DISIOR™
A PARAGON 28® COMPANY

Bonelogic® 2.2

INSTRUCTIONS FOR USE

IFU VERSION 7.0 June 2025

Contents

1 General Information 6

1.1 Intended use 6

1.2 Indications for use 6

1.3 Contraindications 6

1.4 Target patient group 7

1.5 Hardware specification 7

1.6 Imaging data quality requirements 7

1.7 System configuration 9

1.7.1 Local workstation operations 9

1.7.2 Cloud environment operations 9

1.7.3 Connection to cloud 9

1.8 Licensing 10

1.9 Version and updates 10

1.10 Cybersecurity 10

1.11 OS patching 11

1.12 Uninstallation 11

1.13 Release notes for Bonelogic® 2.2 12

2 Workflow & Instructions For Use 15

2.1 Installation 15

2.1.1 Installation and license activation 15

2.1.2 Set how your PC and Bonelogic® use the dedicated graphics card 15

2.1.3 First time logging in 16

2.1.4 Selecting a dataset for training and first use 16

2.1.5 Connecting the Bonelogic® software as DICOM sender/receiver 16

2.2 Overall software workflow 18

2.3 Load data 18

2.3.1 Load DICOM image series locally 18

2.3.2 Load DICOM series via PACS 20

2.3.3 Reopen a case 20

2.4 Semi-automated analysis 20

2.4.1 Mark the bones (Basic process) 20

Copyright © Disior Ltd. All rights reserved.

2.4.2 How to edit the bone marking 22
2.4.3 Additional steps for difficult cases 22
2.4.4 Starting the Semi-Automated analysis 24
2.5 AI Assisted Analysis 24
2.6 Review the results 26
2.6.1 3D View sheet 26
2.6.2 Results sheet 29
2.6.3 2D view sheet 31
2.7 Saving and exporting the results 32
2.7.1 Save report 32
2.7.2 Save case 32
2.8 Manual segmentation 33
2.9 Planning tool 36
2.9.1 Choose the bones 37
2.9.2 Reposition the bone(s) 38
2.9.3 Place and adjust the saw approach 39
2.9.4 Conduct osteotomy / Cut the bone 41
2.10 Help & Basic Troubleshooting 44
2.10.1 Report an issue via Bonelogic® 44
2.10.2 Send image for analysis 44
2.10.3 Email support 44
2.10.4 Reporting serious incidents 44
2.10.5 Troubleshooting Guide 46
3 Residual Risk, Errors and Warnings 49
3.1 Residual risk 49
3.1.1 Image processing error 49
3.1.2 Results inaccuracy 49
3.1.3 Misuse 49
3.2 Error messages 50
3.2.1 Analysis failure 50
3.2.2 DICOM and case opening failures 50
3.2.3 Saving results failures 50

Copyright © Disior Ltd. All rights reserved.

3.3 Warnings messages 51
3.3.1 Image quality 51
3.3.2 Limited field of view 51
3.3.3 Landmark location 52
3.3.4 Contact between bones 52
3.3.5 Laterality selection and bone selection 52
3.4 Software guidance notifications 52
3.5 Informative messages 53
3.4.1 Informative message examples 53
3.4.2 Informative processing message example 53
4 Automated anatomical measurements: methodology and definitions 54
4.1.1 Introduction 54
4.1.2 Foot and ankle measurements 54
5 Regulations & Labelling 65
5.1 Standards 65
5.2 CE marking 65
5.3 Economic Operators 65
5.3.1 Manufacturer 65
5.3.2 Switzerland Authorized Representative (CH-REP) 65
5.4 UDI 66
5.5 GMDN 66
5.5.1 Code and name 66
5.5.2 Definition 66
5.6 Symbols used 66
6 Data management & software architecture 68
6.1 Software architecture 68
6.2 Cloud domain address 68
6.3 Microsoft Azure connection specification 69
6.4 Disior Cloud environment 69
6.5 Linking of computed analysis result to the original image 69
6.6 Data processing 70
6.6.1 Elements 70

Copyright © Disior Ltd. All rights reserved.

6.6.2 Data flow description 71
7 Addendum – Multilingual safety information 73
7.1 English 73
7.2 French 75
7.3 Finnish 77
7.4 Swedish 79

Copyright © Disior Ltd. All rights reserved.

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.

Caution: A user training is required for safe use of the software.

Mandatory user action to read the instructions for use

1.1 Intended use

Bonelogic software is intended to be used by orthopaedic healthcare professionals to assist in the characterization of anatomical structures of foot and ankle using three-dimensional mathematical modeling and radiographic measurements. The combined information from the structural models and the radiographic measurements can be used for diagnostic and treatment planning purposes. The medical imaging type intended to be used as the input of the software is computed tomography (CT).

1.2 Indications for use

Bonelogic software is to be used by orthopaedic healthcare professionals for diagnosis and surgical planning in a hospital or clinic environment.

Bonelogic software provides:

- Automatic and semi-automatic segmentation of structures from CT imaging input,
- Three-dimensional mathematical models of the anatomical structures of foot and ankle,
- Measurement templates containing radiographic measures of foot and ankle, and tools for manually obtaining linear and angular measurements,
- Surgical planning application for foot and ankle using three-dimensional models of the anatomical structures and radiographic measures.

The three-dimensional models of the anatomical structures combined with the measurements can be used for the diagnosis of orthopaedic healthcare conditions. The surgical planning application containing the three-dimensional structural models combined with the measurements can be used for the planning of treatments and operations to correct orthopaedic healthcare conditions of foot and ankle.

1.3 Contraindications

The Bonelogic software is not intended for other anatomies than foot and ankle. Using unvalidated medical imaging modality (such as MRI) as input DICOM for the software is not allowed. The software output alone cannot be used for diagnostic of the orthopaedic healthcare condition and plan for the surgical operation without careful professional assessment. Any physical model generated from the output of the software is not validated for diagnostic or surgical planning purposes.

Copyright © Disior Ltd. All rights reserved.

1.4 Target patient group

Target patient group is from adults (over 16 years) to geriatric without any specific limits for demographics. The intended target population excludes pediatric patients and high-risk population with respect to the medical condition.

1.5 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 (until end of Microsoft support, Oct 2025) Windows 11
Display	:	Full HD (1920×1080 px)
Internet connection	:	10 Mbit/s
(Optional) Intranet (PACS)	:	100 Mbit/s

1.6 Imaging data quality requirements

The quality of the visualization and outputs from Bonelogic software is dictated by the quality and resolution of the original DICOM image series. This section describes the imaging parameters required for safe and effective use of the software. The accepted image parameters are presented in Table 1. Please note, the Semi-Automated Analysis accepts images outside the given parameters, but deviations from the given range may potentially impact the accuracy or reliability of the results.

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.

Table 1 Required parameters of image series.

Parameter	AI Assisted Analysis	Semi-Automated Analysis
Image Modality	CT, CBCT, WBCT in DICOM format	CT, CBCT, WBCT in DICOM format
Image Type	Original Primary Axial series	Optimally Original Primary Axial series
Image dimensions	Maximum: 390 mm x 390 mm x 390 mm	N/A
Image reconstruction	Optimally hard kernel	Optimally hard kernel
Field of view	Maximum distal 1/3 of the tibia/fibula	Up to full length tibia/fibula

Copyright © Disior Ltd. All rights reserved.

File size	≤ 2 GB (Decompressed)	≤ 2 GB (Decompressed)
Voxel Size	≤ 0,75 mm Note: < 0,4 mm resampled to 0,4 mm	Optimally ≤ 0,75 mm Note: < 0,4 mm resampled to 0,4 mm

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

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

Certain DICOM tags, with conformance to NEMA PS 3.1 - 3.20 2023e, 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 DICOM tags are listed in Table 2.

Table 2 Required DICOM tags.

Tag	**Name**	**Required tags by imaging modality**	
		CT	Enhanced CT
(0008,0016)	SOP Class UID	×	×
(0028,0004)	Photometric interpretation	×	×
(0028,0010)	Rows	×	×
(0028,0011)	Columns	×	×
(0028,0100)	Bits Allocated	×	×
(0028,0102)	High bit	×	×
(0028,0030)	Pixel Spacing	×	×
(0020,0037)	Image Orientation (Patient)	×	×
(0020,0032)	Image Position (Patient)	×	×
(0028,0008)	Number of Frames		×
(0020,0013)	Instance number	x	

Copyright © Disior Ltd. All rights reserved.

(0028,1025)	Rescale Intercept	x	
(0028,1053)	Rescale Slope	x	
(0018,0050)	Slice Thickness		x

For CBCT imaging, the typical imaging parameters are presented in Table 3.

Table 3 Typical CBCT imaging parameters.

Standard protocol for imaging	
Original Primary Axial series	
400 projections	
No filtering	
Voxel size:	0.4 × 0.4 × 0.4 mm^3
Tube voltage:	90-130 kVP (Peak kilo voltage output of the X-Ray generator used)
Tube current:	5-10 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 support (disior.support@paragon28.com).

1.7 System configuration

Bonelogic software consists of the following two modules:

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

1.7.1 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.

1.7.2 Cloud environment operations

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

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.

1.7.3 Connection to cloud

Bonelogic software has a cloud connection. The cloud computer is hosting the Solver. 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 solver files are sent to Cloud for computing using a secure connection (HTTPS). The solver files include a) compressed

Copyright © Disior Ltd. All rights reserved.

DICOM files, and b) manually input patient information. 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 68.

1.8 Licensing

Bonelogic software license is user specific and managed during the installation process. User access to the workstations is controlled by the customer.

1.9 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.

1.10 Cybersecurity

The cybersecurity controls of Bonelogic software are presented in Table 4.

Table 4 Cybersecurity controls

User authentication and access control:	Microsoft Azure Active Directory (AD)
Data transfer protocol:	Hypertext Transfer Protocol Secure (HTTPS)
Encryption:	Transport Layer Security (TLS)
Data encryption:	Encrypted data at rest
Anti-virus policy:	Computers using Bonelogic software should have up-to-date virus and malware protection

The local IT firewall configuration should allow the traffic on workstations where Bonelogic software is installed as presented in Table 5. The IT network configuration needs to be completed by qualified IT personnel.

Table 5 Local IT firewall configuration

Purpose	Destination
Cloud domain	https://prod-southcentralus-p28-apim.azure-api.net
DICOM (query & retrieve)	PACS server
Windows authentication	Domain controller
Access shared network drive	Network file share

Copyright © Disior Ltd. All rights reserved.

Caution: Failure to comply with cybersecurity practices of IT network may result to loss of data confidentiality or integrity, and loss of product availability.

1.11 OS patching

There are no known issues with the Windows OS patches. The default update policy of the local site IT applies, but it is recommended to update the local workstation Windows OS with the latest security patches.

1.12 Uninstallation

In case the user wants to remove the software from the client workstation, it can be done through “Uninstall” function within Windows “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.

Copyright © Disior Ltd. All rights reserved.

1.13 Release notes for Bonelogic® 2.2

Bonelogic® 2.2 is a minor software revision for Bonelogic® 2.1.

Release number 2.2.1

Notes date September 12th, 2024

Notes version 2.0

Overview of the software

Bonelogic 2.2 is intended to be used by orthopaedic healthcare professionals to assist in the characterization of anatomical structures of foot and ankle using three-dimensional mathematical modeling and radiographic measurements. The combined information from the structural models and the radiographic measurements can be used for diagnostic and treatment planning purposes. The medical imaging type intended to be used as the input of the software is computed tomography (CT).

The release has been tested with following hardware:

1. Standard Laptop or Desktop PC with Windows 11
2. 16 GB RAM
3. Dedicated Graphics Cards with 1 GB of memory
4. Minimum 50 GB Hard Drive space
5. Internet connection to Disior Cloud

Note: The users are region-specific (US or EU). The performance of the software is adjusted by the region, and it impacts the data processing. See more information in section Data processing.

Purpose

This is an iterative Bonelogic software release. The features included in the software release are:

1. Load DICOM
2. Open existing CASE
3. (Optional) Select structures
4. (Optional) Segment structures
5. Run analysis
6. Manipulate 3D
7. Manipulate DICOM
8. Toggle visibility
9. Manual segmentation
10. Surgical planning
11. Manual measurements
12. Results
13. SAVE|EXIT
14. IFU, information for safety, labeling and UDI

New software features in this release

1. Cloud infrastructure changed from proprietary servers to Microsoft Azure based.
2. Automatic analytics workflow to complement the existing semi-automatic workflow.

Copyright © Disior Ltd. All rights reserved.

3. Manual input for patient information linked to the analyzed case.

Excluded software features in this release

1. Hand and Wrist module is not supported with Bonelogic version 2.2 onwards.

Software enhancements in this release

- Improved reliability (less software crashes)
- Improved processing of long tibia and fibula bones

Compatibility

Cases saved with earlier versions of Bonelogic software can be opened with Bonelogic 2.2. However, for full functionality, it is required to re-analyze cases from DICOM image series. Cases saved with Bonelogic 2.2 are not supported with older versions of the product.

- Case files created with Bonelogic 2.0 can be opened and viewed, but image analysis, results, surgical planning/virtual osteotomy and case saving functionalities are unavailable.
- Case files created with Bonelogic 2.1.0 are not supported.
- Case files created with Bonelogic 2.1 can be opened and viewed, but image analysis and case saving functionalities are unavailable.

Installation notes

Bonelogic 2.2 is a standalone software. As part of the installation process, earlier version of Bonelogic 2 is uninstalled. In case of earlier Bonelogic 1.0 software version, uninstallation is not part of the installation process of Bonelogic 2.2. Earlier installations of Bonelogic 1.0 software version may be uninstalled utilizing “Uninstall” function within Windows “Settings”, “Apps and Features”. The installation process involves updating the installed version of Visual C++ runtime.

Support

Product documentation with instructions for use, installation instructions and information on release updates can be found from https://www.disior.com/. Direct link to electronic instructions for use is also available through the software HELP page. Customer support is available through Software HELP page and through disior.support@paragon28.com. A paper copy of this manual may be provided by sending a request to 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.

To the maximum extent permitted by applicable law, Disior is not liable to the Customer for any lost profits, or for indirect or consequential damages. For the sake of clarity, it is stated that Disior is not liable to the Customer for any damages that result from the use of the Disior Services or from the results obtained from the use of the Disior Services. These limitations of liability shall not apply in cases of intentional misconduct or gross negligence.

Copyright © Disior Ltd. All rights reserved.

Contact

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

Copyright © Disior Ltd. All rights reserved.

2 Workflow & Instructions For Use

The main purpose of the software is to assist in 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. 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. Organization information (name & region)
    d. Name and email address for all users.
3. Download, install and run the Bonelogic software.
    a. Open the installer file. Select 'Yes', accept the license agreement, 'Next', choose if you want to create a desktop shortcut, 'Next', 'Install' and 'Finish'.
4. Disior™ support team will provide a link for registration, follow the link for user activation and password generation. **NOTE:** The region needs to be selected and this will impact the data processing (see chapter Data management & software architecture).
5. Ensure from the Hospital IT that the Disior Cloud server domain is accessible from the network (see section 6.4).

If you require any assistance throughout the process, you may email or call the Disior support team at disior.support@paragon28.com and +358 50 483 6433.

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.

Copyright © Disior Ltd. All rights reserved.

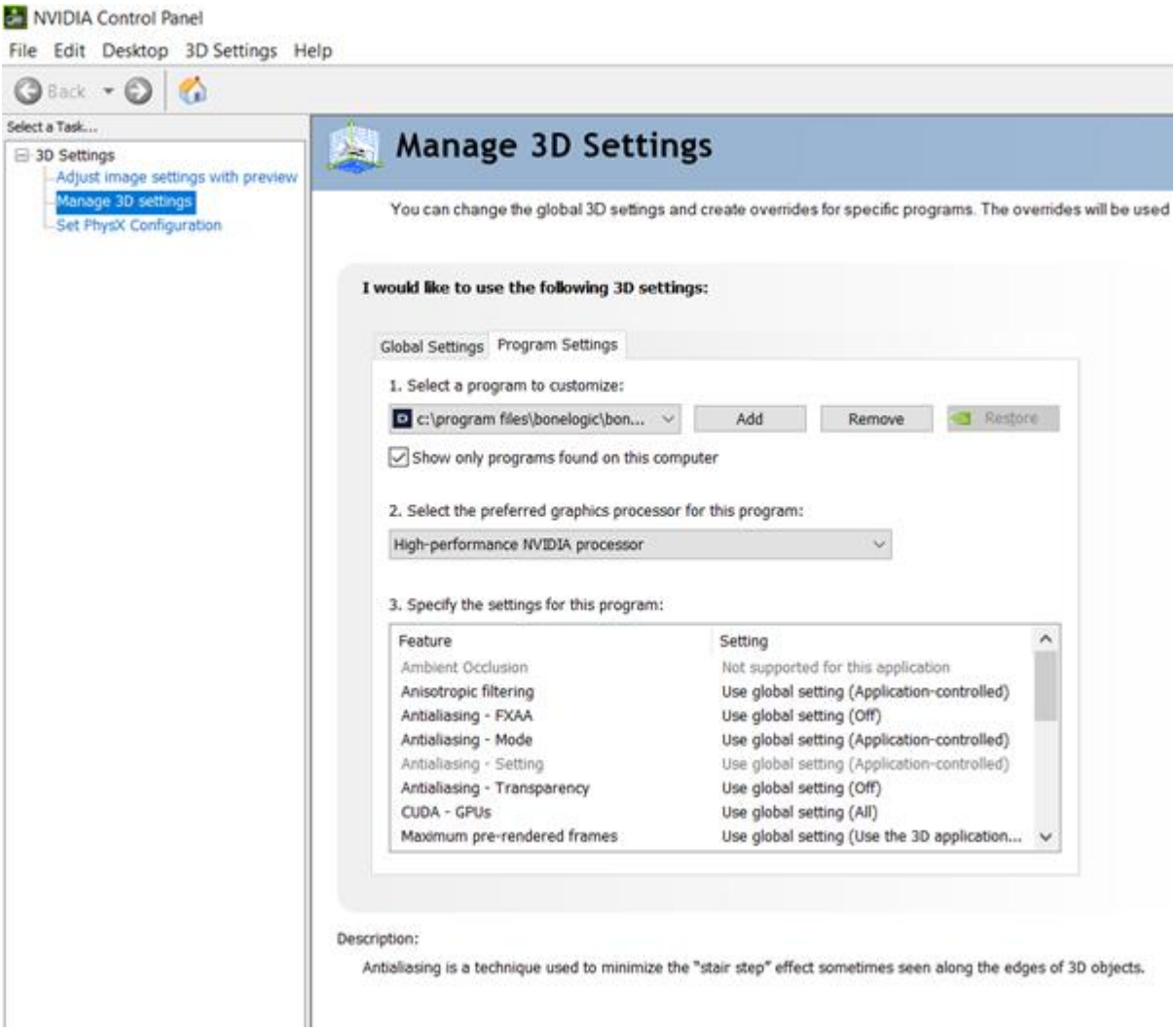


Image 1 Detailed view of the setting page for the dedicated graphics card, example is from the NVIDIIA system.

2.1.3 First time logging in

After receiving the registration link and completing it, you can conduct the setup for first use:

1. Run the Bonelogic software.
2. Enter your email address and the password you have generated.

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 accessible 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

Copyright © Disior Ltd. All rights reserved.

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.

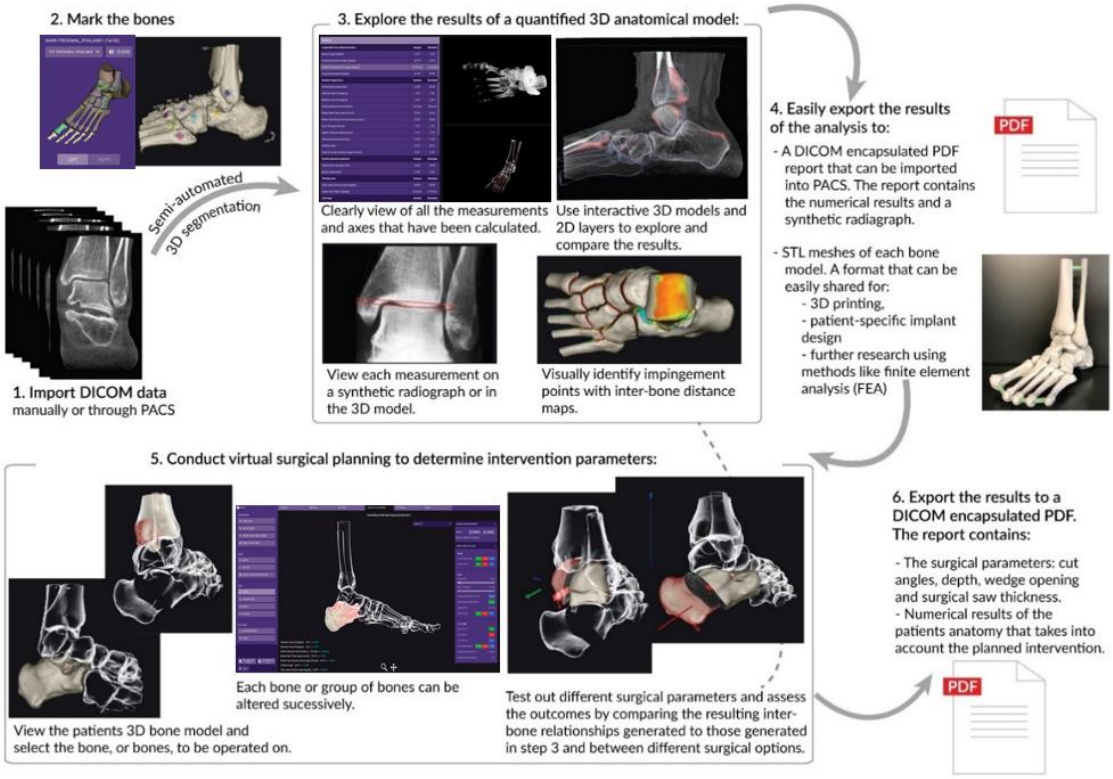
You will then need to follow the PACS providers instructions on how to add a DICOM receiver, and use the AE title, Port and Bonelogic workstation IP address to establish the connection.

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 68.

Copyright © Disior Ltd. All rights reserved.

2.2 Overall software workflow

The figure below illustrates the Semi-Automated workflow. Both workflows (AI Assisted and Semi-Automated) are described in detail within this document. Before starting the use of Bonelogic, please refer to chapter 1.6 Imaging data quality requirements, to ensure safe and effective use of the software. The time required for analysis is typically less than 5 minutes (excluding time required to upload/download the images/results).



Caution: The analysis results provided in the software shall be subject to careful expert assessment. Software output has high repeatability, however, due to various measurement protocols, differences in weightbearing and non-weightbearing images, 2D and 3D measurements as well as automatic and manual measurements, the different methodologies may produce different measurement 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[1].

[1] If you forget your password, click the forget password button on the login page and you will forwarded to the password reset page. After processing the verification code, you can reset your password.

Copyright © Disior Ltd. All rights reserved.

- Click ‘Open DICOM Browser’ and select the folder containing the DICOM image series you want to analyze.
- For folders containing multiple DICOM image series, all series will be listed in the software with metadata displayed (Image 2).
    - 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).

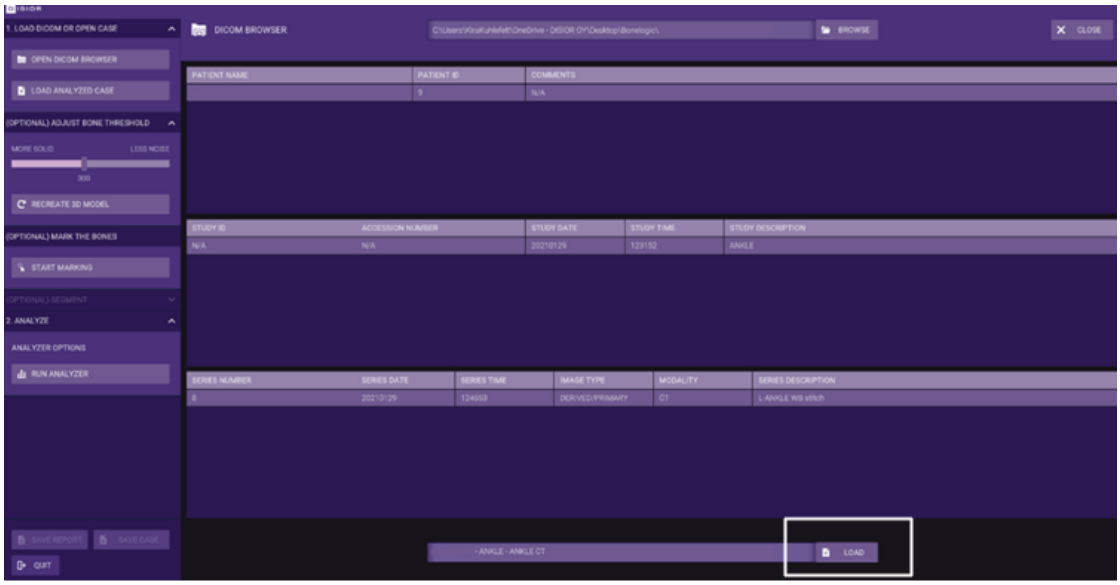


Image 2 DICOM browser showing uploaded image series. Press 'LOAD' to open the image and to create the initial 3D render.

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).

Copyright © Disior Ltd. All rights reserved.

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.
- Click 'Load Analyzed Case' and select the case file you want to review.
    - .dfcase file extension refers to foot and ankle module cases. See Release notes for Bonelogic® 2.2 for compatibility with cases created with earlier versions.
- Once the case has loaded, the '3D view' sheet will be displayed.

2.4 Semi-automated analysis

Observe and adhere to the requirements presented in the Imaging data quality requirements before uploading images into the software. If the images used fulfill all the requirements for AI Assisted analysis, you may proceed to section AI Assisted Analysis.

- **Note**: The AI Assisted Analysis is disabled for images that does not meet the requirements.

2.4.1 Mark the bones (Basic 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 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 (Image 5). All bones that are present in the DICOM image series and the guide must be marked (Image 6).
- 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',

Copyright © Disior Ltd. All rights reserved.

- Right-click and drag to ‘PAN’,
- Mouse wheel to ‘ZOOM’.

- The bones that can be selected in the software are shown in Image 7.
  - **Note:** 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 (TIBIA) as shown (RED) in the guide on the left panel of the software. Only mark one foot and analyze it separately.

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

Copyright © Disior Ltd. All rights reserved.

Image 6 Fully marked foot, ready to be analyzed.

Image 7 Bones to be marked in the Foot & Ankle 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 ˅ (OPEN) or ^ (CLOSE), select the bone from the list, then click ‘CLEAR’ and reselect each bone.

2.4.3 Additional steps for difficult cases

2.4.3.1 How to deal with extended Field of View images

CBCT or CT scans of extremities that includes additional bones (not currently included in the marking list, such as femur/patella), will need to be marked as follows:

- Select the ‘OTHER’ item from the selection dialogue box.
- Mark the additional bones with ‘OTHER’ label (Image 8).

Copyright © Disior Ltd. All rights reserved.

Image 8 Marking of additional bones 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 9).
- 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 9 Example of a segmentation result

Copyright © Disior Ltd. All rights reserved.

2.4.4 Starting the Semi-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 check if image contains metal.
- Then click 'RUN ANALYZER'.
- The analysis starts after confirming the image laterality and inputting patient information (Image 10) (available on PDF report):
    - Patient Age,
    - Patient's Sex,
    - Patient's Height,
    - Patient's Weight,
    - Image type (pre-operative or post-operative),
    - Patient Deformities (for pre-operative or post-operative images),
    - Performed Procedures (for post-operative images).

  Note: The information provided does not affect the analysis results.

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

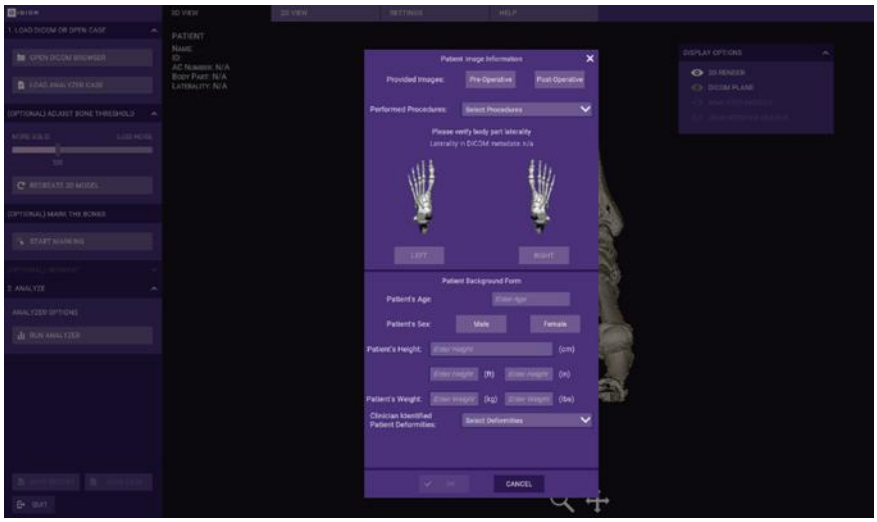


Image 10 Fill the patient information, confirm the laterality and Press 'OK' to initiate analysis.

2.5 AI Assisted Analysis

- The analysis can be started after the foot and ankle DICOM image is loaded – click 'RUN ANALYZER'.
    - NOTE: Observe and adhere to the requirements presented in the Imaging data quality requirements before uploading images into the software. The AI Assisted Analysis is disabled if the images do not meet the requirements, please move back to section Semi-automated analysis.

Copyright © Disior Ltd. All rights reserved.

- NOTE: For difficult cases (e.g. abnormal anatomies), extended Field of View (any image dimension over 39 cm or e.g., femur/patella visible) or if the AI assisted analysis fails to analyze the case correctly, please move back to section Semi-automated analysis

- Confirm the laterality of the foot and fill in patient information – click 'OK' (see Image 10).
  Note: The information provided does not affect the analysis results.
- As an intermediate step, the analysis provides a preliminary list of bones in the image and whether there is metal present (Image 11):
  - Confirm the preliminary analysis – click 'OK'.
    - **Note**: In the Foot & Ankle module, the 2nd – 5th middle and distal phalanges are not included in the final analyzed model even if visible in the preliminary analysis.

    Or
  - Reject the preliminary analysis and perform bone marking manually (according to section 2.4 Semi-automated analysis) – click 'CANCEL'.
  - **Note:** if the preliminary analysis does not include any bones, check that the correct laterality was chosen.

Caution: Before the analysis is started you must select the correct laterality.

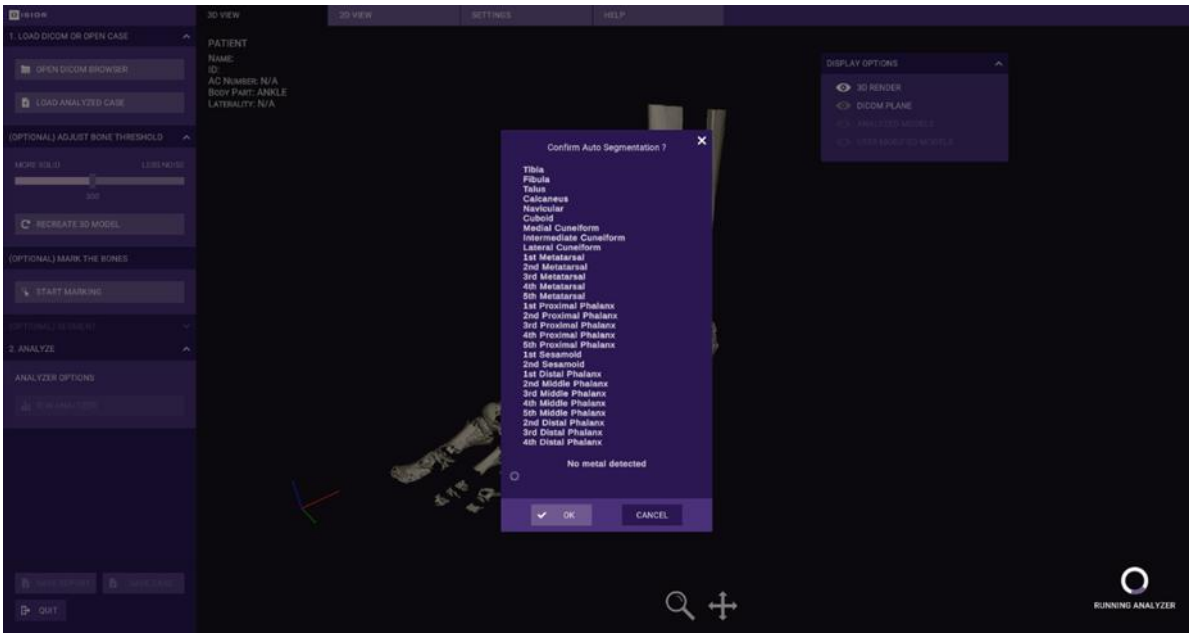


Image 11 Confirm the preliminary list of bones present in the image and whether there is metal present.

Copyright © Disior Ltd. All rights reserved.

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 (Image 12):

- 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 13).

Image 12 Detailed view of the 3D VIEW sheet with the different panels shown.

Copyright © Disior Ltd. All rights reserved.

Image 13 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 (Image 14).

- 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 14 Fusion images can be created to check the conformity of the 3D model to the original DICOM images series.

Copyright © Disior Ltd. All rights reserved.

2.6.1.3 Manual measurement

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 15.
- 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 15 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 16.
- 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.

Copyright © Disior Ltd. All rights reserved.

Image 16 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 (Image 17).

- To get a more detailed view of each measurement simply click on any measurement in the list.
- A digitally reconstructed radiograph (DRR) 'projection' as well as 3D models are 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 54.

Copyright © Disior Ltd. All rights reserved.

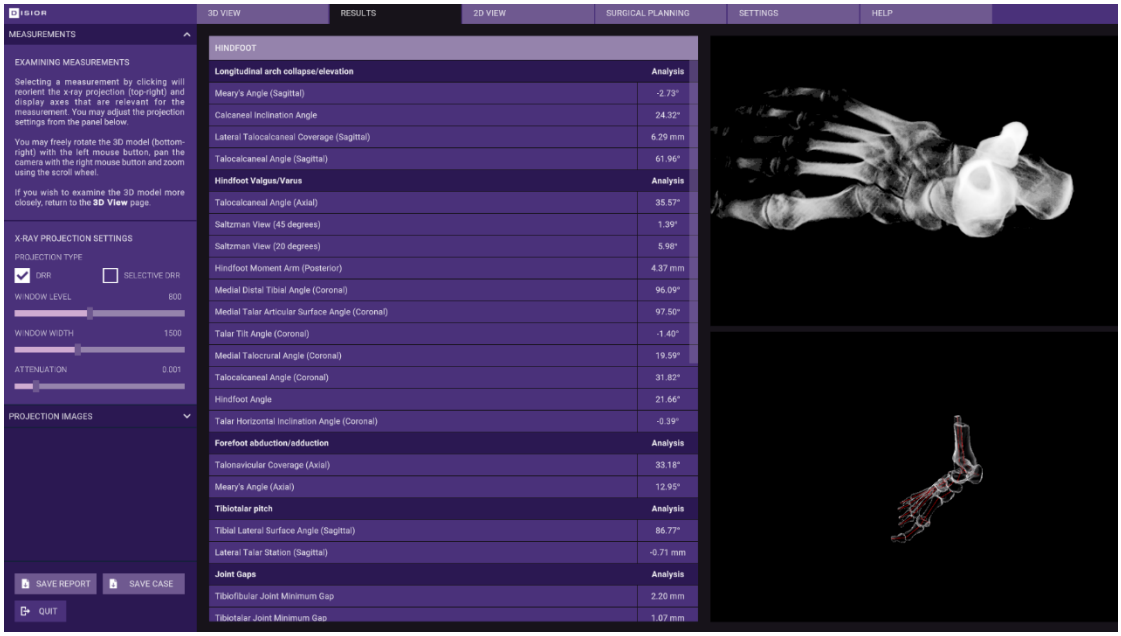


Image 17 The results page features the numerical results of the bone alignment analysis, a DRR and a 3D model for each measurement.

2.6.2.2 Projection images

Projection images, digitally reconstructed radiographs (DRRs), can be created on the 'RESULTS' sheet (Image 18):

- 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 (WINDOW LEVEL) and brightness (WINDOW 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'.

Copyright © Disior Ltd. All rights reserved.

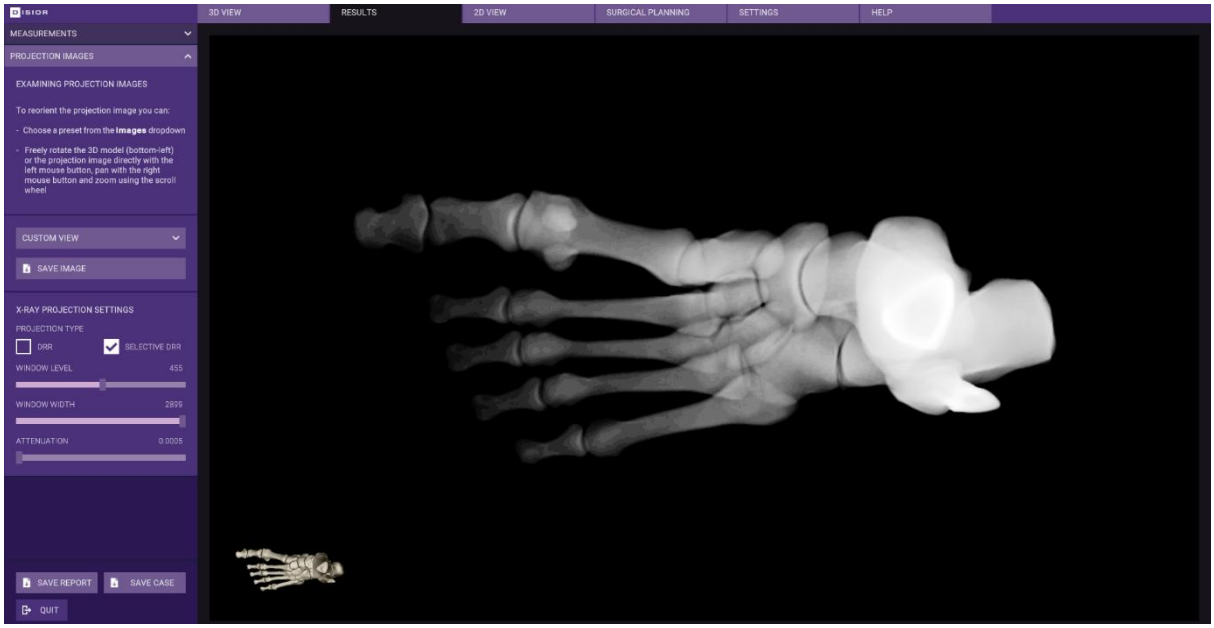


Image 18 Projection images panel on the results sheet for making custom DRRs.

2.6.3 2D view sheet

The 2D VIEW sheet can be used to review the original DICOM image series across three orthogonal viewing windows (Image 19).

- 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.

Copyright © Disior Ltd. All rights reserved.

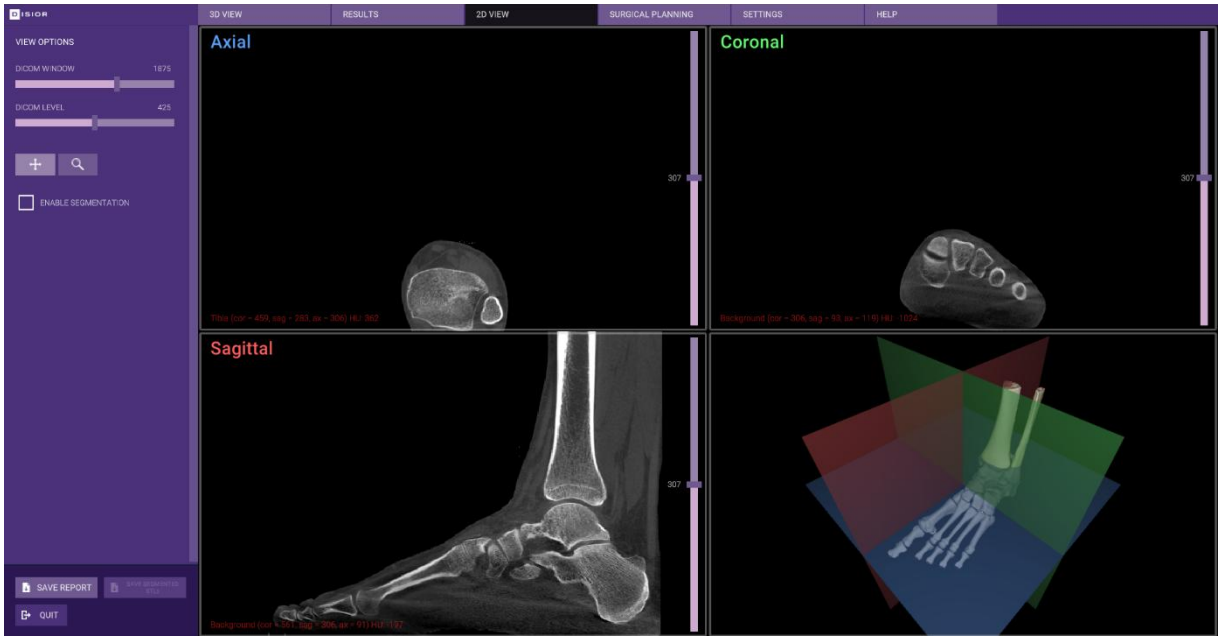


Image 19 The 2D VIEW sheet shows the DICOM image series in three orthogonal views.

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.

Note. It is recommended practice to export the report for any critical items, as the export report can be reviewed offline without network connection.

2.7.1 Save report

To export the results and 3D models:

- Click the 'SAVE REPORT' button in the bottom left corner (Image 20). 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 models are exported to DICOM standard Patient-Based Coordinate System.

2.7.2 Save case

To save the case for viewing again in Bonelogic (Image 20):

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

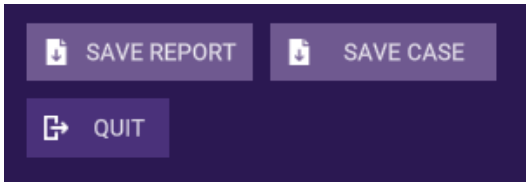


Image 20 Saving functions in Bonelogic

Copyright © Disior Ltd. All rights reserved.

2.8 Manual segmentation

If you have purchased the additional 'PLANNING' module, then the 'MANUAL SEGMENTATION CONTROLS' will be enabled on the 2D VIEW sheet (Image 21).

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 22):
    - 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 23) – 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 24) – 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 25).
- The modified models can be exported as STLs via the SAVE SEGMENTED STLS button in the bottom left corner (Image 26).

Caution: The manual segmentation modifications are not affecting the measurements.

Copyright © Disior Ltd. All rights reserved.

Image 21 The 2D VIEW sheet with the manual segmentation tools shown on the left-hand panel.

Image 22 Detail of the ANNOTATION SELECTION drop down menu.

Copyright © Disior Ltd. All rights reserved.

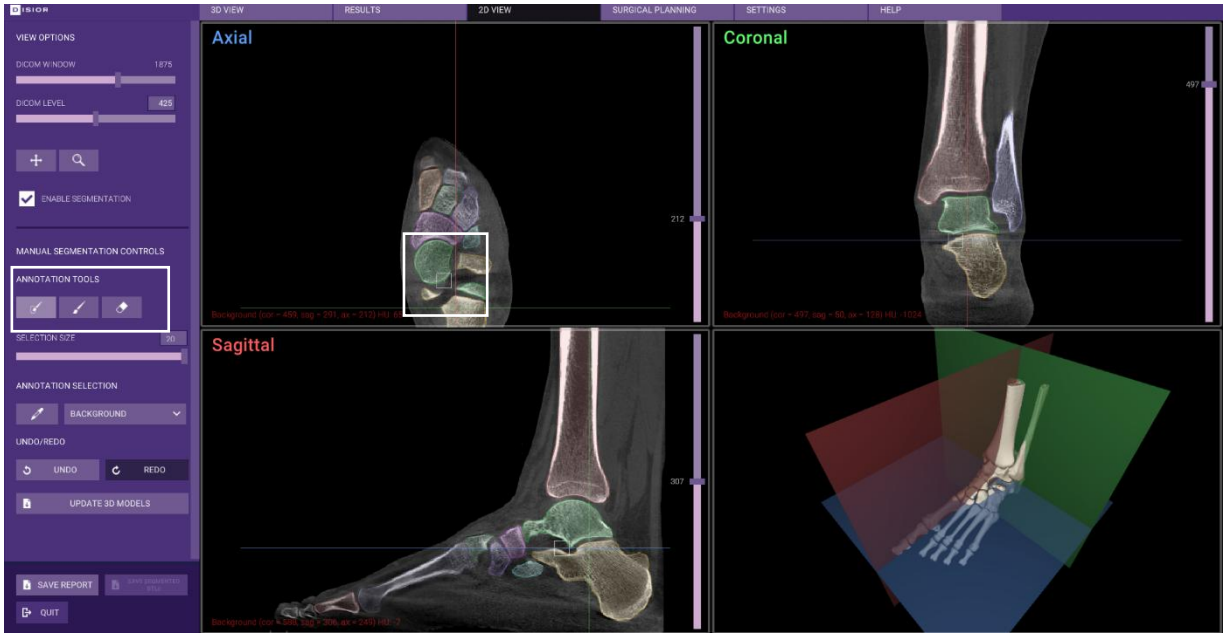


Image 23 Example of Smart Tool, ANNOTATION TOOLS, for modifying the 3D models

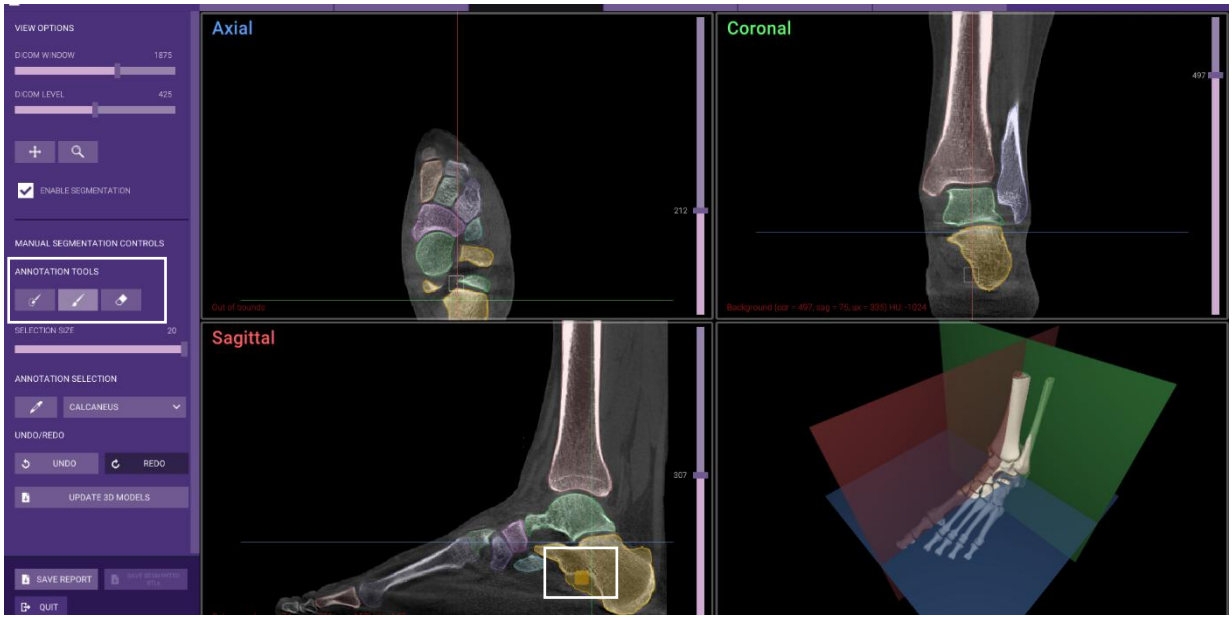


Image 24 Example of the Brush Tool, ANNOTATION TOOLS, for modifying the 3D models.

Copyright © Disior Ltd. All rights reserved.

Image 25 USER MODIFIED MODELS as seen on the 3D VIEW sheet, note the surface texture is different on elements that have been modified.

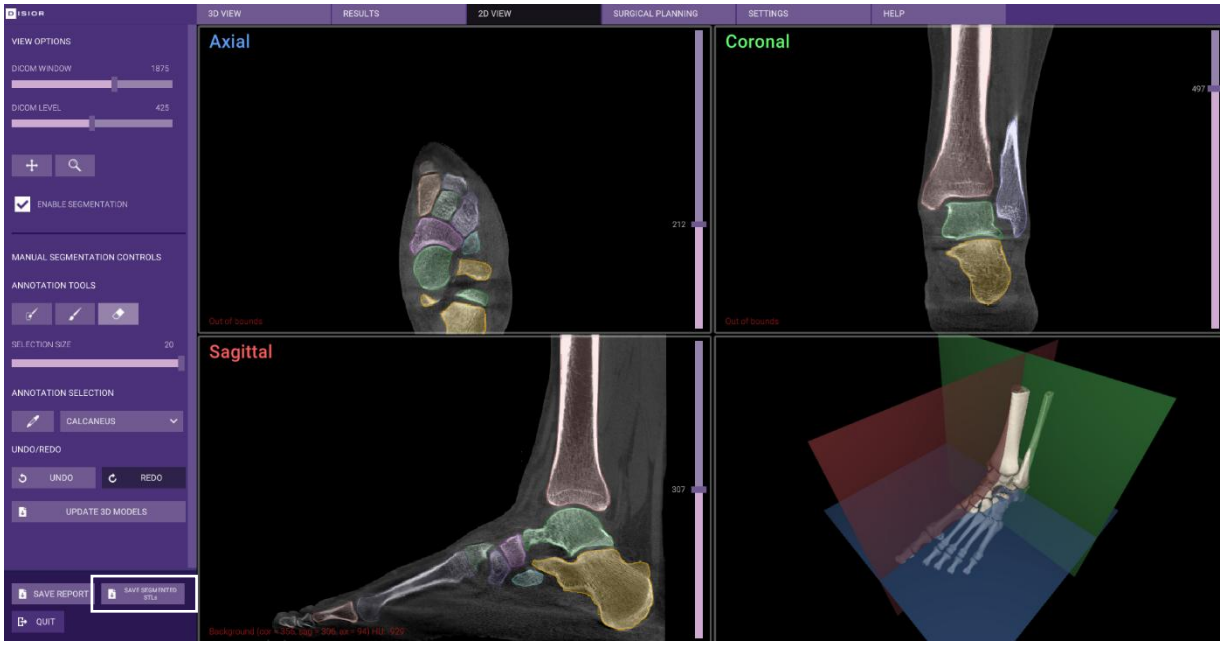


Image 26 To export the STLs of the modified 3D models, click SAVE SEGMENTED STLs.

2.9 Planning tool

The SURGICAL PLANNING sheet can be used to plan various repositioning and osteotomy procedures of the bones in the foot and ankle. 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 'SURGICAL PLANNING' sheet.

Copyright © Disior Ltd. All rights reserved.

2.9.1 Choose the bones

- To select the bone that you 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 27).
    - 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 28).
    - The chosen bone will be opaque in the model, the rest of the bones remain transparent.
    - Additional bones selected for surgical planning appear blue.

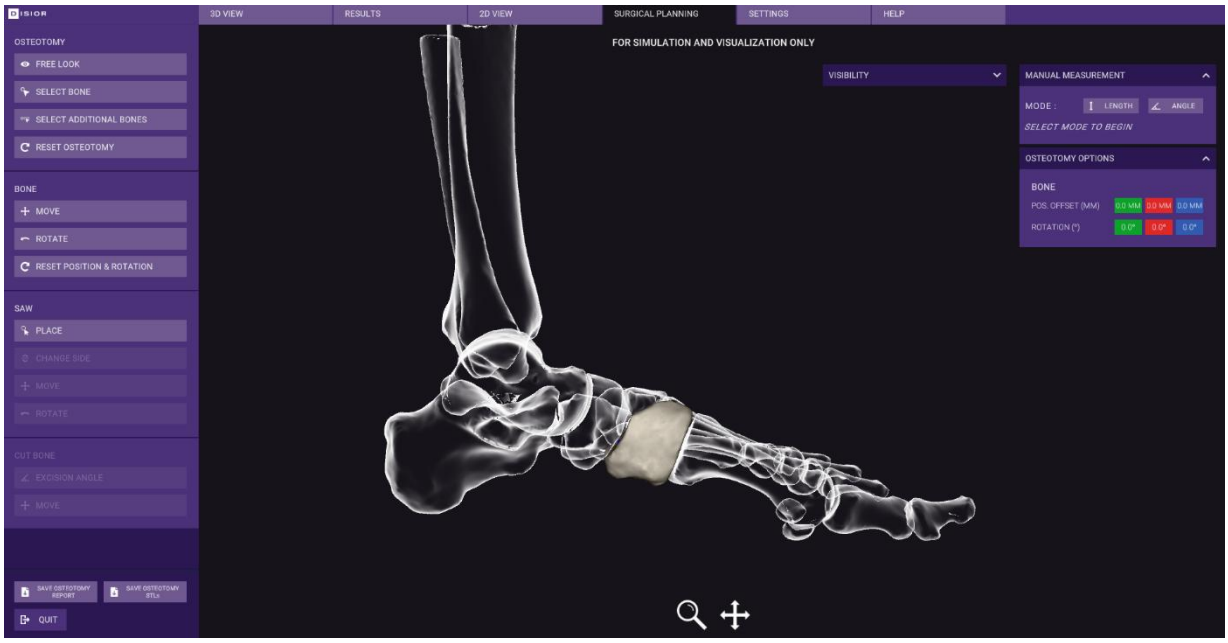


Image 27 Surgical planning sheet with one bone selected.

Image 28 Adding additional bones to create a group for a surgical plan.

Copyright © Disior Ltd. All rights reserved.

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 29).
        - 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 30).
        - 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 29).
- 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 30).
    - 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 30).
- ‘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 30).

Caution: 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.

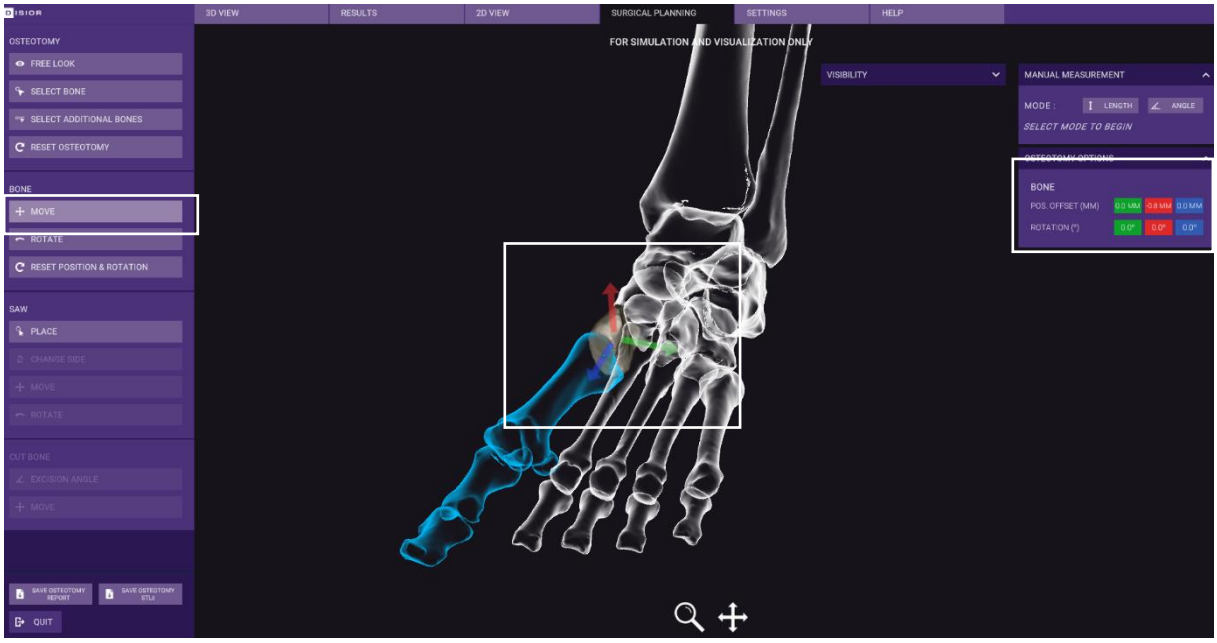


Image 29 Detailed view of the 'MOVE' function.

Copyright © Disior Ltd. All rights reserved.

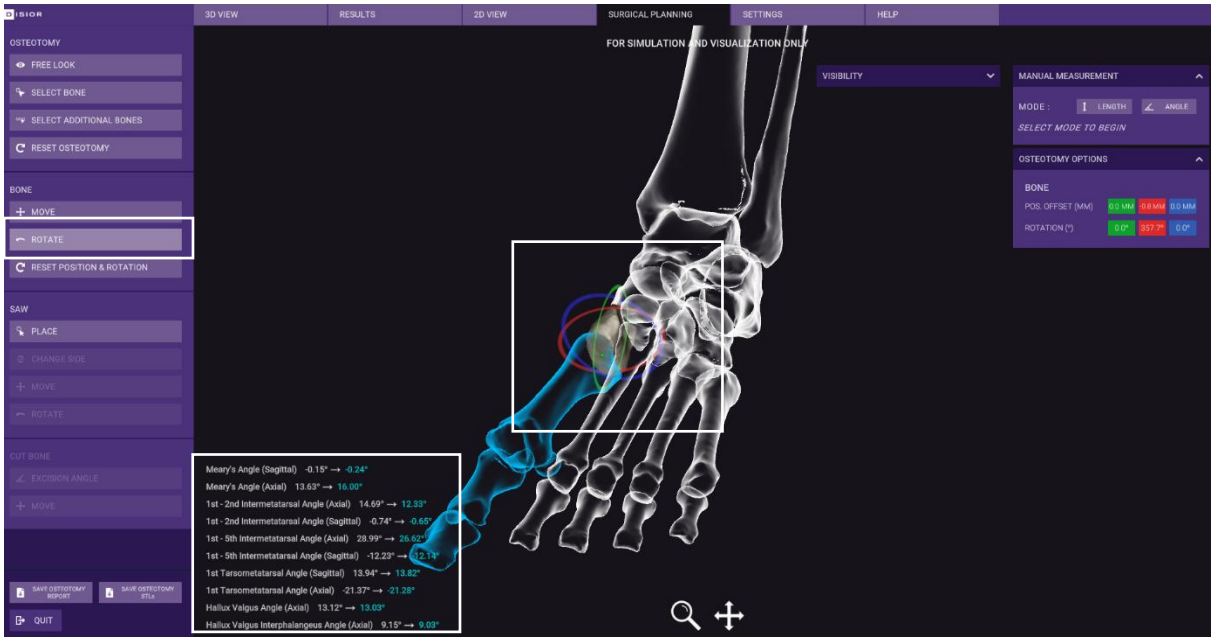


Image 30 Detailed view of the 'ROTATE' bone function.

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 31).
- The active side of the bone will be highlighted in red. You can swap which side is active with the ‘CHANGE SIDE’ button (Image 31).
- 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 31).
    - 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 32):
        - 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 33):
        - 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 32 and Image 33:
    - 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.

Copyright © Disior Ltd. All rights reserved.

- Saw depth – is measured from bone surface to tip of the saw.

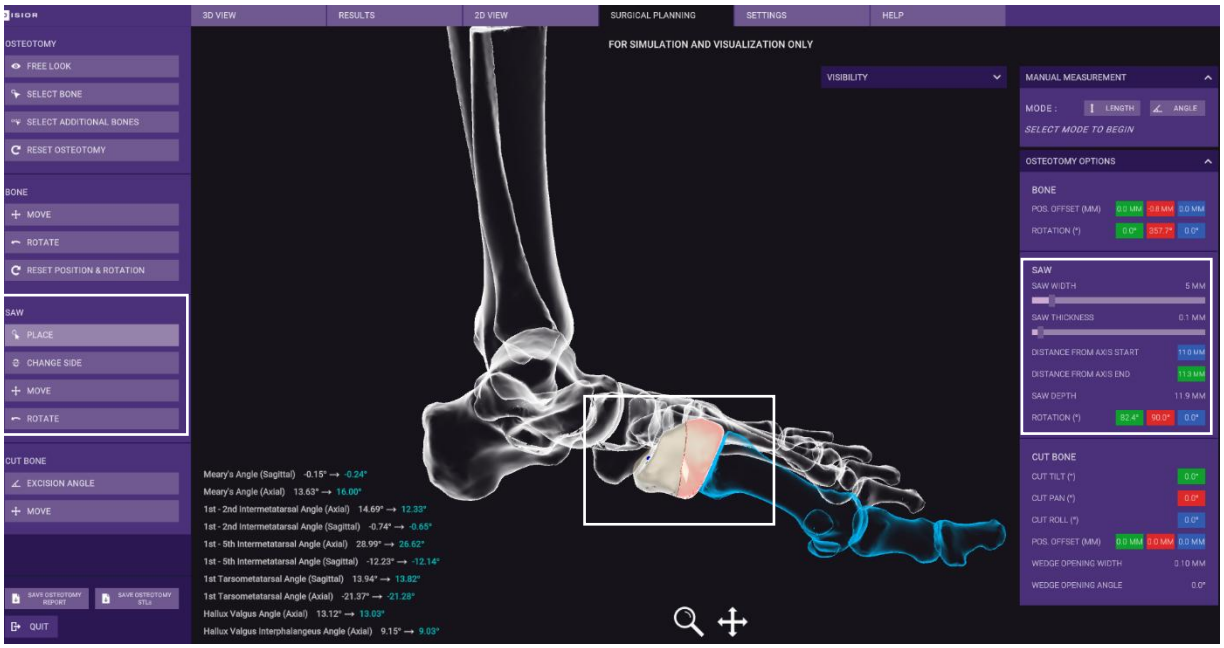


Image 31 Detailed view of the place saw function and saw parameters

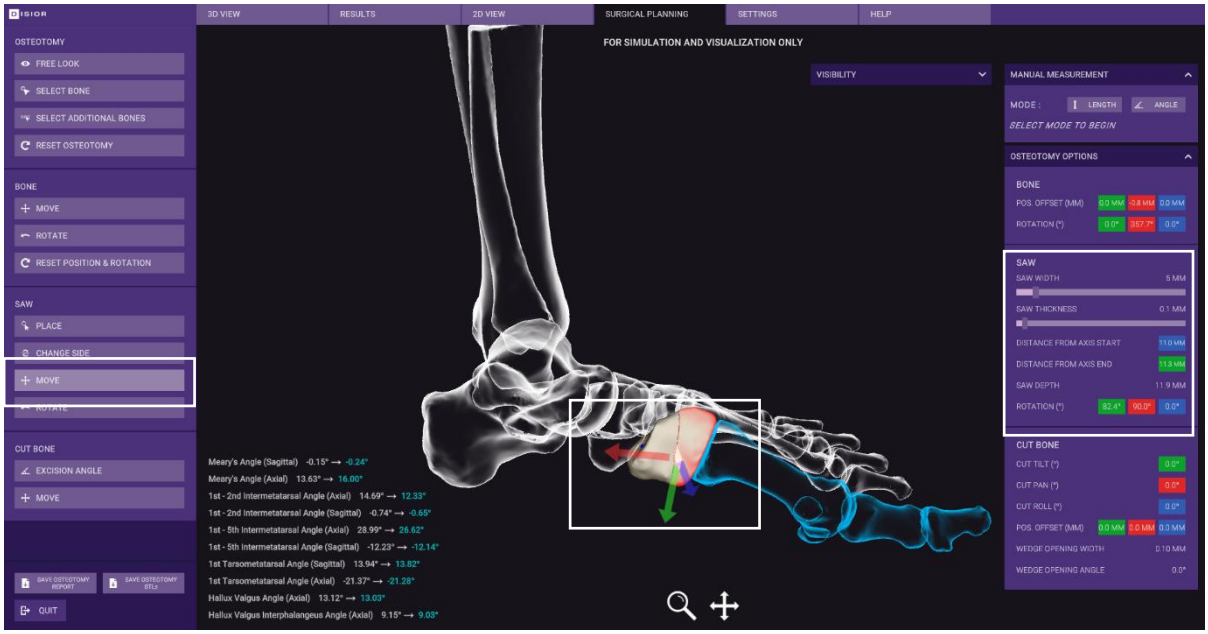


Image 32 Detailed view of the move saw function, with arrow handles shown

Copyright © Disior Ltd. All rights reserved.

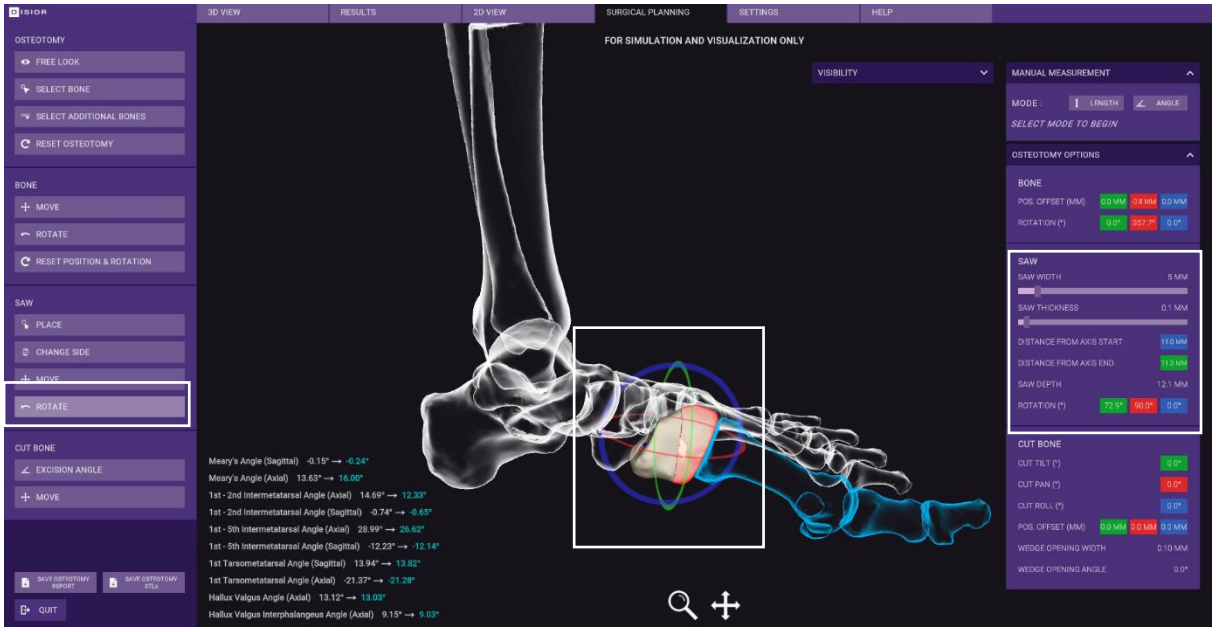


Image 33 Detailed view of the rotate function in the saw options, with circular handles shown

2.9.4 Conduct osteotomy / Cut the bone

- To create open or closed wedges (examples shown in Image 34, Image 35 & Image 36) 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.

Copyright © Disior Ltd. All rights reserved.

- After making a simulated osteotomy the results page is updated to reflect the differences in bone alignment (Image 37) see sections and 4.1.2.1 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 STLS’ button, haves the 3D bone models with the repositioning and cuts as a series of STLs.

Image 34 Detailed view of tools to create an open/closed wedge osteotomy analytics and use of bone visibility toggling.

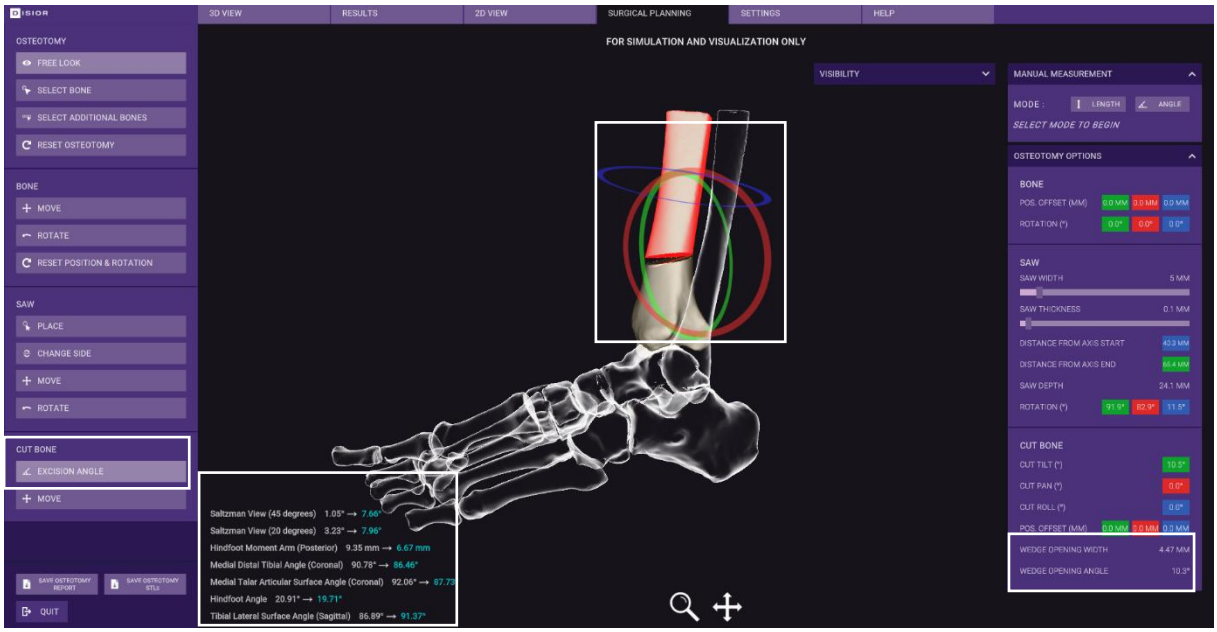


Image 35 Example of an exaggerated open wedge osteotomy.

Copyright © Disior Ltd. All rights reserved.

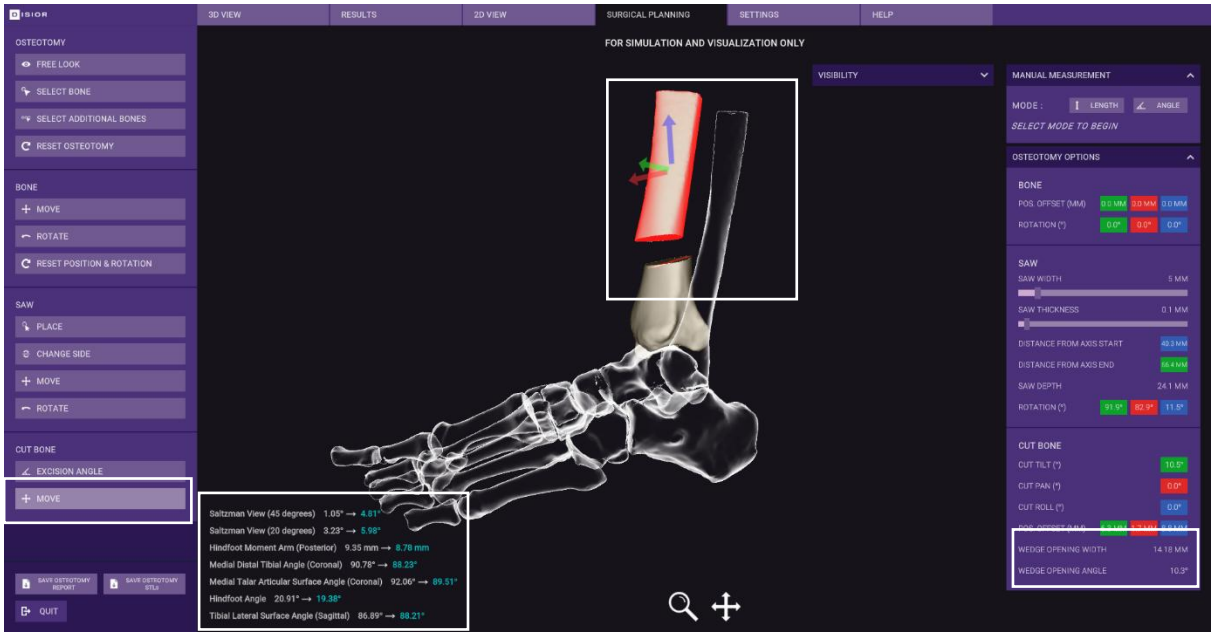


Image 36 Example of a position adjustment osteotomy showing changes in bone alignment.

HINDFOOT		
Longitudinal arch collapse/elevation	**Analysis**	**Simulated**
Meary's Angle (Sagittal)	-0.15°	-0.15°
Calcaneal Inclination Angle (Sagittal)	23.79°	23.79°
Lateral Talocalcaneal Coverage (Sagittal)	10.16 mm	10.16 mm
Talocalcaneal Angle (Sagittal)	57.94°	57.94°
Hindfoot Valgus/Varus	**Analysis**	**Simulated**
Talocalcaneal Angle (Axial)	35.09°	35.09°
Saltzman View (45 degrees)	1.05°	4.81°
Saltzman View (20 degrees)	3.23°	5.98°
Hindfoot Moment Arm (Posterior)	9.35 mm	8.78 mm
Medial Distal Tibial Angle (Coronal)	90.78°	88.23°
Medial Talar Articular Surface Angle (Coronal)	92.06°	89.51°
Talar Tilt Angle (Coronal)	-1.27°	-1.27°
Medial Talocrural Angle (Coronal)	11.41°	11.41°
Talocalcaneal Angle (Coronal)	17.45°	17.45°
Hindfoot Angle	20.91°	19.38°
Talar Horizontal Inclination Angle (Coronal)	0.70°	0.70°
Forefoot abduction/adduction	**Analysis**	**Simulated**
Talonavicular Coverage (Axial)	34.00°	34.00°
Meary's Angle (Axial)	13.63°	13.63°
Tibiotalar pitch	**Analysis**	**Simulated**
Tibial Lateral Surface Angle (Sagittal)	86.89°	88.21°
Lateral Talar Station (Sagittal)	0.73 mm	0.73 mm

Image 37 Detailed view of the measurements sheet showing original and simulated bone alignment analytics.

Copyright © Disior Ltd. All rights reserved.

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 38. A description of the issue will expediate the process.

Note: 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 39.

Note: 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 within 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)

2.10.4 Reporting serious incidents

Any serious incident related to the use of this product should be reported to both the manufacturer and the health authority/competent authority where the product is installed.

Please provide the following information:

- Date of the incident
- Description of the incident, including any patient or user impact/injury
- The product version used
- Contact information (facility, address, contact person, title, and telephone number)

Copyright © Disior Ltd. All rights reserved.

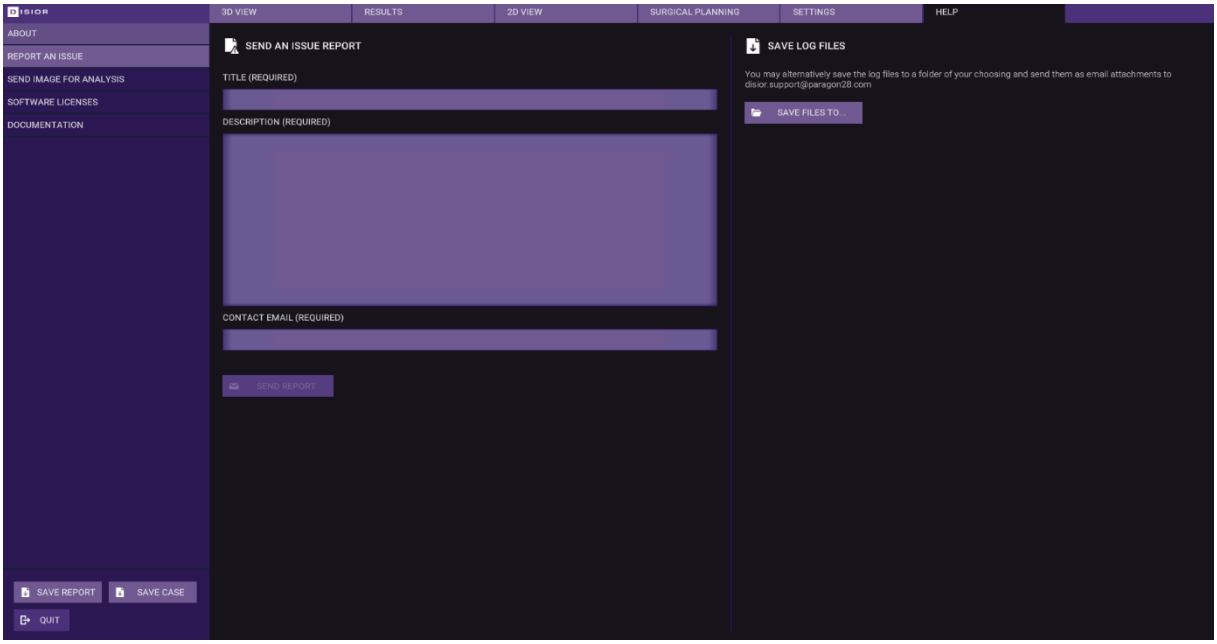


Image 38 Detailed view of the Send an Issue Report form on the Help sheet.

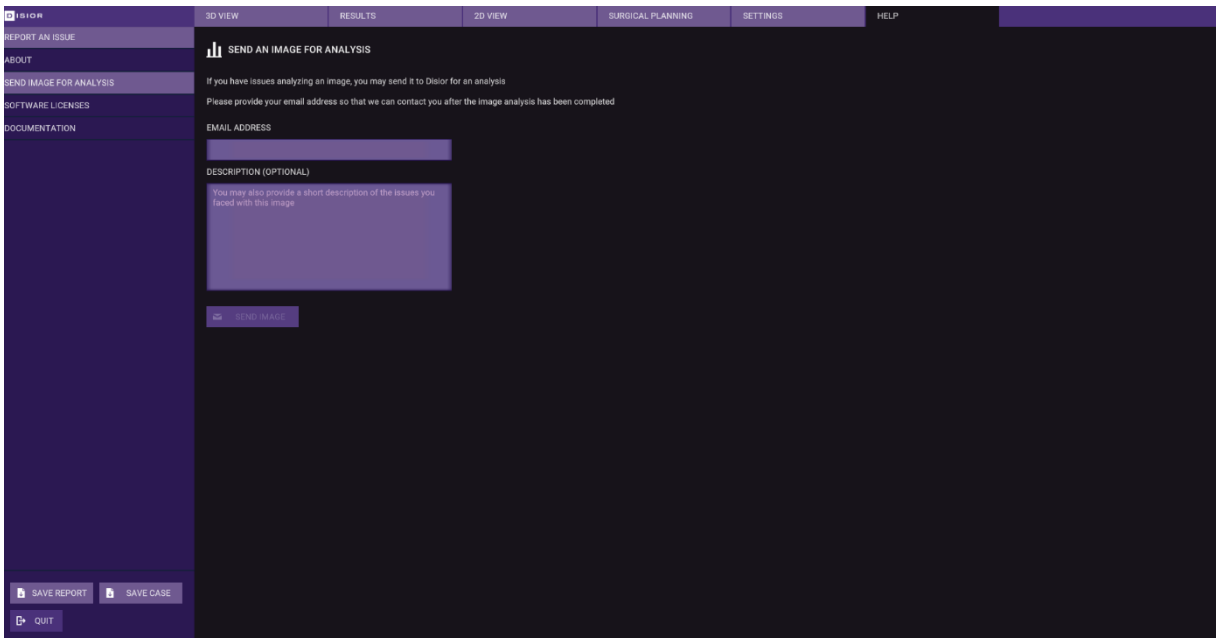


Image 39 Detailed view of the Send Image for Analysis form on the Help sheet

Copyright © Disior Ltd. All rights reserved.

2.10.5 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 the Disior Cloud domain is whitelisted.
Installation First time logging in	Password is incorrect	Prior logging in the software, the user needs to create their email specific password, which is used to log in the software. It may also contain letters that look similar e.g. uppercase i 'I' and lowercase L 'l. So we recommend that you copy-paste this password into the password field.
Log in	License not verified	Please contact the Disior support team (disior.support@paragon28.com).
Log in	Username not recognized	Your username is your email address that was used to create the user password. Please contact the Disior support team (disior.support@paragon28.com).
Login	New user	Prior logging in the software, the user needs to create their email specific password, which is used to log in the software.
Login	Password incorrect	If you have forgotten the password, press the 'forgot your password?' on the login page, it will redirect you to a site where you can change your password. On the password change page, you will be prompted for verification code. After requesting, receiving and typing in the verification code, you can change your password. Password rules: The password must be between 8 and 64 characters. The password must have at least 3 of the following: • a lowercase letter • an uppercase letter • a digit • a symbol
Load DICOM data	Taking a long time to list the data in the chosen folder	The time taken to load and list all DICOM image series is dependent on the number of datasets in the chosen directory.

Copyright © Disior Ltd. All rights reserved.

Initial 3D render	No data is shown after the DICOM is loaded	Please adjust the Hounsfield unit slider and click 'recreate 3D model'. This should fix the problem, if not please send the dataset to Disior™ for review via the HELP page, as instructed on page 44.
Mark the bones	Poor segmentation result	For difficult cases, follow the instructions at Additional steps for difficult cases on page 22. 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 44.
AI Assisted Analysis	AI Assisted Analysis disabled	Please adhere to the requirements in 1.6 Imaging data quality requirements. If the images used meets the requirements and the AI Assisted Analysis is disabled, please contact disior.support@paragon28.com.
AI Assisted Analysis	Preliminary analysis – no bones detected	If no bones are detected in the preliminary analysis, check that the chosen laterality is correct.
Mark the bones	Fragments of fractured bones look fused or incorrect	The software is not intended to be used to identify fragments of a fracture. If you suspect a patient DICOM image series contains a fracture and has been segmented poorly, please check by using the 'Create a fusion image' instructions on page 27. If there are fragmented pieces, then please follow the 'Send image for analysis' instructions on page 44.
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 7 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

Copyright © Disior Ltd. All rights reserved.

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.

Copyright © Disior Ltd. All rights reserved.

3 Residual Risk, Errors and Warnings

3.1 Residual risk

Bonelogic software is a standalone medical software operated by orthopaedic healthcare professionals. There are three residual risks remaining in the software: 1) image processing error (e.g. registration failure), 2) results inaccuracy (due to e.g. registration or measurement inaccuracy), and 3) misuse. The residual risks are related to hazardous situations based on delayed clinical decisions (software availability due to errors) or incorrect clinical decisions (due to results inaccuracies) with typically indirect harm associated for the patient. In all cases, the imaging data quality requirements (section 1.6) should be observed for input images and the output of the software shall in all cases be subject to careful orthopaedic expert assessment.

3.1.1 Image processing error

Overview for residual risks that may lead to image processing error:

- Input image data quality not meeting requirements (see section 1.6), e.g. images with limited field-of-view, abnormal anatomies
- Issues with Data access or corruption

When this type of error occurs (see section 3.2), the user is notified and encouraged to seek an alternative method for patient diagnosis and treatment planning.

3.1.2 Results inaccuracy

Overview for residual risks that may lead to results inaccuracy:

- Input image data quality not meeting requirements (see section 1.6), e.g. image with low resolution, low contrast, abnormal anatomies.
- Negligent use of the software (incorrect assignment of laterality, structures or measurement points), or using output without reviewing results (e.g. model to DICOM comparison)

Small registration inaccuracies are unlikely to impact measurements. The software attempts to detect conditions where inaccuracies may occur, and warning messages are triggered (section 3.3). 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.

3.1.3 Misuse

Overview for residual risks that are related to misuse:

- Off-label use (e.g. using images from unsupported anatomies or imaging modalities, or using output beyond the intended use)
- Using software without reading the IFU, proper training, or proper professional qualification

The software should only be used according to its intended use and indications (see chapter 1).

Copyright © Disior Ltd. All rights reserved.

3.2 Error messages

The software issues an error message to mitigate potentially hazardous situations with image availability and analysis failure, or when there are general image or data processing errors (including license availability). In these error situations, the user should seek alternative methods for the analysis and contact Disior support (disior.support@paragon28.com).

3.2.1 Analysis failure

ERROR ANALYSIS FAILED

Check the input data and rerun the analysis

If the problem persists, contact Disior support

3.2.2 DICOM and case opening failures

ERROR DICOM DATA UNSUITABLE FOR ANALYSIS

PLEASE CHECK THE DICOM DATA OR CONTACT DISIOR SUPPORT

ERROR: FOLDER NOT FOUND

PLEASE CHECK THE SELECTED PATH

ERROR: UNABLE TO OPEN THE DICOM IMAGE

PLEASE SELECT ANOTHER SERIES OR CONTACT DISIOR SUPPORT

3.2.3 Saving results failures

ERROR: SAVING OSTEOTOMY REPORT FAILED

PLEASE MAKE SURE THE REPORT IS NOT OPEN IN ANOTHER PROGRAM AND TRY AGAIN

ERROR: INVALID LOCATION FOR SAVING

PLEASE CHOOSE ANOTHER LOCATION

ERROR: SAVING THE CASE FAILED

PLEASE TRY AGAIN

Copyright © Disior Ltd. All rights reserved.

ERROR: SAVING THE STL MODELS FAILED

PLEASE CONTACT DISIOR SUPPORT

3.3 Warnings messages

In case of 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.

3.3.1 Image quality

WARNING
Inadequate image quality. Large spacing between slices

WARNING
Inadequate image quality. Large pixel spacing

Check the imaging data quality requirements

Rerun the analysis using images fulfilling the requirements or use the results with caution

3.3.2 Limited field of view

WARNING
Inadequate field of view or quality “bone name”

Check the imaging data quality requirements

Copyright © Disior Ltd. All rights reserved.

Rerun the analysis using images fulfilling the requirements or use the results with caution

3.3.3 Landmark location

WARNING
Inaccurate measurement “bone name”

Check the related measurements

3.3.4 Contact between bones

WARNING
Contact detected “bone name”

Check the related measurements

3.3.5 Laterality selection and bone selection

WARNING
Abnormal anatomy detected

Check input data

Rerun the analysis or use the results with caution

3.4 Software guidance notifications

THE IMAGE FIELD-OF-VIEW IS TOO LARGE FOR AI ASSISTED ANALYSIS, PLEASE PROCEED WITH SEMI-AUTOMATED ANALYSIS.

THE IMAGE IDENTIFICATION CHARACTERISTICS DO NOT MEET AI ASSISTED ANALYSIS REQUIREMENTS (ORIGINAL/PRIMARY/AXIAL), PLEASE PROCEED WITH SEMI-AUTOMATED ANALYSIS.

AI ASSISTED ANALYSIS DISABLED, PLEASE PROCEED WITH SEMI-AUTOMATED ANALYSIS.

Copyright © Disior Ltd. All rights reserved.

3.5 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.

3.4.1 Informative message examples

DOWNLOADED INSTRUCTIONS FOR USE

LICENSE NOT FOUND – PLEASE CONTACT DISIOR SUPPORT

LEGACY CASE LOADED, IMAGE ANALYSIS AND CASE SAVING FUNCTIONALITIES ARE UNAVAILABLE DUE TO INCOMPATIBLE DATA

3.4.2 Informative processing message example

Copyright © Disior Ltd. All rights reserved.

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 that are currently available for foot and ankle area:

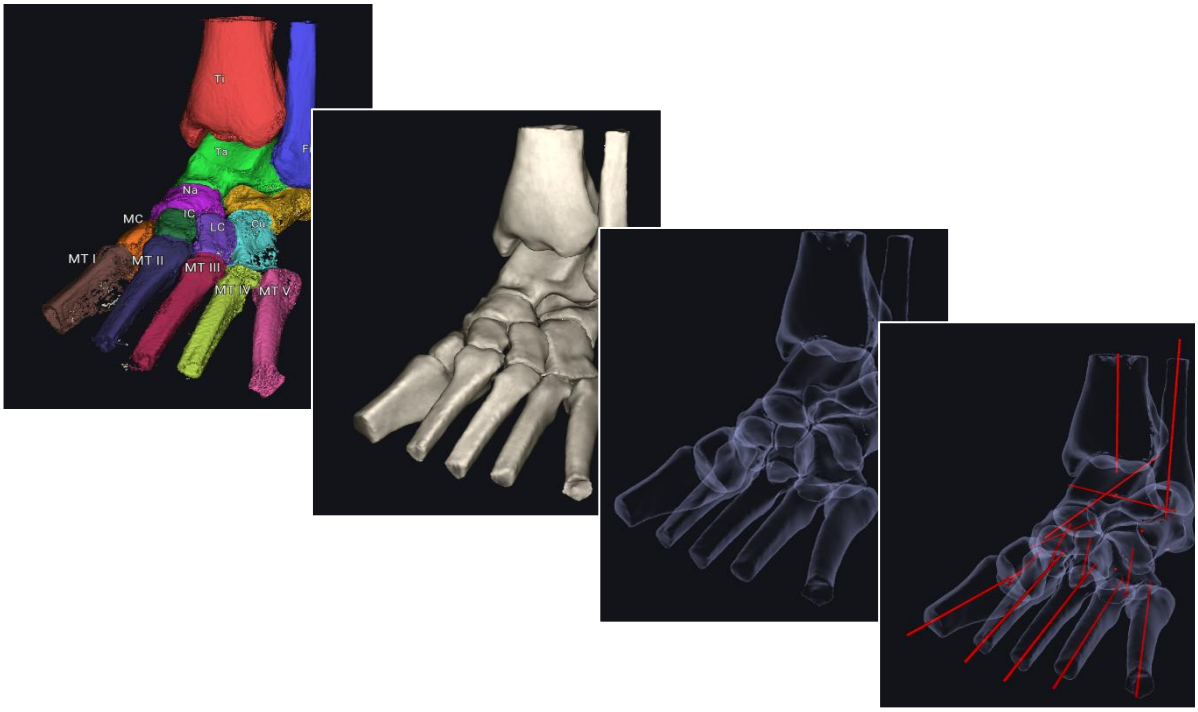
1. The foot and ankle - measurements are calculated to define the:
    - State of the arch
    - Valgus/varus condition of the foot
    - Forefoot deformity
    - Hallux valgus

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

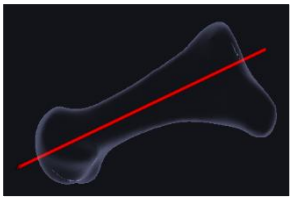
4.1.2 Foot and ankle measurements

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.
    - Floor plane = imaging device ground level
2. Measures are shown with + or – signs

Copyright © Disior Ltd. All rights reserved.

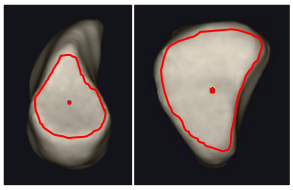


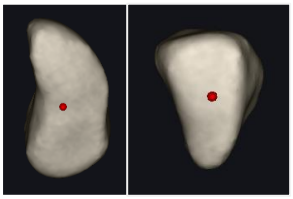
4.1.2.1 Bone axis definitions



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

1. Longitudinal axis: The software determines the shaft region of the bone and its centre curve. Robust line fitting is used to find an axis representative for the curve.

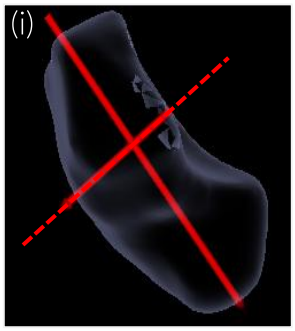




Cuneiform bones

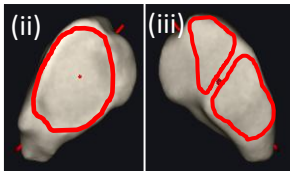
Cuneiform anteroposterior axis: The axis drawn between cuneiform posterior and anterior articular surface centre points.

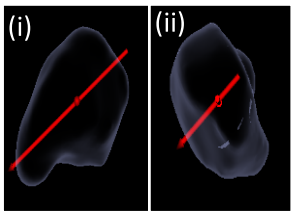
Copyright © Disior Ltd. All rights reserved.



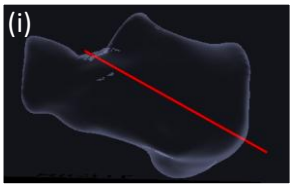
Navicular (c)

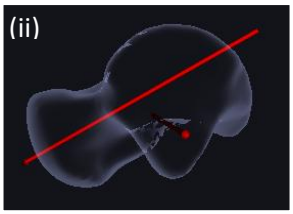
1. Longitudinal axis (i): goes through the (ii) talonavicular articular surface weighted centre point and the (iii) navicular–medial cuneiform–intermediate cuneiform articular surface weighted centre point.





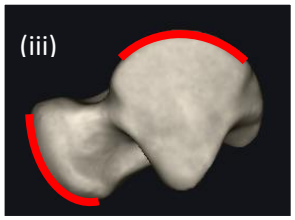
2. Perpendicular axes: A subset of the bone is projected into plane perpendicular to bones longitudinal axis (i-ii). Line fitting is used to measure the axes.

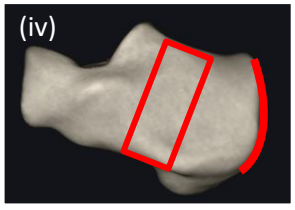




Talus, calcaneus

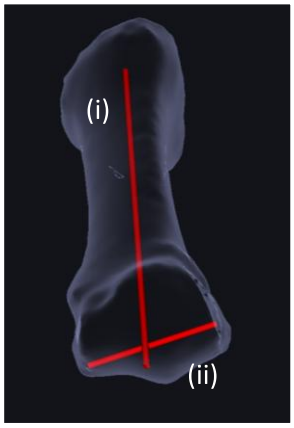
1. Longitudinal axis (i & ii): The software scans bone and determines its cross-section at various locations. Weighted center point is computed for each cross-section. Robust line fitting is used to find a straight-line representative for the cross-section points.





2. Secondary axes: Additional projections of joint facets and tendon insertion (iii &iv) are used to determine bone alignment.

Copyright © Disior Ltd. All rights reserved.

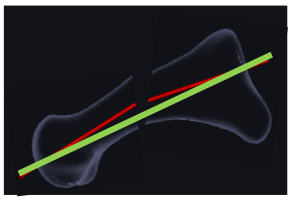


1st Metatarsal Distal Mediolateral Axis

The software determines the distal articular surface of the metatarsal (MT) bone and fits a barrel geometry to it. The mediolateral axis direction is the barrel's central axis**.**

i) longitudinal axis

ii) distal mediolateral axis



Surgical planning metrics

- During the Surgical planning 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).

Copyright © Disior Ltd. All rights reserved.

4.1.2.2 Hindfoot

4.1.2.2.1 Longitudinal arch collapse/elevation

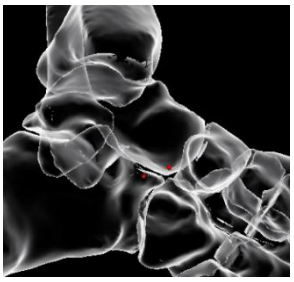
Meary's Angle (Sagittal)

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

- Decrease in angle → Foot shifts towards pes planus
- Increase in angle → Foot shifts towards pes cavus

Calcaneal Inclination Angle

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



Lateral Talocalcaneal Coverage (Sagittal)

The vertical distance between the most inferior point on the talus head and the most superior point of the calcaneus anterior column in the sagittal view

- Negative value → Talar point is above calcaneal point
- Positive value → Talar point is below calcaneal point

Talocalcaneal Angle (Sagittal)

The angle between the talus and calcaneus longitudinal axes measured in sagittal view

Copyright © Disior Ltd. All rights reserved.

4.1.2.2.2 Valgus/varus

Talocalcaneal Angle (Axial)

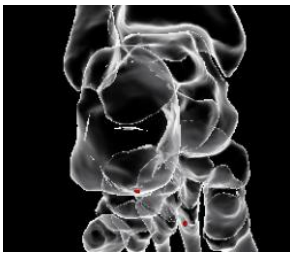
The angle between the talus longitudinal axis and the calcaneus longitudinal axis

- Decrease in angle → Hindfoot shifts towards valgus
- Increase in angle → Hindfoot shifts towards varus

Saltzman Views

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

- Decrease in angle → Hindfoot shifts towards valgus
- Increase in angle → Hindfoot shifts towards varus



Hindfoot Moment Arm (Posterior)

The mediolateral distance (mm) between the longitudinal axis of the tibia and most inferior point of the calcaneus

- Larger value in mm → Hindfoot shifts towards valgus
- Smaller value in mm → Hindfoot shifts towards varus

Medial Distal Tibial Angle (Coronal)

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

- Decrease in angle → Medial inclination
- Increase in angle → Lateral inclination

Medial Talar Articular Surface Angle (Coronal)

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

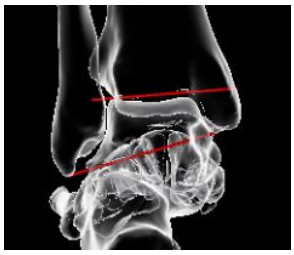
- Decrease in angle → Foot shifts towards varus
- Increase in angle → Foot shifts towards valgus

Copyright © Disior Ltd. All rights reserved.

Talar Tilt Angle (Coronal)

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

- Decrease in angle → Joint gap increases on lateral side
- Increase in angle → Joint gap increases on medial side

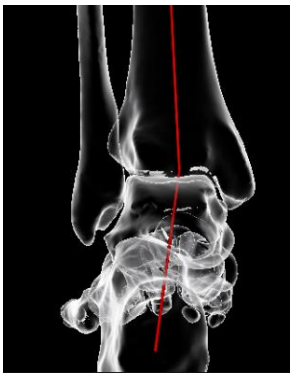


Medial Talocrural Angle (Coronal)

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)

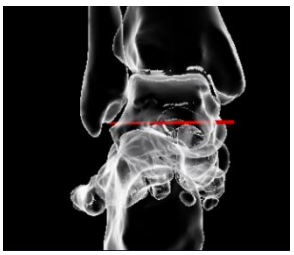
The angle between the talus and calcaneus inferosuperior axes measured in posterior view



Hindfoot Angle

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

- Decrease in angle → Hindfoot shifts towards varus
- Increase in angle → Hindfoot shifts towards valgus



Talar Horizontal Inclination Angle (Coronal)

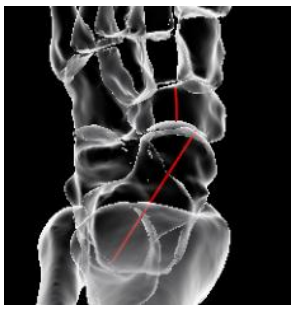
The angle between talus mediolateral axis and the floor plane, measured in coronal view

- Decrease in angle → Talus pronation
- Increase in angle → Talus supination

Copyright © Disior Ltd. All rights reserved.

4.1.2.3 Midfoot

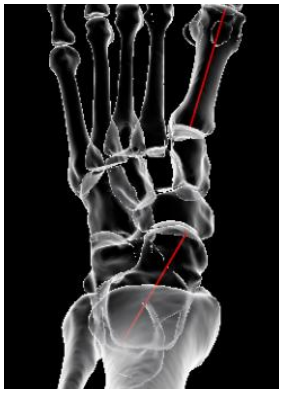
4.1.2.3.1 Abduction/adduction



Talonavicular Coverage (Axial)

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

- Decrease in angle → Forefoot adduction
- Increase in angle → Forefoot abduction

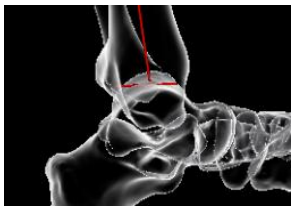


Meary's Angle (Axial)

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

- Decrease in angle → Foot shifts towards pes cavus
- Increase in angle → Foot shifts towards pes planus

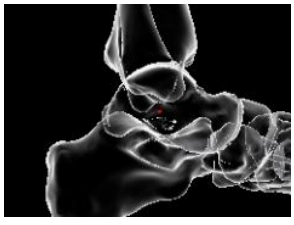
4.1.2.3.2 Tibiotalar pitch



Tibial Lateral Surface Angle (Sagittal)

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

- Decrease in angle → Posterior inclination
- Increase in angle → Anterior inclination

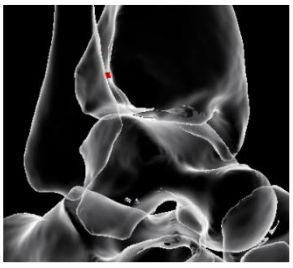


Lateral Talar Station (Sagittal)

The posteroanterior distance between the tibial longitudinal axis and the talus trochlea mediolateral axis in the sagittal view

- Negative value → Talus is posterior to tibial longitudinal axis
- Positive value → Talus is anterior to tibial longitudinal axis

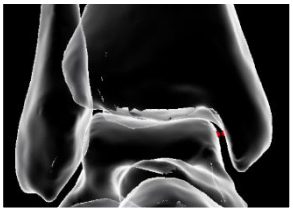
4.1.2.3.3 Joint Gaps



Tibiofibular Joint
Minimum Gap

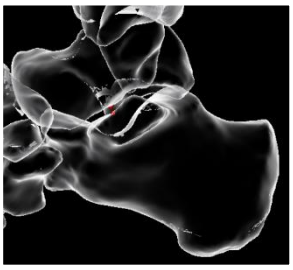
Minimum normal distance measured from the tibia to the fibula on the articular surface region

Copyright © Disior Ltd. All rights reserved.



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

4.1.2.4 Forefoot

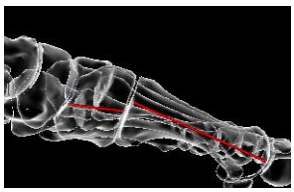
4.1.2.4.1 Intermetatarsal Angles

The angle between the longitudinal axes of the metatarsals

- 1st – 2nd Intermetatarsal angle (Axial)
- 1st – 2nd Intermetatarsal angle (Sagittal)
- 1st – 5th Intermetatarsal angle (Axial)
- 1st – 5th Intermetatarsal angle (Sagittal)

- Decrease in angles → 1st MT shifts towards valgus
- Increase in angles → 1st MT shifts towards varus

4.1.2.4.2 Tarsometatarsal angles



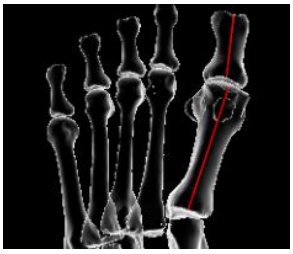
The angle between the longitudinal axes of the metatarsal and the cuneiform

- 1st tarsometatarsal angle (Sagittal)
- 2nd tarsometatarsal angle (Sagittal)
- 3rd tarsometatarsal angle (Sagittal)
- 1st tarsometatarsal angle (Axial)
- 2nd tarsometatarsal angle (Axial)
- 3rd tarsometatarsal angle (Axial)

- Decrease in angles → 1st MT shifts towards valgus
- Increase in angles → 1st MT shifts towards varus

Copyright © Disior Ltd. All rights reserved.

4.1.2.4.3 Hallux Valgus



Hallux Valgus Angle (Axial)

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

- Increase in angle → 1st PP shifts towards valgus
- Decrease in angle → 1st PP shifts towards varus

Interphalangeal Angle (Axial)

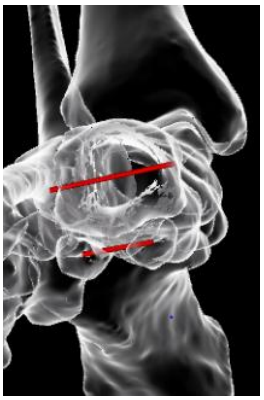
The angle between the 1st proximal phalanx longitudinal axis and the 1st distal phalanx (DP) longitudinal axis measured in the axial view

- Increase in angle → 1st DP shifts towards valgus
- Decrease in angle → 1st DP shifts towards varus

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

- Increase in distance → Sesamoids shift laterally
- Decrease in distance → Sesamoids shift medially



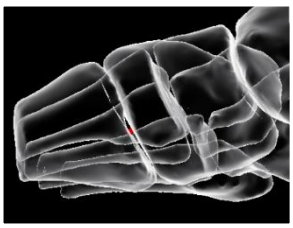
Sesamoid Complex – 1st Metatarsal Rotation

The angle between the 1st metatarsal distal mediolateral axis and the axis connecting the center points of the sesamoids measured in direction perpendicular to the 1st metatarsal longitudinal axis

- Increase in angle → 1st MT shifts towards pronation
- Decrease in angle → 1st MT shifts towards supination

Copyright © Disior Ltd. All rights reserved.

4.1.2.4.4 Joint Gaps



Tarsometatarsal I Joint Minimum Gap

Minimum normal distance measured from the medial cuneiform to 1st metatarsal on the articular surface region

Copyright © Disior Ltd. All rights reserved.

5 Regulations & Labelling

5.1 Standards

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

Standard:	
EN ISO 13485:2016/A11:2021	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 14971:2019/A11:2021	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/A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices provides safety to the patient, users and others
EN ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

5.2 CE marking

Bonelogic software is a Class IIa medical device in the European Union complying the applicable requirements of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

CE 0598

5.3 Economic Operators

5.3.1 Manufacturer

For feedback related to the Bonelogic product, please contact:

Manufacturer: Disior Oy (Ltd.)
HTC Helsinki, Building Pinta, 4th floor
Tammasaarenkatu 3
00180 Helsinki, FINLAND
Telephone: +358 50 483 6433
www.disior.com
disior.support@paragon28.com

5.3.2 Switzerland Authorized Representative (CH-REP)

CH REP

MedEnvoy Switzerland
Gotthardstrasse 28, 6302 Zug, Switzerland

Copyright © Disior Ltd. All rights reserved.

5.4 UDI

The UDI of a Bonelogic product is comprised of the UDI-DI (model of a device, Bonelogic 2.2) and the UDI-PI (production identifier, i.e. software version).

UDI-DI: (01) 06429810209221

UDI-PI: (10) 2.2.z

5.5 GMDN

5.5.1 Code and name

50484 CAD/CAM software

5.5.2 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).

5.6 Symbols used

Symbol	Regulation/Standard	Symbol meaning
	EN ISO 20417:2021 ISO 1070-W001	General warning safety sign. Placed together with a supplementary symbol or text.
	EN ISO 15223-1:2021 5.4.4	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	EN ISO 20417:2021 ISO 1070-P001	General prohibition safety sign. Placed together with a supplementary symbol or text.
	EN ISO 20417:2021 ISO 1070-M001	Mandatory action safety sign. Placed together with a supplementary symbol or text.
	EN ISO 20417:2021 ISO 1070-M002	Mandatory action safety sign or a text string to the effect that it is a mandatory action to read the instructions for use.
	EN ISO 15223-1:2021 5.4.3	Indicates the need for the user to consult the instructions for use or the electronic instructions for use. eIFU Indicator may contain the URL of the Instructions For Use (IFU).
	N/A	Information symbol in software to indicate further information on a situation.

Copyright © Disior Ltd. All rights reserved.

MD	EN ISO 15223-1:2016 Medical device	Indicates the product is a medical device
CE 0598	Regulation (EU) 2017/745	CE marking indicates that a product complies with applicable European Union Regulation. Notified body designator 0598.
	EN ISO 15223-1:2021 5.1.1	Indicates the medical device manufacturer .
℞ Only	21 CFR 801.109	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
CH REP	MedDo, 1 July 2020, Art. 4h	Natural or legal person domiciled in Switzerland with mandate for obligations under the Ordinance

Copyright © Disior Ltd. All rights reserved.

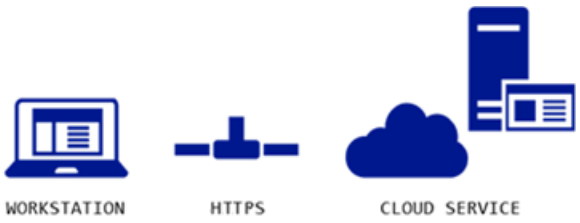
6 Data management & software architecture

Illustration of the Bonelogic® software architecture and listed functionalities is below. 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. No patient information or other DICOM information is stored on the local workstation.
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. DICOM data and user defined parameters are sent to cloud service using HTTPS connection.
    b. HTTPS connection is secured with a TLS certificate.
4. Computations, cloud service
    a. DICOM data is de-identified.
    b. Cloud solver calculates analysis models and measurements.
    c. Results are saved as numeric data.
    d. Result models are created in STL format.
    e. EU: Original DICOM data is deleted, USA: Original DICOM data is deleted, de-identified data is retained
    f. Measurement results can be used for diagnostic purposes.
5. Result presentation, local workstation
    a. Numeric results and STL files are downloaded via HTTPS connection.
    b. Results are shown on the graphics screen for examination.



6.2 Cloud domain address

The HTTPS address to the Disior™ cloud is https://prod-southcentralus-p28-apim.azure-api.net.

Copyright © Disior Ltd. All rights reserved.

6.3 Microsoft Azure connection specification

The client is connecting to the Microsoft Azure AD service for username and license verification when the client software is started. The connection is created over the internet utilizing HTTPS (Hyper Text Transfer Protocol Secure) protocol through TCP port 443.

The username and password are client specific. The amount of subsequent connection attempts is restricted against “brute force attacks”, also known as Denial of Service (DoS) attacks.

Data transfer is done using HTTPS protocol secured by TLS certificate (TLS 1.2). Short network disconnections during upload/analysis/download are tolerated by the system, and the process continues after the connection is re-established.

6.4 Disior Cloud environment

The analysis server specification:

- The server used for the analysis calculation is physically located in USA (for USA customers) and EU (for European customers)
- The client side needs to have whitelisted the domain for Disior Cloud
- A separate instance is formed for each analysis calculation.
- The server is protected by Azure network elements and layered network structure
- The Cloud instance is running on Linux Operating System

6.5 Linking of computed analysis result to the original image

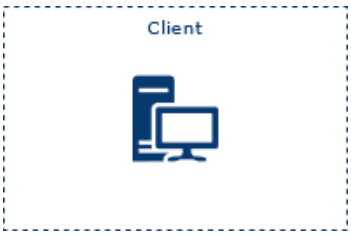
When DICOM data is opened in the client program, a timestamp and the file structure is created. This information is used to link the analysis result back to the image file after analysis results is sent back to the client program.

Copyright © Disior Ltd. All rights reserved.

6.6 Data processing

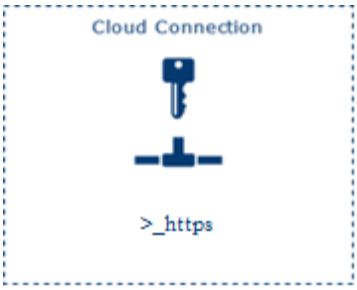
6.6.1 Elements

Element 1: DISIOR™ in hospital internal network



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

Element 2: DISIOR™ Cloud connection



1. Disior cloud at https://prod-polandcentral-p28-apim.azure-api.net (Microsoft Azure based, HTTPS/TLS certificate, domain needs to be whitelisted by Hospital IT)
2. Workstation is connected and user identified with user specific name and password. Connection log file is stored.
3. DoS prevention at server network

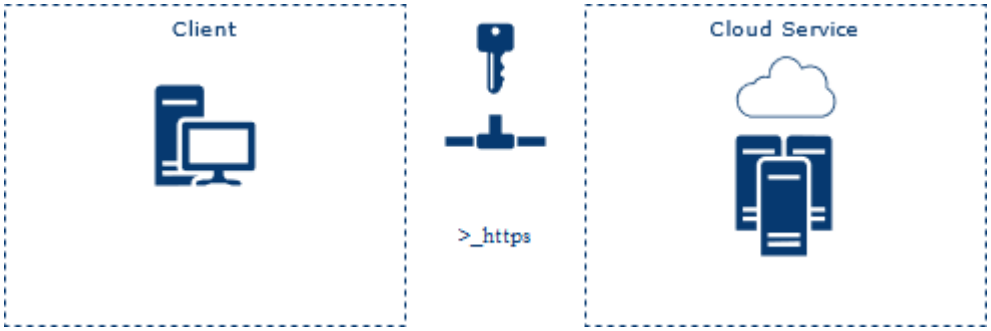
Element 3: DISIOR™ Cloud

1. The Cloud service is physically located in USA (for USA customers) and EU (for European customers)
2. Separate instance is formed for each analysis
3. No patient identifiable information data is stored
4. Log files are stored and image data is stored in USA
5. Server is protected by Microsoft Azure API Management
6. Cloud instances are updated regularly

Copyright © Disior Ltd. All rights reserved.

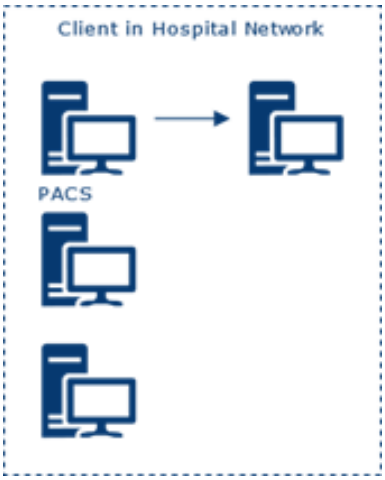
6.6.2 Data flow description

Step 1: License check for the Disior™ software



1. Client initiates license check from Disior Cloud
2. License check from database
3. After verification, user with valid license is authenticated

Step 2: Image study send from PACS



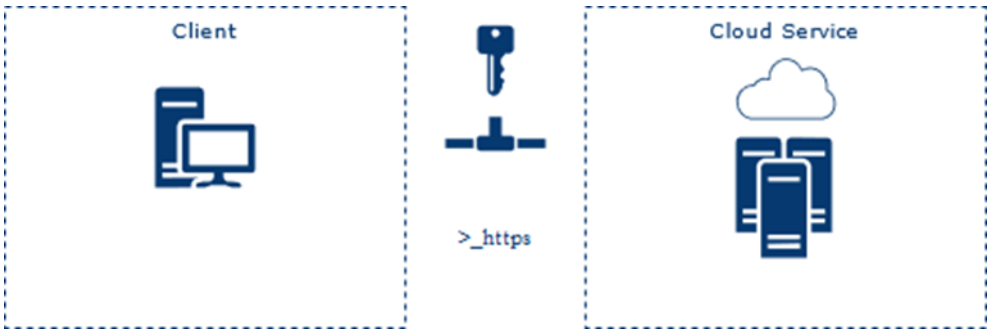
1. Study is sent from PACS with AE title and IP
2. Study is stored temporarily as .DCM file(s) in AppData folder

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), the user is prompted for patient evaluation information
4. After user input, the patient evaluation information and the image series is sent to the Cloud for analysis

Copyright © Disior Ltd. All rights reserved.

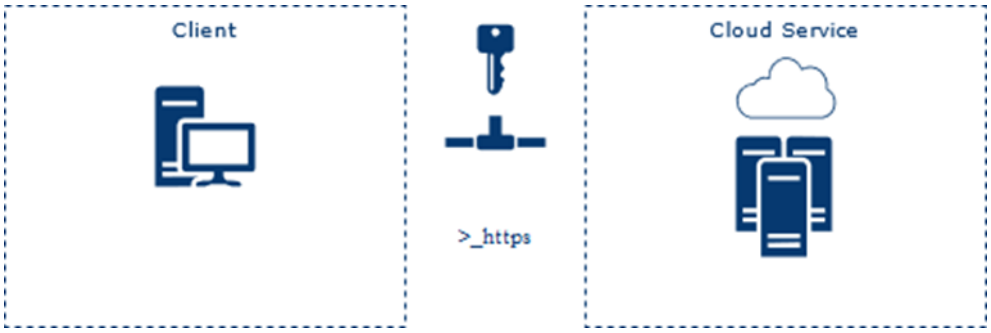
Step 4: Analysis in DISIOR™ cloud



1. Client initiates the file transfer through secure HTTPS connection
4. Client monitors cloud analysis in software: the secure HTTPS connection is open until solver is ready
6. Client receives the results files and the secure HTTPS connection is closed

2. Server receives the image series, which is then de-identified
3. The image series is analyzed
5. After the solver is ready and analysis is successful, results file is sent to client through the secure HTTPS connection
7. Forced deletion of original image series files. De-identified image series is retained (USA only)

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. Forced deletion of the instance.

Copyright © Disior Ltd. All rights reserved.

7 Addendum – Multilingual safety information

7.1 English

The information consists of safety related warnings and precautions information included in the Instructions for Use and appearing in the software user interface (UI).

Errors

1. **ERROR:** ANALYSIS FAILED. PLEASE CONTACT DISIOR SUPPORT.
2. **ERROR:** LOGIN FAILED
3. **ERROR:** DICOM DATA UNSUITABLE FOR ANALYSIS. PLEASE CHECK THE DICOM DATA OR CONTACT DISIOR SUPPORT
4. **ERROR:** FOLDER NOT FOUND. PLEASE CHECK THE SELECTED PATH.
5. **ERROR:** UNABLE TO OPEN THE DICOM IMAGE. PLEASE SELECT ANOTHER SERIES OR CONTACT DISIOR SUPPORT
6. **ERROR:** INPUT VOLUME IMAGE DOES NOT MEET ANALYZER REQUIREMENTS, PLEASE CHECK IMAGE DIMENSIONS!
7. **ERROR:** COULD NOT LOAD ANALYZER INPUT DATA. TRY TO START THE ANALYZER AGAIN. IF THE PROBLEM PERSISTS, CONTACT DISIOR SUPPORT.
8. **ERROR:** SAVING OSTEOTOMY REPORT FAILED. PLEASE MAKE SURE THE REPORT IS NOT OPEN IN ANOTHER PROGRAM AND TRY AGAIN
9. **ERROR:** INVALID LOCATION FOR SAVING. PLEASE CHOOSE ANOTHER LOCATION
10. **ERROR:** SAVING THE CASE FAILED. PLEASE TRY AGAIN
11. **ERROR:** SAVING THE STL MODELS FAILED PLEASE CONTACT DISIOR SUPPORT

Warnings

1. **WARNING:** INPUT IMAGE SPACING BETWEEN SLICES DOES NOT MEET ANALYZER REQUIREMENTS. PLEASE USE AN IMAGE WITH DISTANCE BETWEEN SLICES LESS THAN 0.75 MM OR USE ANALYSIS RESULTS WITH CAUTION.
2. **WARNING:** INPUT IMAGE PIXEL SPACING DOES NOT MEET ANALYZER REQUIREMENTS. PLEASE USE AN IMAGE WITH PIXEL SPACING LESS THAN 0.75 MM OR USE ANALYSIS RESULTS WITH CAUTION.
3. **WARNING:** DICOM IMAGE QUALITY IS NOT ADEQUATE FOR ANALYSIS, THE RESULTS MAY BE INACCURATE
4. **WARNING:** PORTION OF “BONE NAME” VISIBLE IN THE IMAGE IS NOT SUFFICIENT FOR MEASUREMENT.
5. **WARNING:** MEASUREMENTS OF “BONE NAME” POINTS MAY BE INACCURATE.
6. **WARNING:** CONTACT DETECTED IN “BONE NAME”.
7. **WARNING:** ANALYZER DETECTED ABNORMAL BONE POSITIONING OR ANATOMY. PLEASE CHECK THE LATERALITY AND RERUN THE ANALYZER, OR USE ANALYSIS RESULTS WITH CAUTION.
8. **WARNING:** ANALYZER DETECTED ABNORMAL BONE POSITIONING OR ANATOMY. PLEASE CHECK THAT BONES ARE MARKED CORRECTLY AND RERUN THE ANALYZER, OR USE ANALYSIS RESULTS WITH CAUTION.

Copyright © Disior Ltd. All rights reserved.

Cautions

1. **Caution:** A user training is required for safe use of the software. Mandatory user action to read the instructions for use
2. **Caution:** 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/fragmented bones in the image, fusion structures, or other image related defects or inaccuracies, the results can be inaccurate.
3. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.
4. **Caution:** The analysis results provided in the software shall be subject to careful expert assessment. Due to various measurement protocols, differences in weightbearing and non-weightbearing images, 2D and 3D measurements as well as automatic and manual measurements may produce different measurement results.
5. **Caution:** Before the analysis is started you must select the correct laterality
6. **Caution:** Before the analysis is started you must select the correct laterality and check 'SEGMENT METAL' option if image contains metal.
7. **Caution:** The manual segmentation modifications are not affecting the measurements.
8. **Caution:** 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.

Prohibitions

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

Reporting serious incidents

Any serious incident related to the use of this device should be reported to both the manufacturer and the health authority/competent authority where the device is installed.

Please provide the following information:

- Date of the incident
- Description of the incident, including any patient or user impact/injury
- The device version used
- Contact information (facility, address, contact person name, title, and telephone number)

Copyright © Disior Ltd. All rights reserved.

7.2 French

Les informations consistent en des avertissements liés à la sécurité et les informations de précautions incluses dans les instructions d'utilisation et qui apparaissent dans l'interface utilisateur du logiciel (UI).

Erreurs (Errors)

1. **ERREUR:** ÉCHEC DE L'ANALYSE. VEUILLEZ CONTACTER LE SUPPORT DISIOR.
2. **ERREUR:** ÉCHEC DE LA CONNEXION
3. ERREUR: DONNÉES DICOM INADAPTÉES À L'ANALYSE. VEUILLEZ VÉRIFIER LES DONNÉES DICOM OU CONTACTER LE SUPPORT DISIOR
4. ERREUR: DOSSIER INTROUVABLE. VEUILLEZ VÉRIFIER LE CHEMIN SELECTIONNÉ.
5. ERREUR: IMPOSSIBLE D'OUVRIR L'IMAGE DICOM. VEUILLEZ SELECTIONNER UNE AUTRE SÉRIE OU CONTACTER LE SUPPORT DISIOR
6. ERREUR: LE VOLUME DE L'IMAGE FOURNIE NE RÉPOND PAS AUX ÉXIGENCES DE L'ANALYSEUR, VEUILLEZ VÉRIFIER LES DIMENSIONS DE L'IMAGE !
7. ERREUR: IMPOSSIBLE DE CHARGER LES DONNÉES D'ENTRÉE DE L'ANALYSEUR. ESSAYEZ DE RELANCER L'ANALYSEUR. SI LE PROBLÈME PERSISTE, CONTACTEZ LE SUPPORT DISIOR.
8. ERREUR: LA SAUVEGARDE DU RAPPORT DE L'OSTÉOTOMIE A ÉCHOUÉ. VEUILLEZ-VOUS ASSURER QUE LE RAPPORT N'EST PAS OUVERT DANS UN AUTRE PROGRAMME ET RÉESSAYER.
9. ERREUR: EMPLACEMENT NON VALIDE POUR LA SAUVEGARDE. VEUILLEZ CHOISIR UN AUTRE EMPLACEMENT
10. ERREUR: L'ENREGISTREMENT DU CAS A ÉCHOUÉ. VEUILLEZ RÉESSAYER
11. ERREUR: L'ENREGISTREMENT DES MODÈLES STL A ÉCHOUÉ, VEUILLEZ CONTACTER LE SUPPORT DISIOR

Avertissements (Warnings)

1. **AVERTISSEMENT:** L'ESPACEMENT ENTRE LES COUPES DE L'IMAGE FOURNIE NE RÉPOND PAS AUX EXIGENCES DE L'ANALYSEUR. VEUILLEZ UTILISER UNE IMAGE AVEC UNE DISTANCE ENTRE LES COUPES DE MOINS DE 0,75 MM OU UTILISER LES RÉSULTATS DE L'ANALYSE AVEC PRUDENCE.
2. **AVERTISSEMENT:** L'ESPACEMENT DES PIXELS DE L'IMAGE UTILISÉE NE RÉPOND PAS AUX EXIGENCES DE L'ANALYSEUR. VEUILLEZ UTILISER UNE IMAGE AVEC UN ESPACEMENT DE PIXELS INFÉRIEUR À 0,75 MM OU UTILISER LES RÉSULTATS DE L'ANALYSE AVEC PRUDENCE.
3. **AVERTISSEMENT:** LA QUALITÉ DE L'IMAGE DICOM N'EST PAS ADÉQUATE POUR L'ANALYSE, LES RÉSULTATS PEUVENT ÊTRE INEXACTS.
4. **AVERTISSEMENT:** LA PARTIE DU "NOM DE L'OS" VISIBLE DANS L'IMAGE N'EST PAS SUFFISANTE POUR LA MESURE.
5. **AVERTISSEMENT:** LES MESURES DES POINTS DU « NOM DE L'OS » PEUVENT ÊTRE INEXACTES.
6. **AVERTISSEMENT:** CONTACT DÉTECTÉ DANS "NOM DE L'OS".
7. **AVERTISSEMENT:** L'ANALYSEUR A DÉTECTÉ UN POSITIONNEMENT OU UNE ANATOMIE OSSEUSE ANORMAL(E). VEUILLEZ VÉRIFIER LA LATÉRALITÉ ET RELANCER L'ANALYSE, OU, UTILISER LES RÉSULTATS DE L'ANALYSE AVEC PRÉCAUTIONS.

Copyright © Disior Ltd. All rights reserved.

8. **AVERTISSEMENT:** L'ANALYSEUR A DÉTECTÉ UN POSITIONNEMENT OU UNE ANATOMIE OSSEUSE ANORMAL(E). VEUILLEZ VÉRIFIER QUE LES OS ONT ÉTÉ CORRECTEMENT MARQUÉS ET RELANCER L'ANALYSE, OU, UTILISER LES RÉSULTATS DE L'ANALYSE AVEC PRÉCAUTIONS.

Précautions (Cautions)

1. Attention: Une formation des utilisateurs est nécessaire pour une utilisation en toute sécurité du logiciel. Il est nécessaire pour l'utilisateur de lire les instructions d'utilisation.
2. Attention: En cas de faible contraste d'image, d'os manquants sur l'image, de trop petites portions d'os visibles sur l'image, d'artefacts (des structures métalliques sur l'image par exemple), d'os fracturés/fragmentés sur l'image, de structures de fusion ou d'autres défauts ou inexactitudes liés à l'image, les résultats peuvent être inexacts.
3. Attention: La loi fédérale (États-Unis) limite la vente de cet appareil par ou sur ordonnance d'un médecin.
4. Attention: les résultats d'analyse fournis dans le logiciel doivent faire l'objet d'une évaluation approfondie par des experts. En raison de divers protocoles de mesure, les différences entre les weight-bearing images (image en charge) et les non weight-bearing images (image sans charge), les mesures 2D et 3D ainsi que les mesures automatiques et manuelles peuvent produire des résultats de mesure différents.
5. Attention: Avant de démarrer l'analyse, vous devez sélectionner la bonne latéralité
6. Attention: Avant le début de l'analyse, vous devez sélectionner la latéralité correcte et cocher l'option "SEGMENT METAL" si l'image contient du métal.
7. Attention: Les modifications de segmentation manuelle n'affectent pas les mesures.
8. Attention: les résultats fournis dans l'outil de planification doivent faire l'objet d'une évaluation approfondie par des experts. L'utilisateur doit considérer le terme POUR LA SIMULATION ET LA VISUALISATION UNIQUEMENT. Les résultats préopératoires ne représentent pas les résultats postopératoires définitifs.

Interdictions (Prohibitions)

1. Le logiciel Bonelogic ne prend pas en charge l'utilisation d'image par résonance magnétique (IRM).

Signalement des incidents graves (Reporting serious incidents)

Tout incident grave lié à l'utilisation de ce produit doit être signalé au fabricant et à l'autorité sanitaire/autorité compétente où le produit est installé.

Prière de fournir les informations suivantes :

- Date de l'incident
- Description de l'incident, y compris tout impact/blessure sur le patient ou l'utilisateur
- La version du produit utilisée
- Vos coordonnées (établissement, adresse, nom du contact, fonction et numéro de téléphone)

Copyright © Disior Ltd. All rights reserved.

7.3 Finnish

Tässä osiossa pitää sisällään turvallisuuteen liittyvät varoitukset ja huomiot mitä esiintyy käyttöohjeissa ja laitteen käyttöliittymässä.

Virhe (Error)

1. **Virhe:** Analyysi epäonnistui. Ota yhteyttä Disiorin tukeen.
2. **Virhe:** DICOM DATA ei ole soveltuva analyysia varten. Tarkista DICOM data tai ota yhteyttä Disiorin tukeen.
3. **Virhe:** Sisäänkirjautuminen epäonnistui.
4. **Virhe:** Kansiota ei löytynyt. Tarkista valittu hakemisto.
5. **Virhe:** DICOM kuvan avaaminen epäonnistui. Valitse toinen kuvasarja tai ota yhteyttä Disiorin tukeen.
6. **Virhe:** Syötetty DICOM kuva ei vastaa analyysin vaatimuksia, tarkista kuvan mitat.
7. **Virhe:** Analyysiin syötetyn datan lataaminen epäonnistui. Yritä käynnistää analyysi uudestaan. Jos ongelma jatkuu, ota yhteyttä Disiorin tukeen.
8. **Virhe:** Osteotomia raportin tallentaminen epäonnistui. Varmista ettei raportti ole auki toisessa ohjelmassa ja yritä uudestaan.
9. **Virhe:** Virheellinen sijainti tallennukselle. Yritä valita toinen sijainti.
10. **Virhe:** CASE tallennus epäonnistui. Yritä uudestaan.
11. **Virhe:** STL mallin tallentaminen epäonnistui. Ota yhteyttä Disiorin tukeen.

Varoitukset (Warnings)

1. **Varoitus:** Syötetyn kuvan leikkeiden välinen etäisyys ei vastaa analyysin vaatimuksia. Käytä kuvaa, jossa leikkeiden väli on vähemmän kuin 0.75mm tai käytä tuloksia harkiten.
2. **Varoitus:** Syötetyn kuvan pikselien välinen etäisyys ei vastaa analyysin vaatimuksia. Käytä kuvasarjaa, jossa pikselien väli on vähemmän kuin 0,75mm tai käytä tuloksia harkiten.
3. **Varoitus:** DICOM kuvan laatu ei ole riittävä analyysiä varten, tulokset saattavat olla epätarkkoja.
4. **Varoitus:** Kuvassa näkyvä osuus “luun nimi” ei ole riittävä mittausta varten.
5. **Varoitus:** “Luun nimi” mittaukset saattavat olla epätarkkoja.
6. **Varoitus:** Kontakti havaittu “luun nimi”
7. **Varoitus:** Analyysi havaitsi epänormaalin luun asennon tai anatomian. Tarkista valittu lateraalisuus ja käynnistä analyysi uudestaan, tai käytä tuloksia harkiten.
8. **Varoitus:** Analyysi havaitsi epänormaalin luun asennon tai anatomian. Tarkista että luut ovat merkitty oikein ja käynnistä analyysi uudestaan, tai käytä tuloksia harkiten.

Huomiot (Cautions)

1. **Huomio:** Käyttökoulutus on vaadittu tuotteen turvalliselle käytölle. Käyttäjän on noudatettava käyttöohjetta.
2. **Huomio:** Mikäli kuvassa on huono kontrasti, puuttuvia luita, näkyvissä liian pieniä alueita luista, artefaktoja (esim. metallisista rakenteista), murtuneita/fragmentoituneita luita, fuusioita, tai muita kuvaan liittyviä vääristymiä tai epätarkkuuksia, tulokset voivat olla epätarkkoja.

Copyright © Disior Ltd. All rights reserved.

3. **Huomio:** (Vain USA) Liittovaltion laki rajoittaa tämän laitteen myynnin vain lääkärin määräämällä reseptillä.
4. **Huomio:** Ohjelmiston tuottamat analyysitulokset on tarkistettava huolella asiantuntijan toimesta. Eroavaisuudet mittausprotokollien, kuvilla painonvarauksella ja ilman, 2D- ja 3D-mittausten, sekä automaattisten ja käsin mitattujen tulosten välillä voivat tuottaa eroja mittaustuloksiin.
5. **Huomio:** Ennen analyysin aloitusta, sinun on valittava oikea lateraalisuus.
6. **Huomio:** Ennen analyysin aloitusta, sinun on valittava oikea lateraalisuus ja valittava 'SEGMENT METAL' mikäli kuvassa on metallia.
7. **Huomio:** Manuaaliset segmentoinnin muutokset eivät vaikuta mittaustuloksiin.
8. **Huomio:** Suunnittelutyökalun tuottamat tulokset on tarkistettava huolella asiantuntijan toimesta. Käyttäjän on huomioitava että tulokset ovat vain VISUALISOINTIA VARTEN. Preoperatiiviset tulokset eivät edusta lopullisia postoperatiivisia tuloksia.

Kiellot (Prohibitions)

1. Bonelogic ohjelmisto ei tue magneettiresonanssi (MR) kuvien käyttöä.

Vaaratilanteista ilmoittaminen (Reporting serious incidents)

Laitteen käyttöön liittyvistä vaaratilanteista on ilmoitettava valmistajalle ja terveydenhuollon valvovalle viranomaiselle siinä maassa, johon laite on asennettuna.

Oheiset tiedot on toimitettava:

- Päivämäärä jolloin vaaratilanne tapahtui
- Kuvaus vaaratilanteesta tai vahingosta joka aiheutunut potilaalle tai käyttäjälle
- Laitteen versio
- Yhteyshenkilön nimi (laitos, osoite, yhteyshenkilön nimi, nimike ja puhelinnumero)

Copyright © Disior Ltd. All rights reserved.

7.4 Swedish

Informationen består av säkerhetsrelaterade varningar och försiktighetsåtgärder inkluderade i användningsinstruktionerna samt som uppkommer i programvarans användarsgränssnitt.

Felmeddelanden

1. **FELMEDDELANDE:** MISSLYCKAD ANALYS. VÄNLIGEN KONTAKTA DISIOR SUPPORT.
2. **FELMEDDELANDE:** MISSLYCKAD INLOGGNING.
3. **FELMEDDELANDE:** DICOM DATAN ÄR OLÄMPLIG FÖR ANALYS. VÄNLIGEN KONTROLLERA DICOM DATAN ELLER KONTAKTA DISIOR SUPPORT.
4. **FELMEDDELANDE:** MAPPEN HITTADES INTE. VÄNLIGEN KONTROLLERA SÖKVÄGEN.
5. **FELMEDDELANDE:** KAN EJ ÖPPNA DICOM BILDEN. VÄNLIGEN VÄLJ EN ANNAN BILDSERIE ELLER KONTAKTA DISIOR SUPPORT.
6. **FELMEDDELANDE:** INMATADE DICOM BILDERNA UPPFYLLER INTE KRAVEN FÖR ANALYS. VÄNLIGEN KONTROLLERA BILD DIMENSIONERNA!
7. **FELMEDDELANDE:** UPPLADDNING AV INMATAD DATA I ANALYSEN MISSLYCKADES. FÖRSÖK STARTA OM ANALYSEN. IFALL PROBLEMET KVARSTÅR, KONTAKTA DISIOR SUPPORT.
8. **FELMEDDELANDE:** BESPARNING AV OSTEOTOMI RAPPORTEN MISSLYCKADES. VÄNLIGEN KONTROLLERA ATT RAPPORTEN INTE ÄR ÖPPNAD I ETT ANNAT PROGRAM OCH FÖRSÖK IGEN.
9. **FELMEDDELANDE:** OGILTIG PLATS FÖR BESPARNING. VÄNLIGEN VÄLJ EN ANNAN PLATS.
10. **FELMEDDELANDE:** BESPARNING AV CASE MISSLYCKADES. VÄNLIGEN FÖRSÖK IGEN.
11. **FELMEDDELANDE:** BESPARNING AV STL MODELLERNA MISSLYCKADES, VÄNLIGEN KONTAKTA DISIOR SUPPORT.

Varningar

1. **VARNING:** INMATADE BILDENS AVSTÅND MELLAN SNITTEN MÖTER INTE KRAVEN FÖR ANALYS. VÄNLIGEN ANVÄND EN BILD MED LÄGRE AVSTÅND ÄN 0.75MM MELLAN SNITTEN ELLER ANVÄND RESULTATEN MED FÖRSIKTIGHET.
2. **VARNING:** INMATADE BILDENS PIXELAVSTÅND MÖTER INTE KRAVEN FÖR ANALYS. VÄNLIGEN ANVÄND EN BILD MED LÄGRE AVSTÅND ÄN 0.75MM MELLAN SNITTEN ELLER ANVÄND RESULTATEN MED FÖRSIKTIGHET.
3. **VARNING:** DICOM BILDKVALITETEN ÄR INTE TILLÄMPLIG FÖR ANALYS. RESULTATEN KAN VARA FELAKTIGA.
4. **VARNING:** ANDELEN SYNLIG “BENETS NAMN” I BILDEN ÄR INTE TILLRÄCKLIG FÖR MÄTNING.
5. **VARNING:** MÄTPUNKTERNA FÖR “BENETS NAMN” KAN VARA FELAKTIGA.
6. **VARNING:** KONTAKT UPPTÄCKT I “BENETS NAMN”.
7. **VARNING:** ONORMAL BENPLACERING ELLER ANATOMI UPPTÄCKT I ANALYSEN. VÄNLIGEN KONTROLLERA LATERALITETEN OCH GÖR OM ANALYSEN ELLER ANVÄND RESULTATEN MED FÖRSIKTIGHET.
8. **VARNING:** ONORMAL BENPLACERING ELLER ANATOMI UPPTÄCKT I ANALYSEN. VÄNLIGEN KONTROLLERA ATT BENEN ÄR KORREKT MARKERADE OCH GÖR OM ANALYSEN ELLER ANVÄND RESULTATEN MED FÖRSIKTIGHET.

Copyright © Disior Ltd. All rights reserved.

Försiktigheter

1. **Försiktighet:** Användarutbildning krävs för säker användning av programvaran. Det är obligatorisk för användaren att läsa igenom användningsinstruktionerna.
2. **Försiktighet:** Vid följande fall kan resultaten vara felaktiga: dålig bildkontrast, ben saknas från bilden, andelen synligt ben i bilden är för låg, artefakter (t.ex. från metal strukturer i bilden), frakturerade/fragmenterade ben i bilden, fusions strukturer eller andra bildrelaterade brister/felaktigheter.
3. **Försiktighet:** USA:s offentliga lagstiftning begränsar denna programvara till försäljning av eller på order av en läkare.
4. **Försiktighet:** Analysresultaten försedda av programvaran bör tillämpas på basen av noggrann sakkunnig bedömning. På grund av diverse mätningsprotokoll, skillnader mellan viktbärande och icke viktbärande bilder, 2D och 3D mätningar samt automatisk och manuell mätning kan ge olika mätningsresultat.
5. **Försiktighet:** Rätt lateralitet bör väljas innan analysen påbörjas.
6. **Försiktighet:** Innan analysen påbörjas bör rätt lateralitet väljas samt markera valet 'SEGMENT METAL' ifall bilden innehåller metall.
7. **Försiktighet:** Ändringarna gjorda med manuell segmentering påverkar inte mätningarna.
8. **Försiktighet:** Resultaten försedda av planerings verktyget (planning tool) bör tillämpas på basen av noggrann sakkunnig bedömning. Användaren bör beakta informationen ENDAST FÖR SIMULERING OCH VISUALISERING. Preoperativa resultaten representerar inte slutliga postoperativa resultaten.

Förbud

1. Bonelogic programvaran stöder inte användning av magnetisk resonanstomografi (MRI) bilder.

Rapportering av allvarliga tillbud

Alla allvarliga tillbud relaterade till användning av denna produkt bör rapporteras till både tillverkaren samt hälsomyndigheterna/behörig myndighet i landet där produkten är installerad.

Vänligen ange följande information:

- Datum då tillbudet inträffade
- Beskrivning av tillbudet, inklusive eventuell påverkan/skada av patient eller användare
- Programvarans version
- Kontaktuppgifter (facilitet, address, kontaktperson, titel och telefonnummer)

Copyright © Disior Ltd. All rights reserved.