Use of AI to Aid 2D Echo Interpretation: A comparison of VMS+™ 4.0 and VMS+™ 3.0.

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Whitepaper prepared by

Ventripoint Diagnostics Ltd.

Executive Summary

Ventripoint Diagnostics Ltd.'s latest product, VMS+™ 4.0, introduces AI-assisted point placement to improve the user experience through simplifying the image analysis process. In the previous release, VMS+™ 3.0, the user was required to place and manipulate a guide template to place points on anatomical landmarks of each 2D echo image. Once placed in the approximate location, the user would further refine their position. With VMS+™ 4.0, the application automatically places anatomical points onto each 2D echo image during the processing phase. The user is then prompted to review and move these points to their final position if necessary.

In addition to simplifying the image processing phase, this study demonstrates that VMS+™ 4.0 AI-assisted point placement can also improve the accuracy of the final position of the anatomical points, that is, after review by the user.

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Introduction

Ventripoint Diagnostics Ltd. (Ventripoint) has developed Ventripoint Medical System Plus 4.0 (VMS+™ 4.0), intended to record, analyse, store and retrieve digital ultrasound images for computerized 3D image processing.

The VMS+™ is a groundbreaking advancement in cardiac imaging that transforms 2D echocardiograms (2D echo) into 3D heart models which calculate cardiac volumes and ejection fractions during the systolic and diastolic phases of the cardiac cycle. VMS+™ is a diagnostic aid that provides a point of care solution to better communicate the heart's structure and function without the need for cardiac magnetic resonance imaging (cMR).

VMS+™ is intended for operation by healthcare professionals trained in cardiac sonography and/or echocardiography, and requires users to select frames in the echo video representing the heart in end-systole (ES) and end-diastole (ED), and place points on specific anatomical structures in the image.

The central VMS+™ technology, Knowledge Based Reconstruction (KBR), is used to generate 3D cardiac models from 2D echo. KBR is proprietary algorithm created from Ventripoint's catalogue of thousands of cMR. This catalogues uniquely includes the anatomy from a range of congenital heart conditions as well as standard pathologies. Using the principle of sparse data, KBR can recreate a right ventricle chamber from just 37 anatomical structures identified across seven 2D echo images. Using this multi-point approach reduces the reliance on the positional accuracy of a single point placed by the user.

In VMS+™ 3.0, the previous version, the user processes images by manually dragging, rotating, and resizing a template onto the image to obtain an initial point placement, and then adjust individual point locations. This process can be lengthy, requiring up to 20 minutes per patient. In VMS+™ 4.0, software is introduced to automate the initial point placement. The user is still required to review and adjust each point location, if necessary, but the time required for processing is reduced.

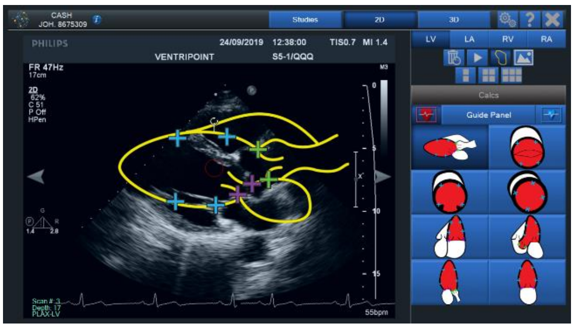

Image 1: Screen-shot from VMS+™ 3.0 showing the use of a template to label structural features. The template is sized and rotated manually before points are placed.

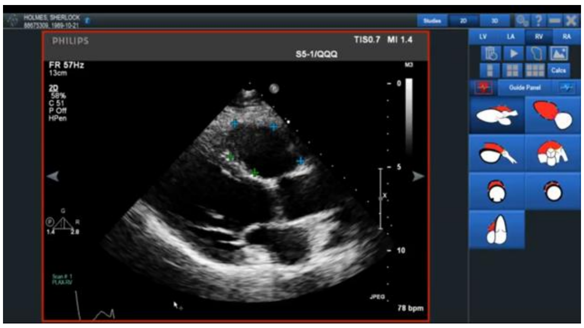

Image 2: Screen-shot from VMS+™ 4.0 showing the position of features as identified using AI-assist. Note that the user is required to review and confirm final location of points.

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This study aims to determine whether the application of AI-assisted initial point placement deployed within VMS+™ 4.0 increases the level of agreement between the final position of the anatomical points (after user adjustment) and their ideal position.

In this study, representative users of VMS+™ performed anatomical point placement on de-identified 2D echo images of the heart using VMS+™ 4.0 and VMS+™ 3.0. The statistical analysis compares the proportion of anatomical points which agree with the expert-defined valid positions, as determined by expert reference segmentation, when using VMS+™ 3.0 against VMS+™ 4.0.

Problem Statement

Does VMS+™ 4.0 AI-assisted point placement lead to better final anatomical point positional agreement with expert-defined Regions of Interest (RoI)?

The Null Hypothesis states that there is no significant difference in the agreement of the final position of anatomical points placed and the expert-defined RoI, between users of VMS+™ 3.0 and VMS+™ 4.0.

Study Design

This was a retrospective study using images from 20 de-identified patients, 10 adult and 10 paediatric, undergoing clinical ultrasound imaging procedures with a cardiologist. For each patient, 4 heart views, each with a diastole and systole image, were randomly selected: in total, the dataset included 160 images.

2 representative users (experienced sonographers, employees of Ventripoint) of the VMS+™ device processed images using VMS+™ 3.0 and VMS+™ 4.0. Images were randomly distributed among the two users, so each user processed half the images with one version of VMS+™, and then other half of the images with the alternative version. One user processed images using VMS+™ 3.0 first while the other user processed images using VMS+™ 4.0 first.

A Reference Standard segmentation for each point on each image was generated by a sonographer and at least two expert cardiologists, with a third cardiologist available for adjudication. The cardiologists used in this study act as advisors to Ventripoint.

A code script was used to compare each processed image with the Reference Standard segmentation to determine whether all final anatomical point localizations on each image were within their respective segmented region (i.e., processed image is accurate).

Reference Standard Generation

A sonographer experienced with anatomical landmarks in the heart segmented valid regions for all anatomical points on each image using Label Studio software. This was done by placing points around the Region of Interest to generate a polygon.

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The images were distributed equally between two expert cardiologists for primary review. Reviewers agreed or disagreed with the initial segmentation. If the primary reviewer disagreed with the initial segmentation, they would edit the segmentation.

Reviewed images were then provided to the second cardiologist for secondary affirmation. The reviewers were blinded to whether they were the primary or secondary reviewer. The secondary reviewer then agreed or disagreed with the reviewed segmentations. If the secondary reviewer agrees with the segmentation, it would be used as the Reference Standard for the image. If the secondary reviewer disagrees with the segmentation, they would edit the file. If the change was minimal (defined as only one or two points on the polygon are shifted), the edited image was used as the Reference Standard. If the change is not minimal, segmentations by the primary and secondary reviewer would be provided to a third expert cardiologist, who would generate a final segmentation to be used as the Reference Standard.

All sonographers and cardiologists involved in the generation of the Reference Standard were blinded to processed images.

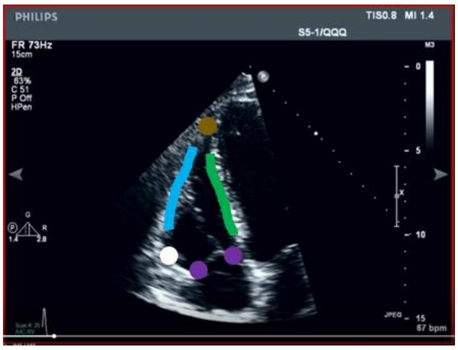

Image 3: An illustration of the Reference Standard showing the mark-up of anatomical landmarks on an 2D echo image. These areas indicate acceptable Regions of Interest for specific VMS+™ point types.

Image Processing

All images were randomly distributed between two representative users of the VMS+™ software. User one processed the 2D echo images that were distributed to them using VMS+™ 3.0, and images that were distributed to the other user using VMS+™ 4.0. One user completed image processing with VMS+™ 3.0 first, while the other user processed images using VMS+™ 4.0 first.

The users processing images were blinded to the reference standard segmentations.

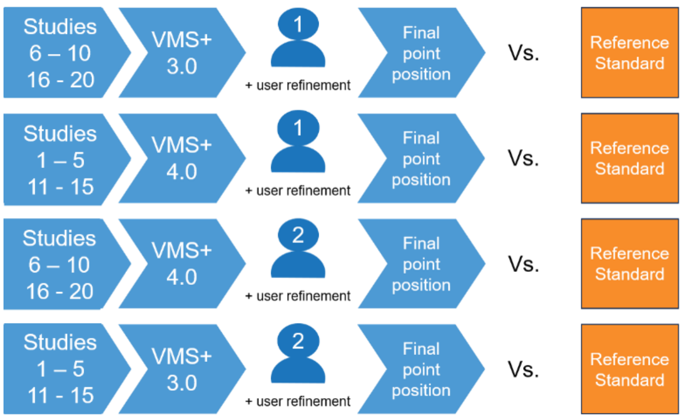

Diagram 1: the study process outlining how each set of study images were analysed using VMS+™ 3.0 and VMS+™ 4.0, in addition to user refinement, before comparison to the Reference Standard for each image.

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Validity of Anatomical Point Localisation

A code script (Python) was used to compare each processed image with the Reference Standard segmentation to determine whether all final anatomical point localizations on each image are within their respective segmented region (i.e., processed image is accurate).

Primary Endpoint

The primary endpoint was the proportion of points from a single 2D echo image placed by the user where their final position agreed with the Reference Standard.

Statistical Analysis

The primary analysis was performed using a t-Test; two-sample assuming unequal variances.

The null hypothesis stated that there was no difference between the number of anatomical points agreeing with the Reference Standard regardless of whether the user used VMS+™ 3.0 or VMS+™ 4.0.

Study demographics

The study was conducted using images from 20 de-identified patients, 10 adult and 10 paediatric, who underwent clinical ultrasound procedures of the right ventricle by cardiologists. 8 images from 4 heart views, 1 in systole and 1 in diastole for each heart view, were obtained from each patient. The dataset included a total of 160 images, with 80 images in diastole and 80 images in systole.

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Results

Primary Analysis

Based on the primary analysis, the t-Test rejected the Null Hypothesis indicating that there was a significant difference between the agreement levels between VMS+™ 3.0 and VMS+™ 4.0, $t(317) = -2.1213$, $p = 0.035$.

Version	Observations	Mean	Variance
VMS+™ 3.0	160	0.756	0.036
VMS+™ 4.0	160	0.800	0.033

Additional analysis

The user agreement with the Reference Standard when using VMS+™ 4.0 was superior to VMS+™ 3.0, with over 60% of points in agreement in 85% of cases.

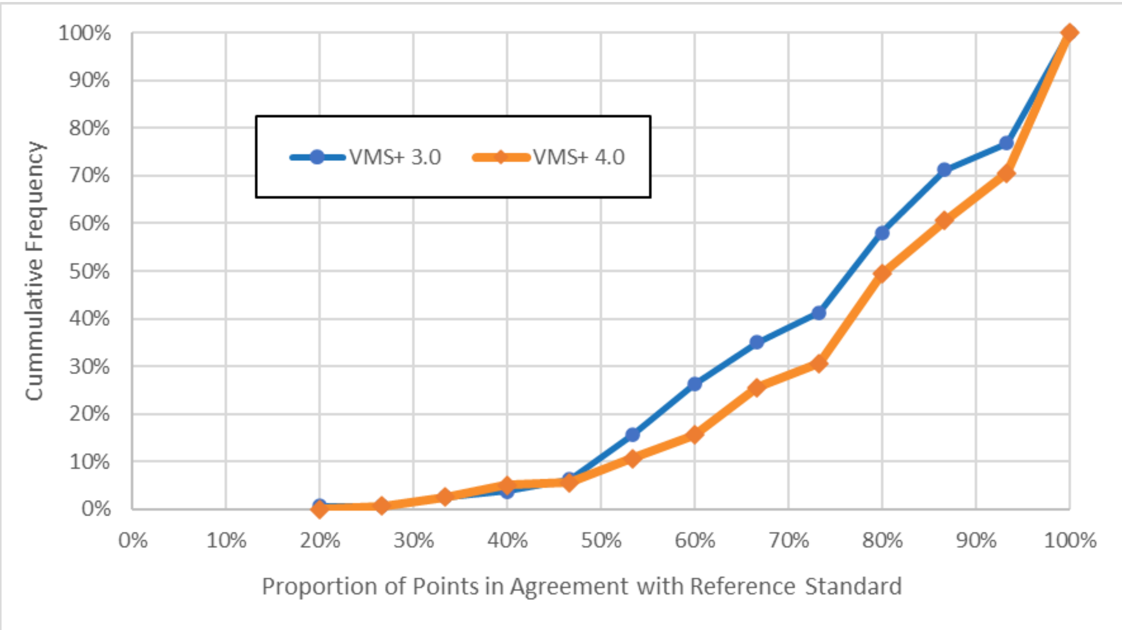

Chart 1: The cumulative frequency of the proportion of points in agreement with the Reference Standard comparing VMS+™ 3.0 and VMS+™ 4.0

Bootstrapping

The agreement scores for VMS+™ 3.0 and VMS+™ 4.0 were processed using a linear bootstrapping resampling method with 2,500 resamples.

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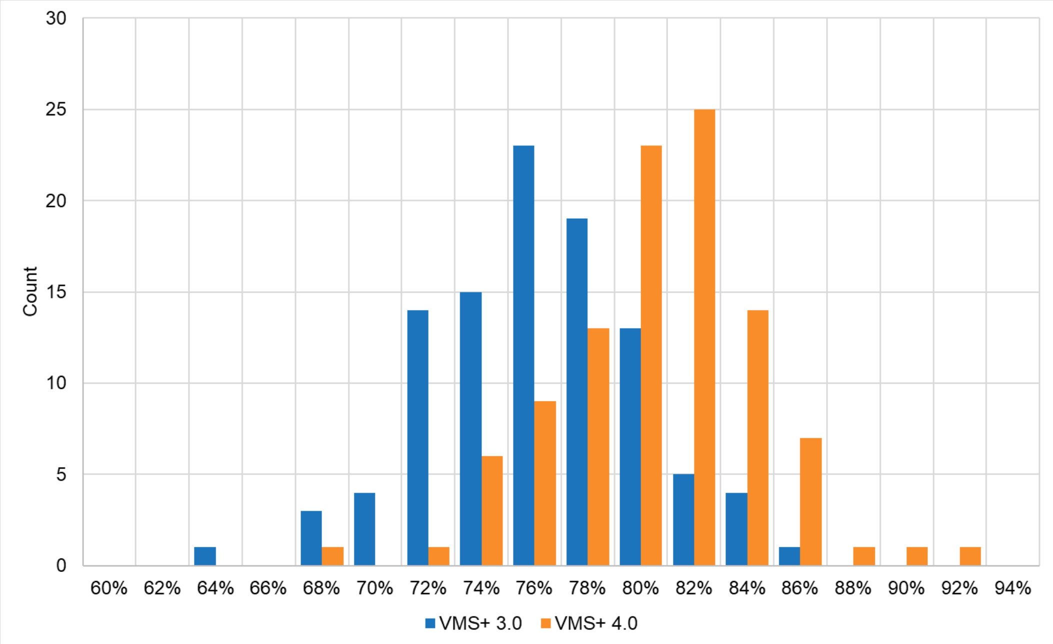

Chart 2: The distribution of agreement scores comparing VMS+™ 3.0 and VMS+™ 4.0 using linear bootstrapping resampling.

			95% Confidence Interval	
Version	**Resamples**	**Mean**	**Lower**	**Higher**
VMS+™ 3.0	2500	0.756	0.675	0.820
VMS+™ 4.0	2500	0.800	0.745	0.871

Discussion and Overall Conclusions

In this study, users who used VMS+™ 4.0 to initially position anatomical points demonstrated a higher level of agreement of their final point position to the Reference Standard when compared to VMS+™ 3.0.

VMS+™ uses its KBR to generate cardiac MR-accurate volumetric measurements from 2D echo images. For a single right ventricle reconstruction, VMS+™ uses 37 anatomical points across seven different echo views on both the ED and ES frames. This multi-point approach reduces the reliance on the accuracy of a single point. However, a sufficient number of points must be placed within the correct region of interest for an accurate result to be calculated.

The AI model used in VMS+™ 4.0 was trained on hundreds of 2D echo images across the full range of views used within the application. To improve the positional accuracy, the model was also trained on intermediate frames, that is, 2D echo images between the extremes of the ED and ES frames. The development team found that this approach significantly boosted the accuracy of the model overall through improved recognition of relevant features, whilst discarding irrelevant structures and noise.

Accurately interpreting a 2D echocardiogram requires a high-level of skill and experience. 2D echocardiograms are dynamic in nature, and image quality is highly

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dependent in operator skill and patient anatomy. When processing a 2D echocardiogram, experienced sonographers and cardiologists base their analysis both on the features that they see within the frame, the position of that feature in previous and subsequent frames (as anatomical landmarks move dynamically through the cardiac cycle), and their own experience and knowledge of cardiac structures.

In this way, the development team hypothesises that the AI-model may be able to recognise engrained cardiac features. Highlighting these anatomical features, via the initial placement of points, may assist the user in determining a more accurate final position to place their points.

This study demonstrates that the application of AI-assisted point placement in VMS+™ 4.0 enabled users to significantly increases the number of points placed in the region of interest as defined by the Reference Standard versus users of VMS+™ 3.0.

Limitations

The methodology used did not explore the impact of 2D echo image quality, ultrasound probe type and a full range of patient pathologies had on the agreement score.

Moreover, this study did not assess the agreement score between the initial position of the points placed using VMS+™ 4.0 (before user refinement) and the Reference Standard.

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