English

English

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 i900 system is an intraoral 3D scanner intended to record topographical characteristics of teeth and surrounding tissues digitally.
The i900 system produces 3D scans for use in computer-assisted design and manufacturing of dental restorations.

1.2 Indication for Use

The i900 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 i900 system.
The i900 system can also be used in full-arch scans, but various factors (intraoral environment, operator's expertise, and laboratory workflow) may affect the final results.

1.3 Contraindications

The i900 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 i900 system is designed for use by individuals with professional knowledge in dentistry and dental laboratory technology.
- The user of the i900 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 i900 system and the provided software. The user should check the accuracy of the results and assess each individual case.
- The i900 system must be used in accordance with its accompanying User Guide.
- Improper use or handling of the i900 system will void its warranty. If you require additional information on the proper use of the i900 system, please contact your local distributor.
- The user is not allowed to modify the i900 system.

1.5 Symbols

No.	Symbol	Description
1	SN	Serial number
2	MD	Medical device
3		Date of manufacture
4		Manufacturer
5		Caution
6		Warning
7		Read the user guide
8	CE	The official mark of the Europe Certificate
9	EC REP	Authorized representative in the European community
10		BF type of applied part
11		WEEE mark
12	Rx Only	Prescription use (U.S.A)
13	MET	MET mark
14		AC
15		DC
16	50°C -10°C	Temperature limitation: -10 – 50°C (14 – 122°F)
17	80 % 20%	Humidity limitation
18	1100 hPa 800 hPa	Atmospheric pressure limitation

19		Fragile
20		Keep dry
21		This way up
22		Stacking more than fourteen layers is prohibited
23		Consult instructions for use

1.6 i900 Components Overview

No.	Item (Model Name)	Qty	Appearance
1	i900 Handpiece	1ea	
2	i900 Handpiece Cover (MO1-HC1)	1ea	
3	Reusable Tip (Large) (MO1-RTL)	2ea	
4	Reusable Tip (Medium) (MO1-RTM)	2ea	
5	Calibration Tool (MO1-CT1)	1ea	
6	Practice Model	1ea	
7	Desktop Cradle (MO1-DC)	1ea	
8	Wall Mount Holder (MO1-WH1)	1ea	
9	Power Delivery Cable (2.5 m)	1ea	
10	Power Delivery Cable (2 m)	1ea	
11	USB Flash Drive (Installer of Medit Scan for Clinics included)	1ea	
12	User Guide	1ea	

1.6.1 Additional Components (Sold Separately)

No.	Item (Model Name)	Qty	Appearance
1	Reusable Tip (Small) (MO1-RTS)	4ea	

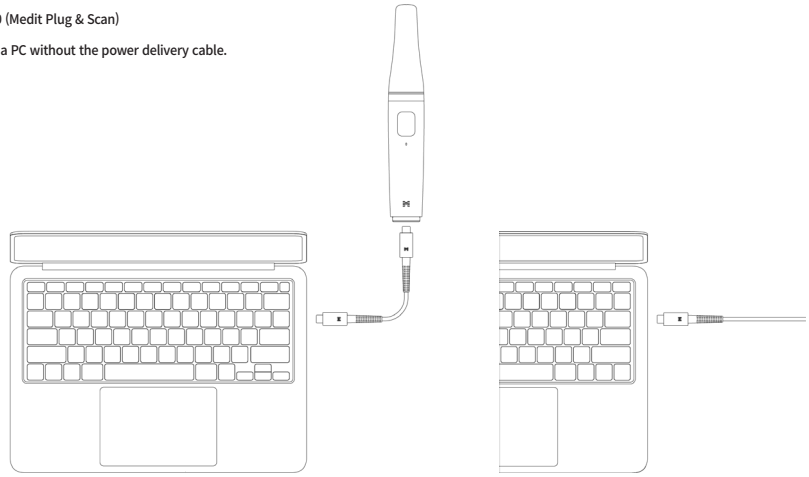
CAUTION

- 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.

1.7 Setting Up the i900 System

1.7.1 Basic Settings of i900 (Medit Plug & Scan)

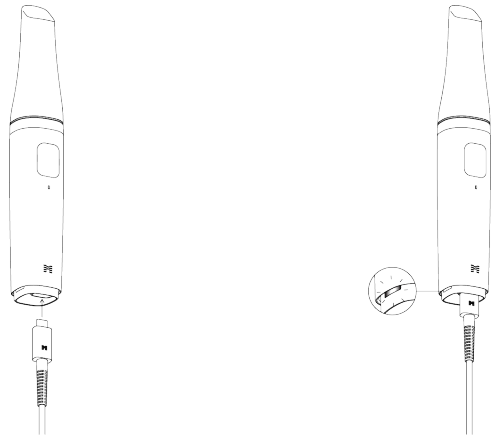
You can also connect i900 directly to a PC without the power delivery cable.



Turning On the i900

① Connect the i900 to your PC with the power delivery cable, and the scanner will automatically power on.

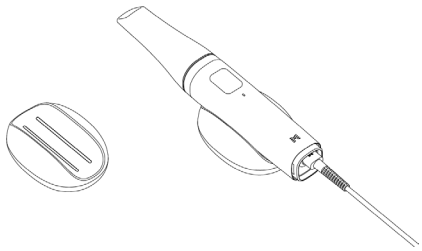
② When power is applied, the rear LED lights up blue.



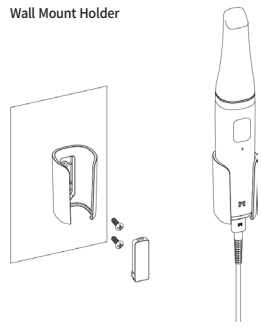
Turning Off the i900

When you disconnect the power delivery cable, the scanner switches off.

Desktop Cradle



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 i900 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 i7-12700H AMD Ryzen 7 7735H AMD Ryzen 7 6800H	Intel Core i7-13700K Intel Core i7-12700K AMD Ryzen 7 7700X AMD Ryzen 7 5800X	M1 Pro (10-core CPU, 16-core GPU) M2 (8-core CPU, 10-core GPU) M2 Pro (10-core CPU, 16-core GPU)
RAM	32GB		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

Minimum System Requirements

	Windows OS		macOS
	Laptop	Desktop	Laptop/Desktop
CPU	Intel Core i5-13500H Inter 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)
RAM	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

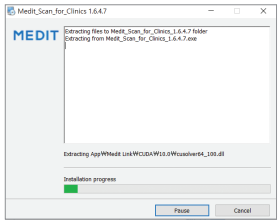
For accurate and up-to-date system requirements, please visit www.meditlink.com.

Use PC and monitor certified IEC 60950, 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.

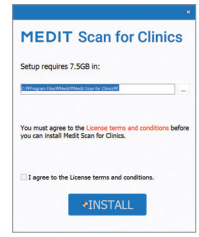
2.2.2 Medit Scan for Clinics Installation Guide

① Run the “Medit_Scan_for_Clinics_X.X.X.exe” file.

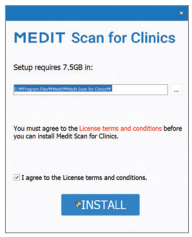


② Select the setup language and click “Next.”

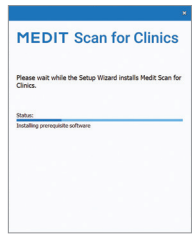
③ Select the installation path.



④ Read the “License Agreement” carefully before checking “I agree to the License terms and conditions.” and then click “Install.”

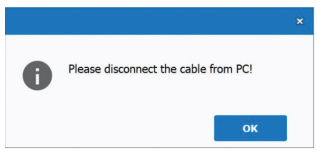


⑤ It may take several minutes to finish the installation process. Please do not shut down the PC until the installation is complete.



⑥ After the installation is complete, restart the PC to ensure optimal program operation.

The installation will not be processed while the i900 system is connected to a PC. Please be sure to disconnect the i900 USB 3.0 cable from the PC before the installation.

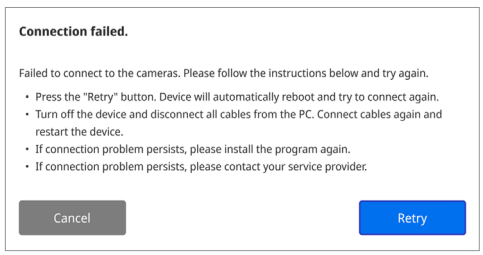


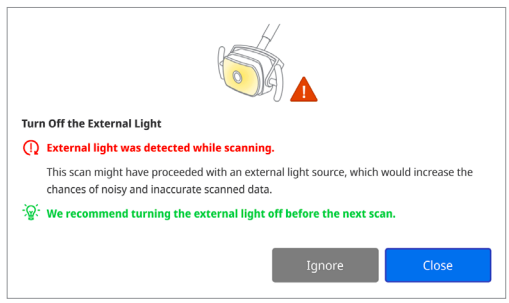
2.2.3 Medit Scan for Clinics User Guide

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

2.3 Error Messages

The Medit i900 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. 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 i900 system besides calibration, cleaning, and sterilization. Preventive inspections and other regular maintenance are not required.

3.1 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 Menu > Settings > Calibration Period (Days).

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 via Menu > Settings > Calibration Period (Days). The default calibration period is 14 days.

3.1.1 How to Calibrate i900

① Turn on the i900 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 i900 handpiece.
④ Turn the dial of the calibration tool to the starting position.
⑤ Put the i900 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.

3.2 Cleaning, Disinfection, Sterilization Procedure

3.2.1 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

- Clean the tip immediately after use with soap water and a brush. We recommend using a mild dishwashing liquid. Make sure the mirror of the tip is completely clean and stain-free after cleaning.
  If the mirror appears stained or foggy, repeat the cleaning process and rinse thoroughly with water. Dry the mirror carefully with a paper towel.
- Clean the reusable tips with disinfectants containing 15% or less Isopropyl Alcohol (IPA) and dry them.
  - » Please refer to the disinfectant product manual for proper use.
  - » You can find the list of recommended disinfectants in the Medit Help Center at https://support.medit.com/hc.
- Remove the tip from the used solution and rinse thoroughly after cleaning and sterilization.
- Use a sterilized and non-abrasive cloth to dry the mirror and the tip gently.

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 using 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 for 10 minutes at 135°C (275°F) at gravity type and dry for 30 minutes.
  - » Sterilize for 4 minutes at 134°C (273.2°F) at pre-vacuum type 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 and thereafter must be disposed of as described 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's manual of the autoclave manufacturer you are using to determine whether the required conditions are met.

CAUTION

- The mirror found in the 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, such as distortion of the tip, that occurs during cleaning, disinfection, or sterilization operations that are not following the guidelines above.

3.2.2 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 i900 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.

3.2.3 Handpiece

After treatment, clean and disinfect all other surfaces of the i900 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 by unplugging the power delivery cable from the device.
② Clean the filter on the front end of the i900 handpiece.
   » If alcohol is poured directly into the filter, it may seep inside the i900 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 i900 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 i900 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.

3.2.4 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.

3.3 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)

3.4 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. 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 i900 system should only be operated by dental professionals and technicians who are trained to use the system. Using the i900 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 i900 system according to the guidelines in the safety guide.

Any serious incident that has occurred related to the device should be reported to the manufacturer and the competent authority of the member state in which the user and patient are established.

4.1 System Basics

The i900 system is a high-precision optical medical device. Acquaint all the following safety and operating instructions before the installation, usage, and operation of i900.

CAUTION

- 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 i900 handpiece and its accessories for any sharp edges.
- When not in use, the i900 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 i900 system.
- Do not place the i900 system on any heated or wet surface.

- Do not block the air vents located at the rear of the i900 system. If the equipment overheats, the i900 system may malfunction or stop working.
- Do not spill any liquid on the i900 system.
- The i900 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 i900 system.
- 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 i900 system.
- Always place the plug of the power cord of the i900 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 tips on the floor, do not attempt to reuse them. 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 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 i900 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 i900 system.
- In the event of a severe accident involving the i900 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 electirical insulation and maintain electrical safety, a coating is applied to insulate the device except on the areas where the USB ports are located.

4.2 Proper Training

WARNING

Before using your i900 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 i900 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.

4.3 In Case of Equipment Failure

WARNING

If your i900 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.
- Contact the manufacturer or authorized resellers.
- Modifications to the i900 system are prohibited by law as they may compromise the safety of the user, patient, or a third party.

4.4 Hygiene

WARNING

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

- Handling and replacing the tip.
- Using the i900 system on patients.
- Touching the i900 system.

WARNING

The i900 system and its optical window should be always kept clean. Before using the i900 system on a patient, be sure to:

- Sterilize the i900 system as described in the section "3.2 Cleaning, Disinfection, Sterilization Procedure."
- Use a sterilized tip.

4.5 Electrical Safety

WARNING

- The i900 system is a Class I device.
- To prevent electric shock, the i900 system must only be connected to a power source with a protective earth connection.
  If you cannot insert the i900-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 i900 system for any other purpose than its intended use.
- The i900 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 i900 system. Only qualified service personnel should access the system.
- Do not connect the i900 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 i900 system and avoid spilling any liquid on the system.
- Never spill liquid of any kind on the i900 system.
- Condensation due to changes in temperature or humidity can cause moisture buildup inside the i900 system, which may damage the system. Before connecting the i900 system to a power supply, be sure to keep the i900 system at room temperature for at least two hours to prevent condensation. If condensation is visible on the product surface, the i900 should be left at room temperature for more than 8 hours.
- You should only disconnect the i900 system from the power supply via its power cord.
- When disconnecting the power cord, hold the plug 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.
- Avoid pulling on the communication cables, power cables, etc. used with the i900 system.
- Use only medical adapters provided for use with the i900. Other adapters could damage the i900 system.
- Do not touch the connectors of the device and the patient simultaneously.

4.6 Eye Safety

WARNING

- The i900 system projects a bright light from its tip during scanning.
- The bright light projected from the tip of the i900 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 i900 handpiece. It is irradiated only inside the i900 handpiece and does not go outside.
  The blue light visible inside the i900 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 i900 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 i900.

4.7 Explosion Hazards

WARNING

- The i900 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 i900 system near flammable anesthetics.

4.8 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 i900 system.
- For more information on peripherals used with i900, check the respective manufacturer's manuals.

5. Electro-Magnetic Compatibility Information

5.1 Electromagnetic Emissions

The i900 system is intended for use in the electromagnetic environment as specified below. The customer or the user of the i900 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 i900 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 i900 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 i900 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 i900 or shielding the location.

5.2 Electromagnetic Immunity

- **Guidance 1**

  The i900 system is intended for use in the electromagnetic environment as specified below.
  The customer or the user of the i900 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 i900 system requires continued operation during power mains interruptions, it is recommended that the i900 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 30 kHz CW modulation 65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	8 A/m 30 kHz CW modulation 65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	Resistance to magnetic fields was tested and applied only to surfaces of enclosures or accessories accessible during intended use.

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 i900		
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 i900 system is intended for use in the electromagnetic environment specified below. The customer or the user of the i900 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. **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 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:
	6 Vrms 150 kHz to 80 MHz In ISM Bands amateur	6 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

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 i900 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 i900 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 i900 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 i900 could result in high electromagnetic emissions or reduced electromagnetic immunity from this equipment and result in improper operation.

[1] For some services, only the uplink frequencies are included.

6. Specifications

Model Name	MO1-i900	
Trade Name	i900	
Packing Unit	1 set	
Rating	5 V ⎓, 3 A	
Classifications for Protection Against Electric Shock	Class I, Type BF Applied Parts (Reusable Tip)	
* This product is a medical device.		
Handpiece (including medium-size tip)		
Dimension	223.4 x 36.7 x 35.3 mm (L x W x H)	
Weight	165 g	
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		
Dimension	160 x 48.5 mm (H x Ø)	
Weight	205 g	
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
Emission limits per environment		
Environment	Hospital environment	
Conducted and radiated RF Emissions	CISPR 11	

CE

EC REP

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