

Medit i500
Extended Warranty

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1 About this guide

Convention in this guide

This user guide uses various symbols to highlight important information so as 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 medium risk of personal injury.

CAUTION

The CAUTION symbol indicates safety information that, if ignored, could result in 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.

2 Introduction and overview

2.1 Intended Use

The i500 system is a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. The i500 system produces 3D scans for use in computer-assisted design and manufacturing of dental restorations.

2.2 Indication for use

The i500 system should be used on patients who require 3D scanning for dental treatments such as:

- Single custom abutment
- Inlays & Onlays
- Single Crown
- Veneer
- 3 Unit Implant Bridge
- Up to 5 Unit Bridge
- Orthodontics
- Implant Guide
- Diagnosis Model

2.3 Contraindications








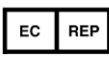







The device is not intended to be used to create images of the internal structure of teeth or the supporting skeletal structure.

It is not intended to be used for cases with more than four (4) subsequent edentulous tooth positions.

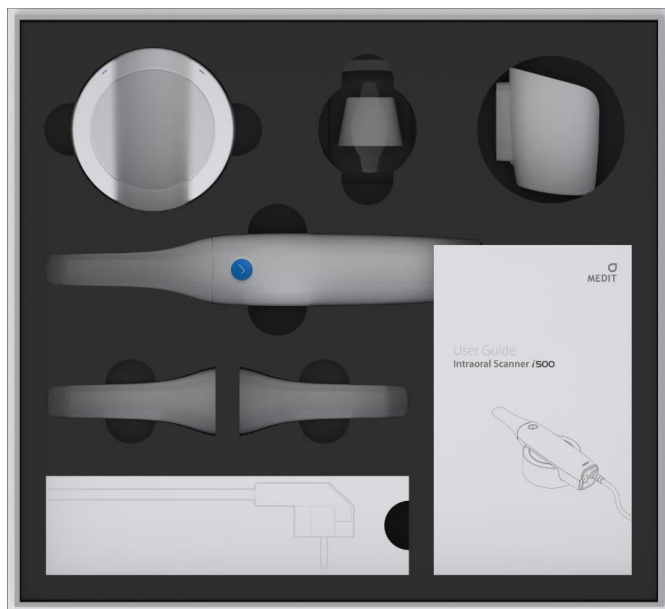
2.4 Qualifications of the operating user




This device is designed for use by persons with professional knowledge in dentistry and dental laboratory technology. The user of this device is solely responsible for determining whether or not this device is suitable for a particular patient case and circumstances. The user is solely responsible for the accuracy, completeness and adequacy of all data entered into this device and the provided software. The user has to check the correctness and accuracy of the results and to assess each individual case. The i500 system must be used in accordance with its accompanying user guide. The user is not allowed to modify the i500 system. Improper use or handling of the i500 system will void its warranty, if any. If you require additional information on the proper use of the i500 system, please contact your local distributor.






2.5 Symbol

No	Symbol	Description
1		The serial number of the object
2		Date of manufacture
3		Manufacturer
4		Caution
5		Warning
6		Instruction for User Manual
7		The official mark of Europe Certificate
8		Authorized representative in the European Community
9		Type of applied part
10		WEEE Mark
11		Prescription use (U.S)
12		MET mark
13		AC
14		DC
15		Protective Earth (ground)

2.6 i500 Components Overview

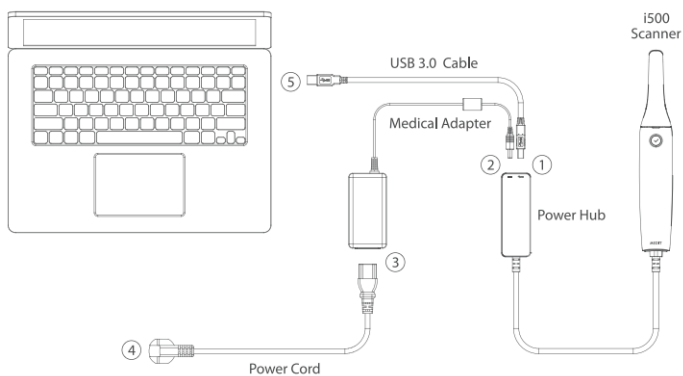


No	Item	Qty	Appearance
1	i500 Handpiece + Power Hub	1ea	
2	i500 Handpiece Cover	1ea	
3	Reusable Tip	3ea	

4	Desktop Cradle	1ea	
5	Wall Mount Holder	1ea	
6	USB 3.0 Cable	1ea	
7	Medical Adapter + Power Cord	1set	
8	USB Memory (pre-loaded with image acquisition software)	1ea	
9	User Guide	1ea	

2.7 Setting up the i500

2.7.1 Basic settings of i500



- ① Connect the USB 3.0 Cable to the Power Hub



- ② Connect Medical Adapter to the Power Hub



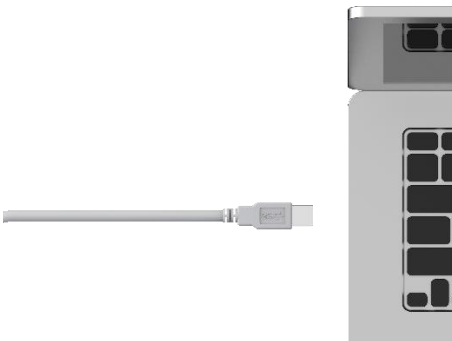
- ③ Connect Power Cord to the Medical Adapter



- ④ Connect Power Cord to a Power Source



- ⑤ Connect the USB 3.0 Cable to the PC

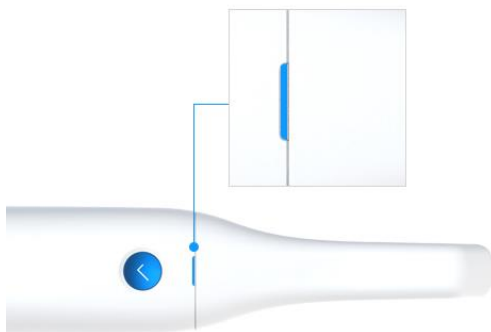




Turn on the i500
Press the power button of i500 scanner

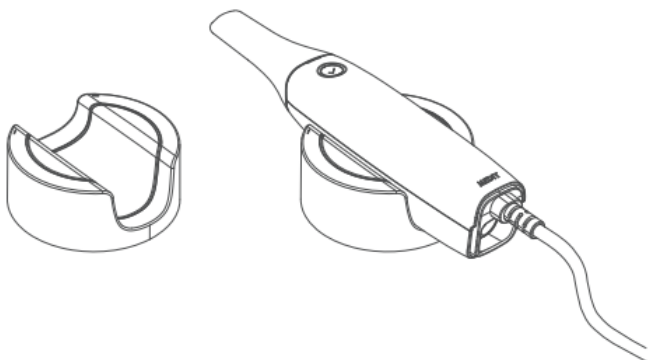


Wait until the USB connection indicator turns blue

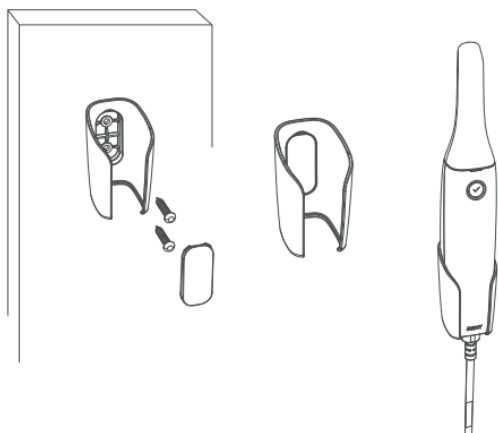


Turn off i500
Press and hold the power button of i500 for 3 seconds

2.7.2 Placing on Desktop Cradle



2.7.3 Installation of Wall Mount Holder



3 Image Acquisition Software Overview

3.1 Introduction

The image acquisition software provides a user-friendly working interface to digitally record topographical characteristics of teeth and surrounding tissues using the i500 scanner.

3.2 Installation

3.2.1 System Requirement

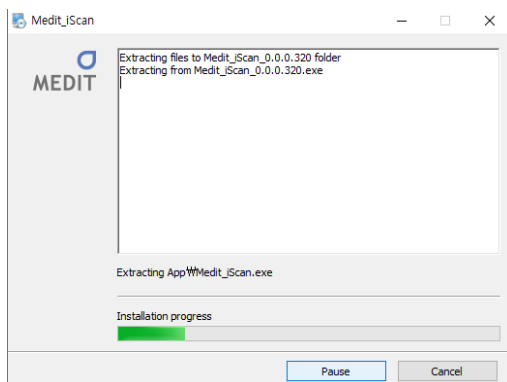
	Laptop	Desktop
CPU	Above Intel Core i7-7700 HQ	Above Intel Core i7-7700
RAM	Above 16 GB	Above 16 GB
Graphic	Above Nvidia GTX 1050	Above Nvidia Geforce GTX 1050
OS	Window 10 64 bit	



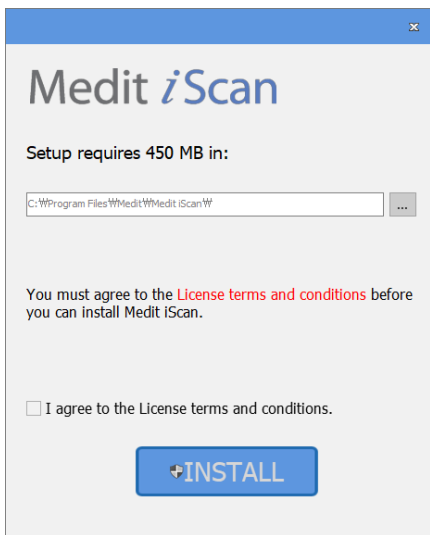
Use PC and monitor certified IEC 60950, IEC 55032, IEC 55024

3.2.2 Installation Guide

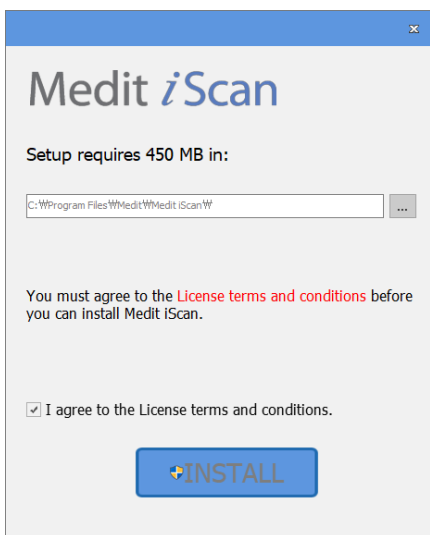
➤ Run Medit_iScan_X.X.X.X.exe



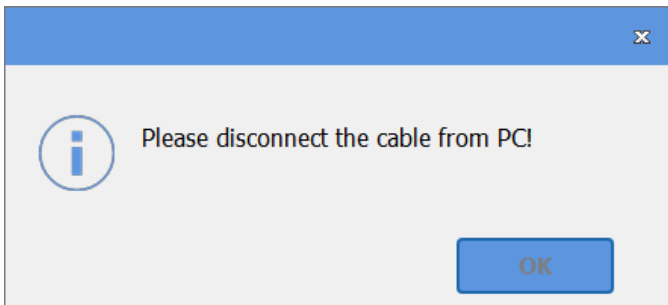
- Select the installation path



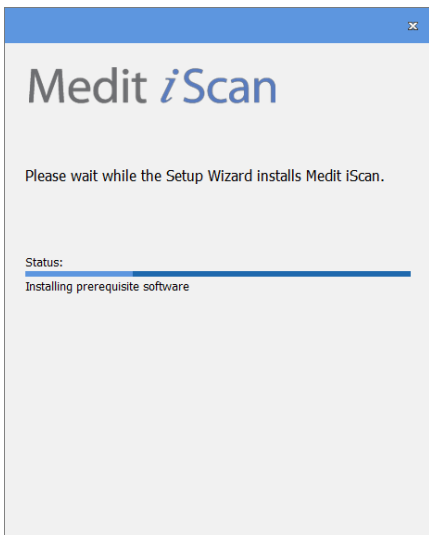
- Read the "License Agreement" carefully before checking "I agree to the License ~" then click **Install**



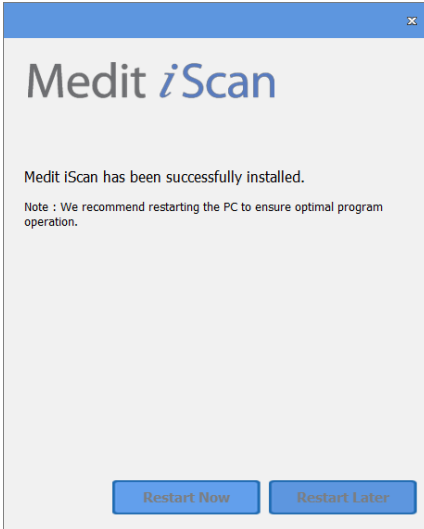
- If the scanner is connected, please disconnect the scanner from the PC by removing the USB cable.



- It may take up to several minutes to finish the recommended installation process. Please do not shut down the PC until installation is completed.



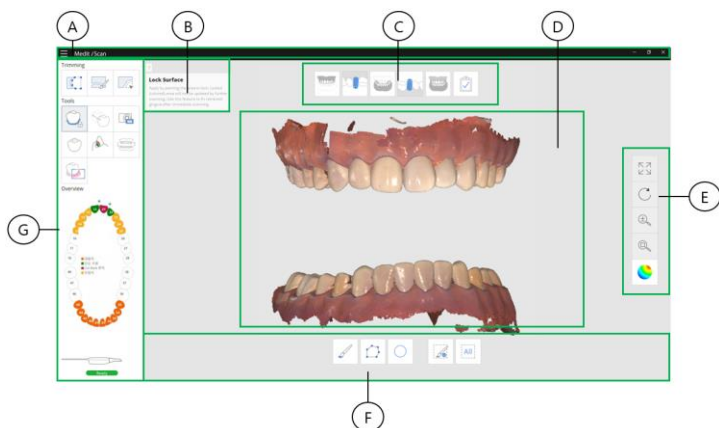
- After installation is completed, we recommend restarting the PC to ensure optimal program operation.



3.3 Model Control in View Screen Using Mouse

Button	Action	Usage
Left	Click	Starts selection or deletion of entities in view screen when using the polyline selection or polyline trimming tool.
	Drag	Selects or deletes entities in view screen when using the Brush selection or Brush trimming tool.
Wheel	Drag	Moves model in view screen.
	Scroll	Zooms in/out the model in view screen.
Right	Click	Completes selection or deletion of entities in view screen when using the polyline selection or polyline trimming tool.
	Drag	Rotates model in view screen.

3.4 User Interface



A. Title Bar

B. Guide Message

C. Stage Bar

D. View Screen

E. Sub Tool Bar

F. Command Option


G. Main Tool Bar












3.4.1 Title Bar

The Title Bar consists of the Menu, Minimize/Maximize/Restore Window, Exit for the image acquisition software. It also shows patient information.

Menu	The Menu includes the tools to manage the project, such as New, Open, Save, as well as the tools to change settings and to exit the application. It also shows the information for the application.
Patient information	Shows information of the current patient.
Minimize	Minimizes the application.
Maximize or Restore	Maximizes or restores the application to its normal size.
Exit	Saves the current model and terminates the application.

Menu

Click the  button to show all commands in the Menu.

	New	Creates new case.  This function is available when the image acquisition software is used as a standalone.
	Open	Opens existing case.  This function is available when the image acquisition software is used as a standalone.
	Save	Saves all changes in current case.
	Export	Exports the results to general file formats.  Additional license is needed to use this function.
	Exit	Saves the current model and terminates the scanning application.
	Setting	Provides options for setting environment such as scanning options.
	Help	Loads the help contents.
	About	Shows program information, version number and copyright.

Setting

Show Scan Timer	<input checked="" type="checkbox"/>	
Show Scan Number	<input checked="" type="checkbox"/>	
Use Automatic Scanning Start		
- Maxilla And Mandible	<input type="checkbox"/>	
- Occlusion	<input type="checkbox"/>	
Use High Resolution Scanning	<input checked="" type="checkbox"/>	
Show Hole During Scanning	<input type="checkbox"/>	
Use Audio Feedback	<input checked="" type="checkbox"/>	
<input type="button" value="Change Sound"/>		
Use Auto Save	<input type="checkbox"/>	
Send Anonymous Usage Statistics	<input checked="" type="checkbox"/>	
Adjust Color Texture		
Dark	<input type="range" value="25"/>	Bright
<input type="button" value="Default"/>		

Show Scan Timer	Shows scan time during scanning process in the upper left corner of the View Screen.
Show Scan Number	Shows the number of images taken during scanning process in the upper left corner of the View Screen.
Use Automatic Scanning Start	<p>The system starts scanning automatically:</p> <ul style="list-style-type: none"> • When the tip is close to the teeth, the system starts capturing images. • When the tip is away from the teeth, the system stops capturing images. <p>If this option is set to "Off", the scanning start process is performed by the button on the device.</p>
Maxilla And Mandible	Applies Automatic Scanning Start to maxilla and mandible.
Occlusion	Applies Automatic Scanning Start to occlusion.
Use High Resolution Scanning	Acquires the 3D images with higher amount of detail.
Show Hole During Scanning	Shows any holes during scanning to assist in acquiring optimal 3D model.
Use Audio Feedback	Indicates the status of the scanner through various sounds.
Connect	Audio when i500 and image acquisition software are connected.
Scanning	Audio during optimal scanning.
HD Camera	Audio when taking 2D images using HD Camera.
Use Auto Save	Saves the project automatically.
Send Anonymous Usage Statistics	Settings to send/stop sending anonymous usage statistics to Medit.



About collection of anonymous statistics

Medit is striving to constantly improve the product and user experience by collecting certain information such as :

- Hardware and software configurations such as OS, graphics, etc.
- Patterns and trends in how our software is used, such as frequency and performance
- Diagnostic information

The usage statistics will help the development team to better understand user requirements and prioritize improvements in future releases.

We will never collect personal information such as your name, company name, MAC address, or any other personally identifiable information.

We cannot and will not reverse-engineer any collected data to find specific details concerning your projects.

Adjust Color Texture	Adjusts the brightness of the 3D model. The color of the 3D model is optimized in the i500 image acquisition software. When viewing data using other software, the resulting colors may be slightly different from the i500 image acquisition software.
Default	Restores all settings to system default.

3.4.2 Guide Message

Shows information to guide you through the scanning process such as command functions and useful information on the current situation.

1	Removes all entities within a polyline shape drawn on the screen.
2	Removes all entities on a freehand-drawn path on the screen.
3	Removes all entities connected to a selected position.
4	Apply by painting the area to lock. Locked (colored) area will not be updated by further scanning. Use this feature to fix retracted gingiva after immediate scanning.
5	Performs the alignment of one and two bite scans manually.
6	Takes 2D images without 3D Model and shares the taken images with laboratory.
7	Analyzes the interference between the maxilla and mandible and shows the result with color map.
8	Analyzes the undercut area based on insertion direction.

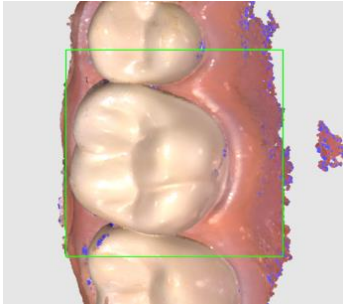
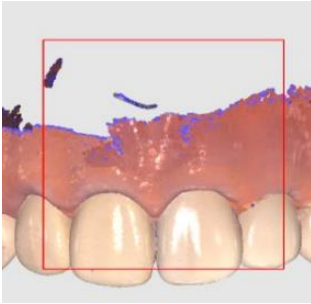
3.4.3 Stage Bar

The Stage Bar indicates the current scanning step.

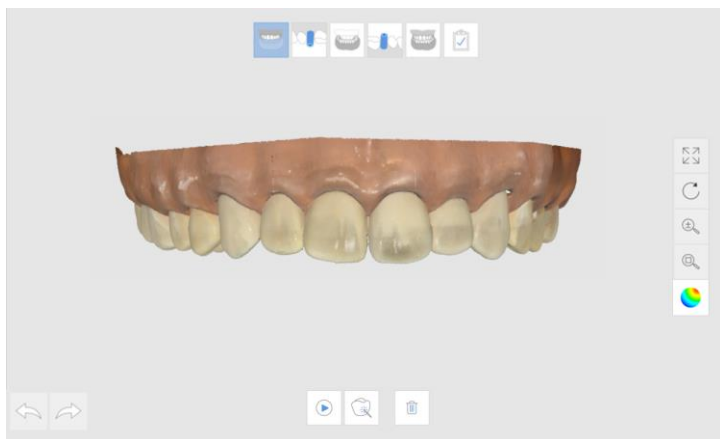


Indication during scanning

The color of the rectangle box that appears during scanning indicates the status of the scanning process:







Green rectangle	Red rectangle
	
Scanning and alignment is at its optimal.	Alignment is lost.

3.4.3.1 Scan Maxilla



Acquires the 3D image of the maxilla.

Command Option Detail

	Start Scan	Starts the scanning process. You can also start the scanning process using the function button on the device.
	Stop Scan	Stops the scanning process. You can also stop the scanning process using the function button on the device.
	Optimize	Aligns 3D images for more accurate scanning. All noise will be deleted after optimization process.
	Clear All	Removes all 3D images of maxilla to start over.
	Undo	Undo previous scanning.
	Redo	Redo previous scanning.

3.4.3.2 Scan Mandible



Acquires the 3D image of the mandible.

Command Option Detail



Start Scan

Starts the scanning process. You can also start the scanning process using the function button on the device.



Stop Scan

Stops the scanning process. You can also stop the scanning process using the function button on the device.



Optimize

Aligns 3D images for more accurate scanning. All noise will be deleted after optimization process.



Clear All

Removes all 3D images of mandible to start over.



Undo

Undo previous scanning.



Redo

Redo previous scanning.

3.4.3.3 Scan Scanbody








Acquires the 3D image of the scanbody for maxilla.



Acquires the 3D image of the scanbody for mandible.

Command Option Detail







	Start Scan	Starts the scanning process. You can also start the scanning process using the function button on the device.
	Stop Scan	Stops the scanning process. You can also stop the scanning process using the function button on the device.
	Clear All	Removes all 3D images of scanbody to start over.
	Undo	Undo previous scanning.
	Redo	Redo previous scanning.

3.4.3.4 Scan Occlusion



Acquires the 3D image of the occlusion alignment.

Command Option Detail

	Start Scan	Starts the scanning process. You can also start the scanning process using the function button on the device.
	Stop Scan	Stops the scanning process. You can also stop the scanning process using the function button on the device.
	Optimize	Optimize the align between maxilla and mandible.
	Clear All	Removes all 3D images of occlusion alignment to start over.
	Bite 1	Acquires the 3D model for occlusion alignment.
	Bite 2	Acquires the 3D model for occlusion alignment of the opposite side of Bite 1.



Undo

Undo previous scanning.



Redo

Redo previous scanning.

3.4.3.5 Complete



Completes the scanning process then generates the result data.

3.4.4 View Screen

Displays live video and captured images.

3.4.5 Sub Tool Bar

The Sub Tool Bar contains the tools to control 3D Model in the View Screen.



Pan

Moves the model.



Rotate

Rotates the model.



Zoom
In/Out

Zooms in/out of the model.





Zoom Fit

Places the model in the middle of the screen.



Color
Texture

Displays texture information of the model.

Texture On	Texture Off
	

3.4.6 Command Option

Shows the available options for the currently running command. For detailed information of the options, please refer to the option description for each command.

3.4.7 Main Tool Bar

The Main Tool Bar contains useful commands for editing and analyzing the 3D model, as well as the device status.

3.4.7.1 Trimming

Removes unnecessary data, such as soft tissues and noise.

3.4.7.1.1 Polyline Trimming



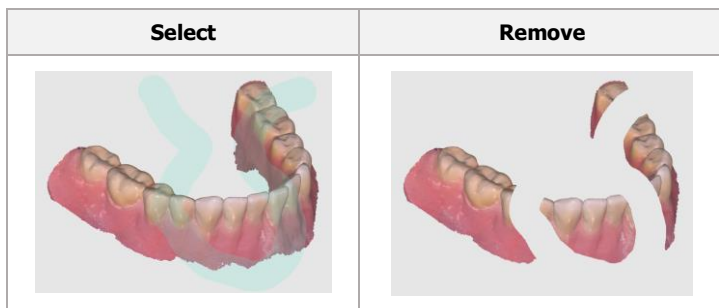
Removes all entities within a polyline shape drawn on the screen.



3.4.7.1.2 Brush Trimming



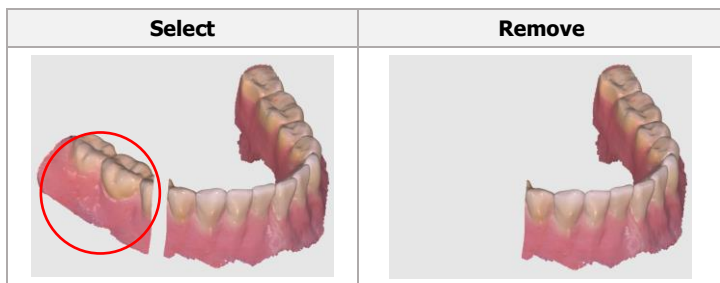
Removes all entities on a freehand-drawn path on the screen. The brush comes in 3 different sizes.



Quick Trimming

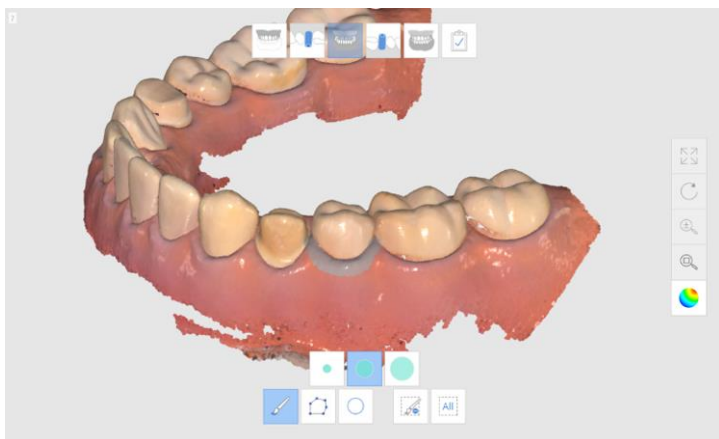


Removes island data or soft tissues by picking.



3.4.7.2 Tools

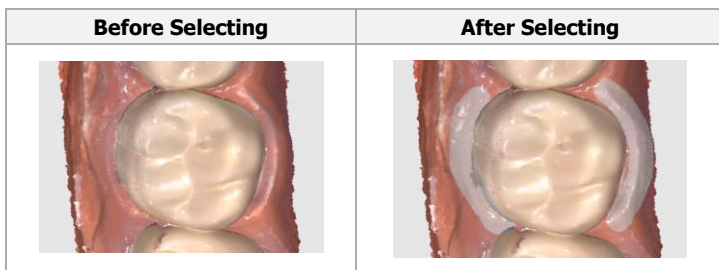
3.4.7.2.1 Lock Area



Apply by painting the area to lock. Locked (colored) area will not be updated by further scanning. Use this feature to fix retracted gingiva after immediate scanning as it might collapse. You can still trim the locked surface. Deleted locked surface can be re-scanned.

How to lock the area

- Press the "Lock Area".
- Choose a selection tool.
- Select the area you want locked. The selected area is indicated by a different color.






How to unlock the area

- Click "Clear Selected Area"
- Select the area to unlock
- If you want to unlock all area, click "Clear All"

Command Option Detail

Selection Tools

Various selection methods are available in the Lock Surface command.

	Brush Selection	Selects all entities on a freehand-drawn path on the screen. The brush comes in 3 different sizes.
	Polyline Selection	Selects all entities within a polyline shape drawn on the screen.
	Circle Selection	Selects all entities within circular area.



Clear
Selected
Area

Clears selection of selected area on a freehand-drawn path on the screen. The brush comes in 3 different sizes.



Clear All
Area

Clears all selected area.

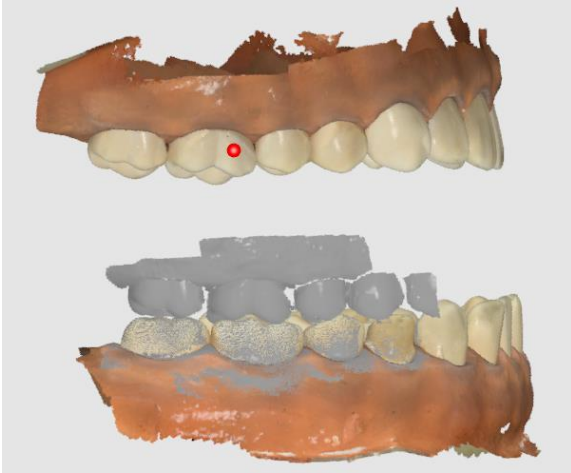
3.4.7.2.2 Manual Alignment



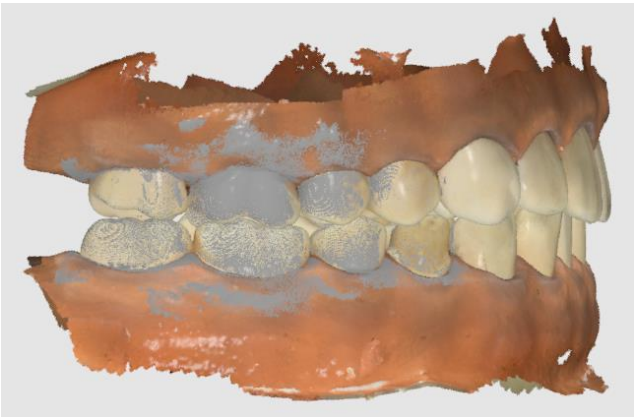
Performs the alignment of two bite scans manually.

How to use Manual Alignment

- Click "Manual Alignment".
- Place the marker points on the maxilla or mandible.



- Place the marker points on the occlusion.



- The system will calculate the occlusion alignment based on marked points pairing.

Command Option Detail

Undo selected marker points

You can undo the selected maker points using "Remove Marker Point".



Removes marker point.

Move Maxilla and Mandible

Reset the position of Maxilla and Mandible.



Moves maxilla to non-overlapping position from the 3D model for occlusion alignment.



Moves mandible to non-overlapping position from the 3D model for occlusion alignment.

Undo and Redo the transformation

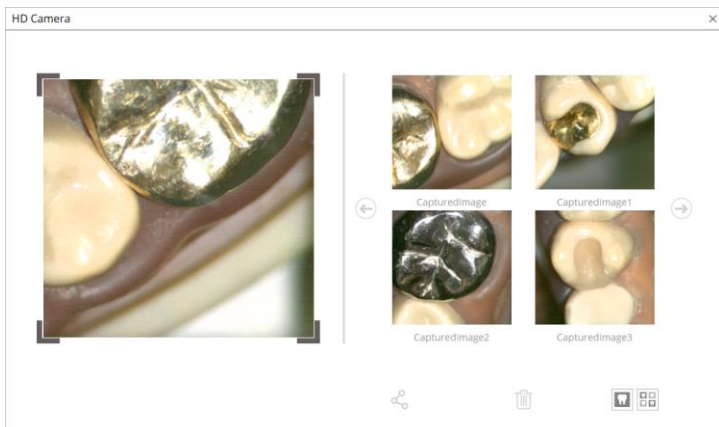


Undo previous transformation.



Redo previous transformation.

3.4.7.2.3 HD Camera



Takes 2D images without taking 3D data and shares the images with laboratory.

Option Detail



Changes the sharing state.



Deletes selected image.



Moves to previous/next page.




Changes the view style of thumbnail.

How to use HD Camera

- Click "HD Camera".
- Move the tip into the patient's mouth.
- Place the tip on the region of interest and press function button on the device.
- 2D image is saved in the gallery.

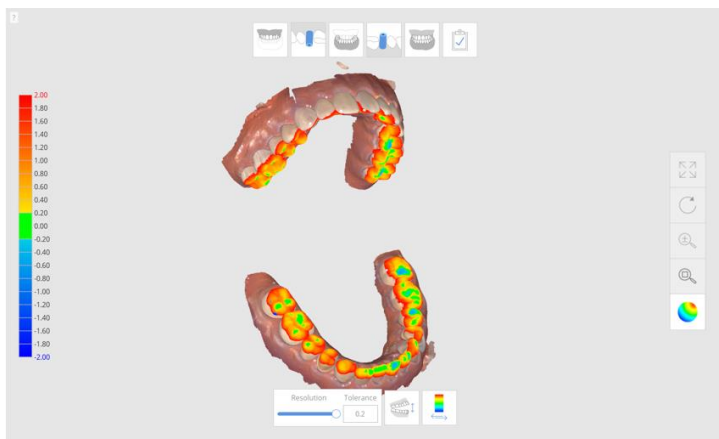
How to change status of sharing

- Click and select the image to share (or to stop sharing).
- Click the  button

How to change the name of image


- Click and select the image.
- Click on the same image.
- Type the new name.

3.4.7.2.4 Occlusion Analysis



Analyzes the interference between the maxilla and mandible and shows the result with color map.

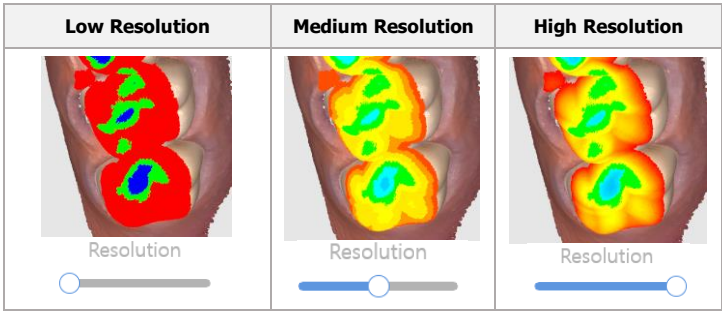
How to use

- Click "Occlusion Analysis"
- Change the view style between "Show All" and "Contact Area" by clicking on the  button.
- Change the segmentation of color range using the "Resolution" slider bar.

Command Option Detail

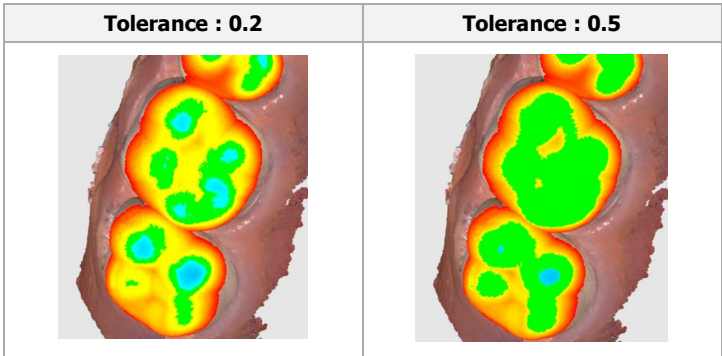
Resolution

You can change the resolution of the color range by using the slider bar.



Acceptable Tolerance

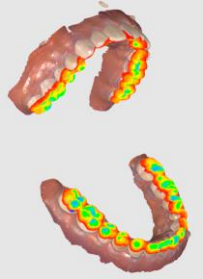

You can set the acceptable tolerance range. If the deviation of data is within the tolerance range, it will be displayed in green.



Switch View Style



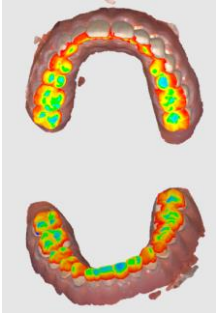
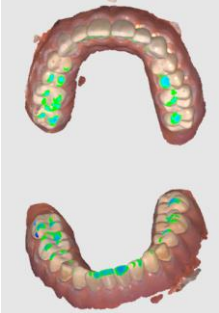
Changes the viewing style between opened jaw and closed jaw.

Opened Jaws	Closed Jaws
	

Switch Deviation Style



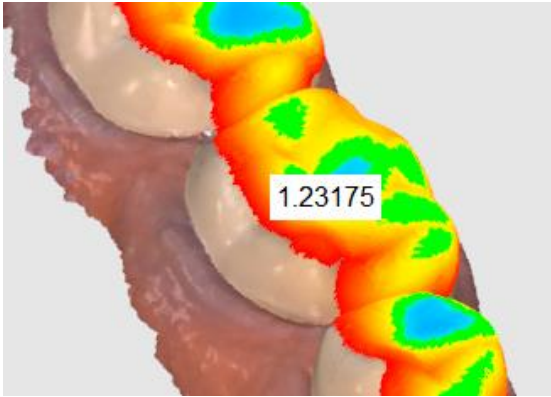
Changes the color deviation style between show all and contact area.

Show All	Contact Area
	

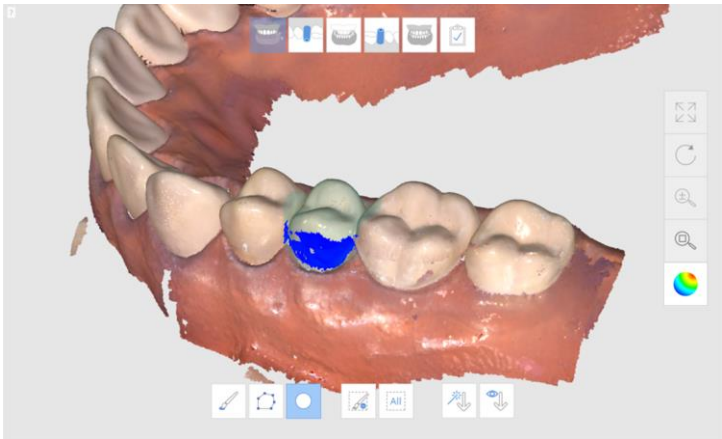


Check the value of deviation

When you move the mouse on the colored area of the 3D model, the system will show the value of the deviation.



3.4.7.2.5 Undercut Area Analysis








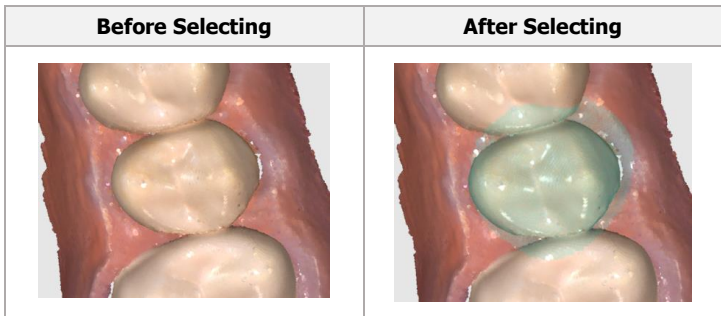
Analyzes the undercut area based on insertion direction. You can set the insertion direction via two methods.

Command Option Detail



Selection Tools

Various selection tools are available in the Undercut Analysis command

	Brush Selection	Selects all entities on a freehand-drawn path on the screen. The brush comes in 3 different sizes.
	Polyline Selection	Selects all entities within a polyline shape drawn on the screen.
	Circle Selection	Selects all entities within circular area.
	Clear Selected Area	Clears selection of selected area on a freehand-drawn path on the screen. The brush comes in 3 different sizes.
	Clear All	Clears all selected area.



Set Insertion Direction

	Auto Direction	System automatically calculates the direction in which the undercut area is minimized, then displays the undercut area on the View Screen.
	Manual Direction	System calculates the undercut area based on the direction specified by user, then displays the undercut area on the View Screen.

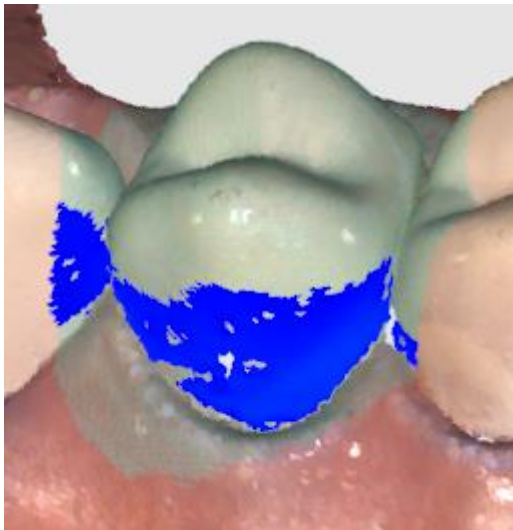
How to calculate the undercut region by the auto direction

- Click "Undercut Analysis".
- Set the region of interest to calculate the undercut area.



If you do not set the region of interest, the system will calculate the undercut region using all the 3D models in the View Screen.

- Click "Auto Direction"



How to set the insertion direction manually

- Click "Undercut Analysis"
- Adjust the direction of the model by using the Move, Rotate, Zoom In/Out tools
- Click "Manual Direction"

3.4.7.2.6 Swap Maxilla & Mandible



Swaps maxilla and mandible scans. This is useful if the operator accidentally scanned the wrong jaw.

3.4.7.2.7 Result Preview



Shows the preview result of selected area to check the quality of data before actual processing.

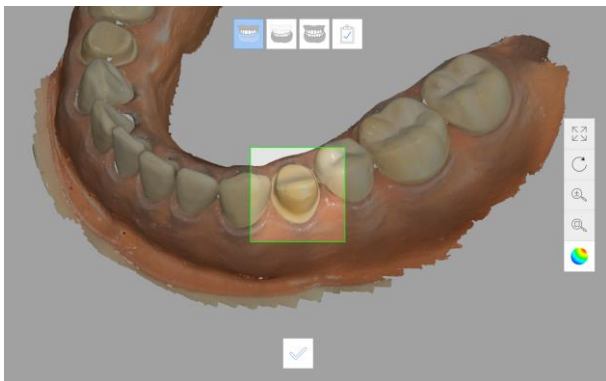
Command Option Detail




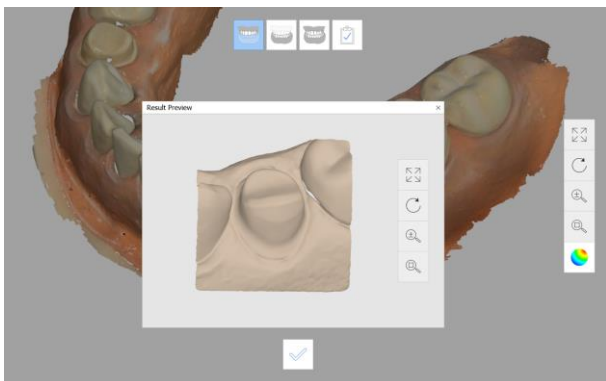
Performs the calculation for previewing result.

How to use

- Click "Result Preview".
- Moves the model into the green rectangle.



- Click 
- System shows the preview result on the pop-up window.



3.4.7.3 Overview

Shows the information of the teeth for treatment.

Overview



This information is available only when the image for treatment is provided from order system.

3.4.7.4 Device Status

	Not Connected	Indicates the i500 is not connected.
	No Tip	Indicates the tip is not mounted.
	Connecting	Indicates the i500 is trying to connect.
	Rebooting	Indicates the i500 is rebooting.
	Ready	Indicates the i500 is ready for use.
	Scanning	Indicates the i500 is currently in the process of scanning.
	Sleep	Indicates the i500 is in sleep mode.
	Overheating	Indicates the i500 is overheated.

4 Maintenance

4.1 Calibration

The i500 system provide the factory calibration with very precise condition as default and user does not need to perform the calibration process generally.

The calibration process is needed when the quality of 3D model is not reliable or accurate to previous results. If you meet this situation, you should contact to the manufacturer or authorized resellers and calibrate your device for optimal usage.

4.2 Reusable tip

The i500 reusable tip is the part of the scanner that is inserted into the patient's mouth during scanning. The tip can be reused for a limited number of times, but it must be cleaned and sterilized between patients to avoid cross-contamination.

4.2.1 Cleaning and sterilization procedure

- Clean the tip manually using soap water and a brush. Inspect the mirror of the tip after cleaning. If the mirror appears stained, smudged or has a milky haze, repeat the cleaning process using a soft dish brush and soap water. Dry the mirror carefully with a paper towel.
- Put the tip in a paper sterilization pouch. The pouch should be sealed. Make sure it is airtight by using either a self-adhesive pouch or a heat-sealed pouch.
- Sterilize the wrapped tip in an autoclave with the following conditions:
 - At 121°C for a minimum of 30 minutes

Use an autoclave program that dries the wrapped tip before opening the autoclave.

CAUTION

- The mirror in the tip is a delicate optical component. It should be handled with care as its clean and undamaged surface is critical for scan quality. Be careful not to scratch or smudge it before scanning a patient.
- Never autoclave a tip that is not wrapped as this will leave stains on the mirror which cannot be removed. See the autoclave manual for more information.
- New tips must be cleaned and sterilized / autoclaved before using them for the first time.
- The scanner tip can be re-sterilized up to 10 times and must be disposed afterwards as described in the next section on Disposal.

4.2.2 Disposal

CAUTION

- The scanner tip must be sterilized before disposal. Sterilize the tip as described above.
- Dispose the scanner tip as you would other clinical waste.

4.3 Updates to Image Acquisition Software

The Image acquisition software automatically checks for updates when the software is running.

When a new version of the software is available, the system will automatically download the new version.

5 Safety Guide

Please adhere to all safety precautions 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.

The i500 system should only be operated by dental professionals and technicians who are trained to use the system. Using the i500 system for any purpose other than its intended usage as outlined in section "2.1 Intended Use" may result in injury or damage to equipment. Please handle the i500 system according to the guidelines in the safety guide.



WARNING

Please read the safety guide carefully. Failure to follow the safety precautions as highlighted in the guide may result in injury or damage to equipment.

5.1 System Basics



CAUTION

- The USB 3.0 cable connector to the Power Hub is the same as a regular USB cable connector. However, the device may not operate normally unless the regular 3.0 USB cable is used with the i500.
- The connector provided by the Power Hub is designed specifically for the i500 and should not be used with any other device.
- 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.
- Before using the system, check that there are no issues such as physical damage, loose parts, and wear. If there is any visible damage, do not use the product and contact the manufacturer or your local representative.
- Check the i500 body and its accessories for any sharp edges.
- Always keep an eye on the product and your patient while using the product to check for abnormalities.
- If the equipment fails to operate normally, such as having issues with accuracy, stop using the product and contact the manufacturer or authorized resellers.

5.2 Safety and Warning

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

5.2.1 Preventive Inspection Before Use of the System

CAUTION

Ensure that all components provided are free from physical damage. Safety cannot be guaranteed if there is any physical damage on the unit.

5.2.2 Modification of the System

CAUTION

- Modifications to the i500 system are prohibited by law, as they may compromise the safety of the user, patient or a third party.

5.2.3 Approved Software Only

CAUTION

- Install and use only approved programs to ensure proper functionality of the i500 system.

5.2.4 Proper Training

WARNING

- Before using your i500 system on your patients:
 - You should have been trained on how to use the system, or you should have read and fully understood this user guide.
 - You should be familiar with the safe use of the i500 system as detailed in this user guide.
 - Before using or after changing any settings, the user should check that the live image is displayed properly in the camera preview window of the program.

5.2.5 In Case of Equipment Failure



WARNING

- If your i500 system is not working properly, or if you suspect that there is a problem with the equipment:
 - Remove the device from the patient and discontinue use immediately.
 - Disconnect the device from the PC and check for errors.
 - Contact the manufacturer or authorized resellers.
 - The i500 system should not be dismantled arbitrarily.

5.3 Mechanical Hazards



WARNING

- If you drop the i500 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.
- If the i500 unit 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.
- When not in use, the i500 should be kept mounted on a desk stand or wall mount stand.
- Do not install the desk stand on an inclined surface.
- Carefully arrange all cables so that you or your patient do not trip or get caught in the cable. Any pulling tension on the cables may cause damage to the i500 body.

5.4 Explosion Hazards



WARNING

- The i500 system is not designed to be used near flammable liquids or gases, or in environments with high oxygen concentrations.
- There is a risk of explosion if you use the i500 system near flammable anesthetics.

5.5 Electrical Safety



WARNING

- The i500 system is a Class 1 device.
- To prevent electric shock, the i500 system must only be connected to a power source with a protective earth connection. If you are unable to insert the i500-supplied plug into the main outlet, contact a qualified electrician to replace the plug or outlet. Do not try to circumvent these safety guidelines.
- The i500 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 i500 system. Only qualified service personnel should access the system.

- Do not connect the i500 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:
 - The total short circuit current of all connected equipment 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 i500 system and avoid spilling liquid on the system.

- Condensation due to changes in temperature or humidity can cause moisture buildup inside the i500 unit, which may damage the system. Before connecting the i500 system to a power supply, be sure to keep the i500 at room temperature for at least 2 hours to prevent condensation. If condensation is visible on the product surface, the i500 should be left at room temperature for more than 8 hours.
- You should only disconnect the i500 system from the power supply via its power cord.
- The radiation characteristics of the i500 system makes it suitable for use in industry and hospitals. (CISPR 11 class A). If the i500 system is used in a residential environment (CISPR 11 class B), it may not provide adequate protection from radio frequency communications.
- Before disconnecting the power cord, make sure to turn off the power on the device using the power switch on the main unit.
- Only use the power adaptor supplied together with the i500. Using other power adaptors may result in damage to the system.

 CAUTION

- Avoid pulling on the communication cables, power cables, etc. used in the i500 system.

5.6 Eye Safety

 WARNING

- The i500 system projects a bright light from its tip during scanning.

The bright light projected from the tip of the i500 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 sources exposure, you may experience temporary reduction in visual acuity, pain, discomfort, or visual impairment, which increases the risk of secondary accidents.

5.7 Pacemaker and ICD Interference Risk

 WARNING

- Do not use the i500 system on patients with pacemakers and ICD devices.
- It is forbidden to use the i500 system for patients using pacemakers due to the risk of interference.

5.8 Hygiene



WARNING

- For clean working conditions and patient safety, ALWAYS wear clean surgical gloves when:
 - Handling and replacing the tip.
 - Using the i500 on patients.
 - Touching the i500 system.
- The i500 main unit and its optical window should be kept clean at all times.
- Before using the i500 on a patient, be sure to:
 - disinfect the i500 system
 - use a sterilized tip

5.9 Safety when scanning with i500



CAUTION

- The i500 system is a high-precision optical measuring device. Any shock to the system caused by dropping or bumping the device may cause serious damage. Make sure to follow these guidelines:
 - Always mount the i500 main unit on its desktop cradle or wall mount holder when not in use.
 - Do not place any object on the i500 body.
 - Do not pull or bend the cable connected to the i500.
 - Do not spill any liquid on the i500 body.
 - Do not place the i500 on any heated or wet surface.
 - Always be sure to hold the i500 body securely when dismantling from its holder or cradle, as well as during scanning.
 - Always place the power cord of the i500 system in an easily accessible location.
- Due to its fragile nature, i500 tips should be handled with care. To prevent damage to the tip and its internal mirror, be careful to avoid contact with a patient's teeth or restorations.
- Do not scan for more than 10 minutes at a time.

5.10 Protection from overheating



WARNING

- Do not block the air vents located at the rear of the i500 system. If the equipment overheats, the i500 system may malfunction or stop working.

5.11 Technical Maintenance



CAUTION

- Equipment maintenance should be carried out only by a MEDIT employee or a MEDIT-certified company or personnel.
- In general, the user does not need to perform maintenance work on the i500 system except for cleaning, disinfection and sterilization. Preventive inspections and regular maintenance are not required.

6 Electro – Magnetic Compatibility Information

6.1 Electro-Magnetic Emissions

This EUT is intended for use in the electromagnetic environment as specified below.

The customer or the user of the EUT should ensure that it is used in such an environment.

RF Emissions CISPR 11 – Group 1

The EUT uses RF energy only for its internal functions.

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 EUT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

6.2 Elector-Magnetic Immunity

This EUT is intended for use in the electromagnetic environment as specified below. The customer or the user of the i500 system should ensure that it is used in such an environment.

Electrostatic discharge (ESD) IEC 61000-4-2

Floors should be of wood, concrete or ceramic tiles. If floors are covered with a synthetic material, the relative humidity should be at least 30%.

IEC 60601-1-2 Test Level	Compliance Level
± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 15 kV air

Electrical fast transient/burst IEC 61000-4-4

Mains power quality should be that of a typical commercial or hospital environment.

IEC 60601-1-2 Test Level	Compliance Level
± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency

Surge Line-to-line IEC 61000-4-5

Mains power quality should be that of a typical commercial or hospital environment.

IEC 60601-1-2 Test Level	Compliance Level
± 0,5 kV ± 1 kV	± 1 kV

Surge Line-to-ground IEC 61000-4-5

Mains power quality should be that of a typical commercial or hospital environment.

IEC 60601-1-2 Test Level	Compliance Level
± 0,5 kV ± 1 kV ± 2 kV	± 2 kV

Voltage dips IEC 61000-4-11

Mains power quality should be that of a typical commercial or hospital environment. If the user of the EUT image intensifier requires continued operation during power mains interruptions, it is recommended that the EUT image intensifier be powered from an uninterruptible power supply or a battery.

IEC 60601-1-2 Test Level	Compliance Level
0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°

Voltage interruptions IEC 61000-4-11

Mains power quality should be that of a typical commercial or hospital environment. If the user of the EUT image intensifier requires continued operation during power mains interruptions, it is recommended that the EUT image intensifier be powered from an uninterruptible power supply or a battery.

IEC 60601-1-2 Test Level	Compliance Level
0 % UT; 250/300 cycle	0 % UT; 250/300 cycle

RATED power frequency magnetic fields (50/60Hz) IEC 61000-4-8

Power frequency magnetic fields should be at levels characteristic of a location in a typical commercial or hospital environment.

IEC 60601-1-2 Test Level	Compliance Level
30 A/m	30 A/m

Conducted RF IEC 61000-4-6

Portable and mobile RF communications equipment, including cables, should be used no closer to any part of the EUT than the recommended separation distance as calculated using the equation below, according to the frequency of the transmitter.

Recommended separation distance

$$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$$

$$d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$$

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

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:



IEC 60601-1-2 Test Level	Compliance Level
3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

Radiated RF IEC 61000-4-3

Portable and mobile RF communications equipment, including cables, should be used no closer to any part of the EUT than the

recommended separation distance as calculated using the equation below, according to the frequency of the transmitter.

Recommended separation distance:

$$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$$

$$d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$$

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

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:



IEC 60601-1-2 Test Level	Compliance Level
3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz

7 Specification

Model Name	i500	
SW version	Medit iScan V1.1.0.0	
Rating	+9V = 4A	
DC Adapter		
Model name	ATM036T-P090	
Input voltage	Universal 100~240 Vac / 50~60 Hz input, without any slide switch	
Output	+9V / 0~4A	
Case dimension	100 x 50 x 33mm (W x L x H)	
EMI	CE / FCC Class A, 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	
Handpiece		
Dimension	264 x 44 x 54.5mm (W x L x H)	
Weight	280g	
Applied part	Type BF	
Power Hub		
Dimension	109.5 X 37 X 19.8 mm (W x L x H)	
Weight	80g	
Operating & Storage conditions		
Operating condition	Temperature	18°C to 28°C
	Humidity	20 to 75% relative humidity (non-condensing)
	Air pressure	800 hPa to 1100 hPa
Storage condition	Temperature	-5°C to 45°C
	Humidity	20 to 80% relative humidity (non-condensing)
	Air pressure	800 hPa to 1100 hPa
Transport condition	Temperature	-5°C to 45°C
	Humidity	20 to 80% relative humidity (non-condensing)
	Air pressure	620 hPa to 1200 hPa
Emission limits per environment		
Environment	Hospital environment	
Conducted and radiated RF	CISPR 11	

EMISSIONS	
Harmonic distortion	See IEC 61000-3-2
Voltage Fluctuations and flicker	See IEC 61000-3-3

EC REP

EU representative

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