

X-Smart IQ™

User Manual



PAGE INTENTIONALLY LEFT BLANK

Table of contents

	Introduction	6
1	Indications for Use	7
2	Contraindications	8
3	Warnings	9
4	Precautions	14
5	Adverse Reactions	15
6	Step by Step Instructions	16
6.1	Document Symbols	16
6.2	DENTSPLY ENDO IQ™ Application Compatibility	16
6.3	Package Contents	17
6.4	Components not included	18
6.5	System Setup	18
6.5.1	Turning on the iPad® and setting the Volume	18
6.5.2	Activating the AssistiveTouch	19
6.5.3	Activating the WiFi	21
6.5.4	Activating the Bluetooth®	21
6.5.5	Installing and Updating the DENTSPLY ENDO IQ™ Application	22
6.5.5.1	Firmware update	22
6.5.6	Setting up the Complete System	23

6.6	Motor Handpiece	25
6.6.1	Description of the Motor Handpiece	25
6.6.1.1	Description of the LED Colors	26
6.6.1.2	The Auto Reverse (AutoRev) Functionality	28
6.6.1.3	Description of the Sounds	29
6.6.1.4	Stand-by Mode	29
6.6.1.5	Battery Care	30
6.6.2	Inserting and removing the File	30
6.6.2.1	Inserting the File	30
6.6.2.2	Removing the File	31
6.6.3	Stand-alone mode: operation without the DENTSPLY ENDO IQ™ Application	31
6.7	DENTSPLY ENDO IQ™ Application	32
6.7.1	Starting the Application	32
6.7.2	Editing or creating a User Profile	33
6.7.3	Connecting the Motor Handpiece	34
6.7.3.1	Connecting a Second Motor Handpiece	36
6.7.3.2	Disconnecting the Motor Handpiece	37
6.7.4	Interface Presentation	38
6.7.5	Three Modes of Use	41
6.7.5.1	Motor Handpiece Information and Settings	42
6.7.5.2	Start Treatment	43
6.7.5.3	Start and Record Treatment	44
6.7.6	Treatment Reports	45
6.7.6.1	Treatment Details	46
6.7.6.2	Treatment Notes	47
6.7.7	Customize File Sequences	48
6.7.7.1	Create new File	50
6.7.7.2	Create File Sequence	51
6.8	Storing and charging the Motor Handpiece	52

7	Cleaning, Disinfection and Sterilization	53
7.1	Foreword	53
7.2	Single Use of Custom Barrier	53
7.3	Disinfection of Components	53
7.4	Lubrication of the Contra-Angle	56
7.5	Cleaning, Disinfection and Sterilization of the Contra-Angle	57
7.5.1	Pre-Treatment of the Contra-Angle	58
7.5.2	Machine-based Reprocessing of the Contra-Angle (Thermal-Disinfection)	59
7.5.3	Sterilization of the Contra-Angle (Autoclaving)	60
7.5.3.1	Approved Sterilization Procedure of the Contra-Angle	61
8	Technical Characteristics	62
9	Motor Handpiece Error Code	64
10	Troubleshooting	66
11	Warranty	68
11.1	Exclusion of Liability	69
12	Disposal of the Product	70
13	Identification of Symbols	71
13.1	Normative Symbols	71

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. 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.



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

Telephone +41 21 843 92 92
Fax +41 21 843 92 93
info@dentsplymaillefer.com
www.dentsplymaillefer.com

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.

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.

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 (DIN EN 60601-1-2:2007).
- 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 8 requirements.
- 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

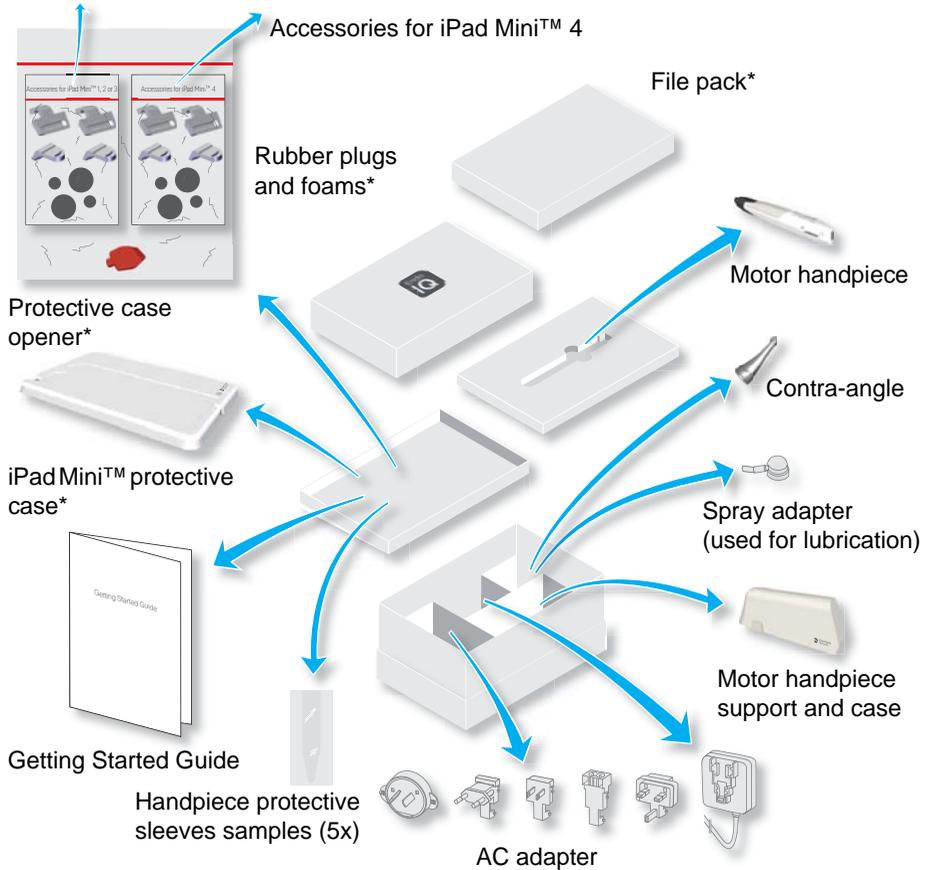
6.2 DENTSPLY ENDO IQ™ Application Compatibility

Specification	Description
iPad® requirement	<ul style="list-style-type: none"> • iPad Mini™ • iPad Mini™ 2 • iPad Mini™ 3 • iPad Mini™ 4
Operating System	<ul style="list-style-type: none"> • iOS 9.x • iOS 10.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.
 <p>Not all components presented below are available in all kits.</p>	

Accessories for iPad Mini™ 1, 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.
	<p>The application uses sounds to give general information, see 6.6.1.3 Description of the Sounds.</p>

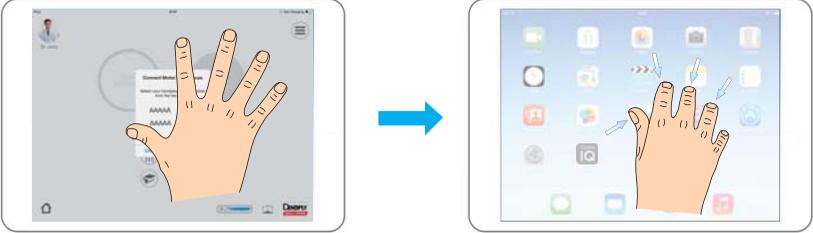
6.5.2 Activating the AssistiveTouch

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 .
	<p>It is also possible to use the 5 fingers to swipe in and to return to the Home screen.</p>
	

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®.

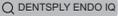
N°	Key	Action
A		Select Settings.
B		Select Bluetooth®.
C		Set Bluetooth® to ON.
	To connect the motor handpiece to the iPad®, see 6.7.3 Connecting the Motor Handpiece.	

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	 DENTSPLY ENDO IQ	Search and download the DENTSPLY ENDO IQ™ application.
	<p>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.</p>	
	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.

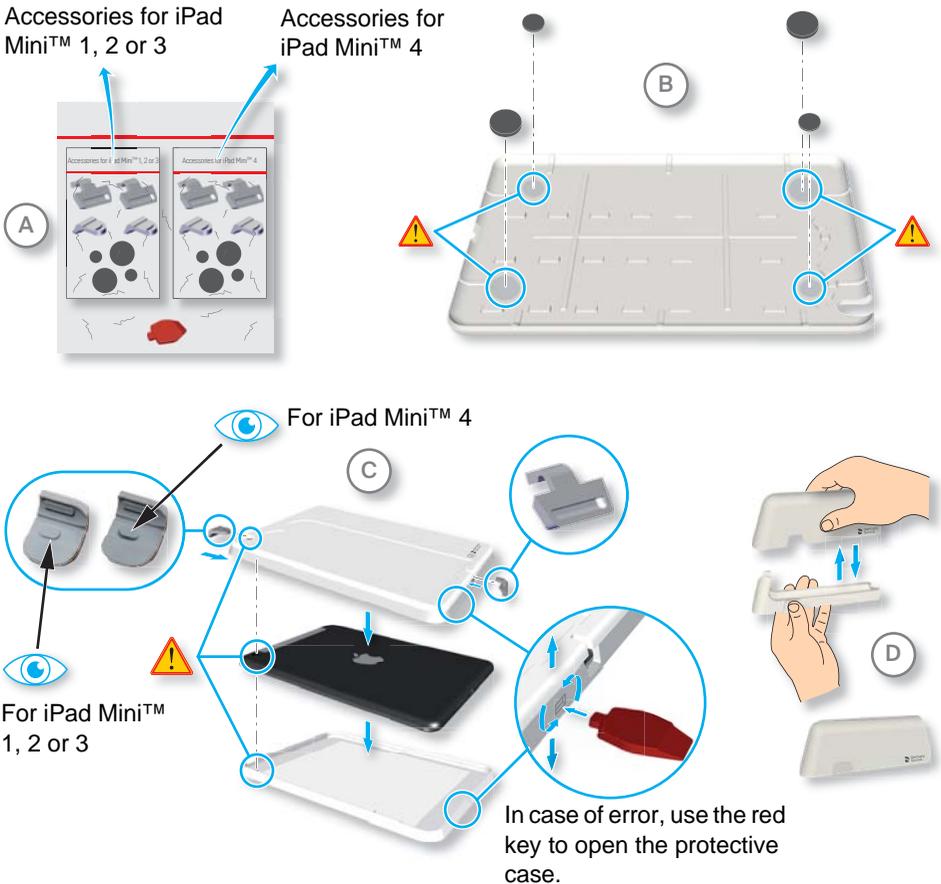
Follow the instructions on the screen to execute the update.



Connect the motor handpiece to the AC adapter before starting the firmware update. See [6.8 Storing and charging the Motor Handpiece](#).

6.5.6 Setting up the Complete System

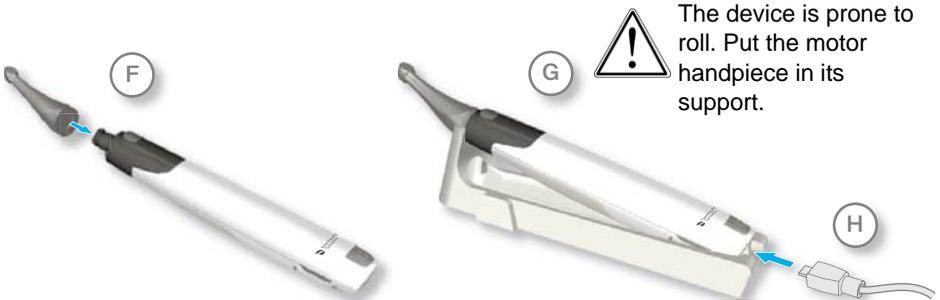
N°	Action
A	According to your iPad Mini™ model, use the suitable kit.
B	Stick the foams of your kit at the places indicated on the protective case.
C	Enclose and center the iPad Mini™ in the protective case. Place the corresponding plugs on the camera and the charging port.
	Pay attention to the iPad 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



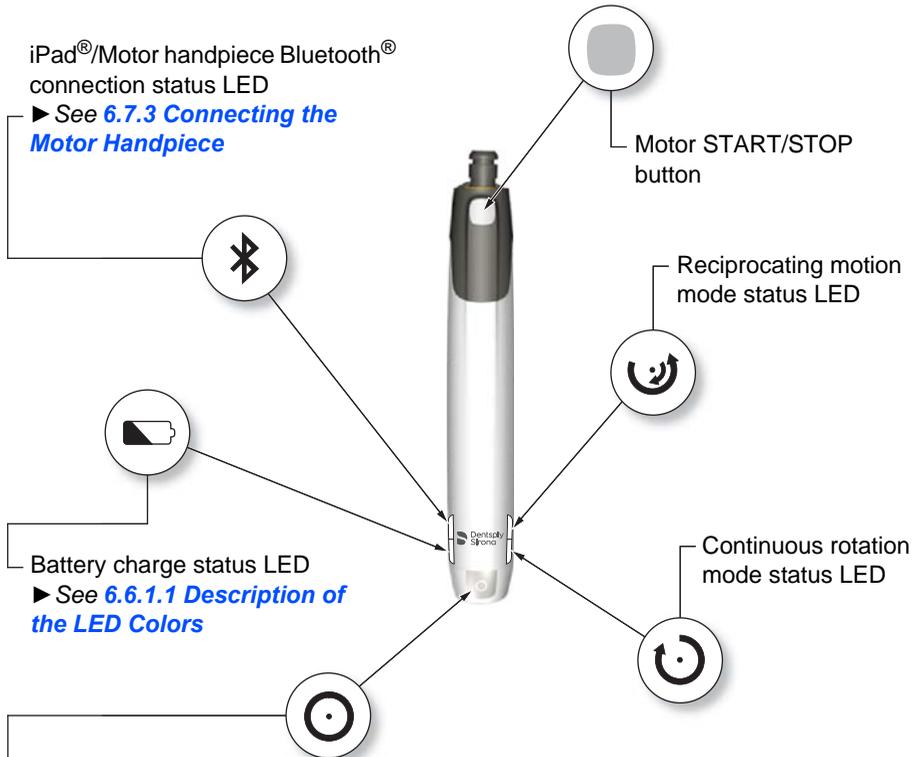
Positions 1 and 4 have a limited stability. Monitor the device carefully if you choose one of these positions.



The device is prone to roll. Put the motor handpiece in its support.

6.6 Motor Handpiece

6.6.1 Description of the Motor Handpiece



iPad®/Motor handpiece Bluetooth® connection status LED

► See [6.7.3 Connecting the Motor Handpiece](#)

Battery charge status LED

► See [6.6.1.1 Description of the LED Colors](#)

Multifunction button:

- 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.

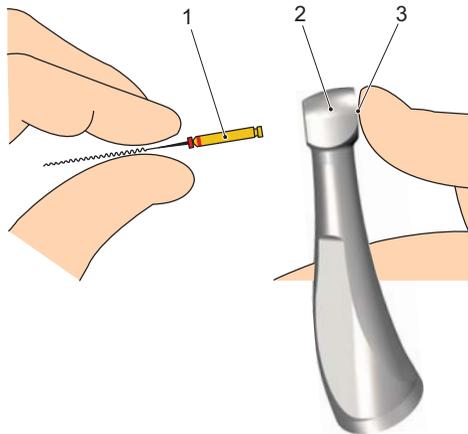
6.6.2 Inserting and removing the File

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.

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.

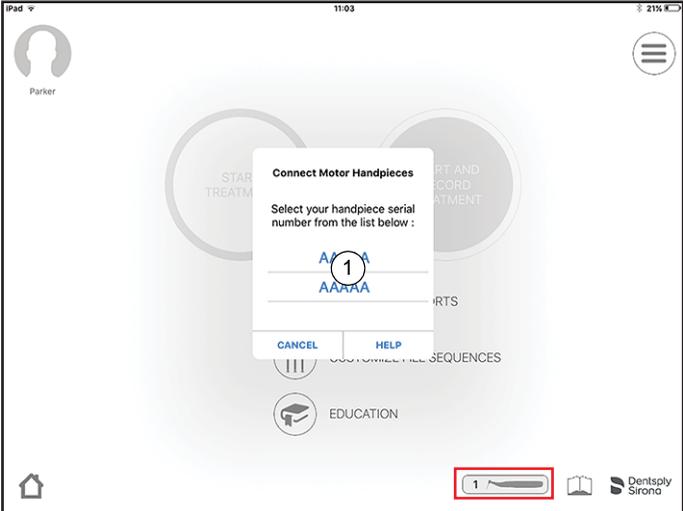


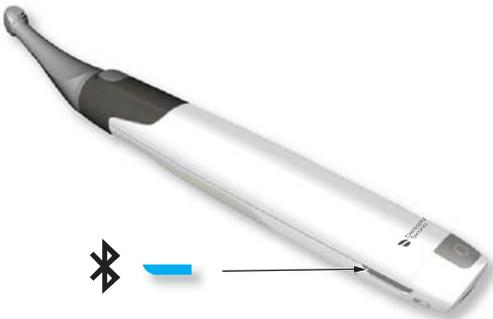
If there is only one user defined, you will be automatically connected as this user.

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>
	<p>The email address is used as the default recipient for treatment reports.</p> <p>To use this function, you must have an email address defined in the settings of the iPad® to send the treatment reports.</p>	

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.
	<p>The serial number (2) can be found at the back of the motor handpiece.</p>
	 <p>The image shows the back of a silver motor handpiece. A label contains the following information: SN AAAAA, REF 31090, x-smart IQ, Mallefer Instruments Holding Sàrl, Chemin du Vauger 3, CH-1336 Ballégny, Switzerland. A circled number '2' with an arrow points to the serial number 'SN AAAAA'.</p>
	<p>When the motor handpiece is connected : The icon (3) appears.</p>
	 <p>The screenshot shows a software interface with three menu items: TREATMENT REPORTS, CUSTOMIZE FILE SEQUENCES, and EDUCATION. At the bottom, there is a home icon, a Bluetooth signal strength indicator showing 82%, a battery level indicator, and the Dentsply Sirona logo.</p>
	<p>The Bluetooth® LED on the motor handpiece is now blue.</p>
	 <p>The image shows a motor handpiece with a Bluetooth symbol and a blue LED indicator. An arrow points to the blue LED, indicating it is active.</p>

6.7.3.1 Connecting a Second Motor Handpiece



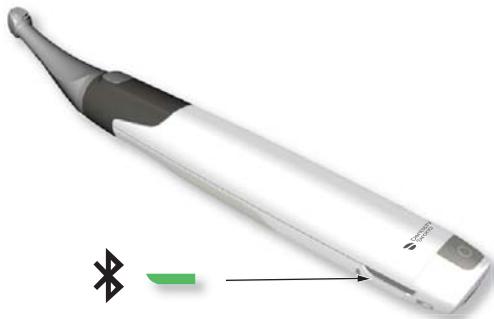
It is not possible to connect more than two motor handpieces to the **DENTSPLY ENDO IQ™** application.



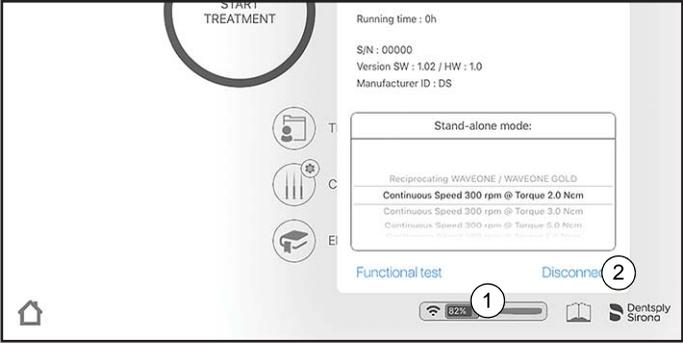
If two motor handpieces are connected to the **DENTSPLY ENDO IQ™** application, they have the same motor settings.

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

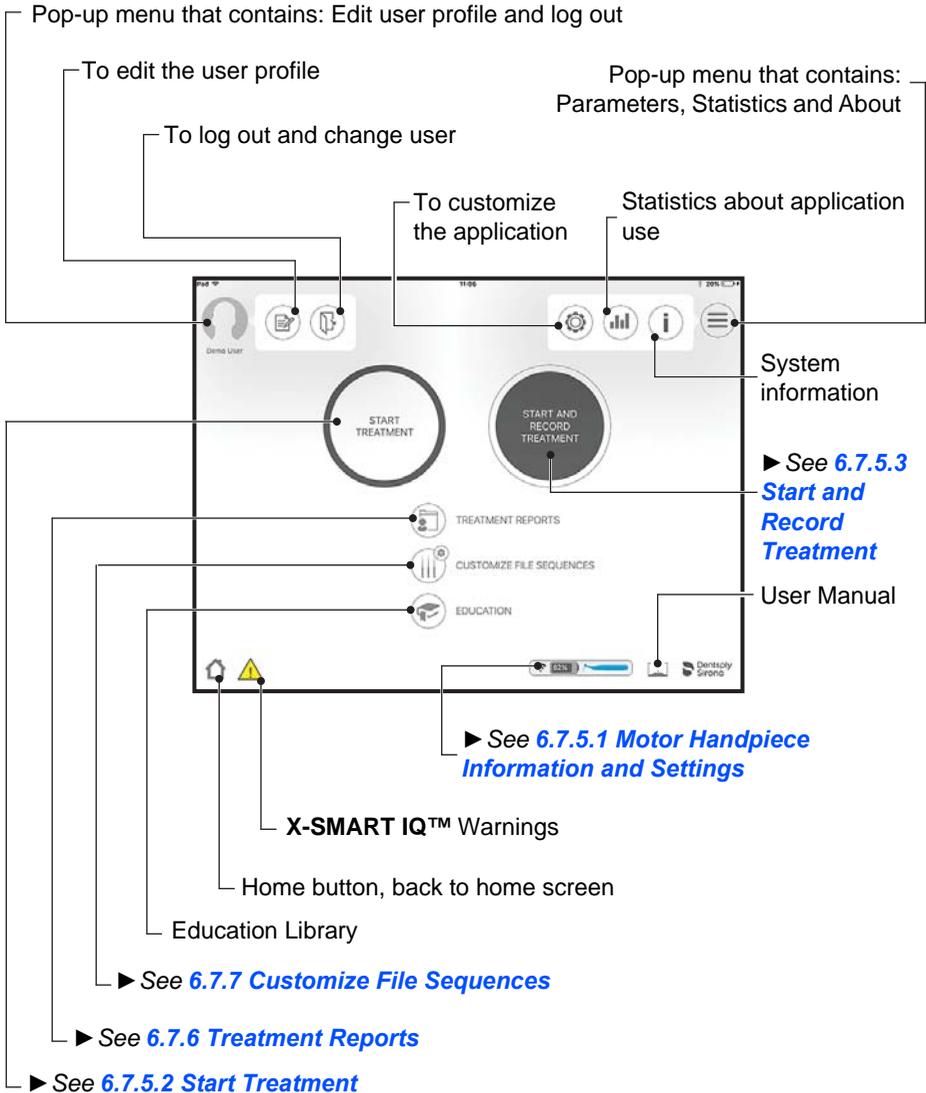
The second motor handpiece can be recognized by the green Bluetooth® LED and the following icon on the **DENTSPLY ENDO IQ™** application.



6.7.3.2 Disconnecting the Motor Handpiece

N°	Action
A	Click on the icon (1).
B	Select Disconnect (2) and confirm the operation.
	
	<p>The motor handpiece disappears from the status bar.</p>

6.7.4 Interface Presentation



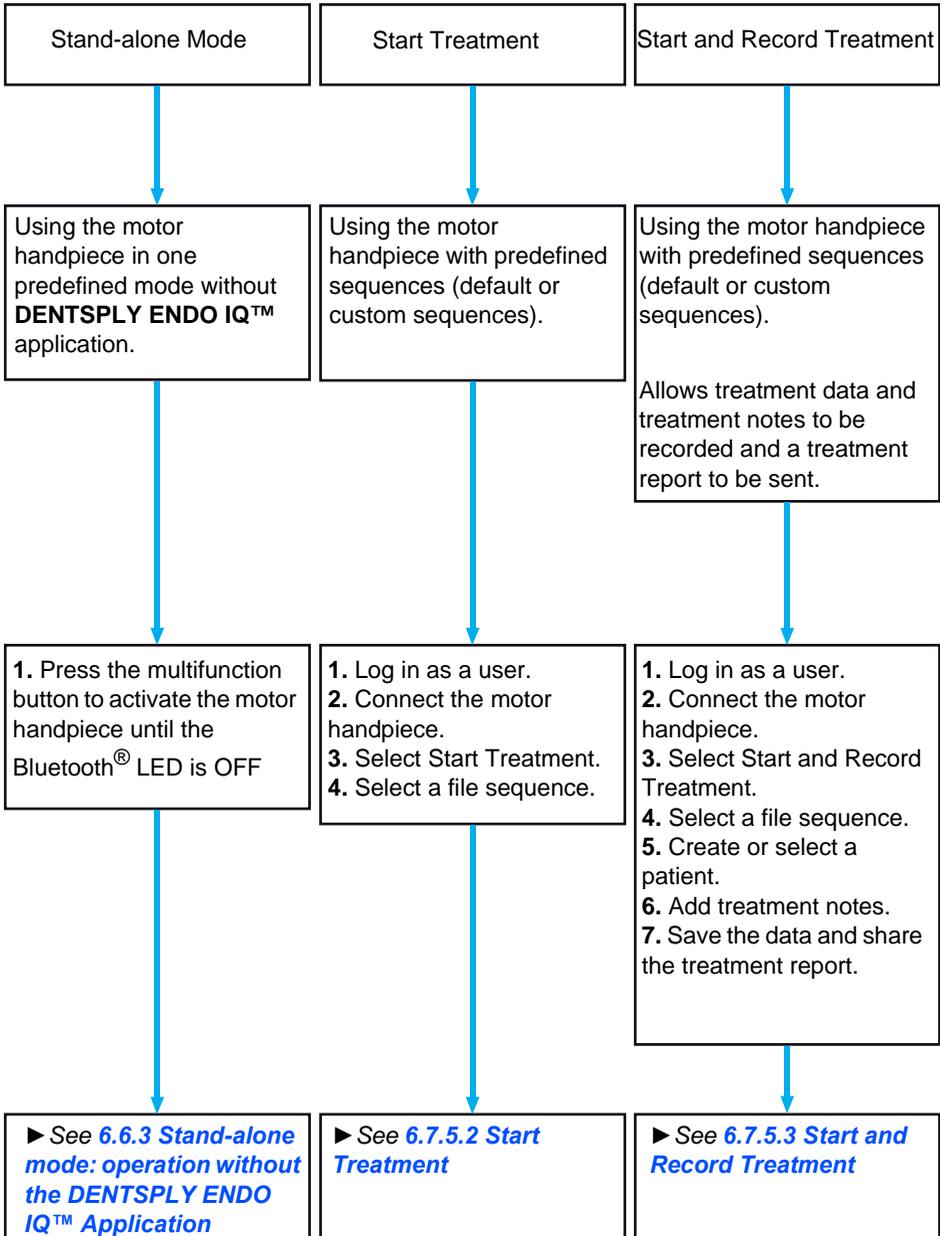
The following buttons are also present in the application:

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

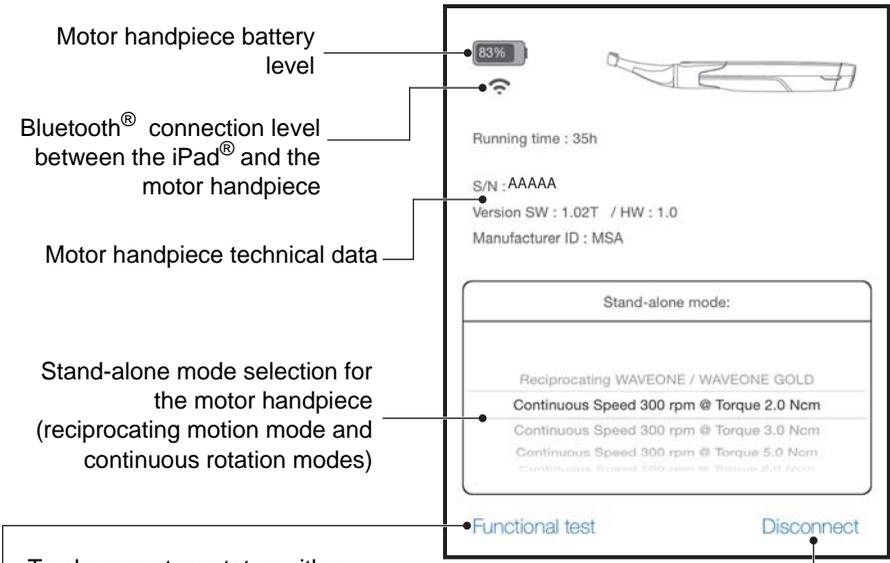
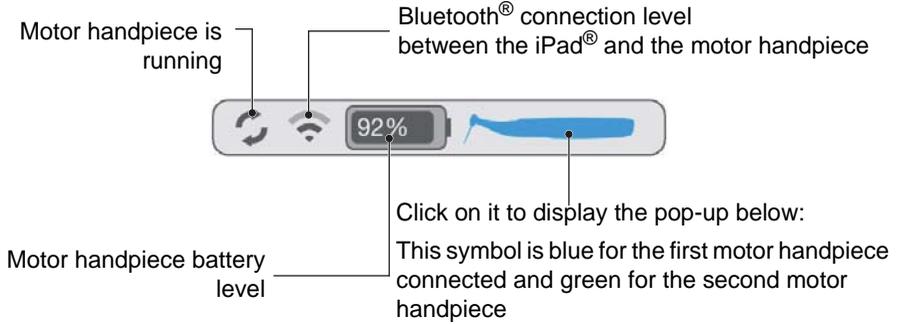
The following labels are also present in the application:

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



To share system status with a Technical support centre

To disconnect the motor handpiece.
▶ See **6.7.3.2 Disconnecting the Motor Handpiece**

6.7.5.2 Start Treatment

The screenshot shows the application interface with the following elements and annotations:

- Top Left:** "To adjust the torque and speed parameters" - points to the Torque (2.0 Ncm) and Speed (300 rpm) sliders.
- Top Right:** "Click or swipe to move to next file or press the multifunction button. Double press the multifunction button to move to the previous file" - points to the circular bargraph.
- Center:** "Real time torque value (displayed in a circular bargraph)" - points to the circular bargraph.
- Bottom Left:** "To set auto reverse function. ▶ See 6.6.1.2 The Auto Reverse (AutoRev) Functionality" - points to the "Auto Rev" toggle switch.
- Bottom Center:** "Motor turns in reverse when activated" - points to the "Auto Rev" toggle switch.
- Bottom Right:** "To display a torque graph in real time" - points to the graph icon in the bottom right corner.
- Bottom Right (Lower):** "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" - points to the "CAL" button.
- Bottom Right (Lower):** "To select a file system or a file sequence. ▶ See 6.7.7 Customize File Sequences" - points to the "CAL" button.



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

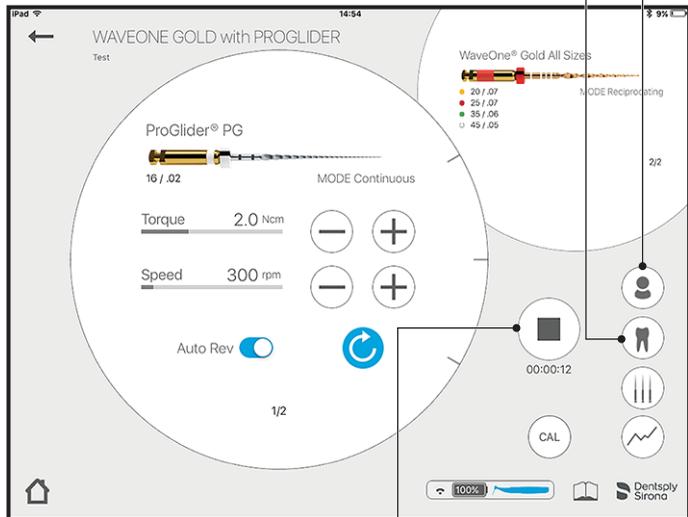


The buttons and functions described in "Start Treatment" are also applicable to "Start and Record Treatment".

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.

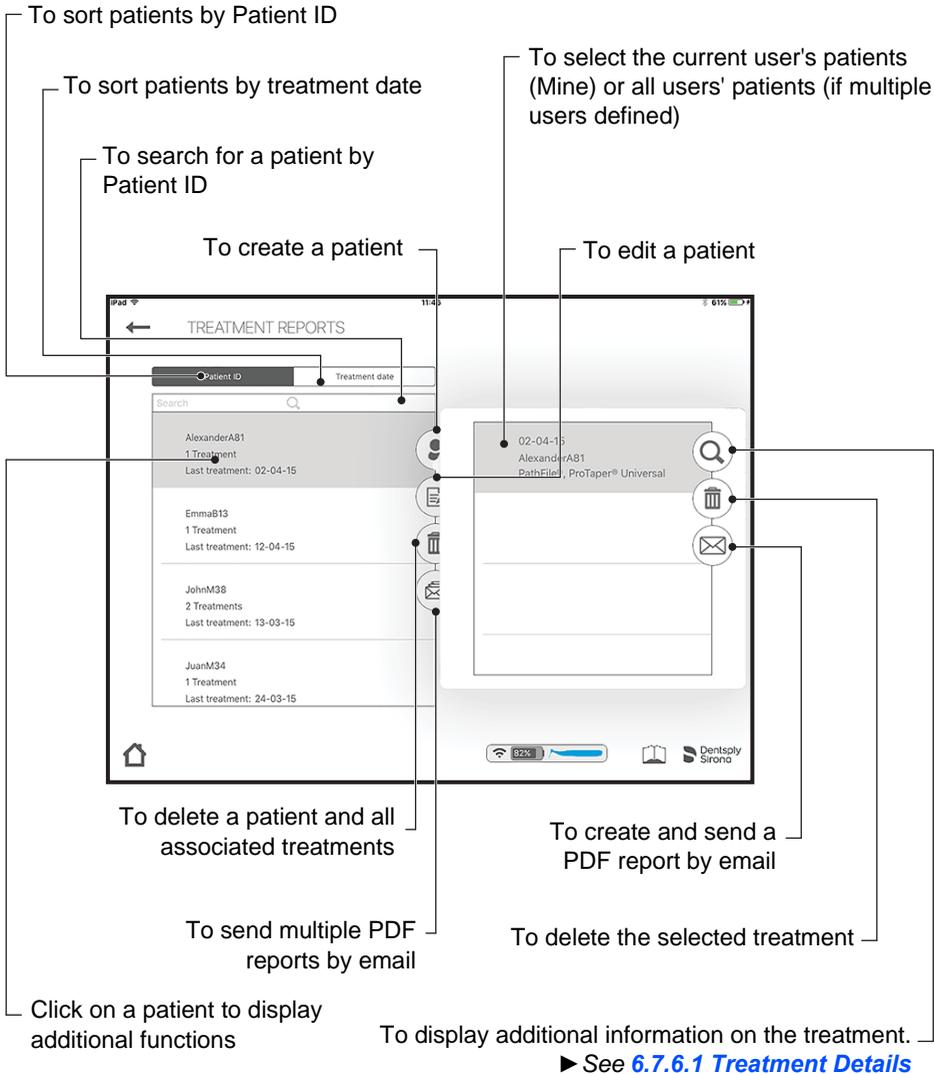
When you confirm, it opens the "Treatment Details" screen

► 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.

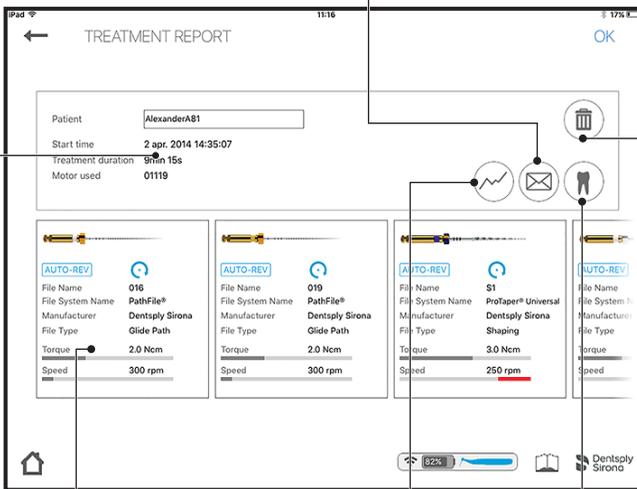


6.7.6.1 Treatment Details

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

To add an extra canal

Information related to the treatments:
 Canal type, Length, Obturation Method, Obturation Product, Obturation Size, File and Note

Canal type	Length	Last file used	Obturation method	Obturation product
Palatal	18.0mm	ProTaper® Universal F3	Single Cone	GP Points for ProTape
Distobuccal	22.0mm	ProTaper® Universal F3	Single Cone	No value
Mesiobuccal	22.0mm	ProTaper® Universal F3	Single Cone	No value
Mesiobuccal2	22.0mm	ProTaper® Universal F3	Single Cone	No value
No value	No value	No file	No value	No value

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.

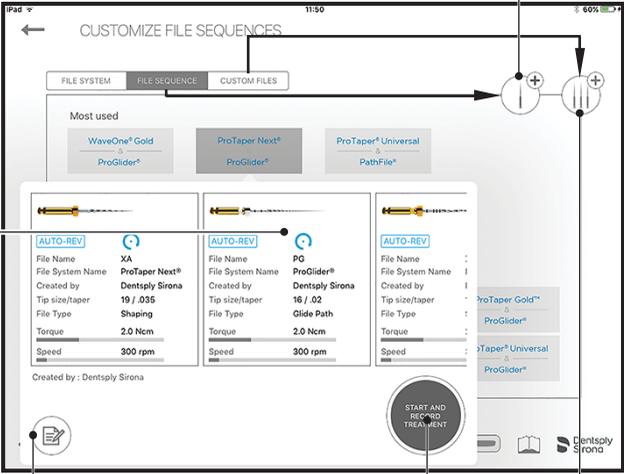
The file sequences are divided into 4 categories:

- 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](#)).

Create new file sequence
▶ See [6.7.7.2 Create File Sequence](#)



Information about the selected file system

To edit a file sequence

Custom file
▶ See [6.7.7.1 Create new File](#)

▶ See [6.7.5.3 Start and Record Treatment](#)

File Name	File System Name	Created by	Tip size/taper	File Type	Torque	Speed
XA	ProTaper Next®	Dentsply Sirona	19 / .035	Shaping	2.0 Ncm	300 rpm
PG	ProGlider®	Dentsply Sirona	16 / .02	Glide Path	2.0 Ncm	300 rpm



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

File color

Selection of the Auto Reverse Function mode.
▶ See [6.6.1.2 The Auto Reverse \(AutoRev\) Functionality](#)

File picture

Indicates the type of rotation for the file

- Continuous Rotation File Systems
- Reciprocating File Systems

To save the created file

File name

Name of the file system

Name of the manufacturer

Tip size and tip taper of the custom file

Maximum rotation speed

Maximum torque

File purpose
No File Type, Shaping, Glide Path, Cavity Access or Retreatment

CREATE NEW FILE

11:18 100%

OK

AUTO-REV

File Name

File System Name

Manufacturer

Tip size/taper /

Color

File Type

Torque 0.5 Ncm

Speed 250 rpm

02% Dentsply Sirona

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.

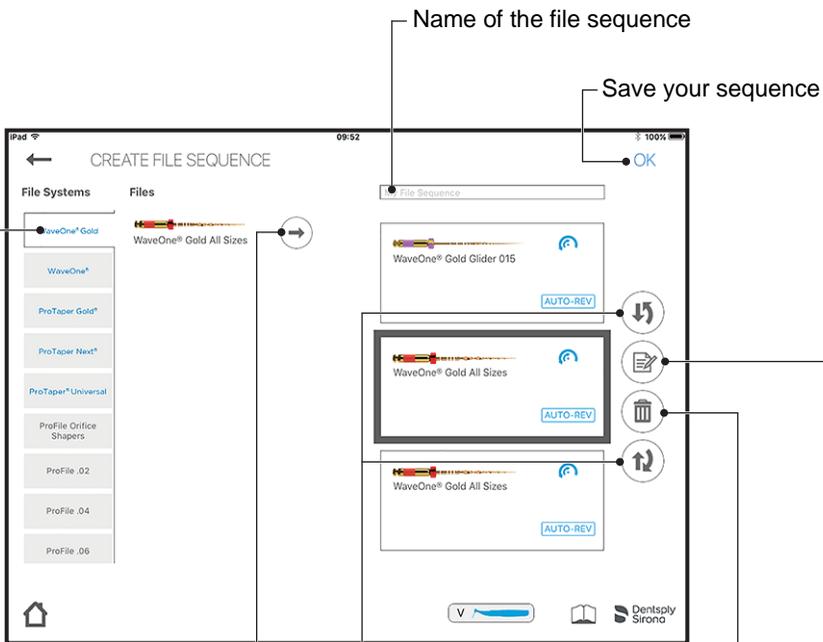


A custom file can only be deleted if not used in any sequence.

Select the file system for your sequence.

Select "Others" to insert a custom file.

► See [6.7.7.1 Create new File](#)



Click on the arrow to add the file in your sequence

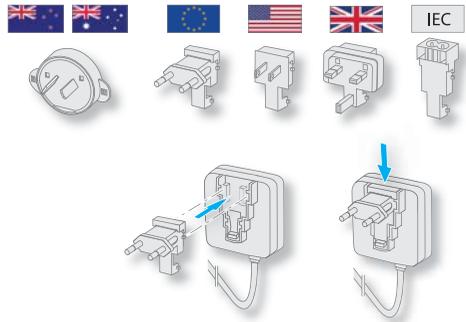
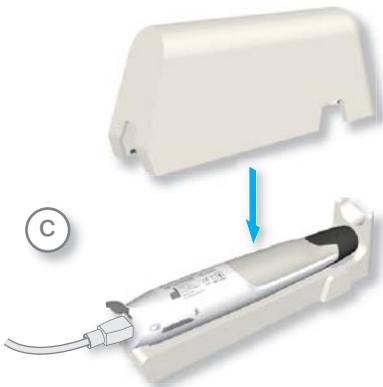
Move the position of the file in the sequence

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 55](#) 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.

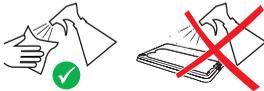
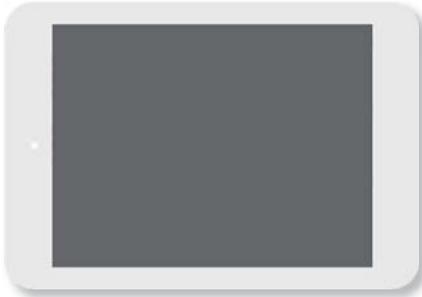


Please refer to the manufacturer's information on use of the disinfectant.

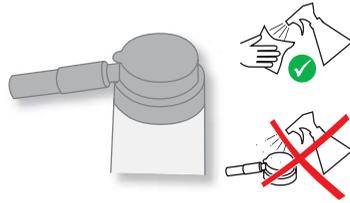
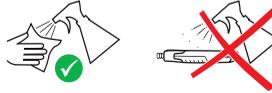
For wipe-down disinfection of components proceed as follows:

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 55 .

iPad Mini™ protective case



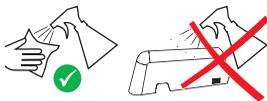
Motor handpiece



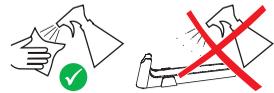
Spray adapter



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.



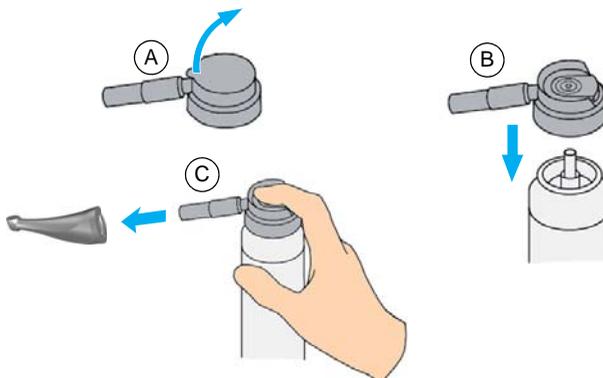
Use the spray adapter included to lubricate the contra-angle.



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 56)	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 59
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 61
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 61
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 61

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	<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 cleaning solution: e.g. 0.5% (v/v) deconex 24 LIQ, Borer Chemie.</i></p> <p><i>Use neutralizing solution: e.g. 0.25% (v/v) deconex 26 plus, Borer Chemie.</i></p> <p><i>Deionized water (DI) or water that has this degree of purity is recommended for cleaning.</i></p>
	<p>Ensure the 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 Contra-Angle.</p>	

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

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 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™ • iPad Mini™ 2 • iPad Mini™ 3 • iPad Mini™ 4
Operating System	<ul style="list-style-type: none"> • iOS 9.x • iOS 10.x
EMC Tables	See www.dentsplymallefer.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
	<p>The Motor START/STOP button sensor is not working properly</p>	<p><i>Reset the device (see 6.6.1 Description of the Motor Handpiece).</i></p>
	<p>Bluetooth radio module failure</p>	<p><i>Reset the device (see 6.6.1 Description of the Motor Handpiece).</i></p>
	<p>Calibration failed</p>	<p><i>Lubricate the contra-angle (see 7.5.3.1 Approved Sterilization Procedure of the Contra-Angle) and perform the calibration again.</i></p> <p><i>If the error persists, try to replace the contra-angle and perform the calibration again.</i></p>
	<p>Battery charge not sufficient to perform a firmware upgrade.</p>	<p><i>Charge the device until the BATTERY indicator turns green. Restart the firmware update.</i></p>
	<p>General firmware failure</p>	<p><i>Reset the device (see 6.6.1 Description of the Motor Handpiece).</i></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 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> <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®.	iPad® switched off (empty battery). <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>
	iPad® Bluetooth® switched off. <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>
	Motor handpiece far from the iPad®. <i>Place the motor handpiece near the iPad® and re-connect it (see 6.7.3 Connecting the Motor Handpiece).</i>
The contra-angle cannot be calibrated.	The calibration procedure may have been interrupted by increased resistance in the contra-angle. <ol style="list-style-type: none"> 1. <i>If calibration has been interrupted, calibrate the motor handpiece again to rule out the possibility of a motor fault.</i> 2. <i>Clean and lubricate the contra-angle (see 7.5 Cleaning, Disinfection and Sterilization of the Contra-Angle).</i> 3. <i>Start the calibration procedure again.</i>
Motor handpiece is getting hot.	Overheating. <i>The device switches off automatically if it overheats. Allow the device to cool down and start again the motor handpiece.</i>
A reciprocating instrument has become jammed in the root canal.	Treatment was not performed properly. <i>Remove the reciprocating instrument with pliers by rotating clockwise carefully.</i>
A rotary instrument has become jammed in the root canal.	Treatment was not performed properly. <i>Select reverse rotation, start the motor handpiece and rotate the instrument out of the root canal carefully.</i>

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

PAGE INTENTIONALLY LEFT BLANK

www.dentsplymaillefer.com



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

Registrado por: DENTSPLY Indústria e Comércio Ltda.
Rua Alice Hervê, 86 – Petrópolis-RJ. CEP 25665-010
www.dentsply.com.br – Central de Relacionamento: 0800 721 1200
CNPJ 31.116.239/0001-55 - Indústria Brasileira
Responsável Técnico: Marcelle Cortezia – CRF/RJ nº 7999
Cadastro ANVISA Nº: 80196889041