Ventripoint Diagnostics Ltd.

Usability Study of the VMS 3.0

Whitepaper

Prepared by

Ventripoint Diagnostics Ltd.

Simple Change, but **Significant**

Ventripoint Diagnostics provides a time-effective and reliable alternative to cardiac MRI assessments, allowing a clinician to assess their patients with greater ease and autonomy.

Introduction

Borne out of a need for a more child-friendly approach to cardiac diagnostics, Ventripoint created a diagnostic tool that can measure cardiac metrics without the constrains of a cMRI. The typical constraints of a cMRI are due to the MRI scan requiring complete stillness from the patient, which most children have difficulty completing and therefore require sedation. The system was developed to be used as an alternative to cMRI scanners, decreasing the number of times a patient needs to undergo a cMRI scan. The VMS+ is the latest iteration of Ventripoint's KBR technology that recreates the shape of a patient's heart in 3D through captured 2D ultrasound images at specific angles and locations. Based on the 3D model, the volumes and ejection fractions of the heart are derived for all four chambers. The VMS+ allows the clinician to operate the diagnostic scanner themselves and retrieve the data in minutes.

The product was tested in a controlled environment with representative users and tasks designed to measure the ability (i.e., effectiveness, efficiency, and satisfaction) of the complete product. This provides a realistic setting to understand how sonographers will integrate the VMS+ into their workflow and identify any disturbances in workflow or in daily use. The goal is to validate that the representative users can interact with the given device in a safe, effective manner and that the device does not induce dangerous use errors.

How It Works

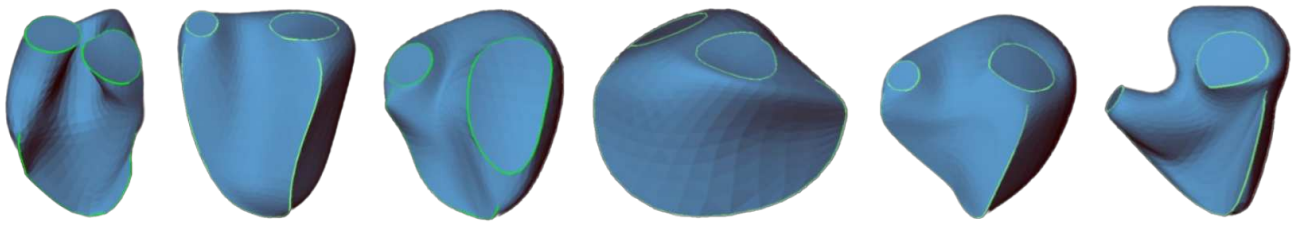
> "It is wonderful and I learned from the VMS+. Can see the 3D view on the 2D scan plane more clearly. Can visualize the heart and get ejection fractions easily."
>
> -Usability test participant #12

> "Makes you a better sonographer because you think about the landmarks when scanning."
>
> -Usability test participant #4

The VMS+ is intended to be used with any standard 2D ultrasound system and can be used for any disease or disorder for which volumes and ejection fractions are warranted or desired. The VMS+ records the probe position of the standard cardiac probe associated with any 2D ultrasound machine and tracks the ultrasound transducer's 3D spatial coordinates and orientation by utilizing a position sensor connected to the ultrasound transducer. There is a separate position sensor that tracks and corrects for any patient movement.

The VMS+ follows the typical workflow of a sonographer or cardiologist during the examination of a patient, and the subsequent analysis of the data collected during that examination. A typical workflow is expected to take approximately 15 mins for the patient with or without the addition of the VMS+ into the workflow.

Following acquisition, the user must place anatomical landmarks on the standard ultrasound views that are associated with a typical echo study. Once the specific landmarks are entered, the KBR calculates and derives the volumetric measurements and the shape of the chamber being analyzed. The VMS+ creates a complete 3D model of the heart using position and orientation data acquired during an echo study and the 2D ultrasound images by using a database of MRI images as reference. These are used to calculate the end-diastolic and end-systolic volumes (EDV, ESV), ejection fractions (EF), stroke volumes, and cardiac outputs.



Rastell Repair | **Pulmonary Hypertension** | **Ebstein's Anomaly** | **Double Oultlet Right Ventricle** | **Tetralogy of Fallot** | **RV to PA Conduit**

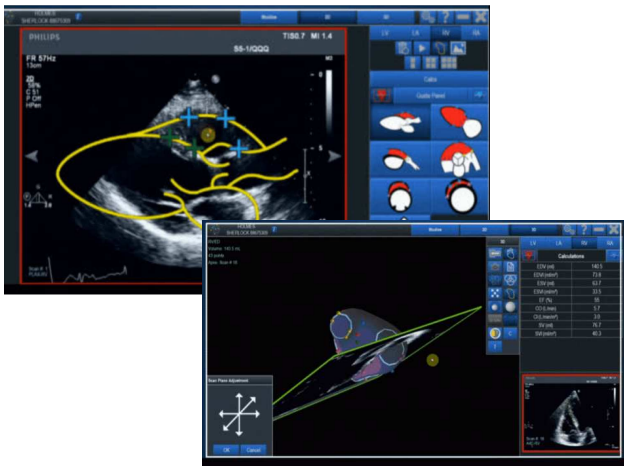
3D representation of different cardiac conditions using VMS+

VMS+ Features

Working with our clinicians, we were able to improve the design of this new model of VMS+ and implement essential features for user adoption based on intuitive usability and efficiency. Our goal with this latest model of the VMS+ was to make the design simple but significant:

(1) reduce the number of clicks to get a result
(2) minimize data entry by user to get started
(3) provide an easy and intuitive workflow from start to finish-no recall needed.

The changes to the VMS+ 3.0 include the following:



User Interface (UI) to support a simple and logical acquisition workflow

Sensor placement screens are displayed to guide the user in proper placement of the transducer sensor and patient sensor.

Guide as to the different views that need to be collected are displayed to the user during acquisition.

User Interface (UI) to support a simple and logical analysis workflow

A point placement guide was added that shows the proper placement of the anatomical landmarks needed by KBR to generate a 3D model from which are derived the cardiac metrics.

Minimal data entry and auto-population

Patient information is auto-populated from the ultrasound machine.

Integrated into their echo workflow

Clinician does not need to adapt or adjust their workflow to implement the VMS+. The VMS+ is designed to be integrated into their workflow. It sits off to the side and does not separate the clinician from the ultrasound machine and patient.

User can customize workflow

Clinicians can use different workflows in the acquisition of the study-either label each view as they acquire or collect the entire study and label on the workstation.

The added features work together to allow the user to produce the most accurate images possible and reduce the incidences of user-error. The added features were brought about by the invaluable insights of our existing customers and key opinion leaders.

The Study

> "Superior add-on to the ultrasound imaging procedure which is lacking to what have on market to get RV volume."
>
> -Usability test participant #4

> "Need in hospital to get accurate volumes in different pathologies."
>
> -Usability test participant #3

The participants for the study were recruited and were selected to represent the typical user for the VMS+, including experience with cardiac ultrasound.

The participants in the study received training prior to the usability test that was representative of the type of training new users of the VMS+ would receive.

Due to the retention of training decays over time, the usability study did not occur immediately following training. A break of at least one (1) day elapsed between the training and the usability testing to provide participants with an opportunity for training decay to occur.

In the study, the participants were asked to complete a set of task scenarios in the most efficient and time effective manner. The participants of the test received instructions of their task and were expected to complete the tasks correctly. The tasks were as follows:

- Login
- Entering patient information
- Sensor setup
- Pairing
- Image Acquisition/Scanning
- Placing Anatomic Structure Points
- 3D Visualizations and Calculations
- Quality Control of Results

Testing & Assessment

As part of the usability testing, data by:

1. Participant Observation: Participants were observed interacting with the device for successful completion of or outcome from critical tasks.

2. Debriefing Interview: After completion of all tasks, participants were interviewed to obtain their perspectives and qualitative feedback on device use, particularly related to any use problems that occurred, such as obvious use error. The observation data collection included any instances of observed hesitation or apparent confusion and were paused to discuss problems when they arose.

3. Questionnaire: Ease of use ratings were collected through debriefing interviews with the participants and by completion of a questionnaire in which participants were asked to rate various aspects of the system on a 5-point Likert scale, according to performance to measure their agreeance with statements about their experience using the device. The participants were also interviewed on perceived level of difficulty while performing the tasks, how they would assess any use difficulties or problems, and how comfortable they were with operating the VMS+.

The written answers in the participants' own words and the usability ratings provide excellent feedback about the VMS+ system.

We asked participants to rate their experience on a Lickert scale of 1 to 5 for various criteria.

After participants had completed the tasks, we administered a questionnaire about the usability of the device.

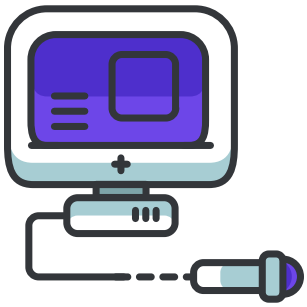
We collected metrics on the successful completion of each task and compared overall task success rates.

Participants & Test Environment

13 Sonographers

Participants

The participants in the study were comprised of 13 healthcare professionals who have appropriate training in cardiovascular technology, diagnostic medical sonography, echocardiography, and a specialty in cardiology. These users had prerequisite experience performing echocardiograms, ultrasound imaging in order to evaluate chamber size, valve function, and blood flow. While they have extensive experience with cardiac ultrasound, none of the participants had experience with the VMS+ 3.0. The study participants were selected to represent the typical user for the VMS+.



Dim lighting
Hospital bed
Ultrasound machine

Test Environment and Conditions of Use

The simulated use testing was conducted in a simulated echo environment that was representative of the actual use environment and condition of use so that the results of testing can be generalized to actual use. During testing, participants were studied in how they performed actual tasks. Data was collected from test participants using the device in realistic use scenarios while under simulated conditions of use. The device was used with a mannequin and simulated ultrasound imaging for all required views. Test environment included a small room with dim lighting, hospital bed, and an ultrasound machine.

Training

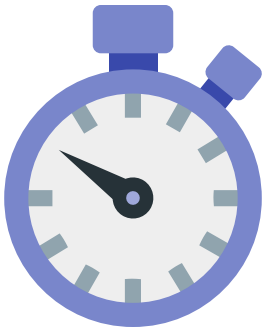
The participants in the study received approximately three hours of training prior to the usability test. The training was representative of the type of training new users of the VMS+ would receive, including in-class training and hands on training that focuses on acquisition of images, analysis, and workflow.
The hands-on training encourages the use of the user manual, training images, and heat trainer model. As part of the training, a demonstration with a test subject with normal heart anatomy was used for training purposes. These images were used as part of the training tools for participants on analysis using the VMS+, including point placement, 3D visualization, and calculations. The image acquisition included capturing the correct views, important characteristics, image quality, tracking system, and suggested workflow.

In-class and hands-on training

The analysis portion focused on correct point placement, storing studies, and report generation.

A general list of the tasks that users were given training on included:

- system setup
- preparation of patient
- starting a new study
- acquisition of views
- image capture
- ED/ES frame selection
- point placement protocols
- 3D visualization and calculations
- management of studies.



3 hours training

These tasks were part of the assessment that the user underwent after training was completed.

Evaluative Metrics

The evaluation portion of the user study focused on multiple aspects. Find them here:

Observation of actual task performance with the successful completion of the critical task given.
The task will be scored as a critical error if the participant requires extended guidance.

Percentage of successful tasks completed
If the user can complete the entire workflow without being hindered by an incomplete component, then the task is scored as successfully completed.

Completion rate of critical tasks
Percentage of test participant who complete the task without critical errors. A critical error is an error resulting in incorrect or incomplete outcome.

Error-free rate
Percentage of test participants who complete the task without any errors, either critical or non-critical.

Scenario completion time
The time to complete a single session should be within 15 minutes.

Number of significant use/critical errors made and use problems
Deviations at completion from the targets of the scenario. Seen as unresolved errors that occur at some point throughout the process and produce an incorrect outcome.

Observation of Non-critical errors
Errors that can be recovered by the participant and do not obstruct the completion of the task. Non-critical tasks can sometimes be undetected by the participant but are generally identifiable by frustration from the participant.

Dialog scripts
Adherence to dialog scripts.

Intervention required
The number of times a participant requires intervention within the function or workflow

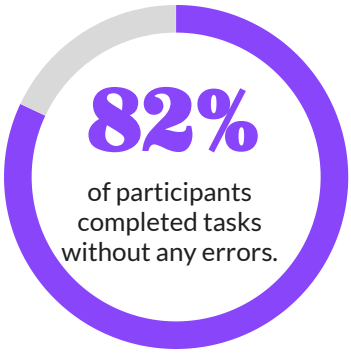
Unable to proceed
The number of times a user is unable to proceed with smooth workflow

Analysis & Results

98%

of participants

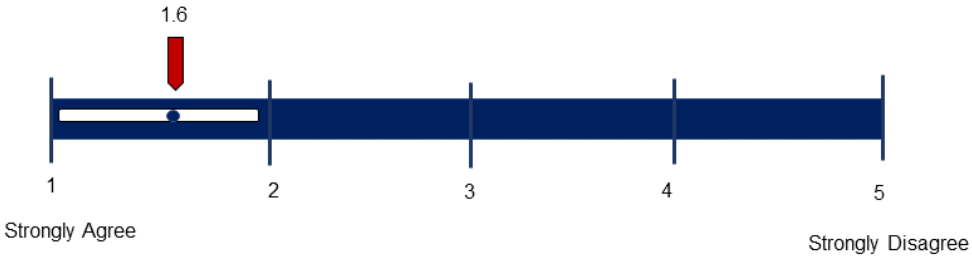
completed all tasks with no critical errors.



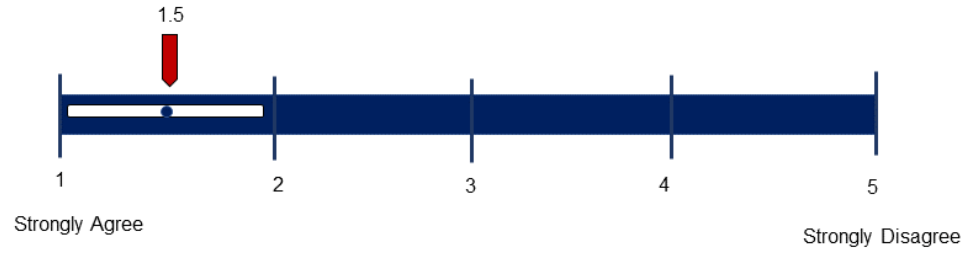
The results were divided into 11 sections that recorded the number of critical errors, measured completion rate, and error-free rate. Completion rate is defined as the percentage of test participants who successfully complete the task without critical errors. A critical error is defined as an error that results in an incorrect or incomplete outcome. If the participants required assistance from the test administrator in order to achieve a correct output, the task was scored as a critical error/performance failure and overall completion rate was affected. As mentioned, error-free rate is the percentage of test participants who complete the task without any errors, both critical or non-critical.

The average completion rate was 97.8% for the entire process and the average error-free rate was 81.7%. The results from the user study were not only measured success rate metrics, but user feedback given in the user's own words as well as post-task ease-of-use ratings. The VMS+ scored extremely high for ease-of-use and confidence in using the system after only one training session.

Average Ease of Use Rating



Average Confidence of Use Rating



All 13 users had positive qualitative feedback about the VMS+ and provided different perspectives for its use and benefits. What was commonly agreed on was that being able to measure ejection fraction and right ventricle volume is a significant feature. This was noted by a user as being "critical" for patient measurement, especially in hospital settings where there is a greater risk of error when volume is measured manually. A common response to the series of questions was that the VMS+ would be successfully implemented into the user's own clinical environment.

Conclusion

> “Exceeded expectations based on knowledge of previous model. Sleakness, design, and usability. Other model was overwhelming to use. Portable to bedside.”
>
> -Usability test participant #13

The conclusion from the human factors/usability study was that the VMS+ is safe and effective for the intended users and the clinical environment. Overall, users had a positive response to using the VMS+ and described the technology as being intuitive and easy to use. It is important to note that the high task completion scores were taken after one series of training, without assistance from Ventripoint associates. In a real life setting, the VMS+ customer or user would have multiple training sessions. This demonstrates how the VMS+ does not require extensive training in order to be a functional part of the diagnostic process. The usability study results confirmed the value of having an alternative diagnostic tool comparative to cMRI that can be easily learned and integrated into a typical echo workflow.

The VMS+’s unique ability to view the 3D image on a 2D scan plane provides greater insight to the sonographer. Through this study, Ventripoint was able to identify design recommendations that can be implemented in future releases for optimized usability, as well as verify that there is a need for the VMS+ to improve patient care.

Learn more about the VMS+ 3.0: **www.ventripoint.com**

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