Instructions for Use

English

Ultrasound Workspace 7.0

PHILIPS

Contents

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1 Read This First

CAUTION

U.S. Federal law restricts this product to sale by or on the order of a physician.

The Ultrasound Workspace user information is intended to assist you with the safe and effective operation of your product. Before attempting to use the product, read the user information and strictly observe all warnings and cautions.

The user information for your product describes the most extensive configuration of the product, with the maximum number of options and accessories. Some functions described may be unavailable on your product's configuration.

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About the Instructions for Use

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP IT FOR FUTURE REFERENCE

The instructions for use for Ultrasound Workspace are included in PDF format in the software.

1. Click ?. The **About** screen opens.
2. Click **Help** at the bottom of the screen.
3. The system displays the instructions for use in the configured system language in a new window or browser tab.

If the instructions for use are updated, you will also find the latest versions here: www.philips.com/ifu

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

Contact your local representative for technical support.

Information that is essential for the safe and effective use of your product appears throughout your instructions for use as follows:

WARNING

Warnings highlight information to avoid a hazardous situation, which could cause death or serious injury.

CAUTION

Cautions highlight information to avoid a hazardous situation, which could cause minor or moderate injury or equipment damage.

NOTE

Notes bring your attention to information that will help you operate the product more effectively.

Country Labels

To see labeling information for specific countries:

1. Click ?. The **About** screen opens.
2. Click **Documentation** at the bottom of the screen.
3. Double click the requested country label.

   The system displays the information required by local regulations in a new window or browser tab.

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If the country labels are updated, you will also find the latest versions here: www.philips.com/ifu

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

Contact your local representative for technical support.

Intended Use

The product is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities.

The product is not intended to be used for reading of mammography images.

Indication for Use

Indications for use of the product are quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physician in the diagnosis.

Contraindications

None known.

Intended Patient Population

The product is available for adult, pediatric, and fetal patient populations. Other than as specified in the product labeling, there are no patient population restrictions for the product.

Intended Clinical Benefits to Patients

The expected clinical benefits of the product are related to the device's intended purpose to view, quantify and manage ultrasound and catheterization laboratory (cath lab) image data. These clinical benefits can be broadly classified as providing standardized image analysis and quantification during and after ultrasound and cath lab examinations.

Intended User Group

The product is intended to be used only by licensed medical practitioners or assistant medical technicians.

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Intended Use Environment

Intended Use Environments are inside and outside of Hospitals, Clinics, and Physician´s offices.

Customer Service

Philips representatives are available worldwide to answer questions and to provide maintenance and service. Please contact your local Philips representative for assistance. You can also contact the following offices for referral to a customer service representative, or visit the "Contact Us" websites:

www.healthcare.philips.com/main/about/officelocator/index.wpd

TOMTEC Imaging Systems GmbH

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Support: + 49 89 321 75 740
E-Mail: support.UWS@philips.com

TOMTEC Corporation USA

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Support: +1 855 486 6832
E-Mail: support.UWS.NAM@philips.com

Philips Ultrasound LLC

22100 Bothell Everett Hwy
Bothell, WA 98021-8431, USA
Support: +1 800-722-9377

NOTE

Any serious incident occurring in connection with this Philips product shall be reported immediately to the manufacturer or Philips representative and the competent authority.

Symbols

The following symbols may be used on the system and its accessories and packaging:

Symbol	Standards and Reference	Reference Description	Additional Information
Rx only	FDA 21 CFR 801.109	--	USA federal law restricts this device to sale by or on the order of a physician.

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Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.1.3 ISO 7000-2497	Date of Manufacture	Identifies the date of manufacture.
	ISO 15223-1, Symbol 5.1.1 ISO 7000 - 3082	Manufacturer	Identifies the legal manufacturer.
	ISO 15223-1, Symbol 5.7.7	Medical Device	Identifies the product as a medical device.
	ISO 15223-1, Symbol 5.7.10	Unique Device Identifier	--
	ISO 15223-1, Symbol 5.1.5 ISO 7000-2492	Batch code	Batch code
	ISO 15223-1, Symbol 5.1.6 ISO 7000-2493	Catalogue number	Catalogue number
	ISO 15223-1, Symbol 5.1.10	Model number	Model number
	ISO 15223-1, Symbol 5.1.2	Authorized representative in the European Community/European Union	Indicates that the authorized representative is in the European Community/European Union.
	EU MDR 2017/745, Article 20, Annex V	CE Mark of Conformity	Indicates conformance with the European Medical Device Regulation 2017/745 (EU MDR).
	ISO 15223-1, Symbol 5.4.3 ISO 7000-1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use or electronic instructions for use (eIFU). When a symbol is accompanied by additional text, it denotes the location of the instructions for use.

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Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.4.4	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	--	Authorized representative in Switzerland	Indicates that the authorized representative is in Switzerland.

Data Handling

Please refer to the **Technical Specification** (www.philips.com/ifu) of the Philips product for data formats which can be read by this product.

- Data compression used for storing images from this product
- Minimum frame rate for acquiring datasets
- Data cropping of datasets which include more than 1 cardiac cycle

Transport, Storage and Disposal

Use the original packaging for safe transport and storage of the installation media. Store the installation media under the environmental conditions usual for office workstations, preferably in a dark place. Do not expose the installation media to direct sunlight and heat.

Dispose CD/DVD and the customer information according to the legal guidelines of your country. Recycle the materials mentioned before, if it is regulated by law in your country.

Lifetime Specification

- 2 years after product version termination if successor product version follows.
- 5 years in case no successor product version follows.

Contact your service representative for further information.

2 Safety

Carefully read the information of this section before using the product. This section contains important information on operating safety and handling of the product as well as information on service and support.

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CAUTION

U.S. Federal law restricts this product to sale by or on the order of a physician.

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.

CAUTION

For safe operation, this product must be used in an appropriate environment with, for example, suitable lighting and sound levels, to ensure optimal readability and minimal distractions.

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Data Handling

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

Due to our continuous development of leading-edge research products problems with your archive of research data may occur, in case:

- **Subsequent software versions or third party software use different data formats. (Relief: Store data on a separate hard drive.)**
- **Special measurement and archived views provided by one product version cannot be restored with future versions.**

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CAUTION

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

CAUTION

The displayed DICOM image information in the software comes from your DICOM device. Philips is not responsible for any incorrect or missing information due to a use error or device malfunction on the DICOM device itself.

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.

Installation and Maintenance

CAUTION

Only persons according to Intended User Group or IT experienced persons may perform installation, setup and upgrade.

Service and any configuration of this product shall be performed only by Philips or your local representative. Otherwise, warranty may be void.

CAUTION

Philips 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, Philips is not responsible for safety, reliability and performance of the system. Especially if:

- **Installation, configuration or modifications are performed by persons, who are not authorized by Philips.**
- **The product is not operated in accordance with the manual.**
- **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.

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CAUTION

The user is responsible for all changes to the system settings. This can lead to system damage and warranty void.

CAUTION

The user is responsible for the installation of any third party software. The software may be incompatible to Philips software. Contact your local representative for further information on installing third party software.

CAUTION

Log on as "Administrator" before licensing this product or module. The operation of some products depends on superior licenses.

CAUTION

The product is ready for use if the installation process is finalized without error messages.

NOTE

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

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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.

CAUTION

The information contained in this user manual is intended only for the operation of this product. It does not include information on images derived from imaging modalities like US, XA, NM or MR and how to acquire them. Please refer to the operating instructions of your imaging equipment for further information.

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Measurements

CAUTION

The user is required to determine whether the labeling of an image is correct. Double-check the stage, view and acquisition method of each image. Philips is not responsible for the correctness of image labeling.

CAUTION

In the case of a poorly reconstructed image, as determined by the above criteria or by the user's clinical experience and training, dimensional 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 contain ECG data. ECG data is intended only for basic rhythm identification, and not for diagnostic purposes.

CAUTION

The user is responsible for determining if the selected kind of manual calibration is suitable for the corresponding dataset. In case of incorrect usage incorrect measurement results may occur.

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 M-Mode, Doppler and 2D Images measurements only the desired and reasonable measurement packages should be used for the according images. In case of incorrect usage incorrect results may occur.

CAUTION

The user has to check ES and ED markers and correct their position if necessary.

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CAUTION

Measurement accuracy

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 manual 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.

Mandatory requirements for each measurement are the correct reproduction of the acquired anatomy and the performing of measurements according to the 'lege artis' standard. The accuracy of the Measurement Tools was verified on a representative test-phantom.

For information about measurement functions and their corresponding accuracy please refer to chapter “Measurements” on page 196.

CAUTION

The product was not developed to have an automatic diagnostic tool. It provides suggestions for contour finding and derives measurement values from them. It is the responsibility of the user to verify these results before making a diagnostic decision, even if this review occurs solely in a third-party solution that uses the results of this product. If there is any doubt as to the accuracy of these results, the contour finding and measurement values should be repeated using standard evaluation methods, considering the normal ranges for the given patient.

CAUTION

The user is responsible for the definition of cardiac contours in acquired views.

NOTE

3D Auto MV, **3D Auto RV**, **3D Auto TV**, **3D Auto CFQ** and **Semi-Automated Measurements** (**IMAGE-COM**) apply artificial intelligence for contour proposals. **2D Auto LV** uses artificial intelligence for automated segmental wall motion scoring.

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3 Security Considerations

CAUTION

The product must only be used within a secured, private network environment (e.g. only accessible from software clients inside of the network) that meets the minimum security requirements as defined for the specific setups for single seat and server client installations. For more information, see the **Technical Specification** (www.philips.com/ifu). Using the product otherwise is not secure and results in severe risk for disclosure of sensitive data or the integrity of the system in general. Philips is not responsible for any security incidents that may result from using the product beyond these restrictions.

Security standards like user identification, password handling or automatic timed session terminations are offered by this product. Further actions to support cybersecurity (e.g. security updates, malware protection or network communication protection) need to be taken by the local IT or Security/Cybersecurity responsible at user site.

Protection can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats. Following industry standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The practical implementation of technical security elements varies by site and may employ several technologies, including firewalls, virus-scanning software, authentication technologies, etc. As with any computer-based system, protection must be provided such that firewalls and/or other security devices are in place between the medical system and any externally accessible systems.

Following security and industry best practices, security strategies should address:

- Physical security: e.g. locks, cameras, keycards, sensors, and so on, for restricting unauthorized access.
- Operational security: e.g. access/authorization controls, change management, network segmentation based on data classification, password protection of BIOS, disabling booting from external drives like USB, disabling unused ports/services.
- Procedural security: e.g. unattended workstation locking, no sharing of access credentials, termination checklists, risk management (that is, performing risk assessments and mitigating identified risks), and so on.
- Security policies: e.g. ensuring that the system service documentation and media, CDs, and DVDs are securely stored; and that systems are in line with your IT security policies.
- Training and awareness;
- Contingency planning;

When installing a new system or upgrading an existing system, it is important to work with your IT department to ensure that the proper security measures and policies are in place.

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User Authentication

Ensure that Ultrasound Workspace host PCs are configured for user authentication and that the individuals using Ultrasound Workspace host PCs have a user name and password. You can use this information to protect the data in the folders and individual files. Use strong passwords for access to Ultrasound Workspace host PCs and data.

Operating System

Ensure that the operating system and applications on Ultrasound Workspace host PCs are kept current with patches, updates, and upgrades.

Network Security

If the Ultrasound Workspace host PC is connected to a local area network, the network should be securely configured, providing protection against computer viruses and other harmful code or traffic. Ensure that the local area network uses appropriate protection, such as using only secure wireless technologies, firewalls, intrusion-detection systems, and virus scanners.

Firewalls

The use of a firewall appliance as a good security practice is highly recommended. It is advised that the customer takes proper precautions to limit, control or eliminate unwanted access.

You can obtain a list of the ports, services and protocols that must be configured in the firewall from your service representative.

Remote Administration

If remote administration is used on the Ultrasound Workspace host PCs, ensure that they are configured for secure remote administration.

Malware Prevention and Detection

Security safeguards to protect the system against the intrusion of malware (viruses, Trojans, worms,) are recommended. Malware prevention software should be configured to receive automatic updates. Additionally, be sure to adhere to local IT policies and procedures regarding malware infection, which may include disconnecting from the network until the situation is resolved.

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Operational Security

CAUTION

To keep the system secure, it is recommended to follow proper operational security measures like:

- **Password-protected BIOS**
- **Disallow booting from external drives in the boot order.**
- **Disable unused I/O device interfaces.**
- **Disable unused services and ports.**
- **Control physical access to the product. Only authorized personnel should have access.**
- **Create and enforce policies that ensure unauthorized users cannot gain access.**

Physical Security and Limited Access to Systems

CAUTION

It is important to consider physical security measures like keeping the system in a secure location, limiting access to only authorized personnel, proper locking measures, card-key or other access limitations, and so on. Access to systems must be limited to authorized users and controls must be implemented to ensure that unauthorized users cannot gain access.

NOTE

Contact your service representative for further information.

Protecting Personal Information

It is essential that policies and procedures for the proper handling of personal or sensitive data are in place. Consider the confidentiality, integrity, and the availability of the types of data. Each organization using this product must provide the protective means necessary to safeguard personal information consistent with each country law, code and regulation, and consistent with the company policies for managing this information.

Although the handling of personal data is outside the scope of this document, in general, each organization is responsible for identifying the following:

- Who has access to personal data and under what conditions an individual has the authorization to use this data?
- How is the data stored, under what conditions and by whom it is stored?
- How is the data transmitted and under what conditions is this data transmitted?

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CAUTION

When disposing of the hard drive, first purge all sensitive data using software capable of DoD 5220.22-M standards, or comparable.

Media such as CDs, DVDs, USB drives, and printouts must be disposed of in a secure manner when they are no longer needed, since they might hold sensitive information.

Protecting Personal Health Information

CAUTION

Protecting personal health information is a primary part of a security strategy. Considering the nature of the product, the information stored is highly personal and sensitive and should be protected following HIPAA or Council of the European Union security and privacy rules.

The system does not encrypt patient health information when stored. Unencrypted patient health information will be present in the system files, backup files, and files saved to primary, auxiliary, and portable storage devices. Thus, particular care must be taken with this information when designing backup, archiving, and disaster recovery plans to ensure the utmost security and confidentiality.

Additionally, industry standard methods and best practices of applying disk level encryption may be applied to protect data at rest. Philips recommends a careful examination of the encryption method as it may affect the overall performance of the system.

Take measures to compensate for resource drain when encrypting\decrypting files or data. This will need to be identified during the beginning stages of implementation, prior to server build.

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CAUTION

When disposing of the hard drive, first purge all sensitive data using software capable of DoD 5220.22-M standards, or comparable.

Media such as CDs, DVDs, USB drives, and printouts must be disposed of in a secure manner when they are no longer needed, since they might hold sensitive information.

About the EU Directives

If applicable, your facility's security strategy should include the practices set forth in the Directive on Privacy and Electronic Communications (Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002) concerning the processing of personal data and the protection of privacy in the electronic communications sector. In addition, your facility should also consider any additional, more stringent standards put forward by any individual EU countries; that is, Germany, France, and so on. For more information, visit http://eur-lex.europa.eu/homepage.html

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About Setting up a Testing Environment

Customers are encouraged to put policies in place to maintain proper operating systems, anti-virus, and Microsoft security updates and service packs, driver updates, new hardware and changes to existing hardware, and so on. Ultrasound Workspace is a software-only product. Proceed with caution when you make any changes to any part of the system. Be sure to set up a test environment that mimics the current environment for testing changes to the system before deploying the changes into the live environment. Real patient data should not be used for the test/demo environment. Any such test setup must use de-identified data only.

About HIPAA Rules

If applicable, your facility's security strategy should include the standards set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the United States Department of Health and Human Services. You should consider both the security and the privacy rules and the HITECH Act when designing policies and procedures. For more information, visit https://www.hhs.gov/hipaa/index.html.

Further Security Information

User Accounts

We suggest user accounts (example: for installation, monitoring, troubleshooting, remote access purpose, runtime and emergency account) with proper read/write/execute access levels to shared resources (shared network drives, services, database) be created as per Hospital's IT policy.

Network

CAUTION

Product security depends on the security of the existing network infrastructure and the product configuration. DICOM and HL7 communication requires additional configuration of all communication partners for encrypted communication. Unsecured DICOM and HL7 communication can lead to the disclosure of sensitive personal data.

Disclosure

TeamDev JxBrowser and Microsoft WebView2 are used within the product. JxBrowser and WebView2 may send data back to Google or Microsoft. Thus, you might detect unexpected traffic from the system. This is normal. To our best knowledge, no sensitive data is transferred by JxBrowser. Nevertheless, you can block the traffic with your firewall without any impact on the behavior of the product.

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4 Ultrasound Workspace

Ultrasound Workspace is a clinical software package for reviewing, quantifying and reporting digital medical data. The software can be integrated into third party platforms.

Platforms enhance the workflow by providing the database, import, export and other services. All analyzed data and images will be transferred to the platform for archiving, reporting and statistical quantification purposes.

Ultrasound Workspace consists of the following optional modules:

- IMAGE-COM
- AutoStrain LV / SAX / RV / LA / 2D Auto LV*
- 3D Auto RV*
- 3D Auto MV*
- 3D Auto TV*
- 3D Auto CFQ*
- 4D LV-ANALYSIS*
- 4D CARDIO-VIEW*
- 4D SONO-SCAN*
- REPORTING
- DATACENTER (incl. STUDY LIST, DATA MAINTENANCE, WEB REVIEW)

(* The advanced clinical applications are not available in the web browser.)

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Installation

For information about the system installation, please contact your service representative.

For information about the system requirements, refer to the **Technical Specification** (www.philips.com/ifu).

GUI Elements

Common Components

This section presents a general overview of all used common components of Ultrasound Workspace.

Toolbar

Provides easy access to the most often used functions on the respective screen. Depending on license and different scenarios, the availability of features in the STUDY LIST may vary.

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Information Bar

Displays the most important study and patient information:

- Study Date
- Patient Age
- Patient Name
- Current Age
- Patient ID

If some information is missing, it is indicated by: **--**

User Information Area

Displays all information related to the current user. It can also display the hospital name (if configured).

Thumbnails/Preview Area

Displays all objects related to the selected study. Each DICOM object is represented by a dedicated image preview. Depending on the modality and on the DICOM Object Type, additional information will be added as overlay following a specific scheme. When the user performs mouse over on the image in the Preview Area, the image will be magnified.

Imaging Viewport

The imaging viewport (or diagnostic 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. Four colored corners indicate the tile as the active one.

Toolspace

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

It is mainly organized in tabs which are logically organized, based on the specific clinical imaging module.

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Main Interface Elements

This section presents a general overview of the main graphical user interface (GUI) elements of Ultrasound Workspace modules.

STUDY LIST GUI

Information Bar (Patient Study Info)
Toolbar
Search Area
Result Area
Thumbnails/Preview Area
User Information

DATA MAINTENANCE GUI

Information Bar (Patient Study Info)
Toolbar
Global Study / Patient Information
5 sub areas: (1) Study Info; (2) Edit Patient and Study; (3) Split and Merge; (4) De-Identification; (5) Report History
Thumbnails/Preview Area
User Information

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WEB REVIEW GUI

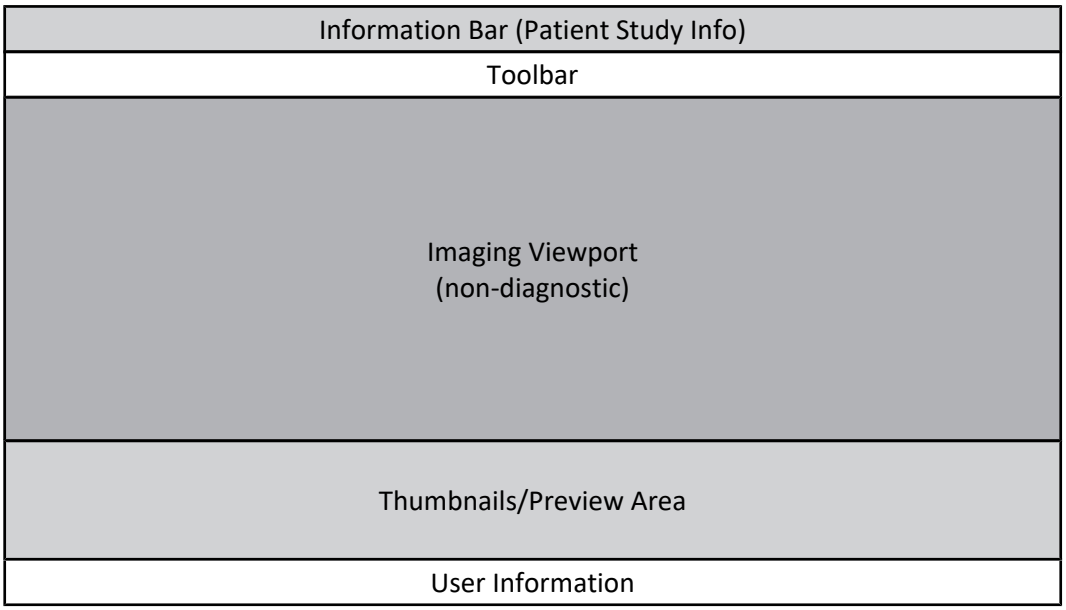

IMAGE-COM GUI - Default

Default appearance for desktop client

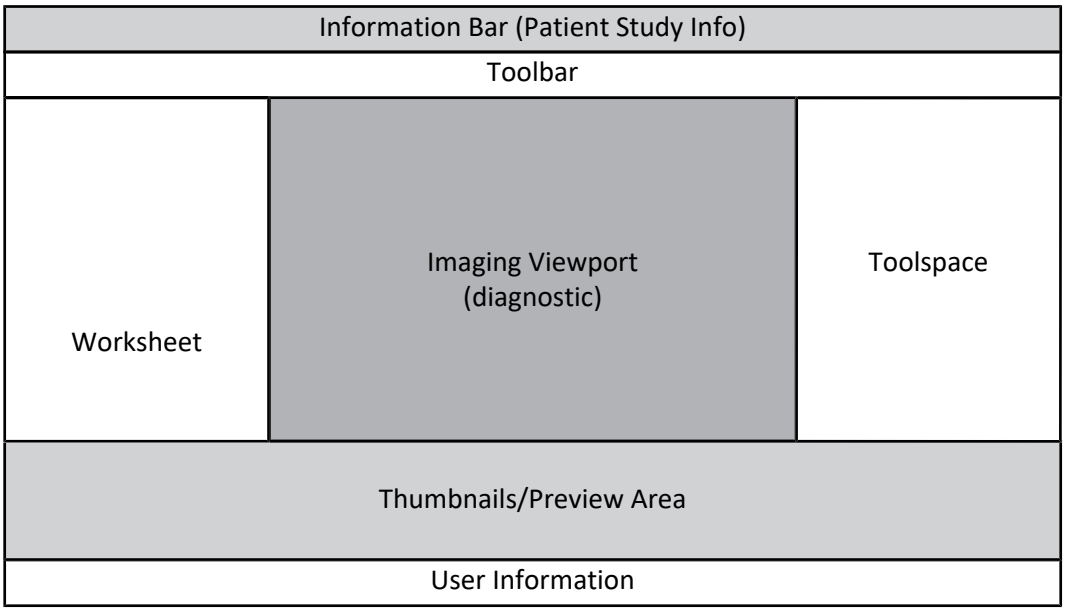

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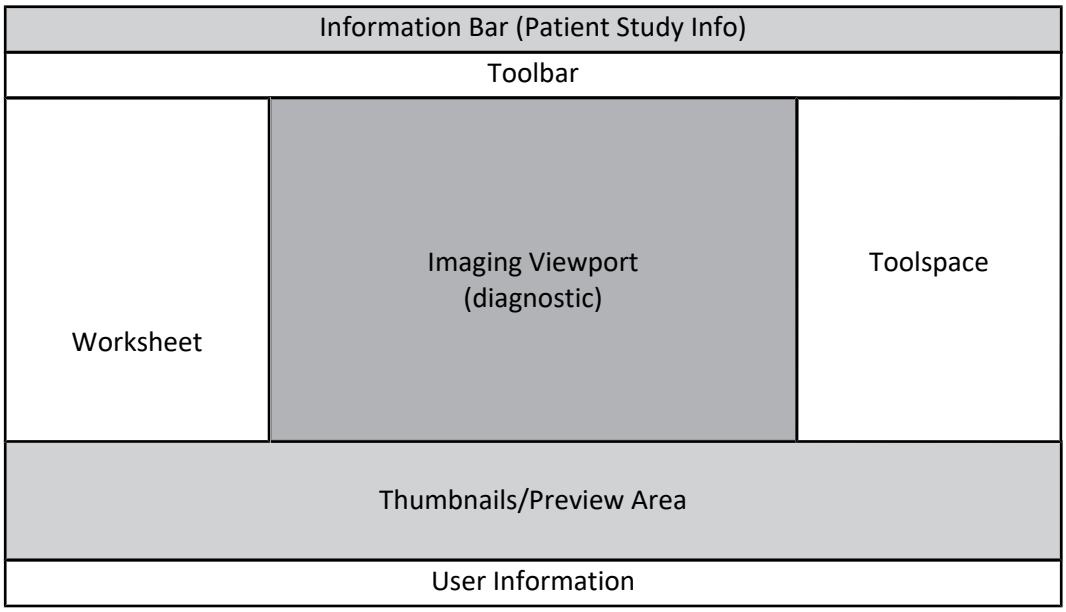
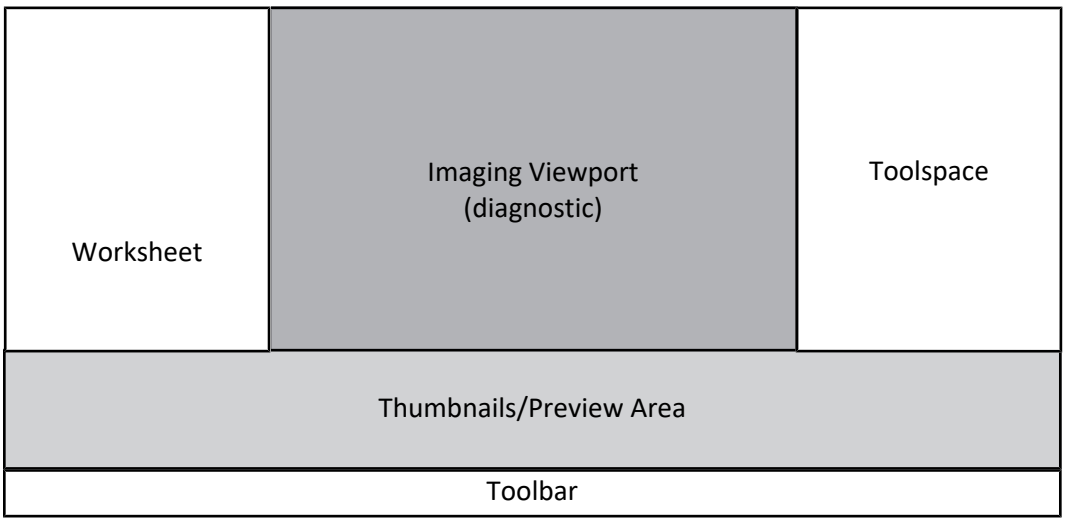
IMAGE-COM GUI (browser based) - Default

Default appearance for web browser client

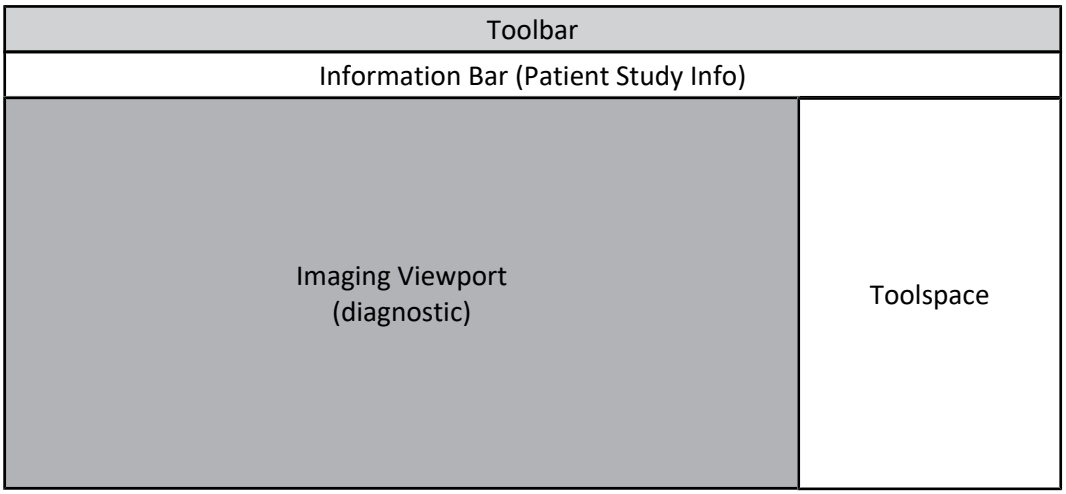


Styling 01

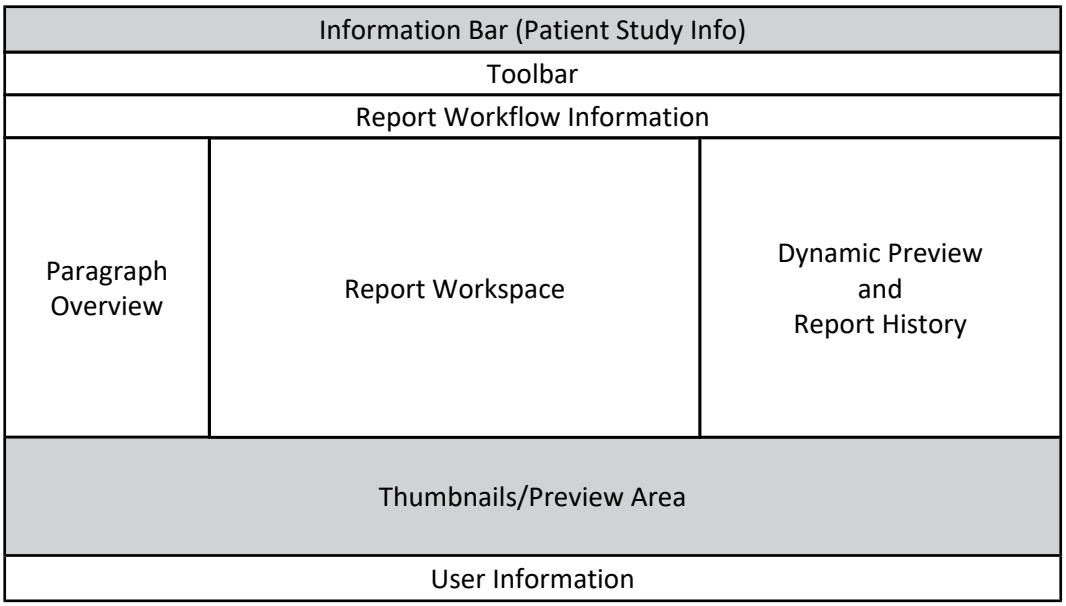
Appearance depends upon integration into 3rd party system.



Advanced clinical application GUI



REPORTING GUI



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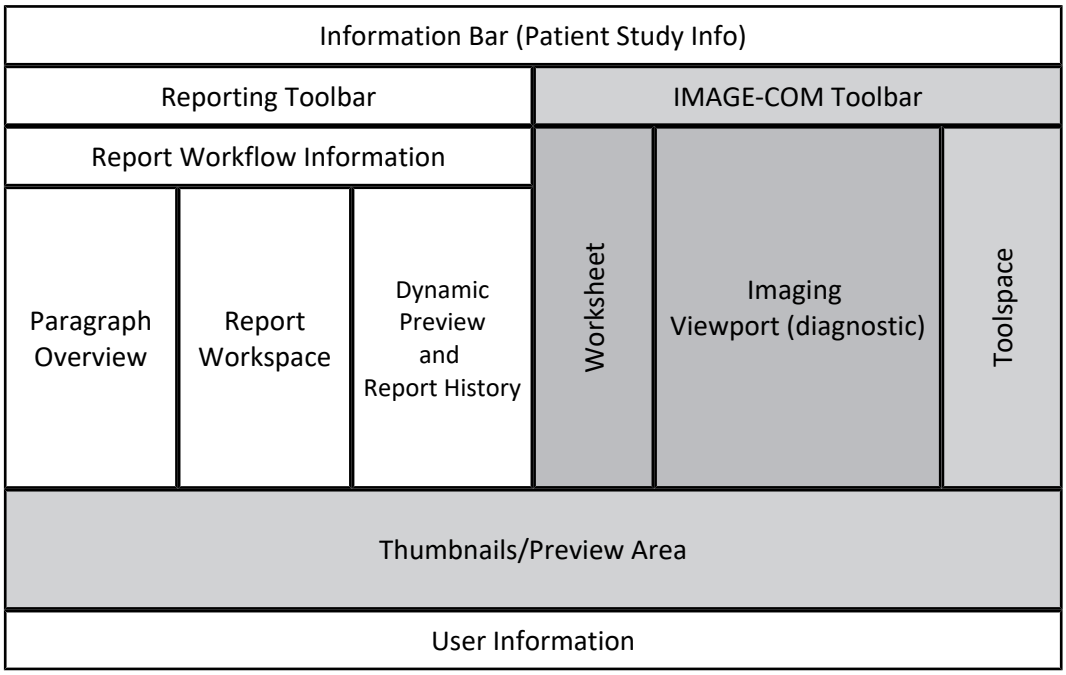
Split View for IMAGE-COM and REPORTING GUI



Display Setup Overview and Workflow

The user workflow may vary depending on the number of available screens (monitors) and the type of client.

Desktop client: Philips applications are physically installed on a workstation.

Web browser client: Philips applications are available via web browser. No local installation is needed.

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Philips modules can be setup to be able to manage 1 or 2 screens:

Name	Description
Single monitor client setup	• One screen for desktop or web browser client. • Primary display configuration is available.
Dual monitor client setup	• Uses two screens and it is available only for the desktop client. • Primary display and Secondary display configurations are available.

For more information, see also chapter “Customize the Client” on page 37.

Web browser client – single monitor setup

All modules (except the clinical application packages) will be displayed on the primary display/ web browser.

Monitor 1
Primary Display Modules:
STUDY LIST
IMAGE-COM
WEB REVIEW
REPORTING
Split view for IMAGE-COM and REPORTING

Desktop client – single monitor setup

All modules will be displayed on the primary display.

Monitor 1
Primary Display Modules:
STUDY LIST
IMAGE-COM
WEB REVIEW
REPORTING
Clinical Application Packages

Desktop client – dual monitor setup

The Ultrasound Workspace client always opens on the primary display. When opened, the REPORTING module will always appear on the primary display too. IMAGE-COM and all clinical application packages always appear on the secondary display.

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Monitor 1	Monitor 2
Primary Display Modules:	**Secondary Display Modules:**
STUDY LIST	IMAGE-COM
REPORTING	Clinical Application Packages
WEB REVIEW	

5 Working with Ultrasound Workspace

When your system administrator has assigned your username and password, you can access Ultrasound Workspace. Your system administrator should ensure you can access the server and the modules for your daily routine work. Because Ultrasound Workspace is a highly customizable product, your interaction with Ultrasound Workspace may be different from that of other users.

CAUTION

Be aware that the product only enforces a basic password policy. You are responsible for the quality of your login credentials. To prevent unauthorized access and improve security we recommend you to use strong passwords for your user accounts, i.e., with as many characters as possible (maximum 64), including numbers, letters and special characters and are created randomly at best. These requirements are meet best by using password managers on your system.

CAUTION

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

Logging On

1. Double-click the icon that was placed on your desktop during installation, to start the application.
   Alternatively:
   - Select the application from the start menu.
   - Enter the URL in the web browser, to start the application in the web browser.
2. Enter username and password into the login screen.
3. Click **Login** or press **Enter**.

Ultrasound Workspace is launched and the module STUDY LIST is preselected. Your username is displayed in the user information bar at the bottom of the screen.

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NOTE

Contact your system administrator for the URL.

NOTE

If the application icon is not available on your desktop, go to the installation folder (default path: C:\ProgramData\Philips\UltrasoundWorkspace\TTA-Client\DesktopClient) and double-click the file **DesktopClient.exe**.

Change your Password

1. Click  in the right corner at the top of the screen.
2. Select **User Settings** from the drop-down list.
3. Enter your current password.
4. Enter your new password
5. Confirm your new password by entering again.
6. Click **OK**.

Locking the System

If you need to leave the Ultrasound Workspace software unattended for a period of time, but will return and continue working, you can lock it to prevent unauthorized access to patient data while you are away.

1. Press **Ctrl+Alt+Delete**.
2. Click the option to lock your computer.

You are not logged off, but the Ultrasound Workspace software is secured. Use your password to unlock the software and continue where you left off.

NOTE

Ultrasound Workspace software logs off the user automatically after a timeout.

Logging Off

1. Click  in the user information bar at the bottom of the screen.
2. Click **OK**.

Your work is saved and the next user can log on.

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Customize the Client

You can customize the start screen of the Ultrasound Workspace client. The configurations are saved for each user individually.

Setup a dual monitor workstation

NOTE

This feature is not available in the web browser.

Ultrasound Workspace client is displayed on one monitor (primary display) by default. To change the settings for two monitors, do the following:

1. Click  in the right corner at the top of the screen.
2. Select **User Settings** from the drop-down list.
3. Select the **Client Setup** tab.
4. Click **Identify Monitors** to display the monitor number on all available monitors.
5. Select the monitor number from the drop-down list to set the screen for the primary display (**STUDY LIST** and **REPORTING**).
6. Select the monitor number from the drop-down list to set the screen for the secondary display (**IMAGE-COM**).
7. Click **OK**.

General setup for STUDY LIST launch

To change the general settings, do the following:

1. Click  in the right corner at the top of the screen.
2. Select **User Settings** from the drop-down list.
3. Select the **Client Setup** tab.
4. Do any of the following:
   - To set the default action of **Double-click on a selected study**, select one of the options in the drop-down list.
   - To set the default **Search view** of the search bar, select one of the options in the drop-down list.
5. Click **OK**.

NOTE

When using monitors with different display resolution, log off and log in again for proper scaling after the setup.

Export preset

To change the export preset, do the following:

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1. Click  in the right corner at the top of the screen.
2. Select **User Settings** from the drop-down list.
3. Select the **Client Setup** tab.
4. To define the **Export preset**, select one of the opitions in the drop-down list.
5. Click **OK**.

CAUTION

Be aware that exporting patient data can lead to disclosure of sensitive information. Use the **de-identification** function whenever feasible for data you intend to export.

6 STUDY LIST

STUDY LIST provides an overview of patient study data stored on your system, which you want to process. This module is the first entry point to all Ultrasound Workspace modules.

STUDY LIST Controls

Icon	Name	Description
	**Delete selected study**	Deletes one or more selected studies from the data base and file archive.
	**Reload**	Reloads study from long-term archive if the status is Nearline/Offline.
	**Assign to Physician**	Assigns the selected study to the specific user.
	**Set study to analyzed**	Sets study status to analyzed.
	**Set study to viewed**	Sets study status back to viewed.
	**Archive selected**	Archives the selected study to a specific long-term archive (PACS, NAS,..).

STUDY LIST Preferences

You can sort, reorder, hide and add columns in your study list. Customizations are saved for each user individually.

NOTE

Column **Modality** and **Object Type** cannot be sorted as they can contain multiple value types.

Do one of the following:

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Sort STUDY LIST

1. To sort the study list, click on the heading of any column.
2. To reset the sorting back to factory default, click  .

Reorder columns

1. To reorder the columns, drag (left-click and hold the click) the heading of any column and drop it to the preferred position.
2. To reset the ordering back to factory default, click  .

Add and hide columns

1. Click  on the top left side of the result area.
2. Select and/or deselect the columns.
3. To reset the columns displayed back to factory default, click  .

Working with STUDY LIST

Daily Routine and Clinical Workflow Support

Basic and advanced search

You can search for many parameters in the study list. Do any of the following to set filter in the study list:

- Click  on the left side of the search bar, to show all search fields or hide all advanced search fields.
- Enter your search term (e.g. patient name) or select one from the drop-down list.
- Combine multiple search terms.
- Click  to apply the filter.
- Click  to clear the content of all filters.

NOTE

If you have left the STUDY LIST open for a long time without working in Ultrasound Workspace, click  to update the study list.

Quick filters

Use quick filters in the daily routine as working lists. After you have applied a filter to the study list, you can save it as a quick filter. To create a quick filter, do the following:

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1. Click  in the search bar to open the **Add new Filter** dialog box.
2. Enter a filter name.
3. Click **OK**.

You can apply the quick filter when selecting it from the drop-down list in the search bar.

Quick filter configuration

- To open the **Quick Filter Configuration** dialog box, click  in the search bar.
- To edit the name of a quick filter, click  , type changes and then click  .
- To delete a quick filter from the list, click  .
- To move a quick filter in the list up or down, click  or  .
- To save your configurations, click **OK**.

Select study

- To select a study, click on an entry in the study list. Patient and study information of the selected study is displayed on the top of the window.
- To select more than one study, press **Ctrl + click** on the entries.
- The number of selected entries is displayed in the results panel. The maximum number of selectable studies is 40.

Assign study to a user

To define the responsibility for the next clinical work step, you can assign a study to a specific user.

NOTE

This function is permission restricted. If your user account does not have this permission, contact your supervisor for further assistance.

1. Select one or more studies from STUDY LIST.
2. Click  in the STUDY LIST toolbar, to open the **Assign to Physician** dialog box.
3. Enter the user name of the assignee or click **Assign to me**.
4. Click **OK**.

The assigned user name is listed in column **Assigned to**.

Delete study

This function deletes one or more studies from the data base and main archive permanently.

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NOTE

This function is permission restricted. If your user account does not have this permission, contact your supervisor for further assistance.

- Select the amount of studies to delete.
- Click  .
- Click **OK** to confirm your action.

STUDY LIST Status Types

Status of study review

Study Status	Description	Further Information in Column
No Images	Study is ordered, but no images are available yet.	--
New	Study contains images that have not yet been further reviewed or analyzed.	--
Viewed	The status is automatically assigned when a study is opened for review in IMAGE-COM.	• **Viewed by** • **Viewed at**
Analyzed	User has marked the study as 'Analyzed'.	• **Analyzed by** • **Analyzed at**
External	Study was not analyzed or reported within Ultrasound Workspace.	--

NOTE

The function Set to Analyzed is permission restricted. If your user account does not have this permission, contact your system administrator to acquire the necessary permission.

Status of report

Report Status	Description	Further Information in Column
New	No report has been started yet.	--
Started	The report was started by a user who opened the reporting module, selected the corresponding workspace and started the report.	--
Preliminary	The report was set to preliminary by a user.	• **Reported by** • **Reported at**
Finalized	The report is in a complete state and was set to finalize by a user.	• **Finalized by** • **Finalize at**

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Report Status	Description	Further Information in Column
Migrated	The study is migrated from the IMAGE-ARENA application. The migrated report is available as PDF file.	

Status of archiving

Archiving Status	Description	Further Information in Column
Not Archived	The study is not archived.	--
Partially Archived	Not all DICOM objects of the study could be archived or new objects where created on an already archived study.	--
Archived	The whole study including all DICOM objects is archived.	--

Status of availability

Availability	Description	Further Information in Column
Unavailable	The whole study or parts of the study are unavailable. There is no possibility to reload.	--
Online	The whole study is stored locally and is available for review.	--
Offline	The whole study or parts of the study are already removed from the local archive and must be reloaded to make it available for review.	--
Nearline	The whole study or parts of the study are no more available and require human intervention to bring it back online (e.g. USB memory sticks, CD/DVD optical media).	--

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Study Import

Import Local Data via included DICOM Import Tool

The DICOM Import Tool is accessible from STUDY LIST and offers the possibility to import DICOM data from the hard disk or a data storage device such as CDs, DVDs or USB sticks.

NOTE

This feature is not available in the web browser.

1. To open the DICOM Import Tool dialog box, click on the right side of the navigation bar. Alternatively:
   - Move the cursor to any entry into the study list.
   - Right-click to open the menu and select .
2. To start scanning, do one of the following:
   - Drag & drop any directory containing DICOM data.
   - Or click to scan a file directory.
   - Or click to load a **DICOMDIR**.
3. Select the data you want to import. If no particular selection is done, the complete result of the scan view will be considered for import.
4. To import the data, click .
5. Click to update the study list.

Import Study Data via DICOM Query/Retrieve

If a DICOM device is configured by your system administrator, DICOM query/retrieve is available on your system. To import study data via DICOM query/retrieve, do the following in the search bar of the STUDY LIST:

1. Click in the search bar and select from the drop-down list the remote archive .
2. Enter your search term. Combine multiple search terms.
3. Click to apply the filter.
4. Select one or more studies for import and click . To select more than one study, press Ctrl + click on the entries.
5. To find your imported studies, switch back to the .

NOTE

A timestamp in the column **Announced at** shows you the import date and time of each study.

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Study Export

NOTE

This function is permission restricted. If your user account does not have this permission, contact your supervisor for further assistance.

You can export studies to hard disk in two ways.

- Export as DICOMDIR.
- Export DICOM files including a basic viewer as ISO file which can be further used to burn a CD or DVD.
- For information about de-identification function, see chapter "De-Identified Study Export" on page 46.

CAUTION

Be aware that exporting patient data can lead to disclosure of sensitive information. Use the **de-identification** function whenever feasible for data you intend to export.

Export Study to DISC

NOTE

This feature is not available in the web browser.

Do the following:

1. Select one or more studies for export and click  . To select more than one study, press Ctrl + click on the entries.
   Alternatively:
   - Right-click to open the menu and select  .
2. Select the export format DICOMDIR.
3. Select the target folder for the export and confirm.

Burn a CD or DVD from an ISO file

NOTE

This feature is not available in the web browser.

NOTE

Before you start burning, first change the default operating system application for opening ISO files to **isoburn.exe** for each client. The application is usually available under C:\Windows\System32.

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Do the following:

1. Select one or more studies for export and click  . To select more than one study, press Ctrl + click on the entries.
   Alternatively:
   - Right-click to open the menu and select  .
2. Select the export format ISO file.
3. Select the target folder for the export and confirm.
4. Go to the exported file and double-click on it to open the burn dialog.
5. Select the burning device and click **Burn**.

Export Study via Copy To …

If a DICOM device is configured by your system administrator, you can send one or more studies to a long-term archive with the **Copy To …** function.

Do the following:

1. Select one or more studies for export and click  . To select more than one study, press Ctrl + click on the entries.
   Alternatively:
   - Right-click to open the menu and select  .
2. Select from the DICOM Device from list.
3. Click **OK**.

Archive Study to Long-Term Archive

If a long-term archive is configured by your system administrator, you can store one or more studies in long-term archives with the **Archive Selected** function.

Do the following:

1. Select one or more studies for archiving. To select more than one study, press Ctrl + click on the entries.
2. Click  in the toolbar of STUDY LIST.
   Alternatively:
   - Right-click to open the menu and select  .

In case the study is archived and set to offline, click  , to import the study back to the local archive for review.

7 DATA MAINTENANCE

DATA MAINTENANCE contains features to maintain patient, visit and study related data and gain insight into DICOM data as well as features to monitor the report history.

DATA MAINTENANCE Controls

Icon	Name	Description
	Validate Storage	Validates the storage for all DICOM objects of an archived study.
	Reclassify Study	Reclassifies the file type and file subtype for all DICOM objects in the study.
	Restore Measurements	Imports measurements from a DICOM device for a study.

DATA MAINTENANCE Workflow Procedures

De-Identified Study Export

NOTE

This function is permission restricted. If your user account does not have this permission, contact your supervisor for further assistance.

NOTE

This feature is not available in the web browser.

The de-identified study export functionality allows to export a de-identified copy of the current study while the original study is left untouched.

In this case, de-identification means that DICOM attributes are modified in the exported study. In addition, the user has the option to apply overlay boxes to the displayed images to overlay burned-in information.
For information on the DICOM attributes affected by the de-identified study export feature, contact your service representative.

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1. Select the study.
2. Click  in the right corner at the top of the screen and select  .

   Alternatively:

   - Right-click to open the menu and select  .
3. Update the already de-identified data on the left **DICOM Metadata De-Identification** panel (e.g. Patient ID, Patient Name, and Study Description).
   - If the study contains at least one SR, a flagged checkbox to include SR objects appears.
   - Deselect the checkbox in case no SR shall be included in the de-identified export.
   - Select the checkbox in case 3D objects shall be considered for export.
4. To exclude particular images from the de-identified export, deselect the checkbox from the **Image List** panel.
5. To cover sensitive data on a specific image, select the image from the **Image List** to display it as preview image on the right panel **Apply overlay boxes on images**.
   - Left click on the image to start drawing an overlay box, release the left-click to keep the state.
   - Drag and drop the overlay box body  to adjust existing overlay boxes.
   - Drag and drop the overlay box contour  to resize an existing.
   - Select a single overlay box, then click on Delete selected overlay on image  to remove the selected box.
   - Click  to remove all overlay boxes from the selected image.
6. Click  to transfer the available overlay boxes from the current preview image to all images listed in the Image List.
7. Click  to clear all overlay boxes from all images listed in the **Image List**.
8. To download de-identified study, click  .
9. Select the export format.
10. Select the target folder for the export and confirm.

NOTE

If 3D objects are selected for export, they might not be completely de-identified.

Edit Patient and Study Data

NOTE

This function is permission restricted. If your user account does not have this permission, contact your supervisor for further assistance.

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1. Select the study.
2. Click in the right corner at the top of the screen and select .

   Alternatively:

   - Right-click to open the menu and select .
3. Correct the patient or study data. Enter date and time designations in the proposed format or chose the year, month and date.
4. Click .

Split and Merge Records

Split and merge provides the following features:

- Merge duplicate patient records in order to provide a consistent patient history.
- Split a patient record by creating a new patient record and reassigning visits and studies to it.
- Reassign studies which have been acquired on a wrong patient record or associated to a wrong visit record.

NOTE

This function is permission restricted. If your user account does not have this permission, contact your supervisor for further assistance.

Search Patient

- Select a study.
- Click in the right corner at the top of the screen and select .

  Alternatively:

  - Right-click to open the menu and select .
- On the secondary patient panel, click .
- Enter one or multiple search fields or select from the drop-down list.
- Click or press **Enter** to apply the filter.
- Double-click on the patient record from the results. It will be displayed as **Secondary Patient**.

Create New Patient

- Select a study.
- Click in the right corner at the top of the screen and select .

  Alternatively:

  - Right-click to open the menu and select .

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- On the **Secondary Patient** panel, click .
- Enter at least the highlighted fields. Enter date and time designations in the proposed format or select the year, month, and date.
- Click to save the new patient record and display it as **Secondary Patient**.

Merge Patients

- Select any study of the patient record you intend to keep.
- Click in the right corner at the top of the screen and select .

  Alternatively:

  - Right-click to open the menu and select .
- Select the secondary patient as described in **Search Patient**.
- Click .
- Click the confirmation dialog and click **OK**. The merged studies are now added to the patient history.

Reassign Visits or Studies

- Select any study of the patient record you intend to reassign.
- Click in the right corner at the top of the screen and select .

  Alternatively:

  - Right-click to open the menu and select .
- Select the secondary patient as described in **Search Patient** or **Create New Patient**.
- To identify the correct study to operate on, click for further details.
- Left-click on a card and hold the click to drag the card.
  - Where a is displayed, dropping the card is not allowed. On drop the card will return to its initial position.
  - Where a drop is allowed, the system highlights the drop position:
- Drop the card on the intended position of the current patient or secondary patient by releasing the mouse click.
  - The original position of the card is highlighted by a red frame and font color.
  - • The new position of the card is highlighted by a green frame and font color.
- Click .
- Check the confirmation dialog and click **OK** to confirm the your action or click cancel to come back to the previous state.

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NOTE

The current study is the study that has been selected when entering **DATA MAINTENANCE**. When the current study is moved to the **Secondary Patient**, this will change the current patient record you are working on, for example when entering another tab in **DATA MAINTENANCE**. In this case, the message "**Patient information will change with safe confirmation."** appears.

Delete Single DICOM Images or Other DICOM Objects

NOTE

This function is permission restricted. If your user account does not have this permission, contact your supervisor for further assistance.

1. Select the study.
2. Click in the right corner at the top of the screen and select .

   Alternatively:

   - Right-click to open the menu and select .
3. Select the objects you want to delete.
4. Click .
5. Click **OK**.

8 WEB REVIEW

WEB REVIEW is a basic and non-diagnostic image viewer. It is intended to view the following modalities in a web browser:

- US 2D images and 3D representation images
- XA images

9 IMAGE-COM

IMAGE-COM is a basic module for reviewing and measuring digital medical data. It supports routine workflows for loading, analyzing and saving medical studies, e.g. for the purpose of creating reports. IMAGE-COM is where basic measurements can be performed and the entry point for advanced analysis modules. Study related routine measurements can be imported, displayed, edited and exported to accompanying reporting systems.

IMAGE-COM Fundamentals

1. Select a study, which contains datasets for this application and double-click.

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2. For paging through the study, use the **paging navigation** buttons.
3. To manage clips, use **playbar** buttons.
4. To perform specific steps (e.g. review, measurements, and **Stress Echo**), use the tools in the tool space and select the desired tab.
5. To delete an image mark it for deletion via smart region, or right-click. Images will be deleted by closing **IMAGE-COM** after a confirmation message. Measurements of deleted images will stay available via the **Worksheet**.
6. All prior studies are displayed in the **Patient History** tab.
7. Advanced clinical application packages (e.g. 4D applications) can be loaded with a right-click on the selected tile.

IMAGE-COM Layouts

Per default, ultrasound studies (US) open up in a quad-screen, X-Ray Angiographic studies (**XA**), IntraVascular Ultrasound (**IVUS**) studies and IntraVascular Optical Coherence Tomography (**IVOCT**) studies are launched in a full screen mode. The default can be changed in user settings .

Overlay Information

Different overlay information is available. The user settings offer additional display options. The basic overlays are:

- Current frame (dynamic value)/total number of frames of multi-frame object.
- Heart Rate: Value available in the DICOM information of the image.
- Available (dynamic value)/suggested frame rate:
  - Available frame rate is a dynamic value that changes during play loop phase and may differs from the suggested frame rate for networking reasons.
  - Suggested frame rate value is part of the DICOM information found in the image.
- Exam: Study date, patient age at the exam date
- Pullback Rate (if modality = **IVUS**, **IVOCT**, **OCT**): Value available in the DICOM information found in the image if the probe is retrieved via a mechanical system.
- IMAGE-COM (browser based) related notification area:
  - Compressed image: The compression can be deactivated with just one click
  - Uncompressed image: The compression can be activated with just one click.
  - The expected frames per second (**FPS**) rate is not reached during current cineplay mode.

Thumbnails

The thumbnail bar shows a preview of all data included in the selected study. Additional filter options enable the user to display only a subset of the data.

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Reviewing 3D/4D Objects

1. 3D/4D objects can be reviewed. A 3D symbol is displayed in the thumbnail bar.
2. To adapt the **MPR** views, drag and drop the 3D object into the workspace and adjust the Lines of Intersection (**LOI**) or use the center point navigation to move the intersection of both LOIs.

3. The **D'art** can be used for displaying the tissue reconstruction. The **D'art** allows to visualize any 3D structure in an intuitive way with just two clicks.
4. To define a region of interest and a viewing direction, click and set two points. Length and start/endpoints of the **D'art** arrow can be changed.

Side by Side Comparison

NOTE

Contact your system administrator if you benefit from setting up a proactive prefetching mechanism that ensures the timely availability of previous studies for comparison during the review process.

Multiple studies (**US** and/or **XA**) of one patient in the database (secondary studies), are listed in . There are two possibilities to compare studies:

Comparing single images

Drag and drop images of a secondary study into an active study.

- Select the secondary study in the **patient history** tab.
- The thumbnails of the secondary study are displayed in the thumbnail area and can be moved into the diagnostic area. Images of the secondary study (visible by a light blue frame) include study date and time.

Comparing studies

1. To open the complete study in a separate tab, click on in the **patient history** tab.
2. The PDF icon indicates an existing pdf report. This report can also be opened.

NOTE

The Worksheet always displays the measurement of the primary study.

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XA/DSA Review

1. Load a XA Vascular Study.
2. Adjust the sharpening value to enhance image quality.
3. Play the loop and identify the frame where the injection of the contrast agent begins.
4. Click , to set this frame as mask frame.
5. Click (**Subtraction**) to display the DSA image and play the loop.
6. Adjust the level of subtraction by setting the corresponding slider to the desired value.
7. Click (**Peak Opacification - Summation**) to display the sum of all resulting **DSA** images.
8. Motion artifacts (e.g. due to patient's respiration) can be corrected by the pixel shift function.
   - Click , to activate pixel shift.
   - Reposition the frame by dragging its border to trigger the automated pixel shift correction.
   - The pixel shift can be further refined by moving the cursor while keeping **LMB** pressed on the symbol at the center of the image.

XA Calibration

The **XA Calibration** tab offers tools to calibrate XA images or clips.

Isocenter Calibration

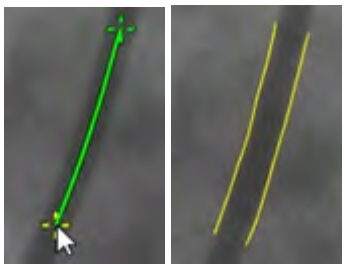
Isocenter Calibration is based on the Isocenter Reference System attributes delivered by the acquisition device. It is used automatically in case the selected XA clip provides all required attributes.

- Click **OK** to confirm the calibration factor.

Catheter Calibration

Catheter Calibration uses the diameter of the catheter as reference size.

1. Select a frame that shows the catheter in good contrast.
2. Mark a straight section of the catheter by setting two points with LMB clicks within the catheter. The distance between the points shall be at least three times the catheter diameter. Setting the second point triggers an automated detection of the borders of the catheter.



3. Select the real catheter size, or manually enter a value in the calibration tool space and click **OK** to confirm the calibration.

The calibration accuracy is related to a low variance value which is calculated by the software and displayed in the tool space (optimal: less than 8%).

Point to Point calibration

This calibration method is based on a known distance.

1. Select the frame that shows the reference distance in good contrast.
2. Draw a line over the length of the known distance with two LMB clicks.
3. Manually enter the length of the reference distance.
4. Click **OK** to confirm the calibration.

Navigation

Name	Description
Smart Regions	Temporary icons in the image region. Icons of the correspondent functions are visible by positioning the cursor over a tile for a short time.
LOI Navigation	Cut plane can be adjusted
Image Navigation	Images can be moved and rotated in the view tiling.

Add Annotations

The tools tab offers tools for placing labels within a dataset. Annotations can be added by selecting the kind of annotation and click into the dataset to write.

Additionally, a de-identification box can be placed on the dataset to cover e.g. patient information. In the user settings the user can select if he wants to keep the de-identification after restart (default).

Perform Measurements in IMAGE-COM

Each exam type is divided into measurement groups and packages.

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Performing a Labeled Measurement

Before you perform a labeled measurement, you can optionally select a previously defined measurement preset in the filter options.

1. Navigate through the groups and packages of the active exam type.
2. Click on measurement to activate.
3. Perform the measurement on a selected image object.
4. To complete the measurement, double-click or right-click.
5. To review results, move the cursor over the opened package in the measurement menu.
6. To exit the procedure, press **Esc**.

Example: Simpson biplane

Select the exam type **Adult Echo**.

1. Select **Left Ventricle**.
2. Select **Simpson**.
3. Select the end-diastolic frame of an apical 4CH view and select **EDV (A4C)**.
4. To place the first dot in the image at the septal mitral annulus and set points along the endocardial wall, left-click.
5. To close the contour, place the last dot at the opposite mitral annulus position with double-click or right-click.
6. To choose a proper position of the rotation axis, move the cursor.
7. Repeat the procedure with **ESV (A4C)**.
8. Continue with the **2CH view**.
9. To review results, move the cursor over the opened package in the measurement menu.
10. To exit the procedure, press **Esc**.

Example: Left Ventricle/M-Mode

1. Select the exam type **Adult Echo**.
2. Select the group **Left Ventricle**.
3. Select the package **M-Mode**.
4. Select **Diastole** and set the first point on the **IVS** (Inter Ventricular Septum) leading edge.
5. Place the other points until you reach the outer border of the **Posterior Wall**.
6. Repeat the procedure with **Systole**.

Example: Mitral Valve Inflow PW Doppler

1. Select the exam type **Adult Echo**.
2. Select the group **Mitral Valve**.
3. Select the package **MV**.

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4. Place the first point on the **E Peak** of the **MV Inflow** and drag the **Deceleration Slope** to the right position.
5. Click a second time to confirm the **Deceleration Slope** measurement.
6. Place the third point on the **A Peak** of the **MV Inflow**.

Example: TAVI/TAVR measurements

1. Select the exam type **Adult Echo**.
2. Select the group **Aortic Valve**.
3. Select the package **TAVI/TAVR**.
4. The aortic Min and Max annulus dimension area are measured in the **SAX**.
5. Click **Ao Ann Minor** - left-click for the first point and a second to finish the distance measurement.
6. Click **Ao Ann Major** and do the same for the maximum distance; afterwards click **Annulus Area**.

The aortic ring diameter, aortic sinus Valsalva diameter, aorta sinotubular junction diameter are measured in the LAX.

Aortic root measurements should be made at end-diastole.

Example: Vascular measurements

1. Select exam type **Extracranial**.
2. Select group **Common Carotid Artery**.
3. Select package **CCA Right Prox**.
4. Select **PSV** and set the first dot at the peak systolic velocity. IMAGE-COM moves forward to **EDV**.
5. Set the dot at the end diastolic point.
6. To review results, move the cursor over the opened package in the measurement menu.
7. To exit the procedure, press **Esc**.

Example: XA measurement

1. Select exam type **Coronary Arteries**.
2. Select group related to the coronary vessel under investigation e.g., **Major Coronary Arteries** > **RCA**.
3. Choose the frame where the stenosis is clearly visible.
4. Select the measurement **Reference diam** and draw a distance of the vessel width in the proximal (or distal) position where the vessel diameter can be considered normal.
5. Select the measurement **Lesion diam** and draw a distance of the vessel width in the obstruction position where the vessel width is minimal.
6. Select the **Lesion length** measurement and start to draw points from the proximal to the distal reference of the vessel, trying to follow the vessel curvature.

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7. To review results, move the cursor over the opened package in the measurement menu.
8. To exit the procedure, press **Esc**.

Cath-QLVA

Cath-QLVA is a clinical solution for quantitative left ventricular function analysis based on angiographic images.

Starting Cath-QLVA

1. Select a study, which contains datasets for this application and double-click.
2. Select a vascular ultrasound image or clip and drag and drop it into the workspace.
3. Click (**Measurement package**).
4. Select the **Left Ventricle** exam type.

Calibration

1. Click (**XA Calibration** tab) to calibrate the image.
2. Confirm Isocenter calibration or select one of the options:
   - **Catheter Calibration**
   - **Point to Point calibration**

Example: Catheter calibration

1. Click two times on a straight part of the catheter.

2. The size of the catheter will be automatically detected.

3. Click **OK** to confirm the calibration value.

The calibration accuracy is related to a low variance value which is calculated by the software and displayed in the tool space (optimal: less than 8%).

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Performing the measurement

1. To select a frame with a high level of contrast, click (**Next frame**) or (**Previous frame**).
2. Or scroll with the mouse wheel to the suitable frame.
3. Select **Left Ventricle** exam type and group in the measurement menu.
4. Select the **Volume** package.
5. Click **RAO**.
6. Start the contour on one side of the annulus by using left-clicks.
7. Complete the contour on the opposite side of the annulus by using a right-click or a double-click.
8. Confirm the length of the disc summation with a left-click.
9. The workflow continues automatically. Repeat Step 1. - 4. at the **ESV** phase.
10. Move the cursor out of the workspace to visualize the values in the upper left hand corner.
11. Insert the **HR** manually to calculate cardiac output and cardiac index.

Performing a Generic Measurement

To perform a generic measurement and to assign it to a labelled measurement, do the following:

1. Select a generic measurement: **2D/Doppler/M-Mode**.
2. To start the measurement, select the desired measurement with left-click. To de-select left-click again.
3. You can find the results on the right upper corner.
4. To label the measurement afterwards, right-click on the result and select the according label.

Do any of the following to review the measurement results:

- To see all results of an active package, move the cursor into the toolspace area.
- To see the result of a dedicated measurement, move the cursor over the respective measurement button.
- To get back to the dataset and the specific frame where the measurement was performed, click on the right of a measurement package.
- To get back to the frame in which the measurement was performed, click on the measurement overlay in the image.
- Check the **Worksheet** for display all imported or measured results.

Semi-Automated Measurements

For some measurements an automatically proposes initial contouring is offered.

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The following are optional semi-automatic measurement tools in IMAGE-COM.

- AutoLV
- AutoStrain
- AutoLA
- AutoIMT
- Cath-QCA

AutoLV

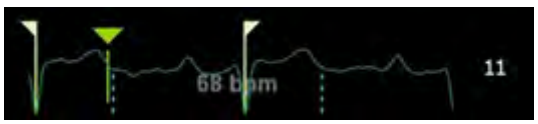
AutoLV is a tool for biplane left ventricular volume quantification based on contour proposals. Left ventricular volumes and **Ejection Fraction** results are visualized for immediate assessment of left ventricular function.

Starting AutoLV

1. Select a study, which contains datasets for this application and double-click.
2. Drag and drop an apical **4CH** and **2CH** view from preview into the workspace.
3. The software expects the standard image orientation. Use , to correct the image orientation (if required).

Select cardiac cycle (optional)

1. Select cardiac cycle (optional). The middle cardiac cycle is selected by default.



2. To define the cardiac cycle in each view, adjust the reference markers of the ECG by drag and drop the white flags to define one cardiac cycle.

   - Or double-click a cardiac cycle.
   - Or use the green darts.

Measurement

1. Click (**Measurement tab**).
2. Select the **Left Ventricle** measurement group.
3. Select the **Simpson** measurement package.
4. Click (**Automatic Detection**) of the **4CH** view.
5. Move the cursor onto the image and click the schematic segmental view to define which view is the **4CH** view.

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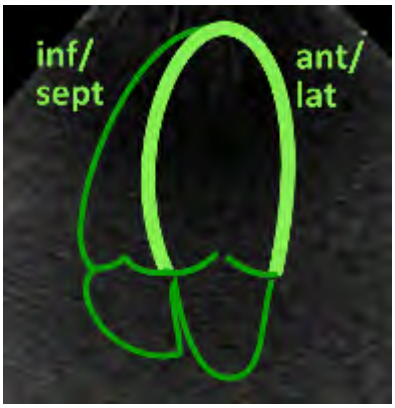
6. Continue with the **2CH** view, which is selected automatically.



Contour editing

1. To adjust the end diastolic or end systolic contour, scroll with your mouse wheel through the cardiac cycle and modify it via drag and drop.
   - Or click (**Show measurement**) on the right in the measurement menu.
2. To add additional points, click between the existing points.
3. To delete points, right-click them.
4. Click and insert the HR manually, to calculate cardiac output and cardiac index or measure it in:
   - M-Mode image
   - CW Doppler image
   - PW Doppler image

Saving options

The results are automatically stored.

- To save a screenshot, click (**Secondary Capture**).
- To visualize all values and review the measurements, launch the **Worksheet** (see “Worksheet” on page 69).

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AutoStrain

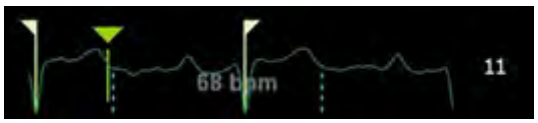
AutoStrain is a quantification tool of global and regional function based on contour detection and tracking. It supports a bull's eye display of Time to Peak Longitudinal Strain and End-Systolic Longitudinal Strain. Further, this add-in provides the calculation of GLS (Global Peak Longitudinal Strain).

Starting AutoStrain

1. Select a study, which contains datasets for this application and double-click.
2. Drag and drop an apical 4CH, 3CH and 2CH view into the workspace.
3. The software expects the standard image orientation. Use , to correct the image orientation (if required).

Select cardiac cycle (optional)

1. Select cardiac cycle (optional). The middle cardiac cycle is selected by default.



2. To define the cardiac cycle in each view, adjust the reference markers of the ECG by drag and drop the white flags to define one cardiac cycle.

   - Or double-click a cardiac cycle.
   - Or use the green darts.

Measurement

1. Click (**Measurement tab**)
2. Select the **Left Ventricle** measurement group.
3. Select the **Strain (3P)** measurement package.
4. Click (**Automatic Detection**) of the 4CH view.
5. Move the cursor onto the image and click the schematic segmental view to define which view is the 4CH view.

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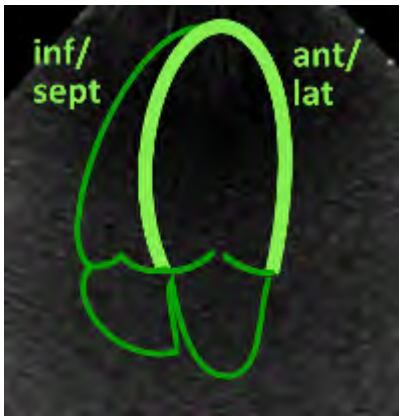

6. Continue with the 2CH and 3CH view, which are selected automatically.

The layout is reorganized, so that 4CH, 2CH and 3CH view are shown together with a bull's eye view.

Contour editing

The views are shown in the end-diastolic frame. If border editing is needed, it is highly recommended to start editing in ED.

1. Edit the contour with drag and drop and wait a second after releasing the contour until the colored strain display is back.
2. To visualize the tracking, click (**Play**) at the toolbar on the top.
3. To go back to ED or ES frame, click the **D/S** buttons.
4. To visualize the longitudinal strain curves based on 18 segments, click **Show Strain curves**.

Measure AVC (optional)

1. To measure the aortic valve closure time, click the **AVC** option.
2. Select a Doppler image of the aortic valve and drag it into the workspace.
3. Measure the aortic valve closure time with two left-clicks.
   - Or, to manually insert the aortic valve closure time, click (**Manual Input Dialog**).

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Saving options

The results are automatically stored.

- To save a screenshot, click (**Secondary Capture**).
- To visualize all values and review the measurements, launch the **Worksheet** (see "Worksheet" on page 69).

AutoLA

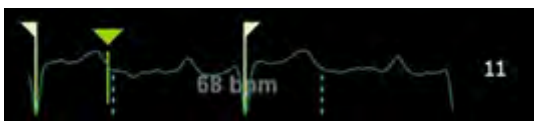
AutoLA is a tool for biplane left atrial volume quantification based on automatic contour proposals.

Starting AutoLA

1. Select a study, which contains datasets for this application and double-click.
2. Drag and drop an apical 4CH and 2CH view into the workspace.
3. The software expects the standard image orientation. Use , to correct the image orientation (if required).

Select cardiac cycle (optional)

1. Select cardiac cycle (optional). The middle cardiac cycle is selected by default.



2. To define the cardiac cycle in each view, adjust the reference markers of the ECG by drag and drop the white flags to define one cardiac cycle.

   - Or double-click a cardiac cycle.
   - Or use the green darts.

Measurement

1. Click (**Measurement tab**).
2. Select the **Left Atrium** measurement group.
3. Select the **Simpson** measurement package.
4. Click (**Automatic Detection**) of the 4CH view.
5. Move the cursor onto the image and click the schematic segmental view to define which view is the 4CH view.
6. Continue with the 2CH view, which is selected automatically.

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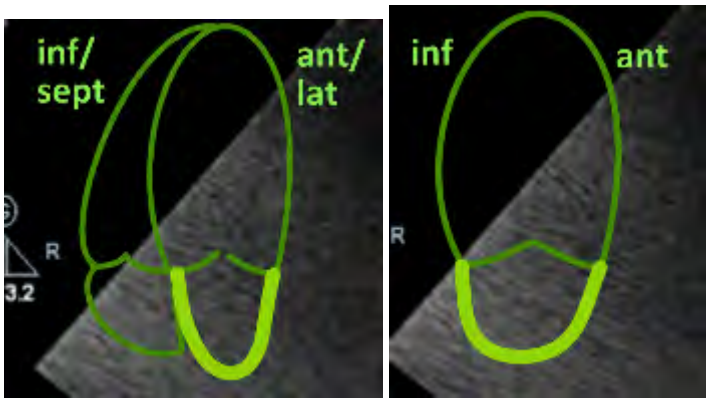

Contour editing

1. To adjust the end-systolic contour, scroll with your mouse wheel through the cardiac cycle and modify the contour via drag and drop.
   - Or click (**Show measurement**) beside the measurement.
2. To add additional points, click between the existing points.
3. Right-click to delete points.

Saving options

The results are automatically stored.

- To save a screenshot, click (**Secondary Capture**).
- To visualize all values and review the measurements, launch the **Worksheet** (see "Worksheet" on page 69).

AutoIMT

AutoIMT is a fast, intuitive and reliable method to measure the thickness of tunica intima and tunica media layers (mean IMT thickness) of vessels such as the carotid artery.

Starting AutoIMT

1. Select a study, which contains datasets for this application and double-click.
2. Select a vascular ultrasound image or clip and drag and drop it into the workspace.
3. Click (**Measurement tab**).
4. Select a vascular exam type such as **Extracranial**.
5. Click (**Automatic Detection**) of the selected IMT measurement.

Performing AutoIMT

1. Start with a left-click.
2. Define the size of the measurement window.
3. The red dotted line illustrates the minimum recommended length.

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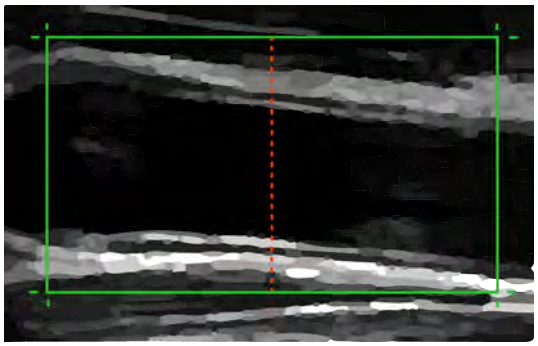
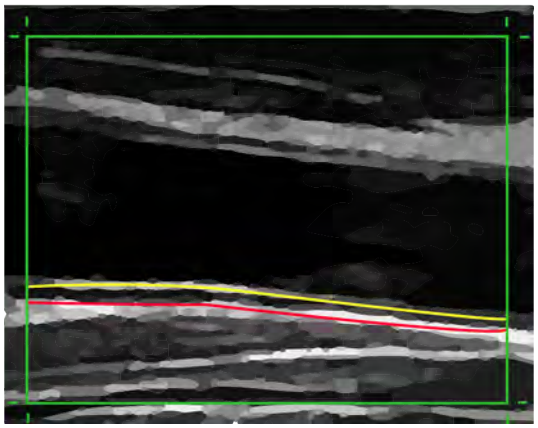


4. Complete the measurement with a second left-click.
5. The borders of the detected intima and media layers are visualized in the image.
6. The measurement result value (mean far wall IMT thickness) is displayed in the upper left hand corner of the view.



Saving options

The results are automatically stored.

- To save a screenshot, click (**Secondary Capture**).
- To visualize all values and review the measurements, launch the **Worksheet** (see "Worksheet" on page 69).

Cath-QCA

Cath-QCA is a clinical solution for quantitative coronary analysis. It supports fast contour detection of coronary arteries based on automatically detected vessel contours.

Starting Cath-QCA

1. Select a study, which contains datasets for this application and double-click.
2. Select a vascular ultrasound image or clip and drag and drop it into the workspace.
3. Click (**Measurement tab**).
4. Select the **Coronary Arteries** exam type.

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Calibration

1. Click (**XA Calibration** tab) to calibrate the image.
2. Confirm Isocenter calibration or select one of the options:
   - **Catheter Calibration**
   - **Point to Point calibration**

Example: Catheter calibration

1. Click two times on a straight part of the catheter.

2. The size of the catheter will be automatically detected.

3. Click **OK** to confirm the calibration value.

The calibration accuracy is related to a low variance value which is calculated by the software and displayed in the tool space (optimal: less than 8%).

Performing the measurement

1. To select a frame with a high level of contrast, click (**Next frame**) or (**Previous frame**).
2. Or scroll with the mouse wheel to the suitable frame.
3. Click **Major Coronary Arteries** in the measurement menu.
4. Click the right package: **LAD**, **RCA**, **LCX**, or **LCA Main**.
5. Click (**Automatic Detection**) beside stenosis.
6. Left-click to set the first point within the vessel.

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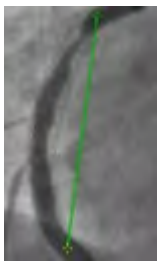
NOTE

The start and end point of the measurement must be placed in a healthy part of the vessel. The start and end point must be at least one lesion length away from the lesion. The start and end point can still be moved after setting.

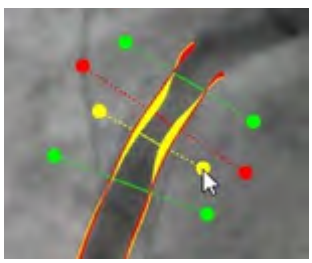
7. Right-click to set the second point within the vessel.



The stenosis will be detected automatically between the start and end point.

8. To visualize the values in the upper left hand corner of the view, move the cursor out of the workspace.

9. You can move the displayed diameter landmarks – which correspond to the markers in the result diagram – by drag and drop.



Saving options

The results are automatically stored.

- To save a screenshot, click (**Secondary Capture**).
- To visualize all values and review the measurements, launch the **Worksheet** (see "Worksheet" on page 69).

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Stress Echo

Stress echo allows reviews of 2D stress echo studies. Clips of different stress stages are synchronized for a side-by-side view and incorporated for visual and quantitative analysis (manual wall motion scoring).

Selection of clips for review

For each stage related view more than one clip can be available.

- To review all available clips, select one view/stage.
- To select one image for the review, select the image by double-click.
- If no image is selected all images will be displayed in the review.
- With a single click several images can be selected for the review.

Relabel a view

- Click to the displayed label in the view tiling and choose the right view to relabel.

Review and comparison

To review and compare special stages and views select one of the following options:

Name	Description
Sort by Stage	Sorts all views regarding their stage.
Sort by View	Sorts all views regarding their view name.
Compare	You can compare up to four different stages with up to three different views by checking the stages/views in the list.
Shuffle	This is a predefined sort by view selection with a 2x2 layout. This mode is only available for two stage protocols.

Wall motion scoring in Stress Echo

To perform a wall motion scoring do the following:

- Select sector model: ASE 16 or ASE 17
- Select scoring model: 4 up to 7 Points
- Select scoring style: colors, points or colors and points
- Left-click to dye a wall segment for scoring.
- To score all unscored segments as normal click  .
- To clear all scorings of segments click  .

Defaults for wall motion scoring options can be customized in the settings by clicking  and selecting the **Stress Echo** tab.

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Module Start of Additional Clinical Applications

Start a clinical application with one dataset

1. Select a study which contains a dataset for this application and start **IMAGE-COM**.
2. Select a suitable dataset or a bookmark within the preview area.
3. Right-click and select the name of the clinical application to start it.

Start a clinical application with multiple datasets

1. Select a study which contains multiple datasets for this application and start **IMAGE-COM**.
2. Select suitable datasets or a bookmark in the preview area. To mark datasets, use **crtl+left-click** on the thumbnail or use  (checkmark smart region). A checkmark indicates marked datasets.
3. Right-click and select the name of the clinical application to start it with all marked objects.

Worksheet

The **Worksheet** offers an overview about all available measurements. Measurements can be reviewed, deleted or edited.

Navigation in the Worksheet

The compact **Worksheet** opens as a factory default. Click  to maximize the **Worksheet**.

NOTE

The Worksheet sidebar status is saved client specific.

1. Open a measurement group and click on a measurement package to open all measurements of this package in the **Worksheet** area.
2. Scroll through the **Worksheet** area with the mouse wheel.

When navigating in the measurement menu, the **Worksheet** synchronizes with the selected measurement group and package.

Following filter options are available to get an overview of all available measurements:

- Click  (activated per factory default) to filter for all measured values.
- Click  to filter for missing recommended or required fields.
- Click  to show measurements with range indicator.
- Click  to show measurements which are outside the range.
- By configuration, measurement results can be exported as .txt or .csv files with  .
- All performed measurements can be printed with  .

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NOTE

The filter options are saved client specific.

Reviewing and editing measurements in the compact Worksheet

The compact **Worksheet** provides an overview of all **value to use** measurements.

- To reload a measurement in the image review area, click into a measurement line. In case the **value to use** is average, the last performed measurement is loaded.

Reviewing and editing measurements in the maximized Worksheet

If measurements were performed multiple times the **value to use** (e.g., for reporting) can be selected as following:

- Navigate to a measurement group and click on a measurement package to open all measurements of this package.
- Adapt the entry of the drop list. Available methods are: **Avg** (factory default), **First**, **Last**, **Min** and **Max**.

Measurements can be edited and added manually via the measurement fields.

To delete measurements the following options are available:

- To delete one measurement, click into a measurement field and click  .
- To delete a whole column of a measurement package, click  .
- To reload a measurement in the image review area, click into a measurement field and click  .

NOTE

The reload function is available for labeled measurements which were performed in IMAGE-COM or on-cart. For the ultrasound scanner export configurations and settings refer to the corresponding instruction for use or contact your service representative.

NOTE

A measurement can be performed up to 5 times. In case this number is exceeded FIFO (First In First Out) will be applied.

Biological parameters in the Worksheet

The **Worksheet** offers a section for biological parameters. Values can be adapted manually via the input fields.

NOTE

The formula for BSA can be customized in the Administration Configuration. For details see “BSA Calculation Formula” on page 182.

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QualitySeal

The **QualitySeal** checks all available measurement fields for their requirement status and the defined normal ranges. By default, the published normal ranges are used.

In case **QualitySeal** is active the recommended and required measurement fields are marked with yellow and red frames if they are empty. The measurement packages show yellow and red exclamation marks.

Measurement packages in **IMAGE-COM** and **Worksheet** use the following symbols:

Icon	Name	Description
!	Yellow exclamation mark/frame	Empty recommended field
!	Red exclamation mark/frame	Empty required field

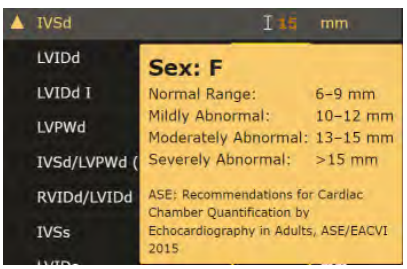
You can evaluate if a measurement result is in or outside the normal ranges. Move the cursor over a measurement field to display the related normal ranges.

- The explanation appears automatically.
- If applicable the publication title is displayed.
- A measured value highlighted in orange shows that it is out of the normal range.

The following symbols are displayed for each measured value for which a normal range has been defined:

Icon	Description
▲	Measured value is **above** the normal range.
▼	Measured value is **below** the normal range.
●	Measured value is **within** the normal range.

Normal ranges can depend on conditions, like gender dependent normal ranges. For further information on how to customize the normal ranges, see chapter “QualitySeal Customization” on page 167).



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NOTE

Measured values that are outside the normal range are also labeled in the printed **Measurement List**  .

10 REPORTING

REPORTING provides various workspaces which are dedicated to different clinical applications and supports the workflow within clinical institutions. Measurements can be imported, modified and exported in order to support connected reporting systems.

REPORTING Fundamentals

Workspaces

The REPORTING module offers you a variety of workspaces for the different types of clinical examinations. You can create and customize multiple report templates for each workspace (see chapter “REPORTING Customization” on page 156). The following workspaces are available per factory default:

Echocardiography

- TTE
- TEE
- TEE Pre/Post OP
- Stress
- Pediatric
- Pediatric TEE
- Pediatric TEE Pre/Post OP
- Fetal

Vascular examination

- Extracranial
- Transcranial
- Extremity Venous
- Extremity Arterial
- Aortic Iliac
- Renal Duplex
- Abdominal Duplex
- Graft Duplex

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- Dialysis Access

Generic

- Generic

Point-of-Care

- Extended FAST Exam (EFAST)
- Focused Abdominal Aorta
- Focused Transthoracic Cardiac Ultrasound
- Focused Transesophageal Cardiac Ultrasound
- Focused Thoracic
- Focused Renal/Urinary Tract
- Focused Biliary
- Focused Ocular
- Focused Bowel Examination
- Focused Testicular Examination
- Focused Obstetrical Pelvic Ultrasound
- Focused Non-Obstetrical Pelvic Ultrasound
- Focused Soft Tissue/Musculoskeletal
- Focused Lower Extremity Venous
- Undifferentiated Chest Pain and Dyspnea
- Undifferentiated Hypotension
- Regional Anesthesia

Every workspace contains several tabs.

Workspace tabs

Name	Description
Basic Info	It is available for all workspaces. Data is shared for all workspaces. Additional information to a study can be appended.
Procedure	It is available for all workspaces. Additional information to a performed procedure can be appended.
Clinical Findings (Interpretation)	This tab is workspace-specific and can consist of multiple tabs. You can create clinical findings by using predefined text modules. You can adapt the list of predefined text modules, see “Choice Lists & Summary” on page 157.
Wall Motion	Manual wall motion scoring is available for TTE, TEE, TEE Pre/Post OP, Stress, Pediatric, Pediatric TEE and Pediatric TEE Pre/Post OP.

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QuickFill Function

Accelerate your REPORTING workflow by using the **QuickFill** function. Start filling empty fields of a report with clinical content, free text entries, wall motion scorings, drawings and edited report blocks in the dynamic preview. Save it as a QuickFill template by click on  and naming it. Reuse it for further clinical reports by applying the appropriate QuickFill from the drop-down. Already existing entries and quantity fields are excluded and not overwritten.

Enter the **Manage QuickFill** dialog box with  to edit the names of QuickFills and/or change their order by dragging and dropping. User QuickFills can be shared globally. The date reflects the initial creation date.

Populate From Function

Accelerate your REPORTING workflow by using the **Populate from** function. If one or more finalized previous studies for the same patient and workspace are available, you can populate a report with clinical content, free text entries, wall motion scorings, drawings and edited report blocks in dynamic preview from previous study data. Already existing entries are not overwritten, quantity/measurement fields are excluded.

Previous studies are sorted by date and time. The drop-down list is limited to a maximum of 5 previous studies.

Report (Dynamic Preview)

Before you finalize and print your report, check the report in the Preview pane and if necessary, modify it with the following functions.

You can edit the entries in the report blocks directly. Every modified report block is marked with  . To restore to the initial entry, hover over  and click **Restore to** and confirm with **OK**.

You can insert images directly from IMAGE-COM diagnostic area or from the REPORTING thumbnail bar into the dynamic preview. Multi-frame images have to be paused.

NOTE

Up to 10 images can be inserted into an image report block on the print report. You can also import .jpeg from the local desktop by drag and drop.

NOTE

When inserting a multi-frame image from the thumbnail bar to the dynamic preview only the first frame is added to the print report.

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REPORTING Controls

The toolbar of REPORTING provides controls regarding workflow and report status handling. Some of the controls vary somewhat, depending on the license option and selections.

Workflow controls

Icon	Name	Description
	**Change Report**	Change report during reporting Filled fields and imported measurements will stay (if available in the new workspace).
	**Show All Measurements**	Show or hide empty measurement fields
	**Dynamic Preview**	Show or hide dynamic preview
	**Import Results**	Import updated measurements

Report state controls

The following report state controls are used to create preliminary and final reports.

Icon	Name	Description
	**Set to Preliminary**	Set report to preliminary
	**Finalize**	Set report to finalized (requires user authentication by factory default, see chapter “REPORTING Customization” on page 156)
	**Unfinalize**	Set report to unfinalized
	**Back to Started**	Set report back to started

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QuickFill controls

The following controls are used to create and manage QuickFills.

Icon	Name	Description
	**Create new QuickFill**	Create a prefilled clinical report as a QuickFill template
	**Manage QuickFill**	Manage your QuickFill templates
	**Clear Report**	Clear entries in the current report completely
QuickFill Management Controls		
	**Download QuickFill**	Download one or all generated QuickFills
	**Upload QuickFill**	Upload a QuickFill template
	**Share Globally**	Share a QuickFill template globally
	**Delete**	Delete a QuickFill template

Report preview controls

The following controls are used for the zoom and print preview.

Icon	Name	Description
	**Shrink to Fit**	If possible, the printout of a report can be scaled down to print on one or fewer pages.
	**Print**	PDF preview of print report
	**Zoom in**	Adjust the preview are to be bigger.
	Zoom out	Adjust the preview are to be smaller. Zoom out is enabled only after a zoom in.
	**Reset**	Adjust the preview to the original size.

REPORTING Workflow Procedure

The REPORTING procedures vary somewhat, depending on the selected workspace. The following is a typical scenario for the workflow tasks in reporting. The scenario provides an overview of the tasks involved in using the REPORTING module.

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Select the Workspace and Report

When starting the REPORTING module, the report selection page provides different workspaces per factory default. You can create and customize multiple report templates for each workspace (see chapter “REPORTING Customization” on page 156).

- Select a report corresponding to one of the workspaces.

Add Additional Information to a Study

The Basic Info tab contains patient, study and staff information. Some of this information is transferred from the calling platform (i.e., ultrasound machine) and is displayed in read-only mode within the workspace.

To add additional information:

- Select items from predefined drop-down lists (for customization see chapter “Choice Lists & Summary” on page 157).
- Enter content into a text field manually or use copy and paste.

Add Additional Information to a Procedure

The Procedure tab contains further parameters (i.e. patient related information like height, weight, BP), which is transferred from the calling platform (i.e. ultrasound machine). It is displayed read-only in the workspace.

To add additional information:

- Select items from predefined drop-down lists.
- Enter content into a text field manually or use copy and paste.
- Dynamically increase the tables with  or decrease with  to enter further procedure details (for TTE, TEE, TEE Pre/Post OP, Stress, Pediatric, Pediatric TEE, Pediatric TEE Pre/Post OP and Generic).

Create Clinical Findings

To create clinical findings in the Interpretation tab:

- Select items from predefined drop-down lists.
- Enter text into a text field manually or use copy and paste.
- Show or hide all available measurements fields by clicking  on the top bar.
- Change pre-defined auto summary by moving your cursor to field. Add content to the summary with  , remove content with  .

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Import Measurement Results

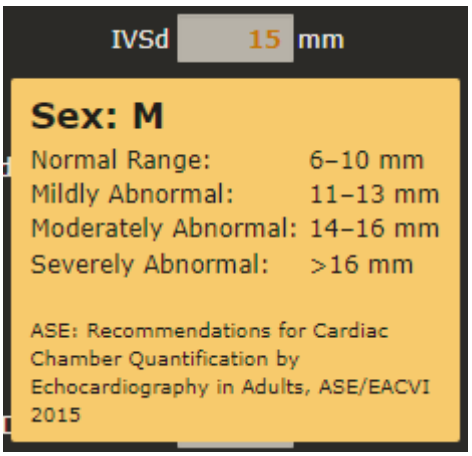
The import of measurements and stress stages with associated wall motion scorings happens automatically on the first start of REPORTING. If additional measurements or wall motion scoring is performed after initial launch of report:

- Click the button  to import and update the measurements and stress stages.

Evaluate Normal Ranges

You can evaluate if a measurement result is inside the published normal ranges. Move the cursor over a measurement field to display the related normal ranges.

- The explanation appears automatically.
- If applicable the publication title is displayed.
- A measurement value highlighted in orange shows that it is out of normal range.
- Normal ranges can be dependent on conditions (e.g. gender dependent normal ranges, for customization see chapter “QualitySeal Customization” on page 167).



The normal ranges are displayed on the print report together with an indication arrow for measurement values that are out of normal range (for customization see chapter “QualitySeal Customization” on page 167).

IVSd	15 mm	▲ (6–10)

If the normal range includes at least one negative value, an * is displayed for measurement values that are out of normal range.

Wall Motion Scoring in REPORTING

Wall motion scoring is a segment-by-segment visual and qualitative evaluation of the left ventricular function. Generally, wall motion scoring is performed by viewing the images and ranking the tissue motion.

Defaults for wall motion scoring options can be customized in the WMS Options Editor (see chapter “Choice Lists & Summary” on page 157 in REPORTING Customization).

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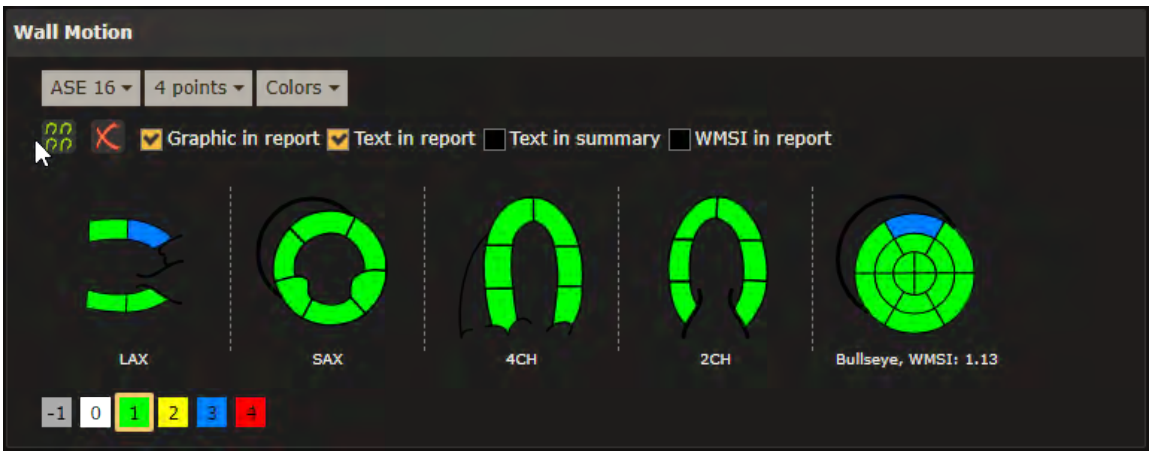
To perform a wall motion scoring do the following:

- Select sector model: ASE 16 or ASE 17
- Select scoring model: 4 up to 7 Points
- Select scoring style: colors, points or colors and points (the mouse courser changes the color according to the score value).
- For scoring, select a wall segment by clicking on it.
- To score all unscored segments as normal, click .
- To clear the scoring of all segments, click .

Different wall motion scoring options are available for REPORTING:

- Graphic in report: Show wall motion graphic on print report.
- Text in report: Add text for wall motion findings to left ventricle report block.
- Text in summary: Add text to summary section.
- Wall Motion Scoring Index (WMSI) in report: Show WMSI on print report.



Add Stage for Stress Echocardiography

The Stress workspace allows documentation of clinical findings of a stress echocardiography. In the Stress Interpretation tab do the following to document on different stress stages:

1. Click **Add Stage**.
2. Enter stage name by typing free text in the text box or selecting an existing stress stage from the drop-down list. This entry is mandatory to continue with the next step.
3. Click **OK**.
4. To remove a stage, click .

In the Wall Motion tab, wall motion scoring can be performed for each stress stage in the same manner.

NOTE

A performed Stress Echo in IMAGE-COM is available the first time when starting a stress report.

Drawing Editor for Vascular Examination

The Drawing Editor allows you to document findings for vascular examinations graphically. Per factory default drawings of clinically relevant structures are available. An empty canvas is also available in the vascular and generic workspaces.

To create a drawing do the following:

Navigate to the Drawings paragraph in the clinical findings tab.

To open the Drawing editor, click on the image you want to edit.

Perform drawings by utilizing the available controls in the toolbar.

Close the Drawing Editor to save the drawing.

By default, the drawing is included in the preview of the report. To remove the drawing from the preview, deselect the checkbox.

Drawing editor controls and keyboard shortcuts

Icon	Name	Description
	**Select Tool** [v]	Select an item in your performed drawings.
	**Panning**	Pan through the drawings with left-click.
	**Pencil Tool** [q]	Draw single curves.
	**Vessel**	Draw vessels with a certain thickness. The default thickness is 10.
	**Line Tool** [l]	Draw a straight line.
	**Rectangle Tool** [r]	Draw a rectangle.
	**Ellipse** [e]	Draw an ellipse.
	**Text tool** [t]	Enter annotations.
	**Undo** [z]	Undo last drawings.

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Icon	Name	Description
	**Redo** [y]	Redo drawings.
	**Clone Elements** [d]	Copy a drawing element.
	**Delete** [del]	Delete a drawing element.
	**Move to top** [Ctrl + shift]	Bring drawing element to top layer.
	**Move to bottom** [Ctrl + shift]	Bring drawing element to bottom layer.
	**Change fill color**	--
	**Change stroke color**	--

11 AutoStrain LV

AutoStrain Left Ventricle (AutoStrain LV) provides global longitudinal strain (GLS) measurements for apical four-chamber (A4C), apical two-chamber (A2C), and apical three-chamber (A3C) views. For best results, use three apical long-axis loops. Using three loops enables one-click results, bull's eye plots, and results for each of the views plus an average of the three. If you use only one or two loops, the AutoStrain LV can quantify the loops, but it does not produce bull's eye plots from them or average their results.

Ejection Fraction (EF) can be measured using the Biplane Simpson method. The AutoStrain LV supports images with or without native data and with or without an ECG signal. To quantify loops without an ECG signal, you must manually enter the cardiac cycle timing.

The AutoStrain LV calculates the heart rate on all loops. If the difference between minimum and maximum heart rate is more than 10%, the message, "HR Variation > 10%" appears.

AutoStrain LV Controls

The AutoStrain LV provides the following additional controls.

AutoStrain LV controls

General

Icon	Name	Description
	**Brightness**	Adjusts image brightness. To reset the slider to zero, click the icon.

Icon	Name	Description
	**Contrast**	Adjusts image contrast. To reset the slider to zero, click the icon.
	**Multi-Pane View**	Switches to multi-pane view.
	**Single-Pane View**	Switches to single-pane view.
	**Show ED Frame**	Displays the ED frame.
	**Show ES Frame**	Displays the ES frame.

Labeling

Icon	Name	Description
	**Delete View Labels**	Deletes the labeling of all loops.
	**Reset**	Deletes Labels, new labeling is needed to start workflow from scratch.

Cardiac Cycle

Icon	Name	Description
	**Reset**	Resets edits in Cardiac cycle workflow steps, 1. Edits in cardiac cycle selection / border adjustment. 2. Edits of M-mode line.

Strain Tracking Revision

Icon	Name	Description
	**Delete Contours**	Deletes the contours for the corresponding loop and starts 3 points initialization to create a new contour.
	**Reset**	Deletes all edits on the contour and triggers new **Strain** calculation.

Strain Analysis

Icon	Name	Description
	**Show Bullseye**	Shows the bullseye display.
	**Show Strain Rate Waveforms**	Shows the strain rate waveforms.
	**Show Strain Waveforms**	Shows the strain waveforms.
	**Show Measurements**	Shows or hides the regional strain measurements on the loop overlay.

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Icon	Name	Description
	**Edit AVC**	Allows you to edit the aortic valve closure timing.
	**Transparency**	Sets the transparency of the contour visualization.
	**Reset**	Deletes all edits on the contour and triggers new **Strain** calculation.

EF Tracking Revision

Icon	Name	Description
	**Delete Contours**	Deletes the contours for the corresponding loop and starts 3 points initialization to create a new contour.
	**Reset**	Deletes all edits on EF contour and triggers new EF tracking based on ED Strain contour.

EF Analysis

Icon	Name	Description
	**Reset**	Deletes all edits on EF contour and triggers new EF tracking based on ED Strain contour.

AutoStrain LV Settings

Settings set the operating parameters for various features. These settings allow you to control the display of the labels on the images and to set the defaults for the options.

Name	Description
A2C Left/Right Inverted	Sets the default orientation of the apical two-chamber view label to left-right inverted.
A3C Left/Right Inverted	Sets the default orientation of the apical three-chamber view label to left-right inverted.
A4C Left/Right Inverted	Sets the default orientation of the apical four-chamber view label to left-right inverted.
Up-Down	Sets the default image orientation of all view labels to top-bottom inverted.
Transducer Type	Sets the default transducer type to TTE or TEE.
Default Measurement Layer	Sets the default measurement layer to Endo or Mid layer.
Regional Measurement Timing	Selects whether **End-Systolic** or **Peak-Systolic** segmental strain measurements appear in the bull's eye display and as an overlay on the images.
Color Scheme	Sets a default color scheme to global or view-based for visualization of segments and waveforms.

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AutoStrain LV Workflow Procedures

The following is a typical scenario for the workflow tasks or image-processing procedures. The scenario provides an overview of the tasks involved in using the workflow.

NOTE

This application automatically labels the views, analyzes the views, and presents the results in **Strain Analysis**, **SWM**, and **EF Analysis**.

Module Start

1. Start the platform software (e.g. IMAGE-COM).
2. Select a study, which contains datasets for this application.
3. Select up to three loops (Press **Ctrl** + left-click on the images).
4. Right-click and select the name of the application to start it.

Labeling a Loop

If the auto-labeling of the loops fails you can correct the labeling by deleting the labels first.

1. Click one of the loop labels (A2C, A3C, or A4C).
2. Move the pointer over the loop that corresponds to the label. A reference drawing is overlaid on the loop.
3. To set the label, click inside the loop.
4. Repeat steps 1 through 3 for the remaining loops.

Adjusting the Cardiac Cycle

By default, the middle beat of a long loop is selected for quantification. Cardiac cycle adjustment provides an M-Mode view derived from the 2D loop.

NOTE

All frames between the **ED Start** and **ED End** markers are interpreted as a single cardiac cycle.

1. Click **Cardiac Cycle.**
2. To help visualize valve closure, atrial contraction, and annular motion, adjust the axis of the M-Mode view.
3. To change the selected beat in the loop, do one of the following:
   - Click  or  to select a new beat.
   - Double-click a beat to select it.

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4. Drag the **ED Start** and **ED End** markers to the start and end of the cycle. If you drag the horizontal bar, **ED Start** and **ED End** are moved together. The image is synchronized with the selected border.

Obtaining an Accurate Border

If the automatic endocardial border contours are not accurate, you can revise them. When you make changes to the end-diastole (ED) frame, the changes affect the whole cardiac cycle. When you make changes to the end-systole (ES) frame, the changes affect only the neighboring frames. ED is not affected by changes to ES. The annular tracking points should be placed at the mitral annulus, where the leaflets attach.

1. Click **Strain Tracking Revision**.
2. To adjust points, drag them to a new position.
3. To delete the existing borders and manually place the points, click  .
4. If you deleted the contours, place the points in the right view as shown in the reference drawing.
5. When finished, click **Strain Analysis**. The results update with the new tracking points.

Editing Aortic Valve Closure

The closure of the aortic valve marks the end of the systole phase. If the wrong frame of the loop is marked as end systole (ES), you can edit the aortic valve closure (AVC). Editing the ES time has no effect on the GLS measurement. The end-systolic strain and peak-systolic strain values are recalculated after the change.

1. Click **Strain Analysis**.
2. Click  (**Edit AVC**).
3. Drag the ES line. While moving, the corresponding B-Mode image is shown in the upper view.

Working with Waveforms

1. To display strain waveforms, click  .
2. To display strain rate waveforms, click  .
3. Do any of following:
   - To display the waveforms associated with a view, click that view.
   - To display segmental curves for all views, select
     - the **Endo** tab to display the endocardial layer results,
     - the **Mid** tab to display the mid-myocardial layer results,
     - or the **LV Length** tab to display either mid or endo layer curves depending on which layer was previously shown.
   - To display the name of a waveform, hover over the waveform.

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- To display the value at a point on the waveform, click the waveform. To dismiss the value, click outside the waveform.

EF Tracking Revision

1. Click **EF Tracking Revision**.
2. To adjust points, drag them to a new position.
3. To delete the existing borders and manually place the points, click  .
4. If you deleted the contours, place the points in the left view as shown in the reference drawing.
5. When finished, click **EF Analysis**. The results update with the new tracking points.

EF Analysis

- To review EF and volume waveforms, click **EF Analysis**.
- To revise the automatic border contours, click **D** or **S** to edit the end-diastolic or end-systolic contour.
- To display the volume waveform of the biplane measurement, the A4C view or the A2C view, click on the corresponding tab in results view.

AutoStrain LV Results

When exit the application, you can save the measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

Global Results Endo

- **GLS Endo Peak A4C**
- **GLS Endo Peak A2C**
- **GLS Endo Peak A3C**
- **GLS Endo Peak Avg**

Global Results Mid

- **GLS Mid Peak A4C**
- **GLS Mid Peak A2C**
- **GLS Mid Peak A3C**
- **GLS Mid Peak Avg**

LV Length Results

- **Diastolic Major Axis A4C**
- **Systolic Major Axis A4C**

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- **Diastolic Major Axis A2C**
- **Systolic Major Axis A2C**

Ejection Fraction Biplane

- **EF (BP)**
- **EDV (BP)**
- **EDVI* (BP)**
- **ESV (BP)**
- **ESVI* (BP)**
- **SV (BP)**

Ejection Fraction A4C

- **EF (A4C)**
- **EDV (A4C)**
- **EDVI* (A4C)**
- **ESV (A4C)**
- **ESVI* (A4C)**
- **SV (A4C)**

Ejection Fraction A2C

- **EF (A2C)**
- **EDV (A2C)**
- **EDVI* (A2C)**
- **ESV (A2C)**
- **ESVI* (A2C)**
- **SV (A2C)**

(*Not available in all variants, requires height and weight of the patient.)

12 AutoStrain SAX

AutoStrain Short Axis (AutoStrain SAX) provides global circumferential strain (GCS) measurements for basal, mid-ventricular, and apical short axis views of the left ventricle. The AutoStrain SAX supports images with or without native data and with or without an ECG signal. To quantify loops without an ECG signal, the cardiac cycle timing must be defined manually.

AutoStrain SAX calculates the heart rate on all loops. If the difference between minimum and maximum heart rate is more than 10%, the message "HR Variation > 10%" appears.

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AutoStrain SAX Controls

The AutoStrain SAX provides the following additional controls.

AutoStrain SAX controls

Icon	Name	Description
	**Show ED Frame**	Displays the ED frame.
	**Show ES Frame**	Displays the ES frame.

AutoStrain SAX Settings

These settings determine the operating parameters for various features. They contain options to define default orientation of the view labels.

Name	Description
Up-Down	Sets the default image orientation of all view labels to top-bottom inverted.
SAX Basal Left/Right Inverted	Sets the default orientation of the basal SAX view label to left-right inverted.
SAX Mid Left/Right Inverted	Sets the default orientation of the mid-ventricular SAX view label to left-right inverted.
SAX Apical Left/Right Inverted	Sets the default orientation of the apical SAX view label to left-right inverted.

AutoStrain SAX Workflow Procedures

The following is a typical scenario for the workflow tasks or image-processing procedures. The scenario provides an overview of the tasks involved in using the workflow.

Module Start

1. Start the platform software (e.g., IMAGE-COM).
2. Select a study, which contains datasets for this application.
3. Select up to three SAX loops (Press **Ctrl** + left-click on the images).
4. Right-click and select the name of the application to start it.

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Labeling a Loop

Before initializing the contour tracking the loops must be labeled manually in the View Labeling workflow step.

1. The Basal SAX view label is preselected but can be changed manually by selecting another one of the view labels (Basal, Mid, or Apical).
2. Move the pointer over the loop/view that corresponds to the label. A reference drawing is overlaid on the loop.
3. To set the label, left-click inside the loop.
4. Once a view is labeled the subsequent label is automatically selected.
5. Repeat steps 1 through 3 for the remaining loops.

Adjusting the Cardiac Cycle

By default, the middle beat of a long loop is selected for quantification. Cardiac cycle adjustment provides an M-Mode view derived from the 2D loop.

NOTE

All frames between the **ED Start** and **ED End** markers are interpreted as a single cardiac cycle.

1. Click **Cardiac Cycle.**
2. To help visualize myocardial motion, adjust the axis of the M-Mode view.
3. To change the selected beat in the loop, do one of the following:
   - Click  or  to select a new beat.
   - Double-click a beat to select it.
4. Drag the **ED Start** and **ED End** markers to the start and end of the cycle. If you drag the horizontal bar, **ED Start** and **ED End** are moved together. The image is synchronized with the selected border.

Initialize Contour Tracking

To initialize the automatic contour tracking one must define initial endocardium contours for all loaded views.

1. Click **Tracking Revision**.
2. Click  next to the view label for which you want to add a contour.
3. To draw a contour place points by left-clicks at the endocardial border within the view. To finish drawing and closing the contour line do a right-click.
4. To delete the existing borders and manually place the points, click  of the same view again.
5. Repeat the previous steps for all contours.
6. When finished, click **Analysis**. The results update with the new tracking points.

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Correcting Contours

If the automatic endocardial border contours are not accurate, one can revise them. When you make changes to the contour of the end-systolic (ES) frame, the changes affect the whole cardiac cycle. When you make changes to the end-diastolic (ED) contour, the changes affect only the neighboring frames. The ES contour is not affected by changes to the ED contour. The annular tracking points should be placed at the mitral annulus, where the leaflets attach.

1. Click **Tracking Revision**.
2. To adjust points, drag them to a new position.
3. To delete the existing borders and manually place the points, click  .
4. If you deleted the contours, place the points in the left view as shown in the reference drawing.
5. When finished, click **Analysis**. The results update with the new tracking points.

Working with Waveforms

1. To display strain waveforms, click  .
2. To display strain rate waveforms, click  .
3. Do any of following:
   - To display the waveforms associated with a view, click that view.
   - To display the name of a waveform, hover over the waveform.
   - To display the value at a point on the waveform, click the waveform. To dismiss the value, click outside the waveform.

AutoStrain SAX Results

When exiting the application, you can save measurements and a bookmark. For information about the measurement accuracy, see chapter “Measurements” on page 196.

Global Results

- **GCS Endo Peak Basal [%]**
- **GCS Endo Peak Mid [%]**
- **GCS Endo Peak Apical [%]**

13 AutoStrain LA

AutoStrain Left Atrium (AutoStrain LA) provides left atrial strain measurements from apical four-chamber loops. For best results, acquire an LA-centric loop from the apical four-chamber view. AutoStrain LA supports images with or without native data and with or without an ECG signal. To quantify loops without an ECG signal you must manually enter the cardiac cycle timing.

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The automated strain detection measures reservoir strain, conduit strain, and contraction strain at both end-diastole and atrial precontraction (PreA).

AutoStrain LA Controls

The AutoStrain LA provides the following additional controls.

AutoStrain LA controls

Icon	Name	Description
	**Edit PreA**	Selects a layout that allows editing the PreA.
	**Show ED Frame**	Displays the ED frame.
	**Show ES Frame**	Displays the ES frame.

AutoStrain LA Settings

These settings allow you to control the display of the labels on the images and to set the defaults for options.

Name	Description
Up-Down	Sets the default image orientation of all view labels to top-bottom inverted.
A4C Left/Right Inverted	Sets the default orientation of the apical four-chamber view label to left-right inverted.
Transducer Type	Sets the default transducer type to TTE.
LA Reference Frame	Selects whether the **End-Diastolic (ED)** or **Atrial Contraction** (PreA) frame is used as the LA reference frame.

AutoStrain LA Workflow Procedures

The following is a typical scenario for the workflow tasks or image-processing procedures. The scenario provides an overview of the tasks involved in using the workflow.

NOTE

This application automatically labels the views, analyzes the views, and presents the results in **Strain Analysis**, **SWM**, and **EF Analysis**.

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Module Start

1. Start the platform software (e.g. IMAGE-COM).
2. Select a study, which contains datasets for this application.
3. Select a suitable dataset within the preview window.
4. Right-click and select the name of the application to start it.

Labeling a Loop

If the automatic detection of the loop type is incorrect, do one of the following.

- Click  (Settings), change the Default Image Orientation to match the image you loaded, and restart the application.
- Choose another loop to quantify.

Adjusting the Cardiac Cycle

By default, the middle beat of a long loop is selected for quantification. Cardiac cycle adjustment provides an M-Mode view derived from the 2D loop.

NOTE

All frames between the **ED Start** and **ED End** markers are interpreted as a single cardiac cycle.

1. Click **Cardiac Cycle.**
2. To help visualize valve closure, atrial contraction, and annular motion, adjust the axis of the M-Mode view.
3. To change the selected beat in the loop, do one of the following:
   - Click  or  to select a new beat.
   - Double-click a beat to select it.
4. Drag the **ED Start** and **ED End** markers to the start and end of the cycle. If you drag the horizontal bar, **ED Start** and **ED End** are moved together. The image is synchronized with the selected border.

Obtaining an Accurate Border

If the automatic endocardial border contours are not accurate, you can revise them. When you make changes to the end-diastole (ED) frame, the changes affect the whole cardiac cycle. When you make changes to the end-systole (ES) frame, the changes affect only the neighboring frames. ED is not affected by changes to ES. The annular tracking points should be placed at the mitral annulus, where the leaflets attach.

1. Click **Strain Tracking Revision**.
2. To adjust points, drag them to a new position.

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3. To delete the existing borders and manually place the points, click  .
4. If you deleted the contours, place the points in the right view as shown in the reference drawing.
5. When finished, click **Strain Analysis**. The results update with the new tracking points.

Editing the PreA

1. Click Analysis.
2. Click  (**Edit PreA**).
3. Drag the **PreA** marker to the onset of atrial contraction.

Working with Waveforms

To display the value at a point on the waveform, click the waveform. To dismiss the value, click outside the waveform.

AutoStrain LA Results

When exit the application, you can save measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

ED Reference Results

- **LASr ED**
- **LAScd ED**
- **LASct ED**

PreA Reference Results

- **LASr AC**
- **LAScd AC**
- **LASct AC**

14 AutoStrain RV

AutoStrain Right Ventricle (AutoStrain RV) provides right ventricle strain measurements from right-ventricle focused 2D loops.

The automated strain detection measures both the global RV and free wall strain measurement. The AutoStrain RV supports images with or without native data and with or without an ECG signal. To quantify loops without an ECG signal you must manually enter the cardiac cycle timing.

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NOTE

This application automatically labels the views, analyzes the views, and presents the results in **Strain Analysis**, **SWM**, and **EF Analysis**.

AutoStrain RV Controls

The AutoStrain RV provides the following additional controls.

AutoStrain RV controls

Icon	Name	Description
	**Edit PVC**	Selects a layout that allows editing the PVC.
	**Show ED Frame**	Displays the ED frame.
	**Show ES Frame**	Displays the ES frame.

AutoStrain RV Settings

These settings allow you to control the display of the labels on the images and to set the defaults for options.

Name	Description
A4C Left/Right Inverted	Sets the default orientation of the apical four-chamber view label to left-right inverted.
Up-Down	Sets the default image orientation of all view labels to top-bottom inverted.
Transducer Type	Sets the default transducer type to TTE or TEE.
Regional Measurement Timing	Selects whether **End-Systolic** or **Peak-Systolic** segmental strain measurements appear in the bull's eye display and as an overlay on the images.

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AutoStrain RV Workflow Procedures

The following is the typical workflow for tasks or image-processing procedures.

Module Start

1. Start the platform software (e.g. IMAGE-COM).
2. Select a study, which contains datasets for this application.
3. Select a suitable dataset within the preview window.
4. Right-click and select the name of the application to start it.

Labeling a Loop

If the automatic detection of the loop type is incorrect, do one of the following.

- Click (Settings), change the Default Image Orientation to match the image you loaded, and restart the application.
- Choose another loop to quantify.

Adjusting the Cardiac Cycle

By default, the middle beat of a long loop is selected for quantification. Cardiac cycle adjustment provides an M-Mode view derived from the 2D loop.

NOTE

All frames between the **ED Start** and **ED End** markers are interpreted as a single cardiac cycle.

1. Click **Cardiac Cycle.**
2. To help visualize valve closure, atrial contraction, and annular motion, adjust the axis of the M-Mode view.
3. To change the selected beat in the loop, do one of the following:
   - Click or to select a new beat.
   - Double-click a beat to select it.
4. Drag the **ED Start** and **ED End** markers to the start and end of the cycle. If you drag the horizontal bar, **ED Start** and **ED End** are moved together. The image is synchronized with the selected border.

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Obtaining an Accurate Border

If the automatic endocardial border contours are not accurate, you can revise them. When you make changes to the end-diastole (ED) frame, the changes affect the whole cardiac cycle. When you make changes to the end-systole (ES) frame, the changes affect only the neighboring frames. ED is not affected by changes to ES. The annular tracking points should be placed at the mitral annulus, where the leaflets attach.

1. Click **Strain Tracking Revision**.
2. To adjust points, drag them to a new position.
3. To delete the existing borders and manually place the points, click  .
4. If you deleted the contours, place the points in the right view as shown in the reference drawing.
5. When finished, click **Strain Analysis**. The results update with the new tracking points.

Working with Waveforms

Do any of the following:

- To display the name of a waveform, hover over the waveform.
- To display the value at a point on the waveform, click the waveform. To dismiss the value, click outside the waveform.

AutoStrain RV Results

When exit the application, you can save measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

Global results

- **RVFWSL Endo**
- **RV4CSL Endo**

15 2D Auto LV

2D Auto Left Ventricle (2D Auto LV) provides:

- Global Longitudinal Strain (GLS) measurements in the endocardial or mid myocardial layer,
- Segmental Wall Motion,
- and Ejection Fraction (EF) measurements for apical four-chamber (A4C), apical two-chamber (A2C), and apical long-axis (A3C) views.

For best results, use three apical long-axis loops for GLS. Using three loops enables one-click results, bull's-eye plots, and results for each of the views plus an average of the three. If you use only one or two loops, the 2D Auto LV can quantify the loops, but it does not produce bull's-eye plots from them or average their results.

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The Segmental Wall Motion assists clinicians with assessing Left Ventricular (LV) wall motion within an adult transthoracic echo (TTE) examination. The Segmental Wall Motion uses 3 apical views: A4C, A2C, and A3C. It provides wall motion scores for each of the 17 segments of the LV, and an overall Wall Motion Score Index (WMSI). WMSI is the statistical mean of the score of all evaluated segments.

NOTE

This feature is applicable to adult populations (18 years of age and above) undergoing routine TTE examinations.

Ejection Fraction (EF) can be measured using the Biplane Simpson method. The 2D Auto LV supports images with or without native data and with or without an ECG signal. To quantify loops without an ECG signal, you must manually enter the cardiac cycle timing.

The 2D Auto LV calculates the heart rate on all loops. If the difference between minimum and maximum heart rate is more than 10%, the message, "HR Variation > 10%" appears.

2D Auto LV Controls

The 2D Auto LV provides the following additional controls.

2D Auto LV controls

General

Icon	Name	Description
	**Brightness**	Adjusts image brightness. To reset the slider to zero, click the icon.
	**Contrast**	Adjusts image contrast. To reset the slider to zero, click the icon.
	**Multi-Pane View**	Switches to multi-pane view.
	**Single-Pane View**	Switches to single-pane view.
	**Show ED Frame**	Displays the ED frame.
	**Show ES Frame**	Displays the ES frame.

Labeling

Icon	Name	Description
	**Delete View Labels**	Deletes the labeling of all loops.
	**Reset**	Deletes Labels, new labeling is needed to start workflow from scratch.

Cardiac Cycle

Icon	Name	Description
	**Reset**	Resets edits in Cardiac cycle workflow steps, 1. Edits in cardiac cycle selection / border adjustment. 2. Edits of M-mode line.

Strain Tracking Revision

Icon	Name	Description
	**Delete Contours**	Deletes the contours for the corresponding loop and starts 3 points initialization to create a new contour.
	**Reset**	Deletes all edits on the contour and triggers new **Strain** calculation.

Strain Analysis

Icon	Name	Description
	**Show Bullseye**	Shows the bullseye display.
	**Show Strain Rate Waveforms**	Shows the strain rate waveforms.
	**Show Strain Waveforms**	Shows the strain waveforms.
	**Show Measurements**	Shows or hides the regional strain measurements on the loop overlay.
	**Edit AVC**	Allows you to edit the aortic valve closure timing.
	**Transparency**	Sets the transparency of the contour visualization.
	**Reset**	Deletes all edits on the contour and triggers new **Strain** calculation.

EF Tracking Revision

Icon	Name	Description
	**Delete Contours**	Deletes the contours for the corresponding loop and starts 3 points initialization to create a new contour.
	**Reset**	Deletes all edits on EF contour and triggers new EF tracking based on ED Strain contour.

EF Analysis

Icon	Name	Description
	**Reset**	Deletes all edits on EF contour and triggers new EF tracking based on ED Strain contour.

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Segmental Wall Motion

Icon	Name	Description
	**Reset**	Deletes all edits on the segmental scores and triggers new SWM detection.
	**Set all segments to normal**	A shortcut that sets all segments to value 1.

2D Auto LV Settings

Settings set the operating parameters for various features. These settings allow you to control the display of the labels on the images and to set the defaults for the options.

Name	Description
A2C Left/Right Inverted	Sets the default orientation of the apical two-chamber view label to left-right inverted.
A3C Left/Right Inverted	Sets the default orientation of the apical three-chamber view label to left-right inverted.
A4C Left/Right Inverted	Sets the default orientation of the apical four-chamber view label to left-right inverted.
Up-Down	Sets the default image orientation of all view labels to top-bottom inverted.
Transducer Type	Sets the default transducer type to TTE or TEE.
Default Measurement Layer	Sets the default measurement layer to Endo or Mid layer.
Regional Measurement Timing	Selects whether **End-Systolic** or **Peak-Systolic** segmental strain measurements appear in the bull's eye display and as an overlay on the images.
Color Scheme	Sets a default color scheme to global or view-based for visualization of segments and waveforms.

2D Auto LV Workflow Procedures

The following is a typical scenario for the workflow tasks or image-processing procedures. The scenario provides an overview of the tasks involved in using the workflow.

NOTE

This application automatically labels the views, analyzes the views, and presents the results in **Strain Analysis**, **SWM**, and **EF Analysis**.

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Module Start

1. Start the platform software (e.g. IMAGE-COM).
2. Select a study, which contains datasets for this application.
3. Select up to three loops (Press **Ctrl** + left-click on the images).
4. Right-click and select the name of the application to start it.

Labeling a Loop

If the auto-labeling of the loops fails you can correct the labeling by deleting the labels first.

1. Click one of the loop labels (A2C, A3C, or A4C).
2. Move the pointer over the loop that corresponds to the label. A reference drawing is overlaid on the loop.
3. To set the label, click inside the loop.
4. Repeat steps 1 through 3 for the remaining loops.

Adjusting the Cardiac Cycle

By default, the middle beat of a long loop is selected for quantification. Cardiac cycle adjustment provides an M-Mode view derived from the 2D loop.

NOTE

All frames between the **ED Start** and **ED End** markers are interpreted as a single cardiac cycle.

1. Click **Cardiac Cycle.**
2. To help visualize valve closure, atrial contraction, and annular motion, adjust the axis of the M-Mode view.
3. To change the selected beat in the loop, do one of the following:
   - Click  or  to select a new beat.
   - Double-click a beat to select it.
4. Drag the **ED Start** and **ED End** markers to the start and end of the cycle. If you drag the horizontal bar, **ED Start** and **ED End** are moved together. The image is synchronized with the selected border.

Obtaining an Accurate Border

If the automatic endocardial border contours are not accurate, you can revise them. When you make changes to the end-diastole (ED) frame, the changes affect the whole cardiac cycle. When you make changes to the end-systole (ES) frame, the changes affect only the neighboring frames. ED is not affected by changes to ES. The annular tracking points should be placed at the mitral annulus, where the leaflets attach.

1. Click **Strain Tracking Revision**.

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2. To adjust points, drag them to a new position.
3. To delete the existing borders and manually place the points, click  .
4. If you deleted the contours, place the points in the right view as shown in the reference drawing.
5. When finished, click **Strain Analysis**. The results update with the new tracking points.

Editing Aortic Valve Closure

The closure of the aortic valve marks the end of the systole phase. If the wrong frame of the loop is marked as end systole (ES), you can edit the aortic valve closure (AVC). Editing the ES time has no effect on the GLS measurement. The end-systolic strain and peak-systolic strain values are recalculated after the change.

1. Click **Strain Analysis**.
2. Click  (**Edit AVC**).
3. Drag the ES line. While moving, the corresponding B-Mode image is shown in the upper view.

Working with Waveforms

1. To display strain waveforms, click  .
2. To display strain rate waveforms, click  .
3. Do any of following:
   - To display the waveforms associated with a view, click that view.
   - To display segmental curves for all views, select
     - the **Endo** tab to display the endocardial layer results,
     - the **Mid** tab to display the mid-myocardial layer results,
     - or the **LV Length** tab to display either mid or endo layer curves depending on which layer was previously shown.
   - To display the name of a waveform, hover over the waveform.
   - To display the value at a point on the waveform, click the waveform. To dismiss the value, click outside the waveform.

EF Tracking Revision

1. Click **EF Tracking Revision**.
2. To adjust points, drag them to a new position.
3. To delete the existing borders and manually place the points, click  .
4. If you deleted the contours, place the points in the left view as shown in the reference drawing.

5. When finished, click **EF Analysis**. The results update with the new tracking points.

EF Analysis

- To review EF and volume waveforms, click **EF Analysis**.
- To revise the automatic border contours, click **D** or **S** to edit the end-diastolic or end-systolic contour.
- To display the volume waveform of the biplane measurement, the A4C view or the A2C view, click on the corresponding tab in results view.

Applying Segmental Wall Motion

NOTE

Segmental Wall Motion requires that the images were taken with supported transducers, have standard orientations, are not pediatric, and that all three apical views are available. If any of these conditions are not met for images, the corresponding workflow step is grayed out.

1. Click **Segmental Wall Motion**.
   - Each apical view is divided into six segments, and each segment is given a wall motion scoring ranging from 1-3. The scores are displayed directly on the apical images. They are also summarized in a 17 segment bull's-eye plot.
     - Normal - 1
     - Hypokinesis - 2
     - Akinesis - 3
   - Calculates the statistical mean of all 17 segments called **Wall Motion Score Index** (WMSI).
2. Examine the outcome.

In the event you disagree with any of the automatically provided wall motion scores, the scores on each of the apical images can be modified.

1. Click the box to show the score.
2. Select a different wall motion score value from the displayed drop-down menu.

This new value will then be reflected in the apical view, the bull's-eye plot, and the **Wall Motion Score Index**.

NOTE

An asterisk (*) appears when the score is modified away from the automatically provided score.

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2D Auto LV SWM Feature Performance

A study was conducted to evaluate Segmental Wall Motion (SWM) algorithm performance. Wall Motion Score Index (WMSI) was assessed for the same exams in **2D Auto LV** and in **LVivo**, the 510(k) cleared and CE-marked software by **DiA Imaging Analysis**, used as a ground truth for the study. The result of the study is presented below.

Outcome	Sample Size (number of exams/subjects)	Pearson's correlation coefficient (r) (95% r)	p-value
WMSI	78	0.957 (0.933,0.972)	<.0001

For detailed information about the study which was conducted to evaluate the performance of the SWM feature see chapter “2D Auto LV SWM Feature Performance Study” on page 205.

2D Auto LV Results

When exit the application, you can save the measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

Global Results Endo

- **GLS Endo Peak A4C**
- **GLS Endo Peak A2C**
- **GLS Endo Peak A3C**
- **GLS Endo Peak Avg**

Global Results Mid

- **GLS Mid Peak A4C**
- **GLS Mid Peak A2C**
- **GLS Mid Peak A3C**
- **GLS Mid Peak Avg**

LV Length Results

- **Diastolic Major Axis A4C**
- **Systolic Major Axis A4C**
- **Diastolic Major Axis A2C**
- **Systolic Major Axis A2C**

Segmental Wall Motion

- **Wall Motion Score Index**

Ejection Fraction Biplane

- **EF (BP)**

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- **EDV (BP)**
- **EDVI* (BP)**
- **ESV (BP)**
- **ESVI* (BP)**
- **SV (BP)**

Ejection Fraction A4C

- **EF (A4C)**
- **EDV (A4C)**
- **EDVI* (A4C)**
- **ESV (A4C)**
- **ESVI* (A4C)**
- **SV (A4C)**

Ejection Fraction A2C

- **EF (A2C)**
- **EDV (A2C)**
- **EDVI* (A2C)**
- **ESV (A2C)**
- **ESVI* (A2C)**
- **SV (A2C)**

(*Not available in all variants, requires height and weight of the patient.)

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16 3D Auto RV

The 3D Auto RV is a right ventricular quantification tool for routine clinical work, pulmonary hypertension, and right-sided heart failure. The application helps to overcome complexity of right-ventricle analysis by calculating standard values based on a semi-automatically generated 3D surface model.

3D Auto RV Controls

The 3D Auto RV provides the following additional controls.

3D Auto RV controls

Icon	Name	Description
	**Save**	Saves a named adjustment to the acquisition window.

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Icon	Name	Description
	**Edit ED**	Selects end-diastole layout for focused end-diastole editing. End-diastole can be edited in also.
	**Edit ES**	Selects end-systole layout for focused end-systole editing. End-systole can be edited in also.
	**Edit ED and ES**	Selects a layout that allows editing both the end-diastole and end-systole frames.
	**Edit Tricuspid Valve**	Allows you to edit the placement of the valve points in the tricuspid valve views.
	**Retracking**	Triggers retracking of the contours after you have completed end-diastole edits.
	**Show/Hide View Planes**	Shows or hides the MPR view planes in the Beutel view.
	**Display Beutel Solid**	Displays the Beutel model as a solid 3D object.
	**Display Beutel Solid and ED Wireframe**	Displays the Beutel model as a 3D solid object and the end-diastole frame as wireframe.
	**Display Wireframe**	Displays the Beutel model as a 3D wireframe.

3D Auto RV Workflow Procedures

The following is the typical workflow for tasks or image-processing procedures using 3D Auto RV. The module requires a minimum of 10 frames per cardiac cycle and a minimum frame rate of 10 frames per second.

Making Manual View Adjustments

The 3D Auto RV automatically tracks the right ventricle for TTE datasets. Manual adjustments can be made to adjust the landmarks, track a different heartbeat, or change the default settings. 3D Auto RV defaults to automatically track contours and launch in **Tracking Revision** with dataset acquired using right ventricular heart model acquisition from EPIQ system. For other acquisition modes the software starts in **View Adjustment**. Additionally, if the default TTE Acquisition Window is changed or if **RV Init-And-Track (TTE Preset Only)** is not selected in the user settings the automatic tracking will not be performed.

- In **View Adjustment**, points can be adjusted to match the reference image. Automatic landmarks are blue and green. Adjusted landmarks become yellow.
- To select a different beat, click  or  above the ECG display.
- When you have finished, click **Tracking Revision**. The results are recalculated.

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Saving a Custom Acquisition Window Preset

If different settings for the acquisition window is preferred, those settings can be saved as a preset.

1. Click **View Adjustment**.
2. Make changes to the acquisition window.
3. Click  .
4. In **Acquisition Windows** click Add.
5. Type the **New Acquisition Window Name** and then click **OK**.
6. This preset can also be selected as default.

Revising the Tracking

The Tracking Revision workflow step allows review of the automatically detected borders and as well as the ability to edit if necessary.

The tricuspid valve view is used to adjust the valve landmarks. Only the valve points are displayed in this view. You can edit both the tricuspid valve points (blue) and the pulmonary valve points (pink). If the pulmonary valve points are not visible, rotate the MPRs to bring them into view.

- Under Edit, choose the borders you want to edit. You can choose to edit the borders in the end-diastole frame, the end-systole frame, both end-diastole and end-systole frames, or the tricuspid valve view.
- To edit the valve points, select  (**Edit Tricuspid Valve**).
- To zoom a view, click  on one of the views. To return to the un-zoomed view, click  again.
- To move a point: click, hold and drag it to a new location.
- If you change the end-diastolic contour, click  to retrack the contour.
- To enter the next step, click **Analysis**.

Exporting the Beutel Model

The Beutel model is the 3D representation of the right ventricle. You can export the Beutel model in different formats.

1. Click  (**Export Beutel**).
2. Choose a 3D export format from **Save As Type**.
3. Type a file name and choose a place to store the model.
4. Click **Save.**

Review Results in Analysis

In the Analysis step, you get an overview over your analysis results.

Global results: To make changes, go the **View Adjustment** or **Tracking Revision** steps.

2D: Contours can be edit here. Click on a 2D measurement result and change the displayed contour according to your needs.

3D Auto RV Results

When exit the application, you can save measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

2D results

- **FAC**
- **RVDd base (RVD1)**
- **RVDd mid (RVD2)**
- **RVLd (RVD3)**
- **RVLS (Freewall)**
- **RVLS (Septum)**
- **TAPSE**

Global results

- **EDV**
- **EDVi***
- **EF**
- **ESV**
- **ESVi***
- **SV**

(*Not available in all variants, requires height and weight of the patient.)

17 3D Auto MV

3D Auto MV provides a morphological and functional analysis of the mitral valve (MV) using 3D/4D echocardiography data. Models of anatomical structures such as MV annulus, leaflets and the closure line are generated. The derived parameters allow quantification of pre- and post-operative valvular function and a comparison of morphology.

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3D Auto MV Controls

The 3D Auto MV provides the following additional controls.

3D Auto MV Controls

Icon	Name	Description
	**Set End Diastolic Frame**	Selects a layout that allows editing the end diastolic frame.
	**Set End Systolic Frame**	Selects a layout that allows editing the end systolic frame.
	**Set Reference Frame**	Selects a layout that allows editing the reference frame.
	**Set the Apical Aortic Annulus Point (AA)**	Applies the Apical Aortic Annulus Point (AA) as disabled or available.
	**Show or Hide Cutplane**	Displays Cutplane.
	**Show or Hide 3D Decorations**	Applies 3D Decorations.
	**Show or Hide Mitral Valve Model**	Applies the Mitral Valve Model.
	**Show or Hide Topology Texture**	Applies Topology Texture.
	**Show or Hide Tissue Rendering**	Applies Tissue Rendering.
	**D'art**	Excises an interesting slice out of the 3D-dataset.

3D Auto MV Workflow Procedures

Module Start

1. Select a study, which contains datasets for this application.
2. Start the platform software (e.g. IMAGE-COM).
3. Select a suitable dataset within the preview window.
4. Right-click and select 3D Auto MV to launch.

View Alignment

Definition of ED/ES position, alignment of US volume and positioning of landmarks.

After application startup, automated proposals are generated for ED/ES position, alignment of the US volume and landmark positioning. The user needs to review and correct if necessary.

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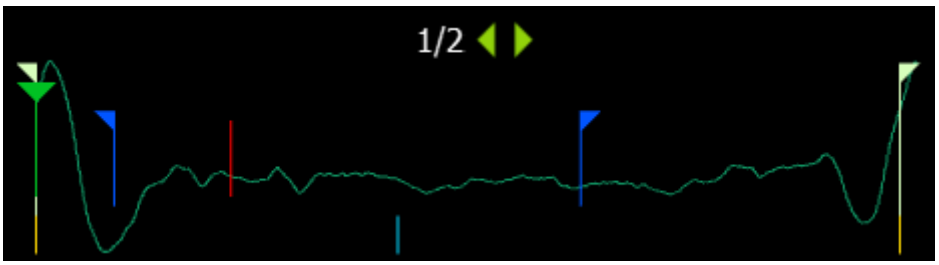
The automated proposal is only there if TEE data is used.

Set frames of interest (optional)



1. Select cardiac cycle using the buttons above ECG
2. Stop the animation of the clip.
3. Define the systolic range (MV is closed) of the cardiac cycle (if necessary)
4. To position the blue flags at the end-diastolic and the end-systolic frame, use the buttons in tool space under Cardiac Cycle (if necessary).

Adjust long axis

Verify if the data set is orientated correctly. The left atrium should be above the left ventricle. The application offers the opportunity to manually adjust the view by axis navigation. To adjust (if necessary), drag and drop to straighten appropriately. The views will be reoriented accordingly.

Adjust long axis orientation

1. Rotate the cyan LOI in the SAX view until it intersects the Aortic Valve.
2. Verify if a 3CH view is displayed in the lower right.

Set MV annulus landmarks

Position the mitral annulus landmarks (MA1 - MA4) at the mitral annulus.

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Set landmark in 3CH view

Position the anterior landmark (A) at the end of the anterior leaflet. The coaptation point (C) has to be positioned at the leaflet tip. The aortic annulus (AA) can be positioned optionally. If it is not part of the imaging sector it can be deactivated with the tool space button.

Next step (Static Model Review)

To enter the next step, click **Static Model Review**.

Static Model Review

Review and correction of automatically detected MV model.

Check the calculated 3D MV model

Check the 3D model of the Mitral Valve (MV) vs. the real anatomy displayed as cut planes and 3D view. The purpose of this function is **LOI Rotation** and **Orbit** (only 3D).

Edit commissures (optionally)

1. To activate the edit commissure tool, click **Edit the position of the commissures**. The display changes from the mixed triple layout to the vertical 1x2 Layout (two 3D views) and at the right tile the animation of the clip is started.
2. To create a clear and detailed representation of the MV coaptation, use the render tools provided at the **Tools** tab.
3. Replace the position of the commissures with single-clicks on the valve model in the static view.

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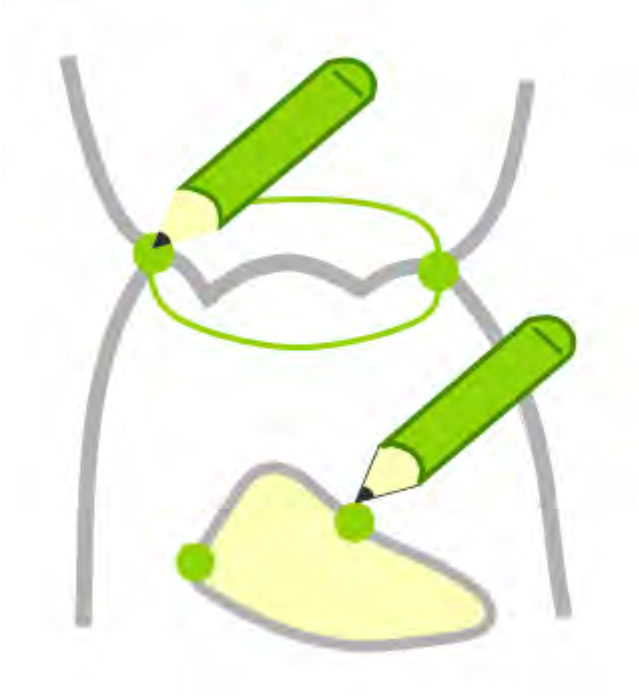
Edit the MA Annulus and Trigones positions

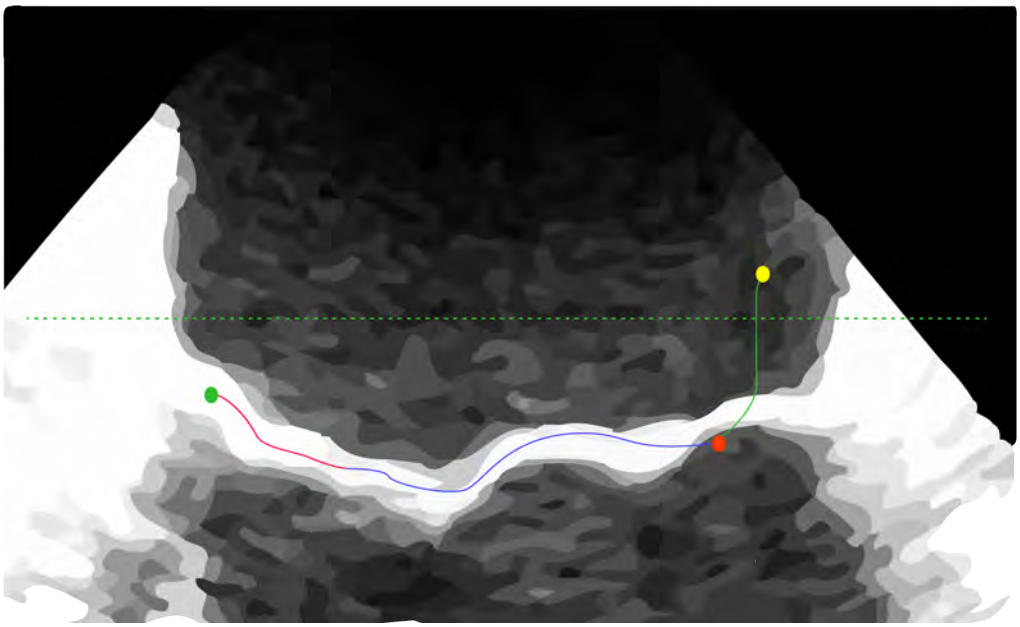
Edit the Mitral Annulus with the mouse (drag and drop) in the Annulus view.

- Different editing **Pen Sizes** are available in the tool space.
- Use the purple LOI to rotate around MV center point and review annulus in all orientations.

Edit Trigones positions

- Move T1 and T2 along the Mitral annulus in the 3D View to adjust its position. The Annulus View shows the corresponding cut plane.





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Define open and closed coaptation regions via zipper.

In order to measure defect sizes, it is crucial to define exactly where the leaflets are closed and open. Therefore, it is possible to adjust (see mouse arrow on image) at the end of coaptation line along this line. The green part of the coaptation line is defined as closed and it is not possible open the leaflets through editing. The red part is defined as open and it is possible to create an Open Coaptation region during editing. The Coaptation View shows the corresponding cut plane while moving the puller.

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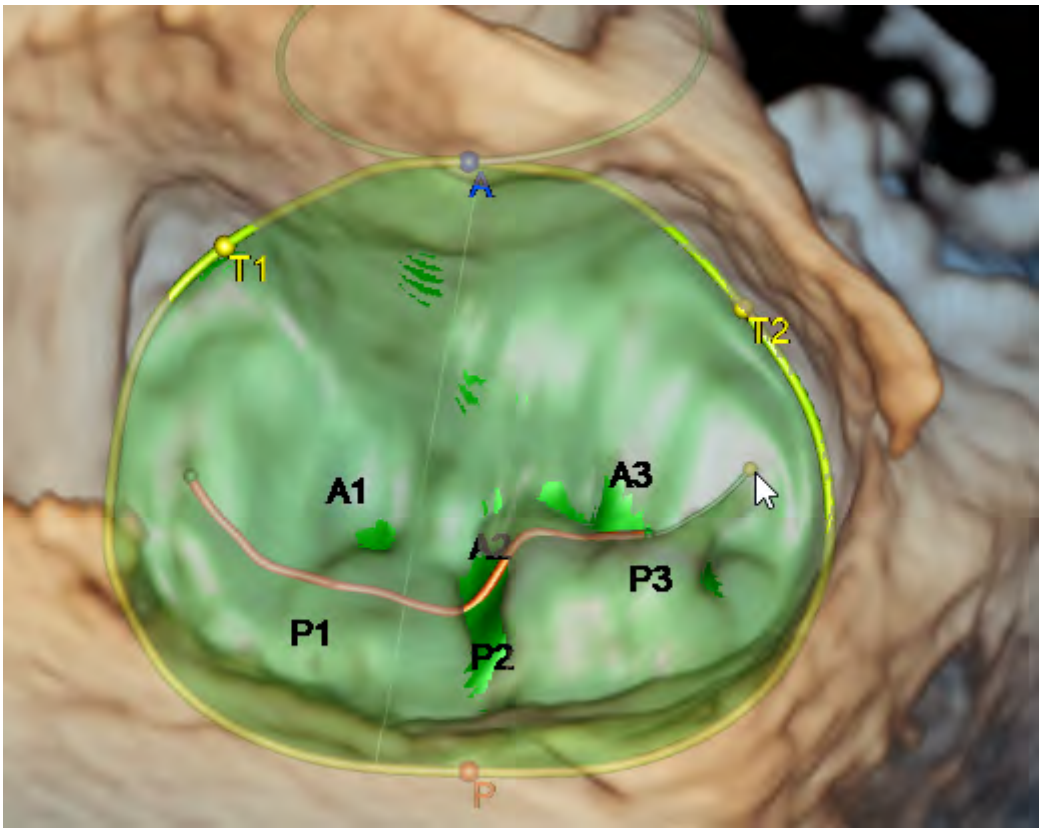

The initial MV model always has a closed coaptation line which can be edited freely and is thus defined as open coaptation region. Move the pullers to delimit open and closed coaptation regions.

Edit open coaptation region

Open the leaflets through editing in coaptation view to create an open coaptation region (if necessary).

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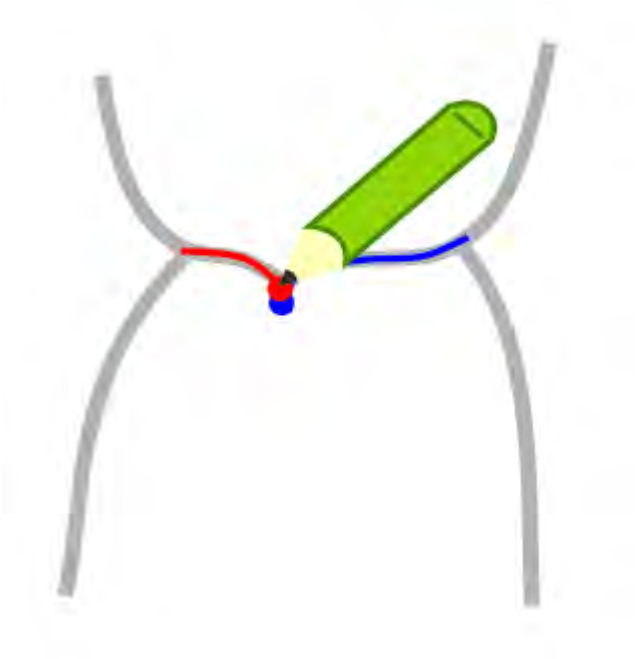

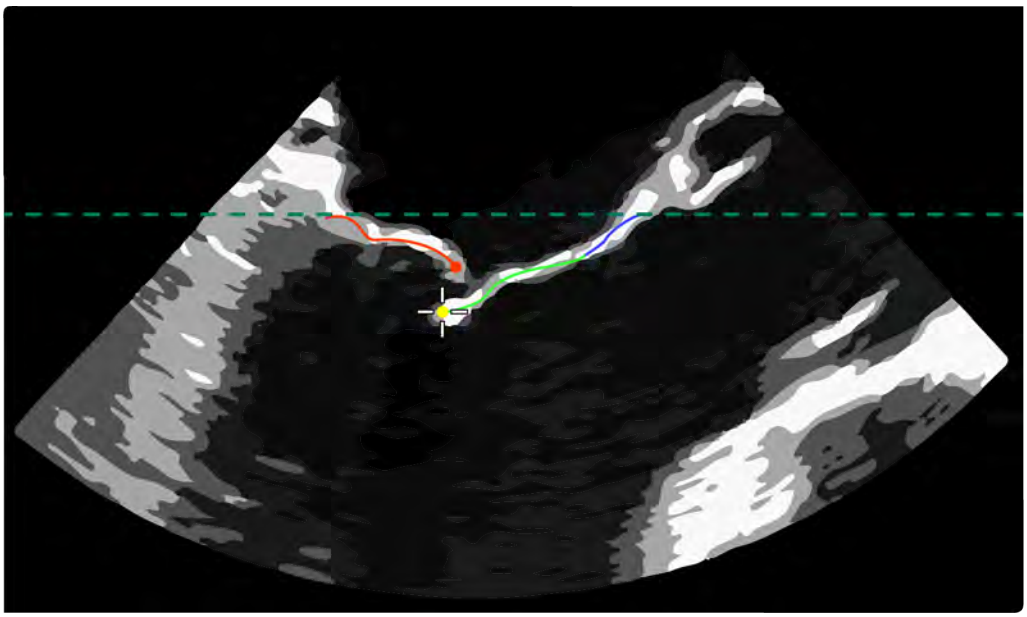

Next step (Dynamic Model Review)

To enter the next step, click **Dynamic Model Review**.

Dynamic Model Review

Review and correction of automatically detected leaflet contours on all frames of the systolic range.

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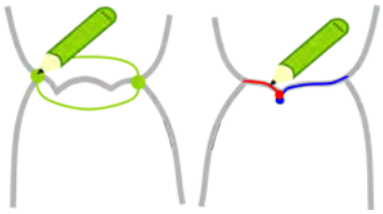
Check the calculated 3D MV model

Check the 3D model of the Mitral Valve (MV) vs. the real anatomy displayed as MPRs and 3D. The purpose of this function is **LOI Rotation** and **Orbit** (only 3D).

Edit the 3D MV model contours

Edit the contours with the mouse (drag and drop) in the views displayed in the top row.

- Different edit **Pen Sizes** are available in the tool space.
- Each of the long axis views correspond to one of the LOIs in the SAX view.
- Each LOI rotates around its own point of rotation.
- The LOI with rotation center at the anterior annulus and its corresponding upper right MPR fits best for adjusting the coaptation and leaflet contours.
- The LOI with rotation point in the MV center and its upper left MPR view are best suitable for editing the annulus contour.



Step through all frames

Use the Playbar tools to review the systolic phase frame by frame (for which a model of the MV exists) to evaluate and/or edit the model.

Editing only affects the displayed frame.

Next step (Analysis)

To enter the next step, click **Analysis**.

Analysis

Review of MV geometry, associated measurements automatically generated by the software, and manual measurements if performed by the user.

Show D'art layout

To reduce the 3D image to a size which only contains the details of interest for an analysis, use the D'art tool.

Show result layout

It’s only for review.

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Show 5-tile layout

Use the LOI Rotation tool to position up to three different cut planes within the 3D tile for displaying specific details. The three upper tiles represent the MPRs of the cut planes defined in the 3D view.

Show planimetry

Use the provided LOIs in the MPRs views to get arbitrary intersections for placing manual measurements (e.g. the opening area of a stenotic valve during diastole).

Measurement tools

Use the measurement tools for performing user defined measurements on MPRs.

3D Auto MV Results

When exit the application, you can save measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

Annulus results

- **AP Diameter**
- **AL-PM Diameter**
- **Sphericity Index**
- **Intertrigonal Distance**
- **Commisural Diameter**
- **Saddle-Shaped Annulus Area (3D)**
- **Saddle-Shaped Annulus Perimeter (3D)**
- **D-Shaped Annulus Area (2D)**
- **D-Shaped Annulus Perimeter**

Shape results

- **Annulus Height**
- **Non-planar Angle**
- **Tenting Volume**
- **Coaptation Depth**
- **Tenting Area**
- **Ao-MV Angle**

Coaptation results

- **Maximum Prolapse Height**
- **Maximal Open Coaptation Gap**

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- **Maximal Open Coaptation Width**
- **Total Open Coaptation Area (3D)**

Leaflets results

- **Anterior Leaflet Area**
- **Posterior Leaflet Area**
- **Distal Anterior Leaflet Angle**
- **Posterior Leaflet Angle**
- **Anterior Leaflet Length**
- **Posterior Leaflet Length**

Miscellaneous results

- **Annulus Area (2D)**
- **Anterior Closure Line Length (2D)**
- **Anterior Closure Line Length (3D)**
- **Posterior Closure Line Length (2D)**
- **Posterior Closure Line Length (3D)**
- **C-Shaped Annulus**

Dynamic measurement results

- **Annular Displacement (max)**
- **Annular Displacement Velocity (max)**
- **Tenting Volume Fraction**
- **Annulus Area Fraction (2D)**

18 3D Auto CFQ

3D Auto Color Flow Quantification (3D Auto CFQ) application provides quantification of Mitral Regurgitation (MR) volume based on 3D color flow images. This application uses a known fluid dynamic model of flow that is adapted to the acquired color information. This allows quantitative assessment of mitral valve leakage during systole. The derived result supports the assessment of mitral regurgitation volume.

The 3D Auto CFQ software is a semi-automated quantitative imaging algorithm, as users are expected to review and concur with the initialization and generated results.

NOTE

This feature is applicable to adult populations (18 years of age and above) undergoing routine TEE examinations.

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3D Auto CFQ Controls

The 3D Auto CFQ provides the following additional controls.

3D Auto CFQ Controls

Icon	Name	Description
	**Set End Diastolic Frame**	Selects a layout that allows editing the end diastolic frame.
	**Set End Systolic Frame**	Selects a layout that allows editing the end systolic frame.
	**Set Reference Frame**	Selects a layout that allows editing the reference frame.
	**Show or Hide Cutplane**	Displays Cutplane.
	**Show or Hide Tissue Rendering**	Applies Tissue Rendering.
	**Show or Hide Tricuspid Valve Model**	Applies the Tricuspid Valve Model.
	**Show or Hide 3D Decorations**	Applies 3D Decorations.
	**Isovelocity**	Shows or hides the isovelocity shells on the acquired data in MPR and volume views.
	**Show Color Only**	Shows color information only.
	**Show Tissue Only**	Shows tissue information only.
	**Show Color and Tissue**	Shows both color and tissue information

3D Auto CFQ Workflow Procedure

Module Start

1. Select a study, which contains datasets for this application.
2. Start the platform software (e.g. IMAGE-COM).
3. Select a suitable dataset within the preview window.
4. Right-click and select **3D Auto CFQ** to launch.

View Alignment

You can adjust the views to set the alignment of the volume and positioning of landmarks.

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1. Click **View Adjustment**.
2. If necessary, adjust the frames of interest by doing the following:
   – Stop the loop and use the cinebar controls to define the systolic range. The mitral valve should be closed when you define the systolic range.
   – Drag the flags to the end-diastolic and end-systolic frames (or) use the controls under Cardiac Cycle to set currently shown frame as ED or ES.
3. If necessary, adjust the long axis (LAX) views by dragging the left atrium (LA) and left ventricle (LV) points so that the lines bisect the two chambers. The height of the line is unimportant.
4. In the short axis (SAX) view, click the cyan line of intersection. Move the cursor back and forth to rotate the 3D volume and intersect with the aortic valve. Verify your adjustment in the three-chamber (3CH) view.
5. Drag the mitral annulus points (MA1 - MA4) to the mitral annulus.
6. Drag the anterior landmark (A) to the end of the anterior leaflet.
7. Drag the coaptation point (CL) to the leaflet tip.
8. Drag and drop the Aortic Annulus (AA) point to the Aortic Annulus.

Reviewing the Static Model

You can review the static model and, optionally, edit the commissures. To edit commissures, use the following procedure:

1. Click **Static Model Review**.
2. Click  .
3. If necessary, click the **Rendering** tab and adjust the view, and then return to the **Workflows** tab.
4. Check the cursor position (cross) on the static and dynamic volume views. Click to replace the position of commissures.
5. Click  again to return to the static model review.
6. Edit the annulus in the **Annulus View** (top left) and the coaptation in the **Coaptation View** (top right) by dragging the points and lines. Leaflets can be edited in both views. You can rotate the view axis in the **SAX** view.
7. Define open and closed coaptation regions with the help of the "zipper mode" (yellow dots in the mitral valve model). When you move the control along the coaptation line, green means the region is closed, and blue means the region is open. Quantify how much the leaflet coaptation is open in the **Coaptation View**.

Reviewing the Dynamic Model

You can review the dynamic model (systolic only) and, optionally, edit the 3D contours. You can edit the contours on every frame. Your edits are not applied to other frames. To edit contours, use the following procedure:

1. Click **Dynamic Model Review**.
2. Check the 3D model of the mitral valve against the ultrasound views.
3. If necessary, use the lines of intersection (LOIs) in the **SAX** view to adjust **Annulus View** or **Coaptation View** to get a better view of the contours.
4. If necessary, adjust the contours by dragging the points.

Reviewing the Flow Regions

1. Click **Flow review**.
2. Check the **Isovelocity** shells together with the color data.
3. Click the mitral valve regurgitation indication (purple color) on the schematic MV model. You can navigate from one flow zone to the next.
4. Review the flow frame by frame.

Excluding the Outflow from MR Detection

NOTE

The left ventricular outflow of the aortic valve may be mistakenly identified as mitral regurgitation.

The aortic exclusion feature will exclude the LV outflow.

1. Adjust the aortic exclusion radius using the slider.
2. Check the size of the excluded zone on the MV model.
3. Run a new flow detection by clicking  .
4. Navigate from one flow zone to the next by clicking on the MV model.

3D Auto CFQ Feature Performance

A study was conducted to evaluate the performance of the 3D Auto CFQ software using transesophageal echocardiography (TEE) cardiac clips. Clinical experts quantified the Mitral Regurgitant Volume (RVol) with the 3D Auto CFQ software. The results were compared to the Cardiac Magnetic Resonance imaging (CMR) RVol, which served as the ground truth for the study. The acceptance criteria were set as follows: a maximum allowable difference of ±61.6 ml and a mean difference of ±19 ml.

Additionally, another study was conducted to evaluate the performance of the 3D Auto CFQ software in quantifying Peak Flow Rate using TEE cardiac clips. The results from the 3D Auto CFQ software were compared to the results from the 2D PISA method, used as the ground truth. The acceptance criteria for this study were a maximum allowable difference of ±144.88% and a mean difference of ±30.77.

The results of the study are presented below.

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Methods Comparison	Mean Difference% (95% LCI, UCI) ± SD (n)	Lower End of 95% LoA	Upper End of 95% LoA
3D Auto CFQ vs. CMR RVol Measurements	-12.10 (-17.38, -6.81) ± 18.98 (52)	-49.29 (-58.37, -40.20)	25.09 (16.01, 34.18)
3D Auto CFQ Peak Flow Rate vs. PISA	-0.07 (-6.58, 6.45) ± 21.16 (43)	-41.55 (-52.76, -30.33)	41.42 (30.20, 52.63)

For detailed information about the study which was conducted to evaluate the performance of the **3D Auto CFQ** software see chapter "3D Auto CFQ Feature Performance Study" on page 206.

3D Auto CFQ Results

When exit the application, you can save measurements and a bookmark. For information about the measurements accuracy, see chapter "Measurements" on page 196.

Results

- MR 3D Reg Volume
- MR 3D Flow Rate

19 3D Auto TV

The 3D Auto TV application provides a morphological and functional analysis of Tricuspid Valve (TV) for 3D echocardiography (echo) data. This application generates models of tricuspid valve structure. The derived parameters allow quantification of pre- and post- operative valvular function and a comparison of morphology. The tricuspid annulus model provides automatic measurements, and you can make additional manual measurements.

The 3D Auto TV application provides the following features and measurement capabilities:

- A semi-automatic tricuspid annulus anatomy identification and analysis tool that generates a 3D model of the TV anatomy.
- Automated alignment produces landmark proposals, view alignments, and end-diastolic and end-systolic frame markers that are modifiable and require user acceptance.
- Comprehensive cardiac quantification measurements.

NOTE

This feature is applicable to adult populations (18 years of age and above) undergoing routine TTE/TEE examinations.

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3D Auto TV Controls

The 3D Auto TV provides the following additional controls.

3D Auto TV Controls

Icon	Name	Description
	**Set End Diastolic Frame**	Selects a layout that allows editing the end diastolic frame.
	**Set End Systolic Frame**	Selects a layout that allows editing the end systolic frame.
	**Set Reference Frame**	Selects a layout that allows editing the reference frame.
	**Reset Auto Adjustment**	Resets landmarks and orientation from heart model.
	**Show or Hide Cutplane**	Displays Cutplane.
	**Show or Hide Tissue Rendering**	Applies Tissue Rendering.
	**Show or Hide Tricuspid Valve Model**	Applies the Tricuspid Valve Model.
	**Show or Hide 3D Decorations**	Applies 3D Decorations.
	**Surgical View Direction**	Defines the surgical view direction in the volume rendering.
	**Ventricular View Direction**	Defines the ventricular view direction in the volume rendering.
	**Show/Hide View Planes**	Shows or hides the MPR view planes in the Beutel view.

3D Auto TV Workflow Procedures

Module Start

1. Select a study, which contains datasets for this application.
2. Start the platform software (e.g. IMAGE-COM).
3. Select a suitable dataset within the preview window.
4. Right-click and select **3D Auto TV** to launch.

View Alignment

You can adjust the views to set the alignment of the volume and positioning of landmarks.

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1. Click **View Adjustment**.
2. If necessary, adjust the frames of interest by doing the following:
   - Stop the animation of the clip and use the play bar tools to define reference frame (mid-systole).
   - Position the blue flags at the end-diastolic and the end-systolic frame with drag and drop.
3. Place the TV in the middle of the valve and Right Ventricle (RV) in the ventricle center to keep the axis perpendicular to the valve and move the short axis (SAX) plane to the middle of aorta.
4. Place Aortic Valve (AV) in the center of aorta.
5. Position the tricuspid annulus points (TA1 - TA4) at the annulus.

Static Review

You can review and edit the volume of the automatically detected static TV model. To edit the TV model, use the following procedure:

1. Click the **Static Review**.
2. Check the 3D model of the TV against the ultrasound views.
3. Rotate the long axis view along the vertical axis in the single long axis (LAX) view, or you can rotate all LAX view via the short axis (SAX) lines of intersection (LOI) rotation at once.
4. If required, editing of annulus model intersections with mouse (drag and drop) in the LAX MPR views can be done in any rotated view and different Edit Sizes are selectable in the tool space.

Commissure Points

You can add the leaflet model and edit the commissure landmarks on selected leaflet. To add and edit leaflet model, use the following procedure:

NOTE

Commissure points is an optional workflow step. Use the Commissure points to display the leaflet landmarks in the following steps.

1. Click the **Commissure points**.
2. Select correct leaflet model from six models in commissure workflow.
3. Click the commissure landmark in the volume display and move the landmark along the TV model.
4. If required, you can manually add a landmark for the papillary muscle in the MPR.

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Dynamic Review

You can review and edit the automatically detected annulus contours in end-diastole and end-systole frame. To edit the annulus contours, use the following procedure:

1. Click the **Dynamic Review**.
2. Check the 3D model of the tricuspid annulus against the ultrasound views.
3. Rotate the long axis view along the vertical axis in the single LAX view or you can rotate all LAX views via the SAX LOI rotation at once.
4. If required, editing of annulus model intersections with mouse (drag and drop) in the LAX MPR views can be done in any rotated view and different Edit Sizes are selectable in the tool space.

Analysis

You can review the measurements generated by the software and perform the manual measurements on TV geometry.

1. Click the **Analysis** workflow, and Annulus, Generic and Device measurement tabs are displayed on the screen.
2. Review the list of annulus values measured by the software in the **Annulus** tab.
3. Click the measurement value to view the corresponding overlay in the volume.
4. Check the graph to view the changes in the measured value on the complete heart cycle.
5. Click the **Generic** tab on the screen to perform or review the manual measurements on TV model.

NOTE

Device measurements can be activated in the user setting in the view adjustment.

6. Click the **Device** tab on the screen, and it shows three packages in the device section as following.
   - TV Ann Anterolateral-to-Posteromedial (AP) / Septal-lateral (SL) measurements
   - Subvalvular Anterolateral-to-Posteromedial (AP) / Septal-lateral (SL) measurements
   - Supravalvular C-Shaped Perimeter and Aortic Valve (AV) anchor distance

NOTE

All the measurement values show as "–" on device tab initially. This avoids export of the measurements prior to review and edit.

7. Click a measurement on the **Device** tab, the respective package values are appear on the screen and you can review and edit the values in MPR view.
8. Click the TV Ann AP / SL measurements , and you can view the annulus level measurements.

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NOTE

You need to check and edit the S-point by dragging the point in SAX view. Distances are calculated based on the S-Point location.

9. Click the Subvalvular AP / SL measurements.

NOTE

Before clicking subvalvular level measurement, S-Point needs to be defined.

10. Edit the length in SAX section, and angles and level are fixed by S-Point.
11. Click the **Supravalvular C-Shaped Perimeter** and AV anchor distance, it shows the Spline with 4 mm distance from annulus in supravalvular direction.
12. Define the start point and end point (AV and Coronary Sinus (CS) anchor) of the Spline in volume section.
13. The angle of the 4 mm distance can be edited in the LAX MPRs around the complete spline.
14. To edit the angle, Rotate the LAX LOI along the vertical center and edit the 4 mm distance marker on the fix annulus point.

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3D Auto TV Automation Performance

A study was conducted to evaluate the automation performance of the 3D Auto TV software. Transesophageal echocardiography (TEE) and transthoracic echocardiography (TTE) cardiac clips were used for TV annulus measurements by clinical experts using the 3D Auto TV software. The results were then compared to manual measurements performed by the same reviewers using the Ultrasound Workspace (formerly known as TOMTEC-ARENA) 4D Cardio-View application, which served as the ground truth for the study.

The acceptance criteria for the study were defined as follows:

- For distance (shape): a maximum allowable difference of ±46% and a mean relative error of ±17%
- For circumference (size): a maximum allowable difference of ±52% and a mean relative error of ±24%

The results of the study are presented below.

	TEE Subjects			TTE Subjects		
Methods Comparison 3D Auto TV vs. 4D Cardio-View	**Mean Difference (95% LCI, UCI) ± SD (n)**	**Lower LoA (95% CI)**	**Upper LoA (95% CI)**	**Mean Difference (95% LCI, UCI) ± SD (n)**	**Lower LoA (95% CI)**	**Upper LoA (95% CI)**
Annulus Size						
2D perimeter in ED (%)	3.75 (2.75, 4.75) ± 4.96 (97)	-5.97 (-7.64, -4.81)	13.47 (12.31, 15.14)	-0.78 (-2.35, 0.78) ± 7.90 (100)	-16.26 (-18.86, -14.43)	14.69 (12.86, 17.29)
2D perimeter in ES (%)	0.15 (-0.95, 1.25) ± 5.47 (97)	-10.57 (-12.40, -9.29)	10.86 (9.58, 12.70)	0.45 (-1.18, 2.09) ± 8.24 (100)	-15.70 (-18.42, -13.79)	16.61 (14.70, 19.33)
Annulus Shape						
Max ED diameter (%)	1.69 (0.49, 2.89) ± 5.95 (97)	-9.97 (-11.97, -8.58)	13.36 (11.96, 15.36)	-1.13 (-2.93, 0.67) ± 9.09 (100)	-18.95 (-21.94, -16.84)	16.69 (14.58, 19.68)
Min ED diameter (%)	7.05 (5.79, 8.31) ± 6.26 (97)	-5.22 (-7.32, -3.75)	19.31 (17.85, 21.41)	0.68 (-0.95, 2.30) ± 8.21 (100)	-15.41 (-18.12, -13.51)	16.76 (14.86, 19.47)
Max ES diameter (%)	-0.60 (-1.95, 0.74) ± 6.66 (97)	-13.66 (-15.90, -12.10)	12.46 (10.89, 14.69)	0.56 (-1.23, 2.35) ± 9.03 (100)	-17.13 (-20.11, -15.04)	18.26 (16.16, 21.23)

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	TEE Subjects			TTE Subjects		
Methods Comparison 3D Auto TV vs. 4D Cardio-View	**Mean Difference (95% LCI, UCI) ± SD (n)**	**Lower LoA (95% CI)**	**Upper LoA (95% CI)**	**Mean Difference (95% LCI, UCI) ± SD (n)**	**Lower LoA (95% CI)**	**Upper LoA (95% CI)**
Min ES diameter (%)	1.38 (-0.02, 2.77) ± 6.91 (97)	-12.17 (-14.49, -10.55)	14.92 (13.30, 17.25)	0.67 (-1.05, 2.40) ± 8.69 (100)	-16.36 (-19.22, -14.34)	17.70 (15.69, 20.57)

For detailed information about the study which was conducted to evaluate the automation performance of the **3D Auto TV** software see chapter “3D Auto TV Automation Performance Study” on page 209.

3D Auto TV Results

When exit the application, you can save measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

Annulus

- **TV Ann Perimeter 3D**
- **TV Ann Perimeter 2D**
- **TV Ann Max (2D)**
- **TV Ann Min (2D)**
- **TV Ann Perimeter Derived Diam 2D**
- **TV Ann Height (3D)**
- **TV Ann Area (2D)**

Device

- **TV Ann AP Diam (2D)**
- **TV Ann SL Diam (2D)**
- **Subvalvular 5 Plane AP Diam (2D)**
- **Subvalvular 5 Plane SL Diam (2D)**
- **Supravalvular AV – Ao Center Diam**
- **Supravalvular C-Shaped Perimeter**

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20 4D LV-ANALYSIS

4D LV-ANALYSIS provides morphological and functional analyses of the left ventricle. Based on 3D echo datasets a 4D model (**Beutel**) is generated that represents the cavity of the LV and optionally also the LA. Volumes, Strain and Displacement are quantified on a global and segmental level.

4D LV-ANALYSIS Controls

The 4D LV-Analysis provides the following additional controls.

4D LV- Analysis Controls

Icon	Name	Description
	**Edit ED**	Selects end-diastole layout for focused end-diastole editing. End-diastole can be edited in  also.
	**Edit ES**	Selects end-systole layout for focused end-systole editing. End-systole can be edited in  also.
	**Edit ED and ES**	Selects a layout that allows editing both the end-diastole and end-systole frames.
	**Calculate Mass**	Adds the left ventricle mass.
	**Show/Hide View Planes**	Shows or hides the MPR view planes in the Beutel view.
	**Principal Tangential Strain** or **3D Displacement**	Displays the Tangential Strain values. or Displays the 3D Displacement values.
	**Circumferential Strain** or **Circumferential Displacement**	Displays the Circumferential Strain values. or Displays the Circumferential Displacement values.
	**Longitudinal Strain** or **Longitudinal Displacement**	Displays the Longitudinal Strain values. or Displays the Longitudinal Displacement values.
	**Radial Strain** or **Radial Displacement**	Displays the Radial Strain values. or Displays the Radial Displacement values.
	**Rotation**	Displays the Rotation values.
	**Global Volume LV**	Displays the Beutel model as a solid 3D object.

Icon	Name	Description
	**Segmental Volumes LV**	Displays the Beutel model as a segmental 3D object.
	**Dynamic Parameter Map**	Displays the Beutel model as a dynamic parameter map.
	**"Time To Peak" Map**	Displays the time to peak values of a Beutel model on a static map.
	**"ES" Map**	Displays the end-systolic values of a Beutel model on a static map.

4D LV-ANALYSIS Workflow Procedures

4D LV-ANALYSIS is structured in four workflow steps: LV View Alignment, Timings Definition, LV Tracking Revision and Analysis. Per default, the application performs LV View alignment and Timings Definition automatically and opens in LV Tracking Revision. However, the ability to go back steps is possible.

The automated workflow can be deactivated by unchecking **LV Init-and-Track** in **User Settings**.

The following is the typical workflow for tasks or image-processing procedures using 4D LV-ANALYSIS. The 4D LV module requires a minimum of 10 frames per cardiac cycle and a minimum frame rate of 10 frames per second.

Module Start

- Select a study which contains datasets for this application.
- Start the platform software (e.g. IMAGE-COM)
- Select a suitable dataset within the preview window.
- Right-click and select 4D LV-ANALYSIS to launch.

LV View Alignment

Manual adjustment of automatically detected axes.

Select cardiac cycle

The option to select a specific cardiac cycle from a multicycle dataset is available.

Adjust MV - Apex Axis

Reposition one of the axis endpoints by drag and drop to match reference diagram. Position the landmarks (MV, LV Apex) as described in the following:

- MV – Place this landmark at the annulus level in the middle of the MV.
- Apex – Place this landmark at the apex of the left ventricle.

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Each landmark repositioning results in adjustment of each view. Redo the adjustments in each LAX view until the positions of the landmarks (MV, Apex) are correct in each standard view.

Define AV orientation

Rotate the LOIs in the SAX view until the AV landmark is positioned on the Aortic valve and the 3CH view is shown on the top right.

Next step

To enter the next step, click Timings Definition.

Timings Definition

Display of estimated time points for end-diastolic and end-systolic frame. User can adjust if needed.

Check the M-Mode plane

The M-Mode in the lower part shall show the annular displacement. Rotate the LOI until annular displacement is visible.

Adjust marker for ED and ES

You can adjust the vertical marker for end-diastolic and end-systolic frame on the M-Mode view.

Next step

To enter the next step, click **LV Tracking Revision**.

LV Tracking Revision

This is a display of the automatically calculated 3D surface model of the ventricle (Beutel) and its derived contours. The dynamic Beutel can be modified by contour editing at the ED or ES frame.

Check the dynamic 3D model of the LV

Check the model contours vs. the anatomy displayed as cut planes in ED and/or ES. For this purpose, use the functions **LOI slice**, **Orbit** (only 3D view) and the **Edit ED/ES** or layout options.

Edit the 3D model contours

Edit the contour directly on the view planes using the mouse. The tools provided in the tool space section: **Pen Size** can be used to determine size of editing area for each view.

Editing the contours will provide a real-time update to the associated values.

After editing the ED contour, it is recommended to perform a retracking to propagate changes to the complete cardiac cycle. All changes to ES contours will be deleted during retracking.

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(Optional) Add epicardial contour

An epicardial contour can be added by clicking on the **Add Epicard** button in order to calculate the LV mass. The epicard contour can be edited as described before.

Next step

To enter the next step, click **Analysis**.

Analysis

Display of different parameters derived from the dynamic surface model of the contemplated ventricle. These parameters are displayed as text results for the following:

Global LV parameters

- **EDV**
- **EDVi***
- **ESV**
- **ESVi***
- **SV**
- **EF**
- **Mass**
- **SDI**
- **GLS (3D)**
- **GCS (3D)**
- **Twist**
- **Torsion**
- **Length**

Next to these parameters a chart displays the global volume-time curve corresponding to the dynamic Beutel.

(* not available in all variants)

Additional Parameters

Display of additional parameters (e.g. deformation imaging) as global or segmental text results, segmental time curves and static or dynamic parametric maps.

Parametric maps are applied to the tracked surface model of the left ventricle (Beutel) and to the Polar plot. They are available as dynamic maps and as static delay maps (time-to-peak maps). Further parameter values are aggregated into segmental time curves and some important measurement values.

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4D LV-ANALYSIS Results

When exit the application, you can save measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

Global LV results

- **EDV**
- **EDVi***
- **EF**
- **ESV**
- **ESVi***
- **GCS**
- **GLS**
- **Mass**
- **SDI**
- **SV**
- **Torsion**
- **Twist**
- **Length**

Additional parameters - regional results

- **Segmental LV Volumes**
- **3D displacement**
- **Circumferential displacement**
- **Circumferential strain**
- **Longitudinal displacement**
- **Longitudinal strain**
- **Principal tangential strain**
- **Radial displacement**
- **Radial strain**
- **Rotation**

(*Not available in all variants, requires height and weight of the patient.)

21 4D CARDIO-VIEW

4D CARDIO-VIEW is an advanced analysis tool for 3D/4D echocardiography data. Anatomical structure visualization, volume measurements (LV and/or generic), and specified or manual measurements are possible. Various tools are available for rendering that display 2- and 3-dimensional morphology and function for defined structures.

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4D CARDIO-VIEW Controls

4D CARDIO-VIEW provides the following controls.

Icon	Name	Description
	**D’art**	Excises an interesting slice out of the 3D-dataset.
	**Multi-Slice D'art**	A user adjustable distance - determined by the D’art arrow - will be divided into equidistant slices instead of the whole volume. The distance can be defined by two mouse clicks.
	**Cutplane**	Displays the cutplane (with or without color information)
	**Synchronize**	Synchronizes the orientation of the 3D volume with the active MPR.

4D CARDIO-VIEW Workflow Procedures

D'art an Example of an ASD Dataset

Visualization of any 3D structure

1. Look for a 2D view where the ASD can be detected. To rotate or move through the views, use the lines of intersection.
2. Select the 3 MPR and 3D layout.
3. To define the region of interest and viewing direction for the 3D view, click  and set two distance points at one of the displayed 2D views.
4. To rotate the 3D reconstruction, use drag and drop.
5. To adjust the region of interest, move the base or click the D’art arrow.
6. The 3D reconstruction is updated immediately.

Multi-Slice an Example of a LV Dataset

Cutting a selected region in several planes.

1. Select a 3D dataset.
2. Select a 2CH view.
3. To define the slicing area, click the  and set two distance points inside one of the 2D views.
4. To adjust the region of interest, move the base or click the D’art arrow.

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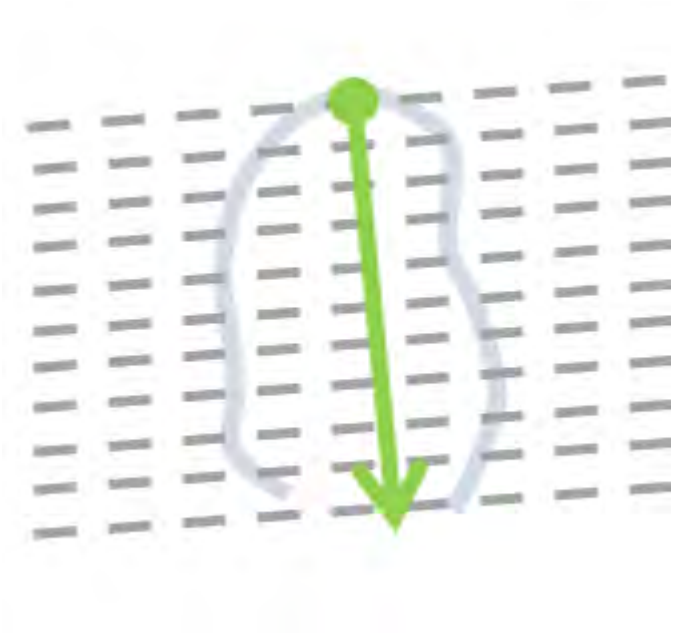

TAVR Measurements

In this section you can perform TAVR standard measurements.

1. Select a measurement.
2. Move your cursor into the image region.

The measurement can be performed at one of the 2D views or at the 3D reconstruction.

Left Ventricle Volume Measurements

Calculation of end-diastolic/end-systolic volume, ejection fraction, stroke volume, and mass of the left ventricle

View adjustment

After entering the Left Ventricle Volume state the software aligns the dataset with default orientation.

1. To redefine the end-diastolic and end-systolic frame, search for the corresponding frame and select it by the corresponding D (**Set end-diastole**) and S (**Set end-systole**). ED and ES are marked as blue flags within the frame slider.
2. To position the SAX at any level to help finding the AV orientation, click **LOI navigation**.
3. Position the **Apex** and **MV** in the LAX view and the **AV** in the SAX view.
4. To zoom, use the mouse-wheel.

Setting initial contours

1. Draw at least two open LV contours for each phase. Optionally, you can select the **Add epicard to end-diastolic contour**.

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2. The system automatically lists all results which can be calculated with the input.
3. To change the contours, drag and drop them.

Analysis

1. To adjust contours (if required), drag and drop them.
2. Use LOIs to navigate through views.
3. Change the **Pen Size**.
4. The display of results and Beutel will simultaneously be adjusted.

Results:

- **EDV**
- **ESV**
- **EF**
- **SV**
- **Mass**

The calculated volumes can be displayed together with the tissue within the **Review** tab.

Generic Volume Measurements

Calculation of generic volume of any structure (atrium, tumors...)

View adjustment

After entering the **Generic Volume** state the software aligns the dataset with default orientation.

- Search the frame which represents the structure of interest best.
- To position the volume of interest in the center point, use **Smart Region** navigation.

Setting initial contours

- Draw at least two closed contours and close each contour with double-click.
- To change the contours, drag and drop them.

Analysis

- To adjust contours (if required), drag and drop them.
- Use LOIs to navigate through views.
- Change the **Pen Size**.
- The display of results and Beutel will simultaneously be adjusted.

Result:

- **GV**

The calculated volume can be displayed together with the tissue within the **Review** tab.

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Generic Measurements

Different generic measurements are available and can be performed any time on each tiling.

- Distance
- Area
- Curve
- Angle

Navigation

Use the smart regions (**Orbit**, **Rotate**, **Pan**, **Slice**, **Zoom**) to navigate the MPR views or use the **LOI** Navigation to align the MPR views.

4D CARDIO-VIEW Results

When exit the application, you can save measurements and a bookmark. For information about the measurements accuracy, see chapter “Measurements” on page 196.

TAVR results

- **Ann-Ost left diam**
- **Ann-Ost right diam**
- **Annulus Area**
- **Annulus Circumference**
- **Annulus d(area)**
- **Annulus dmin**
- **Annulus dmax**
- **Ao Ann diam**
- **Ao SV diam**
- **Ao STJ diam**

Volume results

- **EDV**
- **EF**
- **ESV**
- **GenVol**
- **Mass**
- **SV**

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22 4D SONO-SCAN

4D SONO-SCAN is an advanced analysis tool for 2D, 3D and 4D ultrasound data. Features for review, rendering and analysis of B-Mode and Color Doppler Images (CDI) are encompassed over a wide variety of data formats. Different layouts, standard navigation tools and rendering techniques support the workflow of radiologic review. Further basic 2D and 3D volume measurements are offered.

4D SONO-SCAN application offers various layouts which are divided into view tiles. Left-click inside a tile to tag it as the active one. Four colored corners indicate the tile is active. Within each tile there are colored lines visible, which indicate the positions of perpendicular multiplanar reconstructions (MPR).

A 3D visualization of the MPRs is available at the 3D.

NOTE

There are two ways to move sliders:

- Grab slider by drag and drop and move it to the desired position.
- Or click as often as needed on that side of the slider in the slider range until the slider reaches the desired position.

4D SONO-SCAN Controls

For more information about the common controls, see chapter “Common Controls” on page 184.

4D SONO-SCAN Toolbar Controls

The Toolbar contains often needed functionalities.

Layout selection controls

Only one layout can be selected at a time - combinations are not possible.

Icon	Name	Description
	**Curved Slice Layout**	Displays a 2x2 tile layout containing one reference MPR (first quadrant) and three views in which the curved slices are displayed. The first MPR view is the reference MPR in which the user defines the shapes (their contours) of up to three curved slices. The resulting curved slices are displayed in the **1** to **3** numbered curved slice views.
	**Multi-Slice Layout**	Is a view where it is possible to review the acquired volume divided in different equidistant slices. The number of slices can be defined by certain presets. Five different layouts (Single -, 2x1, 2x2, 3x3, and 4x4 layout) are available.

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Icon	Name	Description
	**Multi-Slice D'art Layout**	Resembles the multi-slice functionality. A user adjustable distance - determined by the D'art arrow - will be divided into equidistant slices instead of the whole volume. The distance can be defined by two mouse clicks.
	**Cubic View Layout**	The volume rendering in the 3D View is exchanged by a rectangular box-shaped wire frame which represents the size of the acquired volume.
	**Default Volume Layout**	The default volume layout displays one or 3 orthogonal MPR views and one 3D view. Two different layouts (2x1, and 2x2 layout) are available.

4D SONO-SCAN Toolspace Controls

The Toolspace contains measurement tools, animation features and other settings needed to adjust image quality of MPRs, Curved Slices and the 3D view. Their effect also depends on the image quality of the loaded dataset and on the details the user wants to see.

The **4D SONO-SCAN** Toolspace has the following tabs:

- Render Settings tab
- Tools tab
- Measurement and Annotation tab
- Layout Settings tab
- Color Settings tab

 The **Render Settings** tab lists tools for adjusting the image quality of MPRs and the 3D view.

Render mode controls

Icon	Name	Description
	**Gradient Mode**	Applies adjusted and mixed gradient shading and texture shading algorithms for a maximum image quality and the freedom to tailor images according their application.
	**HQ-Rendering**	Enables a photorealistic volume rendering with adjustable light source.
	**Skeleton**	Enables Maximum Intensity Difference Accumulation (MIDA), a mixture of gradient volume rendering and Maximum Intensity Projection (MaxIP).
	**X-Ray Mode**	Applies algorithms, which use a semitransparent shading model with the emphasis put on bright structures.
	**Cavity**	Displays an inversion of the gradient mode in which the gray values found within the 3D volume are inverted.

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Gradient/Intensity controls

These controls only affect the 3D view.

Icon	Name	Description
	**Gradient**	Mixes and adjusts the gradient shading and texture shading algorithms for a maximum image quality and the freedom to tailor images according their application.
	**Intensity**	Adjusts the concentration or strength of the texture shading algorithm.

3D filter controls

These controls only affect the volume rendering of the 3D view.

Icon	Name	Description
	**No Filter**	Displays the original volume rendering.
	**Moderate**	Applies a moderate low-pass filter to the volume rendering which removes artifacts and noise to get a smooth image.
	**Medium**	Applies a medium low-pass filter to the volume rendering which removes artifacts and noise to get a smooth image.
	**Heavy**	Applies a strong low-pass filter to the volume rendering which removes artifacts and noise to get a very smooth image.

2D filter controls

These controls are only applicable to MPRs.

Icon	Name	Description
	**Abdomen**	Preset is designed for a better display of structures in the abdomen like the liver and the spleen.
	**Carotid**	Preset is designed to improve the display of the carotid.
	**OB**	Preset is designed to improve the display of fetuses.
	**Thyroid**	Preset is designed to improve the display of the thyroid.

Thick slice control

The Thickness slider and editable number field adjusts the thickness of MPRs.

Tissue palette

Name	Description
3D	Applies one of the available color schemes to the 3D.

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Name	Description
MPR	Applies one of the available color schemes to the MPRs.

 The Tools tab contains volume segmentation tools and features to animate the displayed 3D volume.

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Animation tools controls

These controls are only applicable to 3D view.

Icon	Name	Description
	**Vertical Rotation**	Starts/stops a rocking motion of the 3D around its vertical axis.
	**Horizontal Rotation**	Starts/stops a rocking motion of the 3D around its horizontal axis.
	**Toggle Speed**	Toggles between fast and slow rocking motion.
	Angle	Adjusts the size of the rocking motion-angle. The set angle corresponds with the view angle onto the 3D volume between the start and end-positions of the rocking motion. The angle value [°] can be typed into the corresponding field or set via the slider displayed below.

Slice animation controls

These controls are only applicable to MPRs.

Icon	Name	Description
	**Start/Stop Slice Animation**	When started, the MPR of the active view moves through the volume in the viewing direction. The slice distance and the speed of the movement can be adjusted.
	Speed	Changes the speed of the animated sequence.
	**Slice Distance**	Determines the position of first and last MPR of the slice animation. Drag and drop the markers to reposition them.

Scalpel controls

This section contains controls used to manually segment the 3D volume.

Icon	Name	Description
	**Keep Surrounding**	Removes an unwanted sector defined by a freehand spline drawn within the 3D view or MPRs. Keep the left mouse button pressed while moving the mouse to define the region that shall be removed. All parts of the 3D volume below the defined area will be removed.
	**Keep Inside**	Removes everything outside a sector defined by a freehand spline drawn within the 3D view or MPRs. Keep the left mouse button pressed while moving the mouse to define the region that shall be removed. All parts of the 3D volume outside of the defined area will be removed.

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Icon	Name	Description
	**Keep Surrounding (Box)**	Removes an unwanted sector defined by a rectangular spline. Keep the left mouse button pressed while the spline/rectangle is drawn by mouse move. Releasing the pressed button ends the drawing of the rectangle.
	**Keep Inside (Box)**	Removes everything outside a sector defined by a rectangular spline. Keep the left mouse button pressed while the spline/rectangle is drawn by mouse move. Releasing the pressed button ends the drawing of the rectangle.
	**Small Eraser**	Removes everything beneath the mouse pointer. Keep the left mouse button pressed while moving the eraser circle over the parts of the 3D volume that shall be removed. Can be applied in MPRs and the 3D view.
	**Medium Eraser**	Removes everything beneath the mouse pointer. Keep the left mouse button pressed while moving the eraser circle over the parts of the 3D volume that shall be removed. Can be applied in MPRs and the 3D view.
	**Large Eraser**	Removes everything beneath the mouse pointer. Keep the left mouse button pressed while moving the eraser circle over the parts of the 3D volume that shall be removed. Can be applied in MPRs and the 3D view.
	**Reset Scalpel Action**	Restores all previously removed parts of the 3D volume.

 The Measurement and Annotations tab contains basic 2D measurement as well as Disc-Summation and Single-Click volume measurement tools.

All measurement can be applied within MPRs. After a measurement is finished it is also visualized in the 3D view.

Measurements are numbered consecutively in the order they were performed.

The measurement results are displayed in the upper left corner of the view tile in which they were created and in the 3D view. Clicking on the measurement result in the 3D view restores the plane and phase of the MPR in which they were created.

NOTE

The measurement functionalities are only available on calibrated datasets. They can only be performed on static images. Stop any animation before performing measurements.

NOTE

Measurements and their results are only visible in the phase and plane in which they were created.

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Basic measurements controls

Icon	Name	Description
	**Distance**	Measures a distance between two points. Start and end point can be repositioned by drag and drop.
	**Angle**	Calculates an angle between three points. Each point can be repositioned by drag and drop.
	**Area**	Calculates an area defined by a free-form spline. Fix/close the end of the curve/spline with double-click or a right-click. Reposition one of the points by drag and drop. Add a point to the spline with a click on the line between two points. Delete one point of the spline with a right-click on it.
	**Curve**	Calculates a curve defined by a spline. Fix/close the end of the curve/spline with double-click or a right-click. Reposition one of the points by drag and drop. Add a point to the spline with a click on the line between two points. Delete one point of the spline with a right-click on it.
	**Delete Last Measurement**	Only removes the last measurement performed or changed.
	**Delete All Measurements**	Removes all existing measurements.

Disc summation controls

Icon	Name	Description
	Current Plane	Shows next/previous plane.
	Disc Thickness	Adjusts the thickness of each plane.
	Propagate Discs	Uses a copy of the last contour for the next plane when checked.
	**Delete Last Disc**	Removes the last disc created or changed
	**Delete All Discs**	Removes all existing discs.
	Show 3D Volume	Checking this box also shows the tissue volume rendering in the 3D view.
	**Disc Transparency**	Determines the transparency of the disc summation model in the 3D view. A value of 0 creates a solid surface. Increasing this value makes the discs more transparent.

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Single-click volume controls

Icon	Name	Description
	**Set Volume**	Changes the cursor to a cross. A left-click on a MPR after pressing this button initializes the volume calculation.
	**Update Volume**	Recalculates the volume based on the last detected volume and new threshold value.
	**Cut Volume**	Changes the cursor to a cross and activates the segmentation function.
	**Delete Volume**	Deletes the calculated volume.
	**Rectangular ROI**	Shows a rectangle as overlay in the active MPR view. The detection of volumes is limited to the volume enclosed by the rectangle.
	**Circle ROI**	Shows a circle as overlay in the active MPR view. The detection of volumes is limited to the volume enclosed by the circle.
	**Threshold**	Threshold settings can help to define which structures are relevant for the detection. Gray values above the adjusted threshold are taken into account for the detection, and gray values below are ignored.
	**Auto Echo**	Activates the automatic region search.
	**Low Echo**	Activates the detection of low echo (dark) regions.
	**High Echo**	Activates the detection of high echo (bright) regions.

 The Layout Settings Tab contains different layout concepts. The content of this tab changes with respect to the selected layout.

Volume layout controls

Icon	Name	Description
	**Center Point Navigation**	When active two perpendicular lines are displayed within each MPR which correspond to the other MPR planes. The point of intersection is the center point, which can be moved by dragging it to a new position within the active view.

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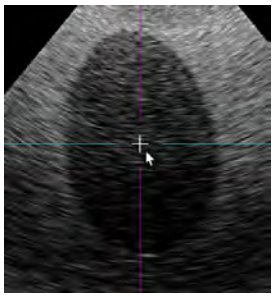
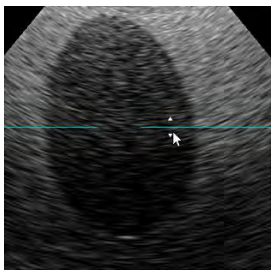
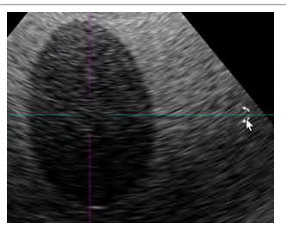
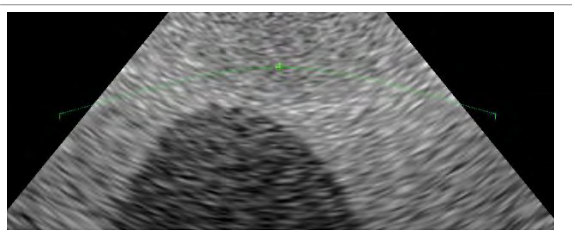
Icon	Name	Description
		Each line can also be moved in parallel and rotated around the center point. The mouse cursor indicates the possible movement by changing its shape depending on where the mouse cursor is positioned above the line. By clicking on the intersection a cross appears and indicates the center point can be dragged to another position. 
		When two small straight arrows appear the line can be moved in parallel to its current position. 
		When two curved arrows appear the line can be rotated around the center point. 
	Region of Interest	When active 4 small angles enclosing a rectangular region (ROI) are displayed in each MPR view. Additionally a dotted line – the flexible cutline - connects the two upper edges of the ROI in the first MPR view (A-Plane). The shape of the flexible cutline can be adjusted. The volume outside of the ROI will not be displayed in the 3D view. 

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Icon	Name	Description
		Keep the left mouse button pressed on a green angle and move the mouse to resize the ROI horizontally and/or vertically. Keep the left mouse button pressed on the green point within the Flexible Cutline. Move the mouse to redefine the position of this point within it and to reshape it too.
	**Synchronize**	Synchronizes the orientation of the 3D volume with the active MPR.

Cubic view controls

The volume rendering in the 3D View is exchanged by a rectangular box-shaped wire frame which represents the size of the acquired volume. Three modes are available, which visualize the spatial arrangement of the MPRs within the wireframe in different ways. The positions of the MPRs (in relation to each other) within the 3D wireframe correspond to the planes of the MPR views.

Icon	Name	Description
	**Box Mode**	The three orthogonal MPRs are displayed onto the user-facing faces of a cuboid (rectangular box). The size of the cuboid, respectively the positions of the MPRs, is customizable. The size of the wireframe limits the size of the box. Keep the left mouse button pressed at the faces of the box (MPR planes) while moving the mouse in order to relocate them.
	**Niche Mode**	The niche mode is an inversion of the box mode, so that the MPRs are displayed onto the sides of a rectangular niche which is cut out of the wireframe box. Keep the left mouse button pressed at the faces of the box (MPR planes) while moving the mouse in order to relocate them.
	**Plane Mode**	In plane mode the MPR planes as displayed within the wireframe in their full size. Keep the left mouse button pressed at the MPR planes while moving the mouse in order to relocate them.

Curved slice layout controls

A curved slice is a MPR whose plane is not flat (as in normal MPRs) but undulated. The shape of the curved slice is defined by manually drawing its contour (freehand curve) in a reference MPR view.

The curved slice layout displays a 2x2 tile layout containing one reference MPR (first quadrant) and three views in which the curved slices are displayed.

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The first MPR view is the reference MPR in which the user defines the shapes (their contours) of up to three curved slices. The resulting curved slices are displayed in the 1 to 3 numbered curved slice views.

Icon	Name	Description
	**Curved Planar Reconstruction**	When pressed the user can create a new curved slice by drawing its contour within the reference view. The freehand curve is defined by multiple support points set with left-click. The line is interpolated between the support points. A right-click finishes the curve. After completion of the line it can still be edited by adding new points with the left mouse button or dragging its support points to new positions using drag & drop. A point of the spline can also be deleted with a right-click.
	**Direct**	Displays the curved slice as the unfolding of the corresponding contour. It shows the true length of the curved slice.
	**Projected**	Displays the curved slice as the projection onto a flat plane.
	**Delete Spline**	Removes the last drawn contour and its associated curved slice.
	**Delete All Splines**	Removes all contours and their associated curved slices.
-	**Thickness**	To change the thickness of a thick curved slice: Use the arrow up/down buttons. Type the desired value in the Thickness field.

Multi-slice controls

The multi-slice mode displays multiple parallel, equidistant MPRs.

It provides 4 different layouts consisting of either 2, 4, 9 or 16 MPR views. The amount of MPR views equals the amount of displayed slices. One of the displayed MPR views can optionally either display the reference view or an additional slice.

The reference view shows the position of each individual slice in respect to the acquired volume data.

The reference view can either show the A-, B- or C-Plane. The selected reference plane therefore also affects the orientation and position of the slices within the volume.

To cut a specific part of the volume, the user must move the MPR plane relative to the slices.

Icon	Name	Description
	**Reference Display**	When active it replaces the tile in the upper left corner with the reference view plane, which is orthogonal to the distribution direction of the equidistant slices. Each slice is represented as a dashed line within the reference view.

Icon	Name	Description
	**A-Plane**	When active the B-Plane is the reference view and the volume is sliced in vertical direction. It displays the equidistant slices in direction of the A-Plane.
	**B-Plane**	When active the A-Plane is the reference view and the volume is sliced in vertical direction. It displays the equidistant slices in direction of the B-Plane.
	**C-Plane**	When active the A-Plane is the reference view and the volume is sliced in horizontal direction. It displays the equidistant slices in direction of the C-Plane.
	Slice Pitch	The slice pitch value is customizable and defines the distance between each slice. It indirectly also defines the extent of the region which is sliced up.

Multi-Slice D'art controls

The multi-slice D’art mode is similar to the normal multi-slice mode, but allows the user to directly define the extend of the region that shall be sliced up.

It provides 3 different layouts consisting of 4, 9 or 16 MPR views. The first MPR view is the reference view which shows the position of each individual slice in respect to the acquired volume data.

When the Multi-Slice D’art mode is activated the currently active MPR view is used as reference view and toggled to single view mode. The user defines the length of the region to be sliced up by drawing an arrow within the reference view. A left-click defines the start point of the arrow and right-click sets the end point. By setting the end point of the arrow the application automatically switches to the Multi-slice layouts. The length, position and direction of the arrow can be edited within the reference view by dragging and dropping its start or end point.

The displayed slice pitch value is calculated by the application (length of arrow divided by amount of slices) and cannot be altered by the user.

 Color Settings tab contains controls that allow changing different layout concepts of Doppler datasets.

Color display mode controls

These controls are only applicable to 3D.

Icon	Name	Description
	**Plane Cut Tissue**	Displays Color Doppler contents and a cut plane.
	**Cube Cut Tissue**	Displays Color Doppler contents and the tissue.
	**Fusion 3D**	Displays Color Doppler contents shining through the tissue.

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Icon	Name	Description
	**Cube Cut All**	Displays Color Doppler contents and the tissue cut at a defined point.
	**Doppler**	Displays Color Doppler contents.
	**MIP Doppler**	Displays Color Doppler contents in a projection of maximum intensity.

Color component controls

Icon	Name	Description
	**Show Tissue**	Displays only tissue.
	**Show Doppler and Tissue**	Displays Color Doppler contents and tissue.

Color threshold/transparency controls

These controls are only applicable to 3D.

Name	Description
Color Threshold	Separates an object of interest from the background and/or unwanted data (noise). Threshold settings help to define which structures are relevant for the reconstruction and which ones are not. Color values above the adjusted threshold are taken into account for the reconstruction, and color values below are ignored.
Color Transparency	Determines the appearance of a rendered volume. A value of 10 creates a solid surface. Increasing this value the transparency of the volume is increased too.

Color texture intensity control

This function is only applicable to 3D.

Icon	Name	Description
	**Color Texture Intensity**	Adjusts the concentration or strength of the texture shading algorithm.

CDI settings

These controls are only applicable to the Doppler parts. Velocity and velocity turbulence are available as sub modes of CDI (Color Doppler Imaging).

Name	Description
Palette	Applies one of the available color schemes to the Color Doppler parts of the volume.
Balance	Changes the part of pixels within the MPRs which can be displayed in terms of color. Distracting color parts can be removed by adaptation of the balance value.

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Name	Description
Baseline	Shifts the baseline of the color LUT. It can be used for a better display of anatomical structures.
Baseline Reverse	Mirrors the color scale bar around its baseline.

4D SONO-SCAN Workspace Area Controls

The Workspace Area contains functionalities for dataset, MPR and 3D handling. They are available as buttons, context menus and mouse actions.

Navigation by mouse action and smart regions

Six navigation modes are available for manipulating the orientation of MPRs and the 3D view. The corresponding smart regions are placed directly within each view tile and become visible by moving the cursor over them.

Workspace area controls

Icon	Name	Description
	Mouse Wheel - Zoom	Zooms the active view tile.
	**Axis-Wise**	Keep the left mouse button pressed and move the cursor to rotate the tile content around its vertical or horizontal axis. While the left mouse button is pressed the rotation can only be performed around one axis. Release the button, keep it pressed again, and move the cursor to the other direction the rotation around the other axis is selected.
	**View Direction**	Indicates from which side of the data volume the user has a look at the correspondent MPR.
	**Volume Indicator**	Represents the spatial position of a MPR or the 3D. The scan direction is indicated by two colors. The red side of the Volume Indicator represents the first view and the blue one represents the last view of the acquired dataset. Only at the 3D tile the Volume Indicator additionally shows 2D cut planes as colored wireframes. The active MPR tile is indicated by colored edges. The spatial position of this MPR within the 3D is represented by a 2D cut plane (displayed as a wireframe). It has the same color such as the edges of the active MPR. Based on an active tile and the color of its edges, each other tile has a pair of correspondingly colored view direction markers along its borders.
	**Frame Slider**	Marks the currently displayed frame/volume within the clip.

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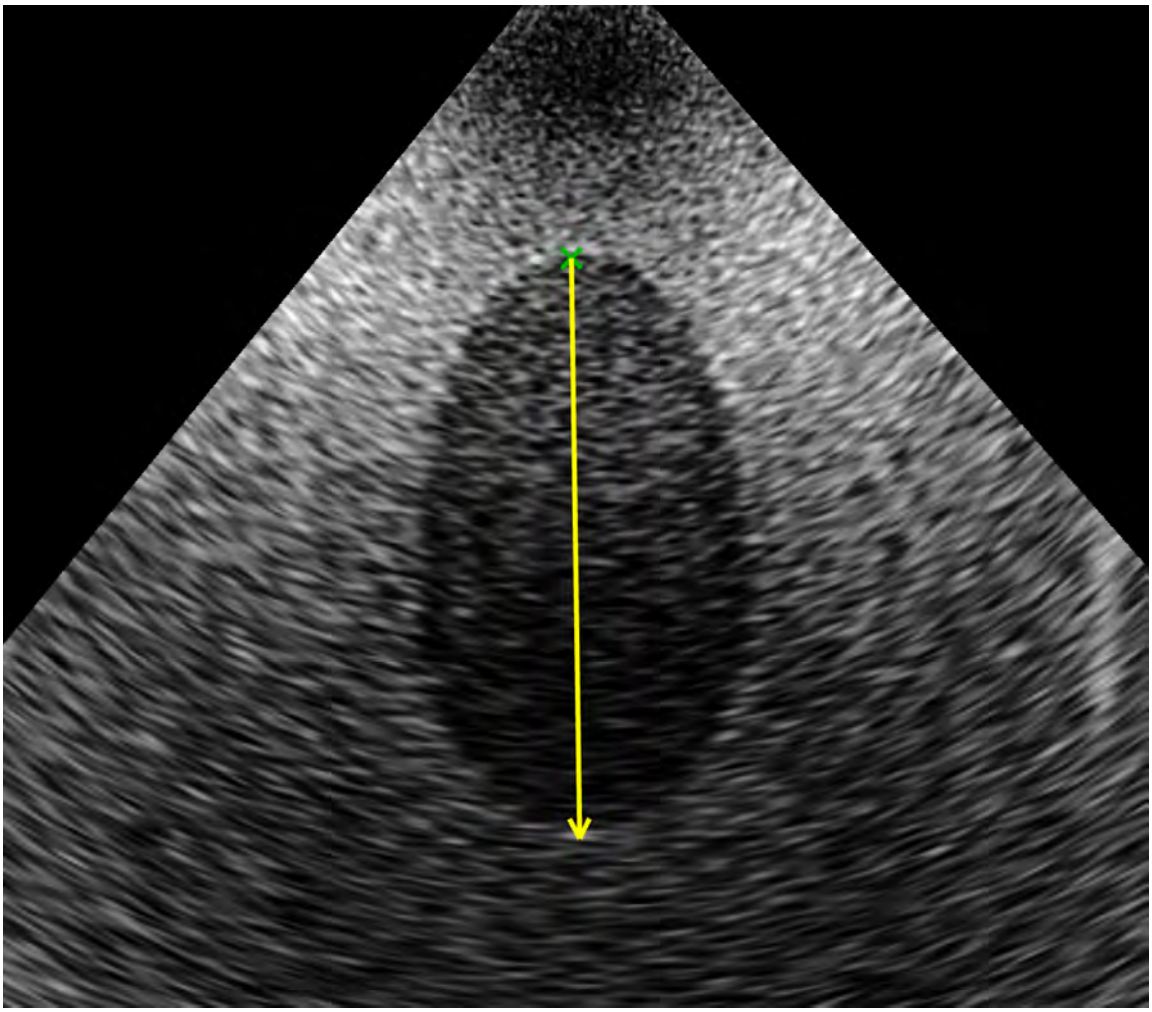
4D SONO-SCAN Workflows

Disk Summation

Disc-Summation is used to measure the volume of simple shaped, symmetric structures. The total volume is calculated by summing up the volumes of a number of consecutive discs. The amount, thickness and shape of the discs are customizable. Each disc contour is drawn by the user in MPR planes who slice up the structure which shall be measured.

When entering the Disc-Summation mode the active MPR view is used as reference MPR and toggled to single view mode. The reference MPR is used to define the overall extend or size of the object whose volume shall be measured.



The user defines the length of the region to be sliced up by drawing an arrow within the reference view. Depending on the slice thickness, the region defined by the arrow is divided into a certain number of parallel and equidistant slices.

The Disc-Summation mode provides three different layouts. Each layout shows at least one reference MPR, a 3D view (containing 3D visualization of the disc) and a number of MPR views which hold the disc contours.

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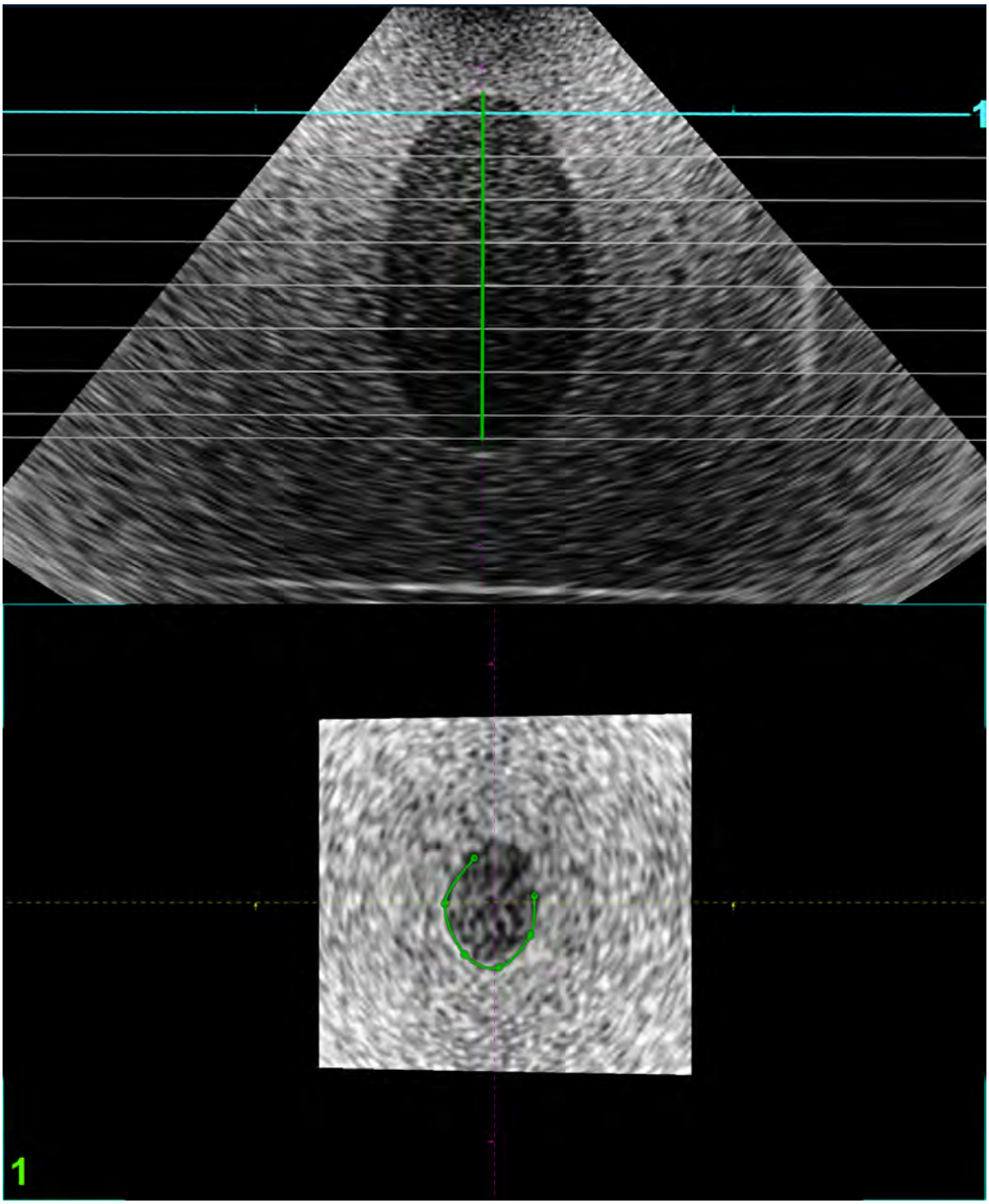
Turning the mouse wheel while the cursor is in a MPR view switches between the slices. Numbers at the lower left corner of MPR views and on the lines in the reference view indicate which slice is displayed in each MPR view.



When the propagate discs check box is marked the contour of the previous slice is automatically copied to the next one.

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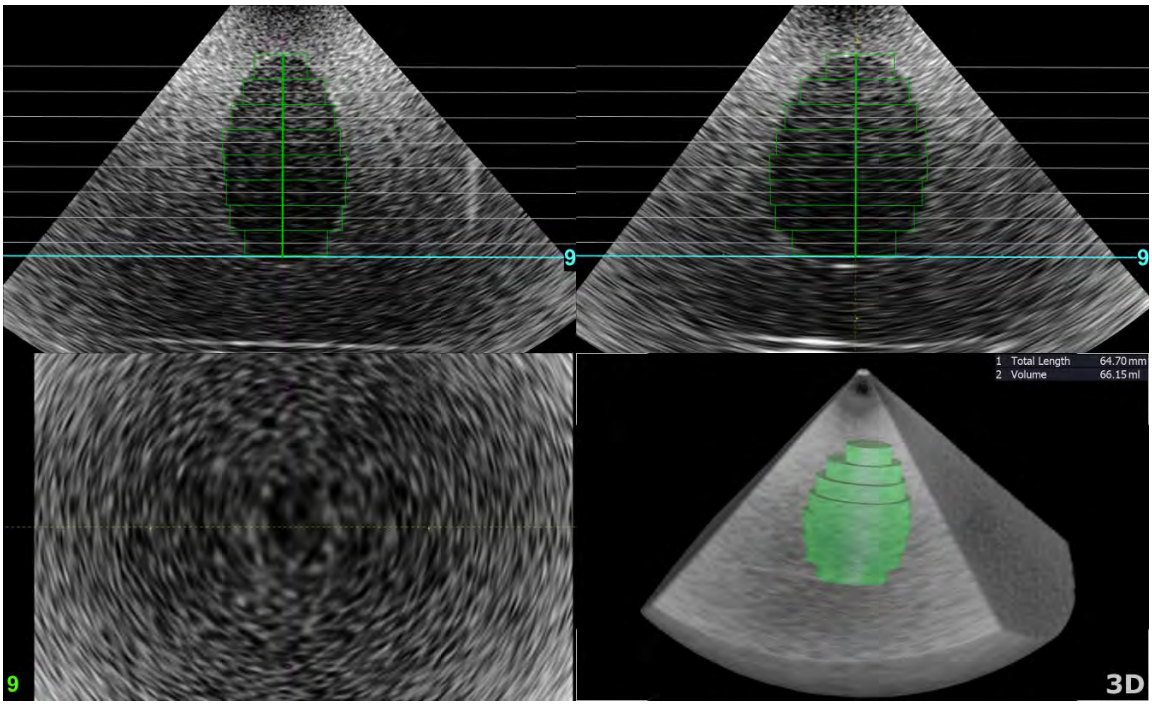

Single Click Volume

NOTE

The **Single Click Volume** function was especially designed to find follicle-shaped volumes. It might not deliver the expected results when applied to larger or more complicated shapes.

Single Click Volume is used to measure the volume of high-contrast structures, such as lesions, in a convenient, automated way.

When activated – by selecting the  (**Set Volume**) – the user starts the volume-detection by selecting a point within the lumen/structure she wants to measure.

Using the high- or low-echo mode either bright or dark structures are detected.

Detection sensitivity can be customized by the threshold slider.

The region in which the software detects can be limited by a customizable rectangular and circular shaped frame.

The detected structure and the corresponding measurement result are visualized in the 3D view.

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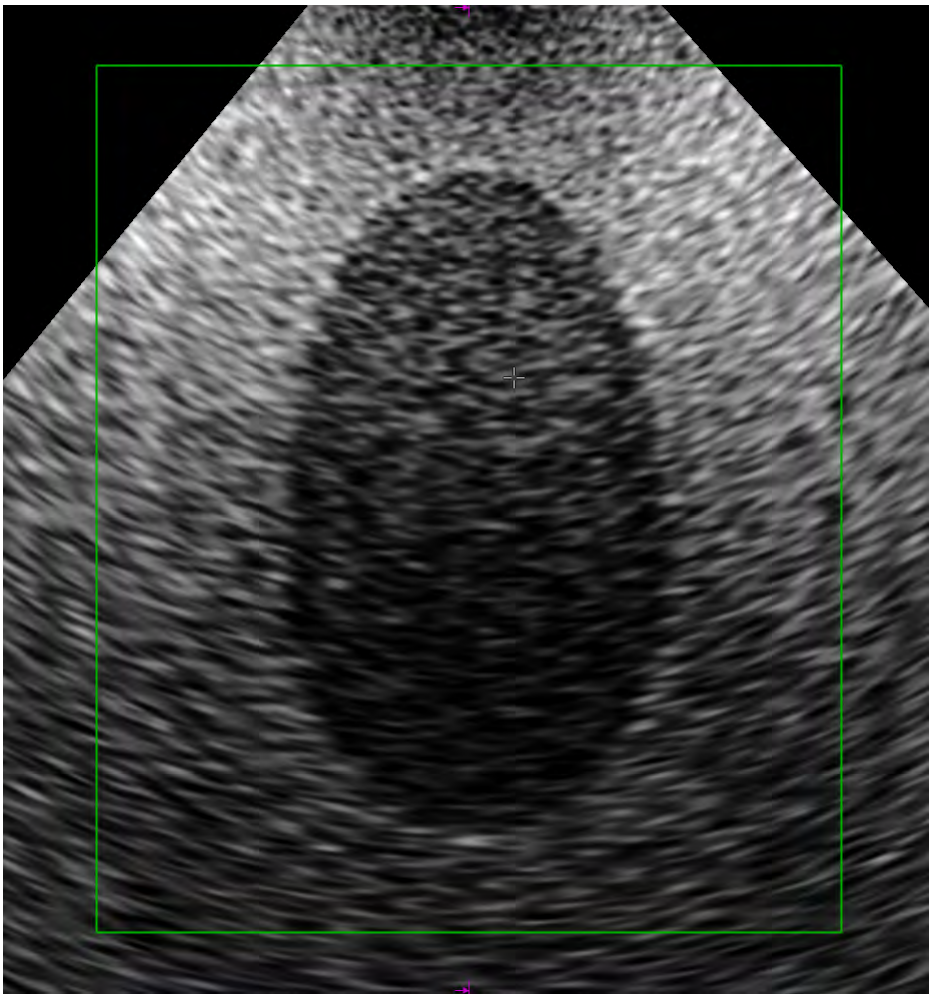

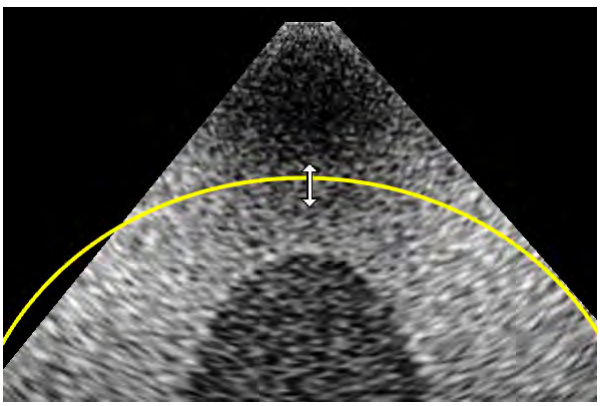

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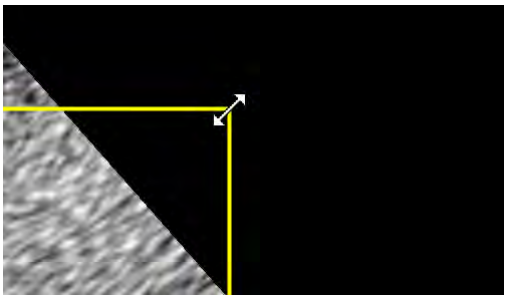
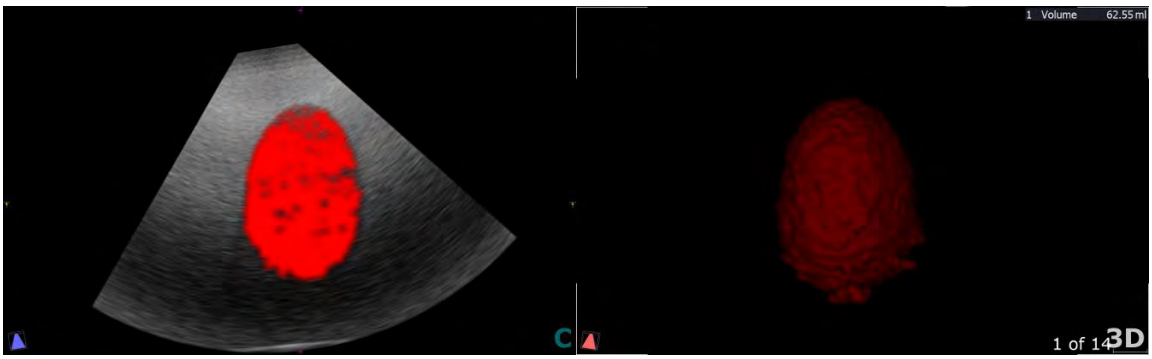
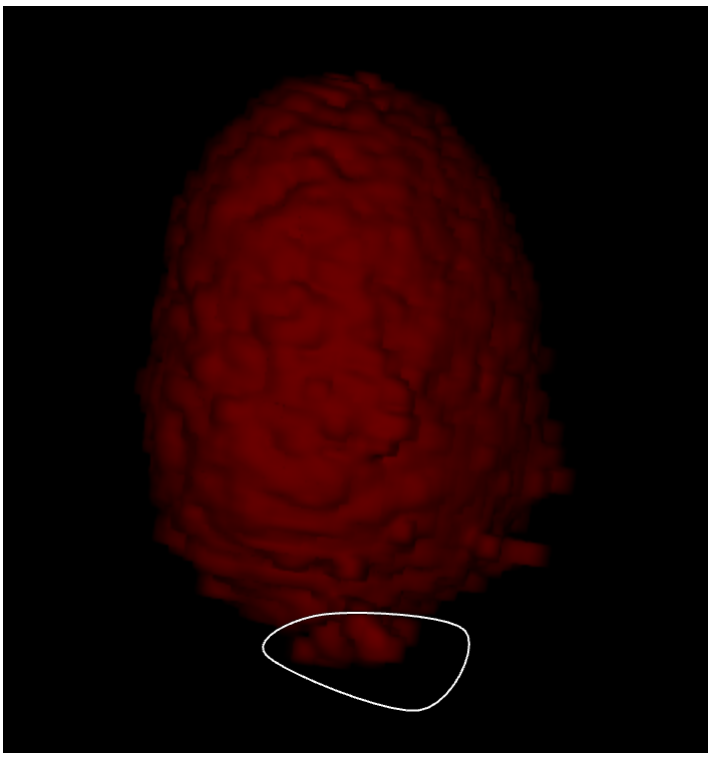


The detected volume can be further segmented with the (**Cut Volume**) function - by drawing a free-shaped form around the part which shall be removed.

It can be applied within the 3D view as well as MPR views.





23 REPORTING Customization

REPORTING customization provides various customization options for workspaces and individual reports. Multiple reports can be created and customized per workspace and the content can be adapted to customer needs.

NOTE

A dedicated user permission is needed to edit the **REPORTING customization**.

Contact your customer service representative for further assistance in REPORTING customization.

REPORTING Customization Controls

Main interface elements

REPORTING customization provides the following controls to access different customization pages:

Icon	Name	Description
	**Choice Lists & Summary**	Customize selection fields and set defaults to report and summary content.
	**Paragraphs & Groups**	Set defaults to the availability and accessibility of paragraphs and groups.
	**Reports & Font**	Create different reports per workspace. Set default report blocks that appear on each print report. Customize font formatting of report blocks for different reports.
	**Global Settings**	Global settings for Workflow and the Print Format.
	**QualitySeal**	Define recommended and required fields. Set Normal Ranges and Z-Scores.
	**Header & Footer**	Individualize the header and footer section of each print report.
	**Import/Export Customization**	Import and export reporting customizations.

User Actions

For REPORTING customization the following actions are available:

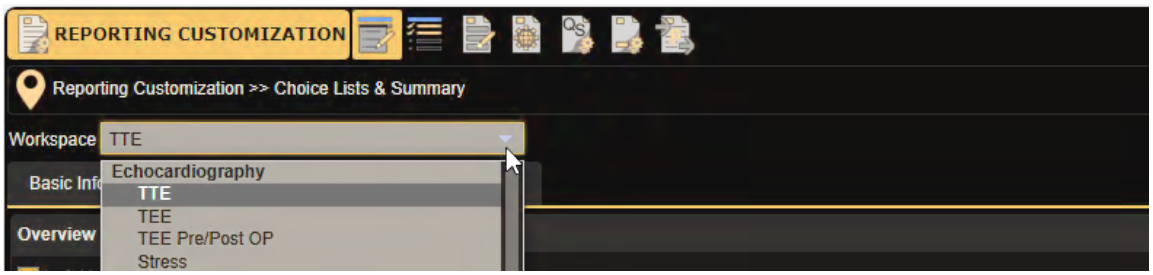
Icon	Name	Description
	**Save Customization**	

Icon	Name	Description
	Cancel	
	Download Customization File	Export the current customization.
	Upload Customization File	Import a customization.
	Restore to Factory Settings	Set changes back to factory settings.

REPORTING Customization Preferences

The following is a typical scenario for the workflow tasks in REPORTING customization. The scenario provides an overview of the tasks involved in using the REPORTING customization module.

Some customization pages require the selection of the workspace or report to be customized. For that a selection field appears on the upper left of the customization page:

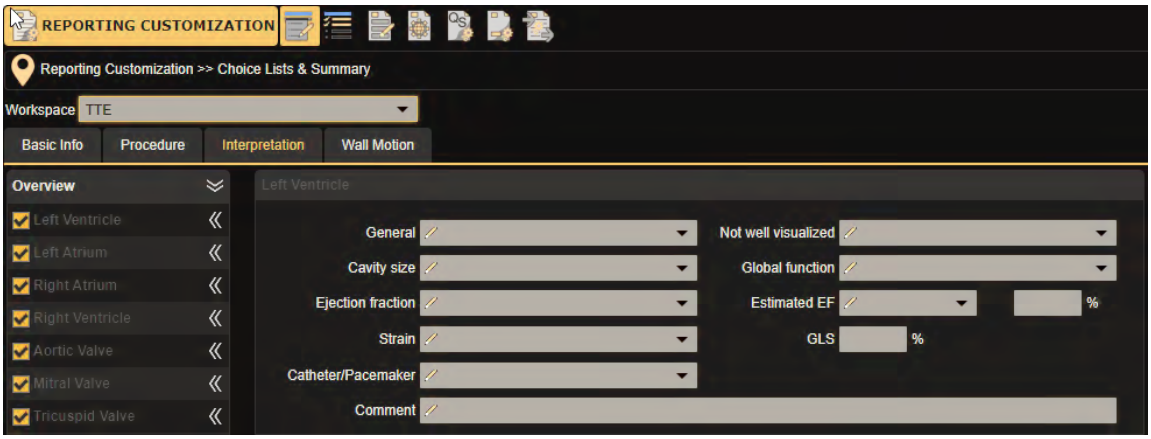


Module Start

- Start the platform software (e.g. Ultrasound Workspace CLIENT).
- The first page that appears is the STUDY LIST page, focused on the Local Archive.
- Select on the top toolbar to open the Settings drop-down.
- Select to open REPORTING customization.

Choice Lists & Summary

Selecting (**Edit Text Field/Choice List**) on the left end of a text field or selection field allows to customize selection fields and set defaults to report and summary content.



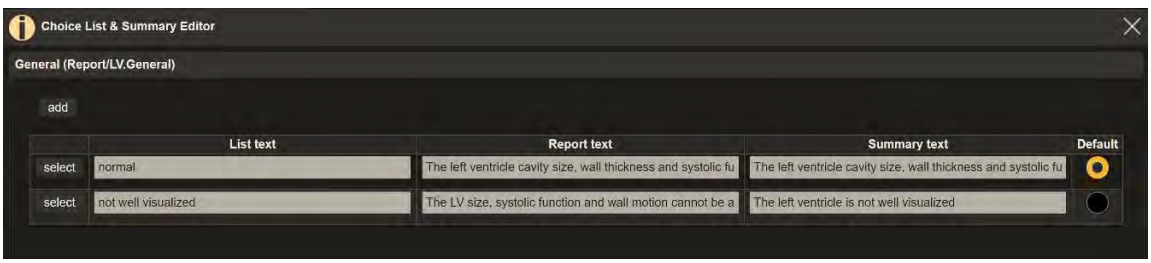
Text field summary editor

To add or remove a text field to the auto summary as default, select or deselect **Add content to auto summary** in the Text Field Summary Editor.

Choice list & summary editor

To add, change or remove choice list items from selection fields and change or add report and summary texts:

1. Add a new selection item to the field.
2. Add, change or remove the **List text**.
3. Add, change or remove the **Report text**.
4. Add, change or remove the **Summary text**.
5. Set a List text as default value for the field by selecting it in the **Default** column:
   - Only one value can be selected if the field has a single selection option.
   - Multiple default values can be selected if the field has a multiple selection option.



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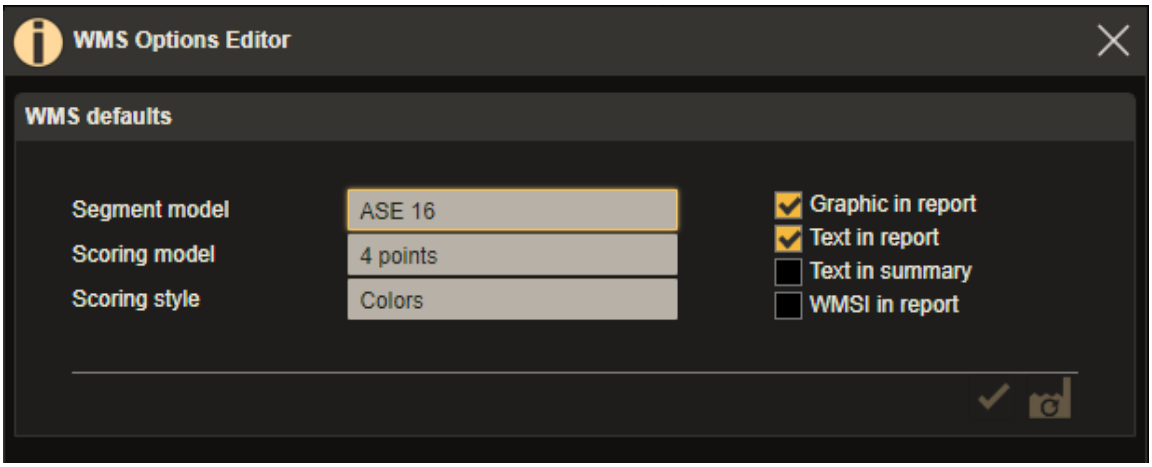
NOTE

The changes are made only for the selected field. It is important to double check that the added or modified List text of a selection item corresponds correctly to the report and summary text if available.

WMS options editor

Set default options for manual wall motion scoring. The options can be changed by selecting and deselecting the different options:

- **Graphic in report**: Show wall motion graphic on print report.
- **Text in report**: Add text for wall motion findings to left ventricle report block.
- **Text in summary**: Add text to summary section.
- **WMSI in report**: Show wall motion scoring index on print report.



NOTE

The wall motion scoring options can be set on the fly when scoring the segments in REPORTING.

Paragraphs & Groups

Set defaults to the availability and accessibility of paragraphs and groups for each workspace.

Paragraphs and groups in each tab in the selected workspace can be selected or deselected in the overview column.

- Only selected paragraphs and groups will be shown by default in the respective workspace and tab.
- However, the deselected paragraphs will not disappear but can always be added additionally in the interface.
- Changes that are made within multiple paragraphs and tabs in one workspace are remembered - so it is only necessary to save once per workspace.

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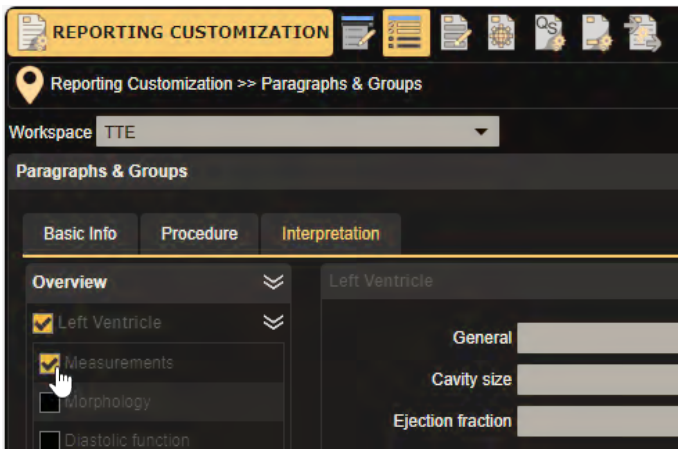

Reports & Font

Customize reports and font for different workspaces.

In the **Reports and Font** customization it is possible to generate multiple reports and configure the font per report. For each report the default report blocks that shall appear on the print report can be set individually. Report blocks can be reordered and the title can be renamed. New custom measurement blocks can be created and added to the print report.

It is also possible to configure the font size and style of the report blocks available for each report. All customization of report blocks or font configurations are displayed in the preview area.

In the **Reports and Font** customization there are four main sections: **Set of Reports**, **Print Report Blocks**, **Font** and **Preview**.

Set of reports

The Set of Reports displays all available reports and is reflected on the report selection page of the REPORTING module. The factory settings include one factory report per workspace. Following workflow steps are available:

1. Generate a new report for a workspace.

   To generate a new report click (**Add New Report**). A new report is added to the set of reports with a unique report ID:

   A newly generated report contains the factory report block customization for the corresponding workspace in the section for **Print Report Blocks**.

2. Edit a report label

   To edit the label of a report click (**Edit Report Label**). This opens the Report Label Editor where a new label can be entered in the text box:

3. Copy a report

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To copy a report click  (**Copy Report**). A copy of the selected report is added to the set of reports with a unique report ID. The report block customization is copied from the selected report and the Print Report Blocks section for the new report will look exactly the same.

4. Delete a report

   To delete a report click  (**Delete Report**).

NOTE

Only custom reports can be deleted. Factory default reports cannot be deleted.

In case a study is linked to a deleted report, the study will be mapped to the factory default report for that workspace.

Print report blocks

The Print Report Blocks section contains three columns:

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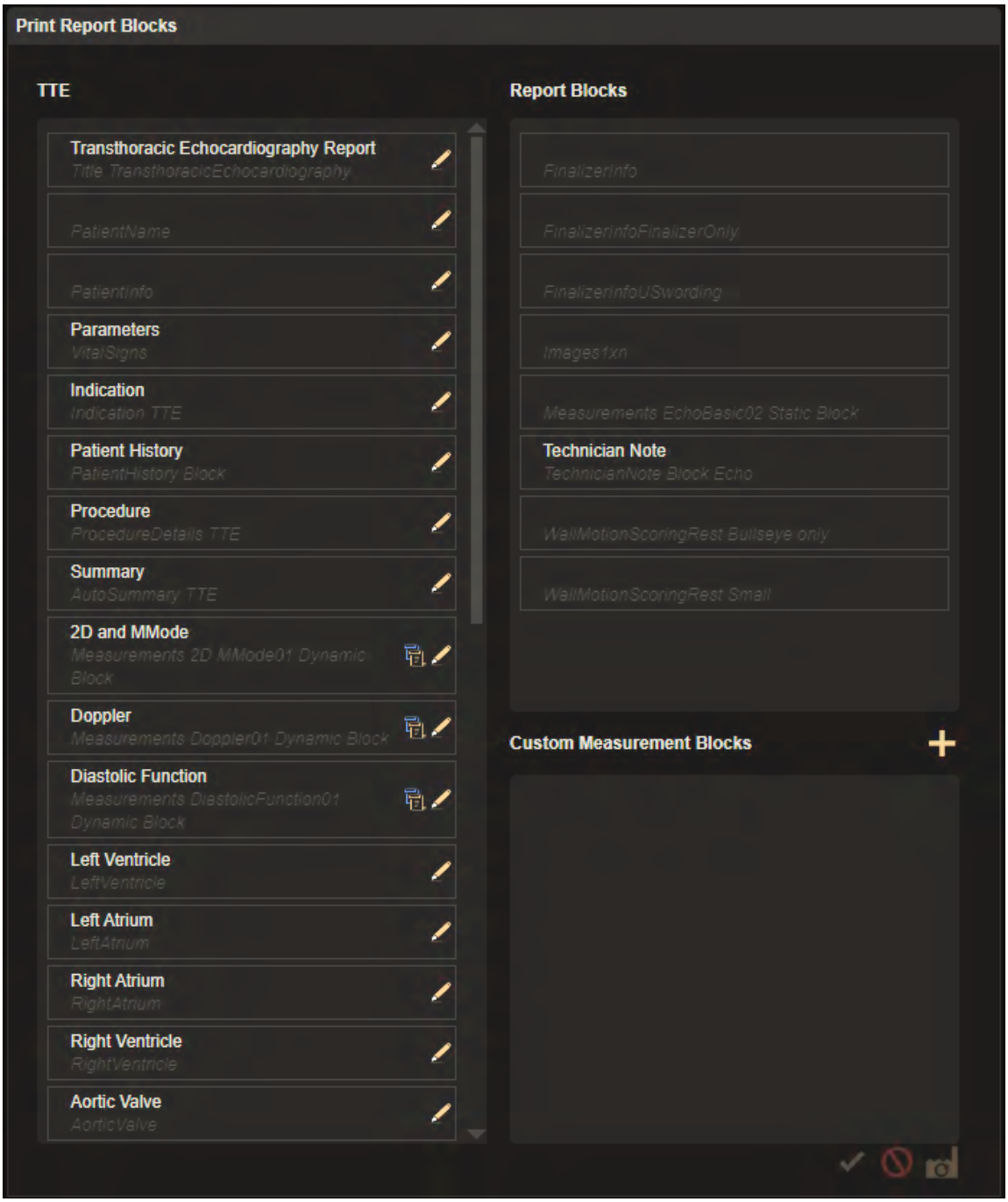

Column 1 displays the currently used report blocks on the print report for the selected report (e.g. TTE)

- Report blocks can be moved up and down by drag-and-drop to change the order in which they appear on the print report.
- Moving a report block to the right column will remove that block from the print report.
- The label of a report block can be edited with a click on (**Edit Block Label**). This opens the **Report Block Label Editor** to edit the **Block Label** text box.

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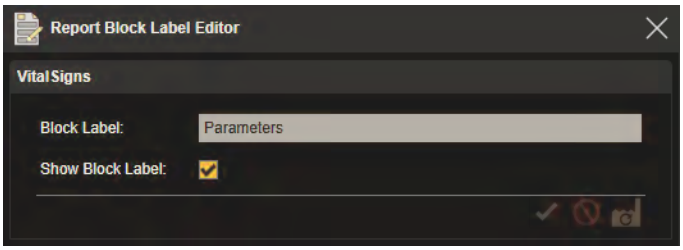
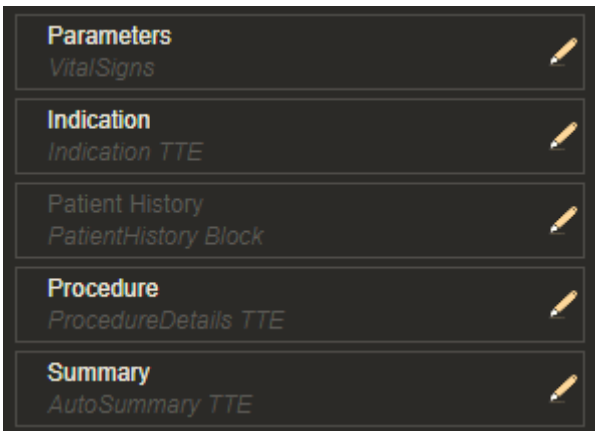


By checking **Show Block Label**, the label of the report block will be visible on the print report. This is indicated with a highlighted label in the report block:



NOTE

When editing the label for the **Title Report Block** the report title on the print report is changed.

It is important to double check changes made for report block labels as it must be in correspondence to the clinical report block content.

NOTE

In the Fetal and Stress workspace there are report blocks which are grouped together.

Report blocks in these groups can only be moved within the group. The whole group can then be moved as a whole respective to the other report blocks (i.e. the ECG Block cannot be moved above the Stress Parameter Block alone).

Report blocks in these groups can be individually removed from the print report but the whole group cannot be removed at once. In case that all blocks from one group are removed an empty place holder block will stay in the left column but nothing is displayed on the print report. To move blocks that were originally in a group back to the print report they have to be moved back into this place holder block.

Column 2 displays the set of all available Report Blocks that are currently not used for that report in alphabetical order.

- Moving a report block to the left column will add the report block to the print report at the position it was moved to.

NOTE

Report block labels can only be edited for report blocks assigned to the left column.

Column 3 displays the customized measurement blocks. There are two ways to create customized measurement blocks:

- Copy a certain preset Measurement Block: This option is useful if the new Measurement Block is merely a modification of a preset block.

- Create an empty Measurement Block by adding a new Measurement Block with (**Add New Measurement Block**).

Both ways open the Measurement Block Editor containing the following fields:

Name	Description
Block ID	A unique block ID is created for each new block, this field is read only and cannot be modified.
Block Label	Name for the header of the new Measurement Block. If block is a copy, label is also copied.
Show Block Label	If this is selected, the header will be shown on the print report, if it is deselected only the measurement table will be displayed.
Columns	It is possible to generate a 2 or 3 column measurement table.
Table Type	A static measurement block always displays the whole measurement table no matter what is filled, a dynamic measurement block only displays the filled measurements without the empty fields.
Show Block Border	Hide or display table borders on the print report.
List of Measurements	List of all available measurements, it can be searched by Group Name, Package Name or Measurement Label.

NOTE

The created Measurement Block will be available for all workspaces and generated reports. A Measurement Block can be configured on the print report for multiple reports belonging to the same workspace. The Measurement Block Label can be defined for each report separately in the left column.

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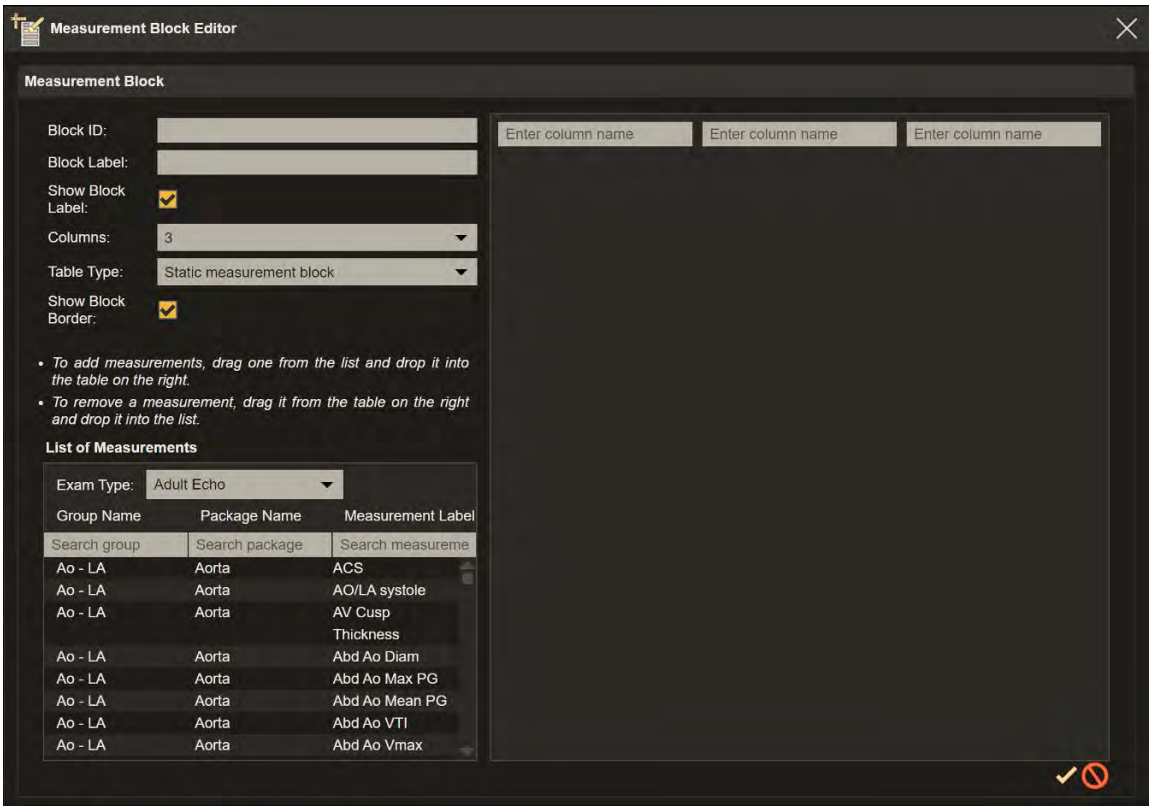


The preview of the measurement table is displayed on the right (red box) and can be modified as follows:

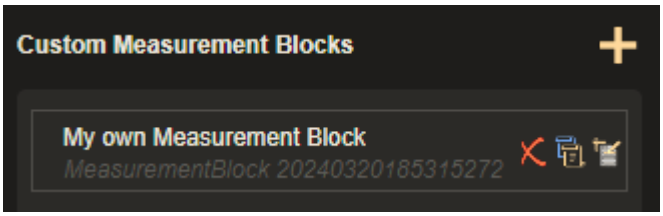
- Set names for the columns of the table.
- Additional measurements can be added to the table by drag-and-drop from the List of Measurements.
- Measurements can be removed by dragging them from the table back to the List of Measurements.
- The order within the table can be changed by dragging the measurements around.

NOTE

To identify the Group Name and Package Name of a measurement its field ID is shown, when moving the mouse over the measurement in the table:

The new measurement block is saved by selecting the **Save Customization** button and is then available with its block ID in the **Custom Measurement Blocks** column 3.

It can then be treated like any other report block with the addition that it is possible to delete , copy and edit it as well:



Font

Name	Description
Group	A list of all options that can be configured according to the available report blocks for the selected report (e.g. TTE). A complete list of options is only visible for the factory report of the **Stress** workspace.
Size	A list of all the font sizes that can be used for the configuration.
Bold	If you select **Bold**, the selected group will be displayed in bold in the print report. The results will be displayed in the preview as soon as the configuration is saved.

Preview

The **Report Customization Preview** displays the saved results of the report block customizations and font configurations.

Global Settings

To set global settings for **Workflow** and the **Print Format**:

- Select or deselect the authentication dialog for finalizing the report.
- Select or deselect back to study list while finalizing the report.
- Select page format (A4 or letter) for print report.
- Select or deselect the shrink to fit functionality.
- To apply these settings, save the customization and restart the Ultrasound Workspace.

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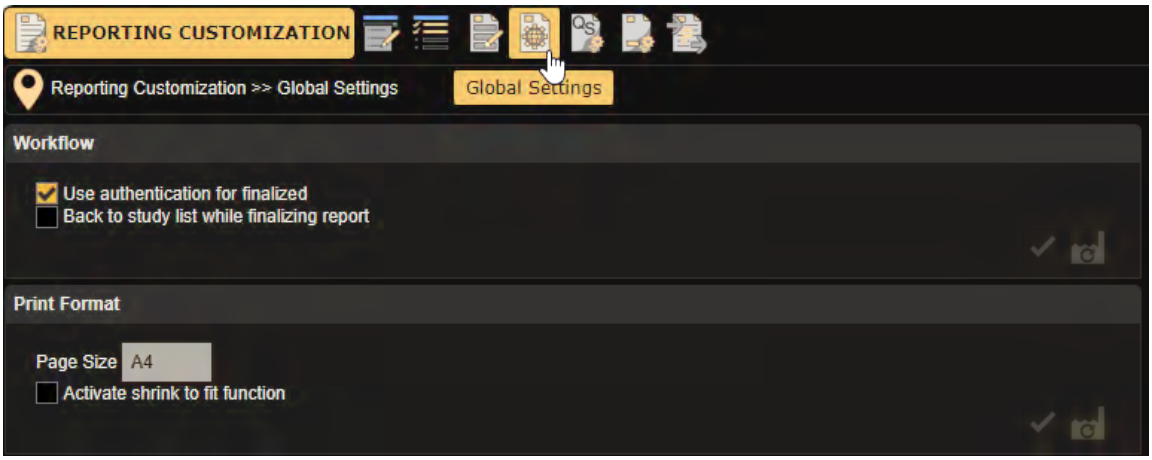


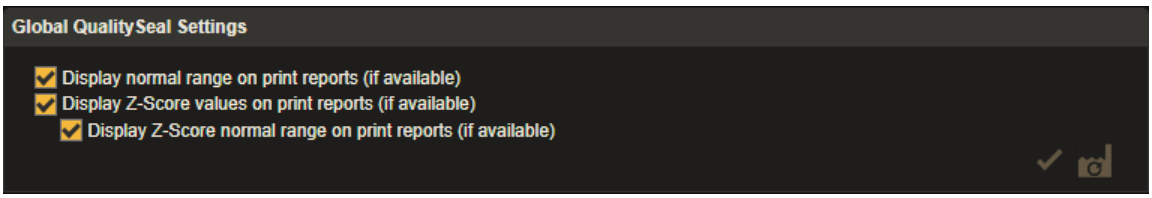
QualitySeal Customization

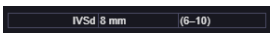
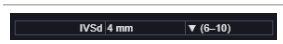
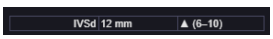
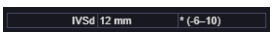
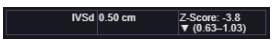
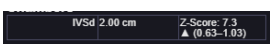
The QualitySeal (QS) customization allows to customize normal ranges and define recommended and required fields.

Global QualitySeal settings

With the global settings the normal range and the Z-Scores can be generally turned on and off on the print report if available.

To apply these settings, save the customization and restart the Ultrasound Workspace.



Setting	Description
Display normal range on print reports (if available)	
	Enable/disable displaying normal ranges on the print report tables.
 	An arrow indicates if values are under/over normal range.
	If the normal range includes at least one negative value, a * icon is displayed for values out of normal range.
Display Z-Score values on print reports (if available)	
	Enable/disable displaying Z-Scores on the print report tables.
 	If this box is selected the check box Display Z-Score normal range on print reports (if available) becomes available to enable/disable displaying the normal range of the Z-Scores on the print report tables.

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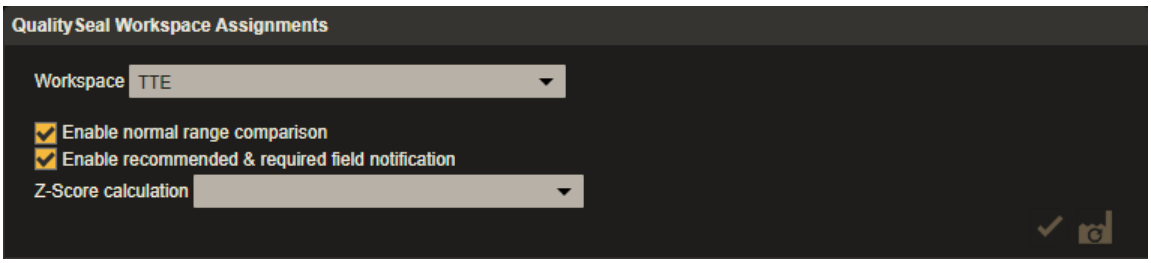
QualitySeal workspace assignments

With the workspace assignments the functionality **per workspace** is defined.

To apply these settings, save the customization and restart the Ultrasound Workspace.



Setting	Description
Enable normal range comparison	Enable/disable normal range comparison.
Enable recommended & required field notification	Enable/disable the notification functionality for recommended and required fields.
Z-Score calculation	Select a method for Z-Score calculation and corresponding normal ranges.

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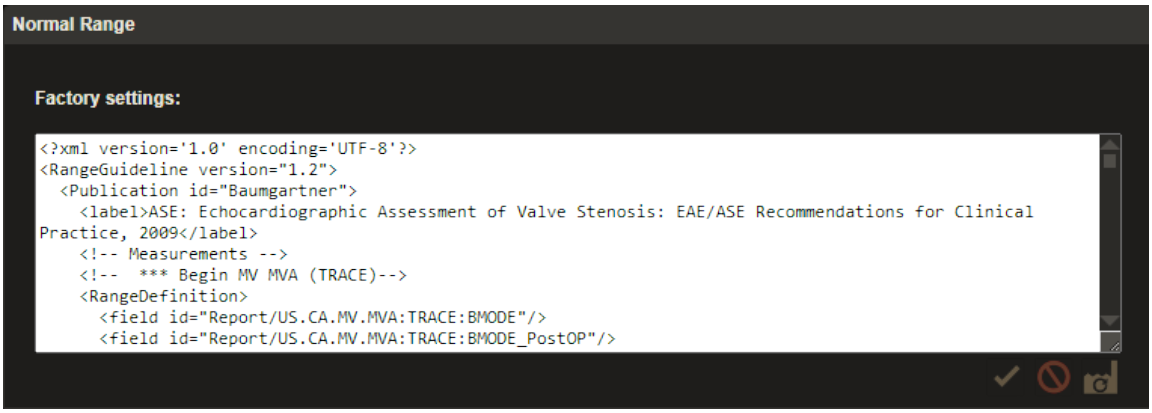
Normal range customization

The normal ranges can be customized for each individual measurement. Factory default settings are included in the initial QS delivery, and are standard to the publications used as clinical reference. The file is encoded in XML format.



Unconditional QS definition of range

Defining a new range, shall respect the following syntax:

```
<RangeDefinition>
<field id="Report/US.CA.MV.MVA:TRACE:BMODE"/>
<field id="Report/US.CA.MV.MVA:TRACE:BMODE_PostOP"/>
<unit>cm2</unit>
<NormalRange>
    <label><tr context="reporting">Normal Range</tr></label>
    <min>4</min>
    <max>5</max>
<GradeRange>
    <label><tr context="reporting">Mild</tr></label>
    <exclmin>1.5</exclmin>
    <exclmax>4</exclmax>
</GradeRange>
<GradeRange>
    <label><tr context="reporting">Moderate</tr></label>
    <min>1.0</min>
    <max>1.5</max>
</GradeRange>
<GradeRange>
    <label><tr context="reporting">Severe</tr></label>
    <exclmax>1.0</exclmax>
</GradeRange>
</NormalRange>
</RangeDefinition>
```

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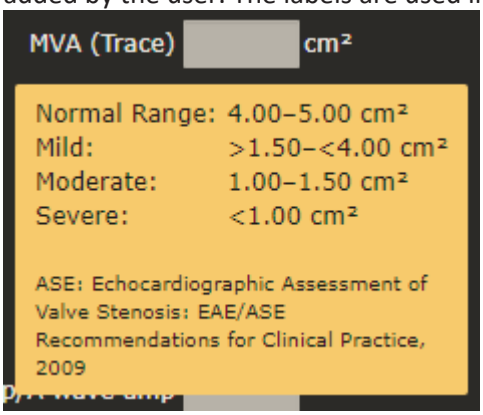
XML Tag	Description
<RangeDefinition>	Required element for range definition.
<field id>	ID of the field to be defined (can contain multiple field IDs).
<unit>	Unit corresponding to the <max> and <min> values. The unit conversion for the Tool-tip and Report is being done automatically (e.g.: if the definition of the range is given in mm and the field is reported in cm, the cm unit will be used in all locations).
<NormalRange>	Normal range definition shall include a <label>, minimum and maximum elements.
<GradeRange>	Definition of <label> and ranges for abnormal values.

The following labels are by factory default available and can be used within the normal and grade range definition:

- Normal Range
- Mild
- Mild to Moderate
- Moderate
- Moderate to Severe
- Severe
- Significant Stenosis
- Aortic Sclerosis
- Mildly Abnormal
- Moderately Abnormal
- Severely Abnormal

The labels can be modified by the user (linkage should be considered). Additional labels can be added by the user. The labels are used in the measurement's tool-tip.



A field ID can be obtained by using the following shortcut: Ctrl + Click applied on the label or value box corresponding to the measurement of interest. The functionality is available in the REPORTING module.

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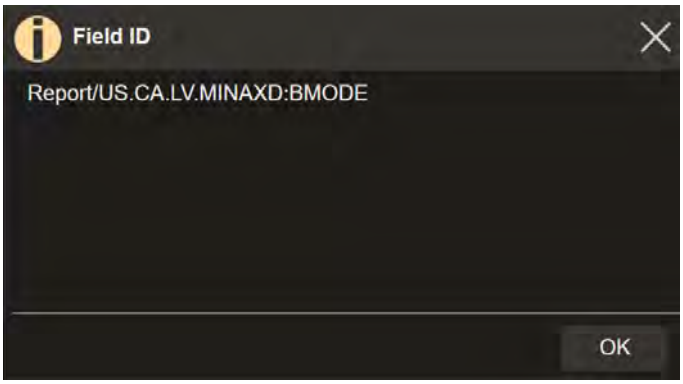


Conditional QS definitions

On top of unconditional range definition, conditional ranges can also be defined. These conditions specify which ranges the QS will display, depending on a pre-set condition.

Gender condition definition

```
<Condition id="sex">
    <label><tr context="reporting">Sex</tr></label>
    <dataId>Patient/Sex</dataId>
</Condition>
```

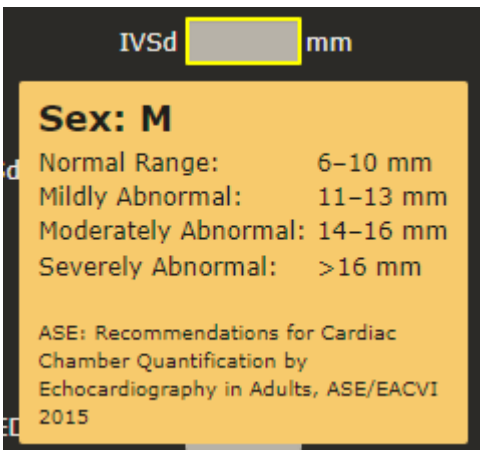
General condition syntax

```
<Condition id="abc">
    <label><tr context="reporting">abc</tr></label>
    <dataId>Report/SomeField</dataId>
    <unit>unit</unit>
    <precision>precision</precision>
</Condition>
```

XML Tag	Description
<Condition id = " ">	Condition definition block with name of the condition.
<dataId>	ID of the key generating the condition (i.e. Gender, Age, etc.). Any finding key can be used to define the condition. The finding key shall always be prefixed by “Report/”.
<unit>	Unit corresponding to the condition specifications. The unit used in the condition must respect the field definition unit: i.e. if the unit definition is in cm, the condition unit should also be a denominator of distance (m, mm, km...). No conversions are possible (inch, mile, etc.).
<precision>	Definition used to define the <min> and <max> numeric formats. The **minimum (<min>)** defined value is considered to be inclusive (≥), while the **maximum (<max>)** defined value is not considered inclusive (<). If no precision is specified, the default value is 0 (if input format is not respected, the QS will throw an error and the QS will not be functional).

The unconditional range definition is then extended with a condition statement: `<ifequals condition="abc" value="x"/>`

```
<RangeDefinition>
<NormalRange>
    <label><tr context="reporting">Normal Range</tr></label>
    <ifequals condition="sex" value="M"/>
    <min>0.6</min>
    <max>1.0</max>
<GradeRange>
    <label><tr context="reporting">Mildly Abnormal</tr></label>
    <min>1.1</min>
    <max>1.3</max>
</GradeRange>
<GradeRange>
    <label><tr context="reporting">Moderately Abnormal</tr></label>
    <min>1.4</min>
    <max>1.6</max>
</GradeRange>
<GradeRange>
    <label><tr context="reporting">Severely Abnormal</tr></label>
    <exclmin>1.6</exclmin>
</GradeRange>
</NormalRange>
</RangeDefinition>
```



User modified normal ranges will be indicated in the measurement tool-tip.

Recommended & required fields customization

User defined recommended and required fields can be configured. Factory default configuration respects IAC standards.

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A field ID can be obtained by using the following shortcut: Ctrl + Click applied on the label or value box corresponding to the field of interest. The functionality is available in the REPORTING module.

Recommended fields

Recommended fields will have an orange bordered frame for visual indication.

Field definition syntax must respect the following layout:

```
<Recommended>
    <field id="Report/US.CA.LV.IVSD:BMODE"/>
</Recommended>
```

The following syntax allows for only one of the following fields to be conditioned. If any of these fields has an input, the visual indication (orange frame) will disappear from all other fields enclosed in this definition.

Usage scenario: Value can be measured using multiple methods, but the recommendation states that only one value is necessary for a complete report.

```
<Recommended>
    <Any>
        <field id="Report/US.CA.LV.IVSD:BMODE" />
        <field id="Report/US.CA.LV.IVSD:MMODE" />
    </Any>
</Recommended>
```

Required fields

Required fields will have a red bordered frame for visual indication.

Field definition syntax must respect the following layout:

```
<Required>
    <field id="Report/US.CA.LV.MINAXD:BMODE"/>
</Required>
```

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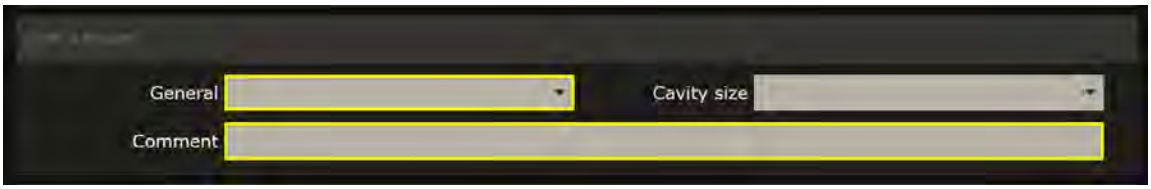
The following syntax allows for only one of the following fields to be conditioned. If any of these fields has an input, the visual indication (red frame) will disappear from all other fields enclosed in this definition.

Usage scenario: Value can be measured using multiple methods, but the requirement states that only one value is necessary for a complete report.

```
<Recommended>
    <Any>
        <field id="Report/US.CA.LV.MINAXD:BMODE"/>
        <field id="Report/US.CA.LV.MINAXD:MMODE"/>
    </Any>
</Recommended>
```

Not only measurement fields can be defined as recommended or required fields. The same syntax can be used to define selection items or text boxes:

```
<Recommended>
    <field id="Report/LA.General"/>
    <field id="Report/LA.Comment"/>
</Recommended>
```



Header & Footer

Adapt Header and Footer of reports to customer needs

The Header and Footer customization is used to individualize the header and footer section of the print report. The customization is done for each report separately using the customization tool.

The following can be added into the header and footer:

- Images or logos
- Plain text
- Page numbers
- Fields from workspace

Images/Logos

Images or logos can be included in the header and footer. The factory default settings for the header include a default logo in the upper right corner. Other logos and/or images in JPEG format can be included in the header and footer sections by drag and drop.

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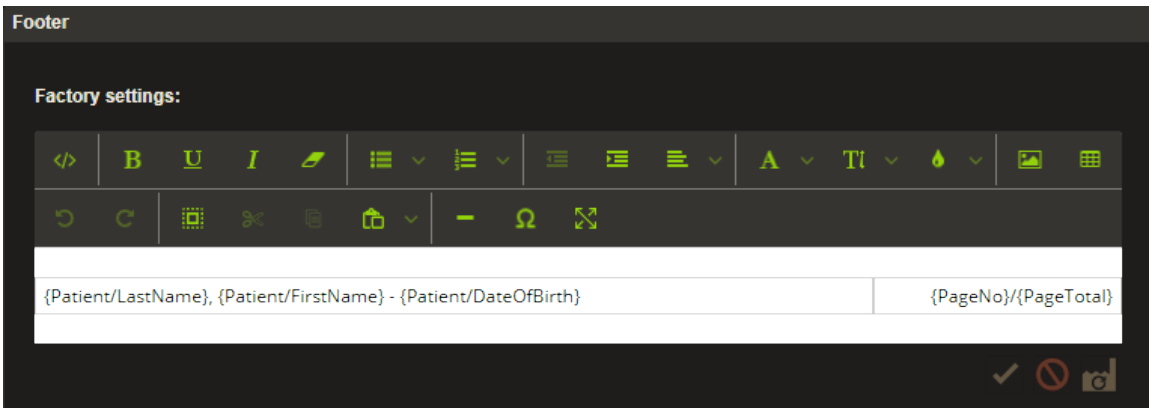
In the factory settings sections of the header and footer customization you can see automatically the changes and format it. Select **Display header only on the first page**, if the header should be only displayed on the first page of the print report.

Text and pagination

Plain text and pagination can be included in the header and footer. The factory default settings for the footer include the current page number {PageNo} and the total number of pages the report has {PageTotal} (see code example below). Any other text can be added manually and formatted.



Fields from the workspace

Workspace fields are included by adding their ID to the header or footer section.

A field ID can be obtained by using the following shortcut: Ctrl + Click applied on the label or value box corresponding to the field of interest.

All patient data like **Patient ID**, **Name**, study data like **Study ID**, **AccessNo.** and workflow data like **Preliminary**, **Finalizer Name**, **Date** can be included. The following options are available for workspace fields:

XML Tag	Description
{FieldPrefix/FieldID}	This will include both the field label and the field value, e.g. {Report/Sonographer} will become "Sonographer: John Sonographer" in the header/footer.
{FieldPrefix/FieldID#Label}	This will only include the field label, e.g. {Report/Sonographer#Label} will become "Sonographer" in the header/footer.
{FieldPrefix/FieldID#Value}	This will only include the field value, e.g. {Report/Sonographer#Value} will become "John Sonographer" in the header/footer.

Import/Export Customization

Import/Export customizations for fast reporting.

When importing a customization the current status of the selected customization is overwritten. Deselected customizations will be preserved.

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NOTE

It is only allowed to import a customization file of the same software version.

When importing a REPORTING customization the Selective Import opens with following options:

Choice List & Summary

- Customizations related to the “Choice Lists & Summary” on page 157.

Text Field Summary

- Customizations related to the “Choice Lists & Summary” on page 157.

WMS Options

- Customizations related to “Choice Lists & Summary” on page 157.

Paragraphs & Groups

- Customizations related to the availability and accessibility of “Paragraphs & Groups” on page 159.

Report Customizations

- All report customizations, including custom measurement blocks and labels.

QualitySeal including:

- Display normal range on print reports
- Display Z-Score values on print reports
- Display Z-Score normal range on print reports
- Enable normal range comparison
- Enable recommended & required field notification
- Z-Score calculation
- Normal Range
- Recommended & Required Fields

Header & Footer

Switch on/off authentication dialog for finalization

- Settings for workflow in “Global Settings” on page 166.

Switch on/off auto back to study list while finalizing report

- Settings for workflow in “Global Settings” on page 166.

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Print format including:

- Page size for print report
- Display header only on the first page for print report
- Shrink to fit setting

For example, in the current status of the REPORTING customization a TEE report (e.g. TEE long report) is customized including a custom Measurement Block e.g. MMT TEE. When importing a report customization e.g. Custom TTE the complete Reports Customization is set to factory settings and thereafter the new report customization is imported. This implies that the custom TEE long report with its MMT TEE Measurement Block is no longer available and only the Custom TTE report with its custom Measurement Blocks is from then available on the Reports customization page.

NOTE

The import functionality triggers an export of the respective REPORTING customization to recover customization blocks, which are overwritten by the import file.

Back to Factory Settings

The global **Back to Factory** settings section allows to restore the complete REPORTING customization for all workspaces.

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24 Measurement Customization

Measurement Customization Fundamentals

The structure of a measurement menu is as follows:

			Example
Group Defined within the measurement menu for a set of measurement packages			Left ventricle
	Package Set of measurements		2D
		Input Single measurement	RV/LV Diastole
		Sub-Input	RVAWd

Mesurement Customization Controls

Icon	Name	Description
	**Lock**	It indicates packages that are defined as "connected measurements". It is not possible to deselect or move only parts. Therefore, the checkmarks for all these measurements are grayed out.
	**Information**	It displays CAP packages. CAP packages can only be moved as a whole. CAP packages are only available in the Worksheet.

Measurement Customization Preferences

Create and Manage Presets

Start the Measurement Menu Editor

The default installation location is **C:\ProgramData\Philips\UltrasoundWorkspace\TTA-Client\ImageCom\MeasurementMenuEditor\MeasurementMenueEditor.exe**.

When you open the Measurement Menu Editor the software asks for an **MMCResource.arc** file to open.

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If there is no existing file, select a location where to store it and click **Open**. The software creates a file named MMCResource.arc. Individual file names such as e.g. MenuVersion1.arc instead of MMCResource.arc are allowed.

- If an MMCResource.arc file is downloaded from the server before, select this file and click **Open**.
- If an existing MMCResource.arc (e.g. “MenuVersion1.arc”) is renamed, select this renamed file.
- If you have to extend the **TTE Guideline** preset, load the MMCResource.arc file from **C:\ProgramData\Philips\UltrasoundWorkspace\TTA-Client\ImageCom\configuration**.

Customize the preset

The editor shows the same menu structure as displayed in **IMAGE-COM** (factory default preset). Checkmarks in front of a group, package, or measurements, symbolize which measurements are displayed in the **IMAGE-COM** measurement menu.

Do one of the following, to select, deselect and reorder groups, packages or single measurements, edit group and package names:

- Uncheck anything that you do not want to be displayed in your user-defined preset.
- Click **Edit selected item name** to edit factory group and package names.
- Drag and drop groups, packages and measurements to change their order.
- Create custom groups or packages:
  - Click **Create new Group** or **Create new Package**.
  - Add packages or measurements from other groups or packages per drag and drop.

    Items that are dragged from their original group or package to a new one are not really moved but copied.
  - Click **Edit selected item name** to edit custom group and package names.
  - Click **Delete selected item** to delete custom groups or packages.
  - Click **Delete selected item** to unlink packages or measurements from groups or packages.

    Only the copy is deleted, the item will stay at its original location.

NOTE

Packages with  or  can only be checked once in a preset.

Adjust the Worksheet

To adjust the findings in the Worksheet of a package, do the following:

1. Click the **Worksheet** button to open the findings dialog box:

   The dialog box displays all measurements and calculations that can be derived from the corresponding measurement menu configuration.

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  - Checkmarks in front of a measurement or calculation symbolize which of these are displayed in the **Worksheet**.
  - Uncheck everything that should not be displayed on the **Worksheet**.
  - Adapt the order of the measurements as it should be displayed on the **Worksheet**.
2. Click **Save**.

Save the preset

Click **Save** to store the current status of the preset to the location selected when opening the file. Do one of the following:

- Save as new preset: Enter a new name in the corresponding field.
- Save changes: To save changes for an already existing preset checkmark **Overwrite existing preset**.

Set preset as default

1. Select a particular preset from the drop-down menu.
2. Checkmark the default preset field on the right hand side.

Save the preset once again and do not forget to checkmark **Overwrite existing preset**.
(If the checkmark is not set, a message will appear.)

Delete the preset

Click **Delete Preset** to delete a selected preset. The factory preset cannot be deleted.

Exit the Measurement Menu Editor

Click **Quit** to exit the editor.

NOTE

The user must be aware of the **QualitySeal** settings. Switching off the **QualitySeal** relevant measurements is the responsibility of the user.

NOTE

Before the preset is available in the filter options of IMAGE-COM, the customized configuration file (*.arc) must be uploaded to the administration area (**Administration** >> **Configuration** >> **Measurements**). Administrator permission is required.

NOTE

The measurement menu editor cannot run in parallel with the desktop client. This causes the desktop client to freeze or the editor cannot be started.

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Units & Precision Customization

The customization of units and precision is site-specific.

NOTE

An administrator permission is needed to change the units & precision set in the **Administration Configuration**. The units & precision set affects labeled measurements in **IMAGE-COM** and **REPORTING**.

Following units & precision sets are available:

- Recommended
- Backward Compatibility (factory default)
- Core Lab
- Small
- Small (mm, cm/s, 10th)
- Small (mm, cm/s, 100th)
- Small (mm, m/s, 10th)
- Small (mm, m/s, 100th)
- Small (cm, m/s, 10th)
- Small (cm, m/s, 100th)
- Option 1

NOTE

This customization option does not affect results that are shown within CAPs. Units & Precision of generic measurements may have differing factory default dimensions. Therefore it might happen that a labeled distance (e.g. **RVAWd**) is shown in cm whereas its corresponding generic distance measurement is in mm. If the simultaneous display of these results is not wanted, click  .

Example

As most of the distance measurements are defined as 'Medium distance', therefore an RVAWd of 4 mm will change as shown for the different Units & Precision sets:

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	Backward Compatibility	Recommended	Core Lab	Option 1	Small
RVAWd	4 mm	0.40 cm	4 mm	4.00 mm	4.0 mm
					4.0 mm (mm, cm/s, 10th)
					4.00 mm (mm, cm/s, 100th)
					4.0 mm (mm, m/s, 10th)
					4.00 mm (mm, m/s, 100th)
					0.4 cm (cm, m/s, 10th)
					0.40 cm (cm, m/s, 100th)

NOTE

Contact your service representative for further information.

Value to Use Customization

The customization of the value to use in the **Worksheet** is site-specific. It affects the aggregation method for calculations as well as for the export of measurements.

NOTE

An administrator permission is needed to change the value to use in the **Administration Configuration**.

Regarding value to use, measurements are divided into two groups:

1. Velocities (All Doppler velocities: **PW-Doppler**, **CW-Doppler** and **Tissue Doppler**).
2. All other measurements (Everything else apart from velocities).

For each of these two groups, the value to use options are: **Avg** (factory default), **First**, **Last**, **Min**, **Max**.

NOTE

Any study-specific value to use settings that have been defined for individual measurements in the **Worksheet** will be preserved and not overwritten. The factory default value to use setting for CAP measurements is **Last** and will not be overwritten.

BSA Calculation Formula

The customization of the **BSA calculation formula** is site-specific. It affects the **BSA calculation formula** to be used for all modules.

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NOTE

An administrator permission is needed to change the **BSA calculation formula** in the **Administration Configuration**.

Following BSA calculation formula are available:

- DuBois (factory default)
- Mosteller
- Boyd (weight only)
- Haycock

NOTE

The BSA calculation formula will also affect pediatric and fetal Z-Score calculation. It is recommended to use the same BSA calculation formula as in the according Z-Score reference. Contact your service representative for further information.

Measurement Label Language

The customization of the measurement label language is site-specific. It affects the language for measurement labels to be used for all modules.

NOTE

An administrator permission is needed to change the measurement label language in the **Administration Configuration**.

Following measurement label language options are available:

- English (factory default)
- Regional (Site Settings)

NOTE

When selecting regional as measurement label language the chosen language from the regional settings in the **Administration Configuration** applies.

NOTE

The exported **Measurement List** is translated according to the chosen measurement label language. All other export formats (DICOM, XML and TXT) stay in English even if the measurement label language is set to regional.

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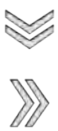
25 Appendix

Common Controls

The controls are shown in their default appearance. They may vary in color depending on the specific configuration. The meaning of each control remains the same.

Window Management

Controls to manage the **Ultrasound Workspace** windows.

Icon	Name	Description
	**IMAGE-COM**	Opens the **IMAGE-COM** module (license-dependent). Only available in a workstation-based solution. In dual monitor mode, the module is opened on the second screen.
	**REPORTING**	Launches the **REPORTING** module (module license-dependent).
	**About**	Opens the **About** screen. Displays all product information, the instructions for use and the country labels.
	**Refresh**	Refreshes a view or window.
	**Refresh Hint**	Hints to click refresh. If displayed either patient demographics, visit or study information has been updated in the background, or DICOM objects have been received or deleted.
	**Minimize**	Minimizes the current application.
	**Exit**	Closes the application or view.
	**Back to STUDY LIST**	Closes all opened modules and the **STUDY LIST** appears again.
	**REPORTING & IMAGE-COM**	Open simultaneously the **IMAGING** and the **REPORTING** modules (license-dependent) on a selected study. Only available in the web browser.
	**WEB REVIEW**	Opens a basic and non-diagnostic image viewer. Only available in the web browser.
	**Collapse/Expand Panel**	Collapses/expands an area or panel.
	**Pin/Unpin Panel**	Pin/unpin an area on the screen.
		

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Icon	Name	Description
	**Toggle full screen mode**	Opens current application to full screen view. Only available in the web browser.
	**Toggle full screen mode**	Exits application from full screen view. Only available in the web browser.

Toolbar

The **Toolbar** provides access to frequently used functions.

Icon	Name	Description
	**DATA MAINTENANCE**	Launches the **DATA MAINTENANCE** module.
	**Settings**	Used as an entry point to access to the following settings: **User Settings**, **ADMINISTRATION** and **REPORTING CUSTOMIZATION**.
	**Displays Pixels 1:1**	
	**Hide/Show Overlays**	
	**Auto Layout Off**	
	**Auto Layout On**	
	Layouts	Controls the display of tilings and layouts (rows x columns)
	**1x1**	Layout 1x1
	**2x1**	Layout 2x1
	**1x2**	Layout 1x2
	**2x2**	Layout 2x2
	**3x2**	Layout 3x2
	**2x3**	Layout 2x3
	**3x3**	Layout 3x3
	**4x3**	Layout 4x3
	**2x4**	Layout 2x4
	**3x4**	Layout 3x4

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Icon	Name	Description
	**4x4**	Layout 4x4
	**3x5**	Layout 3x5
	**4x5**	Layout 4x5
	**4x6**	Layout 4x6
	Playback Mode	
	**Previous Page**	
	**Next Page**	
	**Previous Frame**	
	**Play**	
	**Pause**	
	**Next Frame**	
	**Speed**	Changes the speed of the animation sequence.
	Synchronization	Shows the relative applied synchronization method.
	**Free Mode**	No alignment
	**Start**	Align only the first frame
	**Align**	Align all frames
	Border Mode	Moves boundary flags of ECG.
	**Free**	
	**Full R-R**	
	**Single R-R**	
	**Systole**	
	**Diastole**	

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Icon	Name	Description
	**Go to Reference Frame**	
	Other Options	
	**Reset**	Resets a view or window back to default.
	**Save Bookmark**	Saves a bookmark in a study to restore the application status.
	**Save Secondary Capture**	Creates and stores the static or dynamic content of the workspace as a DICOM secondary capture, depends on the playback mode.
	**Export Image / Clip**	Exports the image or clip to a user-selectable file storage location, depends on the playback mode.
	**Quick Print**	A dialog box appears to print the previewed object on the printer selected.
	**Export Values**	Exports measurements to a txt file in a user-selectable file location.
	**Export Beutel**	Exports the coordinates of a surface mesh to a user-selectable file storage location.
	**Restore Measurements from DICOM device**	Import measurements from DICOM device for study.

Thumbnails / Preview Area

Icon	Name	Description
	**3D**	Labels an object which contains 3D Volume information.
	**Clip**	Indicates that the image is a clip.
	**Bookmark**	Bookmark in a study to restore the application status.

Toolspace

Enhance and analyze medical images for better diagnosis and treatment.

Icon	Name	Description
	**Patient History**	Shows history studies for the currently opened patient.
	**Review**	Shows image rendering settings.
	**Stress Echo**	Shows the **Stress Echo** workflow.
	**Measurements**	Shows available measurements for application.

Icon	Name	Description
	**Tools**	Shows available tools for the application.
	**Reset**	Resets a view or window back to default.
	**Annotation**	Adds new text or edits an existing text as an overlay on the image. Text can be added on all frames of a clip, or only on a specific frame.
	**Annotation (selected frame only)**	
	**Arrow**	Places an arrow as an overlay on the image. The arrow can be added on all frames of a clip, or only on a specific frame.
	**Arrow (selected frame only)**	
	**Delete Last**	Deletes last information on one image.
	**Delete All**	Deletes selected information on all images.

Smart Regions

Mouse-over smart regions in medical imaging provide interactive information when you hover your cursor over specific areas of an image.

Icon	Name	Description
	**D´art**	Excises an interesting slice out of the 3D-dataset.
	**Show/Hide View Planes**	Displays 3 LAX MPRs (2CH, 3CH and 4CH) and one SAX MPR. The level of the SAX MPR can be modified by LOI navigation.
	**Orbit**	Rotates a selected MPR and the spatial arrangement of MPRs around its vertical/horizontal axes.
	**Slice**	Moves a selected cut plane in parallel slices.
	**Rotation**	Rotates a selected MPR or the Spatial arrangement of MPRs around the axis perpendicular to the screen.
	**Flip Horizontal**	Flips images horizontally.
	**Flip Vertical**	Flips images vertically.

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Icon	Name	Description
	**Rotate 90° Clockwise**	Rotates an image 90° clockwise.
	**LOI Slice**	Moves parallel slices backward and forward.
	**LOI Rotation**	Rotates around the axis perpendicular to the screen.
	**Pan**	Pans images.
	**Zoom**	Zooms an image.
	**Contrast**	Changes and resets image contrast.
	**Brightness**	Changes and resets image brightness.
	**Invert**	Inverts the width of an XA image.
	**Threshold**	Changes the threshold of an image.
	**Transparency**	Changes the transparency of an image.
	**Mark image for deletion**	Mark an image or clip for deletion after closing the review application.
	**Marked for deletion**	An image or clip is marked for deletion after closing the review application.
	**Checkmark**	Mark an image or clip.
	**Unlocked**	An image or clip is unlocked.
	**Locked**	An image or clip is locked.
	**Reset**	Resets a view or window back to default.
	**Backward**	
	**Forward**	

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Alternative Common Controls

The following controls can be displayed with alternative symbols based on specific configurations. The meaning of each control remains the same.

Control Names	Default Appearance	Alternative Controls
Toolbar		
About		
Displays Pixels 1:1		
1x1		
2x1		
1x2		
2x2		
3x2		
2x3		
3x3		
4x3		
2x4		
3x4		
4x4		
3x5		
4x5		
4x6		
Previous Frame		

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Control Names	Default Appearance	Alternative Controls
Play		
Pause		
Next Frame		
Speed		
Smart Regions		
Flip Horizontal		
Flip Vertical		
Pan		
Zoom		
Rotate 90° Clockwise		
Reset		
Brightness (for US data) **Window Center** (for XA data)		
Contrast (for US data) **Window Width** (for XA data)		
Invert		

Image Settings

Tissue Rendering Controls

Name	Description
MPR Brightness	Controls tissue brightness of MPR views.
2D Gain	Controls the gain of tissue in MPRs and the 3D view.
MPR Chroma Map	Controls tissue chroma maps for MPR views.
MPR Gray Map	Controls the grayscale of tissue in MPR views.

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Name	Description
MPR XRES	The **Cosmix** filter is not applied at 0. The **Cosmix** filter is applied to tissue in MPRs and the 3D view for values between 1 and 5.
3D Vision Mode	Selects between various **Vision** modes.
GlassVue	Control to turn **GlassVue** on or off.
3D Tissue Brightness	Controls the brightness of tissue in the 3D view. Only applicable in non **TrueVue** modes.
Echo Gain	Controls the gain of tissue in the 3D view.
MPR/3D Gain	Controls the gain of tissue in MPRs and the 3D view. Replaces **Echo Gain** in **IMAGE-COM**.
3D Tissue Smoothing	Controls the smoothing of tissue in the 3D view.
3D XRES	Control to turn **3D XRES** on or off. Only applicable in non **TrueVue** modes.
3D Chroma Map	Controls the color lookup tables for 3D tissue data. Only applicable in non **TrueVue** modes.
3D Tissue Transparency	Controls tissue transparency in the 3D view. Only applicable in **GlassVue** mode.
3D Compress	A control that allows you to select a compression curve for image display. A higher compression curve makes the image softer, a lower compression curve creates a high-contrast image. Not applicable in **GlassVue** mode.
Light Source Position	Only applicable in **TrueVue** modes.
Light Source Top Left	Positions the light source at the top-left corner of the 3D view.
Light Source Top Right	Positions the light source at the top-right corner of the 3D view.
Light Source Front	Positions the light source in front of the 3D volume.
Light Source Bottom Left	Positions the light source at the bottom-left corner of the 3D view.
Light Source Bottom Right	Positions the light source at the bottom-right corner of the 3D view.
Light Source Behind	Positions the light source behind the 3D volume.

Color Rendering Controls

Name	Description
MPR Write Priority	A control that sets the threshold at which 2D grayscale echo information is considered strong enough to indicate a solid structure, such as a heart wall, rather than blood flow. Even if that structure may move.
Baseline	A control used to change the position of the zero baseline for color **Doppler** data. The zero baseline represents zero velocity or frequency in the **Doppler**, **Tissue Doppler Imaging**, or color display. It affects MPRs and the 3D view.
Invert	Inverts the colors of the active color map.

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Name	Description
3D Color Vision Mode	Selects between various color vision modes.
3D Color Gain	Controls the gain of the color (**Doppler**) data in the 3D view.
3D Color Threshold	Controls the threshold (the brightness value under which data is not displayed) of color (Doppler) data in 3D view. Only applicable in non **TrueVue** modes.
3D Color Smoothing	Controls smoothing of color data in the 3D view.
3D Flow Direction	Controls the display of the color flow directions in the 3D view. **All** displays positive and negative velocities. **Forward** only shows positive velocities. **Reverse** only shows negative velocities. Only applicable in non **TrueVue** modes.
3D Color/Tissue Toggle	Controls to toggle tissue and color data.
Show color and tissue	Display color and tissue information (default).
Show color only	Display only the color information and clips tissue.
Show tissue only	Display only tissue information and clips the color.
Wall Filter	A control to set the wall filter setting during **Doppler** or color imaging. A wall filter removes low-frequency **Doppler** signals that come from slow-moving reflectors, e.g. near vessel walls.
Variance	A control that enables the variance display during color imaging. Variance is the difference in blood flow within a given number of samples. It indicates changes in blood flow or possible turbulence due to an obstruction. The variance can be assigned a color, such as green, to make it more visible during an examination.
3D ROI Box	Controls to switch between tissue and color ROIs.
Edit tissue ROI	Shows the tissue ROI and lets the user adjust its size. The tissue ROI defines a rectangular volume in which tissue is displayed in the 3D view.
Edit color ROI	Shows the color ROI and lets the user adjust its size. The color ROI defines a rectangular volume in which color is displayed in the 3D view.
Reset ROIs	Resets both ROIs to their original size.

Table of Keyboard Shortcuts

- IMAGE-COM
- 4D LV-ANALYSIS
- 4D CARDIO-VIEW
- 3D Auto MV
- ECHO-COM

Shortcut	Function
<Ctrl + '+'>	Zoom in

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Shortcut	Function
<Ctrl + '-'>	Zoom out
<Ctrl + Cursor left>	Go to the start position slider
<Ctrl + Left-click>	Select/deselect list entries or tiles
<Ctrl + Mouse wheel>	Zoom in/out
<Ctrl +Cursor right>	Go to the end position slider
<Cursor left>	Decrement the actual frame
<Cursor right>	Increment the actual frame
<Delete>	Delete the last created or activated measurement at the active tile
<End> or <Ctrl + Cursor down>	Go to last page
<Home> or <Ctrl + Cursor up>	Go to first page
<Left-click>	Activate tile
<Mouse wheel>	Step forth and back through a sequence
<n>	Go to the next measurement in a package
<Page down> or <Cursor down>	Go page down
<Page up> or <Cursor up>	Go page up
<Return>/<Enter>	Toggle tile display
<Shift + Left-click> on first and last entry	Multi selects full range of entries
<Shift + Mouse wheel>	Slice MPR
<Shift + Tab>	Activate previous tile
<Space>	Start/stop the sequence(s)
<Tab>	Activate next tile

Abbreviations and Definitions

Name	Description
2CH or **A2C**	Apical two chamber view of the heart
3CH or **A3C**	Apical three chamber view of the heart
3D	3D: 3D rendering view
4CH or **A4C**	Apical four chamber view of the heart

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Name	Description
Assistant Medical Technician	Person with medical education in the appropriate field of medical imaging. This education shall enable him to interpret medical images such as Ultrasound, MRI, XA and others.
AV	Aortic valve
Beutel	Beutel: Evaluated and optimized static/dynamic model of the left ventricle.
BPM	Beats per minute: Number of heartbeats per unit of time.
CFQ	Color Flow Quantification
DICOM	Digital Imaging and Communications in Medicine
DICOM Metadata	Header Information of a DICOM file
DSA	Digital Subtraction Angiography
ECG	Electrocardiogram
ED	End-diastole
ES	End-systole
LAX	Long axis view
Licensed Medical Practitioner	Medical doctor with specific education in the appropriate field of medical imaging. This education shall enable him to interpret medical images such as Ultrasound, MRI, XA and others.
LM	Landmark
LOI	The Line of intersection represents the cross section of another imaging plane with the currently displayed one.
LV	Left ventricle
LVOT	Left ventricle outflow track
Main Archive	Local data storage of Ultrasound Workspace
MPR	Multiplanar reconstruction of an image
MR	Mitral regurgitation
MV	Mitral valve
Orbit	Functionality for the rotation of a reconstruction around its vertical/horizontal axis
OS	Operating System
Polar Plot	2-dimensional illustration of the surface of the left ventricle. This surface can be covered by different maps (e.g. parametric maps).
PreA	Time point before left atrial contraction
ROI	Region of interest

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Name	Description
RV	Right ventricle
SAX	Short axis view
Slice	Functionality for moving in parallel slices through a dataset
SWM	Segmental Wall Motion
TEE	Transesophageal echocardiography
TTE	Transthoracic echocardiography
TV	Tricuspid valve
Visit	Refers to a hospital visit of a patient and its associated information (e.g., visit number used for billing/accounting).
WMS	Wall Motion Scoring
WMSI	Wall Motion Scoring Index

Measurements

Basic Measurements

Basic measurements are generic, manual measurement tools.

All basic measurements can be reviewed and edited. Points can be repositioned by drag and drop. In curved measurements, additional points can be defined with a left-click on the contour; points can be deleted with right-click. The measurement must be finished with right-click or double-click.

Relative Error:
Limit of Agreement (LoA) specification is a relative error with a 97,5% confidence (that 95% of all differences will be withing the LoA).

Acceleration

Measure	Unit	Relative Error
Acceleration (= Acceleration Rate)	m/s^2	n/a (Calculation out of time and velocity)
Time	ms	+/- 5%
Maximal Velocity (Vmax)	m/s	+/- 5%

Module: IMAGE-COM

Data: Spectral Doppler

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AC/DC

Measure	Unit	Relative Error
Acceleration Rate (AR)	m/s²	n/a (Calculation out of time and velocity from P1 and P2)
Acceleration Time (AT)	ms	+/- 5%
Deceleration Rate (DR)	m/s²	n/a (Calculation out of time and velocity from P2 and P3)
Deceleration Time (DT)	ms	+/- 5%

Module: IMAGE-COM

Data: Spectral Doppler

Comments: Acceleration, Deceleration

Angle

Measure	Unit	Relative Error
Angle	° (degree)	+/- 5%

Modules: IMAGE-COM, 4D CARDIO-VIEW, 3D Auto MV, 4D SONO-SCAN

Data: 2D, MPR, XA, VR (4D CARDIO-VIEW, 3D Auto MV)

Comment: Angle between two lines defined by 3 points.

Angle 4Pt

Measure	Unit	Relative Error
Angle°	° (degree)	+/- 5%

Module: IMAGE-COM

Data: 2D, MPR, XA

Comment: Angle between two lines defined by 4 points.

Area

Measure	Unit	Relative Error
Area	cm²	+/- 5%
Circumference	mm	+/- 5%

Modules: IMAGE-COM, 4D CARDIO-VIEW, 3D Auto MV, 4D SONO-SCAN, 3D Auto TV

Data: 2D, MPR, XA

Comment: Generic area measurement

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Curve

Measure	Unit	Relative Error
Length of a Spline	mm	+/- 5%

Modules: IMAGE-COM, 4D CARDIO-VIEW, 3D Auto MV, 4D SONO-SCAN, 3D Auto TV

Data: 2D, MPR, XA

Comment: Curve defined by the length of a curved line consisting of at least 3 points.

Disks / Volume

Measure	Unit	Relative Error
Area	cm^2	+/- 5%
Circumference	mm	+/- 5%
Major Axis	mm	+/- 5%
Volume	cm^3	+/- 10%

Module: IMAGE-COM

Data: 2D, MPR, XA

Comment: Method of disk summation

QCA

Measure	Unit	Relative Error
Reference diameter (prox.)	mm	+/- 15%
Reference diameter (dist.)	mm	+/- 15%
Reference diameter	mm	+/- 15%
Lesion diameter	mm	+/- 15%
Lesion length	mm	+/- 15%
Stenosis diameter	%	+/- 15%
Stenosis area	%	+/- 15%

Module: IMAGE-COM

Data: XA

Comment: Reference diameter, lesion diameter and lesion length are only available for calibrated images. Stenosis diameter and stenosis area are available for calibrated and uncalibrated images.

Distance

Measure	Unit	Relative Error
Distance	mm	+/- 5%

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Modules: IMAGE-COM, 4D CARDIO-VIEW, 3D Auto MV, 4D SONO-SCAN, 3D Auto TV

Data: 2D, M-Mode, MPR, XA

Comment: Distance between two points

E/A Slope

Measure	Unit	Relative Error
E	m/s	+/- 5%
A	m/s	+/- 5%
E/A (calculated)	°	n/a (Calculation from E and A velocity)
Time	ms	+/- 5%
Slope	m/s^2	n/a (Calculation out of time and velocity from P1 and P2)

Module: IMAGE-COM

Data: Spectral Doppler

Ellipse

Measure	Unit	Relative Error
Diameter 1	mm	+/- 5%
Diameter 2	mm	+/- 5%
Circumference	mm	+/- 5%
Area	cm^2	+/- 5%

Module: IMAGE-COM

Data: 2D, MPR, XA

Heart Rate

Measure	Unit	Relative Error
Heart Rate	H.B./min	n/a (Calculation out of two time points)
Time/Cycle	ms	+/- 5%

Module: IMAGE-COM

Data: M-Mode, Spectral Doppler

Comment: Measurement of cardiac cycle length

LV Distance

Measure	Unit	Relative Error
Interventricular Septum (IVS)	mm	+/- 5%

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Measure	Unit	Relative Error
Left Ventricle Internal Dimension (LVID)	mm	+/- 5%
Left Ventricle Posterior Wall Thickness (LVPW)	mm	+/- 5%

Module: IMAGE-COM

Data: 2D, M-Mode, MPR

Comments: Left ventricular distances: The three succeeding distances IVS, LVID and LVPW are lying on one ray. They are measured in one step.

PHT

Measure	Unit	Relative Error
Maximal Velocity (Vmax)	m/s	+/- 5%
Pressure Half Time (PHT)	ms	n/a (Calculation out of P1 and P2 time)
Time	ms	+/- 5%
Slope	m/s^2	n/a (Calculation out of time and velocity from P1 and P2)

Module: IMAGE-COM

Data: Spectral Doppler

PIRI

Measure	Unit	Relative Error
Time Averaged Maximum Velocity (TAmx)	cm/s	+/- 5%

Module: IMAGE-COM

Data: Spectral Doppler

Slope

Measure	Unit	Relative Error
Time	ms	+/- 5%
Distance	mm	+/- 5%
Velocity	m/s	n/a (Calculation out of time and velocity from P1 and P2)

Module: IMAGE-COM

Data: M-Mode

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Time

Measure	Unit	Relative Error
Time	ms	+/- 5%

Module: IMAGE-COM

Data: M-Mode, Spectral Doppler

Velocity

Measure	Unit	Relative Error
Velocity	m/s	+/- 5%
Pressure Gradient (PG)	mmHg	n/a (Calculation out of velocity from P1)

Module: IMAGE-COM

Data: Spectral Doppler

VTI

Measure	Unit	Relative Error
Velocity Time Integral (VTI)	cm	+/- 5%
Maximal Velocity (Vmax)	m/s	+/- 5%
Mean Velocity (Vmean)	m/s	+/- 5%
Maximal Pressure Gradient (PGmax)	mmHg	n/a (Calculation out of velocity)
Mean Pressure Gradient (PGmean)	mmHg	n/a (Calculation out of time and velocity)

Module: IMAGE-COM

Data: Spectral Doppler

VTI+HR

Measure	Unit	Relative Error
Velocity Time Integral (VTI)	cm	+/- 5%
Maximal Velocity (Vmax)	m/s	+/- 5%
Mean Velocity (Vmean)	m/s	+/- 5%
Maximal Pressure Gradient (PGmax)	mmHg	n/a (Calculation out of velocity)
Mean Pressure Gradient (PGmean)	mmHg	n/a (Calculation out of time and velocity)
Heart Rate	H.B./min	n/a (Calculation out of two time points)

Module: IMAGE-COM

Data: Spectral Doppler

Comment: Velocity Time Integral and Heart Rate

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Semi-Automatic Measurements Created by Advanced Applications

All semi-automatic measurements are proposed by the software. They can be reviewed and edited by the user.

Semi-Automatic measurements are based on numerical models of anatomical structures which are detected in the ultrasound data.

Distance

Measure	Unit	Deviation
Distance between two points	mm	< 10%
	cm	≤ 5%
Displacement		
3D	mm	< 1mm abs
Longitudinal	mm	< 1mm abs
Circumferential	mm	< 1mm abs
Radial	mm	< 1mm abs
Regional Strain		
Principal tangential	%	< 2.5% abs
Longitudinal	%	< 2.5% abs
Circumferential	%	< 2.5% abs
Radial	%	< 2.5% abs
Global Strain		
Longitudinal	%	< 20%
Circumferential	%	< 20%
Sphericity Index	none	< 15%
Velocity	mm/s	< 10%

Modules: 4D LV-ANALYSIS, 3D Auto MV, 3D Auto RV, AutoStrain LV, LA, RV, 3D Auto TV

Data: 4D Data, 2D B-Mode

Comments: Distance = Distance between two points; Displacement = Distance between a point at a reference time point and a time point t; Regional Strain = Relative length change of a distance; Global Strain = Relative length change of a curved contour; Sphericity Index = Distance ratio; Velocity = First derivative of displacement;

Curve

Measure	Unit	Deviation
Length of a spline	mm	< 5%

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Modules: 3D Auto MV, 3D Auto TV

Data: 4D Data

Angle

Measure	Unit	Deviation
Angle defined by 3 points	°	< 5%
Rotation	°	< 3° abs
Torsion	°/cm	< 5°/cm abs
Twist	Twist	< 6° abs

Modules: 4D LV-ANALYSIS, 3D Auto MV, 3D Auto RV

Data: 4D Data, 2D B-Mode

Comments: Rotation = Rotation angle around an axis; Torsion = (Rotation Base – Rotation Apex)/ Base-Apex Distance; Twist = Rotation Base – Rotation Apex;

Area

Measure	Unit	Deviation
2D: Area of a plane	cm^2	< 5%
3D: Area in 3D space	cm^2	< 15%
Area Ratio	%	< 10%

Modules: 3D Auto MV, 3D Auto RV, 3D Auto TV

Data: 4D Data, 2D B-Mode

Comment: Area Ratio = Relative area change;

Volume

Measure	Unit	Deviation
Volume enclosed by a mesh object	ml	< 10%
Volume	cm^3	< 10%
Volume ratio	none	< 10%
Mass	g	< 10%

Modules: 4D CARDIO-VIEW, 4D LV-ANALYSIS, 3D Auto MV, 3D Auto RV, AutoEF, AutoStrain LV

Data: 4D Data, 2D B-Mode

Comments: Volume Ratio = Relative Volume change; Mass = Volume * density;

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Systolic Dyssynchrony Index

Measure	Unit	Deviation
SDI	%	< 15%
SD-ttP-LS	%	< 15%

Modules: 4D LV-ANALYSIS

Data: 4D Data, 2D B-Mode

Comments: SDI (Systolic Dyssynchrony Index) = Standard deviation of time-to-minimum peak segmental volume curves relative to cardiac cycle length; SD-ttP_LS (Standard Deviation of Longitudinal Strain Time-To-peak Values) = Standard deviation of time-to-minimum peak longitudinal strain curves relative to cardiac cycle length;

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Feature Performance

2D Auto LV SWM Feature Performance Study

Clips from all the intended views (A2C, A3C and A4C) were included in the study. The demographic and clinical characteristics for the population whose data were used in the study are presented below.

	Subjects[1] (Mean ± SD (n) or % (n/N))
Age (years)	61.7 ± 15.9 (81)
Gender	
Male	54.3% (44/81)
Female	45.7% (37/81)
Race	
Black or African American	54.3% (44/81)
White	28.4% (23/81)
Unknown	13.6 % (11/81)
Other/Mixed	3.7% (3/81)
Height (cm)[1]	171.5 ± 11.9 (71)
Weight (kg)[1]	87.7 ± 21.3 (71)
BMI (kg/m2)[1]	29.7 ± 6.6 (71)
BSA (m2)[1]	2.0 ± 0.3 (71)

[1] Height, Weight, BMI and BSA data were not available for ten subjects, race was not available for eleven subjects.

Characteristic	Subjects (Mean ± SD (n) (Min, Max) or % (n/N))
LV Function Assessment[1]	
Normal	58.0% (47/81)
Mild-Moderate	8.6% (7/81)
Moderate-Severe	17.3% (14/81)
Severe	16.1% (13/81)

[1] Assessment performed at the initial standard of care subjects' examination.

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3D Auto CFQ Feature Performance Study

The demographic and clinical characteristics for the population whose data were used in the study are presented below.

	Subjects (N=52) Mean ± SD (N) (Min, Max) or % (xx/N)
Age (years)	57.46 ± 10.84 (52) (38.00, 81.00)
Gender	
Male	80.77 % (42/52)
Female	19.23 % (10/52)
Race	
Asian	100% (52/52)
BMI (kg/m2)	25.23 ± 3.58 (52) (19.00, 35.70)

Characteristic	% (xx/N[1])
MR Jet Number	N= 52
Single	86.54 % (45/52)
Multiple	13.46 % (7/52)
MR Jet Centricity	N=52
Centric	23.08 % (12/52)
Eccentric	76.92 % (40/52)
MR Jet Type	N=52
Holosystolic	84.62 % (44/52)
Non-holosystolic	15.38 % (8/52)

[1] Each clip was assessed for the number of jets, jet centricity and jet type by three reviewers participating in the study. The results provided are based on a minimum of 2/3 agreement between the reviewers.

Performance of fully automated (unedited, no user interaction) and semi-automated (user interaction) 3D Auto CFQ compared to CMR within each demographic group and clinical characteristics are presented below.

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Variable	Semi-Automated 3D Auto CFQ RVol vs CMR RVol			Automated 3D Auto CFQ RVol vs CMR RVol		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower End of 95% LoA	Upper End of 95% LoA	Mean Difference (95% LCI, UCI) ± SD (n)	Lower End of 95% LoA	Upper End of 95% LoA
Overall	-12.10 (-17.38, -6.81) ± 18.98 (52)	-49.29 (- 58.37, -40.20)	25.09 (16.01, 34.18)	-10.49 (-16.03, -4.94) ± 19.92 (52)	-49.52 (-59.06, -39.99)	28.55 (19.01, 38.09)
BMI <25	-10.21 (-17.20, -3.22) ± 16.93 (25)	-43.39 (- 55.50, -31.29)	22.97 (10.86, 35.07)	-10.51 (-18.36, -2.66) ± 19.02 (25)	-47.79 (-61.39, -34.19)	26.76 (13.16, 40.36)
BMI >=25	-13.84 (-22.09, -5.59) ± 20.86 (27)	-54.73 (-69.01, -40.45)	27.04 (12.76, 41.32)	-10.46 (-18.80, -2.13) ± 21.08 (27)	-51.77 (-66.20, -37.35)	30.85 (16.42, 45.27)
Male	-11.15 (-17.32, -4.98) ± 19.80 (42)	-49.96 (-60.59, -39.33)	27.66 (17.03, 38.29)	-8.84 (-15.20, -2.49) ± 20.40 (42)	-48.82 (-59.77, -37.87)	31.14 (20.19, 42.09)
Female	-16.07 (-26.98, -5.17) ± 15.24 (10)	-45.95 (-65.25, -26.64)	13.80 (-5.50, 33.11)	-17.39 (-29.51, -5.28) ± 16.93 (10)	-50.58 (-72.01, -29.14)	15.79 (-5.65, 37.22)
Age <60	-15.34 (-23.36, -7.32) ± 20.27 (27)	-55.07 (-68.95, -41.19)	24.40 (10.52, 38.28)	-12.93 (-21.45, -4.42) ± 21.53 (27)	-55.13 (-69.87, -40.39)	29.26 (14.53, 44.00)
Age >=60	-8.60 (-15.69, -1.50) ± 17.19 (25)	-42.28 (-54.57, -29.99)	25.09 (12.80, 37.38)	-7.85 (-15.31, -0.38) ± 18.08 (25)	-43.27 (-56.20, -30.35)	27.58 (14.66, 40.51)

Variable	Semi-Automated 3D Auto CFQ RVol vs CMR RVol			Automated 3D Auto CFQ RVol vs CMR RVol		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower End of 95% LoA	Upper End of 95% LoA	Mean Difference (95% LCI, UCI) ± SD (n)	Lower End of 95% LoA	Upper End of 95% LoA
MR Jet Number						
Single	-11.17 (-16.55, -5.78) ± 17.93 (45)	-46.30 (-55.57, -37.03)	23.97 (14.70, 33.24)	-9.03 (-14.68, -3.39) ± 18.78 (45)	-45.85 (-55.56, -36.13)	27.78 (18.06, 37.49)
Multiple	-18.08 (-41.76, 5.60) ± 25.61 (7)	-68.27 (-110.90, -25.63)	32.11 (-10.52, 74.74)	-19.83 (-43.72, 4.06) ± 25.83 (7)	-70.46 (-113.47, -27.45)	30.80 (-12.21, 73.81)
MR Jet Centricity						
Central	-11.17 (-18.53, -3.82) ± 11.58 (12)	-33.86 (-46.81, -20.92)	11.52 (-1.42, 24.46)	-10.88 (-19.13, -2.64) ± 12.97 (12)	-36.31 (-50.81, -21.81)	14.54 (0.04, 29.05)
Eccentric	-12.37 (-19.03, -5.72) ± 20.80 (40)	-53.14 (-64.61, -41.68)	28.40 (16.93, 39.86)	-10.37 (-17.31, -3.43) ± 21.71 (40)	-52.91 (-64.88, -40.95)	32.18 (20.21, 44.14)
MR Jet Type						
Holosystolic	-12.21 (-18.28, -6.14) ± 19.97 (44)	-51.34 (-61.79, -40.89)	26.92 (16.47, 37.38)	-9.74 (-16.05, -3.44) ± 20.73 (44)	-50.38 (-61.23, -39.52)	30.89 (20.04, 41.75)
Non-holosystolic	-11.48 (-22.51, -0.45) ± 13.20 (8)	-37.35 (-57.07, -17.63)	14.38 (-5.34, 34.10)	-14.59 (-27.18, -1.99) ± 15.07 (8)	-44.12 (-66.63, -21.60)	14.94 (-7.57, 37.46)

A performance comparison between automated and semi-automated outputs for 3D Auto CFQ is presented below.

Methods Comparison	Mean Difference (95% LCI, UCI) ± SD (n)	Lower End of 95% LoA	Upper End of 95% LoA
3D Auto CFQ automated vs. Semi-automated RVol	1.61 (-0.22, 3.44) ± 6.56 (52)	-11.26 (-14.40, -8.11)	14.48 (11.33, 17.62)
3D Auto CFQ automated vs. Semi-automated Peak Flow Rate	12.34 (-0.71, 25.38) ± 46.85 (52)	-79.50 (-101.93, -57.06)	104.17 (81.74, 126.61)

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3D Auto TV Automation Performance Study

The demographic and clinical characteristics for the TTE and TEE population whose data were used in the study are presented below.

	TEE Subjects (mean ± SD (n) and (min, max) or % (n/N))	TTE Subjects (mean ± SD (n) and (min, max) or % (n/N))
Age (years)	79.0 ± 7.9 (150[1]) (42.0, 93.0)	60.2 ± 19.2 (99[2]) (18.0, 98.5)
Gender		
Male	20.0% (30/150)	47.0% (47/100)
Female	80.0% (120/150)	52.0% (52/100)
Unknown	N/A	1.0% (1/100)
Race		
Asian	8.0% (12/150)	8.0% (8/100)
Black or African American	4.7% (7/150)	48.0% (48/100)
White	66.7% (100/150)	38.0% (38/100)
Other/Mixed/Unknown	20.7% (31/150)	6.0% (6/100)
BMI (kg/m2)	26.5 ± 5.8 (150) (14.5, 47.1)	26.2 ± 5.4 (99[2]) (16.7, 49.1)

[1] Demographics data summarized for the first 150 subjects enrolled in the TRISCEND II study (TEE data source for the study)

[2] Data for one TTE subject was not available for age and BMI, so they were excluded from those statistics.

Severity of Tricuspid Regurgitation	TEE Subjects (mean ± SD (n) (min, max) or % (n/N))	TTE Subjects (mean ± SD (n) (min, max) or % (n/N))
None	0.0% (0/97)	30.0% (30/100)
Mild	0.0% (0/97)	33.0% (33/100)
Moderate	0.0% (0/97)	29.0% (29/100)
Severe or more	100.0% (97/97)	8.0% (8/100)

Performance of fully automated (unedited, no user interaction) and semi-automated (user interaction) 3D Auto TV compared to 4D Cardio-View within each demographic group and clinical characteristics for the TTE population are presented below. The TEE individual demographic data were not available as such, subgroup analyses were not feasible.

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Performance table for 2D perimeter in ES (%) - TTE

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Overall	0.45 (-1.18, 2.09) ± 8.24 (100)	-15.70 (-18.42, -13.79)	16.61 (14.70, 19.33)	-8.98 (-10.69, -7.27) ± 8.57 (99)	-25.77 (-28.62, -23.78)	7.82 (5.83, 10.66)
BMI						
BMI<25	-0.11 (-2.44, 2.22) ± 7.57 (43)	-14.94 (-19.22, -12.45)	14.73 (12.24, 19.00)	-9.88 (-12.38, -7.37) ± 8.15 (43)	-25.85 (-30.45, -23.17)	6.10 (3.42, 10.70)
BMI>=25	0.56 (-1.71, 2.84) ± 8.50 (56)	-16.11 (-20.14, -13.59)	17.23 (14.72, 21.26)	-8.29 (-10.67, -5.91) ± 8.89 (56)	-25.71 (-29.92, -23.08)	9.14 (6.51, 13.35)
Gender						
Male	-1.69 (-3.52, 0.15) ± 6.26 (47)	-13.95 (-17.28, -11.96)	10.57 (8.59, 13.90)	-10.28 (-12.55, -8.00) ± 7.74 (47)	-25.45 (-29.57, -23.00)	4.90 (2.44, 9.02)
Female	2.04 (-0.50, 4.58) ± 9.13 (52)	-15.86 (-20.40, -13.07)	19.94 (17.16, 24.48)	-7.80 (-10.35, -5.25) ± 9.17 (52)	-25.77 (-30.33, -22.98)	10.17 (7.38, 14.73)
Age						
Age<60	0.85 (-1.69, 3.38) ± 8.43 (45)	-15.68 (-20.29, -12.95)	17.37 (14.65, 21.99)	-7.66 (-10.62, -4.70) ± 9.84 (45)	-26.95 (-32.34, -23.77)	11.63 (8.45, 17.02)
Age>=60	-0.21 (-2.34, 1.93) ± 7.82 (54)	-15.53 (-19.33, -13.19)	15.12 (12.77, 18.91)	-10.07 (-12.06, -8.09) ± 7.26 (54)	-24.30 (-27.82, -22.12)	4.15 (1.97, 7.67)
Race						
Asian	-1.62 (-11.60, 8.37) ± 11.94 (8)	-25.03 (-52.35, -17.69)	21.79 (14.46, 49.12)	-8.11 (-18.14, 1.91) ± 11.99 (8)	-31.62 (-59.06, -24.25)	15.39 (8.02, 42.83)

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Black or African American	1.12 (-0.82, 3.07) ± 6.70 (48)	-12.00 (-15.51, -9.89)	14.25 (12.14, 17.76)	-7.73 (-9.99, -5.47) ± 7.77 (48)	-22.96 (-27.03, -20.51)	7.50 (5.05, 11.57)
White	-1.35 (-3.73, 1.04) ± 7.26 (38)	-15.58 (-20.05, -13.07)	12.89 (10.38, 17.35)	-10.73 (-13.66, -7.81) ± 8.90 (38)	-28.18 (-33.64, -25.10)	6.71 (3.63, 12.17)
Other/Mixed/ Unknown	7.41 (-11.43, 26.24) ± 15.17 (5)	-22.32 (-85.97, -11.40)	37.13 (26.21, 100.78)	-8.99 (-18.32, 0.34) ± 7.52 (5)	-23.72 (-55.26, -18.31)	5.74 (0.33, 37.28)
Severity of Tricuspid Regurgitation						
None	-0.95 (-3.98, 2.08) ± 8.11 (30)	-16.85 (-22.74, -13.78)	14.95 (11.87, 20.83)	-9.23 (-12.80, -5.67) ± 9.54 (30)	-27.93 (-34.84, -24.31)	9.46 (5.84, 16.37)
Mild	-0.56 (-3.23, 2.11) ± 7.52 (33)	-15.31 (-20.40, -12.56)	14.18 (11.44, 19.28)	-8.34 (-11.26, -5.42) ± 8.23 (33)	-24.47 (-30.05, -21.46)	7.79 (4.78, 13.37)
Moderate	2.73 (-0.75, 6.22) ± 9.17 (29)	-15.23 (-22.05, -11.71)	20.70 (17.18, 27.51)	-8.44 (-11.63, -5.25) ± 8.38 (29)	-24.86 (-31.09, -21.64)	7.98 (4.76, 14.21)
Severe or More	1.66 (-4.65, 7.98) ± 7.55 (8)	-13.15 (-30.43, -8.51)	16.47 (11.83, 33.75)	-13.11 (-19.48, -6.74) ± 6.89 (7)	-26.61 (-44.99, -22.18)	0.40 (-4.03, 18.77)

Performance table for 2D perimeter in ED (%) - TTE

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Overall	-0.78 (-2.35, 0.78) ± 7.90 (100)	-16.26 (-18.86, -14.43)	14.69 (12.86, 17.29)	-12.30 (-14.01, -10.59) ± 8.57 (99)	-29.10 (-31.94, -27.10)	4.51 (2.51, 7.35)
BMI						
BMI<25	-0.50 (-2.59, 1.59) ± 6.78 (43)	-13.79 (-17.62, -11.56)	12.80 (10.57, 16.63)	-11.72 (-14.08, -9.35) ± 7.68 (43)	-26.76 (-31.09, -24.24)	3.33 (0.80, 7.66)
BMI>=25	-1.35 (-3.59, 0.89) ± 8.36 (56)	-17.73 (-21.69, -15.26)	15.03 (12.56, 18.99)	-12.74 (-15.22, -10.27) ± 9.25 (56)	-30.86 (-35.24, -28.13)	5.38 (2.65, 9.76)
Gender						
Male	-2.46 (-4.69, -0.23) ± 7.60 (47)	-17.35 (-21.38, -14.94)	12.43 (10.02, 16.47)	-13.09 (-15.22, -10.95) ± 7.27 (47)	-27.33 (-31.19, -25.02)	1.16 (-1.15, 5.02)
Female	0.36 (-1.75, 2.47) ± 7.59 (52)	-14.53 (-18.30, -12.21)	15.25 (12.93, 19.02)	-11.58 (-14.26, -8.91) ± 9.62 (52)	-30.43 (-35.22, -27.51)	7.27 (4.34, 12.05)
Age						
Age<60	-1.38 (-3.48, 0.71) ± 6.97 (45)	-15.05 (-18.87, -12.80)	12.28 (10.03, 16.10)	-11.50 (-13.86, -9.13) ± 7.87 (45)	-26.92 (-31.23, -24.38)	3.93 (1.39, 8.24)
Age>=60	-0.64 (-2.90, 1.62) ± 8.29 (54)	-16.88 (-20.90, -14.40)	15.60 (13.11, 19.62)	-12.96 (-15.46, -10.47) ± 9.14 (54)	-30.87 (-35.30, -28.13)	4.94 (2.20, 9.37)
Race						
Asian	-2.34 (-8.37, 3.69) ± 7.22 (8)	-16.48 (-32.99, -12.05)	11.81 (7.37, 28.31)	-11.54 (-19.58, -3.51) ± 9.61 (8)	-30.38 (-52.36, -24.47)	7.29 (1.39, 29.28)

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Black or African American	-0.87 (-2.91, 1.17) ± 7.03 (48)	-14.65 (-18.34, -12.44)	12.91 (10.70, 16.59)	-11.36 (-13.36, -9.36) ± 6.90 (48)	-24.88 (-28.49, -22.71)	2.16 (-0.01, 5.78)
White	-1.83 (-4.17, 0.51) ± 7.13 (38)	-15.80 (-20.17, -13.34)	12.13 (9.67, 16.51)	-13.08 (-15.89, -10.28) ± 8.53 (38)	-29.80 (-35.04, -26.86)	3.63 (0.69, 8.87)
Other/Mixed/ Unknown	6.66 (-11.87, 25.19) ± 14.92 (5)	-22.59 (-85.23, -11.84)	35.91 (25.16, 98.55)	-16.53 (-40.31, 7.26) ± 19.16 (5)	-54.07 (-134.5, -40.27)	21.02 (7.22, 101.41)
Severity of Tricuspid Regurgitation						
None	-1.52 (-4.12, 1.08) ± 6.96 (30)	-15.16 (-20.20, -12.52)	12.12 (9.48, 17.17)	-12.10 (-15.18, -9.02) ± 8.25 (30)	-28.27 (-34.25, -25.14)	4.06 (0.94, 10.05)
Mild	-2.10 (-4.86, 0.66) ± 7.78 (33)	-17.35 (-22.63, -14.51)	13.15 (10.31, 18.42)	-12.62 (-15.47, -9.76) ± 8.05 (33)	-28.40 (-33.86, -25.46)	3.17 (0.23, 8.63)
Moderate	0.32 (-3.01, 3.65) ± 8.75 (29)	-16.83 (-23.33, -13.47)	17.46 (14.10, 23.97)	-12.07 (-15.88, -8.26) ± 10.02 (29)	-31.70 (-39.15, -27.85)	7.56 (3.71, 15.01)
Severe or More	3.44 (-3.16, 10.03) ± 7.89 (8)	-12.03 (-30.08, -7.18)	18.90 (14.05, 36.95)	-12.56 (-19.50, -5.63) ± 7.50 (7)	-27.26 (-47.27, -22.44)	2.14 (-2.69, 22.14)

Performance table for Max ES diameter (%) - TTE

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Overall	0.56 (-1.23, 2.35) ± 9.03 (100)	-17.13 (-20.11, -15.04)	18.26 (16.17, 21.23)	-9.44 (-11.35, -7.52) ± 9.61 (99)	-28.27 (-31.45, -26.03)	9.39 (7.15, 12.57)
BMI						
BMI<25	0.11 (-2.73, 2.95) ± 9.24 (43)	-17.99 (-23.20, -14.95)	18.21 (15.17, 23.42)	-9.85 (-12.91, -6.78) ± 9.95 (43)	-29.36 (-34.97, -26.08)	9.66 (6.39, 15.28)
BMI>=25	0.53 (-1.76, 2.82) ± 8.55 (56)	-16.24 (-20.29, -13.71)	17.29 (14.76, 21.34)	-9.13 (-11.64, -6.61) ± 9.41 (56)	-27.57 (-32.02, -24.79)	9.32 (6.54, 13.77)
Gender						
Male	-2.09 (-4.11, -0.06) ± 6.90 (47)	-15.61 (-19.28, -13.42)	11.44 (9.25, 15.11)	-11.24 (-13.77, -8.70) ± 8.64 (47)	-28.17 (-32.76, -25.43)	5.69 (2.95, 10.28)
Female	2.54 (-0.18, 5.27) ± 9.79 (52)	-16.65 (-21.52, -13.66)	21.73 (18.75, 26.60)	-7.81 (-10.66, -4.97) ± 10.21 (52)	-27.83 (-32.91, -24.72)	12.21 (9.10, 17.29)
Age						
Age<60	0.71 (-2.09, 3.51) ± 9.31 (45)	-17.54 (-22.64, -14.53)	18.96 (15.95, 24.06)	-8.79 (-12.13, -5.45) ± 11.12 (45)	-30.59 (-36.68, -27.00)	13.01 (9.41, 19.10)
Age>=60	0.04 (-2.26, 2.35) ± 8.45 (54)	-16.52 (-20.62, -13.99)	16.60 (14.07, 20.70)	-9.98 (-12.22, -7.74) ± 8.20 (54)	-26.05 (-30.03, -23.59)	6.10 (3.64, 10.08)
Race						
Asian	0.61 (-12.11, 13.34) ± 15.22 (8)	-29.21 (-64.03, -19.87)	30.44 (21.09, 65.26)	-6.38 (-19.53, 6.78) ± 15.73 (8)	-37.21 (-73.20, -27.55)	24.46 (14.79, 60.45)

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Black or African American	0.77 (-1.53, 3.07) ± 7.92 (48)	-14.75 (-18.91, -12.26)	16.29 (13.80, 20.45)	-8.49 (-11.09, -5.89) ± 8.95 (48)	-26.03 (-30.72, -23.22)	9.05 (6.23, 13.74)
White	-1.15 (-3.46, 1.16) ± 7.03 (38)	-14.93 (-19.24, -12.50)	12.63 (10.20, 16.95)	-11.37 (-14.28, -8.46) ± 8.86 (38)	-28.73 (-34.17, -25.67)	5.99 (2.93, 11.43)
Other/Mixed/ Unknown	7.21 (-11.23, 25.65) ± 14.85 (5)	-21.89 (-84.22, -11.20)	36.32 (25.62, 98.64)	-8.74 (-20.87, 3.40) ± 9.78 (5)	-27.90 (-68.92, -20.85)	10.42 (3.38, 51.45)
Severity of Tricuspid Regurgitation						
None	-0.34 (-3.92, 3.25) ± 9.60 (30)	-19.16 (-26.12, -15.52)	18.48 (14.84, 25.45)	-9.57 (-13.70, -5.45) ± 11.06 (30)	-31.24 (-39.26, -27.05)	12.09 (7.90, 20.11)
Mild	-1.05 (-3.74, 1.64) ± 7.58 (33)	-15.91 (-21.04, -13.14)	13.80 (11.03, 18.94)	-9.14 (-12.16, -6.11) ± 8.53 (33)	-25.86 (-31.64, -22.74)	7.59 (4.47, 13.37)
Moderate	2.44 (-1.36, 6.23) ± 9.97 (29)	-17.10 (-24.51, -13.27)	21.97 (18.14, 29.38)	-9.37 (-13.12, -5.62) ± 9.86 (29)	-28.69 (-36.02, -24.91)	9.95 (6.16, 17.28)
Severe or More	3.79 (-3.14, 10.72) ± 8.29 (8)	-12.45 (-31.40, -7.36)	20.03 (14.94, 38.98)	-10.55 (-18.43, -2.67) ± 8.52 (7)	-27.25 (-49.97, -21.77)	6.15 (0.67, 28.88)

Performance table for Min ES diameter (%) - TTE

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Overall	0.67 (-1.05, 2.40) ± 8.69 (100)	-16.36 (-19.22, -14.34)	17.70 (15.69, 20.57)	-6.49 (-8.39, -4.58) ± 9.55 (99)	-25.20 (-28.37, -22.98)	12.22 (10.00, 15.39)
BMI						
BMI<25	0.45 (-1.66, 2.56) ± 6.87 (43)	-13.01 (-16.89, -10.75)	13.91 (11.65, 17.79)	-7.78 (-10.40, -5.16) ± 8.51 (43)	-24.47 (-29.27, -21.67)	8.90 (6.10, 13.71)
BMI>=25	0.59 (-2.04, 3.22) ± 9.80 (56)	-18.63 (-23.27, -15.73)	19.81 (16.91, 24.45)	-5.49 (-8.24, -2.75) ± 10.24 (56)	-25.56 (-30.41, -22.53)	14.57 (11.54, 19.42)
Gender						
Male	-0.74 (-3.08, 1.60) ± 7.97 (47)	-16.36 (-20.60, -13.83)	14.88 (12.35, 19.12)	-7.12 (-9.91, -4.34) ± 9.49 (47)	-25.73 (-30.78, -22.72)	11.48 (8.47, 16.53)
Female	1.68 (-0.85, 4.21) ± 9.08 (52)	-16.11 (-20.63, -13.35)	19.47 (16.71, 23.99)	-5.91 (-8.60, -3.23) ± 9.65 (52)	-24.83 (-29.63, -21.89)	13.00 (10.06, 17.80)
Age						
Age<60	1.70 (-0.98, 4.38) ± 8.93 (45)	-15.81 (-20.70, -12.92)	19.21 (16.32, 24.10)	-4.04 (-7.14, -0.94) ± 10.31 (45)	-24.24 (-29.89, -20.91)	16.17 (12.84, 21.81)
Age>=60	-0.45 (-2.71, 1.82) ± 8.29 (54)	-16.70 (-20.72, -14.21)	15.81 (13.32, 19.83)	-8.53 (-10.83, -6.23) ± 8.43 (54)	-25.04 (-29.13, -22.52)	7.98 (5.46, 12.07)
Race						
Asian	-2.88 (-9.86, 4.10) ± 8.35 (8)	-19.24 (-38.33, -14.11)	13.48 (8.35, 32.57)	-7.92 (-16.25, 0.42) ± 9.97 (8)	-27.46 (-50.28, -21.34)	11.63 (5.50, 34.44)

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Black or African American	1.82 (-0.48, 4.11) ± 7.91 (48)	-13.68 (-17.83, -11.19)	17.31 (14.82, 21.46)	-4.81 (-7.36, -2.27) ± 8.75 (48)	-21.97 (-26.56, -19.22)	12.34 (9.59, 16.93)
White	-1.42 (-4.12, 1.28) ± 8.21 (38)	-17.51 (-22.56, -14.68)	14.68 (11.84, 19.72)	-8.52 (-11.99, -5.05) ± 10.57 (38)	-29.23 (-35.72, -25.58)	12.19 (8.54, 18.68)
Other/Mixed/ Unknown	8.45 (-8.19, 25.08) ± 13.40 (5)	-17.81 (-74.04, -8.16)	34.71 (25.06, 90.94)	-4.82 (-13.22, 3.57) ± 6.76 (5)	-18.08 (-46.45, -13.21)	8.43 (3.56, 36.80)
Severity of Tricuspid Regurgitation						
None	-0.55 (-3.15, 2.04) ± 6.94 (30)	-14.15 (-19.19, -11.52)	13.04 (10.41, 18.08)	-6.24 (-9.57, -2.91) ± 8.91 (30)	-23.71 (-30.17, -20.33)	11.23 (7.85, 17.69)
Mild	0.21 (-2.93, 3.36) ± 8.88 (33)	-17.19 (-23.20, -13.94)	17.62 (14.37, 23.63)	-5.82 (-9.32, -2.31) ± 9.89 (33)	-25.20 (-31.90, -21.59)	13.56 (9.95, 20.26)
Moderate	2.80 (-1.12, 6.72) ± 10.31 (29)	-17.40 (-25.06, -13.44)	23.00 (19.04, 30.66)	-5.82 (-9.60, -2.05) ± 9.93 (29)	-25.28 (-32.66, -21.47)	13.63 (9.82, 21.02)
Severe or More	-0.55 (-6.75, 5.66) ± 7.42 (8)	-15.10 (-32.09, -10.54)	14.01 (9.44, 30.99)	-13.46 (-20.75, -6.16) ± 7.89 (7)	-28.92 (-49.96, -23.84)	2.00 (-3.07, 23.04)

Performance table for Max ED diameter (%) - TTE

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Overall	-1.13 (-2.93, 0.67) ± 9.09 (100)	-18.95 (-21.94, -16.84)	16.69 (14.58, 19.68)	-13.23 (-15.14, -11.33) ± 9.54 (99)	-31.93 (-35.09, -29.71)	5.46 (3.24, 8.62)
BMI						
BMI<25	-1.21 (-3.67, 1.25) ± 8.00 (43)	-16.90 (-21.41, -14.26)	14.47 (11.84, 18.99)	-12.86 (-15.51, -10.21) ± 8.63 (43)	-29.77 (-34.63, -26.93)	4.04 (1.21, 8.91)
BMI>=25	-1.47 (-4.02, 1.08) ± 9.52 (56)	-20.13 (-24.64, -17.31)	17.19 (14.38, 21.71)	-13.52 (-16.26, -10.77) ± 10.25 (56)	-33.61 (-38.47, -30.58)	6.57 (3.54, 11.43)
Gender						
Male	-2.96 (-5.42, -0.50) ± 8.38 (47)	-19.38 (-23.83, -16.72)	13.46 (10.80, 17.91)	-14.30 (-16.63, -11.96) ± 7.95 (47)	-29.89 (-34.12, -27.36)	1.29 (-1.23, 5.52)
Female	0.10 (-2.44, 2.63) ± 9.09 (52)	-17.73 (-22.25, -14.96)	17.92 (15.15, 22.44)	-12.27 (-15.27, -9.28) ± 10.76 (52)	-33.36 (-38.71, -30.08)	8.81 (5.54, 14.16)
Age						
Age<60	-2.94 (-5.47, -0.41) ± 8.43 (45)	-19.45 (-24.07, -16.73)	13.58 (10.86, 18.19)	-13.77 (-16.60, -10.93) ± 9.43 (45)	-32.24 (-37.40, -29.20)	4.71 (1.67, 9.87)
Age>=60	-0.04 (-2.51, 2.44) ± 9.06 (54)	-17.78 (-22.18, -15.07)	17.71 (15.00, 22.11)	-12.79 (-15.44, -10.14) ± 9.69 (54)	-31.79 (-36.49, -28.88)	6.21 (3.30, 10.91)
Race						
Asian	-2.35 (-11.05, 6.35) ± 10.41 (8)	-22.75 (-46.57, -16.36)	18.05 (11.66, 41.87)	-11.50 (-21.82, -1.18) ± 12.35 (8)	-35.70 (-63.95, -28.12)	12.70 (5.11, 40.95)

Variable	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
Black or African American	-1.44 (-3.74, 0.86) ± 7.92 (48)	-16.96 (-21.12, -14.47)	14.09 (11.60, 18.25)	-12.65 (-14.90, -10.40) ± 7.76 (48)	-27.86 (-31.93, -25.42)	2.57 (0.12, 6.64)
White	-2.35 (-4.93, 0.24) ± 7.87 (38)	-17.77 (-22.61, -15.05)	13.08 (10.36, 17.91)	-14.20 (-17.19, -11.21) ± 9.09 (38)	-32.03 (-37.62, -28.89)	3.62 (0.48, 9.21)
Other/Mixed/ Unknown	8.56 (-12.40, 29.52) ± 16.88 (5)	-24.53 (-95.37, -12.37)	41.64 (29.48, 112.48)	-14.23 (-41.10, 12.64) ± 21.64 (5)	-56.65 (-147.5, -41.06)	28.19 (12.60, 119.01)
Severity of Tricuspid Regurgitation						
None	-2.69 (-5.83, 0.45) ± 8.40 (30)	-19.16 (-25.26, -15.97)	13.78 (10.60, 19.88)	-14.16 (-17.75, -10.56) ± 9.63 (30)	-33.02 (-40.01, -29.37)	4.71 (1.06, 11.69)
Mild	-2.29 (-5.40, 0.82) ± 8.77 (33)	-19.47 (-25.41, -16.27)	14.89 (11.69, 20.83)	-13.24 (-16.37, -10.12) ± 8.81 (33)	-30.51 (-36.48, -27.29)	4.02 (0.80, 9.99)
Moderate	0.13 (-3.57, 3.84) ± 9.74 (29)	-18.96 (-26.20, -15.21)	19.22 (15.48, 26.46)	-12.71 (-16.67, -8.75) ± 10.42 (29)	-33.13 (-40.88, -29.13)	7.71 (3.71, 15.46)
Severe or More	4.93 (-2.55, 12.41) ± 8.94 (8)	-12.60 (-33.07, -7.11)	22.46 (16.96, 42.92)	-11.39 (-21.00, -1.78) ± 10.39 (7)	-31.76 (-59.47, -25.07)	8.97 (2.29, 36.69)

Performance table for Min ED diameter (%) - TTE

	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
Variable	**Mean Difference (95% LCI, UCI) ± SD (n)**	**Lower LoA (95% CI)**	**Upper LoA (95% CI)**	**Mean Difference (95% LCI, UCI) ± SD (n)**	**Lower LoA (95% CI)**	**Upper LoA (95% CI)**
Overall	0.68 (-0.95, 2.30) ± 8.21 (100)	-15.41 (-18.12, -13.51)	16.76 (14.86, 19.47)	-8.55 (-10.62, -6.47) ± 10.40 (99)	-28.93 (-32.38, -26.51)	11.84 (9.42, 15.29)
BMI						
BMI<25	1.43 (-0.74, 3.60) ± 7.05 (43)	-12.39 (-16.37, -10.07)	15.24 (12.92, 19.22)	-7.86 (-10.78, -4.93) ± 9.50 (43)	-26.48 (-31.84, -23.35)	10.77 (7.64, 16.13)
BMI>=25	-0.11 (-2.50, 2.28) ± 8.93 (56)	-17.61 (-21.84, -14.97)	17.39 (14.75, 21.61)	-9.07 (-12.05, -6.10) ± 11.10 (56)	-30.83 (-36.09, -27.55)	12.68 (9.40, 17.94)
Gender						
Male	-0.70 (-3.26, 1.86) ± 8.73 (47)	-17.81 (-22.45, -15.04)	16.41 (13.64, 21.05)	-9.26 (-12.09, -6.43) ± 9.64 (47)	-28.17 (-33.29, -25.11)	9.64 (6.58, 14.77)
Female	1.69 (-0.40, 3.78) ± 7.52 (52)	-13.04 (-16.78, -10.75)	16.42 (14.13, 20.16)	-7.90 (-10.99, -4.81) ± 11.09 (52)	-29.64 (-35.16, -26.26)	13.85 (10.47, 19.36)
Age						
Age<60	1.77 (-0.61, 4.16) ± 7.93 (45)	-13.78 (-18.12, -11.21)	17.33 (14.76, 21.67)	-5.63 (-8.35, -2.92) ± 9.05 (45)	-23.37 (-28.33, -20.45)	12.11 (9.18, 17.06)
Age>=60	-0.46 (-2.72, 1.80) ± 8.28 (54)	-16.69 (-20.71, -14.21)	15.77 (13.29, 19.79)	-10.97 (-13.95, -8.00) ± 10.90 (54)	-32.34 (-37.63, -29.07)	10.40 (7.13, 15.68)
Race						
Asian	-0.34 (-6.27, 5.58) ± 7.09 (8)	-14.23 (-30.45, -9.88)	13.55 (9.19, 29.76)	-7.41 (-16.86, 2.04) ± 11.31 (8)	-29.58 (-55.45, -22.63)	14.76 (7.81, 40.63)

	Semi-Automated 3D Auto TV vs 4D CardioView			Fully Automated 3D Auto TV vs 4D CardioView		
Black or African American	1.14 (-1.18, 3.46) ± 7.99 (48)	-14.52 (-18.71, -12.01)	16.79 (14.28, 20.98)	-6.78 (-9.29, -4.28) ± 8.64 (48)	-23.71 (-28.24, -21.00)	10.14 (7.43, 14.67)
White	-0.62 (-3.39, 2.14) ± 8.41 (38)	-17.11 (-22.27, -14.20)	15.87 (12.96, 21.03)	-9.99 (-13.60, -6.38) ± 10.98 (38)	-31.51 (-38.25, -27.71)	11.53 (7.73, 18.27)
Other/Mixed/ Unknown	5.37 (-6.54, 17.28) ± 9.60 (5)	-13.44 (-53.71, -6.52)	24.18 (17.27, 64.45)	-16.28 (-37.82, 5.26) ± 17.35 (5)	-50.28 (-123.10, -37.79)	17.73 (5.23, 90.54)
Severity of Tricuspid Regurgitation						
None	0.78 (-2.12, 3.67) ± 7.76 (30)	-14.43 (-20.06, -11.49)	15.98 (13.04, 21.61)	-6.98 (-10.45, -3.52) ± 9.27 (30)	-25.16 (-31.89, -21.64)	11.19 (7.67, 17.92)
Mild	-0.77 (-4.05, 2.50) ± 9.24 (33)	-18.89 (-25.15, -15.51)	17.34 (13.96, 23.60)	-9.48 (-13.41, -5.54) ± 11.10 (33)	-31.24 (-38.76, -27.18)	12.29 (8.23, 19.81)
Moderate	1.79 (-1.12, 4.69) ± 7.64 (29)	-13.19 (-18.87, -10.26)	16.76 (13.83, 22.44)	-8.54 (-12.83, -4.24) ± 11.29 (29)	-30.66 (-39.06, -26.33)	13.59 (9.25, 21.98)
Severe or More	2.26 (-4.30, 8.81) ± 7.84 (8)	-13.11 (-31.06, -8.30)	17.63 (12.81, 35.57)	-10.88 (-18.93, -2.83) ± 8.70 (7)	-27.94 (-51.15, -22.34)	6.17 (0.58, 29.39)

Performance comparison between automated and semi-automated outputs for 3D Auto TV within the TEE and TTE populations are presented below.

	TEE Subjects			TTE Subjects		
3D Auto TV vs. 3D Semi-automated	**Mean Difference (95% LCI, UCI) ± SD (n)**	**Lower LoA (95% CI)**	**Upper LoA (95% CI)**	**Mean Difference (95% LCI, UCI) ± SD (n)**	**Lower LoA (95% CI)**	**Upper LoA (95% CI)**
Annulus size						
2D perimeter in ES (mm)	-10.99 (-13.28, -8.70) ± 11.37 (97)	-33.27 (-37.20, -29.34)	11.29 (7.36, 15.22)	-10.72 (-12.28, -9.16) ± 7.83 (99)	-26.06 (-28.74, -23.38)	4.63 (1.95, 7.31)
2D perimeter in ED (mm)	-12.09 (-14.22, -9.96) ± 10.56 (97)	-32.79 (-36.45, -29.14)	8.62 (4.97, 12.27)	-13.96 (-15.92, -12.00) ± 9.84 (99)	-33.24 (-36.60, -29.87)	5.33 (1.96, 8.69)
Annulus shape						
Max ES diameter (mm)	-3.77 (-4.54, -3.00) ± 3.82 (97)	-11.25 (-12.57, -9.93)	3.71 (2.39, 5.03)	-3.89 (-4.47, -3.30) ± 2.95 (99)	-9.66 (-10.67, -8.66)	1.89 (0.89, 2.90)
Min ES diameter (mm)	-2.44 (-3.16, -1.71) ± 3.60 (97)	-9.49 (-10.73, -8.24)	4.61 (3.36, 5.85)	-2.31 (-2.76, -1.87) ± 2.24 (99)	-6.71 (-7.48, -5.95)	2.08 (1.32, 2.85)
Max ED diameter (mm)	-4.30 (-5.06, -3.53) ± 3.78 (97)	-11.71 (-13.02, -10.41)	3.12 (1.81, 4.43)	-5.02 (-5.75, -4.29) ± 3.67 (99)	-12.21 (-13.47, -10.96)	2.17 (0.92, 3.43)
Min ED diameter (mm)	-2.62 (-3.35, -1.89) ± 3.62 (97)	-9.71 (-10.96, -8.46)	4.47 (3.22, 5.72)	-3.19 (-3.72, -2.66) ± 2.68 (99)	-8.44 (-9.36, -7.53)	2.06 (1.14, 2.98)
Additional Measurements						
2D perimeter Derived Diameter in ES (mm)	-3.50 (-4.23, -2.77) ± 3.62 (97)	-10.59 (-11.84, -9.34)	3.59 (2.34, 4.84)	-3.41 (-3.91, -2.91) ± 2.49 (99)	-8.30 (-9.15, -7.44)	1.47 (0.62, 2.33)
2D perimeter Derived Diameter in ED (mm)	-3.85 (-4.52, -3.17) ± 3.36 (97)	-10.44 (-11.60, -9.28)	2.74 (1.58, 3.91)	-4.44 (-5.07, -3.82) ± 3.13 (99)	-10.58 (-11.65, -9.51)	1.70 (0.62, 2.77)

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3D Auto TV vs. 3D Semi-automated	TEE Subjects Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)	TTE Subjects Mean Difference (95% LCI, UCI) ± SD (n)	Lower LoA (95% CI)	Upper LoA (95% CI)
3D perimeter in ES (mm)	-13.34 (-15.65, -11.03) ± 11.48 (97)	-35.84 (-39.81, -31.87)	9.16 (5.19, 13.13)	-11.86 (-13.52, -10.21) ± 8.31 (99)	-28.14 (-30.98, -25.30)	4.42 (1.58, 7.26)
3D perimeter in ED (mm)	-14.26 (-16.41, -12.10) ± 10.69 (97)	-35.21 (-38.91, -31.52)	6.70 (3.01, 10.40)	-15.17 (-17.29, -13.05) ± 10.62 (99)	-35.99 (-39.62, -32.36)	5.65 (2.01, 9.28)
Height in ES (mm)	-2.54 (-2.92, -2.16) ± 1.90 (97)	-6.27 (-6.93, -5.61)	1.19 (0.53, 1.84)	-1.24 (-1.59, -0.89) ± 1.77 (99)	-4.71 (-5.31, -4.10)	2.23 (1.62, 2.83)
Height in ED (mm)	-2.65 (-3.05, -2.26) ± 1.96 (97)	-6.49 (-7.16, -5.81)	1.18 (0.51, 1.86)	-1.40 (-1.75, -1.05) ± 1.77 (99)	-4.87 (-5.48, -4.27)	2.07 (1.47, 2.68)
Area in ES (mm)	-2.09 (-2.63, -1.54) ± 2.71 (97)	-7.39 (-8.32, -6.45)	3.22 (2.28,4.15)	-1.79 (-2.10, -1.48) ± 1.54 (99)	-4.82 (-5.34, -4.29)	1.24 (0.71, 1.76)
Area in ED (mm)	-2.54 (-3.08, -2.00) ± 2.68 (97)	-7.80 (-8.73, -6.87)	2.72 (1.79, 3.65)	-2.55 (-2.93, -2.16) ± 1.95 (99)	-6.36 (-7.03, -5.70)	1.27 (0.61, 1.94)

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