Bonelogic CMF Orbital 2.1

INSTRUCTIONS FOR USE

VERSION 4.0 October 2025

DISIOR

Contents

Introduction

This User Guide describes the functionality of the Bonelogic CMF Orbital – the orbital analysis software manufactured by Disior Oy (Ltd.) and instructs how to use it.

Intended use

Bonelogic CMF Orbital is intended to be used by specialized medical doctors to assist in characterization of orbital fractures. The shape characterization is based on visual representation of the orbital shapes, with the fractured orbital shape versus the healthy orbital shape in the graphics window. The software provides templates for reconstruction sketching which are intended to be used in preliminary design of orbital reconstruction plates. The design templates can be outputted from the software.

The templates outputted from the software in STL file format are for visualization purposes only. Their direct usage in the manufacturing of reconstructive parts is strictly prohibited.

Indications for use

The broken to intact volumetric sizes of the orbital cavities can be compared to each other in order to obtain an indication of the trauma. The sketching tools can be used to outline the reconstruction area which can also be given a thickness value thus producing a reconstruction template. The template can be locally adjusted and the locations for fixation screws can be added. The sketched template may be outputted and further utilized in the design of orbital reconstruction plates. The three-dimensional (3D) orbital models from the software can be used in visualization purposes and can be outputted from the software as well.

Hardware specification

The minimum requirements are:

Computer	:	Desktop or laptop PC
Processor (CPU)	:	Intel i5, Intel i7 or Intel Xeon
Graphics card (GPU)	:	Dedicated graphics card
Memory	:	8 GB RAM
Hard drive	:	50 GB
Operating system (OS)	:	Windows 10 (until end of Microsoft support, Oct 2025) Windows 11
Display	:	Full HD (1920×1080 px)
Internet connection	:	10 Mbit/s
(Optional) Intranet (PACS)	:	100 Mbit/s

System configuration

The Disior Bonelogic CMF software consists of the following two modules:

1. Local workstation: User interface with pre- and postprocessing functionalities.
2. Cloud environment: Orbital and fractured shape solutions.

Local workstation operations

The user controls pre-processing including the imaging data management, postprocessing and visualization, in a local workstation. Connection to Disior™ cloud service is required:

- Internet connection to Disior Cloud (disioranalytics.com:3698)

Cloud environment operations

After the image data has been preprocessed and visualized in the local user interface (local workstation), and the solver and analyzer starting parameters have been set, the solver and the analyzer files are sent to Cloud for computing using a secure connection (SSH).

When the computations are ready, the results are returned to the user's local workstation where they can be read in, post-processed and visualized.

Imaging data quality requirements

The visualization of the image data and the output representations are dependent on the data quality and resolution of the original image set (DICOM file). The image data should be scanned using hard reconstruction kernels. The effective slice thickness should be less than 1 mm. For optimal use, select the original primary axial series. Some DICOM files are not suitable for 3D rendering, due to missing data. Make sure you select the optimal DICOM file for this purpose, and that no data is missing from the data set.

For assistance and help, please contact Disior.

Version and updates

The user can see the version of the software at any time. The version is shown at the upper left-hand corner of the application window. Disior informs the customers on the availability of new software versions.

Workflow

The main purpose of the software is the characterization of orbital fractures based on CT or CBCT images. The analysis can be run for cases with fractured rim.

The analysis detects two most significant defect regions. Due to the automatic mirroring, the analysis only works with patients with one broken orbit.

How to get started

To start using the software, you will need to:

1. Define the computer for installation (see Hardware specification), run IdGenerator program shared by Disior and send the generated ID by e-mail to Disior.
2. Receive the installation file from Disior.

Install the software

The installation link will ask you to ‘Run’ or ‘Save’ the file. Choose ‘Save’ and follow the instructions.

Open the installer file. Select ‘Run’, ‘Yes’, ‘Next’, ‘Install’ and ‘Finish’ to the questions and accept the license agreement.

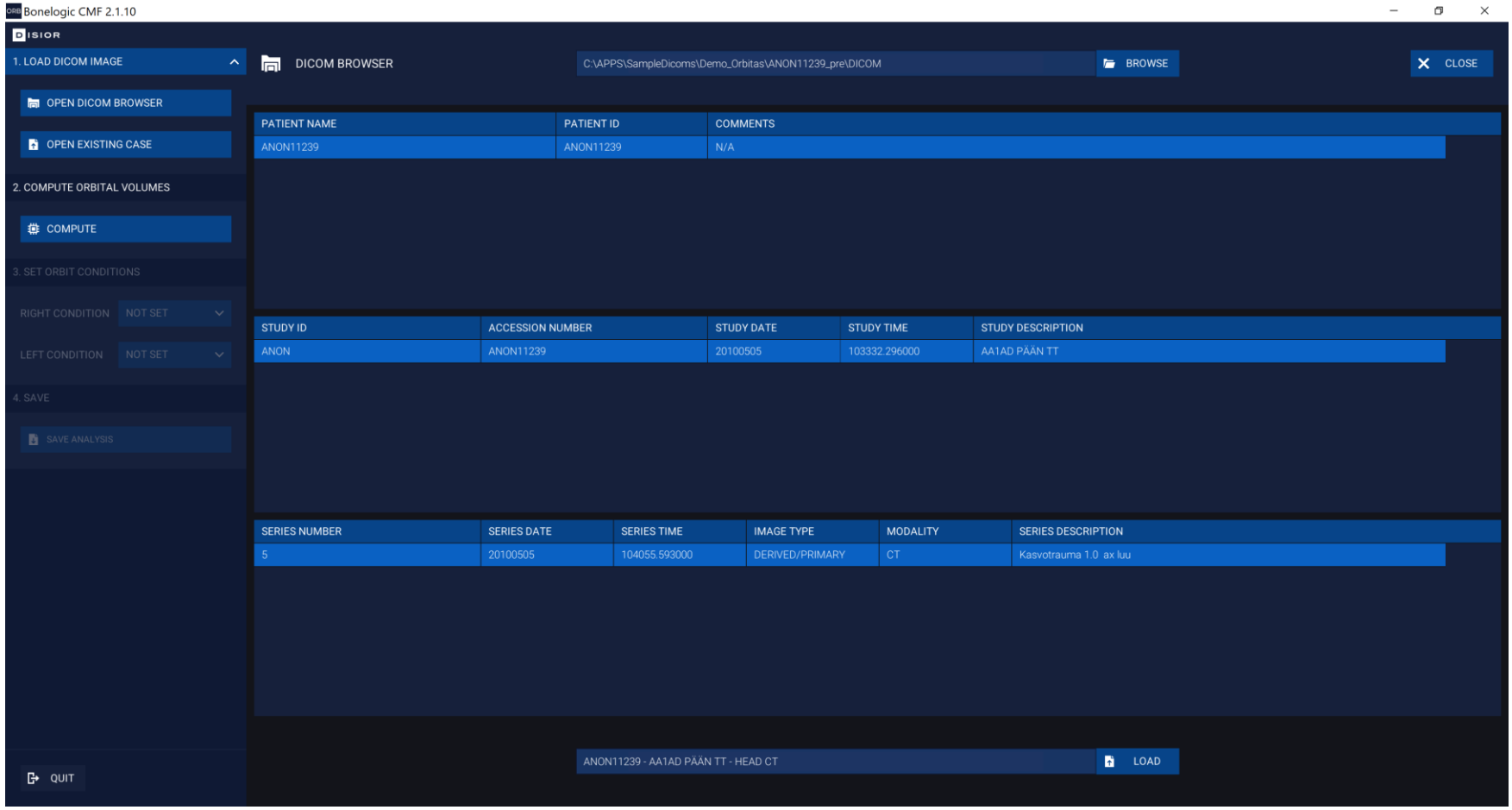
Your software is now ready for use.

The analysis results provided in the software shall be subject to careful expert assessment. The user is responsible of the adequate evaluation of the results.

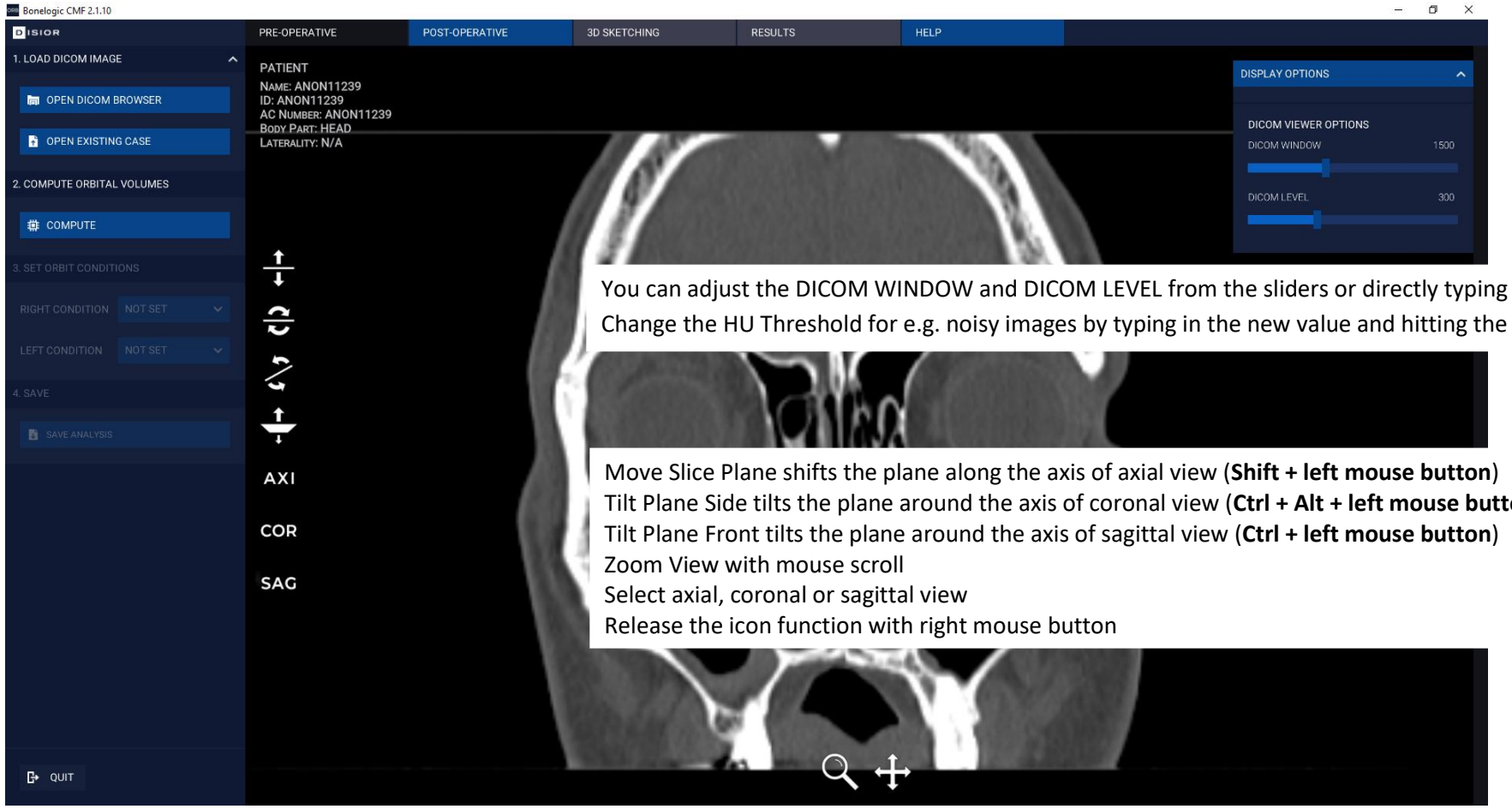
Step 1: Start here

LOAD DICOM IMAGE

To get started, open the program on your workstation. Load the DICOM image you want to examine or start working on a previously saved case. You can also load a folder with multiple DICOM series. In case of very large amount of data, the loading can take several minutes. The program works with standard DICOM images.



If you are analyzing a pre-operative case, open the image ‘PRE-OPERATIVE’ interleaf. With post-operative cases choose the ‘POST-OPERATIVE’ interleaf.



You can adjust the DICOM WINDOW and DICOM LEVEL from the sliders or directly typing in the values.
Change the HU Threshold for e.g. noisy images by typing in the new value and hitting the check button.

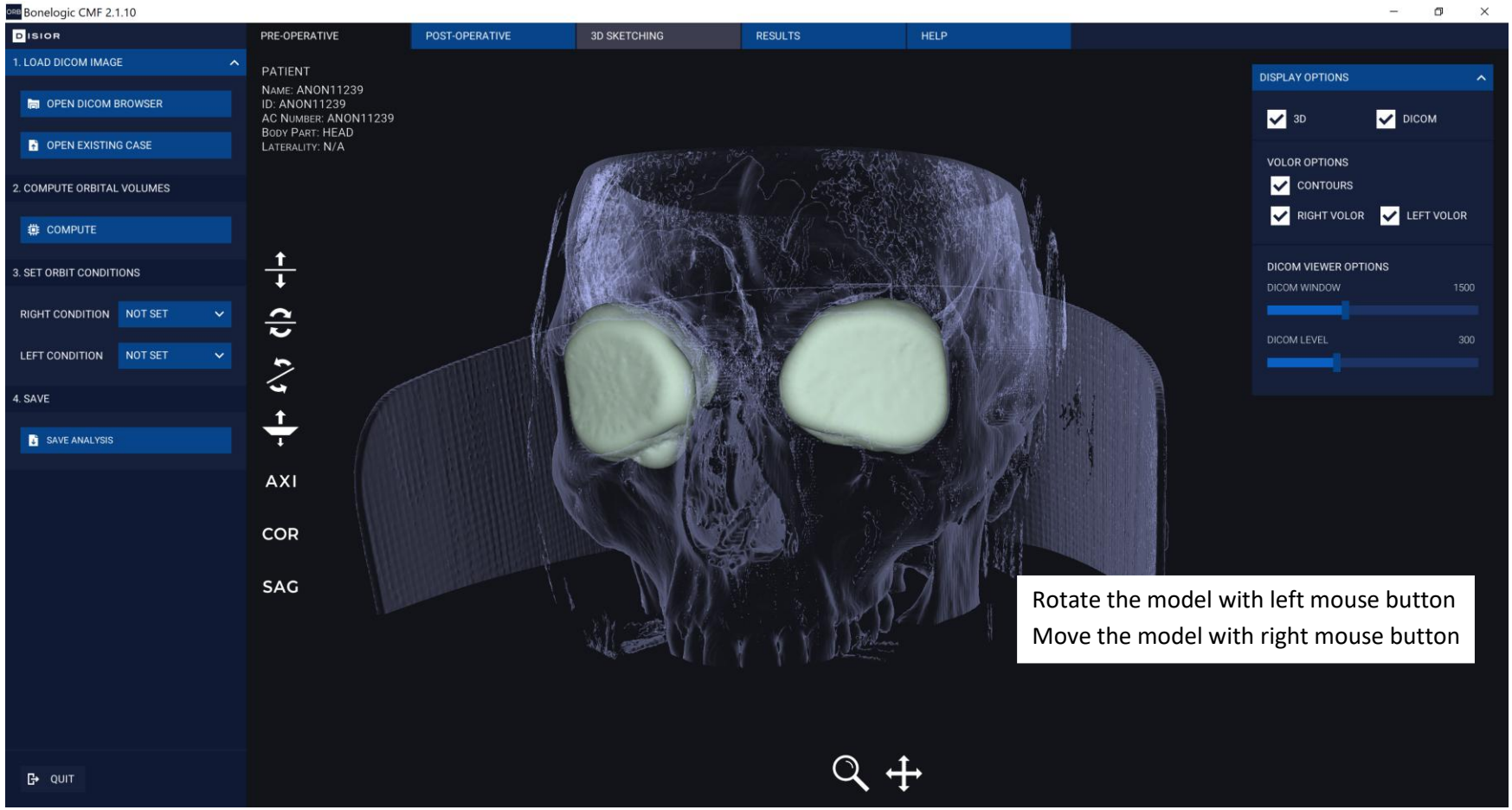
Move Slice Plane shifts the plane along the axis of axial view (**Shift + left mouse button**)
Tilt Plane Side tilts the plane around the axis of coronal view (**Ctrl + Alt + left mouse button**)
Tilt Plane Front tilts the plane around the axis of sagittal view (**Ctrl + left mouse button**)
Zoom View with mouse scroll
Select axial, coronal or sagittal view
Release the icon function with right mouse button

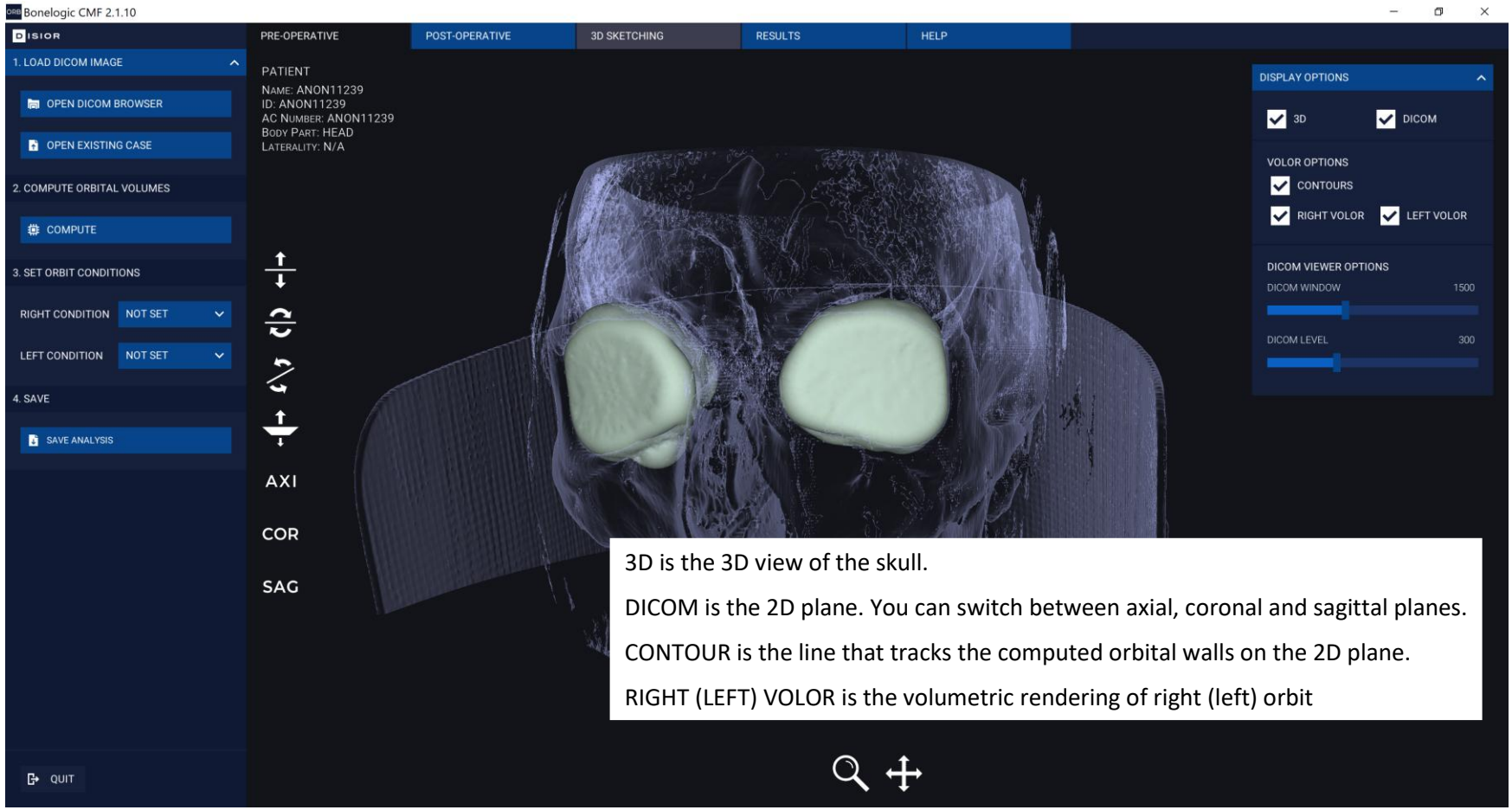
The HU threshold has no effect on the analysis results.

Step 2: Orbital volume solver

Orbital Volume Models

To run the volume solver, click ‘COMPUTE’. The program tracks the orbital walls and the anterior closing. It shows the shape and volume of the orbital cavity as a 3D model of the surface.





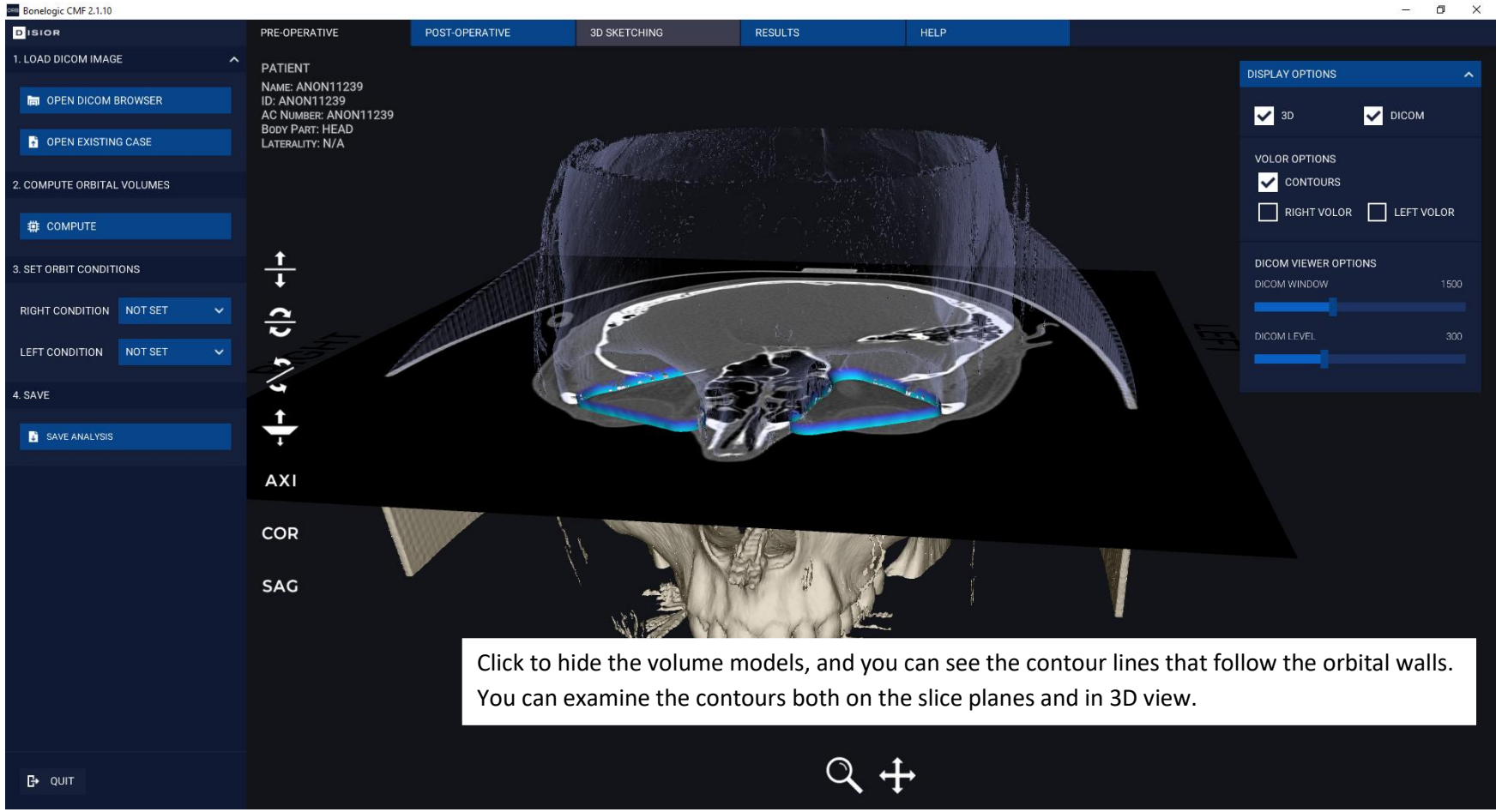
3D is the 3D view of the skull.

DICOM is the 2D plane. You can switch between axial, coronal and sagittal planes.

CONTOUR is the line that tracks the computed orbital walls on the 2D plane.

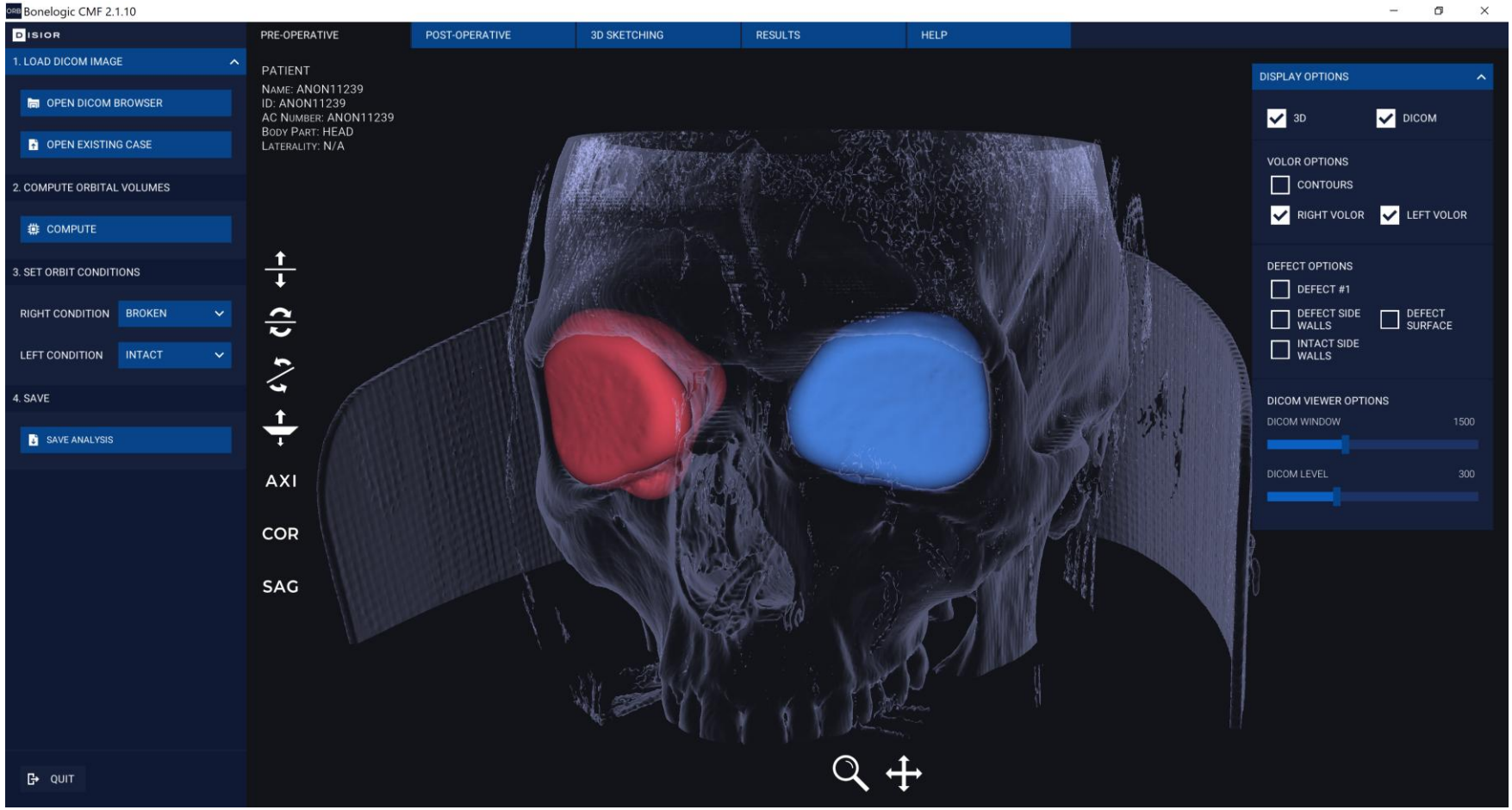
RIGHT (LEFT) VOLOR is the volumetric rendering of right (left) orbit

Auxiliary objects (e.g. an oxygen mask) or specific anatomical features (e.g. orbital emphysema) visible in the image may affect the outcome and should be considered carefully.



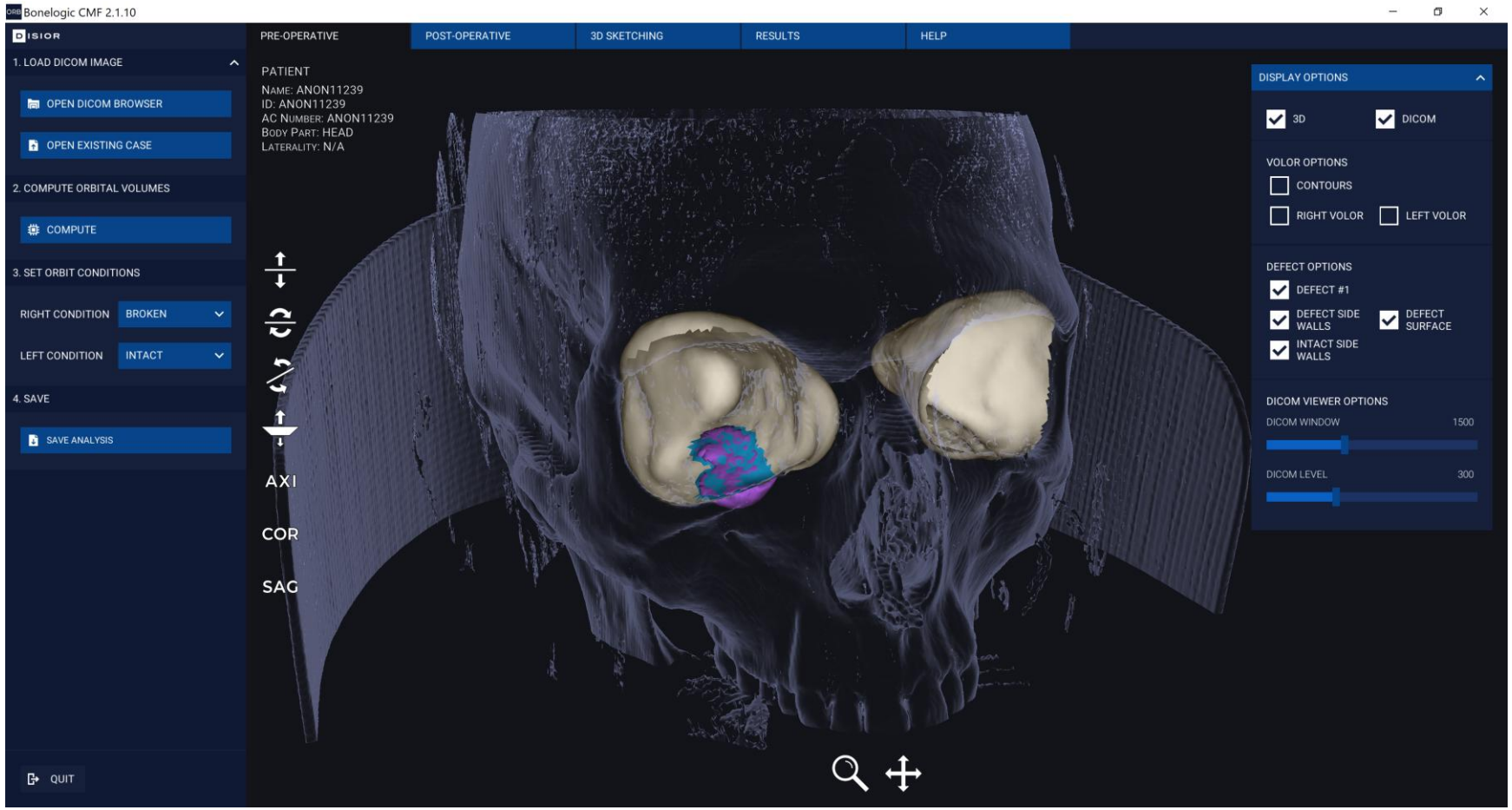
Step 3: Defect analyzer

To initialize the analyzer, choose broken and intact sides by checking them from ‘RIGHT / LEFT CONDITION’ drop-down menus under ‘SET ORBIT CONDITIONS’.

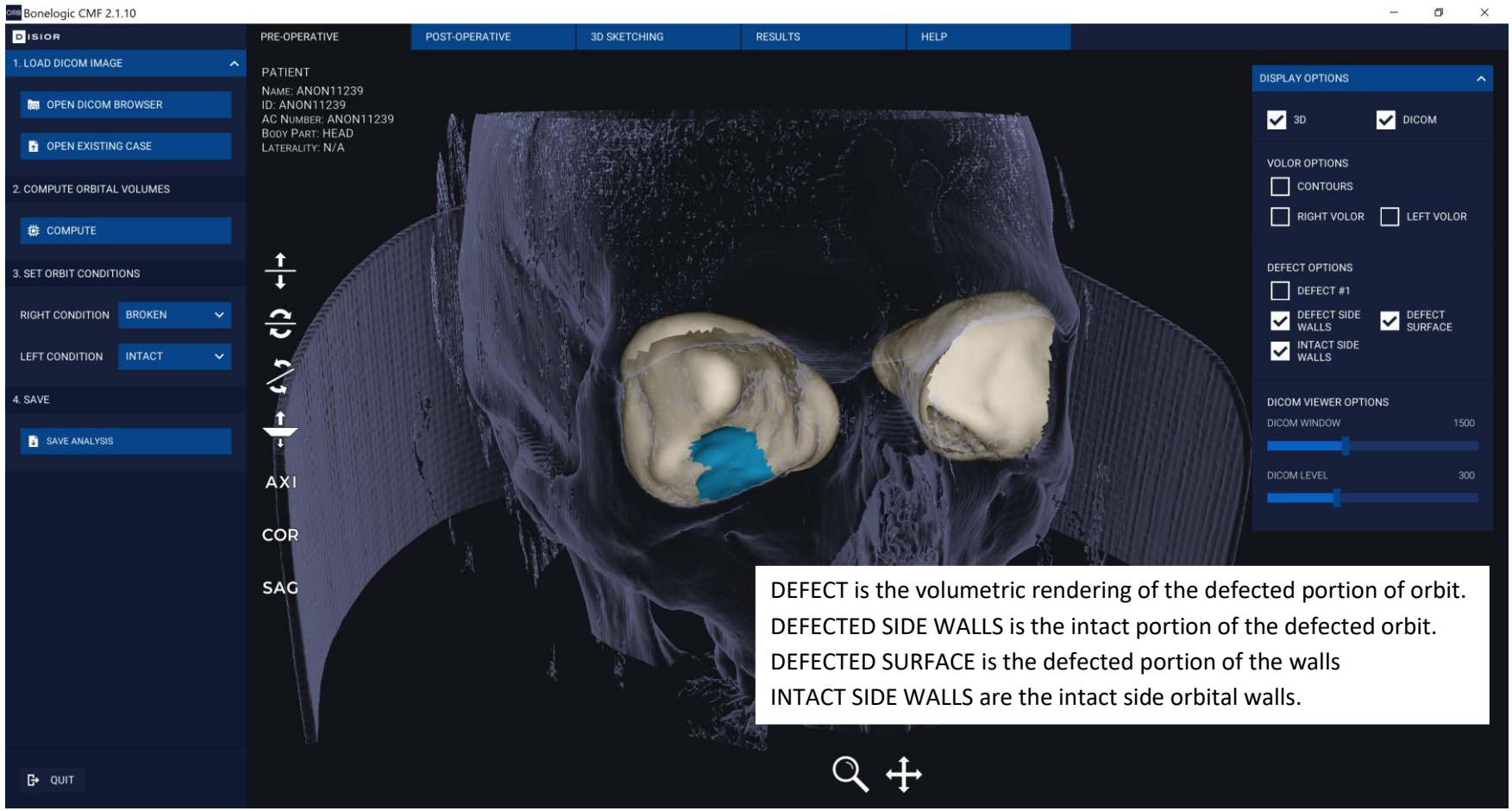


The analyzer compares the two orbits. It calculates the difference in size and shape, and as a result, gives you the shape, size and location of the defected region.

To view the contour lines and the 3D intersection marking the defected area, you can either use the slice planes, the 3D view, or their combination. The tick boxes on the left panel and the viewport icons allow you to change views for optimal visibility.

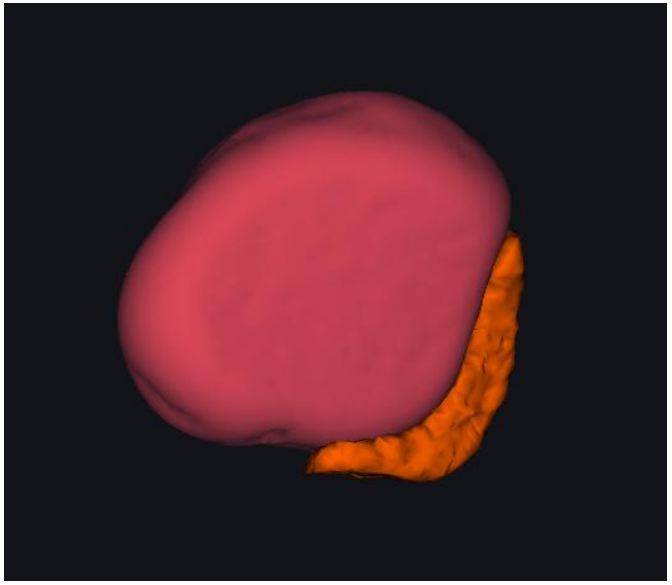


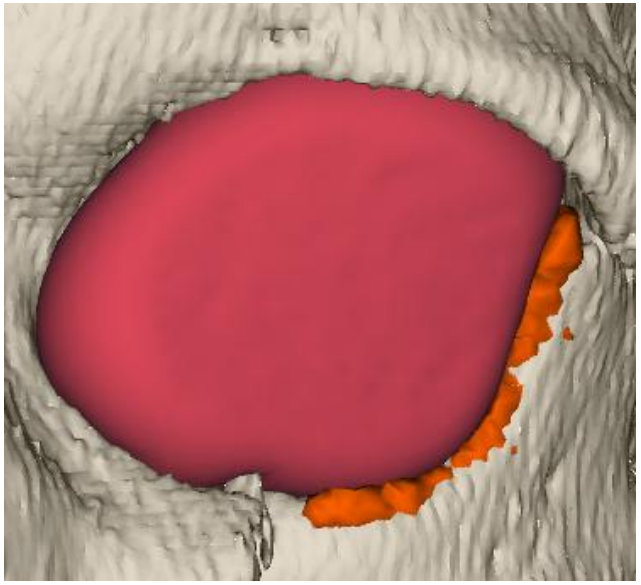
The analyzer repositions the defected regions using the data from the intact side. You can view the walls of both orbits in 3D using the tick boxes on the right panel. The repositioned areas of defected orbit are marked with turquoise color.



Multiple Defects

The analyzer detects two most significant defect regions. The regions are found at the locations where the differences between the shapes of intact and broken orbits are maximized.



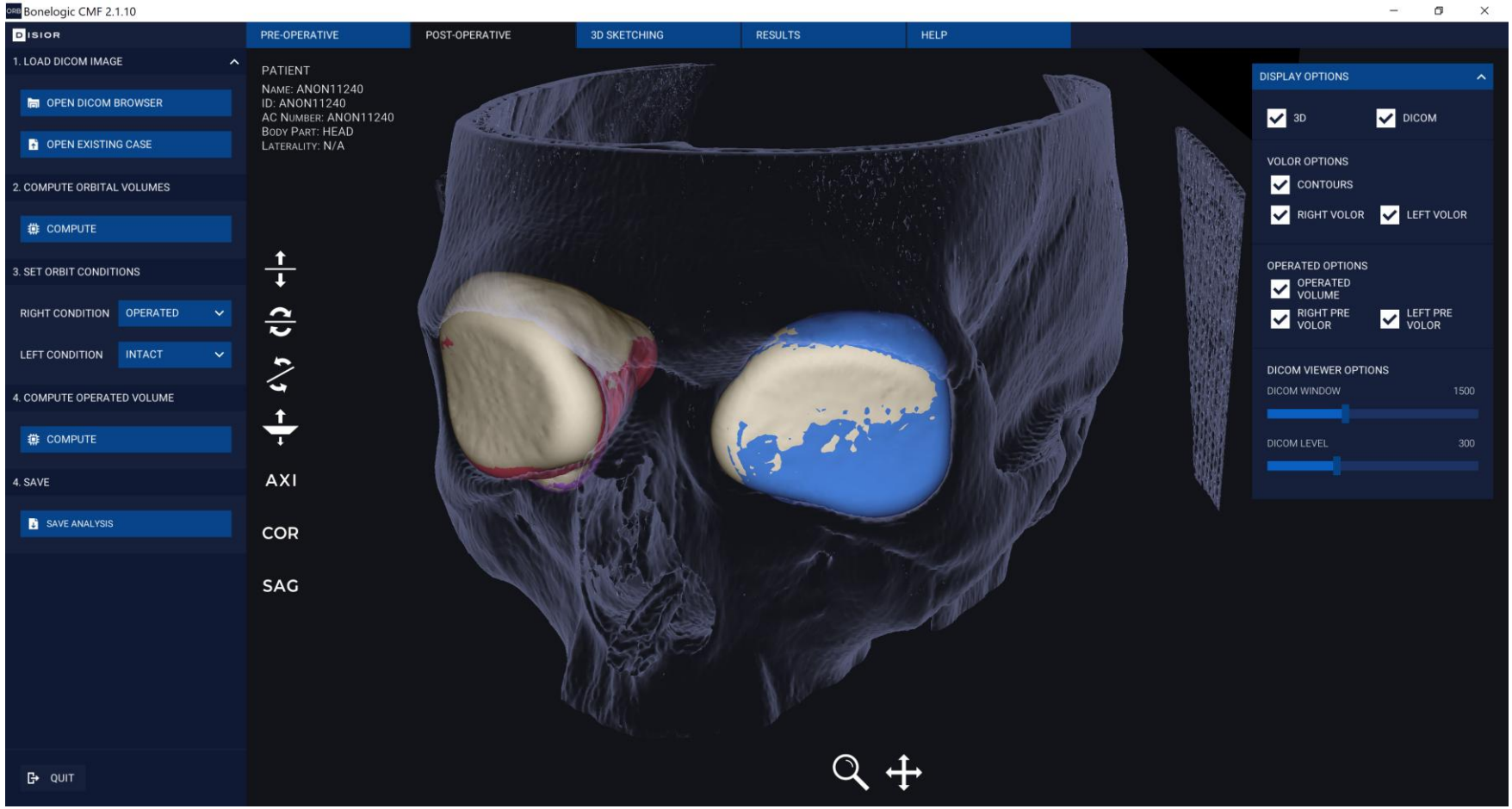


Defect Volume

Defects enlarging the volume of orbital cavity is highlighted in violet and have positive sign for the volume (e.g. orbital fracture). Defects reducing the volume of orbital cavity has orange color and negative sign (e.g. rim fracture).

Step 4: Pre- versus post-operative analysis

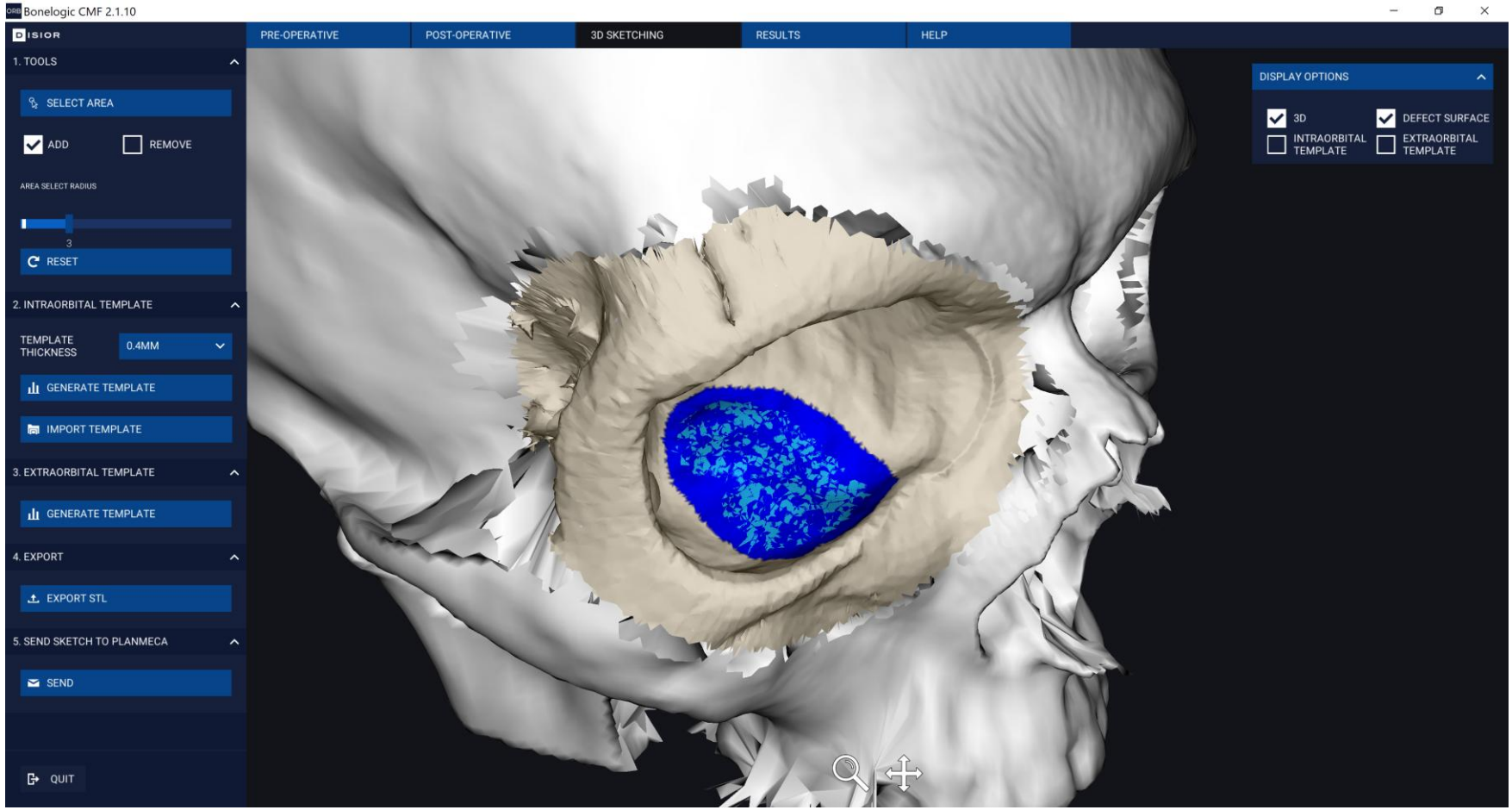
The analyzer detects defected regions by comparing the broken and intact orbits. In post-operative analysis the software may also detect defects but note that these represent the regions of maximum difference between orbital shapes, not necessarily fractures. Software informs you in both pre- and post-operative cases if the shape difference is too small for the analyzer to be detected.



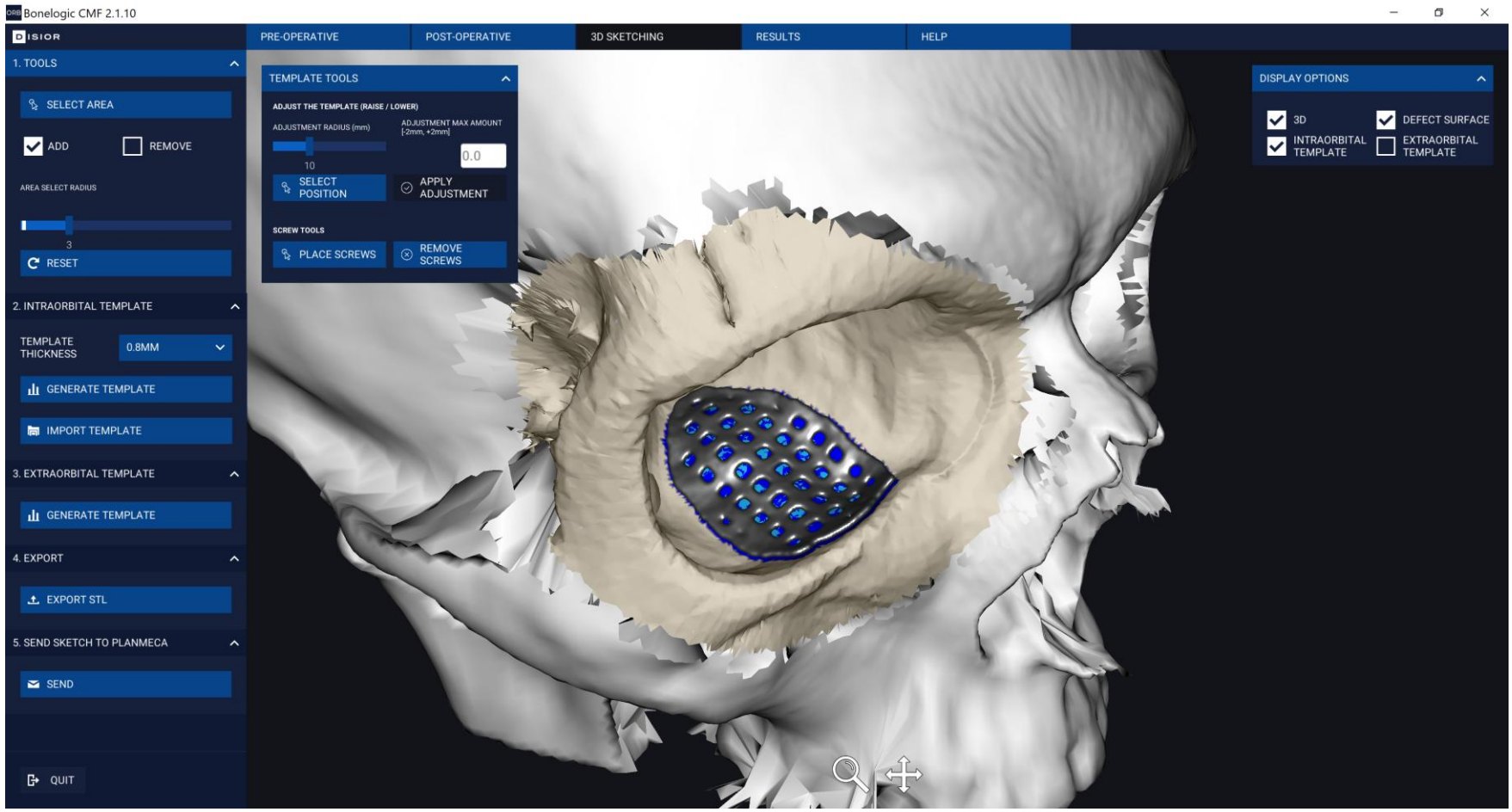
You can also do comparative studies with pre- and post-operative orbits by superimposition on the interleaf ‘POST-OPERATIVE’. In order to that, analyze pre-operative case on the sheet ‘PRE-OPERATIVE’ and post-operative case on ‘POST-OPERATIVE’. For superimposition on the interleaf ‘POST-OPERATIVE’, choose operated and intact sides by checking them from ‘RIGHT / LEFT CONDITION’ drop-down menus under ‘SET ORBIT CONDITIONS’ and click on ‘COMPUTE’.

Step 5: User defined reconstruction templates

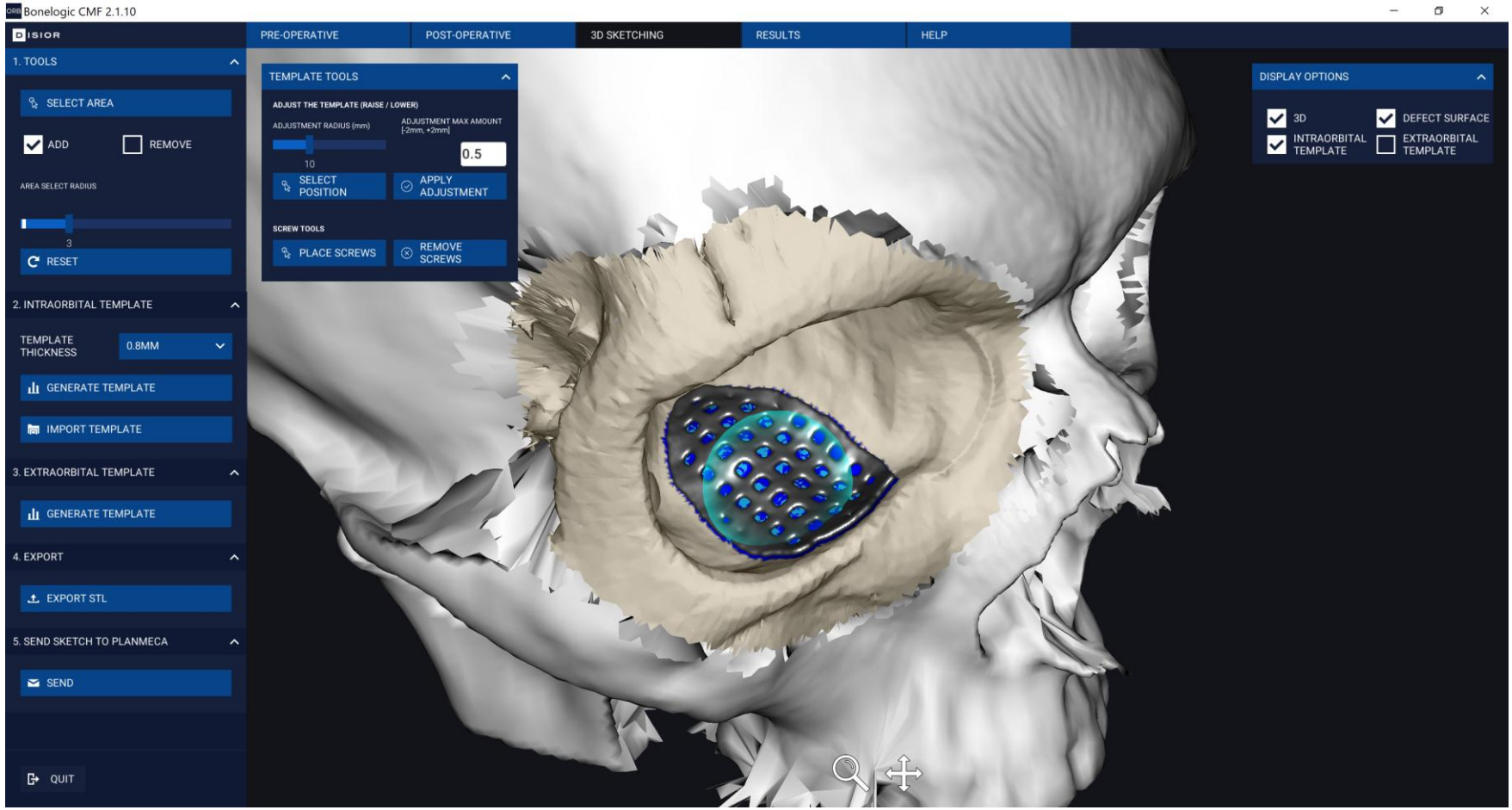
On the interleaf ‘3D SKETCHING’ you can define the area for template of reconstructive plate and select area for 3D printing of orbital walls. You can use the drawing tool by using ‘SELECT AREA’ with ‘ADD’ or ‘REMOVE’. The drawing area can be tuned with the slider (in mm). You can use ‘RESET’ to start over. The drawing is done with left mouse button. The defined area is seen in blue.



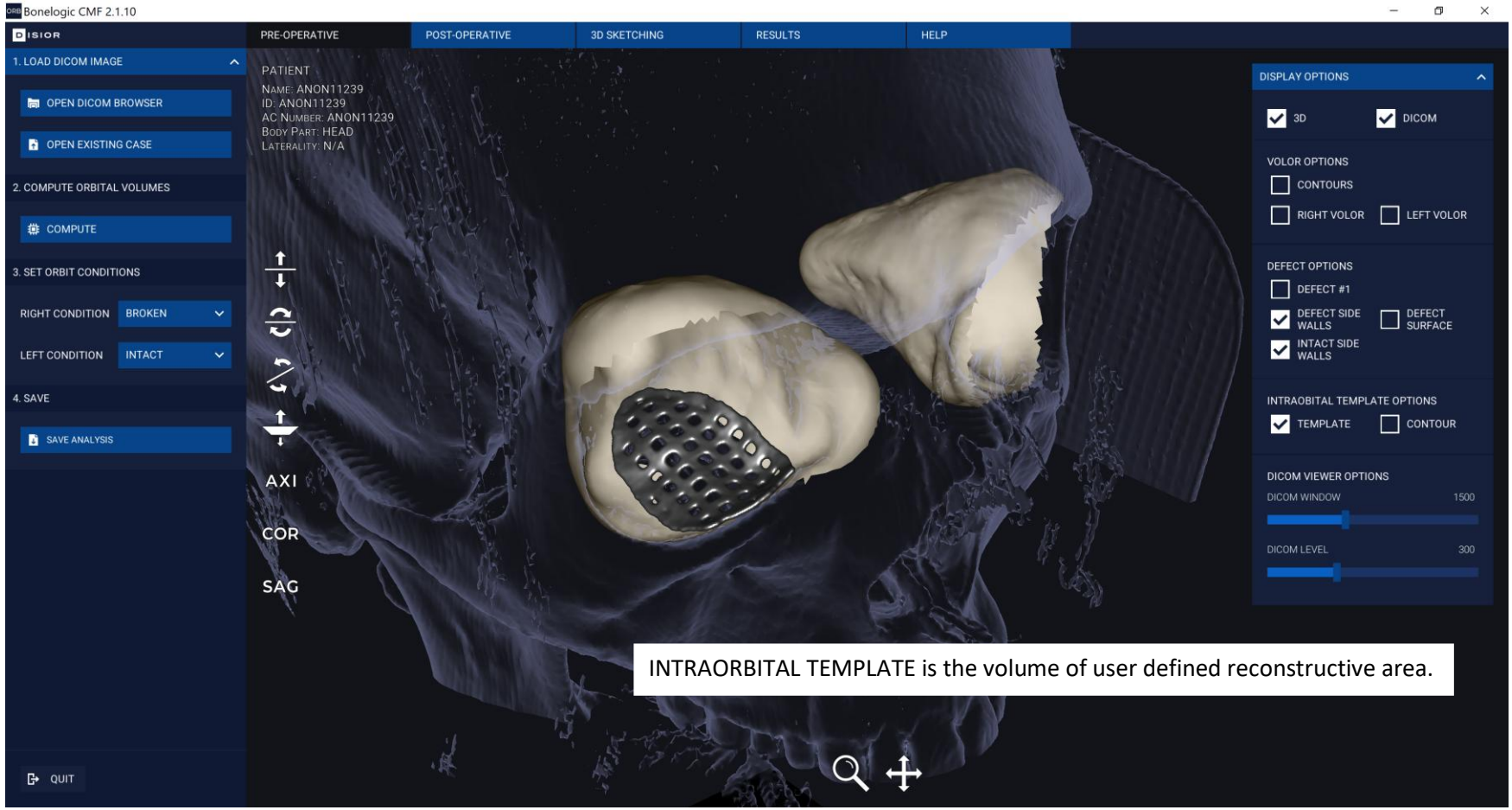
For ‘INTRAORBITAL TEMPLATE’ you can add thickness to the defined area from drop down menu ‘TEMPLATE THICKNESS (IN MM)’. Create the volume with ‘GENERATE INTRAORBITAL TEMPLATE’.



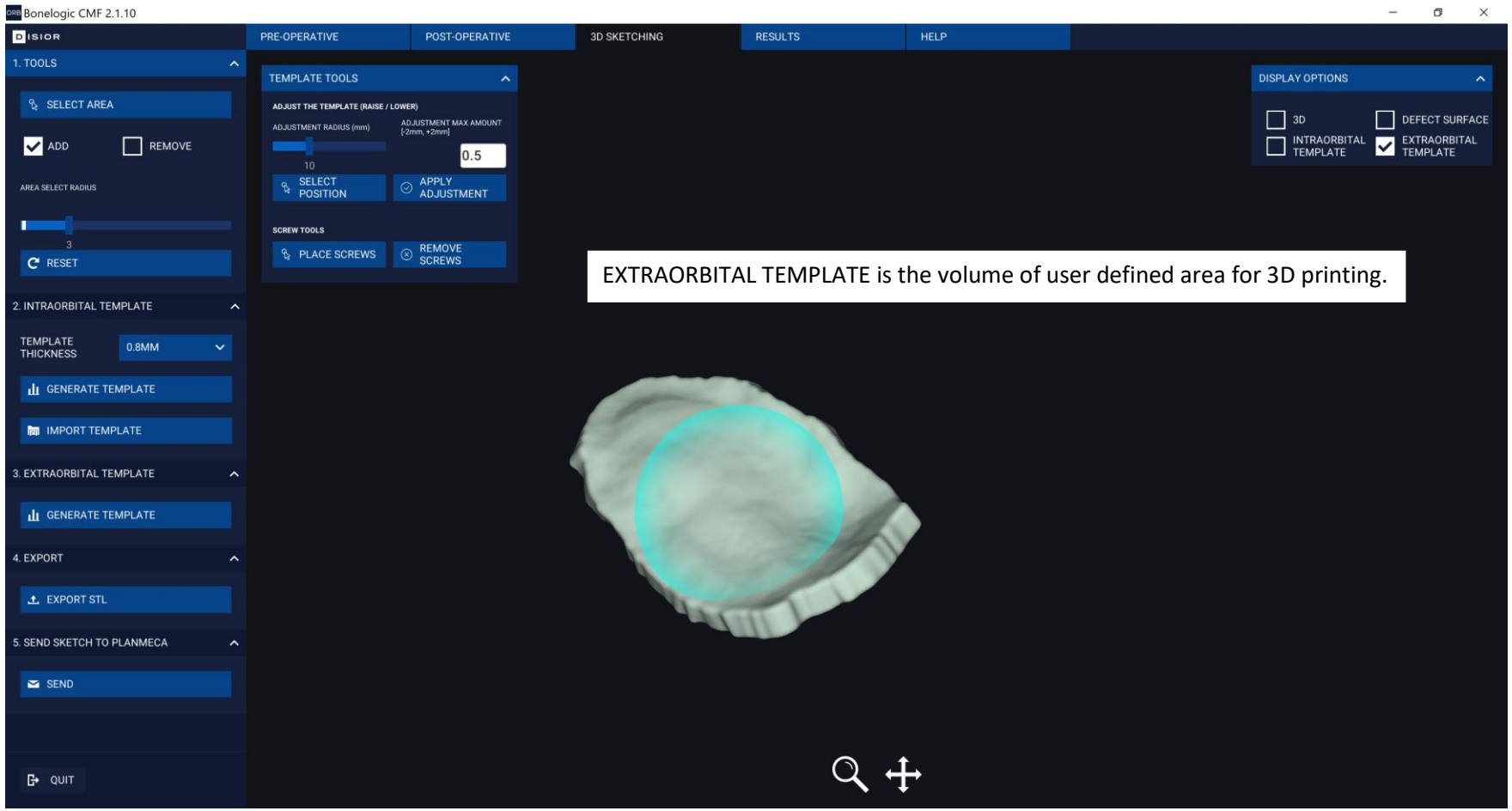
After creating the ‘INTRAORBITAL TEMPLATE’, you can apply overcorrection and mark places for screws. For over-correction you need to set the ‘CENTER POINT’ and the ‘RADIUS’ of the overcorrection area. The ‘ADJUST AMOUNT’ input field specifies, how much the plate can move in the direction normal to the plate. The screw points can be marked using ‘PLACE’ and ‘REMOVE SCREWS’ buttons.



You can investigate the template positioning against pre-operative DICOM also on the interleaf ‘PRE-OPERATIVE’.



You can also define area for 3D printing by using ‘EXTRAORBITAL TEMPLATE’. Use the drawing tools to define the area and create volume for 3D printing with ‘GENERATE TEMPLATE’ under ‘EXTRAORBITAL TEMPLATE’.



Additional options

SAVE ANALYSIS, REPORT and EXPORT STL

On the interleafs ‘PRE-OPERATIVE’ and ‘POST-OPERATIVE’, you can use SAVE ANALYSIS to save your case study in software specific format.

On the interleaf ‘RESULTS’ use REPORT to save PDF report.

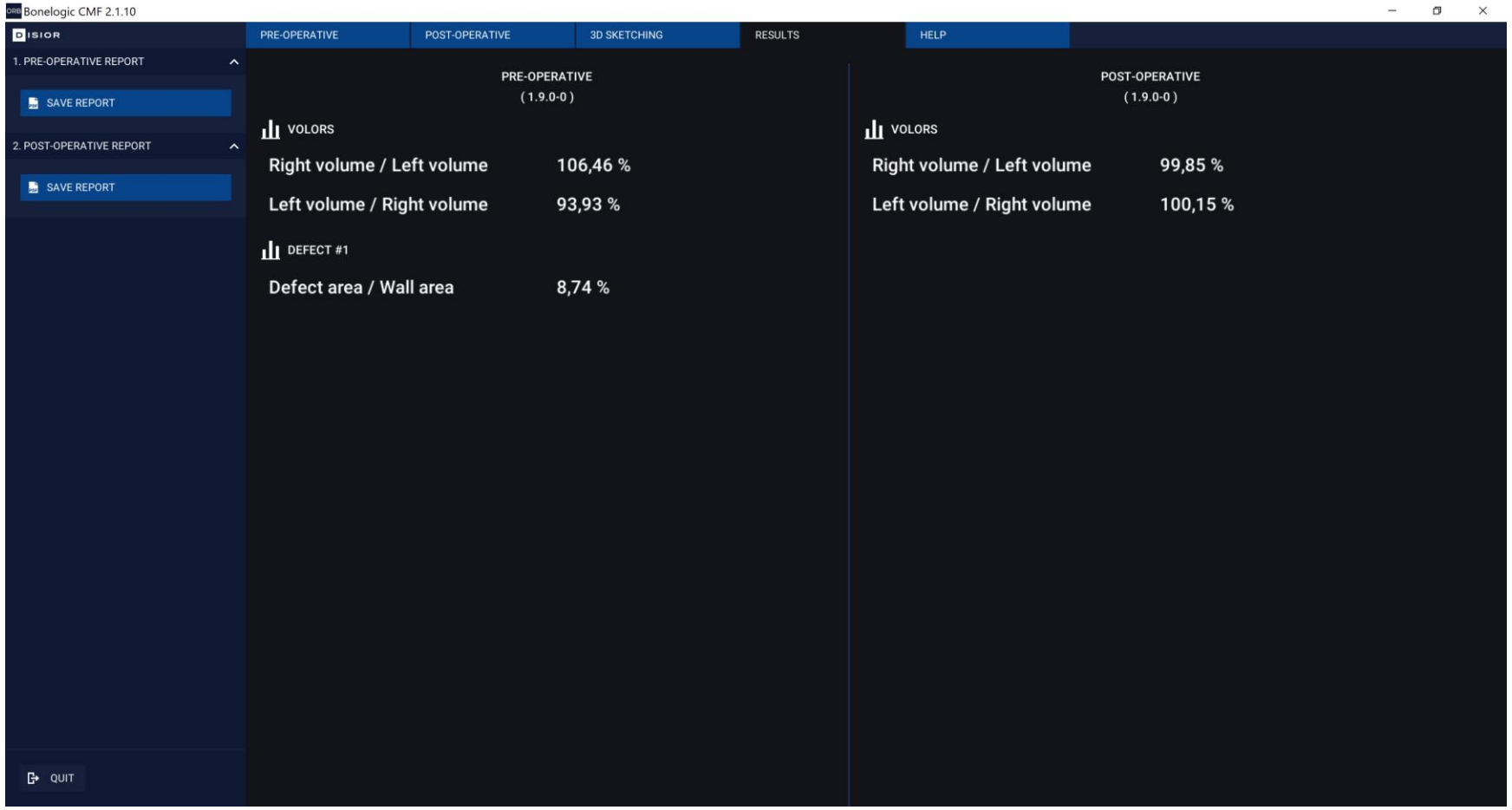
On the interleaf ‘PRE-OPERATIVE’ you can export STL files. EXPORT STL creates the following models:

1. Extraorbital Template
2. Intraorbital Template
3. Repositioned Skull Model

The templates outputted from the software in STL file format are for visualization purposes only. Their direct usage in the manufacturing of reconstructive parts is strictly prohibited.

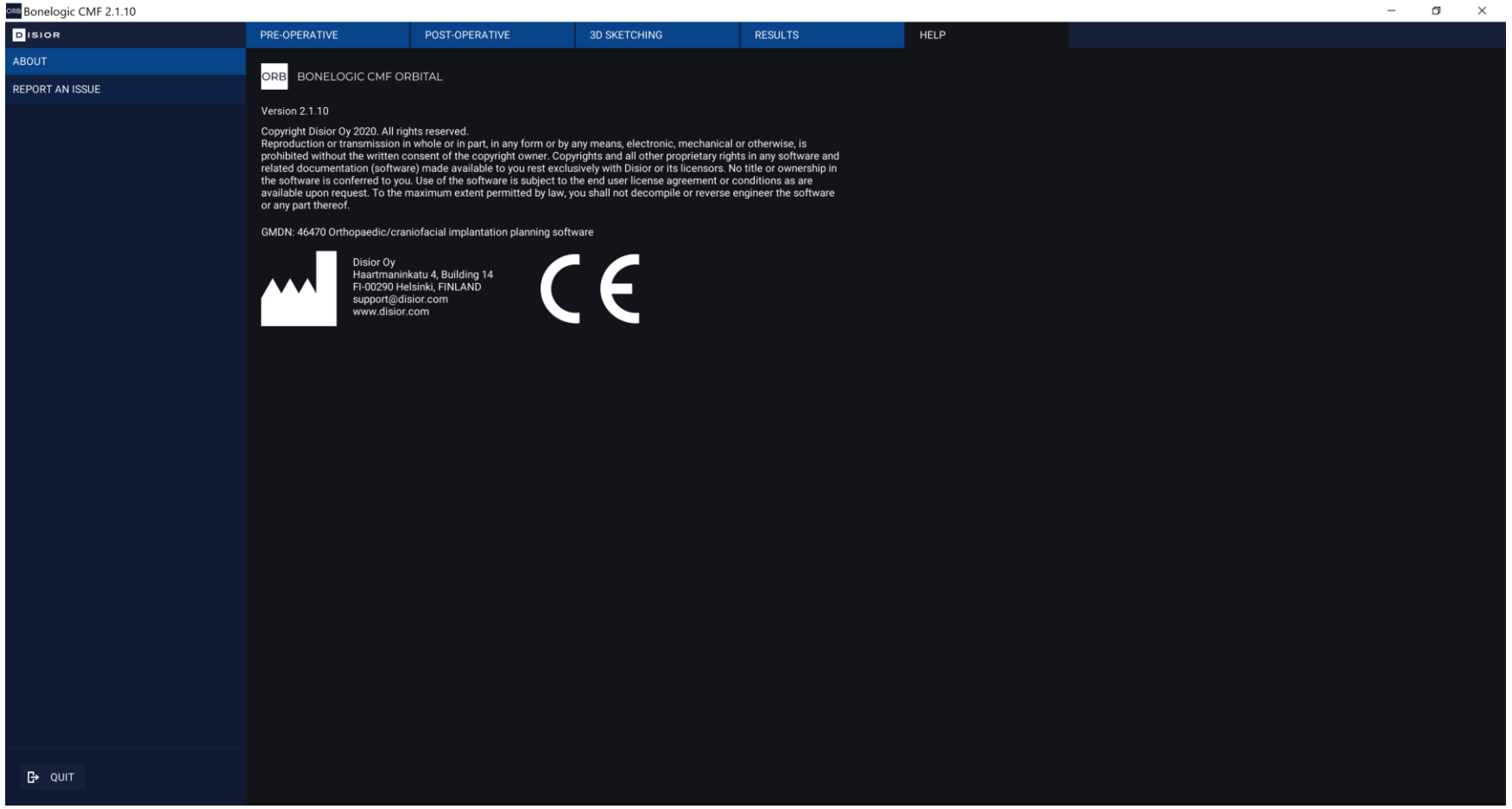
Results Summary

You can see a summary of all numerical results on ‘RESULTS’ sheet. The results are proportional.

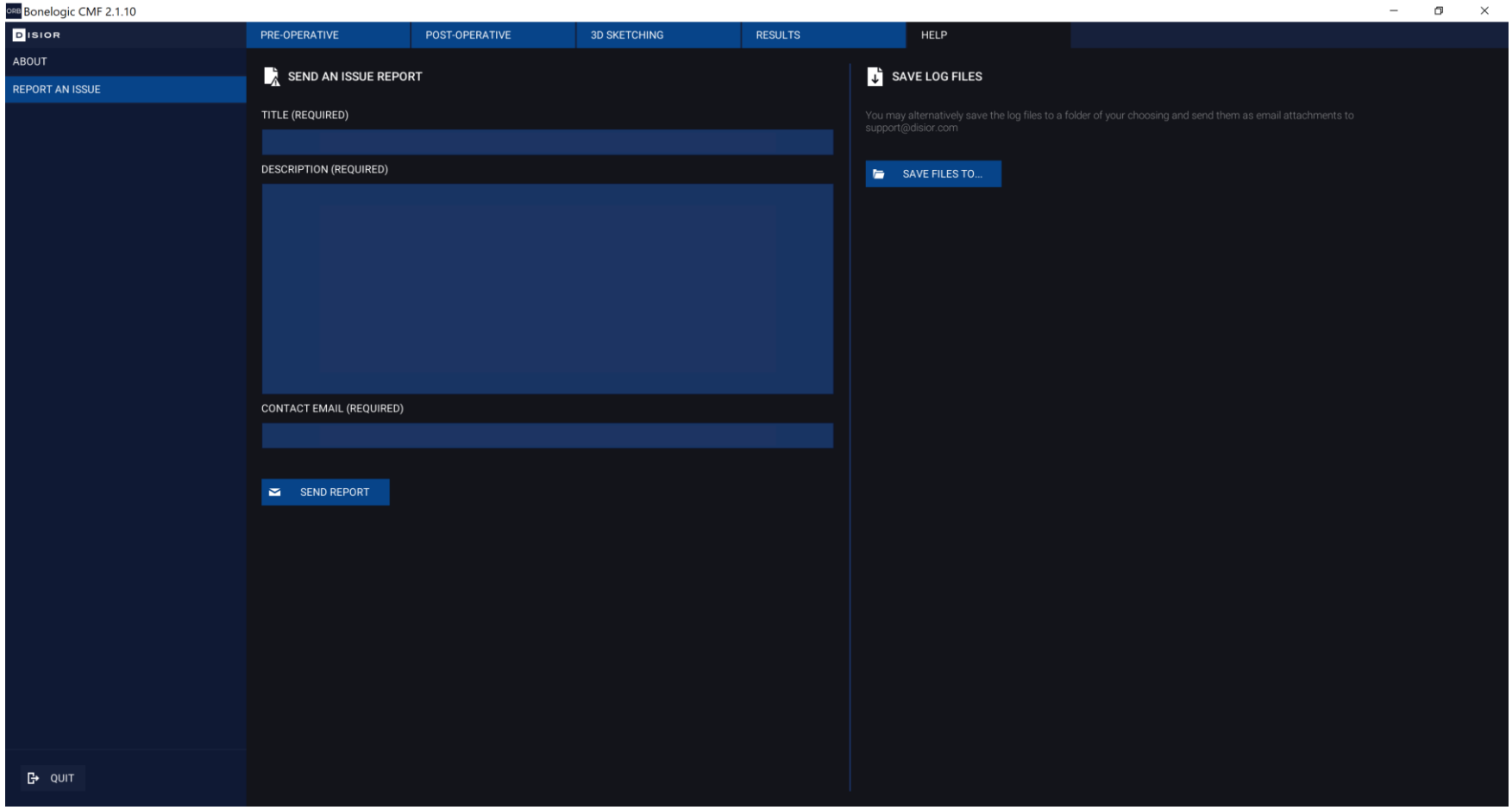


User Help

The USER HELP interleaf displays the software name and version, the manufacturer information, the copyright notice, the GMDN number and the CE mark.



You can use the HELP interleaf to report problems to Disior. You can also save log-files in order to help debugging.



Cybersecurity

User authentication and access control – Windows authentication (Microsoft authentication technologies).

Channel encryption – Secure Shell (SSH) cryptographic network protocol for operating network services.

Data encryption – The data at rest is encrypted for all application data. This can be achieved by using storage technologies which support the latest encryption standards and provide sufficient prevention against physical or virus/malware intrusion. The Bonelogic CMF Orbital software is not bound to a particular technology or vendor.

Anti-virus policy – All computers where the Bonelogic CMF Orbital software is installed should have an anti-virus program running.

Firewall – The local IT firewall configuration should allow the following traffic on workstations where the Bonelogic CMF Orbital software is installed.

Purpose	:	Destination
DICOM (query & retrieve)	:	PACS server
Windows authentication	:	Domain controller
Access shared network drive	:	Network file share

OS patching

There are no known issues with the Windows OS patches. The default update policy of the local site IT applies.

Regulation and standards

Bonelogic CMF Orbital has been designed to comply the following standards:

Standard:	
EN ISO 14971	Medical devices – Application of risk management to medical devices
EN 62304	Medical device software – Software life cycle processes
EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices provides safety to the patient, users and others

Distributors and maintenance

For feedback related to the Disior CMF Orbital product, please contact:

Manufacturer: Disior Oy (Ltd.)
HTC Helsinki, Building PINTA,
Tammasaarenkatu 3,
00180 Helsinki, FINLAND
Telephone: +358 50 483 6433
www.disior.com
disior.support@paragon28.com

CE marking

Bonelogic CMF Orbital software is a Class I medical device in the European Union complying the applicable requirements of the Medical Device Directive (93/42/EEC).

CE

Installation

For detailed instructions of Disior Bonelogic CMF Orbital installation, please contact the Disior software distributor or Disior directly. In case of pre-installed software in the imaging device, follow the instructions of the imaging device provider.

To start using the software, you will need to:

1. Define the computer for the installation, run the IdGenerator program provided by Disior and send the generated computer ID to Disior.
2. Disior will send you the installation file.
3. The installation link asks you to Run or Save the file. Choose Save and follow the instructions.
4. Open the installation application. Select OK, Run or Next to all questions.

Software architecture

Disior Bonelogic CMF Orbital software pre-processing and visualization module is installed to local desktop or laptop workstation. Numerical computations are provided as cloud service. The software uses network address ‘disioranalytics.com’, which routes the connection to the Disior™ cloud service.

1. DICOM data, local workstation
    a. DICOM image is loaded to Bonelogic CMF Orbital local desktop software
    b. Raw pixel data is separated from the DICOM data and saved in binary format
    c. No patient info or other DICOM-info is stored
2. Pre-processing and visualizations, local workstation
    a. 3D-model and 2D-representation are shown on screen
    b. User defines solver parameters and starts computations
3. File upload to cloud, local workstation
    a. Raw pixel data and user defined parameters are sent to cloud service using SSH connection
    b. SSH connection is secured with a password/key file combination
4. Computations, cloud service
    a. Cloud solver calculates orbital volumes, fracture volume and other desired elements
    b. Results are saved as numeric data
    c. Result visualizations are created in STL format
    d. Pixel data is deleted
    e. Numeric results can be used for statistics and software development
5. Result presentation, local workstation
    a. Numeric results and STL files are downloaded via SSH-connection
    b. Results are shown on the graphics screen for examination

Errors and warnings

Error messages

The software issues an error message in three potentially hazardous situations: image availability, analysis failure and software license availability. In all these three error situations, the user should seek alternative methods for the analysis and contact Disior support (disior.support@paragon28.com).

Image availability

Analysis failure

License availability

Warning messages

In a case of a poor image quality, the software issues a warning message. The software checks the DICOM attributes related to the image quality, e.g. Pixel Spacing, Slice Thickness and Pixel Aspect Ratio, and issues the warning message below if the image quality is not adequate.

Image quality

Informative messages

Additionally, informative messages may appear during the operation of the software. These messages are aimed to offer relevant information on the computations, the results and the availability of the software.

Informative message example

Symbols used

Symbol	Regulation/Standard	Symbol meaning
	Medical Devices Directive 93/42/EEC	CE marking indicates that a product complies with applicable European Union regulations.
	EN ISO 15223-1:2016 Manufacturer	Indicates the medical device manufacturer .
	EN ISO 15223-1:2016 Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	EN ISO 15223-1:2016 Caution	Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions.
	N/A	Error symbol in software to indicate a potentially hazardous situation.
	N/A	Warning symbol in software to indicate a potentially hazardous situation.
	N/A	Information symbol in software to indicate further information on a potentially hazardous situation.