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Dentsply Sirona

X-Smart IQ™

Directions for Use



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Table of contents

Introduction **6**

1 Indications for Use **7**

2 Contraindications **8**

3 Warnings **9**

4 Precautions **17**

5 Adverse Reactions **18**

6 Step by Step Instructions **19**

6.1 Document Symbols 19

6.2 **DENTSPLY ENDO IQ™** Application Compatibility 19

6.3 Package Contents 20

6.4 Components not included 21

6.5 System Setup 21

6.5.1 Turning on the iPad® and setting the Volume 21

6.5.2 Activating the AssistiveTouch 22

6.5.3 Activating the WiFi 24

6.5.4 Activating the Bluetooth® 24

6.5.5 Installing and Updating the **DENTSPLY ENDO IQ™** Application 25

6.5.5.1 Firmware update 25

6.5.6 Setting up the Complete System 26

6.6 Motor Handpiece 28

6.6.1 Description of the Motor Handpiece 28

6.6.1.1 Description of the LED Colors 29

6.6.1.2 The Auto Reverse (AutoRev) Functionality 31

6.6.1.3 Description of the Sounds 32

6.6.1.4 Stand-by Mode 32

6.6.1.5 Battery Care 33

6.6.2 Inserting and removing the File 34

6.6.2.1 Inserting the File 34

6.6.2.2 Removing the File 34

6.6.3 Stand-alone Mode 35

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6.7 **DENTSPLY ENDO IQ™Application** ... 36
6.7.1 Starting the Application ... 36
6.7.2 Editing or creating a User Profile ... 37
6.7.3 Connecting the Motor Handpiece ... 38
6.7.3.1 Connecting a Second Motor Handpiece ... 40
6.7.3.2 Disconnecting the Motor Handpiece ... 41
6.7.4 Interface Presentation ... 42
6.7.5 Three Modes of Use ... 45
6.7.5.1 Motor Handpiece Information and Settings ... 46
6.7.5.2 Start Treatment ... 47
6.7.5.3 Start and Record Treatment ... 48
6.7.6 Treatment Reports ... 49
6.7.6.1 Treatment Details ... 50
6.7.6.2 Treatment Notes ... 51
6.7.7 Customize File Sequences ... 52
6.7.7.1 Create new File ... 54
6.7.7.2 Create File Sequence ... 55
6.8 Storing and charging the Motor Handpiece ... 56

7 Cleaning, Disinfection and Sterilization ... 57
7.1 Foreword ... 57
7.2 Single Use of Custom Polyethylene Barrier ... 57
7.3 Disinfection of Motor Handpiece ... 58
7.4 Lubrication of the Contra-Angle ... 61
7.5 Cleaning, Disinfection and Sterilization of the Contra-Angle ... 62
7.5.1 Pre-Treatment of the Contra-Angle ... 64
7.5.2 Machine-based Reprocessing of the Contra-Angle (Thermal-Disinfection) ... 65
7.5.3 Sterilization of the Contra-Angle (Autoclaving) ... 66
7.5.3.1 Sterilization Procedure of the Contra-Angle ... 67

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8 Technical Characteristics 68

9 Motor Handpiece Error Code 70

10 Troubleshooting 72

11 Warranty 74

11.1 Exclusion of Liability 75

12 Disposal of the Product 76

13 Identification of Symbols 77

13.1 Normative Symbols 77

14 Electromagnetic Emissions and Immunity 79

14.1 Essential Performance 79

14.2 Compliant Cables and Accessories 79

14.3 Instructions for Maintaining BASIC Safety and Essential Performance for the Expected Service Life 79

14.4 Compliance with Emission and Immunity standard 80

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Introduction

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

These Directions for Use are always kept up to date by DENTSPLY Tulsa Dental Specialty Systems (hereafter Dentsply Sirona) to bring them in line with the latest developments. You will find the current version on www.dentsplysirona.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 Directions for Use, 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 seven calendar days to any address in North America). To order, simply send your request to tulsacustserv@dentsplysirona.com.

The Directions for Use are available in other languages on request. These Directions for Use have 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 Directions for Use 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.

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2 Contraindications

Read the following contraindications before use.

- **X-SMART IQ™** must not be used 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.)

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3 Warnings

Read the following warnings before use.

- The motor handpiece is intended for endodontic treatment and may only be used by trained and qualified dentists.
- Do not use **X-SMART IQ™** for implants or any other dental procedure outside endodontics.

Environmental conditions

- 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).
- 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.
- 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 2,000m (~ 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).

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- 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 Mini™ generates, uses and can radiate radio-frequency energy. The use of the iPad Mini™ 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 Mini™'s electromagnetic compatibility.
- The iPad Mini™ 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.
- An FDA cleared barrier sleeve must be used to cover the iPad in its protective case with the recommended dimensions of 14.5" x 18".

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- Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

During treatment

- Gloves, a Custom Polyethylene Barrier over the handpiece (use only Custom Polyethylene Barriers provided by Dentsply Sirona made specifically for this handpiece), and a rubber dam are mandatory during treatment.
- If any irregularities with the device should occur during treatment, switch it off. Contact Dentsply Sirona or your Dentsply Sirona authorized service partner.
- No thermal hazard risk exists for patients.

Battery

- The battery charging port on the handpiece is a proprietary connection. Only use the charger and cable supplied with the handpiece. 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.
- Follow all local laws and regulations regarding the storage and shipment of lithium-ion batteries. (See Transport Section).
- Always check to ensure that both the motor handpiece and the iPad Mini™ have a sufficient battery charge before starting treatment.

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Transport

- Intact devices can be transported by land freight or air freight in the original packaging. The applicable requirements must be met.
- 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.

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

- For international shipping of lithium-ion batteries, refer to the International Air Transport Association (IATA) guidelines, located at http://www.iata.org/lithiumbatteries.
- For shipping of lithium-ion batteries within the United States, refer to the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) site at http://www.phmsa.dot.gov/hazmat/guidance.

Contra-angle

- Only use the original Dentsply Sirona contra-angle.
- Contra-angles must be checked for damage before they are reused. Damaged products must be replaced.
- 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 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.

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Root Canal Instruments

- Before use, ensure the instrument is securely locked in place.
- Use the torque and speed settings recommended by the instrument manufacturer. 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.
- Use only undamaged root canal instruments. Please refer to the information provided by the manufacturer.
- 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.
- Never use continuous rotary instruments in reciprocating mode.
- Never use reciprocating instruments in rotary mode.

iPad Mini™, iPad Mini™ protective case and motor handpiece support/cover

- Dentsply Sirona recommends using the iPad Mini™ protective case indicated in 6.5.6 Setting up the Complete System.
- The operating conditions and limitations specified by Apple® must be complied with.
- An FDA cleared barrier sleeve must be used to cover the iPad Mini™ in its protective case with the recommended dimensions of 14.5" x 18".
- Ensure the iPad Mini™ and the accessories are in a stable position during the treatment.
- The motor handpiece cover can be magnetically attached to the iPad Mini™ protective case. The device can fall if subjected to abrupt movements.
- Do not disable the iPad Mini™ sound when using **X-SMART IQ™**.

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- Do not disinfect the iPad Mini™ protective case if the protective plugs are not properly inserted.

Cleaning, Disinfection and Sterilization

- The use of the Custom Polyethylene Barrier over the motor handpiece is mandatory. The barrier is designed for single use and must be disposed of after use.
- Do not place the **X-SMART IQ™** motor handpiece in an autoclave unit or washer-disinfector.
- 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.
- Never place the components listed on page 60 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. Instead, spray a paper towel with the surface disinfectant or use a pre-moistened disinfectant towelette (wipe).
- 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 wipe- down disinfection ensure that the charging cable is not connected and that the charging socket is closed.
- Do not use CaviCide1™ or CaviWipes1™ on any items shown or listed on page 60.
- 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.
- 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.

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

DENTSPLY ENDO IQ™ application

- It is strongly recommended that all open applications are closed before launching the **DENTSPLY ENDO IQ™** application.
- Dentsply Sirona cannot be held liable for the developed application if unauthorized modifications have been made (e.g. jailbreaking). It is the user's responsibility to ensure that all patient information and data is protected in accordance with HIPAA regulations.
- User must follow appropriate behaviour to protect data on the iPad Mini™, such as activating the device master password, activating the encryption of the backup on iTunes® and avoid using the iPad Mini™ outside of the medical environment.
- Treatment notes linked to patients in the application are subject to the requirements of the applicable legislation on data privacy.
- 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 Mini™ using iTunes®.
- **DENTSPLY ENDO IQ™** application does not replace your Dental Practice Management Software.

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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 (voice 1-800-662-1202 or fax 1-800-597-2779)

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4 Precautions

Read the following precautions before use.

- Safety and effectiveness have not been established in pregnant women and children.
- Please check the compatibility of your **DENTSPLY ENDO IQ™** application before updating the iPad Mini™ operating system.
- Always install the latest version of the **DENTSPLY ENDO IQ™** application. Regularly check for updates on the App Store®.

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5 Adverse Reactions

There are no known adverse reactions.

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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

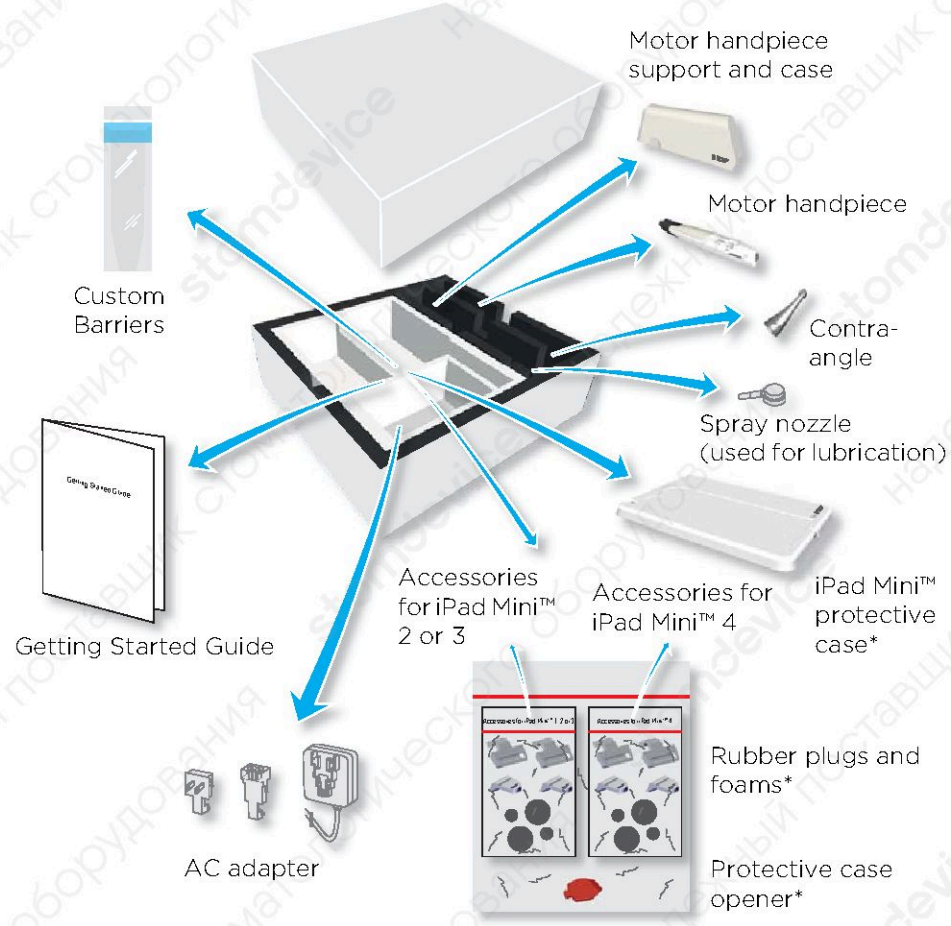
Specification	Description
iPad® requirement	• iPad Mini™ 2 • iPad Mini™ 3 • iPad Mini™ 4
Operating System	• iOS 11.x • iOS 12.x

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

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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.



*These components are not available in all kits.

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6.4 Components not included

The following components are not included in the kit:



iPad Mini™ 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 Mini™.
B	Adjust the volume to maximum.
	The application uses sounds to give general information, see **6.6.1.3 Description of the Sounds**.
	

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6.5.2 Activating the AssistiveTouch

The AssistiveTouch feature replaces the actions of the iPad Mini™ 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.	

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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 5 fingers to swipe in and to return to the Home screen.
	

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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 Mini™.

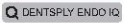
N°	Key	Action
A		Select Settings.
B		Select Bluetooth®.
C		Set Bluetooth® to ON.
		To connect the motor handpiece to the iPad Mini™, see **6.7.3 Connecting the Motor Handpiece**.

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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 Mini™.

6.5.5.1 Firmware update

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

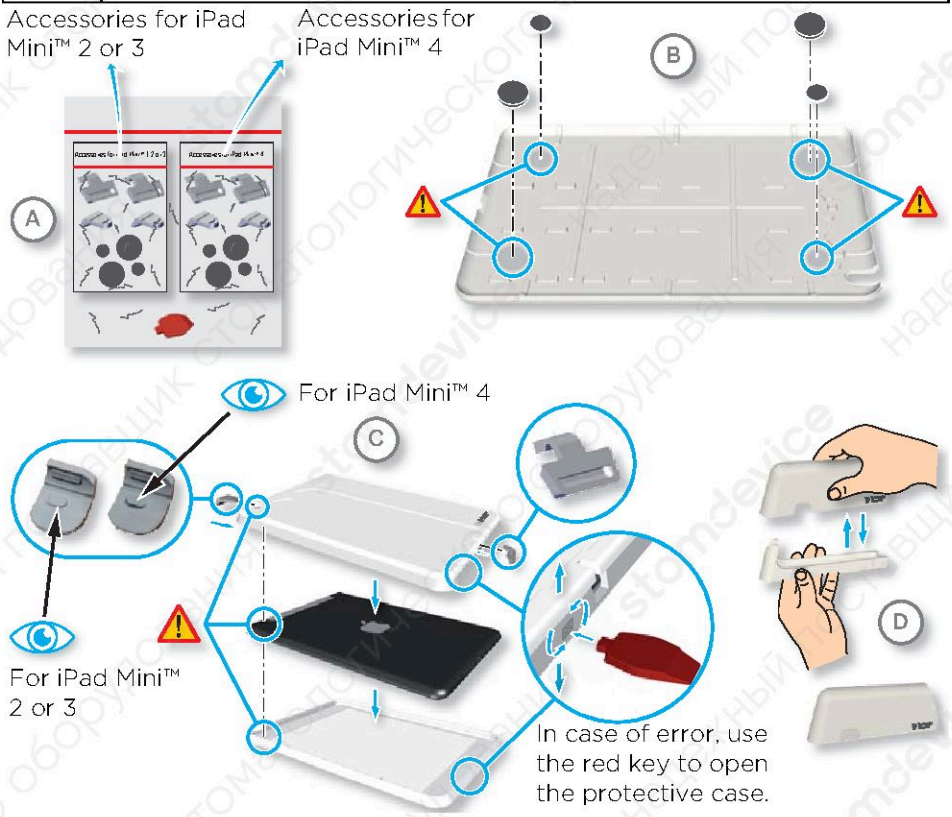
Follow the instructions on the screen to execute the update.

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

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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. An FDA cleared barrier sleeve must be used to cover the iPad Mini™ in its protective case with the recommended dimensions of 14.5"x 18".
	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.



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N°	Action
E	Install the motor handpiece cover as a protective case holder.
	Place the assembly on a steady surface. Multiple configurations are possible.
	Ensure the motor is not running before connecting or disconnecting the contra-angle.
F	Insert the contra-angle on the motor handpiece.
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

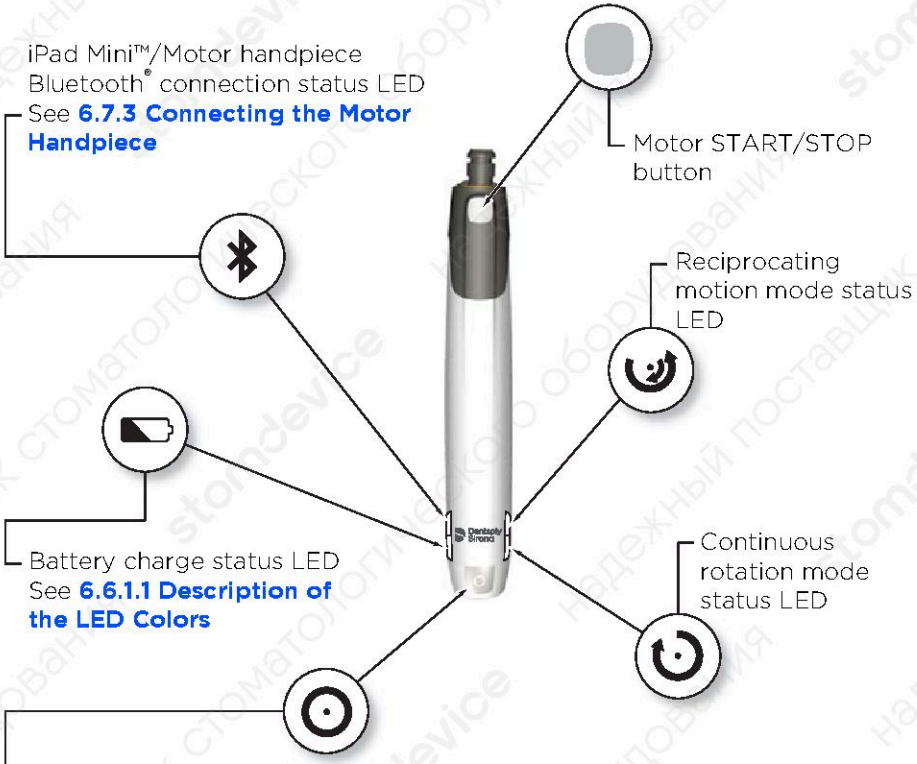




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6.6 Motor Handpiece

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.

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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 Mini™, the motor handpiece is locked (Motor START/STOP button LED is yellow).
		Motor handpiece connected to the iPad Mini™. See **6.7.3 Connecting the Motor Handpiece**.
		Connection lost. See 10 Troubleshooting.

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Button/LED	State	Description
		Second motor handpiece connected to the iPad Mini™. See **6.7.3.1 Connecting a Second Motor Handpiece**.
		Motor handpiece in stand-alone mode. See **6.6.3 Stand-alone Mode**. ** Must use* **DENTSPLY ENDO IQ™** *Application for initial set-up.*
		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**.

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Button/LED	State	Description
		Low battery level. Sufficient charge to complete most cases. 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. Do not use on patient until charged. 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).

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6.6.1.3 Description of the Sounds

Mode	Description
Device running in continuous rotation	Intermittent sound when: • The device is rotating in reverse. • The torque measured is about 75% over the defined torque.
Device running in reciprocating motion	Intermittent sound when: • The instrument is subject to increased friction. • After switching to forward rotation.
Battery charge level	• 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 *(inactive for 35 s)*	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 *(inactive for 30 min)*	All LEDs OFF.	Bluetooth® OFF, device not visible on status bar.	Press the multifunction button.

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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, there is sufficient charge to complete most cases.
- Charge the battery no more than once a day.
- If possible, 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 drained, 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.
- Autonomy: 2 days with 8 treatments per day or 16 total treatments.

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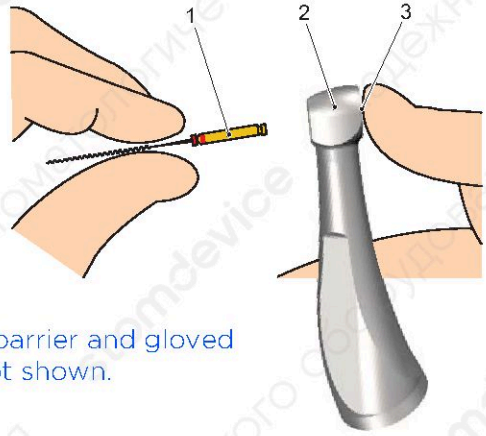
6.6.2 Inserting and removing the File

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**).



Custom barrier and gloved hands not shown.

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6.6.3 Stand-alone Mode

The motor handpiece can be used without connection to the iPad Mini™ and the **DENTSPLY ENDO IQ™** application. This mode is called stand-alone mode. 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 default setting defines the parameters used in stand-alone mode until the next time the handpiece is connected to the **DENTSPLY ENDO IQ™** application.

- Connect the motor handpiece to the **DENTSPLY ENDO IQ™** application.
  See **6.7.3 Connecting the Motor Handpiece**.
- Choose one of the available default settings for the stand-alone mode from the dropdown menu.
  See **6.7.5.1 Motor Handpiece Information and Settings**.

See **6.6.1.1 Description of the LED Colors** 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**.

User may not change settings when using in stand-alone mode.

User will be unable to set up default settings without connection to the **DENTSPLY ENDO IQ™** application.

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6.7 DENTSPLY ENDO IQ™Application

6.7.1 Starting the Application

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

- Treatment log and reporting system (see **6.7.6.1 Treatment Details**).
- File library (see **6.7.7 Customize File Sequences**).
- User profile 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 Apple iOS version.

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

N°	Key	Action
A	Endo IQ	Start the application.

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6.7.2 Editing or creating a User Profile

The first time you use the application, you will be automatically connected as a default user.

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**. *Enter a user name and an email address.* *Email address is optional.*
		To add a new user, follow the steps below.
B		Log out (see **6.7.4 Interface Presentation**).
C		Create a user. *Enter a user name and an email address.* *Email address is optional.*
		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 Mini™ to send the treatment reports.

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6.7.3 Connecting the Motor Handpiece

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

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

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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.
	

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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.





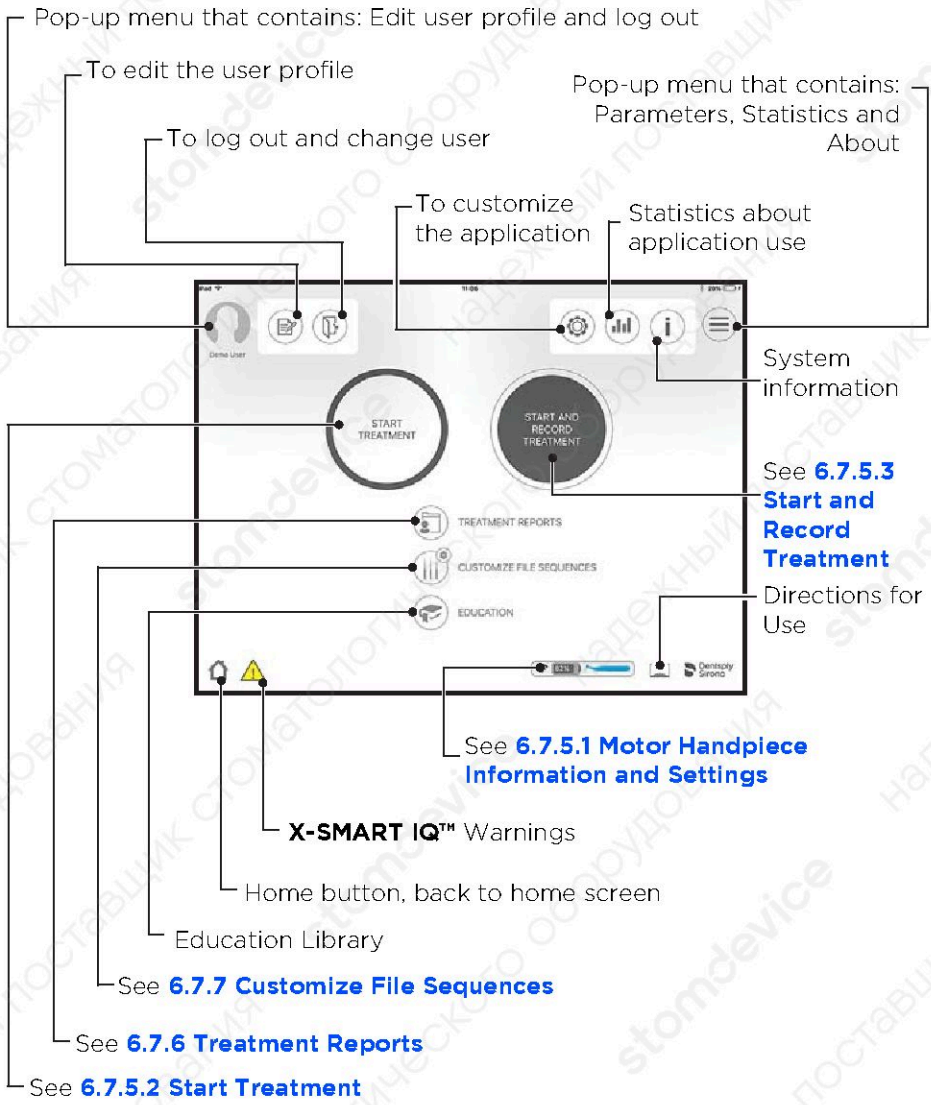
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6.7.3.2 Disconnecting the Motor Handpiece

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**.
	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**.

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6.7.4 Interface Presentation



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The following buttons are also present in the application:

Button	Action
	Takes you back to the previous page without saving.
OK	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**).
CAL	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

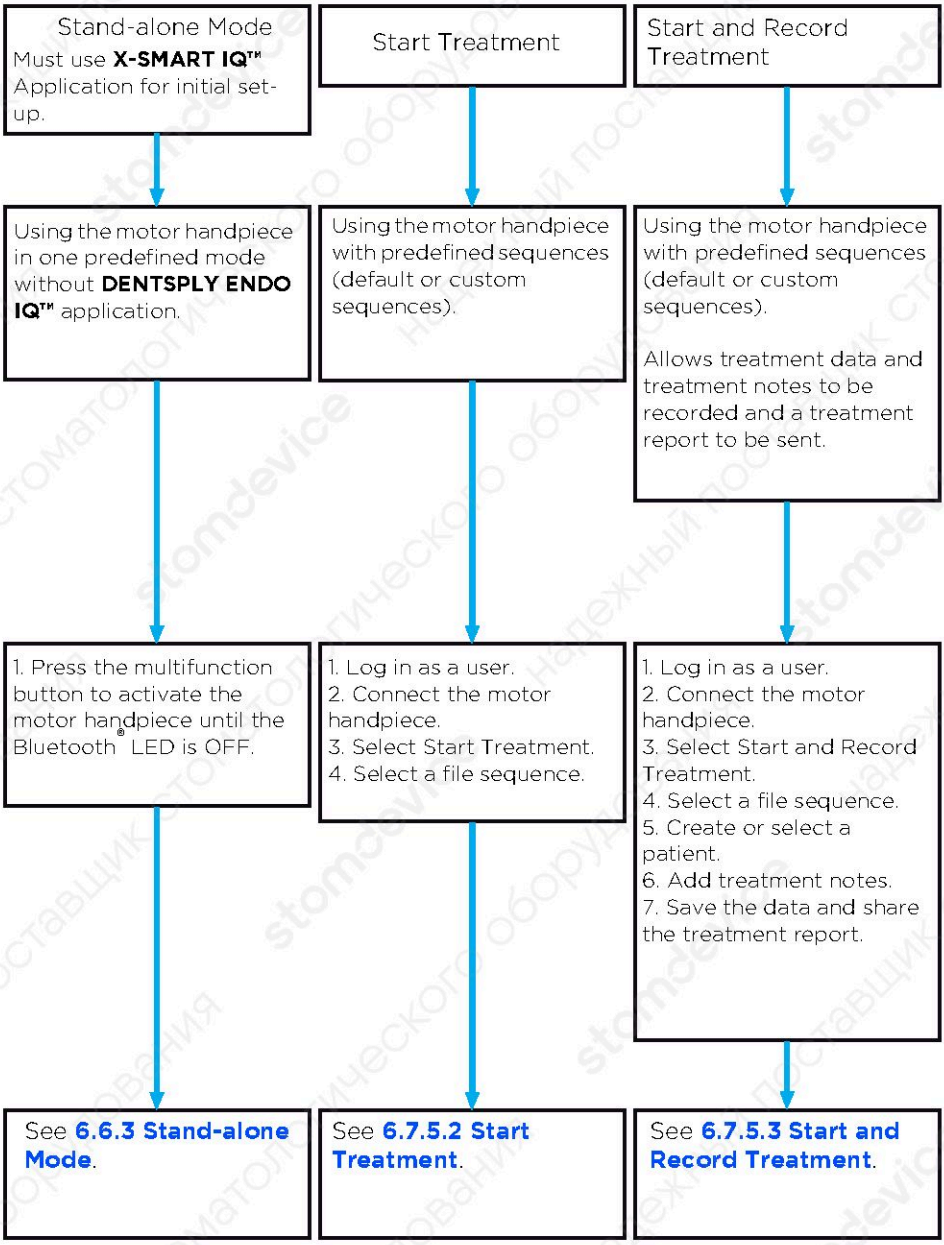
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The following labels are also present in the application:

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

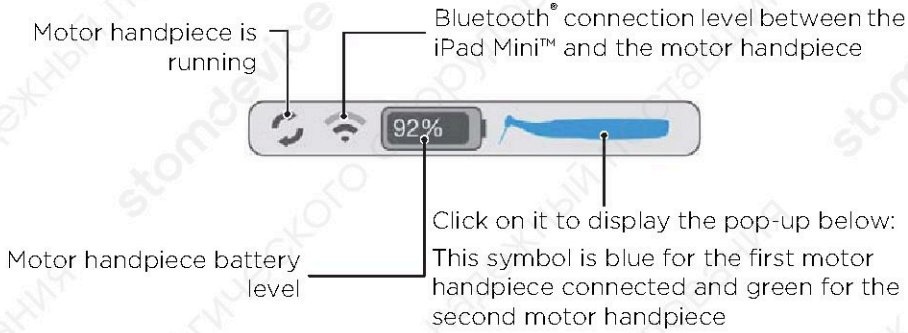
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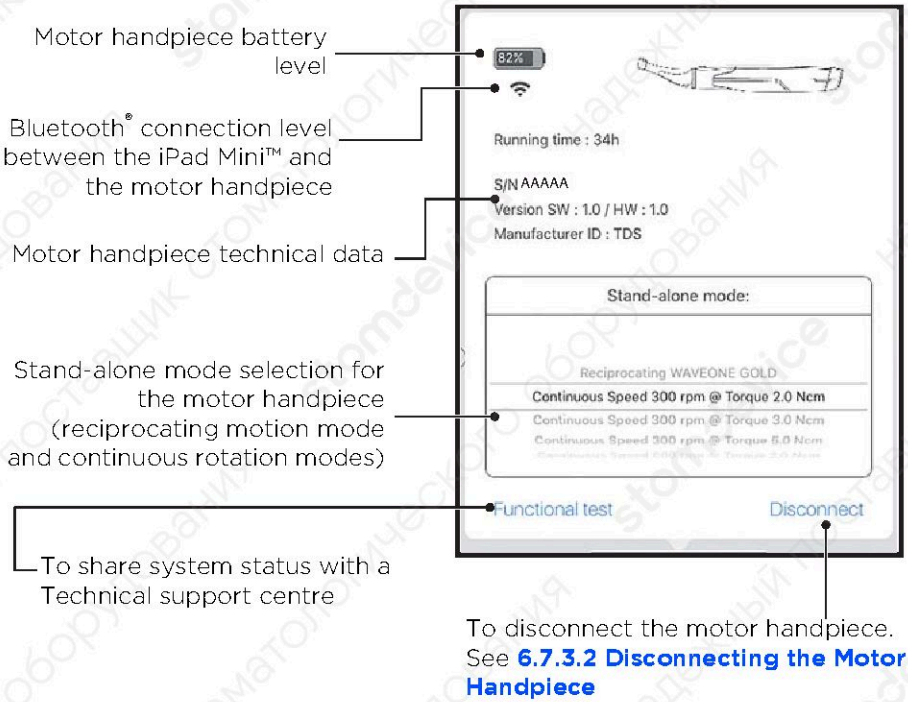
6.7.5 Three Modes of Use



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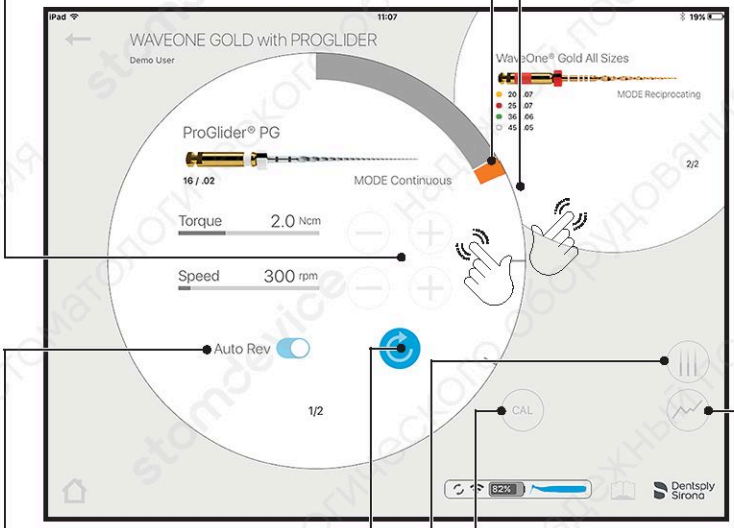
6.7.5.1 Motor Handpiece Information and Settings





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6.7.5.2 Start Treatment



Calibration is recommended before each treatment. This is required to ensure the motor parameters are accurate.

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

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

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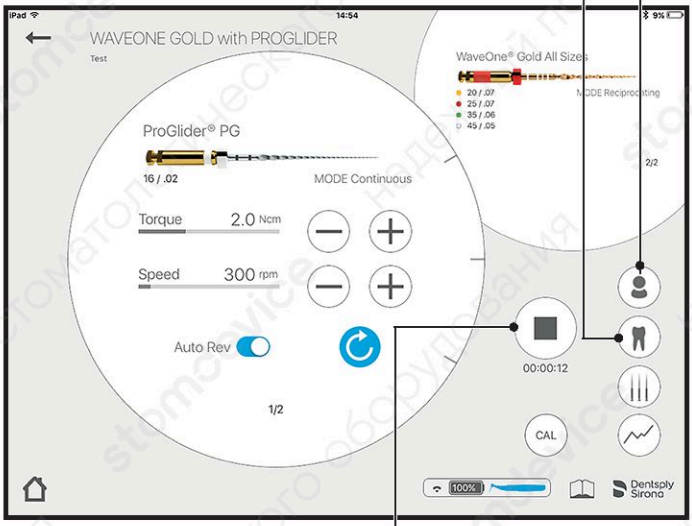
6.7.5.3 Start and Record Treatment

Dentsply Sirona cannot be held liable for the developed application if unauthorized modifications have been made (e.g. jailbreaking). It is the user's responsibility to ensure that all patient information and data is protected in accordance with HIPAA regulations.

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

To assign the current treatment to a record

To record 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.

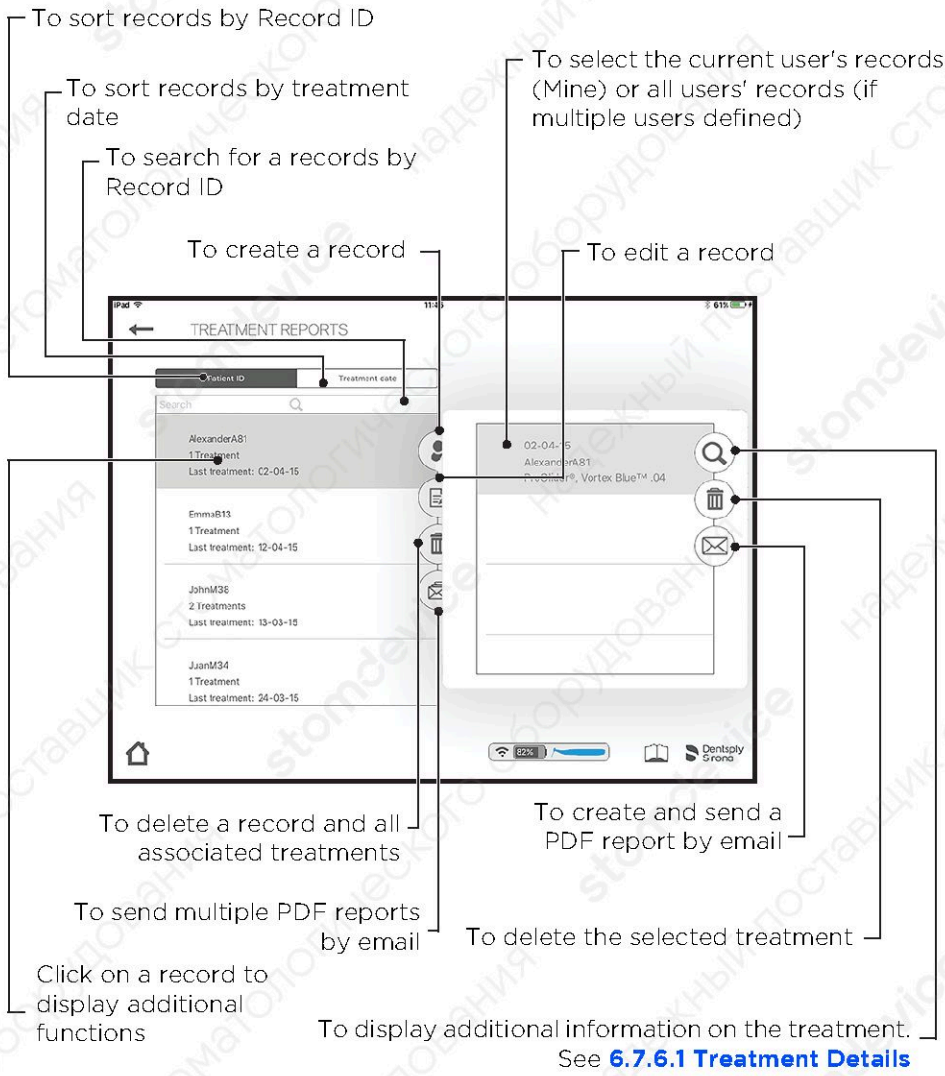
When you confirm, it opens the "Treatment Details" screen
See **6.7.6.1 Treatment Details**

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6.7.6 Treatment Reports

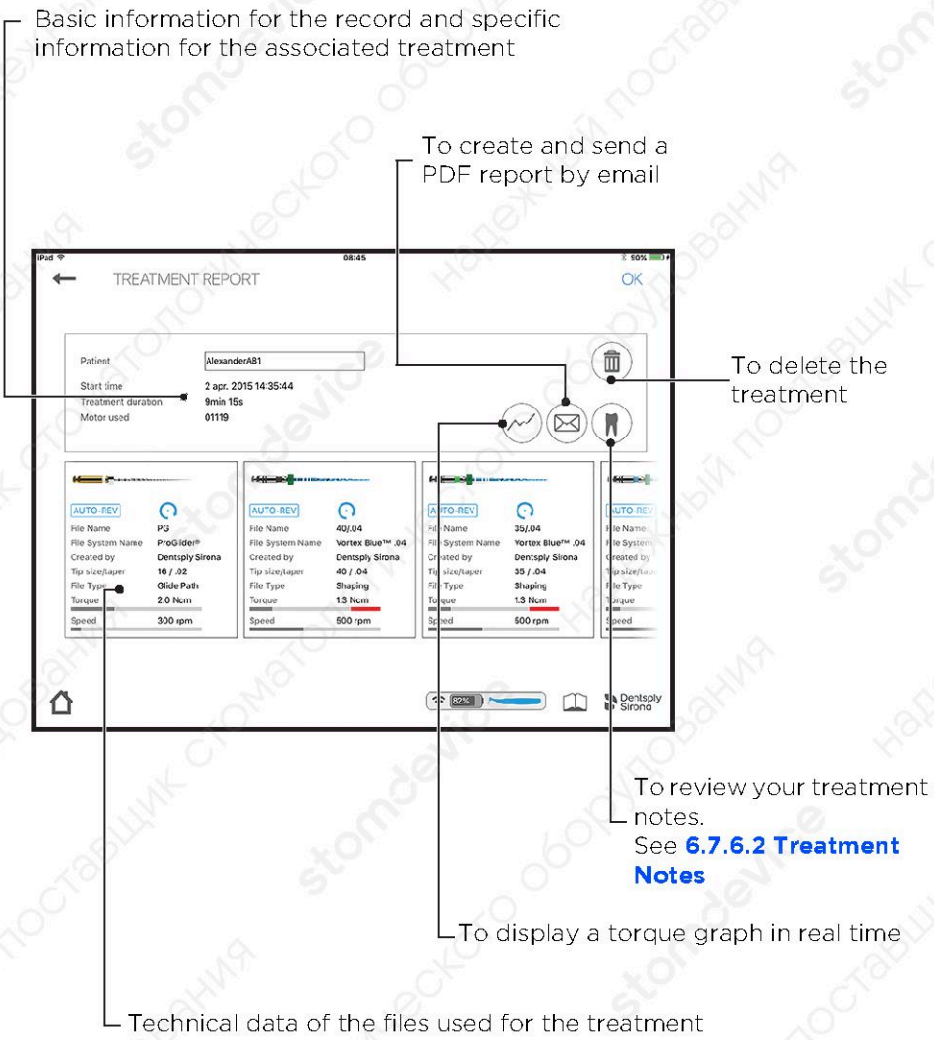
Treatment reports allow you to:

- Create, edit, delete a treatment record.
- View, edit or delete the treatments associated with the records.



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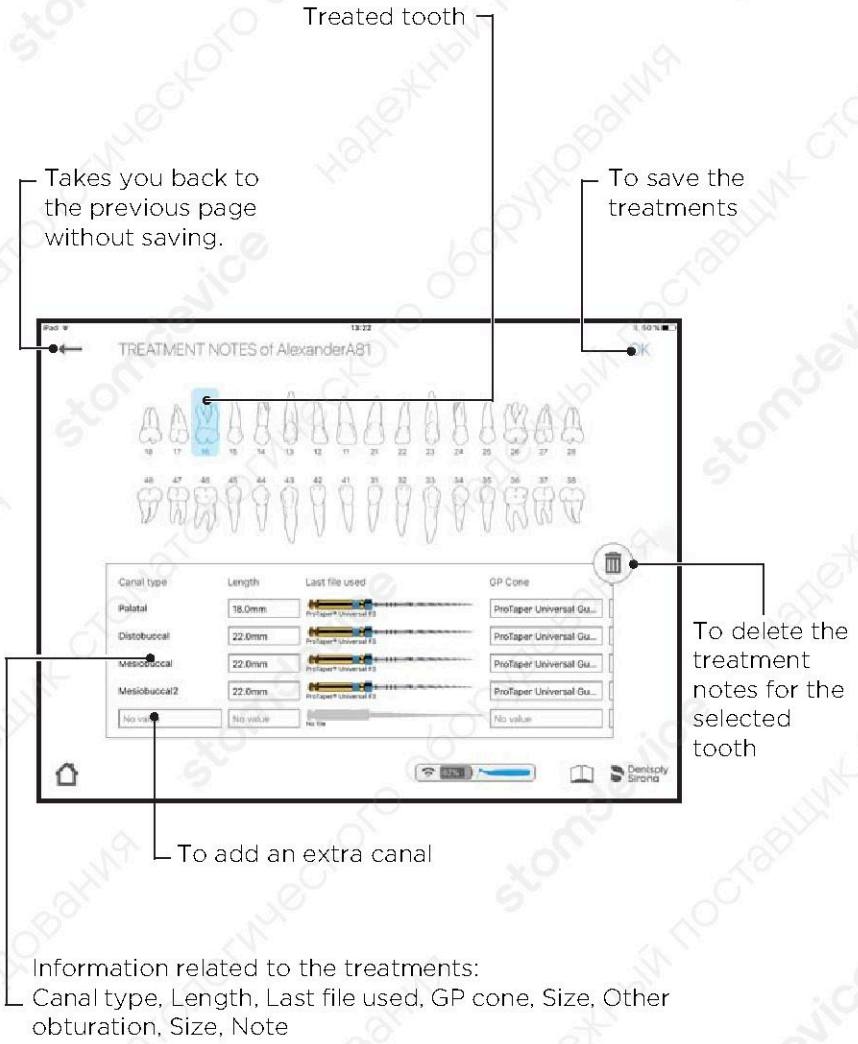
6.7.6.1 Treatment Details



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6.7.6.2 Treatment Notes

The tooth numbering system can be changed in the system setup.



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6.7.7 Customize File Sequences

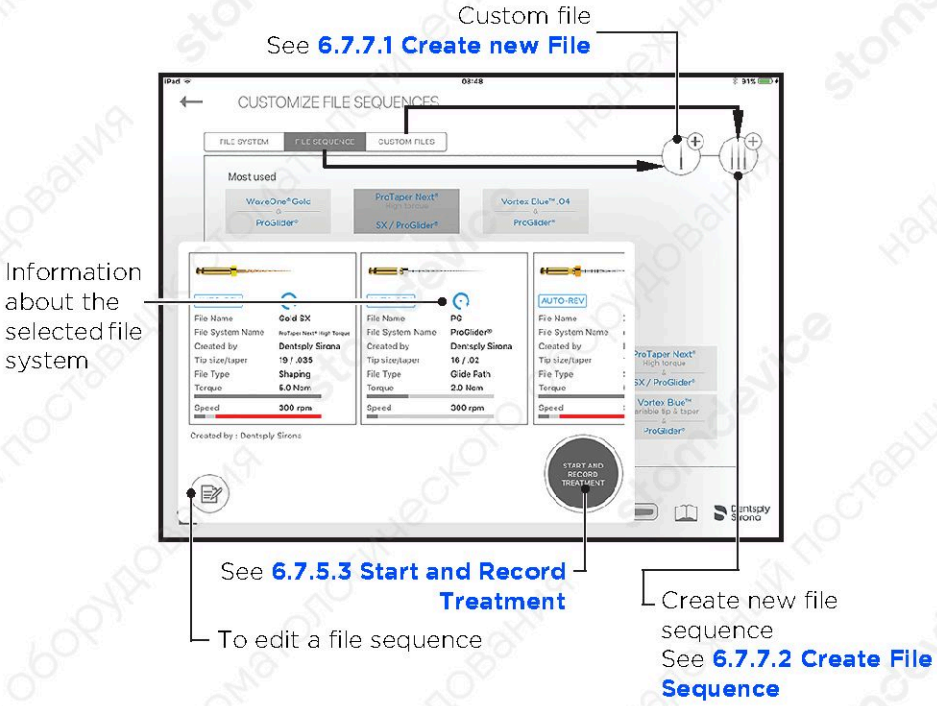
A file sequence is a collection of files that are used during a treatment. It is composed of files provided by Dentsply Sirona.

The file sequences are divided into 3 categories:

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

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 as desired by the clinician.
- Start and record a treatment from the chosen file (see **6.7.5.3 Start and Record Treatment**).



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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.



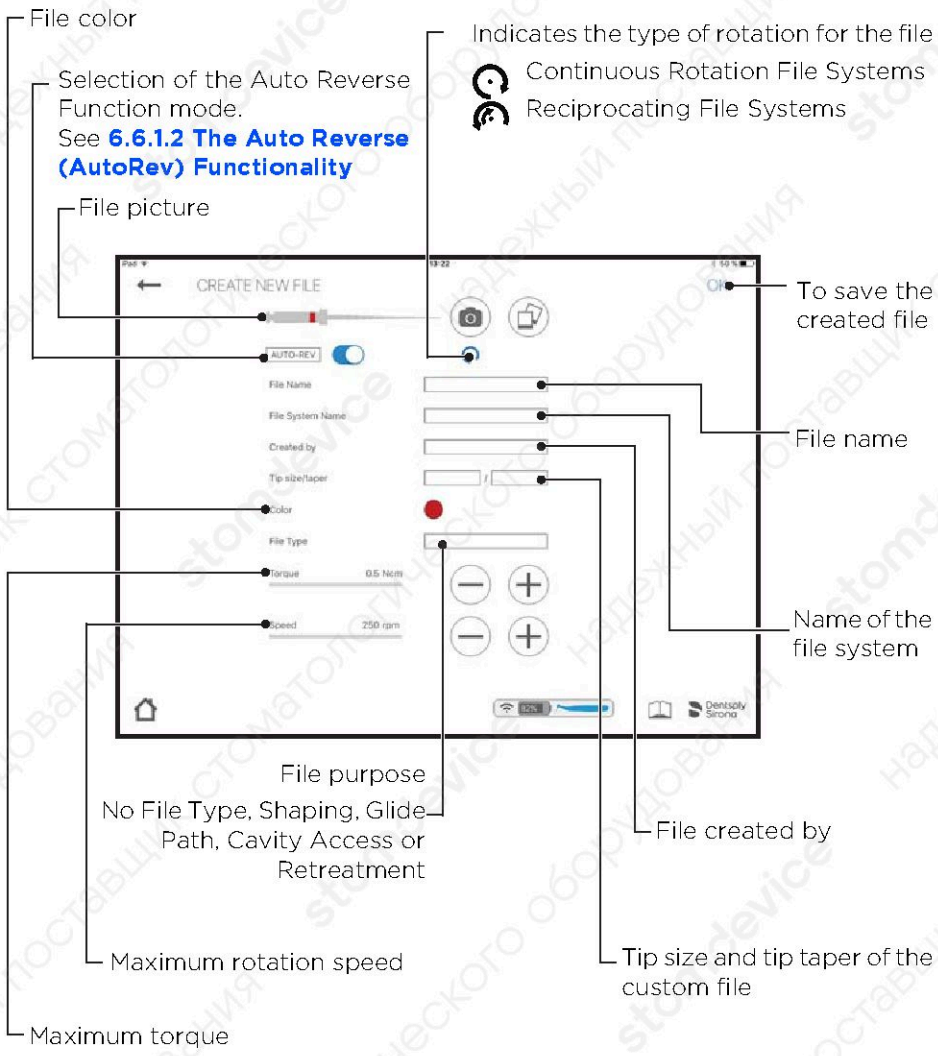
Torque and speed values are liable to modification by the file manufacturers without notice; therefore, present values in the file library must be checked prior to use.



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.

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6.7.7.1 Create new File

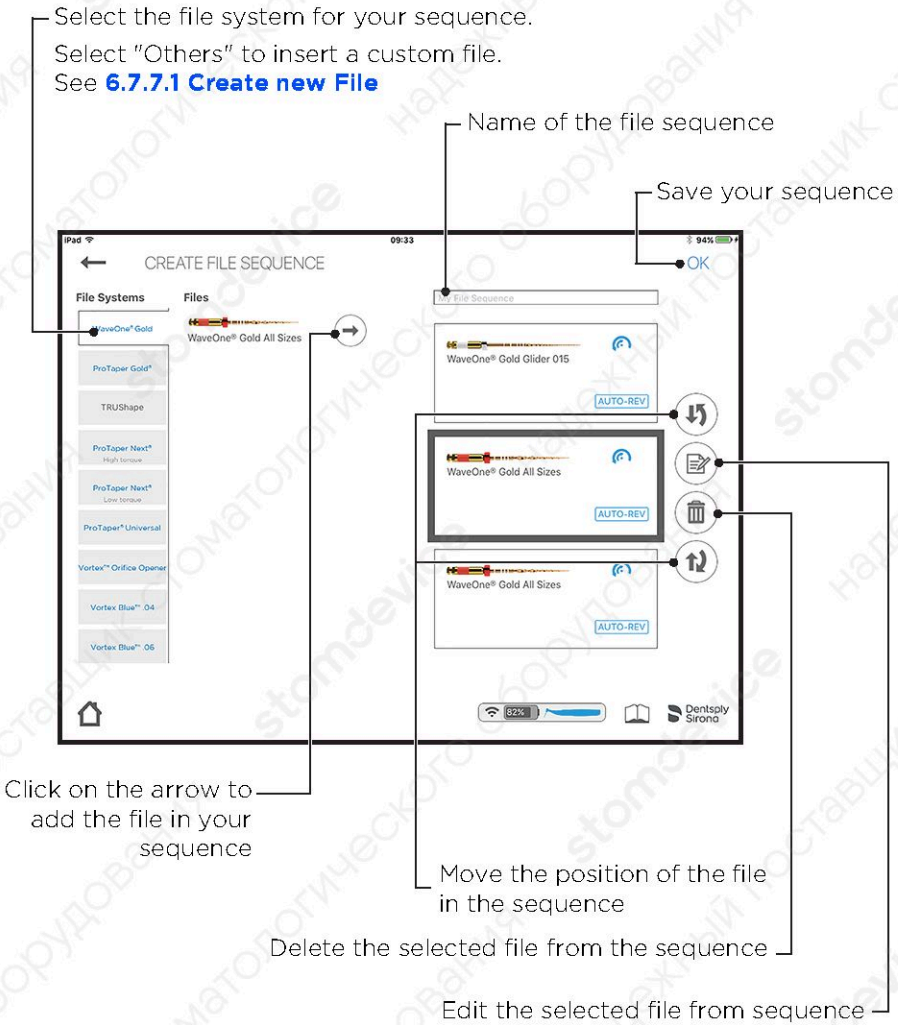


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6.7.7.2 Create File Sequence

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.

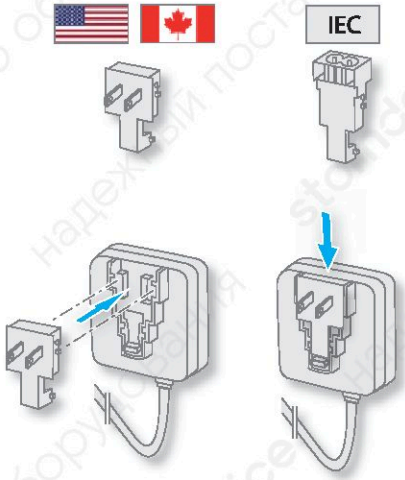


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6.8 Storing and charging the Motor Handpiece

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

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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 (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.

7.2 Single Use of Custom Polyethylene Barrier



The Custom Polyethylene Barrier does not replace cleaning and disinfection of dental instruments. Please clean and disinfect dental instruments after each patient as described by the instrument manufacturer.



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



Please refer to the instructions for use on the Custom Polyethylene Barrier box.

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7.3 Disinfection of Motor Handpiece

The components listed on **page 60** 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 (Thermal Disinfection) or sterilization.

Never place the components listed on **page 60** 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. Instead, spray a paper towel with the surface disinfectant or use a pre-moistened disinfectant towelette (wipe).

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 Custom Polyethylene Barrier, clean and disinfect the handpiece regularly. When subjecting the motor handpiece to wipe- down 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.

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For wipe-down disinfection 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 lightly 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 60**. Please use VoloWipes™.

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Motor handpiece



VoloWipes™



iPad Mini™ protective case



VoloWipes™



VoloWipes™



Spray nozzle

Motor handpiece cover



VoloWipes™



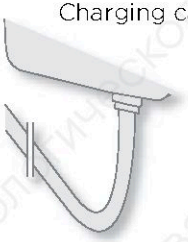
Motor handpiece support



VoloWipes™



Charging cable



VoloWipes™



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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 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.

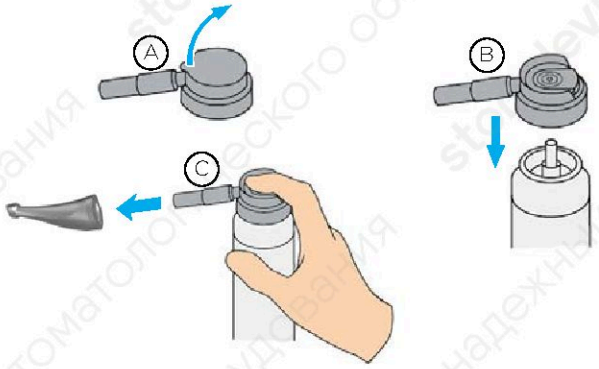
Lubricate the contra-angle immediately after thermal disinfection.

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



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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.

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Overview of Contra-Angle Cleaning, Disinfection and Sterilization					
Method	**Pre-Clean / Wipe down**	**Lubricate (for complete instructions, see Section 7.4, page 61)**	**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° / 5min	Drying performed automatically during the drying cycle in the washer-disinfector.	For additional information, see Section **7.5.2, page 65**
Contra-angle Sterilization and Drying time via Dynamic Air Removal Prevacuum Cycle					
Dynamic air removal (pre-vacuum) Sterilization	Yes	Prior to	Sterilize at 132°C / 4min or 270°F / 4min	Dry time is 30 minutes	For additional information, see Section **7.5.3.1, page 67**
Dynamic air removal (steam flush pressure pulse) Sterilization	Yes	Prior to	Sterilize at 132°C / 3min or 270°F / 4min	Dry time is 30 minutes	For additional information, see Section **7.5.3.1, page 67**
Overview of contra-angle Sterilization and Drying time Via GRAVITY – DISPLACEMENT STEAM					
GRAVITY – DISPLACEMENT STEAM	Yes	Prior to	Sterilize at 121°C / 30min or 275°F / 30min	Dry time is 30 minutes	For additional information, see Section **7.5.3.1, page 67**
GRAVITY – DISPLACEMENT STEAM (EU Market Only)	Yes	Prior to	Sterilize at 134°C / 10min or 275°F / 10min	Dry time is 30 minutes	For additional information, see Section **7.5.3.1, page 67**
GRAVITY – DISPLACEMENT STEAM	Yes	Prior to	Sterilize at 132°C / 15min or 270°F / 15min	Dry time is 30 minutes	For additional information, see Section **7.5.3.1, page 67**

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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.

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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.	*Use washer-disinfector conforming to EN ISO 15883, e.g. Belimed WD, programme: neutral.* *Use cleaning solution: e.g. 0.5% (v/v) deconex 24 LIQ, Borer Chemie.* *Use neutralizing solution: e.g. 0.25% (v/v) deconex 26 plus, Borer Chemie.* *Deionized water (DI) or water that has this degree of purity is recommended for cleaning.*
	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.	

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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), calibration is not required.

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7.5.3.1 Sterilization Procedure of the Contra-Angle

Operation	Remarks
Packaging Place the contra-angle in sterile barrier packages conforming to EN 868-5.	*Clean and disinfect before sterilization. The contra-angle should also be lubricated before sterilization.* *Make sure you only use dry sterile items.* *Use a sterilization temperature with tolerance in compliance with ISO 17665.*
Sterilization **Dynamic Air Removal (pre-vacuum) Sterilization** Sterilize at 132°C for 4min. or 270°F for 4min. **Dynamic Air Removal (steam pulse pressure pulse) Sterilization** Sterilize at 132°C for 3min. or 270°F for 4min. **Gravity-Displacement Steam** Sterilize at 121°C for 30min. or 250°F for 30min. **Gravity-Displacement Steam** Sterilize at 134°C for 10min. or 275°F for 10min. (EU Market Only) **Gravity-Displacement Steam** Sterilize at 132°C for 15min. or 270°F for 15 min.	*Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.* *Steam sterilization in accordance with AAMI ST 79.*
Drying/Storage Dry time for all methods is 30 minutes	*Before resuming operation: wait until the contra-angle attachment has cooled down and is completely dry.* *Store sterile contra-angles in a dry, dust-free place at room temperature.*

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8 Technical Characteristics

Specification	Description
Manufacturer	Dentsply Tulsa Dental Specialties Johnson City, TN 37604 USA Phone: 1-800-662-1202 Fax: 1-800-597-2779 tulsacustserv@dentsplysirona.com www.dentsplysirona.com
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) Dependent on motor speed
Speed range of the micromotor shaft	1 200 – 5 100 rpm (in rotary mode). Independent of contra-angle reduction
Type of protection against electrical shock	Class II and internally powered equipment
Applied part	BF (contra-angle)

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Specification	Description
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 and reciprocating
Ambient conditions	• Use: in enclosed spaces; • Ambient temperature: 15°C - 35°C; (59°F - 95°F) • Relative humidity: < 80%; non- condensing at 0°C (32°F); • Operating altitude < 2 000 m (~ 6561ft 8in) above sea level; • Maximum housing temperature according to IEC 60601-1:2006
Medical device class	Class I / regulation: 872.4200
Conditions for transport and storage	• 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 Output Power: 6 mW Frequency Range: 2400.0 - 2483.5 MHz
iPad® requirement	• iPad Mini™ 2 • iPad Mini™ 3 • iPad Mini™ 4
Operating System	• iOS 11.x • iOS 12.x
EMC Tables	See **14 Electromagnetic Emissions and Immunity**

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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***).*
 OFF	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***).*

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

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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.	**The ON/OFF button is blocked or faulty.** *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.*
The handpiece cannot be switched on.	**The battery is completely flat (all LEDs off).** *Connect the motor handpiece to charger (see* **6.8 Storing and charging the Motor Handpiece***).*
	The handpiece no longer responds (the LEDs are lit but the motor handpiece does not respond when the button is pressed). *Perform a reset (see* **6.6.1 Description of the Motor Handpiece***).*
	The motor handpiece automatically switches to ready mode. *The multifunction button is faulty. Contact your service center.*
The motor handpiece cannot be connected to the iPad Mini™.	**The Bluetooth® connection has failed.** *iPad Mini™:* *1. Activate Bluetooth® on your iPad Mini™ under settings (see* **6.5.4 Activating the Bluetooth®***).* *2. Perform a reboot on your iPad Mini™ (press and hold the iPad Mini™ ON / OFF button for a few seconds).* *Motor handpiece:* *Perform a factory reset (see* **6.6.1 Description of the Motor Handpiece***).*

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Problem	Cause / Solution
Lost connection between the handpiece and the iPad Mini™.	**iPad Mini™ switched off (empty battery).** *The handpiece keeps the last used settings for 5 min. You can either recharge the iPad Mini™ and reconnect the motor handpiece or use it in stand-alone mode.*
	iPad Mini™ Bluetooth® switched off. *Switch on the Bluetooth® on the iPad Mini™ and reconnect the motor handpiece (see* **6.5.4 Activating the Bluetooth®** *and* **6.7.3 Connecting the Motor Handpiece***).*
	Motor handpiece far from the iPad Mini™. *Place the motor handpiece near the iPad Mini™ and re-connect it (see* **6.7.3 Connecting the Motor Handpiece***).*
The contra-angle cannot be calibrated.	**The calibration procedure may have been interrupted by increased resistance in the contra-angle.** *1. If calibration has been interrupted, calibrate the motor handpiece again to rule out the possibility of a motor fault.* *2. Clean the contra-angle (see* **7.5 Cleaning, Disinfection and Sterilization of the Contra-Angle***).* *3. Start the calibration procedure again.*
Motor handpiece is getting hot.	**Overheating.** *The device switches off automatically if it overheats. If this occurs, discontinue use and contact customer service at (voice) 1-800-662-1202 (fax) 1-800-597-2779 or email tulsacustserv@dentsplysirona.com*

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11 Warranty

Dentsply Sirona warrants the **X-SMART IQ™** against defects in material and workmanship under normal practices of installation, use, and servicing.

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

Motor Warranty Replacement Fee*		
First Replacement in Year 1	Year 1 & Year 2	Year 3
$0**	$99***	$199***

* This chart only refers to the motor handpiece and not the contra-angle or accessories included with the **X-SMART IQ™**

** $0 cost for the first return. Additional returns will incur a $99 service fee.

*** Dentsply Sirona reserves the right to replace 2nd and 3rd year returns with a refurbished motor.

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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 these Directions for Use.
- Cleaning, disinfection and sterilization methods contrary to the directions in these Directions for Use.
- Contra-angle maintenance contrary to the directions in these Directions for Use.
- Work or repairs performed by unauthorized persons.
- Damage caused to or by the iPad®.
- Rights under the warranty or statutory guarantee are rendered void if the device is opened without permission.
- Electrical installations in the room must meet the provisions of IEC 60364-7-710 ("Installation of electrical equipment in rooms used for medical purposes") and the regulations applicable in your country.

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

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12 Disposal of the Product

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

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).

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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
	Do Not Throw Away. This product and all its components must be recycled.
	Consult Instructions for Use
	Sterilizable in a steam sterilizer (autoclave) up to temperature specified

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Symbol	Identification
	Opened packages are not replaced
	Alternate current
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Keep dry
	Fragile, handle with care
	Direct current (connection for power supply)
	Use by date
	Do not sterilize
	Do not re-use
	Caution, consult instructions for use
	Plastic
	Accessory

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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.

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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	-

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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.

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Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle (at 0, 45, 90, 135, 180, 225 and 315° phase angle) < 5% U_T (> 95% dip in U_T) for 1 cycle (at 0 phase angle) 70% U_T (30% dip in U_T) for 25/30 cycles (at 0 phase angle) < 5% U_T (> 95% dip in U_T) for 250/300 cycles (at 0 phase angle)	< 5% U_T (> 95% dip in U_T) for 0.5 cycle (at 0, 45, 90, 135, 180, 225 and 315° phase angle) < 5% U_T (> 95% dip in U_T) for 1 cycle (at 0 phase angle) 70% U_T (30% dip in U_T) for 25/30 cycles (at 0 phase angle) < 5% U_T (> 95% dip in U_T) for 250/300 cycles (at 0 phase angle)	Mains power quality should be that of a typical commercial or hospital environment. 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.
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.			

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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	$d = 0.35 \times \sqrt{P}$

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Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 0.35 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \times \sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

a
Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobiles radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which **X-SMART IQ™** is used exceeds the applicable RF compliance level above, **X-SMART IQ™** should be observed to verity normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating **X-SMART IQ™**.
b
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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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.			

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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

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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.					
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50% duty cycle square wave signal. [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.					

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