

# Ventripoint Medical System Plus (VMS+ 3.0) User Manual



DMR003-UMEN Rev 02

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# Manufactured by Ventripoint Diagnostics Ltd.

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This Medical Device meets the essential requirements of the Medical Device Directive 93/42/EEC.

## Customer Support

If you have questions about the user information, please contact Ventripoint Customer Support.

To request a paper copy of the user manual, please contact Ventripoint Customer Support. A paper copy can be provided within 7 calendar days at no additional cost.

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### **WARNING**

United States federal law restricts this device to sale by or on the order of a physician. Only trained medical personnel may use this device for its intended use.



## WARNING

Do not use the system for purposes other than those intended and expressly stated by Ventripoint.

## Model

Ventripoint Medical System Plus (VMS+ 3.0) (Referred to as 'VMS+' throughout the manual).

## Regulatory Requirements

This product complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.



This manual is a reference for the VMS+ 3.0. It applies to all versions of the VMS+ 3.0 system unless otherwise specified.

## Conformance Standards

The Ventripoint products are tested to meet all applicable requirements in relevant Health Canada regulations and standards, FDA regulations, and EU Directives and European standards. Any changes to accessories, peripherals or any other part of the system must be approved by Ventripoint. This product complies with the regulatory requirements of the following:

Standard/Directive	Scope
93/42/EEC	Medical Devices Directive (MDD)
IEC60601-1:2005/AMD1:2012	Medical Electrical Equipment, Part 1; General Requirements for Safety
IEC60601-1-2:2014 (Ed. 4.0)	Medical Electrical Equipment – part 1-2. Collateral standard: Electromagnetic compatibility – Requirements and tests.
ISO 13485:2016	Medical Devices – Quality management systems – Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices - - Part 5: Tests for in vitro cytotoxicity

ISO10993-10	Biological evaluation of medical devices - - Part 10: Tests for irritation and skin sensitization
IEC 62304:2006/Amd 1:2015	Medical device software - - Software life cycle processes

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## About This Manual

This manual is intended to assist you with the safe and effective operation of your Ventrpoint product. Before attempting to operate the product, read this manual and strictly observe all warnings and caution notices. Pay special attention to the information in the “Safety” section.

This manual is also available on the Ventrpoint website in pdf format.

## Safety

Please read this information before using your VMS+ system. This section covers general safety information only, including cautions, warnings and other information about what you must do to ensure safe and proper performance of the VMS+ system. This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device. Report any serious safety incident that occurs in relation to the VMS+ system to Ventrpoint and to the competent authority of the country in which the user and patient are established.



### **WARNING**

Warnings alert you that a potential safety hazard exists and describes precautions to protect the equipment from damage or injury to the operator or patient.



### **CAUTION**

Cautions indicates that a potential hazard may exist and contains precautions that must be followed to protect equipment, data, or software, and consequently voiding your warranty or service contract or ways that you could lose patient or system data.

**NOTE** Highlights important information that will aid you in operating the product more effectively.

## Intended Audience

This document is intended for healthcare professionals who operate the Ventrpoint product. Users of the device must be trained in cardiac sonography and/or echocardiography.

## Intended Use

The VMS+ is an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3D image processing.

The VMS+ is indicated for use in patients where all heart chamber volumes and ejection fractions are warranted or desired.

## Indications for Use

This product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgment and best clinical procedure.

## Contraindication

The VMS+ is not intended to be used on patients with pacemaker/defibrillator; permanent or temporary and any kind of similar implanted device.

## Environment

VMS+ is a transportable system intended for use in professional healthcare facility environments where healthcare is provided by healthcare professionals.



### **WARNING**

Do not use the system for purposes other than those intended and expressly stated by Ventripoint. Do not misuse the system, and do not use or operate the system incorrectly.



### **WARNING**

Installation, use, and operation of this product is subject to the law in the jurisdictions in which the product is used. Install, use, and operate the product only in a way that does not conflict with the applicable laws or regulations, which have the force of law.

## Product Description

The Ventripoint VMS+ is a medical device that recreates the shape of a heart using a knowledge-based reconstruction algorithm by capturing 2D ultrasound images at specific angles and locations. The subsequent reconstructed heart is used to calculate the volume. The volume can be any one of the four chambers, either at end-diastolic and/or end-systolic.

The VMS+ is intended to be used with any standard 2D ultrasound system.

The VMS+ records the ultrasound images from a video output of the 2D ultrasound machine and tracks the ultrasound transducer's 3D spatial coordinates and orientation by utilizing a position sensor connected to the ultrasound transducer. There is a separate position sensor that tracks and corrects for any patient movement.

### **Major Features**

- Acquires ultrasound cardiac images from a host ultrasound system.
- Acquiring position and orientation of the transducer during scanning.
- Tracks patient movement.
- Displays the different cardiac views that were captured as video clips.
- Enable the user to drop key points on the ultrasound images.

- Send the points to the KBR engine resulting in the extraction of a wire mesh display of the heart shown in 3D.
- Allow the user to interact with the 3D wire mesh volume for optimum viewing.
- Generates the following measurements:
  - Systolic volume
  - Diastolic volume
  - Ejection Fraction
- Measurements are stored with the images for later retrieval.
- A report is generated with all measurements and derived parameters.
- Sends and retrieves studies to a DICOM PACS server.

## Basic Safety Precautions

Before using the system, read these warnings and the “Safety” section. This section covers general safety only. Safety information that applies only to a particular task is included in the procedure for that task.



### **WARNING**

Do not use the system until you have read, understood, and know all the safety information and safety procedures contained in this “Safety” section.



### **WARNING**

Only Ventripoint-trained personnel may modify the VMS+.



### **WARNING**

Do not use the system until you have been properly trained on the safe and effective operation of the VMS+ system.



### **CAUTION**

The equipment is to be only used in conjunction with ultrasound machines. Do not connect other equipment to the VMS+.



### **CAUTION**

There is a magnetic field present. Do not use the system if you have a pacemaker or ferrous metal instruments/tools on your person.



### **CAUTION**

Do not place the sensors within 300 mm (12 in) of a patient with a pacemaker.

## Electrical Safety

This equipment has been verified by a recognized third-party testing agency as a Class I device with Type B patient-applied parts. (The safety standards met by this system are included in the [Specifications](#) section). For maximum safety, observe these warnings and cautions:



### WARNING

The VMS+ needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.



### WARNING

To avoid electrical shock, use only supplied power cords and connect only to properly grounded (wall/mains) outlets.



### WARNING

The VMS+ needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.



### WARNING

Given the sensitivity of the system to magnetic fields, do not use in close proximity to MRI machines. It is recommended to keep at least 50 meters away from any MRI rooms.



### CAUTION

For information on electromagnetic emissions and immunity as it applies to the system, see [Electromagnetic Compatibility](#). Ensure that the operating environment of your system meets the conditions specified in the referenced information. Operating the system in an environment that does not meet those conditions may degrade system performance.



### CAUTION

If the power cord is damaged (exposure of the core, disconnection, etc.), contact your service representative to change for a new one. Operating the system with a damaged power cord may cause an electric shock or fire.



### CAUTION

When you disconnect the power plug from the wall outlet, always pull the plug (not the cable). Do not drag the cord itself. Doing so may result in damage to the cord, leading to fire or electric shock.



### CAUTION

Verify that your system is powered off before plugging the power cord into a wall outlet.



### CAUTION

Do not connect any peripheral devices to the system other than those provided by Ventripoint. Failure to comply with this instruction may result in poor performance of the product.



**CAUTION**

Do not use near devices which intrinsically transmit radio waves (e.g. cellular phone, radio transceiver, mobile radio transmitter, etc.). Use of these devices near this equipment may affect performance of the device. These devices should be turned off.

**NOTE**

If this equipment is found to be affected by magnetic interference, re-locate the device, increase the separation between the unit and the source of the interference, or consult your Ventripoint service representative for assistance.

## Mechanical Safety

Mechanical failure or unintended use of the equipment can result in physical injury to patients or operators. A list of precautions related to mechanical safety follow, observe these precautions when using the system.



**WARNING**

The roll stand post operates by pneumatic pressure and will travel upward when disengaged. Ensure that nothing will obstruct upward travel before turning the Height Adjustment Knob or pressing the Foot Pedal.



**WARNING**

Do not attempt to disassemble any component of the roll stand.



**CAUTION**

To avoid injury, Ventripoint recommends against lifting the system roll stand.



**CAUTION**

Ensure that the cables for all patient-applied parts are secure before moving the system



**CAUTION**

Do not park the system on an incline.

## Warning Symbols

The system may use the following warning symbols. For additional symbols used on the system, see the “Safety” section.

Symbol	Description
	Identifies a safety note.

	<p>Dangerous voltages: Appears adjacent to high-voltage terminals, indicating the presence of voltages greater than 1,000 Vac (600 Vac in the United States).</p>
	<p>Indicates that the user should see the instructions for use for safety information.</p>

## Navigating the Touch Screen

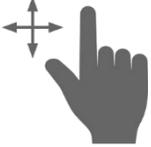
VMS+ communicates with the user in a number of ways:

- Menus
- Message boxes
- Screens
- Tool Bar icons

Most of these options can be navigated either by using your finger to tap the touch screen, or by using both the scrolling and clicking functions of the Mouse and/or Keyboard.

## Touch Gestures

Action	Mimics	Use
 <p>Single finger tap</p>	<p>Left mouse click</p>	<p>Selecting buttons Selecting points Placing points</p>
 <p>Single finger double tap</p>	<p>Double left mouse click</p>	<p>Opening a study from the studies list</p>
 <p>Single finger tap and drag</p>	<p>Left mouse click and drag mouse pointer in any direction</p>	<p>Rotating 3D model Moving cine bar indicator Setting Brightness/Contrast</p>
 <p>Single finger tap and hold</p>	<p>Right mouse click</p>	<p>Deleting points</p>

 Single finger swipe		Scrolling through thumbnails Scrolling through Studies list
 Two finger spread	Mouse scroll forward	Zoom in
 Two finger pinch	Mouse scroll backward	Zoom out

## Product Compatibility

Do not use your system in combination with other products or components, unless Ventripoint expressly recognizes those other products or components as compatible. For information about such products and components, contact your Ventripoint representative. Changes and additions to the system should be made only by Ventripoint or by third parties expressly authorized by Ventripoint to do so. Such changes and additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned.

## Installation and Maintenance

### Expected Service Life

The expected service life for this model of the VMS+ is at least three (3) years from the manufacturing date under the provision of regular maintenance by Ventripoint service personnel.

### Inspecting the System

System preventive maintenance should be performed at least once a year and corrective maintenance as needed by Ventripoint service personnel. No servicing can be done while the equipment is in use.

#### CAUTION



Only Ventripoint service personnel may perform installation, assembly, upgrade, readjustments, extensions, maintenance, service, and any modification or repair of this product, otherwise, warranty may be void. Please contact Ventripoint for further information.



### CAUTION

Training is required for all users prior to using the VMS+ for its safe and effective use. Training materials will be provided with on-site training to all users by Ventripoint clinical personnel during installation of the system.



### WARNING

No modification of this equipment is allowed. Any changes or additions made by non-Ventripoint service personnel may void the Ventripoint warranty.



### CAUTION

Ventripoint Diagnostics Ltd. assumes no liability for problems attributable to unauthorized modifications, additions, or deletions to this product, or unauthorized installation of third-party software.



### CAUTION

Use the VMS+ in accordance with all instructions for use.



### CAUTION

Follow all instructions provided to avoid damage during cleaning. Failure to do so could void your warranty.



### CAUTION

If any defects are observed or malfunctions occur, DO NOT operate the equipment, and inform your Ventripoint representative immediately.

## Disposal of System



The European Union Directive on Waste Electrical and Electronic Equipment (WEEE) which is an EU-wide legislation, as implemented in each Member State, requires that waste electrical and electronic equipment carrying the mark (left) must be disposed of separately from normal household waste. The VMS+ should be disposed of according to local regulations and the WEEE directive. The mark on electrical and electronic products only applies to the current European Union Member States.

### WARNING



Do not dispose of the device (or any parts of it) with industrial or domestic waste. The system may contain materials such as lead, tungsten, or oil, or other hazardous substances that can cause serious environmental pollution. The device also contains privacy-sensitive information, which should be properly removed (scrubbed). Ventripoint advises you to contact your Ventripoint service representative before disposing of this system.

## Electromagnetic Compatibility (EMC)

This section includes information on electromagnetic emissions and immunity as it applies to the system. VMS+ complies with the requirements of IEC 60601-2, Class A.

In case of issues related to EMC, please contact your Ventripoint representative.

The information and warnings contained in this and other sections should be observed when using the system to ensure its EMC.

The recommended tables for electromagnetic emissions per sub-clause 5.2 of IEC 60601-1-2:2007 (3<sup>rd</sup> edition) and electromagnetic immunity are provided on the following pages:

### WARNING



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

### WARNING



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

### WARNING



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VMS+ 3.0, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

### NOTE

The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to make mitigation measures, such as relocating or re-orienting the equipment.

**Table C.1 – Emission Class and Group Compliance**

The VMS+ is intended for use in the electromagnetic environment specified below. The customer or the user of the VMS+ 3.0 should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The VMS+ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The VMS+ is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings
Harmonic Emissions IEC 61000-3-2	Class A	

<p>Voltage Fluctuations/Flicker Emissions IEC 61000-3-3</p>	<p>Complies</p>	<p>used for domestic purposes, provided the following warning is heeded:  <b>Warning:</b> This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocation the VMS+ or shielding the location.</p>
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**Table C.2 – Immunity Test Level Compliance**

<p>The VMS+ is intended to use in the electromagnetic environment specified below. The customer or the user of the VMS+ should assure that it is used in such an environment.</p>			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Electrostatic Discharge (ESD) IEC 61000-4-2</p>	<p>±8 kV Contact ±15 kV Air</p>	<p>±8 kV Contact ±15 kV Air</p>	<p>Floors should be wood, concreted or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</p>
<p>Electrical Fast Transient/Burst IEC 61000-4-4</p>	<p>±2 kV for power supply lines</p>	<p>±2 kV for power supply lines</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Surge IEC 61000-4-5</p>	<p>±0.5 kV, ±1 kV line to line &amp; ±0.5 kV, ±1 kV, ±2 kV line to ground</p>	<p>±0.5 kV, ±1 kV line to line &amp; ±0.5 kV, ±1 kV, ±2 kV line to ground</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p>0% <math>U_T</math> (100% dip in <math>U_T</math>) For 0,5 cycle  0% <math>U_T</math> (100% dip in <math>U_T</math>) For 1 cycles  70% <math>U_T</math> (30% dip in <math>U_T</math>) For 30 cycles  0% <math>U_T</math> (100% dip in <math>U_T</math>) For 5 sec</p>	<p>0% <math>U_T</math> (100% dip in <math>U_T</math>) For 0,5 cycle  0% <math>U_T</math> (100% dip in <math>U_T</math>) For 1 cycles  70% <math>U_T</math> (30% dip in <math>U_T</math>) For 30 cycles  0% <math>U_T</math> (100% dip in <math>U_T</math>) For 5 sec</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the VMS+ requires continued operation during power mains interruptions, it is recommended that the VMS+ be powered from an uninterruptible power supply or a battery.</p>
<p>Power Frequency Magnetic Field (50/60 Hz) IEC 6100-4-8</p>	<p>30 A/m</p>	<p>30 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical</p>

			commercial or hospital environment.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

**Table C.3 – Immunity Test Level Compliance**

The VMS+ is intended for use in the electromagnetic environment specified below. The customer or the user of the VMS+ should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the VMS+ including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz  3 V/m 90 MHz to 2,7 GHz  RF communication equipment inside 80 MHz to 6 GHz	6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz  3 V/m 90 MHz to 2,7 GHz  RF communication equipment inside 80 MHz to 6 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup> .
NOTE 1 At 80 MHz and 900 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VMS+ is used exceeds the applicable RF compliance level above, the VMS+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating the VMS+.			
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

**Table C.4 – Recommended Separation Distances**

<b>Recommended separation distances between portable and mobile RF communications equipment and the VMS+</b>
--

The VMS+ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VMS+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VMS+ as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	150 kHz to 80 MHz $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Prevention of Static Electricity Interference

Interference from static electricity can affect electronic components in the sensors.

The following cautions can help to reduce the likelihood of electrostatic discharge/static shock:



### CAUTION

To help reduce electrostatic discharge (ESD) place anti-static mats between the system and the patient bed.

## Device Labels and Symbols

The following symbols may be used on the equipment and its accessories and packaging.

Labels/Icons	Purpose
	Date of Manufacture
	Manufactured by

Labels/Icons	Purpose
	Representative in the European Community
	Indicates conformance with European Council Directive 93/42/EEC.
	Serial number
	Indicates that the user should consult the instructions for use for safety information that are located in the Help screen.
	Type B applied part
	Caution. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Prescription only; USA federal law restricts this device to sale by or on the order of a physician.
	Indicates the weight of the system.
	Temperature limits to which the medical device can be safely exposed.
	Humidity limits to which the medical device can be safely exposed.
	Pressure limits to which the medical device can be safely exposed.

Labels/Icons	Purpose		
	Alternating Current. To indicate on the rating plate that the equipment is suitable for alternating current only; to identify the relevant terminals.		
	Indicates the need for separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment.		
	Telephone Number		
	Fragile		
	Keep Dry		
	Warns of system over-balance due to external force. (Do not push on the monitor to move the system.)		
	Caution, Magnetic hazard. Cautions user of magnetic field present and that the right precautions need to be taken in that area be no one working with pacemakers or metals.		
	Indicates a hazard to patients with pacemakers. Do not place field generator within 300 mm (12 in) of a patient with a pacemaker.		
	Refer to instruction manual/booklet.		
<table border="1" data-bbox="159 1556 407 1665"> <tr> <td data-bbox="167 1566 277 1650"></td> <td data-bbox="277 1556 399 1665">Maximum Load 2.3 kg</td> </tr> </table>		Maximum Load 2.3 kg	Maximum load of basket cannot exceed 2.3 kg.
	Maximum Load 2.3 kg		
	Caution, consult accompanying documents		
	Electricity warning. Warns of dangerous voltages.		

Labels/Icons	Purpose
	Hard Disk Drive
	Battery (n/a to VMS+)
	Power status
	Power on/off
	Volume mute
	Decrease volume
	Increase volume
	Decrease screen brightness
	Increase screen brightness
	LCD on/off
	Clean me (locks screen for cleaning)
	Turn off camera capabilities (n/a for VMS+)

Labels/Icons	Purpose
	Function (n/a for VMS+)
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.

## System Overview

Use this section to become familiar with the system and its components.

The VMS+ has two operational modes; the Console and a Review and Analysis Workstation.

- Console:** The system is installed and provisioned by Ventripoint. It contains the necessary hardware for capturing ultrasound images, tracking the 3D coordinates of the ultrasound transducer, and completing the reconstructions. This system is designed to work with any commercially available two-dimensional (2D) ultrasound system.
- Review and Analysis Workstation:** The Workstation is used by users for conducting study analysis created by the VMS+. The Review and Analysis Workstation only consists of the analysis portion of the VMS+ application. This system is not provisioned by Ventripoint. For the minimum requirements for running VMS+ on a Review and Analysis Workstation, see [Setting up a VMS+ Workstation](#) .

## System Components

The system consists of the following components:

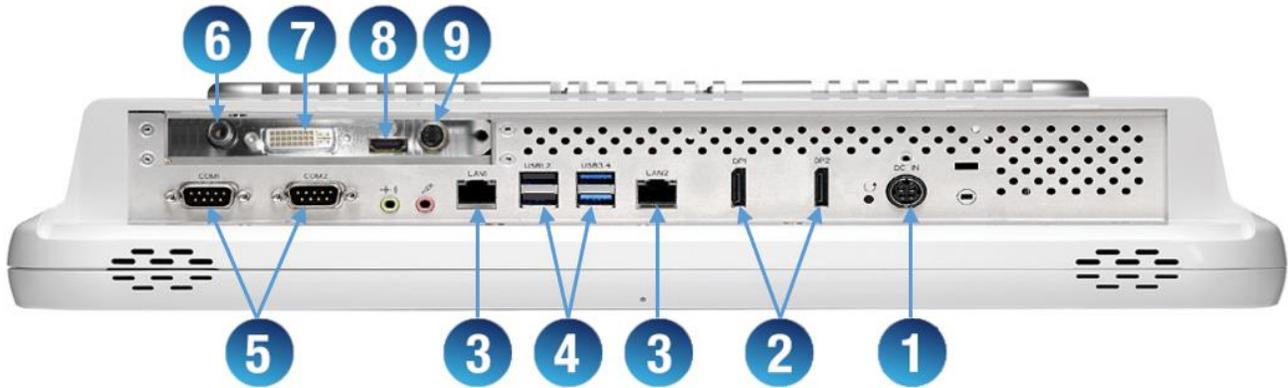


**System Components**

- 1** Touchscreen computer.
- 2** Computer controls
- 3** Wire utility basket.
- 4** Power supply
- 5** Variable height roll stand base with adjustment pedal

- 6** Manual computer adjustment lever.
- 7** I/O and Power
- 8** Cable wrap
- 9** Locking casters x 5

**In/Out (I/O) Control Panel**



- 
- 1** DC-in

---

  - 2** DP x 2

---

  - 3** LAN x 2 (Use only one LAN port consistently)

---

  - 4** USB 3.0 x 2 (Right), USB 2.0 x 2 (Left)

---

  - 5** RS232 (Right), RS232/422/485 (Left)

---

  - 6** Trigger in – Female phono

---

  - 7** DVI-I single link female connector (analog/DVI video input)

---

  - 8** HDMI/DVI Digital/Analog Video input (HDMI HDCP is not supported)

---

  - 9** S-Video/Composite Color or Monochrome

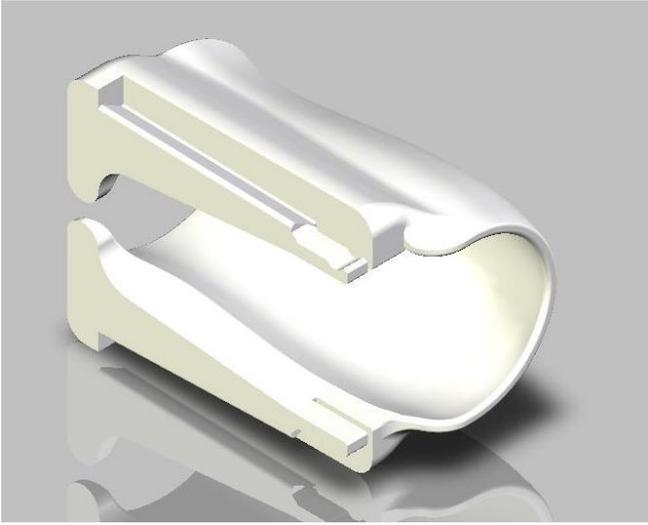
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### Power Cords and Plugs

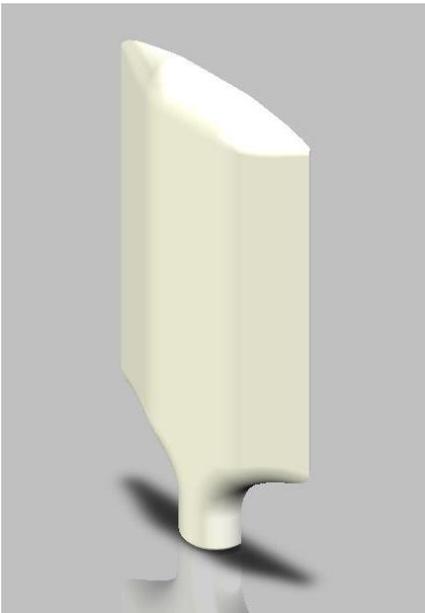
The cable types listed here are supplied with the system based on your particular country of use.

DESCRIPTION	LENGTH	POWER RATING	PICTURE
North American 10Amp Hospital Grade Cord Set w/C13	3.05m/10.0ft	125VAC/10A	
Continental Europe 10Amp Cord Set w/ C13 Connector	3.50m/11.48ft	250VAC/10A	
United Kingdom/Ireland Cord Set w/C13 Connector	3.50m/11.48ft	250VAC/10A	
Swiss 10 Amp Cord Set	2.50m/8.2ft	250VAC/10A	

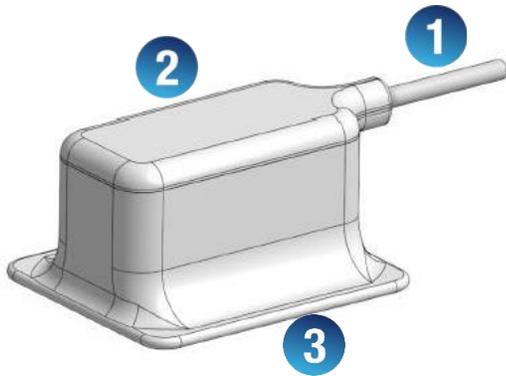
**Transducer Sleeve**



**Transducer Sensor**



**Patient Sensor**



- 1** USB cable

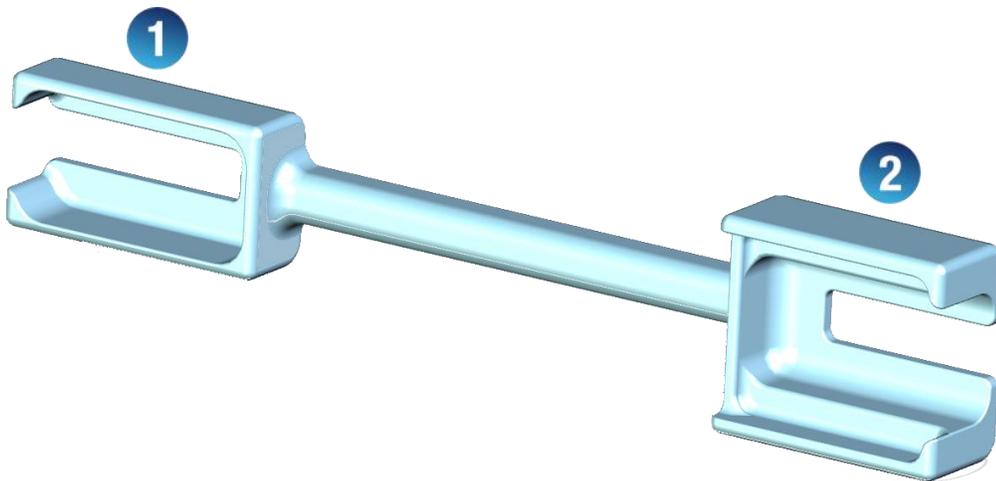
---

- 2** Top surface (holds the PCB)

---

- 3** Bottom and/or patient surface (holds a magnet)

### Pairing Baton



- 1** Patient sensor slot

---

- 2** Transducer sensor slot

## Patient Data Protection

The VMS+ application does not encrypt patient data. It is your responsibility to configure your workstation to meet your local security policies and regulatory requirements.

Ventripoint recommends that you protect patient data by encrypting your device and setting a password or passcode as a screen lock for your device, in accordance with your institution's security policies and requirements.

When you are finished using the console, you can briefly press the on/off control on the device to lock the screen and prevent unauthorized access to patient data, or you can simply shut down the system, which logs you off automatically.

The VMS+ is not intended for long-term storage of patient data. Export exams frequently and delete them after they are exported. You can send patient data to PACS/DICOM. You can also delete all patient data from the VMS+ and Copy To/From removable media.

VMS+ software also logs who is signed in, what actions were taken by the user and how long they were signed in. See [Log files](#).

When you are finished using the system, you can log off manually, or you can simply shut down the system, which logs you off automatically. The system stores a record of each user logon. For more information on protecting patient data, see [System Security](#).

## Patient Information Screen

The Patient Information Screen is displayed when creating a New Study. You are required to enter data into the required fields as indicated by the red asterisks.

**New Study** Patient Information

\* MRN

Accession #

\* First Name

Middle Name

\* Last Name

Height  cm /  feet  in.

Weight  kg /  lbs

Heart Rate  BPM

\* Gender

\* Birth Date

Analysis

\* Required Fields

Patient Information screen – New Study

At any time, you can edit the Patient Information that you have entered for a study, as long as it has not been sent or retrieved from PACS. The Patient Information can be accessed via the 2D, 3D, Report or Help screens and includes additional information fields that you can enter data for the Patient.

- Height
- Weight
- Heart Rate
- Blood Pressure
- Record Information

The screenshot shows a 'Patient Information' dialog box with the following fields and values:

- MRN: [Empty]
- Accession #: [Empty]
- First Name: [Empty]
- Middle Name: [Empty]
- Last Name: [Empty]
- Gender: Unknown
- Birth Date: 2000, 1, 1
- Height: [Empty] cm / [Empty] feet [Empty] in.
- Weight: [Empty] kg / [Empty] lbs
- Heart Rate: [Empty] BPM
- Blood Pressure: [Empty] / [Empty] mmHg
- Analysis: Standard Analysis
- Record Information:
  - Facility: Ventripoint
  - Clinician: MichelleNeedles
  - Referring MD: [Empty]

Patient Information screen – 2D, 3D, Report or Help screen

► **To edit patient information**

1. In the table of available studies on the main workspace, select a study.
2. Select **Open**.
3. Select the  patient information icon in the top left corner of the screen to open the Patient Information screen. Patient Information screen can be opened on either the 2D, 3D, Report or Help screens.
4. Make the appropriate changes to the Patient Information.
5. Select **OK** to save the changes made or **Cancel** to cancel your changes.



### **CAUTION**

Before saving, editing, or reviewing the data of a patient, ensure that its contents correspond to the patient name and/or MRN. This provides additional assurance that the stored data correspond to the correct patient.



### **CAUTION**

Once a study has been received from or sent to PACS, the Patient Information cannot be edited.

## Viewing Audit Logs

The VMS+ provides the data to enable a user to create an audit report for a specific time period. The ability to sort entries in the audit log according to date, time, patient identification and/or user identification is permitted. Log files are retained for six (6) months.

Audit logs record the following information about access to patient data:

- When an employee logs in, including date and time
- The number of failed login attempts on a console
- What information was accessed by the person logged in
- What Protected Health Information (PHI) was changed and by whom
- What data was saved/deleted/modified and by whom

Log files are found in “C:\ProgramData\VentriPoint\logs” and can only be accessed by users with Administrator privileges.

## User Account Management

There are two types of user accounts: Administrators and Standard Users.

Administrators are given their administrator user account and password by the Ventripoint Service Representative during the installation process. It is suggested that Administrators change this password immediately and that they do not share this password with other users.

Each user of the VMS+ will need their own account with their own password.

You will log into the system, add new users, delete existing users and change passwords using the Microsoft Windows login screen.

### **NOTE**

User facility is responsible for user management, in accordance with your institution's security policies and requirements.

### ► **Creating a new user account**

1. As an Administrator, log into the VMS+.
2. Go to the Windows start menu.



3. Open **Settings**.



4. Go to **Accounts**.

5. Go to **Family & other people**.

6. Select '**Add someone else to this PC**'.

7. Select '**I don't have this person's sign in information**'.

8. Select '**Add a user without Microsoft account**'.

9. Enter a user name.

10. Do not enter a password.

11. A Standard user is added. Standard users will not have access to the system's window desktop.

12. Click **Next**.

13. Open Windows Control Panel.

14. Select **User Accounts**.

15. Select **User Accounts** again.

16. Select **Manage another account**.

17. Select the user you want to manage.

18. You will have the following options:

- a. Change the account name
- b. Create a password
- c. Change the account type
- d. Delete the account
- e. Manage another account

► **To change account type**

1. As an Administrator, log into the VMS+.

2. Go to the Windows start menu.



3. Open **Settings**.



4. Go to **Accounts**.

5. Go to **Family & other people**.

6. Select the user you want to edit.
7. Select **Change account type**.
8. Select **Standard** or **Administrator** from the drop-down menu.
9. User account type is updated.

► **To change a password**

**NOTE** Passwords can only be changed by users with Administrator privileges.

1. As the user, log into the VMS+.
2. Go to the Windows start menu.  

3. Under password, select **Settings**.
4. Select **Change account settings**.
5. Select **Sign-in Options**.
6. Under Password, select **Change**.
7. Enter current password.
8. Enter a new password.
9. Re-enter the new password.
10. Select **Next**.
11. Select **Finish**. Password is updated.
1. .

► **To delete a user**

1. As an Administrator, log into the VMS+.
2. Go to the Windows start menu.



3. Open **Settings**.



4. Go to **Accounts**.

5. Go to **Family & other users**.
6. Select the user you want to delete.
7. Select **Remove**.
8. Select **Delete account and data**.

► **To unlock an account**

1. Click Windows button + R.
2. Enter **lusrmgr.msc**.
3. Select **OK**.
4. Type **Local Users and Groups** into Windows search bar.
5. Select **Users** folder.
6. Select **User**.
7. Double click on the user
8. Select **More Actions** or right click.
9. Select **Properties**.
10. Uncheck the **Account is locked out** option.
11. Select **Apply**.
12. Click **OK**.

## Turning System ON and OFF

► **To switch on the console**

1. Plug the power cable into the power adaptor jack of the power supply provided with the system. The medical panel PC unit uses voltage between 100-240 VAC.



**CAUTION**

Use only the power cable that matches the voltage of the power outlet, which has been approved and complies with the safety standard of your particular country.



The power supply is a forming part of the medical device.

2. Connect the appropriate AC power supply adapter output to the rear of the unit (DC IN).
3. Push the power plug of the power cable into the wall power outlet socket.



**WARNING**

If the mains supply is not within the specified range, do not connect the unit to the power source.

4. Make sure to allow sufficient slack in the cable so that the plug is not pulled out of the wall if the system is moved slightly.
5. Make sure that the power outlet socket is located near the equipment and the power plug is easily accessible at all times during use of the equipment.



**CAUTION**

Use only power cord supply cables and plugs provided by Ventripoint to ensure safety and EMC compliance.



**CAUTION**

To help assure grounding reliability, connect to a “hospital grade” or “hospital only” grounded power outlet. Never use an extension cord or adapter plug.

6. Press  (on/off button) on the bottom left of the front control panel of the console. The console power indicator light is illuminated green. After initialization, the Studies screen is displayed.



► **To switch off the console**

Switching off the console when the VMS+ application is closed., the system performs an automatic shutdown sequence. Turning off VMS+ properly is important for system reliability.

1. On the front of the computer, press the power button.



2. Unplug the power cord from the power adaptor jack to disconnect the device from the power source as shown.



## CAUTION

If the system is not going to be in use for an extended period of time, it is recommended that you disconnect the system from the AC mains.

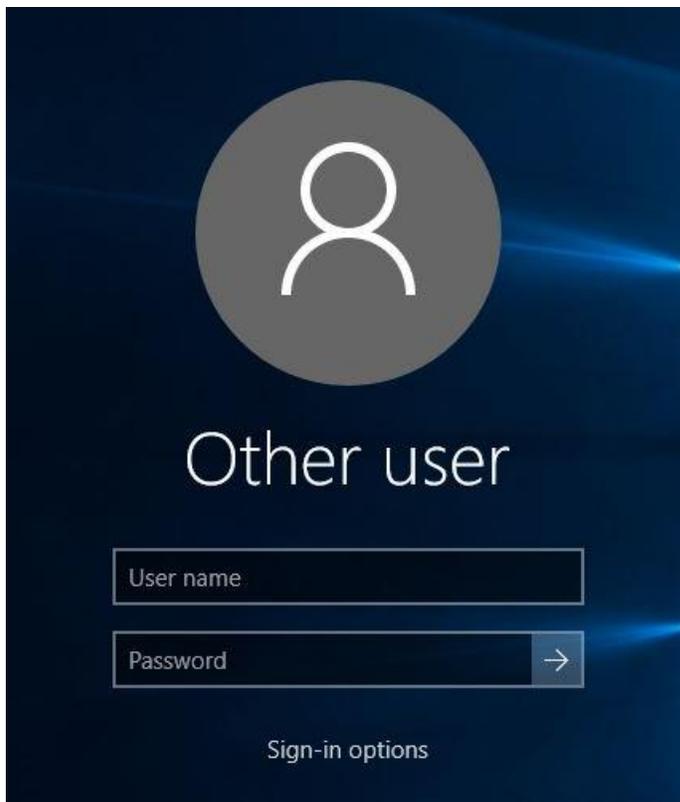
## Getting Started

### User Login

VMS+ requires that you log on to the system with your credentials (user name and password). The log on procedure depends on whether you are signing in to the VMS+ or the Workstation.

#### ► To log on to the System

1. During the turn-on process the system will require the user to enter a password in order to operate it. Personal IDs and associated passwords can be configured in Windows by the System Administrator. See [Creating a new user account](#).
2. The Operator Login Window appears, requesting for an ID and password when Power up sequence is completed, or when it is required.



3. Click **OK**. You are now logged on to the system and the Studies screen is displayed.



### CAUTION

Users have five attempts to enter the correct password. If the incorrect password is entered, the user will be locked out of the system after the fifth attempt. An administrator will be required to reset the user's password.



### CAUTION

Administrators also have five attempts to enter their password. If the incorrect password is entered, the Administrator will be locked out of the system after the fifth attempt. Contact your Ventripoint Service Representative to reset the password.

## Logging off from the System

When you have finished with a patient, you *should* log off from the System.

### ► To log off from the System

1. Click the  **Close** button at the far right of the application toolbar. The VMS+ application closes, and you are logged off from the system

**NOTE** After 30 minutes of inactivity, the VMS+ will automatically log out the current user and display the login screen.

## Adjusting the Touch Screen

Viewing images and other information on the monitor can be affected by lighting in the room. To avoid glare, you can tilt the monitor from its upright position.

Loosen the lever on the back of the monitor. Hold the top of the monitor and the bottom of the monitor and push backward or forward for easy adjustment. The range for tilting the monitor is approximately 15°.

## Connecting VMS+ to Ultrasound

VMS+ is not intended to be permanently connected to an ultrasound machine. When an ultrasound machine is moved from one room to another, it is necessary to disconnect the VMS+ from the ultrasound machine and then reconnect it.

### WARNING



It is the responsibility of the organization responsible for the system to ensure that when connecting the VMS+ to an ultrasound machine that the combined system conforms to the applicable requirements in IEC 60601-1:2005/AMD1:2012. Failure to comply will result in poor performance of either electrical equipment.

### ► To connect the VMS+

1. Connect the video input cable from the VMS+ to the ultrasound system.

2. Connect the Ethernet cable.



### CAUTION

The VMS+ must be configured for each make and model of the ultrasound system and ultrasound transducer probes.

#### ► To disconnect the VMS+:

1. Remove the patient sensor from the patient and place in the sensor holster located on the console
2. Remove the transducer sensor from the transducer sleeve.
3. Remove the transducer sleeve from the transducer.
4. Log off from VMS+.
5. Turn off the system by using the Computer Power button (do not proceed to following step until power light on the computer turns off).
6. Use your thumb and index finger, grip firmly on the power cord to disconnect the main power cable from the electrical socket. Loosely coil the power cable and secure with the hooks on the pole of the rolling stand.
7. Unplug all cables from the ultrasound system that connect to the VMS+.
8. Wrap up unplugged cables and secure them in the cable cleat (i.e. hooks) on the VMS+ pole of the roll stand.
9. Lower the system to its lowest position.
  - a. With your foot, press the lever on the base while simultaneously holding the computer and gently pushing down.



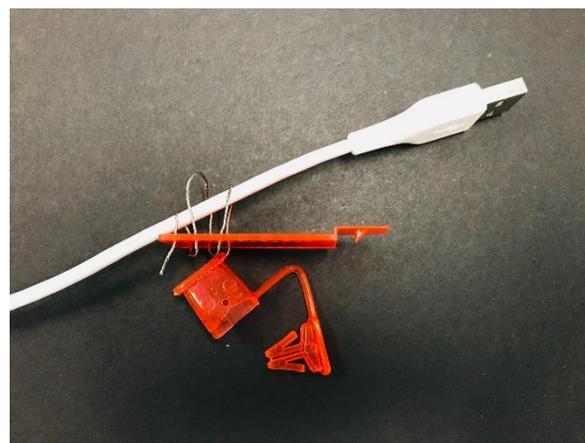
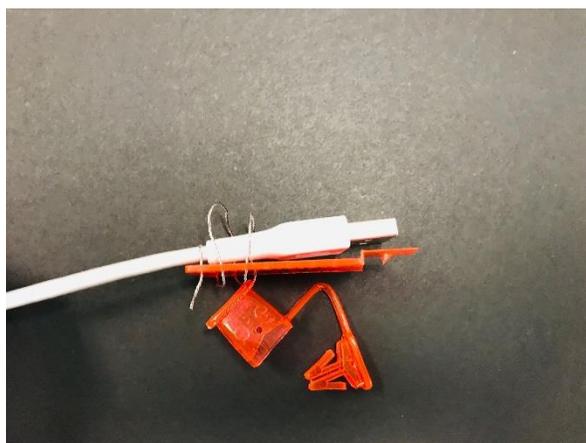
- b. Release your foot when the monitor has reached its minimum height.

## Connecting Sensors to System

1. Keep the USB Sensor separate from each other.
2. Open the USB Cable Lock package.
3. Insert the wire loop through the holes on the USB Cable lock in a loose manner where there is enough space left for the head of the sensor USB cable to slide through it.



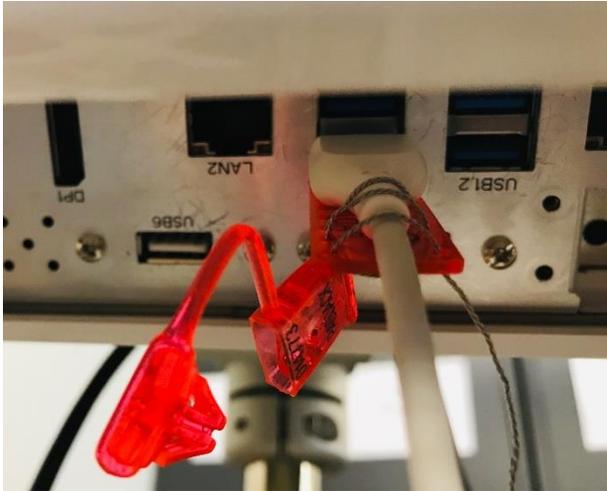
4. Insert the Sensor USB cable through the wire loop, pulling at least 2 inches through the loop, as shown below.



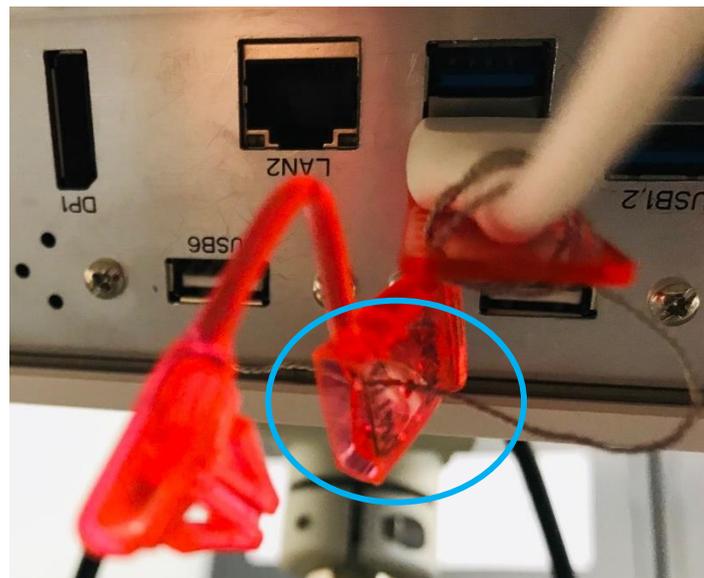
5. Insert USB cable lock into the USB port and lock it in place.



6. Once the USB cable lock is in place slowly pull the USB Sensor cable back bringing the USB connector of the cable close to the USB Port and connect it to the USB Port.



7. Tighten the wire around the USB cable. Put the loose end of the wire loop through the hole on the lock. (You will need a needle- nose plier for this step)



8. Lastly, put the arrow head of the lock in the socket and lock it in place.



9. Repeat the process for second sensor cable.

## Starting a New Study

Beginning a study consists of five steps:

- Creating a new study or patient record (see below)
- Selecting an ultrasound transducer
- Connecting sensors (see [Sensor Setup](#))
- Pairing (see [Pairing the Sensors](#))
- Scanning

### ► To start a new study

1. Go to the Studies screen.

MRN	Name	Birth Date	Scan Date	Study ID	Clinician	Accession #	PACS Status
1	1, 1	2000-01-01	2018-12-13	1202.1301			
VMS-363 A...	S, P	2010-01-01	2018-12-13	1202.1300			
1	1, 1	2000-01-01	2018-12-13	1202.1299			
1	1, 1 1.	2000-01-01	2018-12-13	1202.1294			
vms535	S, P	2010-01-01	2018-12-13	1202.1292			Archived
CirsEgg	IE33-02, Cal...	0001-01-01	2018-12-05	1202.1291			
11	11, 11	1999-11-11	2018-12-05	1202.1290			
timeout test	s, p	2010-01-01	2018-12-03	1202.1284			
SANITY	S, P	2010-01-01	2018-12-03	1202.1272			
45567	hirson, res	1961-12-11	2018-11-29	1202.1253			
fff	jones, 7777	2018-11-15	2018-11-15	1234.1288		5555	
44555	test2, kingst...	2018-11-14	2018-11-14	1234.1280			
546456	test, kingston	2018-11-14	2018-11-14	1234.1279			
33333	hirson, des	2018-11-13	2018-11-13	1234.1276			
vps005 4 ch...	hirson, des	2018-11-01	2018-11-01	1234.1225	User		
vps004 LV ...	hirson, des	2018-11-01	2018-11-01	1234.1224			
vps002	hirson, des	2018-11-01	2018-11-01	1234.1222		111	

2. Select New.



3. The Patient Information screen is displayed.

**New Study**    Patient Information

<p>* MRN <input style="width: 100%;" type="text"/></p> <p>Accession # <input style="width: 100%;" type="text"/></p> <p>* First Name <input style="width: 100%;" type="text"/></p> <p>Middle Name <input style="width: 100%;" type="text"/></p> <p>* Last Name <input style="width: 100%;" type="text"/></p>	<p>Height <input style="width: 30px;" type="text"/> cm / <input style="width: 30px;" type="text"/> feet <input style="width: 30px;" type="text"/> in.</p> <p>Weight <input style="width: 30px;" type="text"/> kg / <input style="width: 30px;" type="text"/> lbs</p> <p>Heart Rate <input style="width: 30px;" type="text"/> BPM</p> <p>Blood Pressure <input style="width: 30px;" type="text"/> / <input style="width: 30px;" type="text"/> mmHg</p> <p>* Gender <input style="width: 100%;" type="text"/></p> <p>* Birth Date <input style="width: 30px;" type="text"/> YYYY <input style="width: 30px;" type="text"/> MM <input style="width: 30px;" type="text"/> DD</p> <p>* Analysis <input style="width: 100%;" type="text"/></p> <p style="color: red; font-size: small;">* Required Fields</p>
---	---

4. Fill in the fields. Required fields are marked by a red asterisk:

- \*MRN: Type the patient's Medical Record Number (hospital-provided).
- Accession: Type the patient's Accession number (hospital-provided).
- \*First Name: Type the patient's first name.
- Middle Name: Type the patient's middle name.
- \*Last Name: Type the patient's last name.
- \*Gender: Select Male, Female or type another option in the text box provided.

- **\*Birth Date:** Select the month, day, and year in which the patient was born.
- **\*Analysis:** Select the patient's analysis type from the drop-down menu. Available options include: Standard Analysis, Tetralogy of Fallot (TOF), RV to PA Conduit, HLHS, D-TGA (Atrial Switch), and PAH.

Additional information can be entered and reviewed from the 2D, 3D or Report screens by selecting the  on the application toolbar. The additional fields are listed below:

- **Blood Pressure:** Enter the patient's blood pressure.
  - **Heart Rate:** Enter the patient's heart rate.
  - **Height:** Enter the patient's height. Enter the height in either imperial or metric and the other field will populate automatically.
  - **Weight:** Enter the patient's weight. Enter the weight in either imperial or metric and the other field will populate automatically.
  - **Facility:** Displays the facility in which the patient is being examined. This information is configured at the time of installation and cannot be modified.
  - **Clinician:** Displays the name of the user who is currently logged in to the system and cannot be modified.
  - **Referring MD:** Type the name of the physician who referred the patient.
5. Select **Next**. The Next button will only be enabled when all the Required fields are filled in.
  6. The Sensor Setup screen is displayed. Attach the transducer sleeve to the transducer, slide the transducer sensor onto the transducer sleeve, then place the patient sensor on the patient. See [Sensor Setup](#).
  7. After setting up the sensors, both sensors must be paired. See [Pairing](#).

**NOTE** The list of available transducers is configured when the system is installed. Each facility will determine the set of transducers that will be available for each VMS+.

## Sensor Setup



### CAUTION

Prior to acquiring first image, optimize the ultrasound system for a single imaging depth that will be used for all acquired images.



### CAUTION

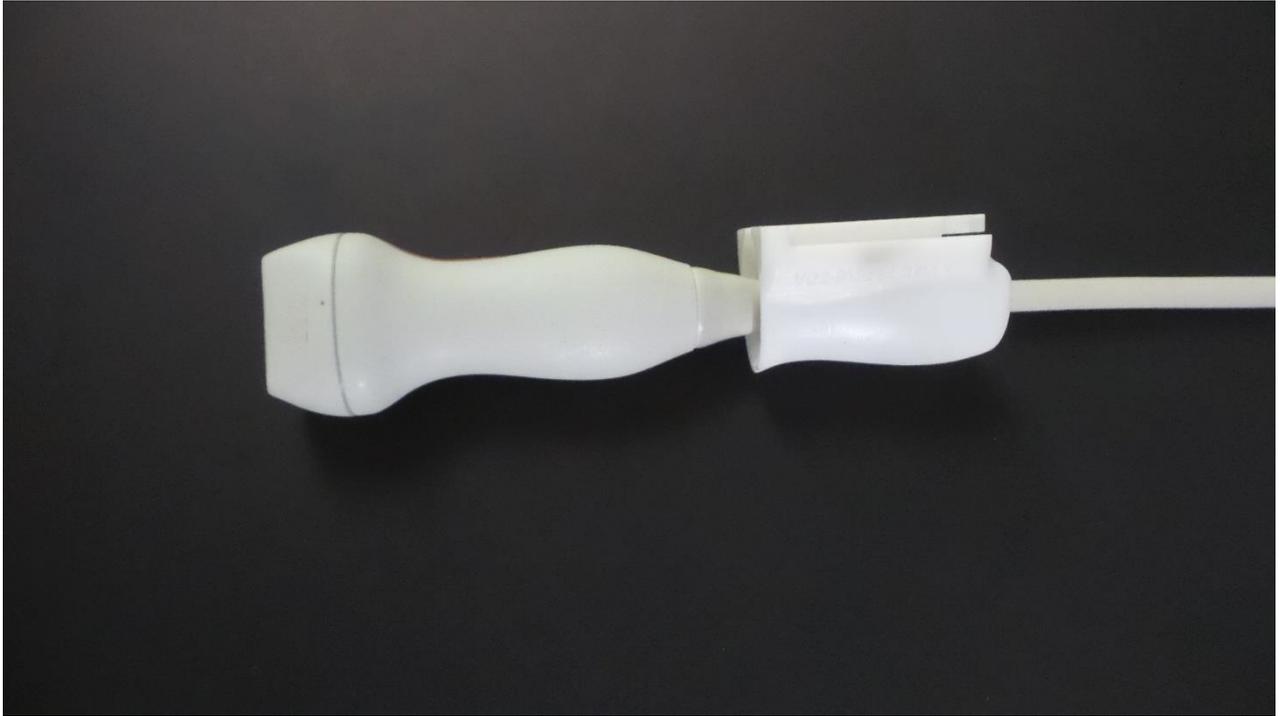
The sensors are to be kept at least 5 cm apart at all times. Placing the sensors at less than 5 cm for more than 10 seconds magnetizes the sensors. When not in use, sensors should be stored in sensor holsters located on either end of the system monitor.



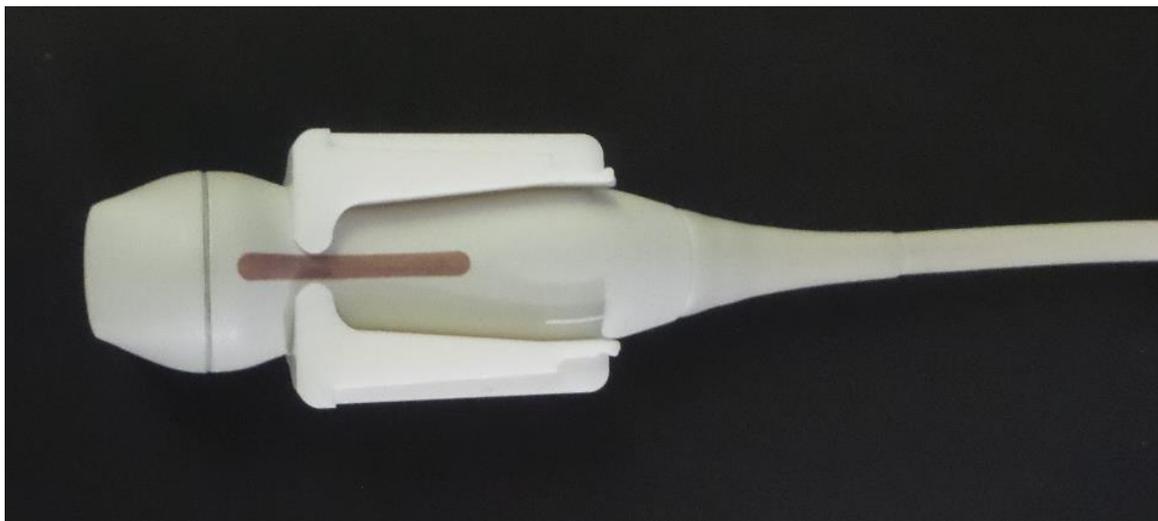
### CAUTION

Sensors should not be unplugged from system and should remain plugged in when not in use.

1. Select your ultrasound transducer from the drop-down menu.
2. Attach the transducer sleeve to the transducer by sliding the transducer sleeve onto the transducer cable.



3. Snap the transducer sleeve onto the body of the transducer.





**CAUTION**

The orientation of the transducer sleeve on the transducer is very important for acquisition. The proper orientation is to have the opening of the transducer sleeve on the same side as the transducer indicator.

4. Slide the transducer sensor onto the transducer sleeve.



## Preparing the Patient

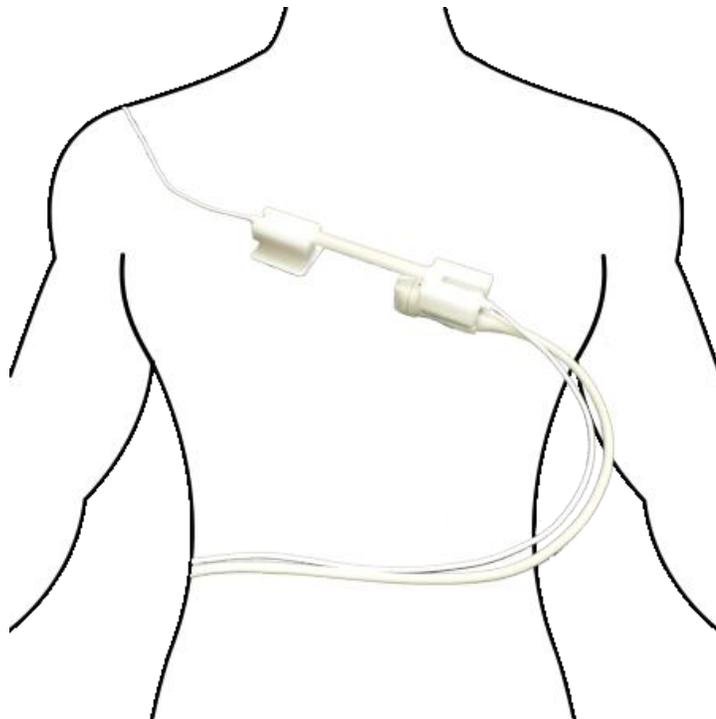
### ► To prepare the patient

1. Take care to remove ferrous items (jewelry, coins) from patient and Clinician.
2. Attach one Sensor Adhesive Pad to the back of the Patient Sensor. See [Attachment of Sensor Adhesive Pad](#) for more information on the scanning process.
3. Attach the Patient Sensor to the Patient. Choose a spot on the right side of the patient's sternum where the patient sensor can be securely anchored and will be at least 5 cm away from the transducer sensor at all times during scanning. Drape the cable from the patient sensor over the patient's right shoulder as shown below.



### WARNING

Do not touch any ports (e.g. USB or DVI) while simultaneously touching the patient.



## Attachment of Sensor Adhesive Pad

Sensor Adhesive Pads are used to attach the Patient Sensor to the patient's skin.

**CAUTION**

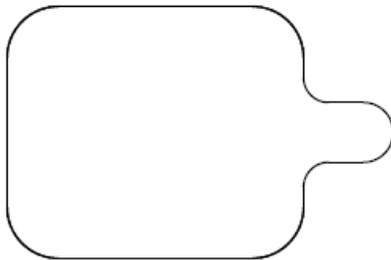
Before each patient exam, attach a new sensor adhesive pad to the Patient Sensor.

**CAUTION**

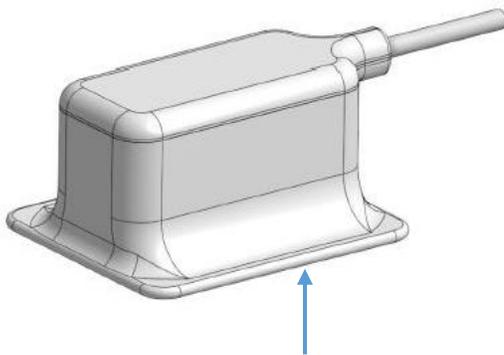
The Patient Sensor must be cleaned when the sensor adhesive pad is removed and before a new one is applied. See [Transducer Sleeve, Transducer Sensor, Patient Sensor, and Pairing Baton Maintenance](#).

**► To attach a sensor adhesive pad**

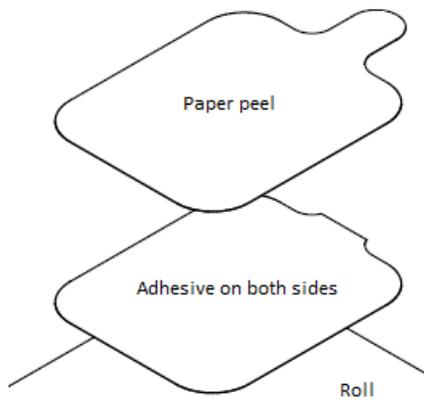
1. Ensure that any previous sensor adhesive pads are removed and the Patient Sensor has been thoroughly cleaned.
2. Remove one sensor adhesive pad from the roll, exposing one adhesive side of the pad for adhesion to patient contacting surface of the patient sensor.



3. Press the sensor adhesive pad firmly in place to the bottom of the patient sensor, ensuring full contact over the entire surface area.



4. Pull on the tab end to remove liner and expose other adhesive surface for application to patient.



5. Place the Patient Sensor on the patient. See [Preparing the patient](#).

### Patient Sensor Placement Guide

1. Select the **Patient Sensor Placement** button. A Patient Sensor Placement screen is displayed.



When the Patient Sensor is not in range.



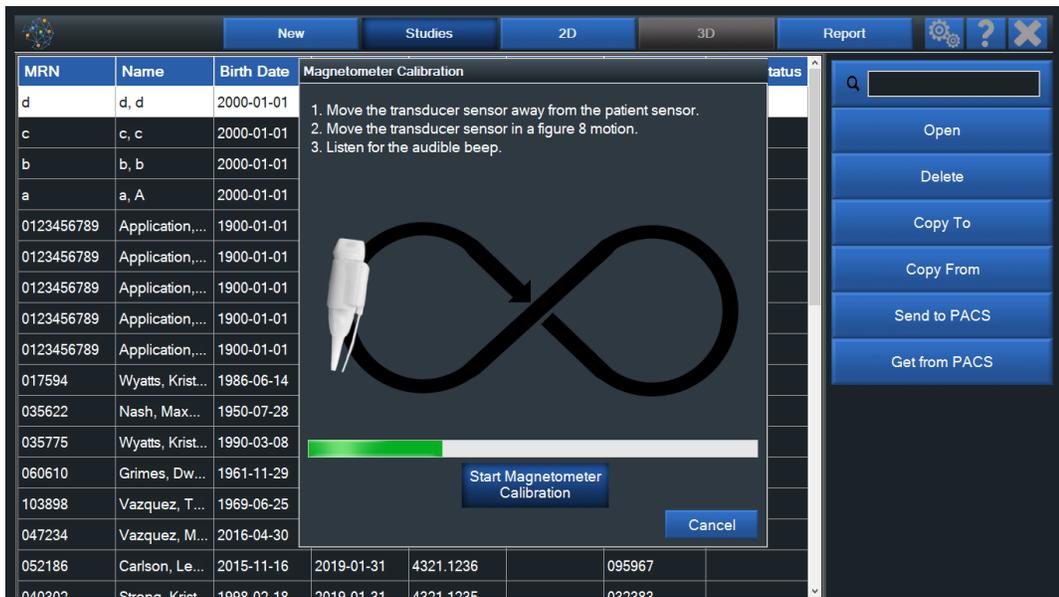
When the Patient Sensor is in range.

2. Place the patient sensor on the patient in the location that you think is ideal for scanning of the apicals and parasternals. See [Preparing the Patient](#). Move the transducer sensor to the different windows of interest as shown and check if the signal is valid.
3. As you move to the different windows, the display will show “**IS In Range**” in green to indicate that the sensors are in range or “**NOT In Range**” in red if the sensors are not within range.
4. Once you are satisfied with the location of the patient sensor, select **Cancel** to close the Patient Sensor Placement screen.
5. Select **Next** to proceed to Pairing screen.

## Magnetometer Calibration

1. If pairing is not successful after 30 seconds, a Magnetometer Calibration screen will be displayed.
  - a. Select the **Start Magnetometer Calibration** button.
  - b. Move the transducer sensor about 0.5 metres away from the patient sensor, but still within the working area of the bed.
  - c. To calibrate, move the transducer sensor in a figure 8 motion until you hear the audible beep signalling that the calibration is successful.

Ensure you keep the sensor attached to a transducer. While the calibration is taking place, the transducer sensor will blink orange and green continually until the calibration is complete.



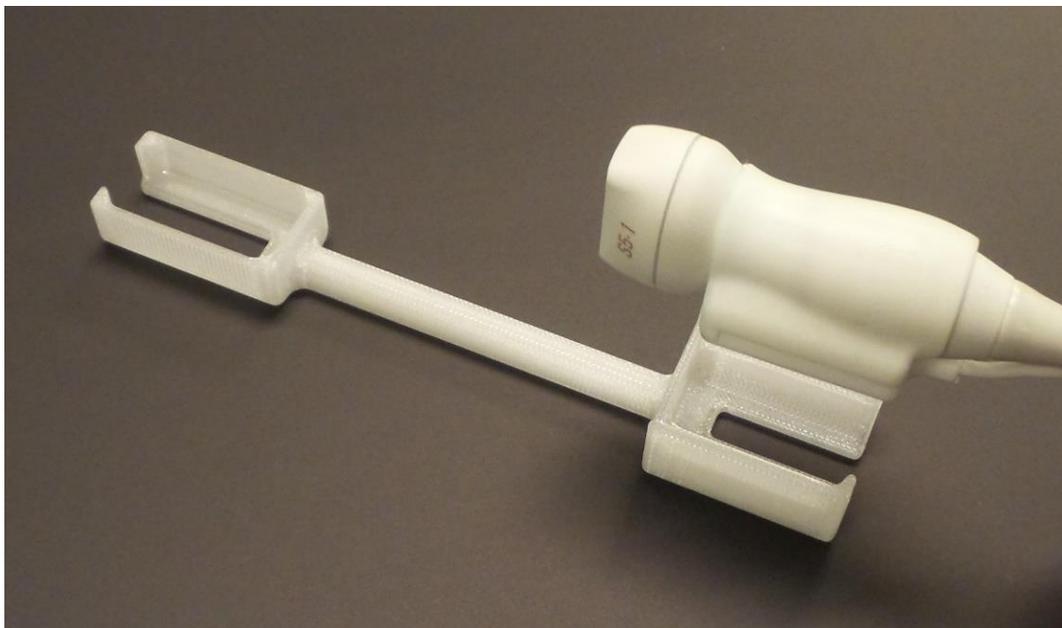
d. If the Magnetometer Calibration is successful, select Cancel. the Pairing screen is displayed. Clip both the transducer sensor and patient sensor into the pairing baton slots. Pairing will be completed automatically when successful.

2. The Scan screen will be displayed, and you can acquire scans.

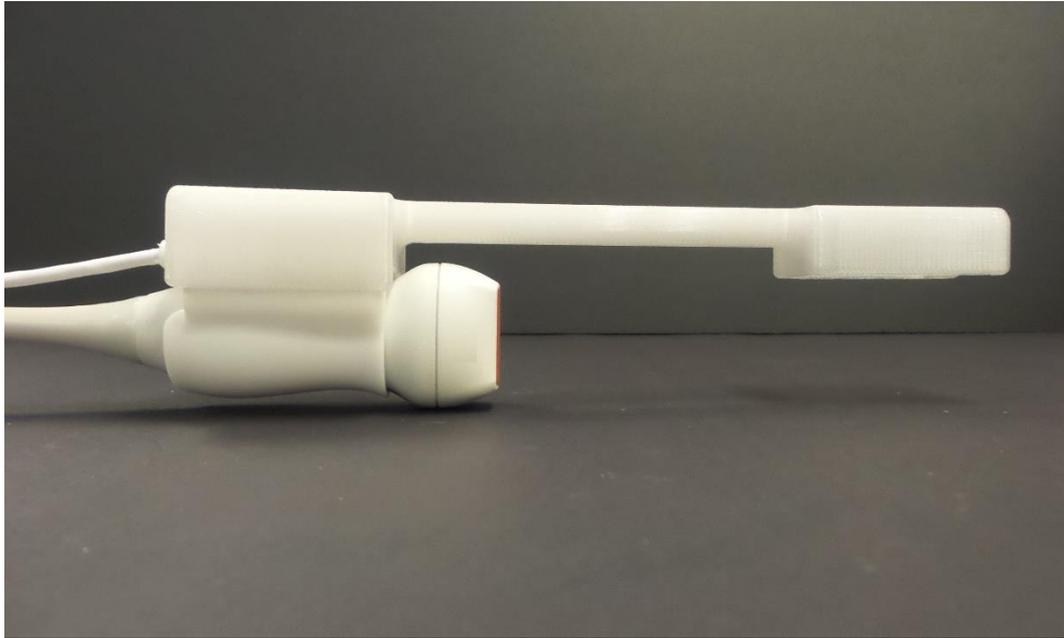
### Pairing the Sensors

1. Clip the transducer sensor into the pairing baton slot.

A



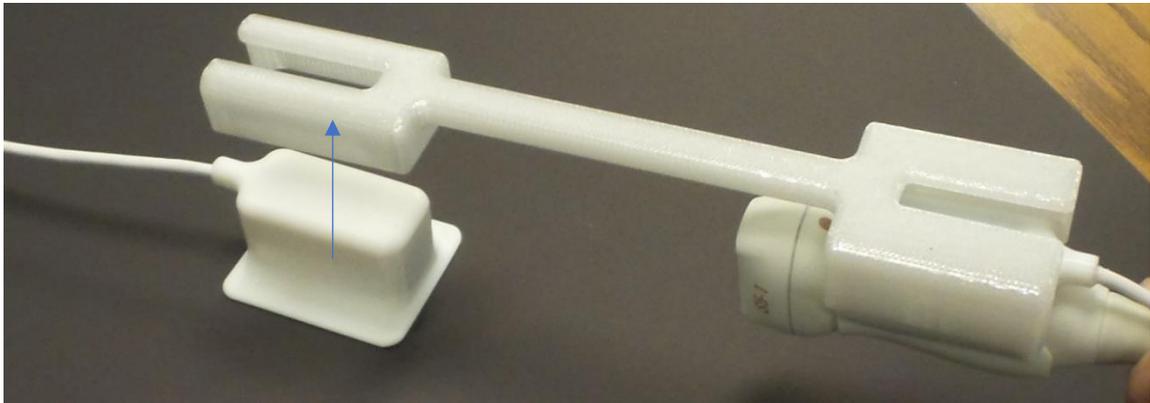
B



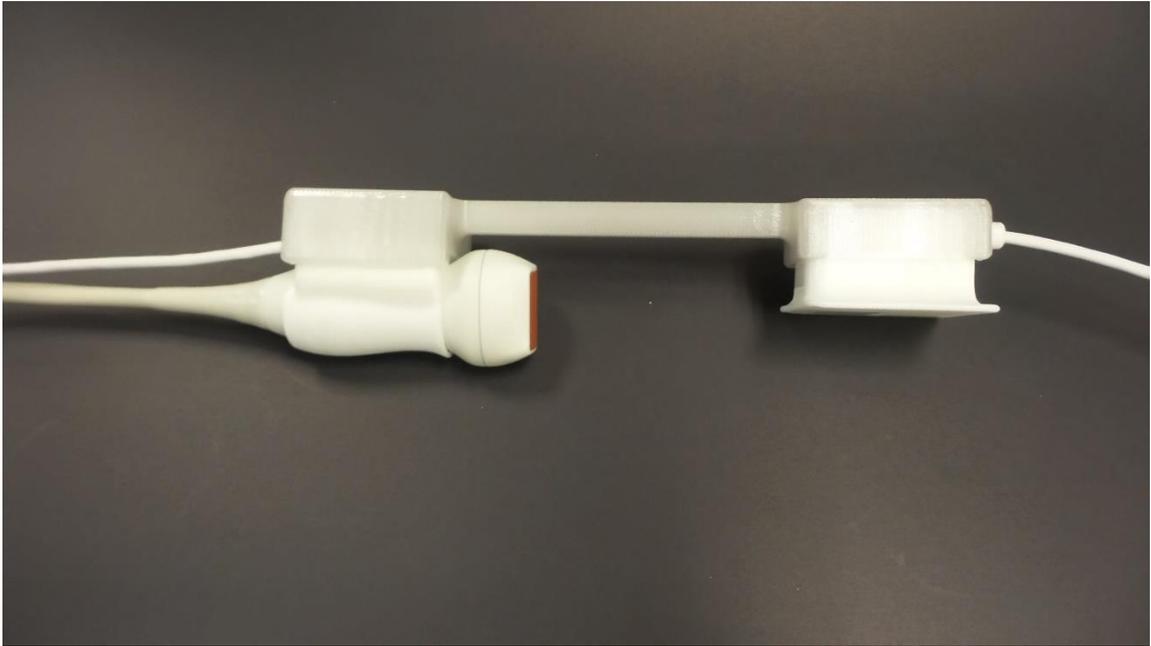
**NOTE** Transducer sensor LEDs will be orange when the system is turned on.

2. Slide the baton onto the patient sensor.

A



B



**NOTE** Patient sensor LEDs will be orange when the system is turned on.

3. Once the setup is complete, pairing will happen automatically. Both the transducer sensor and patient sensor will turn from orange to green when pairing is successful.

**NOTE** Both the transducer sensor and patient sensor LEDs will be orange until pairing is successful. Both sensor LEDs will turn from orange to green when pairing is successful.

4. Once the pairing is complete, the Scan screen is displayed. See [Capturing Scans](#) for more information on the scanning process.

## Using the VMS+ Software

### Overview

The VMS+ software is organized in screens as follows:

1. [Studies](#)
2. [2D](#)
3. [3D](#)
4. [Report](#)

After you create a new study or open an existing study, you can use the application toolbar to move back and forth between screens.

**NOTE** The New button and Scan Screen are not available on the Workstation.

The application toolbar buttons located at the top of the VMS+ program window have three states to help you navigate through the screens:



The current screen is dark blue and the button on the application toolbar will appear 'pressed in'.



The current screen is light blue and the button on the application toolbar will appear enabled



Disabled screens or tools (i.e. noninteractive component or element) are gray .

### Application toolbar

Located along the top of the VMS+ program window:



Use this button when you want to create a new study.



Opens the Studies screen. Use this screen to create a new study, open an existing study, delete a study, copy a study to or from a USB or network location, and archive or retrieve a study to or from PACS.



Opens the 2D screen. Use this screen to select your end diastolic (ED) and end systolic (ES) frames and mark anatomical structures according to Ventripoint Point Placement Guide.



Opens the 3D screen. Use this screen to view the generated 3D model and use tools to validate the quality of reconstruction and the overall coverage of the heart chambers.



Opens the Report screen. Use this screen to add study information, review the analysis and save the report to a USB.

### Application controls

Button	Name	Function
	<b>System Settings</b>	Opens the System Settings. Includes a Scan tab (for System only), General tab and PACS tab. See <a href="#">System Settings</a> for tab details.
	<b>Help</b>	Opens the Help and Support screen. Access the VMS+ User Manual PDF, Support Contact Information and Remote Assistance.

	<b>Minimize</b>	Only available on the Workstation. Minimize the application to your PC's taskbar.
	<b>Close/Log out</b>	On the Console, this button logs out the current user. On the Workstation, this button closes the application.

## Studies Screen

The studies screen in [Figure 1](#) appears after you log into the system.



MRN	Name	Birth Date	Scan Date	Study ID	Clinician	Accession #	PACS Status
1	1, 1	2000-01-01	2018-12-13	1202.1301			
VMS-363 A...	S, P	2010-01-01	2018-12-13	1202.1300			
1	1, 1	2000-01-01	2018-12-13	1202.1299			
1	1, 1 1.	2000-01-01	2018-12-13	1202.1294			
vms535	S, P	2010-01-01	2018-12-13	1202.1292			Archived
CirsEgg	IE33-02, Cal...	0001-01-01	2018-12-05	1202.1291			
11	11, 11	1999-11-11	2018-12-05	1202.1290			
timeout test	s, p	2010-01-01	2018-12-03	1284			
SANITY	S, P	2010-01-01	2018-12-03	1202.1272			
45567	hirson, res	1961-12-11	2018-11-29	1202.1253			
ffff	jones, 7777	2018-11-15	2018-11-15	1234.1288		5555	
44555	test2, kingst...	2018-11-14	2018-11-14	1234.1280			
546456	test, kingston	2018-11-14	2018-11-14	1234.1279			
33333	hirson, des	2018-11-13	2018-11-13	1234.1276			
vps005 4 ch...	hirson, des	2018-11-01	2018-11-01	1234.1225	User		
vps004 LV ...	hirson, des	2018-11-01	2018-11-01	1234.1224			

Figure 1 Studies Screen

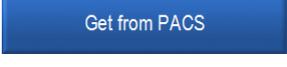
- 1 Studies list.
- 2 Application toolbar buttons. See [Application toolbar buttons](#).
- 3 Application controls. See [Application controls](#).
- 4 Studies screen buttons.



Search the entire Studies list by entering text. The Studies list is filtered by what you enter in the text field.



Opens the highlighted study from the Studies list.

	Deletes one or more studies from the Studies list.
	Copy a study to a USB or Network Location. Only displayed if enabled on the General tab in System Settings.
	Copy a study from a USB or Network Location. The copied study is added to the Studies list. Only displayed if enabled on the General tab in System Settings.
	Clone a study that already exists in the Studies list. Only displayed if enabled on the General tab in System Settings. You cannot clone a cloned study.
	Send DICOM studies to PACS. Only displayed if enabled in the PACS tab in System Settings.
	Retrieve DICOM studies from PACS. DICOM studies are added to the Studies list. Only displayed if enabled in the PACS tab in System Settings.
	Only available on the Workstation. Imports MRI data and adds the study to the Studies list. Only displayed if enabled on the General tab in System Settings.
	Only available on the Workstation. Imports 3D echo data and adds the study to the Studies list. Only displayed if enabled on the General tab in System Settings.

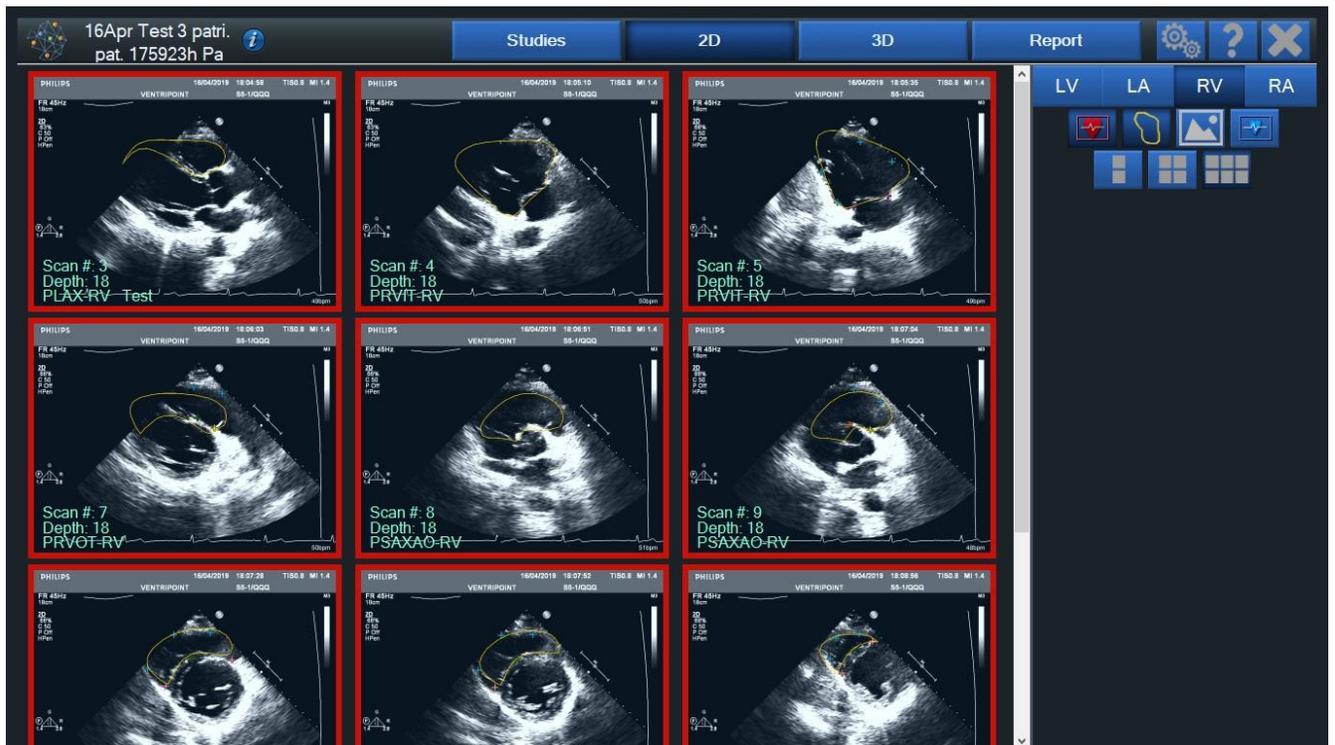
## Reviewing a Study

### ► To review a study

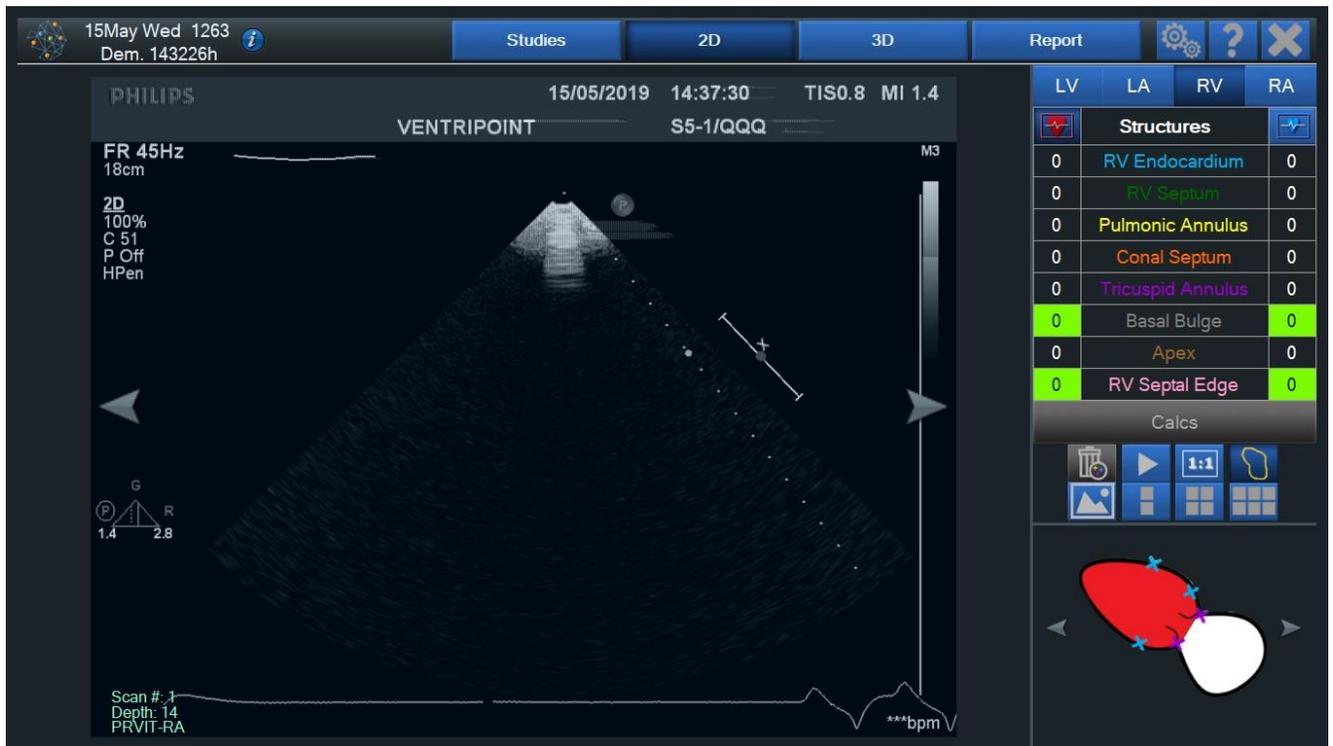
1. Go to the Studies screen.



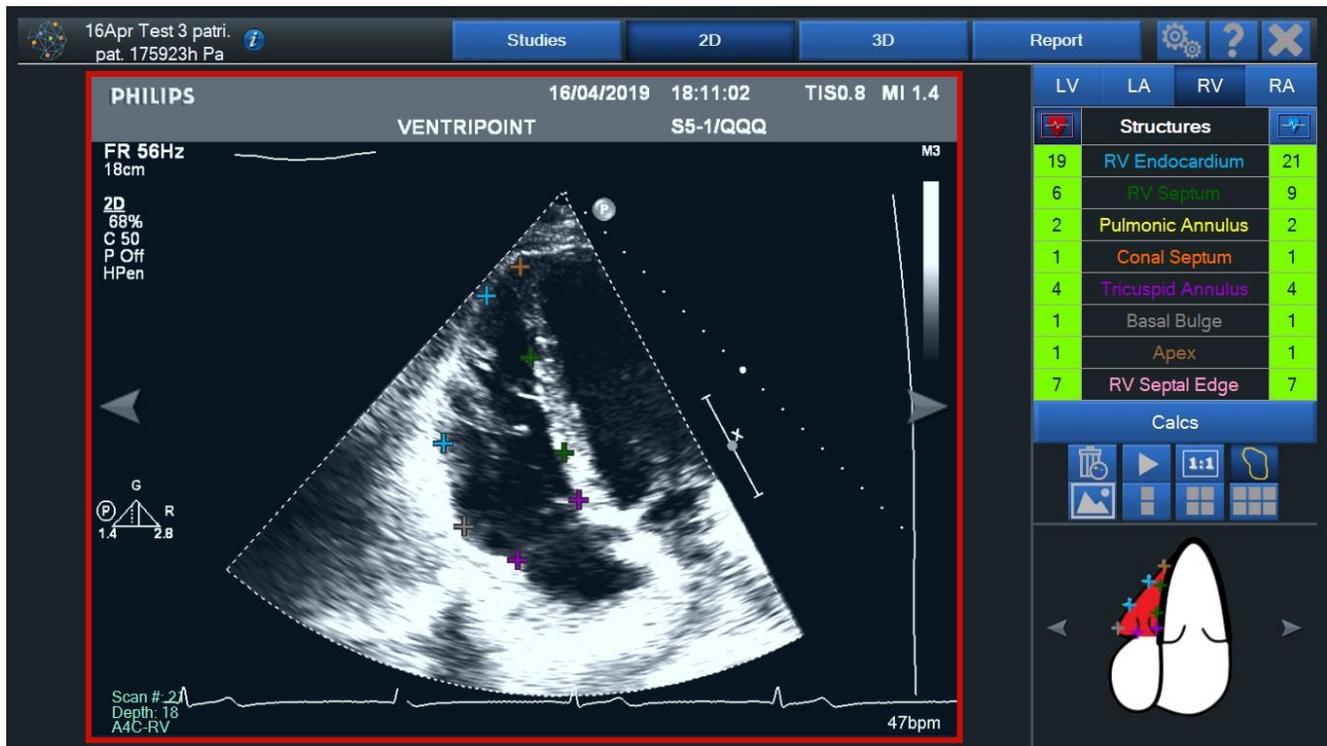
2. Select a study row to highlight it (see top row in image above highlighted in white).
3. Select **Open**. Study is loaded into the 2D screen thumbnail view, see image below.



4. Select a thumbnail. Image is loaded into the 2D screen single image view.



5. Add, edit and/or delete anatomical structure points selected from the Structures table. See [Selecting ED and ES Frames and Anatomical Structures](#).
- 6.
7. When enough points have been placed according to the [VMS+ Image Acquisition Protocol](#), the **Calcs** button becomes enabled.



8. Select Calcs. The 3D screen is displayed. Review the calculations, enabled/disable some of the 3D tools, see [Reviewing the 3D Model](#).

## Opening a Study

### ► To open a study

1. From the Studies screen:
  - a. Select a study from the list on the main workspace then select **Open**.
  - b. On a Console, double-tap or double-click the study row that you want to open. On a Workstation, double-click a study row that you want to open.
2. The selected study is opened in the 2D screen.

## Deleting a Study

### ► To delete a study

1. In the studies list, select the study that you want to delete.
2. Select **Delete**. A message appears, asking whether you are sure that you want to delete the study.
3. Select **Yes** to delete the selected study, or **No** to keep the selected study.

**NOTE**

The VMS+ console hard drive has enough storage for approximately 50 studies. Once the hard drive reaches a minimum threshold, the system will warn that space is low. Please move studies off of the VMS+ as soon as possible. Once the hard drive reaches critical space, the VMS+ will not allow further scanning.

## Cloning Studies

Cloning enables you to make an exact duplicate of an existing study apart from the study identification. Once you make a clone, you will have two different studies with the same images and patient demographics.

**NOTE**

You can only clone a study if the Cloning feature is enabled in Settings. For more information, see [Settings](#).

**NOTE**

Cloning copies all data and information to the cloned study, but it does not copy the Calculations. Calculations must be run for each chamber using the **Calcs** button.

► **To clone a study**

1. From the Study screen, select a study from the studies list.
2. Select **Clone**. A dialog is displayed.
3. Verify that you wish to continue with cloning by selecting **Yes** on the dialog. A progress bar will be displayed during the cloning process.
4. When the clone has been created, a dialog will be displayed showing success or failure. The dialog will also display the new cloned study ID and the study ID from which it was cloned.
5. (Optional) Open the clone and go to the Report Screen. The original study ID, the user who cloned the study, and the clone date will be displayed in the Study Information text box.

## Copying a Study

Studies should not be stored long-term on the VMS+ console. The VMS+ enables storing of data to external databases (Network Server, removable media). Use the Studies screen to move one or more studies from your local system to a mapped drive or USB device or add a study from a mapped drive or USB device to the System. The system provides USB ports that can be used to connect USB storage devices.

**CAUTION**

VMS+ system may become vulnerable to security breaches when it accepts removable media. Removable USB storage devices may contain viruses and/or malware. Ventripoint recommends that you use newly formatted USB storage devices.



### CAUTION

Ventripoint does not recommend that the use of USB storage devices for long-term storage/archiving. Follow your IT department's recommended practices for intended use of USB storage devices.

### NOTE

Copying a study to another location does not remove the local copy from the System. To make additional space on the System's hard drive, you must manually delete studies that you no longer want in the studies list.

### NOTE

The system supports the following USB devices: Single-partition USB flash memory drives, USB flash memory drives that do not use or contain any antivirus or other executable software, USB hard drive devices, and USB 2.0 compliant devices. You can only copy to or from one device at a time.

#### ► To copy a study to a mapped drive or USB device

1. On the Studies screen, select the study that you want to copy.
2. Select **Copy To**. A copy dialog is displayed. The dialog displayed includes available mapped drives, USBs and the amount of space required, if you do not have enough space, the copy process will not proceed.
3. Select a mapped drive or USB device.
4. Select **OK** to continue with copying or **Cancel** to cancel copying.

**NOTE** You can only copy a study to/from a USB device if the Copy To/Copy From features are enabled in Settings. For more information, see [Settings](#).

5. If the study already exists on the mapped drive or USB, an overwrite dialog is displayed. Select **OK** to replace the existing version with the current version or **Cancel** to cancel the copy procedure.
6. After the study has been copied successfully, a copy success dialog is displayed.
7. Select **OK**. The study is now on the mapped drive or USB.

#### ► To copy a study from a mapped drive or USB device

1. On the Studies screen, select **Copy From**.
2. A copy dialog is displayed. The dialog displayed includes available mapped drives, USBs and the amount of space required, if you do not have enough space, the copy process will not proceed.
3. Select a study from the mapped drive or USB device.
4. Select **OK** to continue with copying or **Cancel** to cancel copying.

You will only be able to copy from a mapped drive if a mapped drive was configured for your system at time of installation. Only one mapped drive shall be available per System.

5. If the study already exists on the mapped drive or USB, an overwrite dialog is displayed. Select **OK** to replace the existing version with the current version or **Cancel** to cancel the copy procedure.
6. After the study has been copied successfully, a copy success dialog is displayed.
7. Select **OK**. The study is added to the studies list.

#### WARNING



It is your responsibility to ensure that the security of your device and the protection of patient data meet your local security policies and regulatory requirements. Before copying studies, consult your healthcare IT security department to ensure that you are in compliance with your department's specific policies and regulations regarding the handling of patient information.

### Sending Studies to PACS

**NOTE** You can only send a study to PACS if the Enable PACS feature is enabled in Settings. For more information, see [Settings](#).

#### ► To send a study to PACS

1. On the Studies screen, select a study that you want to send.
2. Select **Send to PACS**. A send to PACS confirmation dialog is displayed.
3. Select **OK** on the dialog to continue to send to PACS or **Cancel** to cancel the operation.
4. A send to PACS progress dialog is displayed.
5. The Status column in the studies list will now be populated with either of the following:
  - a. Failed – Study was not sent to PACS successfully. Contact your Administrator or IT Department.
  - b. Archived – Study was successfully sent to PACS.

### Getting Studies from PACS

**NOTE** You can only get a study from PACS if the Enable PACS feature is enabled in Settings. For more information, see [Settings](#).

#### ► To get a study from PACS

1. On the Studies screen, select **Get from PACS**. A Search DICOM server dialog is displayed.
2. You can search for your study by entering data into any or all the following fields:
  - a. Study ID
  - b. MRN
  - c. Accession #
  - d. First Name
  - e. Last Name

**NOTE** At least three (3) characters must be entered into at least 1 text box for the search operation to be launched. Otherwise, an error message will be displayed.

**NOTE** The study ID is case-sensitive.

**NOTE** Limited to 260 characters for Study ID naming.

3. Select **Search**. One of the following statuses is displayed beside the search button:
  - Ready – displayed when the Search DICOM server dialog is opened.
  - No studies were found – displayed when no studies were found on the DICOM server.
  - Retrieved too many studies. Please limit your search query – displayed when more than 30 studies were found for the information entered
  - Retrieved studies – displayed when less than 30 studies were found.
4. When the list is populated, select to highlight a study. Retrieve button is activated when a study is selected from the list.
5. Select **Retrieve**. The following additional statuses could be displayed beside the search button:
  - Retrieving study – displayed when the study is being retrieved.
  - OK – displayed when the study has been imported successfully.
  - Could not import study from PACS – displayed when retrieving fails.
6. (Optional) Select **Cancel** on the DICOM server dialog to cancel the retrieval.
7. If the study being retrieved already exists in the current studies list a dialog will be displayed to notify you and the study will not be retrieved. Select **OK** to return to the Search DICOM server dialog or **Cancel** to dismiss the get from PACS process.
8. When the Get from PACS retrieval process has completed, a success dialog will be displayed. Select **OK**.
9. The study is added to the current studies list and the Status column is updated with Retrieved.

## Importing MRI

Importing MRI is a feature that is only available on the Workstation.

**NOTE** You can only import an MRI if the Importing MRI feature is enabled in Settings. For more information, see [Settings](#).

► **To import an MRI**

1. From the Studies screen, select **Import MRI**. Windows Explorer is displayed.
2. Open the folder with the MRI data you want to import and select the “DICOMDIR” FILE residing in the folder.
3. Select **Open**. A progress bar will be displayed.
4. (Optional) Select **Cancel** on the progress bar dialog to cancel import of the MRI.
5. A Selection Step dialog will be displayed. Before the import starts, you must select what thumbnails/images of the MRI you wish to import. Choose the default selection section to set to “ALL” or “NONE”. A green border will be displayed around the thumbnails/images that you have selected to import. Select or unselect thumbnails by clicking them as desired. You can modify the outlay of the thumbnails in the dialog window using the grid switch buttons in the left upper corner of the window.
6. Select **Next**. A Ready to Import! dialog is displayed.
7. Confirm the number of selected scans and then select **FINISH** on the **Ready to Import!** dialog.

**NOTE** You can abort the process or return back and modify your selections by selecting the Cancel and Back buttons, respectively.

8. The Patient Information screen is displayed. Enter the required patient information (indicated by red asterisks).
9. Select **OK**. A progress bar will be displayed.
10. (Optional) Select Cancel on the progress bar dialog to cancel import of the MRI.
11. The Patient Information dialog is displayed.
12. Once all required fields are entered, the dialog is dismissed and the Studies screen is displayed. The MRI study is added to the Studies list.
13. Load the study to the 2D screen and select a thumbnail to load into single image view.
14. Select points from the structures table, run calculations and review the results in the 3D screen. See [Selecting ED and ES Frames and Anatomical Structures](#) for more details.

## Importing 3D Echo Images

Importing 3D Echo images is a feature that is only available on the Workstation.

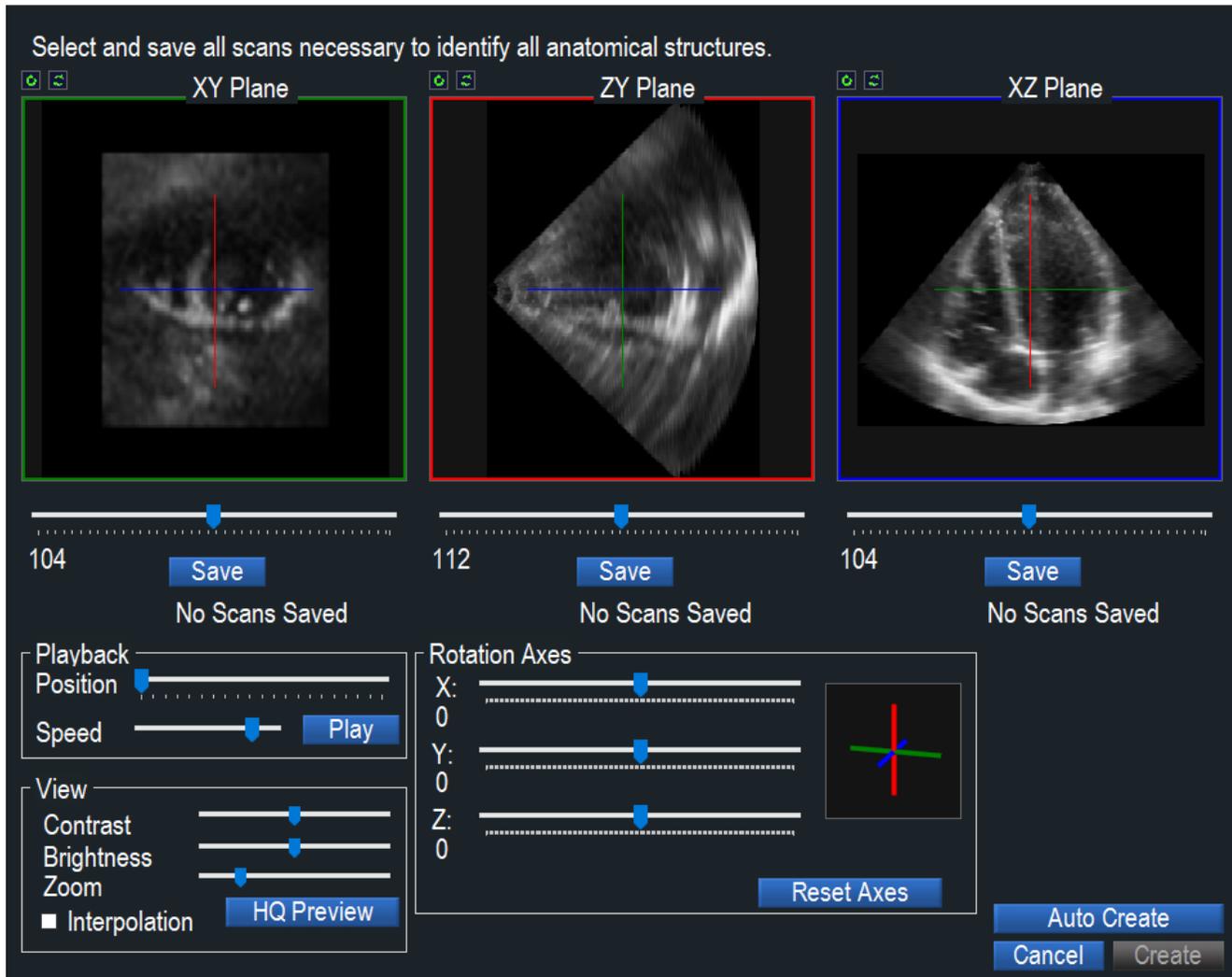
**NOTE** You can only import a 3D Echo image if the Importing 3D Echo feature is enabled in Settings. For more information, see [Settings](#).

► **To import a 3D Echo image**

1. From the Studies screen, select **Import 3D Echo**. Windows Explorer is displayed.
2. Find and highlight the 3D Echo you want to import. 3D Echo's must be in a \*.dcm file format.
3. Select **Open**. A progress bar is displayed.

**NOTE** If the selected file is corrupted or in a work format, the following message is displayed:  
"Cannot load 3D echo file. Select OK button to return back to the Studies list.

4. (Optional) Select **Cancel** on the progress bar dialog to cancel import of the 3D Echo.
5. A 3D Echo dialog is displayed.
6. The 3D Echo dialog includes many options and steps to ensure that the data you import are necessary to identify all anatomical structures.
  - a. 3 scan plane windows are displayed. XY Plane, ZY Plane and XZ Plane. Use the cine bar slider beneath each window to select your scan, then select **Save**.
  - b. You can choose to playback the images in the Plane windows, by selecting **Play** in the Playback section. You can also select the cine loop position where playback begins and at what speed playback should be.
  - c. Edit the brightness and contrast by using the Brightness and Contrast sliders in the View section.
  - d. Zoom the images by using the Zoom slider in the View section.
  - e. Select Interpolation
  - f. Select HQ Preview to see the images in the Plane windows in High Quality.
  - g. Edit the axes for each plane by using the X, Y and Z sliders in the Rotation Axes section. If you do not like your edits, just select the **Reset** button to reset the axes to their original setting.
  - h. Flip the images around the axis depicted on them either by clicking two orientation flip buttons above the upper left corner of the images or by clicking the axis' representation on the images themselves.



7. (Optional) Allow the VMS+ software to create scans for the import by selecting **Auto Create to import all available scans**.
8. Select **Create** when you have selected all your scans.
9. (Optional) Select **Cancel** to cancel import of the 3D Echo.
10. A 'Generating...' progress bar will be displayed. The total number of scans saved will also be displayed.
11. The Patient Information screen is displayed. Enter the required patient information (indicated by red asterisks).
12. Select **OK**.
13. (Optional) Select **Cancel** to cancel the import of the 3D Echo.
14. The 3D Echo is displayed in the 2D screen.
15. Select points from the structures table, run calculations and review the results in the 3D screen. See [Selecting ED and ES Frames and Anatomical Structures](#) for more details.

## Scanning

Use the Scan screen to capture and review 2D scans of the patient's heart. For more information about proper setup of the patient and the scanning equipment, see the [Quick Start](#).

The default scan duration is 2 seconds. If necessary, you can change the duration on a per-patient basis. See [System Settings](#).

### Scan Screen

Use the Scan screen seen in [Figure 2](#) to capture views of the heart for post-scan analysis.

You can access the Scan screen only when acquiring scans for a New Study.

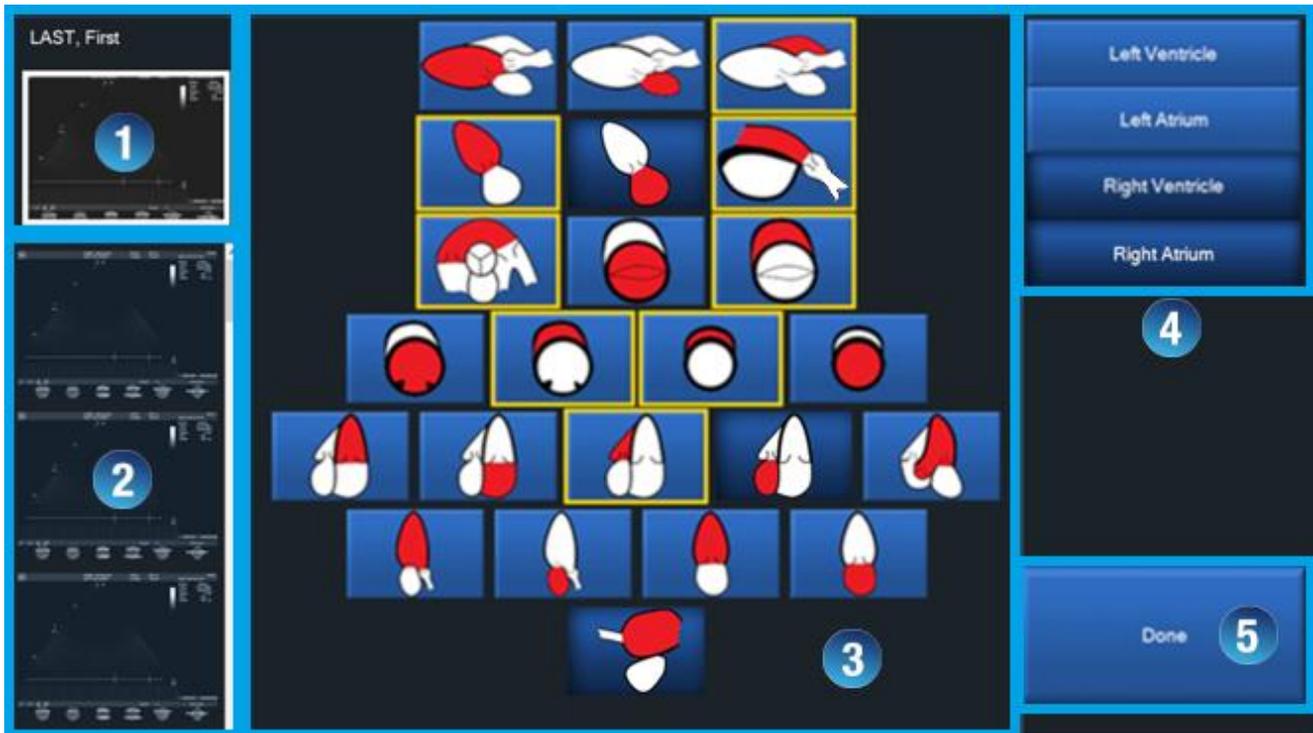


Figure 2 Scan Screen During Acquisition

- 1 Live scan window.
- 2 Thumbnail list. Select a thumbnail from the thumbnails list to go to the [Scan review screen](#).
- 3 Anatomical buttons. Displayed in the main image area.  
Select an anatomical button to acquire a scan for that view. A label for that specific view will be displayed on the scan when viewed in the 2D and 3D screen and will display the appropriate view in the Points Placement Guide.  
You can acquire multiple images for one view. You can also change the label in the 2D screen.



Parasternal Long Axis for Left Ventricle.  
Label is displayed as PLAX-LV.

---



Parasternal Long Axis for Left Atrium.  
Label is displayed as PLAX-LA.

---



Parasternal Long Axis for Right Ventricle.  
Label is displayed as PLAX-RV.

---



Parasternal Right Ventricular Inflow Tract for Right Ventricle.  
Label is displayed as PRVIT-RV.

---



Parasternal Right Ventricular Inflow Tract for Right Atrium.  
Label is displayed as PRVIT-RA.

---



Parasternal Right Ventricular Outflow Tract for Right Ventricle.  
Label is displayed as PRVOT-RV.

---



Parasternal Short Axis Aortic Outflow for Right Ventricle.  
Label is displayed as PSAXAO-RV.

---



Parasternal Short Axis Mitral Valve for Left Ventricle.  
Label is displayed as PSAXMV-LV.

---



Parasternal Short Axis Mitral Valve for Right Ventricle.  
Label is displayed as PSAXMV-RV.

---



Parasternal Short Axis Mid for Left Ventricle.  
Label is displayed as PSAXMID-LV.



Parasternal Short Axis Mid for Right Ventricle.  
Label is displayed as PSAXMID-RV.



Parasternal Short Axis Distal for Right Ventricle.  
Label is displayed as PSAXDISTAL-RV.



Parasternal Short Axis Distal for Left Ventricle.  
Label is displayed as PSAXDISTAL-LV.



Apical Four Chamber for Left Ventricle.  
Label is displayed as A4C-LV.



Apical Four Chamber for Left Atrium.  
Label is displayed as A4C-LA.



Apical Four Chamber for Right Ventricle.  
Label is displayed as A4C-RV.



Apical Four Chamber for Right Atrium.  
Label is displayed as A4C-RA.



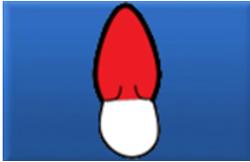
Apical Five Chamber for Left Ventricle.  
Label is displayed as A5C-LV.



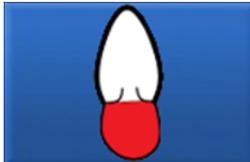
Apical Three Chamber for Left Ventricle.  
Label is displayed as A3C-LV.



Apical Three Chamber for Left Atrium.  
Label is displayed as A3C-LA.



Apical Two Chamber for Left Ventricle.  
Label is displayed as A2C-LV.



Apical Two Chamber for Left Atrium.  
Label is displayed as A2C-LA.



Subcostal Inferior Vena Cava for Right Atrium.  
Label is displayed as SCIVC-RA.

**4** Heart chamber buttons.



Select the chamber (s) for which you want to acquire scans. Once selected, the anatomical view buttons related to the chamber will be highlighted with a yellow border.

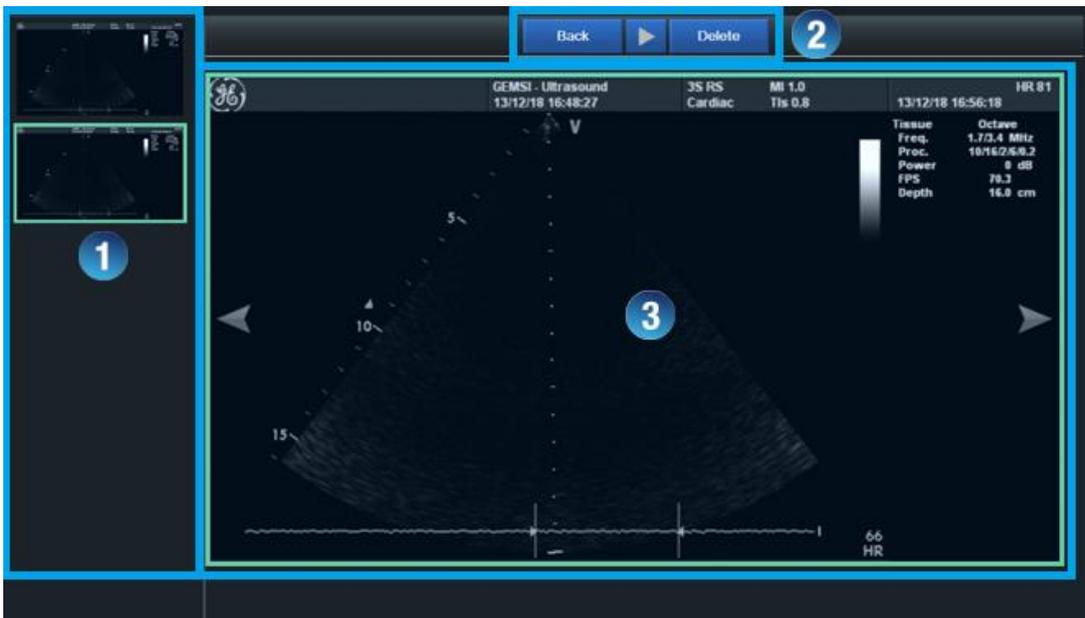
**5** Done



When you are done scanning, select Done. Enter the depth and a heart rate (not required and can be entered from the 2D or 3D screen if required).

**Scan Review screen**

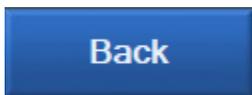
The Scan Review screen (see [Figure 3](#)) will be displayed after selecting a thumbnail from the Scan screen.



**Figure 3:** Scan Review Screen

**1** Thumbnail list. Select a thumbnail from the thumbnails list to display it in the main image area. Selected thumbnail is highlighted with a green border.

**2** Scan Review screen toolbar buttons.



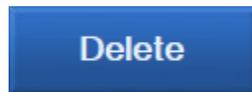
Returns you to the Scan screen.



Play button. Plays back the cine.



Pause button. Pauses playback of the cine.



Deletes image displayed in main image area.

**3** Main image area.



Previous arrow. Displayed directly on the main image area. Select to display the previous scan acquired in the study.



Next arrow. Displayed directly on the main image area. Select to display the next scan acquired in the study.

► To select a different image

1. Select any thumbnail from the thumbnails list on the left side of the screen. Once selected, the thumbnail border will turn green.
2. (Optional) If the thumbnails list extends beyond the screen, use the scroll bar to scroll through all thumbnails.
3. The thumbnail scan is now displayed in the main image area.
4. (Optional) You can also select either the   next or previous arrows directly on the scan displayed in the main image area.

▶ **To play/pause the scan**

1. With any scan displayed in the main image area, select the  play button.
2. To stop playback, select the  pause button.

▶ **To return to the Scan screen**

1. With any scan displayed in the main image area, select  **Back**.
2. The Scan screen is displayed.

▶ **To delete a scan**

1. With any scan displayed in the main image area, select  **Delete**.
2. (Optional) Select **Cancel** to cancel the deletion.
3. On the confirmation dialog, select **OK**.
4. The scan is deleted, and the thumbnail is removed from the thumbnails list.

## Capturing Scans

Review the [Image Acquisition Protocol](#) prior to acquisition.



### CAUTION

Keep the sensors at least 5 cm apart during the scanning.

### NOTE

If the sensors are brought too close, you may have to repeat the study. Placing the sensors at less than 5 cm for more than 10 seconds magnetizes the sensors and will require a magnetometer calibration. If you choose to repeat the study, click **OK** and you will be taken back to the New Study Screen. If you do not want to repeat the study, click **Cancel** and you will be returned to the Studies screen.

## ► To capture scans

1. Select an anatomical image button to acquire a scan for that view. VMS+ software labels the scans according to the view selected. See the [Scan screen during acquisition](#) section for a list of labels according to the button selected.

**NOTE** If a live video feed does not appear in the Live Scan Window, ensure the HDMI cable is properly connected and secured. Ensure the ultrasound is set to output a video signal. If you are still not able to see a video feed, please contact Ventripoint support.

2. When reviewing these acquired scans in the 2D screen, the Guide window will display an image to show you where to place the required points for improved volume calculation accuracy.
3. At the start and end of each scan capture, an audible beep is heard and each time a scan is captured, a thumbnail of the scan appears in the thumbnail list located on the left of the screen, below the live scan window.

**NOTE** If the sensors are outside of the acceptable range, an audible sound will signal you and the sensor LEDs will blink orange.

4. After you have acquired enough scans, click **Done**.
5. Pair the sensors for the second and final time. The Done with Scanning dialog box appears.
6. In the **Scan Depth** list, select the scan depth that was used during the study. If you used multiple scan depths, click the most common one. During End Diastolic/End Systolic (ED/ES) frame selection you may correct the specified scan depths for each scan in Settings on the 2D.
7. Verify that the displayed patient heart rate is correct in the Heart Rate text box. Adjust it as required.

**NOTE** After clicking **OK**, you will not be able to acquire additional scans for this study. If you need additional scans, click **Cancel** and you will be returned to the Scan screen where you can begin to acquire scans again.

8. Click **OK**. The Studies screen appears.
9. Select the new study and press open. The 2D Screen is displayed and you can now begin identifying ED and ES frames.
10. From this point on, VMS+ automatically saves your changes.

## ► To delete scans

1. Select a thumbnail. When a thumbnail is selected, the single scan view is displayed.
2. Select **Delete**. A confirmation dialog is displayed.
3. Select **OK** to continue with the deletion or **Cancel** to discard the deletion.

## 2D Screen

Use the 2D screen to select your End Diastolic (ED) and End Systolic (ES) frames and mark anatomical structures according to Ventripoint's [Anatomical View and Point Placement](#) Guide.

You can access the 2D screen from the Studies (once a study is selected), 3D, Report or Help screens

The 2D screen has two views – Thumbnail view and Single image view.

- Thumbnail view (see [Figure 4](#))

Default view when a study is opened. Scroll through the list of acquired scans displayed as image thumbnails. Select to display the thumbnails in either a single, double or three column view. Select a thumbnail to load into Single image view.

- Single image view (see [Figure 5](#))

Load a single thumbnail into Single image view when you want to set your ED and ES frames, place points and generate Calculations (see [Selecting ED and ES Frames and Anatomical Structures](#)). You can select the next or previous scans in your study by using the next/previous arrows on the image in the main image area. You can also select a different scan to view in single image view by going back to Thumbnail view and scrolling through the list of images.

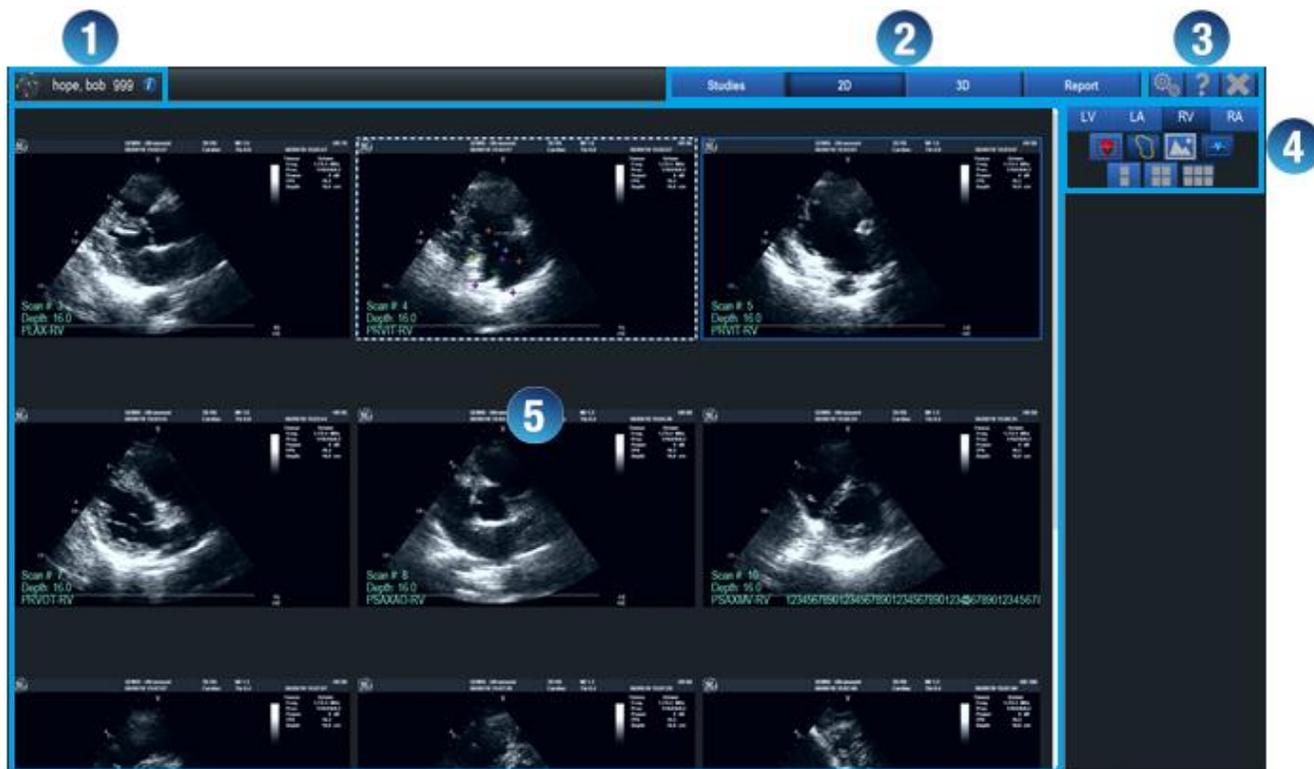


Figure 4 2D screen in thumbnail view

Patient Information.

- 1 Displays the Patient's last name, first name, first letter of their middle name (if entered) and MRN number (if entered).

Edit or enter additional Patient Information using the  button.

- 
- 2 Application toolbar buttons. See [Application toolbar buttons](#).

- 
- 3 Application controls. See [Application controls](#).

- 
- 4 2D screen controls.



LV tab. Select to display the views associated with the Left Ventricle Chamber.



LA tab. Select to display the views associated with the Left Atrium chamber.



RV tab. Select to display the views associated with the Right Ventricle Chamber.



RA tab. Select to display the views associated with the Right Atrium Chamber.



ED button. Displays the frame of the currently displayed image for the End Diastolic phase. Image will be displayed with a red border.



ES button. Displays the frame of the currently displayed image for the End Systolic phase. Image will be displayed with a blue border.



Borders. Enabled by default. Displays how the 3D model intersects each of the 2D images. This is the only tool in the 3D View pane that affects the 2D images.



Image Settings. Displays the Settings flyout. Adjust Brightness, Contrast or Reset to default.



Single-column button. Displays thumbnails in a single-column layout.



Two-column button. Displays thumbnails in a two-column layout.



Triple-column button. Displays thumbnails in a three-column layout.

- 
- 5 Thumbnail list. Scroll through the list then select a thumbnail to load into single image view. The thumbnails have 4 different states.



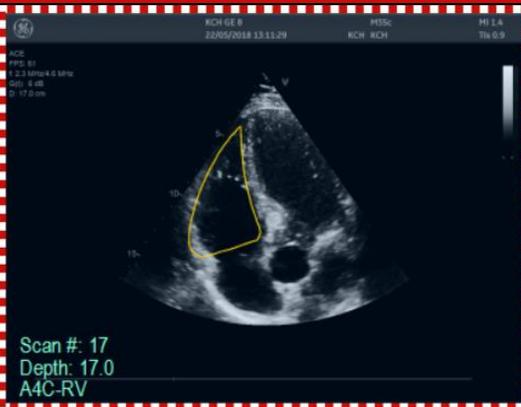
Thumbnails displayed with no border have no ED or ES frames set and therefore no points have been placed.



Thumbnails with a blue border have an ES frame set.



Thumbnails with a red border have an ED frame set.



Thumbnails with a dashed white border indicates that it was just viewed in the 2D screen single image view.

► To change thumbnail view

1. You can view thumbnails in three different views.

2. While in thumbnail view, select the single column  button.
3. The thumbnails are displayed in a single column view.
4. Select the  double column button.
5. The thumbnails are displayed in a double column view.
6. Select the  triple column button.
7. The thumbnails are displayed in a triple column view.

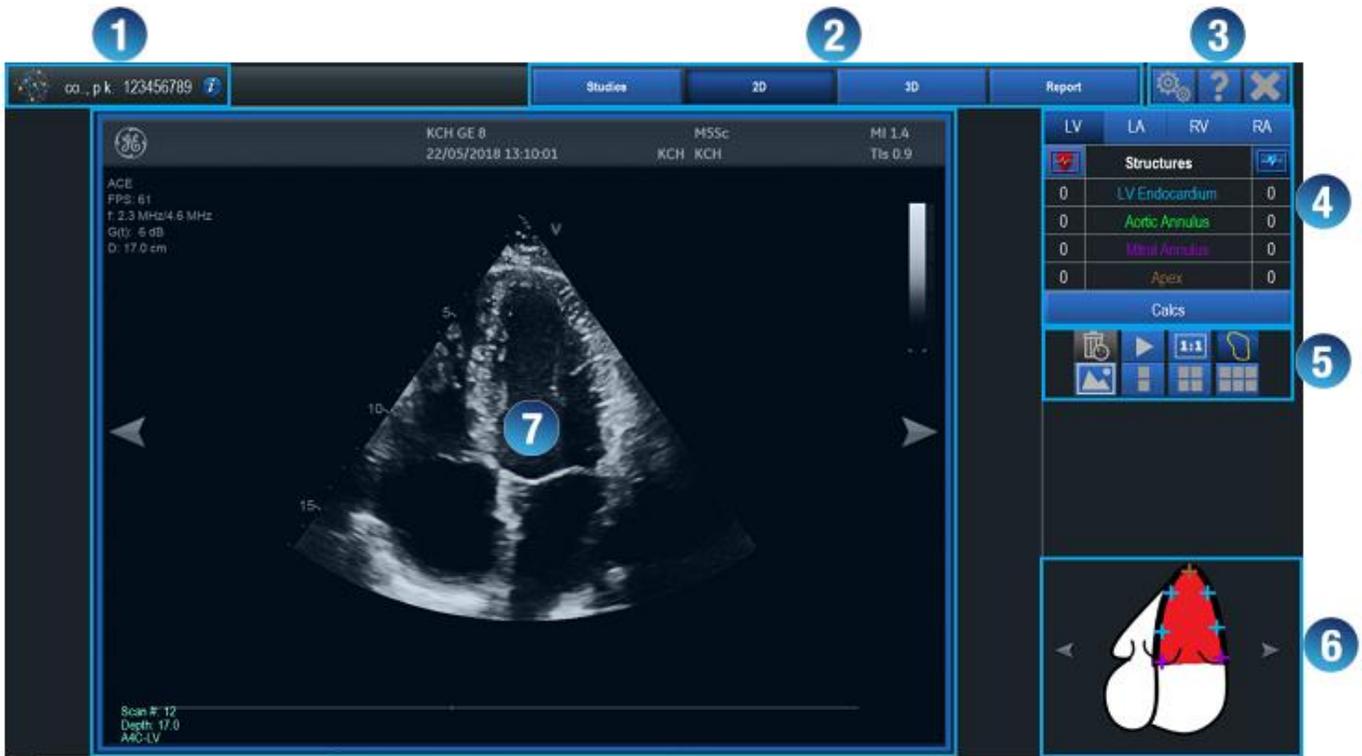
▶ **To view all ED or ES images**

1. While in thumbnail view, tap the  ED or  ES button.
2. Only the ED or ES thumbnails are displayed. ED thumbnails are displayed with a red border and ES thumbnails are displayed with a blue border.

▶ **To remove borders on all images**

1. Borders are enabled by default.
2. While in thumbnail view, tap the  borders button.
3. Borders are no longer displayed on any thumbnail.
4. Select the borders button again to enable borders .

1. .



**Figure 5: 2D screen in single image view**

Ventripoint Logo and Patient Information.

- 1** Displays the Patient's last name, first name, first letter of their middle name (if entered) and MRN number (if entered).

Edit or enter additional Patient Information using the  button.

- 2** Application toolbar buttons. See [Application toolbar buttons](#).

- 3** Application controls. See [Application controls](#).

- 4** Structures table. Select a chamber tab, then select an anatomical structure point to place on your image. Select a point from either the ED or ES column to set the frame for that phase. When all of the required points have been placed, the Calcs button becomes enabled.

LV

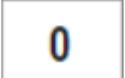
LV tab. Select to display anatomical points associated with the Left Ventricle chamber.

LA

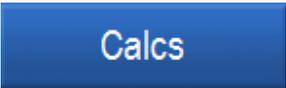
LA tab. Select to display anatomical points associated with the Left Atrium chamber.

RV

RV tab. Select to display anatomical points associated with the Right Ventricle chamber.

	RA tab. Select to display anatomical points associated with the Right Atrium chamber.
	ED button. Displays the frame of the currently displayed image for the End Diastolic phase. Image will be displayed with a red border.
	ES button. Displays the frame of the currently displayed image for the End Systolic phase. Image will be displayed with a blue border.
	Anatomical points column with no points placed.
	Active anatomical points column with no points placed.
	Anatomical points column with one point placed, but not enough to meet the requirements.
	Active anatomical points column with one point placed and green font – green font indicates that the required amount of points has been placed.
	Anatomical points column with the required amount of points placed.

**5** 2D screen controls.

	Select this button when you are ready to perform a 3D construction. Once selected, the 3D screen will automatically be displayed. This button will only be enabled when enough points have been placed to satisfy the requirements for a VMS+ 3D construction.
	Image Settings. Displays the Settings flyout. Edit Brightness and Contrast (these will apply to all images in a Study) or reset to their original values. You can also change the depth, image label or create a custom label.
	Borders. Select to show how the 3D model intersects each of the 2D images. This is the only tool in the 3D View pane that affects the 2D images.
	1:1 button. Scales the image to a 1 to 1 scale of its original size.
	Fit button. Fits the image to fill the workspace.
	Delete. Deletes all points placed on the image.
	Play button. Plays the cine.



Pauses the cine during playback.



Single-column button. Displays thumbnails in a single-column layout.



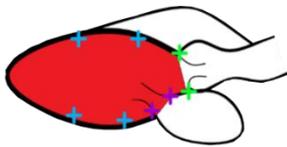
Two-column button. Displays thumbnails in a two-column layout.



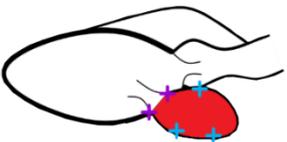
Triple-column button. Displays thumbnails in a three-column layout.

6

Guide window. Displays a points placement guide image that corresponds to both the image you have displayed in the main image area and the chamber tab you have selected. Place points according to the points placement guide to ensure accurate calculations.



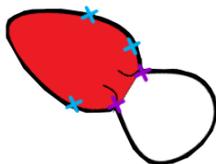
Parasternal Long Axis for Left Ventricle (PLAX-LV).  
Requires 4 x **LV Endocardium**, 2 x **Mitral Annulus**, 2 x **Aortic Annulus** anatomical points placed.



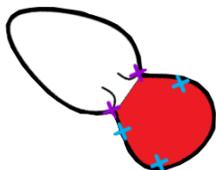
Parasternal Long Axis for Left Atrium (PLAX-LA).  
Requires 3 x **LA Endocardium**, 2 x **Mitral Annulus** anatomical points placed.



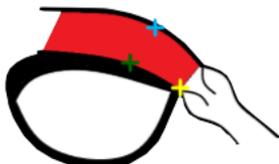
Parasternal Long Axis for Right Ventricle (PLAX-RV).  
Requires 3 x **RV Endocardium**, 2 x **RV Septum** anatomical points placed.



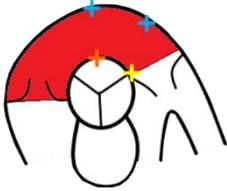
Parasternal Right Ventricular Inflow Tract for Right Ventricle (PRVIT-RV).  
Requires 3 x **RV Endocardium**, 2 x **Tricuspid Annulus** anatomical points placed.



Parasternal Right Ventricular Inflow Tract for Right Atrium (PRVIT-RA).  
Requires 3 x **RA Endocardium**, 2 x **Tricuspid Annulus** anatomical points placed.

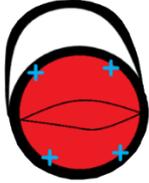


Parasternal Right Ventricular Outflow Tract for Right Ventricle (PRVOT-RV).  
Requires 1 x **RV Endocardium**, 1 x **RV Septum**, 1 x **Pulmonic Annulus** anatomical points placed.



Parasternal Short Axis Aortic Outflow for Right Ventricle (PSAXAO-RV).

Requires 2 x RV Endocardium, 1 x Conal Septum, 1 x Pulmonic Annulus anatomical points placed.



Parasternal Short Axis Mitral Valve for Left Ventricle (PSAXMV-LV).

Requires 4 x LV Endocardium anatomical points placed.



Parasternal Short Axis Mitral Valve for Right Ventricle (PSAXMV-RV).

Requires 2 x RV Endocardium, 2 x RV Septal Edge, 1 x RV Septum anatomical points placed.



Parasternal Short Axis Mid for Left Ventricle (PSAXMID-LV).

Requires 4 x LV Endocardium anatomical points placed.



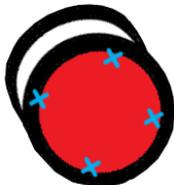
Parasternal Short Axis Mid for Right Ventricle (PSAXMID-RV).

Requires 2 x RV Endocardium, 2 x RV Septal Edge, 1 x RV Septum anatomical points placed.



Parasternal Short Axis Distal for Right Ventricle (PSAXDISTAL-RV).

Requires 2 x RV Septal Edge anatomical points placed.



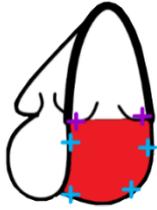
Parasternal Short Axis Distal for Left Ventricle (PSAXDISTAL-LV).

Requires 4 x LV Endocardium anatomical points placed.



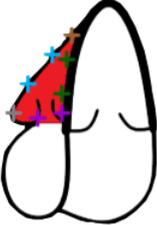
Apical Four Chamber for Left Ventricle (A4C-LV).

Requires 1 x Apex, 4 x LV Endocardium, 2 x Mitral Annulus anatomical points placed. Apex can be placed on either A4C, A3C, or A2C.



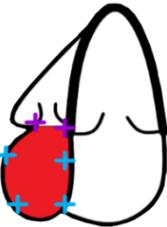
Apical Four Chamber for Left Atrium (A4C-LA).  
Requires 4 x LA Endocardium, 2 x Mitral Annulus anatomical points placed.

---



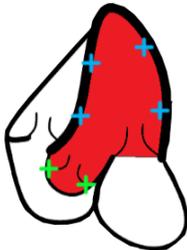
Apical Four Chamber for Right Ventricle (A4C-RV).  
Requires 2 x RV Endocardium, 2 x Tricuspid Annulus, 2 x RV Septum, 1 x Apex, 1 x Basal Bulge anatomical points placed.

---



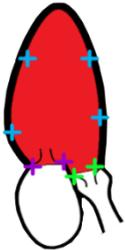
Apical Four Chamber for Right Atrium (A4C-RA).  
Requires 4 x RA Endocardium, 2 x Tricuspid Annulus anatomical points placed

---



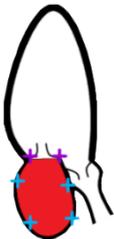
Apical Five Chamber for Left Ventricle (A5C-LV) (Optional)  
Requires 4 x LV Endocardium, 2 x Aortic Annulus anatomical points placed.

---



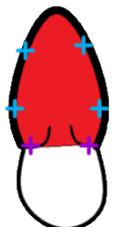
Apical Three Chamber for Left Ventricle (A3C-LV).  
Requires 4 x LV Endocardium, 2 x Aortic Annulus and 2 x Mitral Annulus anatomical points placed.

---



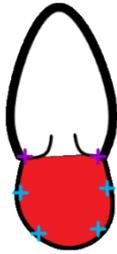
Apical Three Chamber for Left Atrium (A3C-LA).  
Requires 4 x LA Endocardium and 2 x Mitral Annulus anatomical points placed.

---



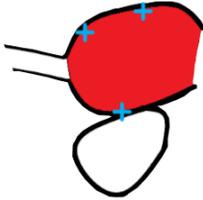
Apical Two Chamber for Left Ventricle (A2C-LV).  
Requires 4x LV Endocardium and 2 x Mitral Annulus anatomical points placed.

---



Apical Two Chamber for Left Atrium (A2C-LA).  
Requires 4 x **LA Endocardium** and 2 x **Mitral Annulus** anatomical points placed.

---



Subcostal Inferior Vena Cava for Right Atrium (SCIVC-RA).  
Requires 3 x **RA Endocardium** anatomical points placed.

---



Previous arrow. Displayed directly on the Guide window. Select to display the previous image in the points placement guide.

---



Next arrow. Displayed directly on the Guide window. Select to display the next image in the points placement guide.

---

**7** Main image area.



Previous arrow. Displayed directly on the main image area. Select to display the previous scan acquired in the study.

---



Next arrow. Displayed directly on the main image area. Select to display the next scan acquired in the study.

---

► **To select the next/previous image in a study**

You may return to the thumbnail view to select a different image to view in single image view, or you can select the next/previous arrows.

1. Select the  previous arrow.
2. The previous image acquired is now displayed in the main image area.
3. Select the  next arrow.
4. The next image acquired is now displayed in the main image area.

► **To play/pause the image cine loop**

1. With an image displayed in single image view, select the  play button.
2. The cine plays and loops continuously.
3. Select the  pause button.

4. The cine stops playing.

► **To remove borders on all images**

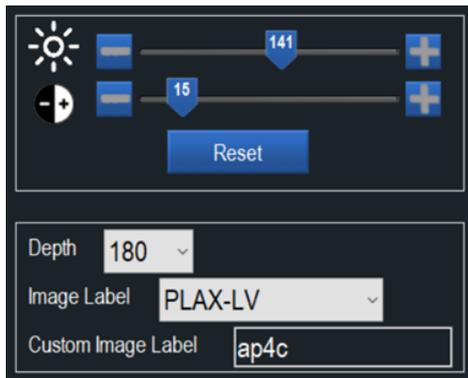
Borders are enabled by default. Enabling or disabling borders in single image view, also enables/disables borders in thumbnail view.

1. While in single image view, tap the  borders button.
2. Borders are no longer displayed on the image.
3. Select the borders button again to enable borders .

► **To adjust brightness/contrast for all images**

Although only one image is displayed, adjusting the brightness/contrast in single image view will affect all images.

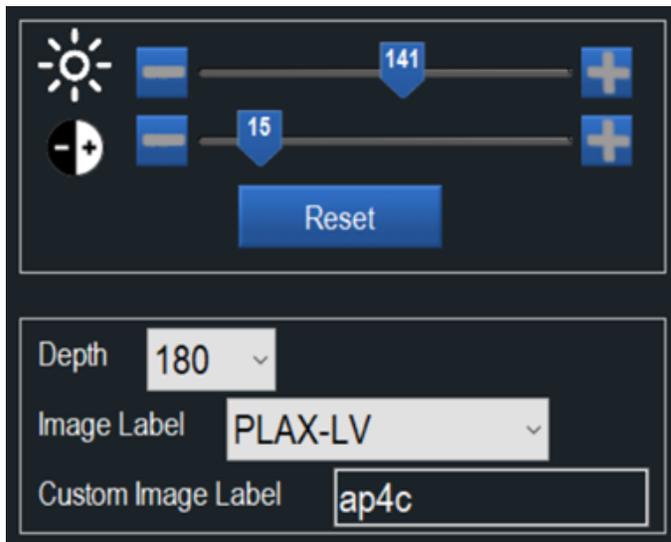
1. While in single image view, tap the  Image Settings button.
2. Image Settings is displayed.



3. Adjust the brightness/contrast settings using the '+' or '-' buttons or the sliders.
4. Brightness and contrast are adjusted and saved automatically for all images.
5. (Optional) Reset the brightness and contrast to their original settings by selecting **Reset**.

► **To adjust the depth for an image**

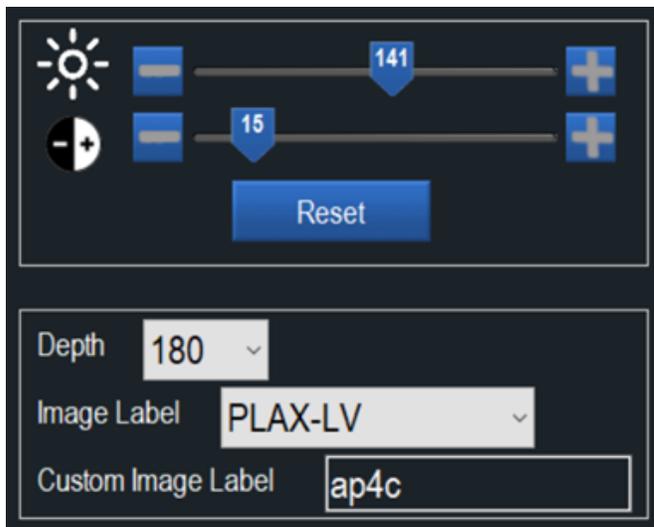
1. While in single image view, tap the  Image Settings button.
2. Image Settings is displayed.



3. Open the depth drop-down menu and select a depth. Depth is automatically saved for the image once selected.

► **To change the image label for an image**

1. While in single image view, tap the  Image Settings button.
2. Image Settings is displayed.

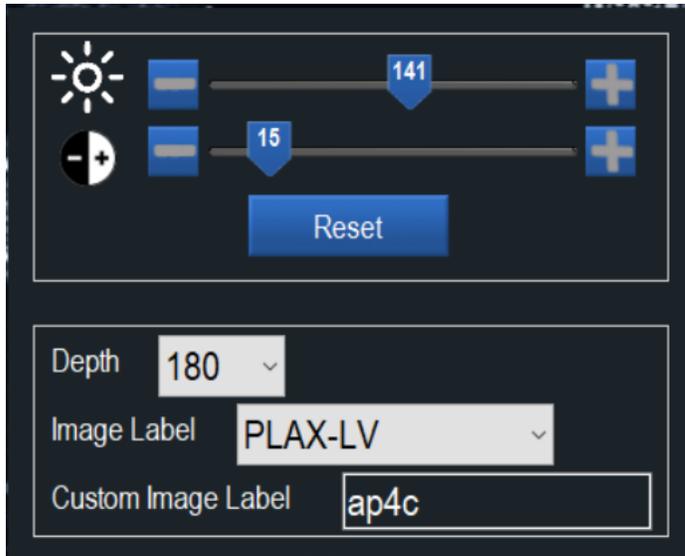


3. Open the Image Label drop-down menu and select a label. The label is automatically saved for the image once selected.

► **To add a custom image label to an image**

1. While in single image view, tap the  Image Settings button.

2. Image Settings is displayed.



3. Enter text in the Custom Image Label text box. Custom image label is automatically saved. The custom image label is added to the right of the image label on the bottom left corner of the image.



► **To scale the image**

1. While viewing an image in single image view, select the  1:1 button.
2. The application will display the image to a 1 to 1 scale of its original size.

3. Select the  Fit button to revert back to the default view where the application fits the image to fill the workspace.

► **To delete points from an image**

1. While viewing an image in single image view, select the  delete button.
2. A confirmation dialog will be displayed to confirm if you wish to proceed with the deletion.
3. (Optional) Select **Abort** to cancel the deletion.
4. Select **Delete**. All points are deleted from the image.

## Selecting ED and ES Frames and Anatomical Structures

After you have finished scanning the patient, the Studies screen appears. Select and open the new study to use the 2D screen to set the End Diastolic (ED) and End Systolic (ES) frames and place anatomical structure points.

Once adequate points are placed on an image, volumes are then measured at the ED and ES phases of the cardiac cycle and calculations are displayed on the 3D screen.

### ► To set an ED/ES frame and place an anatomical structure point

1. On the 2D screen, select a thumbnail image that you want to work with. The image will be displayed in the main workspace.
2. Select the heart chamber you are working with from the structures table.

Each tab represents a chamber of the heart. The example below has the LV or Left Ventricle tab selected.



3. Tap and swipe left and right on the bottom half of the image area to select the appropriate ED frame.
4. On a Workstation, use a left-click on a mouse and drag or wheel.
5. Select an ED point from the structures table by tapping a structure box in the ED column.
6. On a Workstation, use a left-click on a mouse to select a point.
7. Place the point on the image by tapping on the image and placing the point according to the points placement image displayed in the Guide window (bottom-right corner). A points list for each structure is listed in the [Points Placement Protocol](#).
8. On a Workstation, use a left-click on a mouse to place a point. Once placed, the image frame will turn red.
9. Continue to place all the required points for the selected ED frame. When the required points are placed for a structure, its ED box will be green instead of white.
10. Repeat steps 3-7 for the ES frame and points. The ED and ES frames that you select will be applied to the image for any chamber that you select for that image (via the LV/LA/RV/RA tabs on the Structures table).

The interval you determined by setting both an ED and ES frame will be applied to all images in the entire study once an initial ED or ES frame is placed. VMS+ allows you to edit both ED and ES frames if no points have been placed on the frame.

11. Select **Calcs** when you have completed ED and ES points placement. The 3D screen will be automatically displayed and the Calcs table will be populated with volume measurements and a 3D model will be displayed in the main workspace. You can select to generate calculations at any time, so long as the **Calcs** button is enabled.

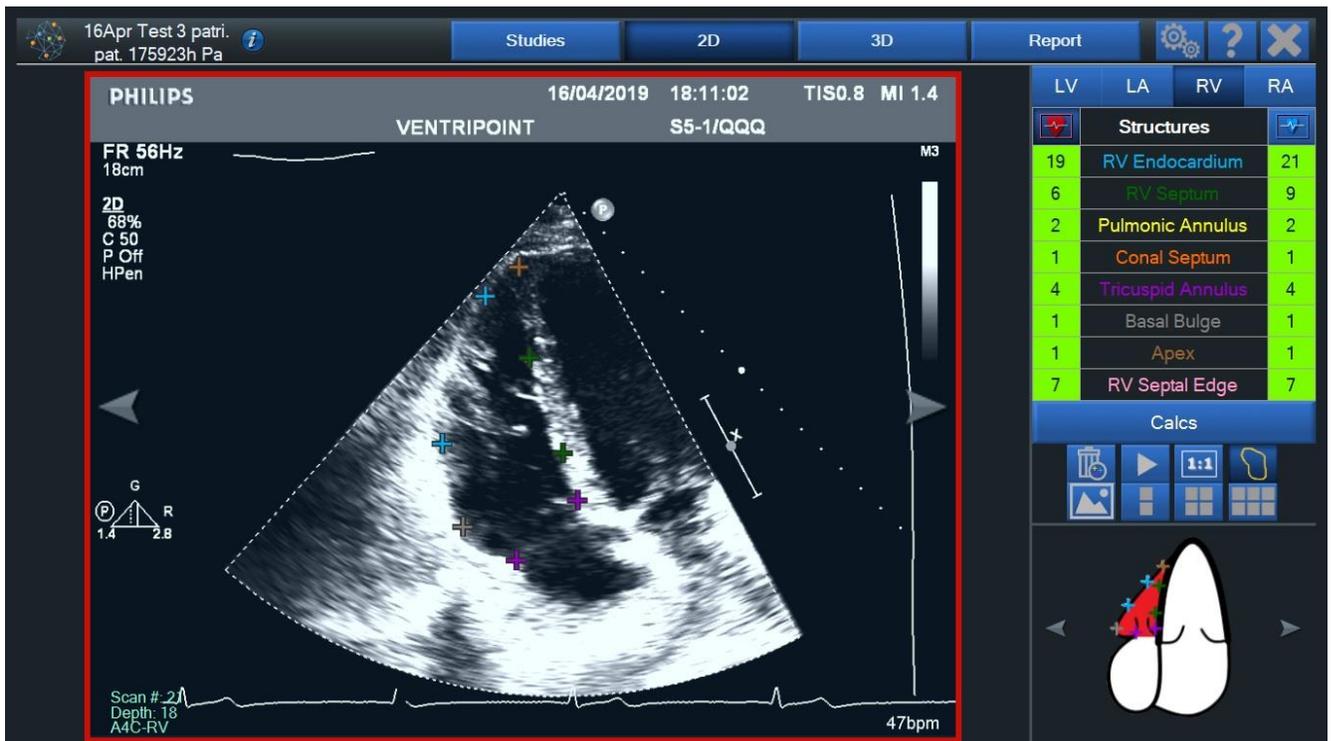
#### NOTE

Use the options on the right panel in the 3D screen to switch views, rotate the 3D model, view how points appear on the model, or take a snapshot of the model to add to the report data. For more information about using these options, see the [Validating Results](#) section.

**NOTE** When you select **Calcs**, volumes will be calculated for all images and phases that have the required amount of points placed.

► **To change the set ED or ES frame for an image**

1. Ensure that there are no points placed on the image by selecting Delete.
2. Then select another ED or ES structure point from the Structures table and place on the new frame.
3. The new frame will display a blue border for a set ES frame or a red border for a set ED frame.



► **To delete points**

1. Select **Delete** when in single image view and then tap **OK** on the confirmation dialog.
2. To delete one point, tap and hold or double tap on the point you want to delete.
3. On a Workstation, to delete one point, hover the mouse pointer over a point then right-click.

**NOTE** If you change the ED or ES frame, or delete a point, you must run the volume calculations again for that image by selecting **Calcs**.

4. Return to the thumbnail view by selecting a thumbnail button and continue to place points accordingly.

**NOTE** After viewing an image in the main workspace, when you return to the thumbnail view, the thumbnail you viewed will have a dashed border to indicate that you viewed it last.

## 3D Screen

### Adjusting Image Settings

You can adjust the settings of the image, such as scan depth, brightness, contrast. Select **Settings** from the 2D screen to display a Settings flyout. You can also change the image label or create a custom image label that is displayed on the image that you are working with.

#### Brightness and contrast

▶ **To adjust brightness and contrast in Settings**

1. In either single image view or thumbnail view, select **Settings**. The Settings dialog is displayed.
2. Move the Brightness slider left to decrease or right to increase brightness.
3. Move the Contrast slider left to decrease or right to increase contrast.

▶ **To adjust brightness and contrast directly on an image**

1. Load an image into single image view.
2. On a System: On the top half of the image area, tap and drag left or right to adjust the brightness and tap and drag up or down to adjust the contrast.
3. On a Workstation: On the top half of the image area, left mouse click, hold and drag left or right to adjust the brightness and left mouse click, hold and drag up or down to adjust the contrast.

▶ **To reset the brightness and contrast settings**

1. In either single image view or thumbnail view, select **Settings**. The settings dialog is displayed.
2. Select **Reset**. Both the Contrast and Brightness settings are reset to the original image brightness and contrast settings.

**NOTE** Highlights important information that will aid the user in operating the product more effectively.

#### Depth

▶ **To adjust the depth**

1. In single image view, select **Settings**. The Settings dialog is displayed.
2. Select a scan depth from the Scan Depth drop-down menu.

**NOTE** Changing the scan depth will remove any previous calculations for the current study. After changing the scan depth, you must re-run calculations by selecting **Calcs**.

3. Select **Calcs**. The new 3D reconstruction and calculations displayed will reflect your changes to the scan depth.

**NOTE** Changing the scan depth changes it only for the image that you are viewing.

## Image labels

You can change the original image label or add a custom image label. An image label is displayed on the lower-left corner of the 2D image. Image labels can also be disabled if you do not wish to see them on your image. See [System Settings](#) for more information.

### ► To change an image label

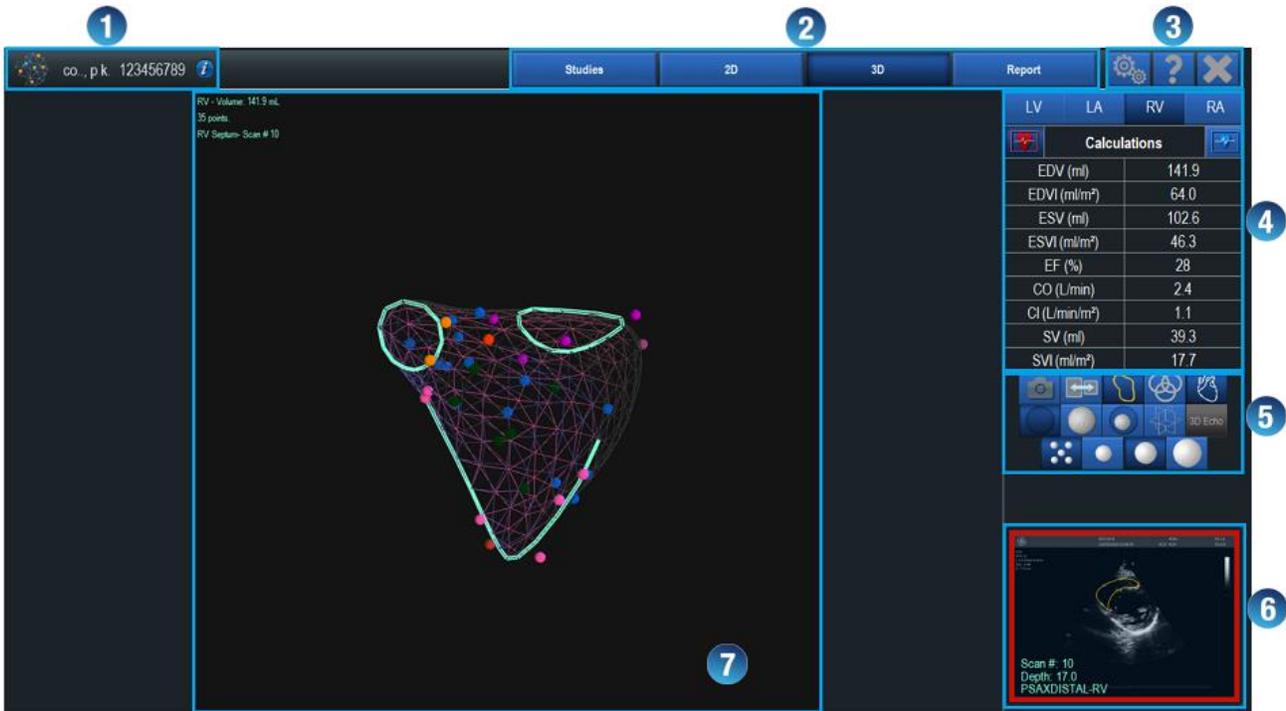
1. In single image view, select **Settings**. The Settings dialog is displayed.
2. From the Image Label drop-down menu, select a label. The new label is displayed on the image.

### ► To add a custom label

1. In single image view, select **Settings**. The Settings dialog is displayed.
2. Enter text in the Custom Image Label text box. You may enter up to 50 characters per annotation.
3. The custom image label is displayed on the image3D Screen

The 3D screen in [Figure 6](#) is displayed automatically when you select the **Calcs** button from the 2D screen. Calculations are performed and a 3D model is displayed in the main image area of the 3D screen. If you edit points when on the 2D screen after a calculation has been performed, you must select **Calcs** from the 2D screen again in order for the 3D model to be up-to-date on the 3D screen.

You can access the 3D screen from the 2D, Report or Help screens once calculations have been performed.



**Figure 6: 3D Screen**

Ventripoint Logo and Patient Information.

- 1** Displays the Patient's last name, first name, first letter of their middle name (if entered) and MRN number (if entered).

Edit or enter additional Patient Information using the  button.

- 2** Application toolbar buttons. See [Application toolbar buttons](#).

- 3** Application controls. See [Application controls](#).

- 4** Calculations table.

LV

LV tab. Select to display the calculations for the Left Ventricle chamber.

LA

LA tab. Select to display the calculations for the Left Atrium chamber.

RV

RV tab. Select to display the calculations for the Right Ventricle chamber.

RA

RA tab. Select to display the calculations for the Right Atrium chamber.



ED button. Displays the End Diastolic phase for the 3D model or 2D image, whichever is displayed in the main image area.



ES button. Displays the End Systolic phase for the 3D model or 2D image, whichever is displayed in the main image area.

---

5

### 3D screen controls.



Snapshot. Takes a snapshot of the current 3D or 2D image



Swap. Swaps the main image with the 2D window.



Borders. Select to show how the 3D model intersects each of the 2D images. This is the only tool in the 3D View pane that affects the 2D images.



Mesh. Select to show the mesh surface on the 3D model.



Intersections. Select to show how each of the 2D ED/ES frames intersects the 3D model. Each 2D image that was acquired during the study will be depicted by a Yellow Border *within* the 3D model. This feature shows how well the area of the heart chamber was covered by 2D scanning.



Combined View. Select to superimpose the ED and ES models. If you select Combined View, the only other check boxes that can be selected are Outlines and Borders (all others are unavailable).

When viewing the atria chambers of the heart, it is possible that a larger volume will obscure views of the smaller volume. The VMS+ software will detect this and display the larger volume as a mesh so as not to obscure the view of the smaller volume (displayed as solid).



Solid. Select to show a solid representation of the image. If you select Solid, the mesh surface and any other elements located inside the mesh will be hidden.



Outlines. Select to show sharp edges of the key anatomical structures (Pulmonic, Tricuspid valves, and Apex).



Scan Plane.

For 2D images – Select the Scan Plane button to display a moveable Scan Plane Adjustment window. Click a point on the 3D model to show how the 2D image that was used to pick the point intersects the 3D model. Select an additional point, and an additional scan plane is displayed on the 3D model for that point. Continue to add scan planes to the 3D model, remove a scan plan

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---

by selecting a point on the scan plane you wish to remove. See [To work with Scan Planes](#) for more information.

For MRI and 3D Echo images – Select the Scan Plane button, then click a point on the 3D model to show how the 2D image that was used to pick the point intersects the 3D model. If you click a different point on the 3D model, the 2D image will be replaced with a new one that corresponds to the new point.

---



Points. Select to show points on the 3D model.

---



Small point size. Select to show small points on the 3D model.

---



Medium points size. Select to show medium points on the 3D model.

---



Large point size. Select to show large points on the 3D model.

---

6

2D window. Select a point on the 3D model to display the 2D image where that point is placed.

Swap views with the 3D model to display the 2D image in the large image area.

---

7

Main image area. Displays the 3D model by default. Swap the 2D image with the 3D model.

---

### ► To swap the 3D model with the 2D model

When entering the 3D screen, the default view is to display the 3D model in the main image area and a 2D image on the bottom right corner.

1. While viewing the 3D model in the 3D screen, select the  swap button.
2. The 2D image is now displayed in the main image area and the 3D model is displayed on the bottom right corner.

### Taking snapshots of images

When you have finished reviewing and refining your study, you can take snapshots of your 3D model and/or 2D images. You can take a snapshot of an image only when it is displayed in the main workspace.

For the 3D model, three types of snapshots can be included in the report:

- ED
- ES
- Combined view (ES superimposed on ED).

Select the 3D view of interest and select the Snapshot button to add that view to the report. Selecting the snapshot button again, removes the previously taken snapshot. Snapshots can be taken with any of the 3D View plane selections enabled.

For 2D images, you can take a snapshot of either an ED phase or an ES phase. The 2D snapshots can be taken with the Borders option on or off.

**NOTE** If you add or delete points for ED or ES, or change scan depth, all previously taken snapshots will be removed from the report. You will need to complete another 3D reconstruction and re-take the snapshots.

**NOTE** You can take up to 20 snapshots of a 3D model or 2D image.

**NOTE** You cannot take a snapshot of an image that does not have an ED or ES frame set.

▶ **To take a snapshot of a 3D model**

1. Load a 3D model into the main workspace.
2. Select **Snapshot**. A message appears verifying that the snapshot has been taken successfully.
3. Select **OK**.

▶ **To take a snapshot of a 2D Image**

1. Load a 2D image into the main workspace.
2. Select to display either the ED or ES frame.
3. Select the **Snapshot**. A message appears verifying that the snapshot has been added to the Report and a small green camera icon is displayed in the upper right corner.
4. Select **OK**.

▶ **To remove a snapshot from an Image**

1. Load an image into the main workspace that has the small green camera icon displayed in the upper right corner.
2. Select **Snapshot**. A message appears verifying that the snapshot has been removed successfully from the Report and the blue camera icon is removed.

## Validating Results

After you have identified anatomical structures by picking points on the End Diastolic (ED) and End Systolic (ES) frames and created 3D reconstructions, you are ready to validate your results.

In this section of the workflow, you will see how well the points that you picked fit the 3D model. You can refine the 3D model by making precise adjustments to the points that you picked, thereby ensuring the highest possible accuracy.

## Reviewing the 3D Model

The first step in reviewing your results for quality is to examine how the borders on the 3D model intersect and align with the anatomical structures displayed on the 2D images for the study.

Next, review the border intersections of the 3D model to confirm good coverage of the heart chambers. In a study with good coverage of the heart chambers, proper alignment of the 3D borders

on the endocardium and valve rings of the 2D images has been shown to provide reliable information about the heart chambers shape and volumes.

Finally, review all the points on the 3D model. If the points that you picked adhere to the surface of the 3D model, it is most likely an accurate representation. Points that do not adhere to the model can indicate that the reconstruction is not accurate, suggesting patient motion or respiratory variation during scanning. You may want to review those point selections that do not adhere to the mesh.

From the 3D screen, select which features you want to view when examining the 3D model. When you first run calculations, the Mesh, Points, and Outlines are selected by default.

The 3D screen contains the following features:



**Borders.** Select to show how the 3D model intersects each of the 2D images. This is the only tool in the 3D View plane that affects the 2D images.



**Mesh.** Select to show the mesh surface on the 3D model.



**Intersections.** Select to show how each of the 2D ED/ES frames intersects the 3D model. Each 2D image that was acquired during the study will be depicted by a Yellow Border *within* the 3D model. This feature shows how well the area of the heart chamber was covered by 2D scanning.



**Combined View.** Select to superimpose the ED and ES models. If you select Combined View, the only other check boxes that can be selected are Outlines and Borders (all others are unavailable).

When viewing the atria chambers of the heart, it is possible that a larger volume will obscure views of the smaller volume. The VMS+ software will detect this and display the larger volume as a mesh so as not to obscure the view of the smaller volume (displayed as solid).



**Solid.** Select to show a solid representation of the image. If you select Solid, the mesh surface and any other elements located inside the mesh will be hidden.



**Outlines.** Select to show sharp edges of the key anatomical structures (Pulmonic, Tricuspid valves, and Apex).

---

### Scan Plane.



For 2D images – Select the Scan Plane button to display a moveable Scan Plane Adjustment window. Click a point on the 3D model to show how the 2D image that was used to pick the point intersects the 3D model. Select an additional point, and an additional scan plane is displayed on the 3D model for that point. Continue to add scan planes to the 3D model, remove a scan plane by selecting a point on the scan plan you wish to remove. See [To work with Scan Planes](#) for more information.

For MRI and 3D Echo images – Select the Scan Plane button, then click a point on the 3D model to show how the 2D image that was used to pick the point intersects the 3D model. If you click a different point on the 3D model, the 2D image will be replaced with a new one that corresponds to the new point.

---



**Points.** Select to show points on the 3D model.



**Small points.** Select to show small sized points on the 3D model.



**Medium points.** Select to show medium sized points on the 3D model.



**Large point.** Select to show large sized points on the 3D model.

---

▶ **To review the 3D model**

Go to the 3D screen. The 3D model fills the main workspace.

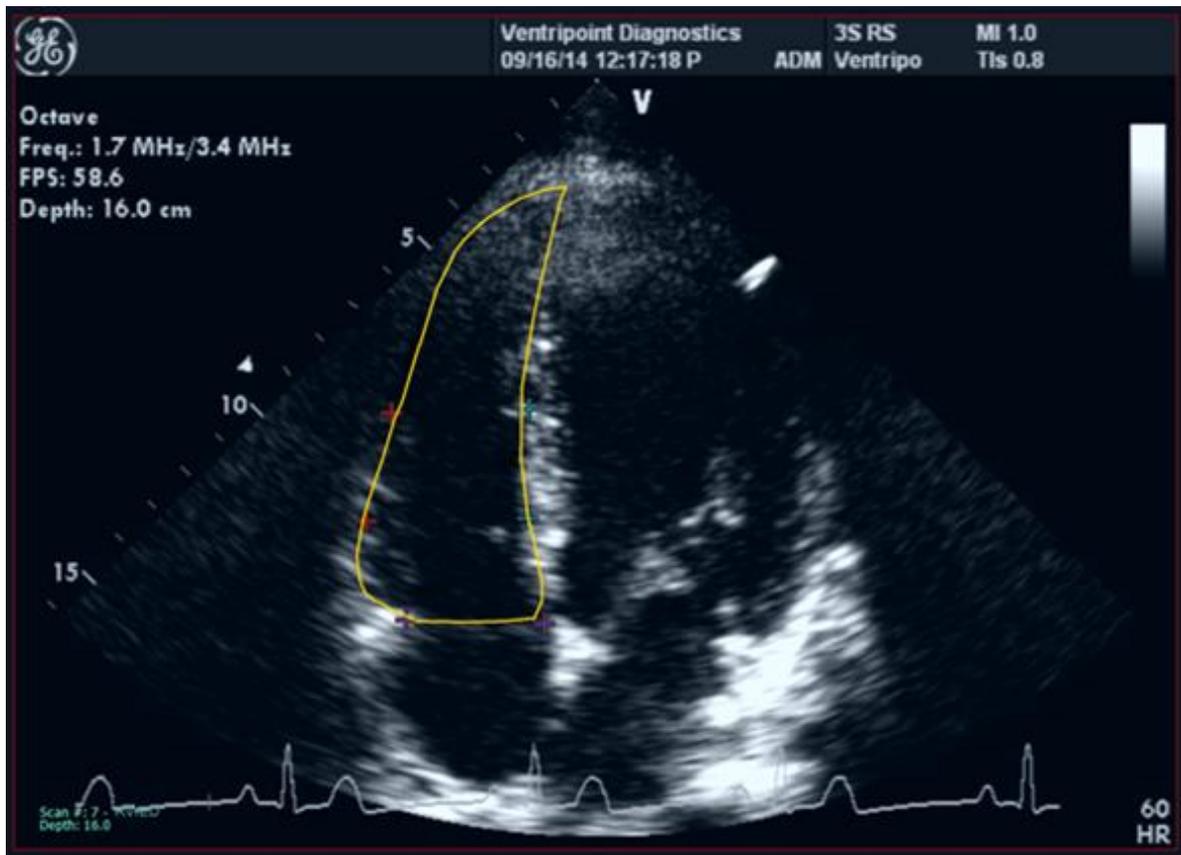
▶ **To change the size of the 3D model**

On the System, use a two-finger spread action to enlarge or pinch action to minimize.

On the Workstation, use the wheel of a mouse to roll forward to enlarge and back to minimize.

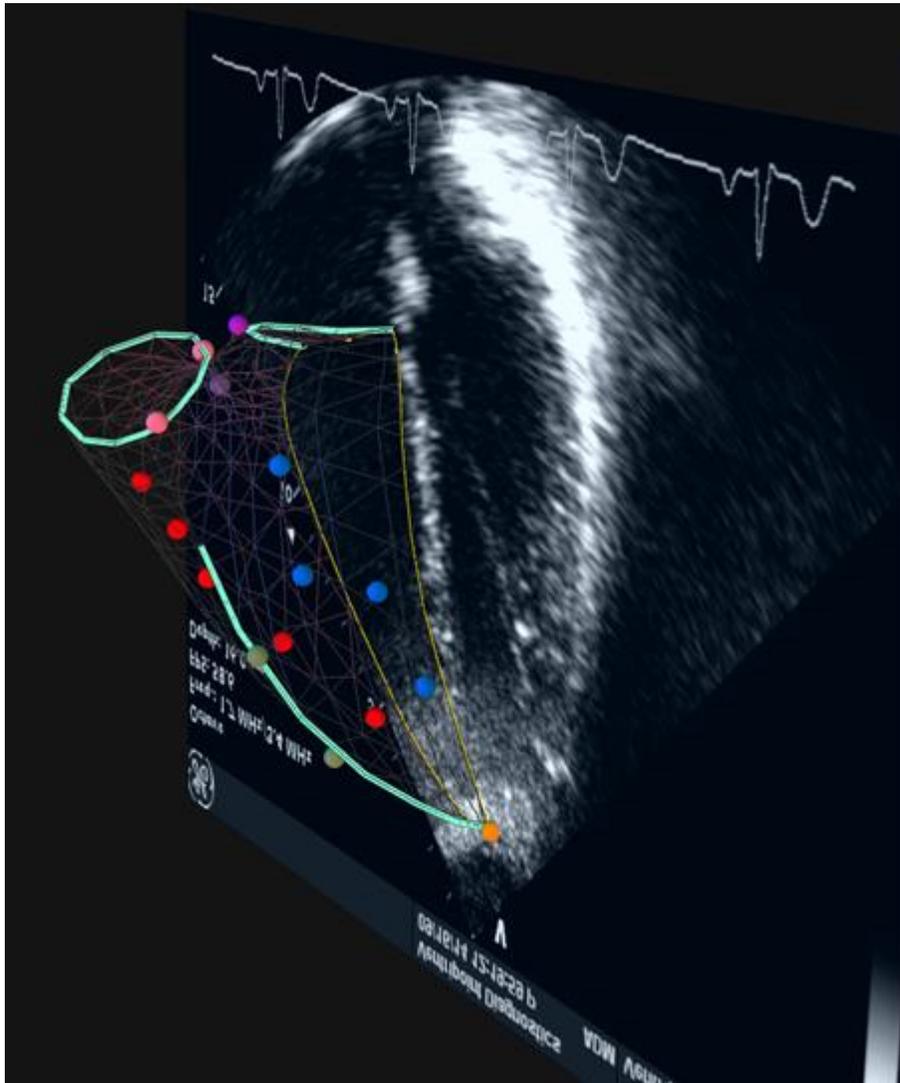
▶ **To rotate the 3D model**

1. On the System, tap and hold, then drag in any direction within the main workspace.  
On the Workstation, right-click and hold anywhere in the main workspace, then drag your mouse pointer in the direction that you want to rotate the image.
2. Click the **Swap Views** button so the 2D image fills the main workspace.
3. In the 3D View dialog, select the **Borders** check box. A yellow outline appears on the image on the main workspace so you can examine how well the lines from the 3D model match up with the anatomical structures. This helps you determine how well the 3D model intersects the 2D image.
4. The 3D model *must* intersect the selected heart chamber accurately. See the image below with borders selected.



5. Click the **Swap Views** button again, so that the 3D model fills the main workspace.
6. In the 3D View dialog, select the **Scan Plane** check box.
7. Click a point on the 3D model. The 2D scan image used to pick that point is now intersected with the 3D model on the main workspace. See the image below with a 3D model using the Scan Plane feature.

**NOTE** Highlights important information that will aid the user in operating the product more effectively.



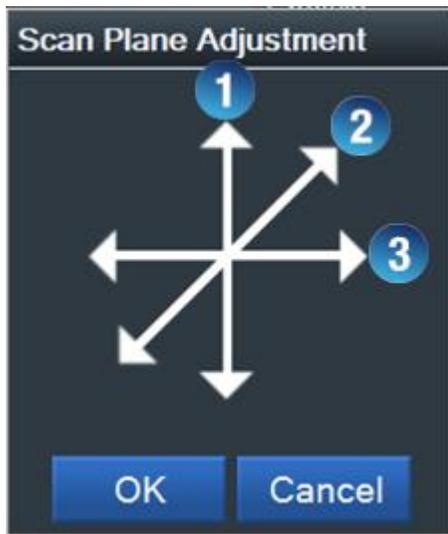
8. In the Cals table, review the volumetric analysis numbers. Now that you have reviewed the 3D model, you can use that information to refine your results as necessary.

► **To work with Scan Planes**

Viewing the intersections of the 2D image with the 3D model helps to verify the accuracy of the volume measurements. You will only need to use this feature if the borders from the 2D screen are out of alignment.

The Scan Plane Adjustment tool will allow for manual adjustment of the position of a scan plane relative to other planes. You will be able to align anatomy for adjusting the views relative to each other ie. annulus and apex.

1. With the 3D model in the main image area, select the Scan Plane button. A Scan Plane Adjustment window is displayed.



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**1** **Y axis adjustment.** Select an arrow to adjust the active plane (green border) up or down on the Y axis.

---

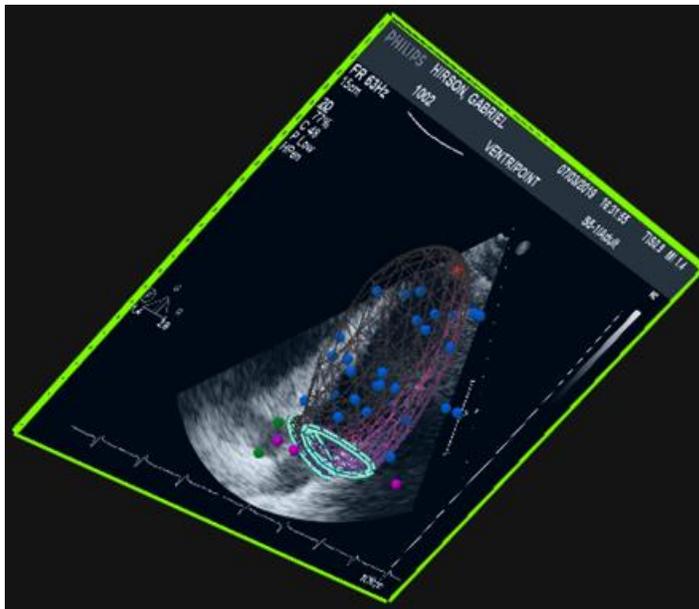
**2** **Z axis adjustment.** Select an arrow to adjust the active plane (green border) in or out on the Z axis

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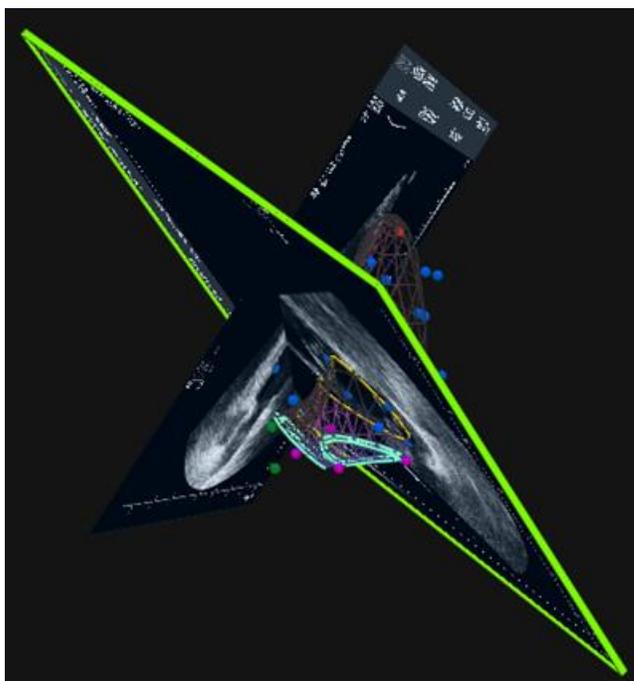
**3** **X axis adjustment.** Select an arrow to adjust the active plane (green border) left or right on the X axis.

---

2. Select a point on the 3D model to display an active scan plane for that point.



3. Continue to add additional scan planes for additional points as required.



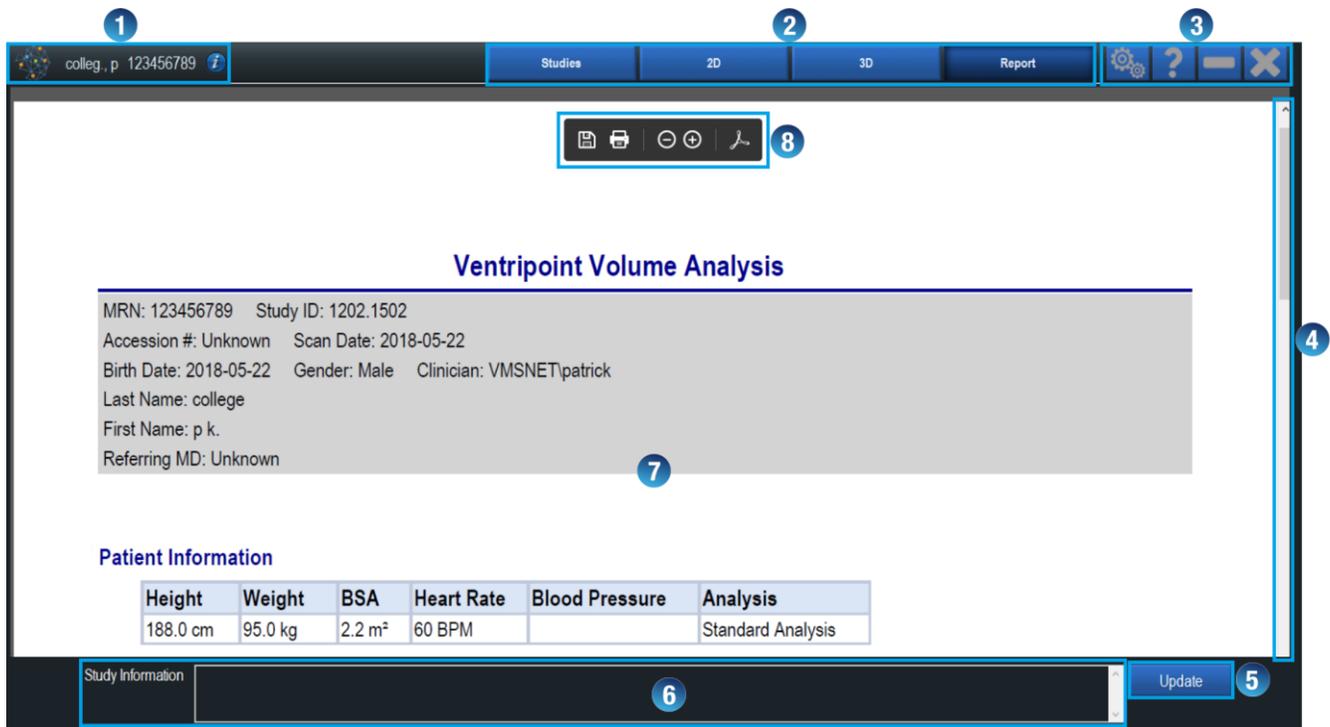
**NOTE** As new scan planes are added, the most recently added scan plane will automatically be the active Scan Plane with a green border. To activate a different Scan Plane, simply select a point on the desired Scan Plane.

4. (Optional) Select **Cancel** on the Scan Plane Adjustment window to discard all scan planes from the 3D model.
5. With the desired Scan Plane activated, adjust the X, Y and Z axes by using the arrows provided in the Scan Plane Adjustment window. Adjustments are made in 1 mm increments.
6. When you are done with your adjustments, select **OK** on the Scan Plane Adjustment window.
7. (Optional) Select **Cancel** to discard all scan planes and scan plane adjustments.
8. Return to the 2D screen and run **Calcs** for the required heart chambers.

**NOTE** Rerunning calculations is required after a scan plane adjustment.

## Report Screen

The Report screen in [Figure 7](#) is used to review information for an existing patient (i.e. measurements, images), confirm results, add or update comments, and save a Report to a USB device.



**Figure 7: Report screen**

- 1 Displays the Patient's last name, first name, first letter of their middle name (if entered) and MRN number (if entered).  
Edit or enter additional Patient Information using the  button.

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- 2 Application toolbar buttons. See [Application toolbar buttons](#).

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- 3 Application controls. See [Application controls](#).

---

- 4 Scroll bar. Move the scroll bar up/down to view different sections or pages of the report.

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- 5 Update button. Enter, edit or delete content in the Study Information box, then select Update to apply your changes.

---

- 6 Study Information. Enter, edit or delete content. Select Update to apply your changes. Study Information is added to the bottom of the report.

---

- 7 Report. The report has several different sections.

Report header	Included on every page of the report. Includes the Patient's MRN, study ID, Accession number, scan date, birth date, gender, Clinician's name who performed the study, last name, first name (and middle initial) and their referring MD (if entered).
Patient Information	Patient information includes the Patient's height, weight, body surface area (BSA), heart rate, blood pressure and the type of analysis selected. If any of these are blank, the information was not entered by the Clinician before the report was created.
Results	Each heart chamber has its own table of results and includes the ED Volume, ED Volume Index, ES Volume, ES Volume Index, Ejection Fraction, Cardiac Output, Cardiac Index, Stroke Volume, and Stroke Volume Index.
Study Information	Enter, delete or edit information about the study in the Study Information text box below the report and select Update to update the report with your changes.
3D Visualizations	On the 3D screen, you can take snapshots of the 3D model in End-Diastolic, End-Systolic and combined views.
ED Scans	On the 3D screen, swap the 3D model with the 2D model and take an End-Diastolic snapshot of any image.
ES Scans	On the 3D screen, swap the 3D model with the 2D model and take an End-Systolic snapshot of any image.



Adobe Reader toolbar. Select the top area of the report to evoke the Adobe Reader toolbar. Save, print (if printer is attached), increase/decrease size of report, or evoke the full Adobe workspace.

► **To view and/or create a report**

1. From either the Studies screen, 2D screen or 3D screen select **Report** from the application toolbar.
2. The Report screen appears for the selected study. The report appears on the main workspace as a PDF.
3. (Optional) In the Study Information box at the bottom of the screen, review (or add to) the comments that the Clinician entered for this study.
4. Select Update if anything was added or edited in the Study Information box. The Study Information is updated on the Report in the Study Information section.
5. (Optional) Select **Back** to return to the 3D screen.

► **To scroll through a report**

1. Select the scroll bar on the right of the report screen.

2. Drag the scroll bar up or down to scroll through the report pages.

▶ **To edit a report**

Only the Study Information can be edited when viewing a report.

1. Select the Study Information box at the bottom of the report screen. Tap anywhere in the box if on a System, left-mouse click anywhere in the box if on a Workstation.
2. Enter, delete or edit existing text.
3. Select **Update**.

▶ **To edit the size of the report**

1. Select the top portion of the report to display the Adobe Reader toolbar.
2. On the embedded Adobe Reader toolbar, select  repeatedly to reduce the size of the report.
3. On the embedded Adobe Reader toolbar, select  repeatedly to increase the size of the report.

▶ **To save a report to a USB drive**

1. Select the top portion of the report to display the Adobe Reader toolbar.
2. On the embedded Adobe Reader toolbar, select the **Save** icon. Windows Explorer is displayed.
3. Find and highlight the USB drive where you wish to save the Report.
4. (Optional) Enter a custom Report name.
5. Click **Save**.

## VMS+ Image Acquisition Protocol

There are a minimum number of views that you *should* acquire.

The table describes the minimum number of views that you *should* acquire

and is included in the Appendix under the Quick Reference Guide, which includes pictures of the anatomical structures and the points placement. See [Anatomical View and Point Placement](#).

### CAUTION



The image acquisition protocol is designed to provide optimal coverage of each chamber efficiently, with alternate views recommended to provide greater anatomical coverage to ensure quality results. Additional/alternate views can be acquired as appropriate. It is recognized that, due to the imaging limitations inherent in TTE, some views might not be optimal. It is incumbent upon the user to utilize all possible views to insure complete

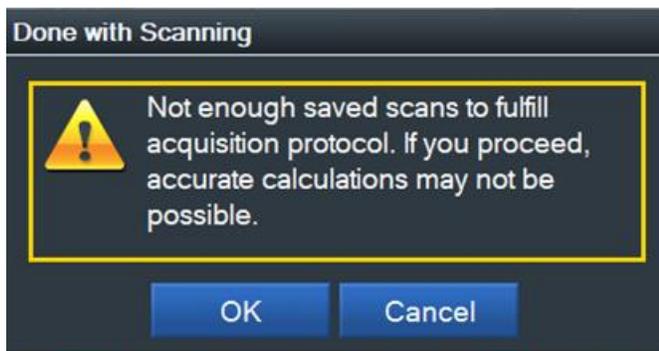
visualization of the entire chamber and the associated anatomical points necessary for 3D visualization and calculations.

### CAUTION



Regardless of the sequence and/or quality of the acquired images, the points placement above should be followed for optimal results. Using the protocol described above, the user places points on the mandatory anatomical structures as directed, utilizing the 3D viewer to ensure that the points are being placed on the expected anatomical structure. Although the protocol lists a certain amount of anatomical points to be placed prior to running the first 3D visualization, the number of initial points may vary at the user's discretion secondary to image quality, anatomical variations and acoustic limitations.

The software will warn you if you wish to proceed to post-scan analysis when not all the views have been acquired. Ventripoint suggests a minimum number of views for you to achieve an accurate volume calculation when performing analysis.



#### ► To discard a study

If you do not want the scans that you have already captured, you can discard the study.

1. From the Scan screen, select a thumbnail.
2. The Scan Review screen is displayed with the selected thumbnail in the main image area.
3. Select **Delete**.
4. Continue to select delete until all the acquired scans are deleted. Once all the scans have been deleted, the Scan screen will be displayed automatically.
5. Select **Done**.

Select **OK**. The Studies screen will be displayed, and the study has been discarded.

## System Security

Ventripoint ensures compliance with data protection and privacy standards and regulations. Ventripoint has implemented certain measures into the VMS+ software to ensure the device remains safe and effective throughout its lifecycle. To gain access to patient data, you must be authenticated/access authorized by logging onto the system using a user ID and a password. Authorization to the system is dependent upon authentication credentials and/or roles, including standard user(s) and administrative user. When you are finished using the system, you can log off manually or simply shut down the system, which logs you off automatically. Only a registered user can change the password.

A user account is added to the VMS+ software upon installation; this user account has Administrative privileges and only this user can perform the following:

- Add/delete user accounts
- Lock/unlock user accounts. Any user, either Standard or Administrative, will be locked out after 5 failed attempts. If an Administrator is locked out, please contact Ventripoint.
- Change passwords. Password lengths and character types (i.e. number, letter, symbol) are not limited.

After 30 minutes of inactivity, sessions are automatically terminated, and the user is logged out.

VMS+ software also logs who signed in, what actions were taken by the user and how long they were signed in. See [Log files](#). Log files are archived on the system for at least six (6) months and then deleted.

Users are not “locked out” by hardware or software system features. To protect data, you should not install any other third-party software (utilities or applications programs) on the computer, excluding anti-malware/anti-virus software. The system should not be used for email or internet access.

A user account, VP Tech, also comes activated on the VMS+ system. Do not delete, disable or change the password for this account. No modification to the privileges of this account should be made. This is a back up account and only Ventripoint Technicians are authorized to use it.

### CAUTION



Do not use the internal hard drive for long-term image storage. External storage media or network-based server solution is recommended for study long-term archive. Perform backup of the patient archive stored on the local hard drive at least once a week and delete them after they are exported.

The OS for the system has an anti-malware and anti-virus component built in to protect the system and a firewall which regulates the ports and limits access to and from the ports.

Should the device be compromised by malware/virus, the OS system should quarantine it and send a notification to the user. Upon detection of a cybersecurity vulnerability or incident, refrain from using the device and contact your Ventripoint Representative for further information. VMS+ is compatible with any third-party anti-virus/anti-malware software as dictated by each institutions IT policy. Routine security and antivirus scanning by the institution is recommended. Ventripoint is continuously evaluating the

need for additional actions to reduce vulnerability of the equipment, including evaluation of new security patches for the third-party software used. Microsoft (and other) security patches that addresses serious issue with VMS+ will be made available to customers after Ventripoint verification of those patches.

No software updates are required and/or permitted by the user. All OTS required for operation of the device is integrated in the VMS+ software and cannot be changed by the user.

Encryption has been used to protect information that ensures the effective operation of the system.

Automatic updates of the operating system are disabled. Updates require intervention and will not be initiated by the device. As a preventive measure, it is recommended that access to internet is not permitted from this system.

Major configuration changes can only be made by users with administrative privileges.

**NOTE** CopyTo/CopyFrom is configured to not allow any exe., bat, cmd, ds, dll, ws, ps, msi, zip, ar, js, py, ph, or pl files to be copied.

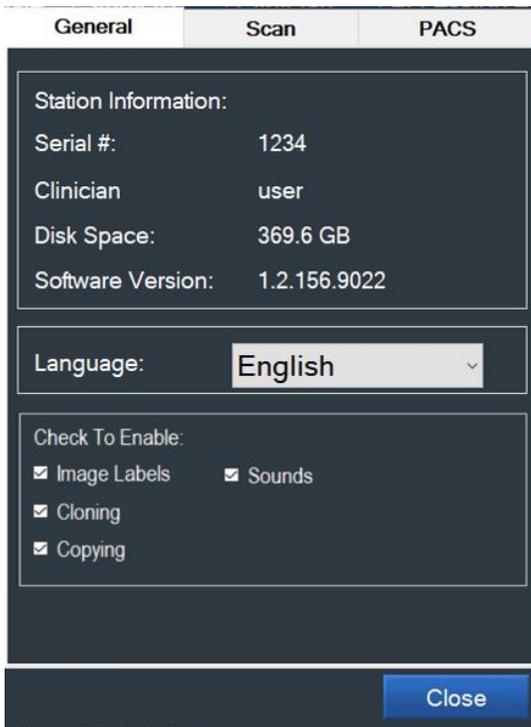
**NOTE** Auto-run is disabled on all USB ports.

## System Settings

Configure settings for your System or Workstation, by setting your preferences in  System Settings.

System Settings is divided into three tabs:

- General – General Information about the System, Language selection and where you enable and disable functions on the Studies screen.

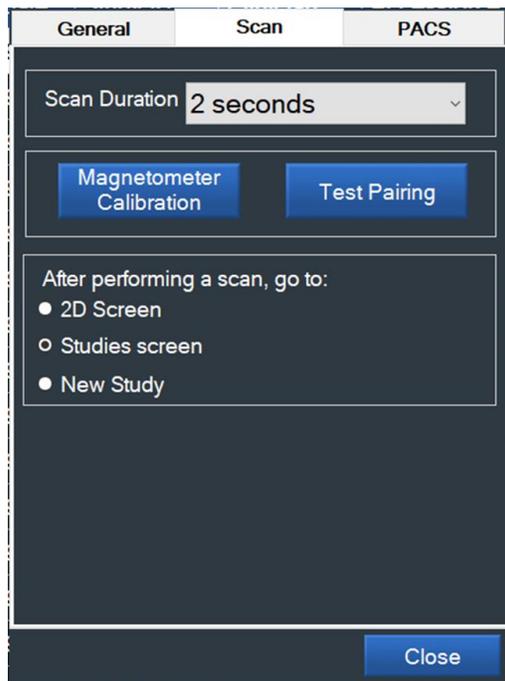


System

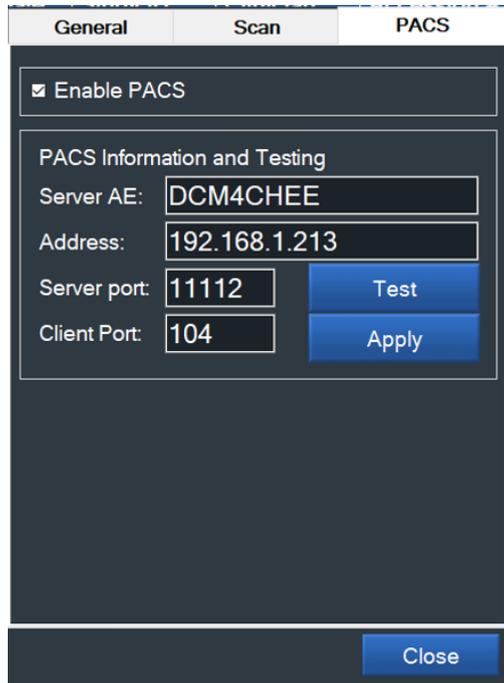


Workstation

- Scan – Only available on the System. Set scan duration, perform a [Magnetometer Calibration](#) (required when turning on the system, if moving the system or changing region of interest), test the sensor pairing, enable or disable sounds and automatic sending of studies to PACS, and select what screen to display after a scan is completed.



- PACS – Enable and disable sending or getting studies from PACS, setup PACS information and test PACS.



## General Settings

### ► To set General settings

1. Select  **System Settings**.
2. Select the **General** tab.
3. General information about the System is displayed.
  - Serial #: System serial number.
  - Clinician: Name of current user.
  - Disk Space: Amount of available space on the System's hard drive.
  - Software Version: Current VMS+ software version currently installed.
4. Select a language from the drop-down menu. Options available are English, Français and Deutsch.

Once a different language is selected, the software will shut down and you will have to restart the application.

5. Several features can be enabled or disabled on this tab:
  - Image Labels: Check/Enable to display Image Labels on thumbnails, 2D and 3D images. Image Labels include the Scan #, Depth and Anatomical View Label (applied at time of acquisition), Custom Label (if created) for thumbnails and 2D images. Check/Enable to display the Volume and number of points placed on a 3D model.
  - Cloning: Check to enable cloning and to display a Clone button on the Studies screen. See [Cloning Studies](#) for more information.
  - Copying: Check to enable copying and to display a Copy To/Copy From button on the Studies screen. See [Copying A Study](#) for more information.
  - Sounds: On by default, sound will be heard when acquiring scans, pairing the Sensors, opening studies, etc. Uncheck to mute the sounds.

- Importing MRI: Check to enable importing of MRI studies. Only available on the Workstation.
  - Importing 3D Echo: Check to enable importing of 3D Echo. Only available on the Workstation.
6. Select **Close** to save your selections.

## Scan Settings

### ▶ To set Scan settings

Only available on a System.

1. Select  **System Settings**.
2. Select the **Scan** tab.
3. Default scan length during acquisition is 2 seconds. (Optional) Select either 3, 4 or 5 seconds from the Scan Duration drop-down menu.
4. By default, system sounds are turned on. To disable these sounds, uncheck the Sounds checkbox. Sounds are heard when you select an anatomical button to acquire a scan and then again when the scan has been acquired. You will also hear sounds when pairing the transducer sensor to the patient sensor
5. (Optional) Run a calibration of the magnetometer in the transducer sensor from the Scan tab.

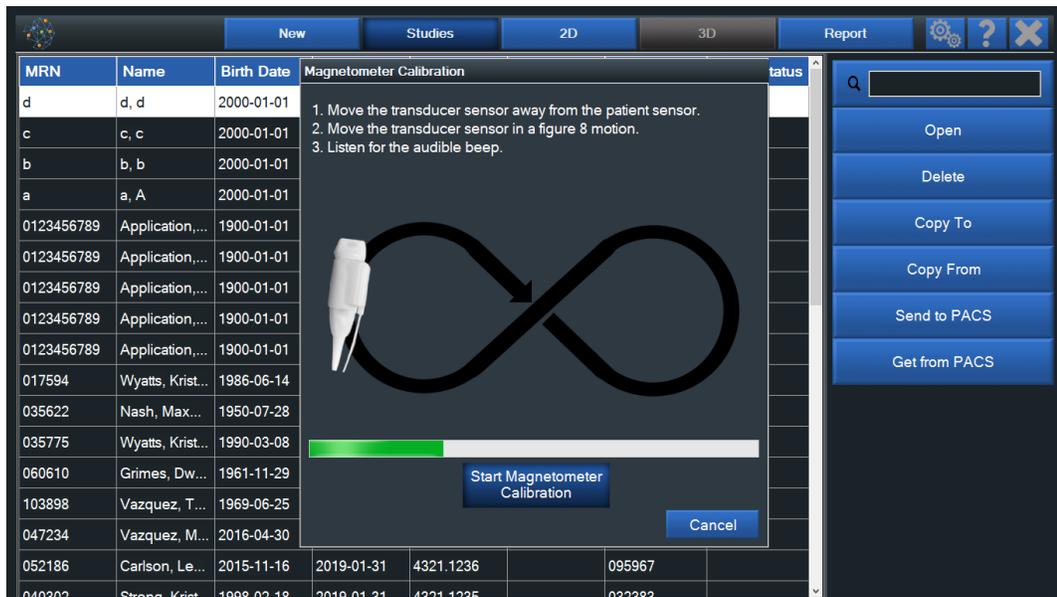
### CAUTION



If the system has been idle for more than 30 minutes between sessions, a magnetometer calibration is recommended.

- a. Select the **Start Magnetometer Calibration** button.
- b. Move the patient sensor away from the field of interest.
- c. To calibrate the magnetometer, move the transducer sensor in a figure 8 motion above the bed at least 0.5 meters away from the patient sensor until you hear the audible beep signalling that the calibration is successful.

Ensure you keep the sensor attached to a transducer. While the calibration is taking place, the transducer sensor will blink orange and green continually until the calibration is complete.



- d. If the Magnetometer Calibration is successful, Select cancel to proceed.
6. You can also test the sensor pairing by selecting the Test Pairing button. Follow the instructions outlined in the [Pairing the Sensors](#) section.
7. Select what screen you want displayed after acquisition is completed. Choose from the 2D screen, Studies screen or the Patient Information screen and create a new study.
8. Select **Close** to save your selections.

## PACS Settings

### ► To set PACS settings

1. Select  **System Settings**.
2. Select the **PACS** tab.
3. Check the Enable PACS checkbox to enable PACS. When enabled, the Send to PACS and Get from PACS buttons are displayed on the Studies screen.
4. Enter PACS information:
  - Server AE: Application Entity ID name of the PACS.
  - IP Address: The IP address of the PACS server.
  - Server Port: The number of the port on the PACS server to be used for DICOM communications with your local host.
  - Client Port: The number of the port on the local host to be used for DICOM communications with the PACS server.

**NOTE** Server port numbers may vary for different PACS servers and may be different from the default ones. Consult your IT administrator to configure the system for your PACS.

## WARNING



When configuring the local (client) port on a workstation, make sure your chosen value is not used by any previously installed DICOM-related software. If another service or application is accessing the same port simultaneously with your VMS+ software, both will fail to process DICOM communications successfully.

5. Select **Apply** to save the recently entered data.
6. Select the **Test** button to test connectivity to the configured PACS server. A PACS verification dialog is displayed.
7. On the PACS verification dialog, a status will be displayed:
  - Ready – ready to run test
  - Pass – Connectivity test completed successfully
  - Fail – Failed to connect to PACS server
8. If the status reads Ready, select **Test**.

**NOTE** If the test fails, please contact your IT Department and/or Ventripoint Customer Support to help resolve the issue.

9. Select **Close** on the PACS Verification dialog when testing is completed.
10. Select **Close** to save your selections.

## System Information

System information is available in System Settings.

### ► To access System Information

1. Go to  System Settings.
2. Go to the General tab. The following information is provided on the General tab:
  - a. Serial #. Serial number of the System or Workstation.
  - b. Clinician. Name of the currently logged in Clinician.
  - c. Disk Space. Available disk space.
  - d. Software Version.

## Moving the System

When moving or transporting the system, follow the warnings and cautions below to ensure the safety for people, the system, and other equipment.

► **To transport and place unit**

Before moving the system:

1. Follow the guide under [To disconnect the VMS+](#) for instructions.

**WARNING**



Unplug all cables before you move the machine. Remove the power cord from the wall outlet, unplug the ethernet cable from the wall outlet, and disconnect the video cable from the ultrasound. When moving the VMS+, you should take care that the cables will not be damaged under the wheels of the system.

2. Lower the system to its lowest position.

**CAUTION**



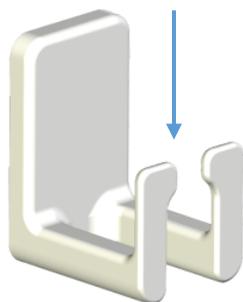
The System will automatically raise to the highest height when you press your foot on the stand base lever. Ensure there are no objects around the system before pressing your foot on the stand base lever.

- a. With your foot, press the lever on the base while simultaneously holding the computer and gently pushing down.



- c. Release your foot when the monitor has reached its minimum height.

3. Ensure that sensor cables are out of the way from the wheels and not protruding beyond the console.
4. Store the sensors in the holsters located on either side of the console.



5. Unlock the wheels.
6. Move the system by pushing or pulling the pole of the stand.



**CAUTION**

Do not let the system strike walls or door frames.



**CAUTION**

Do not attempt to push the roll stand over a threshold (i.e. door, elevator). When a threshold is encountered, have another person help to carefully lift the front wheels over the threshold while you hold the cart steady. Push the cart forward slowly until the rear wheels are over the threshold.

**NOTE**

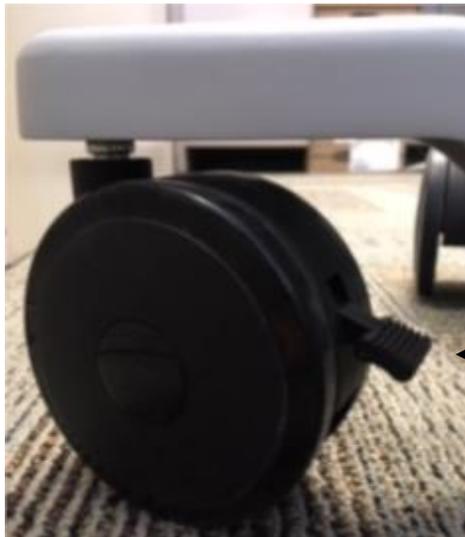
Take extra care when moving the system on inclines. Wheel chair ramps are usually less than five degrees. Avoid ramps that are steeper than ten degrees to avoid tipping over the system.

7. Once the destination is reached, lock the wheels.

▶ **To engage the wheel lock**

2 of the 5 wheels are locking and 3 are non-locking.

1. Press down on the lock pedal. The pedal remains depressed and the wheel is locked.



Lock pedal

▶ **To transport and place unit**

2 of the 5 wheels are locking and 3 are non-locking.

1. Lift up on the lock pedal. The pedal returns to its normal position and the wheel is unlocked.



## Glossary

**Body Surface Area (BSA):** The measured or calculated surface of a human body. The formula for BSA is  $(W^{0.425} \times H^{0.725}) \times 0.007184$ , where W is weight in kilograms (kg), and H is height in centimeters (cm).

**Cardiac Index (CI):** The normalization of cardiac output by BSA. The formula for CI is cardiac output (CO) / BSA.

**Cardiac Output (CO):** The volume of blood ejected per minute. The formula for CO is stroke volume (SV)  $\times$  heart rate.

**Cine Loop:** A video clip, varying in length from 2 to 5 seconds (as determined by the user).

**Cardiac Ultrasound System:** A medical imaging device that visualizes the heart by means of high-frequency ultrasound waves.

**Electromagnetic Compatibility (EMC):** The branch of electrical sciences which studies the unintentional generation, propagation and reception of electromagnetic energy with reference to the unwanted effects that such energy may induce.

**Ejection Fraction (EF):** The formula for EF is  $(EDV - ESV) / EDV$ , where EDV is the End Diastolic Volume, and ESV is the End Systolic Volume. According to the American Society of Echocardiography (ASE) document, "Recommendations for Chamber Quantification" (*JASE* 18, no. 12 [December 2005]: 1440–1463), the normal range for ejection fraction is 32–60.

**End Diastolic (ED) Frame:** The Ventripoint Medical System+ (VMS+) uses an ECG trigger to select ED. By default, unless otherwise specified by the customer, the trigger is configured to capture ED at the onset of the QRS. The user will have the opportunity to override the VMS+ selection for each cine loop acquired.

**End Systolic (ES) Frame:** ES is selected by the user in one cine loop. The timing of that selection will then be applied to all cine loops for that study. The selection of ES can be changed, but this will override the previous selection. VMS+ accepts only one value for ES, and this will be applied to all cine loops.

**Image Acquisition Protocol:** The process defined by Ventripoint for optimizing VMS+ results by defining echo views that guide the user to obtain good coverage of the heart chambers.

**System:** A system provisioned by manufacturing, containing the necessary hardware for capturing ultrasound images and tracking the 3D coordinates of the ultrasound transducer. This system is typically installed in the clinic Echo lab.

**Knowledge Based Reconstruction:** The process of generating a 3D surface model by referencing databases (Ventripoint Knowledge Base) that embody knowledge of shapes that are similar to that of the object being Investigated.

**PACS:** Picture Archiving and Communication System. A technology which provides economical storage of, and convenient access to, images from multiple modalities

**Radio Frequency (RF):** Electric current that oscillate in the frequency wave of 3 kHz to 300 GHz.

**Reconstruction Protocol:** The process defined by Ventripoint for optimizing VMS+ results by entering points on the key anatomical structures on the 2D images that cover the heart, and then revising the placement of those points.

**Scanning Data:** The ultrasound images that VMS+ captures through the video output connection of the ultrasound machine.

**Stroke Volume (SV):** The volume of blood pumped from the left ventricle in one contraction. The formula for SV is  $EDV - ESV$ .

**Tetralogy of Fallot (TOF):** A congenital heart defect that involves four heart malformations: ventricular septal defect (VSD), pulmonic stenosis, overriding aorta, and right ventricular hypertrophy.

**Ventripoint Medical System Plus (VMS+):** The specific diagnostic tools and software used on the client side. VMS+ consists of a commercial, off-the-shelf computer and tracking system sensor, and patented and proprietary methods and software.

**Ventripoint Knowledge Base:** A database of shapes that is used to determine the accurate volume measurements for an object through weighting, interpolation, and scaling. The database includes models derived from magnetic resonance images (MRIs) and echo images.

## Troubleshooting

If you encounter any problems in the operation of your system, review the following information for assistance. If the problem is not covered in this section, contact your Ventripoint representative for assistance.

The troubleshooting table contains a list of problems and the actions to take to correct the problems.

Problem	Solution
The program executes a defective code path that causes a system exception. A message appears, describing the error. After you acknowledge the message, the program closes.	Restart the Ventripoint Medical System+ (VMS+). Any changes that you made to studies before the exception event may have been lost, and you will need to re-enter them. The system records the error in an activity log.
There is insufficient space on the removable media to copy to/from the study.	Either make more space available on the removable media (if you are using a USB device) or insert a removable media that has sufficient space. Retry the copying process.
VMS+ runs out of local storage space. The system closes the current study without saving any changes.	Delete or copy and delete one or more studies from local storage to make room for more studies. Re-enter your changes.
Sensors do not pair	Run through a magnetic calibration.
Sensors LEDs are not working	Unplug the sensors and then plug them back in.

### For Assistance

If you are unable to correct a problem, call your Ventripoint representative.

## Setting Up a VMS+ Workstation

### VMS+ Workstation Software Installation

VMS+ software can be installed on Windows compatible computers by a Ventripoint service personnel. PACS and archive location information requires coordination with your facility's IT Department.

Any study that has been sent to PACS can be accessed from a Workstation.

To install VMS+ Workstation the computer needs to have prerequisite software installed and meet minimum hardware requirements.

### Computer requirements

The minimum requirements for the computer are listed in the table below

Item	Minimum requirements
OS	Microsoft Windows 10
CPU speed	2.0 GHz
RAM	2 GB of available RAM (4 GB strongly recommended)
Hard disk space	100GB of free space
Graphic	Display resolution of 1280x1024 Graphics adaptor supporting DirectX 9.0
USB	At least one USB port available
Pointing device	Mouse with left and right buttons
Alphanumeric keyboard	Required
Installed software	Microsoft Windows 7 or Windows 10 Microsoft .NET 4.0 Microsoft Runtime libraries: Visual Studio 2010, 2008, 2005 DirectX 9.0c Adobe Acrobat Reader 8.0 or above JAVA JRE

**NOTE** The computer running VMS+ software should have an anti-virus software installed.

**NOTE** Password protection should be used on the computer running VMS+ software, since the software is handling patient information (e.g. patient name, ID and birthdate).

## Where to Obtain the Software

Visit [Microsoft's downloads center](#) for the following updates:

- [Microsoft .NET 4.0](#)
- All Microsoft Runtime Libraries
- [DirectX 9.0c](#)

Visit [Adobe downloads center](#) for the following updates:

- [Adobe Acrobat Reader](#)

## Appendix

### Quick Reference Guide

#### Introduction

This document provides imaging tips and suggested point placement for each anatomical view,

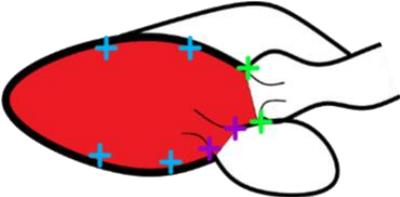
It is important to acquire as many views as possible as outlined in the VMS+ software to acquire the most accurate volumes and ejection fraction measurements possible.

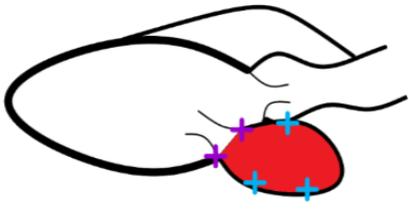
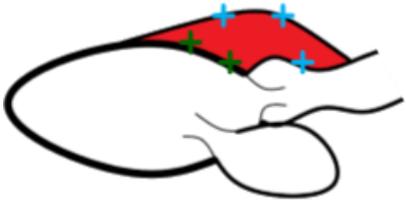
### Imaging tips

- Confirm the optimal position and depth for all windows before acquiring the first image—the patient cannot move after the first image is acquired.
- For each chamber, use the recommended views as determined during acquisition.
- The ED/ES columns in the structures table on the 3D screen will turn green once you have placed the minimum required number of points for that structure.
- The Calcs button will become enabled when enough points have been placed.

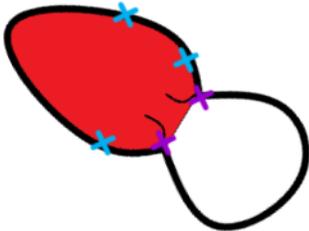
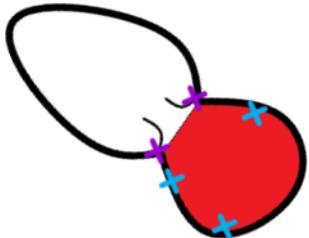
### Anatomical View and Point Placement

#### ► Parasternal Long Axis

Chamber	Point Placement Image	Structure	ED	ES	Point Colour
LV		Aortic Annulus	2	2	+
		Mitral Annulus	2	2	+
		Endocardium	4	4	+
LA		Mitral Annulus	2	2	+

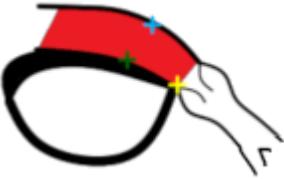
		Endocardium	3	3	+
RV		Septum	2	2	+
		Endocardium	3	3	+

► Parasternal Right Ventricular Inflow Tract

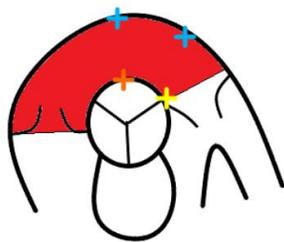
Chamber	Point Placement Image	Structure	ED	ES	Point Colour
RV		Tricuspid Annulus	2	2	+
		Endocardium	3	3	+
RA		Tricuspid Annulus	2	2	+
		Endocardium	3	3	+

► Parasternal Right Ventricular Outflow Tract

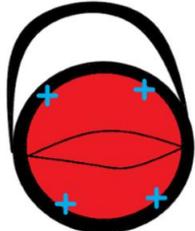
Chamber	Point Placement Image	Structure	ED	ES	Point Colour
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RV		Pulmonic Annulus	1	1	+
		Septum	1	1	+
		Endocardium	1	1	+

► Parasternal Short Axis Aortic Valve

Chamber	Point Placement Image	Structure	ED	ES	Point Colour
RV		Pulmonic Annulus	1	1	+
		Conal Septum	1	1	+
		Endocardium	2	2	+

► Parasternal Short Axis Mitral Valve

Chamber	Point Placement Image	Structure	ED	ES	Point Colour
LV		Endocardium	4	4	+

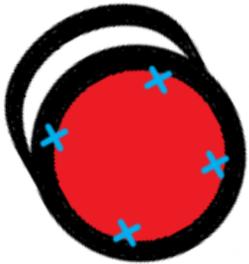
RV		Septal Edge	2	2	+
		Septum	1	1	+
		Endocardium	2	2	+

► Parasternal Short Axis Mid (Papillary)

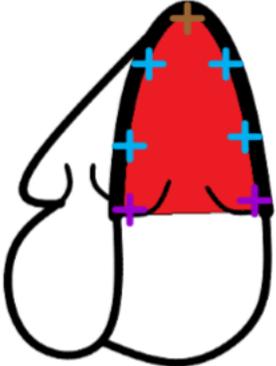
Chamber	Point Placement Image	Structure	ED	ES	Point Colour
LV		Endocardium	4	4	+
RV		Septal Edge	2	2	+
		Septum	1	1	+
		Endocardium	2	2	+

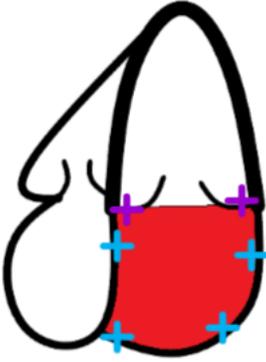
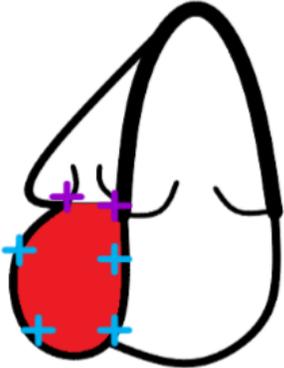
► Parasternal Short Axis Mid Distal (Apex)

Chamber	Point Placement Image	Structure	ED	ES	Point Colour
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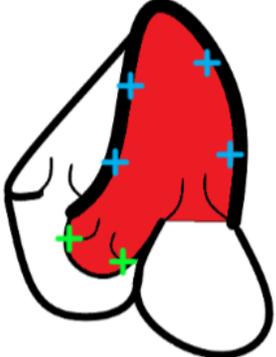
LV		Endocardium	4	4	+
RV		Septal Edge	2	2	+

► Apical 4 Chamber

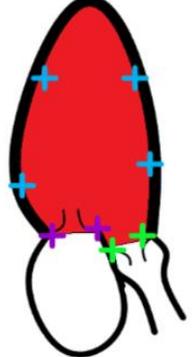
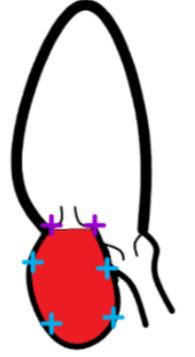
Chamber	Point Placement Image	Structure	ED	ES	Point Colour
LV		Mitral Annulus	2	2	+
		Apex	1	1	+
		Endocardium	4	4	+

LA		Mitral Annulus	2	2	+
		Endocardium	4	4	+
RV		Tricuspid Annulus	2	2	+
		Apex	1	1	+
		Basal Bulge	1	1	+
		Septum	2	2	+
		Endocardium	2	2	+
RA		Tricuspid Annulus	2	2	+
		Endocardium	4	4	+

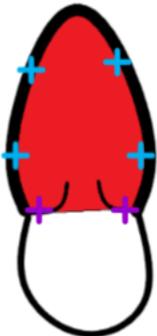
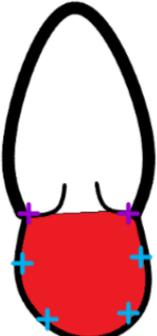
► Apical 5 Chamber

Chamber	Point Placement Image	Structure	ES	ED	Point Colour
LV		Aortic Annulus	2	2	+
		Endocardium	4	4	+

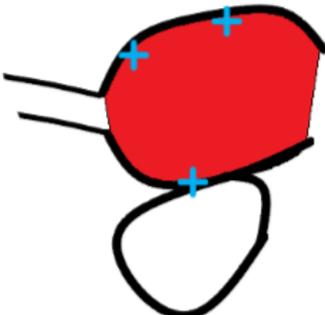
► Apical 3 Chamber

Chamber	Point Placement Image	Structure	ED	ES	Point Colour
LV		Mitral Annulus	2	2	+
		Aortic Annulus	2	2	+
		Endocardium	4	4	+
LA		Mitral Annulus	2	2	+
		Endocardium	4	4	+

► Apical 2 Chamber

Chamber	Point Placement Image	Structure	ED	ES	Point Colour
LV		Mitral Annulus	2	2	+
		Endocardium	4	4	+
LA		Mitral Annulus	2	2	+
		Endocardium	4	4	+

► Subcostal Inferior Vena Cava

Chamber	Point Placement Image	Structure	ED	ES	Point Colour
RA		Endocardium	3	3	+

**Point Placement Summary Table**

View	Chamber	Structure	ED Points	ES Points
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PLAX	LV	Aortic Annulus	2	2
		Mitral Annulus	2	2
		Endocardium	4	4
	LA	Mitral Annulus	2	2
		Endocardium	3	3
	RV	Septum	2	2
		Endocardium	3	3
PRVIT	RV	Tricuspid Annulus	2	2
		Endocardium	3	3
	RA	Tricuspid Annulus	2	2
		Endocardium	3	3
PRVOT	RV	Pulmonic Annulus	1	1
		Septum	1	1
		Endocardium	1	1
PSAXAO	RV	Pulmonic Annulus	1	1
		Conal Septum	1	1
		Endocardium	2	2
PSAXMV	LV	Endocardium	4	4
	RV	Septal Edge	2	2
		Septum	1	1
		Endocardium	2	2
PSAXMID	LV	Endocardium	4	4
	RV	Septal Edge	2	2
		Septum	1	1
		Endocardium	2	2
PSAXDISTAL	LV	Endocardium	4	4

	RV	Septal Edge	2	2
A4C	LV	Mitral Annulus	2	2
		Apex	1	1
		Endocardium	4	4
	LA	Mitral Annulus	2	2
		Endocardium	4	4
	RV	Tricuspid Annulus	2	2
		Apex	1	1
		Basal Bulge	1	1
		Septum	2	2
		Endocardium	2	2
	RA	Tricuspid Annulus	2	2
Endocardium		4	4	
A5C	LV	Aortic Annulus	2	2
		Endocardium	4	4
A3C	LV	Mitral Annulus	2	2
		Aortic Annulus	2	2
		Endocardium	4	4
	LA	Mitral Annulus	2	2
		Endocardium	4	4
A2C	LV	Mitral Annulus	2	2
		Endocardium	4	4
	LA	Mitral Annulus	2	2
		Endocardium	4	4
SCIVC	RA	Endocardium	3	3

## Cleaning and Disinfection

It is important to clean and maintain the system and peripherals. It is your responsibility to appropriately clean and disinfect your device in accordance with the device manufacturer's instructions and your institution's policies for cleaning and disinfecting of medical devices.



### CAUTION

Using cleaners and disinfectants not listed in this guide could damage the components of the VMS+ and void warranty.

## Cleaning the System and Sensor Equipment

Use this method to clean the system and the sensor cables and housing. You can use a mild soap solution. If the equipment has come in contact with blood or infectious material, clean the equipment with a 70% solution of isopropyl alcohol.

Read all [Cautions](#), [Warnings](#) and [Recommendations](#) before you begin.



### WARNING

Always use protective eyewear and gloves when cleaning and/or disinfecting the equipment. If there is visible soil/contamination, assess risk of splashing and spraying of body fluids during cleaning process.

Use the following procedure to clean the display, all external surfaces of the system and the roll stand; and the sensor cables and housing.

1. Before cleaning, turn OFF the system and unplug the power cord from the power source.
2. Wipe with a soft cloth moistened with soap and water.
3. If blood or other infectious biological material comes in contact with the system or any cable, wipe with a 70% solution of isopropyl alcohol.



### CAUTION

Do not use strong solvents, common cleaning products, or abrasive cleansers, which will damage the system surfaces.



### CAUTION

Do not touch the display with sharp objects or use paper towels to clean it, which may damage it.



### CAUTION

When cleaning the system monitor screen, touch screen, mouse, and keyboard, take care not to get any solution inside the housings. Also take care not to scratch the face of the monitor while cleaning it.



### CAUTION

Do not use cleaners containing bleach on the touch screen. It may damage the surface.

4. Remove any residue with a cloth moistened with sterile water.

5. Be sure to dry the equipment to prevent potential corrosion.

## Cleaning the Roll Stand



### WARNING

Allow the roll stand to dry completely before plugging the power cord into the wall outlet.



### CAUTION

Due to the proximity of electrical power and equipment, flammable cleaners should never be used on the roll stand.



### CAUTION

Before using any cleaner on the cart, first test it on a small area to ensure that the surface is not harmed.

## Recommended cleaners and disinfectants

In general, when used in those concentrations as recommended by the manufacturer, the roll stand can be wiped down with the following common non-abrasive cleaning agents such as:

- Water/Distilled Water
- Mild detergent or soapy water
- 10% bleach solution (10% bleach/90% water)
- 3% Hydrogen Peroxide solution
- 70% Ethyl Alcohol solution
- Germicidal Disposable Cloth, (Alkyl dimethyl benzyl ammonium chloride – 0.07%, Alkyl dimethyl ethylbenzyl ammonium chloride – 0.07%, Remaining inert ingredients)
- Windex brand glass cleaner
- Lysol brand Disinfectant All Purpose Cleaner
- Formula 409 brand cleaner
- Methylated Spirits
- Virex II 256 Disinfectant Cleaner
- Virex Tb Disinfectant Cleaner

## Cleaning the Computer

The computer used in the VMS+ is a medical grade computer with the following characteristics:

- UL60601 Certified. The computer is compliant with CDC guidelines for environmental infection control and isolation precautions.
- Antimicrobial. Prevents Surface contamination. Supports infection control initiatives.



### WARNING

Do not spray cleaning agent on the chassis.



### WARNING

Do not use disinfectants that contain phenol.

## WARNING



Do not have liquids seep in or inserting objects into the internal areas of the computer may result in electric shocks from taking and/or short circuiting the internal parts. If liquid has seeped in, immediately disconnect the VMS+ from the power outlet and contact your Ventripoint Representative.

The exterior surfaces of the system can be disinfected using a compatible disinfectant with a wipe method. System surfaces include the monitor screen, the touch screens, and plastic surfaces.

## Recommended cleaners and disinfectants

The following products can be used on system surfaces:

- Mild soap solution
- 70% isopropyl alcohol (IPA)
- T-Spray II (quaternary ammonium-based)
- Opti-Cide 3 (quaternary ammonium/isopropyl alcohol-based)
- Sani-Cloth HB (quaternary ammonium-based)
- Sani-Cloth Plus (quaternary ammonium/isopropyl alcohol-based)
- 0.5% Accelerated hydrogen peroxide

Other products that are based on quaternary ammonium compounds (QUAT) or QUAT/ isopropyl alcohol can also be used in disinfecting system surfaces.

## WARNING



Use cleaners and disinfectants as per hospital protocol that are free of aromatic, chlorinated, ketone, ether, or ester solvents.

## WARNING



Do not autoclave or clean the computer or its peripherals with strong aromatic, chlorinated, ketone, ether or ester solvents, sharp tools or abrasives.

## Cleaning/Disinfecting the computer

1. Turn off the power source and unplug the cord from the outlet before cleaning the unit.
2. Wipe all surfaces of the computer with a dry clean cloth.



## CAUTION

Avoid having liquids seep into the internal components and areas of the medical panel PC unit. If you accidentally spill liquid on the device, disconnect the unit from the power source.

3. Prepare agent as per manufacturer's instructions or hospital protocol.
4. Remove dust from the monitor screen and touch screen with a soft, lint-free cloth. A microfiber cloth is recommended. Clean the monitor screen and touch screen using a liquid screen cleaner specifically designed for LCDs. Spray the liquid onto the cleaning cloth or spray sparingly onto the displays. You can also use pre-moistened screen wipes. Dry the displays with a soft, lint-free cloth.

## Cleaning the Mouse

The mouse contains an antimicrobial, fungistatic agent which protects the product and keeps it cleaner, greener and fresher by inhibiting the growth of microbial bacteria, mold, mildew and fungi on the surface.

1. If using a hospital grade disinfectant spray, thoroughly spray all surface areas and between keys. Use as directed. Wipe away excess moisture prior to use. There is no need to unplug your keyboard or power down your computer.
2. If using alcohol-based disinfectant wipes, thoroughly wipe all surface area with disinfectant wipes. There is no need to unplug your keyboard or power down your computer.

## Recommended cleaners and disinfectants

- Hospital Grade Disinfectant Sprays or Wipes, including medical grade, commercial grade, antibacterial, antiviral and antifungal sprays

## Cleaning Transducer Sleeve, Transducer Sensor, Patient Sensor, and Pairing Baton

The transducer sleeve, sensor and baton should be cleaned properly between patients. These items may be cleaned and disinfected where they are used.



### WARNING

Do not soak the transducer sleeve, transducer sensor, patient sensor, and pairing baton in acids or bases



### CAUTION

Do not pull on the sensor cable. Push back the sensor, with your thumb on the top of the sensor housing closest to the transducer distal end.

1. Wipe the ultrasound transmission gel off the transducer sleeve and transducer sensor (if applicable).
2. Slide the transducer sensor off the transducer sleeve (this will require a small amount of force).
3. Remove the transducer sleeve from the transducer. Slide the transducer off of the transducer towards the cable, then pull the sleeve down off of the cable.
4. Wipe the entire surface of the transducer sleeve with one of the suggested cleaners.
5. Wipe the entire surface of the transducer sensor with one of the suggested cleaners.
6. Wipe the entire length of both the transducer and transducer sensor cables. Wipe away from the transducer/sensor toward the connector end of the cables. Do not wipe the connectors.
7. Leave surface wet for the “contact time” of the cleaner chosen to ensure disinfection.
8. Allow to air dry.
9. Repeat steps 4-8.
10. Wipe the entire surface of the pairing baton with one of the suggested cleaners.
11. Leave surface wet for the “contact time” of the cleaner chosen to ensure disinfection
12. Allow to air dry.
13. Repeat steps 10-12.
14. Remove Personal Protective Equipment.

15. Wash hands.

16. Visually inspect the transducer sleeve and transducer sensor for wear and tear i.e. discoloration, cracking, tearing on the surface. If there is visible damage to either part, dispose of the part.

17. Reinstall the transducer sleeve on the transducer. Slide the sleeve up onto the transducer cable, then slide the sleeve up onto the transducer.

18. Slide the transducer sensor forward, onto the transducer sleeve, until it is securely attached.

### Recommended cleaners and disinfectants

- Hospital Grade Disinfectant Sprays or Wipes, including medical grade, commercial grade, antibacterial, antiviral and antifungal sprays that are free of acids and bases.
- Isopropyl alcohol (70 %)

### Cleaning Sensor Cables

The USB cables for both the Patient Sensor and Transducer Sensor should be cleaned properly after each use. These items may be cleaned and disinfected where they are used.



#### **WARNING**

Do not immerse the sensor cables in the cleaning solution.

1. Disconnect both USB sensor cables from the system.
2. Wipe the entire length of the patient sensor and transducer sensor cables. Wipe away from the sensors toward the connector end of the cables. Do not wipe the connectors.
3. Leave surface wet for the “contact time” of the cleaner chose to ensure disinfection.
4. Allow to air dry.
5. Repeat steps 4-8.
6. Remove Personal Protective Equipment.
7. Wash hands.
8. Reconnect both USB sensor cables to the system.

### Recommended cleaners and disinfectants

In general, when used in those concentrations as recommended by the manufacturer, the sensor cables can be wiped down with the following common non-abrasive cleaning agents such as:

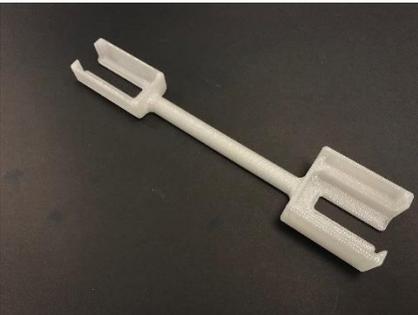
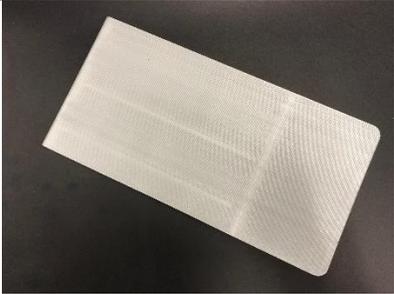
- Soapy Water
- 10% bleach Solution
- 70% Ethyl Alcohol Solutions
- Germicidal Disposal cloth
- Alcohol
- Acetone
- Actichlor
- Isopropyl Alcohol

- Bleach
- Chloride
- Cavi Wipes
- CIDEX

## Accessories

Replacements for the parts listed below are provided by Ventrpoint Diagnostics Ltd. Please contact [support@ventripoint.com](mailto:support@ventripoint.com) to order or inquire about the accessories.

DESCRIPTION	PART NUMBER	PICTURE
DVI to DVI cable	VD-0081	
DVI to VGA cable	VD-0277	
DVI to Display Port	VD-0278	
USB EXTENSION CABLE	VD-0190	

PAIRING BATON	VD-0257	
MOUSE	VD-0012	
MOUSE PAD	VD-0270	

## Specifications

Ventripoint reserves the right to change specifications contained herein or discontinue manufacture at any time without prior notice. Current specifications are supplied with each system purchased or are available from your Ventripoint representative. The VMS+ conforms to the following specifications.

### Pressure, Humidity, Temperature Limits

This system should be operated, stored, or transported within the parameters outlined below.

	Operating Limits	Storage Limits	Transport Limits
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<b>Temperature</b>	0°C to 35°C (32°F ~95°C)	-20°C to 60°C (-4°F ~140°F)	-20°C to 60°C (-4°F ~140°F)
<b>Humidity</b>	10% to 90% @ 35°C, non-condensing	10% to 90%, non-condensing	10% to 90%, non-condensing
<b>Pressure</b>	700 – 1060 hPa	186 – 1060 hPa	186 – 1060 hPa

## Vibration, Shock, Altitudes, EMI/Safety, and IP

<b>Vibration</b>	Operating: 15 g/0.53 oz, 11 ms, half sine wave Non-operating: 50 g/1.76 ozm 11 ms, half sine wave
<b>Shock</b>	Operating: 5 ~ 17 Hz Amplitude: 0.117 ~ 500 Hz Acceleration: 1.0 G Non-operating: 10~55 Hz/0.1 g, 55~500 Hz/2.0 g
<b>Altitudes</b>	Operational: up to 3000 m (9842 feet) Shipping: up to 12192 m (40000 feet)
<b>EMI/Safety</b>	CE / FCC / VCCI Class B/UL 60601-1/EN 60601-1
<b>IP</b>	Front bezel, IP-65 Certified

## Computer

<b>Display</b>	400 nits 1366 x 768 TFT LCD
<b>CPU Support</b>	FCBGA1356 6 <sup>th</sup> generation Intel® Core i7/i5/i3 processor (15 W max.)
<b>Disk Drive Space</b>	2.5" Hard Disk Drive (SATA III)
<b>Expansion</b>	One Mini PCIe Slot One M.2 Type E Slot One PCI-E x 4 expansion slot (loaded 25 W max., can't co-exist with isolated module).
<b>Button</b>	Power Button Audio Adjustment (+/-) Brightness (+/-) LCD on/off Clean me (auto release after 1 minute)
<b>I/O</b>	1 – Isolated 4KV USB 2.0

	<ul style="list-style-type: none"> <li>1 – Isolated 4KV GigaLAN</li> <li>1 – Isolated 4KV RS-232</li> <li>1 – Isolated RS-232/422/485 (the isolated parts verified through Dielectric test 4000 Vac only)</li> <li>1 – RS-232 port</li> <li>1 – RS-232/422/485 port</li> <li>4 – SUB 3.0 port</li> <li>1 – DC-in w/ lock function</li> <li>2 – Gigabit LAN RJ-45 Connectors</li> <li>2 – DP output</li> <li>1 – Line-in</li> <li>1 – Line-out</li> <li>2 – 2W Speaker</li> </ul>
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## Touchscreen

<b>Type</b>	Full flat projective capacitive touch panel
<b>Interface</b>	Controller with USB interface, 5V
<b>Resolution</b>	100 ppi to 25 ppi Based WIN7 definition ppi (Pixel per inch)
<b>Light Transmission</b>	90% ± 3%
<b>Life Time</b>	100 M times

## LCD

<b>Model Name</b>	WMP-15C
<b>Display Type</b>	15.6" LED
<b>Max. Resolution</b>	1366 x 768
<b>Contrast Ratio</b>	500 : 1 (Typ)
<b>Pixel Pitch (um)</b>	252 x 252
<b>Luminance (cd/m2)</b>	400 (TYP)
<b>Viewing Angle</b>	170° (H) 160° (V)

## Electrical Parameters

<b>Power</b>	Close-frame
<b>Type</b>	HPU101-105
<b>Input Rating</b>	AC 100-240 V ~ 47-63 Hz 1.2 – 0.5 A
<b>Output Rating</b>	DC 12 V, 8.33 A
<b>MTBF</b>	100 000 hrs operation at 25°C
<b>Classification</b>	Power by Class I certified power adapter. No applied part.
<b>Mode of Operation</b>	Continuous operation.
<b>System Input Rating</b>	DC 12 V, 8 A

## Mechanical Specifications

<b>Load Range</b>	5 to 23 lb / 2.3 to 10.4 kg
<b>Height Adjustment Range</b>	11" / 28 cm
<b>Minimum Height</b>	34.5" / 87.6 cm
<b>Maximum Height</b>	45.5" / 115.6 cm
<b>Nylon Castors</b>	4" / 10.2 cm diameter dual wheel nylon (2 locking and 3 non-locking)
<b>Base</b>	21" / 53.5 cm diameter aluminum base with built-in 10 lb / 4.5 kg counterweight

## Languages

Localized user interface (including international symbols on key caps) and Help:

- English
- Français
- Deutsch

# Safety and Regulatory Requirements

## Classification

- Class I equipment with Type B applied part
- Ordinary Equipment/Continuous Operation

## Electromechanical Safety Standards Met

The system and software comply with the requirements of IEC 60601-1 Medical Electrical Equipment, General Requirements for Safety, including all applicable collateral and particular standards, as well as all applicable deviations. System users are responsible for ensuring that the chosen device is compliant with the law in the jurisdiction in which the product is used.

## Compliance

Ventripoint products comply with relevant international and national standards and laws. Information on compliance will be supplied by your local Ventripoint representative upon request.