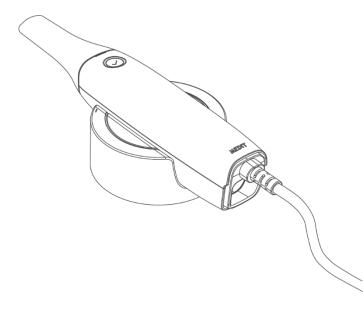
User guide Intraoral Scanner i500



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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.



A 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.



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.

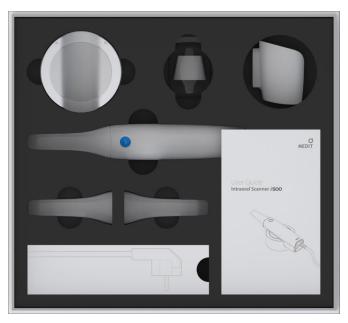
2.4 Qualifications of the operating user

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	SN	The serial number of the object
2	~~	Date of manufacture
3		Manufacturer
4	\triangle	Caution
5	<u>^</u>	Warning
6	(E)	Instruction for User Manual
7	(€	The official mark of Europe Certificate
8	EC REP	Authorized representative in the European Community
9	†	Type of applied part
10	Z	WEEE Mark
11	Ronly	Prescription use (U.S)
12	Compiles with UL 50601-1 CSA C22.2 No. 60601-1	MET mark
13	\sim	AC
14	[==]	DC
15		Protective Earth (ground)

2.6 i500 Components Overview

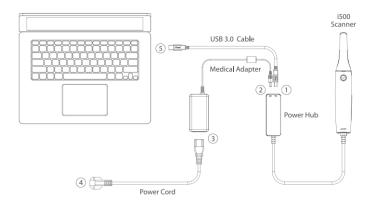


No	Item	Qty	Appearance
1	i500 Handpiece + Power Hub	1ea	
2	i500 Handpiece Cover	1ea	
3	Reusable Tip	3ea	

4	Calibration Tool	1 ea	
5	Desktop Cradle	1ea	
6	Wall Mount Holder	1ea	
7	USB 3.0 Cable	1ea	
8	Medical Adapter + Power Cord	1set	8
9	USB Memory (pre-loaded with image acquisition software)	1ea	A comment
10	User Guide	1ea	AREAT Liters Colliders. Intersoral Reason ROO

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



A Connect Power Cord to a Power Source



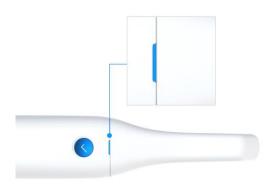
S Connect the USB 3.0 Cable to the PC



Turn on the i500 Press the power button of i500 scanner



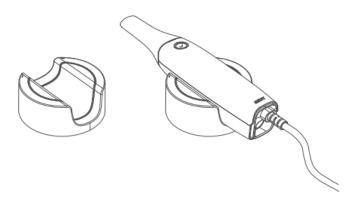
Wait until the USB connection indicator turns blue



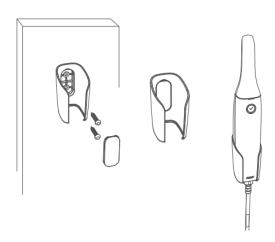


Press and hold the power button of i500 for 3 seconds

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

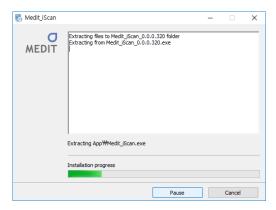
	Laptop	Desktop
CPU	Above Intel Core i7-8750H	Above Intel Core i7-8700
RAM	Above 16 GB	Above 16 GB
Graphic	Above Nvidia GTX 1060	Above Nvidia Geforce GTX 1060
OS	Window 10 64 bit	



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.



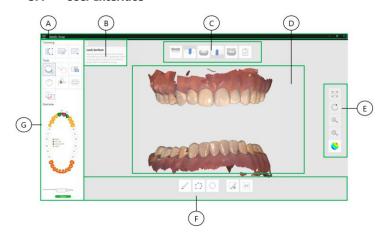
> After installation is completed, we recommend restarting the PC to ensure optimal program operation.



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.
Leit	Drag	Selects or deletes entities in view screen when using the Brush selection or Brush trimming tool.
Wheel	Drag	Moves model in view screen.
Wileei	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.

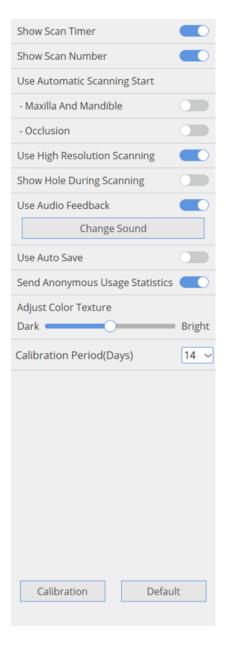
Menu	The Menu includes the tools to manage the project, such as New, Open, Save, as well as the tools to change settings and to exit the application. It also shows the information for the application.
Patient information	Shows information of the current patient.
Minimize	Minimizes the application.
Maximize 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.
ď	Export	Exports the results to general file formats.
\times	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.
(i)	About	Shows program information, version number and copyright.

Setting



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	 The system starts scanning automatically: 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. If this option is set to "Off", the scanning start process is performed by the button on the device.
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.
Calibration Period(Days)	Sets the calibration period of i500.
Calibration	Performs the calibration process to use device in optimal condition.
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 with 3D model data and shares the images with a 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.

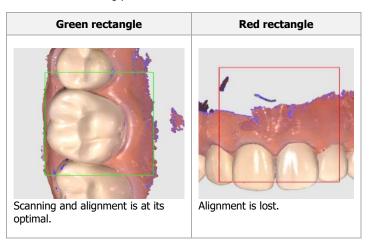
3.4.3 Stage Bar

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:



3.4.3.1 Scan Maxilla





Acquires the 3D image of the maxilla.

•	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.
<u> </u>	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.
\Diamond	Undo	Undo previous scanning.
	Redo	Redo previous scanning.

3.4.3.2 Scan Mandible





Acquires the 3D image of the mandible.

•	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.
€ N	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.
5	Undo	Undo previous scanning.
\overrightarrow{A}	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.

•	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.
\Diamond	Undo	Undo previous scanning.
	Redo	Redo previous scanning.

3.4.3.4 Scan Occlusion





Acquires the 3D image of the occlusion alignment.

(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.
X	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.

$\langle \gamma \rangle$	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

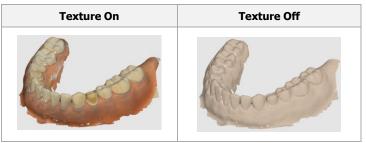
The Sub Tool Bar contains the tools to control 3D Model in the View Screen.

K Z K Z	Pan	Moves the model.
C	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.



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.

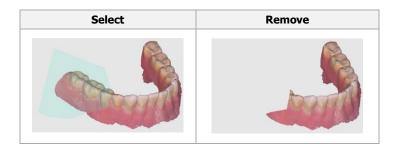
3.4.7.1 Trimming

Removes unnecessary data, such as soft tissues and noise.

3.4.7.1.1 Polyline Trimming



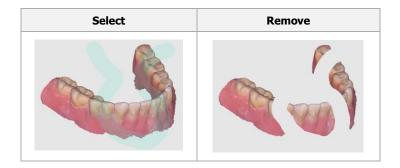
Removes all entities within a polyline shape drawn on the screen.



3.4.7.1.2 Brush Trimming



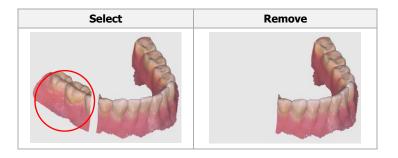
Removes all entities on a freehand-drawn path on the screen. The brush comes in 3 different sizes.



Quick Trimming



Removes island data or soft tissues by picking.



3.4.7.2 Tools

3.4.7.2.1 Lock Area

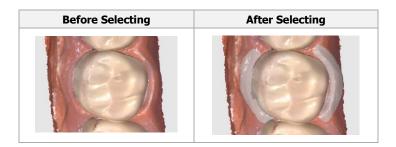




Apply by painting the area to lock. Locked (colored) area will not be updated by further scanning. Use this feature to fix retracted gingiva after immediate scanning as it might collapse. You can still trim the locked area. Deleted locked area can be re-scanned.

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.

S	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.



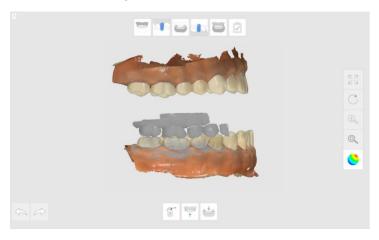
Clear Selected Area Clears selection of selected area on a freehand-drawn path on the screen. The brush comes in 3 different sizes.



Clear All Area

Clears all selected area.

3.4.7.2.2 Manual Alignment

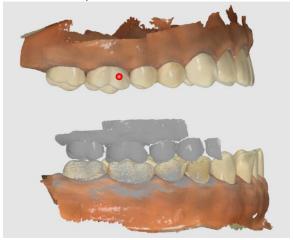




Performs the alignment of two bite scans manually.

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 with 3D model data and shares the images with a 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

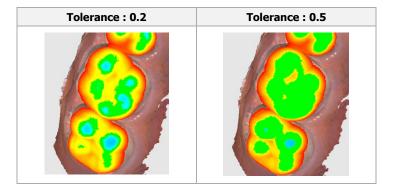
Resolution

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



Acceptable Tolerance

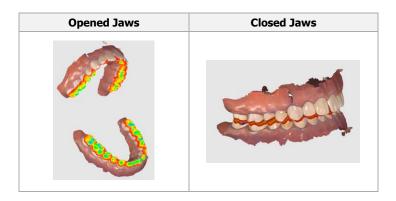
You can set the acceptable tolerance range. If the deviation of data is within the tolerance range, it will be displayed in green.



Switch View Style



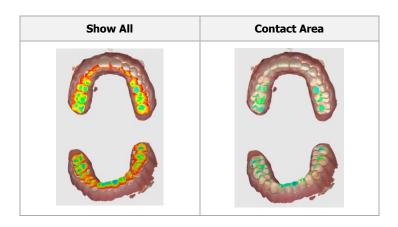
Changes the viewing style between opened jaw and closed jaw.



Switch Deviation Style



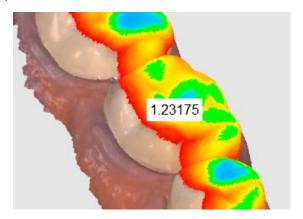
Changes the color deviation style between show all and contact area.



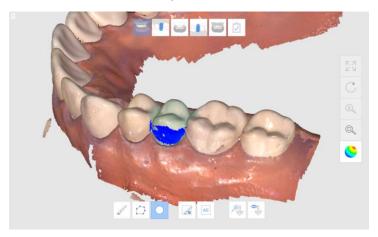


Check the value of deviation

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

S	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.
All	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.

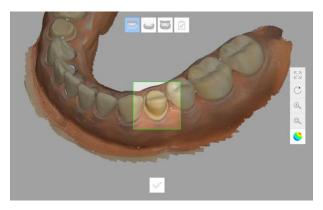
Command Option Detail



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

4 Maintenance

4.1 Calibration

The calibration process is essential in producing precise 3D models. You should perform the calibration process periodically.

Calibration is required when:

- The quality of the 3D model is not reliable or accurate as compared to previous results.
- Environmental conditions such as temperature has changed.
- Calibration period has expired.
 You can set the calibration period as detailed in 2.4.1.1 > Menu
 Setting > Calibration Period(Days)

The calibration panel is delicate. Do not touch the panel directly. When the calibration process does not perform properly, check the panel. If the calibration panel is contaminated, please contact your service provider.

We recommend performing the calibration process periodically. You can set the calibration period via File Menu > Setting > Calibration Period(Days).

The default calibration period is set to 14 days.

How to calibrate the i500

- > Turn on the i500 and connect the device to the software.
- > Run Calibration Wizard from File Menu > Setting > Calibration
- > Prepare the Calibration Tool and i500.



> Turn the dial of the calibration tool to the position 1.



> Put the tip of the i500 into the calibration tool.



- > Click Next to start calibration process.
- When the tip is mounted in the correct position, the system will automatically acquire the data at the position



- When data acquisition is completed at the position _____, turn the dial to the next position.
- ➤ Repeat the steps for positions 2 ~ 8 and LAST position.
- When data acquisition is completed at the _______ position, the system will automatically calculate and show the calibration result.



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.

A 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.

Safety Guide

Please adhere to all safety precautions as detailed in this user quide 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**



- 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 \triangleright 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 \triangleleft 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.
- The calibration process should be carried out if the temperature of the environment has changed.
- The calibration panel is delicate. Do not touch the panel directly. ⋗ When the calibration process does not perform properly, check the panel. If the calibration panel is contaminated, please contact your service provider.
- \triangleright 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 safetv.

5.2.1 **Preventive Inspection Before Use of the System**



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



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



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

5.2.4 Proper Training



MARNING

- Before using your i500 system on your patients: \triangleright
- 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.
- \triangleright 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 \triangleright trip or get caught in the cable. Any pulling tension on the cables may cause damage to the i500 body.

5.4 **Explosion Hazards**



- 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**



- 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.
- \triangleright 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 \triangleright 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 \triangleright 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.
- \triangleright 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. \triangleright Using other power adaptors may result in damage to the system.



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 eves. 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



- Do not use the i500 system on patients with pacemakers and ICD devices.
- \triangleright 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.
- \triangleright 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: \triangleright
- disinfect the i500 system
- use a sterilized tip

5.9 Safety when scanning with i500



- 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 dismounting 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



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 calibration, 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
\pm 8 kV contact \pm 2 kV, \pm 4 kV,	± 8 kV contact ± 15 kV air
\pm 8 kV, \pm 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	± 2 kV 100 kHz repetition
frequency	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	± 2 kV
± 1 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

$$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$$

$$d=[rac{3,5}{E1}]\sqrt{P}$$
 80 MHz to 800 MHz

$$d = \left[\frac{7}{E_1}\right]\sqrt{P}$$
 800 MHz to 2,5 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	3 V 0,15 MHz – 80 MHz 6 V in
ISM bands between 0,15 MHz	ISM bands between 0,15 MHz
and 80 MHz 80 % AM at 1 kHz	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:

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

$$d = [\frac{3.5}{E_1}]\sqrt{P}$$
 80 MHz to 800 MHz

$$d=[\frac{7}{E_1}]\sqrt{P}$$
 800 MHz to 2,5 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 %	3 V/m 80 MHz – 2,7 GHz 80 %
AM at 1 kHz	AM at 1 kHz

Specification

Model Name	i500		
SW version	Medit iScan V1.1.1.0		
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 Pi	rotection)	
	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		
Calibration Tool			
Dimension	165 x 55mm (H x Ø)		
Weight	280 g		
Operating & Storage conditions			
	Temperature	18°C to 28°C	
Operating	Humidity	20 to 75% relative	
condition		humidity (non-	
Condition		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	
	Temperature	-5°C to 45°C	
Transport	Humidity	20 to 80% relative	
condition		humidity (non-	
		condensing)	
	Air pressure	620 hPa to 1200 hPa	
Emission limits per environment			

Environment	Hospital environment
Conducted and radiated RF EMISSIONS	CISPR 11
Harmonic distortion	See IEC 61000-3-2
Voltage Fluctuations and flicker	See IEC 61000-3-3

EC REP

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Revised Date: 2018-05-15 Revision No.: 1.1.1.0