

**English**

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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 i500 system is not intended to be used to create images of the internal structure of teeth or the supporting skeletal structure.
- The i500 system is not intended to be used for cases with more than four (4) subsequent edentulous tooth positions.






## 2.4 Qualifications of the operating user

- The i500 system is designed for use by persons with professional knowledge in dentistry and dental laboratory technology.
- The user of i500 system 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 i500 system 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.
- 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.
- The user is not allowed to modify the i500 system.










## 2.5 Symbol

No	Symbol	Description
01		The serial number of the object
02		Date of manufacture
03		Manufacturer
04		Caution
05		Warning
06		Instruction for User Manual
07		The official mark of Europe Certificate
08		Authorized representative in the European Community
09		Type of applied part
10		WEEE Mark

## 2 Introduction and overview

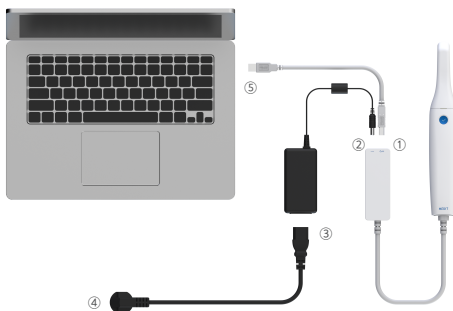
11	 only	Prescription use (U.S)
12	 Complies with IEC 60601-1 EN 60601-1 EN 60601-1-2 EN 60601-1-8 EN 60601-1-10 EN 60601-1-11 EN 60601-1-12 EN 60601-1-13 EN 60601-1-14 EN 60601-1-15 EN 60601-1-16 EN 60601-1-17 EN 60601-1-18 EN 60601-1-19 EN 60601-1-20 EN 60601-1-21 EN 60601-1-22 EN 60601-1-23 EN 60601-1-24 EN 60601-1-25 EN 60601-1-26 EN 60601-1-27 EN 60601-1-28 EN 60601-1-29 EN 60601-1-30 EN 60601-1-31 EN 60601-1-32 EN 60601-1-33 EN 60601-1-34 EN 60601-1-35 EN 60601-1-36 EN 60601-1-37 EN 60601-1-38 EN 60601-1-39 EN 60601-1-40 EN 60601-1-41 EN 60601-1-42 EN 60601-1-43 EN 60601-1-44 EN 60601-1-45 EN 60601-1-46 EN 60601-1-47 EN 60601-1-48 EN 60601-1-49 EN 60601-1-50 EN 60601-1-51 EN 60601-1-52 EN 60601-1-53 EN 60601-1-54 EN 60601-1-55 EN 60601-1-56 EN 60601-1-57 EN 60601-1-58 EN 60601-1-59 EN 60601-1-60 EN 60601-1-61 EN 60601-1-62 EN 60601-1-63 EN 60601-1-64 EN 60601-1-65 EN 60601-1-66 EN 60601-1-67 EN 60601-1-68 EN 60601-1-69 EN 60601-1-70 EN 60601-1-71 EN 60601-1-72 EN 60601-1-73 EN 60601-1-74 EN 60601-1-75 EN 60601-1-76 EN 60601-1-77 EN 60601-1-78 EN 60601-1-79 EN 60601-1-80 EN 60601-1-81 EN 60601-1-82 EN 60601-1-83 EN 60601-1-84 EN 60601-1-85 EN 60601-1-86 EN 60601-1-87 EN 60601-1-88 EN 60601-1-89 EN 60601-1-90 EN 60601-1-91 EN 60601-1-92 EN 60601-1-93 EN 60601-1-94 EN 60601-1-95 EN 60601-1-96 EN 60601-1-97 EN 60601-1-98 EN 60601-1-99 EN 60601-1-100	MET mark
13		AC
14		DC
15		Protective Earth (ground)

### 2.6 i500 Components Overview

No	Item	Qty	Appearance
01	i500 Handpiece + Power Hub	1ea	
02	i500 Handpiece Cover	1ea	
03	Reusable Tip	4ea	
04	Calibration Tool	1ea	
05	Desktop Cradle	1ea	
06	Wall Mount Holder	1ea	
07	USB 3.0 Cable	1ea	
08	Medical Adapter + Power Cord	1set	
09	USB Memory (Pre-loaded with image acquisition software)	1ea	
10	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



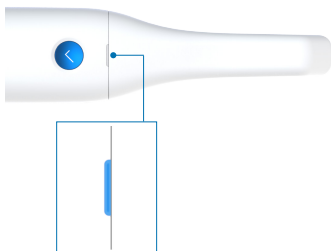
## 2 Introduction and overview


 Turn on the i500

Press the power button of i500.



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 system.

## 3.2 Installation

### 3.2.1 System Requirement

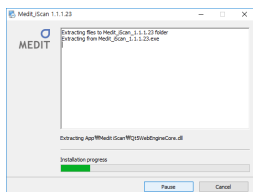
	Laptop	Desktop
CPU	Above Intel Core i7-8750H	Above Intel Core i7-8700K
RAM	Above 16 GB	Above 16 GB
Graphic	Above Nvidia Geforce GTX 1060	Above Nvidia Geforce GTX 1060
OS	Window 10 64 bit	



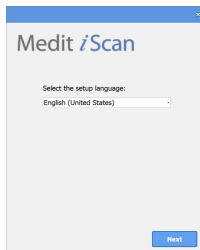
Use PC and monitor certified IEC 60950, IEC 55032, IEC 55024

### 3.2.2 Installation Guide

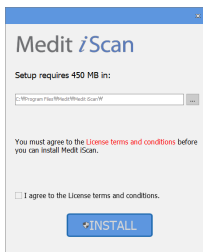
① Run Medit\_iScan\_X.X.X.X.exe



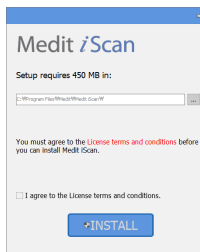
② Select the setup language then click “Next”



③ Select the installation path



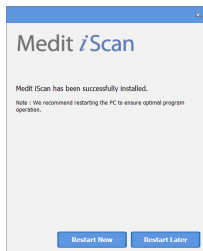
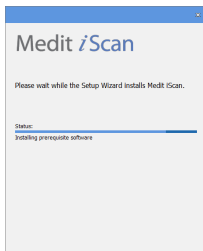
④ Read the “License Agreement” carefully before checking “I agree to the License ~” then click Install



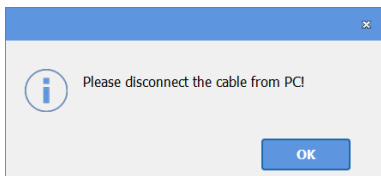


### 3 Image Acquisition Software Overview

- ⑤ It may take up to several minutes to finish the recommended installation process. Please do not shut down the PC until installation is completed.
- ⑥ After installation is completed, we recommend restarting the PC to ensure optimal program operation.



- ⑦ If the scanner is connected, please disconnect the scanner from the PC by removing the USB cable.



### 4 Maintenance

#### ⚠ CAUTION

- Equipment maintenance should only be carried out by a MEDIT employee or a MEDIT-certified company or personnel.
- In general, users will not need to perform maintenance work on the i500 system besides calibration, cleaning and sterilization. Preventive inspections and other regular maintenance are not required.

#### 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 Menu > Settings > Calibration Period(Days)



The calibration panel is a delicate component. Do not touch the panel directly. Should the calibration process not be performing 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 Menu > Settings > Calibration Period(Days). The default calibration period is set to 14 days.

### How to calibrate the i500

- Turn on the i500 and launch the image acquisition software.
- Run Calibration Wizard from Menu > Settings > Calibration
- Prepare the Calibration Tool and the i500 handpiece.
- Turn the dial of the calibration tool to the position **1**.
- Put the handpiece into the calibration tool.
- Click "Next" to start the calibration process.
- When the calibration tool is mounted in the correct position, the system will automatically acquire the data at position **1**.
- When data acquisition is completed at position **1**, turn the dial to the next position.
- Repeat the steps for positions **2** ~ **8** and the **LAST** position.
- When data acquisition is completed at the **LAST** position, the system will automatically calculate and show the calibration results.

## 4.2 Cleaning, Disinfection, Sterilization Procedure

### 4.2.1 Reusable tip

The reusable tip is the part which is inserted into the patient's mouth during scanning. The tip is reusable for a limited number of times, but needs to be cleaned and sterilized between patients to avoid cross-contamination.

- The tip should be cleaned manually using disinfecting solution. After cleaning and disinfection, inspect the mirror inside the tip to ensure that there are no stains or smudges.
- Repeat the cleaning and disinfection process if necessary.

- Carefully dry the mirror using a paper towel.
- Insert the tip into a paper sterilization pouch and seal it, making sure that it is airtight. Use either a self-adhesive or heat-sealed pouch.
- Sterilize the wrapped tip in an autoclave with the following conditions:
  - » At 121°C(249.8°F) for 30 minutes, and 15 minutes drying period
- Use an autoclave program that dries the wrapped tip before opening the autoclave.



#### **CAUTION**

- The mirror found in the tip is a delicate optical component which should be handled with care to ensure optimal scan quality. Be careful not to scratch or smudge it as any damage or blemishes may affect the data acquired.
- Make sure to always wrap the tip before autoclaving. If you autoclave an exposed tip, this will cause stains on the mirror which cannot be removed. Check the autoclave manual for more information.
- New tips need to be cleaned and sterilized / autoclaved before their first use.
- Scanner tips can be re-sterilized up to 20 times and must thereafter be disposed as described in the section on disposal (4.3).
- Medit will not be responsible for any damage including distortion, blackening etc.

#### **4.2.2 Mirror**

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

- Disconnect the scanner tip from the i500 handpiece.
- Pour alcohol on a clean cloth or cotton-tipped swab and wipe the mirror. Make sure to use alcohol that is free of impurities which may stain the mirror. You can use either ethanol or propanol (ethyl-/propyl alcohol).
- Wipe the mirror dry using a dry, lint-free cloth.
- Make sure the mirror is free of dust and fibers. Repeat the cleaning process if necessary.

#### **4.2.3 Handpiece**

After treatment, clean and disinfect all other surfaces of the handpiece except for the scanner front (optical window) and end (air vent hole).

Cleaning and disinfecting must be done with the device turned off. Use the device only after it is completely dry.

##### **Recommended cleaning and disinfecting solution:**

Denatured alcohol (aka. ethyl alcohol or ethanol) – typically 60-70% Alc/Vol.

The general cleaning and disinfecting procedure is as follows:

- Turn off the device using the power button.

- Unplug all cables from the power hub.
- Attach the handpiece cover to the front of the scanner.
- Pour the disinfectant onto a soft, lint-free and non-abrasive cloth.
- Wipe the scanner surface with the cloth.
- Dry the surface with a dry and clean, lint-free and non-abrasive cloth.



#### **CAUTION**

- Do not clean the handpiece when the device is turned on as the fluid may enter the scanner and cause a malfunction.
- Use the device after it is completely dry.



#### **CAUTION**

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

#### **4.2.4 Other components**

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



#### **CAUTION**

- Chemical cracks may appear if improper cleaning solution is used during cleaning.

### **4.3 Disposal**



#### **CAUTION**

- The scanner tip must be sterilized before disposal.
- Sterilize the tip as described in section 4.2.1.
- Dispose the scanner tip as you would any other clinical waste.
- Other components are designed to conform with the following directives:
  - » RoHS, Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment. (2011/65/EU)
  - » WEEE, Waste Electrical and Electronic Equipment Directive. (2012/19/EU)

### **4.4 Updates to Image Acquisition Software**

The image acquisition software automatically checks for updates when the software is in operation.

If there is a new version of the software being released, the system will automatically download it.

## 5 Safety Guide

Please adhere to all the 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.

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 strictly 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.

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 the equipment. Please handle the i500 system according to the guidelines in the safety guide.

### 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 a 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.
- Ensure that all components provided are free from physical damage. Safety cannot be guaranteed if there is any physical damage to the unit.
- Before using the system, check that there are no issues such as physical damage, loose parts, and wear and tear. 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.
- 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.
- Do not place any object on the i500 body.
- Do not place the i500 on any heated or wet surface.
- 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.
- Do not spill any liquid on the i500.
- Do not pull or bend the cable connected to the i500.
- 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.
- Always place the power cord of the i500 system in an easily accessible location.
  - Always keep an eye on the product and your patient while using the product to check for abnormalities.
  - 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.
  - 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.
  - If the i500 is dropped on the floor or if the unit is impacted, it must be calibrated before use. If the instrument is unable to connect to the software, consult the manufacturer or authorized resellers.
  - If the equipment fails to operate normally, such as having issues with accuracy, stop using the product and contact the manufacturer or authorized resellers.
  - Install and use only approved programs to ensure proper functionality of the i500 system.

## 5.2 Proper Training



### WARNING

- Before using your i500 system on patients:
- You should have been trained 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 use or after changing any settings, the user should check that the live image is displayed properly in the camera preview window of the program.

## 5.3 In Case of Equipment Failure



### WARNING

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

## 5.4 Hygiene



### WARNING

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

## 5 Safety Guide

- Handling and replacing the tip.
- Using the i500 on patients.
- Touching the i500 system.

The i500's 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

### 5.5 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. The use of 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 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.

- Disclaimer for risks involving patients with epilepsy

The Medit i500 should not be used on patients that have been diagnosed with epilepsy due the risk of seizures and injury. For the same reason, dental staff who have been diagnosed with epilepsy should not operate the Medit i500.

## 5.7 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.

## 5.8 Pacemaker and ICD Interference Risk



### WARNING

- Do not use the i500 system on patients with pacemakers and ICD devices.
- Check each manufacturer's instructions for interference by peripheral devices, such as computers used with the i500 system.

# 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.



## 6 Electro – Magnetic Compatibility Information

### 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.

Immunity Test	Compliance	Electromagnetic Environment - Guidance
Harmonic emissions IEC 61000-3-2	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.
Voltage fluctuations/ Flicker emissions	Complies	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, $\pm 8$ kV, $\pm 15$ kV air	$\pm 8$ kV contact $\pm 15$ 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
$\pm 2$ kV 100 kHz repetition frequency	$\pm 2$ 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
$\pm 0.5$ kV , $\pm 1$ kV	$\pm 1$ 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
$\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV	$\pm 2$ 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

## 6 Electro – Magnetic Compatibility Information

### 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

$$d = \left[ \frac{3.5}{\sqrt{E_1}} \right] \sqrt{P}$$

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

$$d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$$

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

<b>Model Name</b>	<b>i500</b>
Rating	+9V = 4A
<b>DC Adapter</b>	
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
<b>Handpiece</b>	
Dimension	264 x 44 x 54.5mm (W x L x H)
Weight	280g
Applied part	Type BF
<b>Power Hub</b>	
Dimension	109.5 X 37 X 19.8 mm (W x L x H)
Weight	80g
<b>Calibration Tool</b>	
Dimension	165 x 55mm (H x Ø)
Weight	280 g

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 EMISSIONS	CISPR 11	
Harmonic distortion	See IEC 61000-3-2	
Voltage Fluctuations and flicker	See IEC 61000-3-3	

**EC REP** EU representative

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