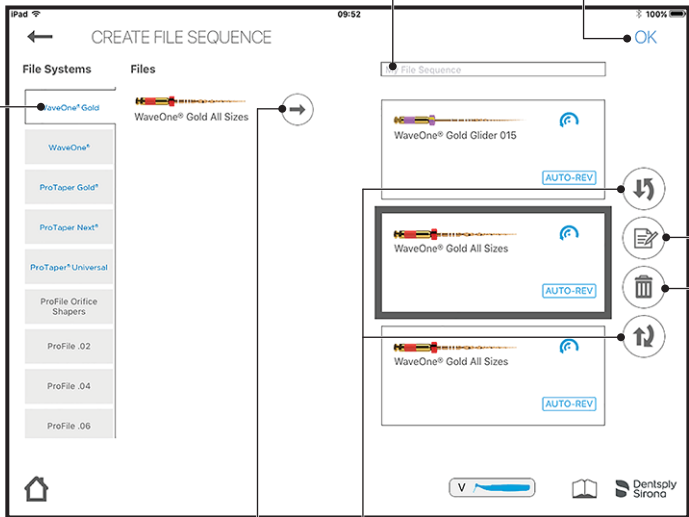


A custom file can only be deleted if not used in any sequence.

Select the file system for your sequence.

Select "Others" to insert a custom file.

► See [6.7.7.1 Create new File](#)



Name of the file sequence

Save your sequence

Click on the arrow to add the file in your sequence

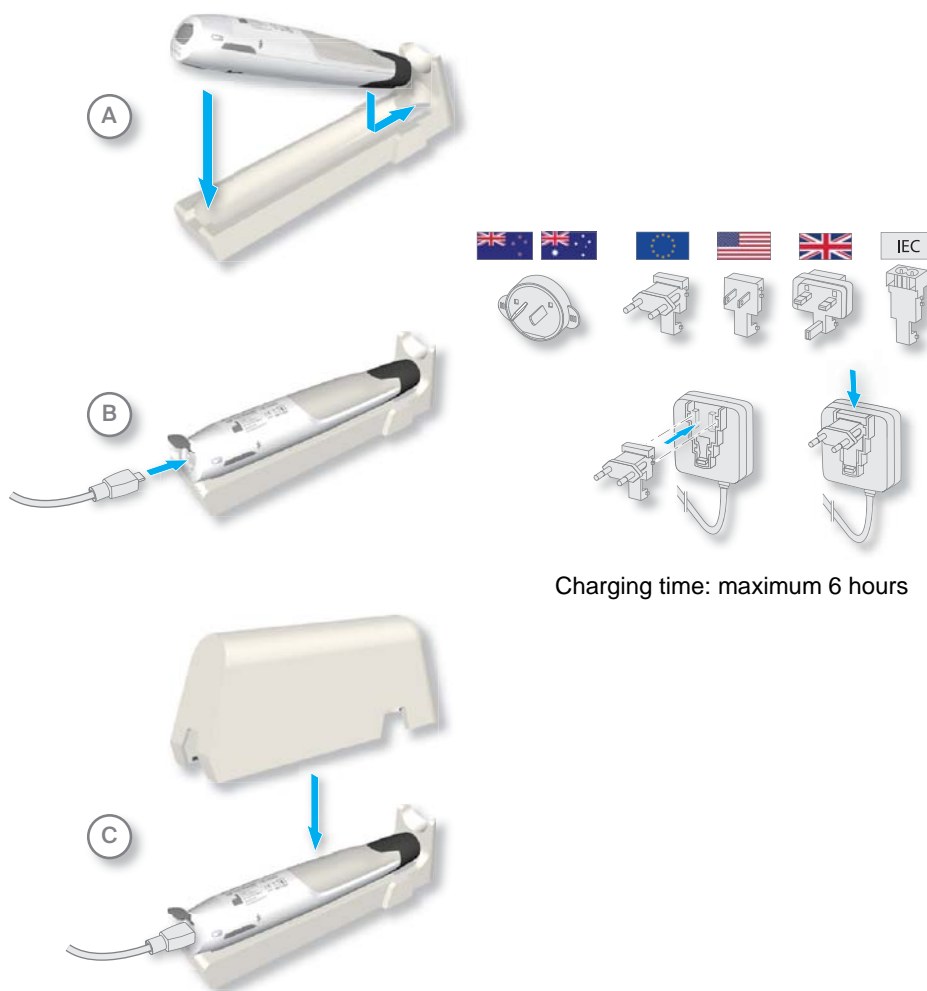
Move the position of the file in the sequence

Delete the selected file from the sequence

Edit the selected file from sequence

6.8 Storing and charging the Motor Handpiece

N°	Action
A	Store the motor handpiece in the motor handpiece holder
B	Plug in the motor charger.
C	Fit the motor handpiece cover.



Charging time: maximum 6 hours

7 CLEANING, DISINFECTION AND STERILIZATION

7.1 Foreword

Regular maintenance of **X-Smart IQ™** is essential to ensure that work performed is completely hygienic and that the device will have a long service life.

The components of **X-Smart IQ™** have not been disinfected or sterilized when they are delivered. Please perform the necessary steps before the first treatment.

You are 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 (disinfector, sterilizer) and that the validated parameters are maintained in every cycle.

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



Do not place the **X-Smart IQ™** motor handpiece in an autoclave unit or washer-disinfector.



Wear protective clothing during all cleaning, disinfection and sterilization processes.

7.2 Single Use of Custom Barrier



The use of Custom Barrier over the motor handpiece is mandatory. The barrier is designed for single use and must be disposed of after use in accordance to territorial applicable regulations.



[Please refer to the instructions for use on the Custom Barrier box.](#)

7.3 Disinfection of Components

The components listed on [page 58](#) must be cleaned and subjected to a wipe-down with a disinfection wipe prior to and following each treatment. They are not approved for machine-based cleaning (i.e. Thermal disinfection, washer disinfectors) or sterilization.



Never place the components in a washer-disinfector, autoclave or ultrasonic bath.



If you use a disinfectant in the form of a spray, never spray the devices and accessories directly.



Only use surface disinfectants that are certified by officially recognized institutes, do not contain chlorine and have been declared aldehyde-free.





In addition to using the handpiece barrier, clean and disinfect the handpiece regularly. When subjecting the motor handpiece to wipedown disinfection ensure that the charging cable is not connected and that the charging socket is closed.

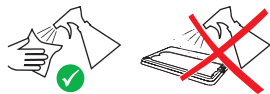
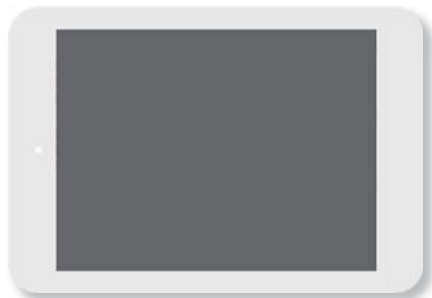


Please refer to the manufacturer's information on use of the disinfectant.

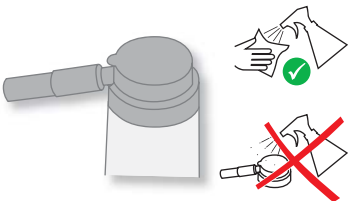
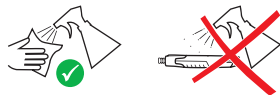
For wipe-down disinfection of components proceed as follows:

N°	Action
A	Separate the motor handpiece cover from the iPad Mini™ protective case.
B	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™.
C	Thoroughly disinfect surfaces with a soaked wipe (min. 30 seconds), making sure the entire surface is wetted, and allow to act (contact time > 30 minutes). If large surfaces have to be treated, use more than one wipe where necessary.
	Dentsply Sirona recommends the use of Dentsply VoloWipes™.
	Do not use CaviCide1™ or CaviWipes1™ on any items shown or listed on page 58 .

iPad Mini™ protective case

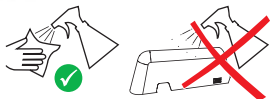
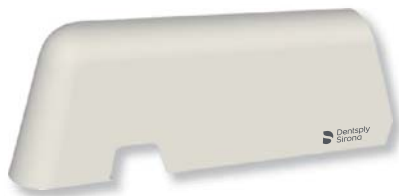


Motor handpiece

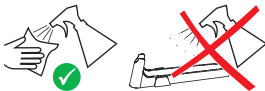


Spray adapter

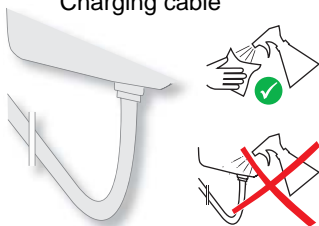
Motor handpiece cover



Motor handpiece support



Charging cable



7.4 Lubrication of the Contra-Angle

It is essential to lubricate the contra-angle after every internal cleaning procedure, before every sterilization or after 30 min. of use, but at least once a day.

Dentsply Sirona recommends the use of W&H Service Oil F1 MD-400 Oil Spray Can, 400ml.



When lubricating the contra-angle take care to ensure that no oil gets into the motor handpiece. Contamination of the motor handpiece with oil can damage it and have a negative impact on safety during operation.



Lubricate the contra-angle immediately after thermal disinfection.



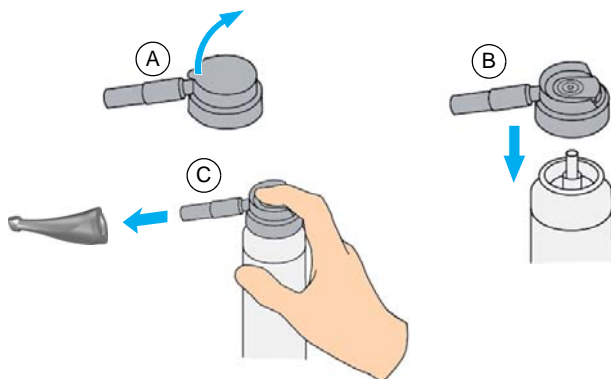
Use the spray adapter included to lubricate the contra-angle.



Dentsply Sirona recommends reprocessing the contra-angle using a fully automatic reprocessing device, e.g. the adapter available from Dentsply Sirona.

Please perform the following steps to lubricate the contra-angle:

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



7.5 Cleaning, Disinfection and Sterilization of the Contra-Angle

The contra-angle must be pre-cleaned, thermal-disinfected (if applicable) and sterilized prior to and following 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 Contra-Angle**.



Frequent reprocessing has minimal effects on the service life of contra-angles. The end of the product service life is normally dependent on wear and damage caused by use.



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

Method	Pre-Clean/ Wipe down	Lubricate (for complete instructions, see Section 7.4, page 59)	Temp / Time	Dry Time	DFU Section/ Page
Thermal disinfection (if applicable). Sterilization required following this step	Yes	After	Cleaning at 65°C / 5min. Disinfection at 90° / 5 min	Drying performed automatically during the drying cycle in the washer-disinfector	For complete instructions, see Section 7.5.2, page 62
Sterilization	Yes	Prior to	Sterilize at 134°C / 3 min	Dry time is 30 min	For complete instructions, see Section 7.5.3.1, page 64
Sterilization	Yes	Prior to	Sterilize at 132°C / 4 min	Dry time is 30 min	For complete instructions, see Section 7.5.3.1, page 64
Sterilization	Yes	Prior to	Sterilize at 121°C / 15 min	Dry time is 30 min	For complete instructions, see Section 7.5.3.1, page 64

7.5.1 Pre-Treatment of the Contra-Angle



Do not place the contra-angle in a disinfectant solution or in an ultrasonic bath.



Wear protective gloves during preparation and transportation of the contra-angle.



Use only cleaning agents that do not have a protein-binding effect.



Prior to any manual pre-treatment, detach the used file and separate the contra-angle from the motor handpiece.



No special transport container is required for the contra-angle. Transport is not subject to any special requirements.






If necessary, rinse the contra-angle under running water in order to remove any coarse soiling.



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 Contra-Angle (Thermal-Disinfection)

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

7.5.3 Sterilization of the Contra-Angle (Autoclaving)



The fast sterilization procedure and the sterilization procedure with non-packaged accessories are not permissible. In addition, do not use hot-air sterilization, radiation sterilization or sterilization with formaldehyde, ethylene oxide or plasma.



Always calibrate the motor handpiece after the contra-angle has been sterilized or exchanged. See [6.7.5.2 Start Treatment](#) for the calibration function from the **DENTSPLY ENDO IQ™** application.



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



Calibrate the motor handpiece without any files attached.



If you only use the motor handpiece in reciprocating mode (without the **DENTSPLY ENDO IQ™** application), no calibration is required.

7.5.3.1 Approved Sterilization Procedure of the Contra-Angle

N°	Operation	Remarks
A	Packaging Place the contra-angle in sterile barrier packages conforming to EN 868-5.	<i>Clean and disinfect before sterilization. The contra-angle should also be lubricated before sterilization.</i> <i>Use a sterilization temperature with tolerance in compliance with ISO 17665.</i>
B	Sterilization Dynamic Air Removal Steam Sterilization. Sterilization at 134°C (274°F) for at least 3 min. Sterilization at 132°C (269.6°F) for at least 4 min. Sterilization at 121°C (249.8°F) for at least 15 min.	<i>Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.</i> <i>Steam sterilization in accordance with EN 13060 or EN 285.</i>
C	Drying/Storage Dry time for all methods is 30 minutes.	<i>Before resuming operation: wait until the contra-angle attachment has cooled down and is completely dry.</i> <i>Store sterile contra-angles in a dry, dust-free place at room temperature.</i>







8 TECHNICAL CHARACTERISTICS






Specification	Description
Manufacturer	Maillefer Instruments Holding Sàrl Chemin du Verger 3 CH-1338 Ballaigues Switzerland
Model	X-Smart IQ™
Dimensions (Length x Height x Width)	206 mm x 24.6 mm x 24.8 mm
Material	PBT / PET Stainless steel 316L TPE (thermoplastic elastomer) Silicone ABS/PC Somalac VP290 Glass
Weight	180 g
Contra-angle	Contra-angle compatible with rotary and reciprocating files, with a 2.35 mm shaft conforming to ISO 1797-1:2011, Type 1
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)
Speed range of the micromotor shaft	1 200 – 5 100 rpm (in rotary mode)
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	Continuous operation

Specification	Description
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; • Operating altitude < 2 000 m (~ 6561ft 8in) above sea level; • Maximum housing temperature according to IEC 60601-1:2006
Medical device class	Class IIa, Rule 9, according to MDD 93/42/EEC (Annex IX).
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
Bluetooth®	Bluetooth 4.0 low energy (P=6 mW) Frequency range: 2 400 – 2 483.5 MHz Device contains transmitter with: FCC ID: RFRMSR IC-ID: 4957A-MSR Working distance: 25 m
iPad® requirement	<ul style="list-style-type: none"> • iPad Mini™ 2 • iPad Mini™ 3 • iPad Mini™ 4
Operating System	<ul style="list-style-type: none"> • iOS 11.x • iOS 12.x
EMC Tables	See www.dentsplymaillefer.com

9 MOTOR HANDPIECE ERROR CODE

If a failure occurs on the motor 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	Re-initialize the motor handpiece with a Factory Reset (see 6.6.1 Description of the Motor Handpiece).
	Battery empty	Charge the battery (see 6.8 Storing and charging the Motor Handpiece).
	Motor overheating	Wait for a few minutes and press the multifunction button to reactivate the motor handpiece.
	Motor hardware failure	Reset the device (see 6.6.1 Description of the Motor Handpiece).
	Battery failure	Return the instrument to your service center.
	General hardware failure	Reset the device (see 6.6.1 Description of the Motor Handpiece).

State	Failure	Solution
	The Motor START/STOP button sensor is not working properly	<i>Reset the device (see 6.6.1 Description of the Motor Handpiece).</i>
	Bluetooth radio module failure	<i>Reset the device (see 6.6.1 Description of the Motor Handpiece).</i>
	Calibration failed	<i>Lubricate the contra-angle (see 7.5.3.1 Approved Sterilization Procedure of the Contra-Angle) and perform the calibration again.</i> <i>If the error persists, try to replace the contra-angle and perform the calibration again.</i>
	Battery charge not sufficient to perform a firmware upgrade.	<i>Charge the device until the BATTERY indicator turns green. Restart the firmware update.</i>
	General firmware failure	<i>Reset the device (see 6.6.1 Description of the Motor Handpiece).</i>

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 service center.



*Also refer to the any error codes which may be indicated on the device, as described in chapter **9 Motor Handpiece Error Code**.*

Problem	Cause / Solution
Running motor cannot be stopped during preparation.	<p>The ON/OFF button is blocked or faulty.</p> <p><i>Briefly press the multifunction button once to stop the motor. Start and stop the motor again. If the error has not been remedied, contact your service center.</i></p>
The handpiece cannot be switched on.	<p>The battery is completely flat (all LEDs off).</p> <p><i>Connect the motor handpiece to charger (see 6.8 Storing and charging the Motor Handpiece).</i></p>
	<p>The handpiece no longer responds (the LEDs are lit but the motor handpiece does not respond when the button is pressed).</p> <p><i>Perform a reset (see 6.6.1 Description of the Motor Handpiece).</i></p> <p><i>The motor handpiece automatically switches to ready mode.</i></p>
	<p>The multifunction button is faulty.</p> <p><i>Contact your service center.</i></p>
The motor handpiece cannot be connected to the iPad®.	<p>The Bluetooth® connection has failed.</p> <p><i>iPad®:</i></p> <ol style="list-style-type: none"> <i>1. Activate Bluetooth® on your iPad® under settings (see 6.5.4 Activating the Bluetooth®).</i> <i>2. Perform a reboot on your iPad® (press and hold the iPad® ON / OFF button for a few seconds).</i> <p><i>Motor handpiece:</i></p> <p><i>Perform a factory reset (see 6.6.1 Description of the Motor Handpiece).</i></p>

Problem	Cause / Solution
Lost connection between the handpiece and the iPad®.	<p>iPad® switched off (empty battery).</p> <p><i>The handpiece keeps the last used settings for 5 min. You can either recharge the iPad® and reconnect the motor handpiece or use it in stand-alone mode.</i></p>
	<p>iPad® Bluetooth® switched off.</p> <p><i>Switch on the Bluetooth® on the iPad® and reconnect the motor handpiece (see 6.5.4 Activating the Bluetooth® and 6.7.3 Connecting the Motor Handpiece).</i></p>
	<p>Motor handpiece far from the iPad®.</p> <p><i>Place the motor handpiece near the iPad® and re-connect it (see 6.7.3 Connecting the Motor Handpiece).</i></p>
The contra-angle cannot be calibrated.	<p>The calibration procedure may have been interrupted by increased resistance in the contra-angle.</p> <ol style="list-style-type: none"> <i>1. If calibration has been interrupted, calibrate the motor handpiece again to rule out the possibility of a motor fault.</i> <i>2. Clean and lubricate the contra-angle (see 7.5 Cleaning, Disinfection and Sterilization of the Contra-Angle).</i> <i>3. Start the calibration procedure again.</i>
Motor handpiece is getting hot.	<p>Overheating.</p> <p><i>The device switches off automatically if it overheats. Allow the device to cool down and start again the motor handpiece.</i></p>
A reciprocating instrument has become jammed in the root canal.	<p>Treatment was not performed properly.</p> <p><i>Remove the reciprocating instrument with pliers by rotating clockwise carefully.</i></p>
A rotary instrument has become jammed in the root canal.	<p>Treatment was not performed properly.</p> <p><i>Select reverse rotation, start the motor handpiece and rotate the instrument out of the root canal carefully.</i></p>

11 WARRANTY

Dentsply Sirona certifies that the device has been properly designed, that the highest quality materials have been used, that all the necessary tests have been performed and that the device complies with the relevant laws and regulations.

Full performance capability of **X-Smart IQ™** is covered by a 12-month warranty and that of the contra-angle is covered by a 24-month warranty that commences on the date of delivery to the customer (as indicated on the delivery documents bearing the serial number of the product, issued by the seller upon sale).

Only within the term of the warranty is the customer entitled to warranty services and only on condition that he or she informs Dentsply Sirona of the defect in writing within two months after the date the defect was discovered.

In the event of a substantiated claim, the repair will be performed as soon as possible by the Technical Equipment Service of Dentsply Sirona or a service partner authorized by Dentsply Sirona.

This warranty only covers the exchange or repair of individual components or parts that are affected by manufacturing defects. The costs incurred by the dental dealer's technical personnel for visiting the customer and the customer's cost of packaging will not be reimbursed by Dentsply Sirona. The customer is not entitled to file claims with Dentsply Sirona that go beyond repair, e.g. indemnity claims. This warranty does not cover any compensation for direct or indirect personal injury or damage to property of whatever nature. The customer is not entitled to demand compensation for device outage times.

The warranty does not cover losses where Dentsply Sirona produces evidence that they have been caused by negligence on the part of the user with regard to normal maintenance (as indicated in the User Manual), especially when subjecting the battery to charging, discharging and maintenance in accordance with the User Manual and with regard to careful and regular maintenance of the contra-angle.

The warranty explicitly excludes defects that:

- have been caused by damage in transit to Dentsply Sirona/to a service partner authorized by Dentsply Sirona for the purpose of repair;
- have been caused by atmospheric events such as lightning strike, fire and moisture. This warranty is automatically rendered void if the product has been improperly repaired, modified or otherwise tampered with by the user or unauthorized third parties.

The warranty is only valid if the device sent in for repair is accompanied by the invoice confirming the date of delivery of the product.

Legal claims, resulting from product-liability law for example, and claims filed with the person from whom the customer purchased the product, especially ones filed with the dental dealer, shall remain unaffected.

11.1 Exclusion of Liability

In the following cases the manufacturer declines all liability:

- Use of **X-Smart IQ™** for purposes and applications that differ from the specific requirements made in this User Manual.
- Cleaning, disinfection and sterilization methods contrary to the directions in this User Manual.
- Contra-angle maintenance contrary to the directions in this User Manual.
- 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 country.

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













12 DISPOSAL OF THE PRODUCT















Comply with your national regulations, guidelines and requirements for the disposal of end-of-life electrical equipment and batteries. Specialist dental dealers will be pleased to provide you with country-specific information concerning disposal.

Make sure the product or battery is not mixed with other types of waste when it is being disposed of. Prior to disassembly and disposal your device must not be contaminated and must have been completely reprocessed (Cleaning/Disinfection/Sterilization).

13 IDENTIFICATION OF SYMBOLS

13.1 Normative Symbols

Symbol	Identification
	Serial number
	Lot number
	Catalogue number
	Refer to instruction manual / booklet
	Electronic instruction for use
	Date of manufacture
	Manufacturer
	Class II equipment
	Type BF applied part
	Recycling: PLEASE DO NOT THROW AWAY! This product and all its components must absolutely be recycled through your distributor
	Direct current (connection for power supply)
	Sterilizable in a steam sterilizer (autoclave) at temperature specified

Symbol	Identification
	Opened packages are not replaced
	CE Mark
	Alternate current
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from rain
	Fragile, handle with care
	Accessory
	Use by date
	Do not sterilize
	Do not re-use
	Caution, consult accompanying documents
	Plastic

14 ELECTROMAGNETIC EMISSIONS AND IMMUNITY

14.1 Essential Performance

The essential performance of the **X-Smart IQ™** system was identified as driving a medical device such as an endodontic instrument in continuous rotary movement or an alternate reciprocating one with defined settings.

14.2 Compliant Cables and Accessories

The use of accessories and cables other than specified by the manufacturer may results in increase emissions or decrease immunity of this product.

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

14.3 Instructions for Maintaining BASIC Safety and Essential Performance for the Expected Service Life

Do not change the once installed final application due to EMC view. If the environment doesn't correspond to the conditions listed in chapter [14.4 Compliance with Emission and Immunity standard](#), some actions are required to match those conditions.

The climatic environmental conditions could affect the life of critical components of the product (varistors, electrolytic capacitors, mains filters,...).

The presence of transmitters near the product could affect its performances. The distances mentioned in the tables below could help to prevent any disturbances of the equipment in normal operation.


14.4 Compliance with Emission and Immunity standard

Guidance and manufacturer's declaration - electromagnetic emissions		
X-Smart IQ™ is intended for use in the electromagnetic environment specified below. The customer or the user or X-Smart IQ™ 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™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	X-Smart IQ™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	-
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	-

Guidance and manufacturer's declaration - electromagnetic immunity			
X-Smart IQ™ is intended for use in the electromagnetic environment specified below. The customer or the user of X-Smart IQ™ should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
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 (at 0, 45, 90, 135, 180, 225 and 315° phase angle)</p> <p>< 5% 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>< 5% U_T (> 95% dip in U_T) for 250/300 cycles (at 0 phase angle)</p>	<p>< 5% U_T (> 95% dip in U_T) for 0.5 cycle (at 0, 45, 90, 135, 180, 225 and 315° phase angle)</p> <p>< 5% 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>< 5% 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™ requires continued operation during power mains interruptions, it is recommended that X-Smart IQ™ be powered from an uninterruptible power supply or a battery.</p>
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration electromagnetic immunity			
X-Smart IQ™ is intended for use in the electromagnetic environment specified below. The customer or the user of X-Smart IQ™ should assure that it is used in such an environment.			
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	Portable and mobile RF communications equipment should be used no closer to any part of X-Smart IQ™ , including cables, than the recommended separation distance calculated from that equation applicable to the frequency of the transmitter. $d = 0.35 \times \sqrt{P}$
	6 Vrms 150 kHz - 80 MHz in ISM and amateur radio bands	10 Vrms	 $d = 0.35 \times \sqrt{P}$

<p>Radiated RF IEC 61000-4-3</p>	<p>10 V/m 80 MHz to 2.7 GHz</p>	<p>10 V/m</p>	<p>$d = 0.35 \times \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 0.7 \times \sqrt{P}$ 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> 
<p>NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a</p> <p>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™ is used exceeds the applicable RF compliance level above, X-Smart IQ™ 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™.</p> <p>^b</p> <p>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and X-Smart IQ™			
X-Smart IQ™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of X-Smart IQ™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and X-Smart IQ™ 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.			

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment					
Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
380 - 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
430 - 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
800 – 960	GSM 800 / 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
1700 – 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28

2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5100 – 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.					
<p>a) For some services, only the uplink frequencies are included.</p> <p>b) The carrier shall be modulated using a 50% duty cycle square wave signal.</p> <p>c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p>					

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