Disior Bonelogic® Software Installation and Configuration

Introduction

This is the installation and configuration guide for Bonelogic® software manufactured by Disior Oy.

Intended use

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

Indications for use

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

Installation and first use

In case of pre-installed software in the imaging device, follow the instructions of the imaging device provider.

To start using the software, you will need to:

1. Define the computer for installation, run Disior ID Generator program provided by Disior and send the generated ID by e-mail to Disior. In addition, inform Disior for the email address(es) of the user(s) and request user account activation.
2. Disior will send you the installation file and SSH key.
3. The installation link asks you to ‘Run’ or ‘Save’ the file. Choose ‘Save’ and follow the instructions.
4. Open the installation application. Select ‘OK’, ‘Run’ or ‘Next’ to all questions.
5. Open the Bonelogic® software. At the first start, the software will prompt to import SSH key (if not pre-installed).

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6. If the user account has temporary password provided by Disior, change the password as requested by the software.

System configuration

Bonelogic® software consists of the following two modules:

1. Local workstation: User interface with pre- and postprocessing functionalities.
2. Cloud environment: Analysis solution.

Local workstation operations

The user controls pre-processing including the imaging data management, postprocessing and visualization, in a local workstation. The specification for workstation is as follows:

- Standard Laptop or Desktop PC with Windows 10
- 16 GB RAM
- Dedicated Graphics Cards with 1 GB of memory
- Minimum 50 GB Hard Drive
- Internet connection to Disior Cloud (IP 192.89.29.230, port 3693)

Cloud environment operations

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

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

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.

Licensing

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

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Continuity and recovery

In case of possible software error situation, the software needs to be re-started. The software is not storing any databases or records, so no back up storage or similar is in use for any data. All data from the software is stored either locally to the workstation or to other data storage systems controlled by the customer. For the cloud computing system, Disior has a backup system ready to be taken into use if interruptions or errors occurs. Disior has built an automatic monitoring system for the cloud computing performance.

Uninstallation

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

Application verification and Log Files

The software installed to the local workstation is storing log files to monitor its' technical performance. The log files can be used to track error situations. The log files are stored as "Player.log" in the local application data (AppData) folder. Similarly, cloud computing related technical log files are stored in the cloud as "Solver_log.txt". Separate log file is generated for every instance.

Connection to cloud

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

Data management

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

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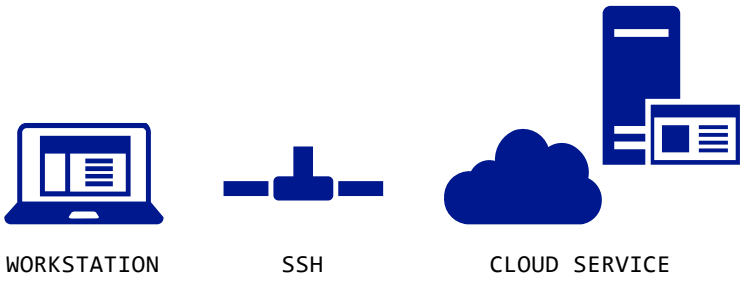
Software architecture

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

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



IP address

The IP address to the Disior cloud is 192.89.29.230. The server listens on port 3693.

Connecting the Bonelogic® software as DICOM sender/receiver

The Bonelogic® software can act as DICOM receiver to receive imaging data. Respectively, the Bonelogic® software can act as DICOM sender for sending data. The settings for DICOM sending/receiving functionality are defined in the software during installation. The needed information includes inbound and outbound connection specifications.

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Inbound connection: port for the workstation with Disior installation," run DICOM server on startup" ticked on.

Outbound connection: Outbound IP and port for the workstation/server with PACS service, remote AE title for PACS

SSH tunnel specification

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

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

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

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

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

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

Data transfer is done using SFTP protocol.

Analysis server (cloud computing server)

The analysis server specification:

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

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.

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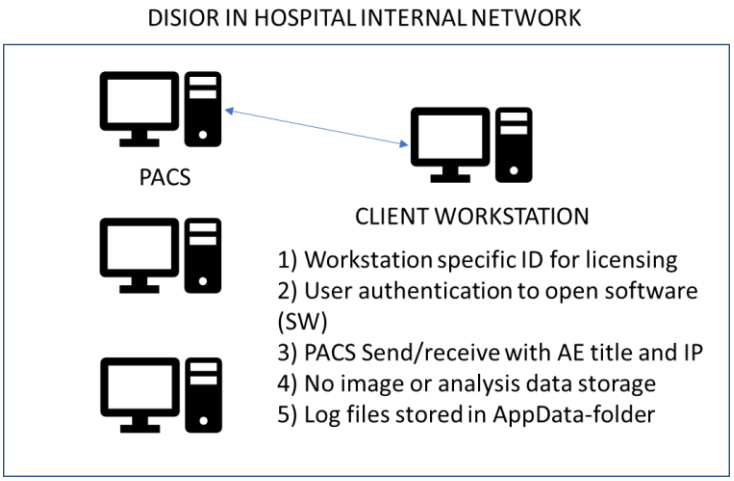
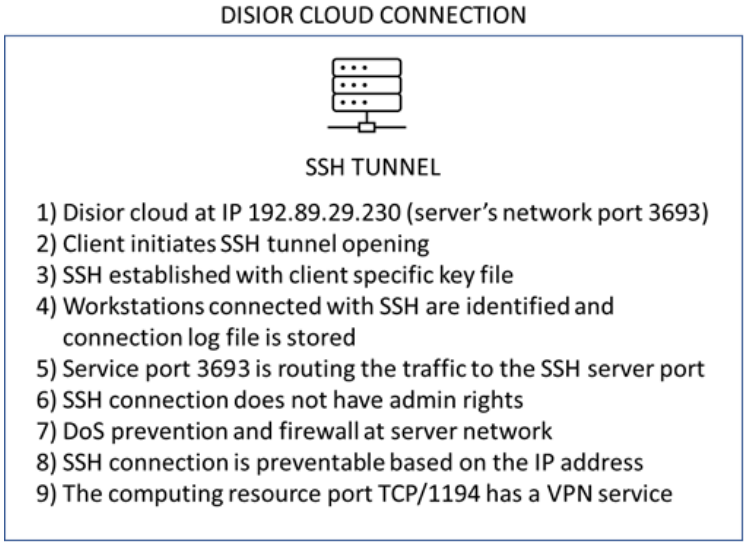
Data processing elements

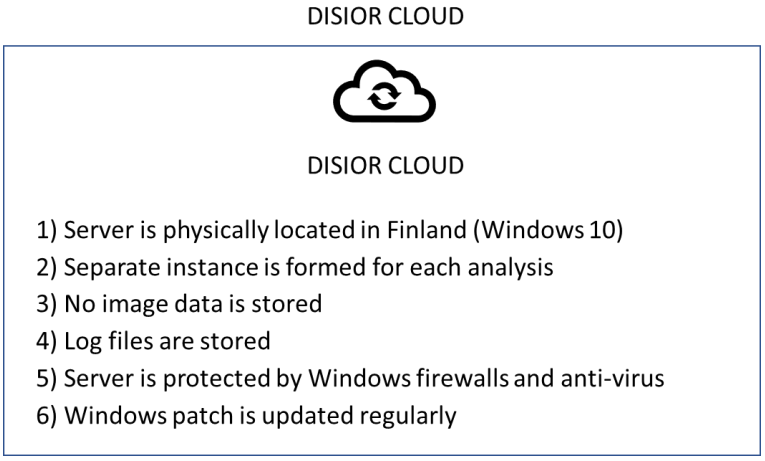
Element 1: DISIOR in hospital internal network



Element 2: DISIOR Cloud connection



Element 3: DISIOR Cloud



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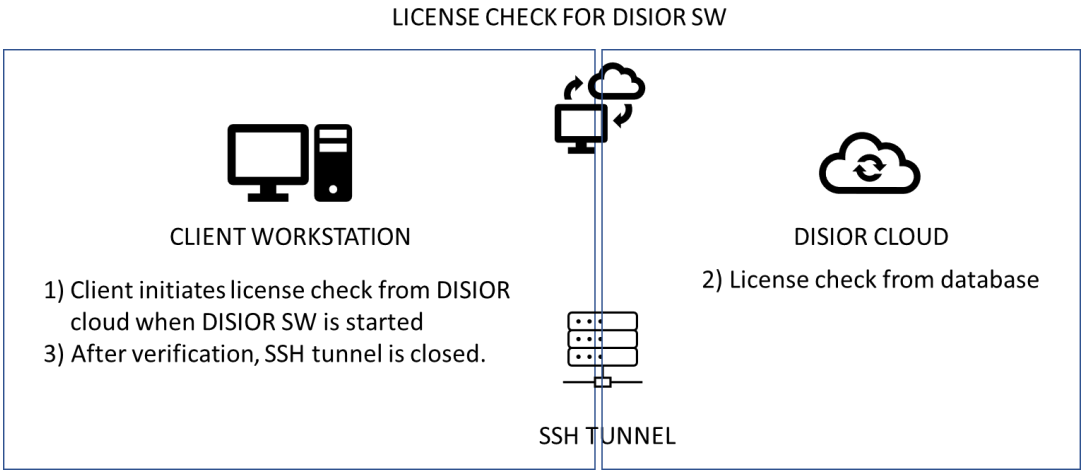
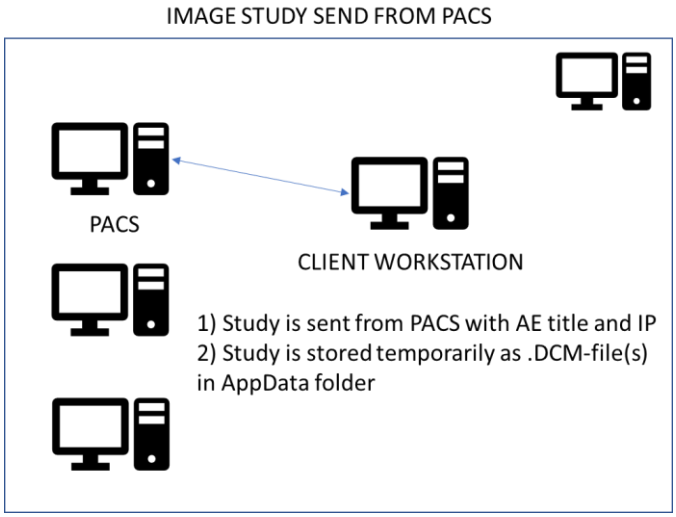
Data flow description

Step 1: License check



Step 2: Image study send from PACS



Step 3: DICOM Image handling in client workstation

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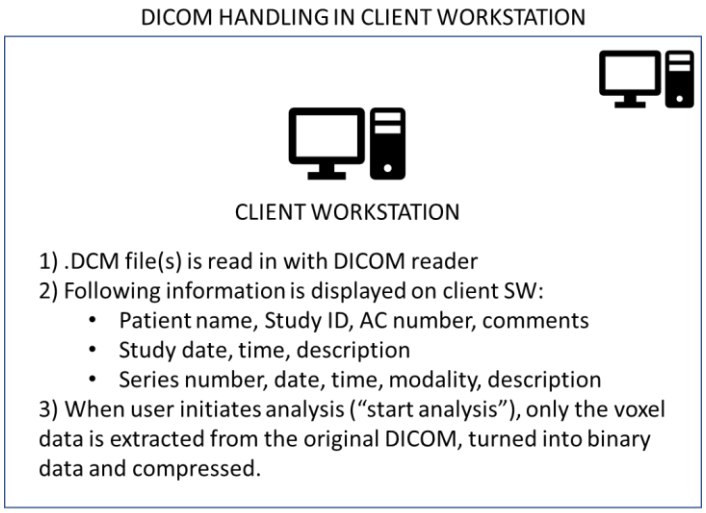
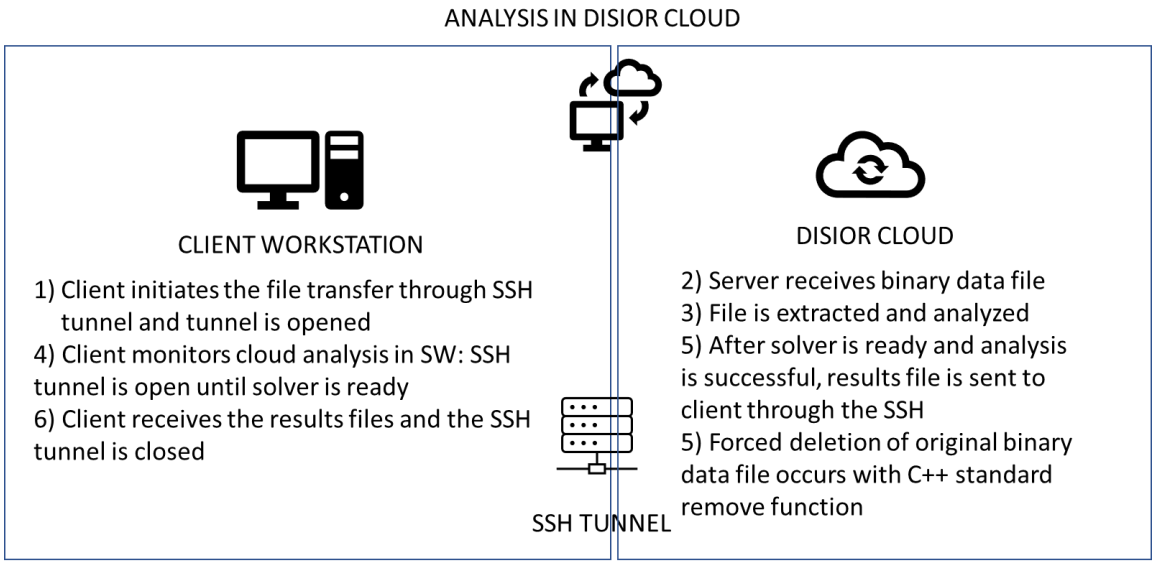


Step 4: Analysis in DISIOR cloud



Step 5: Save and exit

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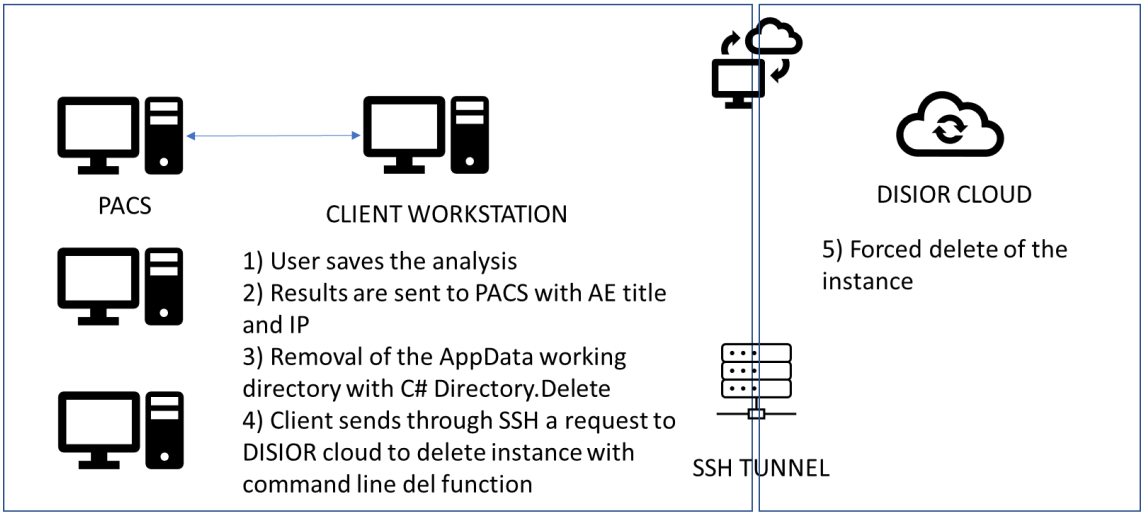
SAVE AND EXIT



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