Ligence Heart

For 3.42.0 version

INSTRUCTIONS FOR USE

English

CE 0197

	Name	Role	Date	Signature
Updated by:	Àlvaro Perez	VP of QR	2025-12-12	
Approved by:	Indra Raudonė	HQR	2025-12-12	

Revision history			
Rev.	**Revision date**	**Description of change**	**Revised by**
1.0	2021-02-28	Document was created	
1.1	2021-10-26	Document is updated according to the notified body comments.	Justinas Balčiūnas
1.2.	2021-12-29	Document is updated according to the notified body comments.	Indra Vaitkevičiūtė
1.3	2022-02-03	Document is updated due to new version 3.0. release	Indra Vaitkevičiūtė
1.4	2022-05-03	Document is updated due to new version 3.1 release	Antanas Kiziela
1.5	2022-06-13	Changes to advanced search, DICOM UI overlay, annotation labels, “escape” key, disabled UI for mobile desktops, updated upload view.	Antanas Kiziela
1.6	2022-07-27	Added volume measurement description. Added new manual (stroke volume) and automated (LE, SE) measurements. Updated illustrations.	Antanas Kiziela
1.7	2022-08-19	Registration view added. New view modes: SCHEMA and MULTIPLANE added.	Antanas Kiziela
1.8	2022-09-21	Automated annotation list updated. Search/query UI updated.	Antanas Kiziela
1.9	2022-10-11	Manual annotations and measurements list updated – added stenosis and regurgitation measurements and annotations. Grade measurement description added.	Antanas Kiziela
1.10	2022-10-19	Updated list of annotations, view modes and measurements. Updated UI images of workspace, report, added Strain view description and images. Updated report elements description.	Antanas Kiziela
1.11	2022-11-08	Updated list of accepted DICOM storage class UIDs. Updated auto measurement functionality user interface description.	Antanas Kiziela
1.12	2022-12-01	Updated company’s address.	Antanas Kiziela
1.13	2023-01-06	Strain icon added in top navigation bar. Added new measurements to the list AR PHT, MV PHT, PR PHT, TV PHT.	Antanas Kiziela
1.14	2023-01-10	New view modes added.	Antanas Kiziela
1.15	2023-01-25	STJ removed from automated measurements.	Antanas Kiziela
1.16	2023-02-10	Product description updated, new use cases and user groups. Strain view description updated.	Antanas Kiziela
1.17	2023-03-21	Product general description update.	Antanas Kiziela
1.18	2023-04-04	Updated description for “Upload the study”.	Karolis Šablauskas
1.19	2023-05-01	Label and risks updated.	Karolis Šablauskas
1.20	2023-05-19	Android app usage updated.	Karolis Šablauskas
1.21	2023-06-14	Updated report view description.	Karolis Šablauskas
1.22	2023-06-28	Updated report view description. Updated measurement labels. Updated product labels.	Karolis Šablauskas
1.23	2023-07-19	Updated list of measurements table.	Karolis Šablauskas
1.24	2023-11-20	Updated user groups. Removed Android app. Added information which measurements are	Karolis Šablauskas

Revision history			
Rev.	**Revision date**	**Description of change**	**Revised by**
		automated in clinical setting. Updated list of known bugs.	
1.25	2023-12-21	Corrected grammatical mistakes with singular and plural forms in the intended user groups. Simplified contraindications table.	Justinas Balčiūnas
1.26	2024-01-29	Labels were updated.	Indra Raudone
1.27	2024-03-24	Removed automated right ventricular and right atrial segmentation related measurements. Reviewed, streamlined and updated cautions and warnings in accordance with the product.	Karolis Šablauskas Justinas Balčiūnas
1.28	2024-05-05	Added one-page report usage information	Karolis Šablauskas Simas Tatoris
1.29	2024-05-13	Updated PDF functionality for one-page report usage.	Karolis Šablauskas
1.30	2024-06-05	Updated User groups. Updated DICOM discarding on upload.	Karolis Šablauskas
1.31	2024-06-19	Updated information about summary generation.	Karolis Šablauskas
1.32	2024-07-29	Updated the list of automated research measurements	Karolis Šablauskas
1.33	2024-08-12	Updated labels.	Karolis Šablauskas
1.34	2024-08-27	Labels were updated.	Karolis Šablauskas
1.35	2024-09-04	Labels were updated.	Karolis Šablauskas
1.36	2024-10-02	Information on how to sign a study was added.	Karolis Šablauskas
1.37	2024-10-22	Labels were updated.	Karolis Šablauskas
1.38	2024-11-22	Labels were updated.	Karolis Šablauskas
1.39	2024-12-18	Labels were updated.	Karolis Šablauskas
1.40	2024-12-23	Labels were updated. Updated information on automatic summary generation logic. Removed strain view. Corrections in the table of contents. Intended use section corrected.	Karolis Šablauskas
1.41	2025-01-14	Labels were updated.	Justinas Balčiūnas
1.42	2025-01-24	Labels were updated. New functionality of snippets and list of previous studies of the patient added.	Karolis Šablauskas
1.43	2025-12-12	Intended Use section modified to align with the European market.	Àlvaro Perez

UAB Ligence

Taikos pr. 54,

Kaunas, Lithuania

LT- 05305

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.

Table of Contents

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. Training videos are 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 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. About the Instructions for Use (IFU)

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP IT FOR FUTURE REFERENCE

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.

Software Installation Manual is added as a separate document to the IFU.

If You require paper version of IFU please ask us by email: support@ligence.io. Paper version of IFU will be sent not later than in 7 days after receiving Your request (to the address You specify).

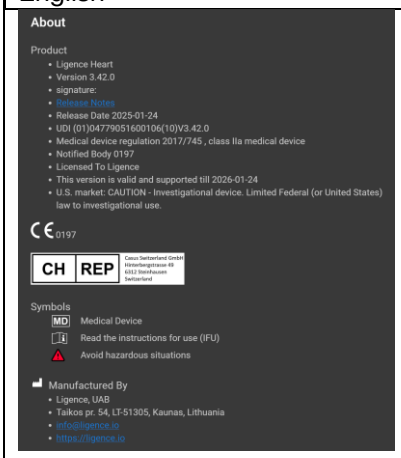
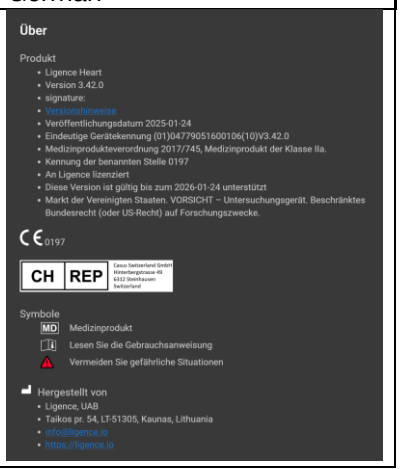
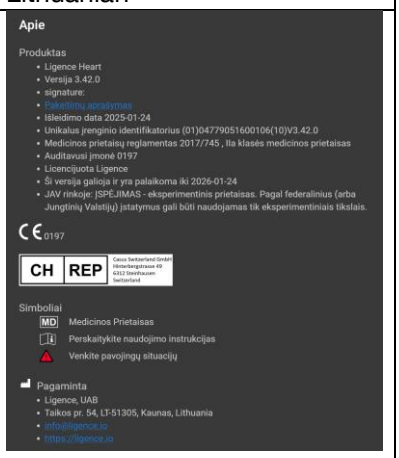
2. Symbols

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.

Symbol	Description
	**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
	**CE Marking of Conformity**.
	**Authorized representative in Switzerland.**

3. Label

English	French	German
		
Italian	Lithuanian	
		

4. Markets and foreign language support

With the CE mark, Ligence Heart software will be sold in the EU, where English language is supported. It can be translated upon request of customers. Currently, Ligence Heart supports the English language.

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:

Ligence, UAB DPO who is responsible for data protection (contacts are public and available at https://www.ligence.io/).

Name, Surname: Simas Tatoris

Tel. +37069302801

Mail: s.tatoris@ligence.io

Reports should include:

- Description of the local and potential impact of the vulnerability;
- A detailed description of the steps required to reproduce the vulnerability. Proof of concept scripts, screenshots, and screen captures are all helpful. Please use extreme care to properly label and protect any exploit code;
- Any technical information and related materials we would need to reproduce the issue.

Once we have received a vulnerability report, Ligence, UAB takes a series of steps to address the issue:

1. Ligence, UAB requests the reporter to keep communicating regarding the vulnerability Confidentially.
2. Ligence, UAB investigates and verifies the vulnerability.
3. Ligence, UAB addresses the vulnerability and releases an update or patch to the software. If for some reason this cannot be done quickly or at all, Ligence, UAB will provide information on recommended mitigations.
4. Release notes include a reference to the vulnerability case.

Ligence, UAB will endeavour to keep the reporter apprised of every step in this process as it occurs.

We greatly appreciate the efforts of security researchers and discoverers who share information on security issues with us, giving us a chance to improve our software and better protect personal health data. Thank you for working with us through the above process.

We'll do our best to acknowledge your emailed report, assign resources to investigate the issue, and fix problems as quickly as possible.

6. Intended use

Ligence Heart is a software used to detect, measure, and calculate various specifications of structure and function of the heart and great vessels by analyzing echocardiographic images.

The device is intended to be used when the patient is not in a life-threatening state of health, time is not critical for medical decisions and no major therapeutic interventions are required.

7. General description

To better understand the method of working of the software, it is convenient to separate the process of echocardiography exam into two steps:

1. **Data acquisition**. During the first step, the operator of an ultrasound machine manipulates a probe interacting with the patient to produce the echocardiographic images of the heart.
2. **Data analysis**. Using medical image viewing software the acquired echocardiography images are opened, annotated, measured and clinical conclusions are drawn based on the generated data.

Having established these steps, it is important to identify how the process of echocardiography exam takes place in the specific case of using Ligence Heart.

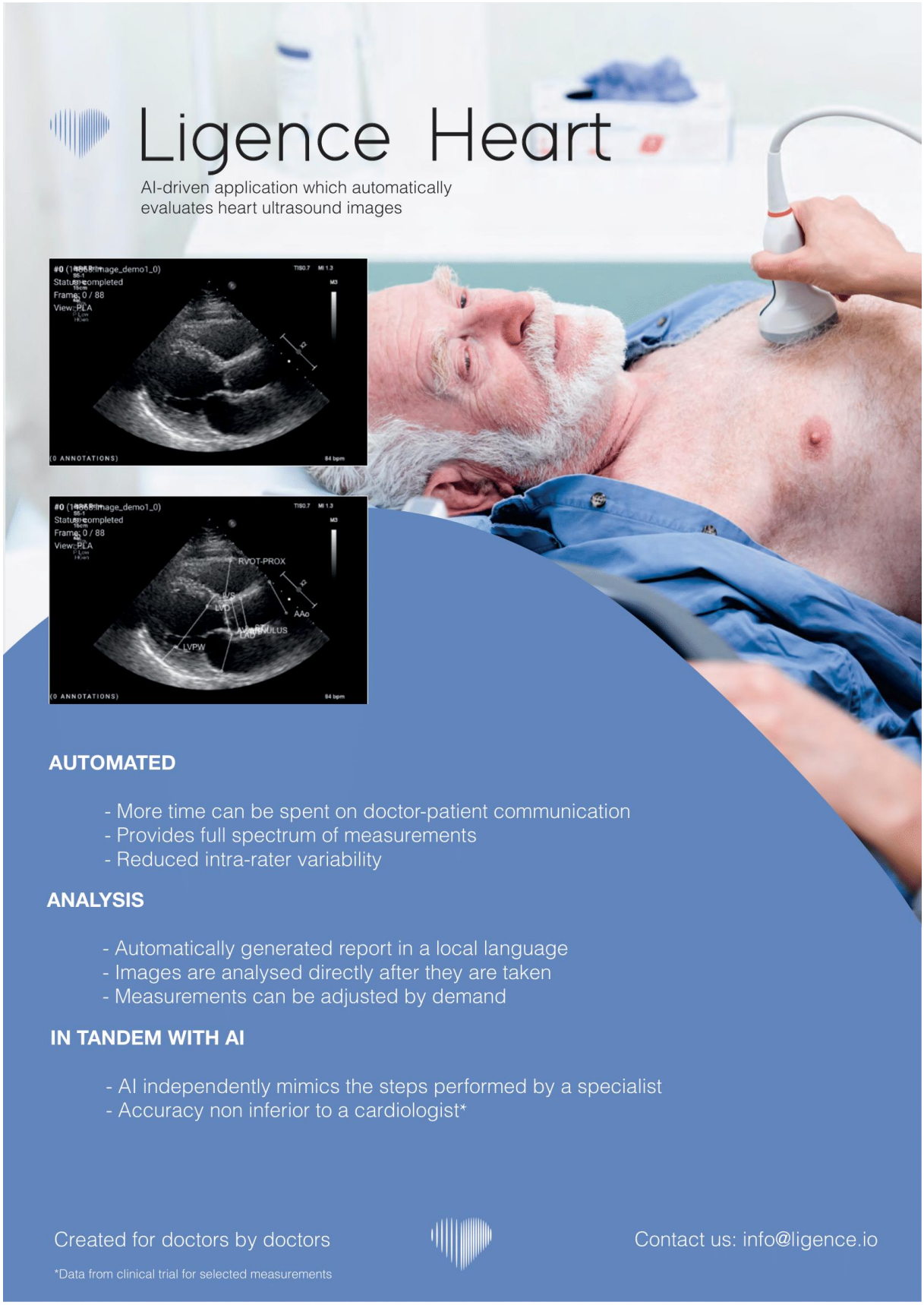
The first step (data acquisition) can send data to Ligence Heart and receive near real-time feedback on the image view and image quality.

The second step (data analysis), the user can store and send multiple images to Ligence Heart and receive near instant annotations, measurements, and reporting. Furthermore, Ligence Heart can be used as a post-processing tool that is accessible via the workstation in the office or any other dedicated area for patient's clinical data analysis.

Ligence Heart can be used to perform fully automated 2D TTE data analysis – image recognition, frames of interest detection, appropriate measurements calculation, automated summary generation based on measurements done. The automatically generated measurements and the finalized report must be approved by a medical professional who is certified and eligible to conduct echocardiography examinations and formulate a report without the use of Ligence Heart automatic functions. The automatically generated and cardiologist approved report of echocardiogram analysis serves only as a decision support tool. The conclusion of diagnosis must be always taken by the cardiologist. Manual ultrasound data analysis: all measurements (same as automated research and clinical) can be done manually.

A complete list of functionalities can be found in the IFU and System requirement specification.

8. Marketing brochure



9. Clinical user groups

There are 2 groups of clinical users that can work with Ligence Heart:

1. **Cardiologists** - Ligence Heart can be used by cardiologists (or medical personnel with equal competences) that are certified and eligible by local legislation to conduct regular echocardiography examinations in a clinical setting. The automatically generated measurements and the finalized report have to be approved by a cardiologist.
2. **Sonographers** - Ligence Heart is designed to support sonographers in their practice of echocardiography examinations within a clinical setting. Sonographers (or medical personnel with equal competences), who are eligible by local legislation to perform echocardiography, can utilize Ligence Heart for analysis and reporting. The automatically generated measurements and the finalized report must be reviewed and approved by a medical professional who is also certified and eligible by local legislation to conduct echocardiography examinations and formulate a report.

These groups are considered non-privileged user groups.

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

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

10. Non-clinical user groups

There is 1 group of non-clinical users that can work with Ligence Heart:

1. **IT Administrators** - Ligence Heart can be configured by IT Administrators which are considered a **privileged** user group. IT Administrators are responsible for managing users.

User group	User management	Environment
IT Administrators	Yes	Clinical & Research

11. Indications and contraindications

Indications

The software is intended to be used in analysis of echocardiography images acquired from patients that are of any gender and race in accordance with the latest guidelines for echocardiography examination. Automatic functionalities should be used in adults on 2D TTE datasets.

Contraindications

The automatic functionalities should not be used to analyze echocardiography images of patients younger than 18 years old. Also, automatic functionalities should not be used to analyze images of patients with heart diseases/procedures done that significantly alter heart anatomy or geometry that significantly distort the echocardiography images. A list of contraindications for automatic functionalities is provided in the table below:

Contraindications for automated functionalities
1. Complex or critical congenital heart disease
2. Heart tumors
3. Prosthetic valves, post-operative heart valves, cardiac geometry changing cardiothoracic surgeries
4. Implantable intracardiac devices
5. Heart arrhythmias (atrial flutter, atrial fibrillations)
6. Aortic dissection

12. Principles of operation of the device

Manual functionalities

The device visualizes echocardiography imaging data and allows inspecting the imaging data and performing measurements by drawing annotations superimposed on the visualized data. The annotations are then used to calculate the relevant geometric and functional heart parameters.

Automatic functionalities

The device performs a series of steps that involve automated recognition of the echocardiography imaging data, recognition of echocardiographic probe position and detecting a set of anatomical (e.g. heart chamber borders, landmarks). The automated functionalities rely on the predictions made by deep neural networks from the echocardiographic images (e.g. echocardiographic probe position recognition, heart chamber border, landmark detection).

13. Explanation of any novel features

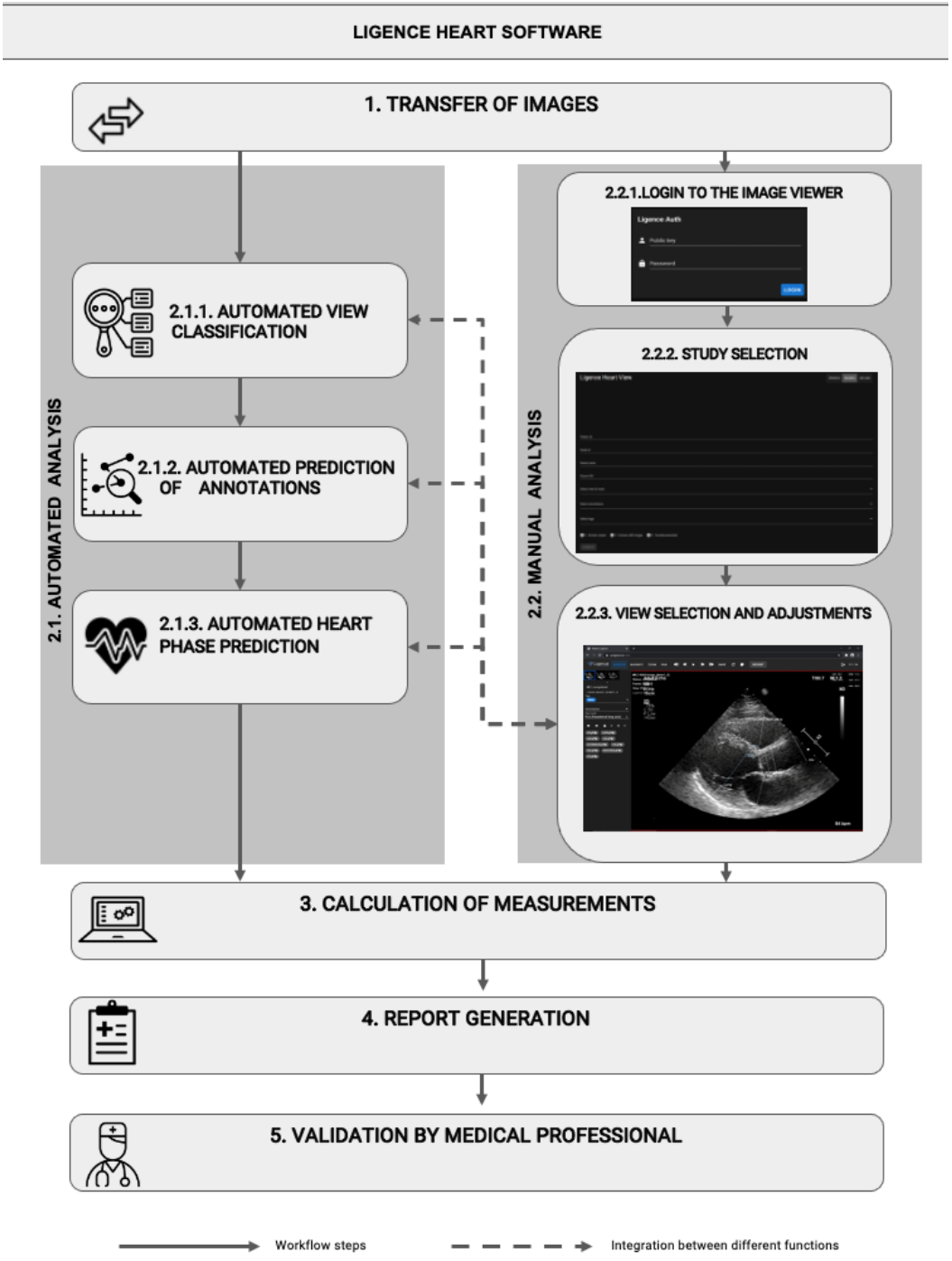
Ligence Heart offers novel functionality that allows automatic analysis of a number of heart structure and function parameters. Therefore, the parameters that are analyzed themselves are not novel, but the automation of some of these measurements is novel (none of the manual functionalities are novel). The automatic functionalities are based on Deep Learning technologies. These automatic functionalities offer the ability to automate activities that are usually performed manually during regular echocardiographic image analysis.

14. Description of all configurations/variants of the product

There is a possibility, on the request of the customer, to have different functionalities of Ligence Heart turned on/off for each customer via the manufacturers control mechanisms. The product basic package will always allow to manually annotate images and receive calculations of measurements. The algorithms to automatically perform some of these manual tasks will be turned on/off depending on the customer needs and sale agreement.

15. General description of key functional elements

Functional elements scheme.



Explanation of the functional elements

Key function	Description
1. *Transfer of echocardiography images*	Personal data is removed from echocardiography images (if needed) and the images are transferred from ultrasound device, ultrasound application, PACS or other data source (storage).
2. *Analysis*	echocardiography images analysis step using automated or manual analysis
2.1. Automated analysis	

Key function	Description
2.1.1. Automated view classification	An Automated system is trained to determine view mode of echocardiography image. This step is needed for further analysis of images
2.1.2. Automated prediction of annotations	Automated system is trained to predict annotations that are used to measure heart anatomy based on the view mode of echocardiography image
2.1.3. Automated heart phase prediction	Automated system tracks 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	Authentication/authorization to the software step needed to be able to access software functionalities
2.2.2. Study selection	Selection of accessible study by filtering/searching step
2.2.3. View selection and adjustments	Study analysis step, cardiologists sets the view mode of echocardiography image, performs annotations, or adjusts measurements already made by automated analysis
3. Calculation of measurements	Calculation of measurements based on the annotations on echocardiography image performed by the combination of manual and automated functions
4. Report generation	Study analysis report, which consists of all annotations, measurements made along with automated suggested diagnosis text, is generated for review and approval of cardiologist.
5. Validation by medical professional	Medical professional validates all annotations and measurements made and adjusts the annotations if needed, updating the report respectively

16. Benefits of using Ligence Heart

The use of Ligence Heart software brings a modern, quicker, and precise way for understanding visual ultrasound data. In addition to manual analysis of ultrasound images, Ligence Heart allows the user to automatically perform parts of the echocardiography image evaluation with non-inferior accuracy compared to cardiologists, reducing the variability of measurements, and reducing the time needed for analysis.

17. Clinical Benefits

Performance of manual functionalities:

- The manual functionalities of Ligence Heart provided are equally accurate and reliable tools for echocardiography evaluation compared to other state of the art CE marked and FDA approved medical software.

Performance of automated functionalities:

- The main clinical benefit is improved workflow for echocardiographic analysis and reporting through machine learning based automation. It potentially reduces analytic time by requiring less manual contouring and adjustments, provides high accuracy, and complete reproducibility (algorithms will provide the same results on the same data).

Ligence Heart performs automated measurements with non-inferior accuracy compared to a certified specialist.

18. 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.

19. Customer Service

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

Contact details:

E-Mail: support@ligence.io

Support Hotline: +37064550126

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.

CAUTION

This product is not intended to be used for emergency diagnosis.

1. Summary of Clinical Evaluation Report

The device's risks were managed according to UAB Ligence internal risk management work instruction, which is based on the ISO 14971:2019 standard. During the risk management activities, the device was:

1. Classified according to the Medical Device Regulation EU 2017/745 directive's Annex VIII as a CLASS IIa medical device according to the rule 11;

2. Identified according to the Medical Device Regulation EU 2017/745 and requirements defined in the ISO 14971:2019 standard's Appendix C;

3. Risks managed (analyzed, mitigated, verified for residual risks). There are no additional measures for risk control identified that have not been implemented and the device is considered safe to use according to its intended purpose.

4. All the risk management activities were carried out by the risk management team.

5. All the testing activities were carried out by the testing team.

UAB Ligence gathers production and post-production information using the following Quality management system's areas:

1. Product realization;
2. Measurements analysis and improvement;
3. Change and problem management;
4. Auditing;
5. Post market follow-up.

The above mentioned activities ensure that internal and external views (in which the product exists) are constantly monitored and if changes occur all associated risks are re-managed.

Risk management report and related documents in the risk management file are updated when needed.

2. Residual Risks

1 residual risk is identified. The hazards and warnings related with the risk are presented in the table below.

Risk No.	Hazard	Warning/Caution
R-13	Automated analysis underperforms when the quality of images is inadequate.	Delay in disease management.

3. Personal Data Security Breach

In case of personal data breach (including but not limited to cybersecurity breach) please immediately (but not later than in 24 hours) inform medical software Manufacturer UAB Ligence by using below mentioned contacts:

UAB Ligence Data Protection Officer

(Contacts of Data Protection Officer are publicly available at www.Ligence.io).

Name, Surname: Simas Tatoris

Tel. +37069302801

Mail: dpo@ligence.io

4. 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.

5. Data Handling

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.

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. Not obviously incorrect behavior could lead to conflicting information.

CAUTION

The user is responsible for the content of reports, findings records and other patient information.

CAUTION

The displayed image information in Ligence Heart software comes from your producing device such as a ultrasound machine. UAB Ligence is not responsible for any incorrect or missing information due to a use error or device malfunction on the device itself that was used to produce images.

NOTE

The quality of any exported object (echo exam) highly depends on the settings performed to the exporting file formats (e.g. compression of images) and information can be lost during this process.

The user remains responsible for determining if the information contained in an exported object can be used for making diagnostic decisions.

6. Installation and Maintenance

1. Installation

Ligence Heart is available installed on premises (hard server or suitable VM), laptop or workstation, for direct connected offline use.

Ligence Heart is an on-premises software application designed to process DICOM images from multiple echocardiography scanners within a hospital's local network. It automatically generates measurements and report text, which can be seamlessly forwarded to the PACS, reporting system, or EMR. 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.
The Ligence Heart software can be fully operated within the local network and installed on customer-provided servers (either virtual machines or physical hardware), a server supplied by Ligence, or a laptop or workstation.

Installation should be performed by Ligence technicians in accordance with the Installation Manual, which is provided as a separate document.

2. 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.

3. Backups and redundancy

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

CAUTION

Installation may be only realized by technicians of Ligence.

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.

7. 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

8. 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

Measurements have been validated and verified in the following modes:

- B-mode
- M-mode
- PW-Doppler
- CW-Doppler
- Tissue Doppler
- Color Doppler

9. 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.

10. 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)
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.
4	Auto-measurement listed but not visible in echocardiographic view	When initiating a new auto-measurement, the measurement is correctly added to the measurement list. However, the corresponding graphical representation does not	Research and development team member	This issue does not impact patient safety. The measurement data is correctly saved and listed. The graphical overlay becomes visible after the user reloads the page.	Difficult to reliably reproduce	The issue does not affect safety, and it cannot be reliably reproduced, making a targeted fix impractical at this time.

#	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
		appear on the echocardiographic view, which may cause confusion or misinterpretation for the user.				

3. REQUIREMENTS AND INSTALLATION

Detailed information is provided in the Installation Manual document.

3.1. USER INTERFACE ELEMENTS

1. User Views

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

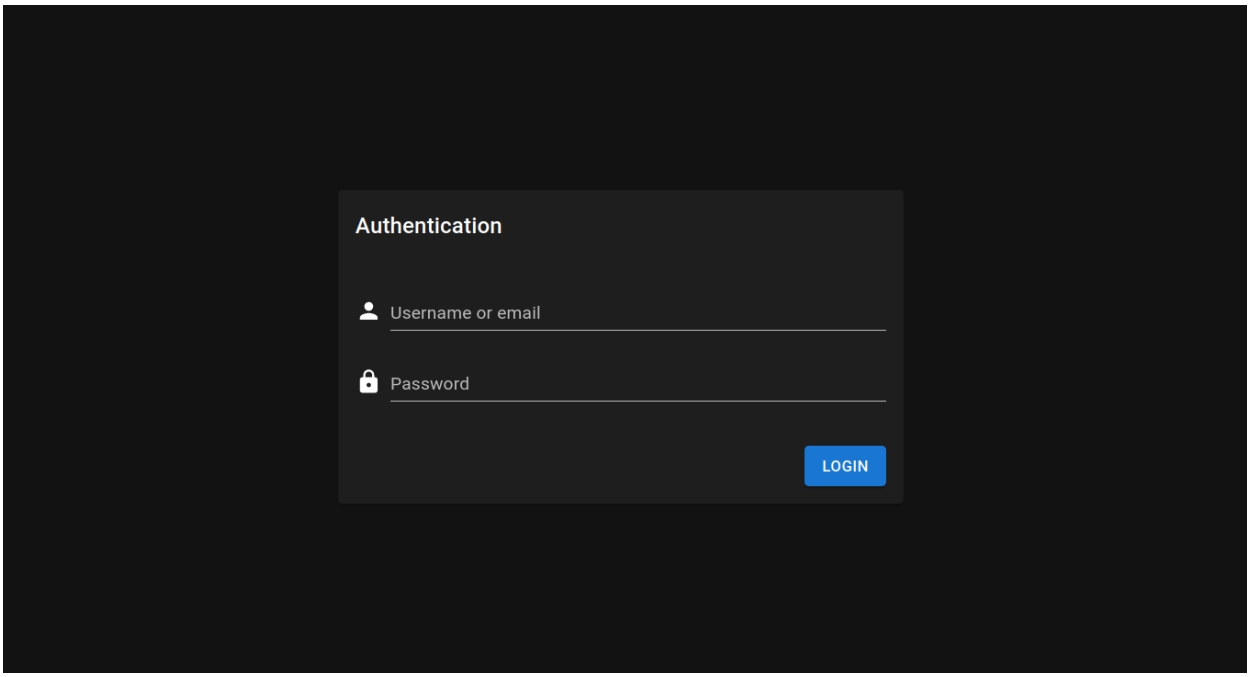
NOTE

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.

1. Login View

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

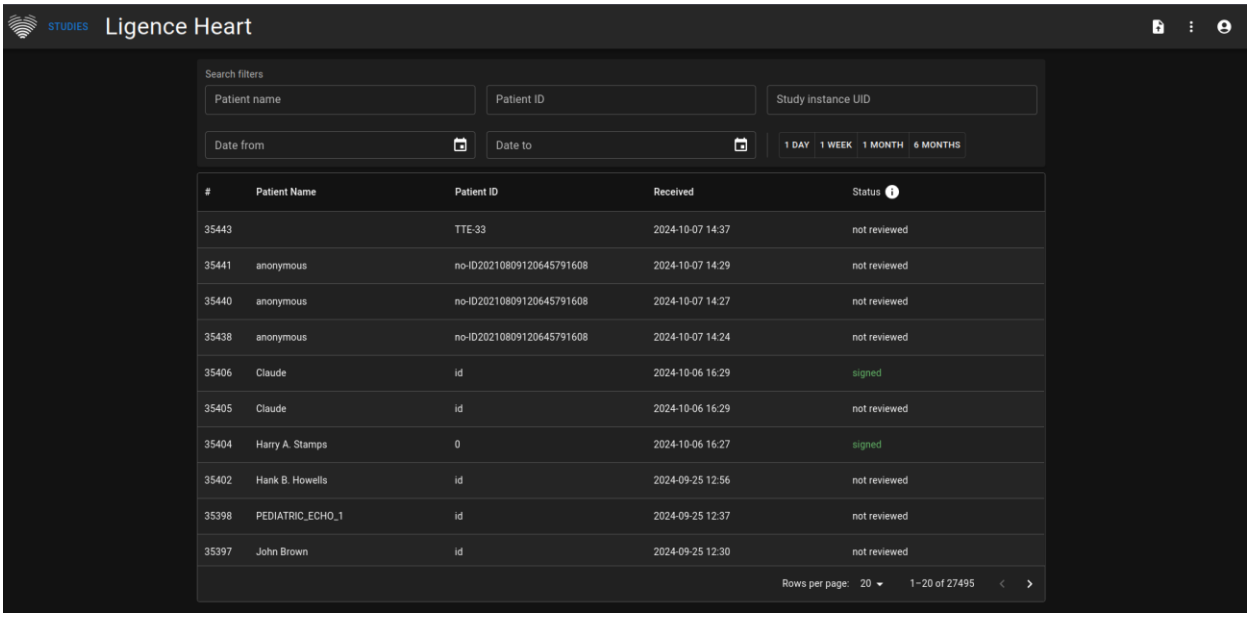


NOTE

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

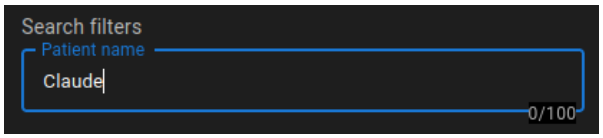
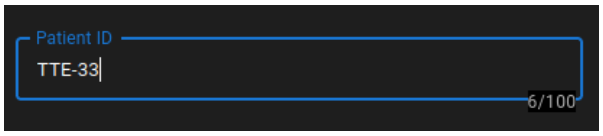
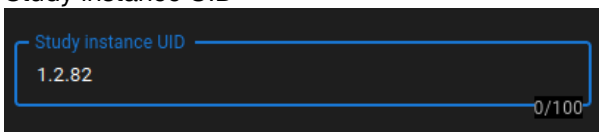
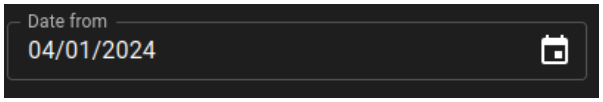
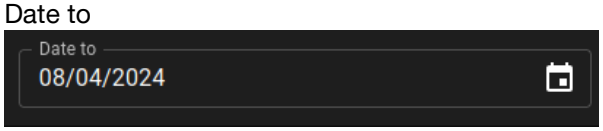
2. Lobby View

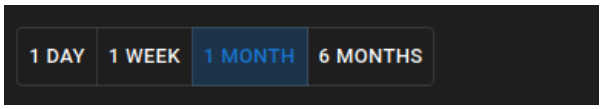
The Lobby View is where you can find all of your most recently received studies.



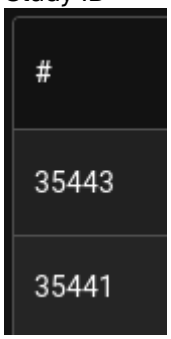
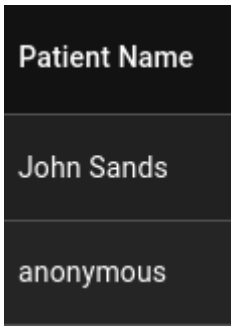
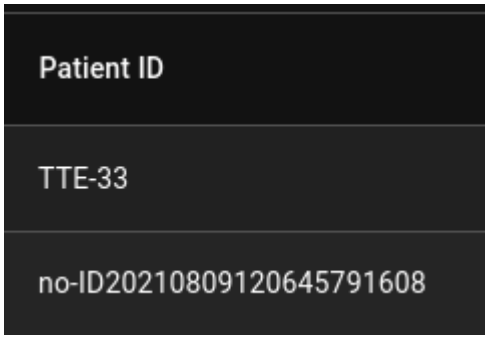
Searching for echocardiographic studies

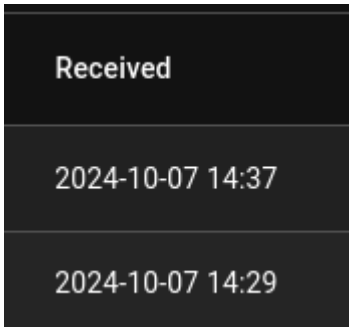
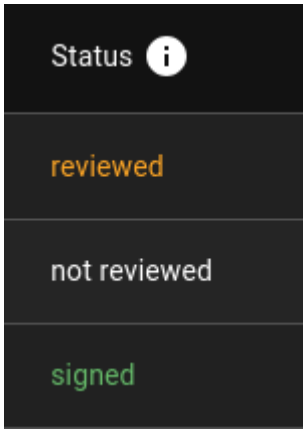
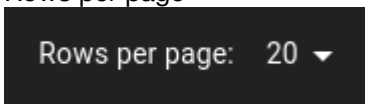
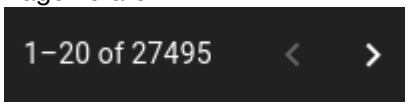
There are multiple ways to search for a specific echocardiographic study in the Lobby View. Entering values in the fields shown below will combine the search filters where a study must meet all of the search criteria that are entered.

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).
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.

Search functionality element	Explanation
Period selection 	Set a period for which to filter the studies.

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.
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.

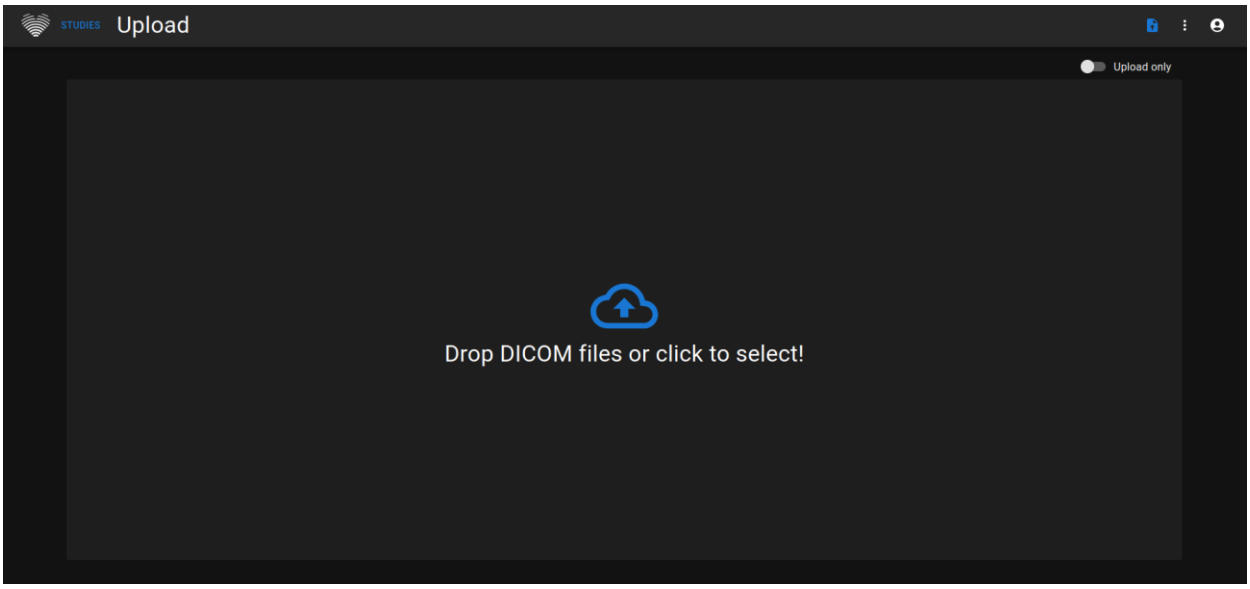
Element	Explanation
	
Status 	Shows the status of a study. signed - This study has been signed by a physician and a final report has been generated. reviewed - This study has been reviewed by a sonographer but the final report has not been generated. not reviewed - This study has not been reviewed.
Rows per page 	Allows changing the number of echocardiographic studies shown per page.
Page iterator 	Allows navigating between different pages of the studies.

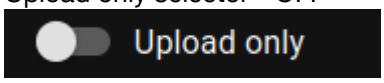
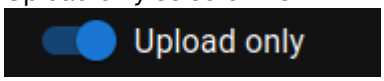
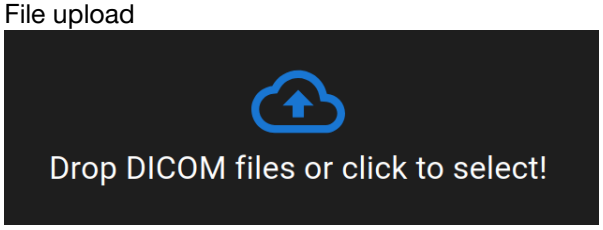
3. Upload View

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

NOTE

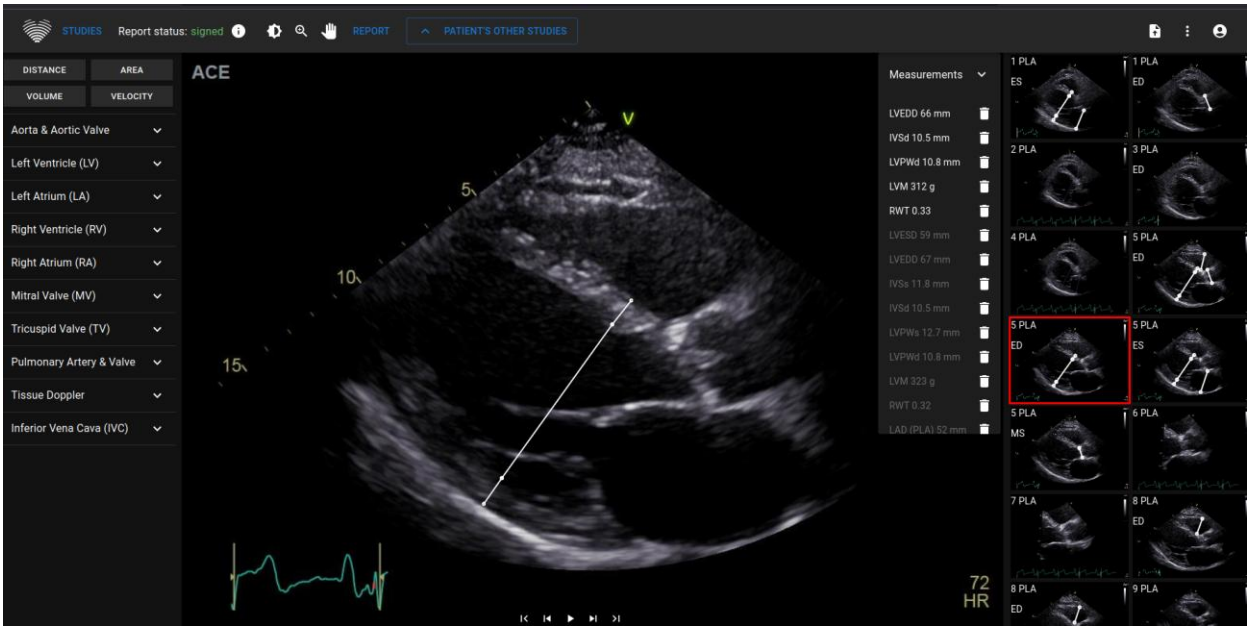
Only DICOM format studies are supported.



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.

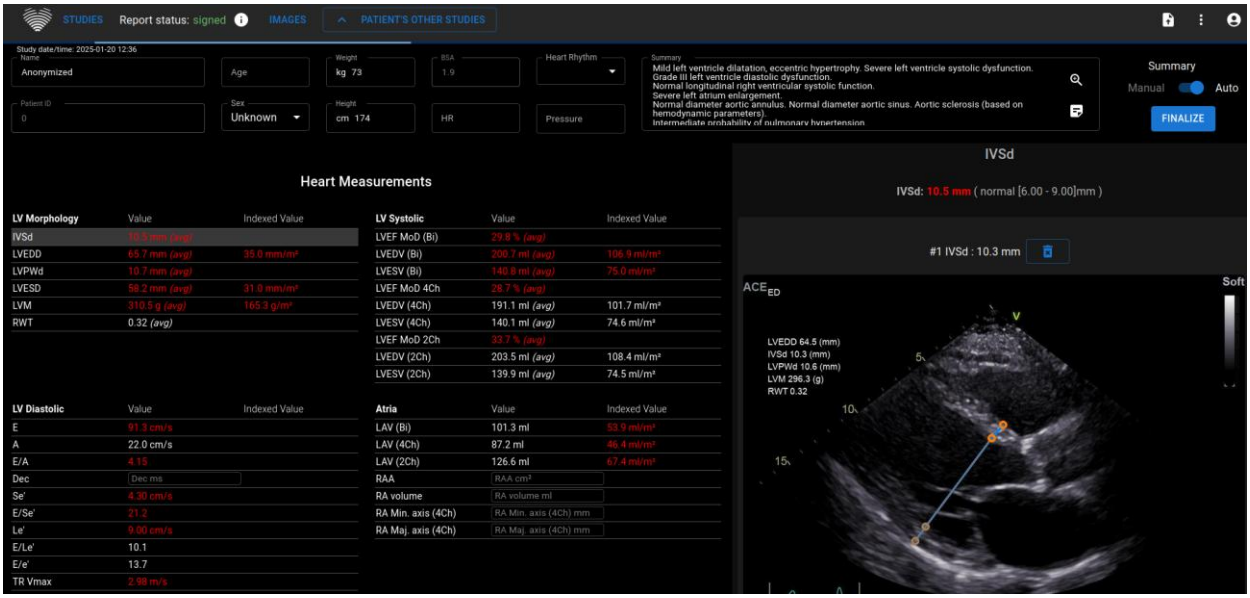
4. Workspace View

This view is dedicated for viewing and analyzing studies.

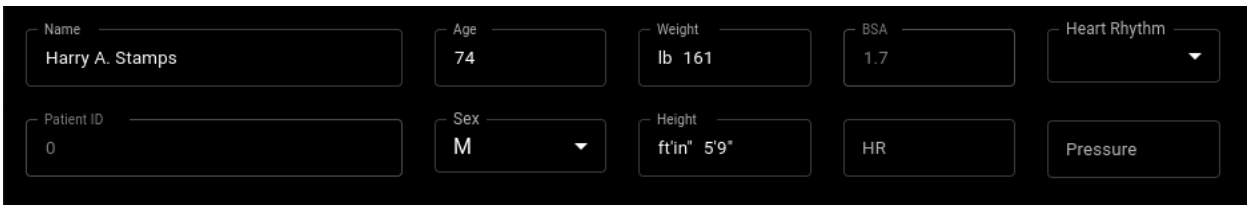


5. Report view elements

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:



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

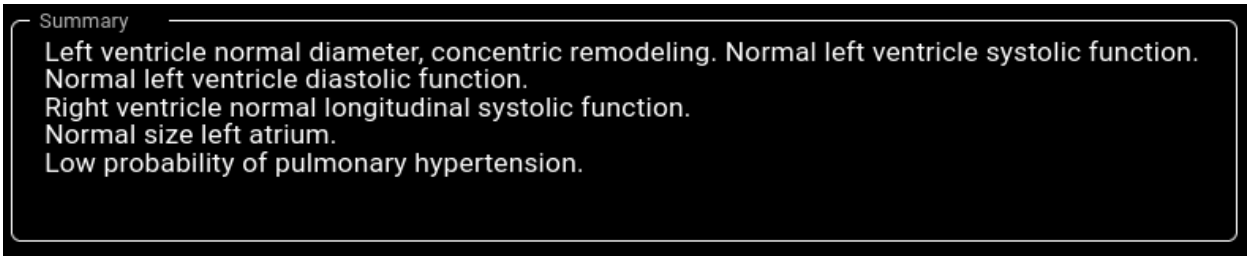
Device can be configured to use imperial or metric system units during deployment:

- 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"

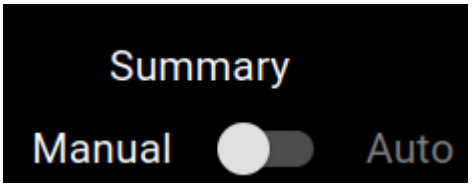
Summary Box

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.



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.



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.

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.

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.

$\in$ - part of the interval. For example, $\in$ [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’.

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 $\in$ [3.1, 3.4) cm	LVEDDi $\in$ [3.2, 3.5) cm	Mild left ventricle dilatation
LVEDDi $\in$ [3.4, 3.6] cm	LVEDDi $\in$ [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://doi.org/10.1016/j.echo.2014.10.003 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://doi.org/10.1016/j.echo.2014.10.003 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://doi.org/10.1016/j.echo.2014.10.003 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/m^2

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://doi.org/10.1016/j.echo.2016.01.011 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/m^2

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://doi.org/10.1016/j.echo.2016.01.011 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. https://doi.org/10.1016/j.echo.2014.10.003 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://doi.org/10.1016/j.echo.2014.10.003 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://doi.org/10.1016/j.echo.2014.10.003 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/m^2	Normal size left atrium
LAVi ∈ [34, 41] ml/m^2	Mild left atrium enlargement
LAVi ∈ (41, 48] %ml/m^2	Moderate left atrium enlargement
LAVi >48 ml/m^2	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://doi.org/10.1016/j.echo.2014.10.003 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/m^2	RAVi ≤28 ml/m^2	Normal size right atrium
RAVi >32 ml/m^2	RAVi >28 ml/m^2	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/m^2	RA Min. i (4Ch) ≤2.2 cm/m^2	Normal size right atrium

RA Min. i (4Ch) >2.2 cm/m^2	RA Min. i (4Ch)>2.2 cm/m^2	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://doi.org/10.1016/j.echo.2014.10.003 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/m^2	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://doi.org/10.1016/j.echo.2014.10.003 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/m^2	AoSi >2.0 cm/m^2	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://doi.org/10.1016/j.echo.2014.10.003 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/m^2	AAoi >1.9 cm/m^2	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://doi.org/10.1016/j.echo.2014.10.003 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 cm^2/m^2 or AVA <1.0 cm^2 ● 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 ● AVAi ∈ [0.6, 0.85] cm^2/m^2 or AVA ∈ [1.0, 1.5] cm^2 ● Vel. ratio ∈ [0.25, 0.50]	Moderate aortic stenosis (based on hemodynamic parameters)
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 cm^2/m^2 or AVA >1.5 cm^2 ● 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://doi.org/10.1093/ehjci/jew335 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 cm^2
	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://doi.org/10.1093/eurheartj/ehv317 Table 8A and Table AB.

Measurement fields

Measurement values are grouped based on different anatomical or functional features.

Abnormal values are shown in red. If the measurement is calculated as an average of multiple measurements, the (avg) text will be shown.

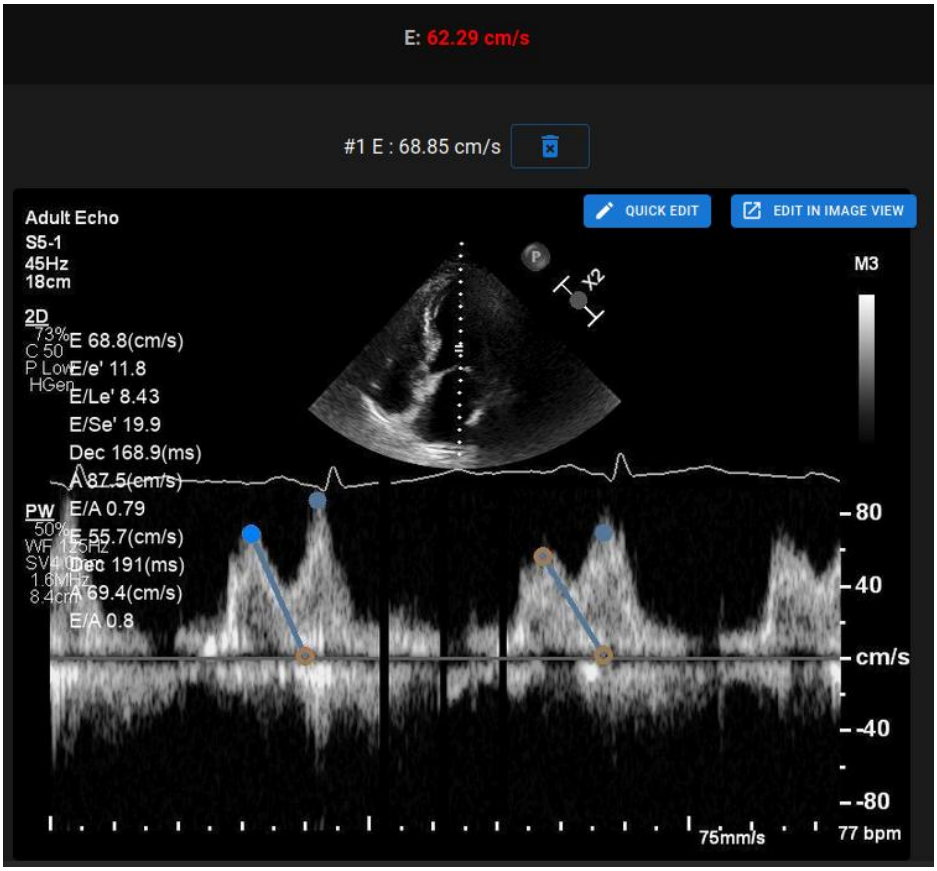
LV Diastolic	Value	Indexed Value
E	62.29 cm/s *(avg)*	
A	78.44 cm/s *(avg)*	
E/A	0.80 *(avg)*	
Dec	179.91 ms *(avg)*	
Se'	3.47 cm/s	
E/Se'	19.86	
Le'	8.17 cm/s	
E/Le'	8.43	
E/e'	11.83	

Illustrations

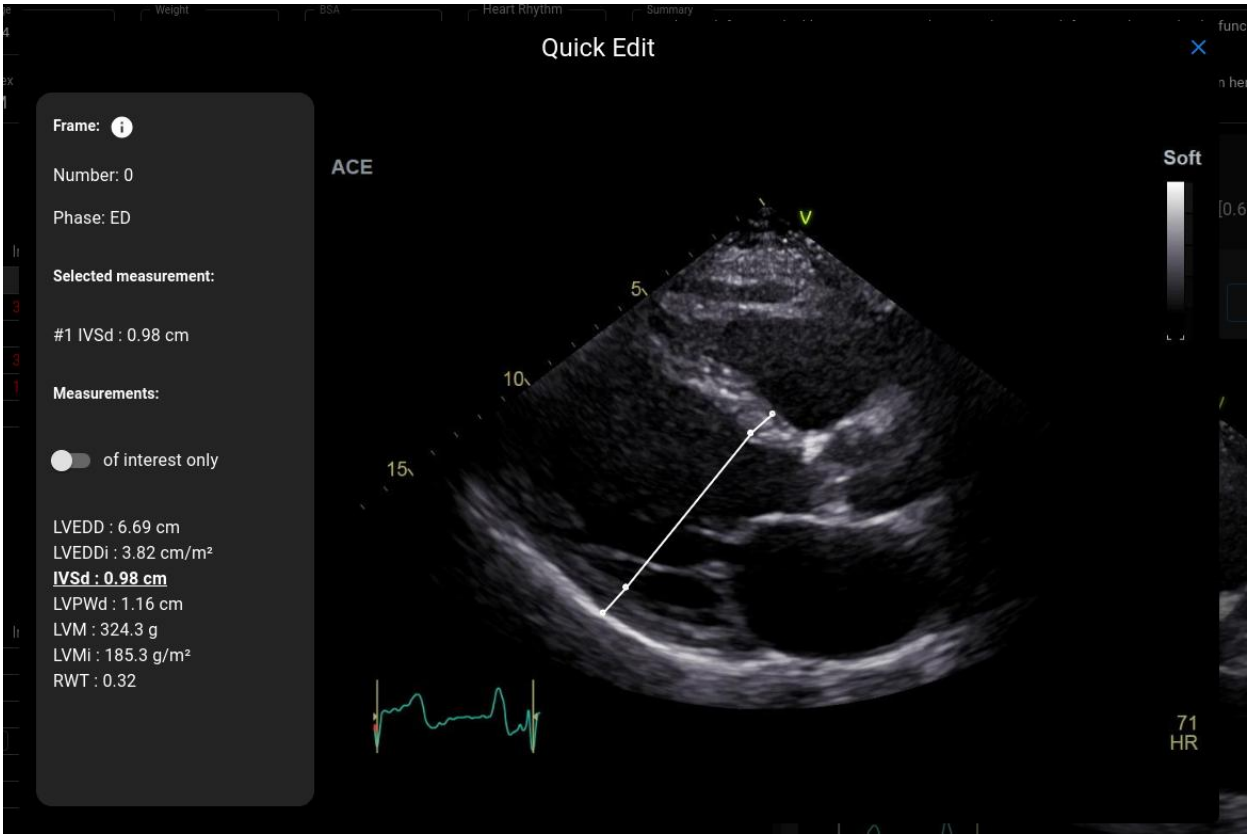
Hovering on one of the measurement rows will show annotations associated with that measurement in the illustration component. The measurement being shown will be highlighted and other measurements will be shown in transparent color.

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

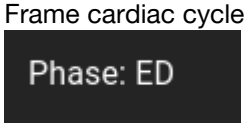
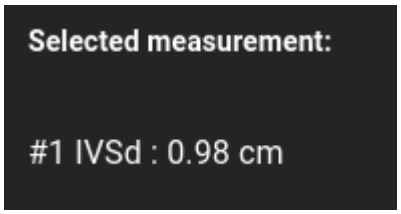
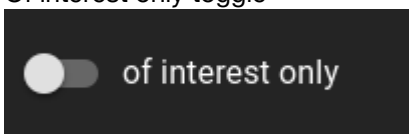
Clicking “EDIT IN IMAGE VIEW” redirects to the specific image in workspace view.



Quick edit



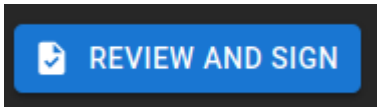
Quick edit mode is entered by clicking on the “QUICK EDIT” button on illustrations.

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

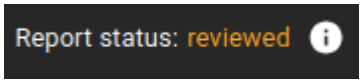
Review study - Sonographer

1. Navigate to report view
2. Review study

3. Click
4. Review the generated PDF



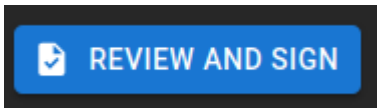
5. Click
6. After confirming report status will change to



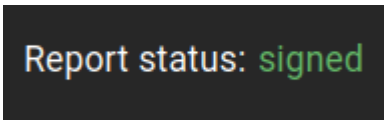
Signing report - Cardiologist

7. Navigate to report view
8. Review study

9. Click
10. Review the generated PDF



11. Click
12. After confirming report status will change to



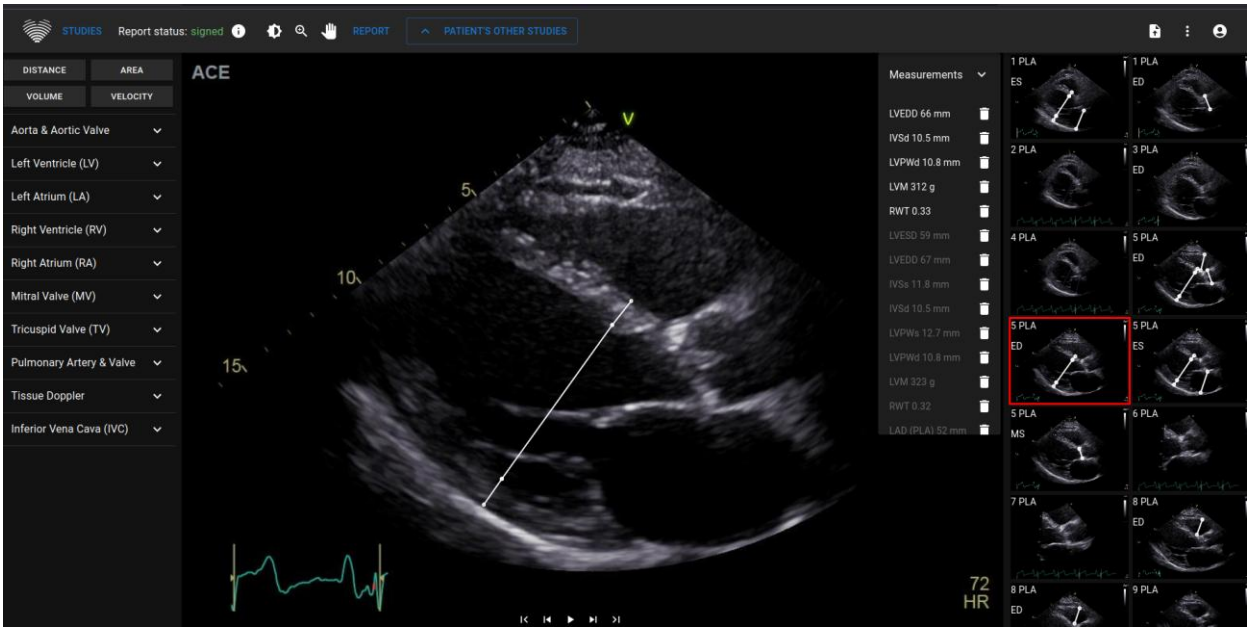
NOTE

Normal values were chosen to accord with the guidelines from European Association of Cardiovascular Imaging (EACVI). Please consult the publication for more information:

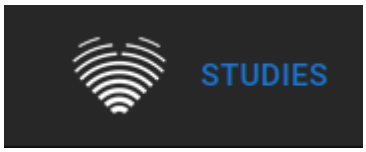
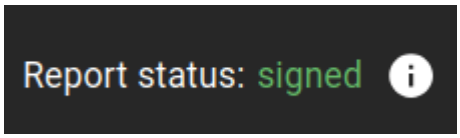
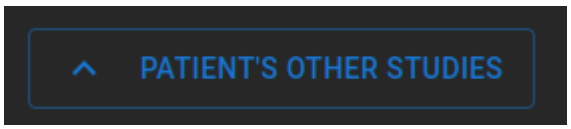
“Standardization of adult transthoracic echocardiography reporting in agreement with recent chamber quantification, diastolic function, and heart valve disease recommendations: an expert consensus document of the European Association of Cardiovascular Imaging 2017”

Can be accessed for free here: https://academic.oup.com/ehjcimaging/article/18/12/1301/4555377

6. Workspace view elements



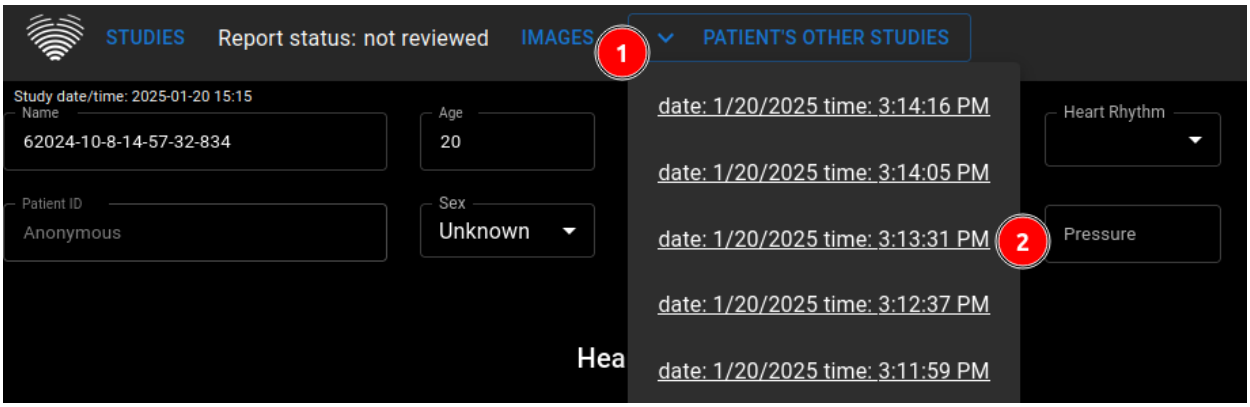
Navigation Bar and Image Tools

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
	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

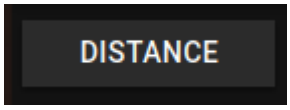
To find other echocardiographic studies based on DICOM Patient ID Attribute:

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



Left Sidebar

Left sidebar contains tools for making measurements

Element	Explanation
	Expand section
	Make a distance measurement

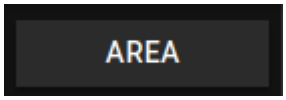
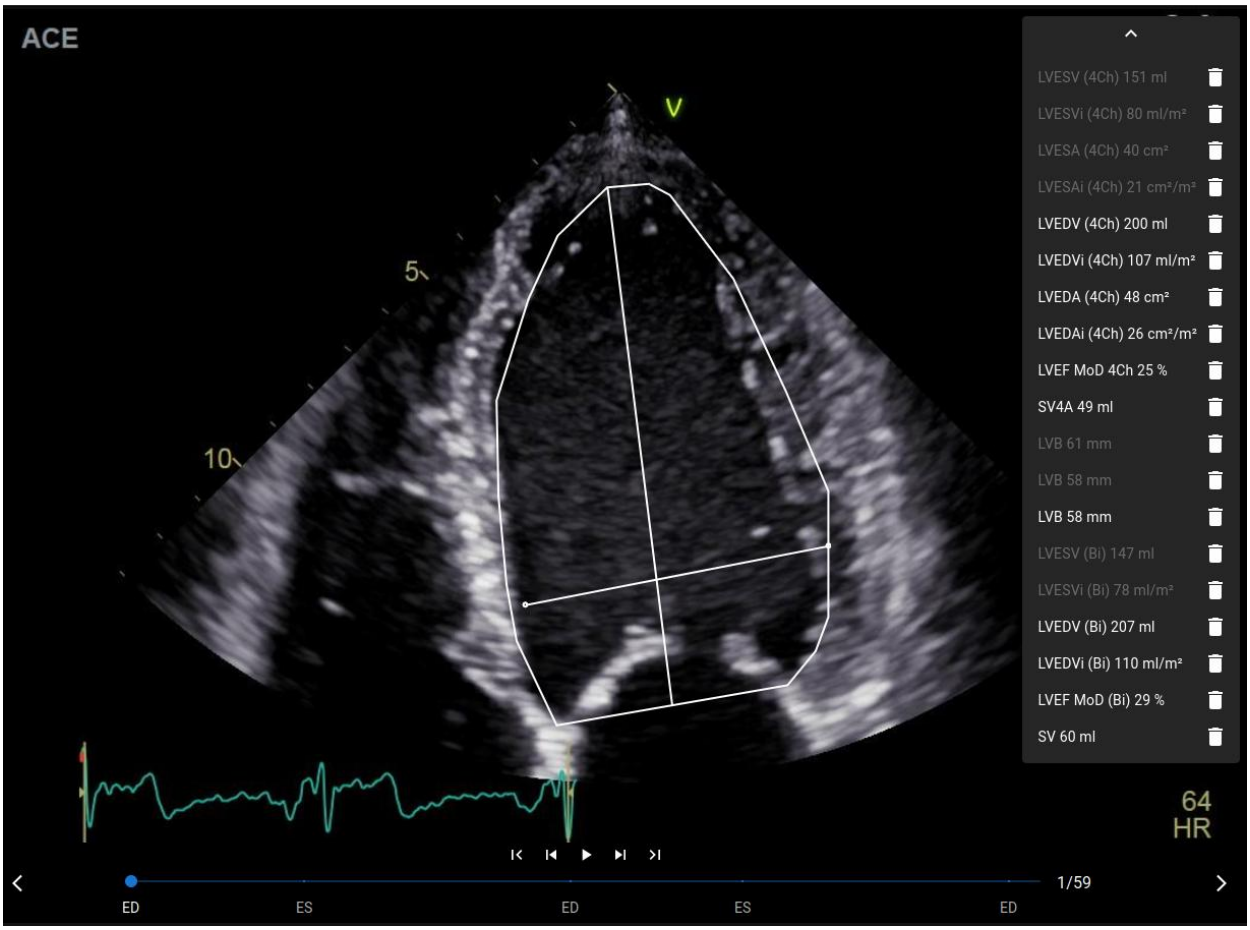
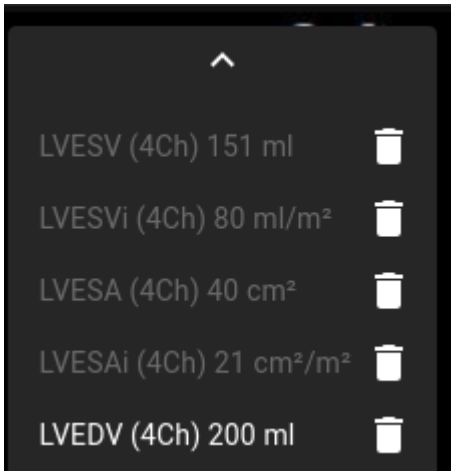
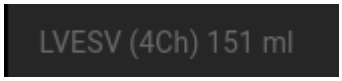
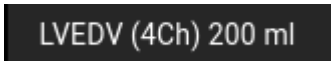
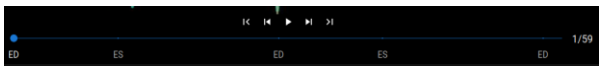
Element	Explanation
	Make area measurement
	Make volume measurement
	Make velocity measurement in Doppler images
Measurement tools 	• Hover on measurement label - show full name of the measurement label • Click on measurement label - make measurement manually • “Auto” - make automated measurement prediction 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)

Image View

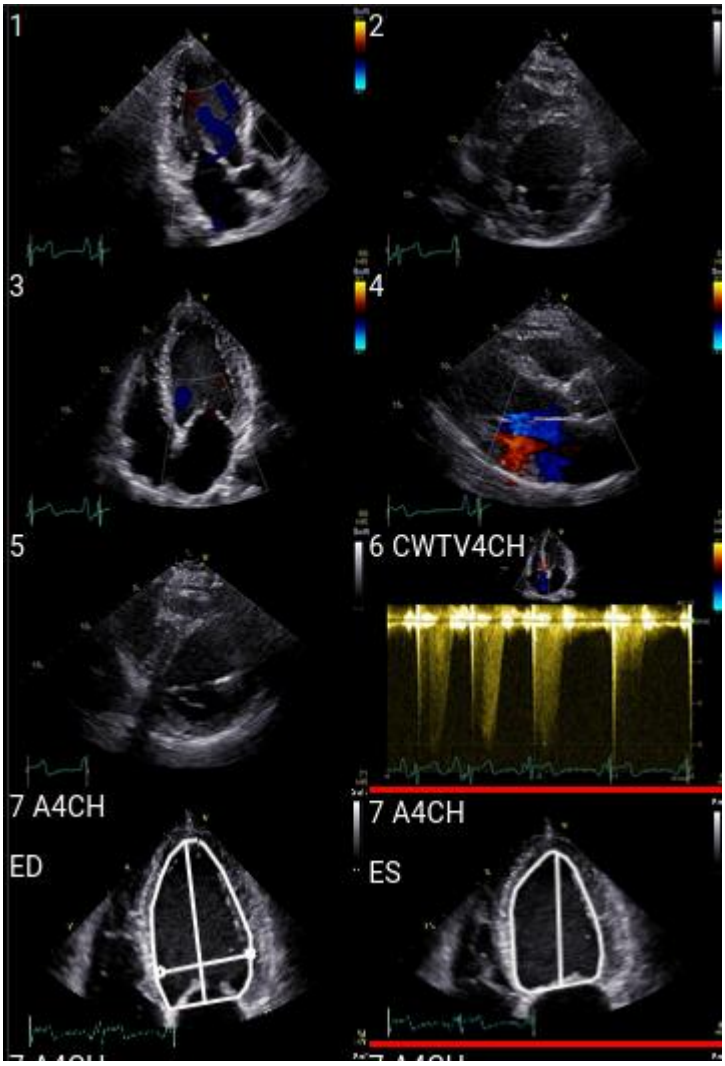


Element	Explanation
	Shows all measurements that have been made in this image.
	Hide/expand list of measurements.
	Measurement has been made in another frame of this image. Clicking on this measurement will scroll the video to the frame containing the measurement.

Element	Explanation
	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
	Go to previous image

Right Sidebar

The right sidebar shows image views of a particular study.


1
2
3
4
5
6 CWTV4CH
7 A4CH
ED
7 A4CH
ES

4. WORKING WITH LIGENCE HEART - DESKTOP CLIENT

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.

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.

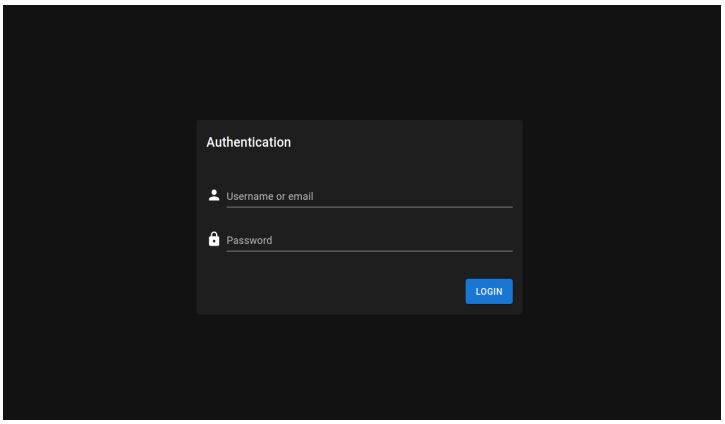
NOTE

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”.



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. 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:

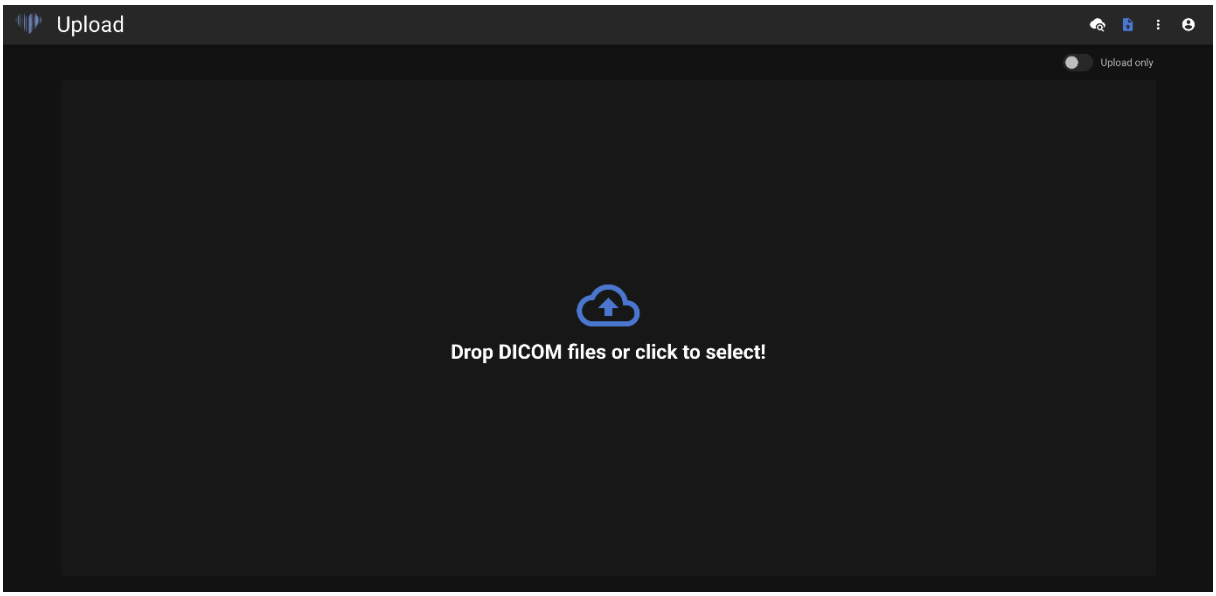
- Change password
- Logout

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.

How to upload a study?

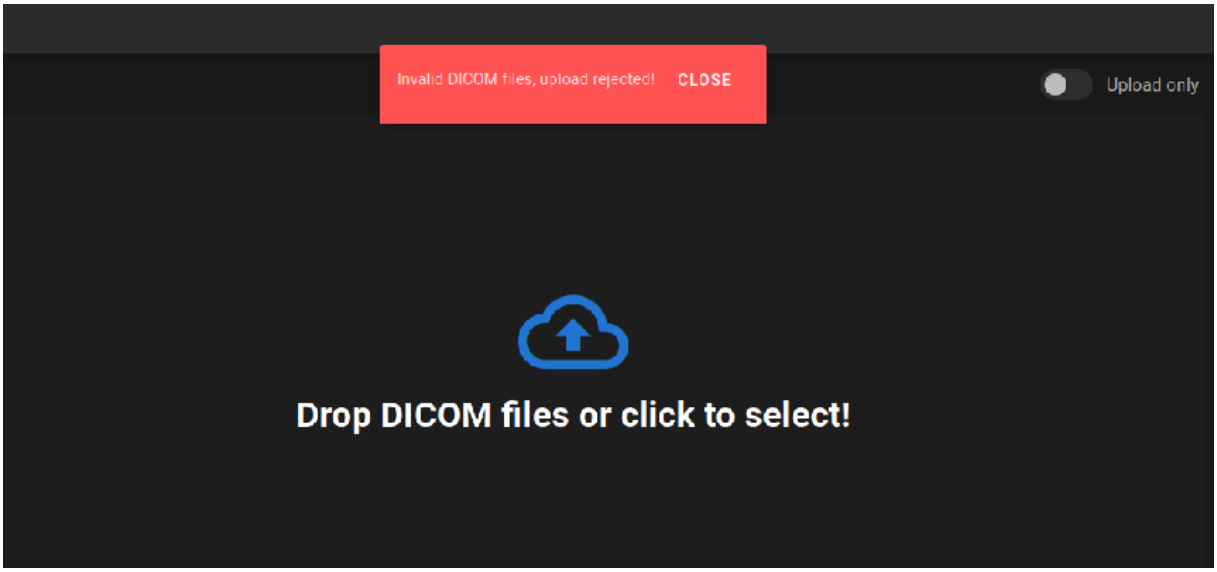
To upload a study simply drag and drop your DICOM format file or press on the blue icon and upload it from your computer.



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

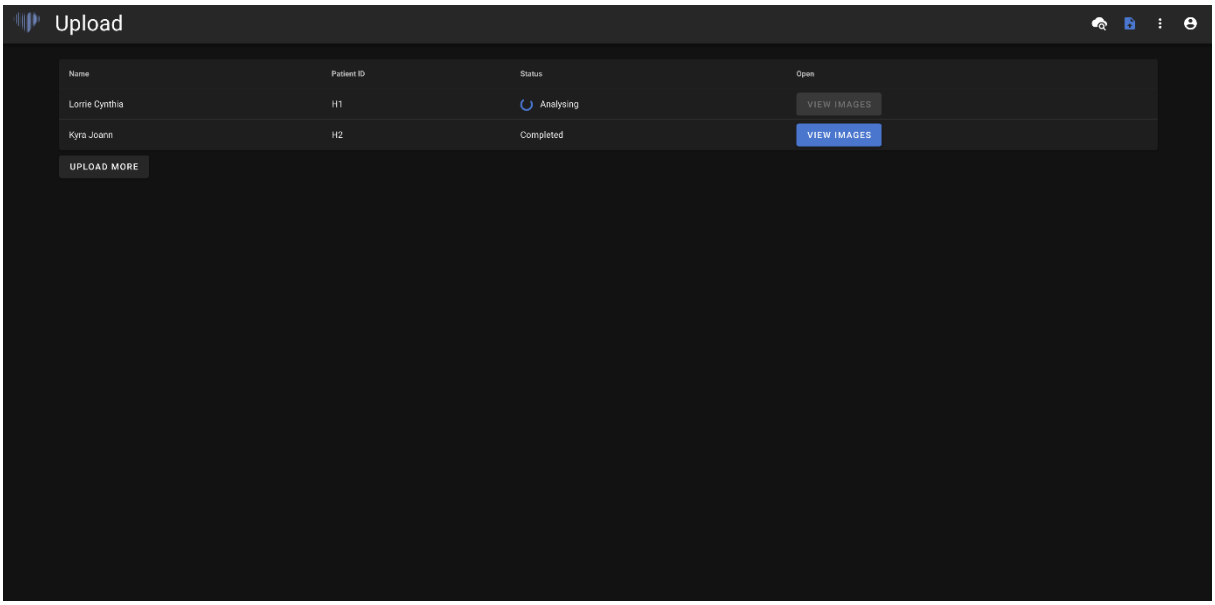
Limitations of upload functionality

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.

Upload completed



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

Invalid files uploaded

In several scenarios the uploaded DICOM files will be rejected and the user will be informed:

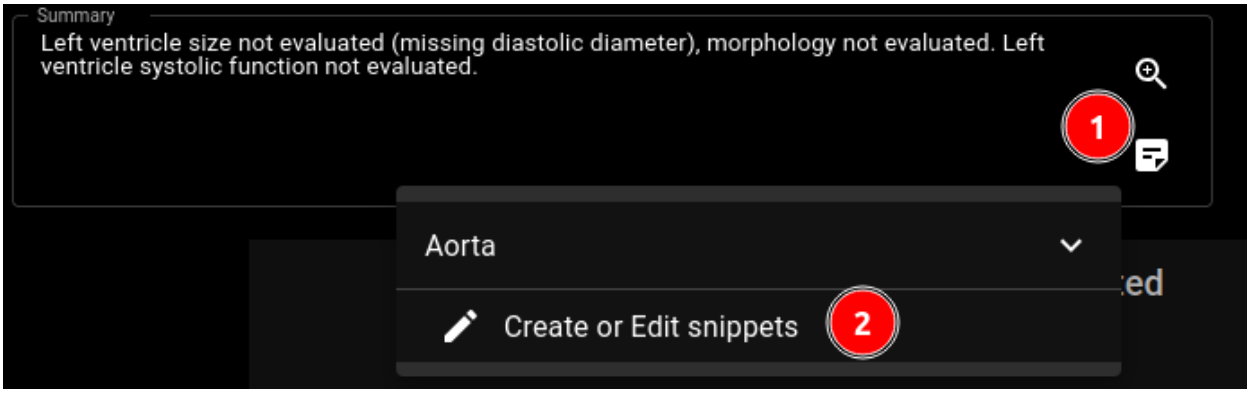
- Unsupported transfer syntax.
- Duplicate DICOM (trying to upload the same DICOM or echocardiographic study twice).
- Study is not of echocardiographic modality.

6. Text Snippets

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

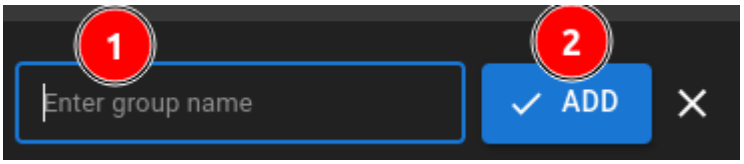
a. Create Text Snippets

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

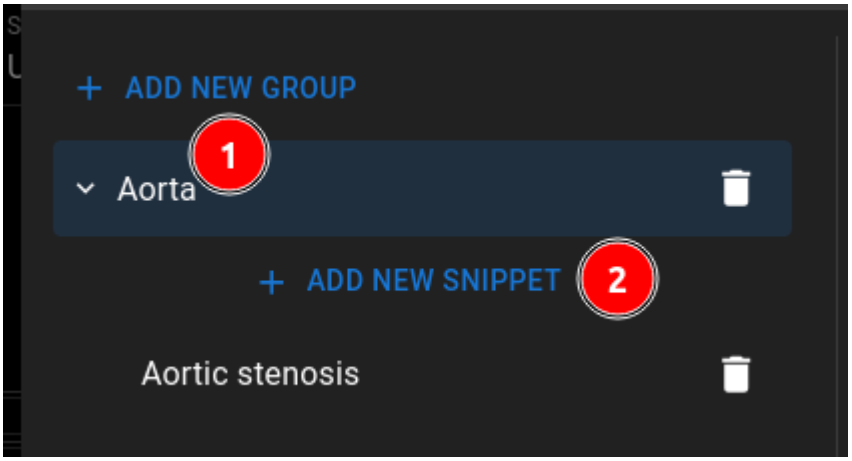


- (Optional) Click “Add new group”

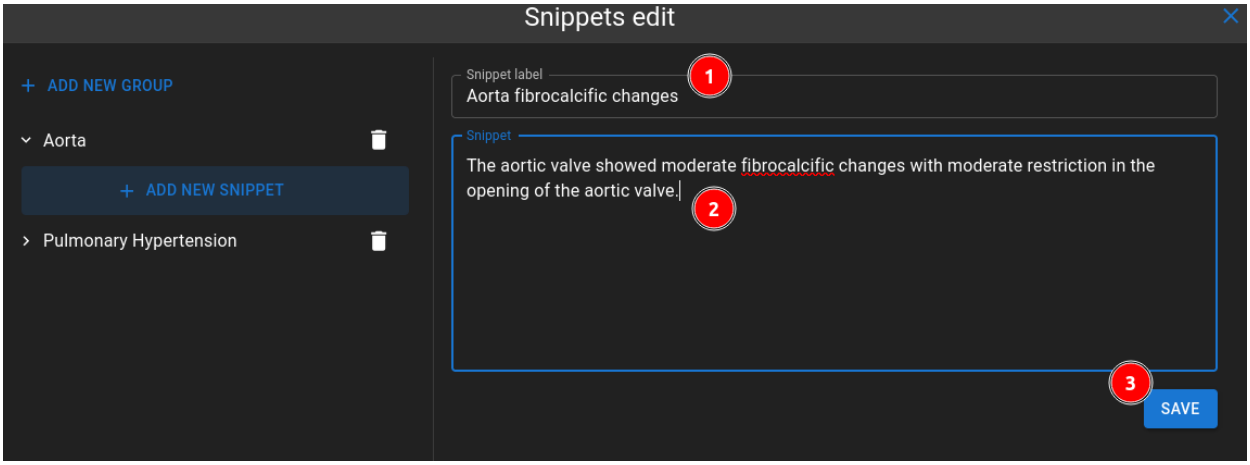
- Enter the name for the group
- Click “Add”



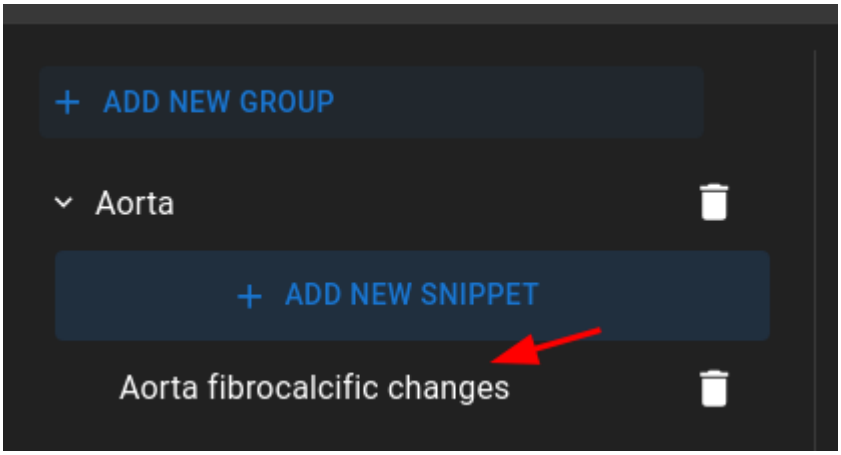
- Select the group to expand it
- Click “Add New Snippet”



- Enter snippet name
- Enter snippet text
- Click “Save”



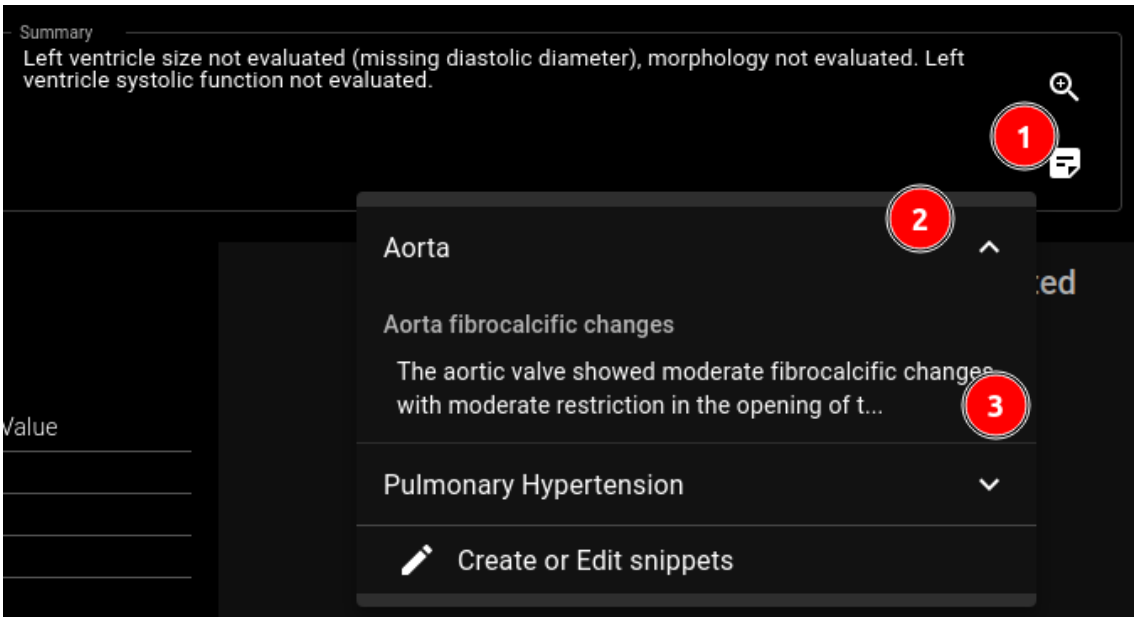
- The new snippet will be shown in the snippet group list



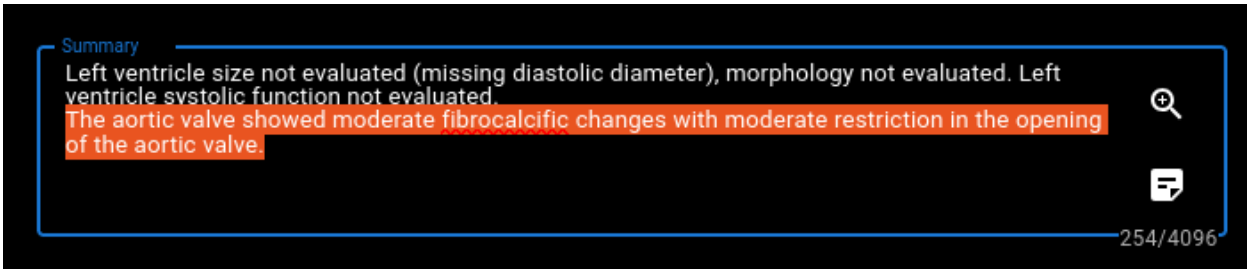
b. Import Text Snippets

- Click Snippets button

- Select group
- Click on the relevant snippet

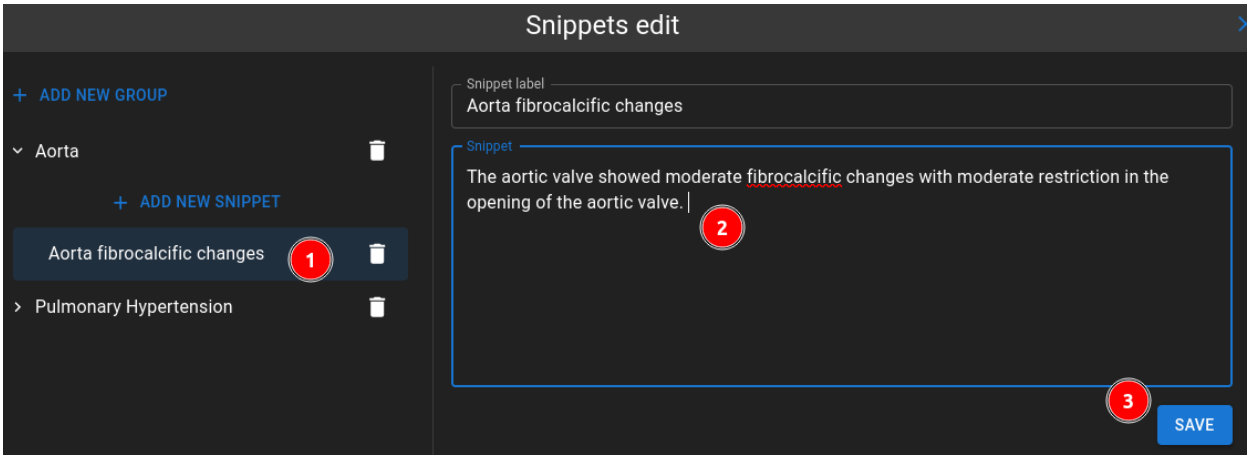


The snippet will be added to the end of the text field.



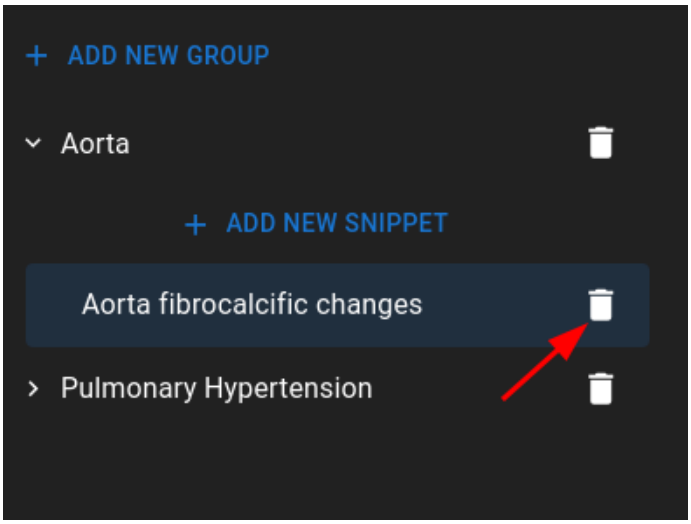
c. Edit Text Snippets

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



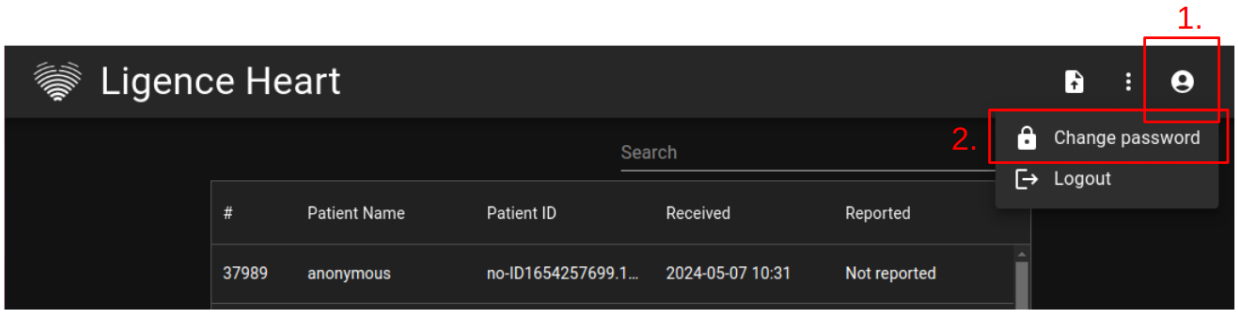
d. Delete Text Snippets or Snippet Groups

Use the recycle bin button to delete a snippet



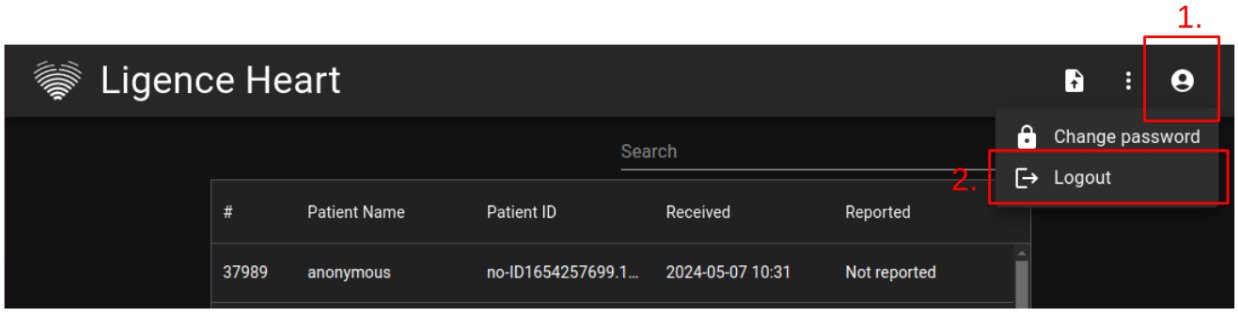
7. Changing Password

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.



8. 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.

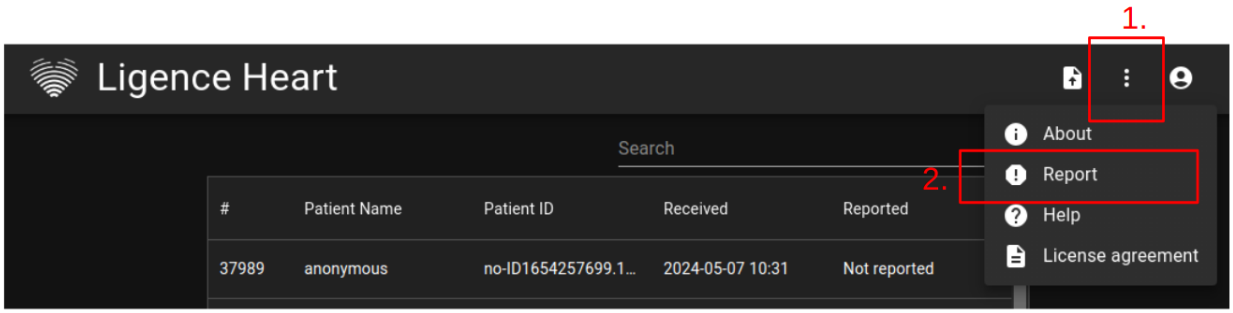
9. Locking the software

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.

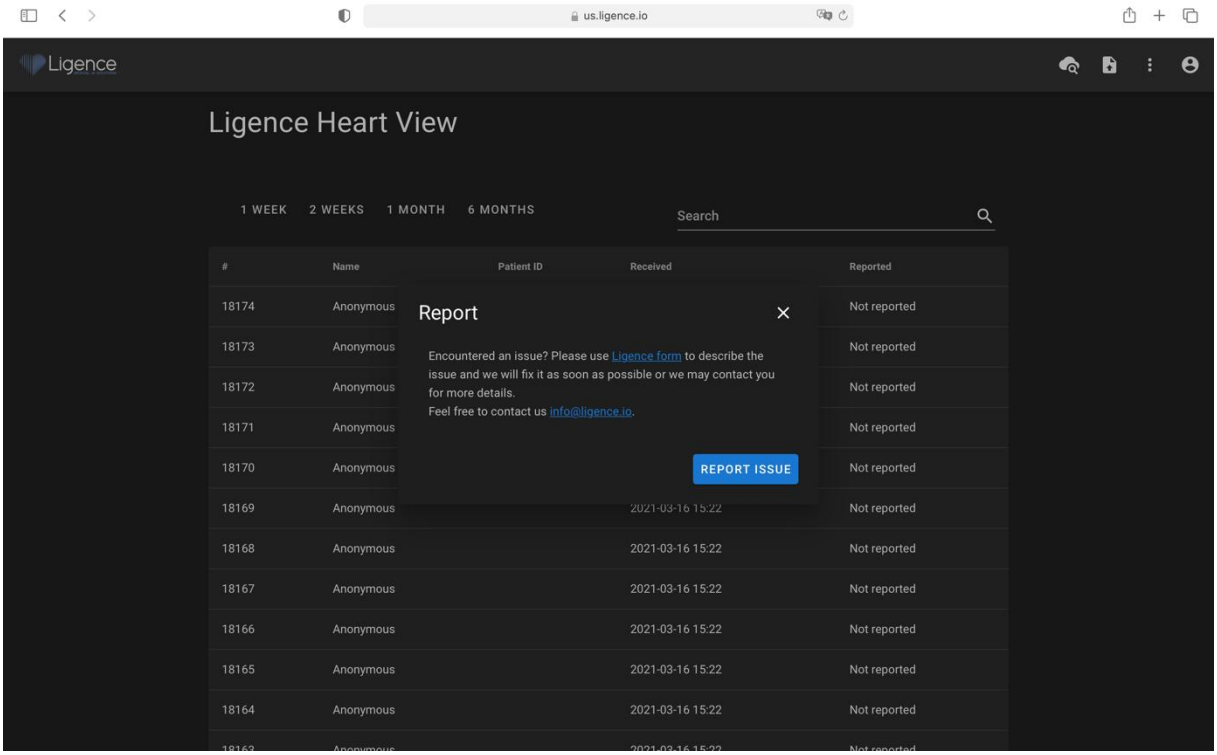
10. Report an issue

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

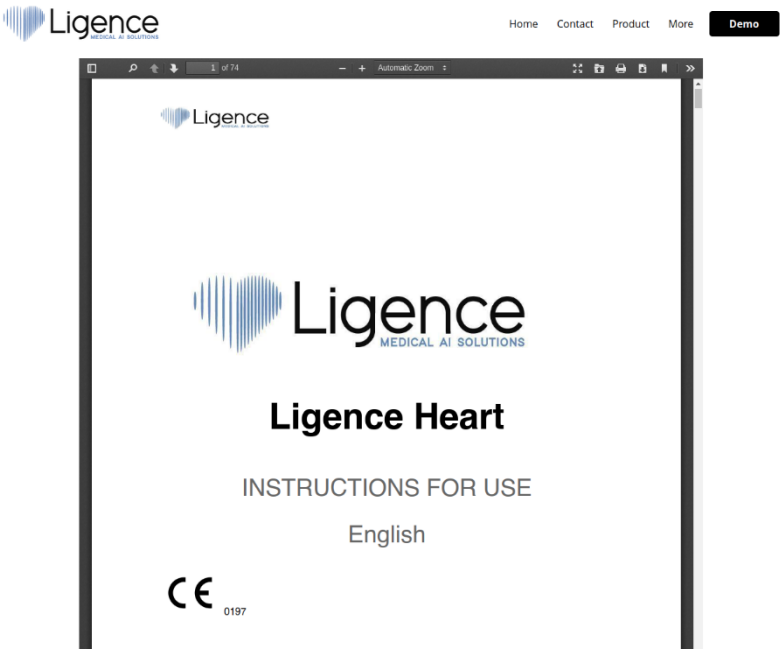
Depending on your issue it may be resolved in varying timeframe. Please consult your Service Level Agreement for more information.

11. 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.



12. 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.

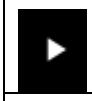
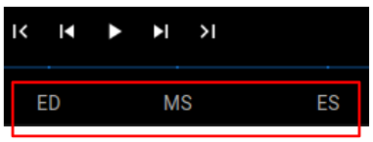
Icon	Name	Function
	Pan	Allows the user to move the ultrasound image frame stack across the screen. Press and hold the image with the left mouse button and move it to any side to move the image stack.
	Toggle label visibility	Enables/disables measurement labels on the measurements (lines, polygons etc.). By default labels are disabled.
	Toggle annotation visibility	Hides/shows annotations on frames.
	Lock/unlock annotations edit	When locked, annotations cannot be made. Edit mode allows annotations to be made.
	Report	Enters the Report View.

13. 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.

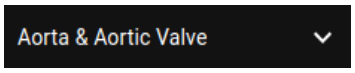
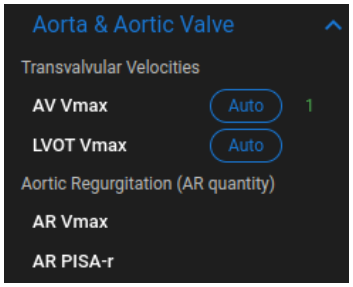
The buttons and their function of the workspace are summarized in the table below.

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.

14. 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:

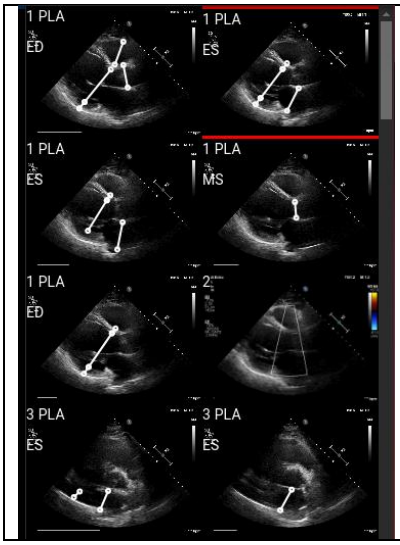
Icon	Name	Function
	Distance measurement	Press it to manually measure distance between two points.
	Area measurement	Press it to manually measure the area of the region of interest.
	Volume measurement	Press It to manually measure the volume of the region of interest.
	Velocity measurement	Press it to 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.
	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.

15. 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:

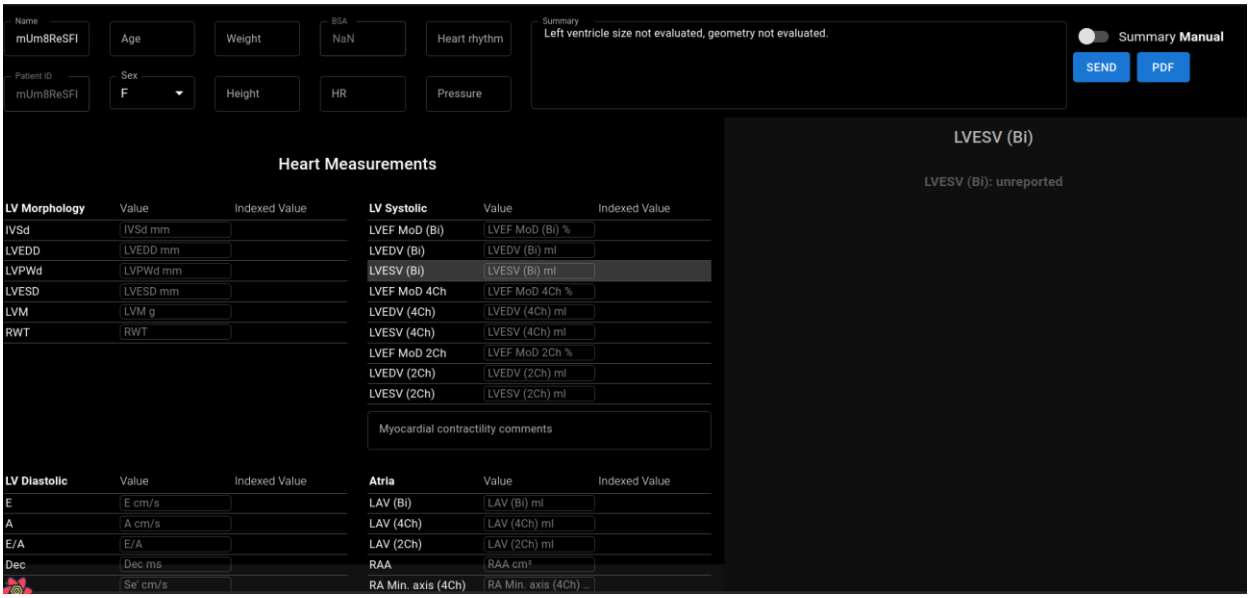
Icon	Name	Function

	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.

16. Study reporting

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

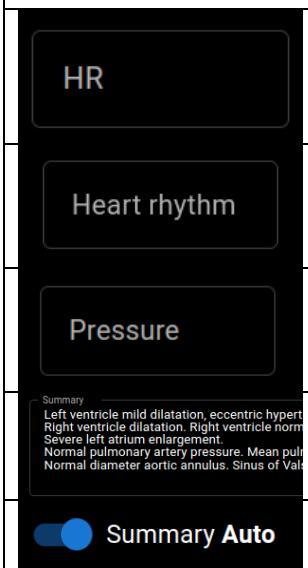
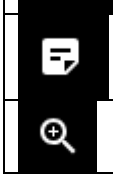
If you decide to go back to the Working View press the Back to study images button.



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.

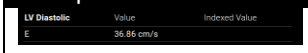
All the fields and functions of the Report View top panel are summarized in the table below:

Component	Name	Function
Study date/time: 2025-01-20 15:15	Study date and time	Shows when the study was received by software

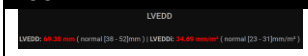
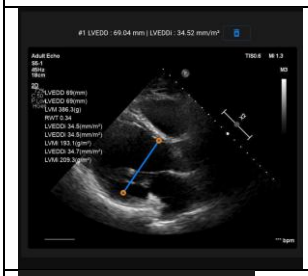
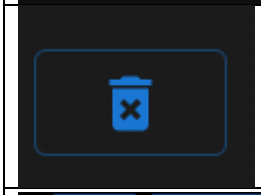
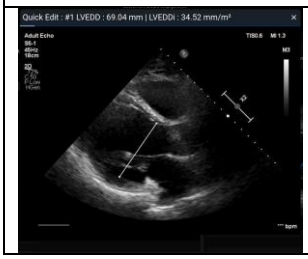
Component	Name	Function
	Name	Allows you to read or enter patient name
	Patient ID	Allows you to read patient ID
	Age	Allows you to read or enter patient age
	Sex	Allows you to read or select patient sex
	Weight	Allows you to read or enter patient weight in kilograms.
	Height	Allows you to read or enter patient height in centimeters
	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.
	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

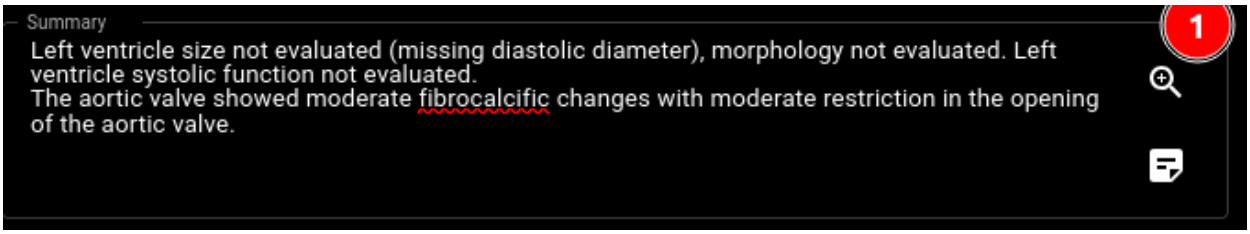
Component	Name	Function
	Non-indexed measurement value	Non-indexed measurement value within normal range for your review
	Non-indexed measurement value	Non-indexed measurement value outside of normal range for your review
	Indexed average measurement value	Indexed measurement value that is averaged of 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
	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:

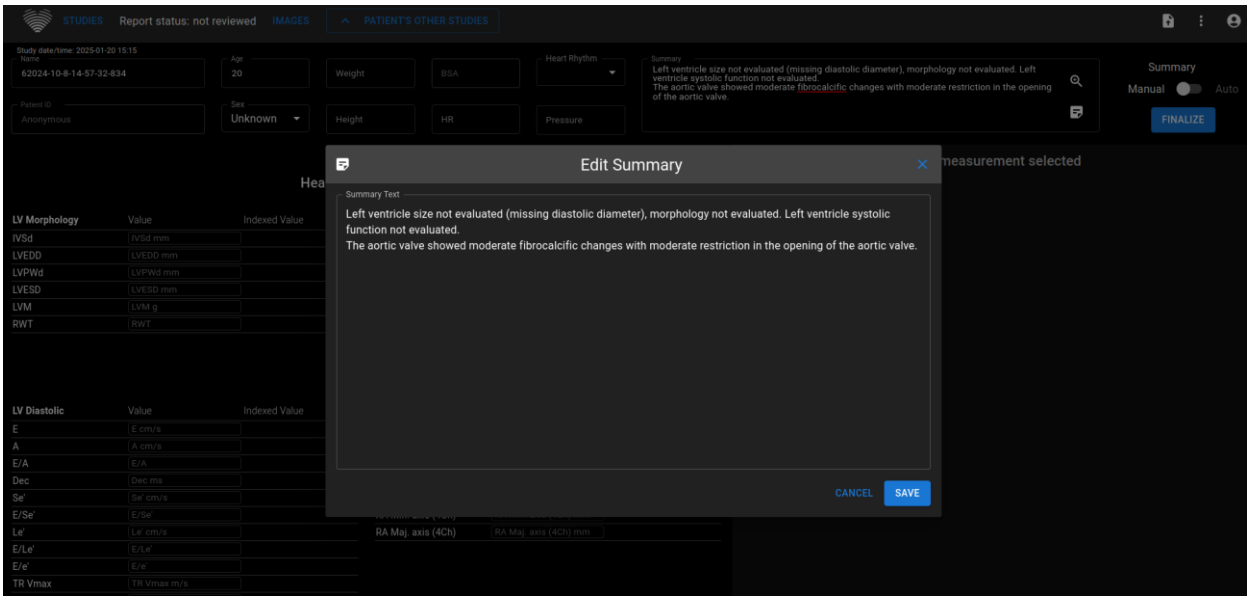
Icon	Name	Function
	Selected measurement header	Specifies the currently selected measurement and its values in more detail
	Selected measurement source	Displays each individual image, its annotations and value for your currently selected measurement
	Delete measurement button	Allows you to delete an 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

Enlarge summary edit field

- Click on the enlarge summary field button



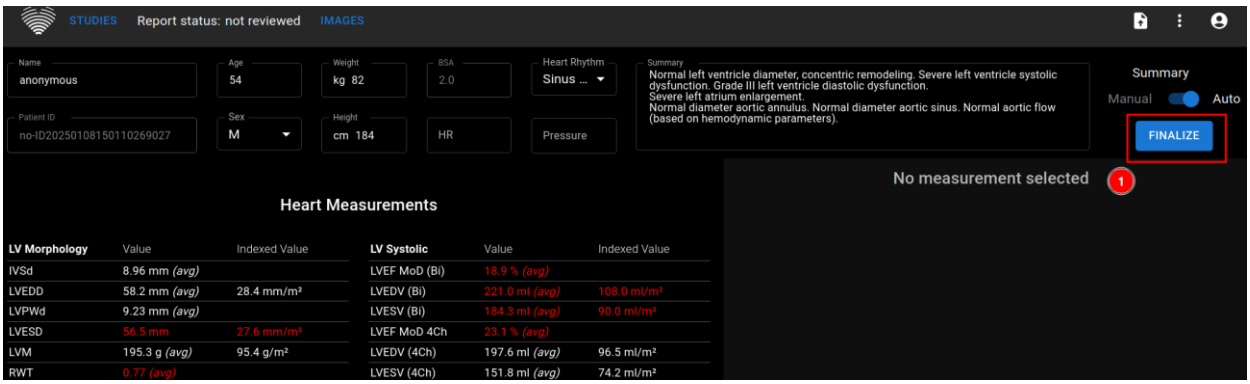
Edit summary in a dedicated screen.



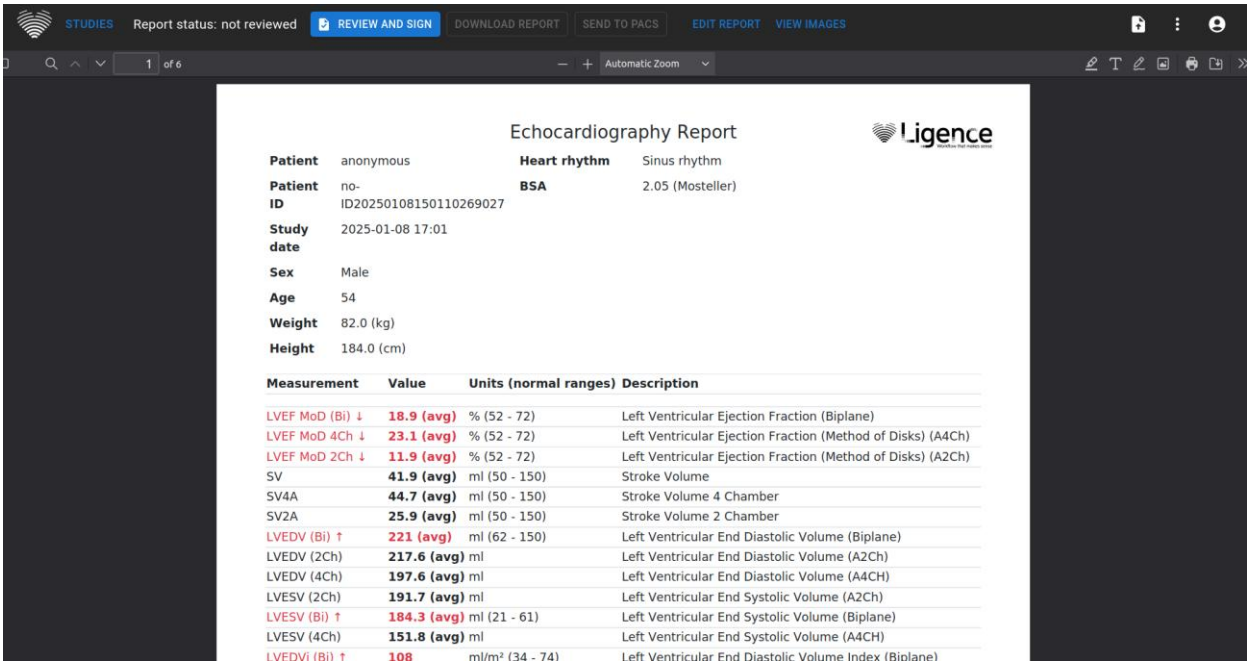
17. Report PDF View

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:

Report status: not reviewed	Report status	Shows the current status of the study report
REVIEW AND SIGN	Review and sign button	Click here to sign the report
STUDIES	Return to studies list button	Go to Lobby View
DOWNLOAD REPORT	Download report button	Download the signed report. Only available after signing the report.
SEND TO PACS	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

18. Main Interface Functions

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.

Making measurements

Annotation function: when 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.

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.

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.

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.

Delete annotation

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

Cancel drawing

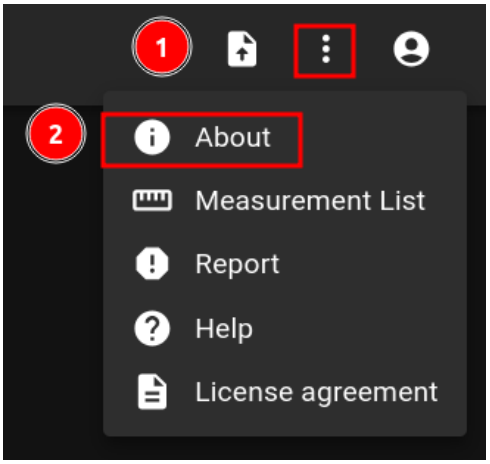
Press "ESC" key to stop drawing active annotation and remove it. Change annotation point

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.

19. 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:

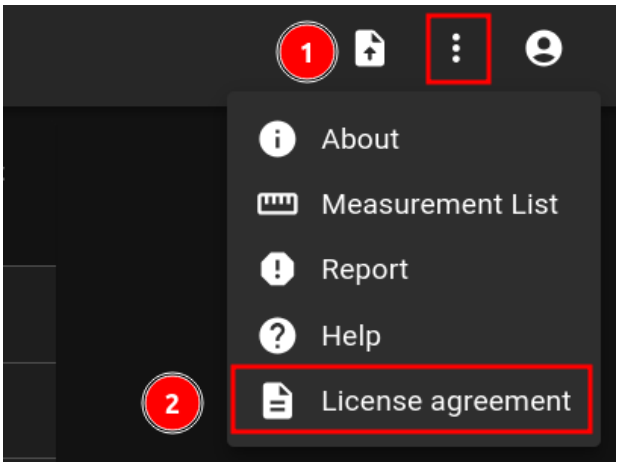
- Name of the manufacturer
- Address
- Email
- Website URL

20. Decommissioning of Software

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

21. 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.

22. User Registration

NOTE

License registration is required for legal software use.

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

1. 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.

1. 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.

3. Keep your PC system up to date with the most current updates for your operating system and browser.

4. 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.

5. Change your password immediately if you think your password has been compromised.

6. Use reputable security software on your PC that provides protection against viruses, "adware" and other forms of malicious software ("malware").

7. Take advantage of "software firewall" features in your security software as added protection for your PC.

8. 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

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

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

3. 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. .

3. 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.

4. The software database is not accessible for the user, therefore no access to any system log files is permitted for the user.

6. ANNEX I

1. List of Measurements

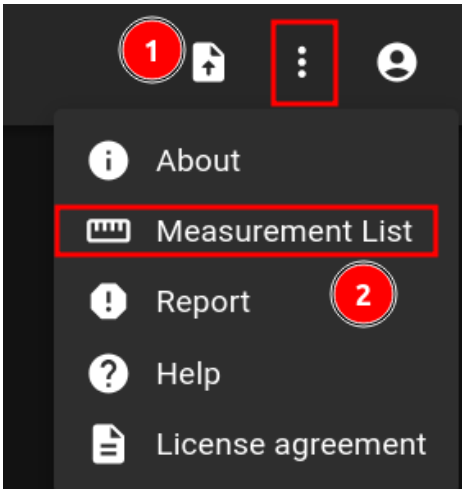
The table below shows the list measurements that can be performed in either automated or manual mode.

Automated Research - This indicates that automated analysis of this measurement has not been validated in a clinical trial.

Automated Validated - This indicates that automated analysis of this measurement has been validated in a clinical trial.

Measurements without ✓ symbols can be performed in manual mode.

The same table can be accessed from the software:



Abbreviation	Description	Automated Research	Automated Validated
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		