



Mia3d

Intra-oral 3D Imaging System

Operator's Manual



The densys3D system comprises an intra-oral scanner and a third party CAD/CAM workstation at the dental lab or central production. The scanning process is straightforward and simple, guided by visual and audible prompts. A complete scan takes just a few minutes, after which a digital file is transferred to a dental lab for completion of the restoration.

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- This device complies with applicable requirements of the Council Directive 93/42/EEC, and also has certification of ISO 13485:2016, AMAR, FDA registration, ARTG

This product is covered by one or more of the following patents as well as a number of pending patents and European patents:

**US8,665,257 US6,402,707 US7,724,932 US7,330,577,
JAP 5106418 US9,222,768 USD790,063S**

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Introduction

This document describes how to operate the densys3D Mia3d Intra Oral 3D Imaging System, from now on referred to as Mia3d.

The Mia3d system package includes the densys3D intra oral camera, also known as the wand. The wand and supporting hardware, software and accessories are a complete stand-alone system for measuring teeth and producing an extremely accurate three dimensional virtual model. This information is used in the construction of dental prosthetics.

Results are available in real time and are saved within the system. The virtual model can be used in the clinic or exported via email to a laboratory for prosthetic production by dental CAD/CAM machines. The device is reusable.



NOTE: This User Manual can be received in French, by contacting

info@densys3d.com

Ce manuel d'utilisation peuvent être reçus en français, en communiquant avec

info@densys3d.com

Preface

This document is divided into three sections:

1. System description
2. Installation
3. Mia3d operating instructions

Conventions

To alert the reader to information essential for the safe and proper use of the equipment the following warning symbols are used:



NOTE: Text presented in this manner presents clarifying information, specific instructions, commentary, sidelights, or interesting points of information.



CAUTION: Text presented in this manner indicates that failure to follow directions could result in damage to equipment or loss of information.



WARNING: Text presented in this manner indicates that failure to follow directions could result in harm to people.

User License Agreement

The use of the densys3D Mia3d intra Oral Imaging System and applications are conditional on acceptance of the license agreement and legal obligations as specified by densys3D.

Indications for use

The densys3D MIA3d intra oral scanning system and accessories is intended to provide a 3D view of the mouth before and after the dental procedure, and to assist the dentist in the construction of dental prosthetics.

Densys3D Hardware

The Densys3D hardware package comprises of the following configuration:

I. Laptop

1. Standard off the shelf Laptop¹

II. Wand

1. Hand-held camera used to view and capture the intra oral scene
2. Connection accessories and cables



Figure 1 – MIA3d System

The wand captures intra oral video data which is reconstructed into three dimensional files. The wand contains:

- Camera
- Optics
- LED lighting
- Feed cables enclosed in biologically non-reactive casing.

¹Meeting minimal requirements list

Wand Hardware Description

Hand piece is impervious to fluid entry. It is made of material that is non-biological tissue reactive. It weighs less than 200 grams and easily fits into the oral cavity whilst leaving room for the hand to grip the wand end extra-orally.

The hardware specifications are as follows:

- Optic system with glass lenses and glass optics.
- Video:
 - Transfer: Color or monochrome real time image acquisition from the wand camera on a continuous basis.
 - Transfer rate: Multi Frames per Second (FPS).
 - Format: Composite Signal from the camera.
 - Focus Range: 0mm – 18 mm.
 - FOV: 16mm x 9mm.
 - Light Source: LED.
 - Pixel viewing size on object of at least 20 microns or greater.
 - Resolution: 1280 X 1024 pixels.
- Connection to the PC / Laptop: USB 3.0
- Input power: 2xUSB 3.0 cable
- Disposable cover of the viewing window.

Wand Physical Description

The wand's weight and appearance are as follows:

- Shape – the handpiece is characterized by a lack of sharp edges or rigid surfaces so the patients' mouth can't be harmed.
- Weight – 200 grams.
- Handle size – 2.5cm diameter, 200mm long
- Cable length – 2m

Work Station Description

The minimum hardware specifications are as follows:

Laptop

Processor:	Intel Core i9
Memory:	32 GB RAM
Power Supply:	140W medical grade adaptor -laptop
GPU:	/ GTX 970M for laptops
Hard disc:	1 TB
SSD:	recommended at least 128 GB
OP –	Windows 10 64-bit home

System Connections

- Wand: 2 x USB 3.0.
- Communication: Wired Ethernet or Wi-Fi connection



NOTE: The Wand includes a stand with a calibration step

Safety Standards



NOTE: The wand has a handle that gives the operator a secure grip

EMC – The system complies with the requirements of the IEC 60601-1-2:2014 standard.

Safety – The system complies with the requirements of the IEC 60601-1-2:2014 standard.

Electrical Hazards



NOTE: The device is supplied with a medical grade power adaptor and cables as listed below, and maybe only be used when the supplied power adaptor



NOTE: The device may only be used when the supplied power adaptor is inserted directly in to the mains outlet.



NOTE: Do not change the power cable to the mains outlet



WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result



NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment



NOTE: Do not use an interface or adaptor to insert several electrical appliances in the same outlet with the device



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

The device has been tested and found to comply with the limits for medical devices under the IEC 60601-1-2 standard. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to other devices in the vicinity. However, it should be noted that interference to other devices is not necessarily caused by this instrument but may come from another source.

Whether or not this device is interfering with other devices can be easily determined by turning it off and on.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the device into an outlet on a circuit different from that which was previously used.
- Consult Densys3D for help.

Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, check that the interruption is not caused by communication equipment operating in the vicinity.

Use of the system with any accessory, transducer or cable other than those specified may result in increased EMISSIONS or decreased IMMUNITY than those specified.

Electrical Specifications:

- Class I equipment
- The equipment may only be used with the medical electrical power supply included, which is one of the two models listed here below.

Power – Win (manufacturer), model PW-M160A-1Y190H

- Type BF applied part 
- No protection against ingress of water (IPX0)
- Equipment not suitable for use in the presence of flammable mixtures
- The unit is classified as continuous operation device
- Guidance and manufacturer's declaration – electromagnetic emissions

Operational Environment

- The maximum operational altitude is 6561ft (2000 meter)
- Operating temperature: 15°C to 40°C
- Humidity: 10%- 90% RH

The MIA3d system is intended for use in the electromagnetic environment specified below. The customer or the user of the MIA3d should insure that it is used in an environment that meets these requirements.

Declaration – electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class A	The MIA3D 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.
Harmonic emissions IEC 61000-3-2	Class A	The MIA3D is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the MIA3D or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

Declaration – electromagnetic immunity			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors 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 N/A	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; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MIA3D requires continued operation during power mains interruptions, it is recommended that the MIA3D be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration – electromagnetic immunity			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the MIA3D, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

<p>Conducted RF IEC 61000-4-6</p>	<p>3V, 6V</p>	<p>3Vrms, 6V</p>	<p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_2} \right] \sqrt{P}$
<p>Radiated RF IEC 61000-4-3</p>	<p>3V/m</p> <p>3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz</p> <p>3V/m from 80MHz to 2.7GHz</p>	<p>3V/m</p> <p>3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz</p> <p>3V/m from 80MHz to 2.7GHz</p>	$d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>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 metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>D Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

<p>Recommended separation distances between portable and mobile RF communications equipment and the MIA3D</p>	
<p>Rated maximum output</p>	<p>Separation distance according to frequency of transmitter</p> <p>m</p>

power of transmitter W	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}] \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}] \sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}] \sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745	704 – 787	LTE Band 13, 17	Pulse modulation	0.2	0.3	9	9

780			on ^{b)} 217 Hz				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulati on ^{b)} 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulati on ^{b)} 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulati on ^{b)} 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulati on ^{b)} 217 Hz	0.2	0.3	9	9
5500							
5785							
<p>^{a)} For some services, only the uplink frequencies are included.</p> <p>^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal.</p>							

^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Non-operational Environment

- Maximum Altitude: 6561ft (2000 meter)
- Temperature: Less than - 15° and above 40°C
- Humidity: 90% @55°C non-condensing.
- Vibration: MIL 810-514E Transportation Vibration Test or equivalent.
- Shipping Shock: Per ASTM 4169-98.

Disinfection and Cleaning

The Mia3d Wand may be cleaned as below or may be used in conjunction with a condom, especially designed and optically suitable for MIA3d use.

Condom

Place correctly over the anterior part of the wand and do not obstruct the viewing window .

The Mia3D Wand contains optics and electronics, and therefore must not be placed in a bath or under running water for cleaning purposes.

1. To clean and disinfect the wand:

- a. The wand should be wiped backwards and forwards with a damp cloth of Esteer Sept wipes (manufactured by Esteer Pharma Gmbh) to remove any visible gross material or fluid on the wand surface.
- b. The wand should be dried with a new disposable tissue from a packet of regular tissues. Or alternatively, a disposable dry cloth wipe.
- c. The wand should be wiped backward and forward with a damp cloth of Ruhof Orthozime® enzymatic detergent diluted according to the manufacturer's instructions.
- d. The wand should be wiped with cloth duped with distilled water.
- e. The wand should be placed on a clean table top or other horizontal surface and using Propano AF spray (manufactured by Esteer Pharma Gmbh) sprayed evenly from a distance of 30cm on all sides with the exception of the bottom side adjacent to the surface. It should be left to dry for one minute.
- f. The wand should be rotated and the steps listed above should be repeated to clean the side of the wand adjacent to the horizontal surface.



NOTE: Please refer to Esteer Pharma GmbH web site for cleaning material and wipes information: <http://www.esteer.com/>

Please refer to Ruhof Corporation web site for cleaning detergent information: <http://www.ruhof.com/CatalogProducts.asp?nProductsID=82>

2. To clean the viewing window:

The following tools must first be prepared

- Q-Tip
- Tooth pick
- Alcohol (70%) or Lens cleaning fluid
- Clean gauze pad or tissue

Follow the process in the following order

1. Take the Q-Tip and deep one side of it in the alcohol of lens cleaning fluid.



2. Place the wet side of the Q-Tip on the gauze pad or toilet paper to absorb the fluid from it.



3. Fold the Lens Tissue Paper once, so it will be two plies and place it on the wand window.



4. Place the wet Q-Tip end over the folded lens tissue paper, which is on the wand's window, and rub the Q-Tip gently over the window back and forth. (Notice: the lens tissue paper it is between the Q-tip and the wand's window).



5. Once you are done moving the entire window, the residue fluid needs to be cleaned from the window as well. To do this, first fold the cleaning tissue paper again so it will have four plies. Place a different part of it on the window.



6. Using the dry end of the Q-Tip and rub it gently over the cleaning tissue paper, which is on the window.



7. Look at the wand window, to see if there is any remaining residue .1

Use source of light to check the reflections from the wand's window.



If any residue remains on the central part of the wand window, please repeat the process up to this point.

8. If there is residue close to the edges of the wand's window, use toothpick over the four plied cleaning tissue paper. Very gently go over the edges of the wand's window with the toothpick.



CAUTION: If you wipe vigorously you may scratch the viewing glass.

When not in use, place the wand in its correct position on the wand stand.



WARNING: The handpiece is not delivered sterile, nor should it be sterile for use. Implementation of the cleaning protocol before use, and in between patients, is required for correct maintenance of the wand.

Biocompatibility

The handpiece is designed using materials which comply with EN ISO 10993-1:2009 standard.

The level of contact as stated in the standard: surface device in limited contact (<24 hours) with a mucosal membrane.

CAUTION



CAUTION: This section contains vital maintenance information that you must follow to avoid damaging the equipment.

Densys3D hardware contains highly-refined optics and electronics. To avoid damaging this equipment:

- Do not drop or bang the wand.
- Avoid contact of the wand with any materials or solutions other than those authorized in the user manual.
- Do not immerse the handpiece in solutions or baths.
- Do not place the wand under a running tap.
- Do not place the wand in an autoclave or a dry heat sterilizer.
- Do not wet the wand, or any part of the Densys3D system, other than in a manner or with a material authorized for use in the user manual.

Installation



CAUTION: Unpacking and installation of the Mia3d system must only be performed by a qualified Densys3D technician.

Unpacking and Inspection

Unpack each Mia3d system component and inspect for physical damage such as scratched panels or damaged connectors, etc. If any damage is noted, immediately notify the supplier so that the damaged components can be replaced.

Make sure to save all packaging material in case repackaging and shipment is necessary. Verify that all listed items were received.

If any item is missing, notify the supplier. Each Mia3d system component is shipped packaged in an individual protective container, or packed in a single box.

The laptop is supplied in its own box from the laptop manufacturer.

The following components should be included in the box supplied from densys3D for the laptop system:

Item	Supplied	Part No.
Medical grade power adaptor (laptop only)	1	D5019
Camera wand assembly	1	D5020
Foot Pedal	1	D5021
Cables: <ul style="list-style-type: none"> • 2m Wand cable • 	1	D4021
Wand Stand	1	D4051

Mia3D Operating Instructions

Mia3d operates on a Windows 10 Operation System.

The following instructions lead you through all the Mia3d wizard pages.



NOTE: The use of the device is restricted to trained personnel only.



NOTE: It is recommended for the User to change the password for Windows account at the first use of the system, and to change it frequently, once in 6 month.

The following instructions lead you through all the Mia3d wizard pages.



CAUTION: Place the wand when not in use face down on the stand



NOTE: The actual implementation of the scan takes less than 60 seconds.

Principal Navigation Aids

In addition to the regular progression of the wizard pages initiated by task executions, you can also navigate between the pages as follows:

- To progress to the next page, click on the green **Next**  button.
- To return to the previous page, click on the blue colored **Back**  button.
- To go to the exit page, click on the red **X**  button.

Wizard Page Tabs

The tabs at the bottom of each page view give you instant indication of how far the wizard has advanced but they are **NOT** used for navigation between wizard pages.

Pre-Scan setup



CAUTION: Before starting a dental scan it is essential to implement the steps described in Pre-Scan setup.

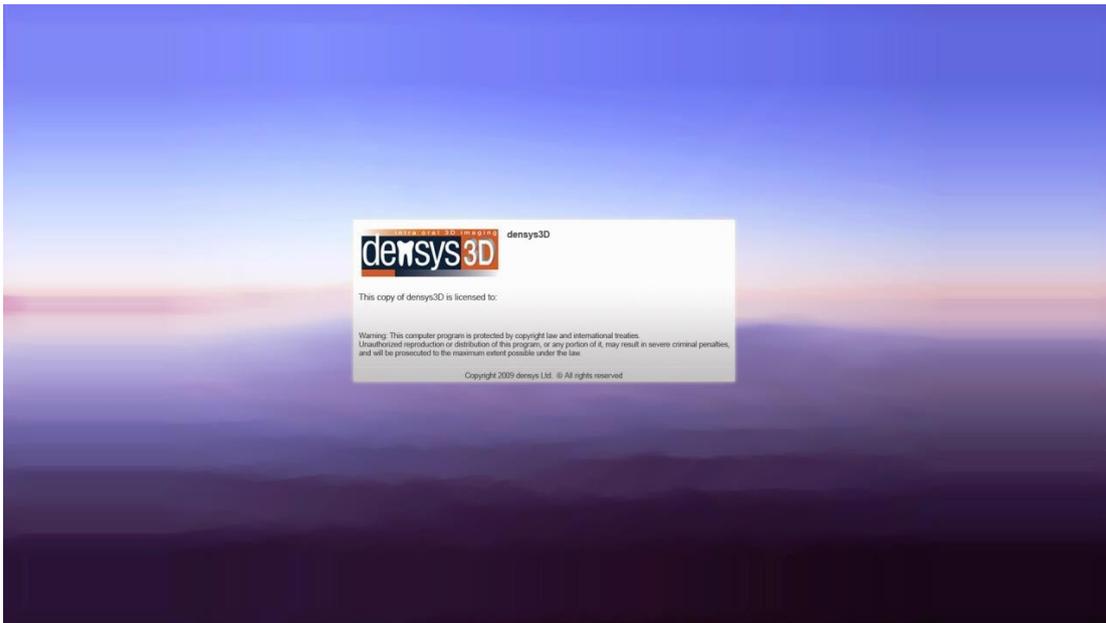
Activating the Application

For first time use please accept the EULA agreement.

For time limited use via licensing please insert the license code you received via email from your distributor into the correct field

To launch the application, click the Densys3D icon on your Desktop, or in the Task Bar.

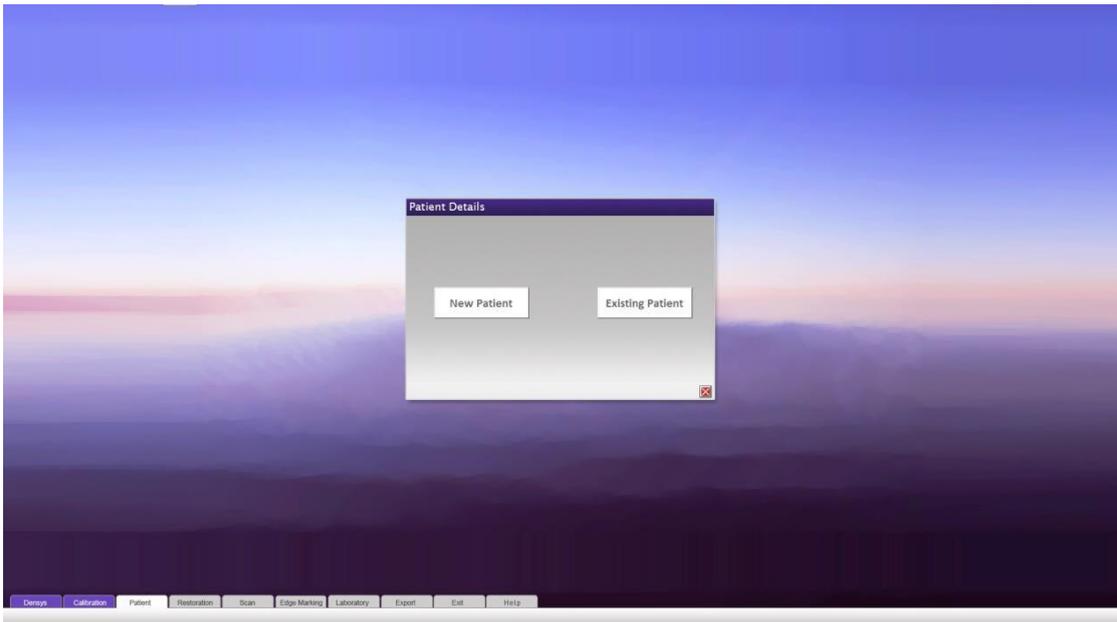
The Densys3D license page is displayed.



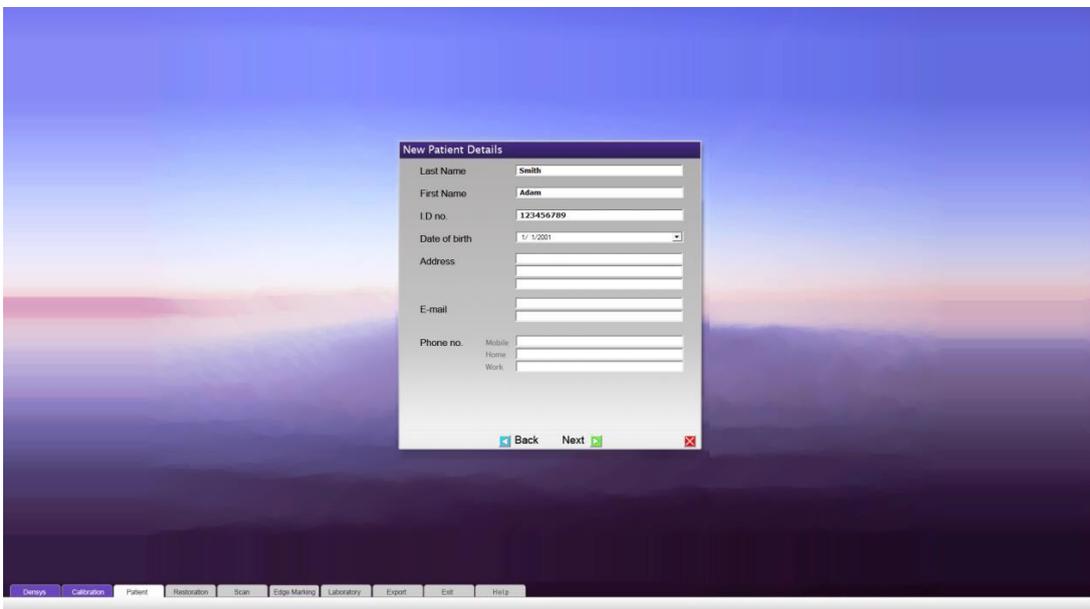
Patient Selection

The Patient Details page is displayed.

1. Click **New Patient** to add a new patient to the patient directory or **Existing Patient** to perform a scan for one of your existing patients.



If you selected **New Patient**, the New Patient Details page is displayed. If you selected **Existing Patient**, skip to the next step in these instructions.

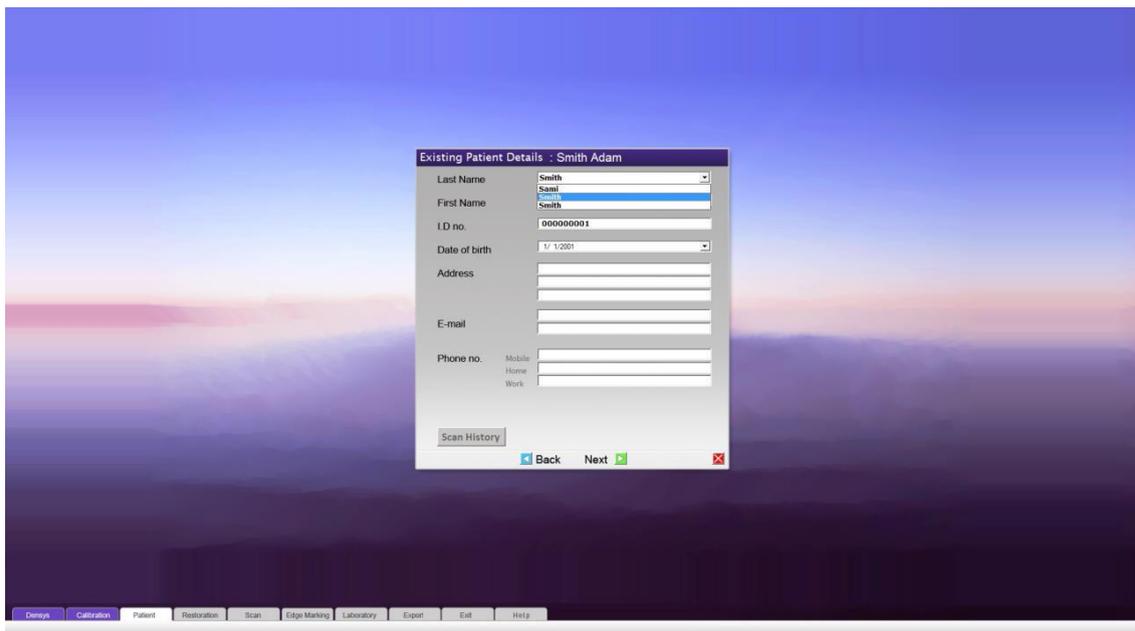


2. In the **New Patient Details** page, enter the following details in the designated fields:
 - **Last Name** – Mandatory Field
 - **First Name** – Mandatory Field
 - **ID no.** – Mandatory Field
 - **Date of birth**
 - **Address**
 - **E-mail**
 - **Phone no. (Mobile, Home, Work)**

After filling in the patient information, click **Next**.

This will automatically register the patient and proceed to the next wizard page.

If you select **Existing Patient** in the **Patient Details** page, a pull down list of existing patients will be displayed. You can select one of the existing patients from this pull down list.



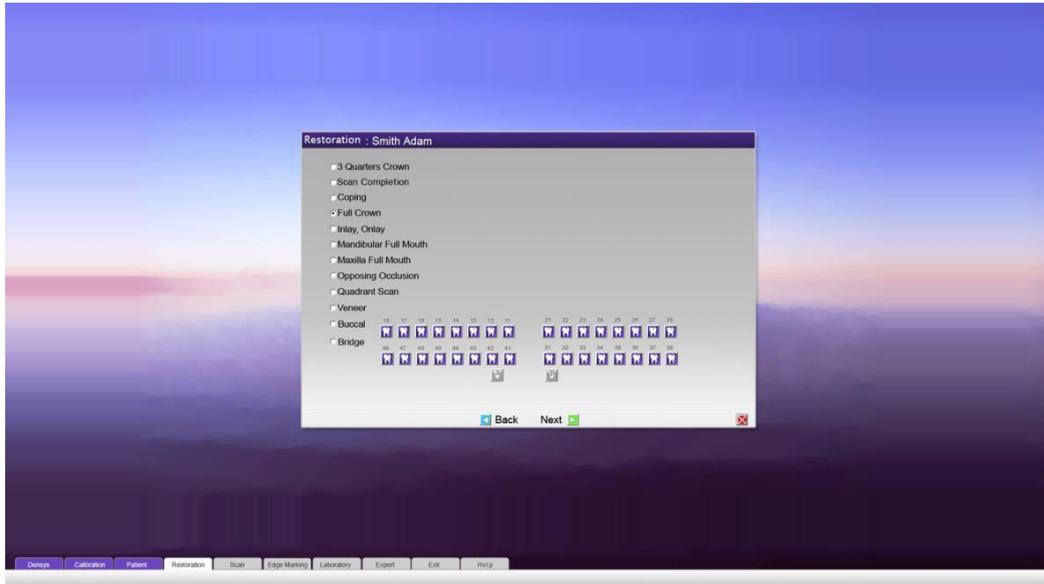
You can then view and edit patient details (see the description for the **New Patient** page in the previous step).

After changing patient details click **Next** to proceed to the next wizard page.

To view all previous scans from this patient click the **Scan History** button on the bottom left corner of the screen.

Restoration

1. In the **Restoration** page, click on a scan option to select it.



The scan options are:

- 3 Quarter Crown 
- Scan Completion 
- Coping 
- Full crown 
- Inlay, Onlay 
- Mandibular Full Mouth 
- Maxilla Full Mouth 
- Opposing Occlusion 
- Quadrant Scan 
- Veneer 
- Buccal 
- Bridge 

2. If you select the Bridge option, the **Abutment**  or **Pontic**  indicators are activated. Click on each of the numbered teeth you want to include in the scan:
 - The selected tooth displays the icon for the treatment chosen.
 - You can undo your tooth selection by clicking again.
3. Click **Next** to save the scan setup and to continue to the next step.

Pre-Scan Setup

1. Setup the wand:
 - Ensure that the wand is cleaned and disinfected to prevent cross infection before use as specified in the Disinfection section.
 - Check that the viewing window is clean and dirt free. If it is dirty preform the cleaning procedure detailed in the Disinfection section.
2. For prepped teeth prepare the patient with two retraction cords, and remove one cord before proceeding to the next step
 Make certain there is no bleeding in the area of the intra oral impression
3.
 -



NOTE: Keeping the intra oral tissues relatively dry and blood free is will aid in achieving a better quality scan.

Scan Screen

After completing the pre-scan setup, click **Next** from the Restoration page (step 3) to open the Scan screen.

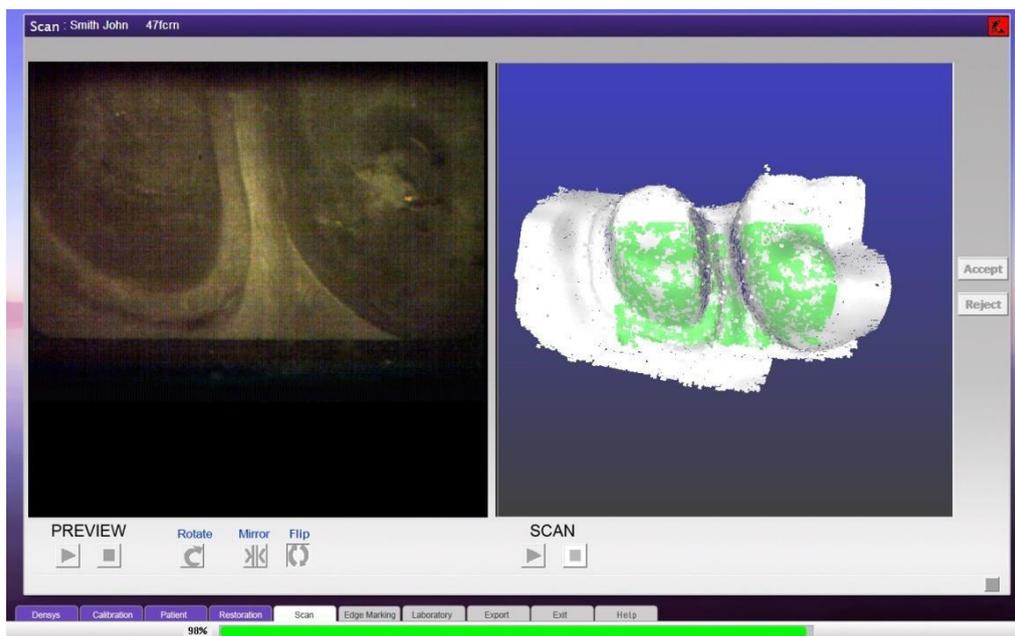


NOTE: Try and parallel the camera to the tooth during the scanning procedure.
Do not touch the tooth with the camera during the scanning procedure.

The Scan screen consists of two windows.

- The left (PREVIEW) window shows the tooth before computation of the data to 3D.
- The right (SCAN) window presents the scan progress in real-time, and the 3D results after the initial data computation to 3D.

As the scan proceeds the currently processed data is displayed in the scan window in green.





NOTE: The scanning method described in the following steps is a suggested, recommended method. Some users may prefer to follow a different method. A new user is advised to practice his scanning technique in the preview window before activating the scan.

Help Tag

There is a Help tag at the bottom-right of the screen.

If pressed a film which shows the appropriate recommended scanning method appears.

Preview

To activate the PREVIEW do one of the following steps:

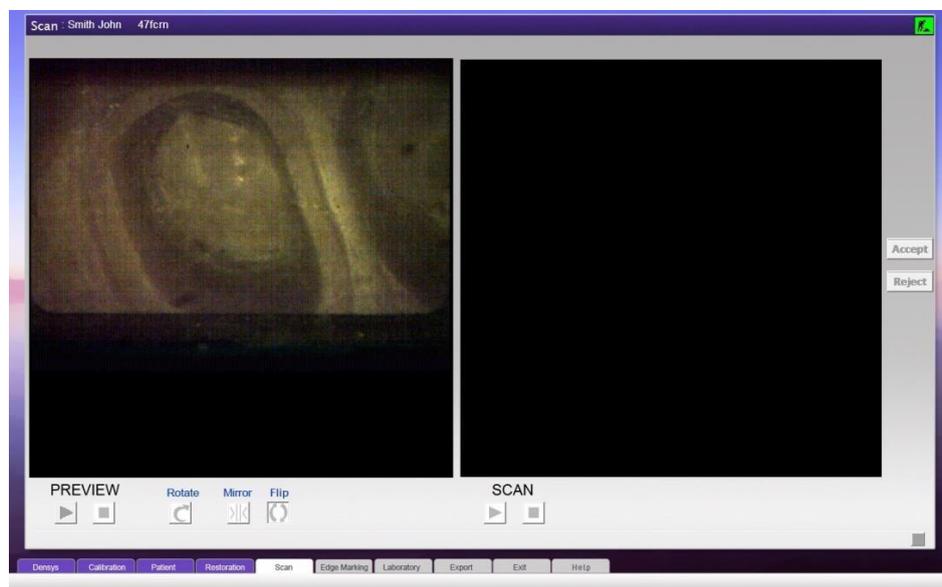
- Click the start button  under the left window (labeled PREVIEW).
- Press the space bar on your keyboard
- Press once on the Foot Pedal

To change the preferred PREVIEW aspect do one of the following steps:

- Click the Rotate button  to turn the view 90 degrees
- Click the Mirror button  to mirror the view
- Click the flip button  to flip the view

To stop the PREVIEW do one of the following steps:

- Click the stop button  under the left window (labeled PREVIEW).
- Press once more the space bar on your keyboard
- Press once more on the Foot Pedal



Scanning



CAUTION: It is preferable that neither direct sunlight, nor the unit halogen light should be directed intra orally during scanning.

Review the following scanning guidelines to obtain high quality scans.

- hold the wand in position opposite the tooth and wait a couple of seconds till the wand beeps before moving to scan
 - Preferably the scan should start by previewing and scanning surfaces, eg buccal and occlusal.
 - Always try and hold the wand as parallel as possible to the surface scanned. Inter-proximally turn the wand to position it as parallel as possible to the surface scanned. Please note, this is difficult to achieve and you will have to compromise on the ideal positioning.
 - For tricky surfaces such as inter- proximal surfaces, hold the wand in position for a second or so.
 - All scans should be a continuous smooth movement and not jerked with sudden movements.
 - When moving the wand from any surface to the occlusal surface, slow down and roll with minimum translation of the wand.
 - When scanning around corners or sharp angles move the wand slightly slower.
 - Keep the area you want to scan in the center of the preview screen.
 - If you jerk suddenly away from the area scanned move back to it as quick as possible
 - For better results, hold the wand as close as possible to the teeth.
 - Do not touch the teeth with the wand. It is preferable to move the wand only in one sweep in one direction and NOT in a back and forth “polishing” movement.
1. Once you are satisfied that the tooth is in focus and the wand is positioned with the chosen view, you can start the scan using the same method used to activate the preview:
 - a. Click the arrow button  under the window to the right (labeled SCAN) to start the scan.
 - b. Press the space bar on your keyboard.
 - c. Press once on the Foot Pedal.



NOTE: Each operator will develop their own favored scanning method and there is no obligation to follow the surfaces in the sequences listed in the above example, but the principles of scanning have to be followed.

2. As you move the wand a real time scan appears in the SCAN window. It covers the same area that is shown in the PREVIEW window to the left.
- The colored dots appearing on the scan screen show the latest data coming into the scan in real-time.
- Green dots – good data coming into the scan is colored green on the right scan window.
- Yellow dots – when the data coming in is yellow the operator should relate to one of the following potential problems about to happen
- a. The scanner is being held to far away and is out of focus
 - b. The scanner is being held at too great an angle to the tooth
 - c. The operator has jerked during the scanning and missed an area – he has to go back to the area last scanned successfully
- Pink dots – the situation is critical and unless the operator corrects as above he will wither get a sub-standard scan or the screen will progress to a red color and stop
- Red dots – the screen and scanning has stopped and the operator must go back and redo or progress to a completion in the scan history screen if appropriate.

Audio

There are audio sounds accompanying the scan that demonstrate the different colored screens. These vary from system to system.

Implants – Scan Bodies



NOTE: Do not use scan bodies or scan implant parts that are symmetrical in shape or have large curved surfaces



NOTE: Use scan bodies that have multiple angular faces in white peek material

Scan bodies that are appropriate include:

Any multi faceted angular face (including radial depressions) scan body e.g.
Densys Scan Body, Straumann Scan Body, Sirona Scan Body

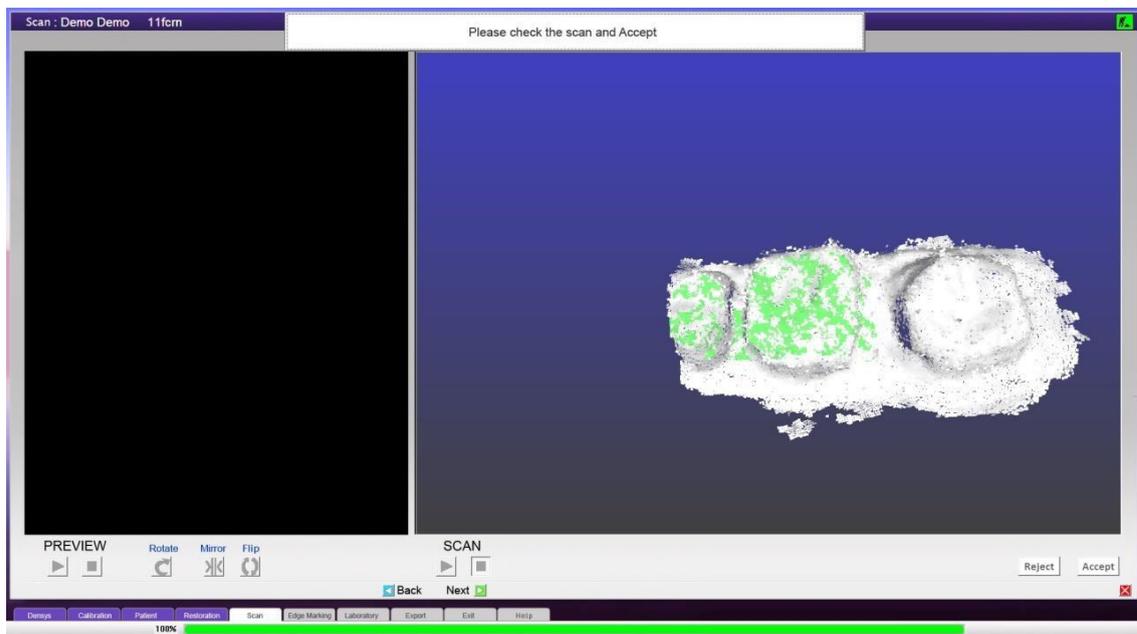
Densys cannot guarantee a successful scan with other implant parts or scan bodies

3. When you are satisfied that you have scanned all the areas of the tooth required for a successful restoration, stop the scan by using the same methods as for starting the preview/scan:
 - a. Click the Stop  button under the SCAN window with the mouse
 - b. Press once again on the space bar on your keyboard
 - c. Press once again on the Foot Pedal

The scan can be viewed by using the mouse, for zoom, pan and rotation.

During the processing time of the scan a green progress bar at the bottom of the screen indicates the scan completion percentage.

When processing is finished (the bar has completed its progress) a message pops up asking you to accept or reject the scan and the **Accept** and **Reject** buttons are enabled.



4. Click **Accept** to accept the scan or **Reject** to redo the scan.

Scan Dialog Screen

After accepting the scan, the application presents you with a number of options. To activate an option, mark the circle next to it and click in the checkbox under the options list:

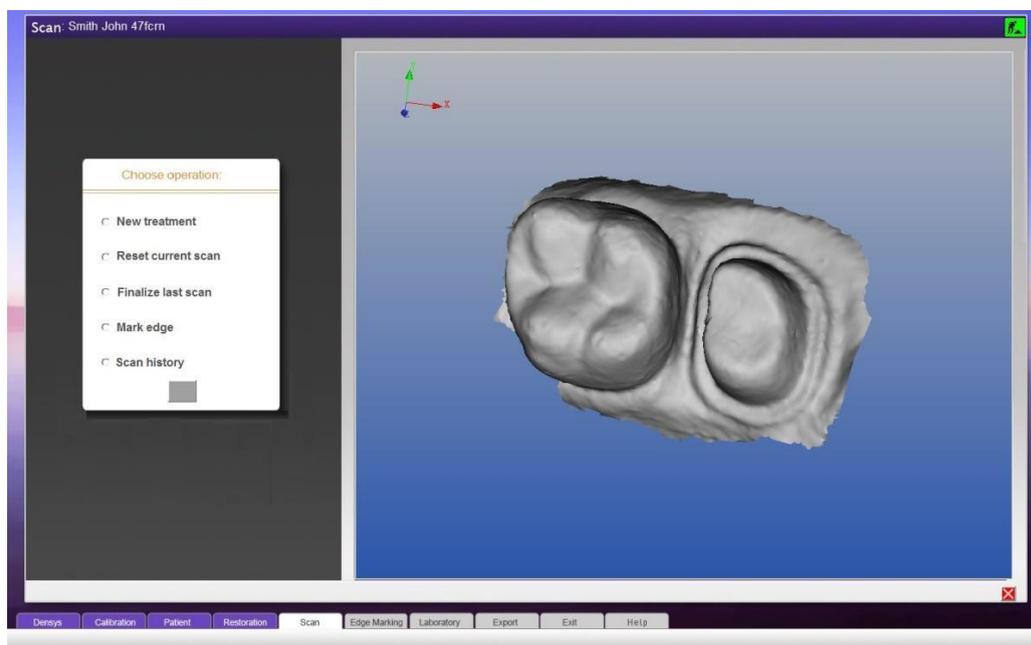
New Treatment — saves the current scan and returns to the restoration screen for initiating a new dental scan for this same patient.

Reset current scan — deletes the current scan data, and returns you to the start of the process in the restoration screen.

Finalize last scan — Reprocesses the scan data to generate a higher resolution 3D image of the scan. This phase can be delayed until later when patient is not present.

Mark edge — Opens the Edge Marking utility kit (refer to Mark Edge section)

Scan History — Moves to the Scan History page.

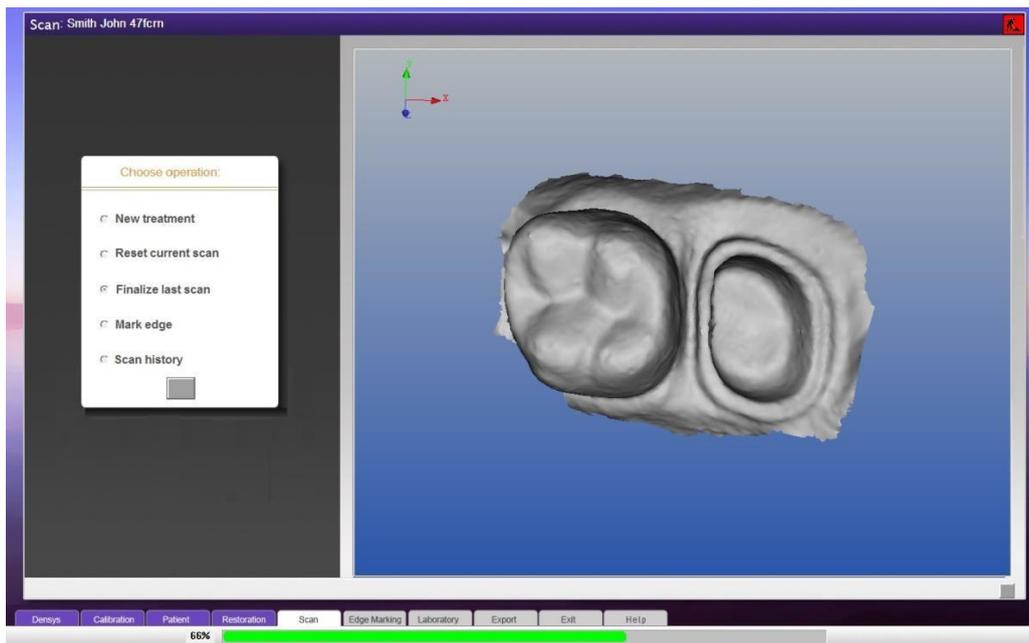


Finalize Last Scan



NOTE: The operator must wait for the scan finalizing to finish to continue scanning

Finalize last Scan gives a higher resolution scan that many operators prefer to work with. When the scan finalizing is in process a task bar shows underneath the screen to the process of the calculation. During this time the scanner will not be available for further scanning. Therefore experienced operators may prefer to finalize after completion of all the clinical scans



Edge Marking

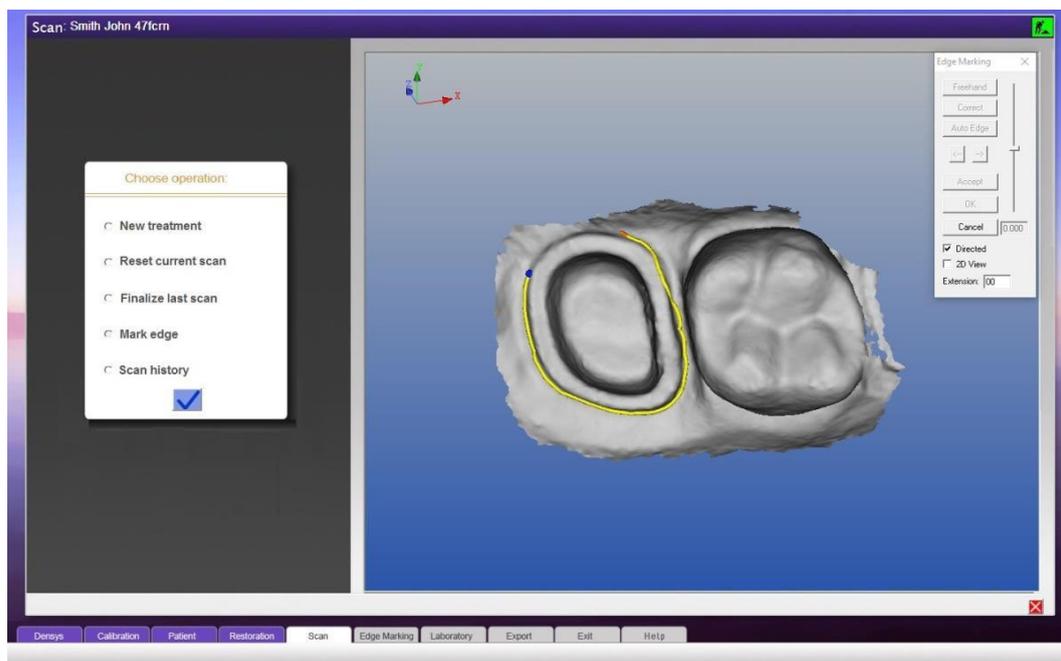


NOTE: Edge marking is essential in restorative virtual impressions to enable an accurate and clearly defined margin for prosthetic manufacture.

Edge marking is required for all scans of prepared teeth for prosthetic restoration

Edge Marking can be activated from two different wizard screens:

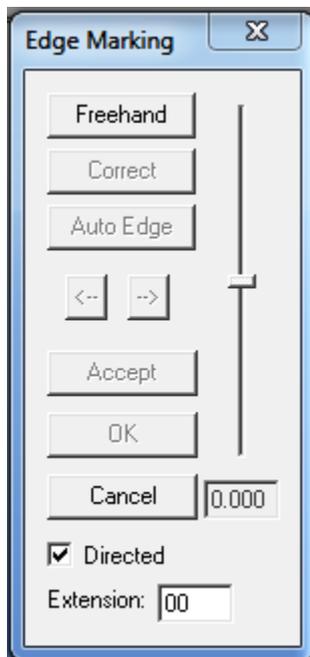
1. Selecting "Mark edge" in the Scan Dialogue screen will open the Edge Marking utility kit.
2. Selecting "Mark edge" in the Scan History Screen.



Once the Edge Marking operation is selected, an **Edge Marking** menu appears in the upper-right hand of the screen:

- To zoom, turn the central mouse wheel.
- You can move between different views of the chosen image to help you more accurately place the pitons that define the edge.
- To rotate the 3D view, click and drag the left mouse button.
- To move the view, click the right mouse button and drag the view.
- To zoom in or out, use the central mouse wheel.

Defining the Edge



To define the edge:

1. Click the **Freehand** button.
2. To place the first piton, point the mouse at a location as near the edge as possible and click once.
You can then circumvent the tooth and a line is automatically placed.
3. Place another piton with a single mouse click.
4. Continue placing pitons around the tooth until you return to the first piton.
5. To complete the edge marking, right click on the first placed piton.
6. After completing the line all the placed pitons will be visible.

You can adjust the contour line in several ways:

- Dragging pitons
- Small step adjustments
- Replacing all the pitons

Adjusting the contour line shape by dragging pitons:

1. Point the mouse cursor at a piton.
2. Click once — hold the mouse down and drag the piton to the desired position.
3. Release the mouse button to deposit the piton.

If there is a contour line it will be updated according to the piton's new location.

Adjusting the contour line in small steps:

1. Add an additional piton by clicking a spot on the contour line.
2. Use this piton by clicking it once and move/drag the contour line.

Correcting the contour line by replacing the pitons:

1. Click the **Correct** button.
All the pitons on the contour line will disappear.
2. Place a minimum of three pitons with two of them positioned on the existing contour line.
3. Make a right-mouse click and the new line and contour will replace the old line between the pitons you added.

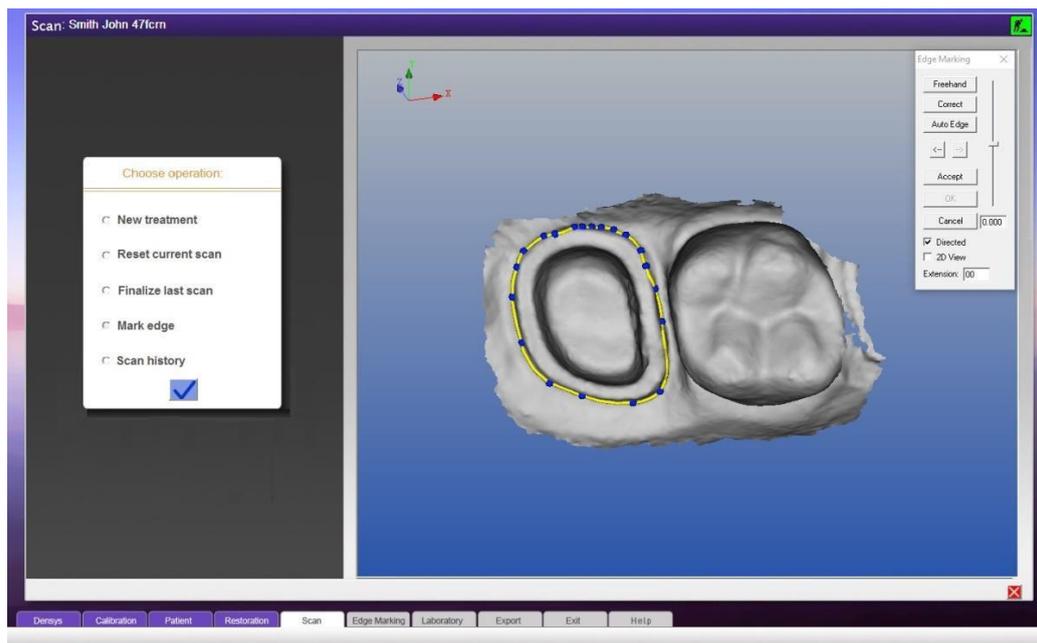
Deleting Pitons

- To delete a single piton point, place the mouse cursor on it and press Delete on the Keyboard.
- To delete all pitons, Click the **Cancel** button in the menu in the upper right corner of the screen (see the above illustration). – Note: This will also remove the contour line between the pitons.

Automatically adjusting the edge marking

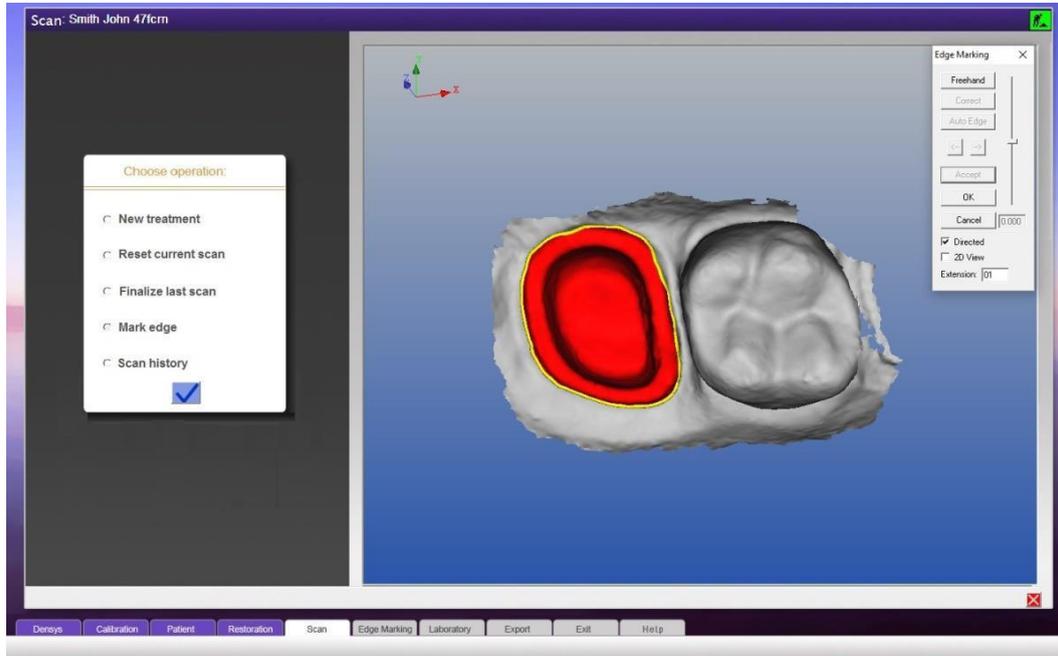
After completing the contour line, there is an option to use the click Auto Edge button. This is a very fine small automatic adjustment of the edge line.

The automatic edge function only works if the edge line is placed within a small distance of the correct clinical edge.



Accepting the edge marking

When you are satisfied that the edge marking is complete click **Accept** to show the isolated preparation and to save the edge marking.



To create a second edge marking line of another preparation, start the process again by clicking the **freehand** button (see the illustration on page 39).



Note: This will only work if you have accepted and saved the previous edge marking. If you click the **Freehand** before accepting the edge marking, the placed pitons with the contour line will disappear.

To exit the interactive function click **OK** in the corner of the Edge Marking screen.

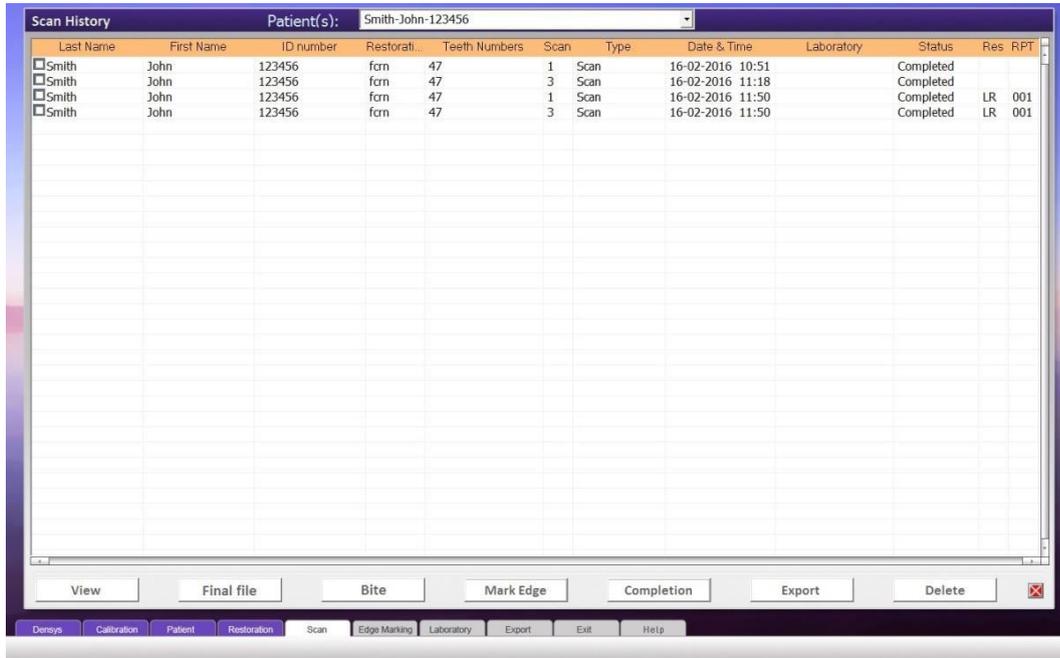
Select one of the following options:

- To exit the edge marking process .
- To export the files resulted from the edge marking process, click Export.

Scan History

The Scan History page can be opened from the Exit screen (refer to Exit Screen) or from the Existing Patient screen (Refer to Existing Patient Screen).

The Scan History screen displays all the saved scans of the patient and enables various actions regarding the scans.



Scan History											
Patient(s): Smith-John-123456											
	Last Name	First Name	ID number	Restorati...	Teeth Numbers	Scan	Type	Date & Time	Laboratory	Status	Res RPT
<input type="checkbox"/>	Smith	John	123456	fcrn	47	1	Scan	16-02-2016 10:51		Completed	
<input type="checkbox"/>	Smith	John	123456	fcrn	47	3	Scan	16-02-2016 11:18		Completed	
<input type="checkbox"/>	Smith	John	123456	fcrn	47	1	Scan	16-02-2016 11:50		Completed	LR 001
<input type="checkbox"/>	Smith	John	123456	fcrn	47	3	Scan	16-02-2016 11:50		Completed	LR 001

The columns in the Scan History screen from left to right are:

- A box for option selection – to select one or more of the scans to view
- Last Name – of the Patient the scan pertains to
 - First Name - of the Patient the scan pertains to
- ID no. - of the Patient the scan pertains to
- Restoration – Restoration Type of the scan
 - Qcrn - 3 Quarter Crown
 - Addn - Scan Completion
 - Cpng - Coping
 - Fcrn - Full crown
 - Inly - Inlay, Onlay
 - Mndb - Mandibular Full Mouth
 - Mxlr - Maxilla Full Mouth
 - Occl - Opposing Occlusion

Qdrt - Quadrant Scan

Vner - Veneer

Bccl - Buccal

Pntc - Bridge

- Teeth numbers – Which teeth were selected for the scan
- Scan – Number of scans performed on the same set of defined teeth
- Type – Scan Type
- Date and Time – Date and time the scan was taken.
- Laboratory – What Laboratory the scan has been exported to
- Status – displays the scan status (Completed / Not Completed)
- Res – Displays HR if the scan is in high resolution
- RPT – Number of times this scan has been finalized

Click on one of the action buttons in the lower portion of the screen to activate a function according to the different sections in this User Manual.

The different buttons are:

View – Can view up to 8 different scans (refer to View)

Final File – Reprocesses the scan data to generate a higher resolution 3D image of the scan. This phase can be delayed until later when patient is not present.

Bite – Prompt you to the Bite Screen. (Refer to Bite)

Mark Edge – Opens the scan with the edge marking utility. Can only open one scan for edge marking. (Refer to Edge Marking)

Completion – Opens the Scan Completion screen. Only choose 2 scans. (refer to Scan Completion)

Export – Prompts you to the Laboratory Screen to choose a laboratory to export the selected scans to. (Refer to Export)

Delete – Deletes any selected scans

View

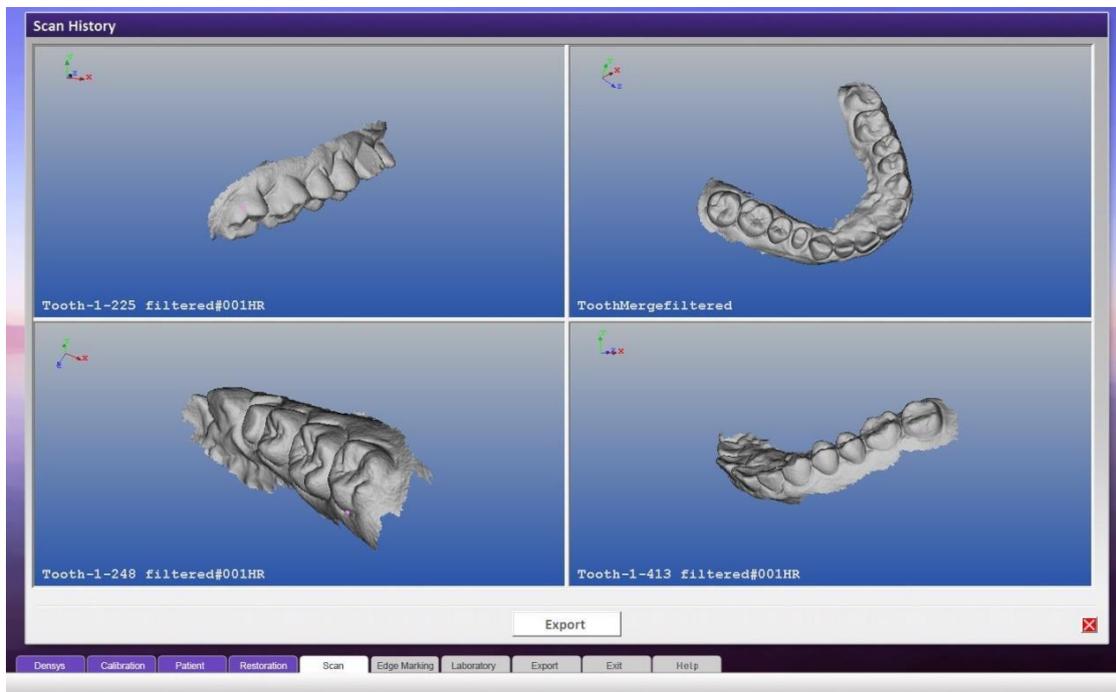
The View Screen can display up to 8 scans.

Each of the views can be independently manipulated with the mouse.

To zoom – Rotate the mouse wheel.

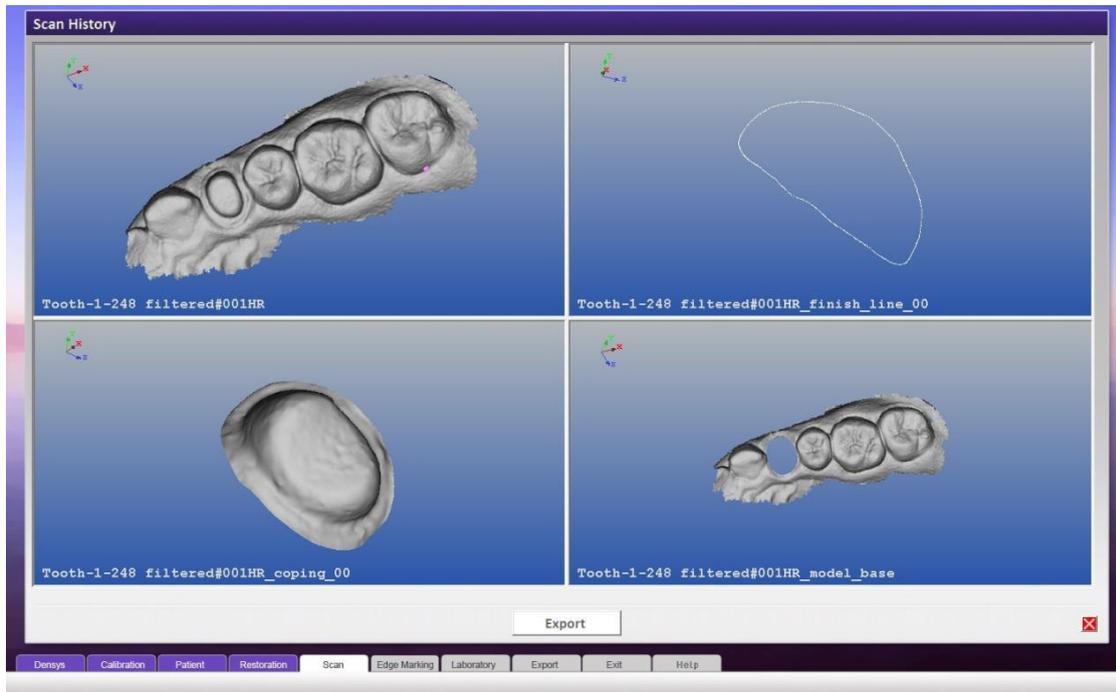
To Pan – Right click and drag.

To Rotate – Left click and drag.



The different edge marking outputs can be displayed in the View screen

1. Select the different output files of the edge marking.
2. Click on the View button on the bottom of the screen.



Bite

Prior to activating the Bite from the Scan History screen, you must have three scans

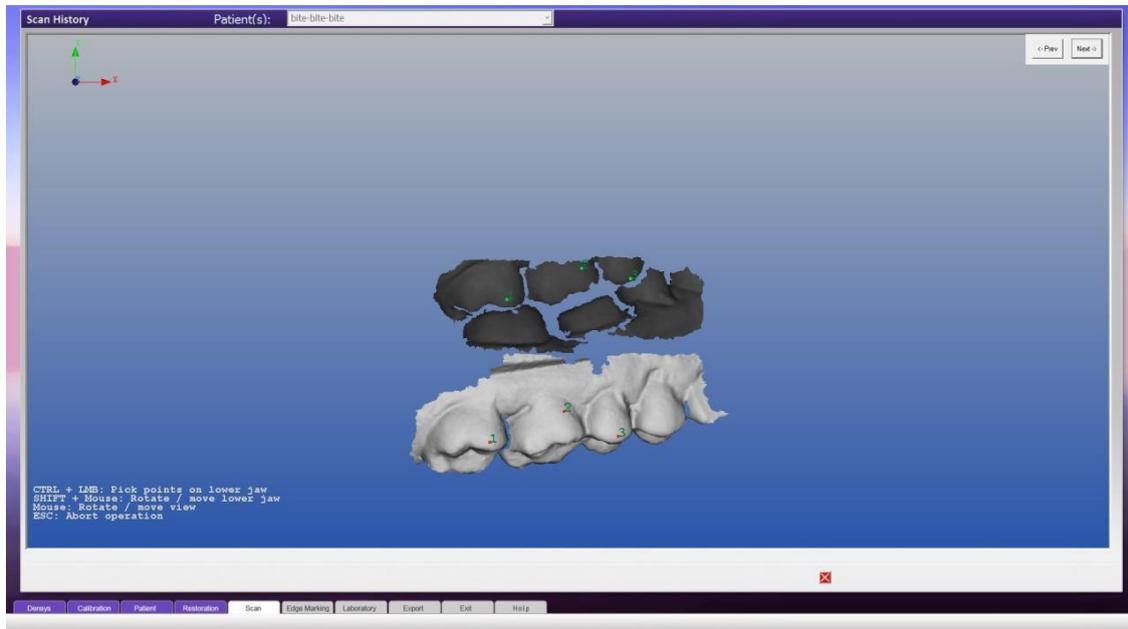
- **Restoration Scan**
- **Opposing Occlusion** – this scan should include the occlusal and buccal surfaces of the opposing teeth to the restoration
- **Buccal Scan** – this scan should include the buccal surfaces of both teeth in the occluded position

The scans should start from the same area in the mouth, e.g. distal or mesial. This will bring them into the same alignment in the Bite screen.

To activate the Bite:

1. Mark the box in the left-hand column of each of the above scans
2. Click the BITE button (at the bottom of the Scan History screen).

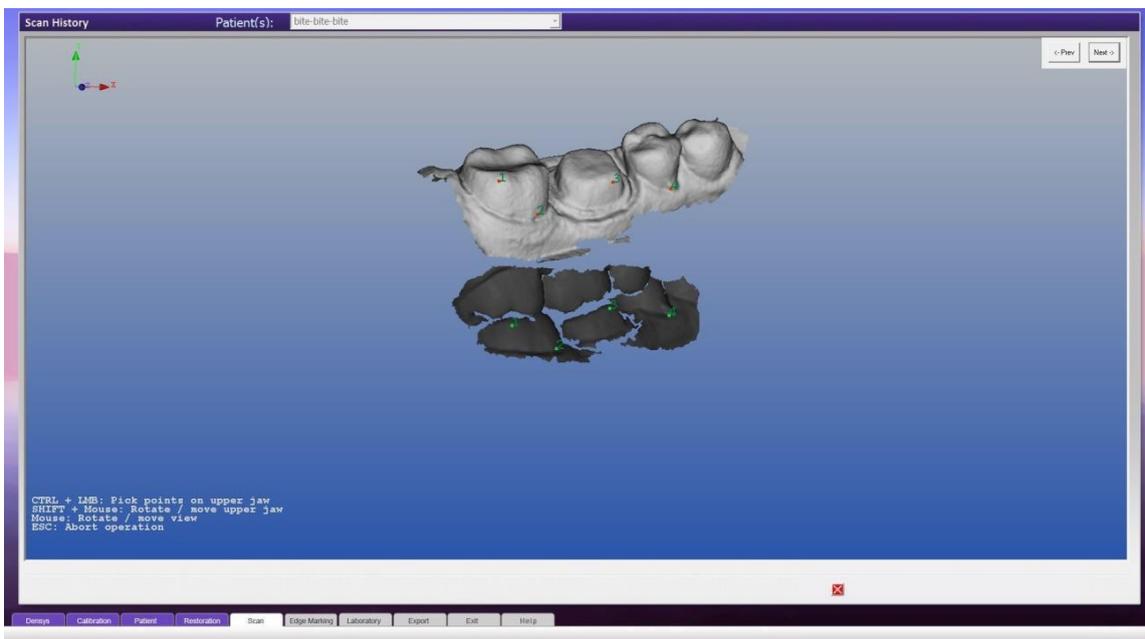
The application displays the Buccal scan and one other scan.



The lighter colored scan is the active scan.

At any time you can press **Escape** to abort the operation and **I** to toggle the instructions at the bottom left corner of the screen.

3. Manipulating the Scan Views:
 - To Rotate the scans – drag the left mouse button.
 - To Move the scans – drag the right mouse button.
 - To rotate or move only the active scan - Shift + left/right mouse button.
4. Press Control + the left mouse button to mark the scan in at least three points, preferably on different teeth and at different height. The points marked will appear as sequential numbers.



5. To remove a marked point, click the **Previous** button (upper right-hand corner of the screen).
6. When finished click the **Next** button - The active scans will change to the passive scan and vice versa.
7. Position the scan for convenient viewing.
 - a. Mark the scan in the same tooth and in approximately the position as in the previous scan with the numbers matching.
 - b. When finished, click **Next** and the third scan will appear on the screen.
 - c. Repeat the sequence of actions of the first two scans.
 - d. Click **Next** to finish the alignment.

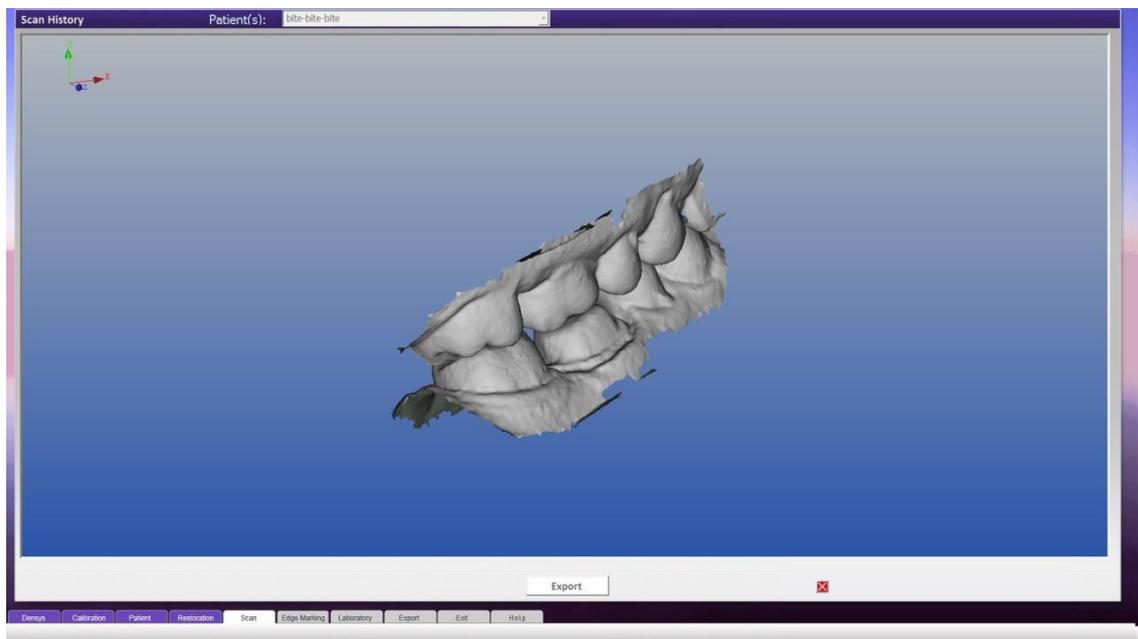
The Bite will be shown in Automatic Best Fit from three different perspectives:

- On the right hand side of the screen is the Bite
- On the upper-left hand side is the Bite and opposing occlusion.
- On the bottom left is the Bite and buccal.

Any interferences or high areas in the collusion appear in highlighted colors.

As the best fit automatic Bite is an ideal situation and may need manual intervention, you are able to manipulate the Bite in the right hand side of the screen.

8. Manipulate the Bite - press SHIFT + left/right mouse button to manipulate the upper jaw.



9. Finish:

To export the files (original scan opposing occlusion, buccal and Bite), click the **Export** button (at the top right of the Bite screen).

Click  to exit the Bite and return to the Scan History

The Bite will appear in the TYPE column as "Bite".

10. To view the Bite, mark the box in the left hand column of the Bite row (in Scan History) and click the **VIEW** button.

Scan Completion / Inserting Missing Areas

Scan completion can be used to add in missing areas or to join adjacent areas, e.g. sextants or quadrants.

Scan completion is semi – automatic.

It will soon be released in a fully automatic version.



NOTE: For all cases there should be an overlap of at least one tooth on the areas to be matched.

Scan Completion can be activated from the **Scan Dialog** screen or the **Scan History** screen.

Scan Dialog screen

1. After the first scan, mark the **Scan Completion** checkbox and click on the box.
2. The application automatically advances to the Restoration screen and selects by default the treatment **Scan Completion**.
3. Click **Next** to go to the Scan screen.
4. Proceed to Preview and Scan (see page 30).
5. Perform the scan.
6. Accept the scan.
7. You will now be prompted the Scan Completion screen



REMEMBER start the scan in the same position and orientation as the original scan

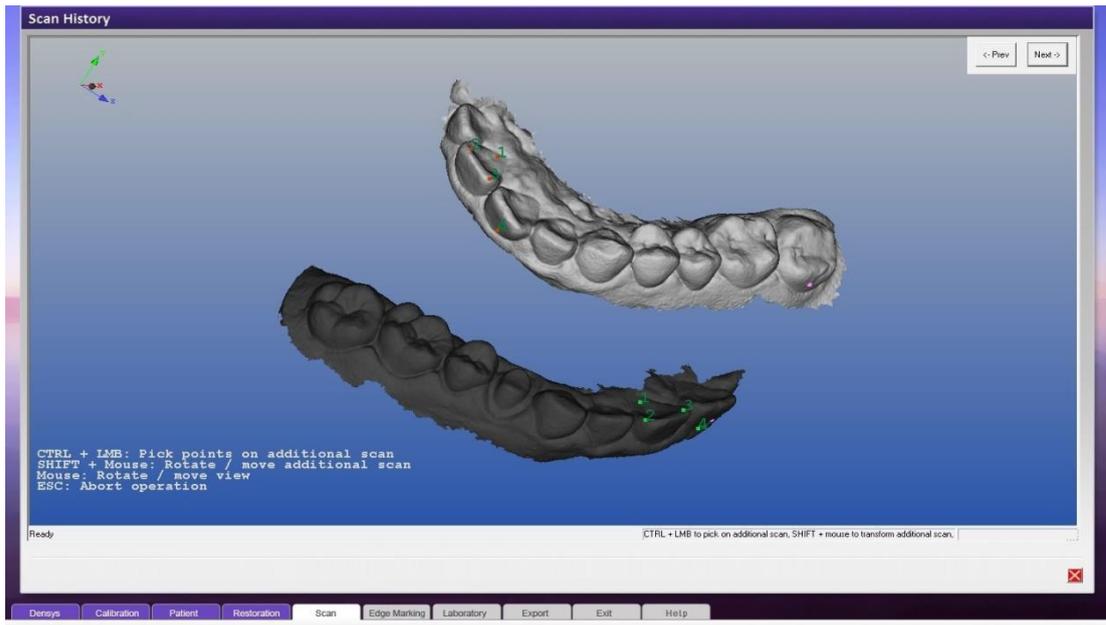
Scan Completion from the Scan History screen

1. In the Scan History screen, mark two scans in the left hand column.
2. Click the **COMPLETE** button (at the bottom of the screen)

You will now be prompted to the Scan Completion screen

Marking the overlapping areas

1. Mark points according to the procedure described in the BITE section (see page 45).
2. Mark the scan in the same tooth and in approximately the position as in the previous scan with the numbers matching.



3. Click on Next.



4. Click on Export to export the scan to a laboratory or click on the  to return to the Scan History screen.

Exporting Scans

After scanning you can export the scan to a laboratory or other party of your choice.

Export is an option in the screens of Scan History, View, Completion and Bite.

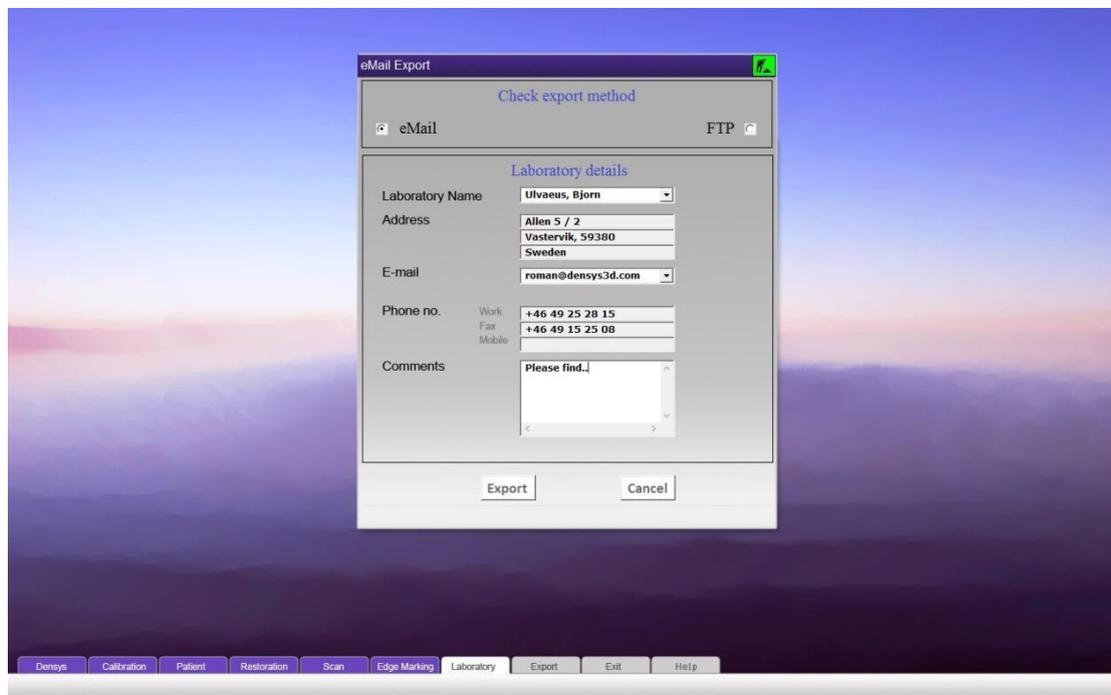
1. Mark **Export Scan**, the wizard advances to the Check Export Method screen
2. Define the Method of your choice by marking the box in the top corner ✓. The left box is for email, and the right box is for FTP – file transfer protocol..



NOTE: Laboratories and FTP are defined in the setup application

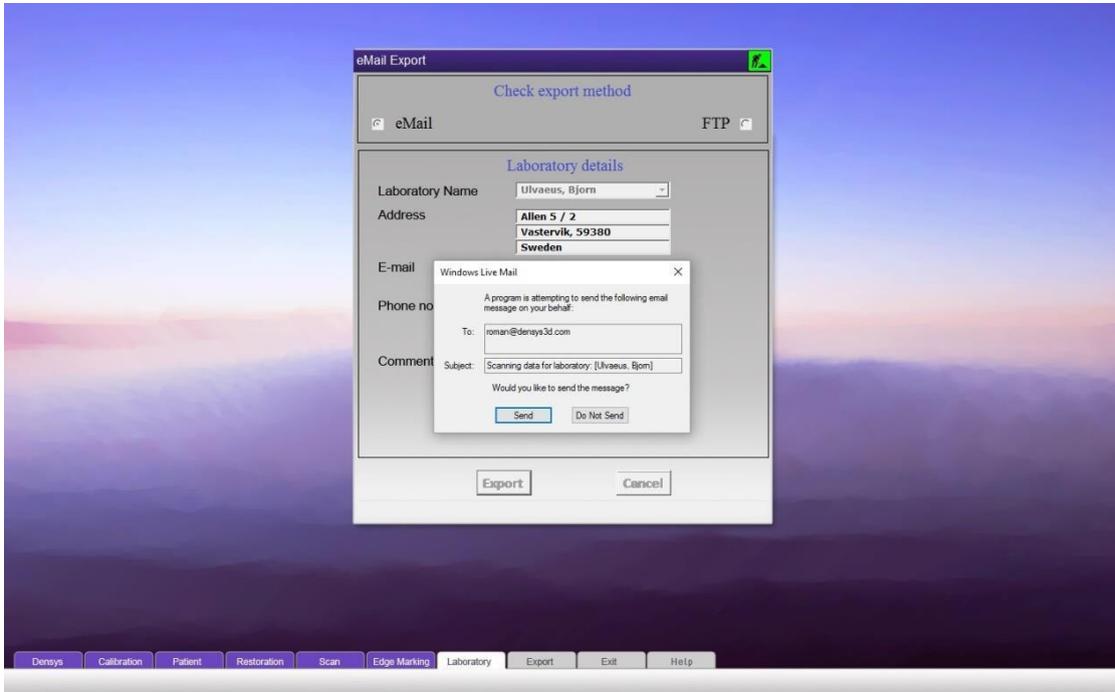
Click on the desired option.

For email

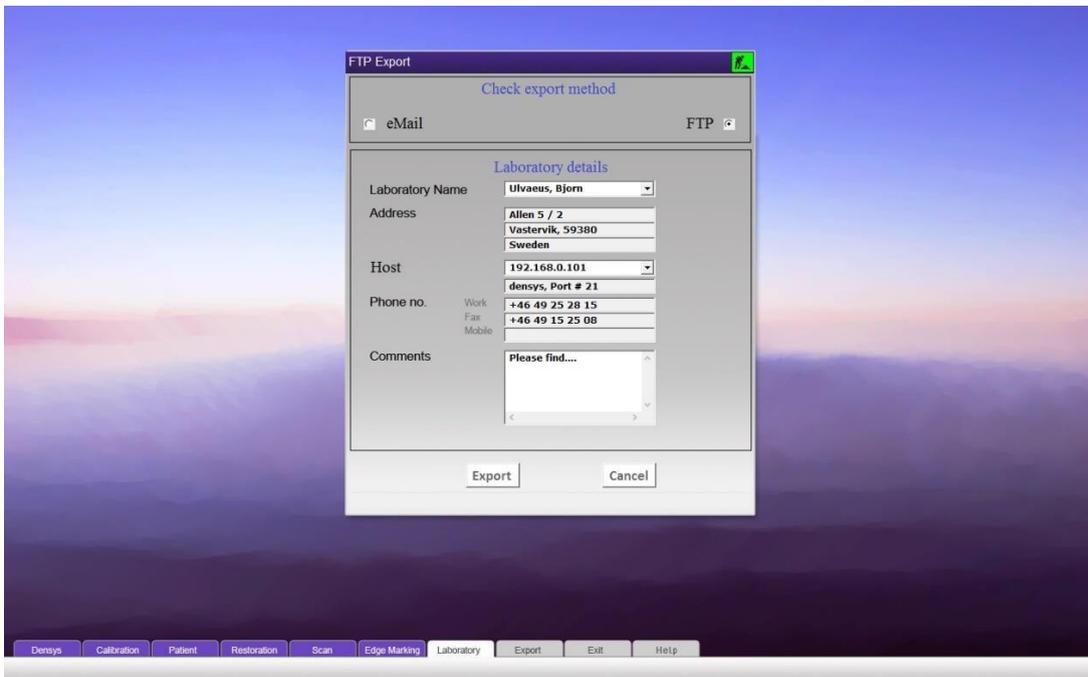


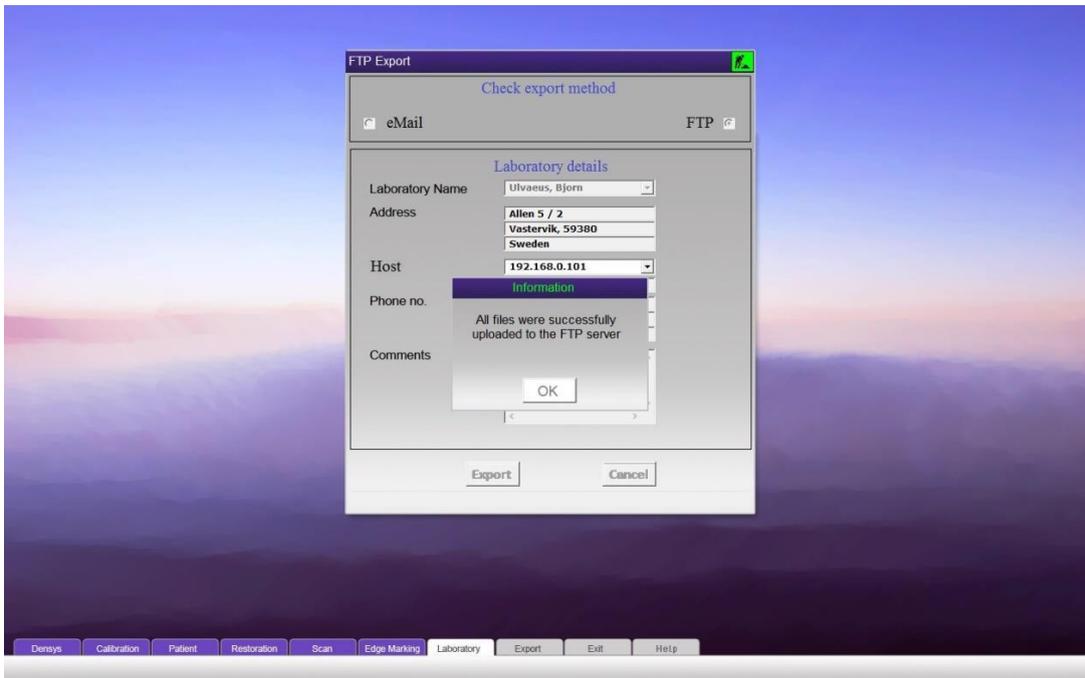
Authorize the mail

3. Use the mail like a regular mail program and send the mail.



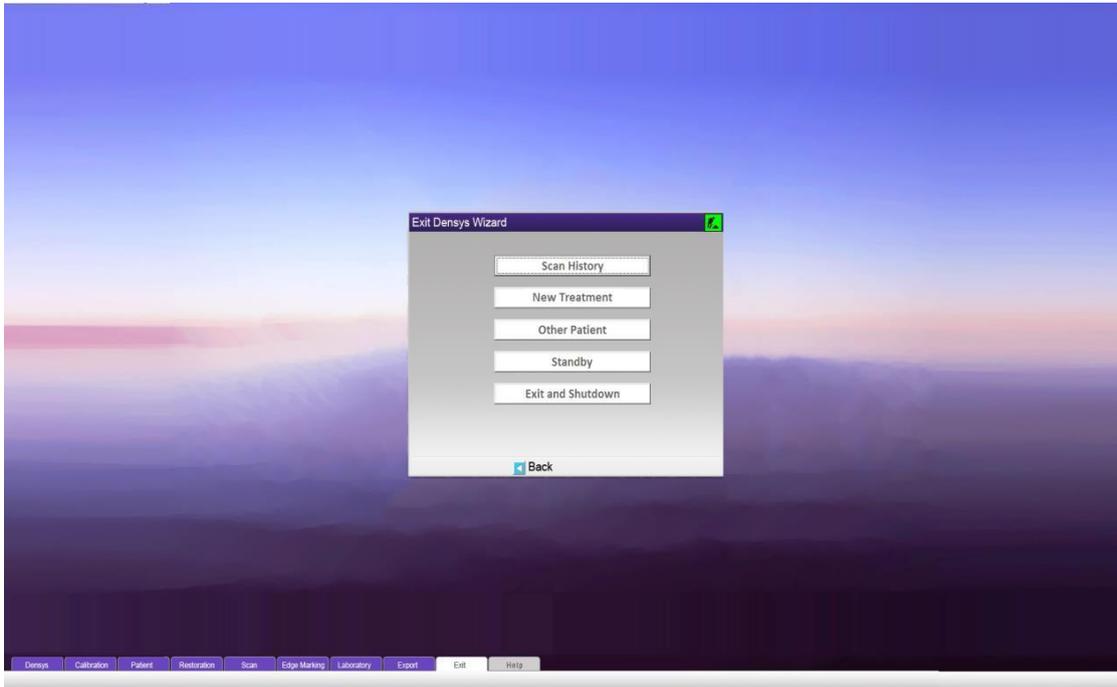
For FTP





Exit Screen

The Exit screen can be opened from the other screens by a click on the  in the bottom right corner.



Available options are:

- Scan History – Opens the Scan History screen.
- New Treatment – Opens the Restoration screen to choose a new treatment for the patient.
- Other Patient – Opens the Patient Details screen to choose between a new or existing patient.
- Standby – Goes into standby and displays a screensaver
- Exit and Shutdown – Shuts down the Mia3d program.

Contact Information

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