



MiiS Horus Scope DDM 100
Digital Dental Mirror
User Manual



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Caution:



U.S. Federal Law restricts this device to sale by or on the order of a dental professional.

1. GENERAL INFORMATION

1.1 Copyrights

All rights reserved in the event of granting of patents or registration as a utility patent.

This user manual is protected by copyright. Unless expressly authorized in writing, dissemination, duplication or other commercial exploitation of this documentation set or communication of its contents or parts of it is not permitted. In case of infringement, the violator may be liable to pay compensation for damages.

Specifications due to technical developments are subject to change. This user manual is not subject to the revision service. Please contact MiiS or authorized dealer to request the latest edition of this manual.

1.2 Trademarks



Logo and Horus Scope is trademark registered by MiiS Inc.

These LOGO and trademark is belonging to MiiS. This manual might be updated in specification, software or hardware at any time without additional notice.

1.3 Safety

PLEASE NOTE:

Prior to installation and start-up of the unit, carefully read the instructions provided herein!

As with all technical devices, the proper function and safe operation of this unit depend on the user's compliance with the safety recommendations presented in these operating instructions.



CAUTION: Always use product in accordance with the directions and recommendations contained in this User Manual.



CAUTION: To reduce the risk of electrical shock, do not try to remove the cover of the product. Servicing should be performed by qualified personnel.



CAUTION: If product gets wet, do not attempt to dry with a heater or microwave.



CAUTION: Avoid subjecting product to vibration or shocks. When the product is not in use, please disconnect the power plug and keep it in a safe place.



CAUTION: Avoid using the product in a dusty environment.



CAUTION: Avoid touching cover glass and mirror to keep clean image quality.



CAUTION: When operating the device, please make sure not to touch the oral of the patient in order to avoid harm.



CAUTION: Products are sold only in line with the BF certified medical sites.



CAUTION: Prior to operating DDM 100, please make sure the dental mirror is assembled well.

2. INDICATION/INTENDED USE:

The DDM 100 digital dental mirror and accessories are indicated for used to record digital photographs and video of the mouth or tooth and surrounding area.

3. SPECIFICATION:

■ Connections	USB 3.0 /2.0
■ Multiuser Application	Plug & Play
■ Handpiece Weight / Length	55 g / 141 mm(excluding USB connector)
■ Dental Mirror Weight /Length	10 g / 41mm
■ Image Resolution	1920 pixels(H)x1080 pixels(V)
■ Focus Type	Focus Free
■ Focal Range:	Fixed Focus
• Handpiece to object	35 mm to 50 mm
• Dental Mirror to object	5 mm to 15 mm
■ Cable Length	2.5 m
■ Power Supply	USB (5V)
■ Lighting	White Light & Blue Light
■ Driver	Standard Windows Driver No additional driver needed
■ Operation System	Windows 7 & Windows 10

4. OPERATION ENVIRONMENT:

- Ambient temperature: 0°C to +35°C
- Relative humidity: 30% to 90%
- Atmospheric pressure: 00hPa to 1060hPa
- Shock (without packing): 10G, duration 6ms

5. TRANSPORTATION AND STORAGE ENVIRONMENT:

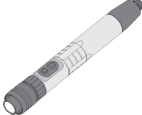




Environment for Transportation

- Ambient temperature: -40°C to +70°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 500hPa to 1060hPa
- Vibration, sinusoidal: 10 Hz to 500 Hz: 0.5G
- Shock: 30G, duration 6ms
- Bump: 10G, duration 6ms

Environment for Storage

- Ambient temperature: -10°C to +55°C
- Relative humidity: 10% to 95%
- Atmospheric pressure: 700hPa to 1060hPa

6. CONTENT:

ITEM	DRAWING	QUANTITY
Handpiece	 A drawing of a dental handpiece, which is a long, cylindrical tool with a handle and a working end.	1
PH Mirror Set	 A drawing of a dental mirror set, consisting of a circular mirror and a handle.	2
USB Cable	 A drawing of a black USB cable, showing the USB connector and the other end.	1
CD ROM	 A drawing of a CD-ROM disc, showing the text "HOFU" and "CD-ROM" on the surface.	1
User Manual	 A drawing of an open book, representing a user manual, with a wrench icon on the right page.	1

7. OPERATION:

Please refer to the following sections for instructions on operating the DDM 100.

7.1 Software Installation

System requirement

Here is the minimum hardware you will need. Read further below to learn about the additional factors that impact compatibility.

Make sure you are using **Windows 7 or Windows 10, 64 Bit.**

Hardware requirement:

Platform:	personal computer/ notebook
CPU:	Intel Core i5 or above
GPU:	1G RAM
RAM:	4 gigabyte (GB)
Display:	1024 x 768
I / O device:	Keyboard, mouse, USB2.0 / 3.0, SD card reader
Internet:	Wi-Fi/WLAN, download/upload 2Mbps, 1Mbps

Installation

Insert CD ROM, system will auto come out the installation interface.

Step by step to finish

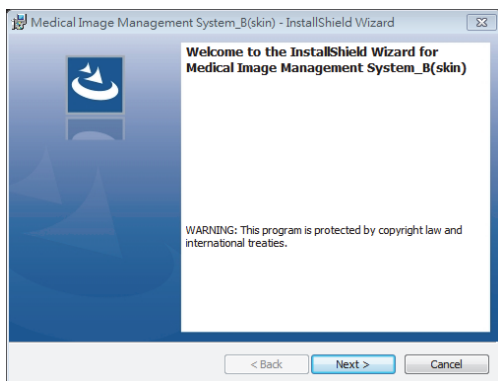
the Image Management Platform (SA1).

Click the installation package

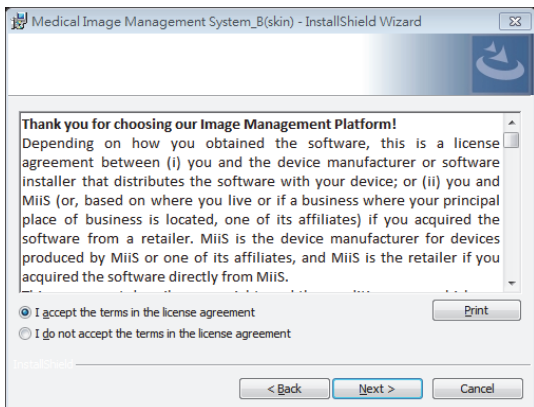


provided by local distributor or

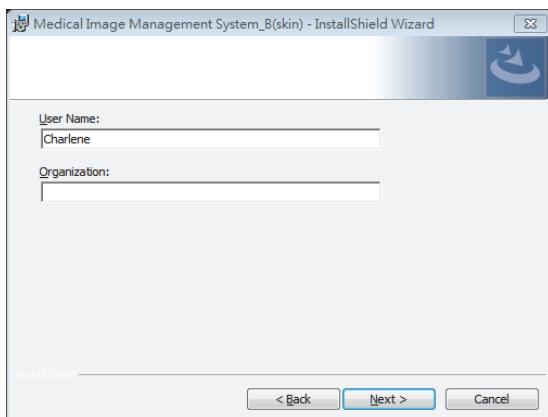
MiiS.
The installation will start automatically. Click [**Next**] to start the installation.



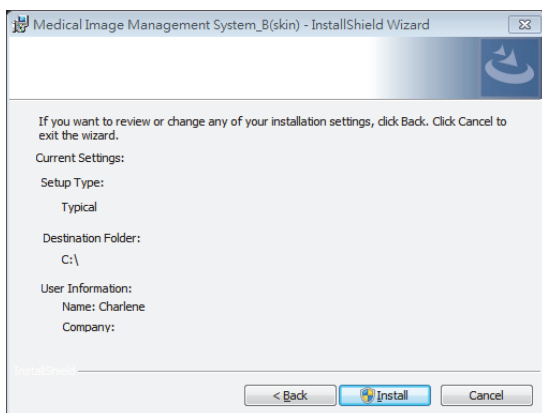
Read the license agreement carefully, choose “I accept the terms in the license agreement” and click [**Next**] to agree to the terms to continue with the installation.



Define User Name and click [**Next**] to continue the installation.

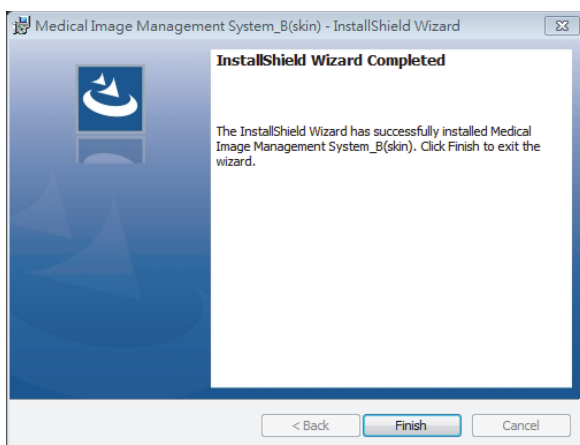


Click [**Install**] to continue the installation.



And the installation will start automatically.

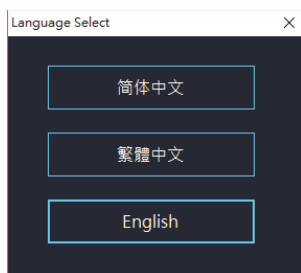
Click [**Finish**] to complete the installation.



Setup for the First Time

When you start the program for the first time, some parameters will be set accordingly.

- Language selection
Select preferred language to operate this program, Simplified Chinese, Traditional Chinese or English.

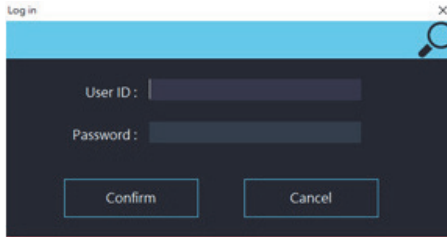


Please note that the language setting cannot be changed after first setup. The difference between the program and the web platform will not affect their performance or compatibility.

- Log in

Enter the user ID and password:

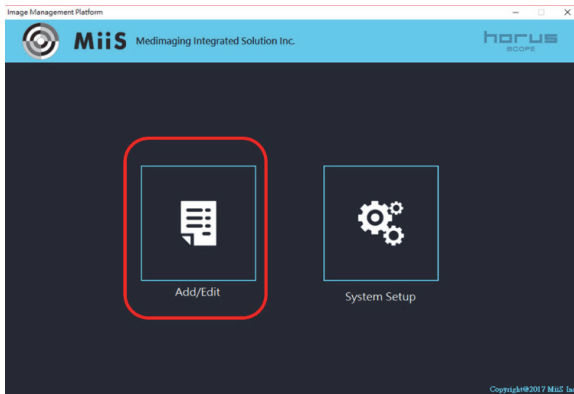
User ID: **admin** Password: **admin**




Patient Management

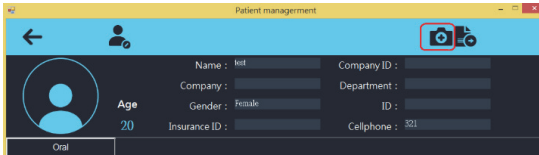
- Create new patient

Step 1: Select the icon “Add/Edit” in Home Page.



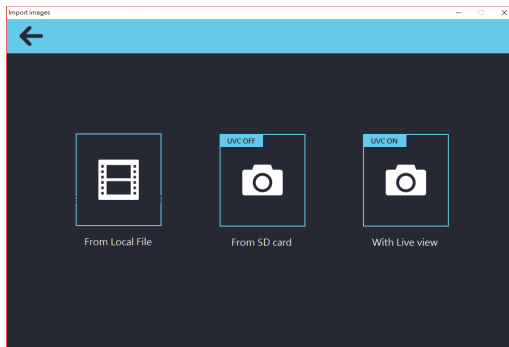
- **Import images**

Step 1: Open the main page of the patient, click  to add images for this patient.




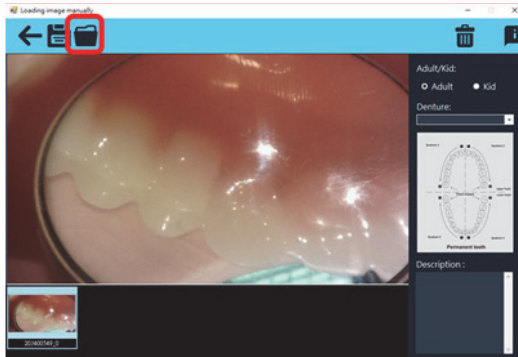
Step 2: import images:

User could do it by 3 ways: (Introduce the icons from the left to the right.)




1. Import Images by selecting images from local files:

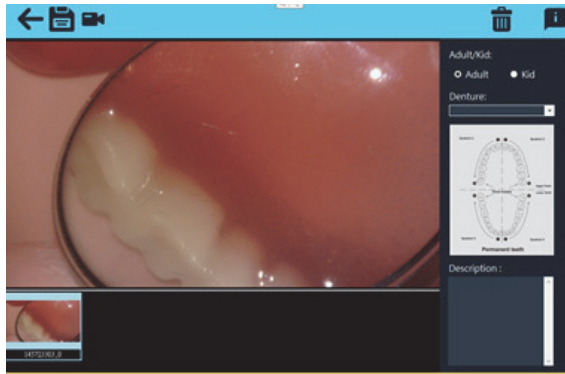
Import images from user's PC / NB directly. Pressing the icon  and select the file in local files.



2. Auto Image Import with UVC Viewer off (Transfer via USB): connect the device (the Horus⁺ scopes) in UVC off mode with user's PC / NB, and the photo will be uploaded to this patient's file automatically.

3. Auto Image Import with UVC Viewer on: connect the device (the Horus⁺ scopes) in UVC on mode with user's PC / NB, user could have live view from the device. In connection, the images / video taken will be uploaded to this patient's file automatically.

User could click the image taken to have a quick look of images, and could click the icon  to back to live view.



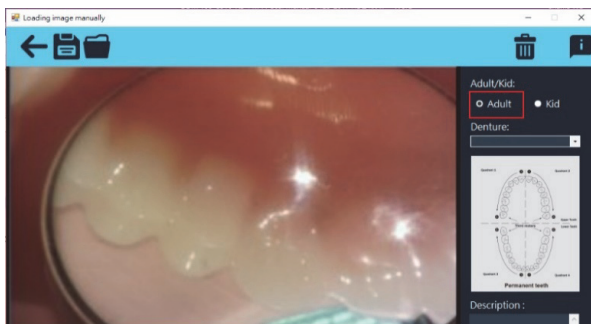
Please note: To optimized user experience and maintain the fluency of software operation, user could only import 40 images once one time.

Step 3: Edit the basic information of the image

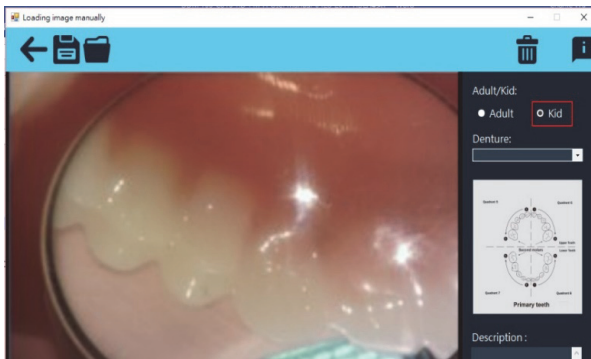
Indicate the basic information of image and leave the description of this image if needed. Follow the instruction to fill in the basic information:

1. Choose it is an image for permanent teeth (Adult) or primary teeth (Kid) : The corresponding image will show up.

Example for choosing “Adult”:



Example for choosing “Kid”:



2. Choose it is an image of which position:

Adult (Permanent teeth)

Upper teethes in quadrant 1: 11~18

Upper teethes in quadrant 2: 21~28

Lower teethes in quadrant 3: 31~38

Lower teethes in quadrant 4: 41~48

Kid (Primary teeth)

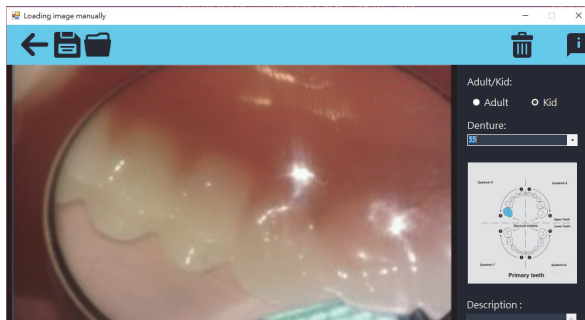
Upper teethes in quadrant 5: 51~55


Upper teethes in quadrant 6: 61~65

Lower teethes in quadrant 7: 71~75

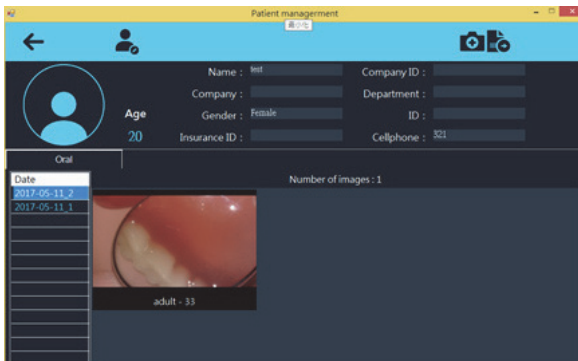
Lower teethes in quadrant 8: 81~85

The teeth chosen by user will be marked in blue correspondingly.

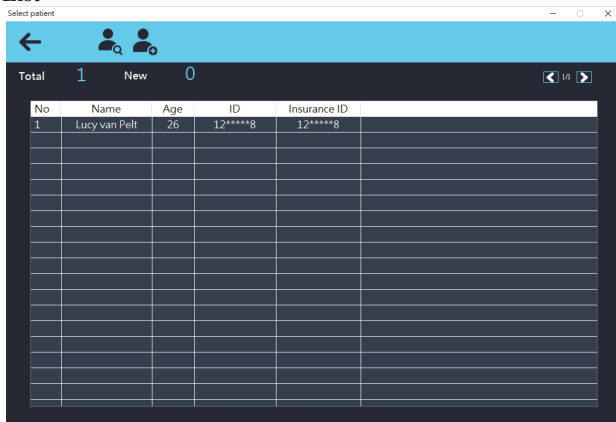


Click  to save the image after reconfirming with the image and all information you entered.


Example of a patient with image uploaded.



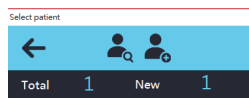
• Patient List



No	Name	Age	ID	Insurance ID
1	Lucy van Pelt	26	12*****8	12*****8

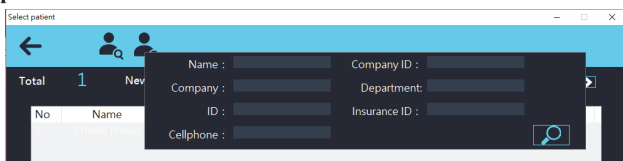
In patient list, user could have an overview for the database. Each page only displays 15 patients. If there are more than 15 patients waiting for diagnosis, user could go to next page by clicking .


The number of “Total” is the sum of all patients recorded in SA 1. And the number of “New” is the sum of patients who have new record today. User could filter the list by clicking the number.




Total	New
1	1

• Search patient's data



Click the icon  to start the function of searching patient's data.

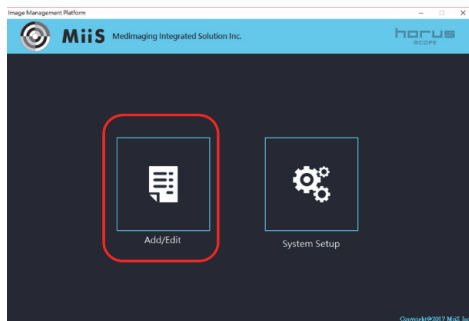
User could fill in the keywords and click . The searching result will come up.

The screenshot shows the same application window after a search. The search form is no longer visible. Instead, there is a table with the following data:


No	Name	Age	ID	Insurance ID	Status Summary	Unprinted
1	Charlie Brown	30	12*****8		0 1 0	0

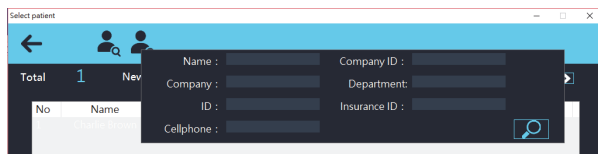
• Image Export


Step 1: Select the icon “Add/Edit” in Home Page.



Step 2: Search for patient's data.

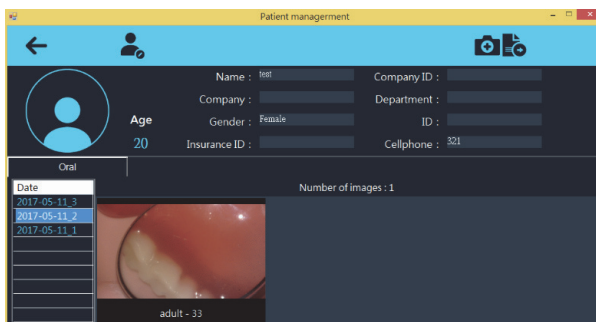
Click the icon  to start the function of searching patient's data.



User could fill in the keywords and click . The searching result will come up.

When having one more results with this information, this program will list all results to let user choose.

Step 3: Choose the date of image.



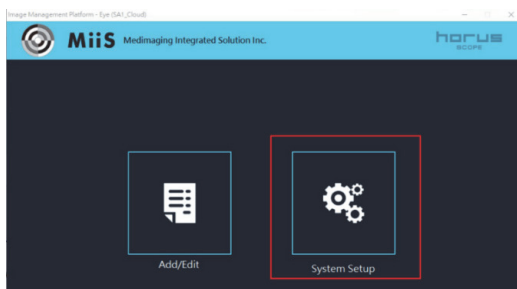
Step 4: Click the icon  to export images.

Choose the path to store the images. The naming rule for images and folder could define in "System setup." We could set the default path of storage in the same page.

Find more details in System Setup section.

System Setup

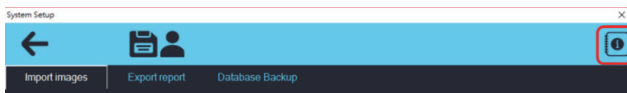
Select the icon “System Setup” in Home Page.



- **Open User Manual**

If there is any question about SA 1, user could find the manual in “System Setup” page.


Click to open the user manual.

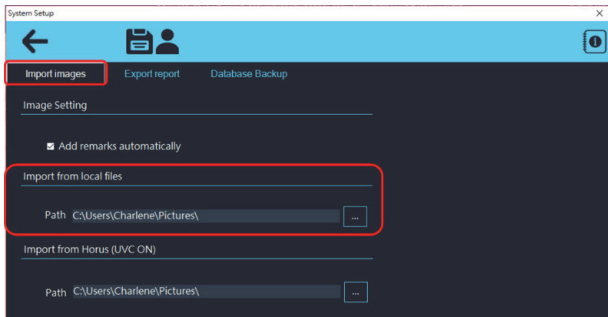


- **Determine the path for image storage**

User could edit the path for image storage in the page “Import images”.

The user can click  to change the path.

Edit the path needs to be updated and click the icon  to save the change.

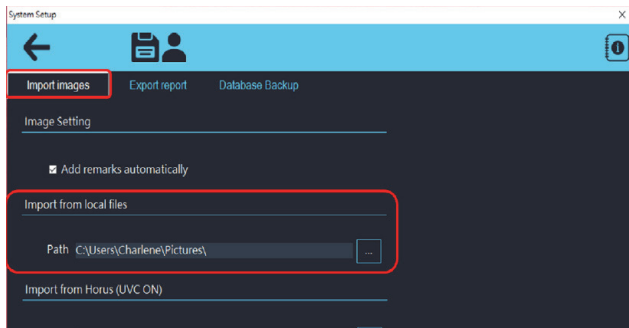



- **Define the storage path and naming rule**

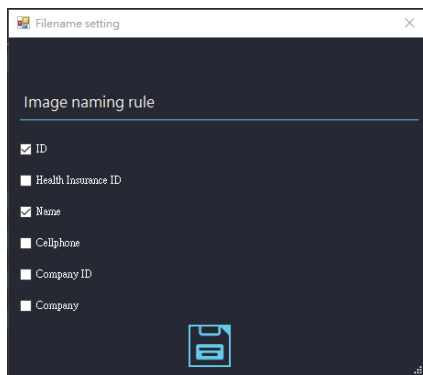
Define the naming rule of images / folder to export in “Export report“ page.

In this section, user could define the path of folder/ images storage as well.

Click [image] to edit the naming rule for image export.




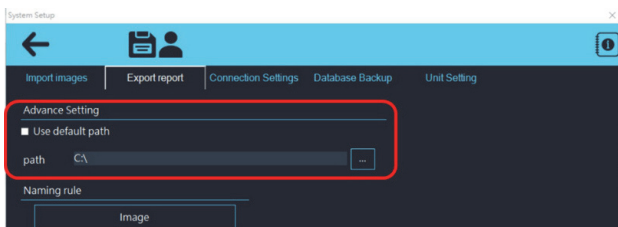
Click all the information user needs to have in the image's name and click the  icon.



With advance setting of default path, user could storage their report in same path, and SA 1 won't ask user to direct where the report stores. Click the checkbox to activate this function.

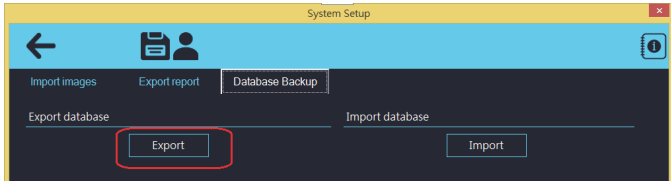
The user can click  to change the path.

Edit the path needs to be updated and click the icon  to save the change.



- **Database backup**

The user can export database regularly. And also can Import database.



Miscellaneous

Usage cautions and notes



Correct operation of the platform is imperative for its safe and successful functioning. You should therefore ensure that you are thoroughly familiar with the user manual before setting up and using the Image Management Platform (SA 1) for the first time.



The user manuals and other documentation enclosed with user should be kept accessible to users at all times to ensure that the information required for the use of user is readily available.



The Image Management Platform (SA 1) is not intended to replace skilled and qualified medical professional. The software should only be used by people who have been trained and is acquainted with its functions, capabilities and limitations.



Users must be aware that the quality, accuracy and correctness of the output data displayed on the screen, printed or sent from the Image Management Platform (SA 1) depends on the quality, accuracy and correctness of the input data, the user's interface with the data, the quality, calibration and other parameters of printer or monitoring device.

The Image Management Platform (SA 1) has been tested extensively, however, it is possible that errors may remain/emerge in the software. Users must be aware of the potential for errors and in case of error or for other assistance contact MiiS or the Representative in local.



Highly suggest that user to back up regularly to secure the database against accidental loss of user / client data.



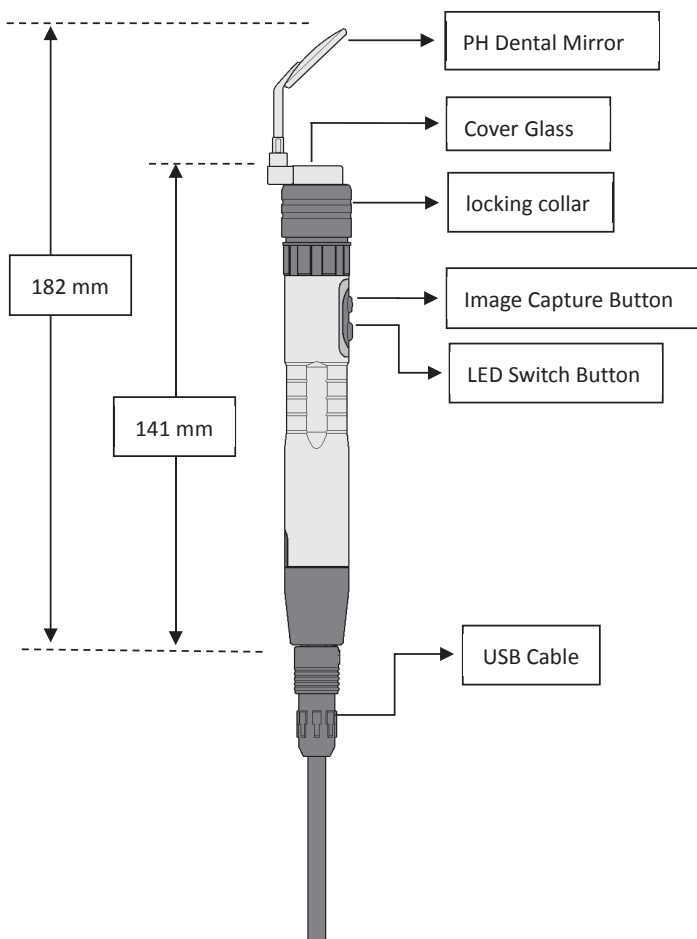
Highly suggest that user should review the database regularly to decrease unnecessary data to optimize the size of database.



Highly suggest that all the report should be reviewed by user or other professional person with care before providing to patients.

7.2 Operation of DDM 100

Product Description:

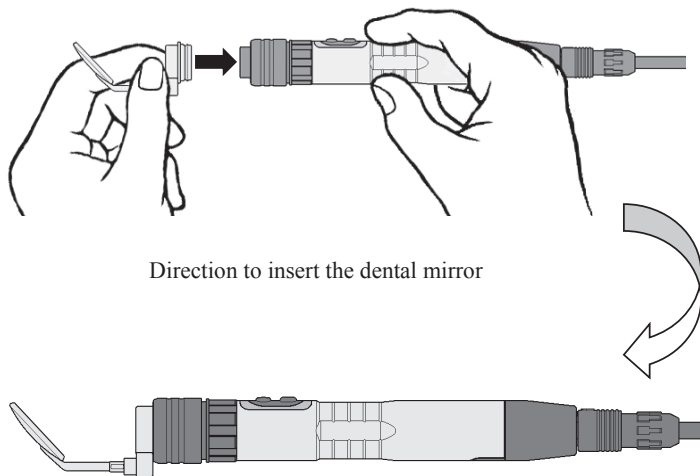


Inspection:

DDM 100 is a focus free inspection camera. No need to do the focusing when inspect the intraoral or extraoral.

- **Intraoral Inspection:**

Insert the dental mirror to the handpiece, and then start intraoral inspection.



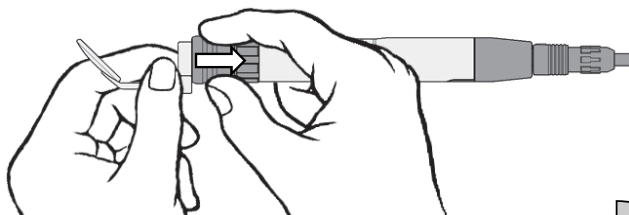
(Intraoral Inspection Mode)



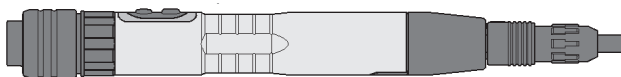
CAUTION: Prior to operating DDM 100, please make sure the dental mirror is assembled well.

- Extraoral Inspection:

Please remove the dental mirror from the handpiece, and then start extraoral inspection.



Hold the locking collar and dental mirror. Push back collar of handpiece.



(Extraoral Inspection Mode)

Note:

1. Please keep viewing object 35~50mm to DDM 100 cover glass to get the good image quality when do the extraoral inspection.

8. CLEANING AND DISINFECTION:

8.1 Cleaning

1. The outer surfaces of the product can be cleaned by using mild cleaning solution such as alcohol to wipe off gross debris.

2. For dental mirror, please follow the listed sterilization instructions.

This is for professional dental use only

* Disinfection before 1st use and right after use

* Cleaning: manual (recommended); Avoid thermo disinfection to preserve the reflecting surface

* Rinse (with deionized water) and dry. Careful inspection;

* Package for sterilization

* Sterilization in Autoclave (18 minutes. at 134°C). Dry Heat (160°C).

Careful inspection

Avoid any contact with other instruments during these processes.

Do not use brushes, coarse sponges or similar to avoid scratches on the mirror.

Do not expose the mirror to temperatures over 180°C/360°F.

8.2 Disinfection

Prior to clean the handpiece or USB cable, please turn the system off, and unplug the USB cable from computer to prevent the electrical shock.

1. After each inspection, please remove the dental mirror and use autoclave to sterilize.

2. The handpiece and cable may be disinfected by wiping EPA approved hospital grade surface disinfectant as per manufacturer's direction.

3. To clean the handpiece, first wipe off dust with water or alcohol, then wipe with gauze or sleeve soaked with EPA approved hospital grade surface disinfectant.



CAUTION

1. Do not heat sterilize or autoclave the handpiece, as this will damage the optics and void the warranty. Do not submerge the handpiece in any liquids.
2. To clean the cover glass, wipe with a cotton pad (soak with alcohol then squeeze out) in one direction.
3. Before cleaning the cover glass, be certain that it is free of any abrasive contaminants. This will help to avoid the formation of scratches while cleaning.
4. To clean and disinfect the handpiece, use a clean cloth and a small amount of alcohol.

Note:

Do not soak the handpiece and be sure to dry it completely.

9. DISPOSITIONS

- Follow the local governing ordinances and recycling plans regarding disposal or recycling of device components, especially when disposing of circuit board, plastic parts that contain brominated flame retardant, or USB cord.
- Follow the local governing ordinances and recycling plans when disposing of the circuit board. Inappropriate disposal may contaminate the environment.
- When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.
- Inappropriate disposal may contaminate the environment.
- When disposing of mirror, follow the disposal procedures for medical waste such as needles, infusion tubes, and metal instruments for surgery as specified by your medical facility to avoid infection outside the facility and environmental pollution.

10. LIABILITY

Medimaging Integrated Solution Inc. considers itself responsible for the effects on safety, reliability and performance of this product only if:

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Medimaging Integrated Solution Inc.
- The electrical installation of the relevant room complies with the requirements.
- The equipment is used in accordance with these instructions for use.

11. WARRANTY

Medimaging Integrated Solution Inc. hereby warrants that for a period of one year from the date of purchase this instrument shall be free from defects in material and workmanship and will perform satisfactorily under normal use and service.

The warranty stated herein is the sole warranty applicable to Medimaging Integrated Solution Inc. products. Medimaging Integrated Solution Inc. expressly disclaims any and all other warranties expressed or implied, including warranties or merchantability or fitness for a particular use. Medimaging Integrated Solution Inc.'s liability with respect to its products expressly limited to the remedies set forth above. The remedies are the buyer's exclusive remedies. Medimaging Integrated Solution Inc. shall under no circumstances be liable for incidental or consequential damages.

12. SYMBOLS AND STANDARD

Symbols



Caution must be taken. Read user's manual before use.



Type BF - Indicates the device is classified as a device with a Type BF applied part.



The operator is advised to read the instructions of user's manual.



Manufacturer.



Date of Manufacture.



CE mark.



European Authorized Representative.

Standards

Electrical safety	IEC 60601-1:2005/A1:2012 (EN 60601-1:2006/A1:2013)
EMC and regulatory compliance	IEC 60601-1-2: 2014 (EN 60601-1-2:2015)
Photobiological safety of lamps and lamp systems	IEC 62471:2006



Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and IEC 60601-1). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible for the system complying with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.

EMC (Electromagnetic Compatibility)

The device complies with the International Electrotechnical Commission standards (IEC 60601-1-2: 2014) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the device in an electromagnetic environment.

EMC (IEC 60601-1-2: 2014)

Guidance and manufacturer's declaration electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device 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.
Harmonic emissions IEC 61000-3-2	Class A *1	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	*2	

*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

Guidance and manufacturer's declaration electromagnetic immunity			
<p>The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2, 4, 8, 15 kV air	±8 kV contact ± 2, 4, 8, 15 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, 1 kV line(s) to line(s) Line to ground	±0.5, 1 kV line(s) to line(s) Line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0.5 cycle (1 phase) 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % UT for 250/300 cycles (50/60 Hz)	0 % UT for 0.5 cycle (1 phase) 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % UT for 250/300 cycles (50/60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (Hz) magnetic field IEC 61000-4-8	30 A/m (50 or 60 Hz)	30 A/m (50 or 60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: U _T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below.
The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3Vrms at 0.15 – 80MHz & 6V at ISM Frequency.	3Vrms(V1=3) at 0.15 – 80MHz & 6V at ISM Frequency.	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (3.5/V1)\sqrt{P} = 1.2\sqrt{P}$ (150 kHz to 80 MHz) $d = (3.5/E1)\sqrt{P} = 1.2\sqrt{P}$ (80MHz to 800MHz) $d = (7/E1)\sqrt{P} = 2.3\sqrt{P}$ (800MHz to 2.7GHz) where P is the maximum output
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.7GHz 80% AM at 1 kHz	3 V/m(E1=3) 80MHz to 2.7GHz 80% AM at 1 kHz	

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above 3 V/m., the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1,2\sqrt{P}$	80 MHz to 800 MHz $d=1,2\sqrt{P}$	800 MHz to 2.7 GHz $d=2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
 NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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Manual



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