

RVLV Software

Instructions for Use AU

Software Version 3.1.2 and onwards

RV/LV Instructions for Use AU

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1 Introduction

1.1 Scope of Manual

This user manual was written for the 4DMedical CT RV/LV Software.
Guidance for using the 4DMedical Protected Platform (4DM-PP) is not included in this document. The 4DM-PP includes a cloud platform which is a subscription-based, scalable software-as-a-service product which allows customers to run computationally-intensive image algorithms in the cloud, on infrastructure maintained by 4DMedical. The 4DM-PP is also available as an on-premise hosted product, targeted at those organizations which desire to keep their image data in-house. This enterprise version of 4DM-PP provides a system by which customers can still benefit from image processing job automation, while integrating with native DICOM tools and workflows. The 4DM-PP with cloud and enterprise options is a separate product developed by 4DMedical.

1.2 Product Overview

4DMedical's CT RV/LV Software identifies the maximal ventricular diameters of the heart and calculates the ratio of right ventricular diameter to left ventricular diameter. This is calculation is produced as a result of four steps: 1) ventricle detection, 2) ventricle segmentation, 3) interventricular septum detection, 4) caliper positioning and measurement.

The 4DMedical CT RV/LV Software utilizes non-gated, contrast-enhanced CT pulmonary angiogram images in DICOM format as input to the software.

The DICOM outputs provided by the RV/LV Software are a RGB image series (Secondary Capture Image Storage SOP Class) and a summary report (Encapsulated PDF Storage SOP Class and/or Secondary Capture Image Storage SOP Class).

2 Symbols

The meaning of the symbols shown on the labeling and/or instructions for use are as follows:


Consult Electronic Instructions for Use


Manufacturer


Date of Manufacture (YYYY-MM-DD)



Medical Device



Unique Device Identifier



Batch Code (Device Version)

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3 Indications for Use and Requirements

The RV/LV Software device is designed to measure the maximal diameters of the right and left ventricles of the heart from a volumetric CTPA acquisition and report the ratio of those measurements. RV/LV analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the ventricles. The RV/LV software provides the user with annotated images showing ventricular measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CTPA cases.

The intended use of this software application provides a calculation of the ratio of right ventricular diameter to left ventricular diameter from contrast enhanced CT images of the chest acquired using a standard CT pulmonary angiogram acquisition.

3.1 Intended Users

This application is intended for use by Thoracic Radiologists, General Radiologists, Pulmonologists, Cardiologists, imaging technologists under the supervision of a physician, or researchers to aid in their assessment of right ventricular enlargement.

3.2 Cautions, Warnings, and Contraindications

There are no known contraindications. Known limitations and precautions related to image quality, anatomy, and artefacts are described in Sections 6 and 7.

3.3 Clinical Performance Validation

The RV/LV Software Clinical Performance Validation has shown that the tool is accurate in measuring the ratio of right ventricular diameter to left ventricular diameter when compared with expert radiologists. RV/LV Software was found to have a bias of 0.01 when RV/LV ratios were compared to ratios calculated by expert radiologists and the zero-line of equality was within the 95% confidence interval of the mean difference. Secondly, 97% of ratios were within the limits of agreement between RV/LV software and three expert radiologists.

3.4 Clinical Benefit

The RV/LV Software provides measurements of the right and left ventricle and the ratio of those measurements. The RV/LV ratio is a well-accepted biomarker of acute pulmonary embolism severity [1] and pulmonary artery pressure [2] .

3.5 Scan Protocol Requirements

The ability to segment a scan is dependent on the resolution; therefore, it is important to analyze the scan resolution. The resolution can be determined by assessing the acquisition protocols from the DICOM data as well as visually assessing the images themselves. Additionally, adequate contrast between the ventricular cavity and the surrounding myocardium is a prerequisite for optimal ventricular segmentation. For optimal performance, the LV attenuation should be > 100 HU. The scan should also be visually assessed to ensure that there are no artifacts or missing information.

3.5.1 Acquisition Parameters

The RV/LV Software will not generate outputs for scans with acquisition parameters that do not meet the requirements as outlined in the table below. In addition, RV/LV Software will not generate outputs unless DICOM Patient Image Orientation (DICOM tag 0020,0037) can be rounded to [+1,0,0,0,+1,0].

DICOM Tag	Name	Required Value
(0018,0050)	Slice Thickness	≤ 4.0 mm
(0008,0060)	Modality	CT
(0028,0030)	Pixel Spacing	≤ 2.0 x 2.0 mm²

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3.5.2 Recommended Protocol

For the RV/LV Software, 4DMedical recommends a contrast enhanced 3D volumetric acquisition with pixel spacing less than 2 mm and slice thickness less than 4 mm for the input scan. Example protocols are listed in the table below. Failure to observe the recommended scan protocol could limit the software's ability to properly segment the left and right ventricles.

Additionaly, adequate contrast between the ventricular cavity and the surrounding myocardium is a prerequisite for optimal ventricular segmention. For optimal performance, the LV attenuation should be > 100 HU.

Acquisition Parameters	
Scan Type	AXIAL
kVp	80-120
mA	200
Contrast Volume (mL)	75-100
Contrast Concentration (mg/mL)	370
Contrast Injection Rate (mL/s)	3
Threshold Attenuation (HU)	80
Reconstruction Parameters	
Kernel	Standard, non-edge enhancing
Thickness (mm)	1.0

3.6 Hardware Requirements

Hardware requirements for running RV/LV are as follows:

- 4 CPU Cores
- 8 GB Ram
- 50 GB Storage

3.7 Product Lifecycle

The software is supported and maintained throughout its active lifecycle. Users will be notified in advance of end-of-support or end-of-life milestones. Use beyond end-of-support is not recommended as performance and cybersecurity cannot be assured.

4 Quality Assessment

The scan quality and possible artifacts must be assessed before utilizing the results produced by the RV/LV Software.This software is designed to run on any input data that satisfies the criteria in Section 3.5.1 and it does not perform any additional quality checking. **It is the responsibility of the medical professional who is using the application (i.e., the Thoracic Radiologist or General Radiologist) to ensure that the input data is of adequate quality.** If the input data is not of adequate quality, the application's results should be disregarded. 4DMedical's CT RV/LV Software is not intended for use as a primary tool for disease detection and/or diagnosis.

Areas of the image where comorbidities or anomalous pathologies are present may give unpredictable results, and the RV/LV results should be interpreted with a knowledge of the location and extent of any comorbidities or anomalous pathologies.

RV/LV was designed and validated on adult hearts and has not been validated on children.

The software is not intended to be used as a stand-alone diagnostic tool and must be used in conjunction with clinical assessment and other imaging findings.

4.1 Algorithm Malfunction or Performance Changes

In the case of an algorithm malfunction or performance change of RV/LV Software, submit an email with details to support@4DMedical.com.

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5 RV/LV Software

5.1 Input

The RV/LV Software requires one DICOM format contrast-enhanced CT pulmonary angiogram acquisition as input.

5.2 Outputs

When run with appropirate input data, the RV/LV Software generates two outputs; the RV/LV Annotated Image Series and the RV/LV Summary Report. More information about these outputs is given below. In the event that the provided data fails the input check process, and Input Check Failure Report will be generated.

5.2.1 RV/LV Annotated Image Series

The RV/LV Annotated Image Series is a Secondary Capture DICOM Image with voxel data that is the input image series with an RGB overlay. The detected interventricular septum in each slice is represented as a green line. There are two solid red lines in each Annotated Image Series. These solid red lines represent the largest ventricular diameter detected by the algorithm. The ventricular diameters in all other slices are marked with dashed lines, either blue or red. The dashed red lines simply indicate that that slice is within 10 slices of the global maximum ventricular diameter. They should be used to assist the user in finding the slice that contains the maximum ventricle measurement.
Figure 1 contains example slices from the RV/LV Annotated Image Series.

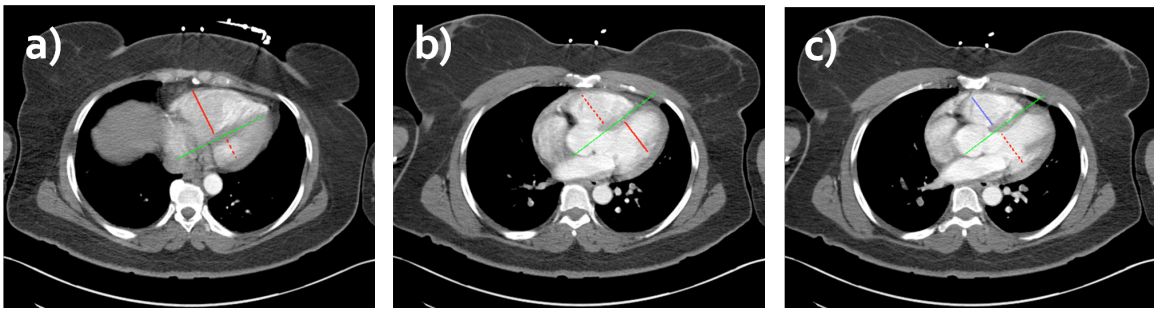


Figure 1: (a) Axial slice of RV/LV Annotated Image Series displaying the largest ventricular diameter of the right ventricle and the detected interventricular septum. (b) Axial slice of RV/LV Annotated Image Series displaying the largest ventricular diameter of the right ventricle and the detected interventricular septum. (c) Axial slice of RV/LV Annotated Image Series slice that does not contain the largest ventricular diameter of the left or right ventricle.

5.2.2 RV/LV Summary Report

The RV/LV Summary Report is a DICOM compatible format file containing results from the RV/LV Software. The SOP Class of the report is either Secondary Capture or Encapsulated PDF Storage. The report summarizes the results of the RV/LV Analysis. It contains patient information, images showing the slices with the maximum ventricular diameters, the RV/LV Ratio, and the individual ventricular measurements if available. An example report is shown below in Figure 2. Note the maximum diameters of the right and left ventricle are determined independently and may occur on different slices.

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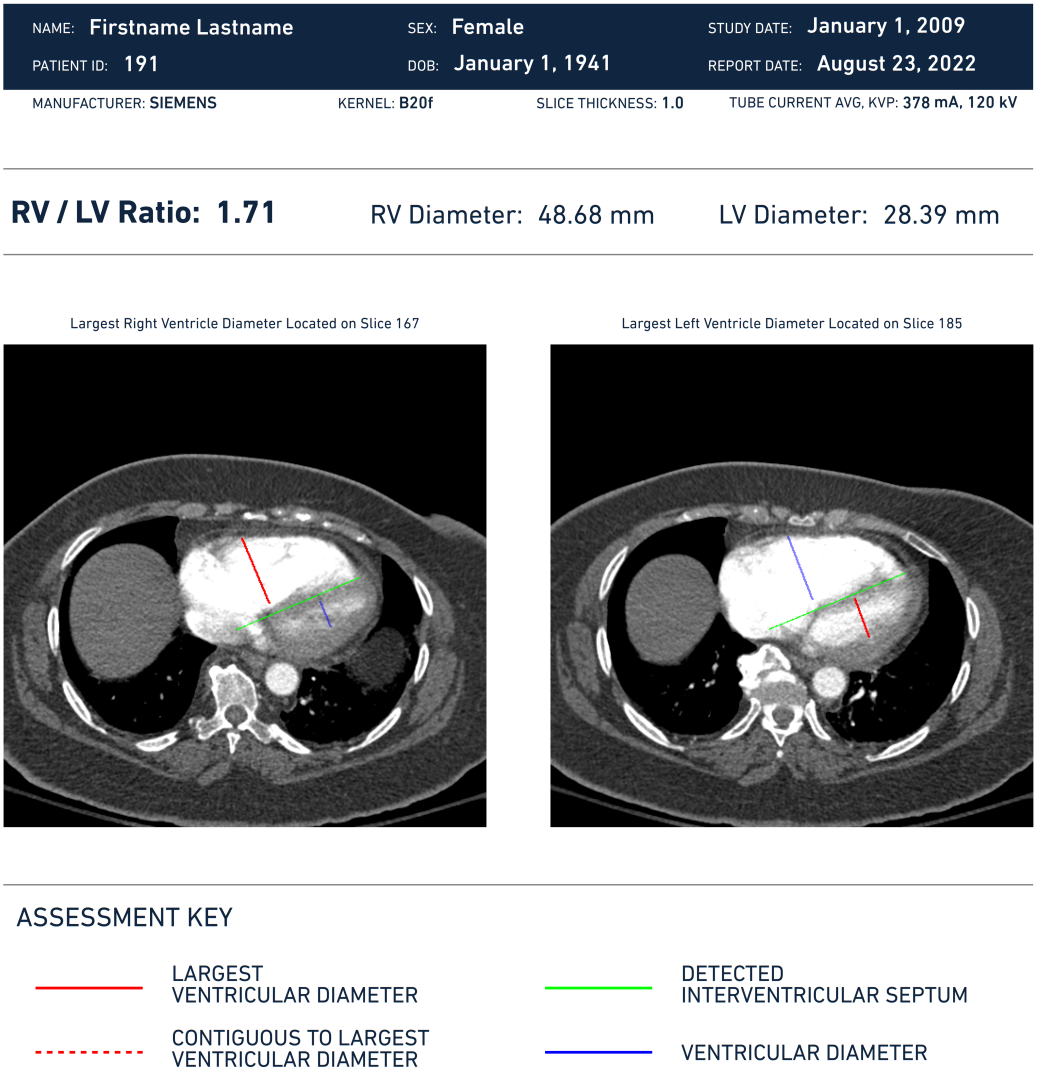


Figure 2: Example RV/LV Summary Report

5.2.3 Input Check Failure Report

The RV/LV Input Check Failure Report is a DICOM compatible format file containing results of the Input Check process. The SOP Class of the report is either Secondar Capture or Encapsulated PDF Storage. The Input Check Failure Report is also available as a PDF file. The report contains patient information, and summarizes whether each input requirement was met. An example report is shown below in Figure 3. In this example, the slice thickness was outside of the specifications.

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ACCESSION NUMBER: 0c4ece44f6b96a	MANUFACTURER: SIEMENS	KERNEL: B20f
STATION NAME: BWCTED	MODEL: Definition AS+	TUBE CURRENT AVG, KVP: 411 mA, 120 kV

	Requirement	Value	Result
Columns	Present	512	✓
Rows	Present	512	✓
Series UID	Present	1661950920.6531496	✓
Modality	CT	CT	✓
Row Spacing	≤ 2mm	0.650390625	✓
Column Spacing	≤ 2mm	0.650390625	✓
Slice Thickness	≤ 4mm	5.0	✗
FOV	≥ (200, 100, 100) mm	(251.0. 333.0. 333.0)	✓
Patient's Age (years)	≥ 18	910	✓
Patient Orientation	(1.0, 0.0, 0.0, 0.0, 1.0, 0.0)	(1.0, 0.0, 0.0, 0.0, 1.0, 0.0)	✓

Figure 3: Example RV/LV Input Check Failure Report

Report Graphics

The report displays two ventricle slice images from the RGB overlay. The slices selected for the report are the slices with largest ventricular diameter for the left and the right ventricle. And example of the image in the report is shown below in Figure 4.

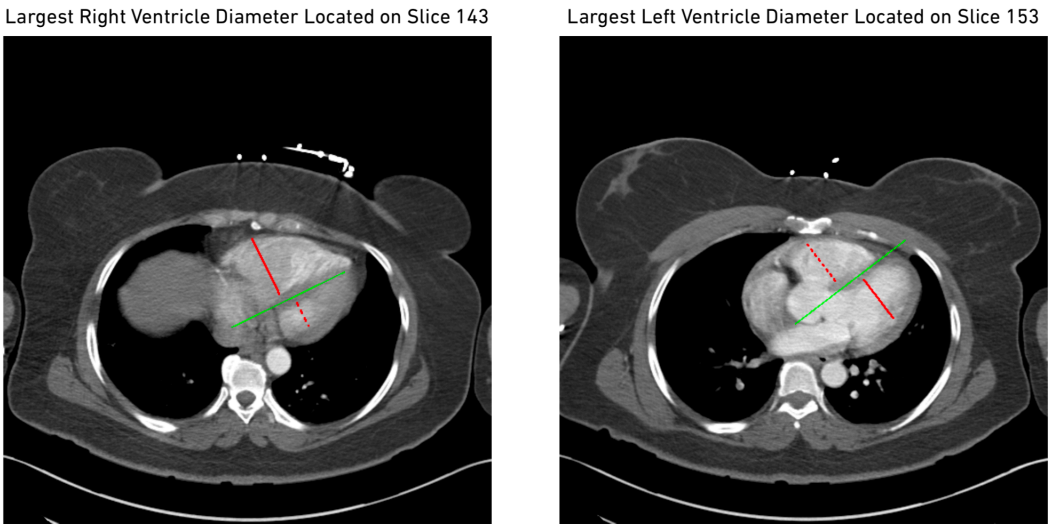


Figure 4: Example of ventricle images in RV/LV Summary Report. The left image displays the slice of the right ventricle with the largest diameter. The right image displays the slice of the left ventricle with the largest diameter.

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6 Possible Encountered Exceptions

The RV/LV Software produces notifications and errors when an exception is encountered within the algorithm. Below are possible errors generated by the software with further descriptions and probable causes of the exceptions.

6.1 Input Errors

`ERROR: Input data invalid::`

This error occurs if one or more acquisition parameters do not meet 4DMedical's requirements. For the details on each required parameter, see Section 3.5.1.

6.2 General Errors

`ERROR: "Cannot compute septums"`

This error indicates the interventricular septum could not be detected. Possible causes include the input image does not contain the heart, the input image is noisy, or there is not adequate contrast between be ventricle chambers and the septum/ myocardium.

If an error occurs, results should not be used for clinical interpretation.

7 Considerations to Reduce Risk

7.1 Protocol

For optimal results, users should follow the CT protocol as outlined in Section 3.5.2.

7.2 Algorithm Limitations

The RV/LV Software checks input parameters and notifies users with warnings or error messages. Even so, there are a small number of cases where no warning or error is given and the output report is generated with potentially misleading results. Below are examples of possible cases. Users of the software should look for this type of output. If present, the results should not be used. The RV/LV Software should only be used by intended users as specified in Section 3.1.

1. Poor Diameter Measurements: This error can be identified by viewing the RV/LV Annotated Image Series or the Report. Figure 5 shows that the red lines, indicating where the diameter measurement is taken, do not extend to the edge of the ventricular cavity

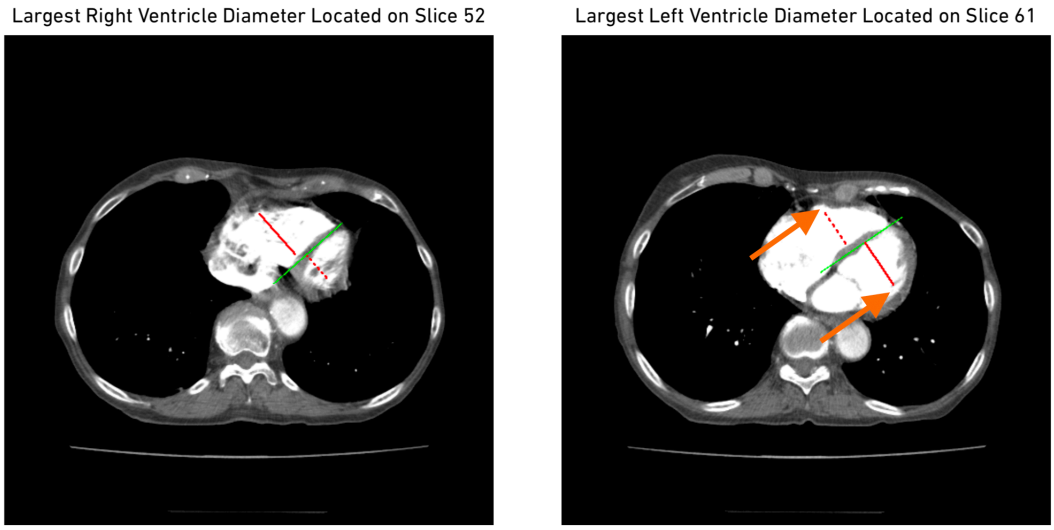


Figure 5: The measurements, indicated by the solid red lines, do not measure the entire distance of the cavity.

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2. Poor Image Contrast: This error can be identified by viewing the RV/LV Annotated Image Series or the Report. In Figure 6 below, there is minimal contrast between the cavity and the surrounding myocardium of the left ventricle. This is caused by a poorly timed CTPA acquisition and can impact both the automated algorithm and the visual QA process.

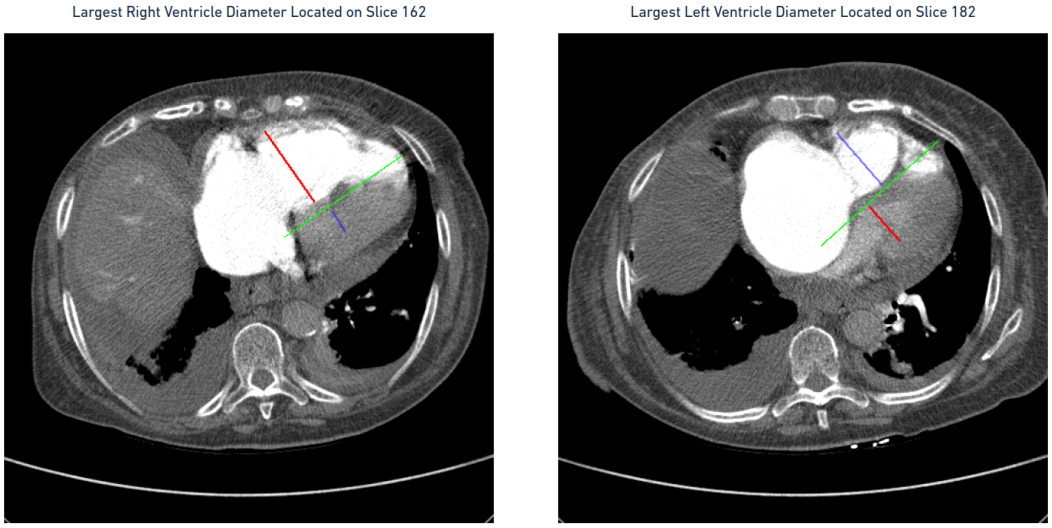


Figure 6: Poor contrast between the cavity and the myocardium can complicate the analysis.

3. Poor Septum Detection: This error can be identified by viewing the RV/LV Annotated Image Series or the Report. In Figure 7 below, the interventricular septum (green line) is poorly detected. The ventricular measurements are made perpendicular to the detected septum, so a poor septum detection can impact the final ventricular measurements and ratio.

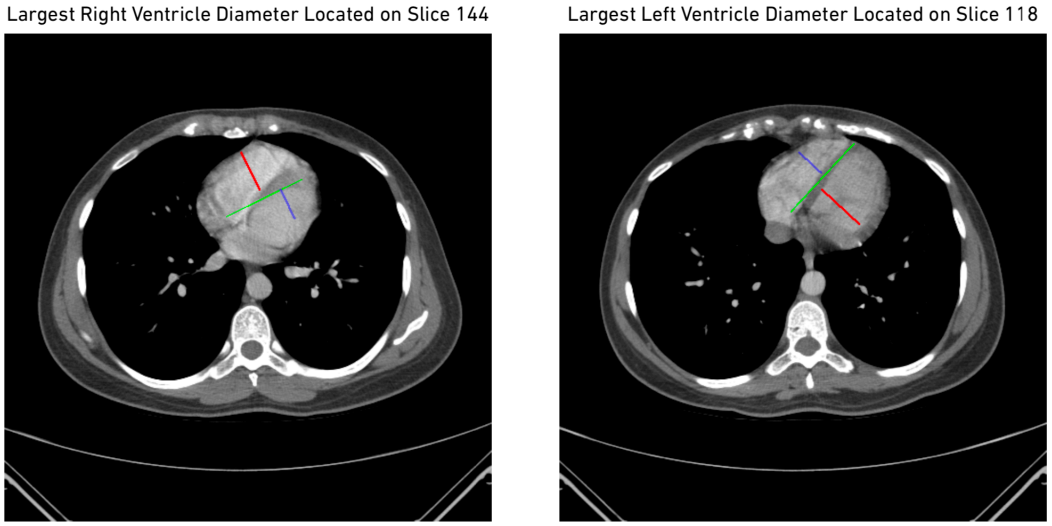


Figure 7: The interventricular septum has been identified incorrectly, leading to a poor segmentation.

7.3 Cybersecurity Recommendations

When deploying systems on which this application will run, please consider the following technical security guidelines:

- Ensure only permitted users are able to sign into the system, using at minimum, a username and strong password.
- Ensure that system firewalls are configured in such a way as to only allow needed traffic to ingress the system.
- Ensure that operating system patches are kept up-to-date, and monitor operating system vendor communications for security and patching-related announcements.
- The Device will only be available when the cloud service or network connection is available.

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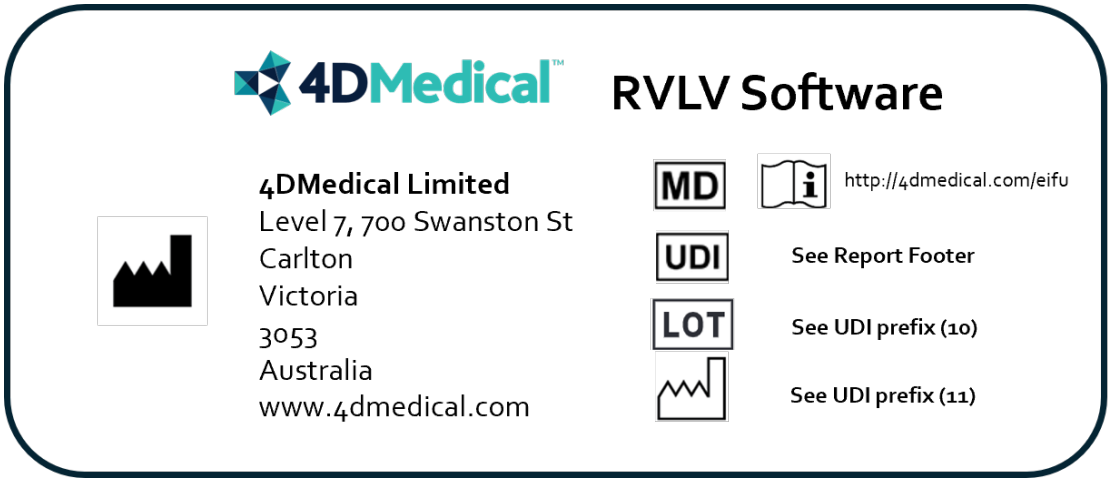
8 Regulatory Information

8.1 Contact 4DMedical

For support, contact 4DMedical using the details below during standard business hours.

Phone: +61 1800 987 226
Address: 4DMedical
Level 7/700 Swanston Street
Carlton, VIC, 3053, Australia
Email: support@4DMedical.com | 4DMedical.com/support

8.2 Software Label



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References

[1] D. Collomb, P. J. Paramelle, O. Calaque, J. L. Bosson, G. Vanzetto, D. Barnoud, C. Pison, M. Coulomb, and G. Ferretti. Severity assessment of acute pulmonary embolism: evaluation using helical CT. *European Radiology*, 13(7):1508–1514, July 2003.

[2] Pei-Ni Jone, Julie Hinzman, Brandie D. Wagner, David Dunbar Ivy, and Adel Younoszai. Right Ventricular to Left Ventricular Diameter Ratio at End-Systole in Evaluating Outcomes in Children with Pulmonary Hypertension. *Journal of the American Society of Echocardiography*, 27(2):172–178, 2014.

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