MyoStrain® User's Manual

Version 6.1

MYOCARDIAL SOLUTIONS

Transforming Cardiac & Cancer Care

https://www.myocardialsolutions.com

COPYRIGHT

Warranty
The information contained in this document is subject to change without notice.

Standards
This document is based on the IEEE Standard for Software User Documentation (1063).

Patents
(7,741,845), (10,524,687), (11,103,153), (11,872,019), Additional Patents Pending

Trademark Credits
MyoStrain® is a trademark of Myocardial Solutions Inc.

Software Version and Date
Myocardial Solutions MyoStrain® Version 6.1, October 2025
MyoStrain® Version 6.1 End Of Life – May 2035

Microsoft is a U.S. registered trademark and Windows is a trademark of Microsoft Corporation.

Caution: U.S.A Federal law restricts this device to sale by or on the order of a physician.

MD MyoStrain®

Manufacture Address:

Myocardial Solutions
4819 Emperor Blvd, Suite 140
Durham, NC 27703
Phone: +1 877- 677-8514

MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 – Suite 123
2595 AM The Hague
The Netherlands

Authorized Representative:
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
Phone: +31.70.345.8570

EC REP

CE 2797 UK CA

UDI

+B672MYOSTRAIN060/$$053501X

This manual is the instructions for use for MyoStrain® version 6.

Warnings:

- MyoStrain is a post-processing software that does not interact with the patient. To obtain the images used for MyoStrain, the user must follow all the Contraindications and Warning from the MR imaging manufacturer, to ensure the safety of the patient and the staff.
- MyoStrain is designed for the analysis of SENC MR images of the heart. The results of quantification will depend on the image quality.
- MyoStrain, is intended to be used by the physician along with other indicators, such as patient history and pain level, to determine the diagnosis of the patient.
- Any serious incident that has occurred in relation to MyoStrain should be reported to Myocardial Solutions Inc. as well as the competent authority of the Member State in which the user/patient is established.

MR Manufactures with approved SENC Pulse Sequences

Philips Ingenia, Ingenia Elition and Ingenia Ambition MR Systems with 5.6 software or higher, with the SENC Pulse Sequence and DDAS Spectrometer

1.5 T United Imaging Healthcare MRI scanners with the SENC Pulse Sequence.

Revision History

DCO No.	Rev.	Revision Description	Issued By	Effective Date
23-1062	A	New Document	F. Aversa	4/17/24
24-1057	B	Grammar and formatting updates	F. Aversa	5/10/24
24-1069	C	Revised for FDA and EUDAMED Compliance	F. Aversa	9/4/24
25-1018	D	Revised for EU Compliance	F. Aversa	3/24/25
25-1027	E	Revised from MedEnvoy feedback	F. Aversa	11/12/25
25-1112	F	Revised for v6.1	F. Aversa	12/10/2025

TABLE OF CONTENTS

1

1. INTRODUCTION

This User's Manual was written to assist you with a better understanding of MyoStrain and to maximize the efficiency of the software. Use this manual to look up information, find out what you need to know, and start your work.

1.1 USING THIS MANUAL

This manual is designed to provide a thorough description of how to use the software to analyze cardiac magnetic resonance (CMR) images.

The following symbols and formats are used to denote different types of instructions:

- All user interface elements have been marked in **bold**.
- Additional information on application functionality or features can be found in small notes.

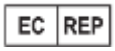
NOTE: Notes are written in this format.

Ø Example: Examples are written in this format.

Caution –Important cautionary information such as warnings and precautions

Information –Consult instructions for use

Manufacturer – Identifies who developed and released the MyoStrain software.



Authorized Representative – Authorized representative in the European community

Unique Device Identifier – Indication that a Unique Device Identifier is present

Medical Device – Indication that the device is a medical device

Importer – Identifies the representative who verifies the device conforms with applicable regulations required for importation in the EU.

1.2 ABOUT MYOCARDIAL SOLUTIONS

Myocardial Solutions, Inc., based in RTP, North Carolina, is a privately held company specializing in unique MR imaging and diagnostic solutions for research, clinical, and OEM markets. "Our mission is to give patients control

over their heart health, providing physicians with unique diagnostic solutions to help transform the detection, prediction, and management of heart dysfunction."

1.3 INTENDED PURPOSE

This section will document the intended purposes of MyoStrain, which will include information such as intended patient population, intended medical indications, contraindications, performance, and benefits.

1.3.1 INTENDED USE

MyoStrain® is a software medical device designed for the quantitative assessment of myocardial strain using cardiac magnetic resonance images collected using SENC or fast-SENC pulse sequences.

1.3.2 INTENDED USERS

MyoStrain® is intended for use by healthcare professionals in clinical settings.

1.3.3 INTENDED PATIENT POPULATION

MyoStrain® is intended for adult and pediatric patients with suspected or known cardiomyopathy, heart failure, cardiotoxicity, and coronary artery disease. It can also be used to monitor patients with no symptoms.

1.3.4 INTENDED MEDICAL INDICATIONS

MyoStrain® provides information that is used for the diagnosis and classification of cardiomyopathy, heart failure, cardiotoxicity, and coronary artery disease.

1.3.5 CONTRAINDICATIONS

MyoStrain® does not have contraindications.

1.3.6 BENEFIT CLAIMS

MyoStrain® reduces the exposure to MRI contrast agents

1.3.7 PERFORMANCE CLAIMS

Measured Parameters -

MyoStrain® measures directly the following parameters, derived from the MRI images or strain data without additional complex mathematical analysis or advanced analysis.

- **Global Strain measurements**

MyoStrain (GLS) LV – Average percentage of peak strain calculated from all Short-Axis LV slices.
MyoStrain (GCS) LV – Average percentage of peak strain calculated from all Long-Axis LV slices.
MyoStrain (GLS) RV – Average percentage of peak strain calculated from all Short-Axis RV views.
MyoStrain (GCS) RV – Average percentage of peak strain calculated from all Long-Axis RV views.

- **Traditional measurements**

MyoStrain® can perform the following traditional cardiac measurements:

LVEF – Percentage of blood emptied from the left ventricle during systole.

LVED Volume – Volume (mL) of blood measured in the LV at Diastole measured across all Long-Axis images. LVED Volume is also displayed as indexed values (mL/m^2) based on body surface area (BSA)

LVES Volume – Volume (mL) of blood measured in the LV at Systole measured across all Long-Axis images. LVES Volume is also displayed as indexed values (mL/m^2) based on body surface area (BSA)

LV Stroke Volume – Difference of volume (mL) between the LVED Volume and LVES Volume. LV Stroke Volume is also displayed as indexed values (mL/m^2) based on body surface area (BSA)

RVEF* - Percentage of blood emptied from the right ventricle during systole.
RVED Volume* - Volume (mL) of blood measured in the RV at Diastole measured across all Long-Axis images. RVED Volume is also displayed as indexed values (mL/m^2) based on body surface area (BSA)
RVES Volume* - Volume (mL) of blood measured in the RV at Systole measured across all Long-Axis images. RVES Volume is also displayed as indexed values (mL/m^2) based on body surface area (BSA)
RV Stroke Volume* - Difference of volume (mL) between the RVED Volume and RVES Volume. RV Stroke Volume is also displayed as indexed values (mL/m^2) based on body surface area (BSA)

The performance of MyoStrain® is defined by the **Limit of Agreement (LOA)**, established through **Bland-Altman analysis,** which quantifies the agreement between MyoStrain® and Cardiac MRI (CMR), as presented in Figure 1-1

Parameters	Limit of Agreement
LVEF	[-10; 13] (%)
LVED Volume	[-23; 25] (mL)
LVES Volume	[-17; 15] (mL)
LV Stroke Volume	[-23; 27] (mL)
RVEF*	[-18; 19] (%)
RVED Volume*	[-22; 47] (mL)
RVES Volume*	[-22; 32] (mL)
RV Stroke Volume*	[-28; 43] (mL)
* Semi Auto Contouring must be enabled, and a completed 3D model is required to generate these measurements	

Figure 1-1: Traditional measurements using MyoStrain®

Quantified Parameters
MyoStrain® quantifies the following parameters based on the measured values.

- **Dysfunctional Segment Quantifications (Threshold-Based Classification**)

Number of LV Segments > -10% – This displays the total number of LV segments calculated by MyoStrain® to have above -10% strain.
Number of LV Segments > -17% – This displays the total number of LV segments calculated by MyoStrain® to have above -17% strain.
Number of RV Segments > -10% - This displays the total number of RV segments calculated by MyoStrain® to have above -10% strain.
Number of RV Segments > -17% - This displays the total number of RV segments calculated by MyoStrain® to have above -17% strain.

- **MyoHealth® Scores**

LV MyoHealth®- Derived measurement showing percentage of LV segments equal to or below -17% strain compared to the total number of LV segments analyzed. It can be expressed by the formula below

RV MyoHealth®- Derived measurement showing percentage of RV segments equal to or below -17% strain compared to the total number of RV segments analyzed. It can be expressed by the formula below

MyoHealth® Score = *[(# of V Segments <= -17%) / (# of V Segments Analyzed)] * 100*

1.3.8 RISKS AND SIDE EFFECTS

As with all medical devices, MyoStrain® has the potential for side effects. Possible side-effects considered in the literature for diagnosis software for cardiac activity are related to delay to diagnosis and disruption of subsequent medical procedures.

Clinical data from MyoStrain®, and literature review on diagnosis software for cardiac activity have not highlighted increased risk of this side effect associated with the software application. Figure 1-2 summarizes the side-effects of MyoStrain®.

Side-effect	Probability
Delay to diagnosis	Rare [0- 0.15%]
Disruption of subsequent medical procedure	Rare [0- 0.15%]

Figure 1-2: Side Effects of MyoStrain

1.3.9 EXPECTED PRODUCT LIFETIME

The "expected lifetime" of the medical device, is 10 years from the date of release.

1.4 DEVICE SPECIFICATIONS

1.4.1 GENERAL DESCRIPTION OF THE DEVICE

MyoStrain® is an image processing software designed to analyze cardiac magnetic resonance (CMR) images for assessing myocardial function. It processes MRI-encoded images acquired using a pulse sequence (SENC/fSENC). The software extracts time-resolved, quantitative strain data per voxel along with other cardiac measurements. MyoStrain® quantifies longitudinal and circumferential strain to describe myocardial wall motion, offering tools to display regional motion properties and variations. MyoStrain® generates clear, easy-to-read reports with intuitive graphics making clinical cardiac imaging reporting efficient and reliable. The reports are interpreted by physicians to support diagnostic decision-making.

1.4.2 DESCRIPTION OF MATERIALS

Not applicable. MyoStrain® is software, delivered electronically. MyoStrain® does not incorporate any medicinal substances, tissues, or blood products.

1.4.3 ACCESSORIES, OTHER DEVICES AND OTHER PRODUCTS

No accessories are available with the MyoStrain® software.

1.4.4 SYSTEM REQUIREMENTS

Recommended Hardware Requirements

- 2.8 GHz i5 Generation 7 Processor (equivalent or better)
- 16GB memory or higher
- 100 GB available hard disk space for installation and additional space for image storage.
- 1920x1080 screen resolution
- Dedicated GPU with at least 2gb onboard memory
- 1000Mbps LAN/Ethernet port
- .NET Framework 4.8 (installed alongside MyoStrain® if not present)
- Visual C++ Redistributable Package 2019 (installed alongside MyoStrain®)

Operating System
The MyoStrain® application is currently supported on Windows 11 (64-bit) Pro, Windows Server 2022, and Windows Server 2025 (Standard)

1.4.5 PRINCIPLES OF OPERATION OF THE DEVICE AND ITS MODE OF ACTION

MyoStrain® an image processing software designed to process cardiac magnetic resonance (CMR) images for assessing myocardial function. Unlike the MRI acquisition pulse sequence, which is used to generate raw cardiac images, the MyoStrain® uses specialized pulse sequence (SENC/Fast SENC) to quantify regional myocardial strain, providing a direct measurement of myocardial function. Then, the software combines the processed images to generate a color-encoded strain map of the heart, where the blood pool is suppressed (black blood imaging), and myocardial strain is visually represented using a graded color scale.

1.4.5.1 IMAGE ACQUISITION AND PROCESSING

MyoStrain® is an advanced cardiac imaging software built on the SENC and Fast SENC pulse sequences, utilizing linear tagging to capture myocardial motion in a single direction.

SENC (**Strain-Encoded MRI)** uses a **fixed frequency encoding** to encode strain information directly into the MR signal. Signal intensities change as the heart contracts (systole) and relaxes (diastole), reflecting regional myocardial strain. The strain information is then extracted by analyzing intensity variations in response to myocardial deformation.

SENC (SENC) employs an **alternating frequency encoding pattern**—low and high tuning—enabling faster acquisition by encoding strain at multiple depths simultaneously. These encoding variations influence signal intensities based on myocardial deformation.

These technologies enable direct and highly precise strain measurements of both the left and right ventricles with exceptional spatial resolution. Designed for efficiency, MyoStrain® provides rapid and reproducible strain assessments in as few as one to three heartbeats. By leveraging the speed and accuracy of SENC-based imaging, it offers a powerful and reliable tool for evaluating myocardial function, ensuring high-quality cardiac assessments in clinical practice. A detailed presentation of the features SENC and fast SENC is provided in Figure 1-3.

Characteristics	SENC	Fast-SENC
Developed since	2008	2017
Tagging type	Uses linear tagging (one direction through the heart muscle layers)	Uses linear tagging (one direction through the heart muscle layers)
MRI sequence pulse	- Modulated SPAMM (Mod-SPAMM) - Single-shot GRE (Gradient Echo) - bSSFP (Balanced Steady-State Free Precession)	- Rapid Modulated SPAMM with Optimized bSSFP - Spiral SENC
Application	Quantifies global and regional strain	Quantifies global and regional strain
Resolution	High spatial resolution	High spatial resolution
Breath-holding	Requires single breath-hold	No breath-holding required
Heartbeat required	4-8 heartbeat/plane	1 heartbeat/plane
Analysis time	Requires dedicated pulse sequence	Analysis time (<10 min)
Speed	Fast	Faster
Complexity	Easy	Simplified
Best case use	Clinical use, early disease detection	Clinical use, early disease detection and Stress tests, real-time strain monitoring

Figure 1-3: Overview of the technical features of SENC and Fast-SENC sequences

1.4.5.2 STRAIN MEASUREMENT AND ANALYSIS

Strain is a quantitative measure of myocardial deformation, expressed as the fractional change in tissue length. MyoStrain® calculates strain on a pixel-by-pixel basis, with:

- **Shortening (contraction) represented as negative values**, e.g., a 25% reduction in myocardial length during systole is shown as **-25%**.
- **Lengthening (stretching) represented as positive values**, e.g., a 5% stretching in an aneurysmal infarct during systole is shown as +5%, which is very rare.

MyoStrain® provides precise measurements of regional myocardial strain for both the left ventricle (LV) and right ventricle (RV), enabling detailed characterization of cardiac contraction and relaxation. The software automatically extracts strain data from the encoded images and generates quantitative strain maps that help detect ischemia, myocardial infarction, or other functional impairments.

The MyoStrain® analysis provides a detailed report of intramyocardial muscle deformation, dividing the left and right ventricles into 48 segments. Each segment is assigned a peak mid-myocardial strain value and a corresponding color for visual interpretation. Since strain is a negative value reflecting myocardial contraction, a higher peak mid-myocardial strain number (i.e., a lower absolute strain value) indicates reduced contractile function in that region.

MyoStrain® does not interact directly with patients but assists physicians in visualizing, calculating, and assessing regional myocardial function. The software also includes MyoHealth® a derived measurement that represents the percentage of ventricular segments with strain values equal to or better than -17%. This metric is displayed only if at least 30 of the 37 left ventricular segments and 8 of the 11 right ventricular segments are analyzed. The MyoHealth® score is calculated using the following formula, for left and right ventricles:

MyoHealth® = [(# of V Segments ≤-17%) / (# of V Segments Analyzed)] * 100

1.4.5.3 USER INTERFACE AND REPORTING

The software features an intuitive graphical user interface (GUI) designed for efficient operation with minimal user interaction. It computes a comprehensive set of strain-derived measurements and motion indices, facilitating in-depth cardiac function analysis. **MyoStrain®** also includes a reporting module that allows results to be formatted into standardized clinical reports, which can be reviewed and interpreted by physicians to support diagnosis and patient management. Figure 1-4 presents the first page of the MyoStrain® report showing a visual representation of the **48 myocardial segments**, highlighting strain values and the MyoHealth metric to facilitate clinical interpretation. The Global MyoStrain Strain Values are classified as follows:

- Normal Strain: <=-17% (healthy myocardial function).
- Borderline Dysfunction: Between -10% and -17%.
- Severe Dysfunction: Above -10% (high risk of myocardial dysfunction).

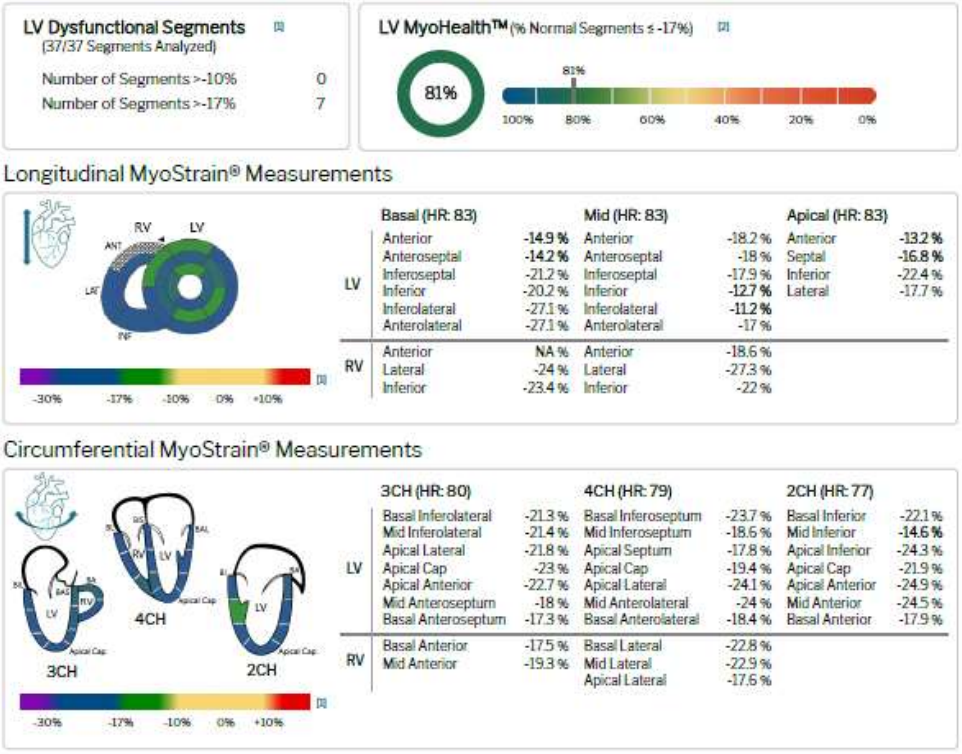


Figure 1-4: MyoStrain® Report for 6.1 (Template-1, Default AHA Model)

1.5 CYBERSECURITY

MyoStrain is only available from Myocardial Solutions, and installations are only authorized on systems identified as being secure. Myocardial Solutions requires that the below practices are being followed before authorizing installation or upgrades of MyoStrain:

- Access to the workstation (internally and externally) is limited to only authorized and trusted users of MyoStrain.
- Access to the workstation is monitored
- Only trusted content (including MyoStrain and its software libraries) will be loaded onto the workstation
- The workstation is equipped with mechanisms designed to detect, respond to, and recover from malware or other compromising applications (Anti-virus, anti-malware software, firewall)

- The workstation must automatically log off and restrict access after a reasonable period
- A backup and disaster recovery plan should be in place on the workstation
- Integrity and confidentiality of data transferred to and from the workstation must be monitored
- MyoStrain data stored on the workstation is encrypted

A log of actions performed by the user are recorded and is accessible to administrator users on the workstation. If LDAP is being used, only an LDAP authorized administrator user can access the logs.

1.5.1 TRANSMISSION OF DATA

MyoStrain can be configured to use any network ports to receive and send data. MyoStrain will only open ports and network paths to locations where the workstation or application is provided access to. Myocardial Solutions will work with the facility to ensure the ports are secure.

MyoStrain will not knowingly transmit data to any devices or systems not identified as a connected PACS server (Section 10.1). MyoStrain will only receive DICOM formatted data sent to it as part of a configured node system. MyoStrain will not transmit any information to an outside server or service without express confirmation on behalf of the operator. Information related to the receiving of data from across a network is logged and is available on the workstation running MyoStrain. The log files can be found in the following path, where (USER) is the logged-in user's name: C:\Users\(USER)\AppData\Local\Myocardial\MyoStrain Test\Logs.

After any data has been sent to MyoStrain, it will be stored in a folder specified during the installation (Default path is C:\MyoStrain\). Datasets sent to MyoStrain will be stored in the same state it is received until manually updated.

1.5.2 ENCRYPTION OF DATA

All information related to the processing of image data during a software exam (.myo save data files) is encrypted. This information cannot be accessed except by MyoStrain. Encryption of image data as well as secure transfer of data is a requirement of the facility prior to installation of the MyoStrain software. When utilizing a network based DICOM transmission system, data sent to the MyoStrain workstation will be encrypted at rest. The encryption algorithm being used is AES-256. If a user-supplied encryption key is used, MyoStrain will be unable to provide the ability to recover any encrypted data if this key is lost.

1.5.3 INTEGRITY OF DATA

MyoStrain will perform a check periodically to verify the integrity of system files and ensure repeatable results on a known dataset. This check verifies analysis integrity if the workstation's cybersecurity has been compromised. This check (known as Self-Check) is conducted upon installation of the software, a reorder form is generated, upon request, or after a year has passed since the last Self-Check. MyoStrain will not launch if this test fails. Please contact Myocardial Solutions (support@myocardialsolutions.com) for more information.

1.5.4 COMPROMISE OF DATA (INCIDENT RESPONSE PLAN)

In the event that MyoStrain has detected unauthorized modifications to itself or its licensing, MyoStrain will cease operation and will not permit further usage of the software. If MyoStrain is not functioning normally (or if the workstation is suspected to be compromised), please contact Myocardial Solutions (+1 919.677.8100, or support@myocardialsolutions.com) to identify the problem and to restore MyoStrain functionality.

1.5.5 AUDIT LOGGING

A record of user actions and file access is recorded in MyoStrain and available for view through the MyoConfigurator. The following actions are recorded and stored in an encrypted database only accessible by an authorized Administrator user of the workstation, or by administrators of MyoStrain through LDAP:

- Successful/failed logins (LDAP only)

- Opening/Creating new exams
- Exporting data/DICOM images
- Modifying an existing exam (the slices/stages modified from the original exam are recorded)
- Deleting a dataset from the MyoWorklist
- Timeout due to inactivity (LDAP only)

Records are stored for a configurable amount of time (6 years default), and the location can be selected by the user. More information regarding accessing Audit Logs can be found in Chapter 10.

1.6 UNINSTALLATION (PERSISTANCE OF DATA)

If MyoStrain is to be uninstalled from the workstation, please contact the Myocardial Solutions Support team (support@myocardialsolutions.com) prior to doing so. Depending on your site's configuration, some information needs to be documented prior to the software being removed. This is to ensure that if MyoStrain is being moved from one workstation to the next, existing license or networking information can be recorded and transferred.

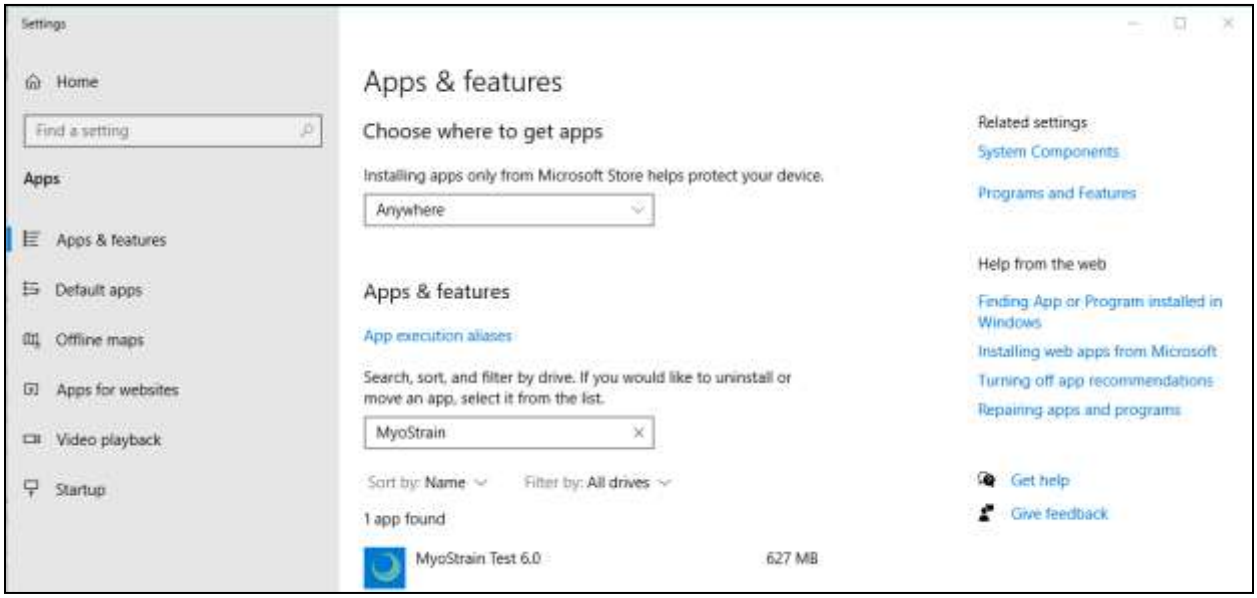


Figure 1-5: Recommended method of uninstalling MyoStrain

It is recommended to use the Apps & Features setting in the Settings menu of Windows to uninstall MyoStrain. Once the MyoStrain software is uninstalled, the following paths will retain data regarding past analyses:

1. C:\MyoStrainBackUp
2. C:\MyoStrain
3. C:\Users\[**USER**]\AppData\Local\Myocardial\

These paths do not include the locations of exams analyzed using MyoStrain. MyoStrain will not delete exam data of past analyses during its uninstallation. It is the responsibility of the site or user to archive, backup, and delete exam information from the workstation after MyoStrain has been uninstalled.

2

2. GETTING STARTED

This chapter explains the installation and default operation of the MyoStrain analysis software.

⚠ Prior to using the MyoStrain software in a clinical or research setting, training from the Myocardial Solutions team on proper usage is required. Please contact your Myocardial Solutions representative or (support@myocardialsolutions.com) for more information.

2.1 INSTALLING MYOSTRAIN V6.1

The MyoStrain installation process on the workstation is a very simple and straightforward process. Installation is performed on-site and configured by Myocardial Solutions on a site-by-site basis. If your site needs to install or reinstall MyoStrain, please contact Myocardial Solutions' support team (support@myocardialsolutions.com) to arrange an installation session.

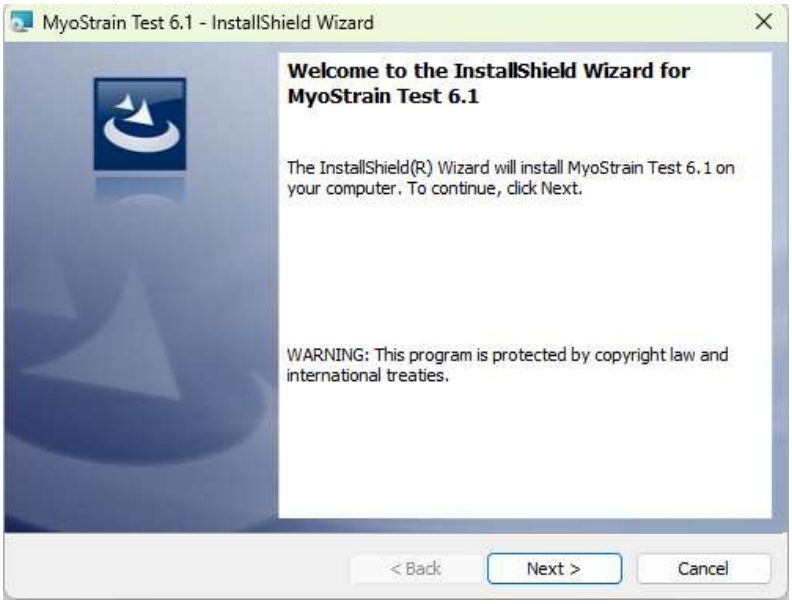


Figure 2-1: Installation Window

1. Launch the MyoStrain installer. Click the **Next** button when the installation screen shown in Figure 2-1 appears.

2. Please read the license agreement, and if you agree select the "I accept the terms in the license agreement" option shown in the second installation window (Figure 2-2).

3. The **Configuration** stage of the installation wizard contains site-specific information which may change from site to site. Please contact your site administrator or Myocardial Solutions for more information on these fields.

Figure 2-2: End User License Agreement – Accept must be selected to continue.

4. After the **Configuration** information has been set, click **Next**. Select **Install** on this last page to initiate the final step of the installation process.

2.1.1 UPGRADING TO V6.1

If a previous version of MyoStrain is already installed on the workstation, the MyoStrain installation package will upgrade the installed version to the current release.

Figure 2-3: Installation Wizard – Upgrading

Upgrading to version 6.1 will attempt to import settings from the previous installation, including PACS server information and Worklist data. During the installation process, a directory must be created to store this information for upgrade, by default MyoStrain will use C:\MyoStrainBackup.

NOTE: The MyoStrain installer will always attempt to upgrade an existing MyoStrain installation. To bypass upgrading, first uninstall the current MyoStrain installation. Ensure the MyoStrain program as well as the MyoWorklist are closed before uninstallation/upgrading.

2.2 ACTIVATING MYOSTRAIN V6.1

Upon launching MyoStrain for the first time, or if the MyoStrain Application license has expired, the **Registration** dialog box will display as shown in Figure 2-4. Copy the value given in the Username field and email it to Customer Support (support@myocardialsolutions.com).

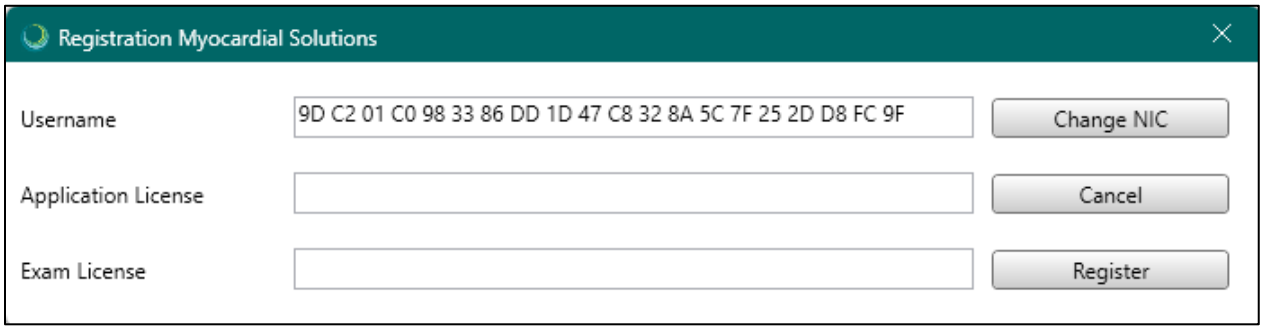


Figure 2-4: Registration dialog box

2.2.1 MYOSTRAIN SELF CHECK

After installing MyoStrain, when a Reorder request is started, or a year after the last check, a Self-Check will be run by the program. This Self-Check system verifies the integrity of installed files on the workstation, then runs a diagnostic analysis to verify measurements being read by the application.

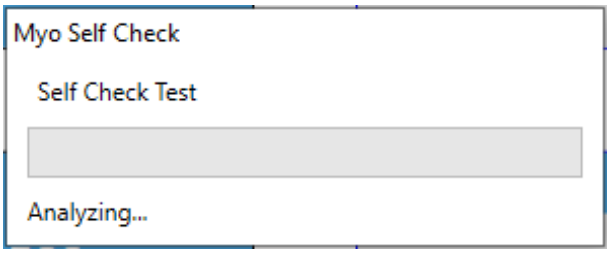


Figure 2-5: Self Check running

A progress bar will appear once the test has begun. After the check has been completed, a dialog box will appear, detailing information regarding the test. If the Self-Check fails, please contact Myocardial Solutions' Technical Support for more information (support@myocardialsolutions.com). The program will not run if the Self-Check fails.

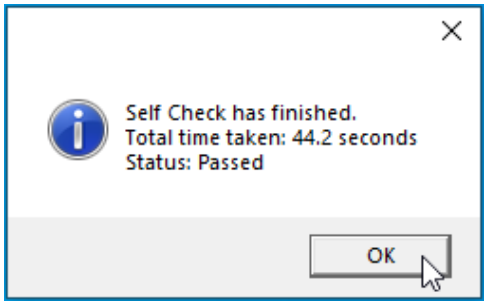


Figure 2-6: Successful Self Check notification

2.3 IMAGE IMPORTATION

MyoStrain provides multiple different methods to import images for analysis. While the methods for importing images may differ, the end goal of quantifying a series of strain images stays the same.

2.3.1 INPUT IMAGES REQUIREMENTS

MyoStrain imports and analyzes SENC images, which are acquired with SENC-ready MRI systems. SENC-ready MRI systems are MRI systems equipped with the SENC pulse sequence. SENC images are identified by specified DICOM series attribute 'SENC'.

NOTE: fSENC (also known as Fast-SENC) is another name for images acquired using the SENC Pulse Sequence.

2.3.2 INPUT IMAGES RESTRICTIONS

MyoStrain processes SENC images and measures the strain in the through-plane direction. The specific strain measured will depend on the orientation of the imaging plane. Circumferential strain is measured from long-axis planes of the heart, while longitudinal strain is measured from short-axis planes.

The prescription of the planes is the responsibility of the MRI scanner operator, who should be properly trained on cardiac imaging and the recognition of the correct views of the heart.

The user of MyoStrain can verify the right orientation (angle tilting) of the acquired planes by reviewing the location and orientation of each plane relative to the anatomical images, as seen on MyoStrain screen. The user therefore can match the type of the strain measured to the location and orientation of the plane.

While MyoStrain can import any properly formatted image, it cannot identify what is an analyzable image. Image quality, acquisition, and other factors can prevent the accurate quantification of image data. Accuracies of measurements are associated with images that were correctly acquired and analyzed by trained operators. It is the responsibility of the trained MRI operator and MyoStrain users to check the quality of the acquired images before post-processing them using MyoStrain.

Other acquisition issues can cause the images to be unanalyzable. Below are 3 examples of mis-acquisition.

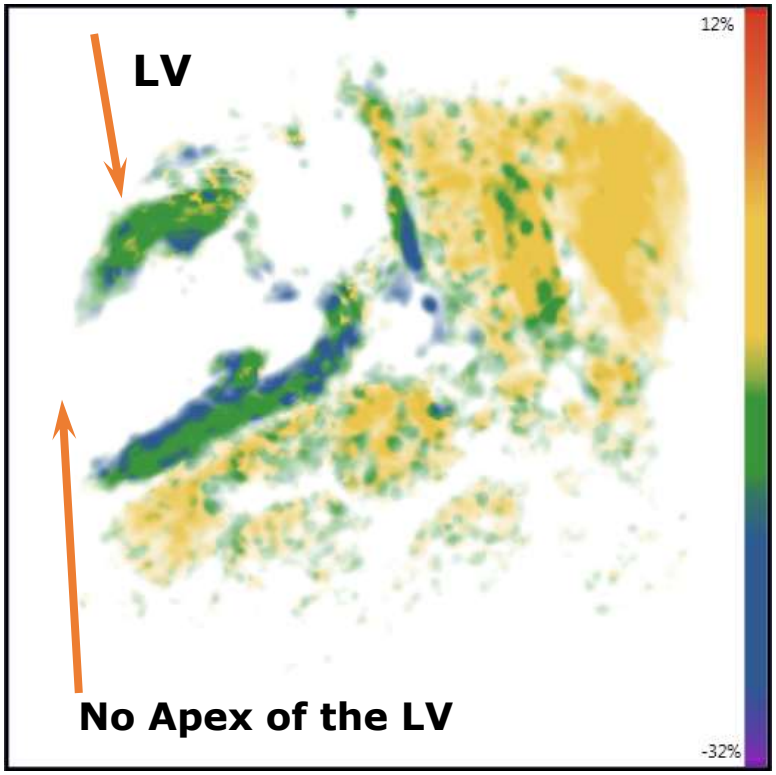


Figure 2-7: Sample Image of 2-chamber view with planning issue

Figure 2-7 demonstrates an image that needs to be re-acquired. In this example, the apex of the 2-chamber view is not captured at systole. During acquisition, the patient shifted their body and caused the heart to fall outside of the field of view. This would require a new acquisition.

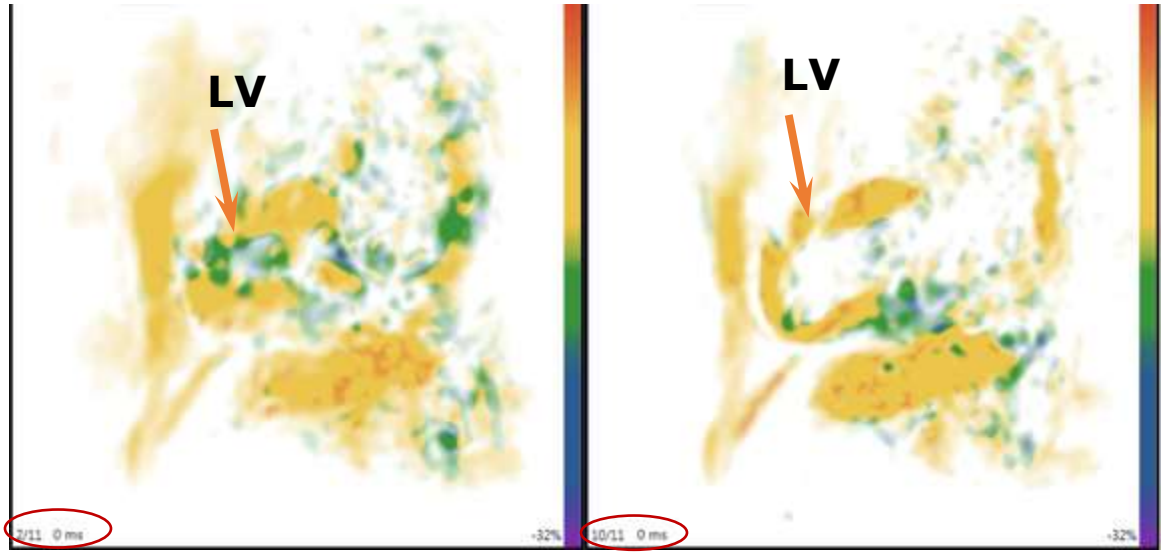


Figure 2-8: Two images of the same 2-chamber view

Figure 2-8 demonstrates an acquisition that began at end-systole (frame 2/11, left) instead of end-diastole (frame 10/11, right). Rather than showing the complete cycle of the heart going from end-diastole, to end-systole, and back to end-diastole, this series is only showing the relaxation from end-systole to end-diastole. This caused the strain to not be applied to the dataset. If the dataset does not show the full diastolic to systolic cycle, the series should be rejected.

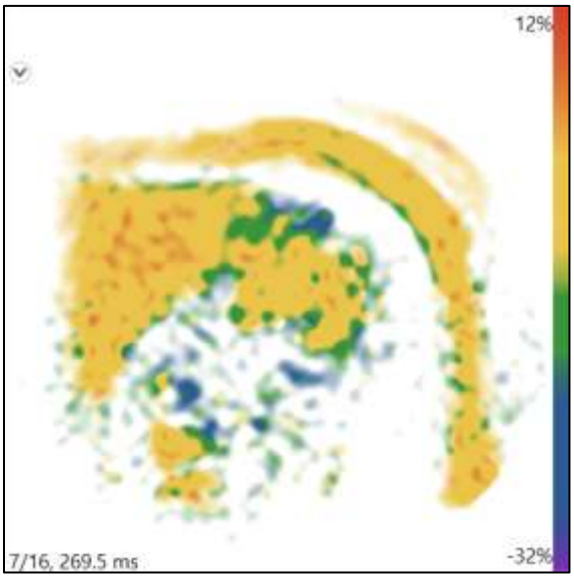


Figure 2-9: Unidentifiable

Figure 2-9 should be rejected as well. In this example, the acquisition plane was not set correctly. For reference, this image is of a 4ch Long-Axis slice. This would require a reacquisition.

All images used for analysis demonstration in chapter 4 can be considered of good analysis quality.

2.3.3 LOCAL FILE IMPORT

In most circumstances, images being analyzed in MyoStrain are typically coming directly from the scanner. In cases where networking is unavailable, or images copied off a CD or flash drive need to be analyzed, local file import is available.

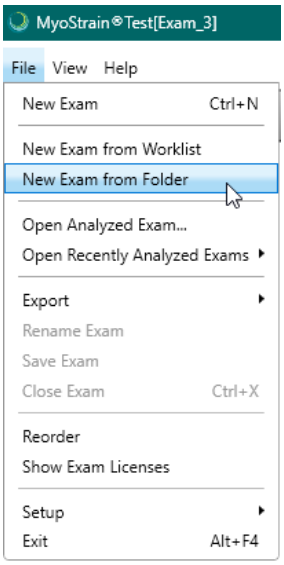


Figure 2-10: Image Import from Folder (New Exam) option found in the File menu

To import a local dataset, click on **File>New Exam from Folder** from the **File** menu found in the upper-left hand corner of the MyoStrain application. A **Browse for Folder** dialog box will appear, prompting the user to select a folder containing DICOM images. All images contained in the folder (this includes any subfolders found in this folder) will be imported into MyoStrain and organized according to stress stage found in the medical image header.

All MyoStrain data used as part of the analysis will be stored in that folder. Image data will be maintained in that folder and is the responsibility of the Facility's IT department to find a secure location to archive and store this exam information.

2.3.4 REMOTE FILE IMPORT

MyoStrain has the capability to import images from a remote location (DICOM Server, PACS, Scanner) through a DICOM network connection. For more information regarding remote file importation, please refer to chapter 10.

After any data has been sent to MyoStrain, it will be stored in a folder specified during the installation (Default path is C:/MyoStrain/). It is the sole responsibility of the Facility's IT Department to ensure that any data sent to MyoStrain is accessed, managed, and archived for future use.

For more information regarding the MyoWorklist, please refer to chapter 10 for more details.

2.4 DICOM CONNECTIVITY CONFIGURATION

When MyoStrain 6.1 is installed, an additional service named MyoWorklist is also installed on the workstation. This service is responsible for managing datasets sent to the application for retrospective analysis from other computers via DICOM. MyoStrain will only receive data pushed from remote locations it has been configured to

receive from and can be configured to receive data from multiple devices. Please contact your PACS or network administrator or support@myocardialsolutions.com to setup this feature. You can also refer to section 10.1 for more information about DICOM connectivity configuration and how to enable MyoStrain to receive images remotely. A DICOM Conformance Statement is available upon request.

NOTE: Only DICOM formatted data can be transferred through this configuration.

2.5 ERROR REPORTING

When using MyoStrain, very rare circumstances may cause the application to encounter an error. If an error does occur, please send the entire error message to Customer Support (support@myocardialsolutions.com) along with your name and the organization/practice you are affiliated with. A representative will contact you to help troubleshoot your issue.

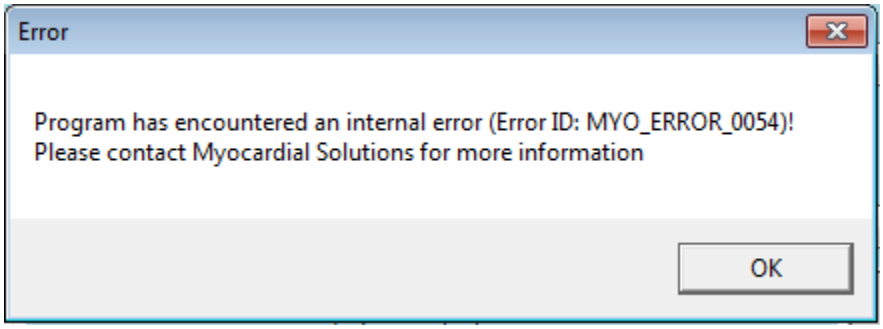


Figure 2-11: Sample error message

In the rare case MyoStrain crashes without generating an error message, please contact Customer Support (support@myocardialsolutions.com) describing any actions preceding the crash. A Customer Support representative will be in contact to assist in troubleshooting the error.

2.6 EXAM LICENSES

MyoStrain operates by using an exam credit once images are received by the application in Stress or Strain analysis mode. If the application no longer has any exam credits remaining, it will not receive or process any new images. To order additional exam credits, launch the **About** menu by clicking on the Myocardial Solutions logo found below the 'X' at the top-right of the application window.

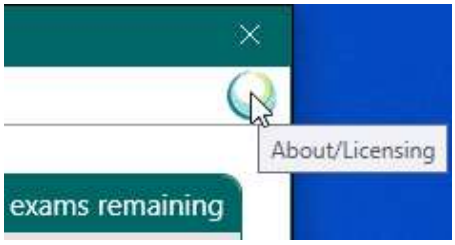


Figure 2-12: License information is available from this menu

The **About** menu, available from both the Exam Selection screen as well as the main program, displays relevant information related to the software license. Exam credits can be requested or added into the program from this menu. Additionally, the Reorder process can be initiated from the File menu by selecting the Reorder button.

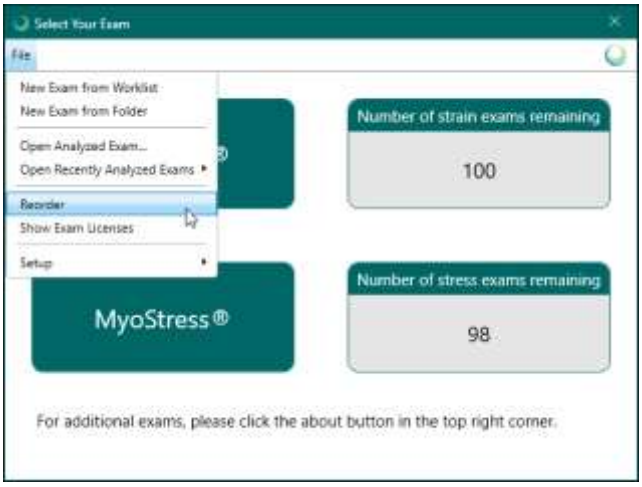


Figure 2-13: Exam selection screen shown at beginning of new exam or at launch with Reorder option highlighted

To view detailed exam license information, click on the **Show Exam Licenses** button shown in the File menu (Figure 2-13), and at the top of the About menu (Figure 2-14). This will display another menu which will display all the exam licenses available to the workstation and their duration (Figure 2-15). Exam licenses will always be consumed starting with the first entry, then cascading down the list until no additional exam licenses are available.

Figure 2-14: Additional exam license information can be found in the About menu

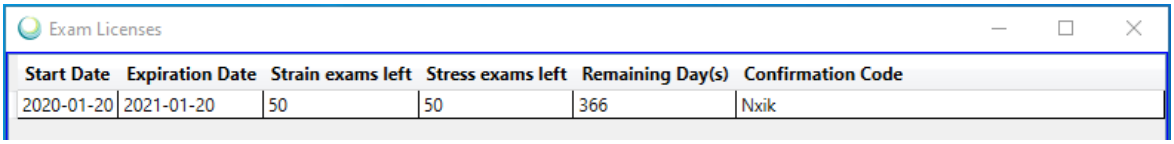


Figure 2-15: List of exam licenses available to the workstation running MyoStrain.

2.6.1 ORDERING ADDITIONAL EXAM LICENSES

NOTE: Please check with your organization's ordering procedures before submitting a request for additional licenses.

Clicking on the **Reorder** button found in the bottom-center of the About menu will launch a new popup window (Figure 2-16). The Reorder form can also be launched from the File menu.

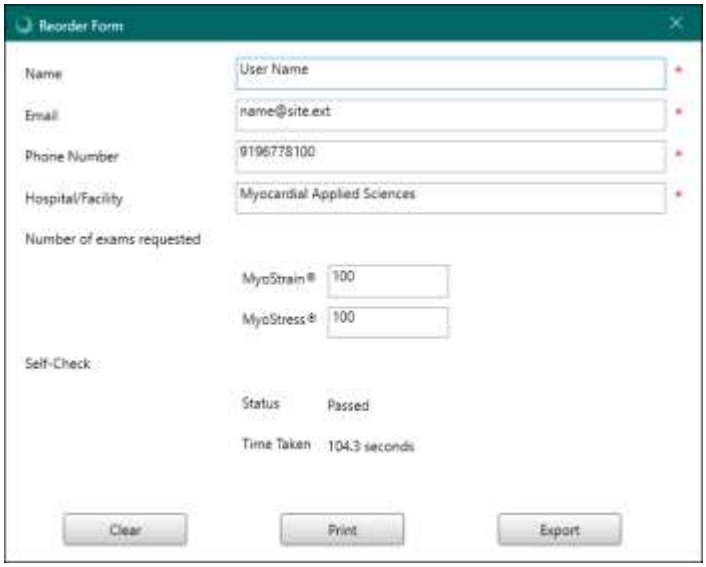


Figure 2-16: License Reorder Form Wizard

After filling in all the required fields (marked by a red asterisk), including a number for Strain and Stress, a report will be available for export. Clicking on the Print button will bring up a Print Dialog box (Figure 2-17) allowing the user to print out a physical copy of the report (provided a printer is available).

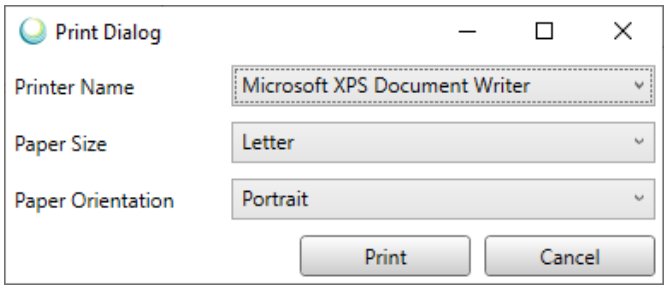


Figure 2-17: Selecting Print from this window will generate a physical copy of the Reorder Form

A digital copy can also be created by using the **Export** button from the **License Reorder** window (Figure 2-18) as well. Select a location to export the report to using the Choose Folder button, rename the Reorder form using the File Name field, then click **Save** to export the report.

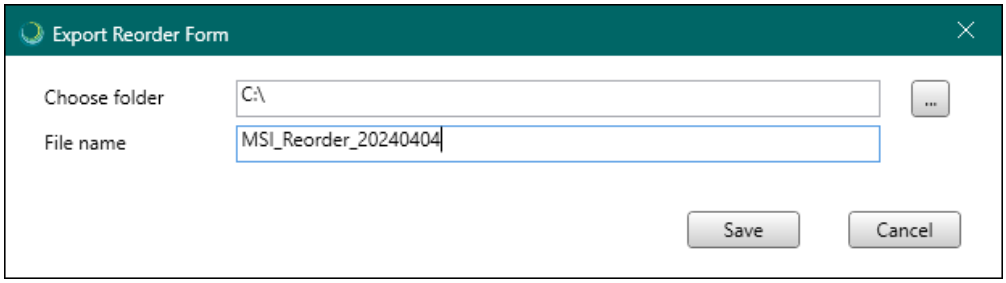


Figure 2-18: Digital copies of the Reorder form can be created here

Once the Reorder form has been created, it must be attached to the Purchase Order sent to Myocardial Solutions for processing. Please refer to the chart below for details on where this Reorder form should be sent.

Email	orders@myocardialsolutions.com
Fax	+1 (919) 591-0404

NOTE: orders@myocardialsolutions.com will not contact you or reply directly to emails. A representative will contact the person listed on the Reorder form, or directly with the person who sent the email if there are any errors.

2.6.2 ADDING ADDITIONAL EXAM LICENSES

By clicking on the Myocardial Solutions logo found either on the **Select Your Exam** or main application window, an About dialog box will appear (Figure 2-19). Clicking on the **Exam License** button will open the Registration window (Figure 2-20). Copy and paste any new license codes into the **Exam License** field and click **Add** to add additional exam credits.

Figure 2-19: MyoStrain About page

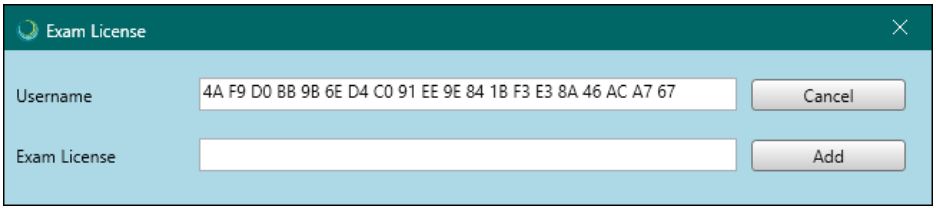


Figure 2-20: Exam License entry screen

NOTE: License codes generated by Myocardial Solutions expire 7 days after being issued.

2.7 APPLICATION LICENSE

In addition to the Exam License, the software is also governed by an Application License. This license determines how long the program will remain active and able to review exams created in the program. The Application License can be found by clicking the **Application License** button found in the **About** screen. If the Application License is expired, MyoStrain will not launch and instead display the Registration window seen in section 2.2.

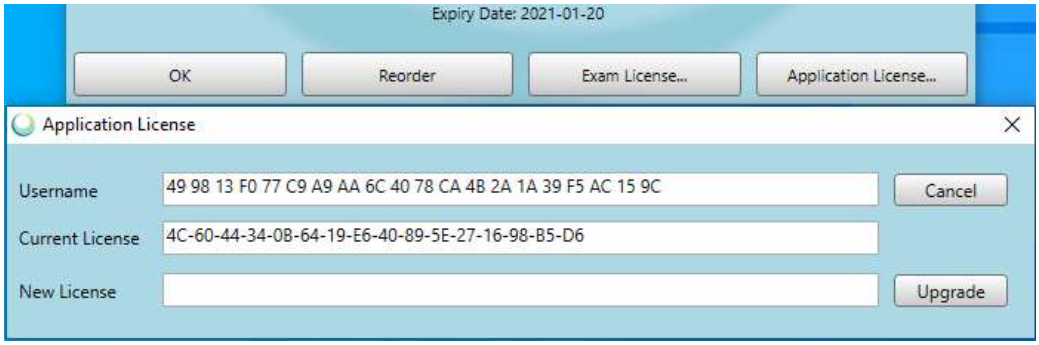


Figure 2-21: Application License menu

NOTE: The MyoStrain Application license is separate from the Exam License. MyoStrain will continue to run if there are no remaining Exam credits, however it will be limited to reviewing previously created MyoStrain exams.

2.8 CLOSING MYOSTRAIN / WORKSTATION MAINTENANCE

Once finished performing analyses in MyoStrain, it's important to shut down the application. This is accomplished by clicking either the X button in the upper right corner of the screen, or by selecting File>Exit option in the application menus.

When closed, MyoStrain will still be able to receive images sent to the workstation and queue them in the MyoWorklist for analysis.

It is highly recommended that MyoStrain is closed before any Windows Updates are applied to the workstation. It is highly recommended that Myocardial Solutions' Support is contacted prior to performing any hardware modifications to the workstation. Changes to the hardware of the MyoStrain workstation may cause the Application License to become invalidated. Any configuration changes to the DICOM network should also be reported to Myocardial Solutions to ensure the transfer of SENC formatted images to the MyoStrain software will not be impacted.

3

3. APPLICATION OVERVIEW

This chapter provides a visual overview of the MyoStrain® application, describing settings and features relating to MyoStrain visualization and quantification. MyoStrain is comprised of 3 different modules: Analysis, MyoHealth® Review, and Report.

3.1 THE MYOSTRAIN® ANALYSIS WORKSPACE

The MyoStrain application is comprised of three windows with several panes used to display information relevant to the current patient's images being analyzed by the software. Most of the data displayed is generated as part of the MyoStrain analysis protocol and minimal interaction is required to display/retrieve this information. When importing a new dataset for analysis, the Analysis tab is what MyoStrain will initially display. It can also be accessed by clicking on the **Analysis** button in the top-middle portion of the application.

Ø Example: For a MyoStress exam, each stage of this scan will be available in the application and organized accordingly, with the lowest and highest stages of stress displayed by default.

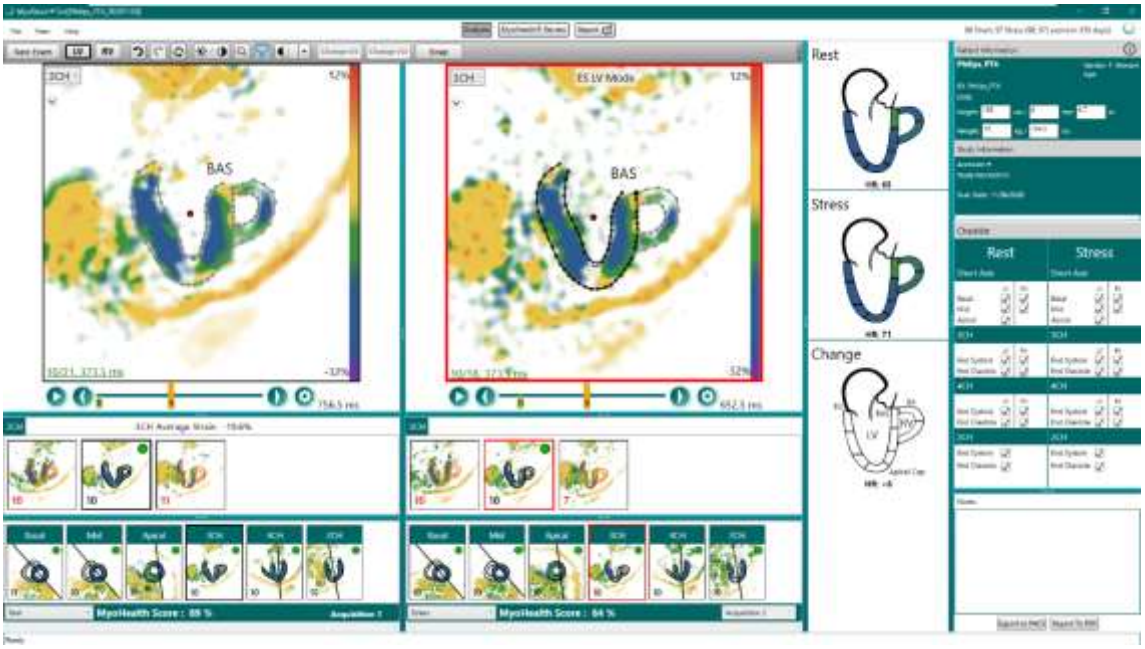


Figure 3-1: Overview of the MyoStrain analysis window

3.1.1 **ANALYSIS WINDOW**

Found in the center of the application, this displays the active slice(s) being analyzed. Information about the currently viewed slice can be adjusted in the upper-left of the image (including heart rate). A drop-down menu is also used to identify the view for importation into the report. The top area of the **Analysis Window** has several options which drive or assist with image analysis. Additionally, located on the right side of the active image is a color scale used to visualize strain on the image.

3.1.1.1 OVERVIEW

Found in the upper-left hand corner of the **Analysis Window**, the View Details shows information regarding the current view and stress analysis stage.

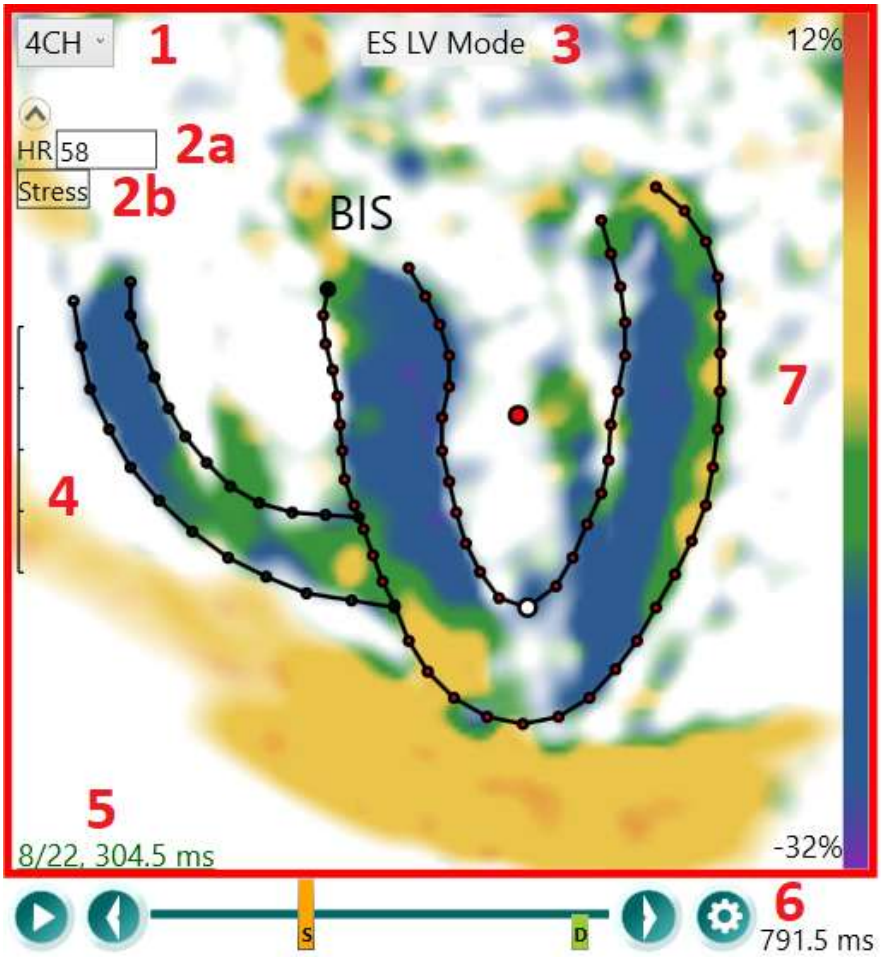


Figure 3-2: 4-Chamber view details (Stress exam)

1. **View Dropdown** – Contains a list of six possible views analyzable during a MyoStrain analysis.
2. **Heart Details (Stress Only)** - Users can view and edit the patient's heart rate directly from this dropdown menu. Click the circle found below the **View Dropdown** to access this section.
    a. **Heart Rate** - This value is tracked independently across each slice and stress stage, allowing manual updates if needed.
    b. **Stress Agent** - Current Stress Stage of the displayed slice.
3. **Display Header** - Current Analysis tool active. In the example, clicking the mouse anywhere inside the analysis window will begin drawing an LV contour.

4. **Measurement Scale** – This is shown on the left-hand side of the **Analysis Window** and displays a reference scale (in cm). This changes size depending on the zoom and acquisition. Disabled by default.
5. **Current Timeframe** (Current Time) - Shown at the bottom of the image in the lower-left hand corner, this displays the currently viewed timeframe, the total number of images available in this slice, and the time of the current timeframe relative to the initial image (in milliseconds). If a mesh is applied to the slice, timeframes marked in green and underlined are used in strain calculation.
6. **Video Playback** – Found below the analysis window itself, this shows the current timeframe, and the timeframes where the End-Systolic and End-Diastolic (LAX views only) meshes are located. More detailed information can be found in section 3.1.1.4.
7. **Strain Scale** – Seen on the right-hand side of the displayed image, this shows the range of colors used to represent the deformation seen in the myocardial tissue.

3.1.1.2 ANALYSIS WINDOW OPTIONS

Displayed at the top of the **Analysis Window**, the Analysis Window Options are buttons intended to assist the mesh drawing process. This includes mesh correction tools and visualization enhancements. Most of these options are also available by clicking the right-mouse button in the active **Analysis Window**.

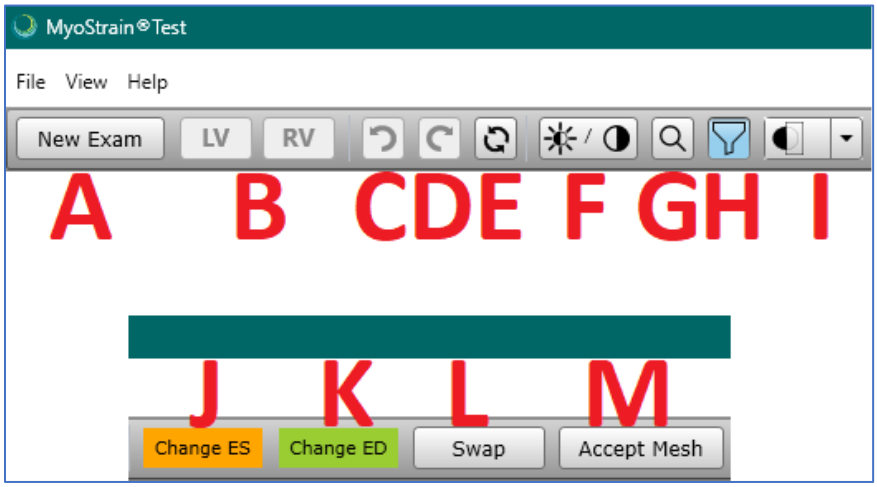


Figure 3-3: Analysis Window options seen during a Stress Exam

A. **New Exam** – Clicking this will begin the New Exam process. The new exam will only be started once a dataset has been selected and confirmed. This button will either function identically to the **New Exam From Folder**, or **New Exam From Worklist** option. This can be changed in the **View>User Interface Settings** page.
B. **LV / RV** – These buttons switch between LV analysis and RV analysis modes. The currently active drawing mode will be highlighted (LV Mode currently enabled in the example).
C. **Undo –** This reverses the most recent mesh drawing or correction. This button will be greyed-out if no mesh data is available.
D. **Redo –** Pressing this will re-apply the most recent action taken by the **Undo** button.
E. **Reset –** This resets the image view to its default state. Any image that has been rotated or meshed can be reset. A notification window will appear to confirm any **Reset** request. Semi Auto Contouring can be re-applied if available.
F. **Brightness/Contrast –** This button is responsible for adjusting the image brightness and contrast for the current acquisition stage. The adjustment can be done by holding down the left-mouse button and moving the mouse in the Analysis Window, or by adjusting the sliders in the Analysis Menu.

G. **Zoom -** Pressing this button brings up a zoom slider bar. Using this slider, the user can zoom in on the image, and by using the mouse cursor in the **Analysis Window**, move the image.

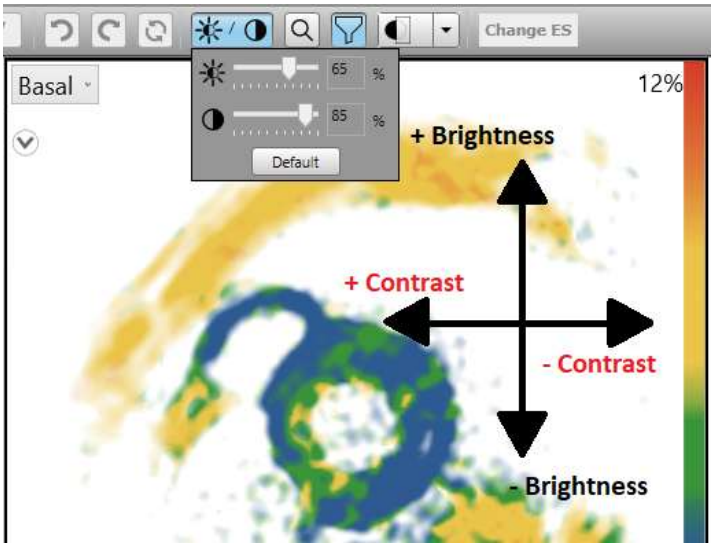


Figure 3-4: Holding the left-mouse button and dragging in the shown directions will adjust the brightness and contrast in the Analysis Menu and vice-versa

H. **Noise Filter -** Unchecking this box will disable the noise filter. The noise filter by default will ignore signal intensity under a certain threshold, improving visual quality of the image.
I. **Slice Display Color –** Clicking this button will invert the currently active Analysis Window's background color. The dropdown menu next to this button also allows for the following:
    - **Current Slice –** Change only the currently displayed and active slice.
    - **All Slices-** Change the background color for all slices.
J. **Change ES –** Moves the Orange placeholder on the **Slice Navigator** to its respective location based on the timeframe when this button is pressed. This timeframe will be used to calculate strain as identified during End-Systole.
K. **Change ED –** Moves the Green placeholder on the **Slice Navigator** to its respective location based on the timeframe when this button is pressed. This timeframe will be used to calculate global measurements identified during End-Diastole.
L. **Swap –** Enabled only when both the ES and ED meshes are available, this will mark the current End Systole timeframe as End Diastole, and vice-versa. This is useful in case the Diastolic timeframe is drawn first instead of the Systolic timeframe on a long-axis image.
M. **Accept Mesh –** Displayed when viewing an un-accepted Semi Auto Contour, clicking this button will set the mesh as Accepted, and its strain measurements will be reported on.

3.1.1.3 RIGHT-CLICK MENU

Right-clicking anywhere inside the **Analysis Window** will display a context menu with many of the same features seen above the **Analysis Window**, but with a few additional capabilities.

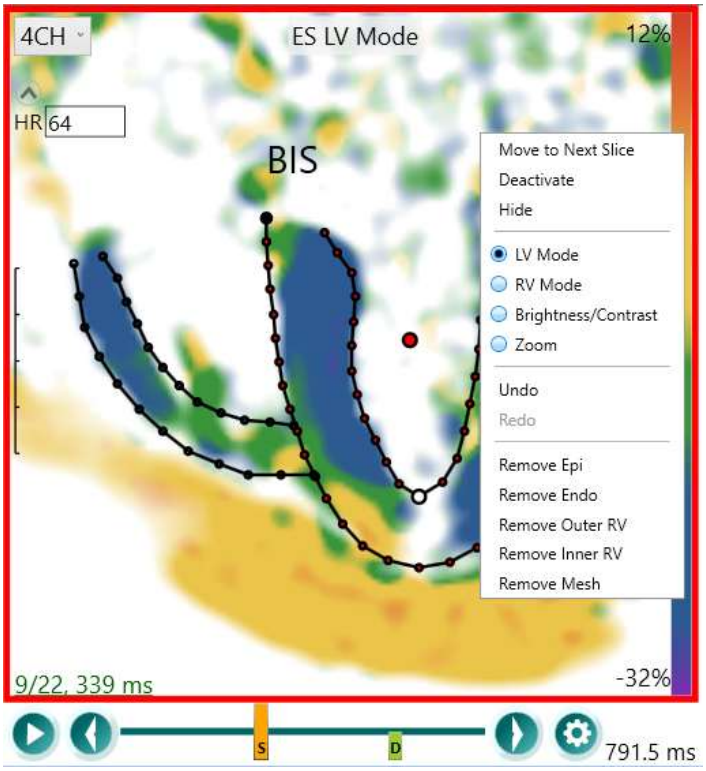


Figure 3-5: Context menu displayed when right-clicking in Analysis Window

The Right-Click menu can be broken down into 4 groups (from top to bottom):

1. **Mesh and Slice Navigation**
    a. **Move to…** - Changes the currently displayed slice/timeframe to the listed option.
    b. **Accept and**… - During Semi Auto Contouring, clicking the Accept button will Activate the slice and convert the recommended contour into a normal contour which will be used for reporting purposes.
    c. **Activate/Deactivate** – When a slice is active, the strain data from that slice is being used for reporting purposes. Deactivating that slice will not delete the mesh data, but will not be used.
    d. **Hide/Unhide** – Moves and de-activates a slice while also greying it out to emphasize exclusion.
2. **Analysis Mode** (Only 1 of these options can be active at a time)
    a. **LV Mode –** Enables LV Analysis mode (RV contours cannot be modified when active)
    b. **RV Mode-** Enables RV Analysis mode (LV contours cannot be modified when active)
    c. **Brightness/Contrast –** Enables Brightness/Contrast adjustment while enabled
    d. **Zoom –** Enables Pan and Zoom adjustment while enabled
3. **Mesh Adjustment**
    a. **Undo -** Undoes the most recent action
    b. **Redo –** Redoes the most recent action
4. **Mesh Removal**
    a. **Remove Epi –** Removes the LV epicardial contour from the mesh.
    b. **Remove Endo –** Removes the LV endocardial contour from the mesh.
    c. **Remove Outer RV –** Removes the RV epicardial contour from the mesh.
    d. **Remove Inner RV –** Removes the RV endocardial contour from the mesh.
    e. **Remove Mesh –** Removes the entire mesh from the image. This does not reset the selected End-Systolic or End-Diastolic timeframe, only the contours.

3.1.1.4 VIDEO PLAYBACK (SLICE NAVIGATOR)

Found below the **Analysis Window**, these buttons will allow the user to navigate between different images in the current slice.

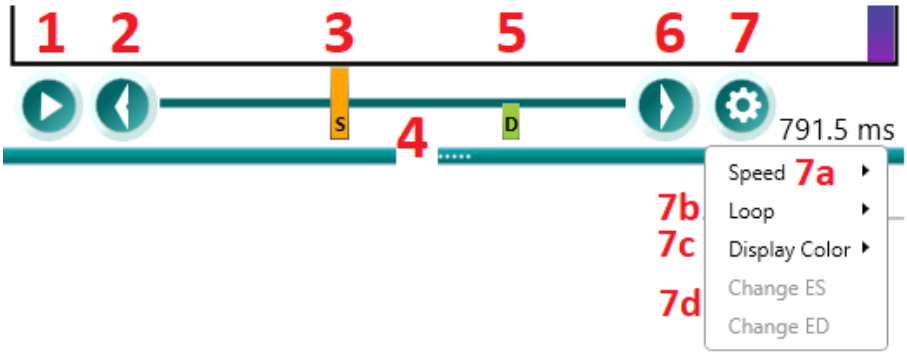


Figure 3-6: Slice Navigator shown with the Settings menu expanded

1. **Play/Pause** – Begins or pauses video playback.
2. **Back** – Moves back one timeframe in the slice
3. **End-Systolic Marker** – Shown in Orange, this marks the timeframe being used as End-Systole.
4. **Slice Navigator** - Shows the current timeframe, as well as the End Systolic (S) and End Diastolic (D) timeframes.
5. **End-Diastolic Marker** – Shown in Green, this marks the timeframe being used as End-Diastole.
6. **Forward** – Advances forward one timeframe in the slice
7. **Settings** – Additional playback settings can be accessed here.
    a. **Speed** – Change the playback speed to move faster or slower.
    b. **Loop** – When the end of the CINE video has been reached, this determines if the slice will repeat, other slices in the view will play, or if playback will progress through all slices.
    c. **Display Color** – Changes the background color of the currently displayed image from light to dark, or vice-versa.
    d. **Change ES/ED** – Sets the current timeframe to End Systole or End Diastole (and copy any accepted meshes to this timeframe as well)

NOTE: You can also use your mouse's scroll wheel or your keyboard's arrow keys to navigate through the images of the slice, forward and backwards.

3.1.1.5 STRAIN LEGEND

Strain data provides a qualitative color scheme to visualize the contraction strength of the heart muscle. These color maps are automatically applied to the images being analyzed during the exam. Figure 3-7 provides a basic guide to the meaning of each color. For more information on Contractility of the myocardium refer to Section 12.2

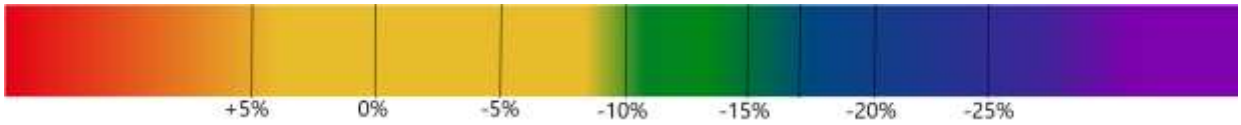


Figure 3-7: Color Map Legend

3.1.1.6 WINDOW ADJUSTMENT

The images shown in the Analysis Window can be increased or decreased in size by adjusting the bars seen below and on the right-hand side of the window. Using the handlebars, left-click and drag the sides of the Analysis

window to adjust the available area for images to be shown. The image will scale to fit into the largest area possible while maintaining the images original properties.

3.1.2 IMAGE LIST

Located under the **Analysis Window**, the **Image List** displays all images that have been imported by MyoStrain as a part of the current patient study. These are grouped by slice, time of acquisition, and stress agent (if performing a stress exam). The bottom row displays all available views in the current stage, while the top row shows all slices corresponding to the view selected in the bottom row. Each MyoStrain thumbnail is a representative image of peak strain across all timeframes for that view, and will display the End-Systolic mesh if available.

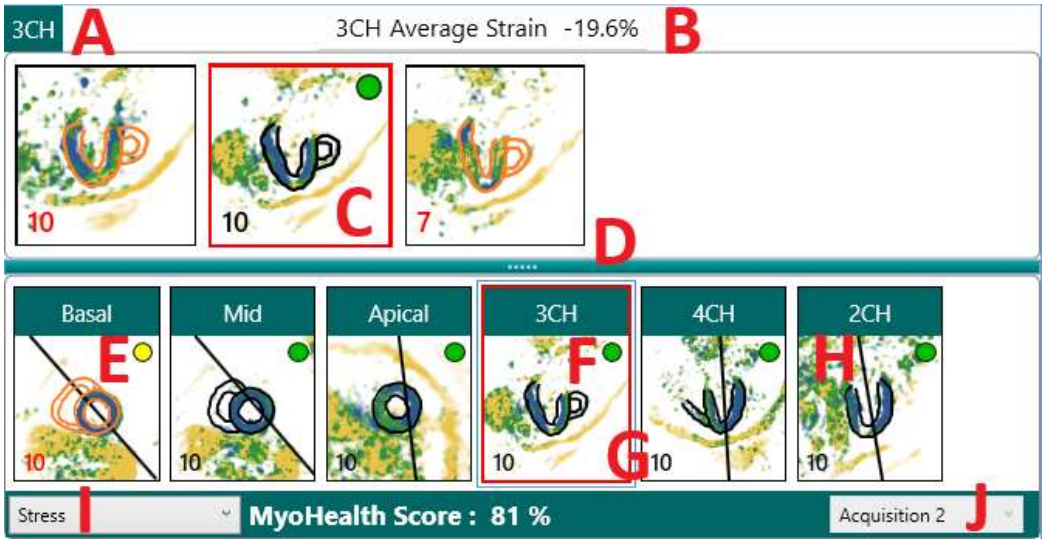


Figure 3-8: Image List as seen during a MyoStrain exam with Semi Auto Contouring enabled

A. **Active View** – All slices labeled with the same view identifier are shown at the top of the Image List when the corresponding view is selected at the bottom of the Image List.
B. **Average Strain (Rest Only)** – This shows the Average Peak Strain across all segments of the active slice (including RV Strain)
C. **Active Slice** – The currently displayed slice in this view. The active slice is shown at the top with a highlighted box surrounding it.
D. **Active Group** – The currently displayed view in the Image List. The active view group is identified with a highlighted box surrounding it.
E. **Inactive Marker** – This yellow circle indicates that a slice is available, and a mesh has been created via Semi Auto Contouring, but has not been accepted. Inactive slices do not provide any strain data or related measurements to the report.
F. **Active Marker** – This green circle indicates that a slice is analyzed and is active. Measurements from active slices are being utilized in the MyoStrain report.
G. **Timeframe Marker** – This identifies the End Systolic timeframe in the slice (red is inactive and black is active in Light Mode)
H. **Relative Plane** – This black line (orange when displayed in Dark Mode) shows the relative plane of the current selected slice (the slice outlined in Red), respective to the displayed slice.
I. **Stress Agent** – This dropdown menu is used to identify the stress agent used in this series. Adjusting this menu will change the label of the stressor used in this study.
J. **Acquisition Group** – This dropdown menu switches between other stress stages available in the study. By default, the last acquisition in the group is displayed as the default stress agent being compared against.

NOTE: If multiple slices are available under a single view, the Semi Auto Contouring tool will attempt to analyze all of them. Semi Auto Contouring will calculate peak strain from each slice and mark its recommendation of the best slice with an inactive marker. Any meshes drawn using Semi Auto Contouring must be reviewed and activated before strain calculations will be used for reporting purposes.

3.1.2.1 STRESS AGENTS AND ACQUISITION

During a stress examination, two dropdown menus will appear below the **Stress Image List** (the group of images on the right-hand side of the Stress Analysis page)**.** The menu on the left identifies the Stress Agent being used for this series of images. Modifying this dropdown will change the label, not the series of images being displayed as the Stress images. The menu on the right lists every series of images (Acquisitions) associated with this study, except for Acquisition 1 which defaults to **Rest**.

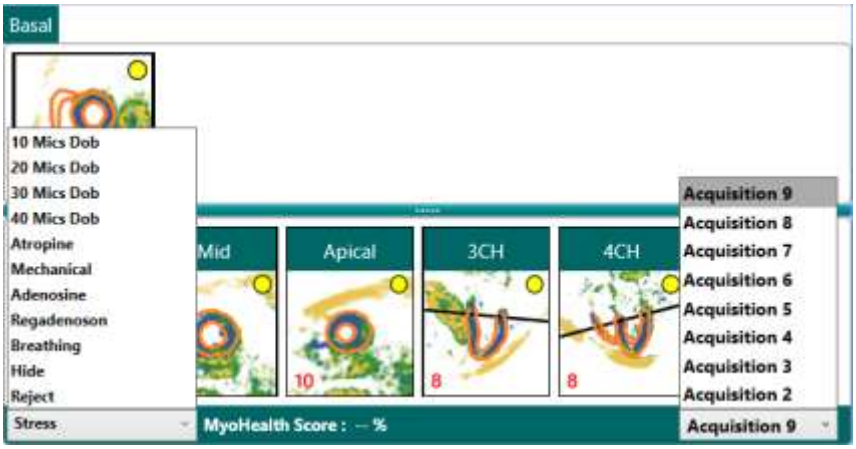


Figure 3-9: Stress Phase dropdown menu seen during Stress exam

NOTE: Any changes to the image made in the **Analysis Window** are also applied in the **Image List**. This includes brightness/contrast changes and drawn meshes.

3.1.2.2 RIGHT-CLICK MENU

Right-clicking a thumbnail inside the **Image List** will display a different context menu than the one seen in the **Analysis Window**. These are useful for toggling between two different slices of the same view to identify differences between them, and to quickly view or hide images.

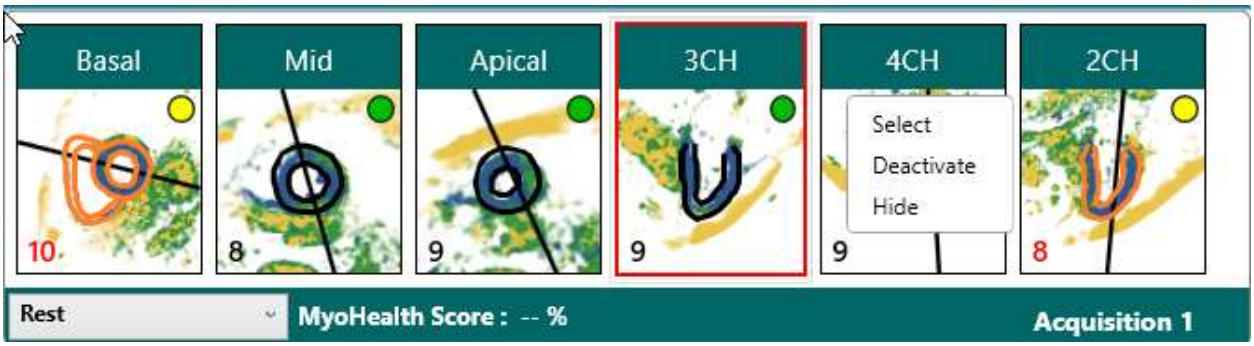


Figure 3-10: In the Image List, green radio buttons mark the slices being reported

- **Select -** Displays the selected slice in the **Analysis Window**

- **Hide -** Greys out the selected slice and pushes it to the end of the current stage in the **Image List**
- **Unhide -** Activates a slice which has been previously hidden
- **Activate -** Enables the selected slice and sets it as active with the Green radio button
- **Deactivate –** Disables the selected slice. Mesh data is not removed, but measurements are not being pulled from this slice for strain reporting.

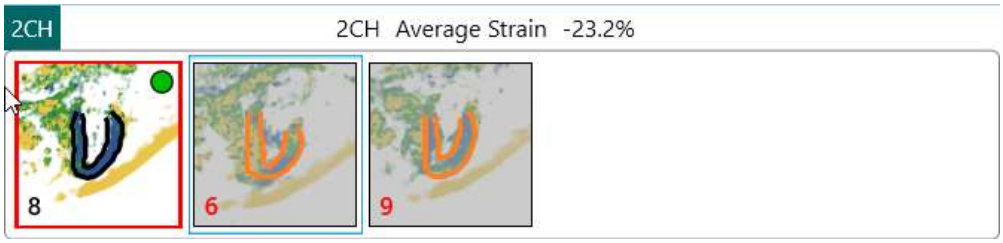


Figure 3-11: Image List with 2 slices hidden from the report

3.1.2.3 IMAGE LIST ADJUSTMENT

The size of the images shown in the Image List can be increased or decreased in size by using the blue handlebars seen underneath each stage of images available.

Figure 3-12: Increasing the size of the Resting stage image list.

3.1.3 ANALYSIS INFORMATION AND PROGRESS

The right-hand side of the Analysis window provides information regarding the current analysis. This includes analysis progress, patient information, AHA models, and a notes section which is carried over across the different modules of the application as well as on reported information collected during the analysis.

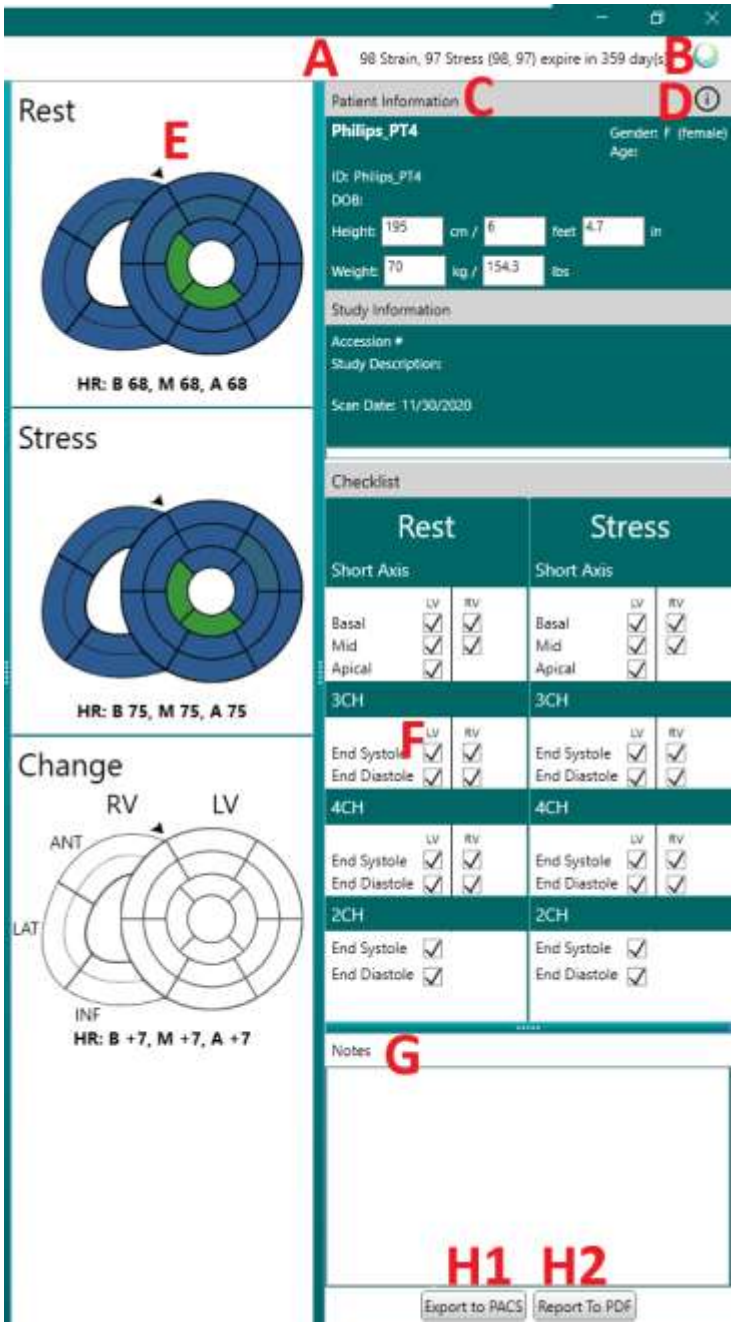


Figure 3-13 – Overall information about the current exam is shown on the right-hand side of MyoStrain

A. **Exam License Information** – Provides information about the remaining exam licenses available to the workstation. Shows the overall number of Strain/Stress remaining, then the number of exams expiring next, along with the number of days remaining for those exams.
B. **About Menu**- Clicking on this icon displays the About menu.
C. **Patient Information** – General information regarding the patient being analyzed. This data is automatically populated from data available on the DICOM images used to store the SENC image data.
D. **Additional Information** – More details regarding the currently displayed patient's information is available by clicking on the I icon shown here.

E. **AHA Models** – Displays strain data in a visual format. Hovering over a segment will display the numerical strain value for that segment.
F. **Checklist** – This provides a visual checklist of the expected contours for a strain or stress exam. When a contour has been completed, a checkmark is placed in the appropriate box, and changes color when completed.
G. **Notes** – This section is a freeform textbox where any findings or notes relevant to the current analysis should be written. These notes are carried across the application and included in the reports exported at the end of the analysis.
H. **Export Buttons**
    1. **Export to PACS** – Begins the export process, with MyoStrain formatted images being created for export to a networked location for archival.
    2. **Export to PDF** – Begins the export process for the MyoStrain report. This is a local copy of the MyoStrain report, which can be viewed in the Report tab as well.

3.1.3.1 LICENSE AND EXAM CREDIT INFORMATION

MyoStrain is governed by the license information provided on activation. Information about the existing license can be seen in the upper-right hand corner of the screen and can be detailed by clicking the Myocardial Solutions logo found below the X of the application window. The license can also be viewed and updated from this menu.

The number of remaining exams is shown in the title bar next to the Myocardial Solutions logo. The title bar will change color to alert the user when the license is close to expiration. Options in the User Interface Settings menu will allow the user to define how this title bar behaves. By default, the warnings are displayed as follows:

- **Yellow**- 30 or fewer days remaining, or 10 or less Strain/Stress exams.
- **Red** – Fewer than 5 Strain/Stress exams.

Simply opening MyoStrain will not consume an exam credit. Re-opening an older exam will also not consume an exam credit. Whenever images are received by the MyoStrain application as part of a new exam, an exam credit will be consumed.

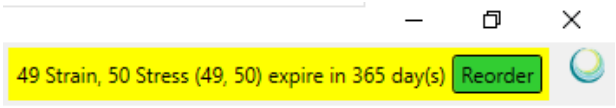


Figure 3-14: Yellow caution warning

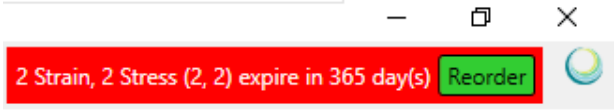


Figure 3-15: Red alert warning

Clicking on the **Reorder** button will launch the Reorder form and launch the Self-Check program as well. These warnings can be modified from the **User Interface Settings** menu under the **Alerts** tab (Section **Error! Reference s ource not found.**).

3.2 THE MYOHEALTH® REVIEW TAB

Whenever a previously analyzed dataset is opened in MyoStrain for review (or whenever the **MyoHealth® Review** button is clicked), the MyoHealth Review interface presents more detailed information gathered during the analysis. These measurements, such as Traditional Global Measurements, are available to the analyst during the

analysis but are not necessary to conduct an accurate analysis of the MyoStrain SENC images. Additional visualization features such as Polar Plots and the 3D Model can also be viewed here.

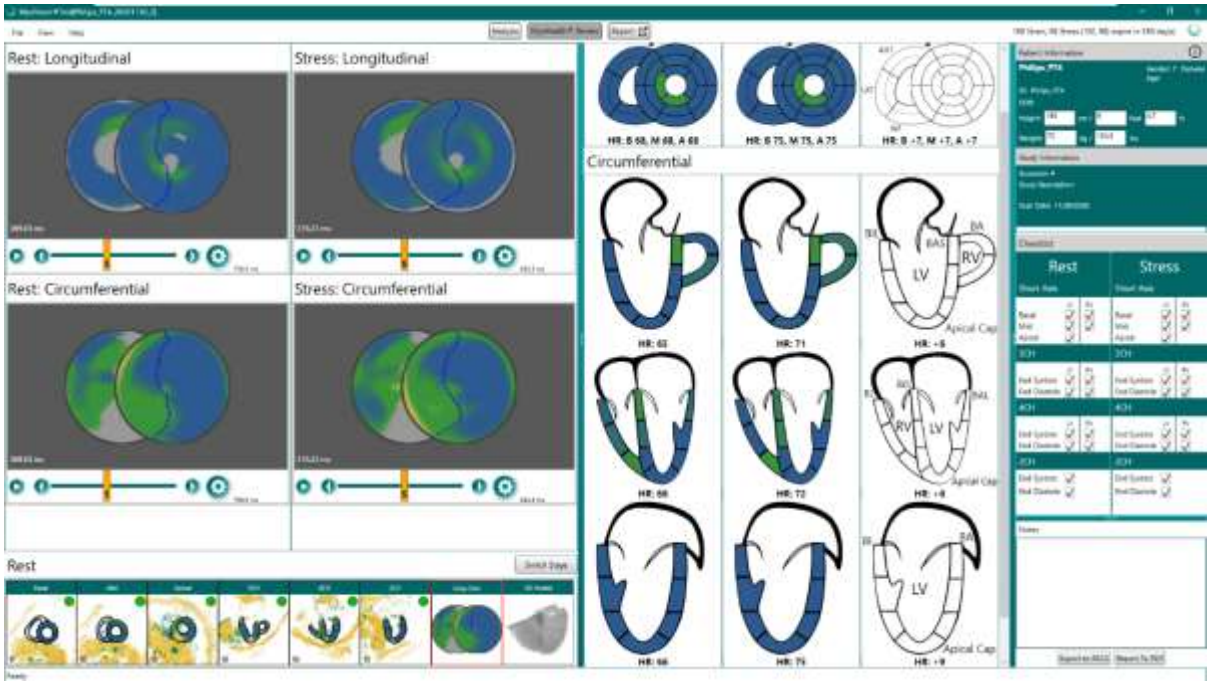


Figure 3-16: Overview of the MyoHealth® Review tab during a Stress exam.

More detailed information regarding the MyoHealth® Review tab can be found in Chapter 11.

3.3 THE MYOSTRAIN REPORT TAB

The Report tab is the 3rd window of the MyoStrain software, which shows the information collected during the analysis in an easy to read and interpret report. The information shown here is identical to the report exported as a PDF using the Report to PDF feature and included as part of the default DICOM series sent back to PACS as part of a typical analysis protocol.

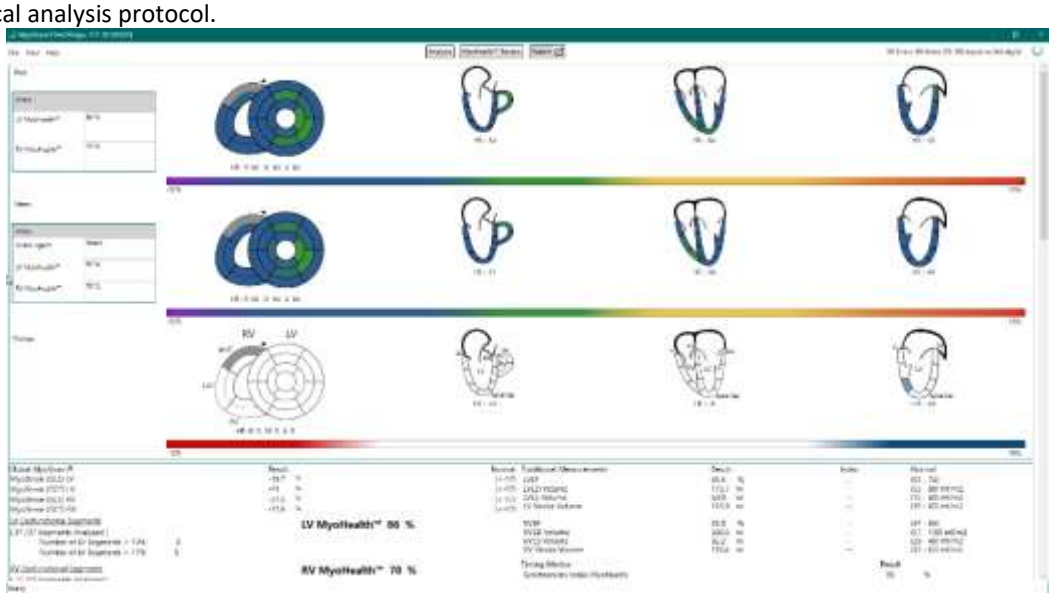


Figure 3-17: Layout of the Report section during Stress Mode

Additionally, the report can be viewed simultaneously during the analysis as a pop-out window. Clicking the pop-out icon in the Report button will separate the report and make it viewable when using the Analysis or MyoHealth Review tab. More information about the report can be found in Chapter 7.

NOTE: Some derived calculations will not appear on the pop-out version of the MyoStrain/MyoStress report. The Timing Metrics group is not displayed on the pop-out but is available in the Report section itself.

3.4 LICENSE AND EXAM CREDIT INFORMATION

MyoStrain is governed by the license information provided on activation. Information about the existing license can be seen in the upper-right hand corner of the screen and can be detailed by clicking the Myocardial Solutions logo found below the X of the application window. The license can also be viewed and updated from this menu.

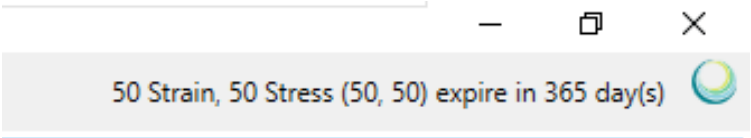


Figure 3-18: Software license with 50 Stress and 50 Strain exams left that expire in 1 year.

3.5 APPLICATION TOP LEVEL MENUS

The **File** menu in the upper-left hand corner of the program provides a few options focused on managing exam data. This is intended for revisiting a previously performed exam, or to close/save a current exam. Each entry labeled with a * will consume an exam credit when successfully run. The options for the File menu are as follows:

- **New Exam***– Clears all data currently loaded into the MyoStrain application and displays the Select Your Exam screen.
- **New Exam from Worklist* -** Opens an in-application version of the MyoWorklist to create new exams.
- **New Exam from Folder*** – Opens a file navigation window which imports all images contained in a folder. MyoStrain will attempt to organize the data based on information available in the DICOM header (data will be organized based on Stress Stage and view)
- **Open Analyzed Exam** - Opens a file navigation window to open an old exam.
- **Open Recently Analyzed Exams** – Displays a list of up to 10 previously performed exams
- **Export** –
    - **Export Anonymous** - Exports an anonymized copy of all available measurements, reports, and images from the current analysis.
    - **Export Data** - Exports a .csv or .xml file containing all raw strain values from all stress levels recorded during the exam. Please refer to section 7.6.3 for more details regarding saving this file.
    - **Export to DICOM -** Exports a copy of all data specified in the Export to DICOM Settings menu to a local folder. The data is exported in DICOM format, which can be viewed with a DICOM viewer or stored in PACS manually. Refer to section 3.5.5 for more information on what is exported.
    - **Export to PACS -** Pushes a copy of all the data specified in the Export to DICOM Settings menu to a selected PACS server. Configured servers will appear in a nested menu when selected. Refer to section 3.5.5 for more information on what is exported.
    - **Report to PDF** - Exports a .pdf file containing the Report. The Stress Report will also contain a copy of the Strain report. Please refer to section 7.6.3 for more details regarding saving this file.
    - **Image** –

        - **Analysis -** Exports an image capture of the currently displayed image in the **Analysis Window**. Adjustments to the image created can be done through the **Image and Video Settings** option in the **Setup** Menu.
        - **3D Model –** Available on the **MyoHealth Review** tab, this exports images of each version of the 3D model at systole. A folder is created containing the JPG formatted images in the location selected.
        - **Polar Plots -** Available on the **MyoHealth Review** tab, this exports an image of all available versions of the polar plots at the current timeframe (Defaults to Systole). A folder is created in the selected path to store these JPG format images.
    - **Video** –
        - **Analysis** - Exports a video of the currently displayed slice in the **Analysis Window.** Adjustments to the video created can be done through the **Image and Video Settings** option in the **Setup** Menu
        - **3D Model** - Exports a video of each available 3D model from beginning to end into a folder specified in the export menu.
        - **Polar Plots** - Exports a video of each polar plot view into a folder specified in the export menu.
- **Rename Exam** - Changes the default name of the exam displayed in the title bar, as well as the exam data folder created during the study. Note: Renaming an exam may not automatically update the file export path, double-check where data is being exported before doing so
- **Save Exam** – Saves the current exam.
- **Close Exam** – Saves, then closes the current exam. This clears all data currently loaded into MyoStrain.
- **Reorder** – Opens a pop-up menu which will begin the Reorder process. Please note that launching this feature will require the self-check to run, which may take a few minutes to complete.
- **Show Exam Licenses** – Opens a pop-up menu which displays all active MyoStrain exam licenses.
- **Setup** –
    - **Local Export Settings –** Opens the Local Export Settings submenu. Please refer to section 3.5.4 for more detailed information.
    - **DICOM Export Settings –** Opens the DICOM Export Settings submenu. Please refer to section 3.5.5 for more information.
    - **Application Settings**
        - **Self-Check -** Starts the Self-Check. Please visit section 2.2.1 for more information.
        - **Analysis Settings** – Launches the User Interface Settings in the Workflow tab, which will modify how MyoStrain analyzes images.
- **Exit** – Closes the program. MyoStrain will save any changes made to the currently opened exam, then close the Analysis Window. If the Dicomizer program is running, it will close after the dataset being processed is complete. Clicking the X in the upper-right corner of MyoStrain will perform the same action.

NOTE: The exam data file is a single DICOM image which contains information related to exam inside the DICOM header for RIS and external PACS applications.

3.5.1 **OPEN ANALYZED EXAM**

MyoStrain is backwards compatible with exams created in MyoStrain starting with version 5.2.4. Opening an old exam will not consume an exam credit. Once opened, an exam is editable and fully modifiable.

NOTE: Modifications to exams imported from older versions of MyoStrain should be reviewed for mesh completeness before exporting exam information.

3.5.2 OPEN RECENTLY ANALYZED EXAM

MyoStrain keeps track of the 10 most recently analyzed exams in a list under this File menu option. Clicking on any of these entries will open that analysis. This action does not consume an exam credit.

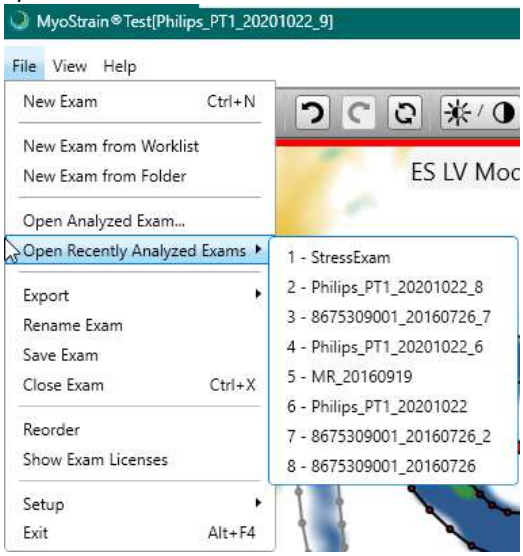
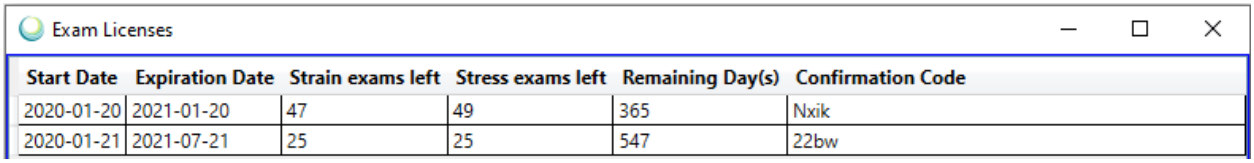


Figure 3-19: Recently Analyzed exams list

3.5.3 SHOW EXAM LICENSES

In addition to the title bar, exam license information can also be viewed using this option from the **File** menu.



Start Date	Expiration Date	Strain exams left	Stress exams left	Remaining Day(s)	Confirmation Code
2020-01-20	2021-01-20	47	49	365	Nxik
2020-01-21	2021-07-21	25	25	547	22bw

Figure 3-20: Exam Licenses added to MyoStrain with their expirations

Each software license runs independently, and MyoStrain will pull exams from the license code that is scheduled to expire first. License codes which have expired will not be displayed in this list.

3.5.4 LOCAL EXPORT SETTINGS

The **Local Export Settings** menu found in the **File>Setup** menu contains three menus of options that changes how MyoStrain exports data for use outside of the application on the local workstation. These settings can also be updated when exporting a video or screenshot by pressing the **Show Advanced Settings** button seen in Figure 3-22.

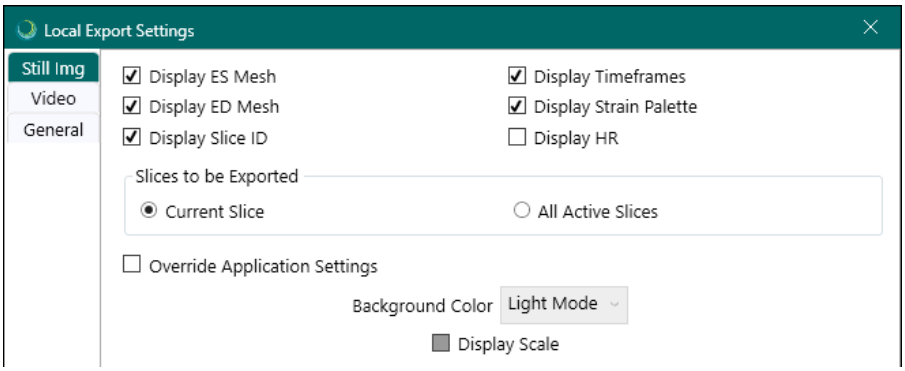


Figure 3-21: Default Video/Screenshot export settings

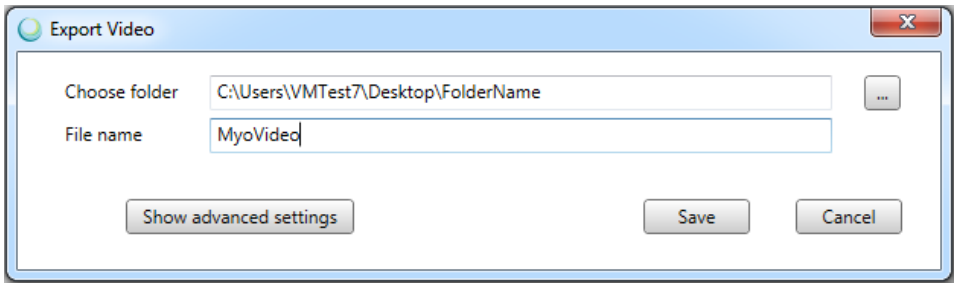


Figure 3-22: Video Export dialog box

Exported videos and screenshots will be exporting using the settings found in the **Video** and **Still Img** tabs respectively. The **General** export settings change how data files are exported.

- **Still Img And Video**
  - **Display ES Mesh** – When checked, the mesh drawn at End-Systole will be included in the output.
  - **Display ED Mesh** - When checked, the mesh drawn at End-Diastole will be included in the output.
  - **Display Slice ID** - Hides or displays the view information typically seen in the upper-left corner of the **Analysis Window**.
  - **Display Timeframes** - Enables or disables the phase/timeframe counter in the lower-left corner of the active slice.
  - **Display Strain Palette** – Hides or shows the strain scale and legend on the right side of the analysis window.
  - **Display HR** – The Heart Rate can also be included or excluded from video/image output.
  - **Slices to be Exported**
    - **Current Slice –** Only export the displayed slices.
    - **All Active Slices –** Export all active slices (green radio button icon)
  - **Override Application Settings –** When enabled, images and video exported will use these settings instead of what MyoStrain is currently displaying.
    - **Background Color -** sets the default background color of slices/images exported from MyoStrain.
    - **Display Scale -** This manages whether the measurement scale shown on the left side of the image will be included.
- **Video Menu**
  - **Video Encoding/Container–** Changes the format which MyoStrain will export videos.
  - **Override Application Settings**
    - **Default Speed –** When enabled, the default playback speed of the videos exported will use this speed instead of what's being used in MyoStrain currently.
- **General**

- **CSV Delimiter –** Changes the token used to separate values in CSV documents exported by MyoStrain. Defaults to comma.

Figure 3-23: General tab of the Local Export Settings menu

3.5.5 DICOM EXPORT SETTINGS

The DICOM Export Settings menu found in the File>Setup menu allows changes to what information is exported from MyoStrain when DICOM images are requested. This affects images exported to PACS, or images exported to the local machine using the File>Export>Export to DICOM feature.

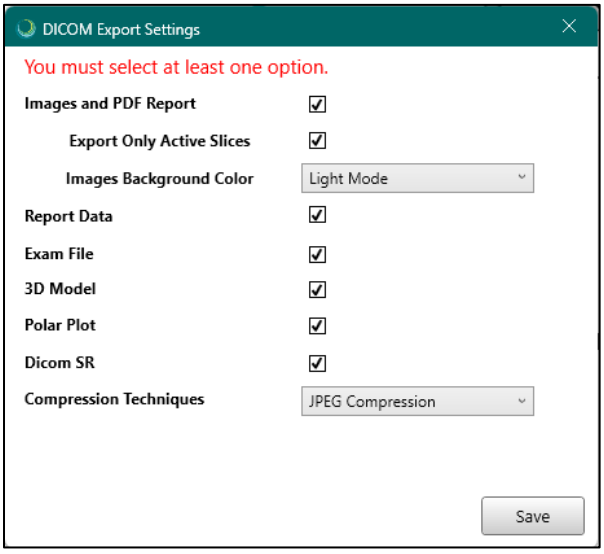


Figure 3-24: DICOM Export Settings Menu

1. **Images and PDF Report** – This enables/disables the MyoStrain/MyoStress report as well as the MyoStrain formatted images with contours.
    a. **Export Only Active Slices** – With this enabled, only the slices which are being reported on in the MyoStrain/MyoStress report are exported to DICOM.
    b. **Images Background Color** – This sets the background color of MyoStrain formatted images sent to DICOM. By default, all MyoStrain images are archived with a light background (regardless of application display mode).
2. **Report Data** - When enabled, this sends a DICOM file with all measurements and other reported data stored in the DICOM header using Myocardial Solutions Private DICOM tags.
3. **Exam File** – Sends a copy of the exam file (.myo) wrapped in a DICOM file for storage on PACS or disk. When sent to the MyoStrain workstation through the Worklist, the exam file is recreated.
4. **3D Model -** Shows the heart at the systolic timeframe rotated around the central axis, with snapshots taken at 15-degree intervals.
5. **Polar Plots** - Shows the polar plot model available at all timeframes for each stage and strain orientation.

6. **Dicom SR –** When enabled, this generates a structured DICOM report, which is separate from the MyoStrain/MyoStress report. This is generally used for automation and clinical reporting purposes.
7. **Compression Techniques –** This changes how images sent from MyoStrain to a networked node are compressed. Below are the options available and their associated transfer syntax (0002,0010)
    a. JPEG Compression – 1.2.840.10008.1.2.4.50 (JPEGBaseline)
    b. RLE Compression – 1.2.840.10008.1.2.5 (RLELossless)
    c. No compression – 1.2.840.10008.1.2 (ImplicitVRLittleEndian)

3.5.6 ANALYSIS/USER INTERFACE SETTINGS MENU

The **Settings** menu found in the **File>Setup** menu (and also in **View>User Interface Settings**) contains options that allows users to customize how MyoStrain displays data. Pressing the Save button in the lower-right hand corner of the window will save any modifications made. This menu contains 5 submenus with different controls in each.

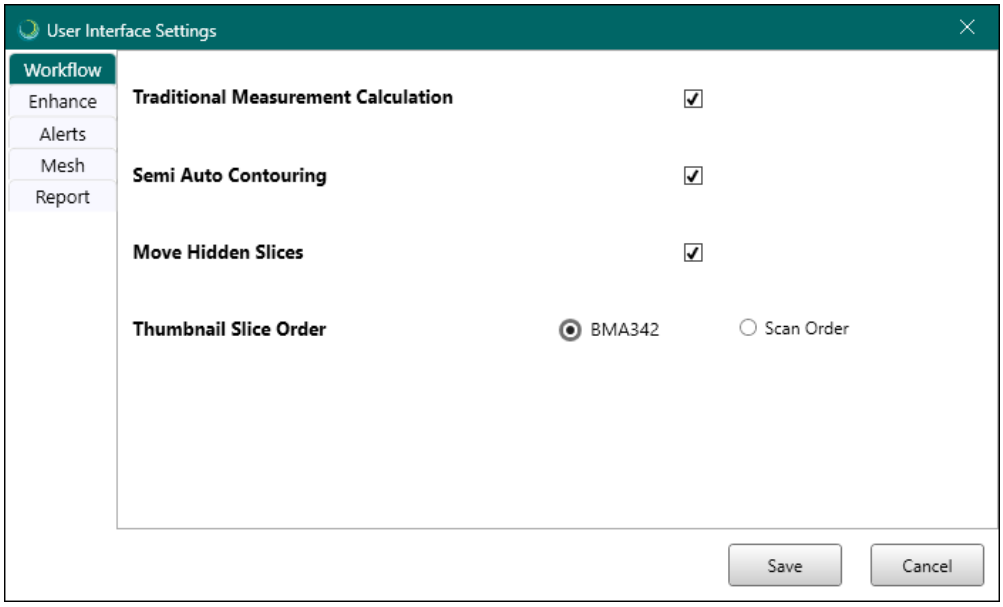


Figure 3-25: User Interface Settings menu found in MyoStrain's File menu

- **Workflow Tab**
    - **Traditional Measurement Calculation –** Enables or disables the collection of "Traditional Measurements" in reporting. With this option off, End Diastolic meshes can no longer be drawn, and measurements such as "LVEF" and "LV Stroke Volume" will be disabled.
    - **Semi Auto Contouring -** Enables or Disables Semi Auto Contouring. Please refer to section 9 for more information.
    - **Move Hidden Slices -** Enabled by default, any image in the **Image List** which was manually hidden will be pushed to the end of the list. When disabled, hidden images will be shown as greyed out.
    - **Thumbnail Slice Order –** Changes the order in which the thumbnails in the **Image List** are displayed.
        - **BMA342** - Displays images in the following order: SAX Basal, SAX Mid, and SAX Apical, followed by LAX 3Ch, LAX 4Ch, and LAX 2Ch. Same order as displayed in the report.
        - **Scan Order** - Displays images based on the order in which they were generated by the MRI scanner. Earliest scans are displayed first.
- **Enhance Tab**
    - **New Exam Default –** Changes the behavior of the New Exam button seen in the upper-right corner of the Analysis page.

        - **From Folder –** Will display the "New Exam From Folder" dialog box when the New Exam button is pressed.
        - **From Worklist –** Will display the MyoWorklist inside MyoStrain, and new exams can be previewed and launched from there.
    - **Analysis Window Background –** Switches the Analysis Window to display with a white background (default), or a dark background. This does not affect the rest of the application, just the window where MyoStrain images are displayed.
    - **Display Relative Planes –** Enable or disable the display of the reference plane shown on thumbnails when a slice is active in the Analysis Window.
    - **Display Scale -** Enables or disables the measurement scale shown on the left-hand side of the Analysis Window
    - **Display Header-** Current analysis tool active, or the next step in the SAC analysis process.
    - **Brightness Contrast Defaults –** This sets the default brightness/contrast values when importing a dataset. Defaults can be set for both the dark and light analysis window backgrounds.
    - **Application Display Mode –** This dropdown changes the background color schema of MyoStrain to either Dark mode or Light mode.
- **Alerts Tab**
    - **Exam Countdown Warning Number –** If either the strain or stress exam count drops below the specified values, the Exam Countdown seen in the upper-right corner of MyoStrain will display Yellow.
    - **Exam Countdown Risk Number –** If either the strain or stress exam count drops below the specified values, the Exam Countdown in the upper-right corner of MyoStrain will display Red.
    - **Application Expiration Warning –** If the application license expires within the specified number of days, a warning pop-up will display each time MyoStrain is launched.
- **Mesh Tab**
    - **Enable Custom Mesh Settings –** Off by default, enabling this will change the way meshes are displayed to the end-user.
    - **Mesh Transparency –** The lower the value, the more transparent the mesh will display. No mesh transparency is enabled by default.
    - **Mesh Point Thickness –** Adjusts the thickness of the individual pins on each contour.
    - **Mesh Line Thickness -** Adjusts the thickness of the lines between each pin on each contour.
    - **Mesh Color Selection –** Allows for the customization of mesh colors for Light and Dark analysis background colors.
        - **Mesh Color (A) –** Color of the lines defining the epicardium and endocardium. When the LV contour is active, the RV will appear inactive, and vice-versa.
        - **Inactive Mesh Color (B) –** Color of contours which cannot be modified
        - **Points (C) –** Color of the pins surrounding the myocardium, this also includes the handlebar in the center of the blood pool.
        - **Reference Marker (D) (SAX Only)-** Marks the location of the LV RV Anteroseptal junction. This marker only appears on Short-Axis images.
        - **Apex Marker (E) (LAX Only) –** Marks the location of the apex point on a Long-Axis image. This point only appears on Long-Axis images.

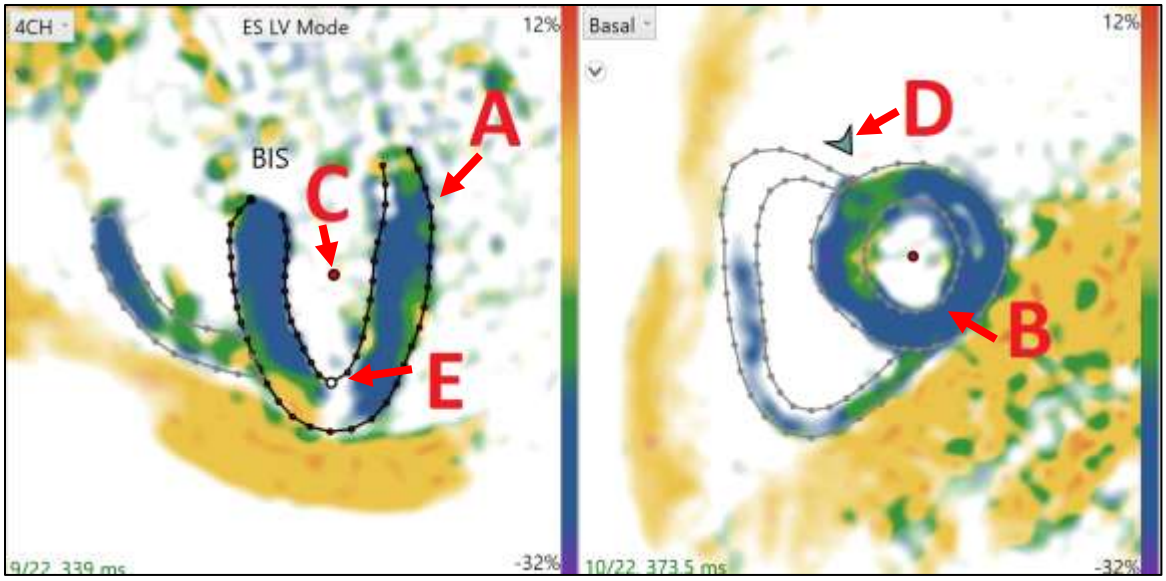


Figure 3-26- Mesh Color customization references during Analysis

- **Report**
  - **Report Type –** Changes the display of the default Long-Axis models shown in the Report Tab and MyoHealth Review tab.
  - **Report Logo –** A custom logo can be applied to the upper-right corner of the PDF report generated by MyoStrain. This logo is included on any reports created by MyoStrain.
  - **Exported Report Template –** The layout of the PDF report can be changed to one of several defaults. Examples of these layouts can be found in section 3.5.9

3.5.7 REPORT TYPE

By default, MyoStrain displays Long-Axis images in the 3/4/2 Chamber View model. If an Analyst or Reviewer wishes to display the Long-Axis data in the same way Short-Axis data is shown, the **Bullseye Plots** option should be selected from the **Report Type** dropdown menu. This option will not affect the Analysis tab's layout.

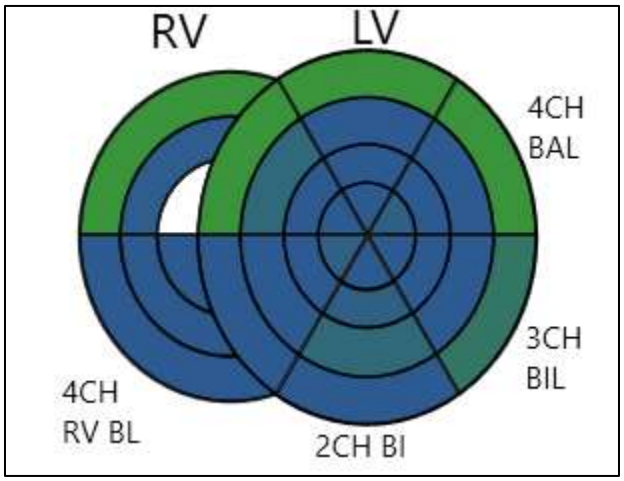


Figure 3-27: The Bullseye Plots display option shown in the User Interface for Report and MyoHealth Review

3.5.8 **REPORT LOGO**

This sub-section allows customization of the MyoStrain/MyoStress report. Using the **Browse** button, a .jpg or .png logo can be imported and displayed in the upper-right corner of the report.

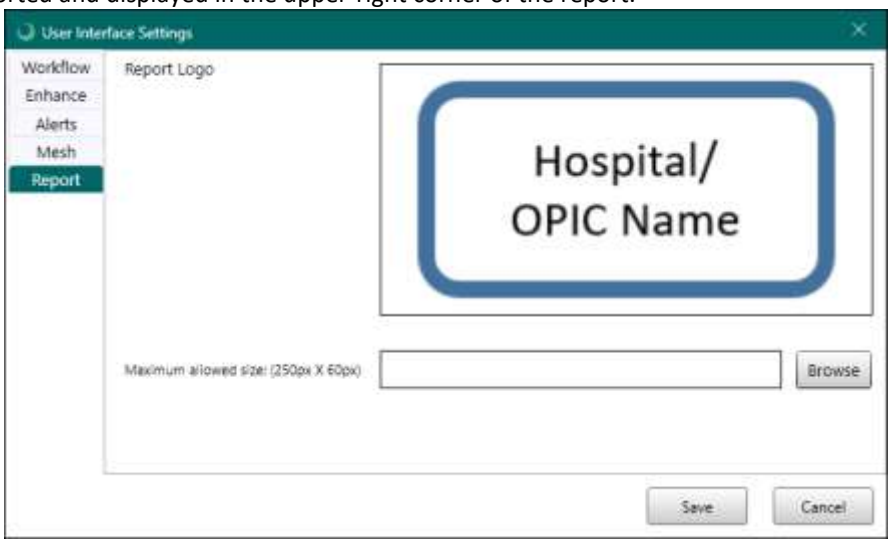


Figure 3-28: Logo selected for use with the MyoStrain report

After the logo has been uploaded, click the Save button to finalize the changes. The logo will appear in the upper-right corner on all pages of the report created at the end of MyoStrain analysis.

NOTE: Images which do not fit the 250x60 pixel window will be resized proportionally to fit in the allotted window.

Figure 3-29:Example image of the top of a MyoStrain report with a custom logo

3.5.9 **EXPORTED REPORT TEMPLATE**

In MyoStrain 6.1, there are a total of 2 different layouts for the exported PDF report (in addition to the customizable Report Logo). This template will be used for the MyoStrain/MyoStress report exported via DICOM, as well as the PDF paper copy. The version used in this manual is the application default (aside from below). The measurements displayed between each report type are the same; just the layout and positions are modified.

Figure 3-30: Non-Default (Template 1) MyoStress report layout available for export

3.5.10 VIEW MENU

Next to the **File** menu at the top of the MyoStrain application, another menu labeled **View** is available.

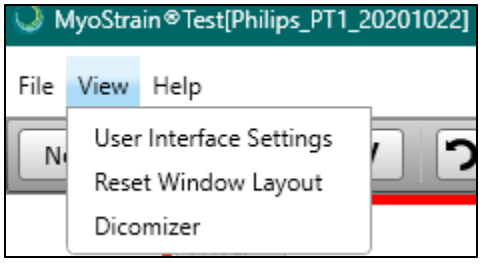


Figure 3-31- View Menu

- **User Interface Settings** – See section **Error! Reference source not found.** for more information, this menu l inks to the Enhance tab of the User Interface Settings menu.
- **Reset Window Layout** - Resets the User Interface (GUI) to its default settings.

- **Dicomizer** – Launches a separate window which tracks the upload progress of datasets being sent to PACS or other systems for archival or reporting purposes.

3.5.11 HELP MENU

Rounding out the 3 top level menu items of MyoStrain, the Help menu provides useful information about the application (such as the license and expiration dates).

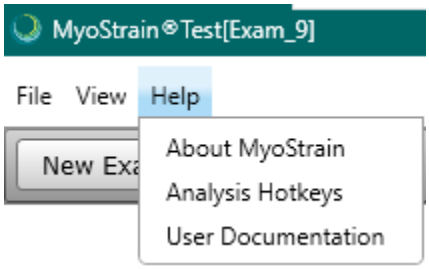


Figure 3-32: Help Menu displayed

- **About MyoStrain** – Displays the About menu (Figure 2-19)
- **Analysis Hotkeys –** Displays a list of quick reference keyboard hotkeys which can assist with analysis
  - **CTRL+Q –** Toggle between light-mode and dark-mode in the analysis window.
  - **CTRL+R –** Toggle between LV and RV analysis modes
  - **CTRL+S –** Set current timeframe as End-Systole
  - **CTRL+D –** Set current timeframe as End-Diastole
  - **CTRL+Z –** Undo most recent action
  - **CTRL+Y –** Redo most recent action
  - **CTRL+(+) –** Zoom-in
  - **CTRL+(-) –** Zoom-out
  - **CTRL+ScrollWheel –** Zoom in/out
  - **CTRL+Shift+ScrollWheel –** Pan image in Analysis Window
  - **Spacebar –** Start/Stop CINE playback
  - **CTRL –** Force Default cursor (Analysis mode mesh application tool)
  - **ENTER –** Accept SAC recommended mesh
- **User Documentation –** Displays a pop-up window with links to the User's Manual in addition to Video Tutorials which provide a visual demonstration of selected features in MyoStrain.

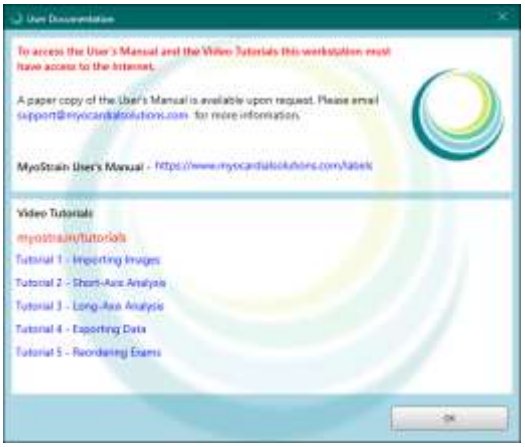


Figure 3-33: User Documentation Pop-up menu with links to video tutorials

3.6 APPLICATION WINDOW ADJUSTMENT

Portions of the MyoStrain application can be resized using the blue dividers seen throughout the program window. To increase or decrease the size of the **Image List**, **Analysis Window**, **Patient Information** or **Findings** sections, simply left-click and hold the 5 dots seen in the middle of the divider (Figure 3-34), then drag the divider to the desired location. The **Analysis Window** will automatically increase the size of the images being viewed to fill in as much available space as possible.

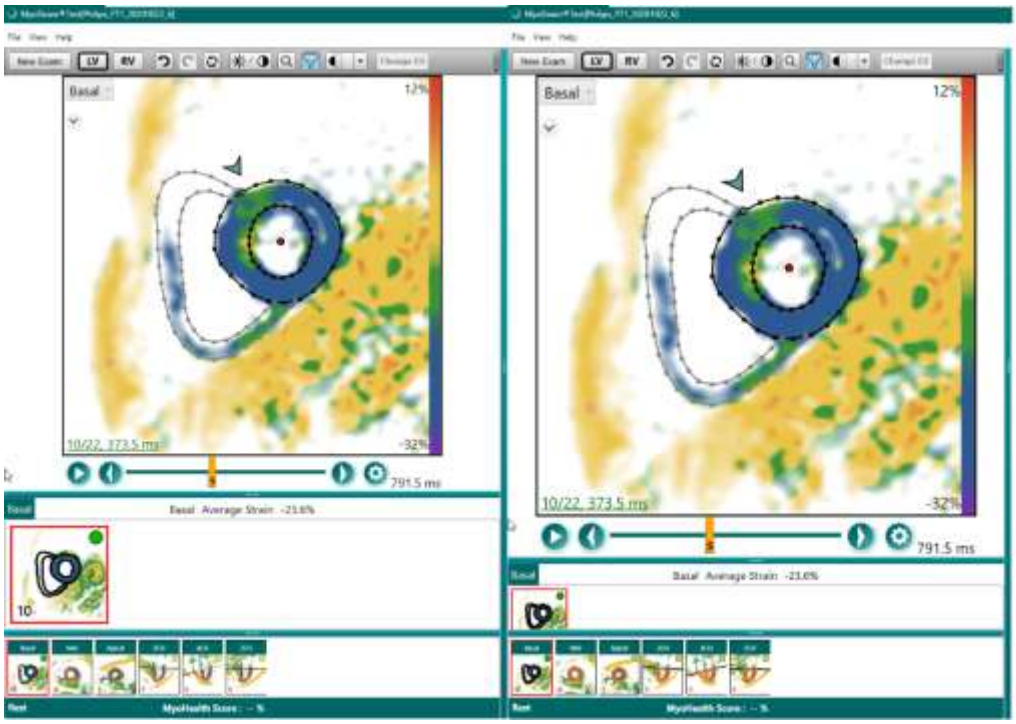


Figure 3-34: Resizing the Analysis Window by decreasing the size of the Image List

4. IMAGE QUANTIFICATION

This chapter provides a detailed walkthrough of the MyoStrain image quantification process. The procedure for measuring and quantifying strain on each view of the myocardium is the same between Strain and Stress exams. Please refer to Sections 5 and 6 for Strain and Stress exam workflow respectively.

Upon opening SENC formatted images from the MR scanner, MyoStrain will display colorized images of the patient's heart. These colors (shown in the color scale Strain Legend) represent the amount of motion (strain) measured at any given point of the myocardium. MyoStrain requires the user to identify/verify the current view and apply a mesh to the left ventricle near end systole to accurately measure peak myocardial strain. Additionally, traditional measurements can also be gathered using the same tool.

Use of Semi Auto Contouring will be covered in Chapter 9. It is imperative that each image is reviewed prior to applying or approving meshes to ensure accuracy in the analysis.

NOTE: When computing the strain after contouring the heart with a mesh, the strain measurements are confined within the mesh and several timeframes before and after the meshed timeframe. Timeframes used in mesh calculation are underlined and highlighted in green in the lower-right corner of the Viewing Window.

4.1 DRAWING THE LV MESH (SHORT-AXIS VIEWS)

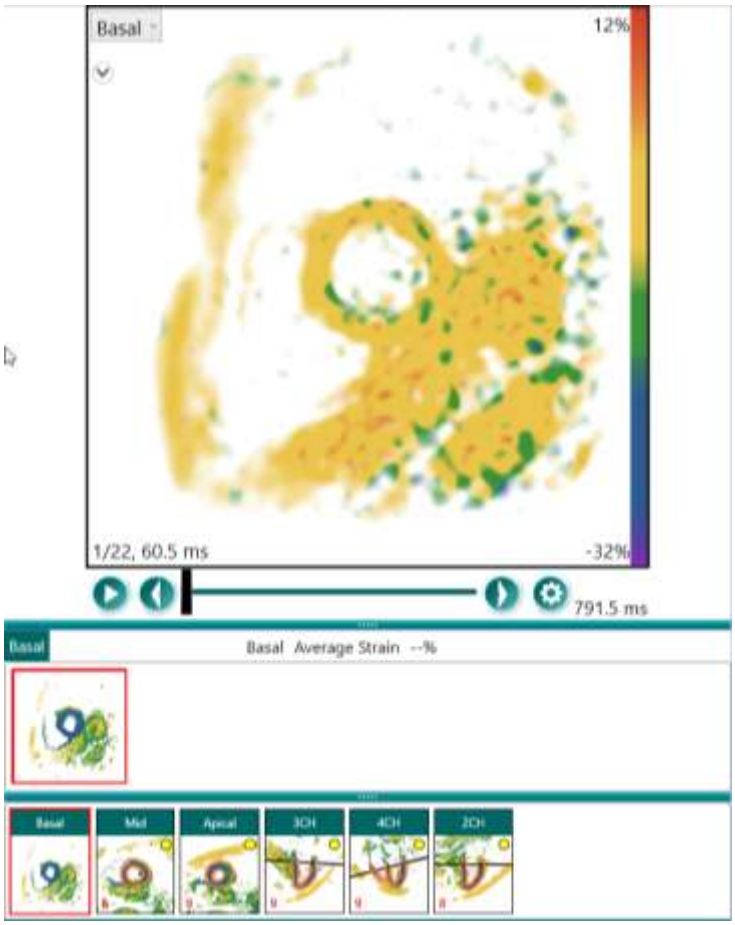


Figure 4-1: MyoStrain exam with three Short-Axis and three Long-Axis slices

1. To draw a short-axis mesh, select one slice in the **Image List** which shows a Basal, Mid, or Apical view.

    a. The bottom row of the **Image List** shows all available views, the top row shows all available slices for the selected view.

2. In the upper-left hand corner of the **Analysis Window**, use the **View Dropdown** menu to select what view is currently displayed. This will set the report to display the data gathered from the mesh in the correct location.

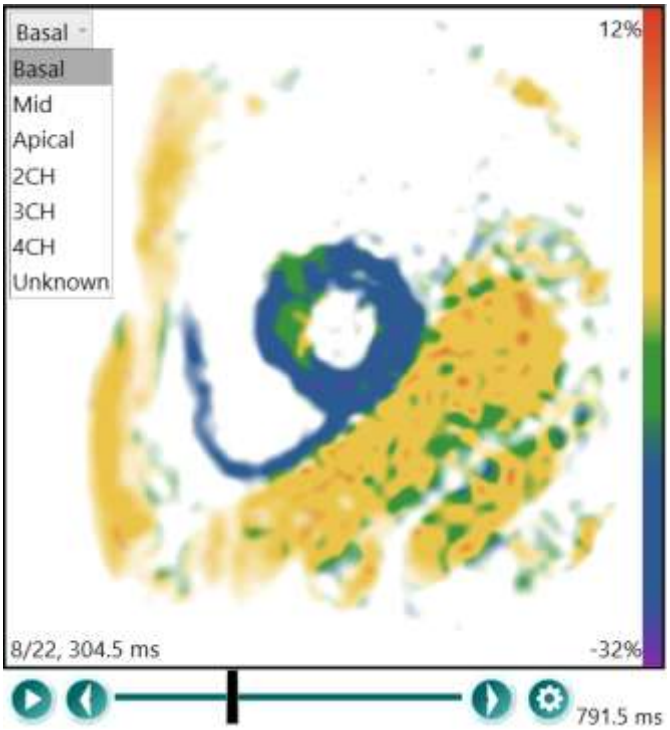


Figure 4-2: Selecting the appropriate view from the View Dropdown

3. Just below the **View Dropdown** menu is a second dropdown menu which tracks the patient's Heart Rate. This can be updated manually in cases where the heart rate was not read correctly.

4. If the image itself is too small, use the handlebars found on the right-hand side of the **Analysis Menu** and above the **Image List** to increase the size of the **Analysis Window** itself.

4.1.1 EPICARDIAL CONTOUR

1. Using either the CINE viewing buttons at the bottom of the image, your mouse scroll wheel, keyboard arrow keys, or the **Slice Navigator**, navigate through the slice to visually identify which image corresponds the most to end-systole.

2. Starting at the RV insertion point (anteroseptal), use your mouse to make at least 4 points clockwise around the epicardial contour by left-clicking the myocardial border and ending on the Inferoseptal RV insertion point.

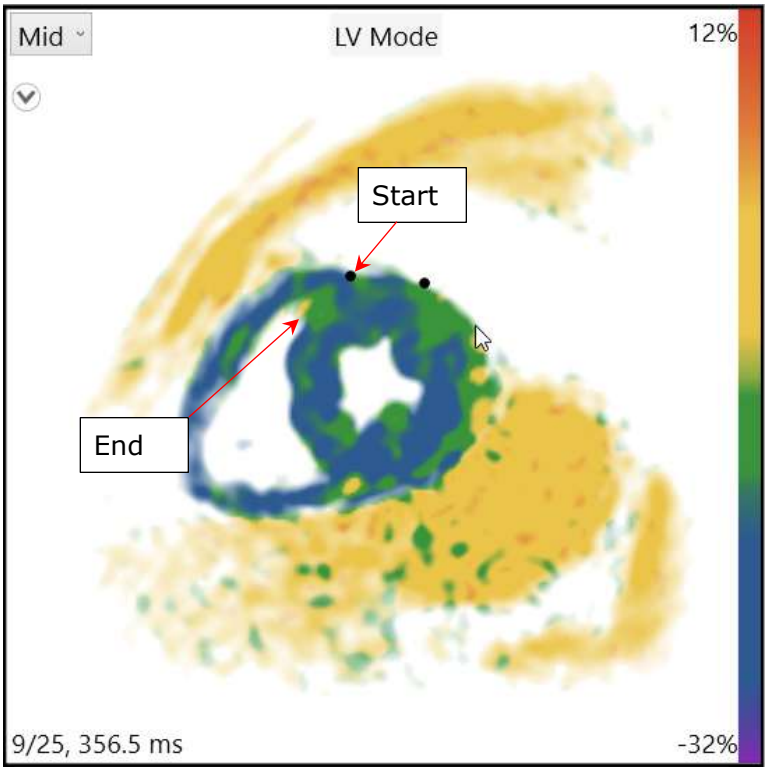


Figure 4-3: Beginning drawing the epicardial contour

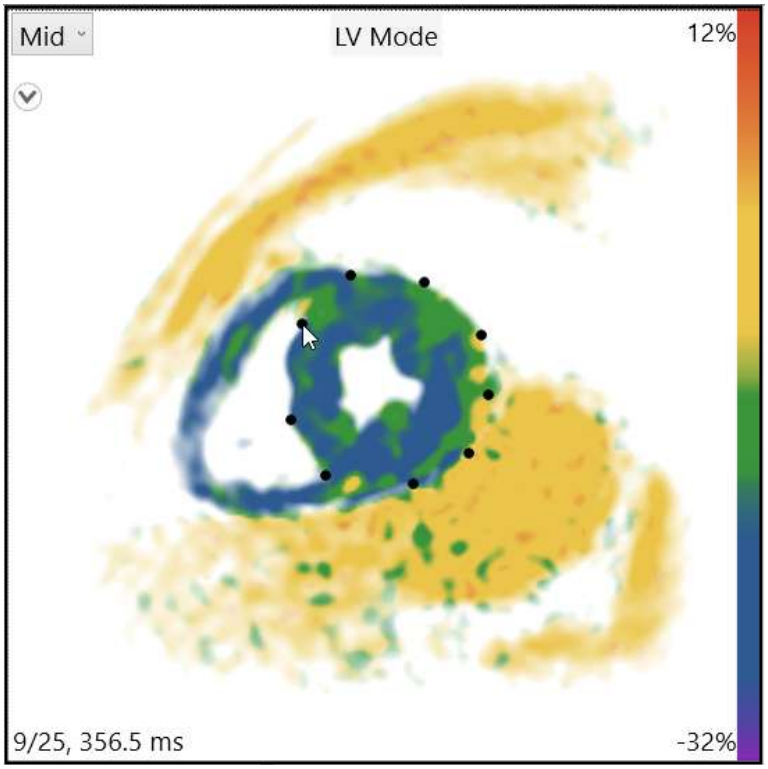


Figure 4-4: Double-clicking here will complete the epicardial contour

3. Double-click the last point of the contour near the starting contour point to complete the drawing.

4. A contour polygon will be created for the epicardium defining several points. The first point created will mark the RV connection point.

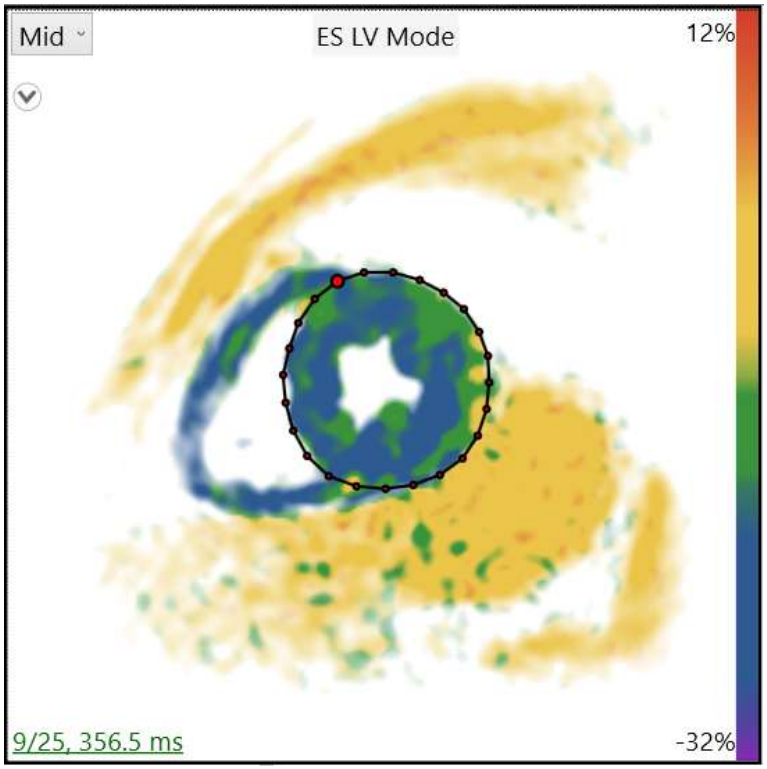


Figure 4-5: Completed epicardial contour

NOTE: Meshes can also be applied by tracing the epicardium while holding down the left-mouse button. Releasing the left-mouse button will complete the drawing.

4.1.2 LV MESH COMPLETION (ENDOCARDIAL CONTOUR)

Using the same drawing method, define the endocardial contour. Since the epicardial contour marks the position of relevant anatomical markers, the endocardial contour can be applied beginning at any point.

NOTE: Papillary muscles should be omitted from any contours.

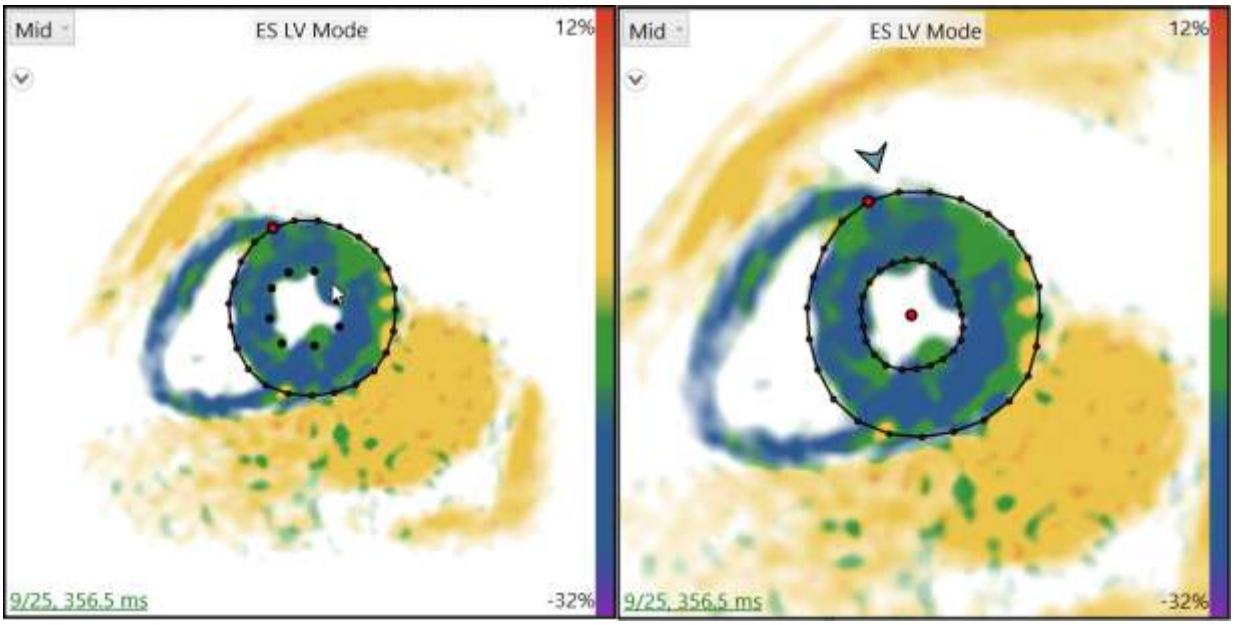


Figure 4-6: Completing the endocardial contour and the finished mesh with RV marker

After the endocardial contour has been added to the mesh, the MyoStrain software will zoom into the image and improve visibility. Ensure that the corresponding Short-Axis model in the **Measures** section is updated after finishing the mesh.

4.1.3 ADJUSTING THE MESH (SHORT-AXIS VIEW)

Once the mesh is applied, changes or updates to the mesh may be required. Common changes may be to adjust the location of the RV insertion point, or to adjust a minor region of an epicardial contour.

1. The blue arrow should be marking the RV insertion point (anteroseptal, outside of RV blood pool)  .

2. You can rotate the mesh by clicking and holding the insertion point arrow and moving it to its appropriate location.

3. If any individual points need to be moved to better fit the myocardium, use your left-mouse button to reposition points on the mesh.

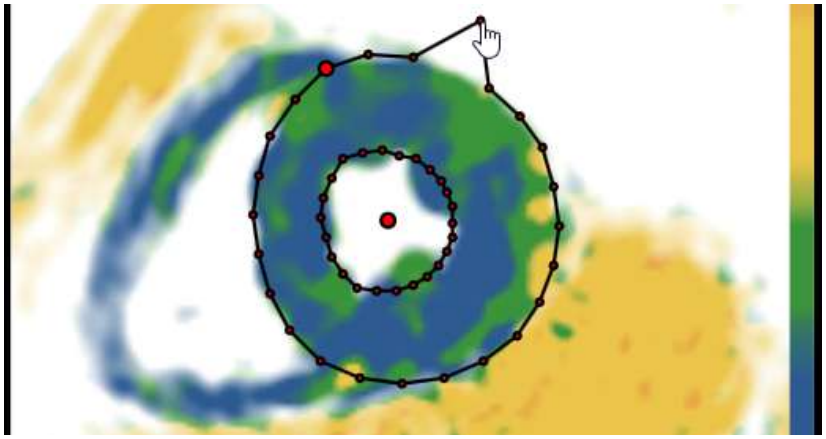


Figure 4-7: Example of a single point mesh correction

4. If a large section of the mesh's epicardial or endocardial contour points need to be redrawn, you may redraw a portion of the contour by left-clicking periodically near the existing mesh, then double-clicking to complete. Additionally, clicking and holding the left-mouse button will allow a contour to be traced onto the myocardium. The mesh will incorporate this new drawing into the existing mesh. (Figure 4-8).
5. If the mesh has been placed in an incorrect location after image rotation, the red dot shown in the center of the LV blood pool can be used to drag the mesh into a different location.
6. The **Undo**, **Redo**, and **Reset** buttons found in the Slice submenu will undo the most recent mesh action, redo the most recent mesh action, and reset the slice to its default state respectively.

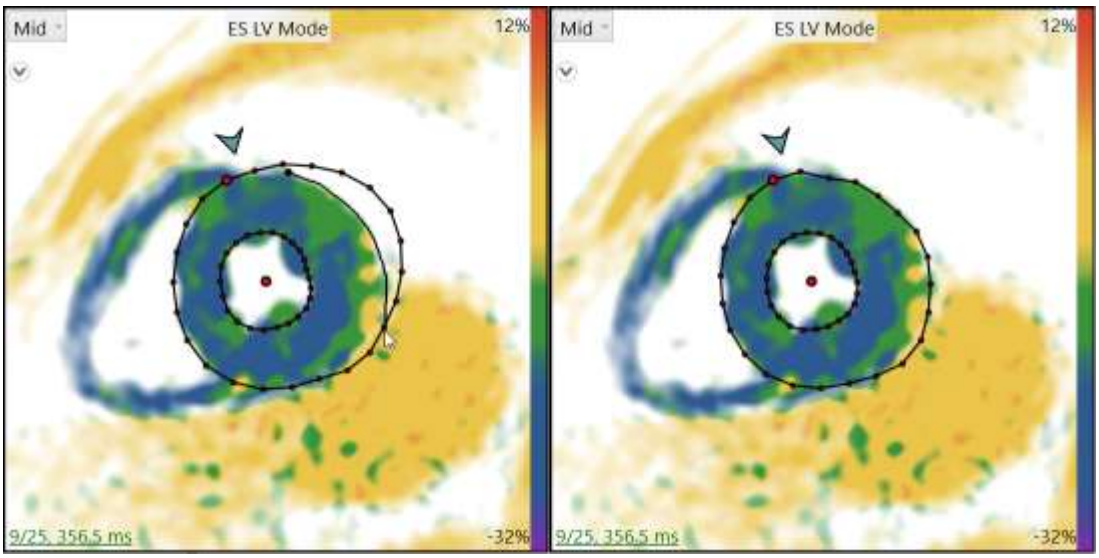


Figure 4-8: Mesh adjustment by drawing a new contour freehanded

4.1.4 **RV QUANTIFICATION (SA BASAL AND SA MID)**

After completing the LV mesh, the RV can be measured by adding additional contours to the existing LV mesh. Please note that Short-Axis RV quantification can only be performed on the Basal and Midcavity slices of the stack.

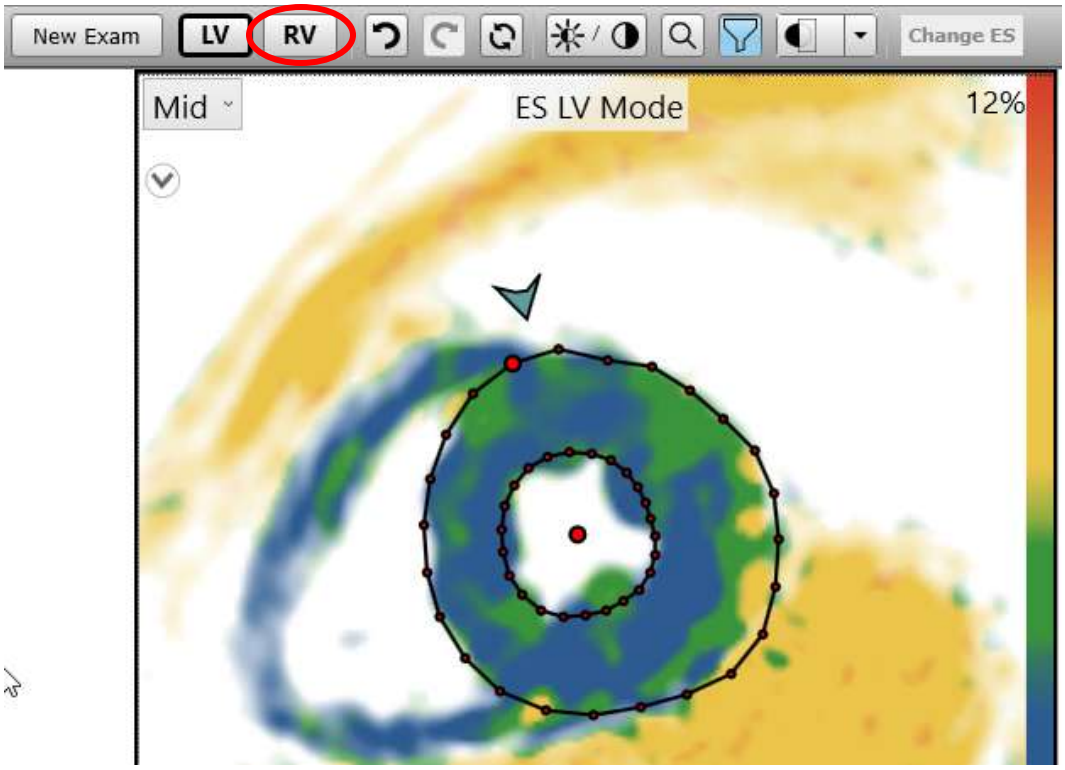


Figure 4-9: Clicking on the RV button after completing the LV mesh will enable RV contouring

First, enable the RV analysis tool by pressing the RV button at the top of the **Analysis Menu** (Figure 4-9). Then, starting at the RV anterior junction, use your mouse to identify the epicardial boundary of the RV wall. Left-clicking first on the RV anterior junction, click multiple times on the epicardial wall moving counter-clockwise, making the last point touch on the RV Inferoseptal junction. Double-clicking on the RV Inferoseptal junction will complete the contour on the RV and will attach itself to the existing epicardial LV contour.

NOTE: You can switch to RV analysis mode by pressing CTRL+R on your keyboard, or by right-clicking the Analysis Window and selecting RV Mode.

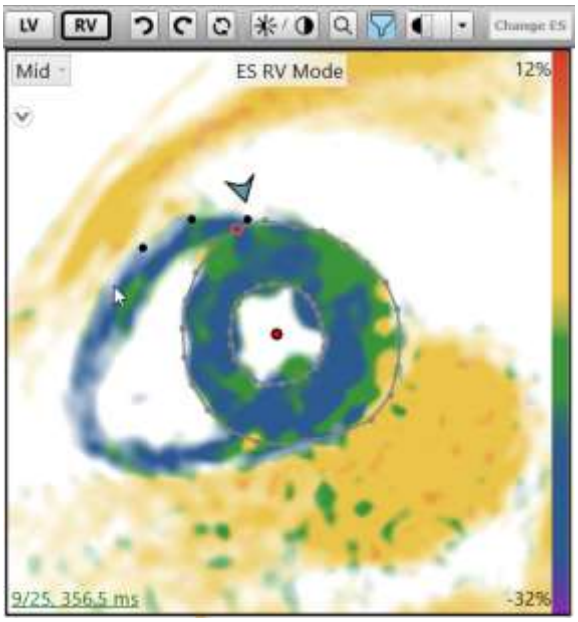


Figure 4-10: Beginning the epicardial RV contour

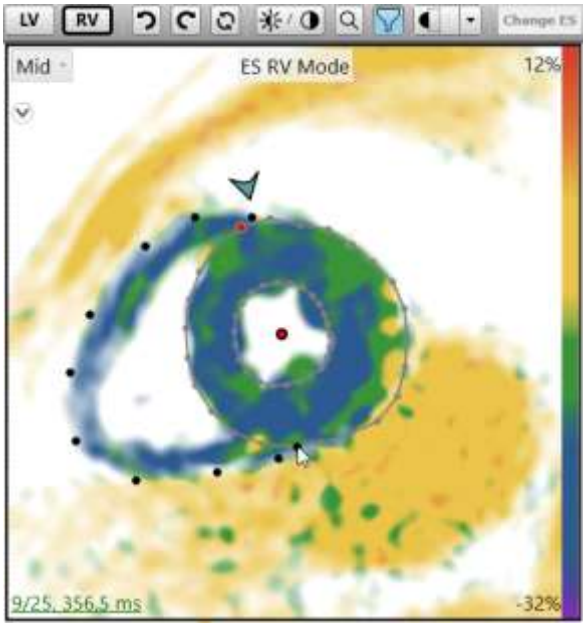


Figure 4-11: Double-clicking here will complete the epicardial RV contour

NOTE: You can also click and hold down the left-mouse button to draw a contour by tracing the epicardium or endocardium.

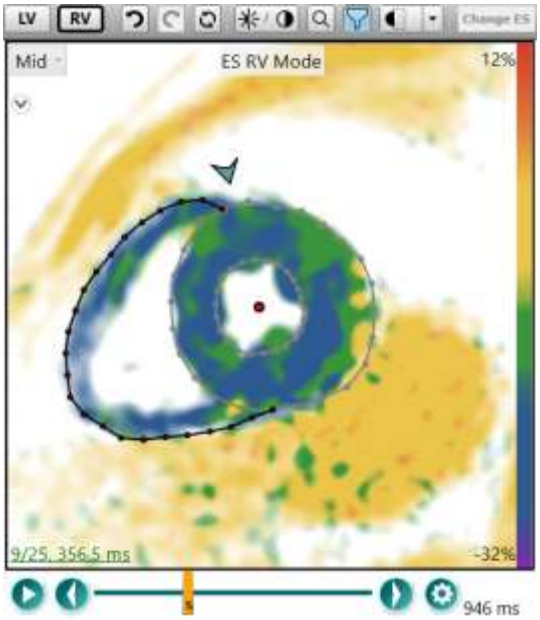


Figure 4-12: Completed RV epicardial contour

Using the same method as before, define the endocardial contour. Once complete, the RV mesh will be fully attached to the existing LV mesh, and measurements from the RV will be displayed in the Report.

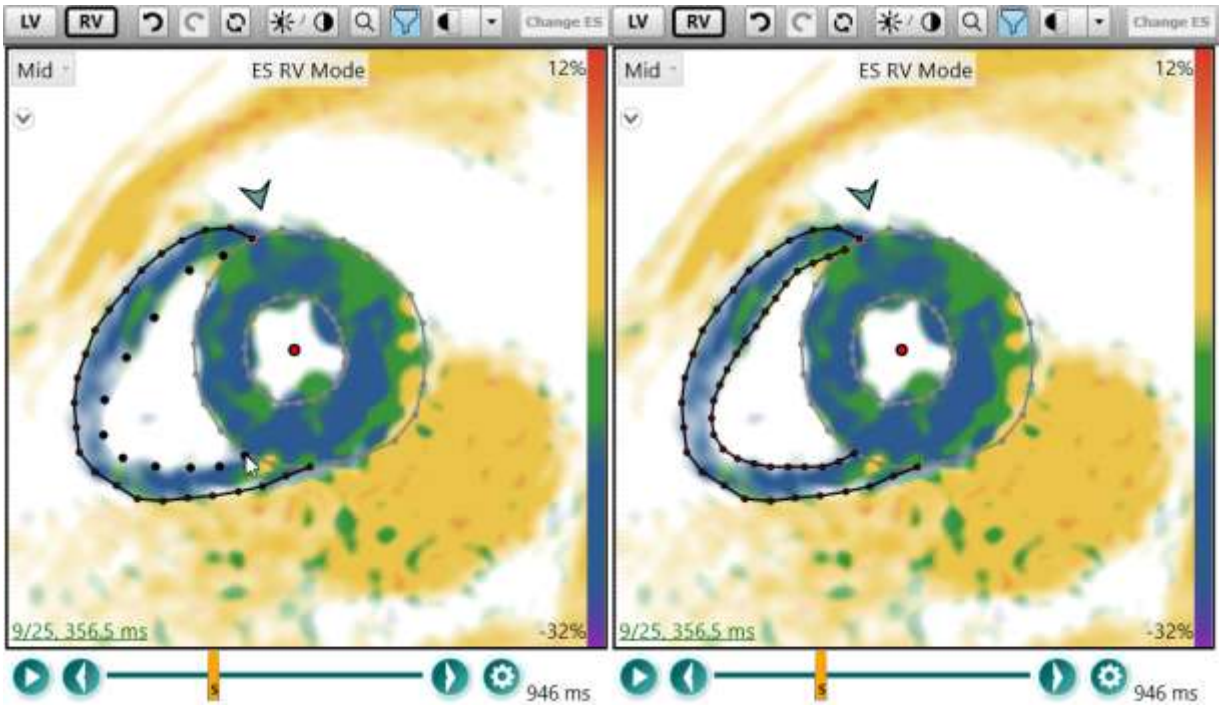


Figure 4-13: Defining the endocardial contour for a complete RV mesh

If adjustments need to be made to the mesh during or after completion, click the **Undo** button to erase the contour or mesh to try again.

4.2 DRAWING THE MESH (LONG-AXIS VIEWS)

1. To draw a long-axis mesh, select one slice in the **Image List** which shows a 2-chamber, 3-chamber, or 4-chamber view of the myocardium.

2. In the upper-left hand corner of the **Analysis Window**, use the **View Dropdown** menu to select what view is currently displayed. This will set the report to display the data gathered from the mesh in the correct location.

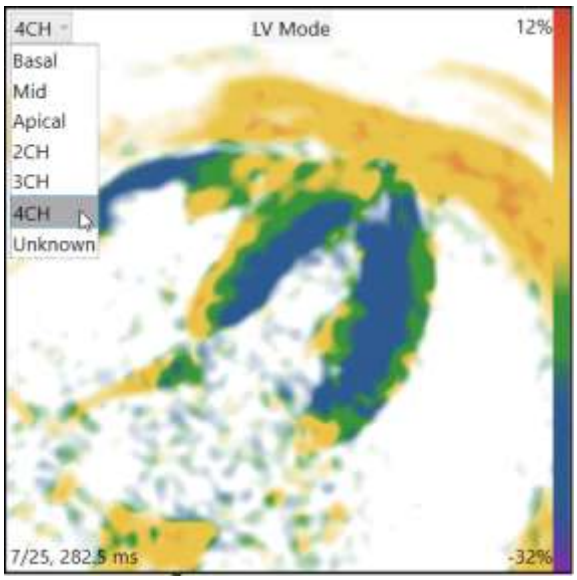


Figure 4-14: Selecting a Long-Axis view from the View Dropdown menu

3. In the upper-left hand corner of the **Analysis Window**, enter or update the patient's heart rate in the textbox below the view selector.

4.2.1 EPICARDIAL AND ENDOCARDIAL LV CONTOURS

1. Using the video playback buttons at the bottom of the image, your scroll wheel, or the **Slice Navigator**, look through the slice to visually identify which image displays best represents end-systole.

2. Starting on either side of the LV, use your mouse to make points around the epicardial contour by left-clicking periodically on the image. A minimum of 4 points must be used to draw this contour.

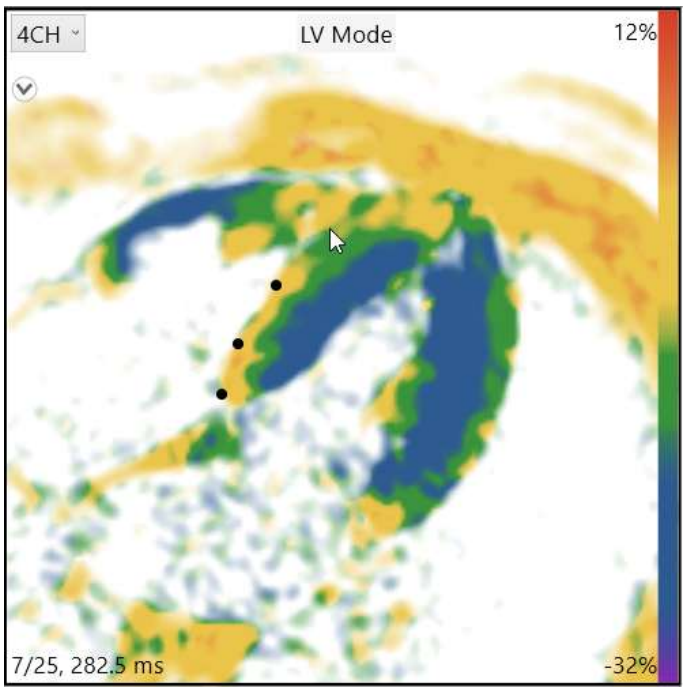


Figure 4-15: Beginning the epicardial contour

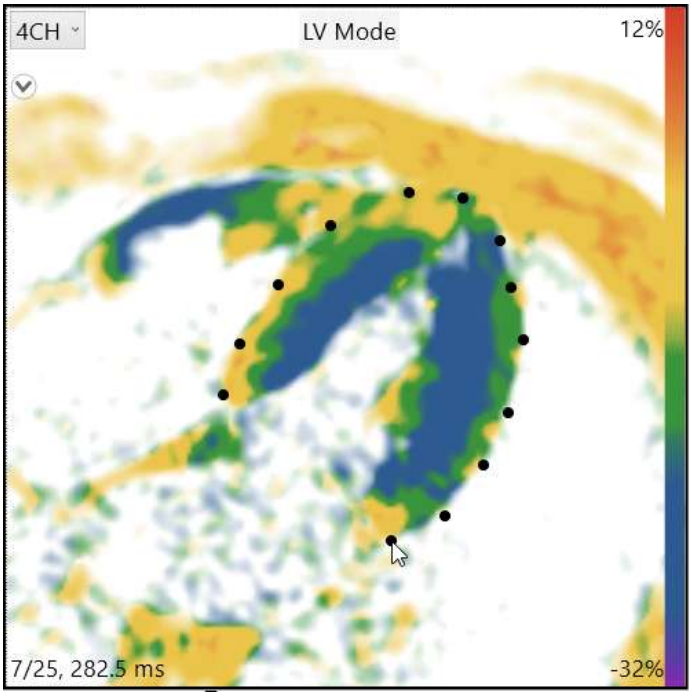


Figure 4-16: Double-clicking here will finish the epicardial contour

3. Double-click on the last point.

4. A mesh contour will be created for the epicardium. Ensure that the red circle is at the apical point of the LV. If this circle is not correctly positioned, use the left-mouse button to drag it into the appropriate location.

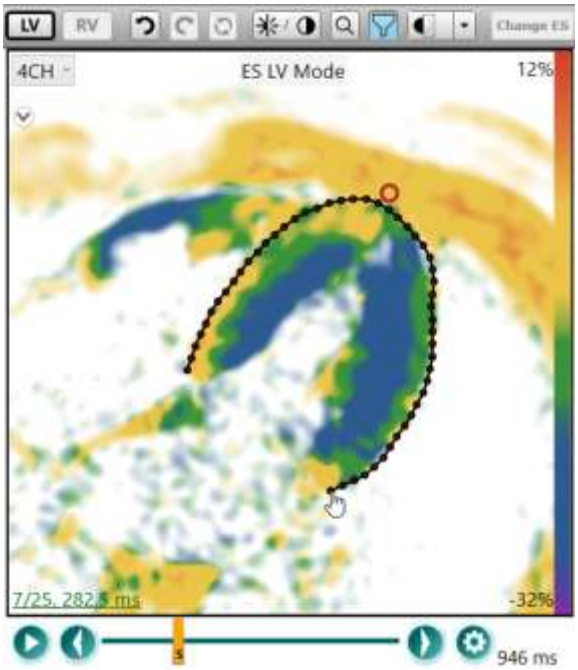


Figure 4-17: Completed epicardial contour with correct apical marker

5. Using the same method, draw the endocardial contour (avoiding the papillary muscles). Upon completion, the image will rotate to match the models shown in the **Measures** section. Additionally, a red dot will appear near the middle of the LV blood pool.

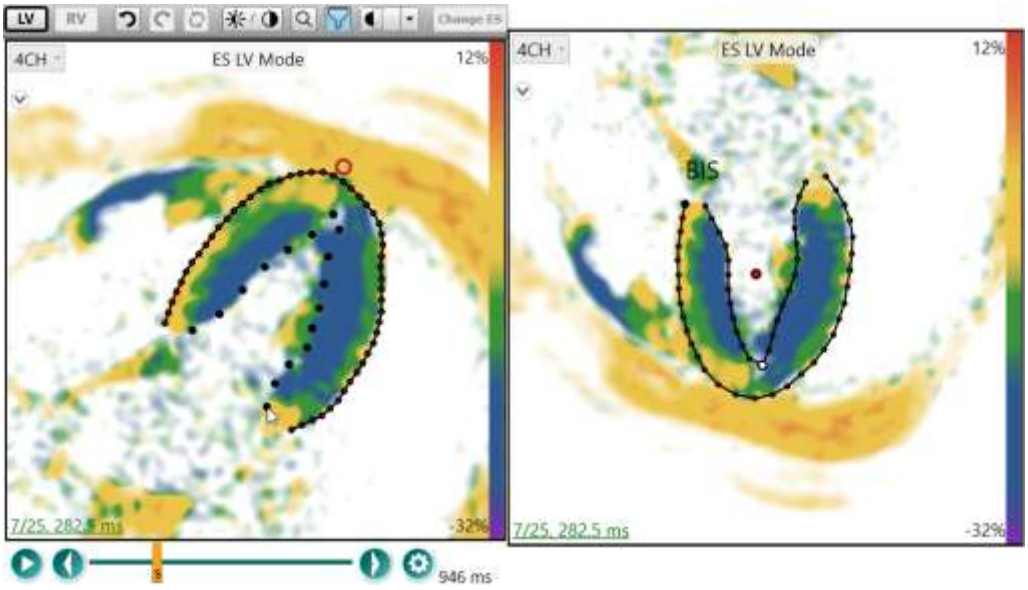


Figure 4-18: A completed epicardial contour with apical marker.

4.2.2 **ADJUSTING THE MESH (LONG-AXIS VIEWS)**

After completing the mesh, adjustments may need to be made to accurately represent the myocardium. Common adjustments may involve redrawing one section of the contour or resetting the reference point shown on the image.

1. Depending on where the final contour drawing of the mesh began will determine where the reference marker is shown on the image. If this reference marker is incorrect, left-clicking on these letters will switch the reference point to the corresponding side.

- BAL – Basal Anterolateral (4ch)
- BIS – Basal Inferoseptal (4ch)
- BAS – Basal Anteroseptal (3ch)
- BIL – Basal Inferolateral (3ch)
- BA – Basal Anterior (2ch)
- BI – Basal Inferior (2ch)

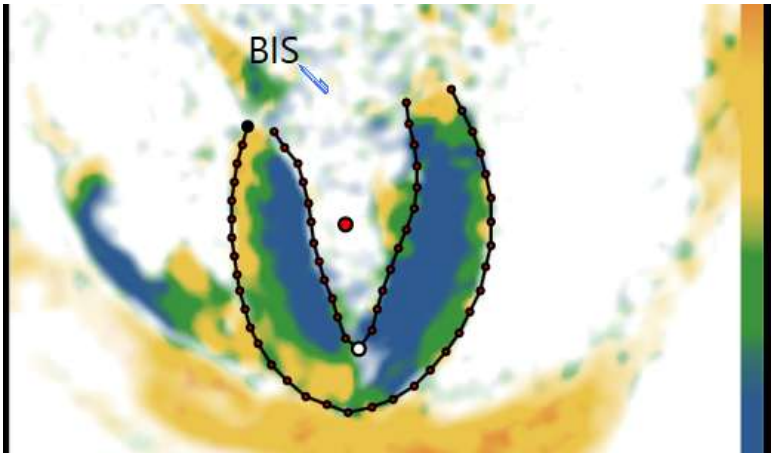


Figure 4-19: The mouse cursor will change when hovering over the reference point. Left-clicking will flip the image and change the reference marker.

2. If any individual points need to be moved to better fit the myocardium, use your left-mouse button to reposition points on the mesh.

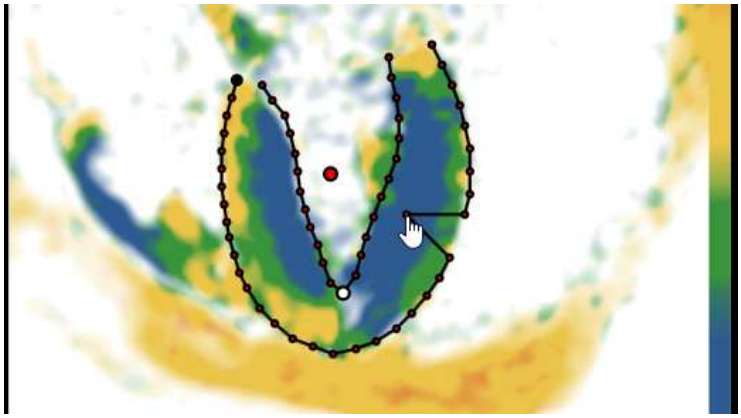


Figure 4-20: Example of a single point mesh correction

3. If a large section of the mesh's epicardial or endocardial contour points need to be redrawn, you may redraw a portion of the contour by left-clicking periodically near the existing mesh. Double-clicking at the end of this correction will signal the completion of the new contour and will be incorporated into the existing mesh (Figure 4-21).
4. If the mesh has been placed in an incorrect location after image rotation, the red dot shown in the center of the LV blood pool can be used to drag the mesh into a different location.
5. If either the endocardial or epicardial contour needs to be moved, click and drag any of the lines of the contour to relocate the drawing.
6. The **Undo**, **Redo**, and **Reset** buttons found in the Slice submenu will undo the most recent mesh action, redo the most recent mesh action, and reset the slice to its default state respectively.

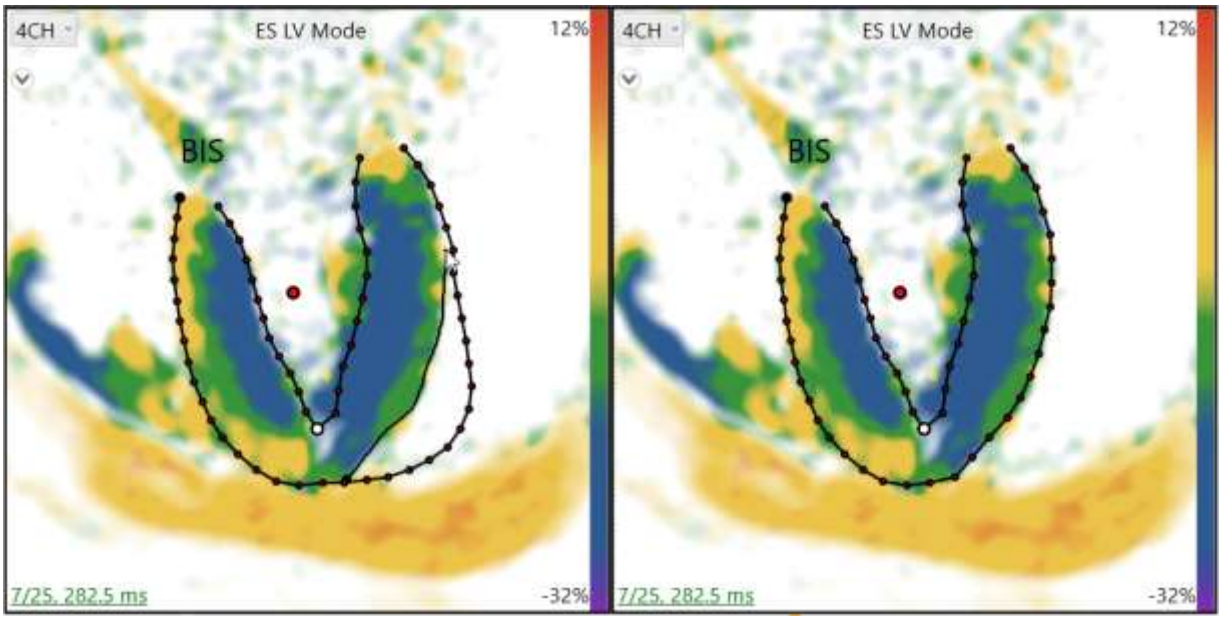


Figure 4-21: Modifying the mesh by redrawing a contour section using the freehand method

After drawing and correcting the mesh, verify that the information displayed in the **Circumferential Strain** subsection of **Measures** reflects the data shown in the **Analysis Window.**

4.2.3 LONG-AXIS RV QUANTIFICATION

After completing the LV mesh, the RV can be measured by adding additional contours to the existing LV mesh. Please note that Long-Axis RV quantification can only be performed on the 3 and 4-chamber views of the LV. Make sure the RV button is selected (Figure 4-22) in the Analysis Menu before applying an RV contour.

NOTE: You can also click and hold down the left-mouse button to draw a contour by tracing the epicardium or endocardium.

NOTE: Applying an RV contour to an LV contour may automatically flip the LV image to adjust Reference Points. Ensure the anatomy matches the Reference Point before continuing.

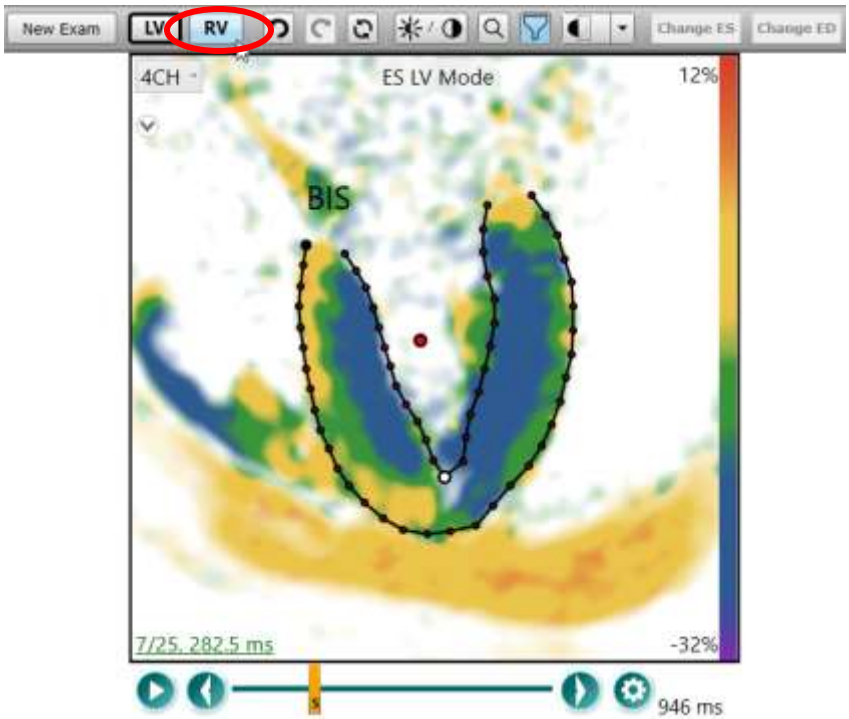


Figure 4-22: Clicking on the RV button after completing the LV mesh will enable RV contouring

4.2.3.1 4-CHAMBER RV MESH

Beginning at the valve plane, trace the epicardial contour by left-clicking periodically along the epicardium.

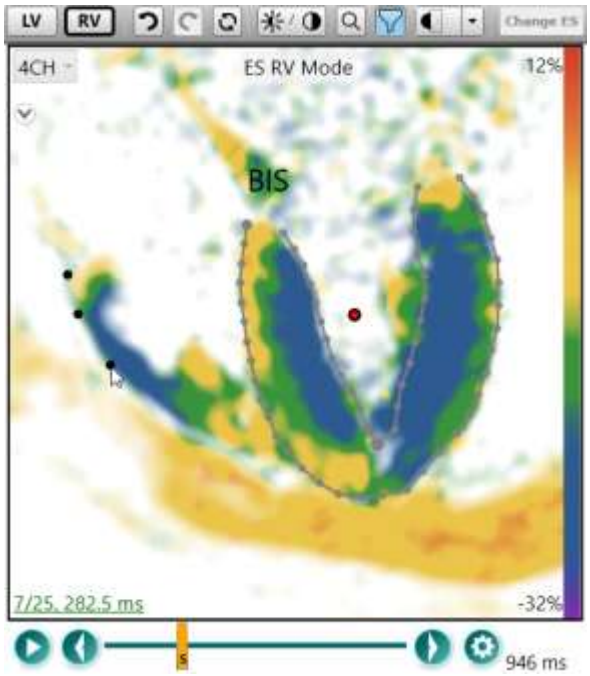


Figure 4-23: Beginning RV contour on 4Ch image

To finalize the first contour, double-click the last point once the apex of the RV has been reached. The contour will automatically attach itself to the existing LV mesh.

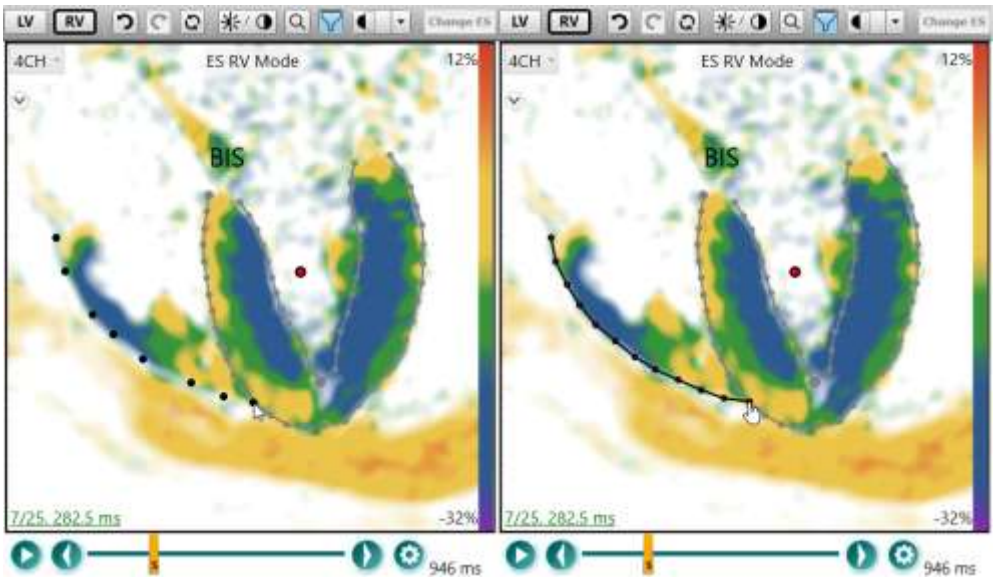


Figure 4-24: Completion of the epicardial RV contour

After completing the epicardial contour, use the same method to define the endocardial contour.

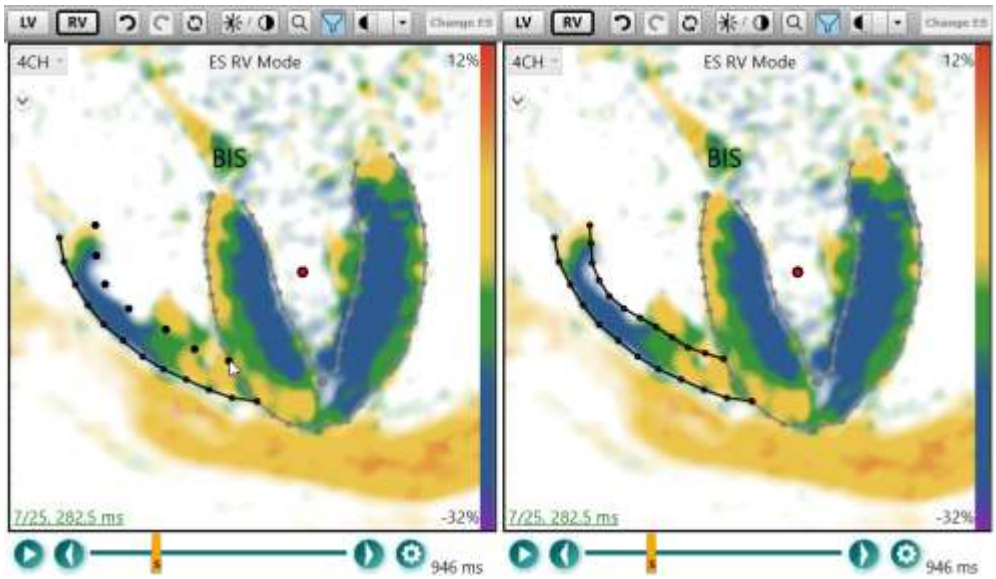


Figure 4-25: Completion of the 4Ch RV contour

NOTE: You can also click and hold down the left-mouse button to draw a contour by tracing the epicardium or endocardium.

4.2.3.2 3-CHAMBER RV MESH

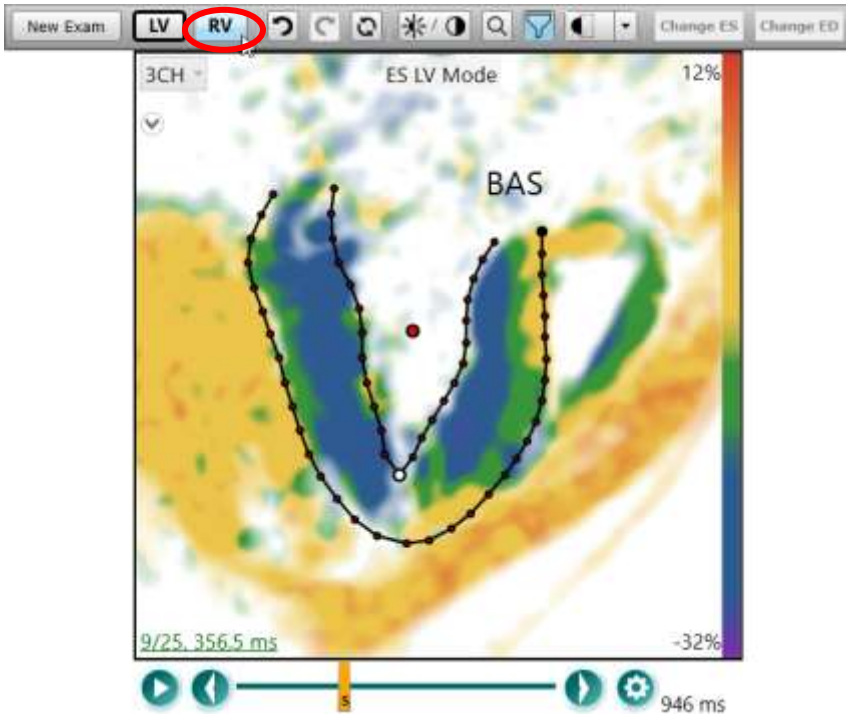


Figure 4-26: 3Ch view with RV button selected

Beginning at either the base of the RV or the top of the Basal Anteroseptal region of the LV, trace the epicardial contour by left-clicking periodically around the epicardium.

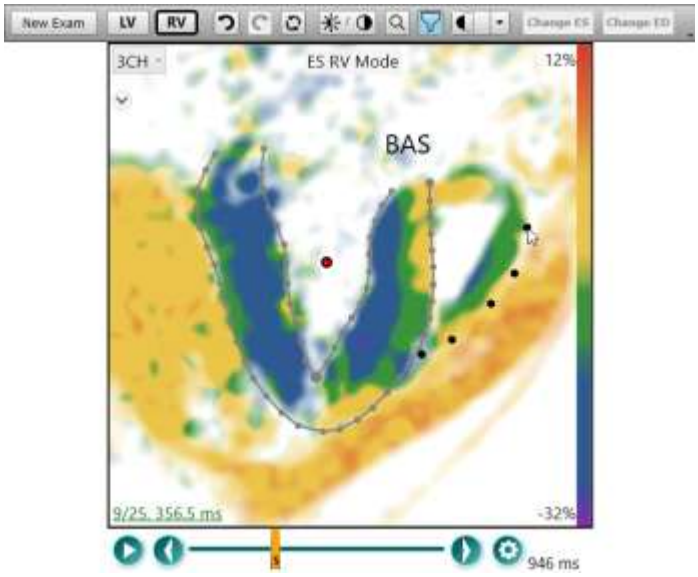


Figure 4-27: Beginning the epicardial RV contour at the mid anterior region

After reaching the mid-anterior region of the heart where the LV and RV re-connect, double-click to complete the contour.

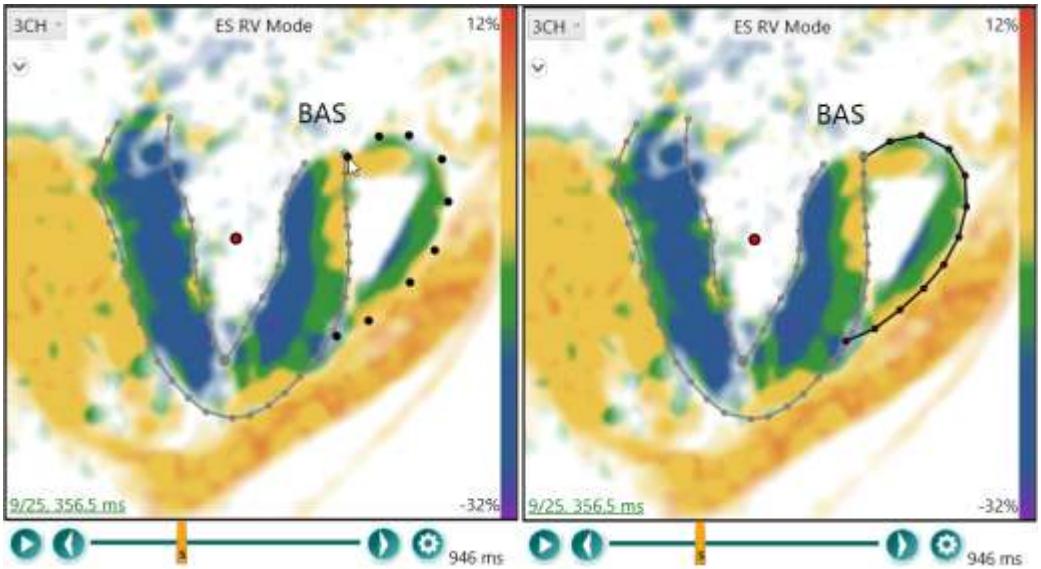


Figure 4-28: Completion of the epicardial RV contour

After tracing the epicardium, repeat the same process for the endocardial contour.

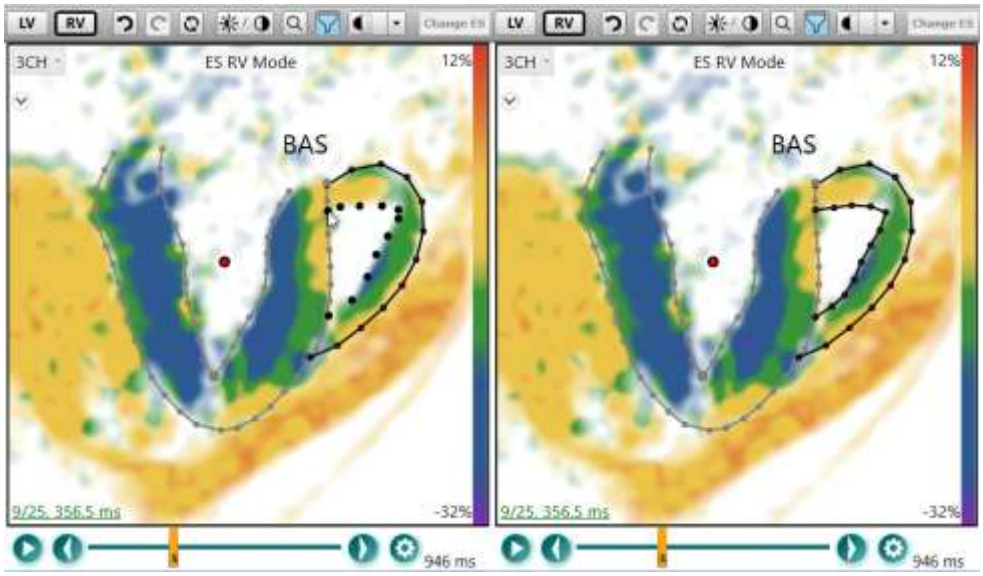


Figure 4-29: Endocardial contour drawn for 3Ch RV

After completing the RV contour, verify the analysis results are being displayed correctly in the **Measurements** field of the **Report**.

4.2.4 **END DIASTOLIC MESH AND TRADITIONAL MEASURES**

In addition to calculating peak systolic strain, MyoStrain calculates traditional measures such as LVEF. These measurements are calculated based on the Long Axis images and should be performed for each Long Axis view in the study. Make sure the **Ejection Fraction** button in the **Analysis Menu** is checked before continuing.

⚠ Strain measurements are not evaluated on Diastolic meshes.

To calculate traditional measures, first visually identify the frame best representing End-Diastole. This can be done using the Slice Navigator, your mouse's scroll wheel, or the CINE viewing buttons at the bottom of the **Analysis Window**.

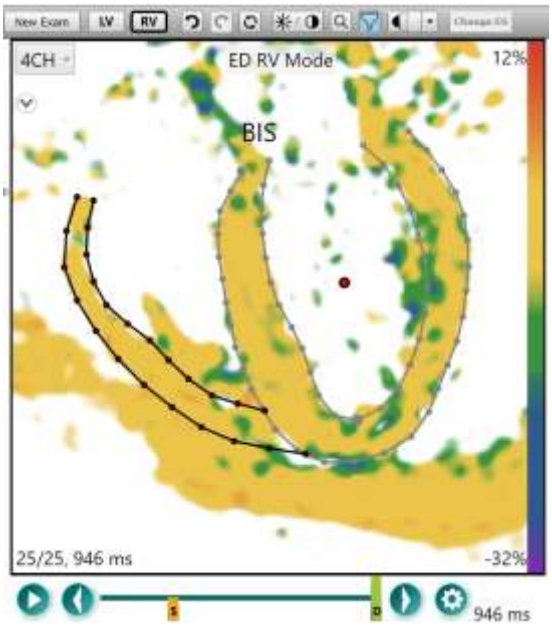


Figure 4-30: End-Diastolic meshed and viewed in the Slice Navigator

NOTE: The End-Diastolic timeframe is usually either the first or last image of a series. It is important to verify the timeframe used is the closest to End-Diastole

After choosing the End-Diastolic timeframe, using the same mesh application methods used in section 4.2.1, apply both an endocardial and epicardial contour to this image. MyoStrain also calculates RV Traditional measurements if those contours are applied to the dataset.

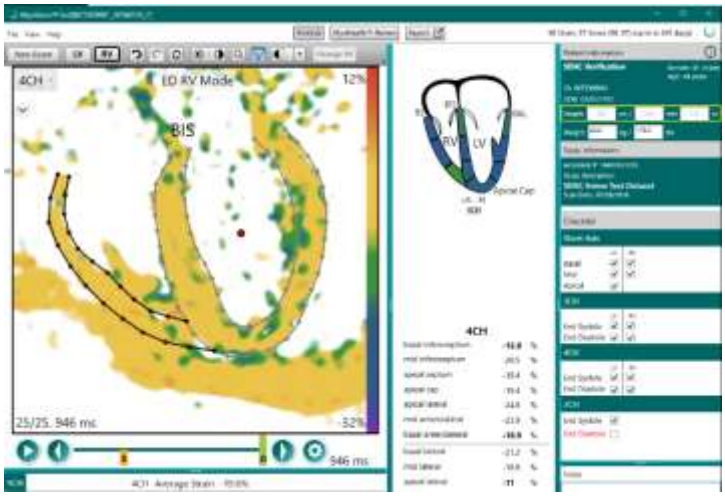


Figure 4-31: End-Diastolic timeframe meshed with checklist showing completion of ES/ED Contours

NOTE: RV Traditional Measurements are only available if Semi Auto Contouring is enabled

After both the systolic and diastolic frames have been meshed, their locations will be marked in the **Slice Navigator** (Diastole in green, Systole in orange) and their measurements will be shown in the **Measures** section.

NOTE: Traditional measurements will only be pulled from the timeframes marked in the Slice Navigator. Use the **Set as ES** and **Set as ED** buttons to re-identify these timeframes if a new time is used in the future.

5. STRAIN EXAM REPORTING

Refer to this chapter of the MyoStrain User's Manual to understand the workflow of a MyoStrain Exam. This chapter should be followed once a patient is ready to be scanned.

5.1 MYOSTRAIN® TEST PROCEDURE

The MyoStrain Test procedure is a simple, fast, and non-invasive process. SENC- formatted Images acquired from the scanner can be imported into the application through either the MyoWorklist or from the workstation if the SENC formatted images are available locally. The below sequence of events is typical for a Strain exam:

1. Send SENC-Formatted images to the MyoStrain workstation.
2. Launch MyoStrain and import images from the previous step to be quantified and visually enhanced.
3. Review and update patient information, then view images in **Analysis Window**
4. Select a view from the Image List, then identify the best representative image for that view.
5. Quantify slice by applying a mesh or approving/modifying a mesh generated from Semi Auto contouring.
6. Repeat steps 4-5 for each slice over six total views (Basal, Mid, Apical, 3CH, 4CH, 2CH).
7. Finalize report and export results.

5.2 IMPORTING SENC IMAGES

Upon launching MyoStrain from the desktop shortcut, the software will display a splash screen labeled "Select Your Exam". From this page, click the **File** menu and select either **New Exam from Worklist**, or **New Exam from Folder**. If MyoStrain is configured to receive images directly from the MRI scanner or PACS, use the Worklist option. Please refer to Chapter 10 for more detailed information about the MyoWorklist and how to launch a dataset for analysis.

Figure 5-1: Use the top shortcut if available, MyoWorklist is available inside MyoStrain

NOTE: The Worklist can be accessed directly from the Desktop or Start Menu through the MyoWorklist application.

If the analysis workstation is not networked or is unable to receive images from PACS, SENC formatted images can be imported from a flash drive or from the local hard drive. Selecting **File > New Exam from Folder** will display a **Browse For Folder** dialog box. Select a folder which contains a single SENC study (MyoStrain will automatically identify if the dataset is a Strain or Stress analysis), then click OK.

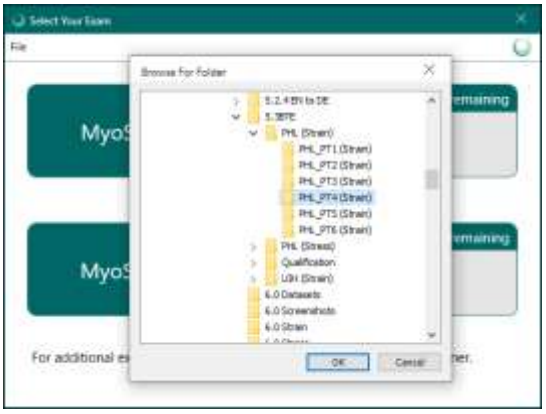


Figure 5-2: Exam Selection Screen

5.3 CONVERTING SENC IMAGES INTO MYOSTRAIN IMAGES

After selecting a dataset from either the Worklist or from a folder, MyoStrain will begin converting the SENC formatted images into MyoStrain images. MyoStrain images refers to the colorized strain information displayed on the image. Opening these images creates the .myo exam file (which contains the mesh information used to identify the LV and RV) and will consume an exam credit and cannot be reversed.

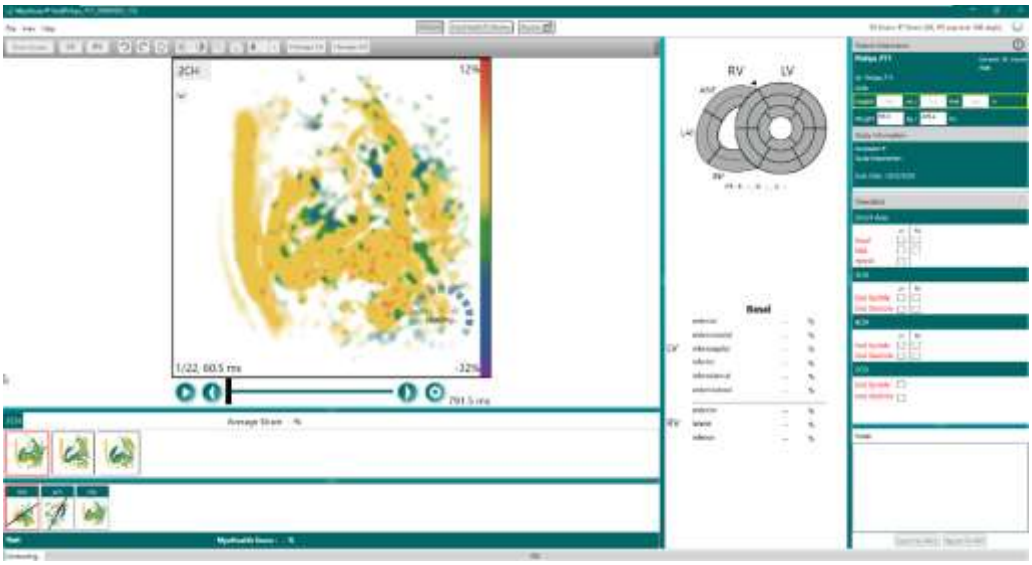


Figure 5-3: MyoStrain in Strain mode receiving images for processing in Semi Auto Contouring

During the import process, MyoStrain will also attempt to quantify the images by automatically applying recommended meshes to each slice if the Semi Auto Contouring feature is enabled. Please refer to Chapter 9 for more information regarding Semi Auto Contouring.

5.4 PATIENT DATA, IMAGE REVIEW, AND SELECTION

Once all images have been loaded into the MyoStrain software, confirm the correct patient's information is displayed in the upper-right corner of the Analysis tab. Review each MyoStrain image to ensure good image quality is present, as well as to review the overall function of the LV/RV. If for some reason the image quality is poor or there was an issue during acquisition, it is recommended to use a different slice if available. It may prove beneficial to hide images so that they are not reviewed again.

If the image quality is good and strain data is clearly visible, proceed to quantify all six slices. Please refer to chapter 4 for detailed instructions on image quantification.

5.4.1 SELECTING ONE VIEW BETWEEN MULTIPLE SLICES

If there are multiple slices available for one view, only one can be used for reporting purposes.

Figure 5-4 shows an off-plane slice on the top, and an on-plane slice on the bottom. Using the relative planes when each slice is selected is helpful to identify where they are relative to other views to select the best one to quantify.

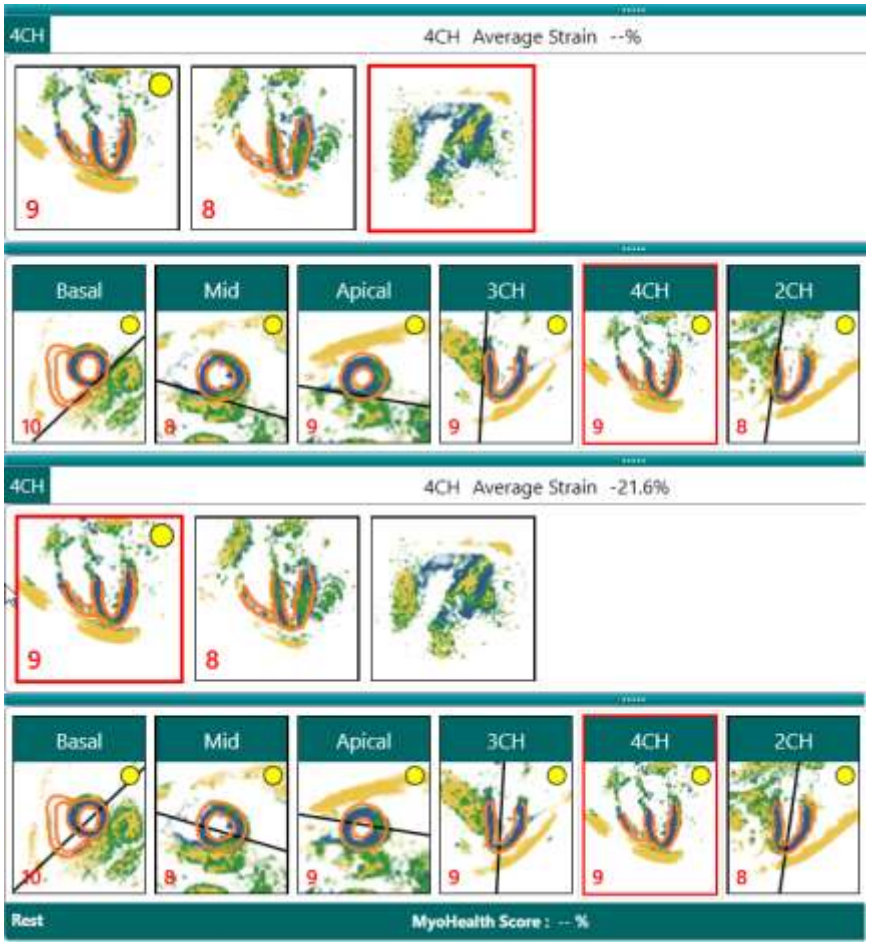


Figure 5-4: Top 4CH view shows poor planning based on the relative planes. Bottom 4CH is recommended since the relative planes pass through the blood pool.

5.5 IMAGE QUANTIFICATION

Once the best view has been selected, review the video prior to analysis. Refer to chapter 4 for methods on manually quantifying the mesh, and refer to chapter 9 if using Semi Auto Contouring as a primary mesh application method. Once the mesh has been applied, accepted, and reviewed; proceed to the next view.

5.5.1 SIGNAL VS NOISE IN IMAGE ANALYSIS

In some situations, applying a mesh to a slice will not result in all segments being displayed in the **Report Section.** If the mesh encounters a region where more than 50% the strain data is determined to be noise, the Measurements section will display that region as "NA". "NA" regions are displayed with black hatchmarks, distinguishing them from unanalyzed slices, which are shown in grey. Both unanalyzed segments, along with "noisy" segments, do not provide strain data towards the MyoHealth® score (for LV segments) or to global strain measurements.

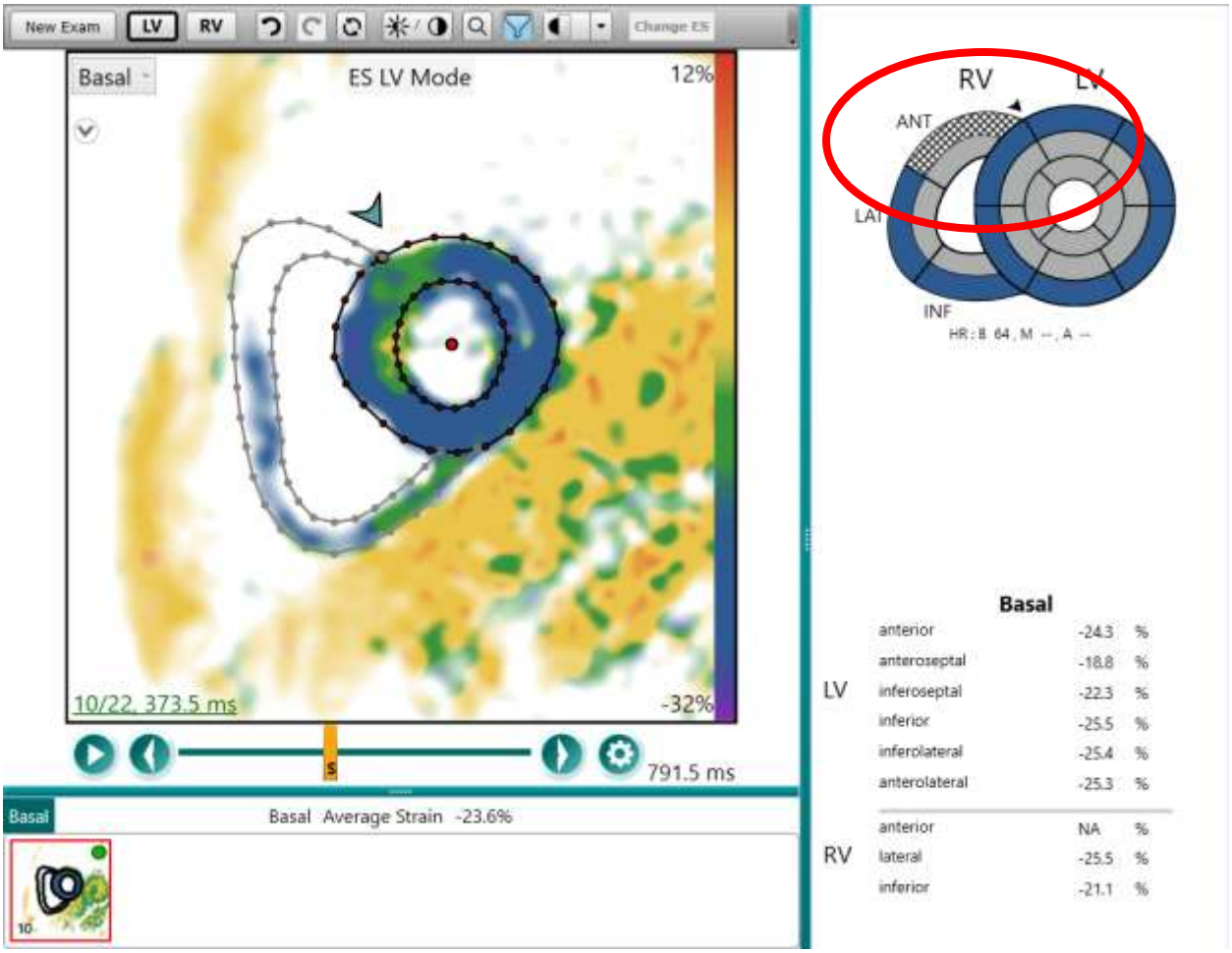


Figure 5-5: Basal Slice analyzed showing the RV Anterior as "NA"

5.5.2 **HIDING IMAGES**

If multiple slices of the same view have been acquired, it may prove useful to move some slices out of the way to ensure they are not included in the analysis. Right-clicking any image in the Image List will bring up a context menu; selecting **Hide** will grey out the slice and move it to the far-right side of the image list. It can be unhidden by right-clicking the greyed-out slice and selecting **Unhide**.

NOTE: Any slices which are not marked as hidden will be used to provide supplemental data to generate the 3D Model.

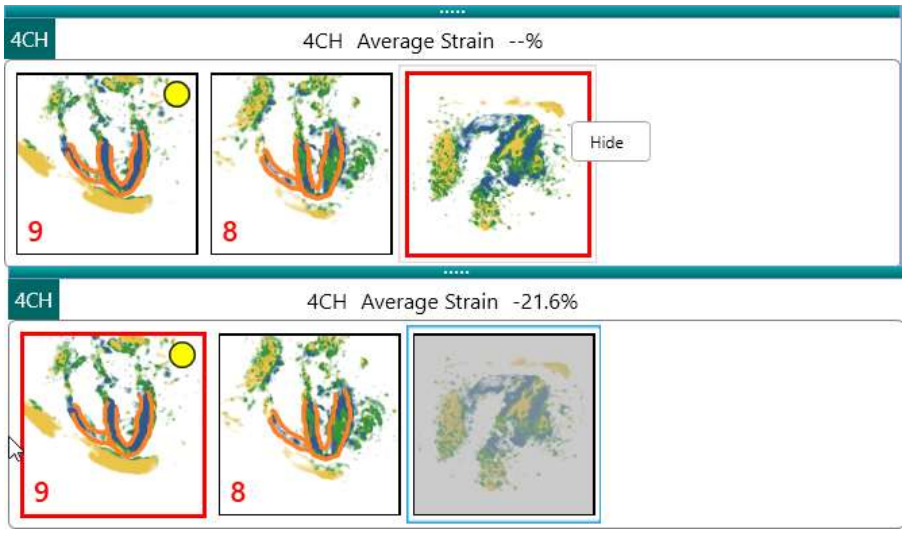


Figure 5-6: Hiding and Unhiding an image in the Image List

5.6 REPORTING AND EXPORTING DATA

After quantifying all six views of the current patient exam, it is recommended to save the quantified exam data before proceeding to the **MyoStrain Review** tab to review the Polar Plots / 3D Model, or before exporting the **Strain Report** and exam data to PACS or to the workstation directly. The **Export to PACS** button and **Report to PDF** buttons in the lower-right corner of the Analysis tab will export the analysis to PACS (using default settings) or export a local copy of the PDF report for printing or reporting purposes.

To save the exam, select **Save** from the **File** menu.

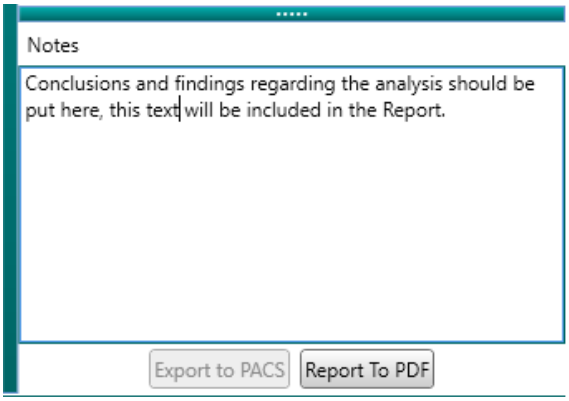


Figure 5-7: Export to PACS and Report to PDF buttons seen in the Analysis tab below the Notes and Patient Information sections

NOTE: The Export to PACS button will be disabled (grey) if a PACS connection has not been setup.

Please refer to chapter 7 for more information on the **Report Viewer** and exporting data from the MyoStrain application.

6

6. STRESS EXAM REPORTING

This chapter introduces the MyoStrain Stress Test post-processing analysis. Refer to this chapter of the MyoStrain User's Manual to understand the workflow of a MyoStrain Stress Exam. This chapter should be followed after a Stress scan has been performed and images sent to the workstation.

6.1 MYOSTRESS TEST PROCEDURE

The MyoStress test is a simple and fast cardiac stress test which can be administered in a very short span of time. SENC- formatted Images acquired from the scanner can be imported into the application through either the MyoWorklist or from the workstation if the SENC formatted images are available locally. The below sequence of events is typical for a Stress exam:

1. Send SENC-formatted images to the MyoStrain workstation.
2. Launch MyoStrain and import images from the previous step to be quantified and visually enhanced.
3. Review and update patient information, then view rest phase images in **Analysis Window**
4. Select representative slice from **Image List** for one view in the rest phase.
5. Quantify the current slice
6. Repeat steps 4-5 for each available view in the rest phase.
7. Advance to next stress phase, then repeat steps 4-6.
8. After all stress phases have been completed, finalize the report and export the results.

6.2 IMPORTING STRESS SENC IMAGES

Upon launching MyoStrain from the desktop shortcut, the software will display a splash screen labeled "Select Your Exam". From this page, click the **File** menu and select either **New Exam from Worklist**, or **New Exam from Folder**. If MyoStrain is configured to receive images directly from the MRI scanner or PACS, use the Worklist option. Please refer to Chapter 10 for more detailed information about the MyoWorklist and how to launch a dataset for analysis.

Figure 6-1: Use the top shortcut if available, MyoWorklist is available inside MyoStrain

NOTE: The Worklist can be accessed directly from the Desktop or Start Menu through the MyoWorklist application.

If the analysis workstation is not networked or is unable to receive images from PACS, SENC formatted images can be imported from a flash drive or from the local hard drive. Selecting **File > New Exam from Folder** will display a **Browse For Folder** dialog box. Select a folder which contains a single SENC study (MyoStrain will automatically identify if the dataset is a Strain or Stress analysis), then click OK.

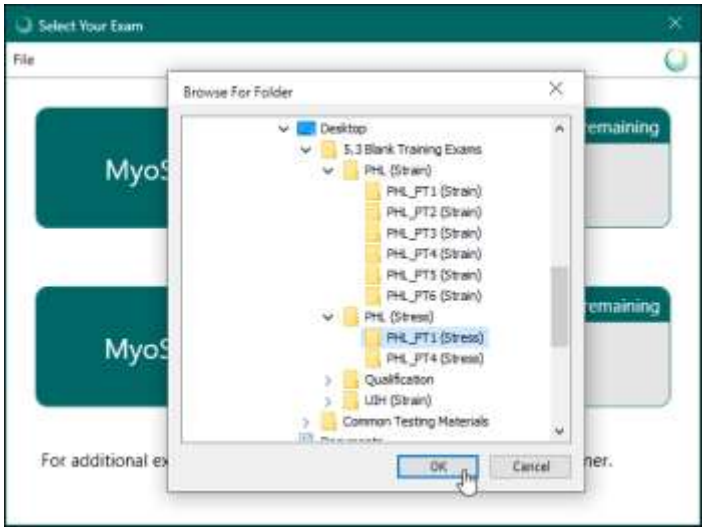


Figure 6-2: Exam Selection Screen

6.3 CONVERTING SENC IMAGES INTO MYOSTRAIN IMAGES

After selecting a dataset from either the Worklist or from a folder, MyoStrain will begin converting the SENC formatted images into MyoStrain images. MyoStrain images refer to the colorized strain information displayed on the image. Opening these images will create the .myo exam file which include the saved mesh information used to identify the LV and RV. This action will consume an exam credit and cannot be reversed. MyoStrain will display the Rest phase images on the left-hand side, and the Stress phase images will display on the right-hand side.

Figure 6-3: MyoStrain application in Stress mode processing images using Semi Auto Contouring

During the import process, MyoStrain will also attempt to quantify the images by automatically applying recommended meshes to each slice if the Semi Auto Contouring feature is enabled. Please refer to Chapter 9 for more information regarding Semi Auto Contouring.

NOTE: MyoStrain will perform Semi Auto Contouring for each stress phase of the imported dataset. When the Rest phase of images has been contoured, review can begin while MyoStrain processes the stress stages.

6.4 PATIENT DATA, IMAGE REVIEW AND SELECTION

Once all images have been loaded into the MyoStrain software, confirm the correct patient's information is displayed in the upper-right corner of the Analysis tab. Review each MyoStrain image to ensure good image quality is present, as well as to review the overall function of the LV/RV. If for some reason the image quality is poor or there was an issue during acquisition, it is recommended to use a different slice if available. It may prove beneficial to hide images so that they are not reviewed again.

If the image quality is good and strain data is clearly visible, proceed to quantify all six slices. Please refer to chapter 4 for detailed instructions on image quantification.

⚠ Traditional measurements are only calculated on the Rest phase.

6.4.1 SELECTING ONE VIEW BETWEEN MULTIPLE SLICES

If there are multiple slices available for one view in a single stress stage, only one can be used for reporting purposes.

Figure 6-4 shows an off-plane slice on the top, and an on-plane slice on the bottom. Using the relative planes when each slice is selected is helpful to identify where they are relative to other views to select the best one to quantify.

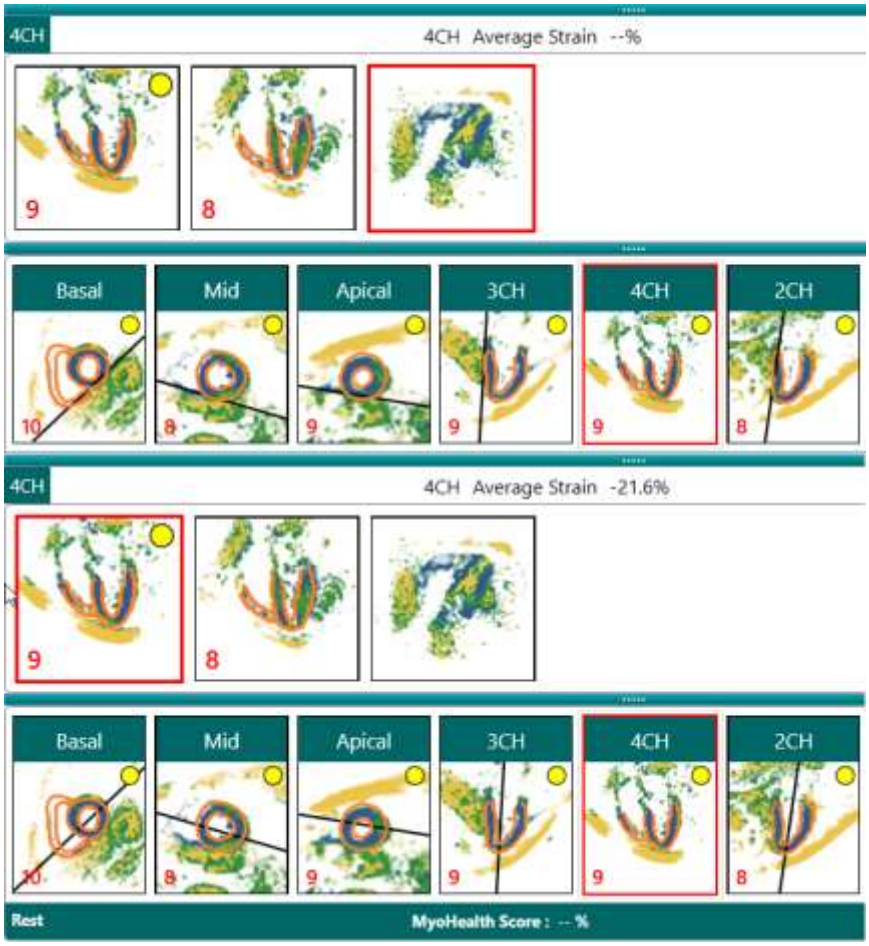


Figure 6-4: Top 4CH view shows poor planning based on the relative planes. Bottom 4CH is recommended since the relative planes pass through the blood pool.

6.5 IMAGE QUANTIFICATION

Once the best view has been selected, review the video prior to analysis. Refer to chapter 4 for methods on manually quantifying the mesh, and refer to chapter 9 if using Semi Auto Contouring as a primary mesh application method. Once the mesh has been applied, accepted, and reviewed; proceed to the next view.

6.5.1 SIGNAL VS NOISE IN IMAGE ANALYSIS

In some situations, applying a mesh to a slice will not result in all segments being displayed in the **Report Section.** If the mesh encounters a region where more than 50% the strain data is determined to be noise, the Measurements section will display that region as "NA". "NA" regions are displayed with black hatchmarks, distinguishing them from unanalyzed slices, which are shown in grey. Both unanalyzed segments, along with "noisy" segments, do not provide strain data towards the MyoHealth® score (for LV segments) or to global strain measurements.

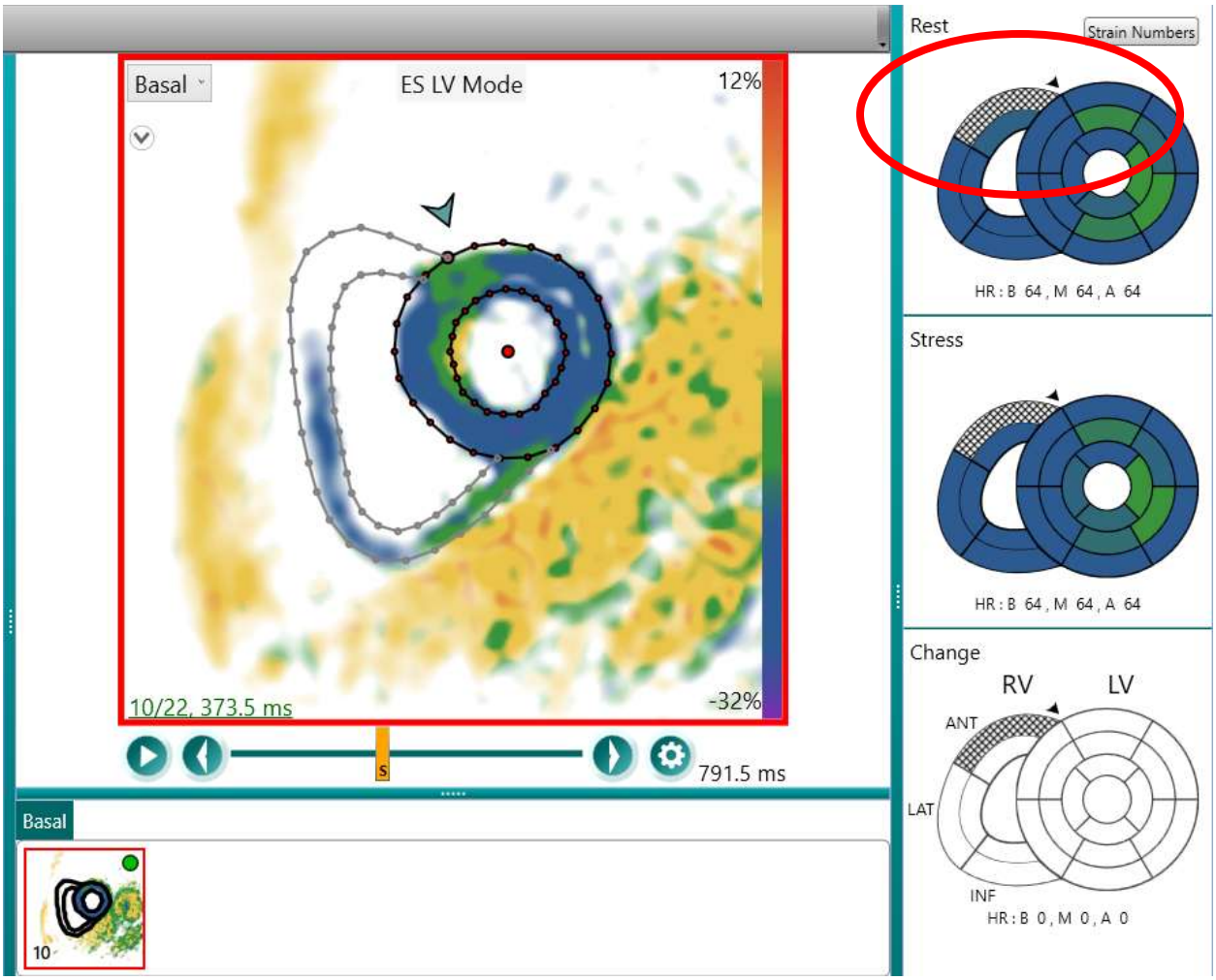


Figure 6-5: Stress Basal Slice analyzed showing the RV Anterior as "NA"

6.5.2 **HIDING IMAGES**

If multiple slices of the same view have been acquired, it may prove useful to move some slices out of the way to ensure they are not included in the analysis. Right-clicking any image in the Image List will bring up a context menu; selecting **Hide** will grey out the slice and move it to the far-right side of the image list. It can be unhidden by right-clicking the greyed-out slice and selecting **Unhide**.

NOTE: Any slices which are not marked as hidden will be used to provide supplemental data to generate the 3D Model.

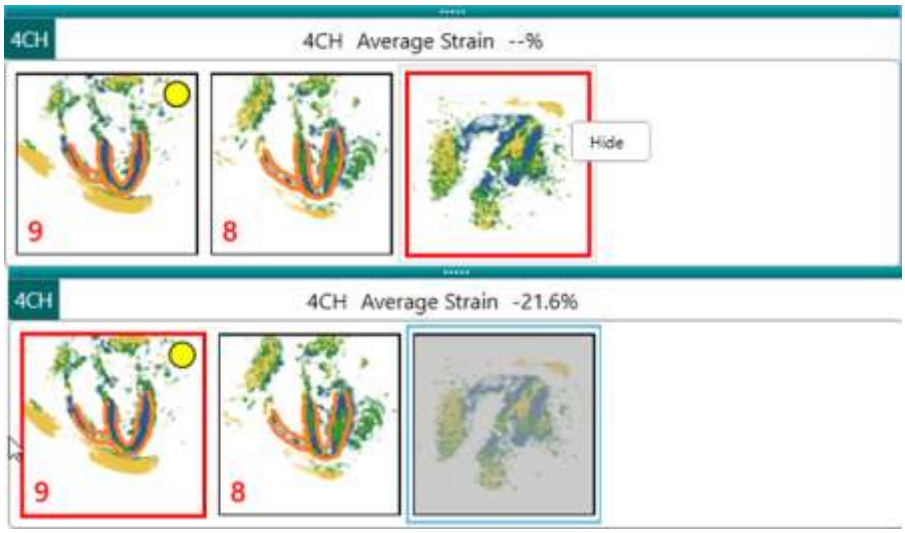


Figure 6-6: Hiding and Unhiding an image in the Image List

6.6 IMAGE ANALYSIS (STRESS PHASES)

After the Rest phase images have been processed, the next stage of stress should be displayed and reviewed prior to analysis. By default, the images seen on the right-hand side of the Analysis tab are the stress phase images.

Figure 6-7: Multiple Stress stages acquired

The drop-down menu on the right-hand side shows the number of different stress stages identified by MyoStrain. Switching the Acquisition # changes the displayed slices in the Stress side. The drop-down menu on the left-hand side labels the Stress agent. The earliest acquisition is defaulted as Acquisition 1 and is set as the Rest phase of images. The last series of images acquired and associated with this dataset should be marked with the highest Acquistion #.

NOTE: When switching between stress agents to display for analysis, make sure to use the Acquisition dropdown on the right to change images, not the label.

⚠ Please refer to your site's stress test procedure for specific instructions regarding testing procedure and stress agent usage.

6.7 IMAGE PROCESSING (STRESS PHASES)

After displaying the next stage of images from a new stress phase, analysis of the Stress phase can begin. When clicking on a view in the Stress phase, the corresponding Active Rest view will automatically display on the left-hand side of the Analysis Window for comparison purposes.

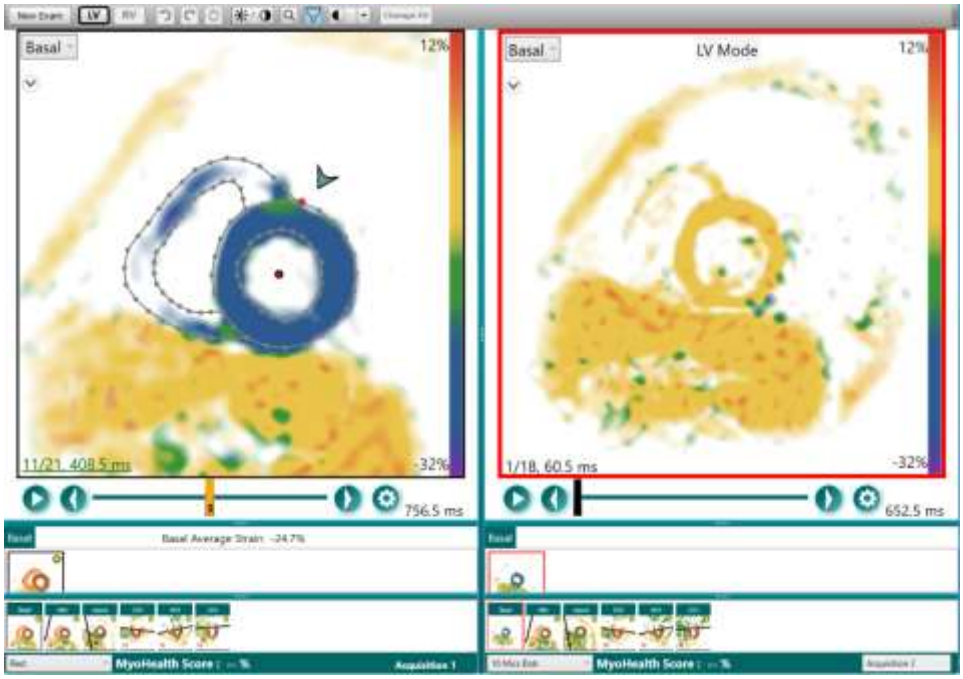


Figure 6-8: Analysis Windows showing both Rest and with 10 Mics Dobutamine

Both **Analysis Windows** have the same behavior as before, except that the window must be highlighted (or active) before interacting with it. The Rest images will always be shown in the left-hand window to allow comparison to a later stress phase in the right-hand window.

NOTE: Brightness/Contrast adjustments will only affect views contained in the highlighted image's series.

6.7.1 REJECTION OF IMAGES

During image acquisition, there may be several stress stages which are incomplete, or are not necessary for this analysis. If a series of images needs to be removed from the analysis, selecting **Reject** as the Stress Agent will cause that stage of images to be deleted from the exam.

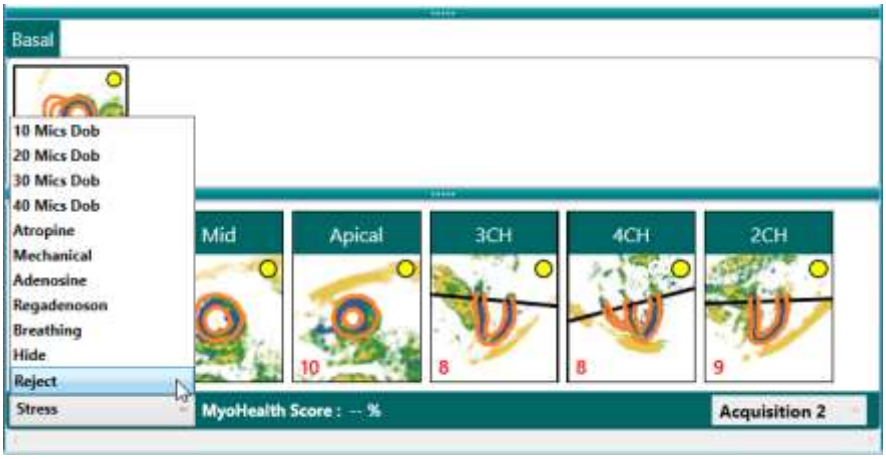


Figure 6-9: Selecting this option will remove any images and meshes from this acquisition stage from the analysis

⚠ Image rejection will irreversibly remove images from the current exam. Images will need to be imported into a new exam if this occurs.

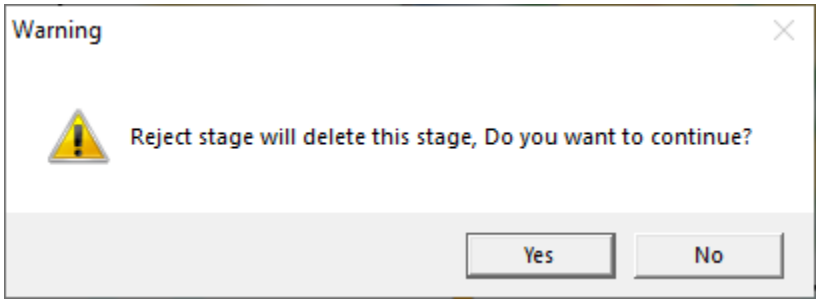


Figure 6-10: Warning message shown when attempting to reject a stress stage

6.8 REPORTING AND EXPORTING DATA

After quantifying all six views of the Resting phase, and six views of the highest Stress phase of a patient scan, it is recommended to save the quantified exam data before proceeding to the **MyoHealth Review** tab to review the Polar Plots / 3D Model, or before exporting the **Stress Report** and exam data to PACS or to the workstation directly. The **Export to PACS** button and **Report to PDF** buttons in the lower-right corner of the Analysis tab will export the analysis to PACS (using default settings) or export a local copy of the PDF report for printing or reporting purposes.

To save the exam, select **Save** from the **File** menu.

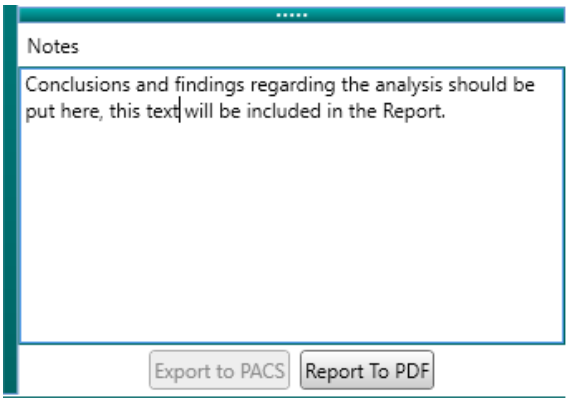


Figure 6-11: Export to PACS and Report to PDF buttons seen in the Analysis tab below the Notes and Patient Information sections

NOTE: The Export to PACS button will be disabled (Figure 6-11) if a PACS connection has not been setup.

Please refer to chapter 7 for more information on the **Report Viewer** and exporting data from the MyoStrain application.

7. REPORT VIEWER AND DATA EXPORT

The Report Page automatically composes a report from the various sources of information that are obtained during the analysis. This report can then be uploaded to PACS or exported as a PDF document to be later archived or printed out for later use.

7.1 REPORT VIEWER OVERVIEW

During a Strain or Stress exam, the **Report Tab** will display the corresponding report measurements during the exam. Additionally, the report can be viewed alongside the Analysis tab, and measurements will automatically update as SENC image processing progresses. When images are imported into a new exam, MyoStrain will automatically format the report to display either a MyoStrain or MyoStress report.

NOTE: Stress exams generate a resting Strain report in addition to the Stress report.

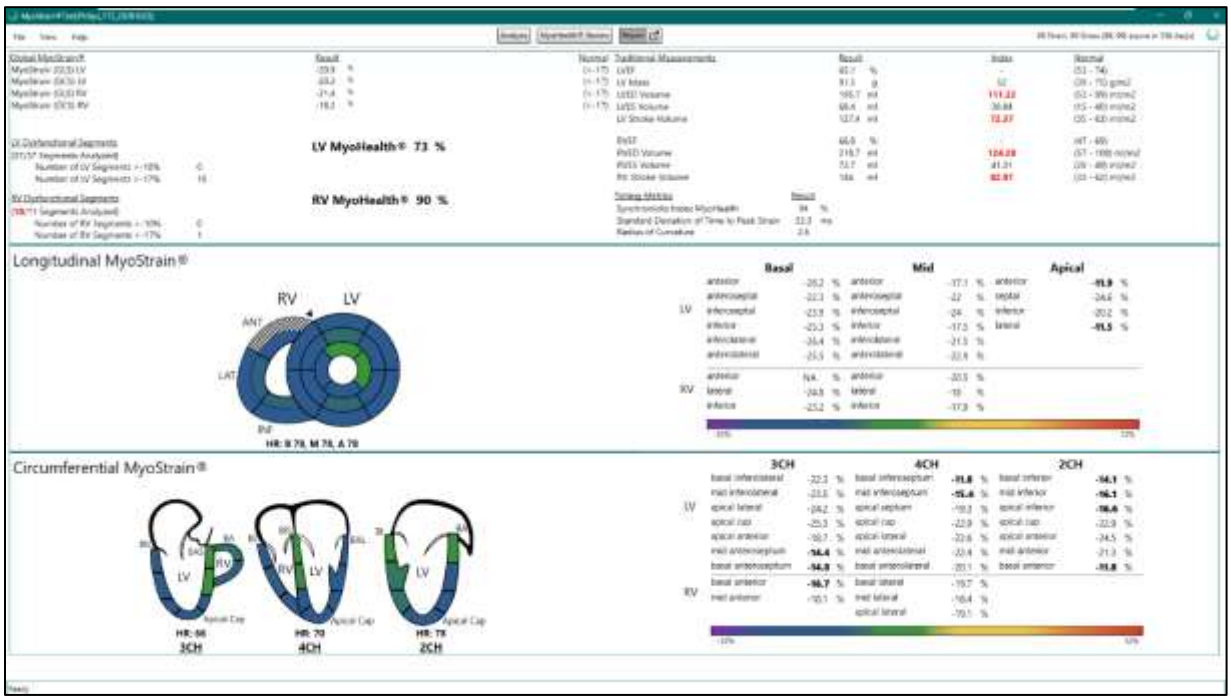


Figure 7-1: Top of the MyoStrain Report tab after completing a SAC Strain exam.

In this section, the below MyoStress report tab image will be used to outline the different sections of the Report tab, and any requirements needed to generate specific measurements.

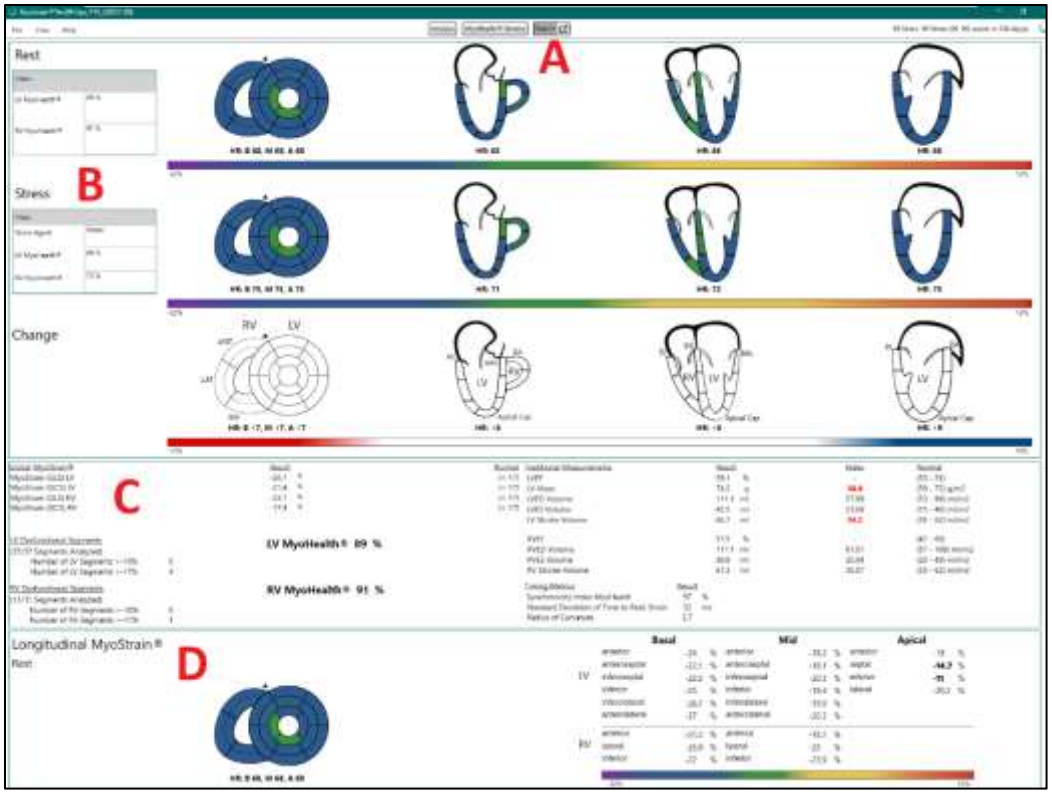


Figure 7-2: Top of the MyoStress report seen after completing a SAC analysis

7.2 REPORT TAB (A)

Figure 7-3: MyoStrain UI Menu buttons

The button to access the Report tab has two faces, the normal display option, or the Pop-out option. Clicking the text (left-hand side) of the **Report** button changes the MyoStrain UI to display the Report. The Pop-out icon (right-hand side) will instead display the report in a separate window, which can then be docked to a secondary monitor to view analysis results during the analysis itself.

NOTE: Certain measurements cannot be displayed (such as Timing Metrics) in the pop-out report. Calculations that take a long amount of processing time can only be displayed in the Report tab itself.

7.3 STRESS MEASUREMENT COMPARISON (B)

This section displays all available Strain measurements gathered from the current Stress study using a standardized AHA model (see section11.3). This comparison section is only displayed during a Stress analysis. Traditional measurements and index values can be found above the AHA models in the **Measurements** section. Strain

measurements, both circumferential and longitudinal, are also displayed with strain ranges shown. Information regarding the calculation of index ranges and normal can be found in section 11.4

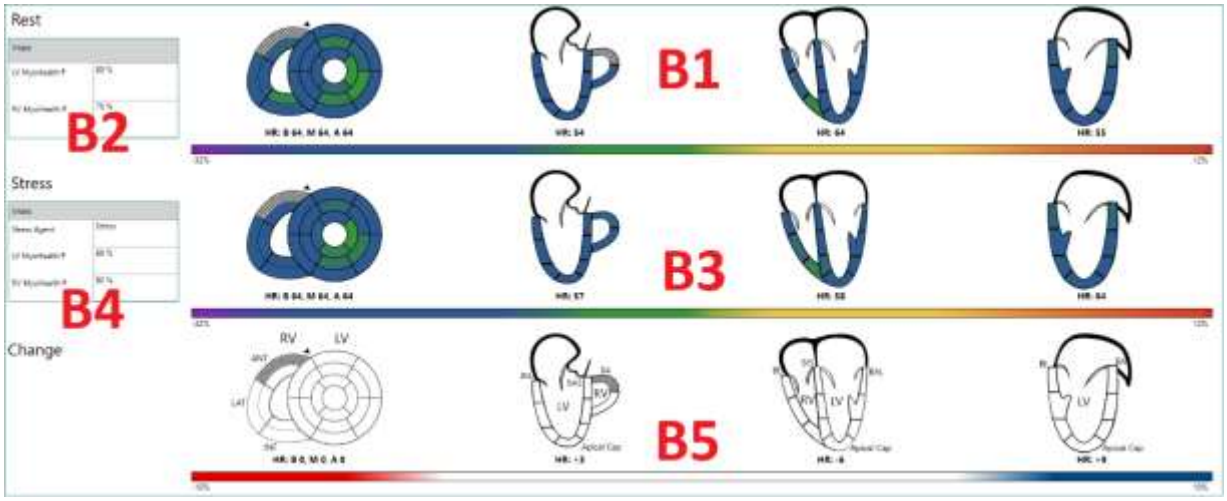


Figure 7-4: Stress Measurements section (seen only in MyoStress exams)

1. Resting AHA Models – Shows the colorized strain measurements from the Rest stage of images.
2. Resting Vitals – Shows the LV MyoHealth and RV MyoHealth score for the Rest Stage.
3. Stress AHA Models – Shows the colorized strain measurements from the highest stage of stress available in the analysis.
4. Stress Vitals- Shows the LV MyoHealth, RV MyoHealth, as well as the Stress Agent used for this stage.
5. Change AHA Models – Shows the change between the Resting and Stressed stages.

NOTE: The Stress Agent displayed is determined by the highest stage of stress agent applied. They are ordered as: Rest, 10MICS, 20MICS, 30MICS, 40 MICS, Atropine, Mechanical, Adenosine, Regadenoson, Breathing, and Stress.

MyoStrain Stress tests will display both resting strain and the strain calculated at the highest level of stress. The MyoStrain report will only display slices which are marked with a green dot in the **Image List** and only display segments if they exceed the signal/noise threshold needed to accurately report strain measurements. Below the Stress exclusive section are the global MyoStrain and traditional measurement calculations.

7.4 GLOBAL MYOSTRAIN AND TRADITIONAL MEASURES (C)

The measures provided in the **Global Measurements** section of the Report tab are calculated as follows:

- **Global MyoStrain® Measurements:**
  - **MyoStrain (GLS) LV** – Average percentage of peak strain calculated from all Short-Axis LV slices.
  - **MyoStrain (GCS) LV** – Average percentage of peak strain calculated from all Long-Axis LV slices.
  - **MyoStrain (GLS) RV** – Average percentage of peak strain calculated from all Short-Axis RV views.
  - **MyoStrain (GCS) RV** – Average percentage of peak strain calculated from all Long-Axis RV views.
- **LV Dysfunctional Segments**
  - **Number of LV Segments > -10%** – This displays the total number of LV segments calculated by MyoStrain to have above -10% strain.
  - **Number of LV Segments > -17%** – This displays the total number of LV segments calculated by MyoStrain to have above -17% strain.
- **RV Dysfunctional Segments**

- **Number of RV Segments > -10% -** This displays the total number of RV segments calculated by MyoStrain to have above -10% strain.
- **Number of RV Segments > -17% -** This displays the total number of RV segments calculated by MyoStrain to have above -17% strain.

- **LV MyoHealth® -** Derived measurement showing percentage of LV segments below -17% strain compared to the total number of LV segments analyzed. It can be expressed by the formula ***[(# of LV Segments <= -17%) / (# of LV Segments Analyzed)] * 100***
- **RV MyoHealth® -** Derived measurement showing percentage of RV segments below -17% strain compared to the total number of RV segments analyzed. It can be expressed by the formula ***[(# of RV Segments <= -17%) / (# of RV Segments Analyzed)] * 100***
- **Traditional Measurements**

NOTE: Traditional Measurements are derived from the 3D model generated through Semi Auto Contouring but will default to 2D meshes if a 3D model cannot be created. Indexed values require the patient's height and weight to be listed in the report to generate the BSA (Body Surface Area) using the Du Bois formula.

- **LVEF** – Percentage of blood emptied from the left ventricle during systole.
- **LVED Volume** – Volume (in mL) of blood measured in the LV at Diastole measured across all Long-Axis images. **Indexed LVED Volume** is calculated by the formula (**LVED Volume** / **BSA**).
- **LVES Volume** – Volume (in mL) of blood measured in the LV at Systole measured across all Long-Axis images. **Indexed LVES Volume** is calculated by the formula (**LVES Volume** / **BSA**).
- **LV Stroke Volume** – Difference of volume (in mL) between the **LVED Volume** and **LVES Volume**. **Indexed LV Stroke Volume** is calculated by the formula (**LVED Volume Index** – **LVES Volume Index**).
- **RVEF* -** Percentage of blood emptied from the right ventricle during systole.
- **RVED Volume* -** Volume (in mL) of blood measured in the RV at Diastole measured across all Long-Axis images. **Indexed RVED Volume** is calculated by the formula (**RVED Volume** / **BSA**).
- **RVES Volume* -** Volume (in mL) of blood measured in the RV at Systole measured across all Long-Axis images. **Indexed RVES Volume** is calculated by the formula (**RVES Volume / BSA**).
- **RV Stroke Volume* -** Difference of volume (in mL) between the **RVED Volume** and **RVES Volume**. **Indexed RV Stroke Volume** is calculated by the formula (**RVED Volume Index** – **LVES Volume Index**).

NOTE: Indexed values require the patient's height and weight to be listed in the report to generate the BSA (Body Surface Area) using the Du Bois formula (.007184* [Height(cm)^0.725] * [Weight(kg)^0.425]).

- **Timing Metrics**

NOTE: Timing Metrics calculations are based on cellular LV measurements rather than regional ones. Each LV region (such as SAX Basal Anterior) is comprised of 4 cells aside from Long Axis Apical Cap segments (which are calculated as a single cell)

- **Synchronicity Index MyoHealth -** Percentage of LV cells with a better regional synchronicity index than 0.9.
- **Standard Deviation of Time to Peak Strain –** Measurement in milliseconds measuring the standard deviation of time between segments reaching peak strain
- **Radius of Curvature –** Sharpness of the peak strain curve. Radius is normalized against strain percentage and the R-R-interval in milliseconds, resulting in a unitless measurement.

NOTE: * in the above chart notes that Semi Auto Contouring must be enabled and a completed 3D model is required to generate these measurements.

Any indexed measurements require the BSA (Body Surface Area) to be populated before any values are shown. The BSA is a derived calculation which requires the patient's Height and Weight to be populated. The indexed measurements are generated using the following formula:

7.5 **REGIONAL MYOSTRAIN MEASUREMENTS**

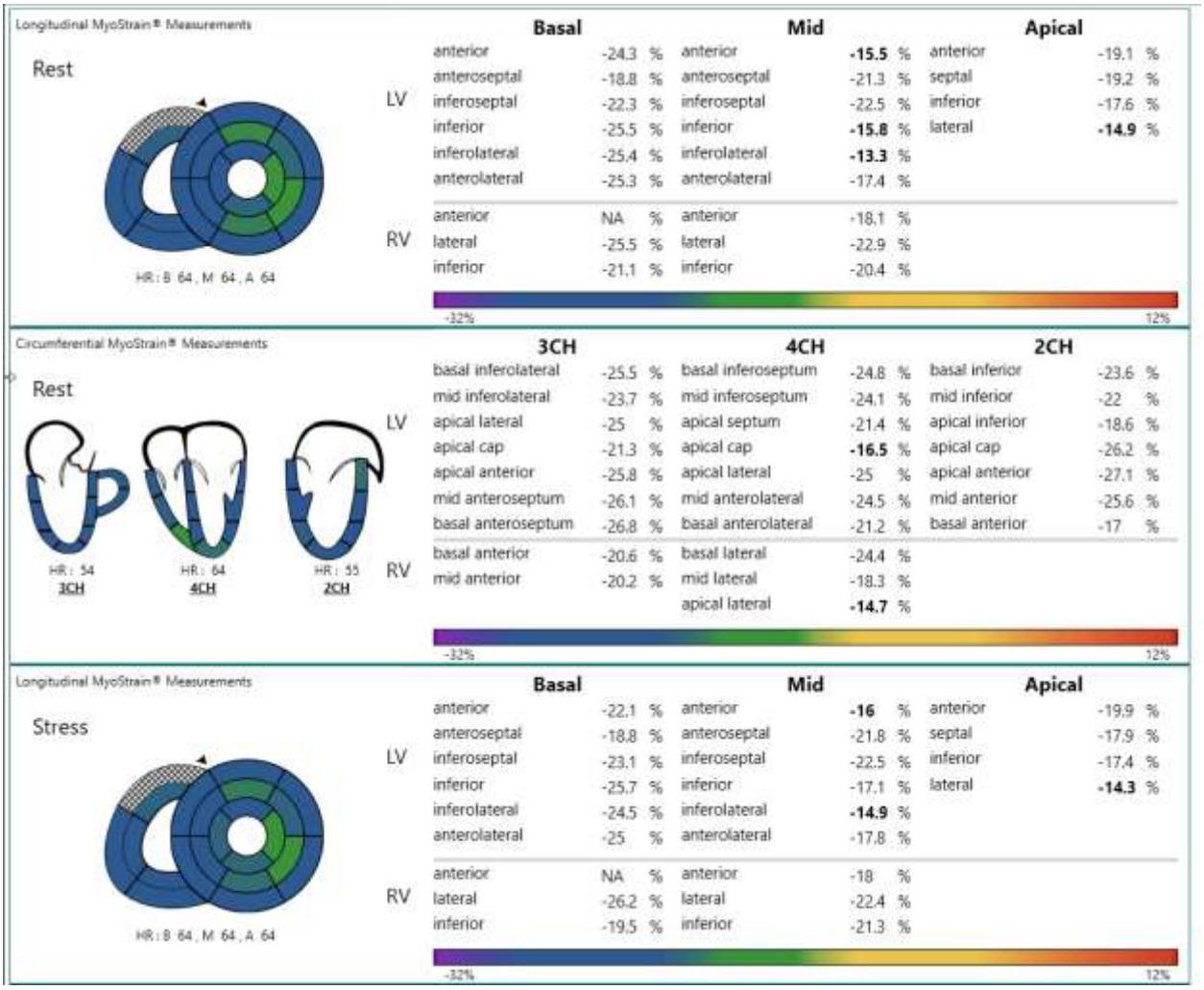


Figure 7-5: Regional MyoStrain measures seen during a Stress exam

Below the Global Measurements section of the Report tab, the regional AHA models for both Longitudinal and Circumferential MyoStrain measurements for both LV and RV at systole. MyoStress exams will display the Rest phase images first, followed by the Stress phase, then the comparison between the two.

NOTE: LV MyoStrain measurements are pulled from the middle-third of each LV Mesh, where RV MyoStrain measurements are calculated across the entire myocardium between epicardial and endocardial RV contours.

When reviewing the Report tab, some enhancements are made to the values displayed to make reading easier.

- Strain/Stress values shown in **BOLD** are strain values between -10% and -17%
- Strain/Stress values shown in red (Dark Mode yellow) are strain values above -10%
- Change measurements shown in red (Dark Mode yellow) denote a reduction in strain between Rest and Stress.
- Change measurements shown in blue (Dark Mode purple) denote an increase in strain between Rest and Stress

7.5.1 **STRAIN LEGEND**

MyoStrain uses a unique color gradient to identify different strain values.. The color legend below provides a basic guide to the meaning of each color.

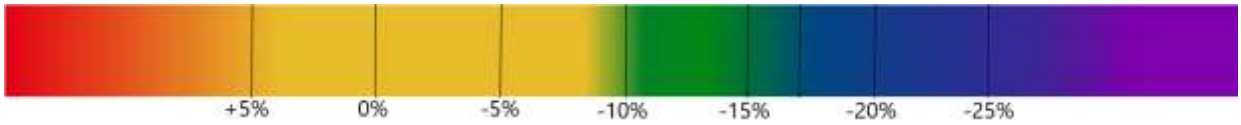


Figure 7-6: Color Legend for Strain

For more information regarding the Strain Legend, please refer to Section 12.2.

In the **Change** section of the MyoStrain Stress Report, a different color scale is used. This section displays the percentage change between the Rest images and the most recent Stress acquisition.

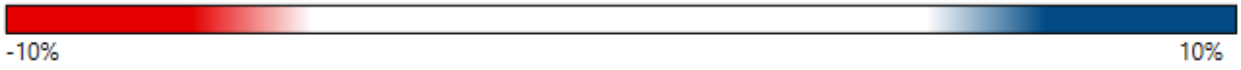


Figure 7-7: Color Legend for Change

Areas which were identified as having marked improvement under stress are displayed in blue, where regions that had reduced function are shown in red.

7.6 **IMAGE, DATA AND REPORT EXPORT (D)**

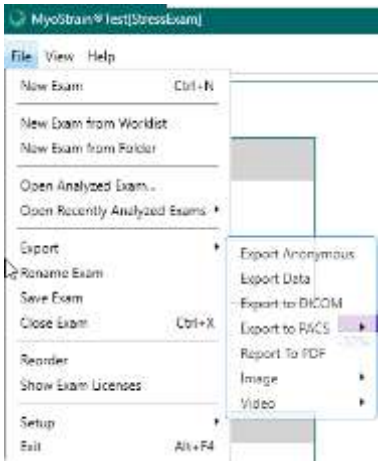


Figure 7-8: Export Options

At any point, data gathered from the exam can be exported for later use. Depending on the analysis workflow, different actions will be required to satisfy reporting requirements and should be identified before continuing. Clicking on the File>Export menu will display all available export options for the currently displayed dataset.

NOTE: Please contact your Myocardial Solutions Representative for more information regarding reporting requirements.

- **Export Anonymous** – Exports an anonymized copy of all available measurements, reports, and images from the current analysis.
- **Export Data –** Exports a .csv or .xml file containing all raw strain values from all stress levels recorded during the exam. Please refer to section 7.6.3 for more details regarding saving this file.
- **Export to DICOM –** Creates a folder in a specified location and exports a local copy of the DICOM images that would typically be sent to PACS.
- **Export to PACS -** Pushes a copy of the final report and the analyzed MyoStrain images (with meshes) to the PACS server (if configured to do so). Details about what information is being uploaded to PACS can be found in the **File>Setup>DICOM Export Settings** menu.
- **Report to PDF –** Exports a .pdf file containing the Report. The Stress Report will also contain a copy of the Strain report. Please refer to section 7.6.3 for more details regarding saving this file.
- **Image –** Exports screenshots of views available in MyoStrain. Accessible only in the Analysis and MyoHealth Review tabs.
- **Video – E**xports videos of views available in MyoStrain. Accessible only in the Analysis and MyoHealth Review tabs.

7.6.1 ANONYMOUS EXPORT

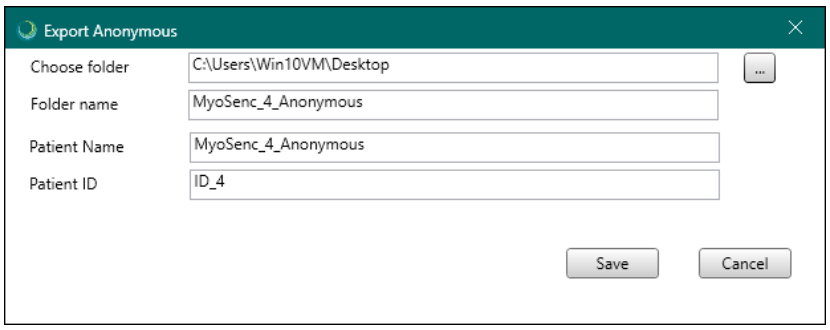


Figure 7-9: Export Anonymous dialog box

Export Anonymous is an additional export option available within MyoStrain. Clicking this button will bring up a dialog box with a few options:

A. **Choose Folder -** This field will display the file path where all exam data will be exported to. A folder will be created in this directory and data copied into it. The ellipsis button will allow the user to identify a new file path for export.
B. **Folder Name –** This text box contains the folder name which will be created in the **Choose Folder** path. This field may not contain the following characters: (* . " / \ ] [: ; | = ,)
C. **Patient Name –** This will overwrite the name of the exported patient with the contents of this text box.
D. **Patient ID –** This will overwrite the Patient ID of the exported patient with the contents of this text box.
E. **Save –** This begins the export process.
F. **Cancel –** This cancels the export process.

7.6.2 EXPORT TO PACS

After pressing the **Export to PACS** button, the MyoStrain application will ask to confirm where to export the data (Figure 7-10). After confirming the export location, MyoStrain will begin processing and sending images back to PACS (Picture Archiving and Communications System) for storage purposes. A window will appear in the background of the MyoStrain application called the "Dicomizer".

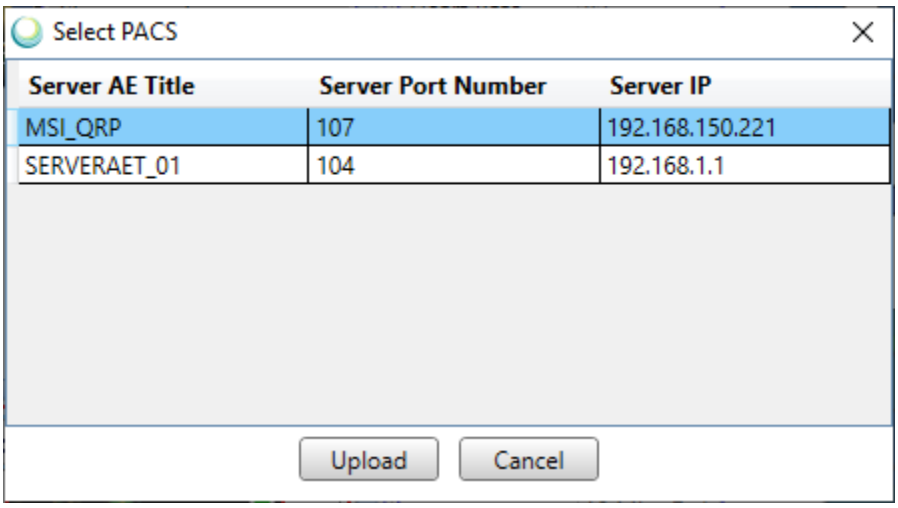


Figure 7-10: Clicking the Export to PACS button will display a PACS selection screen

The Dicomizer will display the current progress of images currently being uploaded. The MyoStrain application and the progress window must remain open while images are still being processed. Closing the application or the Dicomizer window will cancel the upload.

Figure 7-11: Progress window for background image archival

7.6.3 EXPORT DATA, REPORT TO PDF, AND EXPORT TO DICOM (LOCAL EXPORT)

Clicking on either the **Export Data**, **Report to PDF,** or **Export to DICOM** options in the Export section of the File menu will launch a dialog box (Figure 7-12, Figure 7-13, and Figure 7-14) asking where to save data. The Export Data dialog box asks whether the data should be saved as a .csv or .xml document.

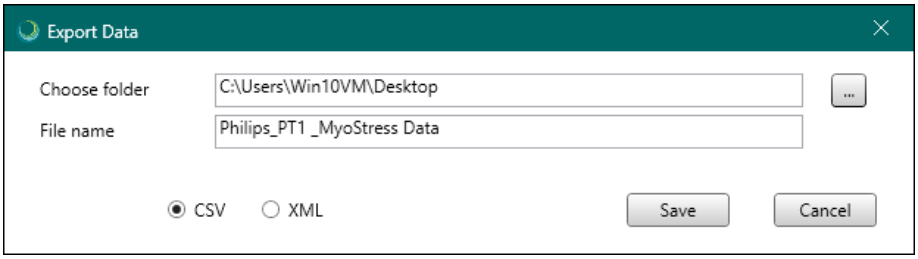


Figure 7-12: Export Data Dialog Box

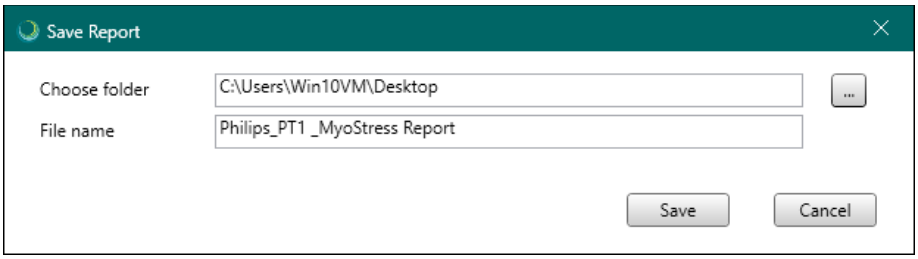


Figure 7-13: Save Report Dialog Box

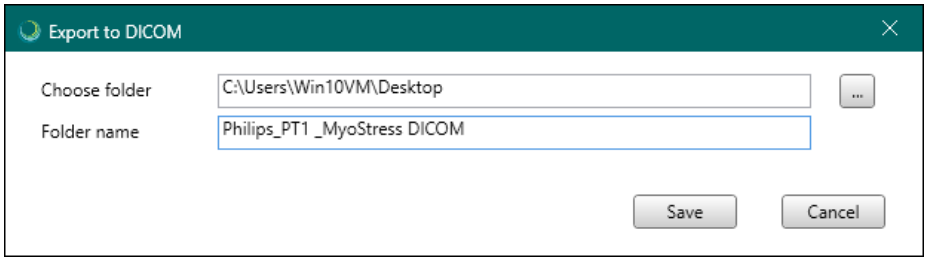


Figure 7-14: Export to DICOM Dialog box

Using this window, navigate to the location designated by your organization to save this report with the **Choose Folder (ellipsis)** button, then click **Save**. The user may provide a unique name to the report by changing the **File Name** text. Export to DICOM will create a folder to store the images in and is labeled **Folder Name** accordingly.

8. PREVIEW MODE (IMAGE PLANNING)

Preview Mode is an additional operation mode available within MyoStrain. It is only available when launching either a Stress or Strain examination from the Worklist.

In the Worklist, next to the **New Exam** button, a **Preview** button is available. Clicking on this button will launch the **Preview** window.

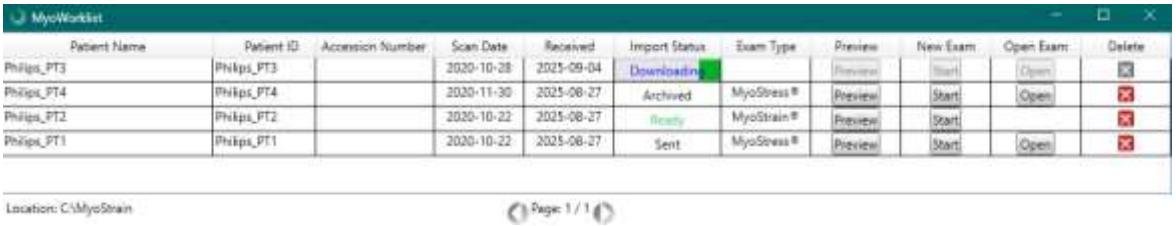


Figure 8-1: Worklist running with several datasets ready for Preview or analysis

Before any actual analysis begins, it may be useful to use **Preview** mode. This allows MyoStrain to display images without consuming any exam credits. This feature is useful for verifying that all the correct SENC images have been sent and that they are of sufficient quality for analysis before using an exam credit.

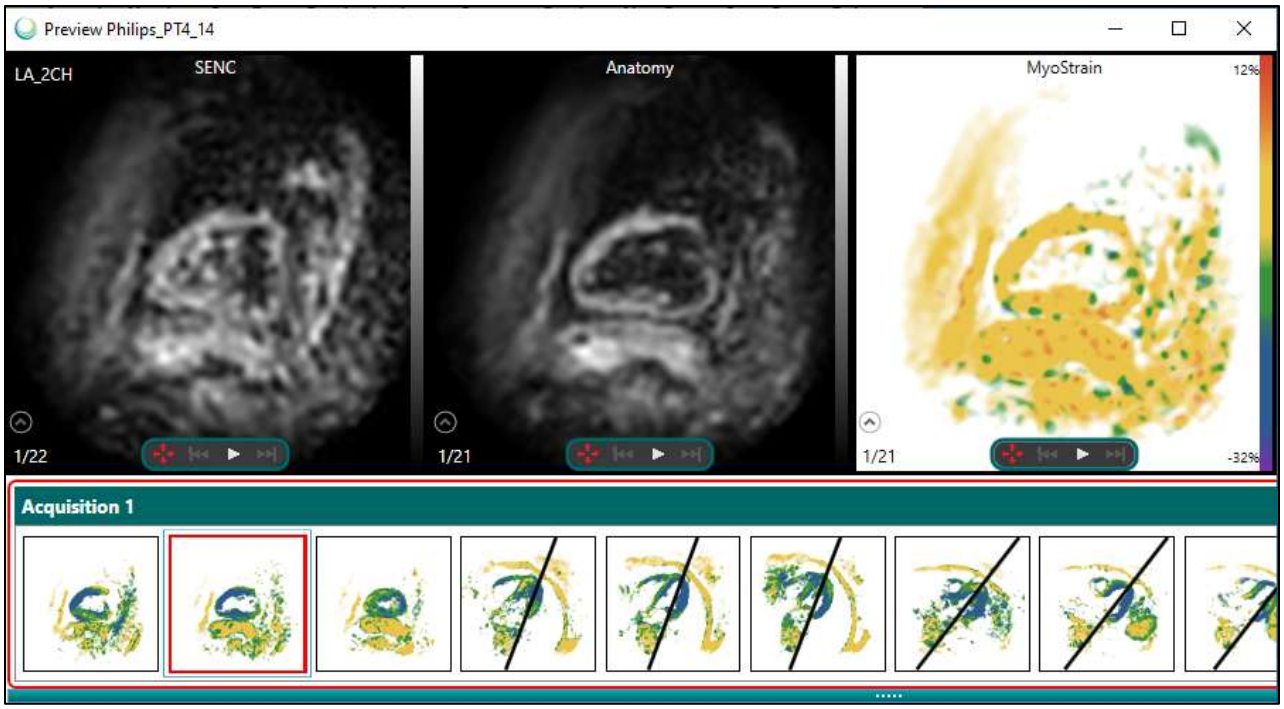


Figure 8-2: Preview with many slices available, 2CH view currently selected

NOTE: Any images imported using **Preview** mode will not consume an exam credit. The images shown cannot be quantified.

The **Preview** window displays 3 different views at the top of the screen of the SENC images pulled from the scanner. Clicking on any of the views in the **Image List** at the bottom of the **Preview** window will display that slice in the following 3 views:

- **SENC** – These are the unencoded SENC images pulled from the scanner. The images when played back shift between the High-Tune and Low-Tune images unique to the SENC pulse sequence.
- **Anatomy** – These are the SENC images recombined without applying the Strain map.
- **MyoStrain** – These are the SENC images with the colorized strain maps applied (default view in MyoStrain)

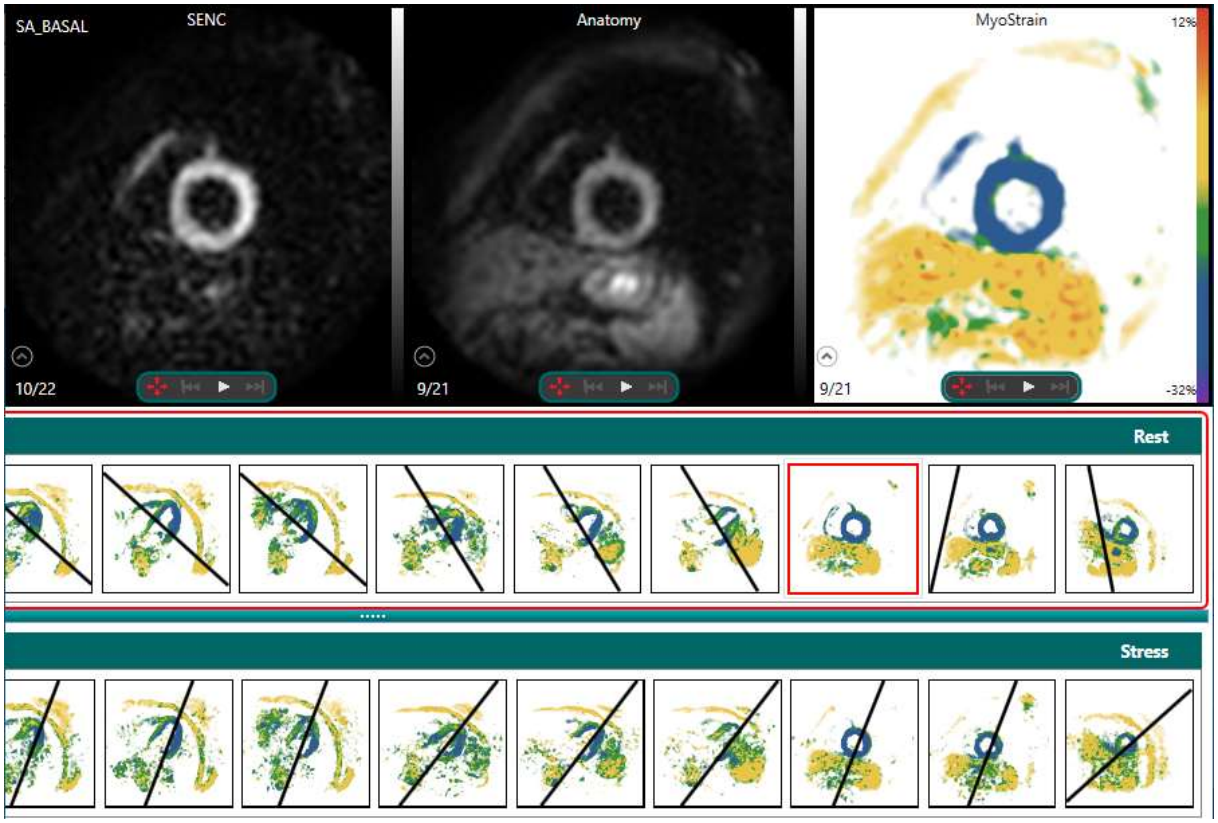


Figure 8-3: Preview Window showing Stress SENC images from the scanner

Using either the mouse scroll wheel, the arrow keys on the keyboard, or the CINE playback buttons found at the bottom of each of the **Analysis Windows,** play through each slice to ensure no artifacts or image abnormalities are present. The **Preview** window will also display all stages of stress acquired as part of the analysis as well.

After reviewing the images, close the **Preview** window to return to the **MyoWorklist**.

9. SEMI AUTOMATIC CONTOURING WORKFLOW

Semi Automatic Contouring is an optional feature which automates most of the analysis process. Using this mode allows the software to automatically apply a mesh to the image being analyzed. This feature can either be enabled or disabled by default. Any meshes applied using Semi Automatic Contouring must be reviewed for accuracy before completion. Methodology for sending images to the workstation is identical with or without automatic contouring active.

The **Semi Automatic Contouring** feature is available for use in both the Strain and Stress examination modes. The ability to enable and disable this functionality is controlled by the **Semi Auto Contouring** button in the **Settings** menu found under **File>Setup>Application Settings>Analysis Settings** in the title bar. This option will only take effect if there are no images currently loaded into the software. Restarting the MyoStrain program or beginning a new exam will enable Semi Automatic Contouring.

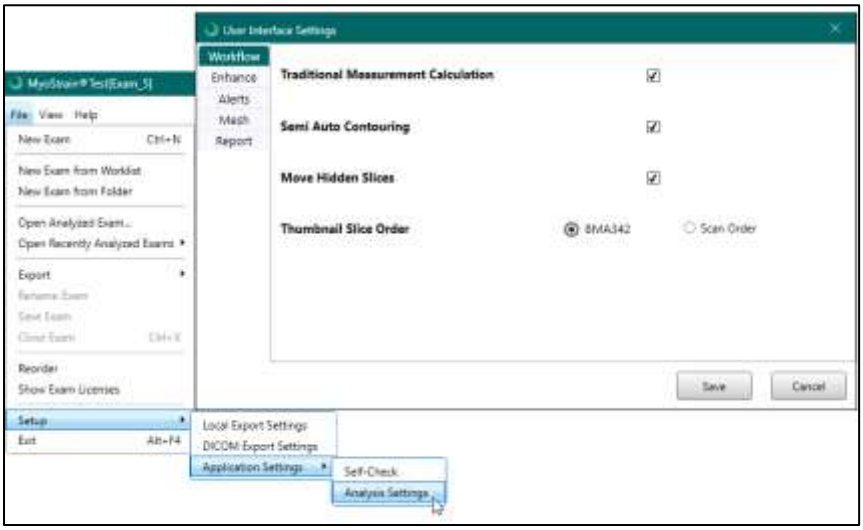


Figure 9-1: Semi Auto Contouring button checked

When **Semi Auto Contouring** is enabled, MyoStrain will attempt to apply a mesh for all Long-Axis and Short-Axis images near End-Systole upon image import. Additionally, if **Traditional Measurement Calculations** are enabled, Semi Auto Contouring will also attempt to identify the End-Diastolic timeframe for Long-Axis images and apply a mesh for that image as well. If MyoStrain is unable to confidently apply a contour to the image, either LV or RV, that mesh will not be drawn. Additionally, MyoStrain will also generate a 3D model and a polar-plot model which show global strain maps over time. These models are dependent on mesh and image quality and will reflect the quality of information displayed.

NOTE: Displaying timing metrics as well as RV Traditional Measurements requires Semi Auto Contouring to be enabled.

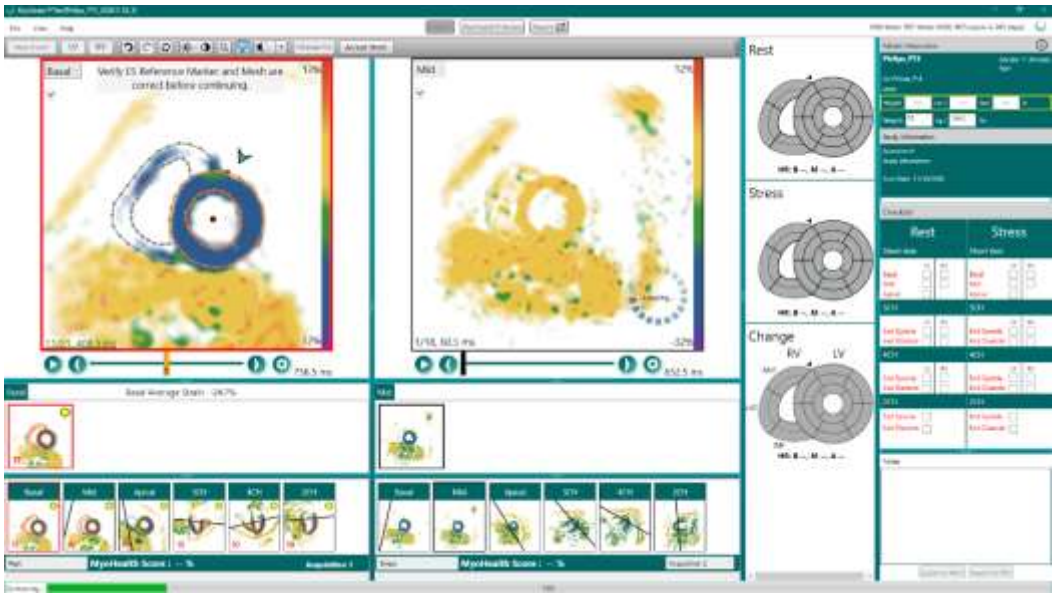


Figure 9-2: MyoStrain in process of receiving and analyzing Stress images

Immediately upon opening SENC images from either the Worklist or from a folder, MyoStrain will begin analyzing them with Semi Auto Contouring. As soon as an image has been processed/analyzed, its thumbnail will be updated in the **Image List** with a mesh attached**.** The lower-left region of the application will display progress messages when importing/analyzing images and will read **Ready** when the current series of images has been processed. All meshes created by MyoStrain through the Semi Auto Contouring tool will display as orange by default and will not display any strain information in the report until accepted or updated.

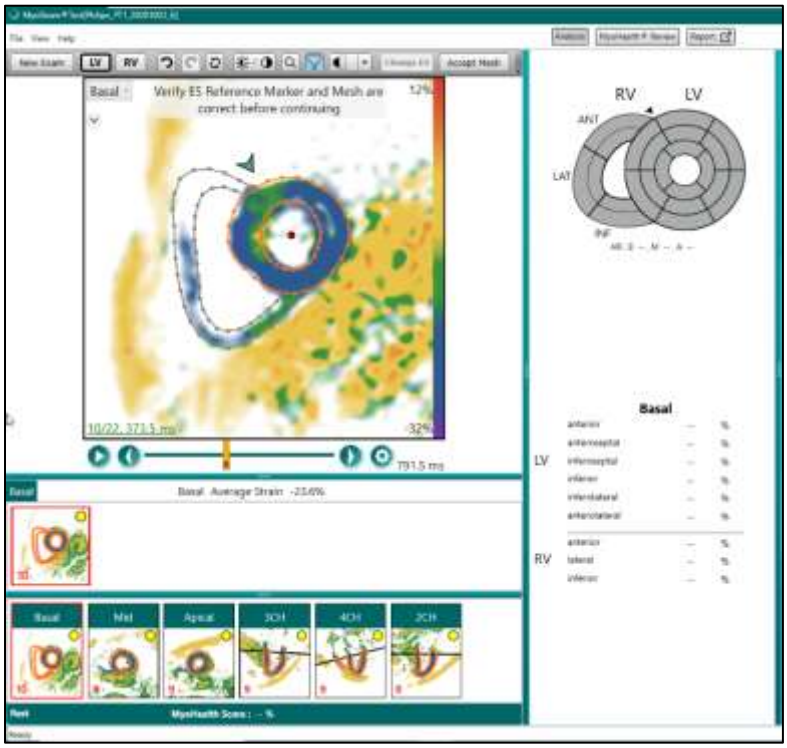


Figure 9-3: All images imported and analyzed, no measurements displayed in Analysis tab

NOTE: If multiple stress stages are included in the dataset, the Resting images will be processed first. These images can be reviewed, modified, and accepted while the software is contouring other stress stages.

Stress image analysis follows the same process as a Strain exam, and the highest stress stage will be used as the representative Stress series. It's highly recommended to perform the following steps when analyzing a dataset with Semi Auto Contouring:

1. Review all images shown in the Resting phase by playing through the video for each slice and view.
    a. Label Unknown slices appropriately (this will cause SAC to contour the slice)
    b. Re-label incorrectly labeled slices (this may cause SAC to re-contour the slice)
2. Going in order from Basal, Mid, Apical, 3CH, 4CH, 2CH:
    a. Identify the representative slice if multiple slices are present. (Hide unused slices)
    b. Identify the End-Systolic timeframe (use the **Change ES** button if the End-Systolic timeframe is not contoured, but is available on the slice)
    c. Correct the suggested contours (both LV and RV if available) or apply missing contours if they are not available.
    d. Identify the End-Diastolic timeframe (use the Change ED button if the End-Diastolic timeframe is contoured but not on the appropriate timeframe) if quantifying a Long-Axis image.
    e. Correct the suggested contours (Both LV and RV if available) or apply missing contours if they are not available.
3. Repeat steps 1 and 2 for each Stress stage (Acquisition with highest stress agent is reported on)

9.1 IMAGE REVIEW AND IDENTIFICATION

After the software has imported images and performed the Semi Automatic Contouring, it is imperative to review all images for completeness and for accuracy. Each thumbnail in the **Image List** will display a suggested mesh (if available) along with the yellow dot indicating that the view must be reviewed first. MyoStrain will not display any strain calculations for that view unless a mesh has been manually reviewed/accepted. As with any automation tool, the analyst is ultimately responsible for the quality of the analysis delivered.

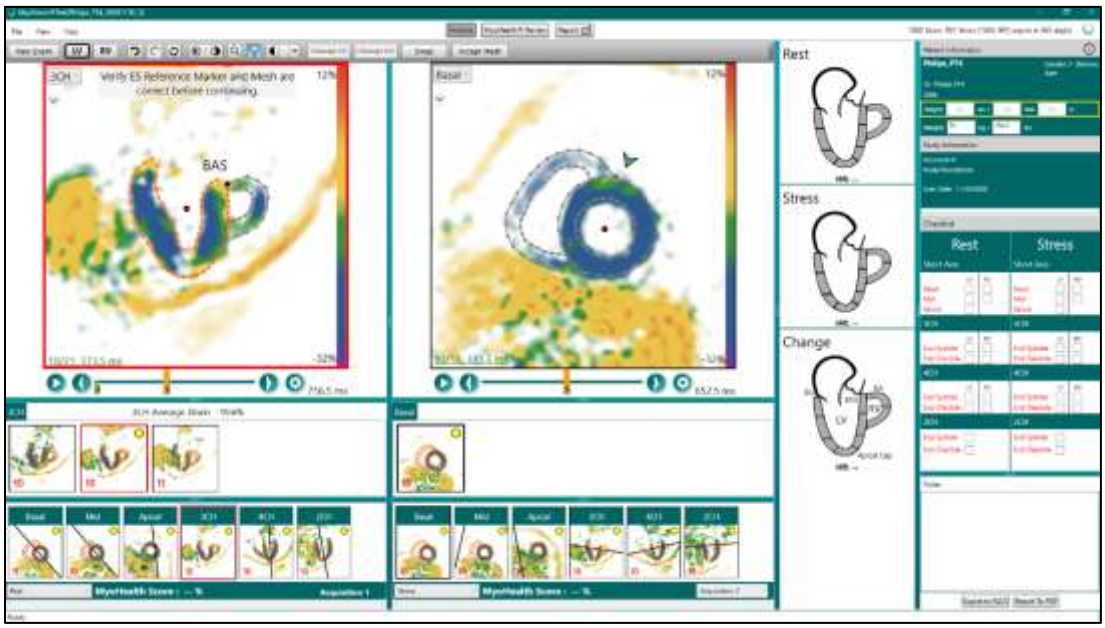


Figure 9-4: Newly imported Stress dataset using Semi Auto Contouring feature

In Figure 9-4, an imported dataset has been contoured using the Semi Auto Contouring feature. The **Display Header** at the top of the active Analysis Window describes the steps necessary to complete the analysis. By clicking on the **Accept Mesh** button found at the top of the **Analysis Window**, no changes to the mesh will be made and its strain measurements will be displayed in the report (Figure 9-5).

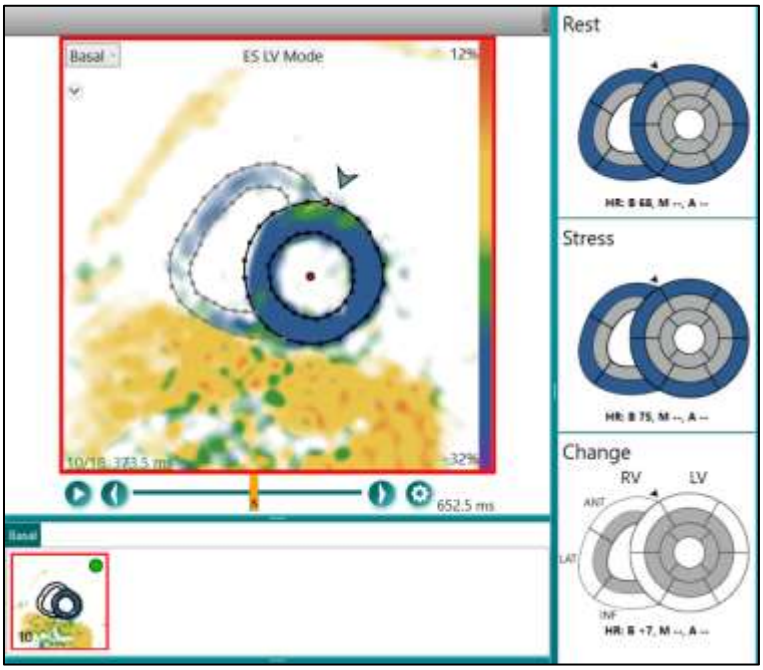


Figure 9-5: Accepted mesh with measurements shown in comparison region of Analysis tab

Semi Auto Contouring will not apply recommended meshes to slices which exhibit poor image quality or are labeled as “Unknown”. Selecting the appropriate view from the View Selection dropdown menu will prompt the application to attempt meshing that slice. Re-labeling an incorrectly identified view may also cause the Semi Auto Contouring tool to attempt to reapply a contour to that slice.

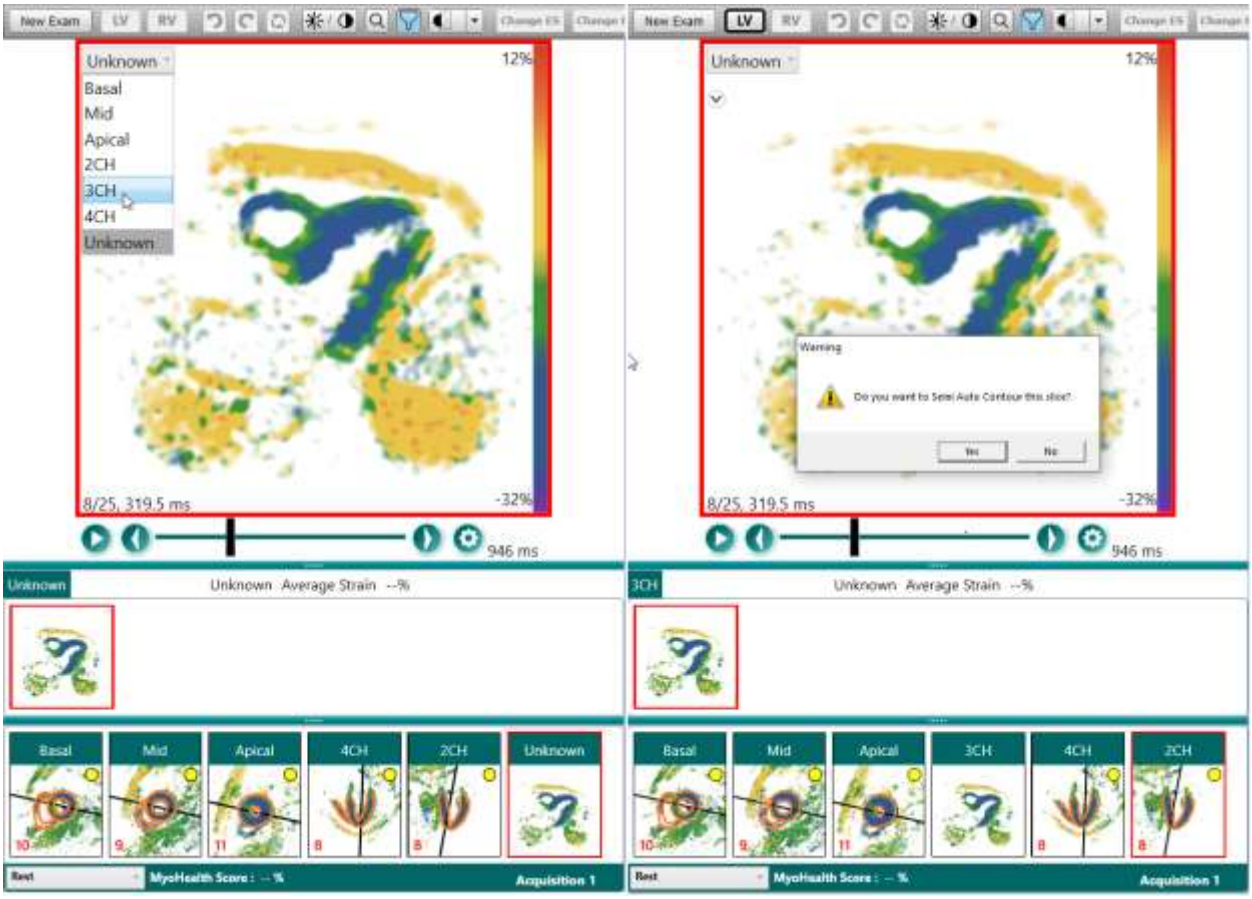


Figure 9-6: Identifying an Unknown view prompts SAC to analyze the slice.

9.1.1 REVIEWING AND UPDATING RECOMMENDATIONS

If multiple views are available, it's recommended to view each slice to review image quality and to verify that the software's recommendations are valid. A typical workflow would review each slice for planning first before making modifications or accepting the representative slice for each view. The estimated strain for each slice is shown when that slice is displayed in the **Analysis Window.**

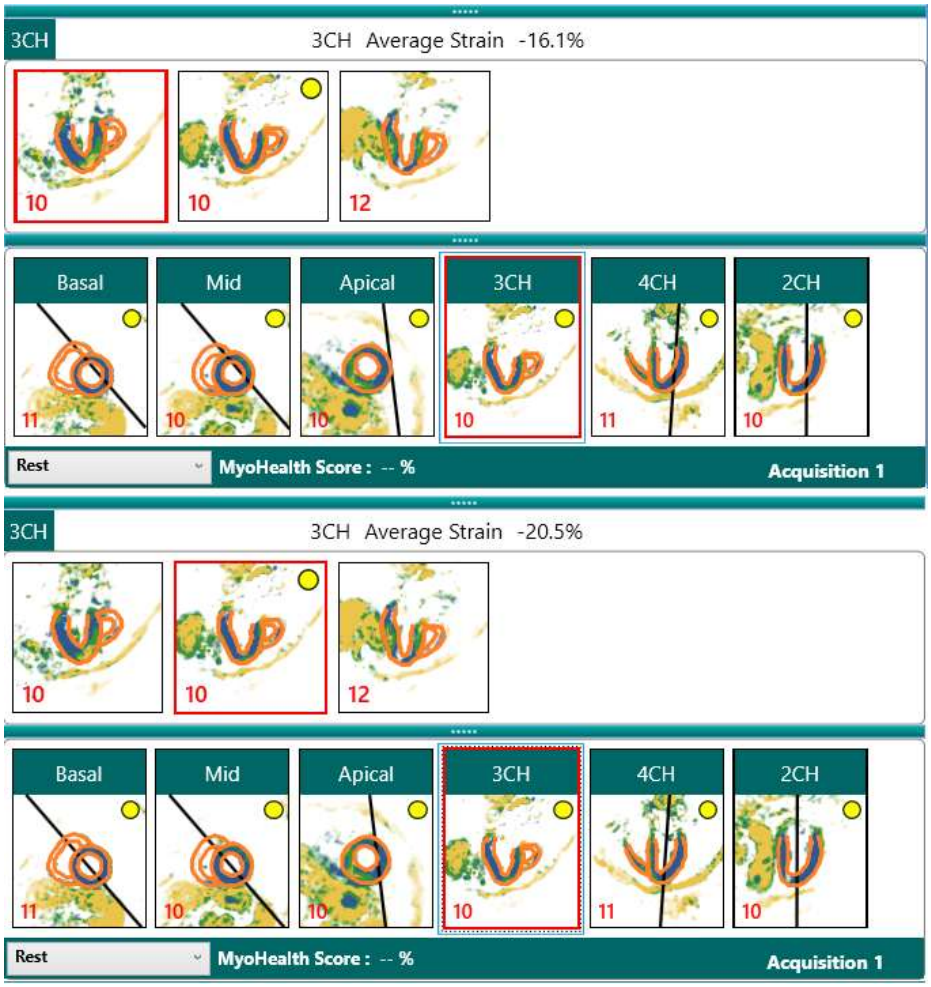


Figure 9-7 – Planing shown for an offplane slice (top) and recommended slice (bottom)

Additionally, any adjustments or modifications to the Semi Auto Contour will result in the mesh being accepted; except for changing the timeframe. If a new timeframe is selected, and the current mesh has not been accepted, MyoStrain will display the mesh generated by Semi Auto Contouring for that timeframe.

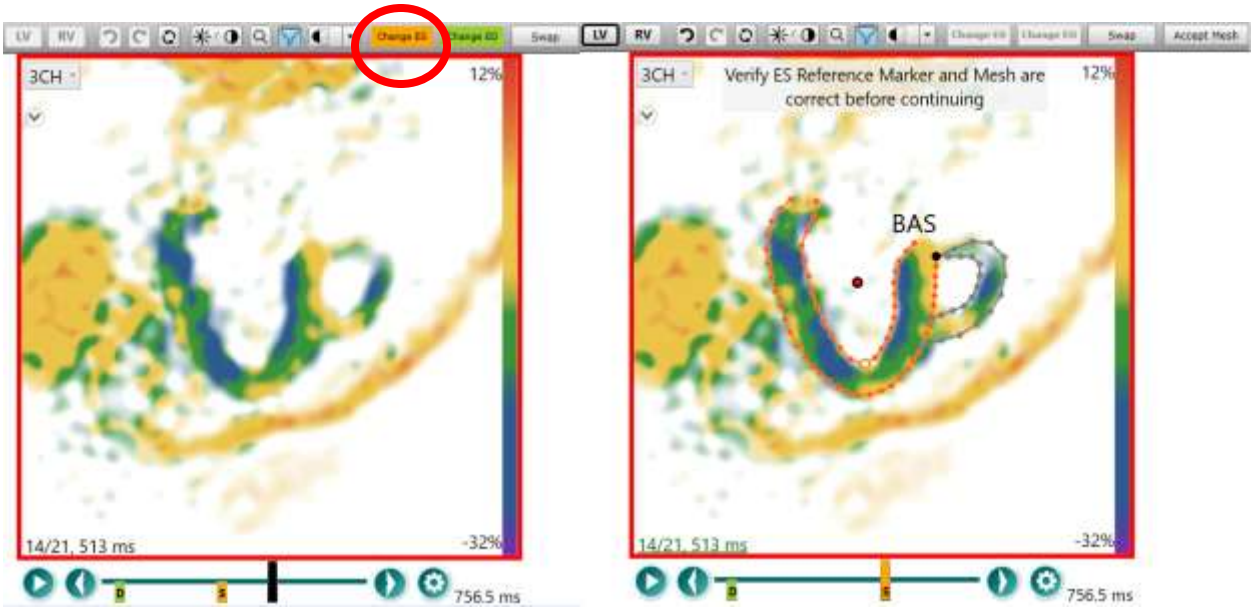


Figure 9-8- Clicking on the Change ES button shows the SAC contour for that timeframe instead of copying the existing mesh like it typically would.

Once accepted, the mesh will change to the default color schema and its measurements will be displayed in the report. Repeat this process until each of the 6 views have an accepted mesh indicated by a green dot in its thumbnail in the **Image List**.

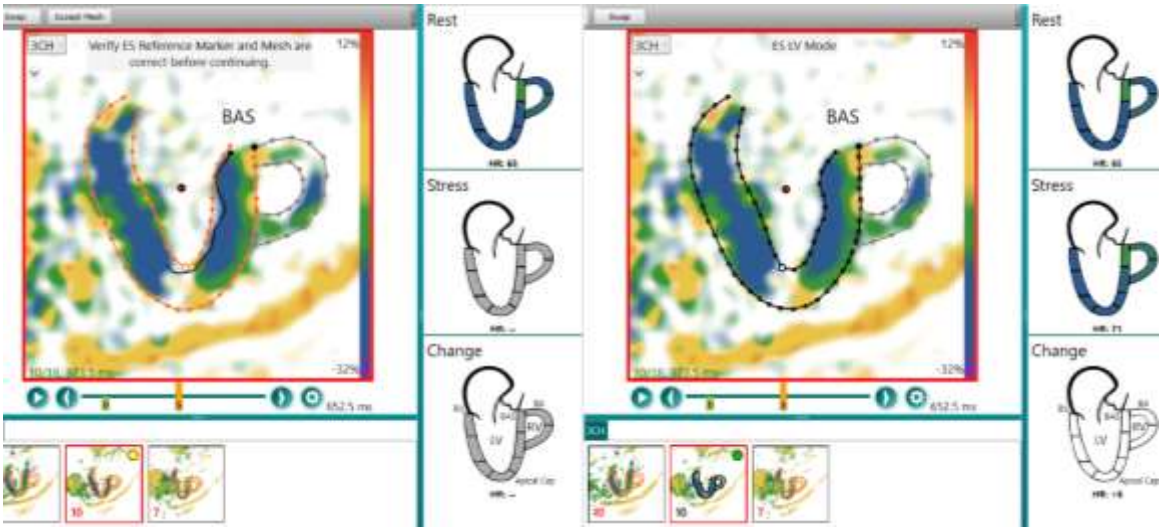


Figure 9-9: Corrections to an Auto Contour cause the mesh to become accepted and reported on

9.2 TRADITIONAL MEASUREMENTS WITH SEMI AUTO CONTOURING

In addition to identifying and contouring End-Systole, the Semi Auto Contour feature will also try to identify and contour the End-Diastolic timeframe as well. Like the End-Systolic mesh, the End-Diastolic timeframe must also be manually reviewed before its calculations will be included in the report. After accepting or modifying the End-Systolic mesh, right-clicking in the Analysis Window and selecting **Move to ED** or clicking the ED label in the Slice Navigator will display MyoStrain's suggested End-Diastolic mesh.

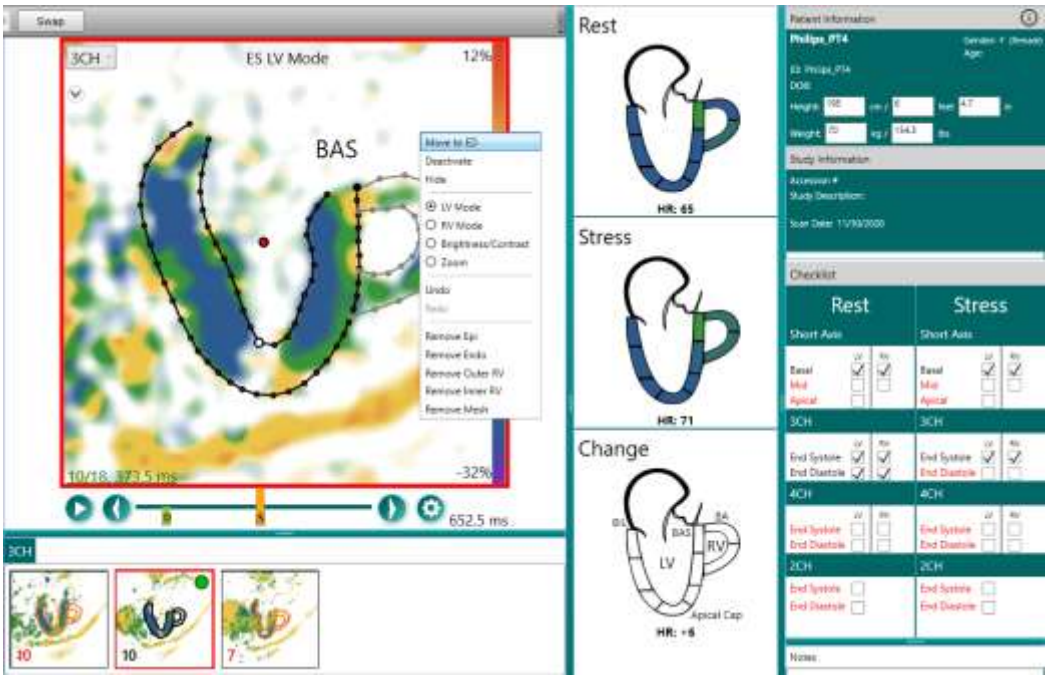


Figure 9-10: Navigating to the suggested End-Diastolic timeframe

NOTE: MyoStrain will display a warning if any Diastolic timeframes have not been accepted, except for stress stages. Reviewing/modifying/accepting diastolic timeframes will improve 3D Model and Polar Plot views.

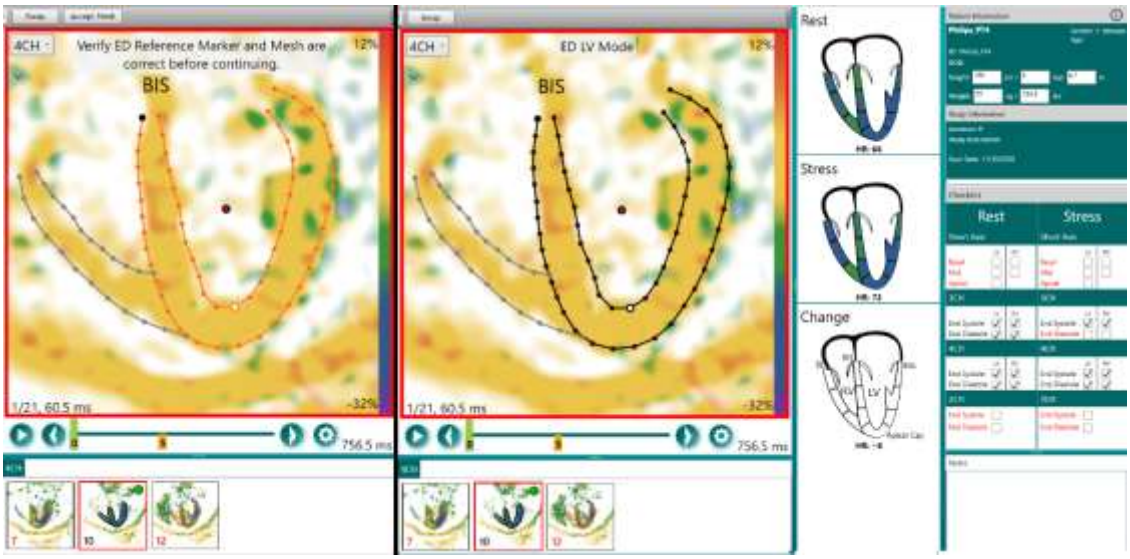


Figure 9-11: Before and after modifying the recommended Diastolic timeframe

NOTE: MyoStrain will use the 3D model generated from Rest stage SAC images to approximate traditional measurements when possible. The 2D meshes will be used if the 3D model cannot be generated.

10. MYOCONFIGURATOR (WORKLIST AND LDAP)

This chapter provides a detailed writeup of the MyoConfigurator, a tool used to configure how data is managed in MyoStrain. This includes the MyoWorklist, a separate service installed alongside MyoStrain. This MyoWorklist is responsible for managing images being sent to the MyoStrain application, hosting .Myo exam files stored in PACS, and how they are presented in the software for analysis. The MyoWorklist service serves multiple purposes: receive new images, preview new images without using an exam credit, revisit previous exams, and launch MyoStrain to analyze any dataset received on command. Encryption, access rights, and user history are also configured here.

10.1 MYOWORKLIST SETUP AND LAUNCH

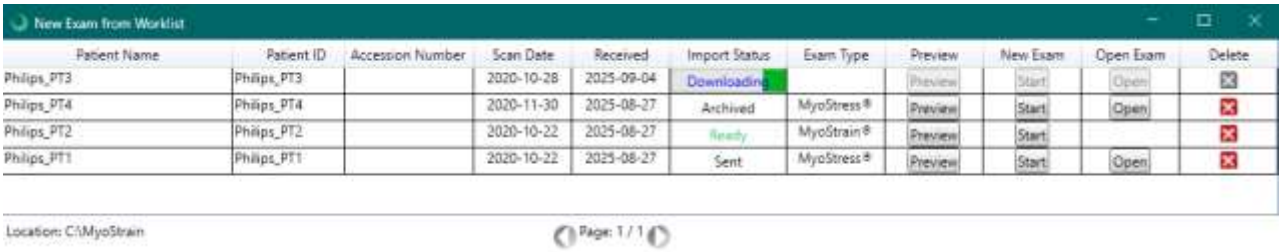


Figure 10-1: MyoWorklist running with multiple datasets available

By default, the MyoWorklist service will automatically launch on Startup and will run in the background listening for new datasets. The Worklist itself can be opened from the Desktop shortcut or directly through MyoStrain using the **File>New Exam from Worklist** feature.

NOTE: The Desktop MyoWorklist feature is unavailable if using MyoStrain in the LDAP authentication mode.

To configure MyoStrain to be able to receive images and exams from a remote modality (PACS server or MRI scanner):

Navigate to the directory where MyoStrain was installed, then run the "MyoConfigurator.exe" application. The default installation directory is: "C:\Program Files (x86)\Myocardial Solutions\MyoStrain Test\######\Release", where ###### is the version of MyoStrain installed.

Figure 10-2: MyoConfigurator requires Administrative privileges to run

1. Click on the **Configure PACS** tab of the MyoConfigurator program.
   a. If Encryption has not been enabled, a pop-up prompt will appear asking to configure this feature. Accepting this prompt will continue to the next step. It is recommended to use the Encryption tab before/after setup to backup a copy of this encryption key.
2. Fill out the 2 available fields in the **Client** section which identify this workstation to your PACS Server.

a. **Client AE Title** – The name which the PACS or scanner identifies as a MyoStrain workstation.
b. **Client Port Number** – Port which MyoStrain will listen on to receive images.
c. **Directory to Receive Images (uneditable) –** Path on the computer where any images received through the network are saved. Exam data will also be saved in this location as well.
d. **Save** – Press this button to save the information added to this section. Green confirmation text will appear upon a successful save.

3. Fill out the 3 available fields in the Server section which match a scanner or PACS pushing images to the analysis software.
    a. **Server AE Title** – Application Entity title of the PACS or scanner pushing images to MyoStrain.
    b. **Server Port Number** – Port which MyoStrain will transmit information back to the server.
    c. **Address Type** – PACS servers can be identified via either Hostname, or IP address
        i. **Server IP** – IPV4 address of the PACS server or scanner sending images.
        ii. **Hostname** – Human readable identifier for a PACS server on the network
    d. **Receive Only** – This option sets MyoStrain to ONLY receive images from a server entity without sending information back. Selecting this option will only require the server's AE Title to be entered to receive images.

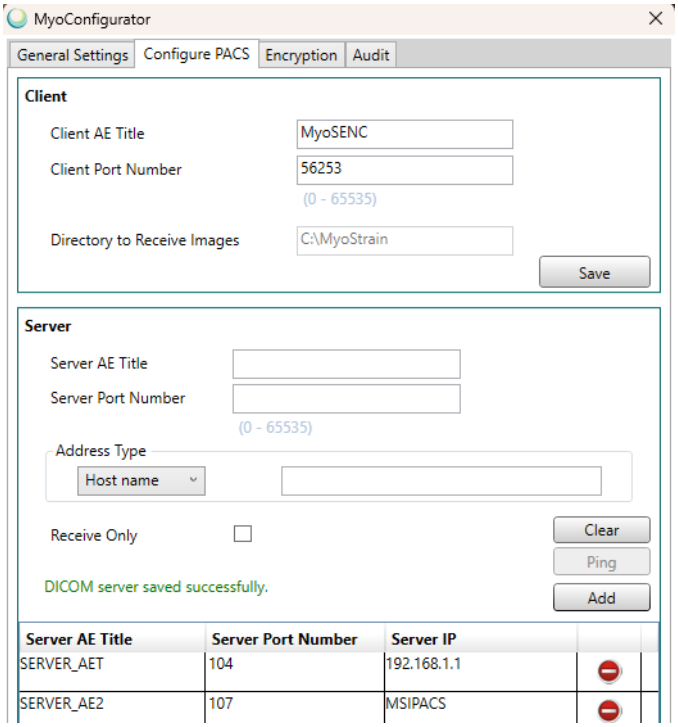


Figure 10-3: Sample Configure PACS setup

NOTE: Images received through DICOM Connectivity will be handled the same as images added directly to the default receiving directory.

4. Pressing the **Ping** button will test the connection. A notification will appear showing if the test was successful or not.

5. Pressing the **Add** button will save the current server's configuration. The server information will appear in a list at the bottom. Pressing the red minus button next to a server will delete that connection.

NOTE: MyoStrain requires a server's IP address to transmit data through the network. MyoStrain will only respond to servers listed in the MyoConfigurator.

10.2 MYOCONFIGURATOR - GENERAL SETTINGS

Worklist and language settings can also be changed in the MyoConfigurator tool. The Worklist settings are found in the **General Settings** tab of the MyoConfigurator tool.

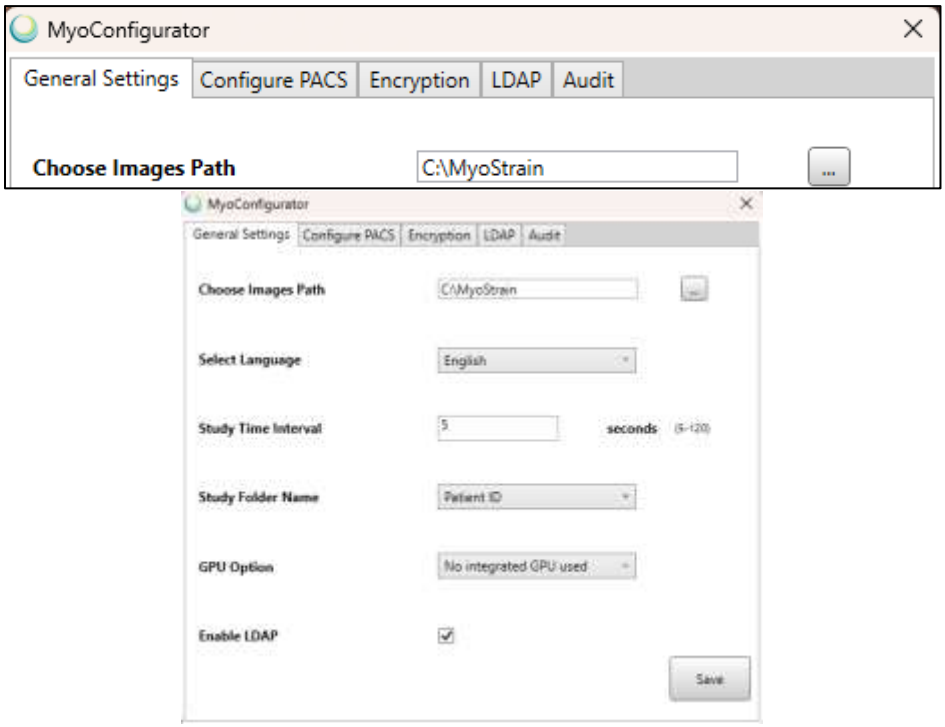


Figure 10-4: Worklist Settings window

- **Choose Images Path** – Clicking the ellipsis button will bring up a Browse for Folder dialog box. Selecting a folder from this location will cause MyoStrain to store all images received from PACS in this folder.
- **Select Language** – Selecting a language from this dropdown menu will restart the application and change the default language to the selected one.
    - **Dutch**
    - **English**
    - **French**
    - **German**
    - **Italian**
    - **Portuguese**
    - **Spanish**
- **Study Time Interval** – Amount of time MyoStrain will wait when receiving images before timing out.
- **Study Folder Name** – Folders created by MyoStrain to store images received through the Worklist will be created using the criteria listed in the dropdown menu.

- **Patient Name** – (0010,0010)
- **Patient ID (default)**- (0010,0020)
- **Accession Number** – (0008,0050)

- **GPU Option** – Enables/Disables GPU hardware acceleration.
- **Enable LDAP** – If checked, MyoStrain will require a connection to a server running Active Directory, and will authenticate users to access MyoStrain. Only users configured in the LDAP tab will be able to access MyoStrain. This option is only available to authorized users, and configuration authorization is available through Myocardial Solutions support.

10.3 MYOCONFIGURATOR ENCRYPTION SETUP

Figure 10-5: Encryption Tab of MyoConfigurator

When configuring the PACS/Network settings, MyoStrain will require that an encryption key is generated before the connection is completed. This key is used to encrypt all data stored in the MyoWorklist. By default, the encryption key is automatically generated by MyoStrain and information needed to regenerate this key is recorded during the installation and configuration process. Figure 10-5 shows the default behavior, and clicking the **Generate Key** button will confirm the usage of the default encryption schema. This key is unique to each computer.

If a unique key is requested, clicking on the No option will display an entry field where a user-authorized key can be supplied.

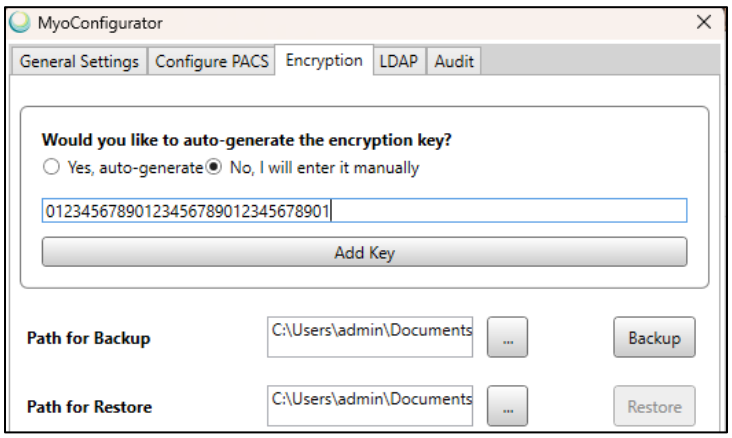


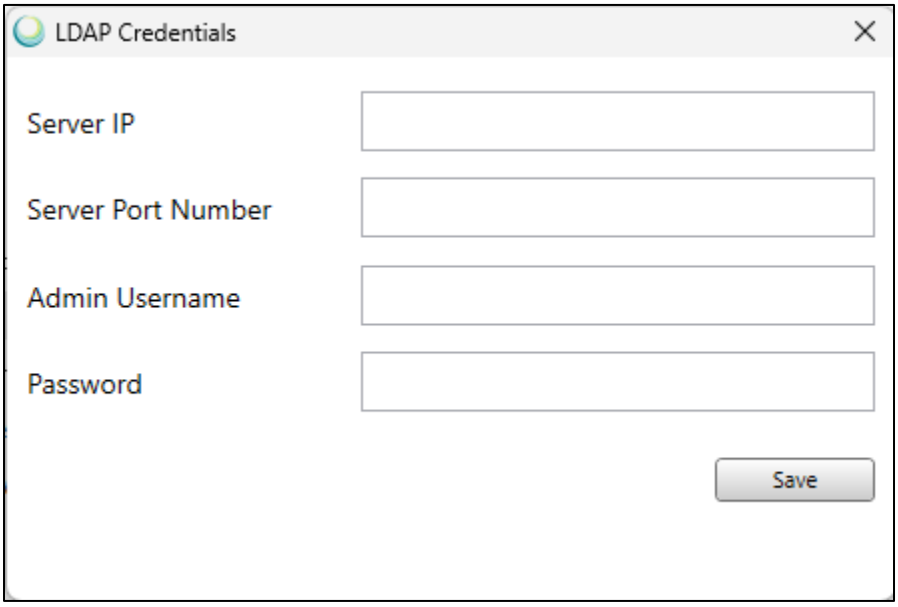
Figure 10-6: User-Provided encryption key entry point

NOTE: In the event where a user-provided key is used for encryption purposes, Myocardial Solutions will be unable to provide a method to decrypt data if the encryption key is lost. Myocardial Solutions can provide decryption capabilities if the default key was used.

- **Path for Backup** – The ellipsis button will let the user select where the encryption key should be exported to. Clicking the Backup button will export the encryption key to the specified destination.
- **Path for Restore** – The ellipsis button will let the user select a key file to import. Only keys exported using the Backup feature above can be restored using this method.

10.4 LDAP SETUP

During setup, if the LDAP option was selected, the MyoConfigurator will display an LDAP configuration window.



- **Server IP** – IP Address or Hostname of the LDAP server
- **Server Port Number** – LDAP server port. Typical defaults are 389 for LDAP, and 636 for LDAPS.
- **Admin Username –** LDAP Administrator Username.
- **Password –** LDAP Administrator password**.**

NOTE: MyoStrain will display a warning message if the LDAP connection is insecure.

The first user configured on this connection will be identified as the Administrator user. After the LDAP connection has been established, the admin user that setup the connection must now authenticate into the MyoConfigurator. After launching the MyoConfigurator, navigate to the LDAP tab to configure the LDAP groups and users for authorized access into MyoStrain. The **Inactivity Timeout** sets the amount of time (in minutes) MyoStrain will remain open if a logged-in user does not perform any actions.

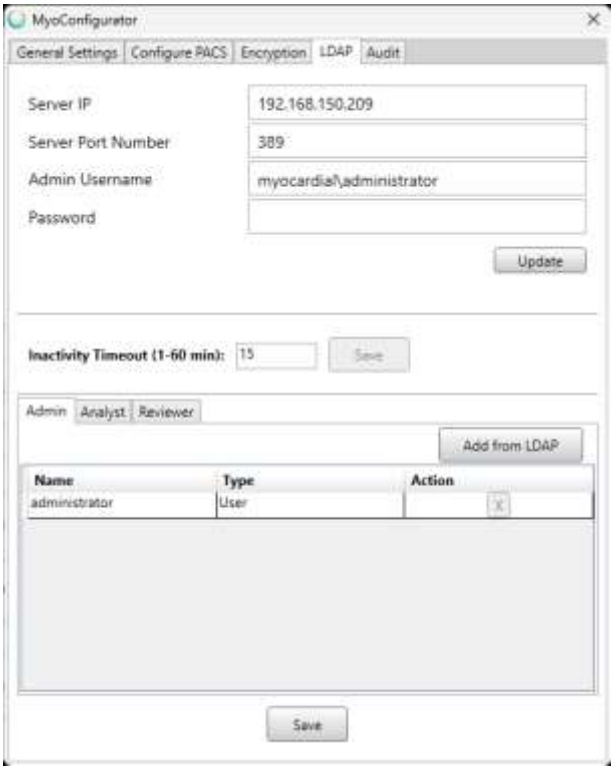


Figure 10-7: LDAP Configuration Tab

10.4.1 ADDING LDAP USERS TO ROLES

Within MyoStrain, there are 3 configurable roles for users to be assigned: Admin, Analyst, and Reviewer. Both individual users as well as user groups defined on the LDAP server may be used. Clicking on the **Add from LDAP** button will display a search box. From there, searching for a name will display User/Group matches found in the LDAP server, and clicking on the **+** button in the **Action** column will add that User/Group to the list.

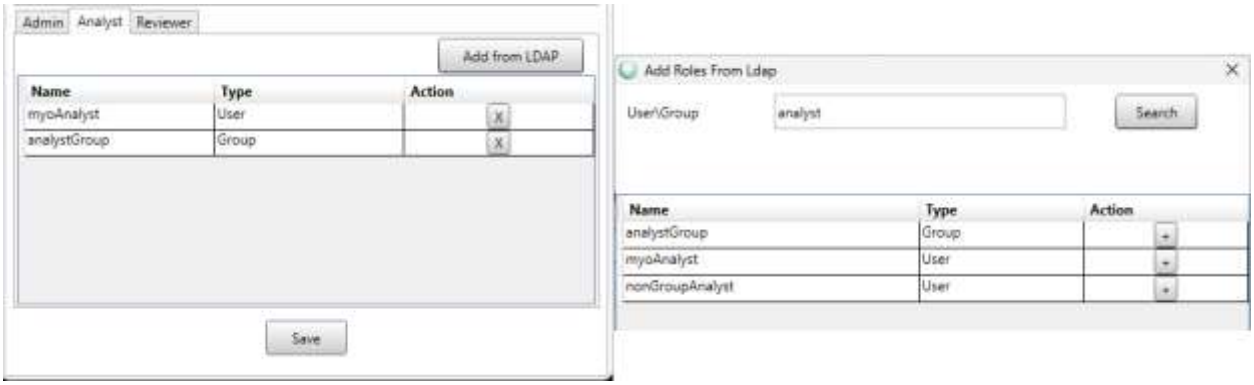


Figure 10-8: Adding users to the Analyst Group in MyoStrain using the Add from LDAP button

10.4.2 LDAP ROLES AND RESTRICTIONS

The 3 roles in MyoStrain are the Reviewer, Analyst, and Admin. The capabilities for each role are defined below.

- **Reviewer** – This user cannot consume exam credits. Reviewers are only able to open and modify previously performed exams. The New Exam from Folder option in MyoStrain and the New Exam button in the MyoWorklist are disabled.

- **Analyst** – This user can perform all actions that a Reviewer role can perform. In addition, Analyst users are also able to use exam credits to start New Exams.
- **Admin** – This user can perform all actions that an Analyst role can perform. In addition, Admin users are also able to access the MyoConfigurator tool to make changes to the application.

10.5 AUDIT LOGS

To review previous analysis activity in MyoStrain, the Audit tab in the MyoConfigurator provides access to the Audit Logs. Access and ability to export Audit logs are only available to Admin users.

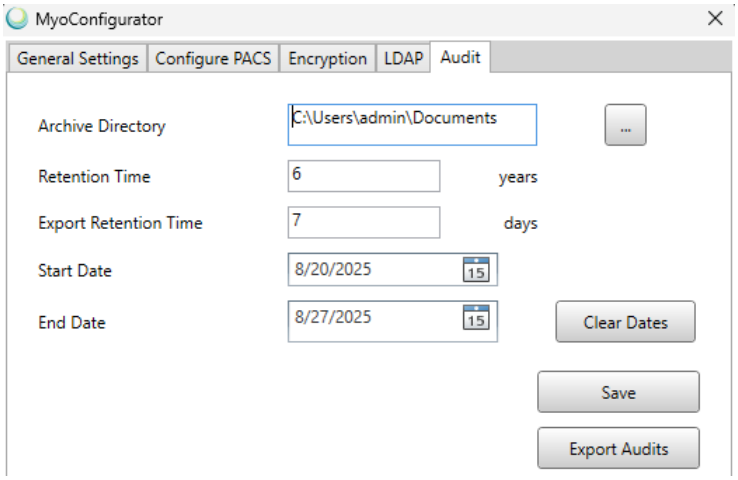


Figure 10-9: Audit Logs Configuration section of the MyoConfigurator

- **Archive Directory** – Location where the Audit Logs will be stored. Network addresses may also be specified.
- **Retention Time –** Records older than the specified timeframe will be removed from the database.
- **Export Retention Time –** Reports generated from this tool will be available N days after export.
- **Start Date –** Beginning date that the exported Audit Logs will cover.
- **End Date –** Ending date that the exported Audit Logs will cover.

Audit logs are exported in a .csv format in chronological order. Each entry is timestamped with the logged-in user and the actions performed by that user. The actions recorded in the Audit Logs are as follows:

- Successful/failed logins (LDAP only)
- Opening/Creating new exams
- Exporting data/DICOM images
- Modifying an existing exam (the slices/stages modified from the original exam are recorded)
- Deleting a dataset from the MyoWorklist
- Adding Exam/Application licenses to MyoStrain
- Timeout due to inactivity

	A	B	C	D	E	F	G
1	Timestamp	UserName	ActionType	Description			
2	8/20/2025 10:35	admin	MyoSecurity	New License added successfully			
3	8/20/2025 11:24	administrator	Login	Successful login from MyoStrain			
4	8/20/2025 11:25	administrator	Start	Start case:3 for patient Philips_PT4with Id:			
5	8/20/2025 11:30	administrator	Export Report to PDF	Export report to PDF from MyoStrain Exam:			
6	8/20/2025 11:30	administrator	Close Exam	Finished Closing Exam Philips_PT4_20201			
7	8/20/2025 11:31:22 AM	administrator	Login	Successful login from MyoConfigurator			

Figure 10-10: Sample Audit Logs

10.6 MYOWORKLIST FEATURES

The MyoWorklist is managed through 2 services that are running at all times on the workstation, MyoWorklistService and MyoCheckerService. When active, regardless of whether MyoStrain is open or closed, or if a user is logged in or not, the MyoWorklist will run in the background and receive any datasets pushed to it for analysis. If the MyoStrain application is closed when a dataset is launched from the worklist, the worklist will automatically launch MyoStrain and load the corresponding dataset.

NOTE: Check the **Import Status** is set to **Ready** or **Sent** before sending data to MyoStrain before processing.

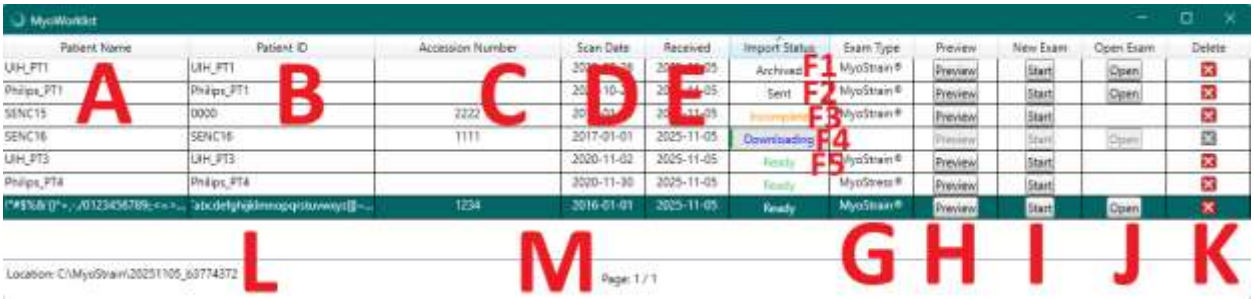


Figure 10-11: MyoWorklist actively downloading datasets

Once a dataset is received by the program, it is added to the list with an **Import Status** of Ready. The images are organized based on their DICOM information and displayed for easy access. Clicking on the title of any column in the MyoWorklist will sort the available datasets by that criteria. Default DICOM tags (####,####) are provided for each entry if applicable.

A. **Patient Name** – (0010,0010) - Name of the patient as listed in the DICOM header
B. **Patient ID** – (0010,0020) - The ID of the patient
C. **Accession Number** – (0008,0050) - A unique ID that is generated for a patient record
D. **Scan Date** – (0008,0020) - YYYY/MM/DD of acquisition of listed dataset
E. **Received** – YYYY/MM/DD of when this dataset was pushed to the workstation for analysis.
F. **Import Status** – Details what state the images are currently. Hovering over this status will display the total number of slices and images available to the dataset.
    1. **Archived** – This dataset has been analyzed in MyoStrain and has been sent to PACS for archival or reporting purposes.
    2. **Sent** – This dataset has been sent to MyoStrain for analysis. This typically means an exam file is available and clicking on the **Start** button will consume an additional exam credit .

3. **Incomplete** – This dataset is missing slices or images which would typically be found in a MyoStrain exam. This includes cases with two or more missing slices, or with slices with fewer than 5 timeframes of information.
4. **Downloading -** This dataset is still being downloaded. Analysis cannot begin until all images have been received.
5. **Ready** – All images in the dataset have been received and are ready for analysis. (Tooltip shown in Figure 10-12).

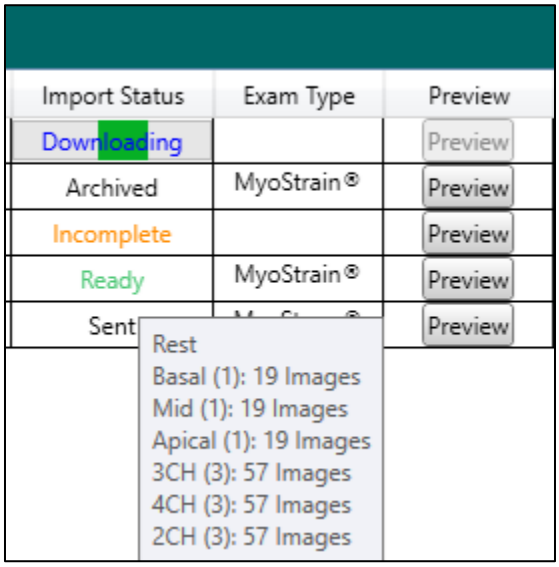


Figure 10-12: Import Status showing information about the study, tooltips showing slice data

G. **Exam Type** – Displays the type of exam that will launch when consuming an exam credit (MyoStrain or MyoStress).
H. **Preview –** This launches the Preview window. More information about the Preview window can be found in chapter 8.
I. **New Exam* -** This field holds the Start button, which will launch these images in a new MyoStrain exam. MyoStrain will launch if it is not open already. ***(This will consume an exam credit).**
J. **Open Exam**- If a dataset sent to the workstation has already been analyzed with MyoStrain and the Exam File was uploaded to PACS, MyoStrain can open that previously analyzed exam. Clicking this will open the folder containing the SENC images and any exam files associated with it (Figure 10-13)
K. **Delete –** This button will remove the dataset assigned to it from the workstation. A warning message will display if images being deleted do not show the *Archived* **Import Status** (Figure 10-14)**.** Multiple datasets can be deleted at once by holding down the Shift key to highlight multiple cases, then clicking the X button.
L. **File Path –** This shows where on the hard disk the exam data is located.
M. **Page Navigator –** A maximum of 100 entries are displayed in the MyoWorklist at a time. More pages will appear when an excess of 100 entries are available in the worklist for analysis.

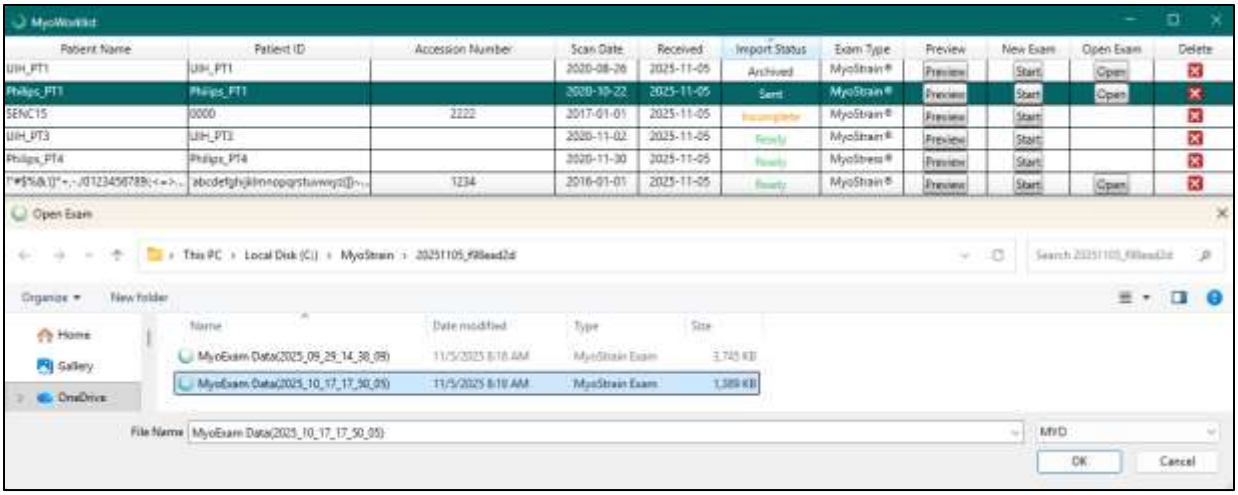


Figure 10-13: Opening a previously analyzed exam archived on PACS and sent for review

After launching the MyoStrain program using the MyoWorklist, additional exams can be launched from here, or from the worklist found within MyoStrain itself.

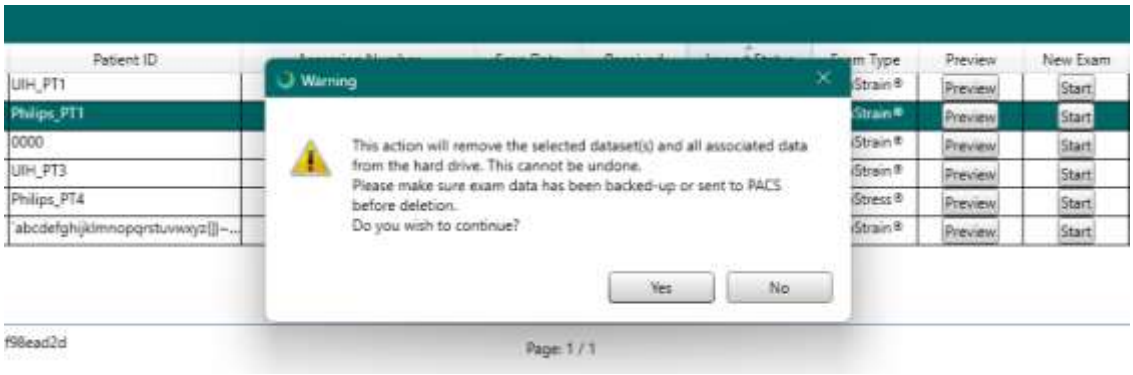


Figure 10-14: Warning message shown when attempting to delete images from the MyoWorklist

NOTE: MyoStrain will automatically determine if a Strain or Stress exam will be launched based on the images received. If Stress images are included with the patient scan, a Stress exam credit will be consumed. Opening an existing exam will not consume an exam credit.

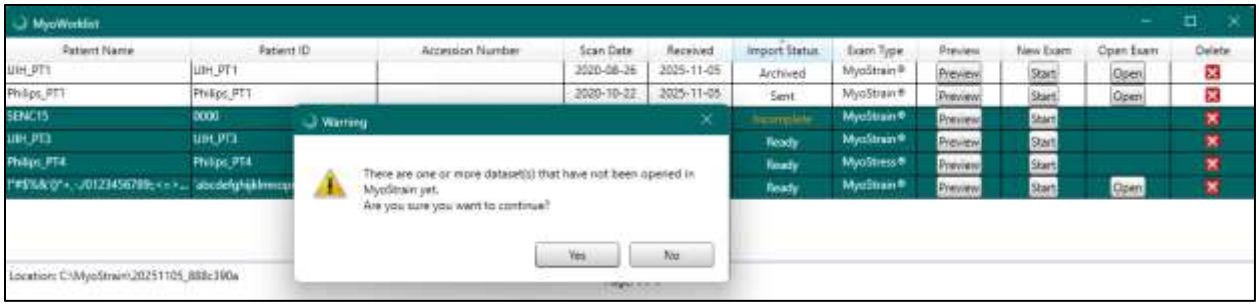


Figure 10-15: Multiple datasets can be selected at once by holding Shift or CTRL. Deleting one highlighted dataset will prompt removal for all highlighted cases.

10.7 IN-PROGRAM MYOWORKLIST

When working within MyoStrain, the MyoWorklist can be accessed by clicking the **New Exam from Worklist** option from the **File** menu (Figure 10-8).

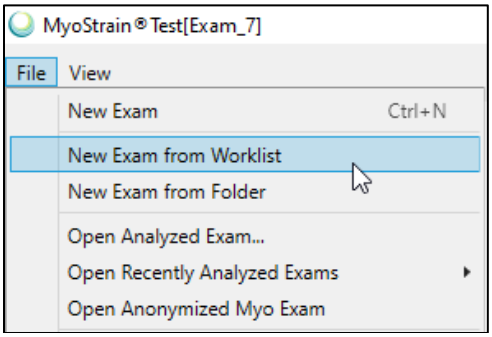


Figure 10-16: Open from Worklist option in the MyoStrain File menu

The **New Exam from Worklist** option will launch an in-application version of the MyoWorklist. From here, pressing the **Start** button will close the currently open exam (if available) and launch the selected one.

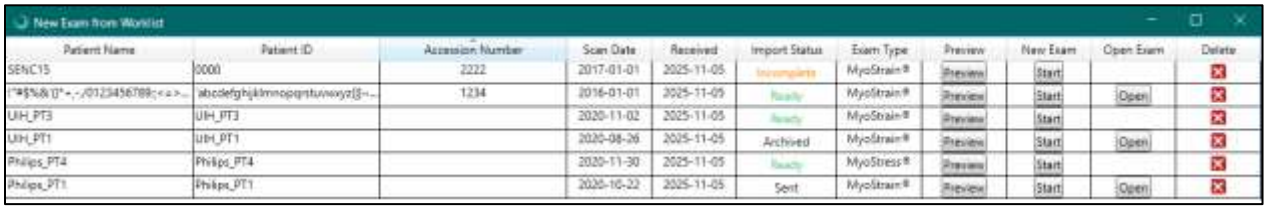


Figure 10-17: New Exam from Worklist dialog box as seen from MyoStrain

NOTE: MyoStrain will automatically determine if a Strain or Stress exam will be launched based on the images received. If Stress images are included with the patient scan, a Stress exam credit will be consumed. Opening an old exam will not consume an exam credit.

11. MYOHEALTH® REVIEW TAB

This section reviews in detail the features and viewing capabilities of the MyoHealth® Review tab. Information regarding exporting the 3D Model, Polar Plots, and how to manipulate or view these new additions are provided here as well.

The MyoHealth Review tab is opened by default whenever a previously analyzed dataset is opened in MyoStrain. Navigation to other sections of the application such as the Report or the Analysis page can be accessed by the buttons in the top middle portion of the application.

Warning: The 3D Model and the Polar Plots are provided for reference. The models are an approximation based on image quality and results gathered from Semi Auto Contouring. Regional strain calculations and measurements can be found in the Report.

11.1 COMMON FEATURES AND REQUIREMENTS

Some features of the MyoHealth Review tab are dependent on certain analysis requirements to be met before they can be utilized. The majority of viewing capabilities are enabled when Semi Auto Contouring is able to successfully contour a dataset with high confidence.

NOTE: When applying the colorized strain information to the 3D Model and Polar Plots, some regions of the myocardium may not have corresponding strain information to display. In those cases, the strain is shown grey.

11.1.1 3D MODEL

The 3D Model is generated from the meshes applied to the dataset. There are two 3D models created for each stage of stress images analyzed, one depicting Longitudinal Strain, the other Circumferential Strain. If the dataset was analyzed without the use of Semi Auto Contouring, or if the 3D Model cannot be fully generated, it will only display a rendering of the Systolic timeframe.

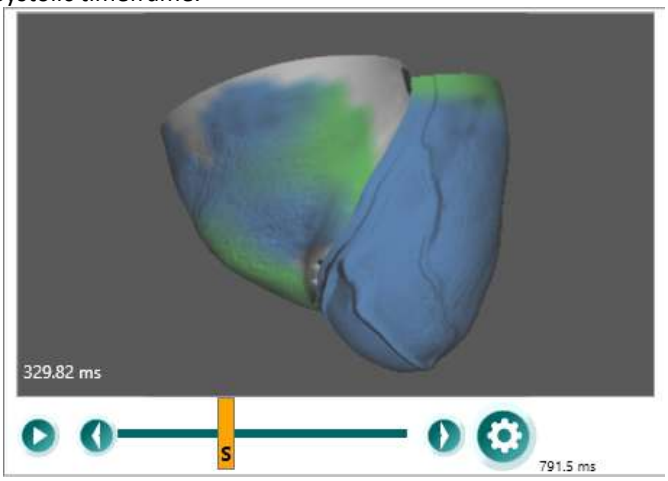


Figure 11-1: 3D Model generated using dataset contoured with Semi Auto Contouring

The 3D model will only provide video playback if Semi Auto Contouring was enabled and could apply contours to most of the slices available to it during the analysis. The 3D model will only provide an RV if the RV contour was applied during the Analysis phase. Additionally, if the Trigger Time DICOM tag (0018,1060) is unavailable, the playback time will default to a 1 second interval.

The playback buttons in the 3D Model view function identically to the Analysis tab. In addition, there are additional visualization features enabled on the 3D Model which are exclusive to this view.

NOTE: If the 3D model could not be generated, the thumbnail will be replaced with an 'X'. The 3D model thumbnail will display in grey, regardless of the strain calculated for the exam.

11.1.1.1 3D MODEL VISUALIZATION FEATURES

When the 3D model is displayed, by default the anterior wall of the myocardium is displayed in front, with the Basal region near the top of the screen, and the apex at the bottom. The mesh can be freely rotated by holding down the left-mouse button and moving the mouse cursor in the window.

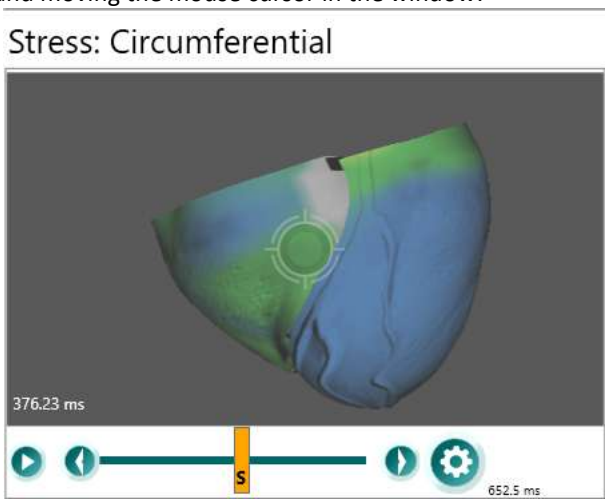


Figure 11-2: Target icon will display when rotating the 3D Model

Additionally, holding down the CTRL button on your keyboard will change the Scroll Wheel's behavior in the 3D Model to allow zooming in and out of the image.

11.1.2 **POLAR PLOTS MODEL**

The Polar Plots model shows strain information calculated from meshes applied to the dataset. There are two Polar Plots models created for each stage of stress images analyzed, one showing Longitudinal Strain, the other Circumferential Strain. If the dataset was analyzed without the use of Semi Auto Contouring, the Polar Plots will only display a rendering of the Systolic timeframe. The grey dotted line in the middle of the LV portion of the Polar Plots represents the septal wall of the LV.

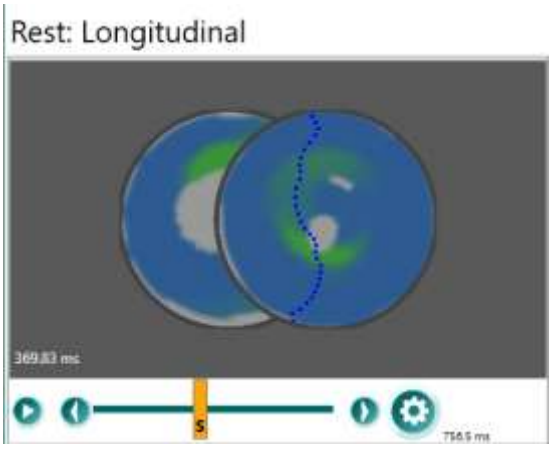


Figure 11-3: Polar Plots generated from dataset using Semi Auto Contouring

Additionally, the Polar Plots will provide video playback only if Semi Auto Contouring was able to apply contours to a majority of the SENC images provided during the analysis. This also holds true for RV contours as well. If the Trigger Time DICOM tag (0018,1060) is unavailable to MyoStrain, the playback time will default to a 1 second interval.

11.2 MYOHEALTH® REVIEW – STRAIN LAYOUT

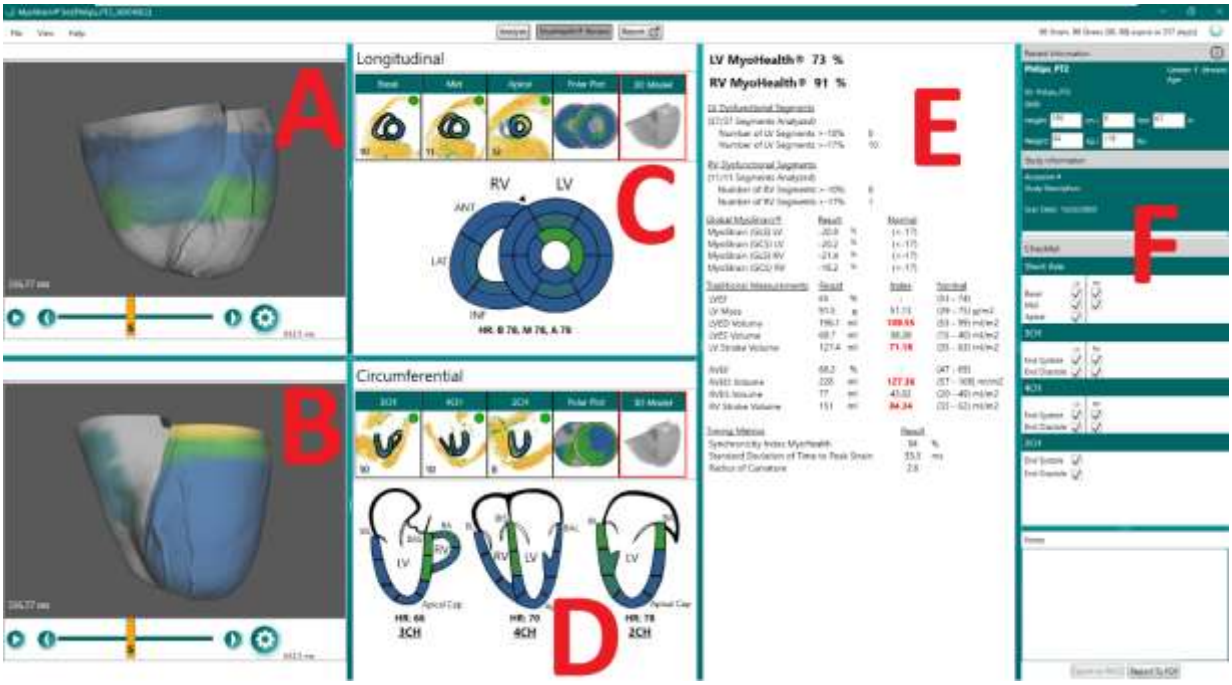


Figure 11-4: Default layout of the MyoHealth Review tab during a Strain exam.

A. **Longitudinal Viewing Window** – Displays the currently selected Short Axis image from the **Image List**
B. **Circumferential Viewing Window** – Displays the currently selected Long Axis image from the **Image List**.
C. **Longitudinal Image List –** Shows only the active Short Axis slices analyzed during the Analysis portion of MyoStrain, including the Longitudinal 3D Model and Polar Plots.
D. **Circumferential Image List** – Shows only the active Long Axis slices analyzed during the Analysis portion of MyoStrain, including the Circumferential 3d Model and Polar Plots.
E. **Global Measurements** – Shows the same global measurements available in the **Report** tab.

F. **Patient Information and Checklist**- Shows the same information available in the **Analysis** tab.

When reviewing a Strain exam using the MyoHealth Review tab, Long Axis and Short Axis views can be shown simultaneously. Longitudinal Strain based meshes will be shown in the top, where Circumferential Strain is shown at the bottom. When multiple views are shown on opposing axes, both Relative Planes will be shown in the Image lists.

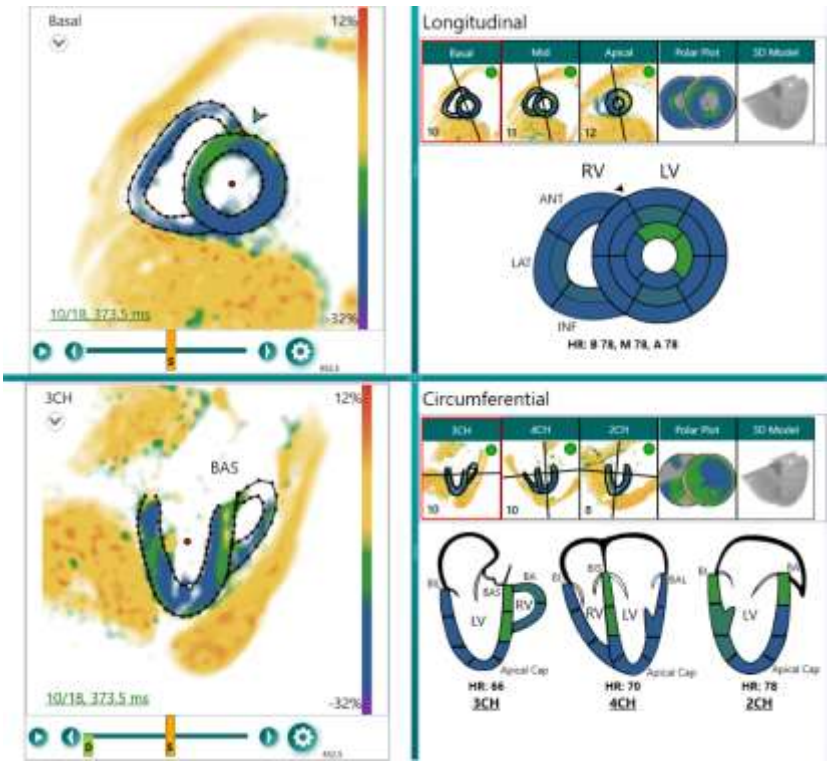


Figure 11-5: Relative planes showing orthogonal planes when viewing multiple slices simultaneously

NOTE: Thumbnails in the MyoHealth Review tab will display the peak strain values calculated from the mesh, not the aggregate strain thumbnails seen in the Analysis tab.

11.3 **MYOHEALTH® REVIEW – STRESS LAYOUT**

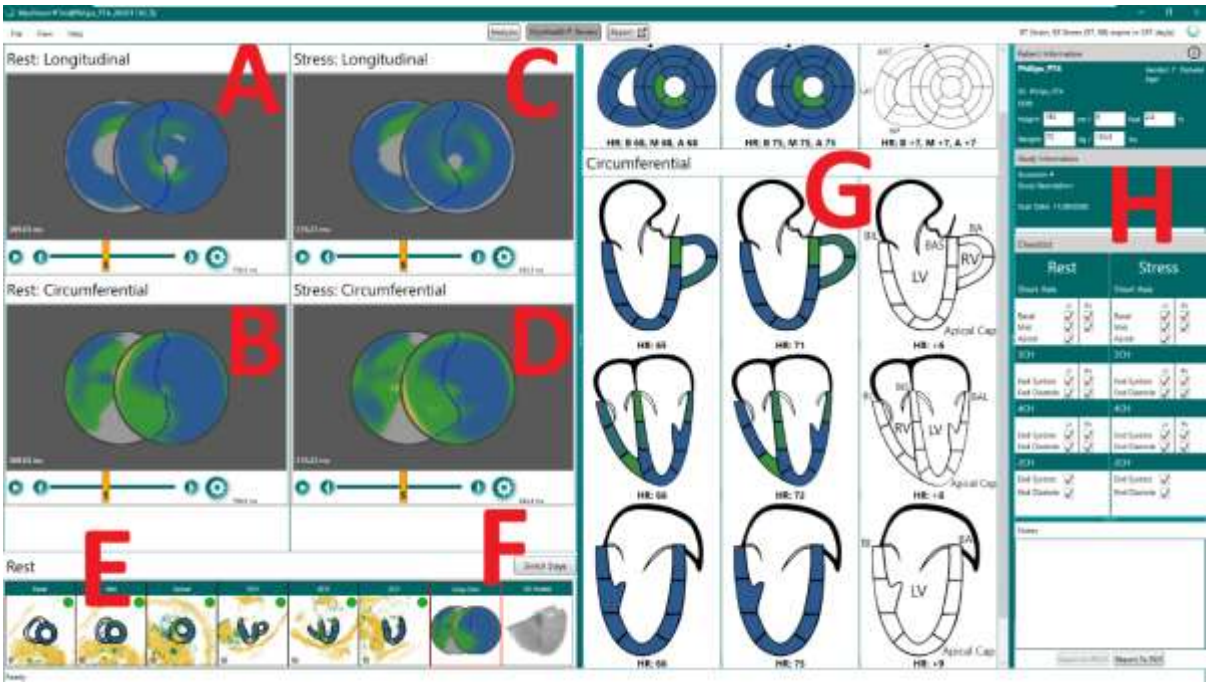


Figure 11-6: Default layout of the MyoHealth Review tab during a Stress Exam

When reviewing a Stress exam in the MyoHealth Review tab, each view selected will display both Rest and Stress images simultaneously. The 3D Model and Polar Plots views will show both the Longitudinal and Circumferential images of the Rest and Stress series simultaneously when selected.

A. **Rest Viewing Window** – Displays the currently selected MyoStrain image's Rest view from the **Image List** (Polar Plots and 3D model will show the Longitudinal version here)
B. **Rest Viewing Window (secondary)** – Displays the corresponding Circumferential 3D Model or Polar Plot model when that view is selected from the **Image List**.
C. Stress Viewing Window – Displays the currently selected MyoStrain image's Stress view from the **Image List** (Polar Plots and 3D Model will show the Longitudinal version here)
D. **Stress Viewing Window (secondary)** – Displays the corresponding Circumferential 3D Model or Polar Plot model when that view is selected from the **Image List**
E. **Image List** – Shows the accepted MyoStrain slices analyzed during the Analysis portion of MyoStrain, including the 3D Model and Polar Plots.
F. **Switch Stage** – Changes the thumbnails displayed in the Image List from Rest to Stress and vice versa.
G. **Strain Regional Measurements** – Shows the same measurements available in the **Report** tab. Hovering the mouse cursor over a segment will display the strain value for that region in the AHA model.
H. **Patient Information and Checklist**- Shows the same information available in the **Analysis** tab.

NOTE: Thumbnails in the MyoHealth Review tab will display the peak strain values calculated from the mesh, not the aggregate strain thumbnails seen in the Analysis tab.

12. EXTERNAL REFERENCES AND RELEASE NOTES

This section outlines any references to outside materials not produced by Myocardial Solutions. These include third-party software libraries and research references.

12.1 THIRD PARTY APPLICATIONS

MyoStrain makes use of multiple third-party libraries which assist with processing and displaying information.

- absl-py - Python application build package
- Accord – Used for exporting video.
- AssimpNet - Memory management module
- astor - Used for reading and writing ASTs (Abstract Syntax Trees).
- cffi - Used to call C code from Python.
- cryptography - Used for secure data storage or transmission.
- DICOM# - Library for processing DICOM Formatted data
- Eigen - Library for linear algebra, matrices, vectors and related maths.
- EO.PDF - Processes and formats PDF documents
- FO-DICOM – Library for processing DICOM images
- gast - A generic AST to represent Python AST.
- GLM - Library for linear algebra, matrices, vectors and related maths. For easy compatibility with OpenGL.
- Gma.QrCodeNet.Encoding.dll - Generates QR codes available on MyoStrain reports
- google-pasta - Library used to help with merging and refactoring of Python code.
- grpcio - Supports gRPC, a high-performance, open-source universal RPC framework.
- h5py - Allows for storing and manipulating data within the HDF5 format.
- HelixToolkit.WPF.SharpDX - 3D model processing
- IJG Library - Processes JPEG compressed DICOM data
- importlib-metadata - Used for package management and accessing package metadata.
- joblib - Used for parallel computing and caching.
- Keras-Applications - Deep learning model library
- Keras-Preprocessing - Utilities for image preprocessing.
- LibJpeg.NET - Compresses JPEG data
- Log4Net - Generates log files
- Markdown - Text-to-HTML conversion tool.
- MarkupSafe - Implements a XML/HTML markup safe string.
- MediaToolkit - Video processing and exporting
- Newtonsoft.json - Generates QR codes available on MyoStrain reports
- Nlog – Library used to add logging to the 3D Model module
- nlohmann_json - Library for loading and reading jsons
- numpy - Package for scientific computing in Python, essential for handling arrays and matrices.
- OpenCV - Library for linear algebra, matrices, vectors and related maths.
- opencv-python - Open source computer vision library, used for image transformations, drawing contours and other image processing tasks.

- opt-einsum - Optimizes Einstein summation for multidimensional arrays.
- pandas - Data analysis and manipulation libary, useful for managing structured data.
- protobuf - Google's mechanism for serializing structured data, used for model saving and data exchange in TensorFlow.
- pycparser - A C parser in Python, useful for interfacing with C code or libraries.
- python-dateutil - Provides extensions to the standard datetime module.
- pytz - Brings the Olson tz database, allows for accurate timezone calculations.
- scikit-learn - Machine learning library for Python.
- scipy - Library used for scientific and technical computing.
- SharpAVI - Library to export videos from MyoStrain
- SharpDX - DirectX processing for 3D Model
- SharpZipLib - Archive processing
- six - Helps with maintaining code that is compatible across Python versions.
- spdlog - Library for logging.
- stb_image - Library for loading images.
- tensorboard - A tool for providing visualization for machine learning workflow.
- tensorflow-directml - TensorFlow variant that uses DirectML for backend, enabling TensorFlow to run DirectX 12 compatible GPUs.
- tensorflow-estimator - A high-level TensorFlow api that simplifies Machine Learning training and predication.
- termcolor - Useful for making logs and console messages more readable.
- threadpoolctl - Manages thread pools for BLAS libraries, specific for controlling parallel computing.
- TinyGLTF - Library for loading and saving 3D models using glTF.
- Topshelf - Service implementation
- typing_extensions - Enables the new type system on older Python versions.
- Werkzeug - WSGI web application library.
- wrapt - A module for decorators and wrappers.
- zipp - Useful for handling package data and resources.

Additionally, MyoStrain includes the following applications as part of its installation:

- .NET Framework 4.8 (if not already available)
- Visual C++ Redistributable Package 2019

Detailed information related to these libraries including version numbers are available upon request through support@myocardialsolutions.com.

12.2 MYOSTRAIN STRAIN SCALE

MyoStrain utilizes mechanical strain, which can be defined as the deformation of a material when compared to a baseline state. MyoStrain measures how much the heart contracts between its baseline state (at diastole) and under strain (at systole), and this is typically a negative ratio under normal circumstances. Strain is a “unitless” measurement as it is the ratio of two lengths, and it can be expressed as a fraction or a percentage value.

More information regarding the strain legend used in the MyoStrain program can be found from the following papers:

- Neizel M, et al. “Strain-encoded MRI for evaluation of left ventricular function and transmurality in acute myocardial infarction.” Circ Cardiovasc Imaging. 2009;2(2):116-122

- Wong DT, et al. “Magnetic resonance-derived circumferential strain provides a superior and incremental assessment of improvement in contractile function in patients early after ST-segment elevation myocardial infarction.” European Radiology. 2014;24:1219-1228.
- Oyama-Manabe N, et al. “Identification and further differentiation of subendocardial and transmural myocardial infarction by fast strain-encoded (SENC) magnetic resonance imaging at 3.0 Tesla” European Radiology. 2011;21(11):2362-2368.
- Neizel M, et al. “Impact of Systolic and Diastolic Deformation Indexes Assessed by Strain-Encoded Imaging to Predict Persistent Severe Myocardial Dysfunction in Patients After Acute Myocardial Infarction at Follow-Up.” Journal of the American College of Cardiology. 2010;56:1056-1062.
- Choi E-Y, et al. “Prognostic value of myocardial circumferential strain for incident heart failure and cardiovascular events in asymptomatic individuals: the Multi-Ethnic Study of Atherosclerosis.” European Heart Journal. 2013;34:2354-2361.
- Koos R, et al. “Layer-specific strain-encoded MRI for the evaluation of left ventricular function and infarct transmurality in patients with chronic coronary artery disease.” Int J Cardiol. 2013;166:85-89.Korosoglou, G et al. “Fast Strain-Encoded Cardiac Magnetic Resonance for Diagnostic Classification and Risk Stratification of Heart Failure Patients” JACC Cardiovasc Imaging 2021 Jun;14(6):1177-1188. doi: 10.1016/j.jcmg.2020.10.024.
- Steen H, et al. Left and right ventricular strain using fast strain-encoded cardiac magnetic resonance for the diagnostic classification of patients with c hronic nonischemic heart failure due to dilated or hypertrophic cardiomyopathies and cardiac amyloidosis. JCMR. 2021;23:45. doi:10.1186/s12968-021-00711-w.
- Korosoglou, G., et al . Systematic review and meta-analysis for the value of cardiac magnetic resonance strain to predict cardiac outcomes. Sci Rep 14, 1094 (2024). https://doi.org/10.1038/s41598-023-50835-5
- Korosoglou, G et al. 2019 Strain-encoded magnetic re sonance: a method for the assessment of myocardial deformation ESC Heart Fail. 2019 Aug; 6(4): 584–602.doi: 10.1002/ehf2.12442
- Pezel T, et al. Regional strain score as prognostic marker of cardiovascular events from the multi-ethnic study of atherosclerosis (MESA). Front Cardiovasc. Med. 2022;9:870942
- Steen H, et al. Multi-parametric non-contrast cardiac magnetic resonance for the differentiation between cardiac amyloidosis and hypertrophic cardiomyopathy. Clinical Research in Cardiology. 2023. doi:10.1007/s00392-023-02348-4.

12.3 **AHA MODEL**

The AHA Models used in MyoStrain are derived from the following publication:

M. Cerqueira et al., “Standardize Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart,” Circulation, 2002;105:539-542

12.4 **NORMAL RANGES OF MYOSTRAIN MEASUREMENTS**

The output of the SENC images post-processing is a report that shows various measurements. One set of measurements is the traditional global measurements (ejection fraction and chamber volumes). These measurements are presented with the normal ranges published by Zhan et al [1]. The other set is the strain measurements (circumferential and longitudinal) presented with the normal ranges of strains as published by Neizel et al [2].

The LOA and accuracy of Strain calculations were based on tests using a mechanical phantom with known actual strain values. Phantom analysis demonstrated that MyoStrain has the *acceptable* LOA of (-5%,+5% (absolute)).

Traditional Global measurements (LVEF and indexed LVEDV, LVESV, and LVSV):

[1] Y. Zhan et al., "Derivation of consolidated normal reference values for right and left ventricular quantification by cardiac magnetic resonance using a novel meta-analytic approach," Journal of Cardiovascular Magnetic Resonance, vol. 18, no. 1, p. O75, 2016/01/27 2016.

Strain (circumferential and longitudinal):

[2] M Neizel et al. "Strain-encoded MRI for evaluation of left ventricular function and transmurality in acute myocardial infarction." Circ Cardiovasc Imaging. 2009;2(2):116-122.

12.5 ACCURACY OF MYOSTRAIN 2D MEASUREMENTS

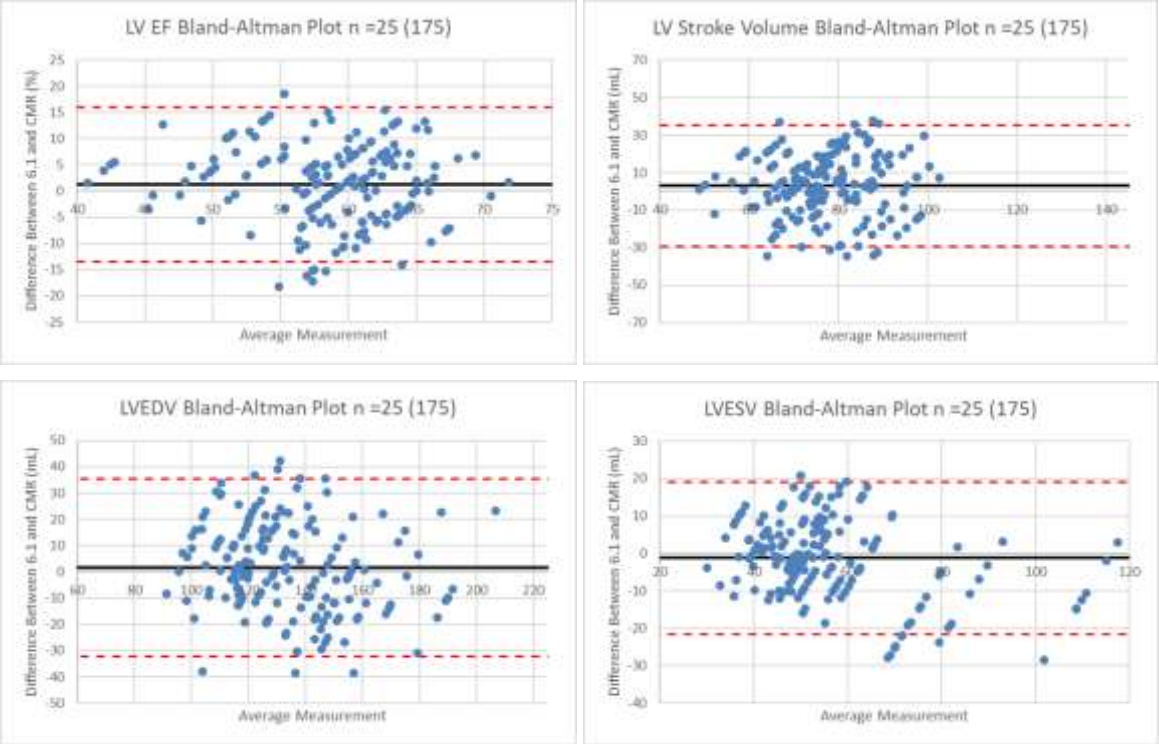
The accuracy of MyoStrain measurements will be determined by the LOA with measurement from CMR measurements. LOA is the difference (disagreement between the measurements of the two devices) range within which fall 95% of all the measurements from the two devices. The LOA depends on many factors, including images quality and inter-operator and inter-observer variabilities. Based on the Bland-Altman analysis of previously published LOAs of traditional measurements from different imaging modalities versus cardiac MRI (Wood PW et al, 2014 & Crean AM et al, 2011), we use the following bounds for the 95% LOA between MyoStrain and CMR data from the Prefect study.

- LVEF: (-20%,+20%)
- LVEDV: (-45mL,+45mL)
- LVESV: (-25mL,+25mL)
- LVSV: (-40mL, +40mL)

Based on a sample size N=175 analyzed exams, MyoStrain demonstrated the following *acceptable* LOA:

- LVEF: (-14%,+16%)
- LVEDV: (-32mL,+36mL)
- LVESV: (-22mL,+19mL)
- LVSV: (-30mL,+35mL)

The Bland-Altman Graphs of these calculations can be seen below:



12.6 **ACCURACY OF 3D MYOSTRAIN GLOBAL MEASUREMENTS**

The accuracy of Myo3D measurements will be determined by the Limit of Agreement (LOA) with measurement from CMR measurements. LOA is the difference (disagreement between the measurements of the two devices) range within which fall 95% of all the measurements from the two devices. LOA depends on many factors, including images quality and inter-operator and inter-observer variabilities. Based on the Bland-Altman analysis of previously published LOA of traditional measurements using different imaging modalities versus cardiac MRI (Wood PW et al, 2014 & Crean AM et al, 2011), we use the following bounds for the 95% LOA between Myo3D and CMR data from the Prefect study.

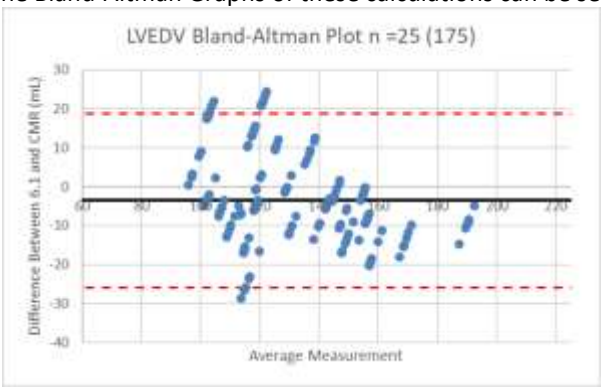
- LVEF: (-20%,+20%)
- LVEDV: (-45mL,+45mL)
- LVESV: (-25mL,+25mL)
- LVSV: (-40mL,+40mL)
- RV EF: (-20%,+20%)
- RVEDV: (-100mL,+100mL)
- RVESV: (-50mL,+50mL)

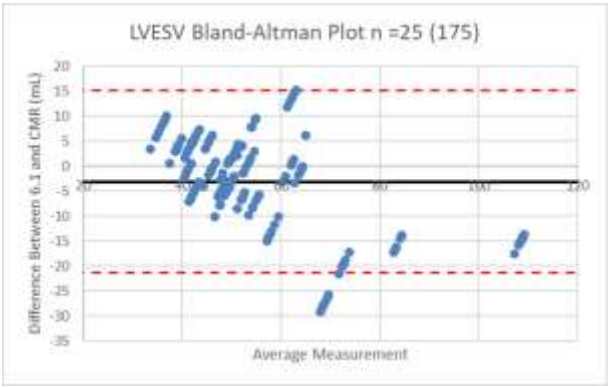
Based on a sample size N=175 analyzed exams, MyoStrain demonstrated the following *acceptable* LOA:

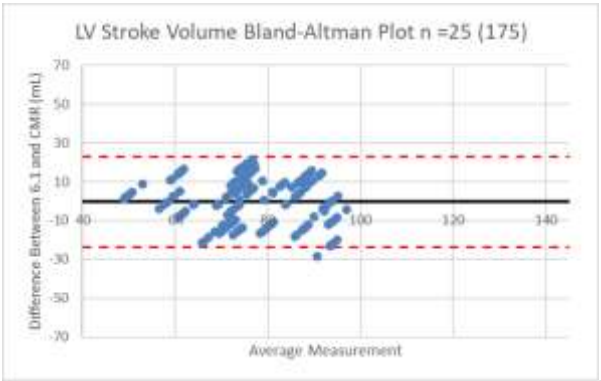
- LVEF: (-11%,+13%)
- LVEDV: (-26mL,+19mL)
- LVESV: (-21mL,+15mL)
- LVSV: (-24mL,+29mL)

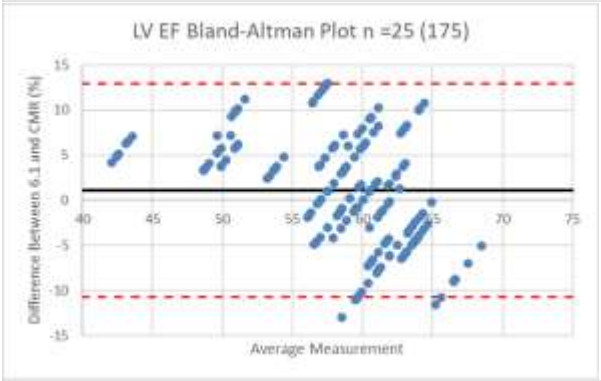
- RVEF: (-6%,+16%)
- RVEDV: (-34mL,+37mL)
- RVESV: (-26mL,+14mL)

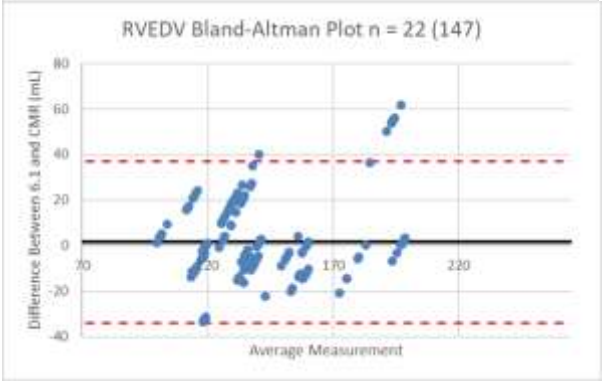
The Bland-Altman Graphs of these calculations can be seen below:

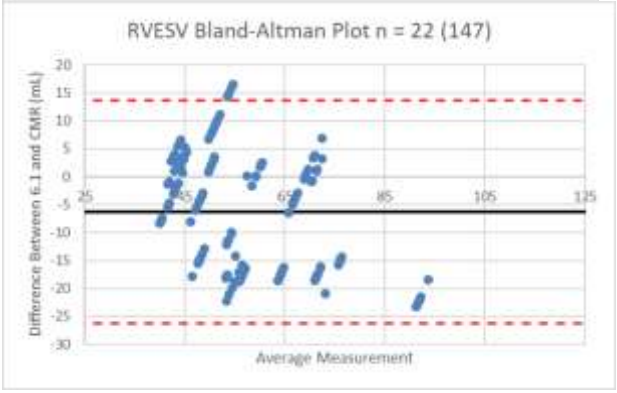


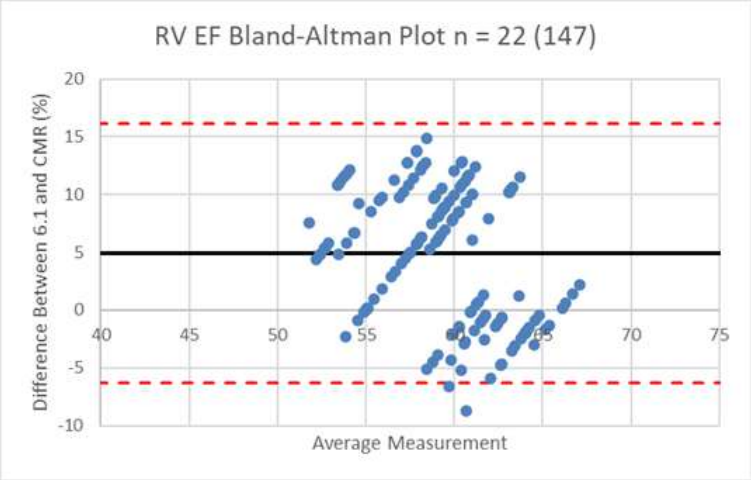












12.7 TIMING METRICS

- Toro-Salazar O, et al. Identification of subclinical myocardial dysfunction by fastSENC cardiac magnetic resonance imaging in cardio-oncology patients. SCMR.2023 January 26;1349140.
- Dodeja A, et al. Novel tem poral strain parameters to assess dyssynchrony using fSENC in congenital heart disease. SCMR. 2023 January 27;1348910

12.8 RELEASE NOTES

- When configuring LDAP, MyoStrain will not alert the user if an insecure connection is being used if the Administrator's username is preceded by the domain (DOMAIN/USERNAME).
- The MyoConfigurator will crash if a blank value is entered as the support code when configuring the LDAP connection.
- When upgrading from MyoStrain 6.0 and 6.0.1, Traditional Measurement calculations and Semi-Auto Contouring will be enabled by default.
- When reviewing a Strain exam in the MyoHealth Review tab, using the Reset Window Layout feature will not reset the Notes section of the GUI.
- The MyoConfigurator will allow a server to be configured with a null hostname; this is not recommended.

12.9 LICENSING AND TROUBLESHOOTING

In some rare circumstances, the MyoStrain application license can fail. These licensing errors can occur if the MyoStrain workstation is modified, the system clock is manually updated, or if MyoStrain is left running while performing operating system maintenance/updates. In cases where the application license is compromised, an error code will display and MyoStrain will not launch. Please contact your Myocardial Solutions representative (or contact support@myocardialsolutions.com), and provide them with a copy of the error code received.

Some common error codes can be found below. If your error code is not listed, please contact Myocardial Solutions for more information.

MYO_0010	The CPU does not match the CPU noted during installation.
MYO_0021	The Application License has expired.
MYO_0049	Inconsistency between recorded/current hardware identifiers.
MYO_0089	Exam License has been activated in MyoStrain already.
MYO_0106	Inconsistency between recorded/current registry identifiers.
MYO_0140	Mismatch between internal exam license counts.

13. GLOSSARY

This chapter lists the various terms used in this User Manual along with their meaning.

AHA Model
The standardized 17 segment heart representation set by the American Heart Association

Anonymous
Without identification. Without any additional external information. The identity of the person cannot be established.

CINE
Movie-like MR imaging. In CINE, MR imaging data is acquired using cardiac gating to form a "movie" sequence of a structure moving in synchrony with the heart.

EF
Ejection Fraction

Endocardium
The innermost layer of tissue that lines the chambers of the heart.

Epicardium
The outer layer of heart tissue.

Exam
A specific type of imaging for specific information. For example, MR tagged images acquired under stress.

fSENC
Another name for the SENC Pulse Sequence. fSENC is a single-heartbeat SENC acquisition.

GUI
Graphical User Interface

LV
Left Ventricle

LVEDV
Left Ventricular End Diastolic Volume

LVESV
Left Ventricular End Systolic Volume

LVSV

Left Ventricular Stroke Volume

MR
Magnetic Resonance - is primarily a medical imaging technique most commonly used in radiology to visualize the internal structure and function of the body.

Myocardium
The muscular tissue of the heart. This is typically referring to the middle layer of the heart wall.

RV
Right Ventricle

Series
Collection of MR images acquired in a single MR scan.

SENC
Strain Encoding

Strain
Deformation of a material when compared to a baseline state. MyoStrain measures how much the heart contracts between its baseline state (at diastole) and under strain (at systole), and this is typically a negative ratio under normal circumstances. Strain is a “unitless” measurement as it is the ratio of two lengths, and it can be expressed as a fraction or a percentage values. Geometrical measure of deformation representing the relative displacement between particles in a material body.

Stress
Measure of how the myocardium responds to exertion.

Study
A collection of series scanned in the same session for a subject.

14. INDEX