imbio

RV/LV

v3.1.0

SOFTWARE USER MANUAL

Imbio Document Number: UM-97 v1.0

Contents

1 Introduction

1.1 Prescription Use Statement

Caution: Federal Law restricts this device to sale by or on the order of a physician.

1.2 Scope of Manual

This user manual was written for the Imbio CT RV/LV Software.

Guidance for using the Imbio Core Computing Platform (ICCP) is not included in this document. The ICCP 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 Imbio. The ICCP 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 ICCP provides a system by which customers can still benefit from image processing job automation, while integrating with native DICOM tools and workflows. The ICCP with cloud and enterprise options is a separate product developed by Imbio.

1.3 Product Overview

Imbio'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 Imbio 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 Imbio CT 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).

1.4 Contact Imbio

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2 Indications for Use and Requirements

The Imbio 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.

2.1 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.

2.2 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. 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. The scan should also be visually assessed to ensure that there are no artifacts or missing information.

2.2.1 Imbio Acquisition Parameters

The Imbio CT 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, Imbio CT 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	$\leq$ 4.0 mm
(0008,0060)	Modality	CT
(0028,0030)	Pixel Spacing	$\leq$ 2.0 x 2.0 mm^2

2.2.2 Imbio Recommended Protocol

For the Imbio CT RV/LV Software, Imbio 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

2.3 Hardware Requirements

Hardware requirements for running RV/LV are as follows:

- 4 CPU Cores
- 8 GB RAM
- 4 GB

3 Quality Assessment

The scan quality and possible artifacts must be assessed before utilizing the results produced by the Imbio CT RV/LV Software.

3.1 Precautions

This software is designed to run on any input data that satisfies the criteria in Section 2.2.1 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. Imbio'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.

4 RV/LV Software

4.1 Input

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

4.2 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.

4.2.1 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.

Below are example slices from the RV/LV Annotated Image Series.

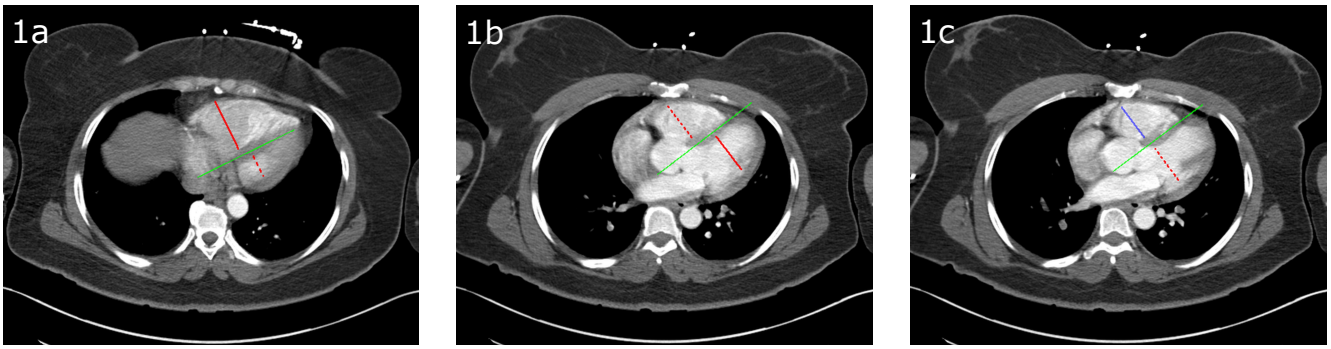

Figure 1: (a) Axial slice of RV/LV Annotated Image Series displaying the largest ventricular diameter of the right ventricle and the detected interventricular septum. (b) Axial slice of RV/LV Annotated Image Series displaying the largest ventricular diameter of the right ventricle and the detected interventricular 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.

4.2.2 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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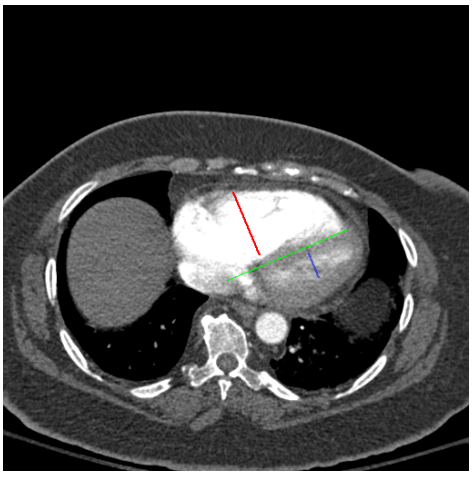
RV/LV ANALYSIS
VERSION 3.1.0

NAME: Firstname Lastname	SEX: Female	STUDY DATE: January 1, 2009
PATIENT ID: 191	DOB: January 1, 1941	REPORT DATE: August 23, 2022

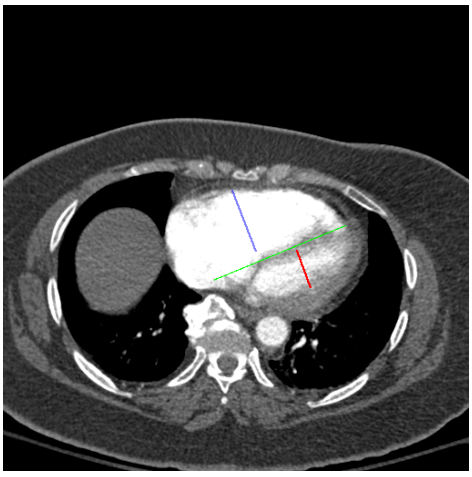
MANUFACTURER: SIEMENS KERNEL: B20f SLICE THICKNESS: 1.0 TUBE CURRENT AVG, KVP: 378 mA, 120 kV

RV / LV Ratio: 1.71 RV Diameter: 48.68 mm LV Diameter: 28.39 mm

Largest Right Ventricle Diameter Located on Slice 167



Largest Left Ventricle Diameter Located on Slice 185



ASSESSMENT KEY

- LARGEST VENTRICULAR DIAMETER
- CONTIGUOUS TO LARGEST VENTRICULAR DIAMETER
- DETECTED INTERVENTRICULAR SEPTUM
- VENTRICULAR DIAMETER

ADDITIONAL INFORMATION

User manual for RV/LV v3.1.0 can be found at https://www.imbio.com/support-documentation.

Figure 2: Example RV/LV Summary Report

4.2.3 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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RV/LV INPUT CHECK REPORT

VERSION 3.1.0

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)	✓

See RV/LV 3.1.0 User Manual (section SCAN PROTOCOL REQUIREMENTS) for more information on input requirements.
User manual can be found at https://www.imbio.com/support-documentation.

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.

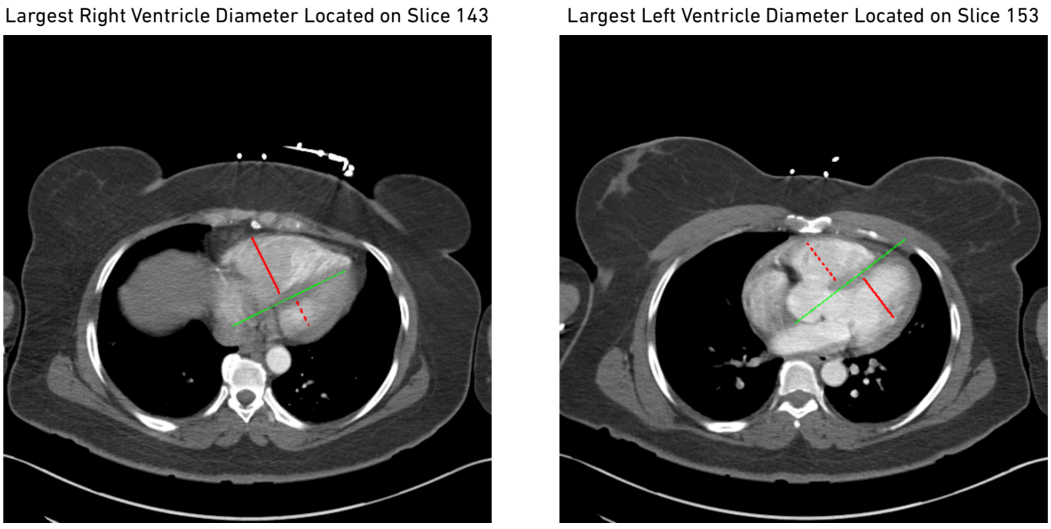

Figure 4: Example of ventricle images in RV/LV Summary Report.
The left image displays the slice of the right ventricle with the largest diameter.
The right image displays the slice of the left ventricle with the largest diameter.

5 Possible Encountered Exceptions

The Imbio CT 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.

5.1 Input Errors

`ERROR: Input data invalid::`

This error occurs if one or more acquisition parameters do not meet Imbio's requirements. For the details on each required parameter, see Section 2.2.1.

5.2 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 adequante contrast between be ventricle chambers and the septum/myocardium.

6 Considerations to Reduce Risk

6.1 Protocol

For optimal results, users should follow the CT protocol as outlined in Section 2.2.2.

6.2 Algorithm Limitations

The Imbio CT 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 Imbio CT RV/LV Software should only be used by intended users as specified in Section 2.1.

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.

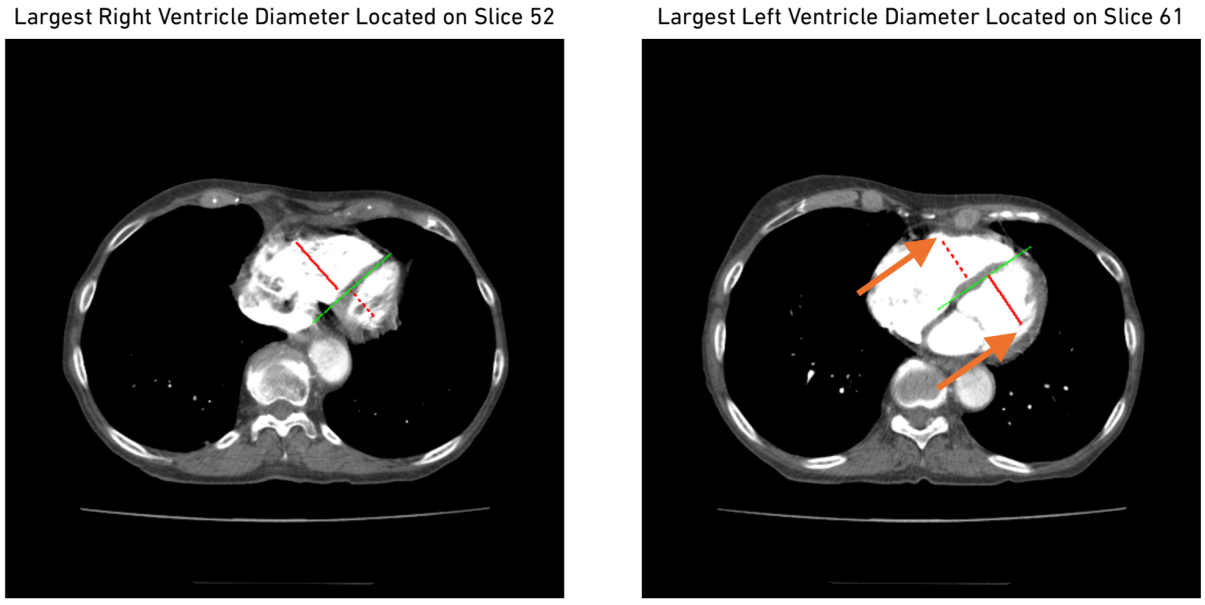

Figure 5: The measurements, indicated by the solid red lines, do not measure the entire distance of the cavity.

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.

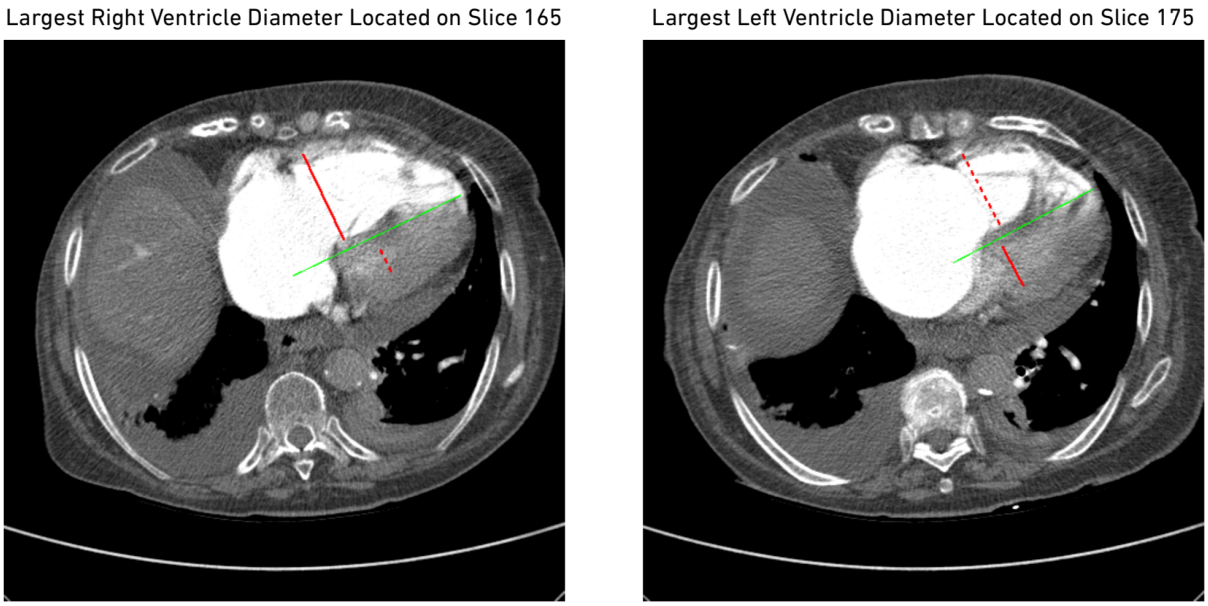

Figure 6: Poor contrast between the cavity and the myocardium can complicate the analysis.

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.

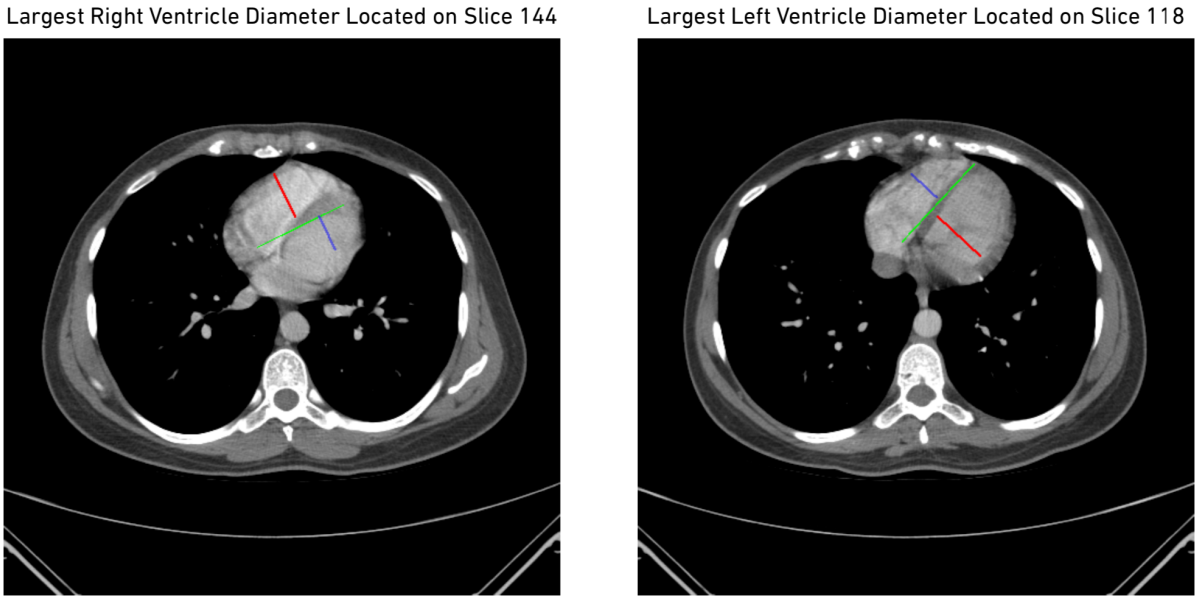

Figure 7: The interventricular septum has been identified incorrectly, leading to a poor segmentation.

7 Software Label