MyoStrain® User Manual

VERSION 5.4

MYOCARDIAL SOLUTIONS

Transforming Cardiac & Cancer Care

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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, Additional Patents Pending

Trademark Credits
MyoStrain® and MyoStress® are trademarks of Myocardial Solutions Inc.

Software Version and Date
Myocardial Solutions MyoStrain Version 5.4, released May 2022
MyoStrain Version 5.4 End Of Life – May 31st 2032

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

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

MD

MyoStrain®

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UDI

This manual is the instructions for use for MyoStrain version 5.4

Indications for Use Statement:

MyoStrain software is an image processing device that post-processes strain-encoded (SENC) images, which are acquired by MRI systems equipped with a SENC pulse sequence. MyoStrain software receives SENC images from MRI storage and archives, and performs extraction of time-resolved, quantitative strain information per voxel and other cardiac measurements, viewing, image manipulations, communications, and printing. Available measurements include longitudinal and circumferential strain to quantitatively describe the wall motion of the heart. Tools are provided to display regional motion properties of the heart.
A report interface is provided. Measurement tools provide information that can be output in standardized or specialized report formats. This interface makes it possible to quickly and reliably fill out a complete clinical report of a cardiac imaging exam with strain. The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians to support the determination of a diagnosis.

Patient Population:
MyoStrain is used by physicians, radiologists, and cardiologists. MyoStrain can read any MRI image created by MyoStrain or the Strain-ENCoded (SENC) pulse sequence, so any patient who can have a SENC Cardiac MRI scan can be included in the patient population.

Contraindications and 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 manufacture, 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.

MR Manufactures with approved SENC Pulse Sequences

Philips MR Systems with 5.6 software or higher, with the SENC Pulse Sequence
United Imaging Healthcare MRI scanners with the SENC Pulse Sequence.

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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 on how to use the to analyze cardiac magnetic resonance (MR) 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.

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

Medical Device – Indication that the device is a medical device

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 KEY FEATURES

The MyoStrain software presents a simple interface that enables you to analyze SENC (Strain ENCoded) MR images without a steep learning curve. MyoStrain enables physicians in private practice, research, and drug development to:

- Analyze short-axis and long-axis views of the LV and RV.
- Quantify and visualize regional function in a format readable by physicians and patients alike
- Create bull's-eye charts and other forms of data presentations.
- Easily visualize heart wall motion changes during stress examinations

Export results in a PDF document.

1.4 SYSTEM REQUIREMENTS

Before you install or use MyoStrain V5.4 ensure that your computer meets the following requirements:

1.4.1 RECOMMENDED HARDWARE REQUIREMENTS

1. 3.2 GHz Gen 4 i3 Processor or higher
2. Windows 10 or Windows Server 2016
    a. Professional Edition or higher
    b. 64-bit versions only
3. 16GB memory or higher
    a. 8GB required
4. 100 GB available hard disk space for installation and additional space for image storage
5. 1920x1080 screen resolution
6. 64-bit video card with 1GB memory
7. 1000Mbps LAN
8. .NET Framework 4.8 (installed alongside MyoStrain if not present)
9. Visual C++ Redistributable Package 2019 (installed alongside MyoStrain)

1.4.2 SCREEN RESOLUTION

Depending on your workstation's configuration, some parts of the application may be hidden or display in an unusual manner. MyoStrain is designed to be flexible and has many options to change how the software displays data. We have tested multiple different form factors and recommend the following settings (your configuration may be different).

Supported resolutions:

1. 1920x1080 (1080p) (Recommended)– Windows Scaling set at 100%
2. 2736x1824 (Microsoft Surface) – Windows Scaling set at 200%
3. 3840x2160 (4k) – Windows Scaling set at 150%

1.4.3 OPERATING SYSTEM

The MyoStrain application is currently supported on Windows 10 (64-bit) and Windows Server 2016.

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

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.

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.

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2. GETTING STARTED

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

2.1 INSTALLING MYOSTRAIN V5.4

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.

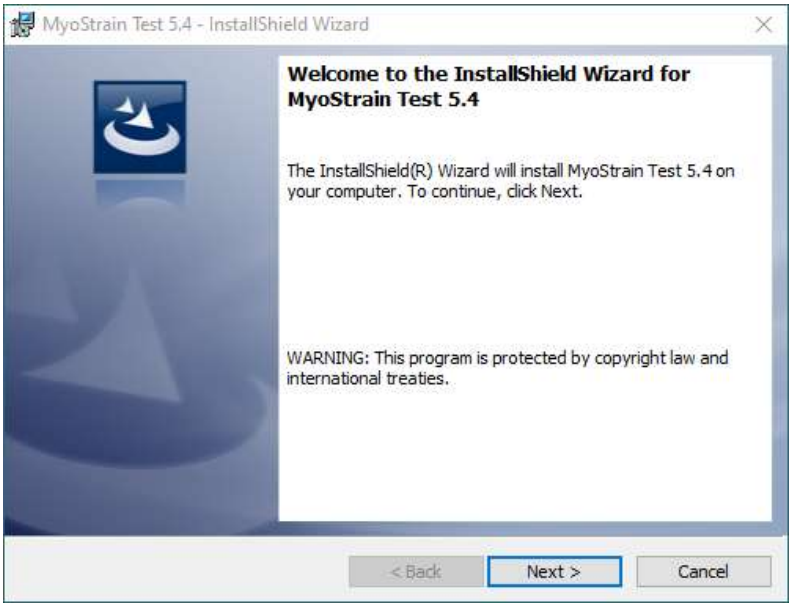


Figure 2-1: Installation Window

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.

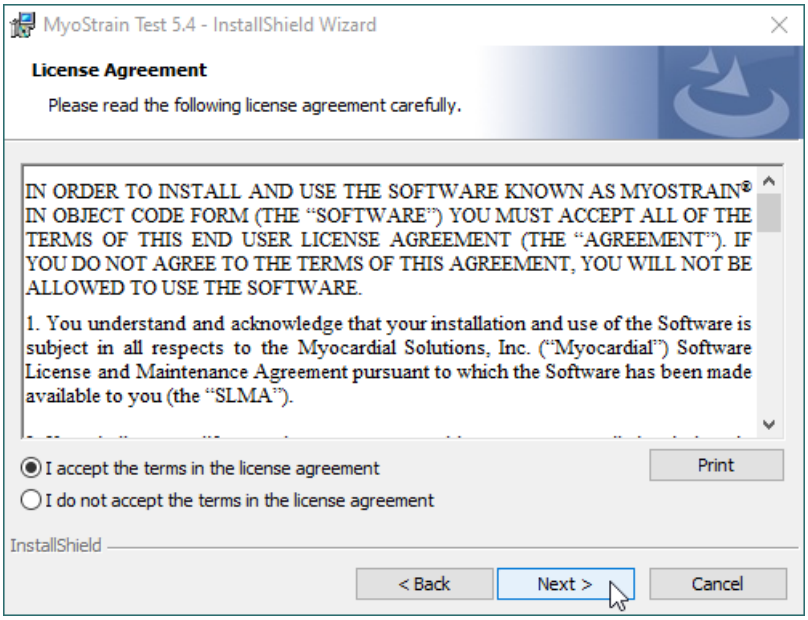


Figure 2-2: End User License Agreement – Accept must be selected to continue

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 V5.4

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.

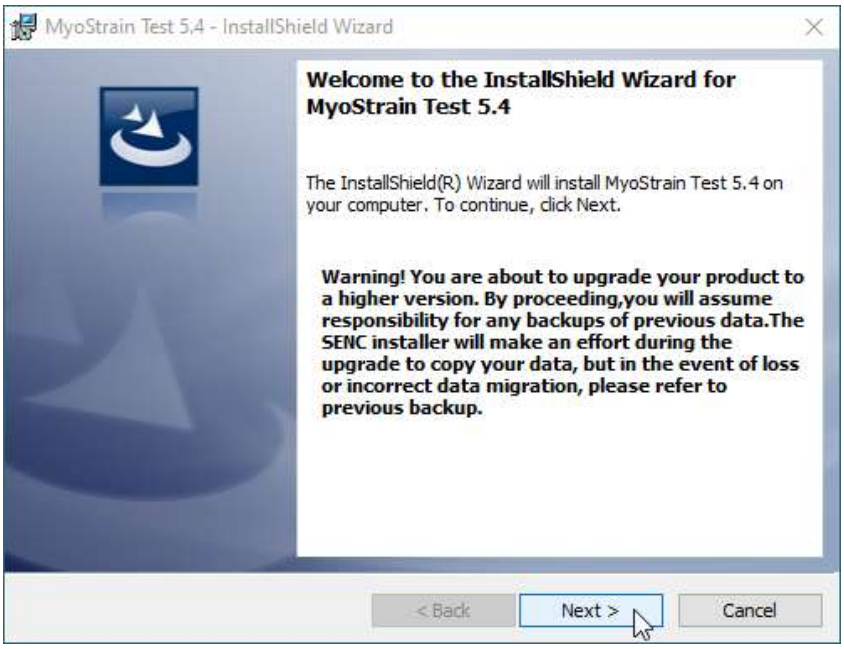


Figure 2-3: Installation Wizard – Upgrading

Upgrading to version 5.4 will import analysis and configuration 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 V5.4

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).

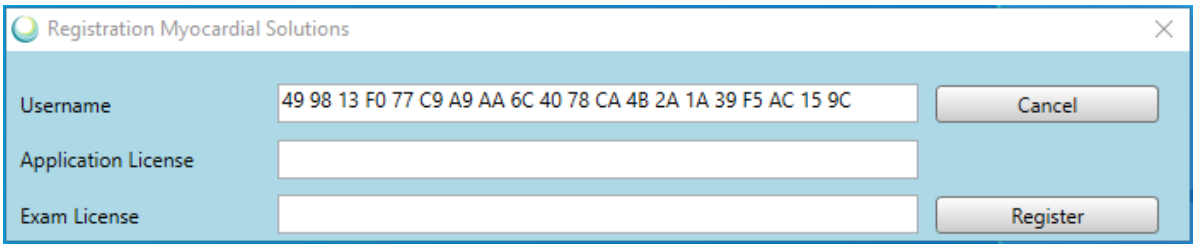


Figure 2-4: Registration dialog box

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.

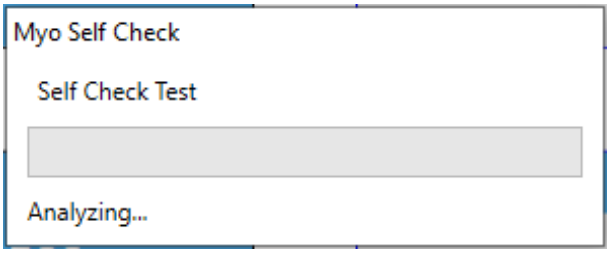


Figure 2-5: Self Check running

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.

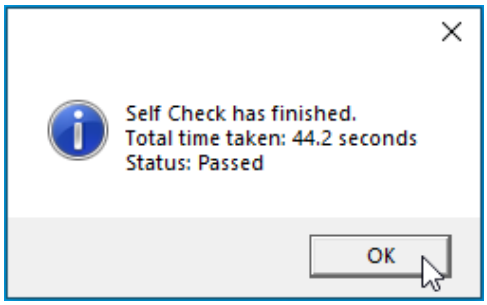


Figure 2-6: Successful Self Check notification

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 resting strain (and in cases of Stress testing, measuring the difference between those and stressed) 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'.

MR Manufactures with approved SENC Pulse Sequences

United Imaging Healthcare MRI Scanners with the SENC Pulse Sequence.
Philips Ingenia, Ingenia Elition and Ingenia Ambition MR Systems with 5.6 software or higher, with the SENC Pulse Sequence.

2.3.2 INPUT IMAGES RESTRICTIONS

MyoStrain processes SENC images and measure 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.

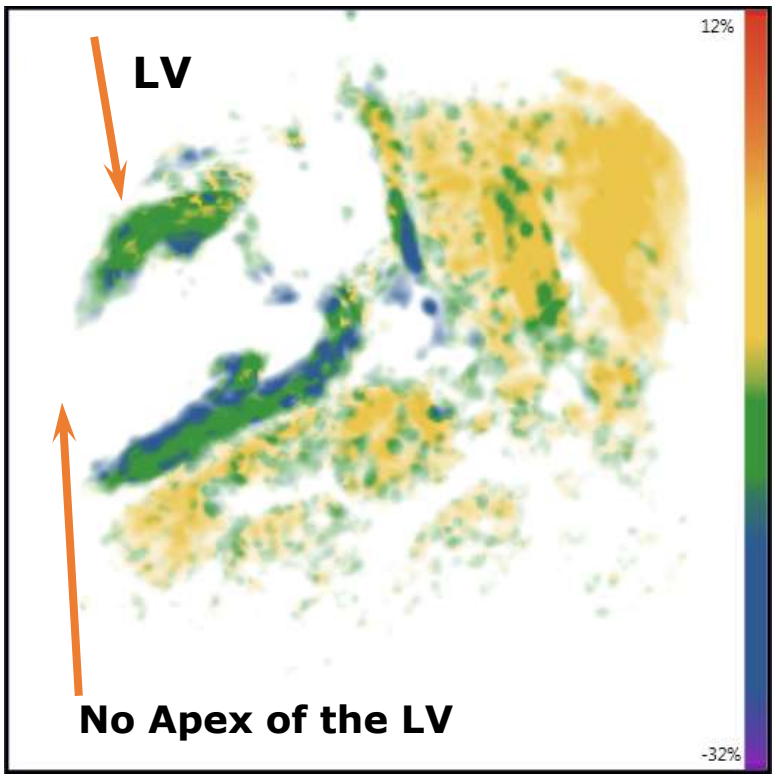


Figure 2-7: Sample Image of 2-chamber view with planning issue

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.

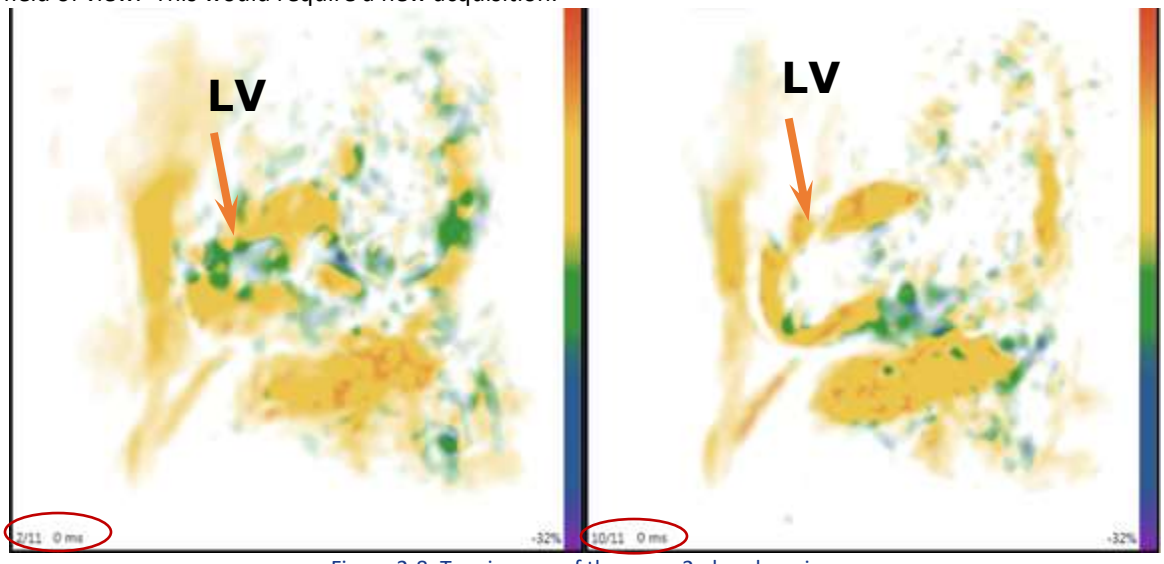


Figure 2-8: Two images of the same 2-chamber view

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.

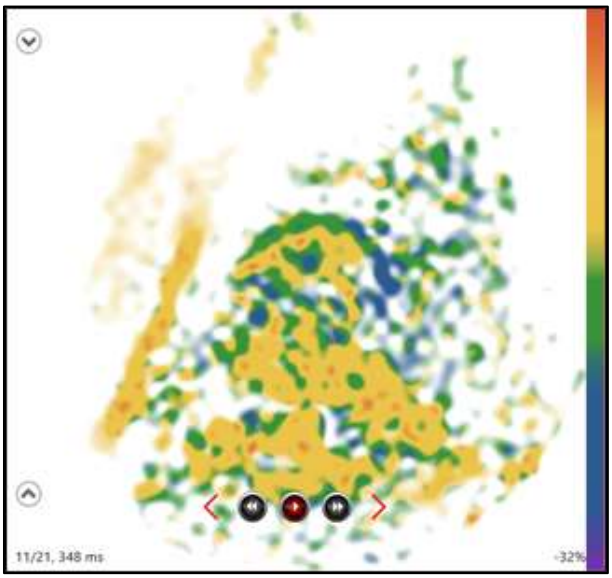


Figure 2-9: Unidentifiable

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 2ch Long-Axis slice. This would require a reacquisition.

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

Please refer to sections 5.4.2 and 6.4.2 for more information on how to reject images from analysis.

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 need to be analyzed, local file import is available.

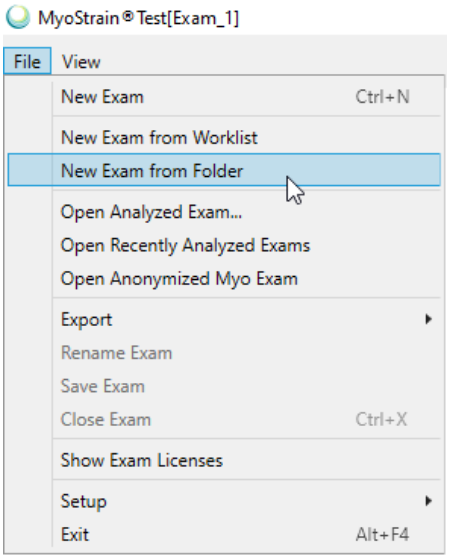


Figure 2-10: Image Import from Folder (New Exam) option found in the File menu

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 medical 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 this 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

For more information regarding remote file importation, please refer to chapter 10. When used as part of a live patient stress examination, MyoStrain will automatically identify and organize images based on stress level. After a timed delay (default setting of two minutes) specified during the installation process, future images will be organized under the next level stress phase if performing a Stress exam. This means that after the last image has been received by the application, any images received before two minutes have elapsed will be included in the current phase. Any images received after the delay has expired will be added to a new stress phase.

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 5.4 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.

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.

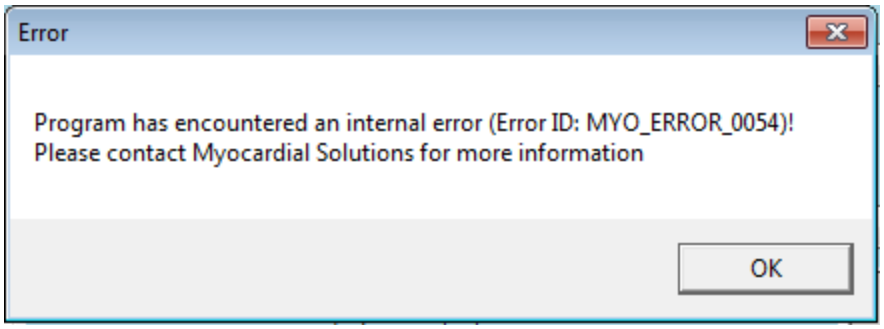


Figure 2-11: Sample error message

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 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.

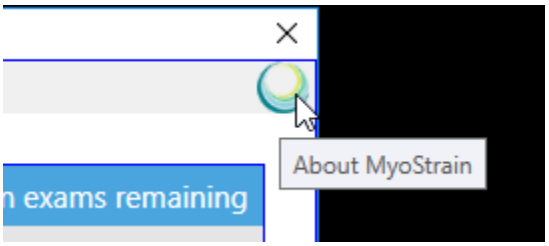


Figure 2-12: License information is available from this menu

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.

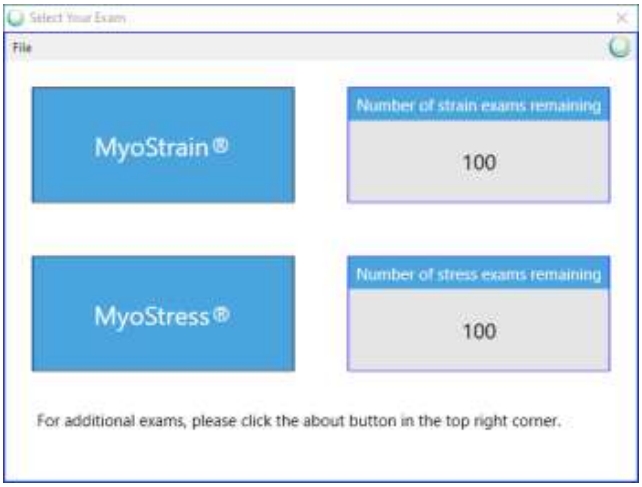


Figure 2-13: Exam selection screen shown at beginning of new exam or at launch

To view detailed exam license information, click on the **Show Exam Licenses** button shown 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.

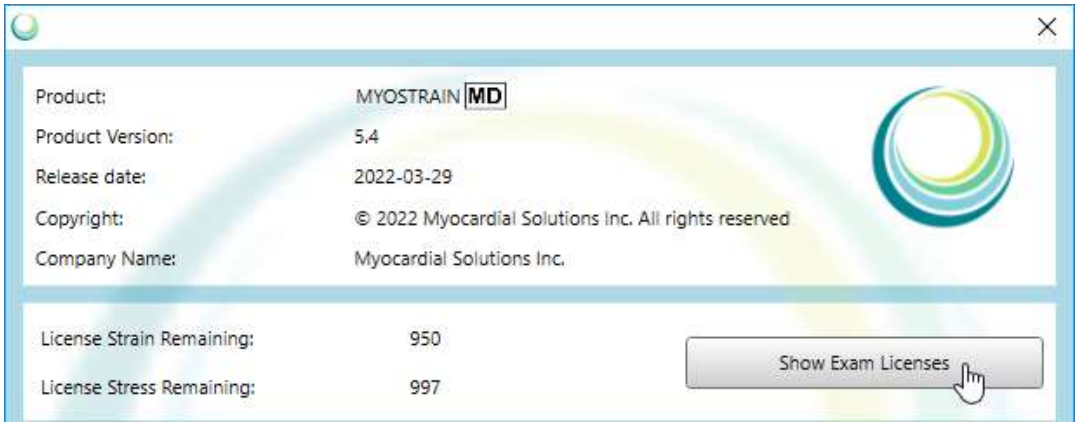


Figure 2-14: Additional exam license information can be found in the About menu

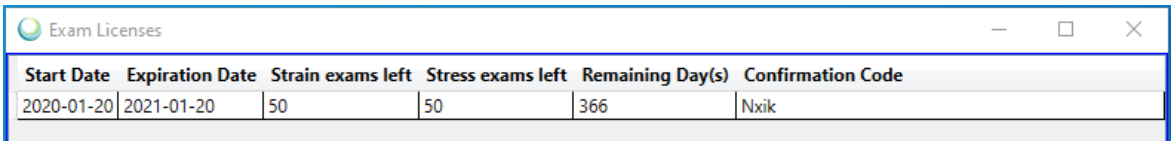


Figure 2-15: List of exam licenses available to the workstation running MyoStrain.

2.6.1 ORDERING ADDITIONAL EXAM LICENSES (REORDER FORM)

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).

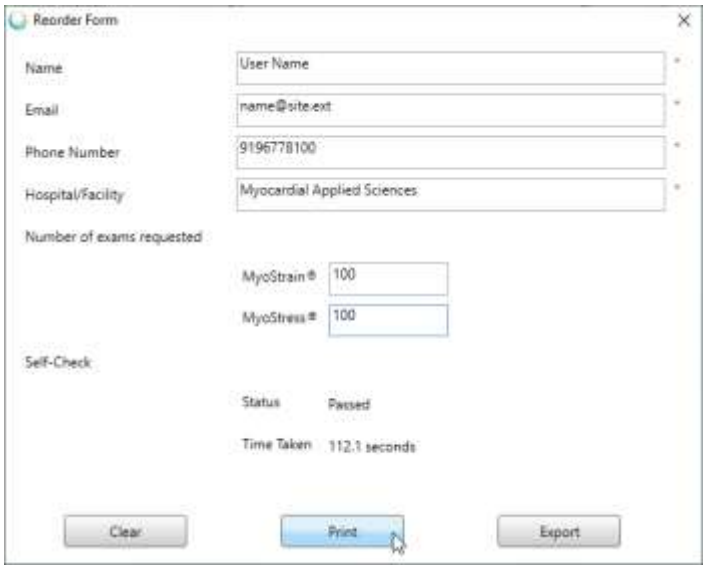


Figure 2-16: License Reorder Form Wizard

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).

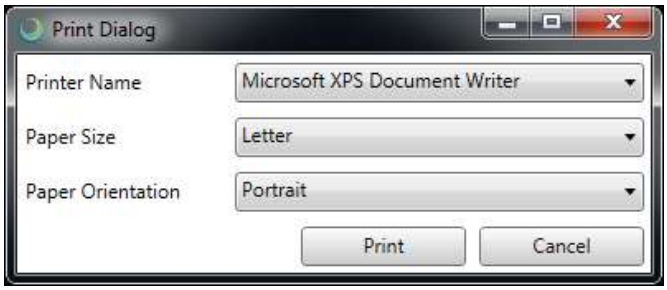


Figure 2-17: Selecting Print from this window will generate a physical copy of the Reorder Form

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 below chart for details 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.

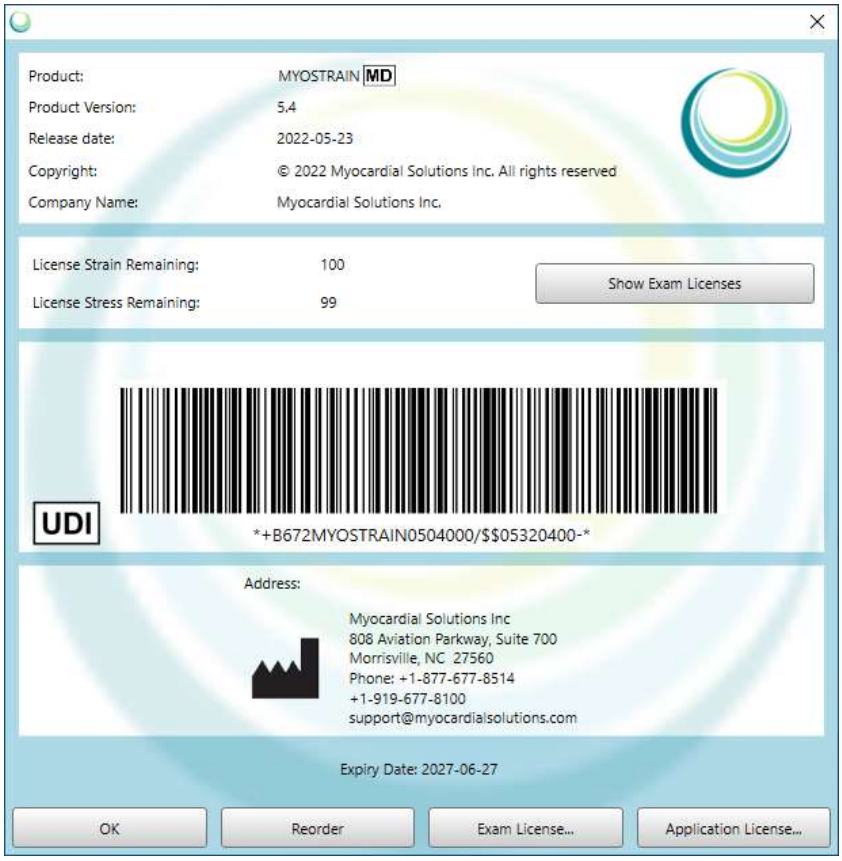


Figure 2-19: MyoStrain About page

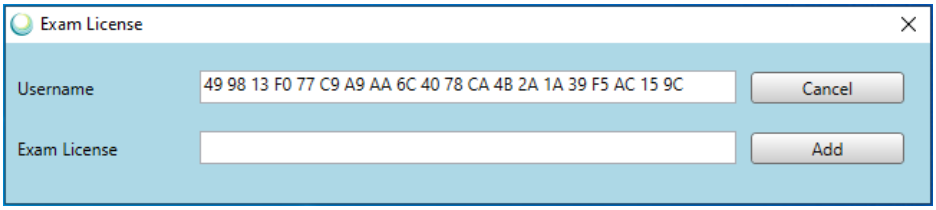


Figure 2-20: Exam License entry screen

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 UNINSTALLING MYOSTRAIN

Before uninstalling MyoStrain, please contact Customer Support (support@myocardialsolutions.com) to validate the exam licenses available to the workstation. If MyoStrain is uninstalled before the exam count is verified, those exams credits will be lost.

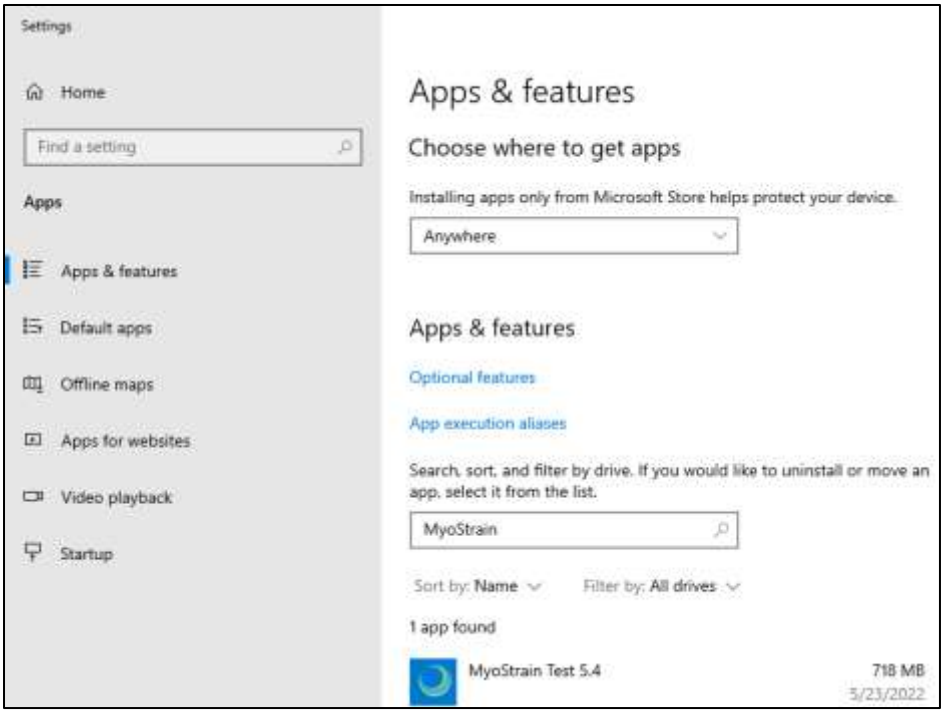


Figure 2-22: Add or Remove Programs in Windows 10

MyoStrain can be uninstalled through Window's "Add or Remove Programs" feature. Please contact your IT Administrator for more information about this Windows feature, or if you are unable to uninstall due to insufficient workstation permissions.

3

3. APPLICATION OVERVIEW

This chapter provides a visual overview of the MyoStrain application, describing settings and features relating to MyoStrain quantification.

3.1 THE MYOSTRAIN WORKSPACE

The MyoStrain application is comprised of a single window with several panes used to display information relevant to the current patient's images being received 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.

Ø Example: Consider a subject who is being imaged with MyoStrain during a stress test. In this case, the subject will be imaged at baseline and at different levels of stress. Each stage of this scan will automatically be imported into the application and organized accordingly. Images in this chapter will be shown in Stress Mode.

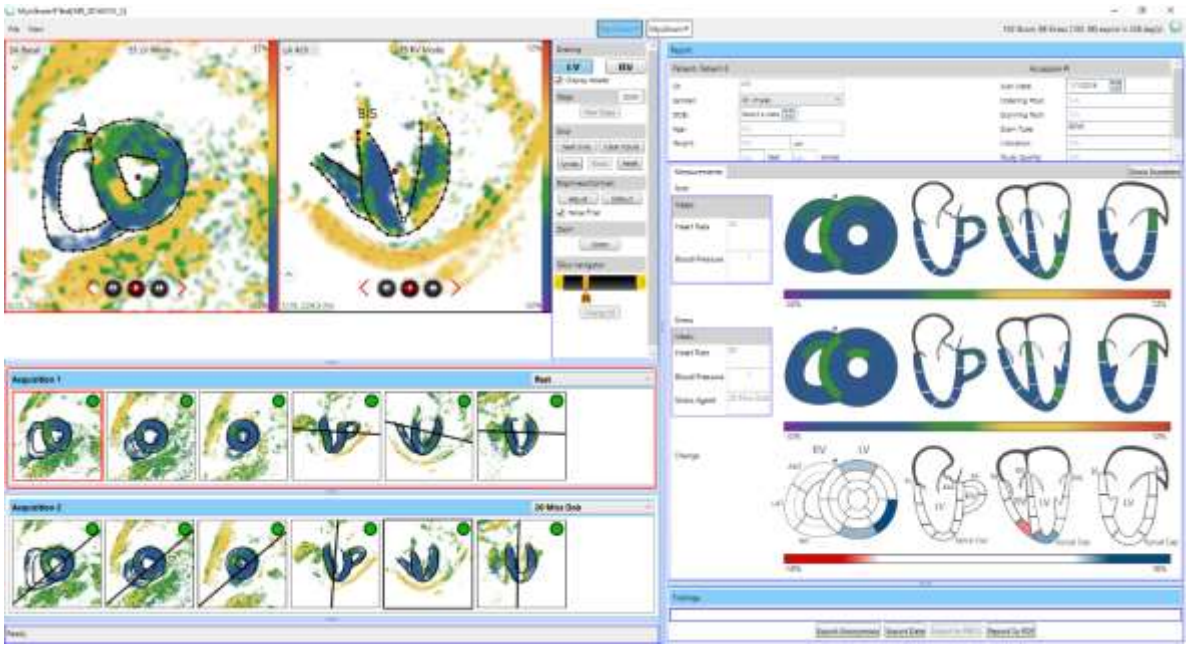


Figure 3-1: Overview of the MyoStrain analysis window

3.2 ANALYSIS WINDOW

Found in the upper-left hand corner of the application, this displays the active slice(s) being analyzed. Information about the currently viewed slice can be added in the upper-left of the image including heart rate and blood

pressure. A drop-down menu is also used to identify the view for importation into the report. The right-hand side of the **Analysis Window** has five options which assist with image analysis. Additionally, located on the right side of the active image is a color range used to visualize strain on the image.

3.2.1 VIEW DETAILS

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

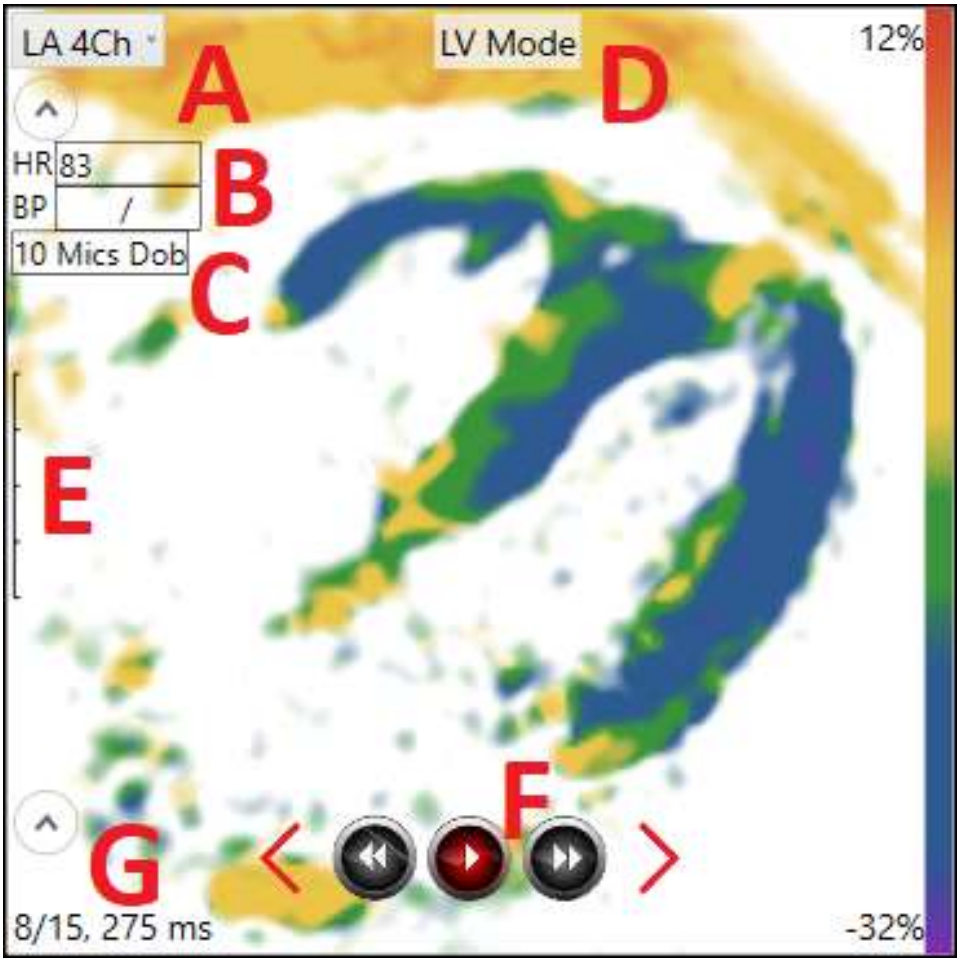


Figure 3-2: 4-Chamber view details (Stress exam)

- **View Dropdown (A)**- Contains a list of six possible views analyzable during a MyoStrain analysis.
- **Heart Details (Stress Mode) (B)**– This dropdown menu displays the patient's heart rate and blood pressure, and allows editing from there. Click the circle found below the **View Dropdown** to access these measures.
    - **HR** - Heart Rate (Stress Mode). This value is constant across the current stress level and must be entered at every stage of stress during an analysis
    - **BP** - Blood Pressure (Stress Mode). This data will be used for each image associated with the current stress level. It is recommended to enter this data as [SYS/DIA].
- **Stress Agent (C)**- Current Stress Stage (Stress Mode). This will display when the second series of images are received by the MyoStrain post-processing software.
- **Display Header (D)** – Current Analysis tool active. In the example, using the mouse anywhere inside the analysis window will begin drawing an LV contour.

- **Measurement Scale (E)**- 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.
- **Video Playback (F)**– This button (found above the timeframe counter) displays or hides the Video Playback buttons. Please refer to section 3.2.3 for more details.
- **Current Timeframe (current time) (G)** – 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.

3.2.2 ANALYSIS WINDOW OPTIONS

Displayed on the right-hand side of the **Analysis Window**, the Analysis Window Options are buttons intended to assist the mesh drawing process. This includes stage timing and visualization enhancements.

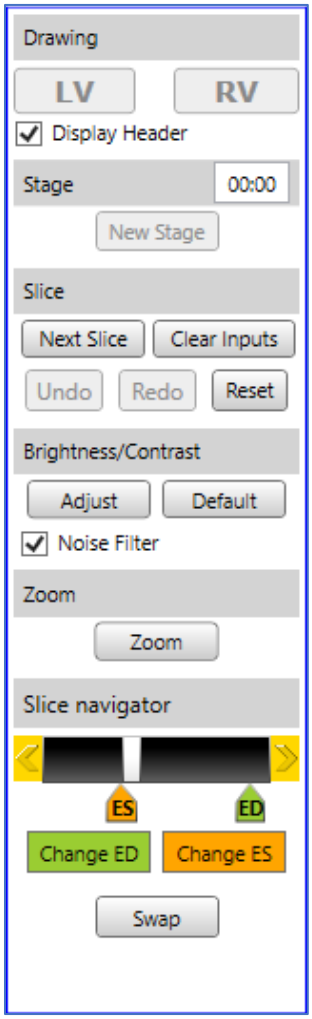


Figure 3-3: Analysis Window as seen during a Stress RV analysis with EF enabled

- **Drawing –**This section displays the various analysis tools available for use in strain quantification.
  - **LV/RV (RV Analysis Only) –** These buttons are displayed on slices where RV quantification is available. **RV** will only be available once an LV mesh has been drawn on the image.
  - **Display Header**- When selected, this displays a message in the top of the **Analysis Window** that describes what MyoStrain is expecting in the **Analysis Window**.

- **Stage (Stress Analysis) -** Displays a timer for the current stage. This counter will reset whenever a new image is received by MyoStrain. Once the timer reaches zero, or the **Next Stage** button is pressed, any new images will be added to a new acquisition stage in the **Image List.**
- **Slice -** These buttons assist the user in image quantification and meshing.
    - **Next Slice -** Changes the image in the **Analysis Window** to the next available slice in the current acquisitions' **Image List**
    - **Clear Inputs (Stress Analysis) -** Clears all text entered in the **View Details**. This does not reset the selected view.
    - **Undo –** This reverses the most recent mesh drawing or correction. This button will be greyed-out if no mesh data is available.
    - **Redo –** Pressing this will re-apply the most recent action taken by the **Undo** button.
    - **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.
- **Brightness/Contrast –** These buttons are responsible for adjusting the image brightness and contrast for the current acquisition stage.
    - **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.
    - **Adjust –** This button, when pressed, will change the mouse cursor to a sun icon and display two slider controls. The brightness and contrast can be adjusted either by moving the sliders, manually updating the percentage number, or via the mouse cursor. Figure 3-4 describes how this adjustment works. Clicking the Adjust button again will save all adjustments.
    - **Reset -** Pressing this button will reset any modifications of the brightness and contrast of the current acquisition.

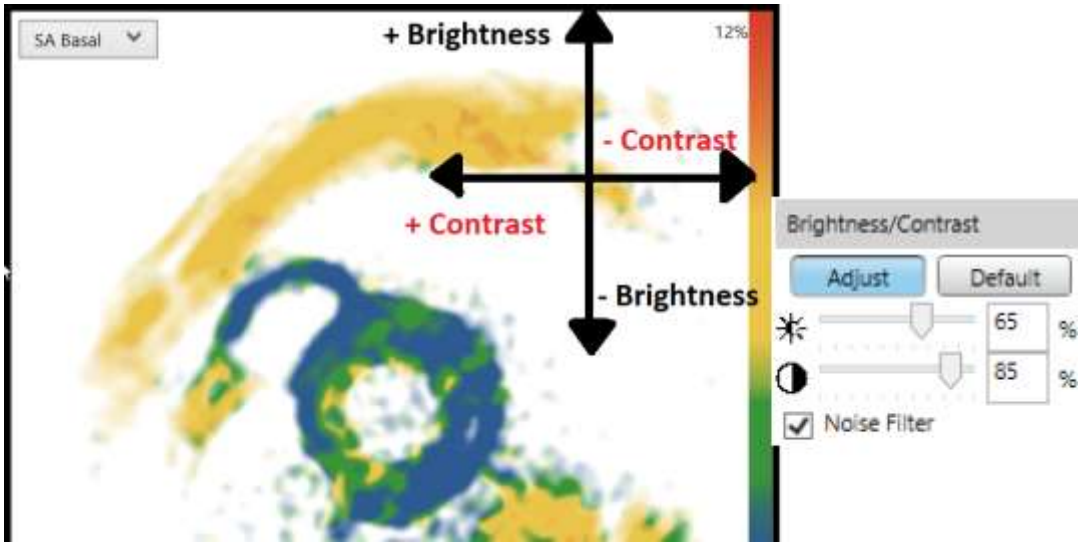


Figure 3-4: Holding the left-mouse button and dragging in the shown directions will adjust the brightness and contrast in the Analysis Menu and vice-versa

- **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.
- **Slice Navigator –** This slide-bar provides another way to navigate through the currently selected slice. Either the buttons or slider will allow navigation between timeframes of the current slice. End-Systolic and End-Diastolic timeframes are marked here as well.
    - **Change ES –** Sets the Orange placeholder on the Slice Navigator to its respective location based on the timeframe this button is pressed. This timeframe will be used to calculate strain as identified during End-Systole.

- **Change ED –** Sets the Green placeholder on the **Slice Navigator** to its respective location based on the timeframe this button is pressed. This timeframe will be used to calculate global measurements identified during End-Diastole.

- **Accept Mesh –** Displayed only when the Semi Auto Contouring tool is enabled; pressing Accept Mesh will accept the software's suggested contouring and apply it to the analysis. This button will disappear once a mesh has been either accepted or corrected. Please visit chapter 9 for more information.
- **Swap –** This button re-labels the current End-Systolic timeframe to End-Diastole, and the original End-Diastolic mesh as End-Systole.

Additionally, many of these features can also be accessed by right-clicking anywhere within the **Analysis Window**.

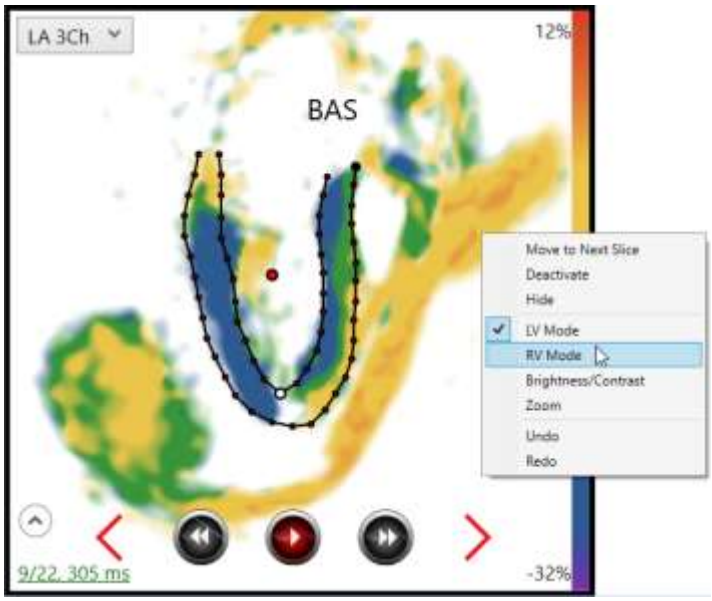


Figure 3-5: Context menu displayed when right-clicking in Analysis Window

The top section of this context menu refers to slice selection and will be covered in further detail by section 3.3.2. The middle section of this right-mouse button menu allows switching between mesh types (LV and RV drawings), the brightness/contrast adjustment tool, and the pan/zoom tool. The bottom section contains mesh actions such as Undo and Redo.

3.2.3 VIDEO PLAYBACK

Clicking on the button found above the Current Timeframe counter will cause several buttons to appear in the **Analysis Window**. These buttons will allow the user to navigate between different images in the current slice.

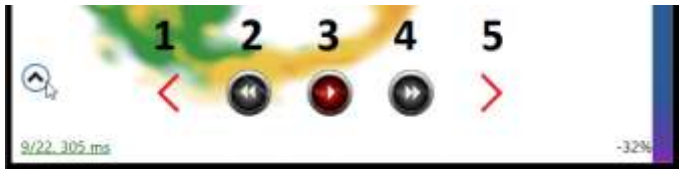


Figure 3-6: CINE playback buttons shown with mouse cursor placement

1. **Rewind Frame** – Navigates one frame backwards in the series
2. **Decrease Speed** - Decreases the playback speed of the series.
3. **Play** - Plays through the entire slice. Press the **Play** button again to stop.

4. **Increase Speed** - Increases the playback speed of the series.
5. **Forward Frame** – Navigates one frame forwards in the series

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

3.2.4 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 3-6 provides a basic guide to the meaning of each color. For more information on Contractility of the myocardium refer to Section 11.2

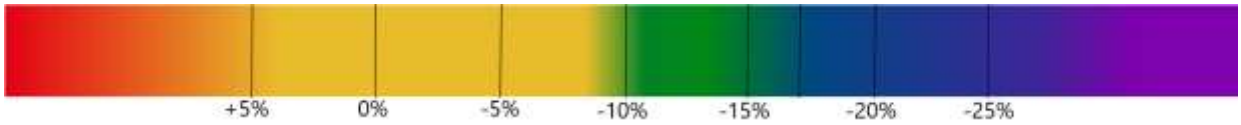


Figure 3-7: Color Map Legend

3.2.5 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.

3.3 IMAGE LIST

Located under the **Analysis Window** by default, the **Image List** displays all images that have been imported by MyoStrain as a part of the current patient study. These are organized by the time of acquisition and correspond to the introduction of stress agents in the study.

During the analysis, there may be colorized dots in the upper-right corner of each thumbnail in the **Image List**. These dots identify the status of that slice in the list.

- Yellow – Mesh has been drawn using Semi Auto Contouring and has not been accepted. The yellow dot also denotes the slice which displays the greatest strain values.
- Green – Mesh has been completed and is selected for use in reports and data output.

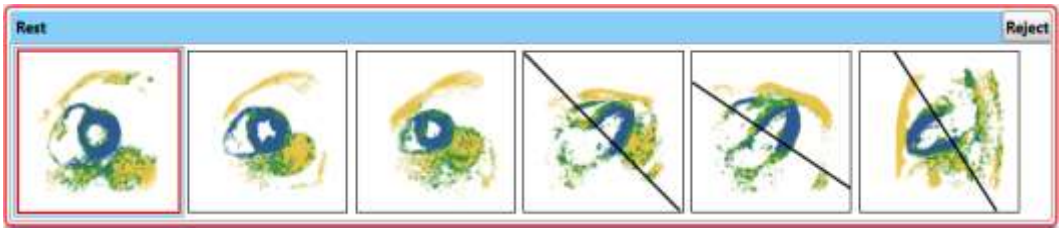


Figure 3-8: Image List as seen during a MyoStrain exam without Semi Auto Contouring enabled

3.3.1 PHASE SELECTION (STRESS EXAM)

During a stress examination, a dropdown menu will appear above each **Image List.** This menu is used to identify and label each series of images over the course of a stress exam.

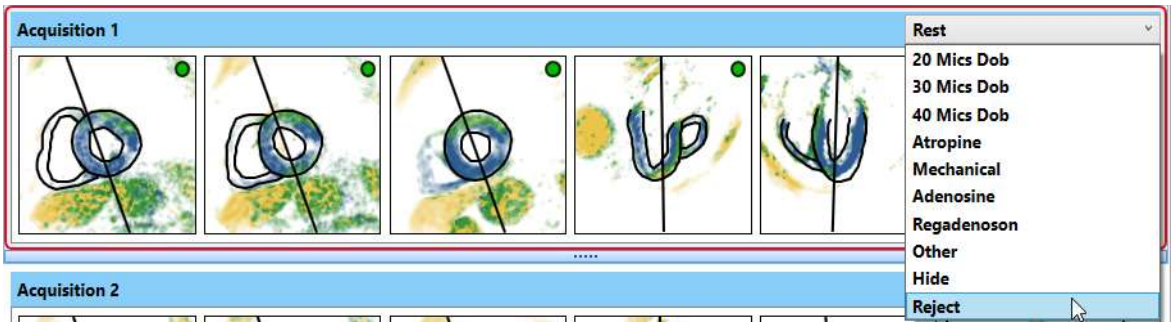


Figure 3-9: Stress Phase dropdown menu seen during Stress exam

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.

3.3.2 DUPLICATE VIEW SELECTION

In some situations, there may be multiple acquisitions of the same view available in the **Image List.** If two or more slices of the same view are analyzed, the software will display and report on only one of these analyzed image stacks.

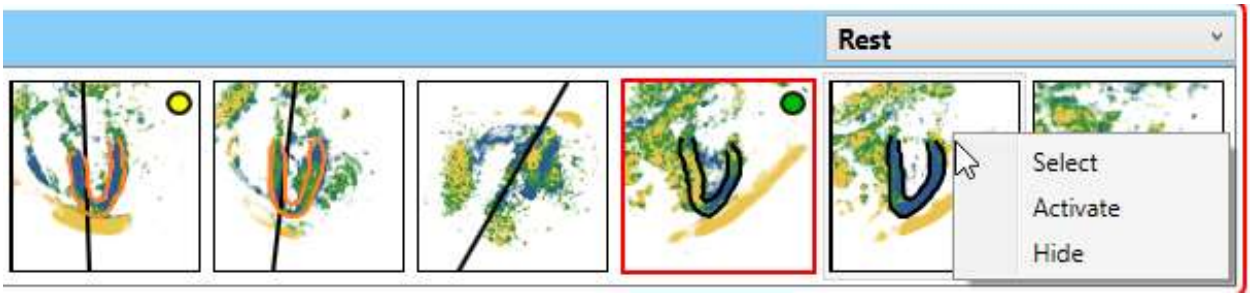


Figure 3-10: In the Image List, green radio buttons mark the slices being reported

Figure 3-10 shows an example where two slices of the same view have been analyzed. Only one of the two slices show a green dot; this slice is considered the Active slice and will be used for the report. Drawing a mesh onto another slice of the same view will cause MyoStrain to automatically set that slice as active. Right-clicking on a slice in the **Image List** brings up a context menu which will enable selection of a different slice for the report.

- **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**
- **Activate -** Enables the selected slice and sets it as active with the Green radio button
- **Unhide -** Activates a slice which has been previously hidden

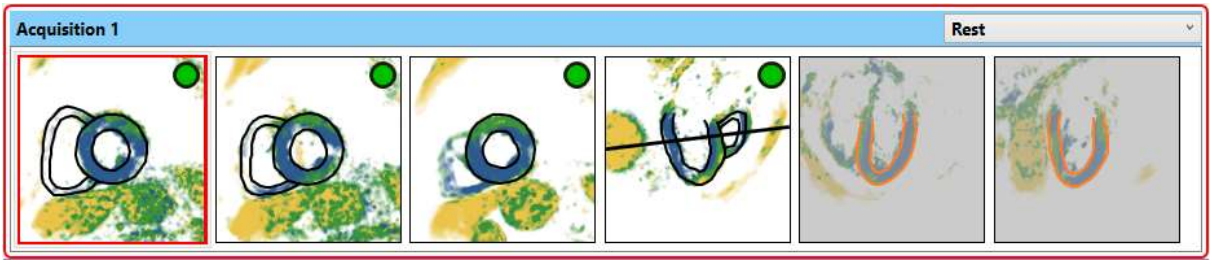


Figure 3-11: Image List with 2 slices hidden from the report

3.3.3 IMAGE LIST ADJUSTMENT

Similar to section 3.2.5, 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.

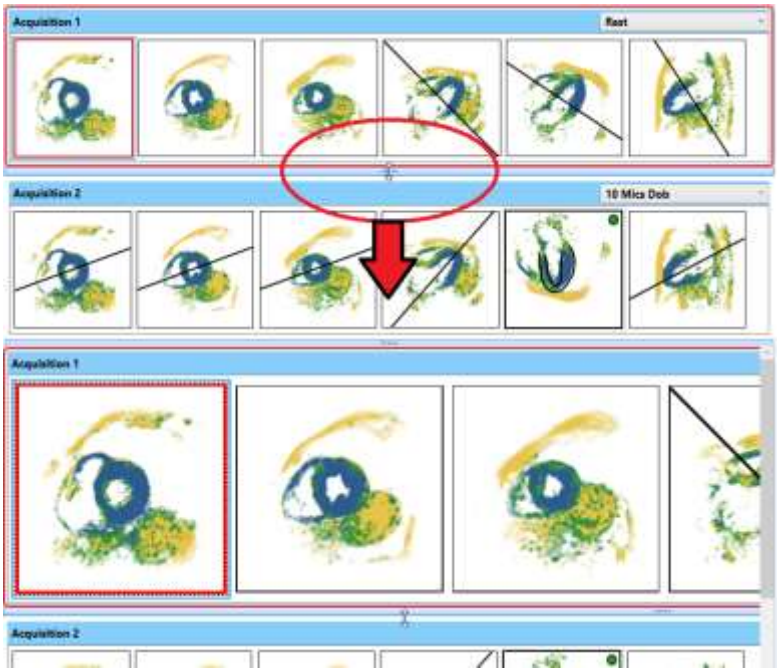


Figure 3-12: Increasing the size of the Resting stage image list

3.4 REPORT VIEWER

The right-hand side of the MyoStrain software displays information gathered from the images imported during an analysis.

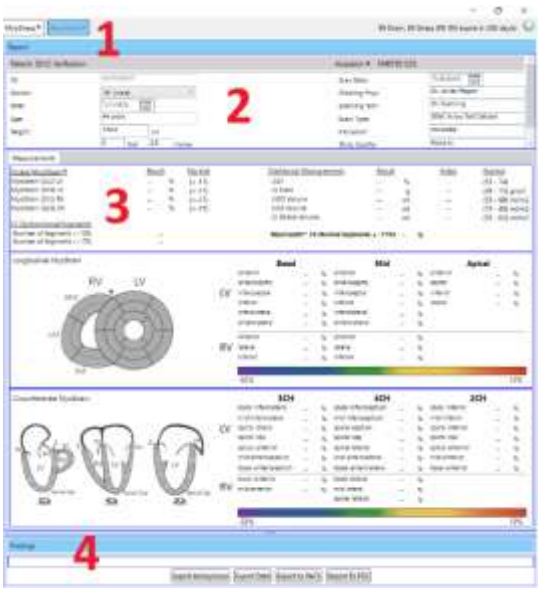


Figure 3-13: Layout of the Report section during Strain Mode

1. Report Mode: see Section 3.4.1

2. The **Patient** header displays all relevant PHI on the current patient.
3. The **Measures** section displays all relevant measurements gathered as part of the current exam
4. The **Findings** header is a freeform textbox used to add any notes or findings relevant to the current analysis

3.4.1 REPORT MODE

At the top of the **Report Viewer** window are two buttons which change how the software displays images sent to it for analysis. Images can be imported as part of a Stress or Strain exam. During a Stress exam, the user can switch between Stress and Strain analysis modes.

Figure 3-14: Reporting under Stress settings

- **MyoStress®** – Enables the **Measures** section in Stress Exam mode. Any images received at this point will exhaust an exam credit (only 1 credit per study).
- **MyoStrain®** – Enables the **Measures** section in Strain Exam mode. Any images received at this point will exhaust an exam credit (only 1 credit per study).

3.5 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.

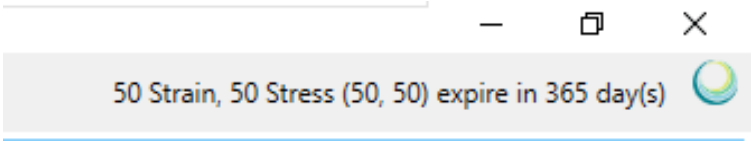


Figure 3-15: Software license with 50 Stress and 50 Strain exams left that expire in 1 year.

3.5.1 EXAM LICENSES

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 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** – 5 or fewer days remaining, or 5 or less 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. Images received during a new stress stage or after rejecting a series will not use a new exam credit.

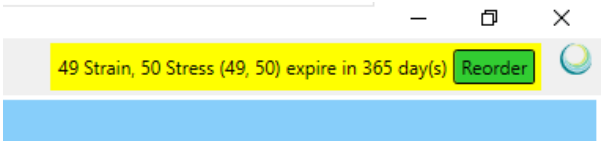


Figure 3-16: Yellow caution warning

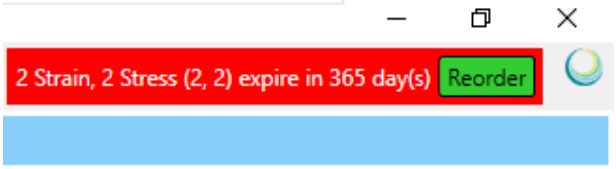


Figure 3-17: Red alert warning

Clicking on the **Reorder** will launch the Reorder form and launch the Self-Check program as well.

NOTE: Setting the Countdown Warning or Countdown Risk numbers to 0 will disable the exam count alert coloring and Reorder button.

3.5.2 OPEN ANALYZED EXAM

MyoStrain is backwards compatible with exams created in MyoStrain starting with version 5.1.1. 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.

3.6 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
- **Open Anonymized Myo Exam** – Opens a searchable menu which links anonymized names to non-anonymized patient information run through MyoStrain.
- **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 7.5.3 for more details regarding saving this file.
    - **Export to DICOM -** Exports a copy of all the data specified in the Export to DICOM Settings menu to a local folder. The data exported is in the DICOM format, which can be viewed with a DICOM viewer or stored in PACS manually.
    - **Export to PACS -** Exports a copy of all the data specified in the Export to DICOM Settings menu to a properly configured PACS server. Configured servers will appear in a nested menu when selected.
    - **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 7.5.3 for more details regarding saving this file.
    - **Image** – 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.
    - **Video** – 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.
- **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.
- **Show Exam Licenses** – Opens a pop-up menu which displays all active MyoStrain exam licenses.
- **Setup** –
    - **Settings –** Opens the Settings submenu. Please refer to section 3.6.3 for more detailed information.
    - **Image and Video Settings –** Opens the Image and Videos Settings submenu. Please refer to section 3.6.4 for more information.
    - **Export to DICOM Settings -** Changes what information is converted to DICOM format when exporting data from MyoStrain.
    - **Report Logo –** Opens the Report Logo Selection submenu. Please visit section 3.6.6 for more information.
    - **Self-Check** - Starts the Self-Check. Please visit section 2.2.1 for more information.
- **Exit** – Closes the program.

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.

3.6.1 **OPEN ANONYMIZED MYO EXAM**

Datasets exported from MyoStrain using the **Export Anonymous** feature can be re-identified using the **Open Anonymous** feature. Entering the anonymized patient's name or ID in the associated field and pressing **Search** will display the associated patient information in the list. Pressing on the **Open** button will open the original, non-anonymized exam.

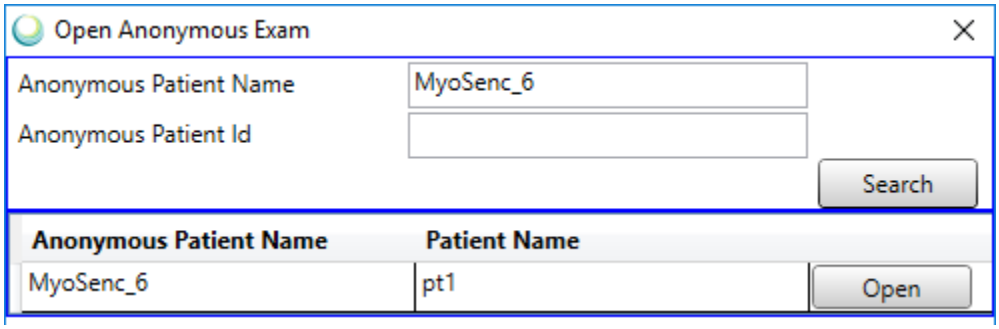
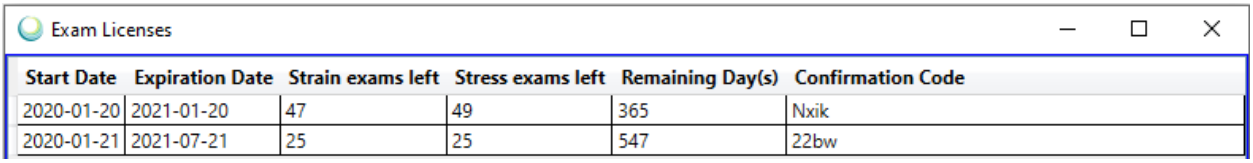


Figure 3-18: Open Anonymous Exam dialog box

3.6.2 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 3-19: 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.

3.6.3 SETTINGS MENU

The **Settings** menu found in the **File>Setup** menu contains options that change how MyoStrain displays data. Pressing the Save button in the lower-right hand corner of the window will save any modifications made.

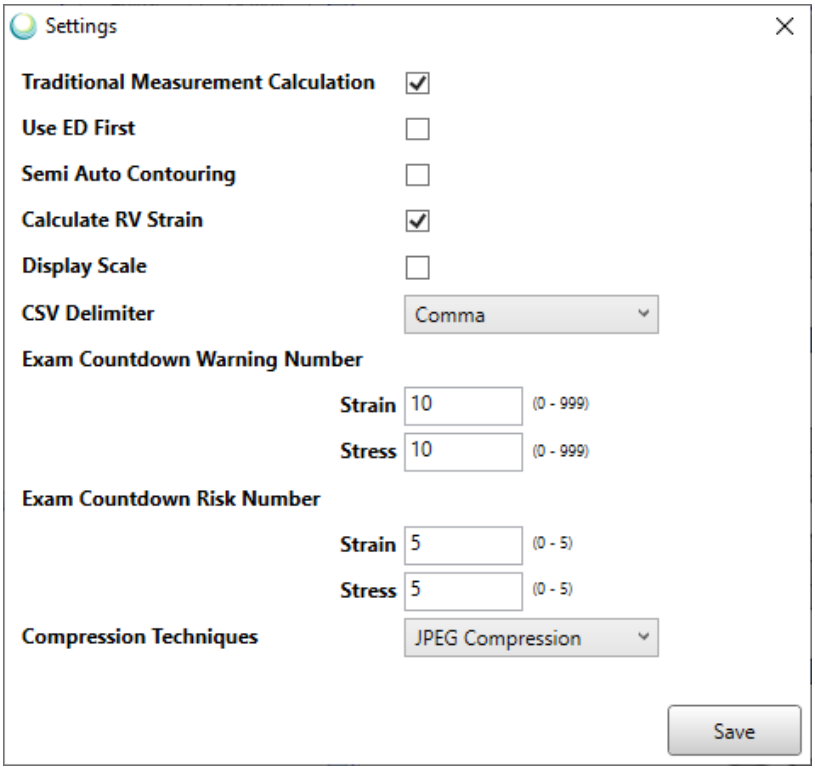


Figure 3-20: Settings menu found in MyoStrain's File menu

- **Traditional Measurement Calculation –** Enables or disables the "Traditional Measurements" section of the Strain report. With this option off, End Diastolic meshes can no longer be drawn, and measurements such as "LVEF" and "LV Stroke Volume" will be disabled.
    - **Use ED First** – When enabled, MyoStrain will instead treat the first drawn mesh on each Long Axis slice as a Diastolic timeframe instead of a Systolic timeframe. This is only available when **Traditional Measurement Calculation** is enabled.
- **Semi Auto Contouring –** Enables or Disables Semi Auto Contouring. Please refer to section 9 for more information.
- **Calculate RV Strain –** Enables or Disables the RV feature of MyoStrain. Contouring of the RV as well as RV measurements and displays are controlled by this option.
- **Display Scale –** Enables or disables the measurement scale shown on the left-hand side of the **Analysis Window**
- **CSV Delimiter –** Changes the output of .csv files created from **Export Data** options found in the **Report** and **File>Export** sections of the software. The default setting is Comma (,)
- **Exam Countdown Warning Number –** If the software has less than the number of exams specified here available, warning messages will appear in yellow at the top of the program to alert all users (Figure 3-16 and Figure 3-17). Setting these values to 0 will disable the warning.
- **Exam Countdown Risk Number –** If the software has less than the number of exams specified here, this will override the **Exam Countdown Warning Number** and a warning will display in red at the top of the program. Setting these values to 0 will disable the risk message.
- **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)
    - JPEG Compression – 1.2.840.10008.1.2.4.50 (JPEGBaseline)
    - RLE Compression – 1.2.840.10008.1.2.5 (RLELossless)
    - No compression – 1.2.840.10008.1.2 (ImplicitVRLittleEndian)
- **Save –** This closes the dialog box and saves all changes made.

3.6.4 IMAGE AND VIDEO SETTINGS

The **Image and Video Settings** menu found in the **File>Setup** menu contains two menus of options that changes how MyoStrain exports videos and images for use outside of the application. These settings can also be updated when exporting a video or screenshot by pressing the **Show Advanced Settings** button seen in Figure 3-22.

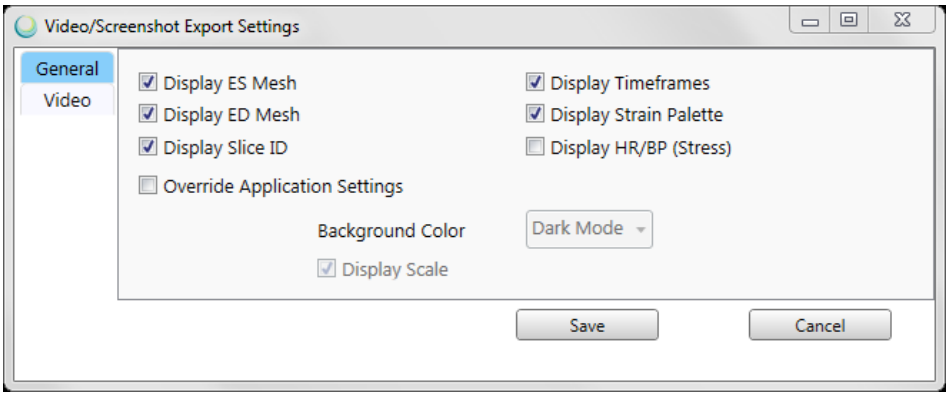


Figure 3-21: Default Video/Screenshot export settings

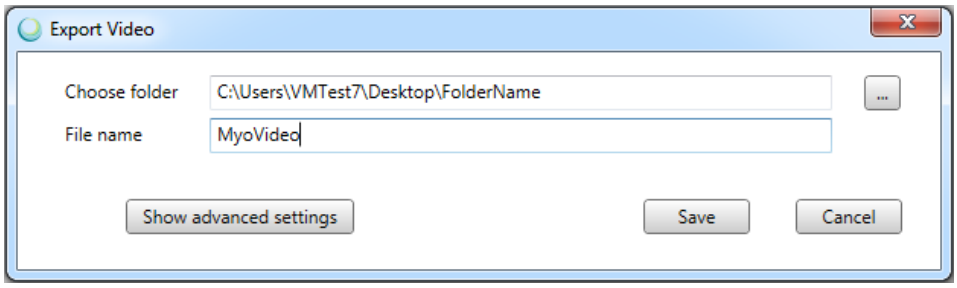


Figure 3-22: Video Export dialog box

Exported videos and screenshots will be pulled from the currently displayed slice and timeframe respectively. The **General** export settings change which UI elements will be added into the exported video/screenshot.

- **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/BP** - If performing a Stress exam, the Heart Rate and Blood Pressure can also be included or excluded from video output.

The **Override Application Settings** button will enable or disable additional settings governed by MyoStrain. The settings found below this checkbox are controlled by this option. If not checked, the video will use the current settings MyoStrain is using at the time of export.

- **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.

Under the **Video** tab, additional settings related to video export are also available. These settings are related to encoder settings and frame rates of exported video.

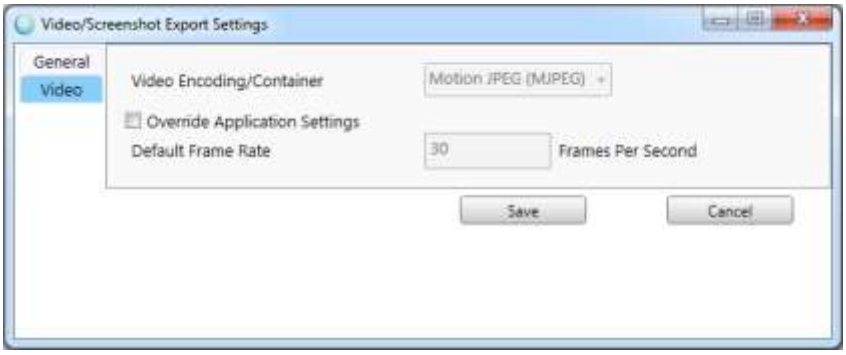
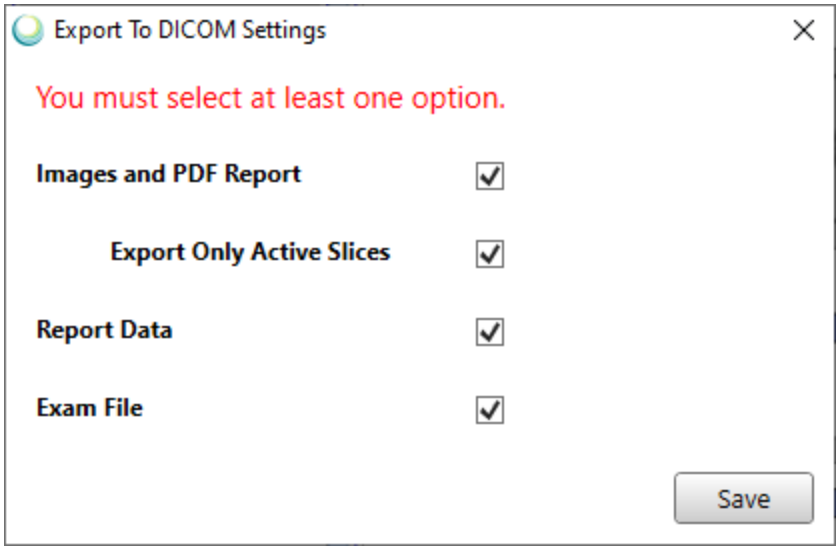


Figure 3-23: Video specific settings

Video Encoding/Container provides 2 options for exporting video, Motion JPEG and Quick Time.

3.6.5 EXPORT TO DICOM SETTINGS

When exporting data to DICOM (either Local or PACS export), MyoStrain exports all data configured for export in the Export to DICOM Settings menu.



- **Images and PDF Report** – Exports the formatted MyoStrain images and a copy of the PDF report when enabled.
    - **Export Only Active Slices** – When enabled, MyoStrain will only export the images used to generate the MyoStrain/MyoStress report at the end of analysis.
- **Report Data** – This file contains exam data which enables cloud-based reporting capabilities (when coupled with MyoCloud technology).
- **Exam File** – This is a copy of the exam file (.myo file) which has been formatted to fit in a DICOM image. This exam file can be read by MyoStrain if imported using the MyoWorklist feature.

NOTE: When updating Export to DICOM Settings, it's recommended to restart MyoStrain before exporting.

3.6.6 **REPORT LOGO**

This 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.

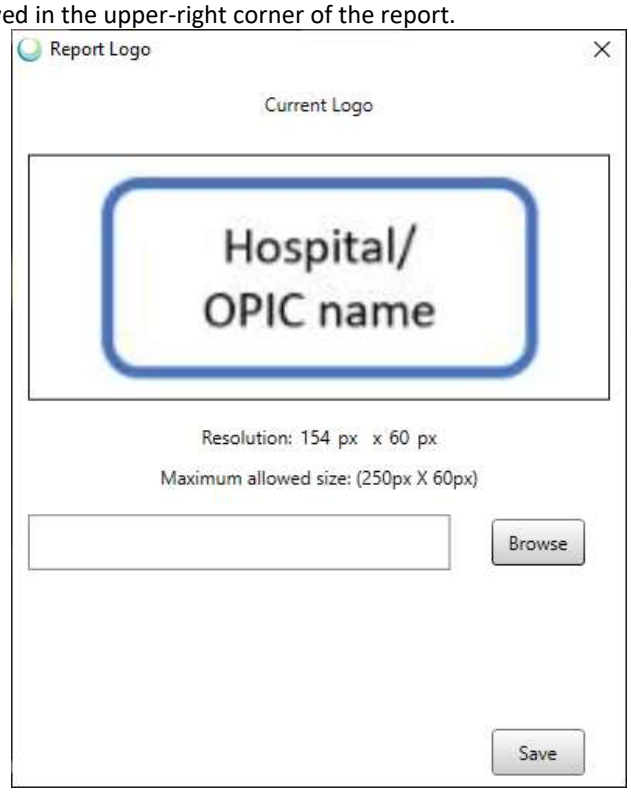


Figure 3-24: Logo selected for use with the MyoStrain report

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 3-25:Example image of the top of a MyoStrain report with a custom logo

3.7 **VIEW MENU**

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

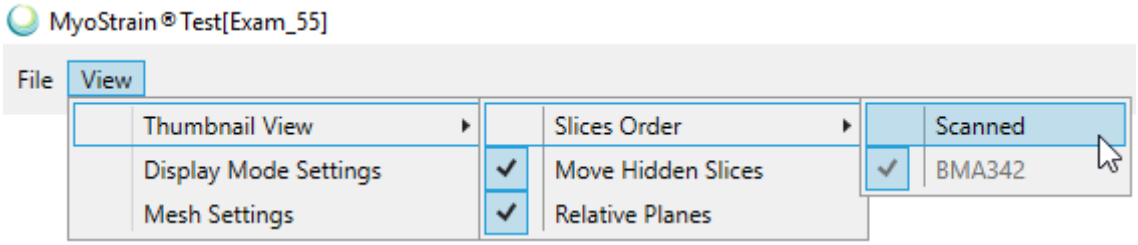


Figure 3-26: All options of the View Menu displayed

The **View** menu changes how images are displayed within MyoStrain's **Image List.**

- **Thumbnail View** – Contains options related to the **Image List**
  - **Slices Order** – Changes the order which images are displayed in the **Image List**.
    - **Scanned** - Displays images based on the on the order in which they were received by MyoStrain. Earliest scans are displayed first.
    - **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.
  - **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.
  - **Relative Planes** - Enabled by default, this displays a black/orange line on each image in the **Image List** except for the currently selected slice. These lines represent the imaging plane for each slice relative to the displayed slice in the **Analysis Window**.
- **Display Mode Settings –** Opens the Display Mode Settings submenu. Please refer to section 3.7.1 for more information.
- **Mesh Settings –** Opens the Mesh Settings submenu. Please refer to section 3.7.2 for more information.

3.7.1 DISPLAY MODE SETTINGS

The Display Mode Settings menu manages the default display of MyoStrain images in the Main Viewing Window, as well as in the Image List. By default, MyoStrain launches in Light Mode (background of MyoStrain images are displayed in white). In addition, the default windowing settings used for Brightness/Contrast adjustment can be set here as well.

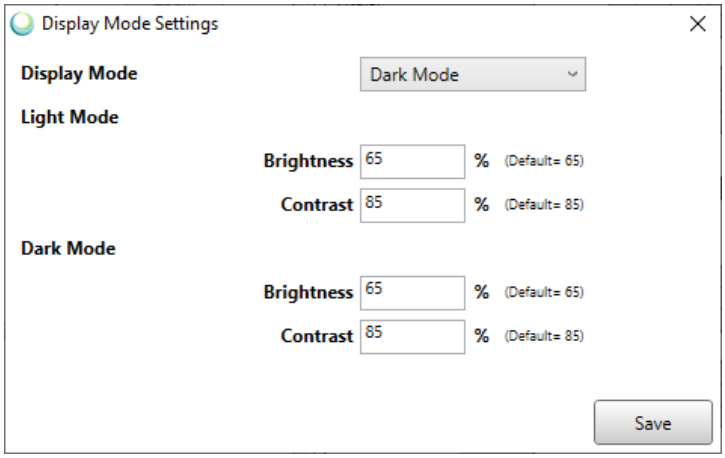


Figure 3-27: Display Mode Settings

3.7.2 MESH SETTINGS

The Mesh Settings menu allows the analyst to adjust aspects of the contours in MyoStrain, such as the mesh's line thickness, coloring, and transparency. To enable and/or change these settings, click on the Override Application

Settings checkbox, then click the Save button after making any changes. Visual changes made to the mesh will apply to the **Analysis Window**, **Image List**, and any images exported from MyoStrain via DICOM or Video.

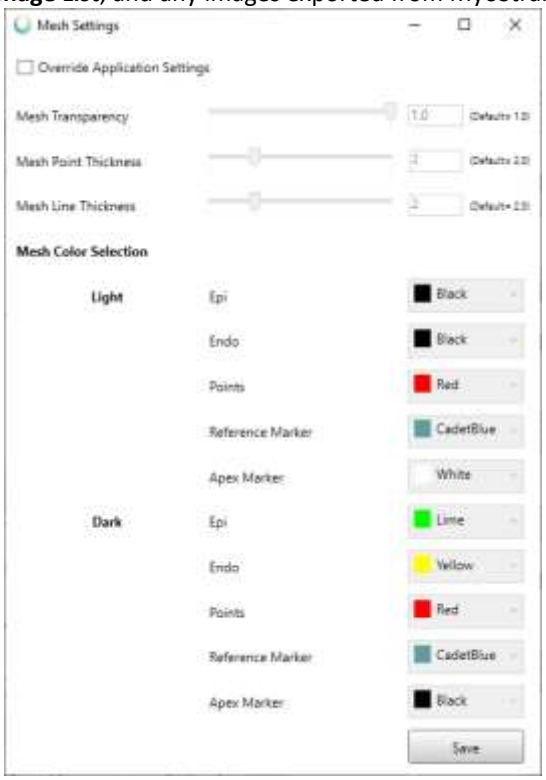


Figure 3-28: Mesh Settings Menu

3.8 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**, **Report** or **Findings** sections, simply left-click and hold the 5 dots seen in the middle of the divider (Figure 3-14), 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.

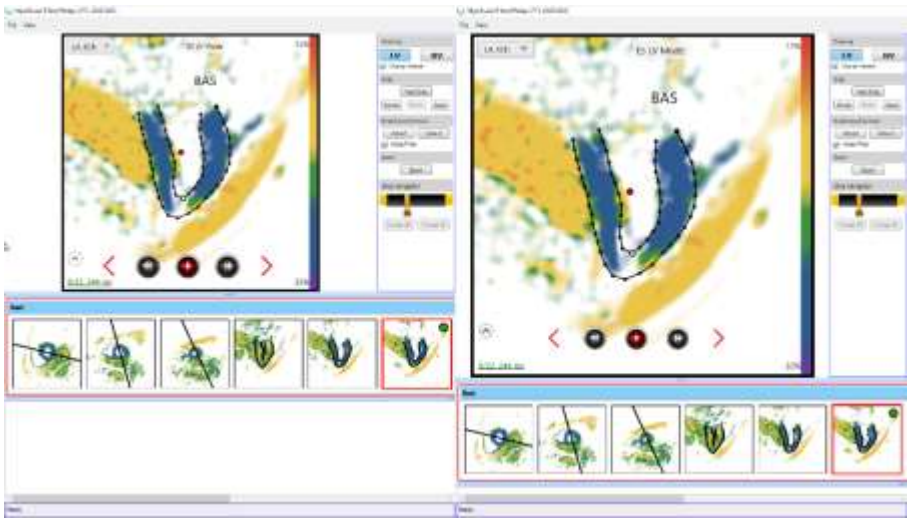


Figure 3-29: Resizing the Analysis Window by decreasing the size of the Image List

4

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 receiving 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 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.

NOTE: When computing the strain after contouring the heart with a mesh, the strain measurements are restricted 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)

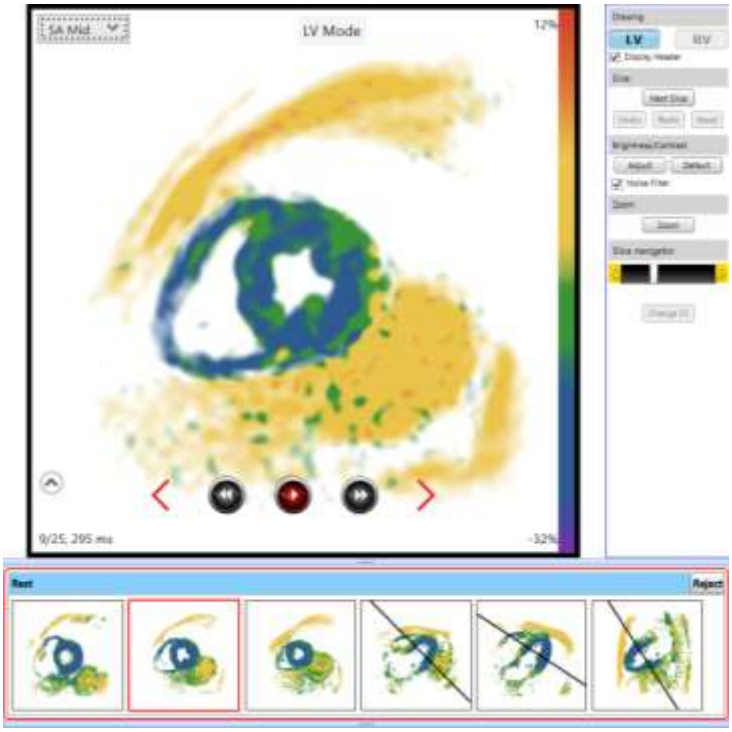


Figure 4-1: MyoStrain Stress exam with three Short-Axis and three Long-Axis slices

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

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.

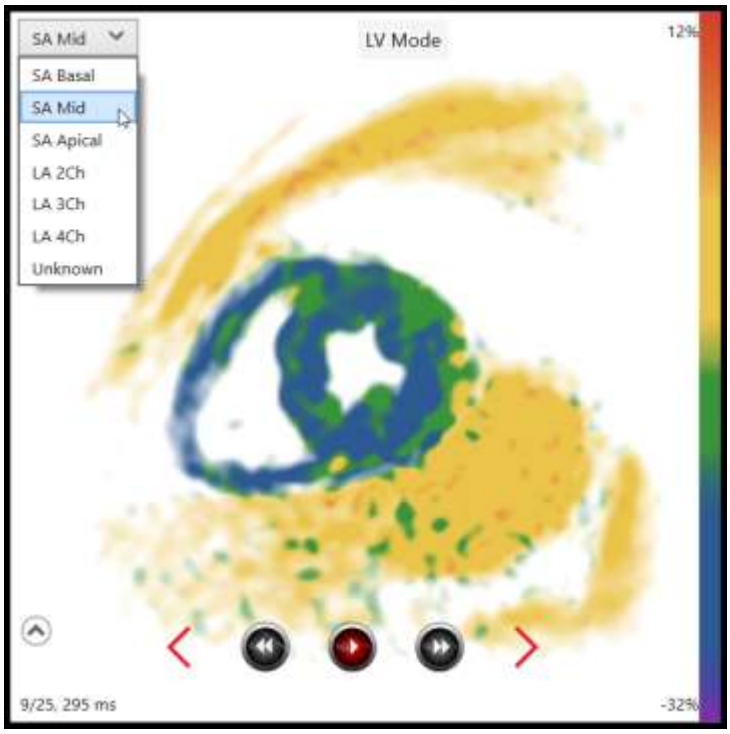


Figure 4-2: Selecting the appropriate view from the View Dropdown

3. In addition to selecting the proper view, enter the patient's heartrate and blood pressure in the textboxes in the **View Details** (if not present). Blood pressure should be reported as {Systolic/Diastolic}.

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, 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.

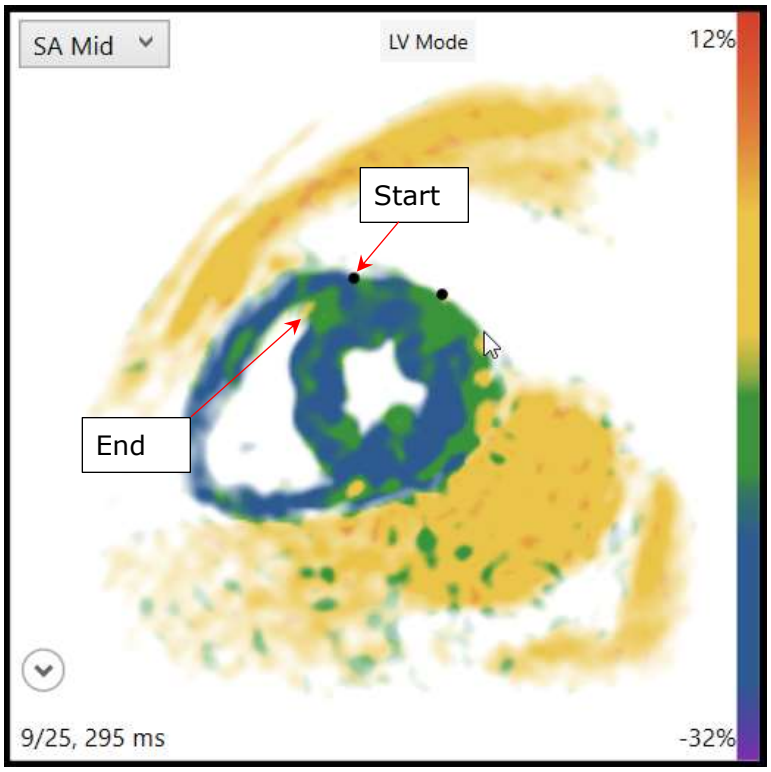


Figure 4-3: Beginning drawing the epicardial contour

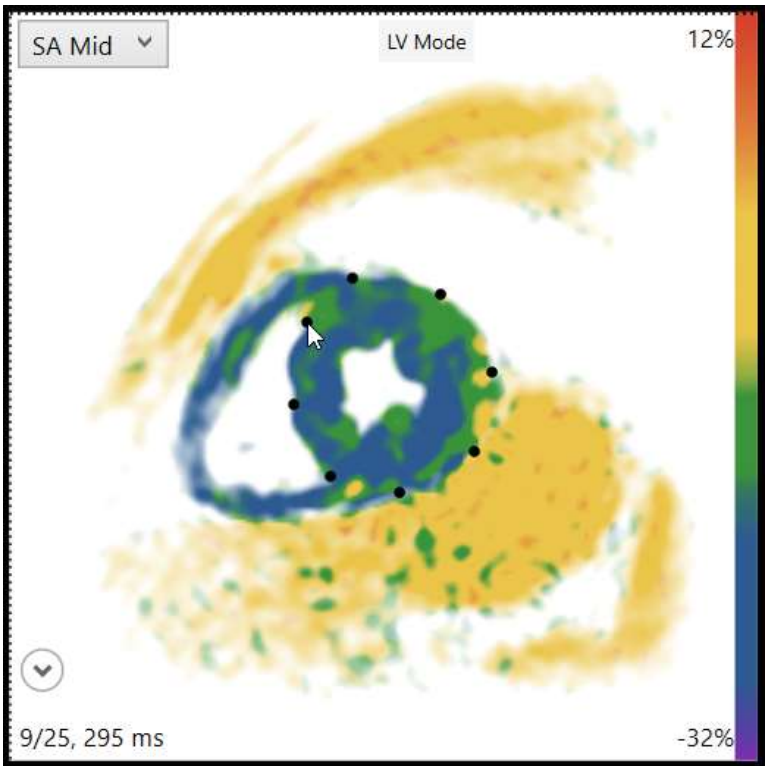


Figure 4-4: Double-clicking here will complete the epicardial contour

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.

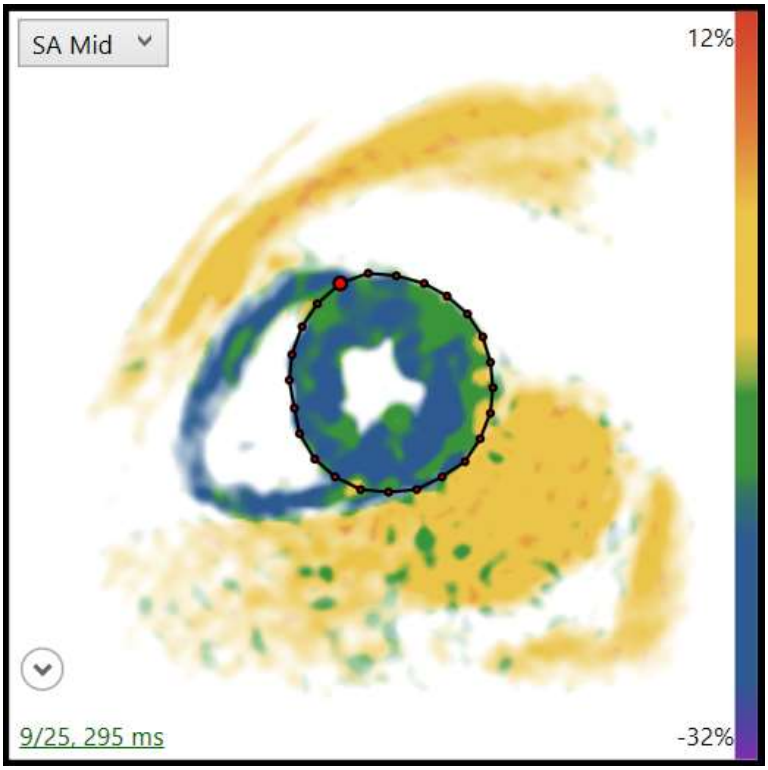


Figure 4-5: Completed epicardial contour

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.

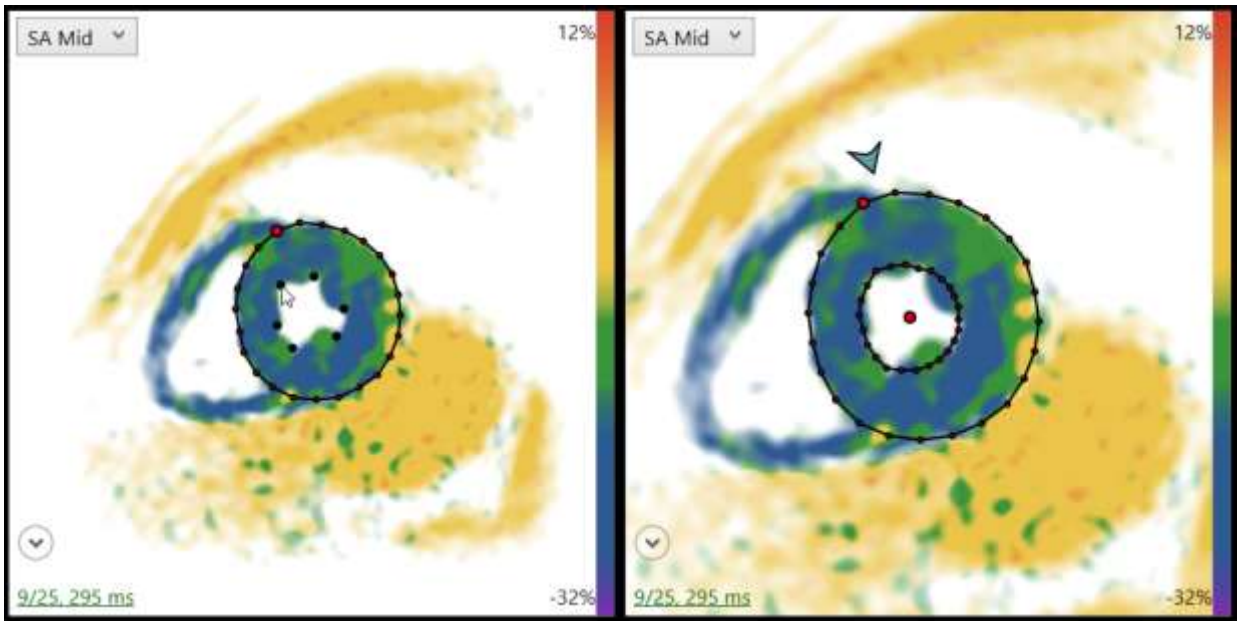


Figure 4-6: Completing the endocardial contour and the finished mesh with RV marker

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.

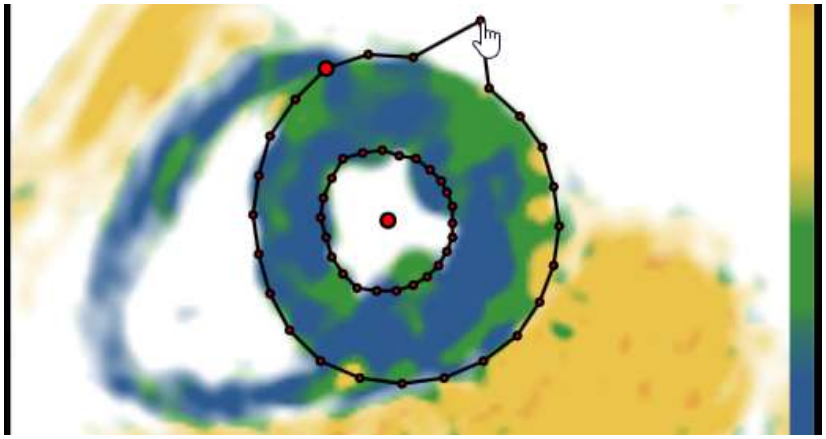


Figure 4-7: Example of a single point mesh correction

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.

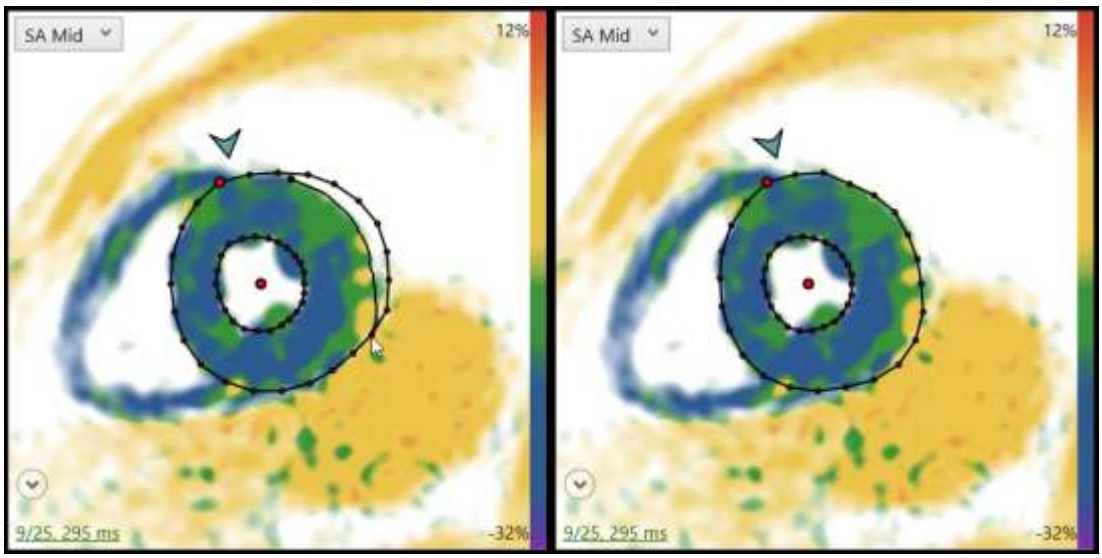


Figure 4-8: Mesh adjustment by drawing a new contour freehanded

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.

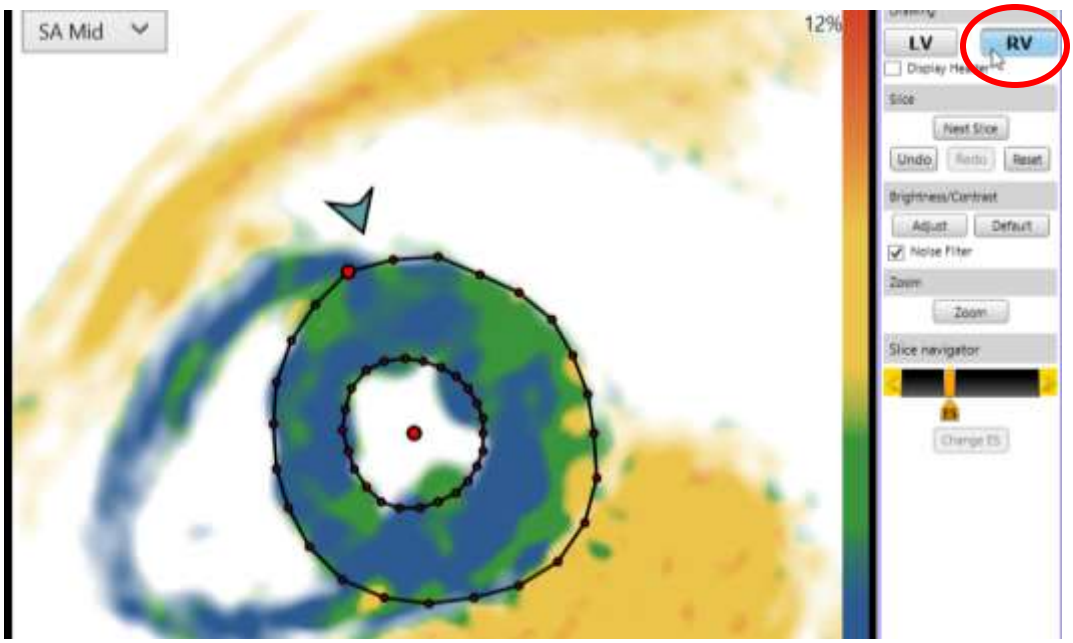


Figure 4-9: Clicking on the RV button after completing the LV mesh will enable RV contouring

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.

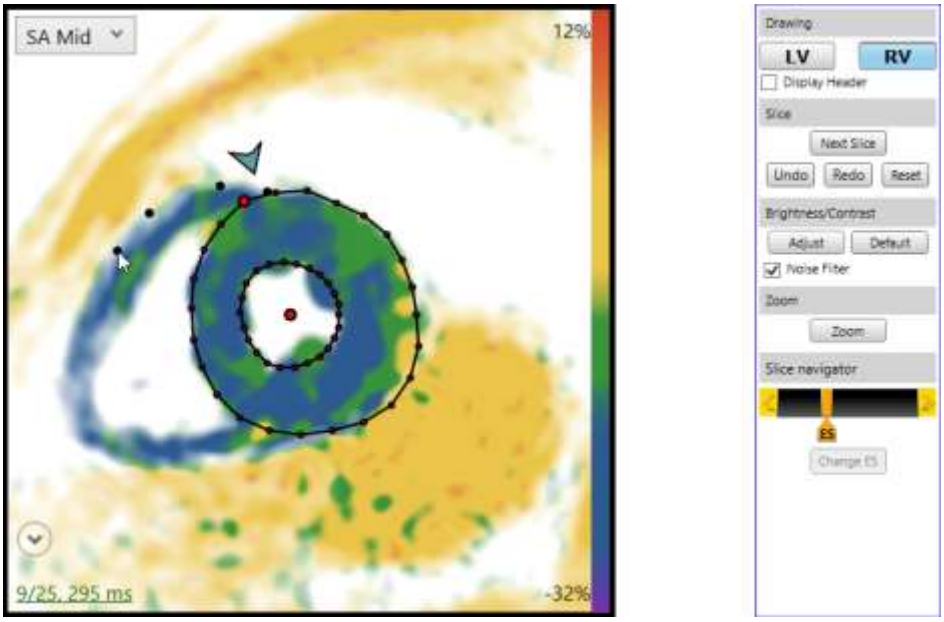


Figure 4-10: Beginning the epicardial RV contour

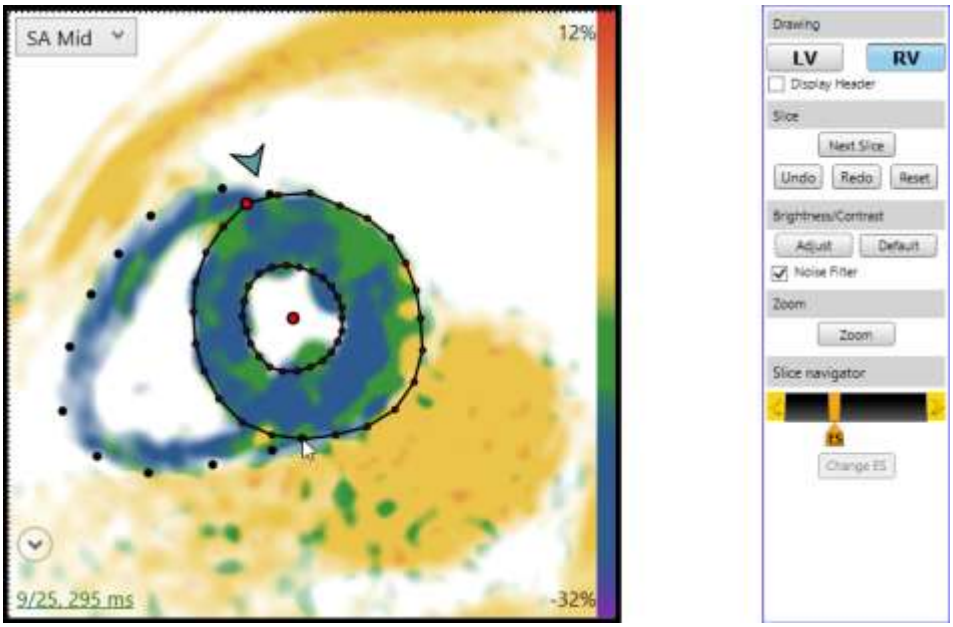


Figure 4-11: Double-clicking here will complete the epicardial RV contour

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

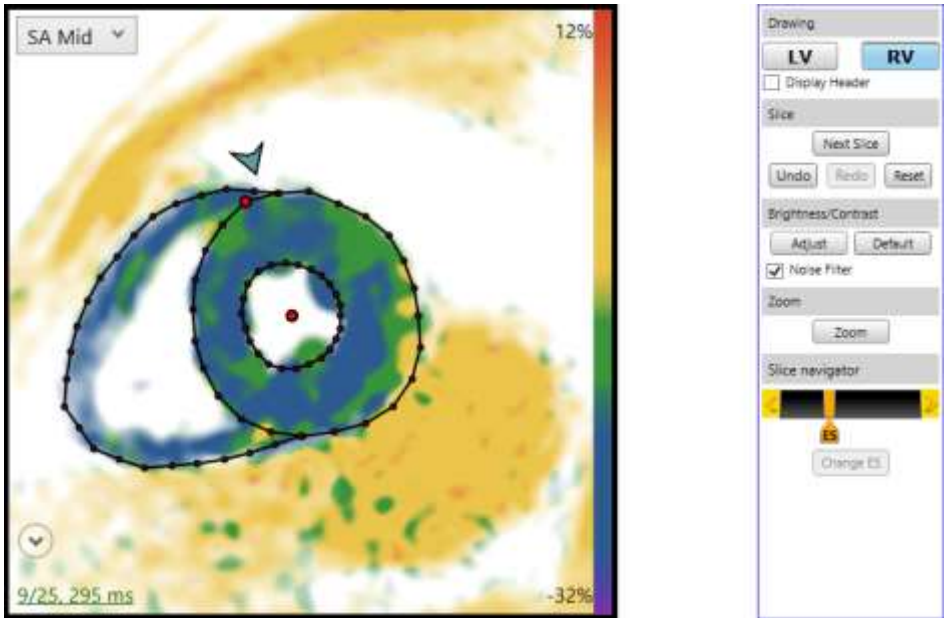


Figure 4-12: Completed RV epicardial contour

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.

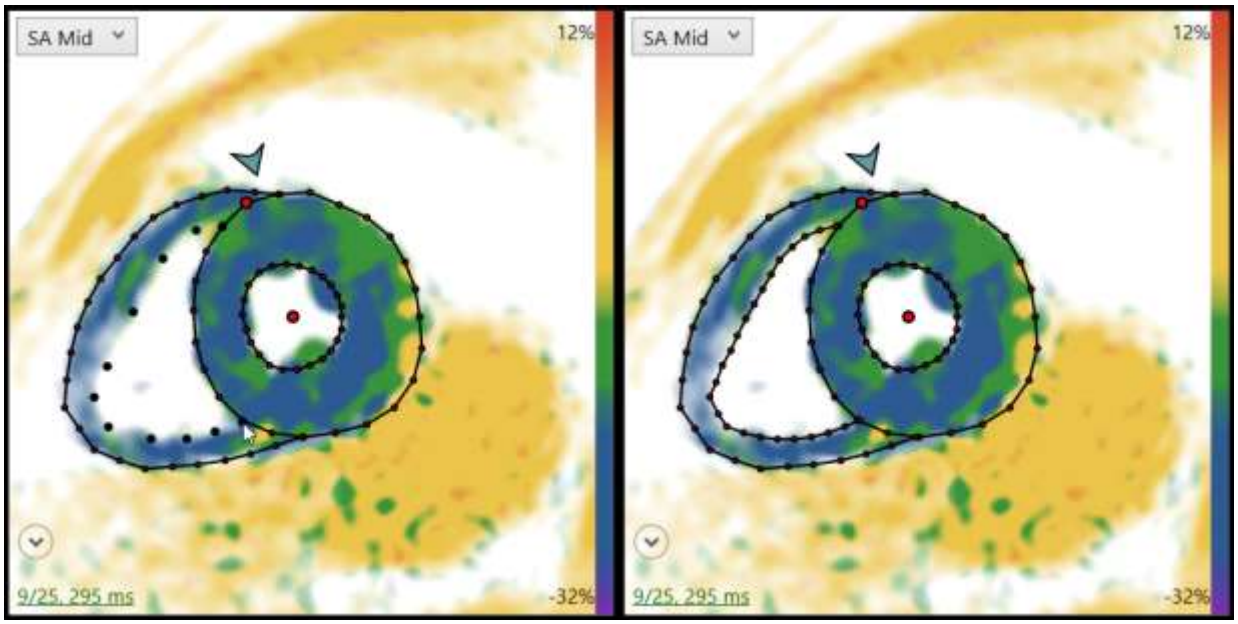


Figure 4-13: Defining the endocardial contour for a complete RV mesh

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.

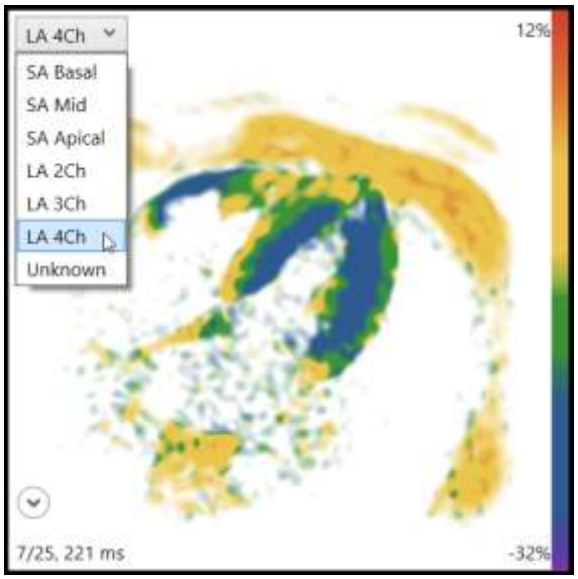


Figure 4-14: Selecting a Long-Axis view from the View Dropdown menu

3. In the upper-left hand corner of the **Analysis Window**, enter the patient's heartrate and blood pressure in the textboxes below the view selector (Stress exams only). Blood pressure should be reported as {Systolic/Diastolic}.

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.

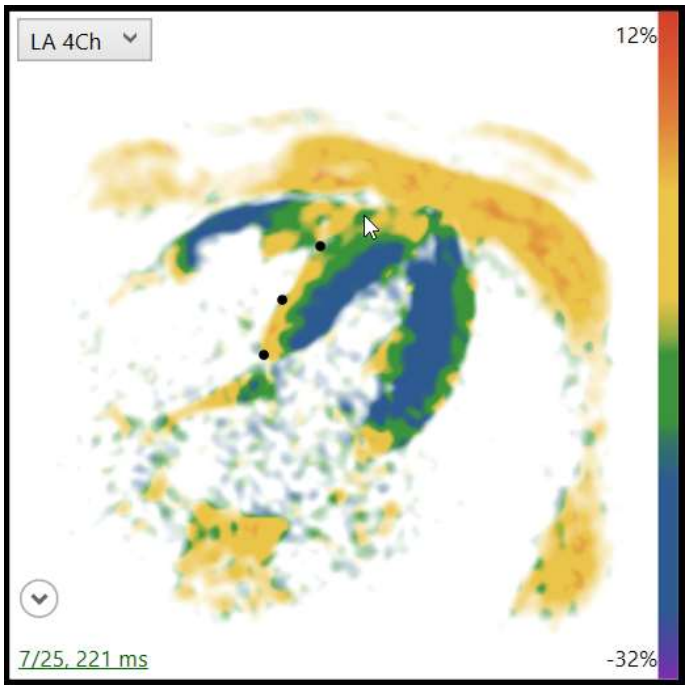


Figure 4-15: Beginning the epicardial contour

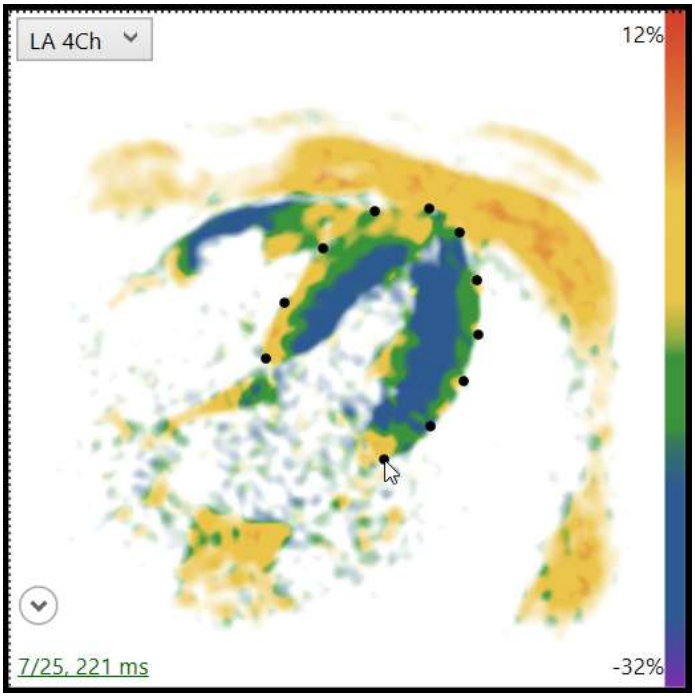


Figure 4-16: Double-clicking here will finish the epicardial contour

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.

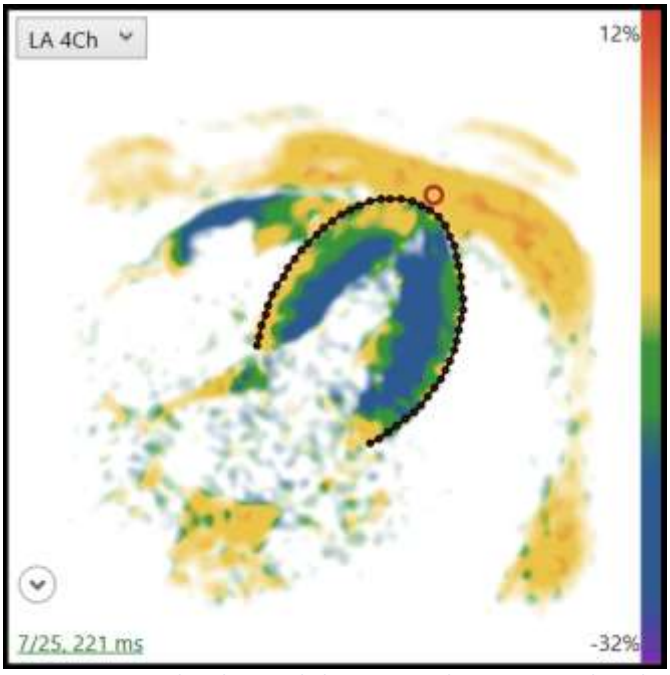


Figure 4-17: Completed epicardial contour with correct apical marker

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.

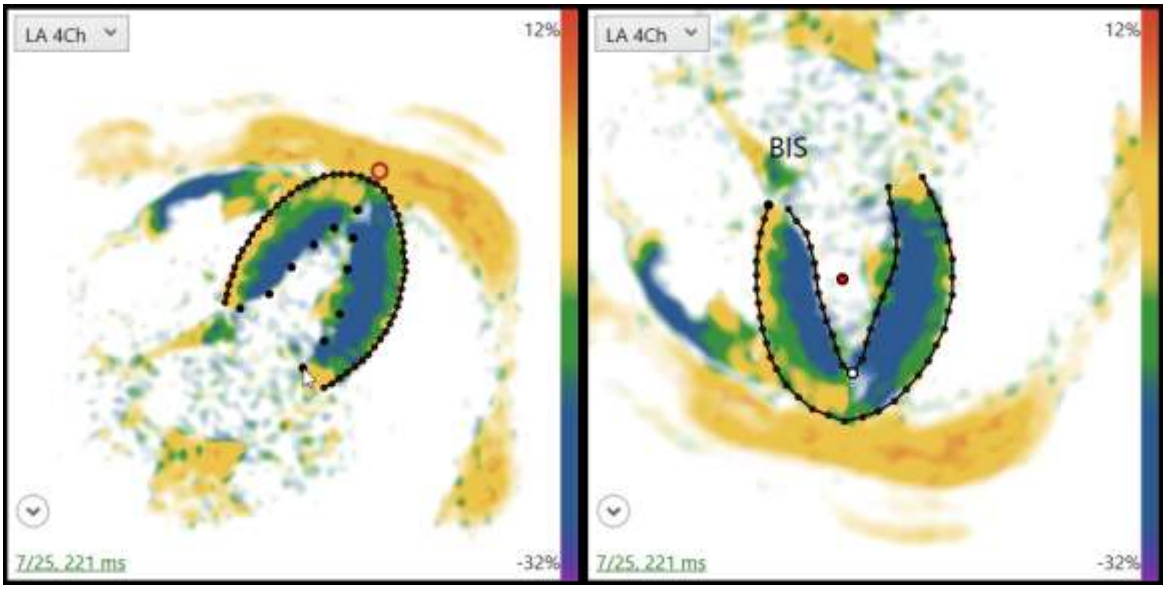


Figure 4-18: A completed epicardial contour with apical marker

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)

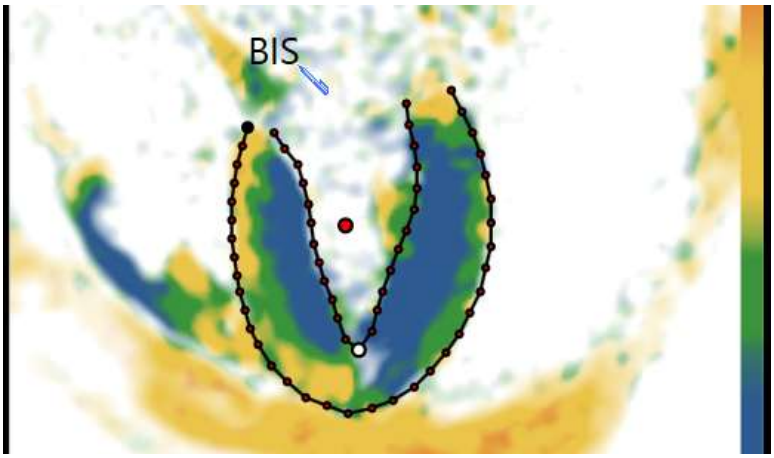


Figure 4-19: The mouse cursor will change when hovering over the reference point. Left-clicking will flip the image and change the reference marker

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.

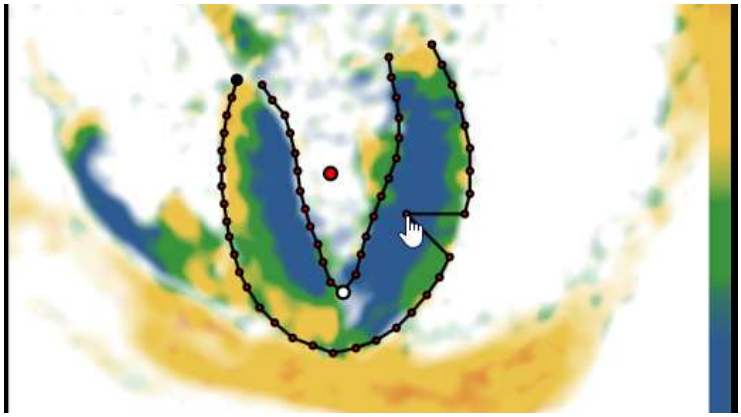


Figure 4-20: Example of a single point mesh correction

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, clicking and dragging any of the lines of the contour will allow relocation of 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.

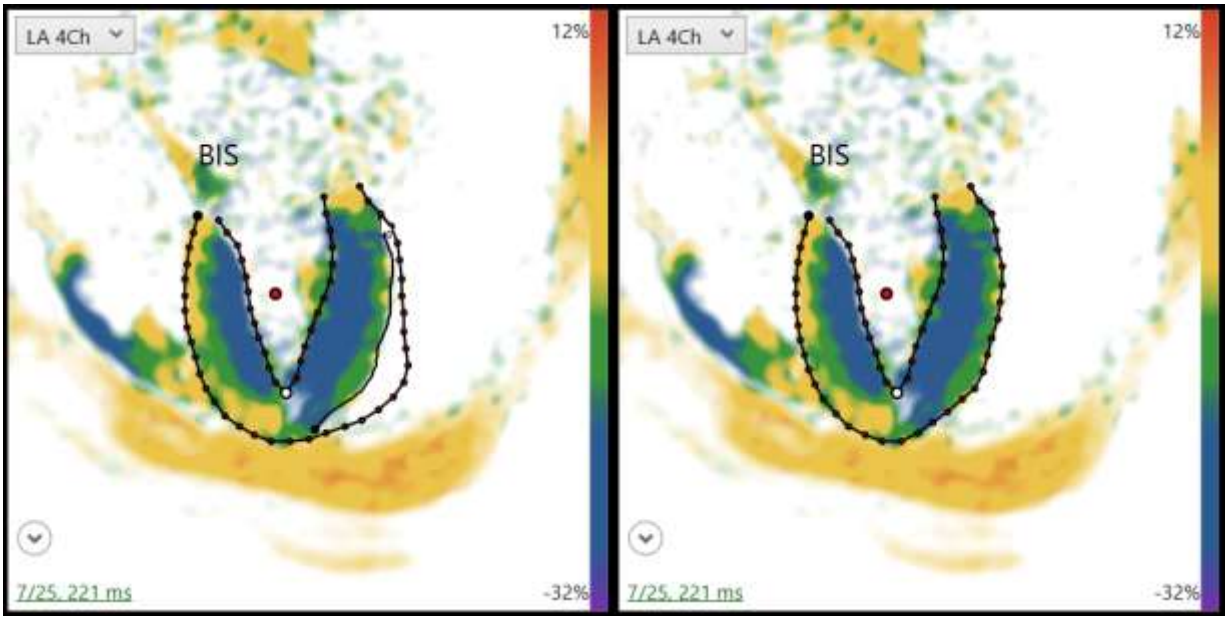


Figure 4-21: Modifying the mesh by redrawing a contour section using the freehand method

After drawing and correcting the mesh, verify that the information displayed in the **Circumferential Strain** subsection of **Measures** is reflecting 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.

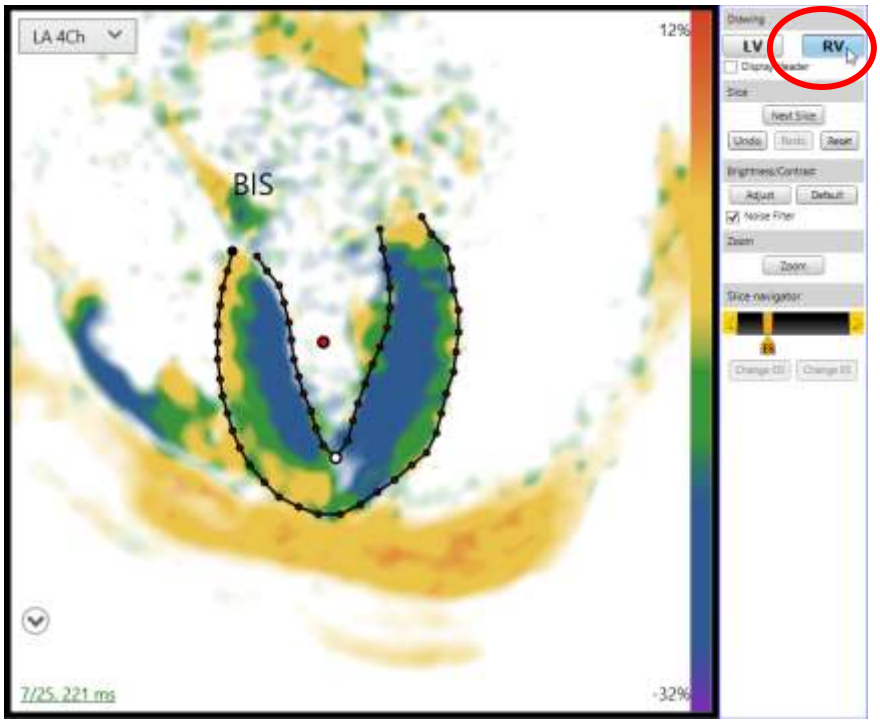


Figure 4-22: Clicking on the RV button after completing the LV mesh will enable RV contouring

4.2.3.1.1 4-CHAMBER RV MESH

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

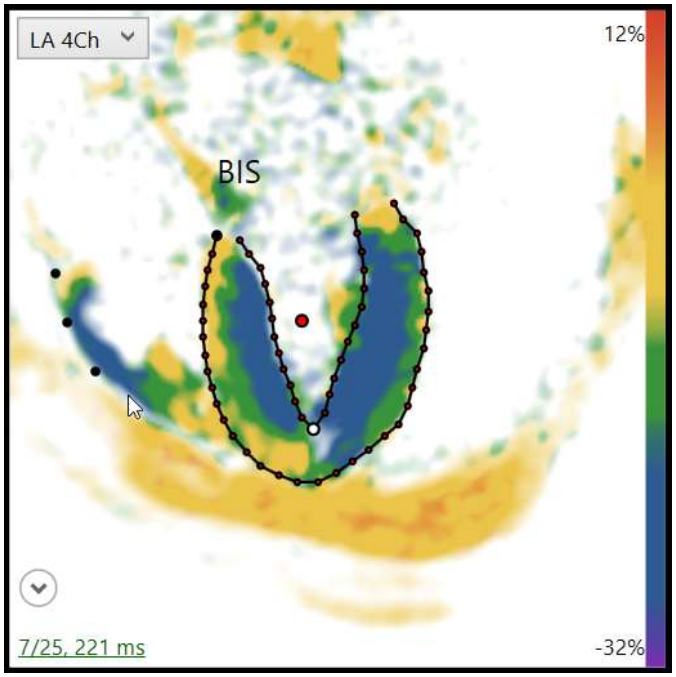


Figure 4-23: Beginning RV contour on 4Ch image

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.

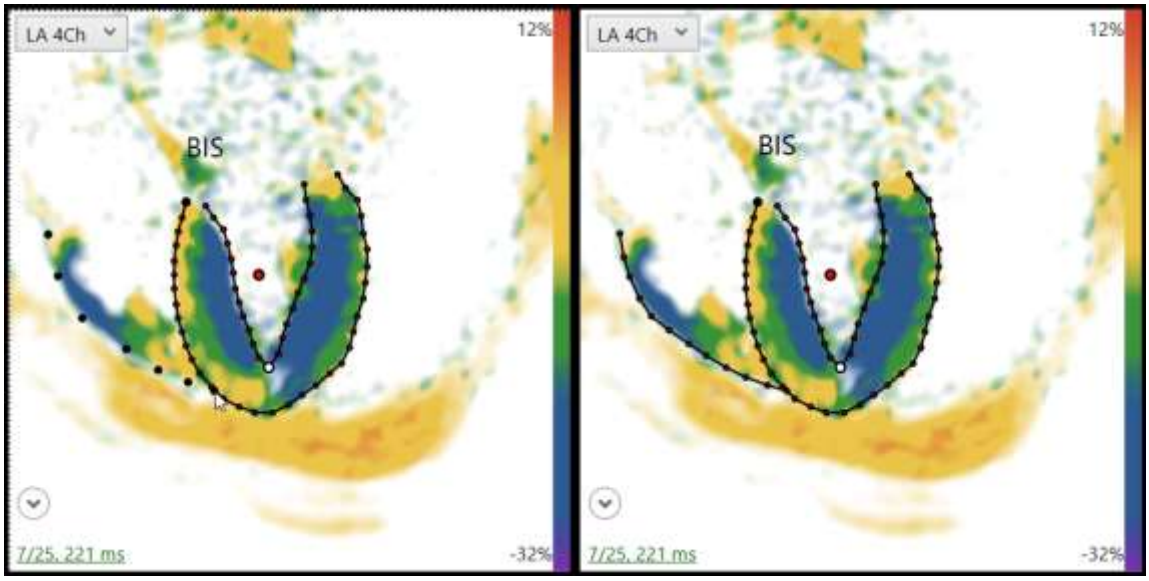


Figure 4-24: Completion of the epicardial RV contour

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

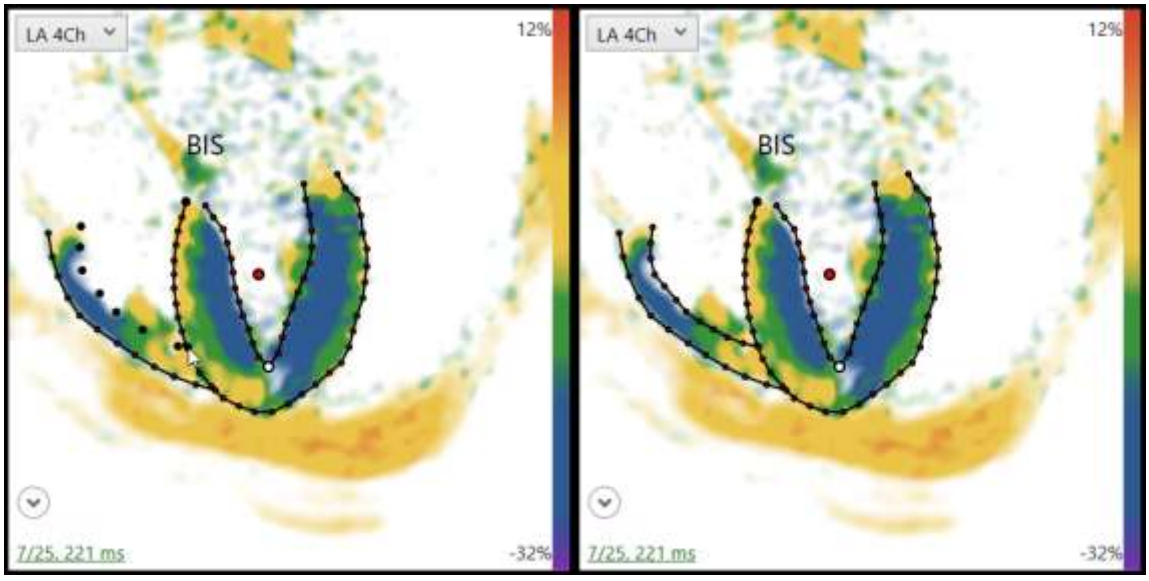


Figure 4-25: Completion of the 4Ch RV contour

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

4.2.3.1.2 3-CHAMBER LONG-AXIS MESH

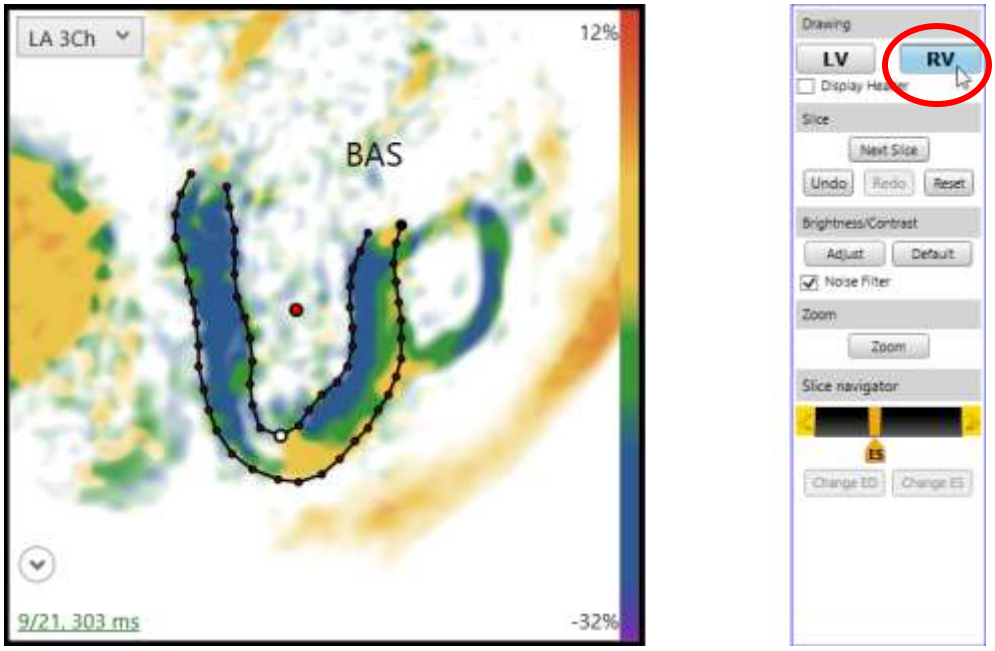


Figure 4-26: 3Ch view with RV button selected

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.

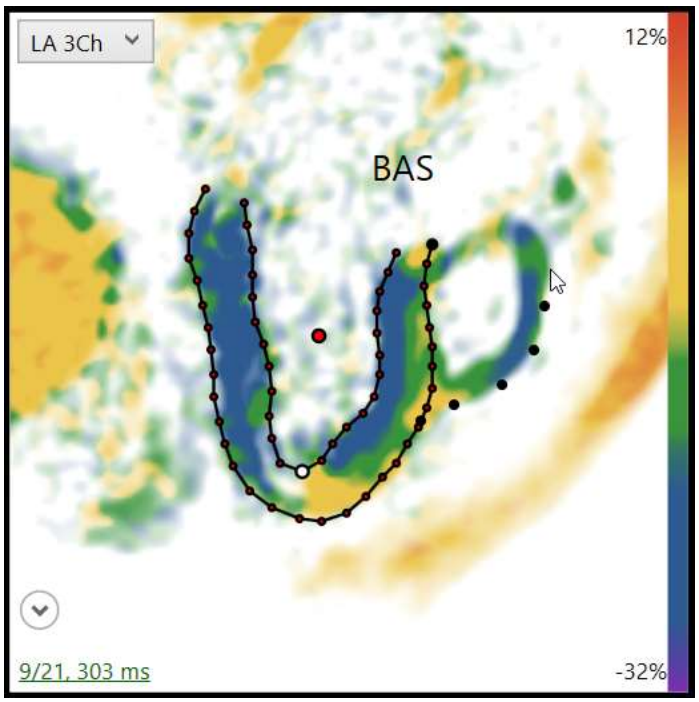


Figure 4-27: Beginning the epicardial RV contour at the mid anterior region

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

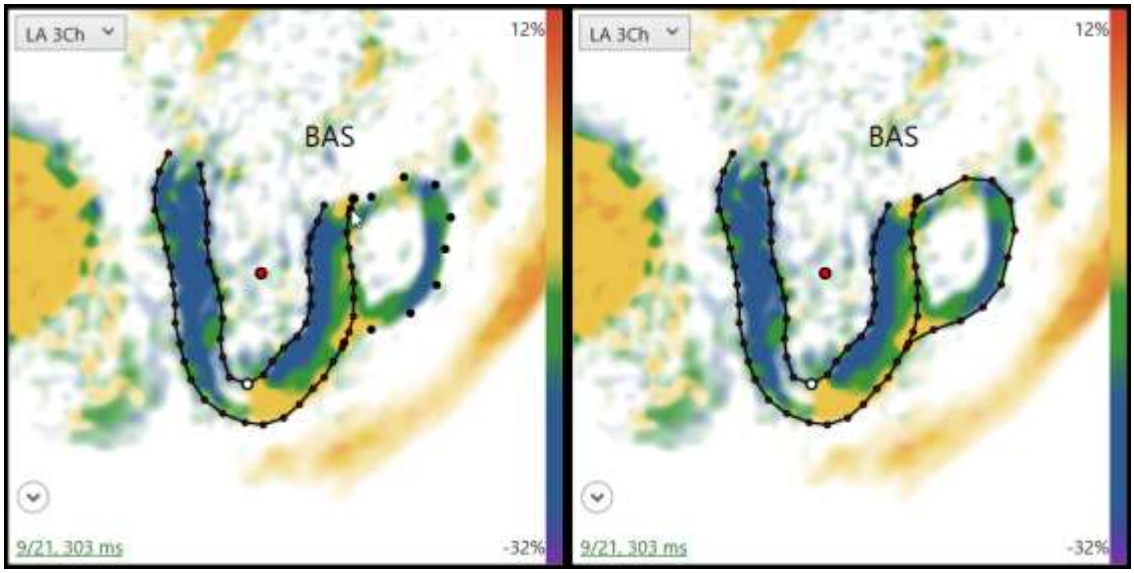


Figure 4-28: Completion of the epicardial RV contour

NOTE: Make sure the RV contour connects to the epicardial wall of the LV contour opposite of the LV endocardial contour. See Figure 4-29 for an example.

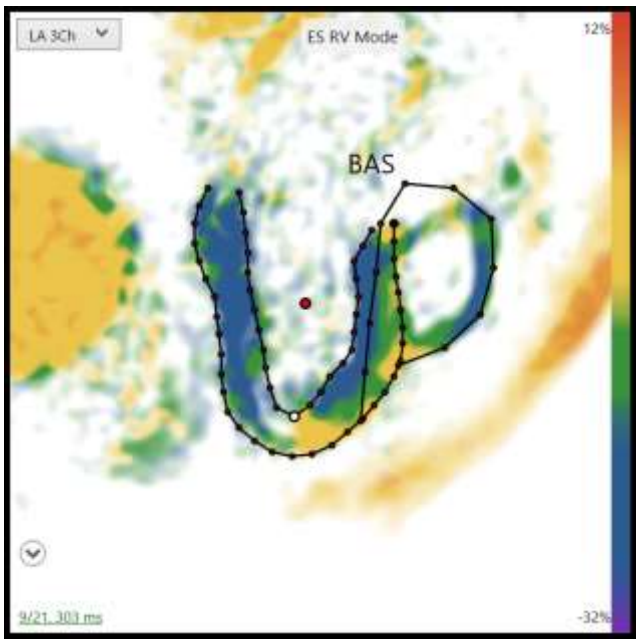


Figure 4-29: An example of an improperly drawn RV contour

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

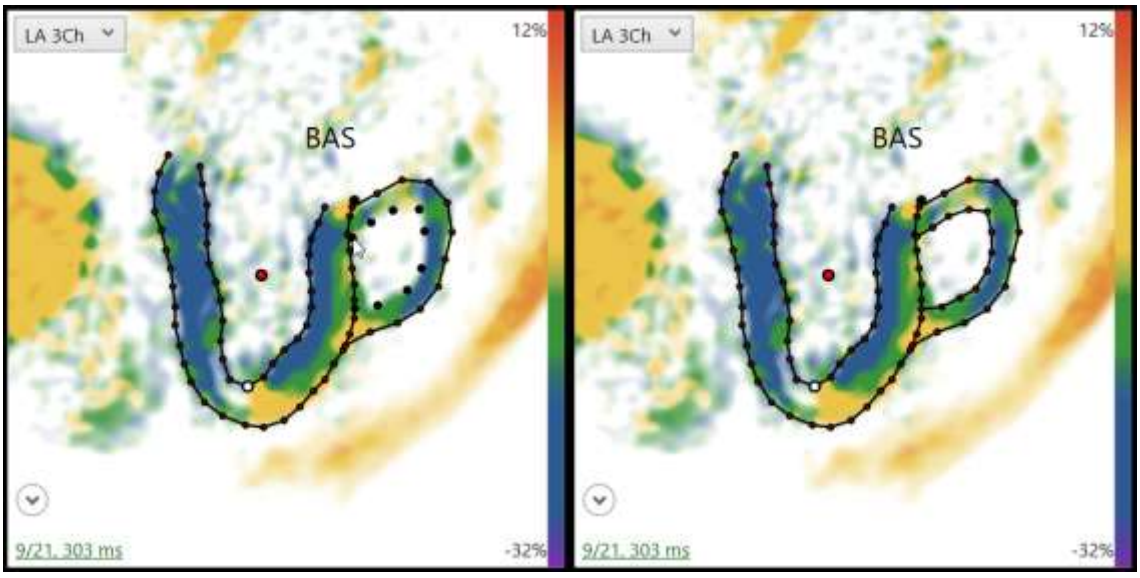


Figure 4-30: Endocardial contour drawn for 3Ch RV

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.

⚠ RV 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**.

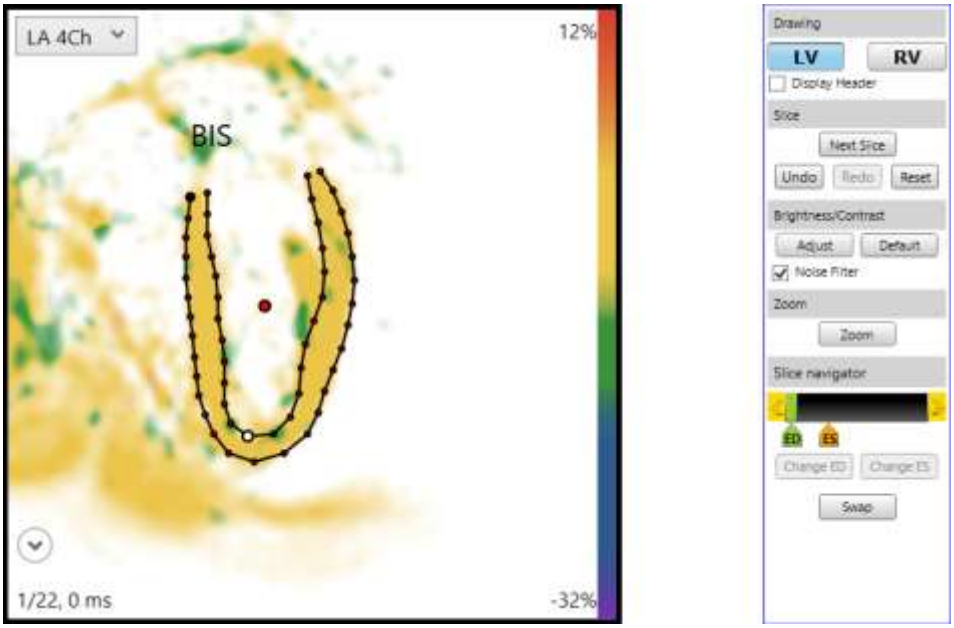


Figure 4-31: End-Diastolic meshed and viewed in the Slice Navigator

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.

Figure 4-32: End-Diastolic timeframe meshed with traditional measurements displayed

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

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. Images acquired from the scanner should automatically be imported into the application. This procedure assumes a technician is operating the MRI scanner, a patient is ready to be scanned, and the MyoWorklist is running in **Single Mode** (please refer to chapter 10 for more information about the MyoWorklist). The below sequence of events is typical for a Strain exam:

1. Launch the MyoStrain Strain exam
2. Enter relevant patient information in **Analysis Window**
3. Select one slice from **Image List**
4. Quantify slice
5. Repeat steps 3-4 for each slice out of six total views.
6. Finalize report and export results

5.2 STARTING THE STRAIN EXAM

Upon launching the MyoStrain application, or by selecting New from the File menu, the software will display a dialog box labeled "Select Your Exam". Click on the top button labeled **MyoStrain®** to launch the MyoStrain Strain exam.

NOTE: Exam Credits will not be used until an image has been received by the software in an analysis mode.

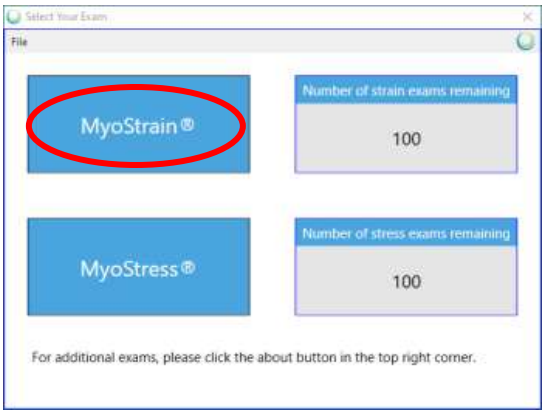


Figure 5-1: Exam Selection Screen

5.3 RECEIVE IMAGES

After selecting **MyoStrain** from the Mode Selection tab found above the Report section, executing the MyoStrain image sequence on the MRI scanner will send images to the workstation. This action will consume an exam credit and cannot be reversed.

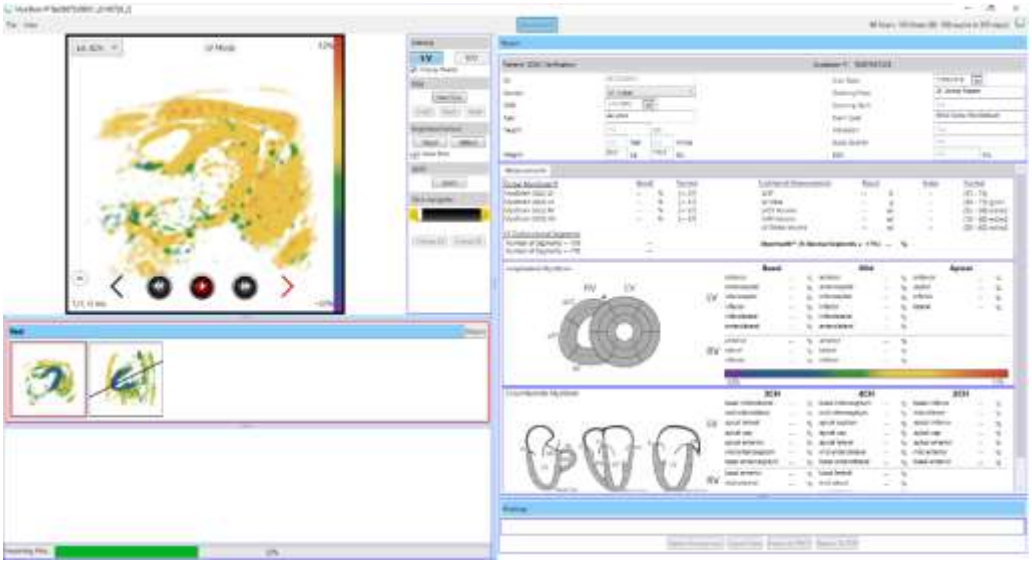


Figure 5-2: MyoStrain in RV Strain mode receiving images

After all six views from the MyoStrain pulse sequence have been received by the MyoStrain application, image review and quantification can begin.

5.4 IMAGE REVIEW AND ANALYSIS

Once all images from the scanner have been transmitted to the MyoStrain software, review each image to ensure good image quality is present. If for some reason the image quality is poor or there was an issue during acquisition, refer to section 5.4.1 to reject a scan. A rescan can be performed without consuming an exam credit provided the exam is not closed during the session.

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 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, which are different from un-analyzed 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.

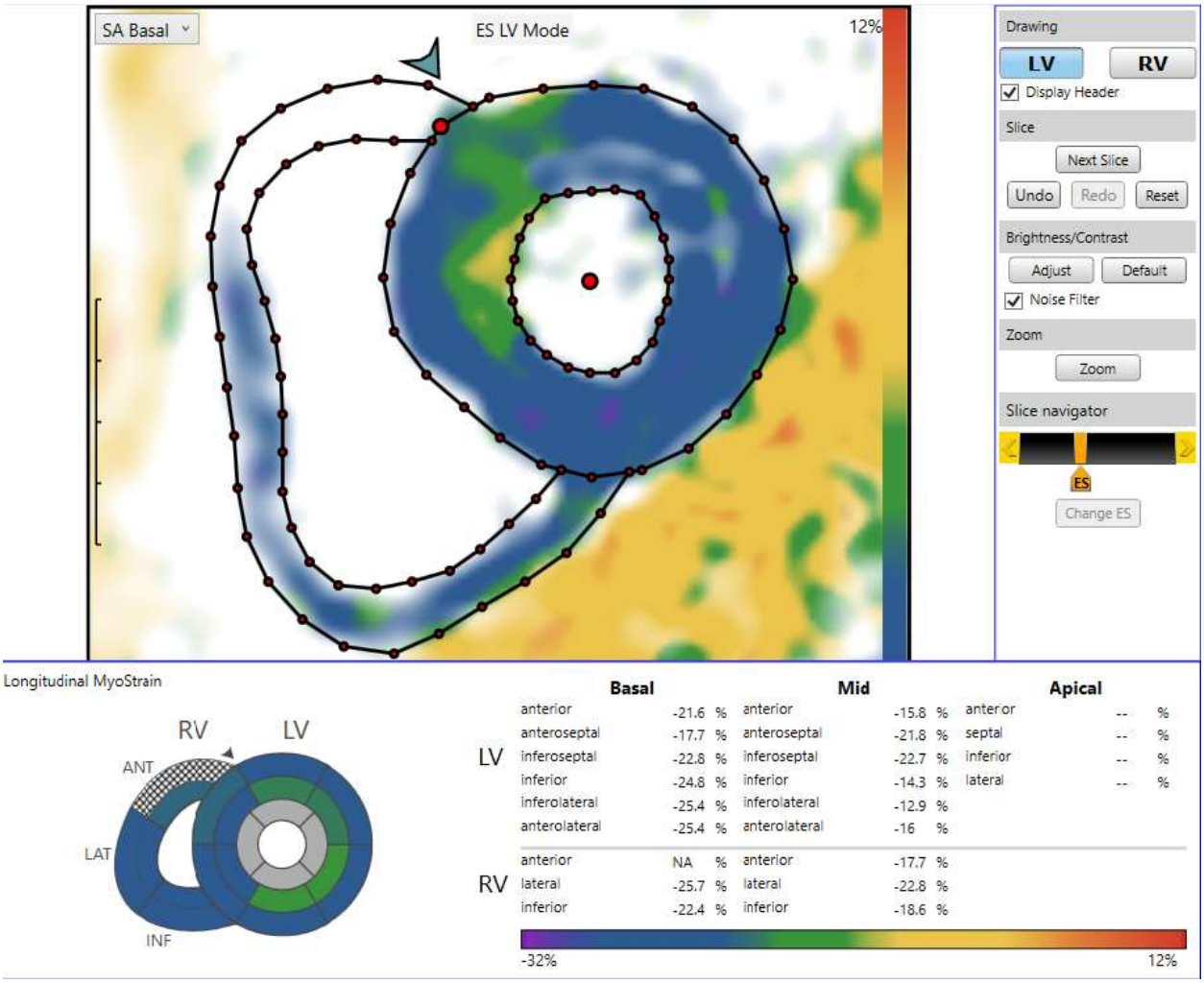


Figure 5-3: Basal Slice analyzed showing the RV Anterior as "NA"

5.4.2 REJECTION OF IMAGES

During the post-processing analysis, any number of issues may arise. This may include patient movement during acquisition, poor image quality, or any number of minor issues. At any point during the analysis, clicking **Reject** (Figure 5-3) in the upper-right corner of the **Image List** will remove those images from the scan.

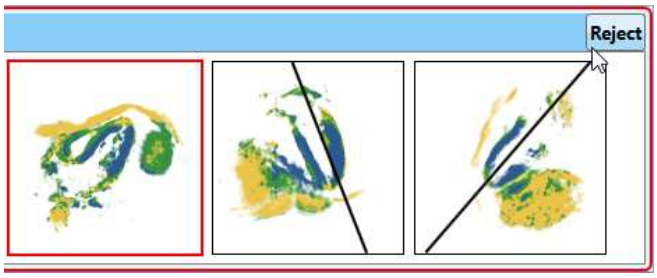


Figure 5-4: Reject button shown in Image List

⚠ Image rejection will irreversibly remove images from the current exam. Images will need to be re-sent to the workstation if this occurs.

5.4.3 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 make sure they are not analyzed. 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**.

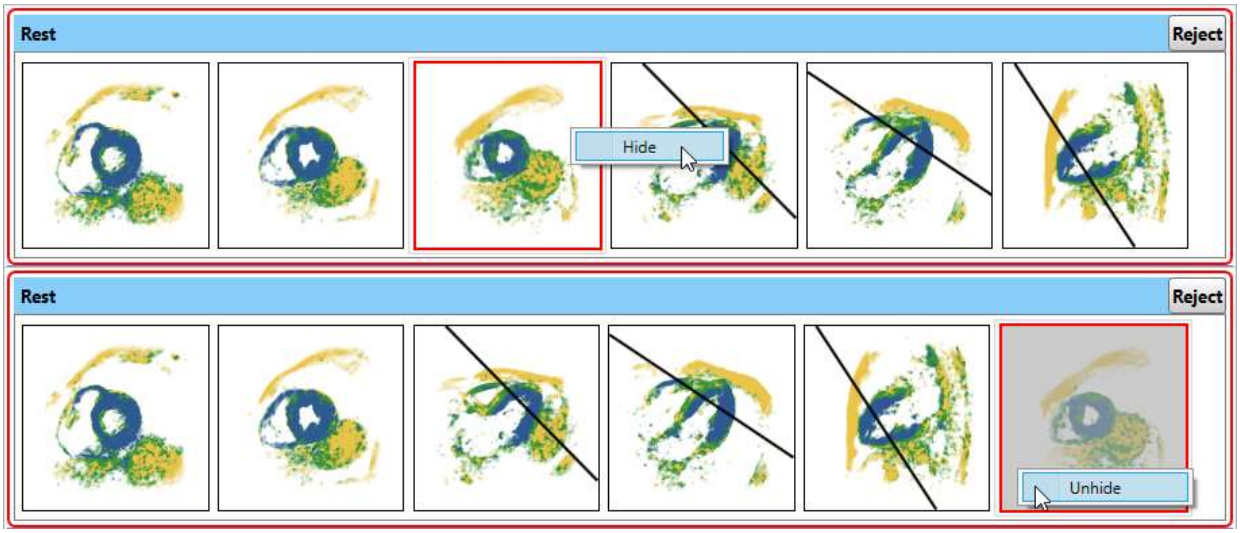


Figure 5-5: Hiding and Unhiding an image in the Image List

5.5 REPORTING AND EXPORTING DATA

After quantifying all six slices of the current patient scan, the analysis portion of the scan is complete and the patient may be removed from the scanner. It is recommended to save the quantified exam data before continuing to the **Report Section** to export the **Strain Report** and exam data.

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

Figure 5-6: RV Strain Report section

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 once a patient is prepped for a stress examination.

6.1 MYOSTRESS® TEST PROCEDURE

The MyoStrain Stress test is a simple and fast cardiac stress test which can be administered in a very short span of time. Images acquired from the scanner should automatically be imported into the MyoStrain Stress Test application. This process assumes an MRI technician is operating the scanner, a patient has been prepared for a stress test scan, and the MyoWorklist is running in **Single Mode** (please refer to chapter 10 for more information about the MyoWorklist). The below sequence of events is typical for a Stress exam:

1. Launch MyoStrain in MyoStress Mode.
2. Enter relevant patient information in **Analysis Window**
3. Set current stress phase for incoming images
4. Select one slice from **Image List** in current stress level
5. Quantify the current slice
6. Repeat steps 4-5 for each image in current stress phase
7. Advance to next stress phase, then repeat steps 2-6.
8. After all stress phases have been completed, finalize the report and export the results.

6.2 STARTING THE STRESS EXAM

Upon launching the MyoStrain application, or by selecting New from the File menu, the software will display a dialog box labeled "Select Your Exam". Click on the button labeled **MyoStress®** to launch the MyoStrain Stress exam.

NOTE: Exam Credits will not be used until an image has been received by the software in this analysis mode.

Figure 6-1: Exam Selection Screen

6.3 RECEIVE IMAGES (REST PHASE)

After selecting **MyoStress®** from the **Mode Selection** tab found above the Report section, executing the MyoStrain image sequence on the MRI scanner will send images to the workstation. This action will consume an exam credit and cannot be reversed.

Figure 6-2: MyoStrain application in Stress mode receiving images

After all six views from the MyoStrain pulse sequence at the patient's resting state have been received by the MyoStrain application, image review and quantification can begin. Images received will be organized based on the order which they were received and labeled as "Acquisition #". Ensure that the dropdown menu in the upper-right hand corner of the Image List is set to read "Rest" as show in (Figure 6-3).

Figure 6-3: Image list with Acquisition 1 set to “Rest”

6.4 IMAGE REVIEW AND ANALYSIS

Once all images from the scanner for the rest stage have been transmitted to the MyoStrain software, review each image to ensure good image quality is present. If for some reason the image quality is poor or there was an issue during acquisition, refer to (6.3.1) to reject a scan. A rescan can be performed without consuming an exam credit if the exam is not closed during the session.

If the image quality is good and the 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 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, which are different from un-analyzed 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.

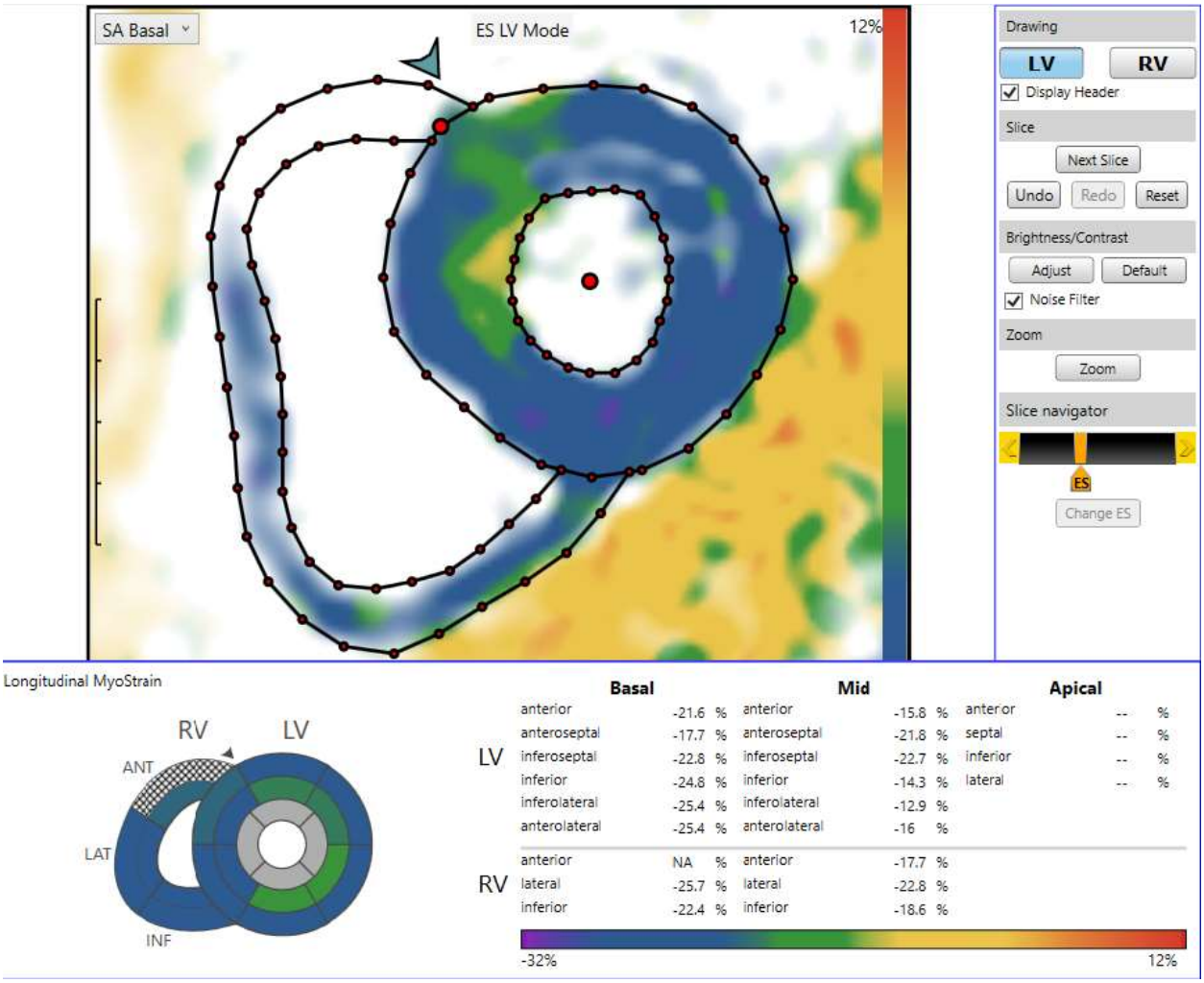


Figure 6-4: Basal Slice analyzed showing the RV Anterior as "NA"

6.4.2 **REJECTION OF IMAGES**

During the post-processing analysis, any number of issues may arise. This may include patient movement during acquisition, poor image quality, or any number of minor issues. At any point during the analysis, selecting **Reject** from the drop-down menu in the upper-right corner of the **Image List** will remove those images from the scan.

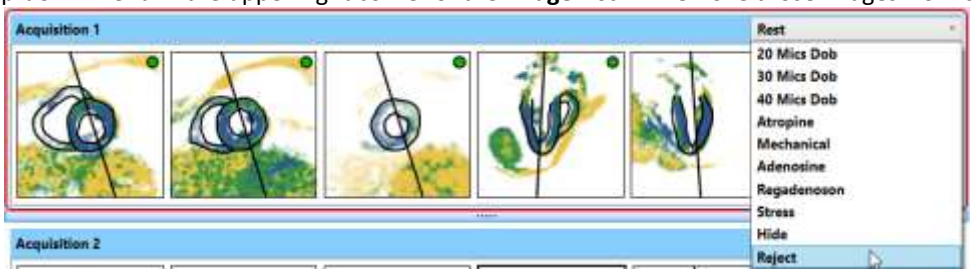


Figure 6-5: Selecting this option will remove any images and meshes from this acquisition stage from the analysis

⚠ Image rejection will irreversibly remove images from the current exam. Images will need to be re-sent to the workstation if this occurs.

6.4.3 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 make sure they are not analyzed. 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**.

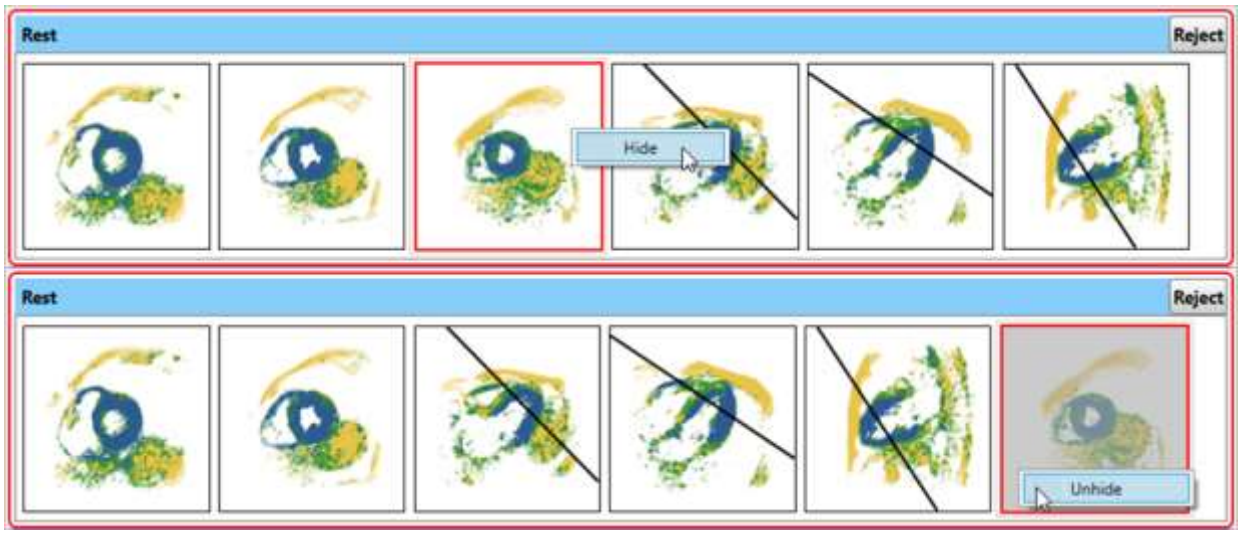


Figure 6-6: Hiding and Unhiding an image in the Image List

Additionally, the entire stage can be hidden as well by selecting Hide from the stage drop-down menu.

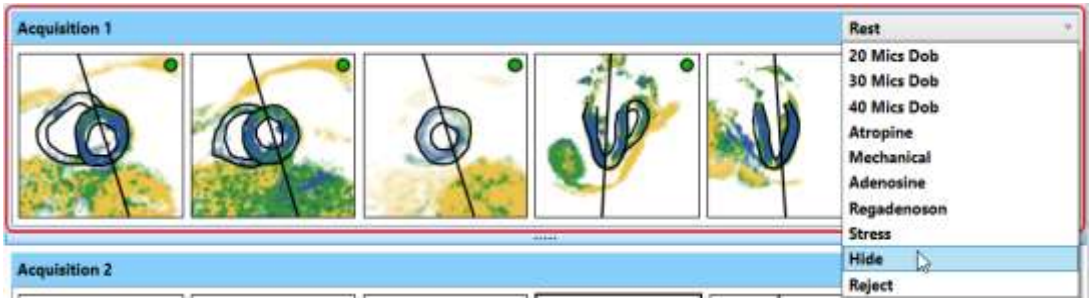


Figure 6-7: Hiding an entire stage moves it to the bottom of the list

6.5 IMAGE ACQUISITION (STRESS PHASES)

After the Rest phase images have been received from the scanner, a timer will display in the **Stage** section of the **Analysis Window**. This timer shows how much time must pass before the software will recognize a new set of images being received as a new stress phase.

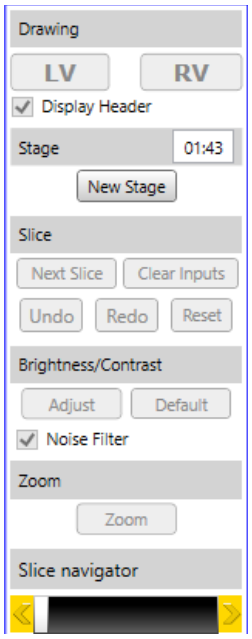


Figure 6-8: Stress Phase timer

Once the stressor has been administered to the patient, the user must allow the timer to expire before beginning the next series of image acquisitions. If images need to be acquired before this timer has expired, pressing the **Next Stage** button will override the timer and manually begin a new stress phase. Any images received by the MyoStrain application after this point will be added to the next **Acquisition** series in the **Image List**.

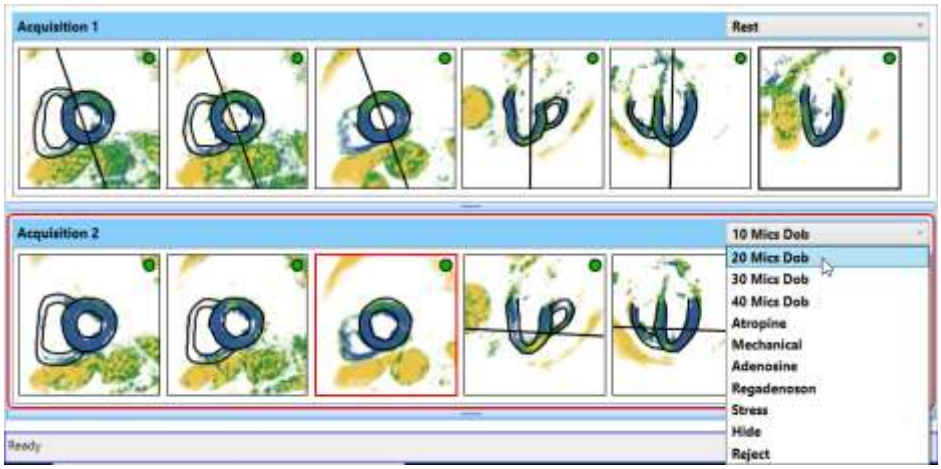


Figure 6-9: Images acquired at new acquisition number

Use the dropdown menu on this new acquisition stage to identify this image series' appropriate stress phase/stressor.

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

6.6 IMAGE PROCESSING (STRESS PHASES)

After receiving the next stage of images from a new stress phase, the behavior of the **Analysis Window** will change and display two different sets of images.

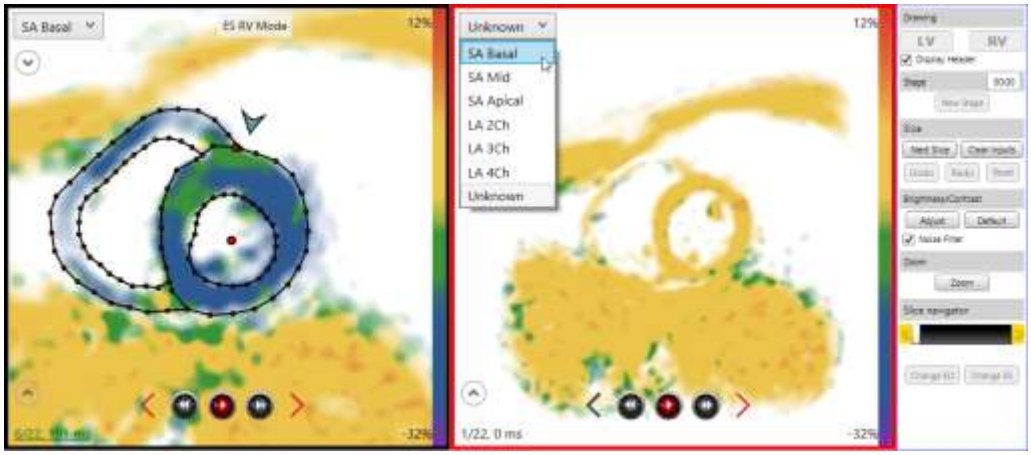


Figure 6-10: Analysis Windows showing both Rest and with 10 Mics Dobutamine

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 REPORTING AND EXPORTING DATA

After quantifying each slice from all stress phases of the current test, the analysis portion of the scan is complete, and the patient may be removed from the scanner. It is recommended to save the quantified exam data before continuing to the **Report Section** to export the **Stress Report** and exam data.

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

Figure 6-11: Stress Report section showing reduction of strain during stress

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

7. REPORT VIEWER AND 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 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 Viewer** will display the corresponding report measurements during the exam.

NOTE: Stress exams generate a resting Strain report in addition to the Stress report. The Strain report can be viewed by clicking the **Strain** button at the top of the Report (Figure 7-1 A).

When images are imported into a new exam, patient information is automatically imported into the report under the **Patient** tab (Figure 7-1 B). The **Measures** section (Figure 7-1 C) is automatically populated with the strain data gathered from the meshes drawn during the exam. The **Findings** section (Figure 7-1 D) is a blank text field which can be used to add any additional information gathered during the exam.

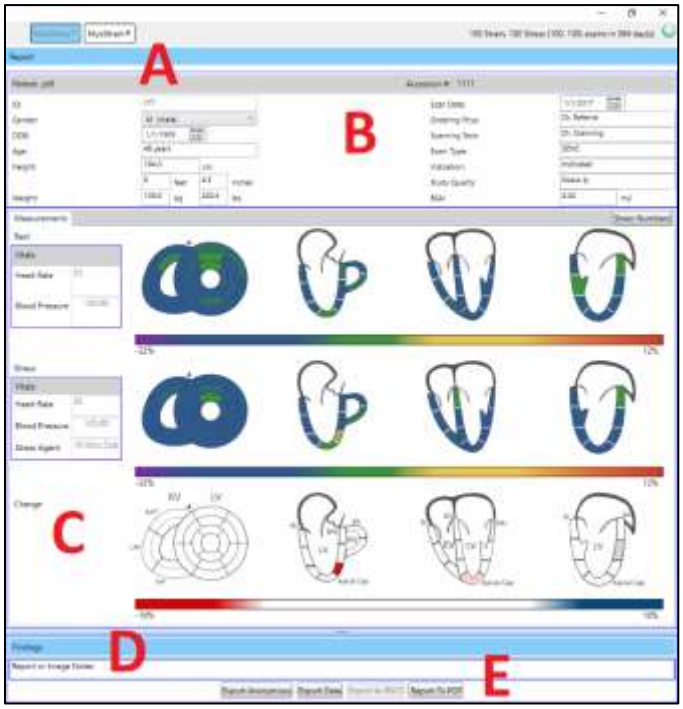


Figure 7-1: Report Section of the MyoStrain Stress Test

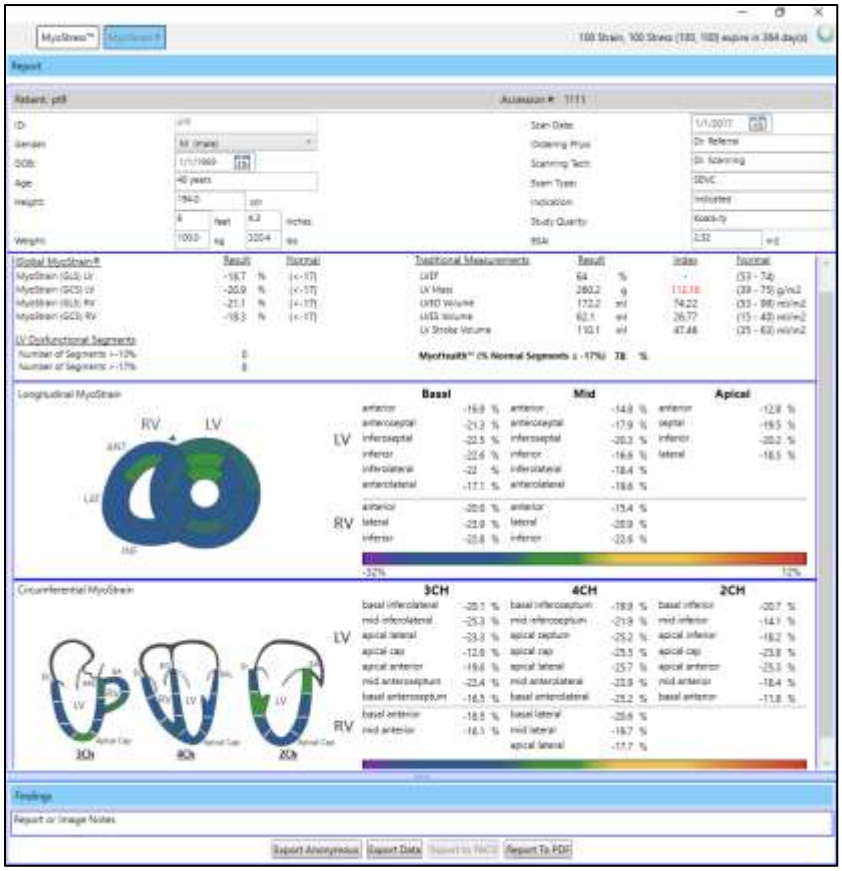


Figure 7-2: Report Section of the Strain Test

7.2 PATIENT INFORMATION (B)

Figure 7-3: Sample Patient Data

If any information was not present in the medical images sent to the workstation, this data may be manually updated by typing the correct information into each text box. You may tab between sections to speed up the entry process.

7.3 MEASURES (C)

This section displays all available measurements gathered from the current study using a standardized AHA model (see section11.3). The measurements and models shown in this section are based on the type of exam currently

being performed. 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.

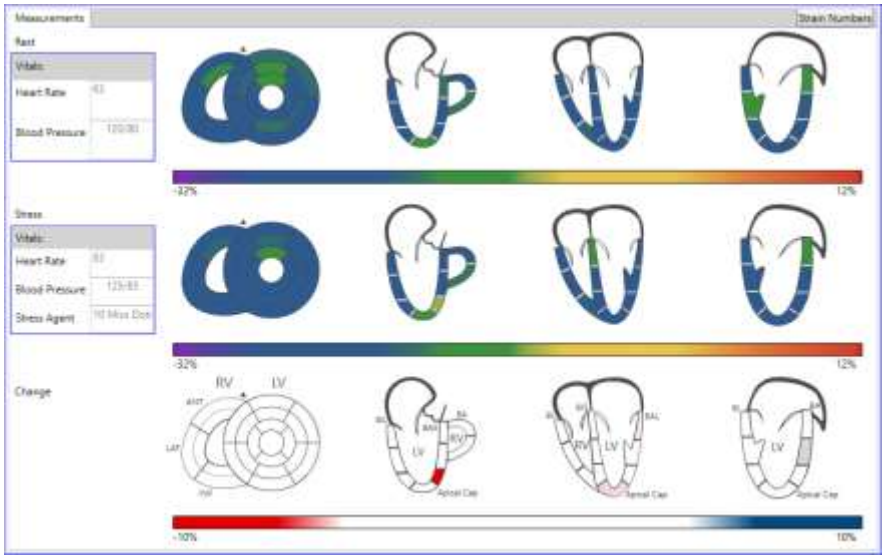


Figure 7-4: Example Stress exam with one stage of stress agent

MyoStress tests will display both resting strain and the strain calculated at the highest level of stress. The **Measurements** section from MyoStrain exams will display resting strain, as well as global circumferential and longitudinal strain. Only slices which are marked with a green dot in the **Image List** have their information displayed here.

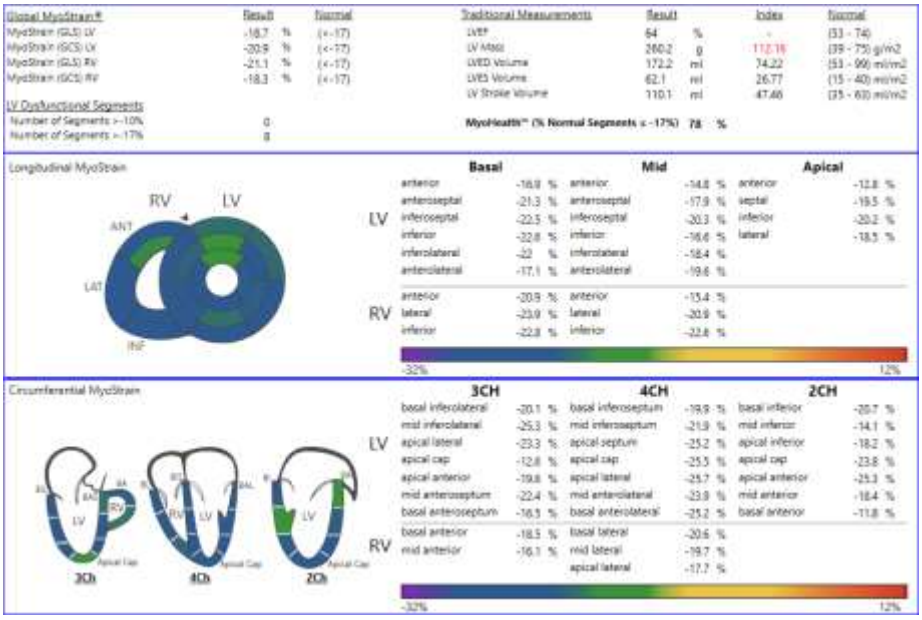


Figure 7-5: Example Strain exam with all 6 views quantified

The measures provided in the **Measurements** pane are calculated as follows:

- **Global MyoStrain® Measurements:**
  - **MyoStrain (GLS) LV** – Average percentage of peak strain calculated from all Short-Axis LV slices. (Previously LV Global Longitudinal Strain (GLS))
  - **MyoStrain (GCS) LV** – Average percentage of peak strain calculated from all Long-Axis LV slices. (Previously LV Global Circumferential Strain (GCS))
  - **MyoStrain (GLS) RV** – Average percentage of peak strain calculated from all Short-Axis RV views. (Previously RV Global Longitudinal Strain (GLS))
  - **MyoStrain (GCS) RV** – Average percentage of peak strain calculated from all Long-Axis RV views.(Previously RV Global Circumferential Strain (GCS))
- **LV Dysfunctional Segments**
  - **Number of Segments < -10%** – This displays the total number of segments calculated by MyoStrain to have above -10% strain.
  - **Number of Segments > -17%** – This displays the total number of segments calculated by MyoStrain to have above -17% strain.
- **Traditional Measurements**
  - **LVEF** – Percentage of blood emptied from the left ventricle during systole.
  - **LV Mass** – Mass of the LV calculated by the Diastolic timeframes contoured on Long-Axis images.
  - **LVED Volume** – Volume (in mL) of blood measured in the LV at Diastole measured across all Long-Axis images.
  - **LVES Volume** – Volume (in mL) of blood measured in the LV at Systole measured across all Long-Axis images.
  - **LV Stroke Volume** – Difference of volume (in mL) between the **LVED Volume** and **LVES Volume**.
- **Vitals (Stress Exam)**
  - **Heart Rate –** BPM of the patient. The heart rate displayed in the Measurements pane is pulled from the first image received as part of that stage.
  - **Blood Pressure –** Displayed as Systolic/Diastolic, the blood pressure displayed is pulled from the first image received as part of the current stage. This can be overwritten from the **Analysis Window.**
  - **Stress Agent -** Displays the greatest stage of stressor applied to the patient.

7.3.1 MYOHEALTH™ MEASUREMENT

MyoHealth™ is a derived measurement which displays the percentage of segments below -17% strain compared to the total number of LV segments analyzed. This measurement is displayed only if at least 30 of the 37 segments required for a full MyoStrain exam are analyzed. RV calculations are not included in this assessment. A formula for calculating MyoHealth is described below.

MyoHealth = [(# of LV Segments Above -17%) / (# of LV Segments Analyzed)] * 100

7.3.2 STRAIN LEGEND

During the MyoStrain analysis, each mesh applied to the dataset will populate the appropriate model in the **Measurements** section. The color legend below provides a basic guide to the meaning of each color.

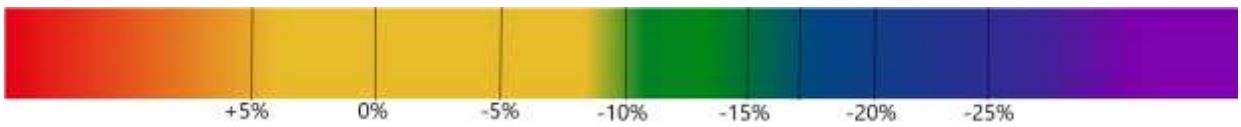


Figure 7-6: Color Legend for Strain

For more information regarding the Strain Legend, please refer to Section 11.2.

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.

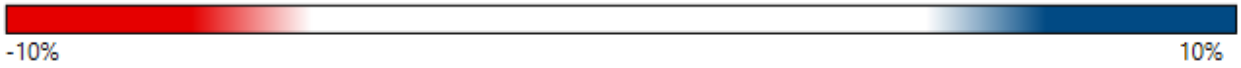


Figure 7-7: Color Legend for Change

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

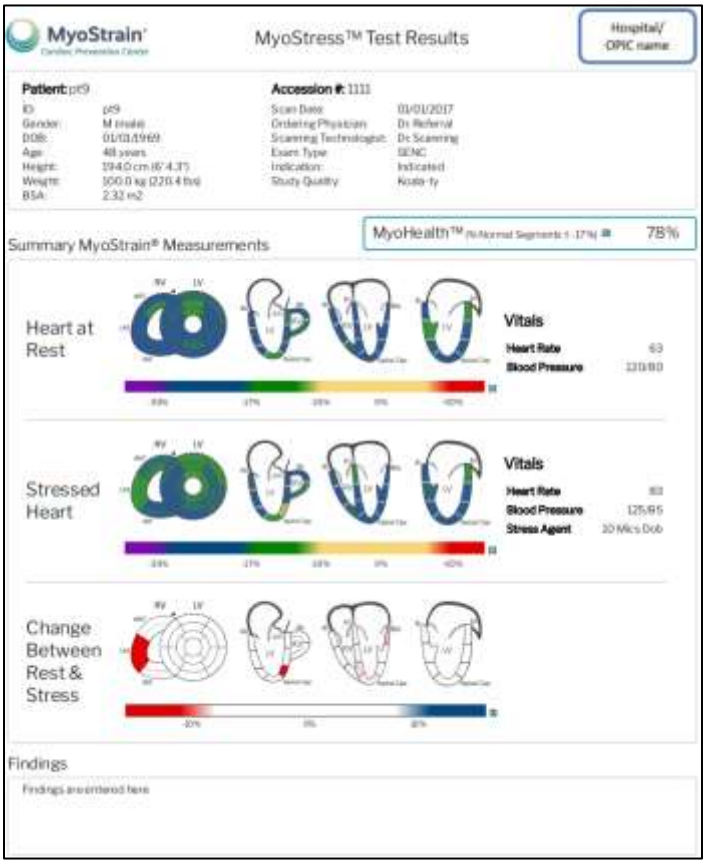


Figure 7-8: Sample Stress report with multiple regions indicated as having reduced strain under stress

In the example above, there are multiple regions which expressed a significant decline in function between Rest and Stress measured with Dobutamine administered. This would potentially indicate an issue with the myocardium in this case.

Additionally, strain values can be displayed during a Stress exam by clicking the **Strain Numbers** (Figure 7-9) button found in the upper-right hand corner of the **Measurements** window in the Stress report.

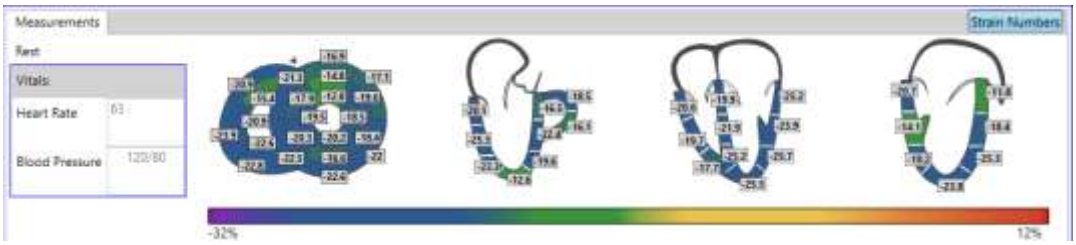


Figure 7-9: Stress Report measurements with Strain Numbers option active

7.4 FINDINGS (D)

The **Findings** section is the last section to be filled out before completing the exam and exporting data for later use. Any text data can be added to this section and will be displayed at the bottom of the final report.

Figure 7-10: Findings section (Stress Test)

After the **Findings** section has been completed (or left blank, the field is optional), proceed to the bottom of the **Report** section to export the data.

NOTE: Saving after finalizing the Report section is a good idea before exporting exam results.

7.5 IMAGE AND REPORT EXPORT (E)

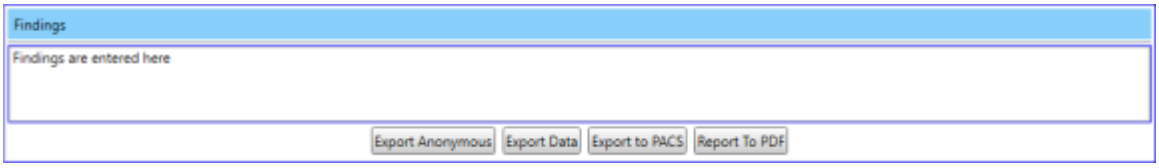


Figure 7-11: Export Options

After the report section has been completed, data gathered from the exam needs to 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.

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 7.5.3 for more details regarding saving this file.

- **Export to PACS -** Pushes a copy of the final report, an exam data file, and the analyzed MyoStrain images (with meshes) to the PACS server (if configured to do so). This is done by taking a screenshot of the report and converting it into a DICOM image. Data selected for export can be configured in the **File>Setup>Export to DICOM 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 7.5.3 for more details regarding saving this file.

7.5.1 ANONYMOUS EXPORT

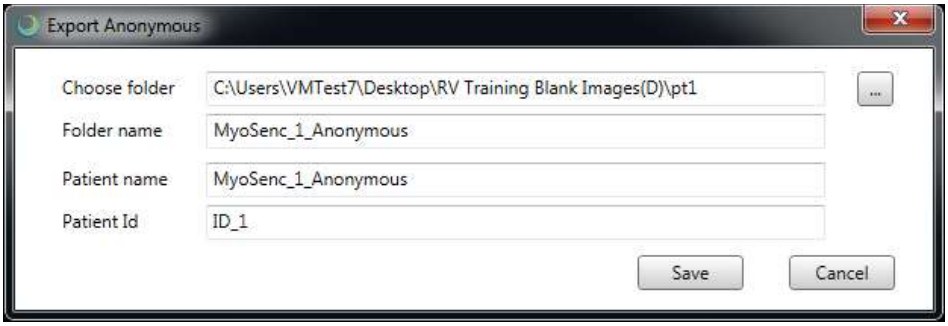


Figure 7-12: Export Anonymous dialog box

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.

7.5.2 PACS EXPORT

After pressing the **Export to PACS** button, the MyoStrain application ask to confirm where to export the data (). 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".

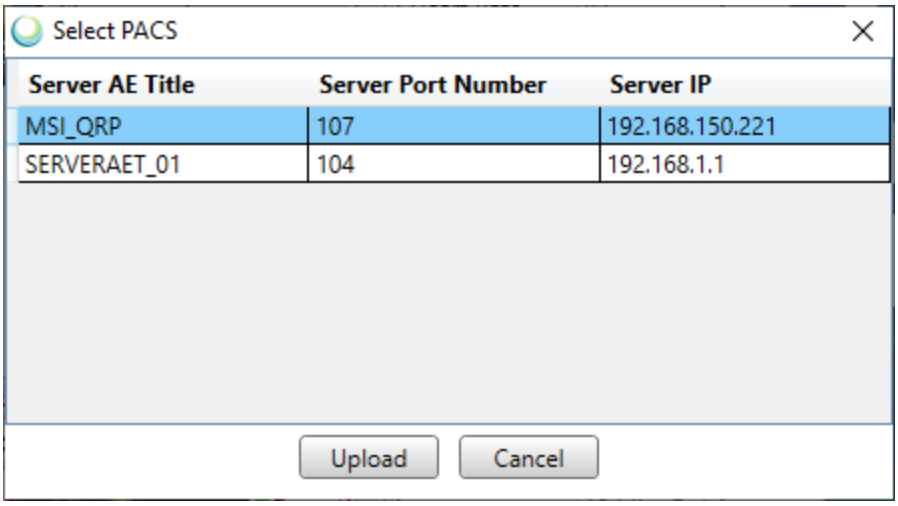


Figure 7-13: Clicking the Export to PACS button will display a PACS selection screen

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.

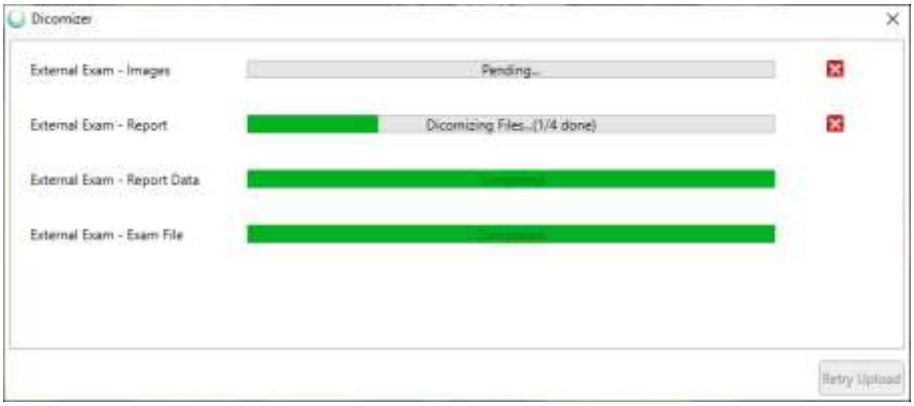


Figure 7-14: Progress window for background image archival

7.5.3 **LOCAL EXPORT**

Clicking on either the **Export Data** or **Report to PDF** buttons at the bottom of the Report section will launch a dialog box (Figure 7-14, Figure 7-16) asking where to save data. The Export Data dialog box asks whether the data should be saved as a .csv or .xml document.

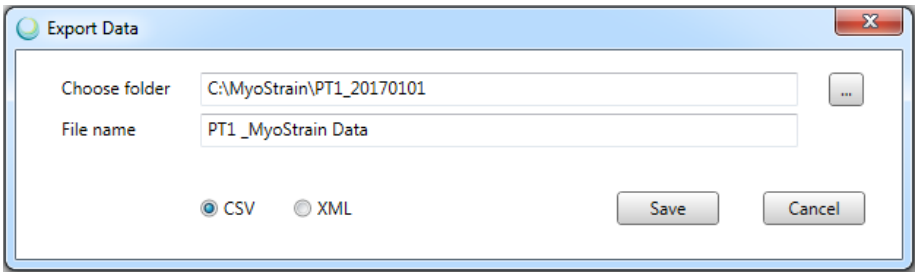


Figure 7-15: Export Data Dialog Box

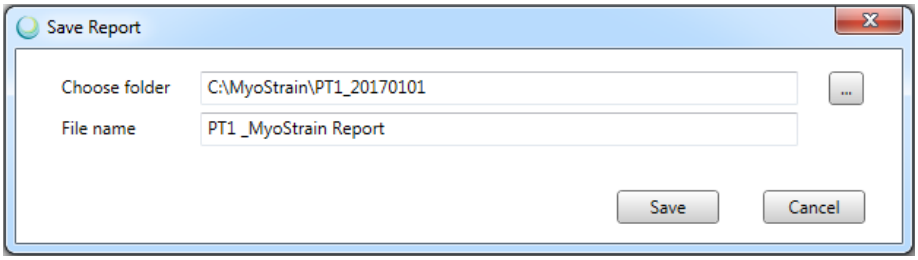


Figure 7-16: Save Report Dialog Box

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.

8

8. PREVIEW MODE (IMAGE PLANING)

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 operating in Multi Mode.

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

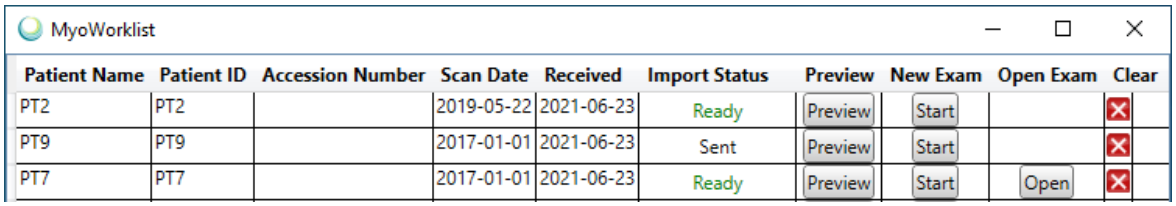


Figure 8-1: Worklist running with several datasets ready for Preview or analysis

Before any actual analysis begins, it may be useful to use **Preview** mode. This allows MyoStrain to display images without consuming an exam credit. Using this feature is useful to ensure the scanner is looking in the correct location and the myocardium is being imaged properly before using an exam credit.

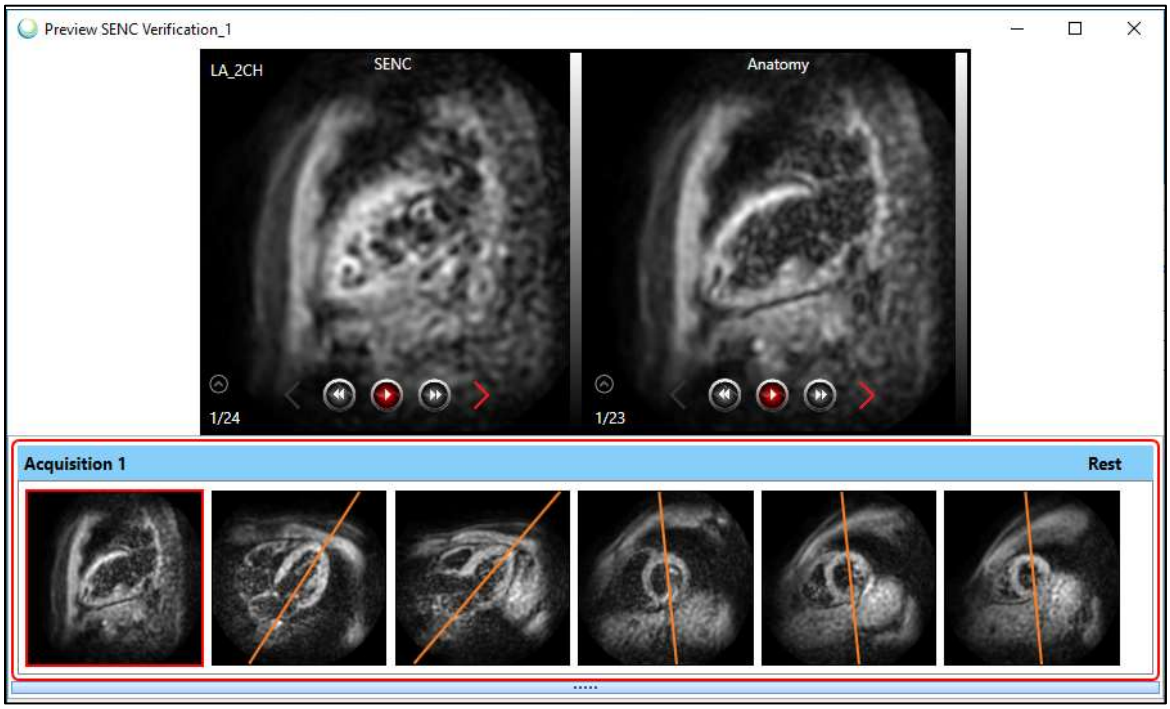


Figure 8-2: Preview with 6 slices available, 2CH view currently selected

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.

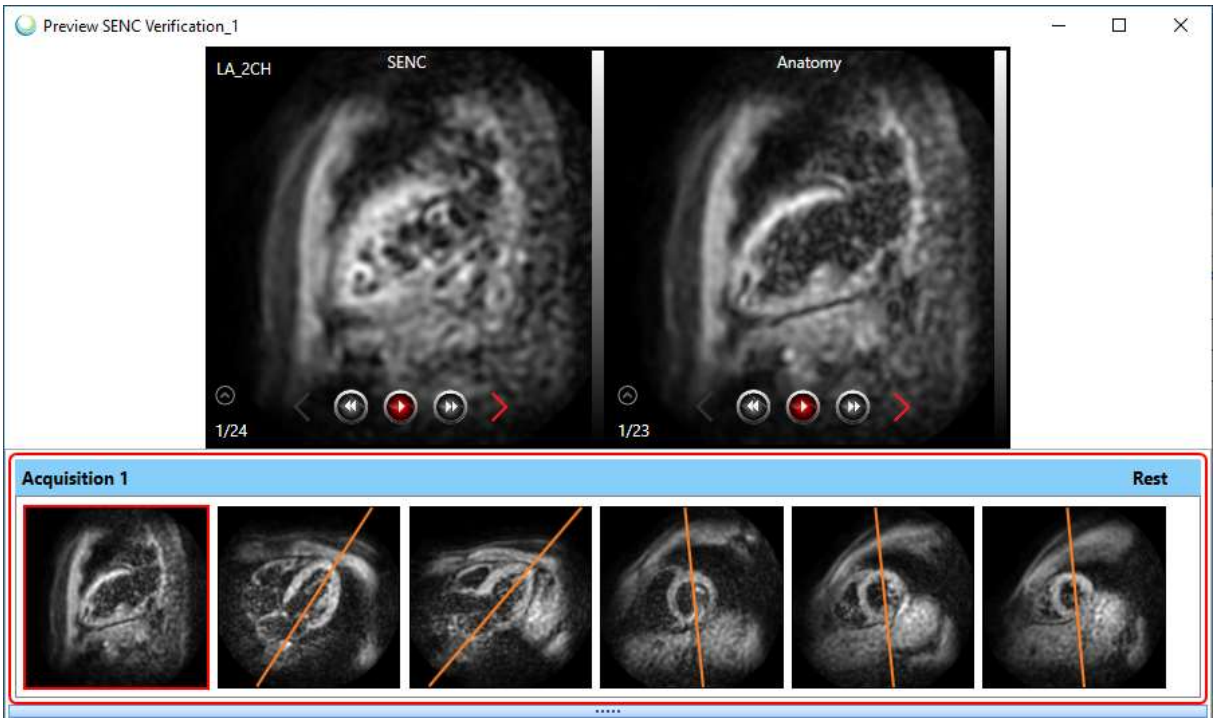


Figure 8-3: Sample 2CH image displaying the raw SENC images from the scanner

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** 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 the Semi-Automatic Contouring.

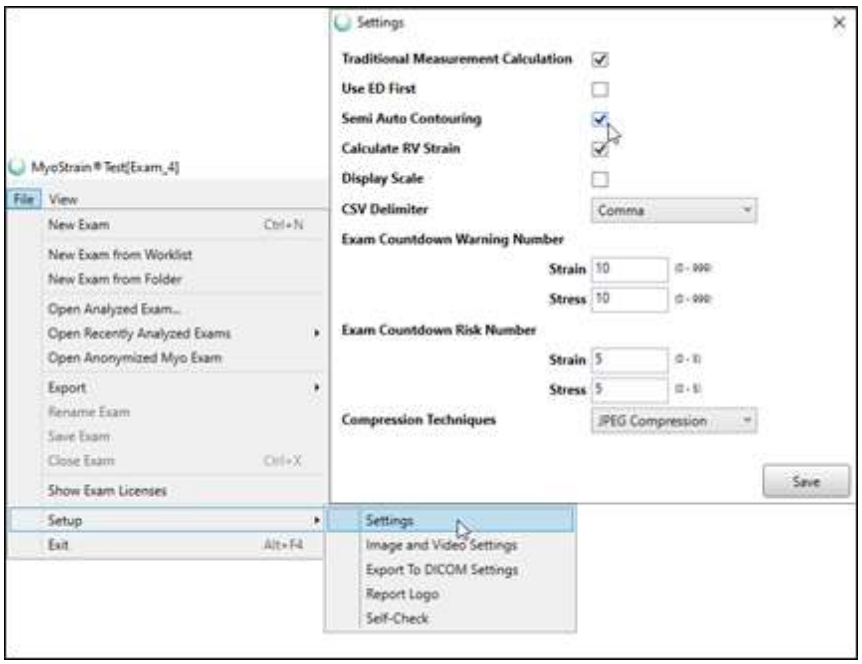


Figure 9-1: Semi Auto Contouring button checked

When **Semi Auto Contouring** is enabled, MyoStrain will attempt to apply a LV mesh for all Long-Axis and Short-Axis images near End-Systole upon image import. Additionally, if Traditional Measurements are enabled, Semi-Auto Contouring will also attempt to identify the End-Diastolic timeframe for Long-Axis images and apply a LV mesh for that image as well. All images, regardless of origin, will attempt to be semi-automatically contoured with this feature enabled. If MyoStrain is unable to confidently apply a contour to the image, no mesh will be drawn.

NOTE: Semi-Automatic Contouring does not perform RV quantification.

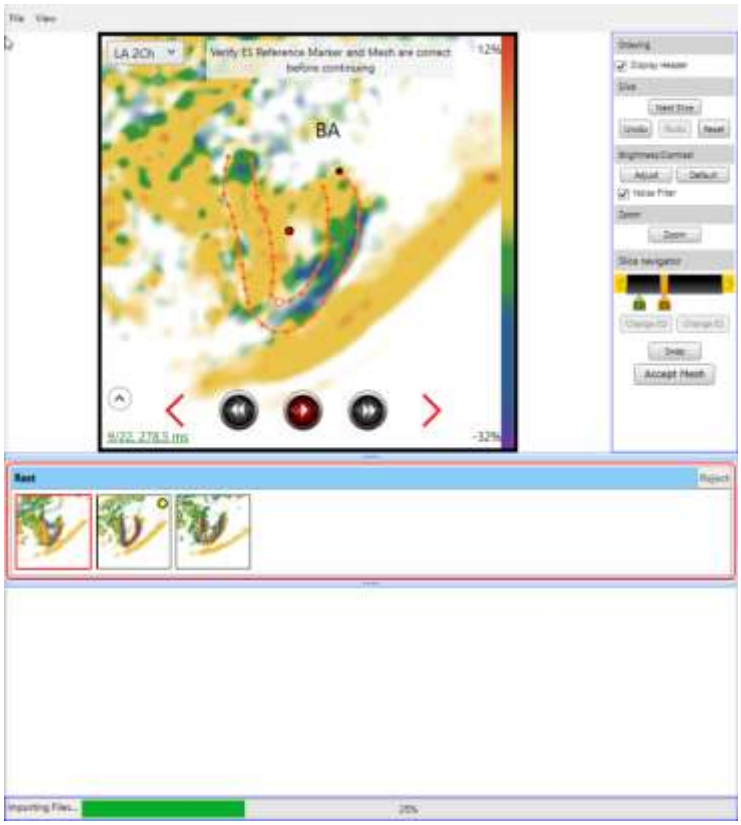


Figure 9-2: MyoStrain in process of receiving and analyzing Strain images

Immediately upon receiving images, either by creating a **New Exam from Folder**, pushed from the **MyoWorklist** or sent directly from the scanner, MyoStrain will immediately begin analyzing images. As soon as an image has been processed/analyzed, it will appear in the **Image List.** 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 and will not display any strain information in the report.

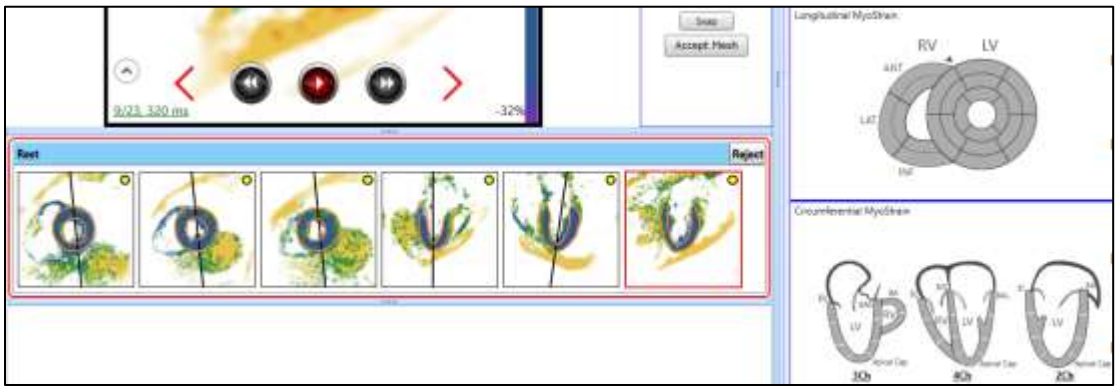


Figure 9-3: All images imported and analyzed, no measurements displayed in report

NOTE: If images are being sent directly from the scanner, either the **New Stage** or **Contour Stage** button in the **Analysis Menu** must be pressed before Semi Auto Contouring will begin analysis.

9.1 IMAGE REVIEW AND ADJUSTMENT

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 it must be reviewed first. MyoStrain will not display any strain calculations until the mesh has been manually reviewed. As with any automation tool, the analyst is ultimately responsible for the quality of the analysis delivered.

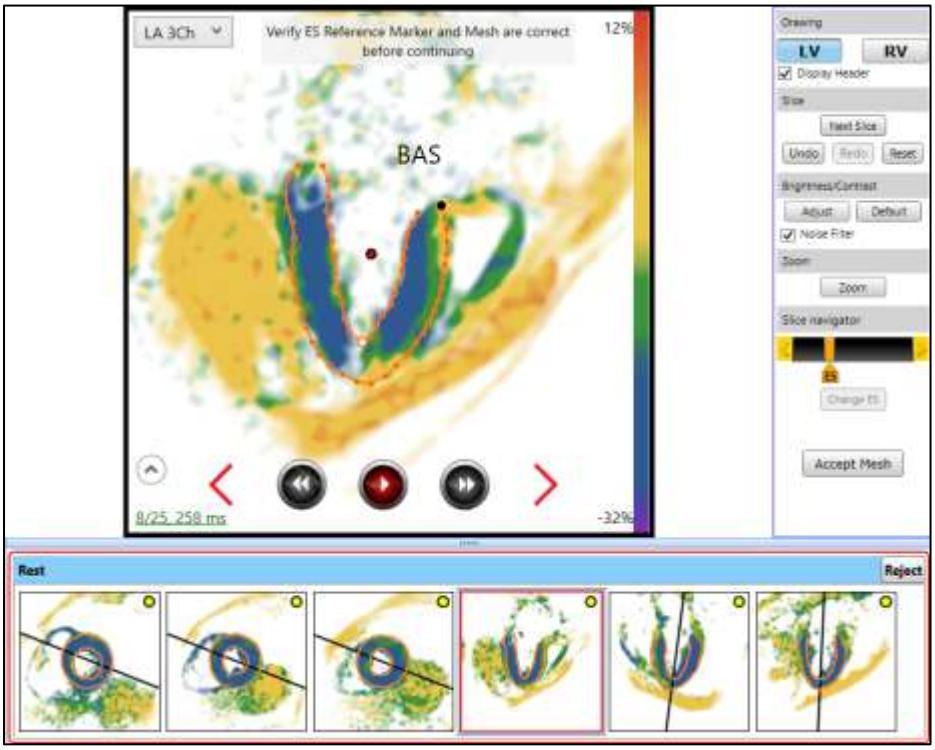


Figure 9-4: Newly imported dataset using Semi Auto Contouring feature

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

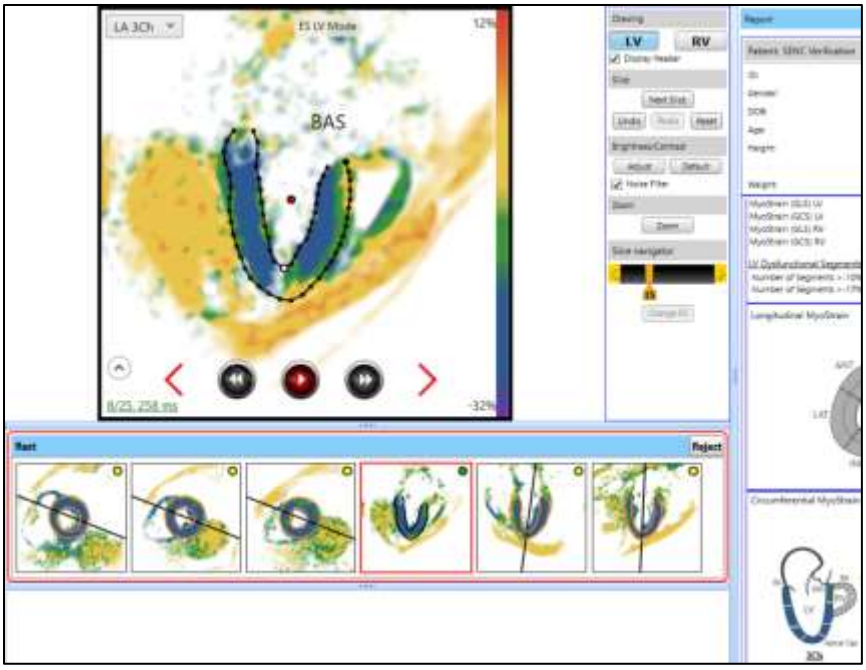


Figure 9-5: Accepted mesh with measurements displayed in report

Additionally, any adjustments or modifications to the Semi-Auto Contour will result in the mesh being accepted; this also includes applying an RV contour. 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**.

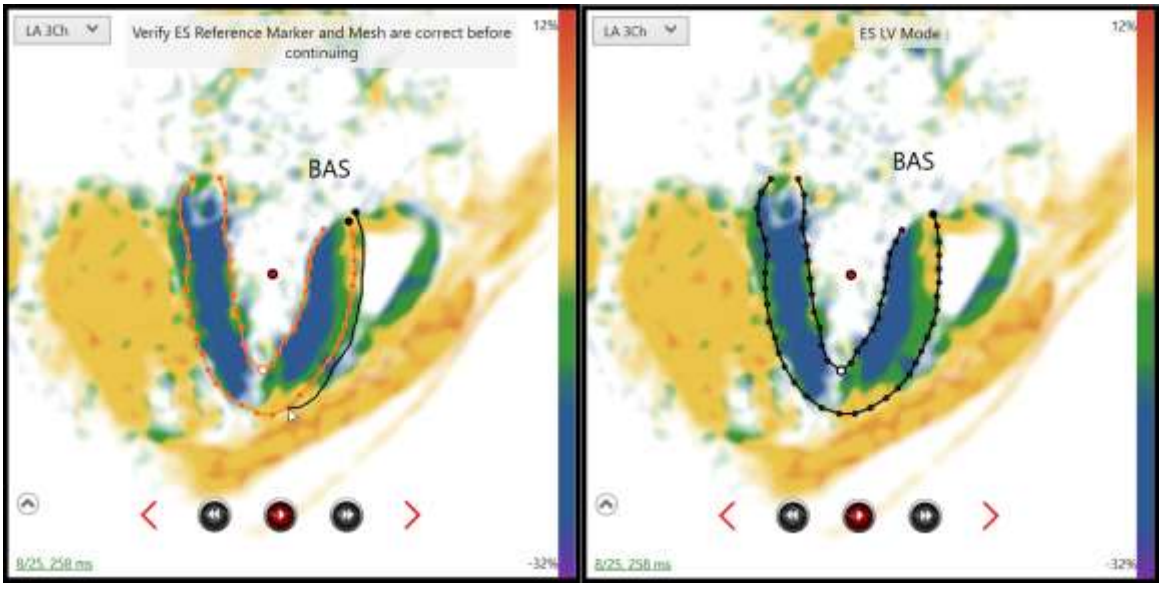


Figure 9-6: Corrections to an Auto Contour cause the mesh to become accepted and reported on

9.2 TRADITIONAL MEASUREMENTS WITH SEMI AUTO CONTOURING

In addition to identifying and contouring End-Systole, the Seni 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 adjusting 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.

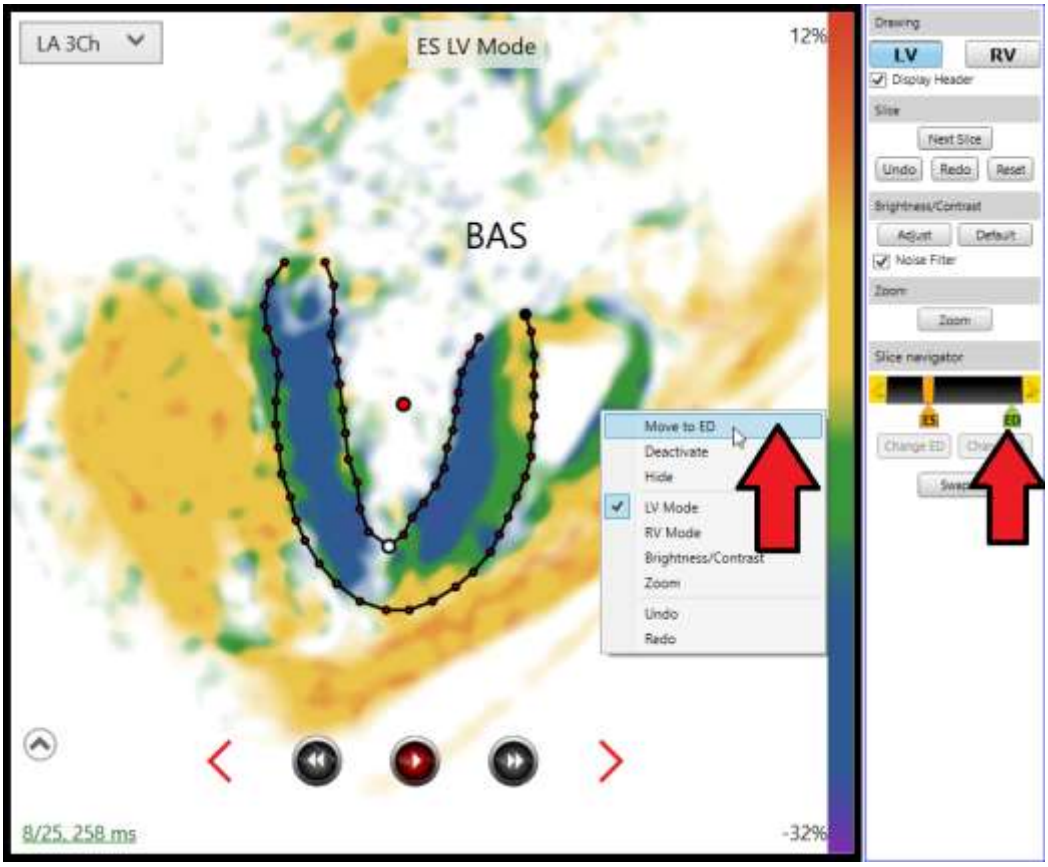


Figure 9-7: Navigating to the suggested End-Diastolic timeframe

NOTE: Semi-Auto Contouring workflow will be reversed if the "Use ED First" option is enabled in the Settings menu. ED will be the first timeframe displayed and will transition to the ES timeframe after acceptance.

Figure 9-8: Semi-Auto Contouring workflow when ED First is enabled

10

10. MYOWORKLIST

This chapter provides a detailed writeup of 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 can be accessed from MyoStrain to receive new images, preview new images without using an exam credit, revisit previous exams, or can run in the background and launch MyoStrain to analyze any dataset received on command.

10.1 MYOWORKLIST LAUNCH AND SETUP

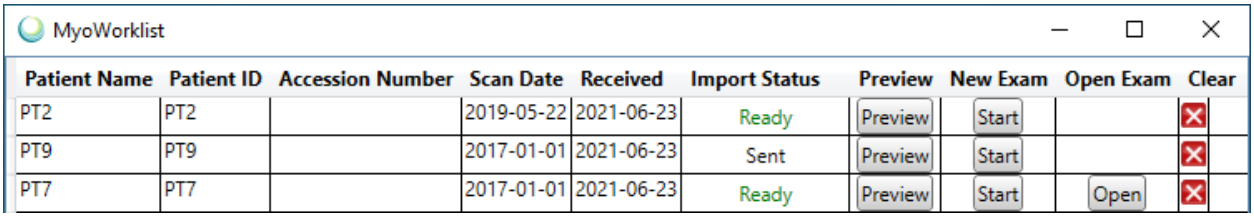


Figure 10-1: MyoWorklist running with multiple datasets available

By default, the MyoWorklist service will automatically launch on Startup and will appear shortly after a user logs into the workstation. Additionally, it can be opened from the Desktop shortcut or directly through MyoStrain.

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.
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. **Server IP** – IP address of the PACS server or scanner sending images.
    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.

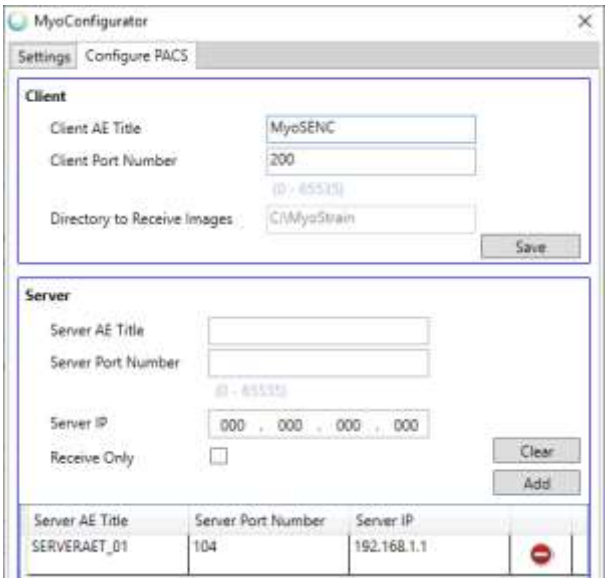


Figure 10-3: Sample Configure PACS setup

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

4. Pressing the **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.

10.2 WORKLIST AND LANGUAGE SETTINGS

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

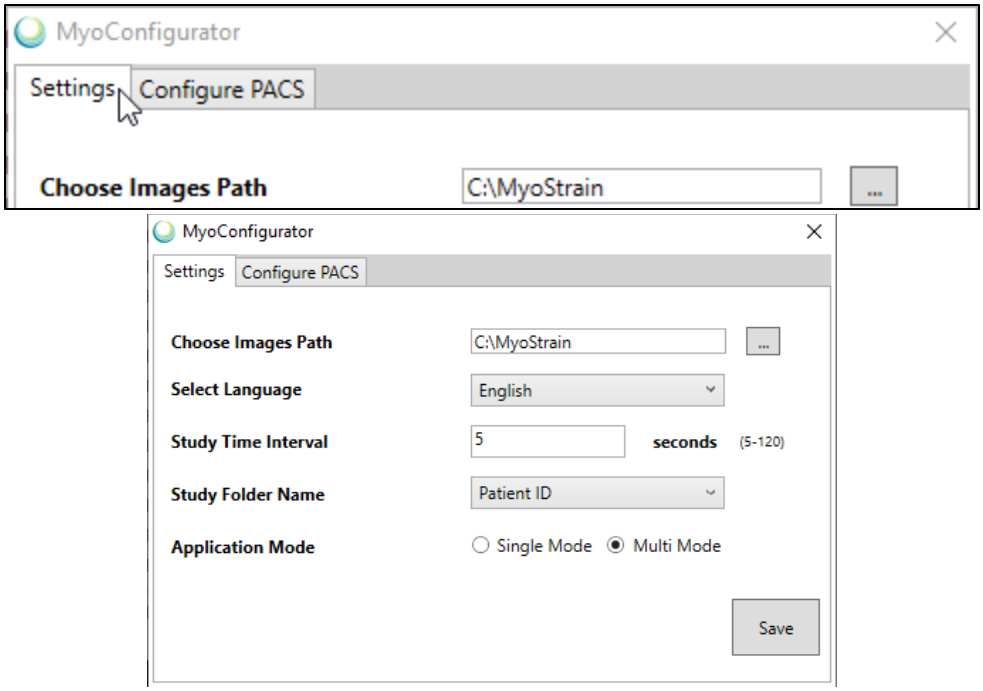


Figure 10-4: Worklist Settings window

- **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 through the network 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.
- **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** - (0010,0020)
    - **Accession Number** – (0008,0050)
- **Application Mode** – Determines whether the Worklist will queue exams for analysis (Multi Mode, 10.2.1) or display the images immediately when they are received and create a new exam (Single Mode, 10.2.2).

10.2.1 MULTI MODE (WORKLIST ENABLED)

Multi-Mode is the default state of the MyoWorklist. When active, regardless of whether MyoStrain is open or closed, the MyoWorklist will run in the background and receive any datasets pushed to it for analysis. If the MyoStrain application is closed, the worklist will automatically launch the program and load the appropriate dataset.

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

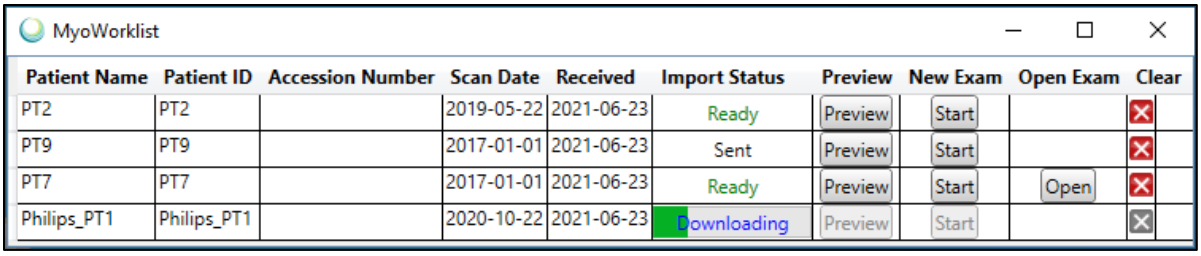


Figure 10-5: MyoWorklist actively downloading datasets

Once a dataset is received by the program, it is added to the active list. The images are organized based on their DICOM information and is 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.

- **Patient Name** – (0010,0010) - Name of the patient as listed in the DICOM header
- **Patient ID** – (0010,0020) - The ID of the patient
- **Accession Number** – (0008,0050) - A unique ID that is generated for a patient record
- **Scan Date** – (0008,0020) - YYYY/MM/DD of acquisition of listed dataset
- **Received** – YYYY/MM/DD of when this dataset was pushed to the workstation for analysis.
- **Import Status** – Details what state the images are currently:
    - **Ready** – All images in the dataset have been received and is ready for analysis.
    - **Sent** – This dataset has been sent to MyoStrain for analysis.
    - **Downloading** – This dataset is still being downloaded. Analysis cannot begin until all images have been received.
- **Preview –** This launches the Preview window. More information about the Preview window can be found in chapter 8.
- **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
- **Open Exam –** If a patient has already been analyzed and the exam file was exported to PACS, MyoStrain will convert the DICOM exam file into a MyoStrain exam file which can be accessed by clicking the Open button (see Figure 10-6).
- **Clear –** This button will remove the dataset assigned to it. The images will not be deleted from the hard drive, but the ability to launch them from the worklist will be.

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

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.

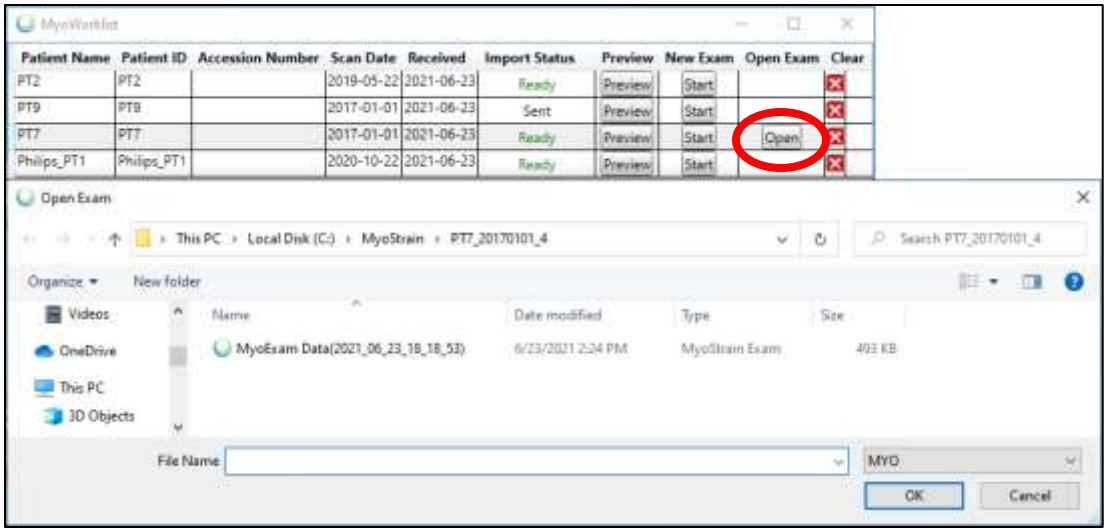


Figure 10-6: Opening a previously analyzed exam stored on PACS and sent to MyoStrain

10.2.2 SINGLE MODE (WORKLIST DISABLED)

The worklist is designed to manage workstations which are responsible for analyzing multiple analyses coming from different systems, or for queueing exams for later analysis if they cannot be analyzed concurrently with the patient scan. Clicking on the **Single Mode** button found at the bottom of the MyoConfigurator will cause the worklist to no longer queue datasets and will instead push the images directly to MyoStrain for analysis. Switching the MyoWorklist into **Single Mode** will also require a workstation restart.

⚠ Images sent to the workstation when running in Single Mode will only be stored and read if MyoStrain is open and running. Otherwise, they will not be stored, and an error will be shown from PACS.

10.3 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).

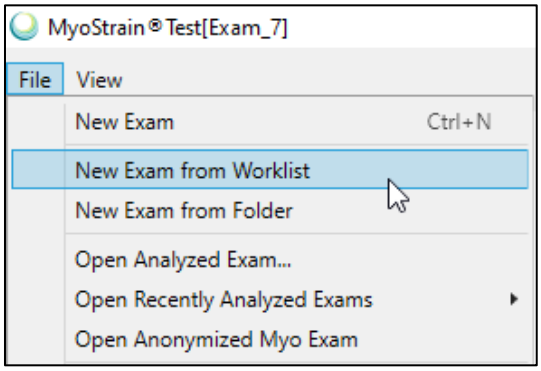
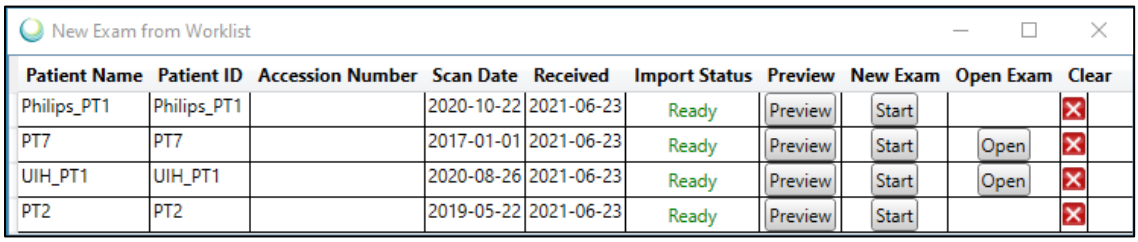


Figure 10-7: Open from Worklist option in the MyoStrain File menu

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.



Patient Name	Patient ID	Accession Number	Scan Date	Received	Import Status	Preview	New Exam	Open Exam	Clear
Philips_PT1	Philips_PT1		2020-10-22	2021-06-23	Ready	Preview	Start		
PT7	PT7		2017-01-01	2021-06-23	Ready	Preview	Start	Open	
UIH_PT1	UIH_PT1		2020-08-26	2021-06-23	Ready	Preview	Start	Open	
PT2	PT2		2019-05-22	2021-06-23	Ready	Preview	Start		

Figure 10-8: 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. EXTERNAL REFERENCES

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

11.1 THIRD PARTY APPLICATIONS

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

- DICOM# - Library for processing DICOM formatted data
- SharpZipLib – Library for archive processing
- IJG Library – Library for processing JPEG compressed DICOM data
- LibJpeg.Net – Library for compressing JPEG data
- EO.PDF – Used for processing and formatting PDF documents
- Log4Net – Used for generating log files
- OpenCV – Image and video processing library
- SharpAVI – Library used to export videos from MyoStrain.
- NumPY – Function library for scientific computation
- ProtoBuf – Saves and restores predictive models
- TensorFlow – Machine learning for semi-automated contouring
- Python 3 Interpreter – Processes scripts for semi-automated contouring
- Python Image Library – Image processing library
- GMA.QRCodeNet – Library which creates QR Codes available on MyoStrain reports.
- SKLearn – Library for data clustering used in image processing
- Ghostscript – Used for wrapping PDF/JPEG images for DICOM usage
- MediaToolKit – Library for video processing and export
- Newtonsoft.Json – Library used for generating QR codes
- TopShelf – Service implementation in MyoStrain

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.

11.2 MYOSTRAIN STRAIN SCALE

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.

11.3 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

11.4 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, chamber volumes and masses). 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].

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

[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.

11.5 ACCURACY OF MYOSTRAIN MEASUREMENTS

The accuracy of MyoStrain measurements are determined by the Limit of Agreement (LOA). The LOA is the range that covers the 95% of differences between the measurement of the two devices. For example, if MyoStrain measures LVEF of 67%, the LOA of (-13,+10) means that 95% for a large number LVEF values of the same subject measured using the gold standard Cine MRI will lie between 54% and 77%. The LOA depends on many factors, including images quality and inter-operator and inter-observer variabilities. This LOA was originally based on two

predicate devices (Diagnosoft HARP for Strain, Diagnosoft VIRTUE for traditional measurements), however these ranges have been reduced to reflect measured accuracy in MyoStrain.

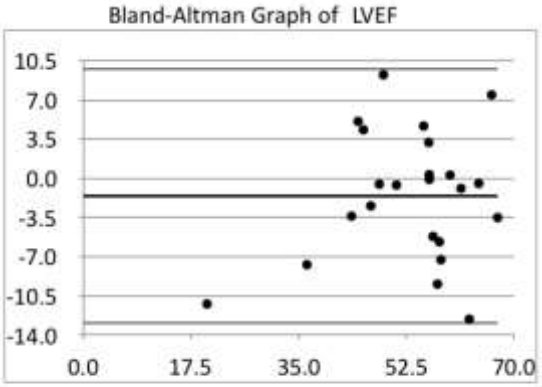
To demonstrate the accuracy of MyoStrain measurements, we calculated the correlation coefficients using Diagnosoft VIRTUE 5.51 measurements of the LV EF, End-Diastolic Volume (EDV), End-Systolic Volume (ESV), Mass, and Stroke Volume (SV). We considered the measurements accurate by requiring that the variations in global measurements due to workstation and user variability to be within the accepted cutoffs of published guidelines and clinical results. We specified that targeted correlation coefficients of the global measures generated by MyoStrain, in comparison to the gold standard cardiac MRI, must be equal or better than the following: EF: $R=0.79$, $p<0.001$, EDV: $R=0.84$, $p<0.001$, ESV: $R=0.94$, $p<0.001$, SV: $R=0.31$, $p=0.05$.
Since the LV Mass is similar to LV volumes, we decided that the R and p values follow the same criteria for EDV.
Our acceptance criteria required the following bounds for the 95% range of measurements differences between MyoStrain and Diagnosoft VIRTUE:

- LVEF: (-20,+20)
- LVEDV: (-45,+45)
- LVESV: (-25,+25)
- LVSV: (-40, +40)
- LVMass: (-35, +35)

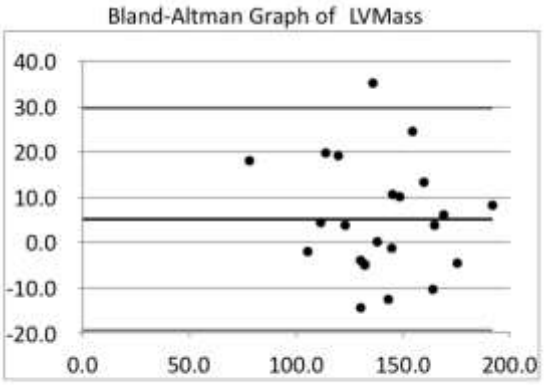
Based on a sample size N=23 of healthy subjects and patients, MyoStrain demonstrated the following *acceptable* LOA:

- LVEF: (-13,+10)
- LVEDV: (-40,+35)
- LVESV: (-19,+21)
- LVSV: (-36,+29)
- LVMass: (-19,+30)

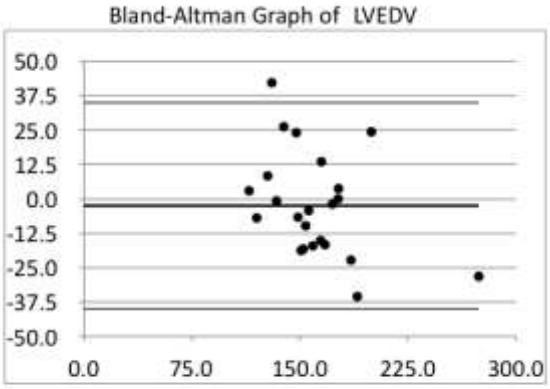
The Bland-Altman Graphs of these calculations can be seen below:



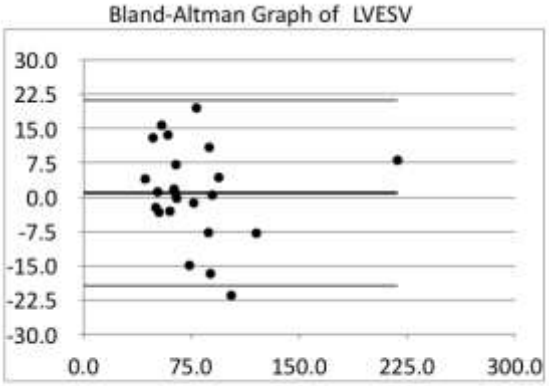
LVEF Limits of Agreement (LOA) is (-13,10)



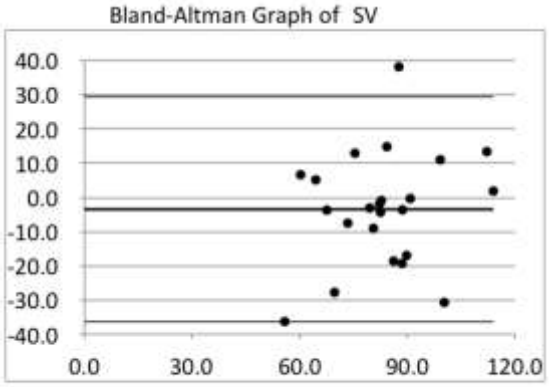
LVMass Limits of Agreement (LOA) is (-19,30)



LVEDV Limits of Agreement (LOA) is (-40,35)



LVESV Limits of Agreement (LOA) is (-19,21)



SV Limits of Agreement (LOA) is (-36,29)

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). Note that LOA of MyoStrain of Strain measured *in vivo* in humans is unknown, could be different.

The aforementioned 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.

12. 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.

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
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.

13. INDEX