Development of a Pullback Device for Intravascular Ultrasound and Photoacoustic Catheter Imaging

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by

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Introduction

1.1. Cardiovascular diseases, coronary artery disease, and vulnerable plaque

Cardiovascular Diseases (CVDs) are the leading cause of death in the world and a major contributor to chronic conditions, with almost one in three succumbing to CVDs in 2016 [1]. In addition to the individual harm caused, on a societal and economic level CVDs are responsible for reduced productivity and increased health care costs [2]. The most common CVD is known as Coronary Artery Disease (CAD), caused by atherosclerosis in the coronary arteries, in which blood flow to the heart muscle is restricted due to a build up of plaque and the hardening of the lumen wall.

While the exact mechanisms behind atherosclerosis are still subject to research, the progression of the disease will be summarised and simplified for our purposes. The stages of progression are illustrated in Figure 1.1. A healthy coronary artery consists of three vessel layers: The inner layer is the tunica intima, lined with a monolayer of endothelial cells on a membrane containing local smooth muscle cells (SMCs). The middle layer is known as the tunica media containing layers of SMCs in an extracellular matrix. The outer layer, the tunica adventitia, is the supporting layer of the vessel comprising of connective tissue, nerves, and vessels. Plaque can form on and in the tunica intima and can consist of an accumulation of lipids, cells, and other substances. Among the first stages of atherosclerosis, there is an immune response in the form of migration of leukocytes from the lumen into the tunica intima and their transformation into macrophages. These cells then ingest lipids and turn into foam cells. Lesion continues when SMCs migrate to and proliferate in the tunica intima, combined with the increased synthesis of an extracellular supporting matrix. In advancing lesions, SMCs and foam cells can die, accumulating under the proliferated SMCs and extracellular matrix, among processes as calcifications and vascularisations of the site. This is known as the necrotic core of the plaque. At this stage the plaque is known as a vulnerable plaque or a thin-cap fibroatheroma

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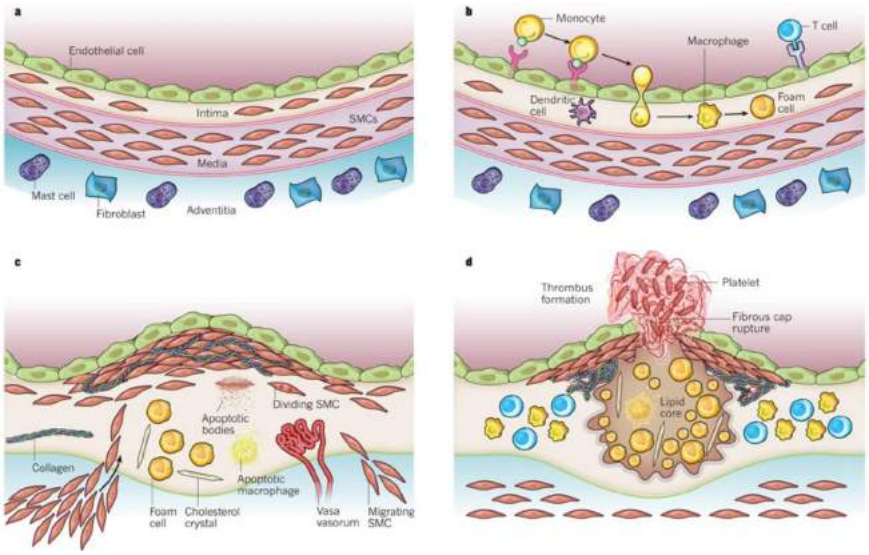


Figure 1.1: Atherosclerosis progression of a muscular artery from Libby e.a., 2011 [3]. Each subfigure shows a stage of progression. **a**: A healthy muscular artery. **b**: Initial progression of an atherosclerotic plaque, where lipids integrate on and into the artery and create an immune response. **c**: Proliferation of SMCs to the tunica intima and accumulation of fatty cells results in the progression of a necrotic core, along with other substances. **d**: Rupture of the TCFA, resulting in the formation of blood coagulation and a thrombus.

(TCFA). This plaque can rupture or erode, activating blood coagulation components on the plaque and the formation of a thrombus. This obstructs oxygen supply to the heart even more in that vessel and can lead to acute coronary syndromes (ACSs)/ major adverse cardiac events (MACEs) [3, 4].

Intravascular diagnostic imaging has enabled the ability for the in vivo assessment of vulnerable plaque characteristics. In a clinical setting this can be utilised for a multitude of vascular imaging problems, such as for example determining intervention, assess the region of interest for stent placement, and assessment of stent thrombosis and restenosis. Intervention is determined based on the morphology and composition of a plaque, which is used as a measure of how vulnerable the plaque is and how likely it is to lead to an ACS. A vulnerable plaque can be characterised by a thin fibrous cap (with a thickness between 50-100 μm), inflammation, and a lipid-rich necrotic core, along with other indicators such as calcification and microvascularisation of the plaque. Plaque burden is also used as a measure for intervention, when more than 70% of the enclosed vessel area is occupied by a plaque [5, 6]. The PROSPECT II study has shown that the chance of a MACE occurring is three times higher within four years of detection of a plaque burden [7].

Current techniques in various stages of development exist in order to image the artery wall from inside the lumen, such as intravascular ultrasound (IVUS), intravascular optical coherence tomography (IVOCT or OCT), near-infrared fluores-

cence (NIRF), near-infrared reflection spectroscopy (NIRS), fluorescence lifetime imaging (FLIm), and intravascular photoacoustics (IVPA). Due to the limitations of each technique, multiple techniques are often combined within one device, creating a multimodal imaging technique. Each of these techniques have their advantages and disadvantages in imaging a plaque and vessel, which are reviewed in various papers [6, 8, 9]. Due to the scope of this thesis, only IVUS and IVPA are discussed.

1.2. Intravascular ultrasound and photoacoustic imaging principles

Intravascular ultrasound (IVUS) is a well known real-time imaging technique for in vivo characterisation of a plaque, based on acoustic reflection characteristics of a tissue. An electric signal is sent to a piezoelectric crystal acting as an ultrasound transducer, which in reaction vibrates, producing ultrasound waves. These waves propagate through the tissue and are reflected according to the tissue's acoustic properties, which are picked up by the same ultrasound transducer. The difference in how much is reflected back to the transducer makes it possible to differentiate between certain tissue types, which results in a grey-scale IVUS image. Typical ultrasound signals can have a frequency between 20 and 40 MHz, Achieving an axial resolution of 200 μm and a lateral resolution of 60-250 μm [10, 11]. While IVUS imaging provides a good view of the lumen of the vessel, can detect lesions, and the exterior of plaques, it can not reliably detect and differentiate a thrombus and lipid-rich regions of vulnerable plaques [12]. To overcome these disadvantages, IVUS is often combined with another imaging modality.

Intravascular photoacoustics (IVPA) is a catheter-based real-time imaging technique of vessels utilising the photoacoustic effect, which is illustrated in Figure 1.2. Laser pulses of a certain wavelength are sent to the tissue, which absorbs optical energy depending on the tissue type and the wavelength of the laser. The tissue expands, creating a pressure rise, and generating broadband acoustic waves through the vessel. This wave can be detected by an ultrasound transducer. By measuring the time of flight of the ultrasound signal, it becomes possible to calculate depth

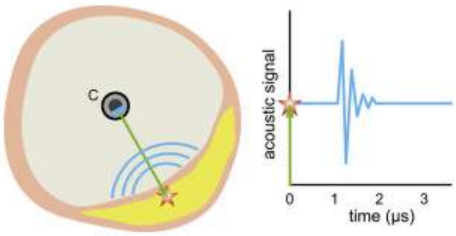


Figure 1.2: Working principle of intravascular photoacoustics. The catheter (C) sends a laser pulse (green), that irradiates the tissue (star), which absorbs optical energy based on the tissue type, expands, and contracts, releasing ultrasound signals (blue) which can be detected with an ultrasound transducer. Image from Jansen e.a., 2014 [13].

and create an acoustic image [13], while optical absorption acts as a measure of tissue composition, allowing for an imaging depth in tissues of several centimetres [14]. The laser pulse repetition rate is limited by the laser generation, in the range of 10-50 Hz [13], and can use a wavelength of between roughly 500 and 1800 nm [11, 15]. Lipids have a specific absorption spectrum with a peak around 1210 nm [16] and a specific absorption feature around 1720 nm [17]. IVPA can use multiple wavelengths within this range to better discriminate between different types of tissues, although single wavelength IVPA is also demonstrated ex vivo [18].

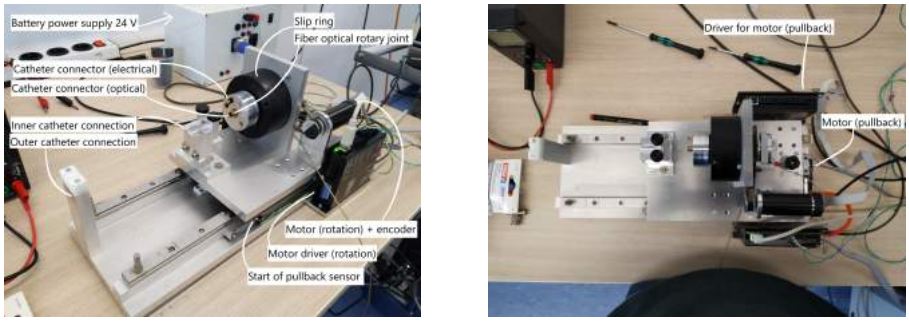
1.3. Intravascular ultrasound and photoacoustic imaging systems

Combined IVUS and IVPA imaging is an emerging technique in various stages of research. Though no market equivalent of such a device exists at this moment, one is being developed by Kaminari Medical in cooperation with Erasmus MC. A catheter imaging device can be seen in figure 1.3, which is in early development. This part is called the pullback system of the device and is responsible for rotation and retraction of the catheter tip relative to the vessel wall. On the proximal end of the device, a console will be present, where a user can control the system, signals are generated for imaging, and returning signals are processed to obtain images. On the distal end of the device an imaging catheter will be connected, which is able to traverse the vasculature to the coronary arteries, transmit the generation signals to the vessel wall, and receive the returning signals of interest.

Before the device can be brought to market, the complete imaging system will have to be tested *in vivo* and several challenges will still have to be solved. Such challenges include, but are not limited to: Developing an imaging catheter which holds all the components necessary for imaging, while being small enough to traverse the vasculature; Developing imaging reconstruction algorithms for combined IVPA and IVUS; Researching if the IVPA signal quality will be sufficient without the flushing of blood in the lumen; And developing a pullback device which is able to drive the catheter, convey IVUS and IVPA signals between the console and the catheter, while being simple to handle. Since this thesis concerns the development of a pullback device, a closer look will be given to the current existing pullback device used by the research at Erasmus MC.

The pullback of figure 1.3 consists of a custom made optical rotary joint (figure 1.4) with a concentric single channel slip ring (JINPAT Electronics LPT025) all placed on a plateau. This plateau is connected to a base via rails to achieve lateral motion, which is driven by a motor (Maxon RE25 118740, 10 W) and connected to a spindle. The rotation of the catheter is driven by a motor connected to a pulley and belt (Maxon RE30 268193, 60 W). This pullback system has been used in one form or another to study the effect of IVPA on the detection of lipids in atherosclerotic vessels [19, 20]. This pullback device has been developed in house by the facility Experimental Medical Instrumentation (EMI).

As can be seen from figure 1.3, this pullback device is quite a long way off from being market ready. Connecting the imaging catheter to the little connectors on the



(a) (b)

Figure 1.3: Current motor unit and pullback system used at Erasmus MC for research on IVPA/IVUS.

pullback is difficult and precise. The device consists of a lot of aluminium support and is heavy as a result. The device has no housing and is overall difficult to handle. The implemented slip ring has been observed to be a source of electrical noise for the returning IVPA and IVUS signals. These problems will have to be solved in the process of developing a pullback device and ultimately a complete catheter imaging system.

1.4. Literature research

One part of the system that was identified as a critical part for the signal paths of IVPA, was the combined optical and electrical rotary joint system. In the early stages of the project, it was seen that this part was vital for not only mitigating losses within the light pulse signal, the losses of which dissipate as heat in the fiber which can result in damages, but also to lower noise induced by the slip ring system

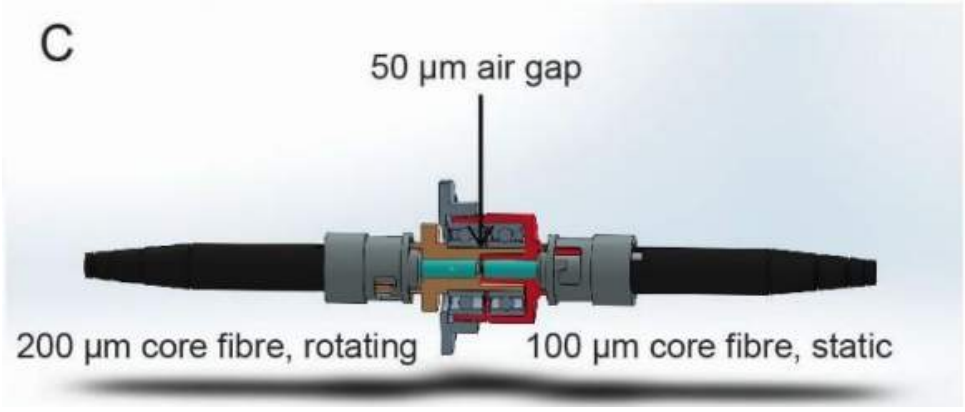


Figure 1.4: Optical rotary joint present in the current pullback system. Taken from Iskander-Rizk e.a., 2019 (Supplementary figure 1C, [20]).

Table 1.1: Summary of scientific literature results based on usage and types of coupling. The configuration of the couplings for all designs was an optical coupling on the axis of rotation with coaxial electrical coupling. OR-PAT: Optical Resolution Photoacoustic Tomography; IVPA: Intravascular Photoacoustics; IVUS: Intravascular Ultrasound.

Paper	Ref.	Year	Primary usage	Optical coupling	Electrical coupling
Bai e.a.	[21]	2014	OR-PAT/IVUS	FORJ (by Princetel Inc.)	Custom-made slip ring
Wang e.a.	[22]	2014	IVPA/IVUS	Free space coupling	*Slip rings*
Hui e.a.	[23]	2017	IVPA/IVUS	Collimator lens coupling	*Slip ring*
Vanderlaan e.a.	[24]	2017	IVPA/IVUS	Air to fiber coupling	Custom RF rotary joint
Iskander-Rizk e.a.	[25]	2019	IVPA/IVUS	Fiber to fiber coupling	*Not specified*
Zhang e.a.	[26]	2019	IVPA/IVUS	Fiber to fiber coupling	*Slip ring*

for IVUS and the returning IVPA signal. The literature research for this project concerned the techniques, methods, and designs incorporating the transmission of electrical and optical signals across relatively rotating media for the application of a combined IVPA and IVUS imaging catheter.

A scientific literature review was performed in Pubmed, IEEExplore, and Scopus databases was performed. Literature containing the ability to transmit optical and electrical signals across a rotary medium compatible with use in intravascular imaging were included. Additionally, a patent search was included using two categories in the Google Patents database. Patents containing both types of transmission with the ability for use in an intravascular imaging system were included.

The scientific literature research resulted in 233 results, which after exclusion resulted in 6 results and are summarised in table 1.1. None of the results contains a complete combined electrical and optical rotary transmissions, while having limited data on the characteristics of that part. From the scientific literature, it becomes apparent that the focus of the included scientific literature is not the design and performance of the rotary joint, but instead the performance of the imaging system. As such, details on those parts are not well documented in the literature, with some optical details being documented and almost none on the electrical characteristics.

The patent search resulted in 599 results, of which 13 patents were included into the review, which can be seen in table 1.2. All results contained an optical transmission on the axis of rotation with electrical transmission being coaxial to that, except for one patent which featured a unique ball-and-socket design. Optical transmission was received by direct fiber to fiber coupling (6 patents), with the use of collimating lenses (6 patents), or with a conical lens (1 patent). Electrical transmission was achieved by the use of slip rings (9 patents), rotary transformer (2 patents), close fitting surfaces separated by a thin dielectric material (1 patent), or sliding contacts (1 patent). All patents featured some detail on the design of the combined rotary joint, while not being specific about any specifications of the performance of those parts. From the patent search, certain techniques and designs become clear. However, patents have the tendency to not be clear on characteristics or specifics, allowing for some freedom in design after patenting the invention. The literature study gives insight in what has been done on electrical and optical transmission across a relatively rotating medium.

Table 1.2: Summary of patent results based on usage, types of coupling, and configuration of the couplings, where *Type 1* denotes an on axis optical coupling with coaxial electrical coupling, and *Type 2* denotes a ball and socket design with electrical contacts on the ball-socket interface with a conical lens in the center. OCT: Optical Coherence Tomography; NIRF: Near Infrared Spectroscopy.

Patent	Ref.	Year	Primary usage	Config.	Optical coupling	Electrical coupling
Cannon	[27]	1988	-	Type 1	Direct fiber-fiber	Brushed slip rings
Richard & Albert	[28]	1993	Underwater camera for fishing	Type 1	Direct fiber-fiber	Slip rings
Robb	[29]	2009	Telephone cable	Type 2	Conical lens	Sliding contacts on a ball-socket interface
Irisawa	[30]	2012	Imaging apparatus for diagnosis	Type 1	Collimating lenses	Slip rings
Schmitt e.a.	[31]	2014	OCT/IVUS imaging catheter	Type 1	Direct fiber-fiber [1] [32]	Transformer
Jones & Baloun	[33]	2015	Rotating antenna assembly	Type 1	Fiber-fiber [1]	Matching stub circuit
Jaffer & Ntziachristos	[34]	2016	NIRF/IVUS imaging catheter	Type 1	Fiber-fiber with index matching fluid	Brushed slip rings
Jenner e.a.	[35]	2016	OCT imaging catheter	Type 1	Collimating lenses	Wire brush slip rings
Li	[36]	2017	Rotating machinery	Type 1	Collimating lenses	Slip rings
W Kromker GmbH[2]	[37]	2018	Medical device support arm	Type 1	Collimating lenses	Slip rings
Yang & Kim	[38]	2018	IVPA/US	Type 1	Collimating lens	Rotary transformer
Zhang e.a.	[39]	2018	-	Type 1	Collimating lenses [1]	Wire brush slip rings
Boccoleri e.a.	[40]	2020	Medical suspension arm	Type 1	Direct fiber-fiber	Slip rings

1.5. Thesis goals

The thesis goal is defined as follows:

> Redesign a Pullback Unit for Combined Intravascular Photoacoustic and Ultrasound Imaging.

The thesis goal can be divided into several more specific subgoals:

- Design a motorised stage and pullback mechanism capable of directing the catheter signal paths.
- Design a pullback-connector interface that is suitable for users of such a product.

1.6. Thesis overview

Chapter 2 gives an overview of all the considerations that go into the designs of the connector interface and pullback device. Chapter 3 shows the results and prototypes of the connector interface, the user experience study on catheter connector devices, and the system design. Chapter 4 will discuss the project and its various parts including limitations and consequences of design choices. The thesis will conclude in Chapter 5.

[1] While this is the main type of coupling, the patent may offer different types of coupling through its different embodiments in the same patent.

[2] W Kromker GmbH is a company, as the patent has no listed inventors.

2

Methods and Materials

This chapter gives an overview of all the considerations that go within the design of a pullback device for intravascular ultrasound and photoacoustic catheter imaging. It will start with an overview of the system (section 2.1), the setting in which the device is used (section 2.2), and the requirements of the system (section 2.3). At this point all considerations come into play, such as the opinion of users of such a product when handling the device, discussed in the user experience study and the subsequent catheter handle unit (sections 2.4 and 2.5). The chapter concludes with all other considerations in the design of such a device (section 2.6).

2.1. Combined intravascular ultrasound and photoacoustic catheter imaging systems

The pullback device to be designed is part of a larger multimodal imaging system. In order to better understand what part the pullback device plays within the system, the whole imaging system will be briefly explained. This system will share similarities with existing catheter imaging systems. Most details however will be specific to the system in development by Erasmus MC and Kaminari Medical.

2.1.1. System overview

A generalised system overview for the successful ultrasound and photoacoustic catheter imaging of a vessel can be seen in figure 2.1. In this figure electrical components are denoted in *blue*, optical components in *yellow*, and mechanical components in *red*.

IVPA signal generation starts with the generation of a pulsed laser transmitted through a first optical fiber to a stationary to rotary interface and connected to a second optical fiber to the tip of the catheter. There it is directed to the vessel wall, which generates a photoacoustic signal (PA signal) picked up by the ultrasound transducer. Similarly, an US generation pulse (US pulse) is created and sent through a coax cable across a stationary to rotary interface to the ultrasound transducer,

which reflect on the vessel wall and get picked up by the transducer (US signal). Both PA and US signals travel back through the coax cable to the the IVUS receiver for further processing.

The whole catheter is rotated by a motor. The whole catheter, motor, stationary-rotary interface and connectors are being pulled back relative to a stationary catheter sheet, in which the rotating elements are located within the patient.

2.1.2. Imaging signal paths

The pullback device needs to be able to transfer signals between the console and catheter, while being able to rotate and to pull back the inner catheter. A simplified signal diagram of the complete imaging system in relation to the pullback device can be seen in figure 2.2. In the figure, blue represents electrical and yellow represents optical signals. The elements in the dashed lines are part of a trigger circuit which controls the timing of the laser pulse and US pulse to the catheter, so that these signals will not overlap within the vessel. The use and details of these signals will be explained per modality.

IVUS signal path

For the IVUS imaging path, a US pulser sends out a US pulse with an amplitude of 200 V and width of 2 ns (Avtech Electrosystems) through coax cables through a transmit/receive switch to the pullback system. Within the pullback system, the signal travels through a slip ring and the pullback-catheter interface. The signal travels to the catheter tip, where it excites the high frequency US transducer with a centre frequency of 50 MHz (ALS Ultrasound) [41] creating US pressure waves, the echoes of which are received by the same transducer. This signal returns through the same coax cable, through the pullback system and to the transmit/receive switch, where

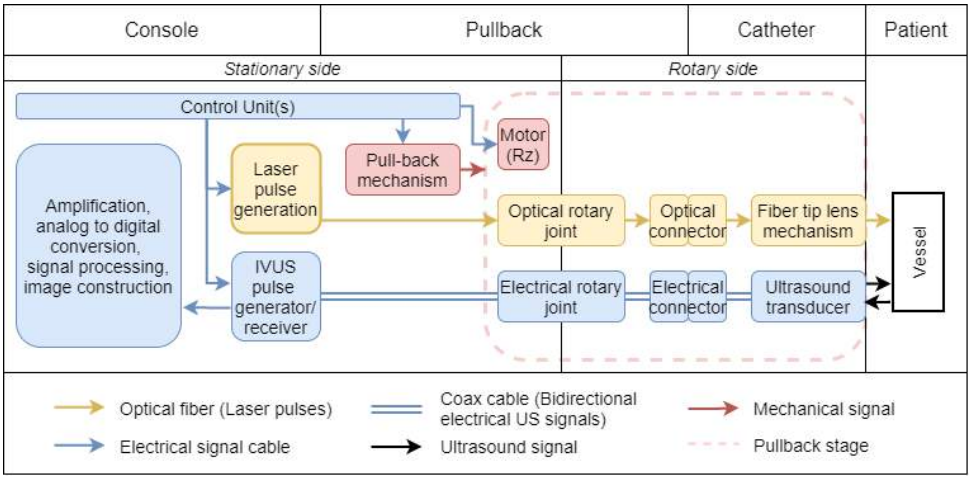


Figure 2.1: Generalised system diagram of a combined IVPA and IVUS imaging system. Electrical components are denoted in *blue*, optical components in *yellow*, and mechanical components in *red*.

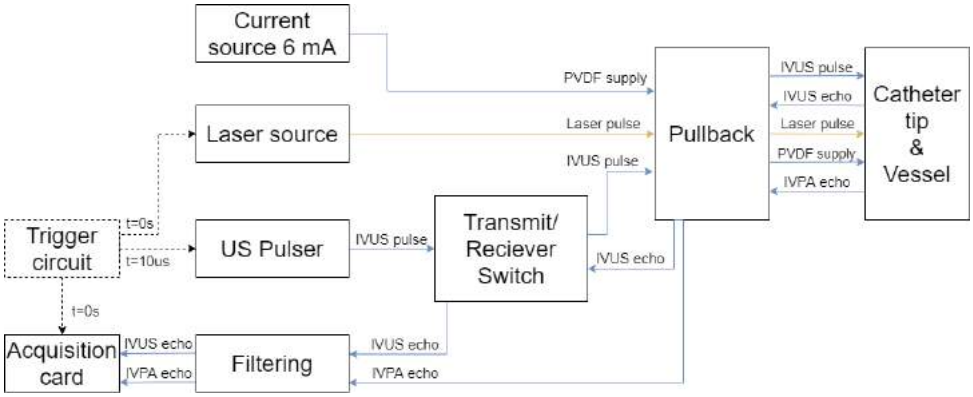


Figure 2.2: Diagram of the simplified signal paths travelling through the pullback device for the multimodal catheter imaging using IVUS and IVPA. A trigger circuit (dashed lines) acts as a control that times the laser and US pulses so that these signals will not overlap in the vessel.

the return signal is filtered from the IVUS pulse, bandpass filtered (f_c = 50 MHz and f_{-3dB} = 20 MHz) and captured by the acquisition card.

IVPA signal path

IVPA imaging starts with the generation of a laser pulse with wavelength 1210 $\pm$ 20 nm and a width of 5 ns, which is sent out through a single mode optical fiber (SMF) to the pullback, through the optical rotary joint and the pullback-catheter interface, to the catheter tip. At the tip, a prism directs the pulse on a section of the vessel wall, generating ultrasonic pressure waves, which are picked up by a low frequency US transducer. It has been observed that more than 80% of the emitted ultrasonic energy of the vessel lies between 2 and 15 MHz, with typical pressures generated are between 50 and 200 Pa [41].

The low frequency US transducer is connected to a readout (application specific) integrated circuit (ASIC) located on a polyvinylidene fluoride (PVDF) base, powered by a bias current of 6 mA. The ASIC amplifies the PA signal and acts as an impedance match of the coax cable. The transducer and ASIC have a sensitivity of 3.8 μV/Pa at 2.25 MHz, with root mean squared (rms) output noise voltage being measured at 259 μV between 1 and 20 MHz, allowing for a minimal detectable pressure of 30 Pa. The bias current is high pass filtered after returning to the proximal catheter, pullback, and before the acquisition card and low pass filtered as well at 20 MHz [41].

2.1.3. System elements

A generalised intravascular catheter imaging system can be seen in figure 2.3 and can be seen as three consecutive elements: The imaging catheter (a), the pullback device (b), and the console (c). In this section, the functionalities of each element will be explained.

(a) (b) (c)

Figure 2.3: Mock-up models of the Kaminari catheter imaging system (made by Cas Verhoeven). (a): The imaging catheter. (b): The pullback device. (c): The console.

Imaging catheter

The imaging catheter consists of coax cables and an optical fiber surrounded by a torque coil, which transfers the rotation from the proximal end of the catheter to the distal end. The catheter tip is located here which contains a prism to direct the light beam towards the vessel wall, a transducer for PA signal reception, and a transducer for US transmission and reception.

The proximal end connects to the pullback device. This connection consists of two functional parts: The catheter handle, which connects to the pullback housing, and an inner catheter connector, which connects the electrical and optical signals as well as allows for transfer of rotation to the catheter tip. A fluid port is generally present to allow flushing of the catheter and vessel with saline or a contrast agent to remove air or blood respectively, improving the image quality.

Pullback device

The pullback device acts as a throughput for the signal paths and is the device that can move the catheter in a way to image the complete vessel of interest. In this device signal paths go from a stationary to a rotary medium through a slip ring and an optical rotary joint for electrical and optical signals, respectively. This rotation is driven by a motor, with all elements mentioned so far being subject to a pullback mechanism. This allows for the combined rotation and pullback of the inner catheter relative to the catheter handle and sheet.

All these pullback elements are located within a pullback housing. The proximal end of the pullback is connected to the console via an umbilical cord, which contains all power and signal paths between the console and the pullback device. Buttons and displays can be present on the housing, allowing a user to control the system without direct access to the console.

Console

The console consists of all parts relating to signal generation, data acquisition, and system control. The signal generation side contains a pulsed laser source for the generation of PA signals, and an US pulser for the generation of IVUS echoes. On the acquisition side, the obtained signals are filtered and sent to an acquisition card,

where the signals are digitised and processed to obtain combined IVUS and IVPA images of a vessel section.

2.2. Use of the device

The pullback system will be used during cardiovascular imaging procedures combined with an imaging catheter like the one seen in figure 2.3. The device will usually be operated by an interventional cardiologist assisted by nurses, but other technical staff could also be present depending on the hospital. An example of a clinical setting where this device will be located can be seen in figure 2.4. In this clinical setting two areas can be distinguished: A sterile field in which the patient is located and a non-sterile field. The imaging catheter will be sterile and single use, while everything between the console and the pullback device will be reusable and non-sterile.

The pullback device will be connected via an umbilical cord to the console in the non-sterile field. Before a procedure, this device will be placed in a sterile sleeve so that the device can enter the sterile field. It is done by a non-sterile person lifting the pullback device from the proximal end, where another sterile person unfolds and packs the sterile sleeve over the device. The sterile sleeve will usually be connected to the device around the connection for the imaging catheter. The sterile person then holds the pullback device in the sterile sleeve, while the non-sterile person pulls the sleeve over the length of the umbilical cord.

Figure 2.4: Operating theatre environment at Erasmus MC. The areas between the patient and table with operating devices is considered the sterile field (here within the blue dashed lines), while the area outside is considered non-sterile. In the middle is a bed on which the patient rests. Near the right arm side of the patient is present the pullback device within a sterile sleeve (marked in the figure by the dashed yellow lines). In this example, the console is integrated within the operating theatre.

After preparation of the imaging catheter in the sterile field, it will be connected to the pullback device. A guide wire is inserted into an artery in the patient's forearm, which will find its way to the coronary arteries while being imaged with an angiogram. The imaging catheter is then inserted and guided to the coronary arteries.

During imaging, the operator of the device will test if the live imaging of the vessel is successful. This live imaging consists of rotating the catheter tip to obtain a 360 degree image. If this imaging is successful, the operator will proceed by pulling back the catheter tip while imaging is being done. This pullback is generally automated by the system, although manual adjustments could be made. The interventional cardiologist obtains more information on how to proceed with the diseased vessel after obtaining imaging. After removing the catheter, possible common procedures following imaging include the insertion of a stent or balloon angioplasty. The imaging catheter could be inserted again to image the result of the intervention. This process is repeated until all areas of interest are evaluated.

After the procedure, the imaging catheter is disconnected from the pullback device and discarded together with the sterile sleeve. The reusable part of the device is superficially cleaned.

2.3. System requirements

The system is subject to external requirements which are the backbone of the design. The pullback system has two main functionalities: 1. It is the interface between the console and the catheter, conveying all signals from one to the other and back, and 2. It should drive the catheter tip. In order to convey the signals from one part to the other, the pullback should be able to:

- transfer a laser pulse signal from the stationary to a rotary side. This laser pulse signal has a pulse energy of 50 μJ, a pulse width of 20 ns, and a wavelength of 1210 or 1720 nm (to be chosen at a later time);
- transfer a high frequency (30-70 MHz) high voltage (200 V) short pulsed (100 ns) US supply signal from the stator to the rotor side, and transfer a high frequency (30-70 MHz) low voltage US signal from the rotor to the stator side in one channel;
- transfer a low frequency (1-20 MHz) signal from the rotor to the stator side, and transfer a DC supply voltage (3.3 V, 6 mA) from the stator to the rotor side in one channel.

In addition, the pullback device should be able to drive the catheter in the following way:

- a minimum catheter rotational speed of 3000 RPM (preferably as high as is possible);
- a minimum catheter pullback speed of 5 mm/s (preferably 30 mm/s).

Connector 1	1 - Strong negative	2 - Slight negative	3 - Neutral	4 - Slight positive	5 - Strong positive
Was it clear to you how the catheter handle should be connected?	☐	☐	☐	☐	☐
Was it clear to you how the inner catheter should be connected?	☐	☐	☐	☐	☐
What was your experience with connecting the catheter handle with the pullback?	☐	☐	☐	☐	☐
What was your experience with connecting the inner catheter with the pullback?	☐	☐	☐	☐	☐
What is your opinion on the size of the catheter handle?	☐	☐	☐	☐	☐
How do you feel about the shape of the catheter handle?	☐	☐	☐	☐	☐
How do you feel about the size of the mock-up pullback?	☐	☐	☐	☐	☐

Figure 2.5: The main questions surveyed during the user experience study.

2.4. User experience study design

One important aspect in the development of a pullback device, is the way users of the product will handle the pullback device. If users do not like to use the device, it is more likely they will not use this device as frequently as is possible, choose different intravascular imaging devices over this one, or create frustration in the use of the device. Furthermore, if there are aspects of the device in usability which are not clear to the user, there is an increased risk in damage to the catheter and the pullback system, which can be a risk to the users or patient.

The goal of the user experience study is to find out what would be considered a suitable connection design between the imaging catheter and the pullback device. Existing catheter handle connectors are investigated to get a sense of the design aspects of such a device. With those aspects, a couple of different catheter handle designs are created, which will be further discussed in section 2.5.

The main subject group for this study includes hospital staff who assist in or perform intravascular imaging in coronary interventions. This includes but is not limited to: Interventional cardiologists, assisting nurses, and assisting technicians (who are only present within Erasmus Medical Center).

This study aims to interview at least 5 users. Since the subject group tends to be a group of very busy people, the study will be limited to 15 minutes. In this time, the participant will be asked to connect and disconnect each catheter handle design. The participants will be asked to score each design on a scale from 1 (very negative) to 5 (very positive) on a number of design aspects. The main questions asked can be found in figure 2.5. If the participant has more time available, the user experience study will be expanded to an interview to get a better understanding of their wishes on such a pullback system. The complete UX study questionnaire can be found in appendix B.

After handling the connector prototypes, each participant will be asked about

their likes and dislikes for a couple of design aspects, with room for additional remarks. During the study, additional remarks and overall observations are noted. The users will be asked to judge each design on the following aspects: Clarity of each connection, experience with each connection, size of the connector, shape of the connector, and size of the mock-up device.

The handling of the pullback device concerns how a user would physically handle such a device before, during, and after an operation as described in section 2.2. It is important that the device is not too large or too heavy to handle or to cause strain in the user's arms and hands. However it is also important the device is not too small and too light, which might cause it to vibrate or rotate easily due to inner mechanics of the device.

2.4.1. Data management plan and HREC application

Delft University of Technology has strict regulations on the collection and preservation of data collected from participants. In compliance with those regulations, a data management plan (DMP) was created to be approved by the Human Research Ethics Committee at Delft University of Technology. This DMP was created using DMPonline, an online tool by Delft University of Technology.

This document, as well as a checklist, the Informed consent form and Information letter accompanying the questionnaire, and a Device report are compiled in appendix B. This DMP application was approved by the HREC.

2.5. Catheter handle unit

The catheter handle unit is the main interface between the disposable catheter and the reusable pullback unit. The handle is the proximal part of the catheter and is to be connected and disconnected to the pullback unit by a user. The catheter handle consists of a stationary handle part being the interface between the user and the catheter, and an internal rotary part, allowing for rotation of and signal transfer between the distal catheter tip and the rest of the system.

2.5.1. Design space

In order to get a sense of the design space, a look was taken at catheter imaging systems and pullback devices present at Erasmus MC. The list of catheter and pullbacks can be found in appendix A and are summarised in table 2.1. From the appendix and the table, it can be seen that catheter connectors, different design approaches can be taken for the connection and disconnection of each catheter. Each different aspect present for connecting the catheter is illustrated in figure 2.6. It can be seen that the design can be seen as a sum of three design aspects: The size, the shape, and the locking-mechanism of the connection.

For the catheter handle size, the part where the user would pick up the catheter, it can be seen that the sizes differ between roughly 5 and 15 cm. For the handle connector mechanism, there is either a keyed hole in which the connector clicks into place, or there is a non-keyed hole in which the connector is inserted and then twisted into place. The inner signal connector also follows two mechanisms.

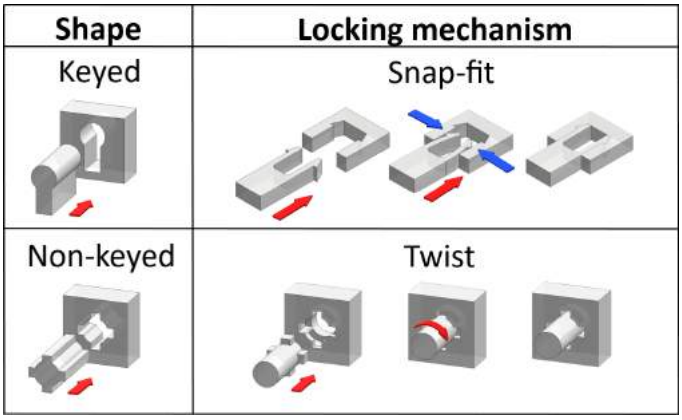


Figure 2.6: Design aspects of a catheter connection.

Either the signal connector is keyed and clicked into place (for the LightLab Imaging catheter, this connector needs to be manually aligned, while for the Infraredx, the signal connector is already aligned with the handle), or the signal connector is aligned by the system itself (in the St. Jude Medical system, due to motorisation pulling the signal connector in after the handle is connected).

The disconnection of the catheter requires the disconnection of the catheter handle together with the inner catheter. Disconnecting one without the other is not desirable as it can lead to damage to the pullback device or to the catheter, as well as frustration in the user. As can be seen in appendix A, the Boston Scientific system makes use of an external disposable pullback sled and does not encounter this problem. It was decided early in development that this pullback device will have an internal pullback mechanism to reduce the amount of disposable products and external moving parts. Of the three remaining catheter imaging system examples, two (St. Jude Medical and Infraredx) make use of an automated eject mechanism to eject both connections at the same time, while one (LightLab Imaging) requires manual disconnection.

It is important to recognise that each design aspect has their advantages and disadvantages for not only the user, but also the design itself. A keyed connector has the advantage that elements of the connector can be automatically aligned with the pullback system, but will require more attention from the user while connect-

Table 2.1: Summary of catheter connectors and their respective pullback systems present at Erasmus MC.

		Handle		Signal		
Company	**Modality**	**Shape**	**Mechanism**	**Shape**	**Mechanism**	**Alignment**
Boston Scientific	IVUS	Keyed	Snap-fit	*Same as Handle*	*Same as Handle*	*N.A.*
LightLab Imaging	OCT	Keyed	Snap-fit	Keyed	Snap-fit	Manual alignment
St. Jude Medical	OCT	Non-keyed	Twist	Non-keyed	Twist	Automated
Infraredx	IVUS/NIRS	Keyed	Twist	Keyed	Snap-fit	Already aligned

ing, while a non-keyed connector requires some alignment process for the inner connector. Two ways to solve the alignment issue are either to have a mechanical piece that aligns the inner connector during connecting, or to have the alignment automated by the system. A snap-fit-mechanism has the advantage of audio feedback to the user that it is connected well, while a twist-mechanism gives a more direct visual feedback.

2.6. System design

2.6.1. Device functionalities and design process

This section describes every functionality which needs to be designed in order to arrive at a complete design for a functional pullback system. Each functionality implementation is dependent on the previous functionalities, which are shortly summarised here. Design considerations for the current design are shown in appendix C.

Signal path This denotes all paths required to obtain an IVUS and IVPA image of a vessel as explained in section 2.1.2. One coax cable is necessary to transmit and receive the US generation and generated signal. One optical fiber is necessary to transmit the laser pulse signal from the console to the vessel, with one coax cable to receive the generated PA signal. The same cable will be used to transmit a supply voltage to an ASIC present in the catheter tip. Connectors between the pullback and the adjacent devices will be treated as connector design, as these are dependent on the usability of the connector.

Rotation The functionality should rotate the catheter tip within the vessel relative to the catheter sheet. It concerns the way the rotation of the signal paths within the catheter is supplied and connected. These will include a motor and control system, power requirements, transfer of the rotation to the signal path, and parts to keep these elements connected.

Pullback The pullback design is the next stage of the design, which should be able to take the signal path and the rotating inner catheter and pull it back relative to the catheter sheet and the pullback device. Design of this stage will concern itself with a way to pull back these parts, as well as guiding of this movement.

Connector The connection of the catheter to the pullback system can be seen as two separate but simultaneous connections: The stationary catheter handle connecting the pullback to the stationary catheter and catheter sheet, and the rotating inner catheter conveying the signals to and from the catheter tip. This connector's design is subject to the wishes of users of the device. Users should be able to easily disconnect both connections from the pullback simultaneously as well.

Housing The housing serves as a barrier, shielding the device's components from the user and its surroundings while also having it in a transportable package. This

design can also be subject to user experience. It should be portable in multiple ways of holding it. The catheter handle and a sterile sleeve connection should connect to the housing. The housing can feature interfaces for control of the device and important indicators.

Control Control of the device concerns itself with regulating the speeds at which the catheter tip is rotated and pulled back and located within the console. Additional buttons and indicators may be present on the pullback device to control and observe the state of the pullback and imaging. These can also be dependent on the wishes and experiences of users of the device.

Sterile sleeve The sterile sleeve is the plastic bag that covers the device so that it can enter the sterile area within the operating room while not being sterile itself. It is important that this sleeve fits the device properly so that it is not too tight to risk a tear or make it difficult to cover the device, while not being too loose to make the device harder to handle. The sleeve should fit so that user-device interfaces like buttons, handles, and connectors can be handled appropriately. The sleeve should cover a good part of the umbilical cord as well, as part of that will enter the sterile area as well.

2.6.2. Design methods

The design method that was chosen for this pullback device was an iterative design method. With this method, an interim design was taken to the technicians at EMI and Erasmus MC to discuss changes to the design. This was done to get feedback on the technical and practical aspects of the design. With their advice it was chosen that components within the device should be of the shelf components as much as is feasible, minimising what needs to be manufactured or assembled in house. The design was iterated upon, until a satisfactory design was obtained. The design is made within the SOLIDWORKS 2020 environment to be made with additive manufacturing unless discussed otherwise with the technicians.

3

Prototyping and Results

This chapter lays out the results of the thesis and is split in three parts. The first part shows the catheter connector prototypes (section 3.1), followed by the results of the user experience study (section 3.2), and ends with the current system design (section 3.3).

3.1. Catheter handle unit

3.1.1. Prototyping

In order to design prototypes for the user experience study, design aspects from section 2.5.1 were mixed. A total of four catheter handle units were designed. Each handle was given three aspects (keyed vs. non-keyed for the shape, twist vs. snap-fit for the locking-mechanism, small vs. large for the size) and each signal connector was given two aspects (keyed vs. non-keyed, automatic vs. manual vs. mechanical alignment), which can be seen in table 3.1. Due to the nature of disconnecting being either manual or (partially) automated by the system, this feature was not taken into account in the design of these prototypes.

For these size of these designs, small was chosen to be smaller than 10 cm in length and large was chosen to be larger than 10 cm. All designs are made within

Table 3.1: Design aspects given to each catheter handle connector prototype.

Aspect	**Connector 1**	**Connector 2**	**Connector 3**	**Connector 4**
Handle size	Small	Small	Large	Large
Handle shape	Keyed	Non-keyed	Non-keyed	Keyed
Handle lock	Snap-fit	Twist	Twist	Snap-fit
Signal shape	Keyed	Non-keyed	Keyed	Non-keyed
Signal alignment	Auto	Mechanical	Manual	Auto
Mock-up size [cm^3]	6x6x25	6x6x40	9x9x30	11x11x35

the SOLIDWORKS 2020 environment and designed to be manufactured with selective laser sintering (SLS). A tolerance of 0.2 mm was taken into account between each part. Space was left within the designs for an SC optical fiber connector. The male connection was placed in the connector and the female connection was placed in the pullback. Each connector prototype is designed to be placed in a pullback mock-up in order to better simulate a pullback and catheter system.

Connector 1

Connector 1 consists of a handle with a keyed, snap-fit-mechanism and can be seen in figure 3.1. The length of the handle is 8 cm with an outer maximum diameter of 4 cm. The click is achieved by bendable fins that snap into place within the pullback connection and it can be disconnected by pushing on these fins. The inner signal connector is already aligned with the catheter handle and therefor the system, and needs no further alignment correction.

Connector 2

Connector 2 consists of a handle with a non-keyed, twist-mechanism and can be seen in figure 3.2. This handle has a length of 5 cm which the user can grab and 10 cm in total length to allow for the transition into the smaller catheter. The diameter of the handle is 4 cm. The inner signal connector consists of a mechanical alignment mechanism that automatically rotates that connector to be aligned with the system connectors when the handle is pushed in.

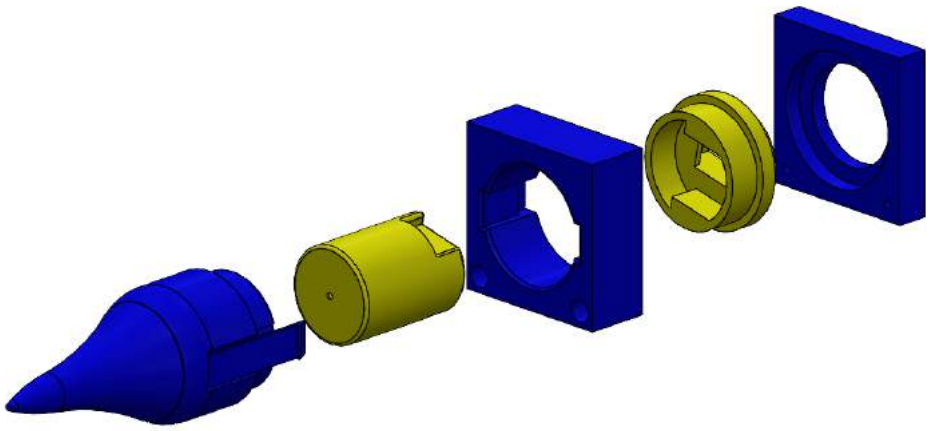


Figure 3.1: CAD model prototype of connector 1. The blue components are stationary, while the yellow components are intended to be rotary.

Connector 3

Connector 3 can be seen in figure 3.3 and consists of a non-keyed, twist-mechanism for its handle. The handle has a length of 14 cm and a maximum diameter of 6 cm, sloping down to 3 cm for the remainder of the handle. The inner signal connector consists of a keyed, manual connector.

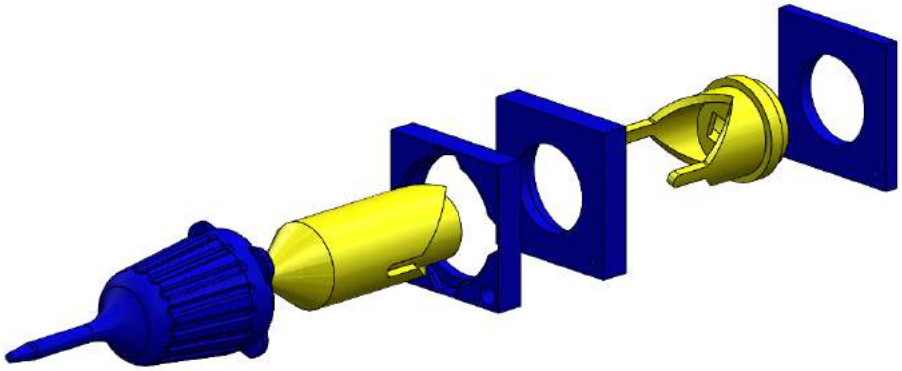


Figure 3.2: CAD model prototype of connector 2. The blue components are stationary, while the yellow components are intended to be rotary.

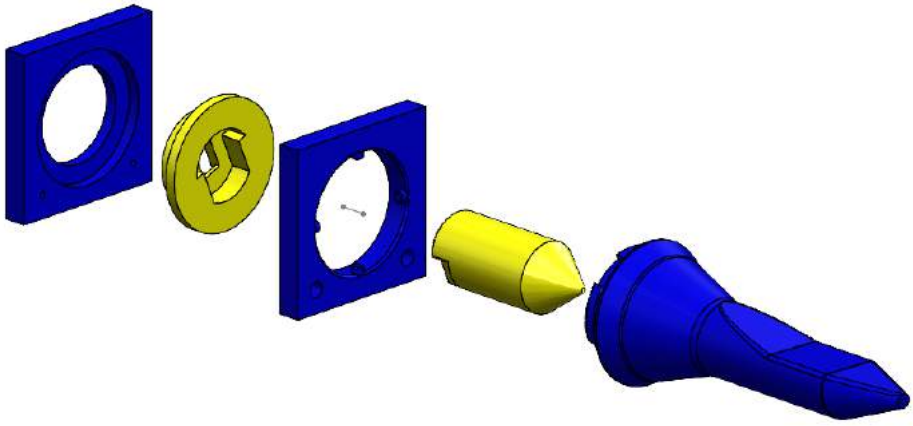


Figure 3.3: CAD model prototype of connector 3. The blue components are stationary, while the yellow components are intended to be rotary.

Connector 4

Connector 4 can be seen in figure 3.4 and consists of a keyed, snap-fit-mechanism for its handle. The width and height are 5.5 cm at its widest point and its length is 11 cm. The inner signal connector is automatically aligned with the rest of the system due to the keyed nature of the handle. The catheter handle clicks into place by pushing against triangular pieces, moving them aside until the handle has moved enough into the pullback connection, after which the triangular pieces move back into the original position with springs, locking the handle into place as can be seen in figure 3.5. This design features an eject button on the top in order to move the triangular pieces back to disconnect the catheter handle. This design also features a couple of components (shown in black) that lock the orientation of the inner signal catheter with the outer catheter to ensure proper alignment of the signal connection. This is achieved with a couple of small cantilevers in the catheter handle that connect to a small indent within the inner catheter. Extrusions on the pullback connector that move these cantilevers, releasing the inner catheter from the handle and allowing it to be freely rotated.

3.1.2. Prints and mock-up pullback designs

The catheter handle unit parts as seen in section 2.5 are printed using SLS by the company Materialise. These have been made to fit within a mock-up pullback device by EMI. An optic fiber with male connector is glued into place into the

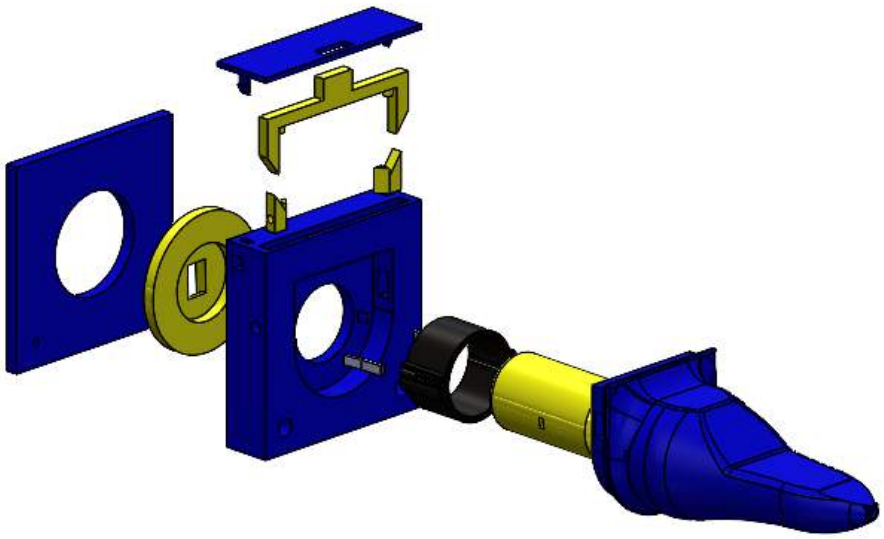


Figure 3.4: Exploded view CAD model prototype of connector 4. The blue components are stationary, while the yellow components are intended to be rotary.

inner connector. In the same way a female optic fiber connector is glued into place in the pullback mock-up. These prototypes can be seen in figure 3.6. The assembled prototype 4's alignment pieces (the black components from figure 3.5) did not survive the printing process.

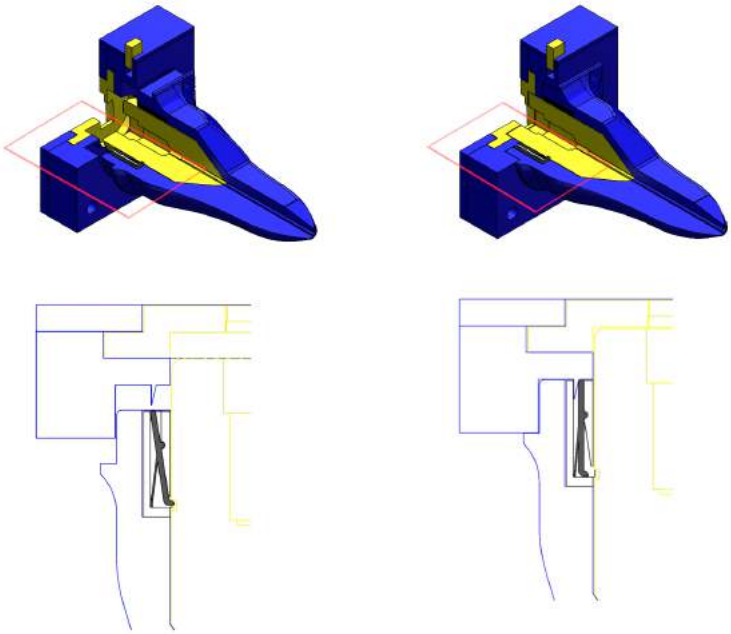


Figure 3.5: The alignment of the inner connector of prototype connector 4.

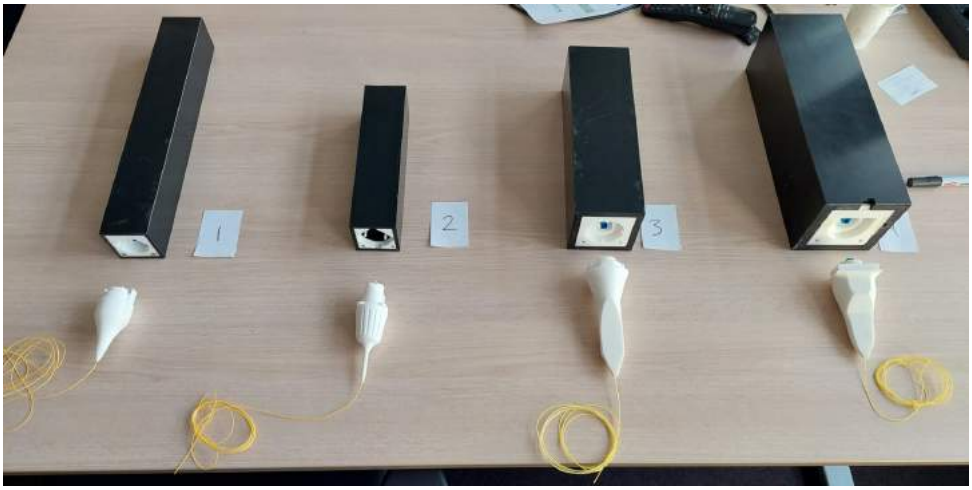


Figure 3.6: All assembled mock-ups of the catheter connector prototypes and housings.

3.2. User experience study

The results of the main part of the user experience study can be found in figure 3.7 and additional user input can be found in appendix E. The number of participants in the study is $n = 5$, specifically 3 technicians and 2 interventional cardiologists. The design aspects being reviewed can be seen in table 3.1.

The designs can be compared with these results. Handles 1, 2, 3, and 4 all seemed to have a relatively favourable clarity on how the handle should be connected, with the least clarity present on handle 4.

Of the snap-fit catheter handles, handle 1 has both positive and very negative experiences, while handle 4 has both very positive and very negative experiences. The experiences seem to favour the twist-in catheter handles 2 and 3, with 3 having slightly more positive results. All handle sizes were deemed acceptable by the participants, with the clear preference going to the smaller handles. From the handle shapes, it can be seen that handle 3 is preferred, closely followed by handle 2.

As for mock-up size, there is a clear preference amongst the group, which is not too big like 4, but not too small either like 1. The best rated size was 9x9x30 cm, with 6x6x40 cm still acceptable.

According to these results, the ideal catheter handle would be connector 3 in the size of connector 2. It would be accompanied by an automated signal connector and a pullback device size of 9x9x30 cm.

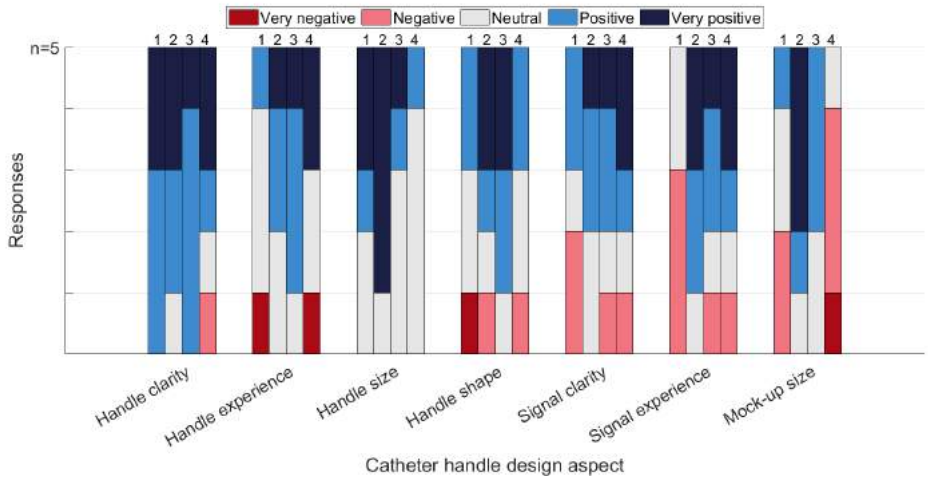


Figure 3.7: The results of the user experience study. Respondents were asked what their experience was on each aspect of each connector on a scale from very negative to very positive. The number on top of each bar corresponds with a connector design.

3.2.1. Additional user input on the catheter handle designs

Participants were welcome to include any and all feedback on the handle designs, which is included in appendix E. This gave some more insight in what aspects did and did not work in each design.

Handle 1 was deemed too small and smooth to be a comfortable handle. The click in mechanism was too frail and finicky, and not stiff enough to create a good click connection. These parts stuck out and were seen as a risk due to being able to snag behind other equipment.

On handle 2 it was remarked that on first glance it looked complicated and not intuitive to connect. However after connecting the device, it does score favourably on its clarity of the handle. The inner alignment piece added to that confusion and should be masked by the handle design. This could also avoid a potential misalignment of that piece, which was seen in two cases.

Handle 3 seemed to be intuitive to connect because of the grooves on the connection end. Most feedback centred around the inner connector, which required manual alignment. Manual alignment in a twist catheter handle was deemed awkward and undesirable.

Handle 4 was the most polarising experience to the subject group. While some liked the plug-and-play nature of the handle, others found it not intuitive at all. Disconnection of the handle by means of pressing an eject button was not clear and should be labelled as such.

Handles 1 and 4 had an already aligned inner connector and as such received almost no feedback on those parts. A twist mechanism catheter was overall preferred due to the certainty of connection.

3.3. System design

The final iteration of the pullback device can be seen in figure 3.8. A smaller version of handle 3 has been added to this design as an example. All intermediate iterations including feedback can be found in appendix F. This design features the signal paths, the rotation, the pullback, a partial connector, and the housing. Not included are a definitive way to connect the catheter to the pullback mechanisms, the signal path connection between the rotary joint and the console, motor wiring, as well as sterile sleeve compatibility.

Housing

The housing can be seen in figure 3.8. This housing has a size of 9.1x8.7x50 cm. The handle goes up to 12 cm in height, with an 3.5 cm extrusion so that a hand might fit underneath it.

Internal mechanisms

The internal mechanisms of the pullback design can be seen in figure 3.9. This part features the signal path and rotation, contained within a small housing (in the figure displayed as a wireframe) on a guidance rail. This rail is 19 cm long with a block of 4 cm where upon the small housing is secured, allowing for a 15 cm pullback. This small housing is connected to a spindle and pullback motor.

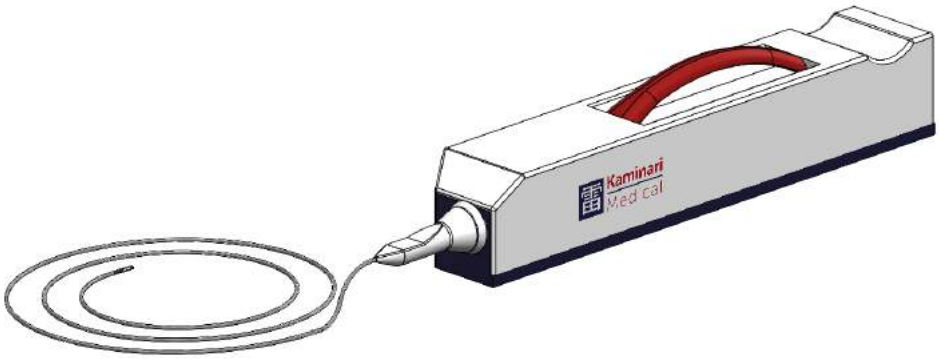


Figure 3.8: Final iteration of the pullback device design.

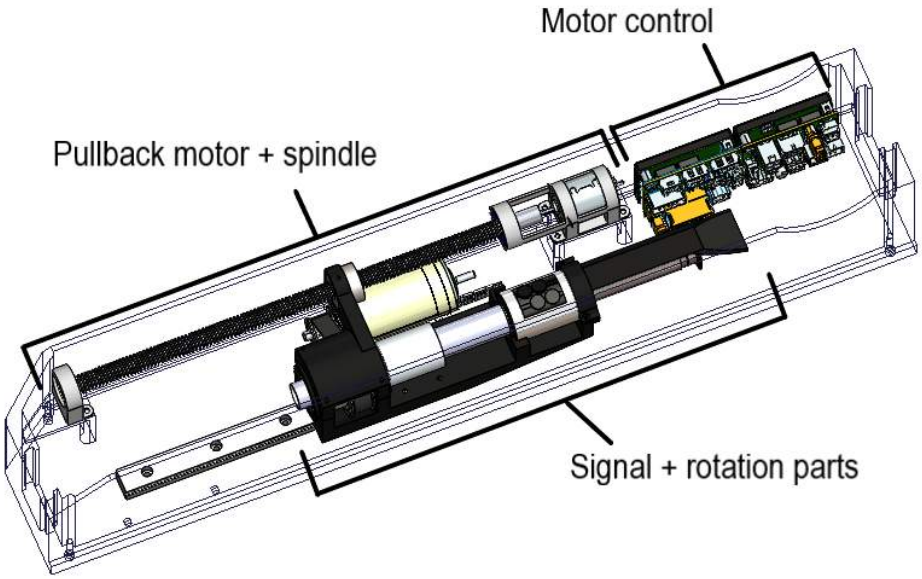


Figure 3.9: Internal elements of the pullback device containing the signal paths, the rotation, the pullback, and motor control. The housing in which the elements are housed are seen in a wireframe display.

A more detailed look on the signal and rotation elements can be seen in figure 3.10. This part is 25 cm long. This together with a 15 cm pullback, 1 cm for both housing walls, and 8 cm for cable bending and a cable guide (not shown) adds up to a 50 cm long pullback device.

A full pullback of the internal mechanisms of 15 cm can be seen in figure 3.11.

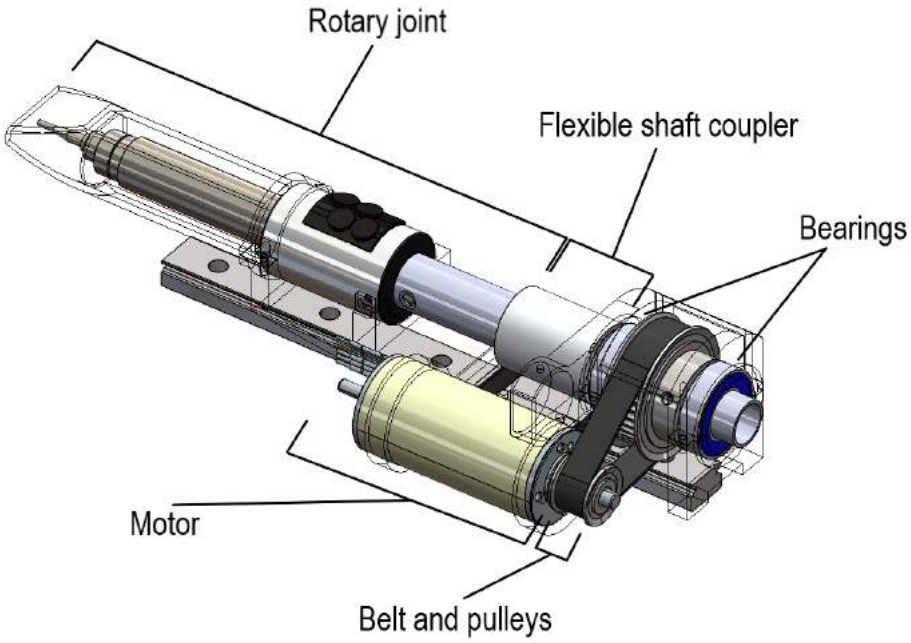


Figure 3.10: Signal and rotation parts of the device contained within a housing. The structure in which the elements are housed are seen in a wireframe display.

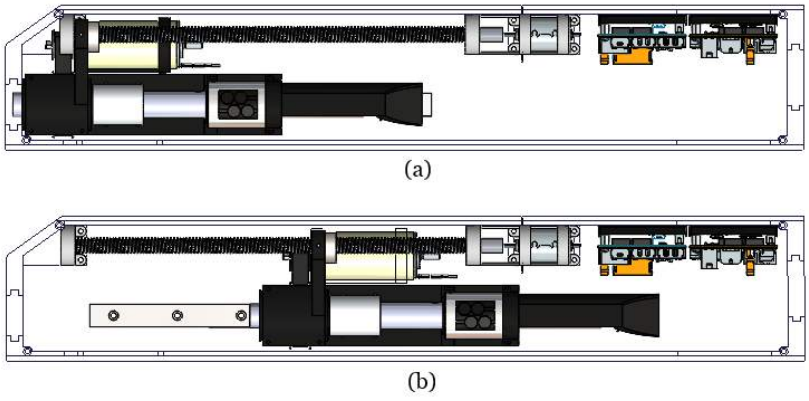


Figure 3.11: A top down view of a 15 cm pullback of the internal mechanisms. (a): The pullback elements at the start of the pullback. (b): The pullback elements at the end of the pullback.

4

Discussion

This section will discuss the various stages of the project, design choices and its consequences, its limitations, and suggestions. The section ends on a summary of future work suggestions.

4.1. Scope of the project

The goal at the start of the project was to design a new pullback device and a user friendly catheter connection. The device would then have to be designed, manufactured, and validated. In the best case scenario, this device would be eligible for use within a clinical setting. During the project however it seemed that the scope of these goals would be too large for a thesis project and the focus was put on the design study of the device.

The design of a medical device brings together a diverse range of design aspects. These include but are not limited to: Electrical (noise) aspects, optical aspects, mechanical aspects, material aspects, system requirements, user wishes, company wishes, regulations, and practical considerations such as delivery times, manufacturing parts, and assembly.

Bringing together this range of aspects that go into the design was part of what makes this a challenging project. There was a need to back up as much considerations as possible by means of scientific literature or calculations. The difficulty here lies in what is considered sufficient motivation for the choices made within a certain time frame, as there always will be some part unknown. Technicians present at Erasmus MC could help fill in parts of the knowledge gap.

This project has been subdivided into the catheter handle connection with the pullback device, and the pullback device itself. While the project has achieved its goals of creating a design for both components, it did not include how these are connected as will be discussed below.

4.2. Catheter handle unit

The catheter handle units have been designed with the goal of collecting feedback from users. The most important limitations of these prototype designs and prints are discussed below.

Automatic signal connection and handle disconnection

The catheter handle design focused on the user experience with regards to handling and connecting the catheter. Disconnecting the catheter handle however is a much more complex task than connecting. Ideally the catheter handle can only disconnect while the inner pullback components are in their starting state, otherwise this disconnection could damage these inner mechanisms. This means the system should know when the pullback is in this state to allow for disconnection. The current mock-ups do not allow for such automatic detection.

One option would be to automate this disconnection (which could also be used for automated alignment during connection). By selecting the ”disconnect catheter”-option, the system would move the inner pullback mechanisms to its starting state, after which it would simultaneously disconnect the inner signal connector and the outer catheter handle.

Flushing of the catheter

A more finalised design should include a fluid inlet, which allows the flushing of the catheter. This fluid will be present between the movable catheter and the catheter sheet. A fluid stopper should be added on the proximal end of the catheter, so that no fluid is able to exit on that end and no fluid will enter the pullback device. Fluid inlets on catheter devices should comply with ISO 594-1.

4.3. User experience study

The user experience study has been performed using the catheter handle prototypes. This yielded results in the form of opinions on these prototypes and catheter imaging systems, serving as an input for the overall system design. The most important notes and limitations are discussed below.

User experience study design

There was a mismatch between the design aspects chosen for the catheter handle prototypes and the user experience questionnaire questions. This was chosen as to not be leading with the questions. It seemed at the time more important to ask for their overall experience as well as some specific design aspects, than to have their input on every design aspect of the device. Often times as long as the experience of the user is good, the specific design aspects are much less important.

It could have been interesting to have a number of handle designs that were identical except for a single aspect to have an easier comparison. More differing designs have been chosen to gain insight in their experience with these differences. This does make it harder to point at specific design aspects and see if they worked or not. There was room within the study for targeted open feedback where these could be discussed.

In hindsight, the first two housings of the mock-ups were too small to fit all internal mechanisms. From the results it seems that there is a preference for a thin and short housing, followed by wide and short, rather than having a elongated housing.

Number of participants

This study used a relatively low number of participants. The participant group within Erasmus MC initially seemed willing to be included, but individual meetings proved difficult to arrange. Interventional cardiologists outside of Erasmus MC that were approached outright refused to participate, stating lack of time.

The low number of participants does not have to be a problem at this stage of development, as this was done to get feedback which can be implemented in a next handle design. If it is deemed necessary, a more finalised set of prototypes (including disconnection) could be tested among the study group.

General consensus

There seemed to be a general consensus for having a twist locking handle with some sort of automatically connecting signal connector. Smaller handles of around 5 cm in length were preferred over the larger ones. There seemed to be a clear preference for handles that looked or felt like designs they were already familiar with, such as handle 2 being similar to the Abbott OCT catheter handle. Since there seemed to be no clear preference on the signal connection mechanism, this will be decided by the housing and control of the total system design.

4.4. System design

Signal connectors

The signal connectors between the optical and electrical parts between the pullback and the inner catheter still present a design challenge. The connectors need to be aligned and fixed, and should not disconnect during the pullback. Furthermore, any forces that are needed to obtain a pullback should not be subjected upon the connectors. The main challenge concerns disconnecting the signal connection. There should be a separate mechanical connection for the pullback and rotation transfer to the catheter. Ideally, these connectors should only be able to be disconnected when the system is in a starting state and when the user allows it. Due to the freedom of movement between the catheter handle and inner catheter, no initial solution could be found.

One way to solve this problem is to automate catheter ejection by a user selecting to eject. The system would then move the pullback to the starting state, after which the catheter handle and inner catheter would be disconnected. The type of signal connector that would be used depends on the method the system would use to disconnect the catheter from the pullback.

Housing and size

The designed housing has a size of 9.1x8.7x50 cm. This is much larger than the preferred size from the UX study of 6x6x40 cm. This is the result of the 15 cm

pullback, the 25 cm signal and rotation paths subject to the pullback, two times 1 cm for the housing walls, and 8 cm cable bending and cable guide. The cable guide is not shown in the model.

There are two main options where the length of the device can be reduced. The first is the space required for the cable bending. Optical fibers exist with a minimum bending radius of 8 mm, greatly reducing the length necessary. Part of the bending cables can go under the rotary joint during the pullback. A custom cable guide will likely have to be designed, since common market solutions tend to be a lot larger.

The second place option concerns the rotary joint. Technicians at Erasmus MC advised to not connect the motor directly to the rotary joint, increasing the length of this part by at least 7 cm. A more compact design can be proposed to Meridian for future designs to decrease this length or the length of the rotary joint in general.

One way other pullback devices reduce space is by integrating all electronic control systems into a custom board. This was outside of the scope of this project since it was chosen to design for off the shelf components. This could also reduce the size of the device.

Motor selection and friction in the rotary joint

As stated by the manufacturer the combined rotary joint a break-in period of 1 to 4 million rotations after which the friction of the part will decrease. The magnitude of this decrease is not known. A motor was selected which could handle the maximum friction just in case. In addition, this friction is highly variable due to the rubber seals within the rotary joint. This combined with the break-in of the seals could have the result that the motor may be oversized for the function it will fulfil.

If it is decided in development to have the rotary joints rotate until their break-in periods have been reached, it will be possible to measure its power requirements and downsize this motor.

Heat generation of internal components

Several components within the device can contribute significantly to heat generation. These are the two motors, the two motor drivers, and the rotary joint during rotation due to friction. During constant rotation, this heat can be very significant. During intermittent rotation this heat generation can be limited, with Maxon stating that temperature of the housing of the motor will increase 2,5 °C per 30 s cycle at max speed.

It is currently unknown what the heat generation within the rotary joint will be. The slip ring part has a maximum rated temperature of 70 °C. Similarly the heat generation in the motor drivers is unknown.

As a result of the heat generation, the rotary joint specifications, as well as lack of ventilation within a sterile sleeve, intermittent motor activation is the preferred method of operation.

Storage

Due to the storage recommendations of the combined rotary joint, the pullback device should be stored vertically. It is also recommended to rotate the rotary joint at least monthly.

4.5. Future work

The following section presents ideas for future work based on this work. This acts as a summary of earlier discussion points into manageable projects.

Catheter handle, signal connection and disconnection

As stated above, the signal connection and disconnection do present a design challenge waiting to be solved, with no straightforward solution on its disconnection. This solution then needs to be implemented into a finished, functional catheter handle design. This could entail in designs for a fluid inlet which only allows fluid to go to the distal end of the catheter, connection for the signals and rotation to the rest of the catheter, material selection, and manufacturing methods.

Manufacturing and validation of the device

The pullback device needs to be manufactured and validated before it can be worked with, which could be a project on its own. Currently all designs have been handed over to EMI for further development.

5

Conclusion

This thesis aimed to develop a pullback device for intravascular photoacoustic and ultrasound catheter imaging. The technique is being developed to identify both position and composition of a plaque during atherosclerosis.

The thesis goal was defined as *"Redesign a Pullback Unit for Combined Intravascular Photoacoustic and Ultrasound Imaging"*. This goal was subdivided into the design of the pullback unit and the design of the catheter connector for users of such a device. Instead of the complete development, the thesis focused on the design study of such a device.

Four catheter connectors were designed, prototyped, and placed in mock-ups for use in an user experience study. The study revealed a clear preference for the connecting mechanisms for both the handle and the signal connection, the size of the pullback device, and the size of the connector. Furthermore it gave insight on catheter imaging systems in a clinical setting. However the low number of participants and differing opinions within the group make it difficult to draw conclusions on the group as a whole. From this study there is a preference on the connector design, however a more integrated connector with the pullback should be developed before production. This future development should include a disconnection method for the signal connection, as well as a fluid inlet, and a method to transfer rotation from the pullback to the catheter.

A preliminary pullback device has been designed. This design includes the signal transfer between the console and the catheter, the rotation and pullback of these elements, and a housing fit for user interaction. Appropriate components have been selected to make sure that this device can deliver on these tasks. The design lacks the connection between the catheter and the pullback, as this is subject to the disconnection methods mentioned. The device is currently rather large, which could be reduced in cooperation with the rotary joint manufacturer in order to reduce the size of that component or to develop better connection methods to the motor. All designs have been handed over to EMI for further development.

In summary a design study has been performed which considers many different

aspects which go into the design and development of a pullback device and catheter handle for use in a clinical setting. Its results gain insight on how to develop such a part and what choices should be considered in the complete design of the catheter imaging system.

The techniques and devices for IVPA/IVUS catheter imaging are currently being developed by Kaminari Medical in cooperation with Erasmus MC. In a clinical setting this can provide an interventional cardiologist with precise knowledge on the position and composition of a plaque, allowing for more precise treatment and better patient outcomes. On a societal level, this better treatment results in less overall chance of another major adverse cardiac event happening while decreasing healthcare costs.

It will still take years before this technique will be present and used in a clinical setting, with many more contributions to be made. Such is the nature of invasive medical device manufacturing. This development is in good hands with Kaminari Medical and Erasmus MC.

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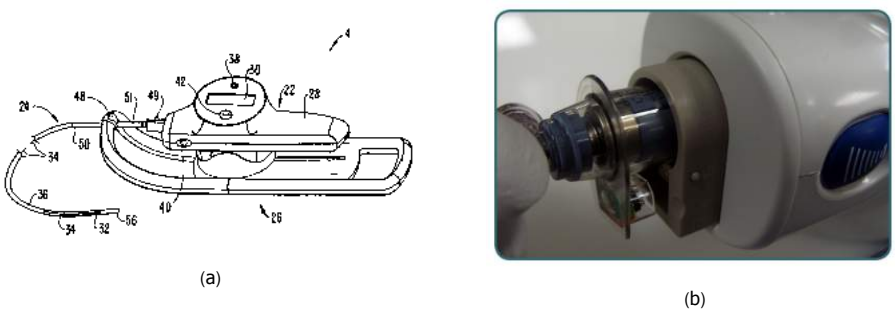
A

Examples of catheter handle connector designs

Boston Scientific's OptiCross

The pullback by Boston Scientific can be seen in Figure A.1 [42]. This system is used for IVUS only. This design features a motor unit which is separated from the pullback unit. A small conical gear on the pullback unit can connect to the bottom of the motor unit allowing for pullback motion. The catheter is first inserted into the motor unit after which the catheter sheet is clicked into place in the pullback unit, allowing for relative motion. The catheter connection is a custom made one and keyed to prevent a wrong connection. The top of the motor unit has buttons allowing for some control by the user. The pullback unit is disposable.



(a) (b)

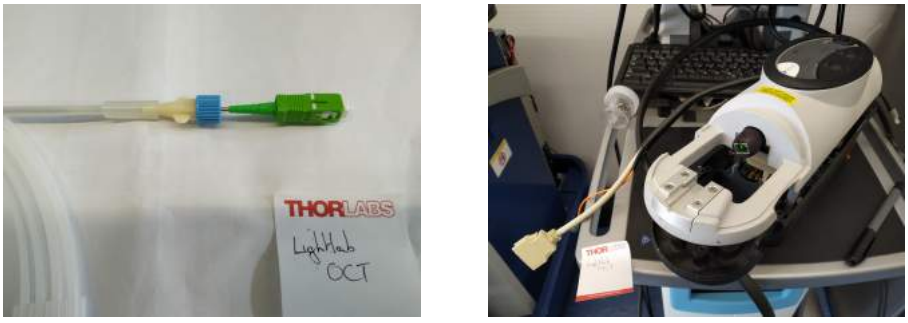
Figure A.1: Pullback system by Boston Scientific. (a) Patent figure of the motor unit in combination with the pullback unit (or pullback sled) [42]. (b) Catheter connection of the OptiCross Coronary Imaging Catheter.

A

LightLab Imaging

The LightLab Imaging pullback and catheter can be seen in Figure A.2. This device is used for IVOCT. The pullback and motor units are featured in one design, where the catheter is connected to the pullback and the catheter sheet to the front of the device in a similar way as the Boston Scientific pullback. The connector is a simple fiber optic SC-P connector. The top of the device has buttons for catheter control.

The inside of the pullback can be seen in Figure A.3. During pullback motion, the inside of the catheter is pulled into the pullback by use of a stepper motor and a screw thread. A pair of rails is attached to an aluminium frame which allows for pullback. The device is heavy due to the use of a solid metal frame and it feels very stable. The motor drivers and additional functionalities are integrated in the PCB at the bottom of the frame.



(a) (b)

Figure A.2: Pullback system by LightLab imaging. (a) The IVOCT catheter. (b) The pullback on top of the console which controls the system.

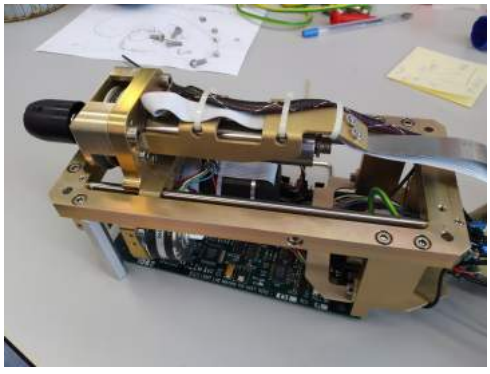


Figure A.3: The inside of the LightLab Imaging pullback.

St. Jude Medical

The pullback and catheter connector by St. Jude Medical (SJM) can be seen in Figures A.4 and A.5. This device is used for IVOCT. The catheter connector consists of an outer keyed connector with internal mechanical alignment. When the catheter is inserted into the pullback, the pullback has an automated procedure to align the connector with its own connector with the use of this mechanical alignment, preventing human error in making the connection. The fiber connector is a standard SC-P connector.

(a) (b)

Figure A.4: Catheter connector of the St. Jude Medical IVOCT Imaging system. (a) Side view of the catheter. (b) Front view of the catheter.

Figure A.5: Pullback system of the St. Jude Medical IVOCT Imaging system. Inside the system, mechanical alignment takes place before the optical path is fully connected.

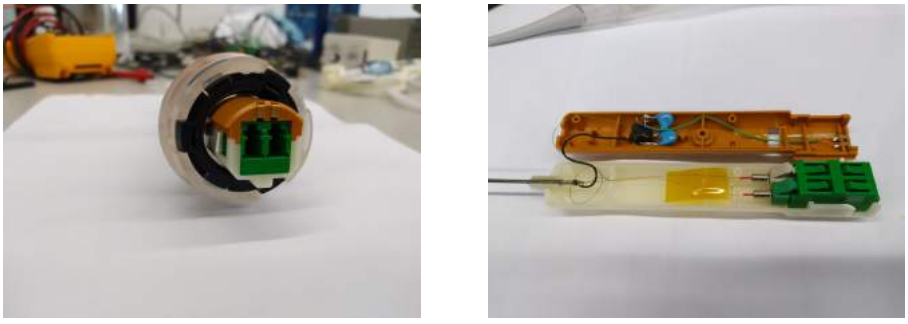
A

Infraredx Makoto

The catheter design of Infraredx can be seen in figure A.6 and the pullback can be seen in figure A.7. The pullback shown is a newer version than the catheter shown, so while they do share design points, these two are incompatible. This catheter is used for combined IVUS and NIRS imaging.

The catheter connector consist of a keyed connector with two optical connector paths for NIRS imaging and a couple of electrical contacts present at the outer side of the keyed connector. For successful connection, first the inner catheter needs to be correctly connected, after which the catheter sheet can be twisted into place. The inside of the catheter connector features an optical female to female connector which is connected to two optical fibers. The electrical path is connected to a transformer to electrically decouple the path before and the path after the catheter in order to prevent any direct electrical path between the system and the patient. All of this is placed within a hard plastic casing connected to a stiff drive shaft, which connects to the catheter drive shaft.

The pullback consists of a well designed housing with a handle. This housing also features a form of control for the user on top of the device.



(a) (b)

Figure A.6: Dualpro catheter connector of Infraredx's Makoto system. (a) Front view of the catheter connector. (b) Inner view of the catheter connector.

(a) (b)

Figure A.7: Pullback system by Infraredx of their Makoto Intravascular Imaging System

B

User experience study

In this appendix, all the relevant documents relating to the user experience study are compiled. These documents were supplied to the Human Research Ethics Committee in compliance to the regulation present at Delft University of Technology regarding data from participants. The Data Management Plan was created using DMPonline, an online tool of Delft University of Technology to create these plans. These documents include:

- the User experience study questionnaire;
- the Data Management Plan;
- the Checklist for the Human Research Ethics Committee at Delft University of Technology;
- the Informed consent form;
- the Information letter; and
- the Device report for the Human Research Ethics Committee.

B

Data Management Plan

The Development of a Motor and Pullback Unit for Intravascular Photoacoustic and Ultrasound Imaging

0. Administrative questions

1. Name of data management support staff consulted during the preparation of this plan.

Yasemin Türkyilmaz-van der Velden

2. Date of consultation with support staff.

2021-06-02

I. Data description and collection or re-use of existing data

3. Provide a general description of the type of data you will be working with, including any re-used data:

Data Management Plan

Type of data	File format(s)	How will data be collected (for re-used data: source and terms of use)?	Purpose of processing	Storage location	Who will have access to the data
User experience input on motor and pullback devices for intravascular imaging catheter systems	physical, .xls file	In-Person Questionnaire	To gain an understanding in the wishes and preferences of users of such a product	Scanned to a password protected student laptop, where after the paper forms will be destroyed. The data will be backed up and encrypted on a USB stick.	Kaminari Medical and the Master Thesis student Izaka Tesselaar
User experience feedback on catheter connector designs	physical, .xls file	In-Person	To note the likes and dislikes of users of prototype catheter connector	Scanned to a password protected student laptop, where after the paper forms will be destroyed. The data will be backed up and encrypted on a USB stick.	Kaminari Medical and the Master Thesis student Izaka Tesselaar
Unique identifier relating to a name	physical, .xls file	In-Person	To identify who answered what	Scanned to a password protected student laptop, where after the paper forms will be destroyed. The data will be backed up and encrypted on a USB stick.	Kaminari Medical and the Master Thesis student Izaka Tesselaar
Name and e-mail address on the informed consent form	physical, .xls file	In-Person	Informed consent	Scanned to a password protected student laptop, where after the paper forms will be destroyed. The data will be backed up and encrypted on a USB stick.	Kaminari Medical and the Master Thesis student Izaka Tesselaar

4. How much data storage will you require during the project lifetime?

- < 250 GB

Data Management Plan

B

II. Documentation and data quality

5. What documentation will accompany data?

- README file or other documentation explaining how data is organised

III. Storage and backup during research process

6. Where will the data (and code, if applicable) be stored and backed-up during the project lifetime?

- Another storage system - please explain below, including provided security measures

During the project, the data collected will be stored on a password protected laptop and backed up on a physical encrypted USB-stick.

IV. Legal and ethical requirements, codes of conduct

7. Does your research involve human subjects?

- Yes

8A. Will you work with personal data? (information about an identified or identifiable natural person)

If you are not sure which option to select, ask your Faculty Data Steward for advice. You can also check with the privacy website or contact the privacy team: privacy-tud@tudelft.nl

- Yes

Data Management Plan

8B. Will you work with any types of confidential or classified data or code as listed below? (tick all that apply)

If you are not sure which option to select, ask your Faculty Data Steward for advice.

- No, I will not work with any confidential or classified data/code

9. How will ownership of the data and intellectual property rights to the data be managed?

For projects involving commercially-sensitive research or research involving third parties, seek advice of your Faculty Contract Manager when answering this question. If this is not the case, you can use the example below.

There is no intellectual property rights related data. This is a master student project and the supervisors will take responsibility of the data after the end of the project.

10. Which personal data will you process? Tick all that apply

- Data collected in Informed Consent form (names and email addresses)
- Signed consent forms
- Email addresses and/or other addresses for digital communication
- Names and addresses

11. Please list the categories of data subjects

A group of professionals relating to intravascular imaging by use of an imaging catheter.

12. Will you be sharing personal data with individuals/organisations outside of the EEA (European Economic Area)?

- No

15. What is the legal ground for personal data processing?

- Informed consent

Data Management Plan

B

16. Please describe the informed consent procedure you will follow:

All study participants will be asked for their written consent for taking part in the study and for data processing before the start of the survey.

17. Where will you store the signed consent forms?

- Same storage solutions as explained in question 6

18. Does the processing of the personal data result in a high risk to the data subjects?

If the processing of the personal data results in a high risk to the data subjects, it is required to perform a Data Protection Impact Assessment (DPIA). In order to determine if there is a high risk for the data subjects, please check if any of the options below that are applicable to the processing of the personal data during your research (check all that apply).
If two or more of the options listed below apply, you will have to complete the DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to receive support with DPIA.
If only one of the options listed below applies, your project might need a DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to get advice as to whether DPIA is necessary.
If you have any additional comments, please add them in the box below.

- None of the above applies

22. What will happen with personal research data after the end of the research project?

- Personal research data will be destroyed after the end of the research project
- Anonymised or aggregated data will be shared with others

23. How long will (pseudonymised) personal data be stored for?

- Other - please state the duration and explain the rationale below

Personal data will be destroyed after completion of the project.

24. What is the purpose of sharing personal data?

- Other - please explain below

It won't be shared.

25. Will your study participants be asked for their consent for data sharing?

- Yes, in consent form - please explain below what will do with data from participants who did not consent to data sharing

Participant who did not consent to data sharing will not have their data shared.

V. Data sharing and long-term preservation

27. Apart from personal data mentioned in question 22, will any other data be publicly shared?

- No other data can be publicly shared - please explain below why data cannot be publicly shared

29. How will you share research data (and code), including the one mentioned in question 22?

- My data will be shared in a different way - please explain below

My data will be shared with my supervisors as part of the master's student project.

30. How much of your data will be shared in a research data repository?

- < 100 GB

31. When will the data (or code) be shared?

- At the end of the research project

32. Under what licence will be the data/code released?

- Other - please explain

Not applicable.

VI. Data management responsibilities and resources

33. Is TU Delft the lead institution for this project?

- Yes, leading the collaboration

The data will be collected under a collaborative project between TU Delft and Erasmus MC in combination with Kaminari Medical, which is a start up company founded by the supervisor of Erasmus MC, prof. dr. Gijs van Soest.

34. If you leave TU Delft (or are unavailable), who is going to be responsible for the data resulting from this project?

The supervisors from TU Delft and Erasmus MC, prof. dr. Paddy French and prof. dr. Gijs van Soest, respectively.

35. What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

Not applicable for this master's project.

Checklist for the Human Research Ethics Committee

Delft University of Technology
ETHICS REVIEW CHECKLIST FOR HUMAN RESEARCH
(Version 18.06.2020)

This checklist should be completed for every research study that involves human participants and should be submitted before potential participants are approached to take part in your research study. This also applies for students doing their Master-thesis.

In this checklist we will ask for additional information if need be. Please attach this as an Annex to the application.

The data steward of your faculty can help you with any issues related to the protection of personal data. Please note that research related to medical questions/health may require special attention. See also the website of the CCMO.

Please upload the documents (go to this page for instructions).

Thank you and please check our website for guidelines, forms, best practices, meeting dates of the HREC, etc.

I. Basic Data

Project title:	**Development of a Motor and Pullback Unit for Intravascular Photoacoustic and Ultrasound Imaging**
Name(s) of researcher(s):	**Izaka Tesselaar**
Research period (planning)	**Aug-sept 2021**
E-mail contact person	**I.P.Tesselaar@student.tudelft.nl**
Faculty/Dept.	**3me**
Position researcher(s):[1]	**Student**
Name of supervisor (if applicable):	**Prof. Dr. Paddy French**
Role of supervisor (if applicable):	

II. A) Summary Research

The overall goal of the project is to develop a subsystem for an intravascular imaging system, which is able to connect to a catheter, and will be used by experts such as intravascular cardiologists. The goal of this research is to receive user experience input on this part of the system and a couple of connector prototypes. The target participants are intravascular cardiologists and adjacent technicians, of which between 10 and 20 people will be interviewed. The questionnaire will consist of a small list of questions combined with connector prototypes. Participants will be asked to connect and disconnect those prototypes and note what their preferences are. Each questionnaire should take around 15 minutes.

B) Risk assessment & risk management

The main risk associated with in-person questionnaires would be the possible transmission of the Corona virus. This risk will be minimised by following the guidelines of the RIVM, with a focus on keeping a distance of 1,5 m between persons, wearing a mask, the cleaning of hands before participation, and the

[1] For example: student, PhD, post-doc

Checklist for the Human Research Ethics Committee

cleaning of prototypes, pens, and other equipment before and after each questionnaire.

B

III. Checklist

Question	Yes	No
1. Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g., children, people with learning difficulties, patients, people receiving counselling, people living in care or nursing homes, people recruited through self-help groups).		x
2. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children or own students)?[2]		x
3. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g., covert observation of people in non-public places).		x
4. Will the study involve actively deceiving the participants? (For example, will participants be deliberately falsely informed, will information be withheld from them or will they be misled in such a way that they are likely to object or show unease when debriefed about the study).		x
5. Sensitive personal data • Will the study involve discussion or collection of personal sensitive data (e.g., financial data, location data, data relating to children or other vulnerable groups)? Definitions of sensitive personal data, and special cases thereof are provided here.		x
6. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants?		x
7. Will blood or tissue samples be obtained from participants?		x
8. Is pain or more than mild discomfort likely to result from the study?		x
9. Does the study risk causing psychological stress or anxiety or other harm or negative consequences beyond that normally encountered by the participants in their life outside research?		x
10. Will financial inducement (other than reasonable expenses and compensation for time) be offered to participants?		x
Important: if you answered 'yes' to any of the questions mentioned above, please submit a full application to HREC (see: website for forms or examples).		
11. Will the experiment collect and store videos, pictures, or other identifiable data of human subjects? [3] .		x

[2] **Important note concerning questions 1 and 2.** Some intended studies involve research subjects who are particularly vulnerable or unable to give informed consent .Research involving participants who are in a dependent or unequal relationship with the researcher or research supervisor (e.g., the researcher's or research supervisor's students or staff) may also be regarded as a vulnerable group . If your study involves such participants, it is essential that you safeguard against possible adverse consequences of this situation (e.g., allowing a student's failure to complete their participation to your satisfaction to affect your evaluation of their coursework). This can be achieved by ensuring that participants remain anonymous to the individuals concerned (e.g., you do not seek names of students taking part in your study). If such safeguards are in place, or the research does not involve other potentially vulnerable groups or individuals unable to give informed consent, it is appropriate to check the NO box for questions 1 and 2. Please describe corresponding safeguards in the summary field.

[3] Note: you have to ensure that collected data is safeguarded physically and will not be accessible to anyone outside the study. Furthermore, the data has to be de-identified if possible and has to be destroyed after a scientifically appropriate period of time. Also ask explicitly for consent if anonymised data will be published as open data.

Checklist for the Human Research Ethics Committee

Question	Yes	No
12. Will the experiment involve the use of devices that are not 'CE' certified? *Only, if 'yes': continue with the following questions:*	x	
➢ Was the device built in-house?	X	
➢ Was it inspected by a safety expert at TU Delft? (*Please provide device report, see: HREC website*)	X	
➢ If it was not built in house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? *(Please provide records of the inspection).*		
13. Has or will this research be submitted to a research ethics committee other than this one? (*if so, please provide details and a copy of the approval or submission).*		x

IV. Enclosures

Please, tick the checkboxes for submitted enclosures.

Required enclosures

- A data management plan reviewed by a data-steward.

Conditionally required enclosures

if you replied 'yes' to any of the questions 1 until 10:
- A full research application

If you replied 'yes' to questions 11:
- An Informed consent form

If you replied 'yes' to questions 12:
- A device report

If you replied 'yes' to questions 13:
- Submission details to the external HREC, and a copy of their approval if available.

Additional enclosures

- Any other information which you feel to be relevant for decisionmaking by the HREC.

V. Signature(s)

Signature(s) of researcher(s)
Date: 13-07-2021

Signature (or upload consent by mail) research supervisor (if applicable)
Date:

B

Informed consent form

Consent Form for The User Experience Questionnaire on Catheter Imaging Systems

Please tick the appropriate boxes	Yes	No
Taking part in the study		
I have read and understood the study information dated 02-06-2021 or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	○	○
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	○	○
I understand that taking part in the study involves filling in a questionnaire about my user experience on catheter imaging devices as well as the evaluation of several catheter connection device prototypes. This evaluation will be in the form of a short interview in which the participant is asked questions about each design which will be written down by the interviewer. All data will be recorded anonymously.	○	○
Risks associated with participating in the study		
I understand that taking part in the study involves the following risks: Very mild physical discomfort through the handling of connector prototypes.	○	○
Use of the information in the study		
I understand that information I provide will be used for evaluation of imaging catheter device systems to be used within the Master Graduation Project. Data produced through this questionnaire will be used within a report and presentation within Delft University of Technology and Erasmus MC in collaboration with Kaminari Medical. In the exceptional case that this work is published outside of these institutions, all data recorded will be anonymous and untraceable to the individual participant.	○	○
I understand that personal information will be pseudo-anonymised by use of a identifier which is located in a separate secured document. Information collected about me that can identify me, such as my name and e-mail address, will not be shared beyond the study group.	○	○
Future use and reuse of the information by others		
I give permission for the User Experience Data and Evaluation of Imaging Catheter Connector Prototypes that I provide to be archived on a password protected student laptop, backed up on a protected USB-stick, so it can be used for future research and learning. Any collected physical data will be destroyed after archiving. Collected data will only be used for academic purposes within the context of this Master Graduation Project and the development of the intravascular photoacoustic and ultrasound imaging device.	○	○

Informed consent form

Signatures

_____	_____	_____
Name of participant	Signature	Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____	_____	_____
Researcher name	Signature	Date

Study contact details for further information:
Izaka Tesselaar, I.P.Tesselaar@student.tudelft.nl

Information letter

PARTICIPANT INFORMATION LETTER

Title of Research:

The Development of a Motor and Pullback Unit for Intravascular Photoacoustic and Ultrasound Imaging

Date:

2-6-2021

Dear Sir / Madam,

You have been asked to participate in a research study titled *The Development of a Motor and Pullback Unit for Intravascular Photoacoustic and Ultrasound Imaging*. This study is being done by Izaka Tesselaar from the TU Delft as part of a Master Thesis Project. In this letter you will find information about the research. If you have any questions, please contact the persons listed at the bottom of this letter.

Background of the research

Cardiovascular diseases are the number one cause of death in the world, with one of the most common disease being Coronary Artery Disease. Ways to mitigate this disease include the imaging of the vessel structure of the heart and the identification of plaque components. A promising new technique that is being developed is the combined use of photoacoustic and ultrasound imaging, which shows advantages over techniques such as optical coherence tomography by being able to differentiate between the tissue types commonly found in an atherosclerotic plaque. In this development it is desirable to not only make the technique useful for intravascular imaging and positive clinical outcomes, but also to make it attractive to use by listening to experts about demands and wishes on the use of such a system.

This research is done as part of a Master Thesis Project of Biomedical Engineering at TU Delft in collaboration with Erasmus MC and Kaminari Medical. Kaminari Medical is a start-up company founded by the Erasmus MC supervisor, which is currently developing the combined intravascular ultrasound and photoacoustic imaging catheter system.

Purpose of the research

The purpose of this research study is to gain an understanding in the user experience of intravascular imaging devices, and will take you approximately 15 minutes to complete. The data will be used as input for user wishes relating to this subsystem of an intravascular imaging system. The subsystem in question relates to the catheter connection which will be located in a sterile field, and a motor and pullback unit just outside of a sterile field which allow for control of the imaging components inside the catheter.

Benefits and risks of participating

By participating in this questionnaire, you will be helping in the creation of an intravascular imaging system that is based on the wishes of the users such a system. The only risk associated with this questionnaire is the very mild physical discomfort through the handling of the catheter connector prototypes.

Information letter

What does participation in the research involve?

Participation within the study includes a short questionnaire about your experience with catheter imaging systems. This is followed by a showing of several catheter handle prototypes. This is then concluded by a short interview about likes and dislikes of each design and additional remarks.

Procedures for withdrawal from the study

Your participation in this study is entirely voluntary and you can withdraw at any time without the need to give a reason. If you give your consent to this research, you have the freedom to come back on this decision. You can request access to and rectification or erasure of personal data. You do not have to give an explanation for your decision. You can do this by contacting the researcher with the contact details below the document.

Confidentiality of data

This investigation requires that the following personal data are collected and used: Your name and e-mail address. To safeguard and maintain confidentiality of your personal information, necessary security steps will be taken. Your data will be stored in a secure storage environment at TU Delft. Data will only be accessible to the researcher, the supervisors at TU Delft and Erasmus MC, and the staff at Kaminari Medical. All data will be processed confidentially and stored using a participant number only.

Your name and e-mail address will be linked to a participant number. This participant number and the informed consent form will be located in a separate key document digitally in a separate and secure location. This way, all your details remain confidential. Only the researcher, the supervisors at TU Delft and Erasmus MC, and the staff at Kaminari Medical can know which participant number you have.

The personal data will be retained for the duration of the Master Thesis Project and will only be used if the researcher deems it necessary to investigate follow up questions based on the answers given in the questionnaire.

The results of this study will be published in possible future scientific publications. Your participant number, name, and e-mail address will never be shared on publications about the research.

Contact Information

If you have any complaints regarding confidentiality of your data, you can contact the TU Delft Data Protection Officer (Erik van Leeuwen) via privacy-tud@tudelft.nl or the Dutch Data Protection Authority (Autoriteit Persoonsgegevens).

On behalf of the researcher, thank you in advance for your possible cooperation.

Researcher name and email address:

Izaka Tesselaar, I.P.Tesselaar@student.tudelft.nl

B

Device report for the Human Research Ethics Committee

Delft University of Technology
INSPECTION REPORT FOR DEVICES TO BE USED IN CONNECTION WITH HUMAN SUBJECT RESEARCH

This report should be completed for every experimental device that is to be used in interaction with humans and that is not CE certified or used in a setting where the CE certification no longer applies[1].

The first part of the report has to be completed by the researcher and/or a responsible technician.

Then, the safety officer (Heath, Security and Environment advisor) of the faculty responsible for the device has to inspect the device and fill in the second part of this form. An actual list of safety-officers is provided on this webpage.

Note that in addition to this, all experiments that involve human subjects have to be approved by the Human Research Ethics Committee of TU Delft. Information on ethics topics, including the application process, is provided on the HREC website.

Device identification (name, location):

Configurations inspected[2]: NA

Type of experiment to be carried out on the device:[3] Evaluation of connector devices

Name(s) of applicants(s): Izaka Tesselaar

Job title(s) of applicants(s): Student (MSc. Biomedical Engineering)

(Please note that the inspection report should be filled in by a TU Delft employee. In case of a BSc/MSc thesis project, the responsible supervisor has to fill in and sign the inspection report.)

Date:

Signature(s):

---

1 Modified, altered, used for a purpose not reasonably foreseen in the CE certification

2 If the devices can be used in multiple configurations, otherwise insert NA

3 e.g. driving, flying, VR navigation, physical exercise, ...

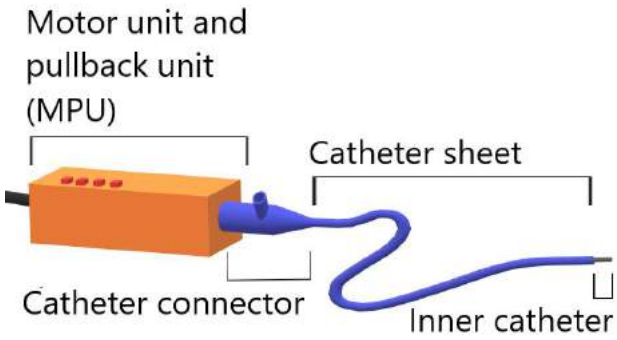
Device report for the Human Research Ethics Committee

Setup summary

The goal of this setup is to get input from real users (interventional cardiologists, technicians, etc.) on the design of a catheter handle. In order to achieve that, several prototype connectors have been produced and will be presented to those users in order to receive their feedback.

The experimental setup will consist of a mock-up Motor and pullback unit (MPU), catheter connector prototypes, and catheter as can be seen in the figure below. The experimental devices will be the catheter connector prototypes which will come in four different shapes and sizes, with differing ways to connect them to the MPU. Participants will be asked to connect and disconnect these prototypes with the mock-up MPU. Successful connection includes connecting the static outer catheter handle (In blue) and the relatively rotating inner catheter (In yellow). This will be followed by small list of questions about their likes and dislikes of each design.

Each connector prototype design is provided below in the appendix.



Device report for the Human Research Ethics Committee

Risk checklist

Please fill in the following checklist and consider these hazards that are typically present in many research setups. If a hazard is present, please describe how it is dealt with.

Also, mention any other hazards that are present.

Hazard type	Present	Hazard source	Mitigation measures
Mechanical (sharp edges, moving equipment, etc.)	Possible	Sharp edges as a result of the manufacturing process	Inspection before use and sanding down of any rough edges
Electrical	No		
Structural failure	No		
Touch Temperature	No		
Electromagnetic radiation	No		
Ionizing radiation	No		
(Near-)optical radiation (lasers, IR-, UV-, bright visible light sources)	No		
Noise exposure	No		
Materials (flammability, offgassing, etc.)	No		
Chemical processes	No		
Fall risk	No		
Other: Transmission of COVID-19	Yes	Surface transmission of COVID-19 through the experimental setup	The cleaning of prototypes before and after each setup
Other:			
Other:			

Appendices

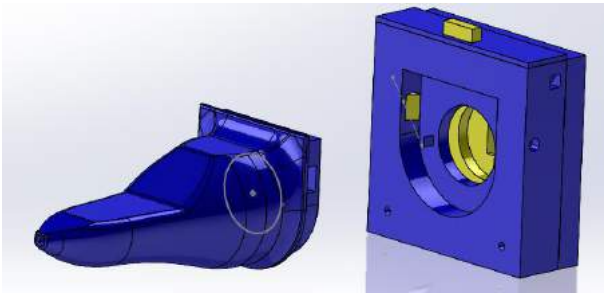
Connector 1:

-Large (connector diam >5 cm)

-Click to connect

-Keyed outer connector

-Non-keyed inner connector



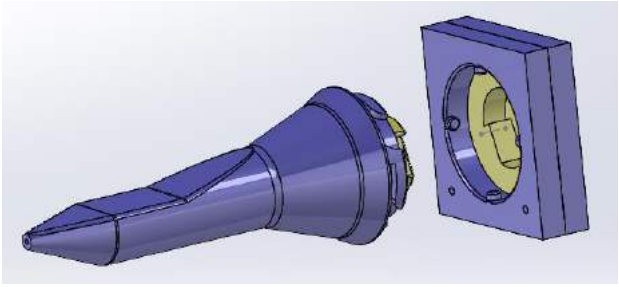
Connector 2:

-Large (connector diam >5 cm)

-Turn to connect

-Non-keyed outer connector

-Keyed inner connector



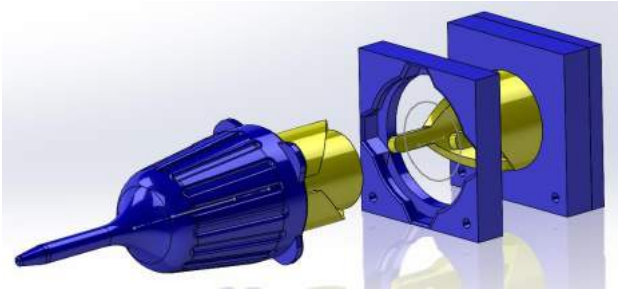
Connector 3:

-Small (Connector diam <5 cm)

-Turn to connect

-Non-keyed outer connector

-Self-adjusting inner connector



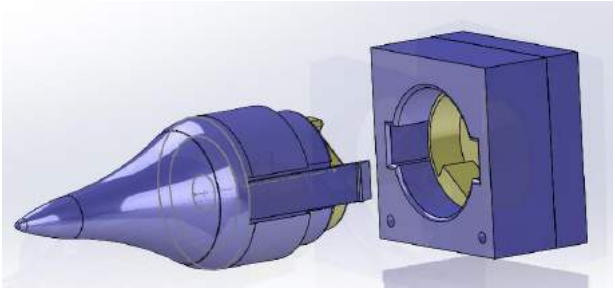
Connector 4:

-Small (Connector diam <5 cm)

-Click to connect

-Keyed outer connector

-Keyed inner connector



B

Device report for the Human Research Ethics Committee

Device inspection

(to be filled in by the AMA advisor of the corresponding faculty)

Name: Peter Kohne

Faculty: 3mE/IO

The device and its surroundings described above have been inspected. During this inspection I could not detect any extraordinary risks.

(Briefly describe what components have been inspected and to what extent (i.e. visually, mechanical testing, measurements for electrical safety etc.)

Date: 12-07-2021

Signature: 

Inspection valid until[4]:

Note: changes to the device or set-up, or use of the device for an experiment type that it was not inspected for require a renewed inspection

4 Indicate validity of the inspection, with a maximum of 3 years

C

Design considerations

C.1. Signal path considerations

Design for the signal path concerns the transmission of signals described in section 2.1.2 from a stationary to a rotary medium and back. Section 1.4 briefly describes the possible techniques available in order to achieve this transmission. It is important to minimise losses within the combined rotary joint and to minimise noise induced in the signal path. Any losses within the optical path will dissipate into heat, which could burn parts of the system. Fibers entering the optical rotary joint should be aligned with each other. Index-matching fluid or lenses may be added between the fibers to minimise diffraction due to the light traversing a fiber-air-fiber interface.

The electrical paths identified in the literature study resulted in slip rings or transformers. Due to the availability of the components, a slip ring was chosen for this application. A typical slip ring connection consists of two parts: A ring and a brush in contact with each other, one of which is rotating and one of which is stationary. Noise can be induced due to resistance fluctuations of the sliding motion between these parts dependent on the geometries, surface conditions, degree of contact, contact force, wear, rotational vibration, and environmental conditions [43, 44].

Component selection

Multiple manufacturers of combined optical and electrical rotary joints, who should be able to produce a component up to the requirements listed in section 2.3, were identified, after which a suitable one was chosen. The identified list of manufacturers can be seen in table C.1.

From table C.1, it can be seen that there are three manufacturers who could deliver a combined rotary joint up to specifications. Moog GmbH was willing to deliver such a product, but had a long response time where it seemed unclear if they were actually interested. After a couple of interactions, no responses were

heard back, dropping them from the consideration. Meridian Laboratory and Moflon Technology had similar pricing at time of consideration. Meridian Laboratory had a longer lead time on their product than Moflon Technology, but seemed much more interested in cooperating.

Moflon Technology offered a plain gold-brushed slip ring for two channels along with a standard optical rotary joint. Meridian Laboratory offered a modification of their MM-2 series slip ring: A brushless oil-sealed, mercury wetted slip ring of which they claimed "perfect signal" at any rotational speed and no maintenance needed. The optical rotary joint would be manufactured by their partner, Spinner GmbH, who has experience in developing such parts for OCT. Due to the level of service at the time, the relatively noiseless slip ring they offered, and their partner's experience, Meridian Laboratory's product was chosen. This slip ring also has the added benefit of reduced physical contact and wear within the component. The main risk is that the combined rotary joint breaks and spills its contents, which can be a substantial harm to users. The component will be confined within a housing and locked into place within the housing to minimise the risk.

It is important to note that any component containing mercury is subject to European and Dutch regulations, as mercury is a restricted substance as listed in Annex II of Directive 2011/65/EU. Annex IV of Directive 2011/65/EU however grants an exemption for "the use of mercury in intavascular ultrasound imaging systems", due to the lack of alternatives in low noise slip ring transmission at higher frequency operation [45].

Development of this part happened parallel to this project. A similar device to the one developed, the MM-2 series slip ring, can be seen in figure C.1.

C.2. Rotation considerations

The catheter tip must rotate inside a vessel and catheter sheet to be able to scan a region of interest. This can be accomplished by distal or proximal actuated catheter tips. Distal actuated tips use an integrated micromotor located in the catheter tip, while proximal actuated tips rotate the tip through a torque coil running through the

Table C.1: List of manufacturers approached, capable of producing a combined optical and electrical rotary joint for IVPA and IVUS imaging. The service column is a combination of the company's response time, as well as their willingness to work together to deliver the product with + being positive, = being neutral, and - being negative.

Company	Interested	Price estimate	Lead time	Service
B-COMMAND	No	*N.A.*	*N.A.*	*N.A.*
Cobham EEE	No	*N.A.*	*N.A.*	*N.A.*
Hangzhou Grand Technology	No	*N.A.*	*N.A.*	*N.A.*
MACCON	No	*N.A.*	*N.A.*	*N.A.*
Meridian Laboratory	Yes	$3950-4450	6-8 weeks	+
Moflon Technology	Yes	$3950	12-15 days	=
Moog GmbH	Yes	Not specified	Not specified	-
Penlink AB	No	*N.A.*	*N.A.*	*N.A.*

Figure C.1: Meridian Laboratory's MM-2 series combined optical rotary joint and slip ring system.

length of the catheter connected to a motor in a pullback device. The second one is chosen due to the relatively large catheter tip used for this imaging technique. A larger tip would make the catheter more difficult to navigate through the vasculature and would be undesirable.

Uniform rotation of the tip is desired for reconstruction of the image from the data acquired during rotation. A rotating catheter tip will feel the effects of nonuniform rotational distortion (NURD) due to the friction between the torque coil and the catheter sheet [46]. NURD is mitigated in the image construction phase and outside the scope of this design. It would be best to supply a uniform rotation, which can be accomplished by the control system of the motor.

Power requirements

Proximal actuation of the catheter tip requires the following elements to be rotated: The catheter tip, the torque coil including cables and fibers, connector elements at the proximal end of the catheter and distal end of the pullback, the rotating elements of the slip ring and optical rotary joint, the rotation transfer between the motor and the catheter, and any rotating connecting elements. Each element will have a moment of inertia to overcome during acceleration and will induce a friction torque during constant rotation resulting in a minimum power requirement for the motor. There are no requirements on how fast the system should be able to accelerate. It is possible to decrease the time it takes to accelerate to lower the power requirement during acceleration. Therefor the most prominent factor for the power requirement is to overcome the friction torque during constant rotation. The methods and measurements to estimate the power requirements of each component during constant rotation can be found in appendix D.1. From these estimates, it can be seen that a catheter requires an applied torque of between 14 and 27 mNm in steady state between 400 and 1200 RPM. This estimated torque is similar to a catheter torque measurement of Durrani e.a., where the torque was measured to be 31.49 mNm at a speed of 42000 RPM [47].

Measurements done by Meridian Laboratory on their product show the friction

torque was between 140 and 230 mNm at 2300 RPM, with an expectance that the trend will continue linearly between 500 to 1000 mNm at a speed of 10000 RPM. The manufacturer did clarify the rotary device has a break-in period of between 1 and 4 million revolutions, after which the friction will drop significantly.

For the sake of selecting a suitable motor, the high end estimate is taken for the pullback elements of 100 mNm per 1000 RPM and 30 mNm for the catheter elements. This means the motor must be able to provide a minimal rotational power to the system of 104 W at 3000 RPM and 1079 W at 10000 RPM.

Motor selection

For the motor and control selection, two motor manufacturers were considered after recommendations by technicians: MAXON and Faulhaber. After comparison, MAXON was chosen due to the plug-and-play parts they offered and the clear documentation on the control systems, which was not present in Faulhaber. This part focuses on the MAXON motor selection. This part of the system will be powered by a DC power source. As such, only DC motors were considered. The most important factors in the selection of this component are discussed below.

The main consideration at this stage of selection is between a brushed DC and a brushless DC (BLDC) motor. Both types of motors have their advantages and disadvantages of which the most important ones are considered below. A brushed motor will generally have a smoother transition whenever electrical power is converted into mechanical power, resulting in lower mechanical and electrical noise compared to a BLDC (especially when using gold contacts instead of graphite). The operating speed and power range of an average BLDC is higher than that of a brushed motor. A BLDC has a much higher lifetime than a brushed motor, since there are no physical brushes within the motor that are subject to wear. In a market setting, it seemed much more important to have a robust system than to have a little less noise, and as such lifetime was chosen as the most important factor. Keeping that factor in mind including the higher operating ranges, a BLDC motor was chosen for this application.

The motor chosen is the MAXON 305014 "EC-4pole 30 ⌀ 30 mm, brushless, 200 watt". This motor is capable of delivering up to 15000 RPM with a torque of 166 mNm during the time it takes to accomplish the pullback. The motor generates relatively high speed and low torque for the application, but this is easily transformed with the use of a belt and pulley system.

Belt and pulleys

The belt and pulleys (similar to the ones included in figure 1.3) are included to transfer the rotation from the motor to the catheter system. Since the motor included will not exceed 15000 RPM, 166 mNm, this belt-pulley system is used to transform this into 5000 RPM, 500 mNm using a 1:3 pulley conversion. A toothed timing belt combined with inverse-toothed timing pulleys are used to prevent slip.

Belts generally have a speed rating which may not be exceeded by the manufacturer's specifications. The highest speed rating found for timing belts are 50 m/s. This results in maximum pulley radii of 3.18 cm at 15000 RPM and 9.55 cm at 5000 RPM.

Vibration and misalignment of axes

It is important to factor in any rotational misalignment that can occur between the motor and the rotating signal elements. Not compensating for this can result in wear on the system and undesirable vibrations. These errors can be axial, spatial, or angular misalignment of the rotating axes.

A flexible shaft coupler is introduced between the motor axis and the system axis. This is a component that allows for small misalignments while still rotating. Each rotating part is fixed to the pullback device with bearings to minimise friction.

C.3. Pullback considerations

The device should be able to pullback the elements within the catheter that image the vessel. All rotating elements within the catheter need to be pulled back from within the pullback device. A robust technique for the pullback would be to connect a motor to a length of threaded rod moving a load along the length of its axis, which was chosen for this application.

Power requirements

An estimation of the power requirements for the pullback are made in appendix D.2. This results in a minimum power requirement of 0.3 W to pull back the rotating elements. This does not take into account the power it takes to pull back a catheter in a catheter sheet within the human body. Motors in similar catheter pullback applications are in the 5 W range and a similar powered motor was taken.

A spindle shaft has been chosen with a pitch of $p = 2$ mm. The rotational speed the motor should supply can be calculated with formula D.5. This results in a minimum motor speed of 150 RPM at a pullback speed of 5 mm/s and 900 RPM at a speed of 30 mm/s. Due to these speeds and the low power, a precious metal brushed DC motor has been chosen for this application.

C.4. Housing considerations

Human-device interaction

A user of the device will need to be able to pick up the device before use. Multiple handling points are introduced within the design: A handle on top of the device, and an indent within the housing at the proximal end of the device. This last feature is included so that a user can handle the device when applying a sterile sleeve around the housing. To ease this interaction, the distal end of the device is also tapered.

In a medical setting, it is important this device can be easily cleaned. This means smooth surfaces are preferred and any edges and shapes in which dirt and contaminants can accumulate should be avoided.

Dimensions

Most of the space inside of the device is reserved to accomplish the pullback itself. The length of this space is determined by the length of the pullback, the size of the parts that are pulled back, and the space necessary for wiring to extend and contract.

The minimum space for the connecting wires is determined by the minimum bending radius of these wires. The part with the smallest bending radius is the optical fiber, which determines the minimum space required for this bending.

The fibers within the current rotary joint have a long-term minimum bending radius of 30 mm. This suggests that a smaller bending radius is possible but not recommended. For future devices, Spinner GmbH. has suggested the use of fibers with a minimum bending radius of 8 mm, reducing the space needed for the cable guide during pullback.

D

Power requirement estimations of various pullback system parts

The goal of this appendix is to obtain an estimate of what the power requirements of the rotational and pullback motors should be during operation. In the new envisioned system, the main rotating component will be the combined rotary joint, of which the power requirements are known (section C.2). This means the main unknowns are the power requirements of a catheter and connecting parts. For simplicity, the connector parts are omitted. The power required to rotate a catheter will be estimated using the old pullback system in the first part. Furthermore the motor requirements for the pullback motor will be estimated in the second part of this appendix. In both cases it is assumed this motor can overcome the start-up torque during acceleration.

D.1. Power estimation of a rotating catheter in steady state

D.1.1. Theory

Here an estimation will be made for the power requirements of the catheter and the rotating components within the old pullback system. The power needed to keep an object rotating can be described by:

$$P_{rot} = \tau \frac{\partial \theta}{\partial t}, \tag{D.1}$$

where τ is the torque of the object and $\frac{\partial \theta}{\partial t}$ is the angular speed of the object. During constant rotation $\frac{\partial \theta}{\partial t}$ is constant and equal to ω. Similar to a linear situation,

the torque of the object will be opposed by an equal but opposite friction torque τ_{fr}. Each component is taken independent of each other for analysis, each having their own power requirement:

$$\begin{aligned} P_{rot} &= P_{rot,catheter} + P_{rot,pullback} \\ &= \omega\tau_{fr,catheter} + \omega\tau_{fr,pullback}, \end{aligned} \tag{D.2}$$

where the subscript *catheter* denotes all rotating elements in the catheter including the catheter tip, torque coil and connector on the catheter side, and *pullback* denotes all rotating elements within the pullback, including the rotary joint, the connector on the pullback side and rotary transmission from the motor to the rotary joint. All this power will be supplied by an electrically driven motor and results in the following power calculation:

$$P_{rot} = P_{M,out} = P_{M,in} - P_{M,loss} = \eta_M P_{M,in} = V_M I_M - R_M I_M^2, \tag{D.3}$$

where the subscript *M* denotes the motor, $P_{M,out}$ the output power the motor generates, $P_{M,in}$ the input power the motor consumes, $P_{M,loss}$ the losses of the motor, R_M the terminal resistance in the motor, V_M the voltage supplied to the motor, and I_M the current supplied to the motor. By measuring the input current and voltages of the motor, estimates can be made on the power consumed by the complete system. Furthermore, the voltage over the motor is proportional to the speed generated, and the current going through the motor is proportional to the torque generated. This proportionality is dependent on the motor and are called the speed constant, $n_{constant}$, and torque constant, $\tau_{constant}$, respectively.

D.1.2. Test setup

To get an estimate of the power requirements of each rotating system, three cases were measured on the old pullback system, which can be seen in figure D.1: The pullback system without a catheter attached, the pullback system with a straight catheter attached, and the pullback system with a bent catheter attached where the distal end is bent in a radius of 10 cm. The first case is used to get an estimate of the power consumption of the pullback elements (slip ring, belt, pulleys), which is then used in the second and third case to get an estimate for the catheter. The third case is a limited simulation of what the catheter may be subjected to when inserted into the human vasculature. The bending radius of this case was chosen to get a sense of what the effect of bending may be, while minimising the risk of damaging the catheter, as it was needed for imaging tests as well. The setup without the catheter is the same as in figure 1.3. The motor used in this setup is the MAXON RE 30 310007 and its relevant characteristics can be seen in table D.1.

After flushing the catheter, the system was configured to the set speed until achieving a steady state. The input power of the motor was than measured by measuring the voltage over the motor input terminals V_M with a digital multimeter and the current going into the motor as measured by the driver of the motor, which can be seen in table D.2. Since the current of the motor is fluctuating due to the

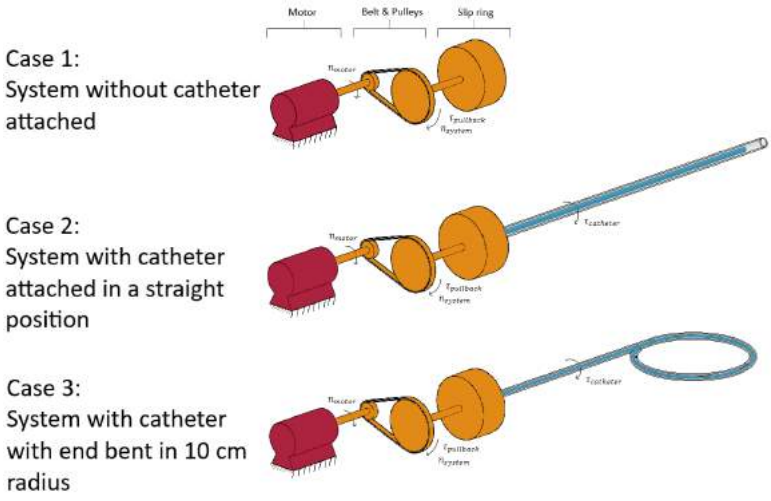


Figure D.1: The three cases for which the input power of the motor was measured to obtain a power estimate from the old pullback system seen in figure 1.3 and an imaging catheter. Case 1 is the old pullback system from Erasmus MC without a catheter attached. Case 2 is the old pullback system with a catheter attached where the catheter is maintained in a straight position. Case 3 is the old pullback system with a catheter is attached, where the distal end is bent in a radius of 10 cm.

nature of the control system, the average estimated value for the current $I_{M,mean}$ was taken together with an error $dI_{M,mean}$ of 100 mA. The error in the voltage measurement dV_M is a result of the significance of the last digit present in the multimeter measurements or the deviation during measurement if that was larger. Each measurement was done for a couple of speeds of the motor. The speed output of the motor is transformed by a belt and pulleys to the speed of the catheter system in a 3:1 ratio.

Table D.1: MAXON motor RE 30 310007 characteristics. Taken from the "RE30 ⌀30 mm, graphite brushes, 60 watt" data sheet of the MAXON DC motor catalogue of March 2021.

Characteristic	Symbol	Value	Unit
Rated power	$P_{M,in}$	60	W
Nominal voltage	V_M	24	V
Supply current	I_M	3	A
Terminal resistance	R_M	611	mΩ
Max. efficiency	η_M	87	%
Torque constant	$\tau_{constant}$	25.9	mNm/A
Speed constant	$n_{constant}$	369	rpm/V

Table D.2: Measurements on the old pullback system for each case.

Speed		Case 1		Case 2		Case 3		Error	
n_{motor} [RPM]	n_{system} [RPM]	V_M [V]	$I_{M,mean}$ [mA]	V_M [V]	$I_{M,mean}$ [mA]	V_M [V]	$I_{M,mean}$ [mA]	dV_M [V]	$dI_{M,mean}$ [mA]
6	2	0.4	400	0.8	900	0.5	650	0.3	100
60	20	0.6	460	0.9	900	0.7	650	0.3	100
300	100	1.3	510	1.5	900	1.4	750	0.1	100
600	200	2.1	550	2.3	920	2.2	850	0.1	100
1200	400	3.7	630	3.9	800	3.9	850	0.1	100
1800	600	5.3	640	5.4	900	5.4	900	0.1	100
2400	800	6.9	640	7.06	900	7.06	950	0.05	100
3000	1000	8.5	770	8.66	900	8.66	1050	0.05	100
3600	1200	10.1	820	10.23	950	10.22	1050	0.05	100

D.1.3. Measurements

The measurements for each case can be seen in table D.2. From the table, it can be seen that the voltage increases similarly for each case with the speed regardless of the load. The input current however has a more unpredictable nature. This can especially be seen in case 2 at motor speeds lower than 600 RPM. This could be attributed to the way that motors do not behave perfectly when operating much lower than their operating speed, resulting in a much lower efficiency of the motor than at nominal speed. The system has a hard time keeping the motor rotating at this speed. This imperfection can also be seen in the voltage measurements, where the variation in measurements is almost as large as the measurements itself. Due to lower relative errors and because the envisioned system will operate at higher speeds, it is better to analyse for the torque measurements the motor speeds above 1200 RPM to get a better estimate.

D.1.4. Estimations

After the 3:1 conversion from the motor to the rest of the system, the power estimates on the pullback and catheter components can be made. These results can be seen in figure D.2.

From figure D.2, it can be seen that in the old system the highest proportion of the power is necessary to keep the pullback elements rotating, which are the rotary joint and the belt pulley systems. As the majority of the rotating mass is located there, this was to be expected. The power of the pullback system without a catheter attached was then used to calculate the share of power in the catheter in the other two situations. The formula's for the power estimation can be seen in equation D.4:

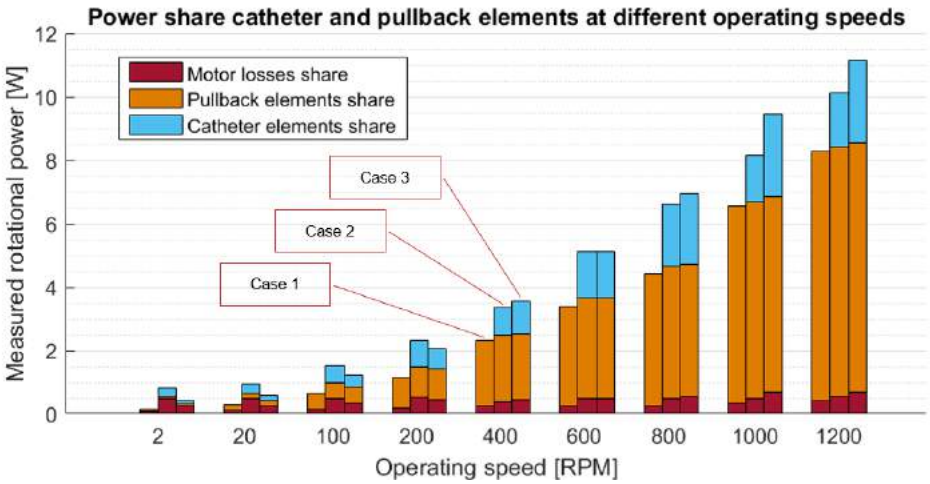


Figure D.2: Power share of the catheter elements, the pullback elements, and the motor losses as measured for the three different cases.

$$\tau_{Pullback} = \frac{\eta_M * 60}{2\pi} * \frac{V_{M,1} * I_{M,mean,1}}{n_{system}}$$
$$\tau_{Catheter} = \frac{\eta_M * 60}{2\pi} * \frac{V_{M,2} * I_{M,mean,2}}{n_{system}} - \tau_{Pullback} \quad \text{(D.4)}$$
$$\tau_{Catheter(bent)} = \frac{\eta_M * 60}{2\pi} * \frac{V_{M,3} * I_{M,mean,3}}{n_{system}} - \tau_{Pullback}$$

The individual torque shares of the catheter and the pullback elements can be calculated with these power estimations, which can be seen in table D.3. In this table, the expected torque shares as calculated by the torque constant of the motor are also shown.

From table D.3, it can be seen that the pullback torque share of the catheter is estimated to be between 10 and 24 mNm at system speeds higher than 400 RPM. Since the error estimated for the current is quite high, the error in the torque calculation is also high, meaning that the catheter torque share can be anywhere between 0 and 35 mNm within these estimations. The calculated torque share, calculated with the current measurement and the motor torque constant, results in similar values to those calculated through the power measurements.

D.1.5. Discussion

The estimates made show that the values predicted are comparable with what was found in literature. One study exists where catheter torque was calculated for an OCT catheter. In that study it was determined that the measured OCT catheter had a torque of 31.49 mNm at a speed of 42000 RPM. The technique with which this

Table D.3: Torque shares of the catheter and pullback elements of the old system. Here τ_{meas} indicates the measured torque share, whereas τ_{calc} is the expected calculated torque expected with the measured current.

Speed		**Pullback**		**Catheter**		**Catheter(bent)**	
n_{motor} [RPM]	n_{system} [RPM]	τ_{meas} [mNm]	τ_{calc} [mNm]	τ_{meas} [mNm]	τ_{calc} [mNm]	τ_{meas} [mNm]	τ_{calc} [mNm]
6	2	297±235	31±8	778±482	39±8	22±30	19±8
60	20	70±38	36±8	80±65	34±8	24±57	15±8
300	100	48±10	40±8	34±15	30±8	19±14	19±8
600	200	46±9	43±8	30±13	29±8	21±12	23±8
1200	400	50±8	49±8	15±12	13±8	19±12	17±8
1800	600	50±8	50±8	20±11	20±8	20±11	20±8
2400	800	50±8	50±8	20±11	20±8	24±11	24±8
3000	1000	59±8	60±8	11±11	10±8	21±11	22±8
3600	1200	63±8	64±8	10±11	10±8	17±11	18±8

has been measured however is not known.

In the old system, the torque of the pullback system elements was measured to be between 50 and 63 mNm for a speed between 400 and 1200 RPM. These numbers are incomparable with the new desired rotary joint. The old system uses a brushed slip ring, whereas the new system will use a wetted slip ring. Due to the conducting mercury inside the device, the inside needs to be firmly sealed, causing the friction torque needing to overcome to go up.

This method assumes that the torque share of the pullback elements and the motor is the same in the case without a catheter as it is with a catheter. As can be seen from table D.2, that is not necessarily the case for relatively low speeds, as the motor draws more current in case 2.

These measurements are of course a simplification of catheter mechanics. A catheter will undergo many more bends and turns when introduced to the human vasculature. The effect of this bending will likely be that the friction within the catheter will go up. No studies have been identified where catheter torque is measured after being introduced into such an environment. A more accurate bending of the catheter was not done in order to minimise the risk of catheter failure, as the catheter was needed in other experiments at the time.

The speeds at which the system was measured was lower than the desired speed of the envisioned new system. The effect of this likely that the friction torque will increase at higher speeds, although the extend of that is not known.

The methods leave room for a lot of improvement

This is especially apparent in the determination of the input current, where the input current was a highly fluctuating value of which the mean value was estimated, taken with a relatively large error value. The original idea of these measurements was to get information and a general estimate on the torque of a catheter. It was seen

close after the estimations were made that this friction torque would be outweighed by the friction torque present in the new combined rotary joint to the point where this value is negligible compared to the uncertainty of the rotary joint. Due to the nature of this report, these very rough estimations are documented as detailed as possible.

The friction torque of the catheter could be more accurately measured if the motor was supplied by a set voltage, which translates to a set speed, while measuring the current and the speed to determine the torque. This hopefully has the advantage of eliminating the large fluctuations in the input current when trying to control the system. More accurate estimations and a lower error could also be achieved if the experiment was repeated. It was chosen not to repeat these measurements. The idea behind this experiment was to get insight about the power share of the catheter, which has been obtained. Due to the relatively low power share of the catheter compared to the rest of the system (mainly the combined rotary joint), more measurements were not considered necessary.

D.2. Power estimations for a pullback motor in steady state

Here, the power necessary to operate the pulling back of the rotary elements will be estimated. This power estimate is based on a system that can be seen in figure D.3. This consists of a load that is being pulled back, a threaded rod connected to the load, and a motor connected to the threaded rod. The forces being enacted on the load, the speed of the pullback, and the torque and speed the motor should deliver are also depicted within the figure.

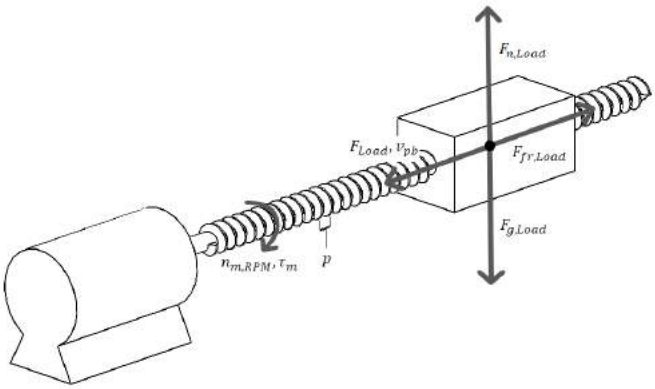


Figure D.3: Diagram of the relevant parameters for the pullback of a load. In it, the forces and speeds are shown that are being enacted upon the load and the threaded rod, supplied by the motor.

To estimate the necessary power the motor should provide in steady state, the applied torque on the threaded rod is estimated. The rotational speed the motor

should supply (in RPM), depends on the pullback speed and the pitch of the threaded rod:

$$n_{m,RPM} = \frac{60}{p} v_{pb}, \tag{D.5}$$

where $n_{m,RPM}$ is the motor rotational speed in rotations per minute, p is the pitch of the threaded rod, and v_{pb} is the desired pullback speed.

Based on the Maxon Formula Handbook, the torque the motor should provide can be calculated with the following formula:

$$\tau_m = \frac{p}{2\pi} \frac{F_{Load}}{\eta} \tag{D.6}$$

where F_{Load} is the force required to move the load along the axis of the threaded rod and η is the efficiency of power conversion between the threaded rod and the load. In the force diagram it can be seen that this force is equal but opposite to the friction force $F_{fr,Load}$, which is the resistance provided by the spindle system. The friction force can be expressed by the friction coefficient, μ, times the normal force of the load, $F_{n,Load}$. This normal force is equal but opposite to the gravitational force exerted on the load, $F_{g,Load}$. In summary the force it takes to move the load along the axis of the pullback can be expressed as such:

$$|F_{Load}| = |F_{fr,Load}| = \mu |F_{n,Load}| = \mu |F_{g,Load}| = \mu mg, \tag{D.7}$$

where m is the mass of the load and g is the gravitational constant taken at 9,81 m/s^2. The minimum power the motor should supply to the system can then be expressed by combining equations D.5, D.6 and D.7 (and with $\omega_m = 2\pi * n_{m,RPS} = 2\pi * n_{m,RPM}/60$):

$$\begin{aligned} P_{m,pb} &= \omega_m \tau_m \\ &= \frac{2\pi}{p} v_{pb} * \frac{p}{2\pi} \frac{\mu mg}{\eta} \\ &= \frac{\mu mg}{\eta} v_{pb} \end{aligned} \tag{D.8}$$

In equation D.8 it can be seen that the power the motor should supply can be expressed as a function of the pullback speed. The value of the mass has been taken at the maximum expected value of 2 kg. The efficiency of the spindle system is taken at 0.8 and the friction coefficient of the spindle system have been taken at 0.42 (sliding steel-on-steel) [48]. The maximum desired pullback speed is taken at 30 mm/s. Plugging in these values gives a minimum power requirement of 0.3 W for the pullback motor.

E

Additional responses user experience study

This appendix will cover all responses not covered by the user experience study covered by section 3.2. The original study focused on the catheter handle designs due to the limited time available of the participants. Participants without this limitation were welcomed to give additional feedback and comments about catheter imaging systems, the results of which are listed here in no particular order. Text within brackets is added to provide context to certain statements. Furthermore the following denotations are used: **R** = Remark, **O** = Observation, **Q** = Question, **A** = Answer.

Observations and remarks during the user experience study

About handle 1

- **R:** The flaps [used to click the connector in place] are sticking out and are a risk. It can hang onto gloves, cables, anything, and could cause harm that way.
- **R:** Handle 1 is too smooth to comfortably hold and turn.
- **R:** Having less parts sticking out is a good design choice.
- **R:** The fins [used to click the connector in place] are finicky.
- **R:** Clear on how it should be connected.
- **R:** Does not click well into place. Does not get excited about this design. It feels too frail.

About handle 2

- **R:** It should be immediately clear how to connect the handle. The turning is not immediately clear.

R: The alignment piece for the inner catheter connection on the catheter side can bump into the alignment piece for the inner catheter connection on the pullback side. It is possible to get both alignment pieces of the catheter handle on one half of the alignment piece in the pullback, which can result in damages.

R: The ribbed handle is great for grip.

R: The click being made is nice for an audible feedback that the handle is connected properly.

R: Not too intuitive and looks complicated. The alignment piece within the handle should be masked so that a user will not be confused by the sight.

O: The alignment piece was inserted incorrectly on the first try causing both alignment pieces of the catheter handle to be on one side of the pullback alignment piece.

R: Favourite design.

R: The alignment pieces are nifty.

About handle 3

R: [The handle has a flat side.] Having a "This side up"-sign on the handle would make it clearer during use.

R: Rotation is immediately clear to the grooves at the proximal end of the connector.

R: Manual inner catheter connection alignment is awkward. Something automatic or automated would be better.

R: Manual alignment of the inner catheter is not desirable. It would be better if it was already aligned so insertion is easier.

R: Looks good and feels solid.

R: The keyed-ness of the inner catheter connector are unclear.

About handle 4

R: The eject button should be clearly labelled (with e.g. a lock symbol, a light indicator, an eject symbol).

R: Easiest handle to connect.

O: Tried to disconnect the handle by pulling it first, without seeing the eject button.

R: The eject button should have a clearer indication of its function. Pulling is the first reaction.

R: The eject button needs better recognition.

R: It is nice to have an already aligned inner catheter connection.

O: Overlooked the eject button.

R: Not clear on how it should be connected.

R: Too short for how wide the design is.

R: The mock-up is too large.

Additional observations and remarks

R: Handle 1 and 2 are nice in size. Handle 3 and 4 are too big.

R: I work with catheter connectors in the way I am trained, so I do not have a initial preference for a twist or click connector. I do think a twist connector gives the better impression on when the connection is made, which is less so with a click connector.

R: Electrical and optical connections may be exposed, but trained users are familiar with the sensitivity of those ends and will be careful.

O: It takes some inspecting before being to able to correctly connect the handle, but this can easily be mitigated by training.

R: A big handle can maybe cause the pullback device to be too large for the operating table and may be an obstruction that way.

R: Prefers a twisting mechanism over a clicking mechanism, because it gives the impression that the catheter is secured well.

R: The design has to be robust and not easily breakable.

R: Prefers something that turns, so that you know it is secured, but would like to hear a click as well at the end of the turning.

R: The pullback device should be designed for and tested with the sterile sleeve, as that is an integral part of the system.

Additional questions and remarks

Q: Could you list the catheter handles from most favourite to least favourite?

A: Abbott OCT, InfraredX, Boston Opticross.

A: 2-4-1-3

A: 2-3-2-1

Q: Do you prefer the bigger or the smaller catheter handles?

A: They are all about the same size.

A: Smaller.

Q: Do you prefer a manual or automatic inner catheter connection?

A: Automatic.

A: Automatic.

Q: Do you prefer a twist or a click connection for the catheter handle?

A: Twist.

A: No preference.

A: Twist.

Q: Is there a feature of a connector you really like or dislike?

A: [Liked handle] 2 -> recognisable by OCT (St Jude)

A: Handle 1 is not very useful. Preferably twisting, then you know for certain that it is secured.

Additional remarks

R: Abbott OCT connector is by far the most pleasant.

R: Makoto [InfraredX pullback device] needs to be lifted with two hands due to the size and weight.

R: Makoto [InfraredX] isn' t used much outside of research purposes. The main imaging technique used is the Opticross HD of Boston Scientific. The participant suspects this is up to agreements with Boston Scientfic, familiarity of the system, or IVUS being sufficient in the goal at hand.

R: The choice of modality is up to the interventional cardiologists.

R: IVUS is being used relatively more nowadays in Erasmus MC as opposed to using imaging with only an angiogram.

R: While the Makoto [InfraredX pullback device] is heavy, the handle on the pullback makes up for it by being easy to hold.

R: Restless patients have been known to drop minor operating accessories of the operating table, but never a pullback device. If it becomes too much, the interventional cardiologist and staff will hold them down.

R: Use of OCT depends per interventional cardiologists. IVUS burdens the patient less due to no contrast needed. Other hospitals may use only OCT.

R: Other hospitals generally don' t have technicians present during the procedure, meaning the interventional cardiologist will do the whole procedure and interpretation, with the help of nurses.

R: IVUS image recognition requires some expertise that is easy to come by at Erasmus MC, which might not necessarily be the case in other hospitals.

R: The Opticross HD of Boston Scientific uses an Umbilical cord of >3 m, which is nice to have.

R: It is better to have a long sterile sleeve over the pullback, so that no non-sterile part of the umbilical comes close to the sterile field.

R: Saint Jude OCT gets grabbed with 2 hands on both sides. It features two indents where it can be hold. It needs to be held with one hand when the sterile bag transfer happens.

R: The Abbott OCT allows for a turning catheter handle, after which the inner mechanism is automatically connected by the system, resulting in a beep as audio feedback that connection has been made.

F

Pullback device design iterations

In this appendix, intermediate iterations of the pullback device design are shown. Each intermediate iteration acts as a feedback moment for technicians, which are then incorporated in the following iteration.

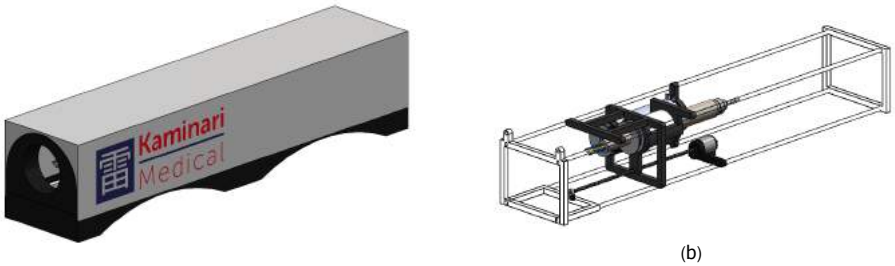
Design for this device featured a continuous process of designing, creating a model, asking for feedback, and incorporating that feedback into a new design. In that sense each iteration is merely a point in the process from which a better design can evolve. This appendix attempts to give some insight in the process that is iterative design for this specific device. All intermediate designs lack the catheter handle and have a hole where the handle should be placed instead.

F.1. First iteration

The first iteration starts with figuring out what a good configuration would be for the signal, rotation, and pullback elements. This iteration can be seen in figure F.1. The figure shows that in this design all signal and rotation elements are suspended within a frame, which connects to the pullback motor via a nut. During pullback this frame is guided by four long straight rods. This pullback is assembled outside of the housing, after which it should be fastened to the lower part of the housing. Start- and stop-switches have been added as part of the frame.

The housing consists of the lower black part on which the device stands and an upper white part that closes the housing. The lower part features indents making it easier the handle the device. Any connectors on the proximal or distal side have not been incorporated yet.

It is important to note that at this stage, different motors were considered resulting in different geometries for the motors and pulleys than the final design.



(a) (b)

Figure F.1: The first iteration of the pullback device. (a): The housing of the pullback device. (b): The inner mechanisms of this iteration.

Feedback

Feedback was given on this iteration of the design by EMI. The most important feedback points are included below.

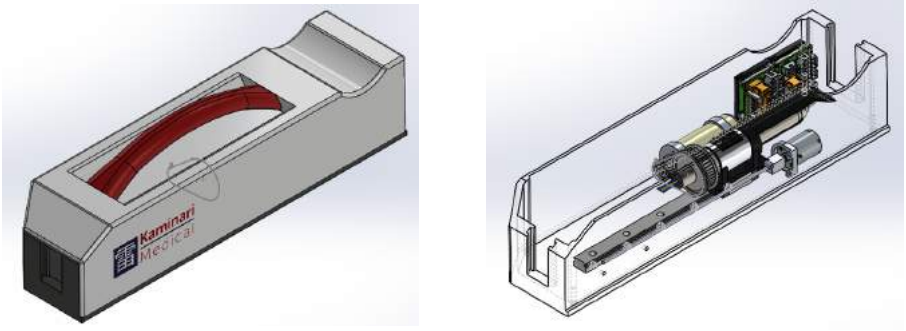
In reality metal guiding rods will never be perfectly straight. This has an added consequence that when introducing two or more contact points, the frame has a chance to get stuck since the framing doesn't align with the rods anymore. There are too many contact points between the metal guiding rods and the frame which holds the signal and rotation parts. The more contact points introduced, the more chance there is that the frame will get stuck when trying to move during the pullback. Finally the interface between the frame and the metal rods is very important, as choosing the wrong materials can cause friction which should preferably be avoided. After consultation, the metal sliding rods to guide the pullback were abandoned for the following iteration.

F.2. Second iteration

The final second iteration can be seen in figure F.2. The main difference from the first iteration is that the frame holding the rotation and signal elements is changed. The guiding of the pullback motion is also changed. The axis of rotation is moved off-centre to better fit the inside mechanisms of the pullback, since a motor needs to be placed adjacent to that axis.

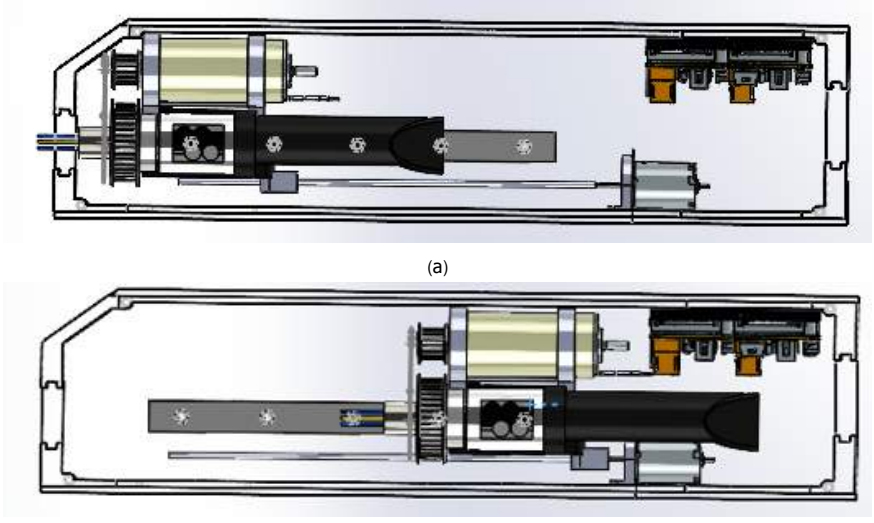
It can also be seen that in this iteration that several features have been added. A handle on the housing makes it easier to pick up the device. The adding of the handle has an additional consequence that space needs to be made within the housing to make room for users being able to put their fingers comfortably between the handle and the pullback device. In this design, that space is approximately 3.5 cm between the handle and the housing.

An indent in the proximal end of the device acts as a way to pick up the device from that side, making it possible to transfer the device from one user to another when applying the sterile sleeve. The distal end of the device is tapered so that the sterile sleeve is easier to apply. The bottom of the housing was changed to no longer have the two indents. The motor drivers have also been given a place within



(a) (b)

Figure F.2: The second iteration of the pullback device. (a): The housing of the pullback device. (b): The inner mechanisms of this iteration.



(a)

(b)

Figure F.3: Top view of the second iteration of the pullback device. (a): The inner mechanisms of the pullback device when it is in a start position. (b): The inner mechanisms of the pullback device when it is in an end position.

the device.

On the rotary joint frame has been added a shield for the rotating elements of the rotary joint, to minimise the chance any wiring would come in to contact with that part and to guide the stationary coax going to the top of the rotary joint. A mechanism has been added to tension the belt.

All rotary and pullback elements are located on a sliding block and rail, but those two centre of masses are not aligned. A suitable sliding block and rail were chosen. The dimensions of this design's housing are 10x8x38 cm, with the handle sticking

out an additional 3 cm.

Feedback

The main point of feedback on this iteration of the design concerns the transfer of rotational energy from the motor to the catheter. In this iteration the rotational energy is transferred from the motor via the pulley-belt-pulley to the combined rotary joint. This design does not account for misalignment of the axes of the rotary joint and the catheter. Furthermore, since the rotation is directly coupled to the rotary joint, it would be more prone to damages due to the small misalignments, which of course should be avoided since this are the most expensive part in the system. One way to fix this problem is to make the rotary joint following rather than leading in the catheter rotation. This means the rotation from the motor should be coupled to the catheter and that rotation should be coupled to the rotary joint by means of a flexible shaft coupler. This is a component that allows for small misalignments between the axes.

The base of the housing could be thicker. In this iteration, the base has a thickness of 5 mm, which is assumed straight. In reality, due to the printing processes and the relatively thin layer, this could bend or twist in a way that is undesirable. EMI suggested to have a base out of steel since that would be very precise, but that would add in weight. In following iterations, it was chosen to have a thicker base instead to mitigate this.

The pullback motor has been connected to the side wall in this version. Since the walls are relatively thin and the motor needs to exert force upon the system, this might cause problems with alignments of axes. The better way would be to mount the pullback motor to the base as well.

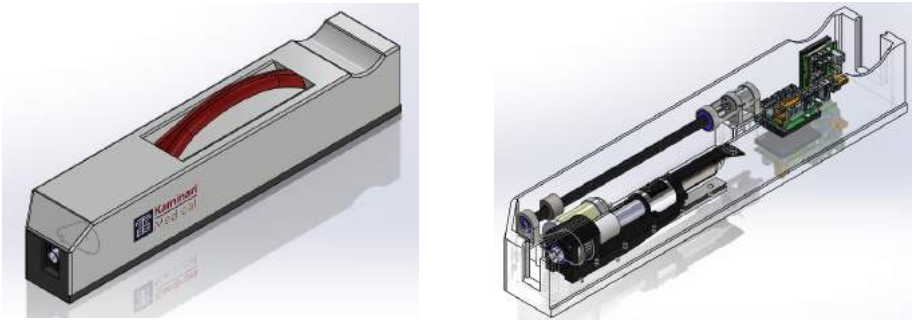
F.3. Third iteration

The third iteration is closest to the final design and features a redesigned frame for the rotation parts. The main added features are where the rotation is coupled to the system, the placing of the pullback motor and spindle, bearings, and as a consequence, the length of the device. An isometric view of the inside of the device can be seen in figure F.4.

In figure F.5, this iteration's signal path is shown. All components that need to be fixed in a single frame are denoted in the figure with an **X**. The pulley is fixed into position with a hollow drive shaft fixed between two bearings fixed to the frame. This drive shaft is connected to the rotary joint with a flexible shaft coupler. This flexible shaft coupler can not be directly connected to the rotary joint (unless a very large shaft coupler was taken) and is fixed to the rotary joint with a hollow shaft. Since every part is moved laterally to accommodate for all these extra parts, the length of the pullback device is increased significantly to 50 cm.

Feedback

In this iteration, the main feedback concerned the fixation of the bearings. The bearings are supposed to allow rotation of an axis, while resisting all other motions, such as axial or lateral forces. Lateral forces on the pullback spindle and bearings



(a) (b)

Figure F.4: The third iteration of the pullback device. (a): Isometric view of the housing of this pullback device. (b): Isometric view of the inner mechanics of this pullback device.

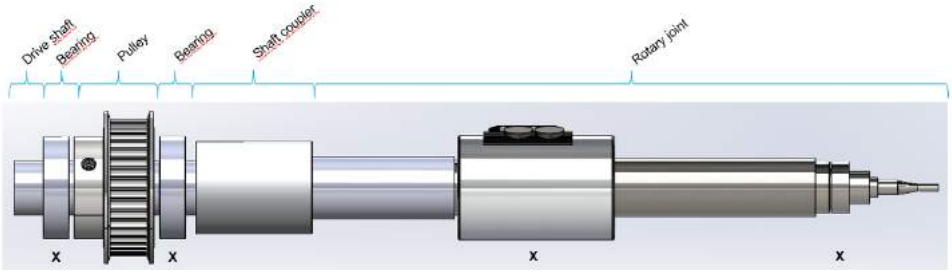


Figure F.5: The signal path of the third iteration that is subjected to the pullback. All parts denoted with **X** are fixed into the same frame.

occur whenever the pullback motor rotates. To counteract these undesirable forces, the bearings need to be fixed into place. One solution to this problem can be seen in figure F.6. In the figure, a rotating axle is shown which is fixed between two bearings, which in turn is fixed in a frame. In this configuration, the bearings resist axial and outward lateral motion due to how the bearings are connected.

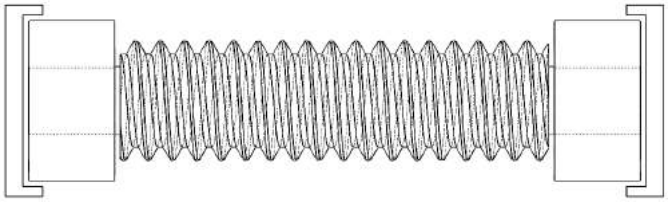


Figure F.6: Schematic of how the bearings should be placed within the device. The bearings here are shown at both ends of the spindle.