

MO3 IFU Rev.0

User Guide

Intraoral Scanner



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About This Guide

Convention in This Guide

This guide uses various symbols to highlight important information to ensure correct usage, prevent injury to the user and others, and prevent property damage. The meanings of the symbols used are described below.

WARNING

The WARNING symbol indicates information that, if ignored, could result in a medium risk of personal injury.

CAUTION

The CAUTION symbol indicates safety information that, if ignored, could result in a slight risk of personal injury, property damage, or damage to the system.

TIPS

The TIPS symbol indicates hints, tips, and additional information for optimal operation of the system.

1 Introduction and Overview

1.1 Intended Use

The Intraoral Scanner system is an intraoral 3D scanner intended to record topographical characteristics of teeth and surrounding tissues digitally. The Intraoral Scanner system produces 3D scans for use in computer-assisted design and manufacturing of dental restorations.

1.2 Indication for Use

The Intraoral Scanner system is for scanning the patient's intraoral features. Various factors (intraoral environment, operator's expertise, and laboratory workflow) may affect the final scan results when using the Intraoral Scanner system.

1.3 Contraindications

The Intraoral Scanner system is not intended to be used to create images of the internal structure of teeth or the supporting skeletal structure.

1.4 Qualifications of the Operating User

CAUTION

- The Intraoral Scanner system is designed for use by individuals with professional knowledge in dentistry and dental laboratory technology.
- The user of the Intraoral Scanner system is solely responsible for determining whether or not this device is suitable for a particular patient's case and circumstances.
- The user is solely responsible for the accuracy, completeness, and adequacy of all data entered the Intraoral Scanner system and the provided software. The user should check the accuracy of the results and assess each individual case.
- The Intraoral Scanner system must be used in accordance with its accompanying User Guide.
- Improper use or handling of the Intraoral Scanner system will void its warranty. If you require additional information on the proper use of the Intraoral Scanner system, please contact your local distributor.
- The user is not allowed to modify the Intraoral Scanner system.

1.5 Symbols

No.	Symbol	Description
1		Serial number
2		Medical device
3		Date of manufacture
4		Manufacturer
5		Caution
6		Warning
7		Read the user guide
8		The official mark of the Europe Certificate

9		Authorized representative in the European community
10		BF type of applied part
11		WEEE mark
12		Prescription use (U.S.A)
13		Nemko NRTL/C Mark
14		AC
15		DC
16		Temperature limitation
17		Humidity limitation
18		Atmospheric pressure limitation
19		Fragile
20		Keep dry
21		This way up
22		Fourteen-Layer stacking prohibited
23		Consult instructions for use
24		The official mark of the United Kingdom
25		Authorized representative in Switzerland
26		Authorized representative in the United Kingdom
27		Model Number
28		Quantity
29		Unique device identifier
30		Non-sterile
30		Stand-by

1.6 Intraoral Scanner Components Overview

No.	Item (Model Name)	Qty	Appearance
1	Intraoral Scanner Handpiece (MO3-i900M)	1 ea	
2	Intraoral Scanner Handpiece Cover (MO3-HC1)	1 ea	
3	Wireless Hub (MO3-WFH)	1 ea	
4	Wall Mount Holder (MO3-WH1)	1 ea	
5	Power Delivery Cable Package (2m/30cm) (MO3-PD4) - Power Delivery Cable (30 cm) 1 ea (MO3-PD3) - Power Delivery Cable (2 m) 1 ea (MO1-PD2) 1 ea	1 set	

6	Rechargeable Battery Package (MO3-REBP) Rechargeable Battery 3ea (MO3-REB)	1 set	
7	Medit Power Adapter (Includes 7 types of connectors) (MO3-MPAP) - Medit Power Adapter(CDM045A3-W200V) 7 types of connectors(MA1-MPA)	1 set	
8	Battery Charger (MO3-BC1)	1 ea	
9	Charging Cable (2 m) (MA1-CC1)	1 ea	
10	Reusable Tip Package (MO1-RTP) - Reusable (Large) Tip 2ea (MO1-RTL) - Reusable (Medium) Tip 2ea (MO1-RTM)	1 set	

11	Calibration Tool (MO1-CT1)	1 ea	
12	Practice Model	1 ea	
13	USB Flash Drive (Installer of Medit Scan for Clinics included)	1 ea	
15	User Guide	1 ea	

1.6.1 Additional Components (Sold Separately)

No.	Item (Model Name)	Qty	Appearance
1	Reusable (Large) Tip Package (MO1-RTL) Reusable (Large) Tip 4ea	1 set	

2	Reusable (Medium) Tip Pacakge (MO1-RTL) Reusable (Large) Tip 4ea	1 set	
3	Reusable (Small) Tip Pacakge (MO1-RTL) Reusable (Large) Tip 4ea	1 set	

- All components listed in 1.6 & 1.6.1 can be purchased separately.
- The availability of items may vary depending on the medical device registration status in each country or region. Please contact Medit or your local distributor to check the availability of specific items.

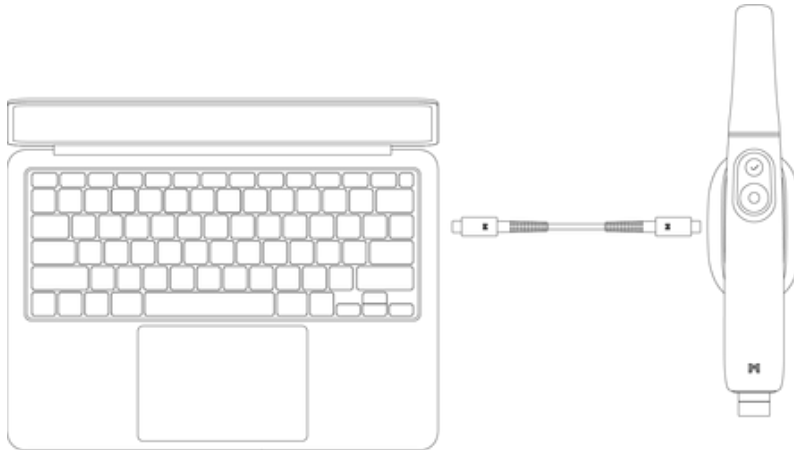
CAUTION

- Keep the practice model in a cool place away from direct sunlight. A discolored practice model may affect the results of the practice mode.
- Medit Scan for Clinics is included in the USB drive. This product is optimized for PC, and using other devices is not recommended. Do not use anything other than a USB port. It may cause malfunction or fire.
- Medit Link Express can be downloaded from the Apple App Store. This product is optimized for iPad, and using other devices is not recommended.

1.7 Setting Up the Intraoral Scanner System

1.7.1 Basic Settings of Intraoral Scanner

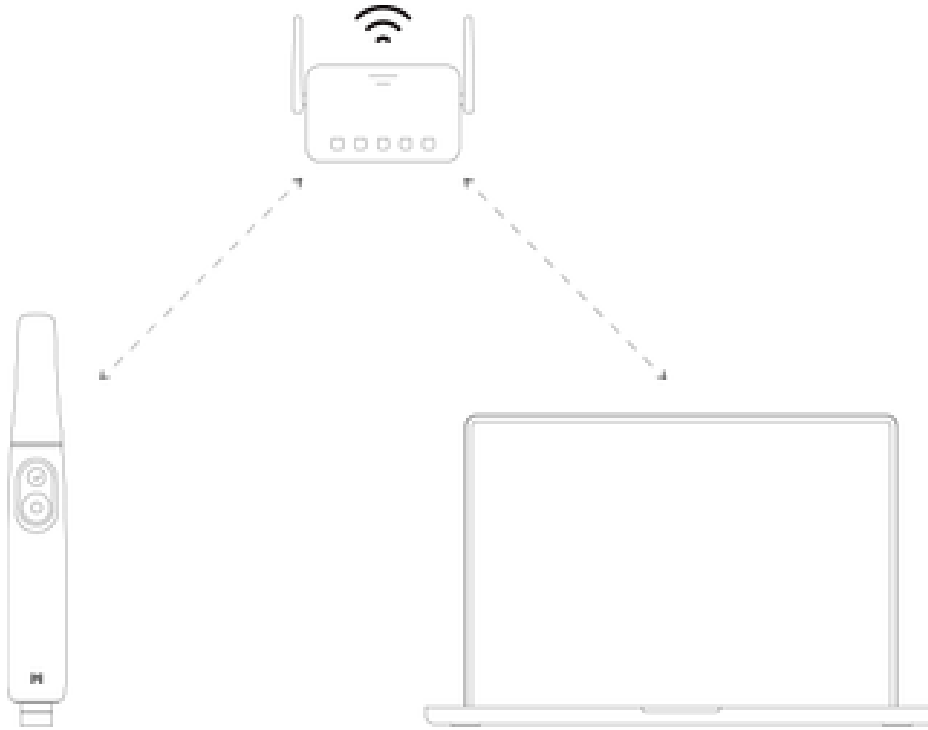
Connect the Intraoral Scanner Wireless Hub



- ① Connect the Power Delivery Cable (30 cm) or the Power Delivery Cable (2 m) to the wireless hub.
- ② Connect the opposite connector of the Power Delivery Cable to a PC.



Connection via a wireless router



Even if the Intraoral Scanner Wireless Hub is not connected to a PC, the scanner can still be connected to the software through a wireless router (for both Medit Scan for Clinics and Medit Link Express).

CAUTION

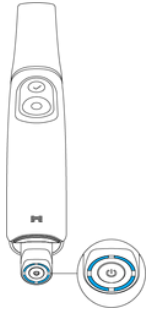
Medit Link Express is available exclusively for iPadOS.

Turning On the Intraoral Scanner

- ① Insert the battery into the bottom of the handpiece and press the power button once.



- ② When power is applied, the rear LED lights up.

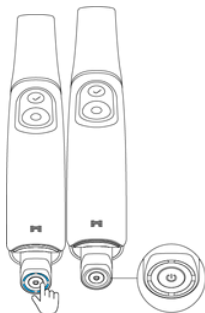


③ Four LEDs on the fuel gauge of the battery indicate the remaining battery level.

- 4 lights: 75 – 100%
- 3 lights: 50 – 74%
- 2 lights: 25 – 49%
- 1 light: 12 – 24%
- 1 blinking light: 1 – 12%
 - * The battery only blinks in the range of 1–12% when it is installed in the handpiece. If the user checks the remaining battery level with the battery alone or installs it in the charger, it doesn't blink and only one LED lights up within the 1–12% range.
- LED lights turned off: 0%

Turning Off the Intraoral Scanner

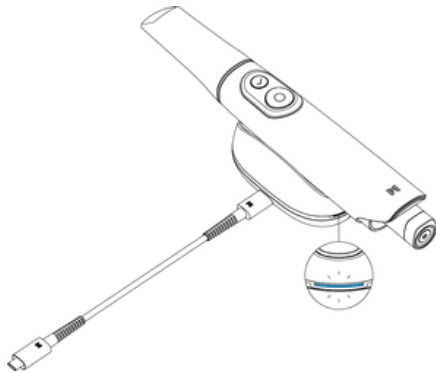
Press and hold the power button until the rear LED is off. Removing the rechargeable battery without turning off the product may shorten the lifespan of both the handpiece and the battery.



1.7.2 How to Use the Wireless Hub

The Intraoral Scanner is a wireless device that operates through a wireless module. For this reason, the Intraoral Scanner handpiece has a transmitter and the wireless hub has a receiver. The Intraoral Scanner system uses Wi-Fi 6E frequency to transmit data and control the Intraoral Scanner handpiece.

Power is supplied by connecting to the wireless hub to the PC using the power delivery cable. The power turns off when the cable is disconnected.



When the handpiece and the wireless hub are turned on, they are ready to pair with each other. The wireless connection is only available either in Medit Scan for Clinics or Medit Link Express. An initial connecting process is required, and after that, they will connect automatically in subsequent uses in Medit Scan for Clinics or Medit Link Express unless the pair is changed.

- Intraoral Scanner uses two antenna modules: 6 GHz for data transmission and 2.4 GHz for the control. The actual frequency depends on the local regulations.
- The actual operational range is up to 5 m, and it may vary depending on the environment.
- 5 GHz Frequency: 5210 – 5855 MHz
- 6 GHz Frequency: 6025 – 6985 MHz
- 2.4 GHz Frequency: 2402 – 2480 MHz

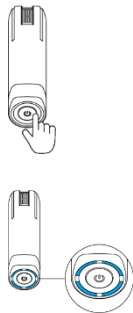
1.7.3 How to Use the Battery

- Rechargeable Battery
 - Li-ion
 - 3.6 Vd.c., 3150 mAh, 11.34 Wh

- Insert the battery at the bottom of the Intraoral Scanner handpiece. Insert the battery into the Intraoral Scanner handpiece with the terminal aligned correctly.



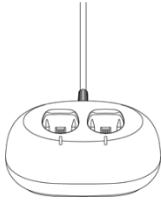
- Battery life lasts up to 1 hour. When the battery is in standalone mode, a single click of the Activation Button will display the battery level via the LED.



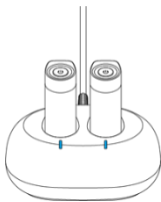
Battery life may vary depending on the user environment and the battery cycle count.

1.7.4 How to Use the Battery Charger

- Connect the Medit Power Adapter to the battery charger power port with the charging cable to supply power. The power turns off when the charging cable is disconnected.



- Insert the rechargeable battery into the battery charger with the charging terminals oriented correctly.



- The battery charger is only for rechargeable batteries. It takes up to 2 hours to be fully charged and the charging time may vary depending on the user environment and the battery cycle count.



The LED on the charger lights up in white when power is supplied without a battery installed.

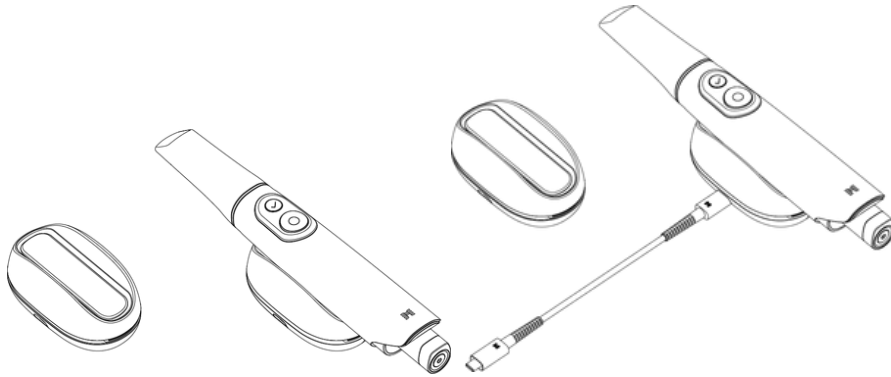
The LED on the charger blinks in blue when the battery is charging. When fully charged, the LED lights up in blue.



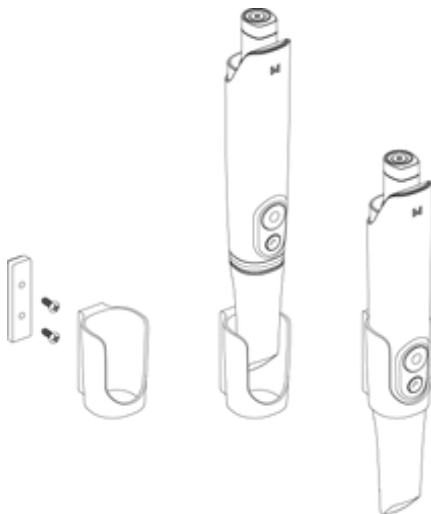
If the battery is not correctly inserted into the battery charger, the LED on the charger will blink in red. In this case, remove the battery from the charger, check both terminals of the battery and the charger for foreign objects, wipe them gently with a soft cloth, and then insert the battery again.

1.7.5 How to Place on the desktop cradle

The wireless hub is designed to resemble a desktop cradle and can function as one.



1.7.6 How to Install the Wall Mount Holder



2 Medit Scan for Clinics Overview

2.1 Introduction

Medit Scan for Clinics provides a user-friendly working interface to digitally record topographical characteristics of teeth and surrounding tissues using the Intraoral Scanner system.

2.2 Installation

2.2.1 System Requirements

Recommended System Requirements

Windows OS			macOS
	Laptop	Desktop	Laptop/Desktop
CPU	Intel Core i7-13700H	Intel Core i7-13700K	M1 Pro (10-core CPU, 16-core GPU)
	Intel Core i7-12700H	Intel Core i7-12700K	M2 (8-core CPU, 10-core GPU)
	AMD Ryzen 7 7735H	AMD Ryzen 7 7700X	M2 Pro (10-core CPU, 16-core GPU)
	AMD Ryzen 7 6800H	AMD Ryzen 7 5800X	
RAM	32 GB		24 GB
Graphic	NVIDIA GeForce RTX 4060 (VRAM 8 GB or higher) NVIDIA GeForce RTX 3070 (VRAM 8 GB or higher) NVIDIA RTX A3000 (VRAM 8 GB or higher) • AMD Radeon is not supported.		–
OS	Windows 10 64-bit Windows 11 (recommended for 12th Gen or later Intel Core processors)		Monterey 12 Ventura 13 Sonoma 14 Sequoia 15

Minimum System Requirements

Windows OS			macOS	iPadOS
	Laptop	Desktop	Laptop/Desktop	iPad
CPU	Intel Core i5–13500H Intel Core i5–12500H AMD Ryzen 5 7535HS AMD Ryzen 5 6600H	Intel Core i5–13400 Intel Core i5–12400 AMD Ryzen 5 7500 AMD Ryzen 5 5600	M1 (8–core CPU, 7–core GPU) M2 (8–core CPU, 8–core GPU)	M2 (8–core CPU, 9–core GPU)
RAM	16 GB		16 GB	16 GB
Graphic	NVIDIA GeForce RTX 4050 (VRAM 6 GB or higher) NVIDIA GeForce RTX 3060 (VRAM 6 GB or higher) NVIDIA RTX A2000 (VRAM 6 GB or higher) • AMD Radeon is not supported.		–	–
OS	Windows 10 64–bit Windows 11 (recommended for 12th Gen or later Intel Core processors)		Monterey 12 Ventura 13	18.1.1

Router Requirements

Standard	WIFI6 (802.11ax) For using 6GHz, WIFI6E needed.
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For accurate and up-to-date system requirements, please visit www.meditlink.com.



Use PC and monitor classified as class I and certified IEC 62368-1 (or IEC 60950-1), IEC 55032, IEC 55024.



The device may not work when using cables other than the USB 3.0 cable provided by Medit. Medit is not responsible for any problems caused by cables other than the USB 3.0 cable provided by Medit. Be sure to use only the USB 3.0 cable included in the package.

2.2.2 Software Installation Guide

- ① Connect the enclosed USB flash drive to a PC.
- ② Run the installation file.
- ③ Select the setup language and click “Next.”
- ④ Choose the installation path.
- ⑤ Read the “License Agreement” carefully, check “I agree to the License terms and conditions,” and then click “Install.”
- ⑥ The installation process may take several minutes. Please do not shut down the PC until the installation is complete.

⑦ After the installation is complete, restart the PC to ensure optimal program operation.

The installation will not be processed while The Intraoral Scanner system is connected to a PC. Please turn off the scanner before starting the installation.

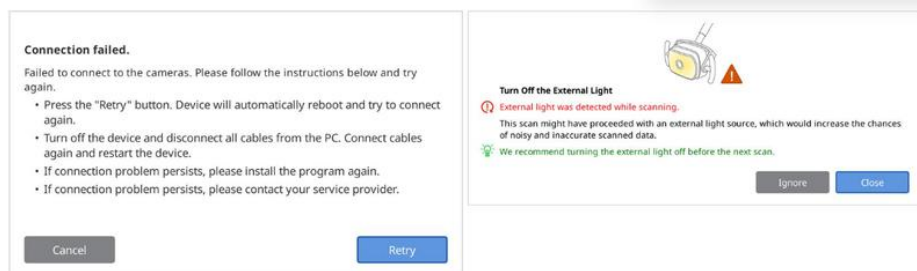
2.2.3 Medit Scan for Clinics User Guide

Please refer to the User Guide of Medit Scan for Clinics: Medit Scan for Clinics > Menu > User Guide.

2.3 Error Messages

The Intraoral Scanner scanner system presents error messages, enabling users to intuitively identify hardware and system conditions. Some messages include solutions to aid users in self-diagnosis and problem resolution.

Error messages are presented in plain text and supplemented with images when needed to enhance comprehension.



CAUTION

If the instructions provided in the error message do not address the issue, please contact the local distributor from whom you acquired your scanner system or support@medit.com.

3 Medit Link Express Overview

3.1 Introduction

Medit Link Express provides a user-friendly working interface to digitally record topographical characteristics of teeth and surrounding tissues using the Intraoral Scanner system.

3.2 Installation

3.2.1 System Requirements

Recommended System Requirements

Category	Details
Model	iPad Pro 7th Generation
Processor	M4 (10-core CPU, 10-core GPU)
RAM	16 GB
OS	iPadOS 18.1.1
Storage	1TB

Minimum System Requirements

Category	Details
Model	iPad Pro 6th Generation
Processor	M2 (8-core CPU, 10-core GPU)
RAM	16 GB
OS	iPadOS 18.1.1
Storage	1TB

Router Requirements

Standard	WIFI6 (802.11ax) For using 6GHz, WIFI6E needed.
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For accurate and up-to-date system requirements, please visit <http://www.meditlink.com>.



~~Use PC and monitor classified as class I and certified IEC 62368-1 (or IEC 60950-1), IEC 55032, IEC 55024.~~



~~The device may not work when using cables other than the USB 3.0 cable provided by Medit. Medit is not responsible for any problems caused by cables other than the USB 3.0 cable provided by Medit. Be sure to use only the USB 3.0 cable included in the package.~~

3.2.2 Software Installation Guide

- ① Go to the Apple App Store and search 'Medit Link Express'.
- ② Download the application.
- ③ Run the application.

3.2.3 Medit Scan for Medit Link Express

Please refer to the User Guide of Medit Link Express: Medit Link Express > Settings > User Guide.

2.3 Error Messages

The Intraoral Scanner scanner system presents error messages, enabling users to intuitively identify hardware and system conditions. Some messages include solutions to aid users in self-diagnosis and problem resolution.

Error messages are presented in plain text and supplemented with images when needed to enhance comprehension.

CAUTION

If the instructions provided in the error message do not address the issue, please contact the local distributor from whom you acquired your scanner system or support@medit.com.

4 Maintenance

CAUTION

- Equipment maintenance should only be carried out by a Medit employee or Medit-Certified company or personnel.
- In general, users are not required to perform maintenance work on the Intraoral Scanner system besides calibration, cleaning, and sterilization. Preventive inspections and other regular maintenance are not required.

4.1 Calibration

Periodic calibration is required to produce precise 3D models. You should perform calibration when:

- The quality of the 3D model is not reliable or accurate when compared to previous results.
- Environmental conditions such as temperature have changed.
- The calibration period has expired.
- You can set the calibration period in the settings.
 - Medit Scan for Clinics: Menu > Settings > Calibration Period (Days).
 - Medit Link Express: Settings > Scanner Information > Calibration Period.



The calibration panel is a delicate component.

Do not touch the panel directly. Check the calibration panel if the calibration process is not performed properly. If the calibration panel is contaminated, please contact your service provider.



If the calibration tool is long exposed to low temperatures below Medit's recommendations mentioned in the use and storage guidance, the rotation motion of the device may be compromised. In that case, forcibly turning the device may cause damage. To avoid it, keep the calibration device in the recommended temperature environment before use.



We recommend performing a calibration periodically.

- You can set the calibration period. The default calibration period is 90 days.
 - Medit Scan for Clinics: via Menu > Settings > Calibration Period (Days).
 - Medit Link Express: via Settings > Scanner Information > Calibration Period.

4.1.1 How to Calibrate Intraoral Scanner

4.1.1.1 How to Calibrate Intraoral Scanner in Medit Scan for Clinics

- ① Turn on the Intraoral Scanner and launch the Medit Scan for Clinics.
- ② Run the Calibration Wizard at the bottom of the main toolbar panel in Medit Scan for Clinics.
- ③ Prepare the calibration tool and the Intraoral Scanner handpiece.
- ④ Turn the dial of the calibration tool to the starting position.
- ⑤ Put the Intraoral Scanner handpiece into the calibration tool.

- ⑥ Click “Next” to start the calibration process.
- ⑦ If the calibration tool is mounted properly in the correct position, the system automatically acquires data.
- ⑧ When data acquisition is complete at the starting position, turn the dial to the next position.
- ⑨ Repeat the steps to the last position.
- ⑩ When data acquisition is complete at the last position, the system automatically calculates and shows the calibration results.

4.1.1.2 How to Calibrate Intraoral Scanner in Medit Link Express

- ① Turn on the Intraoral Scanner and launch the Medit Link Express.
- ② Run the Calibration Wizard at the settings of Medit Link Express.
Medit Link Express > Settings > Scanner Information > Calibration
- ③ Prepare the calibration tool and the Intraoral Scanner handpiece.
- ④ Turn the dial of the calibration tool to the starting position.
- ⑤ Put the Intraoral Scanner handpiece into the calibration tool.
- ⑥ Click “Calibration Now” to start the calibration process.
- ⑦ If the calibration tool is mounted properly in the correct position, the system automatically acquires data.
- ⑧ When data acquisition is complete at the starting position, turn the dial to the next position.
- ⑨ Repeat the steps to the last position.
- ⑩ When data acquisition is complete at the last position, the system automatically calculates and shows the calibration results.

4.2 Cleaning, Disinfection, Sterilization Procedure

4.2.1 Reusable Tip

The reusable tip is the part that is positioned in the mouth of patients during scanning, and is reusable for a limited number of times. The tip needs to be cleaned and sterilized between patient uses to avoid cross-contamination.

Cleaning & Disinfection

- Prepare a cleaning solution.
 - Dilute a general neutral detergent at a 1:100 ratio before use.
 - Clean the reusable tips with a cleaning solution and a brush.
 - Ensure the mirror of the tip is completely clean and stain-free. If the mirror appears stained or foggy, repeat the cleaning process.
- CAUTION**
- The reusable tip has a complex structure, and automatic cleaning may not achieve complete cleaning; therefore, do not clean the reusable tip in an automatic washer.
 - Rinse the reusable tips three times with purified water.
 - Remove moisture with a paper towel and allow them to air-dry completely at room temperature for at least 80 minutes.
 - Disinfect the reusable tips using a disinfectant containing 15% or less Isopropyl Alcohol (IPA) for 1 minute. Then, ensure they are thoroughly dried at room temperature for at least 80 minutes.
 - Before using a disinfectant product, please refer to the product user manual for proper use.
 - You can find the list of recommended disinfectants in the Medit Help Center at <http://support.medit.com/hc> .

Sterilization

- The tip should be cleaned manually using a disinfecting solution. After cleaning and disinfecting, inspect the mirror inside the tip to ensure there aren't any stains or smudges.
- Repeat the cleaning and disinfection process if necessary. Carefully dry the mirror with a paper towel.
- Insert the tip into a paper sterilization pouch and seal it, making sure that it is airtight. Use either a self-adhesive or heat-sealed pouch.
- Sterilize the wrapped tip in an autoclave with the following conditions:
 - Sterilize in a gravity autoclave at 135°C (275°F) for 10 minutes and dry for 30 minutes.
 - Sterilize in a pre-vacuum autoclave at 134°C (273.2°F) for 4 minutes and dry for 20 minutes.

- Use an autoclave program that dries the wrapped tip before opening the autoclave.
- Scanner tips can be re-sterilized up to 150 times. After reaching this limit, they must be disposed of according to the guidelines in the disposal section.
- Autoclave times and temperatures may vary depending on the autoclave type and manufacturer. For this reason, it may not be able to meet the maximum number of times. Please refer to the user manual of the autoclave manufacturer you are using to determine whether the required conditions are met.

CAUTION

- The mirror of the scanner tip is a delicate optical component that should be handled with care to ensure optimal scan quality. Be careful not to scratch or smudge it as any damage or blemishes may affect the data acquired.
- Make sure to always wrap the tip before autoclaving. If you autoclave an exposed tip, it will cause stains on the mirror, which cannot be removed. Check the autoclave manual for more information.
- Tips that have been cleaned, disinfected, and sterilized must remain sterile until they are used on the patient.
- Medit is not responsible for any damage, including tip distortion, caused by cleaning, disinfection, or sterilization procedures that do not comply with the guidelines outlined above.

4.2.2 Mirror

The presence of impurities or smudges on the tip mirror may lead to poor scan quality and an overall poor scanning experience. In such situations, clean the mirror following the steps below:

- ① Disconnect the scanner tip from the Intraoral Scanner handpiece.
- ② Pour alcohol on a clean cloth or cotton-tipped swab and wipe the mirror. Make sure to use alcohol that is free of impurities or it may stain the mirror. You can use either ethanol or propanol (ethyl-/propyl alcohol).
- ③ Wipe the mirror dry using a dry, lint-free cloth.
- ④ Make sure the mirror is free of dust and fibers. Repeat the cleaning process as necessary.

4.2.3 Handpiece

After treatment, clean and disinfect all other surfaces of the Intraoral Scanner handpiece except for the scanner front (optical window) and end (air vent hole). Cleaning and disinfecting must be done with the device turned off. Use the device only after it is completely dry.

The recommended cleaning and disinfecting solution is denatured alcohol (ethyl alcohol or ethanol) – typically 60 – 70% Alc/Vol.

The general cleaning and disinfecting procedures are as follows:

- ① Turn off the power using the battery activation button.
- ② Clean the filter on the front end of the Intraoral Scanner handpiece.
 - If alcohol is poured directly into the filter, it may seep inside the Intraoral Scanner handpiece and cause a malfunction.
 - Do not clean the filter by pouring alcohol or cleaning solution directly into the filter. The filter must be gently wiped with a cotton or soft cloth moistened with alcohol. Do not wipe by hand or apply excessive force.
 - Medit is not responsible for any damage or malfunction that occurs during cleaning that does not follow the guidelines above.
- ③ After cleaning the filter, put the cover on the front of the Intraoral Scanner handpiece.
- ④ Pour the disinfectant onto a soft, lint-free, and non-abrasive cloth.
- ⑤ Wipe the scanner surface with the cloth.
- ⑥ Dry the surface with a clean, dry, lint-free, and non-abrasive cloth.

CAUTION

- Do not clean the Intraoral Scanner handpiece when the device is turned on as the fluid may enter the scanner and cause malfunction.
- Use the device after it is completely dry.
- Chemical cracks may appear if improper cleaning and disinfecting solutions are used during cleaning.

4.2.4 Other Components

- Pour the cleaning and disinfecting solution onto a soft, lint-free, and non-abrasive cloth.
- Wipe the component surface with the cloth.
- Dry the surface with a clean, dry, lint-free, and non-abrasive cloth.

CAUTION

- Chemical cracks may appear if improper cleaning and disinfecting solutions are used during cleaning.

4.3 Disposal

CAUTION

- The scanner tip must be sterilized before disposal. Sterilize the tip as described in the section “[3.2.1 Reusable Tip](#).”
- Dispose of the scanner tip as you would any other clinical waste.
- Other components are designed to conform with the following directives:
RoHS, Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment. (2011/65/EU)
WEEE, Waste Electrical and Electronic Equipment Directive. (2012/19/EU)

4.4 Battery Storage

- Put it in a pack or a box and store indoors in a cool environment out of direct sunlight.
- Store the battery in a dry place with an ambient temperature of from -20°C to $+30^{\circ}\text{C}$ (-4°F to $+86^{\circ}\text{F}$)
- If not used for a long time, the battery self-discharge may accelerate and slip into sleep mode. To minimize the effect of deactivation, store the battery pack in between $+10^{\circ}\text{C}$ – $+30^{\circ}\text{C}$ ($+50^{\circ}\text{F}$ to $+86^{\circ}\text{F}$)
- When charging for the first time after long-term storage, the battery capacity may decrease due to pack deactivation. Restore the battery through several full charge/discharge cycles.

- If the battery is stored for more than 6 months, it should be charged at least once every 6 months to prevent the decrease in shelf life due to self-discharge

CAUTIONS: Battery Safety Specifications

Safety Specifications		
Overcharge	Sense Voltage	4.250 V $\pm$ 0.020
	Steady Voltage	4.050 V $\pm$ 0.05
	Sense Delay	1.0 s $\pm$ 0.3
Over-Discharge	Sense Voltage	2.50 V $\pm$ 0.050
	Steady Voltage	2.90 V $\pm$ 0.10
	Sense Delay	128 ms $\pm$ 38.4
Overcurrent	Sense (Charge)	12.0 A +5.0 / -4.5
	Sense Delay	16.0 ms $\pm$ 4.8
	Sense (Discharge)	Min. 7.5A
	Sense Delay	16.0 ms $\pm$ 4.8
Current consumption at operating mode		Max. 150.0 μ A



The possible safety specifications are determined by the propulsion control module (PCM) in the parts list.

4.5 The Battery Usage Precautions and Disposal Guide

CAUTION

- Be sure to fully understand how to replace the battery before use.
- Use a charger suitable for the specified voltage and current.
- Do not attempt to reverse the charge. Reverse charging may increase the gas pressure inside the battery and cause the battery to leak.

- Do not attempt to recharge a fully charged battery. Repeated overcharging could result in battery performance degradation and overheating.
- Charging efficiency decreases at temperatures below 0°C (32°F) and above +45°C (113°F).
- Do not short-circuit the positive (+) and negative (–) terminals with metallic objects such as metal wires, necklaces, or chains.
- To avoid malfunction or damage, do not drop or throw the battery.
- Do not deform a battery by excessive pressure.
- Do not directly solder anything onto the battery pack.
- Do not allow children to change batteries without adult supervision.
- Do not dispose of the battery as general waste and separate it from recyclables.
- Do not dispose of or throw the battery into a fire. Heat can cause a battery explosion and a fire.
- Separate them from each other when disposing of the secondary batteries with different electrochemical systems.
- Dispose of the battery by discharging it to prevent heat from short-circuiting.
- Battery disposal methods may vary by country and region. Dispose of used batteries under local laws and regulations.

4.6 Updates in Software

4.6.1 Updates in Medit Scan for Clinics

Medit Scan for Clinics automatically checks for updates when the software is in operation. If a new version of the software is released, the system will automatically download it.

4.6.2 Updates in Medit Link Express

Medit Link Express automatically checks for updates when the software is in operation. If a new version of the software is released, the system will automatically download it when the user has enabled automatic updates on iPad

5 Safety Guide

Please adhere to all the safety procedures as detailed in this User Guide to prevent human injury and equipment damage. This document uses the words WARNING and CAUTION when highlighting precautionary messages.

Carefully read and understand the guidelines, including all preventive messages as prefaced by the words WARNING and CAUTION. To avoid bodily injury or equipment damage, make sure to adhere strictly to the safety guidelines. All instructions and precautions as specified in the Safety Guide must be observed to ensure the system's proper functionality and personal safety.

The Intraoral Scanner system should only be operated by dental professionals and technicians who are trained to use the system. Using the Intraoral Scanner system for any purpose other than its intended usage as outlined in the section "[1.1 Intended Use](#)" may result in injury or damage to the equipment. Please handle the Intraoral Scanner system according to the guidelines in the safety guide.

Any serious incident involving the device should be reported to the manufacturer and the competent authority of the member state in which the user and patients are located.

5.1 System Basics

The Intraoral Scanner system is a high-precision optical medical device. Acquaint all the following safety and operating instructions before the installation, usage, and operation of Intraoral Scanner.

CAUTION

- The wireless hub is designed specifically for the Intraoral Scanner and should not be used with any other device.
- This device has been assessed for conformity for use in business environments. When used in residential environments, there is a risk of radio wave interference.
- If the product has been stored in a cold environment, give it time to adjust to the temperature of the environment before use. If used immediately, condensation may occur, which may damage the electronic parts inside the unit.
- Ensure that all components provided are free from physical damage. Safety cannot be guaranteed if there is any physical damage to the unit.
- Before using the system, check that there are no issues such as physical damage or loose parts. If there is any visible damage, do not use the product and contact the manufacturer or your local representative.
- Check the Intraoral Scanner handpiece and its accessories for any sharp edges.
- When not in use, the Intraoral Scanner system should be kept mounted on a desk stand or a wall mount stand.

- Do not install the desk stand on an inclined surface.
- Do not place any object on the Intraoral Scanner system.
- Do not place the Intraoral Scanner system on any heated or wet surface.
- Do not block the air vents located at the rear of the Intraoral Scanner system. If the equipment overheats, the Intraoral Scanner system may malfunction or stop working.
- The battery of the Intraoral Scanner can only be compatible with the Intraoral Scanner system.
- Do not touch the charging terminals of the rechargeable battery with your hands or other instruments.
- If the charging terminal of the rechargeable battery is damaged, do not use it and contact the manufacturer or regional manager.
- If the shape of the rechargeable battery has been deformed by dropping or physical damage, never use it, and contact the manufacturer or regional manager.
- Do not spill any liquid on the Intraoral Scanner system.
- The Intraoral Scanner handpiece and other included components are made of electronic components. Do not allow any kind of liquid or foreign objects to enter.
- Do not pull or bend the cable connected to the wireless hub.
- Carefully arrange all the cables so that you or your patient do not trip or get caught in the cables. Any pulling tension on the cables may cause damage to the Intraoral Scanner system.
- Always place the plug of the Medit Power Adapter of the Intraoral Scanner system in an easily accessible location.
- Always keep an eye on the product and your patient while using the product to check for abnormalities.
- Proceed with calibration, cleaning, disinfection, and sterilization in accordance with the contents of the user guide.
- If you drop the Intraoral Scanner tip on the floor, do not attempt to reuse it. Discard the tip immediately as there is a risk that the mirror attached to the tip may have been dislodged.
- Due to its fragile nature, the Intraoral Scanner tips should be handled with care. To prevent damage to the tip and its internal mirror, be careful to avoid contact with the patient's teeth or restorations.
- If the Intraoral Scanner system is dropped on the floor or if the unit is impacted, it must be calibrated before use. If the instrument is unable to connect to the software, consult the manufacturer or authorized resellers.
- If the equipment fails to operate normally, such as having issues with accuracy, stop using the product, and contact the manufacturer or authorized resellers.

- Install and use only approved programs to ensure the proper functionality of the Intraoral Scanner system.
- In the event of a severe accident involving the Intraoral Scanner system, notify the manufacturer and report it to the competent national authority of the country where the user and patient reside.
- If the PC with the software installed does not have security software or if there is a risk of malicious code intrusion into the network, the PC may be breached with malware (malicious software such as viruses or worms that damage your computer).
- The software for this product must be used in compliance with medical and personal information protection laws.
- To provide electrical insulation and maintain electrical safety, a coating is applied to insulate the device except on the areas where the USB ports are located.
- This product is a 3D precision measuring device and is highly sensitive to external impacts. Performance degradation may occur in the event of external shocks, so careful handling is required.

5.2 Proper Training

WARNING

Before using your Intraoral Scanner system on patients:

- You should have been trained to use the system or read and fully understand this User Guide.
- You should be familiar with the safe use of the Intraoral Scanner system, as detailed in this User Guide.
- Before use or after changing any settings, the user should check that the live image is displayed properly in the camera preview window of the program.

5.3 In Case of Equipment Failure

WARNING

If your Intraoral Scanner system is not working properly or if you suspect that there is a problem with the equipment:

- Remove the device from the patient's mouth and discontinue use immediately.
- Disconnect the device from the PC and check for errors.
- Remove the rechargeable battery from the Intraoral Scanner system.
- Contact the manufacturer or authorized resellers.
- Modifications to the Intraoral Scanner system are prohibited by law as they may compromise the safety of the user, patient, or a third party.

5.4 Hygiene

WARNING

For clean working conditions and patient safety, ALWAYS wear clean surgical gloves when:

- Handling and replacing the tip.
- Using the Intraoral Scanner system on patients.
- Touching the Intraoral Scanner system.

WARNING

The Intraoral Scanner system and its optical window should be always kept clean. Before using the Intraoral Scanner system on a patient, be sure to:

- Sterilize the Intraoral Scanner system as described in the section "3.2 Cleaning, Disinfection, Sterilization Procedure."
- Use a sterilized tip.

5.5 Electrical Safety

WARNING

- The Intraoral Scanner system is a Class I device. The Intraoral Scanner system includes the Intraoral Scanner handpiece, wireless hub, battery charger, and rechargeable battery altogether.
- To prevent electric shock, the Intraoral Scanner system must only be connected to a power source with a protective earth connection. If you cannot insert the Intraoral Scanner-supplied plug into the main outlet, contact a qualified electrician to replace the plug or outlet. Do not try to circumvent these safety guidelines.

- Do not use a grounding-type plug connected to the Intraoral Scanner system for any other purpose than its intended use.
- The Intraoral Scanner system only uses RF energy internally. The amount of RF radiation is low and does not interfere with surrounding electromagnetic radiation.
- There is a risk of electric shock if you attempt to access the inside of the Intraoral Scanner system. Only qualified service personnel should access the system.
- Do not connect the Intraoral Scanner system to a regular power strip or extension cord, as these connections are not as safe as grounded outlets. Failure to adhere to these safety guidelines may result in the following hazards:
 - All connected equipment's total short circuit current may exceed the limit specified in EN/IEC 60601-1.
 - The impedance of the ground connection may exceed the limit specified in EN/IEC 60601-1.
- Do not place liquids such as beverages near the Intraoral Scanner system and avoid spilling any liquid on the system.
- Never spill liquid of any kind on the Intraoral Scanner system.
- Condensation due to changes in temperature or humidity can cause moisture buildup inside the Intraoral Scanner system, which may damage the system. Before connecting the Intraoral Scanner system to a power supply, be sure to keep the Intraoral Scanner system at room temperature for at least two hours to prevent condensation. If condensation is visible on the product surface, the Intraoral Scanner should be left at room temperature for more than 8 hours.
- You should only disconnect the Intraoral Scanner system from the power supply via its power cord or rechargeable battery.
- When disconnecting the power cord or the rechargeable battery, hold the surface to remove it.
- Before disconnecting, make sure to turn off the power on the device using the power switch on the handpiece.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services.
- Use only batteries provided for use with the Intraoral Scanner. Other batteries could damage the Intraoral Scanner system.
- Avoid pulling on the communication cables, power cables, etc. used with the Intraoral Scanner system.

- Use only medical adapters provided for use with the Intraoral Scanner. Other adapters could damage the Intraoral Scanner system.
- Do not touch the connectors of the device and the patient simultaneously.

5.6 Eye Safety

WARNING

- The Intraoral Scanner system projects a bright light from its tip during scanning.
- The bright light projected from the tip of the Intraoral Scanner is not harmful to the eyes. However, you should not look directly at the bright light nor aim the light beam into the eyes of others. Generally, intense light sources can cause eyes to become brittle and the likelihood of secondary exposure is high. As with other intense light source exposure, you may experience a temporary reduction in visual acuity, pain, discomfort, or visual impairment, all of which increase the risk of secondary accidents.
- There is an LED that emits UV-C wavelengths inside the Intraoral Scanner handpiece. It is irradiated only inside the Intraoral Scanner handpiece and does not go outside. The blue light visible inside the Intraoral Scanner handpiece is for guidance, not UV-C light. It is harmless to the human body.
- The UV-C LED operates with a wavelength of 270 – 285 nm.
- Disclaimer for Risks Involving Patients with Epilepsy
- The Medit Intraoral Scanner should not be used on patients that have been diagnosed with epilepsy due to the risk of seizures and injury. For the same reason, dental staff who have been diagnosed with epilepsy should not operate the Medit Intraoral Scanner.

5.7 Explosion Hazards

WARNING

- The Intraoral Scanner system is not designed to be used near flammable liquids, gases, or in environments with high oxygen concentrations.
- There is a risk of explosion if you use the Intraoral Scanner system near flammable anesthetics.
- The rechargeable battery used with the Intraoral Scanner is designed with safety devices included.

- The rechargeable battery shall not be exposed to excessive heat such as sunshine or the like. Failure to observe this could result in the battery explosion. Please be careful with the storage and maintenance of the battery.
- The battery charger is designed to adjust the current supply after charging is complete. But if it is not going to be used for a long time, disconnect the power to the battery charger or remove the fully charged battery from the battery charger.

5.8 Pacemaker and ICD Interference Risk

WARNING

- Implantable Cardioverter Defibrillators (ICDs) and pacemakers may have interference due to some devices.
- Maintain a moderate distance from the patient's ICD or pacemaker when using the Intraoral Scanner system.
- For more information on peripherals used with Intraoral Scanner, check the respective manufacturer's manuals.

5.9 Cybersecurity Safety

- If a cybersecurity incident occurs, stop using the scanner and software immediately. Power off the scanner and log out of the software.
- Promptly report the incident to our support team through email, phone, or other available means of contact. Please refer to the last page of the User Guide for contact information.
- When reporting an incident, please provide as much information as possible, including the time of occurrence and any unusual behavior you noticed. This information will assist us in resolving the issue quickly.

6 Electro-Magnetic Compatibility Information

6.1 Electromagnetic Emissions

The Intraoral Scanner system is intended for use in the electromagnetic environment as specified below. The customer or the user of the Intraoral Scanner system should ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
Emission Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The Intraoral Scanner 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 A	The Intraoral Scanner is suitable for use in all establishments. This includes 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	Class A	
Voltage Fluctuations / Flicker Emissions	Complies	

WARNING

This Intraoral Scanner system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Intraoral Scanner or shielding the location.

6.2 Electromagnetic Immunity

- Guidance 1

The Intraoral Scanner system is intended for use in the electromagnetic environment as specified below. The customer or the user of the Intraoral Scanner system should ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance

Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be made of wood, concrete, or ceramic tiles. If floors are covered with a synthetic material, relative humidity of at least 30% is recommended.
Electrical Fast Transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	The mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode	± 0.5 kV, ± 1 kV differential mode	The mains power quality should be that of a typical commercial or hospital environment.
	± 0.5 kV, ± 1 kV, ± 2 kV common mode	± 0.5 kV, ± 1 kV, ± 2 kV common mode	
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles	The mains power quality should be that of a typical commercial or hospital environment. If the user of the Intraoral Scanner system requires continued operation during power mains interruptions, it is recommended that the Intraoral Scanner system be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Fields (50/60Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a location in a typical commercial or hospital environment.

Proximity Magnetic Fields in the Frequency Range 9 kHz to 13.56 MHz Immunity IEC 61000-4-39	8 A/m	8 A/m	Resistance to magnetic fields was tested and applied only to surfaces of enclosures or accessories accessible during intended use.
	30 kHz CW modulation	30 kHz CW modulation	
	65 A/m	65 A/m	
	134.2 kHz	134.2 kHz	
	PM 2.1 kHz	PM 2.1 kHz	
	7.5 A/m	7.5 A/m	
	13.56 MHz	13.56 MHz	
	PM 50 kHz	PM 50 kHz	
NOTE: U_T is the main voltage (AC) prior to the application of the test level.			

- Guidance 2

Recommended Separation Distances Between Portable and Mobile Communication Equipment and the Intraoral Scanner		
Rated Maximum Output Power of the Transmitter [W]	Separation Distance According to the Frequency of Transmitter [M]	
	IEC 60601-1-2:2014	
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0 \sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0

10	3.8	6.3
100	12	20
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.		

- **Guidance 3**

The Intraoral Scanner system is intended for use in the electromagnetic environment specified below. The customer or the user of the Intraoral Scanner system should ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz Outside ISM Bands amateur	3 Vrms	Portable and mobile RF communications equipment should not be used closer to any part of the Ultrasound System, including cables, than the recommended separation distance. This is calculated using the equation applicable to the frequency of the transmitter.

	6 Vrms 150 kHz to 80 MHz In ISM Bands amateur	6 Vrms	Recommended Separation Distance (d): $d = 1.2 \sqrt{P}$ IEC 60601-1-2:2007 $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 80 MHz to 2.5 GHz IEC 60601-1-2:2014 $d = 2.0 \sqrt{P}$ 80 MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3: The ISM (Industrial, Scientific, and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

- **Guidance 4**

The Intraoral Scanner system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the Intraoral Scanner system. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity					
Immunity Test	Band ¹⁾	Service ¹⁾	Modulation	IEC 60601 Test Level	Compliance Level
Proximity Fields from RF Wireless Communications IEC 61000-4-3	380 – 390 MHz	TETRA 400	Pulse Modulation 18 Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460; FRS 460	FM ± 5 kHz Deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band 13, 17	Pulse Modulation 217 Hz	9 V/m	9 V/m

	800 – 960 MHz	GSM 800:900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse Modulation 18 Hz	28 V/m	28 V/m
	1700 – 1990 MHz	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	28 V/m	28 V/m
	2400 – 2570 MHz	Bluetooth; WLAN 802.11b/g/n; RFID 2450; LTE Band 7	Pulse Modulation 217 Hz	28 V/m	28 V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse Modulation 217 Hz	9 V/m	9 V/m

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

WARNING

- Use of the Intraoral Scanner adjacent to or on other equipment must be avoided as it may result in improper operation. If this use is necessary, it is advisable that this and the other equipment be observed to verify that they are operating normally.
- The use of accessories, transducers, and cables other than those specified or provided by the Medit of the Intraoral Scanner could result in high electromagnetic emissions or reduced electromagnetic immunity from this equipment and result in improper operation.

7 Wireless Compliance Information

7.1 FCC Compliance Statement

FCC ID.: 2A2QMMO3-I900M (Intraoral Scanner), 2A2QM-MO3WFH (Wireless Hub)

Federal Communications Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

IMPORTANT NOTE:

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

- Intraoral Scanner
This equipment was tested for 0cm compliance between the outer housing and the user's extremities (for handles)
- Wireless Hub
This equipment should be installed and operated with minimum 20 cm between the radiator and your body.

FCC Statement as per FCC rule part 15.407 (d)(4):

- FCC regulations restrict operation of this device to indoor use only. The operation of this device is prohibited on oil platforms, cars, trains, boats, and aircraft, except that operation of this device is permitted in large aircraft while flying above 10,000 feet.

7.2 IC Compliance Statement

IC: 27675–MO3I900M (Intraoral Scanner), 27675–MO3WFH (Wireless Hub)

This Class B digital apparatus complies with Canadian ICES–003.

This device complies with Industry Canada license–exempt RSS standard(s).

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Any changes or modifications not expressly approved by the manufacturer could void the user's authority to operate this equipment.

This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

The device could automatically discontinue transmission in case of the absence of information to transmit or operational failure. Note that this is not intended to prohibit transmission of control or signaling information or the use of repetitive codes where required by the technology.

– French / français.

Cet appareil numérique de classe B est conforme à la norme canadienne ICES-003.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- 1) L'appareil ne doit pas produire de brouillage,
- 2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Toute modification ou modification non expressément approuvée par le fabricant pourrait annuler l'autorisation de l'utilisateur de faire fonctionner cet équipement.

Ce dispositif et ses antennes ne doivent pas être situés ou exploités conjointement avec d'autres antennes ou émetteurs.

L'appareil pourrait automatiquement interrompre sa transmission en cas d'absence d'information à transmettre ou de défaillance opérationnelle. Il est à noter qu'il ne s'agit pas d'interdire la transmission d'informations de contrôle ou de signalisation ou l'utilisation de codes répétitifs lorsque la technologie l'exige.

IMPORTANT NOTE:

IC Radiation Exposure Statement

This equipment complies with IC RSS-102 radiation exposure limits set forth for an uncontrolled environment.

– Intraoral Scanner

This equipment was tested for 0cm compliance between the outer housing and the user's extremities (for handles).

– Wireless Hub

This equipment should be installed and operated with a minimum distance of 20 cm (8 inches) between the radiator and your body.

– French / français.

Cet équipement est conforme aux limites d'exposition aux rayonnements IC établies pour un environnement non contrôlé.

– Intraoral Scanner

Cet équipement a été testé pour vérifier la conformité de 0 cm entre le boîtier extérieur et les extrémités de l'utilisateur (pour les poignées).

– Wireless Hub

Cet équipement doit être installé et utilisé avec un minimum de 20cm de distance entre la source de rayonnement et votre corps.

IC Statement as per RSS 248 clause 7:

- Devices shall not be used for control of or communications with unmanned aircraft systems.
- Devices shall not be used on oil platforms.
- Devices shall not be used on aircraft, except for the low-power indoor access points, indoor subordinate devices, low-power client devices, and very low-power devices operating in the 5925-6425 MHz band, that may be used on large aircraft as defined in the Canadian Aviation Regulations, while flying above 3,048 metres (10,000 feet).
- Devices shall not be used on automobiles.
- Devices shall not be used on trains.
- Devices shall not be used on maritime vessels.
- Operation shall be limited to indoor use only.

Transmit Antenna Notice

This radio transmitter [IC: 27675-MO3-I900M (Intraoral Scanner), 27675-MO3-WFH (Wireless Hub)] has been approved by Innovation, Science and Economic Development Canada to operate with the antenna types listed below, with the maximum permissible gain indicated. Antenna types not included in this list that have a gain greater than the maximum gain indicated for any type listed are strictly prohibited from use with this device.

Antenna List

Model	Type	Maximum Gain (dBi)
INNO-AFP-0420	FPCB	2.4GHz : 4.35 dBi 5GHz : 4.51 dBi 6GHz : 6.86 dBi
INNO-AFP-0404-R	FPCB	2.4GHz : 2.09 dBi 5GHz : 3.27 dBi 6GHz : 3.69 dBi
INNO-AFP-0404-L	FPCB	2.4GHz : 2.95 dBi 5GHz : 4.58 dBi 6GHz : 4.79 dBi

7.3 KC Compliance Statement



This device has been assessed for conformity for use in business environments.
When used in residential environments, there is a risk of radio wave interference.

7.4 TELEC (Japan) Compliance Statement



Intraoral Scanner	218-250616
Wireless hub	218-250617

8 Specifications

Model Name	MO3-i900M
Trade Name	i900 Mobility
Packing Unit	1 set
Classifications for Protection Against Electric Shock	Class I, Type BF Applied Parts
This product is a medical device.	
Handpiece	
Dimension	290.2 x 42.0 x 42.0 mm
Weight	321 g (excluding reusable tip and rechargeable battery)
Rating	3.6Vd.c. / 3150 mAh / 11.34Wh
Rechargeable Battery	
Model Name	MO3-REB
Type	Lithium-ion
Output	3.6 Vd.c., 11.34 Wh
Dimension	24.7 x 22 x 77.8 mm
Weight	66.1 g
Capacity	3,150 mAh

Battery Charger	
Model Name	MO3-BC1
Input / Output	12 Vd.c. , 3 A
Dimension	110 x 66 x 50.2mm
Weight	158 g
Wireless Hub	
Model Name	MO3-WFH
Input	5 Vd.c. / 3A
Dimension	109.6 x 65.6 x 51.9 mm
Weight	168g
Medit Power Adapter	
Model Name	MO3-MPA
Input Voltage	Universal 100 – 240 Vac, 50 – 60 Hz input, without any slide switch
Output	5 Vd.c. / 3A 9 Vd.c. / 3A 12 Vd.c. / 3A 15 Vd.c. / 3A 20 Vd.c. / 2.25A
Case Dimension	31.5 x 53.5 x 58 mm
EMI	CE / FCC Class B, Conduction & Radiation met
Protection	OVP (Over Voltage Protection)
	SCP (Short Circuit Protection)
	OCP (Over Current Protection)
Protection Against Electric Shock	Class I
Mode of operation	Continuous
Reusable Tip	
Dimension – Full Tip	Large 36.1 x 34.1 x 90.8 mm (W x H x L)

	Medium 36.1 x 34.1 x 90.4 mm (W x H x L)	
	Small 36.1 x 34.1 x 90.3 mm (W x H x L)	
Dimension – Tip Head	Large 26.9 x 19.7 mm (W x H)	
	Medium 22.4 x 16.3 mm (W x H)	
	Small 18.36 x 13.1 mm (W x H)	
Calibration Tool		
Model Name	MO1-CT1	
Dimension	160 x 48.5 mm (H x Ø)	
Weight	205 g	
Wireless Module		
5 GHz	Frequency Bands	5 210, 5 775 MHz
	Modes	802.11ax 80MHz
6 GHz (Indoor Only)	Frequency Bands	FCC: 6 025 – 6 985 MHz JMIC:6 025 – 6 345 MHz
	Modes	802.11ax 160MHz
2.4 GHz (Bluetooth / Bluetooth LE)	Frequency Bands	2 402 – 2 480 MHz
	Channels	79/40
	Modulation	GFSK
2.4 GHz (Bluetooth LE) Wireless Hub only. Antenna included.	Frequency Bands	2 402 – 2 480 MHz
	Channels	40
	Channel Bandwidth	1 MHz 2 MHz
	e.i.r.p.	9.3 dBm
	Modulation	GFSK

Operating, Storage, and Transport Conditions		
Operating Condition	Temperature	18 – 28°C (64.4 – 82.4°F)
	Humidity	20 – 75% relative humidity (non-condensing)
	Air Pressure	800 – 1,100 hPa
Storage Condition	Temperature	–10 – 50°C (14 – 122°F)
	Humidity	20 – 80% relative humidity (non-condensing)
	Air Pressure	800 – 1,100 hPa
Transport Condition	Temperature	–10 – 50°C (14 – 122°F)
	Humidity	20 – 80% relative humidity (non-condensing)
	Air Pressure	620 – 1,200 hPa

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