VIVO Model 9002 User Manual

INSTRUCTIONS FOR USE

CATHETER PRECISION, INC.

Contents

General Description

The VIVO system is a non-invasive pre-procedure planning tool that provides a 3D map of the heart to aid in identifying the origin of cardiac arrhythmias prior to electrophysiology procedures. VIVO requires acquisition of MRI or CT image combined with standard ECG recordings and electrode placement. Electrocardiographic potentials are measured from the torso using standard 12 lead electrocardiogram (ECG) electrodes placed on the surface of the body. A DICOM image (CT or MR scan) of the thorax and heart is acquired and then segmented to provide a patient specific, three-dimensional (3D) anatomy of the endocardial and epicardial surface of the heart. A 3D photograph of the patient's chest with precise ECG lead positions is merged with the torso and heart model to determine the spatial relationship between them. From these data, the system uses a mathematical algorithm to assimilate the geometrical information and transform the measured body surface signals into epicardial signals by solving the cardiac inverse solution. VIVO software creates, displays, and stores a cardiac activation map that displays the origins of ventricular arrhythmias.

The VIVO system is intended to be used by a physician as a preprocedural tool for any patient receiving ablation to treat cardiac arrythmia. The expected clinical benefits are more targeted and precise ablation of the foci of the arrythmia to reduce the need for additional ablation procedures.

The VIVO system includes an off-the-shelf laptop computer and a handheld 3D camera, which takes data from previously acquired cardiac and thoracic images, standard 12-lead ECG recording made during an arrhythmia and 3D picture of the placement of the ECG leads and positioning patches. This information, obtained prior to the procedure, can be used during pre-procedure planning by a qualified physician.

Indications for Use

VIVO is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

Warnings and Precautions

Warnings

- Confirm ECG electrode placement on the 3D model before VIVO analysis is completed. If ECG electrodes are displaced by greater than 10 mm on the model, the arrhythmia localization may be inaccurate.
- Any malfunction or serious incidents must be reported to Catheter Precision using the information on page 26 and the Competent Authority.

Precautions

- VIVO is not intended to be used as a diagnostic tool
- Read all documentation prior to using VIVO and use VIVO in accordance with all documentation provided
- Do not modify any part of the VIVO system
- The installation and setup of VIVO should only be performed by trained Catheter Precision personnel
- VIVO should not be connected to any equipment that is not supported by or part of the system
- The 3D photograph should be done in conjunction with the 12 lead ECG and placement of the positioning patches
- Segmentation of DICOM images should be performed at end diastole, not systole
- Segmentation errors may impact accuracy of final modeling
- Except for the earliest point of activation, the color-coded activation map has not been clinically validated and as such is provided for illustrative purposes only

Contraindications

There are no known contraindications

System Components

The VIVO system is comprised of the following:

1. Laptop PC
2. 3D Camera and accessories (USB cable, extension stick)
3. Positioning patches

The following components are not supplied but required for use with VIVO:

1. CT or MR data set
2. 12 lead ECG recording system
3. 12 lead ECG electrodes

DICOM Imaging

VIVO is compatible with both CT scans and MR images. Images must be completed prior to map creation.

NOTE: The ECG does NOT have to be performed in conjunction with the imaging.

NOTE: VIVO works best when the acquired imaging meets optimal guidelines. Imaging that does not meet all guidelines will require additional manual adjustments.

System Operation

This VIVO system is only to be used by a clinician that has been trained on the use of the VIVO system.

Getting Started

Begin by powering on the laptop PC by pressing the power button in the upper right-hand corner.

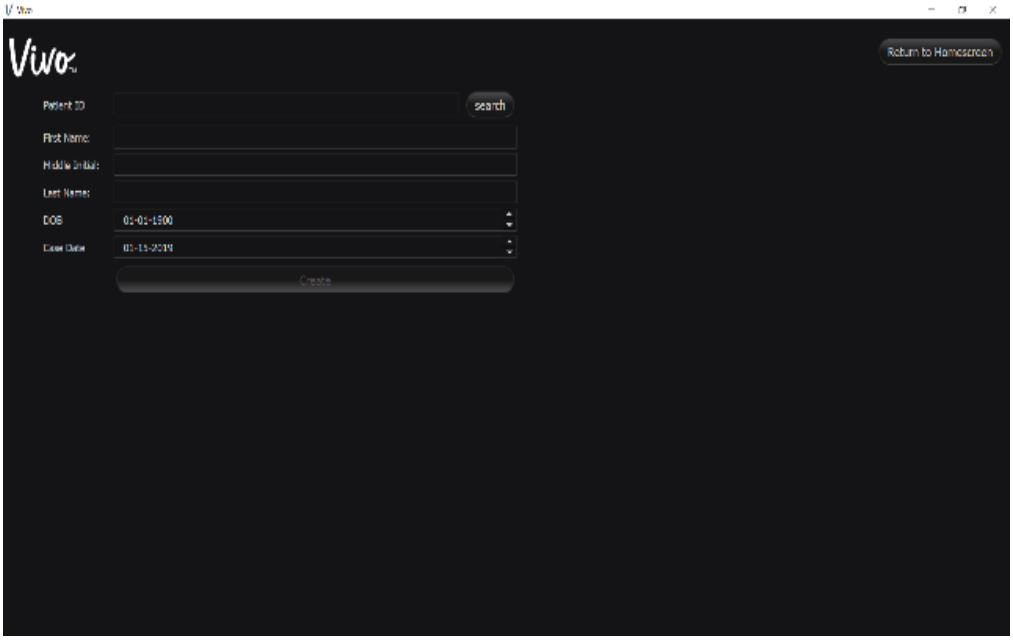
Once prompted, please enter the VIVO password. If this is the first time logging in, the password will be provided to the site by a representative of Catheter Precision.

Start by double clicking on VIVO icon. The following screen should appear:

The options are to Create a new case or Open a previous case.

To create a new case:

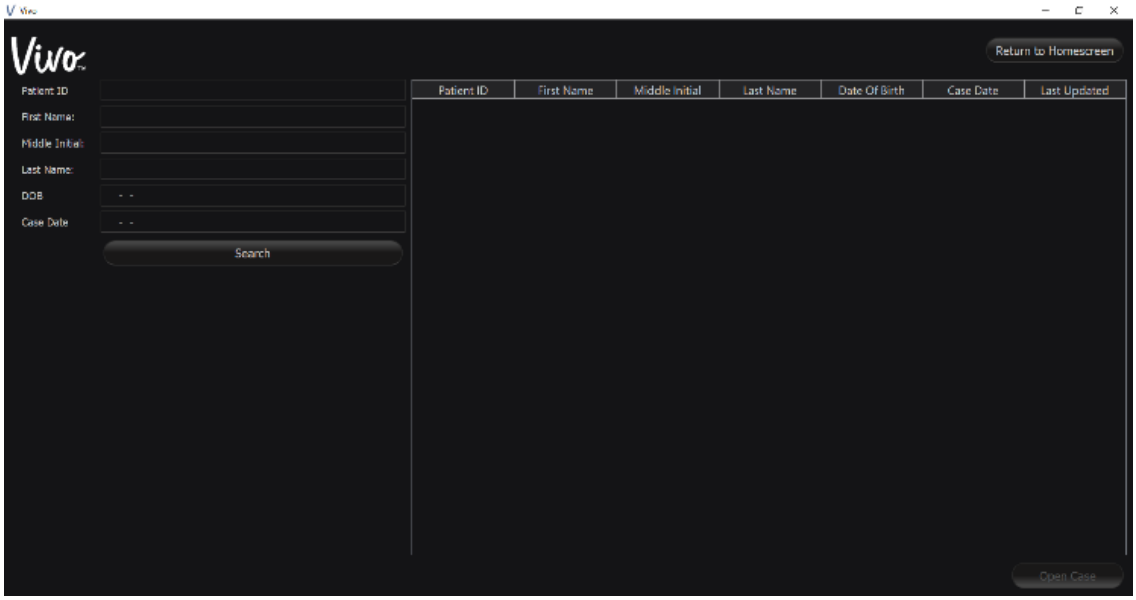
- Select “Create”, the screen below will appear.



- Enter the Patient ID (created by the user)
- Fill in the First Name, Last Name and DOB of the patient
- Once the Case is named and the patient information is entered, the “Create” button will be enabled. Choose this to be taken to the Main Screen of the Graphic User Interface (GUI).

To “Open” an existing case:

- After selecting “Open Case”, the screen below will appear.



- Select “Search” and the list of Cases that are stored on the VIVO system will appear.
- Click on the desired case and “Open Case” in the bottom right corner will be highlighted. Choose this to be taken to the Main Screen of the GUI.

The Main Screen of the GUI has four modules.

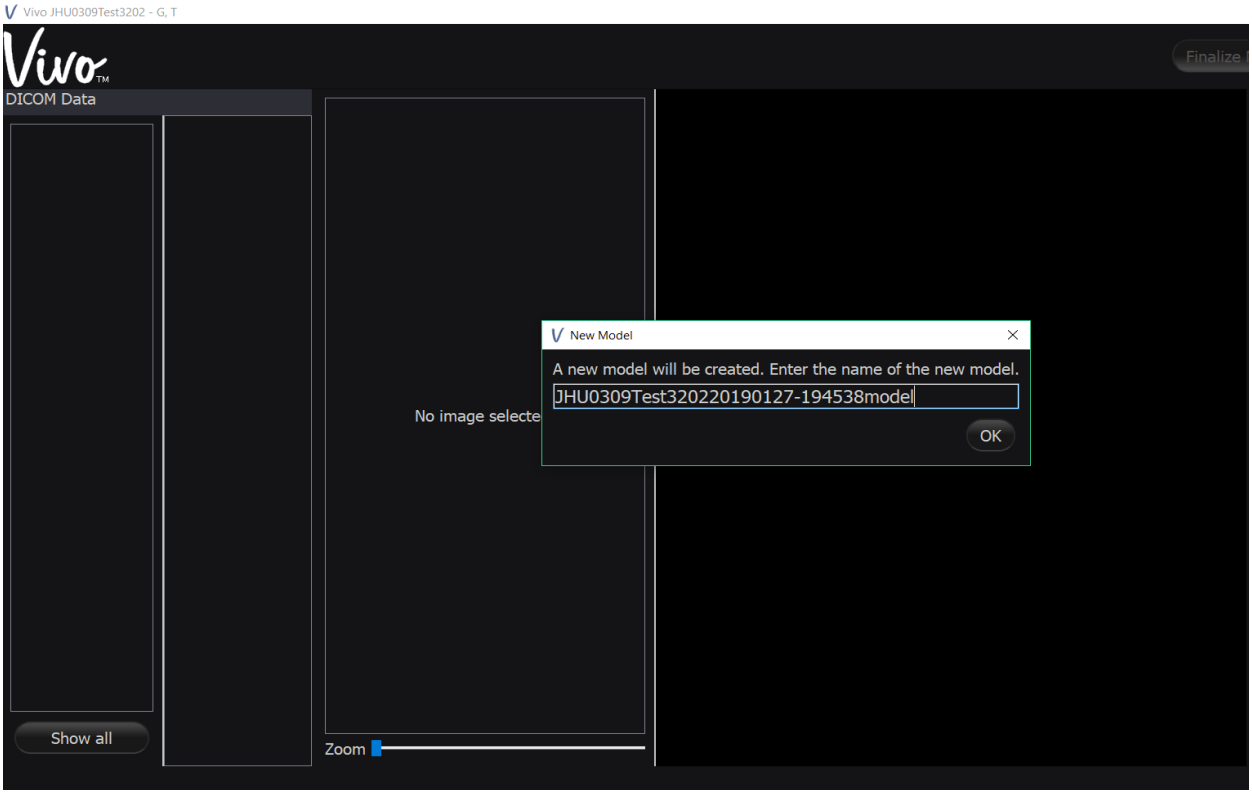
- Anatomy
- 3D Image
- ECG
- Analysis

If creating a new case, select Anatomy. If reviewing a previous case, choose the module needed for review.

VIVO Anatomy

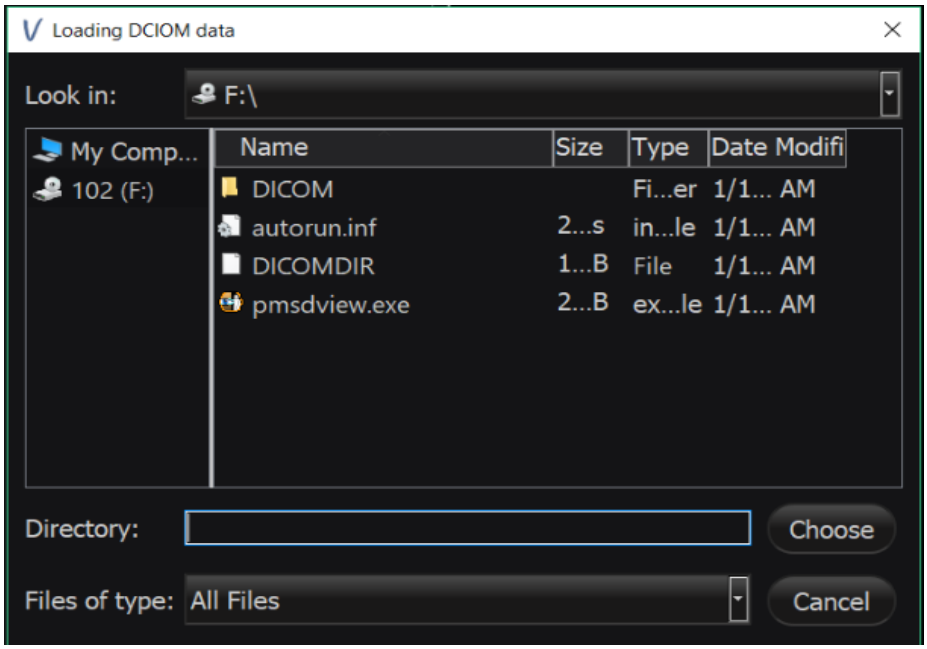
Naming the Model

If a new case has been created the following screen will appear upon opening the Anatomy Module. In the dialog box the user should create a name for the new model. This allows multiple models to be created per patient.



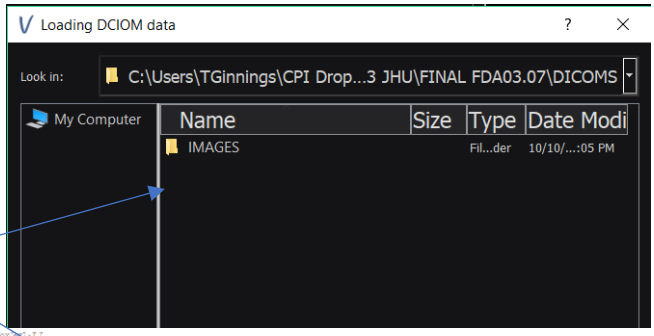
Uploading DICOMs

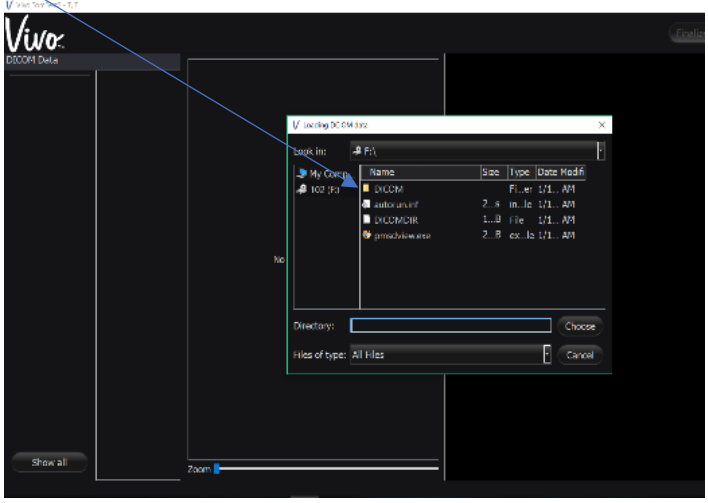
To begin, place a DICOM disc into the internal DVD drive of the computer. A dialog box will appear as in the screen shot below.



Locate the file that contains the patient's imaging data identifying the root folder with the -raw data for the MRI/CT scans.

Note: The folder visible may not always contain the images, the user must select all the way to the root folder or DICOM images will not upload. Examples are to the right.

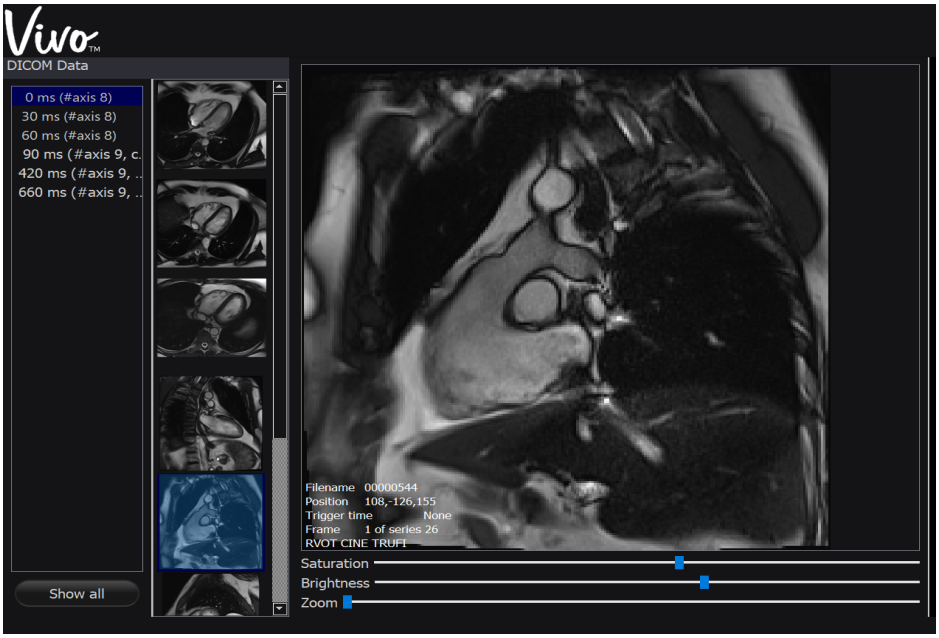




Click and highlight the root folder with the DICOM data and the name of the folder will appear in the directory box. Click "Choose" in the bottom right corner and the upload will begin.

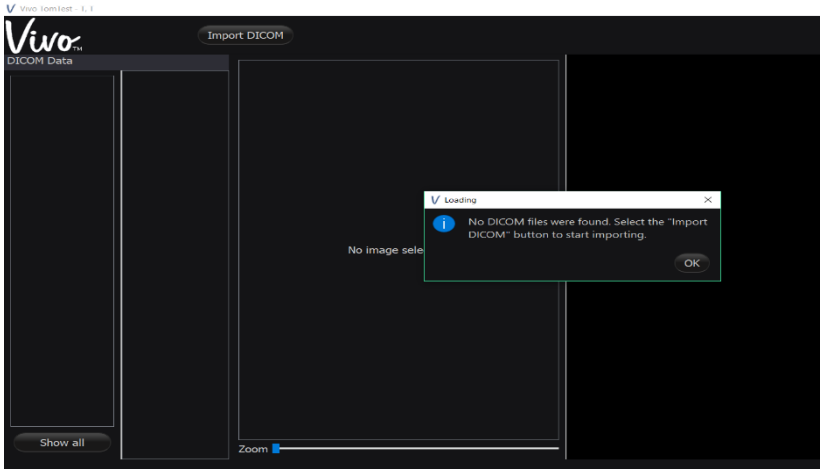
As the DICOM files upload the user will see a dialog box labeled "Loading".

Once copied, the DICOM will appear as in the image below.



If for some reason the DICOM upload is unsuccessful, a box will appear, click OK and the “Import DICOM” button will be highlighted.

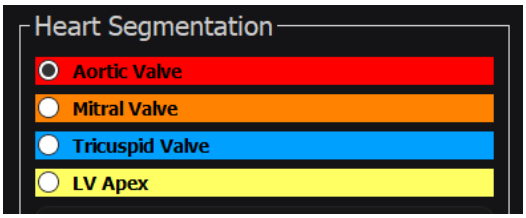
Search the directories as before to locate the DICOM images and try the process again.



Tissue Identification and Segmentation

When segmenting the valves in an MRI, the easiest orientation to capture all three valves is the short axis view. The LV Apex should be segmented in a four-chamber view, or a similar view where you can see the entire chamber.
A minimum of 4 points (seeds) should be placed around each valve and then connected with lines. The line connection is accomplished by pressing shift, left click and dragging a line to meet the circle which appeared when placing the seed.

There will be multiple series, images, and axes. From these data, the user will identify and choose a series to use for segmentation.



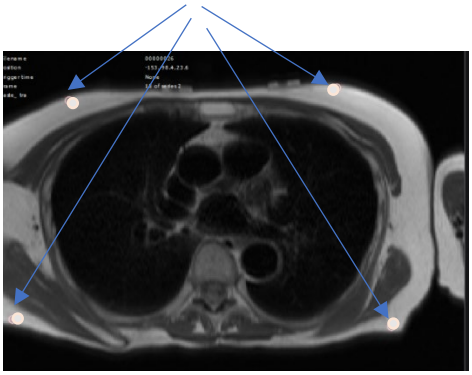
- To place seeds, highlight a tissue to segment.
  - Seeds are placed by right click on the mouse.
  - Seeds can be removed by CTRL and left click.
- The seeds placed will appear as open circles, until a different tissue is chosen, and the previously placed seeds will become solid.
- To check the accuracy of segmentation, choose another image to visualize the placed seeds.
- All valves and LV Apex should be segmented in the same series, though using different images within a series is acceptable.

Once satisfied with the tissue identification and seed placement, select “Start Heart Segmentation”. Once heart segmentation is completed, the user will be presented with up to three heart models to choose from. A visual inspection should be performed to check the outline of each heart model which is closest to the DICOM image. Manual adjustments of the outline may subsequently be required by selecting the “Edit” function.

Torso Segmentation

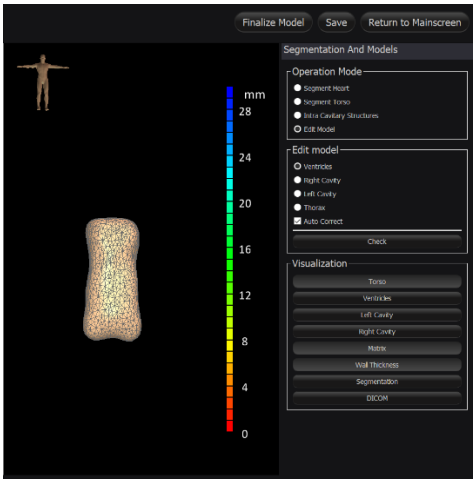
After completion of the heart model, the user should select “Torso” to begin the torso segmentation. The user will initially select a series for torso segmentation.

The user should identify the outline of the torso, just as it was done with the heart tissues and placing four “seeds”.



After placing the seeds, select “Start Torso Segmentation” and the auto-segmentation process will start. Just as it was done with the heart outline, the user should inspect and adjust (edit) the torso outline. Several images should be used to test the accuracy.

After completion of the heart and torso model, the user should check for errors and when there are no errors, finalize the model.

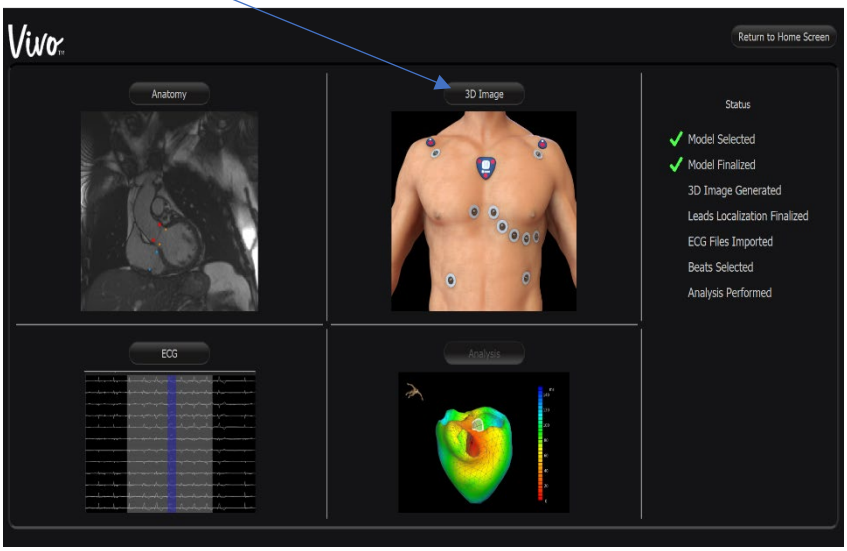


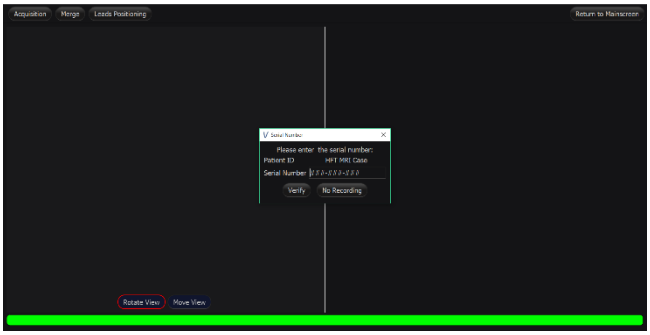
The Anatomy module is now complete as indicated by the green Status check marks on the Main Screen for Model Selected and Model Finalized.

Image Acquisition with 3D Camera

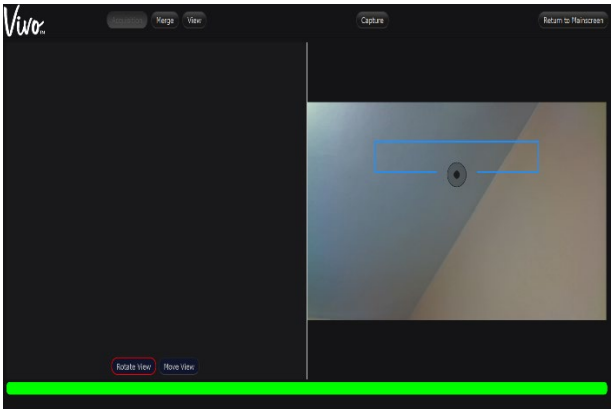
Note: Prior to 3D image acquisition, the Positioning Patches need to be placed on the patient's chest. Please refer to the Instructions for Use included on the back of the positioning patch card for proper placement of the positioning patches.

The user should select 3D image from the Main Screen.

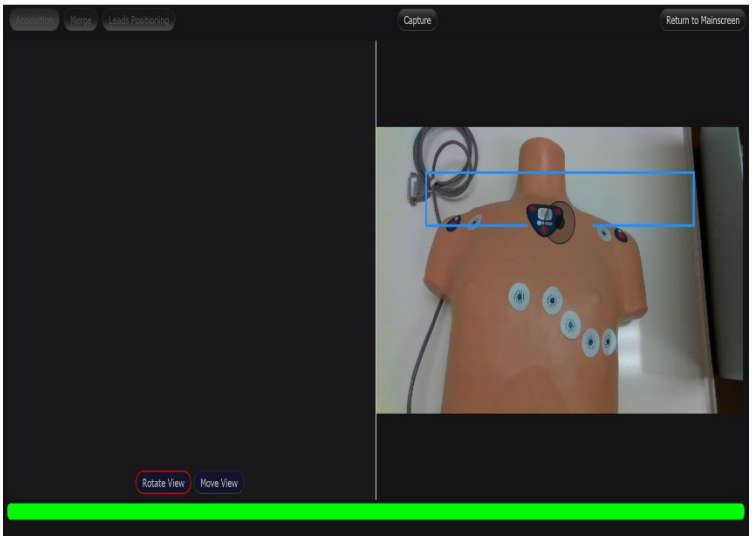




Once opened, the user will be prompted to enter the Positioning Patch serial number. If the serial number has previously been entered, the program will not continue. Once the serial number has been verified the following screen will appear. It is indicating that the camera is connected to the system.

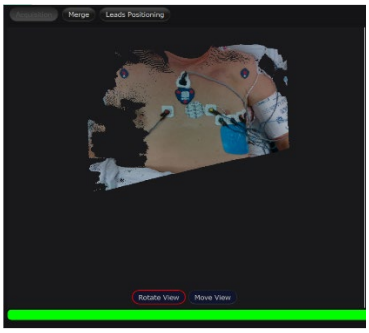


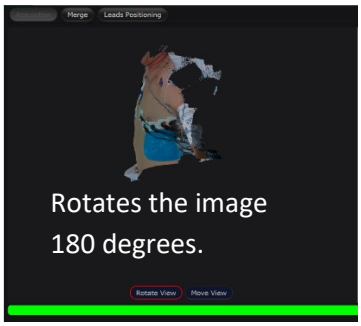
Position the camera over the patient so that all electrodes are visible. Then position the view finder (blue rectangle) over the patient so that the black circle is over the Sternum Patch.

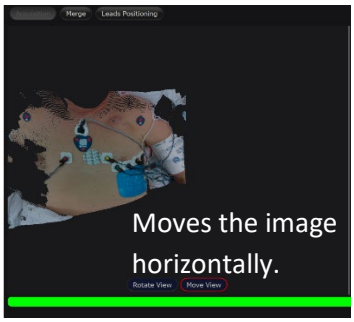


The user should press “Capture” (located in the top middle) to begin the image acquisition process. After selection of the Capture button, the view finder turns purple; while zooming in on the patch, it turns orange. Once the correct framing is reached, it turns green. Once the view finder turns green, the camera must be held in place until the process is complete – approximately 10 seconds. Once acquired, a dialog box will appear asking the user to accept the image. If acceptable, select “ok”.

After image acquisition, the 3D photograph and torso image (from Anatomy) must be aligned, as seen below.

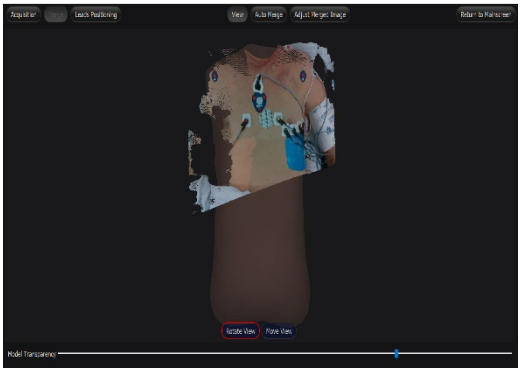






Once satisfied, press “Merge” and proceed with the merge operation. In the new screen (right) select Auto Merge in the top center.

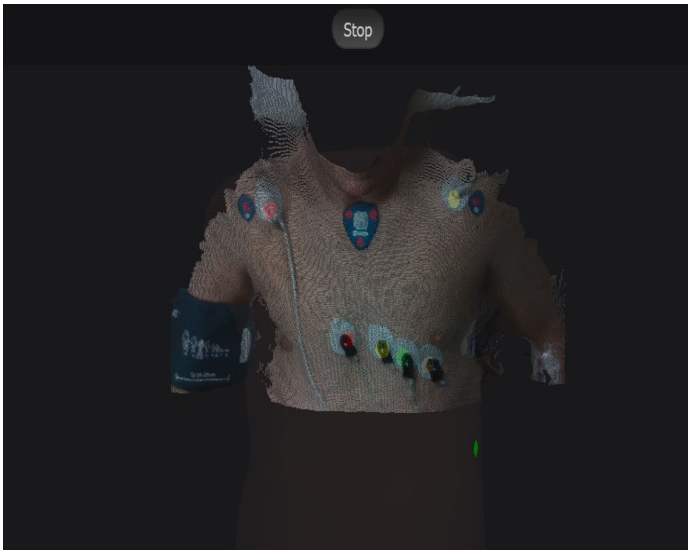
Upon merge completion, conduct a visual inspection of the merged composite to ensure its accuracy.



Positioning the Leads

First, select the “Leads Positioning” button and the Start button. The following screen will appear.

Position the “dots” representing each ECG electrode with the corresponding ECG electrodes of the 3D image as shows below.



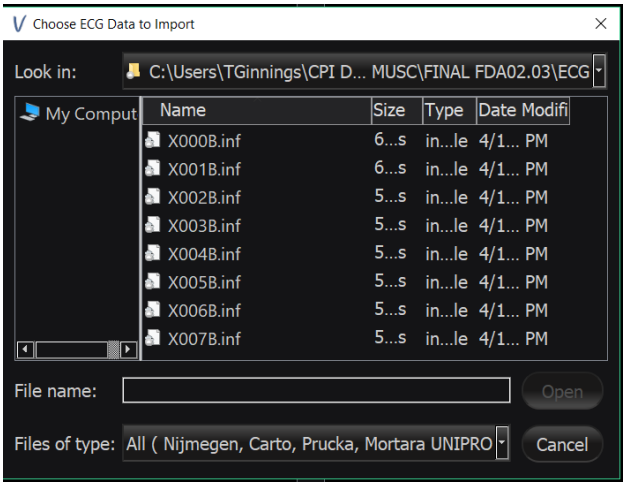
When satisfied with the leads positioning, select Finalize 3D Image. The 3D image has now been merged with the patient specific heart and torso model and Finalized . After returning to the Main Screen, verify that the 3D Image Generated and Leads Localization Finalized status are checked.

ECG Import and Selection

Import an ECG

After opening the ECG module, select Import ECG, as shown below.

Next, open the directory folder. This can come from a USB drive or other media format. Once located, the ECG data files will appear similar to the image below. Left click on the desired ECG file and the open button will highlight for selection.

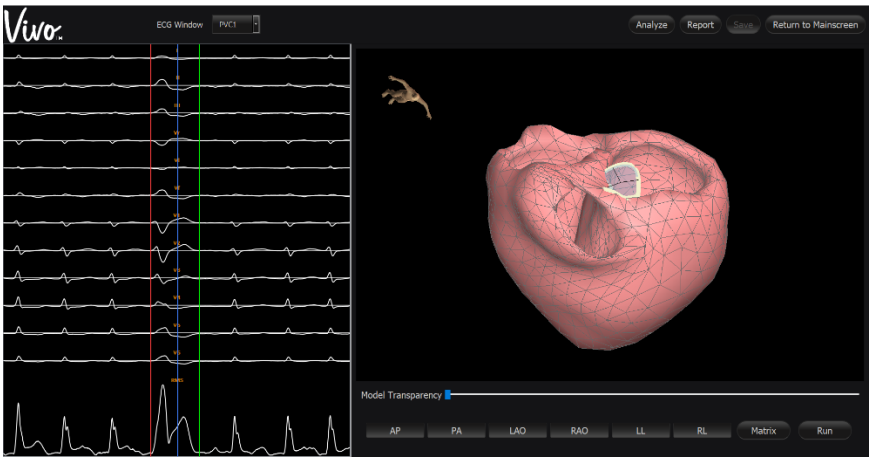


Once imported, the ECG will appear on the left side of the screen. The user should select the beat of interest by hovering the mouse pointer over the beat and double clicking. A blue line will appear over the beat of interest and a grey box will highlight the segment 3 seconds before and after the selected beat as seen below. The user can then name the ECG segment and the ECG beat is ready to be analyzed.

To analyze the beat, select “Analyze”. This will bring the user to the Analysis module.

Analysis

After selecting Analyze in the ECG module, the user will see the below image.

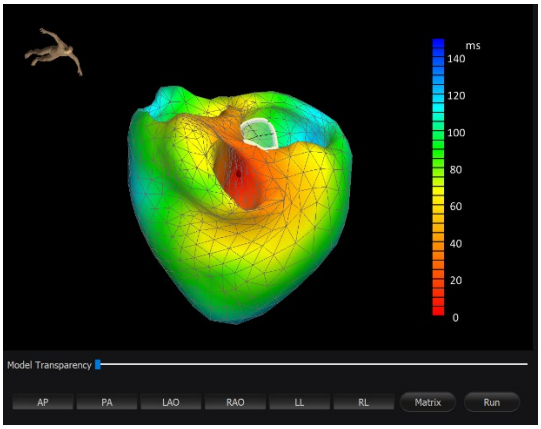


Above the ECG window, select the desired beat from the saved beats drop-down menu. Next, select "Insert ECG Markers". Red, Green and Blue markers will appear on the ECG.

- The green marker should be placed between the T-wave and the P-wave as near to the baseline (0mV) as possible.
- The blue marker should be placed at the end of the QRS, just before the next positive deflection.
- The red marker should be placed at the baseline just before the upstroke of the QRS.

Hovering the mouse pointer over each marker will display the measured timing and amplitude of the signal.

After correct marker placement, select "Analyze". A final activation map will appear. The red dot indicates the earliest point of activation. The process is now complete. Return to the Main Screen and confirm that the "Analysis" status is checked.



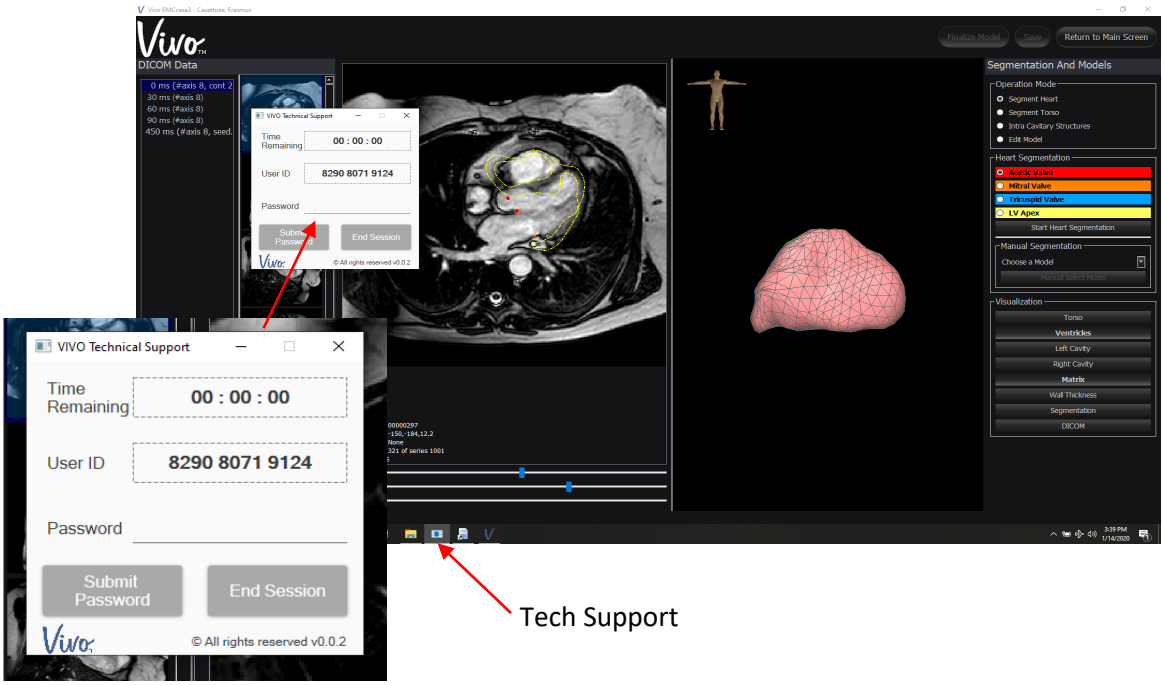
Remote Access Support

The remote access support is a secure process that allows the User to interface directly with CPI support personnel to receive trouble shooting assistance.

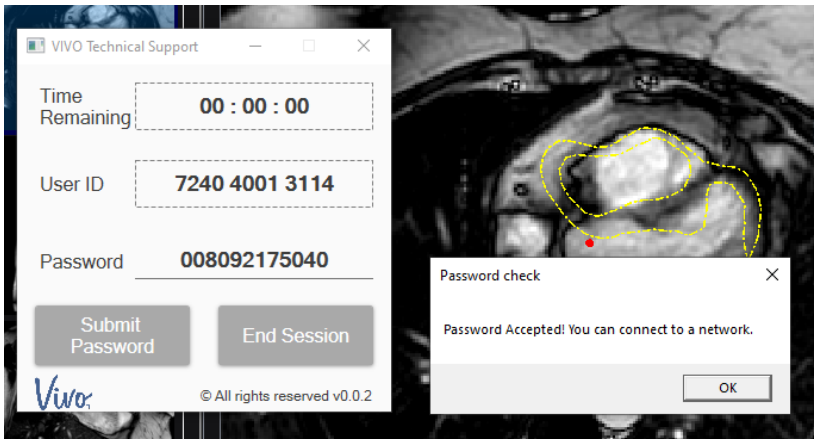
To begin, the User should contact technical support. Once instructed, open the VIVO Technical Support Application. This is located on the bottom menu (task bar).

Once the support application is opened, a new window will open and a User ID will be generated. The User will be instructed to provide technical support with this User ID.

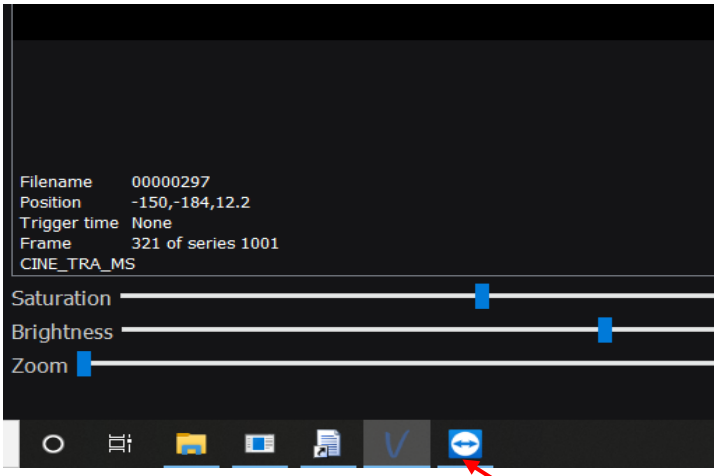
Note: *If connecting to a secured Wi-Fi for the first time, the User may have to enter the Wi-Fi password to access the secure network.*



The CPI technical support will then provide a password to the User, which the User will be instructed to enter in the password field. Once the password is submitted, a window will appear as seen below to notify the User that it has been accepted.

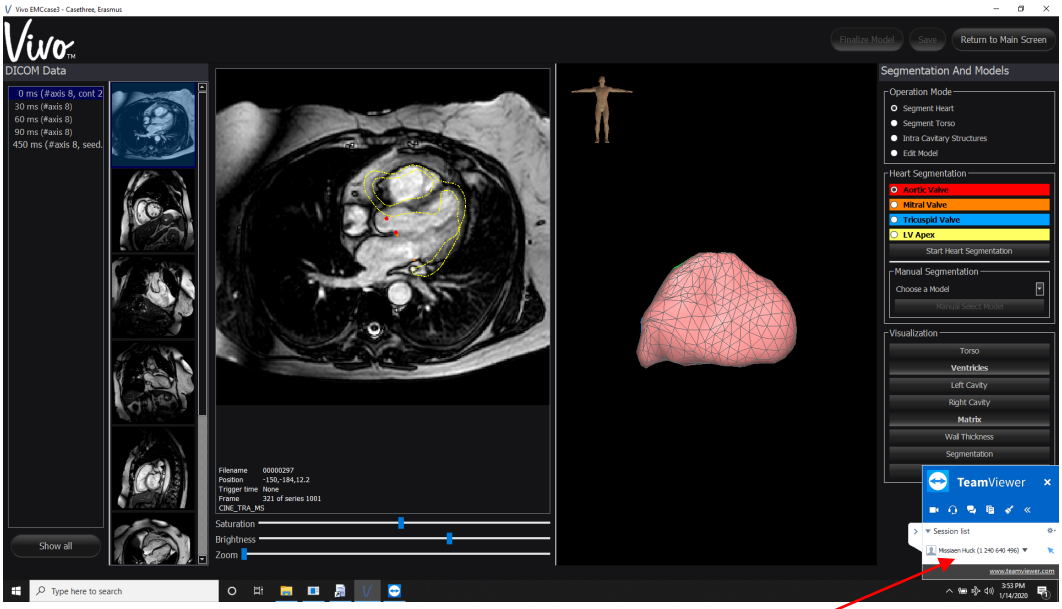


Once the Wi-Fi has been enabled, TeamViewer will automatically launch.



Task bar: indicates that TeamViewer Launched

The Technical Support Admin will now connect to the User's PC and the session will start.



TeamViewer status of remote control from admin computer

Once the support is completed, CPI Technical Support will end the session and Wi-Fi will again be disabled.

Specifications

Operating Environment

- Temperature: 75°F ± 15°F (27°C ± 11°C)
- Relative Humidity: 10 to 90% non-condensing
- Altitude: 0 ft to 10,000 ft (0 m to 3048 m)

Storage Environment

- Temperature: -40°F to 149°F (-40°C to 65°C)
- Relative Humidity: 0 to 95% non-condensing
- Altitude: 0 ft to 35,000 ft (0 m to 10,668 m)

Laptop PC Power Supply Electrical Specifications

- Voltage Input: 100 - 240 VAC (+/-10%), 50/60 Hz, and 1.6A
- Phase: Single
- Power output: 65 W

Safe Disposal

- Positioning patches can be thrown away in normal garbage in similar fashion as ECG lead patches.
- Do not dispose of any electronics, cables or power cords. All electronic components must be returned to Catheter Precision.

VIVO Warranty

VIVO is warranted one year from date of installation. Cables and Camera are warranted for 90 days after date of installation.

Vectraplex

For indications and instructions for use, refer to the User Manual that is contained within the VectraCor packaging.

The Vectraplex Universal ECG cables and software is a third-party product manufactured by VectraCor. Catheter Precision is not responsible for the service or maintenance of the product. VectraCor is solely responsible for any standard, limited, express, or implied warranties offered for the ECG products. Catheter Precision makes no warranties whatsoever whether express or implied, regarding the product. The Customer is responsible for contacting VectraCor directly for any questions or issues with the Vectraplex products +1 973.904.0444.

Symbols

The following symbols are used on the product and packaging.

Symbol	Meaning
	Manufacturer
	Catalog Number
	Lot Number
	Serial Number
	Consult Instructions for Use
	Caution: Read all warnings and precautions in Instructions For Use
	Non-sterile
	Use By
	Date of Manufacture
	Single Use Only
	Medical Device
	Self-certified in accordance with the European Medical Device Directive 2017/745
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare provider
	Recycle Electronic Equipment
	Do not use if the package is damaged

EC REP	Authorized European representative

www.CatheterPrecision.com

CE

Catheter Precision Inc.
1670 Highway 160 West,
Suite 205
Fort Mill, SC 29708, USA
Telephone: +1 973.691.2000

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

MedNet SWISS GmbH
D4 Platz 4
6039 Root D4
Schweiz

VIVO Model 9002 User Manual
81-9002-003_EU Rev11

February 3, 2026