Ligence Heart

For 3.35.0 version

INSTRUCTIONS FOR USE

English

CE 0197

	Name	Role	Date	Signature
Updated by:	Karolis Šablauskas	CPO	2024-07-29	

Approved by:	Indra Raudonė	HQR	2024-07-29	*[signature]*

Revision history				

Rev	Revision date	Description of change	Revised by
1.0	2021-02-28	Document was created	
1.1	2021-10-26	Document is updated according to the notified body comments.	Justinas Balčiūnas
1.2.	2021-12-29	Document is updated according to the notified body comments.	Indra Vaitkevičiūtė
1.3	2022-02-03	Document is updated due to new version 3.0. release	Indra Vaitkevičiūtė
1.4	2022-05-03	Document is updated due to new version 3.1 release	Antanas Kiziela
1.5	2022-06-13	Changes to advanced search, DICOM UI overlay, annotation labels, "escape" key, disabled UI for mobile desktops, updated upload view.	Antanas Kiziela
1.6	2022-07-27	Added volume measurement description. Added new manual (stroke volume) and automated (LE, SE) measurements. Updated illustrations.	Antanas Kiziela
1.7	2022-08-19	Registration view added. New view modes: SCHEMA and MULTIPLANE added.	Antanas Kiziela
1.8	2022-09-21	Automated annotation list updated. Search/query UI updated.	Antanas Kiziela
1.9	2022-10-11	Manual annotations and measurements list updated – added stenosis and regurgitation measurements and annotations. Grade measurement description added.	Antanas Kiziela
1.10	2022-10-19	Updated list of annotations, view modes and measurements. Updated UI images of workspace, report, added Strain view description and images. Updated report elements description.	Antanas Kiziela
1.11	2022-11-08	Updated list of accepted DICOM storage class UIDs. Updated auto measurement functionality user interface description.	Antanas Kiziela
1.12	2022-12-01	Updated company's address.	Antanas Kiziela
1.13	2023-01-06	Strain icon added in top navigation bar. Added new measurements to the list AR PHT, MV PHT, PR PHT, TV PHT.	Antanas Kiziela
1.14	2023-01-10	New view modes added.	Antanas Kiziela
1.15	2023-01-25	STJ removed from automated measurements.	Antanas Kiziela

Revision history			
Rev	Revision date	Description of change	Revised by
1.16	2023-02-10	Product description updated, new use cases and user groups. Strain view description updated.	Antanas Kiziela
1.17	2023-03-21	Product general description update.	Antanas Kiziela
1.18	2023-04-04	Updated description for "Upload the study".	Karolis Šablauskas
1.19	2023-05-01	Label and risks updated.	Karolis Šablauskas
1.20	2023-05-19	Android app usage updated.	Karolis Šablauskas
1.21	2023-06-14	Updated report view description.	Karolis Šablauskas
1.22	2023-06-28	Updated report view description. Updated measurement labels. Updated product labels.	Karolis Šablauskas
1.23	2023-07-19	Updated list of measurements table.	Karolis Šablauskas
1.24	2023-11-20	Updated user groups. Removed Android app. Added information which measurements are automated in clinical setting. Updated list of known bugs.	Karolis Šablauskas
1.25	2023-12-21	Corrected grammatical mistakes with singular and plural forms in the intended user groups. Simplified contraindications table.	Justinas Balčiūnas
1.26	2024-01-29	Labels were updated.	Indra Raudone
1.27	2024-03-24	Removed automated right ventricular and right atrial segmentation related measurements. Reviewed, streamlined and updated cautions and warnings in accordance with the product.	Karolis Šablauskas Justinas Balčiūnas
1.28	2024-05-05	Added one-page report usage information	Karolis Šablauskas Simas Tatoris
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1.30	2024-06-05	Updated User groups. Updated DICOM discarding on upload.	Karolis Šablauskas
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1.32	2024-07-29	Updated the list of automated research measurements	Karolis Šablauskas

UAB Ligence

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Table of Contents

1. READ THIS FIRST

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

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

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

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

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

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

1. About the Instructions for Use (IFU)

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP IT FOR FUTURE REFERENCE

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

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

Please contact UAB Ligence or its affiliates for technical support.

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

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

2. Symbols

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

Symbol	Description
⚠️	**Warning**. Warnings highlight information to avoid a hazardous situation, which could cause death or serious injury.
⚠️	**Caution**. Cautions highlight information to avoid a hazardous situation, which could cause minor or moderate injury or equipment damage.

Symbol	Description
	Note. Notes bring your attention to information that will help you operate the product more effectively.
	Manufacturer. Indicates the name and address of the manufacturer.
	Medical device. Indicates that the product is a medical device.
	Read the IFU. Indicates the need for the user to consult the IFU
	CE Marking of Conformity.
CH REP	**Authorized representative in Switzerland**.

3. Label

English	French	German

Italian	Lithuanian	

4. Markets and foreign language support

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

5. Reporting security issues

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

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

Name, Surname: Simas Tatoris

Tel. +37069302801

Mail: s.tatoris@ligence.io

Reports should include:

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

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

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

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

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

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

6. Intended use

Intended use for US market:

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, use of suboptimal settings (e.g. gain, contrast, depth), or lack of electrocardiogram capture may lead to lower accuracy of the software.

Intended use for other markets:

Ligence Heart is a software used to detect, measure, and calculate various specifications of structure and function of the heart and great vessels by analyzing echocardiographic images and automatically providing echocardiographic report. The device is intended to be used, when the patient is not in a life-threatening state of health, time is not critical for medical decisions and no major therapeutic interventions are required.

7. General description

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

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

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

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

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

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

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

8. Marketing brochure

Ligence Heart

AI-driven application which automatically
evaluates heart ultrasound images
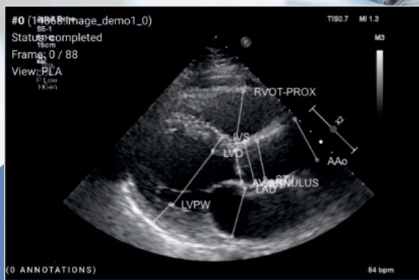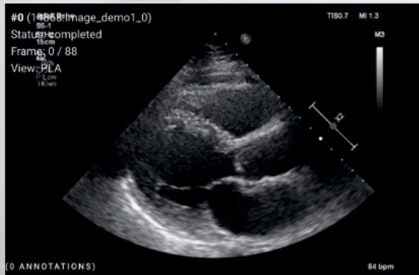
AUTOMATED

- More time can be spent on doctor-patient communication
- Provides full spectrum of measurements
- Reduced intra-rater variability

ANALYSIS

- Automatically generated report in a local language
- Images are analysed directly after they are taken
- Measurements can be adjusted by demand

IN TANDEM WITH AI

- AI independently mimics the steps performed by a specialist
- Accuracy non inferior to a cardiologist*

Created for doctors by doctors   Contact us: info@ligence.io

*Data from clinical trial for selected measurements

9. User groups

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

1. **Cardiologists** - Ligence Heart can be used by cardiologists (or medical personnel with equal competences) that are certified and eligible by local legislation to conduct regular echocardiography examinations in a clinical setting. The automatically generated measurements and the finalized report have to be approved by a cardiologist.

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

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

10.   Indications and contraindications

Indications

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

Contraindications

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

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

11. Principles of operation of the device

Manual functionalities

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

Automatic functionalities

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

12. Explanation of any novel features

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

13. Description of all configurations/variants of the product

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

14. General description of key functional elements

Functional elements scheme.
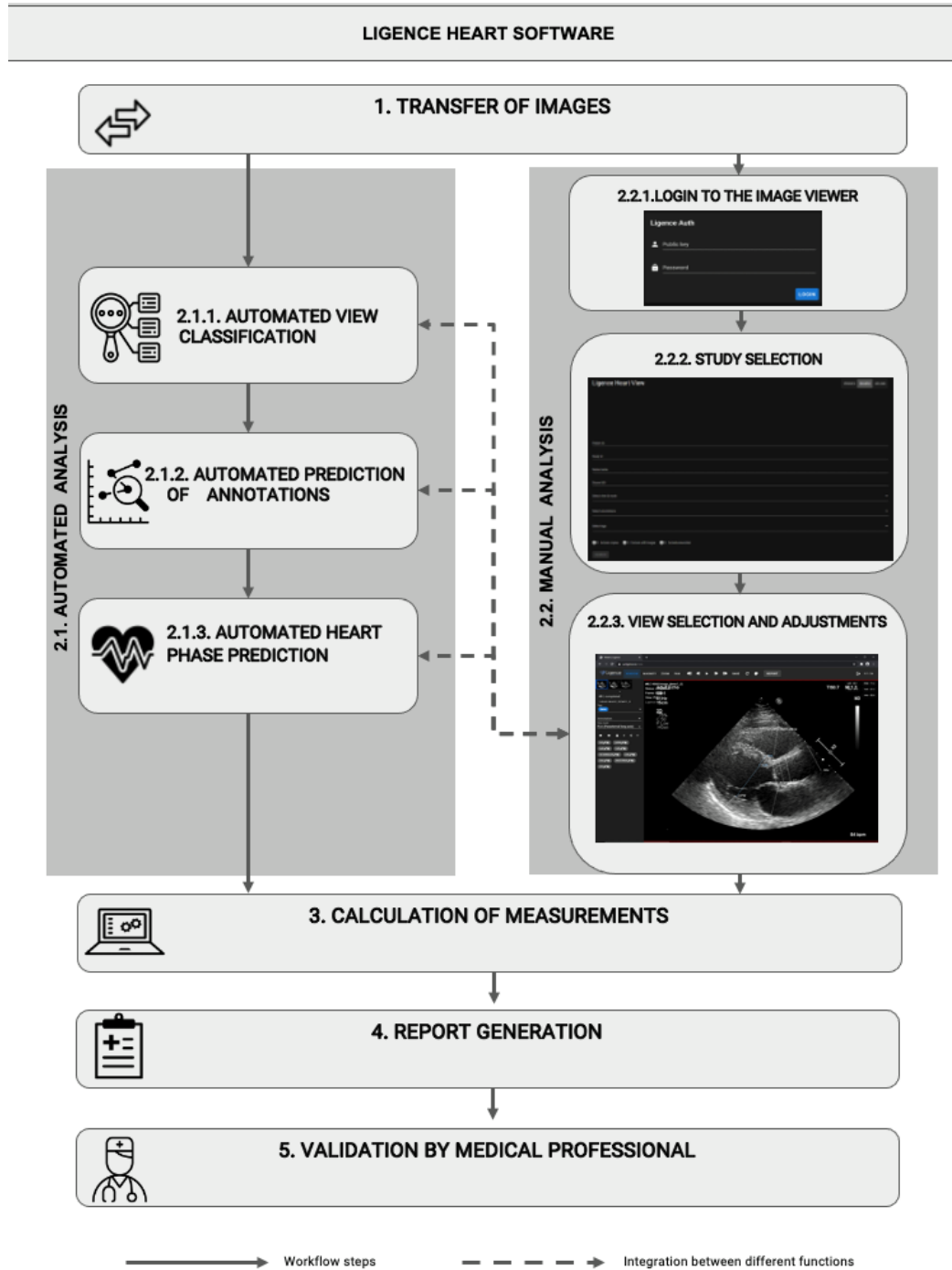
Explanation of the functional elements

Key function	Description
1. Transfer of echocardiography images	Personal data is removed from echocardiography images (if needed) and the images are transferred from ultrasound device, ultrasound application, PACS or other data source (storage).

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

15.   Benefits of using Ligence Heart

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

16.   Clinical Benefits

Performance of manual functionalities:

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

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

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

17.   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.

18.   Customer Service

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

Contact details:

E-Mail: support@ligence.io

Support Hotline: +37064550126

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

2. SAFETY

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

⚠ **CAUTION**

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

⚠ **CAUTION**

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

1. Summary of Clinical Evaluation Report

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

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

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

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

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

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

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

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

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

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

2. Residual Risks

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

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

3. Personal Data Security Breach

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

UAB Ligence Data Protection Officer

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

Name, Surname: Simas Tatoris

Tel. +37069302801

Mail: dpo@ligence.io

4. Serious Incidents Reporting

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

5. Data Handling

Data formats which can be read by this product include:

    a)   DICOM storage classes:

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

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

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

CAUTION

Before saving, editing, or reviewing the data of a patient, ensure that its contents correspond to the patient's name. This provides additional assurance that the stored data correspond to the correct patient. Not obviously incorrect behavior could lead to conflicting information.

CAUTION

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

CAUTION

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

NOTE

The quality of any exported object (echo exam) highly depends on the settings performed to the exporting file formats (e.g. compression of images) and information can be lost during this process. The user remains responsible for determining if the information contained in an exported object can be used for making diagnostic decisions.

6. Installation, Maintenance

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

CAUTION

Only persons according to the Intended User Group may perform installation, setup and upgrade.

Service and any configuration of this product shall be performed only by UAB Ligence or your local representative.

CAUTION

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

NOTE

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

7. 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

Manual functionalities have been validated and verified in the following modes:

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

8. 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 company's security policy. Company's security policy should ensure, that work network and user's workplace is secure – servers and workplaces have on time security patches and updates, required antivirus software, firewalls and other protection means.

NOTE

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

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

NOTE

For users who share the computer and user's account. Ligence Heart is designed with "zero footprint" concept, meaning that no patient data is left on a customer's device: after the end user logs out from Ligence Heart, its cache does not contain any server responses with patient data. However, there are known browser's security bug's that allow 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.

9. List of known bugs

#	Name	Description	How was it discovered?	Evaluation of the impact on safety and effectiveness	Outcome of the evaluation	The rationale for not fixing the bug
1	Image cache in browser	For some browsers cached images are not properly removed and this may cause "out of memory" errors.	Research and development team member	Low. The bug is resolved when the browser is reloaded. No impact on the software's safety and no significant impact on its effectiveness.	Impossible to reliably reproduce.	R-10, R-11

3. REQUIREMENTS AND INSTALLATION

Detailed information is provided in the Installation Manual document.

3.1.   USER INTERFACE ELEMENTS

1. User Views

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

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

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

NOTE

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

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

1. Login View

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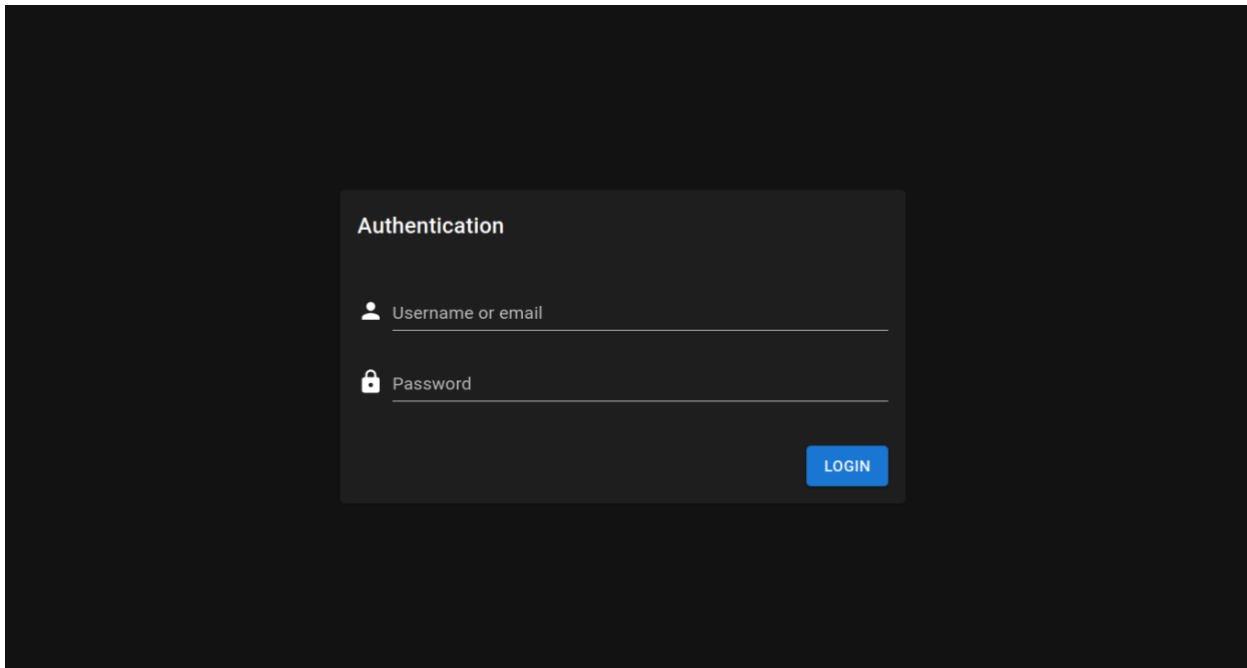
NOTE

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

2. Lobby View

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

3. Upload View

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

NOTE

Only DICOM format studies are supported.
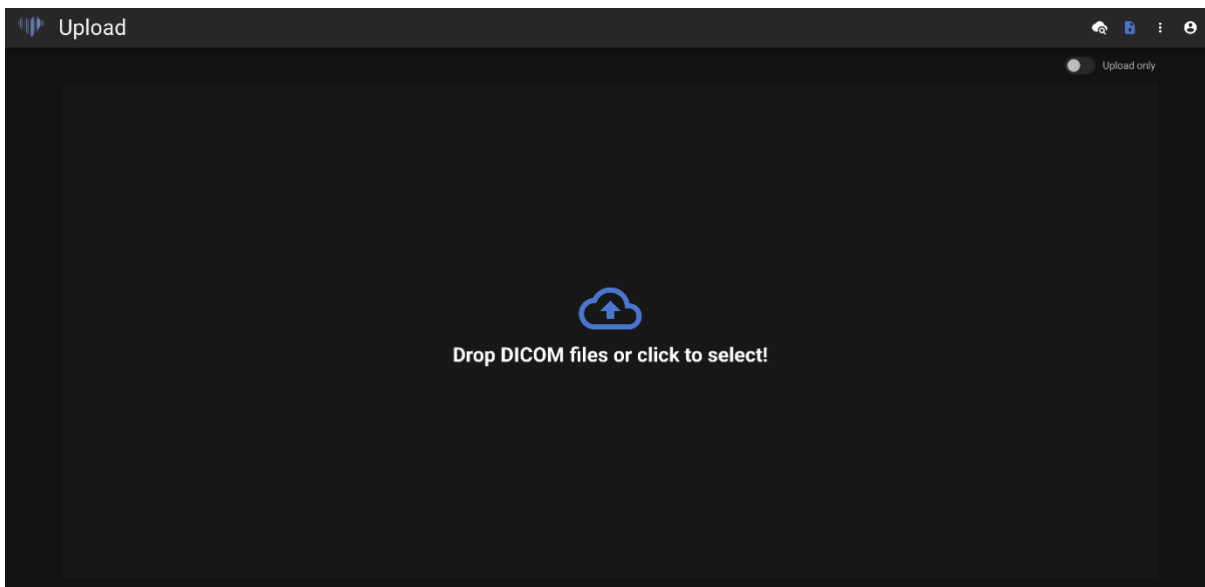
4. Workspace View

This view is dedicated for viewing and analyzing studies.
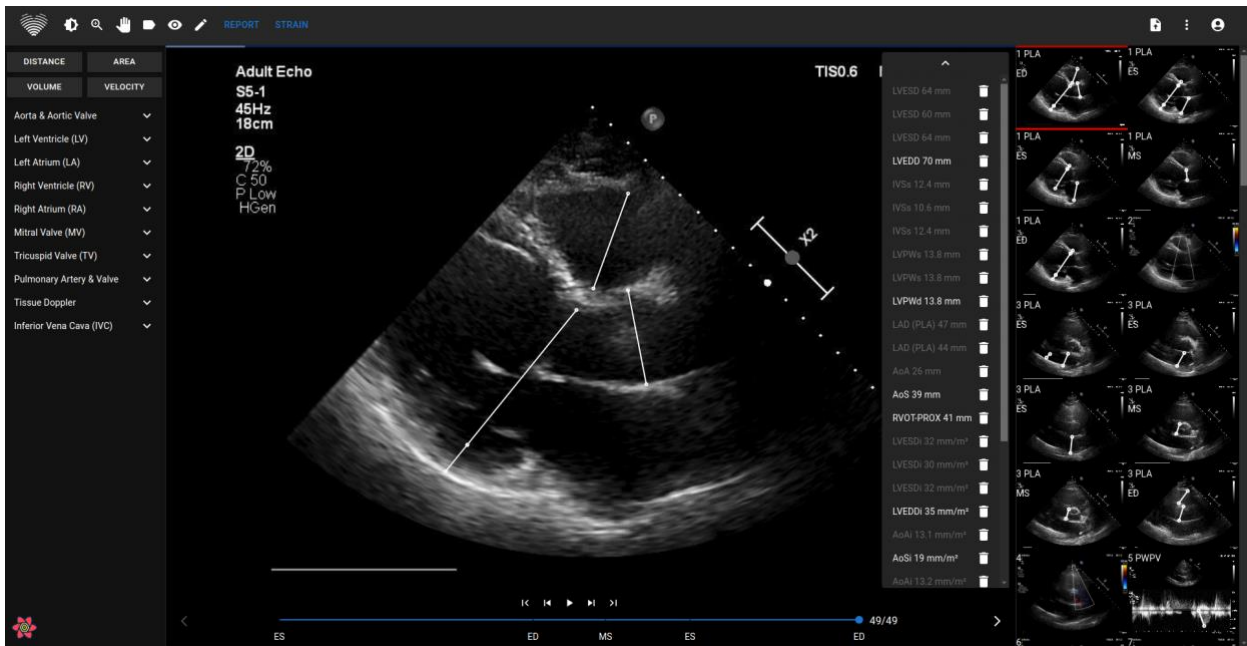
5. Strain View
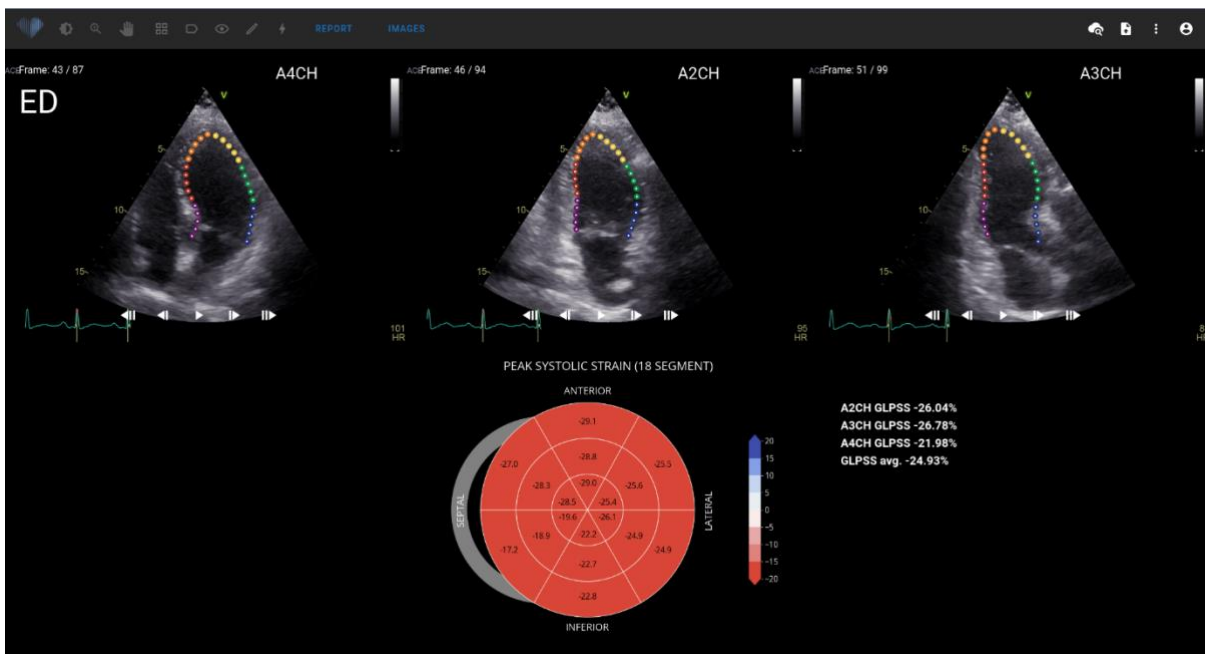
📄 NOTE

The strain functionality is investigational and is **meant to be used for research only**. By default, the strain functionality is locked and is only made available for users with additional agreements for investigational usage.

The strain view displays images that are selected to calculate Global Longitudinal Peak Systolic Strain (GLPSS). In total, three videos can be selected for this measurement (A2CH, A3CH, A4CH). It is possible to have only one or two of these three videos. The user can edit contours in strain edit mode or select other image to be used for strain measurements.

Strain view contains Bullseye 17 or 18 segment chart and strain values for each view with an average of all views. Bullseye chart represents each segment of 17 or 18 segments model, however not all segments are required and chart marks segments that were not evaluated in a gray color.

6. Report view elements

The Report View is dedicated for making two-dimensional transthoracic echocardiography reports. This view allows you to compare your measurements against normal values, review source views from which the measurements were taken and make quick edits to any annotations made. The report is organized by different functional and anatomical domains of the heart. Each of the domains contains a summary and can expanded to visualize measurements belonging to that domain. Valve stenosis and regurgitation parameters are shown in separate tables in the report view. Values for measurements can be entered directly by the user or calculated based on manual and automated analysis.

Example of Report view is shown in the figure below:

Patient Characteristics

The figure below 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 kilograms.
- Height - patient's height in centimeters.
- 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 - text field where the type of heart rhythm (e.g. sinus) can be entered.
- Pressure - systolic / diastolic pressure in mmHg.

Mosteller formula for BSA:

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

Summary Box

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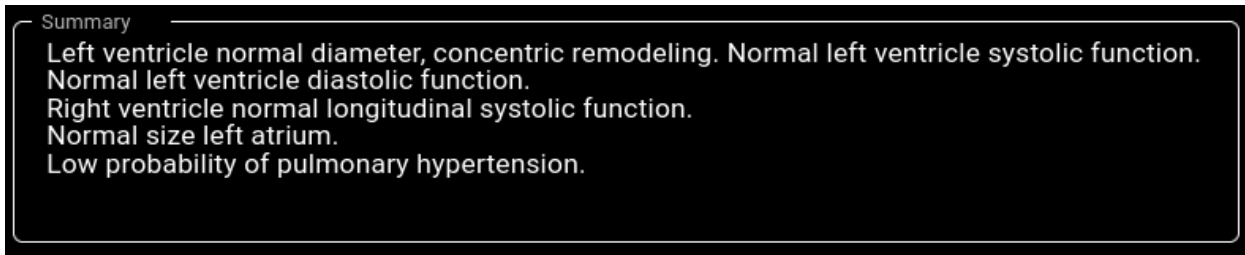
Summary Modes

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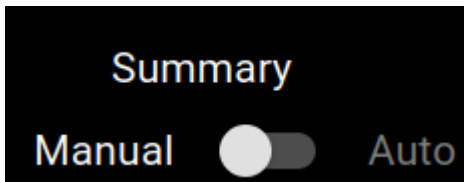
Manual Summary Mode

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

Automatic Summary Mode

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

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

Measurement fields

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

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

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

Illustrations

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

Clicking on "QUICK EDIT" allows adjusting the selected measurement.

Clicking "EDIT IN IMAGE VIEW" redirects to the specific image in workspace view.
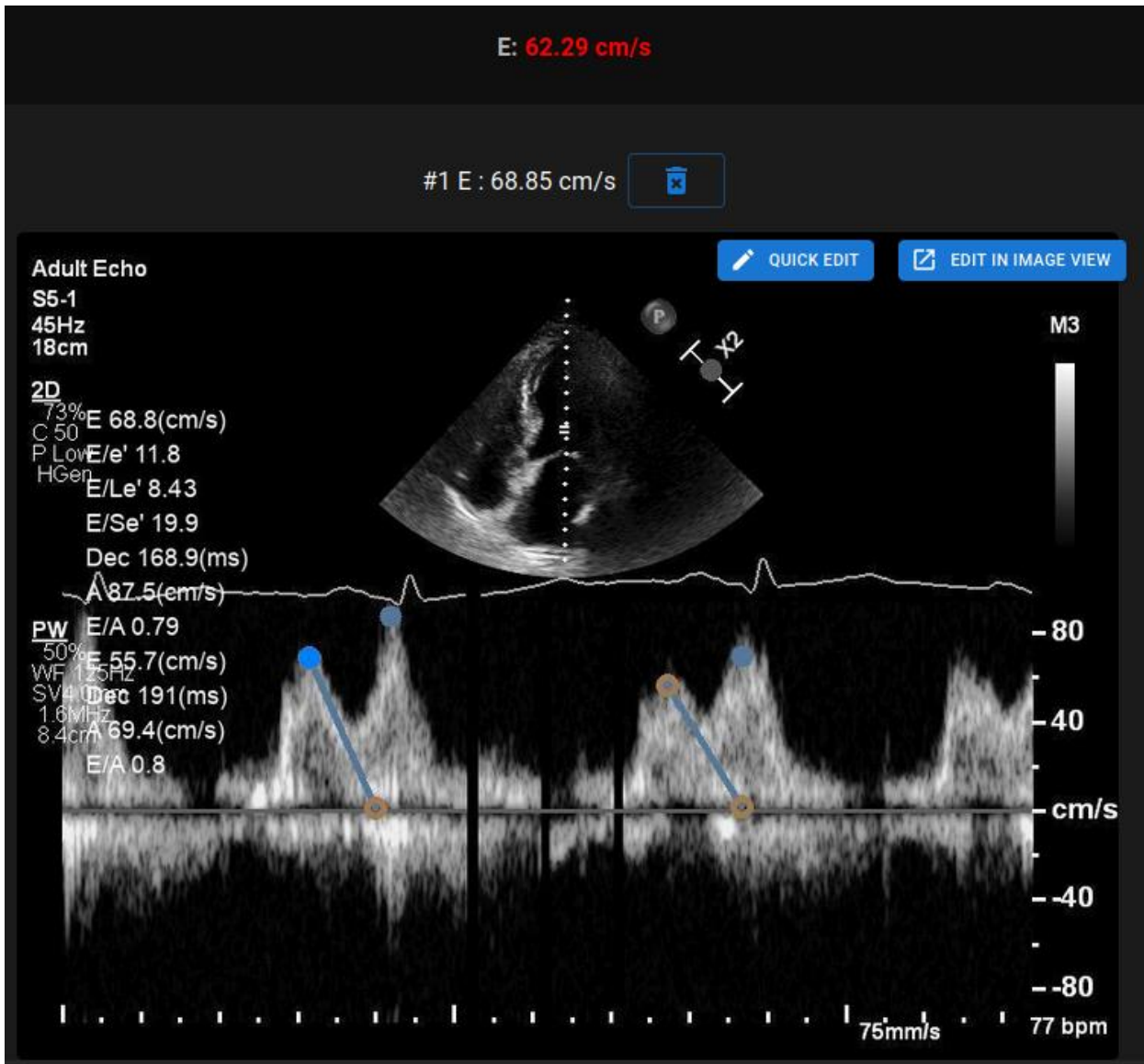
Normal values were chosen to accord with the guidelines from European Association of Cardiovascular Imaging (EACVI). Please consult the publication for more information:

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

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

7. Workspace view elements

This section presents a general overview of workspace view elements.
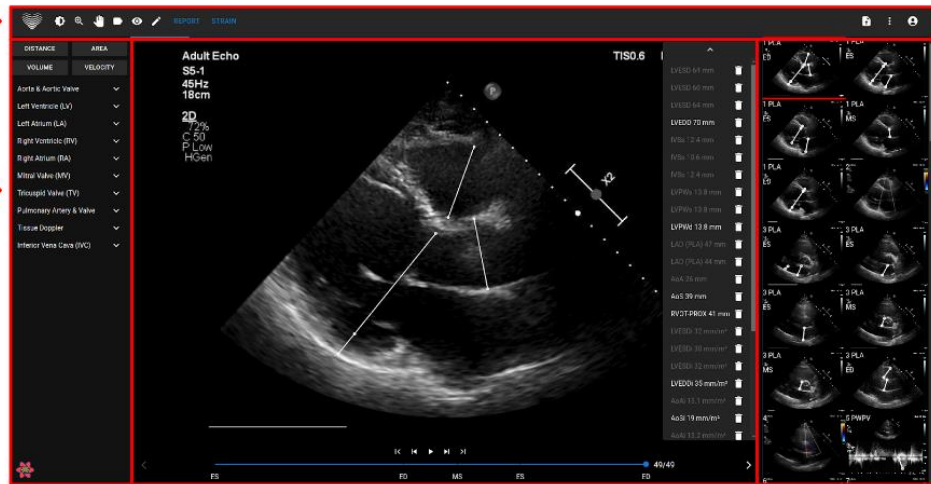
Navigation Bar

The Navigation bar can be seen throughout all the Views. It provides easy access to the most often used functions on the respective view. Navigation bar buttons and functions vary according to the view the user is in.

Left Sidebar

The sidebar could be further subdivided into image views area at the top and tools area below.

The thumbnails area displays all objects related to the selected study. Each DICOM object is represented by a dedicated image preview.

The tools area represents the specific area that contains all detailed controls and features useful for a complete analysis on the selected study.

Workspace

The workspace area displays images of the selected study (depending on the layout organization) within tiles. In case the image is multi-frame, the play of the clip will start automatically.

The filling of the particular tiles within the diagnostic area takes place in a left to right and top to bottom order. Click inside a tile to tag it as your active dataset. Two colored corners indicate the tile as the active one.

Right Sidebar

The right sidebar shows image views of a particular study.

4. WORKING WITH LIGENCE HEART - DESKTOP CLIENT

1. How to acquire images

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

Please consult the publication for more information.

CAUTION

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

2. Logging on

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

NOTE

Be aware that Ligence Heart enforces the following password policy:

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

The following steps should be performed when logging on:

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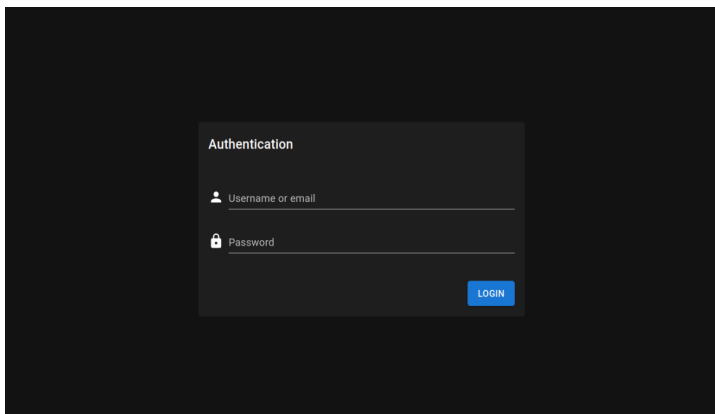
3. Settings Menu

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

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

The drop-down menu dialogue contains the following items:

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

4. Account Menu

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

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

The drop-down menu dialogue contains the following items:

- Change password
- Logout

5. Upload the study

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

How to upload a study?

To upload a study simply drag and drop your DICOM format file or press on the blue icon and upload it from your computer.
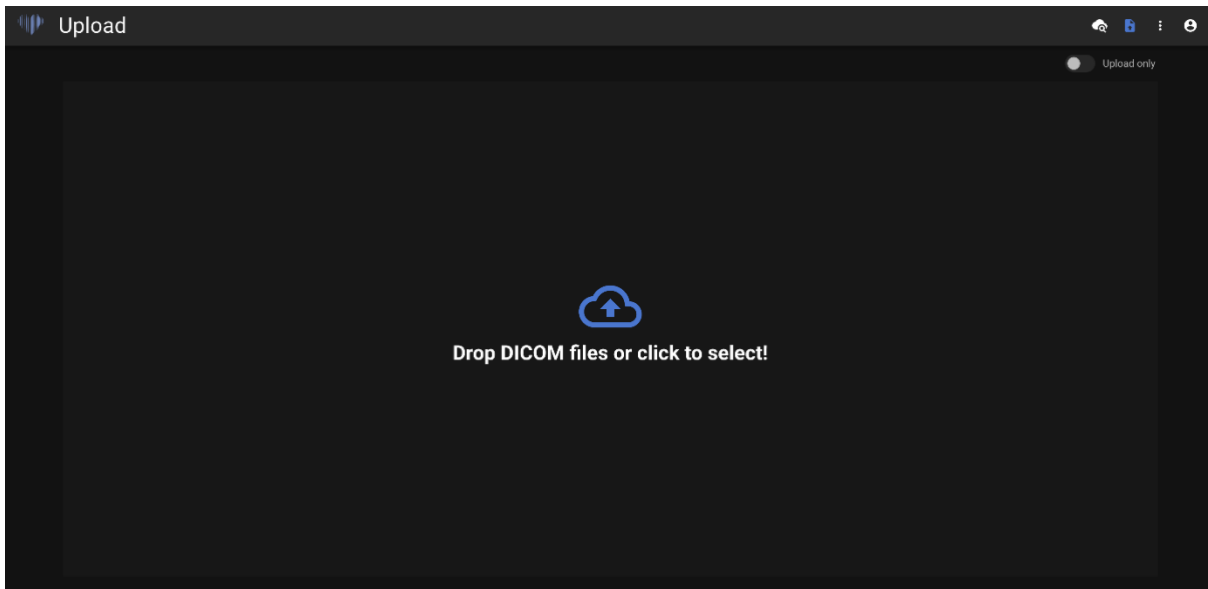
The upload may take several moments and you should see a screen like the one below.

Limitations of upload functionality

It is allowed to upload up to 10 studies at once.
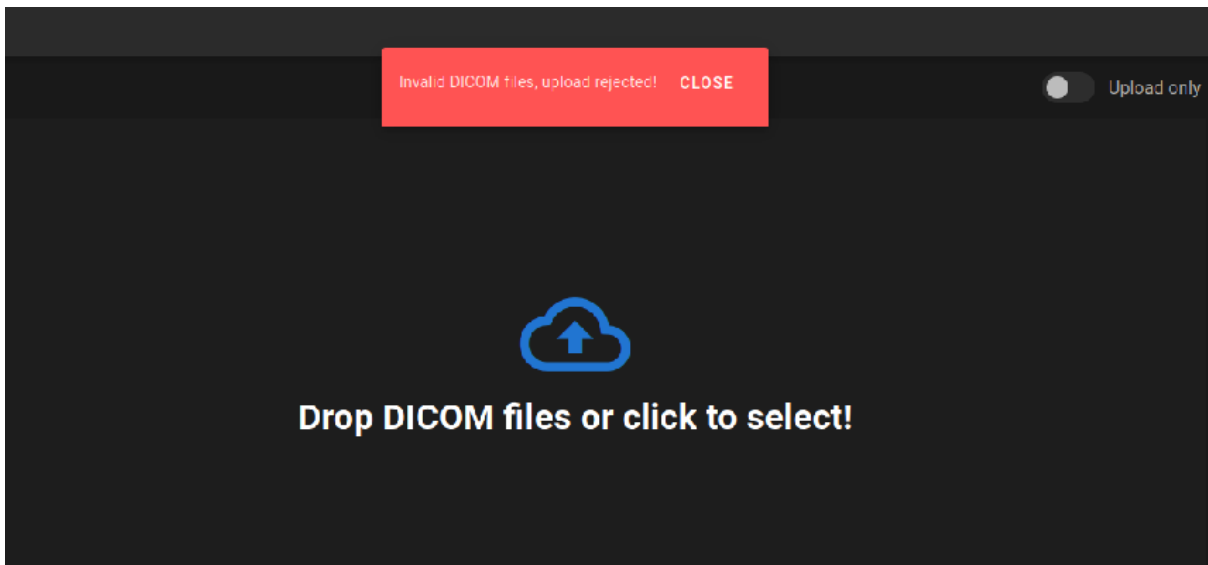
The same DICOM files of DICOM files belonging to the same echocardiographic study can only be uploaded once. Otherwise an error message will be displayed.

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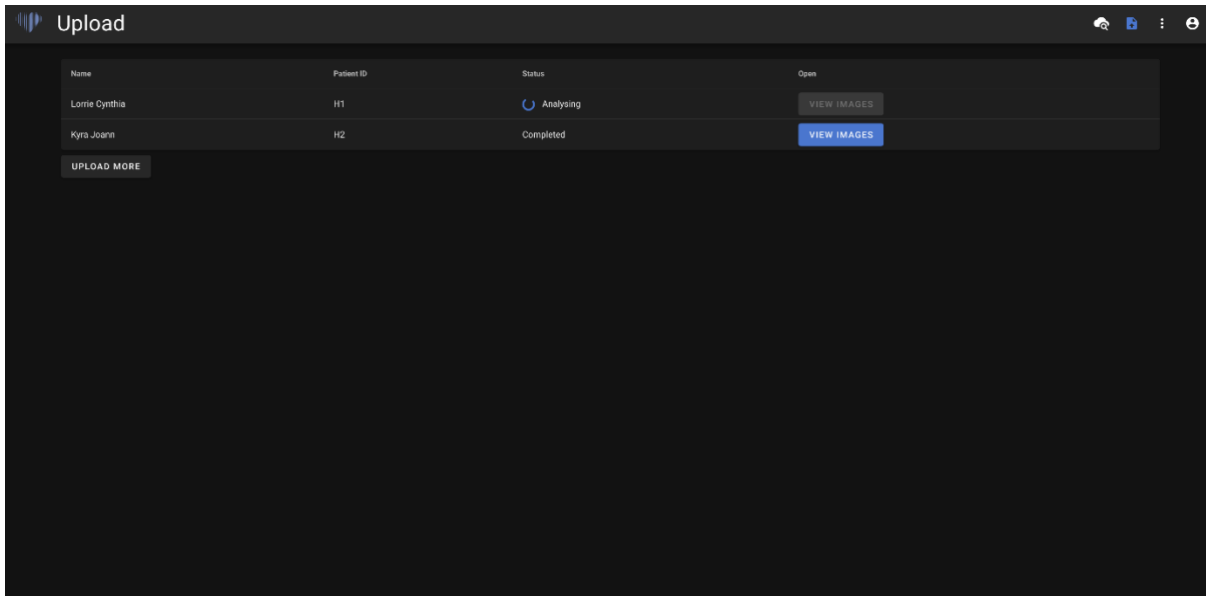
A list of studies uploaded is displayed. Once the study is analysed, you can click "view images" to review.

Invalid files uploaded

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

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

6. 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.
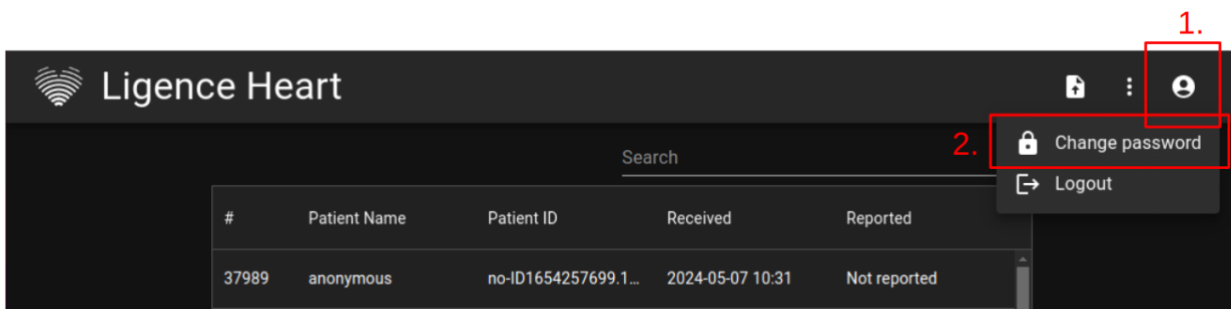
7. Logging Off

To log off from the software, simply press the person button on the top right corner of the screen and the logout button in the drop-down menu.
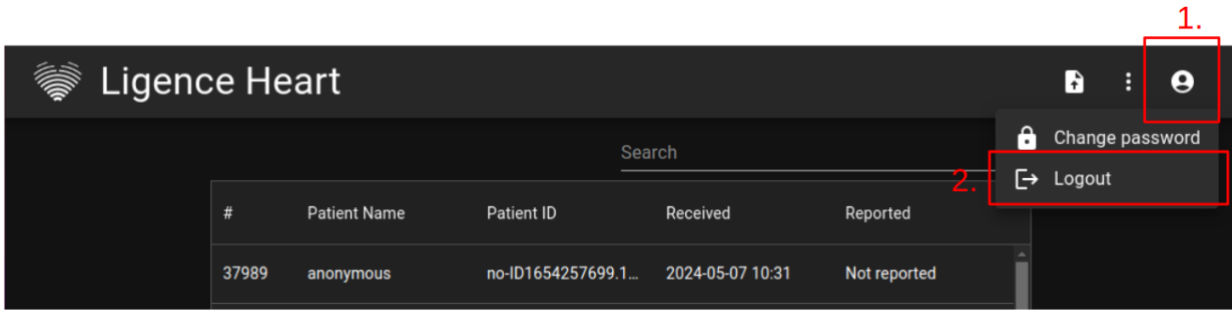
Use the Log Off option if you have finished working with the program. Logging off from the Search window, closes all the Viewer windows that were opened from the Search window and destroys the browser session data.

NOTE

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

8. Locking the software

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

9. Report an issue

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

To report an issue, press the Settings button on the top right and press the Report button in the dialogue.
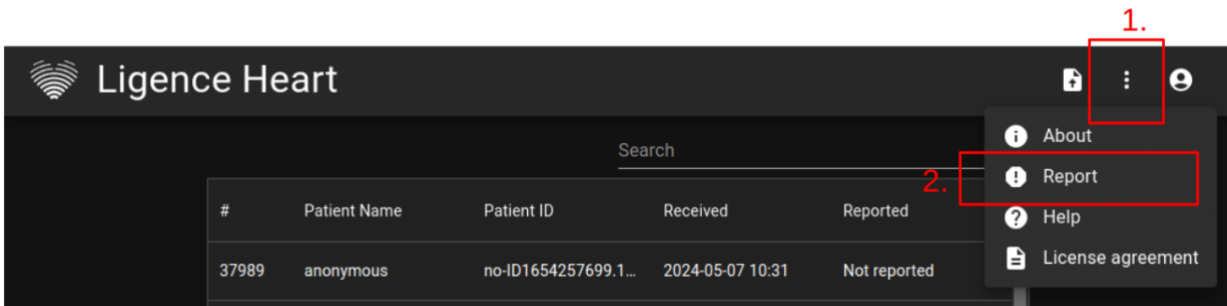
A Report window will appear suggesting possible actions.

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

NOTE

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

NOTE

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

10.   Help

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

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

You will be directed to the website where the latest version of the IFU can be found. Please consult the IFU for more information on the functions and how to operate the Ligence Heart image viewer.
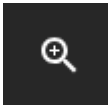
11. Navigation Bar buttons and functions
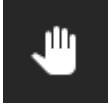
This section covers the Navigation Bar in the **Working View**. It provides easy access to the most often used functions on the screen

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

Icon	Name	Function
	Logo	Navigates to landing (lobby) view.
	Windowing	Allows the user to change the brightness and contrast of an ultrasound image. For the function to take effect the user must position the mouse cursor within boundaries of an ultrasound image, press and hold the left mouse button and move the cursor simultaneously in either direction. Moving the cursor along the x-axis causes a change in brightness, whereas moving the cursor in the y-axis causes a change in the contrast.
	Zoom in/out	Allows the user to zoom in/out the selected ultrasound image frame. When toggled, move the mouse cursor onto the frame. Press and hold the left mouse button and move the cursor in the vertical axis. Moving the cursor up zooms in the frame whereas moving it down zooms out the frame.

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

12.　　Workspace buttons and functions
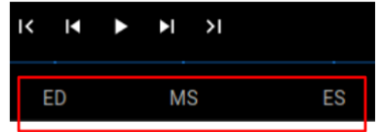
The workspace buttons are located at the bottom of the screen.

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

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

Icon	Name	Function
	Jump to the first frame	Scrolls back the image stack to the very first frame.
	Move back one frame	Moves to the previous frame.
	Play cine	Auto plays the frame stack in a continuous loop.
	Move forward one frame	Moves to the next frame.
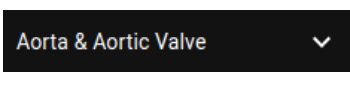
>I	Move to the last frame	Jumps to the last frame of the stack.
<	Navigate to the previous image view	Opens the previous image view.
>	Navigate to the next image view	Opens the next image view.
I< I◄ ► ►I >I ED MS ES	Heart phase select	Allows the user to move to either ES or ED frame if one is marked on that image.
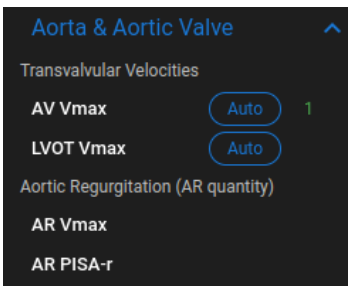
13. Left sidebar buttons and functions

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

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

Icon	Name	Function
DISTANCE	Distance measurement	Press it to manually measure distance between two points.
AREA	Area measurement	Press it to manually measure the area of the region of interest.
VOLUME	Volume measurement	Press It to manually measure the volume of the region of interest.
VELOCITY	Velocity measurement	Press it to manually measure the velocity of the region of interest.
Aorta & Aortic Valve ⌄	Anatomical structure menu buttons and drop-down dialogues	Allows you to manually choose the anatomical structure of interest and see the measurements performed for that structure.
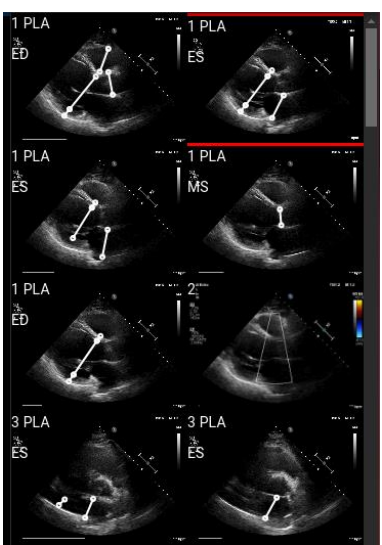
Icon	Name	Function
Aorta & Aortic Valve ∧ / Transvalvular Velocities / AV Vmax (Auto) 1 / LVOT Vmax (Auto) / Aortic Regurgitation (AR quantity) / AR Vmax / AR PISA-r	Drop-down menu dialogue of measurements listed by anatomical structures	Appears when an anatomical structure is chosen in the menu above. Shows all the supported measurements and the number of a frame a particular measurement was performed in. For automated measurements there is a "Auto" button. When activated, it makes automated measurement of selected label on currently active image frame. If it is not possible to make automated measurement, a warning message is displayed, and manual tracing is activated.

14.   Right Sidebar buttons and functions

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

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

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

15.   Study reporting

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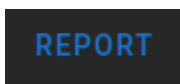
REPORT

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

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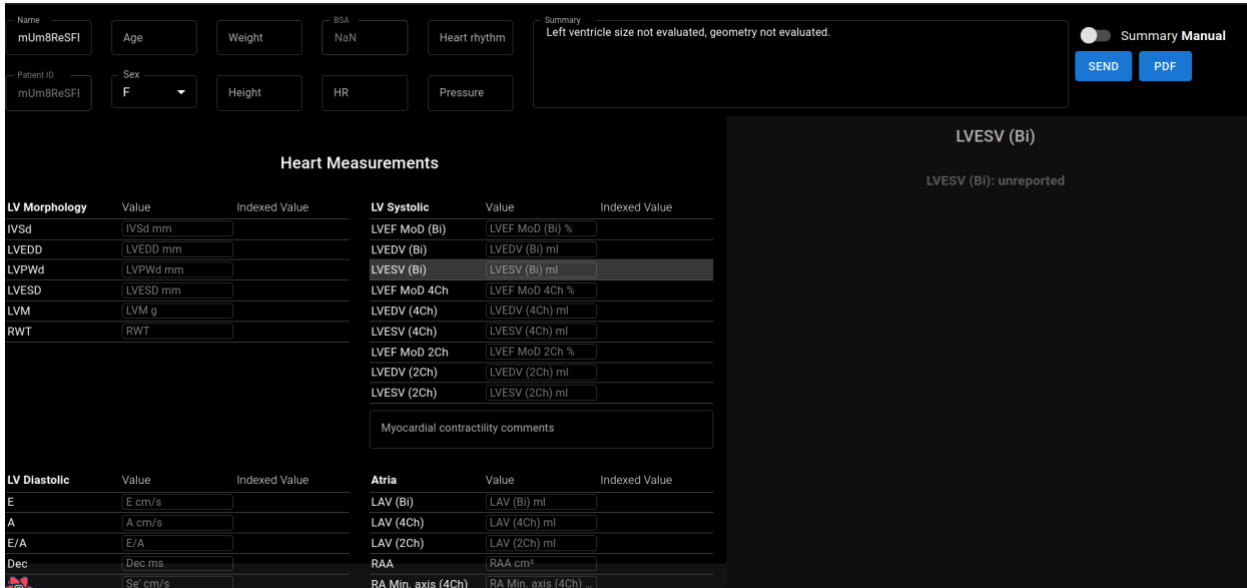
The study report is largely divided into three areas seen on the screen. At the top, you can find general information about the patient, such as name, age, sex, height, weight, summary and other high level information. At the bottom left, you will find the measurements overview, a structured grid of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

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

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

Icon	Name	Function
BSA 2.0	Body surface area (BSA)	Automatically displays body surface area when weight and height data is is available. Displays 'NaN' if BSA has not been calculated, or calculated with an error.
HR	HR	Allows you to enter or read patient heart rate.
Heart rhythm	Heart rhythm	Allows you to enter specifics about the heart rhythm.
Pressure	Pressure	Allows you to read or enter patient systolic and diastolic blood pressure in mmHg.
Summary: Left ventricle mild dilatation, eccentric hypert... Right ventricle dilatation. Right ventricle norm... Severe left atrium enlargement. Normal pulmonary artery pressure. Mean pulm... Normal diameter aortic annulus. Sinus of Val...	Summary field	Allows you to enter the summary report of your study. If left unentered, a report is generated automatically.
Summary **Auto**	Auto summary toggle	Allows you to toggle between automatically generated and manually entered summary
PDF	PDF report	Open report PDF document
SEND	Send report	Sends report to PACS storage.
AAo 30 34 average 32 26 - 34 mm Ascending Aorta Diameter		
Complete list of measurements and values		Shows the complete list of all measurements ant the measured values. Allows you to choose which value or their average (if more than one is measured) to include into the final report.

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

Icon	Name	Function
LV Morphology / Value / Indexed Value — IVSd, LVEDD, LVPWd, LVESD, LVM, RWT	Anatomically grouped measurements	Allows you to review measurement values and select particular measurements for detailed analysis
LV Diastolic / Value / Indexed Value — E 36.86 cm/s	Non-indexed measurement value	Non-indexed measurement value within normal range for your review

Icon	Name	Function
E/A	Non-indexed measurement value	Non-indexed measurement value outside of normal range for your review
Atria ... LAV (Bi) 131.64 ml (avg) 65.82 ml/m²	Indexed average measurement value	Indexed measurement value that is averaged of multiple measurements for your review
RV Size and Function ... RVB mm	Measurement that has no value	Measurement that has no value, but where you can provide a value by entering it manually
Myocardial contractility comments	Free text field	Free text field for you to provide more detailed notes
Aortic Valve Stenosis Grade Not evaluated	Valve stenosis or regurgitation grade selector	Allows you to select stenosis or regurgitation grade for each valve

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

Icon	Name	Function
LVEDD ...	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
QUICK EDIT EDIT IN IMAGE VIEW	Edit measurement annotations buttons	Displayed upon hovering your mouse cursor on the measurement image. Allows you to modify the annotations corresponding to a particular measurement
	Quick edit view	Allows you to modify the annotations by dragging the lines or vertices

16. Main Interface Functions

Scroll stack

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

Making measurements

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

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

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

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

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

Draw area measurement

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

Draw volume measurement

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

Ligence Heart has pre-selected annotations for various measurements.

Grade measurements

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

Delete annotation

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

Cancel drawing

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

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

17.   About

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

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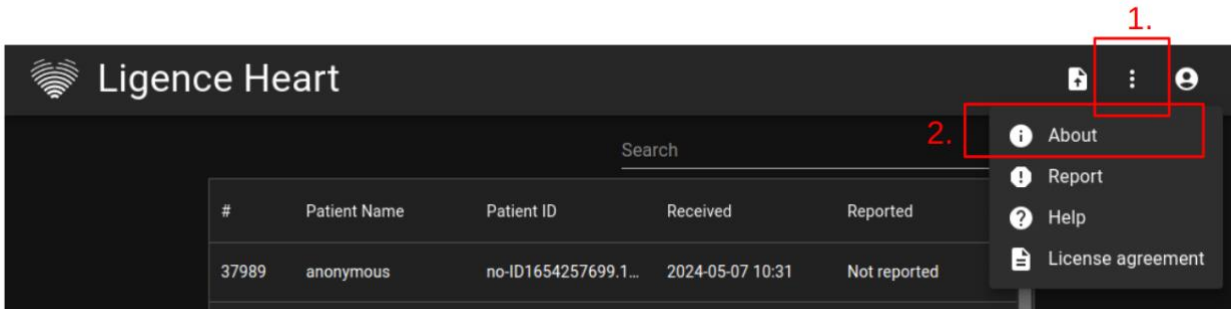
The displayed information on:

Product:

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

Manufacturer:

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

18.   End-User License Agreement

End-User License Agreement can be found in the Settings drop down menu dialogue in the Navigation bar.
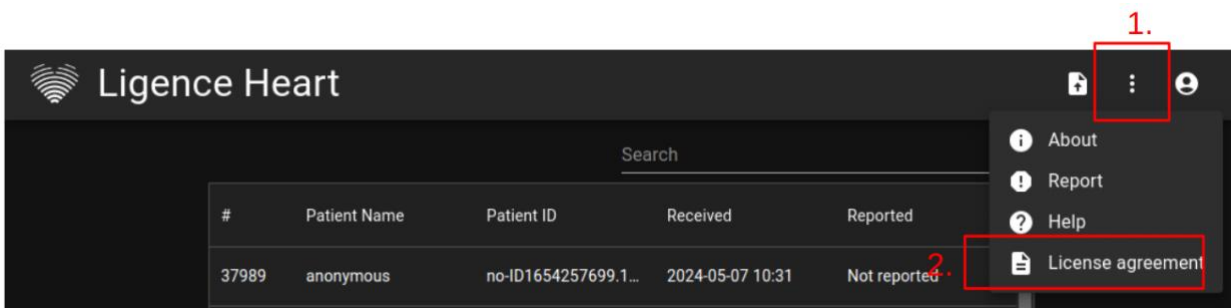
You will be directed to the https://www.Ligence.io/Ligence-heart-eula site where you can read the End-User License Agreement.

NOTE

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

19.   User Registration

NOTE

License registration is required for legal software use.

How to register with Ligence Heart?

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

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

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

5. ANNEX I

1. List of Measurements

Automated Research - measurements which are automated for research/investigational purposes.

Automated Clinical - measurements which are automated clinical purposes.

Abbreviation	Description	Automated Research	Automated Clinical
A	Transmitral A velocity	Yes	Yes
AAo	Ascending Aorta Diameter	No	No
AAoi	Ascending Aorta Diameter Index	No	No
ACT	Acceleration time	Yes	No
AMG	Aortic Mean Gradient	Yes	No
AoA	Aortic Annulus	Yes	No
AoAi	Aortic Annulus Index	Yes	No
AoAr	Aortic Arch	No	No
AoAri	Aortic Arch Index	No	No
AoS	Aortic Sinus Diameter	Yes	No

Abbreviation	Description	Automated Research	Automated Clinical
AoSi	Aortic Sinus Diameter Index	Yes	No
APG	Aortic Peak Gradient	Yes	No
AR EROA	Aortic regurgitation effective regurgitant orifice area	No	No
AR JA	Aortic regurgitation - jet area	No	No
AR PG	Aortic regurgitation - peak gradient	No	No
AR PHT	Aortic Valve Regurgitation Pressure Half-Time	No	No
AR PISA-Alias. Vel.	Aortic regurgitation proximal isovelocity surface area - aliasing velocity	No	No
AR PISA-r	Aortic regurgitation proximal isovelocity surface area - radius	No	No
AR VC	Aortic regurgitation - vena contracta	No	No
AR Vmax	Aortic regurgitation - peak velocity	No	No
Area	Area	No	No
AR-grade	Aortic Valve Regurgitation Grade	No	No
AS-grade	Aortic Valve Stenosis Grade	No	No
AV Vmax	Aortic Peak Velocity	No	No
AV VTI	Aortic Valve Maximum Velocity Time Integral	No	No
AVA	Aortic valve area	No	No
AVAi	Aortic valve area index	No	No
DAo	Descending Aorta	No	No
DAoi	Descending Aorta Index	No	No
Dec	Transmitral E velocity Deceleration time	Yes	No
Distance	Distance	No	No
E	Transmitral E velocity	Yes	Yes
E' RV	E prime right ventricle lateral wall	Yes	No
E/A	E/A ratio	Yes	No
E/e'	E/e' average ratio	Yes	No
FAC	Fractional Area Change	No	No
GLPS2A	Global Longitudinal Peak Systolic Strain 2 Chamber	Yes	No

Abbreviation	Description	Automated Research	Automated Clinical
GLPS3A	Global Longitudinal Peak Systolic Strain Chamber	Yes	No
GLPS4A	Global Longitudinal Peak Systolic Strain 4 Chamber	Yes	No
GLPS	Global Longitudinal Peak Systolic Strain	Yes	No
HV	Hepatic Vein	No	No
IVCcol (B)	Inferior vena cava collapse (BMode)	No	No
IVCcol (M)	Inferior vena cava collapse (MMode)	No	No
IVCde (B)	Inferior vena cava diameter during expiration (BMode)	No	No
IVCde (M)	Inferior vena cava diameter during expiration (MMode)	No	No
IVCdi (B)	Inferior vena cava diameter during inspiration (BMode)	No	No
IVCdi (M)	Inferior vena cava diameter during inspiration (MMode)	No	No
IVSd	Interventricular Septum (diastole)	Yes	Yes
IVSs	Interventricular Septum (systole)	Yes	No
LAA (2A)	Left Atrial Area (A2Ch)	Yes	No
LAA (4A)	Left Atrial Area (A4Ch)	Yes	No
LAAi (2A)	Left Atrial Area Index (A2Ch)	Yes	No
LAAi (4A)	Left Atrial Area Index (A4Ch)	Yes	No
LAD (PLA)	Left Atrial Diameter (PLA view)	Yes	No
LAD Maj. axis (A4)	Left Atrium Diameter Major Axis (A4Ch)	Yes	No
LAD Min. axis (A4)	Left Atrium Diameter Minor Axis (A4Ch)	Yes	No
LAEF	Left Atrial Ejection Fraction	Yes	No
LAV (2A)	Left Atrial Volume (A2Ch)	Yes	Yes
LAV (4A)	Left Atrial Volume (A4Ch)	Yes	Yes
LAV (Bi)	Left Atrial Volume (Biplane)	Yes	Yes
LAVi (2A)	Left Atrial Volume Index (A2Ch)	Yes	Yes
LAVi (4A)	Left Atrial Volume Index (A4Ch)	Yes	Yes
LAVi (Bi)	Left Atrial Volume Index (Biplane)	Yes	Yes

Abbreviation	Description	Automated Research	Automated Clinical
Le'	Lateral e' velocity	Yes	Yes
LVEDD	Left Ventricle End-Diastolic Diameter	Yes	Yes
LVEDDi	Left Ventricle End-Diastolic Diameter Index	Yes	Yes
LVEDV (4Ch)	Left Ventricle End Diastolic Volume (A4Ch)	Yes	Yes
LVEDV (2Ch)	Left Ventricle End Diastolic Volume (A2Ch)	Yes	Yes
LVEDV (Bi)	Left Ventricle End Diastolic Volume (Biplane)	Yes	Yes
LVEDVi (4Ch)	Left Ventricle End Diastolic Volume Index (A4Ch)	Yes	Yes
LVEDVi (2Ch)	Left Ventricle End Diastolic Volume Index (A2Ch)	Yes	Yes
LVEDVi (Bi)	Left Ventricle End Diastolic Volume Index (Biplane)	Yes	Yes
LVEF (2Ch)	Left Ventricular Ejection Fraction (A2Ch)	Yes	Yes
LVEF (4Ch)	Left Ventricular Ejection Fraction (A4Ch)	Yes	Yes
LVEF (Bi)	Left Ventricular Ejection Fraction (Biplane)	Yes	Yes
LVESD	Left Ventricle End-Systolic Diameter	Yes	No
LVESDi	Left Ventricle End-Systolic Diameter Index	Yes	No
LVESV (4Ch)	Left Ventricle End Systolic Volume (A4Ch)	Yes	Yes
LVESV (2Ch)	Left Ventricle End Systolic Volume (A2Ch)	Yes	Yes
LVESV (Bi)	Left Ventricle End Systolic Volume (Biplane)	Yes	Yes
LVESVi (4Ch)	Left Ventricle End Systolic Volume Index (A4Ch)	Yes	Yes
LVESVi (2Ch)	Left Ventricle End Systolic Volume Index (A2Ch)	Yes	Yes
LVESVi (Bi)	Left Ventricle End Systolic Volume Index (Biplane)	Yes	Yes
LVM	Left Ventricular Mass	Yes	No
LVMi	Left Ventricle Mass Index	Yes	No
LVOT MG	Left Ventricle Outflow Tract Mean Gradient	Yes	No
LVOT PG	Left Ventricle Outflow Tract Peak Gradient	Yes	No
LVOT Vmax	Left Ventricle Outflow Tract Peak Velocity	Yes	No
LVOT VTI	Left Ventricle Outflow Tract Velocity Time Integral	Yes	No

Abbreviation	Description	Automated Research	Automated Clinical
LVOTD	Left Ventricle Outflow Tract Diameter (no associated cycle phase)	No	No
LVPWd	Left Ventricle Posterior Wall (diastole)	Yes	Yes
LVPWs	Left Ventricle Posterior Wall (systole)	Yes	No
MR EROA	Mitral regurgitation effective regurgitant orifice area	No	No
MR JA	Mitral regurgitation - jet area	No	No
MR MG	Mitral regurgitation - mean gradient	No	No
MR PG	Mitral regurgitation - peak gradient	No	No
MV PHT	Mitral Valve Pressure Half-Time	No	No
MR PISA-Alias. Vel.	Mitral regurgitation proximal isovelocity surface area - aliasing velocity	No	No
MR PISA-r	Mitral regurgitation proximal isovelocity surface area - radius	No	No
MR VC	Mitral regurgitation - vena contracta	No	No
MR Vmax	Mitral regurgitation - peak velocity	No	No
MR VTI	Mitral regurgitation - Velocity Time Integral	No	No
MR-grade	Mitral Valve Regurgitation Grade	No	No
MS-grade	Mitral Valve Stenosis Grade	No	No
MV MG	Mitral valve - mean gradient	No	No
MV PG	Mitral valve - peak gradient	No	No
MV Vmax	Mitral valve - peak velocity	No	No
MV VTI	Mitral valve - velocity time integral	No	No
MV-ANNULUS A2CH	Mitral valve diameter 2 chamber view	No	No
MV-ANNULUS A4CH	Mitral valve annulus in apical 4 chamber view	No	No
MV-ANNULUS PLA	Mitral valve annulus in parasternal long axis	No	No
PA AD	Pulmonary Artery Annulus Diameter	No	No
PA LBD	Pulmonary Artery Left Branch Diameter	No	No
PA RBD	Pulmonary Artery Right Branch Diameter	No	No
PR JA	Pulmonary Regurgitation Jet Area	No	No
PR JA	Pulmonary regurgitation - jet area	No	No

Abbreviation	Description	Automated Research	Automated Clinical
PR MG	Pulmonary Regurgitation Mean Gradient	No	No
PR PG	Pulmonary Regurgitation Peak Gradient	No	No
PR PHT	Pulmonary Valve Regurgitation Pressure Half-Time	No	No
PR VC	Pulmonary Regurgitation Vena Contracta	No	No
PR Vmax	Pulmonary Regurgitation Peak Velocity	No	No
PR VTI	Pulmonary Regurgitation Maximum Velocity Time Integral	No	No
PR-grade	Pulmonary Artery Regurgitation Grade	No	No
PS-grade	Pulmonary Artery Stenosis Grade	No	No
PV MG	Pulmonary Valve Mean Gradient	No	No
PV PG	Pulmonary Valve Peak Gradient	No	No
PV Vmax	Pulmonary Valve Peak Velocity	No	No
PV VTI	Pulmonary Valve Maximum Velocity Time Integral	No	No
RA Major (A4)	Right Atrial Major Axis Dimension (A4Ch)	No	No
RA Major i (A4)	Right Atrial Major Axis Dimension Index (A4Ch)	No	No
RA Minor (A4)	Right Atrial Minor Axis Dimension (A4Ch)	No	No
RA Minor i (A4)	Right Atrial Minor Axis Dimension Index (A4Ch)	No	No
RA volume	Right Atrium Volume	No	No
RAA	Right Atrial Area	No	No
RAAi	Right Atrial Area Index	No	No
RAP	Mean right atrium pressure	No	No
RAVi	Right Atrium Volume Index (2D)	No	No
RV EDA	Right Ventricle End Diastolic Area	No	No
RV EDAi	Right Ventricle End Diastolic Area index	No	No
RV EDV	Right Ventricle End Diastolic Volume	No	No
RV EDVi	Right Ventricle End Diastolic Volume Index	No	No
RV ESA	Right Ventricle End Systolic Area	No	No
RV ESAi	Right Ventricle End Systolic Area index	No	No

Abbreviation	Description	Automated Research	Automated Clinical
RV ESV	Right Ventricle End Systolic Volume	No	No
RV ESVi	Right Ventricle End Systolic Volume Index	No	No
RV WT	Right Ventricular Wall Thickness	No	No
RVB	Right Ventricular Basal Diameter	No	No
RVL	Right Ventricular Length	No	No
RVM	Right Ventricular Middle Diameter	No	No
RVOT-DIST	Right Ventricular Outflow Tract Distal Diameter (PLA)	No	No
RVOT-PROX	Right Ventricular Outflow Tract Proximal Diameter (PLA)	Yes	No
RWT	Relative Wall Thickness	Yes	No
S' RV	S prime right ventricle lateral wall	Yes	No
Se'	Septal e' velocity	Yes	Yes
STJ	Sinotubular Junction	No	No
STJi	Sinotubular Junction Index	No	No
SV	Stroke Volume (Biplane)	Yes	No
SV2A	Stroke Volume (A2CH)	Yes	No
SV4A	Stroke Volume (A4CH)	Yes	No
TAPSE	Tricuspid Annular Plane Systolic Excursion	No	No
TR EROA	Tricuspid regurgitation effective regurgitant orifice area	No	No
TR JA	Tricuspid regurgitation - jet area	No	No
TR MG	Tricuspid Regurgitation mean gradient	Yes	No
TR PG	Tricuspid Regurgitation peak gradient	Yes	No
TV PHT	Tricuspic Valve Pressure Half-Time	No	No
TR PISA-Alias. Vel.	Tricuspid regurgitation proximal isovelocity surface area - aliasing velocity	No	No
TR PISA-r	Tricuspid regurgitation proximal isovelocity surface area - radius	No	No
TR VC	Tricuspid regurgitation - vena contracta	No	No
TR Vmax	Peak Tricuspid Regurgitation Velocity	Yes	Yes
TR VTI	Tricuspid regurgitation Velocity Time Integral	Yes	No

Abbreviation	Description	Automated Research	Automated Clinical
TR-grade	Tricuspid Valve Regurgitation Grade	No	No
TS-grade	Tricuspid Valve Stenosis Grade	No	No
TV MG	Tricuspid Valve Mean Gradient	No	No
TV PG	Tricuspid Valve Peak Gradient	Yes	No
TV Vmax	Tricuspid Valve Peak Velocity	Yes	No
TV VTI	Tricuspid Valve Velocity Time Integral	No	No
TV-ANNULUS	Tricuspid valve annulus	No	No
Velocity	Velocity	No	No
Volume	Volume	No	No
MVA_PLANIM	Mitral Valve Planimetry Area	No	No
AVA_PLANIM	Aortic Valve Planimetry Area	No	No
TVA_PLANIM	Tricuspid Valve Planimetry Area	No	No
PVA_PLANIM	Pulmonary Valve Planimetry Area	No	No
LVOT_PLNM	Left Ventricular Outflow Tract Planimetry Area	No	No
MVA_DOP	Mitral Valve Area (Doppler)	No	No
TVA_DOP	Tricuspid Valve Area (Doppler)	No	No
PVA_DOP	Pulmonary Valve Area (Doppler)	No	No
LVOT_DOP	Left Ventricular Outflow Tract Area (Doppler)	No	No
MVA_DOPi	Mitral Valve Area (Doppler) index	No	No
TVA_DOPi	Tricuspid Valve Area (Doppler) index	No	No
PVA_DOPi	Pulmonary Valve Area (Doppler) index	No	No
LVOT_DOPi	Left Ventricular Outflow Tract Area (Doppler) index	No	No
MV_ACT	Mitral Valve Acceleration Time	No	No
TV_ACT	Tricuspid Valve Acceleration Time	No	No
AV_ACT	Aortic Valve Acceleration Time	No	No
LVOT_ACT	Left Ventricular Outflow Tract Acceleration Time	No	No
MR_VOL	Mitral Regurgitation Volume	No	No
TR_VOL	Tricuspid Regurgitation Volume	No	No

Abbreviation	Description	Automated Research	Automated Clinical
PR_VOL	Pulmonary Regurgitation Volume	No	No
AR_VOL	Aortic Regurgitation Volume	No	No
PR_PISA_R	Pulmonary regurgitation proximal isovelocity surface area - radius	No	No
PR_EROA	Pulmonary regurgitation effective regurgitant orifice area	No	No
LVB	Left Ventricular Basal Diameter	Yes	No
RVB/LVB	RV / LV basal diameter ratio	No	No
EI	Eccentricity index	No	No
EI D1	LV short-axis diameter perpendicular to the septum	No	No
EI D2	LV short-axis diameter parallel to the septum	No	No