VMS+

User Manual

(USA) 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.

Support

E-mail: support@ventripoint.ca
Phone: +1 (833) 201-8735

Model

Ventripoint Medical System+ (Referred to as ‘VMS+’ throughout the manual).

Compatibility

List of ultrasound devices that are compatible with the Ventripoint VMS+:

- Acuson Sequoia C512
- Acuson Sequoia C256
- Sonosite Titan
- Philips IE-33
- SONOS 4500/5500/7500
- Acuson Aspen
- GE Vivid Systems
- and any other ultrasound device with 2D cardiac transducers

Manufacturer

Ventripoint Diagnostics, Ltd.
2 Sheppard Avenue East, Suite 605
Toronto, ON M2N 7A4, Canada

European Representative

Medes Limited
5 Beaumont Gate
Shenley Hill, Radlett
Hertfordshire
WD7 7AR,
England, UK

CE
0413

Intended Use Statement

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.

Diagnostic Capabilities

The VMS+ is intended for use by qualified medical professionals experienced in examining and evaluating Echocardiograms, for obtaining diagnostic information as part of a comprehensive diagnostic decision-making process within the clinical setting.

Limitations

Results of the VMS+ are dependent upon the overall quality of the 2D acquisition, or exam.

The user is responsible for determining if artefactual characteristics exist.

Artifacts can severely affect the image quality and require a reacquisition. Examples of artifacts are:

- Obvious discontinuity between the resultant borders and the 2D images due to patient motion
- Excess shadowing of images
- Poorly defined anatomy resulting in improper point placement

In the case of a poorly reconstructed image set, as determined by the above criteria or by the user's clinical experience and training, resultant 3D dimensional results should not be relied on.

If for any reason volumetric results are rendered from poorly reconstructed images, these measurements should not be used for making diagnostic decisions.

The user must be committed to the accuracy of the existing images and reconstructed results. Image scans should be repeated if there is the slightest doubt as to the accuracy of images and reconstructed results. The user is responsible for the definition of contours in acquired views.

ECG signal is used by the VMS+ to determine ED. The user must check the VMS+ ED selection and correct their position as necessary.

The accuracy of VMS+ depends mainly on the acquisition method and the operator skills. For detailed information about acquisition methods and accuracies refer to the manual of the Ultrasound imaging device.

All measurements are calculated from the relative positions of anatomical points superimposed over the ultrasound image. Therefore, the validity of the measurements with respect to the ultrasound image depends directly on the operator skills in positioning the anatomical points of interest on the image. When performing point placement, always be aware of this source of human error.

In Vitro testing of VMS+ demonstrates accuracy of results to be within 10% of actual volumes of phantoms tested. The accuracy in the clinical setting may vary when all above factors and conditions are accounted for.

The user is responsible for determining if the reconstructed result is suitable for the corresponding image acquisitions and for determining if the results are relevant for clinical decision making. The results provided by VMS+ are not intended to be a source of advice or to determine or recommend a course of action or treatment for a patient.

Clinical Studies

The safety and effectiveness of the VMS+ is to compute right ventricular volumes and ejection fraction from two-dimensional cardiac ultrasound images in adult patients with pulmonary hypertension was evaluated in a multicenter, open enrollment study (2011052). Subjects who met the screening criteria completed cardiac imaging using cardiac magnetic resonance imaging (cMRI) and Ventripoint Medical System+ ultrasound imaging on the same day. This study achieved its pre-specified success criteria of having the 95% confidence limits for EDV, ESV and EF within ±10% for the VMS+ and cMRI estimates.

Following collection of 75 patient image sets, the images were sent to independent core labs for analysis. The results of echo image point placement and MRI image tracing were documented, and volume data returned to Ventripoint for statistical analysis.

Data Analysis

The primary comparison study is the comparison of EDV, ESV, and EF measurements determined by VMS+/echo with measurements determined by Simpson's method on MRI images. According to the clinical trial protocol the primary criteria for agreement between the two methods is if the 95% confidence interval of the Bland-Altman bias is within the ±10% interval.

It is seen that the 95% confidence intervals of mean percent difference between VMS+ and MRI results are well within the protocol stated acceptance limits of ±10% for EDV, ESV, and EF as demonstrated in the following table:

Table 1: Observed Mean for Percent Difference between VMS+ and MRI

	N	Observed Mean (Std Err) for % Difference between VMS+ and MRI	95% CI for Mean	Limits of Agreement
EDV	75	4.80% (1.35%)	(2.24%, 7.56%)	(-18.2%, 27.8%)
ESV	75	1.76% (1.51%)	(-1.17%, 4.76%)	(-23.9%, 27.4%)
EF	75	2.03% (0.66%)	(0.72%, 3.33%)	(-9.1%, 13.2%)

Performance Studies

Left Ventricle (LV), Left Atrium (LA), and Right Atrium (RA) Hearts Catalogue

Validation testing was conducted using 20 random hearts utilizing a point selection protocol and executing reconstructions on a VMS+ platform to evaluate the robustness of the catalogues.

The catalogue for the LV include the following non-diseased and diseased states:

- Normal hearts
- Tetralogy of Fallot (TOF)
- Pulmonary Arterial Hypertension (PAH)
- Right Ventricle to Pulmonary Artery (RV to PA) Conduits
- Systemic RV

The catalogues for the LA and RA include the following non-diseased and diseased states:

- Normal hearts
- Tetralogy of Fallot (TOF)
- Pulmonary Arterial Hypertension (PAH)
- Right Ventricle to Pulmonary Artery (RV to PA) Conduits
- Systemic RV
- Coarctation

For each study selected, VMS reconstructions were performed with the study masked from the catalogue (the study will not be used by the KBR (Knowledge Based Reconstruction) during reconstruction). Two qualified tracers performed the reconstructions using the VMS+ Review and Analysis System software independently and without knowledge of the actual study volumes.

The remove-one manual cross validation studies achieved their pre-defined success criteria of showing a 95% confidence level in volume difference no worse than 10% compared to the full fit volume.

Safety and Effectiveness

The VMS+ is a non-invasive, non-significant risk technology. No adverse events were reported during the clinical trial. Effectiveness was assessed through bench and clinical performance testing using a standard of care method as a comparator. The VMS+ introduces no new questions concerning safety or effectiveness and is therefore substantially equivalent to the predicate devices.

Contraindications

Pacemaker/defibrillator; permanent or temporary.

Contents

Operational and Safety Considerations

Use the following safety guidelines to ensure the safety of the user and the patient of the VMS+:

Only Ventripoint trained personnel may modify VMS+.

Not for use in oxygen rich environments. Risk for explosion if used in the presence of flammable anesthetics or other flammable gasses or liquids.

The use of accessories, transducers and cables other than those specified by Ventripoint may result in increased EMISSIONS or decreased IMMUNITY of the VMS+.

VMS+ should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the VMS+ should be observed to verify normal operation in the configuration in which it will be used.

To avoid risk of electric shock VMS+ must only be connected to a supply mains with protective earth.

Do not position the VMS+ where it will be difficult to unplug the system from the wall outlet.

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

Portable and mobile RF communications equipment can affect VMS+.

Transportation Considerations

Do not attempt to push the cart over a threshold. 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.

The VMS+ is a transportable device, in that it can be rolled between exam rooms. When transporting the cart, observe the following rules:

1. Lower the cart to its lowest position by pressing the blue lever on the right of the work surface and pressing down on the cart.
2. Lock the keyboard and mouse tray into place.
3. Push the system using the handles on the cart.
4. Lock the transmitter arm into place. Follow the guide under To disconnect the VMS+ for instructions.

Limits

- Pressure Limits
  - Operating: 525 mmHg to 795 mmHg (700 hPa to 1,060 hPa)
  - Storage: 375 mmHg to 795 mmHg (500 hPa to 1,060 hPa)
- Humidity Limits
  - Operating: 20% to 80% (non-condensing)
  - Storage: 15% to 95% (non-condensing)
- Temperature Limits
  - Operating: 10° C to 35° C (50° F to 95° F)
  - Storage: -34° C to 65° C (-29° F to 149° F)
- Altitude Limits
  - Operating: -15.2 to 3048 m (-50 to 10,000 ft)
  - Storage: -15.2 to 10,668 m (-50 to 35,000 ft)
- Transportation Limits
  - Humidity: 15% to 95% (non-condensing)
  - Temperature: -34° C to 65° C (-29° F to 149° F)
- Pressure Limits: 375 mmHg to 795 mmHg (500 hPa to 1,060 hPa)

Power Rating

100-240 V~, 5.0-2.6A, 50/60 Hz

System Disposal

The VMS+ should be disposed of according local regulations and the WEEE directive.

Compliance

Guidance and manufacturer's declaration – electromagnetic emissions		
The VMS+ is intended for use in the electromagnetic environment specified below. The customer or the user of the VMS+ should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	
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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	
NOTE: The EMISSIONS characteristics of VMS+ make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) VMS+ might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the VMS+.		

Guidance and manufacturer's declaration – electromagnetic immunity			
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**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T	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

IEC 61000-4-11	(30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	(30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the AC mains voltage prior to application of the test level.			
Guidance and manufacturer's declaration – electromagnetic immunity			
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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	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. **Recommended separation distance** d = [3.5/V1]□P d = [3.5/E1]□P 80 MHz to 800 MHz d = [7/E1]□P 800 MHz to 2.5 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 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 reorienting or relocating the VMS+.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the VMS+

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 = [3.5/V1]□P	80 MHz to 800 MHz d = [3.5/E1]□P	800 MHz to 2.5 GHz d = [7/E1]□P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.

Applied Parts

ECG Cable	Type BF applied part

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	**Band[a)] MHz**	**Service[a)]**	**Modulation [b)]**	**Maximum power (W)**	**Distance (m)**	**Immunity test level (V/m)**
385	380 – 390	TETRA 400	Pulse modulation [b)]	1.8	0.3	27

			18 Hz			
450	430 – 470	GMRS 460, FRS 460	FM [c)] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation [b)] 217 Hz	0.2	0.3	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b)] 18 Hz	2	0.3	28
1,720 1,845 1,970	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b)] 217 Hz	2	0.3	28
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b)] 217 Hz	2	0.3	28
5,240 5,500 5,785	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation [b)] 217 Hz	0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

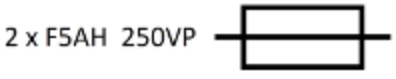
a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Symbols

The following is a list of symbols used on the VMS+.

SYMBOL	MEANING	LOCATION
	Date of Manufacture	System Label
	Manufactured by	System Label
	Representative in the European Community	System Label
	CE mark	System Label
	Power button	Computer monitor
	Serial number	System Label
	ECG connection	Back of Cart
	Ethernet connection	Back of Cart
	Fuse	Near power plug
	Refer to User Manual	On the transmitter arm
	Do not push	Back of Computer monitor

	Consult instructions for use	System Label
	Type BF (Body Floating) electrical shock protection	System Label
	Prescription only	System Label
	Weight	System Label
	Temperature limits	System Label
	Humidity limits	System Label
	Pressure limits	System Label
	Caution, consult accompanying documents	System Cart Label
	Wasted Electrical and Electronic Equipment (WEEE) Directive	System Label
	Fragile	Packaging Label
	No metal in vicinity	On the transmitter box
	Magnetic hazard	On the transmitter box

	No pacemakers	On the transmitter box
	Caution, consult accompanying documents	User manual
	Electricity warning	User manual

Introduction

Welcome

Thank you for purchasing the very finest in advanced heart diagnostic tools from Ventripoint. With the VMS+ and Ventripoint Services (VS), you can create three-dimensional (3D) reconstructions of all four chambers of the heart, and calculate volume and ejection fraction measurements in a matter of seconds, without the hours of manual tracing that the current technology requires. We are confident that you will find the VMS+ an invaluable tool for monitoring patients with heart disease.

About This Guide

This *User Guide* is a reference for the VMS+. It is intended for sonographers and cardiologists who have had prior VMS+ training. More specifically, you *must* have the Ventripoint-sponsored clinical training in image acquisition and the reconstruction process before using this product.

This guide includes a general overview of the system, along with detailed instructions for using it. Other chapters describe system controls, system setup, and troubleshooting. For more information about the system, see Additional References on page 21.

System Description

The Ventripoint Diagnostic System consists of the VMS+ and Ventripoint Services.

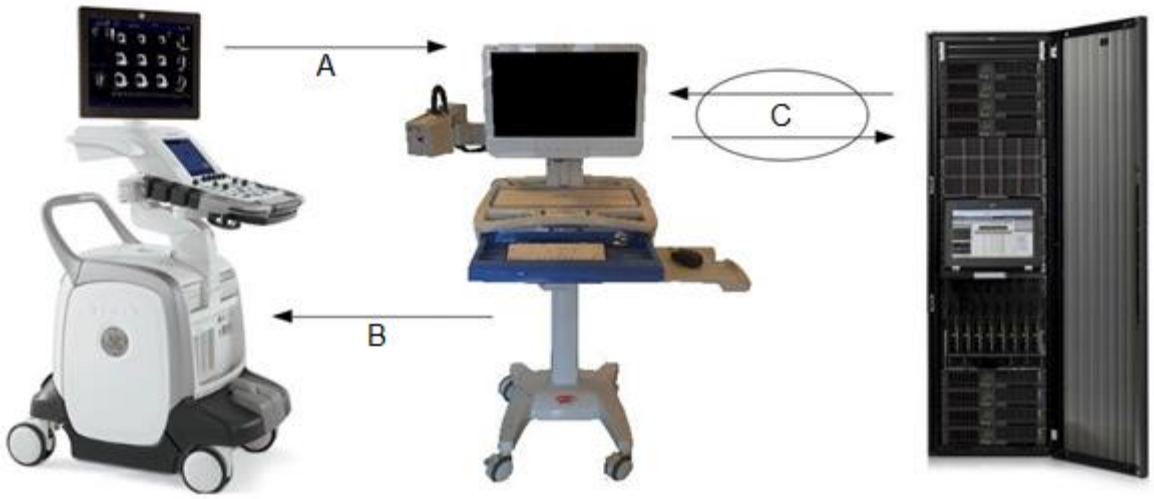
Ventripoint Services are a collection of server-side services that provide an expert system, data tracking services, and other system management services.

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

- **System**: 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 System**: The Review and Analysis System is any system a cardiologist, sonographer, or hospital uses for conducting study analysis created by the VMS+. The Review and Analysis System only consists of the analysis portion of the VMS+ application. This system is not provisioned by Ventripoint. A Review and Analysis System consists of a computer running the Microsoft® Windows® 7 or Microsoft® Windows® 10 operating system. For the minimum requirements for running VMS+ on a Review and Analysis System, see Setting Up a VMS+ Review and Analysis System Computer on page 85.

Ventripoint Diagnostic System



Existing clinic-based ultrasound system | VMS+ | Ventripoint Services

A = Video Out B = 1-volt ECG out C = Secure Internet Connection

The Ventripoint system consists of the following components:

- **Clinic-based Ultrasound System**: Used to capture images of the patient's heart. This is an existing system at the clinical site, integrated with the VMS+ workstation.

- **VMS+**: Contains an electrically shielded personal computer from which cables connect the VMS+ to the ultrasound equipment. VMS+—Consists of:

    - The computer system with attached peripherals: monitor, mouse, and keyboard.
    - Data capture and analysis software.
    - Patient ECG cable: Transmits the ECG signal from the patient to both the Echocardiography system and the computer running the VMS+ software.
    - Hand trigger: Used to capture scans during a patient study with the VMS+.
    - Video capture card: Captures images from the Echocardiography system and stores them in memory for later use by VMS+. This is a PCI card located within the computer.
    - Tracking system: Provides the VMS+ software with 3D coordinates for the images being captured by the video capture card. This hardware system consists of several components: a transmitter located on an arm on the VMS+ cart, a sensor connected to the ultrasound transducer, and a driveBAY controller.

- **Internet connection**: Enables VMS+ to connect to Ventripoint Services for 3D reconstructions.

Typical Workflow

The VMS+ program follows the typical workflow of a sonographer or cardiologist during his or her initial examination of a patient, and the subsequent analysis of the data collected during that examination.

There are five workflow areas in VMS+, generally completed in the following order:

1. The Studies workflow area is the home page for VMS+. Here, you create new studies, open existing studies, archive and export studies and import MRI or 3D Echo images.
2. The Scan workflow area is where you enter patient information just prior to scanning and where image acquisition occurs.
3. The ED/ES workflow area is where you review the automatically selected end diastolic (ED) frames and select one end systolic (ES) frame. In most cases, the software-selected ED frames will be accurate, but you should review them and change individual ED frames as required. You must select one ES frame, from any of the scans taken during the study. The software then automatically generates the ES frames for the remaining scans.
4. The Reconstruction workflow area is where you mark anatomical structures described in the reconstruction protocols. When you have entered the required points, you generate a 3D reconstruction. You can then use additional VMS+ tools to validate the quality of the reconstruction and the overall coverage of the heart chambers. If necessary, you can add, delete, or move points, and then refresh the 3D reconstruction for evaluation of the changes made. You can also take snapshots of the 3D model at ES, ED and combined view, and up to two 2D image snapshots per scan for use in the final report.
5. The Report workflow area is the final step in the process. Here, you provide notes about your analysis of the results. You can also see the 3D views added from the snapshots that you took in step 4, and any historical data that might be available (via Ventripoint Services) from prior studies of the same patient.
6. When you are satisfied that the report is accurate, you save the study. You can then print the final report, save it, or send it via e-mail to the necessary recipients.
7. (Optional) At any time during the workflow, you can open the **Help** menu, which provides access to general help information about each workflow area, and links to the Ventripoint website for more information.

   All changes are automatically saved and sent to Ventripoint Services. Any future editing of the same study on another workstation will be transmitted from Ventripoint Services. In this way, changes made on one workstation will be automatically available on any other workstation where the study is viewed. Later chapters of this guide provide more detailed descriptions of this workflow.

Additional References

The following resources are available to supplement this User Manual*:*

- **Quick Reference Guide**: A reference for on-site training of sonographers for the capture and analysis of quality 3D images of the heart.
- **Cleaning and Disinfection Guide**: A reference for on-site cleaning and disinfection for the VMS+, and included parts and accessories.

Quick Start

This chapter contains a brief overview of the VMS+. It includes information about common tasks such as system setup, patient preparation, and logging on and off the system. It also includes an overview of the user interface that you will see as you perform your workflow.

Preparing the System

VMS+ is not intended to be permanently connected to a hospital 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.

► **To connect the VMS+**

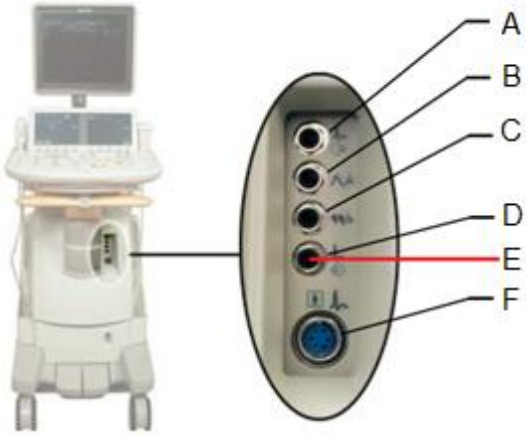
1. Ensure that ultrasound system is on.
2. Connect video input cable from the VMS+ to the ultrasound system. Only 1 of the 3 video inputs on the VMS+ will be available; the remaining 2 inputs will be capped off.

3. Connect ECG Output cable to the VMS+.

4. Connect the ECG Output cable to the Ultrasound Input. Ventripoint will provide an accessory cable to connect the VMS+ ECG Output to the ECG Input of the cardiac ultrasound machine. The accessory cables, connections, and the input locations of some common cardiac ultrasound systems in clinical use are shown below:

Philips IE-33

Figure 1: ENG-HW-667



A = Analog output

B = Pulse/Aux 1 input

C= Phono/Aux 2 input

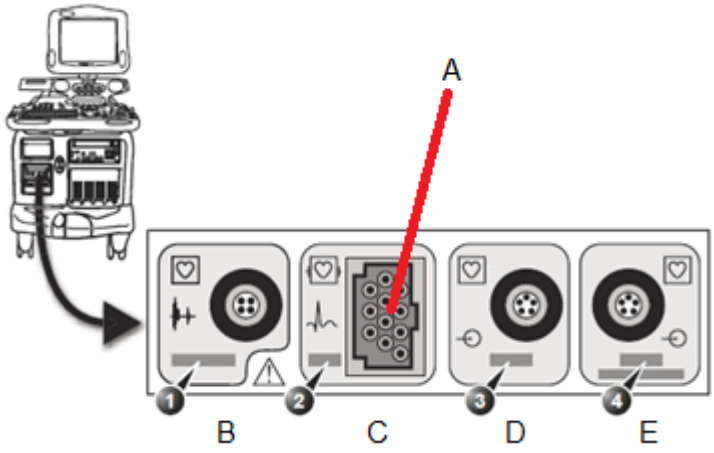
D = High-level ECG input

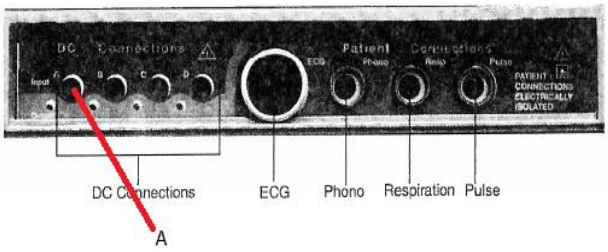
E = Ventripoint ECG input

F = Low-level ECG input

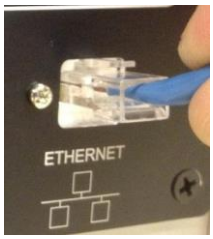
GE Vivid Systems

Figure 2: ENG-HW-666



	A = Ventripoint ECG input B = Phono C = Aux 1 D = Aux 2 (Pressure/Pulse)
Acuson Sequoia 256  *Figure 3: ENG-HW-667*	 A = Ventripoint ECG Input

5. Connect the Ethernet cable.



6. Connect the power cable. An audible beep will sound.
7. Remove the pin holding the transmitter in place by pressing down on the blue center to release.

8. Put the pin back in the hole of the transmitter arm post.

9. Press the power button on the monitor of the VMS+.
10. Wait for the Windows log on screen.
11. Log on using your local or domain user credentials.
12. Mount the 3D tracking sensor to the sleeve on the ultrasound transducer. Secure the sensor cable to the transducer cable using the Velcro cable straps.
13. Check probe and sleeve to confirm that:
    - letters on probe and sleeve match.
    - orientation markers on probe and sleeve are aligned.
    - sleeve is tightly seated on probe.

► To disconnect the VMS+:

Handle VMS+ cables with care to prevent damage.

Note: Required only when moving ultrasound system.

1. Log off from VMS+.
2. Turn off the system by using Windows Shut Down button (do not proceed to following step until power light on the computer turns off).
3. Remove sleeve from probe.
4. Move the transmitter arm back to the storage location with the transmitter just above the arm post.
5. Remove the pin from the post and use it to secure the transmitter to the post.
6. Unplug main power cable from wall, loosely coil it, then secure the cable with the hooks on the side of cart.
7. Unplug all cables from the ultrasound which interface with the VMS+.
8. Wrap up unplugged cables and secure them with the hooks on VMS+.
9. Lower the cart to the lowest position possible using the blue lever on the right side of the cart's worksurface tray.

Preparing the Patient

Preparing the patient before the exam is a critical step to ensuring effective capture of the necessary scan images.

1. Enter patient information into New Study fields per this User Guide.
2. Remove ferrous items (jewelry, coins) from patient and sonographer.
3. Place Ventripoint back wedge behind patient to minimize interference from metal within the bed.
4. Place ECG Electrodes on patient using Lead II configuration.
5. Place Transmitter over the patient taking care to center directly over the Parasternal acoustic window. Ensure that the transmitter is no closer than 22cm to the Ultrasound transducer during parasternal imaging.
6. Ensure proper Transmitter location by placing Ultrasound transducer at Apical acoustic window and ensure the distance is not “OUT OF RANGE”.
7. Discuss breathing technique with patient: All images are to be acquired at end-expiration.
8. Prior to acquiring first image, confirm acoustic windows and optimize single imaging depth for all.

Once first image is acquired, any movement of the Transmitter Arm will cause poor results. DO NOT allow the Transmitter to move after the study is started.

Note: Coach patient to remain still during exam. Movement during image acquisition will produce a poor-quality reconstruction.

Logging on to the System

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 Review and Analysis System mode.

► **To log on to the System**

1. Press CTRL+ALT+DELETE on your keyboard, and then log on to the computer.
2. Use the local or domain user credentials that your system administrator gave to you.
3. The first time you open an existing study, or complete the first acquisition, you will be asked to log on to the Ventripoint Services (VMSNET). A Ventripoint login dialog box appears, prompting you to log on to Ventripoint Services. You *must* enter your VMSNET credentials (typically provided to you after successful completion of the VMS+ Training by your Ventripoint Applications Specialist).
4. In the **User name** box, enter your user name.
5. In the **Password** box, type your password.

6. Click **OK**. You are now logged on to the system. By default, the Studies screen appears after you log on.

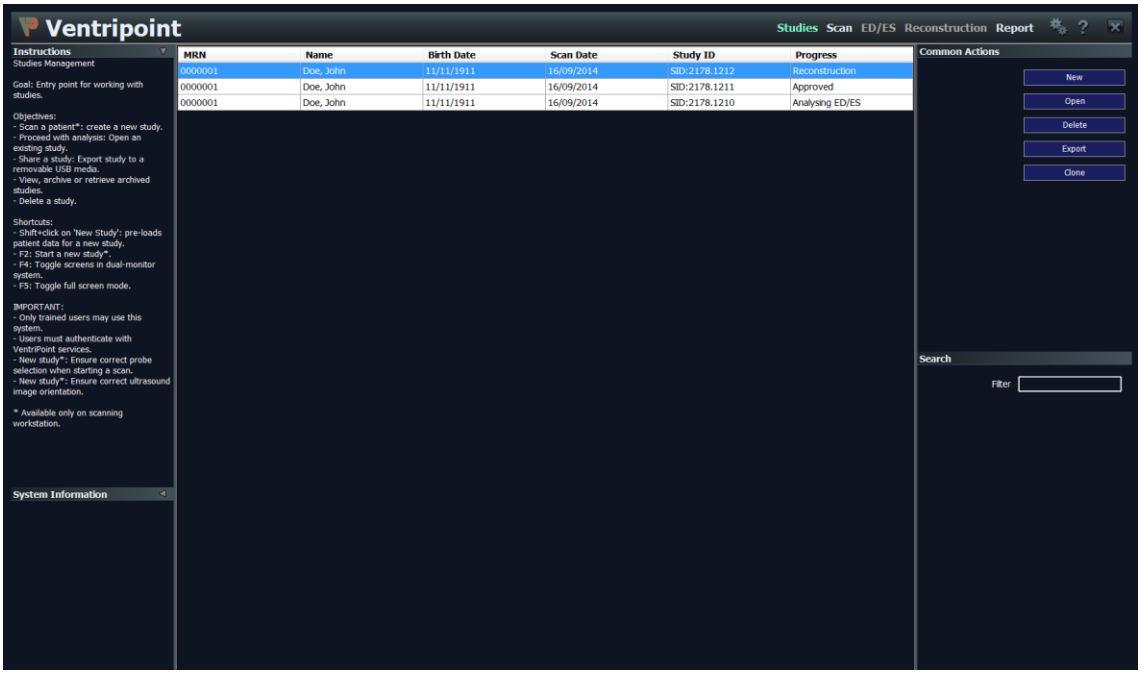


Figure 4: Studies screen

You can change the default workflow screen displayed after initial logon, by using the Preferences dialog box. For more information, see the chapter beginning on page 70.

After you log on to the system for the first time, your log on information is saved. You will not need to log on to VMSNET again, unless your Ventripoint Services credentials change.

► To log on to the Review and Analysis System

1. There is no need to log on to the Review and Analysis System, as you need to be logged on before you can run the Review and Analysis System software.
2. Double-click on the Ventripoint icon located on the desktop.
3. You will be presented with the Studies screen.
4. The first time you attempt to open an existing study, you will be requested to log on with your VMSNET credentials.
5. A dialog box will appear the first time you run the Review and Analysis System software. You must enter your VMSNET credentials.
6. In the **User name** box, enter your VMSNET user name.
7. In the **Password** box, type in your VMSNET password.
8. Click **OK**.

If you select the Remember my password check box, your user credentials will be saved, and you will not be presented with the log on dialog box next time you access the Review Station. You are now logged on to the system. Your log on information is not saved in the Review and Analysis System, so you will need to log on to Ventripoint Services each time.

Understanding the User Interface

The VMS+ program window is organized into several distinct functional areas. The primary activity area, the main workspace, is in the center of the window. Above it, the navigation header shows the primary workflow areas. Informational messaging is displayed on the panel on the left, and actions are typically triggered from the panel on the right.

Navigation Header

The VMS+ workflow takes you through a series of screens, each of which is listed in the navigation header at the top of the VMS+ program window. After you create a new study or open an existing study, you can use the items in the navigation header to move back and forth between the screens.

Note: Not all workflow areas are available in all modes.

To help you navigate the workflow areas, the items in the navigation header are color-coded.

- The current workflow area is brightly colored in cyan (green).
- All workflow areas that you can go to next are neutral-colored (white).
- Unavailable workflow areas are gray.

Navigation header tabs

- **Studies**

  Opens the Studies screen. Use this screen to create a new study, open an existing study, delete a study, export a study to removable media, retrieve an archived study, archive a study to remote storage or send a study to PACS.

  The following icons appear above the main workspace only if your system has been pre-configured for network storage:

	**This Computer**	Click to see all studies stored on this computer.
	**Remote Archive**	Click to see all studies on the remote archive.

Note: When you first start the system, This Computer is always selected

- **Scan**

  Launches the **New Study** wizard followed by the **Scan screen**. Use this screen to record multi-image scans of the patient as described in the *VMS+ Quick Reference Guide*.

- **ED/ES**

  Opens the ED/ES screen. Use this screen to verify end diastolic (ED) and select end systolic (ES) frames.

- **Reconstruction**

  Opens the Reconstruction screen. Use this screen to identify anatomical structures by marking the appropriate points, and then create the 3D model corresponding to the scanned images. Use this screen also to refine and examine the 3D model, adjust points, and refresh the 3D reconstruction.

- **Report**

  Opens the Report screen. Use this screen to annotate the study, approve the study, and preview, save, or print the report.

Navigation header icons

Icon	Name	Function
	**Preferences**	Click to open a separate dialog box that contains a list of user preferences.
	**Help**	Click to open the **Help** menu. Use this menu to access the VMS+ online Help system.
	**Minimize Bar**	Click to minimize the VMS+ program window. This feature is available only when you are running the Review and Analysis System mode.
	**Close**	Click to exit the VMS+ program and log off from the system.
	**Patient Info**	Click to view/edit patient information

Note:	If you rest the mouse pointer on an item in the navigation header, a brief description of its function appears in the tooltip bar, which is located directly above the main workspace on any screen.

Main Workspace

The main workspace is in the center of any screen. When you are working with scan images, they are displayed on the main workspace.

Workspace Panels

On each side of the main workspace is a panel.

Figure 5: Scan screen

Each panel contains one or more panes. You can expand or collapse any pane by clicking in the pane heading.

- **Left panel**

  The left panel contains basic information about the system, and about the data that you are currently working with. It contains the following panes:

  - **Instructions**: Describes your goal in using the current screen, and the activities that you can perform.
  - **Analysis**: Displays volumetric information. This pane appears after you select anatomical structures and enter points.
  - **System Information**: Displays the workstation name, your user name, and the amount of free disk space that is available. The System Information pane is available only on the Studies screen.

- **Right panel**

  The right panel contains controls specific to the data that you are working with on the main workspace of a screen. For example, if you are working on the Studies screen workspace, this

panel contains the Common Actions pane, which contains buttons for creating new studies, working with existing studies, and exporting and archiving studies. If you are working on the Reconstruction screen workspace, it contains the ED/ES 3D Reconstruction, 3D View, and Scan Properties panes.

Note:	You can hide the left and right workspace panels, and the navigation header, by clicking the arrow that appears when you rest your mouse pointer on the outside edge of the panel. To show the panel, repeat the process.

Toolbar Icons

When you are working with scan images, they are displayed on the main workspace. Above the main workspace is a toolbar containing various icons. Some of the icons are available all the time, others are available only when you are viewing a selected scan image or 3D image, and others are available only when you are viewing thumbnail scan images.

The following icons are always available:

Icon	Name	Function
	**ED**	Click to show the ED frames.
	**ES**	Click to show the ES frames.
	**Toggle Text**	Click to show or hide informational text that is overlaid on scan images in the lower left corner of the 2D scan image.
	**Swap Views**	Click to switch views between the 3D image, and the individual scan images.
	**Snapshot**	Click to take a snapshot of the current image.

The following icons are only available when you are viewing thumbnail images:

Icon	Name	Function
	**Show all thumbnails**	Click to show all thumbnails.
	**Single column**	Click to show thumbnails in a single-column layout.
	**Two columns**	Click to show thumbnails in a two-column layout.

	**Three columns**	Click to show thumbnails in a three-column layout.
	**Four columns**	Click to show thumbnails in a four-column layout.

The following icons are only available when you are viewing the reconstruction screen:

Icon	Name	Function
	**Right Ventricle**	Click to view the right ventricle reconstruction.
	**Left Ventricle**	Click to view the left ventricle reconstruction.
	**Right Atrium**	Click to view the right atrium reconstruction.
	**Left Atrium**	Click to view the left atrium reconstruction.

The following icons are only available when you are viewing an individual scan 3D image:

Icon	Name	Function
	**Previous scan**	Click to view the previous image.
	**Next scan**	Click to view the next image.
	**Zoom out or return to thumbnail view**	Click to zoom out if previously zoomed in, or return to the thumbnail view.
	**Zoom Out 1:1**	Click to view the image at its original size.
	**Zoom Fill**	Click to fit the image to the size of the main workspace.
	**Arrow**	Click to pick points. This is the default mouse pointer mode; your mouse pointer will automatically return to this mode after you have finished performing an action in another mode—for example, defining a region of interest (see the next icon description).
	**Define a Region of Interest**	Click to define a region of interest and magnify it. After clicking the icon, click to define one corner of the region that you want to magnify, and then drag to define the entire

		region. When the region that you are defining is large enough, the outline changes from yellow to green. If the outline is yellow, you *must* continue to drag your mouse pointer until the outline becomes green.
	**Light Window**	Click to change the luminosity by using your mouse. Move the mouse pointer up or down to adjust brightness, or left and right to adjust contrast.

Logging Off from the System

When you have finished with a patient, you *must* log off from the system.

► **To log off from the system**

1. Click the **Close** icon at the far right of the navigation header. The VMS+ program 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.

Starting a New Study

The VMS+ follows the typical workflow of a sonographer (or cardiologist) during the initial examination of a patient, and the subsequent analysis of the data collected during that examination. The workflow begins on the Studies screen, where you can choose to create a new study. After selecting the appropriate ultrasound transducer, ensuring that the ultrasound image is configured correctly, and entering patient information, you go to the Scan screen, where you capture the multi-frame scans.

Starting a New Study

► **To start a new study**

Note:	If required by the system, you may be prompted to perform a Tracker Calibration prior to beginning a new study. For more information on this, refer to the Tracker Calibration procedures in Maintaining the System on page 65.

1. In the Common Actions pane on the right panel of the Studies screen, click **New**.
2. If the new study involves a returning patient, and a previous study exists for this patient in the list of existing studies, click to select the previous study, and then hold down the SHIFT key and click **New**. The system pre-enters patient data on the Patient Information screen.
3. The New Study Wizard appears.
4. In the Select Ultrasound Transducer list, click the transducer that you will be using during the scanning session.

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+. Typically, there is one transducer for adult patients and another for pediatric patients.

5. Click **Next**. The Ultrasound Settings screen appears. The horizontal (left-right mirror) orientation of the image on the ultrasound monitor *must* be identical to the orientation of the image displayed on the Ultrasound Settings screen.

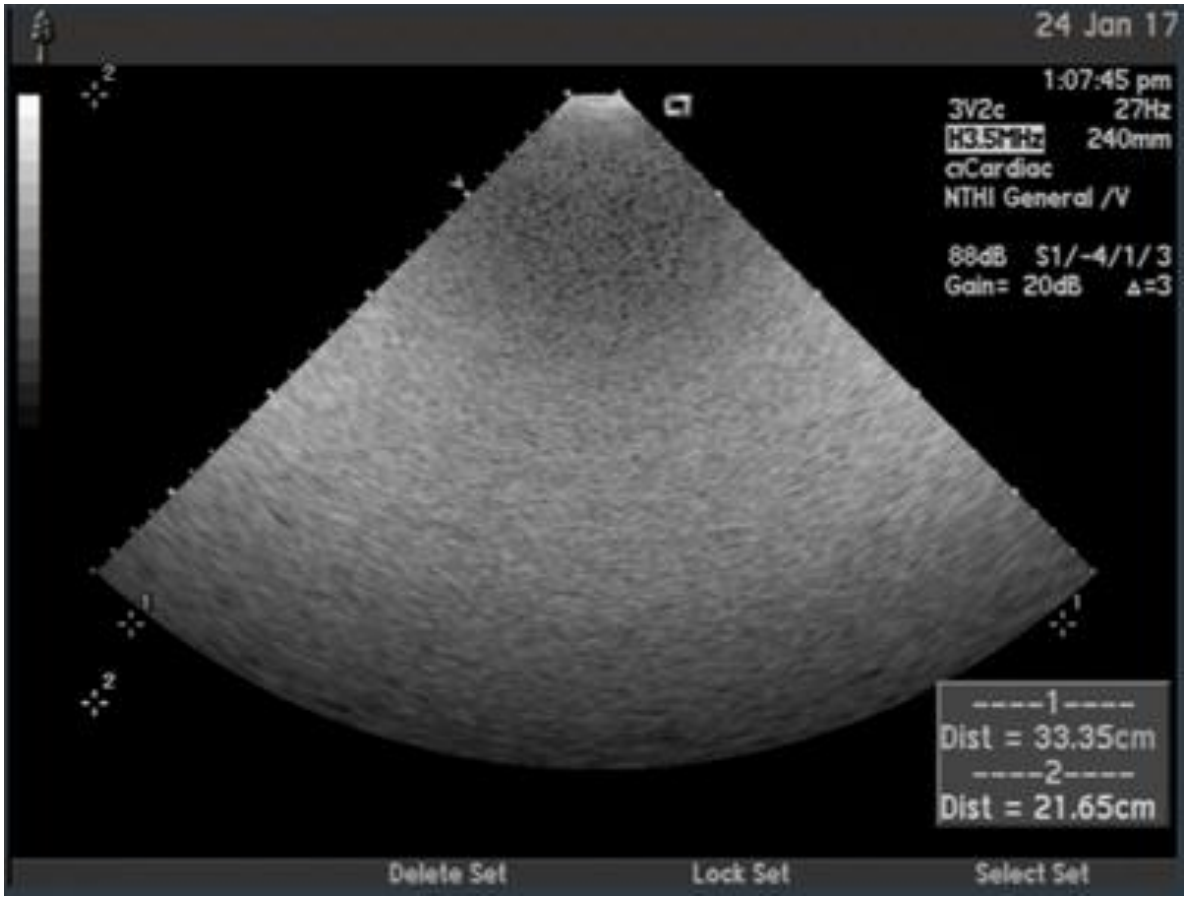


Figure 6: Ultrasound image on the Ultrasound Settings screen

6. If the image configurations match, select the **Confirm Ultrasound Index Marker Settings** check box, and then click **Next**. The Patient Information screen appears.
7. Enter patient data as follows:

- **MRN**: Type the patient's Medical Record Number (hospital-provided).
- **First Name**: Type the patient's first name.
- **Middle Name**: Type the patient's middle name, if applicable.
- **Last Name**: Type the patient's last name.
- **Gender**: Click the patient's gender in the list.
- **Birth Date**: Enter the month, day, and year in which the patient was born. The format depends on your operating system locale (mm/dd/yyyy in the United States).
- **Height**: Type the patient's height in inches (in.) or centimeters (cm), depending on how your system has been configured. If you enter an invalid number, a message appears near the bottom of the screen.
- **Weight**: Enter the patient's weight in pounds (lb.) or kilograms (kg), depending on how your system has been configured. If you enter an invalid number, a message appears near the bottom of the screen.
- **Analysis**: Click the patient's analysis option in the list. Available options include: **Tetralogy of Fallot (TOF)**, **RV to PA Conduit**, HLHS, D-TGA (Atrial Switch), PAH and Standard Analysis.
- **Facility**: Displays the facility in which the patient is being examined. This information is configured at the time of installation and cannot be modified.

- **Sonographer**: Type the name or initials of the technologist performing the scan. Note that you can have the system automatically enter this information by setting the default technologist name in the Options and User Preferences dialog box (see the Setting Options and User Preferences on page 70).
- **Referring MD**: Type the name of the physician who referred the patient.

8. Click **Next**. The Analysis and History Comments screen appears.
9. Type any pre-study comments about the patient, if applicable, and then click **Finish**. The Scan screen appears, and you are ready to begin capturing scans of the patient's heart. For information about capturing scans, see the Capturing Scans on page 39.

Scanning

You 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 section on page 22.

Before capturing the first scan:

- Move the transmitter arm in place according to the Quick Reference Guide instructions.
- You *must* ensure that the ultrasound video output is optimized for viewing on the Ventripoint Medical System+ (VMS+) monitor. This will guarantee that the image quality during post-scan analysis is optimized for the identification of anatomical structures.
- In the Patient Monitor pane on the right panel of the Scan screen, ensure that the **Heart Rate** value is identical to the heart rate displayed on the ultrasound monitor. If it is, this indicates that the echocardiography (ECG) cables are properly connected, and the software can automatically pick the appropriate end diastolic (ED) frames.

VMS+ should not be used with images that display significant cardiac arrhythmias as results using those images have not been studied. In the event a 'significant arrhythmia' is present during image acquisition, the VMS+ will display 'INVALID' under Heart Rate in the Patient Monitor pane.

In the Patient Monitor pane, the **Tracker Distortion** value enables you to monitor ferromagnetic material within the immediate vicinity of the 3D tracking system. This reading will be **None** when the transducer is within range of the 3D transmitter and detects no metal distortion in the environment. When this reading is **High**, either the sensor is out of range, or metal is too close to the 3D tracking system.

In the Patient Monitor pane, the **Transducer Range** value measures the distance from the 3D tracking system transmitter to the 3D tracking sensor, connected to the ultrasound transducer. The farther the sensor is taken away from the transmitter, the less accurate the tracking system becomes. If the sensor is taken farther than 50 centimeters from the transmitter, the 3D positional accuracy is insufficient. The range value will turn red and you will not be allowed to capture scans until the sensor is brought back into range.

The default scan duration is 2 seconds. If necessary, you can change the duration on a per-patient basis. See the Setting Options and User Preferences section on page 70.

Capturing Scans

Use the Scan screen to capture views of the heart for post-scan analysis.

► To capture scans

1. Press the Ventripoint-supplied hand trigger to capture a scan, in accordance with the imaging protocol. You can also begin scanning by doing any of the following:

   - Press SPACEBAR on your keyboard.
   - Click **Capture** in the Scan Control pane, on the right panel of the Scan screen.

   Note the following visual and audible signals during the scanning process:

   - While the scan is being captured, the border around the image turns orange. After the scan has been captured, the border turns back to black.
   - At the start and end of each scan capture, a beep sounds.
   - Each time a scan is captured, a thumbnail of the scan image appears at the bottom of the screen.
   - The Patient Monitor pane displays patient heart rate, tracker distortion, and transducer range information.

Note:	If you are not satisfied with one or more of the scans you have taken you can delete them before finishing capturing your scans. To do so, click on the thumbnail at the bottom of the capture screen. This will change the Scan Control Pane buttons, and display a 'Back' button. Once the scan is deleted, hit Back to return to the scan capture screen.

VMS+ Image Acquisition Protocol

There are a minimum number of views that you *must* capture, refer to the table below.

The software will not allow you to proceed with the workflow unless you capture at least three scans.

If you need to start over, or if you do not want the scans that you have already captured, click the **Clear All** button to delete all scans

View	Region of Interest
Parasternal Long Axis @ Left Ventricle Outflow Tract	Left Ventricle Anteroseptal Inferolateral Endocardium Left Atrium Right Ventricle Endocardium Mitral Valve Annulus Aortic Valve Annulus
Apical 2	Left Ventricle Anterior

	Inferior Endocardium Left Atrium Endocardium Mitral Valve Annulus
Apical 3	Left Ventricle Anteroseptal Inferolateral Endocardium Left Atrium Endocardium Left Ventricle Outflow Tract Mitral Valve Annulus
Apical 4	Left Ventricle Right Ventricle Left Atrium Right Atrium Endocardium Septum Right Ventricle Apex Left Ventricle Apex Mitral Valve Annulus Tricuspid Valve Annulus Basal Bulge
Right Ventricle Inflow Tract	Right Ventricle Free Wall or Anterolateral Endocardium Right Atrium Endocardium Tricuspid Valve Annulus
Right Ventricle Outflow Tract	Right Ventricle Outflow Tract Endocardium Right Ventricle Septum Pulmonary Valve Annulus
Parasternal Short Axis @ Aortic Valve Level	Right Ventricle Right Atrium Left Atrium Endocardium Tricuspid Valve Annulus Pulmonary Valve Annulus Conal Septum
Parasternal Short Axis @ Papillary Muscle Level	Right Ventricle Endocardium Mid-Left Ventricle Endocardium Right Ventricle Septum Right Ventricle Septal Edge
Parasternal Short Axis @ Mitral Valve Level	Right Ventricle Left Ventricle Basal Endocardium Right Ventricle Septal Edge
Parasternal Short Axis @ Apical Level	Right Ventricle Endocardium Left Ventricle Apical Endocardium Septal Edge
Subcostal	Right Atrium Endocardium

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, not all views will be obtainable in every patient. It is incumbent upon the user to utilize all possible views to insure complete visualization of the entire ventricle and the associated anatomical points necessary for reconstruction.

2. After you have captured enough scans, click **Done** in the Scan Control pane. The Done with Scanning dialog box appears.

3. In the **Scan Depth** list, click 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 *must* verify and may correct the specified scan depths for each scan.

Note:	You select the scan depth during the study by using the controls on the ultrasound machine. VMS+ displays both the scan depth that you specified and the ultrasound machine scan depth. You *must* ensure that they match!

4. In the Patient **Heart Rate** box, verify that the displayed patient heart rate is correct. Adjust it as needed.

Note:	After clicking **OK**, you will not be able to capture additional scans for this study. If you need additional scans, click **Cancel**. You will be returned to the start of the scanning process where you can begin capturing scans again.

5. Click **OK**. The ED/ES screen appears. You are now ready to begin identifying ED and ES frames.

Note:	After you click **OK**, the New Study Wizard or the Studies screen may appear instead of the ED/ES screen, depending on the options configured in the Options and Preferences dialog box. For more information, see the Setting Options and User Preferences section on page 70.

From this point on, VMS+ automatically saves your changes to the Ventripoint server. You will occasionally see messages about communications with the server. This guarantees that your study information is always up-to-date when analysis is done on other workstations.

If messages appear, stating that VMS+ was unable to contact Ventripoint Services, contact your system administrator.

Selecting ED/ES Frames

After you have finished scanning the patient, use the ED/ES screen to verify the end diastolic (ED) and select end systolic (ES) frames. Volumes are measured at the ED and ES phases of the cardiac cycle.

The VMS+ automatically detects and marks the first ED frame of every scan, using a hardware-supported R-wave trigger system attached either to the patient's echocardiogram (ECG) electrodes or to the ECG trigger output from the ultrasound system. The trigger notifies the VMS+ the moment the patient's ECG hits the onset of the QRS, and the VMS+ synchronizes the R-wave with the images transmitted from the ultrasound equipment, to determine which frame in a scan is the ED frame. Although the Ventripoint Installation Engineer fine-tuned the automatic ED detection mechanism during installation, you should always review the ED frame selections and make any minor modifications when needed.

► **To validate the selected ED frames**

1. On the ED/ES screen, review the software-selected ED frames.
2. Click the thumbnail image that you want to work with.

> **Note:** Thumbnails (and images when loaded into the main workspace) will display a solid white border until an ED (frame will turn red) or ES (frame will turn blue) frame is set.

3. The selected image appears on the main workspace.
4. If you disagree with the ED frames that the VMS+ selected, traverse the frames until you find the position of the actual ED frame, according to your institutional guidelines; click **Set ED** in the ED/ES pane on the right panel, or press the D key on your keyboard (the border around the image turns red).
5. If you want to adjust the ED frames on all scans, click **Set All ED**. For example, to move ED on all scans two frames forward, move the slider cursor two frames forward on the current scan and click **Set All ED**.
6. After setting initial ED, review other key image acquisitions, i.e. PLAX, SAX, etc., to confirm adequate ED timing for each. If you need to change ED to a different frame for a selected image, simply select **Set ED** again.

> **Note:** Only the ED frame for the selected scan is changed.

7. After you have reviewed all the ED frames, click the **ES** icon on the toolbar above the main workspace.
8. Select ES, using the valve and/or chamber size information according to your institutional guidelines. Starting from the ED frame, review the cine loop, advancing one frame at a time, to determine which frame is closest to the ES point.

9. When you are satisfied with the ES frame, click **Set ES** in the ED/ES pane, or press the S key on your keyboard (the border around the image turns blue). VMS+ now calculates the ES interval and applies it to all scans, automatically selecting the ES frames for every scan.

Note:	The ES interval is the distance between the ED frame and the ES frame that you just selected.

10. Review the software-selected ES frame in each of the other scans.

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.

Although you can change the ES frame in another scan, doing so defines a new ES interval, which will be applied to all other scans.

11. When you are satisfied with the selected ES frames, click **Accept**. The Reconstruction screen appears. You are now ready to identify anatomical structures on the selected scan images.

Be careful when selecting ED and ES. If your selections need to be corrected later, any existing work (for example, anatomical structure marking) will be reset.

Identifying Anatomical Structures

After you have finished reviewing the end diastolic (ED) frames and have selected the end systolic (ES) interval, use the Reconstruction screen to describe the patient's anatomical structures, by selecting key points within the ED and ES frames that contain those structures.

When you select a thumbnail for either ED or ES, a Structures table appears on the 3D Reconstruction pane on the right panel. The Structures table includes three columns:

- **Show:** Contains check boxes that enable you to hide the points for a specific structure. The picked points for each structure are colored according to the label in the Show column.
- **Count:** Displays how many points have been placed for each structure. When the minimal points have been placed for a structure, satisfying VMS+ minimal requirements, the number in this column turns green.
- **Structures:** Displays the names of structures that need to be identified with point placements. For more information about how to pick points for each structure.

In the Structures table, select the anatomical structure that you are going to identify according to the *Point Placement Protocol*:

Point Placement Protocol				
View	**Right Ventricle Points**	**Left Ventricle Points**	**Right Atrium Points**	**Left Atrium Points**
True Apical 4-Ch	Tricuspid Annulus x 2 RV Septum x 2 RV Endocardium x 2 Basal Bulge x 1 Apex x 1	Mitral Annulus x 2 LV Endocardium x 4 Apex x 1	Tricuspid Annulus x 2 RA Endocardium x 4	Mitral Annulus x 2 LA Endocardium x 4
Apical 2-Ch (VLA view)		Mitral Annulus x 2 LV Endocardium x 4		Mitral Annulus x 2 LA Endocardium x 4
PLAX LVOT	RV Septum x 2 RV Endocardium x 3	Aortic Annulus x 2 Mitral Annulus x 2 LV Endocardium x 4		Mitral Annulus x 2 LA Endocardium x 4
Apical LAX 3-Ch view				Mitral Annulus x 2 LA Endocardium x 3
PLAX RVIT	Tricuspid Annulus x 2 RV Endocardium x 3		Tricuspid Annulus x 2 RA Endocardium x 2	
PLAX RVOT	Pulmonic Annulus x 1 RV Endocardium x 1 RV Septum x 1			
PSAX at Aortic Valve	RV Endocardium x 2 Pulmonic Annulus x 1 Conal Septum x 1		Tricuspid Annulus x 1 RA Endocardium x 3	
PSAX at Papillary	RV Endocardium x 2 RV Septal Edge x 2	LV Endocardium x 4		

	RV Septum x 1			
PSAX at Apex	RV Septal Edge x 2			
Subcostal IVC			RA Endocardium x 3	

Regardless of the sequence and/or quality of the acquired images, the above stepwise approach should be followed for placing the initial anatomical points in the reconstruction window 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 reconstruction, the number of initial points may vary at the user's discretion secondary to image quality, anatomical variations and acoustic limitations.

Identifying ED and ES Anatomical Structures

► **To identify ED and ES anatomical structures**

1. On the toolbar above the main workspace of the Reconstruction screen, click either the **ED** or **ES** icon
2. Select a scan from the thumbnail view. A full-size version of the image appears on the main workspace, and the Structures table appears in the 3D Reconstruction pane on the right panel.
3. Review the currently displayed scan image.
4. In the Structures table, select the anatomical structure that you are going to identify according to the *Point Placement Protocol*.
5. On the scan image, pick a point that corresponds to the specific anatomical structure that you are identifying.

> **Note:** In the Structures table, the number in the Count column for the selected anatomical structure is a cumulative total across all scans in the corresponding cardiac cycle.

6. Review all the remaining scans, picking additional points (as described in steps 3 and 4) until you have picked enough to describe each anatomical structure listed in the Structures table. As you select points on the 2D image, the same points appear in 3D in the 3D Viewer, at the bottom of the right panel.

> **Note:** If you pick a point in error, or if you are unsatisfied with a point that you have picked, right-click the point to delete it.

7. After you have selected enough points, the **Need Reconstruction** icon appears above the Structures table, and the **Run** button is enabled.
8. Click **Run**. The points are used for a knowledge based reconstruction (KBR), and a 3D model appears in the 3D Viewer.

Note:	Use the options in the 3D View pane on the right panel 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.

Validating Results

After you have identified anatomical structures by picking points on the end diastolic (ED) and end systolic (ES) scan images, and created 3D reconstructions for both ED and ES, 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 Study Quality is to examine how the borders on the 3D model intersect and align with the anatomical structures displayed on the 2D images.

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.

The right panel of the Reconstruction screen contains the tools that you will use in your review. One important reviewing tool that you will use is the 3D View pane. Here, you can select which features you want to view when examining the 3D model.

When you first run the 3D reconstruction, the **Mesh**, **Points**, and **Outlines** check boxes are selected by default.

The 3D View pane contains the following check boxes:

- **Mesh**: Select to show the mesh surface.
- **Points**: Select to show points.
- **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 is to help guide 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.

Note:	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).
- **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.
- **Scan Plane**: Select, and 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.

You can adjust the point size on the 3D image by using the **Point Size** slider below the check boxes in the 3D View pane. Move the slider to the right to increase point size, and move it to the left to decrease point size.

► To review the 3D model

1. On the toolbar above the main workspace, click the **Swap Views** icon. The 3D model now fills the main workspace. Note that you can make the model smaller or larger by using the scroll wheel on your mouse.
2. Rotate the 3D model to examine, in detail, how well the points adhere to the mesh. Right-click-and-hold anywhere in the main viewing pane, and drag your mouse pointer in the direction that you want to rotate the image. You can rotate the image in any direction or back and forth on its vertical axis by pressing the LEFT ARROW and RIGHT ARROW keys on your keyboard. You can rotate the image up and down on its horizontal axis by pressing the UP ARROW and DOWN ARROW keys on your keyboard.
3. Click the **Swap Views** icon so that the 2D scan image fills the main workspace.

   In the 3D View pane, select the **Borders** check box. A yellow outline appears on the image on the main workspace, and 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 scan image. The 3D model *must* intersect the ventricle accurately.

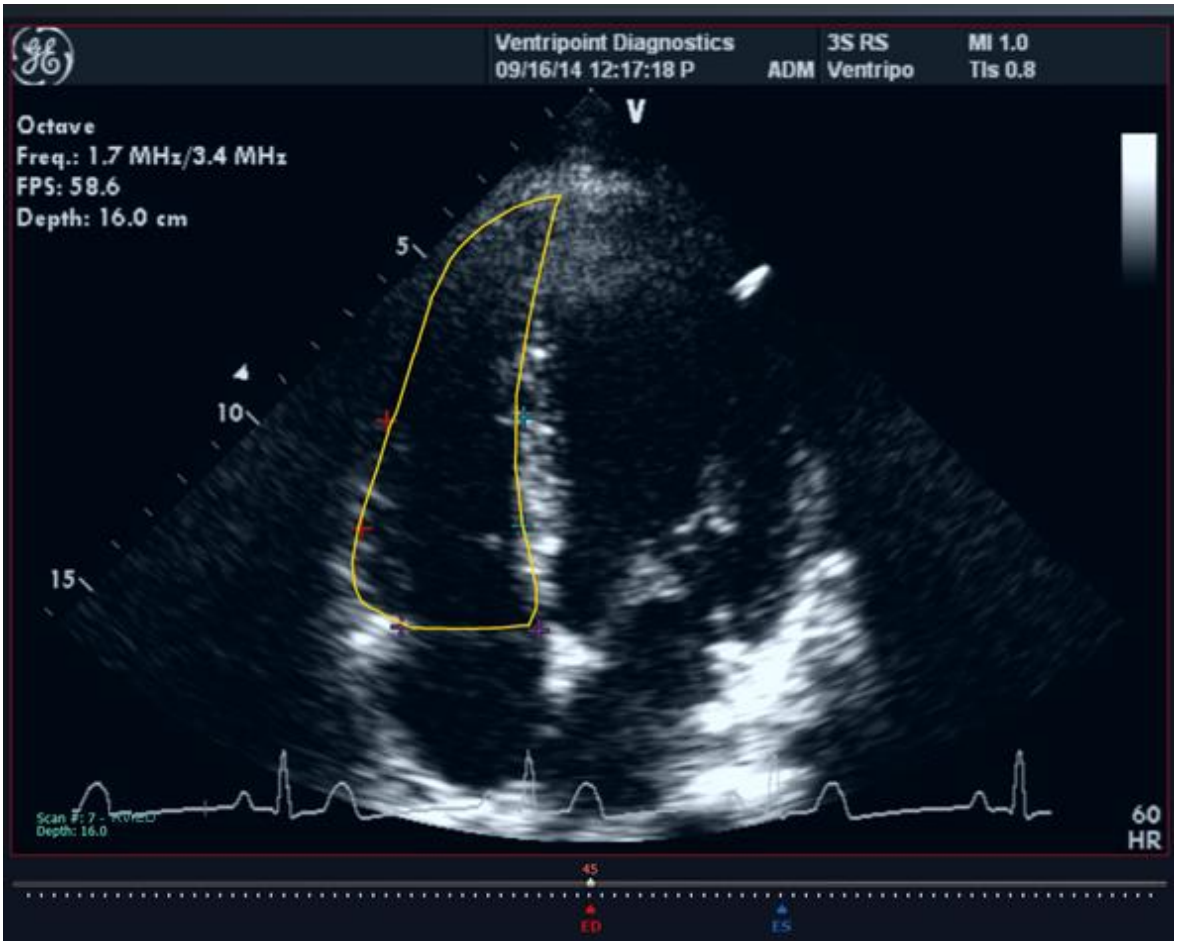


Figure 7: Scan image when Borders is selected

4. Click the **Swap Views** icon so that the 3D model again fills the main workspace.
5. In the 3D View pane, select the **Scan Plane** check box.

   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. When you are verifying the projection of the 3D model onto 2D scan images, take care to ensure proper alignment. You can rotate the image to examine the intersection in detail.

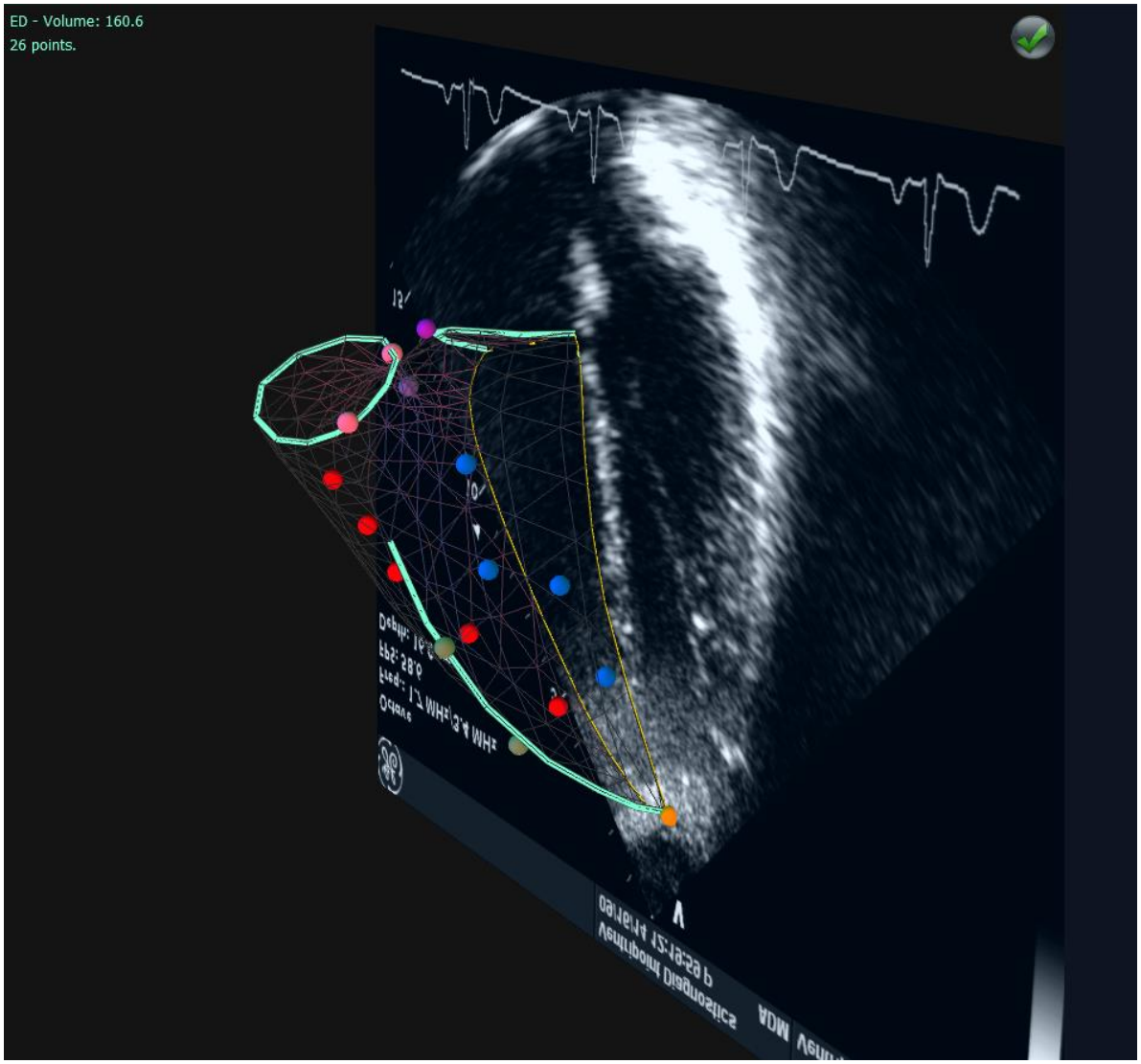


Figure 8: 2D and 3D images intersected using the Scan Plane feature

6. In the Analysis pane on the left panel, review the volumetric analysis numbers. Now that you have reviewed the 3D model, you can use that information to refine your results as necessary.

Refining Results

You can refine scan images by examining anatomical structures in greater detail, moving or deleting points, and otherwise adjusting the scan and 3D images.

View the images in greater detail to compare the 2D and 3D images more closely. Clicking a thumbnail image enlarges it so that it fills the main workspace. Additional tools become available on the toolbar above the workspace, and on the right panel.

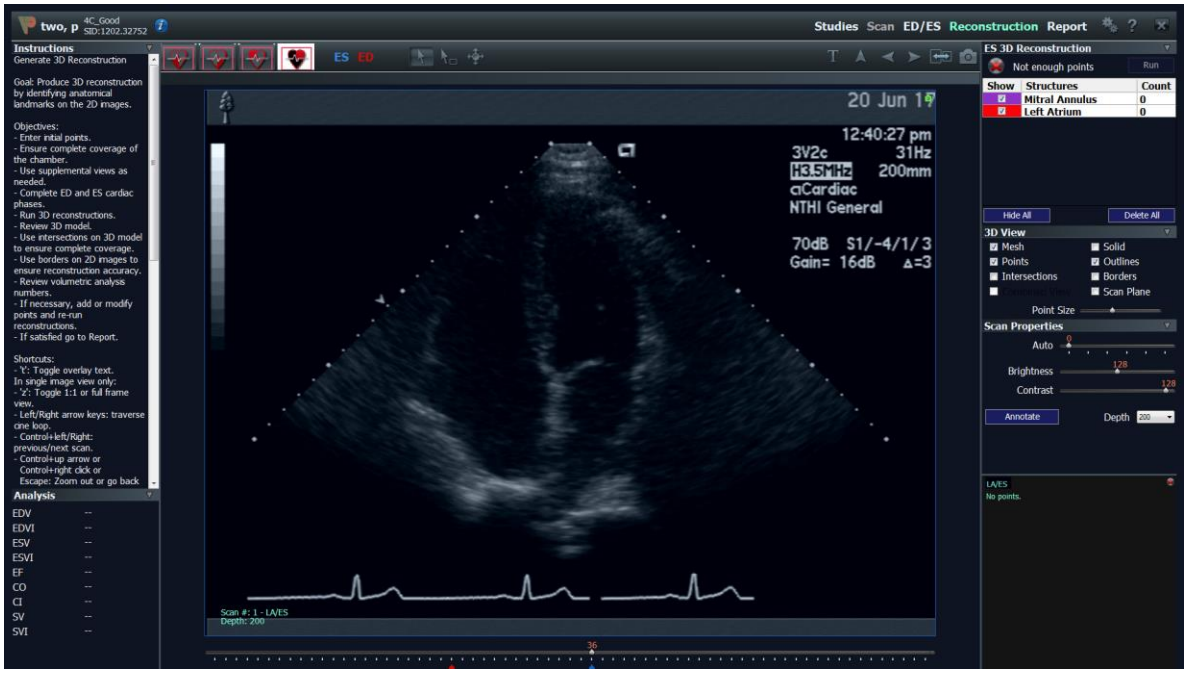


Figure 9: Reconstruction screen with a single scan image filling the workspace

Note: For a quick overview of toolbar items and workspace panels, see the Quick Start section on page 22.

Showing, Hiding, or Deleting ED/ES Structure Points

The 3D Reconstruction pane on the right panel contains a table of anatomical structures. This table shows how many points you have picked for each structure.

You can choose to show, hide, or delete the ED or ES structure points on the image. Note, however, that any changes that you make to an ED image do not affect the ES image, and vice versa.

If you delete too many points from any of the anatomical structures, an icon appears in the 3D Reconstruction pane, indicating that there are **Not enough points**.

Note: Simply adding or deleting a point does not change the 3D model. If you add or delete a point, you *must* rerun the 3D reconstruction to generate an up-to-date 3D model.

To rerun the 3D reconstruction, you *must* pick more points. The number in the Count column indicates the number of points that were picked for the corresponding anatomical structure; this makes it easy to determine which anatomical structures need additional point coverage.

When you have picked enough points, an icon appears in the 3D Reconstruction pane, indicating that the points **Need reconstruction**:

After you run the 3D reconstruction, an icon appears in the 3D Reconstruction pane, indicating that the **Model is up-to-date**.

By default, all anatomical structures are displayed as points on the image. However, you can hide individual structures or all structures.

► To hide individual ED/ES structures

7. In the 3D Reconstruction pane, clear the check box next to the anatomical structure for which you want to hide the points. Points corresponding to that anatomical structure disappear from the image on the main workspace. You can reselect the check box to show the points at any time.

► To hide all ED/ES structure points

8. In the 3D Reconstruction pane, click **Hide All**. All the check boxes in the Show column are cleared, and the label of the **Hide All** button changes to **Show All**.
9. Click **Show All** to show all ED/ES structures.

Note:	Hiding structures does not hide them on the 3D model that is displayed in the 3D Viewer at the bottom of the right panel.

► To delete all ED/ES structure points

Clicking the **Delete All** button deletes all ED or ES points for this study. You will not be able to undo this action, and will need to pick the ED or ES points again.

1. In the 3D Reconstruction pane, click **Delete All**. A message appears, asking whether you want to delete all points.
2. Click **OK** to delete all ED or ES points, or click **No** to cancel. After you delete all ED/ES structure points, the 3D Viewer is empty, and the following message is displayed: **LA/ES** (Chamber/Frame) **No points**.

Note:	Whenever you add or delete an ES or ED point, the 3D model becomes “stale” relative to the new point set. As a result, all volumetric information pertaining to that phase of the cardiac cycle disappears from the Analysis pane on the left panel. For example, if you delete a point on an ED image, the ED volumetric information disappears. However, ES information remains. To repopulate the ED information, rerun the 3D reconstruction for ED.

Deleting Individual Points

When you are reviewing a scan image, you may decide that a point is inaccurate and needs to be deleted.

► To delete points

1. With the 2D scan image displayed on the main workspace, right-click the point that you want to delete. The point is deleted.

2. In the 3D Reconstruction pane, click **Run** to rerun the 3D reconstruction.

Moving Individual Points

You can adjust the position of any point on your image as many times as you want, until you are satisfied that it accurately represents the structure that you want to identify.

► **To move points**

1. With the 2D scan image displayed on the main workspace, click the point that you want to move. This ensures that the correct anatomical structure is selected when you place the point in a new location.
2. Right-click the point. The point is deleted.
3. Click the location where you want to place your new point. The new point appears where you clicked.
4. In the 3D Reconstruction pane, click **Run** to rerun the 3D reconstruction.

Adjusting Scan Properties

You can adjust properties of the scan image, such as scan depth and luminosity, by using the Scan Properties pane on the right panel. You can also annotate the informational text that is overlaid on the scan image that you are working with.

If you decide that the scan depth of a scan image needs to be changed, you can adjust it by using the scan **Depth** list. Remember that changing the scan depth changes it only for the scan that you are viewing. For example, if you are viewing images in scan 2, the scan depth is changed for all of scan 2; the remaining scans in the study are not affected by the change.

► **To adjust the scan depth**

1. In the Scan Properties pane, click the scan depth that you want in the **Depth** list.
2. In the 3D Reconstruction pane, click **Run** to rerun the 3D reconstruction. The new 3D reconstruction reflects your changes to the scan depth.

Luminosity

The luminosity of a scan image is a combination of its brightness and the amount of contrast. You can adjust the luminosity of a scan image by using the brightness and contrast sliders, or by selecting a preset value.

The luminosity controls provide a powerful mechanism for extracting information from digital images, but they require an in-depth understanding of image processing. Therefore, it is best to use the preset values, and then fine-tune the results by using the sliders.

Ventripoint recommends that you experiment with the presets until you develop an intuition for these advanced controls.

► **To adjust luminosity by using the sliders**

1. In the Scan Properties pane, move the **Brightness** and **Contrast** sliders to adjust how the image is rendered.

► **To adjust luminosity by using presets**

2. In the Scan Properties pane, move the **Auto** slider to select a preset value. The luminosity is adjusted to the preset that you selected. If you want to switch from a preset luminosity to individual settings, simply move the **Brightness** and **Contrast** sliders.

Note:	You can also adjust luminosity by using the **Light Window** icon on the toolbar above the workspace. For more information, see the Quick Start section on page 22.

You can add an annotation to the text that appears in the lower-left corner of the 2D scan image. You can also change an annotation that was previously added. Note that annotating a scan image is optional.

► **To annotate a scan image**

1. In the Scan Properties pane, click **Annotate.** The **Annotation** dialog box appears:
2. Enter text in the text box. You may enter up to 50 characters per annotation.
3. Click **OK** to save the annotation, or **Cancel** to discard it. The annotation appears on the overlay.

Taking Snapshots of Images

When you have finished reviewing and refining your study, you are ready to take snapshots of your 3D model and/or 2D images by using the **Snapshot**  icon. The **Snapshot** icon is located on the toolbar above the main workspace. Note that you can take a 3D snapshot only when the 3D model is displayed on the main workspace.

For the 3D model, up to three specific snapshots can be included in the report that you generate after validating the results of your study: ED, ES, and a combined view (ES superimposed on ED). Select the 3D view of interest, and click the Snapshot icon to add that view to the report. Clicking the snapshot button again, removes the previously taken snapshot. Snapshots can be taken with any of the 3D View pane selections checked.

For the 2D images, two snapshots can be taken for each scan; one of an ED image and one of an ES image. The 2D snapshots can be taken with the **Borders** selection in the 3D View pane checked or un-checked.

Note:	If you add or delete points for ES or ED, or change scan depth, all previously taken snapshots and any previous analysis data for the specific cardiac cycle will be removed from the report. You will need to complete another 3D reconstruction, and re-take the snapshots for the specified cardiac cycle.

► To take a snapshot of a 3D Image

1. With the 3D model displayed on the main workspace, click the **Snapshot** icon on the toolbar. A message appears, verifying that the snapshot has been taken successfully.

> **Note:** You can take up to three snapshots of the 3D model: one of ED, one of ES, and a combined view.

► To take a snapshot of a 2D Image

1. From the thumbnail views, select either the ED or ES cycle.
2. Select one of the thumbnails of interest. The single 2D image will appear in the main workspace.
3. (Optional) Select the **Borders** checkbox from the 3D View pane.
4. Click the **Snapshot** icon on the toolbar. A message appears, verifying that the snapshot has been taken successfully. The 2D image now has a small green Snapshot icon displayed in the upper right corner of the image.
5. (Optional) Click the **Snapshot** icon again to remove the snapshot from the Report. Clicking the **Snapshot** icon with any 2D image, where the green Snapshot icon is showing, will result in the snapshot being removed.

> **Note:** You can take up to two snapshots of each 2D image: one of ED and one of ES.

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

Working with Reports

Use the Report screen to review historical data and information for an existing patient, confirm results for each heart chamber, add/update comments, and print a report. You can go to the Report screen at any time to generate a report. A final report can be generated only after a study has been saved. Studies that have not been saved can be printed, but will have a *Preliminary Draft* watermark over the report.

Note: A draft report is regenerated whenever you go to the Report screen. If you add or delete an ED or ES point, you *must* complete a 3D reconstruction for the cardiac phase that changed (ED or ES). Then, you *must* take new snapshots for all three views before they will appear in the report, as well as new 2D snapshots for the cardiac phase that changed.

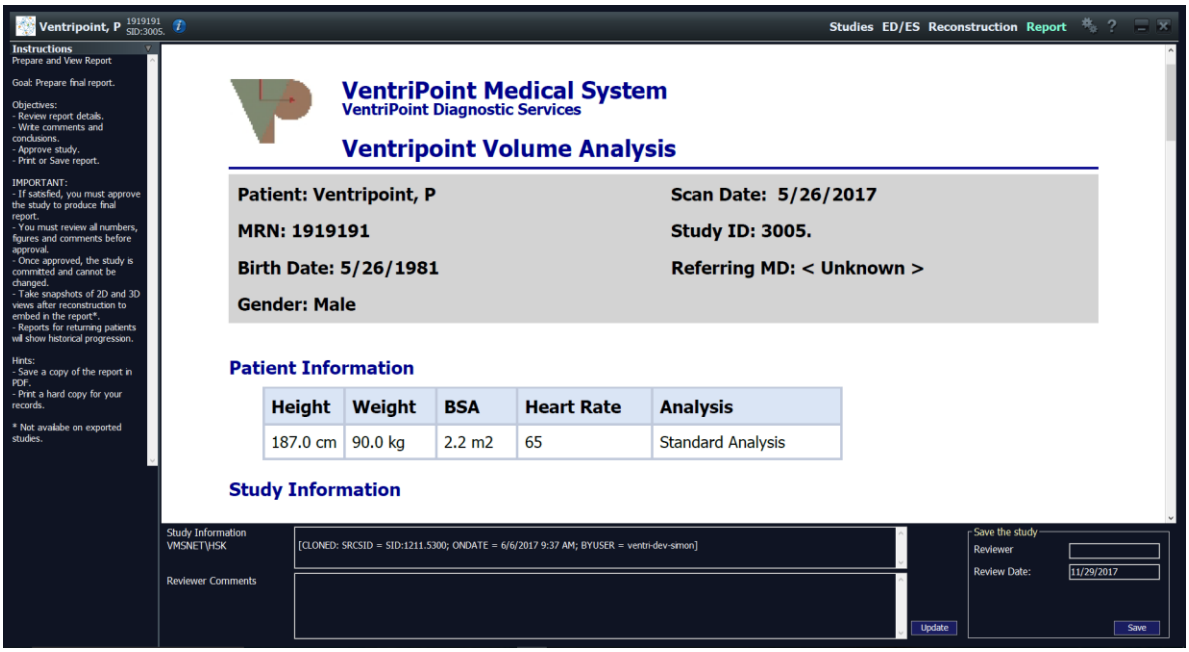


Figure 10: Report screen

Viewing a Report

The VMS+ enables you to view final reports for studies that have been reviewed, and also draft reports for studies that have not yet been reviewed.

► To view a report

1. In the list of available studies on the main workspace of the Studies screen, click to select the study for which you want to open a report.

2. In the navigation header, click **Report**. The Report screen appears for the selected study. The report appears on the main workspace as a PDF.
3. Review the historical data displayed in the report.

> **Note:** The Historical Data table is only included in a Report if the same patient (or same MRN) is used and a previous study has already been saved. The table includes dates, study ID and analysis data for each study.

4. In the **Study Information** box at the bottom of the screen, review (or add to) the comments that the technologist entered for this study.
5. In the **Review Conclusions** box, review (or add) conclusions for this study.

> **Note:** At any point before a study has been saved, you can update the information in the **Study Information** and **Review Conclusions** boxes. After you make the changes, click the **Update** button to add the changes to the report.

Saving a Study

A study *must* be saved before a report can be considered final. Each individual facility determines who has the authority to save a study. Before a study can be saved, all analysis data, snapshots, and comments *must* be reviewed. After it has been saved, the study is committed. With the exception of adding and deleting snapshots, no further changes are permitted to a study after it has been saved.

► **To save a study**

1. In the **Save the study** box at the bottom right of the Report screen, type the name of the person who is reviewing the study in the **Reviewer** box. The system automatically populates the **Review Date** box with the current date; the date field is read only and cannot be modified.
2. In the **Reviewer Comments** box, type any additional comments pertaining to this study. The study cannot be approved if this box is empty.
3. Click **Save**. A message appears, asking whether you are sure that you want to save the study.
4. Click **OK**. The study is now locked and cannot be changed. You can use the embedded Adobe Reader toolbar to print the final report  , save it  , and send it via e-mail  .

Printing a Report

► **To print a report**

1. On the embedded Adobe Reader toolbar, click the **Print** icon. The Print dialog box appears.
2. Click **OK**.

Note: If the selected study has not been previously saved, you can print the report (with snapshots, if they are available) with a *Preliminary Draft* watermark.

Managing Studies

From the Studies screen, you can not only create a new study, but also:

- Open an existing study
- Delete a study
- Archive a study to remote storage over the network
- Retrieve an archived study from remote storage
- Export content to a removable USB device
- Clone a study
- Send studies to the PACS server
- Import MRI
- Import 3D Echo images

Opening an Existing Study

You use the Studies screen to open an existing study for completion, refinement, or review.

► **To open an existing study**

1. In the table of available studies on the main workspace, click to select the study that you want to open, and then click **Open** in the Common Actions pane on the right panel. Or, double-click in the row of the study that you want to open.
2. The selected study is opened in the workflow state in which it was last saved (see the Workflow State column in the table of available studies). You can now complete, review, or refine the information for the study.
3. If you open a study that has been modified by someone else, a **Study Version Conflict** message appears. The message identifies when you last modified the study (local study version), and when the version on the server was modified (server study version) and who modified the study last.
4. To use the study data from your local copy, select **Use Local**. The server data will be overwritten with your data.
5. To use the study data from the server, select **Use Server**. Your local data (any changes you made the last time you worked on this study) will be overwritten by the data on the server.

Opening an Existing Study (Review and Analysis System Mode)

In Review and Analysis System mode, you need to insert a removable media that contains the study that you want to open.

► **To open an existing study (Review and Analysis System mode)**

If the VMS+ Review and Analysis System does not begin immediately, your system may not support the autorun feature. To run the application manually, double-click on the **Vploader.exe** file located on the main directory of the USB flash drive.

Note:	The study data contained on a USB flash drive can be substantial, depending on the number of scans taken for the exported study and the duration of each scan. USB flash drives are inherently slower than hard disk drives; therefore, to maximize your user experience while viewing a study, the entire contents of the USB flash drive are first copied to a temporary location on your hard disk before VMS+ is started. This process can take up to 5 minutes to complete.

1. Insert the device into the USB port. In the root directory of the USB device, double-click the **runvms.bat** file. The study is opened in the VMS+ program, in the workflow state in which it was last saved.

Deleting a Study

Use the Studies screen to delete an existing study from your local hard disk.

► **To delete a study**

1. In the table of available studies on the main workspace, click to select the study that you want to delete.
2. Click **Delete** in the Common Actions pane. A message appears, asking whether you are sure that you want to delete the study.
3. Click **Yes** to delete the selected study from your local hard disk, or click **No** to retain the selected study.

Saving a Study

VMS+ automatically saves a study to your hard disk and the server at designated points. When a study is saved, any new version information is updated in the server database.

If the system detects that someone else has changed the data for this study on the server, you will receive the **Study Version Conflict** message described at the beginning of this chapter.

The data is saved first to local storage, and then to the server.

The following scenarios may arise during the process of saving study data:

- If the remote connection is unavailable, the system saves the study data locally, and it will save the data to the server the next time the study is opened (when the remote connection is available).
- In Review and Analysis System mode, if the remote connection is unavailable, the data will not be saved if you exit the program. A message appears, and you can do either of the following:

  a. Exit the program, losing your changes.
  b. Return to the program, and wait until network connectivity is restored before exiting the program.

- If VMS+ runs out of local storage, the system closes the current study without saving any changes, a message appears, notifying you of a lack of storage space, and you are directed to delete or archive one or more studies to make room on your local hard disk.

Editing Patient Information

Once patient information has been entered during the Start New Study workflow, it can be modified at any time prior to exporting or archiving the study.

► **To edit patient information**

1. In the table of available studies on the main workspace, select the study of interest
2. Click **Open** in the Common Actions pane.
3. Click the  patient information icon to open the Patient Information screen
4. Make the appropriate changes to Patient Identification, Patient Information, and Record Information
5. Click OK to save the changes made
6. Click Cancel to revert to the previously saved information

Note:	The Analysis field becomes read only once scanning has completed, and initial scan depth and heart rate have been selected.

Archiving a Study

Use the Studies screen to move one or more studies from your local system to a shared network location. After it has been archived, the selected study is removed from your local hard disk. Archiving frees additional disk space from the local system hard disk, and it enables other users on Review and Analysis System to open those studies if their computers are configured to access the same archive storage location.

Note:	You can archive a study only if your hospital administrator has previously identified a place on your network for archived studies, and if the location has been configured for network storage. Otherwise, the **Archive** button will not appear on the Studies screen.

► **To archive a study**

1. On the main workspace, in the table listing the available studies on your local hard disk, click to select the study (or studies) that you want to archive.
2. (Optional) To select more than one study, hold down the CTRL key as you click each study. To select several studies in sequence, click the first study, and then hold down the SHIFT key and click the last study.

3. In the Common Actions pane, click **Archive**. The selected studies are moved from local storage to the archive location. After they have been copied, the selected studies no longer appear in the list of available studies on your hard disk.

Retrieving an Archived Study

If an archive location has been configured for your system, you will see two icons at the top of the studies workflow area:

This Computer = 

Remote Archive = 

By default, **This Computer** is selected, which causes the list of studies on your local computer to be displayed. If you select **Remote Archive**, the list of archived studies will be displayed.

Note:	You can retrieve an archived study only if your hospital administrator has previously identified a place on your network for archived studies, and if the location has been configured for network storage.

► **To retrieve an archived study**

1. Click the **Remote Archive** icon above the main workspace. The table on the main workspace displays an updated list of archived studies.
2. Click to select the archived study (or studies) that you want to retrieve.

Note:	Click a column heading to sort the list by patient ID, patient name, date of birth, date of study, study ID, or study workflow state.

3. In the Common Actions pane, click **Retrieve**. A message appears, informing you that the selected archived studies are being copied to your local storage (but they are not being removed from the archive location). After they have been copied, the selected studies appear in the list of studies on your local hard disk.
4. To open a single archived study, select the study and click **Open.** The study will be copied to your local storage and then opened to the workflow state in which it was last saved.

Exporting Studies

VMS+ provides a way to share studies by exporting to a USB device.

► **To export a study**

1. In the table of available studies on the main workspace, click to select the study which you want to export, and then click **Export** in the Common Actions pane. The Export Study to Removable Media dialog box appears with a list of available removable devices to which you can export the study.

2. In the list, click the storage device that you want to use, and then click **Export**. The system copies the appropriate data and program files to selected storage device.

Note:	If No media selected is displayed, you need to insert a blank USB flash drive. Once the blank media has been inserted, wait several seconds for the Space Available to be updated. If necessary, click **Refresh List**, select the removable media again until the Space Available is updated. The **Export** function will become available.

Cloning Studies

Cloning studies is useful during research activities, for example to determine inter-observability metrics. Since there is only one copy of a study, which resides on the Ventripoint server, two users modifying the same study from two different stations will have constant conflict resolution issues and data will be replaced on the server. 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. Two different people can then analyze each study, and then compare the results.

Note:	Only studies created from the system you are working on can be cloned. If you select a study from another system, an error message will be displayed.

► **To clone a study**

1. From the main list view, select a study.
2. Select **Clone** from the Common Actions pane. You will be asked to verify your request:
3. A progress indicator will be displayed during the cloning process.
4. When the clone has been created, a dialog box will be displayed showing success or failure:
5. Make note of the study ID of the clone.
6. Open the clone and go to the Report Screen.
7. The original study ID, the user who cloned the study and the clone date will be displayed in the Study Information pane.

Sending Studies to a PACS Server

Sending studies to a PACS server is a useful operation for instances when sharing a study outside the viewing room or location of the system is needed. Running VMS+ from a Review and Analysis System is also a possibility, but may take longer than desired when time is important.

► **To send a study to PACS**

1. From the main list view, select a study.
2. Select **Send to PACS** from the Common Actions pane. You will be asked to verify your request.
3. If VMS+ detects that the study has already been sent to PACS, you will be prompted to update the study instead. The study on PACS will be appended with all snapshots and reports on the workstation. Select **Update** or **Cancel**.
4. A progress indicator will be displayed during the Send operation.
5. When the study has been sent, a dialog box will be displayed showing success or failure.

Importing MRI

Note: You can only import an MRI if the Importing MRI feature was enabled at installation.

► **To import an MRI**

1. From the Studies screen, select **Import MRI**. Windows Explorer is displayed.
2. Find and highlight the MRI you want to import. MRI's must be in a *.dicomdir file format.
3. Select **Open**. A progress bar will be displayed.
4. An Initial Selection dialog is displayed. Choose whether to start with no scan selected or all selected for import.
5. Select **Next**. A Selection Step dialog is displayed.
6. Before the import finishes, you must select what scans of the MRI you wish to import if you chose to select no scans on the Initial Selection dialog. A green border will be displayed around the scans that you have selected to import.
7. Select **Next**. A Ready to Import! dialog is displayed.
8. Confirm the number of selected scans and then select **Finish**. A progress bar will be displayed.
9. The Patient Information screen is displayed. Enter the required patient information as indicated by the text on the screen.
10. Select **OK**. A progress bar will be displayed.
11. The Studies screen is displayed, and the MRI study is added to the Studies list.

Importing 3D Echo Images

Note: You can only import a 3D Echo image if the Importing 3D Echo feature was enabled at installation.

► **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**. An Import 3D Ultrasound screen is displayed.
4. You must select and save the scans you wish to import.

   The 3D Echo dialog includes many options and steps to ensure that the scans you import are necessary to identify all anatomical structures.

   a) 3 scan plan 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.
5. (Optional) Allow the VMS+ software to create an acceptable number of scans for the import by selecting **Auto Create**.
6. Select **Create** when you have selected all your scans. A 'Generating…' progress bar will be displayed
7. The Patient Information screen is displayed. Enter the required patient information as indicated by the text on the screen.
8. Select **OK.** A progress bar will be displayed.
9. The 3D Echo is displayed in the ED/ES screen.

Maintaining the System

The only maintenance required with the Ventripoint Medical System+ is tracker calibration, which ensures the tracking system accuracy is maintained.

The tracking system *must* be calibrated periodically. You use the Calibrate 3D Tracking System Wizard to calibrate the tracking system.

On the Tracker Calibration reminder screen, you can do any of the following:

- To calibrate the tracking system, click **Open Calibration Wizard**.

> **Note:** You can also open the Calibrate 3D Tracking System Wizard from the Options and Preferences dialog box, see the Setting Options and User Preferences chapter.

- To proceed with creating a new study without calibrating the tracking system, click **Next**.
- To return to the Studies screen without creating a new study or calibrating the tracking system, click **Cancel**.

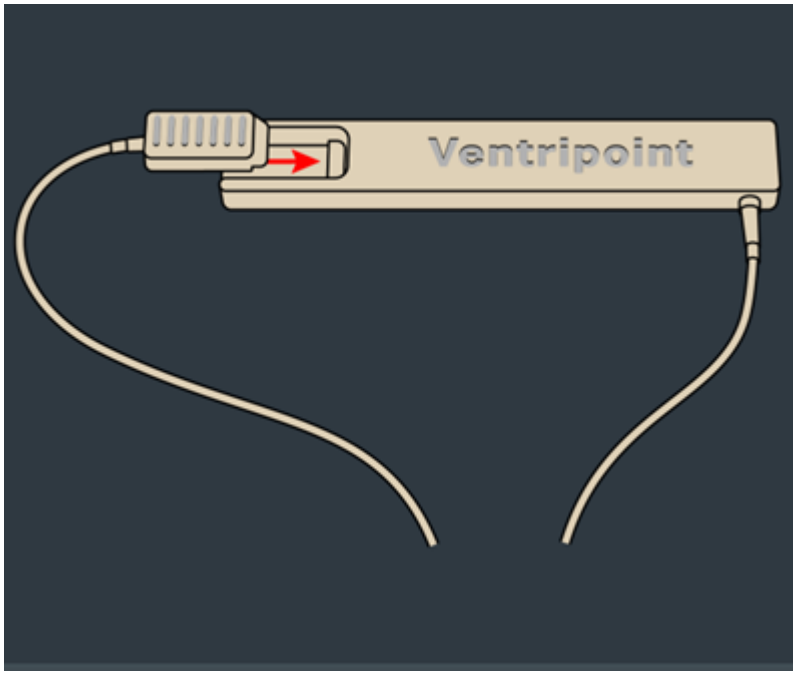
Never pull on the wires! To hold, attach, or detach the sensors, grasp the sensor housing, not the wires.

► To calibrate the tracking system

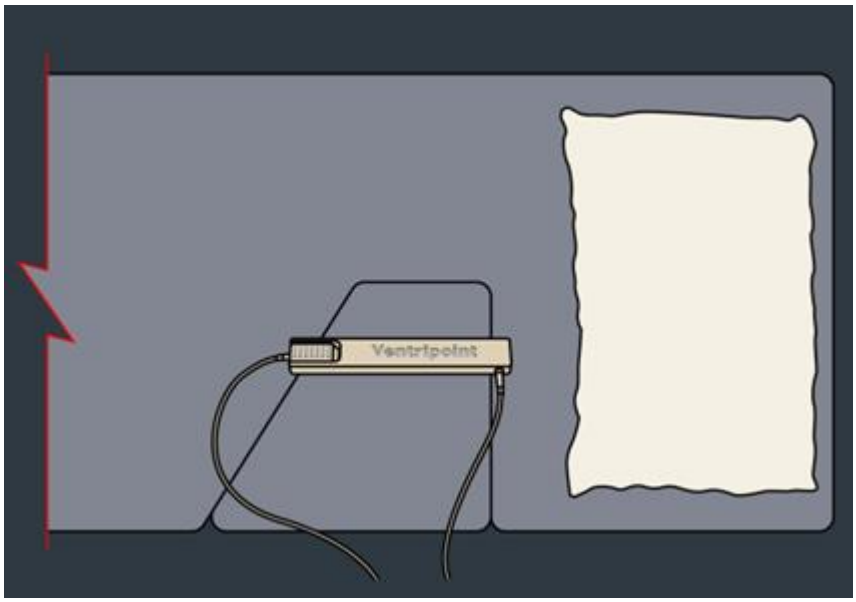
1. Open the Calibrate 3D Tracking System Wizard by clicking **Open Calibration Wizard** in the New Study Wizard.

> **Note:** For information about opening the Calibrate 3D Tracking System Wizard from the Options and Preferences dialog box, see the Setting Options and User Preferences section on page 70.

2. Remove the tracking sensor housing from the ultrasound probe sleeve as shown on the 'Prepare Calibration Baton' screen.
3. Attach the tracking sensor to the calibration baton as shown in the diagram on the Tracker Calibration screen

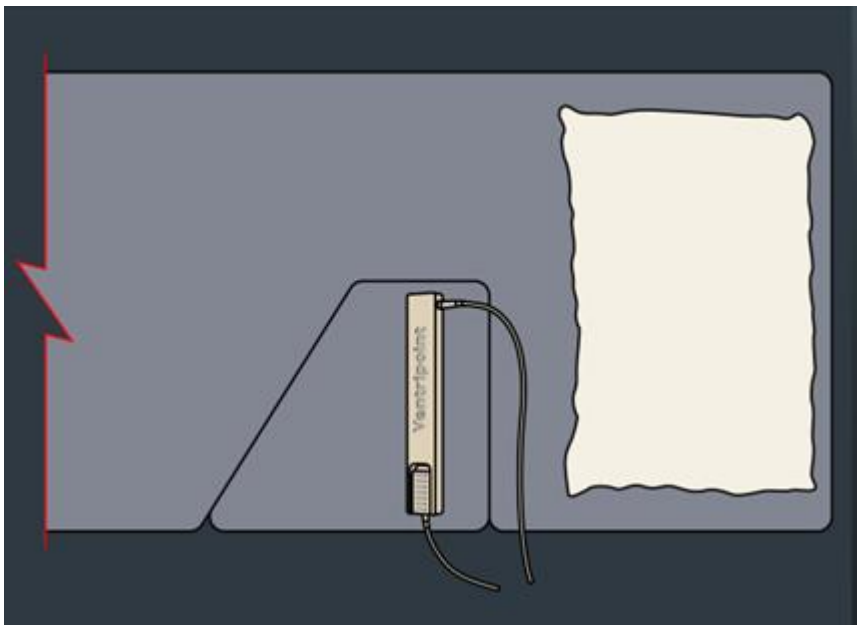


4. Click **Next**. The Acquire Calibration Reading #1 screen appears.
5. Place the calibration baton on the mattress as shown.



6. Click **Acquire**. The **Acquire a calibration reading when ready** message changes to **Calibration reading acquired** (and the icon next to it changes from a yellow exclamation point to a green check mark).

7. Click **Next**. The Acquire Calibration Reading #2 screen appears.
8. Place the calibration baton on the mattress as shown.



9. Click **Acquire**. The **Acquire a calibration reading when ready** message changes to **Calibration reading acquired** (and the icon next to it changes to a green check mark).
10. Click Next. The Calibration Results screen appears. If the calibration was successful, the screen displays a **Tracker calibration test passed** message and a green check mark.

11. If the calibration was unsuccessful, the screen displays a Tracker **calibration test failed** message and a red 'x'.

12. If the calibration failed, click **Back** to repeat the calibration process.

Note:	If tracking system calibration continues to fail, the cause may be changes in the environment, such as magnetic interference, or a critical hardware system malfunction. Contact Ventripoint support as soon as possible. You cannot continue scanning until the maintenance has been successfully completed.

13. If the calibration was successful, click **Finish**. The Tracking System Wizard closes, and the tracking system calibration is complete.

System Support

Corporate Address

Ventripoint Diagnostics Ltd.
2 Sheppard Avenue East, Suite 605
Toronto, ON M2N 7A4, Canada

Web Address

http://www.ventripoint.com

Contacts

Telephone: +1 (833) 201-8735
E-mail: info@ventripoint.ca

Support

Web: http://www.ventripoint.com/support.html
E-mail: support@ventripoint.ca
Phone: +1 (833) 201-8735

Returns

Ventripoint Diagnostics Ltd.
2 Sheppard Avenue East, Suite 605
Toronto, ON M2N 7A4, Canada

Setting Options and User Preferences

You use the Preferences dialog box to set the following program options and user preferences for the Ventripoint Medical System+ (VMS+) software:

- Select the screen that the program opens when you initially log on to the system.
- Select the screen that the program opens after you have finished scanning.
- Select whether the Instructions pane appears on the left panel of a screen.
- Enter the technologist's name so that the system will pre-populate it on all screens where that information is required.
- Test your workstation connection to the Ventripoint server.
- If configured, test your workstation connection to the hospital PACS system.
- Reset your VMSNET credentials.
- Set the duration of your scans.
- Select whether the program provides audio cues when certain steps are completed.

Note: Not all options and preferences will be available for all operational modes.

► **To set options and user preferences**

1. In the navigation header, click the **Options**  icon. The Preferences dialog box appears.
2. Under **After performing a scan**, select the screen that you want the program to open after you have finished capturing scans (that is, after you click **OK** in the Done With Scanning dialog box). Click one of the following option buttons:

   a. **Identify anatomical structures**: The ED/ES screen appears. This is the default setting.
   b. **Go back to the 'Studies' screen**: The Studies screen appears.
   c. **Start a new study**: The New Study Wizard appears.

3. Under **Application startup screen**, select the screen that you want the program to open when you initially log on to the system. Click one of the following option buttons:

   a. **Start a new study**: The New Study Wizard appears. This is the default setting.
   b. **Go to 'Studies' screen**: The Studies screen appears, displaying a list of existing studies on the main workspace.

4. Under **Instructions Panel**, select whether the Instructions pane appears on the left panel of each screen in the workflow. Click one of the following:

   a. **Show**: The Instructions pane is visible. This is the default setting.
   b. **Hide**: The Instructions pane is not visible.

Ventripoint recommends that you keep the Instructions pane visible until you are familiar with the program.

5. Under **Default sonographer name**, type your name in the box (if applicable). The system will pre-populate this information on all screens that require the technologist's name, and also on the study report. The default action is to leave the **sonographer** box blank.
6. Under **Service Options**, click **Test Connection** to test your workstation connection to Ventripoint Services.
7. Click **Test PACS** to test your workstation connection to the hospital's PACS system. This button will not appear if your system has not been configured to utilize the hospital PACS. A PACS verification window will appear that lists the following:

   - **Server AE**: The name of the PACS Application Entity ID.
   - **Address**: The address of the PACS server.
   - **Port**: The port of the PACS server.
   - **Local AE**: VMS Application Entity ID.
   - **Receive Port**: The local port for received studies from the PACS server.
   - **Status**: Will display one of the following messages
     - Ready – ready to run test by clicking on the **Test** button.
     - Pass – Connectivity test completed successfully
     - Fail – Failed to connect to PACS server.
   - **Test**: Click the **Test** button to test connectivity to the configured PACS server.

Note:	If the test fails, please contact Ventripoint Customer Support to help resolve the issue.

8. Click **Reset Credentials** to reset your VMSNET credentials. Use this option whenever you change your VMSNET password.
9. Under **Scan Options**, change the duration of your scans by using the **Scan Duration** list.

Note:	The scan duration value that you select does not persist across studies. The next time you click **New** on the Studies screen, the scan duration will be reset to the default value of 2 seconds.

10. Clear the Play **Sounds** check box if you do not want the program to provide audio cues after you complete certain steps. The **Play Sounds** check box is selected by default.
11. Click Tracker **Calibration** to open the Calibrate 3D Tracking System Wizard. For information about how to calibrate the tracking system, see the **Maintaining the System** chapter beginning on page 65.
12. When you have finished configuring preferences, click **Close**.

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) × 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 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

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 Diagnostic System (VDS): A centralized server, and a system of diagnostic tools and software, that use data from existing medical imaging devices to rapidly generate accurate 3D models and volume measurements of the ventricles of the heart.

Ventripoint Medical System+ (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 echos.

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 chapter, contact Ventripoint or your local representative for assistance.

Problem

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.

Solution

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 that will be uploaded to the server for follow-up by support staff.

Problem

Connection to the server is lost.

Solution

VMS+ will automatically try to re-establish a connection to the server. The system records the error in an activity log that will be uploaded to the server at a later date. Each time an explicit Save command is executed, the system will attempt to reconnect to the server. If connection is not possible when you close the study, the system will copy all your changes to local storage until the next time the study is opened.

Exception: If you are running VMS+ in Review and Analysis System mode when the connection to the server is lost, your data will not be saved when you exit the program. Each time you attempt to exit VMS+, an error message appears if the connection is still unavailable. In this case, do not exit the program until the connection to the server has been re-established.

Problem

There is insufficient disk space available to save a study. All current changes to the study will be lost.

Solution

Delete or archive one or more existing studies. You will need to rescan the patient.

Problem

The system automatically selected an insufficient number of usable end diastolic (ED) frames, and you are unable to locate the minimum number required.

Solution

Return to the Reconstruction screen and attempt to select additional ED frames; delete the study and rescan the patient; or delete the study completely.

Problem

The 3D reconstruction is unavailable because of a server communication error.

Solution

The system will try to reconnect a minimum number of times. The system records the error in an activity log that will be uploaded to the server at a later date. Try the 3D reconstruction again, by selecting the appropriate cardiac phase (ED or ES) and clicking **Run** in the 3D Reconstruction pane. If this is unsuccessful:

- Contact Ventripoint support staff to determine whether there is a server problem.
- Contact hospital administration to determine whether the hospital firewall is inaccessible.

If none of the preceding solutions work, close the study and complete it at a later date, after connection with the server has been re-established.

Problem

There is insufficient space on the removable media to export the study and the program.

Solution

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 export process.

Problem

VMS+ runs out of local storage space. The system closes the current study without saving any changes.

Solution

Delete or archive one or more studies from local storage to make room for more studies. Re-enter your changes.

Keyboard Shortcuts

Studies Screen

Key	Action
SHIFT *and click* **New**	Use the selected study to pre-enter patient data on the Patient Information screen, with the exception of height and weight (which *must* be re-entered each time a patient is scanned).
UP ARROW DOWN ARROW	Move up/down the Studies table.
F2	Begin a new study.

ED/ES Screen

Key	Action
LEFT ARROW RIGHT ARROW	Traverse the cine loop of a single scan in Scan Review mode.
D	Select the end diastolic (ED) frame.
S	Select the end systolic (ES) frame.

Reconstruction Screen

Key	Action
LEFT ARROW RIGHT ARROW	When the 2D image is displayed on the main workspace, traverse the cine loop of a single scan.
LEFT ARROW RIGHT ARROW	Rotate the 3D reconstruction horizontally (around the Y axis).
UP ARROW DOWN ARROW	Rotate the 3D reconstruction vertically (around the X axis).
CTRL+ LEFT ARROW	Go to the previous scan image in Single Image mode.

CTRL+ RIGHT ARROW	Go to the next scan in Single Image mode.
CTRL+ UP ARROW	Switch to Grid mode from Single Image mode. Or, return to the original view from region of interest (ROI) view.
ESC	Switch back to thumbnail view from Single Image mode. Or, return to the original view from ROI view.
SPACEBAR	Switch the 2D workspace view and the 3D Viewer view.
D	Go to the ED frame.
S	Go to the ES frame.
T	Show/hide the informational text overlaid on scan images.
Z	Switch between Zoom Out 1:1 and Zoom Fill in Single Image mode.
F5	Switch to/from maximized screen (hide/show the window header and left panel).
Note:	You can press the following keys on either the main keyboard or the numeric keypad.
0	Show all thumbnails in Grid mode.
1	Show all thumbnails in a single-column layout in Grid mode.
2	Show all thumbnails in a two-column layout in Grid mode.
3	Show all thumbnails in a three-column layout in Grid mode.
4	Show all thumbnails in a four-column layout in Grid mode.

Report Screen

Key	Action
UP ARROW DOWN ARROW	Scroll the report up/down.
CTRL+L	Switch between the normal view and full-page view of a report.
CTRL+P	Open the Print dialog box.

System Administration

The VMS+, as with most computer systems, requires certain configuration and administration tasks in order to provide new and continued user access, and the ability to effectively troubleshoot issues as they arise. The facility administrator is the individual who has the responsibility for these tasks within the VMS+.

VMS+ enables facility administrators to perform the following:

- Account Management
- Setting up users, including:
    - Creating local user accounts and requesting service user accounts.
- Hardware and software configuration requirements of computers to run the VMS+ (other than the systems).
- Archiving studies from systems.
- Contacting Ventripoint Customer Support on behalf of one or more users
- Working with Review and Analysis System.

Account Management

This section discusses how to create and manage the two types of user accounts.

Local Login and Service Login Accounts

In VMS+, there are two primary login accounts. The local account is used to login to the VMS+. The service account is used to access reconstruction and study management services provided by the Ventripoint web service. The local account may be a VMS+ local machine account or in domain-integrated installations, a facility domain account. These two account types are managed differently and have different purposes.

Additionally, there are user and administrator types of local-machine login accounts.

A service login account will be displayed in the VMS+ application with the prefix *VMSNET*. That prefix will appear in the VMS+ application both as a login credential and in messages that warn of possible data conflicts between users who are working simultaneously on the same study.

Again, it is important that as a facility administrator you understand the distinction between a local-machine login account and a Ventripoint service login account as these two accounts must be managed separately.

In the remainder of this document, we will refer to the service login account as the *service account* and the local-machine login account (whether domain integrated or local to a VMS+ workstation) as the *local account*.

Create a User Account

Each user of the VMS+ will need an account setup appropriate to the scope of activities in which they have responsibility. Those involved in scanning activities will require both a local and a service account. Users involved solely in post-scanning activities, such as cardiologists who just read scans and select points, will only require a service account.

Creating a New Local User Account

If the VMS+ was joined to your facility domain during installation, facility users shall use their facility domain accounts to access the VMS+. In that case user management is owned and operated solely by the facility using the facility guidelines and procedures.

If the VMS+ was not joined into your facility domain, you should login to the VMS+ with the administrator credentials provided to you and use the standard Windows User Interface controls (such as Control Panel's User Management Console) to create local accounts for your facility users.

Creating a New Service User Account

You must contact Ventripoint Customer Support to request a new service (VMSNET) account. Ventripoint will create the account on your behalf with a temporary password and will redirect the user to a website to change their password according to the Ventripoint service password strength policy.

Before you request a new service user account, you will need the following information:

- The user's full name.
- A contact email address for the user.

Reset a User Password

The local account password *must* be set on each system itself or in domain-integrated scenarios using the facility password management procedures.

If VMS+ is not joined to the facility domain, you must login to VMS+ as an administrator and use Windows user management console to reset the corresponding user credentials.

Administrators are given their administrator user account and password by the installation engineer during the installation process.

Users may change their own local password by invoking the Windows account security panel using CTRL-ALT-DELETE and selecting **change password**.

To reset a Ventripoint service account password (in cases where the password has been forgotten), the user must contact Ventripoint support and request a new password. Ventripoint will issue a temporary password and direct the user to a website where they can change their password according to Ventripoint password strength policy.

Managing Archives

A system has a large but not unlimited hard-drive capacity. Because of this, it is possible to run out of space on the hard disk for studies. If a system begins to run out of space (as indicated within the VMS+ by a warning message), you will need to either delete existing studies or archive them to a network location.

This section discusses the manual archiving options available on the VMS-PLUS integrated stations. The archiving options enable studies to be moved from the integrated station in order to conserve disk space.

What is an Archive?

A VMS+ archive location is a disk directory which is located somewhere within the medical facility's local area network. Studies may be stored on this directory, and moved back to a system or Review and Analysis System as needed.

The archiving process differs from the exporting process. The exporting process copies study data to a memory stick. The archive process however, moves the data from the local (system) hard drive to the selected archive location.

Exporting a study in no way restricts any later archiving of that study.

Create an Archive

Creation of VMS+ archives is done by the Ventripoint installation technician with input from the medical facility information technology (IT) liaison.

Use the Archive

The following describes how to use the archive as an administrator.

It is important to first get an accurate list of the studies which are not being used by the integrated station users. Once this has been done, you can archive those studies.

Note: Exported studies coordinate their views of a given study via the Ventripoint Web service. Therefore, an exported study does not need to remain on the system hard drive for it to be used elsewhere.

Manual Archiving

The following describes how to archive studies without running the VMS+application.

The studies from a system running Windows 7 or Windows 10, are stored at the following location:

- *%Programdata%\Ventripoint\Studies*

Within this location, the studies are saved to a folder (a.k.a. the Study directory) according to their Station ID and their Study ID. Studies have a name of the form *SID_nnnn_mmmm* where *nnnn* is the numeric station ID and *mmmm* is the numeric Study ID.

Select all of the studies with Study IDs that match the list of studies to be archived, and simply move the files as you would any other disk files to a network location.

Manual Retrieving

To restore manually archived studies (as archived by the Manual Archive process), simply copy the desired studies to the VMS+'s hard disk at the following location:

- *%Programdata%\Ventripoint\Studies*

The VMS+ application will find the restored studies the next time it is run.

Managing PACS Connectivity

VMS+ can be configured to enable sending studies to and receiving studies from your facility PACS server. VMS+ users may send studies to the PACS server using the **Send to PACS** button on the Common Actions pane from the studies screen. During installation, if requested, the Ventripoint installation engineer will configure the VMS+ at your facility (as well as the Review and Analysis System installation package) to inter-operate with your facility PACS server.

The configuration information and connectivity test are available within the VMS+ software application. Please refer to the “Setting Options and User Preferences” chapter for how to view the VMS+ PACS configuration information and how to run the PACS connectivity test.

For details on how to send studies to the PACS server, see “Sending Studies to a PACS Server” section in the Managing Studies chapter.

VMS Configuration Manager

The VMS Configuration Manager can be used by system administrators to configure VMS+.

► VMS Configuration Manager

1. Login as System Administrator to the system where VMS+ is installed.
2. Ensure that VMS+ is not running.
3. Start VMS Configuration Manager from Start\All Programs\Ventripoint.
4. Your Ventripoint facility station ID and the VMS+ version is specified for informational purposes only.
5. To Configure VMS+ change the values per the following:

    a. PACS Configuration
    - **Send To PACS**: Enable or disable feature
    - **Server AE**: Specify server Application Entity
    - **Address**: Specify server address
    - **Server Port**: Specify server receiving port
    - **Client Port**: Specify VMS+ workstation receiving port
    - Click **Apply** to commit the values.
    - Click **Test** (after you committed the specified values)

    b. Archive Configuration
    - **Show Archive**: Enable or disable feature
    - **UNC Path**: The file share UNC path (i.e. \\server\share\path)
    - Use the **Browse** button to search for the UNC location.
    - Click **Apply** to commit the changes

    c. Data
    - **VMS Language**: Specify VMS operating language
    - **Use Metric**: Specify if the system should use Metric or Imperial units of measurement. If selected, Metric units will be used.
    - **ED trigger delay (ms)**: If users need to constantly adjust the ED offset, it is possible here to change the value so that the ED offset is delayed or advanced relative to the cine loop sequence. Consult with Ventripoint support before changing this value.
6. Click **Apply** to commit all your changes. If you click **Close** without Apply, your changes will not take effect.

Setting Up a VMS+ Review and Analysis System Computer

VMS+ enables collaboration on a patient study by allowing the full study data (images and selected points) to be exported to a removable flash drive media (USB thumb drive). The exported and original data are coordinated using the Ventripoint Web service.

The process of exporting a study involves exporting the VMS+ application as well. To run a study from exported media using another machine simply requires that the Review and Analysis System has the necessary hardware and software to run the VMS+ application. This section describes the hardware and software requirements to enable the VMS+ application to execute properly on a Review and Analysis System.

A Review and Analysis System may be installed in a review room or office on compatible Windows computers. The Ventripoint installation engineer will create a folder on the Ventripoint System's main hard-drive with the Review and Analysis System package specifically configured for your facility.

An administrator may use this package and install Review and Analysis System instances in the facility review room or office. Since the package is pre-configured by the Ventripoint installation engineer at setup time there are no configuration steps necessary.

Note, however, that any change to configuration settings that are dependent on interoperability with the facility such as PACS and archive location information requires coordination with Ventripoint support personnel. VMS+ Review and Analysis System computers enable collaboration on a patient study by allowing other machines to run a version of VMS+ that can access the study archive. Any study that has been sent to the archives can be accessed from a Review and Analysis System.

To install VMS+ Review and Analysis System the computer needs to have prerequisite software installed and meet minimum hardware requirements. This section describes the hardware and software requirements to enable the VMS+ Review Station application to be installed properly.

Review and Analysis System Hardware Requirements

- 2.0 GHz CPU
- 1 GB of available RAM (2 GB strongly recommended)
- 10 GB of available hard disk space
- Graphics adaptor supporting DirectX 9.0
- Display resolution of 1280x1024
- Mouse and keyboard entry

Review and Analysis System Software Requirements

- Microsoft Windows 7 or Windows 10
- Microsoft .NET 2.0
- Microsoft .NET 4.0
- Microsoft Runtime libraries: Visual Studio 2010
- Microsoft Runtime libraries: Visual Studio 2008
- Microsoft Runtime libraries: Visual Studio 2005
- DirectX 9.0c
- Adobe Acrobat Reader 8.0 or above

Note:	The exact link locations may change. Refer to the Web sites listed in the next section to download up-to-date package updates.

Where to Obtain the Software

Please visit Microsoft's downloads center for the following updates:

- Microsoft .NET 2.0
- Microsoft .NET 4.0
- All Microsoft Runtime Libraries
- DirectX 9.0c

Please visit Adobe downloads center for the following updates:

- Adobe Acrobat Reader

Installing VMS+ Review and Analysis System

To install the VMS+ Review and Analysis System, use the media given to your IT team during the initial install of the VMS+, labeled “VMS+ Review and Analysis System”. Insert the installation USB and using Windows Explorer, double click the file “install.cmd”. This program will set up the VMS+ Review and Analysis System and create shortcuts to the application.

Accessories

Replacements for the parts listed below are provided by Ventripoint Diagnostics Ltd. Please contact support@ventripoint.com to order or inquire about them. To install the VMS+ Review and Analysis System, use the media given to your IT team during the initial install of the system.

DESCRIPTION	PART NUMBER	PICTURE
LEAD WIRES (set of 3)	ENG-HW-671	
PATIENT ECG CABLE	ENG-HW-670	
ANALOG VIDEO CABLE	ENG-HW-382	
DIGITAL VIDEO CABLE	ENG-HW-442	
VGA VIDEO CABLE	ENG-HW-683	
ETHERNET CABLE	ENG-HW-387	
TRANSDUCER SLEEVE	Part Number varies. Contact Ventripoint for details.	
ECG OUTPUT CABLE	ENG-HW-667	
ECG OUTPUT CABLE	ENG-HW-666