Ligence Heart

For 5.0.0 version

INSTRUCTIONS FOR USE

English

Revision history			
Rev.	**Revision date**	**Description of change**	**Revised by**
1.0	2025-06-12	Document was created	Justinas Balčiūnas
2.0	2025-09-01	● Performance summary (Section 6): the table that describes the ultrasound scanners and transducers used for supportive external component validation is removed. ● Server side requirements (Section 2.4.2.1): Ubuntu 20.04 and CentOS 8.5 are removed. ● Updates (Section 2.4.3): A description of systematic procedures for users to download version-identifiable manufacturer-authorized software and firmware is added. ● Automatic Summary Mode (Section 3.5.5): An example of the generated report including the cited guidelines has been added. ● International References Ranges (Section 3.5.5.2): the reference tables are changed to follow the current guidelines. ● Cybersecurity Instructions and specifications (Section 5.5 SBOM): the section describes how to access the SBOM.	Justinas Balčiūnas
3.0	2025-09-02	● Ligence Heart v4.0.0: This release introduces LV GLS (Left Ventricular Global Longitudinal Strain) analysis, with new strain view elements and measurement functions. ● Additionally, Ligence Heart can be deployed on a private cloud.	Justinas Balčiūnas

Revision history			
Rev.	**Revision date**	**Description of change**	**Revised by**
		● The Instructions for Use (IFU) have been reorganized to follow the user workflow. ● The list of supported web browsers and operating systems has been updated. The limitations section has been updated to specify that automatic measurements are intended for adult patients (≥18 years). ● Additionally, the Settings menu has been renamed to “About and Support” with expanded informational text.	
3.1	2026-04-06	The label was updated for version 4.1.0. The manufacturer’s postal code was corrected.	Simona Steikūnaitė
4.0	2026-05-15	Updated for software version 5.0.0. Labels were revised, and new software improvements were added and described.	Simona Steikūnaitė

UAB Ligence

Taikos pr. 54,

Kaunas, Lithuania

LT- 51305

© 2026, UAB Ligence, Kaunas

Symbols Glossary

	Prescription-only device
	Manufactured By: ● UAB Ligence ● Taikos pr. 54, LT-51305, Kaunas, Lithuania ● info@ligence.io ● https://ligence.io
	https://ligence.io/user-manuals/
[K###### placeholder]	FDA 510(k) number (pending)

All rights reserved in the event of granting of patents or registration as a utility patent.

All names of companies and products mentioned in this IFU may be trademarks or registered trademarks. References to products of other manufacturers are for information purposes only. Such references are intended neither as an approval nor a recommendation of these products. UAB Ligence accepts no liability for the performance or use of such products.

Other brand names, software and hardware names used in this Instructions for Use (IFU) are subject to trademark or patent protection. The quoting of products is for informational purposes only and does not represent a trademark misuse.

This IFU is protected by copyright. Unless exclusively authorized in writing, dissemination, duplication or other commercial exploitation of this documentation set or communication of its contents or parts of it is not permitted. In case of infringement, the violator may be liable to pay compensation for damages.

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

TABLE OF CONTENTS **6**
1. READ THIS FIRST 9
1.1 About the Instructions for Use (IFU) 9
1.2 Symbols 10
1.3 Label 12
1.4 Intended use 12
1.5 General description 12
1.6 Analysis mode configuration 13
1.7 User groups 13
1.8 Contraindications and Limitations 14
1.10 Clinical Benefits 17
1.11 Commencement and Termination of Use 18
1.12 Customer Service 18
2. SAFETY 19
2.1 Residual Risks 19
2.2 Serious Incidents Reporting 19
2.3 Inputs and Outputs 19
2.4 Installation and Maintenance 21
2.4.1 Deployment and Installation 21
2.4.2 On-premise workflow 21
2.4.3 Private cloud network Ligence Heart integration 22
2.4.4 Server side requirements 22
2.4.5 Client side requirements for on premises 23
2.4.6 Updates 23
2.4.7 Backups and redundancy 24
2.5 Malfunction 24
2.6 Measurements 24
2.7 IT security measures 25
2.8 List of known bugs 26
3. USER INTERFACE ELEMENTS 28
3.1 Login View 28
3.2 Lobby View 29
3.2.1 About and Support menu 30
3.2.1.1 About 30
3.2.1.2 Measurement list 31
3.2.1.3 Report 32
3.2.1.4 Help 32
3.2.1.5 End-User License Agreement 33

3.2.1.6 SBOM 33
3.2.2 Account Menu 34
3.2.4 Search bar for echocardiographic studies 34
3.2.5 Study list 35
3.3 Upload View 37
3.4 Workspace View 38
3.4.1 Navigation Bar buttons and functions 39
3.4.2 Image (DICOM) section 40
3.4.3 Left sidebar buttons and functions 42
3.4.4 Right Sidebar buttons and functions 46
3.5 Strain Workspace View 47
3.6 Report View 49
3.6.1 Quick edit window 54
3.7 Report PDF view 56
4. WORKING WITH LIGENCE HEART 58
4.1 User Registration 58
4.2 Logging in 58
4.3 Acquire images 59
4.4 Upload the study 59
4.4.1 Limitations of upload functionality 60
4.4.2 Invalid files uploaded 61
4.5 Opening a study 62
4.5.1 Study Access Scenarios and System Responses 62
4.5.2 Finding other echocardiographic studies from the same patient 63
4.6 Editing Measurements in the Workspace View 63
4.6.1 Scroll stack 63
4.6.2 Making measurements 63
4.6.3 Draw area measurement 64
4.6.4 Draw volume measurement 64
4.6.5 Grade measurements 64
4.6.6 Delete annotation 64
4.6.7 Cancel drawing 64
4.7 Measuring Strain 65
4.7.1 Choose image views 65
4.7.2 Edit image 66
4.7.3 Deleting strain image 69
4.8 Study reporting 70
4.8.1 Patient Characteristics 71
4.8.2 Summary Box 72
4.8.3 Summary Modes 72

4.8.3.1 Manual Summary Mode 72
4.8.3.2 Automatic Summary Mode 72
4.8.4 Measurement fields 86
4.8.5 Illustrations 87
4.8.6 Enlarge summary edit field 87
4.8.7 Text Snippets 88
4.8.7.1 Create Text Snippets 88
4.8.7.2 Import Text Snippets 90
4.8.7.3 Edit Text Snippets 90
4.8.7.4 Delete Text Snippets or Snippet Groups 91
4.9 Finalizing Report 91
4.9.1 Choosing illustrations 92
4.9.2 Reviewal and confirmation of the report 93
4.9.2.1 Sonographer 93
4.9.2.2 Cardiologist 93
4.9.3 Going back to editing 94
4.9.4 Sending to PACS 95
4.10 Changing Password 95
4.11 Locking the software 96
4.12 Logout 96
4.13 Report an issue 96
4.14 Decommissioning of Software 97
5. CYBERSECURITY INSTRUCTIONS AND SPECIFICATIONS 98
5.1 Cybersecurity 98
5.2 Device Security and User Responsibility 98
5.3 Reporting Device Security or Privacy Breaches 99
5.4 Cybersecurity system description 99
5.5 Software Bill of Materials (SBOM) 99
5.6 Reporting security issues 99
6 PERFORMANCE SUMMARY 100
7 ANNEX I 104
7.1 List of Measurements 104
7.2 Automatically Classified Views 115

1. READ THIS FIRST

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

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

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

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

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

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

1.1 About the Instructions for Use (IFU)

The Ligence Heart Instructions for Use (IFU) are provided by default in electronic PDF format. Ligence Heart IFU in PDF format is available on the internet website: https://ligence.io/user-manuals/
You can open the file using a PDF reader application. If you do not have a PDF reader application installed, you can download Adobe Reader from the following website: www.adobe.com
Please contact UAB Ligence or its affiliates for technical support.
Ligence will assist the clients with installing and uninstalling Ligence Heart to ensure proper installation/integration of the device into the computing platform.Please contact Ligence if you have doubts about the installation.

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

Indications for Use:

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

Limitations:

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

1.2 Symbols

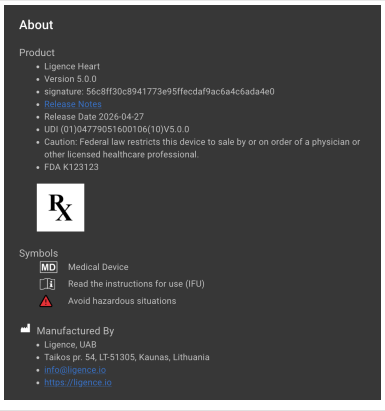
The following symbols may appear in the product documentation or on the labels attached to the product.

Symbol	Standard Reference	Symbol Title	Explanatory Text
	ISO 15223- 1:2016 Reference no. 5.4.4. (ISO 7000-0434A)	Warning	Warnings highlight information to avoid a hazardous situation, which could cause death or serious injury.

	ISO 15223- 1:2016 Reference no. 5.4.4. (ISO 7000-0434A)	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences
	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)	Note	Notes bring your attention to information that will help you operate the product more effectively.
	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)	Manufacturer	Indicates the medical device manufacturer
	ISO 15223- 1:2020 Reference no. 5.7.7	Medical device	Indicates the item is a medical device
	ISO 15223-1:2016 Reference no. A.15	Consult instructions for use or consult electronic instructions for use	Indicates consult instructions for use for an electronic instruction for use (eIFU)
	21 CFR 801.109(b)(1)	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed “healthcare practitioner.” “___", the blank to be filled 10 Ligence Heart Instructions for Use with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the

1.3 Label

English



NOTE: This eLabeling will be updated with K-number and release date after the FDA clearance.

1.4 Intended use

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

Limitations:

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

1.5 General description

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

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

Ligence Heart is a software packaged and distributed in a computing platform for post-processing adult transthoracic echocardiography DICOM studies. Specifically, the software is designed to be hosted on any existing clinical workflow on premises, via integration with a compatible computing platform.

1.6 Analysis mode configuration

Ligence Heart supports a manual analysis path that parallels the automated pipeline while giving you full control over every annotation and measure. The manual functionality allows you to inspect the performed automated annotations and estimated measures, adjust them to recompute the measurements, or delete the automated annotations and trace them manually from scratch.

WARNING

Accepting an inaccurate annotation would propagate an incorrect measurement into the final report because Ligence Heart might not conduct accurate annotations automatically.

Ligence's administrators may disable artificial-intelligence inference at system, study, or user level, leaving the manual pathway for the standard measures.

Additionally, the LV GLS measures may be disabled. In that case, you will not be able to use the automated analysis nor the manual for LV GLS analysis. If LV GLS is enabled, you will be able to use the manual analysis path to adjust the results from the automated analysis at your discretion.

NOTE

Please, contact the Ligence Heart team if the LV GLS analysis is disabled in Ligence Heart and you desire to enable it.

1.7 User groups

Ligence Heart is intended for two clinical user groups:

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

Sonographers - can review studies, accept automated annotations and measurements, edit them, add further manual measurements, or fully replace them with manual entries but not sign reports.

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

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

1.8 Contraindications and Limitations

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

Please note the following additional limitations:

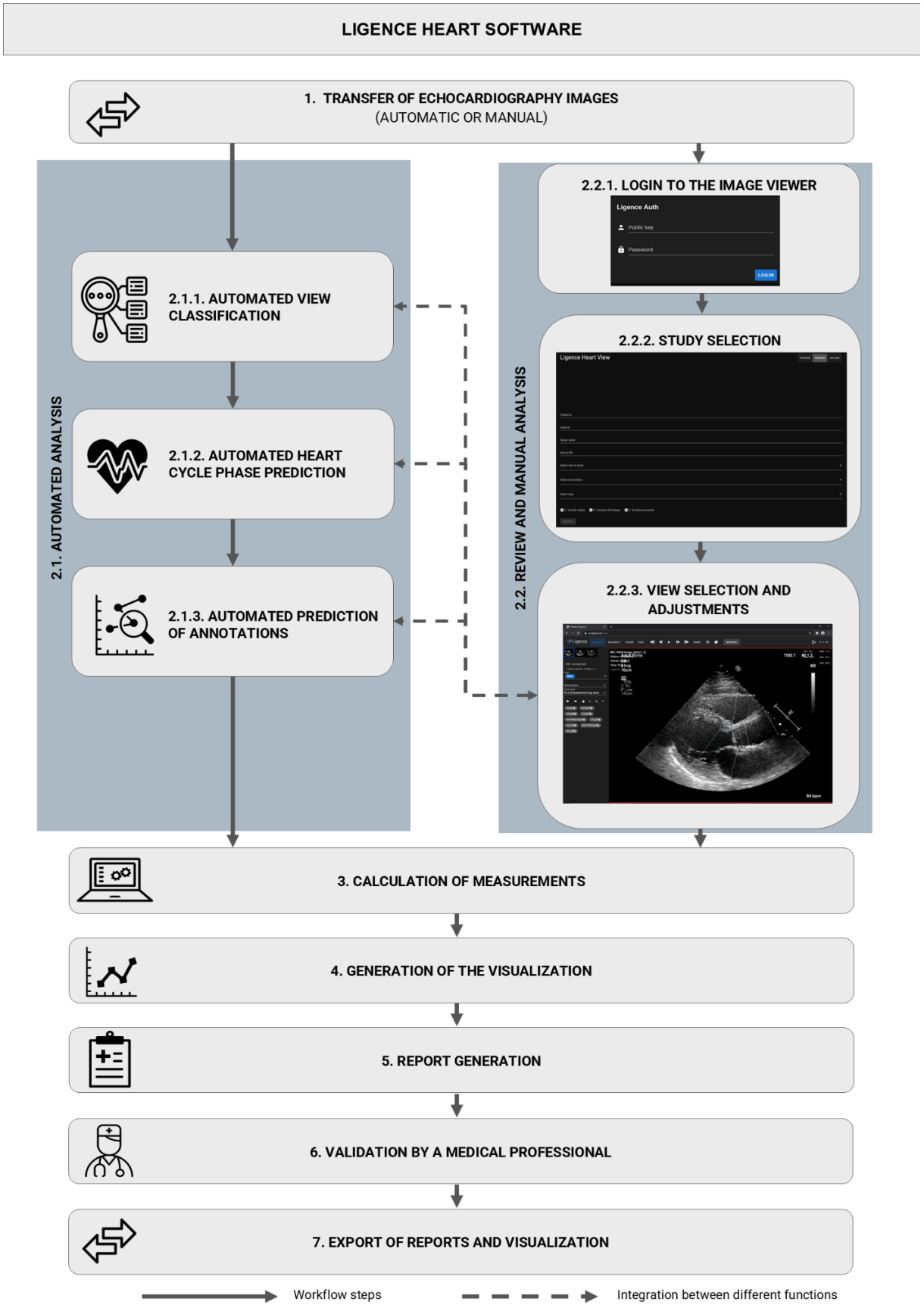
- Poor image capture will lead to poor annotations and subsequent measurements.
- Multiple image quality algorithms are used to filter out images of poor quality.
- Our software complements good patient care and does not exempt the user from the responsibility to provide supervision, clinically review the patient, and make appropriate clinical decisions.
- If no gender is present, female referenced guideline values will be used for conclusions.
- If Body Surface Area (BSA) is not present, indexed values cannot be provided.
- During image acquisition, inappropriate use of the echo machine, use of non-cardiac ultrasound probes, or use of suboptimal settings (e.g. gain, contrast, depth) may lead to lower accuracy of the software.
- Ligence Heart has not been validated in patients with prosthetic or surgically altered cardiac valves, implantable intracardiac devices, or irregular (non-sinus) rhythm; these conditions may affect automated measurement accuracy.
- Ligence Heart is only intended to be used with the population of 18 years old or older.



WARNING

Primary valvular disease might cause some deviations, and Ligence Heart has not been validated to robustly test the performance on patients with primary valvular diseases.

Functional elements scheme:



Key functional elements from figure above are described in the table below.

Key function	Description
1. Transfer of echocardiography images (automatic or manual)	Echocardiography images and the clinical data can be sent to Ligence Heart automatically from the Ultrasound Scanner (via PACS or any other medical image management system) or manually uploaded from a workstation with access to Ligence Heart. Authentication/authorization to access Ligence Heart's functionalities, such as manually uploading data, is mandatory.
2. Echocardiography examination	Echocardiography examination is conducted using automated or manual analysis functions at the user's discretion. If automated analysis functions are enabled for the standard or LV GLS measurements, depending on the configuration (please see more detailed information in Section 1.6), the system automatically performs automated analysis when receiving the images and the clinical data (from the Ultrasound scanner or the workstation when manually uploading them).
2.1. Automated analysis	
2.1.1. Automated view classification	Ligence Heart determines the view mode of the echocardiography image. This step is needed for further analysis of images.
2.1.2. Automated heart cycle phase prediction	Ligence Heart tracks the cardiac cycle and identifies the frames that are crucial for the analysis of echocardiography images, e.g., end-systolic and end-diastolic.
2.1.3. Automated prediction of annotations	Ligence Heart predicts annotations that are used for the standard measures - heart anatomy and functionality - and the LV GLS analysis.
2.2. Review and Manual analysis	
2.2.1. Login to the image viewer	Ligence Heart requires user authentication/authorization to access functionalities. NOTE: The user might have previously accessed Ligence Heart to upload the input data and directly perform the manually-assisted analysis, or the user who conducts the echocardiography examination might be a different person from the user who transfers the images.
2.2.2. Study selection	Selection of the patient study corresponding to the patient to be analyzed for echocardiography examination by filtering/searching.
2.2.3. View selection and adjustments	Study analysis step - you can review the results from the automated analysis (if enabled) and adjust them at your discretion, or directly conduct the manual analysis if automated analysis is disabled (only for standard measures): Standard measures: You can select the desired clip or still frame and choose the desired parameter. Ligence Heart activates context-aware drawing tools - points, lines, or polygons - that match the measurement blueprint LV GLS measures: You can select the desired clips and adjust annotations (cardiac cycle and contour tracking).

3. Calculation of measurements	Calculation of measurements based on the annotations on echocardiography images performed by the combination of manual and automatic functions according to the analysis mode configuration.
4. Generation of visualisations	The software generates elements required for LV GLS analysis: ● Display of contour tracking; ● A bullseye diagram; ● Strain-over-time curves; ● Average and regional GLPS values.
5. Report generation	Study analysis results report, which consists of all annotations and measurements made, along with an automatically suggested report summary text, is generated for review and approval by the users.
6. Validation by a medical professional	Users validate all annotations and measurements in the results report and sign it. If needed, the user adjusts annotations to recalculate measurements and repeat the process to generate the results report.
7. Export of reports and visualization	Users can export reports and visualizations to other external systems in DICOM SR, DICOM SC, DICOM embedded PDF formats.

1.10 Clinical Benefits

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

Conventional workflow (without Ligence Heart)

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

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

Optimized workflow with Ligence Heart:

1. After acquisition, the study is sent to PACS as usual.
2. Ligence Heart automatically
    a. recognises views, cardiac cycle phase and cardiac structures,
    b. generates annotations and measurements for validated measurements,
    c. highlights values that fall outside ASE/ESC/EACVI reference ranges, and
    d. generates a draft structured report.
    e. enables users to make LV strain analysis, generate bullseye diagrams.
3. A reviewing clinician may then:

a. review the images/videos, if desired.
b. manually adjust any of the automated segmentations and measurements, if desired.
c. finalise and approve the report.

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

1.11 Commencement and Termination of Use

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

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

1.12 Customer Service

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

Contact details:

E-Mail: support@ligence.io

Support Hotline: +1 (919) 406-4488

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

2. SAFETY

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

CAUTION



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

2.1 Residual Risks

There are no residual risks.

2.2 Serious Incidents Reporting

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

2.3 Inputs and Outputs

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

Inputs

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

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

Data formats read

Data formats which can be read by this product include:

a) DICOM storage classes:

- 1.2.840.10008.5.1.4.1.1.6 - Ultrasound Image Storage (retired)
- 1.2.840.10008.5.1.4.1.1.6.1 - Ultrasound Image Storage
- 1.2.840.10008.5.1.4.1.1.7 - Secondary Capture Image Storage
- 1.2.840.10008.5.1.4.1.1.3 - Ultrasound Multiframe Image Storage (retired)

- 1.2.840.10008.5.1.4.1.1.3.1 - Ultrasound Multiframe Image Storage
- 1.2.840.10008.5.1.4.1.1.7.1 - Multiframe Single Bit Secondary Capture Image Storage
- 1.2.840.10008.5.1.4.1.1.7.2 - Multiframe Grayscale Byte Secondary Capture Image Storage
- 1.2.840.10008.5.1.4.1.1.7.3 - Multiframe Grayscale Word Secondary Capture Image Storage
- 1.2.840.10008.5.1.4.1.1.7.4 - Multiframe True Color Secondary Capture Image Storage

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

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

Acquisition protocol

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

Outputs

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

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

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

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



CAUTION

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

2.4 Installation and Maintenance

2.4.1 Deployment and Installation

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

The software may be hosted on:

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

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

2.4.2 On-premise workflow

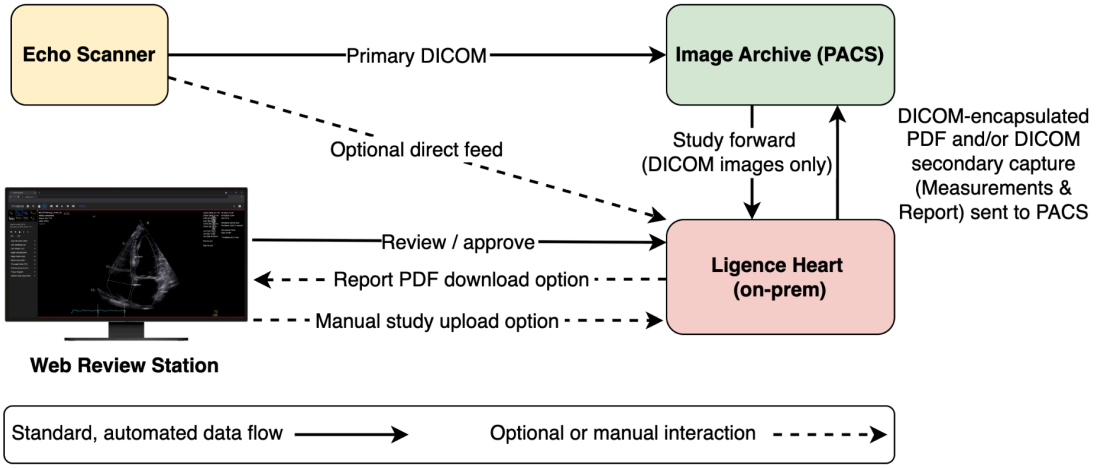
Ligence Heart receives DICOM studies from one or more echocardiography scanners on the local network. It automatically generates measurements and report text, which can be seamlessly forwarded to the PACS. Patient data remains securely within the local network and is inaccessible outside of it unless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

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

Typical sequence:

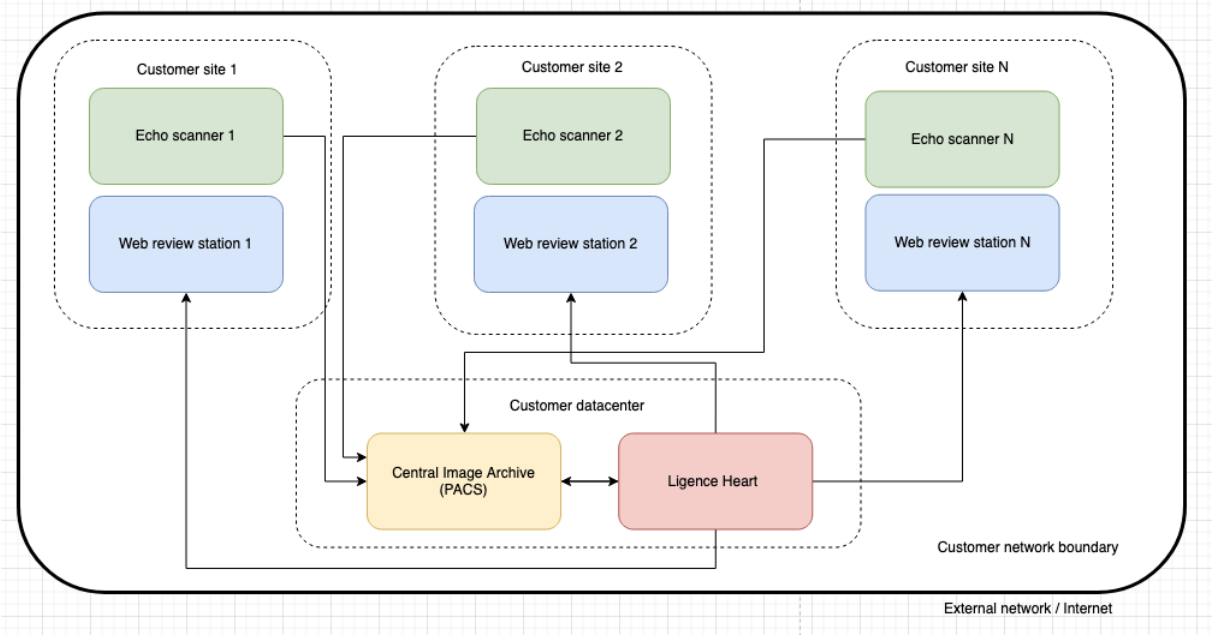
1. Scan acquisition – Echocardiography scans are performed as usual.
2. Image storage – Raw images are sent to the PACS as routine. PACS is configured to automatically forward relevant studies to the Ligence Heart server.
3. Automated analysis – Ligence Heart analyses the study and stores measurements and key images.
4. Results return – A DICOM-encapsulated PDF (or secondary-capture images) containing measurements and provisional report text is sent back to the PACS.
5. Review & approval – Clinicians open the Ligence Heart web application from any workstation in the network (often via a launch link embedded in the PACS). Measurements can be reviewed, edited and approved and the final report is then stored in the PACS.

Clinical Data Flow Between Echo Scanner, PACS, Ligence Heart, and Workstation Users are presented in the figure below.



2.4.3 Private cloud network Ligence Heart integration

Ligence Heart offers integration capabilities with third-party providers, enabling its operation as an application within broader platform AI ecosystems. Figure below illustrates a high-level architectural example, with specific details contingent on the platform. Ligence Heart is deployed on a Kubernetes-like image infrastructure, utilizing non-volatile storage. The partner retains complete control over private cloud access. Within the virtual private network, Ligence Heart software operates via the same access points as in Local Network Ligence Heart integration schemes, allowing the platform to manage access to the Ligence Heart software. High level overview of private cloud architecture with Third Party Platform, the Ligence Heart application is hosted on “App host platform” that controls information flow is shown below.



2.4.4 Server side requirements

CPU cores *	RAM	Storage	Network

16 (32 threads)	32	1000 GB	200 Mbit/s

Minimal software requirements

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

Supported operating systems

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

- Ubuntu 22.04
- Ubuntu 24.04

2.4.5 Client side requirements for on premises

Minimal desktop client hardware requirements

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

Supported operating systems

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

Supported web browsers

- Google Chrome 118.0.5993.88+
- Mozilla Firefox 118.0.2+

Internet Explorer is generally not supported and should be avoided.

2.4.6 Updates

Whenever there is a software update, our dedicated Ligence representative will proactively communicate with you to provide details on the upcoming release. In all cases, you will receive an email when updates are available.

Whenever a new software version is available, Ligence informs the Client about the changes and availability of the new version. Additionally information about the new version is published on the Company website. The Client can use the Company website to verify that a new version has been published.

After a new version is released, the Client can obtain a new version using Docker command. Since access to Docker image registry is restricted. After the Client downloads the new version, Ligence emails SHA256 digests of the Docker images to the Client. The Client then compares the SHA256 digests of the updated Docker image versions.

Ligence will assist the clients with Ligence Heart updates to ensure proper installation/integration of the new version into the computing platform.

On-premises update

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

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

2.4.7 Backups and redundancy

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

CAUTION

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

NOTE

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

2.5 Malfunction

In case of malfunction, please do the following:

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

2.6 Measurements

CAUTION

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

CAUTION

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

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

Safety of Manual Functionalities

CAUTION

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



- B-mode
- PW-Doppler

2.7 IT security measures

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

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

It is highly recommended to run Ligence Heart only from the devices and accounts that are authorized for the user by the company's security policy. Company’s security policy should ensure that the 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.
- 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 bugs that allow it to extract potentially sensitive data from the browser's memory cache after the user logs out and doesn’t close the entire browser application. Therefore, it is recommended to also close the entire browser (not just a particular tab or one of the windows) after logout.

2.8 List of known bugs

#	Name	Description	How was it discovered?	Evaluation of the impact on safety and effectiveness	Outcome of the evaluation	The rationale for not fixing the bug
1	Image all black after waiting for some time (LH-1767)	If multiple tabs are opened in Google Chrome and the user switches between multiple tabs, the image in the Image View center becomes black - not loaded.	Internal testing	Low. Safety is not impacted as the user can refresh the webpage to see the images.	Difficult to reliably reproduce.	Safety is not impacted.
2	Annotations don't appear or disappear (LH-1766) (LH-1510)	In some videos the annotations do not appear if the video is played and later stopped.	Internal testing	Low. Safety is not impacted as the user can refresh the webpage to see the annotations.	Difficult to reliably reproduce.	Safety is not impacted.
3	Annotation loading unlimited spinner (LH-1765)	The user opens an image with annotation, creates new annotation, clicks on it so it gets blue, clicks on image, deletes the annotation, goes to another thumbnail and it keeps on	Internal testing	Low. Safety is not impacted as the user can refresh the webpage to see the annotations.	Reproduction steps are clear, and will be patched with a patch release.	Safety is not impacted.

#	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
		showing that the annotation is loading.				
4	If one side of the LV contour is short in strain analysis - contour is rendered incorrectly (LH-1687)	If user makes one the LV sides <30% of the other wall, the contour becomes incorrect	Internal testing	Low. Safety is not impacted as the user can immediately see that the contour is incorrect and adjust.	Reproduction steps are clear, and will be patched with a patch release.	Safety is not impacted.
5	Drawing of annotations outside DICOM bounds is not disabled (LH-1597)	The user can zoom out outside the ranges of the DICOM and draw annotations that don't have any clinical meaning.	Internal testing	Low. The user can see and delete these measurements if needed.	Reproduction steps are clear, and will be patched with a patch release.	Safety is not impacted.

3. USER INTERFACE ELEMENTS

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

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

- Login View
- Lobby View
- Upload View
- Workspace View
- Strain View
- Report View
- Report PDF View

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

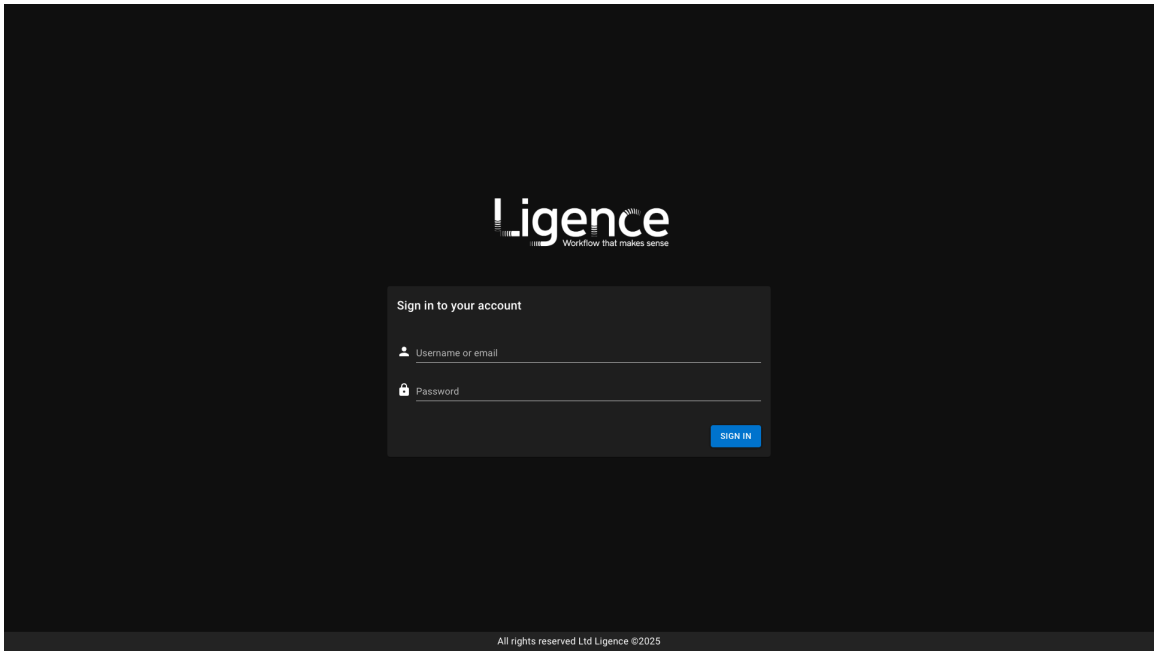
Configuration differences

According to the analysis mode configuration (please refer to the Section 1.6 Analysis mode configuration), Ligence Heart might show the Strain View or not. If LV GLS is disabled, the Strain View will not appear in Ligence Heart and therefore the user will not be able to access that view.

Ligence Heart is designed to be hosted on any existing clinical workflow on premises, via integration with a compatible computing platform. Therefore, Ligence will configure Ligence Heart for integration into each clinical workflow.

3.1 Login View

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



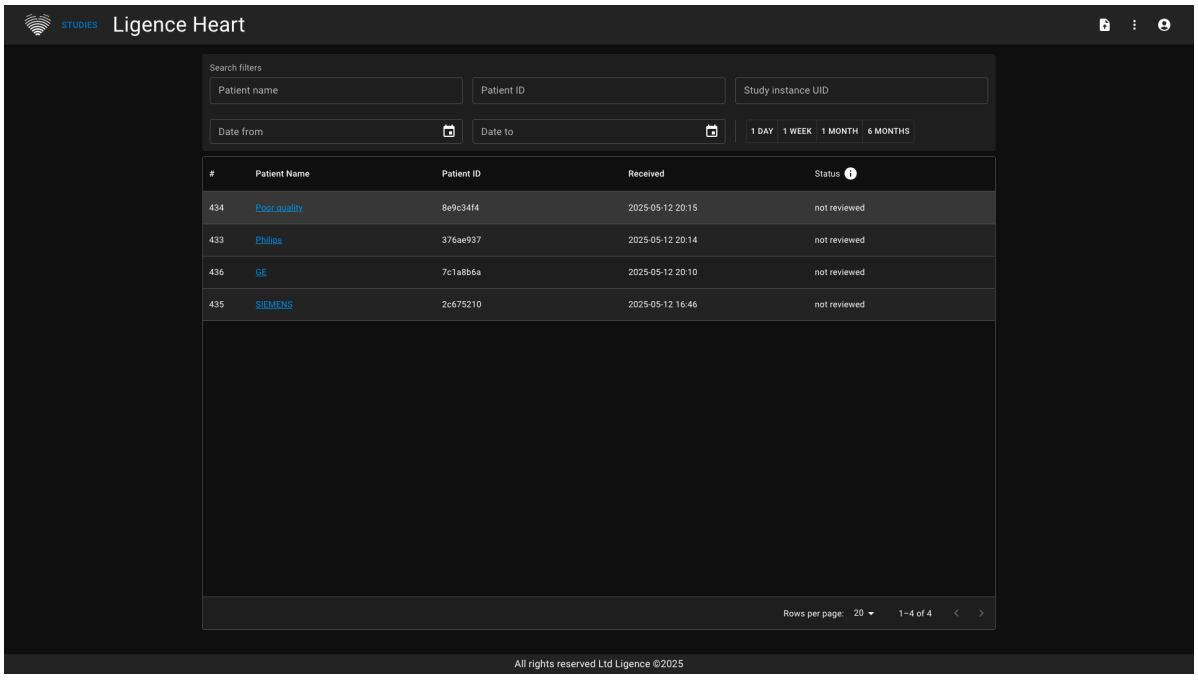
NOTE

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

3.2 Lobby View

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

- Navigation bar with an Upload button, an About and Support menu, and an Account menu
- Search bar for echocardiographic studies
- List of available studies



3.2.1 About and Support menu

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



Upon pressing the About and Support button, a drop-down menu will appear.

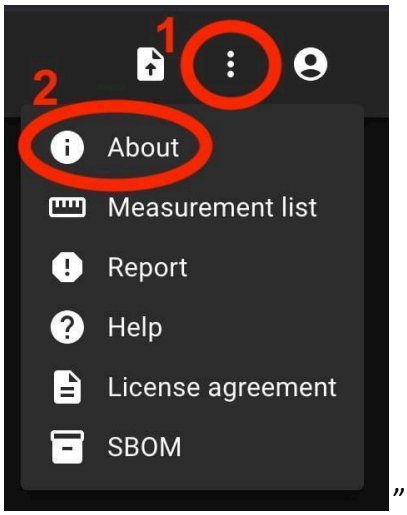
The drop-down menu dialogue contains the following items:

- 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.
- SBOM: links to the downloadable Software Bill of Materials files in a machine-readable format.

3.2.1.1 About

The About button is found in the About and Support drop down menu in the Navigation bar.

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



”

The displayed information on:

Product

- Product name
- Software version
- Signature
- Release notes
- Date built on
- UDI number
- Caution

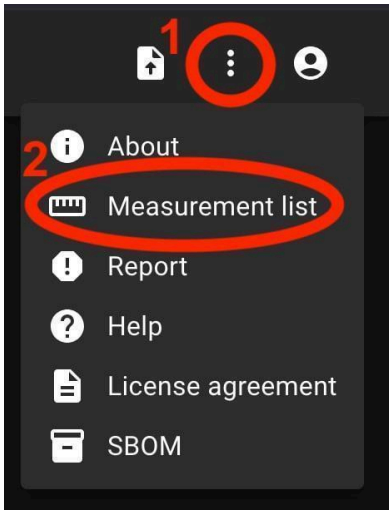
- FDA number

Manufacturer

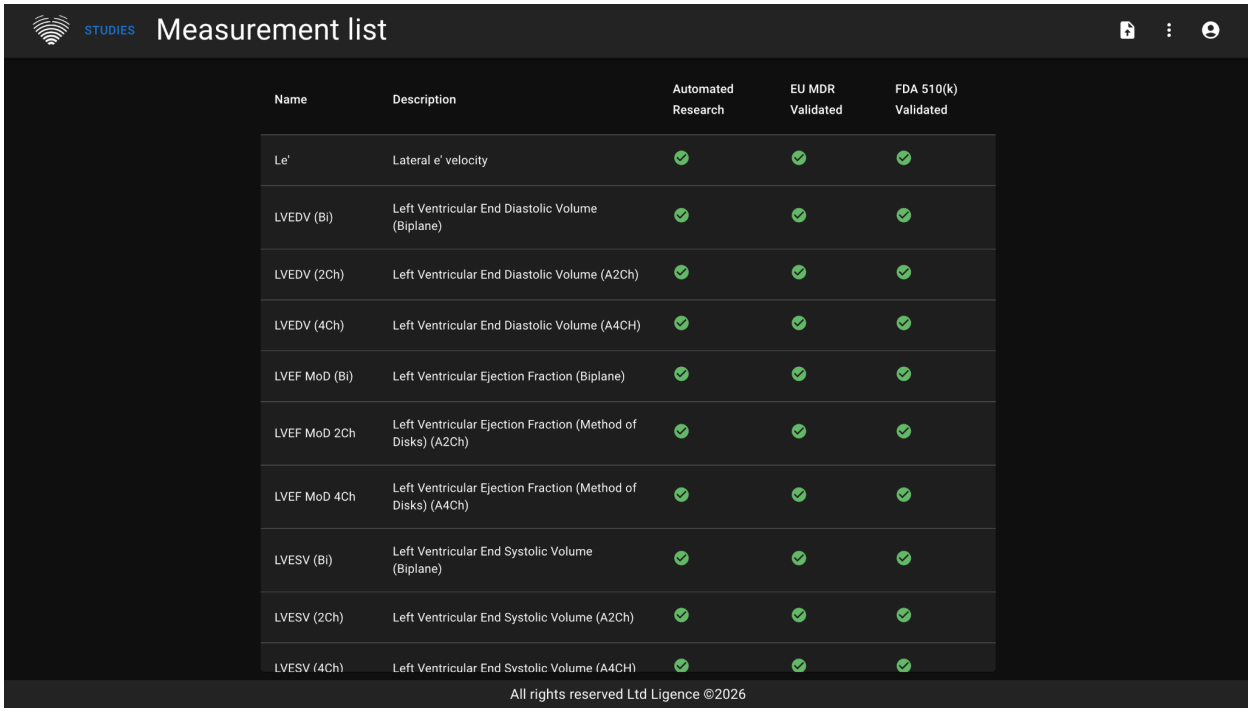
- Name of the manufacturer
- Address
- Email
- Website URL

3.2.1.2 Measurement list

Measurement list can be found in the About and Support drop down menu in the Navigation bar.

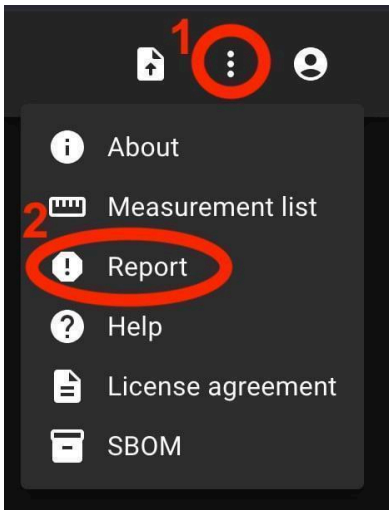


Clicking “Measurement list” navigates to the Measurement list page.

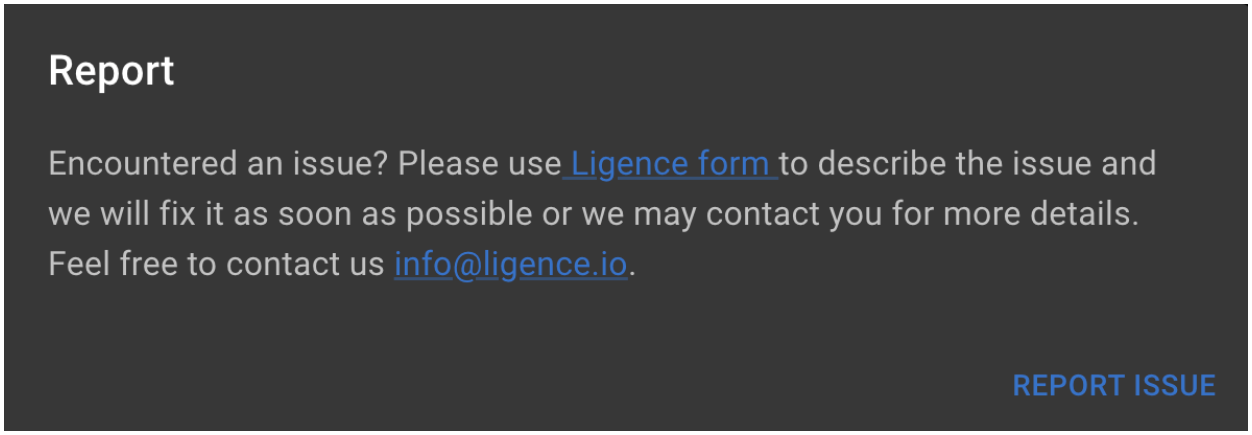


3.2.1.3 Report

Report button can be found in the About and Support drop down menu in the Navigation bar.

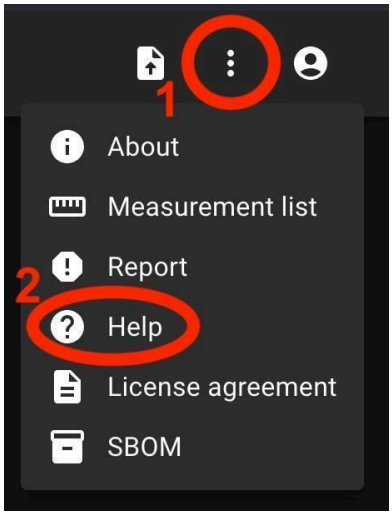


Clicking “Report” opens a pop-up window with information on how to report an issue.



3.2.1.4 Help

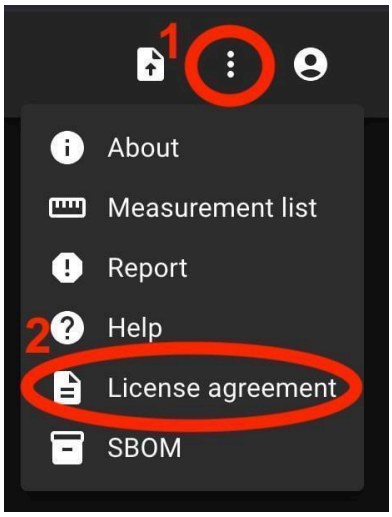
Help button can be found in the About and Support drop down menu in the Navigation bar.



Clicking the “Help” button navigates to User manuals (https://ligence.io/user-manuals/) where all released versions of the Instructions for Use are available.

3.2.1.5 End-User License Agreement

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



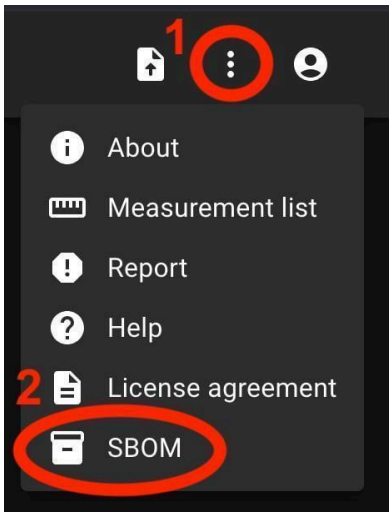
You will be directed to the Ligence Heart EULA (https://www.ligence.io/ligence-heart-eula) site where you can read the End-User License Agreement.

NOTE

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

3.2.1.6 SBOM

SBOM button can be found in the About and Support drop down menu dialogue in the Navigation bar.



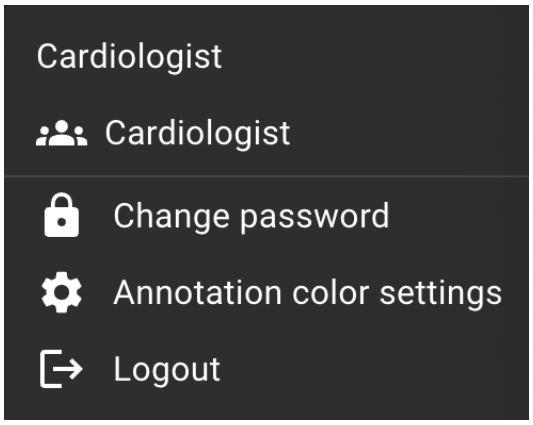
Clicking the “SBOM” button opens a pop-up window that allows the user to download the SBOM file.

3.2.2 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:

- User name – displays the name of the logged-in user.
- User type – indicates whether the logged-in user has a Cardiologist or Sonographer account.
- Change password – opens a pop-up window that allows the user to change their password.
- Annotation color settings – opens a pop-up window that allows the user to customize annotation colors according to their preferences.
- Logout – logs the user out of the system.

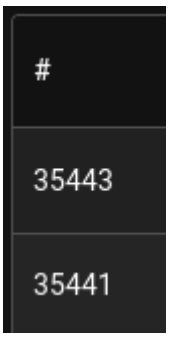
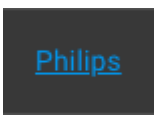
3.2.4 Search bar for echocardiographic studies

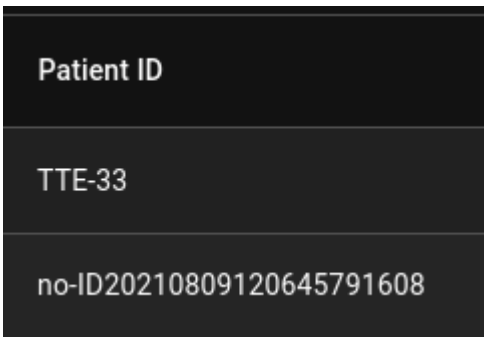
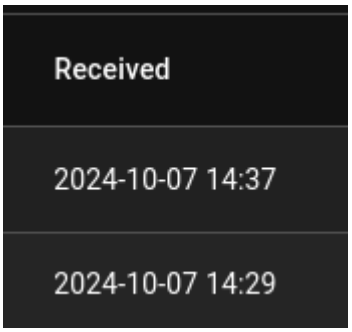
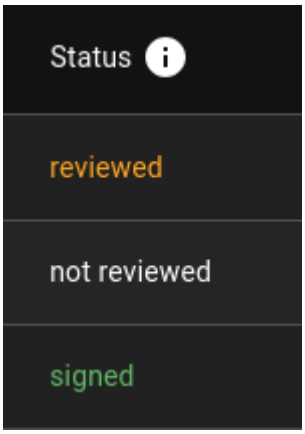
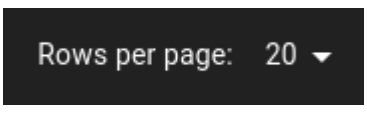
In the Lobby View, the search bar presents multiple fields that can be used to locate a specific echocardiographic study. Values entered in these fields act as combined filters, meaning a study must meet all entered criteria to appear in the search results.

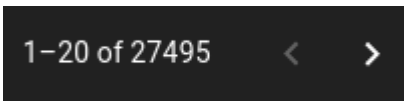
Search functionality element	Explanation
Patient name 	Search based on patient name and surname.
Patient ID	Search based on DICOM Patient ID Attribute (0010,0020).

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

3.2.5 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.

Element	Explanation
	
Received 	This shows date (YYYY-MM-DD) and time when the study has been received by the software.
Status 	Shows the status of a study. ***Signed*** - this study has been signed by a physician and a final report has been generated. ***Reviewed*** - this study has been reviewed by a sonographer but the final report has not been generated. ***Not reviewed*** - this study has not been reviewed.
Rows per page 	Allows changing the number of echocardiographic studies shown per page.
Page iterator	Allows navigating between different pages of the studies.

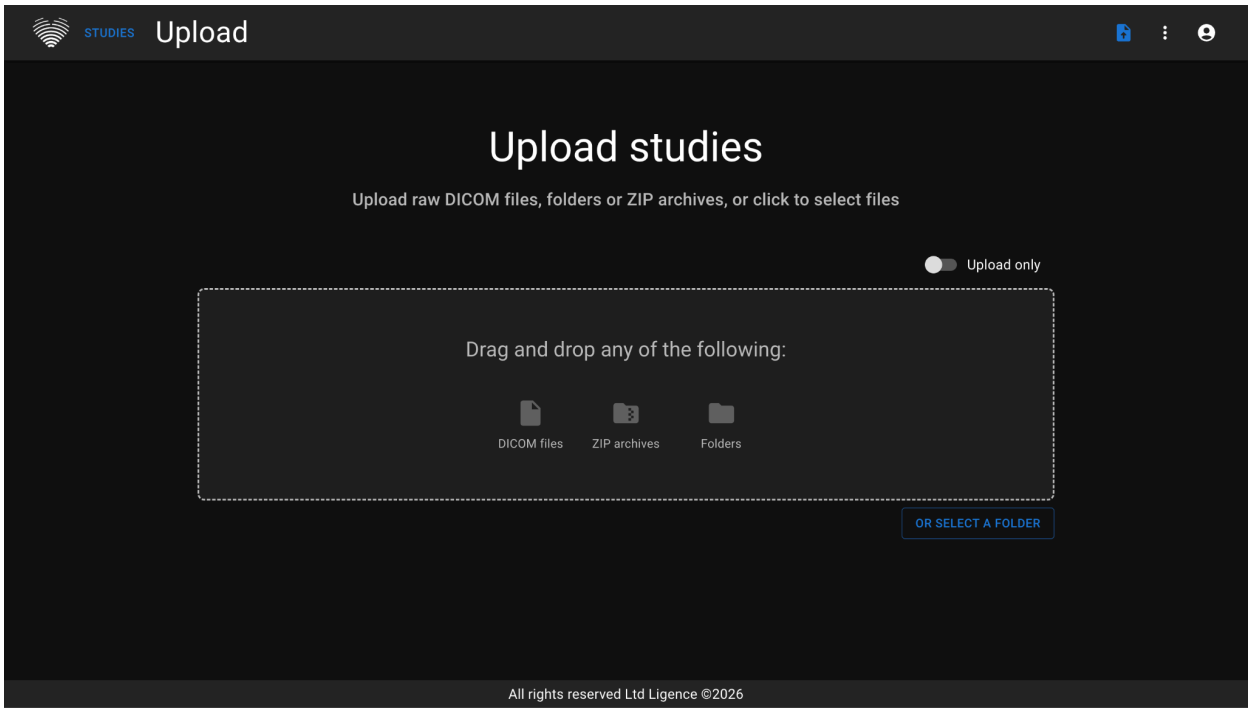
Element	Explanation
	

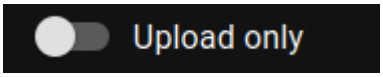
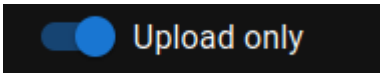
3.3 Upload View

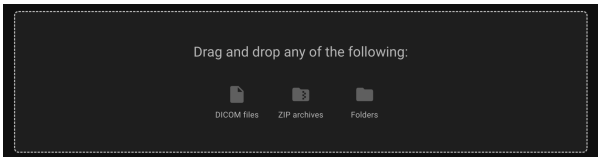
The Upload View is dedicated for uploading studies into the system.

NOTE

Only DICOM format studies are supported.

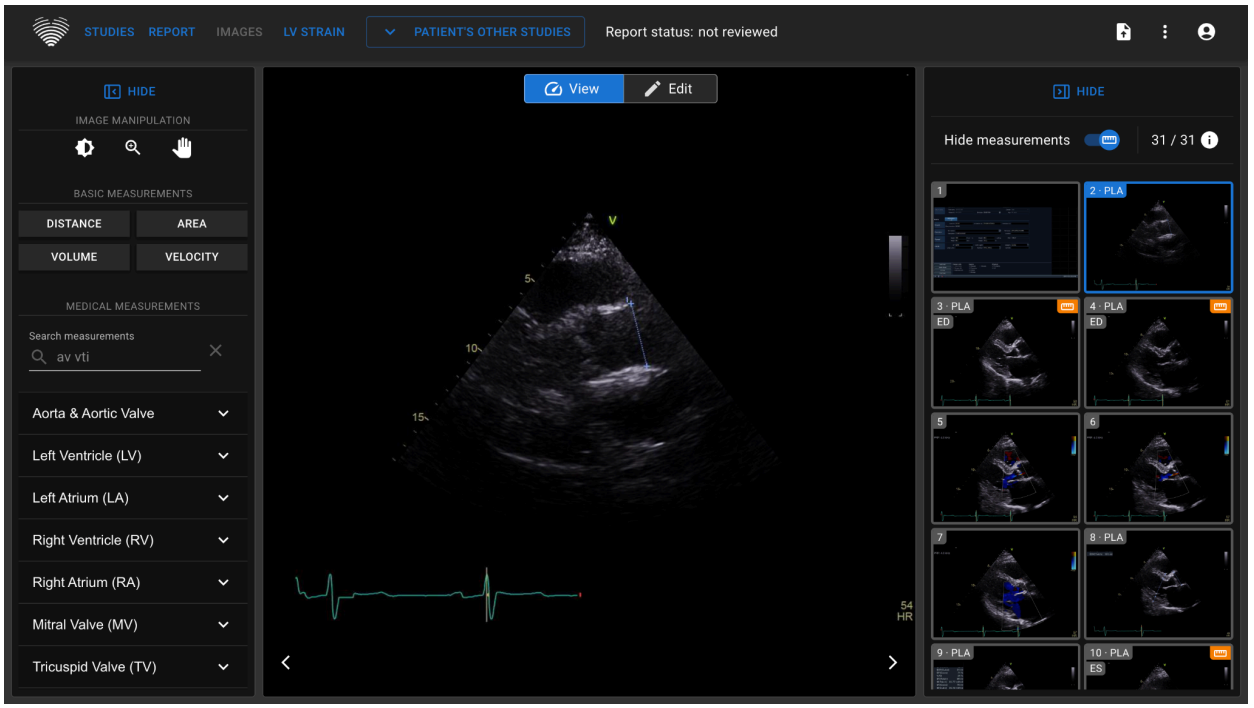


Element	Explanation
Upload only selector - OFF 	Default setting - “Upload only” is inactive. This means that imported DICOM files will get analyzed using automated functionality.
Upload only selector - ON 	“Upload only” set to active. If this setting is used, DICOM files will get imported but no automated measurement prediction will be performed.

Element	Explanation
File upload 	Clicking this element will allow selecting files for upload. Alternatively, files can be dragged and dropped. A maximum of 300 files is supported at once for upload.
	

3.4 Workspace View

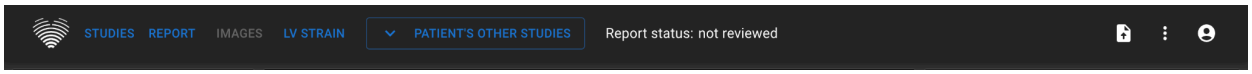
This view is dedicated for viewing and analyzing studies.

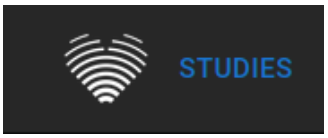
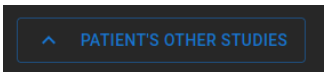
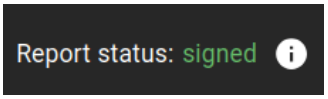


3.4.1 Navigation Bar buttons and functions

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

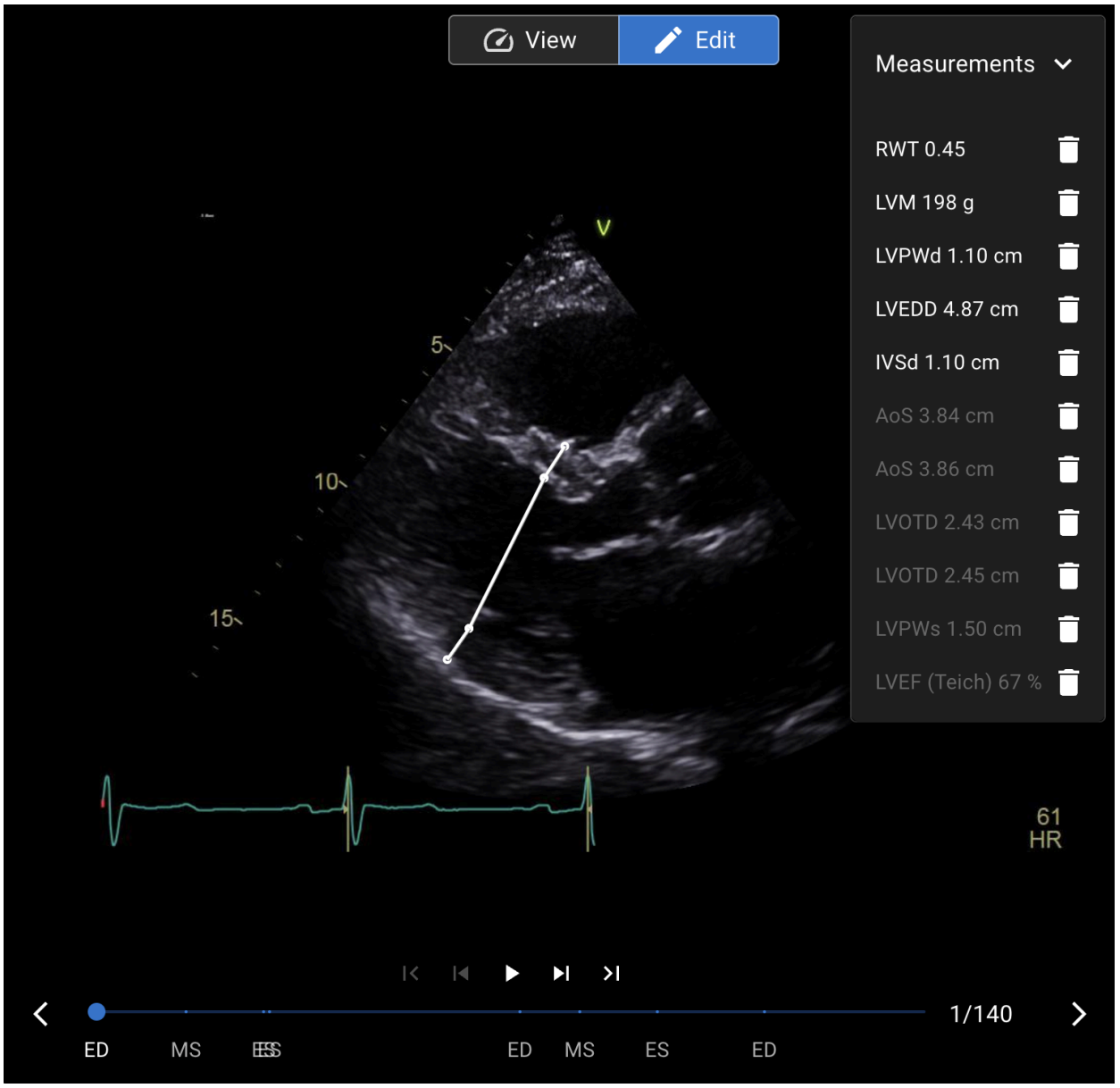
All the buttons and functions are summarized in the picture and table below:



Icon	Name	Function
	Logo	Navigatesto the Lobby view, list of studies
	Report	Navigates to the Report View.
	LV Strain	Navigates to the Left Ventricletrain View.
	Images	The name of the current view.
	Patient's other studies	View list of other studies belonging to the same patient based on DICOM Patient ID Attribute (0010,0020)
	Status	Report status of the current study as explained in the Lobby view section

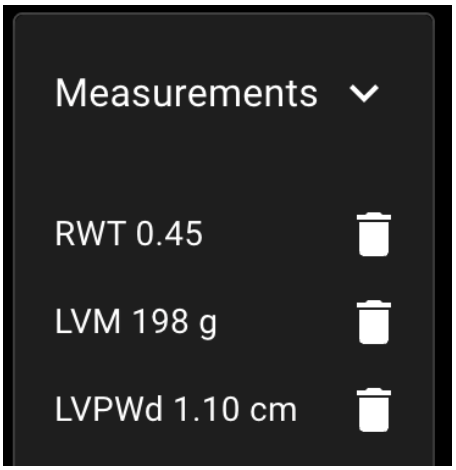
3.4.2 Image (DICOM) section

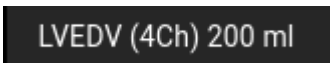
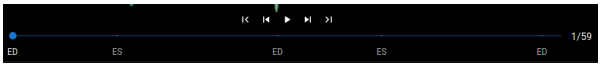
The central section displays the DICOM view currently in use.



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

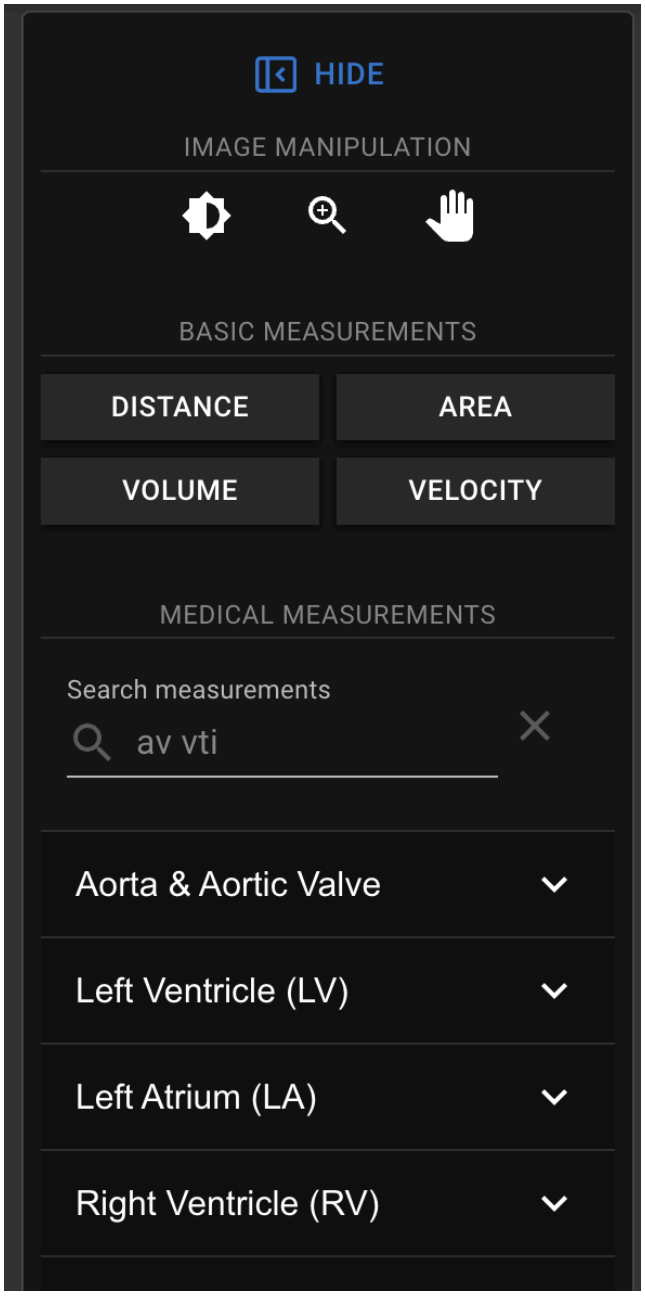
Element	Explanation
	Two DICOM file/workspace viewing modes are available: View and Edit. The mode can be switched using this button or by clicking directly on the image.

Element	Explanation
	View mode plays the DICOM video without loading measurements or annotations, enabling faster study loading and quick review. Edit mode loads existing measurements and annotations associated with the DICOM study, allowing the user to review and modify them.
	The following video control bar functions are available in View mode: ● Switch to the previous frame ● Play or pause the DICOM video ● Switch to the next frame.
	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.

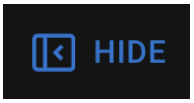
Element	Explanation
	Measurement has been made in the current frame.
	Delete this measurement
	Video playback bar
	Predicted end-diastolic and end-systolic frames. Clicking on text will change the current frame to the selected frame.
	Starting from the left: ● Go to first frame ● Go one frame backward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

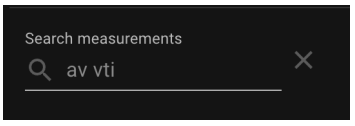
3.4.3 Left sidebar buttons and functions

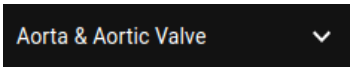
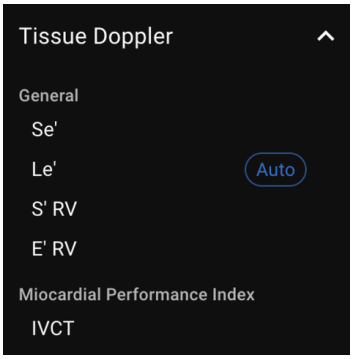
The left sidebar contains all the necessary tools to effectively work with an echocardiogram study.



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

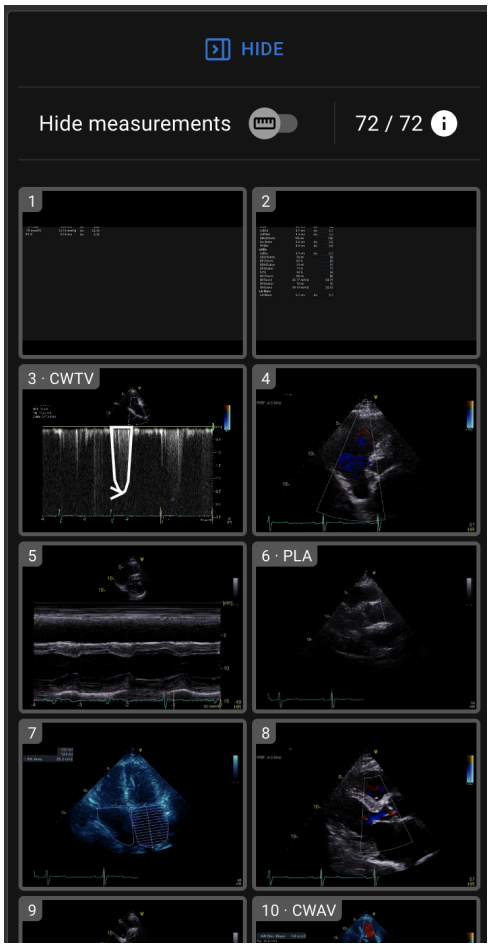
Icon	Name	Function
	**Hide**	**To hide the left sidebar.**
	**Expand**	**To show the left sidebar once it has been hidden.**
	Windowing	Allows the user to change the brightness and contrast of an ultrasound image. For the function to take effect the user must

Icon	Name	Function
		position the mouse cursor within boundaries of an ultrasound image, press and hold the left mouse button and move the cursor simultaneously in either direction. Moving the cursor along the x-axis causes a change in brightness, whereas moving the cursor in the y-axis causes a change in the contrast.
	Zoom in/out	Allows the user to zoom in/out the selected ultrasound image frame. When toggled, move the mouse cursor onto the frame. Press and hold the left mouse button and move the cursor in the vertical axis. Moving the cursor up zooms in the frame whereas moving it down zooms out the frame.
	Pan	Allows the user to move the ultrasound image frame stack across the screen. Press and hold the image with the left mouse button and move it to any side to move the image stack.
	Distance measurement	Press it to manually measure the 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.
	Search bar for measurements	The search for measurements bar allows quick access to measurements by entering the measurement name or abbreviation.
	Expand section	Press it to expand the section.

Icon	Name	Function
	Anatomical structure menu buttons and drop-down dialogues	Allows manual selection of the anatomical structure of interest and displays 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 an “Auto” button. When activated, it makes automated measurement of selected label on the currently active image frame. If it is not possible to make automated measurement, a warning message is displayed, and manual tracing is activated.
	Measurement tools	• Hover over a measurement label – displays the full name of the measurement. • Click on a measurement label – allows manual measurement. • “Auto” – performs an automated measurement prediction for the current frame. • Number – indicates the count of instances of this measurement in the current study. This includes the averaged value used for reporting and summary generation. (For example, a study may contain three LVEDV measurements in the apical 4-chamber view, plus an additional averaged measurement.)

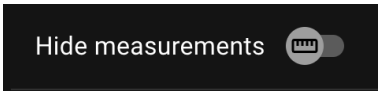
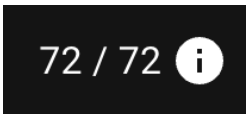
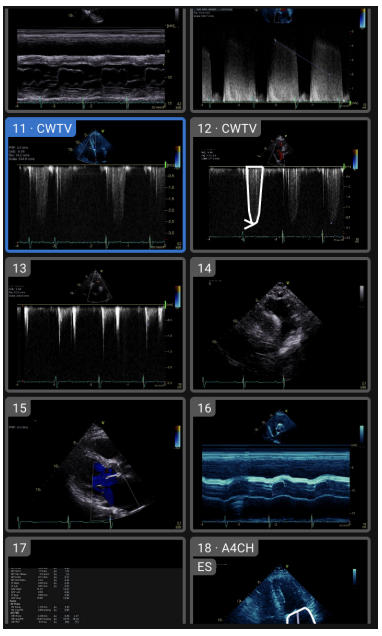
3.4.4 Right Sidebar buttons and functions

The 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:

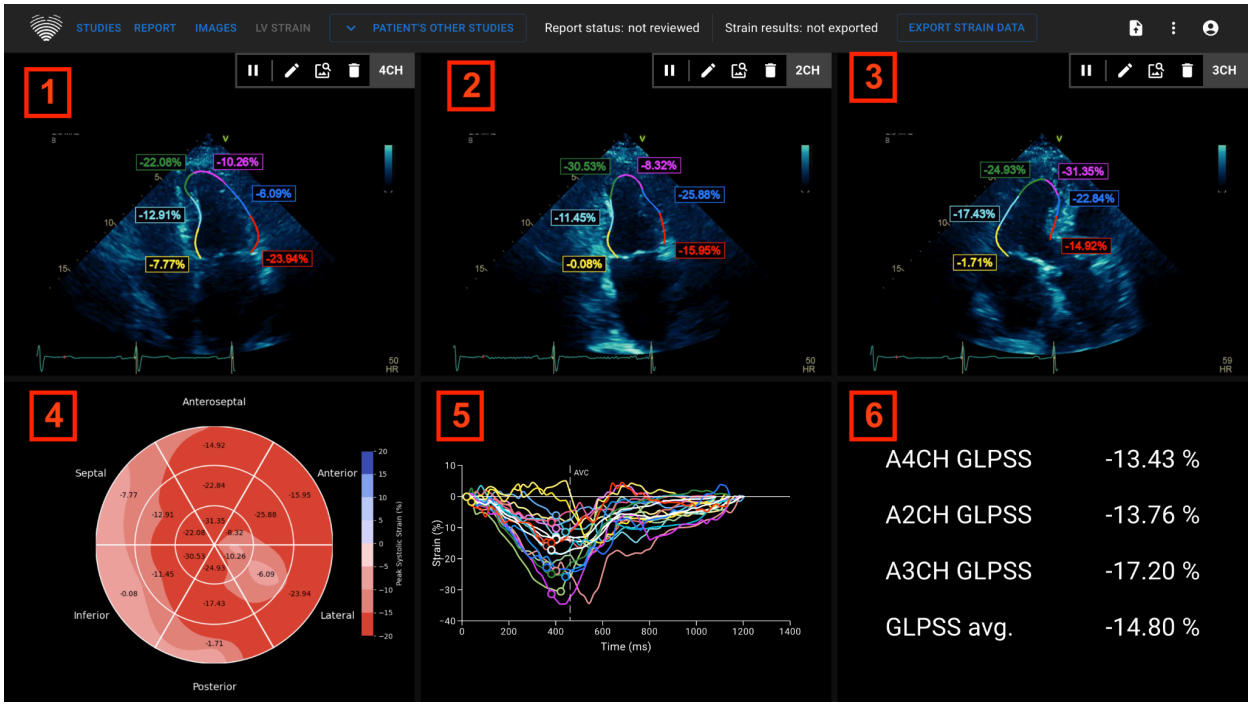
Icon	Name	Function
	Hide	To hide the right sidebar.
	Expand	To show the right sidebar once it has been hidden.

	Hide measurements	Shows or hides measurements in the DICOM video thumbnails. When measurements are hidden, the thumbnail list can be reviewed more quickly and smoothly. When measurements are shown, all frames containing measurements are displayed, which may increase loading time.
	Study DICOM files count	Displays the number of successfully uploaded DICOM files relative to the total number of DICOM files in the study.
	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.

3.5 Strain Workspace View

The Strain Workspace View is divided into a grid 2x3 and contains graphical and interactive elements that facilitate LV GLS analysis.

1. Top left: a slot for A4C image view. This element allows uploading and interacting with the apical four-chamber view DICOM instance.
2. Top middle: a slot for A2C image view. This element allows uploading and interacting with the apical two-chamber view DICOM instance.
3. Top right: a slot for A3C image view. This element allows uploading and interacting with the apical three-chamber view DICOM instance.
4. Bottom left: display of bullseye view.
5. Bottom middle: display of strain-over-time curves view.
6. Bottom right: display of LV GLS and average LV GLS values.



All three apical view fields (top left, top middle, and top right) have a button bar.



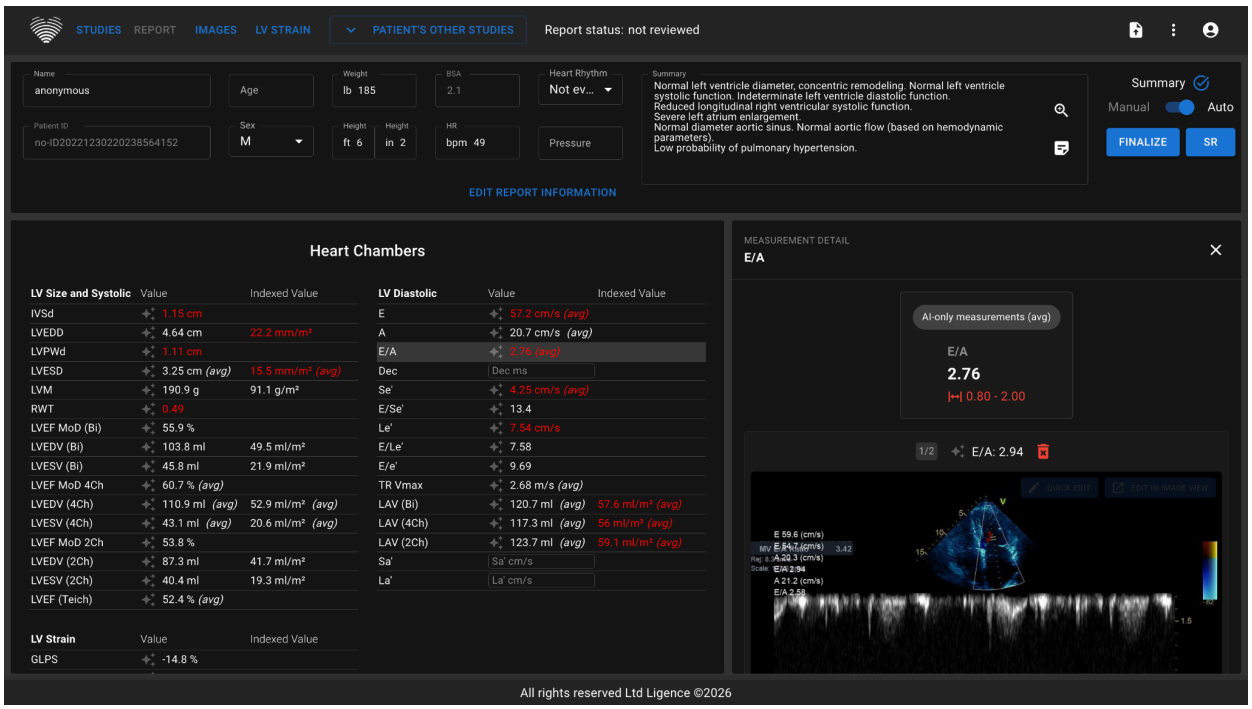
The functions of these buttons are described below.

Component	Name	Function
	Play/Pause	Pressing this button starts or pauses the videos in the strain view
	Edit	Clicking this button opens the Stain Contour and Cycle Edit window.

Component	Name	Function
	Choose DICOM	Clicking this button opens a list of echoviews that could be used for strain analysis
	Delete	Clicking this button deletes the strain analysis made
	Apical view	Indicates which apical view is currently analyzed for strain.

3.6 Report View

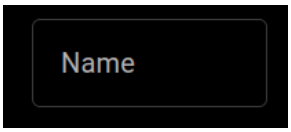
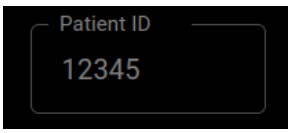
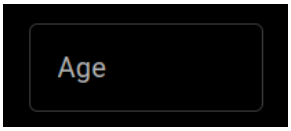
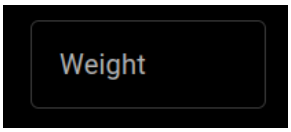
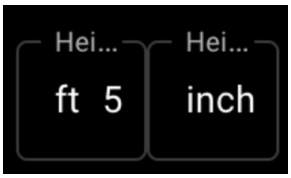
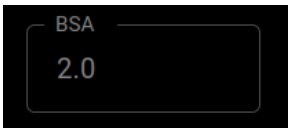
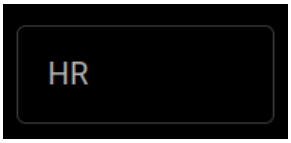
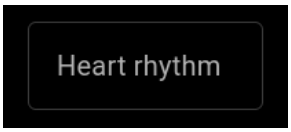
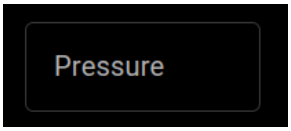
The Report View is dedicated for making two-dimensional transthoracic echocardiography reports. This view allows you to compare your measurements against normal values for the standard measures, review source views from which the measurements were taken and make quick edits to annotations made. The report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

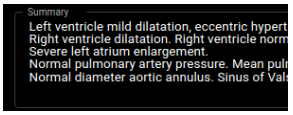
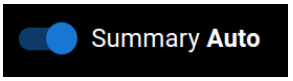


The study report is largely divided into three areas seen on the screen. At the top, you can find general information about the patient, such as name, age, sex, height, weight, summary and other information. At the bottom left, you will find the measurements overview, a structured grid of measurements 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

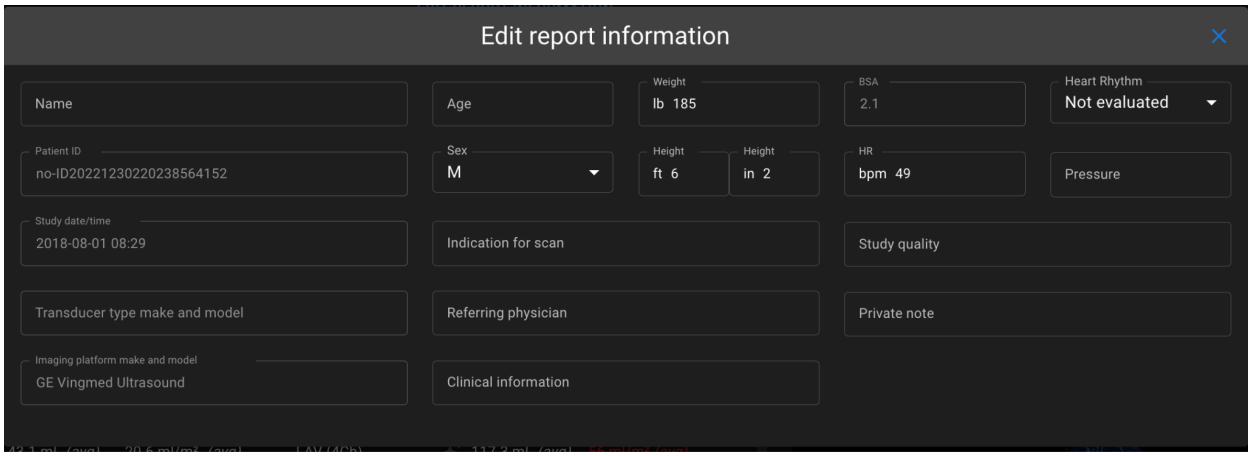
view, which allows you to explore each selected measurement in more detail, review source images and make quick edits to annotations.

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

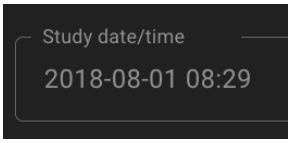
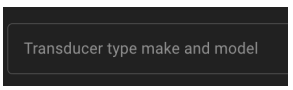
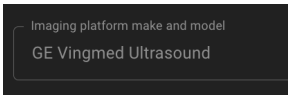
Component	Name	Function
	Name	Allows reading or entering the patient's name.
	Patient ID	Allows reading the patient's ID.
	Age	Allows reading or entering the patient's age.
	Sex	Allows reading or selecting the patient's sex.
	Weight	Allows reading or entering the patient's weight in pounds (lbs).
	Height	Allows reading or entering the patient's height in feet and inches.
	Body surface area (BSA)	Automatically displays body surface area when weight and height data is available.
	HR	Allows entry or reading of the patient's heart rate.
	Heart rhythm	Allows entry of details regarding heart rhythm.
	Pressure	Allows reading or entry of the patient's systolic and diastolic blood pressure (mmHg).

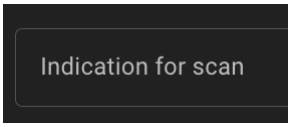
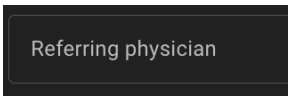
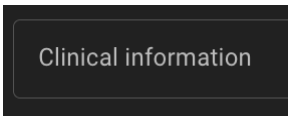
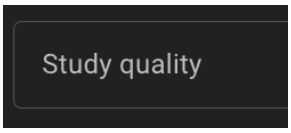
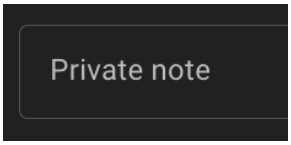
Component	Name	Function
	Edit Report Information	To open a pop-up window with additional report information fields.
	Summary field	Allows entry of the study summary report. If no manual report is entered, a report is generated automatically.
	Auto summary toggle	Allows toggling between automatically generated and manually entered summaries.
	Snippets button	Allows use of text snippets.
	Enlarge summary field	Opens a dedicated screen for summary editing

"Edit Report Information" window

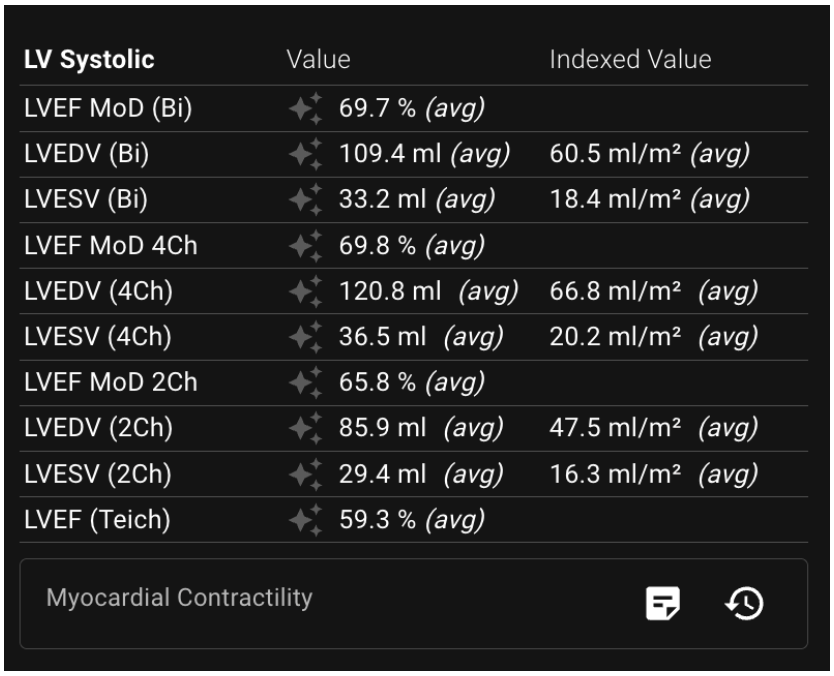


The pop-up "Edit Report Information" window contains the information fields listed above, as well as additional fields described in the table below.

Component	Name	Function
	Study date/time	Shows the date and time study was conducted.
	Transducer type, make and model	Shows the information about the transducer type, make and model used to conduct the study.
	Imaging platform make and model	Shows the information about imaging platform make and model used to conduct the study.

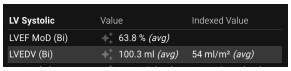
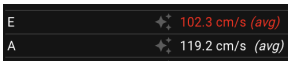
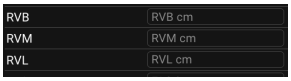
Component	Name	Function
	Indication for scan	Used to enter the indication for the scan.
	Referring physician	Used to enter the referring physician
	Clinical information	Used to enter clinical information.
	Study Quality	Used to enter study quality
	Private Note	Used to enter a private note.

In the Report View, the bottom-left panel displays all measurements in text format, grouped according to cardiac anatomy or function. Additional text fields are provided for entering conclusions, notes, and other relevant clinical information.

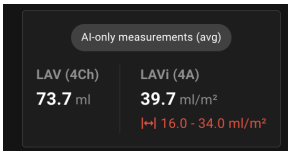
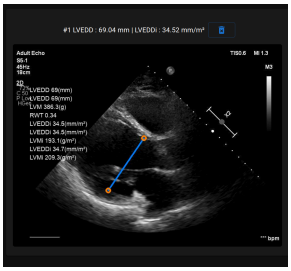
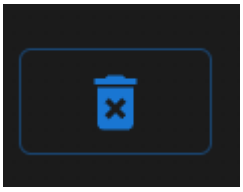


Measurement values may originate from a DICOM SR file, automated analysis performed by Ligence Heart, or manual measurements and entries made within the software. Displayed values include both actual and indexed values, where applicable and when patient body surface area (BSA) has been calculated.

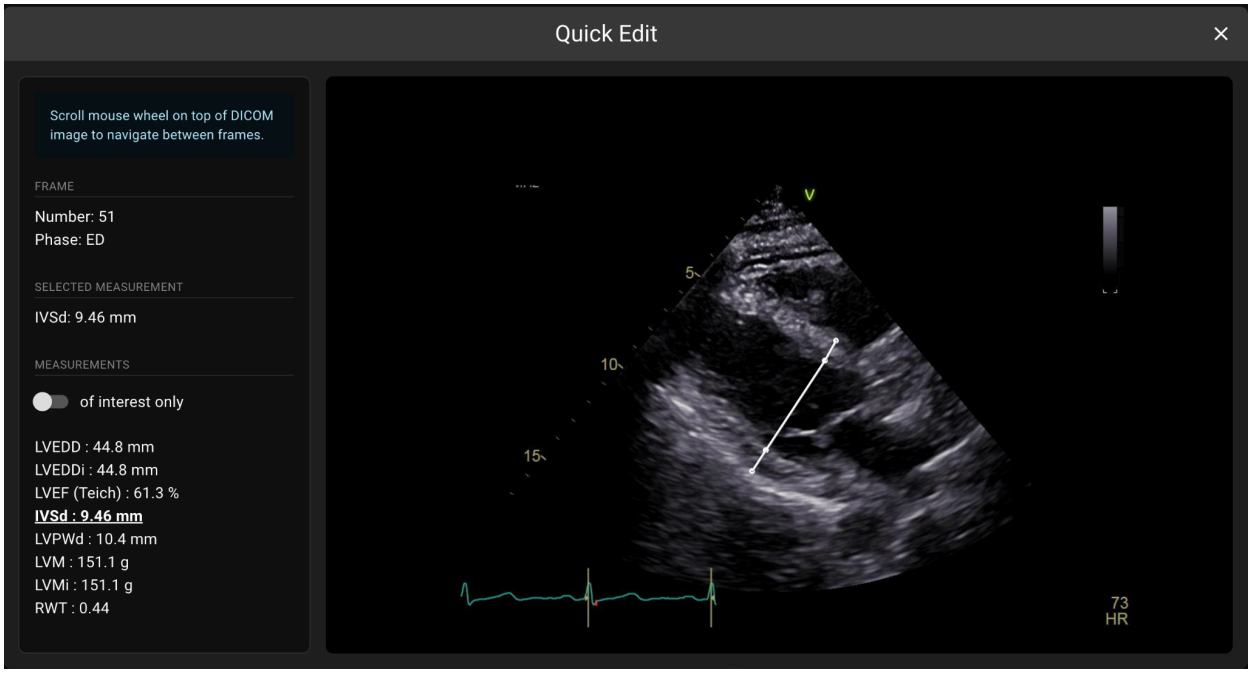
All the fields and functions of the Report View bottom left panel are summarized in the table below:

Component	Name	Function
	Measurement display	Displays: • The name of the cardiac structure or function • The measurement value (reference ranges are displayed when hovering over the value) • The value of the calculated indexed measurement, where applicable.
	Normal/Abnormal values	Measurement values are displayed in two colors: white for values within the normal reference range and red for values outside the normal reference range, to draw the reviewer's attention.
	Free text fields	An empty field next to a measurement indicates that the measurement value can be entered manually.
	Average value	When a measurement value is calculated from multiple entries, the label "(avg)" is displayed next to the measurement value.
	AI reported value	This symbol indicates that the measurement value was generated automatically by Ligence Heart.
	User reported value	This symbol indicates that the measurement value was entered or measured manually within the software.
	Dicom SR reported value	This symbol indicates that the measurement value was imported from a DICOM SR file.
	Mixed AI and user reported values	This symbol indicates that the measurement value is derived from both automatically generated and manually entered or measured values.

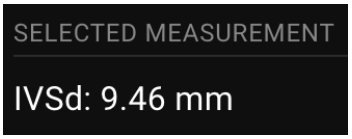
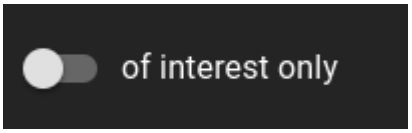
All the fields, buttons and functions of the Report View bottom right panel are summarized in the table below:

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

3.6.1 Quick edit window



The “QUICK EDIT” pop-up window is opened by clicking the “QUICK EDIT” button, which appears when hovering over illustrations in the report view. Allows annotations to be modified by dragging annotation lines or control points without exiting the report view and provides additional information about the selected measurement.

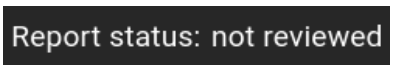
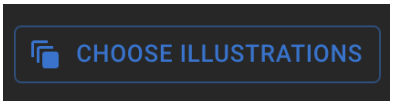
Element	**Explanation**
Frame number 	Shows number of the current frame in the DICOM. The first frame is labeled as “0”.
Frame cardiac cycle phase 	Shows the predicted cardiac cycle phase of the frame: ED - end-diastolic ES - end-systollic MS - mid-systolic PS - peak-systolic FI - frame-of-interest
Selected measurement 	Shows which measurement is being analyzed.
Of interest only toggle 	Controls whether all measurements detected in the frame are displayed or only the analysed measurement. o

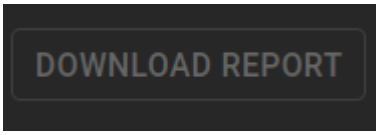
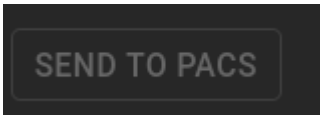
Element	Explanation
	All measurements in the frame.

3.7 Report PDF view

In the report view, clicking the 'Finalize' button (for the cardiologist user group) or the 'Review & Sign' button (for the sonographer user group) opens the PDF version of the report, displayed below.

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

Icon	Name	Function
	Report status	Shows the current status of the study report
	Review and sign button	Click here to sign the report
	Choose illustrations	Click here to choose illustrations that will appear in the report pdf
	Return to studies list button	Go to Lobby View

	Download report button	Download the signed report. Only available after signing the report.
	Send to PACS button	Send the signed report. Only available after signing the report.
	Edit report button	Go to Report view
	View images button	Go to Workspace view

4. WORKING WITH LIGENCE HEART

4.1 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.

4.2 Logging in

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.

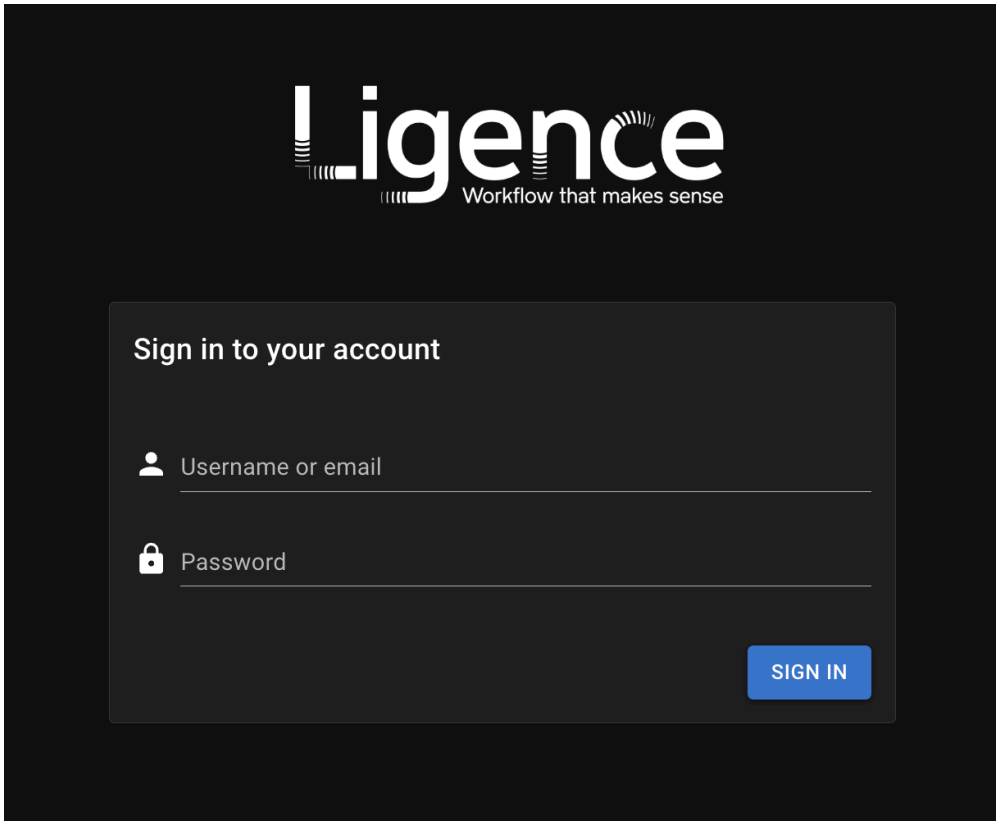
NOTE

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 the "Enter" button on your computer or press "Login".



4.3 Acquire images

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

Please consult the publication for more information.

CAUTION

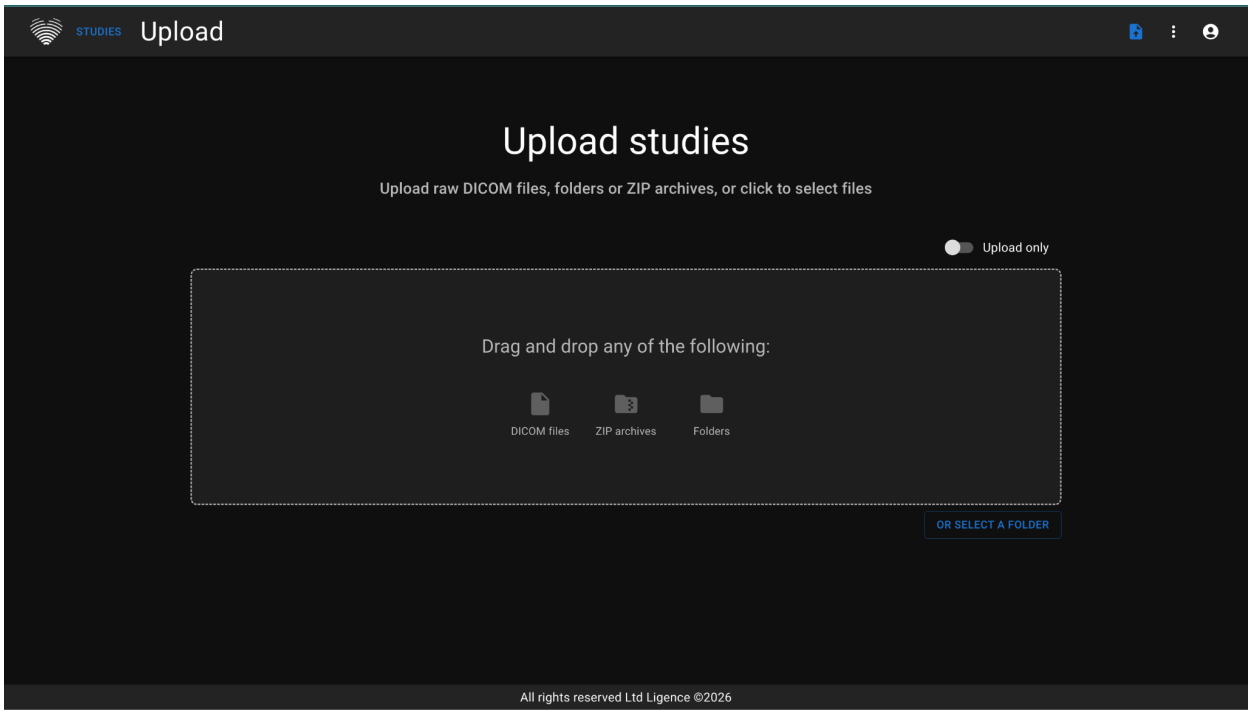
Ligence holds no liability for wrongly acquired image views uploaded to the Ligence Heart.

4.4 Upload the study

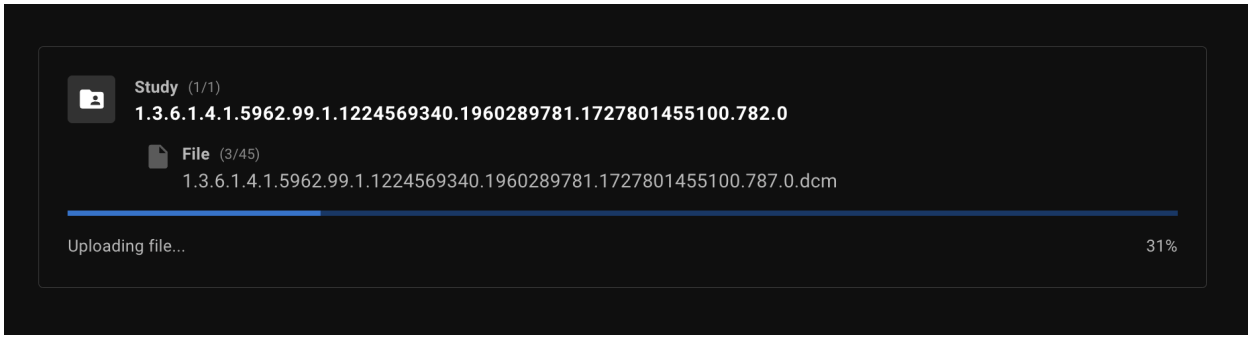
Studies could be uploaded automatically depending on the system configuration. If automatic upload is not available, DICOM files can be uploaded manually from your computer into Ligence Heart by navigating to the Upload View. The Upload view can be accessed by pressing the upload icon on the top right corner of the Navigation bar.



To upload a study simply drag and drop your DICOM format files, folders or zip files or press on the button and upload it from your computer.



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



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

4.4.1 Limitations of upload functionality

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

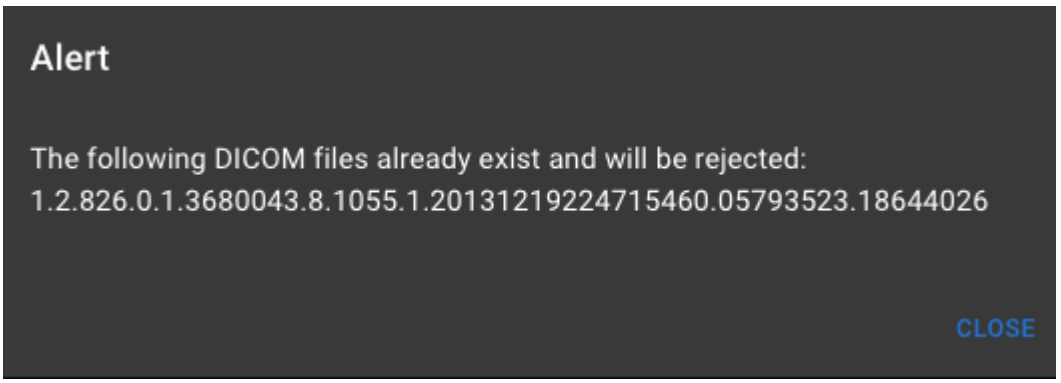
The same DICOM files of DICOM files belonging to the same echocardiographic study can only be uploaded once. Otherwise an error message will be displayed.

4.4.2 Invalid files uploaded

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

Duplicate DICOM Upload

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

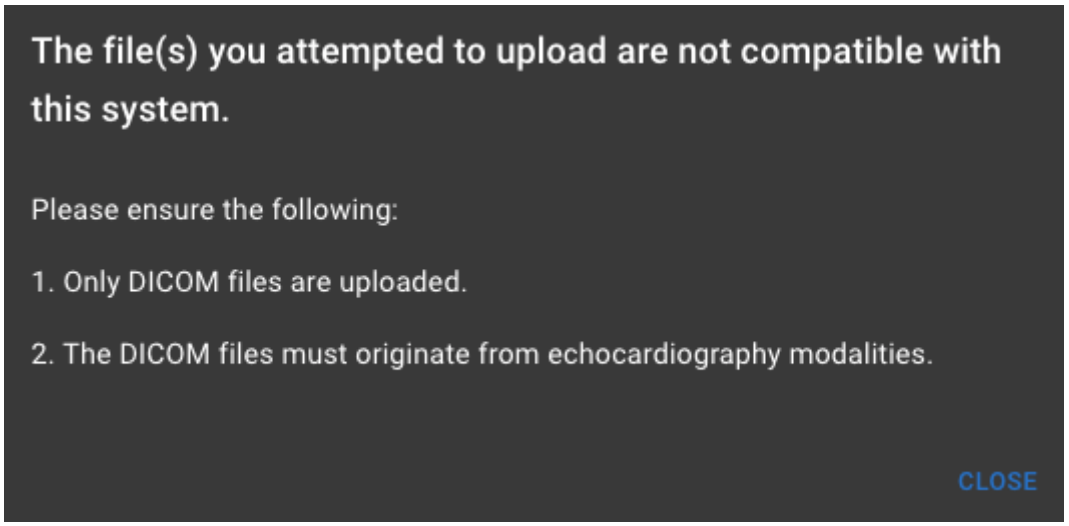


What to do

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

Unsupported Modality or Transfer Syntax

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



What to do

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

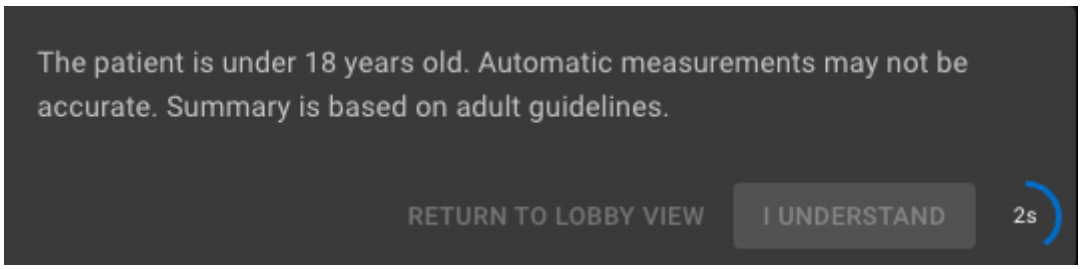
4.5 Opening a study

By clicking on a study in the Lobby View, the user opens the corresponding study in the Report View.

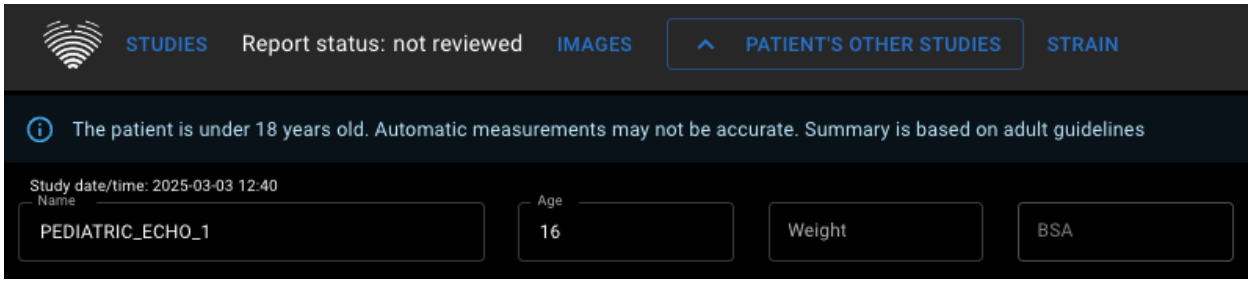
4.5.1 Study Access Scenarios and System Responses

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

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



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



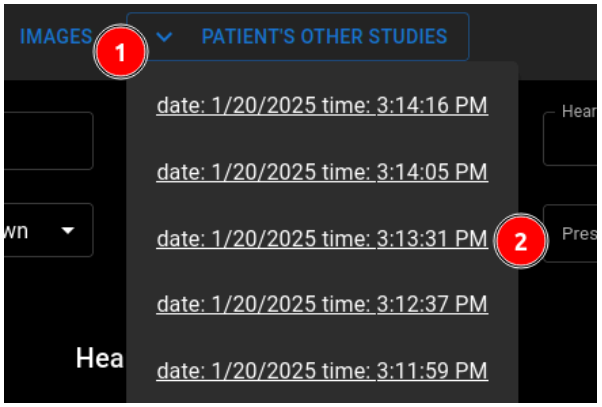
Corrupted images. If the images previously transferred to Ligence Heart are corrupted images because they do not follow the specifications to be accepted by Ligence Heart (the patient and study IDs are not provided, the image modalities and file format are not provided and, the files, as specified in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

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

4.5.2 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.



4.6 Editing Measurements in the Workspace View

Clicking on “Images” in the navigation bar opens the Workspace View, where measurements and associated study images can be reviewed and edited.



4.6.1 Scroll stack

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

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

4.6.3 Draw area measurement

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

4.6.4 Draw volume measurement

The drawing procedure begins the same way as for area measurement. After completing the annotation, an axis appears. To adjust the axis peak point, move its handle

Ligence Heart has pre-selected annotations for various measurements.

4.6.5 Grade measurements

For manual regurgitation and stenosis measurement, a dialog appears. Select the appropriate measurement grade. Press the "Save" button to store the results. To remove a grade measurement, select the "No stenosis" or "No regurgitation" option and save the result.

4.6.6 Delete annotation

Delete annotation: hover over the annotation to be deleted and press either the "BACKSPACE" or "DELETE" key on the device keyboard.

4.6.7 Cancel drawing

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

Change annotation point: select the point to be changed, press and hold the left mouse button, and drag it to the desired position.

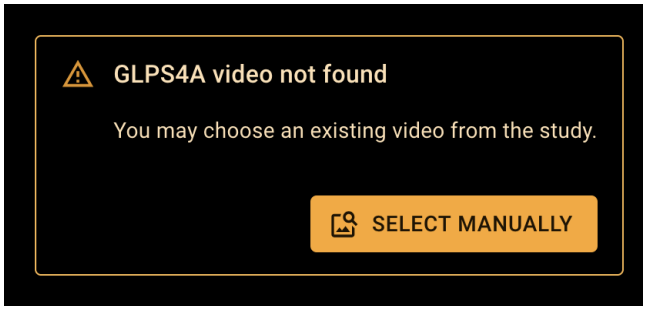
4.7 Measuring Strain

To access the LV Strain module, click on the “Strain” button on the top of the screen.



4.7.1 Choose image views

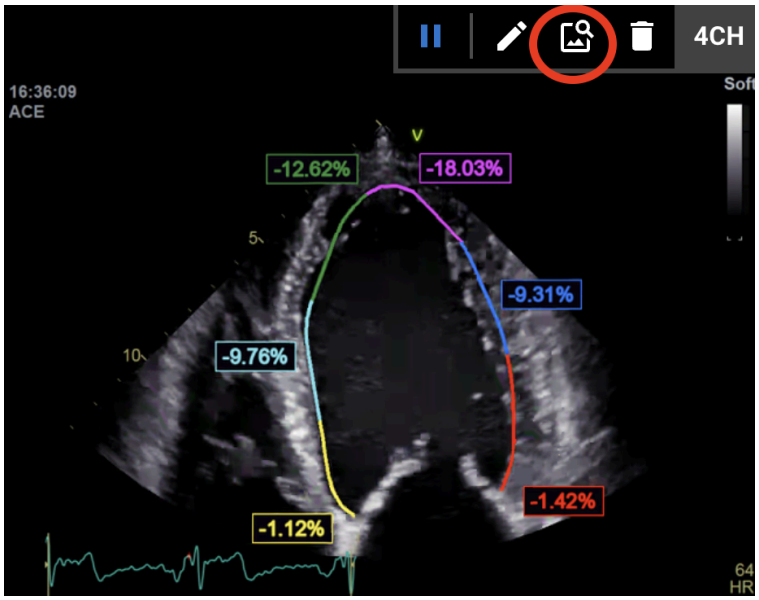
Image views for LV strain analysis, if not chosen automatically, can be chosen from the list of all available DICOM studies by pressing “Select manually”.



The “Select manually” function enables manual selection of an image from the list of all DICOM instances.

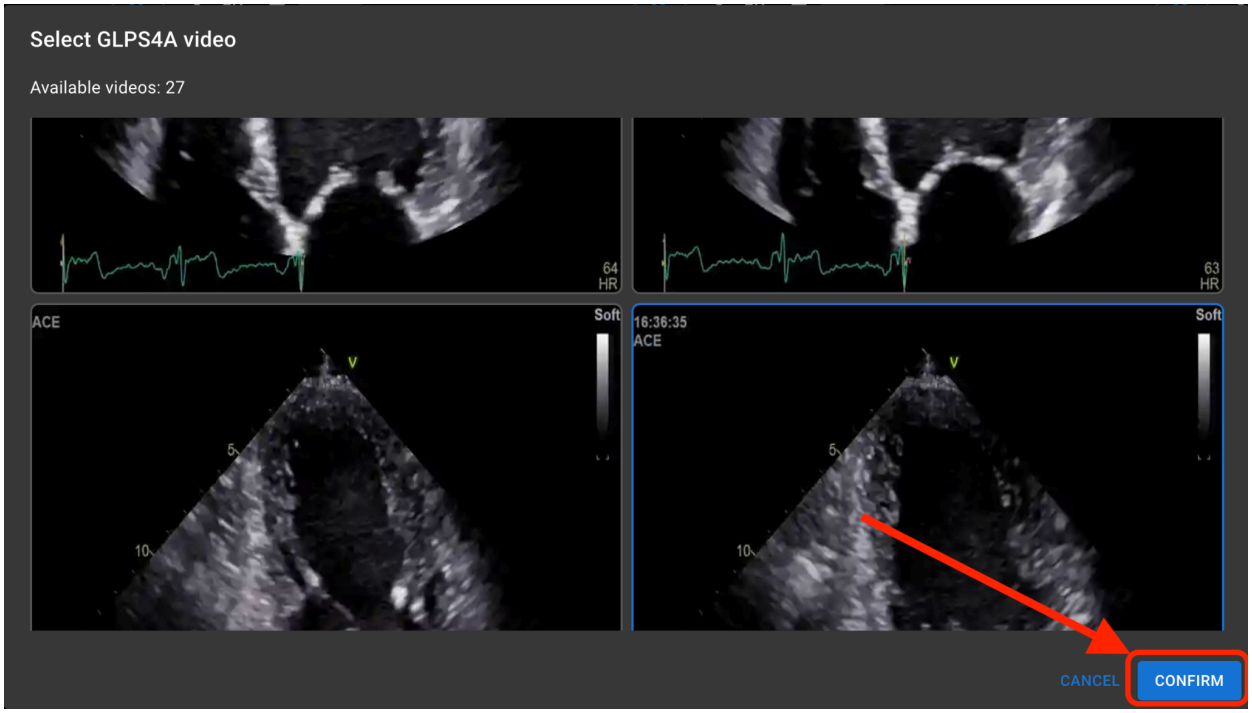
Alternatively, the image used for LV strain analysis can be changed at any time by selecting a different image from the toolbar in the top-right corner of one of the image view slots.

Choose a DICOM image from a toolbar:



After the “Select manually” or “Choose DICOM for strain analysis” function is executed, a new dialog prompts the user to select an image view from all DICOM instances. To choose a required

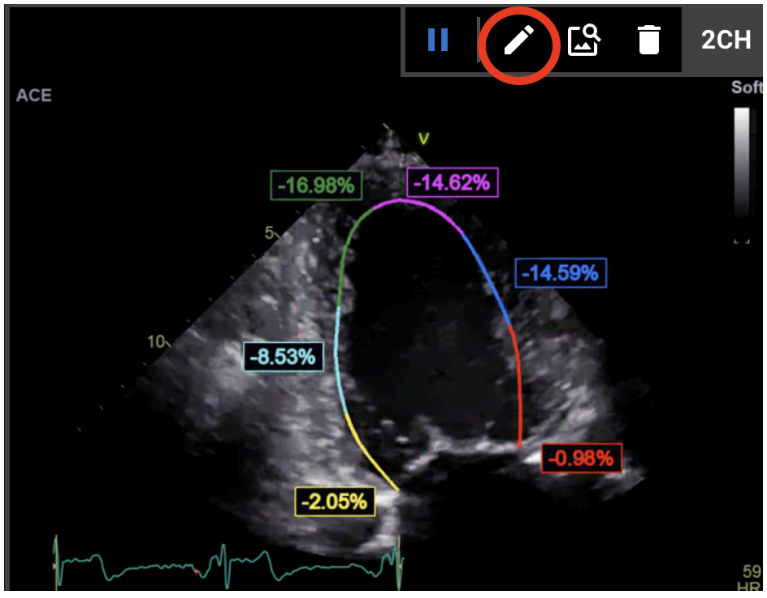
image view, the user must select the right image with a left mouse click and click “Confirm” on the bottom right of the dialog.



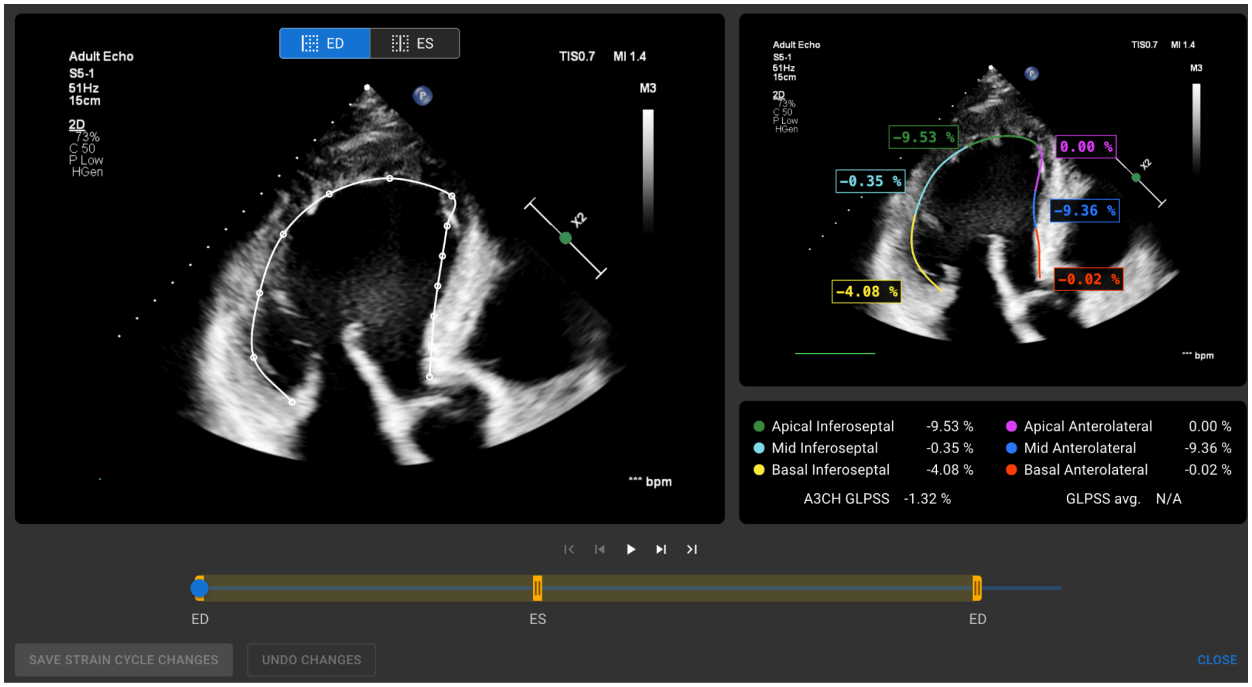
Dialogue prompting to select a new image view.

4.7.2 Edit image

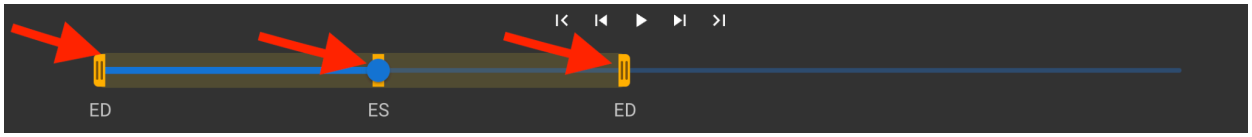
This function allows editing of an image view of interest.



When pressed, a dialogue appears showing the image view and tools for manual adjustments.



The user can change the cardiac cycle by dragging the orange bars for ED (end-diastole) and ES (end-systole). The blue bar is used to change the current frame.



After modifying the cardiac cycle the user must click “SAVE STRAIN CYCLE CHANGES” to save the adjustments.



The user can adjust contour by hovering on the left ventricle contour and dragging the handle points.

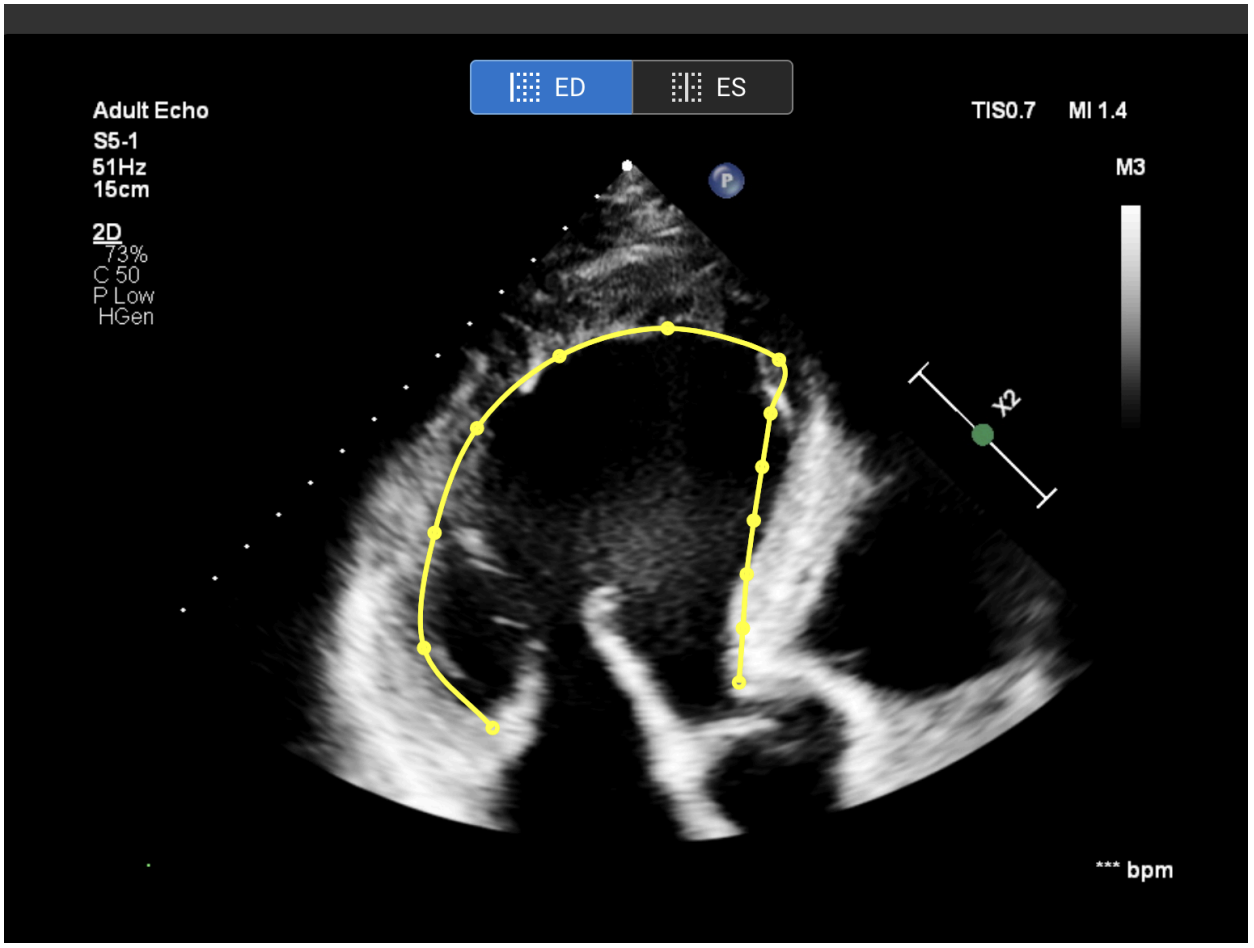


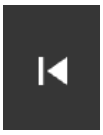
Image Playback

To play/pause the DICOM instance and move around frames a user must use the built-in tools at the bottom of the DICOM instance.



The video playback and frame navigation tools.

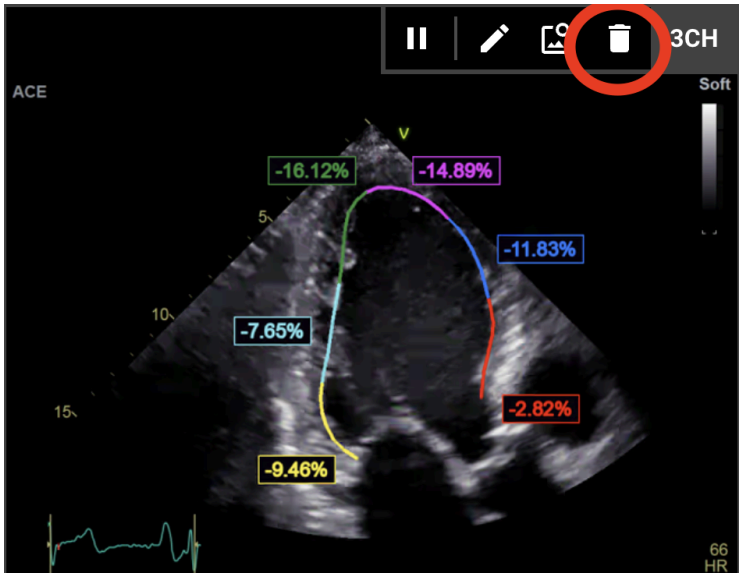
The functions of each tool are summarised in the table below:

Function	Description
	Scroll back to the first frame. This function scrolls the stack of frames to the first frame of the DICOM loop.
	Return by one frame. This function scrolls the stack of frames by one frame backwards.

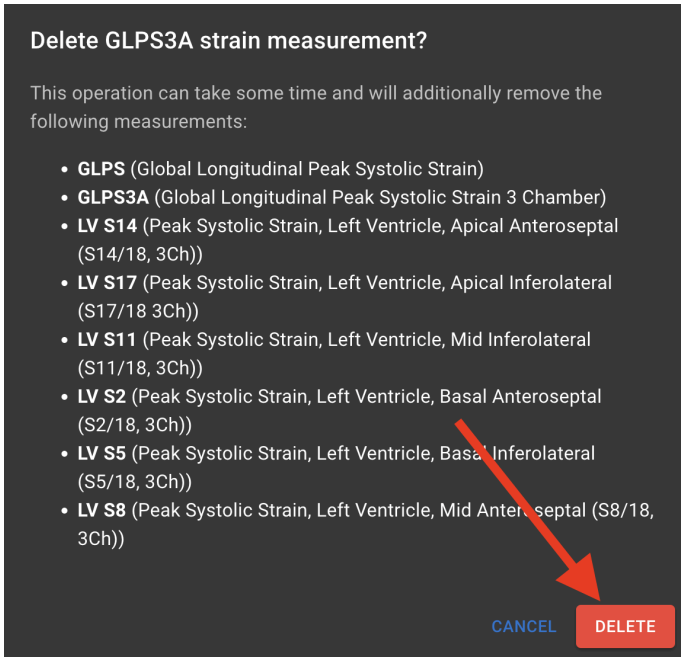
	Play/pause loop. This function plays or pauses the DICOM loop.
	Advance by one frame. This function scrolls the stack of frames by one frame forward.
	Scroll forward to the last frame. This function scrolls the stack of frames to the last frame of the DICOM loop.

4.7.3 Deleting strain image

This function allows the user to delete the strain measurement associated with the selected image view.



A pop-up window will appear, and the user must click the “Delete” button to confirm the removal of the strain measurement from the selected image view.



4.8 Study reporting

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



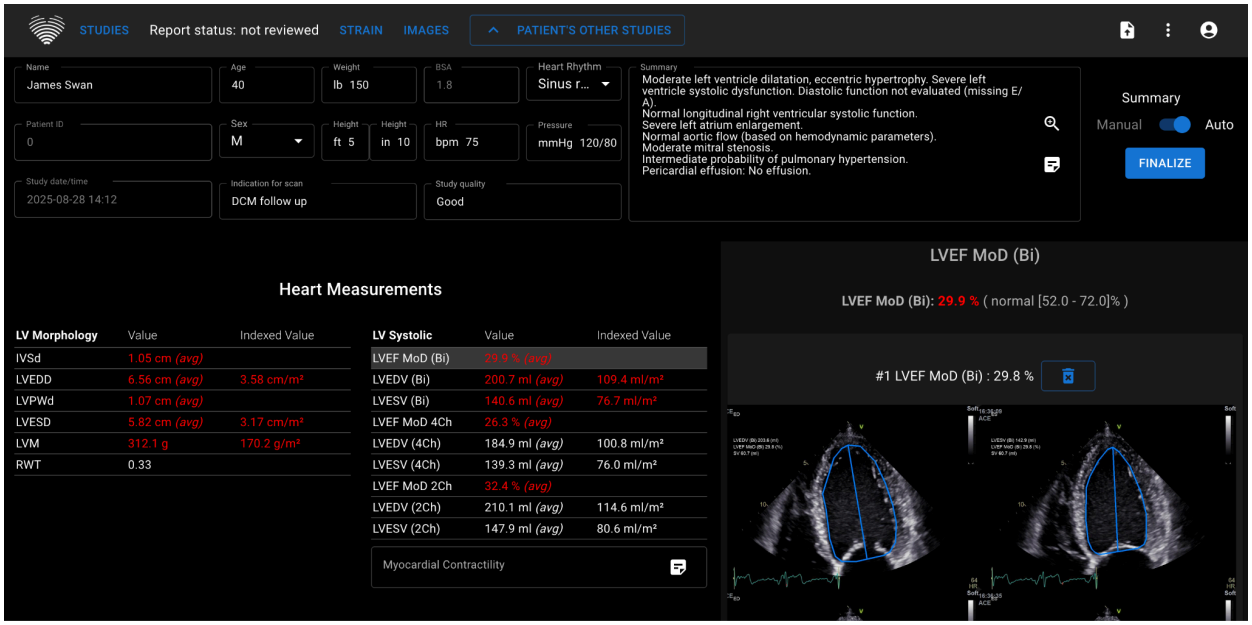
If you decide to go back to the Working View press the Back to study images button.



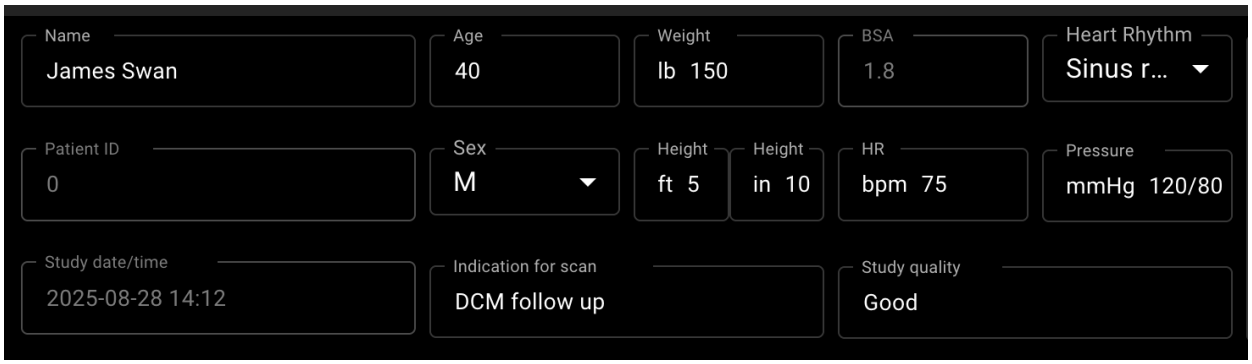
Or if you decide to go back to the Strain View press the “Strain” button.



The Report View is dedicated for making two-dimensional transthoracic echocardiography reports. This view allows you to compare your measurements against normal values for the standard measures, review source views from which the measurements were taken and make quick edits to 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:



4.8.1 Patient Characteristics



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

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

- Indication for scan - freetext field for the scan indication
- Study quality - freetext field for the study quality

Mosteller formula for BSA:

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

Imperial vs metric system units for patient characteristics

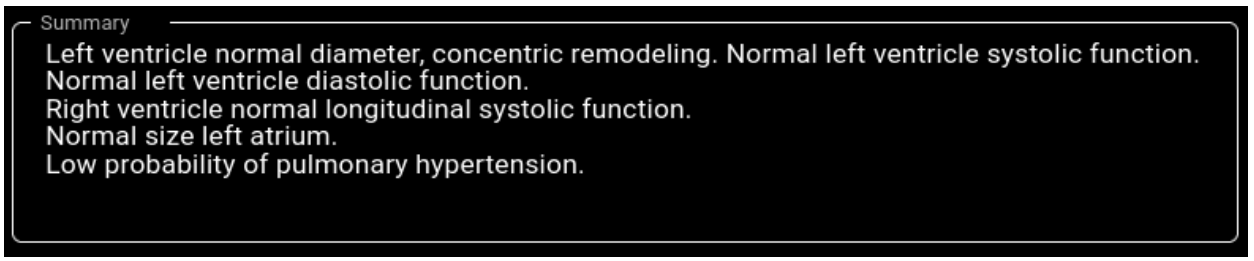
Device can be configured to use imperial or metric system units during deployment:

- 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”

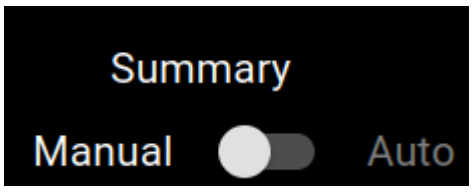
4.8.2 Summary Box

Summary box is a placeholder to write the echocardiographic study impressions in reference to the standard mesures. 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.



4.8.3 Summary Modes

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



4.8.3.1 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.

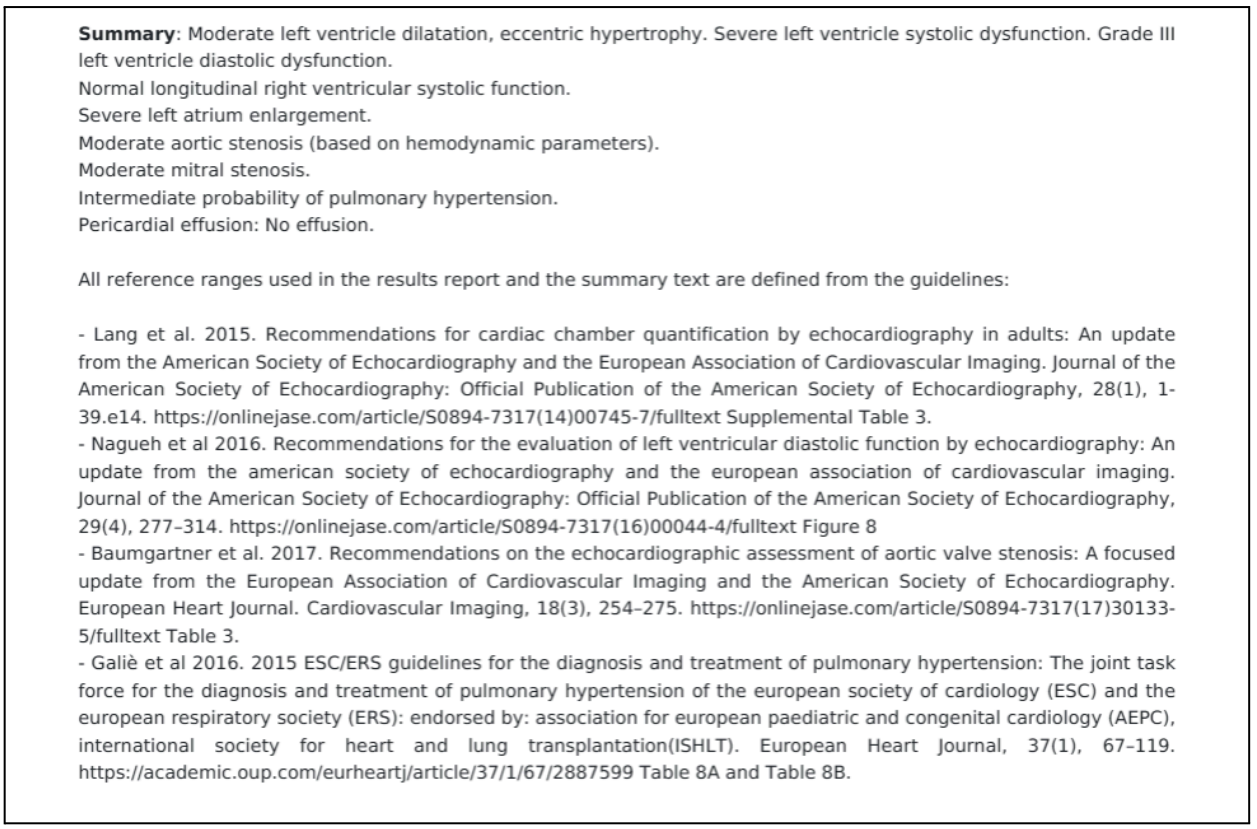
4.8.3.2 Automatic Summary Mode

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.

The clinical guidelines used for the International Reference ranges and generating the summary text in the automatic summary mode are provided to the user below the summary of the generated report. See example figure below:



Summary: Moderate left ventricle dilatation, eccentric hypertrophy. Severe left ventricle systolic dysfunction. Grade III left ventricle diastolic dysfunction.
Normal longitudinal right ventricular systolic function.
Severe left atrium enlargement.
Moderate aortic stenosis (based on hemodynamic parameters).
Moderate mitral stenosis.
Intermediate probability of pulmonary hypertension.
Pericardial effusion: No effusion.

All reference ranges used in the results report and the summary text are defined from the guidelines:

- Lang et al. 2015. Recommendations for cardiac chamber quantification by echocardiography in adults: An update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 28(1), 1-39.e14. https://onlinejase.com/article/S0894-7317(14)00745-7/fulltext Supplemental Table 3.
- Nagueh et al 2016. Recommendations for the evaluation of left ventricular diastolic function by echocardiography: An update from the american society of echocardiography and the european association of cardiovascular imaging. Journal of the American Society of Echocardiography: Official Publication of the American Society of Echocardiography, 29(4), 277–314. https://onlinejase.com/article/S0894-7317(16)00044-4/fulltext Figure 8
- Baumgartner et al. 2017. Recommendations on the echocardiographic assessment of aortic valve stenosis: A focused update from the European Association of Cardiovascular Imaging and the American Society of Echocardiography. European Heart Journal. Cardiovascular Imaging, 18(3), 254–275. https://onlinejase.com/article/S0894-7317(17)30133-5/fulltext Table 3.
- Galiè et al 2016. 2015 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension: The joint task force for the diagnosis and treatment of pulmonary hypertension of the european society of cardiology (ESC) and the european respiratory society (ERS): endorsed by: association for european paediatric and congenital cardiology (AEPC), international society for heart and lung transplantation(ISHLT). European Heart Journal, 37(1), 67–119. https://academic.oup.com/eurheartj/article/37/1/67/2887599 Table 8A and Table 8B.

.

Explanation of the terminology used

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

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

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

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

Priority: The preferred order of using available measurements.

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

International Reference Ranges

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

Left ventricular diastolic diameter in parasternal-long axis

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

Required measurements (at least of one of):

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

Priority (highest priority to lowest priority):

- LVEDDi
- LVEDD

LVEDDi

Criteria (patient is male)	**Criteria (patient is female)**	**Corresponding automatic summary text**
LVEDDi ∈ [2.2, 3.0] cm	LVEDDi ∈[2.3, 3.1] cm	Normal left ventricle diameter
LVEDDi ∈ [3.1, 3.4) cm	LVEDDi ∈ [3.2, 3.5) cm	Mild left ventricle dilatation
LVEDDi ∈ [3.4, 3.6] cm	LVEDDi ∈ [3.5, 3.7] cm	Moderate left ventricle dilatation
LVEDDi >3.6 cm	LVEDDi >3.7 cm	Severe left ventricle dilatation

No LVEDDi	No LVEDDi	Left ventricle size not evaluated (missing diastolic diameter)

If only LVEDD is available (non-indexed):

Criteria (patient is male)	**Criteria (patient is female)**	**Corresponding automatic summary text**
LVEDD ∈ [4.2, 5.8] cm	LVEDD ∈ [3.8, 5.2] cm	Normal left ventricle diameter
LVEDD ∈ [5.9, 6.4) cm	LVEDD ∈ [5.3, 5.7) cm	Mild left ventricle dilatation
LVEDD ∈ [6.4, 6.8] cm	LVEDD ∈ [5.7, 6.1] cm	Moderate left ventricle dilatation
LVEDD >6.8 cm	LVEDD >6.1 cm	Severe left ventricle dilatation
No LVEDD	No LVEDD	Left ventricle size not evaluated (missing diastolic diameter)

References:

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

Left ventricular morphology in parasternal-long axis view

Formulas:

Left ventricular mass (LVM)	Devereux formula 0.8 * (1.04 * (LVEDD + IVSd + LVPWd)^3 - LVEDD^3) + 0.6

Relative wall thickness (RWT)	(IVSd + LVPWd) / LVEDD

Required measurements (all below):

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

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

References:

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

Left ventricular systolic function in apical views

Required measurements (at least of one of):

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

Priority (highest priority to lowest priority):

- LVEF MoD (Bi)

- LVEF MoD 4Ch
- LVEF MoD 2Ch

EF - ejection fraction (one of the prioritised measurements)

Criteria (patient is male)	Criteria (patient is female)	Corresponding automatic summary text
EF ∈ [52, 72] %	EF ∈ [54, 74] %	Normal left ventricle systolic function
EF ∈ [41, 52) %	EF ∈ [41, 54) %	Mild left ventricle systolic dysfunction
EF ∈ [30, 41) %	EF ∈ [30, 41) %	Moderate left ventricle systolic dysfunction
EF <30 %	EF <30 %	Severe left ventricle systolic dysfunction
No LVEF MoD (Bi), LVEF MoD 4Ch and LVEF MoD 4Ch	No LVEF MoD (Bi), LVEF MoD 4Ch and LVEF MoD 4Ch	Left ventricle systolic function not evaluated

References:

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

Left ventricular diastolic function if ejection fraction is normal

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

Required measurements:

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

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

- E/e'

- E/Le’
- E/Se’

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

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

Criteria:

- E/e’ > 14, generally used. If only septal or lateral velocities are acquired, E/Le’ > 13 or E/Se’ > 15
- Se’ < 7 cm/s or Le’ velocity <10 cm/s
- TR Vmax > 2.8 m/s
- LAVi (Bi) or LAVi (4Ch) or LAVi (2Ch) >34ml/m2

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

References:

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

Left ventricular diastolic dysfunction

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

Required measurements:

- E/A ratio (E/A)

Additional measurements:

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

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

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

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

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

Criteria:

- E/e' > 14, generally used. If only septal or lateral velocities are acquired, E/Le' > 13 or E/Se' > 15
- TR Vmax > 2.8 m/s
- LAVi (Bi) or LAVi (4Ch) or LAVi (2Ch) >34ml/m2

Criteria	**Corresponding automatic summary text**
E/A ≤ 0.8 and E ≤ 50 cm/s	Grade I left ventricle diastolic dysfunction
E/A ≥ 2	Grade III left ventricle diastolic dysfunction
(E/A ≤ 0.8 and E > 50 cm/s) or 0.8< E/A <2 2 or 3 criteria are negative	Grade I left ventricle diastolic dysfunction
(E/A ≤ 0.8 and E > 50 cm/s) or 0.8< E/A <2 Only 2 criteria available and 1 positive	Indeterminate left ventricle diastolic function
(E/A ≤ 0.8 and E > 50 cm/s) or 0.8< E/A <2	Grade II left ventricle diastolic dysfunction

2 or 3 criteria are positive	
E/A not available	Diastolic function not evaluated (missing E/A)
E/A ≤ 0.8 and E not available	Diastolic function not evaluated (missing E wave velocity)

References:

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

Right ventricular diameter

Required measurements (at least of one of):

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

Criteria	**Corresponding automatic summary text**
RVM >3.5 cm or RVB >4.1 cm	Right ventricle dilatation
RVM ∈ [1.9, 3.5] cm and RVB ∈ [2.5, 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://onlinejase.com/article/S0894-7317(14)00745-7/fulltext Section "7.1 Linear Measurements"

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 ∈[16, 34) ml/m2	Normal size left atrium
LAVi ∈ [34, 41] ml/m2	Mild left atrium enlargement
LAVi ∈ (41, 48] %ml/m2	Moderate left atrium enlargement
LAVi >48 ml/m2	Severe left atrium enlargement
No LAVi	No text will be generated

References:

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

Right atrium size in apical views

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

Required measurements (at least of one of):

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

Priority (highest priority to lowest priority):

- RAVi
- RA Min. i (4Ch)

RAVi

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

RA Min. i (4Ch)

Criteria (patient is male)	Criteria (patient is female)	Corresponding automatic summary text
RA Min. i (4Ch) ≤2.2 cm/m2	RA Min. i (4Ch) ≤2.2 cm/m2	Normal size right atrium
RA Min. i (4Ch) >2.2 cm/m2	RA Min. i (4Ch)>2.2 cm/m2	Right atrium enlargement
No RAVi and no RA Min. i (4Ch)	No RAVi and no RA Min. i (4Ch)	No text will be generated

References:

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

Aortic 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**
If one the following is true: • AV Vmax ≥4.0 m/s • AMG ≥40 mmHg • AVAi <0.6 cm2/m2 or AVA <1.0 cm2 • Vel. ratio <0.25	Severe aortic stenosis (based on hemodynamic parameters)
If none of the above criteria are true and one the following is true: • AV Vmax ∈ [3.0, 4.0) m/s • AMG ∈ [20, 40) mmHg • AVAi ∈ [0.6, 0.85] cm2/m2 or AVA ∈ [1.0, 1.5] cm2 • 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 cm2/m2 or AVA >1.5 cm2 • Vel. ratio >0.50	Mild aortic stenosis (based on hemodynamic parameters)
AV Vmax is not available	No text will be generated

References:

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

Pulmonary hypertension

Required measurements:

- Peak Tricuspid Regurgitation Velocity (TR Vmax)

Measurements used to determine pulmonary hypertension signs:

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

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

- IVCde (B)
- IVCde (M)

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

- IVCcol (B)
- IVCcol (M)

Echocardiographic signs of pulmonary hypertension:

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

Pulmonary hypertension summary text generation:

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

References:

- Galiè et al 2016. 2015 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension: The joint task force for the diagnosis and treatment of pulmonary hypertension of the european society of cardiology (ESC) and the european respiratory society (ERS): endorsed by: association for european paediatric and congenital cardiology (AEPC), international society for heart and lung transplantation(ISHLT).

European Heart Journal, 37(1), 67–119. https://academic.oup.com/eurheartj/article/37/1/67/2887599 Table 8A and Table 8B.

4.8.4 Measurement fields

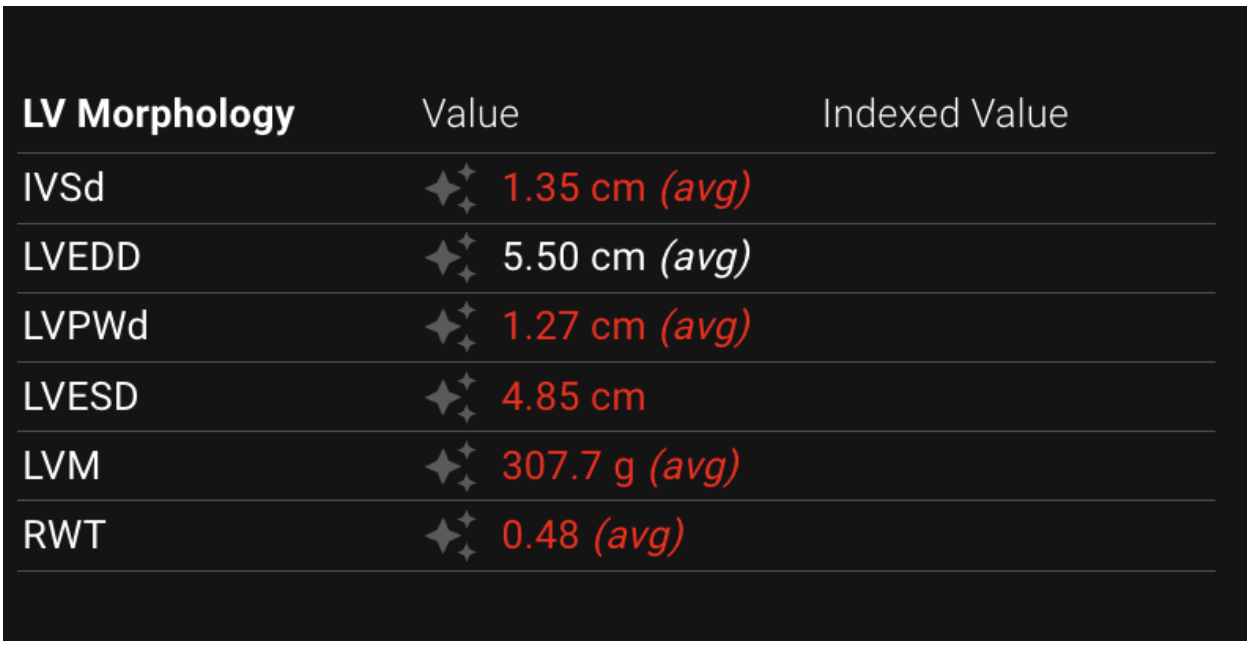
The Measurement Blocks grid in Report View is a fixed table that always displays the full list of measurement labels, arranged by anatomical and functional sections.

- When automated analysis is enabled, Ligence Heart classifies views, generates anatomical annotations, conducts left-ventricular contour tracking, applies formulas, and calculates validated measurements. Each value is derived from the automatically generated annotations, converted to physical units by formulas, and colour-coded against clinical guidelines-based reference ranges only for the quantitative standard measures described in section above. If the measurement is calculated as an average of multiple measurements, the (avg) text will be shown.

When automated analysis is disabled, the grid remains visible but initially blank; for standard measures, individual cells are populated only after the you create or edit annotations in the Workspace View or Quick Edit modal. All subsequent manual entries receive the same guideline comparison and colour-coding as automated values.

NOTE

In the case of the LV GLS measurements, you can not conduct the manual analysis if automated analysis is disabled for LV GLS analysis. LV GLS measurements can be only conducted if the automated analysis mode is enabled (please refer to Section 1.6 Analysis mode analysis). If enabled, you can conduct manual analysis for adjustment of the LV GLS automated analysis at your discretion.



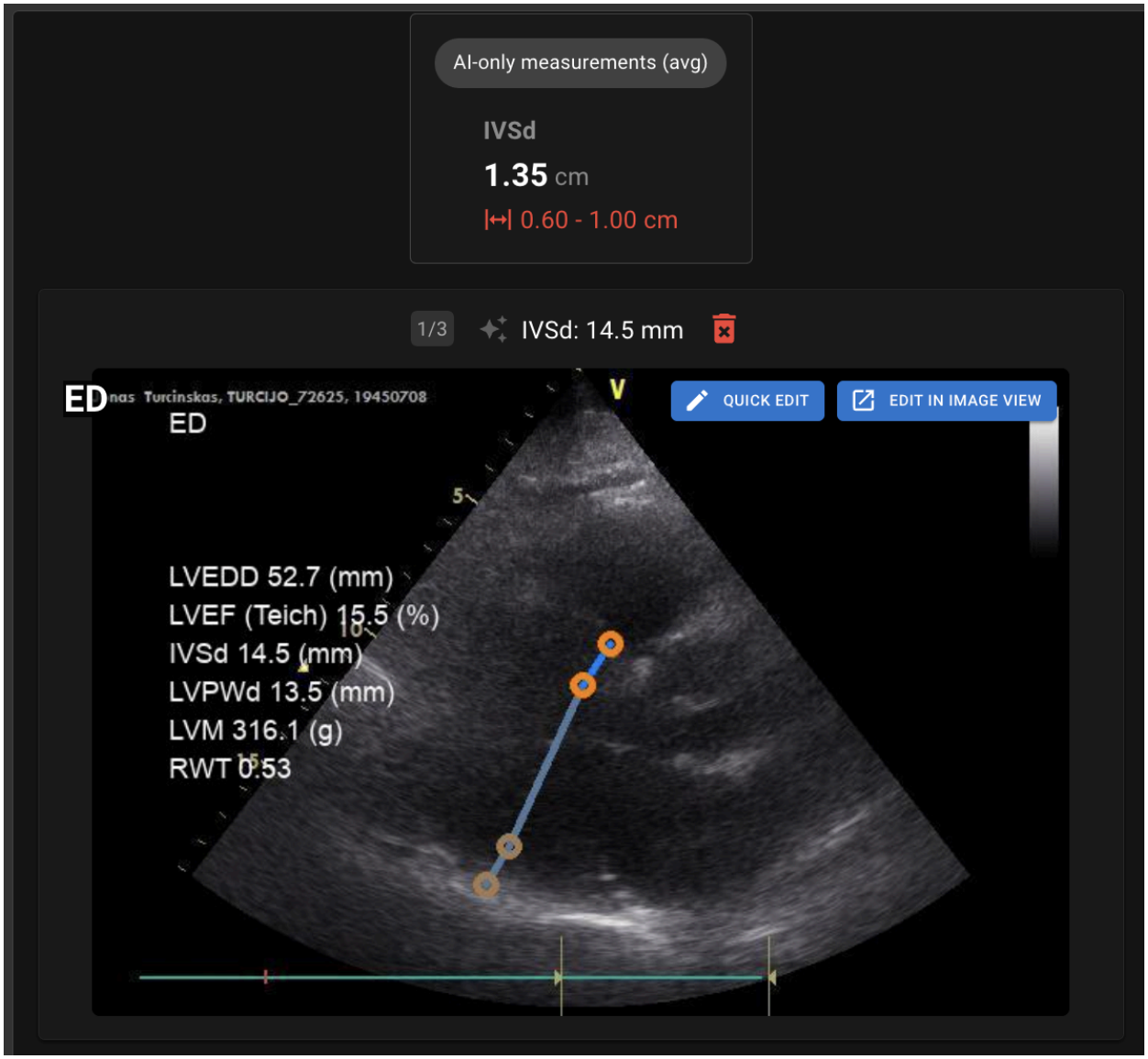
4.8.5 Illustrations

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 quantitative standard measurement.

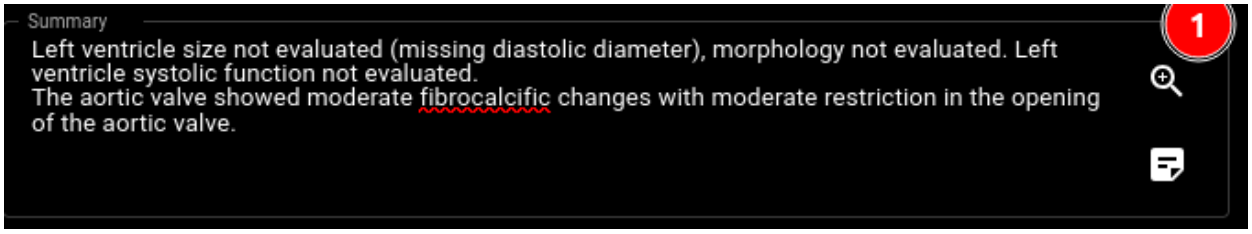
Clicking “EDIT IN IMAGE VIEW” redirects to the specific image in the workspace view.

Clicking “EDIT IN STRAIN VIEW” redirects to the specific analysis in the strain view.

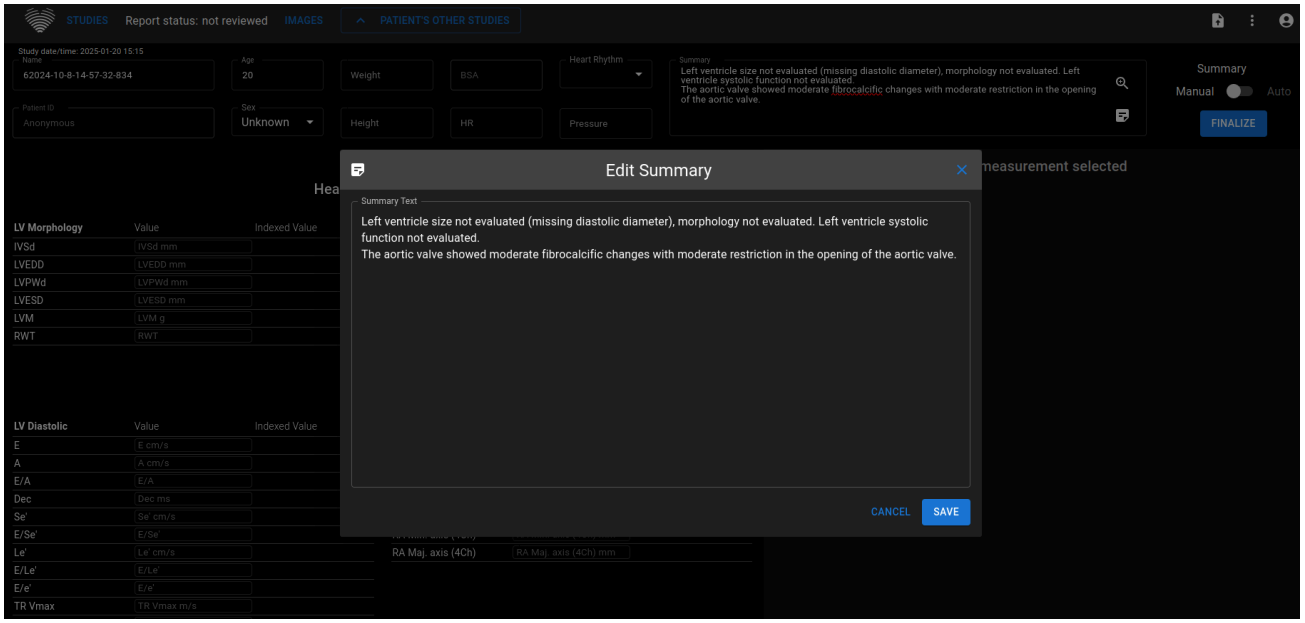


4.8.6 Enlarge summary edit field

Click on the enlarge summary field button



Edit summary in a dedicated screen.

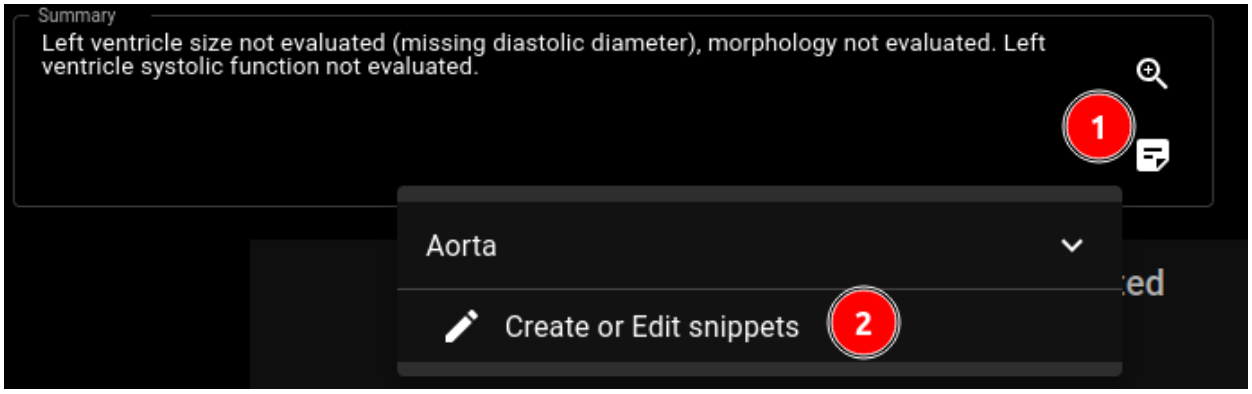


4.8.7 Text Snippets

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

4.8.7.1 Create Text Snippets

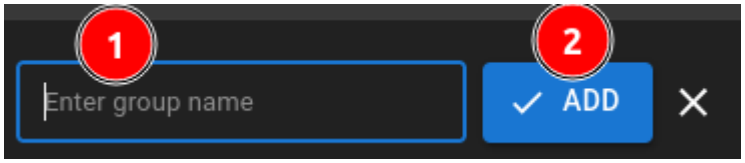
- Click on the Snippets button
- Click “Create or Edit snippets”



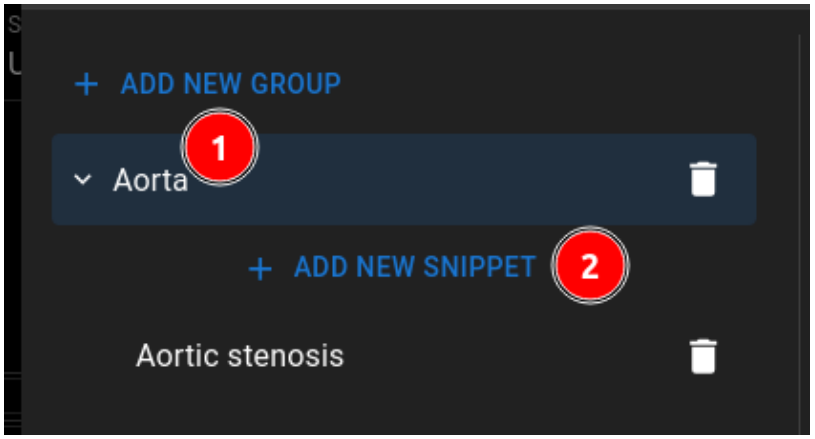
- (Optional) Click “Add new group”



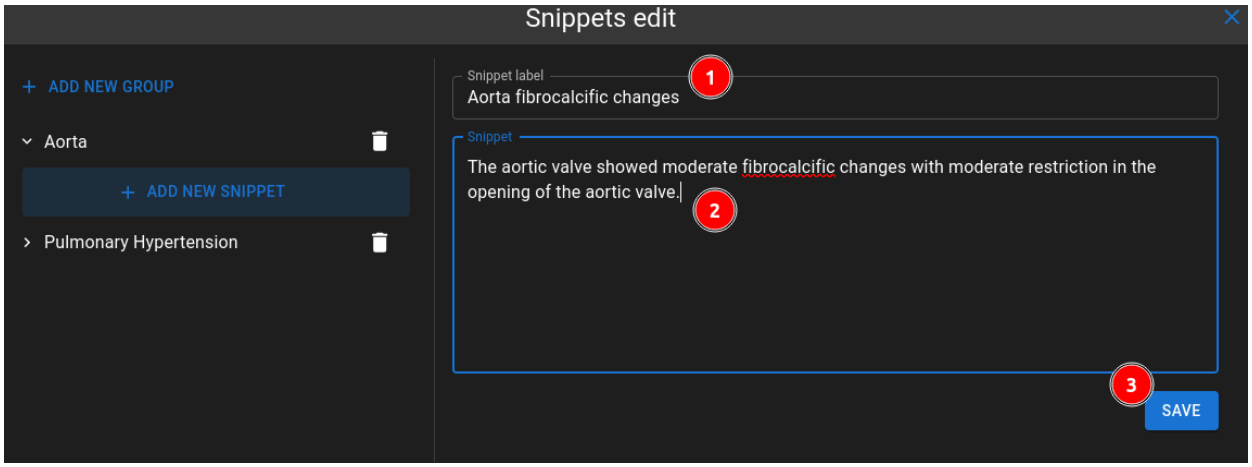
- Enter the name for the group
- Click “Add”



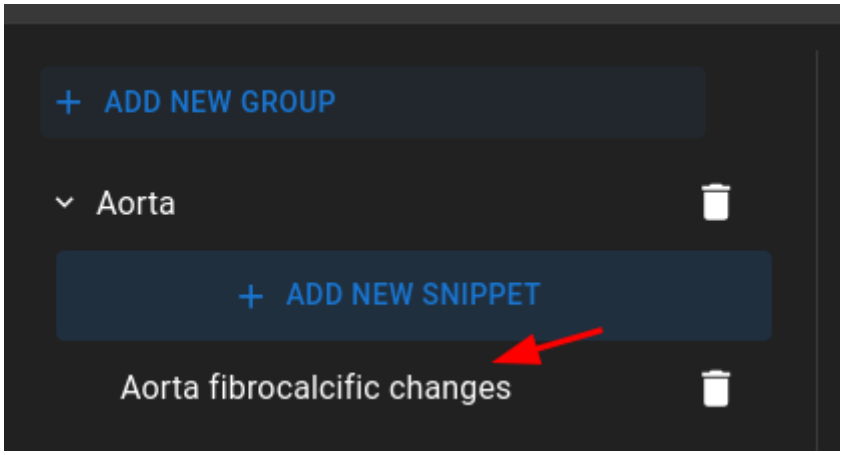
- Select the group to expand it
- Click “Add New Snippet”



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

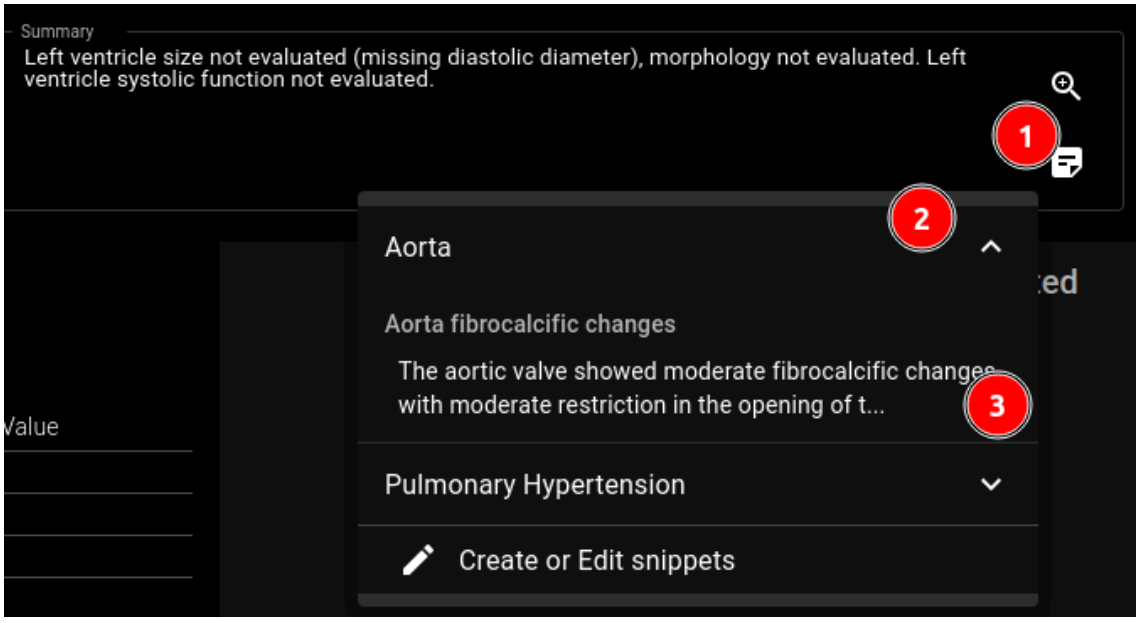


- The new snippet will be shown in the snippet group list

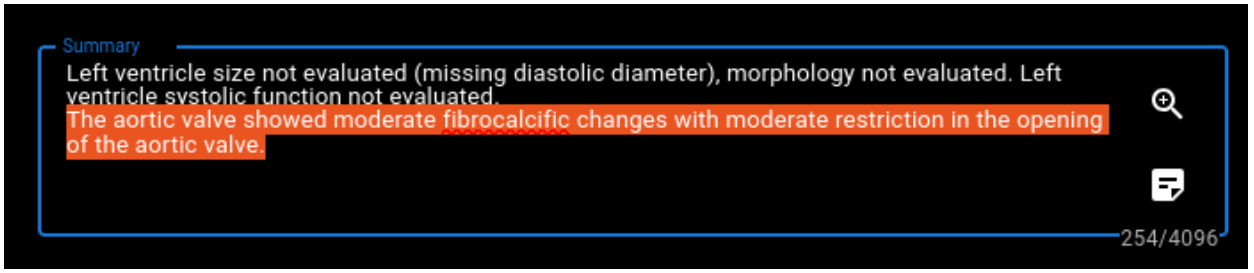


4.8.7.2 Import Text Snippets

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

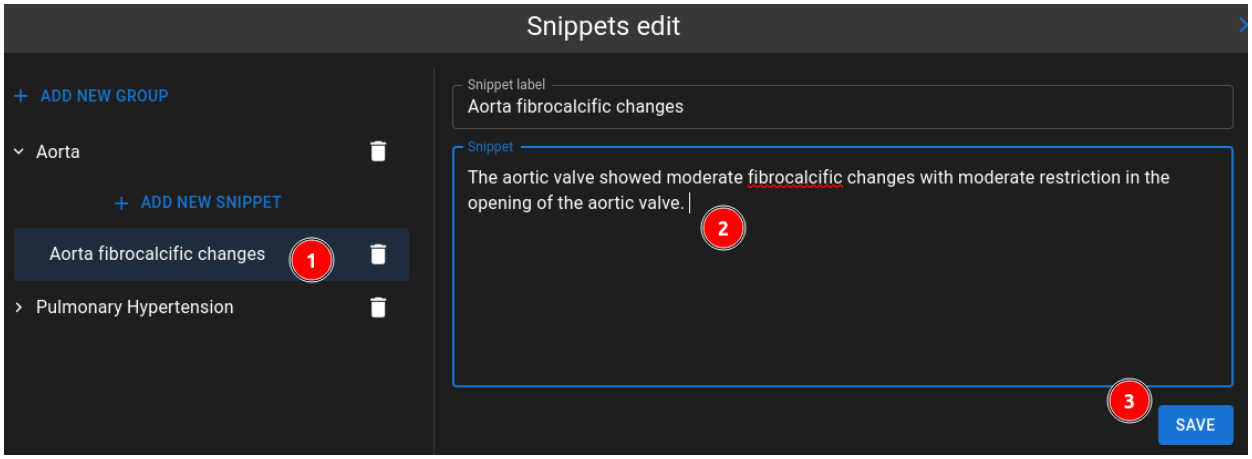


The snippet will be added to the end of the text field.



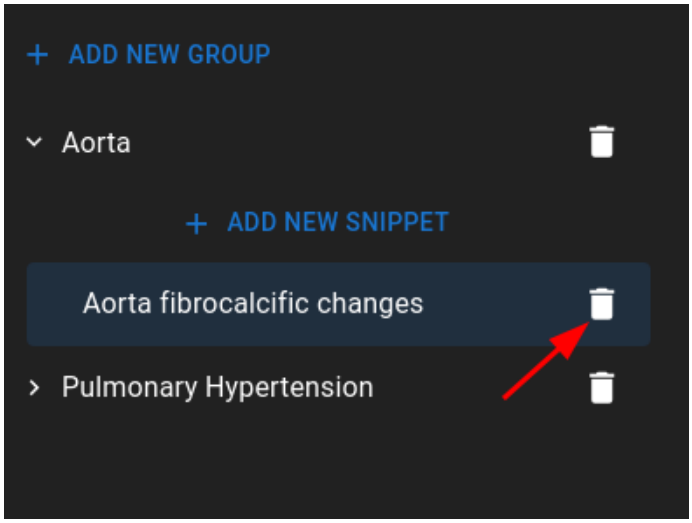
4.8.7.3 Edit Text Snippets

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



4.8.7.4 Delete Text Snippets or Snippet Groups

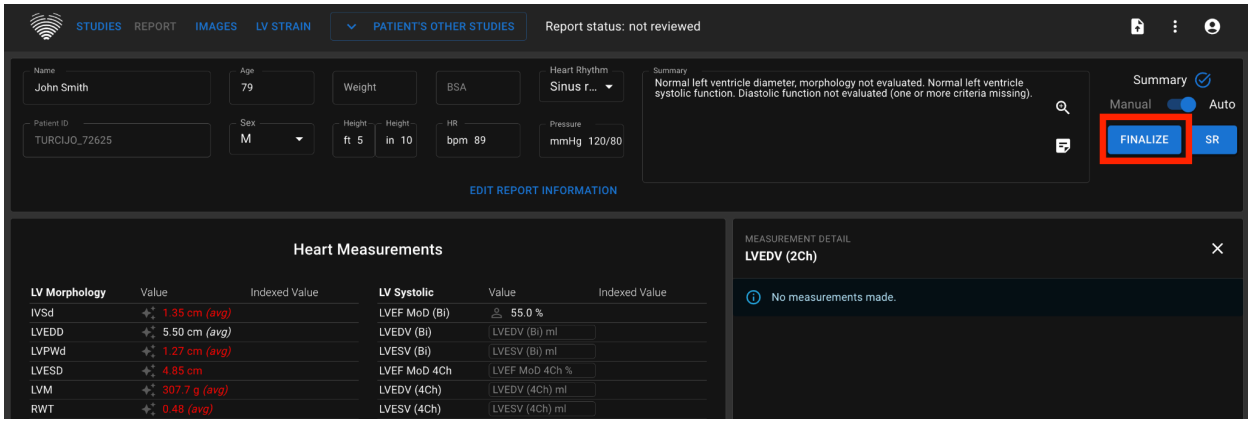
Use the recycle bin button to delete a snippet



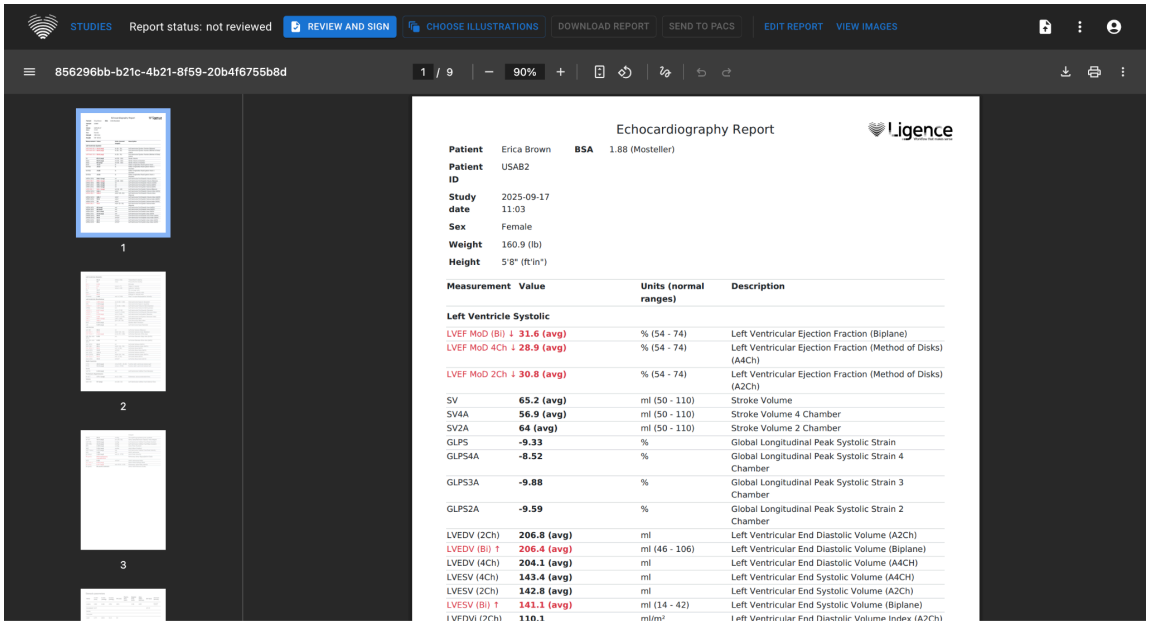
4.9 Finalizing Report

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.

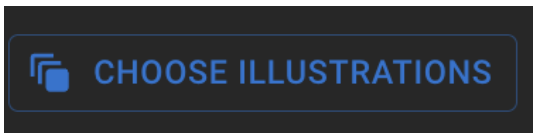


This will open the Report PDF view.

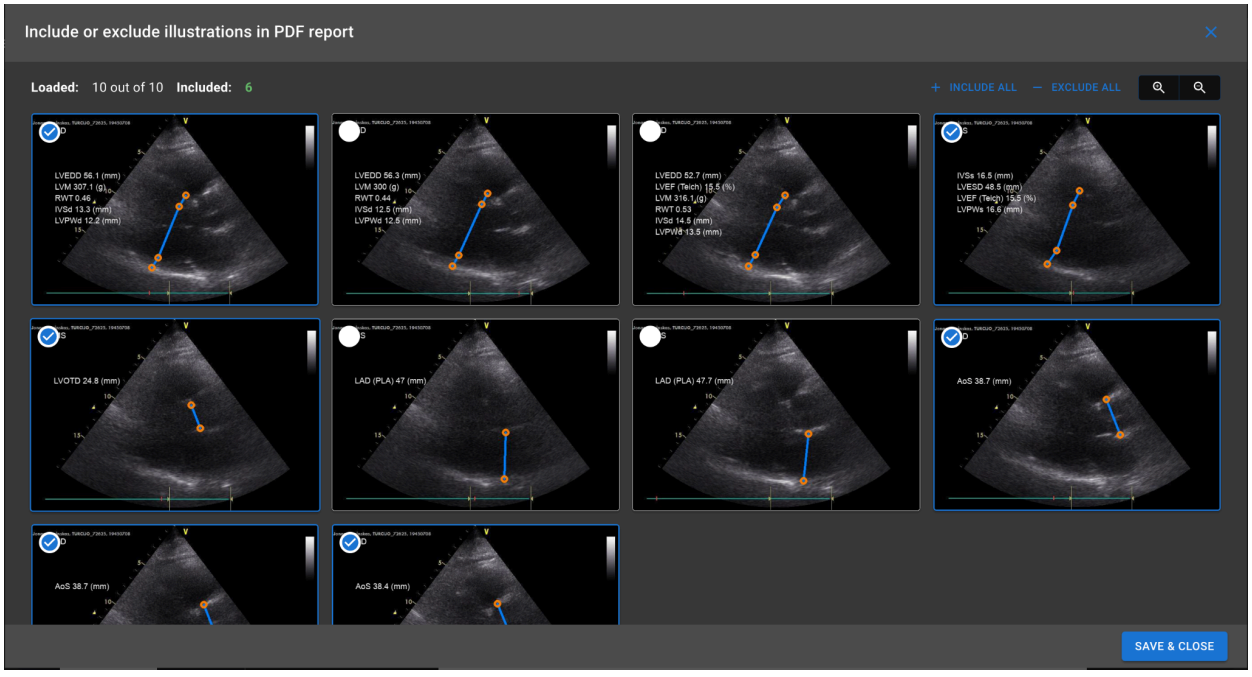


4.9.1 Choosing illustrations

Clicking the ‘Choose Illustrations’ button opens a pop-up window where images for display in the report PDF can be selected.



In the pop-up window click on individual images to include or exclude them, or use the ‘Include All’ and ‘Exclude All’ buttons to select multiple images. Save the changes by clicking the ‘Save & Close’ button.



4.9.2 Reviewal and confirmation of the report

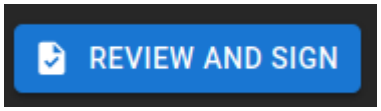
At this stage, the report must be reviewed and confirmed in the system. The available actions depend on the user type: sonographers can review and submit the report, whereas cardiologists can review and provide the final sign-off.

4.9.2.1 Sonographer

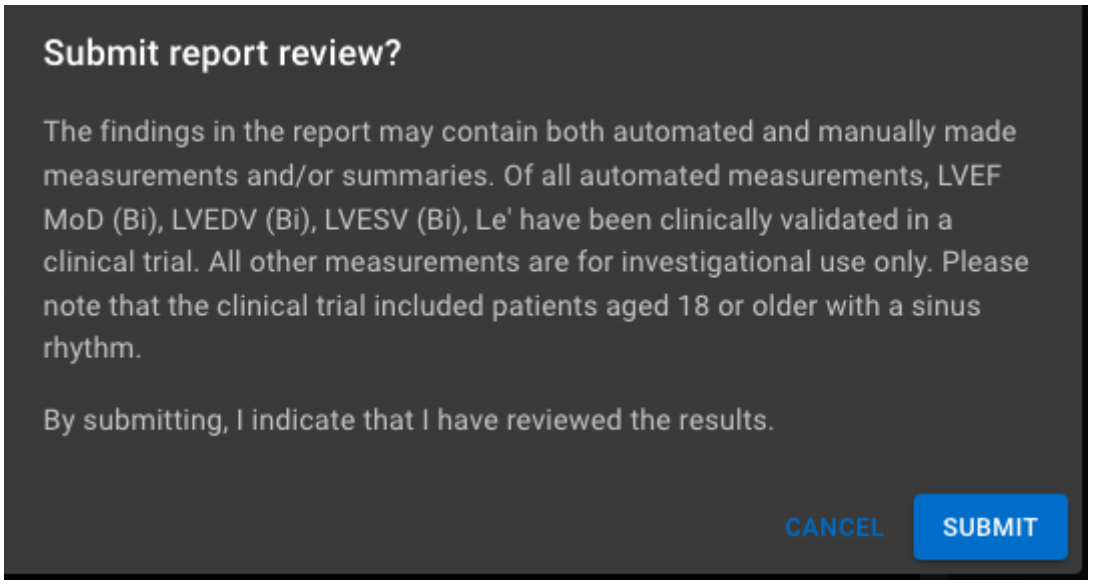
1. Navigate to report view
2. Review study



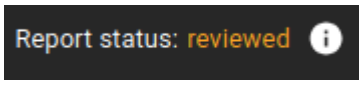
3. Click
4. Review the generated PDF



5. Click
6. Acknowledge limitations and submit



7. After submitting report status will change to

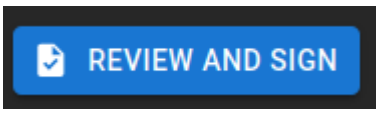


4.9.2.2 Cardiologist

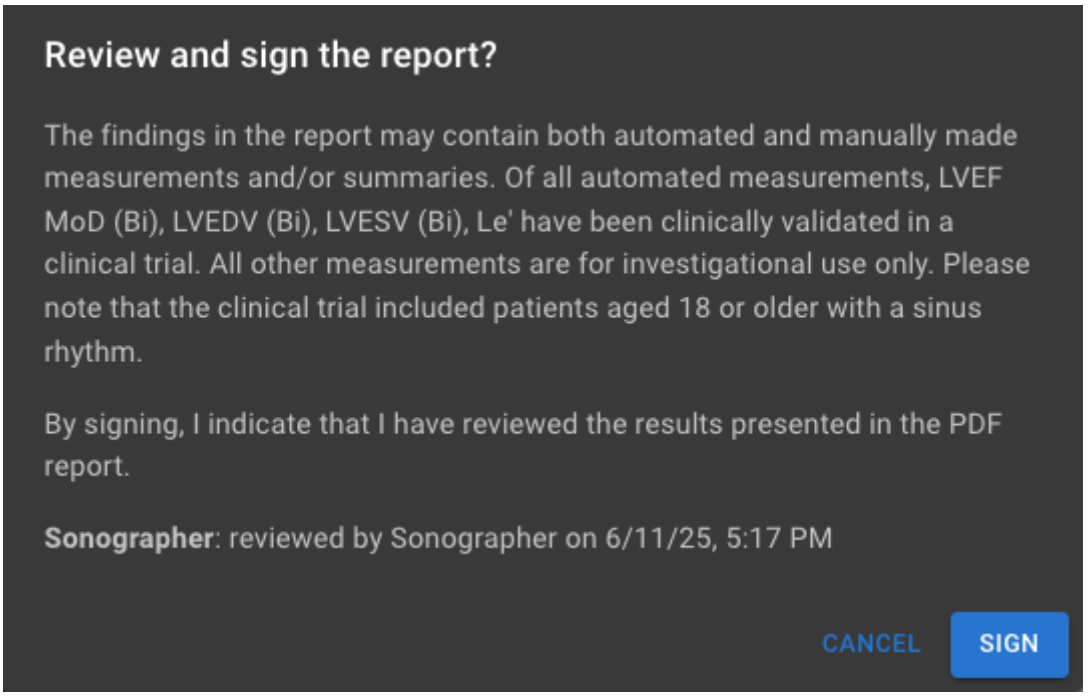
1. Navigate to report view
2. Review study



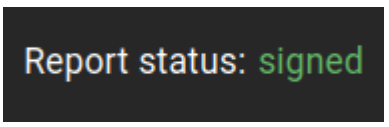
3. Click
4. Review the generated PDF



5. Click
6. Acknowledge limitations and sign



7. After confirming report status will change to



NOTE

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

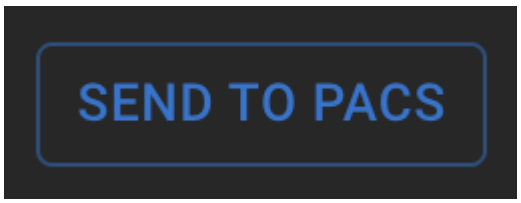
4.9.3 Going back to editing

Pressing the “Report” or “Images” buttons navigates the user to the corresponding views. Any changes made in these views require the report to be reviewed and signed again.



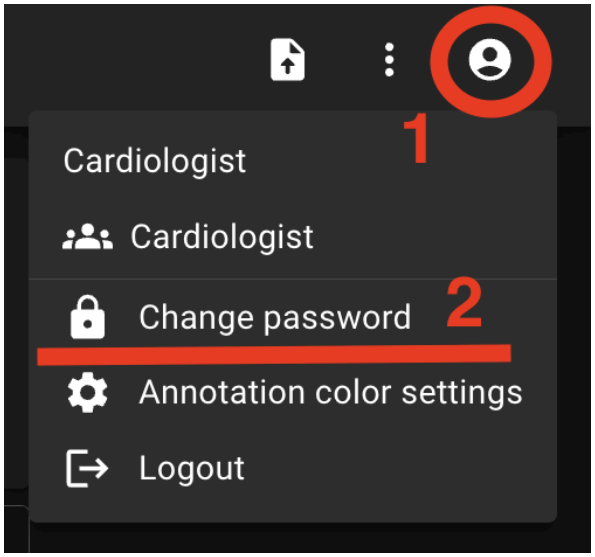
4.9.4 Sending to PACS

In the Report PDF View, a button on the navigation bar becomes active once the report is reviewed and signed. Pressing this button sends the report to the configured system, such as the hospital PACS or another designated storage. The exact process depends on the local system setup and user configuration.

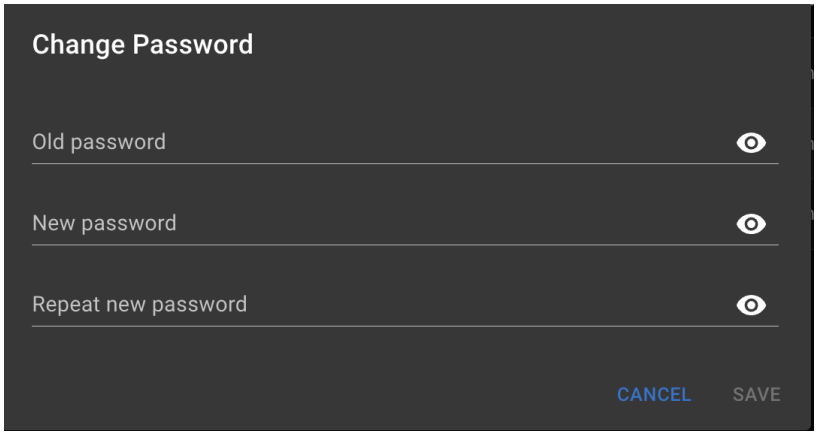


4.10 Changing Password

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.



Clicking the ‘Change Password’ button opens a pop-up window. Enter the current password, the new password, and repeat the new password to change it.

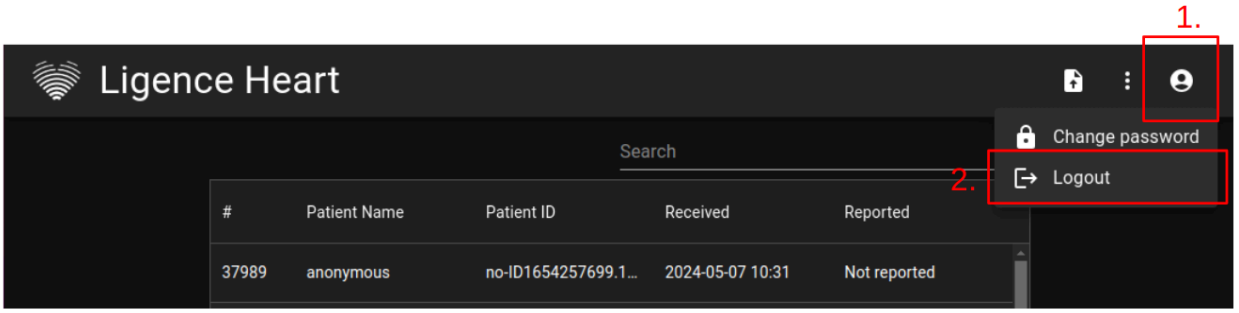


4.11 Locking the software

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

4.12 Logout

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

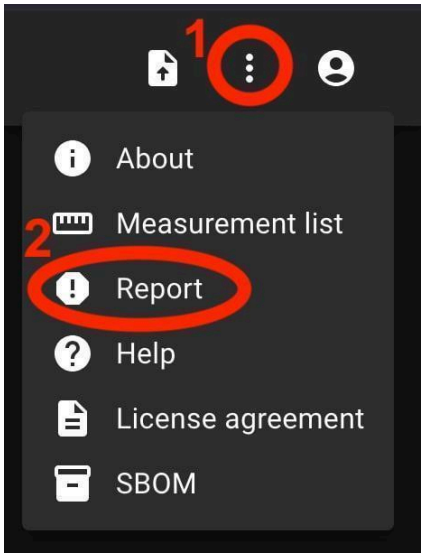
NOTE

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

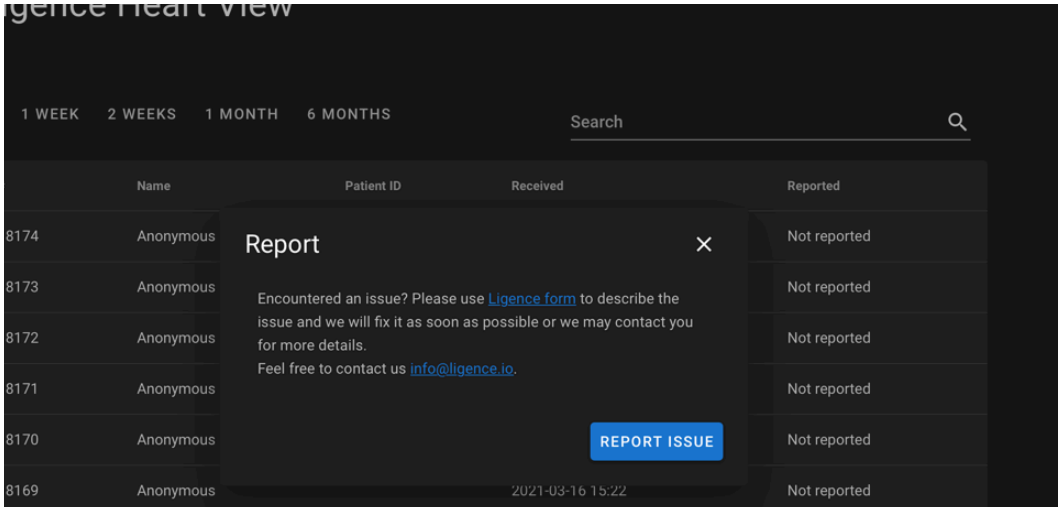
4.13 Report an issue

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 submit the issue (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 time frames. Please consult your Service Level Agreement for more information.

4.14 Decommissioning of Software

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

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.
- Users 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 works correctly and securely, please consider these good practices and precautions to help keep your computer system safe and secure.

5.2 Device Security and User Responsibility

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

5.3 Reporting Device Security or Privacy Breaches

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

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

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

5.4 Cybersecurity system description

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

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

5.5 Software Bill of Materials (SBOM)

The SBOM files for Ligence Heart in machine-readable format are available for download in the application from the “About and Support” menu.

5.6 Reporting security issues

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

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

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

UAB Ligence DPO is responsible for data protection.

6 PERFORMANCE SUMMARY

Ligence Heart underwent comprehensive clinical validation at the Northwestern University Echocardiography Core Laboratory through two multi-reader studies. The primary aim was to evaluate interchangeability of Ligence Heart automated measurements (standard echocardiographic measurement and LV Strain analysis) with reference/gold standard echo core lab human measurements. The validation evaluated agreement between the automated measurements and those obtained by trained independent expert readers for standard cardiac parameters and advanced strain analysis.

Study Cohort

A total of 613 met inclusion/exclusion criteria and were used for validation of both standard measurements and LV strain analysis. The studies were sourced from the Dilated Cardiomyopathy Precision Medicine Study (DCPMS, NCT03037632). The cohort was enriched for abnormal findings with 137 participants representing normal left ventricular ejection fraction (LVEF >50%) and 476 participants with reduced LVEF (<50%). Each study was independently analyzed by three expert readers using commercially available software for clinical practice to establish the reference standard measurements.

Standard Echocardiographic Measurements

From the 613 studies, 528 studies with complete measurements from all three readers were included in the final analysis. Automated measurements were compared against consensus of three independent expert readers using the individual equivalence coefficient (IEC) as the primary endpoint. An echocardiographic parameter is considered acceptable if the IEC upper bound of the 95% confidence interval is < 0.25, indicating that variability between Ligence Heart and human readings does not exceed variability between human readers themselves. All validated parameters met the pre-defined success criterion, with all IEC 95% confidence internal upper bounds below the 0.25 threshold, confirming that automated measurements were valid and reliable.

Parameter	IEC 95% CI	IEC Average	RMSE95% CI	RMSE	Feasibility	BIAS	LOA LB	LOA UB	ICC
A	-0.336	-0.582	6.729	6.018	0.731	-0.245	-12.035	11.545	0.954
E	-0.104	-0.412	11.169	9.777	0.825	0.458	-18.691	19.607	0.932
E/A	-0.357	-0.697	0.327	0.285	0.760	0.014	-0.543	0.572	0.929
E/e	-0.636	-0.859	4.054	3.369	0.599	0.362	-6.207	6.932	0.856
IVSd	0.092	-0.133	1.479	1.402	0.952	-0.501	-3.068	2.066	0.683
LAV	0.099	-0.167	15.359	14.400	0.904	-2.104	-30.033	25.824	0.915
Le	-0.440	-0.632	1.686	1.506	0.809	0.057	-2.894	3.009	0.873
LVED	-0.195	-0.404	3.693	3.449	0.952	-0.687	-7.313	5.939	0.934

Parameter	IEC 95% CI	IEC Average	RMSE95% CI	RMSE	Feasibility	BIAS	LOA LB	LOA UB	ICC
D									
LVEDV	-0.512	-0.640	29.450	27.691	0.919	8.557	-43.076	60.190	0.932
LVEF	0.008	-0.209	7.133	6.771	0.913	-1.415	-14.397	11.567	0.907
LVESV	-0.141	-0.383	28.480	26.211	0.913	9.732	-37.985	57.448	0.941
LVPWd	0.006	-0.186	1.546	1.474	0.952	-0.649	-3.243	1.944	0.522
PTRV	0.221	-0.267	0.286	0.249	0.760	-0.018	-0.506	0.469	0.875
Se	0.193	-0.127	1.080	0.984	0.825	0.279	-1.571	2.130	0.925

Abbreviations: LVEF - Left ventricle ejection fraction (biplane), LVEDV - Left ventricle end-diastolic volume (biplane), LVESV - Left ventricle end-systolic volume (biplane), LVEDD - Left ventricle end-diastolic diameter, IVSd - Intraventriculum septum (diastole), LVPWd - Left ventricle posterior wall (diastole), E - Transmitral E velocity, A - transmitral A velocity, E/A - E and A ratio, Se - Septal E prime velocity, Le - Lateral E prime velocity, E/e - Mitral E velocity and e prime average velocity ratio, PTRV - Tricuspid valve regurgitation peak velocity, LAV - Left atrium volume (biplane).

Note: LVEF = Left Ventricular Ejection Fraction; LVEDV = Left Ventricular End-Diastolic Volume; LVESV = Left Ventricular End-Systolic Volume; IEC = Individual Equivalence Coefficient; ICC = Intraclass Correlation Coefficient; CI = Confidence Interval; LoA = Limits of Agreement.

LV Strain Analysis

From the same cohort, 475 studies with complete strain measurements from all three readers were included in the final analysis. The automated measurements were compared against the reference standard using root mean square error (RMSE) with 95% bootstrap confidence intervals (10,000 iterations), intraclass correlation coefficient (ICC), and Pearson correlation analysis. Bootstrapping provided robust upper bound estimates with 95% confidence that true population RMSE does not exceed the reported values. The device demonstrated excellent agreement for global longitudinal strain and moderate to excellent agreement for segmental strain measurements, confirming interchangeability with expert human measurements using a currently available for clinical practice FDA-cleared AI-based strain analysis system.

Measurement yield (device measurements obtained from studies with complete strain measurements from all three readers): Global longitudinal strain: 413/475 (87%), Segmental strain (all 18 segments): 413/475 (87%)

LV Strain Performance

Parameter	RMSE	RMSE 95% CI UB	IEC	IEC 95% CI UB
GLPS4A	2.667	2.811	-0.430	-0.260
GLPS2A	2.887	3.095	-0.393	-0.172
GLPS3A	3.115	3.406	-0.200	0.131
GLPS	2.471	2.636	-0.561	-0.404
Global average	2.785	2.987	-0.396	-0.176
LV S3	5.944	6.492	2.032	2.767
LV S9	4.979	5.367	2.450	3.313
LV S15	6.103	6.567	1.203	1.776
LV S18	6.196	6.531	1.115	1.579
LV S12	5.782	6.101	1.574	2.067
LV S6	7.864	8.407	1.268	1.804
LV S4	6.473	6.842	1.081	1.541
LV S10	5.095	5.436	1.118	1.697
LV S16	7.011	7.471	1.851	2.550
LV S13	6.347	6.708	0.918	1.380
LV S7	6.223	6.905	2.874	4.087
LV S1	7.451	8.024	2.130	2.872
LV S5	8.120	8.639	0.869	1.302
LV S11	5.837	6.280	1.871	2.515
LV S17	6.258	6.602	1.043	1.468
LV S14	7.554	8.059	2.105	2.797
LV S8	5.932	6.308	2.457	3.242
LV S2	7.205	7.831	2.868	3.885
Segmental average	6.465	6.921	1.713	2.369

Imaging Equipment Overview

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

The clinical-validation dataset is described in the table below.

Manufacturer	Model
GE	Vivid E9, Vivid i, Vivid S6, Vivid S70, Vivid E95, Vivid 7, Vivid q.
Philips	Affiniti 70C, Affiniti 70G, Epiq 7C, Epiq CVx, Epiq 5C, CX50, ie33, HP7500, SONOS. Transducers: S5_1, S2, X5_1, C5_2
Siemens	Acuson Sequoia, SC2000 Transducers: 4V1c-S, 3V2c-S

Clinical-validation dataset's DICOMs utilized phased array probes, with transducer frequencies spanning from 1.4 MHz to 4 MHz. The DICOM cine frame rates varied between 4 and 255 frames per second, averaging 30.59 FPS.

References:

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

7 ANNEX I

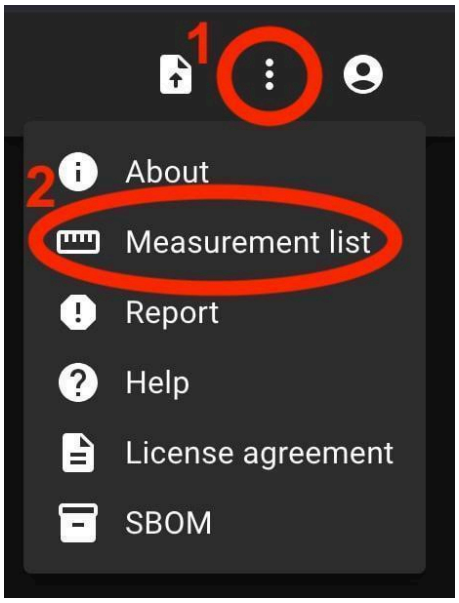
7.1 List of Measurements

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

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

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

The same table can be accessed from the software:



Abbreviation	Description	Automated	Manual
A	Transmitral A velocity	✔	✔
E	Transmitral E velocity	✔	✔
IVSd	Interventricular Septum (diastole)	✔	✔
LAV (Bi)	Left Atrial Volume (Biplane)	✔	✔
Le'	Lateral e' velocity	✔	✔
LVEDD	Left Ventricular End-Diastolic Diameter	✔	✔
LVEDV (Bi)	Left Ventricular End Diastolic Volume (Biplane)	✔	✔

Abbreviation	Description	Automated	Manual
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		✔

Abbreviation	Description	Automated	Manual
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		✔

Abbreviation	Description	Automated	Manual
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		✔

Abbreviation	Description	Automated	Manual
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)		✔

Abbreviation	Description	Automated	Manual
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		✔

Abbreviation	Description	Automated	Manual
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		✔

Abbreviation	Description	Automated	Manual
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		✔

Abbreviation	Description	Automated	Manual
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)		✔

Abbreviation	Description	Automated	Manual
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		✔

Abbreviation	Description	Automated	Manual
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		✔

Abbreviation	Description	Automated	Manual
Velocity	Velocity		✔
Volume	Volume		✔
Measurements unique to LV Strain module			
GLPSS (avg.)	Left Ventricle Global Longitudinal Peak Systolic Strain average	✔	✔
A2CH GLPSS	Global Longitudinal Peak Systolic Strain (Apical 2 Chamber View)	✔	✔
A3CH GLPSS	Global Longitudinal Peak Systolic Strain (Apical 3 Chamber View)	✔	✔
A4CH GLPSS	Global Longitudinal Peak Systolic Strain (Apical 4 Chamber View)	✔	✔
S(1/18)	Left Ventricle Segmental Longitudinal Strain (18 segment model)	✔	✔

7.2 Automatically Classified Views

Ligence Heart automatically tags every incoming image or cine loop. In the current release, the view tags listed below are handled by the validated auto-measurement pipeline, while users may still perform any measurement manually, or launch any available auto-measurement, in any view.

Full view name	Abbreviation
Apical Two-Chamber	A2CH
Apical Four-Chamber	A4CH
Tissue Doppler Pulsed-Wave – Lateral Mitral Annulus	TDPWLMA
Apical Three-Chamber	A3CH