





Ligence Heart

INSTRUCTIONS FOR USE

English

CE 0197

	Name	Role	Date	Signature
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1. READ THIS FIRST

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

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

Ligence Heart does not replace medical professionals and could be used only as an additional support tool. No special facilities or special training (for medical specialists who are certified to perform echocardiographic examination) are required for the use of Ligence Heart.

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.

3. 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.

4. 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 CPO who is responsible for data protection (contacts are public and available at <https://www.ligence.io/>).

Name, Surname: Antanas Kiziela

Tel. +37062760039

Mail: a.kiziela@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.

5. Intended use

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

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

6. General description

In order 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 in order to produce the echocardiographic images of the heart. The images are then saved and stored digitally in DICOM format.
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) remains the same as a regular echocardiography exam in accordance with standard clinical setting and is in no way affected using Ligence Heart software. Ligence Heart software is used to perform the entirety of the second step. To fulfill its intended purpose, the software Ligence Heart is used as a postprocessing tool that is accessible via the sonographer's/physician's workstation in the office or any other dedicated area for patient's clinical data analysis.


Ligence Heart is used as a postprocessing tool to perform the second step (data analysis), during which the following processes take place:


1. Echocardiography images are loaded to the Ligence Heart software via integration to PACS or manual study DICOM files upload.
2. The analysis phase:
 - a) **Manual functionalities** - user of the software manually identifies the relevant structures or features, annotates them, measurement results are displayed in the viewer.
 - b) **Automatic functionalities** - the software has algorithms implemented, that allow automatic identification, annotation, and calculation of a number of relevant heart parameters. These algorithms are based on deep learning technology. The results provided by these algorithms must be reviewed and approved by a clinician.
3. A report is generated. The results of the whole study analysis process are summarized in a report. The report document provides a table of measurements performed, a summary template, an illustrations list of measurements made.

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 physician approved report of echocardiogram analysis serves only as a decision support tool. The conclusion of diagnosis always must be taken by the physician.

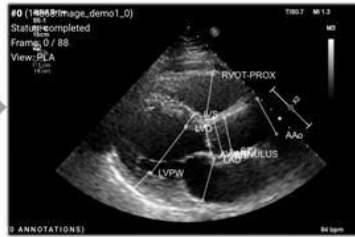
A complete list of Manual functionalities and Automatic functionalities can be found in the IFU and System requirement specification.

7. Marketing brochure





→



Cardiovascular disease (CVD)

- CVDs account for **37%** of disease related deaths globally;
- Over **6M new cases** in EU alone;
- Cost over **210B EUR** for EU economy alone;
- World Health Organisation (WHO) predicts obesity pandemic which is a **major risk factor for CVD**.

Ligence Heart

- Deep learning solution for **cardiac ultrasound analysis**;
- Mimics the steps performed by a cardiologist;
- Automated** morphometric measurements;
- PLA, A4CH, A2CH and even more;
- Easy integration** to PACS;

Echocardiography

- Transthoracic echocardiography (2D TTE) is the **first choice method** for CVD diagnosis;
- Highly **subjective** (variability up to 30%);
- Up to 85% of examination is **manual and repetitive work**.

Value proposition*

- Accuracy up to 94%** (non-inferior to a cardiologist);
- Reduced intra-rater variability**;
- Up to 4x faster study evaluation time for certain measurements****;
- Retrospective analysis** of large cohorts;
- Standardised reporting;

How it works

ANALYSIS



Cloud server or Local server


↑ ↓

→
 →
 →

Ultrasound machine: examination by an ultrasound technician or a cardiologist
 PACS
 Cardiology work station
 Validation by a cardiologist

*Data from clinical trial
**Data from clinical trial for selected measurements

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



8. User groups

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

1. **Sonographer/physician.** Ligence Heart can be used by medical professionals 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 medical professional who is certified and eligible by local legislation to conduct echocardiography examinations and formulate a report.
2. **Administrator.** Ligence Heart can be used by client’s system administrators that are not medical practitioners for the purpose of system administration, but not for clinical purposes.

9. 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 with sinus rhythm.

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 automatic functionalities
Isolated congenital aortic valve disease and bicuspid aortic disease
Isolated congenital mitral valve disease (except parachute valve, cleft leaflet)
Mild isolated pulmonary stenosis (infundibular, valvular, supra-ventricular)
Isolated ventricular septal defect, or patent ductus arteriosus
Sinus venosus defect, ventricular septal defect, or patent ductus arteriosus without residue or sequelae, such as chamber enlargement, ventricular dysfunction, or elevated pulmonary artery pressure.
Anomalous pulmonary venous connection (partial or total)
Anomalous coronary artery arising from the pulmonary artery
Anomalous coronary artery arising from the opposite sinus
Congenital aortic stenosis - subvalvular or supra-ventricular
Atrioventricular septal defect, partial or complete, including primum atrial septal defect (excluding pulmonary vascular disease)
Coarctation of the aorta

Contraindications for automatic functionalities
Double chambered right ventricle
Ebstein anomaly
Marfan syndrome and related heritable thoracic aortic disease, Turner Syndrome, congenital connective tissue disorders with heart or major vessel involvement
Patent ductus arteriosus, moderate or large unrepaired (excluding pulmonary vascular disease)
Peripheral pulmonary stenosis
Pulmonary stenosis (infundibular, valvular, supra-valvular), moderate or severe
Sinus of Valsalva aneurysm/fistula
Sinus venosus defect
Tetralogy of Fallot repaired
Transposition of the great arteries after arterial switch operation
Ventricular septal defect with associated abnormalities (excluding pulmonary vascular disease) and/or moderate or greater shunt.
Any Congenital Heart Disease (repaired or unrepaired) associated with pulmonary vascular disease (including Eisenmenger syndrome)
Any cyanotic Congenital Heart Disease (unoperated or palliated)
Double-outlet ventricle
Fontan circulation
Interrupted aortic arch
Pulmonary atresia (all forms)
Transposition of the great arteries (except for patients with arterial switch operation)
Univentricular heart (including double inlet left/right ventricle, tricuspid/mitral atresia, hypoplastic left heart syndrome, any other anatomic abnormality with a functionally single ventricle)
Truncus arteriosus
Other complex abnormalities of atrioventricular and ventriculoarterial connection (i.e. crisscross heart, heterotaxy syndromes, ventricular inversion).

Contraindications for automatic functionalities
Congenital tricuspid and pulmonary valve disease
Situs inversus or dextrocardia
Heart tumors
Prosthetic valves, post-operative heart valves, cardiac geometry changing cardiothoracic surgeries
Implanted dual-chamber or ventricular pacemaker
Bi-ventricular resynchronizator
Cardioverter-defibrillator
Left ventricle assisting device, Right ventricular assisting device
Heart arrhythmias

10. Principles of operation of the device

Manual functionalities

The device visualizes echocardiography imaging data in a web browser 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).

To summarize, the input to the device is an echocardiography DICOM image. After the image is analyzed using automated and/or manual functionalities, a finalized report is generated, which is the output of the software.

11. Explanation of any novel features

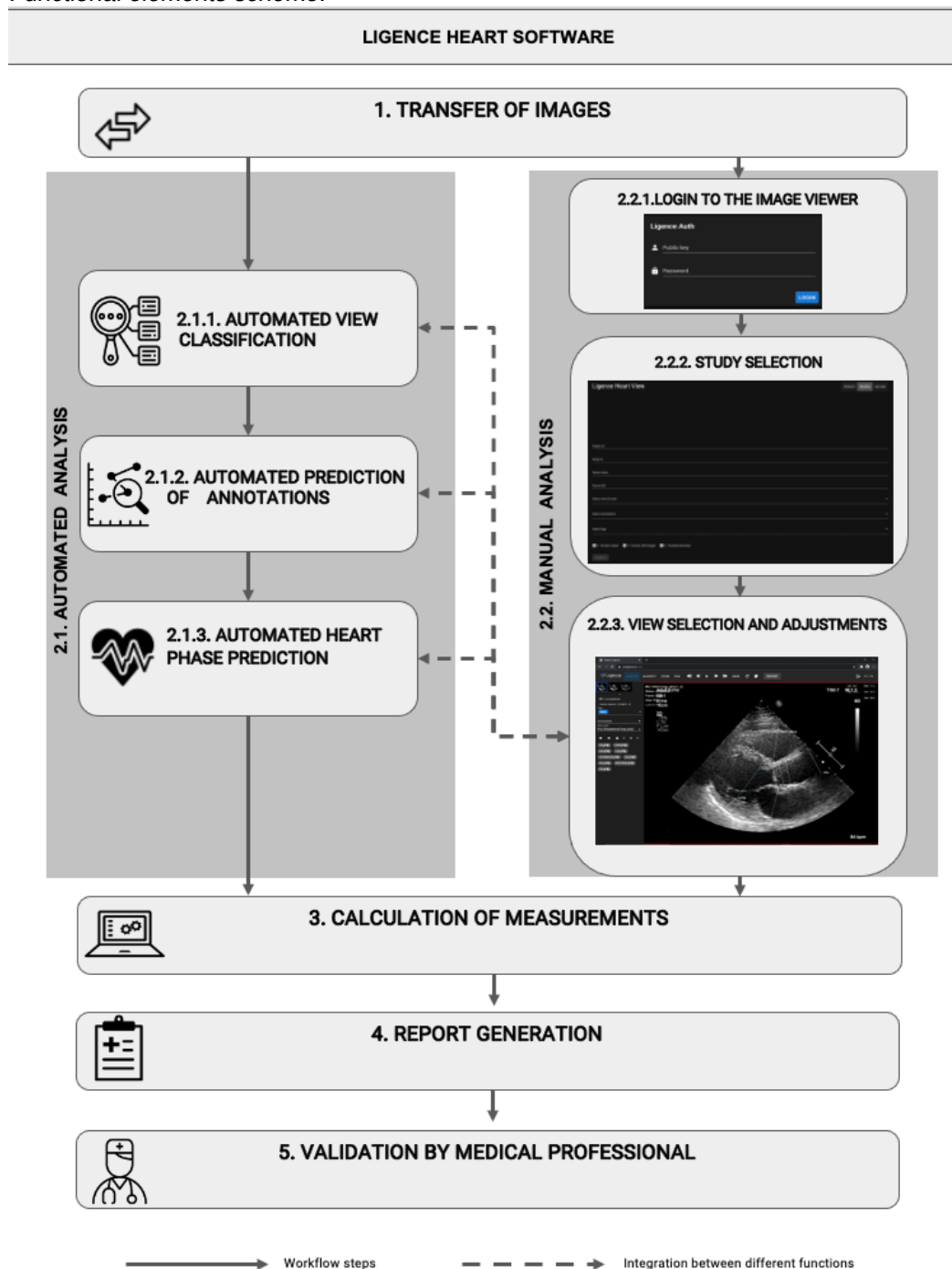
Ligence Heart offers novel functionality that allows automatic analysis of a number of heart structure and function parameters. Therefore, the parameters that are analyzed themselves are not novel, but the automation of some of these measurements is novel (none of the manual functionalities are novel). 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.

12. 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.

13. General description of key functional elements

Functional elements scheme.



Explanation of the functional elements

Key function	Description
1. <i>Transfer of echocardiography images</i>	echocardiography images have personal data removed and transferred from hospital PACS to Ligence Heart software
2. <i>Analysis</i>	echocardiography images analysis step using automated or manual analysis
<i>2.1. Automated analysis</i>	
<i>2.1.1. Automated classification</i> <i>view</i>	An Automated system is trained to determine view mode of echocardiography image. This step is needed for further analysis of images
<i>2.1.2. Automated prediction of annotations</i>	Automated system is trained to predict annotations that are used to measure heart anatomy based on the view mode of echocardiography DICOM image
<i>2.1.3. Automated heart phase prediction</i>	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
<i>2.2. Manual analysis</i>	
<i>2.2.1. Login to the image viewer</i>	Authentication/authorization to the software step needed to be able to access studies
<i>2.2.2. Study selection</i>	Selection of accessible study by filtering/searching step
<i>2.2.3. View selection and adjustments</i>	Study analysis step, physician sets the view mode of echocardiography image, performs annotations, or adjusts measurements already made by automated analysis
3. <i>Calculation of measurements</i>	Calculation of measurements based on the annotations on echocardiography image performed by the combination of manual and automatic functions
4. <i>Report generation</i>	Study analysis report, which consists of all annotations, measurements made along with automated suggested diagnosis text, is generated for review and approval of physician
5. <i>Validation by medical professional</i>	Medical professional validates all annotations and measurements made and adjusts the annotations if needed, updating the report respectively

14. 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.

15. Clinical Benefits

Performance of manual functionalities:

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

Performance of automated functionalities:

- Ligence Heart performs automated measurements with non-inferior accuracy compared to a cardiologist;
- Automatic functionalities perform echocardiographic measurements with lower intra-rater variability than a cardiologist;
- On average automatic functionalities perform the evaluation of echocardiographic images faster than a cardiologist.

16. 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.

17. 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

WARNING




Do not use this software product for any application until you have read, understood and know all the safety information, and safety procedures contained in this SAFETY chapter. Use of this software product without a proper awareness of how to use it safely could lead to fatal or serious injury, clinical misdiagnosis, and/or loss/damage of patient-related data.

CAUTION




Only persons described in the "Intended User Group" shall use the product.

CAUTION



According to common medical sense and the principles of differential diagnosis any diagnostic finding derived from usage of this product must be confirmed by additional diagnostic investigations prior diagnosis performed by a physician. Not obviously incorrect behavior could lead to conflicting information.

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.

18. Residual Risks

No residual risks were identified.

19. 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: Antanas Kiziela

Tel. +370 627 60 039

Mail: dpo@ligence.io

20. 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.

21. Data Handling

Data formats which can be read by this product include the following DICOM 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

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



WARNING

Before saving, editing, or reviewing the data of a patient, ensure that its contents correspond to the patient 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 DICOM image information in Ligence Heart software comes from your DICOM producing device such as 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 DICOM images.



NOTE

The quality of any exported object highly depends on the settings performed to the exporting file formats (e.g. compression of images). Keep this fact in mind that information can be lost that way. The physician has to decide whether the information contained in an exported object can be used for making diagnostic decisions.

22. 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.



CAUTION

As manufacturer and distributor of this product, UAB Ligence is not responsible for safety, reliability and performance of the system if:

- installation, configuration or modifications are performed by persons, who are not authorized by UAB Ligence;
- the product is not operated in accordance with the IFU;
- the product is operated outside of its operating conditions.



CAUTION

The hardware this product is running on has to be maintained regularly by the user.



CAUTION

The user is responsible for all changes to the system settings. This can lead to system damage and software life-cycle support void.



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.

23. User Views



CAUTION

Ligence Heart is not intended for diagnostic purposes on mobile devices with screen resolution less than 960 px.

24. Patient/User Safety



CAUTION

The user must be satisfied with the suitability and completeness of a study for an analysis with this product. If not, the acquisition has to be repeated. For information about performing an acquisition, which is suitable for an analysis with this product, please refer to the operating instructions provided by the manufacturer of your ultrasound equipment.

25. Measurements



WARNING

Ligence Heart is intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis, but it does not directly generate any diagnosis.

The product is not developed to be an automatic diagnostic tool. The automatically generated annotations, 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 physician approved report of echocardiogram analysis serves only as a decision support tool. The conclusion of diagnosis always must be taken by the physician.



WARNING

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.



CAUTION

Ligence Heart shall not be used with any unverified and unvalidated modalities, view modes, or patient populations described in more detail below. UAB Ligence does not carry responsibility for any harm resulting from an inappropriate usage of the software.



CAUTION

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



CAUTION

The user is responsible for determining if artifactual characteristics exist. Artifacts can severely affect the image quality and require a reacquisition. Examples of artifacts are:

- Obvious discontinuity due to a jerky motion during acquisition or because the acquisition range was left.

- Excess shadowing of images.
- Poorly defined anatomy or evidence of distorted anatomical representation.



CAUTION

In the case of a poor image quality, as determined by the above criteria or 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.



CAUTION

Some patient data contains ECG data, which is not intended for diagnostic purposes.



CAUTION

The user is responsible for determining if the desired measurement is suitable for the corresponding dataset and for determining if the measurement results are applicable for diagnostic decisions. In case of incorrect usage incorrect results may occur.



CAUTION

The measurement accuracy of any measurement function is only as precise as the maximum acquired resolution in the screen projection of an image. The accuracy depends mainly on the acquisition method and the operator skills. For detailed information about acquisition methods and accuracies, refer to the IFU of the acquiring device. All measurements are calculated from the relative positions of on-screen graphic symbols superimposed on an over the ultrasound image. Therefore, the validity of the measurements with respect to the ultrasound image depends directly on the operator skills in positioning the graphic symbols over features of interest in the image. When performing measurements, always be aware of this source of human error.

Safety of Manual Functionalities



CAUTION

Manual functionalities have been validated and verified on 2-dimensional transthoracic echocardiography images of adults up to now.



CAUTION

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

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

Safety of Automatic Functionalities



CAUTION

Automatic functionalities are validated and verified only to be used with 2-dimensional transthoracic echocardiographic B-mode images and with patients that do not have previously stated contraindications.



CAUTION

Automatic functionalities have not yet been validated and verified for patients who have:

- Atrial flutter
- Atrial fibrillation
- Acute and subacute endocarditis
- Aortic dissection

26. 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.

WARNING



Running Ligence Heart software on a shared account can lead to unauthorized access to patient’s medical data.

- 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 browser window. Closing the program without Log Off (using browser window close ‘x’ button) 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.

27. List of known bugs

#	Name	Description
1	Image cache in browser	For some browsers cached images are not properly removed and this may cause “out of memory” errors.

3. REQUIREMENTS AND INSTALLATION

Detailed information is provided in the Installation Manual document.

3.1. USER INTERFACE ELEMENTS

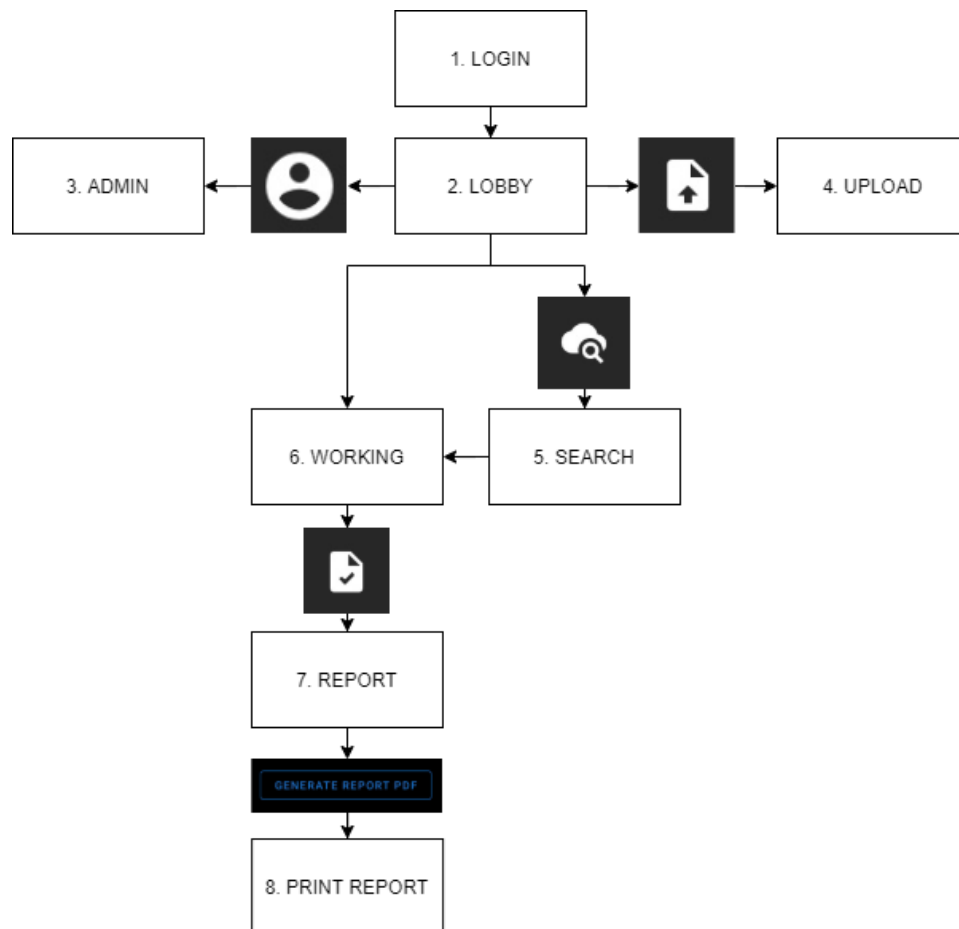
1. User Views

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

There are multiple user views in Ligence Heart:

1. Login View
2. Lobby View
3. Administrator Panel View
4. Registration View (only in demo mode)
5. Upload View
6. Search View
7. Workspace View
8. Strain View
9. Report View
10. Print View

The whole user view architecture is summarized in the diagram below.



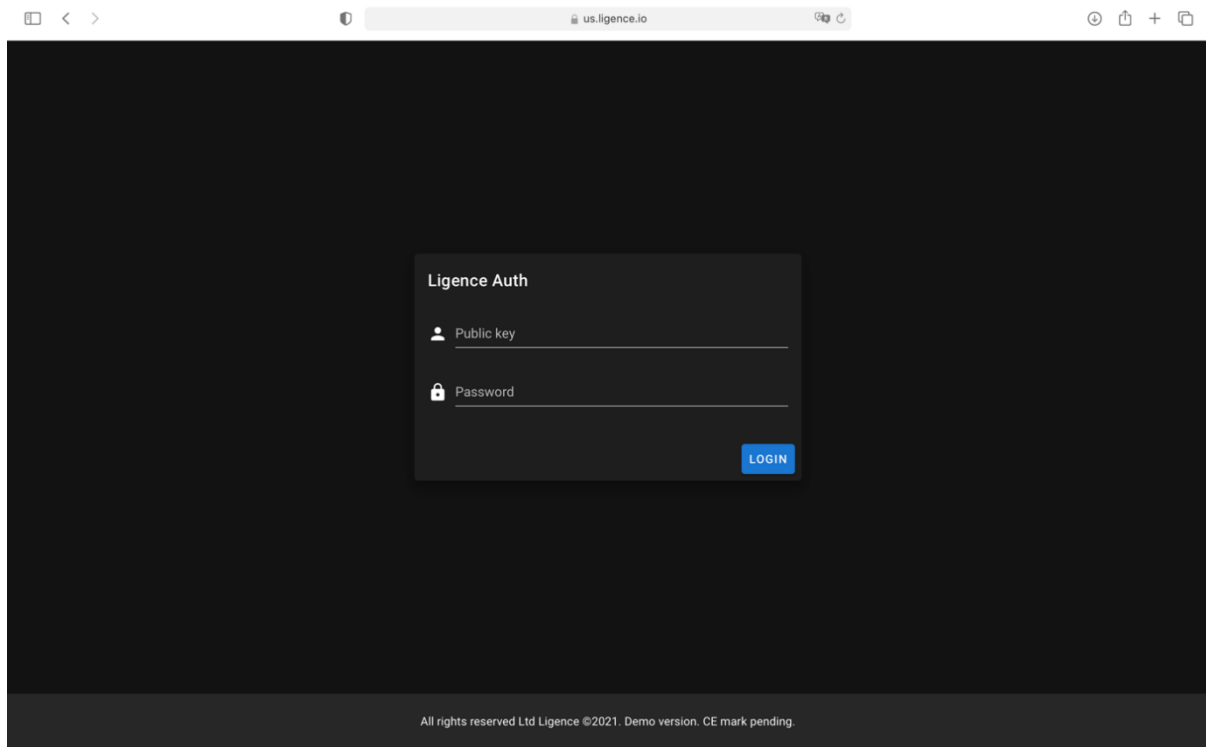
NOTE

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 Public Key and a Password.



CAUTION

Ligence holds no liability on the safety of your account if you share this information with other people. You must not share your unique credentials with anyone ever.

2. Lobby View

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

Ligence Heart

1 WEEK 2 WEEKS 1 MONTH 6 MONTHS Search

Advanced











#	Name	Patient ID	Received	Reported
20764	No Name	1023	2022-06-08 12:21	Not reported
20713	No Name	1017	2022-06-06 09:34	Not reported
20712	No Name	1008	2022-06-06 09:33	Not reported
20711	No Name	1004	2022-06-06 09:31	Not reported
20710	No Name	1167	2022-06-03 20:27	Not reported
20709	No Name	1166	2022-06-03 20:25	Not reported
20708	No Name	1165	2022-06-03 20:23	Not reported
20707	No Name	1164	2022-06-03 20:22	Not reported
20706	No Name	1163	2022-06-03 20:22	Not reported
20705	No Name	1162	2022-06-03 20:21	Not reported
20704	No Name	1161	2022-06-03 20:20	Not reported
20703	No Name	1160	2022-06-03 20:18	Not reported
20702	No Name	1159	2022-06-03 20:15	Not reported
20701	No Name	1158	2022-06-03 20:14	Not reported
20700	No Name	1157	2022-06-03 20:12	Not reported

3. Administrator Panel View

The Administrator Panel View is where you can check users registered with Ligence Heart. You can also modify their Administrator rights, change login credentials of each of users and delete users.

Ligence

Administration panel CREATE USER

Username	Administrator	Actions
user 1	<input checked="" type="checkbox"/>	 
user 2	<input checked="" type="checkbox"/>	 
user 3	<input checked="" type="checkbox"/>	 
user 4	<input checked="" type="checkbox"/>	 
user 5	<input checked="" type="checkbox"/>	 

All rights reserved Ltd Ligence ©2021. Demo version. CE mark pending.

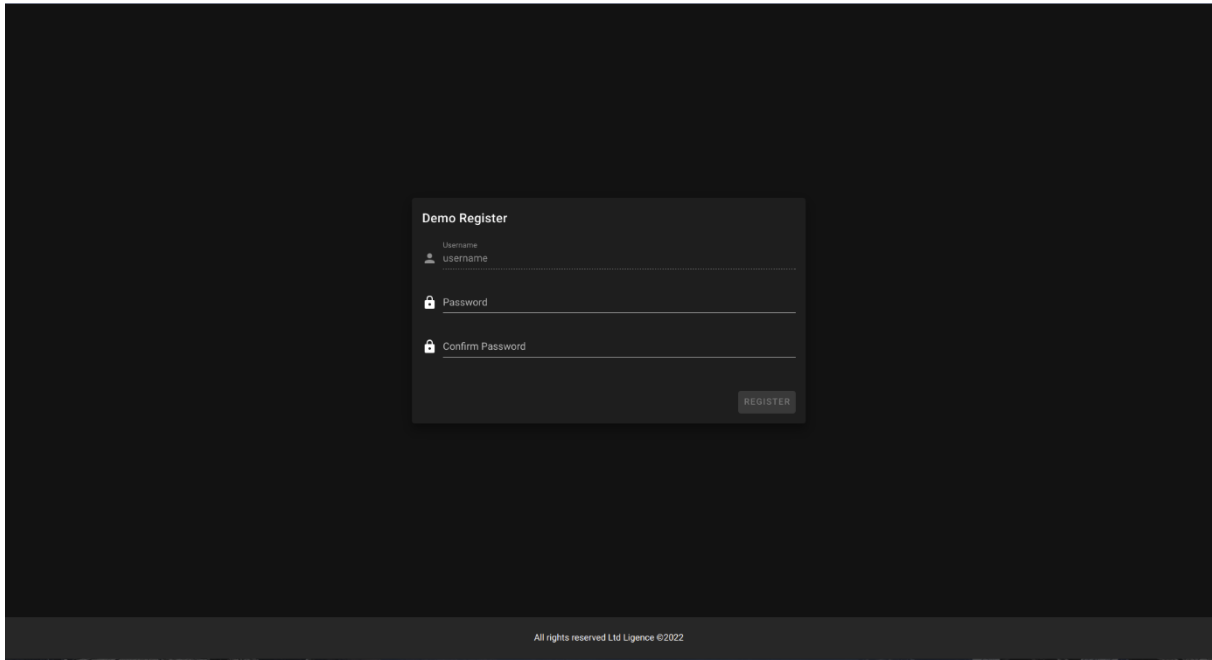


NOTE

Not everyone in your institution will be assigned the Administrator rights and therefore will not have access to the Administrator Panel.

Registration view (demo mode)

This view is only available when the software is running on demo mode.



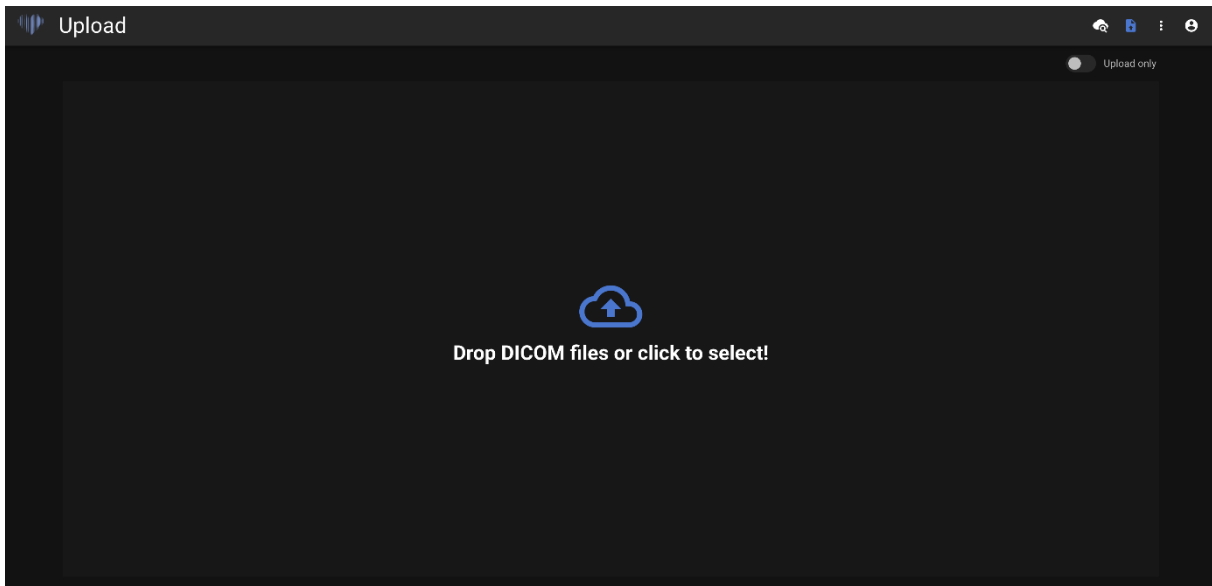
The client must enter password and then repeat the exact same password. Password must contain at least 8 characters. After that – a new user account is created, and the user is redirected to lobby view.

4. Upload View

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

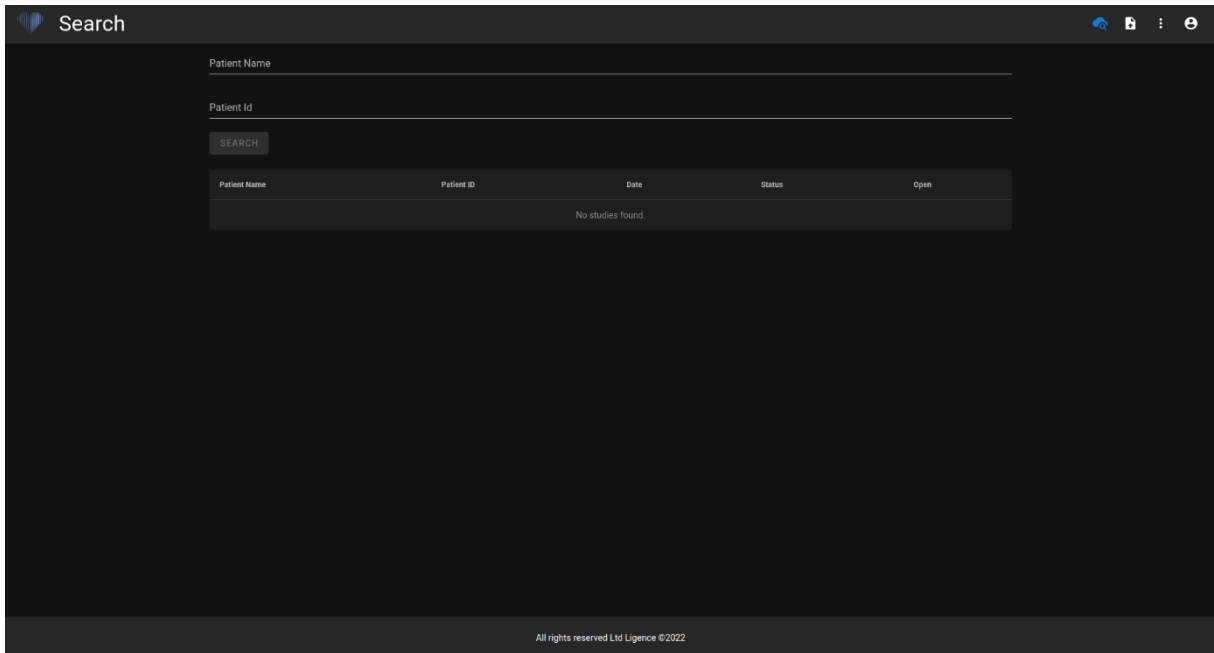
NOTE

Only DICOM format studies are supported.



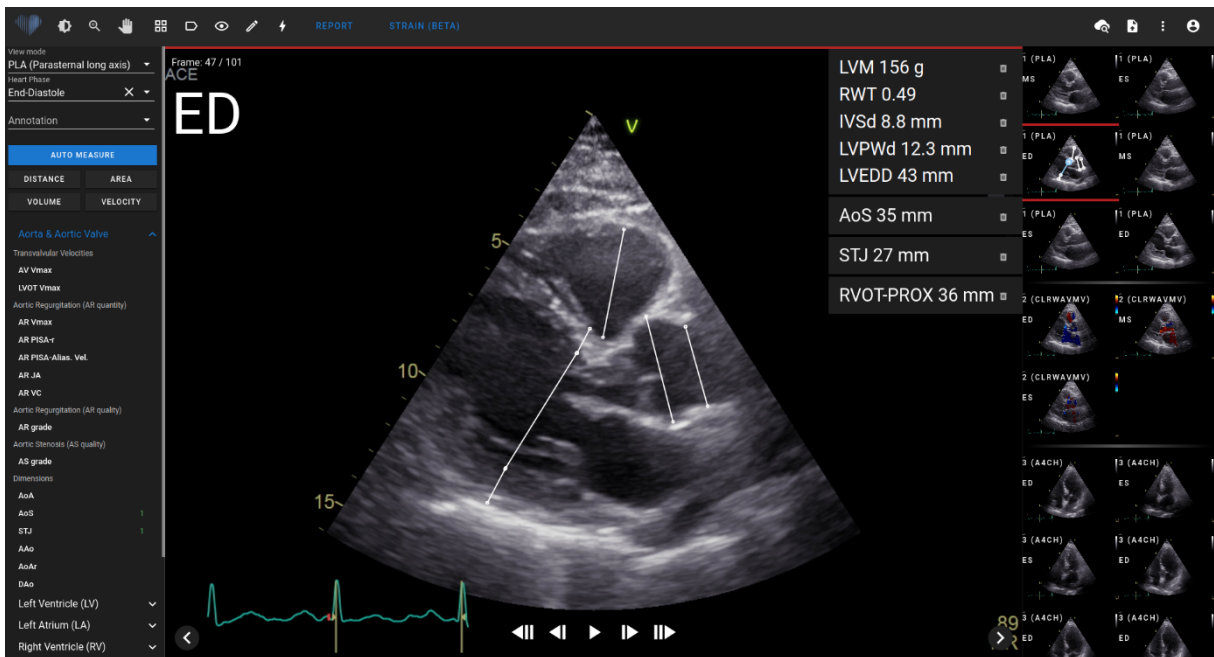
5. Search View

The Search View allows you to effectively search for your studies.

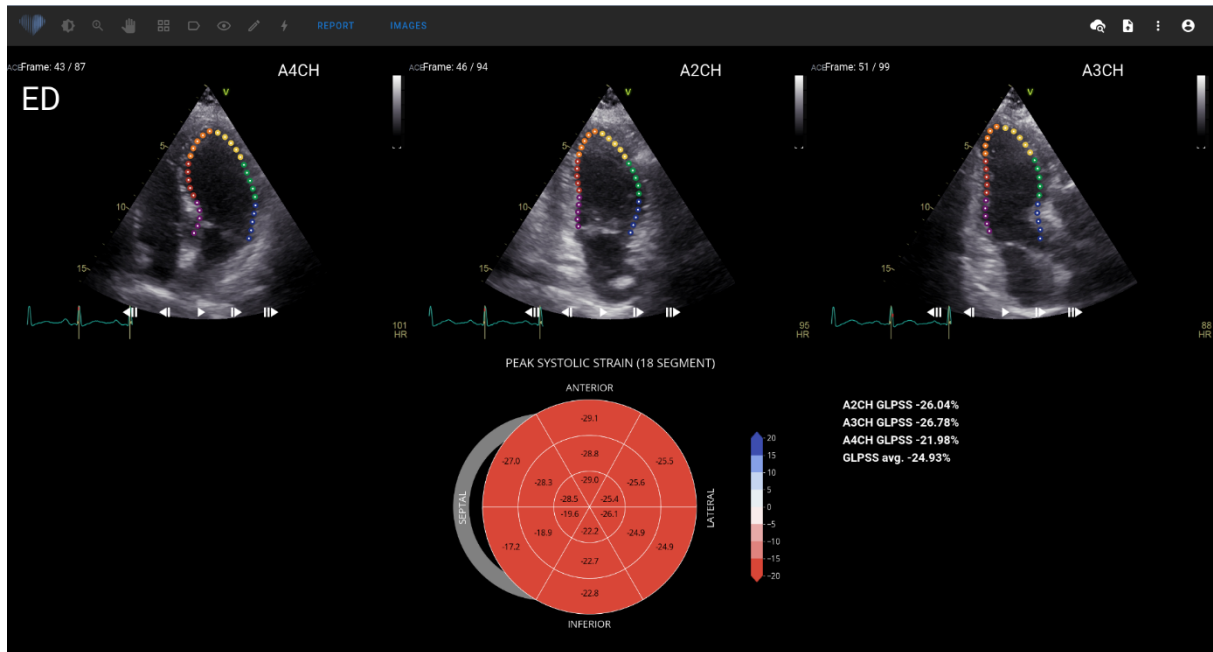


5. Workspace View

This view is dedicated for viewing and analyzing studies.



6. Strain View



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. If no videos are selected for GLPSS measurement – the strain view button is deactivated and strain view is not displayed.

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

7. 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.

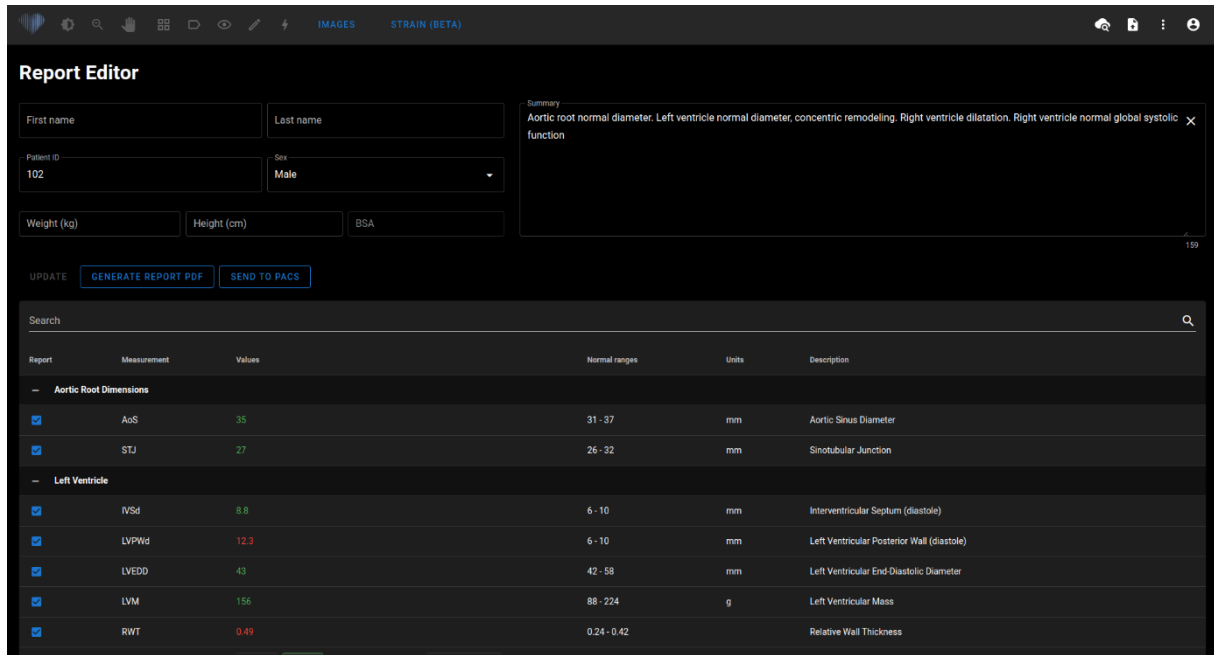


NOTE

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

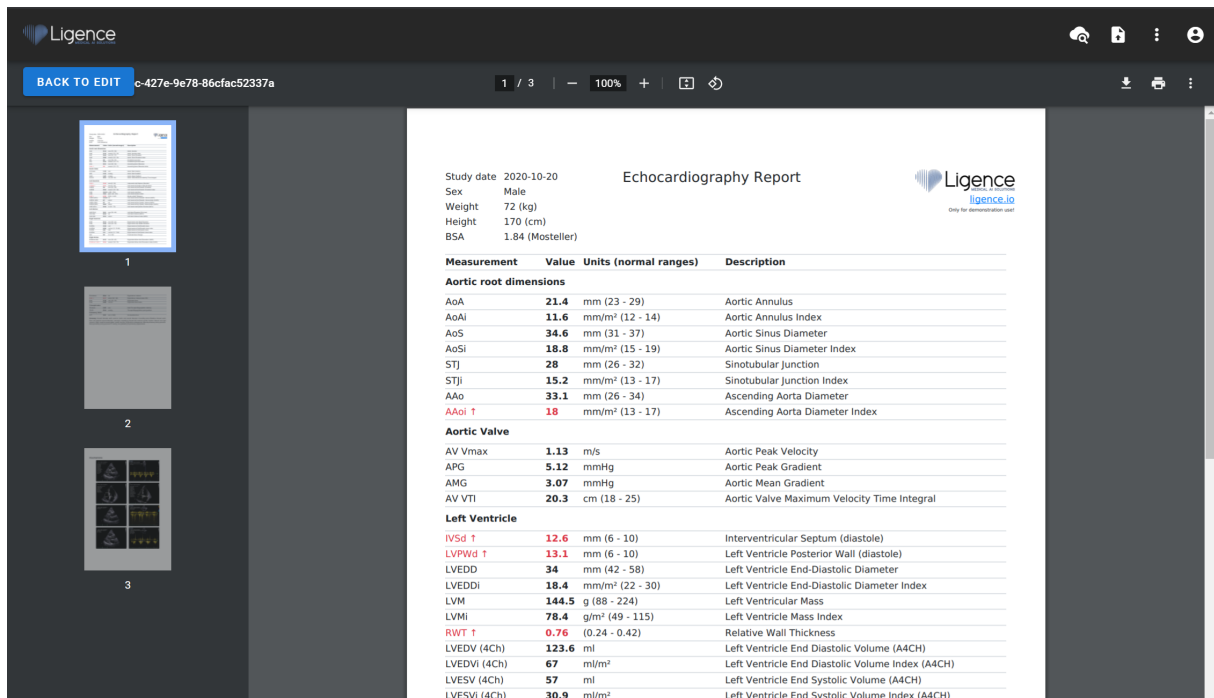
“Standardization of adult transthoracic echocardiography reporting in agreement with recent chamber quantification, diastolic function, and heart valve disease recommendations: an expert consensus document of the European Association of Cardiovascular Imaging 2017”

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



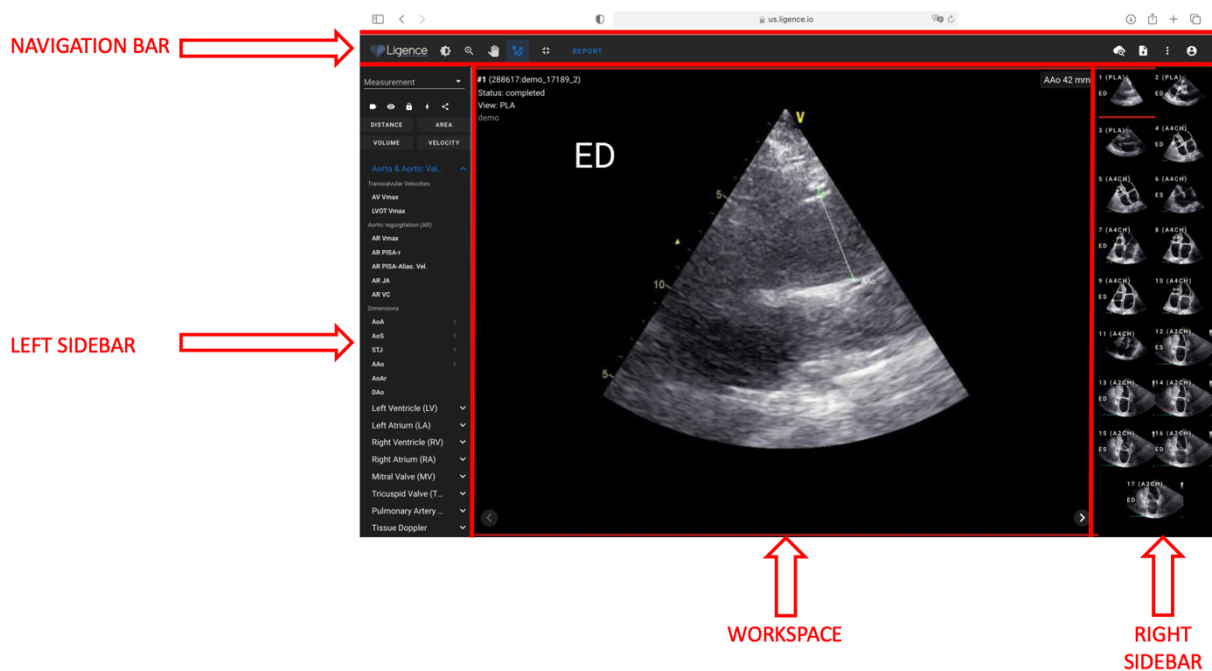
8. Print Report View

The Print Report View is dedicated to review the structured PDF format report once again before printing it. The report can be printed by pressing Print icon on the top right corner. The report can be downloaded to your computer by pressing the Download Report button in blue or on the top right corner. The report, if needed, can be corrected by pressing the Edit Report button in blue. To go back to the images press View Images.



28. 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

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.

29. 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.



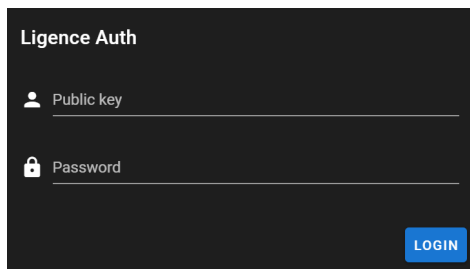
NOTE

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”.



30. Settings Menu

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

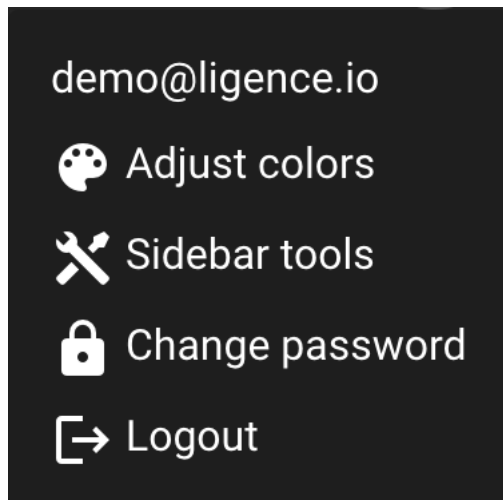


Upon pressing the Settings button, a drop-down menu will appear.

The drop-down menu dialogue contains the following items:

- Your username
- Admin Panel

- Adjust colors
- Sidebar tools
- Change password
- Logout



31. Admin

This part of the Ligence Heart software is only available to users that have been granted the administrator rights. Please check with your institution's information technology department for more information.

The Admin button takes you to the administrator panel where the list of all registered users within your institution can be found.

You can create a new user of Ligence Heart by pressing the “Create User” button on the top right.

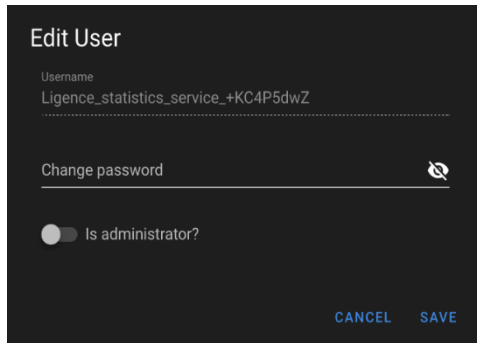


You can enable/disable Administrator rights to each of the users by pressing the slider button.

The information of each user can be corrected by pressing the pencil icon.



The administrator can change the user password for each of the users. Simply enter the new password in the highlighted field and press save to save the changes. If the user is to be made an administrator - press the slider button. If you do not want to make changes - press cancel.



The administrator can delete each of the users by pressing the bin icon button.



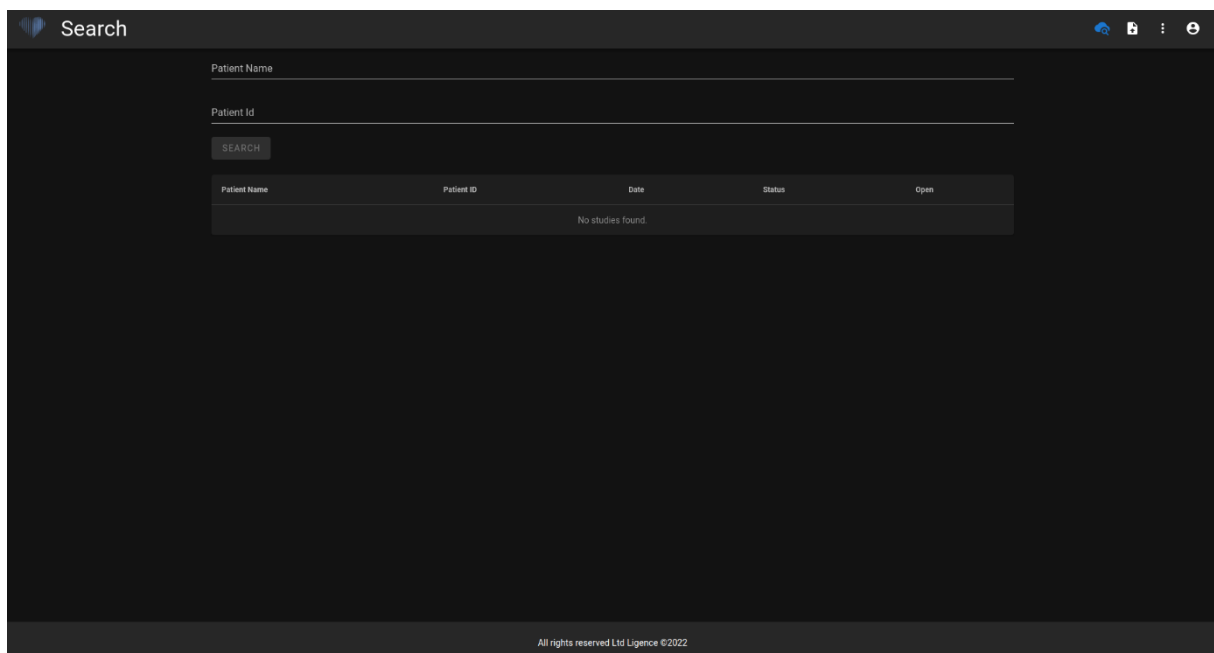
32. Detailed search

By pressing the Search button from the Settings drop down menu you will be directed to the Search View.



The Search View contains these fields:

- Patient name: enter patient name to find unique studies of the particular patient.
- Patient ID: enter patient ID to find a particular study of interest.
- Search button: begin the search from the database.



If the filtered images belong to more than one different study, the report functionality is not available, because it is not clear to which patient study the report is assigned.

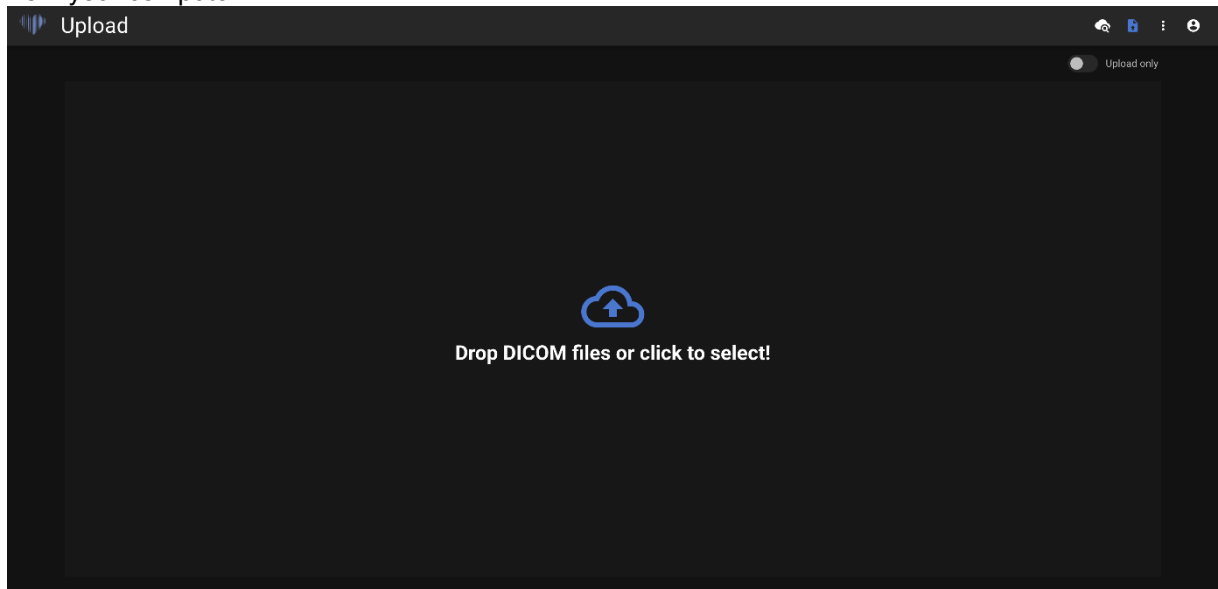
33. Upload the study

You can upload DICOM files directly from your computer into the Ligence Heart by pressing the Upload button from the Settings drop down menu. Make sure that the files has .dcm extension.

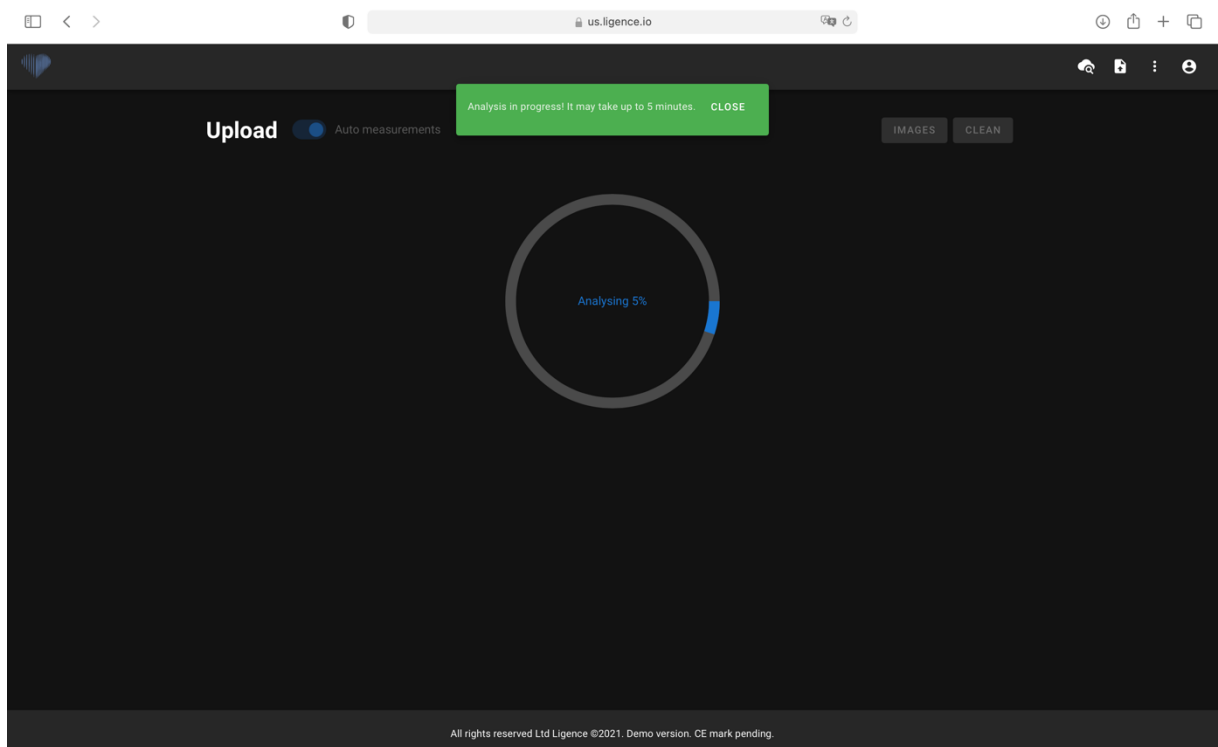


How to upload a study?

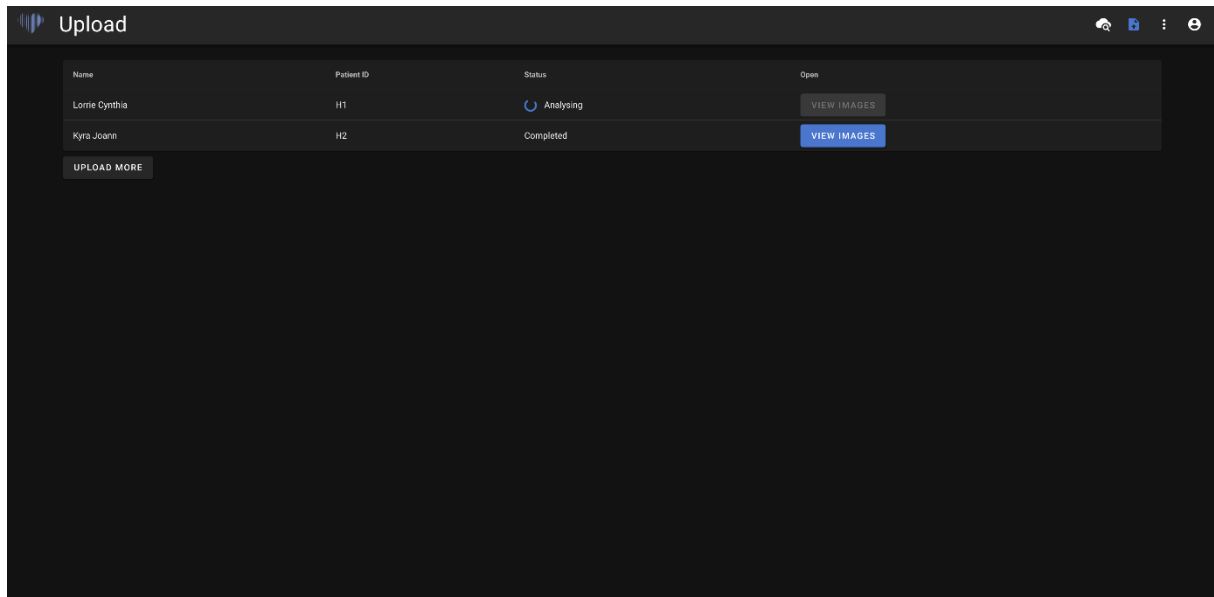
To upload a study simply drag and drop your DICOM format file or press on the blue icon and upload it from your computer.



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



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



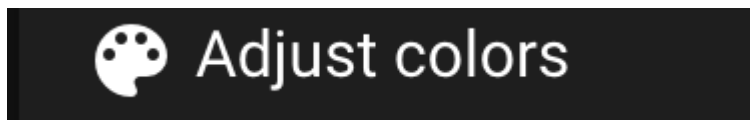
A list of studies uploaded is displayed. Once the study is analysed, you can click “view images” to review.

34. Color picker

Ligence Heart allows you to select a color for annotations that will be applied throughout your annotations.

You can select what annotations will have a particular color.

In the settings tab, press “Adjust colors” button.



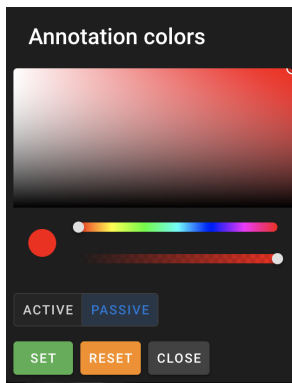
For actively used annotations press “ACTIVE”. This will take effect and all the annotations, upon hovering the mouse cursor on them, will be colored with the color the user has selected.

For passively used annotations press “PASSIVE”. This will take effect and all the annotations will be colored with the color the user has selected.

To select the color of your preference, simply scroll the color picker and then adjust the black and white balance.

To set color for your annotations, press SET.

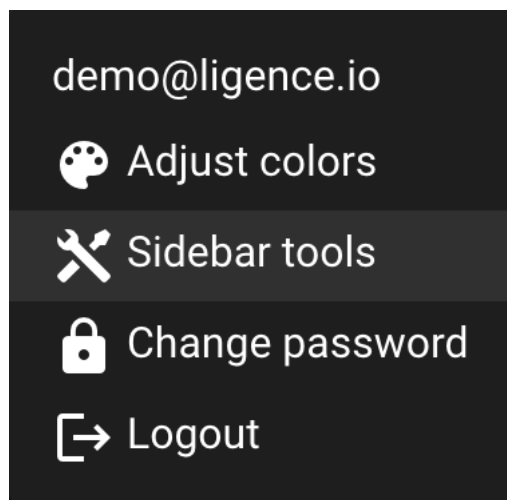
To reset your choice for color for your annotations, press RESET.



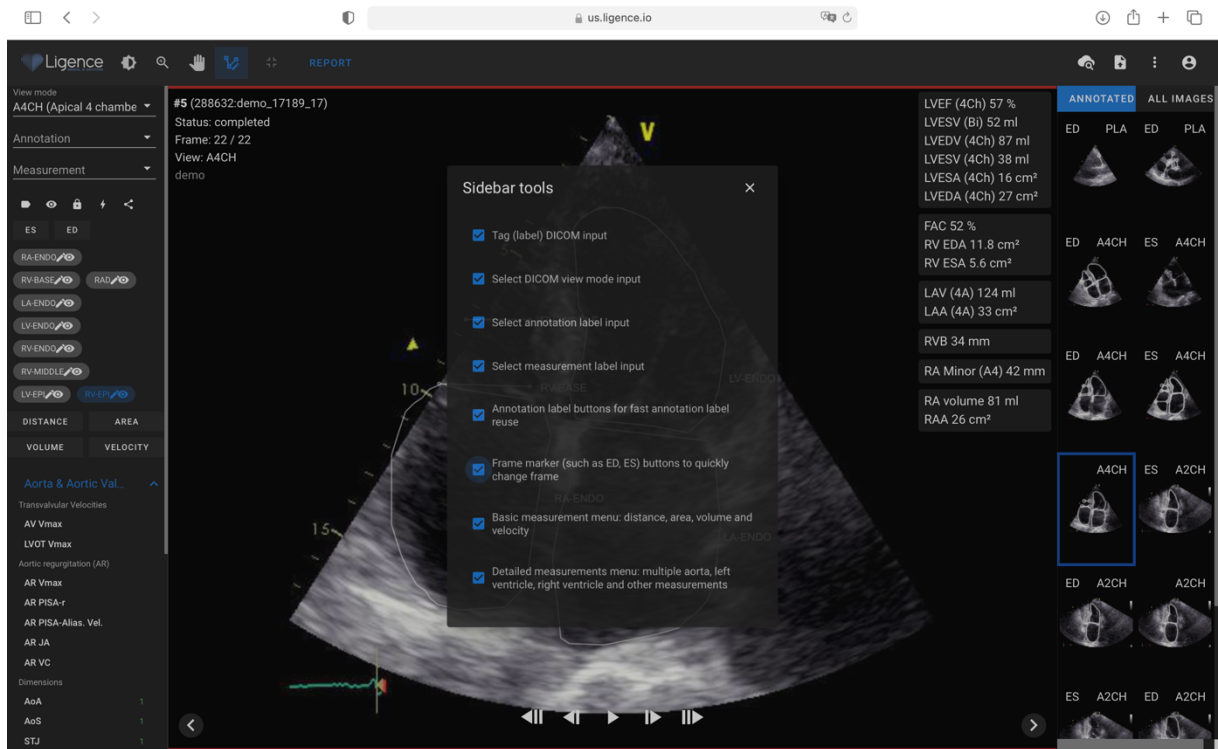
Multiple screen work is supported for Ligence Heart.

35. Sidebar tools

Input options for sidebar tools can be found in the Settings menu.



Press the Sidebar tools button and a dialogue window will appear. Check the boxes for inputs to appear in your sidebar in your Working view. The settings are saved locally on your computer and will appear every time you use Ligence Heart.



The sidebar tools dialogue window allows to choose the options for your sidebar:

- Tag (label) DICOM input
- Select DICOM view mode input
- Select annotation label input
- Select measurement label input
- Annotation label buttons for fast annotation label reuse
- Frame marker (such as ED, ES) buttons to quickly change frame
- Basic measurement menu: distance, area, volume and velocity
- Detailed measurements menu: multiple aorta, left ventricle, right ventricle and other measurements

Tag (label) allows to tag a DICOM and later find it by tag.

Select DICOM view mode input shows echocardiography view mode.

Show annotation label input shows annotation labels.

Show measurement label input shows supported echocardiographic measurements.

Annotation label buttons for fast annotation label reuse shows different annotations that have been already used on a particular image view and therefore can be reused quickly.

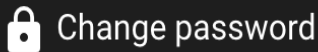
Frame marker buttons allow to quickly jump to a different frame of a particular phase of the heart cycle.

Basic measurements menu: distance, area, volume and velocity shows options to select distance, area, volume or velocity measurement.

Detailed measurements menu: multiple aorta, left ventricle, right ventricle and other measurements shows a selection of more detailed measurements to be made on a particular image.

36. Changing Password

Your password can be changed by pressing the settings button on the top right corner of your screen and then pressing on the change password button.

A dark grey rectangular button with a white padlock icon on the left and the text "Change password" in white.

37. Logging Off

To log off from the software, simply press the settings button on the top right corner of the screen and the logout button in the pop-out menu.

A dark grey rectangular button with a white icon of a door with an arrow pointing right and the text "Logout" in white.

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.



CAUTION!

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

38. Locking the software

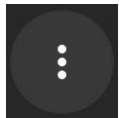
When you are done working with the software or have to leave for a short period of time we recommend logging off either way to prevent unwanted use by other people.

39. Customization

The main functions for customization can be found on the Settings pop-out menu. To access the settings menu, press on the settings icon on the top right corner of your Ligence Heart viewer.

40. Legal and Helpful information

The Legal and Helpful information can be accessed by pressing the triple dot button in the Navigation

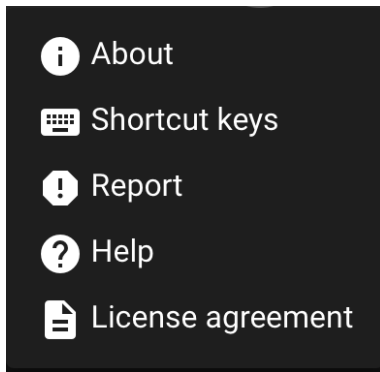


bar.

A menu will appear allowing to choose from the following:

- About: shows the relevant and latest information about the product and manufacturer.
- Shortcut Keys: shows the keyboard shortcuts.
- 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.

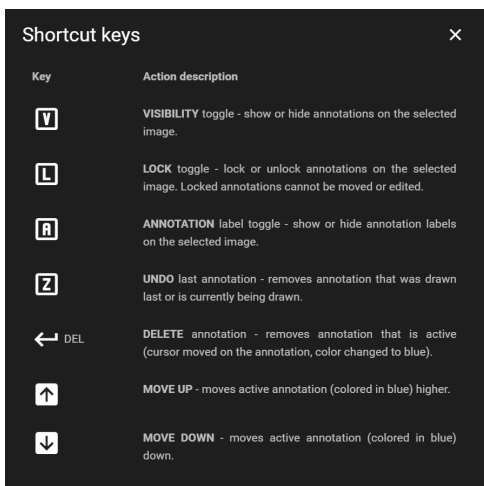


41. Keyboard shortcuts

A keyboard shortcuts summary can be found in the Legal and Helpful information system dialogue upon pressing the Shortcut keys button.



Shortcuts menu will display a table with keyboard shortcuts.



A keyboard shortcut is a sequence or combination of keystrokes on a computer keyboard which invokes commands in a software.

The shortcut commands are listed in the table below with the functions they perform.

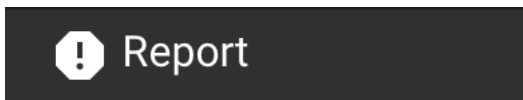
Function	Keyboard shortcut
Hide all annotations	V
Lock all annotation	L
Show/hide labels	A
Delete last annotation	Z
Delete active annotation	Delete, backspace
Cancel drawing	ESC

Function	Keyboard shortcut
Arrow up / down	Moves annotations up or down
Shift + arrow up / down	Moves annotations quicker

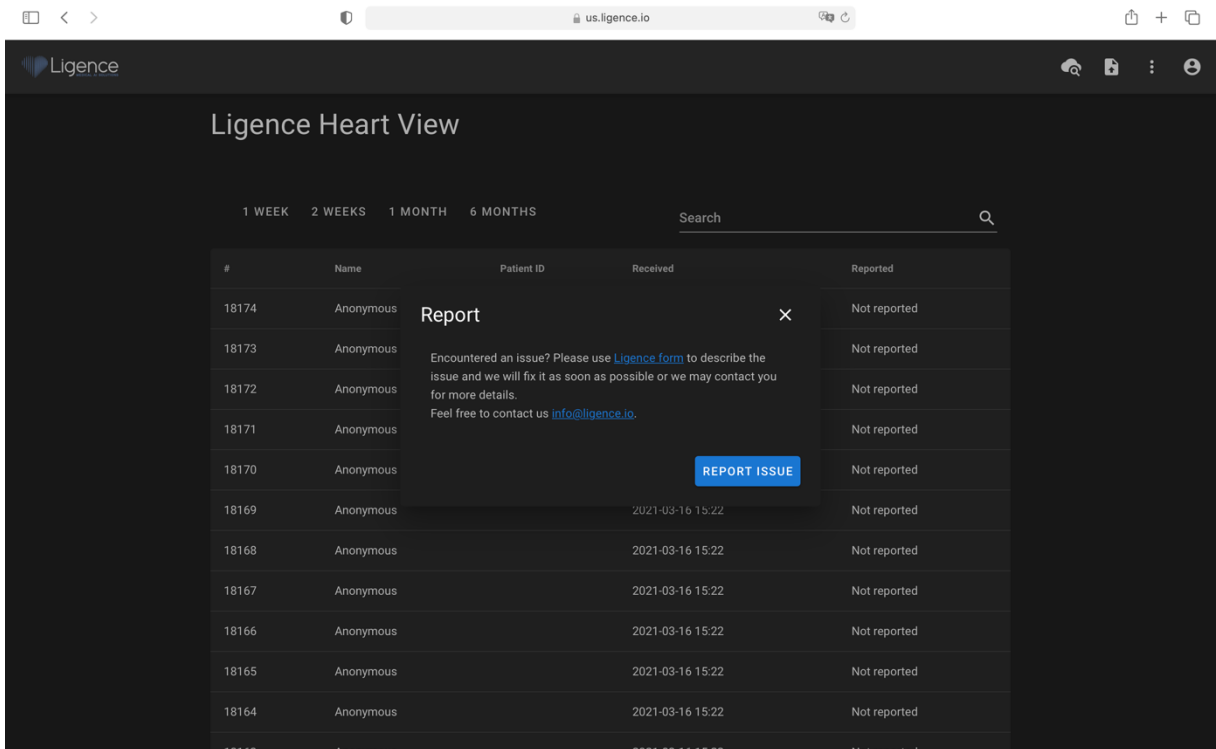
42. Report an issue

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 Legal and Helpful Information 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.

Submit an issue

Your email *

Please enter email

Short description of the problem

Add answer here

Submit



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.



WARNING

UAB Ligence holds no liability for the damages caused by the software if a customer fails to report any concerning issues related to the operation of the software.

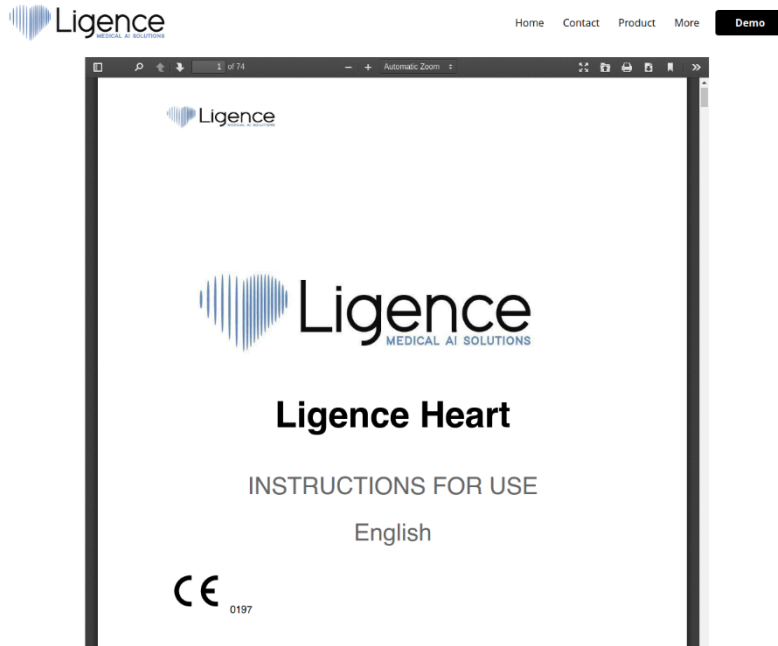
43. Help

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.

 Help

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.






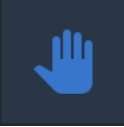



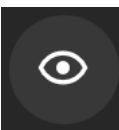


44. Navigation Bar buttons and functions

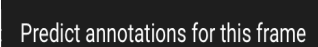
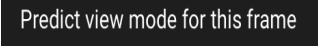
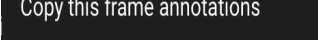

This section covers the Navigation Bar in the Working View. It provides easy access to the most often used functions on the screen

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.
	Exit full screen	Allows to exit full screen and shows four images on the screen.
	Change to full screen	Enters full screen and shows only one image on the screen.
	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.
	Automated features menu	Allows the user to choose automated features for echocardiography image analysis. When pressed, a dialogue appears allowing to choose from automated features.

Icon	Name	Function
  	Automated features	<p>Predict annotations for this frame: automatically detects the image view and performs measurements of that frame according to the image view and heart cycle.</p> <p>Predict view mode for this frame: automatically predicts the view mode of the image e.g. parasternal long-axis, apical four chamber or other.</p> <p>Copy this frame annotations: copies annotations from the closest frame before the selected and pastes them into the next frame.</p>
	Report	Enters the Report View.





45. Workspace buttons and functions




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



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

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


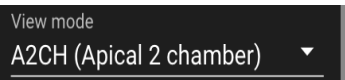

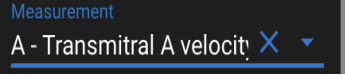
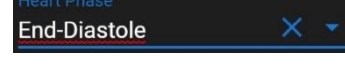

Icon	Name	Function
	Jump to the first frame	Scrolls back the image stack to the very first frame.
	Move back one frame	Moves to the previous frame.
	Play cine	Auto plays the frame stack in a continuous loop.
	Move forward one frame	Moves to the next frame.

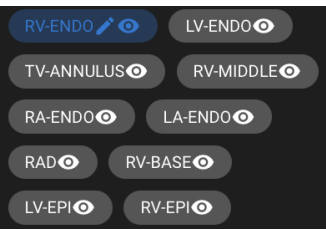





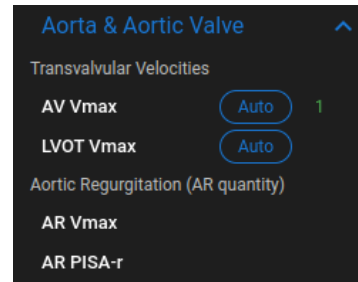
	Move to the last frame	Jumps to the last frame of the stack.
	Navigate to the previous image view	Opens the previous image view.
	Navigate to the next image view	Opens the next image view.

46. 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:

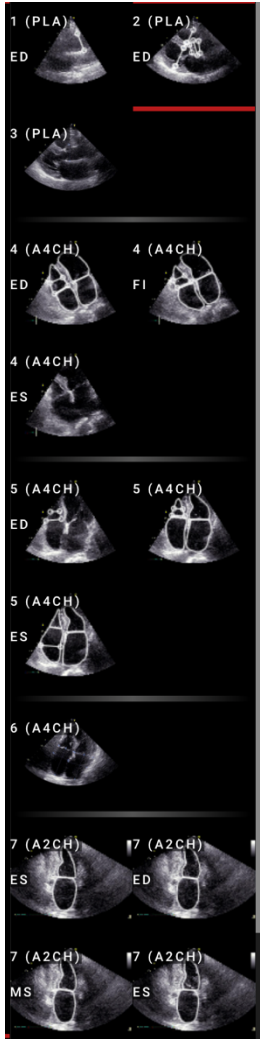
Icon	Name	Function
	Tags pop-up menu slot	Allows the user to select custom tags for the echocardiography studies. Press the arrow to select tags to be shown in the viewer
	View mode pop-up menu slot	Allows the user to select the view mode for the report.
	Annotation pop-up menu slot	Allows the user to select the annotations to make on the studies.
	Measurement pop-up menu slot	Allows you to select the particular measurements to be used on images.
	Heart phase pop-up menu slot	Allows to select heart phase for the current image frame. Applied to B-mode images.
	Heart phase select	Allows the user to move to either ES or ED frame if one is marked on that image.

Icon	Name	Function
	Annotation show/hide/edit	Shows the active annotations in your image view or frame and allows you to show or hide those annotations. When pressed, allows you to make that particular annotation.
	Distance measurement	Press it to manually measure distance between two points.
	Area measurement	Press it to manually measure the area of the region of interest.
	Volume measurement	Press It to manually measure the volume of the region of interest.
	Velocity measurement	Press it to manually measure the velocity of the region of interest.
	Anatomical structure menu buttons and drop-down dialogues	Allows you to manually choose the anatomical structure of interest and see the measurements performed for that structure.
	Drop-down menu dialogue of measurements listed by anatomical structures	<p>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.</p> <p>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.</p>

47. Right Sidebar buttons and functions

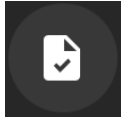
Right Sidebar displays all image views of a particular study and allows easy navigation between them.

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

Icon	Name	Function
	<p>Image view display</p>	<p>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.</p> <p>The image views are sorted automatically (PLA, A4CH etc and ES/ED/MS/None).</p>

48. Study reporting

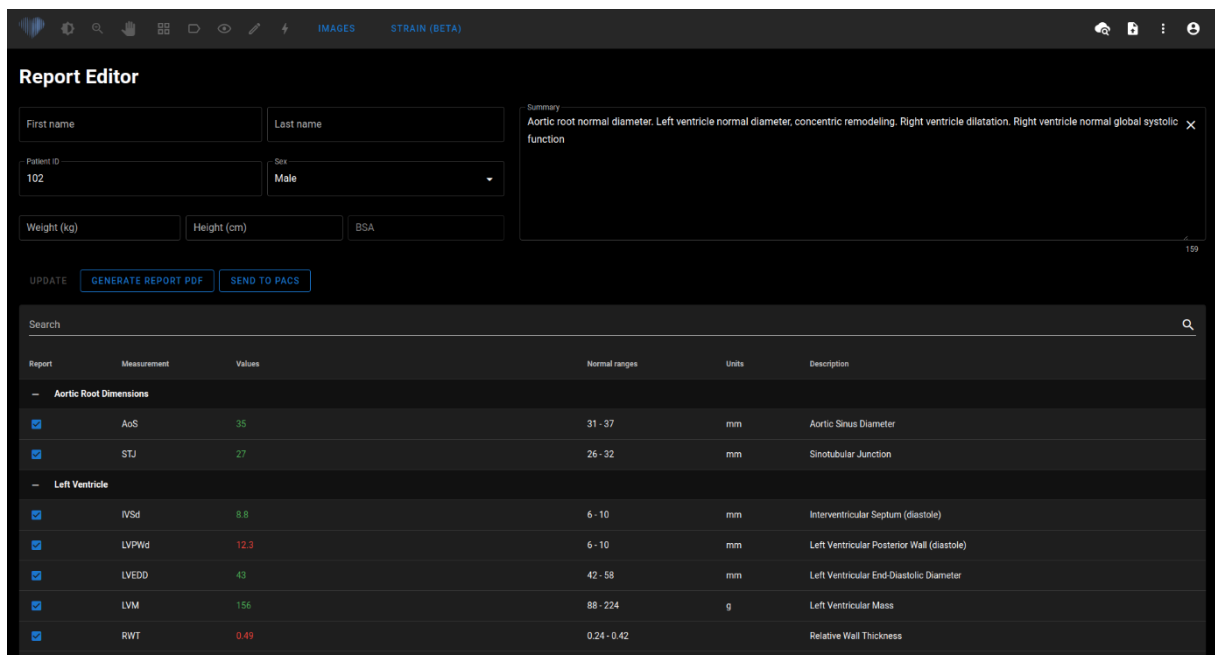
To enter the **Report View** press the View Study Report button in the Navigation bar.



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



To send the report to your PACS/HER, press the Send Report button:



Report Editor

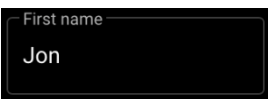
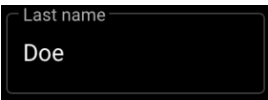

First name: Jon, Last name: Doe, Patient ID: 102, Sex: Male, Weight (kg):, Height (cm):, BSA:.


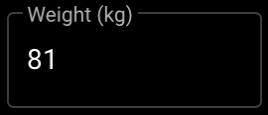
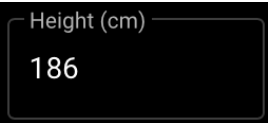
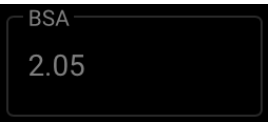





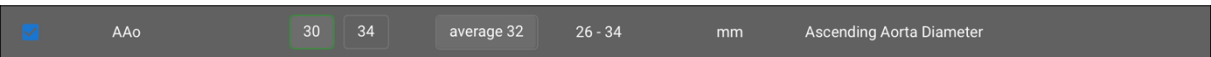
Summary: Aortic root normal diameter, Left ventricle normal diameter, concentric remodeling, Right ventricle dilatation, Right ventricle normal global systolic function.

UPDATE: [GENERATE REPORT PDF](#) [SEND TO PACS](#)

Report	Measurement	Values	Normal ranges	Units	Description
- Aortic Root Dimensions					
<input checked="" type="checkbox"/>	AoS	35	31 - 37	mm	Aortic Sinus Diameter
<input checked="" type="checkbox"/>	STJ	27	26 - 32	mm	Sinotubular Junction
- Left Ventricle					
<input checked="" type="checkbox"/>	IVSd	8.8	6 - 10	mm	Interventricular Septum (diastole)
<input checked="" type="checkbox"/>	LVPWd	12.3	6 - 10	mm	Left Ventricular Posterior Wall (diastole)
<input checked="" type="checkbox"/>	LVEDD	43	42 - 58	mm	Left Ventricular End-Diastolic Diameter
<input checked="" type="checkbox"/>	LVM	156	88 - 224	g	Left Ventricular Mass
<input checked="" type="checkbox"/>	RWT	0.49	0.24 - 0.42		Relative Wall Thickness

All the buttons and functions of the Report View are summarized in the table below:

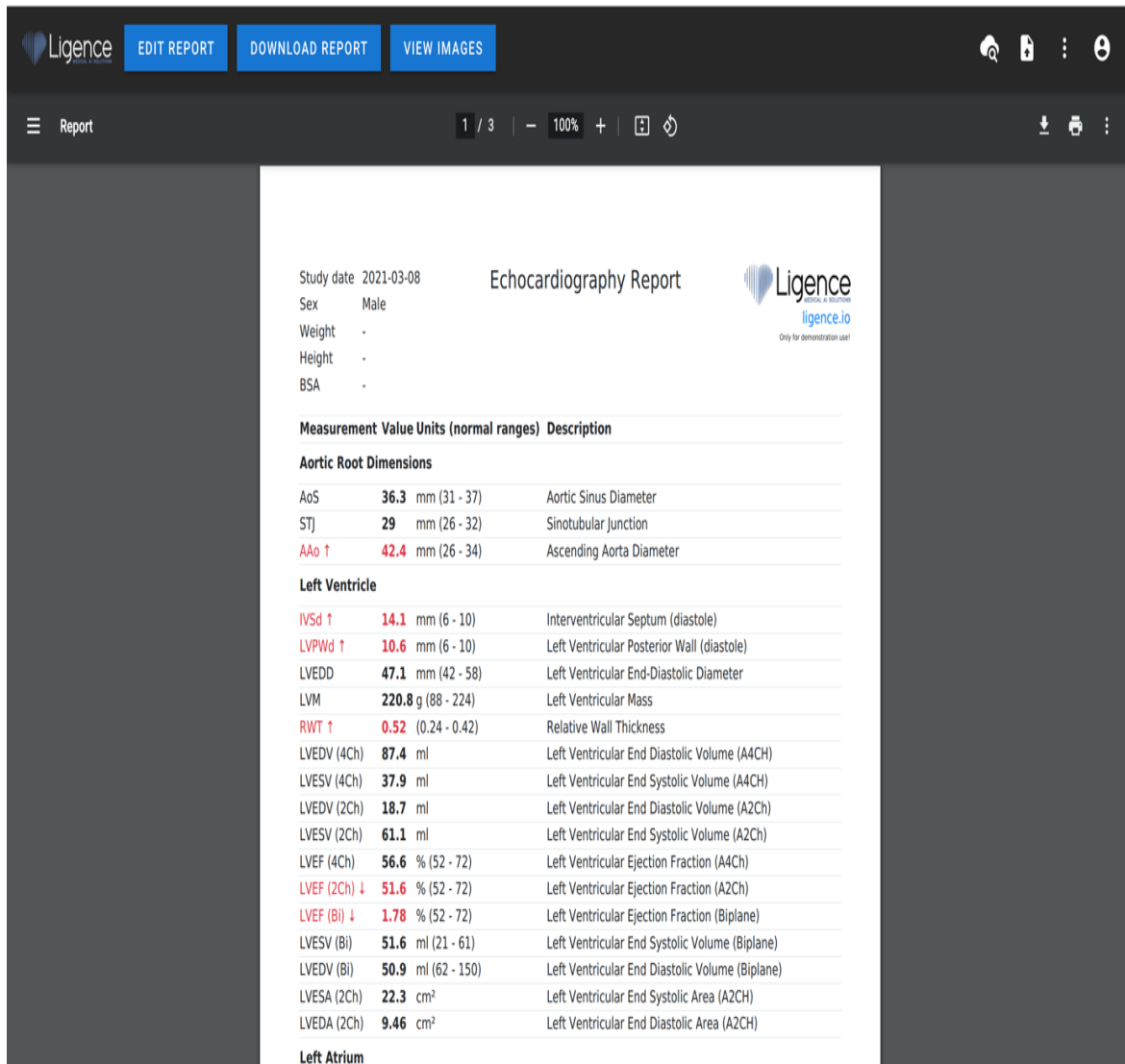
Icon	Name	Function
	First name	Allows you to enter patient first name.
	Last name	Allows you to enter patient last name.
	Patient ID	Allows you to enter patient ID




Icon	Name	Function
	Sex	Allows you to choose patient sex.
	Weight	Allows you to enter patient weight in kilograms.
	Height	Allows you to enter patient height in centimeters
	Body surface area (BSA)	Automatically displays body surface area when weight and height data is
	Summary field	Allows you to enter the summary report of your study. If left unentered, a report is generated automatically.
	Update	Press it to update and save changes in your report.
	Generate report PDF	Press it to generate the final report PDF. A Print Report View will be shown when pressed.
	Back to edit	Goes back from Print Report View to Report View.
	Send to PACS	Sends report to PACS storage.
		
Complete list of measurements and values		Shows the complete list of all measurements and the measured values. Allows you to choose which value or their average (if more than one is measured) to include into the final report.




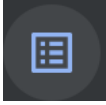
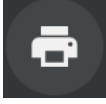

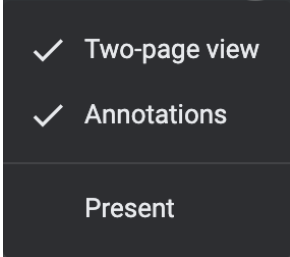
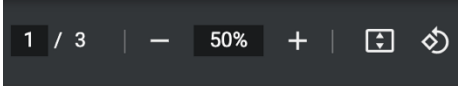
Press the Generate Report PDF button to enter the Print Report View.

The Print Report View can be seen in the picture below:

All the buttons and functions of the Print Report View are summarized in the table below:



Icon	Name	Function
	Edit Report	Returns to Report View.
 OR 	Download Report	Downloads study report to computer memory storage.

Icon	Name	Function
	View Images	Returns to Study View.
	PDF menu	Opens PDF menu.
	Thumbnail display	Shows thumbnails of all pages in the PDF file.
	Outline display	Shows PDF outline.
	Print Study	Print study on a printer.
	More	Opens more options for the PDF file
	<ul style="list-style-type: none"> • Two-page view • Annotations • Present 	<ul style="list-style-type: none"> • Changes PDF display to a two-page view. • Toggles on/off annotations. • Shows present view.
	Other PDF options: <ul style="list-style-type: none"> • Choose PDF page number • Choose zoom size • Expand/contract display • Rotate PDF 	<ul style="list-style-type: none"> • Returns the desired PDF file page. • Zooms in/out the PDF file. • Expands/contracts PDF display • Rotates PDF by 90 degrees.

49. 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. The full list of manual and automated annotations supported by Ligence Heart can be found in ANNEX I.

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.

50. About

About menu is found in the Legal and Helpful information dialogue in the Navigation bar.

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



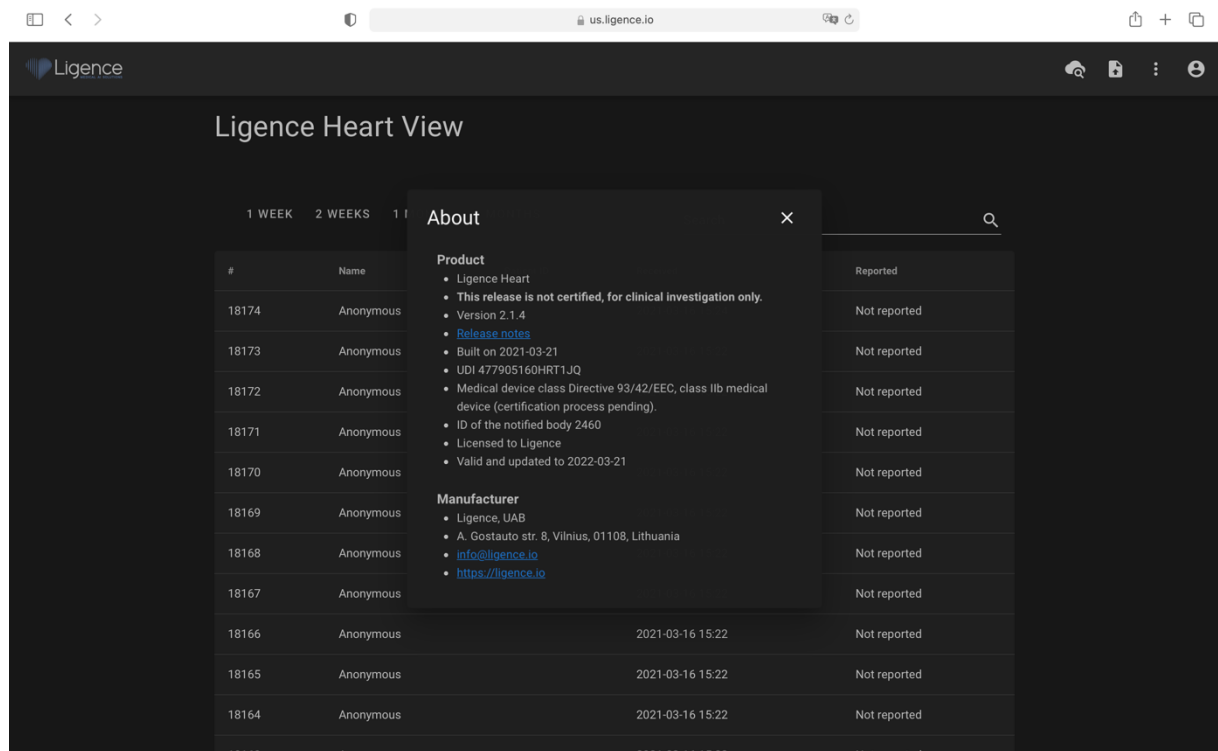
The displayed information on:

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

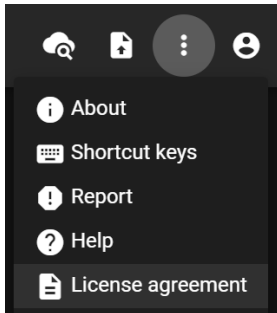
Manufacturer:

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



51. End-User License Agreement

End-User License Agreement can be found in the Legal and Helpful Information 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.

52. 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 Annotations

Abbreviation	Description	Automated
DISTANCE	Distance	No
AREA	Area	No
VOLUME	Volume	No
VELOCITY	Velocity	No

Abbreviation	Description	Automated
LV-ENDO	Left ventricular endocardial border	Yes
LV-EPI	Left ventricular epicardial border	No
LA-ENDO	Left atrial endocardial border	Yes
LA-EPI	Left atrial epicardial border	No
RV-ENDO	Right ventricular endocardial border	Yes
RV-EPI	Right ventricular epicardial border	No
RA-ENDO	Right atrial endocardial border	Yes
RA-EPI	Right atrial epicardial border	No
RVOT-PROX	Right ventricular outflow tract proximal part (PLA)	Yes
RVOT-DIST	Right ventricular outflow tract distal part (PLA)	No
LVOTD	Left ventricle outflow tract diameter	No
LV-LW-MYO	Left ventricular lateral wall myocardium	No
IV-MYO	Intraventricular myocardium	No
RV-DIAMETER	Right ventricle - distance 1 (Diameter)	Yes
RV-BASE	Right ventricle - distance 1 (Base)	Yes
RV-MIDDLE	Right ventricle - distance 3 (Mid)	Yes
RV-WT	Right ventricle wall thickness	No
RAD	Right atrial diameter minor axis	Yes
RAD-MAJ	Right atrial diameter major axis	Yes
LAD-MIN	Left atrial diameter minor axis	Yes
LAD-MAJ	Left atrial diameter major axis	Yes
PAA	Pulmonary Artery Annulus	No
PA-RB	Pulmonary Artery Right Branch	No
PA-LB	Pulmonary Artery Left Branch	No
LAD	Left atrial diameter	Yes

Abbreviation	Description	Automated
LVPW	Left ventricular posterior wall	Yes
LVD	Left ventricular diameter	Yes
IVS	Interventricular septum	Yes
AoS	Aortic sinus	Yes
STJ	Sinotubular junction	Yes
AAo	Ascending aorta	No
TAPSE	Tricuspid Annular Plane Systolic Excursion	No
FORWARD-FLOW	Forward flow wave in Spectral Doppler	Yes
DIRECT-FLOW	Direct flow wave in Spectral Doppler	No
REVERSE-FLOW	Reverse flow wave in Spectral Doppler	Yes
TAPSE	Tricuspid Annular Plane Systolic Excursion	No
IVC	Inferior Vena Cava	No
IVC-EXP	Inferior Vena Cava during expiration	No
IVC-INSP	Inferior Vena Cava during inspiration	No
HV	Hepatic Vein	No
S-PRIME	S prime peak	Yes
E-PRIME	E prime peak	Yes
A-PEAK	A wave peak	Yes
E-PEAK	E wave peak	Yes
E-BASE	E wave base (Deceleration time)	Yes
PHT	Pressure half-time	No
MV	Mitral valve	No
MV-ANNULUS	Mitral valve annulus (MV-1 PLAX, MV-2 4CH, MV-BICOMMISSURAL 2CH)	No
MV-ANT-LEAFLET	Mitral valve anterior leaflet	No
MV-POST-LEAFLET	Mitral valve posterior leaflet	No

Abbreviation	Description	Automated
PV	Pulmonary valve	No
PV-ANNULUS	Pulmonary valve annulus (equivalent to RVOT-DIST)	No
PV-ANT-LEAFLET	Pulmonary valve anterior leaflet	No
PV-R-LEAFLET	Pulmonary valve right leaflet	No
PV-L-LEAFLET	Pulmonary valve left leaflet	No
AV	Aortic valve	No
AV-ANNULUS	Aortic valve annulus	Yes
Ao-ARCH	Aortic Arch	No
DAo	Descending Aorta	No
AV-RC-LEAFLET	Aortic valve right coronary leaflet	No
AV-LC-LEAFLET	Aortic valve left coronary leaflet	No
AV-NC-LEAFLET	Aortic valve non-coronary leaflet	No
TV	Tricuspid valve	No
TV-ANNULUS	Tricuspid valve annulus	No
TV-A-LEAFLET	Tricuspid valve anterior leaflet	No
TV-P-LEAFLET	Tricuspid valve posterior leaflet	No
TV-S-LEAFLET	Tricuspid valve septal leaflet	No
EFFUSION	Pericardial effusion	No
JET-AREA	Regurgitant flow jet area	No
JET-DIAMETER	Regurgitant Flow Jet Diameter	No
FLOW-DIAMETER	Regurgitant Flow Diameter	No
VENA-CONTRACTA	Vena contracta	No
PISA-RADIUS	Color Doppler flow convergence radius	No
AT	Acceleration time	Yes
DT	Deceleration time	Yes

Abbreviation	Description	Automated
ES	End-systole	Yes
ED	End-diastole	Yes
MS	Mid-systole	Yes
MD	Mid-diastole	No
FI	Frame of interest	No
ALIASING	Aliasing velocity	No
AR-GRAD	Aortic Valve Regurgitation Grade	No
AS-GRAD	Aortic Valve Stenosis Grade	No
MR-GRAD	Mitral Valve Regurgitation Grade	No
MS-GRAD	Mitral Valve Stenosis Grade	No
PR-GRAD	Pulmonary Artery Regurgitation Grade	No
PS-GRAD	Pulmonary Artery Stenosis Grade	No
TR-GRAD	Tricuspid Valve Regurgitation Grade	No
TS-GRAD	Tricuspid Valve Stenosis Grade	No
LV-SEG	Left Ventricle Endocardial Wall Segments	Yes

53. List of Supported View Modes

Abbreviation	Description	Automated
A2CH	Apical 2 chamber	Yes
A3CH	Apical 3 chamber	Yes
A4CH	Apical 4 chamber	Yes
A5CH	Apical 5 chamber	Yes
OTHER	Do not fit any category	Yes
SCHEMA	Scheme, diagram or graph	No
MULTIPLANE	Multiple images	No
CLRWAV	Color flow Doppler aortic valve (parasternal long axis)	No

Abbreviation	Description	Automated
CLRWAV3CH	Color flow Doppler aortic valve (apical 3 chamber)	No
CLRWAV5CH	Color flow Doppler aortic valve (apical 5 chamber)	No
CLRWAVA	Color flow Doppler aortic valve (aortic level)	No
CLRWAVMV	Color flow Doppler aortic valve and mitral valve (parasternal long axis)	No
CLRWMV	Color flow Doppler mitral valve (parasternal long axis)	No
CLRWMV2CH	Color flow Doppler mitral valve (apical 2 chamber)	No
CLRWMV3CH	Color flow Doppler mitral valve (apical 3 chamber)	No
CLRWMV4CH	Color flow Doppler mitral valve (apical 4 chamber)	No
CLRWMV5CH	Color flow Doppler mitral valve (apical 5 chamber)	No
CLRWMVLV	Color flow Doppler mitral valve (parasternal short axis left ventricular level)	No
CLRWMVSUB	Color flow Doppler mitral valve (subcostal)	No
CLRWPVA	Color flow Doppler pulmonary valve (aortic level)	No
CLRWTV4CH	Color flow Doppler tricuspid valve (apical 4 chamber)	No
CLRWTV5CH	Color flow Doppler tricuspid valve (apical 5 chamber)	No
CLRWTV	Color flow Doppler tricuspid valve (aortic level)	No
CLRWTVSUB	Color flow Doppler tricuspid valve (subcostal)	No
CLRWVS	Color flow Doppler ventricular septum	No
CWAV	Continuous-wave Doppler Aortic Valve	Yes
CWAV3CH	Continuous-wave Doppler aortic valve (apical 3 chamber)	No
CWAV5CH	Continuous-wave Doppler aortic valve (apical 5 chamber)	No
CWMV2CH	Continuous-wave Doppler mitral valve (apical 2 chamber)	No
CWMV4CH	Continuous-wave Doppler mitral valve (apical 4 chamber)	No
CWTV	Continuous-wave Doppler Tricuspid Valve	Yes
CWTRSUB	Continuous-wave Doppler tricuspid valve (subcostal)	No
CWTV4CH	Continuous-wave Doppler tricuspid valve (apical 4 chamber)	No

Abbreviation	Description	Automated
CWTV5CH	Continuous-wave Doppler tricuspid valve (apical 5 chamber)	No
CWTVPSAB	Continuous-wave Doppler tricuspid valve (basal level)	No
CWAVPLA	Continuous wave aortic valve (parasternal long axis)	No
MMTAPSE	M-Mode Tricuspid Annular Plane Systolic Excursion	No
PLA	Parasternal long axis	Yes
PSAAP	Parasternal short axis (apical level)	No
PSAB	Parasternal short axis base (aortic level)	No
PSAMID	Parasternal short axis (mid-level)	No
PSAMV	Parasternal short axis mitral valve	No
PWLVOT	Pulsed-wave Doppler left ventricular outflow tract	Yes
PWMV	Pulsed-wave Doppler mitral valve	Yes
PWPV	Pulsed-wave Doppler pulmonary valve	Yes
SUB4CH	Subcostal 4 chamber	No
SUBIVC	Subcostal inferior vena cava	No
SUBMMIVC	M-Mode subcostal inferior vena cava	No
SUPRACOSTALDESA O	Supracostal descending aorta	No
TDPWLMA	Tissue Doppler lateral mitral annulus	Yes
TDPWRVLW	Tissue Doppler right ventricular lateral wall	Yes
TDPWSMA	Tissue Doppler septal mitral annulus	Yes
CLRWDAO	Color flow descending aorta	No
CLRWIVSSUB	Color flow interventricular septum (subcostal)	No
CLRWIASSUB	Color flow interatrial septum (subcostal)	No
CLRWIAS4CH	Color flow interatrial septum (apical 4 chamber)	No
PWDAO	Pulsed-wave Doppler Descending Aorta	Yes
PWSVC	Pulsed-wave Doppler Superior Vena Cava	No

Abbreviation	Description	Automated
PWTV	Pulsed-wave Doppler Tricuspid Valve	No

54. List of Measurements

Abbreviation	Description	Automated
A	Transmitral A velocity	Yes
AAo	Ascending Aorta Diameter	No
AAoi	Ascending Aorta Diameter Index	No
ACT	Acceleration time	Yes
AMG	Aortic Mean Gradient	Yes
AoA	Aortic Annulus	Yes
AoAi	Aortic Annulus Index	Yes
AoAr	Aortic Arch	No
AoAri	Aortic Arch Index	No
AoS	Aortic Sinus Diameter	Yes
AoSi	Aortic Sinus Diameter Index	Yes
APG	Aortic Peak Gradient	Yes
AR EROA	Aortic regurgitation effective regurgitant orifice area	No
AR JA	Aortic regurgitation - jet area	No
AR PG	Aortic regurgitation - peak gradient	No
AR PISA-Alias. Vel.	Aortic regurgitation proximal isovelocity surface area - aliasing velocity	No
AR PISA-r	Aortic regurgitation proximal isovelocity surface area - radius	No
AR VC	Aortic regurgitation - vena contracta	No
AR Vmax	Aortic regurgitation - peak velocity	No
Area	Area	No
AR-grade	Aortic Valve Regurgitation Grade	No

Abbreviation	Description	Automated
AS-grade	Aortic Valve Stenosis Grade	No
AV Vmax	Aortic Peak Velocity	Yes
AV VTI	Aortic Valve Maximum Velocity Time Integral	Yes
AVA	Aortic valve area	Yes
AVAi	Aortic valve area index	Yes
DAo	Descending Aorta	No
DAoi	Descending Aorta Index	No
Dec	Transmitral E velocity Deceleration time	Yes
Distance	Distance	No
E	Transmitral E velocity	Yes
E' lat	E prime right ventricle lateral wall	Yes
E/A	E/A ratio	Yes
E/e'	E/e' average ratio	Yes
FAC	Fractional Area Change	Yes
GLPS2A	Global Longitudinal Peak Systolic Strain 2 Chamber	Yes
GLPS4A	Global Longitudinal Peak Systolic Strain 4 Chamber	Yes
HV	Hepatic Vein	No
IVCcol (B)	Inferior vena cava collapse (BMode)	No
IVCcol (M)	Inferior vena cava collapse (MMode)	No
IVCde (B)	Inferior vena cava diameter during expiration (BMode)	No
IVCde (M)	Inferior vena cava diameter during expiration (MMode)	No
IVCdi (B)	Inferior vena cava diameter during inspiration (BMode)	No
IVCdi (M)	Inferior vena cava diameter during inspiration (MMode)	No
IVSd	Interventricular Septum (diastole)	Yes

Abbreviation	Description	Automated
IVSs	Interventricular Septum (systole)	Yes
LAA (2A)	Left Atrial Area (A2Ch)	Yes
LAA (4A)	Left Atrial Area (A4Ch)	Yes
LAAi (2A)	Left Atrial Area Index (A2Ch)	Yes
LAAi (4A)	Left Atrial Area Index (A4Ch)	Yes
LAD (PLA)	Left Atrial Diameter (PLA view)	Yes
LAD Major axis (A4)	Left Atrium Diameter Major Axis (A4Ch)	Yes
LAD Minor axis (A4)	Left Atrium Diameter Minor Axis (A4Ch)	Yes
LAEF	Left Atrial Ejection Fraction	Yes
LAV (2A)	Left Atrial Volume (A2Ch)	Yes
LAV (4A)	Left Atrial Volume (A4Ch)	Yes
LAV (Bi)	Left Atrial Volume (Biplane)	Yes
LAVi (2A)	Left Atrial Volume Index (A2Ch)	Yes
LAVi (4A)	Left Atrial Volume Index (A4Ch)	Yes
LAVi (Bi)	Left Atrial Volume Index (Biplane)	Yes
Le'	Lateral e' velocity	Yes
LVEDD	Left Ventricle End-Diastolic Diameter	Yes
LVEDDi	Left Ventricle End-Diastolic Diameter Index	Yes
LVEDV (2Ch)	Left Ventricle End Diastolic Volume (A2Ch)	Yes
LVEDV (Bi)	Left Ventricle End Diastolic Volume (Biplane)	Yes
LVEDVi (2Ch)	Left Ventricle End Diastolic Volume Index (A2Ch)	Yes
LVEDVi (Bi)	Left Ventricle End Diastolic Volume Index (Biplane)	Yes
LVEF (2Ch)	Left Ventricular Ejection Fraction (A2Ch)	Yes
LVEF (4Ch)	Left Ventricular Ejection Fraction (A4Ch)	Yes
LVEF (Bi)	Left Ventricular Ejection Fraction (Biplane)	Yes

Abbreviation	Description	Automated
LVESD	Left Ventricle End-Systolic Diameter	Yes
LVESDi	Left Ventricle End-Systolic Diameter Index	Yes
LVESV (2Ch)	Left Ventricle End Systolic Volume (A2Ch)	Yes
LVESV (Bi)	Left Ventricle End Systolic Volume (Biplane)	Yes
LVESVi (2Ch)	Left Ventricle End Systolic Volume Index (A2Ch)	Yes
LVESVi (Bi)	Left Ventricle End Systolic Volume Index (Biplane)	Yes
LVM	Left Ventricular Mass	Yes
LVMi	Left Ventricle Mass Index	Yes
LVOT MG	Left Ventricle Outflow Tract Mean Gradient	Yes
LVOT PG	Left Ventricle Outflow Tract Peak Gradient	Yes
LVOT Vmax	Left Ventricle Outflow Tract Peak Velocity	Yes
LVOT VTI	Left Ventricle Outflow Tract Velocity Time Integral	Yes
LVOTDd	Left Ventricle Outflow Tract (diastole)	No
LVOTDs	Left Ventricle Outflow Tract (systole)	No
LVPWd	Left Ventricle Posterior Wall (diastole)	Yes
LVPWs	Left Ventricle Posterior Wall (systole)	Yes
MR EROA	Mitral regurgitation effective regurgitant orifice area	No
MR JA	Mitral regurgitation - jet area	No
MR MG	Mitral regurgitation - mean gradient	No
MR PG	Mitral regurgitation - peak gradient	No
MR PISA-Alias. Vel.	Mitral regurgitation proximal isovelocity surface area - aliasing velocity	No
MR PISA-r	Mitral regurgitation proximal isovelocity surface area - radius	No
MR VC	Mitral regurgitation - vena contracta	No
MR Vmax	Mitral regurgitation - peak velocity	No
MR VTI	Mitral regurgitation - Velocity Time Integral	No

Abbreviation	Description	Automated
MR-grade	Mitral Valve Regurgitation Grade	No
MS-grade	Mitral Valve Stenosis Grade	No
MV MG	Mitral valve - mean gradient	No
MV PG	Mitral valve - peak gradient	No
MV Vmax	Mitral valve - peak velocity	No
MV VTI	Mitral valve - velocity time integral	No
MV-ANNULUS A2CH	Mitral valve diameter 2 chamber view	No
MV-ANNULUS A4CH	Mitral valve annulus in apical 4 chamber view	No
MV-ANNULUS PLA	Mitral valve annulus in parasternal long axis	No
PA AD	Pulmonary Artery Annulus Diameter	No
PA LBD	Pulmonary Artery Left Branch Diameter	No
PA RBD	Pulmonary Artery Right Branch Diameter	No
PR JA	Pulmonary Regurgitation Jet Area	No
PR JA	Pulmonary regurgitation - jet area	No
PR MG	Pulmonary Regurgitation Mean Gradient	No
PR PG	Pulmonary Regurgitation Peak Gradient	No
PR VC	Pulmonary Regurgitation Vena Contracta	No
PR VC	Pulmonary regurgitation - vena contracta	No
PR Vmax	Pulmonary Regurgitation Peak Velocity	No
PR VTI	Pulmonary Regurgitation Maximum Velocity Time Integral	No
PR-grade	Pulmonary Artery Regurgitation Grade	No
PS-grade	Pulmonary Artery Stenosis Grade	No
PV MG	Pulmonary Valve Mean Gradient	No
PV PG	Pulmonary Valve Peak Gradient	No

Abbreviation	Description	Automated
PV Vmax	Pulmonary Valve Peak Velocity	No
PV VTI	Pulmonary Valve Maximum Velocity Time Integral	No
RA Major (A4)	Right Atrial Major Axis Dimension (A4Ch)	Yes
RA Major i (A4)	Right Atrial Major Axis Dimension Index (A4Ch)	Yes
RA Minor (A4)	Right Atrial Minor Axis Dimension (A4Ch)	Yes
RA Minor i (A4)	Right Atrial Minor Axis Dimension Index (A4Ch)	Yes
RA volume	Right Atrium Volume	Yes
RAA	Right Atrial Area	Yes
RAAi	Right Atrial Area Index	Yes
RAP	Mean right atrium pressure	No
RAVi	Right Atrium Volume Index (2D)	Yes
RV EDA	Right Ventricle End Diastolic Area	Yes
RV EDai	Right Ventricle End Diastolic Area index	Yes
RV EDV	Right Ventricle End Diastolic Volume	Yes
RV EDVi	Right Ventricle End Diastolic Volume Index	Yes
RV ESA	Right Ventricle End Systolic Area	Yes
RV ESAi	Right Ventricle End Systolic Area index	Yes
RV ESV	Right Ventricle End Systolic Volume	Yes
RV ESVi	Right Ventricle End Systolic Volume Index	Yes
RV WT	Right Ventricular Wall Thickness	No
RVB	Right Ventricular Basal Diameter	Yes
RVL	Right Ventricular Length	Yes
RVM	Right Ventricular Middle Diameter	Yes
RVOT-DIST	Right Ventricular Outflow Tract Distal Diameter (PLA)	No
RVOT-PROX	Right Ventricular Outflow Tract Proximal Diameter (PLA)	Yes

Abbreviation	Description	Automated
RWT	Relative Wall Thickness	Yes
S' RV	S prime right ventricle lateral wall	Yes
Se'	Septal e' velocity	Yes
STJ	Sinotubular Junction	Yes
STJi	Sinotubular Junction Index	Yes
SV	Stroke Volume (Biplane)	Yes
SV2A	Stroke Volume (A2CH)	Yes
SV4A	Stroke Volume (A4CH)	Yes
TAPSE	Tricuspid Annular Plane Systolic Excursion	No
TR EROA	Tricuspid regurgitation effective regurgitant orifice area	No
TR JA	Tricuspid regurgitation - jet area	No
TR MG	Tricuspid Regurgitation mean gradient	Yes
TR PG	Tricuspid Regurgitation peak gradient	Yes
TR PISA-Alias. Vel.	Tricuspid regurgitation proximal isovelocity surface area - aliasing velocity	No
TR PISA-r	Tricuspid regurgitation proximal isovelocity surface area - radius	No
TR VC	Tricuspid regurgitation - vena contracta	No
TR Vmax	Peak Tricuspid Regurgitation Velocity	Yes
TR VTI	Tricuspid regurgitation Velocity Time Integral	Yes
TR-grade	Tricuspid Valve Regurgitation Grade	No
TS-grade	Tricuspid Valve Stenosis Grade	No
TV MG	Tricuspid Valve Mean Gradient	Yes
TV PG	Tricuspid Valve Peak Gradient	Yes
TV Vmax	Tricuspid Valve Peak Velocity	Yes
TV VTI	Tricuspid Valve Velocity Time Integral	Yes
TV-ANNULUS	Tricuspid valve annulus	No

Abbreviation	Description	Automated
Velocity	Velocity	No
Volume	Volume	No