



Bonelogic™ 2

INSTRUCTIONS FOR USE

IFU VERSION 17.0 January 2024

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1 General Information

This User Guide describes the functionality of the Bonelogic™ software manufactured by Disior™ Oy (Ltd.) and provides instructions how to use it.

1.1 Intended use

Bonelogic software is intended to be used by specialized medical practitioners to assist in the characterization of human anatomy with three-dimensional (3D) visualization and specific measurements. The medical imaging modalities intended to be used in the software are computed tomography (CT), cone beam computed tomography (CBCT) and weight-bearing cone beam CT (WBCT). The intended patient population is adults over 16 years of age.

1.2 Indications for use

Bonelogic software contains the measurement template with a set of distance and angular measures. The measurements can be used for diagnostic purposes. The three-dimensional (3D) models are displayed and can be manipulated in the software. Together, the information from the measurements and the 3D visualization can be used for treatment planning in the field of orthopedics (foot and ankle, and hand and wrist). The 3D models can be outputted from the software for traditional or additive manufacturing. The physical models generated based on the 3D digital models are not intended for diagnostic use.

1.3 Hardware specification

The minimum requirements are:

Computer	:	Desktop or Laptop PC
Processor (CPU)	:	Intel i5, Intel i7 or equivalent CPU
Graphics card (GPU)	:	Dedicated Graphics Card with 1 GB of Memory
Memory	:	16 GB RAM
Hard drive	:	50 GB
Operating system (OS)	:	Windows 10
Display	:	Full HD (1920×1080 px)
Internet connection	:	10 Mbit/s
(Optional) Intranet (PACS)	:	100 Mbit/s

1.4 Imaging data quality requirements

Bonelogic accepts computed tomography imaging data (CT), typically cone beam computed tomography (CBCT) imaging data is used, in the format of a DICOM image series. The software is not designed for the use of magnetic resonance imaging (MRI) data. The quality of the visualization of and the outputs from Bonelogic are dictated by the quality and resolution of the original DICOM image series. DICOM image series should have been reconstructed with hard kernels. The effective slice thickness should be less than 1 mm, optimally below 0.75 mm. Some DICOM image series are not suitable for 3D rendering, due to missing data or uneven spacing between slices. Make sure you

select the optimal DICOM image for this purpose, that no data is missing from the data set and the spacing between slices is even. Maximum file size for the input DICOM images for the system is 2GB.

In case of poor image contrast, missing bones from the image, too low portions of bones visible in the image, artefacts (e.g., from metallic structures in the image), fractured bones in the image, or other image related defects or inaccuracies, the results can be inaccurate.

Certain DICOM tags are required to be present on all images used for analysis. If a tag is missing the DICOM image series is not valid, and the software is unable to use the image series. The required tags are listed below:

- Image Orientation Patient (0020, 0037)
- Image Position Patient (0020, 0032)
- Pixel Spacing (0028, 0030)
- SOP Class UID (0008, 0016)
- Rows (0028, 0010)
- Columns (0028, 0011)
- Number of Frames (0028, 0008) (Only for Enhanced CT Image)

For CBCT imaging, the optimum imaging parameters are as follows:

Standard protocol for imaging

400 projections

No filtering

Voxel size: 0.4 × 0.4 × 0.4 mm³

Tube voltage: 96 kV (KVP, Peak kilo voltage output of the X-Ray generator used)

Tube current: 6.3 mA (X-Ray Tube Current in mA)

Pulse length: 20 ms

In all cases, the medical practitioners using the software should use their professional expertise in judging the results accuracy and compare the results against original DICOM image series. For assistance and help, please contact Disior.

1.5 System configuration

BoneLogic™ software consists of the following two modules:

1. Local workstation: User interface with pre- and postprocessing functionalities.
2. Cloud environment: Analysis solutions also known as the “Solver”.

1.5.1 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, 45.8.131.57:3693)

1.5.2 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 the 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.

1.5.3 Connection to cloud

Bonelogic software has a cloud connection. The cloud computer is hosting the analysis solution. The user controls the pre-processing including the imaging data management, in a local workstation. After the image data has been preprocessed and visualized in local workstation, the analyzer files are sent to Cloud for computing using a secure connection (SSH). The analyzer files include a) voxel data that is extracted and compressed from the original DICOM and b) information on patient coordinate system from the imaging data. For clarity, no patient information or other sensitive DICOM tag information is included in the analysis files. 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.

A full illustration of the software architecture and processes is given in 'Data management & software architecture' page 67.

1.6 Licensing

Bonelogic™ software license is workstation specific and attached to the specific identification of the workstation. Licensing is done during installation process. User access to the workstations is controlled by the customer.

1.7 Version and updates

The user can see the version of the Bonelogic software at any time. Disior is responsible for all updates for the Bonelogic software. The customer will be informed about the update need and the level of urgency. The software also automatically informs the users of the updates available. The customer is responsible for the updates of the operating system and the utility programs as appropriate.



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

1.8 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. Bonelogic software is not bound to a particular technology or vendor.

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

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

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

1.9 OS patching

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

1.10 Uninstallation

In case the user wants to remove the software from the client workstation, it can be done through “Uninstall” function within Windows 10 “Settings” “Apps and Features”. As the software is not creating or maintaining databases, there is no need to uninstall or delete databases from the client workstation. Also license deactivation shall make the software unavailable in the client workstation.

1.11 Release notes for Bonelogic™ 2.1

Bonelogic™ 2.1 is a minor software revision for Bonelogic 2.0

Latest release number 2.1.4

Release date September 15th, 2023

Notes date September 15th, 2023

Notes version 5.0

Overview of the software

Bonelogic 2 software is intended to be used by specialized medical practitioners to assist in the characterization of foot and ankle, and hand and wrist anatomies with 3D visualization and specific measurements. The medical image modalities intended to be used in the software are computed tomography (CT) images, cone beam computed tomography (CBCT) images and weight-bearing cone beam CT (WBCT) images.

The release has been tested with following hardware:

1. Standard Laptop or Desktop PC with Windows 10
2. 8 GB RAM
3. Dedicated Graphics Cards with 1 GB of memory
4. Minimum 50 GB Hard Drive space
5. Internet connection to Disior Cloud (disioranalytics.com, 45.8.131.57:3693)

Purpose

Bonelogic 2 is the second Bonelogic software release with CE certification. The features included in this software release are:

1. Load DICOM
2. Open existing CASE
3. Select bones
4. Run analysis
5. Manipulate 3D
6. Manipulate DICOM
7. Toggle visibility
8. Manual segmentation
9. Virtual osteotomy
10. Manual measurements
11. Results
12. SAVE|EXIT
13. IFU, information for safety, labeling and UDI

New software features in the Bonelogic 2.1 versions

Version 2.1.1:

1. Virtual osteotomy tool
2. Manual segmentation modification tool
3. Added support for bones for foot and ankle:
 - a. Proximal Phalanges and 1st Distal Phalange

- b. Sesamoids
- 4. Added measurements in template foot and ankle:
 - a. Hallux Valgus Angle (Axial)
 - b. Hallux Valgus Interphalangeus Angle (Axial)
 - c. Sesamoid Complex - 1st Metatarsal Lateral Translation
 - d. Sesamoid Complex - 1st Metatarsal Rotation
 - e. Tibiofibular Joint Minimum Gap
 - f. Tibiotalar Joint Minimum Gap
 - g. Talocalcaneal Joint Minimum Gap
 - h. Tarsometatarsal I Joint Minimum Gap
- 5. Added measurements in template hand and wrist:
 - a. Radiotrapezoidal angle
 - b. Radiotrapezoidal angle
 - c. Carpal height ratio
 - d. Ulnar translation ratio
 - e. Radioscaphoidal Joint Minimum Gap
 - f. Radiolunate Joint Minimum Gap
 - g. Scapholunate Joint Minimum Gap
 - h. Scaphotrapezoidal Joint Minimum Gap
 - i. Scaphotrapezoidal Joint Minimum Gap
 - j. Lunotriquetral Joint Minimum Gap
 - k. Lunocapitate Joint Minimum Gap
 - l. Carpometacarpal I Joint Minimum Gap
- 6. Selective digitally reconstructed radiographs
- 7. 2D viewer for combined DICOM viewing
- 8. Manual measurement of 3D length and 2D angle (available at 3D view and virtual osteotomy)

Version 2.1.2:

1. Datasets for multiple patients can be received and retained in the DICOM browser when sent from PACS.
2. Disior Cloud network location changed from fixed IP to network address (may require change to local IT firewall configuration)

Software enhancements in the BoneLogic 2.1 versions

Version 2.1.1:

- improvement for stitched image analysis results
- Continuing improvement in algorithms performing segmentation

Version 2.1.3:

- Password reset functionality restored
- PDF report local copy can be exported when connected to PACS

Version 2.1.4:

- Software pings disioranalytics.com during initial system check
- If user's PC cannot reach servers, error message includes IP of disioranalytics.com host if DNS lookup can be performed

Compatibility

Cases saved with earlier versions of Bonelogic™ software can be opened with Bonelogic 2 version 2.1. However, to see results, utilize manual segmentation or virtual osteotomy tools, it is required to re-analyze cases from DICOM image series.

Cases saved with Bonelogic 2.1 are not supported with older versions of the product.

Installation notes

Bonelogic 2.1 is a standalone software. As part of the installation process, earlier Bonelogic 2.0 is uninstalled. In case of earlier version of Bonelogic 1.0 software version, uninstallation is not part of the installation process of Bonelogic 2.1. Earlier installations of Bonelogic 1.0 software version may be uninstalled utilizing "Uninstall" function within Windows 10 "Settings", "Apps and Features". Depending on installed version of Visual C++ runtime, a new version may be required.

Support

Product documentation with instructions for use, installation instructions and information on release updates can be found from <https://www.disior.com/>. Customer support is available through Software Help-page and through disior.support@paragon28.com

Disclaimer

To the extent permitted by applicable law, the Disior™ Services are provided "as is" without warranty of any kind, either express or implied, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, or accuracy or reliability of results from use of the Disior Services, that the Disior Services will meet specific requirements, that the Disior Services will be uninterrupted, completely secure, free of software errors, defects, and failures.

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Contact

Customer support is available through software Help-page and through disior.support@paragon28.com.

2 Workflow & Instructions For Use

The main purpose of the software is the characterization of human anatomy with 3D visualization and specific measurements. The medical imaging modalities intended to be used in the software are computed tomography (CT), cone beam computed tomography (CBCT) and weight-bearing cone beam CT (WBCT), in the format of a DICOM image series.



Bonelogic™ software does not support the usage of magnetic resonance (MRI) images.

2.1 Installation

2.1.1 Installation and license activation

To install the software, you will need to:

1. Navigate to this webpage - <https://www.disior.com/license-activation.html>
2. Download, install and run the Bonelogic software to generate a unique hardware ID ('DEVICE ID') available on the software login screen for each of the workstations you have bought or are trialing licenses on.
 - a. The installation link will ask you to 'Run' or 'Save' the file. Choose 'Save' and follow the instructions.
 - b. Open the installer file. Select 'Run', 'Yes', 'Next', 'Install' and 'Finish' to the questions and accept the license agreement.
3. Submit the information required to the online form. The form will send on the details to the Disior™ support team (disior.support@paragon28.com) who will process the request within 48 hours. Information required is:
 - a. Type of license – trial or full license.
 - b. The modules required.
 - c. Hardware IDs ('DEVICE ID') for each workstation.
 - d. Organization information (address, main contact name, email address and phone number).
 - e. Email addresses for any other users.
4. A one-time password and Secure Shell protocol (SSH) key file (named 'id_rsa') from Disior (disior.support@paragon28.com) will be sent to you once the activation request has been processed.

If you require any assistance throughout the process, you may email the Disior support team at disior.support@paragon28.com.

2.1.2 Set how your PC and Bonelogic™ use the dedicated graphics card

Set Bonelogic to use the dedicated graphics card and not the integrated graphics card:

- Find the dedicated graphics card control panel or settings (the example used here is of the NVIDIA system).
- Manage 3D settings > Select Bonelogic from the list of programs to customize> Select the dedicated graphics card as the preferred graphics processor for Bonelogic.

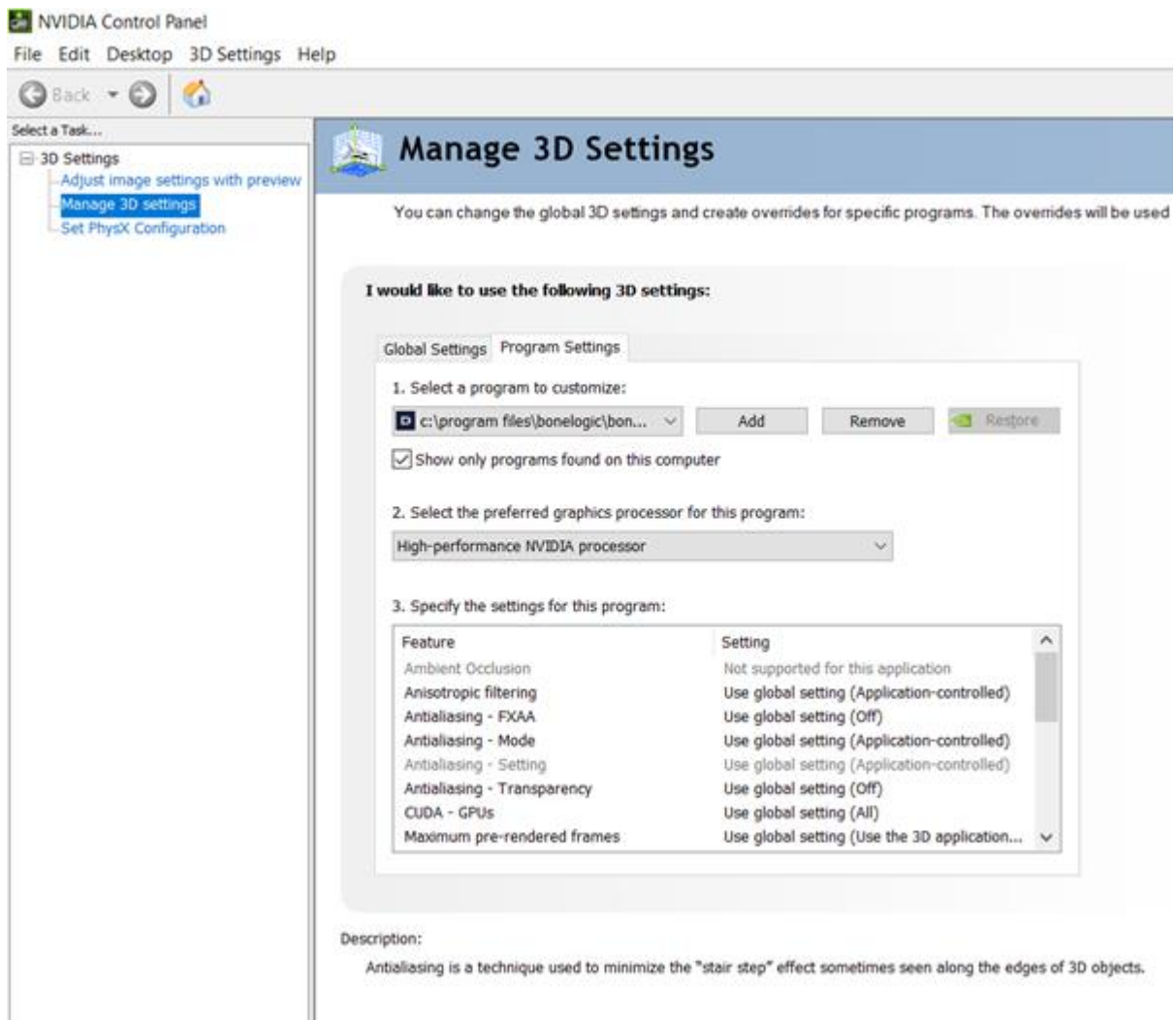


Image 1 Detailed view of the setting page for the dedicated graphics card, example is from the NVIDIA system.

2.1.3 First time logging in

After receiving the SSH key and 1-time password you can conduct the setup for first use:

1. Run the Bonelogic software
2. Enter your email address and 1-time password.
 - a. Copy and paste this password from the email to avoid errors.
3. Import the SSH key.
 - a. Click the import button.
 - b. Select the file named 'id_rsa'.
 - c. Click 'open'.
4. Change the password.
 - a. Passwords must be at least 8 characters long alpha-numeric with at least 1 upper case letter and contain no special characters (e.g. #£\$%&).

If you require any assistance throughout the process, you may email the Disior support team at disior.support@paragon28.com.

2.1.4 Selecting a dataset for training and first use

When using the software for the first time use a DICOM image series you are familiar with, that is of a healthy foot if possible or at least one without significant deformity, fractures, or implants. If you don't have an 'easy' case please contact disior.support@paragon28.com to obtain a training dataset.

2.1.5 Connecting the Bonelogic™ software as DICOM sender/receiver

The Bonelogic™ software can act as DICOM receiver to receive imaging data and as a DICOM sender for sending data. The settings for DICOM sending/receiving functionality should be defined during the installation. To do this you will need to know the IP address of the workstation that the PACS is located on and the IP address of the Bonelogic workstation, then:

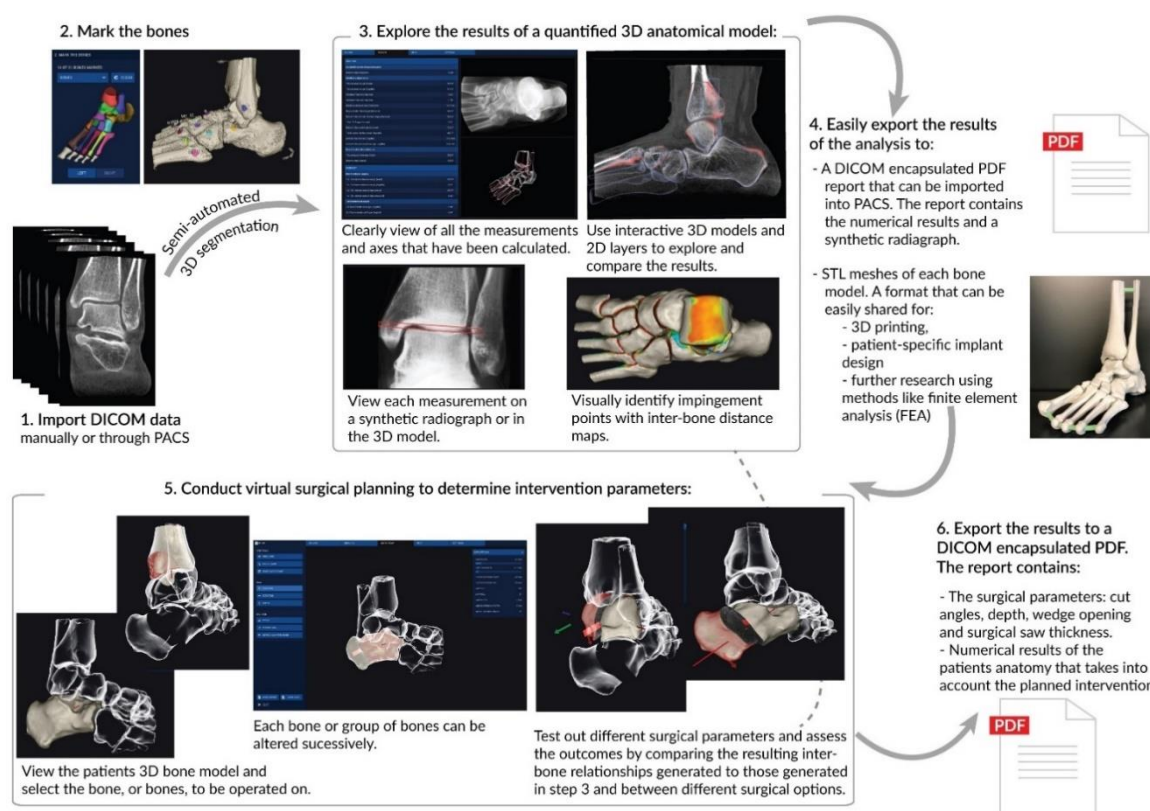
- Navigate to the 'SETTINGS' sheet in the software.
- Fill out the INBOUND CONNECTIONS fields:
 - Tick the 'Run DICOM Server on startup' box.
 - Port – Can be any number but you will need your IT department to confirm if the port is available.
 - Local AE title- Can be anything but we suggest something like 'DISIORSCP'.
- And fill out the OUTBOUND CONNECTIONS fields:
 - IP – The IP address of the workstation that the PACS is on.
 - Port- Needs to be the same as defined in the INBOUND CONNECTIONS section.
 - Local AE title- Needs to be the same as defined in the INBOUND CONNECTIONS section.
 - Remote AE title- The AE title of the PACS.

You will then need to follow the PACS providers instructions on how to add a DICOM receiver, and use the AE title, Port and Bonelogic workstation IP address to establish the connection.

You may need to contact your PACS provider and IT department to set this up and test functionality. Full technical details of this feature are provided in Section 6 'Data management & software architecture' starting on page 67.

2.2 Overall software workflow

Examples using foot and ankle, or hand and wrist datasets are shown throughout the guide, as the software currently supports module for these anatomical areas.



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.



The physical models generated based on the 3D digital models are not intended for diagnostic use.

2.3 Load data

2.3.1 Load dicom image series locally

- Open the Bonelogic™ program on your workstation.
- Login with your user account and choose your Bonelogic module¹.
- Click 'Open DICOM Browser' and select the folder containing the DICOM image series you want to analyze (Image 2).
- For folders containing multiple DICOM image series, all series will be listed in the software with metadata displayed.

¹ If you forget your password, click the forget password button on the login page and submit the email address that you use as username. This will submit a support request to the Disior Support team, who will then send you a new 1-time password. Copy and paste the 1-time password into the software and change it when prompted.

- Select the DICOM image series to analyze from the list generated in Bonelogic™.
- Folders containing large numbers of DICOM series can take several minutes to load.
- Select the primary axial series for the patient you want to analyze and click 'Load'.
- An initial 3D render of the DICOM image series based on a single Hounsfield unit threshold will be displayed (Image 3).

2.3.2 Load DICOM series via PACS

For the Bonelogic software to receive data via the PACS connection, the software and the PACS software must both be open. Each PACS provider will work slightly differently but in general the follow steps should be followed:

- Open Bonelogic and the PACS software
- In the PACS software identify the case you want to send.
- Open the case.
- Locate the DICOM storage option.
- Select the Disior™ AE title from the list of connections.
- Send the data.
- In the Bonelogic software the DICOM image series will be shown on the DICOM BROWSER.
- Select the primary axial series for the patient you want to analyze and click 'Load'.
- An initial 3D render of the DICOM image series based on a single Hounsfield unit threshold will be displayed.

2.3.3 Reopen a case

- Open the program on your workstation.
- Login with your user account and choose your Bonelogic module.
- Click 'Load Analyzed Case' and select the case file you want to review.
 - .dfcase file extension refers to foot and ankle module cases and .dhcase file extension refers to hand and write module cases.
 - Case files created with earlier versions of Bonelogic will need to be run through the analyzer again.
 - Once the case loads into the software, navigate to the bone marking sheet (you do not need to re mark the bones) and then click 'RUN ANALYZER'
 - The new manual segmentation and osteotomy tools will be available to use with your case.
 - Check section 1.11 'Release notes for Bonelogic™ 2.1' for more details.
- Once the case has loaded, the 'RESULTS' sheet will be displayed.

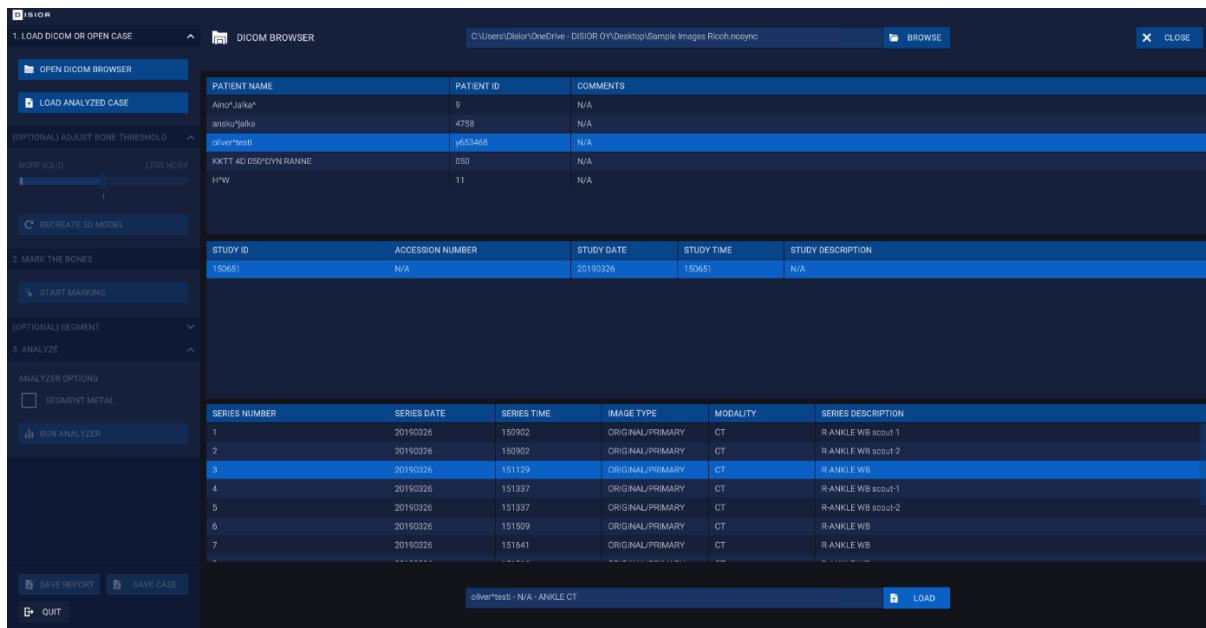


Image 2 Press 'LOAD' to open the image and to create the initial 3D render

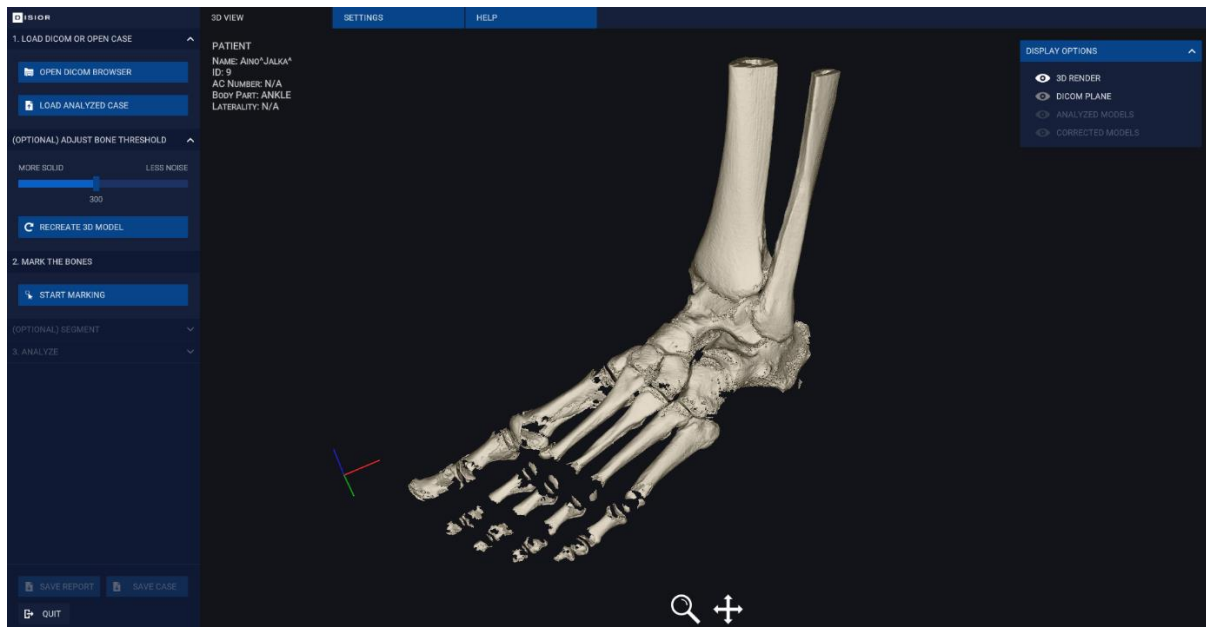
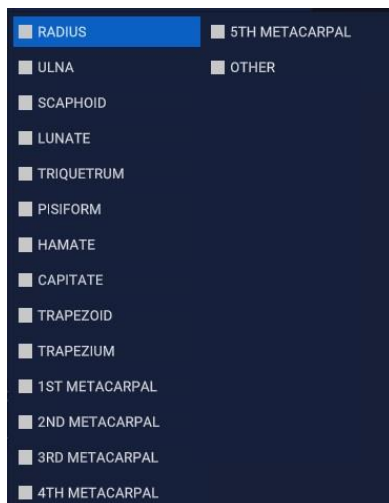


Image 3 You can change the threshold of the render by moving the 'BONE THRESHOLD' slider or typing a number and clicking 'RECREATE 3D MODEL'. Lower numbers include more data (more solid) and higher numbers include less data (less noise).

2.4 Mark the bones

2.4.1 Basic marking process

- Mark the bones to be included in the analysis using the marking tool – click ‘START MARKING’.
- For paired anatomical features the laterality of the study must be selected before marking the bones. For bilateral scans each foot or hand will need to be analyzed separately (Image 4).
- The software will guide you to mark the bones in a specific order using the guide model. All bones that are present in the DICOM image series and the guide must be marked.
- The model may need to be rotated to select not visible bones e.g. sesamoids. Use the ‘ZOOM’ and ‘PAN’ icons on the bottom of the graphics screen to do this. A single right-click on the mouse deactivates the selected tools.
 - Alternatively, these actions can be performed using the mouse:
 - Left-click and drag to ‘ROTATE’
 - Right-click drag to ‘PAN’
 - Mouse wheel to ‘ZOOM’
- The bones that can be selected in the current modules are shown in Image 7 and



- Image 8
 - In the Foot & Ankle module, the 2nd - 5th middle and distal phalanges are not included in the analyzed model but need to be marked if visible in the DICOM image series.



Image 4 First select the laterality 'LEFT' or 'RIGHT'. Click the desired bone (RADIUS) as shown (RED) in the guide on the left panel of the software

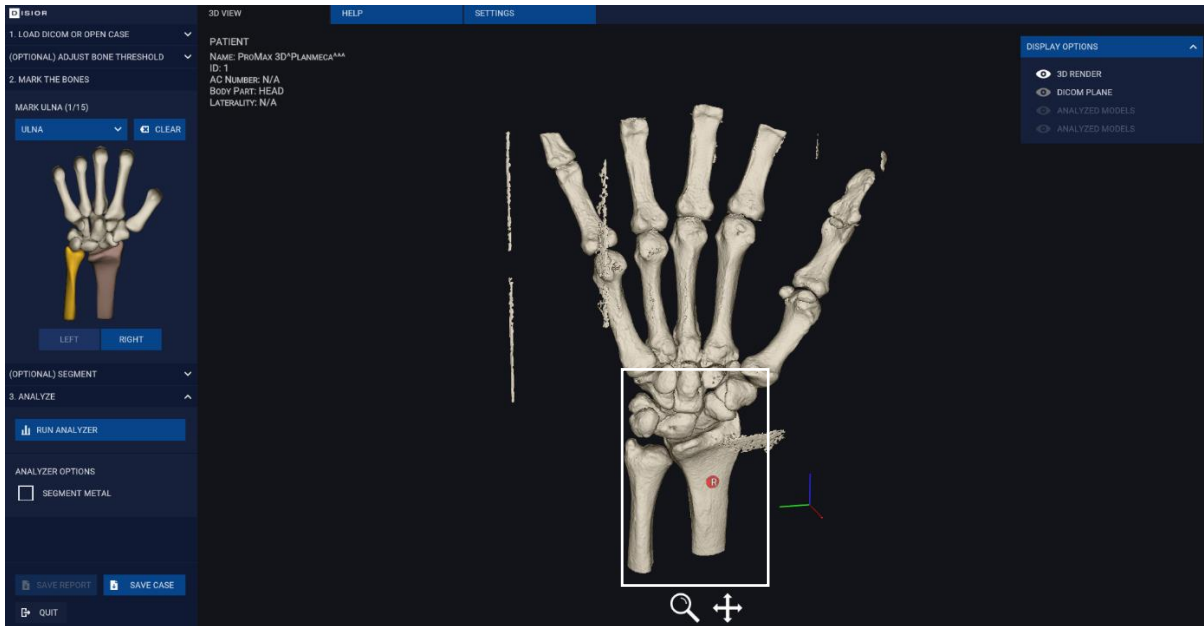


Image 5 A dot with corresponding color (RED) is shown with the bone tag (RADIUS). The next bone (ULNA) will be shown in the guide with a different color (YELLOW)

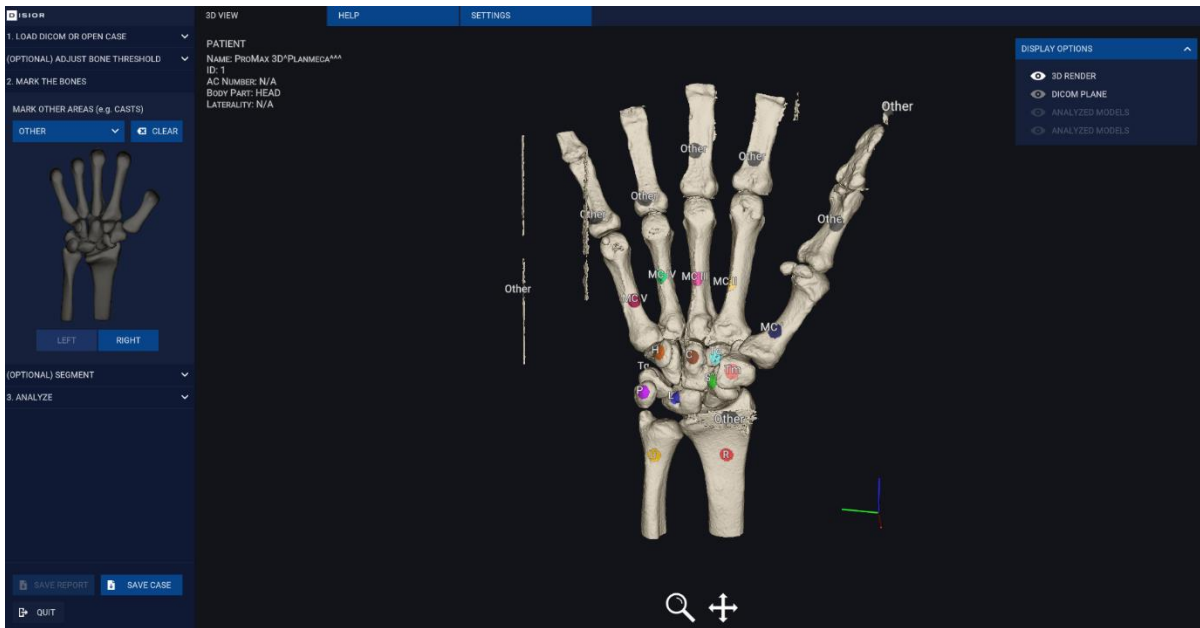


Image 6 Fully marked hand, ready to be analyzed

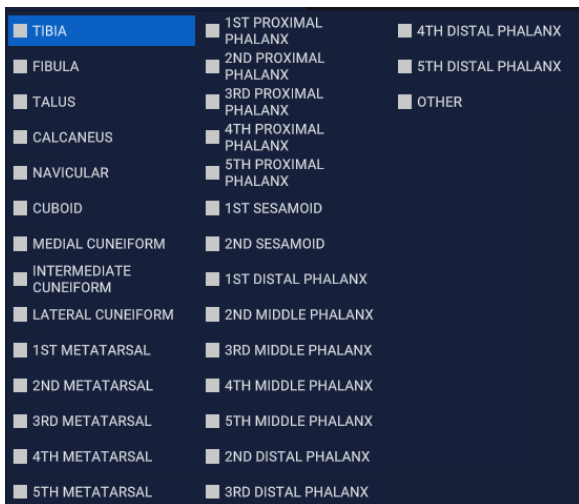


Image 7 Bones to be marked in the Foot & Ankle module



Image 8 Bones to be marked in the Hand & Wrist module

2.4.2 How to edit the bone marking

- To edit the bone marking, click the bone that is marked incorrectly in the guide and click 'CLEAR' to remove the mark and then remark the bone.
- Alternatively open the bone selection dialogue box by clicking \vee (OPEN) or \wedge (CLOSE), select the bone from the list, then click 'CLEAR' and reselect each bone.



Image 9 Bone selection dialogue box

2.4.3 Additional steps for difficult cases

2.4.3.1 How to deal with long bones

CBCT or CT scans of extremities that include extended sections of the tibia/fibula or radius/ulna ('long bones', or additional bones (not currently included in the marking list), will need to be marked as follows:

- Select the 'OTHER' item from the selection dialogue box.
- Mark the excess area of the bone (as shown in Image 10), or the additional bones.



Image 10 Example of long bone marking as other

2.4.3.2 Severe deformity or metal in the field of view

In cases where the patient's anatomy is malformed or there are fused bones or artefacts (due to metal implants or rigs) in the DICOM image series it is advisable to run the segmentation before running the analyzer.

- To preview the results of the segmentation, click 'RUN SEGMENTATION'
- The segmentation result is shown in the graphics screen, the colors indicate each bone (Image 11).
- If there is excessive color leakage (minor leakage is ok) across bone boundaries, you can choose to edit the bone marking and place more marks where the leakage occurs.

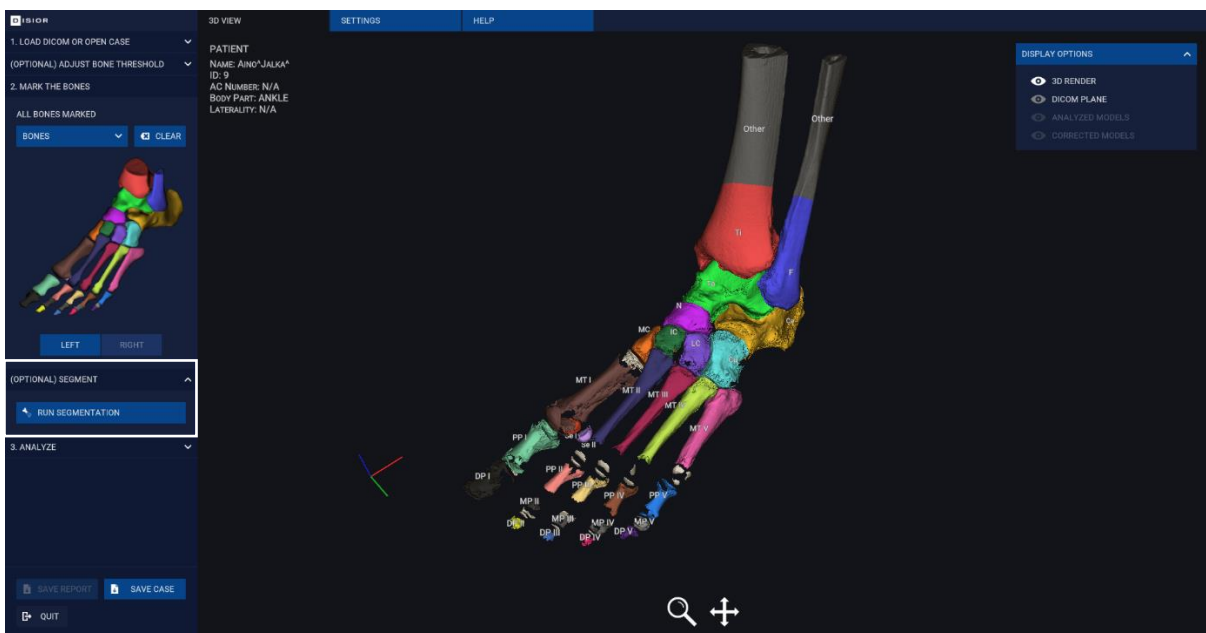


Image 11 Example of a segmentation result

2.5 Automated analysis

Once all the bones are marked and, if run, the segmentation preview looks good, you are ready to submit the DICOM image series to the Disior™ Analyzer. Before this can happen check:

- Whether the DICOM image series contains metal implants, if it does make sure that the 'SEGMENT METAL' box is checked if image contains metal.
- Then click 'RUN ANALYZER'.
- Lastly, confirm the laterality of the anatomical area.

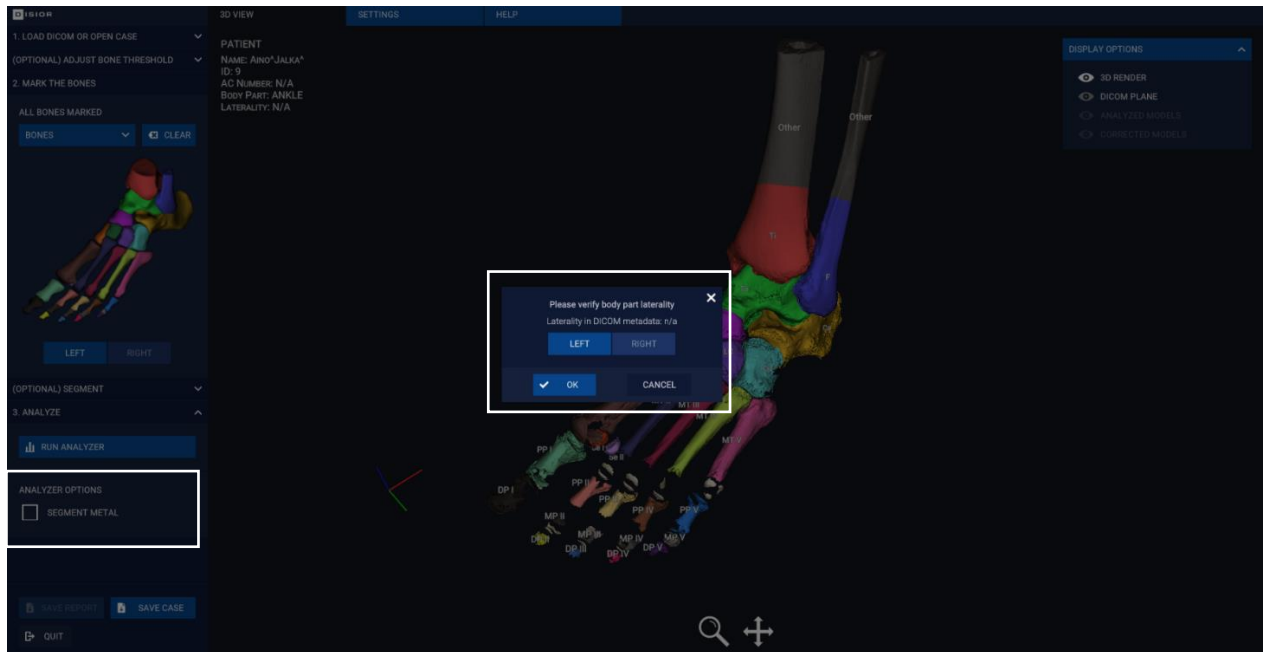


Image 12 Before initializing the analysis, check whether any metal components should be segmented and the laterality of the anatomy.



Before the analysis is started you must select the correct laterality and check 'SEGMENT METAL' option if image contains metal.

2.6 Review the results

2.6.1 3D View sheet

2.6.1.1 Display options for the 3D view sheet

The results of the automated segmentation of the patients' anatomy as presented in the original DICOM image series can be investigated on the '3D VIEW' sheet. There are two panels that can be used to explore the 3D models:

- The 'ANALYZED MODELS' panel is populated by all the individual bone models and the separate parts of each bone model e.g. axis, landmarks.
 - To hide/show all components of an individual bone, click the eye icon.
 - To hide/show an individual component (for example, the axis), click the down arrow to the left of the bones' name and then click the eye icon for the component(s) to be shown/hidden.

- The 'DISPLAY OPTIONS' panel allows you to view the 3D render, the DICOM plane (of the original DICOM image series), the analyzed 3D model and the qualitative distance map. Each can be shown/hidden via the eye icon.
 - Under the ANALYZED MODELS section, it is possible to refine the view of the model to, for example, just the anatomical bone model without the axes, landmarks or measurements points showing. Simply use the show/hide icons for each element.
 - Check the Distance map eye icon to see a color map of the bone-to-bone distances. Use the slider to select the distance ranges of interest Image 14.



Image 13 Detailed view of the 3D VIEW sheet with the three display options panels



Image 14 Example of the distance mapping tool being used to explore the distances between the tibia and talus, note the use of the show/hide options in the 'ANALYZED MODELS' panel to remove bones from the field of view

2.6.1.2 Create a fusion image to check the conformity of the 3D model

To visually validate the analyzed 3D model, create a fusion image between the DICOM images series and the 3D model and check the contours match.

- On '3D VIEW' sheet in the 'DISPLAY OPTIONS' panel, check the 'DICOM PLANE' and the 'CONTOURS' options.
 - Contours (shown in red) show the boundary of the 3D model at the slice level, they are one slice thickness wide.
 - Use the controls on the left-hand side to move the slice plane, to change between axial, coronal, and sagittal views, or to switch the model's transparent side.

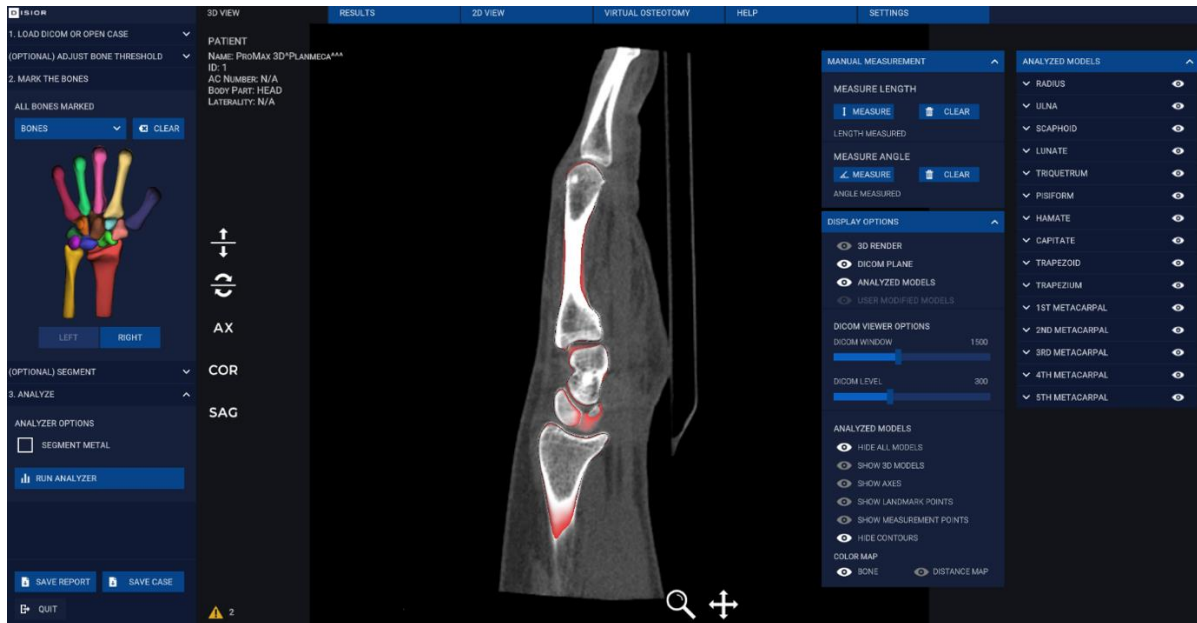


Image 15 Fusion images can be created to check the conformity of the 3D model to the original DICOM images series

2.6.1.3 Manual measurement (version 2.1.1 onwards)

In addition to the many automated measurements provided, it is also possible to perform manual measurements (length and angles) in BoneLogic™.

2.6.1.3.1 3D length measurements

- Manual length measures are calculated in 3D, an example is shown in Image 16.
- To perform a manual 3D length measurement click the 'LENGTH' button and use left-click to determine the start and end points of the length.
 - The pan and zoom tools can help to define the start and end points.
- The result is shown in the MANUAL MEASUREMENT panel.
- To clear the measurement, click the 'LENGTH' button again.

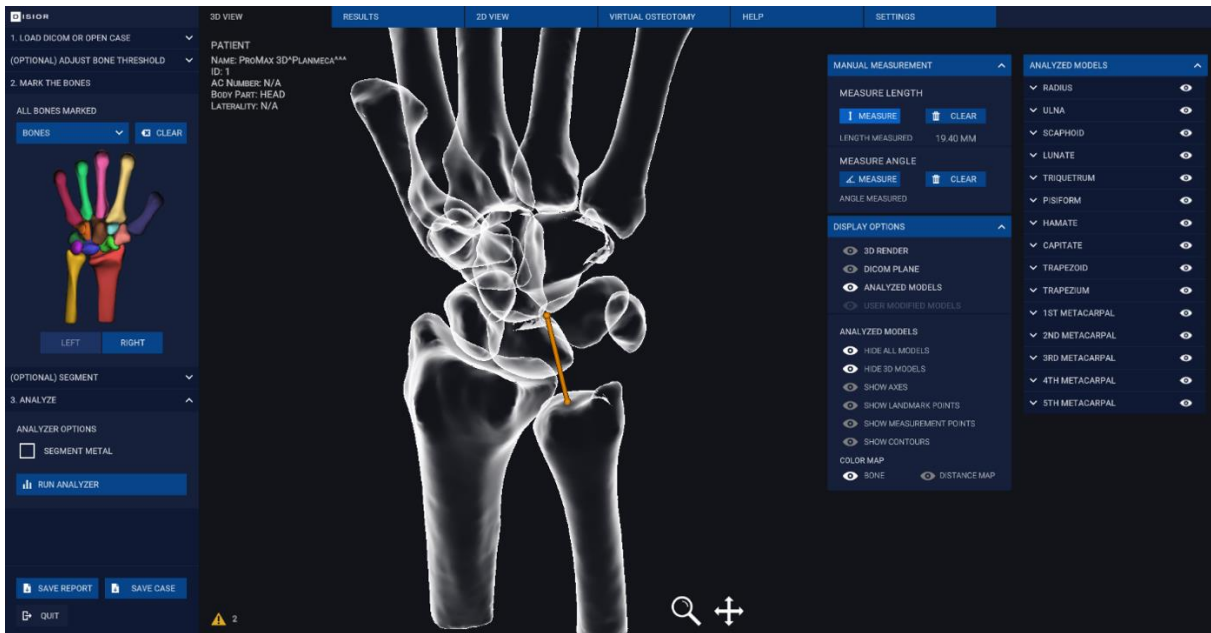


Image 16 3D manual distance measurement

2.6.1.3.2 2D angle measurements

- Manual angle measurements can be performed in 2D, an example is shown in Image 17.
- Set the position of the model using the pan and zoom tools as the view is frozen when performing angle measurements.
- Click the 'ANGLE' button and set the starting point, inflection point, and end point of the angle to be measured.
- The result is shown in the panel.
- To clear the measurement, click the 'ANGLE' button again.



Image 17 Manual 2D angle measurement

2.6.2 Results sheet

2.6.2.1 Measurements

After the analyzer is finished, the results of the bone alignment analysis are shown on the 'RESULTS' sheet.

- To get a more detailed view of each measurement simply click on any measurement in the list.
- A digitally reconstructed radiograph (DRR) 'projection' and a refined 3D model are also generated and shown on the 'RESULTS' sheet.
- The DRR is taken in the plane stated in the measurement name e.g., sagittal as defined by the DICOM coordinates.
- The measurement is determined from the landmarks or 3D bone axes, shown in the 3D view.
- For more details on the measurements please see Automated anatomical measurements: methodology and definitions on page 47.

Measurement	Value
HINDFOOT	
Longitudinal arch collapse/elevation	Analysis
Meary's Angle (Sagittal)	0.75°
Calcaneal Inclination Angle (Sagittal)	24.37°
Lateral Talocalcaneal Coverage (Sagittal)	10.19 mm
Talocalcaneal Angle (Sagittal)	57.09°
Hindfoot Valgus/Varus	Analysis
Talocalcaneal Angle (Axial)	36.55°
Saltzman View (45 degrees)	0.45°
Saltzman View (20 degrees)	2.71°
Hindfoot Moment Arm (Posterior)	10.17 mm
Medial Distal Tibial Angle (Coronal)	89.85°
Medial Talar Articular Surface Angle (Coronal)	92.43°
Talar Tilt Angle (Coronal)	-2.58°
Medial Talocrural Angle (Coronal)	10.11°
Talocalcaneal Angle (Coronal)	16.70°
Hindfoot Angle	22.51°
Talar Horizontal Inclination Angle (Coronal)	0.54°
Forefoot abduction/adduction	Analysis
Talonavicular Coverage (Axial)	37.43°
Meary's Angle (Axial)	15.31°
Tibiotalar pitch	Analysis
Tibial Lateral Surface Angle (Sagittal)	87.73°
Lateral Talar Station (Sagittal)	-0.30 mm
FOREFOOT	
Intermetatarsal Angles	Analysis

Image 18 The results page features the numerical results of the bone alignment analysis, a DRR and a 3d model for each measurement.

2.6.2.2 Projection images

Projection images, digitally reconstructed radiographs (DRRs), can be created on the 'RESULTS' sheet

- To start, select the 'PROJECTION IMAGES' from the left panel select
- To create a DRR including all tissues in the field of view check the 'DRR' box. To restrict the DRR to the bones check the 'SELECTIVE DRR' box.
- The sliders can be used to change the contrast (DICOM WINDOW) and brightness (DICOM LEVEL) of the DDR.
- Choose between the pre-set viewing angles and creating custom views via the drop-down menu. Custom views are created by manipulating the 3D model.
- Save the DRR images by clicking 'SAVE IMAGE'.



Image 19 Projection images panel on the results sheet for making custom DRRs

2.6.3 2D view sheet(version 2.1.1 onwards)

The 2D VIEW sheet can be used to review the original DICOM image series across three orthogonal viewing windows.

- To scroll through the slices in any of the three planes,-use the slider on the right-hand side of each window manually or by typing in a target slice number.
 - The 3D model in the bottom right panel shows the position of each of orthogonal planes within the volume.
- Tools on the left-hand side can be used to manipulate the appearance and position of the DICOM image series:
 - DICOM WINDOW slider will alter the contrast, and DICOM LEVEL will change the brightness of the DICOM image series.
 - To move and zoom in on a specific feature use the pan (+) and zoom (Q) tools. Pan tools works with click and drag, and the zoom tool, left click zooms in and right click zooms out.

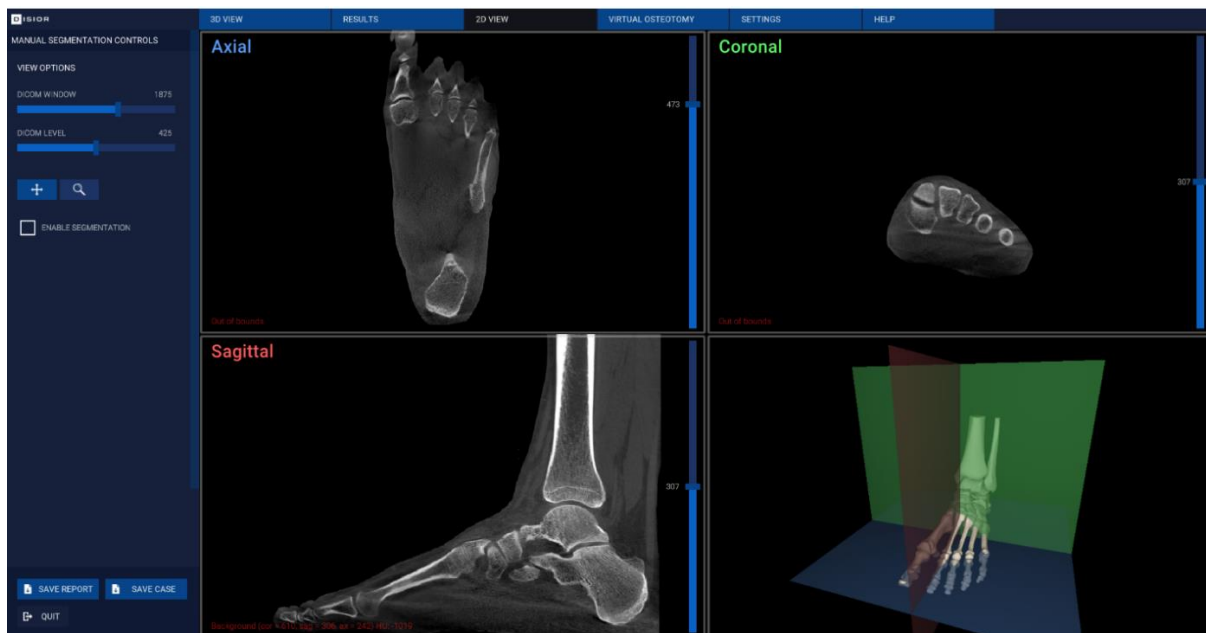


Image 20 The 2D VIEW sheet shows the DICOM image series in three orthogonal views

2.7 Saving and exporting the results

The analysis from Bonelogic™ can be exported from review outside the software and saved in a proprietary format for repeat reviewing in the software later.

2.7.1 Save report

To export the results and 3D models:

- Click the 'SAVE REPORT' button in the bottom left corner (Image 21). This will:
 1. Save the numerical results of the bone alignment analysis and a separate DRR for each measurement to a PDF.
 2. Save the 3D bone models as STLs (3D models).
 - a. The co-ordinates of the model are centered (0,0,0) on the center of the first voxel of the original stack.

2.7.2 Save case

To save the case for viewing again in Bonelogic (Image 21):

- Click the 'SAVE CASE' button in the bottom left corner. This will:
 - Save the entire results as presented in the software in a Disior proprietary format. '.dfcase' are created for foot and ankle analysis and '.dhcase' for hand and wrist analysis.

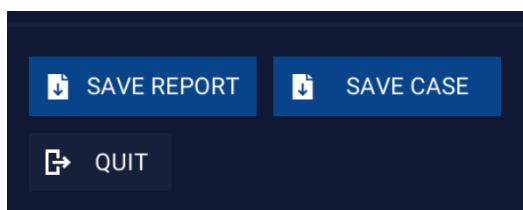


Image 21 Saving functions in Bonelogic

2.8 Manual segmentation

If you have purchased the additional Planning 'VIRTUAL OSTEOTOMY' module, then the 'MANUAL SEGMENTATION CONTROLS' will be enabled on the 2D VIEW sheet (Image 22).

To make edits and refinements to the automated segmentation of the bones:

- Select the element (bone, metal, background) of the model you want to modify. There are two ways to do this with the 'ANNOTATION SELECTION' tools (Image 23):
 - Click the dropper icon to pick a bone (or other model element) from within the field of view with one click.
 - Select the element you want to alter from the drop-down menu.
 - Once selected the bone or element will be shown in the top of the drop-down box.
- The 'ANNOTATION TOOLS' on the left-hand side can then be used to modify the segmentation of that bone or element. From left to right the annotation tools are:
 - The Smart Tool (Image 24) – this works in 3D and considers the Hounsfield unit and bone boundaries. It is best for larger changes that go across multiple slices. This tool allows works by clicking with left mouse button.
 - The Brush Tool (Image 25) – this can be used for free-hand changes but works on the slice that is active. It is best for smaller changes. This tool works by left click or left click and drag.
 - The Eraser Tool - will remove areas from a bone model (area affected is like the brush tool), using left click or left click and drag.
 - The 'SELECTION SIZE' slider can be used to set the size of the three tools.
- Scroll through (using the mouse wheel or the slider) and adjust all slices as necessary.
- Use the undo and redo arrows to review your modification.
- If needed, change the element you are working on with the dropper tool or the drop down in annotation selection, and perform these steps again.
- Once all modifications have been finished click the 'UPDATE 3D MODELS' button.
- A new item will be added to the '3D VIEW' sheet in the 'DISPLAY OPTIONS PANEL' – 'USER MODIFIED MODELS' (Image 26).
- The modified models can be exported as STLs via the SAVE STLS button in the bottom left corner (Image 27).



The manual segmentation modifications are not affecting the measurements.



Image 22 The 2D VIEW sheet with the manual segmentation tools shown on the left-hand panel.

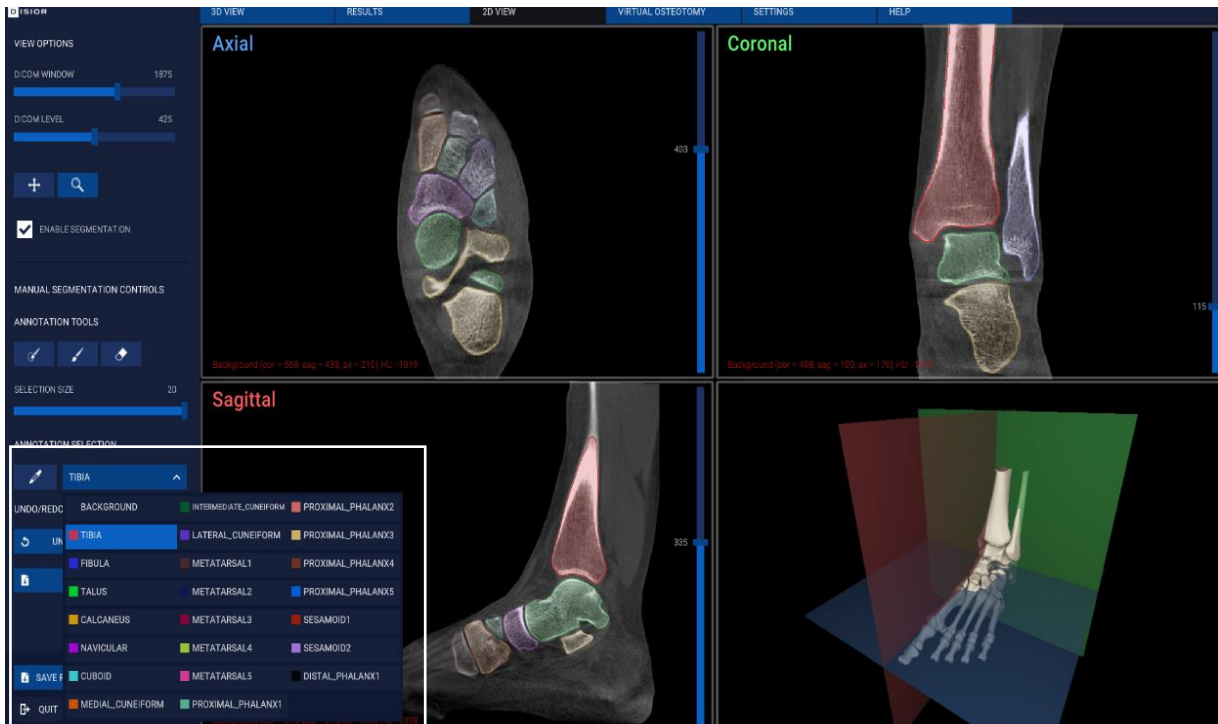


Image 23 Detail of the ANNOTATION SELECTION drop down menu.

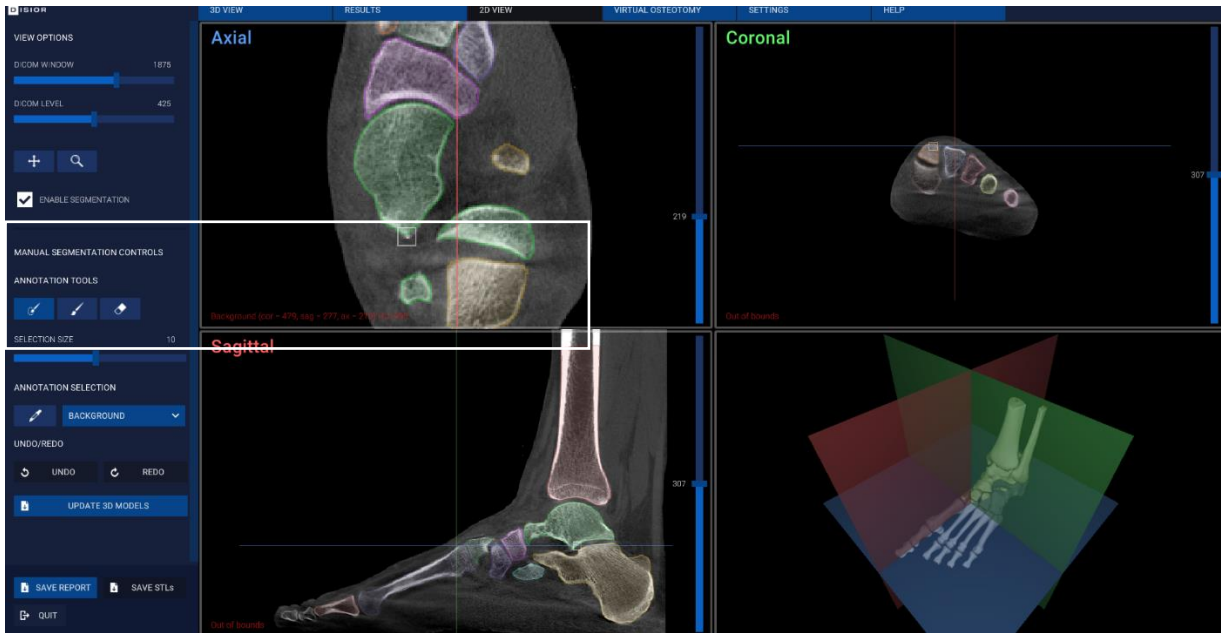


Image 24 Example of Smart Tool, ANNOTATION TOOLS, for modifying the 3D models

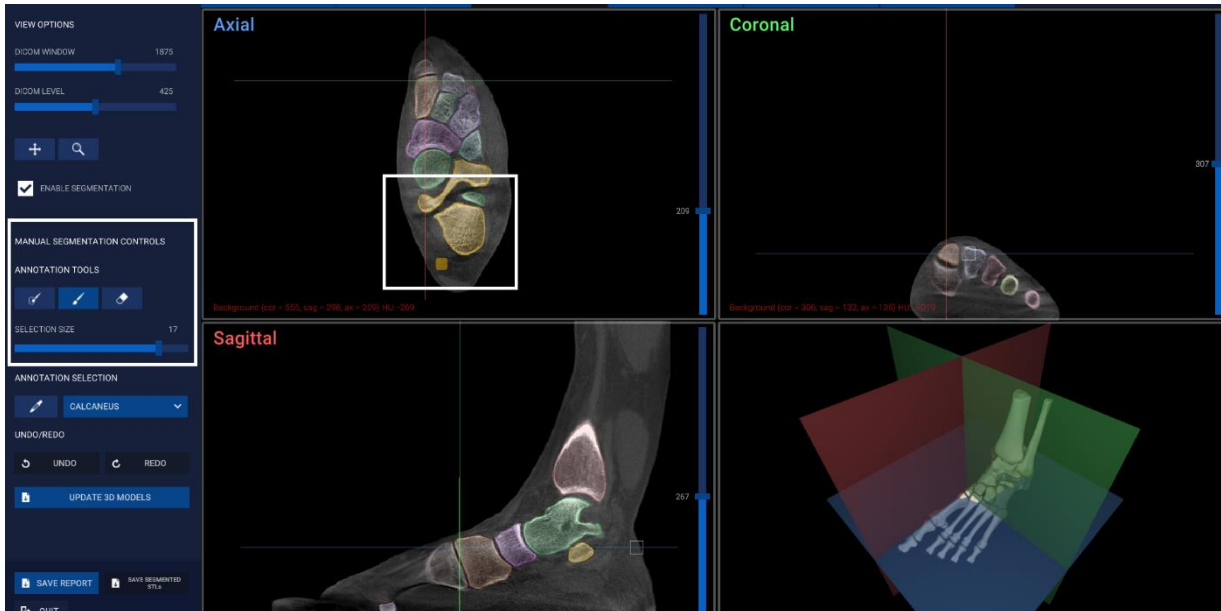


Image 25 Example of the Brush Tool, ANNOTATION TOOLS, for modifying the 3D models.



Image 26 USER MODIFIED MODELS as seen on the 3D VIEW sheet, note the surface texture is different on elements that have been modified.

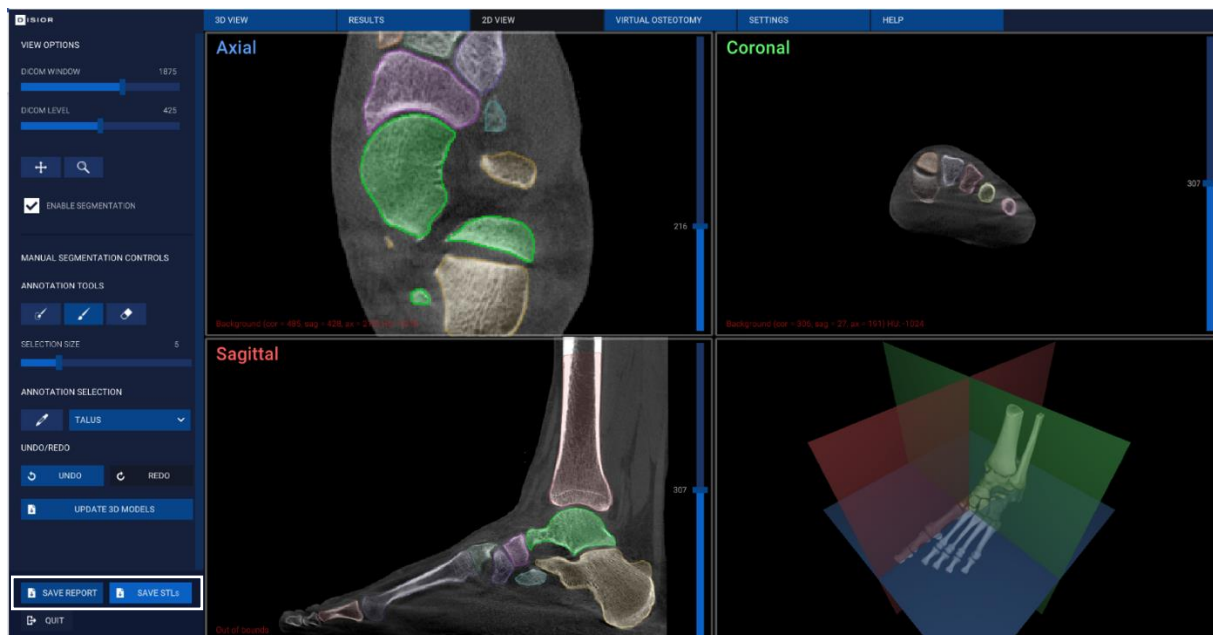


Image 27 To export the STLs of the modified 3D models, click SAVE STLs.

2.9 Planning tool

The VIRTUAL OSTEOTOMY sheet can be used to plan various repositioning and osteotomy procedures of the bones in the hand and foot. The parameters and models of the plan can be exported for use in the operating room or for additional processing by third parties for surgical guide or jig creation. To use the 3D models of the patients' data to plan and assess possible outcomes of an osteotomy, navigate to the 'VIRTUAL OSTEOTOMY' sheet.

2.9.1 Choose the bones

- To select the bone that you wish to operate on, click the 'SELECT BONE' button in the left-hand panel and left click on any bone to select it (Image 28).
 - The chosen bone will remain solid in the model and all others will become transparent.
- Use the 'SELECT ADDITIONAL BONES' button to add extra bones to the model. Click on the bones once to add them to the selection and once to deselect (Image 29).
 - The chosen bone will be opaque in the model, the rest of the bones remain transparent.
 - Additional bones selected for virtual osteotomy appear blue.

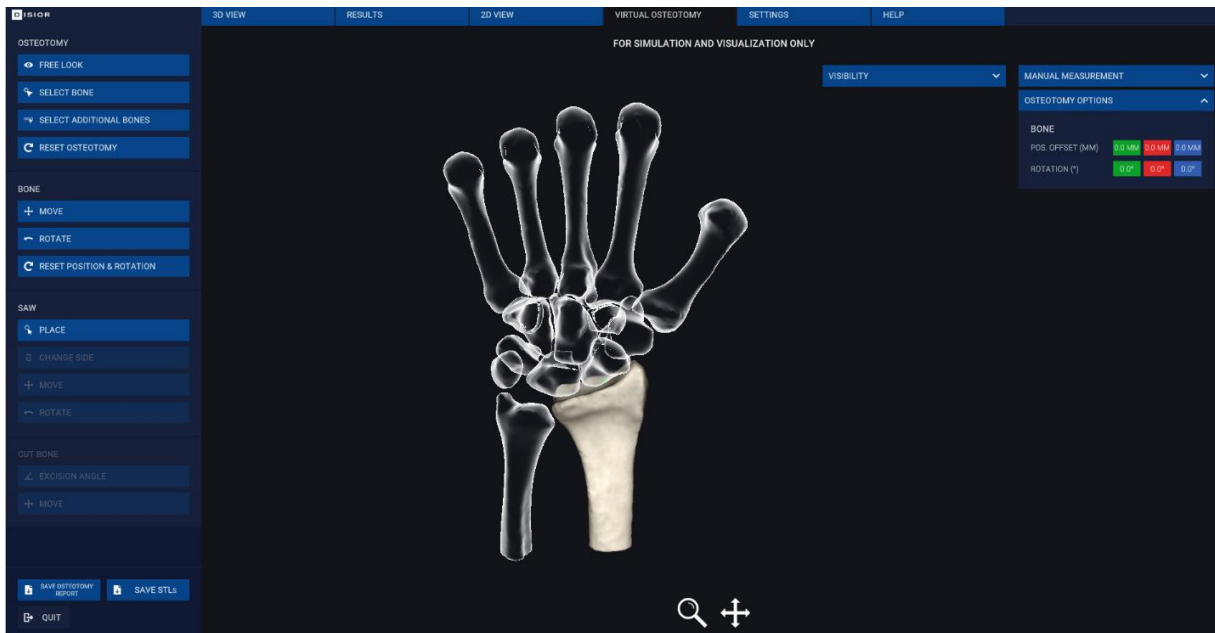


Image 28 Virtual Osteotomy sheet with one bone selected

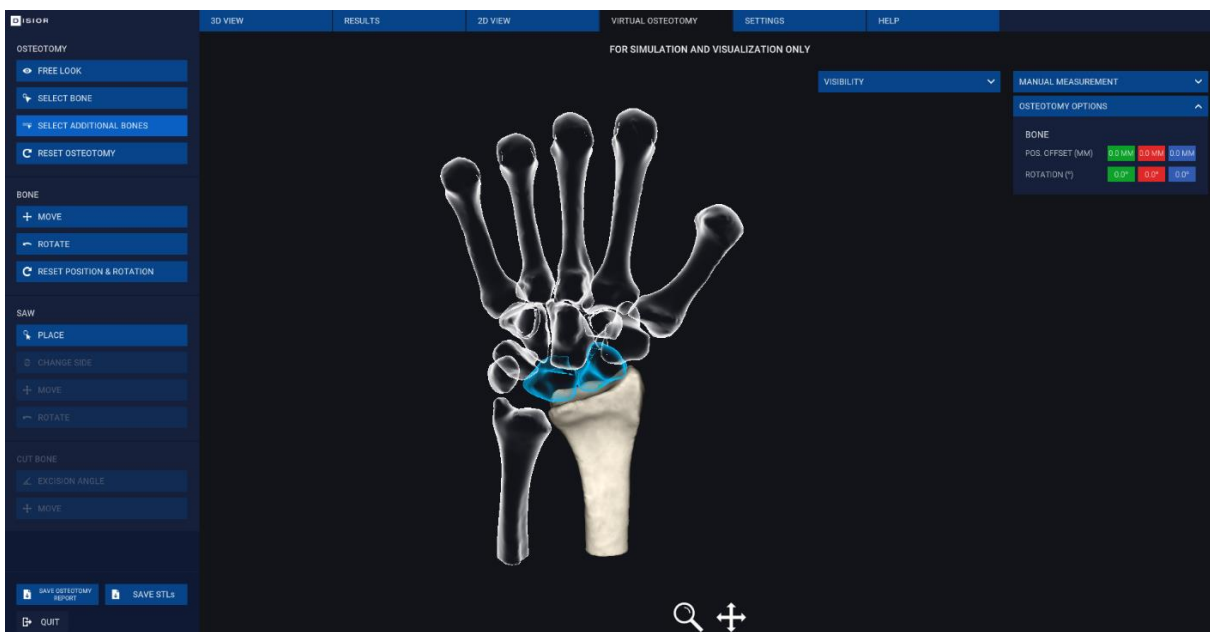


Image 29 Adding additional bones to create a group for a surgical plan.

2.9.2 Reposition the bone(s)

- The position of the selected bone(s) can be translated or rotated using the 'MOVE' and 'ROTATE' buttons in the BONE select of the left-hand panel.
 - Once 'MOVE' button has been clicked, translations in x, y, z can be done using the arrow handles (Image 30).
 - Left click drag on the arrows.
 - After the 'ROTATE' button has been clicked, three circular handles will appear. These can be used to alter the rotation of the bone(s) (Image 31).
 - Left click drag on one of three circular handles to adjust the bone(s) rotation:
 - Green and red handles will rotate the bone against its center point.
 - Blue handle will rotate the bone against its axis.
 - The 'OSTEOTOMY OPTIONS' widget displays the exact translational ('POS OFFSET') or rotational ('ROTATION') adjustments that have been applied (Image 30).
- As changes are made to the bone position the software will display the analytics related to the bone(s) in the bottom left-hand corner. Updated values are not shown for minimum joint gap measurements (Image 31).
 - The original result (as calculated during the analyzer run) in white and the updated values that reflect the changes to the bone in blue (Image 31).
- 'RESET POSITION & ROTATION' button can be used to return the bone to its original position. If multiple bones are selected each bone must be reset individually (Image 31).



The results provided in the planning tool shall be subject to careful expert assessment. The user should consider the output FOR SIMULATION AND VISUALIZATION ONLY. The pre-operative results do not represent the final post-operative results.

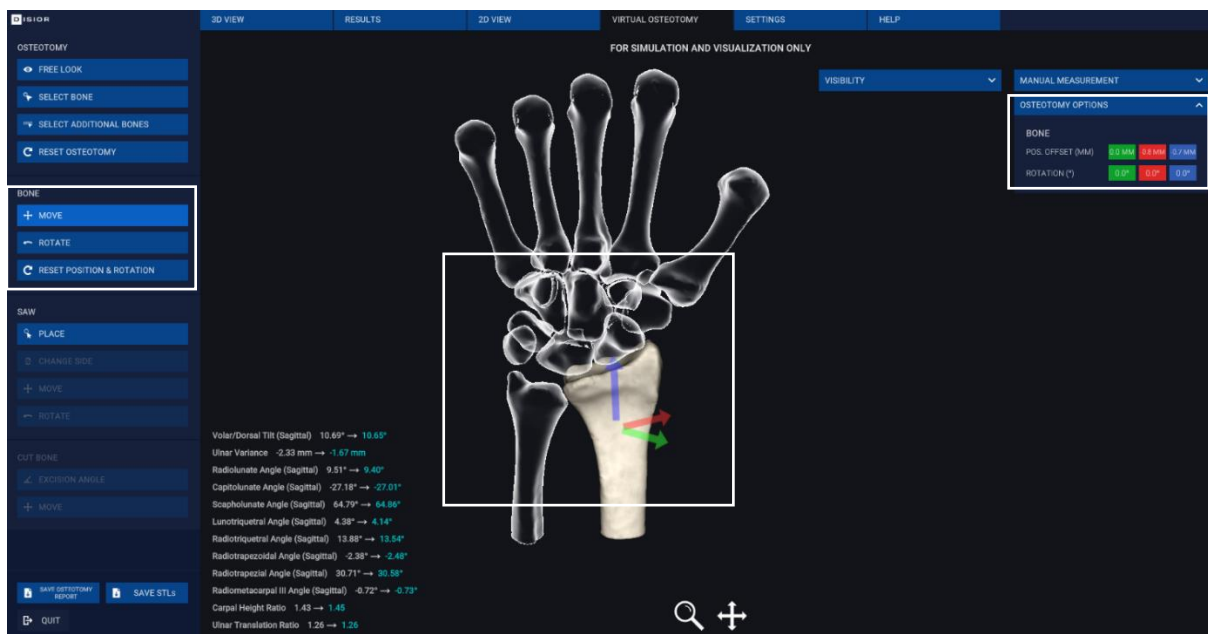


Image 30 Detailed view of the 'MOVE' function.

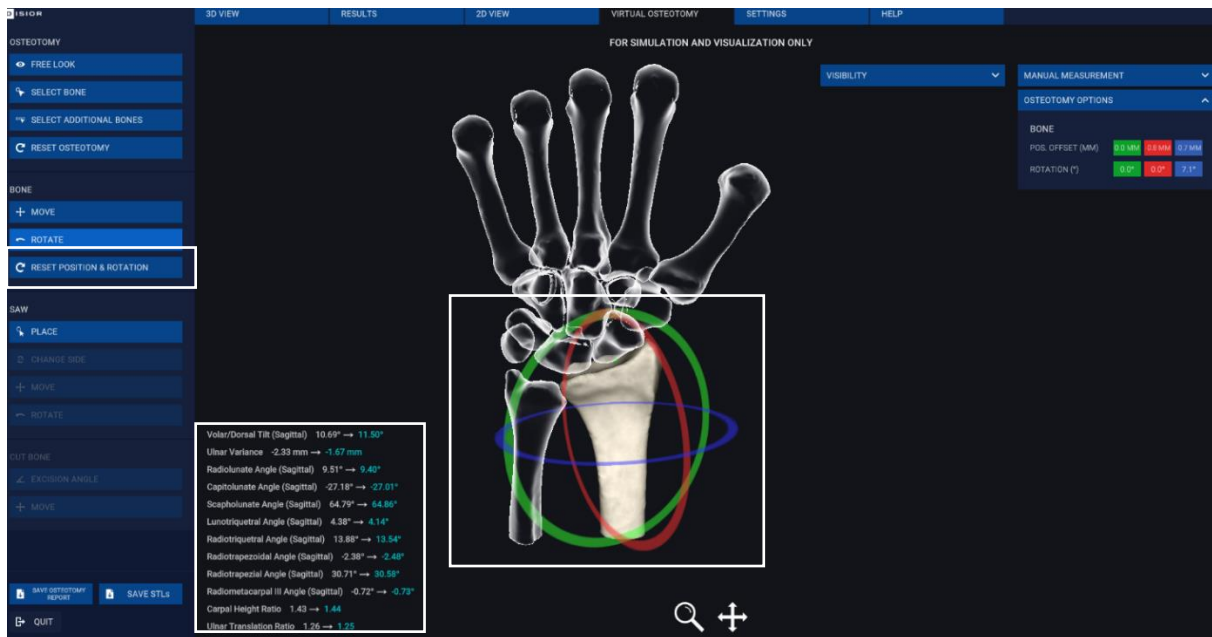


Image 31 Detailed view of the 'ROTATE' bone function.

2.9.3 Place and adjust the saw approach

- Click the 'PLACE' button in the 'SAW' tools in the left-hand panel. Then click the location on the bone where the saw would be placed for the cut in the procedure you are simulating (Image 32).
- The active side of the bone will be highlighted in red. You can swap which side is active with the 'CHANGE SIDE' button (Image 32).
- The width and thickness of the saw can be set with the SAW sliders, this allows you to replicate the saw that could be used in the OR (Image 32).
 - Saw width and thickness are added from the middle of the blade and are made symmetrically along the saw.
- The position of the saw can be refined with the 'MOVE' and 'ROTATE' tools:
 - The move arrows, work by left click and drag (Image 33):
 - The red arrow will move the position of the saw along the bone's longitudinal axis
 - The green arrow will adjust the height of the saw.
 - The blue arrow will adjust the saw depth within the bone.
 - The rotate circular handles, work by left click drag (Image 34):
 - The red handle will rotate the saw horizontally around the tip of the saw.
 - The green handle will rotate the saw vertically about the center point of the saw tip.
 - The blue handle will rotate the saw against the central axis of the blade.
- The exact positioning of the saw is recorded in the SAW section of the OSTEOTOMY OPTIONS panel as shown in Image 33 and Image 34:
 - Distances from axis start/end – are measured along the longitudinal axis of the bone shown as a red line, the entry and exit point.
 - Saw rotation – the rotation of the saw is show across three axes.
 - Saw depth – is measured from bone surface to tip of the saw.

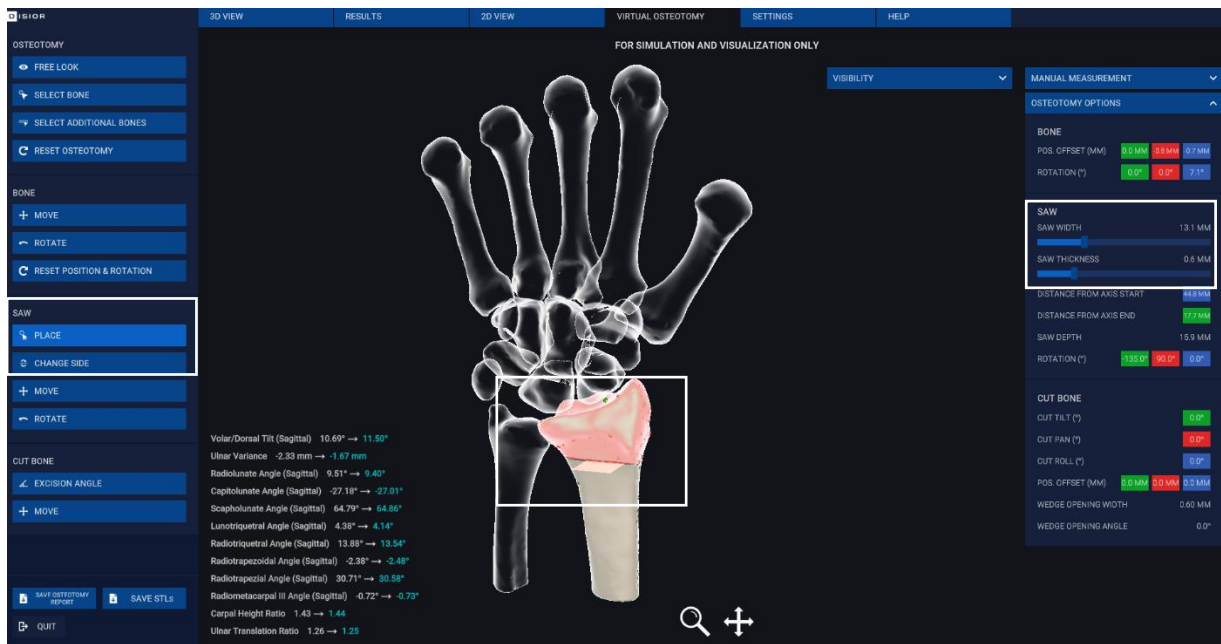


Image 32 Detailed view of the place saw function and saw parameters

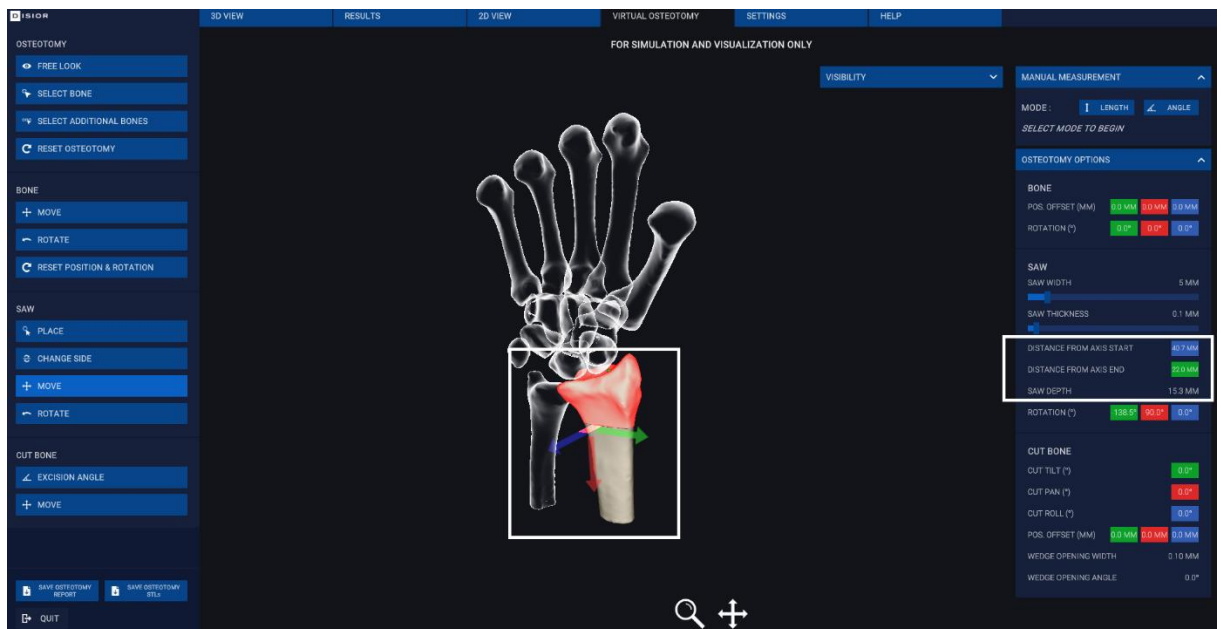


Image 33 Detailed view of the move saw function, with arrow handles shown

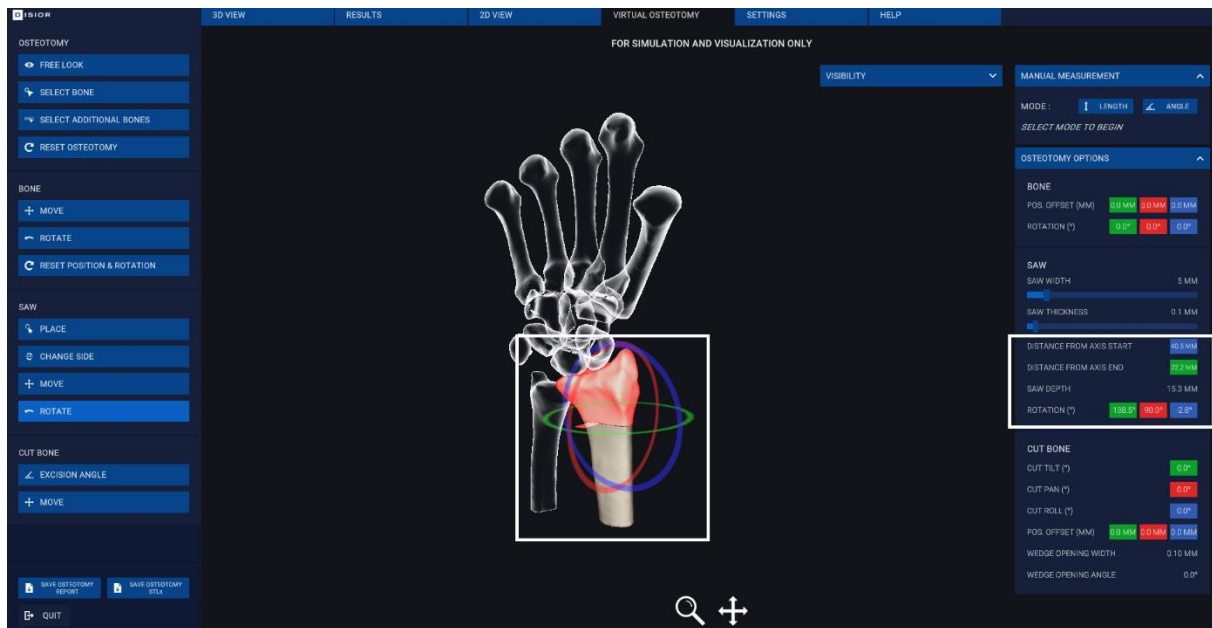


Image 34 Detailed view of the rotate option in the saw options, with circular handles shown

2.9.4 Conduct osteotomy / Cut the bone

- To create open or closed wedges start by clicking the 'EXCISION ANGLE' button: Three circular handles will then appear so that you can make angular adjustments to the position of the cut bone pieces. The 'CHANGE SIDE' button can be used to alter which part of the cut bone you are moving. Click and drag on the circular handles to:
 - Green handle - makes open/closed wedges laterally with the pivot point where the two parts of the cut bone meet.
 - This adjustment is recorded in the CUT BONE parameters 'CUT TILT' 'WEDGE WIDTH' and 'WEDGE ANGLE'
 - Wedge opening width and angle – the width is the distance of the opening of the cut and the angle is the excision angle.
 - Red handle - rotates the cut bone along the center line of the saw.
 - This adjustment is recorded in the CUT BONE parameters 'CUT PAN', 'WEDGE WIDTH' and 'WEDGE ANGLE'
 - Blue handle- rotates the cut bone around the bone's central axis.
 - This adjustment is recorded in the CUT BONE parameters 'CUT ROLL', 'WEDGE WIDTH' and 'WEDGE ANGLE'
- To move the position of the cut bone, click the MOVE button and the three arrow will appear:
 - Green handle – will allow you to move the cut bone laterally or medially.
 - Red handle – will allow to move the cut bone perpendicular to the bone's axis.
 - Blue handle – will allow you to move the cut bone along the bone's longitudinal axis
- To perform further alterations to the bones, simply repeat the previous steps on a new bone (or selection of bones). The software can only account for one cut per bone.
- After making a simulated osteotomy the results page is updated to reflect the differences in bone alignment (Image 38) see sections 4.1.2.1 and 4.1.3.1 how details on how these are calculated.

- To export the surgical plan, click the 'SAVE OSTEOTOMY REPORT' button.
 - This saves the original and simulated bone alignment metrics and the parameters of the surgical plan to a .csv (comma separate values file)
- To save the 3D model of the plan for the creation of jigs or surgical guides, click the 'SAVE STL'S' button, saves the 3D bone models with the repositioning and cuts as a series of STLs.

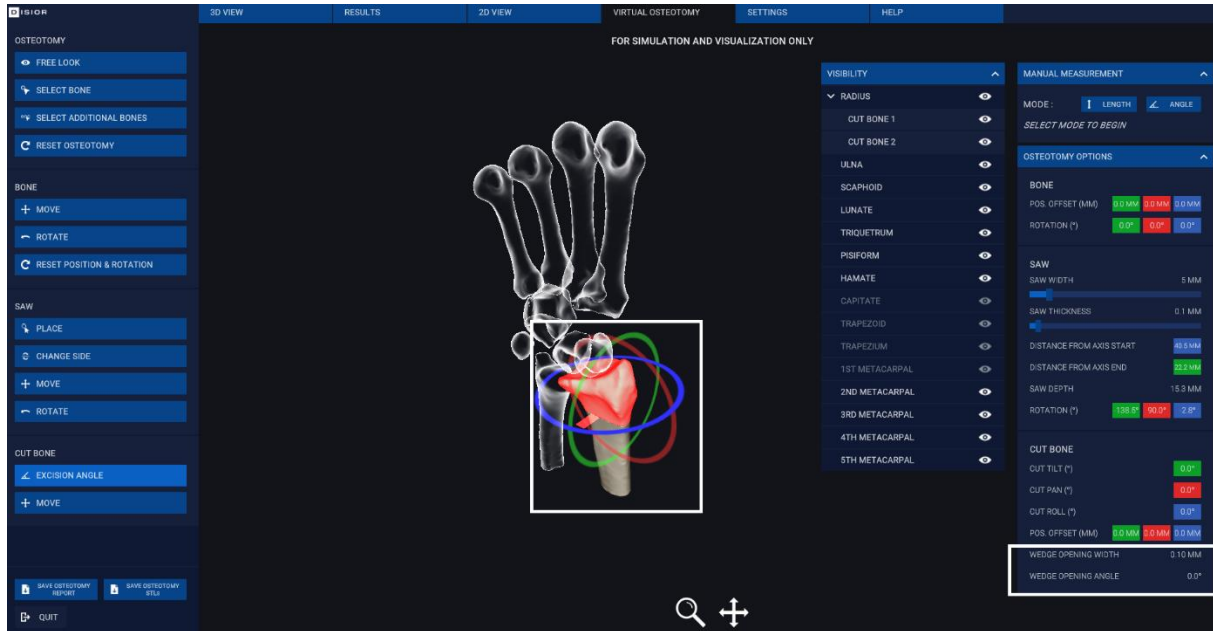


Image 35 Detailed view of tools to create an open/closed wedge osteotomy analytics and use of bone visibility toggling

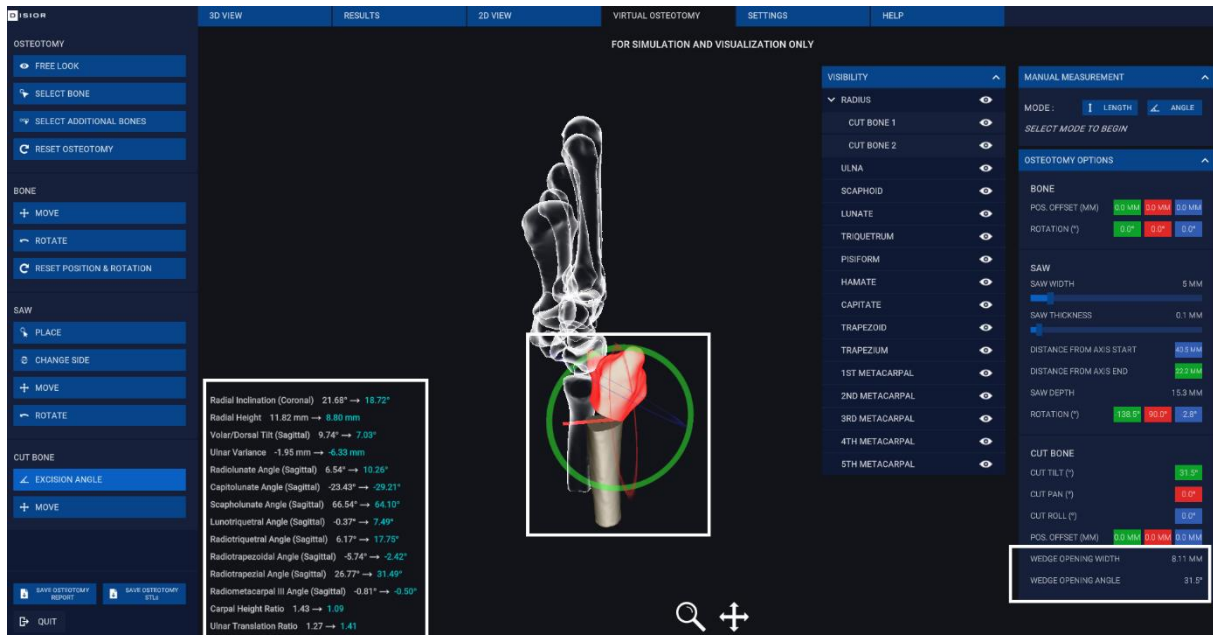


Image 36 Example of an exaggerated open wedge osteotomy

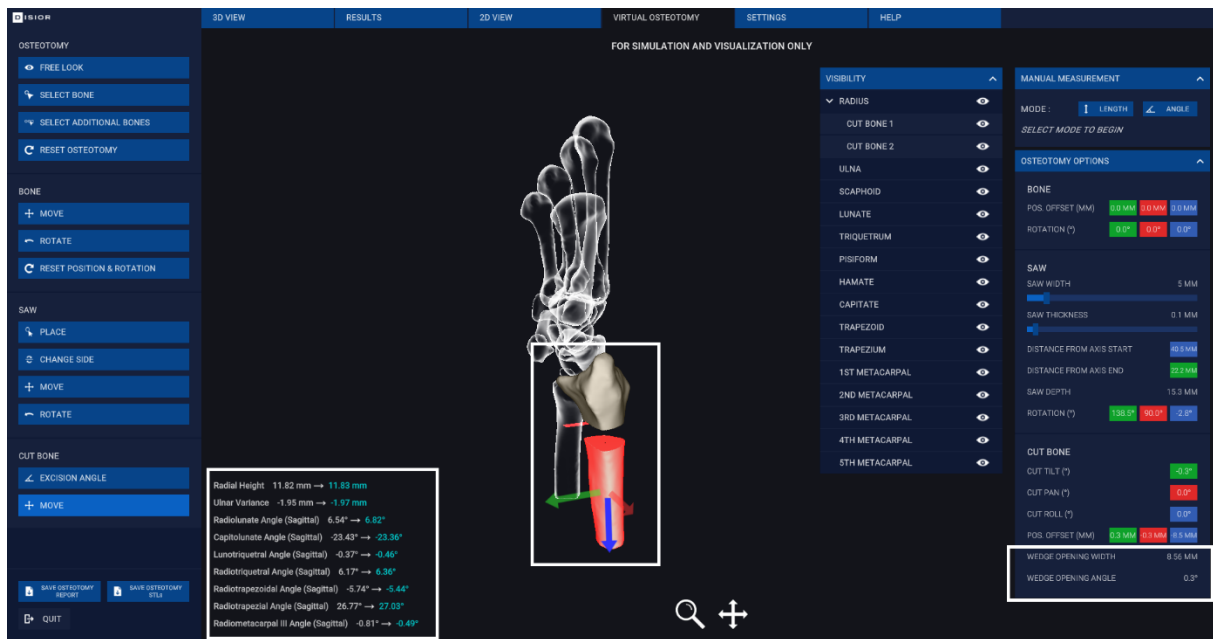


Image 37 Example of a position adjustment osteotomy showing changes in bone alignment

Radius and Ulna Parameters	Analysis	Simulated
Radial Inclination (Coronal)	22.65°	20.49°
Radial Height	12.58 mm	9.46 mm
Volar/Dorsal Tilt (Sagittal)	10.77°	11.11°
Ulnar Variance	-1.79 mm	-7.40 mm
Carpal Alignment	Analysis	Simulated
Radiolunate Angle (Sagittal)	8.76°	0.55°
Capitolunate Angle (Sagittal)	-26.25°	-27.36°
Scapholunate Angle (Sagittal)	65.65°	64.19°
Lunotriquetral Angle (Sagittal)	4.87°	5.58°
Radiotriquetral Angle (Sagittal)	13.63°	6.13°
Radiotrapezoidal Angle (Sagittal)	-3.75°	-11.76°
Radiotrapezial Angle (Sagittal)	30.39°	21.74°
Radiometacarpal III Angle (Sagittal)	-0.83°	-9.49°
Carpal Height Ratio	1.42	1.66
Ulnar Translation Ratio	1.24	1.59
Joint Gaps	Analysis	Simulated
Radioscaphoidal Joint Minimum Gap	1.57 mm	1.34 mm
Radiolunate Joint Minimum Gap	1.42 mm	1.18 mm
Scapholunate Joint Minimum Gap	1.02 mm	1.02 mm
Scaphotrapezoidal Joint Minimum Gap	1.55 mm	1.55 mm
Scaphotrapezial Joint Minimum Gap	1.54 mm	1.54 mm
Lunotriquetral Joint Minimum Gap	1.11 mm	1.11 mm
Lunocapitate Joint Minimum Gap	1.17 mm	1.17 mm

Image 38 Detailed view of the measurements sheet showing original and simulated bone alignment analytics

2.10 Help & Basic Troubleshooting

2.10.1 Report an issue via Bonelogic™

The best way to submit a support request is via the software. On the HELP sheet click 'REPORT AN ISSUE' and fill out all required fields and send the report by clicking 'SEND REPORT' as shown in Image 39. A description of the case, the issue will expediate the process.

Please do not include sensitive data (e.g. identifiable patient data) within the description field.

2.10.2 Send image for analysis

Please fill the email address and provide description of the image before sending the image for analysis then click 'SEND IMAGE' as shown in Image 40.

Please do not include sensitive data (e.g. identifiable patient data) within the description field.

2.10.3 Email support

In case of any problems, please contact Disior™ support via e-mail disior.support@paragon28.com all support requests will be answered with 48 hours, but usually we respond within hours.

Be sure to include the log files- by using the 'Save files to' button on the HELP sheet. If this is not possible due to a software crash or freeze when you can access them at this directory:

C:\Users\XXXX\AppData \LocalLow\DisiorAnalytics\Bonelogic "Player.log" (where XXXX is the username)

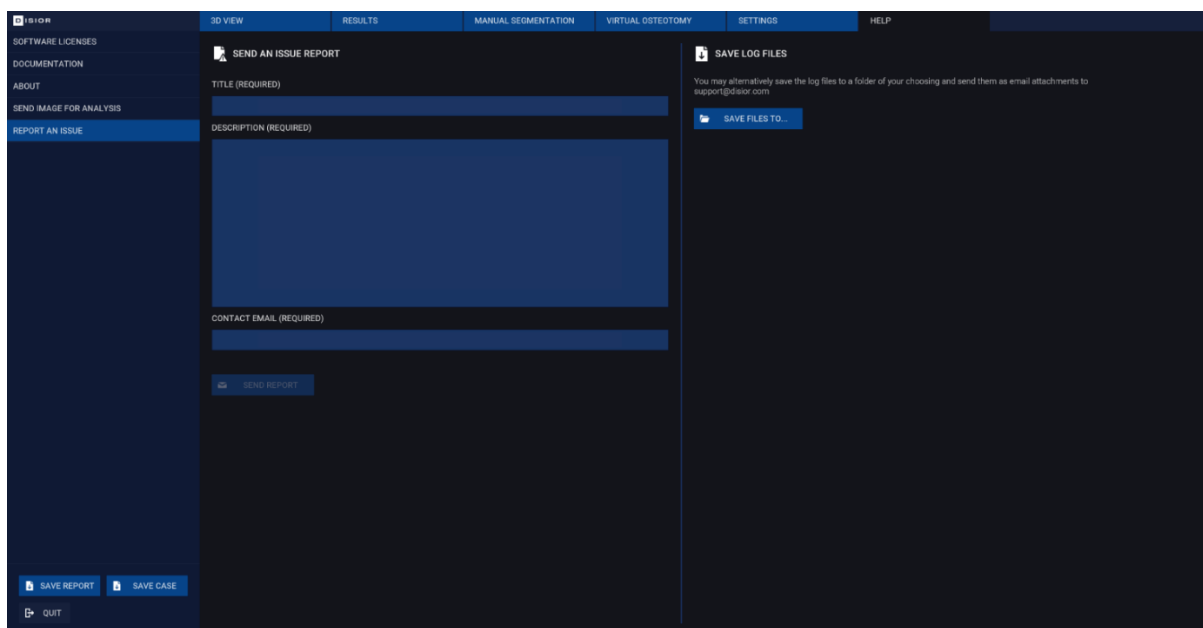
The screenshot shows a software interface with a dark theme. At the top, there is a navigation bar with tabs: '3D VIEW', 'RESULTS', 'MANUAL SEGMENTATION', 'VIRTUAL OSTEDTOMY', 'SETTINGS', and 'HELP'. On the left side, there is a sidebar menu with options: 'SOFTWARE LICENSES', 'DOCUMENTATION', 'ABOUT', 'SEND IMAGE FOR ANALYSIS', and 'REPORT AN ISSUE' (which is highlighted). The main content area is titled 'SEND AN ISSUE REPORT' and contains several input fields: 'TITLE (REQUIRED)', 'DESCRIPTION (REQUIRED)', and 'CONTACT EMAIL (REQUIRED)'. Below these fields is a 'SEND REPORT' button. To the right of the main form, there is a 'SAVE LOG FILES' section with a 'SAVE FILES TO...' button and a note: 'You may alternatively save the log files to a folder of your choosing and send them as email attachments to support@disior.com'. At the bottom left of the interface, there are buttons for 'SAVE REPORT', 'SAVE CASE', and 'QUIT'.

Image 39 Detailed view of the Send An Issue Report form on the Help sheet

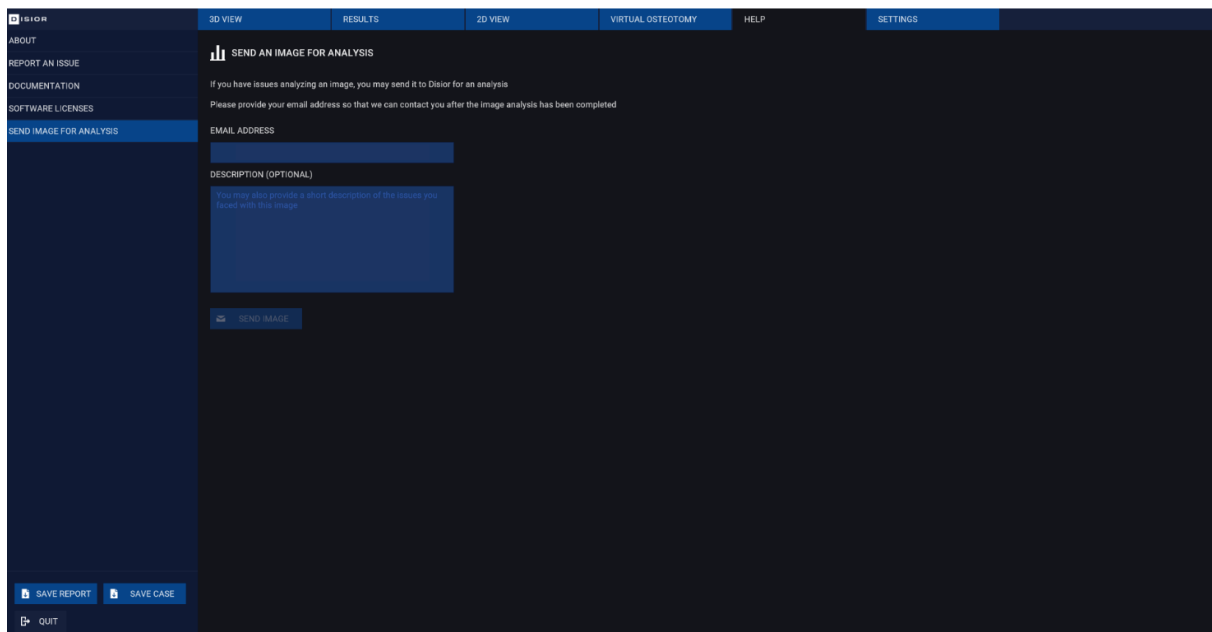


Image 40 Detailed view of the Send Image For Analysis form on the Help sheet

2.10.4 Troubleshooting Guide

Stage	Issue	Solution
Installation- First time logging in	Unable to verify license	There may not be a port in the firewall for a secure connection to be made to the Disior™ cloud. Please contact you IT department to ensure that there is an exception made for the IP and port.
Installation First time logging in	Password is incorrect	When the license was activated, you will have been sent an email with a 1-time password, this is case sensitive. It may also contain letters that look similar e.g. upper case i 'I' and lower case L 'l'. So we recommend that you copy-paste this password into the password field.
Log in	License not verified	Sometimes after a windows update, the device ID of the workstation may change. If this occurs, you will not be able to run the software until the new device ID has been activated by Disior. You can see the device ID when the software is opened. If you suspect that this has occurred, please copy paste the device ID into an email to the Disior support team (disior.support@paragon28.com). If you are unsure if there has been an update or if this device ID has been changed please send Disior the log files, as in the instruction in section 2.10.3 'Email support' on page 41.

Log in	Username not recognized	<p>Your username is your email address that was submitted during the license activation step. It is case sensitive.</p> <p>If this doesn't fix the issue- email disior.support@paragon28.com</p>
Login	New user	<p>If your email address is not recognized and the email was not submitted when the license was activated, please send a request for a new user to be added to the account via disior.support@paragon28.com</p>
Login	Password incorrect	<p>If you changed the password to one that included special characters or have forgotten the password, you will need to submit a password reset request.</p> <p>You will then be sent a new 1-time password to be used. Please copy-paste this into the field. The software will prompt you to change this, please ensure that the new password follows these guidelines:</p> <ul style="list-style-type: none"> • Minimum 8 characters in length • Alpha-numeric • Minimum 1 upper case letter • No special characters (e.g. #£\$%&)
Load DICOM data	Taking a long time to list the data in the chosen folder	<p>The time taken to load and list all DICOM image series is dependent on the number of datasets in the chosen directory.</p>
Initial 3D render	No data is shown after the DICOM is loaded	<p>Please adjust the Hounsfield unit slider and create recreate render. This should fix the problem, if not please send the dataset to Disior™ for review via the HELP page, as above.</p>
Mark the bones	Poor segmentation result	<p>For difficult cases, follow the instructions in section 'Additional steps for difficult cases' on page 21.</p> <p>If additional marks and re-runs of the segmentation step do not help, please send the case to Disior™ to review using the 'Send image for analysis' instructions as on page 41.</p>
Mark the bones	Fragments of fractured bones look fused or incorrect	<p>The software is not intended to be used to identify fragments of a fracture.</p> <p>If you suspect a patient DICOM image series contains a fracture and has been segmented poorly,</p>

please check by using the 'Create a fusion image' instructions on page 25.

If there are fragmented pieces, then please follow the 'Send image for analysis' instructions on page 41.

Review the results	3D model looks squished in the z-axis	This can be due to inconsistent spacing between slices in the original DICOM image series. As stated in the 'Imaging data quality requirements' on page 5 the software is not intended to be used with datasets with inconsistent slice spacing, therefore please try to select a different DICOM image series for analysis.
Software crash	Continuity and recovery	In case of possible software error situation, the software needs to be re-started. The software is not storing any databases or records, so no back up storage or similar is in use for any data. All data from the software is stored either locally to the workstation or to other data storage systems controlled by the customer. For the cloud computing system, Disior has a backup system ready to be taken into use if interruptions or errors occurs. Disior has built an automatic monitoring system for the cloud computing performance.

3 Errors, Warnings and Residual Risk

3.1 Errors

3.1.1 Error messages

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

3.1.1.1 Image availability



ERROR: IMAGE IS UNAVAILABLE (EMPTY OR CORRUPTED), CONTACT DISIOR SUPPORT.

3.1.1.2 Analysis failure



ERROR: ANALYSIS FAILED; RESULTS ARE NOT AVAILABLE, CONTACT DISIOR SUPPORT.

3.1.1.3 License availability



ERROR: SOFTWARE LICENSE IS UNAVAILABLE, CONTACT DISIOR SUPPORT.

3.2 Warnings

3.2.1 Warning messages

In a case of a poor image quality and possible measurement inaccuracies the software issues warning messages. Image quality warning message is given if the DICOM attributes (e.g. Pixel Spacing, Slice Thickness and Pixel Aspect Ratio) are substandard, where “DICOM attribute” is a placeholder for the attribute that has triggered the warning. The limited field of view warning message is given if the field of view of a specified bone is limited and may be causing uncertainties in measurements. The landmark location warning message is issued if there is a possible deviation in landmark location leading to uncertainties in measurements. Warning for contact between bones is an indication of registration inaccuracy within the bone indicated. These warnings appear as below, where “bone name” is a place holder for the exact bone that has triggered the warning. The laterality and bone selection related messages are issued in case the analyzer detects abnormal bone position potentially triggered by incorrect selection.

3.2.1.1 Image quality



WARNING: INPUT IMAGE “DICOM ATTRIBUTE” DOES NOT MEET ANALYZER REQUIREMENTS.

3.2.1.2 Limited field of view



WARNING: PORTION OF “BONE NAME” VISIBLE IN THE IMAGE IS NOT SUFFICIENT FOR MEASUREMENT.

3.2.1.3 Landmark location



WARNING: MEASUREMENTS OF “BONE NAME” POINTS MAY BE INACCURATE.

3.2.1.4 Contact between bones



WARNING: CONTACT DETECTED IN "BONE NAME".

3.2.1.5 Laterality selection



WARNING: ANALYZER DETECTED ABNORMAL BONE POSITIONING OR ANATOMY. PLEASE CHECK THE LATERALITY.

3.2.1.6 Bone selection



WARNING: ANALYZER DETECTED ABNORMAL BONE POSITIONING OR ANATOMY. PLEASE CHECK THAT BONES ARE MARKED CORRECTLY.

3.2.2 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.

3.2.2.1 Informative message example



SOFTWARE LICENSE HAS EXPIRED, CONTACT DISIOR SUPPORT.

3.3 Residual risk

There are three residual risks remaining in the software: 1) registration failure, 2) registration inaccuracy, and 3) measurements.

3.3.1 Registration failure

When this type of error occurs, the user is notified and encouraged to seek an alternative method for patient diagnosis and treatment planning

3.3.2 Registration inaccuracy

Small registration inaccuracies are unlikely to impact measurements. If there are major mismatches between the patient DICOM image and the 3D model, the user will easily detect the geometrical nonconformities. At this point the user should seek an alternative method for the diagnosis and the treatment planning.

3.3.3 Measurements

The measurement accuracy is directly related to registration accuracy, as above.

4 Automated anatomical measurements: methodology and definitions

4.1.1 Introduction

BoneLogic™ automatically calculates distances and angles between bones and specific landmarks necessary to reliably evaluate human anatomy in three-dimensions (3D). This document is a reference for users of BoneLogic. It seeks to:

- Describe the general principles and processes behind the different measurement types.
- List and define the measurements currently available per anatomical area.

4.1.1.1 General Principles

The automated and accurate bone tissue segmentation and shape analysis of BoneLogic software enables:

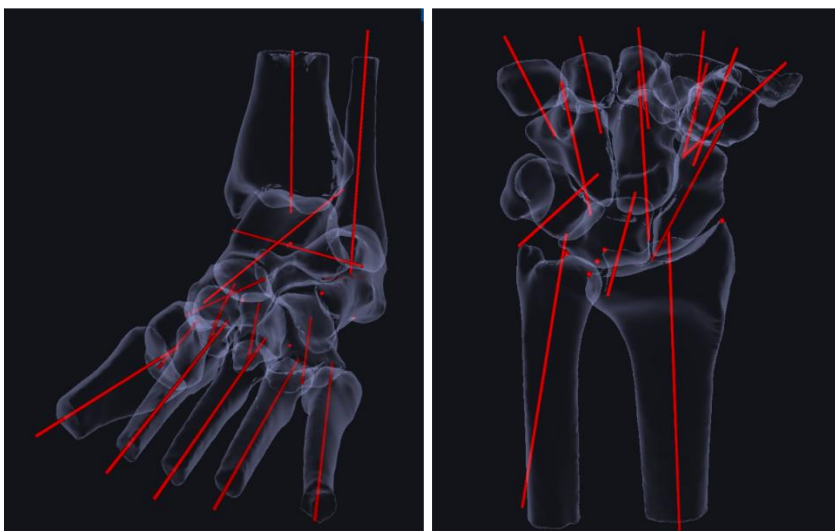
- Visual assessment of bone shape, joint gaps and spaces between bones, for example, in pathologies like arthritis.
- Calculation of inter-bone angles and distances between clinically relevant landmarks in patient specific coordinate system, for example, to quantify dislocations and malformities like flat footedness.

4.1.1.2 Available measurements

Measurements are currently available for two anatomical regions:

1. The hand and wrist - measurements are calculated across two regions:
 - Radius and ulna.
 - Carpal alignment.
2. The foot and ankle - measurements are calculated to define the:
 - State of the arch.
 - Valgus/varus condition of the foot.
 - Forefoot deformity.
 - Hallux valgus

The following sections describe these measurements and defines the axes, landmarks and surfaces used for calculation.



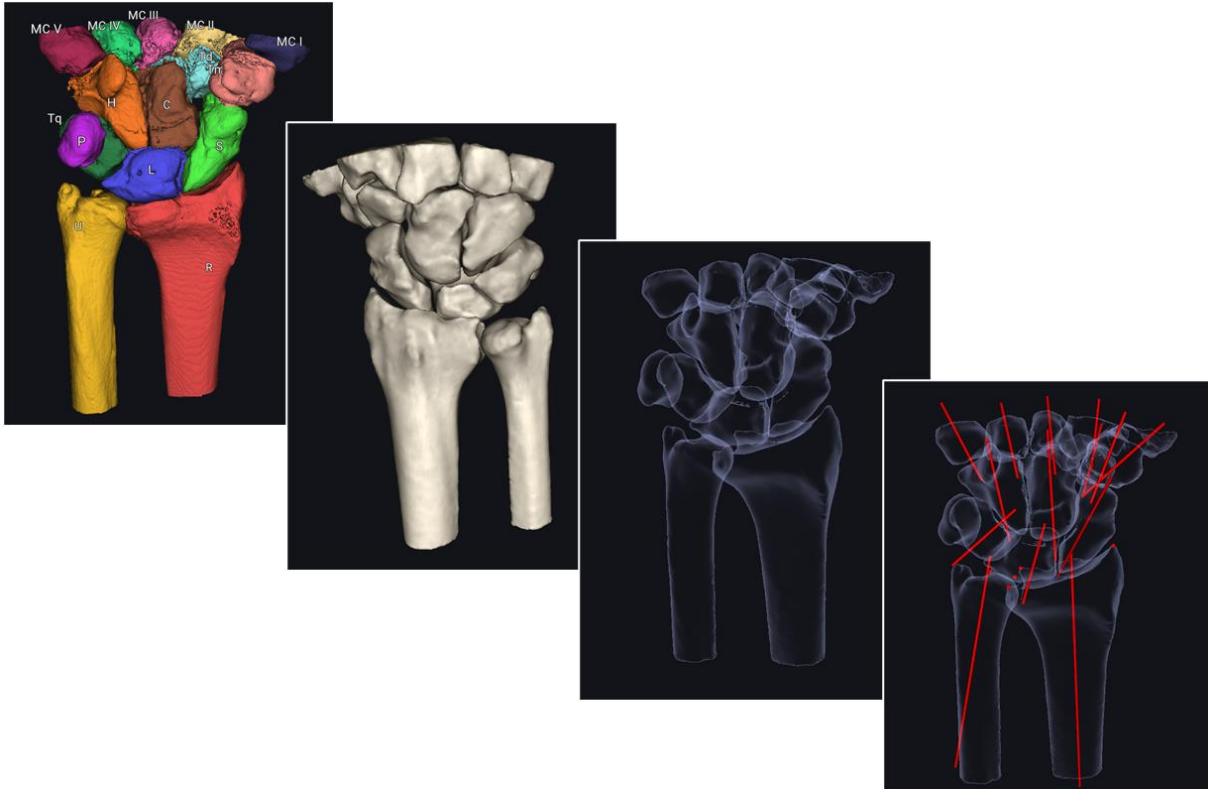
4.1.2 Hand and wrist measurements

All measures are calculated based on 2D projections of 3D bone axes and measurement lines

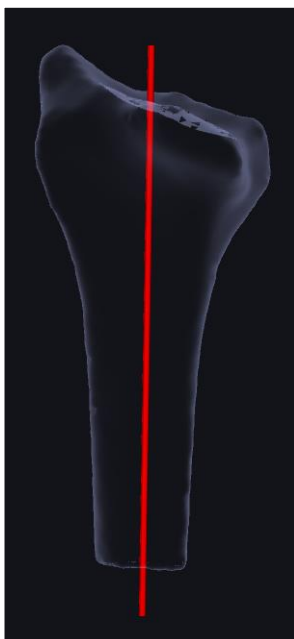
- Coronal and sagittal projection directions are set according to radius alignment.

Measures are shown with + or – sign

- Negative sign on angle measurement refers to more dorsally directed axis with respect to reference axis.



4.1.2.1 Bone axis and landmark definitions

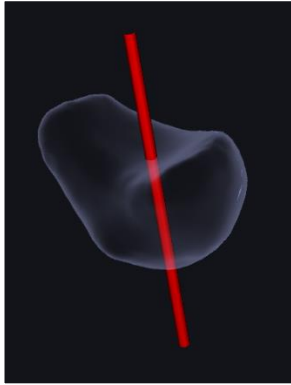


Original results from the solver:

Longitudinal axis:

The software scans the bone and determines its cross-section at various locations. A weighted centre point is computed for each cross-section. Robust line fitting is used to find a straight-line representative for the cross-section points.

- *Radius, ulna, scaphoid, capitate, MC III*



Articular surface normal axis:

The software computes the average surface normal within the articular surface region. Location is in the center of the region.

- Lunate (distal), triquetrum (distal)

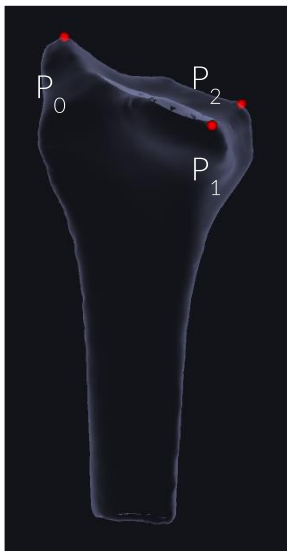
Note that for all the remaining bones (excl. pisiform), axis is also fitted but not used in the measurements.

- Longitudinal axis for MC I, II, IV, V
- Articular surface normal for hamate (distal), trapezoid (proximal), trapezium (proximal)



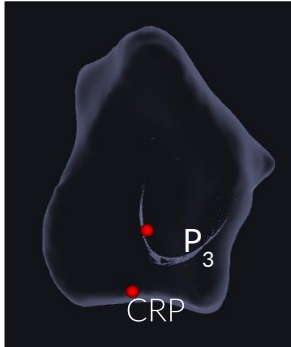
Virtual planning metrics:

- During the virtual osteotomy the bone axes are calculated differently.
- The entry and exit points of the original axis remain the same (red lines), and once a change has been made to a bone the axis is now the line that connects those points (green line).



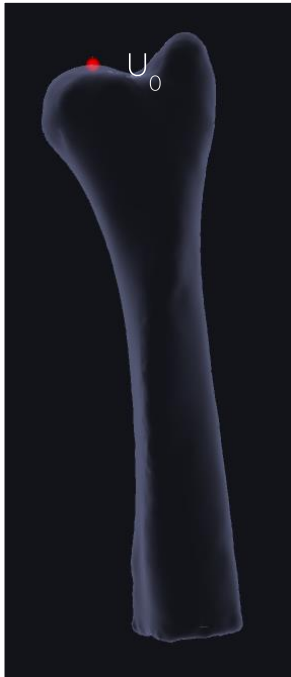
Landmark locations:

1. Radius
 - P₀ is the radial styloid process. It corresponds to the most distal point of radius in the direction of its longitudinal axis.
 - P₁ and P₂ locate in the ulnar volar and dorsal corners, respectively, of distal radius. They are found at the most distant locations seen when scanning a longitudinal axis segment located proximally from the epiphyseal region.



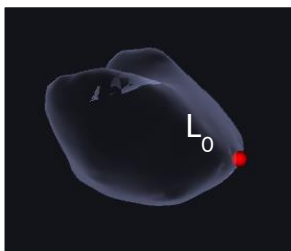
2. Radius

- CRP (central reference point) is the middle point between the landmarks P₁ and P₂.
- P₃ lies on the proximal boundary of the carpal region. The location is the centre point on the ulnar side of the radius distal articular surface.



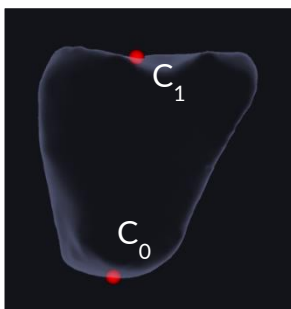
3. Ulna

- U₀ corresponds to the most distal point of ulna distal articular surface in the direction of its longitudinal axis.



4. Lunate

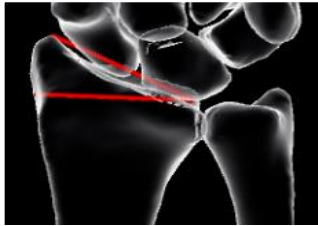
- L₀ corresponds to the ulnar corner point of lunate.



5. Capitate

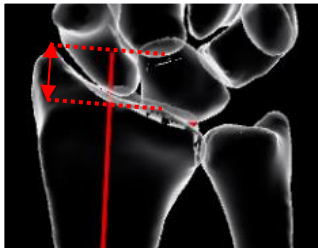
- C₀ and C₁ correspond to the proximal and distal intersection points, respectively, of capitate longitudinal axis and its surface.

4.1.2.2 Radius and Ulna Parameters



Radial Inclination (coronal)

- The angle between the line from CRP (central reference point) to P_0 (tip of radial styloid process) and the line perpendicular to radius longitudinal axis in posteroanterior projection



Radial Height

- The distance between CRP and P_0 measured in the direction of radius longitudinal axis



Volar/Dorsal Tilt (Sagittal)

- The angle between the line from volar rim tip to dorsal rim tip on radius distal articular surface and the line perpendicular to radius longitudinal axis in lateral projection
- Positive (negative) value when the tilt is volar (dorsal)



Ulnar Variance

- The distance between CRP and U_0 (head of ulna distal articular surface) measured in the direction of radius longitudinal axis
- Positive (negative) value when CRP locates more distally (proximally) than U_0

4.1.2.3 Carpal Alignment

Positive (negative) angle value for the secondary bone axis opening on the volar side of the reference bone axis



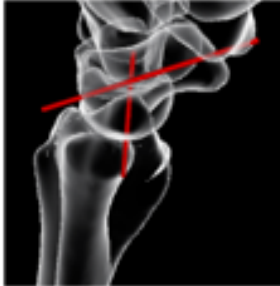
Radiolunate Angle

- The angle between radius (reference) and lunate axes in sagittal projection



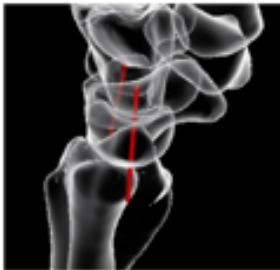
Capitolunate Angle

- The angle between lunate (reference) and capitate axes in sagittal projection



Scapholunate Angle

- The angle between lunate (reference) and scaphoid axes in the sagittal projection



Lunotriquetral Angle

- The angle between lunate (reference) and triquetrum axes in sagittal projection



Radiotriquetral Angle

- The angle between radius (reference) and triquetrum axes in sagittal projection



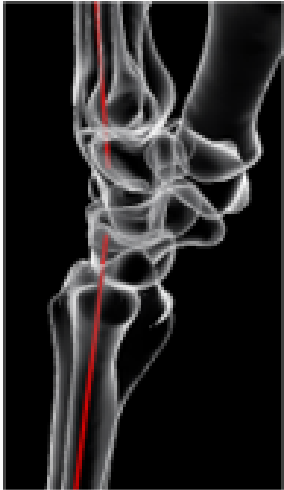
Radiotrapezoidal Angle

- The angle between radius (reference) and trapezoid axes in sagittal projection



Radiotrapezial Angle

- The angle between radius (reference) and trapezium axes in sagittal projection



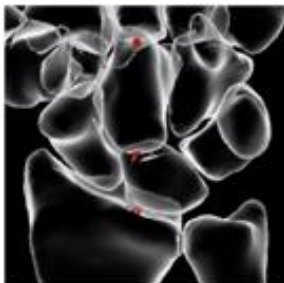
Radiometacarpal III Angle

- The angle between radius (reference) and metacarpal III axes in sagittal projection



Radiometacarpal III Angle

- The angle between lunate (reference) and metacarpal axes in sagittal projection



Carpal Height Ratio

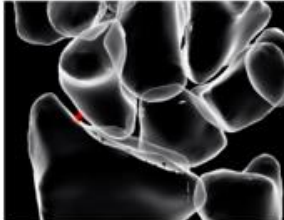
- Carpal region height, from P_3 (capitate distal axis intersection point), divided by the capitate height from C_0 (capitate proximal axis intersection point) to C_1



Ulnar Translation Ratio

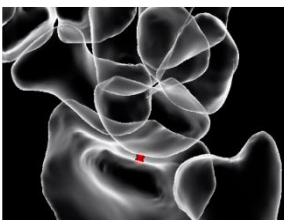
- Distance between P_0 (radial styloid process) and L_0 (lunate lunar corner) divided by the distal between P_0 CRP (central reference point)

4.1.2.4 Joint Gaps



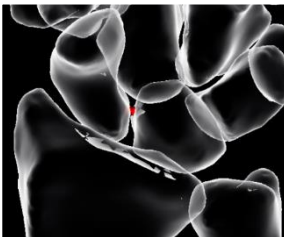
Radioscaphoidal Joint Minimum Gap

- Minimum normal distance measured from the radius to the scaphoid on the articular surface region



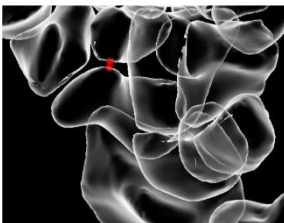
Radiolunate Joint Minimum Gap

- Minimum normal distance measured from the radius to the lunate on the articular surface region



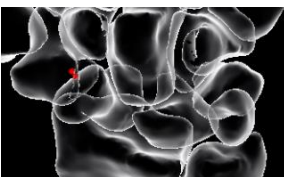
Scapholunate Joint Minimum Gap

- Minimum normal distance measured from scaphoid to lunate on the articular surface region



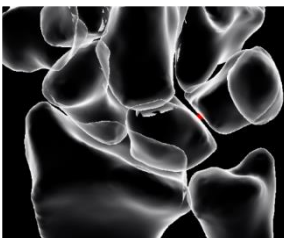
Scaphotrapezoidal Joint Minimum Gap

- Minimum normal distance measured from the scaphoid to the trapezoid on the articular surface region



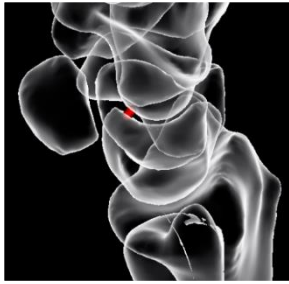
Scaphotrapezoidal Joint Minimum Gap

- Minimum normal distance measured from the scaphoid to the trapezium on the articular surface region



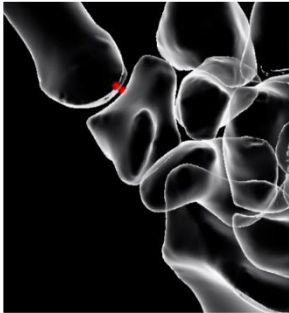
Lunotriquetral Joint Minimum Gap

- Minimum normal distance measured from the lunate to the triquetrum on the articular surface region



Lunocapitate Joint Minimum Gap

- Minimum normal distance measured from the lunate to the capitate on the articular surface region



Carpometacarpal I Joint Minimum Gap

- Minimum normal distance measured from the trapezium to the metacarpal I on the articular surface region

4.1.2.5 Radiographic projection directions



PA (posteroanterior) View

- Projection plane direction is orthogonal to radius longitudinal axis and lateral projection direction.

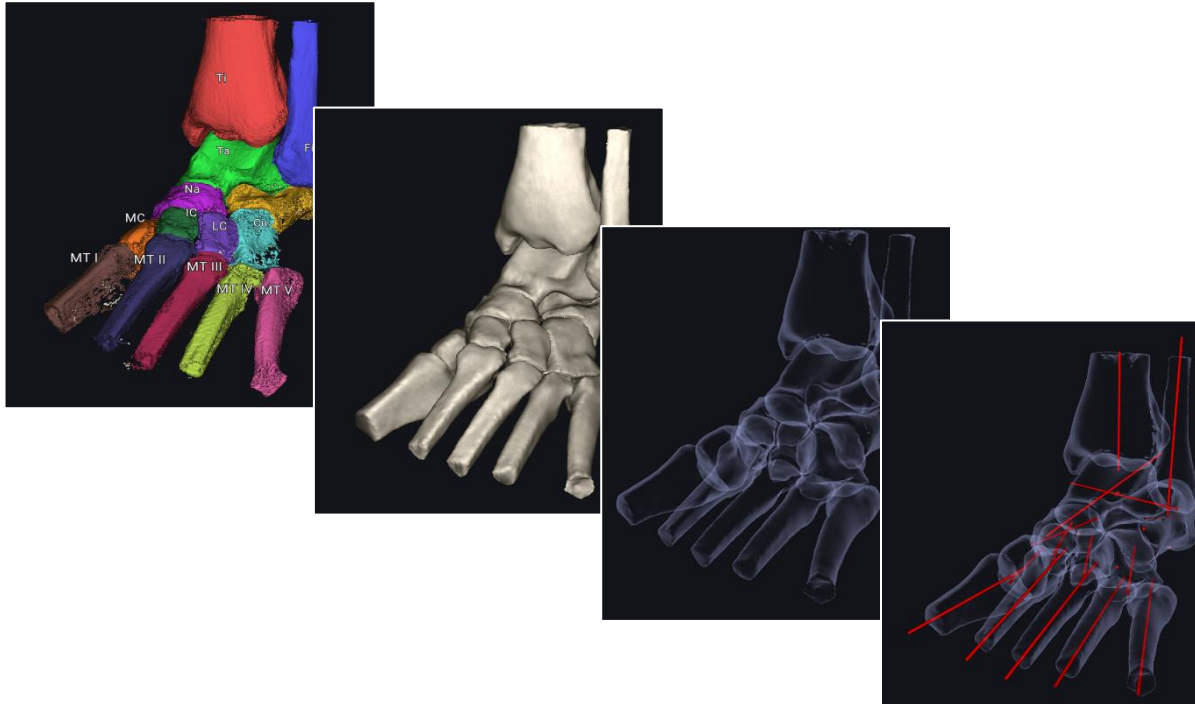


Lateral View

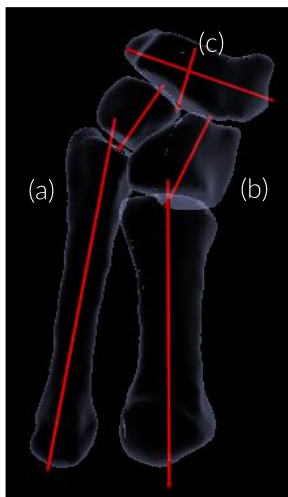
- Projection plane direction is based on the shape of radius. It is perpendicular to the radius longitudinal axis and aligned with the line connecting CRP (central reference point) and P₀ (tip of radial styloid process).

4.1.3 Foot and ankle measurements

1. All angle measurements are calculated based on 2D projections of 3D axes
 - 2D projection planes are deduced from the imaging devices patient coordinate system.
2. Measures are shown with + or – signs
 - Meary's angle (sagittal): negative towards pes planus, positive towards pes cavus.
 - Hindfoot moment arm and Saltzman view: negative towards varus, positive towards valgus
 - Lateral talar station: positive if talus is anterior to tibial longitudinal axis

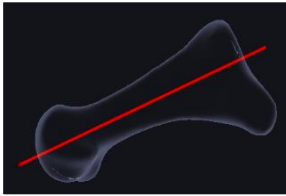


4.1.3.1 Bone axis definitions



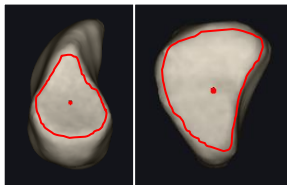
Original analysis from the solver:

Axes are defined differently for each category of bone (a-c).



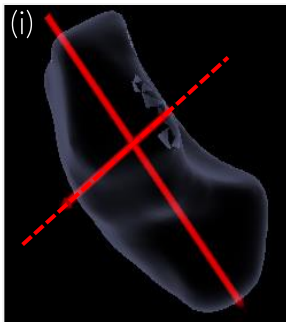
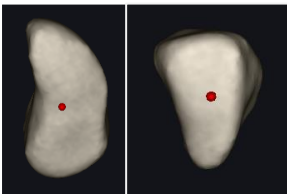
Elongated bones (a) *e.g. Proximal phalanges and metatarsals (I-V)*

1. Longitudinal axis: The software scans the bone and determines its cross-section at various locations. A weighted center point is computed for each cross-section. Robust line fitting is used to find a straight-line representative for the cross-section points.
2. Perpendicular axes: A subset of the bone is projected into plane perpendicular to bones longitudinal axis. Line fitting is used to measure the axes.



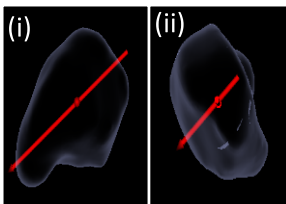
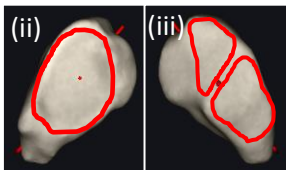
Cuneiforms (b) *e.g. Medial and intermediate cuneiforms*

1. First axis: goes through the navicular- cuneiform articular surface weighted centre, and through the cuneiform- metatarsal articular surface weighted centre point.
2. Perpendicular axes: A subset of the bone is projected into plane perpendicular to bones longitudinal axis. Line fitting is used to measure the axes.

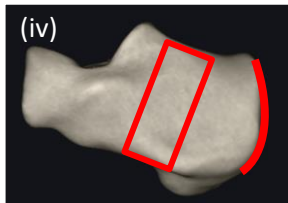
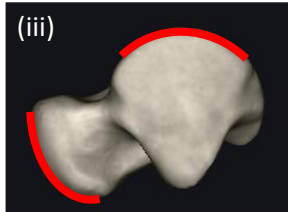
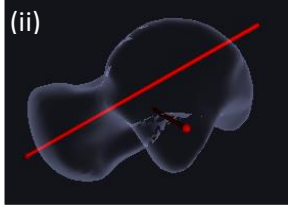
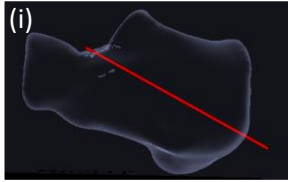


Navicular (c)

1. Longitudinal axis (i): goes through the (ii) talonavicular articular surface weighted centre point and the (iii) navicular–medial cuneiform–intermediate cuneiform articular surface weighted centre point.

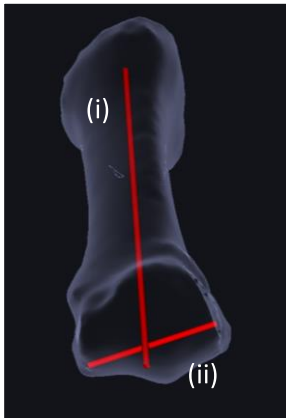


2. Perpendicular axes: A subset of the bone is projected into plane perpendicular to bones longitudinal axis (i-ii). Line fitting is used to measure the axes.



Talus, calcaneus

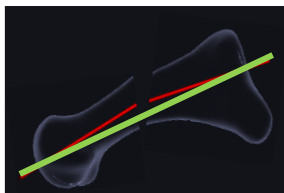
1. Longitudinal axis (i & ii): The software scans bone and determines its cross-section at various locations. Weighted center point is computed for each cross-section. Robust line fitting is used to find a straight-line representative for the cross-section points.
2. Secondary axes: Additional projections of joint facets and tendon insertion (iii & iv) are used to determine bone alignment.



1st Metatarsal

1st Metatarsal distal lateral axis

- The axis between the extreme mediolateral points of the distal end of the 1st metatarsal.
 - i) longitudinal axis
 - ii) distal lateral axis



Virtual planning metrics

- During the virtual osteotomy the bone axes are calculated differently.
- The entry and exit points of the original axis remain the same (red lines) and once a change has been made to a bone the axis is now the line that connects those points (green line).

4.1.3.2 Hindfoot

4.1.3.2.1 *Longitudinal arch collapse/elevation*



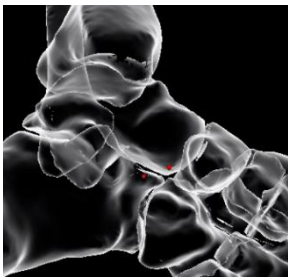
Meary's Angle (Sagittal)

- The angle between the talus longitudinal axis and the 1st metatarsal longitudinal axis



Calcaneal Inclination Angle (Sagittal)

- The inclination of the calcaneal, drawn between posterior and anterior inferior tips of the calcaneus, relative to the floor



Lateral Talocalcaneal Coverage (Sagittal)

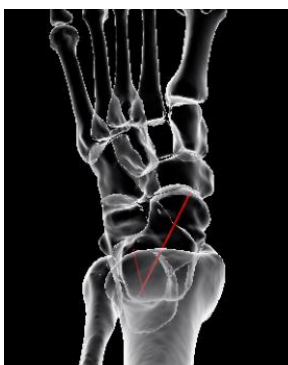
- The distance between the most inferior point on the talus head and the most superior point of the calcaneus anterior column in the sagittal view.
- It is positive when calcaneal point is above talar point, otherwise it is negative



Talocalcaneal Angle (Sagittal)

- The angle between the talus longitudinal axis and the calcaneus axis

4.1.3.2.2 *Valgus/varus*



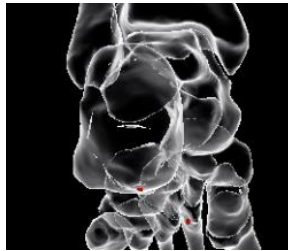
Talocalcaneal Angle (Axial)

- The angle between the talus longitudinal axis and the calcaneus axis



Saltzman Views

- The angle between the tibia axis and the calcaneus axis measured in the posteroanterior direction angulated 45° or 20° from the floor plane, respectively



Hindfoot Moment Arm (Posterior)

- The distance between the longitudinal axis of the tibia and most inferior point of the calcaneus



Medial Distal Tibial Angle (Coronal)

- The angle between the longitudinal axis of the tibia and the tibia distal articular surface mediolateral axis



Medial Talar Articular Surface Angle (Coronal)

- The angle between the longitudinal axis of the tibia and the talus trochlea articular surface axis



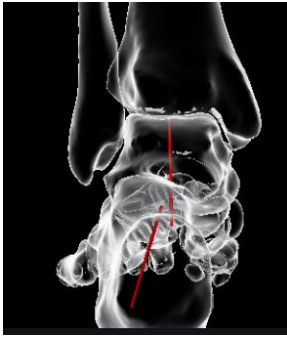
Talar Tilt Angle (Coronal)

- The angle between the tibia distal articular surface mediolateral axis and the talus trochlea articular surface axis



Medial Talocrural Angle (Coronal)

- The angle between the talocrural axis drawn between the distal tips of the fibula and the tibia, and the tibia distal articular surface mediolateral axis



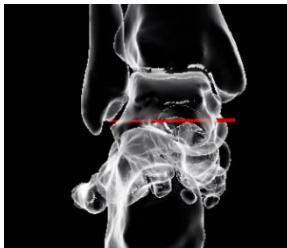
Talocalcaneal Angle (Coronal)

- The angle between the talus inferosuperior axis and the calcaneus axis



Hindfoot Angle

- The angle between the tibia axis and the axis that connects the posterior calcaneal process and the center of the talar dome

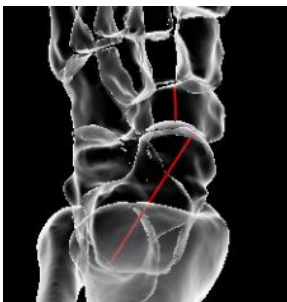


Talar Horizontal Inclination Angle (Coronal)

- The angle between talus mediolateral axis and the imaging device ground level, measured in coronal view.

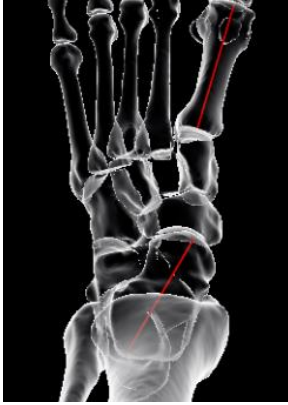
4.1.3.3 Midfoot

4.1.3.3.1 Abduction/adduction



Talonavicular Coverage (Axial)

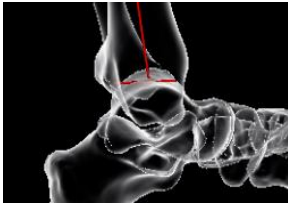
- The angle between the talus longitudinal axis and the navicular axis in the axial view



Meary's Angle (Axial)

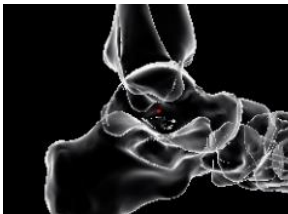
- The angle between the talus longitudinal axis and the 1st metatarsal longitudinal axis

4.1.3.3.2 Tibiotalar pitch



Tibial Lateral Surface Angle (Sagittal)

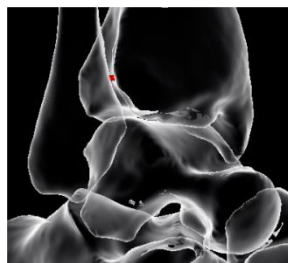
- The angle between the tibia longitudinal axis and anteroposterior axis of tibia distal articular surface in the sagittal view



Lateral Talar Station (Sagittal)

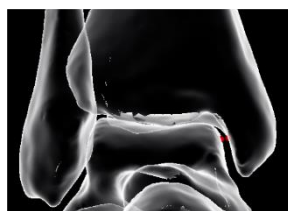
- The distance between the tibial longitudinal axis and the talus trochlea articular surface axis in the sagittal view

4.1.3.3.3 Joint Gaps



Tibiofibular Joint Minimum Gap

- Minimum normal distance measured from the tibia to the fibula on the articular surface region



Tibiotalar Joint Minimum Gap

- Minimum normal distance measured from the tibia to the talus on the articular surface region



Talocalcaneal Joint Minimum Gap

- Minimum normal distance measured from the talus to the calcaneus on the articular surface region

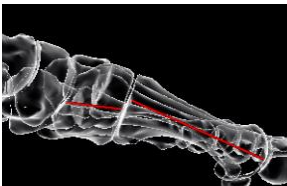
4.1.3.4 Forefoot

4.1.3.4.1 Intermetatarsal Angles



- The angle between the longitudinal axes of the metatarsals
 - 1st – 2nd Intermetatarsal axial angle
 - 1st – 2nd Intermetatarsal sagittal angle
 - 1st – 5th Intermetatarsal axial angle
 - 1st – 5th Intermetatarsal sagittal angle

4.1.3.4.2 Tarsometatarsal angles



- The angle between the longitudinal axes of the metatarsal and the cuneiform
 - 1st tarsometatarsal angle (sagittal)
 - 2nd tarsometatarsal angle (sagittal)
 - 3rd tarsometatarsal angle (sagittal)
 - 1st tarsometatarsal angle (axial)
 - 2nd tarsometatarsal angle (axial)
 - 3rd tarsometatarsal angle (axial)

4.1.3.4.3 Hallux Valgus



Hallux Valgus Angle (Axial)

- The angle between the 1st metatarsal longitudinal axis and the 1st proximal phalanx longitudinal axis measured in the axial view



Hallux Valgus Interphalangeus Angle (Axial)

- The angle between the 1st proximal phalanx longitudinal axis and the 1st distal phalanx longitudinal axis measured in the axial view



Sesamoid Complex – 1st Metatarsal Lateral Translation

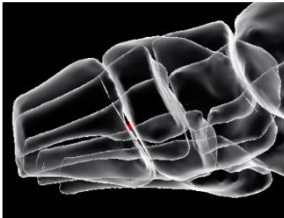
- The mediolateral distance between the 1st metatarsal longitudinal axis and the geometric center point of the sesamoid complex in the AP projection defined by the 1st metatarsal longitudinal axis



Sesamoid Complex – 1st Metatarsal Rotation

- The angle between the 1st metatarsal proximal perpendicular axis and the axis connecting the center points of the sesamoids measured in the coronal plane in the AP projection defined by the 1st metatarsal longitudinal axis

4.1.3.4.4 Joint Gaps



Tarsometatarsal I Joint Minimum Gap

- Minimum normal distance measured from the medial cuneiform to metatarsal I on the articular surface region

5 Regulations & Labelling

5.1 Standards

Bonelogic™ software has been designed to comply the following standards:

Standard:

EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software – Software life cycle processes
EN 62366-1:2015/AC:2016	Medical devices – Part 1: Application of usability engineering to medical devices provides safety to the patient, users and others
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects. Good clinical practice

5.2 CE marking

Bonelogic software is a Class IIb medical device in the European Union complying the applicable requirements of the Medical Device Directive (93/42/EEC Amended by Directive 2007/47/EC).



5.3 Economic Operators

5.3.1 Manufacturer

For feedback related to the Bonelogic product, please contact:



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

5.3.2 Switzerland Authorized Representative (CH-REP)



MedEnvoy Switzerland
Gotthardstrasse 28, 6302 Zug, Switzerland

5.4 GMDN










5.4.1 Code and name

50484 CAD/CAM software

5.4.2 Definition

A software program intended to provide computer-aided design (CAD) or computer-aided manufacturing (CAM) functionality for the production of patient-specific custom-made devices (e.g., orthopedic implants, dental devices, anatomical models), treatment planning, simulation, and/or robotic capabilities for device production (e.g. 3D printing).

5.5 Symbols used

Symbol	Regulation/Standard	Symbol meaning
	EN ISO 15223-1:2016 Medical device	Indicates the product is a medical device
	Medical Devices Directive 93/42/EEC	CE marking indicates that a product complies with applicable European Union regulations. NB indicator 0598.
	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 need for user action due to mitigation of 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 situation.
Rx Only	21 CFR 801.109	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	MedDo, 1 July 2020, Art. 4h	Natural or legal person domiciled in Switzerland with mandate for obligations under the Ordinance

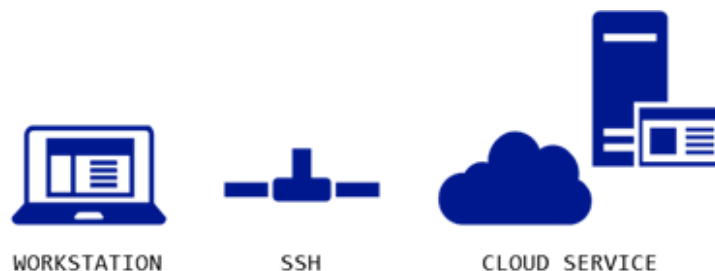
6 Data management & software architecture

Illustration of the Bonelogic™ software architecture and listed functionalities is below. The software is not creating, storing, or maintaining databases. Updating and maintenance of the software is done through local workstation user interface.

6.1 Software architecture

Bonelogic software pre-processing and visualization module is installed to local desktop or laptop workstation. Numerical computations are provided as cloud service.

1. DICOM data, local workstation
 - a. DICOM image is loaded to Bonelogic software.
 - b. Raw pixel data is separated from the DICOM data and saved in binary format.
 - c. No patient information or other DICOM information 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 analysis models and measurements.
 - b. Results are saved as numeric data.
 - c. Result models are created in STL format.
 - d. Pixel data is deleted.
 - e. Measurement results can be used for diagnostic purposes.
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.



6.2 Network address

The software uses network address 'disioranalytics.com, 45.8.131.57:3693', which routes the connection to the Disior™ cloud service.

6.3 SSH tunnel specification

The SSH tunnel is created for license verification when client software is started. After verification, the tunnel is closed. SSH tunnel is opened again when the calculation request is initiated from the client software. SSH tunnel is open throughout the analysis time and closes after results download.

Client software creates the SSH using ssh.net software library.

The username and key file used to establish the connection can be client specific. The key file is stored in the workstation in the installation folder and the password is inside the software code resulting in key-based authentication.

Workstations connected with SSH are identified by the system and the system is storing a logfile for the SSH connections. SSH connection can be restricted based on IP address.

Service port 3693 is not acting as SSH service port directly, it is used to route the traffic to the SSH server port. SSH connection is defined to have basic user rights (not admin or root rights) on the server. The amount of subsequent connection attempts is restricted against “brute force attacks”.

The SSH server is protected by mitigation with port encryption and user configuration.

Data transfer is done using SFTP protocol.

6.4 Analysis server (cloud computing server)

The analysis server specification:

- The server used for the analysis calculation is physically located in Finland.
- A separate instance is formed for each analysis calculation.
- The computing resource port TCP/1194 has VPN service.
- The server is protected by Windows firewalls and anti-virus.
- SSH is in same server as analysis calculations.
- Server Operating system is Windows 10.

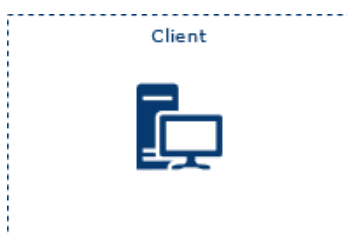
6.5 Linking of computed analysis result to the original image

When DICOM data is opened in the client program, a timestamp and the file structure is created. This information is used to link the analysis result back to the image file after analysis results is sent back to the client program.

6.6 Data processing

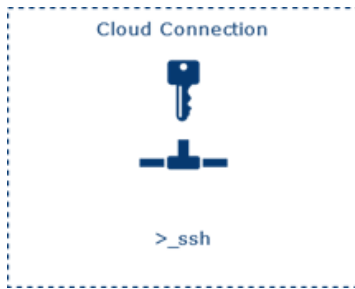
6.6.1 Elements

Element 1: DISIOR™ in hospital internal network



1. Workstation specific ID for licensing
2. User authentication to open software
3. PACS send/receive with AE title and IP address
4. No image or analysis data storage
5. Log files stored in the App Datta folder

Element 2: DISIOR™ Cloud connection



1. Disior cloud at 'disioranalytics.com, 45.8.131.57:3693'
2. Client initiates SSH tunnel opening
3. SSH established with client specific key file
4. Workstation connected with SSG are identified and connection log file is stored
5. Service port 3693 is routing traffic to the SSH server port
6. SSH connection does not have admin rights
7. DoS prevention and firewall at server network
8. SSH connection is preventable based on the IP address
9. The computing resource port TCP /1194 has a VPN service

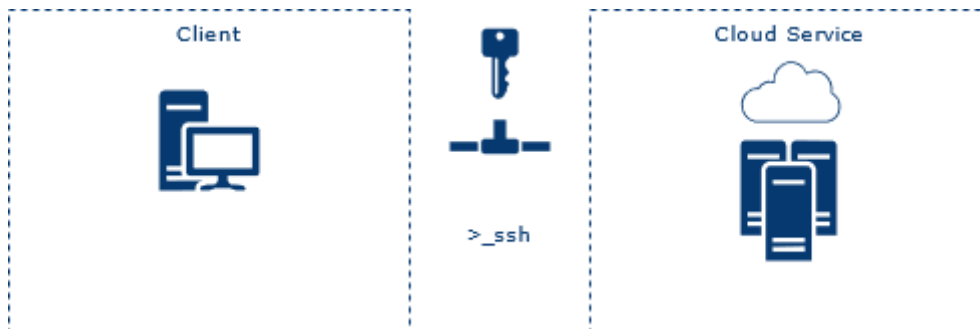
Element 3: DISIOR™ Cloud



1. Server is physically located in Finland (Windows 10)
2. Separate instance is formed for each analysis
3. No image data is stored
4. Log files are stored
5. Server is protected by windows firewalls and anti-virus
6. Windows patch is updated regularly

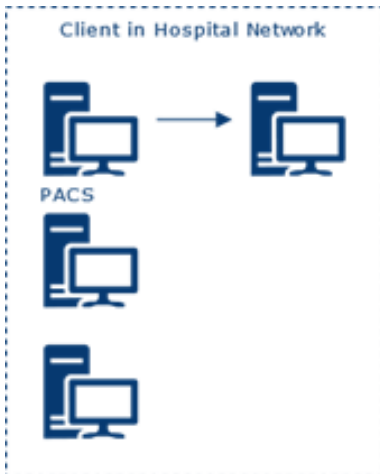
6.6.2 Data flow description

Step 1: License check for the Disior™ software



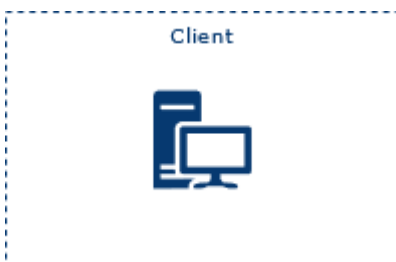
1. Client initiates license check from Disior
2. License check from database
3. After verification, SSH tunnel is closed

Step 2: Image study send from PACS



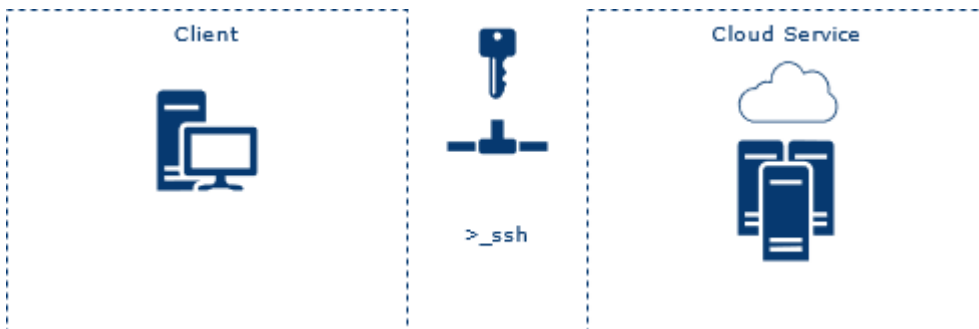
1. Study is sent from PACS with AE title and IP
2. Study is stored temporarily as .DCM file(s) in AppData folder

Step 3: DICOM Image handling in client workstation



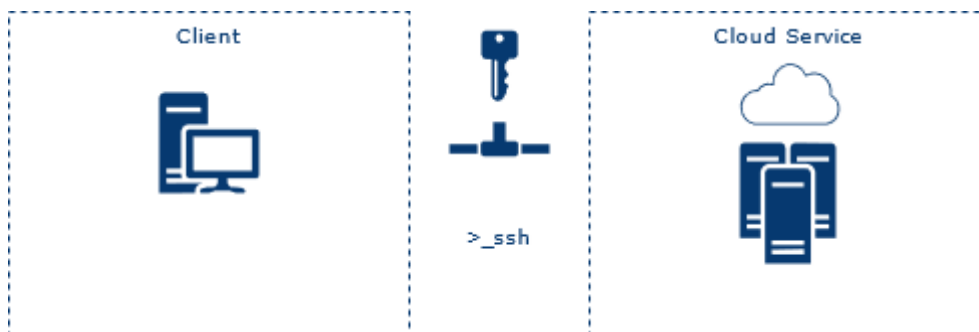
1. .DCM file(s) is read in DICOM reader
2. Following information is displayed on client workstation/software:
 - Patient name, study ID, AC number, comments
 - Study date time, description,
 - Series number, date, time, modality, description
3. When user initiates analysis (start analysis) only the voxel data is extracted from the original DICOM, turned into binary data and compressed.

Step 4: Analysis in DISIOR™ cloud



1. Client initiates the file transfer through SSH tunnel and tunnel is opened
2. Server receives binary data file
3. File is extracted and analyzed
4. Client monitors cloud analysis in software: SSH tunnel is open until solver is ready
5. After the solver is ready and analysis is successful, results file is sent to client through the SSH tunnel
6. Client receives the results files and the SSH tunnel is closed
7. Forced deletion of original binary data files occurs with C++ standard remove function

Step 5: Save and exit



1. User saves the analysis
2. Results are sent to PACS with AE title and IP
3. Removal of the AppData working directory with C# Directory.Delete
4. Clients sends through SSG a request to Disior cloud to delete instance with command del function
5. Forced delete of the instance