Ligence Heart

For 3.42.1 version

INSTRUCTIONS FOR USE

English

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Symbols Glossary

Prescription-only device

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https://ligence.io/user-manuals/

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Specifications due to technical developments are subject to change. This IFU is not subject to the revision service. Please contact the manufacturer or authorized dealer to request the latest edition of the IFU.

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1. READ THIS FIRST

The Ligence Heart Instructions for Use (IFU) describes product's functionalities and is intended to guide and assist you with the safe and effective operation of the product. Before using the product, please read the IFU carefully and thoroughly observe all warnings and cautions.

This IFU describes the most extensive configuration of Ligence Heart with the maximum number of functions. Some functions described may be unavailable on your product's configuration.

Ligence Heart does not replace medical professionals and could be used only as an additional support tool. No special facilities (for medical specialists who are certified to perform echocardiographic examination) are required for the use of Ligence Heart. Access to training video is provided to operators (sonographers and cardiologists) prior to granting access to the software.

Please note that the quality of medical images, sharpness, accuracy, and other parameters relevant to the users, directly depend on the technical capabilities of the medical device, which is generating medical images, on the monitor and printer (if images are printed out) technical capabilities.

UAB Ligence provides this document without warranty of any kind, implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

UAB Ligence takes no liability for errors or omissions in this document and reserves the right to make changes without further notice to improve the Ligence Heart product. UAB Ligence may decide to make improvements or changes in the product described in this document at any time.

1.1 About the Instructions for Use (IFU)

Ligence Heart IFU in PDF format is available on the internet website: https://www.ligence.io/

You can open the file using a PDF reader application. If you do not have a PDF reader application installed, you can download Adobe Reader from the following website: www.adobe.com

Please contact UAB Ligence or its affiliates for technical support.

Ligence will assist the clients with installing and uninstalling Ligence Heart to ensure proper installation/integration of the device into the computing platform.Please contact Ligence if you have doubts about the installation.

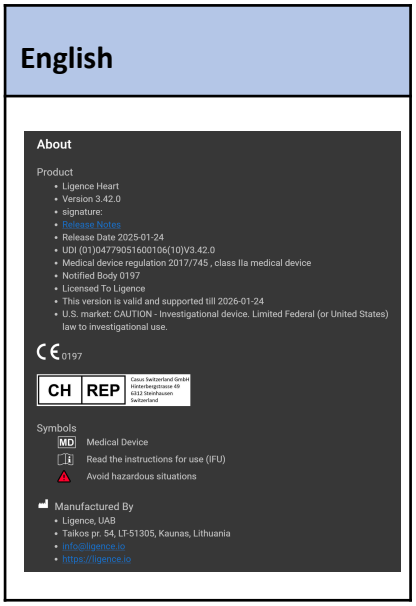
If you require a paper version of IFU please ask us by email: support@ligence.io. It will be sent out no later than 7 days after receiving the request (to the specified address).

1.2 Symbols

The following symbols may appear in the product documentation or on the labels attached to the product.

Symbol	Description
	**Warning**. Warnings highlight information to avoid a hazardous situation, which could cause death or serious injury.
	**Caution**. Cautions highlight information to avoid a hazardous situation, which could cause minor or moderate injury or equipment damage.
	**Note**. Notes bring your attention to information that will help you operate the product more effectively.
	**Manufacturer**. Indicates the name and address of the manufacturer.
	**Medical device**. Indicates that the product is a medical device.
	**Read the IFU**. Indicates the need for the user to consult the IFU
	Prescription only device

1.3 Label



NOTE: This eLabeling will be updated with K-number and Rx symbol after the FDA clearance

1.4 Intended use

Ligence Heart is a fully automated software platform that processes, analyses and makes measurements on acquired transthoracic cardiac ultrasound images, automatically producing a full report with measurements of several key cardiac structural and functional parameters. The data produced by this software is intended to be used to support qualified cardiologists or sonographers for clinical decision making. Ligence Heart is indicated for use in adult patients. Ligence Heart has not been validated for the assessment of congenital heart disease, valve disease, pericardial disease, and/or intra-cardiac lesions (e.g. tumours, thrombi).

Limitations:

- Poor image capture will lead to poor annotations and subsequent measurements.
- Multiple image quality algorithms are used to filter out images of poor quality.
- Our software complements good patient care and does not exempt the user from the responsibility to provide supervision, clinically review the patient, and make appropriate clinical decisions.
- If no gender is present, female referenced guideline values will be used for conclusions.
- If Body Surface Area (BSA) is not present, indexed values cannot be provided.
- During image acquisition, inappropriate use of the echo machine, use of non-cardiac ultrasound probes, or use of suboptimal settings (e.g. gain, contrast, depth) may lead to lower accuracy of the software.

- Ligence Heart has not been validated in patients with prosthetic or surgically altered cardiac valves, implantable intracardiac devices, or irregular (non-sinus) rhythm; these conditions may affect automated measurement accuracy.

1.5 General description

Ligence Heart is an image post-processing software used for viewing and quantifying adult cardiac ultrasound DICOM studies. The device is intended to aid diagnostic review and analysis of echocardiographic data and to generate structured measurement reports.

Ligence Heart automatically identifies standard transthoracic echo views with machine-learning–based view classification, cardiac cycle selection, and border detection, then generates reproducible quantitative left-ventricular volumetric and functional measurements. The results are inserted into a PACS-compatible report that the reviewing cardiologist or sonographer can accept, edit, supplement with additional manual measurements, or entirely replace with manual measurements. The software also organizes, displays, and compares each measurement with reference-guideline ranges. Completed reports export in PDF, streamlining routine echocardiography workflow while leaving final diagnostic responsibility with the clinician.

1.6 User groups

Ligence Heart is intended for two clinical user groups:

Cardiologists - can review studies, accept automated annotations and measurements, edit them, add further manual measurements, or fully replace them with manual entries, and then generate and sign reports.

Sonographers - can review studies, accept automated annotations and measurements, edit them, add further manual measurements, or fully replace them with manual entries, and then generate and sign reports.

User group	Viewing studies	Annotations & Measurements	Study Report generation	PDF Report generation & validation	User management	Environment
Cardiologists	Yes	Yes	Yes	Yes	No	Clinical & Research
Sonographers	Yes	Yes	Yes	No	No	Clinical & Research

Table 1. *User groups*

Users and their groups are set up by Ligence or by integration with user management software such as Microsoft Active Directory.

1.7 Contraindications and Limitations

Our current software aims to automate measurements of left ventricular function and are applicable regardless of normal or disease states. We specifically indicate that our current product will not be reporting measurements associated with complex adult congenital heart disease, valve disease, pericardial disease, and/or intra-cardiac lesions (e.g. tumours, thrombi).

Please note the following additional limitations:

- Poor image capture will lead to poor annotations and subsequent measurements.
- Multiple image quality algorithms are used to filter out images of poor quality.
- Our software complements good patient care and does not exempt the user from the responsibility to provide supervision, clinically review the patient, and make appropriate clinical decisions.
- If no gender is present, female referenced guideline values will be used for conclusions.
- If Body Surface Area (BSA) is not present, indexed values cannot be provided.
- During image acquisition, inappropriate use of the echo machine, use of non-cardiac ultrasound probes, or use of suboptimal settings (e.g. gain, contrast, depth) may lead to lower accuracy of the software.
- Ligence Heart has not been validated in patients with prosthetic or surgically altered cardiac valves, implantable intracardiac devices, or irregular (non-sinus) rhythm; these conditions may affect automated measurement accuracy.

1.8 General description of key functional elements

Functional elements scheme.

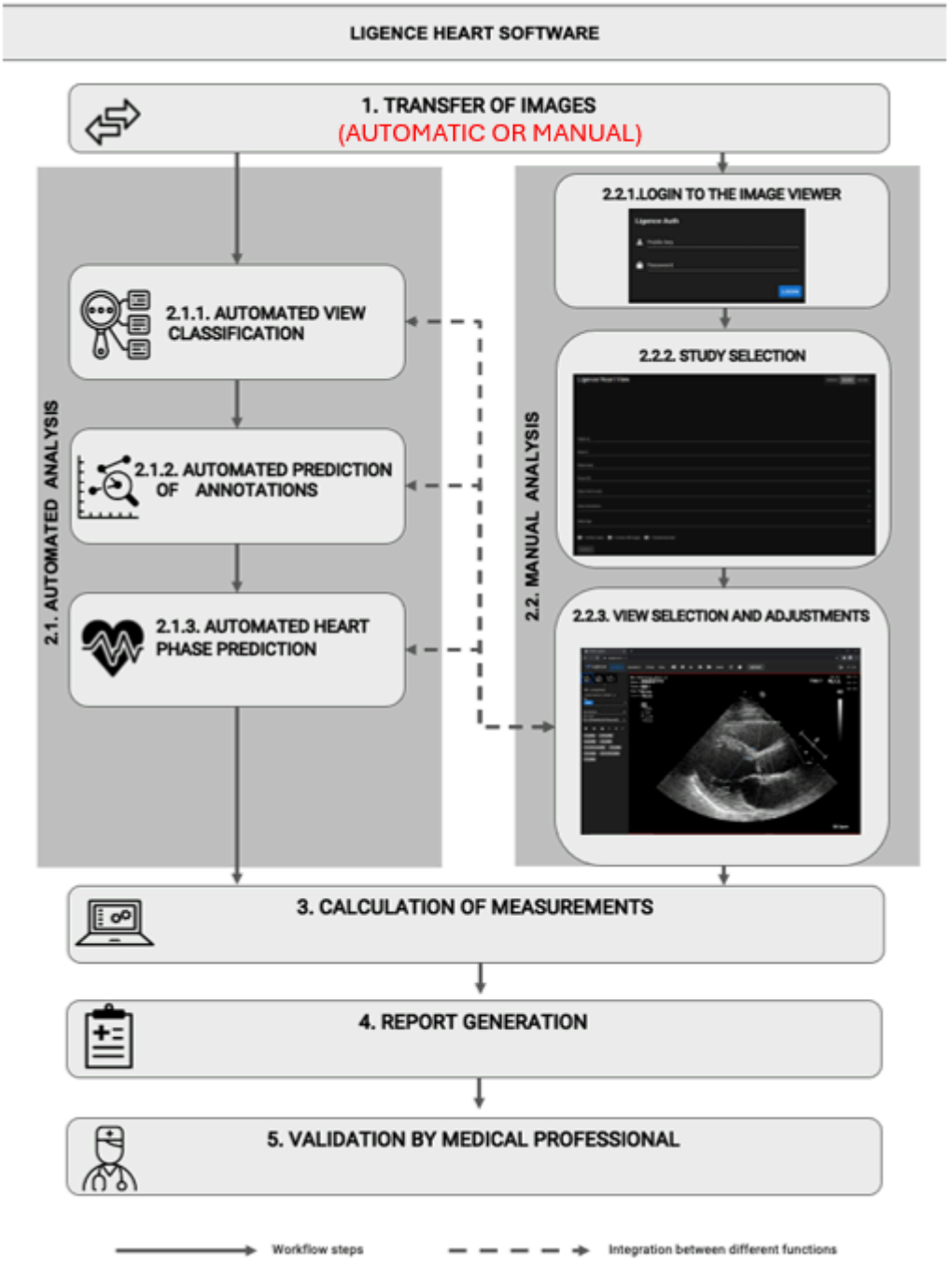


Figure 1. *Ligence Heart's workflow and integration between the different significant functions*

Key functional elements from Figure 1 are described in Table 2 below.

Key function	Description
1. Transfer of echocardiography images (automatic or manual)	Echocardiography images and the clinical data can be sent to Ligence Heart automatically from the Ultrasound Scanner (via PACS or any other medical image management system) or manually uploading the images from a workstation with access to Ligence Heart. Authentication/authorization to access Ligence Heart's functionalities, such as manually uploading data, is mandatory.
2. Echocardiography examination	Echocardiography examination is conducted using automated or manually-assisted analysis functions at the user's discretion. If automated analysis functions are enabled, the system automatically performs automated analysis when receiving the images and the clinical data (from the Ultrasound scanner or the workstation when manually uploading them).
2.1. Automated analysis	
2.1.1. Automated view classification	Ligence Heart determines the view mode of the echocardiography image. This step is needed for further analysis of images.
2.1.2. Automated prediction of annotations	Ligence Heart predicts annotations that are used to measure heart anatomy based on the view mode of the echocardiography image.
2.1.3. Automated heart phase prediction	Ligence Heart tracks the cardiac cycle and identifies the frames that are crucial for the analysis of echocardiography images, e.g., end-systolic and end-diastolic.
2.2. Manual analysis	
2.2.1. Authenticate	Ligence Heart requires user authentication/authorization to access functionalities. **NOTE:** The user might have previously accessed Ligence Heart to upload the input data and directly perform the manually-assisted analysis, or the user who conducts the echocardiography examination might be a different person from the user who transfers the images.
2.2.2. Study selection	Selection of the patient study corresponding to the patient to be analyzed for echocardiography examination by filtering/searching.
2.2.3. View selection and adjustments	Study analysis step - the user sets the view mode of the echocardiography image, identifies the heart cycle phase of interest, performs annotations, or accepts/adjusts/deletes annotations already made by automated analysis (when applicable).
3. Calculation of measurements	Calculation of measurements based on the annotations on echocardiography images performed by the combination of manual and automatic functions.
4. Report generation	Study analysis results report, which consists of all annotations, measurements made, along with an automated suggested

	report summary text, is generated for review and approval by the users.
5. *Validation by a medical professional*	The users validate all annotations and measurements in the results report and sign it. If needed, the user adjusts annotations to recalculate measurements and repeat the process to generate the results report.

Table 2. *Description of key functional elements of the Ligence Heart workflow from Figure 2.*

1.9 Clinical Benefits

Ligence Heart is designed to simplify routine echocardiographic analysis and reporting by automating the most repetitive tasks while keeping every contour and measurement available for users to review and adjust.

Conventional workflow (without Ligence Heart)

1. The sonographer acquires the ultrasound study and transfers the images or cine loops to the hospital PACS.
2. A reviewing clinician retrieves the study and manually
    a. identifies each view,
    b. selects frames of interest,
    c. manually traces borders and performs measurements,
    d. manually refers to standard ASE/ESC/EACVI reference ranges to determine if any of the potentially dozens of measurements performed fall within the normal range of values for that patient, and
    e. Based on measurement results, drafts a report.

Although familiar, this approach can be subjective, labour-intensive and time-consuming.

Optimised workflow with Ligence Heart

1. After acquisition, the study is sent to PACS as usual.
2. Ligence Heart automatically
    a. recognises views, cardiac cycle phase and cardiac structures,
    b. generates annotations and measurements for validated measurements,
    c. highlights values that fall outside ASE/ESC/EACVI reference ranges, and
    d. populates a draft structured report.
3. A reviewing clinician may then
    a. Review the images/videos, if desired.
    b. Manually adjust any of the automated segmentations and measurements, if desired.
    c. Finalise and approve the report.

Clinical validation demonstrated that Ligence Heart's automated measurements achieve accuracy that is non-inferior to those obtained by certified human readers, and that the software produces identical results when the same dataset is re-analysed.

1.10 Commencement and Termination of Use

The provision for use begins upon delivery and / or installation of the Software on your computer and/or workstation. The provision for use is for the period specified in the agreement with your institution, unless you are using a trial or demo version.

The termination of use comes to effect when the period specified on the agreement with your institution comes to an end or when the user violates terms of end-user license agreement or other terms specified in the agreement. Upon such an event, the user must cease all use of the software and delete the unique login credentials assigned to the user. The use of the software will then be automatically terminated, and the user does not have to take any other measures to safely terminate the use.

1.11 Customer Service

Ligence representatives are available to answer questions and to provide maintenance and service.

Contact details:

E-Mail: support@ligence.io

Support Hotline: +1 (919) 406-4488

You can also submit an issue or question using our website:
https://www.ligence.io/submit-issue

2. SAFETY

Please carefully read the information in this section before using Ligence Heart, it contains important information on operating safety and use of the product.

CAUTION

The user remains responsible for determining if the provided results are acceptable for the corresponding echo exam and for their use in supporting diagnostic decisions.

2.1 Residual Risks

There are no residual risks.

2.2 Serious Incidents Reporting

Any serious incident or that has occurred in relation to the device should be immediately reported to the manufacturer (via website: https://www.ligence.io/submit-issue or email support@ligence.io) and to the competent authority of the country in which the user and/or patient is established.

2.3 Inputs and Outputs

Ligence Heart uses defined inputs to perform automated image analysis and reporting. The outputs generated are described in the following sections.

2.3.1 Inputs

PACS or ultrasound scanners pass DICOM files to the backend using DICOM communication protocol. DICOM files - echocardiographic study data saved in DICOM files.
Users interact with the system using a web browser on a laptop/desktop PC by uploading DICOM files, inputting annotations, measurements, or text through the frontend (UI).

1. DICOM files - echocardiographic study data saved in DICOM files that is uploaded to the system using a web browser.
2. Measurement inputs - measurement values inputted into the system. For example, “53” for left-ventricular ejection fraction.
3. Annotation inputs - tracings used for echocardiographic parameter assessment. For example, the contour of the left ventricle.
4. Text inputs - patient and study information fields (for example, patient name, age), study section or whole study summary.

2.3.1.1 Data formats read

Data formats which can be read by this product include:

a) DICOM storage classes:

- 1.2.840.10008.5.1.4.1.1.6 - Ultrasound Image Storage (retired)
- 1.2.840.10008.5.1.4.1.1.6.1 - Ultrasound Image Storage
- 1.2.840.10008.5.1.4.1.1.7 - Secondary Capture Image Storage
- 1.2.840.10008.5.1.4.1.1.3 - Ultrasound Multiframe Image Storage (retired)
- 1.2.840.10008.5.1.4.1.1.3.1 - Ultrasound Multiframe Image Storage
- 1.2.840.10008.5.1.4.1.1.7.1 - Multiframe Single Bit Secondary Capture Image Storage
- 1.2.840.10008.5.1.4.1.1.7.2 - Multiframe Grayscale Byte Secondary Capture Image Storage
- 1.2.840.10008.5.1.4.1.1.7.3 - Multiframe Grayscale Word Secondary Capture Image Storage
- 1.2.840.10008.5.1.4.1.1.7.4 - Multiframe True Color Secondary Capture Image Storage

b) Ultrasound image stream in RGB together with meta data (not in a DICOM format).

JPEG-Baseline-1 data compression is used for storing images from this product.

2.3.1.2 Acquisition protocol and acceptance criteria

A comprehensive guide on standardized acquisition of 2D TTE image views can be found in the article by the American Society of Echocardiography "Guidelines for Performing a Comprehensive Transthoracic Echocardiographic Examination in Adults: Recommendations from the American Society of Echocardiography 2018" and can be accessed here: https://www.asecho.org/guideline/comprehensive-tte-in-adults/.

2.3.2. Outputs

The following outputs are made available to the user through the web interface:

- Study list - a list of echocardiographic studies to which the user has access to.
- Study report - view for editing the echocardiographic study report.
- PDF report - PDF of echocardiographic study report, which can be downloaded for a web browser. See section 3.5.2.1 for more details about the PDF report.
- DICOM videos - interactive video (or still images if DICOM contains a single frame) of a DICOM file.
- Measurements - echocardiographic parameter names, values, indication whether this is an averaged value, and indication if the value falls within normal ranges.
- Annotations - tracings used for echocardiographic parameter assessment. For example, the contour of the left ventricle.
- Text summaries - text summarizing an echocardiographic study or one of its sections.

If Ligence Heart is connected to a PACS, the following outputs are sent to the PACS for storage purposes:

- PDF report - DICOM-embedded PDF report of the echocardiographic study.

- DICOM files - DICOM files containing illustrations of echocardiographic measurements (for example, DICOM Secondary Capture file containing tracings of the left ventricle and B-mode image).

CAUTION

Before saving, editing, or reviewing the data of a patient, ensure that its contents correspond to the patient's name. This provides additional assurance that the stored data correspond to the correct patient.

2.4 Installation and Maintenance

2.4.1 Deployment and Installation

Ligence Heart is supplied as an on-premise solution that is installed inside the hospital's local (private) network. Workflows are fully configurable, the software can be interfaced and integrated with any combination of echo scanners and PACS.

The software may be hosted on:

- a customer-provided physical server;
- a customer-provided virtual machine (VM);
- a high-end laptop or workstation dedicated to Ligence Heart.

Ligence will assist the clients with installing and uninstalling Ligence Heart to ensure proper installation/integration of the device into the computing platform. Specifically, Ligence will conduct the installation (and uninstallation) and/or guide the clients on the installation (and uninstallation) steps.

2.4.2 On-premise workflow

Licenge Heart receives DICOM studies from one or more echocardiography scanners on the local network. It automatically generates measurements and report text, which can be seamlessly forwarded to the PACS. Patient data remains securely within the local network and is inaccessible outside of it unless explicitly permitted and data sharing is enabled by an administrator.

Multiple echo scanners and multiple clients (clinical users accessing via browser) can connect concurrently to a single instance.

Typical sequence

1. Scan acquisition – Echocardiography scans are performed as usual.
2. Image storage – Raw images are sent to the PACS as routine. PACS is configured to automatically forward relevant studies to the Ligence Heart server.
3. Automated analysis – Ligence Heart analyses the study and stores measurements and key images.

4. Results return – A DICOM-encapsulated PDF (or secondary-capture images) containing measurements and provisional report text is sent back to the PACS.
5. Review & approval – Clinicians open the Ligence Heart web application from any workstation in the network (often via a launch link embedded in the PACS). Measurements can be reviewed, edited and approved and the final report is then stored in the PACS.

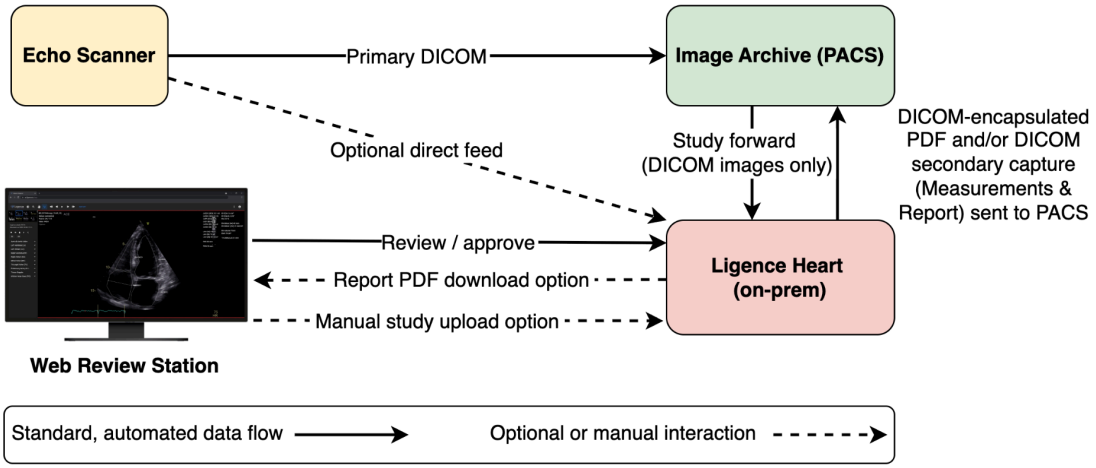


Figure ***2***. Clinical Data Flow Between Echo Scanner, PACS, Ligence Heart, and Workstation Users

2.4.2.1 . Server side requirements

CPU cores *	RAM	Storage	Network
16 (32 threads)	32	1000 GB	200 Mbit/s

Minimal software requirements

The software requires Docker container engine version 20.10.17+ (with Docker Compose version 2.6.0+) installed on a server to run Ligence Heart container. Python3 is required for a software setup.

Supported operating systems

The Ligence Heart software may run on any OS that supports and has a properly installed Docker container engine. Currently, it is tested on the following operating systems:

- Ubuntu 20.04
- Ubuntu 22.04
- CentOS 8.5
- Windows Server 2022 version 10.0.20348 (Build 20348) or higher

2.4.2.2. Client side requirements for on premises

Minimal desktop client hardware requirements

- Processor: 2.33GHz or higher x64-compatible (2 CPUs)
- Memory: 16+ GB
- Network Interface: 100 Mbit/s

Supported operating systems

The system supports any operating system that has properly installed supported web browser and sufficient hardware requirements. However, the software is tested mostly using Ubuntu, macOS and Windows operating systems.

Supported web browsers

- Google Chrome 118.0.5993.88+
- Mozilla Firefox 118.0.2+
- Safari on macOS 17.1+
- Microsoft Edge 118.0.2088.88+

Internet Explorer is generally not supported and should be avoided.

2.4.3 Updates

Whenever there is a software update, our dedicated Ligence representative will proactively communicate with you to provide details on the upcoming release.

On-premises update

Remote installation of the Ligence Heart software package is included in the quotation.

When installed on customer owned VM or hardware, the customer takes full responsibility for hardware support, OS installation, patching, security and access control.

2.4.4 Backups and redundancy

Image data can be backed up in line with local IT policies.

CAUTION

UAB Ligence assumes no liability for problems attributable to unauthorized modifications, additions, or deletions to this product, or unauthorized installation of third-party software.

NOTE

If this product is correctly installed and further used on a system respecting the specified client-side and/ or server-side system requirements and if no unexpected errors are upcoming, this product is maintenance-free.

2.5 Malfunction

In case of malfunction, please do the following:

- Stop using the device

- Refresh the web browser
- If the problem persists, email support@ligence.io

2.6 Measurements

CAUTION

The complete anatomy of the structure that is being evaluated with Ligence Heart has to be visible in the datasets.

CAUTION

In the case of a poor image quality, as determined by the user's clinical experience and training, measurements should not be made. If for any reason measurements are made using a poorly reconstructed image, these measurements should not be used for making diagnostic decisions.

The user must be committed to the accuracy of the existing images and measurement results. Image scans should be repeated if there is the slightest doubt as to the accuracy of images and measurements.

Safety of Manual Functionalities

CAUTION

Automated measurements have been validated and verified in the following modes:

- B-mode
- PW-Doppler

2.7 IT security measures

The “Security requirements” section in the Installation Manual details the required security measures that have to be implemented by the hospital (client). Recommendations on how to install and configure the Ligence Heart software in order to ensure the system security can also be found in the Installation Manual.

Current section describes actions, that should be taken by the user, in order to secure his or her workplace and user’s account against unauthorized access:

It is highly recommended to run Ligence Heart only from the devices and accounts that are authorized for the user by the company's security policy. Company’s security policy should ensure, that work network and user’s workplace is secure – servers and workplaces have on time security patches and updates, required antivirus software, firewalls and other protection means.

NOTE

By default, Ligence Heart software logs off the user automatically after a specified timeout. Deactivating or significantly increasing this timeout is a security risk. It can lead to unauthorized persons being able to access sensitive information or manipulating the system.

- It is recommended to use a browser that is authorized according to the company's security policy, and is compatible with Ligence Heart software. If the company's security policy does not give any recommendations for browsers, we would recommend considering Google Chrome, Mozilla Firefox or Apple Safari as the most secure browser alternatives in the market at the moment.
- An authentication is required for Ligence Heart software. However, the authentication ways may vary. If you are using login and password authentication, keep the password safe from unauthorized access:
    - do not expose the password to other persons.
    - do not allow the browser to save the password.
- Use Ligence Heart log off function, after finishing your work and before closing the application. Closing the program without Log Off is not safe and may lead to unauthorized access to medical data.

NOTE

For users who share the computer and user’s account. Ligence Heart is designed with “zero footprint” concept, meaning that no patient data is left on a customer’s device: after the end user logs out from Ligence Heart, its cache does not contain any server responses with patient data. However, there are known browser security bug’s that allow it to extract potentially sensitive data from the browser's memory cache after the user logs out and doesn’t close the entire browser application. Therefore, it is recommended to also close the entire browser (not just a particular tab or one of the windows) after logout.

2.8 List of known bugs

#	Name	Description	How was it discovered?	Evaluation of the impact on safety and effectiveness	Outcome of the evaluation	The rationale for not fixing the bug
1	Image cache in browser	For some browsers cached images are not properly removed and this may cause “out of memory” errors.	Research and development team member	Low. The bug is resolved when the browser is reloaded. No impact on the software’s safety and no significant impact on its effectiveness.	Impossible to reliably reproduce.	R-10, R-11
2	Incorrect message when trying to reach study without being logged in.	Trying to reach a study using StudyInstanceUID without being logged in doesn’t redirect to the login screen and instead informs the user that study is not found. The essence of the error is that the message displayed to the user is incorrect.	Testing in a research site.	Low. Cybersecurity is not impacted by this bug. The user simply needs to login.	Low impact.	Cybersecurity is not impacted. Simple solution (user need to login first)

#	Name	Description	How was it discovered?	Evaluation of the impact on safety and effectiveness	Outcome of the evaluation	The rationale for not fixing the bug
3	Polygon displayed incorrectly if user edits points too quickly	If a user tries to adjust multiple points in a polygon in rapid succession, some of the adjustments may not be saved.	Research and development team member	Low. Safety is not impacted as the user is immediately shown the saved polygon and can repeat adjustment.	Difficult to reliably reproduce.	Safety is not impacted.

3. USER INTERFACE ELEMENTS

This section presents the main user views of Ligence Heart and explains the navigation tree.

Ligence Heart is accessed through a web application. It contains the following user views:

1. Login View
2. Lobby View
3. Upload View
4. Workspace View
5. Report View
6. Report PDF View

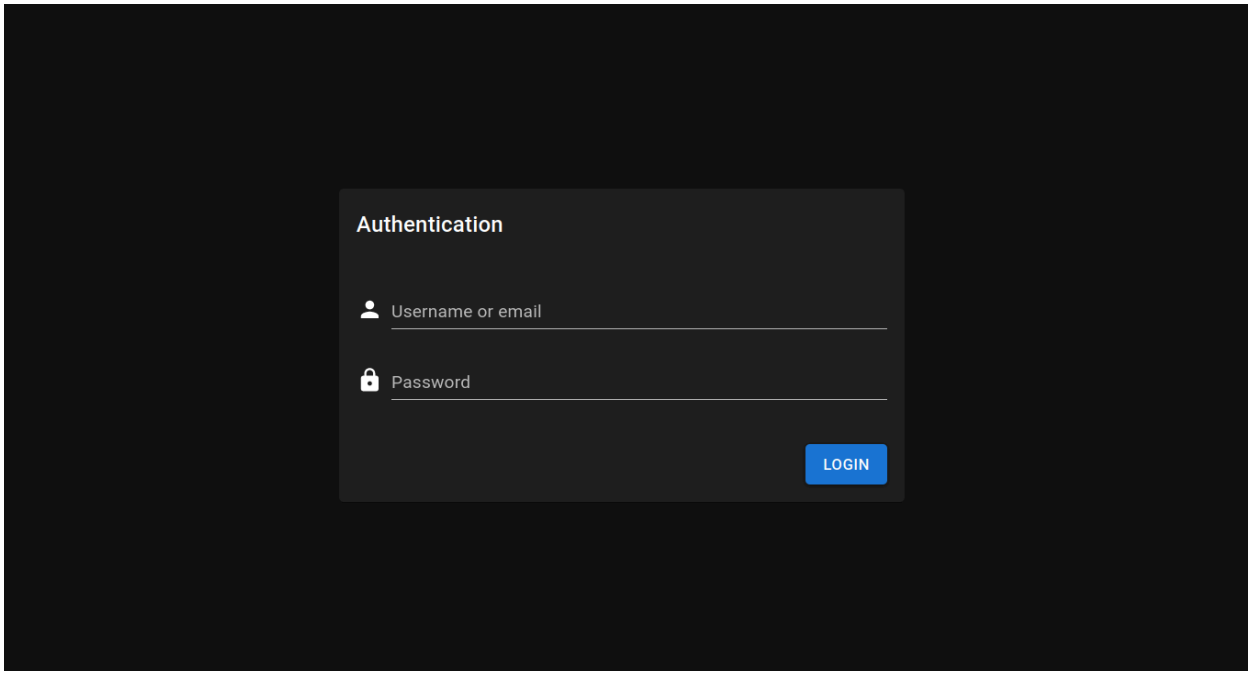
NOTE

Administrator Panel View may not be available depending on your user rights.

The appearance of each view is presented in the pictures below along with descriptions of what can be found in each of them.

3.1 Login View

The Login View is where you must enter your login credentials in order to start using Ligence Heart image viewer.

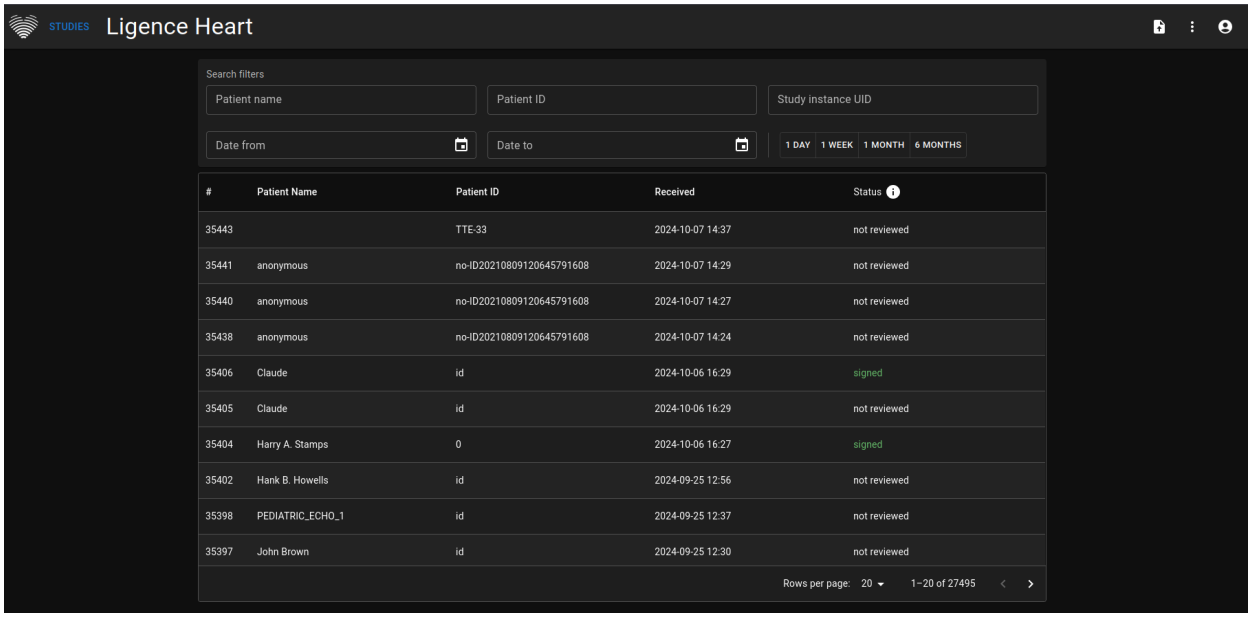


NOTE

Ligence Heart image viewer cannot be accessed without login credentials i.e. a Username and a Password.

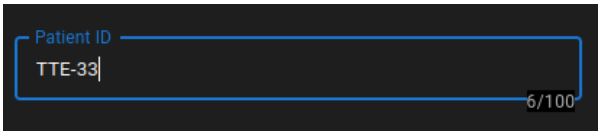
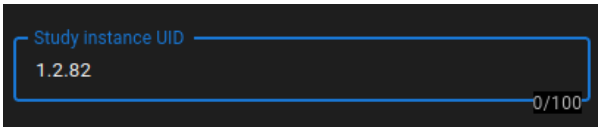
3.2 Lobby View

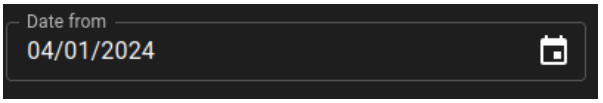
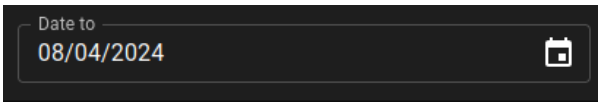
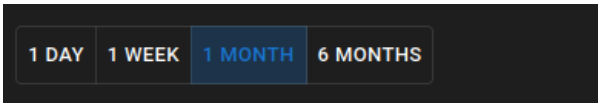
The Lobby View is where you can find all of your most recently received studies.



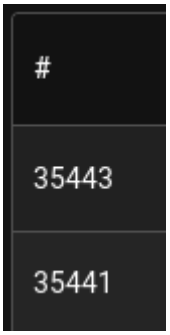
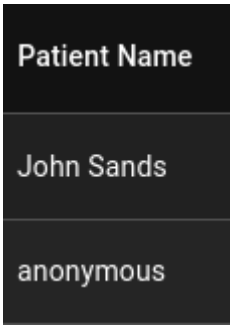
3.2.1 Searching for echocardiographic studies

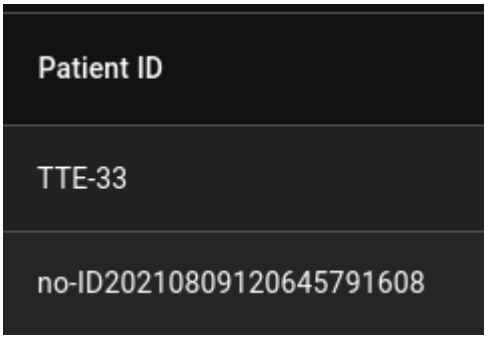
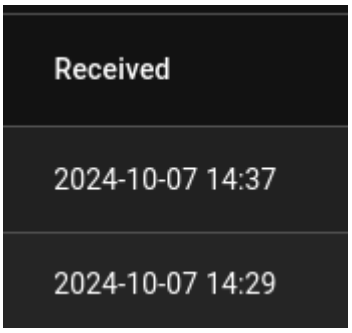
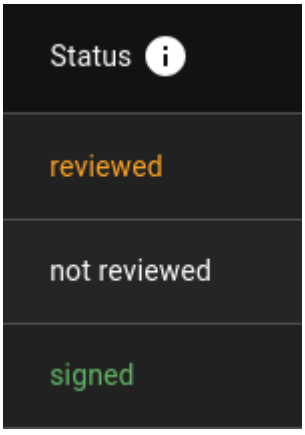
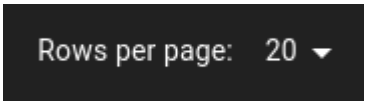
There are multiple ways to search for a specific echocardiographic study in the Lobby View. Entering values in the fields shown below will combine the search filters where a study must meet all of the search criteria that are entered.

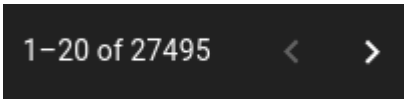
Search functionality element	Explanation
Patient name 	Search based on patient name and surname.
Patient ID 	Search based on DICOM Patient ID Attribute (0010,0020).
Study instance UID 	Search based on DICOM Study Instance UID Attribute (0020,000D).

Search functionality element	Explanation
Date from 	Search for studies that have been received starting from a specific date.
Date to 	Search for studies that have been received starting up to a specific date.
Period selection 	Set a period for which to filter the studies.

3.2.2 Study list

Element	Explanation
Study ID 	This shows the internal ID of the study. This ID is only relevant when using this software.
Patient name 	This shows the patient name as detected in the DICOM file or set by the user.

Element	Explanation
Patient ID 	This shows the patient ID as it is set in DICOM Patient ID Attribute.
Received 	This shows date (YYYY-MM-DD) and time when the study has been received by the software.
Status 	Shows the status of a study. signed - This study has been signed by a physician and a final report has been generated. reviewed - This study has been reviewed by a sonographer but the final report has not been generated. not reviewed - This study has not been reviewed.
Rows per page 	Allows changing the number of echocardiographic studies shown per page.

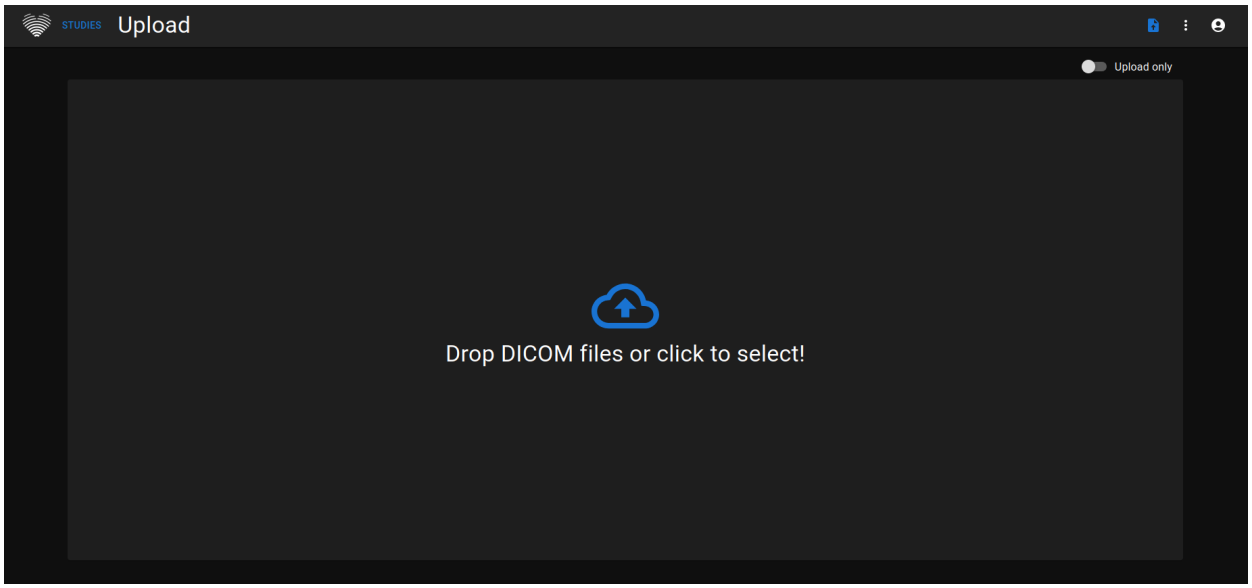
Element	Explanation
Page iterator 	Allows navigating between different pages of the studies.

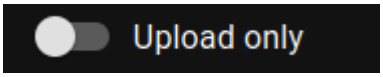
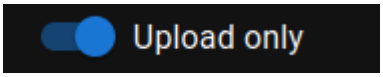
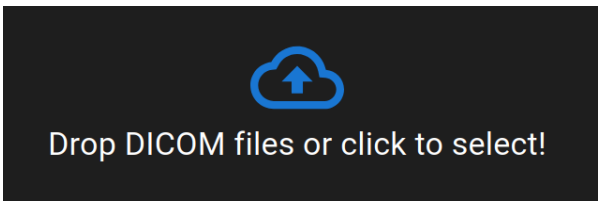
3.3 Upload View

The Upload View is dedicated for uploading studies into the system.

NOTE

Only DICOM format studies are supported.

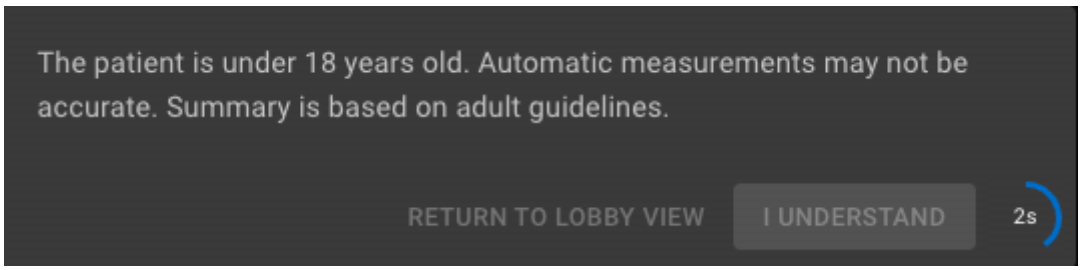


Element	Explanation
Upload only selector - OFF 	Default setting - “Upload only” is inactive. This means that imported DICOM files will get analyzed using automated functionality.
Upload only selector - ON 	“Upload only” set to active. If this setting is used, DICOM files will get imported but no automated measurement prediction will be performed.
File upload 	Clicking this element will allow selecting files for upload. Alternatively, files can be dragged and dropped. A maximum of 300 files is supported at once for upload.

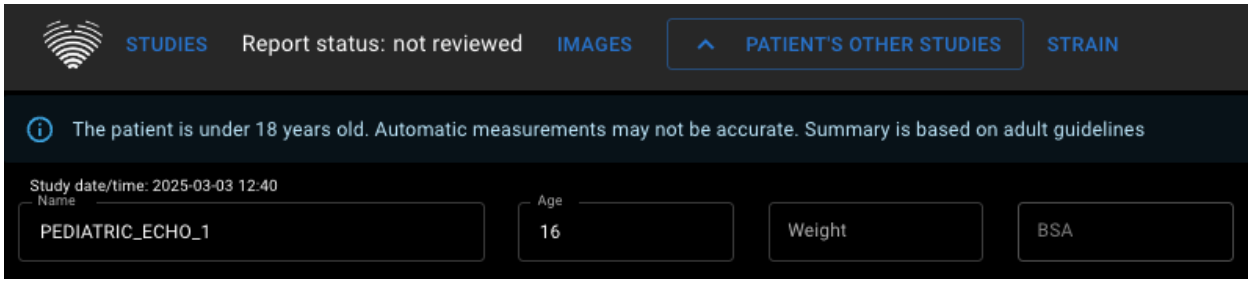
3.3.1 Study Access Scenarios and System Responses

The following scenarios might occur when trying to access the patient study.

Non-adult patients. If the age of the patient is under 18 years old, Ligence Heart's user interface will prompt an alert box to notify the user that Ligence Heart is intended for use in adult patients. The alert box will block the functionality and is only dismissible by clicking a button to acknowledge the risk. The button can be clicked after 5 sec. In addition to the alert box, the intended use is shown in the "About" page in the user interface and the IFU.



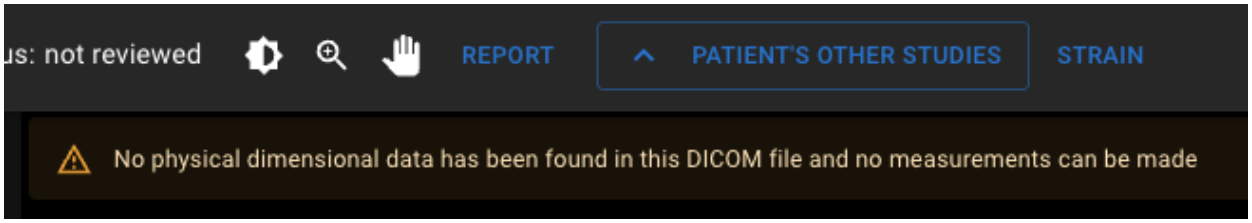
If the patient is under 18 years of age, a notification banner appears at the top of the study screen. This banner informs users that automatic measurements may not be accurate and that the summary is based on adult guidelines.



Corrupted images. If the images previously transferred to Ligence Heart are corrupted images because they do not follow the specifications to be accepted by Ligence Heart (the patient and study IDs are not provided, the image modalities and file format are not provided and, the files, frames number, and the size exceed the limits, as specified in the inputs section), Ligence Heart will not accept the patient study and therefore the user will not be able to find it on the list to access it. Study acquisition should be repeated or uncorrupted studies uploaded.

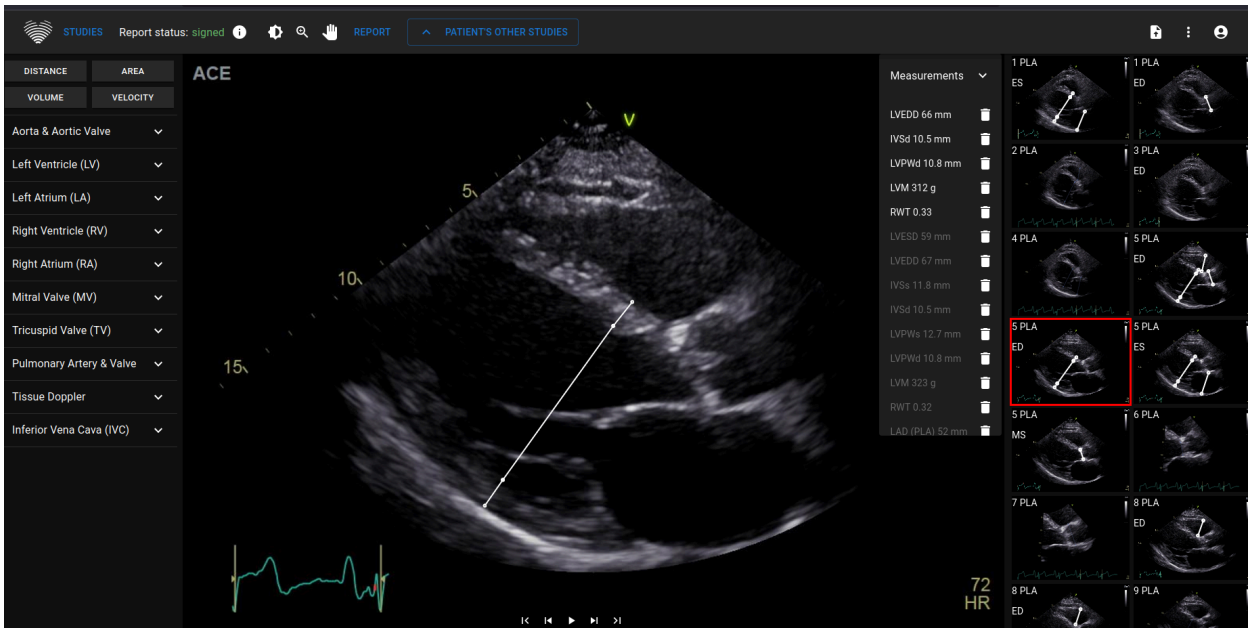
Missing information. If the images are not corrupted and the patient study is accepted by the system, but there is missing information that is not mandatory for the reception of the images such as the patient and study ID, the user might complete the missing information when the user accesses the study.

Missing physical dimensions data. If no physical dimensional data is present in the DICOM file, Ligence Heart displays a warning indicating that measurements cannot be performed. This typically occurs when the DICOM metadata lacks pixel spacing or scaling information required for quantitative analysis. Users are advised to either reacquire the study or upload a version that includes proper DICOM scaling metadata (e.g., pixel spacing) to proceed with analysis.



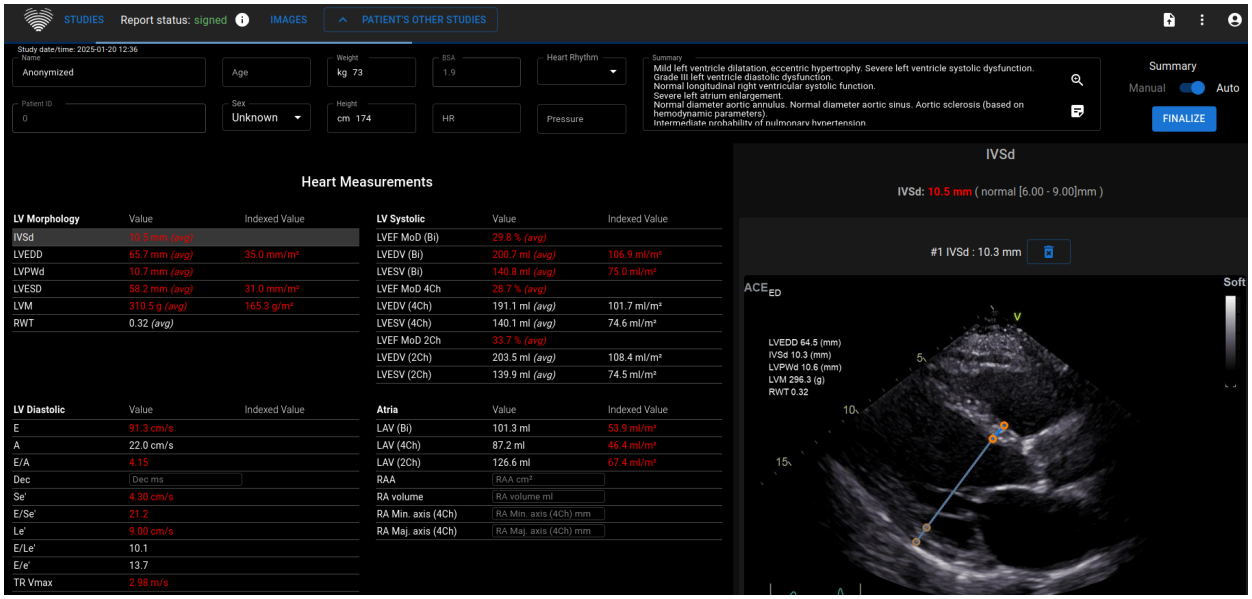
3.4 Workspace View

This view is dedicated for viewing and analyzing studies.



3.5 Report View

The Report View is dedicated for making two-dimensional transthoracic echocardiography reports. This view allows you to compare your measurements against normal values, review source views from which the measurements were taken and make quick edits to any annotations made. The report is organized by different functional and anatomical domains of the heart. Example of Report view is shown in the figure below:



3.5.1 Patient Characteristics

The figure shows patient characteristics fields that are either imported from DICOM files or can be entered by the user. Fields:

- Name - patient name and surname.
- Patient ID - patient ID that is imported from DICOM files, this field can't be entered manually.
- Age - patient's age in years.
- Sex - M (male), F (female).
- Weight - patient's weight in pounds (en-us locale) or kilograms (other locales).
- Height - patient's height in feet/inches (en-us locale) centimeters (other locales).
- BSA - body surface area, this value can't be entered manually, it is calculated automatically using the Mosteller formula shown below.
- HR - heart rate in beats per minute.
- Heart rhythm - selection of sinus rhythm, atrial fibrillation, pacemaker, other or not specified.
- Pressure - systolic / diastolic pressure in mmHg.

Mosteller formula for BSA:

$$BSA = \sqrt{(weight\ [cm]\ x\ height\ [cm])\ /\ 3600}$$

Imperial vs metric system units for patient characteristics

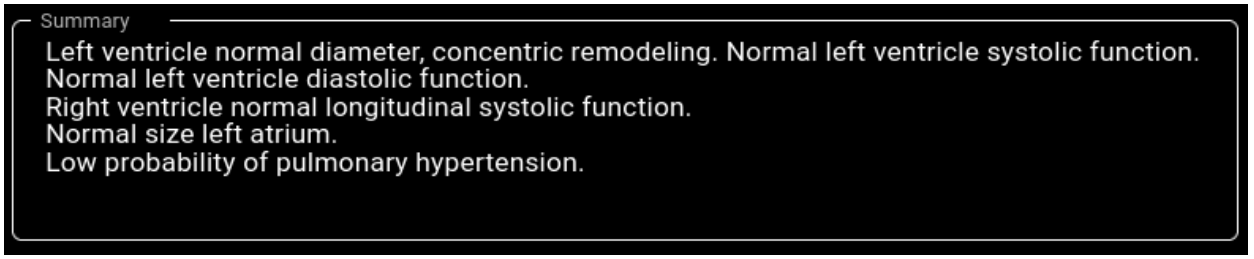
Device can be configured to use imperial or metric system units during deployment:

- Imperial - pounds for weight and feet/inches for height
- Metric system - kilograms for weight and centimetres for height

Entering height in feet/inches should use the following format: <feet>’<inches>”. For example: 5’9”

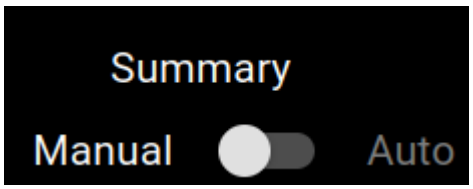
3.5.2 Summary Box

Summary box is a placeholder to write the echocardiographic study impressions. The text added into the summary box will be saved automatically. A summary box is shown below with a text that is meant to be an example.



3.5.3 Summary Modes

Text in the previously shown summary box can be generated using two modes. The component shown in the figure below allows switching between the two modes.



3.5.4 Manual Summary Mode

During manual summary mode which is indicated by the slider position on “Manual”, the text is inputted into the summary box component. The text is automatically saved with no additional input required from the user.

3.5.5 Automatic Summary Mode

During automatic summary mode which is indicated by the slider position on “Auto”, the text in the summary box is generated in an automated manner. This is a deterministic, decision-based text generation. No machine learning or large language models are used during the generation of this text.

The text is generated by taking the measurement values made in automatic or manual way and combining them to generate anatomical and functional feature descriptions.

3.5.6 Explanation of the terminology used

Closed Interval “[ ]”: A range where the boundary values are included. For example, “[5.9” indicates that 5.9 is part of the interval.

Open Interval “( )”: A range where the boundary values are excluded. For example, “6.4)” indicates that values up to, but not including, 6.4 are part of the interval.

∈ - part of the interval. For example, ∈ [2, 5] indicates that values from 2 to 5, including themselves are part of the interval.

Indexed Values: A measurement normalized by dividing it by the Body Surface Area (BSA). For instance, the indexed left ventricular mass is calculated as the left ventricular mass divided by the BSA.

Priority: The preferred order of using available measurements.

- Example 1: For left ventricular ejection fraction, the biplane ejection fraction is prioritized. If only the apical four-chamber view is available, the monoplane apical four-chamber view ejection fraction is used instead. If a four-chamber view is not available, a two-chamber view ejection fraction will be used.
- Example 2: For the transmitral E velocity to e’ average ratio, the priority is as follows:
    - Transmitral E velocity to e’ average.
    - Transmitral E velocity to lateral wall e’.
    - Transmitral E velocity to septal e’.

3.5.7 International Reference Ranges

Below is a list of measurements and corresponding automatic summary texts that can be displayed using International Reference Ranges. If any measurement values required by the International Reference Ranges are missing, then the related automatic summary text will not be displayed.

Left ventricular diastolic diameter in parasternal-long axis

Indexed value (value / BSA) is preferred over non-indexed. I.e. if an indexed value is available, it will be used to generate the text. Non-indexed value will only be used to generate the text if no indexed value is available.

Required measurements (at least of one of):

- Indexed left ventricular end-diastolic diameter (LVEDDi)
- Left ventricular end-diastolic diameter (LVEDD)

Priority (highest priority to lowest priority):

- LVEDDi
- LVEDD

LVEDDi

Criteria (patient is male)	Criteria (patient is female)	Corresponding automatic summary text
LVEDDi <3.1 cm	LVEDDi <3.2 cm	Normal left ventricle diameter
LVEDDi ∈ [3.1, 3.4) cm	LVEDDi ∈ [3.2, 3.5) cm	Mild left ventricle dilatation
LVEDDi ∈ [3.4, 3.6] cm	LVEDDi ∈ [3.5, 3.7] cm	Moderate left ventricle dilatation
LVEDDi >3.6 cm	LVEDDi >3.7 cm	Severe left ventricle dilatation
No LVEDDi	No LVEDDi	Left ventricle size not evaluated (missing diastolic diameter)

If only LVEDD is available (non-indexed):

Criteria (patient is male)	Criteria (patient is female)	Corresponding automatic summary text
<5.9 cm	<5.3 cm	Normal left ventricle diameter
LVEDD ∈ [5.9, 6.4) cm	LVEDD ∈ [5.3, 5.7) cm	Mild left ventricle dilatation
LVEDD ∈ [6.4, 6.8] cm	LVEDD ∈ [5.7, 6.1] cm	Moderate left ventricle dilatation
LVEDD >6.8 cm	LVEDD >6.1 cm	Severe left ventricle dilatation
No LVEDD	No LVEDD	Left ventricle size not evaluated (missing diastolic diameter)

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext Supplemental Table 3.

Left ventricular morphology in parasternal-long axis view

Formulas:

Left ventricular mass (LVM)	Devereux formula 0.8 * (1.04 * (LVEDD + IVSd + LVPWd)^3 - LVEDD^3) + 0.6
Relative wall thickness (RWT)	(IVSd + LVPWd) / LVEDD

Required measurements (all below):

- Relative wall thickness (RWT)
- Indexed value of left ventricular mass (LVMi). Non-indexed left ventricular mass is not used. If BSA is not available - text for left ventricular morphology will not be generated.

Criteria (patient is male)	**Criteria (patient is female)**	**Corresponding automatic summary text**
RWT <0.42 LVMi <115 g	RWT <0.42 LVMi <95 g	normal morphology
RWT >0.42 LVMi >115 g	RWT >0.42 LVMi >95 g	concentric hypertrophy
RWT >0.42 LVMi <115 g	RWT >0.42 LVMi <95 g	concentric remodeling
RWT <0.42 LVMi >115 g	RWT <0.42 LVMi >95 g	eccentric hypertrophy
RWT or LVMi not measured	RWT or LVMi not measured	morphology not evaluated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext Figure 6.

Left ventricular systolic function in apical views

Required measurements (at least of one of):

- Left Ventricular Ejection Fraction (Biplane) (LVEF MoD (Bi))
- Left Ventricular Ejection Fraction (Method of Disks) (A4Ch) (LVEF MoD 4Ch)
- Left Ventricular Ejection Fraction (Method of Disks) (A2Ch) (LVEF MoD 2Ch)

Priority (highest priority to lowest priority):

- LVEF MoD (Bi)
- LVEF MoD 4Ch
- LVEF MoD 2Ch

EF - ejection fraction (one of the prioritised measurements)

Criteria (patient is male)	**Criteria (patient is female)**	**Corresponding automatic summary text**
EF ≥52 %	EF ≥54 %	Normal left ventricle systolic function
EF ∈ [41, 52) %	EF ∈ [41, 54) %	Mild left ventricle systolic dysfunction
EF ∈ [30, 41) %	EF ∈ [30, 41) %	Moderate left ventricle systolic dysfunction
EF <30 %	EF <30 %	Severe left ventricle systolic dysfunction
No LVEF MoD (Bi), LVEF MoD 4Ch and LVEF MoD 4Ch	No LVEF MoD (Bi), LVEF MoD 4Ch and LVEF MoD 4Ch	Left ventricle systolic function not evaluated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of

Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext Supplemental Table 3

Left ventricular diastolic function if ejection fraction is normal

This only applies if the left ventricular ejection fraction is normal.

Required measurements:

- E/e' average ratio (E/e') or E/Lateral e' velocity ratio (E/Le') or E/Septal e' velocity ratio (E/Se')
- Peak Tricuspid Regurgitation Velocity (TR Vmax)
- Left Atrial Volume Index (Biplane) (LAVi (Bi)) or Left Atrial Volume Index (A4Ch) (LAVi (4Ch)) or Left Atrial Volume Index (A2Ch) (LAVi (2Ch))

Priority for E to e' ratio (highest priority to lowest priority):

- E/e'
- E/Le'
- E/Se'

Priority for left atrial volume index (highest priority to lowest priority):

- LAVi (Bi)
- LAVi (4Ch)
- LAVi (2Ch)

Criteria:

- E/e' > 14 or E/Le' > 14 or E/Se' > 14
- Se' < 7 cm/s or Le' velocity <10 cm/s
- TR Vmax > 2.8 m/s
- LAVi (Bi) or LAVi (4Ch) or LAVi (2Ch) >34ml/m2

Criteria	**Corresponding automatic summary text**
<3 criteria are available	Diastolic function not evaluated (one or more criteria missing)
• 3 or 4 criteria evaluated • 1 or 0 criteria are positive	Normal left ventricle diastolic function
• 3 or 4 criteria evaluated • 2 criteria are positive	Indeterminate left ventricle diastolic function
• 3 or 4 criteria evaluated • 3 criteria are positive	Go to evaluation algorithm for "Left ventricular diastolic dysfunction"

References:

- Nagueh et al 2016. Recommendations for the evaluation of left ventricular diastolic function by echocardiography: An update from the american society of echocardiography and the european association of cardiovascular imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 29(4), 277–314. https://onlinejase.com/article/S0894-7317(16)00044-4/fulltext Figure 8

Left ventricular diastolic dysfunction

This only applies if the left ventricular ejection fraction is reduced or left ventricular ejection fraction is normal and diastolic dysfunction is detected.

Required measurements:

- E/A ratio (E/A)

Additional measurements:

- E/A ratio (E/A)
- Transmitral E velocity (E)
- E/e' average ratio (E/e') or E/Lateral e' velocity ratio (E/Le') or E/Septal e' velocity ratio (E/Se')
- Peak Tricuspid Regurgitation Velocity (TR Vmax)
- Left Atrial Volume Index (Biplane) (LAVi (Bi)) or Left Atrial Volume Index (A4Ch) (LAVi (4Ch)) or Left Atrial Volume Index (A2Ch) (LAVi (2Ch))

Priority for E to e' ratio (highest priority to lowest priority):

- E/e'
- E/Le'
- E/Se'

Priority for left atrial volume index (highest priority to lowest priority):

- LAVi (Bi)
- LAVi (4Ch)
- LAVi (2Ch)

Criteria:

- E/e' > 14 or E/Le' > 14 or E/Se' > 14
- TR Vmax > 2.8 m/s
- LAVi (Bi) or LAVi (4Ch) or LAVi (2Ch) >34ml/m2

Criteria	**Corresponding automatic summary text**
E/A ≤ 0.8 and E ≤ 50 cm/s	Grade I left ventricle diastolic dysfunction

E/A ≥ 2	Grade III left ventricle diastolic dysfunction
(E/A ≤ 0.8 and E > 50 cm/s) or 0.8< E/A <2 2 or 3 criteria are negative	Grade I left ventricle diastolic dysfunction
(E/A ≤ 0.8 and E > 50 cm/s) or 0.8< E/A <2 Only 2 criteria available and 1 positive	Indeterminate left ventricle diastolic function
(E/A ≤ 0.8 and E > 50 cm/s) or 0.8< E/A <2 2 or 3 criteria are positive	Grade II left ventricle diastolic dysfunction
E/A not available	Diastolic function not evaluated (missing E/A)
E/A ≤ 0.8 and E not available	Diastolic function not evaluated (missing E wave velocity)

References:

- Nagueh et al 2016. Recommendations for the evaluation of left ventricular diastolic function by echocardiography: An update from the american society of echocardiography and the european association of cardiovascular imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 29(4), 277–314. https://onlinejase.com/article/S0894-7317(16)00044-4/fulltext Figure 8

Right ventricular diameter

Required measurements (at least of one of):

- Right Ventricular Basal Diameter (RVB)
- Right Ventricular Middle Diameter (RVM)

Criteria	**Corresponding automatic summary text**
RVM >3.5 cm or RVB >4.1 cm	Right ventricle dilatation
RVM ≤3.5 cm and RVB ≤4.1 cm or RVM ≤3.5 cm and RVB not available or RVM not available cm and RVB ≤4.1 cm	Normal size right ventricle

RVM not available and RVB not available	No text will be generated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. hhttps://onlinejase.com/article/S0894-7317(14)00745-7/fulltext Section "7.1 Linear Measurements"

Right ventricular global systolic function in 2D B-mode

Required measurements:

- Fractional Area Change (FAC)

Criteria	Corresponding automatic summary text
FAC <35%	Reduced global right ventricular systolic function
FAC ≥35%	Normal global right ventricular systolic function
FAC not available	No text will be generated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext Section "8.3 RV 2D FAC"

Right ventricular longitudinal systolic function

Required measurements:

- S prime right ventricular lateral wall (S' RV)
- Tricuspid Annular Plane Systolic Excursion (TAPSE)

Criteria	Corresponding automatic summary text

S’ RV <9.5 cm/s or TAPSE < 17mm	Reduced longitudinal right ventricular systolic function
S’ RV ≥9.5 cm/s and TAPSE ≥17mm or S’ RV ≥9.5 cm/s and TAPSE not available or S’ RV not available and TAPSE ≥17mm	Normal global right ventricular systolic function
S’ RV not available and TAPSE not available	No text will be generated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext Table 9

Left atrium size in apical views

Indexed value is required, if BSA is not available - no text will be generated.

Required measurements (at least of one of):

- Left Atrial Volume Index (Biplane) (LAVi (Bi))
- Left Atrial Volume Index (A4Ch) (LAVi (4Ch))
- Left Atrial Volume Index (A2Ch) (LAVi (2Ch))

Priority (highest priority to lowest priority):

- LAVi (Bi)
- LAVi (4Ch)
- LAVi (2Ch)

LAVi - left atrial volume index (one of the prioritised measurements)

Criteria	**Corresponding automatic summary text**
LAVi ≤34 ml/m2	Normal size left atrium
LAVi ∈ [34, 41] ml/m2	Mild left atrium enlargement
LAVi ∈ (41, 48] %ml/m2	Moderate left atrium enlargement

LAVi >48 ml/m2	Severe left atrium enlargement
No LAVi	No text will be generated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext section "9.4. Normal Values of LA Measurements".

Right atrium size in apical views

Indexed value is required, if BSA is not available - no text will be generated.

Required measurements (at least of one of):

- Right Atrial Volume Index (2D) (RAVi)
- Right Atrial Minor Axis Dimension Index (A4Ch) (RA Min. i (4Ch))

Priority (highest priority to lowest priority):

- RAVi
- RA Min. i (4Ch)

RAVi

Criteria (patient is male)	**Criteria (patient is female)**	**Corresponding automatic summary text**
RAVi ≤32 ml/m2	RAVi ≤28 ml/m2	Normal size right atrium
RAVi >32 ml/m2	RAVi >28 ml/m2	Right atrium enlargement
No RAVi and no RA Min. i (4Ch)	No RAVi and no RA Min. i (4Ch)	No text will be generated

RA Min. i (4Ch)

Criteria (patient is male)	**Criteria (patient is female)**	**Corresponding automatic summary text**
RA Min. i (4Ch) ≤2.2 cm/m2	RA Min. i (4Ch) ≤2.2 cm/m2	Normal size right atrium

RA Min. i (4Ch) >2.2 cm/m2	RA Min. i (4Ch)>2.2 cm/m2	Right atrium enlargement
No RAVi and no RA Min. i (4Ch)	No RAVi and no RA Min. i (4Ch)	No text will be generated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext section "10. Right Atrial measurements" and Table 13 for RA Min. i (4Ch).

Aortic annulus in parasternal-long axis view

Indexed value is required, if BSA is not available - no text will be generated.

Required measurements:

- Aortic Annulus Index (AoAi)

Criteria	Corresponding automatic summary text
AoAi >1.4 cm/m2	Aortic annulus dilatation
AoAi ≤1.4 cm/m2	Normal diameter aortic annulus
AoAi not available	No text will be generated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext table 14.

Aortic sinus in parasternal-long axis view

Indexed value is required, if BSA is not available - no text will be generated.

Required measurements:

- Aortic Sinus Diameter Index (AoSi)

Criteria (patient is male)	Criteria (patient is female)	Corresponding automatic summary text
AoSi >1.9 cm/m2	AoSi >2.0 cm/m2	Aortic annulus dilatation
AoSi ≤1.9 cm/m2	AoSi ≤2.0 cm/m2	Normal diameter aortic annulus
AoSi not available	AoSi not available	No text will be generated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext table 14.

Ascending aorta in parasternal-long axis view

Indexed value is required, if BSA is not available - no text will be generated.

Required measurements:

- Ascending Aorta Diameter Index (AAoi)

Criteria (patient is male)	Criteria (patient is female)	Corresponding automatic summary text
AAoi >1.7 cm/m2	AAoi >1.9 cm/m2	Aortic annulus dilatation
AAoi ≤1.7 cm/m2	AAoi ≤1.9 cm/m2	Normal diameter aortic annulus
AAoi not available	AAoi not available	No text will be generated

References:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext table 14.

Aortic stenosis

Required measurements:

- Aortic Peak Velocity (AV Vmax)

Additional measurements:

- Aortic Mean Gradient (AMG)
- Aortic Peak Gradient (APG)
- Left Ventricular Outflow Tract Diameter (LVOTD)
- Aortic valve area Index (AVAi) or aortic valve area (AVA)
- Aortic Valve Velocity Ratio (Vel. ratio)

Priority for aortic valve area (highest priority to lowest priority):

- AVAi
- AVA

AV Vmax is ≤ 2.5 m/s

Criteria	**Corresponding automatic summary text**
AV Vmax ≤1.7 m/s	Normal aortic flow (based on hemodynamic parameters)
AV Vmax ∈ (1.7, 2.5] m/s	Aortic sclerosis (based on hemodynamic parameters)
AV Vmax is not available	No text will be generated

AV Vmax is >2.5 m/s

Criteria	**Corresponding automatic summary text**
If one the following is true: ● AV Vmax ≥4.0 m/s ● AMG ≥40 mmHg ● AVAi <0.6 cm2/m2 or AVA <1.0 cm2 ● Vel. ratio <0.25	Severe aortic stenosis (based on hemodynamic parameters)
If none of the above criteria are true and one the following is true: ● AV Vmax ∈ [3.0, 4.0) m/s ● AMG ∈ [20, 40) mmHg	Moderate aortic stenosis (based on hemodynamic parameters)

• AVAi ∈ [0.6, 0.85] cm2/m2 or AVA ∈ [1.0, 1.5] cm2 • Vel. ratio ∈ [0.25, 0.50]	
If none of the above criteria are true and one the following is true: • AV Vmax ∈ [2.6, 3.0) m/s • AMG < 20 mmHg • AVAi >0.85 cm2/m2 or AVA >1.5 cm2 • Vel. ratio >0.50	Mild aortic stenosis (based on hemodynamic parameters)
AV Vmax is not available	No text will be generated

References:

- Baumgartner et al. 2017. Recommendations on the echocardiographic assessment of aortic valve stenosis: A focused update from the European Association of Cardiovascular Imaging and the American Society of Echocardiography. European Heart Journal. Cardiovascular Imaging, 18(3), 254–275. https://onlinejase.com/article/S0894-7317(17)30133-5/fulltext Table 3.

Pulmonary hypertension

Required measurements:

- Peak Tricuspid Regurgitation Velocity (TR Vmax)

Measurements used to determine pulmonary hypertension signs:

- Category A - The Ventricles:
  - Eccentricity index (EI)
  - Right ventricular / Left ventricular basal diameter ratio (RVB/LVB)
- Category B - Pulmonary artery:
  - Pulmonary valve acceleration time (PV ACT)
  - Pulmonary Regurgitation Peak Velocity (PR Vmax)
  - Pulmonary Artery Diameter (PAD)
- Category C - Inferior vena cava and right atrium
  - Inferior vena cava diameter during expiration (BMode) (IVCde (B)) or Inferior vena cava diameter during expiration (MMode) (IVCde (M))
  - Inferior vena cava collapse (BMode) (IVCcol (B)) or Inferior vena cava collapse (MMode) (IVCcol (M))
  - Right Atrial Area (RAA)

IVCde - inferior vena cava diameter during expiration. Priority for IVCde (highest priority to lowest priority):

- IVCde (B)
- IVCde (M)

IVCcol - inferior vena cava collapse. Priority for IVCcol (highest priority to lowest priority):

- IVCcol (B)
- IVCcol (M)

Echocardiographic signs of pulmonary hypertension:

Category A - The Ventricles	**Category B - Pulmonary artery**	**Category C - Inferior vena cava and right atrium**
RVB/LVB >1.0	PV ACT <105 ms	IVCde >21 mm IVCcol <50 %
EI >1.1	PR Vmax >2.2 m/s	RAA > 18 cm2
	PAD >25 mm	

Pulmonary hypertension summary text generation

Criteria	**Corresponding automatic summary text**
All below must apply: ● TR Vmax ≤2.8m/s ● NO presence of echocardiographic signs from at least two different Categories (A/B/C).	Low probability of pulmonary hypertension
All below must apply: ● TR Vmax ≤2.8m/s or not measured ● Presence of echocardiographic signs from at least two different Categories (A/B/C).	Intermediate probability of pulmonary hypertension
All below must apply: ● TR Vmax ∈ [2.9, 3.4] m/s ● NO presence of echocardiographic signs from at least two different Categories (A/B/C).	Intermediate probability of pulmonary hypertension

All below must apply: ● TR Vmax ∈ [2.9, 3.4] m/s ● Presence of echocardiographic signs from at least two different Categories (A/B/C).	High probability of pulmonary hypertension
TR Vmax >3.4 m/s	High probability of pulmonary hypertension
All below must apply: ● TR Vmax not measured ● NO presence of echocardiographic signs from at least two different Categories (A/B/C).	No text will be generated

References:

- Galiè et al 2016. 2015 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension: The joint task force for the diagnosis and treatment of pulmonary hypertension of the european society of cardiology (ESC) and the european respiratory society (ERS): endorsed by: association for european paediatric and congenital cardiology (AEPC), international society for heart and lung transplantation(ISHLT). European Heart Journal, 37(1), 67–119. https://academic.oup.com/eurheartj/article/37/1/67/2887599 Table 8A and Table 8B.

3.5.8 Measurement fields

The Measurement Blocks grid in Report View is a fixed table that always displays the full list of measurement labels, arranged by anatomical and functional sections.

- When automated analysis is enabled, Ligence Heart classifies views, generates anatomical annotations, applies guideline-based formulas, and calculates validated measurements. Each value is derived from the automatically generated annotations, converted to physical units by guideline-based formulas, and colour-coded against ASE/ESC/EACVI reference ranges described in section above. If the measurement is calculated as an average of multiple measurements, the (avg) text will be shown.
- When automated analysis is disabled, the grid remains visible but initially blank; individual cells are populated only after the operator creates or edits annotations in the Workspace View or Quick Edit modal. All subsequent manual entries receive the same guideline comparison and colour-coding as automated values.

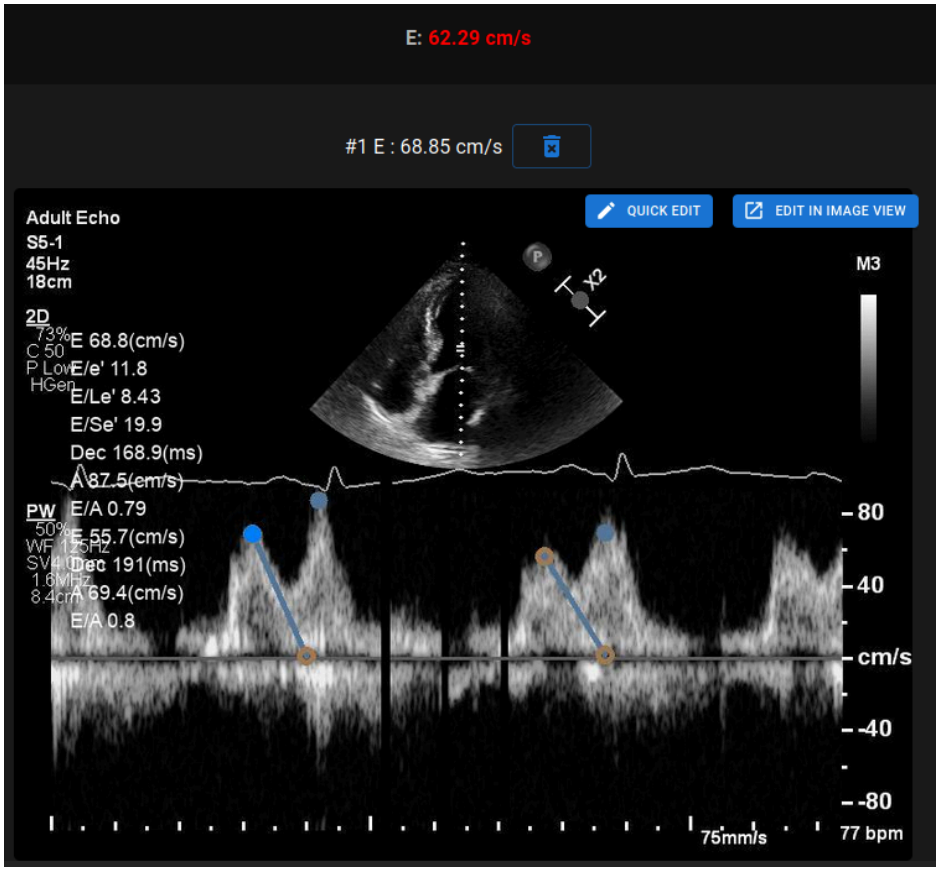
LV Diastolic	Value	Indexed Value
E	62.29 cm/s *(avg)*	
A	78.44 cm/s *(avg)*	
E/A	0.80 *(avg)*	
Dec	179.91 ms *(avg)*	
Se'	3.47 cm/s	
E/Se'	19.86	
Le'	8.17 cm/s	
E/Le'	8.43	
E/e'	11.83	

3.5.9 Illustrations

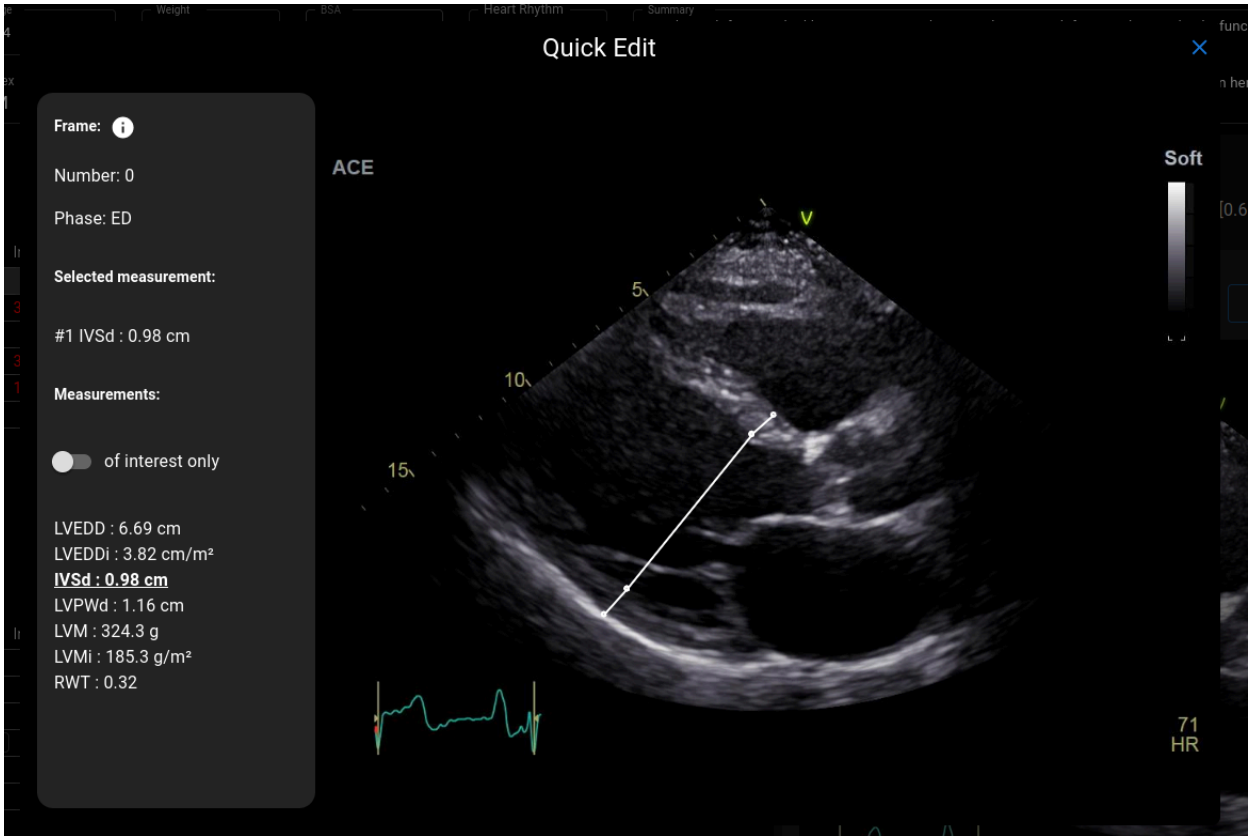
Hovering on one of the measurement rows will show annotations associated with that measurement in the illustration component. The measurement being shown will be highlighted and other measurements will be shown in transparent color.

Clicking on “QUICK EDIT” allows adjusting the selected measurement.

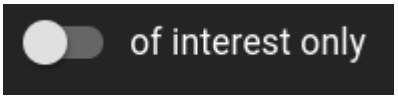
Clicking “EDIT IN IMAGE VIEW” redirects to the specific image in workspace view.

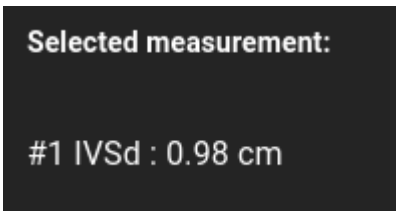
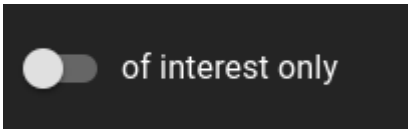


3.5.10 Quick edit



Quick edit mode is entered by clicking on the “QUICK EDIT” button on illustrations.

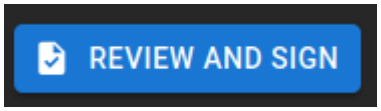
Element	Explanation
Frame number 	Shows number of the current frame in the DICOM. The first frame is labeled as “0”.
Frame cardiac cycle phase 	Shows the predicted cardiac cycle phase of the frame: ED - end-diastolic ES - end-systollic MS - mid-systolic PS - peak-systolic FI - frame-of-interest
Selected measurement	Shows which measurement is being analyzed.

Element	Explanation
	
Of interest only toggle 	Sets whether to show all measurements found in the frame o

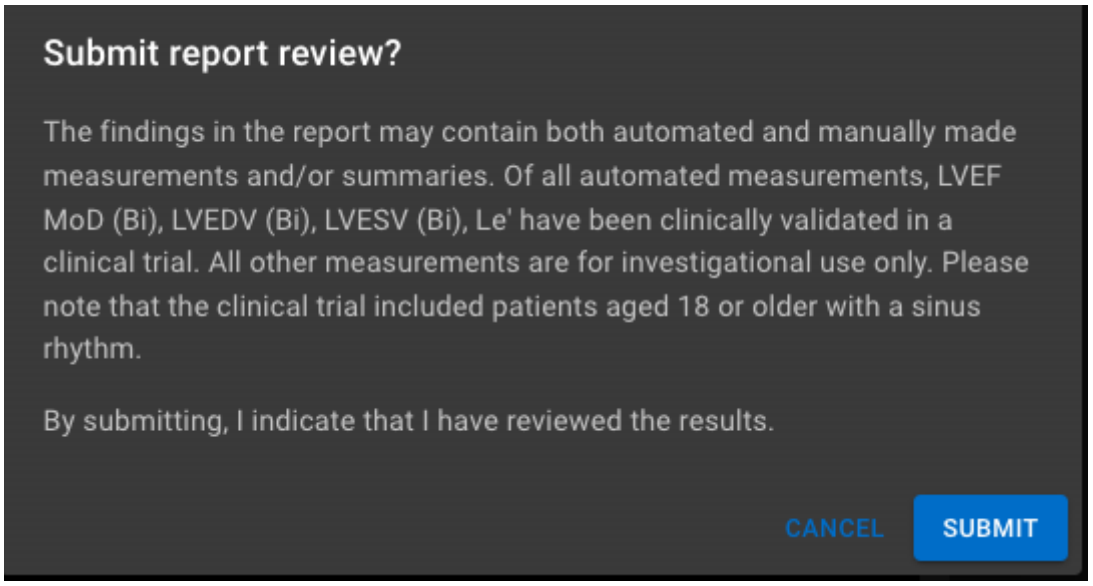
Review study - Sonographer

1. Navigate to report view
2. Review study

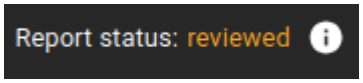
3. Click
4. Review the generated PDF



5. Click
6. Acknowledge limitations and submit



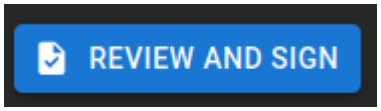
7. After submitting report status will change to



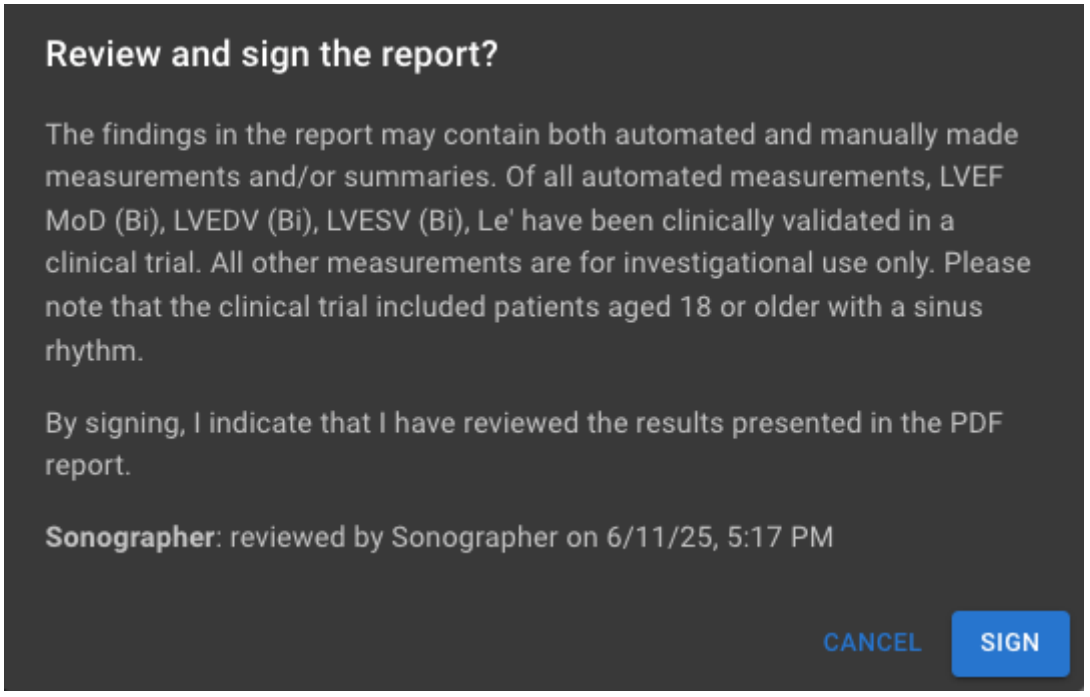
Signing report - Cardiologist

8. Navigate to report view
9. Review study

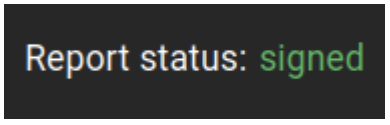
10. Click
11. Review the generated PDF



12. Click
13. Acknowledge limitations and sign



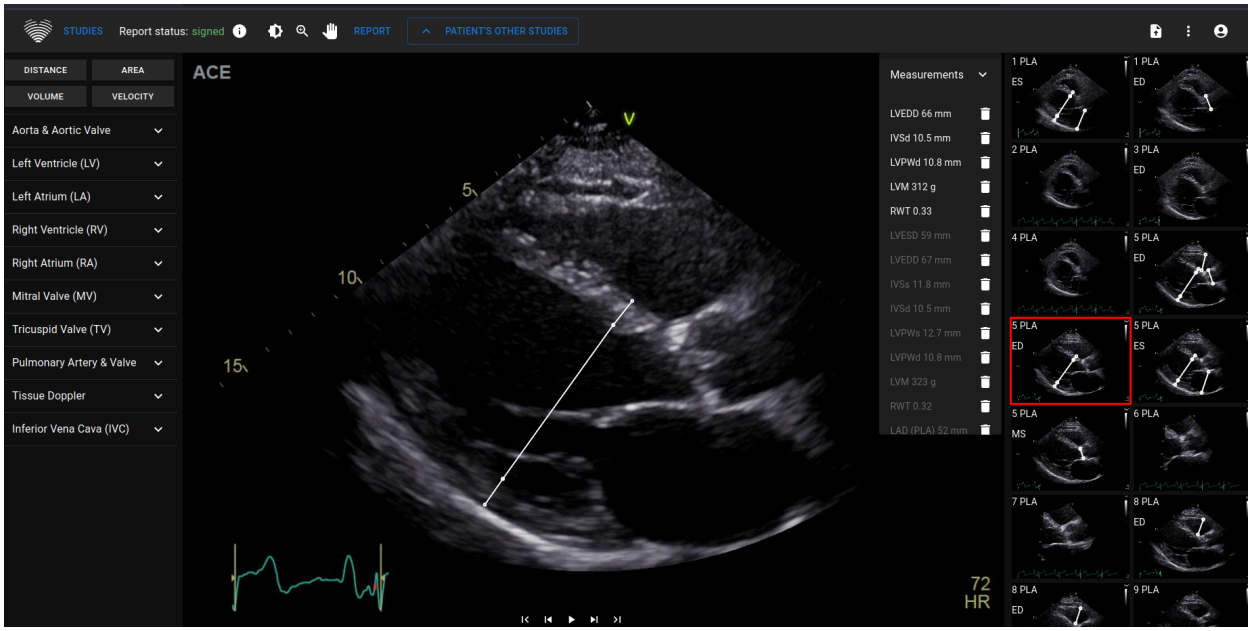
14. After confirming report status will change to



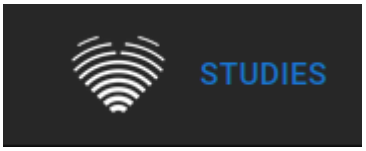
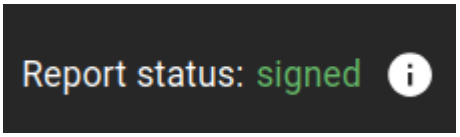
NOTE

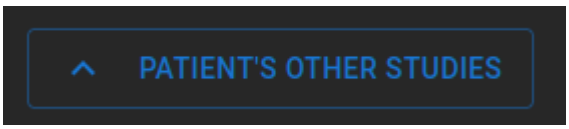
Quantitative measurements are juxtaposed against established benchmarks from organizations including, but not limited to, the American Society of Echocardiography (ASE), the European Society of Cardiology (ESC), and the European Associations of Cardiovascular Imaging (EACVI) and described in detail in section International Reference Ranges.

3.6 Workspace view elements



3.6.1 Navigation Bar and Image Tools

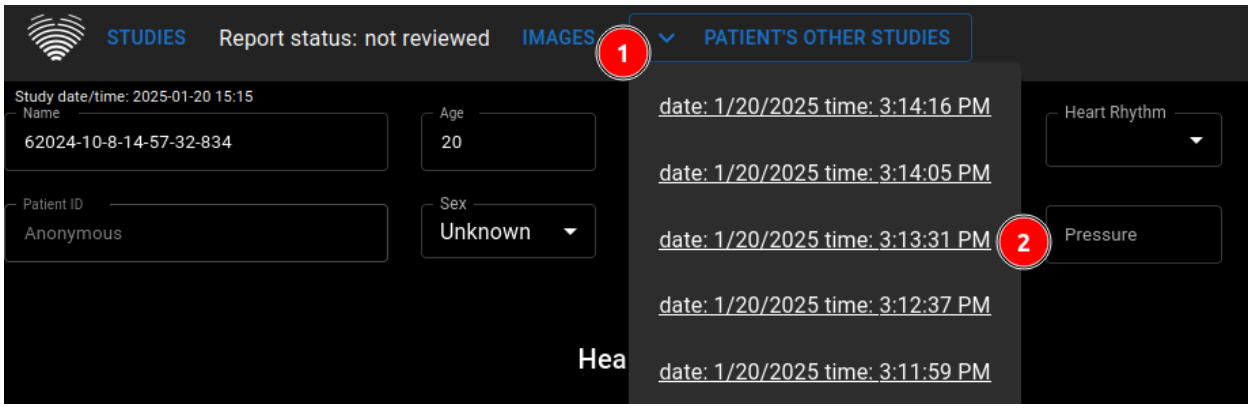
Element	Explanation
	Return to Lobby view, list of studies
	Report status of the current study as explained in the Lobby view section
	Change windowing - click and drag while holding the left mouse key
	Change zoom level - click and drag while holding the left mouse key

Element	Explanation
	View list of other studies belonging to the same patient based on DICOM Patient ID Attribute (0010,0020)
	Pan tool - click and drag while holding the left mouse key
	Toggle labels - click on this to show the labels of the annotations on image
	Toggle annotations - click on this to show annotations on image
	Toggle editing - click on this to disable editing of annotations

Finding other echocardiographic studies from the same patient

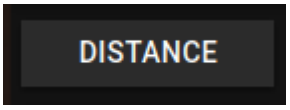
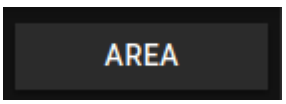
To find other echocardiographic studies based on DICOM Patient ID Attribute:

1. Click on “Patient’s Other Studies”
2. Select one of the available studies based on date and time of the study.



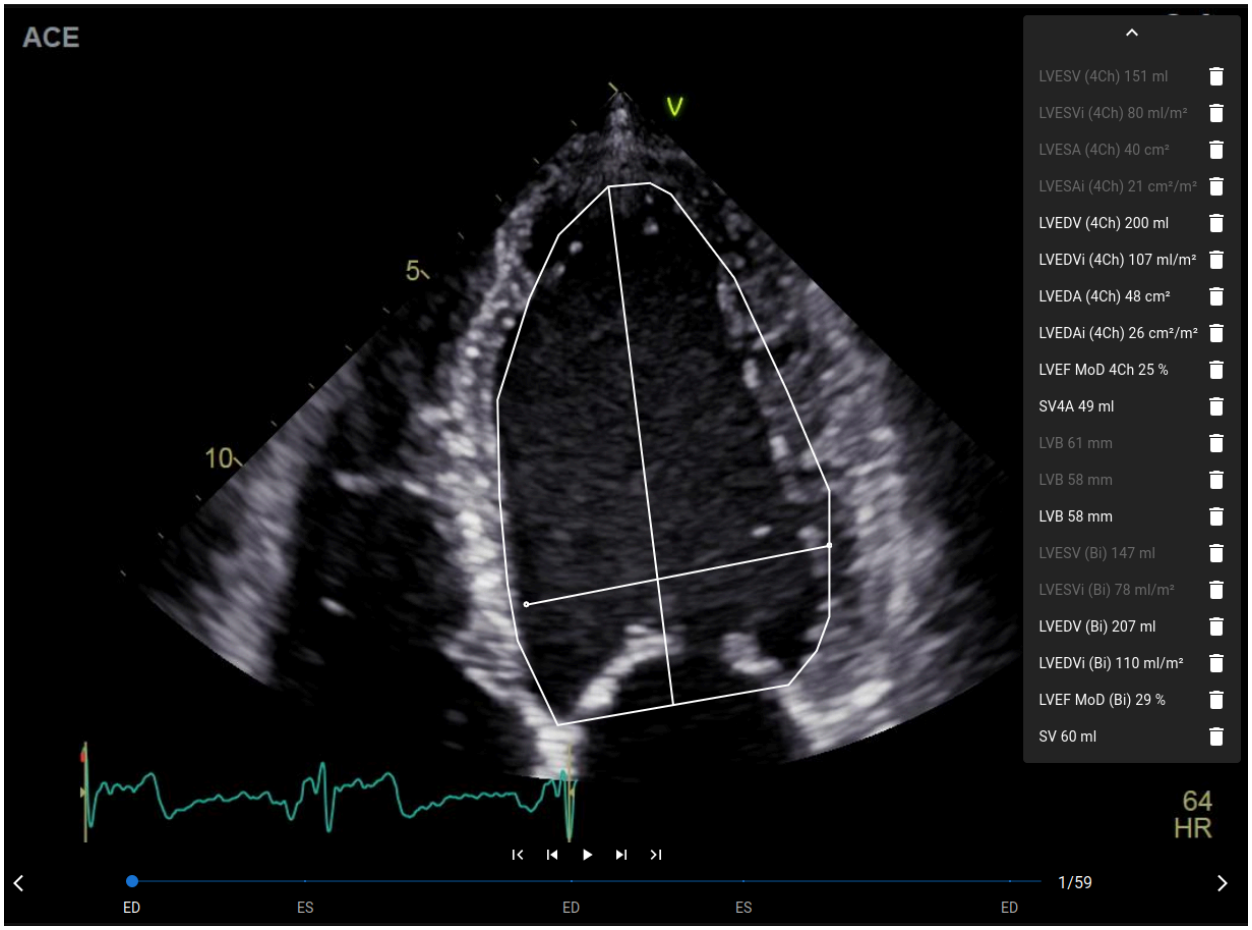
3.6.2 Left Sidebar

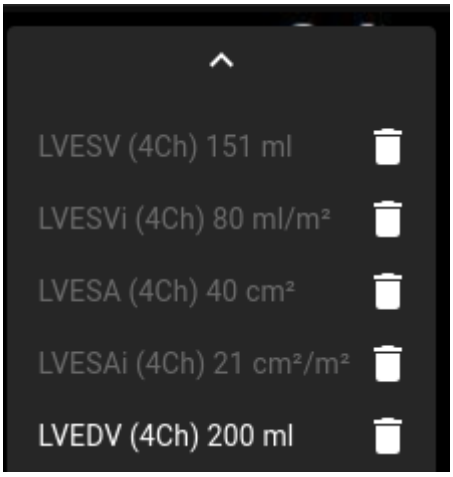
Left sidebar contains tools for making measurements

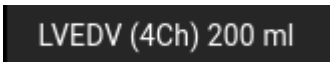
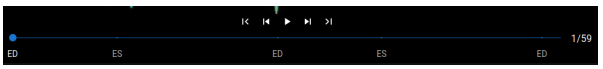
Element	Explanation
	Expand section
	Make a distance measurement
	Make area measurement
	Make volume measurement

Element	Explanation
	Make velocity measurement in Doppler images
Measurement tools 	• Hover on measurement label - show full name of the measurement label • Click on measurement label - make measurement manually • “Auto” - make automated measurement prediction in the current frame • Number - the number of instances of this particular measurement that are available in the current study. This number includes the averaged value used for reporting and summary generation (in this case the study has three repeats LVEDV in apical 4 chamber view and an additional averaged measurement)

3.6.3 Image View



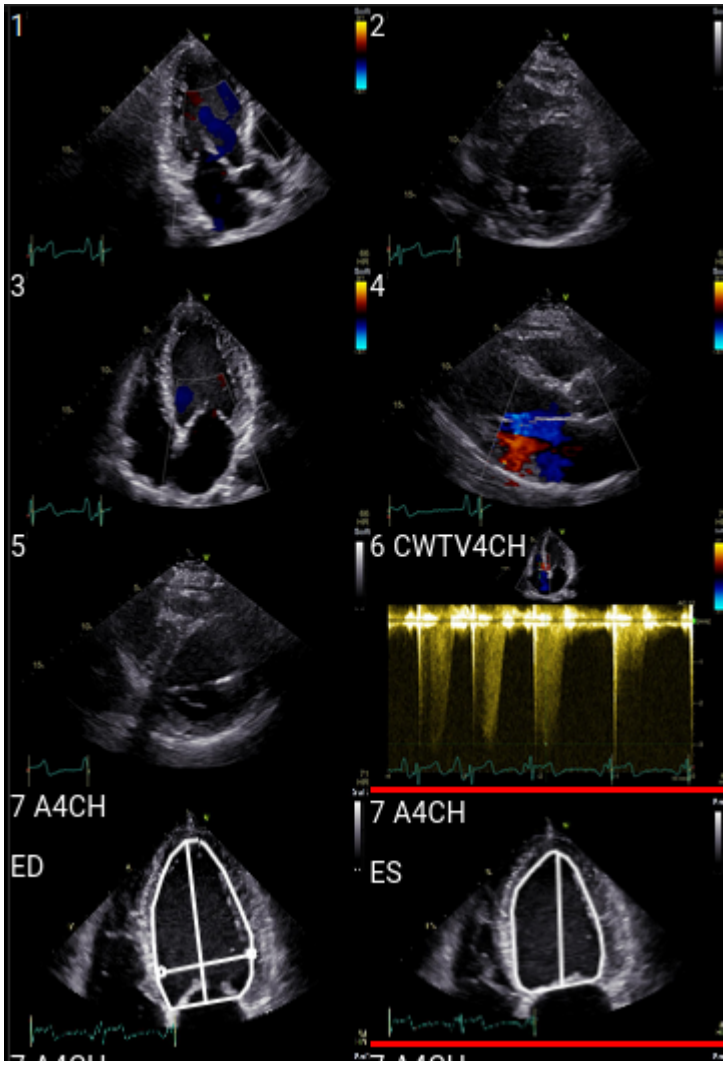
Element	Explanation
	Shows all measurements that have been made in this image.
	Hide/expand list of measurements.

Element	Explanation
	Measurement has been made in another frame of this image. Clicking on this measurement will scroll the video to the frame containing the measurement.
	Measurement has been made in the current frame.
	Delete this measurement
	Video playback bar
	Predicted end-diastolic and end-systolic frames. Clicking on text will change current frame to the selected frame.
	Starting from the left: ● Go to first frame ● Go one frame backward ● Play/stop video ● Go one frame forward ● Go to last frame
	Number of current frame / total number of frames.
	Current frame in the context of video. Slide this element to change the current frame.
	Go to next image

Element	Explanation
	Go to previous image

3.6.4 Right Sidebar

The right sidebar shows image views of a particular study.



4. WORKING WITH LIGENCE HEART

4.1 How to acquire images

A comprehensive guide on standardized acquisition of 2D TTE image views can be found in the article by the American Society of Echocardiography “Guidelines for Performing a Comprehensive Transthoracic Echocardiographic Examination in Adults: Recommendations from the American Society of Echocardiography 2018”, which can be accessed for free here: https://www.asecho.org/guideline/guidelines-for-performing-a-comprehensive-transthoracic-echocardiographic-examination-in-adults/

Please consult the publication for more information.

CAUTION

Ligence holds no liability for wrongly acquired image views uploaded to the Ligence Heart.

4.2 Logging on

When your system administrator has assigned your Ligence Heart username and password, you can access Ligence Heart. Your Ligence Heart system administrator should ensure you can access the server for your daily routine work.

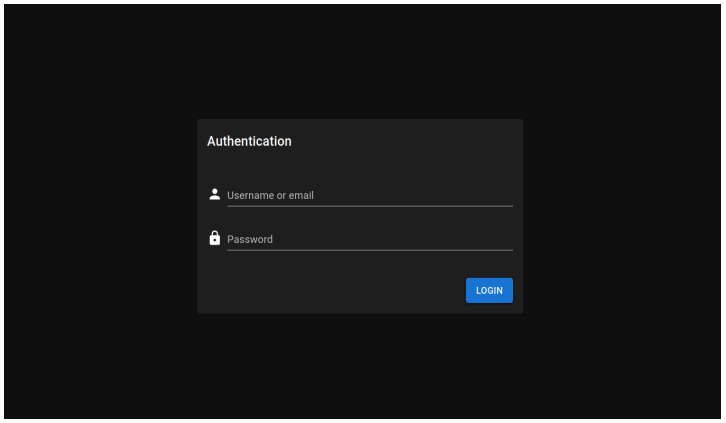
NOTE

Be aware that Ligence Heart enforces the following password policy:

- Your password must contain at least 8 characters.
- Your password must contain at least one uppercase, or capital, letter (ex: A, B, etc.).
- Your password must contain at least one lowercase letter.
- Your password must contain at least one number digit (ex: 0, 1, 2, 3, etc.) or special character (ex. $, #, @, !,%,^,&,*,(,)).

The following steps should be performed when logging on:

1. Open the application through a supported web browser (Google Chrome, Safari, Microsoft Edge) at http://local_area_network_ip_or_name or any other address as stated by your institution.
2. A user will be directed to the Login Authorisation page. A user is asked to enter login credentials (account name and password) into the relevant fields.
3. Click “Enter” button on your computer or press “Login”.



4.3 Settings Menu

The Settings menu can be accessed by pressing the three dots icon on the top right corner of the Navigation bar.

Upon pressing the Settings button, a drop-down menu will appear.

The drop-down menu dialogue contains the following items:

- About: shows the relevant and latest information about the product and manufacturer.
- Report: reports an issue.
- Help: directs a user to the latest version of the IFU.
- License agreement: directs a user to the End-User License Agreement.

4.4 Account Menu

The Account menu can be accessed by pressing the person icon on the top right corner of the Navigation bar.

Upon pressing the Account button, a drop-down menu will appear.

The drop-down menu dialogue contains the following items:

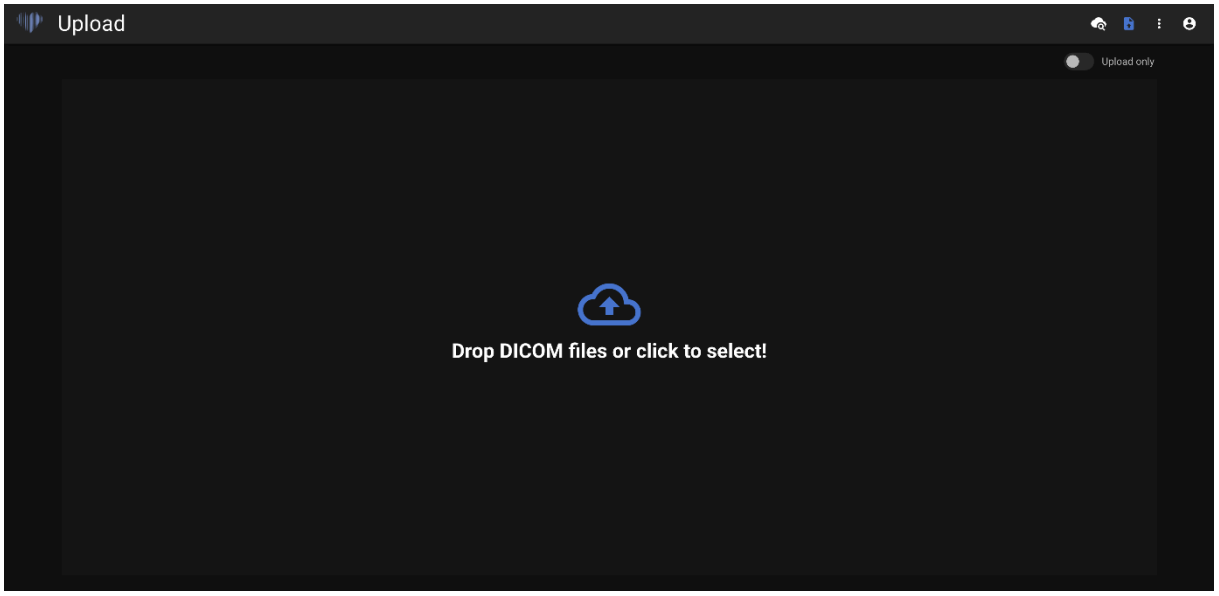
- Change password
- Logout

4.5 Upload the study

You can upload DICOM files directly from your computer into the Ligence Heart by navigating to the upload view. The Upload view can be accessed by pressing the upload icon on the top right corner of the Navigation bar.

4.5.1 How to upload a study?

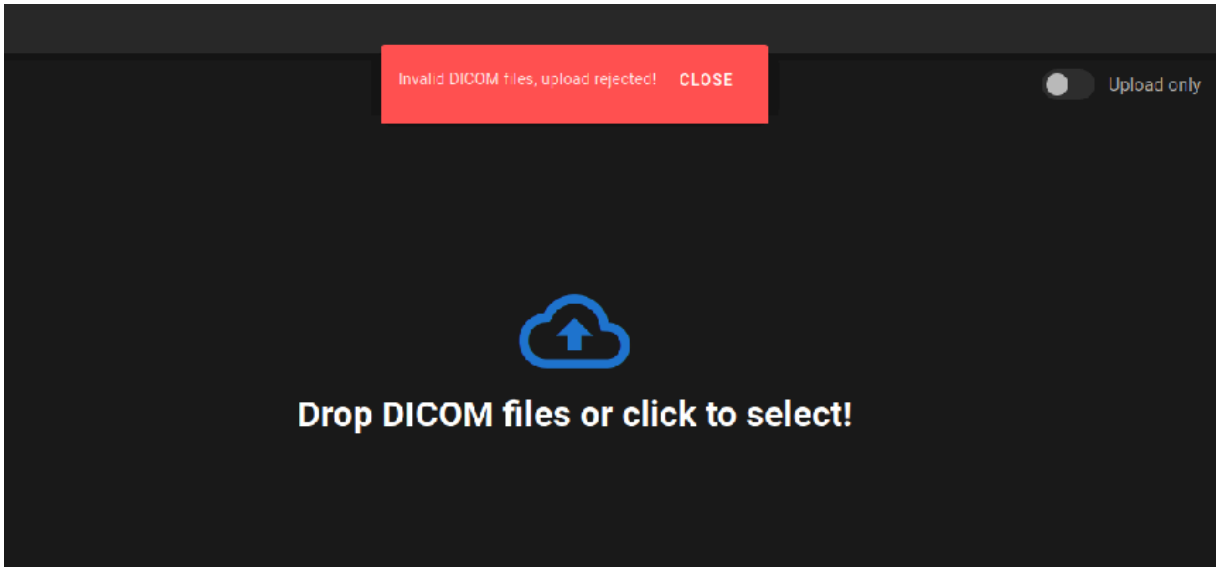
To upload a study simply drag and drop your DICOM format file or press on the blue icon and upload it from your computer.



The upload may take several moments and you should see a screen like the one below.

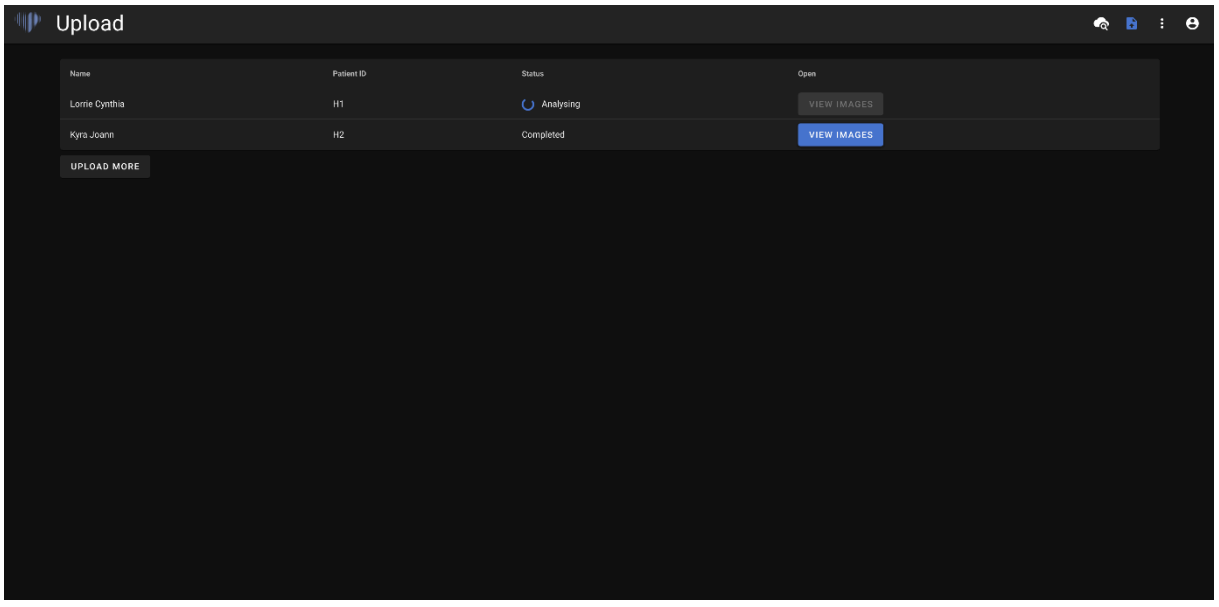
4.5.2 Limitations of upload functionality

It is allowed to upload up to 10 studies at once.



The same DICOM files of DICOM files belonging to the same echocardiographic study can only be uploaded once. Otherwise an error message will be displayed.

4.5.3 Upload completed



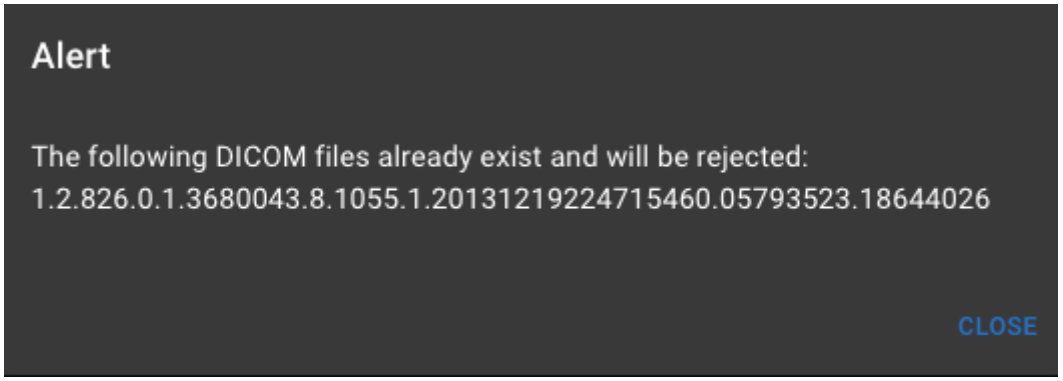
A list of studies uploaded is displayed. Once the study is analysed, you can click “view images” to review.

4.5.4 Invalid files uploaded

In specific cases, Ligence Heart may reject uploaded DICOM files and provide an on-screen alert explaining the reason. These validation checks are in place to ensure compatibility, data integrity, and accurate analysis. The following rejection scenarios may occur:

4.5.4.1. Duplicate DICOM Upload

- If a DICOM file has already been uploaded previously, the system will detect the duplicate based on its unique identifier (SOPInstanceUID) and reject it. A message will be displayed:

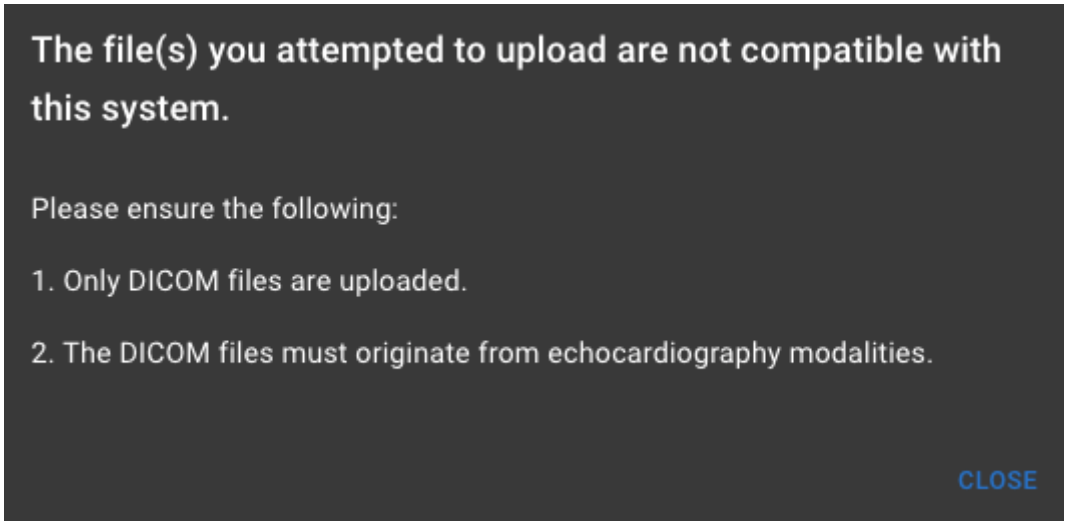


What to do

- Check if the study is already available in the worklist.
- If re-uploading is necessary (e.g., after changes), ensure the file has a different SOPInstanceUID assigned during export.

4.5.4.2. Unsupported Modality or Transfer Syntax

If the file is not from an echocardiographic modality or is encoded using an unsupported transfer syntax (e.g., JPEG 2000), Ligence Heart will reject the upload and display a message like:



What to do

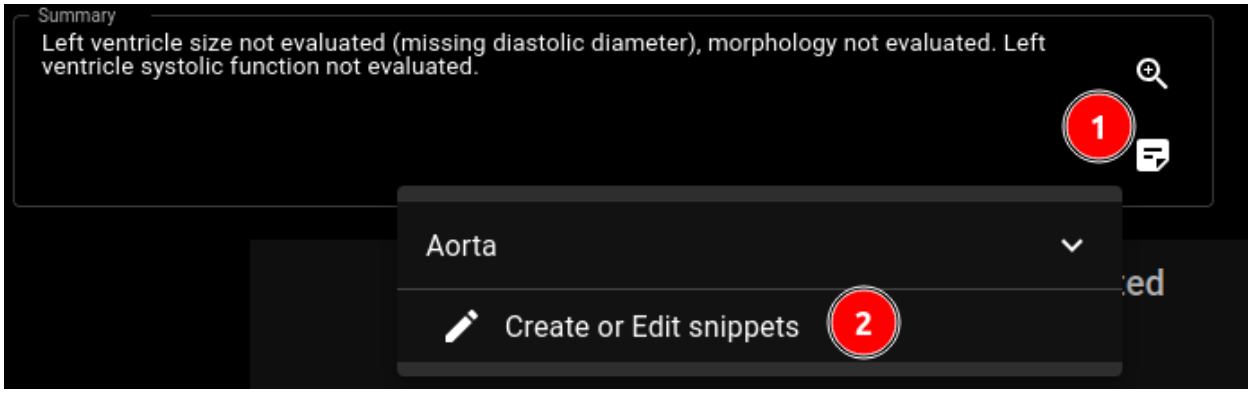
- Confirm that the file was exported from an echocardiographic study (TTE).
- Re-export the study using a supported transfer syntax,
- Contact your PACS administrator or ultrasound vendor if unsure how to change export settings.

4.6 Text Snippets

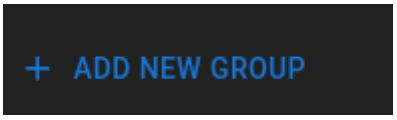
Ligence Heart supports creating text snippets to be used in summary or other description fields.

4.6.1 Create Text Snippets

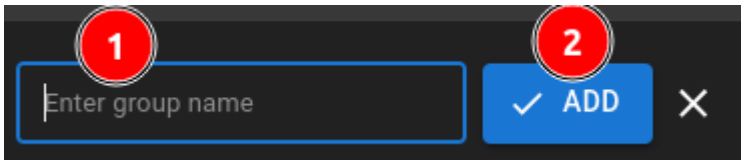
- Click on the Snippets button
- Click “Create or Edit snippets”



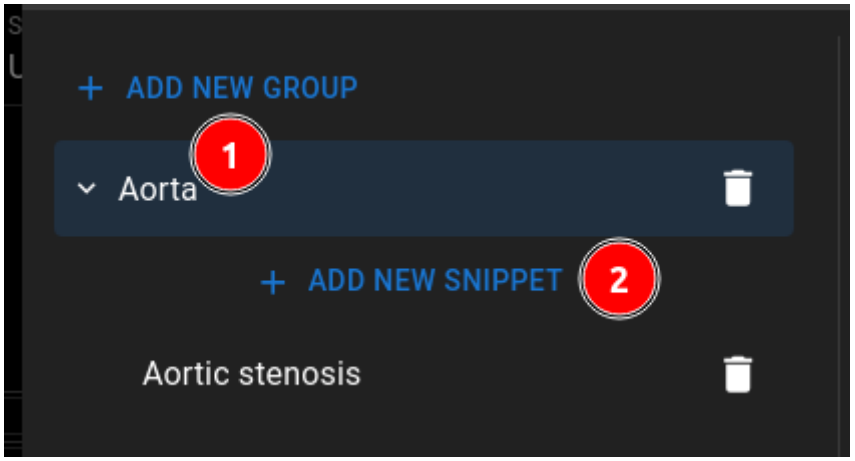
- (Optional) Click “Add new group”



- Enter the name for the group
- Click “Add”

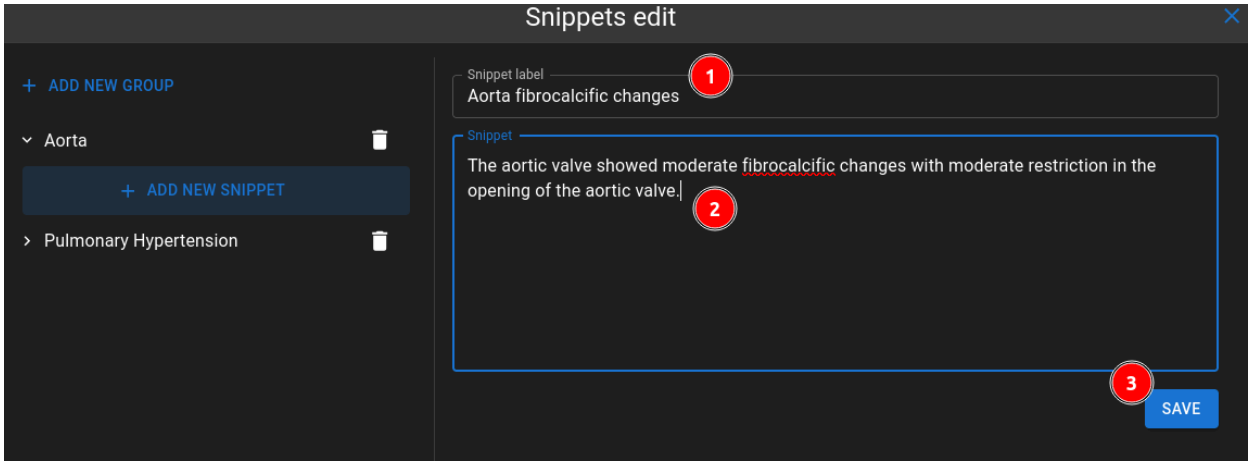


- Select the group to expand it
- Click “Add New Snippet”

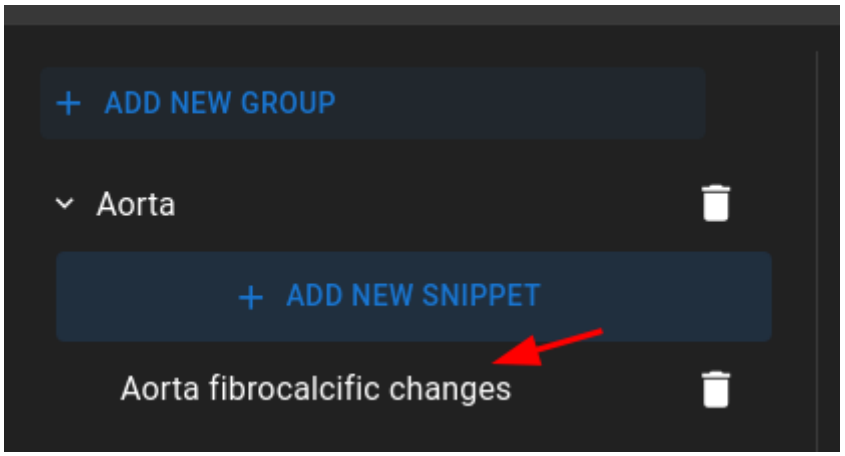


- Enter snippet name

- Enter snippet text
- Click “Save”

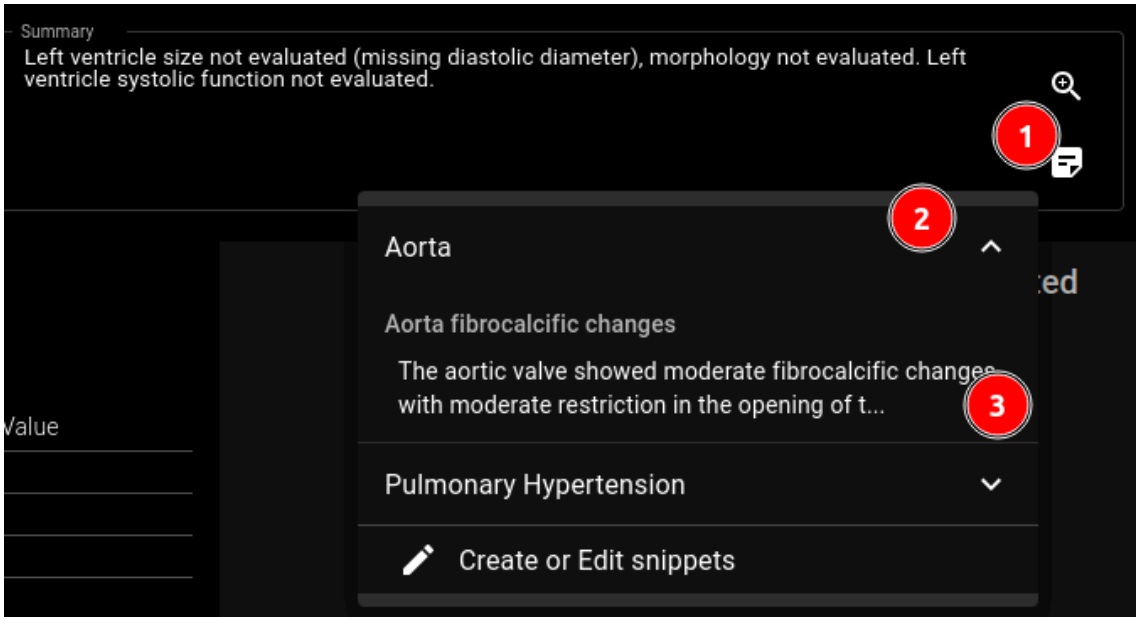


- The new snippet will be shown in the snippet group list

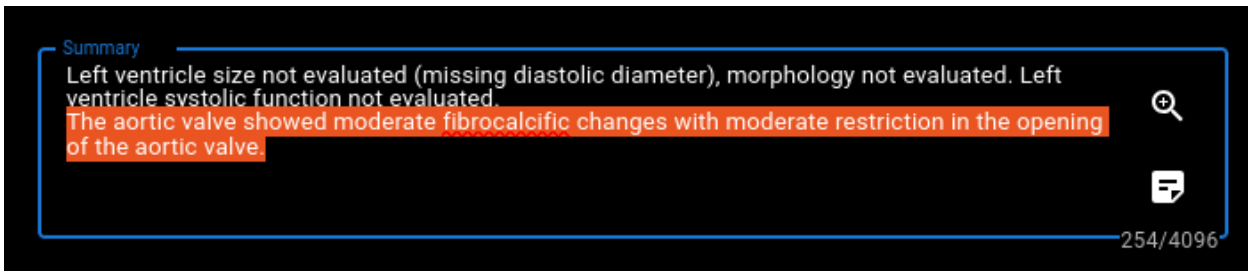


4.6.2 Import Text Snippets

- Click Snippets button
- Select group
- Click on the relevant snippet

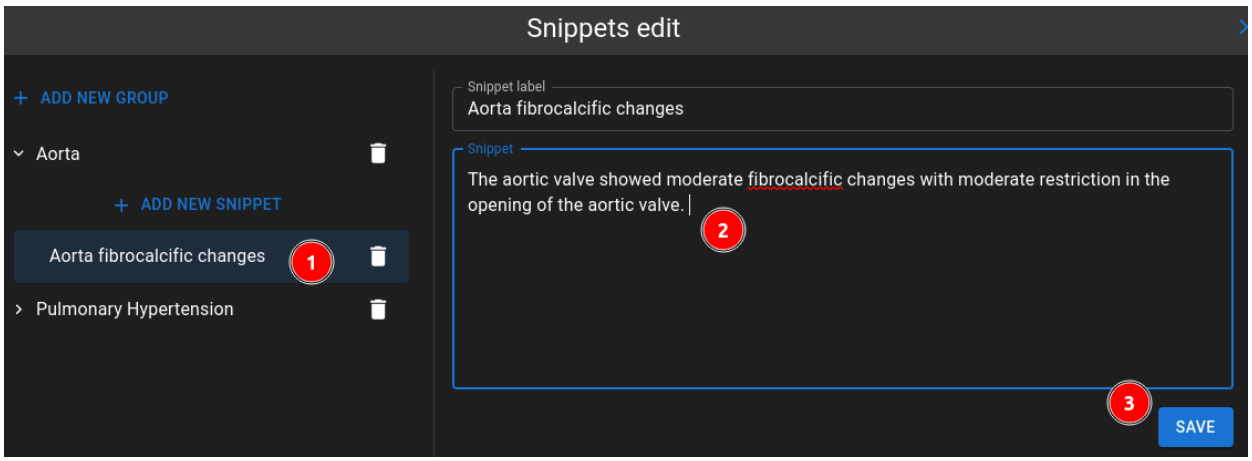


The snippet will be added to the end of the text field.



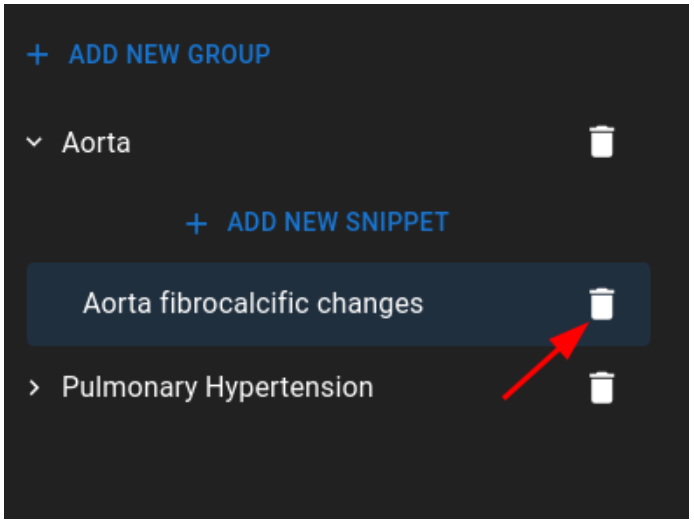
4.6.3 Edit Text Snippets

- Select a snippet
- Update contents
- Click “Save”



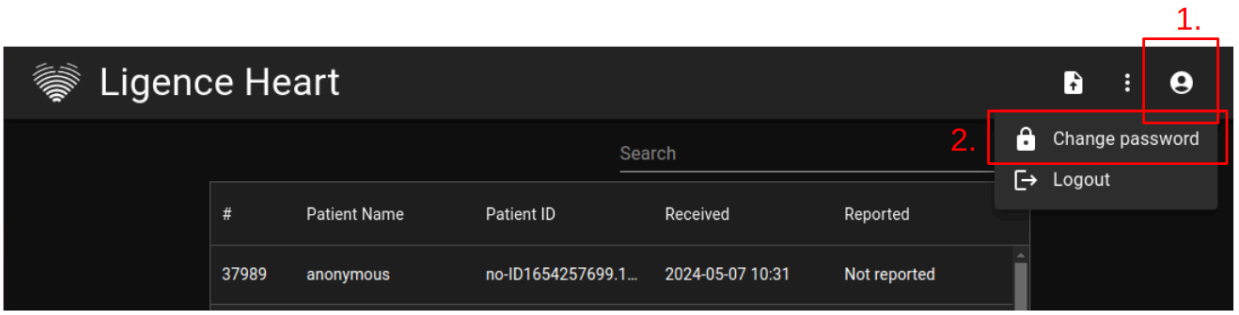
4.6.4 Delete Text Snippets or Snippet Groups

Use the recycle bin button to delete a snippet



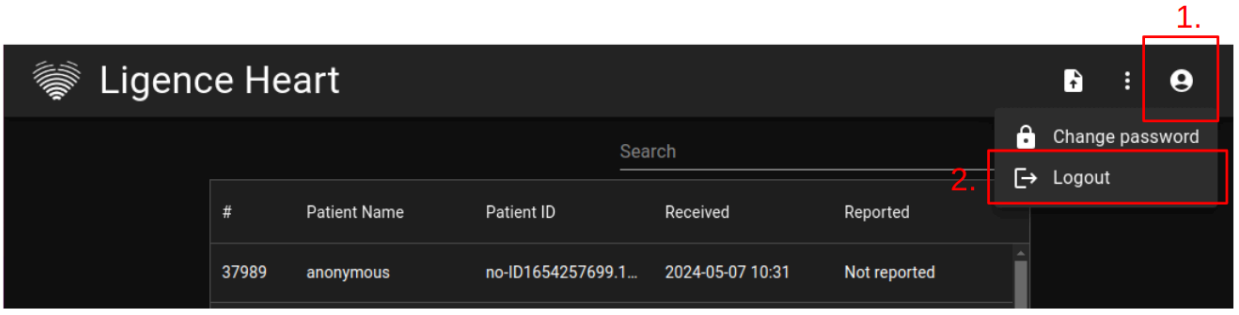
4.6 Changing Password

Your password can be changed by first pressing the person button on the top right corner of your Navigation Bar and then pressing on the change password button.



4.7 Logging Off

To log off from the software, simply press the person button on the top right corner of the screen and the logout button in the drop-down menu.



Use the Log Off option if you have finished working with the program. Logging off from the Search window, closes all the Viewer windows that were opened from the Search window and destroys the browser session data.

NOTE

Please notice, that closing the program without Log Out is not safe and may lead to unauthorized access to medical data.

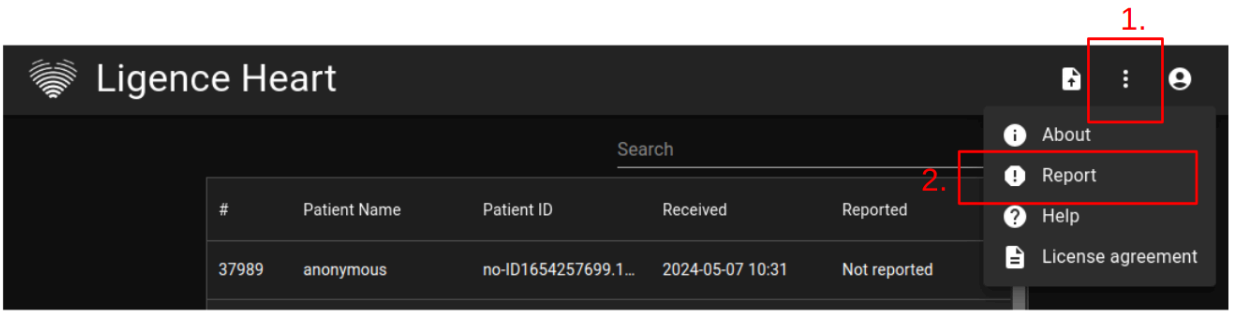
4.8 Locking the software

When you are done working with the software or have to leave for a short period of time we recommend logging off either way to prevent unwanted use by other people.

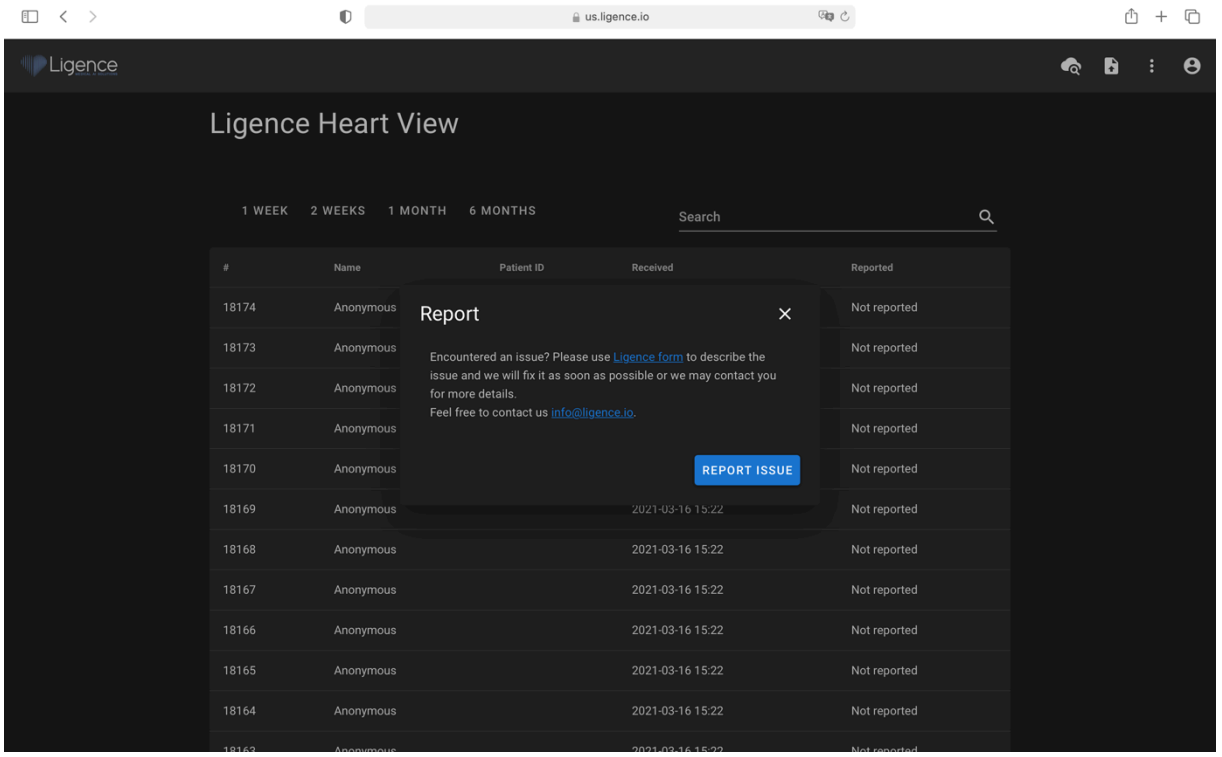
4.9 Report an issue

You can report an issue to Ligence if you meet any inconvenience when using the Ligence Heart image viewer.

To report an issue, press the Settings button on the top right and press the Report button in the dialogue.



A Report window will appear suggesting possible actions.



Simply press the blue button Report Issue on the bottom right of the pop-up window and you will be directed to https://www.Ligence.io/submit-issue website where you can describe your issue and leave your contact details. A representative of Ligence will try to resolve this issue as soon as possible and may contact you in order to understand your issue better.

NOTE

Please check your Service Level Agreement for more information on work hours of Ligence.

NOTE

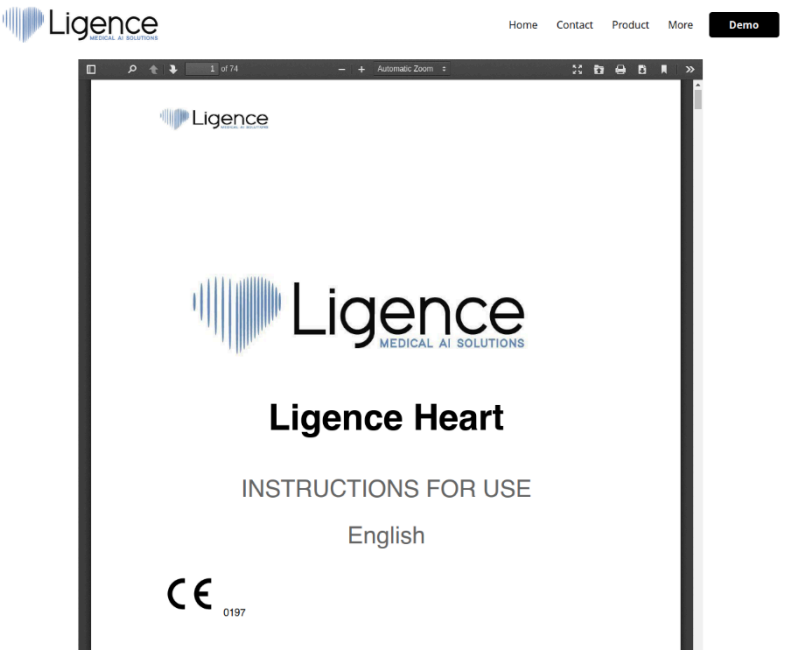
Depending on your issue it may be resolved in varying timeframe. Please consult your Service Level Agreement for more information.

4.10 Help

If you find trouble using the Ligence Heart image viewer you can always consult the IFU

You can find IFU in the Legal and Helpful Information dialogue in the Navigation bar.

You will be directed to the website where the latest version of the IFU can be found. Please consult the IFU for more information on the functions and how to operate the Ligence Heart image viewer.



4.11 Navigation Bar buttons and functions

This section covers the Navigation Bar in the Working View. It provides easy access to the most often used functions on the screen

All the buttons and functions are summarized in the picture and table below:

Icon	Name	Function
	Logo	Navigates to landing (lobby) view.
	Windowing	Allows the user to change the brightness and contrast of an ultrasound image. For the function to take effect the user must position the mouse cursor within boundaries of an ultrasound image, press and hold the left mouse button and move the cursor simultaneously in either direction. Moving the cursor along the x-axis causes a change in brightness, whereas moving the cursor in the y-axis causes a change in the contrast.
	Zoom in/out	Allows the user to zoom in/out the selected ultrasound image frame. When toggled, move the mouse cursor onto the frame. Press and hold the left mouse button and move the cursor in the vertical axis. Moving the cursor up zooms in the frame whereas moving it down zooms out the frame.
	Pan	Allows the user to move the ultrasound image frame stack across the screen. Press and hold the image with the left mouse button and move it to any side to move the image stack.
	Toggle label visibility	Enables/disables measurement labels on the measurements (lines, polygons etc.). By default labels are disabled.
	Toggle annotation visibility	Hides/shows annotations on frames.

Icon	Name	Function
	Lock/unlock annotations edit	When locked, annotations cannot be made. Edit mode allows annotations to be made.
	Report	Enters the Report View.

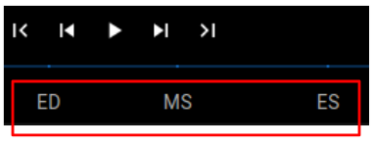
4.12 Workspace buttons and functions

The workspace buttons are located at the bottom of the screen.

The workspace buttons allow you to scroll the frame stack/cine and navigate the image views.

The buttons and their function of the workspace are summarized in the table below.

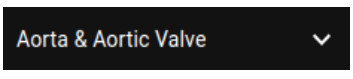
Icon	Name	Function
	Jump to the first frame	Scrolls back the image stack to the very first frame.
	Move back one frame	Moves to the previous frame.
	Play cine	Auto plays the frame stack in a continuous loop.
	Move forward one frame	Moves to the next frame.
	Move to the last frame	Jumps to the last frame of the stack.

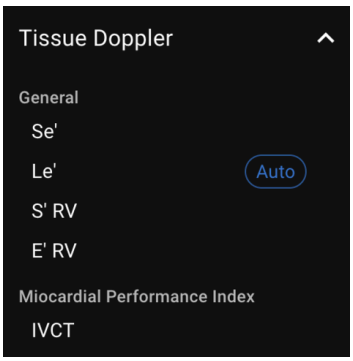
	Navigate to the previous image view	Opens the previous image view.
	Navigate to the next image view	Opens the next image view.
	Heart phase select	Allows the user to move to either ES or ED frame if one is marked on that image.

4.13 Left sidebar buttons and functions

Left sidebar contains all the necessary tools to effectively work with an echocardiogram study:

All the buttons and functions are summarized in the table below:

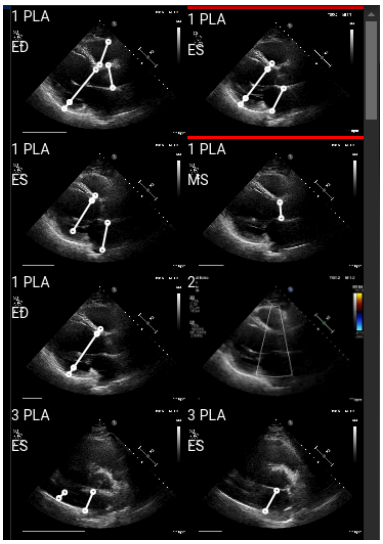
Icon	Name	Function
	Distance measurement	Press it to manually measure distance between two points.
	Area measurement	Press it to manually measure the area of the region of interest.
	Volume measurement	Press It to manually measure the volume of the region of interest.
	Velocity measurement	Press it to manually measure the velocity of the region of interest.
	Anatomical structure menu buttons and drop-down dialogues	Allows you to manually choose the anatomical structure of interest and see the measurements performed for that structure.

Icon	Name	Function
	Drop-down menu dialogue of measurements listed by anatomical structures	Appears when an anatomical structure is chosen in the menu above. Shows all the supported measurements and the number of a frame a particular measurement was performed in. For automated measurements there is a “Auto” button. When activated, it makes automated measurement of selected label on currently active image frame. If it is not possible to make automated measurement, a warning message is displayed, and manual tracing is activated.

4.14 Right Sidebar buttons and functions

Right Sidebar displays all image views of a particular study and allows easy navigation between them.

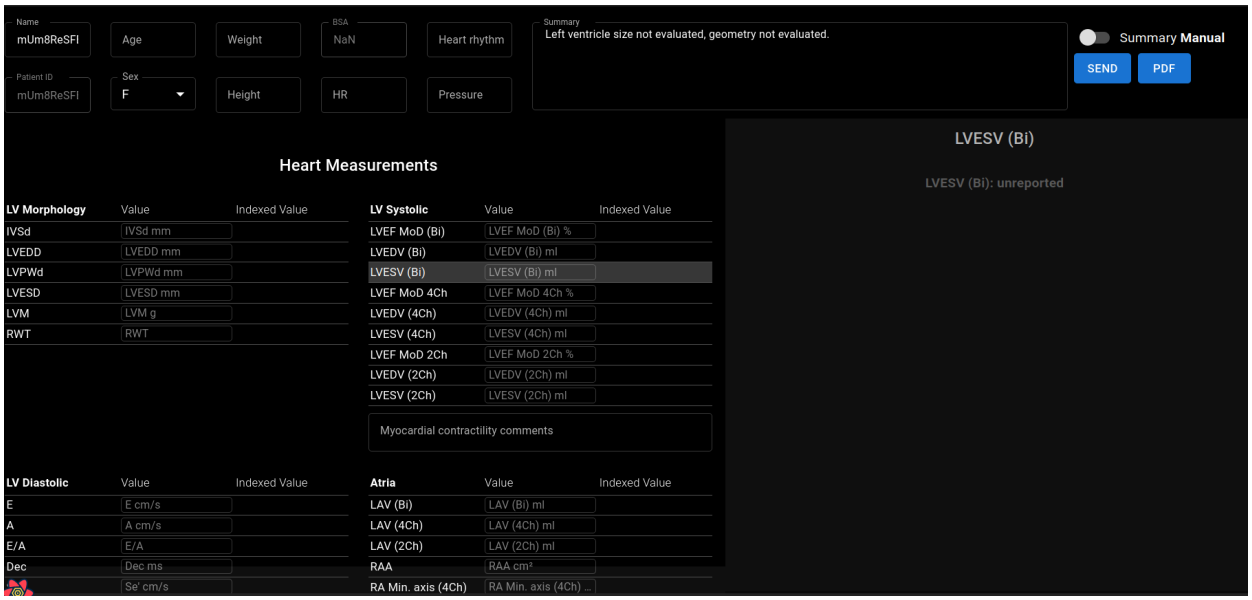
All the buttons and functions are summarized in the table below:

Icon	Name	Function
	Image view display	Allows to select the image view of interest. Opens the image view of interest. The selection of image views can be scrolled from top to bottom and from left to the right. The images are sorted by the date received.

4.15 Study reporting

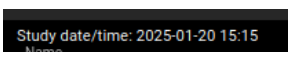
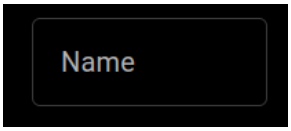
To enter the Report View press the View Study Report button in the Navigation bar.

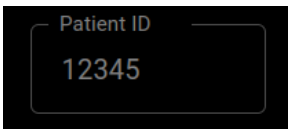
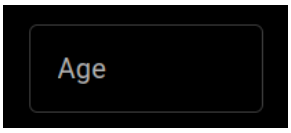
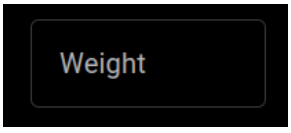
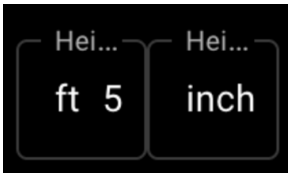
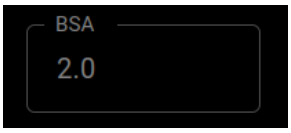
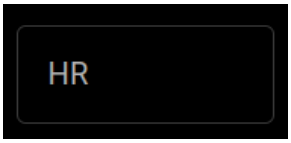
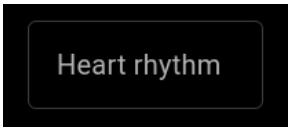
If you decide to go back to the Working View press the Back to study images button.

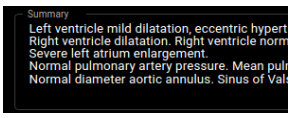


The study report is largely divided into three areas seen on the screen. At the top, you can find general information about the patient, such as name, age, sex, height, weight, summary and other high level information. At the bottom left, you will find the measurements overview, a structured grid of measurements grouped by anatomical structure (i.e. Heart or Valve) and subsections within each anatomical structure. At the bottom right you will find a selected measurement view, which allows you to explore each selected measurement in more detail, review source images and make quick edits to annotations.

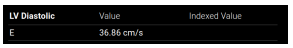
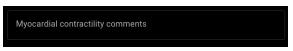
All the fields and functions of the Report View top panel are summarized in the table below:

Component	Name	Function
	Study date and time	Shows when the study was received by software
	Name	Allows you to read or enter patient name

Component	Name	Function
	Patient ID	Allows you to read patient ID
	Age	Allows you to read or enter patient age
	Sex	Allows you to read or select patient sex
	Weight	Allows you to read or enter patient weight in pounds (lbs).
	Height	Allows you to read or enter patient height in feet and inches.
	Body surface area (BSA)	Automatically displays body surface area when weight and height data is is available. Displays ‘NaN’ if BSA has not been calculated, or calculated with an error.
	HR	Allows you to enter or read patient heart rate.
	Heart rhythm	Allows you to enter specifics about the heart rhythm.
	Pressure	Allows you to read or enter patient systolic and diastolic blood pressure in mmHg.

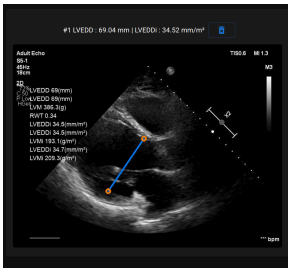
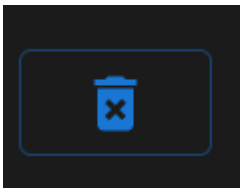
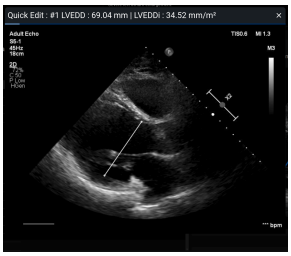
Component	Name	Function
	Summary field	Allows you to enter the summary report of your study. If left unentered, a report is generated automatically.
	Auto summary toggle	Allows you to toggle between automatically generated and manually entered summary
	Snippets button	Use the text snippets functionality
	Enlarge summary field	Opens a dedicated screen for summary editing

All the fields and functions of the Report View bottom left panel are summarized in the table below:

Component	Name	Function
	Anatomically grouped measurements	Allows you to review measurement values and select particular measurements for detailed analysis
	Non-indexed measurement value	Non-indexed measurement value within normal range for your review
	Non-indexed measurement value	Non-indexed measurement value outside of normal range for your review
	Indexed average measurement value	Indexed measurement value that is averaged of multiple measurements for your review
	Measurement that has no value	Measurement that has no value, but where you can provide a value by entering it manually
	Free text field	Free text field for you to provide more detailed notes

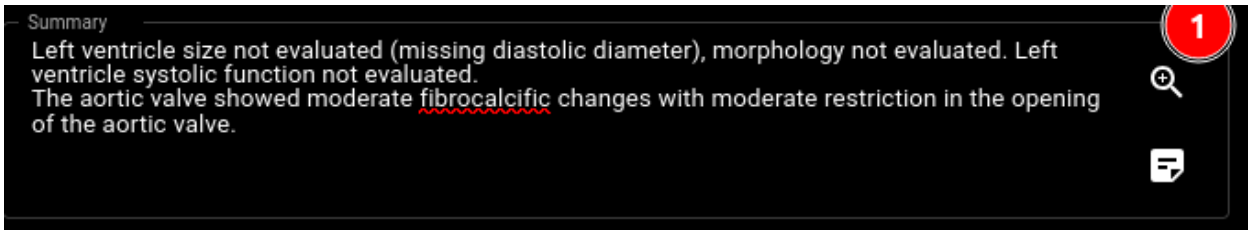
Component	Name	Function
	Valve stenosis or regurgitation grade selector	Allows you to select stenosis or regurgitation grade for each valve

All the fields, buttons and functions of the Report View bottom right panel are summarized in the table below:

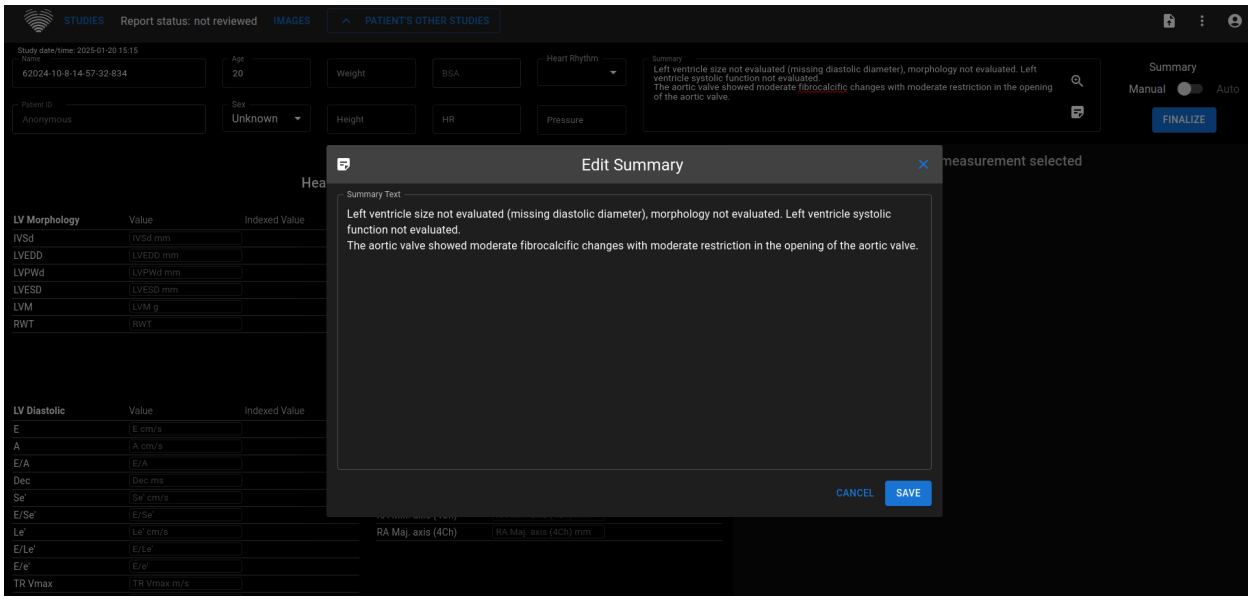
Icon	Name	Function
	Selected measurement header	Specifies the currently selected measurement and its values in more detail
	Selected measurement source	Displays each individual image, its annotations and value for your currently selected measurement
	Delete measurement button	Allows you to delete an individual measurement. Upon clicking this button you will be presented a screen to confirm your intent to delete the measurement. Deleted measurement can’t be recovered.
	Edit measurement annotations buttons	Displayed upon hovering your mouse cursor on the measurement image. Allows you to modify the annotations corresponding to a particular measurement
	Quick edit view	Allows you to modify the annotations by dragging the lines or vertices

4.16.1 Enlarge summary edit field

- Click on the enlarge summary field button



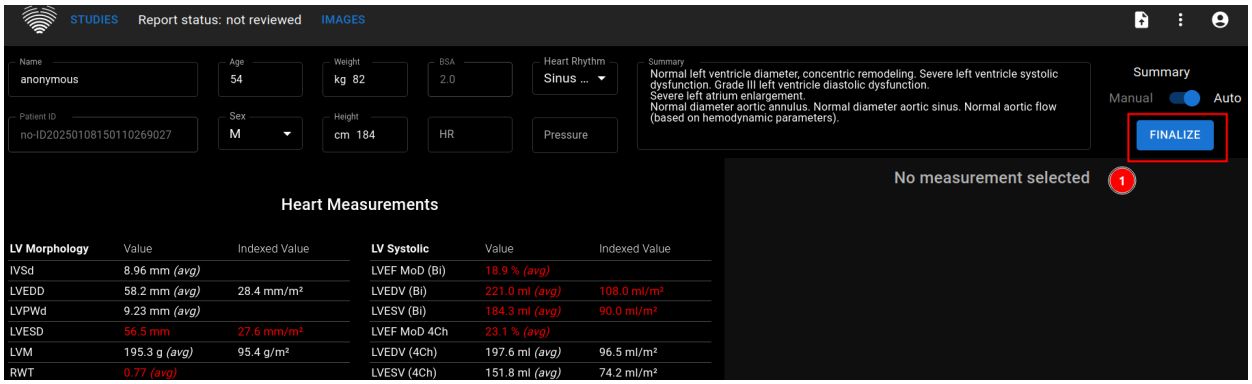
Edit summary in a dedicated screen.



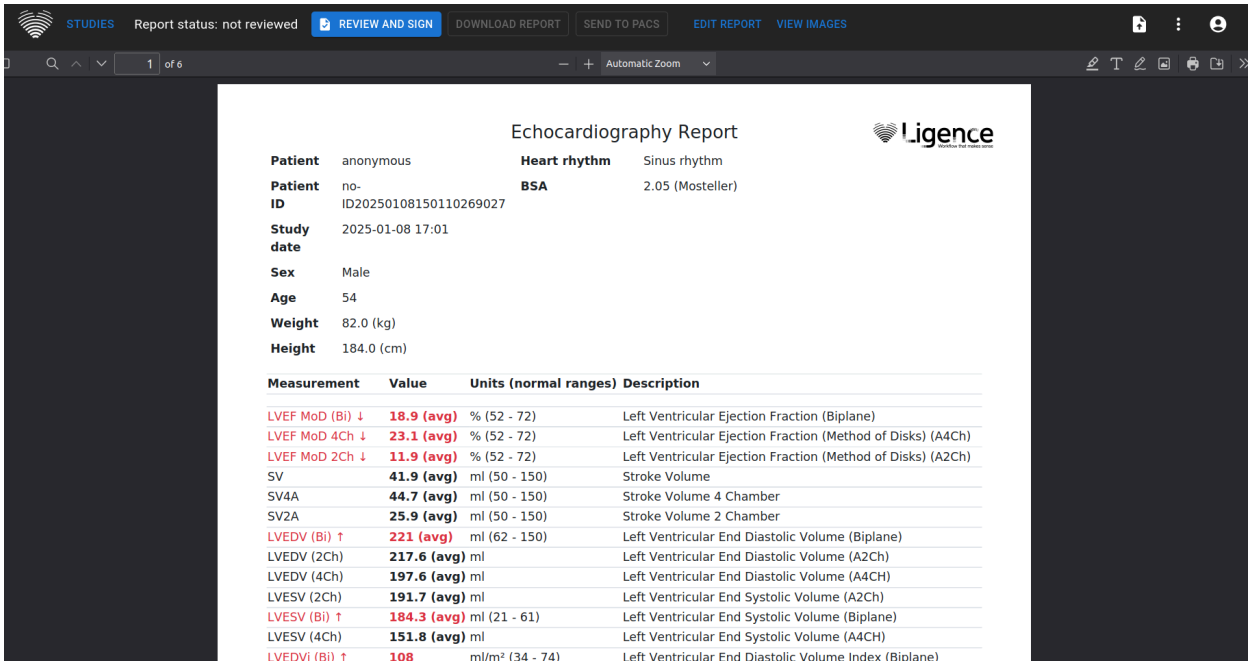
4.16 Report PDF View

This is only available for Cardiologist users.

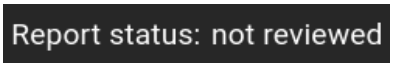
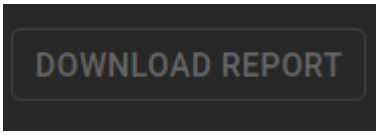
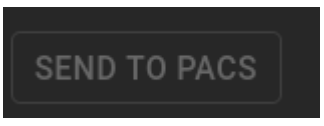
If you want to finalize a report for sending to PACS/printing you can click the “Finalize” button.



This will open the Report PDF view



The specific fields and functions of the Report PDF View top panel are summarized in the table below:

Icon	Name	Function
	Report status	Shows the current status of the study report
	Review and sign button	Click here to sign the report
	Return to studies list button	Go to Lobby View
	Download report button	Download the signed report. Only available after signing the report.
	Send to PACS button	Send the signed report. Only available after signing the report.

EDIT REPORT	Edit report button	Go to Report view
VIEW IMAGES	View images button	Go to Workspace view

4.17 Main Interface Functions

4.18. 1 Scroll stack

Scroll stack function: upon hovering on a displayed cine a user can use the computer mouse wheel (or two fingers on a trackpad) to scroll through a stack of images.

4.18.2 Making measurements

Annotation function: wh.1 en a certain annotation is selected the user can label separate frames. Annotations can be found in the annotation pop-up menu slot. When selecting measurements – the annotation label is selected automatically. There are 4 different types of annotations:

1. Lines
2. Polygons
3. Points
4. Text (for cycle marking or other important labels)

The annotations are used to label heart's anatomical structures using straight lines, polygons and points. There are two ways to make a line and polygons annotations:

1. Start by clicking left mouse button, then drag the mouse, but do not release left button, when you are at finish point, release left button and the annotation is complete.
2. Start by clicking left mouse button, then release the button, then move mouse to the finish point, then click left mouse button and release it, the annotation is complete.

Measurements are automatically saved after being drawn. After drawing annotation you can move annotation handles. Polygon annotation handles can be added, moved or removed after annotation is drawn. Press ctrl keyboard element and pushing on the handle to remove annotation. Press ctrl and push on the polygon line between handles – new handle should appear. Press left mouse button on the handle to move it.

4.18.3 Draw area measurement

The annotation should be closed – have the same starting and ending point. You can do this by double clicking on a point where you want to complete the annotation or joining start and end points of the annotation by a single click.

4.18.4 Draw volume measurement

The drawing procedure begins the same as with area measurement. After annotation is completed, an axis appears. The user can change axis peak point by moving it's handle.

Ligence Heart has pre-selected annotations for various measurements.

4.18.5 Grade measurements

For manual regurgitation and stenosis measurement a dialog appears, and user can select appropriate measurement grade. Results are saved after saved button is pressed. Grade measurement can be removed by selecting "No stenosis" or "No regurgitation" option and saving the result.

5.18.6 Delete annotation

Delete annotation: simply hover over the annotation you want to delete and press either "BACKSPACE" or "DELETE" key on your device keyboard.

4.18.7 Cancel drawing

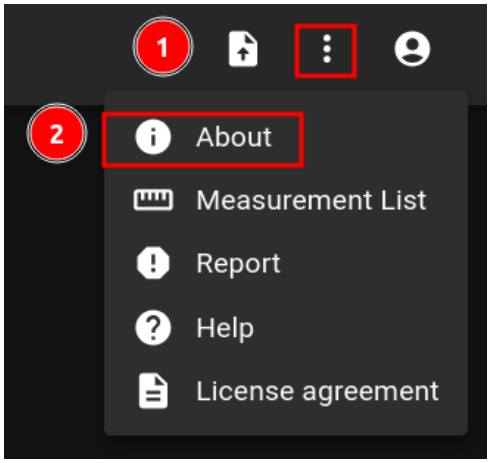
Press "ESC" key to stop drawing active annotation and remove it. Change annotation point

Change annotation point: choose the point you want to change, press and hold the left mouse button and drag it to the point of your choice.

4.18.8 About

About menu is found in the Settings drop down menu in the Navigation bar.

Clicking About menu opens the information window which shows the relevant and latest information about the product and the manufacturer.



The displayed information on:

Product:

- Product name
- Disclaimer on the release version
- Software version
- Release notes
- Date built on
- UDI number
- Certificate
- Notified body ID
- License owner
- Next update

Manufacturer:

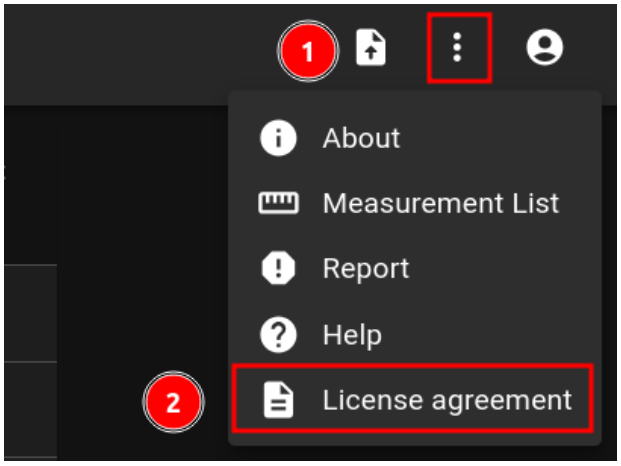
- Name of the manufacturer
- Address
- Email
- Website URL

4.19 Decommissioning of Software

In order to fully remove the device from an on-premise deployment please contact technical support support@ligence.io .

4.20 End-User License Agreement

End-User License Agreement can be found in the Settings drop down menu dialogue in the Navigation bar.



You will be directed to the https://www.Ligence.io/Ligence-heart-eula site where you can read the End-User License Agreement.

NOTE

You are automatically agreeing with the terms and conditions of using the Ligence Heart software when starting to use it.

4.21 User Registration

NOTE

License registration is required for legal software use.

4.21.1 How to register with Ligence Heart?

Please refer to your institution's information technology department for your account login and password. The account logins and passwords are created and assigned by the administrator of your institution.

Please refer to your institution's information technology department for your account login and password. The account logins and passwords are created and assigned by the administrator of your institution. The system administrator holds the responsibility to read and conform to the terms of EULA and ensure that the software is used according to the terms and conditions in his or her institution.

You can open the license agreement by pressing the Legal and helpful information button and then License agreement.

5. CYBERSECURITY INSTRUCTIONS AND SPECIFICATIONS

5.1 Cybersecurity

Ligence Heart uses industry-standard instructions to protect the software, including its system development servers, and the data on those servers by using access enforced firewalls, and SSH secure communications.

- The system architecture is designed to prevent data compromise.
- NIST Recommends standards are used to identify and monitor cybersecurity risks. The company maintains regular security patches. Customers will be notified of potential uncontrolled risks and corresponding updates through Ligence Heart's coordinated vulnerability disclosure process. Updates will be performed by Ligence Heart through a controlled and communicated process.
- User should strictly follow the instructions and technical notes listed in this section to reduce any cyber security risk to the system.

Your safety and the privacy of your information are of the highest importance to Ligence Heart. To help us ensure that our product work correctly and securely, please consider these good practices and precautions to help keep your computer system safe and secure.

5.2 Device Security and User Responsibility

- It is the responsibility of the authorized user to ensure that the device with access to the application is not left unlocked, or otherwise unsecured when not in use, to ensure that non-authorized medical, professional, or otherwise unapproved personnel are not exposed to, or gain access to, ePHI.
- Operators have access to patients' ePHI and must not take snap-shots, screenshots or pictures (e.g. using another device) of any information viewed through the device.
- Keep your PC system up to date with the most current updates for your operating system and browser.
- Do not disclose your password to anybody. Ligence Heart support representative will never ask for your password. If you get a request to disclose your password by email, please contact the support representative immediately and do not reply to the email.
- Change your password immediately if you think your password has been compromised.
- Use reputable security software on your PC that provides protection against viruses, "adware" and other forms of malicious software ("malware").
- Take advantage of "software firewall" features in your security software as added protection for your PC.
- Use the strongest settings on your PC security software that you can use to help guard against accidental contact with malicious software.

5.3 Reporting Device Security or Privacy Breaches

Operators must contact Ligence Heart support team at support@ligence.io or dpo@ligence.io and disclose any suspected or confirmed privacy or security breaches.

When devices are lost, or unauthorized access is discovered or suspected, Ligence Heart support team support@ligence.io should be contacted.

Users should report unavailable service or prohibited access to information to Ligence Heart support team support@ligence.io.

5.4 Cybersecurity system description

The software system is designed to provide several features that protects the system against cyber threats:

1. The device is routinely scanned for known vulnerabilities and timely updates are provided.
2. The system is ready for use after installation by Ligence Heart technicians. No additional system configuration settings are required either for system operation or connection.
3. The software database is not accessible for the user, therefore no access to any system log files is permitted for the user.

5.5 Reporting security issues

If you believe you have discovered a vulnerability in our medical software or have a security incident to report, please contact us:

https://ligence.io/anonymous-security-event-report/ or

Mail: support@ligence.io or dpo@ligence.io

UAB Ligence DPO is responsible for data protection.

5.6 Performance Summary

The primary aim was to evaluate interchangeability of Ligence Heart automated measurements with reference/ gold standard echo core lab human measurements. The study evaluated the agreement between automated echocardiographic measurements generated by Ligence Heart and those obtained by trained human readers at an independent Northwestern Echocardiography Core Laboratory. The primary endpoints assessed agreement between the investigational device (Ligence Heart) and human raters for multiple echocardiographic parameters. The key metric was the individual equivalence coefficient (IEC), a reference-scaled measure of variability. An echocardiographic parameter derived via the automated workflow is considered acceptable if IEC < 0, and the upper bound of the 95% confidence interval is < 0.25.

This threshold reflects non-inferiority relative to human interpretation based on individual bioequivalence principles. In this context, equivalence refers to the condition where variability between Ligence Heart and human readings does not exceed the variability observed between human readers themselves (1-4).

All validated parameters met the pre-defined success criterion. IEC values and their 95% confidence intervals remained below the threshold when compared against triplicate expert reads from Echocardiography Core Laboratory. Thus, Ligence Heart validated measurements are considered interchangeable with human measurements.

References:

1. U.S. Food and Drug Administration (FDA). *Guidance for Industry: Statistical Approaches to Establishing Bioequivalence.* Center for Drug Evaluation and Research (CDER); January 2001. https://www.fda.gov/media/70958/download
2. Obuchowski NA. Sample size calculations in studies of test accuracy. Stat Methods Med Res. 2001;10(4):305–18.
3. Obuchowski NA. Receiver operating characteristic curves and their use in radiology. Radiology. 2014;229(1):3–8.
4. Association for the Advancement of Medical Instrumentation. ANSI/AAMI HE75:2021 Human factors engineering—Design of medical devices. Arlington, VA: AAMI; 2021.

DICOM images from a wide variety of manufacturers were used to validate Ligence Heart software. DICOM metatag data available in these files contained the following manufacturer and models:

Manufacturer	**Model**
GE	Vivid E9, Vivid i, Vivid S6, Vivid S70, Vivid E95, Vivid 7, Vivid q.
Philips	Affiniti 70C, Affiniti 70G, Epiq 7C, Epiq CVx, Epiq 5C, CX50, ie33, HP7500, SONOS. Transducers: S5_1, S2, X5_1, C5_2

Clinical-validation dataset's DICOMs utilized phased array probes, with transducer frequencies spanning from 1.4 MHz to 4 MHz.

Supportive external component-validation dataset:

Manufacturer	Model
GE	LOGIQ S-series 1-9, Vivid S5, Vivid i, Vivid E9, Vivid E95, Vivid S70, Vivid iq, Vivid S6, Vivid S7
Philips	EPIQ 5G, EPIQ 7C, EPIQ 7G, EPIQ CVx, iE33, HD15, QLAB, iU22, Affiniti 70G, CX50
Siemens	ACUSON Redwood, ACUSON SC2000
Canon / Toshiba	TUS-A400, TUS-AI900

Supportive external component-validation DICOMs utilized diverse probes, including convex and phased array types, with transducer frequencies spanning from 1.2 MHz to 5 MHz. The DICOM cine frame rates varied between 1 and 258 frames per second, averaging 35 FPS. DICOMs in supportive external component-validation were processed to demonstrate algorithm robustness but were not included in the statistical non-inferiority analysis (IEC).

6 ANNEX I

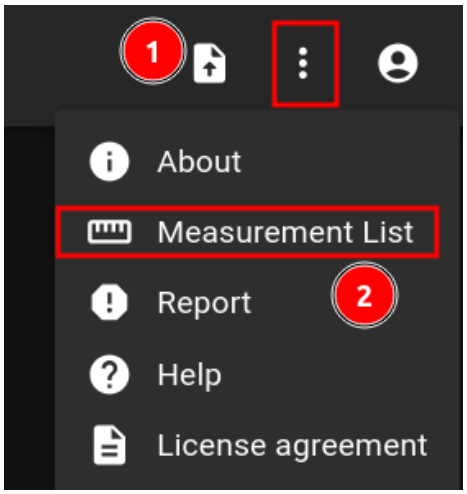
6.1 List of Measurements

The table below shows automated measurements that are validated as well as measurements that can be obtained manually.

✔ in Automated - measurements that have been validated in clinical trials and are considered interchangeable with human made measurements.

✔ in Manual - measurements that can be obtained manually using standard tracing tools.

The same table can be accessed from the software:



Abbreviation	Description	Automated	Manual
A	Transmitral A velocity		✔
E	Transmitral E velocity		✔
IVSd	Interventricular Septum (diastole)		✔
LAV (Bi)	Left Atrial Volume (Biplane)		✔
Le'	Lateral e' velocity	✔	✔
LVEDD	Left Ventricular End-Diastolic Diameter		✔
LVEDV (Bi)	Left Ventricular End Diastolic Volume (Biplane)	✔	✔
LVEF MoD (Bi)	Left Ventricular Ejection Fraction (Biplane)	✔	✔
LVESV (Bi)	Left Ventricular End Systolic Volume (Biplane)	✔	✔
LVPWd	Left Ventricular Posterior Wall (diastole)		✔
TR Vmax	Peak Tricuspid Regurgitation Velocity		✔
Se'	Septal e' velocity		✔
PV ACT	Pulmonary valve acceleration time		✔
AoA	Aortic Annulus		✔
AoS	Aortic Sinus Diameter		✔
AV VTI	Aortic Valve Maximum Velocity Time Integral		✔
E' RV	E prime right ventricular lateral wall		✔

IVSs	Interventricular Septum (systole)		✔
LAD (PLA)	Left Atrial Diameter (PLA view)		✔
LAD Min. axis (4Ch)	Left Atrial Diameter Minor Axis (A4Ch)		✔
LAV (2Ch)	Left Atrial Volume (A2Ch)		✔
LAV (4Ch)	Left Atrial Volume (A4Ch)		✔
LVB	Left Ventricular Basal Diameter		✔
LVEDV (2Ch)	Left Ventricular End Diastolic Volume (A2Ch)		✔
LVEDV (4Ch)	Left Ventricular End Diastolic Volume (A4CH)		✔
LVESD	Left Ventricular End-Systolic Diameter		✔
LVESV (2Ch)	Left Ventricular End Systolic Volume (A2Ch)		✔
LVESV (4Ch)	Left Ventricular End Systolic Volume (A4CH)		✔
LVOT VTI	Left Ventricular Outflow Tract Velocity Time Integral		✔
LVPWs	Left Ventricular Posterior Wall (systole)		✔
RVOT-PROX	Right Ventricular Outflow Tract Proximal Diameter (PLA)		✔
S' RV	S prime right ventricular lateral wall		✔
AAo	Ascending Aorta Diameter		✔
AAoi	Ascending Aorta Diameter Index		✔

AMG	Aortic Mean Gradient		✔
AoAi	Aortic Annulus Index		✔
AoAr	Aortic Arch		✔
AoAri	Aortic Arch Index		✔
AoSi	Aortic Sinus Diameter Index		✔
APG	Aortic Peak Gradient		✔
AV Vmax	Aortic Peak Velocity		✔
AR PISA-Alias. Vel.	Aortic regurgitation proximal isovelocity surface area - aliasing velocity		✔
AR EROA	Aortic regurgitation effective regurgitant orifice area		✔
AR-grade	Aortic Valve Regurgitation Grade		✔
AR JA	Aortic regurgitation - jet area		✔
AR MG	Aortic regurgitation - mean gradient		✔
AR PG	Aortic regurgitation - peak gradient		✔
AR PHT	Aortic Valve Regurgitation Pressure Half-Time		✔
AR PISA-r	Aortic regurgitation proximal isovelocity surface area - radius		✔
AR VC	Aortic regurgitation - vena contracta		✔
AR Vol.	Aortic regurgitation Vol		✔

AR VTI	Aortic regurgitation - velocity time integral		✔
Area	Area		✔
AR Vmax	Aortic regurgitation - peak velocity		✔
AS-grade	Aortic Valve Stenosis Grade		✔
AV ACT	Aortic valve acceleration time		✔
AVA	Aortic valve area		✔
AVA (Planim.)	AVA (Planim.)		✔
AVAi	Aortic valve area Index		✔
DAo	Descending Aorta		✔
DAoi	Descending Aorta Index		✔
Dec	Transmitral E velocity Deceleration time		✔
Distance	Distance		✔
E/A	E/A ratio		✔
E/e'	E/e' average ratio		✔
E/Le'	E/Lateral e' velocity ratio		✔
E/Se'	E/Septal e' velocity ratio		✔
EI	Eccentricity index		✔
EI D1	LV short-axis diameter perpendicular to the septum		✔
EI D2	LV short-axis diameter parallel to the septum		✔

ET	Ejection Time		✔
FAC	Fractional Area Change		✔
HV	Hepatic Vein		✔
IVCcol (B)	Inferior vena cava collapse (BMode)		✔
IVCcol (M)	Inferior vena cava collapse (MMode)		✔
IVCde (B)	Inferior vena cava diameter during expiration (BMode)		✔
IVCde (M)	Inferior vena cava diameter during expiration (MMode)		✔
IVCdi (B)	Inferior vena cava diameter during inspiration (BMode)		✔
IVCdi (M)	Inferior vena cava diameter during inspiration (MMode)		✔
IVCT	Isovolumetric Contraction Time		✔
IVRT	Isovolumetric Relaxation Time		✔
LAA (2Ch)	Left Atrial Area (A2Ch)		✔
LAA (4Ch)	Left Atrial Area (A4Ch)		✔
LAAi (2Ch)	Left Atrial Area Index (A2Ch)		✔
LAAi (4Ch)	Left Atrial Area Index (A4Ch)		✔
LAD Maj. axis (4Ch)	Left Atrial Diameter Major Axis (A4Ch)		✔
LAEF	Left Atrial Ejection Fraction		✔
LAVi (Bi)	Left Atrial Volume Index (Biplane)		✔

LAVi (2Ch))	Left Atrial Volume Index (A2Ch)		✔
LAVi (4A)	Left Atrial Volume Index (A4Ch)		✔
LVEDA (2Ch)	Left Ventricular End Diastolic Area (A2CH)		✔
LVEDA (4Ch)	Left Ventricular End Diastolic Area (A4CH)		✔
LVEDAi (2Ch)	Left Ventricular End Diastolic Area Index (A2CH)		✔
LVEDAi (4Ch)	Left Ventricular End Diastolic Area Index (A4CH)		✔
LVEDDi	Left Ventricular End-Diastolic Diameter Index		✔
LVEDVi (Bi)	Left Ventricular End Diastolic Volume Index (Biplane)		✔
LVEDVi (2Ch)	Left Ventricular End Diastolic Volume Index (A2Ch)		✔
LVEDVi (4Ch)	Left Ventricular End Diastolic Volume Index (A4CH)		✔
LVEF MoD 2Ch	Left Ventricular Ejection Fraction (Method of Disks) (A2Ch)		✔
LVEF MoD 4Ch	Left Ventricular Ejection Fraction (Method of Disks) (A4Ch)		✔
LVESA (2Ch)	Left Ventricular End Systolic Area (A2CH)		✔
LVESA (4Ch)	Left Ventricular End Systolic Area (A4CH)		✔
LVESAi (2Ch)	Left Ventricular End Systolic Area Index (A2CH)		✔

LVESAi (4Ch)	Left Ventricular End Systolic Area Index (A4CH)		✔
LVESDi	Left Ventricular End-Systolic Diameter Index		✔
LVESVi (Bi)	Left Ventricular End Systolic Volume Index (Biplane)		✔
LVESVi (2Ch)	Left Ventricular End Systolic Volume Index (A2Ch)		✔
LVESVi (4Ch)	Left Ventricular End Systolic Volume Index (A4CH)		✔
LVM	Left Ventricular Mass		✔
LVMi	Left Ventricular Mass Index		✔
LVOT ACT	Left ventricular outflow tract acceleration time		✔
LVOTA (Doppler)	Left Ventricular outflow tract area (Doppler)		✔
LVOTAi (Doppler)	Left ventricular outflow tract area (Doppler) Index		✔
LVOT MG	Left Ventricular Outflow Tract Mean Gradient		✔
LVOT PG	Left Ventricular Outflow Tract Peak Gradient		✔
LVOTA (Planim.)	LVOTA (Planim.)		✔
LVOT Vmax	Left Ventricular Outflow Tract Peak Velocity		✔

LVOTD	Left Ventricular Outflow Tract Diameter		✔
LVOTS-grade	Left Ventricular Outflow Tract Obstruction Grade		✔
MG	Mean Gradient		✔
MPI	Miocardial Performance Index		✔
MR PISA-Alias. Vel.	Mitral regurgitation proximal isovelocity surface area - aliasing velocity		✔
MR EROA	Mitral regurgitation effective regurgitant orifice area		✔
MR-grade	Mitral Valve Regurgitation Grade		✔
MR JA	Mitral regurgitation - jet area		✔
MR PISA-r	Mitral regurgitation proximal isovelocity surface area - radius		✔
MR VC	Mitral regurgitation - vena contracta		✔
MR Vol.	Mitral regurgitation Vol		✔
MR VTI	Mitral regurgitation - Velocity Time Integral		✔
MR MG	Mitral regurgitation - mean gradient		✔
MR PG	Mitral regurgitation - peak gradient		✔
MR Vmax	Mitral regurgitation - peak velocity		✔
MS-grade	Mitral Valve Stenosis Grade		✔
MV ACT	Mitral valve acceleration time		✔

MV PHT	Mitral Valve Pressure Half-Time		✔
MV VTI	Mitral valve - velocity time integral		✔
MV-ANNULUS A4CH	Mitral valve annulus (A4Ch)		✔
MV-ANNULUS A2CH	Mitral valve annulus (A2Ch)		✔
MVA (Doppler)	Mitral valve area (Doppler)		✔
MVAi (Doppler)	Mitral valve area (Doppler) Index		✔
MV-ANNULUS PLA	Mitral valve annulus (PLA)		✔
MVA (Planim.)	MVA (Planim.)		✔
MV MG	Mitral valve - mean gradient		✔
MV PG	Mitral valve - peak gradient		✔
MV Vmax	Mitral valve - peak velocity		✔
PA LBD	PA Left Branch Diameter		✔
PA RBD	PA Right Branch Diameter		✔
PA AD	PA Annulus Diameter		✔
PAD	Pulmonary Artery Diameter		✔
PG	Peak Gradient		✔
PR EROA	Pulmonary regurgitation effective regurgitant orifice area		✔

PR-grade	Pulmonary Artery Regurgitation Grade		✔
PR JA	Pulmonary Regurgitation Jet Area		✔
PR PHT	Pulmonary Valve Regurgitation Pressure Half-Time		✔
PR PISA-r	Pulmonary regurgitation proximal isovelocity surface area - radius		✔
PR VC	Pulmonary Regurgitation Vena Contracta		✔
PR Vol.	Pulmonary regurgitation Vol		✔
PR VTI	Pulmonary Regurgitation Maximum Velocity Time Integral		✔
PR MG	Pulmonary Regurgitation Mean Gradient		✔
PR PG	Pulmonary Regurgitation Peak Gradient		✔
PR Vmax	Pulmonary Regurgitation Peak Velocity		✔
PS-grade	Pulmonary Artery Stenosis Grade		✔
PV MG	Pulmonary Valve Mean Gradient		✔
PV PG	Pulmonary Valve Peak Gradient		✔
PV VTI	Pulmonary Valve Maximum Velocity Time Integral		✔
PVA (Doppler)	Pulmonary valve area (Doppler)		✔
PVAi (Doppler)	Pulmonary valve area (Doppler) Index		✔
PVA (Planim.)	PVA (Planim.)		✔

PV Vmax	Pulmonary Valve Peak Velocity		✔
RAA	Right Atrial Area		✔
RAAi	Right Atrial Area Index		✔
RA Min. axis (4Ch)	Right Atrial Minor Axis Dimension (A4Ch)		✔
RA Min. i (4Ch)	Right Atrial Minor Axis Dimension Index (A4Ch)		✔
RA Maj. axis (4Ch)	Right Atrial Major Axis Dimension (A4Ch)		✔
RA Maj. i (4Ch)	Right Atrial Major Axis Dimension Index (A4Ch)		✔
RAP	Mean right Atrial pressure		✔
RA volume	Right Atrial Volume		✔
RAVi	Right Atrial Volume Index (2D)		✔
RV WT	Right Ventricular Wall Thickness		✔
RVB	Right Ventricular Basal Diameter		✔
RVB/LVB	RV / LV basal diameter ratio		✔
RV EDA	Right Ventricular End Diastolic Area		✔
RV EDAi	Right Ventricular End Diastolic Area Index		✔
RV EDV	Right Ventricular End Diastolic Volume		✔
RV EDVi	Right Ventricular End Diastolic Volume Index		✔
RV ESA	Right Ventricular End Systolic Area		✔

RV ESAi	Right Ventricular End Systolic Area Index		✔
RV ESV	Right Ventricular End Systolic Volume		✔
RV ESVi	Right Ventricular End Systolic Volume Index		✔
RVL	Right Ventricular Length		✔
RVM	Right Ventricular Middle Diameter		✔
RVOT-DIST	Right Ventricular Outflow Tract Distal Diameter (PLA)		✔
RWT	Relative Wall Thickness		✔
sPAP	Systolic Pulmonary Artery Pressure		✔
STJ	Sinotubular Junction		✔
STJi	Sinotubular Junction Index		✔
SV	Stroke Volume		✔
SV2A	Stroke Volume 2 Chamber		✔
SV4A	Stroke Volume 4 Chamber		✔
TAPSE	Tricuspid Annular Plane Systolic Excursion		✔
TR PISA-Alias. Vel.	Tricuspid regurgitation proximal isovelocity surface area - aliasing velocity		✔
TR EROA	Tricuspid regurgitation effective regurgitant orifice area		✔
TR-grade	Tricuspid Valve Regurgitation Grade		✔
TR JA	Tricuspid regurgitation - jet area		✔

TR PISA-r	Tricuspid regurgitation proximal isovelocity surface area - radius		✔
TR VC	Tricuspid regurgitation - vena contracta		✔
TR Vol.	Tricuspid regurgitation Vol		✔
TR VTI	Tricuspid regurgitation Velocity Time Integral		✔
TR MG	Tricuspid Regurgitation mean gradient		✔
TR PG	Tricuspid Regurgitation peak gradient		✔
TS-grade	Tricuspid Valve Stenosis Grade		✔
TV ACT	Tricuspid valve acceleration time		✔
TV PHT	Tricuspic Valve Pressure Half-Time		✔
TV VTI	Tricuspid Valve Velocity Time Integral		✔
TV-ANNULUS	Tricuspid valve annulus		✔
TVA (Doppler)	Tricuspid valve area (Doppler)		✔
TVAi (Doppler)	Tricuspid valve area (Doppler) Index		✔
TVA (Planim.)	TVA (Planim.)		✔
TV MG	Tricuspid Valve Mean Gradient		✔
TV PG	Tricuspid Valve Peak Gradient		✔
TV Vmax	Tricuspid Valve Peak Velocity		✔
Vel. ratio	Aortic Valve Velocity Ratio		✔

Velocity	Velocity		✔
Volume	Volume		✔