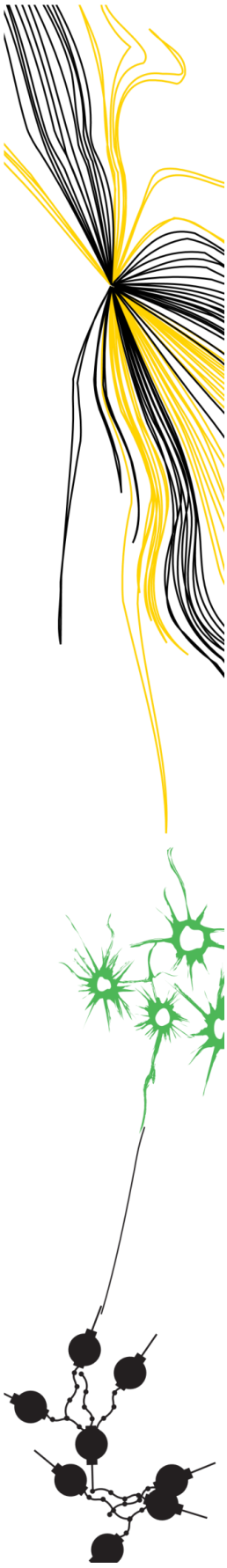

RAM ROBOTICS AND MECHATRONICS

DESIGN OF A RAPID PROTOTYPE END-EFFECTOR OF A CONCENTRIC TUBE ROBOT FOR THE DETECTION OF BLADDER CANCER

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Abstract

Of all cancer diagnoses, 3% is diagnosed as bladder cancer, which makes it the tenth most common cancer type worldwide [1]. Nowadays there are several methods to detect bladder cancer, or establish its state, but most of them are invasive or inaccurate. The method cystoscopy is often used, but goes wrong in 43% of the bladder cancer cases [2]. Therefore, the Next Gen In-Vivo Cancer Diagnostics group is working on developing and validating a prototype optical coherence tomography (OCT) catheter system. This is done by making a concentric tube robot (CTR) for the detection of bladder cancer using digital mapping and OCT of the regions of interest. An end-effector must be designed for this robot, which will be the focus of this thesis. Therefore, the goal will be to *"Design a rapid prototype end-effector of a concentric tube robot for the detection of bladder cancer using digital mapping and OCT of the regions of interest."* This thesis will follow a stepwise structure; Introduction, Design procedures, Conceptualizing, determining a Final design, and Experiment. Lastly, the results of this thesis will be discussed, and recommendations are given for future research.

Contents

Chapter 1

Introduction

In 2018, 17.0 million people were diagnosed with cancer worldwide, of which 3.0 % were diagnosed with bladder cancer [1]. In the Western world, bladder cancer is the fourth most common malignancy in men and the eighth most common in women, with 425.000 and 125.000 diagnoses, respectively [3]. 2.1 % of those people died due to their bladder cancer [1]. To increase the survival rate and quality of life of those cancer patients, it is important to make the correct diagnosis such that the optimal treatment can be given. Yet diagnosing bladder cancer is still difficult. Nowadays several diagnostic methods are available to detect bladder cancer, or establish its state, but most of them are invasive or inaccurate.

Cystoscopy is the most used technique since it is fast and minimally invasive. During cystoscopy, the bladder is examined using a rigid or flexible endoscope. This makes it possible to detect anatomical bladder abnormalities and bladder tumours. Nevertheless, cystoscopy is incorrect in 43 % of bladder cancer cases and is particularly limited in the diagnosis of small flat tumours [2]. One of the reasons that the diagnoses often are incorrect is due to the imaging techniques. Currently, a camera is used to analyse the bladder's inner lining. If the urologist sees peculiar tissue, a biopsy is taken for further examination. This is an inaccurate way since it now depends on the urologist's attentiveness, experience, and perception, which can be different for every urologist. So, although cystoscopy is often used for the detection of bladder cancer, the imaging technique could be improved.

To improve those imaging techniques, digital mapping can be considered. Digital mapping uses specifically processed data from cystoscopy videos, to make high-quality digital panoramic maps of the urinary bladder [4]. When a digital map of the bladder is made, one can see where and if peculiar tissue is located in the bladder. Using such a digital map, this location can be pointed out, making it easier to identify. Besides, small tissue irregularities and differences over time are more clearly seen.

To obtain a high-resolution image, the bladder wall must be scanned accurately. To achieve this, a concentric tube robot (CTR) can be used. These robots are made from several tubes that are nested within one another concentrically [5]. The tubes are made of NiTi (Nickel titanium, also known as Nitinol), which makes the tubes flexible. Because a big part of the robot consists only of those NiTi tubes nested within one another, the robot can be made very thin and flexible. When using a CTR for the use of digital mapping, a clear and fast map of the inner bladder lining can be made. When a suspicious lesion is found using the digital map, optical coherence tomography (OCT) could help to see if the tissue is muscular invasive or not. OCT can determine different layers of the bladder and can distinguish benign from malignant

characteristics [6]. It appears that the sensitivity, specificity, and negative predictive values for the classification of benign or malignant tumour tissue, due to OCT, were respectively 100 %, 90 %, and 89 % higher than without OCT. The sensitivity and specificity for detection of muscle invasion were similarly high [2]. The use of an OCT sensor and digital mapping would therefore be very interesting for the CTR.

To be able to use a camera, light, and an OCT sensor in the CTR, an end-effector needs to be designed. While designing this end-effector it is important to take its sterilization into account. Sterilizing medical devices is important but can be difficult depending on the materials and design of the device. In the medical device world, everything that is used in the operating theatre must be sterile to prevent infections. There are several ways to sterilize a medical device and kill microorganisms. A common method used is steam sterilization or moist heat sterilization. This sterilization method sterilizes the product in an autoclave at temperatures of 121°C for at least 30 minutes or at 131 °C for at least 4 minutes [7]. Especially steam sterilization is commonly used in hospitals to sterilize reusable metal instruments. There are many medical devices however that cannot withstand the temperatures required to sterilize. Therefore, there are two other commonly used sterilization methods: gamma sterilization sterilizes the product using a radioactive gamma beam. And ethylene oxide (EtO) sterilization, which uses toxic gas under defined environmental conditions to kill microorganisms [8]. Gamma sterilization is cheap but can cause degradation of polymers by cross-linking, chain scission, or a combination of both [9]. EtO sterilization is often used as it can be done at room temperature but is not environmentally friendly. So, the method used depends on the properties of the materials used in the design of the device.

The use of those chemicals, radiation, or high temperatures has the consequence that not every material is suitable for these sterilization methods. Common plastic types used for 3D-print techniques, liquid-based, solid-based, powder-based, or polyJet [10] [11], can result in the deformation of the material. Different 3D-print techniques may therefore be considered. When looking at the different printers that are available at RaM, and their specifications, it appears that the Formlabs Form 3 is the most suitable printer for this project. This is a liquid-based printer, with as key features a very high resolution [Z: 25-300 micron; XY - 25 microns, laser spot size - 85 micron] [12] and a wide range, which is preferable for printing the small end-effector. Besides, some of the materials that can be printed with the Formlabs Form 3 are FDA certified as biocompatible materials (based on the international standard for biocompatibility of medical devices, ISO 10994) and can therefore be used for medical applications. BioMed White Resin, for example, is a medical-grade material and USP Class VI certified, which confirms that there are no harmful reactions or long-term bodily effects caused by chemicals that leach out of plastic materials. In addition, BioMed White resin can be sterilized by autoclave, E-beam, gamma, and ethylene oxide. This makes BioMed White resin a suitable choice for this project, due to its high resolution and ease way of sterilization.

Chapter 2

Design procedures

For the design of a device, requirements have to be formulated. Therefore, stakeholders must be acknowledged and functional and technical requirements have to be listed. This chapter will focus on this, after which the first concepts can be made.

2.1 Stakeholders

It is important to create a clear view of which parties are involved in the design process. To accomplish this view, various stakeholders with their interests are identified and listed below.

Urologist
The urologist is the clinical stakeholder that will eventually use the device in practice. Therefore, the urologist must be properly represented when developing and designing the new device. In general, they want an accurate and reliable device that is easy to use. Therefore, a few functionalities are composed. The functionalities associated with this stakeholder are listed below. Each functionality is matched to a requirement, which can be seen in table 2.1 and 2.2.
- F.1.: The device must be sterilizable.
- F.2.: The examination should not cause any additional risks
- F.3.: The camera should be kept in place, while rotating the OCT sensor.
- F.4.: There should be a water nozzle.
- F.5.: The camera should acquire images of similar or better quality than the camera system of the Olympus CYF-VH Flexible video Cystoscope.
- F.7.: It should be possible to rotate and translate the OCT sensor.
- F.8.: The outer diameter of the end-effector should not exceed 6 mm.

Insurance company
The insurance company has an interest in the benefit/cost balance. The impact of the device must outweigh the cost of the device. The insurance company, therefore, has no requirements of its own, but is interested in the requirements that could harm the patient. The functionalities that influence this stakeholder are listed below and can be seen in table 2.1 and 2.2.
- F.1.: The device must be sterilizable.
- F.2.: The examination should not cause any additional risks
- F.8.: The outer diameter of the end-effector should not exceed 6 mm.

European Notified Bodies (NB)
All medical devices to be placed on the European Union market are required to comply with the Medical Device Regulation (MDR, EU 2017/745) [13]. The MDR contains a lot of technical and clinical requirements, that medical devices must comply with. Under the MDR European Notified Bodies are designated to approve the medical device and hence will also influence the development of the device. Requirements preventing additional risks to the patient are important. If the device harms the patient, it will not be approved by the NB. Functionalities that are important for this stakeholder are listed below and can be seen in table 2.1 and 2.2.
• F.1.: The device must be sterilizable.
• F.2.: The examination should not cause any additional risks
• F.8.: The outer diameter of the end-effector should not exceed 6 mm.

Manufacturer of the device
For the manufacturers, the device must be realistic to build. The more complex the production steps are, the more expensive it becomes and the less chance it has to realize. Therefore, the manufacturers have an interest in keeping the overall costs relatively low. The main 'money eaters' are the production and testing costs, specifically the cost of doing a clinical trial if that is required by the authorities to get the device approved. Therefore, the design choices for the device are important, for example, shape and material influence the manufacturing process. The stakeholder itself doesn't have requirements, but the functionalities that influence this stakeholder are listed below and can be seen in table 2.1 and 2.2.
• F.1.: The device must be sterilizable.
• F.4.: There should be a water nozzle.
• F.6.: The part of the end-effector should fit on the CTR and therefore should have an outer diameter of 3,45 mm.
• F.9.: The OCT sensor should fit inside a tube with an outer diameter of 2,7 mm to make translation and rotation of the OCT sensor possible.

Patients
The patients themselves may not be real stakeholders as they do not influence the design. However, the device will be used on the patient. Since it goes into the body of the patients, they prefer that the intervention should not bring any additional risks and that it is minimally invasive. Aspects that could jeopardize this are an extension of the intervention time, which could increase the chance of infection. Some requirements can affect the patient. These requirements are listed below. Each functionality is matched to a requirement, which can be seen in table 2.1 and 2.2.
• F.1.: The device must be sterilizable.
• F.2.: The examination should not cause any additional risks.

Developers of the device
The developer itself would want to design a useful device that can be used in practice, that can help the urologist and the patient with better and faster diagnoses. Therefore, all requirements are listed below, because they all influence the developers. These may not be requirements of the developer himself, but the developer will have to take into account as many requirements as possible. The functionalities corresponding to those requirements are listed below and can be seen in table 2.1 and 2.2.
• F.1.: The device must be sterilizable.
• F.2.: The examination should not cause any additional risks
• F.3.: The camera should be kept in place, while rotating the OCT sensor.

• F.4.: There should be a water nozzle.
• F.5.: The camera should acquire images of similar or better quality than the camera system ofthe Olympus CYF-VH Flexible video Cystoscope.
• F.6.: The part of the end-effector should fit on the CTR and therefore should have an outer diameter of 3,45 mm.
• F.7.: It should be possible to rotate and translate the OCT sensor.
• F.8.: The outer diameter of the end-effector should not exceed 6 mm.
• F.9.: The OCT sensor should fit inside a tube with an outer diameter of 2,7 mm to make translation and rotation of the OCT sensor possible.

2.2 Requirements

2.2.1 Functional Requirements

Table 2.1 provides an overview of all the functional requirements (with corresponding specifications and stakeholders) based on the boundary conditions. Boundary conditions define the boundaries within which the device must operate but are not functions of the device.

Table 2.1: List of functional requirements

No.	Function	No.	Requirement	Stakeholders
F.1.	The device must be sterilizable.	**R.1.**	The device should be resistant to autoclave sterilization (121-132°C) [7], low-temperature sterilization (EtO or gamma irradiation) or another way of sterilization. All the equipment that comes close to or goes into the patient has to be sterilized so the risk of infection is minimized.	Manufacturer, Patients, Developers, Urologist, Insurance company, NB
F.2.	The examination should not cause any additional risks.	**R.2.**	The device should not have sharp edges which can harm the patients.	Developers, Urologist, Insurance company, Patients, NB
F.3.	The camera should be kept in place, while rotating the OCT sensor.	**R.3.**	To obtain a high-quality image when using the OCT sensor, the camera must rNBin in place during the OCT measurement.	Developers, Urologist

2.2.2 Technical Requirements

Table 2.2 provides an overview of all the technical requirements (with corresponding specifications and stakeholders) based on the boundary conditions. Boundary conditions define the boundaries within which the device must operate but are not functions of the device.

Table 2.2: List of Technical requirements

No.	Function	No.	Requirement	Stakeholders
F.4.	There should be a water nozzle.	**R.4.**	To get an image of the bladder wall, the bladder must be partially filled with water. Therefore, a water nozzle will be important.	Developers, Urologist, Manufacturer, Financier
F.5.	The camera should acquire images of similar or better quality than the camera system of the Olympus CYF-VH Flexible video Cystoscope.	**R.5.**	The camera images must be of sufficient quality to be able to conclude the examination.	Developers, Urologist
F.6.	The part of the end-effector that should fit on the CTR and should have an inner diameter of 3,0 mm.	**R.6.**	The end-effector must be designed to fit the concentric tube robot (CTR). Therefore, it should fit on or inside a tube with an outer diameter (OD) of 2,9 mm.	Developers, Manufacturer
F.7.	It should be possible to rotate and translate the OCT-sensor.	**R.7.**	The OCT sensor can make a small translation for focusing on the image, and a rotation of a minimal 180° to get different angles of the region of interest.	Developers, Urologist
F.8.	The outer diameter of the end-effector should not exceed 6 mm.	**R.8.**	To prevent damage to the urethra, OD of the end effect should not exceed 6 mm.	Developers, Urologist, Insurance company, NB
F.9.	The OCT-sensor should fit inside a tube with an outer diameter (OD) of 2,6 mm to make translation and rotation of the OCT-sensor possible.	**R.9.**	The OCT-sensor should fit inside a tube to make rotation and translation of the OCT-sensor possible. This tube may have a maximum of 2,6 mm to fit through the CTR.	Developers, Manufacturer

2.3 Requirements rating

Now that all requirements are defined, they can be ranked based on their importance. This has been done by questioning some stakeholders and looking at the literature, however, it stays subjective. The range of the weighting factor is from 1 to 4. A scaling of 4 means that it is the most important, such as the patient's safety. Factor 3 is still important, such as the goals of the device. Factor 2 indicates medium importance and factor 1 is the least important, all relative to each other. This rating will be used to evaluate the concepts that are explained in chapter 3.

Table 2.3: Table of requirements with their weighting factor and corresponding substantiation

Requirements	**Weight factor**	**substantiation**
Functional requirements		
R.1.	4	Failure to sterilize the device can lead to complications for the patient, such as infections.
R.2.	4	If the device creates additional risks, this can lead to complications for the patient.
R.3.	1	If the camera cannot be held in place, it is difficult to obtain a good image and OCT scan of the area of interest.
Technical requirements		
R.4.	3	If there is no water jet nozzle, the bladder cannot be filled sufficiently, making it more difficult to obtain a clear image of the bladder.
R.5.	3	If the camera cannot provide a clear image, it is difficult to properly inspect the bladder wall.
R.6.	3	If the end effector does not fit on the CTR it can fall off.
R.7.	2	When the OCT sensor can rotate and translate, a good image of the area of interest can be made. Allowing translation allows the OCT sensor to focus and allowing rotation allows an image to be taken from different angles.
R.8.	4	If the end-effector does not fit in the urethra, the device cannot be used.
R.9.	1	If the OCT sensor fits in a tube, rotation, and translation will be more possible.

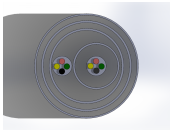
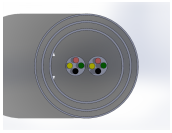
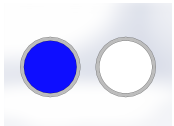
Chapter 3

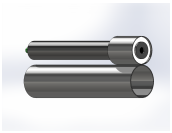
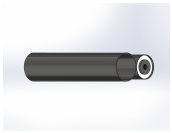
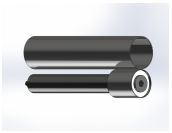
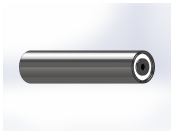
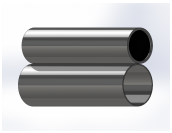
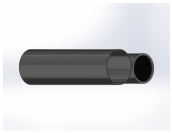
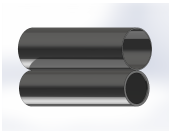
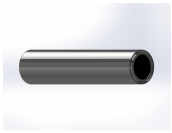
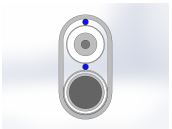
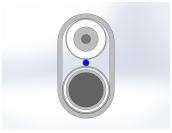
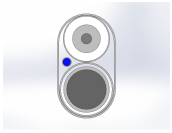
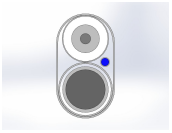
Concept designs

3.1 Morphological scheme

A morphological scheme is made to combine different possibilities for different requirements into several concepts. This diagram is shown in 3.1. The tiny blue numbers represent which solution is chosen for which concept. The drawings of each concept can be seen in the Appendices.

Table 3.1: Morphological scheme

	Option 1	**Option 2**	**Option 3**	**Option 4**	**Option 5**
Wires	 OCT wires in a different tube than water jet and camera and light wires[2, 7]	 All wires and the water jet are in the most central tube [1,3,4,5,6]			
Type of Lights	 Blue light [1,3,7]	 White light [2]	 Blue and White light [6]	No extra light [2,4,5]	
Number of lights	0 (only light from the camera) [1,2,3,6,7]	1 fiber light and light from the camera	2 fiber lights and light from the camera [4,5]	3 fiber lights and light from the camera	

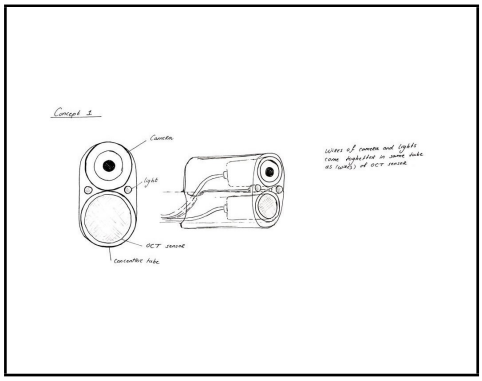
Type of Camera	1/18" Color CMOS LED Camera (MD-V1001LH-91X [1,2,4,5,6,7]	1/10" Color CMOS LED Camera (MD-V1003TL-65) [3]	1/9" Color CMOS 720p LED Camera (FXD-VB20903L-76)		
Position Camera	 Camera on top of tube [1,2,4,7]	 Camera on side of tube	 Camera at bottom of tube	 Camera inside tube [3,6]	 Camera attached with hinges to tube, so it can be placed in front of tube [5]
Position OCT	 OCT on top of tube [3,6]	 OCT on side of tube	 OCT at bottom of tube [1,2,4,5,7]	 OCT inside tube	
Position fiber lights	No extra light [4,5]	 Two lights between OCT and camera [1,2,3,6,7]	 Two lights above and under camera	 One light under camera	 One light above camera
Position water jet	 Water jet under camera [6,7]	 Water jet left of camera	 Water jet right of camera	 Water jet above camera	No water jet [1,2,3,4,5]

Movement OCT	Camera and OCT sensor are moving 3,6	Only OCT sensor moves 2,7	Neither the camera or OCT sensor can move 1,4,5		
Direction OCT movement	OCT sensor can move back and forth	OCT sensor can rotate	OCT sensor can move back and forth and can rotate 2,7	The sensor and camera can't move 1,3,4,5,6	
Protection cap	Without protection cap at the front 1,2,3,4,5	With protection cap at the front 6,7			

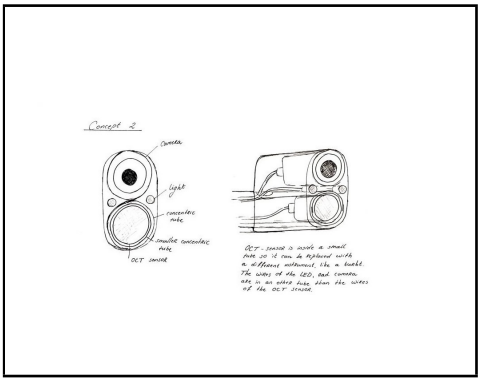
Solution ideas that were not chosen for any of the concepts do not have an enhancement. These solutions were not chosen for several reasons, however most times the solutions were too complex for a realistic implementation of the concepts or were not efficiently arranged.

3.2 Concepts

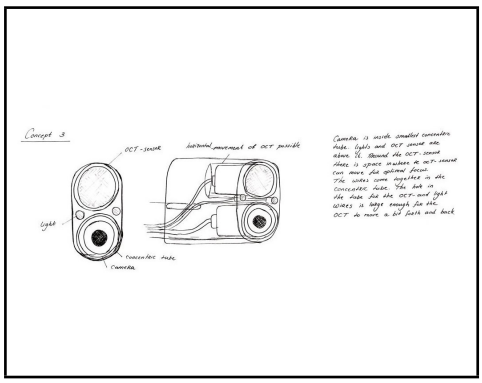
Based on the morphological scheme, various concepts have been made and can be seen below in figure 3.2. Each concept has a short description of how the concept should be interpreted. The concepts were first sketched on paper before some of the concepts were further developed in Solidworks.



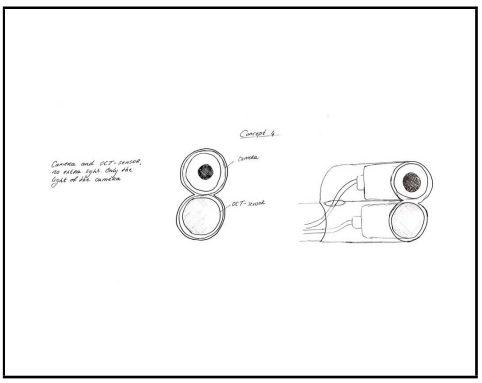
(a) Sketch concepts 1



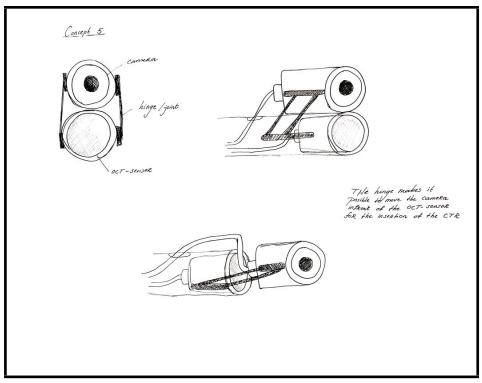
(b) Sketch concepts 2



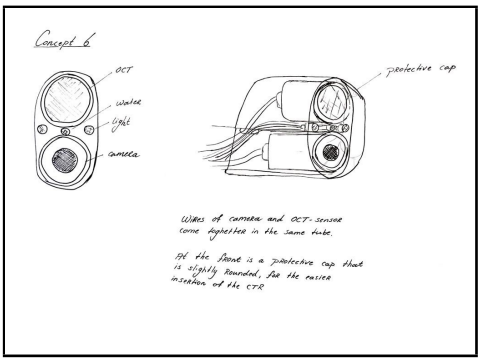
(c) Sketch concepts 3



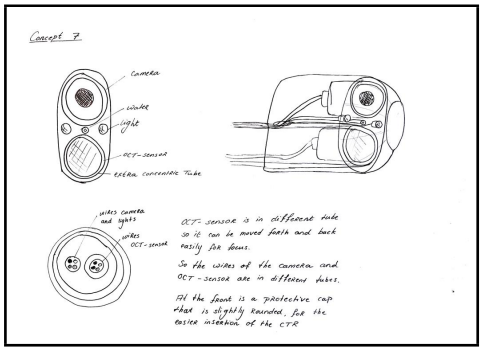
(d) Sketch concepts 4



(e) Sketch concept 5



(f) Sketch concept 6



(g) Sketch concept 7

Figure 3.2: Sketches of all concepts

3.3 Concept evaluation

When the various concepts were made, the concepts were presented to some of the stakeholders. To get a clear picture of the preferences a concept rating was made. In this concept rating, an overview of the requirements with corresponding weighting factors from table 2.3, and substantiation can be seen. The concepts are rated from one to three. Where one means that the concept does not meet the requirement, two means that the concept partially meets the requirement, and three means that the concept fully meets the requirement. The rating was then multiplied by the weighting factor, resulting in a total number of points.

Table 3.2: Requirements rating

		Concept 1		**Concept 2**		**Concept 3**		**Concept 4**	
Requirements	Weight	Rating C1	Rating C1 * Weight	Rating C2	Rating C2 * Weight	Rating C3	Rating C3 * Weight	Rating C4	Rating C4 * Weight
Functional Requirements									
R.1.	4	3	12	3	12	3	12	3	12
R.2.	4	1	4	1	4	1	4	1	4
R.3.	1	1	1	3	3	1	1	1	1
Technical Requirements									
R.4.	3	1	3	1	3	1	3	1	3
R.5.	3	2	6	2	6	3	9	2	6
R.6.	3	3	9	3	9	2	6	2	6
R.7.	2	3	6	3	6	1	3	1	3
R.8.	4	3	12	3	12	1	4	3	12
R.9.	1	2	2	3	3	1	1	1	1
Total:		55		58		43		48	

		Concept 5		**Concept 6**		**Concept 7**	
Requirements	Weight	Rating C5	Rating C5 * Weight	Rating C6	Rating C6 * Weight	Rating C7	Rating C7 * Weight
Functional Requirements							
R.1.	4	1	4	3	12	3	12
R.2.	4	1	4	2	8	2	8
R.3.	1	1	1	1	1	3	3
Technical Requirements							
R.4.	3	1	3	3	9	3	9
R.5	3	2	6	1	3	1	3
R.6.	3	3	9	3	9	1	3
R.7.	2	1	2	1	2	3	6
R.8.	4	1	4	1	4	1	4
R.9.	1	1	1	1	1	3	3
Total:		34		49		51	

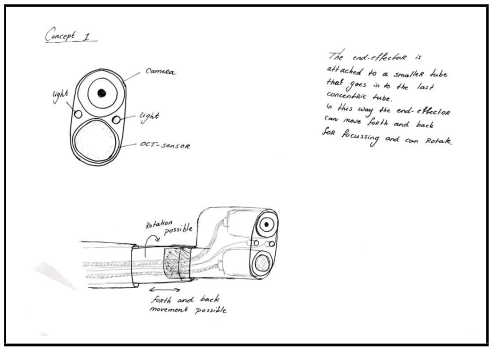
The outcome of the rating shows that concept 1 and concept 2 seem the most suitable, mostly due to their small designs and their ability of a rotating and translating OCT sensor. In chapter 4 these concepts will be further discussed.

Chapter 4

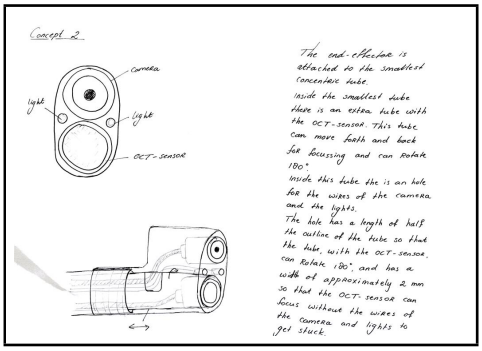
Iteration concept designs

4.1 Concepts

After evaluating all concepts, concept 1 and concept 2 seemed the most suitable. The sketches of those concepts can be seen in figure 3.1a and 3.1b. Those sketches were improved and can be seen in figure 4.1. The figure shows a more detailed sketch of both concepts with a more extensive description.



(a) Extensive sketch concept 1

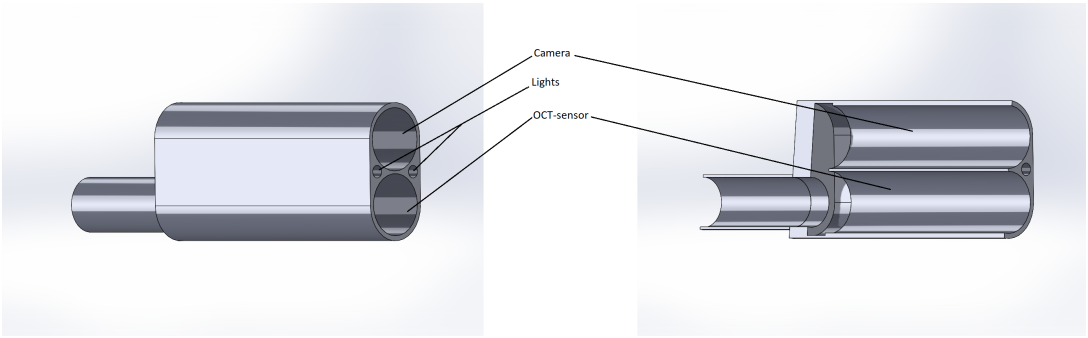


(b) Extensive sketch concept 2

Figure 4.1: Extensive sketches of concepts 1 and 2

Concept 1

Concept 1 is, of the two concepts, the smallest one. It has a height of 5,5 mm and a length of 12 mm, which makes it a compact design. The design contains an OCT sensor, a camera, and two lights. The camera chosen for this design is the 1/18" Color CMOS LED Camera, its specifications can be seen in appendix A.1. The main reason for choosing this camera is due to its small diameter. This makes it possible to keep the height of the design smaller than 6 mm, which is an important requirement. The end-effector is attached to a rigid tube that runs through the CTR to allow rotation and translation of the OCT sensor. Because the entire end-effector is connected to the rigid tube, the camera will also rotate when the OCT sensor is rotated. The wiring from the camera, lights, and OCT sensor runs through this tube to the start of the robot.

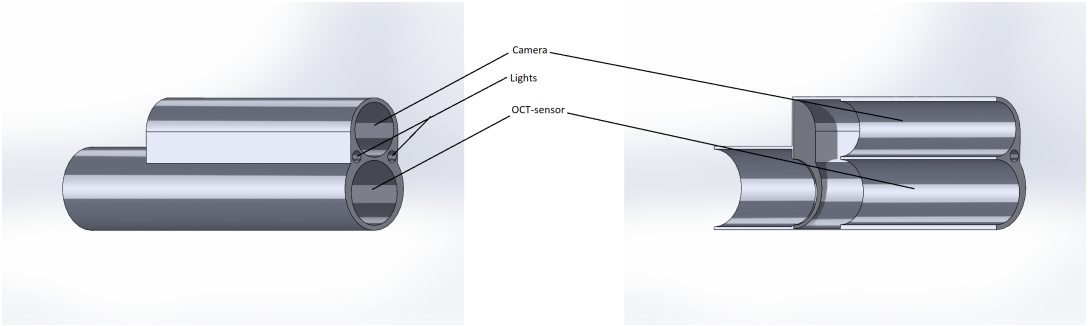


(a) Full image concept 1 *(b) Cross section concept 1*

Figure 4.2: Solidworks design concept 1

Concept 2

Concept 2 is very similar to concept 1 but differs mainly in how the OCT sensor rotates in relation to the camera. This design is a bit bigger than the other concept. It has a height of 6 mm and a length of 13 mm. The same camera, a 1/18" Color CMOS LED Camera, is used for this concept afresh due to its smaller diameter. The rotation of the OCT sensor is possible in a different way than in concept 1. Only the OCT sensor is attached to the rigid tube in this concept. Therefore, the OCT sensor can rotate and translate while the camera remains in the same position. However, the wiring from the OCT sensor, the camera, and the lights must pass through the rigid tube, while only the OCT sensor is inside this tube. A small semi-circular notch has been made in the tube to accommodate the wiring of the camera and lights. A half-circular notch has been chosen so that the OCT sensor can make a rotation of 180°. A rotation of 180° is enough for the OCT sensor to obtain images in all possible directions.



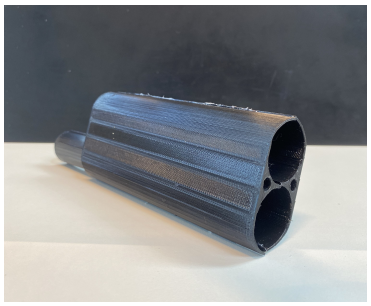
(a) Full image concept 2 *(b) Cross section concept 2*

Figure 4.3: Solidworks design concept 2

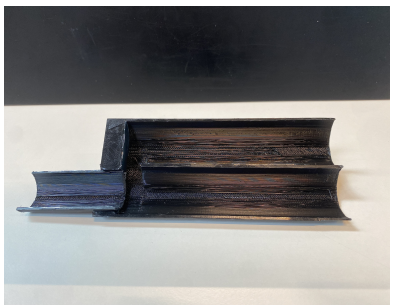
4.2 Concept evaluation

After designing the concepts in Solidworks, they were printed using the Ultimaker 2 printer. The Ultimaker 2 was used because the prototypes did not have to be of high quality, they mainly had to be printed quickly. The concepts were printed on a scale of 1:10, so that they could be properly evaluated. Those concepts can be seen in figure 4.4 and 4.5. After printing the concepts, the designs were presented to some stakeholders, and subsequently, the requirements were reviewed again.

(a) Front view of concept 1 on a scale of 1:10

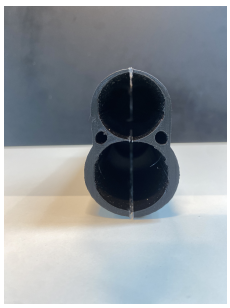


(b) Oblique view of concept 1 on a scale of 1:10

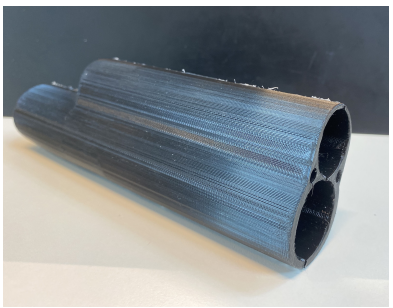


(c) Cross section of concept 1 on a scale of 1:10

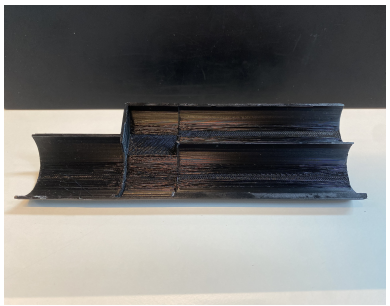
Figure 4.4: Foto's of concept 1 on a scale of 1:10 in different angles.



(a) Front view of concept 2 on a scale of 1:10



(b) Oblique view of concept 2 on scale 1:10



(c) Cross section of concept 2 on a scale of 1:10

Figure 4.5: Foto's of concept 2 on a scale of 1:10 in different angles.

From the discussion with the stakeholders, the requirements were rated. Table 4.1 shows an overview of the requirements with corresponding weighting factors and substantiation. This rating was used to evaluate the concepts and choose the best of them.

Table 4.1: Requirements rating

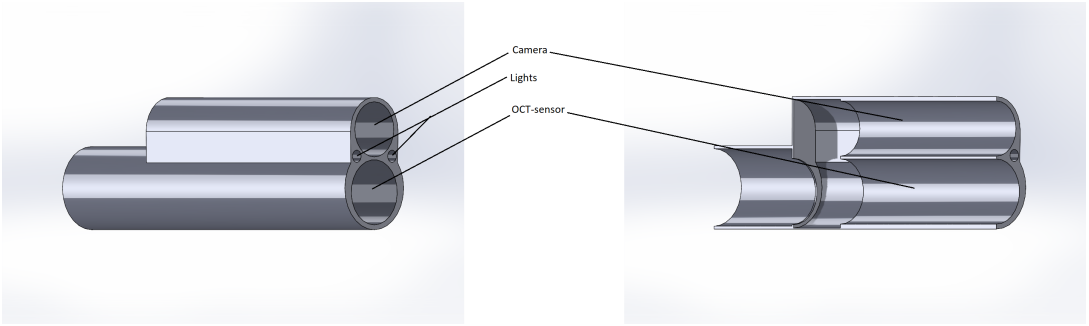
		Concept 1		**Concept 2**	
Requirements	Weight	Rating C1	Rating C1 * Weight	Rating C2	Rating C2 * Weight
Functional requirements					
R.1.	4	3	12	3	12
R.2.	4	1	4	1	4
R.3.	3	1	3	3	9
Technical Requirements					
R.4.	3	1	3	1	3
R.5.	3	3	9	3	9
R.6.	3	3	9	3	9
R.7.	2	3	6	3	6
R.8.	4	3	12	3	12
R.9.	1	2	2	3	3
Total:		60		67	

It can be seen from the table 4.1 that concept 2 is the most suitable. The biggest difference, and the reason why concept 2 is the most suitable, is due to requirement R.3. This requirement says that the camera should be kept in place, while rotating the OCT sensor. This requirement was only present in concept 2, and was of great importance to the urologist. Concept 2 is further improved, and discussed in chapter 5.

Chapter 5

Final Design

After evaluating the concepts, concept 2 seemed the most suitable and best matches the requirements of the stakeholders. The Solidworks design of this concept can be seen below in figure 5.1. After making the design in Solidworks, it was 3D printed on a scale of 1:10. This 3D printed design was shown to some stakeholders. One of those stakeholders was the urologist. The urologist saw the advantages of this design. For example, in this design, the OCT sensor can rotate and translate while the camera remains in place. This is important for obtaining a distinct OCT image. When the OCT sensor can rotate and translate, suspicious tissue can be viewed from multiple angles and a complete image of this tissue can be created. In addition to this advantage, there were also some points for improvement. The design did not have a water jet. To get an image of the bladder wall, the bladder must be partially filled with water. Therefore, the presence of a water jet is important. In addition, the edges of the design were too sharp and has a risk of harming the patient. To prevent this, the edges must be rounded. The printed model also showed that the wall thicknesses had been made too thin. This could cause the design to break, which could lead to unsafe situations. In addition, printing the design at a scale of 1:1 would be very difficult.

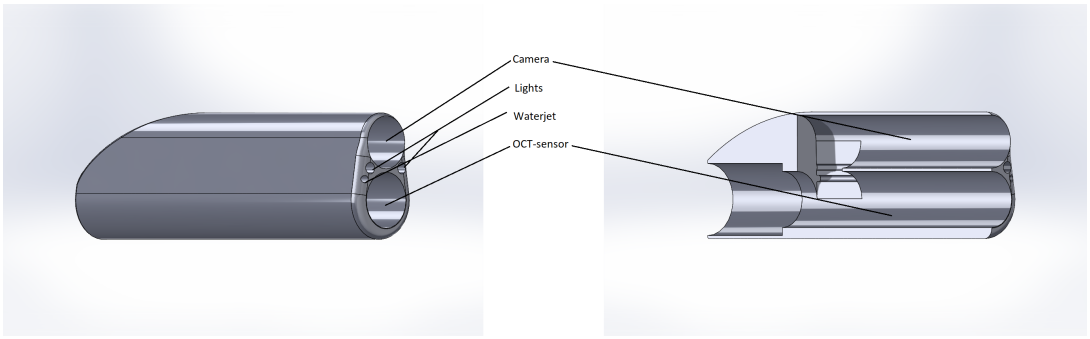


(a) Full image concept 2 *(b) Cross section concept 2*

Figure 5.1: Solidworks design concept 2

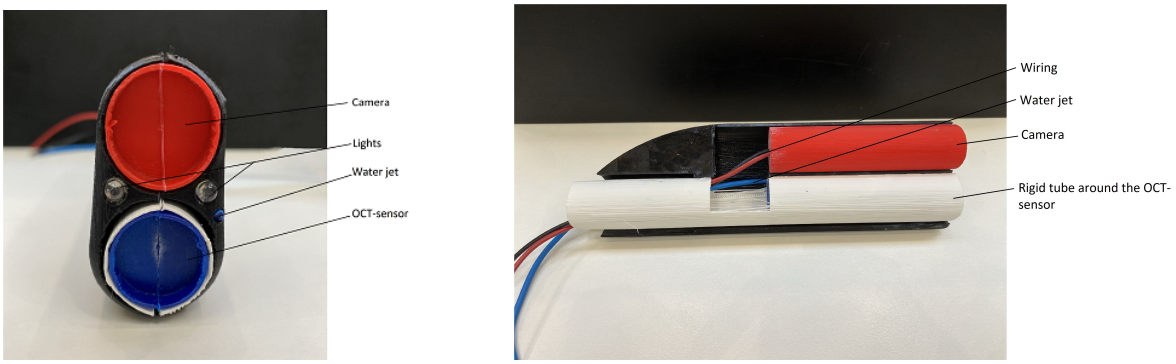
5.1 Design choices

After the adjustments, an improved design was made and can be seen in 5.2. This design was again printed on a scale of 1:10, which can be seen in figure 5.3. The design contains a camera, an OCT sensor, two lights, and, different from the previous concepts, a water jet nozzle. The camera that was chosen is still the 1/18" Color CMOS LED camera. This is because the requirement that the total diameter may not exceed 6 mm to prevent damage to the urethra must be adhered to. If a larger camera was chosen, the diameter would be greater than 6 mm.



(a) Full image concept 3 *(b) Cross section concept 3*

Figure 5.2: Solidworks design concept 3



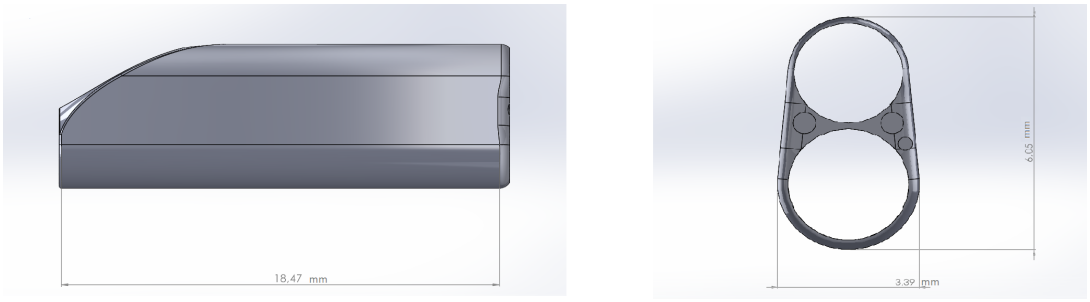
(a) Frond view end-effector 1:10 *(b) Crossection end-effector 1:10*

Figure 5.3: 3D printed representation of the end effector at a scale of 1:10

In figure 5.3 it can be seen that only the OCT sensor is inside a rigid tube which makes rotation and translation possible while the camera remains in the same position. This causes only the wiring of the OCT sensor to pass through the center of the CTR, while it is also required for the water jet and the wiring of the camera and the lights. Therefore, a small semi-circular notch has been made in the tube containing the OCT sensor, to let the water jet nozzle and the wiring of the camera, lights, and OCT sensor join together. A half-circular notch has been chosen so that the OCT sensor can still make a rotation of 180°, while the wires can move freely. A rotation of 180°is enough for the OCT sensor to obtain images from different angles of the region of interest. The notch has a width of 5 mm to allow the OCT sensor to translate for focusing the image.

Two lights, in addition to the lights of the camera, are added. The two extra lights ensure that the camera gets enough light for a clear image. At last, all sharp edges in this concept have been made rounder to avoid damage to the urethra.

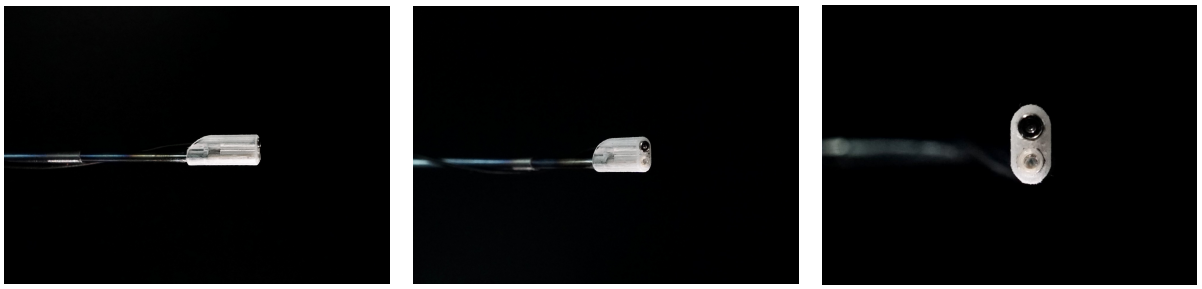
The design has a height of 6 mm, a width of 4 mm, and a length of 18.5 mm. A maximal diameter of 6 mm was chosen because the diameter of the urethra is also 6 mm. If the device was bigger, it could damage the urethra. The width should also have been a maximum of 6 mm, but it turned out to be smaller. It has a length of 18.5mm, because the camera and OCT sensor itself already have a length of 10 mm. This is followed by a spacing where the wiring from the camera and lights and the water jet are joined with the wiring from the OCT sensor. A length of 5 mm has been taken for this. Finally, some space is needed to mount the end-effector on the CTR, which together amounts to a length of 18.5 mm.



(a) Side view with measurements concept 3 *(b) Front view with measurements concept 3*

Figure 5.4: Measurements concept 3

This final design was printed with the Stratasys Objet260 Connex3 printer. This is the highest resolution printer of RaM. It uses PolyJet technology. The Polyjet print head uses liquid photopolymers to create models. It prints layer upon layer of the photopolymers on the build tray [11]. The material now used was Vero Clear, which is perfect for prototypes to test fit, form, and function. The printed prototype can be seen in figure 5.5.



(a) Side view of the end-effector on scale 1:1 *(b) Oblique view of the end-effector on scale 1:1* *(c) Front view of the end-effector on scale 1:1*

Figure 5.5: Foto's of the end-effector on scale 1:1 in different angles.

5.2 Requirements assessment

Table 5.1 helps to check whether the final design meets all the requirements. The Requirement numbers R.1. till R.9. indicate the requirements described in tables 2.1 and 2.2. The design is tested based on whether or not it satisfied the requirements. The symbol '+' means that the design completely satisfied the requirement and the symbol '+/-' means that the design did satisfy the requirement but there is still room for improvement.

Table 5.1: Assessment of the requirements

Requirements	Satisfied	Elaboration
Functional Requirements		
R.1.	+/-	Various types of 3D printing material have been reviewed to look at the ability to sterilize. BioMed White resin would be very suitable for this. However, this has not yet been used in this prototype.
R.2.	+/-	It is difficult to completely rule out additional risks. However, it is taken into account as much as possible. For example, there are no sharp edges on the end-effector that could harm the patient.
R.3.	+	The OCT sensor is in a different rigid tube than the camera. This allows the camera to remain stationary when the OCT sensor is rotated.
Technical Requirements		
R.4.	+	To partially fill the bladder with water, a water jet nozzle has been added to the design.
R.5.	+	The 1/18" Color CMOS LED Camera (MD-V1001LH-91X) is used in the design. This camera gives equivalent image material compared to the Olympus CYF-VH Flexible video Cytoscope.
R.6.	+/-	The part of the end-effector that should fit on the CTR has an OD of 3,39 mm. It turned out that the wall thicknesses were sometimes designed too thin. So when the wall thicknesses become thicker, this may become too tight.
R.7.	+	The OCT sensor is inside a rigid tube. This makes rotation and translation possible, while the camera remains in the same place.
R.8.	+	The OD of the end-effector is 6 mm.
R.9.	+/-	The OCT sensor is personalized. This would allow it to meet the requirement that it will become smaller than 2,6 mm. But since it's not ready yet, it's hard to say for sure.

Chapter 6

Experiment

To test the functionality of the end-effector, an experiment will be done. The purpose of this experiment is to reconstruct a map of the inner layer of a bladder, and to see if the end-effector remains in place. To simplify this experiment, a half-dome is 3D-printed and used instead of a real bladder. The inside of the dome is lined with a print. When looking at the inside of the half doom with a camera, the print makes it more clear to see where the camera is located and easier to reconstruct the map.

6.1 Setup

To perform this measurement, a set-up has been made. The measurement setup consists of a 3d-printed half dome, lined with a print, on a stand. In front of this half-dome, the CTR is placed with the end-effector attached to it. Inside the end-effector, the camera is placed. The measurement setup can be seen in figure 6.1.

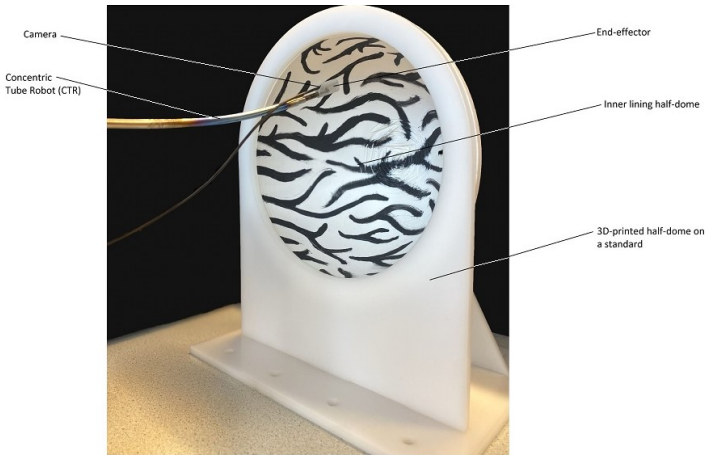


Figure 6.1: Experimental setup

6.2 Measurement

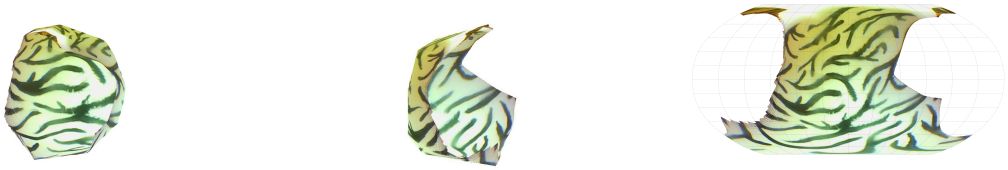
During this measurement, the end-effector containing the camera will be attached to the CTR. The CTR will then be controlled so that it will move slowly through the dome. While moving through the dome, the camera will take snapshots of the inner layer of the dome. The snapshots will then be connected so that a map can be reconstructed.

Before the measurement could begin, the CTR had to be calibrated. By calibrating it can be determined where the end-effector of the robot is located. Besides, in the case of this

measurement, the robot could be set up properly for analysing the half dome. When the robot was properly calibrated, the measurement could begin. It is important for the measurement that the half-dome would not move anymore when the measurement was started. This is because the robot made a very small translation each time after a snapshot was taken. By keeping the translation small, the image can be better attached to the next one, because parts of the images overlap. In figure 6.2 the reconstruction of the inner layer of the half-dome can be seen.

6.3 Results

After the snapshots were made, a 3D model of the inner layer of the half-dome was reconstructed, which can be seen in 6.2 *a* and 6.2 *b*. Besides, a 2D map was made which can be seen in 6.2 *c*.



(a) Reconstruction inner layer of the half-dome front view

(b) Reconstruction inner layer of the half-dome side view.

(c) Reconstruction inner layer of the half-dome as a map.

Figure 6.2: Foto's reconstruction of the half-dome's inner layer.

6.4 Discussion and Conclusion

In figure 6.2 a reconstructed model of the inner layer of the half-dome can be seen. When looking at those reconstructions, it can be seen that the different snapshots fit together well. However, some parts are a bit choppy. When reconstructing the photos into a map, nearest-neighbor interpolation was used. This means that the pixels of one photo are replaced with the pixels of another photo that most closely resemble these pixels. In this way, the photos are put together but can sometimes result in a bit of a choppy image. The mean of the pixels could also have been used, but because the snapshots were made quite close together, this would have resulted in a somewhat vaguer image. If this experiment will be performed again, the distance between each photo should be taken into account.

In figure 6.2 *c* one can clearly see that the digital map is not completely filled. This is due to the lack of photos on the edges of the half dome. Because the CTR is still in its early stages, the experiment took longer than expected. Because of this, only a certain number of snapshots were made where the edges of the half-dome, unfortunately, did not show up well. When repeating this experiment, attention should be paid to taking snapshots of the edges of the half-dome as well.

Although the experiment is still in its early stages, which means there is still much room for improvement, the goal of the experiment, *to reconstruct a map of the inner layer of a bladder, and to see if the end-effector remains in place*, has been achieved. The map is not fully complete, and some parts are a bit choppy, but one can say that it is a clear map of the inner lining of the half-dome, where the snapshots fit together well.

Chapter 7

Discussion

This report presents the design of an end-effector for a concentric tube robot for the detection of bladder cancer. It describes an Introduction, Design procedures, conceptualizing, determining a final design, and Experiment. While working on this thesis, there appeared some points of discussion, which will be explained in this Chapter. In addition, some recommendations will be made.

Table 5.1 shows that the final design almost meets all requirements completely. However, there are some discussion points and recommendations that could benefit future redesigns.

The first requirement of table 2.1 states that the device must be sterilizable. There is still room for improvement in the current prototype. The current prototype is printed using Vero Clear. A polymer that is perfect for printing prototypes to test fit, form, and function, but can't resist the high temperatures or chemicals used during the sterilization process. Besides, Vero Clear isn't a biocompatible material. Also, a point for improvement, because this goes against requirement two. In requirement two, it is stated that the examination should not cause any additional risks. In addition, for this reason, the material used for printing must be improved. The material is not biocompatible , which could cause microplastics to remain behind in the patient. In this report, BioMed White resin was briefly mentioned, an example of a material that is biocompatible and can be sterilized. In a follow-up study, this material or another material that is suitable for this could therefore be further investigated. When the device will be used in practice, it should be printed with a different material.

Requirements six to nine of table 2.2 relate to the dimensions of the end-effector. After printing the end-effector, the wall thickness turned out to be a bit on the thin side. This resulted in very fragile prototypes. When the wall thicknesses were made thicker, the end-effector either became too large or interfered with the dimensions of the CTR, camera, and OCT sensor. In this design, it was therefore decided to leave the wall thicknesses on the thin side, to meet the other requirements. However, this should be taken into account in future studies.

Requirements three, seven, and nine of tables 2.1 and 2.2 relate to the OCT sensor. The OCT sensor is especially designed for this project and was therefore not yet available during the design process and the experiment. This meant that the experiment could only be done with the camera. For further follow-up research, the OCT sensor might be included in the experiment.

Requirement five of table 2.2 relates to the camera. The camera currently used is the 1/18" Color CMOSLED Camera. This camera has a built-in LED light. Something that can be ques-

tioned. There must be enough light for the camera to get clear images, but light integrated into the camera also takes away space. Space that might be more efficient when the lights are separate from the camera. Now the end effector is about 6 mm high and 4 mm wide. This width of 4 mm may go up to a maximum of 6 mm. When this unused space can be used for light, there will be more space for the camera. This free space could, for example, be used to look at a camera with better image quality.

Chapter 8

Conclusion

Bladder cancer is the tenth most common cancer type worldwide [1], and yet cystoscopy is incorrect in 43 % of bladder cancer cases [2]. Therefore an end-effector for a CTR that aims to improve the detection of bladder cancer is designed.

After designing seven concepts for an end-effector that fits this CTR, and redesigning two of them, a final concept was chosen. This final concept was further elaborated in Solidworks, where after some prototyping 3D prints were made on a scale of 1:10. The design has been discussed with some stakeholders, including the urologist, after which some requirements have been adjusted and the latest version of the design has been made.

This final design is printed on a scale of 1:1 and used for measurements. The goal of the measurement was the see if the end-effector fits the CTR and would provide that a clear image of the inner lining of a half-dome can be made using the 1/18" Color CMOS LED camera.

Concluding, the goal of this thesis: *"Design a rapid prototype end-effector of a concentric tube robot for the detection of bladder cancer using digital mapping and OCT of the regions of interest"* has been achieved. The design meets most of the requirements and can be used for digital mapping, which can be concluded from table 5.1 and chapter 6. Further research can use this report to improve the design by taking the recommendations of chapter 7 into account.

References

[1] A. Richters, K. K. Aben, and L. A. Kiemeney, *The global burden of urinary bladder cancer: an update*, Aug. 2020. DOI: 10.1007/s00345-019-02984-4.

[2] S. Pearce and S. Daneshmand, *Enhanced Endoscopy in Bladder Cancer*, Oct. 2018. DOI: 10.1007/s11934-018-0833-9.

[3] Z. Kirkali, T. Chan, M. Manoharan, *et al.*, "Bladder cancer: Epidemiology, staging and grading, and diagnosis," in *Urology*, vol. 66, Dec. 2005, pp. 4–34. DOI: 10.1016/j.urology.2005.07.062.

[4] M. C. Kriegmair, T. Bergen, M. Ritter, *et al.*, "Digital Mapping of the Urinary Bladder: Potential for Standardized Cystoscopy Reports," *Urology*, vol. 104, pp. 235–241, Jun. 2017, ISSN: 15279995. DOI: 10.1016/j.urology.2017.02.019.

[5] H. B. Gilbert, D. C. Rucker, and R. J. W. Iii, "Concentric Tube Robots: The State of the Art and Future Directions," Tech. Rep.

[6] S. P. Lerner and A. Goh, *Novel endoscopic diagnosis for bladder cancer*, Jan. 2015. DOI: 10.1002/cncr.28905.

[7] W. A. Rutala and D. J. Weber, *Authors — Disinfection & Sterilization Guidelines — Guidelines Library — Infection Control — CDC*. [Online]. Available: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/authors.html.

[8] O. Oth, C. Dauchot, M. Orellana, and R. Glineur, "How to Sterilize 3D Printed Objects for Surgical Use? An Evaluation of the Volumetric Deformation of 3D-Printed Genioplasty Guide in PLA and PETG after Sterilization by Low-Temperature Hydrogen Peroxide Gas Plasma," *The Open Dentistry Journal*, vol. 13, no. 1, pp. 410–417, Dec. 2019, ISSN: 1874-2106. DOI: 10.2174/1874210601913010410.

[9] S. Pérez Davila, L. González Rodríguez, S. Chiussi, J. Serra, and P. González, *How to sterilize polylactic acid based medical devices?* Jul. 2021. DOI: 10.3390/polym13132115.

[10] D. Shilo, O. Emodi, O. Blanc, D. Noy, and A. Rachmiel, "Printing the Future—Updates in 3D Printing for Surgical Applications," *Rambam Maimonides Medical Journal*, vol. 9, no. 3, e0020, Jul. 2018. DOI: 10.5041/rmmj.10343.

[11] "What is the Polyjet process in 3D Printing_ Pros and Cons,"

[12] "Using BioMed White Resin," [Online]. Available: https://support.formlabs.com/s/article/Using-BioMed-White-Resin?language=en_US.

[13] M. Zaczyk, "Legal and Normative Requirements Related to Medical Devices for Individual Supply in Clinical Practice," *Ortopedia Traumatologia Rehabilitacja*, vol. 23, no. 5, pp. 381–387, 2021, ISSN: 15093492. DOI: 10.5604/01.3001.0015.4360.

Appendix A

Appendixes

A.1 Camera

For the use of digital mapping, a camera is needed. Therefore, a camera with the right specifications needs to be chosen. Below three different types of cameras with their specifications are listed in table A.1.

Table A.1: Camera specifications of different camera types

	1/18" Color CMOS LED Camera (MD-V1001LH-91X)	**1/10" Color CMOS LED Camera (MD-V1003TL-65)**	**1/9" Color CMOS 720p LED Camera (FXD-VB20903L-76)**
Costs	$1,270	$570	$308
Image Area	741 um × 707 um	1224 um × 1212 um	1.819 mm x1.033 mm
Pixel size	1.75um x 1.75um	3.0um × 3.0um	1.4um x 1.4um
Frame rate	400(H) x 400(V) @30fps	400 x 400 @ 30fps	160 x 120 @ 30fps
Sensitivity	1000mV/Lux-sec	3.0[V/Lux.sec], 2 Lux F3.4	585 mV/(Lux-sec)
Shutter speed	1/30 sec.	x	rolling shutter
Lens	0.5mm/F3.6(91 degree)	1.498mm/F5.0 H=44°27';V=44°3'; D=59°43'	1.32mm/F3.5 (M2.8xP0.2) H=69°8';V=42°44'; D=76°44'
FID	20-05-40mm	45-20-70mm	45-25-80mm
Power	DC 5V, 170mA	DC5V, 200mA(Max)	DC 5V, 120mA
Dimensions (mm)	2.5(D)x11(L)	3.8(D)x10.5/ 80x20(mainboard)	(D)3.65 x 11.1
Cable length	sensor to mainboard: 50cm(OD1.35) mainboard to dimmer: 185cm(OD3.1) dimmer to connector: 15 cm(OD3.1)	camera to mainboard: 80cm(OD1.5) mainboard to connector: 200cm(OD3.5)	camera head to dimmer with S/F button: 100cm(OD1.95) dimmer with S/F button to connector: 100cm(OD1.7)

Connector	USB 2.0 A-type	USB 2.0 A type	USB 2.0 A type
Dimmer	White high intensity LED x 4	White LED x 4	White LED x 6
Image transfer rate	x	x	1280x720@ 15∼30fps (auto) MJPG
Functions	x	x	Brightness, Gamma, White Balance, Saturation adjustable by AMCap Snapshot and Freeze ' frame
OS Support	Win7, Win8, Win10, Linux, Android	Vista, Windows XP, Win7, Win8, Win10	MAC OS, Win10, Win8, Win7, Windows XP, Linux, Android