





Ligence Heart

For 3.14.0 or later version

INSTRUCTIONS FOR USE

English

CE
0197

| | Name | Role | Date | Signature |
|---------------------|-----------------|------|------------|---|
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| Approved by: | Indra Raudonė | QSR | 2023-01-10 |  |

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UAB Ligence

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

Table of Contents

| | |
|--|-----------|
| Table of Contents | 4 |
| 1. READ THIS FIRST..... | 7 |
| 1. About the Instructions for Use (IFU)..... | 7 |
| 2. Symbols | 7 |
| 3. Markets and foreign language support..... | 8 |
| 4. Reporting security issues | 8 |
| 5. Intended use | 9 |
| 6. General description | 9 |
| 7. Marketing brochure | 10 |
| 8. User groups..... | 11 |
| 9. Indications and contraindications | 11 |
| Indications | 11 |
| Contraindications | 11 |
| 10. Principles of operation of the device | 13 |
| Manual functionalities..... | 13 |
| Automatic functionalities | 13 |
| 11. Explanation of any novel features | 13 |
| 12. Description of all configurations/variants of the product..... | 14 |
| 13. General description of key functional elements | 14 |
| 14. Benefits of using Ligence Heart | 15 |
| 15. Clinical Benefits..... | 16 |
| 16. Commencement and Termination of Use | 16 |
| 17. Customer Service..... | 16 |
| 2. SAFETY | 16 |
| 1. Summary of Clinical Evaluation Report..... | 17 |
| 18. Residual Risks | 17 |
| 19. Personal Data Security Breach | 17 |
| 20. Serious Incidents Reporting | 17 |
| 21. Data Handling | 17 |
| 22. Installation, Maintenance | 18 |
| 23. User Views | 19 |
| 24. Patient/User Safety | 19 |
| 25. Measurements | 19 |
| Safety of Manual Functionalities | 20 |
| Safety of Automatic Functionalities | 20 |
| 26. IT security measures..... | 21 |

| | | |
|-------------|--|-----------|
| 27. | List of known bugs | 21 |
| 3. | REQUIREMENTS AND INSTALLATION | 22 |
| 3.1. | USER INTERFACE ELEMENTS | 22 |
| 1. | User Views | 22 |
| 1. | Login View..... | 23 |
| 2. | Lobby View..... | 23 |
| 3. | Administrator Panel View | 24 |
| | Registration view (demo mode) | 24 |
| 4. | Upload View | 25 |
| 5. | Search View | 25 |
| 5. | Workspace View | 26 |
| 6. | Strain View | 27 |
| 7. | Report View..... | 27 |
| 8. | Print Report View | 28 |
| 28. | Workspace view elements | 28 |
| | Navigation Bar..... | 29 |
| | Left Sidebar..... | 29 |
| | Workspace | 29 |
| | Right Sidebar | 29 |
| 4. | WORKING WITH LIGENCE HEART | 29 |
| 1. | How to acquire images..... | 29 |
| 29. | Logging on | 30 |
| 30. | Settings Menu | 30 |
| 31. | Admin..... | 31 |
| 32. | Detailed search | 32 |
| 33. | Upload the study..... | 33 |
| | How to upload a study?..... | 33 |
| 34. | Color picker..... | 34 |
| 35. | Sidebar tools | 35 |
| 36. | Changing Password..... | 37 |
| 37. | Logging Off | 37 |
| 38. | Locking the software..... | 37 |
| 39. | Customization | 37 |
| 40. | Legal and Helpful information | 37 |
| 41. | Keyboard shortcuts..... | 38 |
| 42. | Report an issue | 39 |
| 43. | Help..... | 40 |
| 44. | Navigation Bar buttons and functions | 41 |
| 45. | Workspace buttons and functions | 43 |

| | | |
|-----------|---|-----------|
| 46. | Left sidebar buttons and functions | 44 |
| 47. | Right Sidebar buttons and functions | 46 |
| 48. | Study reporting | 46 |
| 49. | Main Interface Functions | 50 |
| | Scroll stack | 50 |
| | Making measurements | 50 |
| | Draw area measurement | 51 |
| | Draw volume measurement | 51 |
| | Grade measurements | 51 |
| | Delete annotation | 51 |
| | Cancel drawing | 51 |
| 50. | About | 51 |
| 51. | End-User License Agreement | 52 |
| 52. | User Registration | 53 |
| | How to register with Ligence Heart? | 53 |
| 5. | ANNEX I | 53 |
| 1. | List of Annotations | 53 |
| 53. | List of Supported View Modes | 57 |
| 54. | List of Measurements | 60 |

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.

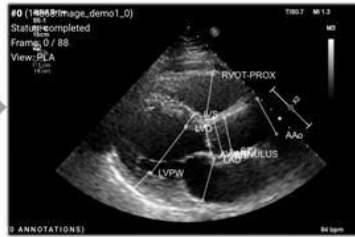
A complete list of Manual functionalities and Automatic functionalities can be found in the IFU and System requirement specification.

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

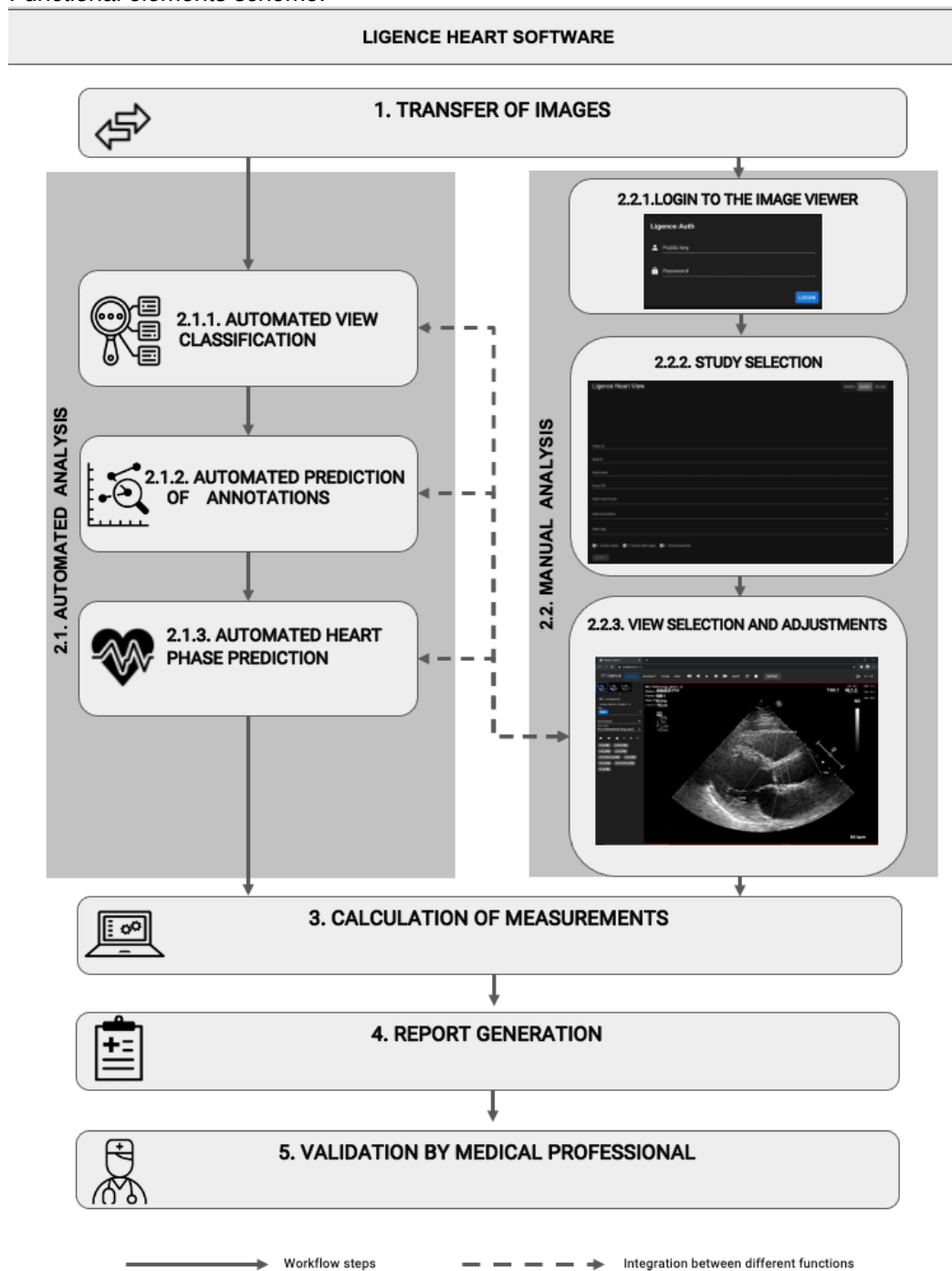
Ligence Heart offers novel functionality that allows automatic analysis of a number of heart structure and function parameters. Therefore, the parameters that are analyzed themselves are not novel, but the automation of some of these measurements is novel (none of the manual functionalities are novel).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

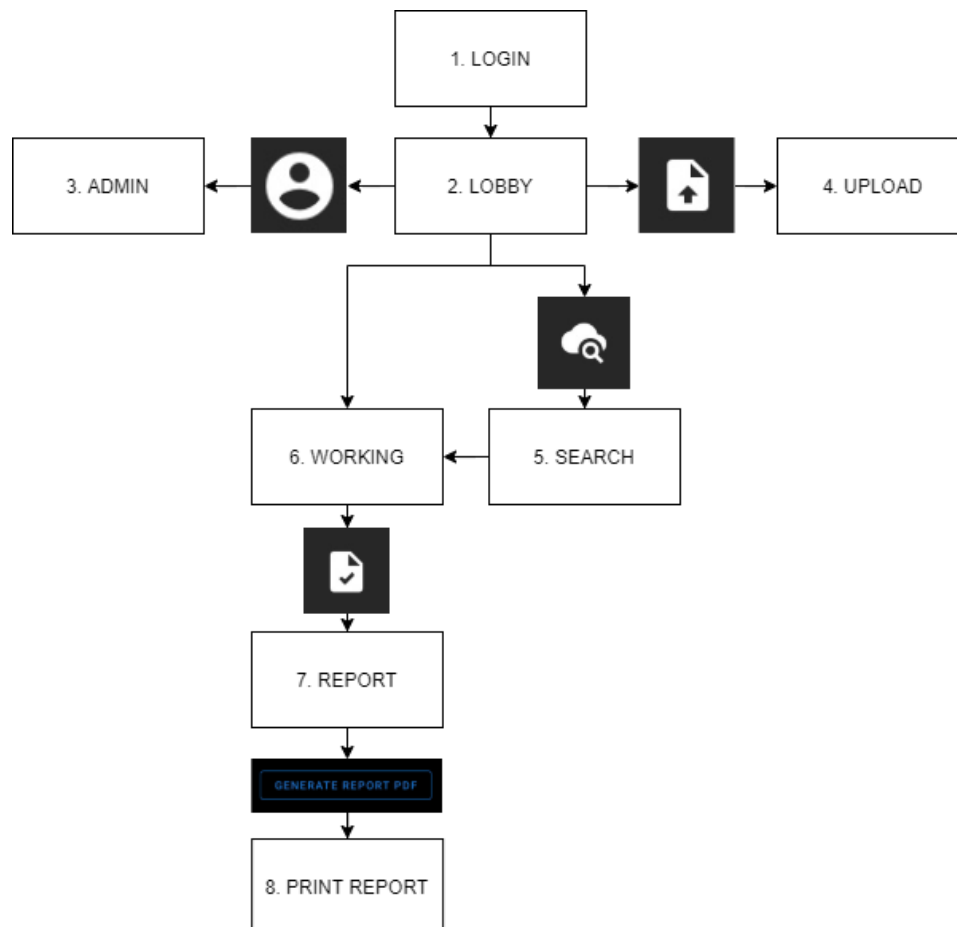
1. User Views

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.



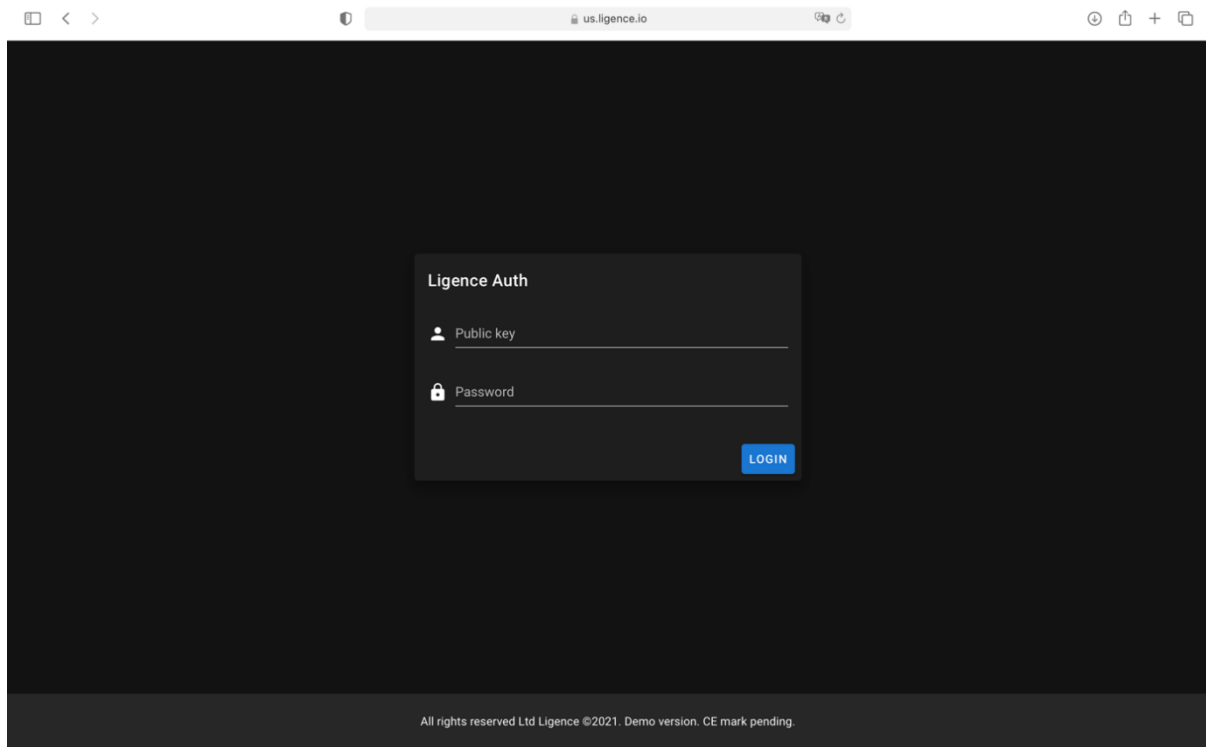
NOTE

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.

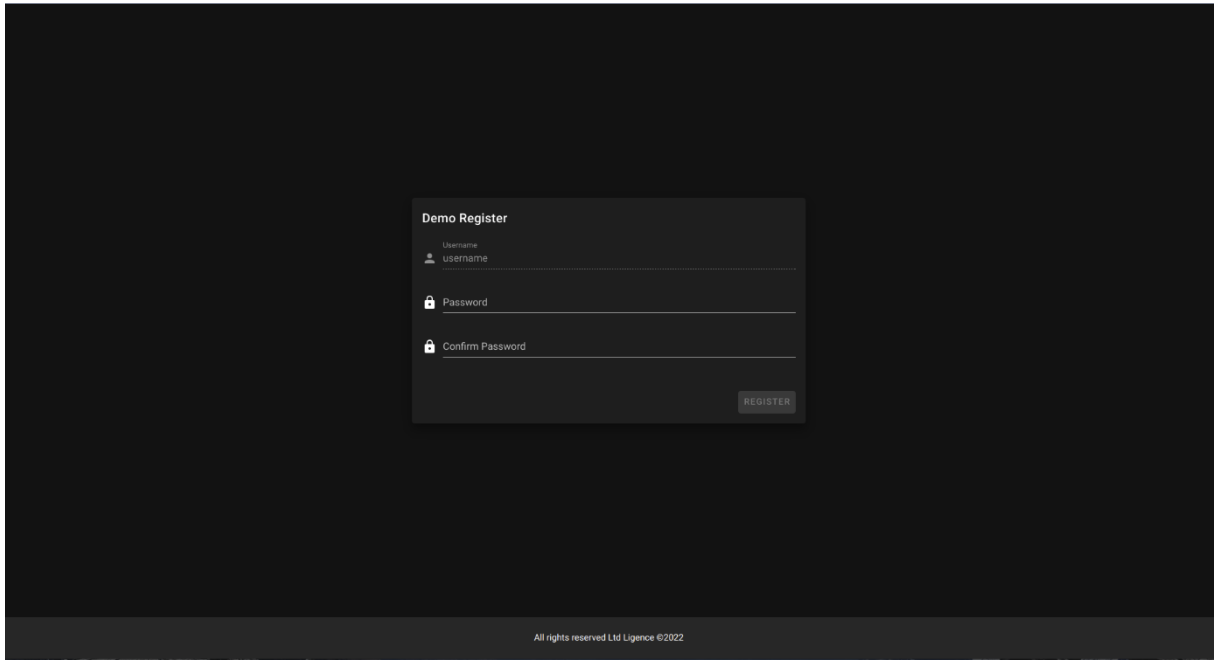


NOTE

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.



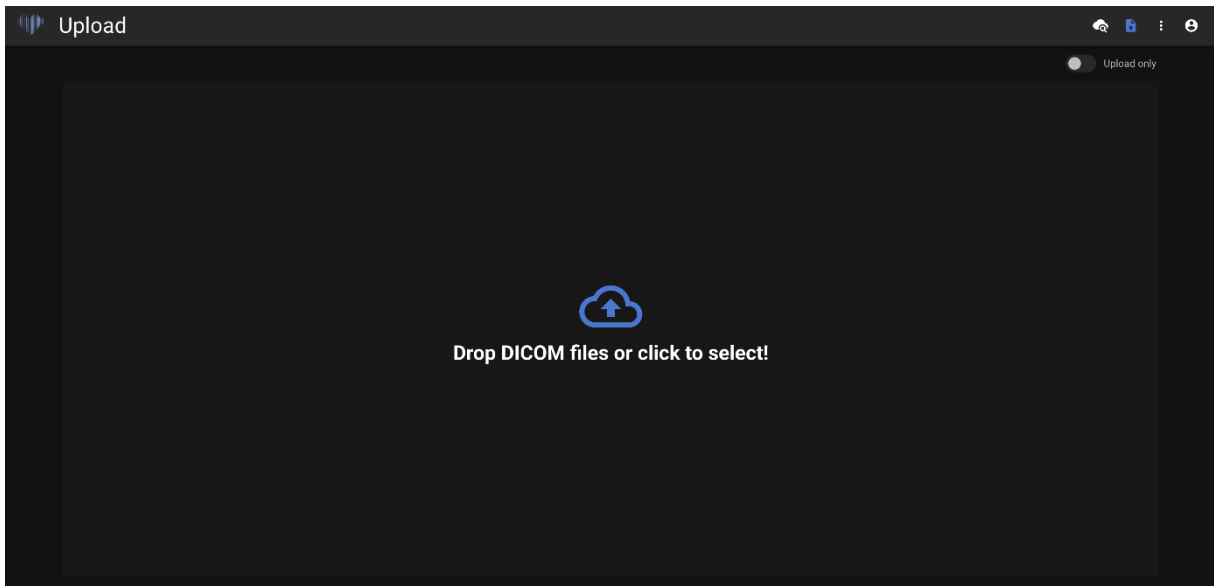
The client must enter password and then repeat the exact same password. Password must contain at least 8 characters. After that – a new user account is created, and the user is redirected to lobby view.

4. Upload View

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

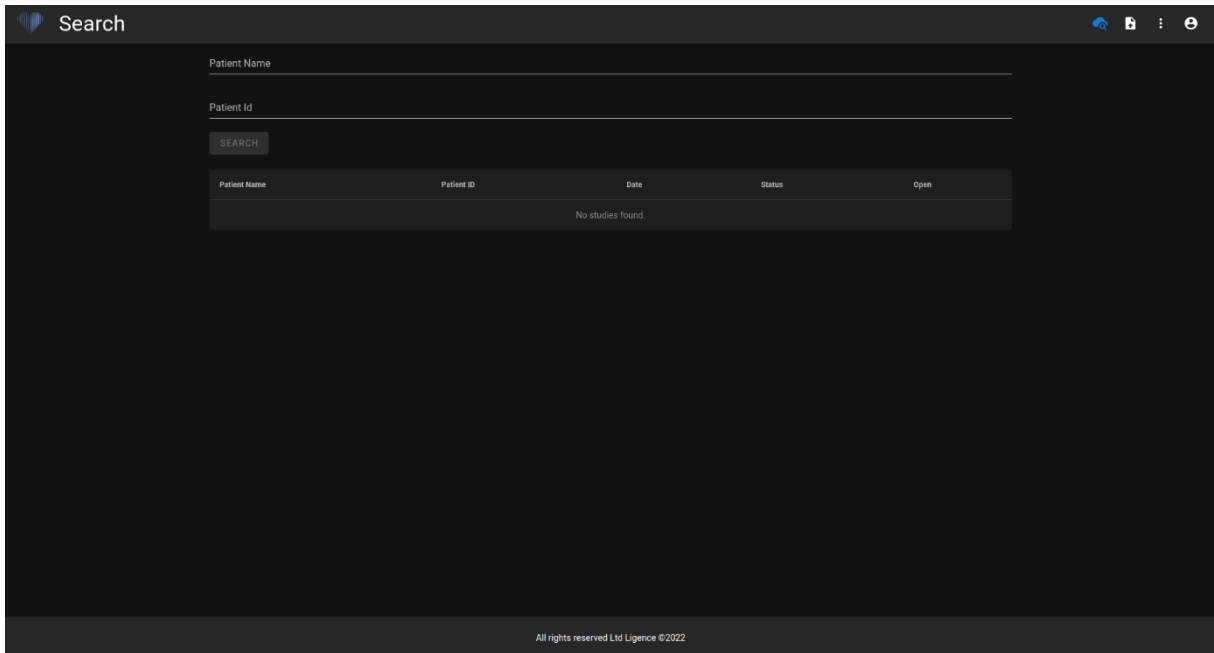
NOTE

Only DICOM format studies are supported.



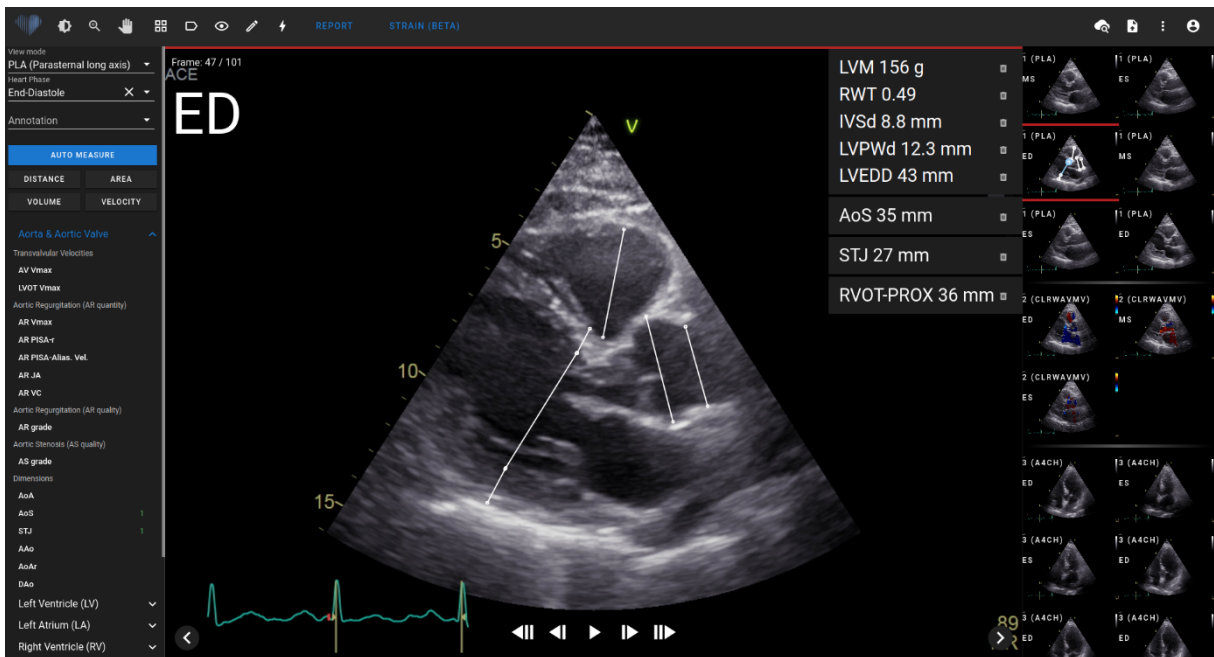
5. Search View

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

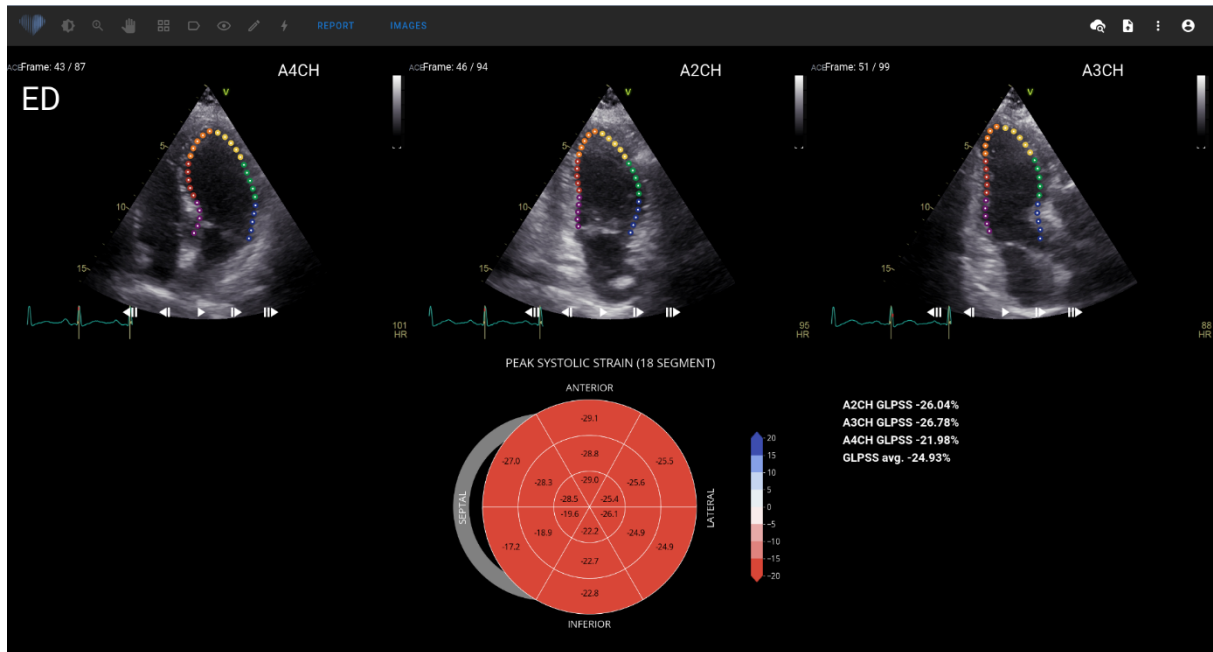


5. Workspace View

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.

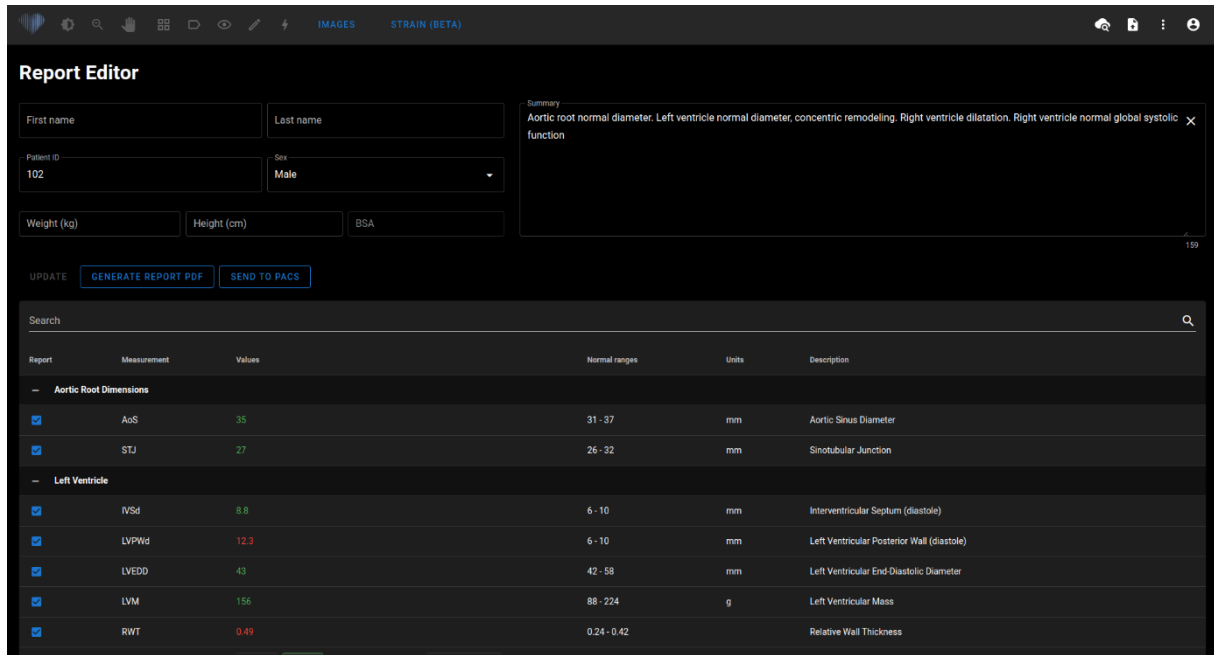


NOTE

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

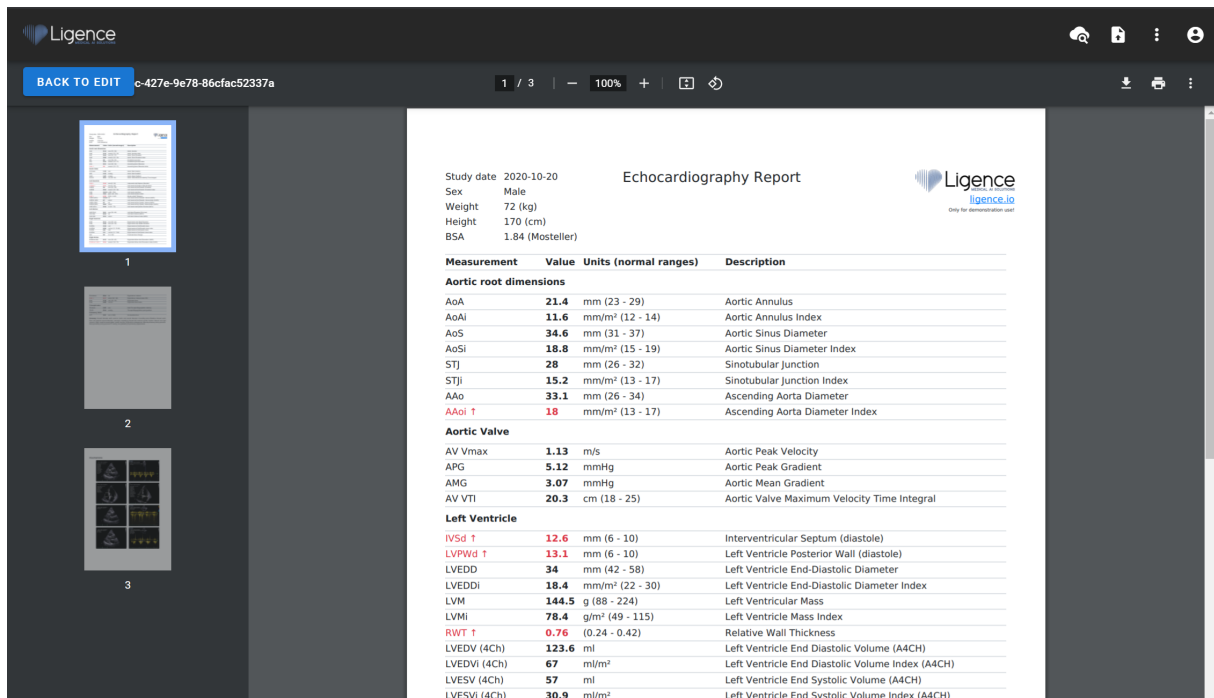
“Standardization of adult transthoracic echocardiography reporting in agreement with recent chamber quantification, diastolic function, and heart valve disease recommendations: an expert consensus document of the European Association of Cardiovascular Imaging 2017”

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



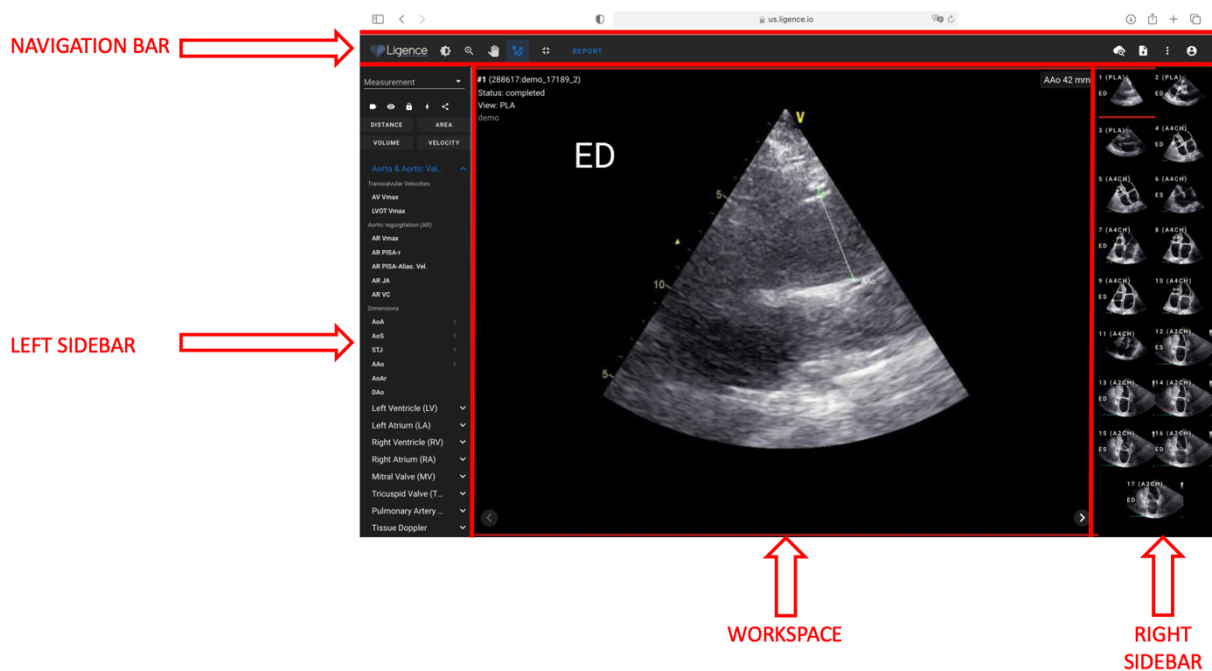
8. Print Report View

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.



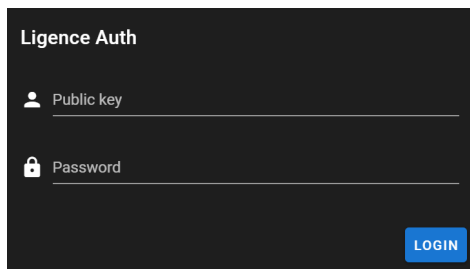
NOTE

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.

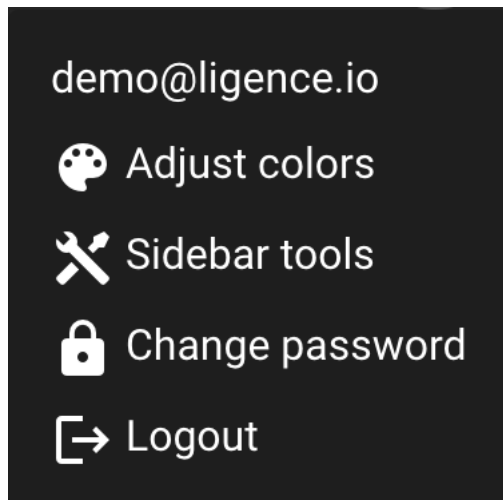


Upon pressing the Settings button, a drop-down menu will appear.

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.



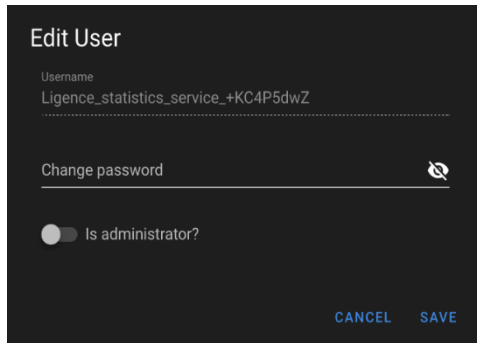
You can enable/disable Administrator rights to each of the users by pressing the slider button.



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.



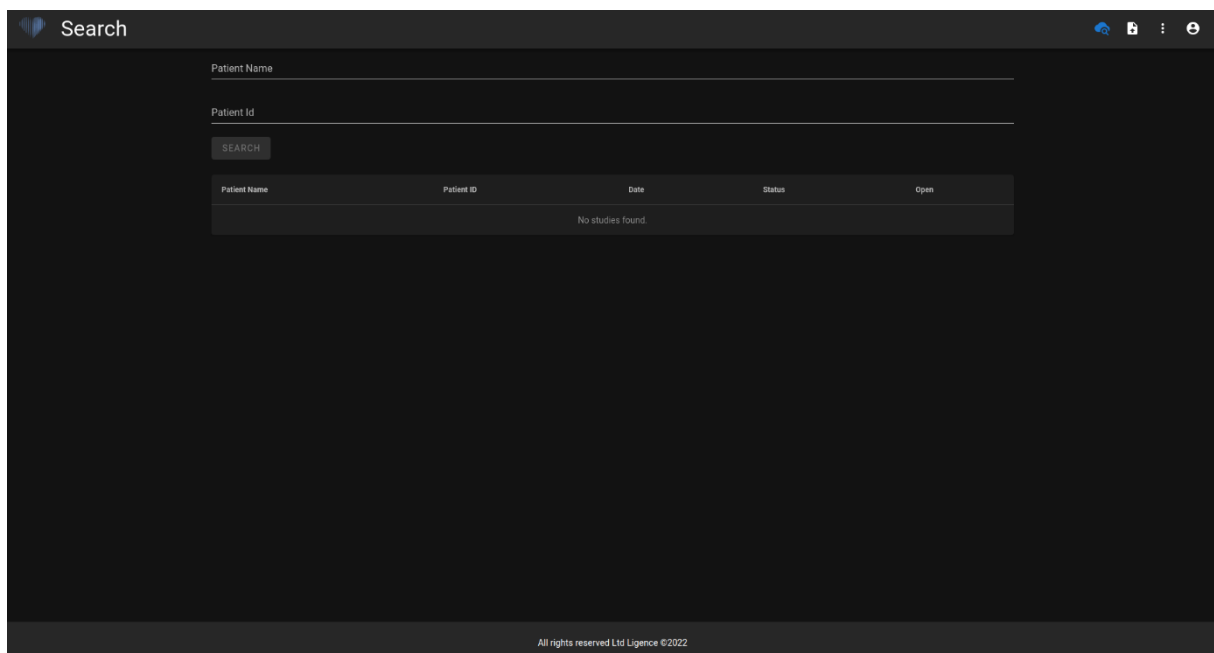
32. Detailed search

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.

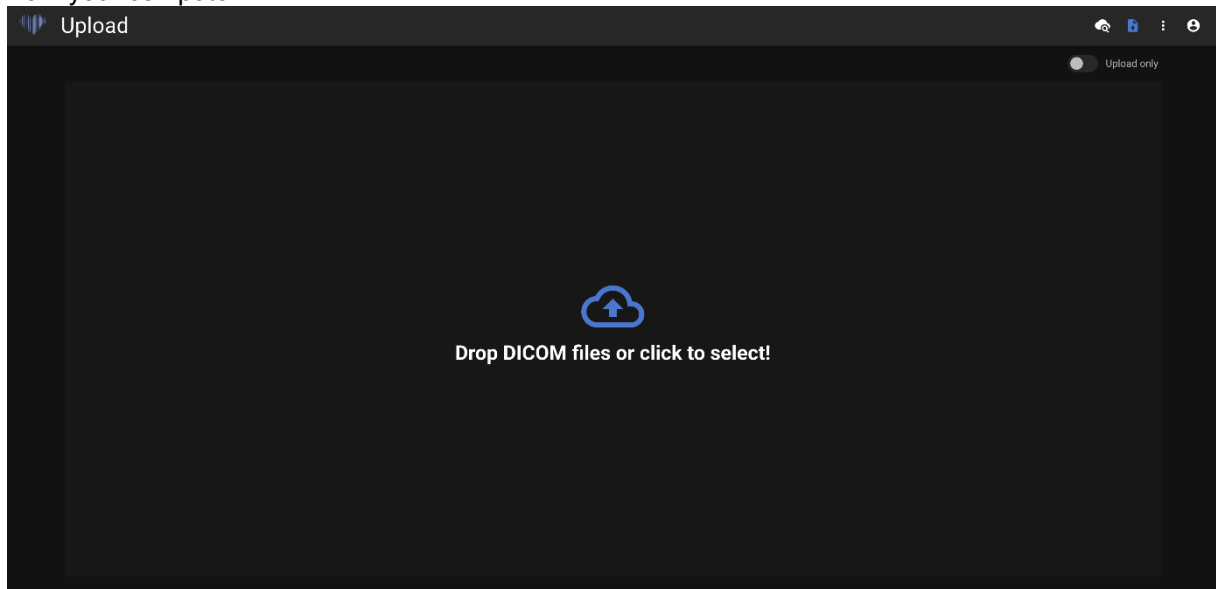
33. Upload the study

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.

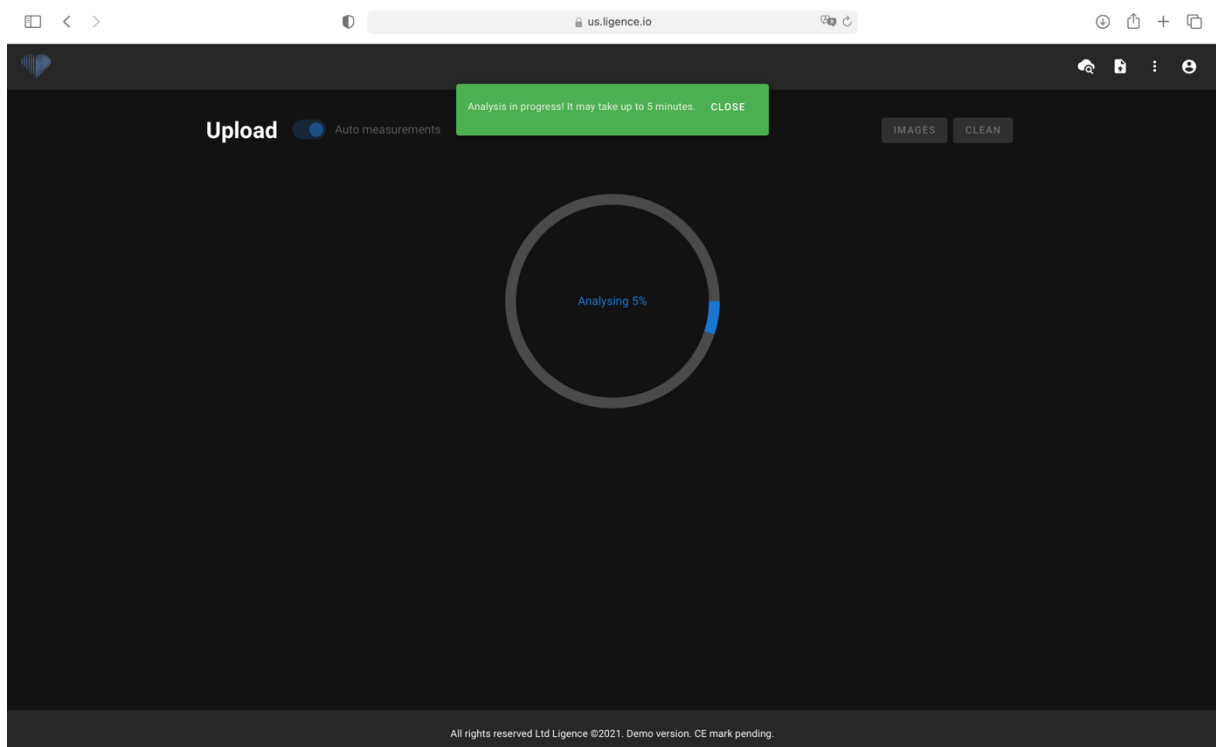


How to upload a study?

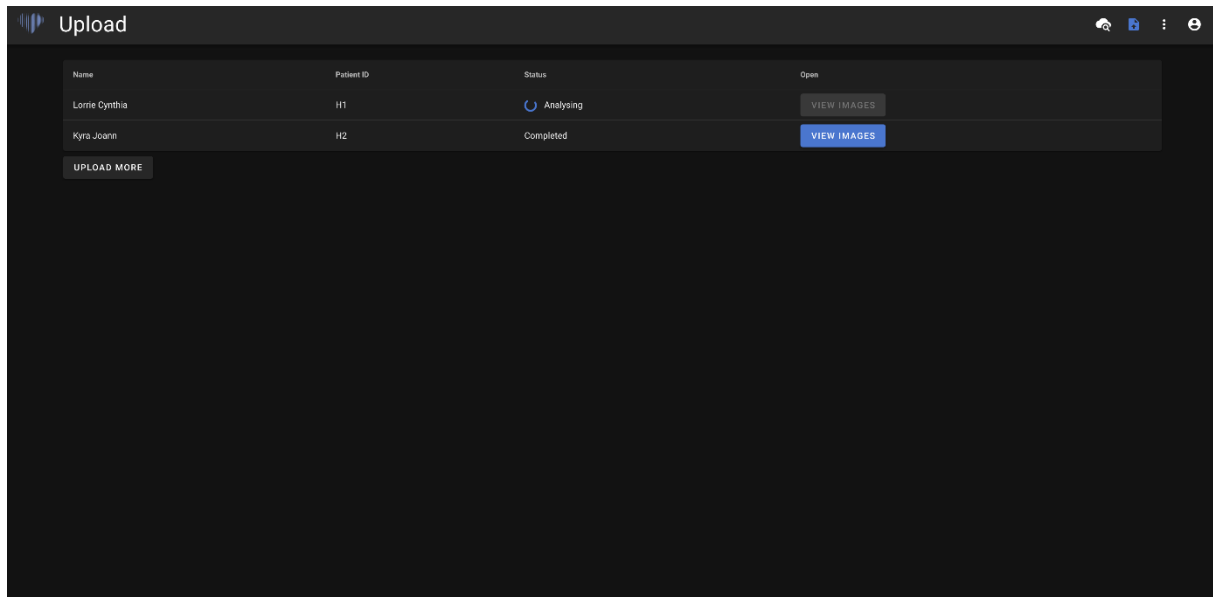
To upload a study simply drag and drop your DICOM format file or press on the blue icon and upload it from your computer.



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.



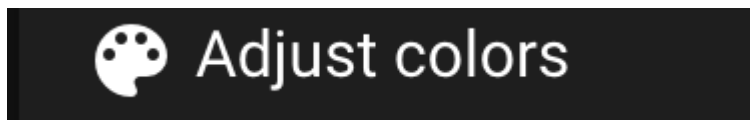
A list of studies uploaded is displayed. Once the study is analysed, you can click “view images” to review.

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.



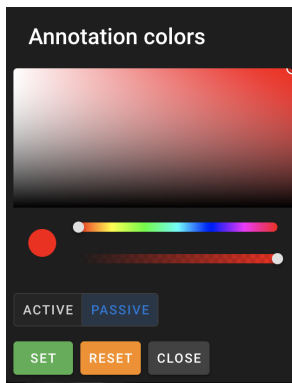
For actively used annotations press “ACTIVE”. This will take effect and all the annotations, upon hovering the mouse cursor on them, will be colored with the color the user has selected.

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.

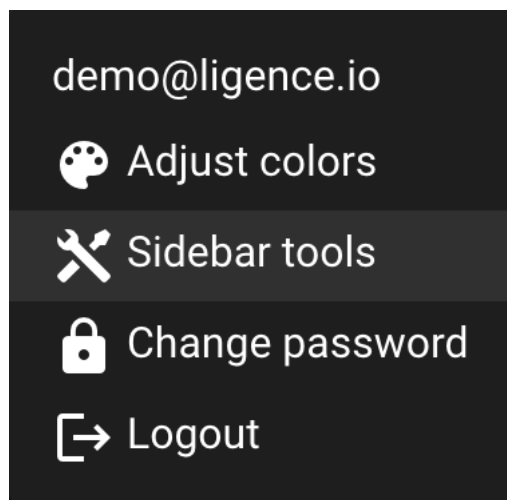
To reset your choice for color for your annotations, press RESET.



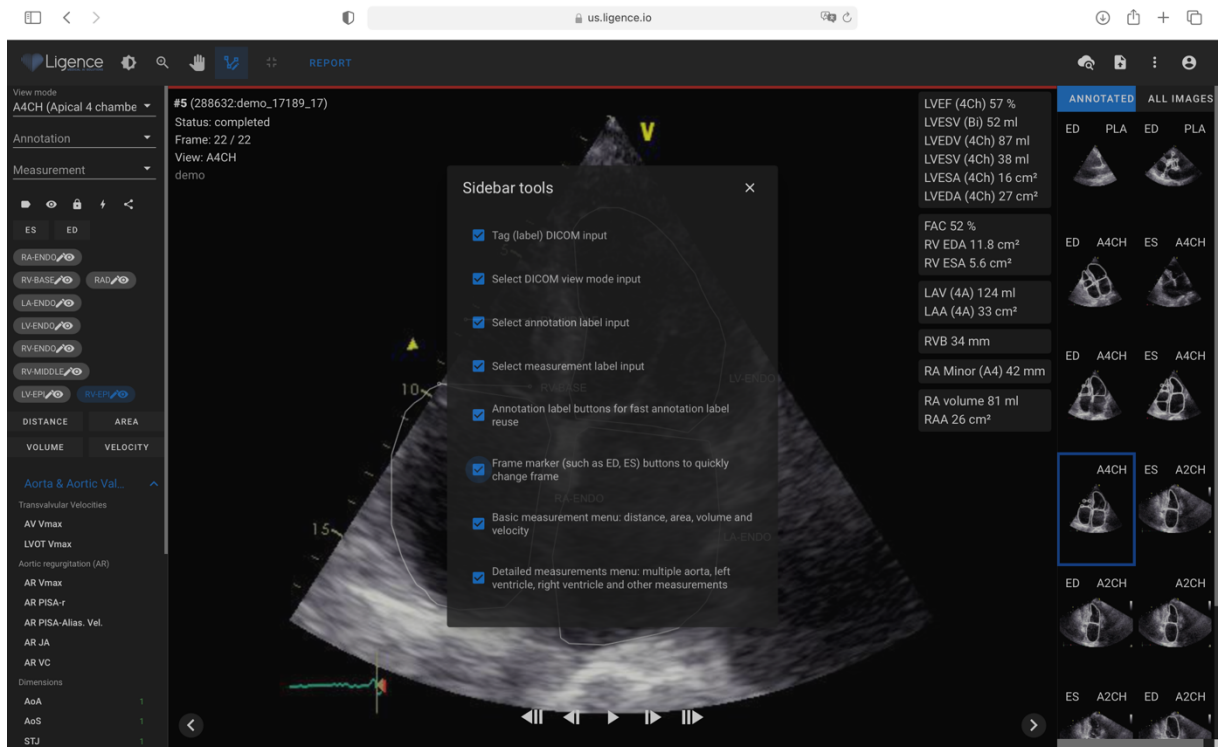
Multiple screen work is supported for Ligence Heart.

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, ED) 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.

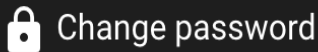
Frame marker buttons allow to quickly jump to a different frame of a particular phase of the heart cycle.

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

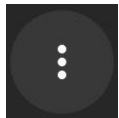
When you are done working with the software or have to leave for a short period of time we recommend logging off either way to prevent unwanted use by other people.

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

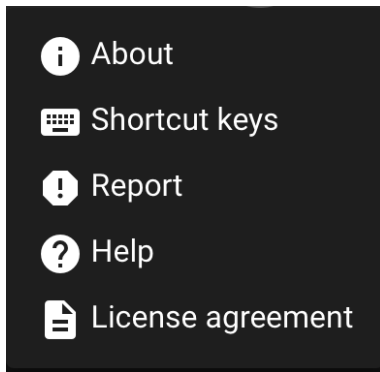


bar.

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.

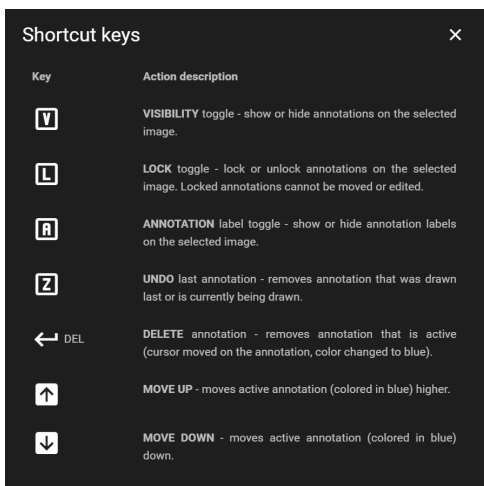


41. Keyboard shortcuts

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.

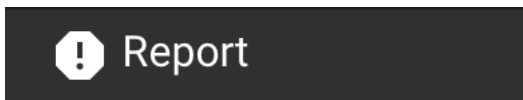
| Function | Keyboard shortcut |
|--------------------------|-------------------|
| Hide all annotations | V |
| Lock all annotation | L |
| Show/hide labels | A |
| Delete last annotation | Z |
| Delete active annotation | Delete, backspace |
| Cancel drawing | ESC |

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

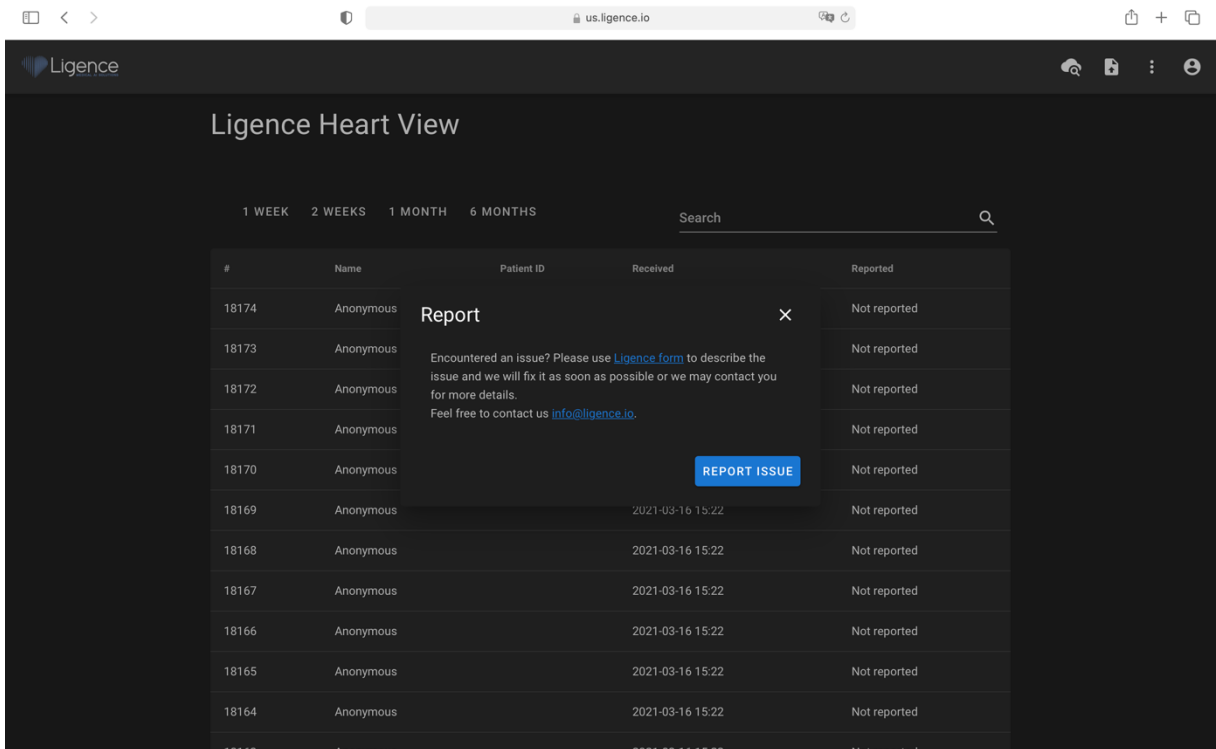
42. Report an issue

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.

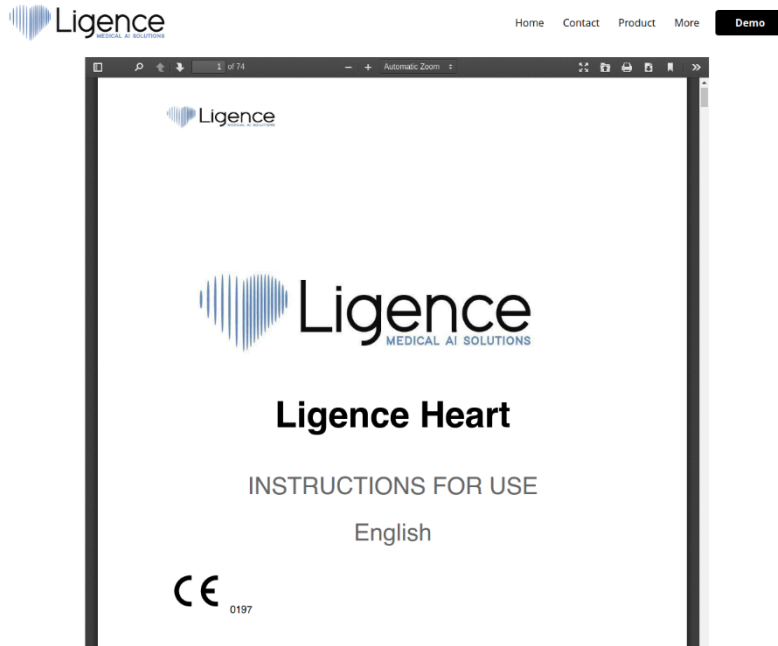
43. Help

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.






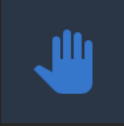



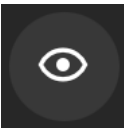


44. Navigation Bar buttons and functions

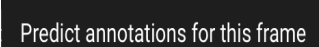
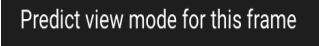
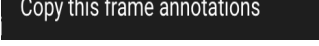


This section covers the Navigation Bar in the Working View. It provides easy access to the most often used functions on the screen

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. |
|  | Strain | Enters the Strain 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.

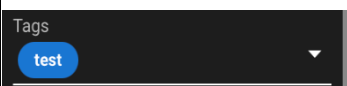
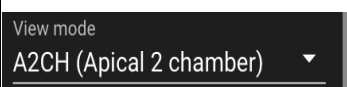


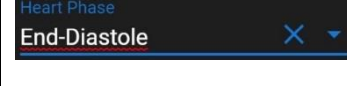

| Icon | Name | Function |
|---|-------------------------|---|
|  | Jump to the first frame | Scrolls back the image stack to the very first frame. |
|  | Move back one frame | Moves to the previous frame. |
|  | Play cine | Auto plays the frame stack in a continuous loop. |

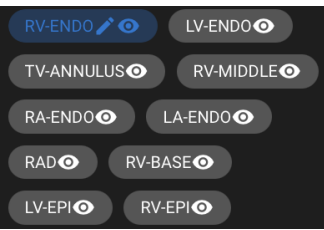





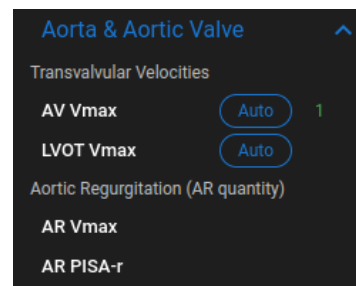
| | | |
|---|-------------------------------------|---------------------------------------|
|  | Move forward one frame | Moves to the next frame. |
|  | Move to the last frame | Jumps to the last frame of the stack. |
|  | Navigate to the previous image view | Opens the previous image view. |
|  | Navigate 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:

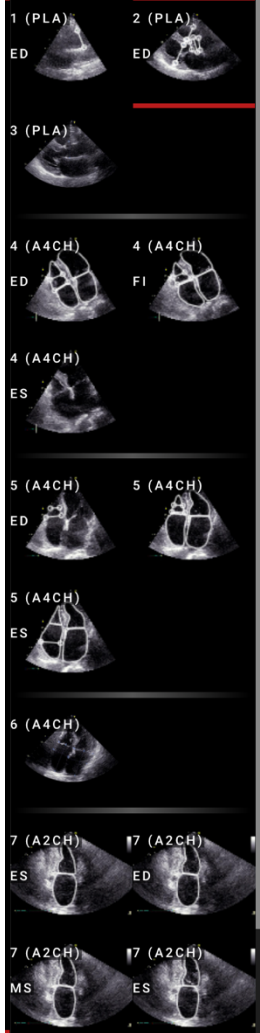
| Icon | Name | Function |
|---|------------------------------|--|
|  | Tags pop-up menu slot | Allows the user to select custom tags for the echocardiography studies. Press the arrow to select tags to be shown in the viewer |
|  | View mode pop-up menu slot | Allows the user to select the view mode 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

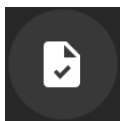
Right Sidebar displays all image views of a particular study and allows easy navigation between them.

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

| Icon | Name | Function |
|--|--------------------|--|
|  | Image view display | <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

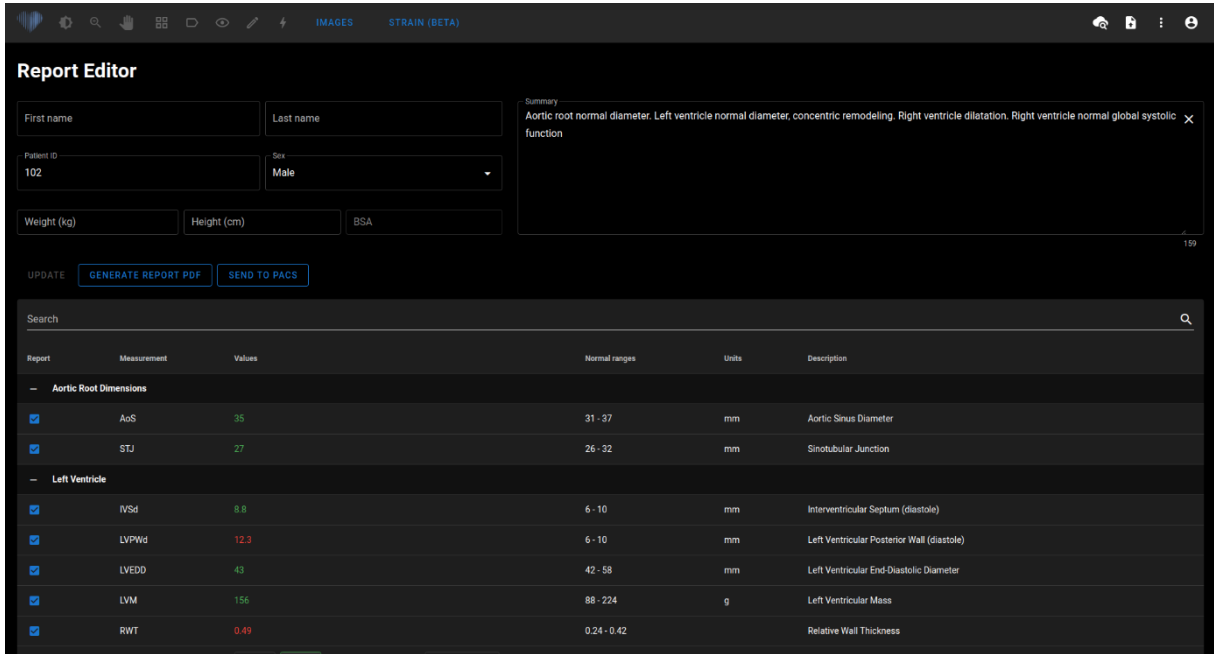
To enter the **Report View** press the View Study Report button in the Navigation bar.



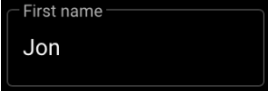
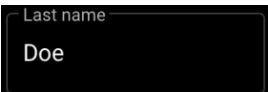

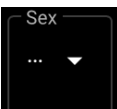
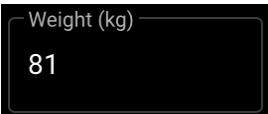
If you decide to go back to the Working View press the Back to study images button.

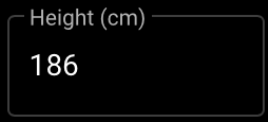
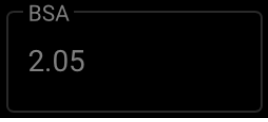
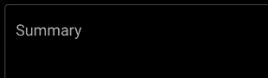




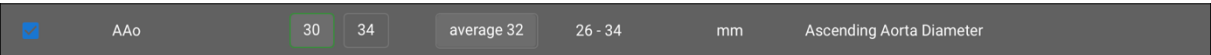


To send the report to your PACS/HER, press the Send Report button:



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 |
|  | Sex | Allows you to choose patient sex. |
|  | Weight | Allows you to enter patient weight in kilograms. |

| Icon | Name | Function |
|--|-------------------------|---|
|  | 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:

Ligence

[EDIT REPORT](#)
[DOWNLOAD REPORT](#)
[VIEW IMAGES](#)

Report

 1 / 3 | - 100% + |

Study date 2021-03-08


Sex Male

Weight -

Height -





BSA -


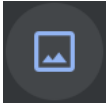
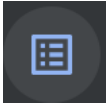
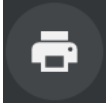
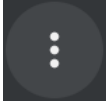
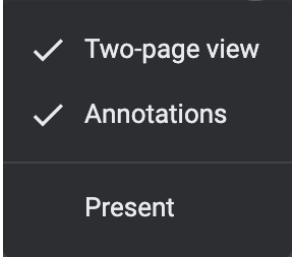
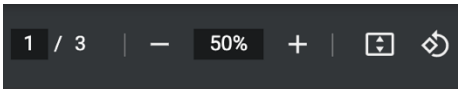
Echocardiography Report



Only for demonstration use!

| Measurement | Value | Units (normal ranges) | Description |
|-------------------------------|-------|-----------------------|---|
| Aortic Root Dimensions | | | |
| AoS | 36.3 | mm (31 - 37) | Aortic Sinus Diameter |
| STJ | 29 | mm (26 - 32) | Sinotubular Junction |
| AAo ↑ | 42.4 | mm (26 - 34) | Ascending Aorta Diameter |
| Left Ventricle | | | |
| IVSd ↑ | 14.1 | mm (6 - 10) | Interventricular Septum (diastole) |
| LVPWd ↑ | 10.6 | mm (6 - 10) | Left Ventricular Posterior Wall (diastole) |
| LVEDD | 47.1 | mm (42 - 58) | Left Ventricular End-Diastolic Diameter |
| LVM | 220.8 | g (88 - 224) | Left Ventricular Mass |
| RWT ↑ | 0.52 | (0.24 - 0.42) | Relative Wall Thickness |
| LVEDV (4Ch) | 87.4 | ml | Left Ventricular End Diastolic Volume (A4CH) |
| LVESV (4Ch) | 37.9 | ml | Left Ventricular End Systolic Volume (A4CH) |
| LVEDV (2Ch) | 18.7 | ml | Left Ventricular End Diastolic Volume (A2Ch) |
| LVESV (2Ch) | 61.1 | ml | Left Ventricular End Systolic Volume (A2Ch) |
| LVEF (4Ch) | 56.6 | % (52 - 72) | Left Ventricular Ejection Fraction (A4Ch) |
| LVEF (2Ch) ↓ | 51.6 | % (52 - 72) | Left Ventricular Ejection Fraction (A2Ch) |
| LVEF (Bi) ↓ | 1.78 | % (52 - 72) | Left Ventricular Ejection Fraction (Biplane) |
| LVESV (Bi) | 51.6 | ml (21 - 61) | Left Ventricular End Systolic Volume (Biplane) |
| LVEDV (Bi) | 50.9 | ml (62 - 150) | Left Ventricular End Diastolic Volume (Biplane) |
| LVEA (2Ch) | 22.3 | cm ² | Left Ventricular End Systolic Area (A2CH) |
| LVEDA (2Ch) | 9.46 | cm ² | Left Ventricular End Diastolic Area (A2CH) |
| Left Atrium | | | |

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

| Icon | Name | Function |
|---|--|---|
|  | 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.

i About

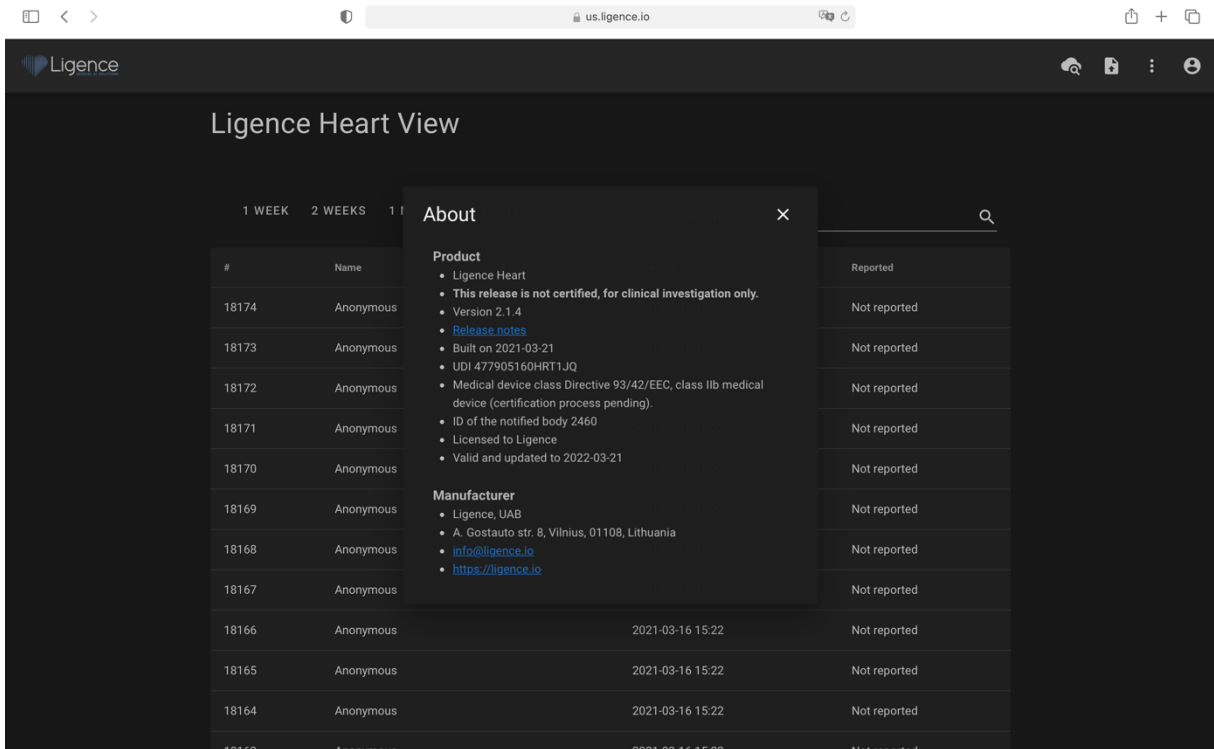
The displayed information on:

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

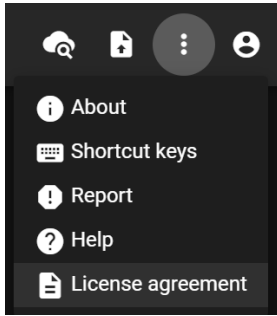
Manufacturer:

- 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 |
| LV-ENDO | Left ventricular endocardial border | Yes |
| LV-EPI | Left ventricular epicardial border | No |

| Abbreviation | Description | Automated |
|--------------|---|-----------|
| 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 |
| LVPW | Left ventricular posterior wall | Yes |
| LVD | Left ventricular diameter | Yes |

| Abbreviation | Description | Automated |
|-----------------|--|-----------|
| 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 |
| PV | Pulmonary valve | No |
| PV-ANNULUS | Pulmonary valve annulus (equivalent to RVOT-DIST) | No |

| Abbreviation | Description | Automated |
|----------------|---------------------------------------|-----------|
| 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 |
| ES | End-systole | Yes |
| ED | End-diastole | Yes |

| Abbreviation | Description | Automated |
|--------------|--|-----------|
| 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 |
| CLRWAV3CH | Color flow Doppler aortic valve (apical 3 chamber) | No |
| CLRWAV5CH | Color flow Doppler aortic valve (apical 5 chamber) | No |

| Abbreviation | Description | Automated |
|--------------|---|-----------|
| 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 |
| CLRWTVA | 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 |
| CWTV5CH | Continuous-wave Doppler tricuspid valve (apical 5 chamber) | No |

| Abbreviation | Description | Automated |
|----------------------|---|-----------|
| 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 |
| PWLVTOT | 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 |
| CLRWDAAO | 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 |
| PWTV | Pulsed-wave Doppler Tricuspid Valve | No |

| Abbreviation | Description | Automated |
|--------------|--|-----------|
| OTHER_BMODE | Do not fit any category in BMode | No |
| OTHER_CW | Do not fit any category in Continuous-wave Doppler | No |
| OTHER_PW | Do not fit any category in Pulsed-wave Doppler | No |
| OTHER_TDPW | Do not fit any category in Tissue Doppler | No |
| OTHER_CLRW | Do not fit any category in Color Doppler | No |
| OTHER_MMODE | Do not fit any category in MMode | 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 PHT | Aortic Valve Regurgitation Pressure Half-Time | No |
| AR PISA-Alias. Vel. | Aortic regurgitation proximal isovelocity surface area - aliasing velocity | No |

| Abbreviation | Description | Automated |
|--------------|---|-----------|
| 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 |
| 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 |

| Abbreviation | Description | Automated |
|---------------------|--|-----------|
| 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 |
| 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 |

| Abbreviation | Description | Automated |
|--------------|---|-----------|
| 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 |
| LVESD | Left Ventricle End-Systolic Diameter | Yes |
| LVEDSi | 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 |

| Abbreviation | Description | Automated |
|--------------------|--|-----------|
| MV PHT | Mitral Valve Pressure Half-Time | 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 |
| 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 PHT | Pulmonary Valve Regurgitation Pressure Half-Time | No |
| PR VC | Pulmonary Regurgitation Vena Contracta | No |

| Abbreviation | Description | Automated |
|-----------------|--|-----------|
| 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 |
| 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 |

| Abbreviation | Description | Automated |
|---------------------|---|-----------|
| 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 |
| 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 |
| TV PHT | Tricuspid Valve Pressure Half-Time | No |
| 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 |

| Abbreviation | Description | Automated |
|---------------------|--|------------------|
| 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 |
| Velocity | Velocity | No |
| Volume | Volume | No |