

3Shape Medical A/S
Implant Studio®
Implant Planning and Surgical Guide Solution



User Manual

www.3shape.com

Rx only

CE
2797

16-Feb-2022

IS-R1.2-J-EN-US

(2.17.3)

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Warnings and Precautions

Indications for Use/Intended Use



Warning! The US Federal law restricts this device to sale by or on the order of a dentist.



Warning! Prior to using the software on clinical cases, please make sure to have received appropriate training and instructions on how to properly operate the software. In order to receive training, the user should initially contact their responsible national reseller. If specific or advanced training is required, end-users should require their responsible reseller to contact 3Shape in order to organize such trainings. Contact details can be found in chapter [Manufacturer information](#).

Implant Studio Workflow Overview



Warning! Implant Studio® must not be used for aligning CT and 3D optical surface scans in edentulous cases! The available alignment tools are not suited for achievement of reliable and accurate alignment results!

Implant Studio Workflow Steps



Warning! Make sure that the quality of the loaded CT scan is sufficient for planning the case and that the relevant areas on the image for the bone analysis are adequate in order to make an accurate and sustainable decision for implant planning and surgery!



Warning! The user needs to ensure that the surface scan is of the required quality for planning the case, and that the relevant areas for the implant planning and placing the surgical guide fully exist.



Warning! Please make sure that the denture segmentation threshold is set such that the segmented denture reflects the exact shape of the real denture. This is to ensure that the shape of the real denture is successfully transformed into a surgical guide. Do not continue your work before this is achieved.



Warning! Make sure the created bone surface model matches the CT scan at least in the areas where you want the guide to rest. An improper model results in a poorly fitting guide.



Warning! It is crucial that the bone surface model is created correctly. It is up to you to adjust and confirm the model. The initial state can be used as a starting point but should be adjusting manually for a proper model creation. Expect to spend some time adjusting and inspecting to find a good fit.



Warning! It is important that you inspect how well the bone surface model fits the bone in the CBCT scan. Continuing the workflow with an imprecise bone surface model can lead to a bad fit of the resulting guide.



Warning! Please make sure that the nerve is correctly placed and that you have chosen the appropriate size of the nerve canal diameter to compensate for potential inaccuracies in the nerve position!



Warning! If the nerve position is not clear due to poor CBCT/CT image quality, the dataset must not be used!



Warning! Please make sure that the presented screenshots and information for the implant positions and implant types as well as, eventually, the surgical guide in the Surgical Report are sufficient in order to make a clear and safe decision to approve or modify the implant or surgical guide position and design.



Warning! Please follow the instructions in the drill protocol.



Warning! If the alignment process is not conducted on the basis of high-quality scans, the foundation for the implant planning procedure is not present.



Warning! Make sure that all relevant markers have been identified in both scans and that the scans are well aligned, particularly in areas where the implants will be placed. Do not continue your work before this is achieved!



Warning! Make sure that you use 2D views, the 3D window and the available alignment quality tools to assist you while using the manual alignment tool. Before confirming the alignment with any manual changes, make sure that scans are well aligned in all relevant areas and not only in local regions.



Warning! To modify the position of an already placed implant, hover the cursor over the implant to drag it in both the 2D views and the 3D window, please assure that the CBCT/CT and surface scans are well aligned, particularly in the area(s) where the implant(s) will be placed. Please check these also for the alignment in the 2D cross section views.



Warning! Please make sure that the correct implant type incl. platform type/ length and diameter is chosen according to the patient clinical situation. Please consider this in particular when planning an implant case near a main anatomical feature like artery or alveolar nerve.



Warning! Be aware that not all displayed implant systems may have regulatory clearance in all countries. Please direct any questions regarding regulatory status in your country towards the implant manufacturer or reseller.



Warning! Please assure that an implant does not collide with an existing implant or tooth root channel. Also, assure that the implant has sufficient bone support in the jawbone including the apical end of the implant.



Warning! During implant placement, please consider that the bone-density in reality can be different than the visualized bone-density displayed on the screen. Please see [Visualization Toolbar](#) section for more details.



Warning! Please always make sure to use the optimal minimum size of the implant/anchor pin/nerve safety zone, accounting for the surgical procedure and choice of surgical tools. A collision between implants/anchor pins or a collision with any other main anatomical structure can cause severe damage, paresthesia and other complications to the patient.



Warning! The user must be able to recognize red and green colors to detect warnings such as *"Collision between implant and nerve"*.



Warning! In case of collision between implant and nerve or between implants, the software will disable access to further steps, i.e. creation of report, protocols as well as the surgical guide design step.



Warning! Please check for potential collision between the sleeves, the visualized drill cylinders and any existing tooth or dental restoration and consider the consequences for the intended treatment procedure. Note that in case of the sleeve collision, all further steps will be disabled.



Warning! The surgical guide should sit stably and firmly in the patient's mouth, and it must not move during surgery. This is to ensure optimal guidance for the drills and implants during surgery. If the guide is bone-supported, visually check that it won't interfere with a nerve before placing it. **Do not use the surgical guide unless you judge the fit to be optimal, safe and completely correct.**



Warning! Before you start using a surgical guide from a new supplier or machine for the first time, we strongly recommend that you validate the physical and functional quality plus the accuracy of the surgical guide! It is the responsibility of the guide manufacturer to ensure that the equipment used is capable of producing surgical guides suitable for guided surgery.



Warning! Be aware that colored areas on the edentulous surgical guide are representing areas that could potentially affect the bite alignment of the guide to the opposing jaw. If you find any critical colored areas, we strongly advise you to reconsider your implant planning, sleeve type and sleeve positioning before continuing.



Warning! When placing a surgical guide in the mouth of an edentulous patient, make sure that it is aligned properly to the opposing jaw. After fixating the guide in the correctly aligned position, it is important to ensure that it sits stably and firmly in the patient's mouth, and that it cannot move during surgery. Do not use the surgical guide unless you judge the alignment and fit to be optimal, safe and completely correct.



Warning! Make sure to design the guide in a way it does not touch the mandibular nerves when placed in the patient's mouth, as this could harm the patient.



Warning! Make sure you consider the mental foramen when designing a bone supported guide. An improper guide design can damage the nerves when placed in the patient's mouth.



Warning! Please refer to the surgical guide manufacturer for information related to material thickness and offset parameters.

Indications for Use

INDICATIONS FOR USE

3Shape Implant Studio® is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in dental implantology and surgical dentistry. This software reads imaging information output from medical scanners such as CT and optical scanners. It allows pre-operative simulation and evaluation of patient anatomy and dental implant placement.

Surgical guides and the planned implant position can be exported as 3D models and the guides can be manufactured using said 3D models when used as input to 3D manufacturing systems.

INTENDED CONDITIONS OF USE

Implant Studio® is to be used in dental clinics and dental laboratories.

CONTRAINDICATIONS

There are no specific contraindications. It is the user's responsibility to assess whether some specific treatment planning decisions can be carried out in practice during the treatment.

INTENDED PATIENT PROFILE

Patients with intraoral defects such as missing teeth or parts of teeth who are being considered for treatment with dental prosthetics.

INTENDED USER PROFILE

Implant Studio® must be operated by trained dental practitioners and dental technicians who are skilled in implant dentistry.



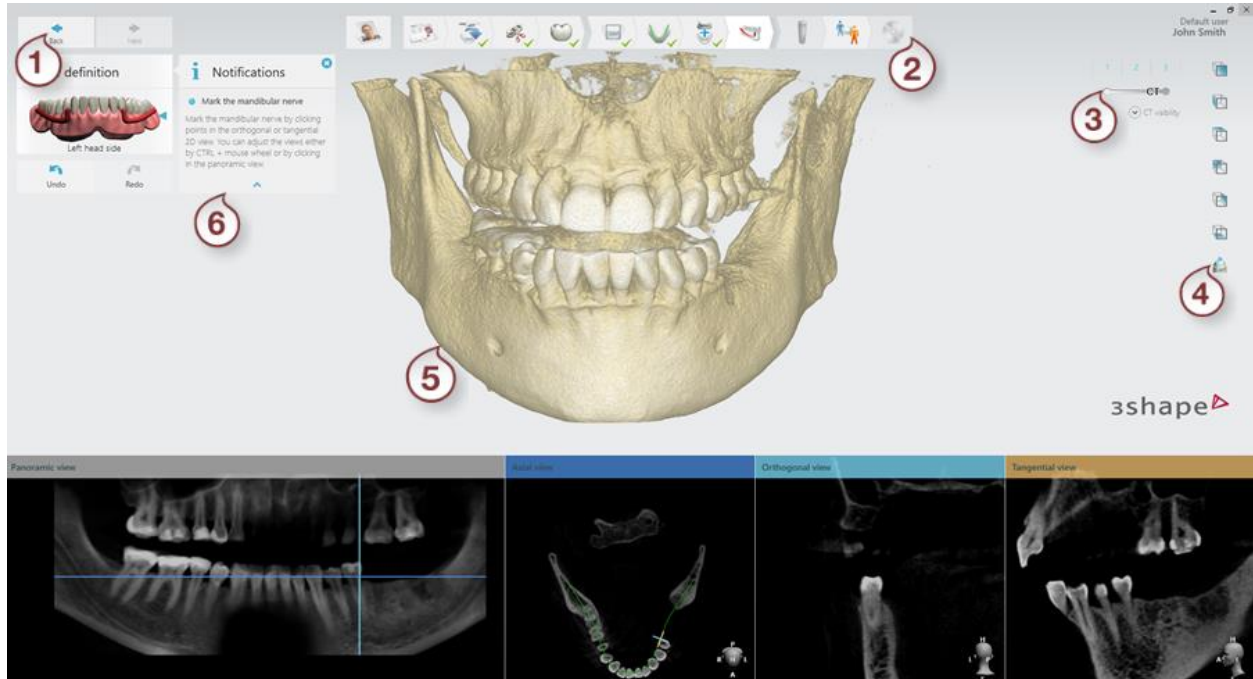
Warning! The US Federal law restricts this device to sale by or on the order of a dentist.



Warning! Prior to using the software on clinical cases, please make sure to have received appropriate training and instructions on how to properly operate the software. In order to receive training, the user should initially contact their responsible national reseller. If specific or advanced training is required, end-users should require their responsible reseller to contact 3Shape in order to organize such trainings. Contact details can be found in chapter [Manufacturer information](#).

1 Using the Software

The following section describes some of the common parts of the software you will interact with.



(1) Navigation Buttons

(4) Viewing Tools

(2) Workflow Bar

(5) 3D Window

(3) Visualization Sliders

(6) Notifications

SOFTWARE NAVIGATION

You can navigate through Implant Studio with the help of the navigation buttons or using the workflow bar:



Clicking on the icons allows you to move between steps. The step is complete if an icon displays a check mark ✓ (1). Icons that are highlighted in white (2) show you which step you are currently on. Greyed out icons mean the steps are disabled until the previous workflow tasks are completed.

To find more information about the steps, go to [Implant Studio Workflow Steps](#).

DESIGN TOOLS

The panel on the left holds the available design tools and settings for each design step.

Here you also have the option to Undo  or Redo  the actions performed in each design step.

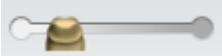
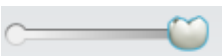
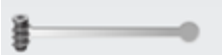
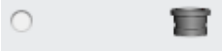
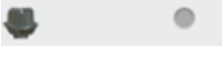
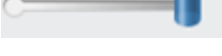
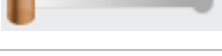
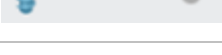
VISUALIZATION TOOLBAR

The Visualization toolbar in the upper right corner of the modeling window allows you to change the model viewing modes and offers the following tools.

VISUALIZATION SLIDERS

Visualization Sliders control the transparency of the models in the 3D window.

Use the Visualization sliders to turn on/off the visibility of the following features:

Slider	Model	Shortcut
	Preparation	S
	Antagonist	A
	Gingiva	
	Active Item	
	Implants	
	Sleeves	
	Generic Abutments	
	Implant Insertion Directions	
	Drilling Cylinders	
	Bone Density	

	Center View Clipping	
	CT Opacity	

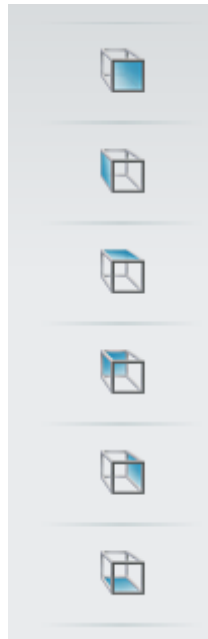
Setup the default views

The software can save the default views under the **1 / 2 / 3** buttons, so that when you click a number, the corresponding default view is displayed.



AUTO-POSITIONING BUTTONS

You can inspect your model from different angles by clicking the corresponding Auto-positioning buttons.



CROSS SECTION

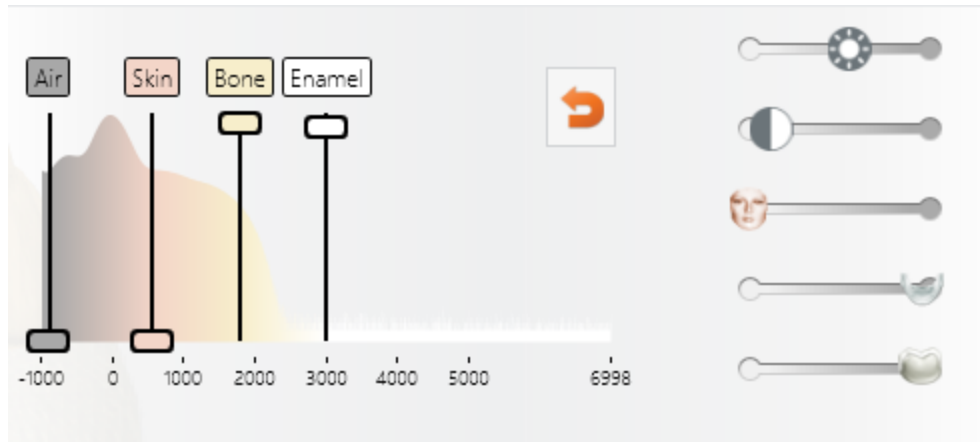
The 2D Cross-section tool allows for inspection and measurement of the dental models.

Enable the **Cross-section**  tool using the button or the **X** shortcut. Define a cutting plane by dragging a line across a section of the 3D models while holding down the left mouse button.

ADJUST CBCT/CT SCAN VISIBILITY

► **Step 1: Click the CT visibility button below the Visualization sliders**

This will open the CT Element Visibility with the sliders for **Air**, **Skin**, **Bone** and **Enamel** visibility.



► **Step 2: Click and drag the sliders to setup the desired CBCT/CT scan visibility**

► **Step 3: Click the *Reset* button to discard changes you have made and return to the default CT visibility settings**

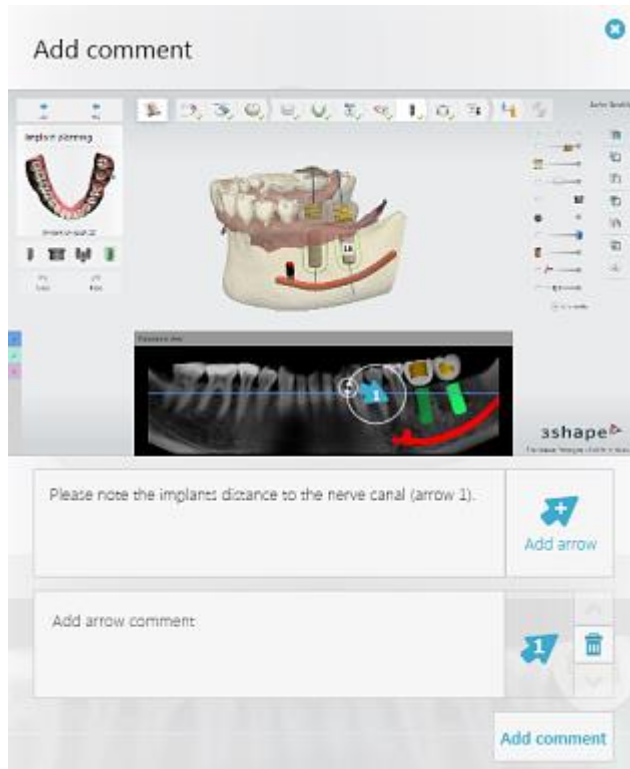


Note! Please use the visualization settings for the CBCT/CT scan and the ability to adjust the grey values to find the optimum for each individual scan.

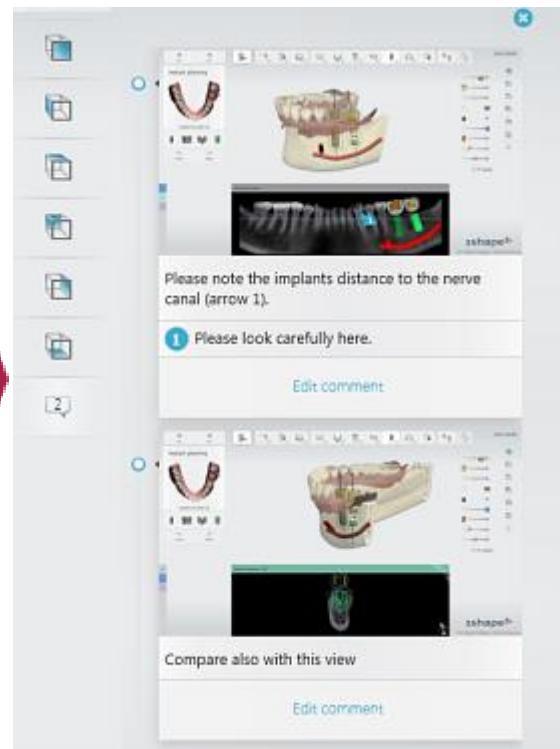
SCREENSHOT TOOL



Click the **Create a screenshot** button, either in the header of a 2D view or on the right side of the screen, to use the **Screenshot** tool. Once clicked, the tool takes a screenshot and opens the Add comment window **(1)** where you can add comments and arrow pointers with text to your screenshot. This additional information will be available under **Show comments (2)** in the 3D window.



(1)



(2)

Once the order has been approved, the screenshots and comments are saved in the surgical report.

NOTIFICATIONS

There are three types of notifications:



The red notifications are violations in the design that must be corrected.



The yellow notifications are observations that can be corrected or accepted.



The blue notifications are hints that contain explanatory text for the chosen step.

MEASUREMENTS



Note! All the measurements in the software are presented either in millimeters or in degrees unless otherwise specified. Both are accurate to two decimals (± 0.005).



Note! The presented bone density value is based on the provided DICOM scan information. The real bone density might differ from the one shown on the screen. For more details please contact your CT manufacturer.

2 Implant Studio Workflow Overview

3Shape Implant Studio® offers three workflows for implant planning and guide design depending on a patient's case:

Tooth-Supported



Patient	Input	Output
Patient with teeth	CBCT/CT scan + Surface scan	Tooth-supported guide

In this workflow you design a guide based on a surface scan of the patient's teeth.



Warning! Implant Studio® must not be used for aligning CT and 3D optical surface scans in edentulous cases! The available alignment tools are not suited for achievement of reliable and accurate alignment results!

Edentulous: Dual Scan Protocol

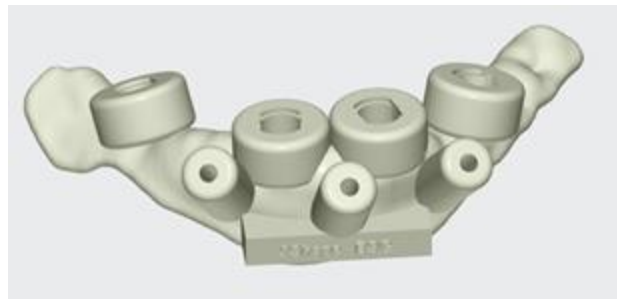


Patient	Input	Output
Edentulous patient	CBCT/CT scan of a patient with	Guide based on denture

	denture + CBCT/CT scan of denture only	(3 design solutions to choose from)
--	--	--

In this workflow you design a guide based on the patient's denture. To work with the edentulous **Dual Scan Protocol** case, you need to import a CT scan of the patient wearing the denture with radiopaque markers and a second CT scan of the same denture scanned alone.

Edentulous: Bone Supported



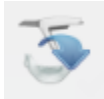
Patient	Input	Output
Edentulous patient	CT scan of a patient	Bone-supported guide

In this workflow you design a guide that will rest on the jawbone of the patient. To work with the edentulous **Bone Supported Guide** case, you need to import only a CBCT/CT scan of the patient's head.

3 Implant Studio Workflow Steps

The Implant Studio workflows are divided into workflow steps. These workflow steps are described in the following sections. Which of them are available depends on which workflow you have chosen.

3.1 Scan Import



The **Scan import** page allows you to load the necessary scans for the workflow if you haven't scanned them as part of the workflow.



Warning! The user needs to ensure that the surface scan is of the required quality for planning the case, and that the relevant areas for the implant planning and placing the surgical guide fully exist.



Warning! Make sure that the quality of the loaded CT scan is sufficient for planning the case and that the relevant areas on the image for the bone analysis are adequate in order to make an accurate and sustainable decision for implant planning and surgery!



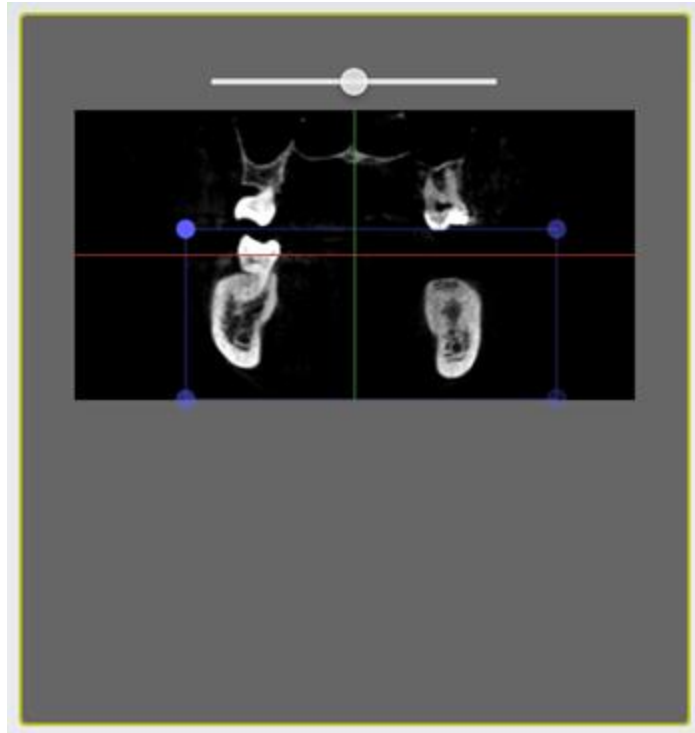
Note! Please check that the scan data is correctly and completely loaded. Also check that the visualization of the CBCT/CT and Surface Scan is working correctly to allow a secure and accurate placement of the implant during the navigated planning and surgical guide design process.

3.2 Cropping



In **Cropping** you can reduce the scan size by cropping the CBCT scan and keeping only that part of a scan that will be used for planning.

Click and drag the corners of the blue cropping box inside the windows to select the part of the CBCT/CT scan that you wish to work with.



3.3 Denture Segmentation

(For **Dual Scan Protocol** workflow only)



In the **Denture segmentation** step, the transformation of the denture CBCT/CT scan into a surface model is performed.

To adjust the model, use the slider.

The **Threshold** slider controls which densities will be included in the resulting model.



Warning! Please make sure that the denture segmentation threshold is set such that the segmented denture reflects the exact shape of the real denture. This is to ensure that the shape of the real denture is successfully transformed into a surgical guide. Do not continue your work before this is achieved.

3.4 Panoramic Curve



In **Panoramic curve** you define a panoramic curve used to visualize and navigate the CBCT/CT scan using 2D views.

The curve is automatically generated but it can also be edited manually.

In the 3D window, move a mouse cursor over the plane and use the available control points to adjust the tilt and position of the plane.

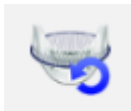
To modify the curve, you can drag the yellow control points in the **Axial** view.



Panoramic curve buttons



Resets the curve to the automatically generated one.



Resets the position of the plane to the initial one.

3.5 Bone Surface Model

(For **Bone-supported guide** workflow only)



In the **Bone Surface Model** step, the transformation of the CBCT/CT scan into a surface model of the bone is performed.

To adjust the bone surface model, use the sliders:

- The **Bone density threshold** slider controls which densities will be included in the resulting model.
- The **Hole closing diameter** will close holes in the model up to the selected size.

Use both the 2D views and the 3D view to inspect the quality of the model before continuing.



Warning! It is crucial that the bone surface model is created correctly. It is up to you to adjust and confirm the model. The initial state can be used as a starting point but should be adjusting manually for a proper model creation. Expect to spend some time adjusting and inspecting to find a good fit.



Warning! It is important that you inspect how well the bone surface model fits the bone in the CBCT scan. Continuing the workflow with an imprecise bone surface model can lead to a bad fit of the resulting guide.



Warning! Make sure the created bone surface model matches the CT scan at least in the areas where you want the guide to rest. An improper model results in a poorly fitting guide.

3.6 Scan Alignment



In this step the scans you have loaded are aligned to each other. The process of alignment depends on the workflow you are in.



Warning! If the alignment process is not conducted on the basis of high-quality scans, the foundation for the implant planning procedure is not present.

1. Tooth-supported:

The software will calculate an initial proposal to an alignment.

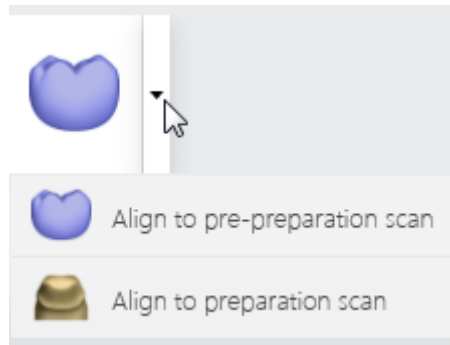


If you want to align the scans manually by three-point alignment press the **Three-point alignment** button. Place three points on the same location in each scan in the windows that show up. It is also possible to mark a region of interest in the views which marks a region that should be of greater interest for the alignment.



Note! Please use only the teeth area while placing the three points for both CBCT/CT and Surface scans and when marking the region of interest.

If you have loaded a preparation scan or performed tooth removal, you can decide which of the scans you want to align to the CBCT/CT scan.



Note! In cases with pre-preparation and preparation scans, the pre-preparation scan and the preparation scan must be aligned to each other prior to loading them into Implant Studio.

2. Edentulous – Dual Scan Protocol:

The radiopaque markers will be placed automatically, however, you can delete them and place new markers instead. Alignment error will be calculated by the software automatically.



Warning! Make sure that all relevant markers have been identified in both scans and that the scans are well aligned, particularly in areas where the implants will be placed. Do not continue your work before this is achieved!

Manual Alignment:

For any workflow, if needed, it is possible to enter **Manual Alignment** to manually adjust the alignment. The mouse and/or the keypad is used to adjust the alignment in the 2D views.



Warning! Make sure that you use 2D views, the 3D window and the available alignment quality tools to assist you while using the manual alignment tool. Before confirming the alignment with any manual changes, make sure that scans are well aligned in all relevant areas and not only in local regions.

Confirm Alignment:

When scans are well aligned in all relevant areas, go to the **Confirmation** sub-step and approve the alignment by marking the **Confirm alignment** checkbox.



Warning! Before clicking the **Confirm Alignment** checkbox, please assure that the CBCT/CT and surface scans are well aligned, particularly in the area(s) where the implant(s) will be placed. Please check these also for the alignment in the 2D cross section views.

3.7 Nerve Definition

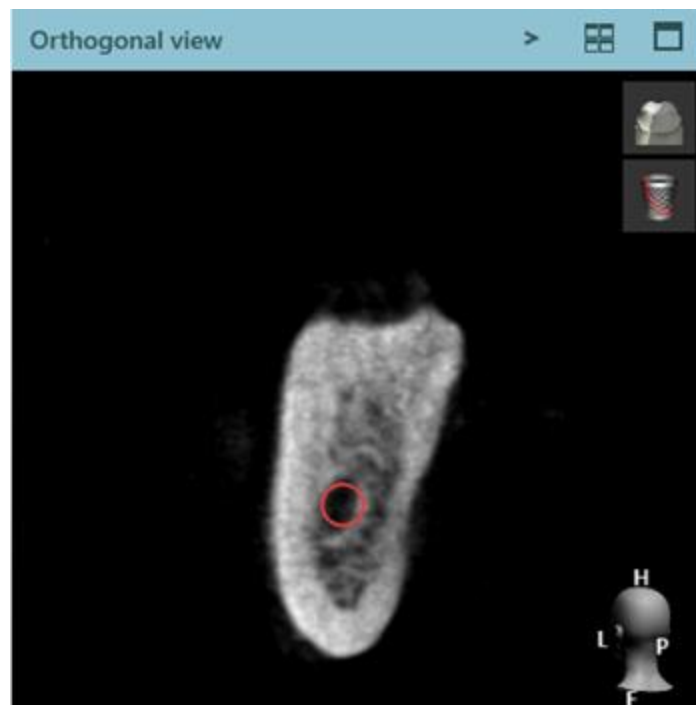


In **Nerve definition** you mark the relevant mandibular nerve canals for your case.

This is done by first navigating to the mental foramen using the **Panoramic** view. Then you can click in the **Orthogonal** view or the **Tangential** view in order to mark the first point of the mandibular nerve. Continue clicking to place more points. You can navigate using the **Panoramic** view to be able to place points along nerve canal in the best possible way.

Adjust the position of the nerve by dragging the placed nerve with the mouse in one of the views, or by starting over.

The size of the nerve can be controlled by holding **Shift** while scrolling the mouse wheel over one of the views.



Warning! Please make sure that the nerve is correctly placed and that you have chosen the appropriate size of the nerve canal diameter to compensate for potential inaccuracies in the nerve position!



Warning! If the nerve position is not clear due to poor CBCT/CT image quality, the dataset must not be used!



Note! Please ensure that the nerve channel is clearly visible in the different views after it is placed.

3.8 Gingiva Detection

(For **Dual Scan Protocol** workflow only)



In **Gingiva detection** the gingival part of the denture should be marked. This gingival surface is used for visualization when planning implants and can be used for the guide design.

The software proposes an initial marking of the gingival surface. This marking can be modified manually using the tools available in the step.

3.9 Implant Planning



In **Implant planning** you perform the placement of implants in relation to the CBCT/CT scan.

Implant type selection

To place an implant, first click the plus button  over one of the teeth in the upper left part of the screen.

This opens the implant selector where you select the desired implant manufacturer, implant line and implant dimensions.



This button allows you to download missing implant libraries.



Warning! Please make sure that the correct implant type incl. platform type/ length and diameter is chosen according to the patient clinical situation. Please consider this in particular when planning an implant case near a main anatomical feature like artery or alveolar nerve.



Warning! Be aware that not all displayed implant systems may have regulatory clearance in all countries. Please direct any questions regarding regulatory status in your country towards the implant manufacturer or reseller.

Implant positioning

When you have selected an implant, use the **2D views** to position it correctly. Use the **Enable clipping plane** option in the **Orthogonal** and **Tangential** views to cut and view the scan accordingly.

To modify the position of an already placed implant, hover the cursor over the implant to drag it either in the 2D views or the 3D window.



Warning! Please assure that an implant does not collide with an existing implant or tooth root channel. Also, assure that the implant has sufficient bone support in the jawbone including the apical end of the implant.



Warning! During implant placement, please consider that the bone-density in reality can be different than the visualized bone-density displayed on the screen. Please see [Visualization Toolbar](#) section for more details.



Note! Please assure that the chosen implant position corresponds to the intended restoration position and the fixation/mounting method for the prosthesis on the implant.

Implant safety zones

Implants have safety zones around them, seen as a green border. If the safety zone border of an implant intersects that of another implant or a nerve, the implant and its safety zone turn red and all the following steps will be disabled.



Warning! Please always make sure to use the optimal minimum size of the implant/anchor pin/nerve safety zone, accounting for the surgical procedure and choice of surgical tools. A collision between implants/anchor pins or a collision with any other main anatomical structure can cause severe damage, paresthesia and other complications to the patient.



Warning! The user must be able to recognize red and green colors to detect warnings such as *"Collision between implant and nerve"*.



Warning! In case of collision between implant and nerve or between implants, the software will disable access to further steps, i.e. creation of report, protocol as well as the surgical guide design step.

Implant planning buttons

	Opens the implant selector to change the type of the selected implant.
	Opens the sleeve selector to change the type of sleeve to be used for the selected implant.
	Opens a menu to group implants together so that they are placed with the same insertion direction.
	Opens a menu to modify the safety zone for the selected implant.
	Shows the shortest distance to other implants.

	Shows the angle between the active implant and the other implants.
	Shows the shortest distance from the implant to the nerve.
	Shows the shortest distance from the implant to the surface scan.

3.10 Guide Design



In **Guide design** you use the software to design a surgical guide. How this is done depends on which workflow you are in.



Warning! Please check for potential collision between the sleeves, the visualized drill cylinders and any existing tooth or dental restoration and consider the consequences for the intended treatment procedure. Note that in case of a sleeve collision, all further steps will be disabled.



Warning! The surgical guide should sit stably and firmly in the patient's mouth, and it must not move during surgery. This is to ensure optimal guidance for the drills and implants during surgery. If the guide is bone-supported, visually check that it won't interfere with a nerve before placing it. **Do not use the surgical guide unless you judge the fit to be optimal, safe and completely correct.**



Warning! Before you start using a surgical guide from a new supplier or machine for the first time, we strongly recommend that you validate the physical and functional quality plus the accuracy of the surgical guide! It is the responsibility of the guide manufacturer to ensure that the equipment used is capable of producing surgical guides suitable for guided surgery.



Note! Please design the surgical guide in such a way that sharp edges are avoided.



Note! As you design the surgical guide, ensure that there is sufficient support and connection between the main structure and the support for sleeves.



Note! We recommend that you refer to your surgical guide manufacturer for information on how they inspect and validate the precision of printed surgical guides. Inspection and validation should be conducted at frequent intervals during the production run.

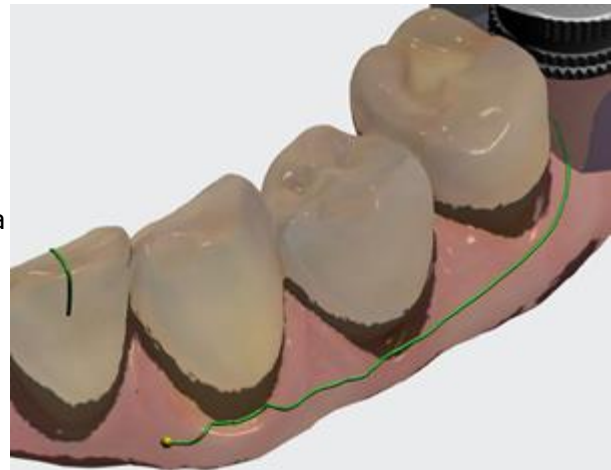
1. Tooth-supported:

Create a guide by marking patch outlines.



Use this button to start a patch:

Then either click points on the model or draw a line on the model until you have a closed outline. To close an outline, click on the yellow sphere at the other end. When an outline is closed, the guide will be built automatically.



2. Edentulous – Dual Scan Protocol:

The model of the patient's denture has been transformed to a surgical guide with added supports for sleeves. Use anchor pins for fixation. You can choose between a regular guide, a two-piece guide, or a dual guide.



Warning! Be aware that colored areas on the edentulous surgical guide are representing areas that could potentially affect the bite alignment of the guide to the opposing jaw. If you find any critical colored areas, we strongly advise you to reconsider your implant planning, sleeve type and sleeve positioning before continuing.



Warning! When placing a surgical guide in the mouth of an edentulous patient, make sure that it is aligned properly to the opposing jaw. After fixating the guide in the correctly aligned position, it is important to ensure that it sits stably and firmly in the patient's mouth, and that it cannot move during surgery. Do not use the surgical guide unless you judge the alignment and fit to be optimal, safe and completely correct.

3. Edentulous – Bone-supported:

Create a guide by marking patch outlines for where the guide should be placed. This is done the same way as for a tooth-supported guide (see above).

For bone-supported guides there is a step called "Local Guide Offset" where you can add additional space between the guide and the bone model. This is useful to control regions of the guide that shouldn't rest on the bone.



Warning! Make sure to design the guide in a way it does not touch the mandibular nerves when placed in the patient's mouth, as this could harm the patient.



Warning! Make sure you consider the mental foramen when designing a bone supported guide. An improper guide design can damage the nerves when placed in the patient's mouth.

Surgical guide settings

For all workflows, you can select one of the available 3D printer manufacturers which have default presets for thickness, teeth/model offset, retention amount and sleeve offset. These values can be adjusted within the acceptable ranges for a given manufacturer.

Manufacturer

3D Systems - ProJet 3510I

Thickness	2.000	mm
Teeth/model offset	0.075	mm
Retention amount	0.000	mm
Sleeve offset	0.035	mm

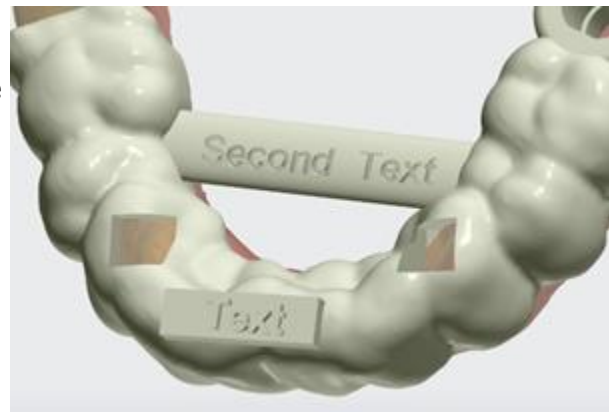


Warning! Please refer to the surgical guide manufacturer for information related to material thickness and offset parameters.

Structural supplements and ID tags

It is possible to add support bars to your guide for increased stability as well as viewing windows so that the fit can be inspected before surgery.

You can also add ID tags to guides for labeling.





Note! The user of Implant Studio may use additive manufacturing equipment to produce a surgical guide pursuant to the user's sublicense under U.S. Patent No. 6,319,006 and its family members. However, the user may NOT use milling or grinding equipment to produce such surgical guide. An additional license and payment is necessary if the user wants to use milling or grinding equipment to produce such surgical guide.



Note! In the US, the physical surgical guide for endosseous dental implant placement is a medical device (regulated under 21 CFR 872.3980). Please contact your local regulatory agency for information regarding the regulatory status and requirements related to manufacture of these surgical guides.

3.11 Approval



In **Approval** you read the approval terms to then approve your implant planning and guide design.

After this is done, you will be able to use the implant planning and guide design. You will also get a final surgical report and a final drilling protocol.

Approving locks the case so that it is no longer possible to modify.

Note that it is possible to make a copy of the case without approvals.



Warning! Please make sure that the presented screenshots and information for the implant positions and implant types as well as, eventually, the surgical guide in the Surgical report are sufficient in order to make a clear and safe decision to approve or modify the implant or surgical guide position and design.



Warning! Please follow the instructions in the drill protocol.



Note! Please check the Surgical Report and Drill Protocol every time before a surgery and make sure that:

- the provided information is correct
- you ordered correct implants based on their order number
- the right drills and sleeves are used for the selected implant type and manufacturer

- drills and sleeves are in a good condition and ready to be used for the surgery

3.12 Save



When you move to the **Save** step, a surgical report and a drilling protocol are saved and CAM output is generated.

4 Implant Studio Settings and Library Downloads

Go to **More > Settings > Implant Studio**. Here you will find settings related to default safety zone values, default surgical guide settings, and the implant library download page, where you can choose which implant and sleeve libraries to download.

5 Manufacturing

The Implant Studio software is only intended to be used with the approved range of production equipment and materials.

The design should only be produced on the machines listed in the software and in this manual. If CAM settings has been provided, these must be used in manufacturing.

Company Name	Product Name	Material Name	CAM Software Settings
3D System	NextDent 5100	NextDent SG	Shade: Orange Print Mode: 50 Micron (layer thickness) Buildstyle: Standard
Asiga	Asiga Max UV	Freeprint Ortho UV	Default
Asiga	Asiga MAX UV / Asiga MAX Pro 4K UV	VOCO V-Print sg	Layer thickness as best: 50 pm. Alignment best at 30° / down to 0° lying occlusal. Minimum one cross brace at least 3 mm thick for arches. Use the support Script provided by Asiga.
Asiga	Pro 2 UV	Whip Mix VeriGuide OS	Select Asiga Pro 2 UV from printer list. Pick 50, 75 or 100 micron Z layer. Supports should be on the external side. Enable Antialiasing.
Asiga	Pro 4K UV	Whip Mix VeriGuide OS	Select Asiga Pro 4K UV from printer list. Pick 50, 75 or 100 micron Z layer. Supports should be on the external side. Enable Antialiasing.
BEGO	Varseo	VarseoWax Surgical Guide	Default
Carbon	Carbon M-Series	Keystone KeyGuide	Resin Dropdown: "Keystone KeyGuide" Print Mode: "Default" Slicing: "Standard"

Carbon	M Series Printer	Whip Mix Surgical Guide resin	Slice thickness: Select "Standard" (100um)
DIO	DIO PROBO - Guide	DIOnavi - SG	Default
DMG	3Delite / 3Demax	LuxaPrint Ortho TRA	Settings are made in Netfabb, printer is executing the job without changing the predefined material settings. Material: DMG LuxaPrint Ortho TRA Parameter set: 19/09 -50µm - Intensity: 20.0 W Layer Thickness: 50 µm Post-cure: LED-Box (i.e., 3Decure, RS Cure) All variable settings on default-values.
EnvisionTEC	D4K Pro Dental	E-Guide	Please follow the official instructions for use of the corresponding machine and material combination.
EnvisionTEC	Envision One Dental	E-Guide	Please follow the official instructions for use of the corresponding machine and material combination.
EOS	FORMIGA P110	PA2200	Layer thickness: 0,10mm
Formlabs	Form 2	Dental SG	Default
Formlabs	Form 3B	Surgical Guide Resin	Select Surgical Guide Resin Set layer thickness to 100 microns Use default support settings
HeyGears	UltraCraft A2D 4K	UltraPrint-Dental Surgical Guide UV	Using default settings.
HeyGears	UltraCraft A2D	UltraPrint-Dental Surgical Guide UV	Using default settings.
HeyGears	UltraCraft DS	UltraPrint-Dental Surgical Guide UV	Using default settings.
Ivoclar	PrograPrint PR5	ProArt Print Splint	Ivoclar PrograPrint CAM Buildstyle "ProArt Print Splint", no further settings needed.
Microlay	Microlay Versus	Keyprint KeyGuide	Profile: Keyprint KeyGuide 100 microns, Version: 5.1 or higher

Phrozen	Sonic 4K and Sonic XL 4K	NextDent SG	100 µm layer height and default printing parameter
RapidShape	D 20 II / D 30 II / D 40 II	VOCO V-Print sg	Alignment best at 30° / down to 0° lying occlusal. Minimum one cross brace at least 3 mm thick for arches. Advantageously: rapidshape C-carrier / C-build platform. Use of the surgical guide support script provided by rapid Shape.
SHERA	SHERAprint 20 / 30 / 40	SHERAprint-ortho plus UV	Use parameters for SHERAprint-ortho plus UV in Netfabb (default settings); anterior region downward
SprintRay	MoonRay S	SprintRay Surgical Guide	Default
Stratasys	Objet 260 Dental / Objet 260 Dental Selection / J720 / Objet30 Dental Prime	MED610	Objet30 Dental Prime and Objet 260 Dental / Dental Selection use Objet Studio, with default settings Stratasys J720 Dental uses GrabCAD Print, with default settings
VOCO	W2P SoftFlex 170HD	VOCO V-Print sg	Layer thickness as best: 50 µm. Alignment best at 30° / down to 0° lying occlusal. Minimum one cross brace at least 3 mm thick for arches. Use the support Script provided by VOCO GmbH. For the best result use the W2P PowerVat.
VOCO	W2P SoftFlex 350-650	VOCO V-Print sg	Layer thickness as best: 50 µm. Alignment best at 30° / down to 0° lying occlusal. Minimum one cross brace at least 3 mm thick for arches. Use the support Script provided by VOCO GmbH. For the best result use the W2P PowerVat.

6 Software Recommendations

Please apply the following recommendations to keep your application running at optimum performance and to prevent uncontrolled access to potentially sensitive data:

Recommendations for Installation and Setup

- Restrict user access to the operating system by setting up a user password.
- Configure the operating system to log off automatically after maximum 10 minutes of inactivity.
- Restrict the access to security features of the operating system in the Action Center of the Windows operating system Control Panel.
- Make sure not to install and connect more clients than the server capacity allows.

Recommendations for Everyday Use

- Before leaving your PC unattended with the application running, lock the application using the CTRL+L keyboard shortcut.
- Before leaving your PC unattended, log off in your Windows operating system using power options or lock it via the WIN+L keyboard shortcut.

Recommendations on General Maintenance

- Always keep your computer operating system up-to-date, with the latest security patches installed.
- You can locate the operating system update log in the default Windows installation folder e.g., *C:\Windows\WindowsUpdate.log*.
- Use anti-virus software and update its database regularly.
- Backup on a regular basis. Always backup before updating or uninstalling this software. For more details on how to backup and restore, please see the Backup & Restore chapter.

Appendix A: Shortcut Keys

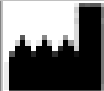
GENERAL

Shortcut	Description
F11	Opens full screen view.
Alt + Right-click and hold	Move the mouse to pan the view.
Shift + Right-click and hold	Move the mouse to zoom the view in and out.
Ctrl + F	Create a feedback report.
Mouse	Description
Right-click and hold	Move the mouse to rotate the model.
Wheel pressed	Move the mouse to pan the view.
Wheel scrolled	Zooms the view in and out.

Appendix B: Contact Information

3Shape is a global company with offices in Europe, Asia and the Americas.

3Shape Implant Studio® is manufactured by the 3Shape Medical A/S.

3Shape Medical A/S	
Holmens Kanal 7 1060 Copenhagen K Denmark	

Representative offices		
3Shape North America North American Sales Somerset Hills Corporate Center 10 Independence Boulevard, Suite 150 Warren, New Jersey 07059, USA	3Shape (Shanghai) Co., Ltd Asian Sales Room 906, Tower A of Eton Place No. 69, Dongfang Road 200120 Shanghai, China	3Shape Latin America Latin American and Caribbean Sales Carrera 13 # 82-91 Oficina 401 110221 Bogotá, Colombia

3shape.com - Visit our corporate website to learn more about 3Shape and our innovations.



Note! The User Manual is supplied in an electronic format which is part of the 3Shape Implant Studio Software and not in a printed format. The User Manual is also available in PDF format at www.3shape.com. You can obtain a free copy of the User Manual in a printed format within 7 days by contacting 3Shape Support.



Note! In case of any serious incident that has occurred in relation to the use of the device, please report the incident to 3Shape at support@3shape.com, and you can also report it to the competent authority of the Member State in which the user and/or patient is established.

Appendix C: Regulatory Representatives

Representatives below should be kept informed in connection with the vigilance and FSCA procedures:

Country	Representative
Australia	Australian Sponsor Emergo Australia Level 20, Tower II Darling Park 201 Sussex Street Sydney, NSW 2000 Australia vigilance@emergogroup.com
Brazil	Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200 Responsável Técnico: Luiz Levy Cruz Martins - CRF-SP: 42415 País de Fabricação: Dinamarca Assistência técnica 3Shape Soluções Tecnológicas para Saúde Ltda Avenida das Nações Unidas 12399 Conjunto 101B Ed. Landmark São Paulo, SP, Brasil Tel: +XX 55 11 3596 3879
Canada	No in-country representative. Please contact 3Shape Medical A/S directly.

EU	3Shape Medical A/S Holmens Kanal 7 1060 Copenhagen K Denmark Tel: +45 70 27 26 20
Japan	MIC Medical Corporation Marketing Authorization Holder(MAH) Division 6F Toranomon 36Mori Building, 3-4-7 Toranomon, Minato-ku Tokyo 105-0001, Japan Tel: +81-3-6880-9310
Korea	MEDISPEED #413, 23 Sejongdae-ro Jongro-gu Seoul Korea Tel: +82-2-735-2011
USA	Medicept 200 Homer Ave # M100-2 Ashland, MA 01721 (508) 231-8842

Appendix D: System Requirements

Please make sure your computer meets the following system requirements prior to using Implant Studio®.

Item	Specifications	Requirements
Processor	Intel Core i5	-
	Intel Core i7 or equivalent	OK
Memory (RAM)	4GB	-
	8GB	-
	16GB	OK
Storage	250GB (HDD or SSD)	-
	500GB (HDD)	OK
	1TB (HDD)	OK
	500GB (SSD)	OK
	1TB (SSD)	IP
Graphics card	1GB NVIDIA GeForce, DirectX 10/11	-
	2GB NVIDIA (GeForce or Quadro), DirectX 10/11. Maxwell or newer architecture recommended	OK
	4GB NVIDIA (GeForce or Quadro), DirectX 10/11. Maxwell or newer architecture recommended	IP
Operating system	Windows 8 Home (64bit)	OK
	Windows 8.1 Home (64bit)	OK
	Windows 10 Home (64bit)	OK
	Windows 7 PRO (32bit)	-
	Windows 7 PRO (64bit)	OK

	Windows 8 PRO (64bit)	OK
	Windows 8.1 PRO (64bit)	OK
	Windows 10 PRO (64bit)	OK
Monitor resolution	1280x1080	-
	1920x1080	OK
	1920x1200	IP
Network	Wi-Fi or wired, internet connection	OK
Mouse	With wheel button	OK
3D mouse	3DConnexion SpaceMouse Pro	IP

OK	Sufficient.
IP	Recommended for Improved Performance.
-	Not supported.



Note! For the Edentulous workflow, 4GB video memory is recommended.



Note! Please assure you have an appropriate graphic card capable of visualizing the CBCT/CT and surface scan in the required quality and resolution according to the system specifications.