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Mechanical Design of an Automated Transesophageal Echocardiography System.

Mekanisk Design av et Automatisert Transøsofagealt Ekkokardiografi System.

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Mechanical Engineering, Process Technology and Product Development

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By
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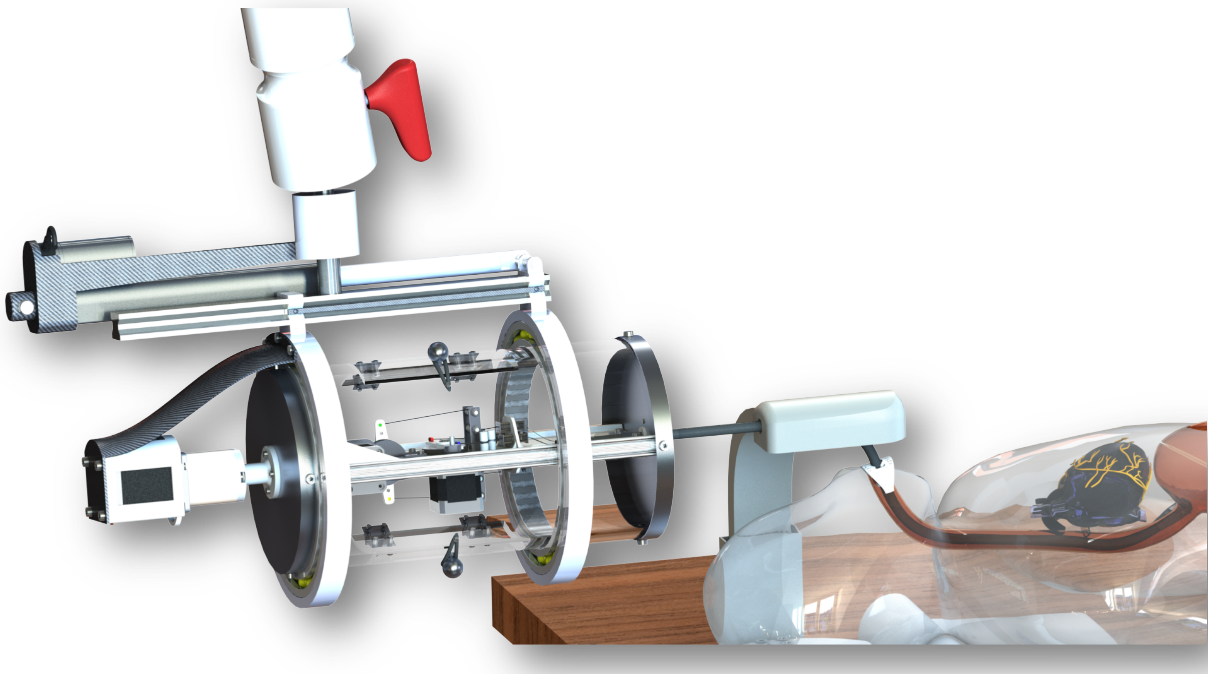

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PREFACE

This project report is a Master's thesis of Science and Technology resulting from a collaborative effort between the Norwegian University of Life Sciences (NMBU) and Oslo University Hospital. The first collaboration between Oslo University Hospital and NMBU was established in 2015 through the master thesis "Design of Catheters for Navigation and Positioning in the Cardiovascular system" by Sletmoen and Hodneland. This collaboration further led to several related theses, focusing on the development of medical equipment to assesss cardiac pathologies.

This thesis concerns concept development and design of mechanical features in a transesophageal ultrasound echocardiography system. This design will enable future automation and joystick manipulation through use of actuators and sensor technology.

Both the authors of this paper has previously finished a bachelor's degree in technology. Jørgen Tveter has written a thesis in mechatronic engineering at the University in Agder. Andreas Hansen has completed his bachelor's degree in mechanical engineering at Høyskolen i Oslo og Akershus.

We would like to thank everyone who has contributed to make this project possible. We thank Professor Nils Bjugstad and Associate Professor Jan Kåre Bøe at NMBU for guidance throughout this thesis, and for making the cooperation with Oslo University Hospital possible. We thank Associate Professor Ole Jakob Elle and MD, PhD Jacob Bergsland for their guidance and knowledge related to the field of automation and heart surgery, as well as for trusting us with this opportunity.

We would also like to express our sincere gratitude to the surgical team at Oslo University Hospital, for showing a tremendous hospitality and for deepening our understanding of TEE and minimally invasive cardiac surgery. Being granted access and insight to the procedures you conduct have been a great asset and a true privilege. Finally a special thank you to Hilde Korslund for making our visits to Oslo University Hospital possible, and for maintaining a continuous dialogue with us.

Ås, 15.05.2019

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ABSTRACT

Transesophageal echocardiography (TEE) is used in heart diagnostics and guidance of minimally invasive cardiac surgery (MICS) procedures, such as MitraClip®. It enables high-quality image surveying of the heart by approaching it via the esophagus. However, conducting TEE during these procedures exposes the echocardiographer to radiation, due to necessary complementary x-ray imaging.

This master's degree of science in technology presents a product design that will contribute to eliminating this health hazard. It is achieved through implementing electric actuators and mechanical solutions that provide all maneuverability necessary to perform a comprehensive TEE examination. The design also enables implementation of sensor technology and further work towards automation. Furthermore, the aim has been to document the development through a detailed report and a simulation of maneuverability. The main drive for conducting this project has been to further the technological field of TEE by contributing to improved health aspects for patients and echocardiographers, and further standardization of minimally invasive cardiac surgery.

The thesis can be divided in two main parts. The first part was a research phase dedicated to acquiring the necessary knowledge of heart pathology, heart valve pathophysiology and relevant surgical procedures. This has been done through literature research and by witnessing MitraClip® procedures conducted at Oslo University Hospital. A state of the art of available technology that can improve TEE technology was also conducted in the initial phase of the project. This initiating phase has provided a clear scope for this thesis.

The second part, a multi-phase product development process, conducted according to product development methodology. First, Alex Osborn's Scamper methodology was applied: all functions necessary to conduct a comprehensive TEE examination have been identified and redesigned in order to work with electric actuation. Second, all the functions have been weighted in order to ensure the best possible solution according to Pugh's method. The interests of all parties involved in a TEE examination were taken into consideration through continuous dialogue with experts at Oslo University Hospital. The final design is a result of a gradual acquisition of knowledge, a comprehensive function analysis and of continuous feedback from supervisors.

A mechanical design that ensures necessary functions from existing solutions have been integrated into a system that enables further implementation of sensor technology and automated control. An actuation unit has been developed in order to manipulate the endoscope in all necessary degrees of freedom. This unit is composed by a linear actuator that elongates the probe in the esophagus' length-axis in addition to three stepper motors that manipulate rotation and flexion of the endoscopes' distal end. The final design also accommodates the metric specifications imposed by the esophagus in addition to the systems adaptability to operating theatres. A successful simulation of the systems maneuverability has been conducted through Simulink, where a joystick was used to manipulate the actuation unit.

The project is the first of a series of intended phases towards a fully autonomous TEE system. Therefore, specifications for motors, sensors and material selections have not been conducted. It is recommended to include multiple disciplines of engineering to address future directions, due to the complexity of the project.

SAMMENDRAG

Transøsofageal ekkokardiografi (TØE) er anvendt i hjertediagnostikk og overvåking av minimalt invasive klaffekirurgiprosedyrer som MitraClip®. Teknikken tilrettelegger for høykvalitets bildeovervåkning av strukturer i hjertet ved å tilnærme seg det via spiserøret. Ved bruk av TØE som bildeveiledning under minimalt invasive prosedyrer blir operatøren av apparatet utsatt for stråling. Dette er forårsaket av nødvendig komplementerende bruk av røntgen.

Denne mastergraden i vitenskap og teknologi presenterer et design av et produkt som vil bidra til å eliminere denne helsefaren. Dette er oppnådd ved implementering av elektriske aktuatorer og mekaniske løsninger som leverer alle nødvendige manøvreringsmuligheter for å kunne gjennomføre en omfattende transøsofageal ekkoundersøkelse. Videre har dette prosjektet blitt dokumentert gjennom en detaljert rapport og en simulering av systemets bevegelser. Drivkraften for å gjennomføre dette prosjektet har vært å videreutvikle teknologien rundt TØE for å bidra til forbedring av helsetilstander for pasienter og kirurger, i tillegg til ytterligere standardisering av minimalt invasive prosedyrer.

Rapporten kan deles inn i to hovedsegmenter. Det første segmentet har vært dedikert til forskning for å tilegne nødvendig kunnskap om hjertepatologi og følgende patofysiologi lokalisert til hjerteventiler. Dette har blitt gjort gjennom omfattende litteratursøk og overværing av mitralklaffprosedyrer ved Oslo Universitetssykehus. Tilgjengelig teknologi som kan bidra til utbedring av TØE har også blitt studert. Denne innledende fasen har ført til klare avgrensninger for oppgaven.

Det andre segmentet har bestått av en flerfase produktutviklingsprosess som er gjennomført i henhold til relevant produktutviklingsmetodikk. Denne metodikken er tilegnet gjennom et femårig utdanningsløp. Alex Osborns Scamper metode er brukt for å kartlegge eksisterende TØE løsninger og dekomponere disse. Videre har de blitt redesignet, slik at de kan samkjøres med elektrisk aktuering. Samtlige designforslag har deretter blitt vektet opp mot hverandre for å sikre et optimalt konsept ved hjelp av Pughs metode. En løpende dialog med fagkyndige ved Oslo Universitetssykehus har ført til at det endelige produktet ivaretar interesser fra alle involverte. Det endelige designet er et resultat av en stegvis tilegning av ny informasjon, en omfattende funksjonsanalyse og kontinuerlig tilbakemelding fra veiledere.

Det er blitt utviklet en komplett mekanisk løsning som ivaretar nødvendige funksjoner fra dagens løsninger. Disse er videre integrert i et system som vil kunne tilrettelegge for videre implementering av sensorteknologi og autonom styring. En aktueringsenhet er blitt utviklet for å kunne styre endoskopet i alle ønskelige frihetsgrader. Denne enheten består av en lineæraktuator som styrer proben i spiserørets lengderetning, og tre steppermotorer som manipulerer rotasjon og defleksjon av endoskopets distal ende. I den endelige løsningen er det også tatt hensyn til spiserørets dimensjoner og systemets plassering i forhold til utforming av operasjonssal. En vellykket simulering av systemets virkemåte er blitt gjennomført i Simulink der en joystick ble benyttet til manøvrering av styringsenheten.

Produktet som er presentert i denne rapporten er fortsatt i en tidlig utviklingsfase. Endelige valg av materialer, sensorer og elektriske komponenter er ikke foretatt for aktueringsenheten. For videre arbeid anbefales det å inkludere flere ingeniørdisipliner grunnet prosjektets omfang.

LIST OF ABBREVIATIONS

Table 1: List of abbreviations.

Abbreviation	Explanation
2CH	Two-chamber
4CH	Four-chamber
AD/DA	Analogue-to-digital/Digital-to-analogue
AR	Aortic regurgitation
AS	Aortic stenosis
AV	Aortic valve
CFA	Color flow assessment
CNC	Computer numerical control
CPB	Cardiopulmonary bypass
DC	Direct current
DOF	Degrees of freedom
EAP	Electroactive polymers
EHS	Environment health and safety
IPD	Integrated product development
LA	Left atrium
LAX	Long-axis
LV	Left ventricle
ME	Midesophageal
MICS	Minimally invasive cardiac surgery
MV	Mitral valve
NRMICS	Non-robotic minimally invasive cardiac surgery
PS	Physical signal
PS	Physical signal
PV	Pulmonary valve
PVC	Polyvinyl chloride
RA	Right atrium
RV	Right ventricle
SAVR	Sternotomy aortic valve replacement
SAVR	Sternotomy aortic valve replacement
SAX	Short-axis
TAVI	Transcatheter aortic valve implantment
TAVI	Transaortic valve implantement
TEE	Transesophageal echocardiography
TG	Trans gastric
TV	Tricuspid valve
UE	Upper esophageal

TERMINOLOGY

Table 2: Explanation of terminology used.

Abdominal	The body structure between chest and pelvis
Actuation	Making a machine or process start to work
Anteflex	To bend forward
Apex	The inferior tip of the heart
Artery	Thick tube that carries blood from the heart to other parts of the body
Biocompatible	A material that is not harmful for the human body
Capillaries	Very thin vessel carrying blood to tissues
Catheter	A long very thin tube used to perform tasks inside the body
Circulatory system	The organs responsible for blood to flow through the body
Congenital	A disease or condition that exists at or from birth
Distal end	A point away from another particular point
Echocardiography	The use of ultrasound to examine the body
Heart valve	A valve that opens and closes, forcing blood to flow in one direction
Hysteresis (sensors)	When the physical property lags behind the changes in effect causing it
Incision	Surgical cut made in skin or flesh to reach inner structures of the body
Leaflet	Thin tissue, present in heart valves
Linearity (sensors)	Difference between an output value and measured physical position
Median sternotomy	Surgical procedure that separates the sternum
Minimally invasive cardiac surgery	Surgical procedure on the heart with a small incision
Open-heart surgery	Surgery in which the heart is exposed and the blood made to bypass it
Pathology	The scientific study of disease
Pathophysiology	The study of disease mechanism
Peri-procedural morbidities	Disease occurring soon before, during or soon after surgery
Precision (sensors)	The ability to repeat an operation to a high level of accuracy
Regurgitation	The act of blood leaking back to where it came from
Resolution (sensors)	A size measurement related to a change of position value
Retroflex	To bend backward
Stenosis	A part of a passage or opening in the body that has become narrow
Thoracic	Area of the chest
Transducer	Electric device that changes one form of energy to another
Transesophageal	Through or across a part of the digestive system
Ultrasound	Special sound waves used in processes examining the body
Vein	Tube that carries blood from the heart to other parts of the body
Visual surveying	An examination of behavior done through visual objects

SYMBOLS AND FORMULAS

Table 3: List of symbols.

Symbol	Definition	Unit
l	Length	mm
L	Length	mm
D	Outer diameter	mm
d	Inner diameter	mm
Z	Withdrawal/advance	mm
θ_x	Anteflex/retroflex	$^\circ$
θ_y	Left/right flexion	$^\circ$
θ_z	Rotation	$^\circ$
m	Mass	kg
r	Radius	mm
F	Force	N
CoG	Center of gravity	$-$
μ	Coefficient of friction	$-$
A	Areal	mm^2
σ	Stress	MPa
π	Pi	$-$

Table 4: List of fundamental formulas.

Description	Formula	Index
Force	$F = m \cdot a$	1
Moment	$M = F \cdot l$	2
Friction force	$F_s = F_n \cdot \mu_s$	3
Area	$A = \frac{\pi \cdot d^2}{4}$	4

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1 Introduction

This first chapter will shed light on the background for this master thesis, as well as give a brief introduction to the field of cardiovascular surgery with the intent of providing the reader with the necessary knowledge. This includes descriptions of the heart and major blood vessels, heart valve pathophysiology, the esophagus and of technologies related to diagnostics and catheter procedures.

1.1 Background

To date, more than 45 000 patients worldwide have undergone mitral valve repair using the mitral clip approach (MitraClip®, Abbott Vascular, USA) [1]. In 2018, 27 MitraClip® procedures were conducted at Oslo University Hospital. These procedures are associated with a high cost, and they are highly dependent on the schedules of the most skillful echocardiographers. This master's degree in technology revolves around transcatheter valve implantation and repair, specifically transesophageal ultrasound image guidance during minimally invasive cardiac surgery (MICS). This type of surgical procedure is carried out by utilizing different types of long, thin and maneuverable catheters. These catheters are introduced to the circulatory system through a small incision in the upper thigh of the patient, allowing it to follow the aorta up to the heart, where it can perform different surgical tasks according to the patient's pathology. A recently published meta-analysis of randomized trials concludes in transcatheter aortic valve implantation (TAVI) showing beneficial results related to risk reduction of death, mortality and reduction in peri-procedural morbidities such as kidney injury and blood transfusion [2]. The study also shows a subgroup within the population, consisting of females, undergoing TAVI having an improved survival rate compared to patients undergoing sternotomy aortic valve replacement (SAVR). This may be a result of less frequent secondary outcomes as acute kidney injury and major bleedings. However, no findings favor TAVI over SAVR after two years of follow-up.

This thesis will focus on imaging technology, specifically an autonomous approach to transesophageal echocardiography (TEE), aiming at aiding surgical intervention for repair of heart valve disorders. During minimally invasive procedures in the heart, surgeons are dependent on being able to see the location of their catheter tools at all times. This is done through a combination of x-ray and echocardiography. Through contributing to a future autonomous TEE approach, the goal is to make the procedure more efficient and reduce the amount of x-ray radiation the physician conducting the TEE is subjected to. Therefore, the product development conducted in this thesis has a potential high societal impact.

1.2 Preliminary study

During the fall of 2018, in the course TIP300 – Concept and Product Realization, the participants of this master thesis conducted a preliminary study. This course focused on learning methodical skills for product development. The study is documented through the course report "Forstudie for utvikling av medisinsk utstyr" [3].

The main project goal was to acquire a more profound knowledge and better understanding of the terminology and the different concepts regarding the use of TEE, and to further develop an early-stage conceptual design that would facilitate further automation of TEE. The report discussed the steerability of the probe with possibilities for rotation, elongation, anteflex and retroflex, left and right flexion, necessary feedback sensors and different approaches to transmission and actuation. The various steering mechanisms were based on earlier NMBU master thesis and implemented to the final concept. In addition, an early concept was designed containing an exterior device in where all of the translations and steering could be applied by linear actuators and electrical motors and with possibilities for position feedback and force feedback for accurate control.

Figure 1: Result of preliminary study.

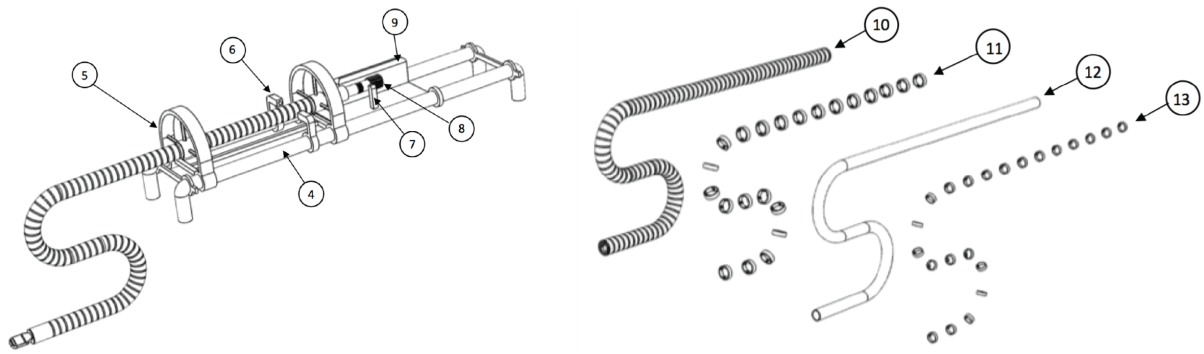


Figure 2: Exploded view of the concept.

The product goal in this prestudy was to design a TEE concept that implemented components necessary to facilitate a future autonomous solution. This involved developing mechanical functions that could be manipulated by actuators. One of the main drives behind this project was to reduce the amount of x-ray radiation the echocardiographers were exposed to during MICS, as well as providing a more standardized approach to the procedures.

1.3 The cardiovascular system

The cardiovascular system consists of the heart and all the arteries, veins and capillaries enabling blood flow throughout the body. The heart has four chambers and functions as a mechanical pump. The upper section of the heart is divided into the right atrium (RA) and the left atrium (LA). The lower section consists of the right ventricle (RV), and the left ventricle (LV). These sub-chambers are divided by one-way valves. On the right side, separating the RA and RV is the tricuspid valve (TV) (figure 3). On the left side, separating the LA and RV is the mitral valve (MV).

The heart is positioned in the center of the chest with its tip, the apex, pointing towards the left side of the body. This results in two-thirds of the hearts mass being on the left side of the body, causing challenges for TEE imaging during MICS [4].

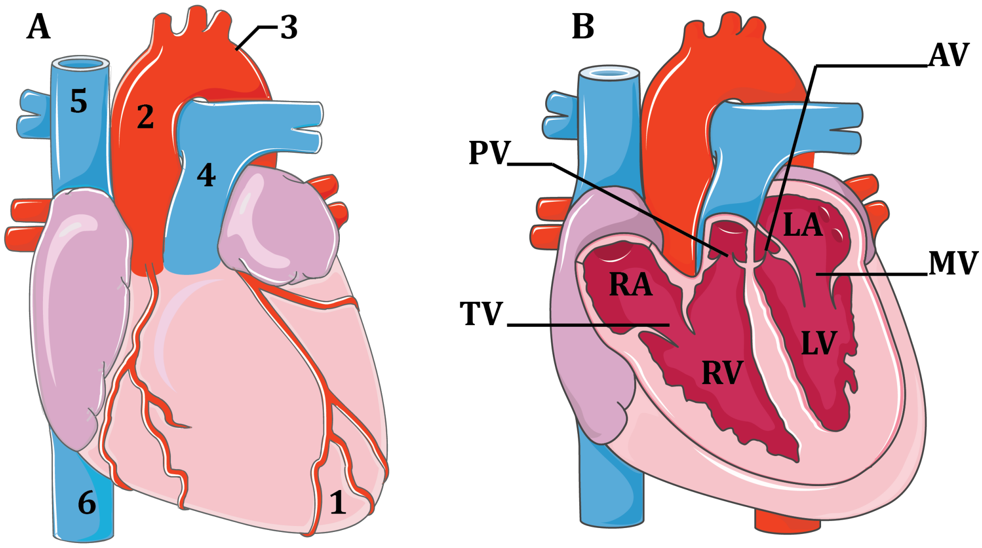


Figure 3: Heart's major arteries, chambers and valves.
(A) *1: Apex, 2: Aorta, 3: Aortic arch, 4: Pulmonary artery, 5: Superior vena cava, 6: Inferior vena cava.* ***(B)*** *RA: right atrium, LA: left atrium, RV: right ventricle, LV: left ventricle, PV: pulmonary valve, AV: aortic valve, TV: tricuspid valve, MV: mitral valve. Adapted from [5].*

All of the valves in the heart have a one-way functionality. They consist of a set of sails, called leaflets, that are supported by a ring of tough fiber tissue. The MV has two leaflets, while the TV, AV, and PV have three (figure 4). The heart pumps through a succession of the one-way valves by contracting the muscles surrounding chambers. After blood has filled the atriums, a contraction pumps it through the respective valve and into the ventricles. When the ventricles are filled with blood, the one-way functionality keeps blood from leaking backward, and a new contraction can pump the blood through the AV and PV and into the circulatory system.

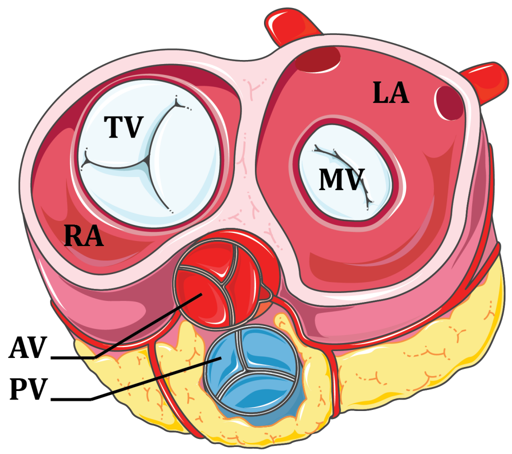


Figure 4: The valves in the heart.
Cross-section through the top of the heart. Adapted from [5].

The blood circulates in two different systems (figure 5). The pulmonary circulation (blue), receives oxygen-poor blood through the superior and inferior vena cava. It passes from the RA, through the TV, and into the RV. When the RV contracts, the blood gets pumped through the PV, into the pulmonary artery and veins, towards the lungs. The blood is re-enriched with oxygen by passing through the capillaries in the lungs. The oxygen-rich blood enters the aortic system (red) as it leaves the lungs.

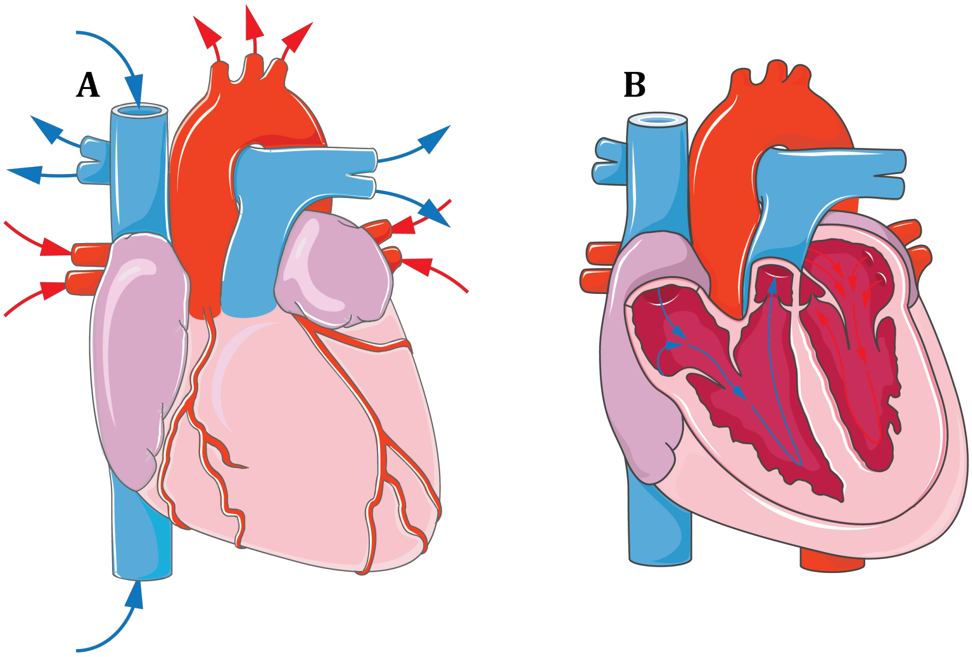


Figure 5: Blood flow to and from the heart.
(A) *External view* ***(B)*** *Internal view. Oxygen-poor blood is pumped into the lungs (blue arrows). Oxygen-rich blood pumped to the body (red arrows). Adapted from [5].*

After the oxygen level has been restored, the blood enters the LA through the main pulmonary veins. Here it gets pumped in the LV through the MV as the LA contracts. Next, a muscle contraction sends it from the LV, through the AV, and into the aortic arch, branching to aortic veins, supplying the body with oxygen-rich blood.

1.4 Heart valve pathophysiology

Heart valve pathologies can be either congenital, meaning that the patient was born with insufficient valve capacity, or acquired, meaning the patient has developed the disease later in life. Abnormal cardiac valve function impairs the pumping function of the heart.

This thesis is mainly focused on aiding surgical procedures surrounding valvular heart diseases. These heart pathologies are usually not regarded as a major public-health problem. However, in a population-based study of 11 911 randomly selected adults representative of the general population, findings uncovered that 615 (5.2%) of the participants suffered from moderate or severe valve disease [6]. This frequency was further increased in subjects older than 65 years of age. This study covered the four most common types of abnormal cardiac valve function.

Abnormal cardiac valve function is often associated with rheumatic fever, an inflammatory disease that can develop after untreated bacterial infection. Rheumatic fever is rare in developed countries du to extensive use of antibiotics, but still an issue in developing countries. Therefore, the increased frequency of mitral stenosis in the older part of the population, might be related to a lack of antibiotics during childhood.

The following sections will describe the most common cardiac valve pathologies and are based on two sources: "Prof Hershel Raff, Prof Micheal Levitzky. Medical Physiology: A systems Approach, 2011." [7], and "Jim Newton, Nikant Sabharwal. Valvular Heart Disease: Oxford Specialist Handbooks in Cardiology" [8].

1.4.1 Mitral stenosis

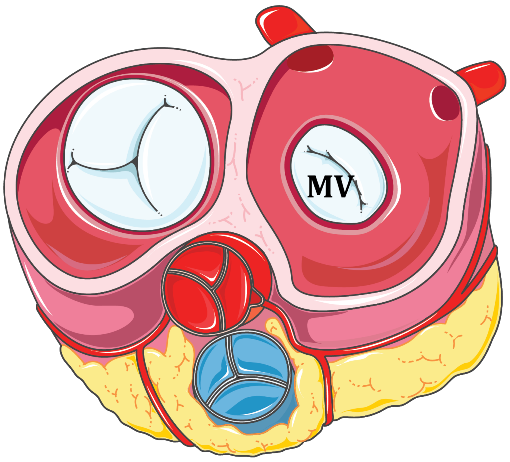


Figure 6: Mitral stenosis.
The passage narrows as the MV thicken and stiffens due to inflammation. Adapted from [5].

Mitral stenosis is a narrowing of the valve which thickens and stiffens as a result of inflammation or a congenital disability (figure 6). The result is a weakened blood flow through the narrowed valve opening due to a reduced flux field for the blood to stream through, as well as increased resistance while passing through the leaflets. This sees to a higher pressure difference between the left atrium and ventricle. As a result, the patient will suffer from increased volume and blood pressure in the atrium and therefore a growth in muscle mass due to increased strain. Further on this results in a reduction of pumping efficiency and an increased chance of blood clots forming in the atrium, which might lead to stroke or other damage if released in the circulation. If the mitral stenosis is severe, it may lead to a lower level of oxygen in the blood due to damage of the blood vessels in the lungs. This eventually results in heart failure. If the stenotic mitral valve requires surgery, it will be carried out through either traditional sternotomy surgery or artificial valve implantation by using a mitral clip procedure.

1.4.2 Mitral regurgitation

Mitral insufficiency is often due to a genetic weakness of the mitral valve tissue. A common form of mitral regurgitation is mitral valve prolapse. This causes the leaflets of the mitral valve to not coalign properly, due to them bulging back into the left ventricle while trying to close. The result is blood leaking from the left ventricle back into the left atrium during systole (when the heart is contracting) (figure 7). With severe regurgitation, the left atrial pressure and volume increase drastically and result in the atrium enlarging to accommodate the extra volume of blood.

The enlargement of the atrium often causes the heart to beat more rapidly in an irregular pattern and hence reduce the pumping efficiency. This may, similar to mitral stenosis, cause blood clots forming in the atrium. If these clots get pumped into circulation, they may cause stroke or other severe damage.

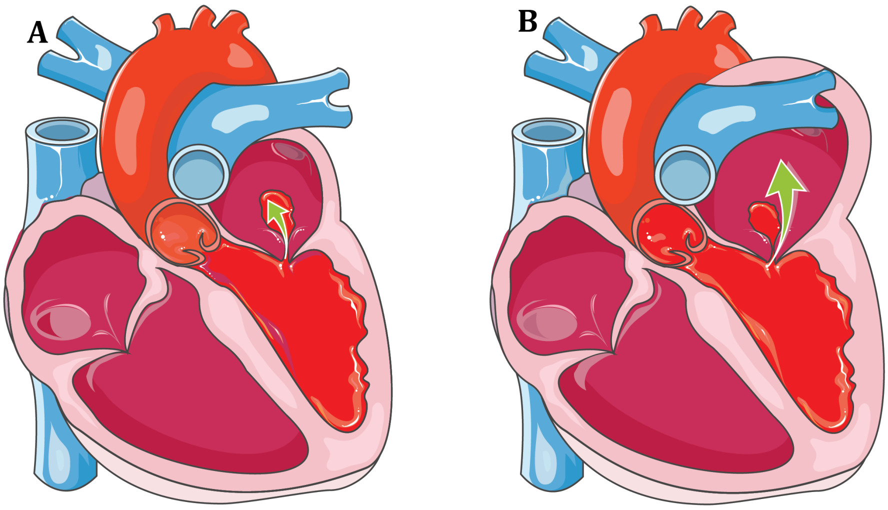


Figure 7: Mitral regurgitation.
(A) *Acute mitral regurgitation,* ***(B)*** *Chronic mitral regurgitation, muscle abnormalities occurring due to strain. Green arrows: Blood leaking back through the mitral valve and into the left atrium. Adapted from [5].*

The treatment of a faulty mitral valve depends on the severity of the diagnosis. With a mild regurgitation, the patient may be free of symptoms, and periodic monitoring of the development will determine if surgery will become necessary at a later date. If the defect becomes more severe, the patient must undergo surgery before the muscle tissue suffers irreversible damage. If the patient is incapable of undergoing surgery, drugs to prevent heart failure or blood coagulation can be prescribed.

1.4.3 Aortic stenosis

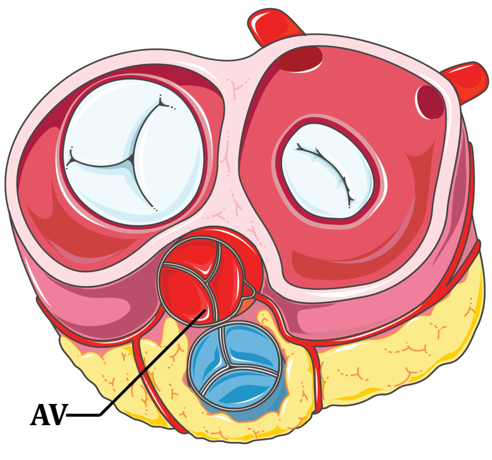


Figure 8: Aortic stenosis.
The aortic valve is highlighted. Adapted from [5].

Aortic stenosis (AS), similar to mitral stenosis, causes the aortic valve to stiffen and thicken due to congenital disabilities (figure 8). Usually this valve opens wide and provides the bloodstream with nearly frictionless passing. If this valve becomes stenotic, a significant pressure difference will be needed to open up the valve and allow the necessary blood flow. This causes a systolic strain on the left ventricular chamber due to the high pressure and a slow rising aortic pressure. Patients suffering from aortic stenosis are subject to a low pulse and an increase of muscle mass in the ventricular chamber. This increase can be compared to the kind of muscle growth achieved through weight lifting.

In case of severe stenosis, the AV might also fail to close properly leading to aortic regurgitation, where blood leaks back to the ventricular chamber during the diastolic period (when the heart rests between beats).

1.4.4 Aortic regurgitation

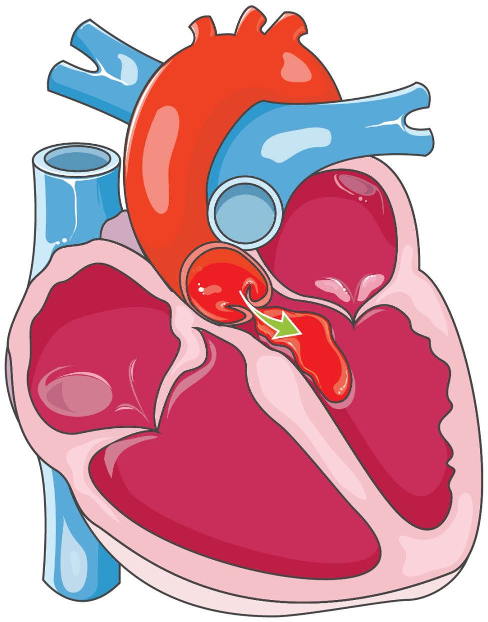


Figure 9: Aortic regurgitation. *Green arrow illustrates the backward blood flow between the aortic valve and the left ventricle chamber. Adapted from [5].*

Aortic regurgitation (AR) to the left ventricular chamber is caused by a deterioration of the aortic valve (figure 9). It occurs as a result of either inflammation due to rheumatic fever or an abnormality in the bicuspid valve. The physiological consequence will variate according to the severity of the leakage. If the deterioration is severe, it results in a weakened sealing ability in the valve and the backward leakage between the aorta and left ventricle will increase. This leakage occurs during the diastolic period. This leads to the aortic pressure dropping faster than usual during resting periods, which further causes low diastolic pressure and a high pulse pressure. With severe aortic insufficiency, the blood flow to tissues in the body will reduce, and therefore increase the workload of the left ventricle. The regurgitation also results in an increase of blood volume and pressure in the left ventricle, which cause the walls and the chamber of the left ventricle enlarging to compensate. This compensation may not be sufficient to meet the required blood flow and may eventually lead to heart failure.

1.5 Surgical procedures

Surgical heart valve repair and replacement can be performed through traditional open-heart surgery as for surgical aortic valve replacement (SAVR), or through minimally invasive procedures as transcatheter aortic valve implantation (TAVI) or mitral clip procedures. The choice of procedure is dependent on the outcome of the pre-surgical examination of the patient. Some patients do not have the physical strength to recover after open heart surgery and might, therefore, undergo a minimally invasive cardiac surgery.

1.5.1 Traditional open-heart surgery

Median sternotomy surgery for SAVR is a procedure where the surgeons make a vertical incision parallel to the sternum (breast bone). After the sternum is revealed one proceeds by dividing it along the center of length axis and separating it to be able to reach the heart (figure 10). When the chest has been opened, one can access the heart and all nearby arteries to be able to replace or repair valves. During this procedure, the patient is connected to a cardiopulmonary bypass (CPB) to maintain circulation in the cardiovascular system. This also eliminates heartbeats and blood flow, making it easier to perform surgery.

A common complication associated with open-heart surgery is systemic inflammatory response syndrome linked to CPB. Of note, the inflammatory risks is significantly higher in patients undergoing SAVR than TAVI [8]. However, infections related to tissue injury does not seem to differ between TAVI and SAVR.

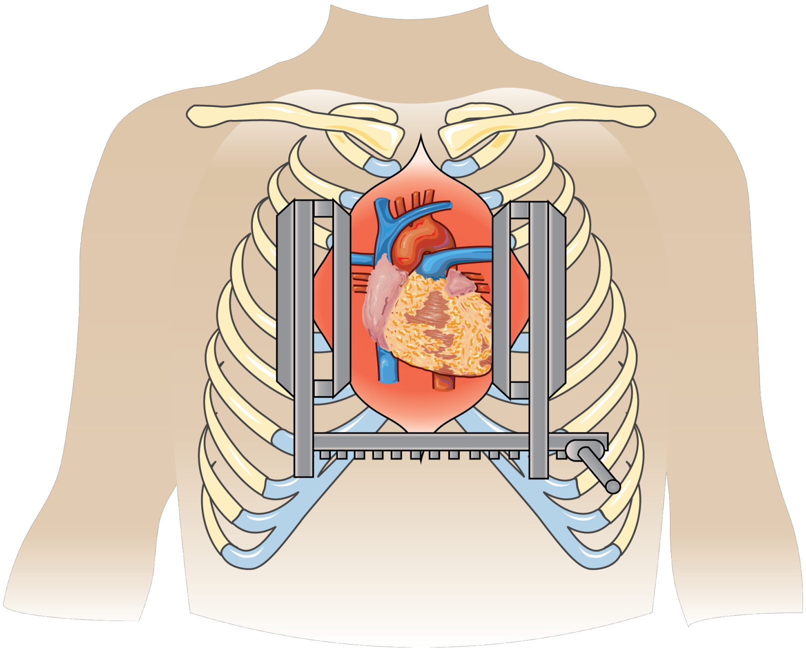


Figure 10: Median sternotomy procedure.
The breastbone is divided along its length axis, and separated by utilizing a retractor. This reveals the heart and allows the cardiologist to access it and perform surgery. Adapted from [5].

In relation to traditional open-heart surgery, both perioperative and postoperative, patients have succumbed to stroke or in worst-case death. Whether or not the patient will go through open-heart surgery is determined by the health and age of the individual. Procedures like SAVR often cause major trauma to the patient, and some of the procedures are therefore carried out through the use of minimally invasive surgery, to lighten both perioperative and postoperative outcomes.

1.5.2 Minimally invasive cardiac surgery

The popularity of minimally invasive cardiac surgery (MICS) has grown substantially over the past two decades. This technique is already worldwide adopted for inoperable and high-risk patients, and has recently gained approval of the American Food and Drug Administration for intermediate-risk patients [10].The field has gone through numerous changes in later years due to technological advancement and growing awareness of the benefits to this approach. This innovation has been driven by a desire to minimize the high risk and long recoveries often associated with complicated procedures that cause physical trauma. Today surgeons can access the heart through small incisions in the torso, neck or groin, and thereby circumvent the necessity of long- lasting open exposures of the patient's torso (figure 11). In addition, MICS also avoids using CPB, therefore, decreasing the risk of inflammatory infections drastically [8].

Although adding some definite advantages, performing surgery inside the heart without a CPB provides some immediate challenges. Since the circulatory system is functional while the patient is undergoing the procedure, the arteries and chambers of the heart will be filled with blood. This results in video imaging not being possible, making the procedure highly dependent on other forms of imaging technology to be able to verify the position of the transcatheter.

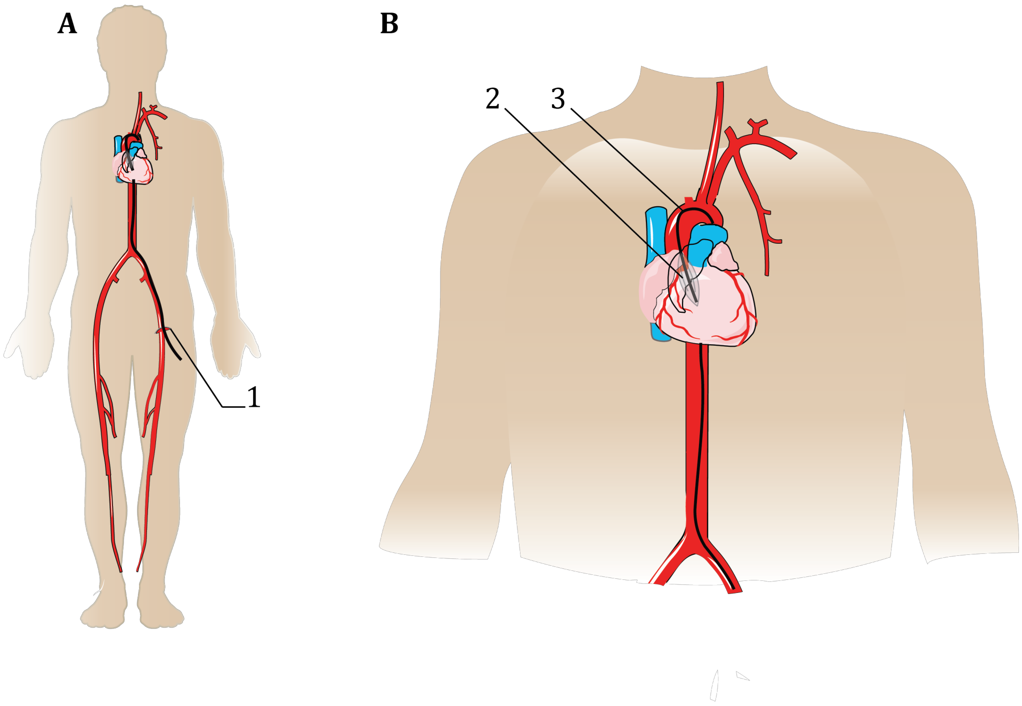


Figure 11: Minimally invasive surgery: TAVI with transfemoral approach.
(A) *Catheter enter through the groin region. 1: Incision in the groin.* ***(B)*** *Enlargement of torso regio. 2: Balloon for artificial valve deployment, 3: Catheter bending around the aortic arch. Adapted from [5].*

Transcatheter aortic valve implantation

TAVI was first used in clinical practice in 2002. Since then there has been a significant increase in the utilization of the technology. This procedure is used to treat patients suffering from aortic stenosis and regurgitation, and has proven to benefit the functional improvement in high-risk patients, both in terms of early and sustained outcomes [11]. However, no data is supporting that TAVI is superior to SAVR in regard to long term benefits. It is mainly used as an alternative for patients that may not be able to handle the strain of traditional open-heart surgery.

By entering the patient's circulatory system through a small incision in the groin (transfemoral approach) surgeons are capable of guiding an artificial valve up to where the aorta enters the heart (figure 12). This is achieved through the use of a transcatheter. By shrinking the artificial valve on the outside of a balloon located to the tip of the catheter, surgeons can easily follow the aorta and leave the new leaflets inside of the weakened original valve. When deployed, the artificial valve replaces the weakened aortic valve, and the leakage is reduced drastically.

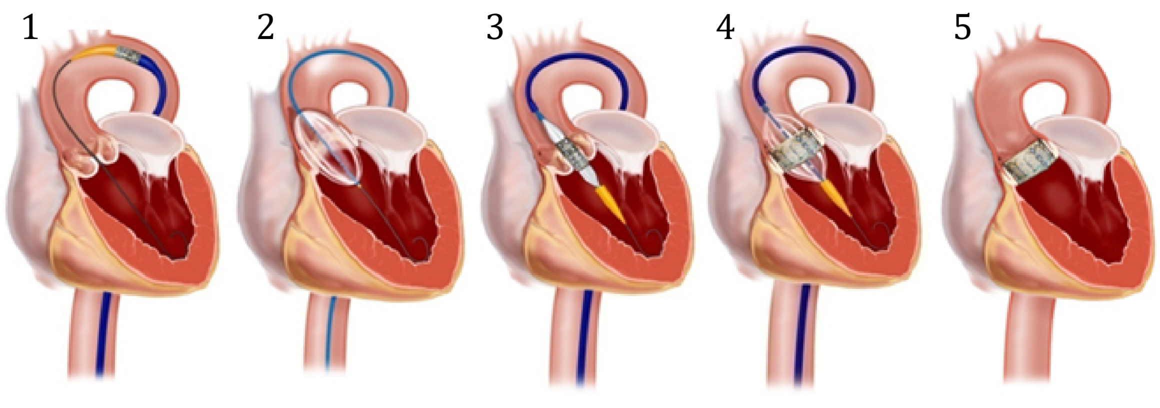


Figure 12: Transcatheter aortic valve implementation (TAVI).
TAVI illustrated through a transfemoral approach. 1: Catheter led through the aortic arch by following a previously inserted guide wire, 2: balloon is filled with liquid in order to expand the AV, 3: catheter with artificial valve is led to its desired position, 4: balloon is filled with liquid in order to deploy artificial valve, 5: artificial valve deployed in the aortic outflow tract, and now functional. [12].

Even though TAVI is not dependent on TEE image guidance while conducting the procedure, it is still to be regarded as an important step for MICS and this project. The technology can in many ways be regarded as the first well-established form of MICS. This is mainly due to its low complex structure and high functionality, resulting in successful procedures and good early post operational results. This has contributed to well-willingness to develop a more extensive range of products to assess different heart valve malfunctions.

MitraClip®

Mitral regurgitation is regarded as the most common valve insufficiency in the USA, and the second most common in Europe, second to aortic stenosis [13]. MitraClip® is a patented device used to repair the leaking MV (figure 13). This method has been implemented at Oslo University Hospital since October 2011. In 2018, 27 MitraClip® procedures have been conducted, and there has already been 10 successful interventions this year at Oslo University Hospital. MitraClip® is currently the only CE-marked percutaneous coronary intervention system assessing mitral valve disorder, although several similar products are in development. The technology has been commercially available since 2003, and it's development can be considered a direct consequence of the well-willingness following TAVI and its improvement of post operational results. This procedure, like any other MICS, is used to aid high risk patients that might not be able to handle the physical trauma brought on by a SAVR.

While conducting mitral clip, surgeons are depending on a combination of x-ray and ultrasound imaging to know the position and form of the catheter. The maneuvering is intricate, since the device has to catch the valve leaflets in order to clamp them together (see figure 14). While maneuvering the device, echocardiographers can range the level of insufficiency on a scale from 1-4, where one is mild, and four is severe leakage [13]. How they determine this will be further elaborated in chapter 1.7.3: Different TEE assessment.

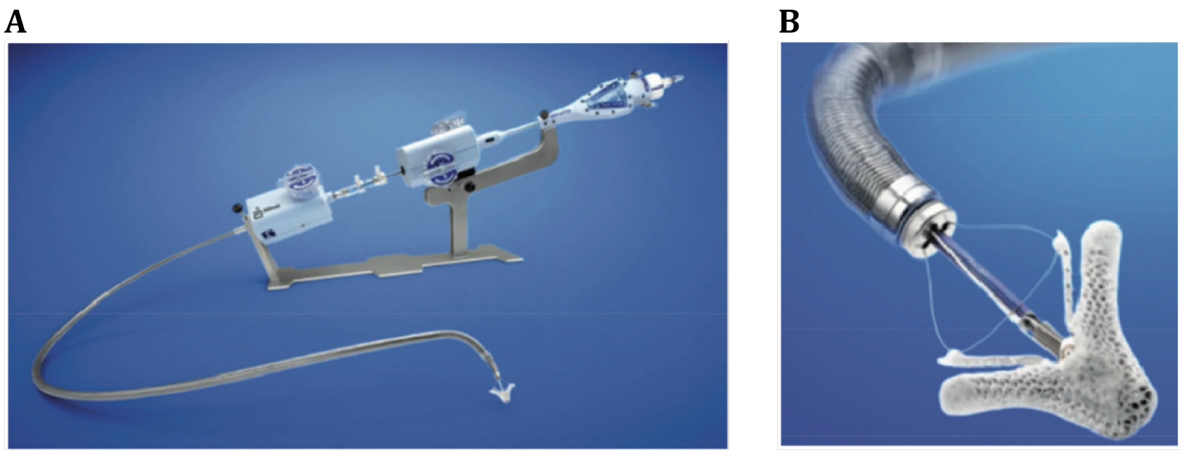


Figure 13: MitraClip® device.
(A) Device used for implantation of MitraClip®. (B) The MitraClip® opened at the distal end of the catheter, ready to catch the leaflets of the MV [13].

The mitral clip procedure is similar to TAVI, but the physical location of the MV requires the device to allow for a more complicated maneuvering. To access the area of interest the catheter must allow for 90° bending and penetration of the wall separating the RA and LA (figure 14).

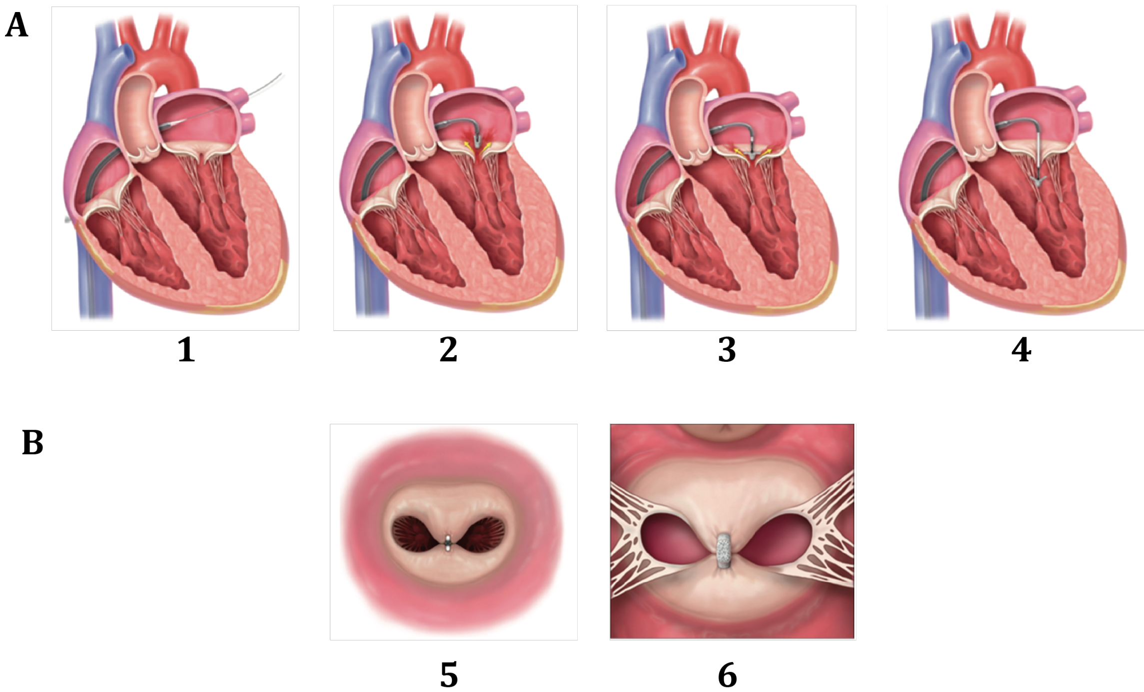


Figure 14: Implantation of the MitraClip®.
(A) The process of locating the MV. 1: Catheter penetrating the wall between RA and LA, 2: Catheter bends to located the MV, 3: The clip is opened, 4: The clip is led through the MV in order to catch its leaflets. (B) Result of successful MitraClip. 1: Clip viewed from the LA, 2: Clip viewed from the LV [13].

1.6 Esophagus

The esophagus is a part of the digestive system transporting food from the pharynx to the stomach. The esophagus is a 250 mm long muscular tube that can be divided into three sections, where the thoracic region is the main area of interest for this study (figure 15).

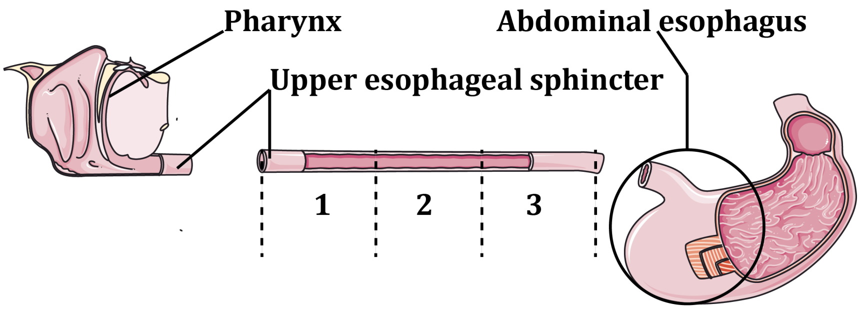


Figure 15: Sections of the esophagus. *1: Upper thoracic esophagus, 2: middle thoracic esophagus, 3: lower thoracic esophagus. Adapted from [5].*

To provide TEE image guidance, one has to insert the ultrasound transducer (figure 16) into the patient's esophagus. The thoracic section of the organ set some of the metric specifications of the TEE system by defining the necessary elongation for achieving a diverse possibility of images, as well as the outer diameter of the endoscope and probe housing.

The thoracic part of the esophagus is 160 mm long and rests directly upon the left ventricle of the heart. The positioning of this organ allows for highly detailed echocardiography as the probe is lead down the muscular tube and pressed up against the heart. However, there are some constrictions associated with the esophagus[4]. The pharyngoesophageal constriction, located in the upper cervical part of the esophagus, is the most demanding and will be elaborated further in chapter 5.2.2: Anatomy.

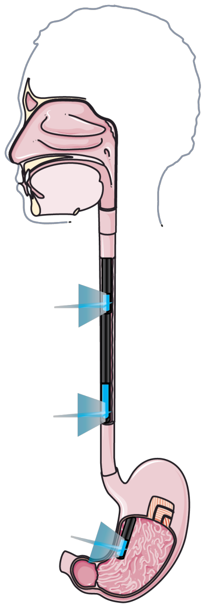


Figure 16: TEE probe guided down the esophagus. *Adapted from [5].*

1.7 Image guidance technology

Abnormal cardiac valve functions are often discovered during regular physical examinations. Doctors diagnose it based on sound characteristics from the heart and surrounding arteries. These sounds are termed heart murmurs and occur during the heartbeat cycle as the valves open and close. If abnormalities are present in one of the valves, it will give a distinctive sound that is loud enough for the physician to hear through a stethoscope. If the patient is diagnosed with cardiac abnormalities, the severity of the diagnosis can be determined through the use of echocardiography. To achieve a detailed image of the heart and surrounding arteries, it is advantageous to approach it through the esophagus by utilizing a TEE probe. This probe has a wide application, spanning from basic diagnostics to image guidance during MICS.

1.7.1 Introduction to transesophageal echocardiography

TEE is a commonly used diagnostic tool to produce real-time imaging of the heart. An ultrasound probe consisting of an ultrasonic transducer, mounted to a long and thin endoscope, is guided down to the thoracic section of the esophagus. Further on it is pressed up against the back side of the heart. When positioned behind the heart, the transducer projects sound waves and collects the echo that bounces back off the different cardiac structures according to their densities. These signals are then processed to produce a live projection of the heart. The procedure was first reported being used in 1971 and has been commercially available since the late 1980s. Since then the equipment has been further developed to contain manipulative tips, adjustable transducers allowing for 180 degrees rotation of the ultrasound plane, and more recently the technology has made it possible to manipulate the signals to form real-time 3D representations [14].

The great benefit of transesophageal imaging is the small layer of tissue between the transducer and the heart. This reduces the wave travel distance compared to an external ultrasound probe, and physicians operating the TEE are also able to use higher frequencies of the ultrasound. To make sure that training and quality of TEE remained consistent, the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists introduced a set of 20 standard views which have been well established in education and widely adopted around the globe [15].

1.7.2 Current TEE solution

Today's TEE probes are highly functional. They enable echocardiographers to achieve all the necessary views to perform diagnostics and monitor MICS. The latter presents some health hazards, due to the operator being forced to expose one hand to x-ray radiation because of manual manipulation (figure 17). Eliminating this problem is one of the main drives behind this thesis.

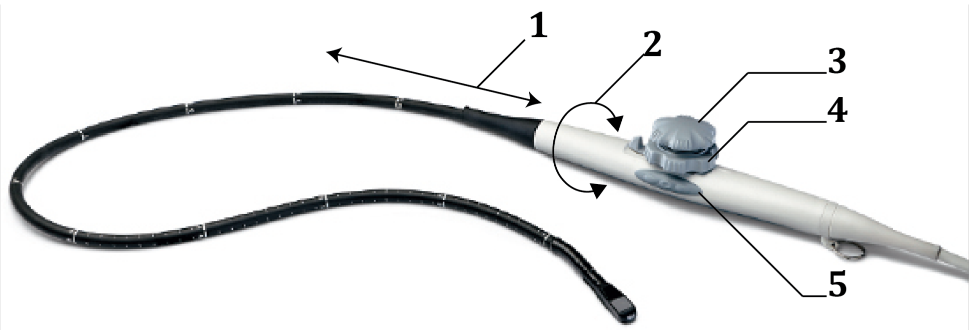


Figure 17: Manipulation of a GE Healthcare Vivid E9 TEE probe.
1: Manual advancement and withdrawal, 2: Manual clockwise and counter-clockwise rotation, 3: Turning of wheel to anteflex and retroflex, 4: Turning of wheel to achieve left and right flexion, 5: Buttons to rotate ultrasound plane [16].

The manual manipulation of the probe allows to locate and assess different regions of the heart.

1.7.3 Different TEE assessments

TEE allows for a wide range of assessments during diagnostics and MICS (figure 18). Through computing, it helps determining the severity of valve insufficiency and muscular abnormalities due to strain.

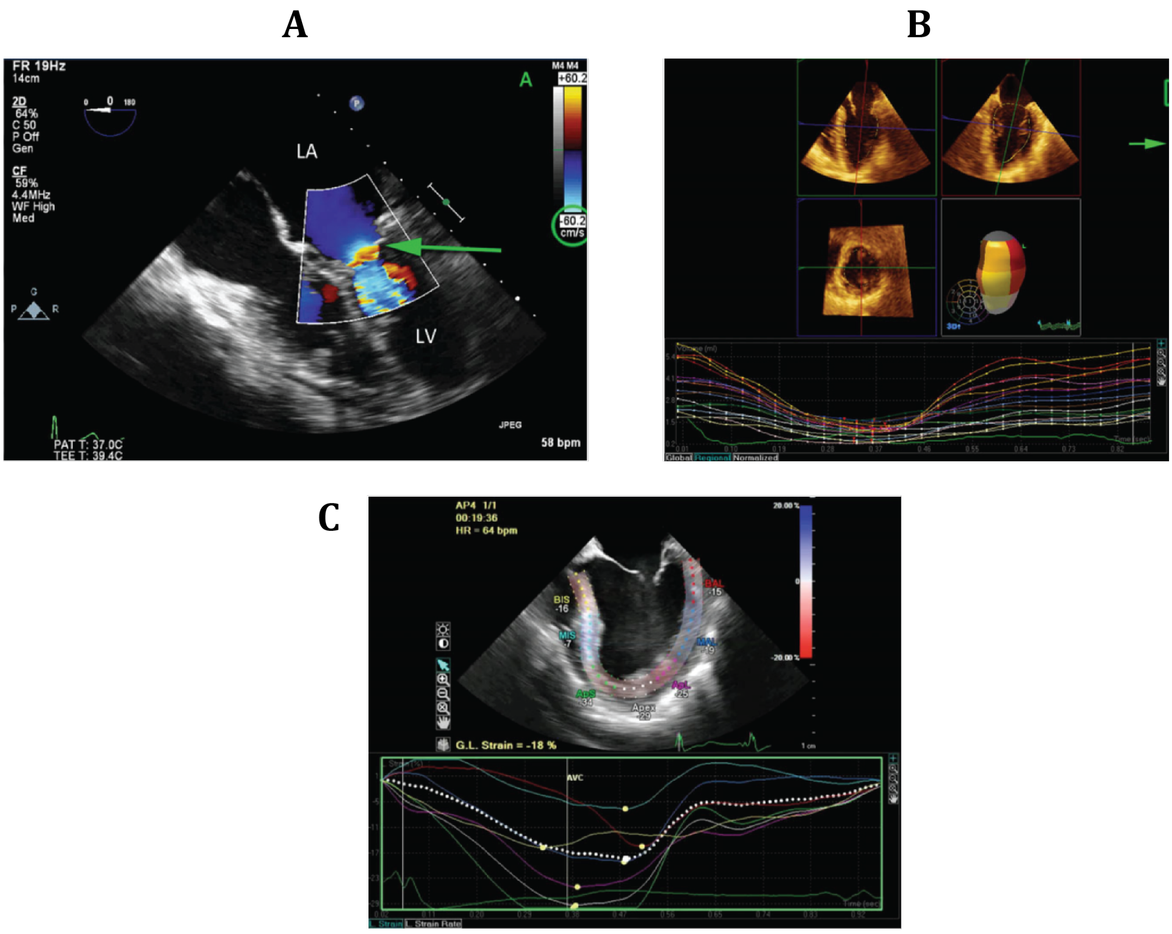


Figure 18: Different assessments performed with TEE.
(A) *CFA addressing mitral valve flow. A color plot indicates the velocity of the blood flow. Yellow areas are flow coming towards the probe, while blue is going away from the probe.* ***(B)*** *Longitudinal strain calculation in LV through 3D echo.* ***(C)*** *Longitudinal strain measurement in LV through 2D echo [17].*

Through color flow assessment (CFA) (figure 18-A) the TEE operator can determine the mitral insufficiency and grade it on a scale from 1-4, where 1 is mild regurgitation, and 4 is severe. This is particularly helpful during MICS guidance. During mitral clip procedures one can continuously determine whether or not one clip provide a sufficient reduction of mitral regurgitation. This was witnessed on a visit to Oslo University Hospital, during a mitral clip procedure.

1.7.4 Essential views

Echocardiographers can have different skill levels in image acquisition. A basic perioperative TEE examination does not require the same knowledge or capability as a comprehensive TEE examination. The American Society of Echocardiography define 11 specific views as necessities during a basic TEE examination, while 9 additional views take the examination to a comprehensive level. During surveying of MICS it is necessary that the echocardiographer is knowledgeable with all views needed to conduct a comprehensive TEE examination and is familiarized to a degree where these can be efficiently achieved.

To reach all of the essential TEE views, the system developed in this project must facilitate all necessary degrees of freedom (DOF) to navigate the heart in a satisfactory manner. The book ”Essential Echocardiography” describes probe manipulation to a high level of detail [17]. In this subchapter, a brief description of nine essential TEE view planes will be presented to illustrate the diversity requirements of ultrasound images. Ultrasound projections (A) used in figures in this chapter are taken from [17], while probe position (B) is adapted from [5]. The full overview of essential views can be found in Appendix B.

Midesophageal (ME) Four-Chamber (4CH) View
In order to achieve a ME four-chamber view, the probe must be elongated 300-350 mm into the esophagus and rotate the ultrasound plane to 0° - 10° (Figure 19). The probe might need minor retroflex adjustments in order to produce a high-quality image.

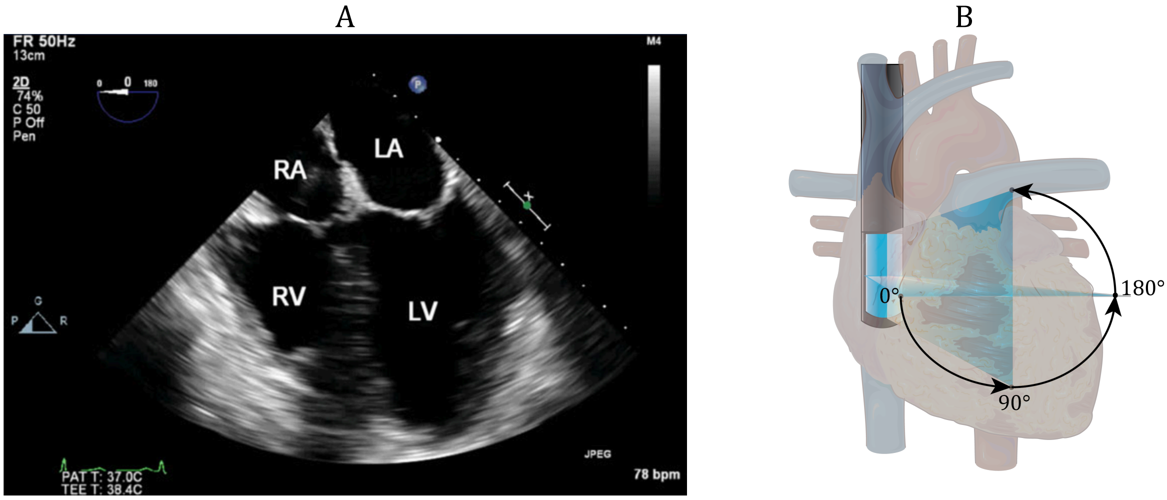


Figure 19: ME Four-Chamber View.

This view shows the RA, RV, LA, and LV, in addition to the structures surrounding them. Through this projection, one can evaluate the sizes of all four chambers, the function of muscles and valves, and the size of the tricuspid and mitral valve. This is necessary in post-operation preparation for MitraClip® procedures.

Midesophageal (ME) Two-Chamber (2CH) View

To reach a ME view of the two left heart chambers the ultrasound plane must be rotated to 80° - 100°. The probe should then be carefully rotated clockwise and counter-clockwise until the LV is revealed.

A B

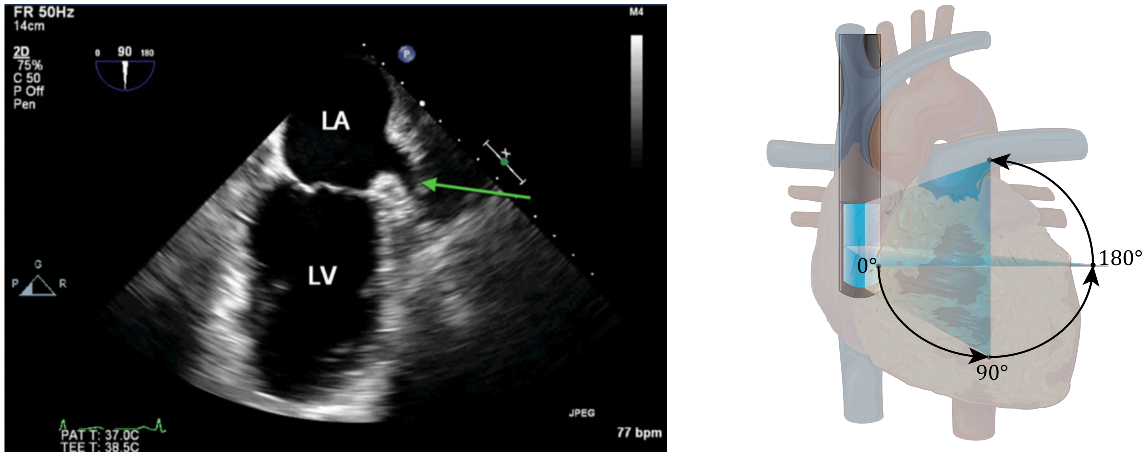


Figure 20: ME Two-Chamber view.

The projection shows the LA, LV, MV, LAA and left upper pulmonary vein. From this image, the echocardiographer can determine MV motion and structure, and other irregularities located to the left section of the heart. Through CFA one can evaluate the severity of mitral regurgitation.

Midesophageal (ME) Aortic Valve (AV) Long-Axis View (LAX)

Achieving a ME AV LAX positioning of the probe, moving on from the SAX, involves rotating the ultrasound plane to 120° – 140°, and making careful clockwise turn of the probe

A B

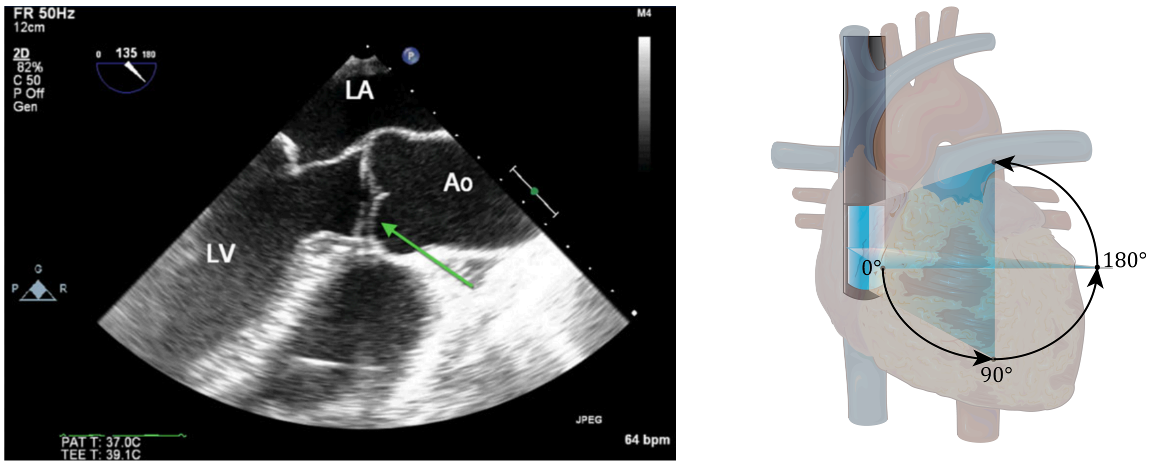


Figure 21: ME AV LAX view. *Green arrow: Aortic Valve.*

This projection provides information regarding the function of the aortic valve, and the echocardiographer can determine if aortic regurgitation is occurring.

Midesophageal (ME) Aortic Valve (AV) Short-Axis View (SAX)

Continuing from the ME LAX, the probe reaches the ME AV SAX through slowly withdrawing the probe, and then rotating the ultrasound plane back to 30°. One should now have a clear view of the AV.

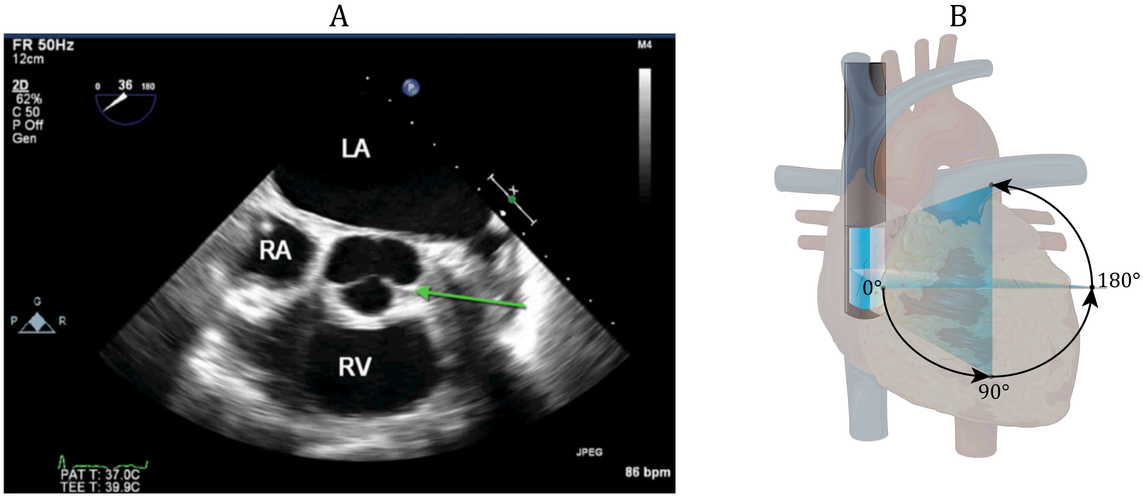


Figure 22: ME AV SAX view. *Green arrow: The aortic valve.*

This projection allows for a detailed view of the aortic valve. The echocardiographer can assess its shape and size, degree of calcification and the mobility of its leaflets.

Transgastric (TG) Midpapillary Short-Axis View (SAX)

From the ME 4CH view, with the ultrasound plane rotated to 0°, the probe is elongated down into the stomach. A gradual anteflex while adjusting the elongation allows visualization of LV and RV.

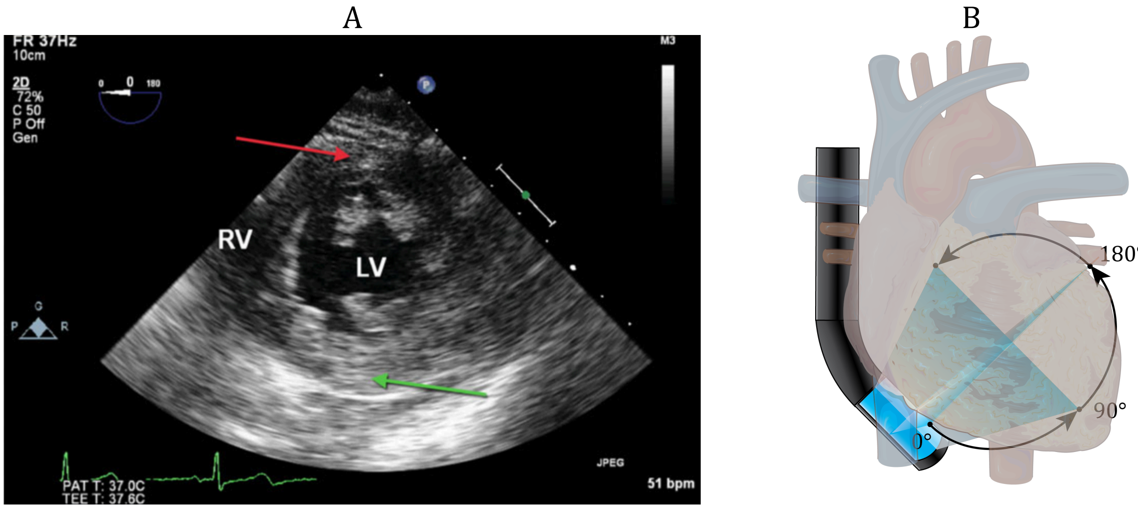


Figure 23: TG SAX view. *Red arrow: interior wall of left ventricle (LV), green arrow: anterior wall of the right ventricle (RV).*

The TG midpapillary SAX view is often used during minimally invasive procedures such as mitral valve replacement. It is often one of the first views assessed due to its visual superiority documenting instability in blood flow. In addition, it provides a good overview of systolic function and muscular behavior of LV and RV.

Descending Aortic Short-Axis View (SAX)
A view of the descending aorta in SAX is obtained through turning the probe clockwise, with an ultrasound plane angle of 0° until Ao is visualized.

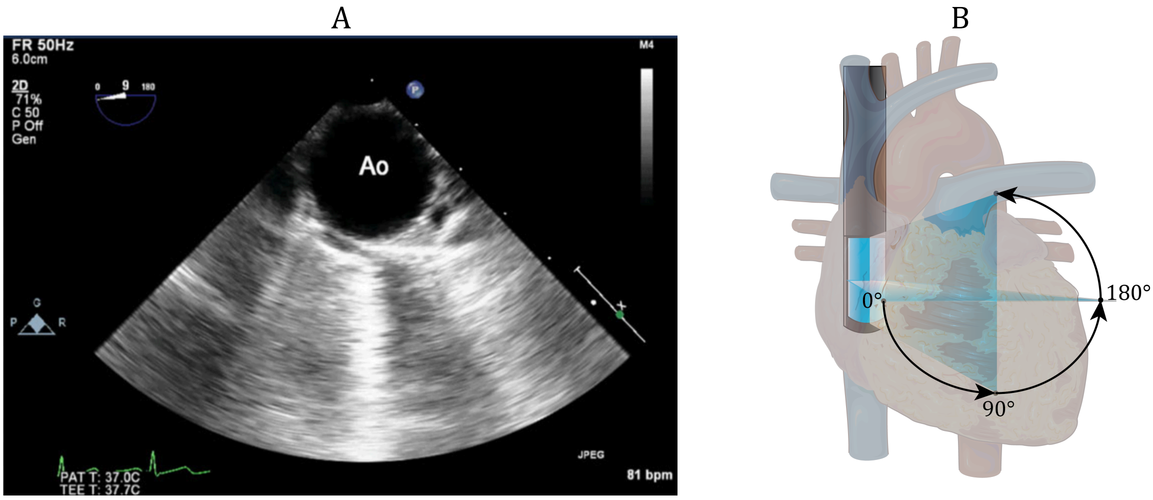


Figure 24: SAX of descending aorta.

With the probe in position for a SAX of the descending aorta, the echocardiograph can measure the diameter of the aorta, making it effective for determining the available space for catheters, if a TAVI procedure is planned.

Transgastric (TG) Basal Short-Axis View (SAX)
Starting from the ME 4CH view, the probe is advanced into the stomach, followed by an anteflex until the desired view of the LV is acquired.

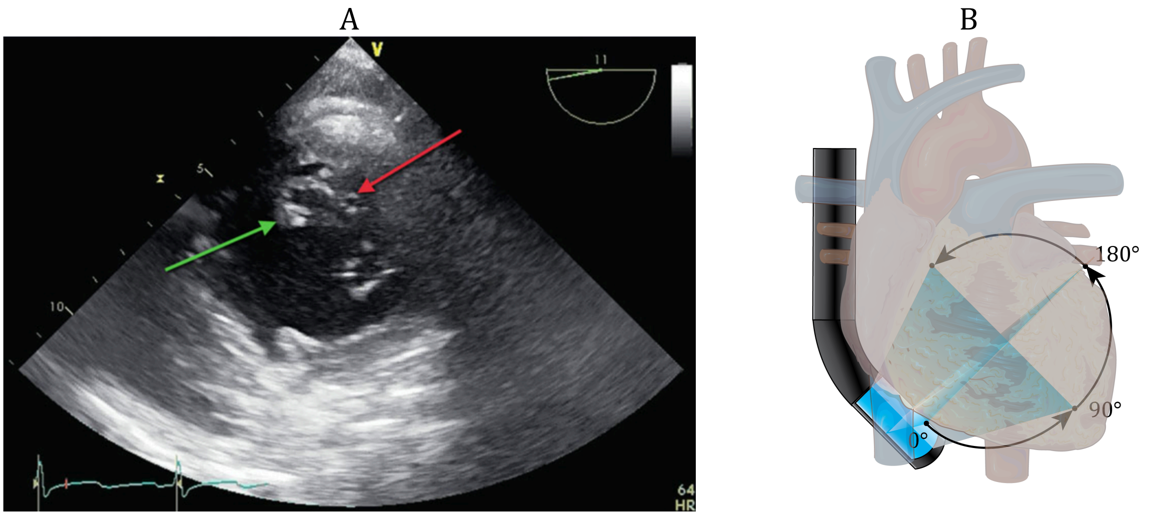


Figure 25: TG Basal SAX view.
Green arrow: anterior mitral valve leaflet, red arrow: posterior mitral valve leaflet.

This projection can be used to determine the amount of calcification of the mitral valve. In addition, mitral valve regurgitation can be addressed through CFA.

Transgastric (TG) Two-Chamber Long-Axis View (LAX)

From the TG 2CH view, the ultrasound plane is rotated to 120 – 140° until the aortic valve is visualized along with the LV and LA.

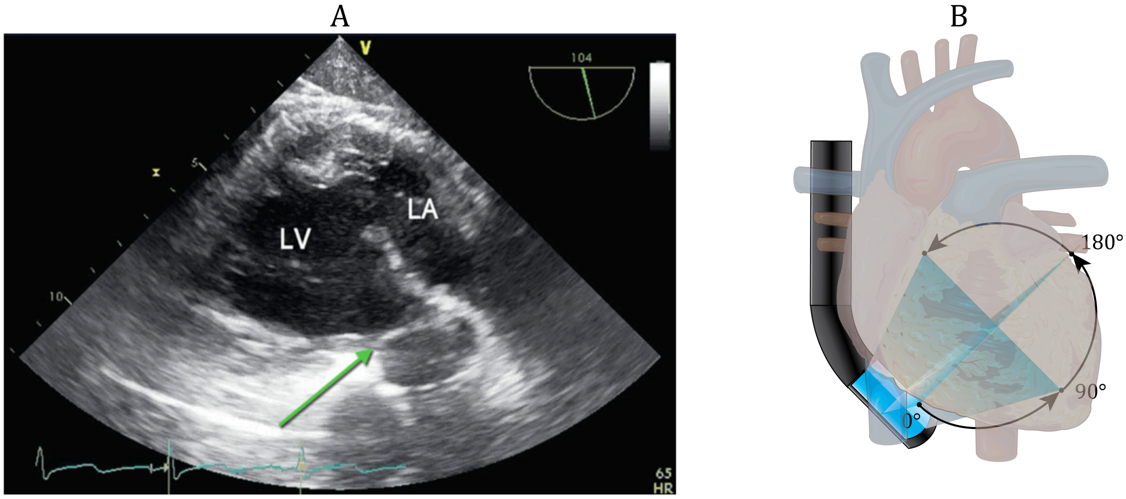


Figure 26: TG Two-Chamber LAX.
Green arrow: the aortic valve.

Similar to the TG Two-chamber view, this projection shows the LV and LA along its length axis. In addition, the LAX view provides images of the left ventricular outflow and aortic valve. A cross-section of the AV is also visible.

Deep Transgastric (TG) Long-Axis View (LAX)

To achieve this view, the probe has to be advanced deep into the stomach, then anteflex and left flexion should be applied before slowly withdrawing the probe until the desired image is revealed.

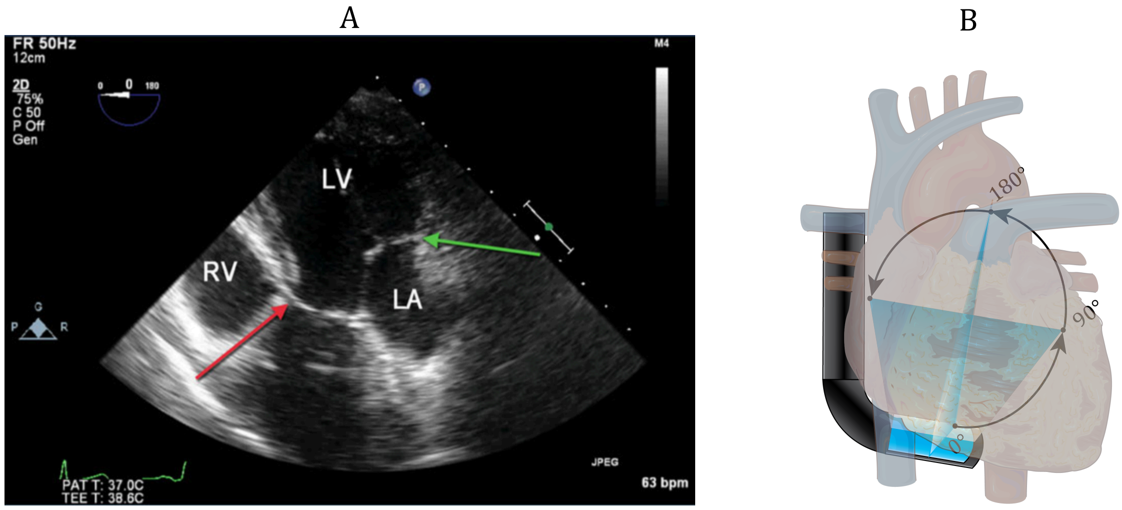


Figure 27: Deep TG LAX view.
Red arrow: aortic valve, green arrow: mitral valve.

The image assesses outflow from the LV and AV, It also shows MV, LA and some of the RV. Through this projection one can determine symptoms like muscle growth in the LV apex. Through CFA one can determine regurgitation and stenosis in the AV and MV.

1.8 Hypothesis

The hypothesis for this master thesis is that electric actuation, combined with joystick control and system automation will improve health conditions for echocardiographers and patients, as well as further standardize minimally invasive cardiac surgery.

1.9 Quality control

The project has been conducted in accordance with the following standards:

ISO 9000:2005 - Quality management systems -- Fundamentals and vocabulary
ISO 9001:2015 – Quality management systems -- Requirements

Medical Standards and guidelines intended for product development and maintenance:

ISO 13485:2016 – Quality management for medical devices
ISO 14971:2012 – Applications and risk management to medical devices
ISO 17664:2017 – Processing of health care products

2 Project plan

This chapter contains the primary objective for the project and a specification of work assignments to be conducted in order to reach the final goal. It will also present a progress plan indicating the time spent on different activities, as well as corresponding milestones throughout the project. Finally, the limitations will be discussed.

2.1 Project objective

The main objective of this thesis is to design a transesophageal echocardiography concept that meets all goals established for the product. Furthermore, the solution will be documented through a detailed report describing the development process, in addition to a video showcasing the systems functions, and a simulation of maneuverability.

The reason for conducting this project is to further the technology by reducing health risks, aspects for both patients and physicians performing TEE during minimally invasive surgery. This involves ensuring accurate positioning of the probe to obtain clear images of the heart and its surrounding arteries, minimizing the x-ray radiation the echocardiographer is exposed to, and continuously prioritizing the patients' safety throughout the concept development.

Specified work assignments

In order to achieve the desired result at the end of this project, some specific work tasks are defined. The elaboration of the work assignments that follows is presented in chronological order. Note that the documentation of the work conducted will be a continuous process throughout all the four phases of the project.

1. Initiating phase:
    - Hold a kick-off meeting with all involved parties to establish guidelines for the project.
    - Build a reliable literature reference list.
    - Establish project goals.
2. Early concept development:
    - Conduct an external expert survey to assess the requirements of the product.
    - Establish product specification and goals.
    - Create function analysis.
    - Generate concepts addressing the required functions.
    - Conduct screening of concepts based on established criteria.
3. Detailed concept development:
    - Create a detailed mechanical solution of the complete system.
    - Visualize the concept through renderings, video, and simulation.
4. Evaluation and finalizing:
    - Review the report in terms of structure, language, and content.
    - Send report to print.
    - Hand in the report.
    - Present the final product.

2.2 Project schedule and milestones

The following Gantt diagram is developed in order to maintain steady progress throughout the project. It will also ensure that goals are achieved in a timely manner. For a larger version of the project schedule, please see Appendix A.

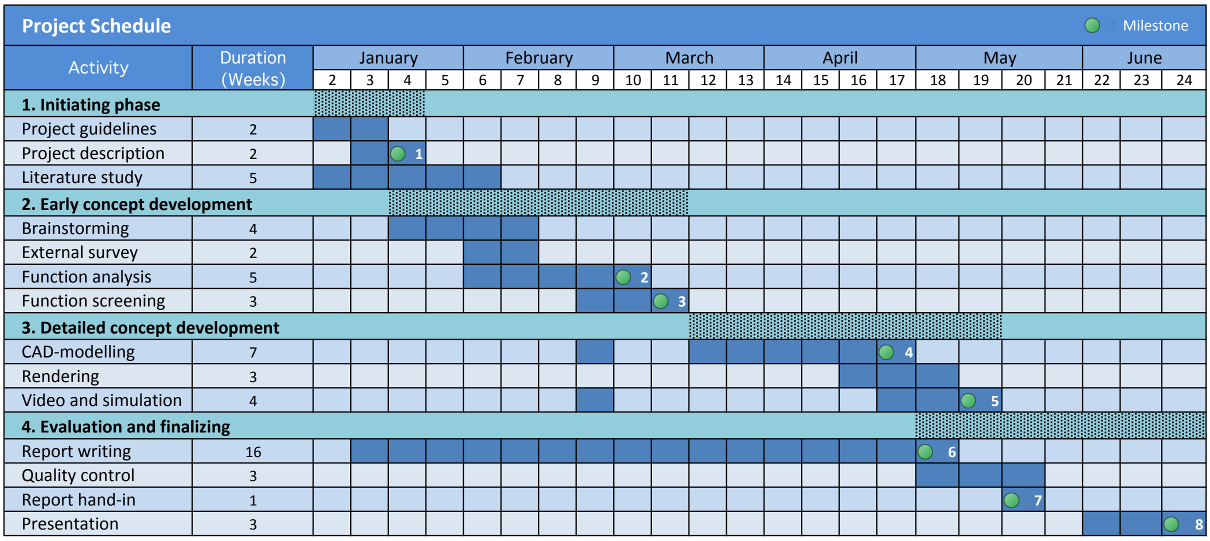


Figure 28: Gantt diagram.

Milestones are specific assignments that have to be conducted in order to move on to the next task. These have all been assigned a deadline for finalization to maintain progression and hand in the report in time for the projects end date. They are listed in the table below.

Table 5: Milestones.

Number	Milestone	Deadline
1	Establish clear goals for the project	January 25th ,2019
2	Develop a function analysis	March 8th, 2019
3	Complete concept screening	March 15th, 2019
4	Finalize CAD-modelling	April 26th, 2019
5	Finish simplified simulation and product video	May 10th, 2019
6	Finalize report writing	May 5th, 2019
7	Hand in report	May 15th, 2019
8	Present the final concept	June 14th, 2019

2.3 Project limitations

In accordance with the short time-frame for this project, some limitations have been established. This has been done in order to deliver within a smaller scope, with a high level of quality and documentation.

- This project will only cover mechanical design and component layout and must be considered an early stage conceptual solution.
- A physical prototype of the product will not be presented since the product will be in a conceptual phase at the end of this project.
- Technical drawings for the final product will not be provided.
- The simulation of the systems maneuverability will be performed through a simplified model. This model will not include all the detailed mechanics of the finalized CAD-model.
- Material selection for the actuation unit will not be conducted.

3 Methodology and tools

In a conceptual development process as presented in this thesis, implementation of methodology is essential to provide structure as well as logical and steady progression to ensure that the main goals are met at the project's deadline. It is also intended for providing the reader with a clear and logical structure, to ensure the message is carried across. This chapter will explain some of the creative methods and tools used in this master thesis as well as the disciplines we have used to achieve our goals.

3.1 Integrated product development

Integrated product development (IPD) is a method based on multidisciplinary collaboration between people, computer systems and business structures that leads to increased efficiency and dividend [18]. Before the introduction of IPD methods, each department would work individually on their specific areas before gathering the different parts at the end. This would often cause delays, misunderstandings, and extended budgets. The implementation of computers made it easier to collaborate across disciplines, especially the enabling the visualization of the final product early on in the project (figure 29). According to the philosophy of IPD, all the stakeholders are being gathered in the planning phase to ensure a common goal. Essentially four key elements should be taken into account in an integrated product development process: design, production, economy and Environment Health and Safety (EHS).

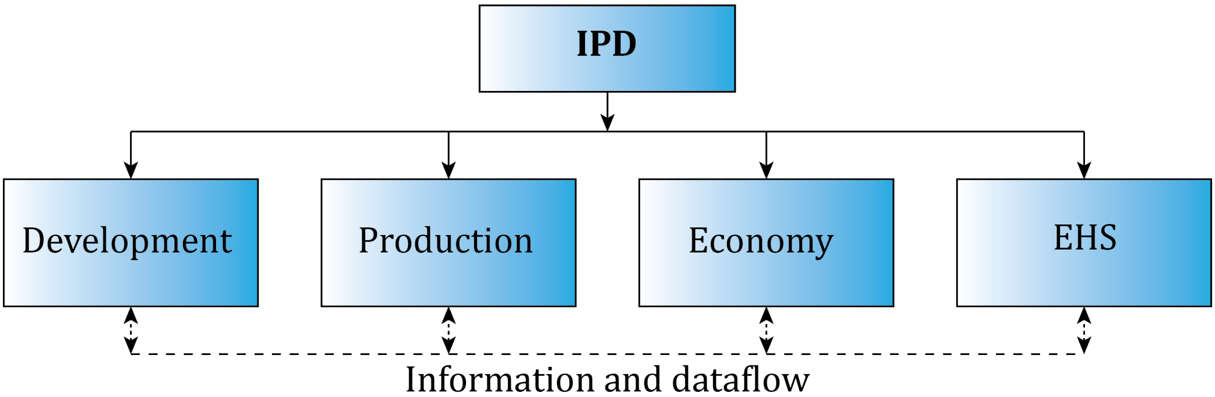


Figure 29: Illustration of IPD functionality.
Clear communication of information and data is paramount to ensure all disciplines are working towards the same goal.

IPD is used throughout this whole project to ensure that the final design achieves the intended goals. The primary focus of the engineer is the development and production branch, at risk of losing sight on other important matters. By continuously being reminded of the IPD model the EHS aspect cannot be neglected. Hence, the developers will always keep a focus on health and safety, which is arguably the most crucial matter when one is discussing patient treatment and surgical procedures. This method is also the foundation for the continuous dialogue conducted with the employees at Oslo University Hospital. This method will be highly present in chapter 5: Product Specification and onwards.

3.2 SCAMPER-technique

SCAMPER is a technique to improve existing products and was first suggested by Alex Osborn in 1953 [19]. SCAMPER is an acronym for substitute, combine, adjust, modify, put to other uses, eliminate, and reverse. It is considered a to-do list that helps enabling creativity. By evaluating the product undergoing development up against the list, new ideas may occur. These ideas may, for instance, involve component selection, material selection, and other applications for already implemented components. This technique is being used in order to achieve an improved final product.

In this thesis, Scamper will be implemented in chapter 7 - Functions and endoscope structure. This method led to sketching and structuring different technological solutions that facilitate the systems' degrees of freedom

3.3 Pugh's method

Decision-matrix method or Pugh's method was developed in the 1980s by the British engineer Stuart Pugh, professor at the University of Strathclyde, Glasgow [20]. The method is often applied in the early stages of product development projects and use selection matrixes to separate concepts. Different solutions are ranked based on how well their necessary functions meet essential criteria. Several criteria can be applied to one function. To provide further nuance, each criterion is weighted in order to emphasize its relative importance (figure 30). The scaling can be defined by the user even though common values are *1-5*, *-1, 0, 1,* and *- = +.*

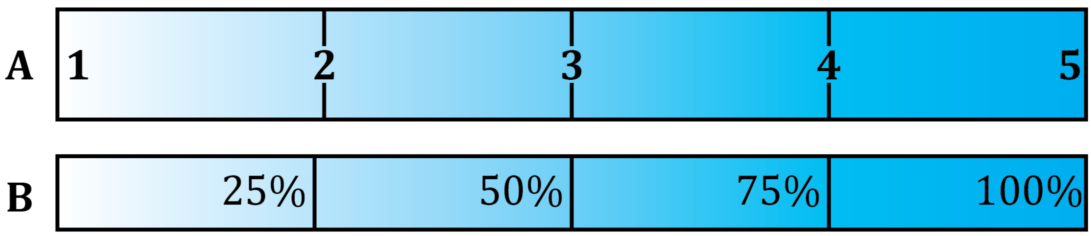


Figure 30: Weighting scale according to Pugh's Method.
***(A)** The score given to a function. **(B)** The weight given to criterion. This will bring more nuance to the selection process, and the score will better reflect the criterion relative to its importance for a specific function.*

This method will be used to navigate the vast number of possibilities to solve different challenges in the technological system. It has been implemented in chapter 5.4: Property evaluation and 8.2 – Screening of alternatives.

3.4 3D-design

The 3D-design in this report is developed using SolidWorks. This has enabled continuous sketching and demonstration of movement throughout the project. This has enabled utilization of CAD-models during the function screening. CAD-models of the heart and the esophagus is acquired through GrabCad Community Archives [21].

3.5 Simulation

The simulation in this report has been developed through importing CAD-models from SolidWorks into Matlab and Simulink. Simulink provides the existing degrees of freedom in SolidWorks with a block diagram which enables simulation. In addition, an environment has been created in Simulink to better illustrate the TEE probes positions relative to the heart. Finally, manual manipulation has been enabled by connecting a joystick to the model.

3.6 Referencing template and literature search

A reference template, providing all essential information about the citations in this thesis, have been developed through use of EndNote. The literature search has been conducted through Oslo University Hospital's medical library and online sources. This report mainly cites books and peer reviewed articles. Online references have to a large extent been used for images. The ones used to provide information are reliable sources like the American Food and Drug Administration and American Society of Echocardiography. A search for active patents on "Automated/Autonomous Transesophageal Echocardiography" has been conducted without any significant findings.

In order to confirm the functionality of all online references, these have been revisited on the 12th of May 2019.

3.7 Software

The following software have been used as tools in this project:

- Microsoft Word for text and table editing.
- Microsoft Excel for Gantt diagram and planning.
- SolidWorks 2018-2019 for visualization, simulations, photo rendering and video.
- CES Edupac for elaboration on materials.
- Adobe Illustrator CC 2018 for figures.
- Simulink 2018 for simulation.
- BANDICAM for video of simulation.
- EndNote for reference managing.

3.8 Process steps

The different project phases have been divided into four main segments. Figure 31 elaborates on distinct iteration processes regarding concept selection and detail design. The model is generated in accordance with the project schedule.

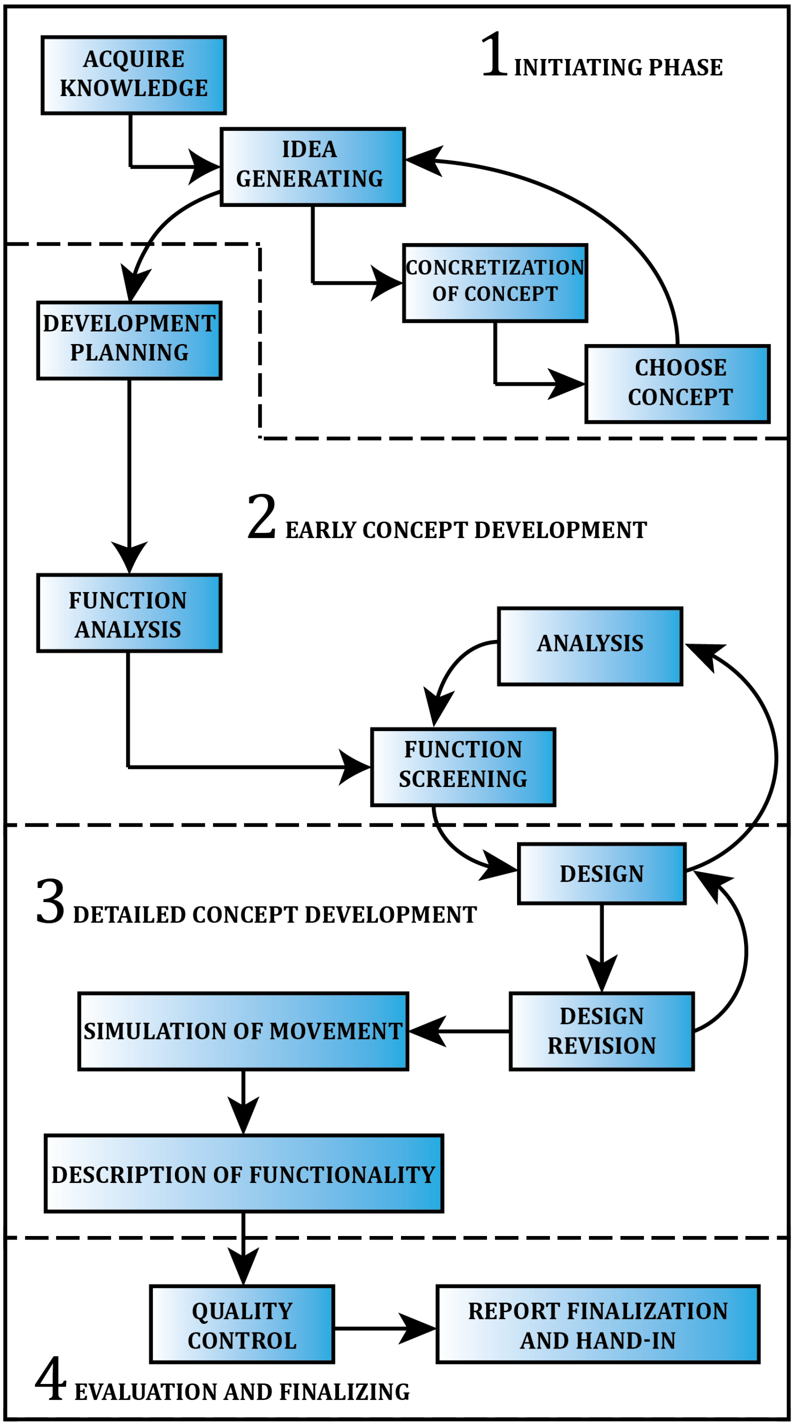


Figure 31: Process steps.
1: Initiating project phase, 2: early development, 3: detailed development and optimization, 4: Finalizing of documentation. Looping arrows: Iterations located to early and late design phases, and future improvements.

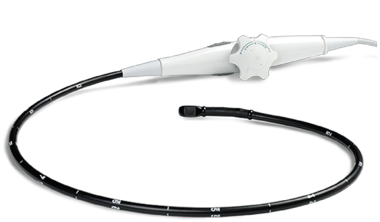
4 Technology review

This chapter will describe some of the currently available technology, with the intention to create an overview of fully functional solutions and to provide inspiration for further concept design. It will also give insight into what is considered biocompatible materials and what is being frequently used by major companies in commercially available products.

4.1 A global view of the ultrasound market

According to the report ”The global ultrasound equipment market in 2018” published by IHS Markit, the global ultrasound market has seen an annual growth of 7.6% from 2016 to 2017, which makes it ”the largest year-over-year growth rate in several years” [22]. The global market shares are dominated by the three major companies GE Healthcare™, Philips Healthcare, and Toshiba Medical. GE Healthcare has maintained its position as the number one supplier of ultrasound devices with a 29% share of global revenues, with Philips following with a total revenue share of 19%. This indicates that the work conducted in this project has a strong commercial potential.

Table 6: Existing TEE probes. *Viewflex is still undergoing development, and is not a TEE probe. Images are gathered from the respective manufacturer website [16, 23-25].*

Product details	Illustration
Vivid E9 CUS **Manufacturer:** GE Healthcare **Pros:** Reliable maneuvering, ergonomic design, user friendly, good image acquisition. **Cons:** Demands continuously hands-on maneuvering from operator	
X8-2T Probe **Manufacturer:** Philips **Pros:** Reliable maneuvering, ergonomic design, user friendly **Cons:** Demands continuously hands-on maneuvering, lesser image quality that i.e GE Healthcare	
Z6Ms TEE Probe **Manufacturer:** Siemens **Pros:** Reliable maneuvering, ergonomic design, user friendly, good image acquisition. **Cons:** Demands continuously hands-on maneuvering from operator **Price:** 49 000 USD	
Viewflex™ **Manufacturer:** St. Jude Medical and Abbott **Pros:** High quality imaging, can lock its position, no need of anesthetic **Cons:** Invasive as it is inserted in arteries and coronaries.	

4.2 Material science

The esophagus probe will not be subject to excessive stress, and strength properties will therefore be neglected throughout this paper. More importantly, material properties should relate to the fragile and small environment of the esophagus. Indeed, the selected material should have a relative stiffness to ensure necessary precision when rotating and flexing, while still being able to bend when inserted down the esophagus. Such factors require materials that must be bendable, but at the same time stiff enough to enable the desired precision of maneuvering.

Another constraint is linked to the highly acidic environment of the stomach, to which the distal part of the endoscope will be submitted to achieve several essential views (see 1.7.4). Therefore, material properties should also allow pH variations.

It is also important to emphasize the inflammatory risk in the esophagus due to performing transesophageal echocardiography. This sets a number of prerequisites for material selection of the invasive part of the device, according to biocompatibility and possibilities for disinfection and sterilization. Previous conducted work in this area provides clear guidelines on the type of materials applicable in this context. However, product specifications from current market leaders are often confidential.

4.2.1 Nitinol

Nitinol (Ni-45Ti) is a nickel-titanium alloy with the ability to undergo reversible phase changes in solid state, ranging from austenitic to martensitic. The ability to achieve both austenitic and martensitic crystal structures, and reverse this crystallization makes this material unique in terms of shape memory and superelastic characteristics. Therefore, it is used in a number of medical applications, such as vascular catheter stents.

The alloys transition temperature, where it changes state, ranges from $-50°C \ to \ 150°C$, depending on composition. Below this temperature it exists in the martensitic phase. By heating the alloy to a degree where it enters it austenitic phase the parent shape (neutral position) can be defined. The parent shape is remembered by the material, even when deformed at lower temperatures. By heating it back to the austenitic phase it will return to its defined shape.

The superelasticity characteristic has a similar effect as the shape memory, and also result in phase transition. This phase transition can be induced by applying stress to the material, making it enter a martensitic phase and change shape. Upon stress removal, the material will return to its austenitic phase and its intended shape will be restored. The material is biocompatible and capable of operating in strong acids with a pH < 4, making it applicable in the distal end of the endoscope.

For this project, the intention is to use Nitinol so that the distal end of the TEE probe will return to its original shape when not subjected to any flex. This involves utilizing the superelastic characteristics of the material.

4.2.2 PVC

PVC (Polyvinyl chloride) is a plastic polymer widely used in the medical field because of its low production cost and high performance. Although PVC is mainly used for disposable products, recent improvements of its quality now allows its disinfection and reuse. Therefore, properties like flexibility, clarity, biocompatibility, and suitability for sterilization makes PVC a well-suited tubing material for catheters.

In order to achieve a relative stiffness in the endoscope it can be advantageous to investigate the properties of sub-categories Shore A60, Shore A65, and Shore A85. These are all flexible PVC and can be extruded in order to achieve multiple lumens to facilitate wire force transmission. All these PVC types are capable of operating in environments with a $pH < 4$, making it applicable for operating within the lower gastric region of the esophagus. For this project, the intention is to use PVC in the endoscope and the probe housing. This will be discussed further in the design chapter 5.3.2: Endoscope structure.

4.2.3 Electroactive polymers

Electroactive polymers, commonly known as EAP, are polymers that achieve deformation when exposed to an electric field. This property is called piezoelectric effect. The motion and capacity of EAP are similar to those of muscle fibers, and it is therefore often used as artificial muscles or actuators. The property of the material and its manufacturing methods have been improved throughout the years, and it is now a popular choice to various applications like biometric robots, snake robots, linear actuators, catheters, and force transmission wires. To date, actuators with as much of 380 % strain enlargement has been developed [26]. However, despite large amounts of research on the subject there are still areas in need of improvement. In particular, required voltages to reach desired deformations may be too high, making it a potential health hazard when used in medical applications. Even though the electric current is low, the high voltages can cause blood clots in case of electric short-circuiting [26]. Achieving the correct response from the material may also be a challenge and potentially cause hysteresis if the EAP does not respond fast enough.

4.3 Electrical components

Further automation of the mechanical design being developed here will rely on the implementation of multiple electrical components. This subchapter will explain some of the possibilities regarding motors, and actuators.

In terms of providers, Nema™, Schneider Electrics™, and Maxon Motors™ have a wide range of products that might accommodate the needs for electrically powered TEE probes. They supply motors, micro-motors, linear actuators and a wide range of control units that will facilitate use of sensors and further automation.

4.3.1 Electrical motors

An electrical motor is a transducer converting electric energy to mechanical energy. Most of these motors are based on the principle that an electric conductor, while in a magnetic field, will be exposed by a force and thus the mechanical connection will rotate. The principals of two types of electrical motors that enable precise rotational movement, making them applicable for this project, will be discussed below.

Stepper motors
A stepper motor allows for a very precise movement both clockwise and counter-clockwise. The motor rotates in steps and the length of these steps depends on the motors design. Available motors advance by just a fraction of a degree and are suitable in applications where slow speed and high torque is required. A microprocessor can be programmed to count and store the input pulses, hence continuously keeping track of the shaft's position [27]. The main advantages of the stepper motor are its precision and affordability. It is often used in industrial applications like CNC and 3D-printing machines. Some of the drawbacks related to this motor are its lack of internal feedback, and the step rotation that may result in sudden and unwanted movements, which may cause problems for certain robotic applications.

Servo motors
There are several different types of servo motors with various applications, but globally common principles of action. They consist of a rotary encoder allowing for very precise angular position (and in some cases velocity) feedback to the control, which will compare the position to the desired output, and reduce the error by further input.

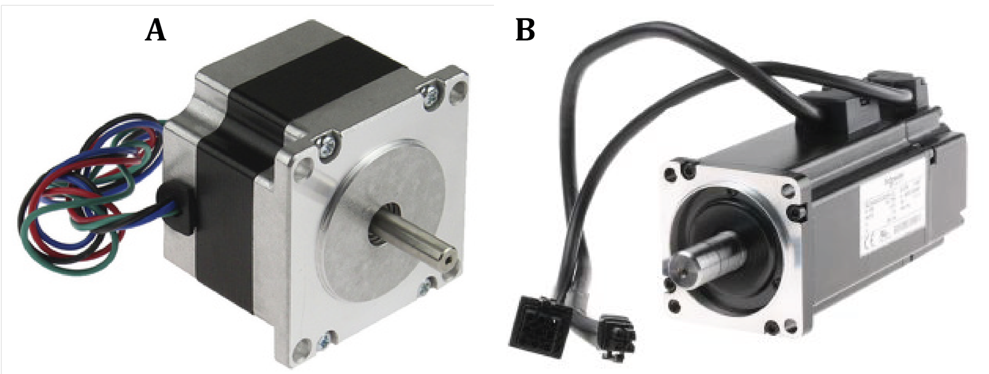


Figure 32: Electrical motors.
(A) *Nema 23 stepper motor [28].* ***(B)*** *Schneider Electrics servo motor [29].*

4.3.2 Linear actuators

A Linear actuator translates input energy into linear motion and is thus able to extend or retract objects. The conversion of motion can be achieved with several different methods and could provide highly applicable solutions to some of the required movements in this concept.

Hydraulic cylinders

Hydraulic cylinders typically consist of a barrel with retract and extend ports, a piston and piston seals. Force is achieved by pressurized fluid delivered from a pump, with the movement direction depending the port the fluid is delivered from. Since liquids have the ability to withstand great compression the hydraulic actuator is able to provide a very precise linear displacement. Due to its high force capacity, it is used for some of the most demanding tasks in the industry, like heavy objects lifting or car brakes.

Electro mechanical actuator

The electro mechanical actuator is based on converting rotary motion from a DC motor to linear motion. This can be achieved by mechanical solutions like ball screw, belts or cams. The motion is very precise and there are several electro mechanical actuators that provide precise internal feedback for position and velocity. The velocity of the linear motion is a result of the transmission ratio caused by the mechanisms and the strength of the DC motor.

Piezoelectric actuator

The piezoelectric actuator is based on the piezoelectric properties of certain materials which expand when submitted to high voltage. Because of the high voltages needed for just a small movement this method can result in very precise actuating. However, the degree of hysteresis can be large and there is no direct correlation between applied voltage and movement.

A B

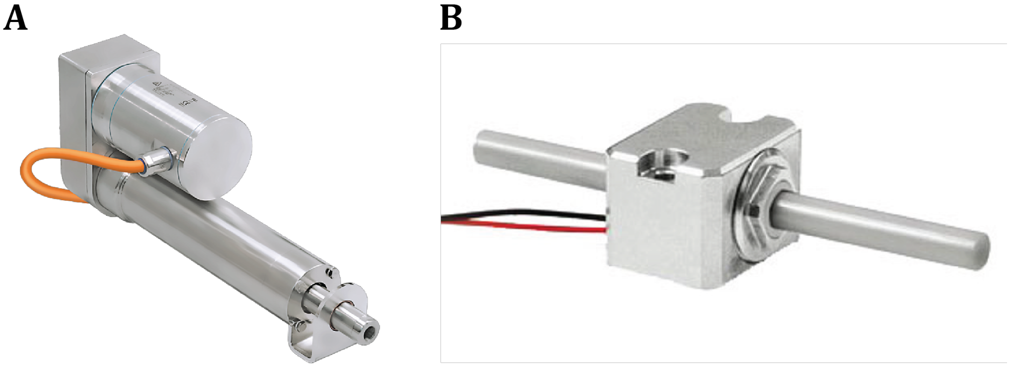


Figure 33: Linear actuators.
(A) *Kollmorgen electromechanical actuator [30].* ***(B)*** *N-422 OEM Piezoelectric actuator [31].*

4.3.3 Sensor technology

The choice of sensors to implement is crucial for the systems performance, as well as for ensuring continuous patient safety. This will enable automation through introducing regulation control to the probe, by constantly measuring output deviance through a feedback loop. The intended internal use of the system dictates high requirements for accuracy, resolution, precision and linearity. These requirements must be met regardless of the type and application of the sensors.

If a sensor has a high precision, it makes operations repeatable. This means that the TEE system could reach a specific view several times in a row, making the operation highly repeatable. If the TEE system repeatedly reaches a view while providing the exact same, or close to exact same projection, the system can be described as highly accurate. Resolution is the minimum increase or decrease of value the sensor can measure "per change". If one sensor is able to measure one-tenth of a millimeter, while another measures three-tenths, the first one will have the highest resolution. Linearity describes the deviance from the output value to the systems actual physical position.

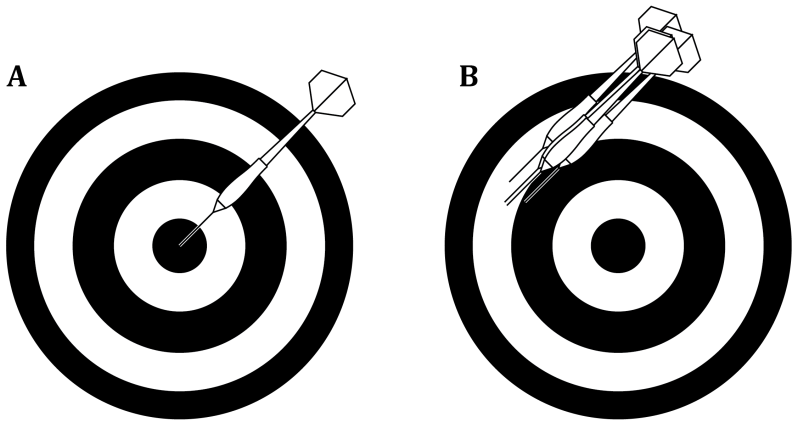


Figure 34: Analogy for sensor measurement.
(A) *One dart arrow hitting a bullseye illustrates a sensors accuracy.* ***(B)*** *Several arrows hitting the dart board in a cluster illustrates a sensors precision.*

Potentiometers
Potentiometers are popular and often cost-effective position sensors. These sensors measure position through voltage drops that change as an electric contact moves along a resistive track. In a high precision system like this, where movements will be made continuously and repeatedly, this kind of sensor might not be the primary choice, due to its vulnerability to mechanical wear. Potentiometers provide a pure analogue signal and a AD/DA-converter must therefore be implemented in the system's actuation housing, which is challenging due to space limitation.

IncOder
IncOders, a new generation of inductive sensors, works much like their predecessors. These sensors work on the same principle as an electrical transformer, except for the wire spools being replaced by printed circuits. This makes them highly adaptable due to their compact design, light weight, and multiple geometric shape options. They are highly accurate in terms of linear and angular position.

Optical sensors
Optical sensors, also termed encoders, measure position through a light beam shining onto an optical disc with an implemented reference point. The light hitting the optical disc is then measured through a photo detector and a position signal is calculated, making it suitable for angular measurements. They are often delivered in a complete package with rotating motors and are therefore ideal for implementation along with a stepper motor. The step-count can vary from 50 – 5000 counts per revolution, providing a sufficient accuracy for the TEE system.

Magnetic sensors
Magnetic sensors measure position through a magnet moving relative to a magnetic detector. With a fairly robust construction it is resistant for external disturbances. Hall sensors, often implemented in electric motors, use this form of measurement. However, their performance is often too modest for an implementation into high precision mechanical operations, like this system. Magnetic sensors are vulnerable to hysteresis, which could c0mpromise their use in a surgical context.

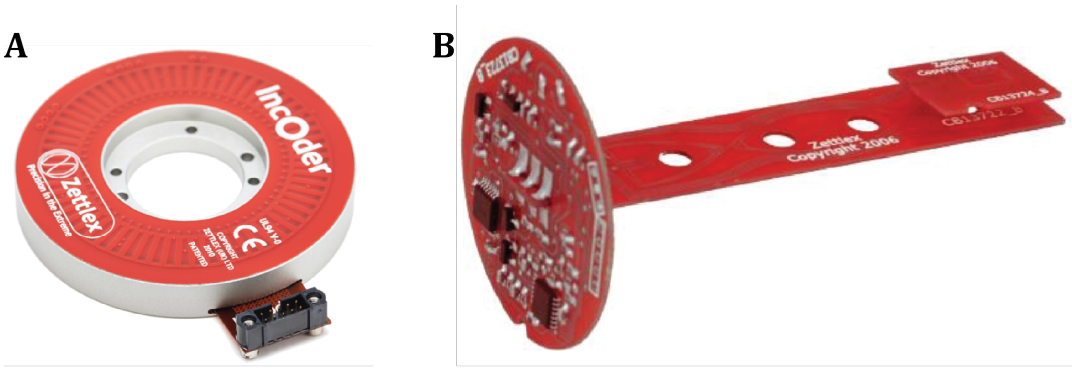


Figure 35: IncOder sensors provided by Zettlex Ltd.
(A) *Angular inductive encoder.* ***(B)*** *Linear inductive encoder [32].*

In the pursuit of an autonomous system, there are many considerations to be made in regards of the sensor choice and specification. Zettlex Ltd provides sensors meeting the requirements for this product and should be taken into consideration in further investigation [33].

4.4 Complementary concepts

The technologies described in this subchapter are relying on different fields of expertise, but should be considered for an autonomous TEE system as their implementation would result in a superior product relative to the current market. This should be further addressed by a multidisciplinary team, and will be included in future directions.

4.4.1 Image recognition technology

Biometry, a statistical analysis of biological data, is a measurement of living tissue and bodily structures. The market for biometric recognition has seen a large growth the later years, as it is like all other markets nurtured by supply and demand. The increase of demand is related to an increased concern regarding security threats. This triggers investments from major actors in the market, and drives innovation. As the demand is met and more actors get into the market, a price reduction will be inevitable.

Through utilization of biometric recognition, the echocardiographer would be able to easily generate images of essential anatomic structures of the heart, as atriums, ventricles or valves. This would imply further processing of the image converted from the transducer's signal by a sensor that can interpret the structures visible to the operator. Then, identified structures would be recognized and located through a machine learning process, providing the desired ultrasound view planes at the echocardiographers command. Installing optical sensors to the system, after the soundwaves have been converted to an image, should make biometric recognition assessment possible in TEE devices. Implementing this technology into the TEE system will increase its commercial value drastically.

Multispectral sensors
These sensors read bandwidths invisible to the human eye and can therefore recognize structures within images that the operator is unable to see. However, calibration is crucial for multispectral sensors and can be very costly.

CMOS sensors
Complementary metal oxide semiconductor sensors convert photons to electrons, much like a solar cell panel, in order to digitally process them. This technology is often used in applications such as digital cameras, machine vision for robots, and processing of satellite photos.

Applying any of these sensors might enable the system to isolate structures from the images, and then fixate on them. It might also introduce higher requirements to the transducers used in the TEE probe. This aspect should be investigated by experts in the field at a later stage in the development process.

4.4.2 Haptic feedback

Haptic feedback is the use of touch sense to communicate with users. The technology available today offer a vast range of products, spanning from vibrating cellphones and joystick resistance, all the way to highly complicated exoskeletons. By 2028 the haptics industry is estimated to be worth over 3 billion USD [34].

Surgeons and other operators often prefer to have a hands-on feel to devices they are using. This presents some challenges related to an automated TEE system, since there will be no direct interaction between the distal end and the echocardiographer. In order to provide them with a finger-touch-feel while manually overriding the system, haptics should be implemented to the final product. This will for instance aid the operator as he provides anteflex to the probe in order to achieve the necessary surface contact between the transducer and the soft tissue in the esophagus.

Haptics would improve joystick control drastically, as well as ensure the patients safety through enabling a touch sensitivity to the operations conducted by the echocardiographer. This should be investigated by experts further into the development process.

5 Product specifications

This chapter presents the product goals and describes product requirements in terms of functions, its metric specifications, maneuverability, and safety aspects. At the end of the chapter a screening of the product properties will be presented in order to map future consideration for the development process.

5.1 Product goals

The product goal is to enable all mechanical movements and geometric properties necessary to conduct a comprehensive TEE examination, with a system layout that allows future automation. The following list contains specific requirements that need to be fulfilled to reach the final goal.

- The product must enable the TEE probe to move with four degrees of freedom.
- The product must contain components that facilitate future autonomous actuation and remote joystick manipulation.
- The external actuation unit should not interfere with surrounding personnel and equipment in the operating theatre.
- The invasive section of the TEE endoscope should have a length of 500 mm, and its total length should be 1000 mm.
- The TEE endoscope should not exceed the inner diameter of the esophagus.
- The product must comply with the medical guidelines for disinfection and sterilization.
- The product must comply with the medical guidelines for risk management in mechanical devices.

The following subchapters will elaborate on challenges related to the product goal.

5.2 Physical restrictions

This concept is meant to operate in a busy environment surrounded by a lot of activity and equipment. The system will be exposed to two different environments that present a variation of challenges (figure 36).

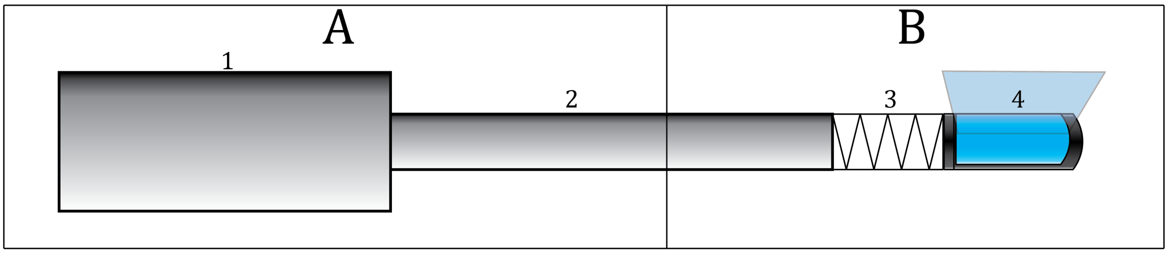


Figure 36: Mock-up of system.
Illustration of what environments the different components of the TEE system is exposed to. ***(A)*** *Operating room (Surrounding environment),* ***(B)*** *Esophagus (Anatomy), 1: Actuation unit, 2: Endoscope, exposed to external surroundings and the esophagus, 3: Distal end, 4: Probe.*

In the two following subchapters, some of the most obvious challenges related to the system's exposure will be elaborated on.

5.2.1 Surrounding environment

The physical design of the TEE system will have to meet a number of accommodations. The operating theatre usually contains large x-ray machines, operating tables, and anesthesia machines, in addition to a medical team consisting of up to ten participants during valve replacement or repair procedures (figure 37). This presents some space limitation, and it is important that the TEE system will not be subjected to any external disturbance.

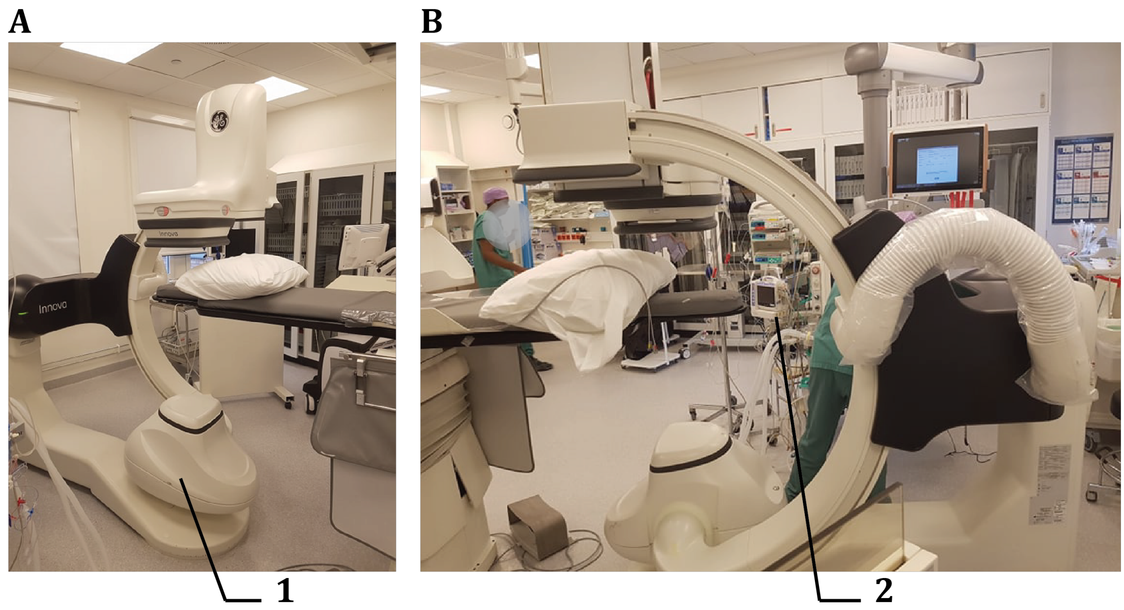


Figure 37: Operating theatre at Oslo University Hospital, Oslo.
(A) *1: The Innova IGS 5 X-ray machine from GE Healthcare. The TEE system has to be built around this device.* ***(B)*** *The TEE operator's perspective of the operating theatre. 2: The anesthesia machine takes up a lot of space and is located in the area where the TEE would be positioned. Personal photo.*

Therefore, the most space-efficient design is to approach the patient's vertical axis, from the anchor of the Innova IGS 5 (figure 37-A). Since the x-ray equipment is of a substantial size, as well as being able to rotate, this presents some challenges related to the anchor of the TEE system. The anchor must be designed to adapt to the configurations present in different operating rooms around the world.

In order to ensure no potential slack, kink or entanglement of the external part of the endoscope, a guide should be implemented. This guide will support the endoscope leading up to the patient's mouth as it advances and withdraws. Importantly, it will also function as a replacement of the TEE-operators hand and prevent it from being exposed to x-ray radiation. This design element will be further discussed in chapter 5.3.2 - Endoscope structure.

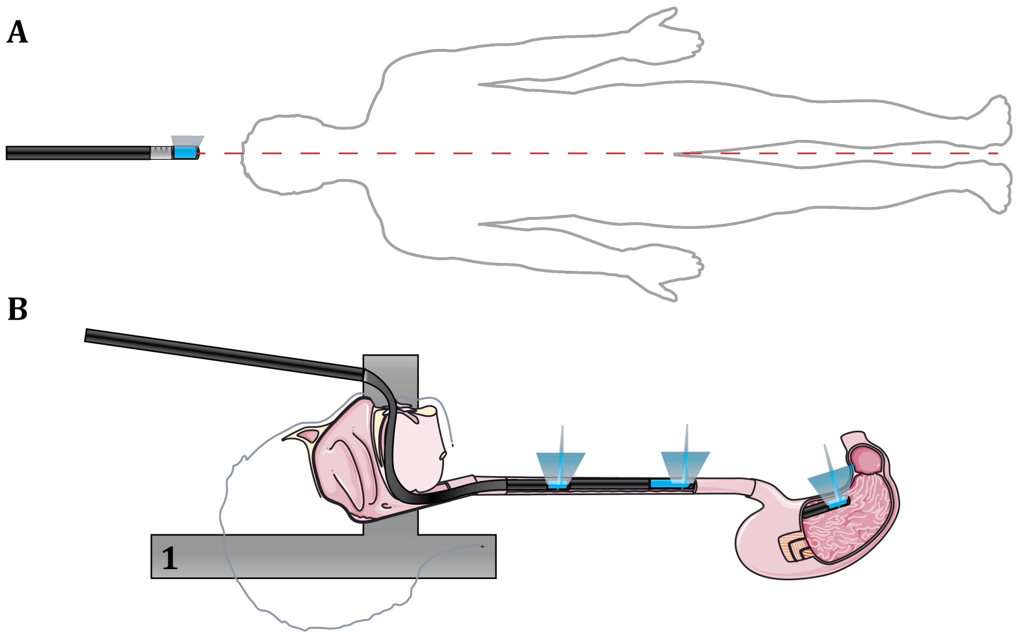


Figure 38: TEE probe relative to patient positioning.
***(A)** TEE probe approaching the patient along his vertical axis. This illustration does not show real size proportions. **(B)** Endoscope inserted into patient. 1: Possible endoscope guide. Adapted from [5].*

5.2.2 Anatomy

The metric specifications of the TEE probe are limited by the esophagus diameter, length and shape (figure 39). The most challenging area is the pharyngoesophageal constriction (B), located to where the pharynx (A) meets the cervical region of the esophagus. This constriction is made up of tighter and circular muscle fibers and has a diameter of about 14 mm. At this location the probe must be able to anteflex. This passage will be determining the largest possible diameter of the TEE probe. Today's commercially available TEE solutions have an outer diameter of approximately 10 mm.

The esophagus (C) is approximately 250 mm long from the pharyngoesophageal constriction down to the diaphragm in the abdominal part of the muscular tube (D). The total length of the probe will have to exceed this measurement in order to access the patient's stomach and achieve a reasonable positioning of the actuating unit in relation to other necessary surgical equipment and people conducting the procedure.

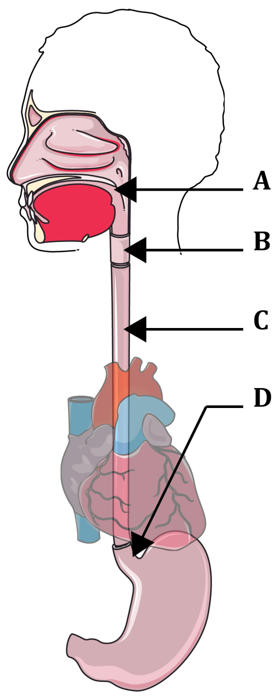


Figure 39: Transesophageal approach.

***(A)** Pharynx. **(B)** Pharyngoesophageal constriction. **(C)** Esophageal tube. **(D)** Diaphragm and lower gastric esophageal region. Adapted from [5].*

One should also assess the difficulties occurring when leading the probe through the pharynx, by reducing the angle at this specific point. This could be achieved by designing an external tube combined with a device that guides the endoscope to the patient's mouth to lead the probe through this region.

5.2.3 Final metric specification

The metric specifications presented in table 7 and figure 40 have been developed in accordance with challenges presented by the operating theatre as well as anatomic boundaries set by the esophagus. All measurements are gathered from "Color Atlas of Human Anatomy: Internal Organs", H.Fritsch, W.Kuehnel, Thieme [4].

Table 7: Metric specification of the system.

Description	Symbol [Unit]	Adult	Unit
Total length of endoscope	L	1000	mm
Invasive length of endoscope	L_I	500	mm
Outer diameter of endoscope	D	10	mm
Length of esophagus	l	250	mm
Inner diameter of esophagus	d	14	mm
Withdraw / Advance (DOF)	Z	180	mm
Anteflex / Retroflex (DOF)	θ_x	± 45	°
Left / Right flexion (DOF)	θ_y	± 45	°
Rotation (DOF)	θ_z	± 35	°

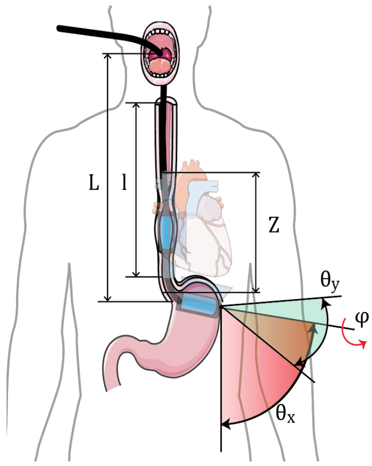


Figure 40: Metric specifications. *Adapted from [5].*

The part of the endoscope entering the patient's esophagus must be approximately 500mm long. In addition to this, there will be an external section stretching from the mouth of the patient to the systems motor housing. The probe housing will have to not exceed the inner diameter of the esophagus in order to prevent any damage the soft tissue in the esophagus.

5.3 Mechanical requirements

In order to achieve high-quality ultrasound imaging, the TEE probe must be able to maneuver around the heart to access different angles. This presents a number of mechanical challenges related to maneuverability, build structure, shape and material selection.

5.3.1 Maneuverability: Required degrees of freedom

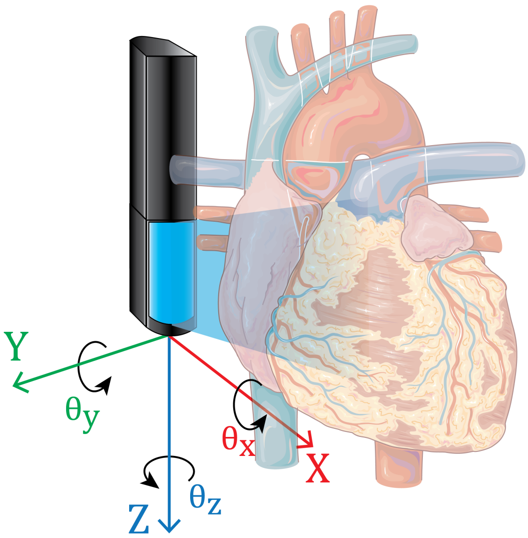


Figure 41: The TEE probe in position behind the heart. *Adapted from [5].*

The distal end of the TEE probe must be able to rotate, deflect and elongate. In traditional TEE there are five different movements available, also including a rotation of the ultrasound plane. The rotation of the plane will not be taken into consideration in our required degrees of freedom (DOF) as this is a well-established technology and will be implemented regardless. The challenges lie with the four functions described below having to be automated. The idea is to be able to duplicate the 20 standard views that are used for comprehensive examinations by today's echocardiographers. This involves many different possibilities of actuation and translation and will be discussed further in the next chapter.

Left and right flexion

Left and right flexion are not often used in TEE since the physical parameters of the esophagus limit the possible sideways movement of the probe. However, to achieve some of the more complicated view-planes necessary to perform a comprehensive TEE examination, one is dependent on entering the lower gastric region of the esophagus. By doing this the probe will anteflex around the bend and position directly below the heart. The left flexion will help to position the transducer below the apex of the heart, creating an excellent deep transgastric view of the left ventricle. By increasing the amount of left flexion, one will address the left ventricle. Flexing it to the right will enable the echocardiographer to achieve images of the right ventricle.

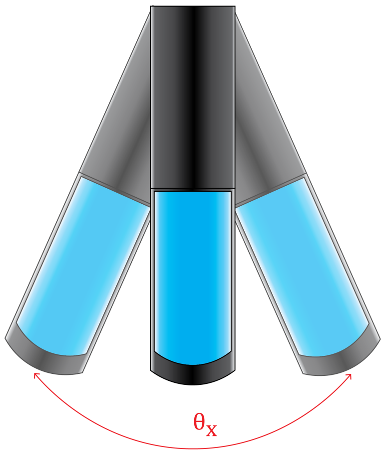


Figure 42: Left and right flexion. Achieved by rotation of x-axis.

Anteflex and retroflex

Surface contact between the ultrasound transducer and the soft tissue in the esophagus is crucial for image acquisition. With the anteflex movement the operator can ensure a satisfactory contact in order to get clear images of the heart. The anteflex is also a necessity when inserting the probe into the patient's throat. At the pharyngoesophageal constriction, the narrowest passage in the esophagus, the operator must be able to provide anteflex in order to get through. The retroflex complements the anteflex for letting go of surface contact in order to maneuver the probe to a different section of the digestive system. This mechanical function can be regarded as the single most important feature in the system.

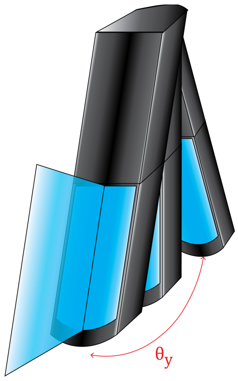


Figure 43: Anterior and posterior flexion.
Achieved by rotation of y-axis.

Clockwise and counterclockwise rotation

This movement allows for alternating between views of the left and right side of the heart, which is important for conducting a comprehensive TEE examination. In current devices, the rotation is achieved by manually turning the TEE endoscope as a whole, hence exposing the echocardiographers hand to x-ray radiation. Eliminating this problem is one of the main drives for conducting this project. In addition, the esophagus is being subjected to friction when the endoscope is rotated. Possibilities related to improving this aspect will be investigated into further detail later in the concept design stage.

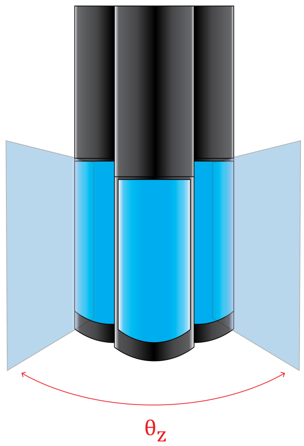


Figure 44: Rotation of probe.
Achieved by rotation of z-axis.

Elongation

Inserting the probe into the esophagus will happen manually, as in existing TEE solutions. After reaching the desired starting position, the operators must be able to maneuver up and down along the transgastric and deep transgastric section of the esophagus. Due to the metric specifications of the esophagus, the probe has to advance approximately 300 mm from its initial position. This will enable the probe to reach all areas needed to be able to achieve a diverse possibility of ultrasound images, from the upper esophageal aortic arch LAX (see appendix A) view to the deep transgastric LAX view.

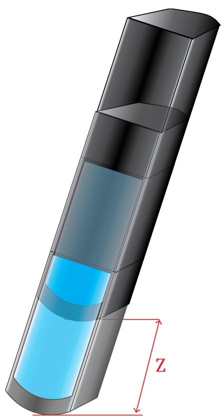


Figure 45: Elongation of z-axis.

A combination of all the DOF mentioned above will provide a versatile TEE probe being able to facilitate all necessary views to ensure sufficient image guidance.

5.3.2 Endoscope structure

There are many considerations to account for regarding endoscope structure. However, these tools have long been used in medicine, and are thus developed and highly functional. This section will introduce the main characteristics that have to be present in the endoscope of the TEE system presented in this thesis.

Relative stiffness

For the TEE probe to be operated with sufficient precision, the endoscope is dependent on a relative stiffness. This implies that no kink or twisting can occur. This is of utmost importance in order to successfully establish a reference point for the control-feedback-loop and continuously being able to manipulate its position. The stiffness is considered relative since the endoscope needs to be able to flex in order to pass through the pharynx and reach its desired reference-point. The majority of this challenge can be worked through by investigating current solutions of TEE endoscopes.

Facilitating Actuation

In order to allow an external actuation unit to affect the distal end, the endoscope needs to be able to house force transmission wires (figure 46). This can be achieved through the use of multi-lumen catheters. By connecting wires to the motors in the actuating unit, pulling them through the lumens in the endoscope, and attach them to the distal end of the endoscope, actuation will be made possible. To achieve sufficient movement the distal end should be designed in a way that allows it to bend easier than the lumen leading up to it. A number of possible solutions will be considered in chapter 7.3: Distal End Structure.

A B

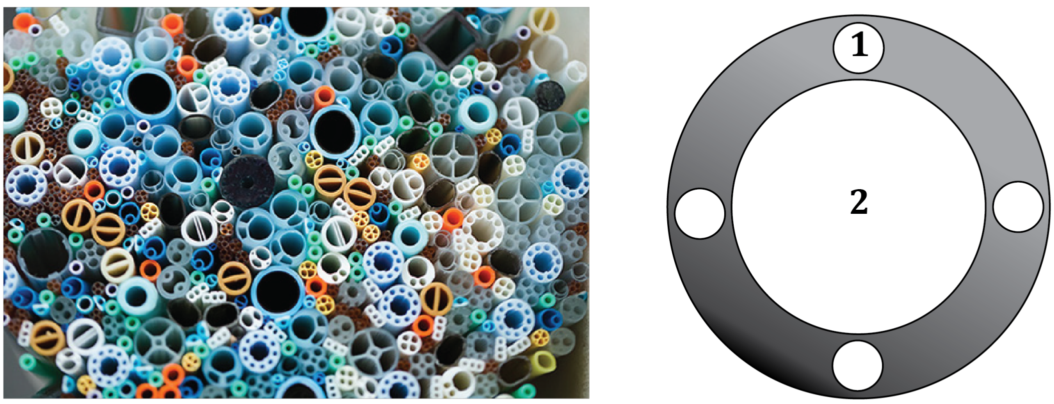


Figure 46: Multi-lumen hoses are a possibility of translating power.
(A) *A variety of lumen hoses [35].* ***(B)*** *Pathway for data transferring and other necessities. 1: Pathway for force transmission wires, 2: Pathway for signal processing and sensor cables.*

Disinfection and sterilization

The endoscope is categorized as a semi-critical medical device, as it comes in contact with the esophagus' mucous membranes. It must therefore adhere to guidelines for sterilization and disinfection of patient-care equipment. The material in the endoscope is required to minimum withstand a disinfection process, but preferably sterilization.

5.3.3 Safety aspects

This following safety requirements must be prioritized during the concept development, and accounted for in the final product:

- The system must operate with a high level of precision to ensure patient safety.
- Possibilities of manual override through the use of a joystick should be available to the operator in case of unforeseen events.
- A kill-switch should be easily accessible for the echocardiographer, and ensure the catheter going back to its reference position (the midesophageal four chamber view).
- The electric components must be fully isolated from the patient in order to prevent short-circuiting.
- The surface and geometric shape of the catheter cannot contain hidden surfaces or sharp edges that might cause inflammation or tearing of tissue in the esophagus.
- Limitations to maximum output in the distal end needs to be restricted by sensors and regulation control.
- All parts of the device that are in contact with the patient should withstand minimally high-level disinfection or sterilization.

5.4 Property evaluation

The following table presents 13 different properties for the automated TEE system. The different properties are given a score from 1 to 5, according to Pugh's method, where 1 is considered irrelevant and 5 is considered utmost necessary. The evaluation is meant to ensure that the design and developmental process are goal oriented and facilitates all the crucial properties to achieve precise, and safe automated echocardiography. The score points have been developed by individual screenings of properties by the authors, as well as feedback generated by the external expert survey presented in chapter 6: External expert survey.

Table 8: Property evaluation.

Property	Description	Score	Explanation
Automation	The endoscopes ability to navigate without human input.	5	The main goal of this thesis is to contribute to future automation of TEE probes.
Maneuverability	The TEE probe's ability to move in space.	5	The endoscope relies on being able to maneuver to achieve good imaging of the heart.
Precision	The accuracy of the TEE probe movement.	5	In order to achieve detailed images, the endoscope relies on highly accurate maneuvering.
Intuitive manipulation	The ability to override the system based on intuition and logic.	3	The system should allow the operator to override the TEE probe based on intuition and logic.
Safety	Sensors must provide sufficient control, and no sharp edges can occur on the endoscope.	5	System malfunction and patient injuries are considered crucial when operating within a human body.

Table 8 continues

Size and ergonomics	The endoscopes ability to fit inside the esophagus.	5	The endoscope has to fit into the esophagus and access the heart. This is of utmost importance.
Weight	The weight of the endoscope.	4	The weight of the endoscope is related to precision and strength (relative stiffness). This is considered important.
Cleaning	How easily the endoscope can be cleaned in between procedures.	4	The endoscope is meant for re-use. It is therefore highly important that the device can be cleaned and sterilized in between procedures.
Cost	The price of the endoscope.	2	The cost of production is at this stage considered close to irrelevant.
Visual design	The aesthetics of the system.	2	The visual design of the TEE system is considered close to irrelevant at this stage of the developmental process.
Retail price	The price per TEE system.	1	The retail price of the automated TEE system is considered irrelevant at this stage of the process.

According to the score, the highest rated properties are *automation*, *maneuverability*, *precision*, *size* and *ergonomics*, and *safety*. Therefore, the design process must focus upon facilitating all the necessary degrees of freedom and meeting size, and ergonomic requirements in order to fit in the esophagus without causing any damage to surrounding tissues. In addition, all implemented electrical components and the mechanical solutions must provide the system with the highest possible precision for future automation.

Weight, *intuitive manipulation* and *cleaning* will be secondary priorities. These properties are also of importance for being able to implement the product in surgical procedures.

The *retail price*, *visual design*, and *cost* are not considered at this stage of the project, the focus being on facilitating maneuverability and future automation.

5.5 Summary of technological challenges

The following list presents challenges that must be considered while analyzing product functions.

- Integrating all necessary actuators into one functional system.
- The required size of the distal end will present challenges for implementation of internal actuation and sensor technology.
- Transmitting external actuating force to movement in the distal end.
- The operating theatre presents challenges regarding the actuation unit's size, as well as its anchoring in the room.
- Preventing x-ray exposure of the echocardiographers hand, while still maintaining a precise system ensuring patient safety.

6 External expert survey

An external survey has been conducted in relation to present and future challenges regarding TEE technology. This chapter presents objectives, a summary of statements and result interpretation. For full content, see Appendix C, where the survey is presented in its entirety.

6.1 Objectives

The survey will be used as a supplement to the function screening and concept generation presented in the next two chapters. The primary objectives of the survey are as listed:

- Provide information in terms of operating existing TEE probes.
- Aid in developing preferable solutions in an automated probe, with insight from people who have experience within the field of cardiology and manipulation of TEE probes.
- Providing information in terms of patient safety.
- Mapping which view planes are considered as most crucial to achieve the best imaging accuracy possible. This will also be helpful later on in the further implementation of automation.
- Provide the authors with insight in terms of necessary motor power.
- Provide the authors with insight in terms of necessary accuracy.

6.2 Survey population

A questionnaire has been developed and distributed amongst individuals that are considered capable of providing insightful feedback to further aid the concept development process and enhance the goal orientation of the project. They have been chosen because of their knowledge within the field of medicine, their hands-on experience with TEE and their knowledge in real-time monitoring of interventional procedures. They are all employees at Oslo University Hospital.

6.3 Results

Three out of five possible respondents have taken the time to answer this survey. This does not provide a big deviance in the answers. However, two respondents are echocardiographers, and one an experienced heart surgeon. This provides highly relevant feedback, from knowledgeable respondents. They provided the project with additional information in regard to desired product features.

6.3.1 Summary of statements

The respondents strongly agree that further development of TEE technology will enhance MICS procedures, and there is a well-willingness towards learning how to master image acquisition through use of electric actuators, joystick control and automation. Furthermore, they provide insight to which functions should be considered most important, and to what extent they effect the image acquisition.

A summary of statements is presented on the following page, as well as feedback to certain questions included in the survey.

Statements concerning placement of the actuation unit and patient approach:

- The probe should enter the mouth in the sagittal plane with 60-90 degrees angle to the long-axis of the patient. If the probe is long enough, the motor housing can be positioned away from the face of the patient.
- The housing should preferably be positioned beside the patients' head in either direction, as the area above and directly behind the patient in the operating theatre is occupied by the anaesthesiologist.

Statements regarding desirable features:

- Robotic maneuvering to improve precision.
- The opportunity to hold the exact same position over time.
- Program the probe to obtain stored previous positions.
- Unless haptics or force limitations are present, perforation of the esophagus could happen.
- Image recognition and subsequent adjustment of position.
- A small monitor on the screen showing the shape of the probe during maneuvering.

As to the question "*What areas could you see presenting challenges in relation to implementing autonomous TEE?*" One respondent answered:

- Respiration and/or mechanical ventilator + cardiac contractions imply that the heart is always moving, and the acoustic window is constantly changing. Also, visualizing different structures within the heart usually requires different acoustic windows, and it's unlikely that one position of the probe will provide all images you need.

Anteflex, clockwise and counter-clockwise rotation of the probe, elongation and rotation of the ultrasound plane are the most important features according to the survey respondents.

6.3.2 Result interpretation

There is a unison agreement to the size of an external actuation unit being important for the operating theatre, and what considerations can be made in order to optimize it's positioning relative to the patient and surrounding equipment and staff in terms of adjustability and approach.

Mechanical properties must enable echocardiographers to achieve all of the 20 standard TEE views. A rotation located to the distal end may be preferable to a fully rotating endoscope due to the friction that occurs between the apparatus and the esophagus.

Implementation of sensor technology has to be precise, as certain images leave room for only 3 mm deviation in order to be satisfactory. Respiration and mechanical ventilation and cardiac contractions implies that the heart is always moving, leading to the acoustic window constantly changing. The system will therefore be relying on regulation control, and implementation of image recognition can resolve this by subsequently adjusting the probe's position.

7 Function analysis and product structure

A functional analysis is the process of breaking down the main goal of the product to smaller segments, in order to identify the requirements for the product to reach its main goal. This is a tool used to aid developers in the task of making a complex product. This chapter will document this process and illustrate different solutions that will help achieve automated TEE imaging. All figures in the function analysis were either modeled in SolidWorks or drawn in Adobe Illustrator.

7.1 Considerations

While developing a new conceptual solution for TEE probes, it is of utmost importance to keep a focus on the operator and patient in order to ensure the quality of the final product. Bringing innovation and technological development to this field will drastically improve the standardization and efficiency to the procedure, and further on reduce the need for highly qualified operators. This will benefit to both institutions conducting surgeries and to patients. These goals are further detailed in figure 47, which served as a basis for the product development.

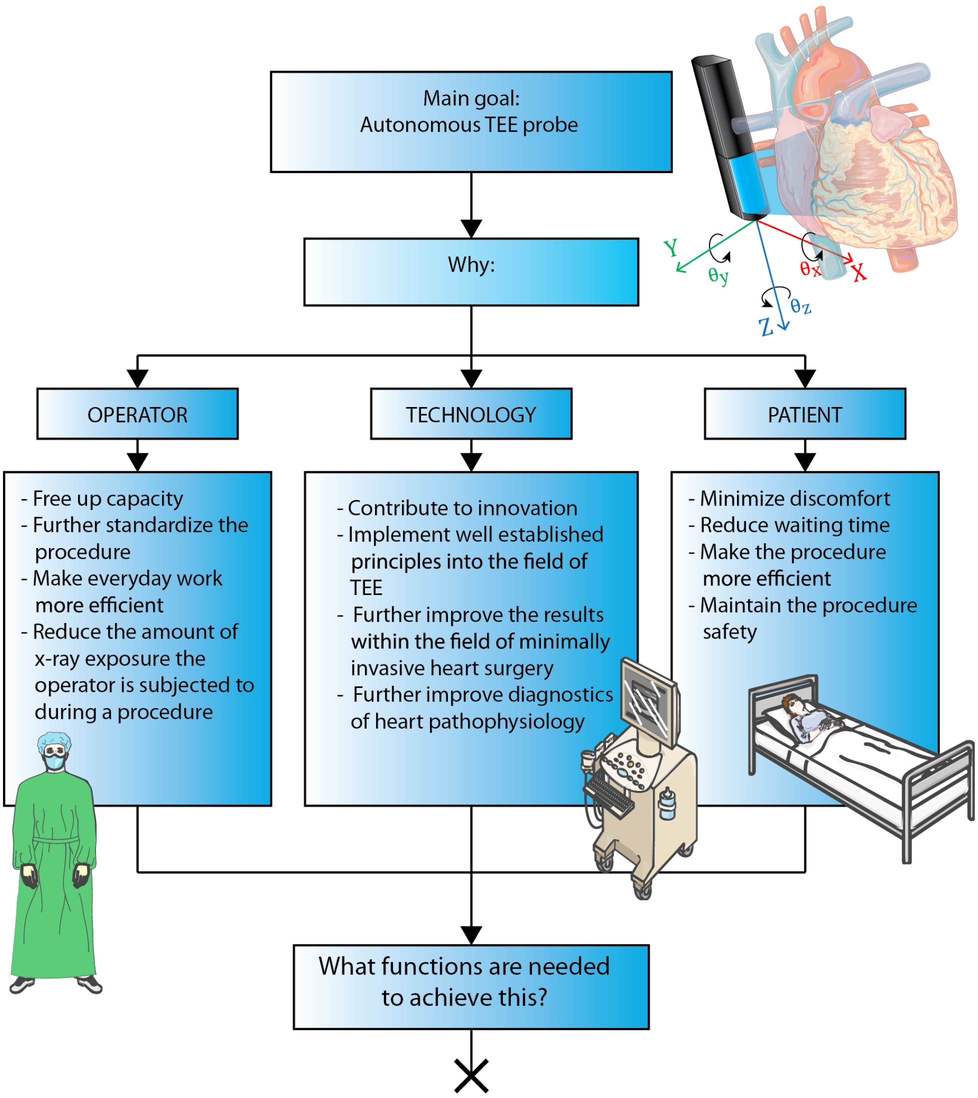


Figure 47: Considerations for the functional analysis.
Adapted from [5].

7.2 Function analysis

To identify the necessary functions for the TEE system, a function analysis has been performed. This analysis provides structure and clearly defines the focus of the development process.

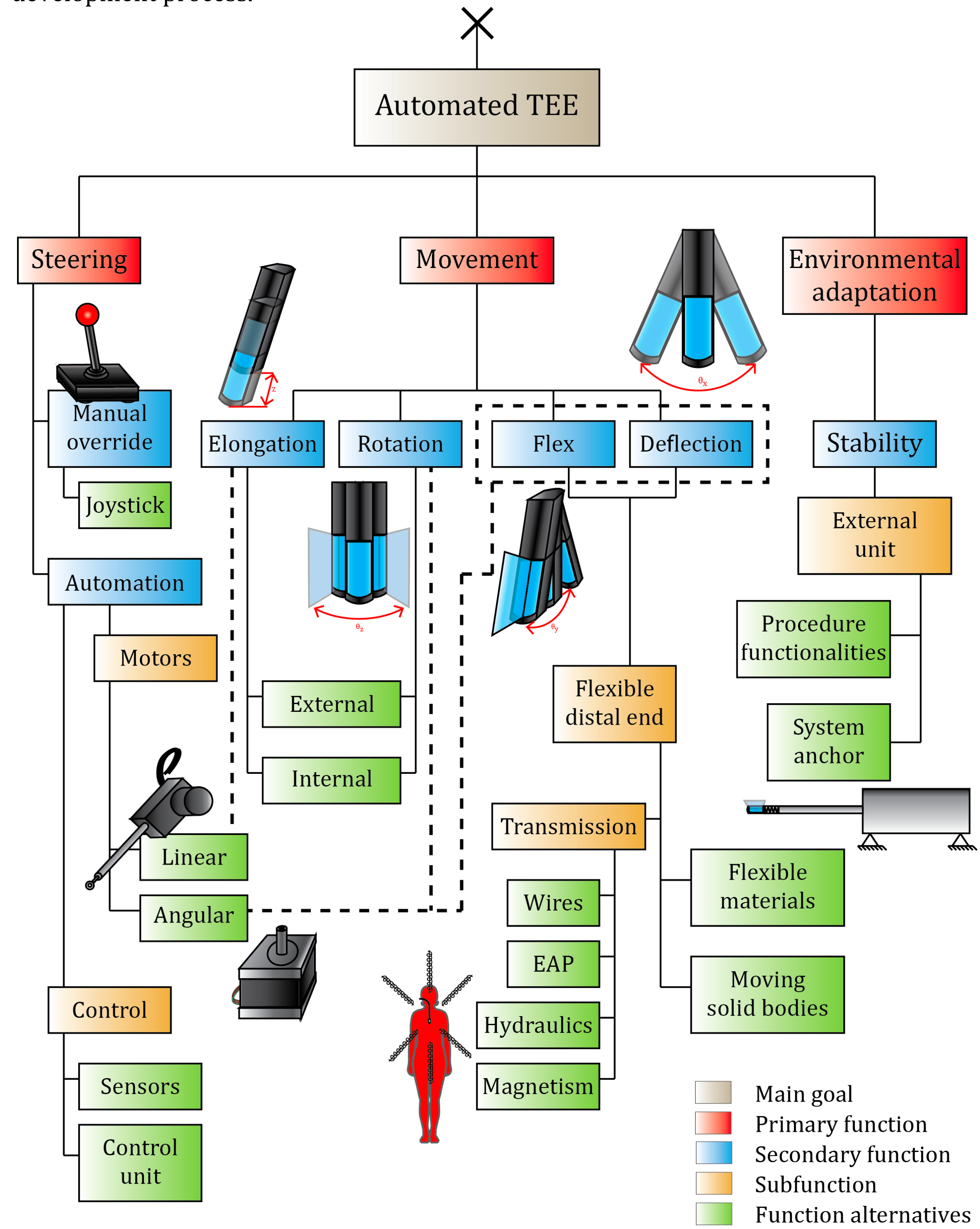


Figure 48: Function analysis.

7.3 Distal end structure

To achieve a diverse range of ultrasound images, one is dependent on facilitating maneuverability that will allow the TEE probe to access the heart from various angles. As mentioned earlier, the distal end of the endoscope needs to provide flex (figure 49). This determines that the tip must allow for easier flexion than the multi-lumen hose leading up to the distal end. In order to facilitate this, several mechanical designs have been developed.

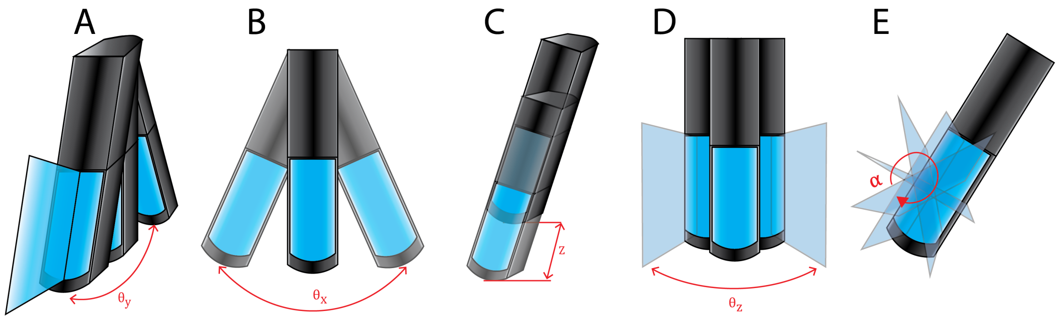


Figure 49: Necessary maneuverability of the TEE probe.
(A) *Anteflex and retroflex.* ***(B)*** *Left and right flexion.* ***(C)*** *Withdraw and advance.*
(D) *Clockwise and counterclockwise rotation.* ***(E)*** *Rotation of ultrasound plane.*

7.3.1 Flex

The flexing of the probe will be achieved by applying an exterior mechanical or electrical force that will be converted to flex or rotation at the distal end (figure 50). The conversions could be achieved by force transmission wires combined with a bendable mechanism in the distal end. All the concepts presented have an intended length of 40-60 mm.

Figure 50: Location of flex mechanism.
Caption: 3: The distal end will house the flex mechanism. It is located in the far end of the system and will operate in the patient's esophagus.

When considering the bending of the TEE probe and catheters in general, force transmission wires are the most common method to convert outside mechanical actuation into the flex at the distal end (figure 51 A-G). However, there are other available methods using different technologies to achieve the same goal (figure 51 H-J). Although these methods are still at the research stage, they will be presented here as equally possible.

Spring mechanism (figure 51A)
This concept is based on a spring, four force transmission wires that are maneuvered from the outside and two metal disc that are fixed to the outer layers. The flex is caused

by pulling the wires which will cause the spring to bend toward the desired angle. A spring is very sensitive to normal forces; hence this may lead to unstable movement.

Coil mechanism (figure 51B)
This concept is based on the same principles as the spring mechanism, but because of the added stiffness more force is required to achieve the desired angular movement. This will result in a more stable bending.

Connecting teeth (figure 51C)
By connecting the individual joints in teeth that allow for some movement, one might be able to achieve flexion in x- and y-axis. Each part is connected by equal patterns and the motion is controlled by force transmission wires. This mechanism results in a stable bending movement. However, the gaps may cause a dead zone and affect the precision in the rotation of the probe.

Alternated rotating Joints (figure 51D)
By implementing alternating rotating joints, one can ensure movement in both x- and y-axis. Some of the endoscopes used in medical practice today are structured this way, and it allows for a high output without requiring much force from the actuating motors. Plastic connectors will be pressed over the joints.

Rigid body linked by pins (figure 51E)
This concept consists of equal solid parts that are linked the way as shown in the picture by small pins. Each part is connected to another with a rotation of 90 degrees along the length-axis and every second part bends in the same direction. The rigid bodies prohibit unwanted motions caused by material defaults and enable a stable movement. The bending motion is controlled by force transmission wires.

Flexible hose (figure 51F)
This concept consists of a flexible hose that will compress due to its holes. The compression will happen on the same side the force transmission wires are being pulled. This method requires a further study of desired material.

Spinal flexion tube (figure 51G)
This solution consists of a series of rings connected by a spine. Wires will be guided through the rings, and this will allow for movement in x- and y-axis. However, the concept might prove challenging in regard to retroflex movement.

Electroactive polymer (figure 51H)
The distal end of the probe may bend when current is applied due to the piezoelectric property of the polymer. This concept only requires current conductors and is therefore well suited for applications in confined spaces, such as the distal end of the TEE system.

Fluid lumens (figure 51I)
The probe consists of elastic channels that transfer fluid to the distal end to build up pressure. The differences of pressure in the channels will cause a bend to the distal end of the catheter. This concept may achieve high precision if correctly designed. However, the risk leakage should be addressed. The lumens will also increase the size of the probe.

Magnetism and micro coils (figure 51J)
This concept is based on a current leading conductor that bends due to a magnetic field. An external magnetic field will set the position and strength of the momentum caused by the coils. This solution would be very space efficient. However, as there is a need for a continuity of the magnetic field and current in the coil there might be an interference with the ultrasound imaging and x-ray, making it difficult to implement.

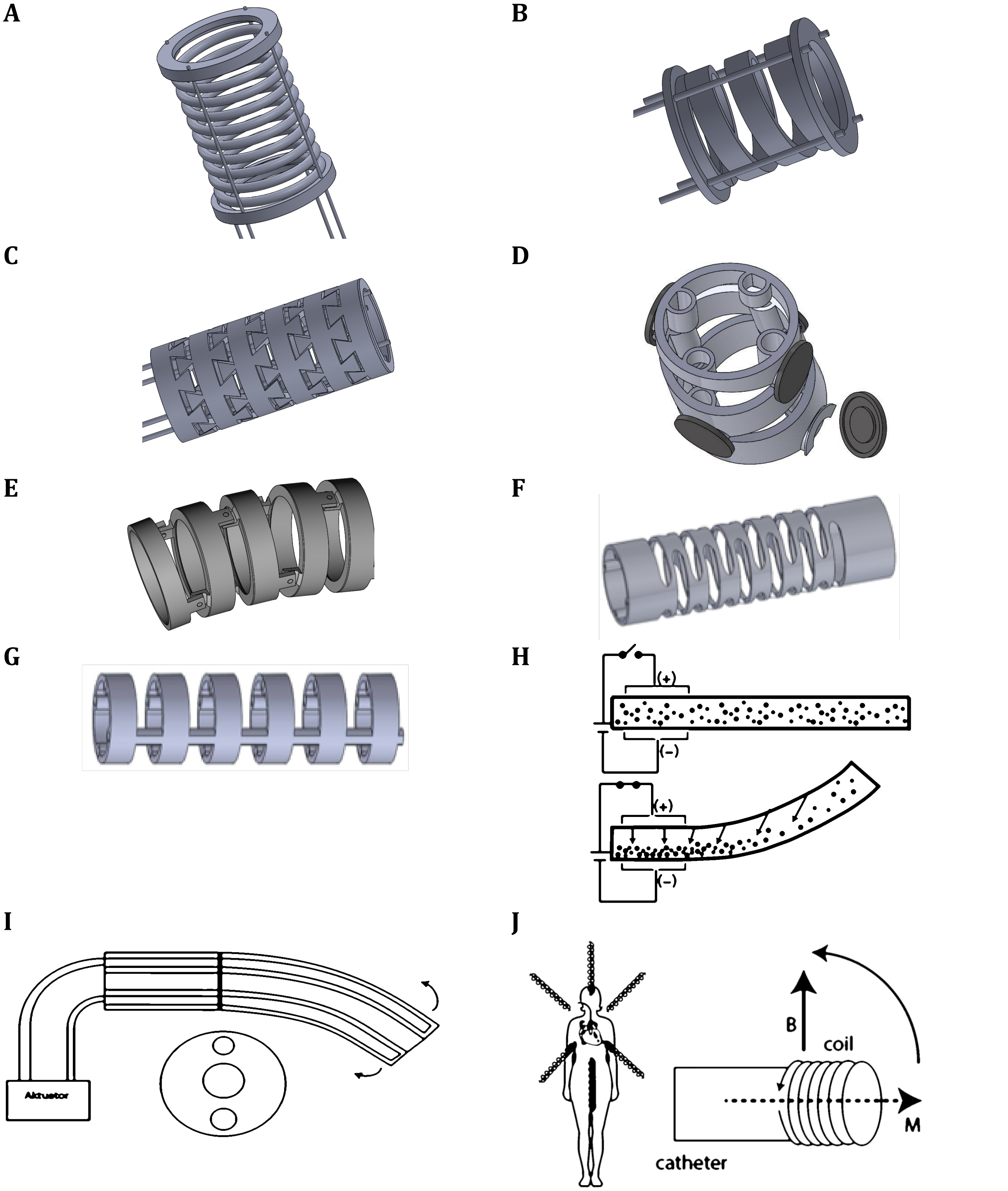


Figure 51: Flex solutions.
(A) *Spring mechanism.* ***(B)*** *Coil mechanism.* ***(C)*** *Connecting teeth.* ***(D)*** *Alternating rotating joints.* ***(E)*** *Rigid body linked by pins.* ***(F)*** *Flexing tube.* ***(G)*** *Spinal flexion tube.* ***(H)*** *Electroactive polymer.* ***(I)*** *Fluid lumens.* ***(J)*** *Magnetism and micro coils.*

7.3.2 Rotation

Rotation of the probe is a necessity in order to reach the desired view-planes. The rotation may be achieved by either a split tube that contains one fixed and one rotating part where rotation is a result of inner mechanisms, or by turning the entire endoscope with its distal end and probe (figure 52). The external rotation may be complemented by guiding the endoscope through an external hose, thus eliminating the friction against the esophagus. Each possible location for rotation has pros and cons that will be considered in the concept screening.

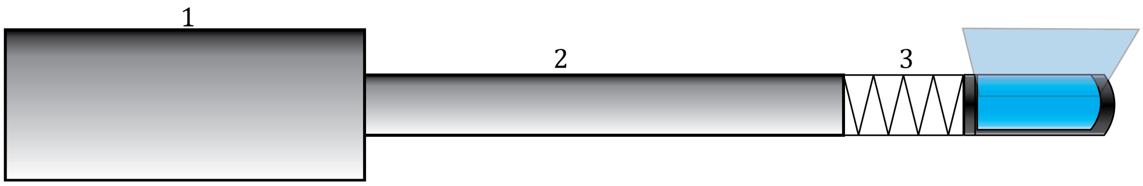


Figure 52: Location of the rotation mechanism.
The rotation mechanism can be achieved in 3 different ways. 1: The whole actuation unit have a rotation implemented, thus rotating the whole endoscope within the esophagus. 2: The endoscope has a local rotation in the proximal end that connects to the actuation unit. With this option, the whole endoscope would also rotate. 3: A local rotation implemented in the distal end by i.e. planet gears and a micro motor.

Distal End Rotation

Inside mechanism/ball screw (figure 53A)
This concept needs two force transmission wires in addition to the flex wires, two metal discs, a screw and a ball nut which is fixed to the upper disc trough magnetism, hence free to rotate. When pulling the force transmission wires, the upper disc will drag the ball nut across the ball screw, hence rotation will occur. The rotating part of the probe is fixed to the ball nut and the non-rotating part is fixed to the discs.

Inside mechanism/micro motor (figure 53B)
Electric brushless motors come in a vast variety of sizes. A small motor in combination with a planetary gear which due to its large number of teeth is able to transfer high torque to the rotating part. The motor is sensible to bending parts and demands a rigid environment.

External rotation

External rotating unit (figure 53C)
This concept will cause the whole endoscope to rotate in the esophagus, much like today's available solutions. This will cause a small friction between the endoscope and the patient's esophagus and may cause some discomfort when they wake up from surgery. However, by rotating the whole external unit one eliminates the problems of force transmission wires entangling before entering the multi-lumen endoscope.

Rotating endoscope (figure 53D)
By implementing a pinion at the external end of the endoscope one can achieve rotation. This will present challenges related to the wires that are guided through the lumens of the endoscope. The pinion must also be hollow in order to guide signal cables through it.

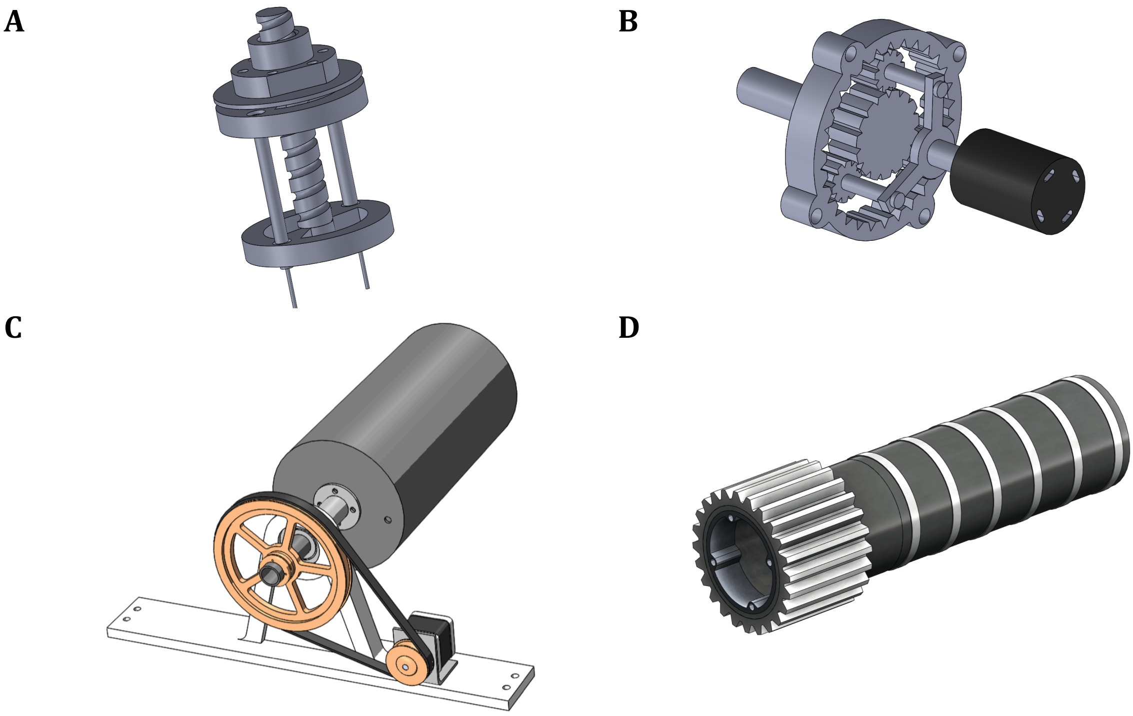


Figure 53: Rotation solutions.
(A) *Ball screw.* **(B)** *Micro motor.* (***C)*** *External rotating unit.* ***(D)*** *Rotating endoscope.*

7.3.3 Elongation

To be able to monitor the heart in its entirety, the TEE system must allow for elongation.

Figure 54: Location of elongation mechanism.
The elongating mechanism can be located in two different positions. 1: External elongation. The actuation unit would be mounted to gliders to enable advancing and withdrawing, thus making the whole endoscope move along the esophagus. 3: Distal end elongation by a local elongation mechanism, where only the probe is advancing and withdrawing.

According to experts consulted, the friction between the endoscope and the patient's esophagus is not a major concern (see Appendix C). The choice of the location for the elongation mechanism is therefore mainly based on the technical challenge presented by each location. Elongation located to the distal end will ensure a precise movement that does not cause irritation of the patient's esophagus. However, it does present some challenges related to the mechanical aspect, and in terms of hygiene and material selection. Implementing all necessary parts into the small distal end might prove challenging from the mechanical perspective. In addition, since the distal end is inside the patient, there should be no hidden surfaces for disinfection.

Distal End Elongation

Compressed spring elongation (figure 55A)
Through a combination of a spring flex, a constant tension on the wires provided by four separate actuators and precise regulation, one should be able to control the elongation of the distal end. As previously mentioned, in the flex section (chapter 7.3.1), this solution is vulnerable to normal forces, which may cause unstable movement.

Screw Elongation (figure 55B)
By utilizing a screw, similar to the ball screw rotation, one can achieve distal end elongation. This solution will require stiffer wires that enable a pull and push collaboration between both of them.

Telescope (figure 55C)
A telescopic elongation, surrounded by an external hose, can provide elongation while at the same time eliminate sharp edges. However, problems related to hidden surfaces will not be resolved. This solution can be achieved through utilizing stiff wires causing linear movement by pulling and pushing on the telescope. This function will need actuators located to the actuation unit and might be unstable when not completely extended or retracted.

External Elongation

Complete elongation of external unit (figure 55D)
By implementing a linear actuator between the system anchor and the actuating unit it can be moved in its entirety in its length-axis. Implementing the elongation after the rotation might also be a possibility in the detailed phase of the concept development.

Gripper function on the endoscope (figure 55E)
By allowing grippers to feed the endoscope along the length of the esophagus one can ensure precise and steady elongation. This requires a flexible surplus of endoscope that must be as long as the desired maximum increment.

Two-part elongation (figure 55F)
Elongation can be achieved by separating the actuating unit into two housings, and having the behind unit moving the front unit through a linear actuator. If force transmission wires are implemented in the rear actuation unit, they will be shielded from entanglement while the endoscope run its entirety onwards to the front actuation unit. A limited rotation could also be implemented in the front housing.

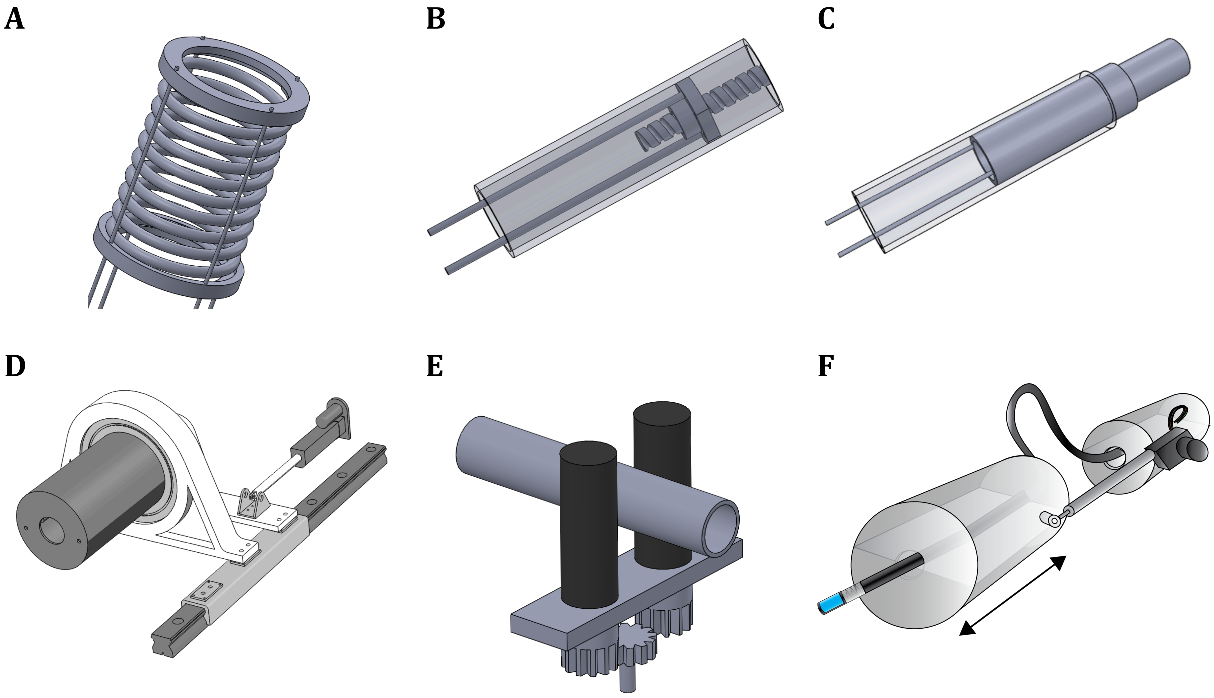


Figure 55: Elongation solutions.
(A) *Compressed spring elongation.* ***(B)*** *Screw elongation.* ***(C)*** *Telescope.* ***(D)*** *Complete elongation of external unit.* ***(E)*** *Gripper function on the endoscope.* ***(F)*** *Two-part elongation.*

7.4 Sensors

The implementation of sensors affects two important aspects. First, it enables regulation control of the system which is necessary in a future autonomous solution. Secondly, the sensors ensure that the TEE system does not injure the soft tissues of the patient. Therefore, sensor technology must be implemented, as it will have crucial impact on the system's performance.

Linear position
Keeping track of the system's linear position is important for the functionality of the system and further automation. One advantage in knowing the linear position of the distal end is that the probe can be regulated to repeat the reach of essential views if calibrated correctly. Linear position tracking can be done by sensors in the distal end and by external sensors reading the position of the actuating unit.

Angular position
Keeping track of the system's angular position is important for functionality and further automation. It can be implemented in the actuation unit through the use of an optical sensor. Angular position sensors are not available in stepper motors. However, the step-count implemented in these motors allow for continuous monitoring of the rotating shafts position. These often work with high level of accuracy.

Velocity

Tracking the velocity of the distal end's movement will be useful in order to ensure a safe system. The sliding of the endoscope inside of the esophagus might result in irritated soft tissue. High velocities lead to a higher friction, therefore, the ability to regulate the system in regard to velocity can help ensuring the patients safety.

Force

Controlling the contact between the probe housing and the soft tissue in the esophagus is essential for the patients' safe being. As the distal end is maneuvered inside of the esophagus, a force sensor should read the severity of this contact. Optimizing the level of surface contact between the probe and the soft tissues is essential for image quality. Today the operator senses the resistance in the esophagus due to the manual manipulating of the probe. This feature should be reproduced in case the operator must override a fully automated system. Force sensors also provide feedback necessary to ensure patient safety. Without present force sensors, the TEE probe might perforate the esophagus. This sensor can either be located in the probe housing or in the actuation unit. An external location would involve integrating the pull on the force wires and the resistance of actuators to compute the contact force.

Image recognition

This function is a desire expressed by the project supervisors and echocardiographers at Oslo University Hospital. Biometric recognition technology would enable the system to identify structures of the ultrasound image that are not visible to the human eye. This allows for further implementation of machine learning algorithms that can enabling the automated system to locate specific TEE views.

Sound

If the probe is capable of picking up on soundwaves coming from the heart it will enable continuously fixation towards the heart, and keeping the plane focused in the right direction. Possible drawbacks regarding this solution are that there might be other sources of sound caused by internal organs or surrounding people. Even if it picks up the correct signal it will have to be properly calibrated to account for which direction the heart is.

7.5 Environmental adaptation of external unit

An external actuation unit will be necessary to achieve the desired manipulation of the TEE probe. All the electric motors actuating on the distal end, as well as the control unit, needs to fit in the operation theatre without disturbing the surgical team. This presents some challenges, as described in chapter 5.2.1. This subchapter will present some possible designs enabling implementation of the autonomous TEE system in an already crowded workspace.

7.5.1 Anchor

Compact Anchor (figure 56A)
By designing a more compact anchor solution, one might be able to attach the actuation unit to an operating table or the Innova IGS 5 with a one-way joint will maintaining adjustability. Attachment can be provided by either brackets or powerful suction cups. Although very space efficient, this solution presents some challenges since the Innova and operating table are maneuverable.

Floor Anchor (figure 56B)
By mounting the actuation unit to a footpeg, the system will be adaptable to different operating rooms. Adjustability will be similar to that of the compact anchor, but the one-way joint will be connected to a 1000 mm arm, to ensure the system reaches the necessary height. This solution might be interfering with the surgical team and other equipment present in the operating theatre.

Roof Anchor (figure 56C)
By designing a roof mount for the actuation unit, it will take up less space in the operating room and provide the endoscope with a natural approach to the patient. Adjustability will be superior to the two previous anchors due to an additional one-way joint. This will enhance the approach to the patient. By mounting the system to the roof, one can pull all electrical wires up along the anchor arms, and through the roof towards the system control station. Installing a roof anchor in the operating theatre will require more work than the two previous suggestions.

7.5.2 Stability

Endoscope guide (figure 56D)
Designing a device that can guide and support the endoscope between the actuating unit and the patient will keep the system stable while reducing the x-ray exposure the surgeons are subjected to. This also aid prevention of any kink occurring in the endoscope as it descends into the patient's mouth.

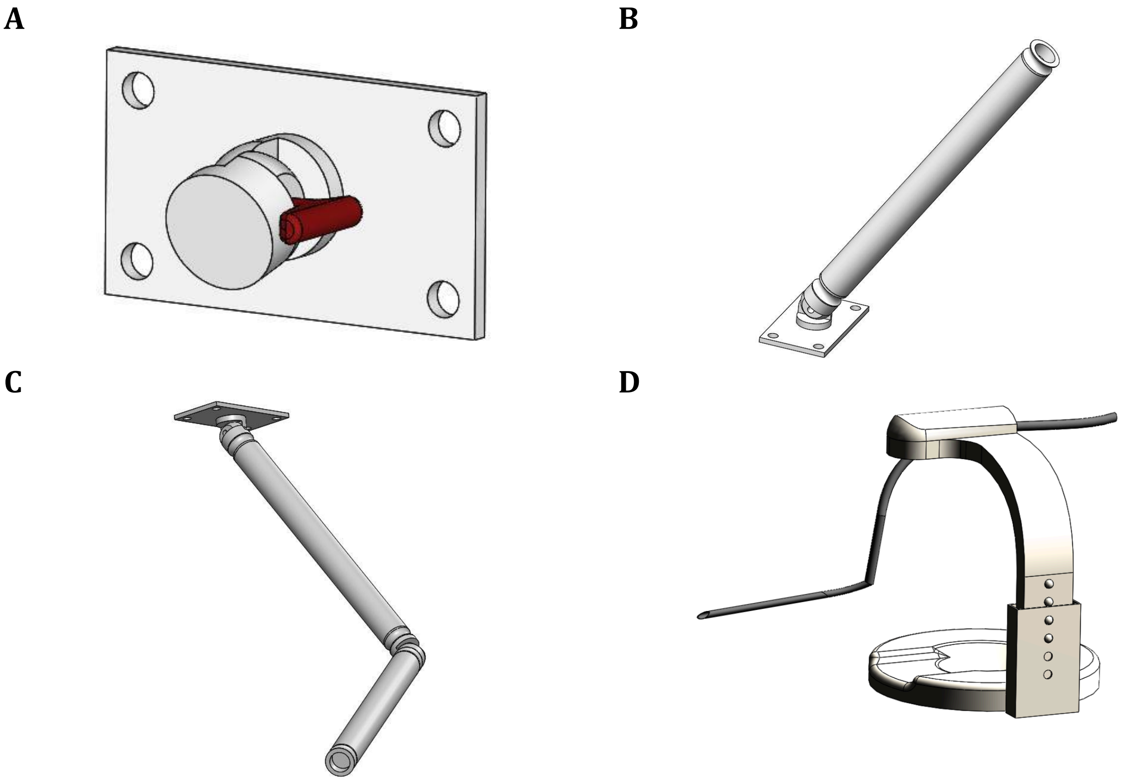


Figure 56: System anchor functions.
(A) Compact anchor. (B) Floor anchor. (C) Roof anchor. (D) Endoscope guide.

7.5.3 Cleaning and disinfection procedures

For an automated TEE system to be usable, it has to accommodate possibilities for cleaning, and disinfection of the complete endoscope. Indeed, these procedures are necessary to ensure that the patient's esophagus is not exposed to bacteria.

Mounting and unmounting of the endoscope (figure 57A)
By unmounting the endoscope from the actuation unit, the team preparing the surgery can easily transport it to and from the disinfection station.

Complete system sterilization (figure 57B)
Without a detachable endoscope the disinfection has to be performed manually and on site.

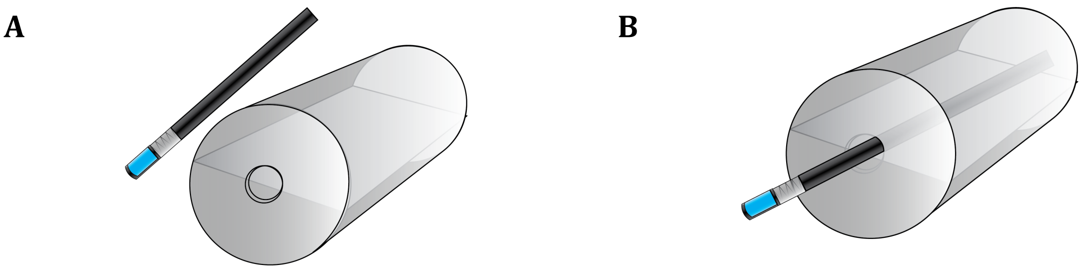


Figure 57: Function alternatives.
(A) *Mounting and unmounting of the endoscope.* **(B)** *Complete system sterilization.*

8 Concept screening

A concept screening has been conducted in order to define the most usable solutions for the detailed design of the TEE system. This chapter presents the screening process in its entirety. This involves developing a selection matrix, establishing criteria, weighing the different criteria and defining the most suitable solutions. At endpoint, a final systematized concept solution will be presented.

8.1 Development of selection-matrix properties

The screening is conducted according to Pugh's method (chapter 3.3). After selecting the most suitable functions from the function analysis, these are scored on how well they meet crucial criteria. The criteria used in this thesis take into account the relation between operator, technology and patient as well as the economic, and sustainable aspect of the final product.

Score scale
Each concept is provided with a score ranging from 1-5, where 1 indicates that the feature does not meet the requirements to a satisfying degree, and 5 to a very good degree.

Criteria
Each concept alternative will be evaluated regarding movability, precision, complexity, risk and compatibility, in correlation with chapter 5.2 – Product properties. The 5 criteria are described as follows.

Movability is essential for the TEE system to reach its desired position. To achieve this, it is important that every single mechanical function used in the final concept facilitates good and controllable motion meeting the required DOF.

Precision is an important feature of medical robotics in general as there is limited tolerance for errors. The functionalities will be rated in function of the degree of precision they can operate individually. Some key points are hysteresis, feedback, and controlled motion.

Complexity will also be considered, as a very complex system eventually could exceed the limitations of this thesis. Hence the functionalities will be rated according to the difficulties of assembly and the number of parts included in the system. It is advantageous to keep the solution as simple as possible.

The risk associated with the different functionalities will be an important aspect in the ranking process, as some concepts may cause harm to the patient.

Interaction and/or compatibility between the different concepts is very important as a bad interaction could result in singularities or entangled force transmission wires. The different alternatives will be ranked on their interactions with other concepts.

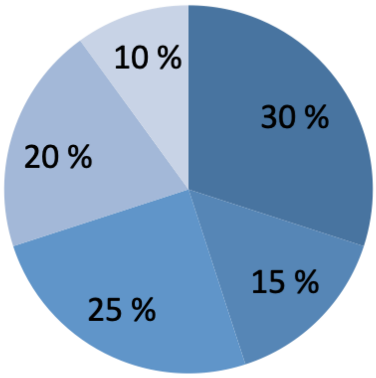
8.2 Screening of alternatives

The criteria will be weighted in relation with the different functions in order to make conclusions based on more nuanced numbers. For instance, complexity will not have as much impact on environmental adaptation as it will have on distal end elongation.

8.2.1 Screening of deflection alternatives

Table 9: Flex functions.

Alternative	Description
A	Spring
B	Coil
C	Connecting teeth
D	Alternating joints
E	Rigid body linked by pin
F	Flexible hose
G	Spinal flexion tube
H	EAP
I	Fluid lumens
J	Magnetic



Criteria weighting in relation to deflection:

Movability: 30 %
The distal ends ability to move is crucial. Especially, it should achieve good surface contact between the probe and soft tissue.

Precision: 15 %
Facilitating precise movement is important for acquiring good images.

Complexity: 25 %
The distal end of the TEE system is small, and hence important to keep the complexity low.

Risk: 20 %
Operating inside the esophagus of the patient involves keeping risk factors to a minimum.

Interaction: 10 %
The mechanics in the distal end must allow for use of force transmission wires or work medium.

Table 10: Screening of the flex functions. *S: score, WS: weighted score.*

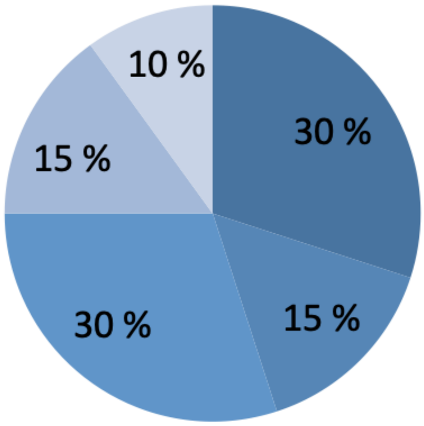
Criteria	Movability		Precision		Complexity		Risk		Interaction		
Weight	30 %		15 %		25 %		20 %		10 %		
ALTERNATIVE	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**SUM**
A	4	1.2	2	0.3	4	1	3	0.6	3	0.3	**3.40**
B	3	0.9	3	0.45	4	1	4	0.8	4	0.4	**3.55**
C	3	0.9	4	0.6	3	0.75	4	0.8	3	0.3	**3.35**
D	5	1.5	4	0.6	3	0.75	4	0.8	3	0.3	**3.95**
E	5	1.5	4	0.6	4	1	4	0.8	4	0.4	**4.30**
F	4	1.2	3	0.45	3	0.75	4	0.8	4	0.4	**3.60**
G	3	0.9	4	0.6	4	1	4	0.8	4	0.4	**3.70**
H	2	0.6	3	0.45	2	0.5	3	0.6	3	0.3	**2.45**
I	4	1.2	2	0.3	2	0.5	2	0.4	3	0.3	**2.70**
J	3	0.9	3	0.45	1	0.25	2	0.4	2	0.2	**2.20**

In this screening, the rigid body linked by pins appear superior due to its low complexity and high functionality.

8.2.2 Screening of rotation alternatives

Table 11: Rotation functions.

Alternative	Description
A	Ball screw
B	Micro motor
C	External rotation
D	Rotating endoscope



Criteria weighting in relation to rotation:

Movability: 30 %
Being able to rotate the ultrasound plane is important for good image acquisition. It is particularly important for images in the lower gastric region of the esophagus.

Precision: 15 %
Locating the correct areas of the heart requires high precision.

Complexity: 30 %
The distal end of the TEE system is small, and it is therefore important to keep the complexity low. If the rotation is located outside the endoscope the complexity will not be as crucial.

Risk: 15 %
Operating inside the esophagus of the patient involves keeping risk factors to a minimum. The turning motion will be in direct contact with soft tissue in the esophagus.

Interaction: 10 %
The rotation must not interfere with any of the other movements of the probe.

Table 12: Screening of the rotation functions. *S: score, WS: weighted score.*

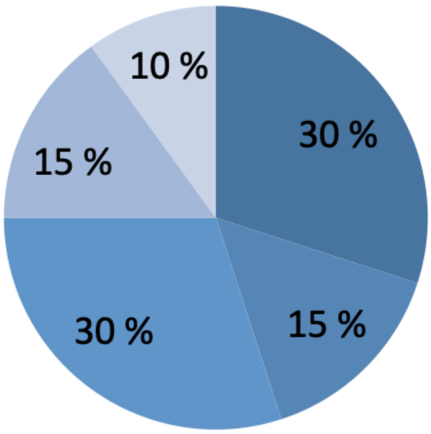
Criteria	Movability		Precision		Complexity		Risk		Interaction		
Weight	30 %		15 %		30 %		15 %		10 %		
ALTERNATIVE	S	WS	S	WS	S	WS	S	WS	S	WS	SUM
A	3	0.9	3	0.45	2	0.6	3	0.45	1	0.1	**2.5**
B	3	0.9	3	0.45	2	0.6	2	0.3	1	0.1	**2.35**
C	4	1.2	4	0.6	4	1.2	4	0.6	4	0.4	**4.00**
D	3	0.9	3	0.45	3	0.9	3	0.45	2	0.2	**2.90**

In this screening, concepts involving an external rotation appear far stronger than distal end rotation. This is mainly due to much lower complexity and better risk management in regard to mechanical errors endangering the patient. An external rotation, implemented in the actuation unit, will be fully functional as long as it is supplemented by a relatively stiff endoscope, with a 1:1 actuation. This means that a 10-degree rotation by the actuation unit will translate to a 10-degree rotation at the distal end.

8.2.3 Screening of elongation alternatives

Table 13: Elongation functions.

Alternative	Description
A	Compressed spring
B	Screw elongation
C	Telescope
D	External unit
E	Gripper function
F	Two part unit



Criteria weighting in relation to elongation:

Movability: 30 %
The distal ends ability to move in the z-axis is an absolute necessity to acquire all necessary locations.

Precision: 15 %
Facilitating precise movement in the z-axis is important for acquiring good images.

Complexity: 30 %
The distal end of the TEE system is small, and it is therefore important to keep the complexity low. High complexity, by elongating the distal end, might create challenges related to hidden surfaces. If the whole endoscope is to elongate the complexity will not be a concern.

Risk: 15 %
Operating inside the esophagus of the patient involves keeping risk factors to a minimum.

Interaction: 10 %
The elongation function must not interfere with any other movement of the probe.

Table 14: Screening of the elongation functions. *S: score, WS: weighted score.*

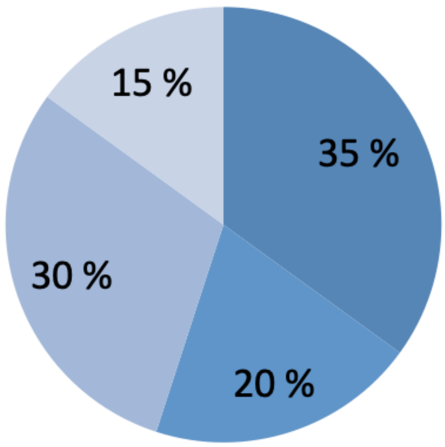
Criteria	Movability		Precision		Complexity		Risk		Interaction		
Weight	30 %		15 %		30 %		15 %		10 %		
ALTERNATIVE	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**SUM**
A	3	0.9	3	0.45	3	0.9	4	0.6	3	0.3	**3.15**
B	4	1.2	4	0.6	2	0.6	4	0.6	1	0.1	**3.10**
C	4	1.2	3	0.45	2	0.6	4	0.6	1	0.1	**2.95**
D	4	1.2	5	0.75	5	1.5	3	0.45	4	0.4	**4.30**
E	3	0.9	4	0.6	3	0.9	3	0.45	3	0.3	**3.15**
F	4	1.2	4	0.6	2	0.6	3	0.45	2	0.2	**3.05**

Implementing elongation in the actuation unit appears superior in the concept screening. This is mainly due to low complexity and risk. External elongation eliminates risks associated with hidden surfaces and bacterial infections. It also simplifies implementation due to a lower number of parts required, and avoid challenges related to size in the distal end.

8.2.4 Screening of sensor alternatives

Table 15: Sensor functions.

Alternative	Description
A	Linear position
B	Angular position
C	Velocity
D	Force
E	Visual surveying
F	Sound



Criteria weighting in relation to sensors:

Movability: 0 %
Movability is not crucial for the sensor choice.

Precision: 35 %
The system precision relies on the sensor.

Complexity: 20 %
The distal end of the TEE system is small, and it is hence important to keep the complexity low. In addition, all data signals must be led through a confined space in the multi-lumen endoscope if the sensor is located in the distal end.

Risk: 30 %
The implementation of this sensor results in a safer system, which is crucial for the patient.

Interaction: 15 %
The sensors must interact properly with the electrical actuators. This means that the sensors must be compatible with the selected actuators.

Table 16: Screening of the sensor implementation. *S: score, WS: weighted score.*

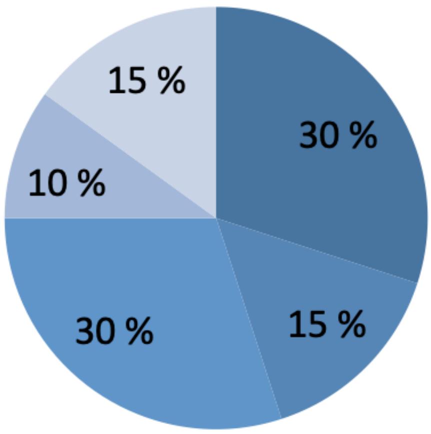
Criteria	Movability		Precision		Complexity		Risk		Interaction		
Weight	0 %		35 %		20 %		30 %		15 %		
ALTERNATIVE	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**SUM**
A			2	0.7	5	1	3	0.9	5	0.75	**3.35**
B			3	1.05	5	1	3	0.9	5	0.75	**3.70**
C			2	0.7	3	0.6	3	0.9	5	0.75	**2.95**
D			4	1.4	3	0.6	5	1.5	4	0.6	**4.10**
E			5	1.75	3	0.6	4	1.2	5	0.75	**4.30**
F			3	1.05	2	0.4	2	0.6	3	0.45	**2.50**

The possibilities of sensor implementation are vast. They can be implemented in the actuation unit as well as the distal end, and a combination of multiple sensors will be necessary to achieve safe and steady manipulation of the probe. Due to this consideration, several possibilities will be brought into the design stage.

8.2.5 Screening of environmental adaptation alternatives

Table 17: Environmental adaptation functions.

Alternative	Description
A	Floor anchor
B	Compact anchor
C	Roof anchor
D	Endoscope guide



Criteria weighting in relation to environmental adaptation:

Movability: 30 %
The opportunity to adjust and hence adapt the system to any given operating room is important.

Precision: 15 %
Providing the system with a stable anchor will lead to better results of the automated movement. There will be less external interference with a proper anchor system.

Complexity: 30 %
Complexity is of some importance as the medical team should be able to adjust the TEE system.

Risk: 10 %
Operating inside the esophagus of the patient involves keeping risk factors to a minimum, also when considering system anchors.

Interaction: 15 %
The anchor system must comply with all other elements in the operating room.

Table 18: Screening of environmental adaptation. *S: score, WS: weighted score.*

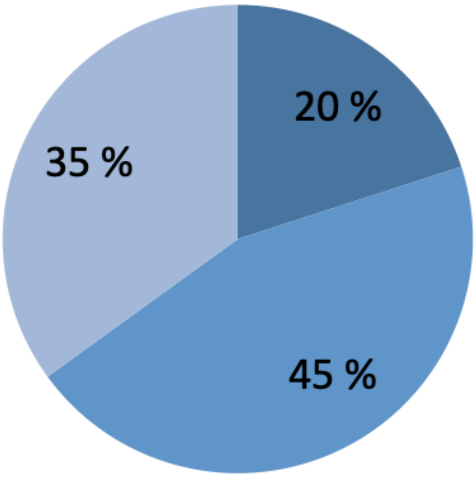
Criteria	Movability		Precision		Complexity		Risk		Interaction		
Weight	30 %		15 %		30 %		10 %		15 %		
ALTERNATIVE	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**SUM**
A	4	1.2	4	0.6	4	1.2	4	0.4	3	0.45	**3.85**
B	4	1.2	4	0.6	2	0.6	4	0.4	4	0.6	**3.40**
C	5	1.5	4	0.6	3	0.9	4	0.4	4	0.6	**4.00**
D	4	1.2	5	0.75	4	1.2	5	0.5	4	0.6	**4.25**

The roof anchor and the endoscope guide appear superior in the screening. These two concepts will ensure that the TEE system does not interfere with the presence of the medical team and other equipment. The endoscope guide will help stabilize the system by leading the endoscope to the patient's mouth, ensuring a good entry-angle and support of the endoscope.

8.2.6 Screening of procedure function alternatives

Table 19: Procedure function functions.

Alternative	Description
A	Mount / Unmount
B	Complete system



Criteria weighting in relation to procedure functions:

Movability: 20 %
The ease of transporting the component/system back and forth to cleaning.

Precision: 0 %
Precision is not important for being able to provide the necessary procedure functionalities.

Complexity: 45 %
The complexity should be kept to a minimum as the medical team will have to mount and unmount different parts of the system.

Risk: 35 %
All procedure functions should be of high quality to avoid risk during mounting and unmounting of the systems components in Everything has to be intuitive.

Interaction: 0 %
Interaction is not of importance for the procedure functions.

Table 20: Screening of procedure functionalities. *S: score, WS: weighted score.*

Criteria	Movability		Precision		Complexity		Risk		Interaction		
Weight	20 %		0 %		45 %		35 %		0 %		
ALTERNATIVE	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**S**	**WS**	**SUM**
A	5	1			4	1.8	3	1.05			**3.85**
B	3	0.6			3	1.35	4	1.4			**3.35**

The unmounting of the endoscope from the actuation unit is preferable to a solution that involves on site disinfection. This presents a design challenge to fulfil this function. The inside of the actuation unit should be accessible in order to perform the disinfection. This requires a system where the endoscope can be disconnected and reconnected without any risk of error.

8.3 Results of screening

The function alternatives that obtained the best scores during the concept screening are presented in table 21. The alternatives will be presented in a system model indicating the location of the different solutions.

Table 21: Preferred solution for system.

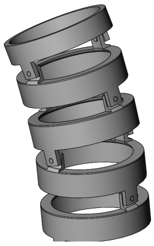
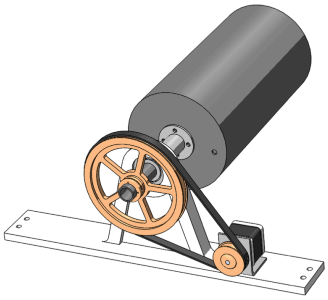
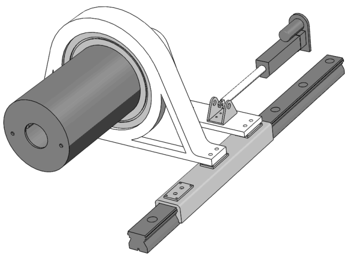
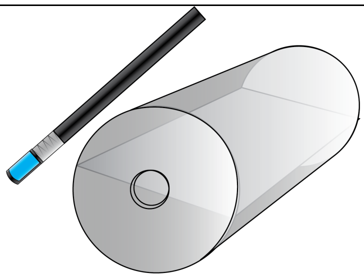
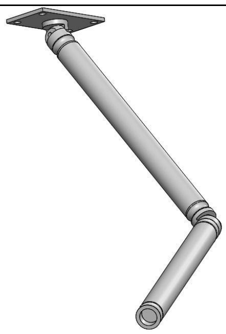
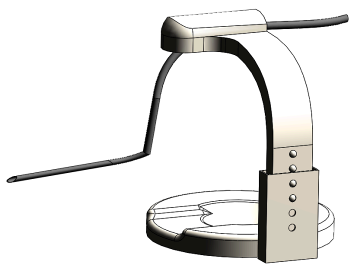
Illustration	Description
	***Rigid body linked by pins*** can achieve flexion in both x- and y-direction. This solution is of low complexity in regard to the amount of parts needed to make it functional, and it will provide enough space for all necessary force transmission wires and signal cables to be pulled through it while enabling good movement.
	With an ***external rotation of the actuation unit***, one can achieve a precise rotation while keeping all the force transmission wires for flex undisturbed. By implementing this solution to the concept, the size constrictions in the distal end is not a concern. A diverse range of motors and transmission methods are applicable in this solution.
	***External elongation on the actuation unit*** with a solid connection to the endoscope will provide a low complexity and wide-range elongation. The system will be precise and robust by using a linear actuator. The actuators often include internal feedback that makes it applicable for the TEE system.
	***Mounting and unmounting*** of the endoscope will allow disinfection of the part of the system that enters the esophagus between each use. This is a necessity to ensure the patient's safety. This involves a quick connection between the endoscope and the actuation unit, and a design preventing errors during reassembly.
	A ***roof anchor*** will ensure adaptability to the operating theatre. This will prevent the medical team from interfering with the system by accidentally touching it during the procedure. A further implementation of a spherical rotating joint would be useful in addition to the two one-way joints.

Table 18 continued: Preferred solutions for system.

	An ***endoscope guide*** will assist the stability of the endoscope as it maneuvers inside the patient, while preventing kink from occurring in its external section. It will also ease the angle in the cervical section of the esophagus by making the patients head lean slightly backward.
Force sensors will contribute to ensure a good and evenly distributed contact between the transducer and the soft tissue in the esophagus. By being able to read this value one can also ensure the patient's safety. This sensor will be crucial for the system.	
Visual surveying will aid a steady and accurate image acquisition. By defining a reference point in the projected ultrasound image one can make the system work towards maintaining its position continuously. Being able to save positions already reached by the echocardiographer, in order to reference them later on, will also be useful.	
Linear and angular position sensors will be important for surveying and regulating the probe's movement. Tracking of position and shape, could be implemented to a user interface, making the surgeon continuously aware of the distal end's shape.	

In order to integrate these solutions into one concept, the main mechanical functions are put into different Scamper schemes to decide which layout provides the ideal system functionality (figure 58). Two concepts are presented, which differ by the placement of the rotating and elongating actuator. Both concepts eliminate problems related to wire entanglement due to rotation.

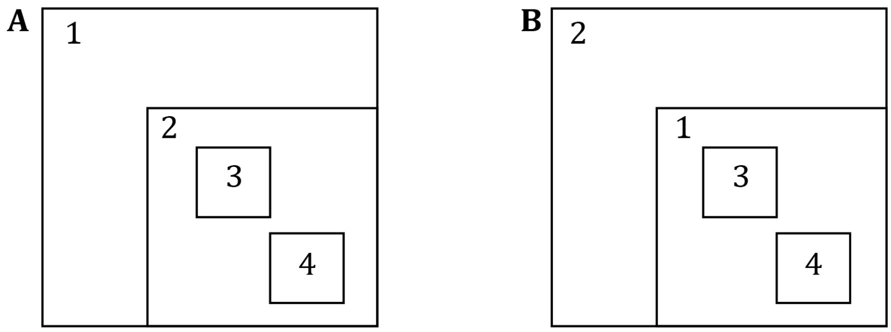


Figure 58: Scamper scheme for actuation unit layout concepts.
(A) *Linear actuator is acting on a rotating actuation unit.* ***(B)*** *Rotating actuator is acting on elongating actuation unit. 1: Elongation, 2: Rotation, 3: Anteflex and retroflex, 4: Left and right flexion.*

After a careful review of the components and their mechanical properties, the decision of bringing Concept A into the detail design phase has been made. This will provide the system with efficient and clear functionality and is considered the most beneficial solution in terms of layout.

8.4 Provisional CAD mock-up

The screening conducted above suggest implementing all of the actuation in an external actuation unit, hence the linear movement of the probe, rotation, and elongation have to be conducted by this unit. A provisional CAD model was made to fully understand how the different functions come together into one system (figure 59).

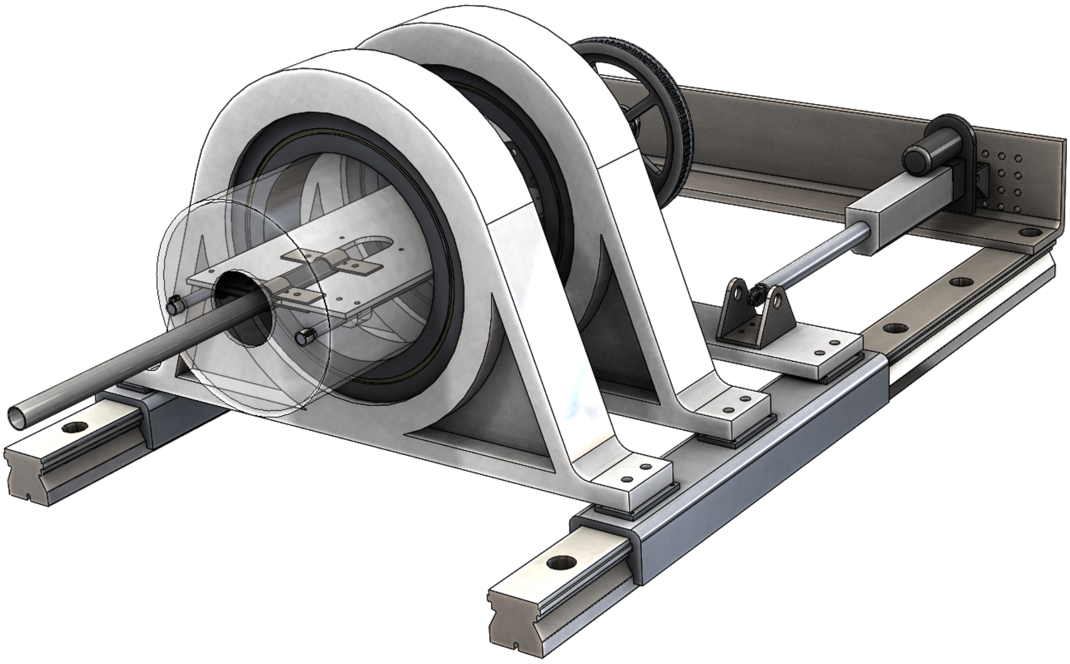


Figure 59: Early stage mock-up of Concept A.

The CAD model in figure 60 is a raw presentation of the actuation unit. The TEE endoscope (1) enters the cylinder (2) and is attached to a plate where the force transmission wires will be connected to the actuators responsible for distal end manipulation. The plate is fixed and will rotate with the cylinder. Since the endoscope will be disconnectable this feature must undergo further development. The design and accessories of the plate will be discussed in detail in chapter 9. The linear displacement of the probe (withdraw and advance) was suggested to be controlled by an external movement and is achieved by slide rails (3) and a linear actuator (4). The rotation of the system is controlled by a motor with a pulley (5) and the rotation is further controlled by a pulley and belt mechanism (5). The large pulley is connected to the cylinder through a shaft and will enable a controlled rotation of the probe (1). The bearings (6) ensures frictionless rotation to the cylinder.

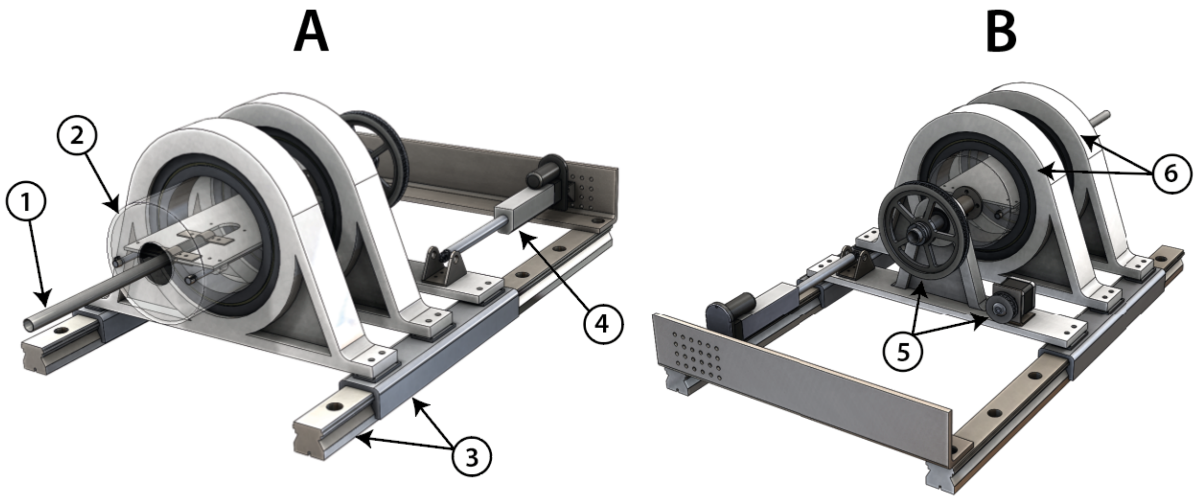


Figure 60: Functions included in concept.
(A) *Front view of actuation unit. 1: Endoscope, 2: Cylinder, 3: Slider rails, 4: Linear actuator* ***(B)*** *Rear view of the actuation unit, 5: Pulleys, 6: Bearings.*
Please note that the endoscope will be longer illustrated here.

8.4.1 Actuation through force transmission wires

The control and attachment of the force transmission wires are important aspects of the actuation unit, since it will be responsible for making the distal end flex. In the system mock-up (figure 60), the functions are supposed to be implemented to the plate in the center of the cylinder.

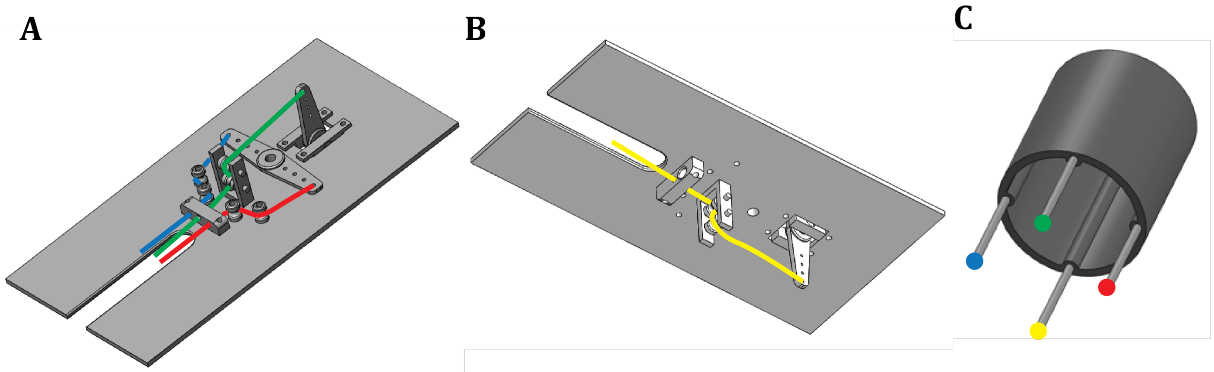


Figure 61: Force transmission wires on actuating plate.
(A) *Top of actuation plate.* ***(B)*** *Bottom of actuation plate.* ***(C)*** *Connecting tip of endoscope with wires relative to each flex direction. Green: Anteflex, yellow: retroflex, red: left flexion, blue: right flexion. The TEE endoscope is inserted to the open section in the plate.*

In figure 61, wires with corresponding movements are attached to the same arm. The attachment points on the arm are located at an equal distance from the axis of revolution. This will eliminate a push-and-pull conflict in the distal end. The wires are guided through reels that ensure maintaining them tight to provide an accurate response. The arms will be manipulated by electric motors.

In accordance with the requirements for sterilization and disinfection of the endoscope, quick connectors to the force transmission wires between the endoscope and the actuation unit should be implemented.

8.4.2 Electric connections

To complete the design of a fully operational system, the different electric components have to be connected to power supplies and drivers. As the main goal of this thesis is to account for the mechanical aspects of the solution, there are some considerations that have to be made regarding the electrical connections.

- The cables transferring signals from the ultrasound transducer need to be connected to the actuation unit trough a quick connector, as the force transmission wires. This will complete the function of separating the endoscope from the actuation unit.
- The roof anchor enables easy access for electric transmission between the actuation unit and the power supply. The wiring could be attached along the anchor arms to limit inconvenience to the operation theatre.
- The external rotation of the actuation unit was the preferable solution to achieve rotation of the distal end. This means the signal cables and the electric conductors supplying the motors inside of the actuation unit will rotate as well. There are two possible solutions regarding this issue.
    - To implement a slip ring at the back end of the actuation unit. This will ensure signal flow regardless of physical rotation.
    - To implement longer wires to make up for the rotation of the system. This solution requires limitations regarding maximum and minimum rotation.
- A driver is needed inside of the actuation unit to supply voltage to the motors. The solution will need to account for this extra device.

8.5 Short survey

After the concept mock-up was finalized, further improvements and desires have been surveyed through discussions at Oslo University Hospital and the workshop at NMBU. Supervisors at OUH expressed a desire to implement design features that would minimize the patient's discomfort, as well as ease the insertion of the TEE probe. This involves straightening out the throat in order to ease the angle in the esophagus, where it connects to the pharynx. These challenges can be resolved by implementing an external tubing to aid the endoscope through this region, in addition to a headrest tilting the patient's head backwards.

The flex and actuation solution have also been discussed with the head engineer at Department of Natural Science at NMBU. This discussion revolved around the flex solutions, specifically actuation and manufacturing possibilities. He could not see any immediate challenges related to these topics and had a positive attitude towards the solutions presented. He considered a potential future prototyping of the device to be achievable.

9 Final design and components

This chapter presents the detailed mechanical design of the TEE system and will elaborate on challenges related to the product goals. It will start with presenting the system in its entirety (figure 62), and thereafter separate the main components into smaller segments. These segments will be discussed in further detail. Finally, the connection between the actuation unit and probe maneuverability will be illustrated.

Figure 62: Complete TEE system inserted into patient.

9.1 Complete TEE System

The final concept emphasizes on well-established mechanical principles in order to make the system predictable and reliable. Figure 63 present the different components of the TEE system.

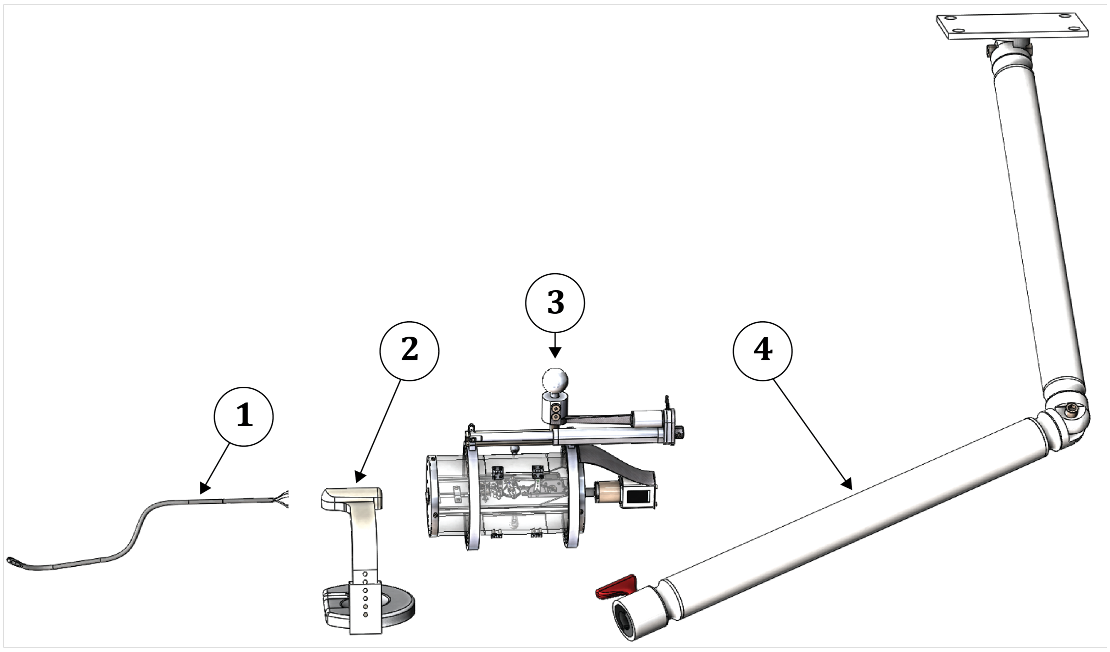


Figure 63: Exploded complete TEE system.
1: Endoscope, 2: Endoscope guide, 3: Actuation unit, 4: Roof anchor.

Table 22: List of main components.

Component number	Component name	Comment
1	Endoscope	Subchapter 9.2: Endoscope
2	Endoscope guide	Subchapter 9.5: Additional parts
2	Actuation unit	Subchapter 9.3: Actuation unit
3	System anchor	Subchapter 9.4: System anchor

The content of table 22 will be described in further detail in the following chapters, laying out the different parts making up all the components.

9.2 Endoscope

There are numerous requirements to the endoscope. The existing TEE probes satisfy these requirements and will also be adaptable to the system design in this report. This has been an inspiration for the work conducted in this project. The final distal end is composed of 6 distinct elements (figure 64).

The endoscope should be made out of PVC Shore 60, making it flexible yet stiff enough to operate with a 1:1 actuation ratio between the actuation unit and probe housing while avoiding kink. It will also be able to withstand acidic environments and disinfection processes. Multi lumen channels will be used in order to translate movement. This material also enables treatment so that the product is free of sharp edges.

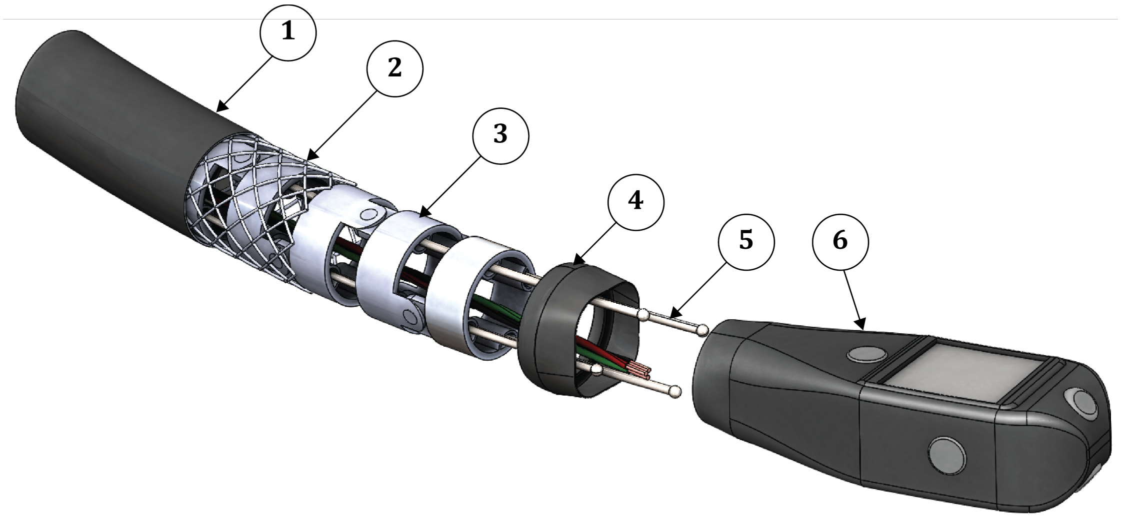


Figure 64: Dissected complete distal end.
1: Soft rubber hose covering distal end, 2: Nitinol hose, 3: Flex mechanism, 4: Sealant between distal end and probe housing, 5: Force transmission wires, 6: Probe housing.

Probe housing

The design of the probe housing allows for sensor implementation (figure 65). It has a geometric shape that complies to medical standards in terms of hidden surfaces and sharp edges. Its size enables it to pass through the pharyngo-esophageal constriction.

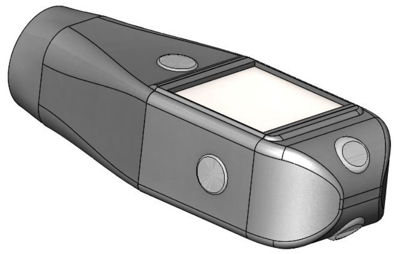


Figure 65: Probe housing.

Flex concept

Through the concept screening process, it was determined that the distal end of this TEE system will consist of a rigid body pin-linked mechanism that allows manipulation in space (figure 66). The concept is similar to the solution implemented into commercially available endoscopes but will now be controlled by electric actuation and mechanical transmission through wires. This is further discussed at the end of this chapter.

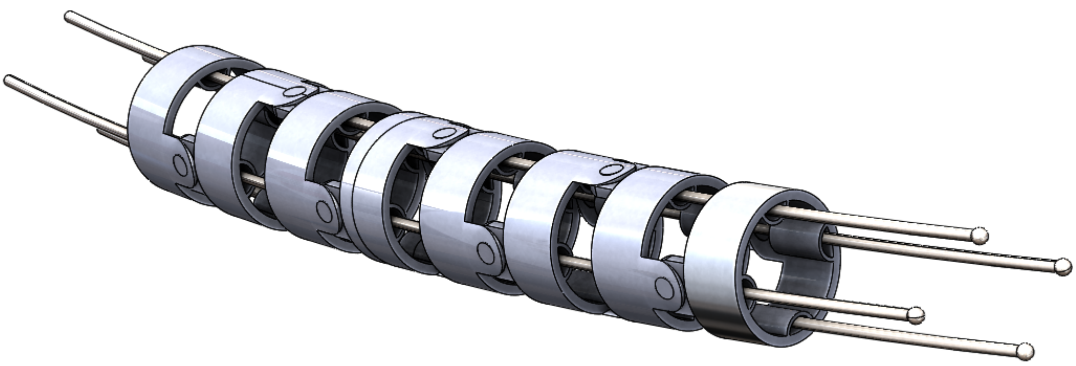


Figure 66: Rigid bodies linked by pins.

Nitinol hose

The nitinol hose is used to make the manipulation of the distal end easier and provide a solid structure. By having actuators apply a constant stress to the part, it will deform to the desired position. When the stress is relieved it will retain its parent position (figure 67). The nitinol hose will make the distal end behave differently than the rest of the endoscope.

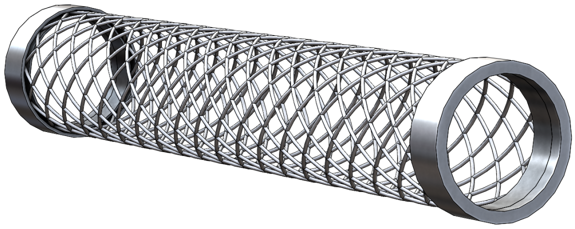


Figure 67: Nitinol hose.

9.3 Actuation unit

The metric specifications imposed by the heart and the esophagus must be assessed in order to facilitate sufficient maneuverability. The actuation unit contains all the components necessary to make the distal end flex, rotate and elongate around the heart (figure 68). It's different components will be presented hereafter.

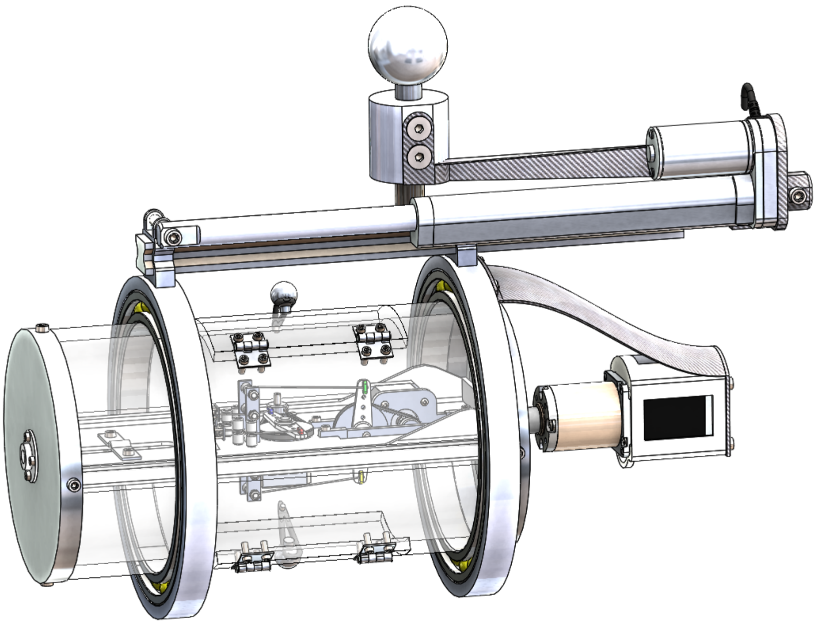


Figure 68: Complete actuation unit.

The final design of the actuation unit is composed by an actuation plate contained in a rotating cylinder (figure 69-1 and 2). This cylinder has an outer diameter of 190 mm. It is rotated by a stepper motor, and mounted to ball bearings allowing it to turn without any friction (figure 69-4 and 6). This part of the system is in its entirety put to motion by a linear actuator (figure 69-3). These components collectively enable the system to navigate the esophagus, and generate all ultrasound projections necessary to conduct a comprehensive transesophageal echocardiography examination.

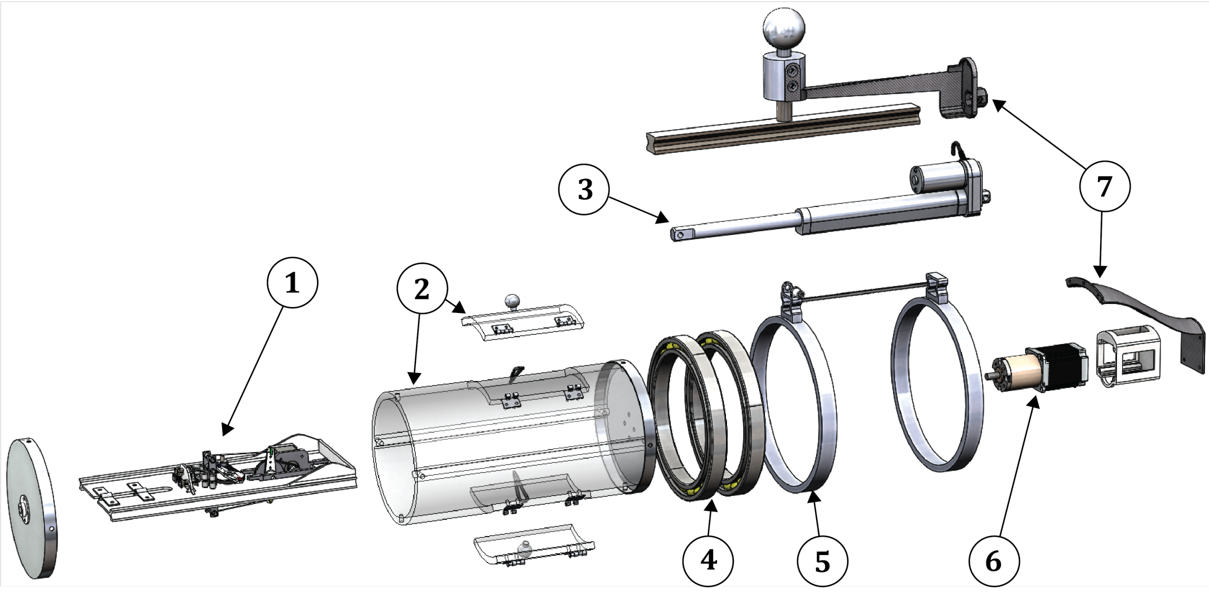


Figure 69: Exploded view of actuation unit.
1: Actuation plate, 2: rotating cylinder housing with hatches, 3: linear actuator, 4: ball bearings, 5: cylinder mount, 6: stepper motor with gearbox, 7: mounting brackets.

The actuating plate is the core of the concept (figure 70). This component contains two electrical motors enabling the distal end to flex in two axes. The top side of the component guides wires for anteflex and left and right flexion. The bottom guides the wire providing retroflex.

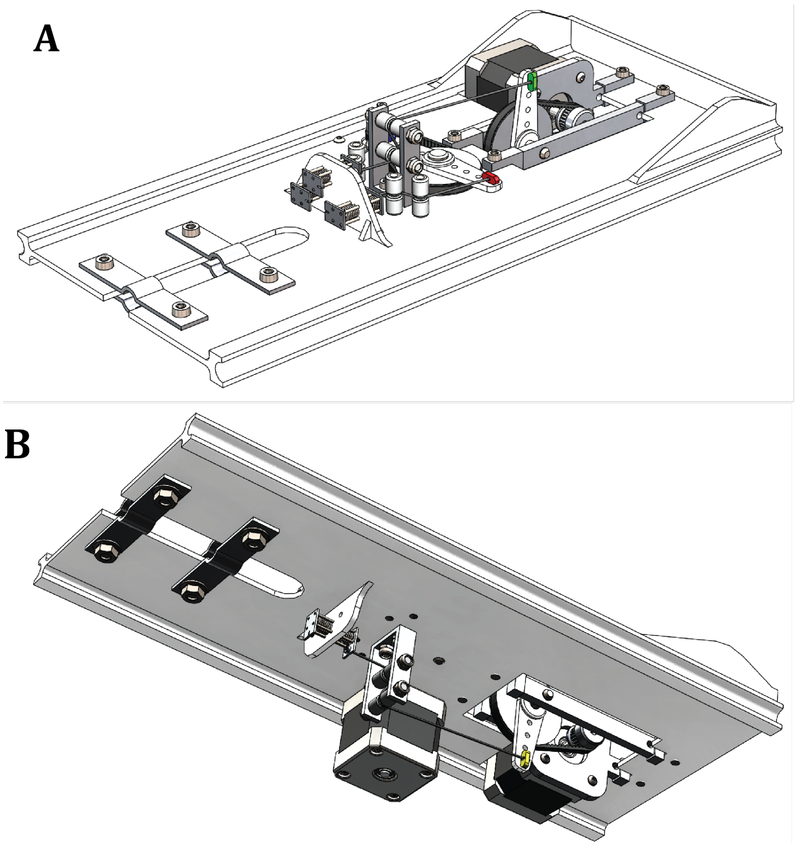


Figure 70: Actuating plate.
(A) *Top side of actuating plate.* ***(B)*** *Bottom side of actuating plate.*

Figure 71 illustrates the wire transmission system.

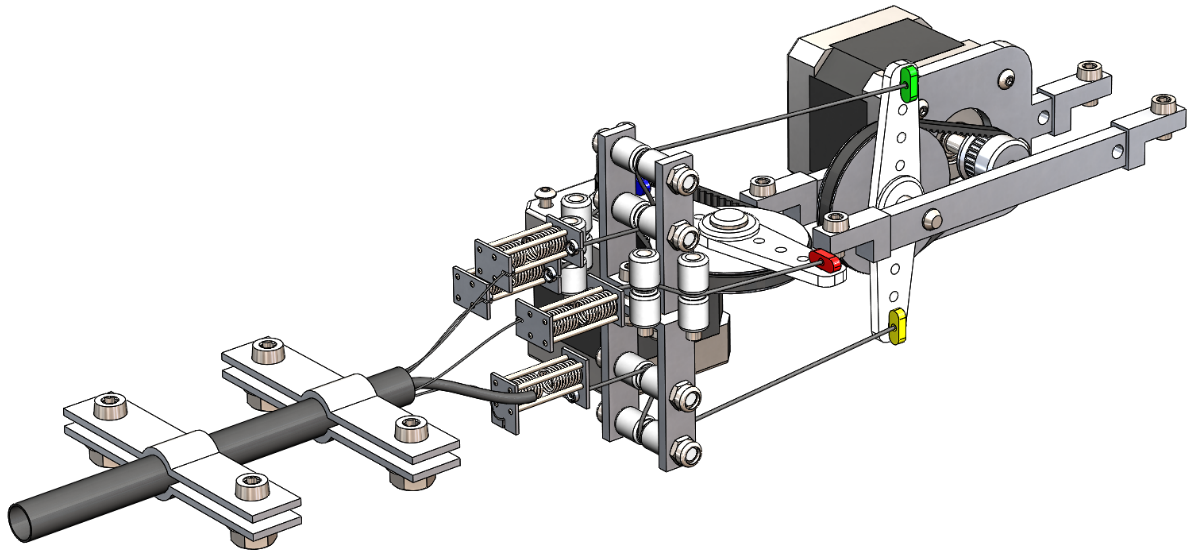


Figure 71: Complete wire transmission system.

9.3.1 Connecting endoscope to actuation unit

In order to disinfect the endoscope between each use, two main accommodations have been made. First, latches have been implemented to the actuation housing, enabling echocardiographers to access the interior of the actuation unit (further elaborated in chapter 9.6.5 - Maintenance). Second, endoscope brackets have been implemented to allow for quick connection of the force transmission wires and support of the endoscope(figure 72-A).

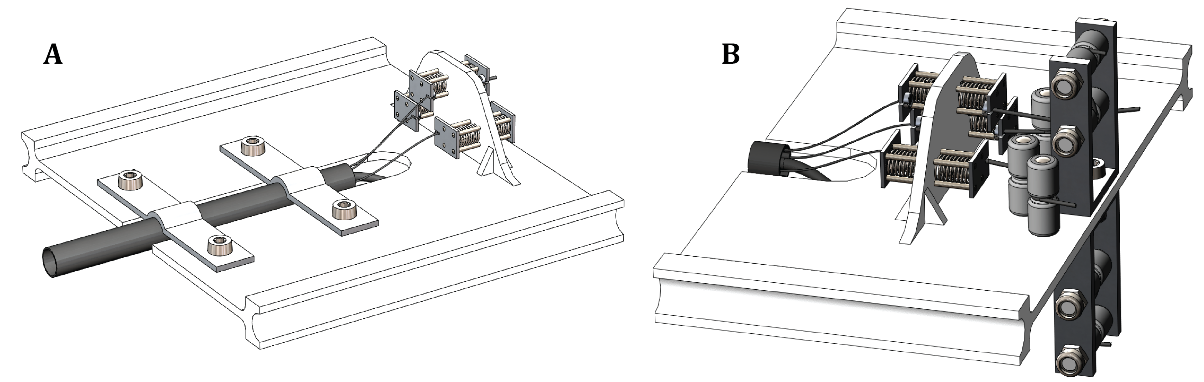


Figure 72: Connection for force transmission wires.
(A) *Endoscope mounting brackets and endoscope force transmission wire connection.* ***(B)*** *Back side of wire mounting bracket. System force transmission wires are led through wire guides.*

The second bracket have springs on each side, connected by pins going through the wall. These pins contain anchor points for the force transmission wires (figure 72-B). When the wires are pulled, corresponding compression and decompression of the springs causes an even movement while eliminating potential slack. Their common objective is to connect the system's and the endoscope's force transmission wires.

9.3.2 Flex movement

The four flex movements will be facilitated through electrical motors mounted to the plate in the actuation unit. The force transmission wires are connected to an arm pivoting around a centered point, which provides the necessary correlation between the pull and push to achieve a satisfactory movement of the distal end (figure 73 and 74). This will be elaborated further in chapter 9.6 - Final design function.

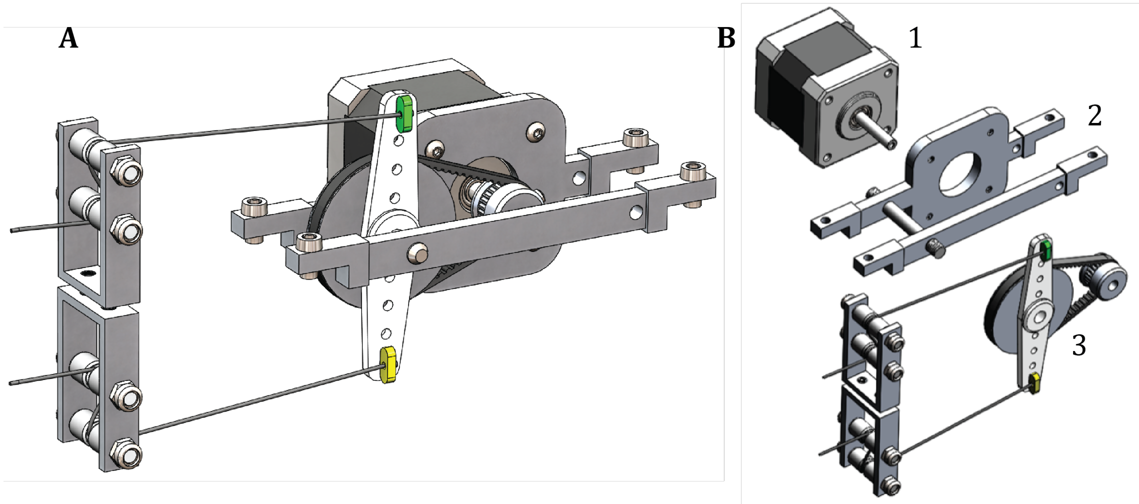


Figure 73: Anteflex and retroflex actuation.
(A) *Stepper motor providing anteflex and retroflex.* ***(B)*** *1: Stepper motor, 2: mounting bracket, 3: pivoting arm connected to pulley and wire.*

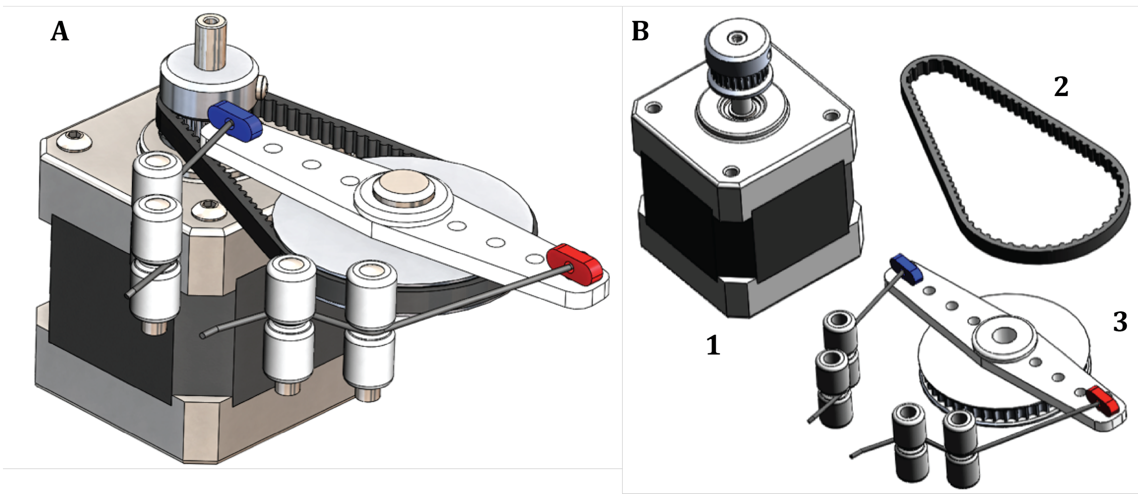


Figure 74: Left and right flexion actuation.
(A) *Stepper motor providing left and right flexion.* ***(B)*** *1: Stepper motor, 2: pulley, 3: pivoting arm connected to wires.*

Motor specifications:
Name: Nema 17 Bipolar Stepper
Step angle: 1,8°
Holding torque: 40 Ncm

9.3.3 Rotation

On the rear side of the actuating cylinder a stepper motor and gearbox will be mounted to a bracket fixed to the bearing housing (figure 75). This motor will provide the system with an accurate rotation and will enable regulation control through step-count. By implementing a gearbox to the motor's shaft, the motor will be able to supply enough torque to easily manipulate the actuation cylinder. The chosen motor comes with a planetary gearbox that make it a suitable choice for high torque and low speed applications.

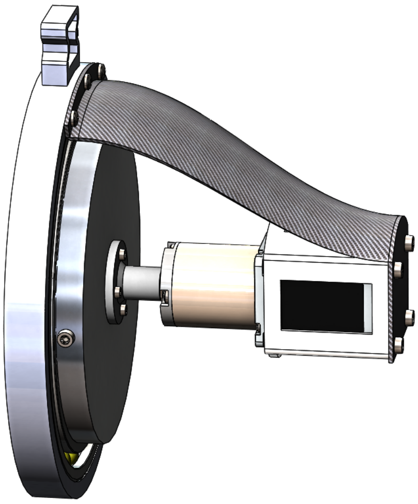


Figure 75: Stepper motor and gearbox provide rotation to the system.

Motor and gearbox specifications:
Name: Nema 23 Bipolar Stepper
Step angle: 1,8°
Holding torque: 103 Ncm
Gearbox ratio: 50: 1

The combination of this motor and gearbox provides a step angle of 0,036°, with 10 000 steps per revolution. This will result in a highly accurate system with possibilities of regulation control through step-count. The ratio of the gearbox can easily be brought down to 20:1, and still provide sufficient resolution. A further investigation of this will be suggested in the future directions.

9.3.4 Elongation

The linear actuator is elongating the system (figure 76). It is attached to the spherical joint through a bracket (1). The elongating shaft (2) of the actuator is connected to one of the ball bearing housings (3), where an arm ensures corresponding movement between the two housings sliding back and forth on a railing. For further improvements, the surface tolerances on the sliding rail should be taken into consideration.

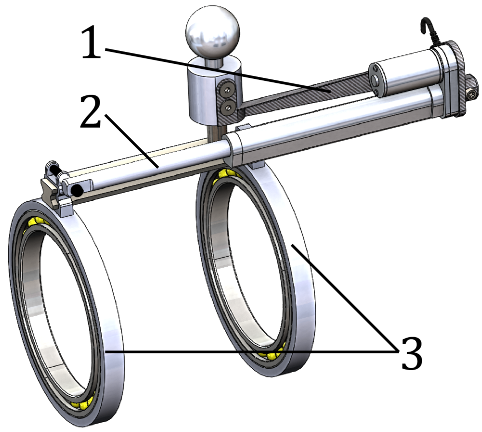


Figure 76: Linear actuator providing elongation. *Bracket ensuring stable movement between the two ball bearing housings is not visible.*

Actuator specifications:
Name: Transmotec DLA-300-IP65
Dynamic force: $200 - 1200\ N$
Speed: $5 - 35\ mm/s$
Stroke length: $50 - 300\ mm$

The linear actuator might be oversized with regard to force output. The component included in this design has been chosen mainly because of its adequate stroke length. A more detailed investigation will be suggested as future direction.

9.4 System anchor

To ensure the best possible patient approach for the system, a spherical joint has been implemented to the anchor system in addition to the two one-axis rotating joints (figure 77). This will enable the system to adapt to equipment and medical team present in the operating theatre.

Figure 77: Complete system anchor

9.4.1 Rotating and spherical joint

Calculations were made in order to ensure the friction between the joints being sufficient (see chapter 10). As an additional safety feature, geometric patterns locking the positions of the one-way joints have been implemented (figure 78-A).

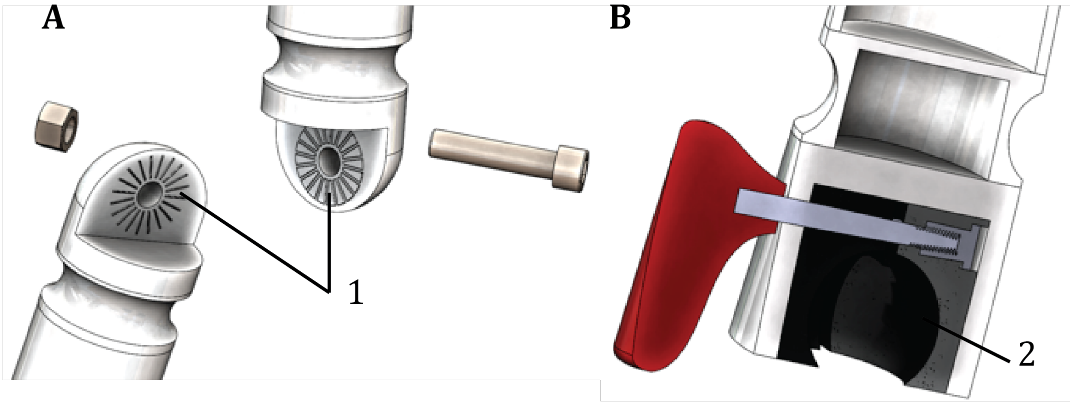


Figure 78: Joints in the system anchor.
(A) *One way joint. 1: Patterns to ensure sufficient friction.* ***(B)*** *Spherical joint. 2: A break shoe will provide sufficient friction to hold the rotating ball in place.*

The spherical connection between the anchor system and the actuation unit enables the echocardiographer to finely adjust the systems approach to the patient (figure 78-B). This component includes a high friction breaking shoe (figure 78-B2) holding the actuation unit in place once the handle is tightened.

9.5 Additional components

Some changes have been made to the endoscope guide during the detail design process in order to improve the entry angle to the pharyngoesophageal constriction. In addition, a complementary mouthpiece has been designed to aid insertion and prevent friction.

9.5.1 Endoscope guide

The endoscope guide has been complemented by a headrest, ensuring a convenient angle of the esophagus while inserting the TEE probe. In addition, this component will support the endoscope in order to prevent kink.

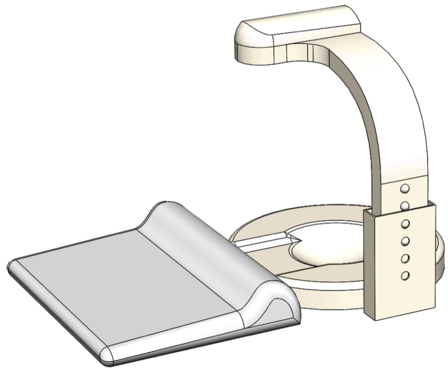


Figure 79: Endoscope guide.

9.5.2 Mouthpiece with tube

A mouthpiece attached to a flexible tube will aid the insertion of the TEE probe and eliminate some of the friction the upper part of the esophagus is subjected to. The tubing should not enter the upper thoracic esophagus to avoid interfering with the probe function. The tube must be manufactured in a material that withstands disinfection processes.

Figure 80: Mouthpiece and tube.

9.6 Final design functions

This chapter illustrates the connection between the actuation unit and the distal end maneuverability. A video on supplementary USB-drive is providing an additional illustration.

9.6.1 Anteflex and retroflex

The stepper motor actuates on an arm rotating around a set point (figure 81-B). This arm ensures the correlation between the push and pull of the force transmission wires. This movement translates through the wires and into an anteflex and retroflex manipulation of the TEE probe (figure 81-A).

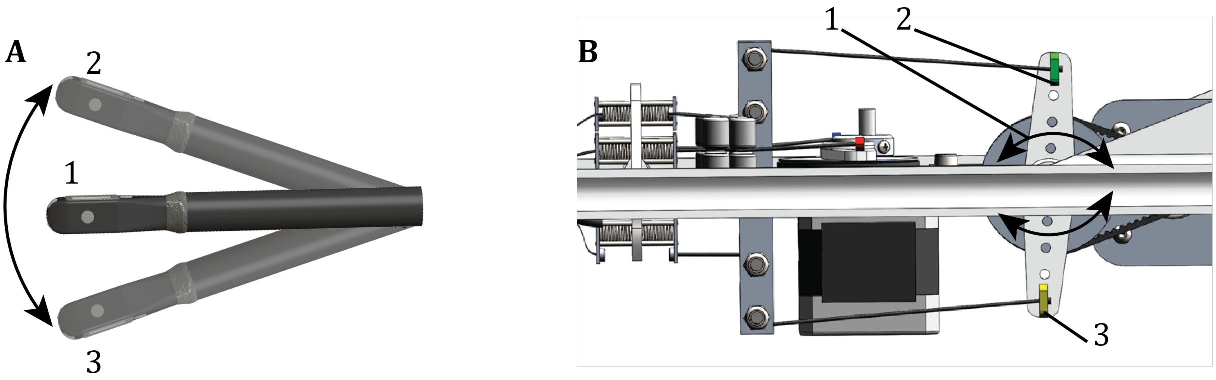


Figure 81: Illustration of anteflex and retroflex function.
(A) Probe movement. 1: Neutral position, 2: Anteflexed, 3: Retroflexed. ***(B)*** *Wire pull through electric actuation. 1: Rotation of arm around centerpoint, 2: Anteflex wire, 3: Retroflex wire.*

9.6.2 Left and right flexion

The stepper motor manipulates the pivoting arm (figure 82-B), and this translates through the force transmission wires controlling the left and right flexion of the TEE probe (figure 82-A).

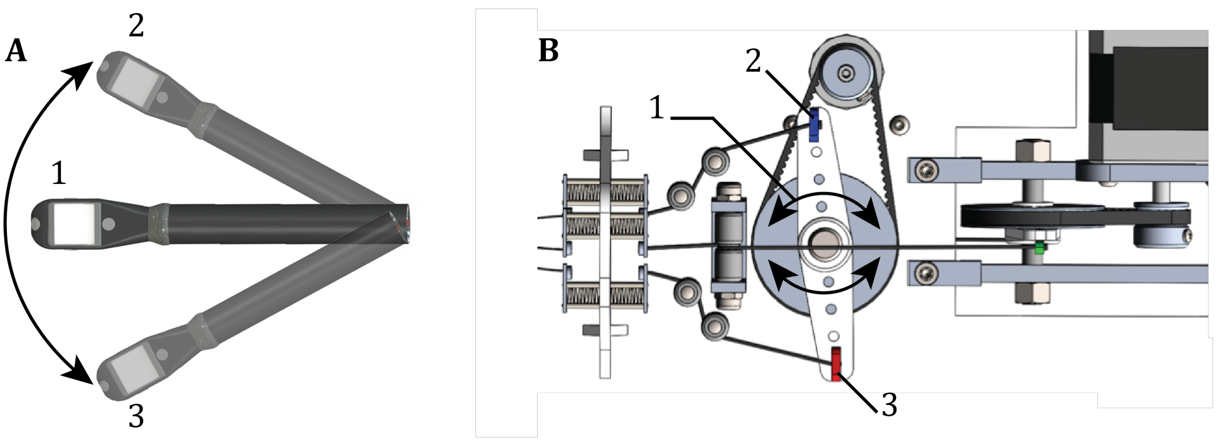


Figure 82: Illustration of left and right flexion function.
(A) Probe movement. 1: Neutral position, 2: Right flexion, 3: Left flexion. ***(B)*** *Wire pull through electric actuation. 1: Rotation of arm around centerpoint, 2: Right flex wire, 3: Left flex wire.*

9.6.3 Elongation

The linear actuator manipulates the TEE probe by advancing and withdrawing the whole actuation unit (figure 83-B). This translates into an equal motion in the distal end (figure 83-A).

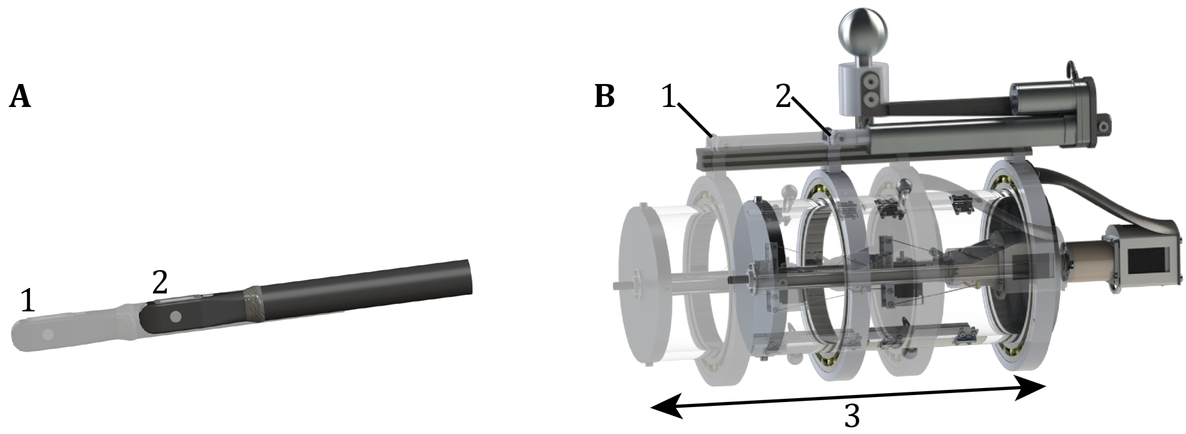


Figure 83: Illustration of elongation function.
(A) *Probe movement. 1: Fully elongated, 2: Initial position.* ***(B)*** *Linear actuator manipulating actuation unit. 1: Fully elongated, 2: Initial position, 3: Max elongation = 300 mm.*

9.6.4 Rotation

The stepper motor rotates the actuation unit through a gearbox (figure 84-B). Through a endoscope allowing a 1:1 relation, the mechanical output from the gearbox translates into an equal rotation at the distal end of the endoscope (figure 84-A).

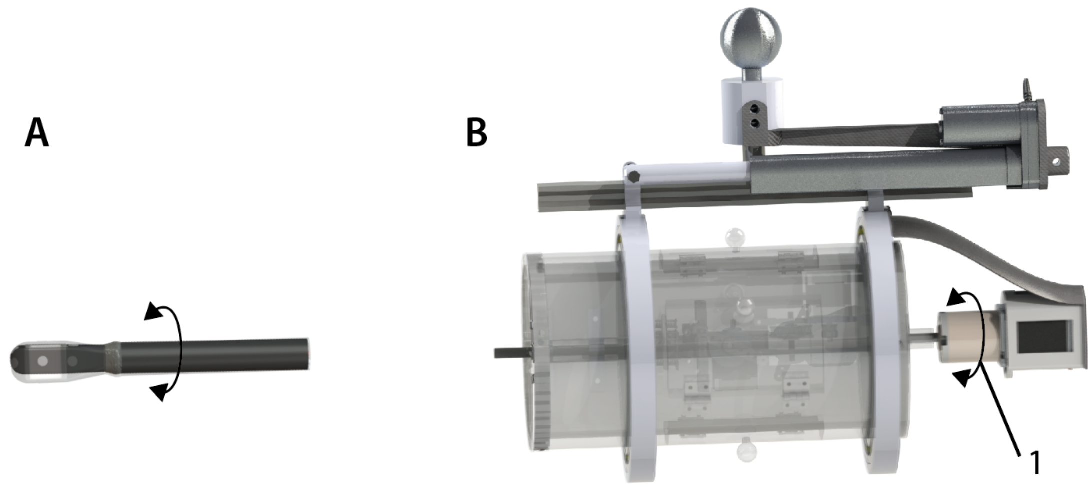


Figure 84: Illustration of rotation function.
(A) *Probe movement.* ***(B)*** *Stepper motor manipulating actuation unit. 1: Rotation around the motor's shaft.*

9.6.5 Maintenance

This design function is implemented make the final product comply to ISO 17664:2017 – Processing of health care products. This standard sets clear regulations on how to process the endoscope in terms of treatment at the point of use, preparation before cleaning, cleaning, disinfection, drying, inspection and maintenance.

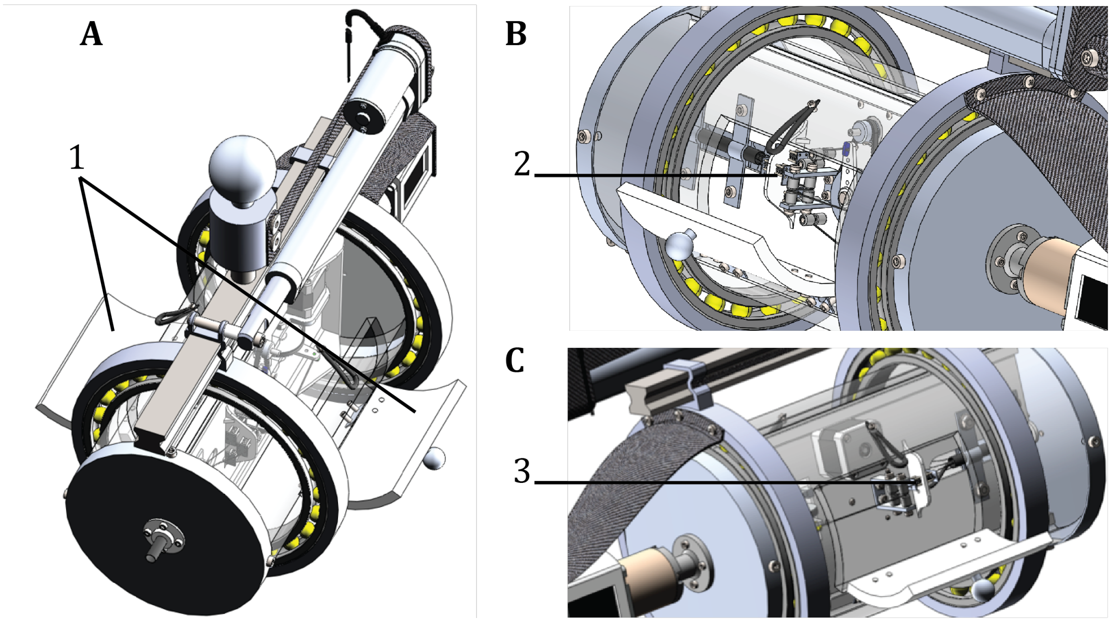


Figure 85: Enabling of probe disinfection.
(A) *Complete TEE actuation unit in maintenance position, 1: Open hatches.* ***(B)*** *Top of actuation plate, 2: Disconnection of anteflex, and left and right flexion.* ***(C)*** *Bottom of actuation plate, 3: Disconnection of retroflex.*

In order to sterilize or disinfect the endoscope, the TEE system should be able to achieve a preset maintenance position (figure 85-A). The echocardiographer can then access the inside of the unit to disconnect the force transmission wires (figure 85-B and C). To ensure correct reassembly the wires should be color coded (figure 86-1).

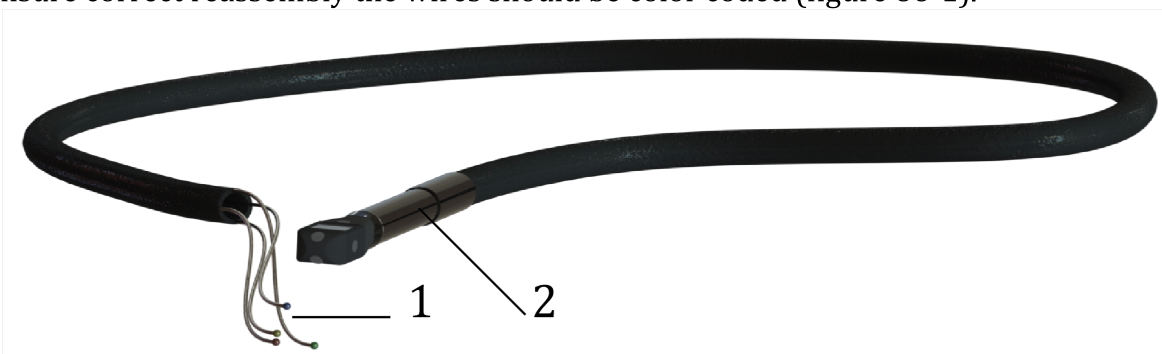
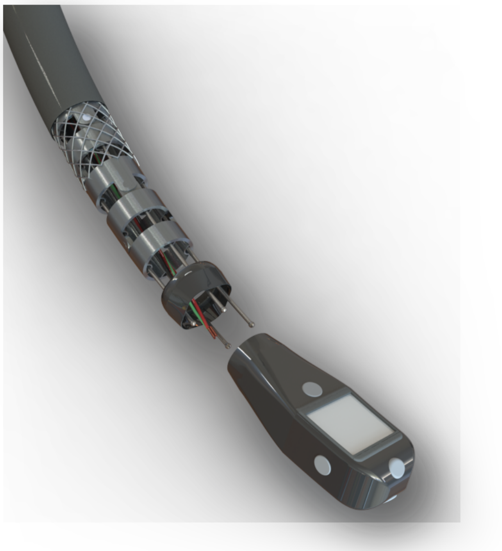


Figure 86: Disconnected TEE endoscope.
1: Color coded force transmission wires, 2: Surfaces of distal end.

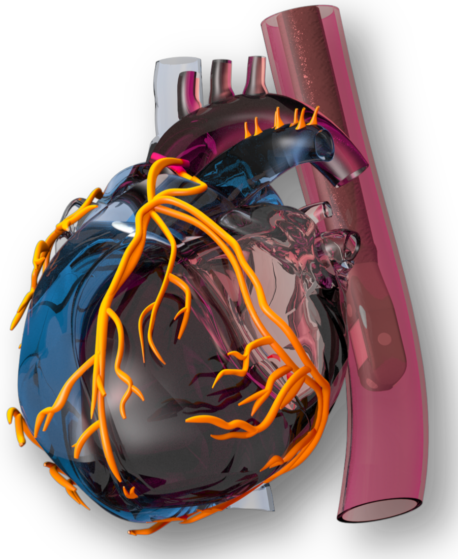
To comply with ISO 14971:2012 in terms of risk assessment, the distal end must not have any hidden surfaces where it connects to the endoscope (figure 86-2).

9.7 Presentation

A



B



C

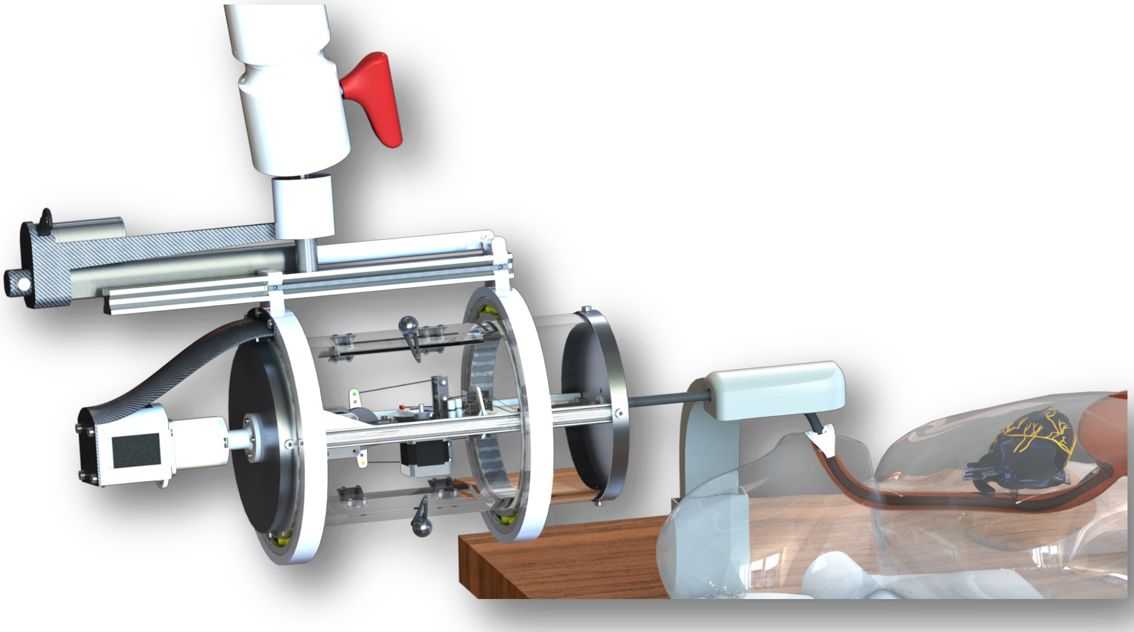


Figure 87: ***(A)*** *Distal end.* ***(B)*** *Probe inside of the esophagus.* ***(C)*** *The system in relation to the patient.*

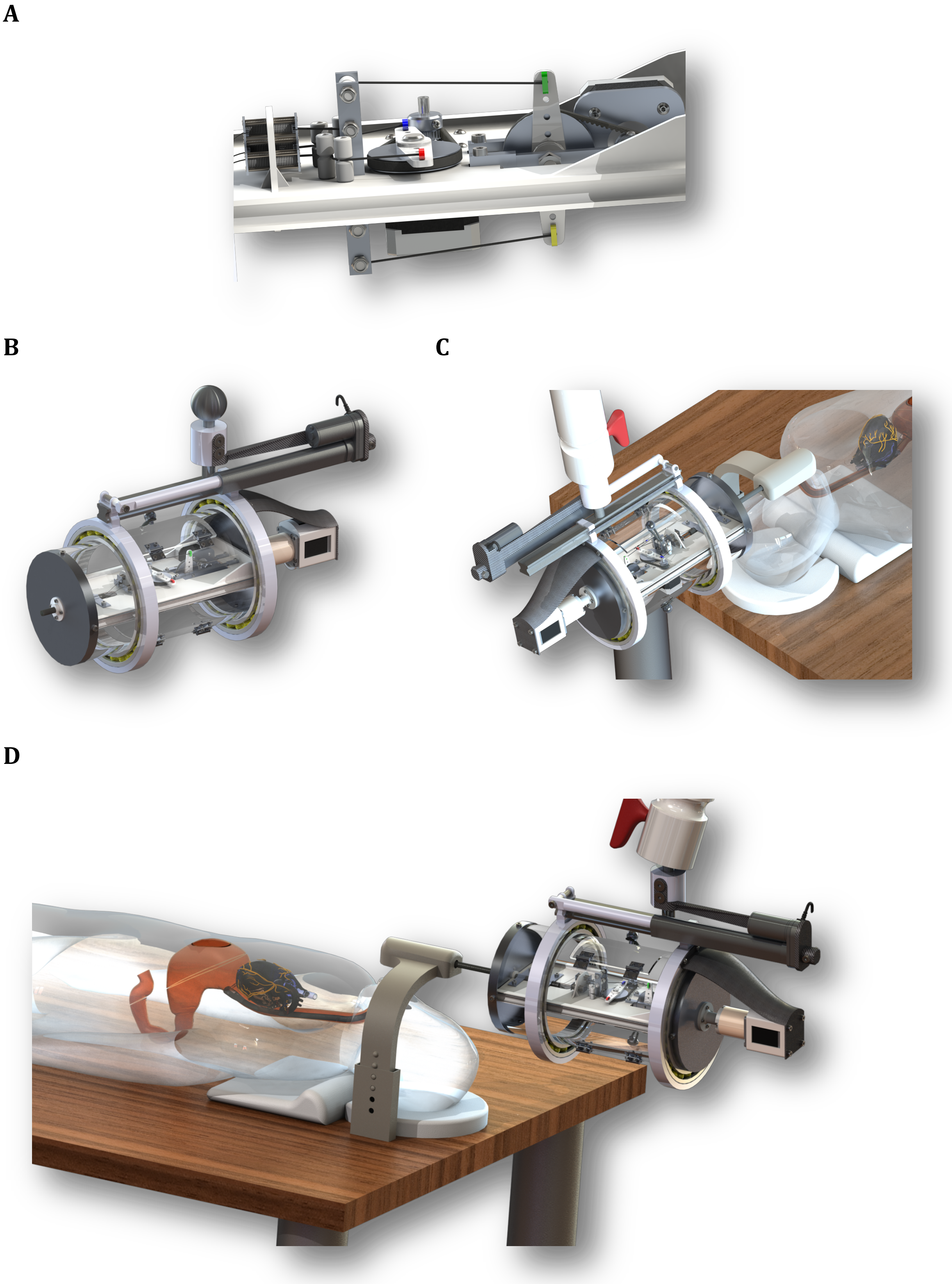


Figure 88: ***(A)*** *Actuating plate.* ***(B)*** *Actuation unit.* ***(C)*** *System from above.* ***(D)*** *Left side view of the system.*

10 Calculations

Calculations have been made regarding the robustness of the roof anchor arm.

10.1 Roof anchor connection

The revolute joint connecting the two anchor arms is supposed to be adjustable between operations, however, during procedures any movement could eventually cause disastrous outcomes. The only thing keeping the system at rest is the friction between the circular profiles caused by the preloaded bolt. In the final design, the bolt diameter is set to 12mm. As this is the most critical area of the structure, a worst-case scenario with a 90-degree angle between the arms (figure 89) is calculated below with respect to the diameter of the bolt.

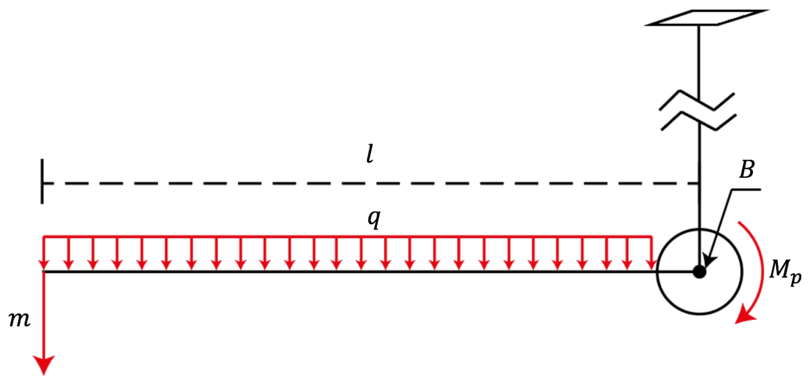


Figure 89: Load scenario where the angle between the two anchor arms is 90 degrees.
l: length of the arm, m: mass of the actuating unit, q: the weight of the arm, M_p: moment caused by the preloaded bolt and friction, B: bolt (point). Illustration is not in real size.

The following masses and lengths correspond to the final design of the complete system where the density and volume of the profiles have been accounted for: The total mass of the actuation unit is set to 10 kg, where the heaviest objects are the bearings, the linear actuator, and the different brackets. The total length of the arm is $1000mm$, and the weight of the arm is set to 3 kg, approximated equals to 0.03 N/mm.

To ensure that the system remains static after the bolt is preloaded, the sum of the moments about the revolute joint have to equal zero.

$$\sum_{\leftarrow}^{\rightarrow} M_B = 0 \tag{10.1.1}$$

$$M_p - \frac{q \cdot l^2}{2} - m \cdot g \cdot l = 0 \tag{10.1.2}$$

$$M_p = \frac{0{,}03 \cdot 1000^2}{2} + 10 \cdot 9{,}81 \cdot 1000 = 113100Nmm \tag{10.1.3}$$

The friction between the two circular profiles caused by the preloaded bolt has to overcome a total moment of 113.1 $kNmm$.

In order to calculate the moment caused by friction, some assumptions have been made (figure 90). The center of gravity in relation to the friction force is set to two-thirds of the radius. This is based on the estimation that the circle could be split into an infinite number of small triangles if neglecting the area of the bolt, and the fact the centroid of a right triangle is located at one-thirds of the length of the legs pointing away from the right angle.

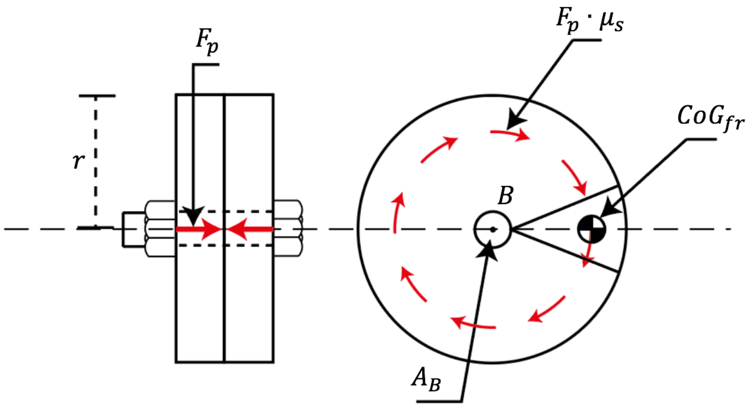


Figure 90: Representation of bolt connecting the circular profiles of the one-way joints.
$\boldsymbol{r}$: radius of the circle, $\boldsymbol{F_p}$: The force caused by the preloading, $\boldsymbol{F_p \cdot \mu_s}$: static friction force, $\boldsymbol{CoG_{fr}}$: center of gravity of the friction force. $\boldsymbol{A_B}$: area of the bolt, $\boldsymbol{B}$: bolt.

The formula of the relation between a friction force and its corresponding normal force is:

$$F_s = F_n \cdot \mu_s \tag{10.1.4}$$

Where $\mu_s$is the coefficient of friction depending on various variables, for instance, like the material of the two contact surfaces, the surface structures, or the surrounding temperature. According to figure 90, the following formula describes the moment caused by the friction.

$$M_p = \frac{2}{3} \cdot r \cdot F_p \cdot \mu_s \tag{10.1.5}$$

The radius of the circular connecting profiles is 50mm, and the coefficient of friction between two aluminum profiles is approximately 1.0. The minimum preload of the bolt to keep the system static is:

$$F_p = \frac{3}{2} \cdot \frac{M_p}{r \cdot \mu_s} = \frac{3}{2} \cdot \frac{113100}{50 \cdot 1{,}0} = 3393N \tag{10.1.6}$$

As the joint's angle is adjustable, the bolt has to be fastened manually. It is estimated that it is possible to preload the bolt with up to 15% of the ultimate tensile strength of the material. The formula below shows the minimum area of the bolt when considering the given estimations. A reasonable value of $400MPa$ is set as the ultimate strength of the bolt, which represent the physical property of a 4.6 bolt.

$$A = \frac{F_p}{0{,}15 \cdot \sigma_u} = \frac{3393}{0{,}15 \cdot 400} = 56{,}6mm^2 \tag{10.1.7}$$

Below is an estimation of the diameter of the bolt, which does not account for the type or properties of the threads.

$$A = \frac{\pi \cdot d^2}{4} \rightarrow \; d = \sqrt{\frac{4 \cdot A}{\pi}} = \sqrt{\frac{4 \cdot 188}{\pi}} = 8{,}5mm \tag{10.1.8}$$

To improve the friction, grooves can be implemented on the connecting surfaces (figure 78-A). Rubber surfaces would also increase the friction. However, the calculations show that the M12 bolt chosen in the structure is sufficient.

11 Simulation

To thoroughly document the final concept, and to get a better grasp of the ideas surrounding the functions, a simulation has been made. This will contribute to the implementation of system feedback control in the future development of this product. Calculations have been made on forward kinematics for further development of the simulation, see Appendix D.

11.1 Simulation setup

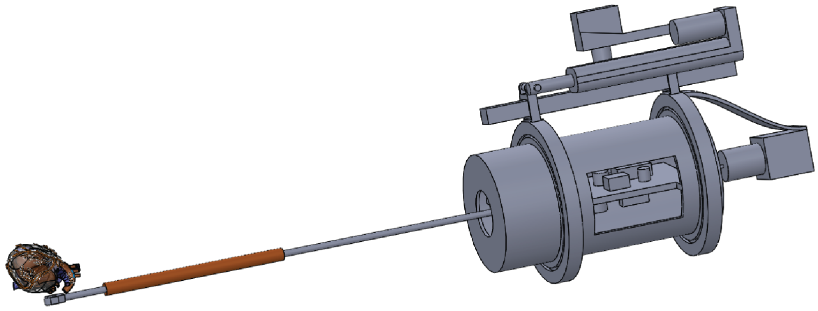


Figure 91: Complete Simulink model.

A simplified model with 4 DOF was made in SolidWorks and imported into Simulink trough the add-in; SimMechanics (figure 91). These mechanical properties of the model are presented in a block-diagram. It has since gone through several steps to enable joystick manipulation and the final result is shown in the figure 92, and Appendix E.

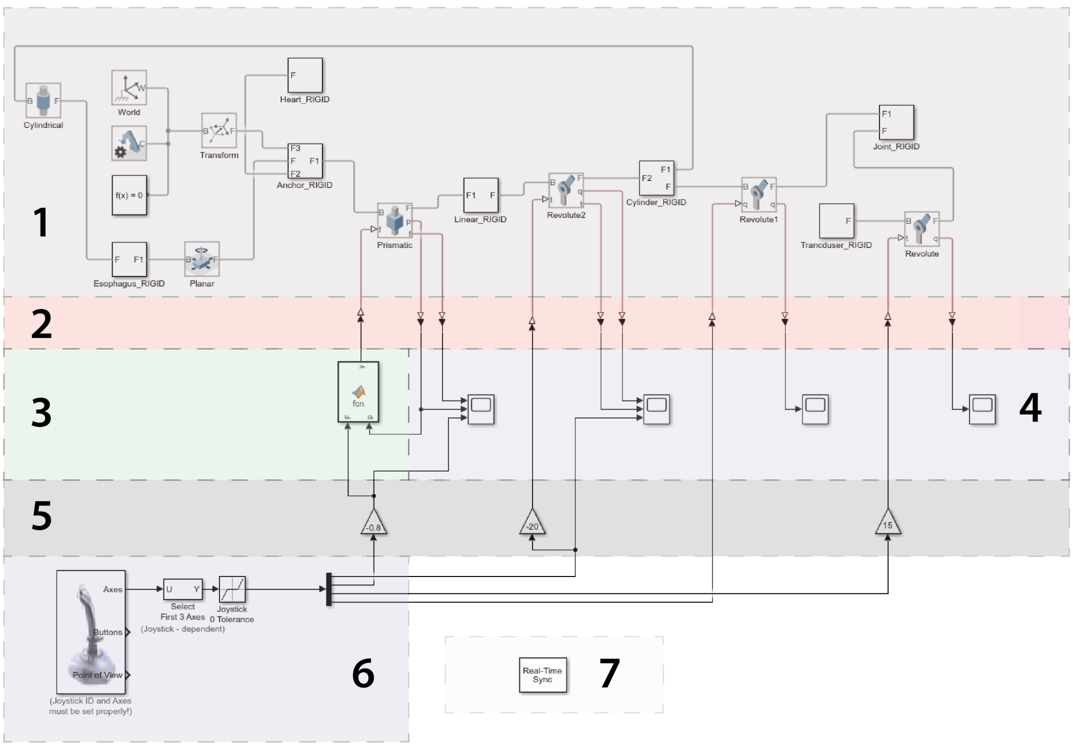


Figure 92: Simulink scheme.
1: Physical model, 2: Simulink-PS/PS-Simulink blocks (physical signals), 3: Regulator, 4: Scopes, 5: Calibration, 6: Joystick inputs, 7: Real-Time Sync. See next page for further elaboration.

The upper section of the system (figure 92-1) shows the physical model as it was imported from SolidWorks. The model contains different parts and joints for movement. The prismatic joint and the three revolute joints in this section have several inputs and outputs, and has been the main focus of interest since they control the desired motions of the system. The two other joints in the first section can be discarded, as they represent the esophagus and the heart, which are both stationary.

The second section of the system (figure 92-2) shows several Simulink-PS (Physical signal)/PS-Simulink blocks that are needed to translate the inputs from the joystick to physical signals and backward, like AD/DA converters.

Section three (figure 92-3) shows a simple regulation which is connected to the input and the output of the prismatic joint, meaning the elongation function of the concept and its objective is to set boundary locations to the linear actuator. It reads the output position of the actuator and controls the input afterwards.

Section four (figure 92-4) shows the scopes reading output signals of the actuators; in this program one may receive position, velocity, acceleration, and force.

Section five and six (figure 92-5/6) shows the joystick block and some necessary functions in order to calibrate the input signals received by the joystick, that vary from 0-1 depending on the force applied, into meaningful physical signals to the different joints. The Real-Time sync block in section seven (figure 92-7) enables real-time synchronization between the input and the systems' output and allow for real-time movements in the mechanical window of Simulink (figure 93).

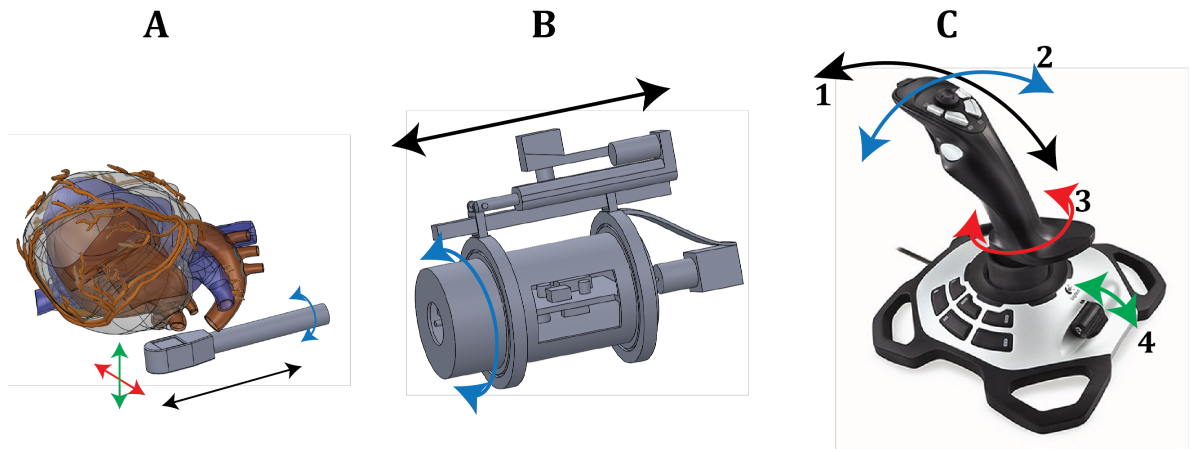


Figure 93: Joystick manipulation of the Simulink model.
(A) *Probe behind heart.* ***(B)*** *Simplified system model.* ***(C)*** *Joystick, 1: Elongation, 2: Rotation, 3: Left and right flexion, 4: Anteflex and retroflex. [36].*

11.2 Conducting the simulation

The simulation of the TEE system was first conducted at Gaustad, Oslo University Hospital (figure 94 and 95). A video of the simulation is attached as a file on the USB-drive complementing the report. This video contains a short walkthrough of how to manipulate the actuators through a joystick.

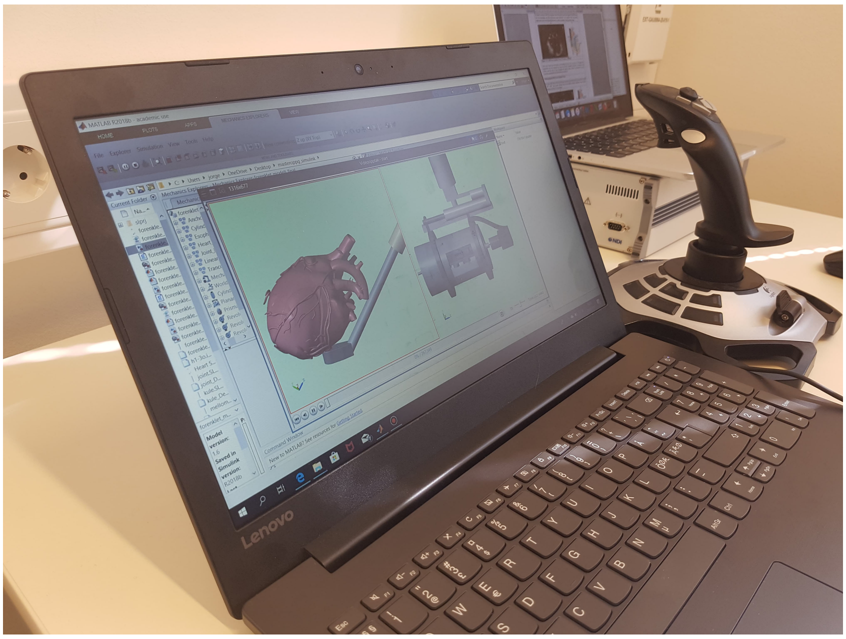


Figure 94: Setup of computer and joystick while conducting the simulation.

A

B

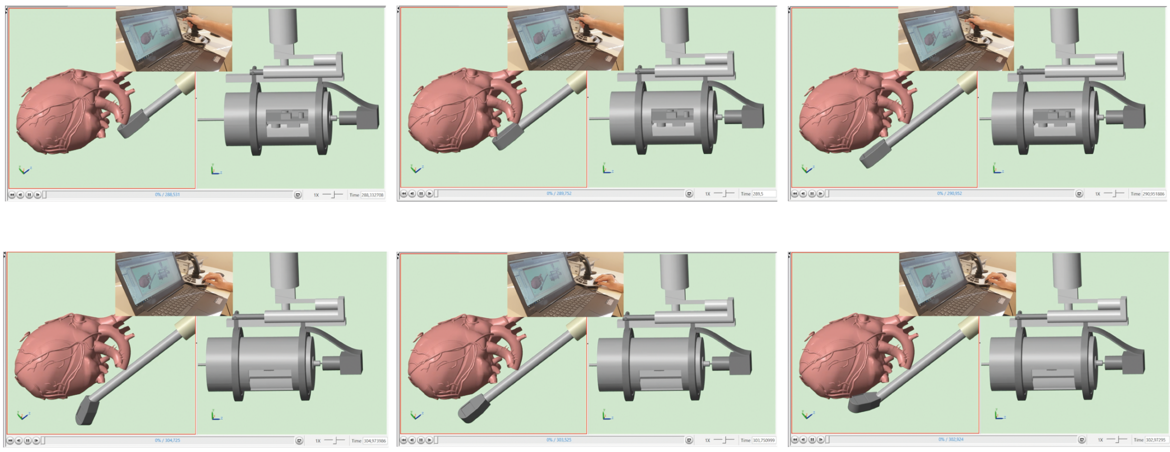


Figure 95: Step by step manipulation.
(A) *Advancing the probe through pushing the joystick forward.* ***(B)*** *From retroflex to anteflex by manipulating the throttle control on the joystick.*

12 Process evaluation and discussion

This chapter presents a discussion and evaluation of the project process.

Initiating phase

With the intent of dedicating our master thesis to medical technology, a preliminary study was written during our previous semester. This gave us some background in relation to heart pathophysiologies and minimally invasive cardiac surgery at the time this thesis started. Contact had already been established with Oslo University Hospital, which enabled us to witness conducting of mitral clip procedures. Without the prestudy, writing this project would have been difficult in terms of acquiring the necessary knowledge and insight. However, several questions remained at that time to fully comprehend the challenges related to implementing automated TEE in the operating theatre. In addition, even though the objective and framework of this theses were well defined, the project desgin had to account for future developments involving differet fields of expertise. This resulted in the initiating research phase being more time-consuming than what we first expected. There has been a focus upon using peer-reviewed scientific articles, rather than popular science sources, to ensure a high-quality of information. During this research phase, the reference list was built at The University of Oslo's medical library through books and publications related to medicine, medical technology and medical practice.

Early concept development

Development of medical equipment is often done under a confidentiality clause, and we were not able to access documentation on existing TEE probes. We therefore went through many iterations in the early concept. However, at a fare conducted at Oslo Metropolitan University we were able to inspect a dissected colonoscope. Examination of the functionality of this device proved helpful for the design of the solution.

Detailed concept development

Establishing contact with manufacturers like GE Healthcare and gaining insight to their product range has proven difficult. A meeting with the software team at GE was conducted in the beginning of April, however, we did not succeed in establishing contact with their mechanical department. This effort was made during the initial phase of the detail design. Having a more proactive approach towards this, and establishing contact at an earlier stage, would have most likely been time-saving for the early concept development. The existing TEE probes contain highly functional mechanical solutions, and being granted insight to these would have made the project more efficient.

During the detailed concept development, the majority of our resources was put into design thinking. Further development of the provisional system mock-up involved spending time CAD-modelling. This optimization was conducted at the expense of the report writing, which led us having to make up for the time in the evaluation and finalization phase.

Evaluation and finalizing

The solution in this report is still at an early conceptual stage. It will require complementing work from graduating master students for it to reach its final goal. We were committed to provide a well documented and structured report that would be useful for future students. Embarking on a complicated design with such a limited time frame set boundaries for the level of detail the final product can have. Limiting the scope to a smaller section of the project, enabling us to focus on one specific mechanical solutions, would have resulted in more details. However, it would not have provided a comprehensive basis for future work.

Nevertheless, the final product presented contains well established mechanical principles, and will be functional if developed further. We hope this thesis could be a keystone in the collaboration between NMBU and OUH for improvement of echocardiography procedures. In this perspective, it would be recommended to involve multiple disciplines of engineering due to the systems complexity. We strongly believe this product can have a high commercial and societal impact.

13 Conclusion and future directions

The main objective of this thesis has been to design a mechanical foundation for a future automated TEE concept. In addition, the solution was intended documented through a detailed report, a video showcasing the systems functions, and a simulation of maneuverability.

13.1 Result and recommendations

The result of this thesis is a concept where all mechanical functions required to obtain high quality ultrasound images are addressed. This concept also enables further work towards a fully automated product, and implementation of a remote joystick override control. The report documents the concept to a level of detail providing solid basis for future master students who will work towards the goal of a fully autonomous system.

<u>The following functions have been designed and implemented in the final concept:</u>

- A TEE system that can navigate through sufficient degrees of freedom, meeting all requirements for probe positioning:
    - Advance and withdraw by linear actuator
    - Rotation by stepper motor fitted with gearbox.
    - Anteflex/retroflex through use of stepper motor and wires.
    - Left and right flexion through use of stepper motor and wires.
- A system anchor that allows the TEE system to adapt to its surroundings and approach the patient in an appropriate manner:
    - Roof-anchoring.
    - Two arms with rotating joints allowing two-axis adjustment.
    - A spherical ball-joint allowing for three-dimensional adjustment.
    - An endoscope guide ensuring a good machine-to-patient approach.
- A TEE endoscope with correct surface requirements and material choice complying with medical standards in terms of cleaning:
- An endoscope and probe housing that meet required dimensions to avoid damaging the patient's soft tissues:
    - Endoscope diameter equals 10 mm.
    - Complete flex solution fits inside the endoscope.
    - Probe housing diameter less than 14 mm.
- All components in the design facilitate further work towards a fully automated system and joystick manipulation through:
    - A Simulink diagram allowing for further maneuverability studies.
    - Electrical components that allows for sensor control or step-count.
- The probe housing and actuation unit that facilitates implementation of sensors. Sensor technology will ensure safety features by monitoring:
    - Pressure.
    - Angular positioning.
    - Linear position.
    - Image recognition technology.

13.2 Future directions

In order to achieve a fully automated TEE system, the presented concept will require further development by several generations of graduating engineering students. The project would involve multidisciplinary approach including electrical engineering, automation engineering and software engineering. The mechanical functionality is well established, however, it requires detailed calculations before a prototype is made. The layout allows for easy adaptations in order to conduct further investigations of electrical motors and linear actuators, by simply changing parameters on the plate inside the actuation unit and brackets holding external actuators.

<u>Further directions should include:</u>

- Mechanical improvements:
  - Optimize the physical size of the actuation unit.
  - Further investigate the components that would allow the system to move frictionless.
  - Calculate forces applied to the transmission wires in order to reach the desired bending in the distal end.
  - Calculate the desired pull length in order to achieve optimal bending in the distal end.
- Detailed selection of electrical components:
  - Optimization of linear actuator in regard to power and size.
  - Optimization of angular actuators in regard to power and size.
- Further implementation of automation:
  - Detailed mapping of signals required to make the electric actuators behave properly.
  - Limit the maximum output of electrical components to enhance safety.
  - Determine the ideal sensors for the system in terms of precision, accuracy, revolution and linearity.
  - Determine what solutions that can be implemented in regard to biometric recognition and haptics. These are both highly desired by the project supervisors at Oslo University Hospital.
- Further improvement of simulation:
  - Incorporate sinusoidal signals to the simulation in order to simulate system disturbance related to heart beat and respiration.
  - Apply a more detailed environment to the simulation by incorporating a see-through esophagus.
- Develop a functional and informative interface.
  - Through the external survey, Echocardiographers at Oslo University Hospital expressed a desire to have an interface showing the current position and shape of the distal end.

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15 Appendixes

Appendix A – TEE: Essential Views

Appendix B – Project Schedule

Appendix C – Questionnaire for external expert survey

Appendix D – Calculations on forward kinematics

Appendix E – Figure 90: Simulink scheme.

Appendix F – USB-drive

Appendix A – TEE: Essential Views

Midesophageal (ME) Four-Chamber View

In order to achieve a ME four-chamber view the probe must be elongated 300-350 mm into the esophagus, and rotate the ultrasounda plane to 0° - 10° (Figure 9-B). The probe might need minor retroflex adjustments in order to produce a high quality image.

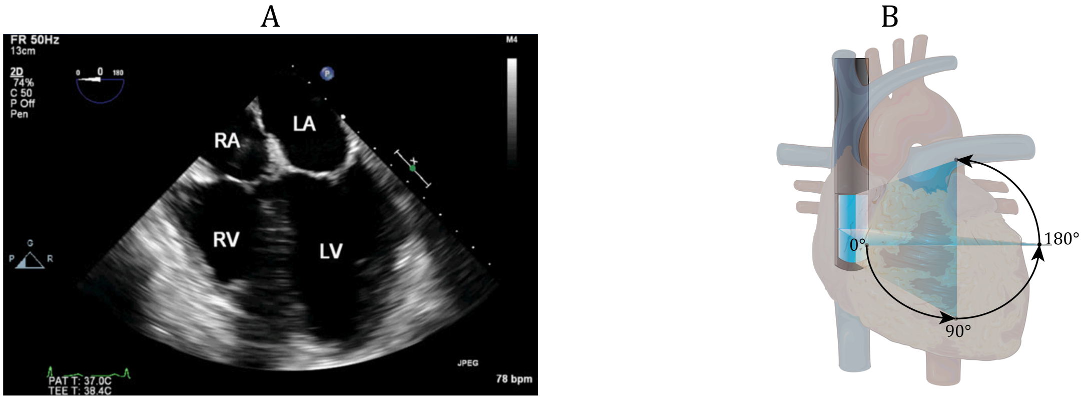


Figure 1: (A) *ME Four-Chamber View.* **(B)** *Position of probe.*

This view shows the RA, RV, LA and LV, in addition to the structures surrounding them. Through this projection one can evaluate the sizes of all four chambers, function of muscles and valves, and the size of the tricuspid and mitral valve, which is necesarry in post-operation preparation for MitralValve procedures.

Midesophageal (ME) Two-Chamber View

To reach a ME view of the two left heart chambers the ultrasound plane must be rotated to 80° - 100°. The probe should then be carefully rotated clockwise and counter-clockwise until the LV is revealed.

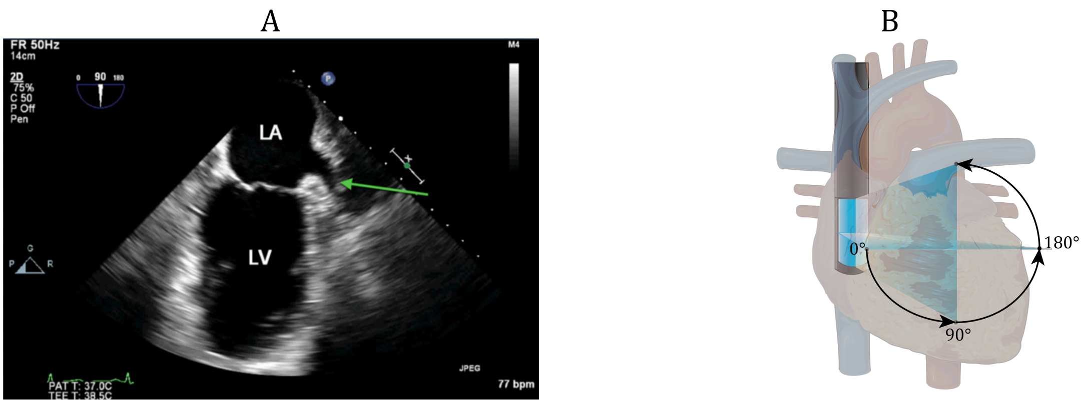


Figure 2: (A) *ME Two-Chamber View.* **(B)** *Positioning of probe.*

The projection shows the LA, LV, MV, LAA and left upper pulmonary vein. From this image the echocardiographer can determine MV motion and structure, and other irregularities located to the left section of the heart. Through color flow assesment one can evaluate the severity of mitral regurgitation.

Midesophageal (ME) Long-Axis View (LAX)
Moving on from the previously located ME two-chamber view, one can locate the ME LAX through rotating the ultrasound plane to 120° – 160°, depending on patients size.

A B

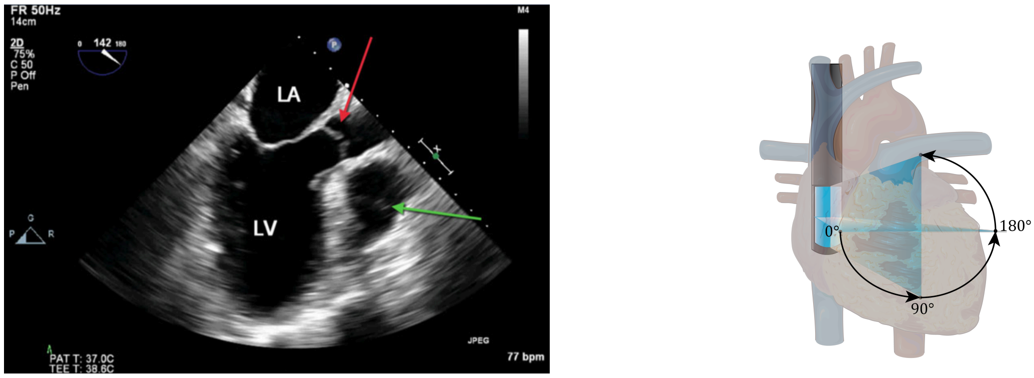


Figure 3: ME LAX ultrasound projection related to probe position.
(A) ME LAX projection, **(B)** Position of probe, adapted from [S3]. *Red arrow: aortic valve, green arrow: right ventricular outflow.*

The projection allows for a detailed size examination of the LV, LA, AV. One can also determine outflow from the LV and flow in the MV through color flow assesment.

Midesophageal (ME) Aortic Valve (AV) Short-Axis View (SAX)
Continouing from the ME LAX, the probe reaches the ME AV SAX through slowly withdrawing the probe, and then rotating the ultrasound plane back to 30°. One should now have a clear view of the AV.

A B

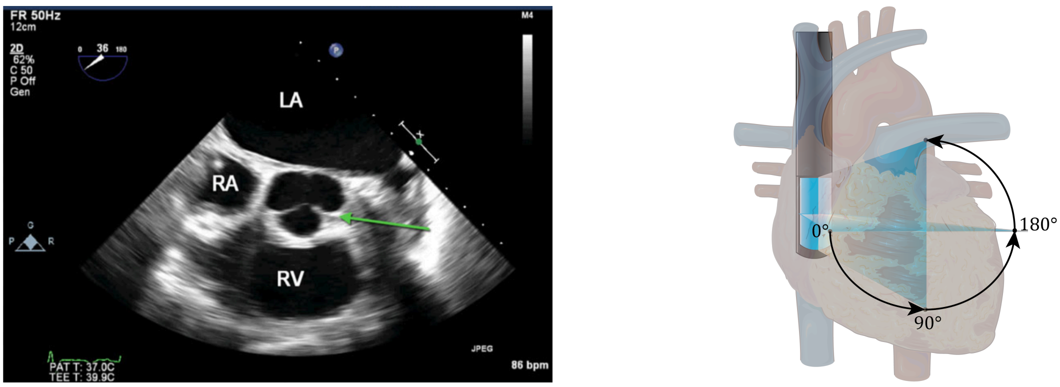


Figure 4: A: ME AV SAX, B: Position of probe. *Green arrow: The aortic valve.*

This projection allows for a detailed view of the aortic valve. The echocardiographer can assess its shape and size, degree of calcification and the mobility of its leaflets.

Midesophageal (ME) Aortic Valve (AV) Long-Axis View (LAX)

To achieve a ME AV LAX positioning of the probe, moving on from the SAX, rotate the ultrasound plane to 120° – 140°, and make a carefull clockwise turn of the probe.

A B

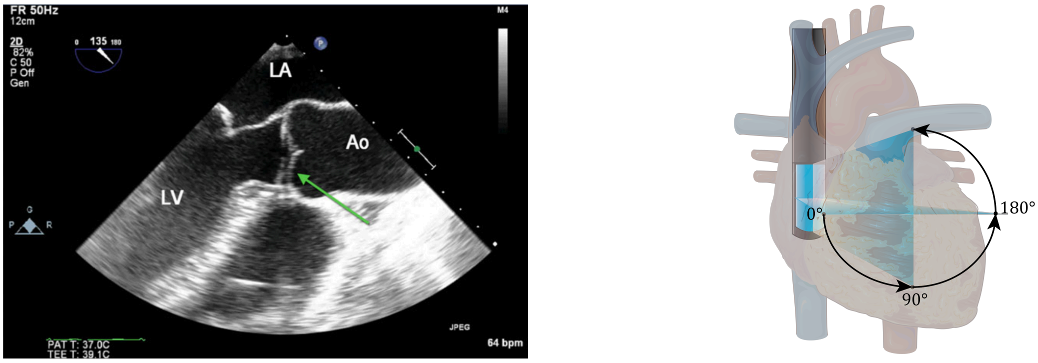


Figure 5: A: ME AV LAX, B: Position of probe. *Green arrow: Aortic Valve.*

This projection provides information regarding the function of the aortic valve, and the echocardiographer can determine if there is any aortic regurgitation occuring.

Midesophageal (ME) Right Ventricular (RV) Inflow-Outflow View

Starting from the ME AV SAX view, carefully turn the probe clockwise so that the RA and RV becomes visible. Rotate the ultrasound plane to 60° – 90°.

A B

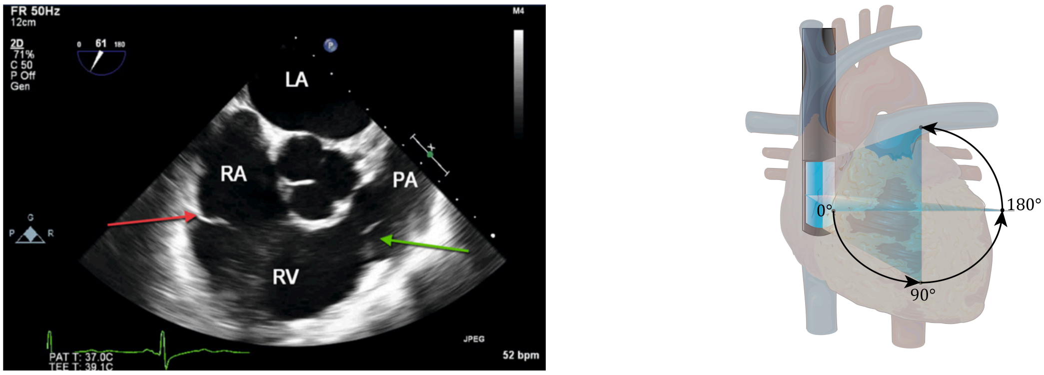


Figure 6: A: ME RV projection, B: Probe positioned in the ME region.
Red arrow: tricuspid valve, green arrow: pulmonic valve.

This projection shows an overview of the RA, LA, RV and the pulmonary artery as well as the tricuspid valve. Through color flow assesment one can determine if there is any regurgitation or stenosis occuring in the tricuspid or the pulmonary valve [S2].

Midesophageal (ME) Bicaval View
To achieve a bicaval view, rotate the ultrasound plane to 90° – 110° and turn the probe clockwise.

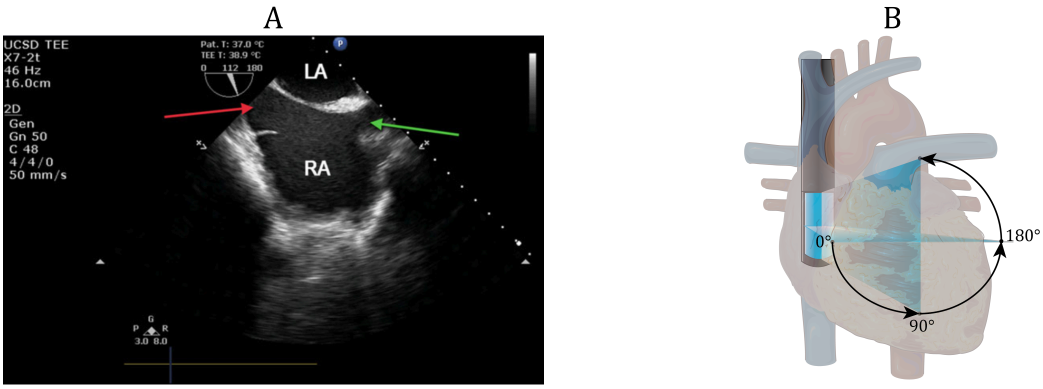


Figure 7: A: ME Bicaval View, B: Probe positioned in the ME region.
Red arrow: inferior vena cava, green arrow: superior vena cava.

This projection allows for assesment of the size of the atriums. It also proves helpful for guidance of catheters entering the heart through the superior vena cava. Through CFA one can determine the flow in the inferior and superior vena cava.

Midesophageal (ME) Ascending Aortic Short-Axis View (SAX)

Return to ME 4CH view and return ultrasound plane to 0°. Now withdraw the probe slowly until the desired view of the ascending aorta (Ao). Slight use of antiflex in addition to minor rotation of the ultrasound plane might be necessary to get a clear image.

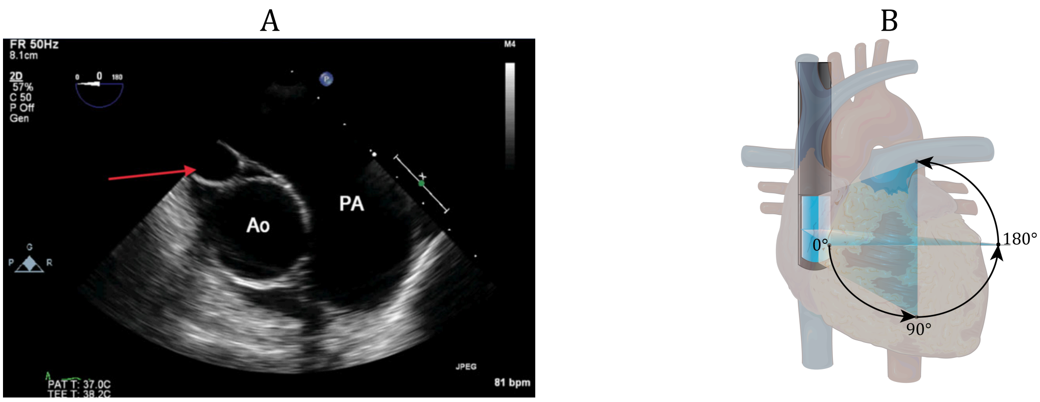


Figure 8: A: ME SAX, B: Probe positioned in the ME region.
Red arrow: superior vena cava. Ao: ascending aorta, PA: pulmonary artery.

This projection provides a clear view of the aorta, ascending into the heart, and a cross-section of the pulmonary artery crossing the top of the LA. This view is not widely used during catheter based heart valve repair and implantation.

Midesophageal (ME) Ascending Aortic Long-Axis View (LAX)

To achieve a ME ascendig aortic LAX keep the ascending aorta centered in the image and turn the ultrasound plane to 90°. Minor adjustments to the anteflex might be necessary to achieve a clear LAX view.

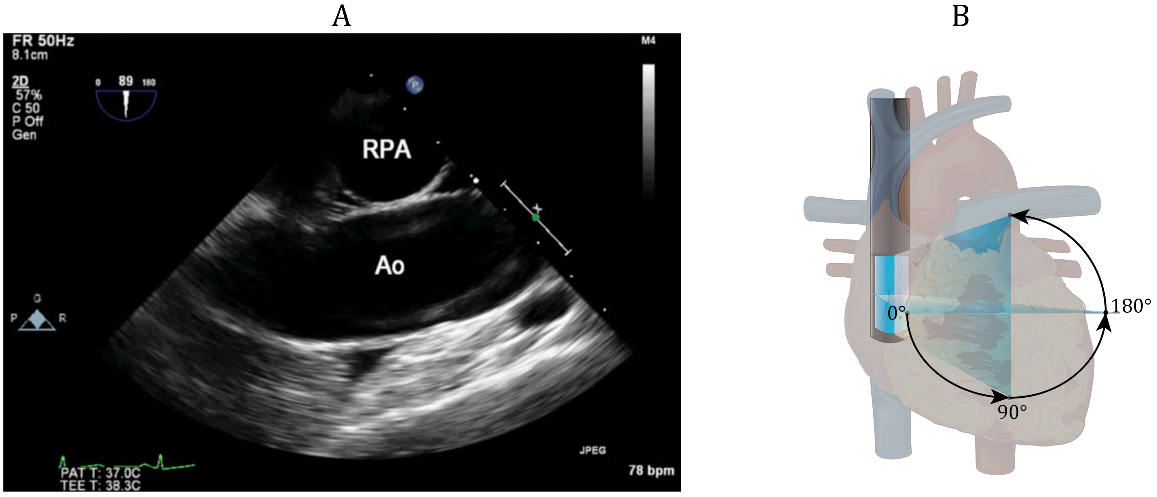


Figure 9: A: ME LAX, B: Probe positioned in the ME region.

This projection has the same application as the ME SAX view, but the axis are reversed. This provides a cross-section longitudal view of the aorta, and a cross-section image of the right pulmonary artery.

Transgastric (TG) Midpapillary Short-Axis View (SAX)

Return to ME 4CH view, with a ultrasound plane rotated to 0°. Now elongate the probe down into the stomach. Maintain a plane rotation of 0° and gradually anteflex while adjusting the elongation until LV and RV are visualized.

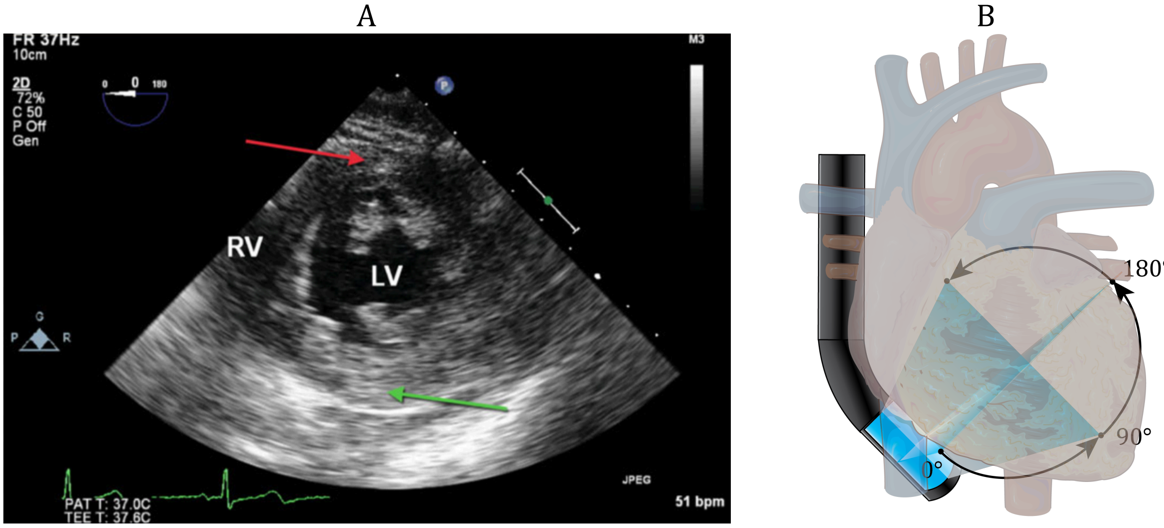


Figure 10: A: TG SAX, B: Probe positioned in the TG region. *Red arrow: inerior vall of left ventricle (LV), green arrow: anterior wall of the right ventricle (RV).*

The TG midpapillary SAX view is often used druing minimally invasive procedures such as mitral valve repair. It is often one of the first views assessed due to its visual superiority documenting instability in blood flow. In addition it provides a good overview of systolic function and muscular behaviour of LV and RV.

Descending Aortic Short-Axis View (SAX)
A view of the descending aorta in SAX is obtained through turning the probe clockwise, with an ultrasound plane angle of 0° until Ao is visualized.

A B

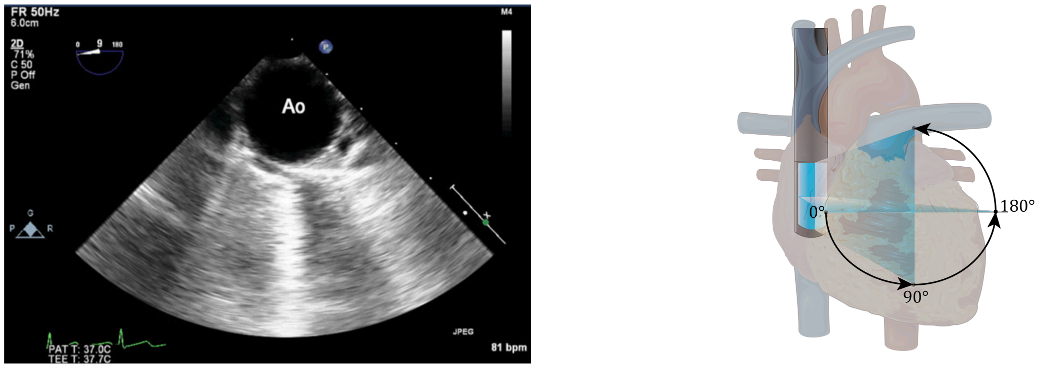


Figure 11: A: SAX of descendig aorta, B: Probe positioned in the ME region.

With the probe in position for a SAX of the descending aorta, the echocardiograph can measure the diameter of the aorta, making it effective for determining the available space for catheters if the patient suffers from irregularities in the aorta.

Descending Aortic Long-Axis View (LAX)
While in a descending aortic SAX, rotate the ultrasound plane to 90°.

A B

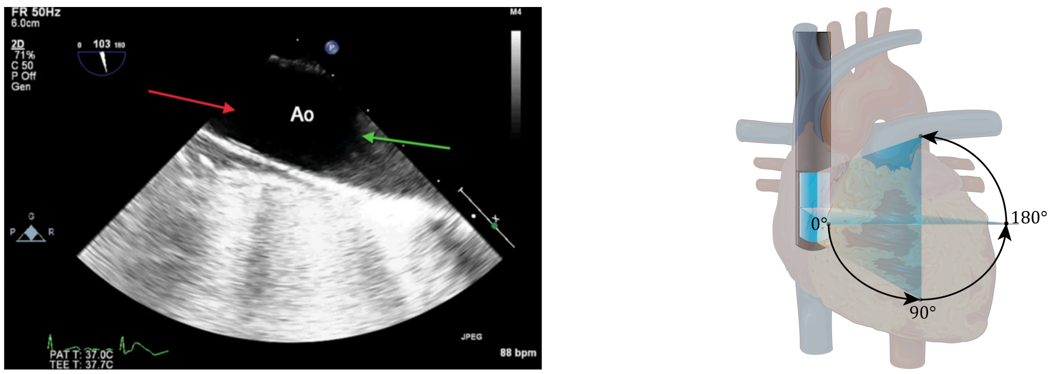


Figure 12: A: LAX of descending aorta, B: Probe positioned in the ME region.
Red arrow: distal aortic segments, green arrow: proximal aortic segments.

This view provides the same assessements as the SAX, and in addition offers help in determening aortic valve regurgitation by applying spectral Doppler.

Transgastric (TG) Basal Short-Axis View (SAX)
Starting from the ME 4CH view, advance the probe into the stomach, followed by an anteflex until the desired view of the LV is aquired.

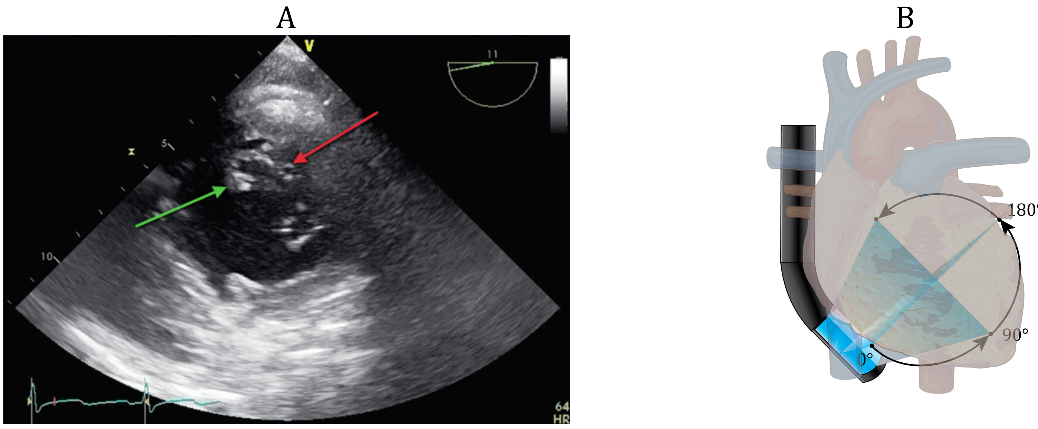


Figure 13: A: TG Basal SAX, B: Probe positioned in the TG region.
Green arrow: anterior mitral valve leaflet, red arrow: posterior mitral valve leaflet.

This projection can be used to determine the ammount of calcification of the mitral valve. In addition mitral valve regurgitation can be adressed through CFA.

Transgastric (TG) Two-Chamber View
Proceed from a TG midpapillary SAX view, and rotate the ultrasound plane to 90° – 110°. The two left heart chambers should now be visible.

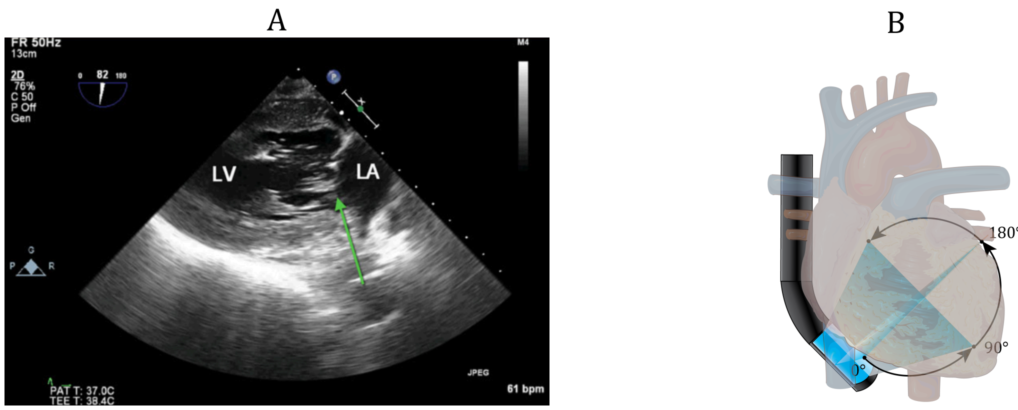


Figure 14: A: TG Two-Chamber view, B: Probe positioned in the TG region.
Green arrow: mitral valve.

This projection shows a view of the LV along its length axis. It is helpful to inspect motion abnormalities of the posterior and anterior wall of the LV.

Transgastric (TG) Two-Chamber Long-Axis View (LAX)

Proceed from the TG 2CH view by rotating the ultrasound plane to 120 – 140°. Stop the rotation when the aortic valve is visualized along with the LV and LA.

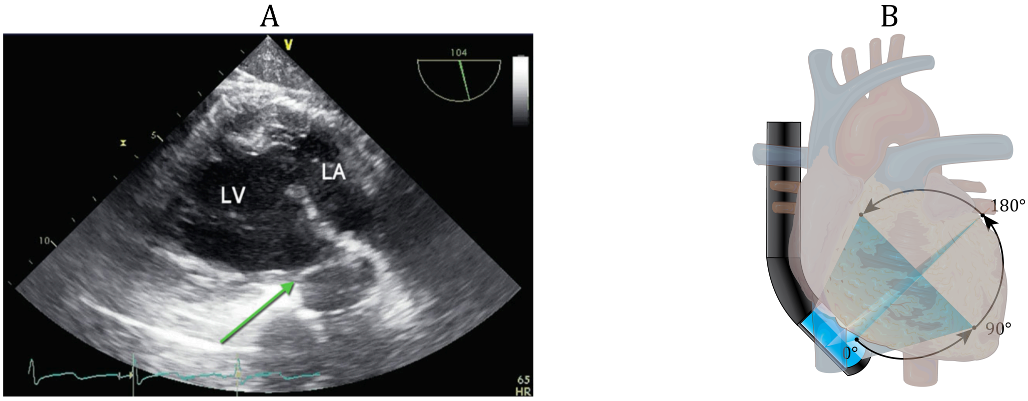


Figure 15: A: TG Two-Chamber LAX, B: Probe positioned in the TG region.
Green arrow: the aortic valve.

Similar to the TG Two-chamber view, this projection shows the LV and LA along its length axis. In addition the LAX view provides images of the left ventricular outflow and aortic valve. A cross-section of the aortic valve is also visable.

Deep Transgastric (TG) Long-Axis View (LAX)

Advance the probe deep into the stomach. Apply anteflex and left flexion and withdraw slowly until the desired image is revealed.

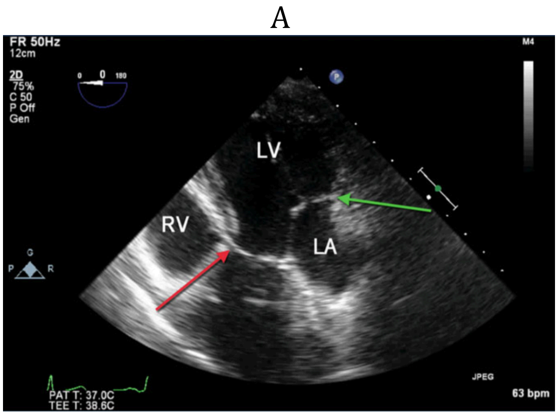


Figure 16: A: Deep TG LAX, B: Probe positioned in the deep TG region.
Red arrow: aortic valve, green arrow: mitral valve.

The image assesses outflow from the LV and AV, It also shows MV, LA and some of the RV. Through this projection one can determine symptoms like muscle growth in the LV apex. Through CFA one can determine regurgitation and stenosis in the AV and MV.

Transgastric (TG) Right Ventricular (RV) Inflow View

Advance from the TG midpapillary SAX view by carefully turning the probe clockwise until the RV is centered in the image. Rotate the ultrasound plane to 90 – 110° until the RV inflow is revealed.

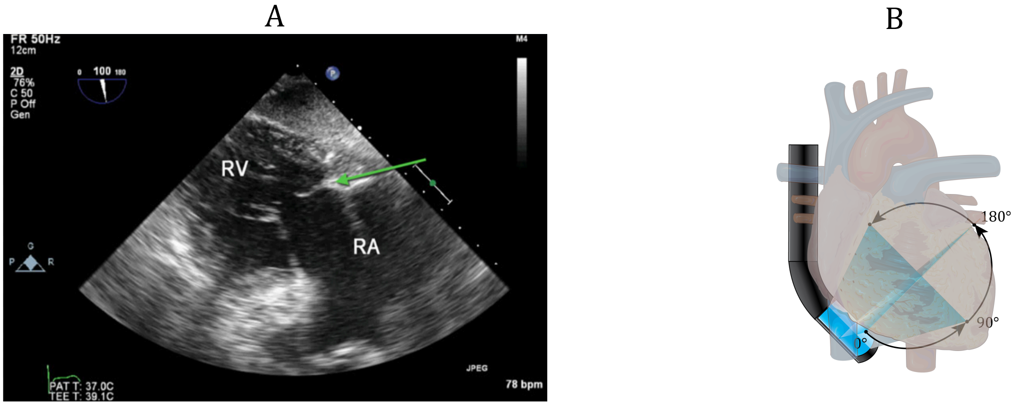


Figure 17: A: TG RV Inflow, B: Position of probe.
Green arrow: tricuspid valve.

Through this projection one can evaluate thickness of the RV wall and its pumping function. The view is also great for determening size and leaflet motion of the TV.

Upper Esophageal (UE) Aortic Arch Long-Axis View (LAX)

From ME descending aortic SAX, withdraw the probe carefull and turn it clockwise until the aorta appears as an oval shape.

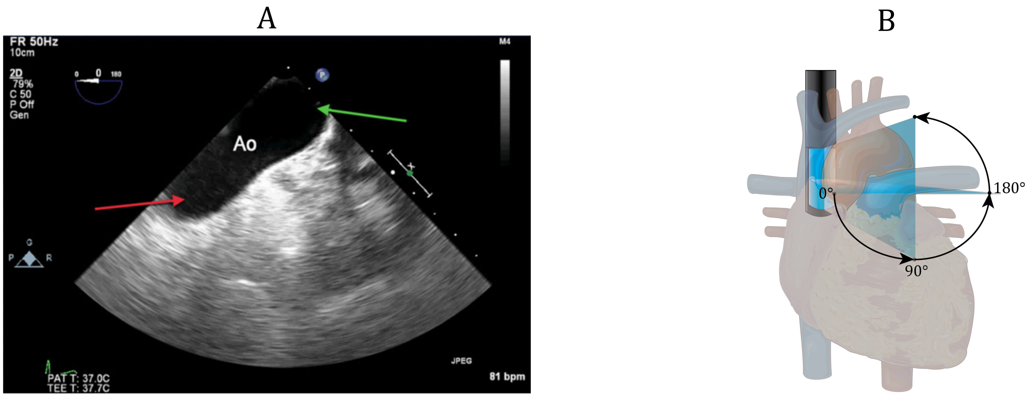


Figure 18: A: UE Aortic Arch LAX, B: Position of probe.
Red arrow: proximal aortic arch, green arrow: distal aortic arch.

This view is mainly inteded for studying the aortic arch in regards of irregularities and dissections.

Upper Esophageal (UE) Aortic Arch Short-Axis View (SAX)
To achieve the aortix SAX view, advance from the LAX by rotate the ultrasound plane 70 – 90°.

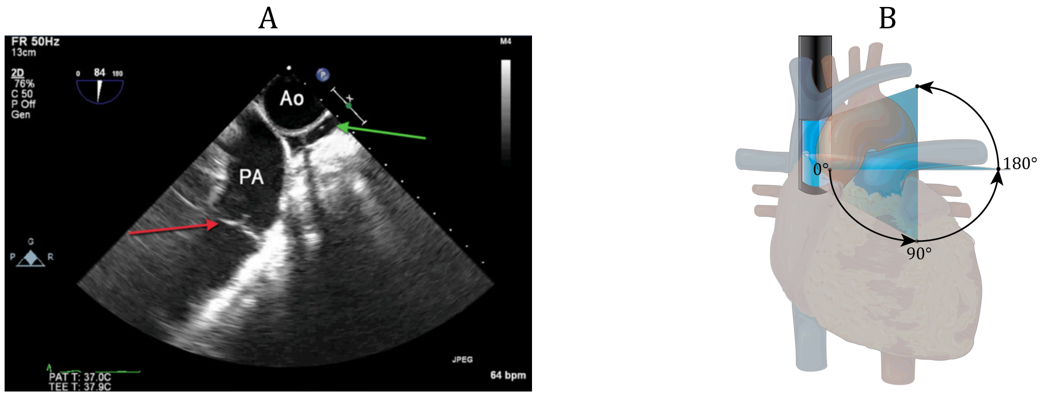
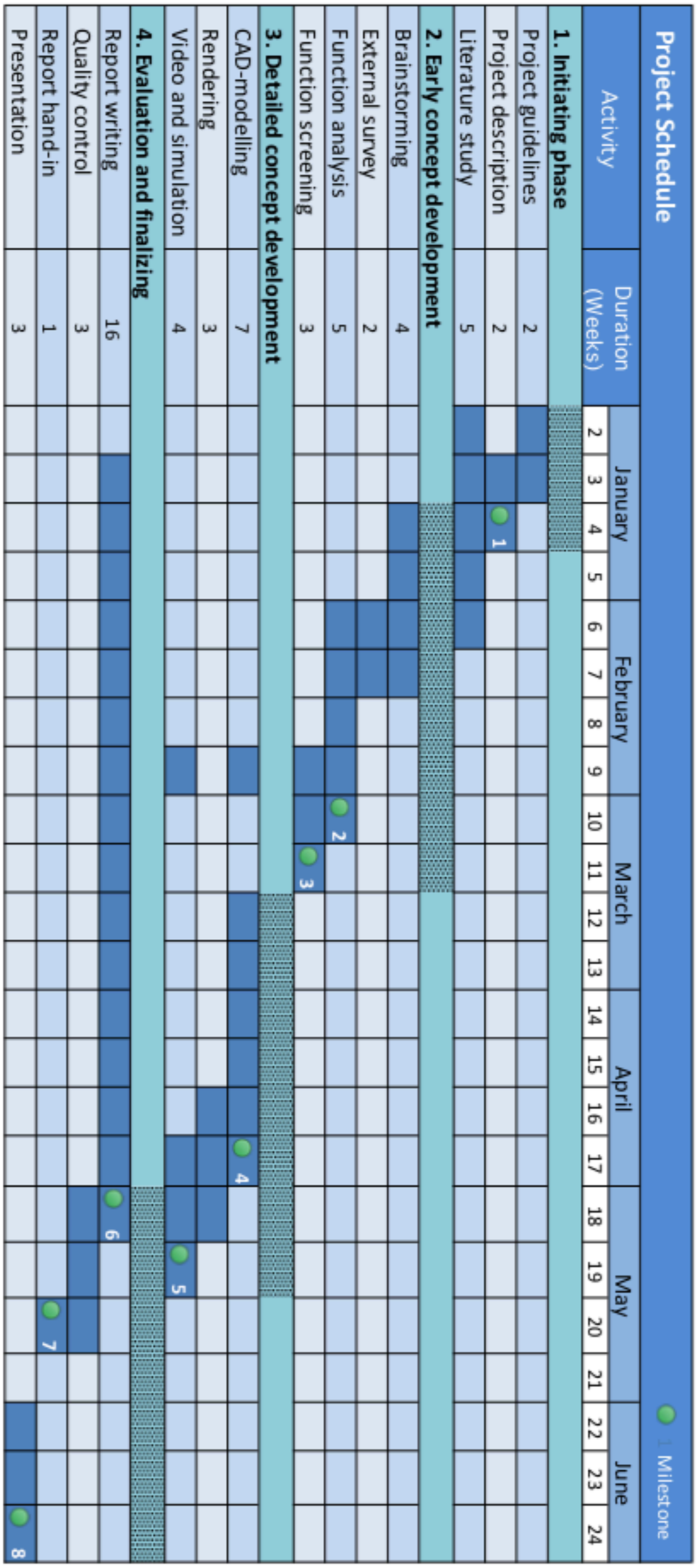


Figure 19: A: UE Aortic Arch SAX, B: Positioning of probe.
Red arrow: pulmonic valve, green arrow: brachiocephalic vein.

Similar to the UE LAX view, this image provides som additional information regarding the PV and the brachiocephalic vein. This view is achieved through rotating the ultrasound plane 90 degrees.

Appendix B – Project schedule



Appendix C – Questionaire for external expert survey

Questionnaire related to Automated Transesophageal Echocardiography

This survey is related to our master thesis regarding design and development of automated transesophageal echocardiography probes. The work is being conducted at NMBU on behalf of Rikshospitalet.
We would appreciate if you could take 10-15 minutes out of your day to provide us with some helpful feedback in terms of TEE, and thus further aid the development of this concept.The survey contains a total of 18 questions.

Feel free to answer this survey in Norwegian if that is preferable.

Thank you for your time.

Best regards
- Andreas Hansen and Jørgen K. Tveter

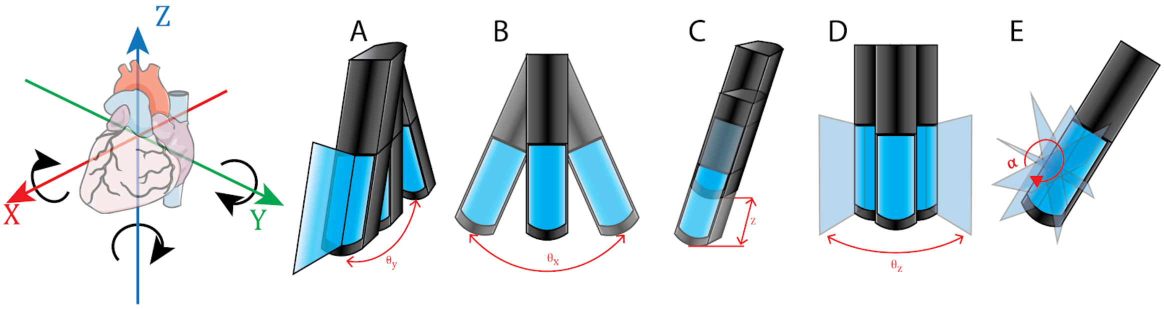
1. **E-postadresse** *

2. **Please fill in your name in the box below. (Will not be published)**

3. **Further development of TEE technology is important for heart valve repair and replacement.**
Markér bare én oval.

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree

4. **What manipulation(s) would you consider most important for good image acquisition? (You may choose multiple alternatives)**



Merk av for alt som passer

- [ ] A: Anteflex / Retroflex
- [ ] B: Left and right flexion
- [ ] C: Alongation
- [ ] D: Clockwise and counterclockwise rotation
- [ ] E: Rotation of ultrasound plane

5. **Being able to use the anteflex/retroflex-wheel while inserting the TEE probe into the patients esophagus is crucial.**

Markér bare én oval.

- ◯ Strongly disagree
- ◯ Disagree
- ◯ I have no opinion on the matter
- ◯ Agree
- ◯ Strongly Agree

6. **The size of the external actuating unit (motor housing) is important in an operating room in relation to the equipment already implemented.**

Markér bare én oval.

- Strongly disagree
- Disagree
- I have no opinion on the matter
- Agree
- Strongly agree

7. **Considering the external motor housing, what are your thoughts on its placement relative to the patient? (For instance: What angle would be ideal regarding entering the patients mouth?)**

8. **Considering the external motor housing, what are your thoughts on its placement and size relative to other implemented equipment and the staff present during surgery?**

9. **Achieving exact positioning of the TEE probe is crucial for good image quality.**

Markér bare én oval.

- Strongly disagree
- Disagree
- I have no opinion on the matter
- Agree
- Strongly agree

10. **In relation to the previous question: Approximately how much, if any, room for deviation is there?**

____

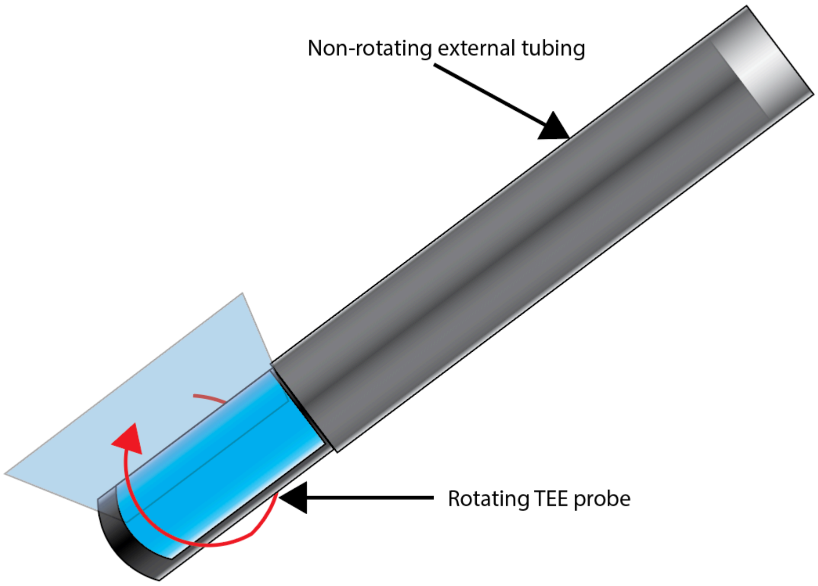
____

____

____

____

11. **I consider rotation at the distal end superior to a fully rotating endoscope, where the endoscope is located inside an external tube which is not subject to rotation.**



Markér bare én oval.

- Strongly disagree
- Disagree
- I have no opinion on the matter
- Agree
- Strongly Agree

12. **The esophagus is vulnerable to the friction presented by a rotating and elongating TEE probe.**

Markér bare én oval.

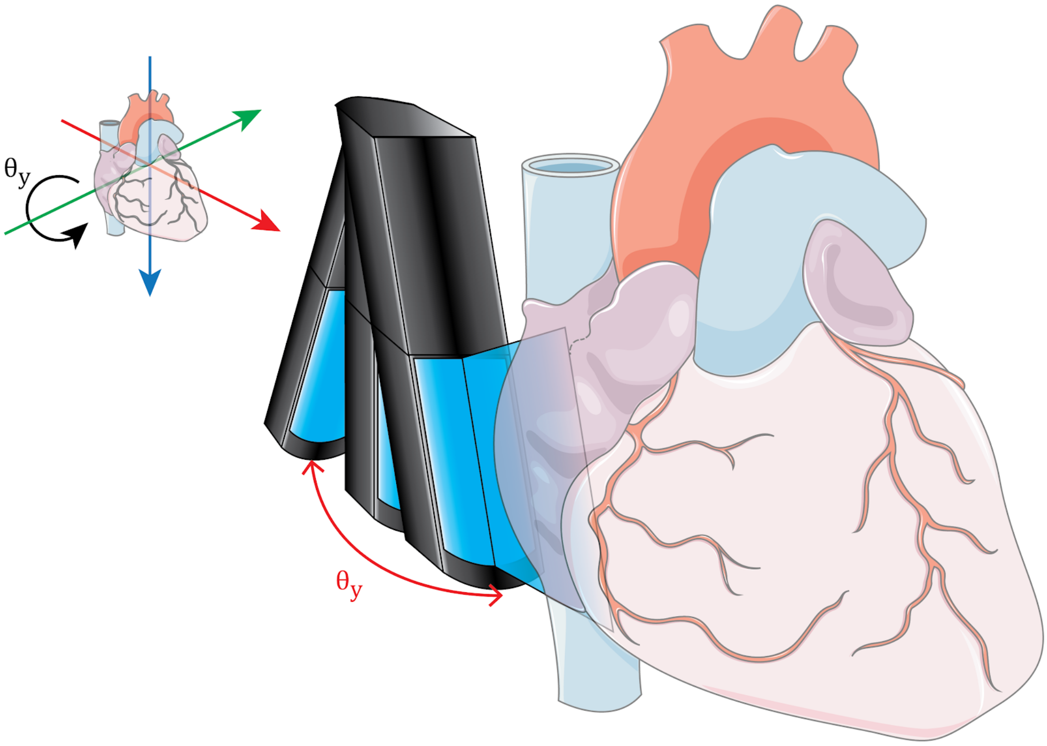
- Strongly disagree
- Disagree
- I have no opinion on the matter
- Agree
- Strongly agree

13. **All the 20 standard TEE view-planes are necessary to acquire good images during minimally invasive heart surgery and for diagnosing patients.**

Markér bare én oval.

- Strongly disagree
- Disagree
- I have no opinion on the matter
- Agree
- Strongly agree

14. **Achieving good surface contact between the transducer and the esophagus is necessary to acquire high quality imaging. If you have any experience operating TEE, please elaborate on your process regarding surface contact and the amount of force you apply to the anteflex.**



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15. **If you are an operator of TEE probes: Would you be willing to learn how to operate a new and different system combined of electric actuation and joystick manipulation, instead of using the existing mechanical approach?**

Markér bare én oval.

- No
- Maybe
- I have no opinion on the matter
- Yes

16. **What would you consider an improvement in terms of maneuverability in TEE probes?**

17. **In terms of patient safety, what would you consider the highest risk factors related to automation of TEE probes and the soft tissues they are operating in?**

18. **What areas could you see presenting challenges in relation to implementing autonomous TEE?**

19. **In a future scenario where TEE is fully automated: How do you see this effecting procedures related to heart valve repair and replacement?**

20. **Do you have any supplementary comments regarding functions that might help strengthening TEE technology?**

____

____

____

____

____

☐ Send meg en kopi av svarene mine.

Questionnaire related to Automated Transesophageal Echocardiography

3 svar

Please fill in your name in the box below. (Will not be published)

3 svar

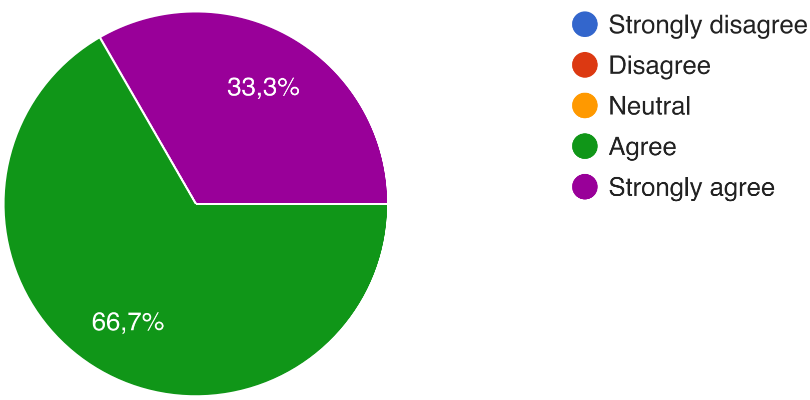
Henrik Brun

Jan Otto Beitnes

Jacob Bergsland

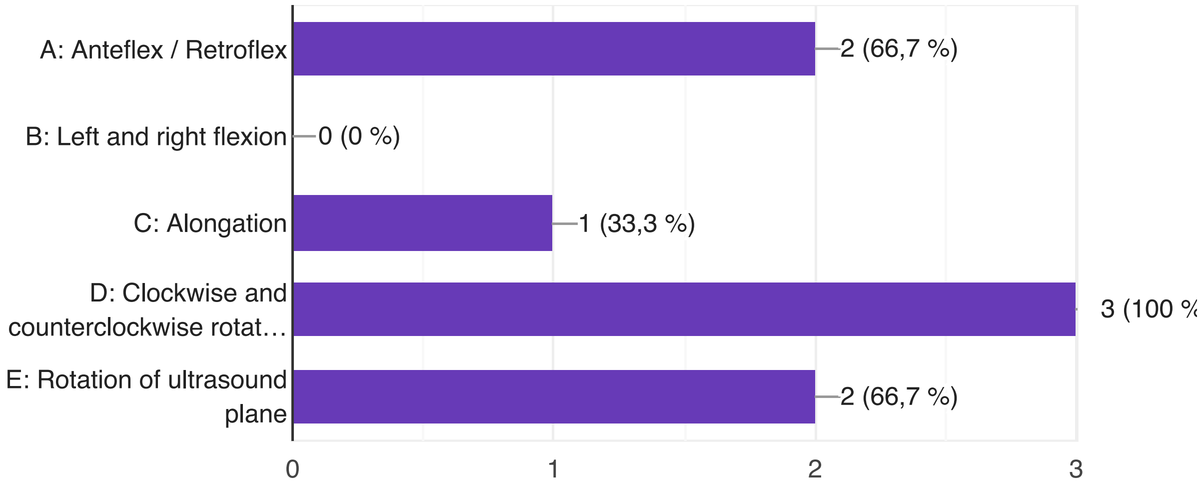
Further development of TEE technology is important for heart valve repair and replacement.

3 svar



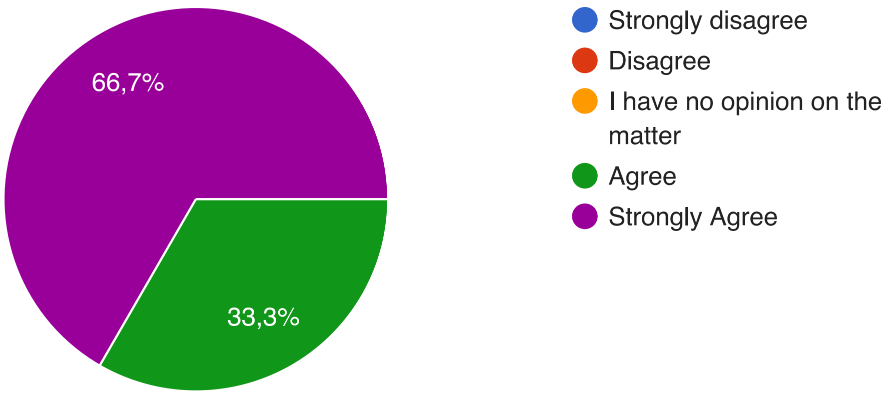
What manipulation(s) would you consider most important for good image acquisition? (You may choose multiple alternatives)

3 svar



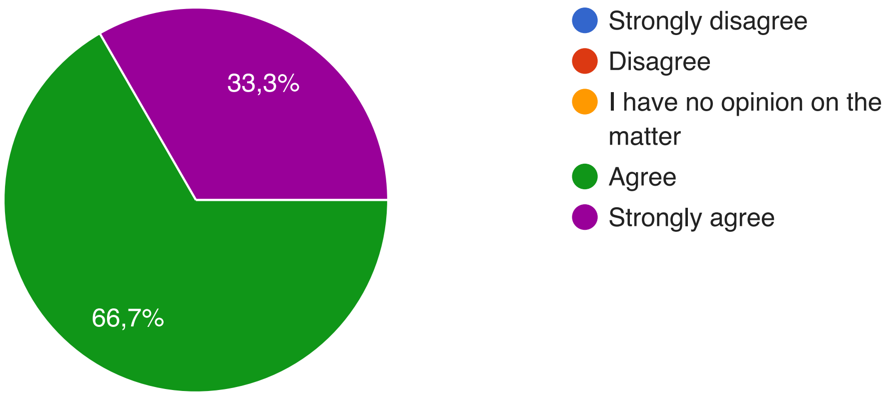
Being able to use the anteflex/retroflex-wheel while inserting the TEE probe into the patients esophagus is crucial.

3 svar



The size of the external actuating unit (motor housing) is important in an operating room in relation to the equipment already implemented.

3 svar



Considering the external motor housing, what are your thoughts on its placement relative to the patient? (For instance: What angle would be ideal regarding entering the patients mouth?)

3 svar

90-100

The probe should enter the mouth in the sagittal plane with 60-90 degrees angle to the long-axix of the patient. If the probe is long enough, the motor housing can be positioned away from the face of the patient.

180 degrees

Considering the external motor housing, what are your thoughts on its placement and size relative to other implemented equipment and the staff present during surgery?

3 svar

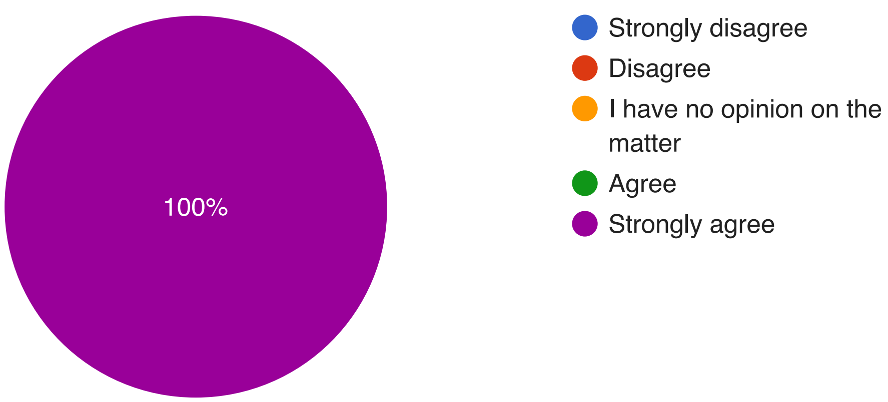
On flexible arm. Close to pasient - Easy to move

The housing should preferrably be positioned beside the patients head in either direction, as the area above and directly behind the patient in the OR is occupied by the anaesthesiologist.

As small as possible or further away

Achieving exact positioning of the TEE probe is crucial for good image quality.

3 svar



In relation to the previous question: Approximately how much, if any, room for deviation is there?

3 svar

3-5 mm , less for kids

Sometimes less than 1 cm to lose acoustic window.

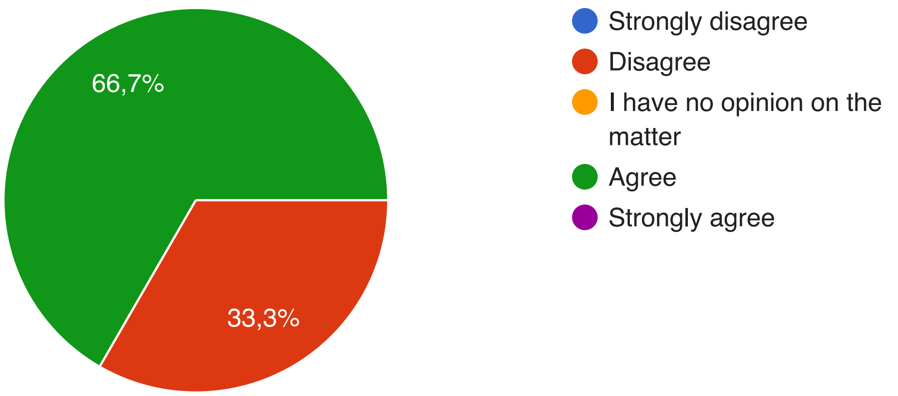
Hard to say

I consider rotation at the distal end superior to a fully rotating endoscope, where the endoscope is located inside an external tube which is not subject to rotation.

3 svar

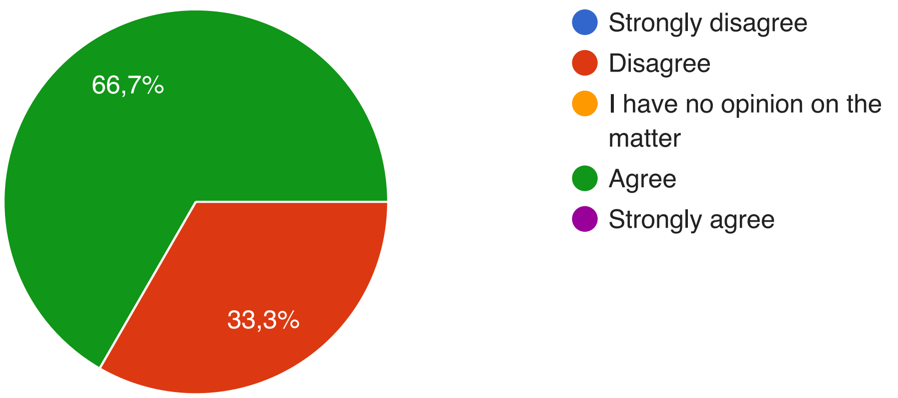
The esophagus is vulnerable to the friction presented by a rotating and elongating TEE probe.

3 svar



All the 20 standard TEE view-planes are necessary to acquire good images during minimally invasive heart surgery and for diagnosing patients.

3 svar



Achieving good surface contact between the transducer and the esophagus is necessary to acquire high quality imaging. If you have any experience operating TEE, please elaborate on your process regarding surface contact and the amount of force you apply to the anteflex.

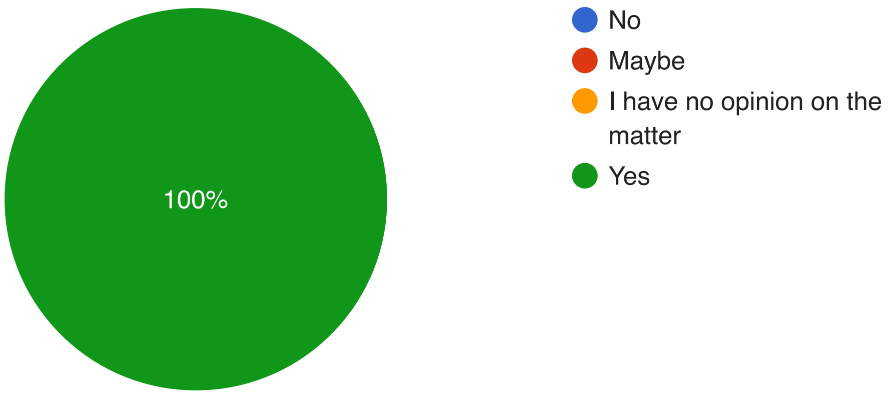
2 svar

Definitely important! No big pressure. Just contact

In (mid)esophageal views, very little flexion or force is usually necessary. For transgastric views, more flexion and force will be required.

If you are an operator of TEE probes: Would you be willing to learn how to operate a new and different system combined of electric actuation and joystick manipulation, instead of using the existing mechanical approach?

3 svar



What would you consider an improvement in terms of maneuverability in TEE probes?

3 svar

Stability for tiny micro tee brobes

A small "monitor" on the screen showing the shape of the probe during maneuvering. Robotic maneuvering to improve Precision, the opportunity to hold the exact same position over time and to program the probe to obtain "stored" previous positions.

Controllable stable positioning

In terms of patient safety, what would you consider the highest risk factors related to automation of TEE probes and the soft tissues they are operating in?

3 svar

Time to image , procedures are often moving quickly

Risk for perforation if "tactile feedback" or force limitations are not programmed.

Unless haptics are present, perforation of the esophagus could happen

What areas could you see presenting challenges in relation to implementing autonomous TEE?

3 svar

Choose procedure without stress

Respiration and/or mechanical ventilator+ cardiac contractions imply that the heart is always moving and the acouistic window is constantly changing. Also: visualizing different structures within the heart usually requires different Acoustic Windows, and it's unlikely that one position of the probe will provide all images You need.

Image recognition and subsequent adjustment of position

In a future scenario where TEE is fully automated: How do you see this effecting procedures related to heart valve repair and replacement?

3 svar

Reducing need for cardiologist in or

In theory, the echo-cardiologist can be replaced by the automated probe and the entire oprocedre can be run by the invasive cardiologist and the anaesthesiologist ?!

Could reduce operating time and make personnel more cost effective

Do you have any supplementary comments regarding functions that might help strengthening TEE technology?

2 svar

Long procedures with low stress level

Clearly, the market is asking for miniaturized TEE-probes or ICE-probes with full 3D functionality to allow procedures With less need for sedation/general anastehesia....

Appendix D - Forward kinematics

Equations of movement/Forward kinematics:

Forward kinematics is used to establish the position and orientation of the end-effector of a robot with several joints. The mathematically expression contains different variables like the angle of rotational joints or the extraction of prismatic joints along with several system defined constants. In this report the equation of movement of the distal end will be derived using the Denavit Hartenberg method.

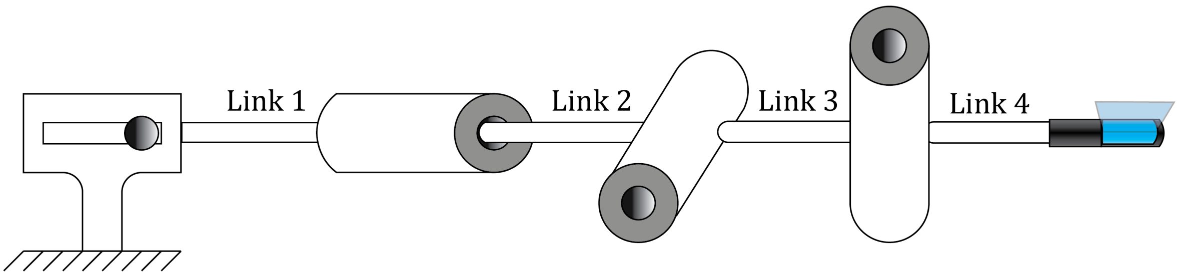


Figure 1: System model.
Caption: Figure shows the different joints and links of the system where the base joint is prismatic (extraction and retraction). The rotation of the system is represented by the second left joint. The two joints to the right (flexions) are separated with a distance of zero for simplification but could also have been represented by a spherical joint.

The Denavit Hartenberg or D-H convention states that by carefully selecting the coordinate frames of the joints one can express each homogeneous transformation A_i as a product of four transformations.

$$A_i = Rot_{z,\theta_i} Trans_{z,d_i} Trans_{x,a_i} Rot_{x,\alpha_i}$$

$$A_i = \begin{bmatrix} c_{\theta_i} & -s_{\theta_i} & 0 & 0 \\ s_{\theta_i} & c_{\theta_i} & 0 & 0 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \begin{bmatrix} 1 & 0 & 0 & 0 \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 1 & d_i \\ 0 & 0 & 0 & 1 \end{bmatrix} \begin{bmatrix} 1 & 0 & 0 & a_i \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \begin{bmatrix} 1 & 0 & 0 & 0 \\ 0 & c_{\alpha_i} & -s_{\alpha_i} & 0 \\ 0 & s_{\alpha_i} & c_{\alpha_i} & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

$$A_i = \begin{bmatrix} c_{\theta_i} & -s_{\theta_i} c_{\alpha_i} & s_{\theta_i} s_{\alpha_i} & a_i c_{\theta_i} \\ s_{\theta_i} & c_{\theta_i} c_{\alpha_i} & -c_{\theta_i} s_{\alpha_i} & a_i s_{\theta_i} \\ 0 & s_{\alpha_i} & c_{\alpha_i} & d_i \\ 0 & 0 & 0 & 1 \end{bmatrix} = \begin{bmatrix} R_{xx} & R_{xy} & R_{xz} & P_x \\ R_{yx} & R_{yy} & R_{yz} & P_y \\ R_{zx} & R_{zy} & R_{zz} & P_z \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

Where the relative position of the body i with respect to the previous $(i-1)$ body is described by the upper right $3x1$ submatrix P, while the $3x3$ submatrix R describes the rotation.
The four D-H parameters θ_i, d_i, a_i and α_i are associated with link i and joint i.

$\theta_i =$ joint angle between x_{i-1} and x_i measured about z_{i-1} and is a constant for prismatic joints and a variable for revolute joints.

d_i = offset along the previous z_{i-1} axis to the common normal. This parameter is a variable for prismatic joints and a constant for revolute joints.
a_i = distance along x_i from o_i to the intersection of the x_i and z_{i-1} axes.
α_i = angle between z_{i-1} and z_i measured about x_i.

The total transformation of the end in respect to the base coordinates is the product of the transformations between all of the links.

$$T_i^0 = A_1 \cdot A_2 \cdot\cdot A_n$$

To select the coordinate frames of the joints there are some considerations to be made. The z axis should always point along the direction of extraction for prismatic joints and along the axes of revolution for revolute joints. For the base joint, the x and y axes are arbitrary chosen, however for the next joints there are some rules on how to set the other axes. If the axes z_i and z_{i-1} are parallel the x_i and y_i axis may point in the same direction as the previous. If the axes z_i and z_{i-1} intersects the normal axis is set to x_i and the y_i is chosen in regard to the right-hand rule.

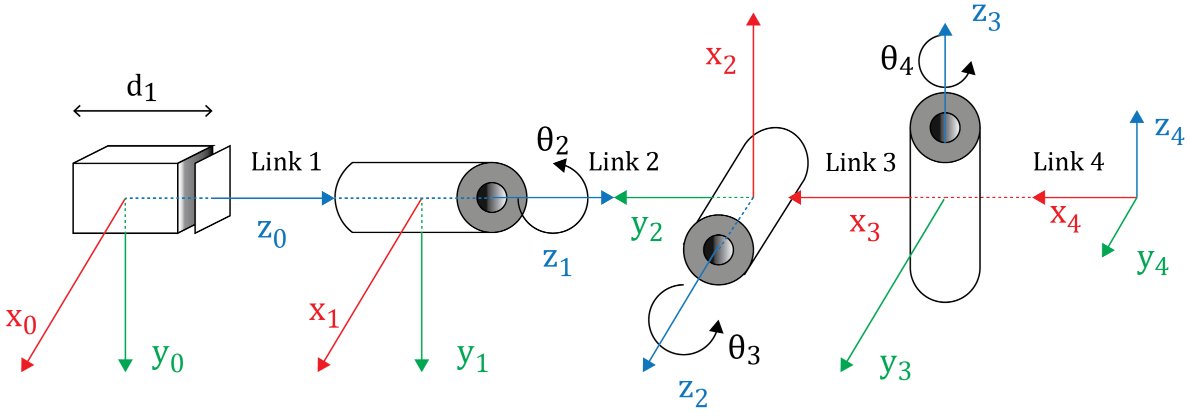


Figure 2: Illustration of the complete setup of the coordinate system and its variables.

The figure above is a representation of the system where Link 1 connects the linear actuator and the revolute chamber, and its length is dependent on the variable d_1. The tube is represented as Link 2 and its orientation is dependent on the variable θ_2. Link 3 is the imaginary link between the ante flex and retroflex and its length is set to zero. Link 4 is a replica of the distal end of the tube and its orientation is dependent on both θ_3 and θ_4.
The four parameters for each of the links are derived in the table below.

	a_i	d_i	α_i	θ_i
Link 1	0	d_1*	0	$\theta_1 = 0$
Link 2	0	d_2	−90	θ_2*
Link 3	0	$d_3 = 0$	90	θ_3*
Link 4	0	d_4	0	θ_4*
*variables.				

When inserting the parameters into the transformation matrixes we reach the final variable dependent equation of motion.

$$A_1 = \begin{bmatrix} 1 & 0 & 0 & 0 \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 1 & d_1 \\ 0 & 0 & 0 & 1 \end{bmatrix} \qquad A_2 = \begin{bmatrix} c_{\theta_2} & 0 & -s_{\theta_2} & 0 \\ s_{\theta_2} & 0 & c_{\theta_2} & 0 \\ 0 & -1 & 0 & d_2 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

$$A_3 = \begin{bmatrix} c_{\theta_3} & 0 & s_{\theta_3} & 0 \\ s_{\theta_3} & 0 & -c_{\theta_2} & 0 \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \qquad A_4 = \begin{bmatrix} c_{\theta_4} & -s_{\theta_4} & 0 & 0 \\ s_{\theta_4} & c_{\theta_4} & 0 & 0 \\ 0 & 0 & 1 & d_4 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

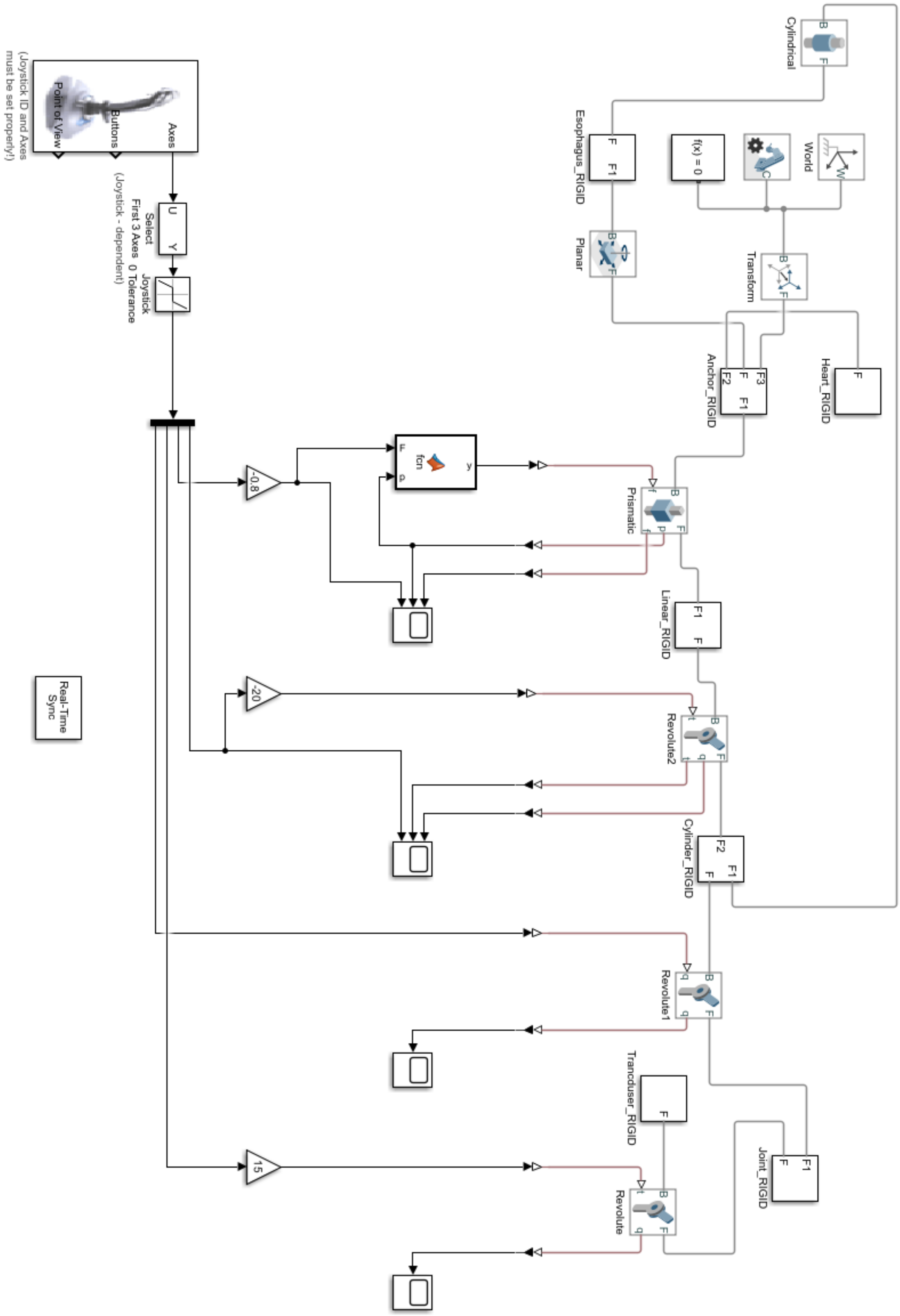
$$T_4^0 = A_1 \cdot A_2 \cdot A_3 \cdot A_4$$

$$T_4^0 = \begin{bmatrix} c_{\theta_2}c_{\theta_3}c_{\theta_4} - s_{\theta_2}s_{\theta_4} & -c_{\theta_4}s_{\theta_2} - c_{\theta_2}c_{\theta_3}s_{\theta_4} & c_{\theta_2}s_{\theta_3} & c_{\theta_2}s_{\theta_3}d_4 \\ c_{\theta_3}c_{\theta_4}s_{\theta_2} + c_{\theta_2}s_{\theta_4} & c_{\theta_2}c_{\theta_4} - c_{\theta_3}s_{\theta_2}s_{\theta_4} & s_{\theta_2}s_{\theta_3} & s_{\theta_2}s_{\theta_3}d_4 \\ -c_{\theta_4}s_{\theta_3} & s_{\theta_3}s_{\theta_4} & c_{\theta_3} & d_1+d_2 + c_{\theta_3}d_4 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

where the position of the end-tip relative to the base reference is:

$$P_x = c_{\theta_2}s_{\theta_3}d_4$$
$$P_y = s_{\theta_2}s_{\theta_3}d_4$$
$$P_z = d_1+d_2 + c_{\theta_3}d_4$$

Appendix E – Simulink Scheme



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