BUILDING AN ASSURANCE CASE FOR

AORTAGEOMRECON SOFTWARE

Portuse the name of your software, Arabady will mow this. Expand it like you did an the rext proje.

BUILDING AN ASSURANCE CASE FOR AORTA GEOMETRY RECONSTRUCTION SOFTWARE

$$\operatorname{BY}$$ JINGYI LIN, M.Eng.

A REPORT SUBMITTED TO THE DEPARTMENT OF COMPUTING AND SOFTWARE AND THE SCHOOL OF GRADUATE STUDIES OF McMaster University IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF Masters of Engineering

© Copyright by Jingyi Lin, August 2023 All Rights Reserved Masters of Engineering (2023)
(Department of Computing and Software)

McMaster University

Hamilton, Ontario, Canada

TITLE: Building an Assurance Case for Aorta Geometry Recon-

struction Software

AUTHOR: Jingyi Lin

M.Eng. (Computing and Software CRP),

McMaster University, Hamilton, Canada

SUPERVISOR: Smith Spencer

NUMBER OF PAGES: xvi, 59

Abstract

Assurance cases have been proven to be effective developing a real-time system software.

Another domain that requires the high standard correctness, completeness, and consistency is medical software.

Throughout the development of the Aorta Geometry Reconstruction software, we implicitly listed the evidences that are essential to build our confidence in the software for assurance cases, build the artifact and the evidences simultaneously.

Finally, we present this software with the list of the evidences built for assurance cases, to show that the assurance cases can apply well on the medical software - write the last - emphasize results; be as specific as possible

Your Dedication
Optional second line

Acknowledgements

Acknowledgements go here.

Contents

A	bstra	uct	ii			
A	Acknowledgements Notation, Definitions, and Abbreviations					
N						
D	eclar	ation of Academic Achievement	xv:			
1	Introduction		1			
	1.1	Objective	2			
	1.2	Background	5			
	1.3	Thesis Outline	Ę			
2	Aor	rtaGeomRecon Research and Development	6			
	2.1	Existing Methods	7			
	2.2	Segmentation Algorithm	10			
	2.3	3D Slicer Extension Development	19			
3	Ass	urance Cases and Selected Evidence for AortaGeomRecon	2 5			
	3.1	Assurance Case Development	25			

٨	Vou	ır Appendix	56
	4.2	Future Works	54
	4.1	Thesis Summary	52
4	Con	aclusion and Future Works	52
	3.5	Assurance Case for Inputs Assumptions	50
	3.4	Assurance Case for Operational Assumptions	47
	3.3	Assurance Case for Implementation	35
	3.2	Assurance Case for Software Specification Requirements	28

List of Figures

1.3	Simple Assurance Case Diagram	5
2.1	ITK-Snap's Bubble Segmentation UI	8
2.2	3D Slicer Built-in Segmentation UI	9
2.3	The Aorta Seeds	11
2.4	Level Sets Segmentation	13
2.5	A Labek Image	14
2.6	A Destance Thap	15
2.7	Code that shows how to calculate the threshold Range	15
2.8	A segmented mage	16
2.9	Segmentation Result	18
2.10	Jupyter Notebook Research	19
2.1	1 3D Slicer UI	21
2.12	2 AortaGeomRecon Module UI	22
2.13	3 AortaGeomRecon Warning message	23

Aorta

3

4

27

28

3.1

3.2

	po space	
3.3	AortaGeomRecon SRS Assumptions	30
3.4	AortaGeomRecon Functional Requirements	31
3.5	AortaGeomRecon Non-Functional Requirements	32
3.6	AortaGeomRecon Traceability Matrix Letween Data Definitions and	
	Instance Model	33
3.7	AortaGeomRecon Traceability Matrix between Requirements and Other	
	Sections	34
3.8	AortaGeomRecon Traceability Matrix Between Assumptions and Other	
	sections	34
3.9	AortaGeomRecon Assurance Cases for Implementation	35
3.10	AortaGeomRecon Design Document website	36
	AortaGeomRecon Design Document Glossary	37
3.12	AortaGeomRecon Anticipated Changes	38
3.13	AortaGeomRecon Modules	39
3.14	AortaGeomRecon Module Decomposition Example	40
3.15	AortaGeomRecon Modules Traceability Matrices	41
3.16	AortaGeomRecon Part of the Traceability Matrix on Modules and Code	42
3.17	Spyder Variable Explorer	45
3.18	AortaGeomRecon Assurance Case Operational Assumptions	47
3.19	AortaGeomRecon User Manual on GitHub README	48
3.20	AortaGeomRecon User Instructions on YouTube	49
3.21	AortaGeomRecon Assurance Case Inputs Assumptions	50
2 99	Aorta Geom Recon Warning Message	51

List of Tables

Notation, Definitions, and Abbreviations

Definitions

Aorta

(ii) oscaran iv) desceran The aorta is the largest artery of the body and carries blood from the heart to the circulatory system. It has several sections: The Aortic Root is the transition point where blood first exits the heart. It functions as the water main of the body. The Aortic arch, is the curved segment that gives the aorta its cane-like shape. It bridges the ascending and descending aorta. Throughout the documentation, forta would only include Ascending aorta, Aortic arch and Descending aorta. Abdominal aorta is not considered as the interested part.

Ascending Aorta

The ascending aorta is the first part of the aorta, which is the largest blood vessel in the body. It comes out of your heart and pumps blood through the aortic arch and into the descending aorta.

Descending Aorta

The descending agree is the longest part of your agree (the largest artery in your body). It begins after your left subclavian artery branches from your aortic arch, and it extends down into your belly. The descending agree runs from your chest (thoracic agree) to your abdominal area (abdominal aorta).

Organ Segmentation

The definition of the organ boundary or organ segmentation is helpful for the orientation and identification of the regions of interest inside the organ during the diagnostic or treatment procedure. Further, it allows the volume estimation of the organ, such as the aorta.

Inferior Inferior is the direction away from the head; the lower (e.g., the foot is part of the inferior extremity).

Superior Superior is the direction toward the head end of the body; the upper (e.g., the hand is part of the superior extremity).

Slice A 2-dimensional image is retrieved from a 3-dimensional volume.

Kernel Size The size of the kernel for binary dilation.

Label Map A labeled map or a label image is an image that labels each pixel of a source image.

Binary Dilation

Binary dilation is a mathematical morphology operation that uses a structuring element (kernel) for expanding the shapes in an image.

These seem to be in random xii Wipholsetical works if you order. On them a legical order. Apholsetical works if you don't have another aption.

shouldn't those be defined with your shouldn't those be defined with your should you have globally

rms_error

Value of RMS change below which the filter should stop. This is a convergence criterion.

Maximum iteration

Number of iterations to run

Curvature scaling

Weight of the curvature contribution to the speed term.

Propagation scaling

Weight of the propagation contribution to the speed term.

Segmented slice

Level Sets

A 2-dimensional image retrieved by applying SITK's ThresholdSegmentationLevelSetImageFilter with the euclidean distance transform image, the original image, and the threshold value calculated with the mean and the standard deviation of the intensity values that were labeled as the white pixel.

Contour Line A contour line (also isoline, isopleth, or isarithm) of a function of two variables is a curve along which the function has a constant value so that the curve joins points of equal value.

Level Sets are an important category of modern image segmentation techniques based on partial differential equations (PDE), i.e. progressive evaluation of the differences among neighboring pixels to find object boundaries. The pictures below demonstrate an example of how Level Sets method work on finding the region of the heart.

xiii

Lere

What
picture?
If your

It starts with a seed contour that is within the region of interest, then by finding the gradient based on the contour line, the segmentation result will propagate towards outside of the region until the maximum difference between the neighboring pixels are reached.

Threshold Coefficient

ful he adjocithmic defenture chije to

This coefficient is used to compute the lower and upper threshold passing through the segmentation filter SITK's ThresholdSegmentationLevelSetImageFilter. The algorithm first uses SITK's Label-StatisticsImageFilter to get the mean and the standard deviation of the intensity values of the pixels that are labeled as the white pixel. Larger values with this coefficient imply a larger range of thresholds when performing the segmentation, which leads to a larger segmented region.

Stop Limit This limit is used to stop the segmentation algorithm. It is used differently in segmentation in inferior direction and segmentation in superior direction.

Euclidean distance transform

The cuclidean distance transform is the map labeling each pixel of the image with the distance to the nearest obstacle pixel (black pixel for this project).

DICOM Digital Imaging and Communications in Medicine (DICOM) is the standard for the communication and management of medical imaging information and related data.

Abbreviations

AGR AortaGeomRecon

AortaGeomRecon

3D Slicer's extension module, Aorta Geometry Reconstruction

DICOM Design Document

DICOM Digital Imaging and Communications in Medicine

MG Module Guide

SITK SimpleITK

SRS Software Requirements Specification

Declaration of Academic Achievement

colleagues or other contributors to the contents of the thesis. Potential mino section paragraphs:

() Medical suffware is control a critical comparant of patient
diagnoss I tealment. - define medical software, give examples

- gre examples of whay what it does I why st D contral I end by saying in the report you! I fow on awth glom.

econdruct. Say how that soft the north year is used to

tred and disaprose I trest cardiac difference in the software.

Diven the Importance of med soft there and construct soft,

we need a means to build confidence in the software.

The this report we explore the use of abundance cases,

the In this report we explore the use of abundance cases,

adding around cases, give a cutation

I define around cases, give a cutation - voint to Smith of all the sofety without, give cutations
- point to Smith of al CISE poper as presenting high-liket
- point to Smith of al CISE poper as presenting high-liket
overson I mothertier xvi
will built or this by adding here delarl or the enrichmed diject
ive.

The student will declare his/her research contribution and, as appropriate, those of

the for the main point,
- a potential outline of the
who is given above

Chapter

Introduction

The trustworthiness and assurance that a system will perform as anticipated need thorough testing. When software carries the critical responsibility of examining the human body, administering medication to patients, saving millions of lives, and conversely, even the tiniest bug or error in the implementation process could lead to serious consequences for individuals' well-being. These issues arise when there are problems with how the system works, whether we expected them or not. It's also influenced by factors such as the environment it's in, the risks it might face, and people who might want to cause harm. To have confidence in the system, we need to pay attention to its main qualities and gather strong evidence that it's performing as desired.

Medical software is challenging to ensure its reliability. The way it's built is very delicate, making it difficult for users to assess its inner workings. However, lacking implementation details makes it hard to trust it, especially for something as critical as medical software.

In this context, we aim to explore the feasibility of applying assurance cases to

medical software from the outset of development. With carefully selected arguments and evidence, we intend to demonstrate to domain experts that the software delivers accurate outputs when used for its intended purpose in its designated environment, and within its assumed operating conditions.

to, Reinfice the story of this chapter. In this study, we present the outcomes of integrating assurance cases throughout the development of medical software to bolster stakeholders' confidence in the software's capabilities. The software, known as AortaGeomRecon, represents a 3D Slicer extension module designed to semi-automatically construct a 3D model of the aorta using CT scans from a patient's chest. Assurance cases function as a method to provide assurance for a system by presenting arguments that substantiate claims about the system. These arguments are based on evidence related to the system's design, development, and tested behavior.

This case study initially introduces the challenge of Organ/Aorta Segmentation and examines existing solutions, which might necessitate time and effort from domain experts. Subsequently, we elucidate the workflow and logic of our algorithm, along with the operational environment for utilizing this module within 3D Slicer. Finally, we delve into our assurance cases, encompassing chosen arguments and supporting evidence. Through this discussion, we elucidate how these specific components contributed to fostering confidence in the reliability of the medical software.

sector. What is the process you , ce did you focus on?

1.2 Background

Don't leave blanks blu headings Eve a Godnop of this Section.

1.2.1 Aorta

Aorta is the largest artery that carries blood from the heart to the circulatory system. It has a cane-liked shape with Ascending aorta, Aortic arch and Descending aorta.

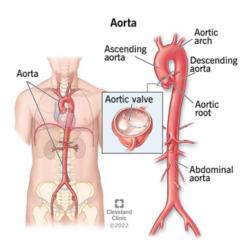


Figure 1.1: Aorta

Lefine all or mynt or first waste

Aorta segmentation in CT scans is important for:

- Coarctation of the aorta
- · aorliz aneurism (8p.
- Aortic calcification quantification
- To guide the segmentation of other central vessels.

1.2.2 Organ Segmentation

The definition of the organ boundary or organ segmentation is helpful for the orientation and identification of the regions of interest inside the organ during the diagnostic or treatment procedure. Further, it allows the volume estimation of the organ, such as the aorta.

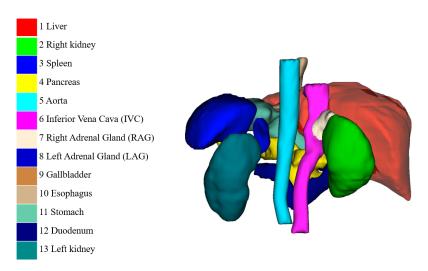


Figure 1.2: Organ Segmentation [12]

1.2.3 Assurance Case

An assurance case can be thought of as a specific type of argumentation used in various cases. When building an assurance case, you're essentially making a point that specific evidence backs up a particular statement. The fundamental structure is depicted in Figure 1.3. So, an assurance case essentially boils down to an organized collection of arguments, backed by a body of evidence, that helps validate the belief in a specific claim.

In a practical sense, creating an assurance case involves beginning with a main

Add

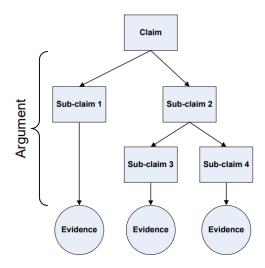


Figure 1.3: Simple Assurance Case Diagram [3]

claim and then breaking it down into smaller claims through a step-by-step process.

These smaller claims, at the most basic level, are supported by concrete evidence.

botton

1.3 Thesis Outline

The thesis is organized into three broad parts. In chapter 2, we introduce our program AortaGeomRecon by mentioning the existing methods, the AortaGeomRecon's algorithm overview and step by step workflow. We explain necessary terms and information to understand how the software functions and the 3D Slicer extension module that the user interacts with to get the segmentation result with our algorithm. In chapter 3, we present our assurance case, some sections of our SRS, Design Documents, Module Guide, Algorithm Review, and a test case we developed for verifying and validating the correctness of program AortaGeomRecon. Finally, future work is proposed and conclusions are drawn based on the developed assurance case, SRS, segmentation algorithm and 3D Slicer module extension.