Development of a myocardial perfusion phantom

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Preface

[todo] this

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Contents

1 Introduction

Myocardial Perfusion Imaging (MPI), or, simply put, the imaging of the blood flow in the heart muscle, plays an important role in diagnosing heart failure or detecting Coronary Artery Disease (CAD). Imaging systems like Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Single-Photon Emission Computed Tomography (SPECT), or Positron Emission Tomography (PET) can visualise a (radioactive) contrast bolus in the supplying arteries and in underlying myocardial tissue, whose flow can give an indication of narrowed or blocked blood vessels.

Many variations in the visualisation process of myocardial perfusion, including variations in hard- and software, can (significantly) influence the outcome and in turn have consequences for patient treatment. These variations need to be validated against a well-known baseline.

A myocardial perfusion phantom will be developed that is able to simulate the blood flow in the heart muscle, i.e. the myocardium, and is able to mimic cardiac defects like (significant) stenosis.

Document overview

[todo] This section

Abbreviations

CAD Coronary Artery Disease

CT Computed Tomography

MPI Myocardial Perfusion Imaging

MRI Magnetic Resonance Imaging

PET Positron Emission Tomography

SPECT Single-Photon Emission Computed Tomography

2 Experiments

This section describes the outcome of the various experiments performed, both at the university as well as at the ZGT in Hengelo.

The experiments are evaluated based on the average flow, see , the standard deviation, see , and the min and maximum measured flows.

$$\mu = \frac{1}{K}\sum_{n=1}^{K} x_i, \text{ K = \# of samples} \tag{2.1}$$

$$\sigma = \sqrt{\frac{\sum_{n=1}^{K}(x_i-\mu)^2}{K}}, \text{ K = \# of samples} \tag{2.2}$$

2.1 University experiments

The complete set-up is tested to verify the performance of the phantom before proceeding with the hospital experiments, its results are shown in table 2.1.

Table 2.1: Flow accuracies university experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		Myocardium	
μ	[L/min]	4.964864		0.459017	
σ (68.2%)	[L/min]	0.01198	0.24129%	0.003746	0.815983%
2σ (95.4%)	[L/min]	0.023959	0.482579%	0.007491	1.631967%
Min	[L/min]	4.9324	0.653882%	0.4535	1.201867%
Max	[L/min]	4.9878	0.46196%	0.4704	2.479916%

2.2 Hospital experiments

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Table 2.2: Flow accuracies first hospital experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		Myocardium	
μ	[L/min]	4.957553		0.08652323	
σ (68.2%)	[L/min]	0.017964	0.362361%	0.000914	1.0564%
2σ (95.4%)	[L/min]	0.035928	0.724722%	0.001828	2.1128%
Min	[L/min]	4.8959	-1.24362%	0.0856	-1.06704%
Max	[L/min]	5.0051	+0.959075%	0.0879	+1.591209%

Table 2.3: Flow accuracies second hospital experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		Myocardium	
μ	[L/min]	4.266208		0.2597461	
σ (68.2%)	[L/min]	0.015116	0.354327%	0.002062	0.793716%
2σ (95.4%)	[L/min]	0.030233	0.708654%	0.004123	1.587431%
Min	[L/min]	4.2236	-0.99873%	0.256	-1.442222%
Max	[L/min]	4.3163	+1.174156%	0.2692	+3.639662%

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Table 2.4: Flow accuracies third hospital experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		Myocardium	
μ	[L/min]	4.957478		0.078503	
σ (68.2%)	[L/min]	0.017672	0.35647%	0.000455	0.580096%
2σ (95.4%)	[L/min]	0.035344	0.712941%	0.000911	1.160192%
Min	[L/min]	4.8890	-1.3813%	0.0771	-1.78664%
Max	[L/min]	5.0054	+0.966664%	0.0794	+1.143198%

Table 2.5: Flow accuracies fourth hospital experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		Myocardium	
μ	[L/min]	1.958676		0.085269	
σ (68.2%)	[L/min]	0.032411	1.654761%	0.000728	0.85379%
2σ (95.4%)	[L/min]	0.064823	3.309521%	0.001456	1.707581%
Min	[L/min]	1.8828	-3.87382%	0.0839	-1.6058%
Max	[L/min]	2.0123	+2.737788%	0.0883	+3.554323%

Table 2.6: Flow accuracies fifth hospital experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		Myocardium	
μ	[L/min]	1.957693		0.210906	
σ (68.2%)	[L/min]	0.012358	0.631266%	0.005557	2.634648%
2σ (95.4%)	[L/min]	0.024716	1.262531%	0.0111113	5.269295%
Min	[L/min]	1.9192	-1.96626%	0.201	-4.69679%
Max	[L/min]	1.9827	+1.277357%	0.2349	+11.37674%

May 2, 2019

Table 2.7: Flow accuracies sixth hospital experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		LCx		LAD		RCA	
μ	[L/min]	2.449		0.223		0.177		0.205	
σ (68.2%)	[L/min]	0.010	0.409%	0.0219	9.839%	0.176	3.502%	0.015	7.222%
2σ (95.4%)	[L/min]	0.020	0.817%	0.043	19.679%	0.012	7.004%	0.030	14.444%
Min	[L/min]	2.42	1.190%	0.195	12.614%	0.164	6.965%	0.169	17.645%
Max	[L/min]	2.472	0.925%	0.299	34.220%	0.199	12.810%	0.244	19.186%

Table 2.8: Flow accuracies seventh hospital experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		LCx		LAD		RCA	
μ	[L/min]	2.467		0.242		0.135		0.227	
σ (68.2%)	[L/min]	0.011	0.440%	0.013	5.394%	0.004	3.179%	0.016	6.887%
2σ (95.4%)	[L/min]	0.022	0.880%	0.0261	10.788%	0.009	6.359%	0.031	13.774%
Min	[L/min]	2.443	0.937%	0.220	8.882%	0.127	5.594%	0.197	13.033%
Max	[L/min]	2.490	0.932%	0.292	20.733%	0.1468	9.038%	0.271	19.503%

Table 2.9: Flow accuracies eighth hospital experiment. Percentage relative to average flow. "Min" percentage is said percentage below average flow, whereas "Max" percentage is said percentage above average flow.

		Aorta		LCx		LAD		RCA	
μ	[L/min]	2.440		0.252		0.241		0.224	
σ (68.2%)	[L/min]	0.014	0.571%	0.013	5.229%	0.007	3.006%	0.013	5.920%
2σ (95.4%)	[L/min]	0.028	1.142%	0.026	10.457%	0.014	6.012%	0.026	11.839%
Min	[L/min]	2.408	1.300%	0.230	8.778%	0.217	10.036%	0.195	12.608%
Max	[L/min]	2.465	1.032%	0.301	19.458%	0.265	10.109%	0.267	19.594%

3 Requirements verification

The next section goes into detail on the failed, non-tested, and other requirement statuses. The requirements and their status are shown in section 3.2.

[done] Seperate table into FR, TFR and TR.

[done] remove FR, TFR, and TR from requirement column.

3.1 Discussion

3.1.1 Failed

GFQ05

- Upper limit cardiac output equal to 8 L/min.

The submersible pump is not capable of generating enough torque to pump 8 L/min. However, since the phantom provides a constant output rather than a pulsatile output, it is not necessary (and not desirable) to have such high flow rate. When the heart fills itself, the blood flow becomes zero. The tracer in the ventricle then emits gamma rays that are picked up by the detectors. When providing a constant flow, the tracer enters and exits the ventricle faster. Therefore, to compensate, the constant flow rate needs to be lower.

SIMT05

- Phantom's compartment model should match the currently practised protocol.
  - A The tracer specified in section 3.2.4. (ICT requirements).
  - B The contrast agent is absorbed by the myocardium to approximately 1.2% of administered activity in 5 minutes.
  - C Contrast accumulates in skeletal muscles, spleen, liver, and kidneys (potential interference).

For A), see ICT requirements. The phantom has failed to meet SIMT05 B), for the first design. The second design of the myocardial chambers, used in the last three hospital experiments, did have a form of temporarily trapping. The holes on the flow path allowed for tracer to exit the flow line and be temporarily trapped. The removal of the tracer has been delayed. SIMT05 C) has not been tested. However, a orientation syringe with a remaining activity was placed in the FOV. It was not possible to interpret that experiment since no phantom was visible in the scanner's images.

ICT05

- Tracer protocol should match the currently practised protocol.
  - A See TFR-ICQ01.
  - B Tracer is injected, as bolus, via infusion pump.
  - C A pre-bolus is to precede the main bolus.

The specific requirement in question, is C). A) is points to a different requirement, and B) is moved to a different requirement. C) is failed because no pre-bolus is injected. A pre-bolus is not in the D-SPECT clinical protocol of the ZGT. The pre-bolus requirements is based on papers.

ICQ02

- Pre-bolus activity is equal to 37 Mega Becquerel.

Since no pre-bolus is administered, this requirement is no longer valid.

PRT05

- TR-PRT05 The phantom must be easily be cleared of air bubbles.

The open chamber design, used in the first 5 hospital experiments, were easily cleared of air bubbles by tilting the phantom. The second design, with the second compartment, proved more difficult to clear (if at all succeeded). The air is trapped in a compartment only accessible through the holes in the flow lines. The path of least resistant is straight through and only a small part passes through the holes which does not create the proper amount of flow necessary to force any remaining air out.

PRQ04

- Left ventricle dimensions.

  A Internal Apical-Annular distance is between 69.4 and 105.8 Millimetre.
  B Internal Septal-Lateral distance is between 38.2 and 55.6 Millimetre.
  C Internal Anterior-Inferior is between 46.9 and 68.5 Millimetre.
  D Myocardial wall thickness is between 4.8 and 9.8 Millimetre.
  E Internal volume is between 47 and 156 Millilitre.

The phantom does not meet requirements A), C), and E). The apical-annular distance is approximately 144mm such that the Luer connectors can be attached and subsequently the elbow connectors and tubes. The heart is not perfectly cylindrical, which explains the difference between the ranges given in B) and C). The overall design is based on simplified cardiac inserts and a 40mm diameter was chosen such that the volume is approximately in the middle of the range given in E). However, since the cylinder was extended to make room for the Luer connectors, the phantom failed to meet requirement E) and due to its cylindrical shape, also failed to meet requirement C).

SQT01 and SQT02

- Emergency shut down of flow set-up when arterial pressure exceeds TFRGFQ07.
- Emergency shut down of flow set-up when flow cannot be controlled, i.e. erratic or absent.

Since the no emergency stops have been implemented, the set-up fails to meet requirements SQT01 and SQT02.

3.1.2 non-tested

[done] FR03

[done] 01

FR04

- Cardiac defects must simulate the complex relation between stenotic and non-stenotic arteries.

Although the requirements remains untested, it can be said that it is validated. The phantom uses a combination of a branching aorta with flexible tubing ("coronary arteries"). These flex-

ible tubing can be narrowed (i.e. made stenotic) by using a hose clamp or a surgical clamp to completely block an tube. The flow will then find its own way through the phantom, and thus mimicking the complex relation between stenotic and non-stenotic arteries.

GFT02

- Flow generators need to be interchangeable.

Similarly to FR04, this requirement remains untested. However, it can be said it is validated since the flow generators are easily interchanged (assuming the new flow generator is controllable via open loop voltage control). The controller will have to tuned for optimum performance.

GFQ01

- Upper limit myocardial perfusion equal to 300 mL/min/100g.

Converted upper limit, per average human heart (310 grams), is 930 mL/min. The upper limit that has been tested, is 780 mL/min. Theoretically, the upper limit is the flow generator's output. The aorta can be fully closed, forcing all the flow through the myocardium.

GFQ03

- Typical perfusion rate during stress between 190 and 300 mL/min/100g.

Converted range, per average human heart (310) grams), is between 589 and 930 mL/min. The lower range has been verified but not the upper limit, as mentioend in discussion of GFQ01.

SIMT05 C)

- Phantom's compartment model should match the currently practised protocol.

  A The tracer specified in section 3.2.4. (ICT requirements).
  B The contrast agent is absorbed by the myocardium to approximately 1.2% of administered activity in 5 minutes.
  C Contrast accumulates in skeletal muscles, spleen, liver, and kidneys (potential interference).

For A), see ICT requirements. The phantom has failed to meet SIMT05 B). SIMT05 C) has not been tested. However, a orientation syringe with a remaining activity was placed in the FOV. It was not possible to interpret that experiment since no phantom was visible in the scanner's images.

ERQ01

- Electric power.

  A Supply voltage equal to 230 Volt.
  B Supply current at TR-ERQ01 A) significantly less than 6 Ampere.
  C Supply type is equal to AC.
  D Supply frequency is equal to 50 Hertz.

The measurement case is supplied by the standard Dutch power mains, 230 Volt, 50 Hertz AC, therefore validating A), C), and C2). However, current measurements have not been performed but can be theoretically determined. The maximum input current would be 6 Ampere at 230 Volt AC. However, the system operates on 12 Volt DC which thus requires a transformer. An ideal transformer has no energy loss and obeys the law of energy conservation. From a black

box point of view, 230 Volt AC with 6 Amperes enters the black box and 12 Volt DC at X Amperes exits the black box. The relation is given by equation 3.1, where V_p is 230 Volt AC, V_s is 12 VAC, and I_p is 6 Ampere. The conversion from 12 VAC to 12 VDC is neglected and assumed ideal. A maximum of 115 Ampere would be available for the pumps, which is the biggest power drain. The measurement case has two parallel input fuses of 2A at 230VAC. At maximum input power, this would result in 38 Ampere that is available for the entire system. The Arduino and sensors do not use much (mA range) but the pump can draw up to 5 Ampere which would be 0.25 Ampere on the input.

[done] check progress report for the AC input fuse

$$\frac{V_p}{V_s} = \frac{I_s}{I_P} \rightarrow I_s = I_p \frac{V_p}{V_s} \tag{3.1}$$

3.1.3 other

GFQ06 through GFQ09

- Lower limit arterial pressure is equal to 56 mmHg.
- Upper limit arterial pressure is equal to 155 mmHg.
- Mean Arterial Pressure (MAP)is equal to 89 mmHg.
- Typical MAP is between 70 and 110 mmHg.

All requirements state the pressure ranges or limits in the arteries. However, since a constant flow is used, these requirements are no longer applicable. The lower and upper limits, GFQ06 and GFQ07, have not been tested at all. GFQ08 and GFQ09 have been monitored and would have been verified if the requirements were still applicable.

PRQ03

- Phantom's outer dimensions.

  A Basal-Apical distance is approximately equal to 120 Millimetre.
  B Left-Right Lateral distance is approximately equal to 80 Millimetre.
  C Anterior-Posterior distance is approximately equal to 60 Millimetre.

The outer dimensions are not important, as long as it fits in the QRM phantom (which is a separate requirement). Therefore, the outer dimensions of the phantom are no longer applicable.

PRQ05

- Right ventricle dimensions.

  A Internal Apical-Annular distance is between 44.8 and 79.2 Millimetre.
  B Internal Septal-Medial distance is between 19.2 and 40.0 Millimetre.
  C Internal Anterior-Inferior distance is between 42.2 and 73.6 Millimetre.
  D Myocardial wall thickness is between 1.0 and 3.8 Millimetre.
  E Internal volume is between 24.9 and 163.0 Millilitre.

The phantom does not have a right ventricle. Therefore, PRQ05 is no longer applicable.

3.2 Overview

Table 3.1: Functional requirements (FR)

#	Description	Result	Note
FR01	The phantom must be able to simulate blood flow at high flow rates (aortic flow).	V	AIF is directly simulated by means of pumping.
FR02	The phantom must be able to simulate blood flow at low flow rates (myocardial flow).	V	Myocardial flow is a function of the aortic flow rate, and relative pressure in the chambers and aorta.
FR03	An AIF can be extracted from the left atrium, or alternatively from the left ventricle.	V	4DM can select an ROI in both but has not been tested in the phantom.
FR04	Cardiac defects must simulate the complex relation between stenotic and non-stenotic arteries.	NT	The phantom has not been tested on this matter. However, the chambers have regulators on their exit, controlling the flow through the chamber, and the input tubes can be clamped to completely close a branch.
FR05	The phantom must be able to visualise (and measure) at least two active segments of the 17-segment ventricle model.	V	The current phantom has three (active) chambers.
FR07	Tracer protocol must be equivalent to that used in clinical scans with D-SPECT.	V	The same tracer and in injection protocol is used as in clinical scans.

Table 3.2: Technical function requirements (TFR)

#	Description	Result	Note
GFT01	A variable, but constant, flow is to be generated, i.e. non-pulsatile.	V	The pump generates a constant flow that can be adjusted via the GUI.
GFT02	Flow generators need to be interchangeable.	NT	In theory, the pumps are interchangeable assuming the pumps are controllable via open-loop voltage control. Meaning, the pump is controlled by supplying a variable voltage where a higher voltage means higher RPM and thus higher flow rate. The controller however, might require additional tuning for accurate control.

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#	Description	Result	Note
GFT03	Flow feedback control for flow generators	V	A flow sensor must be connected and enabled, and selected in the pump menu of the GUI. Flow feedback control is enforced. The system cannot be initialised without a flow feedback setting for every enabled pump.
GFQ01	Upper limit myocardial perfusion equal to 300 mL/min/100g	NT	An average adult heart weighs approximately 310 grams, resulting in an upper limit of 930 mL/min/heart. The upper limit has been tested up to 780 mL/min. However, it is possible to increase the flow rate, theoretically, up to the pump flow. The aorta flow passes through a regulator that can be fully open, fully closed, or anywhere in between. If the regulator is closed, all flow **must** flow through the myocardium (assuming the pump can generate the pressure required).
GFQ02	Lower limit myocardial perfusion equal to 60 mL/min/100g.	V*	Per average adult heart, that would result in a lower limit of 186 mL/min. The lower limit has been tested to be 120 mL/min at 5 L/min aortic flow. Theoretically, the flow can be reduced by the myocardial resistance by closing the regulator (each myocardial chamber has a regulator). It has not been tested for the R3 chamber design (used for experiments on May 2, 2019).
GFQ03	Typical perfusion rate during stress between 190 and 300 mL/min/100g.	NT	Per average adult heart, that would result in a range between 589 and 930 mL/min. The lower range has been verified but the upper range has only been theoretically verified.
GFQ04	Typical perfusion rate during rest between 60 and 95 mL/min/100g.	V	Per average adult heart, that would result in a range between 186 and 295 mL/min/heart. These ranges have been verified by experiments that were set to 300 mL/min myocardial flow at 5 L/min aortic flow.
GFQ05	Upper limit cardiac output equal to 8 L/min.	F	The current pump is unable to generate 8 L/min of cardiac output.

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#	Description	Result	Note
GFQ06	Lower limit arterial pressure equal to 56 mmHg	N.A.	Lower limit is only applicable in pulsatile flow.
GFQ07	Upper limit arterial pressure equal to 155 mmHg	N.A.	Upper limit is only applicable in pulsatile flow.
GFQ08	Mean arterial pressure equal to 89 mmHg.	N.A.	Although not applicable due to a constant flow rate, the pressure has been less than 89 mmHg during all but one experiment. Average pressure has been 60 to 80 mmHg but 546 mmHg in the second hospital experiment. In that experiment, a significant portion of the main flow (5 L/min) was directed to the myocardium increasing the system's pressure significantly. Subsequent experiments are performed on 2 or 2.5 L/min.
GFQ09	Typical MAP between 80 and 110 mmHg.	N.A.	See previous.
GFQ10	Feedback control accuracy equal to 5%	V*	As is shown in section 2, the accuracy is typically around 1%. However, when the aortic flow rate is set to 2 L/min, the accuracy becomes significantly worse. The relatively cheap pump is unable to provide enough pressure to overcome the flow resistance at a lower voltage (i.e. lower flow rate).
MFPQ01	Flow measuring accuracy less than or equal to 5%.	V*	The sensors have not been calibrated. Manufacturers claims a 3% accuracy for the UF08B, and 2% for the FCH-m-POM-LC.
MFPQ02	Pressure measuring accuracy less than or equal to 5%	V*	The sensors have not been calibrated. Manufactuerer claims a 2.5% accuracy for the 40PC100G2A and 4% for the 40PC15G1A.
MFPQ03	Absolute flow resolution greater or equal than 1 mL/min.	V*	The absolute flow resolution can be approximated by $^{1[L/min]}/_{output[L/min]}$. For the FCM-m-POM-LC, with 1mm nozzle, the absolute resolution is 0.12 mL/min and 1mL/min for the UF08B.
MFPQ04	Sampling rate greater or equal to 10 Hz.	V	The Arduino Due samples at 100 Hz. The GUI plots at 10 Hz.

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#	Description	Result	Note
SIMT01	An AIF must be extractable from the left ventricle, as per software requirement.	V	An ROI can be taken in the left ventricle. However, due to orientation problems, proper quantitative results have not been achieved.
SIMT02	Stenotic arteries are mimicked in a physiological way by phisically narrowing (or increasing flow resistance) of certain arteries.	NT	It is possible to physically clamp (surgical clamps) one or more tubes to mimic a blocked artery. It is also possible to put a hose clamp on one or more tubes to mimic a narrowed artery.
SIMT03	Different stenotic severity, should be possible by, for example, variable flow resistors or interchanging components.	V	It is possible to use the flow regulators for each of the three myocardial chambers to increase or decrease the flow going through the chambers. Furthermore, clamps or hose clamps can be used to mimic blocked or narrowed in a specific artery.
SIMT04	The phantom must be compatible with D-SPECT protocol A) through H)	V	The aortic side-branch branches out 3 times and then branches out 3 more times for each myocardial chamber. The flow from each chamber is measured seperately and can thus be compared to the 17-segment model. However, there are no 17 distinct chambers but that prevent the outcome to be compared to a 17-segment model. An AIF can be taken in the left ventricle, an atrium is not present. However, due to orientation problems, it has not been possible to achieve quantitative results. The patient chair is flattened for the experiments and thus mimic a supine position.
SIMT05	Phantom's compartment model should match the currently practised protocol A) through C).	F/NT	For A) see ICT requirements. For B) the first, simplified, model does not trap the tracer. For C) contrast accumulation has not been tested. An "orientation syringe" has been placed in the field of view but has not been evaluated.
ICT01	Tracer volume is variable.	V	There are no limits concerning tracer volume that can be injected.

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#	Description	Result	Note
ICT02	Tracer activity is variable, also see TFR-ICQ03.	V	There are no limits concerning tracer activity that can be injected. Care must be taken in selecting what activity to use since it affect the extracted frames and/or saturation of the sensors.
ICT03	Tracer agent is variable.	V	If needed, the tracer agent can be interchanged.
ICT04	Tracer injection is reproducible, also see TFR-ICT05.	V	Tracer is injected by a clinical infusion pump that is fully independent of the rest of the system.
ICT05	Tracer protocol should match the currently practised protocol, A) and C).	F	For A), see TFR-ICQ01. For C), a pre-bolus did not preceded the main bolus.
ICQ01	Tracer to be used is equal to Technetium (^{99m}Tc) Tetrofosmin.	V	-
ICQ02	Pre-bolus activity is equal to 37 Mega Becquerel.	F	No pre-bolus had preceded the main bolus.
ICQ03	Typical main bolus activity is between 500 and 700 Mega Becquerel.	V	Although the initial bolus activity was 100 and 200, the last measurements were performed using a 500 Mega Becquerel bolus.
ICQ04	Typical main bolus volume is between 1 and 2 millilitre.	V	-
ICQ05	Typical bolus injection speed is between 1 and 2 millilitre per second.	V	-
ICQ06	Saline flush after tracer injection is equal to 30 millilitre.	V	-

Table 3.3: Technical requirements (TR)

#	Description	Result	Note
PRT01	The phantom's left ventricle is to be placed inside the QRM TRX-116, see TR-PRQ01	V	The left ventricle is inside the clearance hole of the thorax phantom.
PRT02	The phantom's left ventricle must fit in the D-SPECT's imaging area.	V	Although a part of the phantom is outside the "high-accuracy" area, the required part of the left ventricle is in the "high-accuracy" area.

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#	Description	Result	Note
PRT03	The phantom must be anatomically shaped, A) through H).	V*	For C), the myocardial chambers surround the cylindrical (simplified) left ventricle. For E) and F) both the arteries and veins run outside of the myocardium and attach to the top and bottom of each chamber. For G) and H), the cross-sectional shapes are verified in SolidWorks, but have not yet been verified in the myocardial perfusion images. Initial visualisation shows a cross-sectional shape of a circle, but not proper distribution.
PRT04	The flow set-up is to remain horizontal (preventing additional flow resistance).	V	Two LAB-Jacks ensure that the set-up is flexible regarding the height. Therefore, the flow set-up can remain horizontal when the fat rings are added.
PRT05	The phantom must easily be cleared of air bubbles.	V/F	The first myocardial chambers (two filled with different sponges, one empty control) were easily released of air by tilting the phantom. The second myocardial chambers (2-compartment type) are more difficult to clear of air and will require a venting port.
PRQ01	Short Axial Diameter less than 100 millimetre.	V	The Short Axial diameter is 72mm.
PRQ02	Weight on patient chair less than 171 kilogram.	V	Not measured. The phantom and the flow set-up do not come close to a combined weight of 10 kilogram. All other parts are not placed on the patient chair.
PRQ03	Phantom's outer dimensions, A) through C).	N.A.	Other than PRQ01 and PRT02, the outer dimensions of the phantom are not important.
PRQ04	Left ventricle dimensions, A) through E).	F/V	The left ventricle is 144mm long, and has a diamter of 40mm. Therefore failing A) and C) but validating B). The volume is roughly 181 mL and therefore fails E) due to the larger size required for the Luer connectors.
PRQ05	Right Ventricle dimensions, A) through E).	N.A.	The phantom does not contain a right ventricle.

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#	Description	Result	Note
PRQ06	Phantom resembles weight of an average human heart.	V	The phantom's dimensions are based on the average of various CT/MRI measurements. The 250 to 350 range is based on average human heart and thus validates this requirement.
PRQ07	Flow path height relative to platform, due to the fat rings.	V*	The flow path is adjustable in the range between 120 and 170 due to a LAB-JACK scissor lift. It cannot reach 245mm height but can be made fit by adding spacers.
ERT01	No high-density or "High-z" material is to be used.	V	The only metal in the set-up, is the iron in the LAB-JACKS. However, they are not between the tracer and the detectors and therefore do not are not a problem.
ERT02	The phantom's left and front side must remain free.	V	The phantom does not have any wires, tubing or anything other than the QRM thorax phantom between the ventricle phantom and the detectors.
ERQ01	Electric power, A) through C).	V/NT	The power supply is standard Dutch power mains consisting of 230 Volt AC at 50 Hertz. The power consumption has not been tested.
EIT01	Adjust output of flow generators.	V	The flow rate can be adjusted by using the GUI.
EIT02	Serial communication between control/monitoring systems and external interface.	V	A USB cable is attached between the measurement set-up and the laptop that runs the external interface (GUI).
EIQ01	Live plotting frequency of system's flow and pressure is equal to 10 Hertz.	V	The plot is updated every 100 milliseconds.
SQT01	Emergency shut down of flow set-up when arterial pressure exceeds TFR-GFQ07.	F	No emergency shut down has been implemented. An emergency shut down consists of the user pressing the stop button or turning of the power using the switch on the front side of the measurement case.
SQT02	Emergency shut down of flow set-up when flow cannot be controlled, i.e. erratic or absent.	F	
SQT03	No reversed flow out of the phantom is allowed.	V	A one-way valve directly after the motor prevents any backwards flow when the pump is turned off.

Continues on next page.

#	Description	Result	Note
SQT04	Any leaks that may occur are trapped in a collection tray.	V	A custom leak tray has been designed and made in which the flow set-up is build.

209 [done] check physical requirements

210 [done] check simt05

211 [done] check pressures

4 Discussion & conclusion

4.1 Discussion

The majority of the requirements have been verified, or verified under certain conditions. Some requirements have been failed, some have not been tested and the rest are no longer applicable.

The two most important requirements that have not been met, are SIMT05 B) and PRT05. SIMT05 B) states that the tracer should be trapped to approximately 1.2% of the administered activity. The R3 chamber design, using tubes with 1mm holes, does in a way trap the tracer, but only temporarily. This prevents the software from accurately calculating the myocardial flow since it is based on a 2-compartment model. PRT05 states that the phantom must be easily be cleared of air bubbles. During experiments with the first myocardial chamber design, the air bubbles were easily removed by tilting the phantom. However, the R3 chamber design was not cleared of air bubbles properly despite being able during university experiments. The lack of venting may be caused by the work flow at the hospital (less manoeuvre room, less time spent trying to vent) or by it being a design flaw. New experiments with the current set-up, and with identical configuration, should show whether it is a design flaw or work flow error.

Nevertheless, the main goal of the first phase phantom, was to determine if a more anatomically correct perfusion phantom can be designed and realised that is compatible with clinical practice. 4DM recognised enough features to allow reconstruction of the images.

4.2 Conclusion

Despite its flaws, the first phase phantom showed that the phantom can be used in conjunction with the 4DM clinical software. The second phase will require a redesign of various parts of the flow set-up and/or phantom.