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Master thesis TU Delft
Industrial Design Engineering

Specialisation Medisign

Design for the intraoperative assessment of tissue perfusion

TU Delft
Catharina Hospital Eindhoven

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Master thesis

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Master thesis report
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Cover image: Michiel Jansz. Van Mierevelt & Pieter van Mierevelt, *Anatomische les van dokter Willem van der Meer, 1617*. Collection Prinsenhof, Delft. Photograph by Theun Okkerse.

Preface

Already during my bachelors, I became interested in the design for the medical sector, a field wherein products can serve great purposes. After two years of enjoying my work as an industrial designer at a small design agency in Rotterdam, I still felt the urge to do more within the medical field. Along with my desire to get my master's degree, the choice was easily made and two years later I find myself writing these last words in my master thesis.

I am grateful that I may end my master with this project that confirmed me in my choice to dive back into a life as a student and chase my interests.

I want to thank the people involved in this project, my chair Richard Goossens, mentors Jack Jakimowicz and Dennis Schaap for their feedback and rich insights during this venture. Next, I want to express my appreciation to Maarten Verwaal for providing me with essential advice and measurement equipment and several electronic components. Last but not least, I want to thank my mentor Wolf Song for his feedback, advises, great humour and frankness during our meetings.

I hope that you, as a reader, will enjoy this report as much as I had compiling it.

Glossary

Anastomosis: surgical made connection between adjacent blood vessels or parts of the intestine or other channels.
Angiography (FA): medical imaging technique to vizualise the inside of bloodvessels and organs of the body.
Biocompatibility: the material is free of toxic ingredients.
Bright spots: an area wherein a high density of light reflection exists.
Colectomy: resection of the large bowel (colon).
Contrast dye: Dye that becomes fluorescent when hit by a specific wavelength.
Disinfection: the process of cleaning an object to destroy bacteria.
Ex-vivo: assessment taking place outside a living body.
In-vivo: assessment taking place inside a living body.
False negative: indication that a given condition does not exists, when it does.
False positive: indication that a given condition exists, when it does not.
Fluorescence: emission of light by a substance that has absorbed light or electromagnatic radiation.
Gastrointestinal: relates to the colon and stomach area.
ICG: Indocyanine Green (contrast dye).
Image registration or registration: transformation of different sets of data into one coordinated system.
Ischemic: a restriction in blood supply to tissue, causing a shortage of oxygen to maintain cellular metabolism.
Malignancy: the tendency of a medical condition to become progressively worse.
Metastasis: the medical term for the spread of cancer to different parts of the body.
MD: Measurement device.
OR: short for operation room, also called operation theatre, wherein the surgeries are performed.
Resection: surgical removal of a part an organ or other bodily part.
ROI: Region of Interest.
Sterilization: the process eliminating bacteria and other microorganisms of an object.

Summary

This Master thesis project addresses the challenge to objectively assess real time tissue perfusion of the digestive tract during open gastrointestinal surgery, with the aim to increase the quality of the assessment and eventually prevent avoidable post-operative complications. Because of cancer in the colon, parts of this organ might be cut out to eliminate this disease. After removal, the residual parts are connected by means of a suture. A leakage of such connection is a severe complication and potentially life threatening for the patient and associated with a poor healing of this surgical wound. Adequate blood perfusion of this wound is important for this healing and thus lowers the risk of such leakages. Understanding the tissue perfusion is therefore of the utmost importance. By means of a contrast dye, a special light and camera, this perfusion can be made visual, even underneath tissue. Although this imaging technique can provide essential data, the information is still subjected by, amongst the perception of the individual surgeon, various external factors. Ideally, we could provide objective information that is not susceptible to these factors. To do so, software and hardware developments are needed. This project contributes to the development of the hardware. Factors that affects this objectification are allotted and it is researched how design can control or even eliminate them. In the synthesis we focus on two of the major factorial influencers, namely; external light and the manner of acquisition.

The proposed design includes the means to exclude this external light and a manner to standardise distance from camera to the surgical site. The design serves to assess if controlling these factors truly improves the objectification of the imaging technique.

This thesis is separated into five main chapters. The first will entail the analysis wherein the technical and workflow aspects of the challenge are addressed. Next, the findings are converted to possible design solutions in the synthesis. Followed by the technical elaboration of the design. The thesis will end with an evaluation of the design and project and recommendations for the design and future research.

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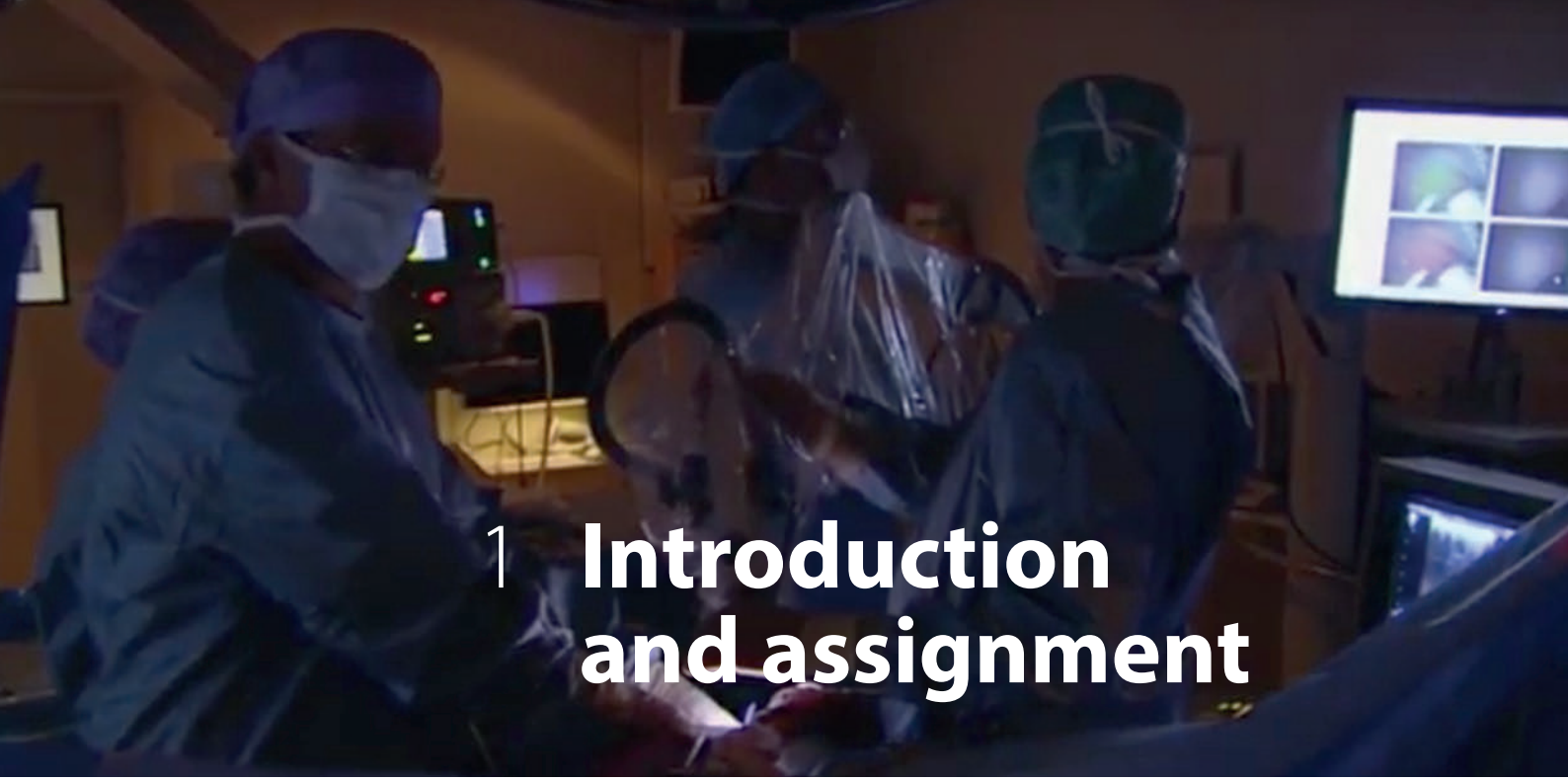


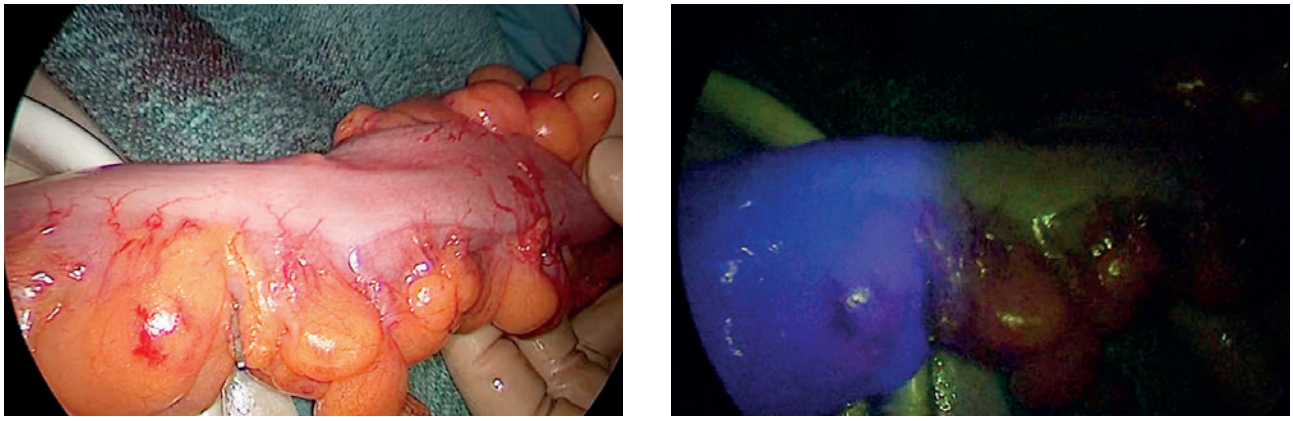
1 Introduction and assignment

Fig 1.1. **Imaging procedure, source youtube.**

1.1

The Catharina Hospital in Eindhoven is a large hospital with special focus on cancer and cardiovascular medicine. Hence, a unique wide variety of complex and extended surgical procedures, ranging from laparoscopic to conventional open surgery, is performed. Besides, this highly complex clinical patient care is accompanied by a special interest in a wide variety of research projects to develop new treatments and improve patient care.

This project revolves around gastrointestinal open-surgery which is the practice of surgery that focusses on the gastrointestinal tract, or digestive system. During these surgical procedures multiple actions must be performed to remove, alter or repair the current situation in the human body. This could involve resection, a term for surgically removing a part of tissue, structure or organ, to cut out a tissue that is known to be cancerous or diseased. Especially the resection of bowel tissue can cause major complications since an anastomosis has to be formed to achieve continuation of the gastrointestinal tract. An anastomosis is the surgical made connection between adjacent blood vessels, parts of the intestine or other channels of the body to repair a defect or make the anatomy functional again after tissue is removed (i.e. resection). Anastomotic leakage, or leakage from a stapling line, is a frequent and major complication and potentially life threatening for the patient (Degett, Andersen, & Gögenur, 2016). Moreover Ptok et al. (2007) indicate an increase of local cancer reappearance after an anastomotic leakage of 10.1 to 17.5%. Several factors are identified as possible causes of an anastomotic leakage such as surgical techniques, cardiovascular status, suture material or devices. However, insufficient blood supply seems to play a key role (Boni et al., 2016). Currently, objective assessment of adequate tissue perfusion near the anastomotic site is performed by visual interpretation and manual feedback. Both methods leave room for error, even for experienced surgeons. Indocyanine green-based fluorescence angiography (ICG-FA) is a relatively new technique for intraoperative assessment of gastrointestinal anastomotic perfusion. Indocyanine green is a molecule that binds to the plasma proteins when injected intravascular. Its ability to become fluorescent when exposed to near infrared light makes real-time evaluation of tissue perfusion possible (Luo et al., 2011) see figure 1.2. The technique uses special cameras that



1.1

Fig 1.2. **Anatomical view of the bowel (left and ICG fluorescence of bowel perfusion assessment (right). Adapted from Boni et al. (2016).**

can be incorporated in laparoscopic, open and robotic surgery, which makes it easier to incorporate ICG-FA to existing surgical procedures, see figure 1.1. (Marano et al., 2013).

1.2 Problem definition

Although the technique seems to be promising, the final assessment is still subjected to the perception of the individual surgeon, as the image recordings are influenced by various external factors that result in an non-standardised output image that is still open for incorrect interpretation. To do reliable subjective and eventually objective evaluation of the tissue perfusion via this ICG-FA technique, Prof. ir. Jack Jakimowicz and Dennis Schaap initiated this project that aims for standardisation of the output image. A method considering all factors that could influence registration to gain reliable information on tissue perfusion. Not only interference from external light and reflections of camera light on surgical instruments could disturb the registration and affect the output image, but the fluorescence visibility of indocyanine green seems heavily related to the distance and slope of the camera lens to the tissue and are crucial, especially in patients undergoing open surgery. To overcome the above and meet the requirements this standardisation of the output image demands the development of software (i.e. improvements on objective readability of the output images) and hardware (i.e. standardisation of the data acquisition). In this project the focus will be the development of the hardware and the TU Eindhoven will carry out a project to develop the software. To summarise, it is important to standardise this recording technique and gain the same factorial recording conditions in all patients to be able to do these reliable subjective and eventually objective evaluation of the tissue perfusion. The hypothesis is that when these external factors are controlled, an image can be created that is less susceptible to inadequate assessments by surgeons due to incorrect interpretation of the output image. This will potentially not only lower the risk of complications and prevent (avoidable) harm to the patient, but will also preclude additional costs that are associated with these complications.

1.3 Assignment

The aim of the project is to:
'Develop a system that facilitates positioning and fixation of an ICG-FA camera module in- or onto a desired position and allows intraoperative data/image acquisition to take place in an environment wherein light interference affecting the desired output image can be controlled or excluded'.

The development of such a system will guarantee the standardisation of the data acquisition during the IGC-FA in open surgery. See figure 1.3 for a visual representation of setup conditions.

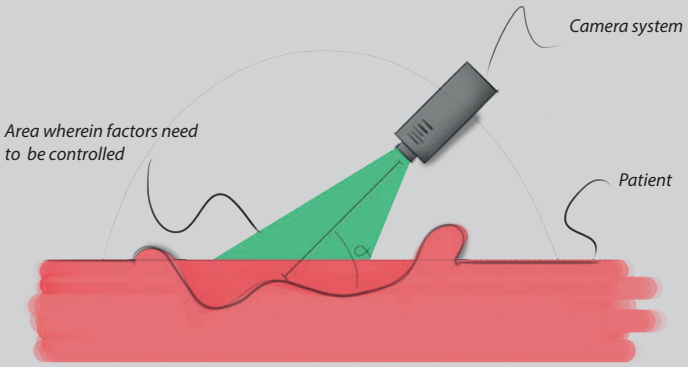


Fig 1.3. **Visual representation of setup-conditions.**

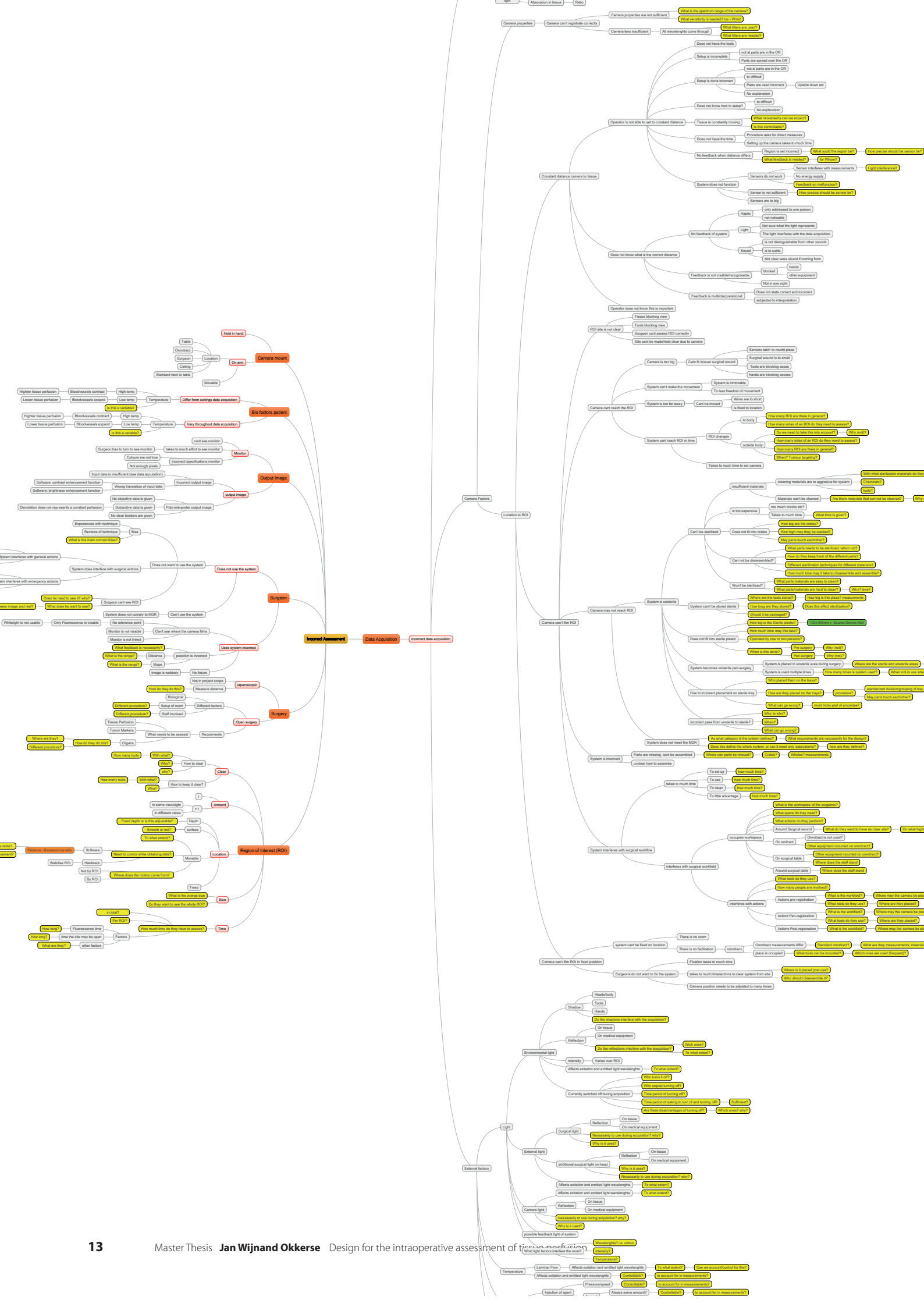
In the proposed, we will tackle the following challenges:

- How to position and fixate the camera module on- or into the desired location and position?
- How to communicate adequate placement of camera to targeted user?
- How to exclude interference of external light sources affecting the output image?
- How to exclude interference of camera light reflection on medical equipment affecting the output image?

Since the product will be used in a clinical environment, being the operating theatre, the design should meet the Medical Device Regulations and other requirements the environment might bring in. To avoid mistakes, the design requires to be clear, intuitive, easy to be used and suitable for implementation in daily practice. In general, the technique (system) will be used in a planned manner; before resection to determine tissue that needs to be removed and/or at the end of a procedure to validate good outcomes. Besides the usability, the speed and accuracy of the (intraoperative) system placement are of importance.

The aimed design-result of the project is a prototype that can be tested in a preclinical setup on its functionalities and working principle.

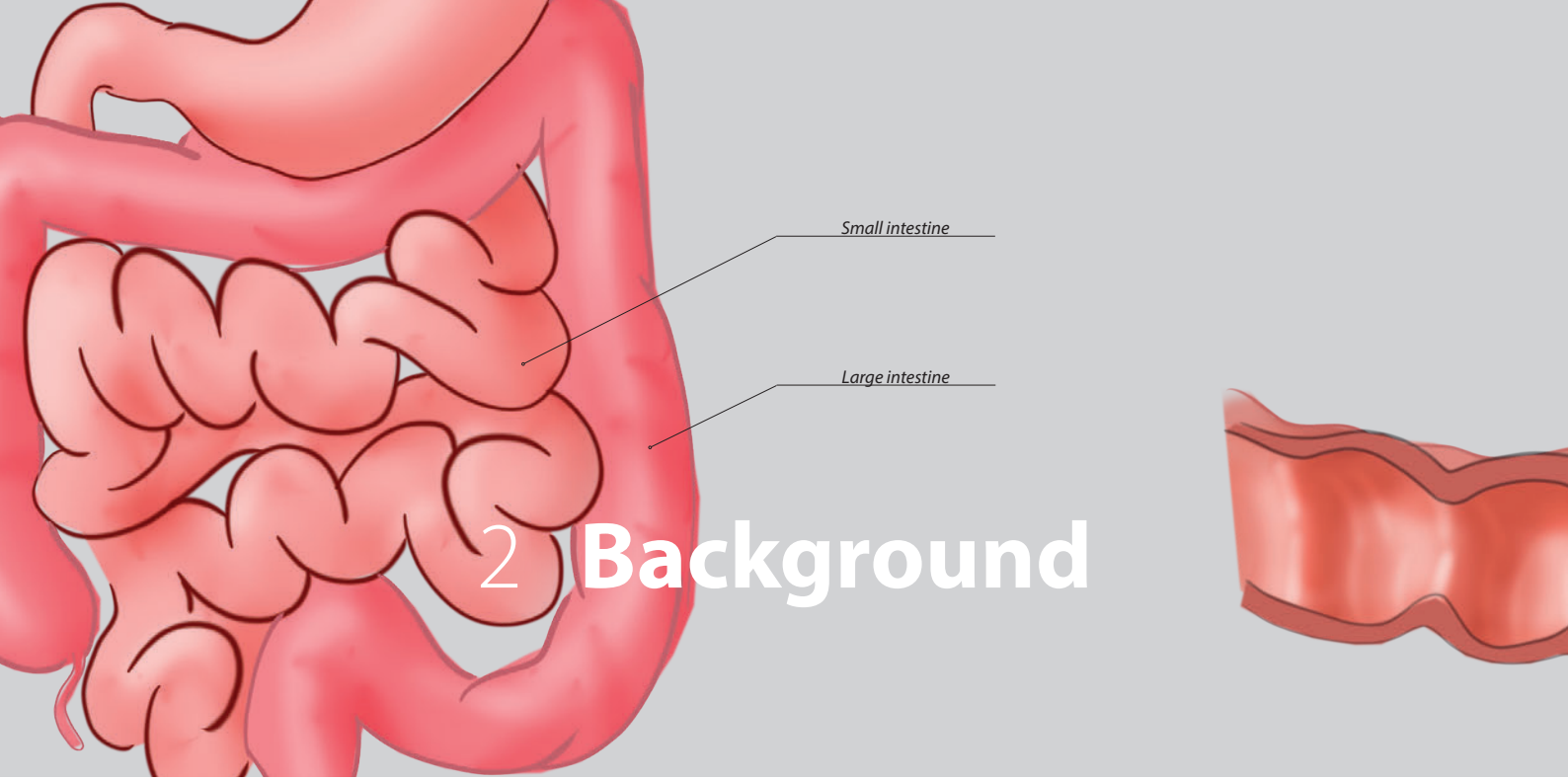
> Fig 1.4. **At the start of the analysis phase mindmaps were made to gain overview of all the factors that could or need to be considered during the project.**


Incorrect Assessement
Data Acquisition
Incorrect data acquisition
Camera Factors
Location to ROI
Camera can't film ROI
Camera can't film ROI in fixed position
Camera can't reach the ROI
Camera may not reach ROI
Camera can't registrate correctly
Camera properties are not sufficient
What is the spectrum range of the camera?
What sensitivity is needed? lux - W/m2
Camera lens insufficient
All wavelenghts come through
What filters are used?
What filters are needed?
Camera properties
Absorption in tissue
Ratio
Constant distance camera to tissue
Operator is not able to set to constant distance
Does not have the tools
Setup is incomplete
not al parts are in the OR
Parts are spread over the OR
Setup is done incorrect
not al parts are in the OR
to difficult
Parts are used incorrect
Upside down etc
No explanation
Does not know how to setup?
to difficult
No explanation
Tissue is constantly moving
What movements can we expect?
Is this controllable?
Does not have the time
Procedure asks for direct measures
Setting up the camera takes to much time
No feedback when distance differs
Region is set incorrect
What sould the region be?
How precise should be sensor be?
What feedback is needed?
for Whom?
System does not function
Sensors do not work
Sensor interferes with measurements
Light interference?
No energy supply
Feedback on malfunction?
Sensor is not sufficient
How precise should be sensor be?
Sensors are to big
Does not know what is the correct distance
No feedback of system
Haptic
only addressed to one person
not noticable
Light
Not sure what the light represents
The light interferes with the data acquisition
Sound
is not distinguishable from other sounds
is to suttle
Not clear were sound if coming from
Feedback is not visable/recognisable
hands
blocked
other equipment
Not in eye sight
Feedback is multiinterpretational
Does not state correct and incorrect
subjected to interpretation
Operator does not know this is important
ROI site is not clear
Tissue blocking view
Tools blocking view
Surgeon cant assess ROI correctly
Site cant be made/held clear due to camera
Camera is too big
Cant fit in/over surgical wound
Sensors takin to mucht place
Surgical wound is to small
Tools are blocking acces
hands are blocking access
System can't make the movement
System is immovable
To less freedom of movement
System is too far away
Cant be moved
Wires are to short
is fixed to location
System cant reach ROI in time
ROI changes
In body
How many ROI are there in general?
How many sides of an ROI do they need to assess?
Why (not)?
outside body
Takes to much time to set camera
Camera may not reach ROI
System is unsterile
Can't be sterilized
insufficient materials
cleaning materials are to aggresive for system
With what sterilization materials do they
Chemicals?
tools?
Materials can't be cleaned
Are there materials that can not be cleaned?
too much cracks etc?
Is too expensive
Takes to much time
What time is given?
Does not fit into crates
How big are the crates?
How high may they be stacked?
May parts touch eachother?
Can not be disassembled?
What parts needs to be sterilized, which not?
How do they keep track of the different parts?
Different sterilization techniques for different materials?
How much time may it take to disassemble and assemble?
Won't be sterilized?
What parts materials are easy to clean?
What parts/materials are hard to clean?
Why? time?
System can't be stored sterile
Where are the tools stored?
How big is this place? measurements
How long are they stored?
Does this affect sterilization?
Should it be packaged?
Does not fit into sterile plastic
How big is the Sterile plastic?
How much time may this take?
Operated by one or two persons?
When is this done?
Pre-surgery
Why (not)?
Peri-surgery
Why (not)?
System becomes unsterile peri-surgery
System is placed in unsterile area during surgery
Where are the sterile and unsterile areas
System is used multiple times
How many times is system used?
When not in use whe
Who placed them on the trays?
Due to incorrect placement on sterile tray
How are they placed on the trays?
procedure?
standerized division/grouping of tray
May parts touch eachother?
What can go wrong?
most tricky part of procedure?
Who to whom?
incorrect pass from unsterile to sterile?
When?
What can go wrong?
System does not meet the MDR
As what category is the system defines?
What requirements are neccesarily for the design?
Does this define the whole system, or can it meet only subsystems?
how are they defines?
System is incorrect
Parts are missing, cant be assembled
Where can parts be missed?
Crates?
Wholes? measurements
unclear how to assemble
System interferes with surgical workflow
takes to much time
To set up
how much time?
To use
how much time?
To clean
how much time?
To little advantage
how much time?
interferes with surgical workfield
occupies workspace
What is the workspace of the surgeons?
What space do they need?
What actions do they perform?
Around Surgical wound
What do they want to have as clear site?
On what light
On omitract
Omitract is not used?
Other equipment mounted on omnitract?
On surgical table
Other equipment mounted on omnitract?
Where does the staff stand?
Around surgical table
Where does the staff stand?
interferes with actions
What tools do they use?
How many people are involved?
Actions pre-registration
What is the workfield?
Where may the camera be plac
What tools do they use?
Where are they placed?
Actionf Peri-registration
What is the workfield?
Where may the camera be plac
What tools do they use?
Where are they placed?
Actions Post-registration
What is the workfield?
Where may the camera be pla
Camera can't film ROI in fixed position
system cant be fixed on location
There is no room
There is no facilitation
omnitract
Omnitract measurements differ
Standard omnitract?
What are they measurements, materials
place is occupied
What tools can be mounted?
Which ones are used (frequent)?
Fixation takes to much time
Surgeons do not want to fix the system
takes to much time/actions to clear system from site
Where is it placed post use?
Who should disassemble it?
Camera position needs to be adjusted to many times
External factors
Light
Environmental light
Heads/body
Shadow
Tools
Hands
Do the shadows interfere with the acquisition?
On tissue
Reflection
On medical equipment
Do the reflections interfere with the acquisition?
Wich ones?
To what extent?
intensity
Varies over ROI
Affects exitation and emitted light wavelenghts
To what extent?
Currently switched off during acquisition
Who turns it off?
Who requist turning off?
Time period of turning off?
Time period of asking to turn of and turning off?
Sufficient?
Are there disadvantages of turning off?
Which ones? why?
Surgical light
Reflection
On tissue
On medical equipment
Nessesarily to use during acquisition? why?
Why is it used?
External light
Reflection
On tissue
On medical equipment
additional surgical light on head
Why is it used?
Nessesarily to use during acquisition? why?
Affects exitation and emitted light wavelenghts
To what extent?
Affects exitation and emitted light wavelenghts
To what extent?
Camera light
Reflection
On tissue
On medical equipment
Nessesarily to use during acquisition? why?
Why is it used?
possible feedback light of system
What light factors interfere the most?
Wavelenghts? i.e. colour
Intensity?
Temperature?
Temperature
Laminar Flow
Affects exitation and emitted light wavelenghts
To what extent?
Can we account/control for this?
Affects exitation and emitted light wavelenghts
Controllable?
to account for in measurements?
Pressure/speed
Controllable?
to account for in measurements?
Injection of agent
Always same amount?
Controllable?
to account for in measurements?
Surgeon
Does not use the system
Camera mount
Hold in hand
On arm
Location
Table
Omnitract
Surgeon
Ceiling
Standard next to table
Movable
Bio factors patient
Differ from settings data acquisition
Temperature
Higher tissue perfusion
Bloodvessels contract
High temp
Lower tissue perfusion
Bloodvessels expand
Low temp
Is this a variable?
Vary throughout data acquisition
Temperature
Higher tissue perfusion
Bloodvessels contract
High temp
Lower tissue perfusion
Bloodvessels expand
Low temp
Is this a variable?
Output Image
Monitor
cant see monitor
Surgeon has to turn to see monitor
takes to much effort to see monitor
Colours are not true
Incorrect specifications monitor
Not enough pixels
output image
Incorrect output image
Input data is insufficient (see data acquisition)
Wrong translation of input data
Software: contrast enhancement function
Software: brightness enhancement function
Poly-interpreter output image
No objective data is given
Subjective data is given
No clear borders are given
Denotation does not represents a constant perfusion
Surgeon
Does not want to use the system
System does interfere with surgical actions
System interferes with general actions
em interferes with emergency actions
Surgeon cant see ROI
Does he need to see it? why?
What does he want to see?
seen image and real?
Can't use the system
System does not comply to MDR
Uses system incorrect
No reference point
Can't see where the camera films
Monitor is not visable
Monitor is not linked
position is incorrect
Distance
What is the range?
Slope
What is the range?
What feedback is neccesarily?
image is wobbely
No fixture
Whitelight is not usable
Only Fluorescence is visable
Surgery
laparoscopic
Not in project scope
Measure distance
How do they do this?
Biological
Different factors
Setup of room
Different procedure?
Staff involved
Different procedure?
Open surgery
Tissue Perfusion
Tumor Markers
What needs to be assesst
Requirments
Organs
How do they do this?
Where are they?
Different procedure?
Region of Interest (ROI)
Clear
How many tools
With what?
Who?
How to clear
why?
How many tools
With what?
Who?
How to keep it clear?
Amount
1
> 1
in same view/sight
in different views
Location
Depth
surface
Smooth or not?
To what extend?
Movable
Need to control while obtaining data?
Software
Hardware
Stabilise ROI
Not by ROI
By ROI
Where does the motion come from?
Fixed
Size
What is the averge size
Do they want to see the whole ROI?
Time
In total?
Per ROI?
How much time do they have to assess?
Fluorescence time
How long?
How long?
time the site may be open
Factors
What are they?
other factors
Distance - fluorescence ratio

Analysis

To gain a solid understanding of the needs to fulfil the assignment a sound analysis needs to be conducted. This will entail literature research, accompanied by own research and observations. First, background information will be given concerning the technique, the reason of use and its opportunities ending with the problem faced for the current state of art of the technique and a main research question for further analysis. Next, a technical analysis will follow concerning a deeper understanding on the working principle of the current used system, which factors do interfere with the technique and how they should be approached in the design. Thereafter, the workflow of the user and its environment will be researched together with the flow wherein the final design will be used. The chapter will close with a conclusion and answer to the main research question.

< Fig 1.5. **Surgical procedure at Catharina Hospital, still from youtube.**



2 Background

Fig 2.1. **Small and large intestine of the gastrointestinal tract.**

In this chapter we will dive into the context of the project. The aim is to develop a common understanding of the technique and procedure that will result in a more focussed technical and workflow analysis.

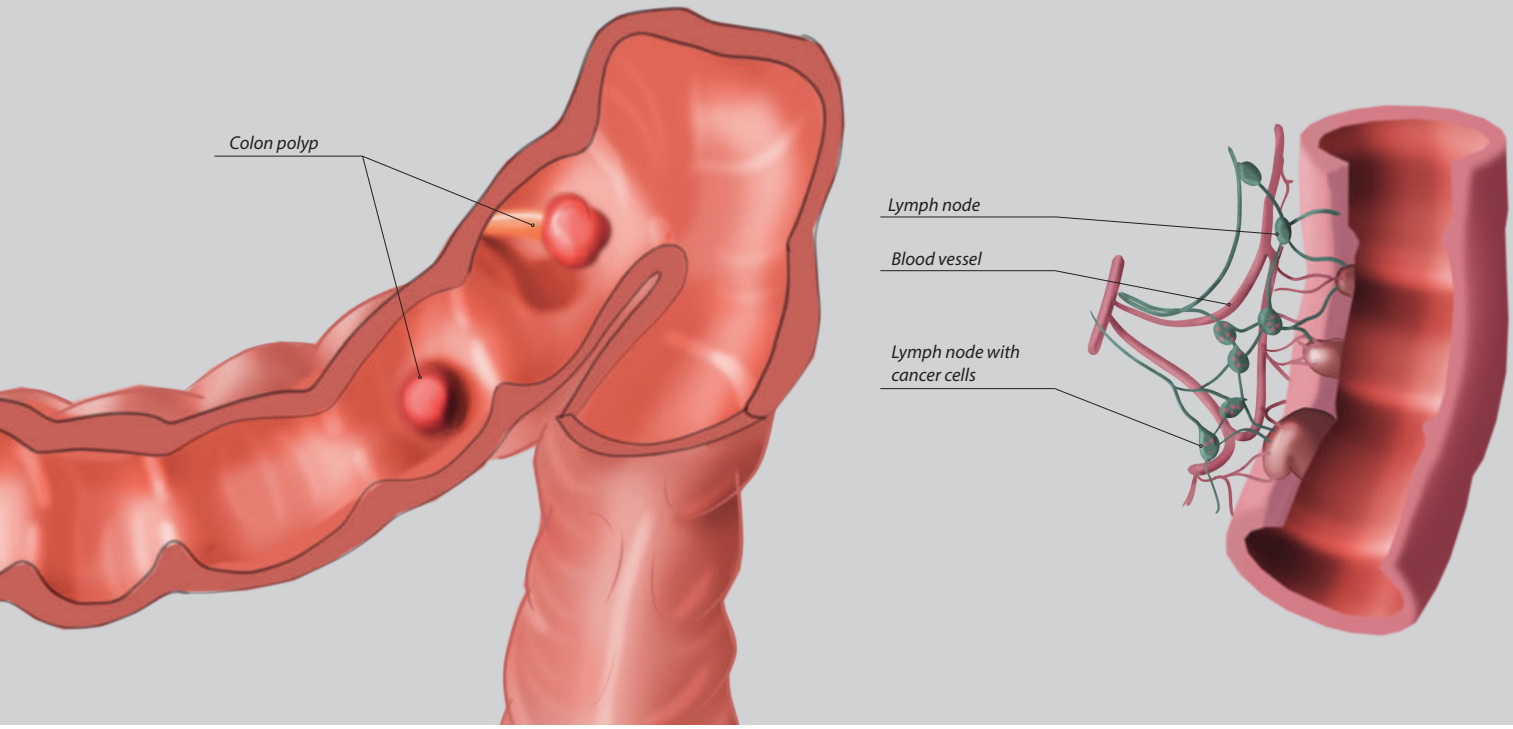


Fig 2.2. left: **Bowel with colon polyps on wall.**
Fig 2.3. right: **Grow of cancer into blood - and/or lymph vessels.**

2.1 Oncology

In 2016 around 108.000 people were diagnosed with cancer in the Netherlands which is a growth of 2,4% compared to 2015 (Nederland Integraal Kankerinstituut, 2018). Integraal Kankercentrum Nederland (IKNL) suspects a rise in new cancer patients in the upcoming years due to, amongst other things, the population aging. Although the number of deaths has increased over the past 20 years, there is a decrease in morbidity from cancer if the growth and aging of the population is taken into account (Nederland Integraal Kankerinstituut, 2018). When cells in the body start to grow out of control and crowd out normal cells, it is called cancer (The American Cancer Society, 2018), see figure 2.2.This project resolves around the consequences of colorectal cancer that is the second most common cancer and the third most common cancer to cause death in Europe according to Ferlay et al. (2013). This cancer type starts in the colon or the rectum and depending on where it starts is named colon- or rectal cancer. Most colorectal cancers start with the growth of a polyp on the inner lining of the colon or rectum, forming an abnormal piece of bulging tissue, see figure 2.4. Not all, but some will change into cancer over time. Roughly there are two types of polyps:

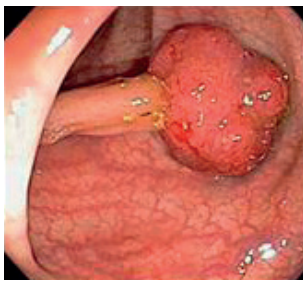


Fig 2.4. **Polyp growth in colon (Bowel Cancer Australia, 2018b)**

- *Adenomatous polyps (adenomas):* a type that is associated to change into cancer and is therefore called a pre-cancerous condition.
- *Hyperplastic- and inflammatory polyps:* a type of polyp which is more common, but in general not pre-cancerous (The American Cancer Society, 2018).

If cancer forms in a polyp, it can grow inside the wall of the colon or rectum and ultimately grow into blood- or lymph vessels (fig. 2.3) and is described in four stages:

- *Stage 1:* The tumour is limited to the mucous membrane or the inner layer of the muscle tissue in the bowel.
- *Stage 2:* The tumour grows through the muscle layer of the bowel.
- *Stage 3:* Metastases in the lymph nodes in the vicinity of the tumour.
- *Stage 4:* Metastases in more distant lymph nodes and/or in other organs and tissue.

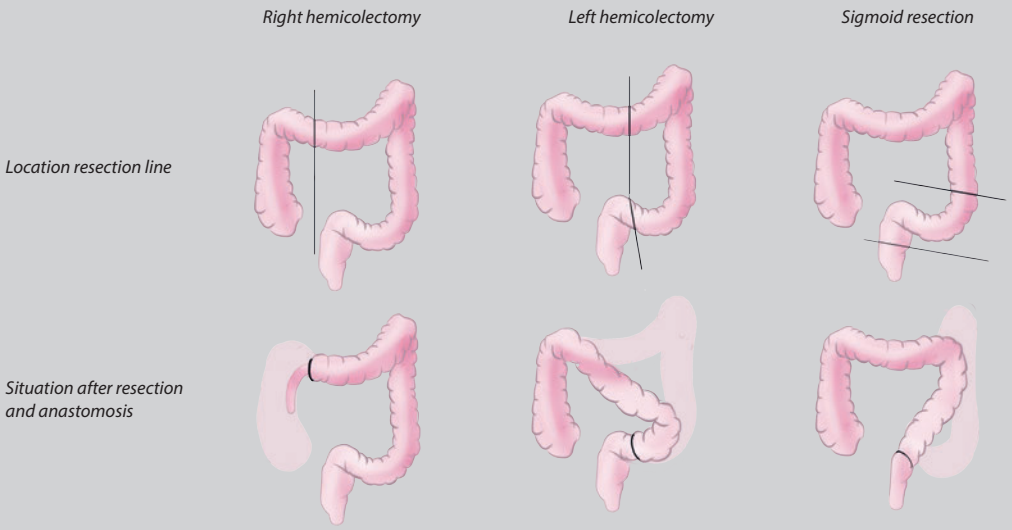


Fig 2.5. **General resection types for colorectal cancer**

With the increase of the above stages the changes of survival drop drastically. Five years after treatment for stage 1, 90 to 100% of the patients is alive. For stage 2 this is 80 to 90% and stage 3 is associated with no more than 35 to 80%. After five years only 0 to 35% of the patients treated for stage 4 are still alive (Vrijland, van Driel-Rooks, van der Spek, & Coene, 2011).

2.1.1 Treatment

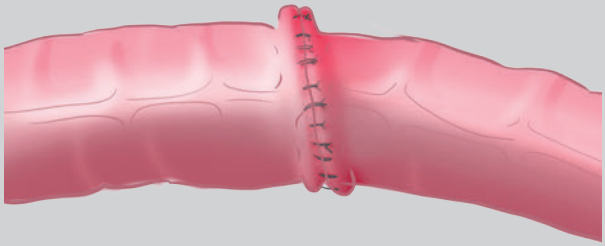
Dependent on the stage the cancer is in, different procedures are required such as surgery, chemotherapy or radiotherapy. For colorectal cancers, surgery is the most common treatment wherein the cancerous or unhealthy tissue is removed operational during open-surgery or laparoscopic surgery. This can involve resection of tissue, organ or parts of an organ. Bowel resection, or partial colectomy, removes the part of the bowel or rectum known to be diseased or cancerous (Staff Healthwise, 2017). The location of the tumour determines the part of the tissue that needs resection. In short three types can be distinguished, see figure 2.5:

- *Right hemicolectomy:* the cancer is on the right side of the large bowel, wherein half of the colon is removed.
- *Left hemicolectomy:* the cancer is on the left side of the bowel, wherein half of the colon is removed.
- *Sigmoid colectomy:* the cancer is found in the sigmoid colon.

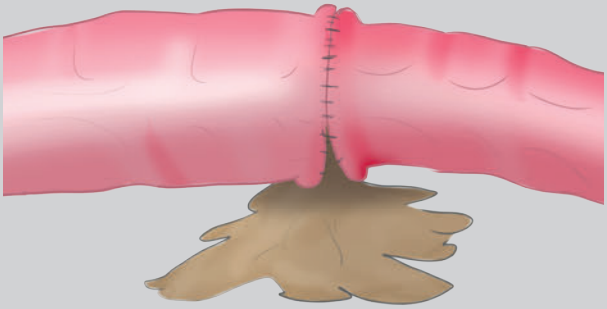
Radiation- and chemotherapy may be given preoperative to shrink the tumour to allow easier removal of the cancerous tissue. These preoperative therapies are called neoadjuvant therapies. But often these therapies are given after the surgery (adjuvant therapies) to kill any cancer cells that are left after surgery (Bowel Cancer Australia, 2018).

2.1.2 Operation

This project will focus on the open kind of surgery. Open surgery requires an incision in the abdomen to uncover the bowel or rectum, after which the surgical team will clamp of the diseased part of the organ and remove it.



Anastomosis



Anastomosic leakage

2.2 Anastomosis

2.2.1 Anastomosis and Stoma

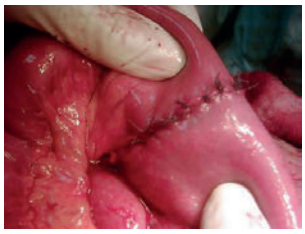
After resection of the diseased tissue piece, the two parts of the colon are sewn back together to make the anatomy functional again, in this case the continuity of the colon or rectum. This surgical connection is called an anastomosis, see figure 2.6 and 2.8. Whether an anastomosis is possible depends on the surgical procedure and location of the resection as these can affect the healing process of the connection. This healing process is strongly related to the blood perfusion of the anastomotic site. When insufficient, healing will be obstructed. The closer the resection is to the anus (the more distal), the higher the risk of poor tissue perfusion (Vrijland et al., 2011). When it is insufficiently safe to make an anastomosis, the surgeon can choose to create a stoma, an opening made on the outside of the body for waste to pass through to be collected into a bag around the stoma, see figure 2.10.

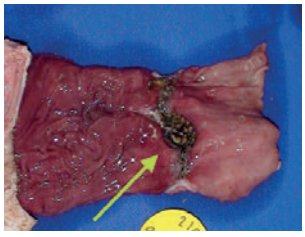
2.2.2 Anastomotic leakage

An anastomotic leakage (AL) is a defect in the bowel wall at the anastomotic site, leading to loss of fluid and content and thereby a severe complication of colorectal surgery (McDermott et al., 2016), see figure 2.7 and 2.9. This frequent and major complication is potentially life threatening for the patient (Degett et al., 2016). Thereby it results in a prolonged hospital stay as re-operation has to be performed, leading to additional patient risk and an undeniable financial impact (Chadi et al., 2016). Anastomotic leakage after resection in colonic surgery ranges between 3% and 19% (Wada et al., 2017) and is dependent on several factors. Gender, location of the AL, metastatic disease, a deteriorated cardiovascular status caused by diabetes or smoking, form some of the non-modifiable risk factors next to intraoperative consideration such as an surgical procedure longer than 4 hours, blood-loss, blood transfusion, surgical techniques, suture material or devices (McDermott et al., 2016) (Boni et al., 2016).

Fig 2.6. **Anastomosis**

Fig 2.7. **Anastomotic leakage**





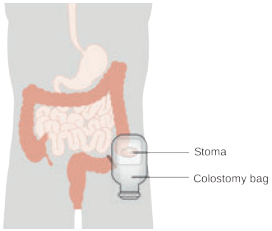


Fig 2.8. **Anastomosis**

Fig 2.9. **Macroscopic anastomotic leakage in deep rectal anastomosis of a pig (Wenger et al., 2015).**

Fig 2.10. **Stoma after colostomy.**

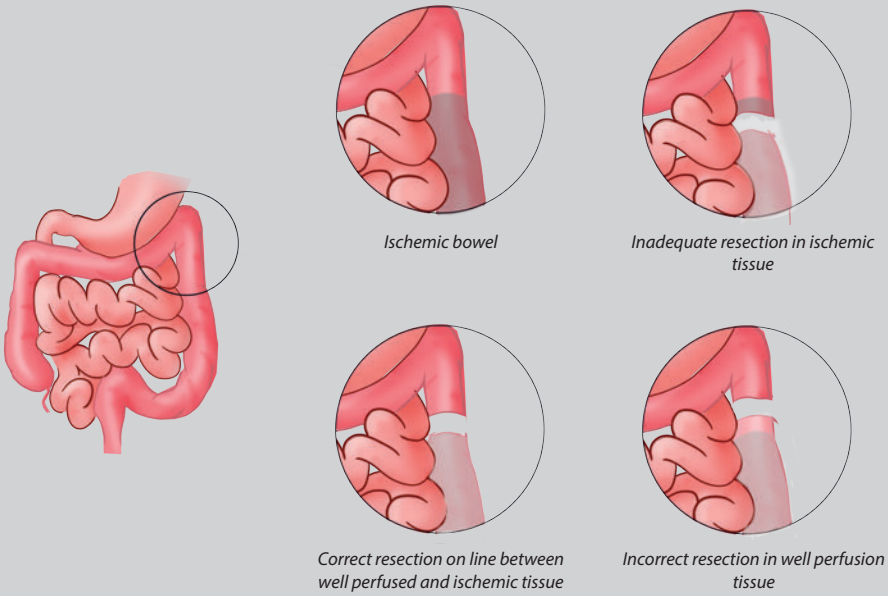
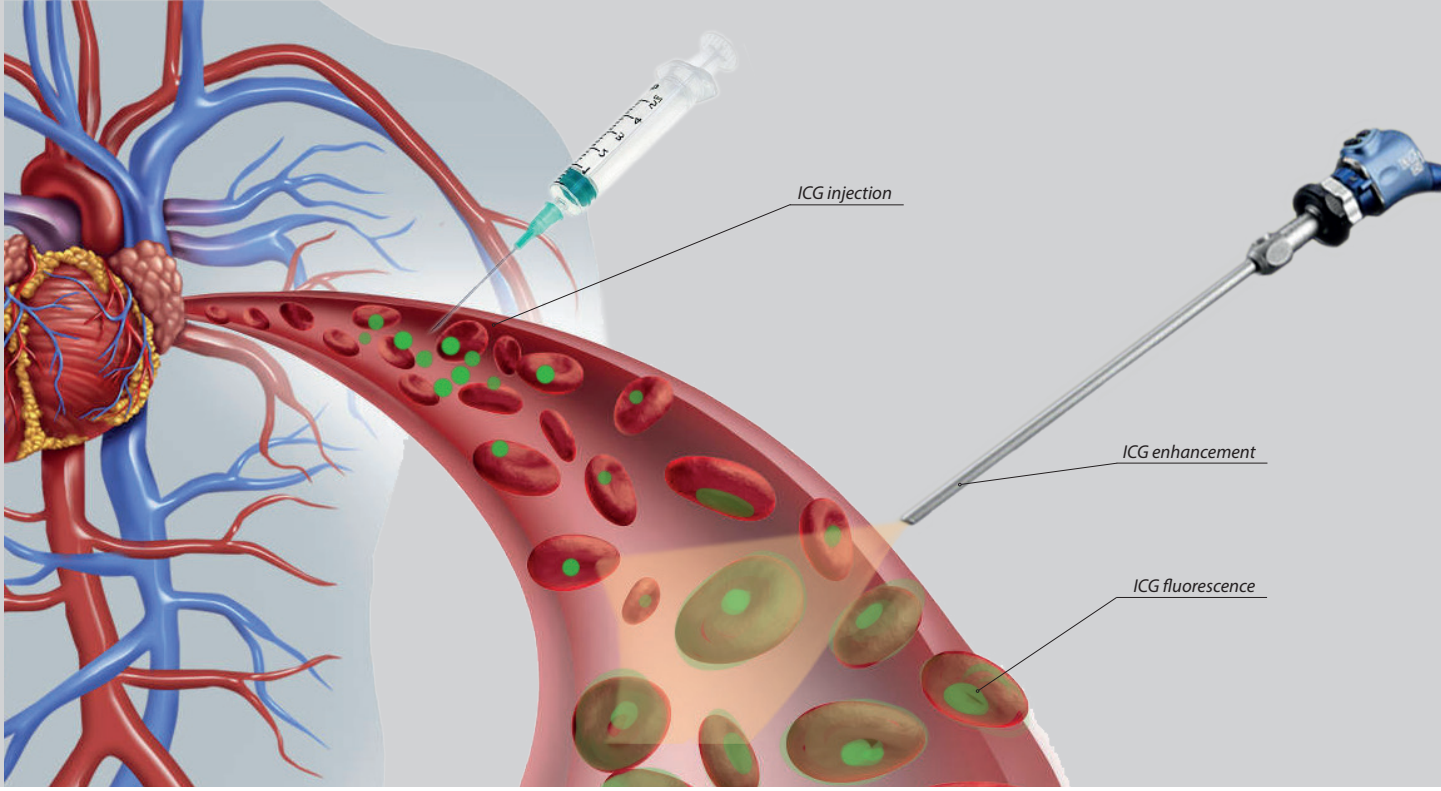


Fig 2.11. **Adequate and inadequate location of resection line.**

2.2.3 Preventing Anastomotic leakage

An adequate blood perfusion of the site wherein the anastomosis is to be made or is made is crucial for a good healing of the wound and thereby prevention of an anastomotic leakage (Kumagai et al., 2016), and thus ischemia of the colon increases the change of an AL. Ischemia may have postoperative causes, such as a diminished blood flow due to a clot in an artery supplying the colon, by bowel obstruction due to scar tissue or tumour (Mayo Clinic Staff, 2015) or as a complication of surgery (Al-Khyatt, Thomas, Humes, & Lobo, 2013). The assessment of this perfusion is an important aspect of the surgical procedure and requires experience. This evaluation of the tissue perfusion determines the place of transection of the bowel, ideally placed in a well perfused area, see figure 2.11. The assessment is done on subjective clinical indicators such as colour of the tissue, bleeding edges and palpable pulsation of arteries. Adequate determination of the resection line and finally the resection is important and must be accurate. Taking too less, and thereby leaving ischemic or diseased tissue to suture, will increase the change of an AL. It would seem a safer option to take too much, ensuring adequate perfusion. However, this will result in less colon length and thus a further reach towards the anastomotic site and can thereby potentially lead to unsafe situations. Not only as more of the colon need to be stabilised, and thus more cutting and prolonged surgical time, but it could lead to higher tensile force on the anastomosis. These higher tension forces will affect the suture and lower perfusion as it will cause blood vessels to narrow.

Thus, adequate assessment of the to be resected tissue piece is important. Still, by the naked eye and manual feedback it is difficult even for experienced surgeons (Nachiappan, Askari, Currie, Kennedy, & Faiz, 2014). Technology can help to adequately assess the tissue perfusion. Imaging techniques make it possible to provide the surgical team with an additional view of the anastomotic site with information that is not visible by the naked eye. One of those imaging techniques is Indocyanine Green Fluorescence Angiography.



2.3 Indocyanine Green Fluorescence Angiography

Fig 2.12. **Schematic drawing showing intravenous administration of ICG. Along the lines of Papadia et al. (2016)**

Indocyanine Green based Fluorescence Angiography (ICG-FA) is a fluorescence imaging technique with a great potential in several areas in the surgical future. The technique can visualise features that are invisible under conventional light and thereby has a significant impact on clinical diagnostics. The technique makes use of fluorescent dyes that can be injected intravenous and that enables, amongst other things, differentiation of malignant tumours from healthy tissue in an early stage or the evaluation of blood perfusion in organs and tissue. This is done by its capability to become fluorescent when near-infrared light (NIR) hit the contrast dye, see image 2.12. The use of this technique improves the surgeon's performance and, consequently, the patient safety. The technique is seen as a safe and simple manner to acquire real-time data without expensive equipment such as PET, X-ray and MRI (Papadia, Imboden, & Mueller, 2016). As ICG fluorescence enhances whole blood, it allows vivid visualisation of the demarcation line between non- and well perfused tissue (Kumagai et al., 2016) and thus is extremely useful for surgeons to adequately access the tissue perfusion of an anastomosis and thereby preventing anastomotic leakage, see figure 2.13.

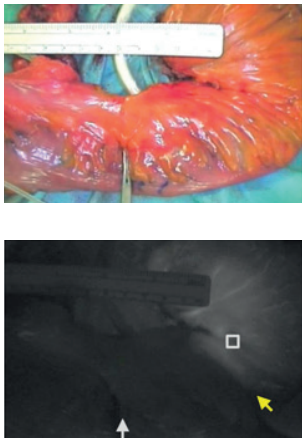


Fig 2.13. **Above: Bowel perfusion under white/visible light. Below: Bowel perfusion under ICG light. Adapted from Wada et al. (2017).**

2.3.1 Principle of fluorescence imaging

In 1852, George Gabriel Stokes observed a rather interesting phenomenon were Fluorite minerals emitted light when exposed to ultraviolet light (Stokes, 1852). This phenomenon, or fluorescence as Stokes coined it, is the emission of light by a material that has absorbed light or other electromagnetic radiation (i.e. excitation light). The phenomenon is caused by sensitivity of delocalised electrons (Papadia et al., 2016). To effectuate fluorescence of the contrast dye, a light source must send out a bundle of light with a specific wavelength to excite the fluorophore. The excitation light travels through tissue to reach the contrast dye, situated under the tissue surface. When this light energy is absorbed by the molecules of a fluorophore, it promotes the delocalised electron from the ground state to a higher energy level. After this phase the electron will return to its ground state as it releases energy and thereby emits the photon. This transition in energy between absorbed and the

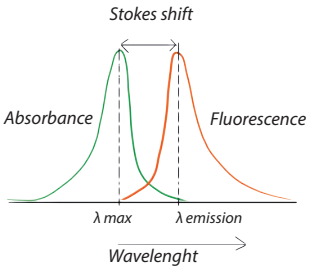


Fig 2.14. **Stokes shift**

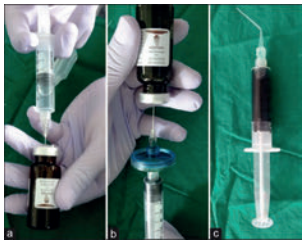


Fig 2,15. **Preparation of Indocyanine Green dye solution. Adapted from Shingnapurkar et al. (2016).**

emitted photon results ultimately in a change in wavelength. The shift of shorter wavelengths of the absorption light to longer wavelengths is called the Stokes shift, see figure 2.14. This emitted wavelengths can thereby be detected by a camera system and makes it possible to differentiate the contrast dye from other objects via a monitor screen (Keereweer et al., 2013).

2.3.2 Fluorescent dye

There are several materials that have fluorescent capabilities. This project focuses on Indocyanine Green (ICG), which is a widely used near infrared (NIR) fluorescent water-soluble dye used in several clinical applications such as intra-operative lymph node identification, tumour imaging, superficial vascular imaging and marking ischemic tissues (Starosolski et al., 2017), see figure 2.15. Indocyanine Green can be administered intravenously where it will bind to plasma proteins causing it to be confined within the intravascular space and make blood perfusion assessment possible. The fluorescence properties of Indocyanine Green are best visible in near-infrared light (λ= 760 – 780 nm) and have a fluorescence emission peak at λ =830 nm, see figure 2.16 (Wada et al., 2017). On account of these specific properties ICG is particularly suitable for medical application as there is virtually no florescent interference from the main components of blood (haemoglobin and water) as for the great difference in their fluorescence emitting spectrum (Papadia et al., 2016). The fluorescence lifetime, or the time the ICG fluosphore spends in the excitation state before returning to its ground state by emitting a photon, is 0.166 nano seconds and thus the fluorescence reaction is almost instant after enhancement by the excitation light (Gerega et al., 2011). The time from ICG injection to enhancement of tissue and vessels ranges from 20 to 120 seconds (Wada et al., 2017). Once enhanced, these obvious enhancements last about 15 minutes, up until the liver secretes the contrast dye into bile (Kumagai et al., 2016).

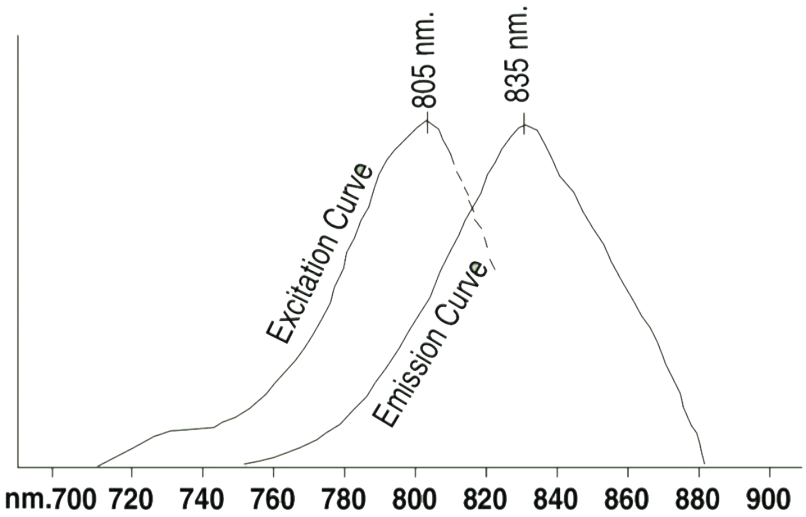


Fig 2.16. **Excitation- and emission spectra of whole blood containing .05 mg/ml of sterile Indocyanine Green.** http://www.akorn.com/documents/catalog/sell_sheets/17478-701-02.pdf**.**

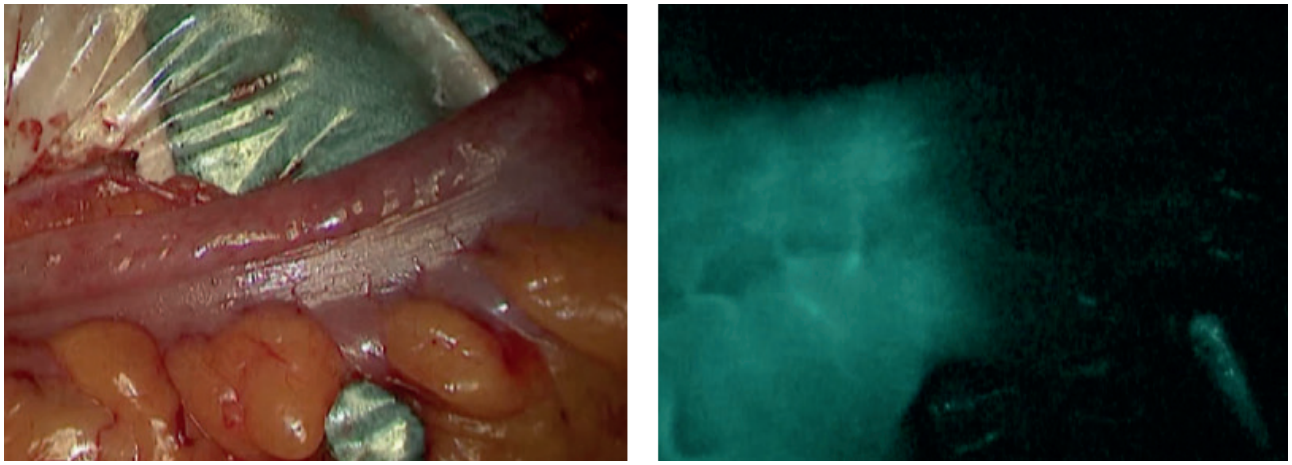


Fig 2.17. **Identification of the ischemic bowel. left; view using white light. right; the view using near infra-red light after injection of ICG. Adapted from Boni et al. (2014).**

2.4 Objective assessment

Although Indocyanine Green Angiography seems to be promising, however the assessment is still subjected to the perception of the individual surgeon, as the image recordings are influenced by various external factors that result in a non-standardised output image that is still open for incorrect interpretation. The intensity of the brightness of the contrast dye, shown to the surgeon on the screen, is not absolute but rather relative, see figure 2.17 and results cannot be compared among patients (Yamamoto, Orihashi, & Sato, 2013). It is known that the ICG fluorescence output images are influenced by the manner of image acquisition. Not only patient's factors and external light conditions may influence the acquisition, but also the distance of the camera to the object, surgery time and even temperature may affect the output images. Therefore, it is important to define these factors and understand them to control and objectify the ICG output images, enabling the surgeon to rely on the objectivity of the ICG output images and is aware of the factors influencing the output image. The aim of this project is to design a prototype that can control the most important factors to gain a more objective output image.

The main research question in the analysis part will be:

'How can design control the external factors bound to a subjective ICG output image and improve its objectivity?'

3 Technical

Fig 3.1. **Camera with sterile sleeve (Austvet Endoscopy, n.d.).**

This chapter will cover the technical analysis of the project and will entail the following subjects:

- **Light influence on ICG angiography**
- **Light in the operating theatre**
- **Patient factors**
- **Surgical Factors**
- **Medical Device Regulation**
- **Light measurement**
- **Conclusion**

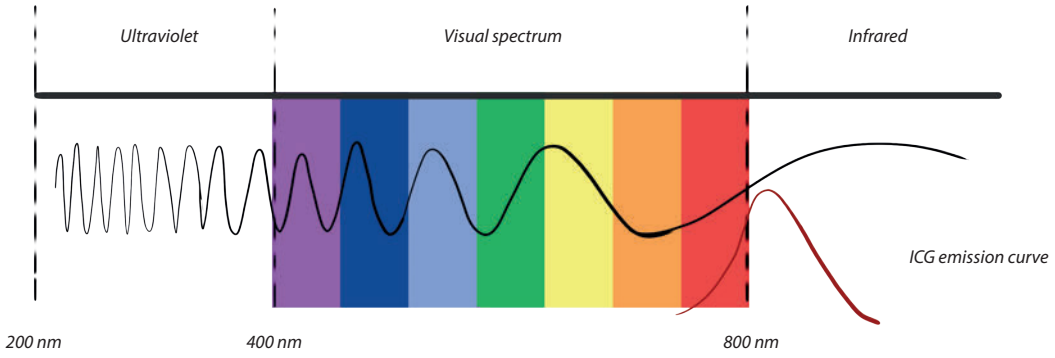


Fig 3.2. **Light spectrum with ultraviolet, visual and infrared spectrum. Note the ICG emission curve in the visible and infrared region.**

3.1 Light influence on ICG angiography

An important (external) factor that needs to be considered is the light involved during the acquisition of the fluorescence of the contrast dye. To understand how light will interfere or interact with the emitted light of the dye, a solid understanding on the phenomenon of light is needed. In this chapter this phenomenon is explained and how it interacts with the ICG acquisition.

3.1.2 Light

Light is a part of the electromagnetic radiation spectrum and is a form of energy that travels in waves with a speed of nearly 2.99×10^8 m/s in a vacuum (Ryer, 1997). White light contains an equal mix of wavelengths of the visual spectrum. Light we perceive as a colour does emit an uneven mix of wavelengths, see figure 3.2. Each wavelength corresponds to a spectral colour. The human eye can observe wavelengths from 400 to 700 nm, known as the visible spectrum. Outside this spectrum there is infrared, with wavelengths between 700 and 1000 nm and ultraviolet between 200 and 400 nm. We can describe light by its wavelength, see figure 3.3, energy and frequency. Light can be described by its photon energy; the energy that is carried by a single photon. This amount of energy is proportional to the wavelengths. The higher the wavelength, the higher the photon energy. To promote a decolonised electron of ICG, a certain threshold of energy is needed and thus not all wavelengths can enhance the ICG. The optical intensity, or the optical power of the light per unit area, is the product of photon energy and photon flux, the number of photons per second per unit area (Paschotta, 2017). This power density is calculated by multiplying the energy of the photons by the photon flux, resulting in the energy that strikes a surface per unit time (W/m^2) (PV Education, 2018). Another term often used expressing the power of light is lumen (lm), which takes the varying sensitivity of the eye for different wavelengths into account (Jung, Mattsson, & Bridge, 2008).

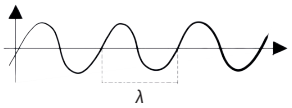


Fig 3.3. **Schematic view of wavelength λ [nm]**

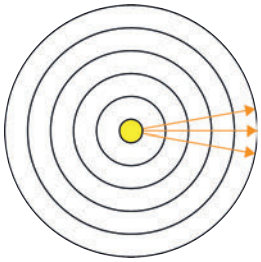


Fig 3.4. **Light rays propagating equally from light source.**

3.1.2.1 *Brightness*

Light propagates equally to all directions from a light source (Keiser, 2016) and thus the slope of the observer towards the light source is not a factor that will decrease intensity, see figure 3.4. Nevertheless, the density of the propagated light, and thereby its intensity, will decrease as the light source becomes more distal according to the inverse-square law. Depict a spherical screen around a light source with a radius of 1 and a surface area of $4\pi r^2$, see figure 3.4. The total number of photons per second that will hit this screen will be the same for a second screen with a radius 2 and thus more distal from the light source. The density of the photons will decrease by a quarter as they are distributed over 4 times the area. And thus the photon density and thereby the intensity of the light will quadratically decrease or increase as a function of distance from a light source (Lavalle, 2016). The same applies to the fluorescence intensity of the contrast dye and therefore standardisation of the distance from camera to tissue is important. Not only the distance can affect the observed brightness of the ICG fluorescence but also the concentration of the contrast dye does affect the intensity, see figure 3.5.

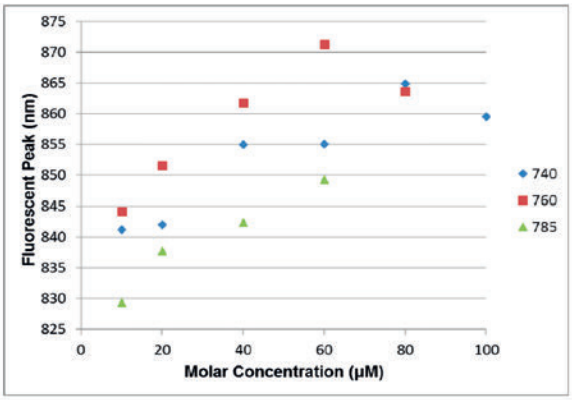


Fig 3.5. **Average pixel values of images when the distance between the ICG and excitation light (740 nm LED) were changed (150, 200, 250). n=3. Adapted from Hong, Kim, Lee, Sohn, & Kim (2016).**

3.1.3 Tissue penetration and reflection

Before the excitation light can enhance the contrast dye, it needs to travel through the above lying tissue to reach the blood vessels inside the intestines. The same goes for the emission light before it can hit the camera. The reach of the light, or penetration depth, depends on the light and tissue properties, see figure 5. When light strikes a surface of a material multiple behaviours can occur, namely: transmission, reflection and absorption, see figure 3.6. Usually all the three behaviours occur simultaneously.

3.1.3.1 *Propagation and Scatter*

The energy of the light travels through the material and exits on the other side. The transmitted light rays are slowed down in certain materials and bend (refracted) according to Snell's law wherein the degree of refraction depends on angle of incidence and material properties (Greivenkamp, 2004). The more perpendicular the ray of incidence of the excitation light is to the tissue, the less refraction will come to play and thus the transmission through tissue will be greater. In case the material is not transparent, such as tissue, the rays scatter into various directions before exiting, called scattering. Scatter takes place when the photon atoms change the direction of propagation due to different tissue structures and inherent different refraction indices. Ultimately scatter limits the light penetration, however there is a gradual increase in skin penetration of light at longer wavelengths (Fodor, Ullmann, & Elman, 2011).

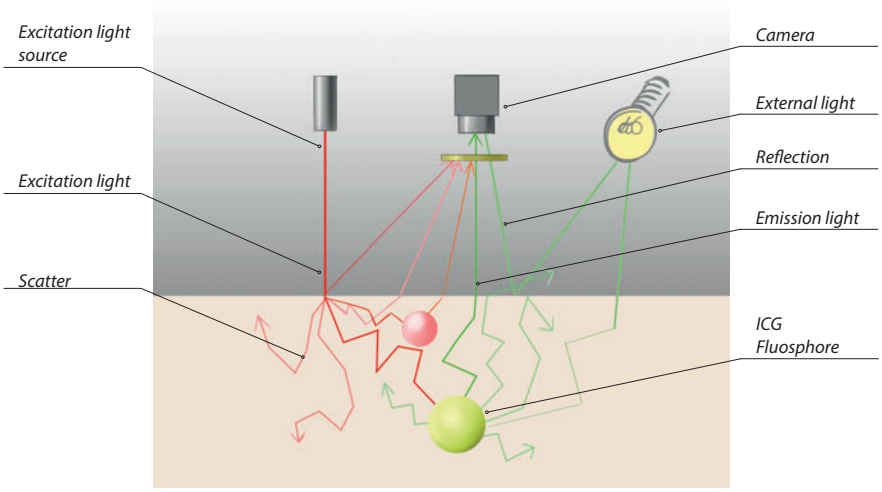


Fig 3.6. **Behaviour of light striking a surface.**

3.1.3.2 Reflection

If light is deflected from the surface it is called reflection. The manner the light reflects depends strongly on the surface properties of the object. A smooth or polished surface (e.g. blood) will reflect the rays in the same way: the exit angle is equal to the entry angle, called specular reflection. In case the surface is rough the light will reflect in arbitrary directions; called diffuse reflection (He et al., 1991). According to Fodor, Ullmann, & Elman (2011) the amount of light that is reflected decreases with the decreasing angle of incidence and the least reflection will occur when the light hits the tissue perpendicular.

3.1.3.3 *Absorption*

The contrast dye is not the only component inside the tissue that will absorb the excitation light. Hemaglobin and water are the principle optical absorption molecules in the living body (Fodor et al., 2011). The first maintain strong absorption properties of light waves up to 600 nm, while the latter has strong absorption against wavelengths larger than 900 nm. In general, the permeability of light in the living body is poor and the penetration depth of visual light has a maximum of 3 mm. However, the near-infrared wavelengths of the excitation light and emission light of ICG can penetrate to relative deep tissue as the absorption of hemaglobin and water is low (Shikayama, 2016), called the optical window. Thereby, the scatter of light is depended on its wavelengths; the longer the wavelength the lower the scatter. On these abilities the Near-infrared wavelengths of the excitation light (750-800 nm), but also the ICG emission light (600 - 900 nm) can be visualised up to 5-10 mm of depth (Ishizawa, Saiura, & Kokudo, 2016), see figure 3.7. Nevertheless, because of absorption by blood the fluorescence signal in organs with high blood volumes, such as the liver or highly vascularised tumours may seem lower when surrounded by less-absorbing tissue. Likewise, less-absorbing tissue (e.g. cysts and lymph nodes) may seem brighter. This variety in absorptions and scattering between the different tissues has to be considered during image-guided surgery (Keereweer et al., 2013).

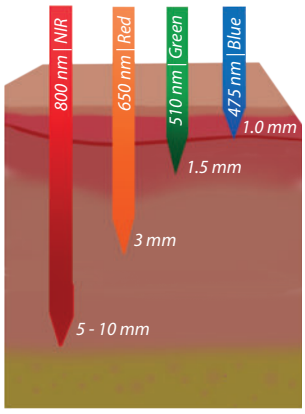


Fig 3.7. **Light penetration depth in tissue. Along the lines of Keereweer et al. (2016).**

Thus, not all photons of the excitation light will and can result in emission photons of the ICG. This ratio of absorbed and emitted photons is called the Quantum efficiency (Q.E.) and is usually expressed by:

$$Q.E.(\%) = (\text{Fluorescence} / \text{Excitation}) \times 100\%$$

This efficiency is dependent on the factors mentioned earlier and the ICG concentration. According to Kusano, Kokudo, Toi, & Kaibori (2016) the Q.E. of ICG is common to be 1.2%, however they do state that the relationship between the concentration and fluorescence intensity is nonlinear and thus quantitative measurements are difficult. Consequently we see in research of Malachowski & Zmija (2010) a Q.E. for ICG in water of 4%. Nonetheless, they do state that this percentage is lower for ICG in blood. As a reference we will therefore take a safer ICG Q.E. of 5% for this project to estimate the amount of interference of external light.

3.1.4 Autofluorescence

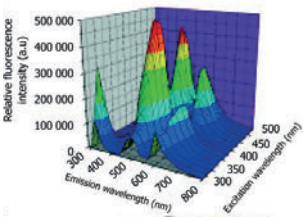


Fig 3.8. **Autofluorescence spectra for normal colonic tissue. Adapted from Li & Xie, 2005)**

The contrast dye is not the only material that has fluorescence properties. Autofluorescence is the fluorescence of, among other things, amino acids in the tissue by enhancement of the excitation light. When this autofluorescence is in the same spectrum range of the ICG it could result in false positives and thus, it is important to know the autofluorescence of colonic tissue in a wide range of excitation wavelengths. According to Li & Xie (2005) the primarily fluorescence peaks in normal colonic tissue occur at the excitation-emission wavelengths pairs of 280-330, 350-330, 350-480, 350/460-605 and 460-520 nm. In adenomatous colonic tissue additional emission peaks at 635 and 710 nm were observed, see figure 3.8. To conclude, the autofluorescence on colonic tissue, in normal and cancerous state, is low to non-existing for the emission spectra around 800 nm and for the excitation lights lower or equal to 520 nm. Exposure to light spectra from 280 up to 520 nm will most probably not result in autofluorescence of colonic tissue in the ICG spectrum. Still we must note that precise autofluorescence spectra of colonic tissue with ICG excitation light remain unclear. However, according to Shikayama (2016) ICG fluorescence is not affected with big issues of autofluorescence by surrounding tissue due to its unique optical window.

Fig 3.9. **Karl Storz system. System, scope, D-light & camera.**

3.1.5 Light and equipment

Other aspects to be considered are the camera properties. At the Catharina hospital the Karl Storz system is used for the assessment of tissue perfusion, see figure 3.9, and exists out of several units, among which: a camera head, an image processor, a Karl Storz D-light light source and a laparoscope. The camera used at the Catharina Hospital is the TH 102 H3-Z FI of Karl Storz.

3.1.5.1 *Dynamic range*

An important camera property influence on the measured intensity of the contrast dye is its dynamic range. It describes the ratio between the maximum and minimum

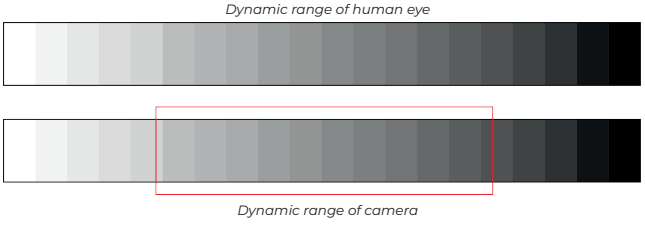


Fig 3.10. **Dynamic range**

measurable light intensity. By means of this property recorded intensities depend on the maximum and minimum intensity, see figure 3.10.
In figure 3.11 two images of the Karl Storz camera are shown. In both pictures pixel one has the same intensity. Nevertheless, due to a higher surrounding intensity (i.e. the surrounding pixels) the light intensity of pixel one seems lower in figure 3.11, as it causes a shift in the dynamic range. The same can happen due to reflection of light on tissue. To overcome this effect, the dynamic range of the camera should be wide, or the light intensity of the acquisition site should not contain high or low peaks. These high peaks, or bright spots, can be caused by direct reflection on the surface; also known as glare.

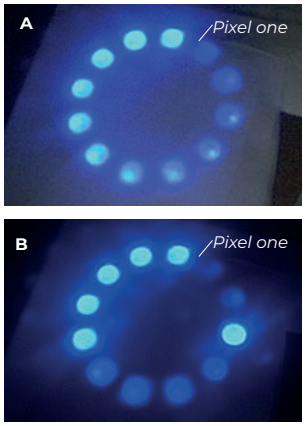


Fig 3.11. **Karl Storz camera view influenced by different observed intensities. A: pixel one surrounded by other pixel intensities. B: pixel one surrounded by higher pixel intensities, whereby observed intensity of pixel one decreases.**

3.1.5.2 *D-light & Scope*

The white light and NIR-light of the Karl Storz system is provided by the Karl Storz D-light, see figure (x). The white- and NIR light both have the same exit. They can be turned on and off individually. The brightness of the white light can be adjusted and is usually set to 50% during the procedure. Furthermore, the device has a standby mode, that will lower the brightness of the white light to a minimum. To a complete exclusion of the white light the D-light should be switched off or the ICG mode should be switched on. The camera is attached to a 30 or 0 degree rigid 10-mm laparoscope to collect white- and ICG light for respectively the visualisation of the anatomical conditions and detection of the ICG (Schols, Bouvy, van Dam, & Stassen, 2015). The light travels through the laparoscope via glass fibres. The camera can still turn on its Y-axes when mounted on the scope, and thus can still be adjusted to a correct view when the scope is fixated on a mechanical arm.

3.1.5.3 *Excitation light*

The spectrum of the Karl Storz Excitation light is measured in a dark box, see figure 3.12. and spans from 660 to 810 nm, see figure 3.14. The assumption is that when an image is taken with the Karl Storz camera, a black image would appear as the excitation light would be in a lower wavelength spectrum than the ICG emission light and both would be parted by means of filters. However, it is observed that the camera makes a registration of reflectance of the excitation light on the spectroscope, see figure 3.13. In an assessment situation reflectance of excitation light on tissue will ultimately be registered as being fluorescence of the ICG and consequently can result in false positives. Though, it should be noted that this reflection might be eliminated due to absorption of this excitation light by tissue and contrast dye. To exclude any false positives of ICG fluorescence due to

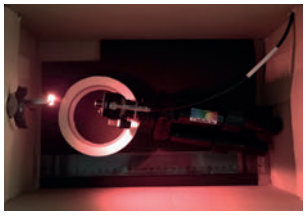


Fig 3.12. **Measurement of excitation light in dark box.**

Fig 3.13. **Karl Storz image, observed reflection of excitation light on spectroscope.**

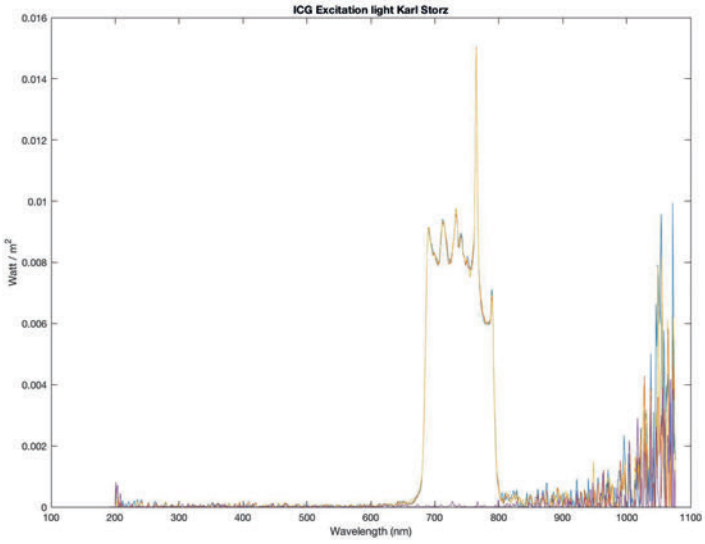


Fig 3.14. **Excitation light spectrum**

reflectance of excitation light, the emission light spectrum and that of the excitation light should not interfere. Currently we see an overlap in excitation and emission light. Whether the two spectra could really be separated would be a valuable research, but not feasible within this project.

3.1.5.4 *White light*

To control the fluorescence of the ICG, a controlled excitation light should be applied, as fluorescence of the ICG is subjected to the amount of excitation photons. Figure 3.15. shows the excitation light of the Karl Storz and the white light of the Karl Storz on 50% of its intensity. It is visible that the two do overlap, which results in an enhancement of the ICG by both excitation- and white light. This will result in a change of fluorescence intensity when the white light is altered in intensity or is switched off. To overcome this issue, the white light should be adjusted to a spectrum that does not interfere with the excitation light or should be set to a standardised intensity.

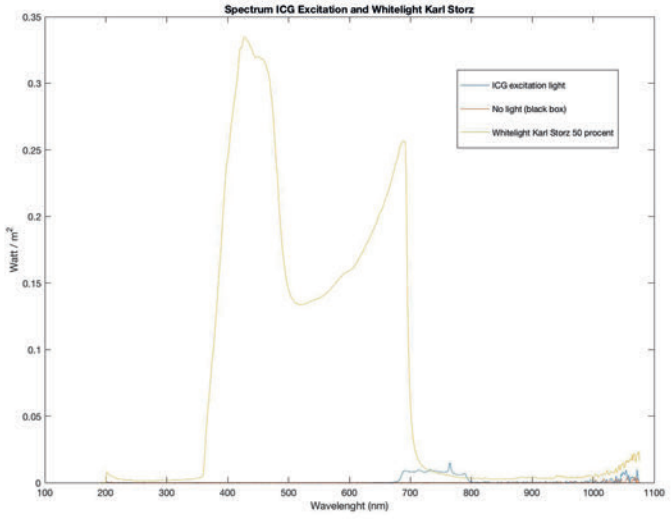


Fig 3.15. **White light spectrum (yellow line) and ICG excitation light (blue line).**

3.1.5.5 *Camera working principle*

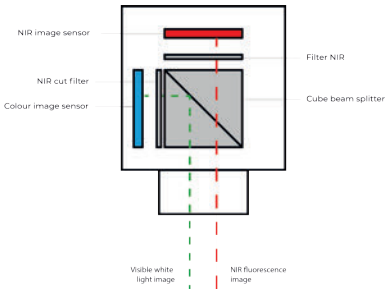


Fig 3.16. **Working principle of Karl Storz ICG camera.**

The light that enters via the tip of the laparoscope whereupon the camera is attached is redirected to different sensors by means of a cube beam splitter. This splitter 'divides' the incoming light into specific spectra and by doing so a coloured image and an NIR fluorescence image can be created, see figure 3.16. This implies that adjustments to only the white light or the NIR light should be done inside the camera (i.e. behind the cube beam flitter) otherwise both will be affected and could affect the penetration depth of the excitation light.

3.1.6 Glare & bright spots

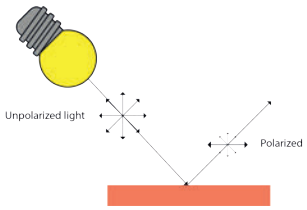


Fig 3.17. **Polarised light reflection.**

Glare is the reflection of light that washes out image contrast and blocks image features by excessive and uncontrolled brightness and is therefore closely related to and may challenge the earlier discussed dynamic range of the camera. In the ICG procedure this can lead to overexposed images that lose information due to 'bright spots'. When the ICG image is later registered on the white light image, some information on ICG intensity or anatomical view could not be visible, see figure 3.19. The glare is caused by reflection on tissue or other materials, such as surgical instruments and retractors. To minimise hinder from reflectance of the latter some instruments have a matted finish or get less reflective by means of dried up blood, a trick that is often used by the surgical team (de Weert, 2005). This issue does not solely apply to the white light, but also affects the infrared excitation light. The possibilities to decrease glare are shown in figure 3.18.

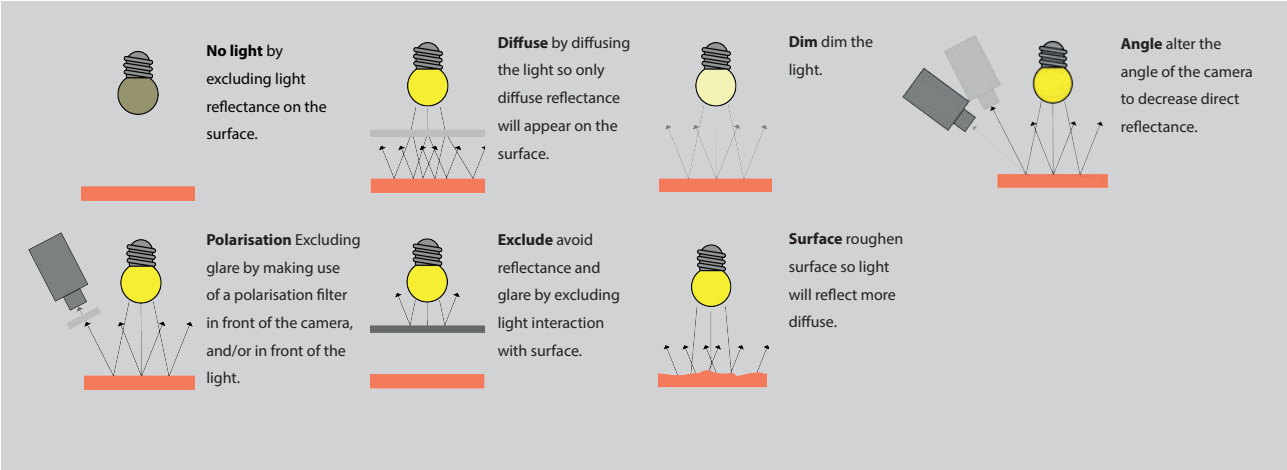


Fig 3.18. **Possibilities to decrease glare.**

3.1.6.1 *Anti-glare filter*

When light reflects upon a surface it can become polarised and form a high intensity as it travels in a more uniform direction. Normally a light wave vibrates in multiple directions or planes, but when polarised it vibrates in one plane more than the other and thus can form extremely bright regions, see figure 3.17. To overcome this, a polarisation filter can be applied that only allows certain vibration directions. Nevertheless, when polarised light in a specific direction hits a diffuse surface, most of the light becomes randomly polarised and reflects in arbitrary

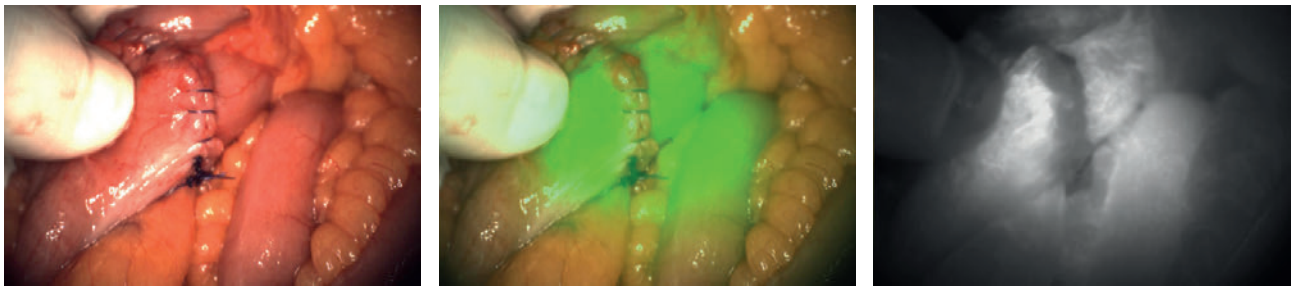


Fig 3.19. **Colorectal anastomosis; a new connection between colon and rectum. A: white -light anatomical image, B: Registration white-light and ICG image. C: solely ICG image. Adapted from Quest (2018).**

directions. However, areas where strong reflections exist, preserve much of the polarisation angle of the incoming light. According to Matthijs van Hemstum (personal communication, May 30, 2018) the best way to decrease glare due to polarisation is therefore to use two polarisation filters; one in front of the light source and one in front on the camera. By placing a polarizing filter on the camera lens, rotated perpendicular to the angle of polarisation, strong reflections of the polarised light will be absorbed. Diffused light from the area where no glare exists is then transmitted to the camera lens, reducing the effect of glare, see figure 3.20. A downside of anti-glare filters is that not all reflectance demands the same filter angle, hence the filters should be adjusted and turned to the most ideal situation wherein the least bright spots appear.

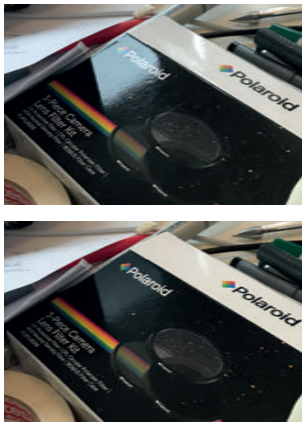


Fig 3.20. **Test with polarisation filter. A: without polarisation filter. B: with polarisation filter. Still the amount of glare is heavily subjected to slope.**

3.1.6.2 *Diffuse*

Another possibility that is researched to decrease or even eliminate glare is by diffuse light. Figure 16 shows the results of a test with a LED light behind different diffuse filters (under the same angle) on a phantom model. We see some slight changes in the light conditions, however the observed different in bright spots seems negligible. The angle seems to play a greater role. Figure 3.22 shows images of light under different incidence angles with one of the diffuse filters.

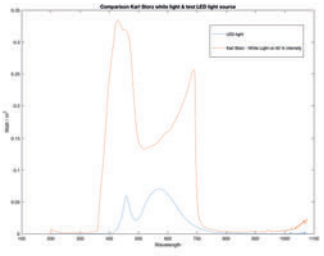


Fig 3.21. **Comparison test LED source and white light of Karl Storz on 50% of its intensity.**

3.1.6.3 *Intensity*

Next a test with different light intensities is conducted. Figure 3.23. shows 4 different light intensities. The LED source that is used for the test in comparison with the Karl Storz white light is seen in figure 3.21. We see that lowering the intensity does have an influence on the contrast of the images. However, it must be noted that the camera whereby the tests are conducted does influence the output image by its software and we must consider that the intensity of the test LED source is significantly lower than the Karl Storz. We observed that the overall brightness did decrease, however did not have a strong effect on the bright spots.

3.1.6.4 *HDR*

Another manner to overcome or decrease the issue of bright reflections captured by a camera is to make use of a High Dynamic Range function. In this function the camera takes more than one photo with different contrast settings and calculates an average between the highest and lowest intensity of a point. This could be an option for the anatomical view but not for the ICG as it will not provide a true image.

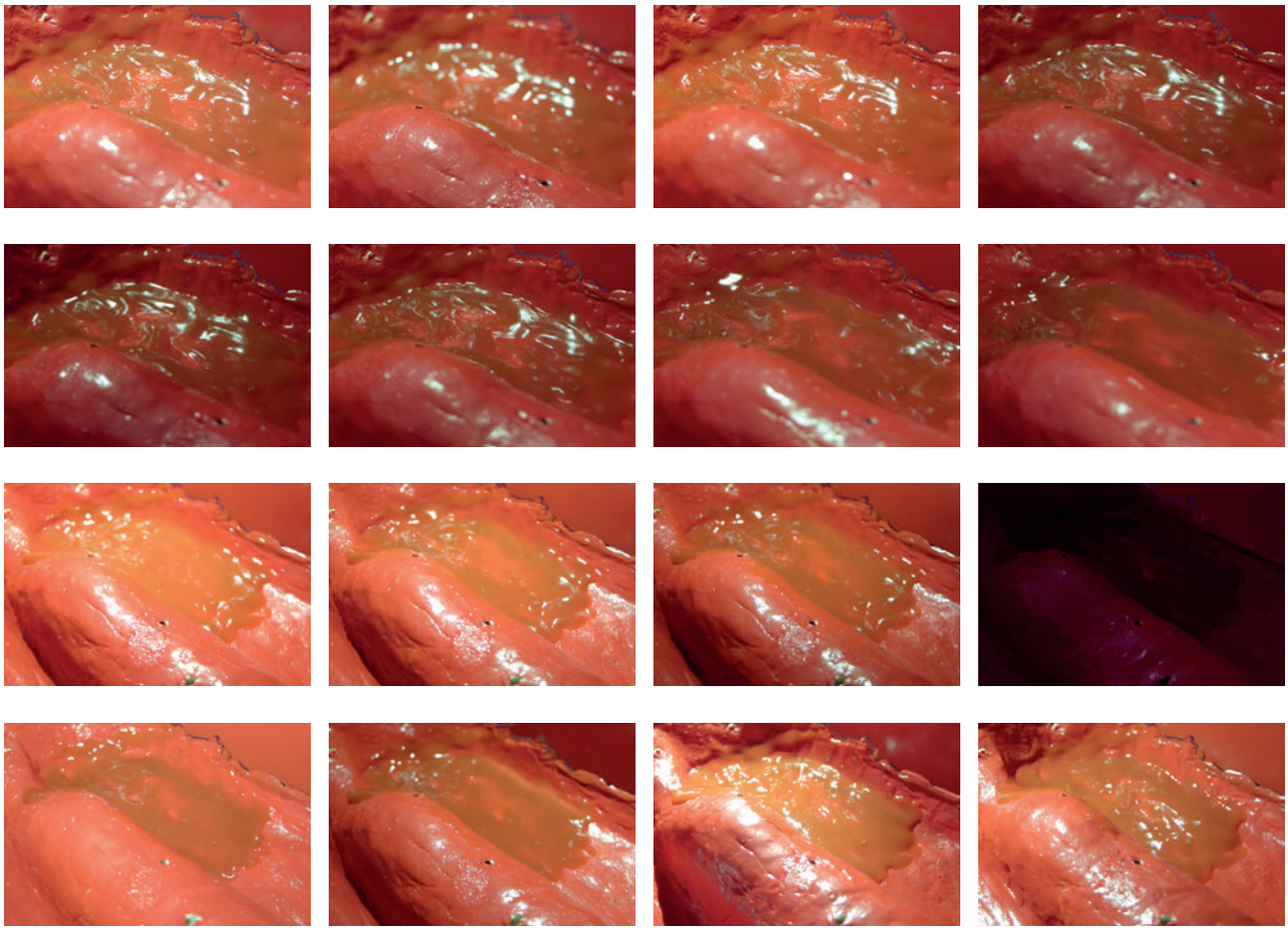


Fig 3.22. **Different light filters before LED light. A: no filter. B: Filter 1. C: Filter 2. D: All Filters.**

Fig 3.23. **Different angles with diffuse filter before LED light.**

Fig 3.24. **Different light intensity. Change in contrast of camera. No great difference in bright spots observed.**

Fig 3.25. **Different angles. A: light in line with cam. B: Light from right side. C. Light in opposite angle as cam. D. Light from left side.**

3.1.*6.5* *Angle of incidence*

As seen in figure 3.23. different light angles seem to have a great impact on the observed bright spots. In figure 3.25. different angles of incidence are tested. When the light comes from the opposite angle to the position of the camera the bright spots seems to increase, see figure 3.25. We observed a decrease in the bright spots with an angle of incidence of the light source in line with the line of sight of the camera.

3.1.7 **Conclusion**

Light from a point propagates equally to all directions and thus its observed

intensity is not affected by the slope of the camera to the object. Nevertheless, the observed intensity is related to the distance of the camera to the object. Captured fluorescence intensity depends not only on distance but also on ICG concentration and should be considered during the procedure. The aforementioned slope does affect the propagation and reflectance of light trough and on the tissue. When the excitation light hits the ROI (tissue) perpendicular, it is assumed to have a deeper penetration depth as it would limit possible occurrence of reflections on the surface and scatter inside the tissue. The Karl Storz system has an excitation light that ranges from 660 to 810 nm and does contain a white light with a spectrum that violated the region of the excitation and emission light (approximately 650 to 850 nm). Therefore, this white light should have a standard intensity when an ICG procedure is performed to ensure a controlled enhancement of the ICG or should be altered by means of filters. Glare, produced by reflection of light, can challenge the dynamic range of the Karl Storz camera and will result in bright spots on the image and so cause loss of information. To overcome this issue the camera properties could be reconsidered, or the lighting conditions changed. The latter can be changed by means of polarisation- and/or diffuse filters or lowering the light intensity. Nevertheless, these bright spots are still heavily affected by the angle of incidence of the light, and as the surface of the ROI knows several angles it might be hard to control. Thereby, making use of filters can only be applied to the white light, as it will otherwise decrease the penetration depth of the excitation light. And as for the construction of the camera and scope using filters in front of the scope is not possible. These filters should be built inside the camera, or an additional light source should be added. Otherwise both excitation and white light will be filtered. Thereby, it is highly likable that the camera already contains polarisation filters.

3.2 Light in the operation theatre

Proper lighting is of the utmost importance for the surgical team to execute a surgical procedure. The lighting must comply to high standards and requirements and may not hinder the surgical team due to, amongst other things, formation of shadow or due to brightness (de Weert, 2005). To avoid hinder of heavy luminescence of the blood the general light in the operation theatre is somewhat blue of its colour. To shine light in the deepest regions of the surgical wound the light from the lamps above the surgical table is converged into a focus point that is placed at the wound or skin height. From this point it divergences to enlighten the whole surgical wound that is often wider than the edges of the wound. According to Centre for Evidence-Based Purchasing (2010), task lighting, such as head lights, is the best solution to lighten otherwise difficult areas of the body, such as the abdominal cavity. The use of such headlights is also seen during the project's observations. The near-infrared (NIR) fluorescence signal from the ICG is usually weak in comparison with the NIR wavelengths transmitted from the surgical lights, resulting in a negative impact of these light on the fluorescence image (Zhu et al., 2014). Therefore, they are switched off during an ICG-FA procedure at the Catharina .

3.2.1 Lighting conditions

For the surgical team it is important to have a true view on the anatomical sight, meaning that the colours are true and not altered by means of the lighting. The quality of the light is measured in the colour rendering index (CRI) and denoted with the term Ra. The closer the CRI number is to the value of 100, which is the value of natural light, the truer the colours are rendered to the human eye. For surgical lights the CRI of R9 is important as it measures the trueness of the colour red (Centre for Evidence-Based Purchasing, 2010).

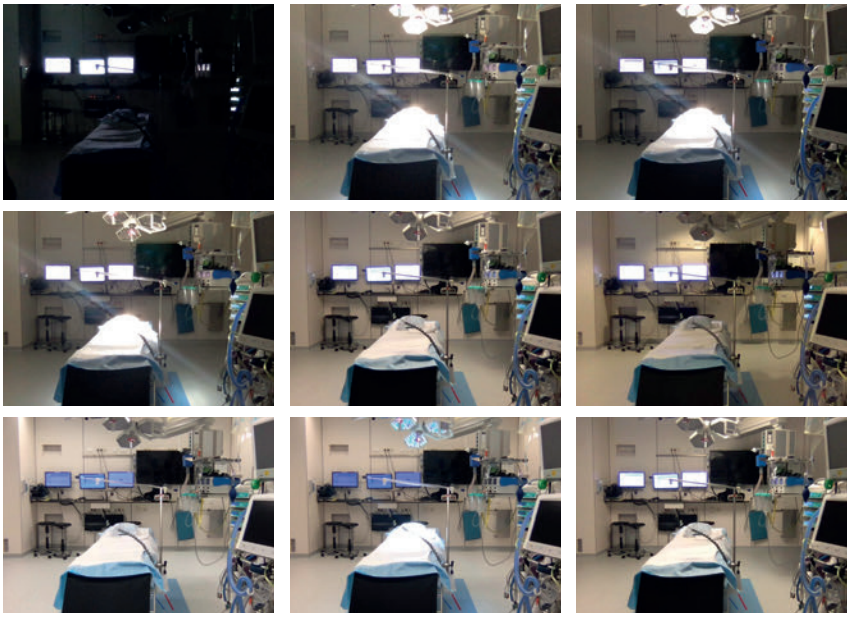


Fig 3.26. **Selection of images showing different lighting conditions in operation theatre 6 during light measurments.**

The lighting conditions in operation theatre 4 and 6 of the Catharina Hospital are measured in various conditions to obtain an understanding if and how these will interact with the conditions needed for an objective assessment of the ICG, see figure 3.26. The results of this study will be discussed in the synthesis chapter and details of the test setup can be found in appendix (X).

3.2.2 Conclusion

For a surgical procedure sufficient quality lighting is important. If the project would demand the use of permanent light filters in front of the surgical light to avoid light interference with the ICG spectrum the trueness of the light should be considered, or detachable filters should be used.

3.3 Patient factors

People differ, and thus is a factor that can influence the ICG output images or provide a different meaning to the output image shown to the surgeon for the particular patient. In this chapter the most important aspects will be discussed.

3.3.1 Blood flow

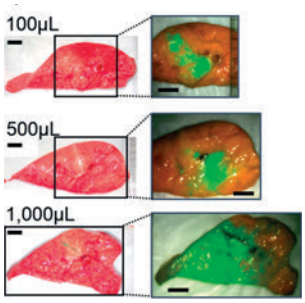


Fig 3.27. **Injection volume's correlation to fluorescence area. Adapted from Wada et al. (2015).**

ICG can be used to visualise a demarcation line between ischemic and non-ischemic tissue. Nevertheless, as the pulsatile flow of the blood produced by the cardiac output of the hart contains a constant pulsatile pressure, eventually the ICG enhanced blood will cross the demarcation line into the ischemic tissue. When this is not considered, the surgeon might make an insufficient decision. Hence, time is an important aspect regarding an adequate assessment. The blood flow and -volume differs per patient and thus if the ICG fluorescence intensity is used as a parameter for blood flow evaluation, the volume of injected contrast dye should be calculated for each individual patient (Kumagai et al., 2016). Figure 3.27. shows the (exaggerated) effect of different ICG concentrations in correlation with the fluorescence area.
Nonetheless, by the standard doses injected in the patient this effect won't affect the assessment too much. Though it is hypothesised that temperature is a parameter that has great influence on the blood perfusion.

3.3.2 Temperature and blood flow

Inside the operating theatre there is a constant temperature around 20 ºC. Via the laminar flow above the surgical table the sterile field is kept free of any micro-organisms in the air. This flow affects the temperature inside the surgical wound and will ultimately influences the blood flow. To regulate the body temperature arteries, veins and capillaries can narrow to decrease heat loss or expand to increase heat loss, and temperature differences can thus influence the vessel radius and thereby the blood flow (McMeeken, 1994), see figure 3.28. A surgeon must consider the patient conditions regarding his actions and assessments. If the ICG image shows

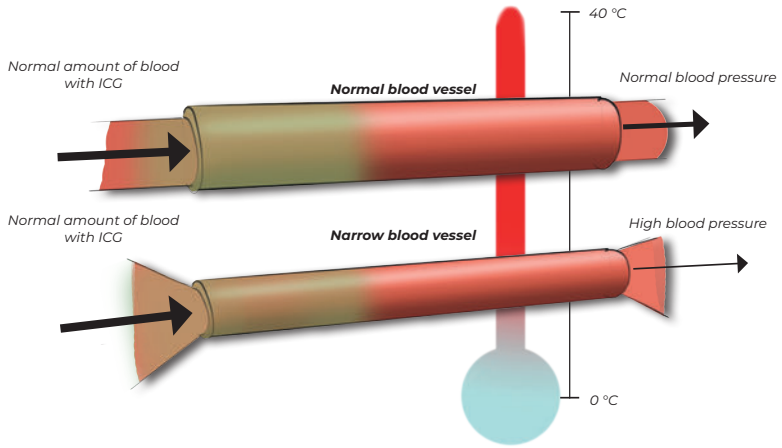


Fig 3.28. **Schematic view on temperature and vessel radius correlation.**

inadequate or low blood flow on certain areas, it does not necessarily mean that this part is ischemic as it could be a result of temperature influence on vessel radius. When temperature increases again the vessels radius could increase, resulting in a better blood flow and consequently a different ICG output image for the same ROI. Temperature differences could potentially lead to false negatives or -positives and thus could lead to an increased change on an AL. Temperature does not have further influence on the fluorescence intensity itself, according to research of Ohtsubo & Kusano (2016) see figure 2.29.

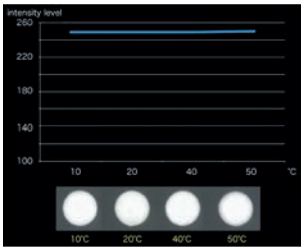


Fig 3.29. **Fluorescence intensity in accord with temperature (from 10ºC to 50º Celcius). Adapted from (Ohtsubo & Kusano, 2016).**

3.3.2.1 Research

To see whether temperature does affect the ICG image and to what extent, a research is set up. The test will be done by means of a thermographic camera that can capture infrared radiation and thereby show the temperature of objects in a thermogram. The wavelengths used to compile this heatmap range outside the ICG spectrum and thus could be used without interfering with the ICG fluorescence.

3.3.2.2 Approach

Simultaneously to the ICG assessment by the surgeon with the Karl Storz system a thermogram will be made of the ROI, whereby the two output images can be compared. Next, the same will be done for the resected tissue in an ex-vivo assessment. This tissue is expected to drop in temperature and several thermograms will be made along with ICG images. Lastly the two will be compared to see if the ICG fluorescence changes in relation to temperature. The research would not be highly scientific but could provide a good first impression how ICG output images correlate to temperature variations of the tissue.

3.3.2.3 Conclusion

As these tests depend highly on patients and procedures this research could not be conducted due to these practical reasons. However, it would still be an interesting research to conduct.

3.4 Medical Device Regulations

Medical devices and products are used throughout the world to treat patients every day. A medical device can be any apparatus, software, appliance, material or other article intended to be used for diagnostic or treatment of a human being. To ensure a certain safety and performance level, the European Commission developed rules and regulations any medical device should comply to. When it does, it may carry a CE-certification and it may be sold on the European market. The same goes for the American marked where the FDA will classify a product. The medical device regulations (MDR) comes with some general requirements for a medical product, mostly ensuring the safety of the patient and users by eliminating risks in design, manufacturing, use, transport and storage. To ensure the design will meet these and other requirements, a risk analysis can be conducted by means of an ISO standard for medical devices (i.e. ISO 14971 medical devices – application of risk management to medical devices)(European Union,2017). To see what requirements are needed for the design, the medical device regulations created a division for products, named the product classification. The classification of the to be designed product, that is likely to be an addition to the surgical arm or laparoscope, will fall under the 2a classification using annex 8, as it will be attached to an invasive product, namely a laparoscope (European Union, 2017). The same classification holds for a device to cover the surgical site. This classification will finally determine if a notified body is necessary for the design.

3.4.1 Electronics

If the design will contain electronics it should comply to the EN 60601-1:2006/ A1:2013/A12:2014 norm. For example, an electronic medical device should ensure the system minimises leakage currents under normal operation and isolate the patient from ground.

3.4.2 Conclusion

The product will most likely fall under the 2a classification, which means the manufacturer must declare their conformity with the MDR and ensure that the device complies to all essential requirements. To receive a CE-certification a notified body must be obtained.

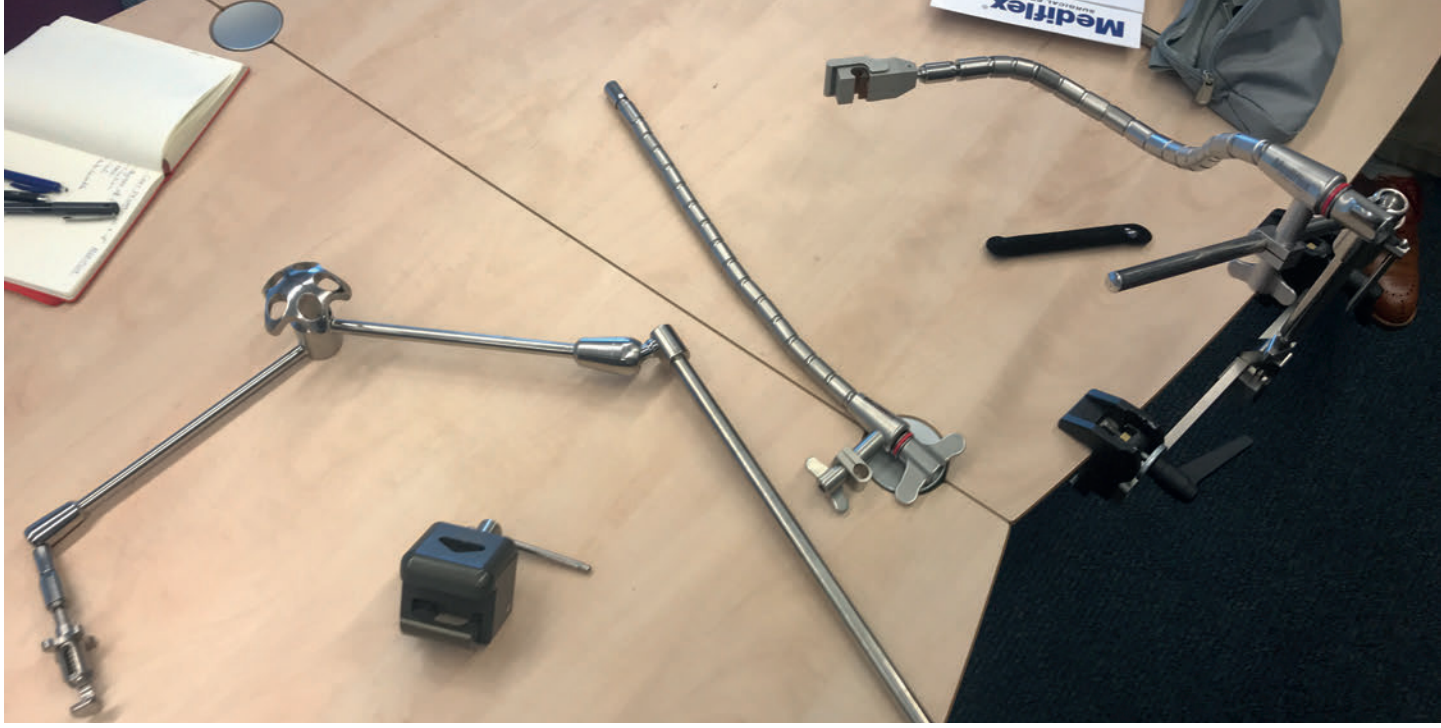


Fig 3.30. **Surgical mechanical arms. Martins arm on the left and Flexible arm in the right.**

3.5 Surgical equipment

During the surgery several surgical instruments are used. In this chapter some that are likely to interact with the design, are discussed.

3.5.1 Mechanical arm

Whether the camera system is easy and ergonomically to handle during a surgical procedure, depends a lot on the surgical arm. It does not solely position and repositions the camera, but could become an obstacle for any surgical procedure if placement is incorrect. It is important that the arm can be fixated by one hand, as the other is occupied holding the scope. Two different arms are tested on their working principle and feasibility for the project.

3.5.1.1 *Martins arm*

The Karl Storz ICG system can be accompanied with a Martins Arm, the left arm in figure 3.30. This arm is mounted on the side of the surgical table and can be fixated in position by means of one lever or rotary knob in the middle hinge of the arm. This knob will not only fixate its own hinge, but also the two ball-socket joints by means of friction, see figure 3.31. The arm can hold a total weight of 2.3 kg in horizontal position (Gert Priem, personal communication, July 10, 2018). According to the experience of surgeons it takes too much time to set up the arm; 'When the arm is finally set up, the whole operation is over'. This time is mostly lost on mounting the equipment to the table rail, that is covered by surgical drapes and is on an unergonomic height (i.e. low). The arm contains 5 degrees of freedom that makes adequate positioning of the camera possible. However, due to its construction the arm will collapse when the rotary knob is turned too loose as friction on joints disappears. According to the personnel of the Sterilisation Department of the Catharina Hospital, the arm is easy to sterilise.

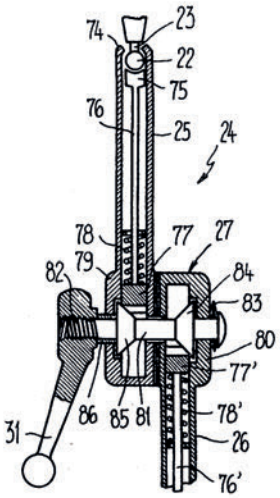


Fig 3.31. **Working principle Martins arm, whereby the lever (31) put force on the internal steel rods (76) resulting in a friction force on the ball-socket joints (22).**

3.5.1.2 *Flexible arm*

To position the laparoscope a flexible arm can be used, the right arm on figure 3.30. The arm can be fixed or loosened by means of a single lever at the base of the arm. It will tighten the separate links by means of an internal wire, see figure

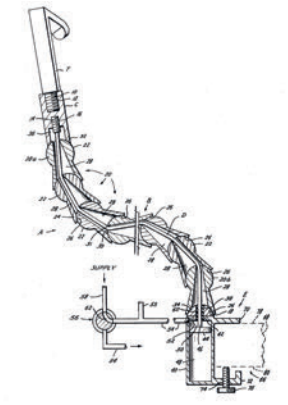


Fig 3.32. **Working principle of flexible arm.**

3.32. This makes it possible to easily adjust the camera to its position and fixate it with the other free hand and hold an object of maximum 2 kg on its place. It was experienced to be easy to place and fixate the arm in several positions and assessed as practical in a surgical procedure. However according to the sterilisation department, the arm needs more attention in the sterilisation program, although according to the reseller the arm is very suitable for autoclaving if the internal wire is turned lose and so enough space exists between the links to expose all areas of the arm to the autoclave.

3.5.1.3 *Other arms*

Next to this, a flexible arm for placements of photograph equipment is tested on usability for the project, see figure 3.33. For positioning they are adequate but not strong enough to hold a scope on a stable position.

3.5.1.4 *Comparison*

Both arms are technically feasible for the project, but from a surgical usability point of view the flexible arm would be more ideal. Due to its construction the internal wire could be set to a certain threshold tension and can support the camera without collapsing into the surgical wound. And is thereby a safer option to use compared to the Martins arm. Nevertheless, this needs more validation by means of a prototype.

Fig 3.33. **Flexible camera arm**

3.5.1.5 Practical and recommendation

However, from a practical point of view this project will make use of the Martins arm principle, as it can be bought cheaply and is more easily to adjust. Thereby, producing a flexible arm is too time consuming and buying one is out of the order. Nevertheless, for a final product system the flexible arm (FlexArm Plus) is advised.

3.5.2 **Omnitract**

To (keep) open the surgical wound an omnitract system is used, see figure 3.34. The base of the omnitract consists out of a sterile field post connected to the surgical table rail, a wishbone frame and the retractors that can be attached to the wishbone frame that will hold the surgical wound open. An Omnitract system can be setup in approximately one minute and is mounted in such a manner it will float approximately 40 to 50 mm above the patient and the surgical wound (Surgicalinservice, 2010). The Whishbone arms are approximately 400 mm long with a diameter of 10 to 15 mm. When used for a gastrointestinal surgery at least 4 retractors are used. Surgical gauze tampons used to absorb bodily fluids or protect fragile tissue from the retractors, can be hold by the same or additional retractors. The retractors are located on the wishbone according to the shape of the surgical wound. They leave enough room for an additional mount for a camera arm. The omnitract system covers the two long sides of the surgical wound and depending on the surgeon's preference or location of the region of interest, a camera can be attached on both sides. According to the experience of the surgeons, the omnitract stands firmly in place once locked, and, although not with full weight, a person can lean on the wishbones without adjusting its locking position.

Fig 3.34. **Omnitract on sterile field post (Medi Plast, n.d.).**

3.5.2.1 *Conclusion*

Though it would need more testing, it seems feasible to attach a camera system of approximately 2000 grams on the wishbones. The benefit of this location would be that the arm does not need a great reach and could thus remain small, light and

assumable easier in use. However, as the wishbones are round they will not offer a shape lock for the mount of the arm to stay in position. A location, with almost the same benefits, that does provide a shape-lock is the sterile field post.

3.5.3 Surgical drapes

To limit contamination of the surgical wound, instruments and the surgeon's hands, a surgical sterile drape and a sterile instrument field is used, see figure 3.35. In general, there are two kinds of sterile drapes; breathable drapes and non-breathable drapes. The latter is commonly used in open surgery as the drapes have contact with moist and liquids (e.g. blood and bodily fluids). According to Susanne Verstraten (Design department of Medical Europe) (personal communication, April 28, 2018) a sterile drape is made of several material layers, according to their purpose, but in general they are made from PE. A common layer configuration is a green PP spunbone nonewoven material, a PE film and a thicker PP spunbone nonwoven material. The spunbone materials provides comfort and absorption while the PE film ensures liquid isolation. Surgical drapes are made by laminating machines whereby different rolls of materials are bound together by means of heat and/or glue. After the laminating process the drapes are cut (e.g. by laser) to their shape.

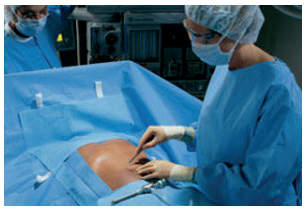


Fig 3.35. **Surgical drapes in abdominal surgery (indiamart, n.d.)**

3.5.3.1 *Light penetration & Custom drapes*

Surgical drapes can be manufactured in all sorts of standard or custom shapes and materials but a light blocking drape, that could form an opportunity for this project, is not yet available on the market. And thus, the current drapes used by the Catharina Hospital are penetrated by light, although they do lower its intensity, see figure 3.36. Though, it is possible to manufacture custom drapes and thereby it is feasible to add new layers or even add plastic parts into the material as long as the surgical drape meets the NEN13795 norm.

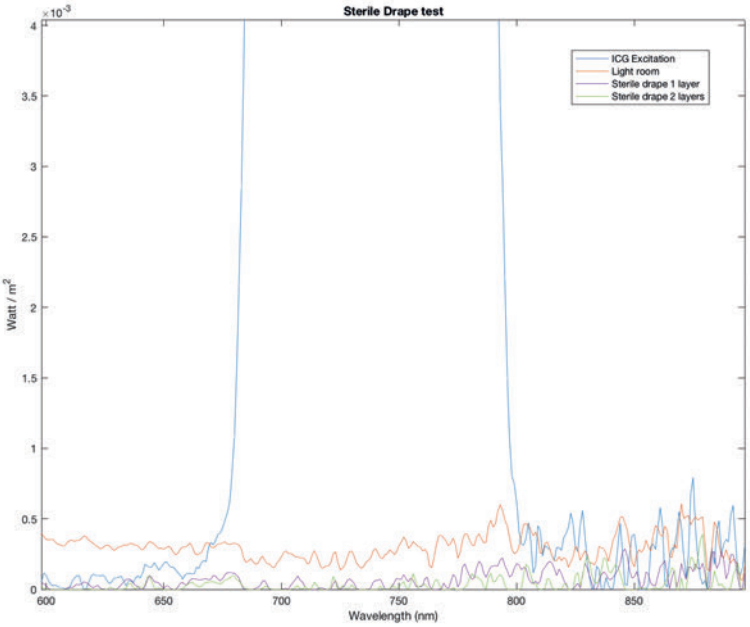


Fig 3.36. **light penetration through a surgical drape**.

4 Workflow

Fig 4.1. **Operation room 6 of Catharina Hospital (Catharina Ziekenhuis, 2013).**

To understand how the design will be and should be used, an understanding of the workflow of the surgical team during an ICG procedure and further use of the product is needed. Therefore, the chapters will follow the steps of the design in an ICG procedure from use in the operating theatre, to sterilisation, back to storage. See figure 24 below.

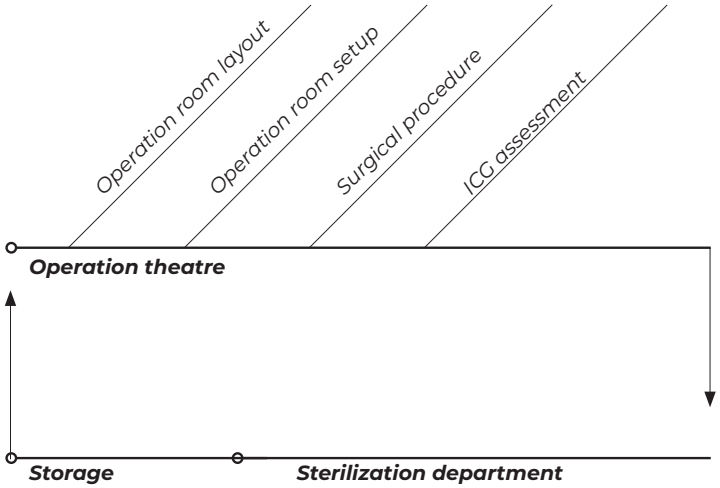


Fig 3. **Schematic visualisation of the usefllow of the design.**

4.1 Operating theatre

4.1.1 Room layout

The layout of the operation rooms is divided into three areas; the operating table is in the central zone and marks the surgical area, a parking zone along the walls for items that are not immediately required in the surgery and a zone that serves as the circulation space of the room. Next to this, the room is divided by graduation of sterility needed in a sterile area, an anaesthesiology area and a non-sterile area. Figure 4.2., shows a setup of operation room 6 at the Catharina Hospital, one of the rooms where observations are conducted.

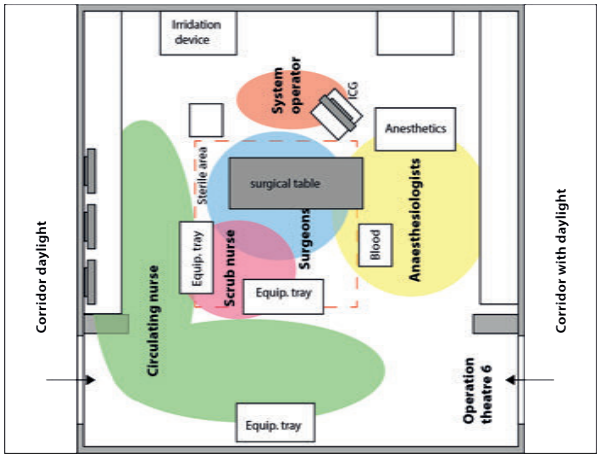


Fig 4.2. **Layout of operation theatre 6 at the Catharina hospital.**

4.1.1.2 *Circulating nurse (unsterile)*

The circulating nurse makes sure that all the equipment is in the room and ensures a safe situation for the patient. They help the sterile personnel with their transitions from unsterile to sterile, and provides the scrub nurse with the necessary surgical equipment.

4.1.1.3 *Scrub nurse (sterile)*

The scrub nurse is inside the sterile field and provides the surgical team with the necessary surgical tools.

4.1.1.4 *Anaesthetist (unsterile)*

The anaesthetist administers the anaesthetics and other intra-vascular supplies to the patient, such as the contrast dye. Thereby they constantly monitor the patient's parameters.

4.1.1.5 *Surgeons (sterile)*

The surgical team inside the sterile field, that is the surgeon and surgical assistants. They perform and hold responsibility for the actual surgery.

4.1.1.6 *Camera operator (sterile & unsterile)*

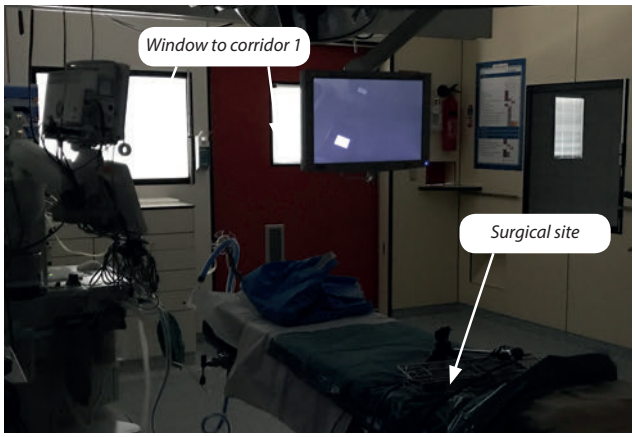
For a surgical procedure that involves an imaging technique often two more persons are involved, namely the camera operator and the camera system operator. The camera operator, the one that positions the camera, falls within the sterile field. During the observed surgeries the camera operator was an additional person to the surgery, although it occurs the surgeon also operates the camera. The camera system operator is outside the sterile field and handles the camera system to record or adjust the output image for the surgical team. During one of the surgical

Fig 4.3. **Corridor 1 adjucent to OR 4,5 and 6 (Alcomel, 2006).**
Fig 4.4. **Corridor 2 adjucent to OR 4,5 and 6 (Alcomel, 2006).**

observations a total of 13 persons (including the patient) were present in the room and thus, along with all the equipment, it can be quite full. When equipment is not used, it is therefore moved back to a position out of the working field.

4.1.2 Room light conditions

At the Catharina hospital the operation rooms are not all similar and differ in size, setup, specialised equipment and lighting conditions. The lighting conditions are important during an ICG procedure. To prevent external light interfering with the ICG, light inside the rooms is decreased as much as possible. Figure 4.5. and figure 4.6. show the darkest light scenario during daytime in respectively operation room 4 and operation theatre 6. There is a great difference in lighting conditions. In operation theatre 4 there is, next to the windows in two the doors, a big window that lets daylight through from the corrior, see figure 4.3. & 4.4. Via a spectrometer the lighting conditions inside the rooms are measured for different light-scenarios that will be discussed in the synthesis. See appendix (light measurement for details).



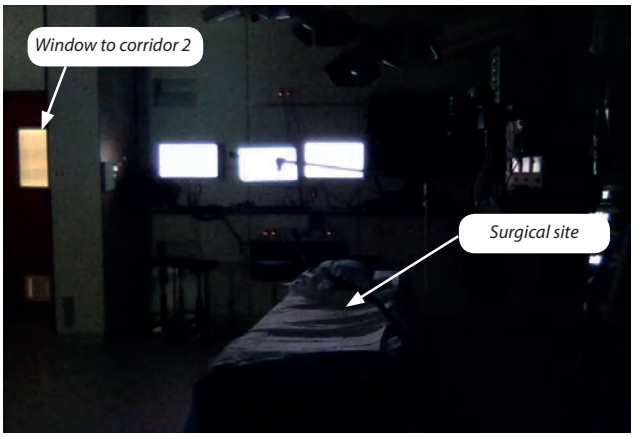


Fig 4.5. (left) **Dark scenario OR4**
Fig 4.6. (right) **Dark sceneario OR6**

4.1.3 Sound conditions

Although 55 dB is the limit recommended by the World Health Organisation to avoid hinder and ensure adequate personnel communication (McNeer, Bennett, & Dudaryk, 2016), the operation theatres are sought to be the noisiest clinical environment with an average sound level ranging from 51 to 75 dB with peaks up to 119 dB (Hasfeldt, Laerkner, & Birkelund, 2010) generated by various types of instruments and personnel. Most monitoring devices alert the personnel by means of beeping sounds (a short mostly high-pitched sound). The pitches, duration and interval may differ according to the type of device, the patient's condition, urge of the notification and should comply to the International Electrotechnical Commission standard medical audible alarm sounds (60601-1-8). Sound can thus be alarming in a surgical setting and it's source and purpose should therefore be clear (Edworthy & Baldwin, 2016).

4.1.4 Imaginge equipment

At the Catharina hospital they make use of two different imaging systems, namely the Quest Spectrum system and the Karl Storz system, see figure 4.7. & 4.8.

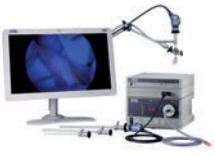


Fig 4.7. **Karl Storz ICG system (Karl Storz, n.d.)**

Fig 4.8. **Quest Spectrum Platform (Quest Medical Imaging, n.d.)**

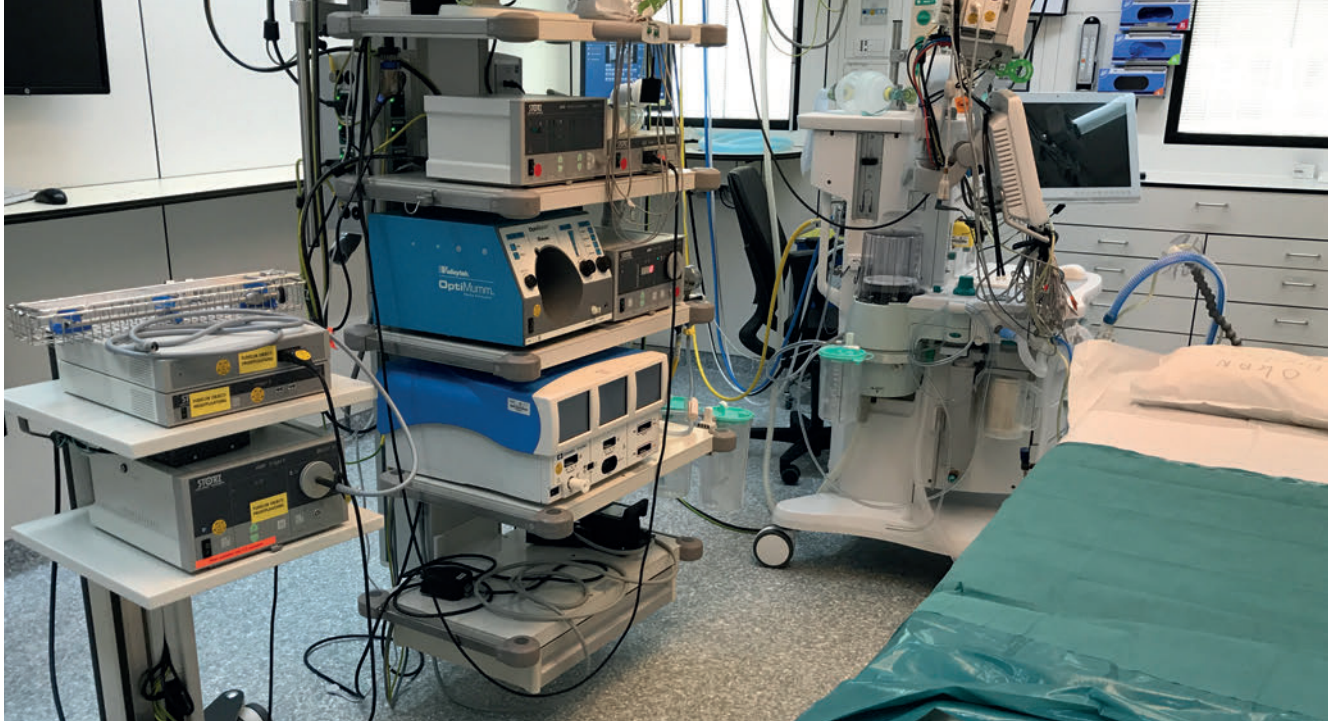


Fig 4.9. **Karl Storz ICG movable trolley (left) and Karl Storz ICG equipment on permanent location on ceiling tower (middle) at operation theatre 4 at the Catharina Hospital.**

Although this system can be operated by holding the camera in hand, the Quest Spectrum system at the Catharina is equipped with a mechanical arm between camera and system trolley. Before an image is taken, the trolley is moved to an arm-reaching distance of the surgical site. At the Catharina Hospital the equipment of the Karl Storz imaging system can be set up in two manners, namely on a permanent location in the room as a standard room setup or on a movable trolley, see figure 4.9. During the observations it is seen that moving the Quest Spectrum system trolley requires some room and will inconveniently block a part of the sterile field and thus moving space of the surgeons. The same holds for the Karl Storz mobile trolley.

4.1.5 Sterile

All persons in the room have their own spots they are allowed to go to. The sterile area, the area in which the actual surgery takes place, may only be entered under sterile conditions. This applies to persons as well as devices. When equipment enters the sterile area, it should be sterilised. The most ICG camera systems are not sterile before they will breach into the sterile field and therefore are wrapped in a sterile sleeve during the surgery, see figure 4.10. To do so the camera operator (sterile) needs help from the system operator (unsterile) or circulating nurse (unsterile). Figure 4.11. shows how a Fluoptics imaging camera system is put into a sterile drape during the surgery. For the Karl Storz ICG imaging system, the same is done for the camera and cord, see figure (X), the laparoscope is not covered as it enters the operation room under sterile conditions. During the observations it is seen that this preparation for the Quest system takes approximately 2 minutes.

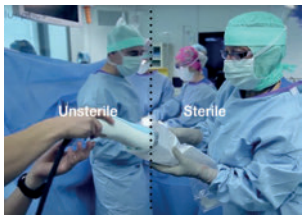


Fig 4.10. **Camera with sterile sleeve (Austvet Endoscopy, n.d.).**
Fig 4.11. **Transition of Fluoptics fluorescence camera from unsterile to sterile with sterile sleeve (Fluoptics, 2014).**

4.1.6 Conclusion

Protocol is of high importance in the operation room. For the design it is important to consider the workflow and how the product is presented to the surgical team, regarding sterility.

4.2 Colorectal open surgery

As this project resolves around the assessment of tissue perfusion of a gastrointestinal anastomosis it is necessarily to understand the workflow and work-conditions during this procedure. The team setup depends on the kind of surgical procedure and its complexity. The standard team setup for open colorectal surgery consist of a surgeon, the first assistant, the second assistant, anaesthesiologist and a scrub nurse/physician, see figure 4.12.

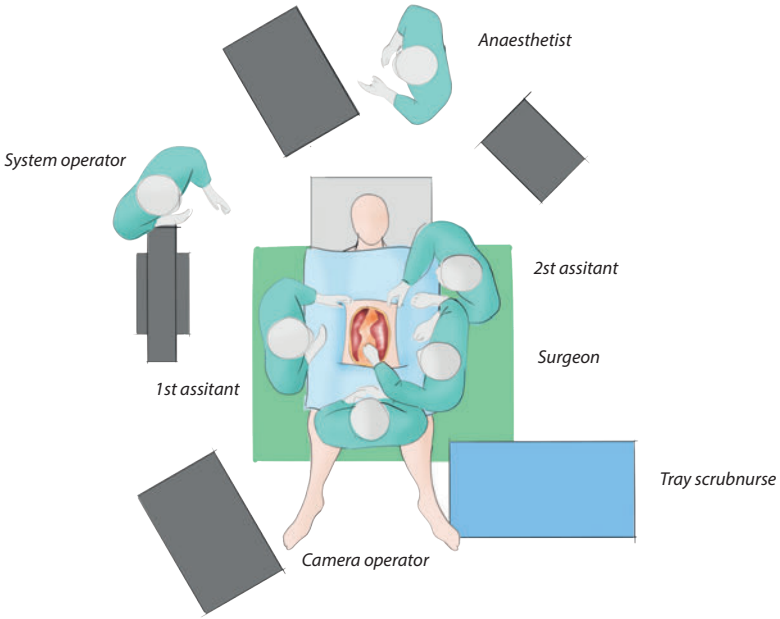


Fig 4.12. **General setup of abdominal fluorescence surgery**

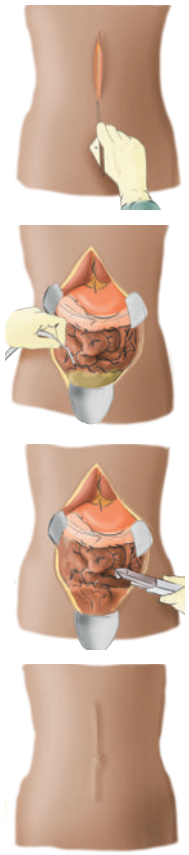


Fig 4.13.. **a. Midline incision b. Stabilising bowel c. Bowel resection d. close**

4.2.1 Surgical procedure

To expose the gastrointestinal tract and perform the necessarily actions, the surgeon will make a vertical midline incision to enter the abdominal cavity, see figure 4.13a. When the incision is made, the surgical staff will open up the abdomen and keep it open by the means of retractors, see figure 4.13b(Stein, 2017). Once the abdominal cavity is open, they will mobilise the colon or region of interest. Depending on the location of the ROI other intestines are moved to clear view on, and gather access to the ROI. This involves incisions in the gastrointestinal tract and, in case of earlier operations, might involve incisions into scar tissue. Blood suction and suction of other bodily liquid might be needed to keep the surgical site clear, see figure 4.13b. Once the region of interest is mobilised and the surgical wound is stabilised by means of retractors, the ROI is assessed on malignant or diseased tissue. If the area of resection is determined, the surgeon will make the resection. The resection is done with a linear cutting stapler, see figure 4.13c, sometimes after clamps are set next to the resection line (Vella & O'Dwyer, 2002). As the surgeons can perform multiple surgeries a day, the day starts with an update meeting wherein the patient's situations and surgical approaches are discussed multidisciplinary. Normally the surgical team is present during the hole procedure, unlike the anaesthetist and sometimes the circulating nurse who are often taken over by others for a necessarily break.

4.2.1.1 Emergency

It could occur that during the surgery complications come to play. When this

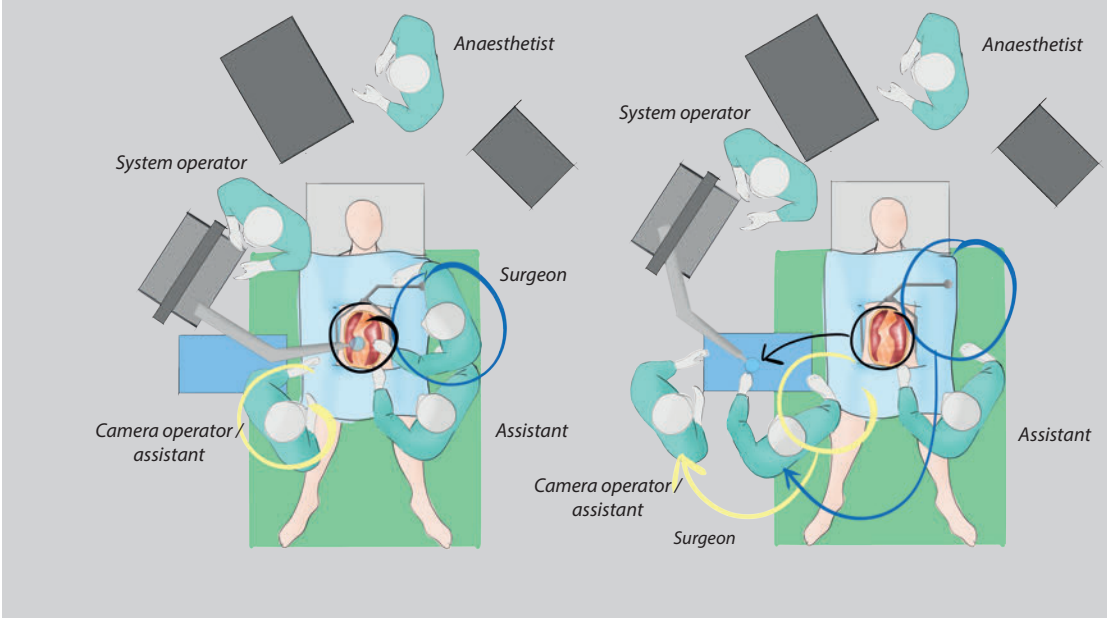


Fig 4.14. **Setup in-vivo assessment (left) to an ex-vivo assessment (right).**

happens, it is of importance for the surgical staff to take adequate and fast actions. And thus, should have enough space and clear access to the surgical wound or equipment. Personnel and objects that are not involved in these actions should not thwart these activities.

4.2.2 Imaging technique

When the bowel and area of interest is exposed and stabilised, the surgical team can make the call to start the imaging procedure. Before the camera module is put into position, the anaesthesiologist administers the ICG contrast dye to the patient. (In case of tumour visualisation, a different contrast dye, that attaches itself to the malignant tissue, is injected 4 days before the surgery). It then takes up to 3 minutes before the ICG is distributed correctly in the vascular system. This time can be used to put the camera system in place by the camera- and the system operator in concert with the surgeon. The zoom and focus of the camera are adjusted under sterile conditions. Next, the surgical staff asks the anaesthesiologist to turn off the environmental and surgical lights for better detection of the fluorescence signal and to prevent light interference.

4.2.2.1 *Camera setup*

When the camera is not on a moving trolley, first the arm is set into place. Usually the arm is mounted to the surgical table rail. The camera is put into a sterile drape and attached to the laparoscope, whereafter the camera and laparoscope are attached to the mechanical arm; ready to be used.

4.2.2.2 *Ex vivo*

During the first observation the imaging technique was used to detect malignant tissue in the colon. During this procedure the assessment was done in-vivo as well as ex-vivo and did require repositioning of the camera system to be focused on a cart adjacent to the operation table, see figure 4.14.

During the ICG imaging the surgeon might perform a resection of the (non-) fluorescent tissue. To do so, clear sight and access is needed. According to Albertine (2011) this is the reason why handheld camera devices are not sufficient in case the surgeon is also the camera operator.

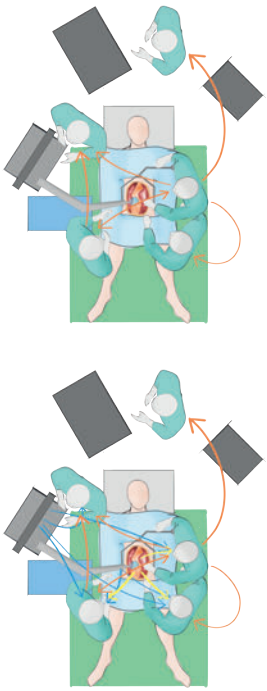


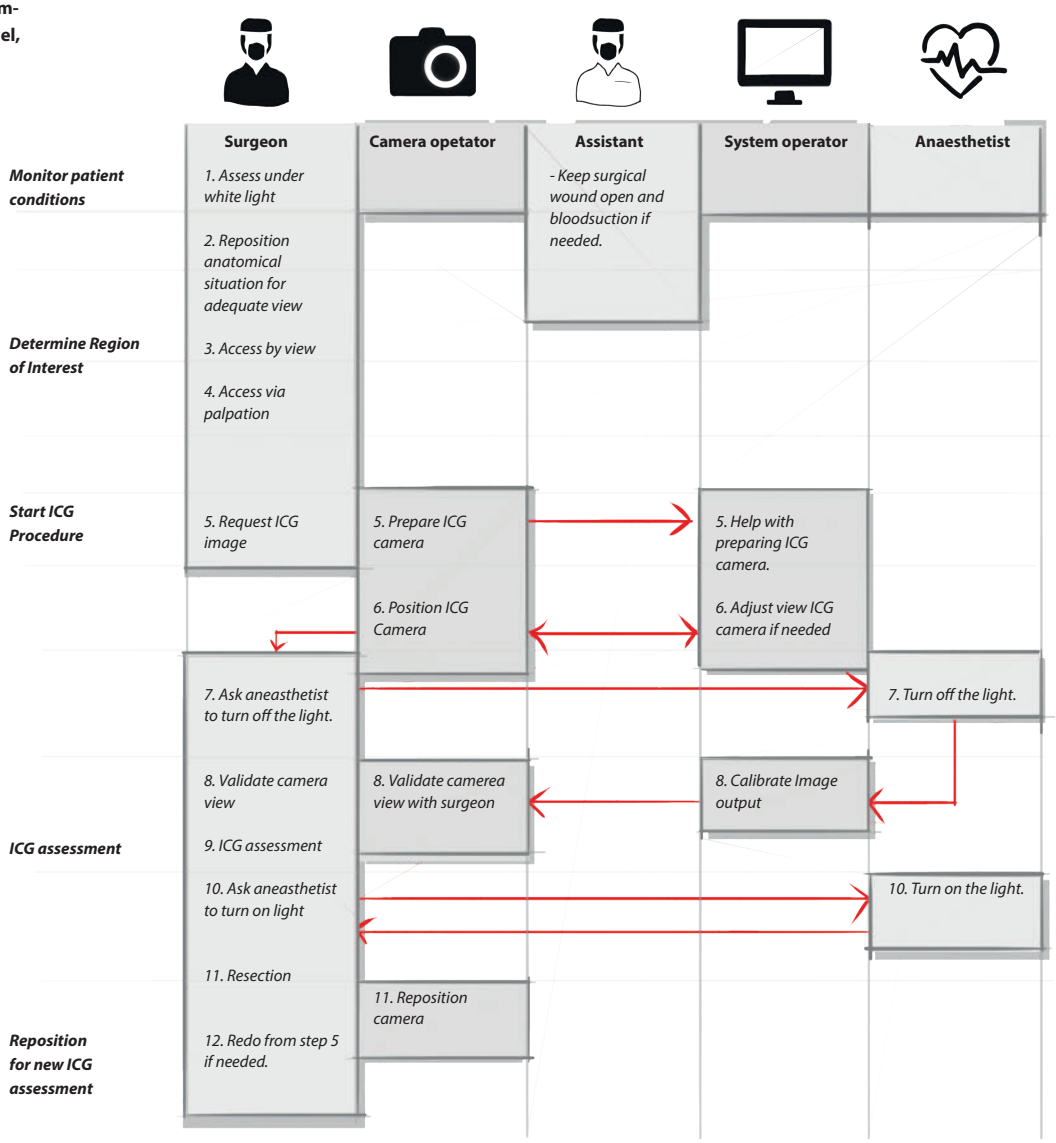
Fig 4.15. above: **Communication lines personnel.** below: **All communication lines (e.i. personnel, anatomy, devices).**

4.2.3 Communication

Communication is key during the procedure. It is observed that the communication between the surgical team inside the sterile field and the system operator is smooth and adequate. However, the communication between the surgical team and the anaesthetist isn't always flawless. Upfront the ICG assessments the lights in the room must be turned off and as the anaesthetists are closest to the light switch, they are asked by the surgeon to do so. It turned out that the anaesthetist did not always expect the question, and, on some instances, the surgical team had to ask multiple times. Hereby, time is lost. The communication with the devices, in particular the monitor whereupon the ICG images are presented is adequate, however not always ideal. Due to space limitation it could occur that the system operator blocks the line of sight to the monitor of the camera operator and surgeon, as observed in operation theatre 6. Nevertheless, in operation theatre 4, the monitor is attached to an arm on the ceiling and thus could be placed in a more ideal location.

4.2.4 Schematic

In the image below a simplified schematic timeline of the procedure is compiled out of information from the observations.



4.3 Mental model

To understand the needs of the surgical team to become familiar with the blood perfusion of an ROI the sensemaking model is used. This model can provide a schematic overview of the needs and workflow during the assessment.

4.3.1 Sensemaking model

Sensemaking is the process of searching for a frame and fil this frame with data to answer task specific questions' (Russell & Stefik, 1993). Throughout a task, one is *'facing gaps, building bridges across those gaps, evaluating outcomes and moving on'* (Dervin, 2006). The interplay between frames and data is bidirectional as *'frames shape and define the relevant data, and data mandate that frames change in nontrivial ways'* (Klein, Moon, & Hoffman, 2006) and thus sensemaking is an iterative process. For the surgical team, and especially for the surgeon who has the final responsibility for an adequate assessment of the blood perfusion, the frame would be to become familiar with the blood perfusion in the region of interest, see figure 4.17. To do so the surgeon seeks information from different sources (referred to as data sets) to compile a complete mental-model or frame of the scenario. Whenever they find a knowledge gap they search for data to fill this 'open' space. During the current ICG assessment there are, next to information from the surgical team members, two main data sets namely (figure 4.18.):

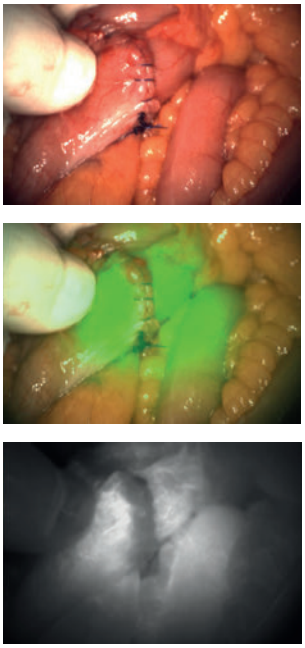
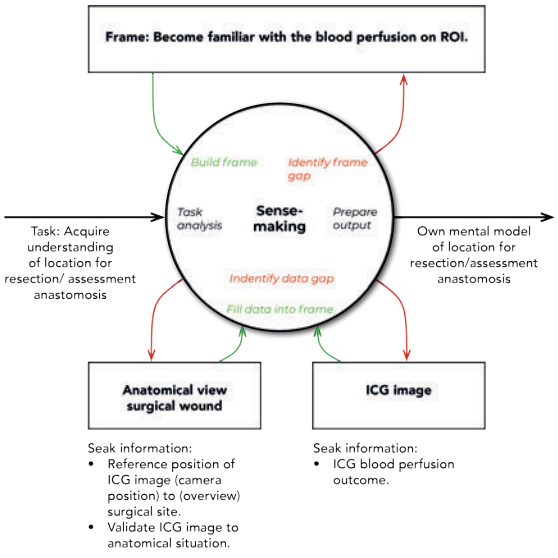
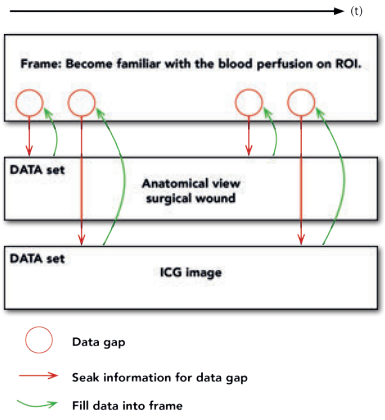


Fig 4.16. **Colorectal anastomosis; a new connection between colon and rectum. A: white -light anatomical image, B: Registration white-light and ICG image. C: solely ICG image. Adapted from Quest (2018).**

- *Data set: Anatomical view*
  Provides the surgeon with information on the anatomical status and overview on the positioning of the camera (i.e. data set: ICG image).

- *Data set: ICG Image*
  This data set provides the surgical team with three different views: an image of the camera view under white light, an image of the ICG fluorescence and a registered image of both white light and ICG images, see figure 4.16. The first is used to validate camera position, lighting conditions and as reference of the anatomical conditions. The second is used to validate in detail the fluorescence signal of the contrast dye and the latter is used as overview of the perfusion conditions.





< Fig 4.17. **The iterative process of sensemaking**

> Fig 4.18. **Data sets to fill the information gaps of the mental model**

4.3.2 Conclusion

If the ICG image provides the surgeon with an anatomical view, an ICG view and an image registration view, an understanding of the blood perfusion can already be established. However, to validate the camera position, relate the ICG images to the patient conditions in a wider overview the surgeon may want to have a view on the anatomical site. Therefore, the system will ideally not, or on a low level, interfere with these data sets.

4.4 Sterilisation department

All procedures involving contact with a patient's tissue by a medical device or surgical instrument, forms a major risk of infection. Proper disinfection and sterilisation of the reusable medical equipment is thus essential. Therefore, it is important that the product is able to meet the disinfection and sterilisation requirements. The classification of the sterilisation and disinfection of medical equipment exists out of three levels: sterilisation for critical items with contact to sterile tissue, high-level disinfection for items that contact mucous membranes and low-level disinfection for noncritical items that only contact intact tissue (Rutala & Weber, 2004).The sterilisation consists out of several steps: The instruments or items are checked on missing parts and undergo a prewash and/or an ultrasonic wash before they are placed in the washing machine, whereby foreign material (e.g., soil, and organic material) is removed. For the washing machine the instruments should be disassembled as much as possible and stacking the instruments in the

Fig 4.19. **Sterrad NX1000 Sterilisation device.**

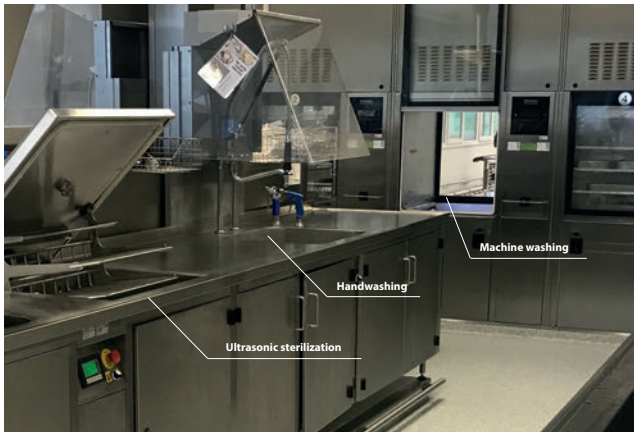


Fig 4.20. **Washing machines and autoclaves at the sterilisation department at the Catharina hospital.**

washer should be avoided to allow adequate cleaning (Rutala & Weber, 2004). The equipment is checked for completeness and if necessarily receive maintenance. Instruments that do not require sterilisation are stored to be transported if needed. The instruments that need sterilisation are prepared and packed to go into the autoclave sterilisation machines. The packaging and sterilisation are checked and finally stored. The sterilisation is done under high temperatures; 134°C in a short 4 minutes program and 121°C for a 6 minutes program, dependent on the specifications of the instrument (figure 4.20). If instruments may not be cleaned on high temperatures they are cleaned under 55°C by the Sterrad NX100, which takes approximately 45 minutes. For plastics they often use a preheating program, where they heat the plastics slowly to an adequate sterilisation temperature to ensure the material will endure. As the design could have contact with the surgical wound, sterilisation is needed and requires the design to be watertight and endure these high temperatures or could be sterilised in the Sterrad NX100, see figure 4.19.

4.4.1 Conclusions

The geometry of the design should contain as little as possible gaps or areas that are hard to reach. Fast and simple disassembly of parts of the system would simplify and speed-up the sterilisation workflow. Ideally the system does not have to be disassembled and could follow the same sterilisation steps as one.

5 Conclusions

Fig 5.1. **Michiel Jansz. Van Mierevelt & Pieter van Mierevelt, *Anatomische les van dokter Willem van der Meer,* 1617. Collection Prinsenhof, Delft.**

'How can design control the external factors bound to a subjective ICG output image and improve its objectivity?'

To achieve a more objective ICG output image there are several factors that need to be considered or controlled. A system that facilitates this would need the following aspects:

5.1 **Distance of scope to object**

As light intensity is subjected to the inverse square rule; the system should facilitate a manner to measure the distance from the camera eye to the object.

5.2 **Slope of scope to object**

The more perpendicular the light ray hits an object; the less reflection and scatter will appear. Especially for the excitation light this is of importance regarding the penetration depth. The system would therefore ideally facilitate a manner to determine the incidence angle of excitation light to the object.

5.3 **Temperature**

There is a correlation between the blood flow and the tissue temperature due to contraction of blood vessels. Although the effect on the ICG images needs more research, it could be beneficial if the system could provide the surgical team with a temperature measurement of the ROI, ideally in the form of a thermograph.

5.4 **Light**

Light from sources other than the excitation or emission light can affect the ICG output image. Therefore, these lights should be excluded. Ideally the system provides the surgical team with information about the light conditions around the ROI. This could be done by a zero measurement upfront an ICG assessment, to ensure all external light (i.e. external light inside the ICG spectrum) is excluded.

5.5 **Surgical light**

Light properties are important regarding the anatomical view and the system should not affect these conditions outside an ICG assessment.

5.6 **Reflection**

Glare on the ROI can challenge the camera properties and thereby give an untrue ICG output. Therefore, the system would need to operate in a light condition with minimal reflections on tissue and equipment. For the equipment this can either be done by mattering the equipment itself, or by diffusing or dimming the light. However, the angle of incidence of the light seems to play a crucial role and as the tissue surface contains various angles, this might be hard to control.

5.7 **Workflow**

An objective ICG assessment of tissue perfusion is subjected to time, as blood will eventually breach out of the intravascular space and can reach ischemic tissue due to the capillary flow and thus, if not accounted for, can result in a false-positive or -negative assessment. Therefore, it is important that the system does not extensively prolong the surgical time.

5.8 **Communication**

It is observed that time is lost due to some miscommunication between personnel (especially between surgical team and anaesthetics). Mostly this is because the surgical team can't turn off the light themselves. This issue can be addressed either by ensuring everyone inside the operation theatre is aware of the desired workflow, or by providing the surgical team with a mean to turn off the lights themselves.

5.9 **Mental model**

For an adequate assessment the surgeons should be able to relate the ICG image to the anatomical condition of the patient. To do so, ideally the region on interest stays uncovered as the anatomical view, provided by the camera, seems not sufficient enough in all cases.

5.10 **Administration**

As the fluorescence intensity of the ICG is subjected to its concentration, it is important to consider patient's individual physique regarding the administered volume of contrast dye. The ICG is presented on the OR in a glass bottle. As lighting in the OR contains excitation wavelengths, it can't be excluded that the contrast dye will already be enhanced before injection. To ensure this won't happen, packaging or light conditions need to be considered.

5.11 **Fluorescence**

According to Crane et al. (2011), one should test all materials in the OR and operating field for autofluorescence prior to a surgery as sterile drapes and surgical hand cloves can be auto fluorescent under the ICG excitation light.

5.12 **Practical consideration**

As for the available time the project will focus on an advice on how to position the camera, a manner to measure the distance from camera to object and a manner to exclude external light from the surgical wound.

6 Design requirements

Fig 6.1. **Suture after abdominal surgery, Arabian sea (U.S. Navy, 2011).**

This project is faced with two main challenges; on the one hand to exclude or control any external factor that could influence the registration and on the other hand provide a minimal interference with the surgical actions. If the second requirement is not met, and the system will interfere too much with the workflow of the surgeon, the system will fail its function. Likewise, if the system would fit in the workflow, but could not account for influences of external factors, the system will fail its function.

To achieve this, the design would need to comply to the following requirements and ideally to the following wishes:

6.1 General

- May not hinder the patient or user (or indirect users) in its intended use.
- May not hinder or alter the excitation light of the Karl Storz system.
- The placement of the product components should not significantly increase the time needed for the surgical procedure (average of 3 hours).
- The design needs to comply to the medical Rules and Regulations.
- System use should not drastically change the workflow.

6.2 Location

- Should be able to detect distance of camera to tissue.
- Should be able to communicate distance of camera to tissue to user.

6.3 Light exclusion

- Should withhold wavelengths of 700 to 900 nm from light sources other than the Karl Storz excitation light to interact with the ICG or camera.
- The product may not worsen the lighting conditions during the ICG.

6.4 Mechanical

- The system can hold the arm, scope, camera and measurements device in a stable position.

- The arm can hold the scope, camera and measurement device in a stable position.
- The system can, once mounted, be positioned with two hands.
- The system can, once mounted and positioned, be fixated by one hand.
- The product may not damage other equipment.
- The product plus scope and camera may not exceed 2 kg.

6.5 **Materials**

- The components of the product are suitable for sterilization.
- If components require a different sterilization flow, they can be disassembled by the sterilization department.

6.6 **Wishes**

- Should be able to detect slope of camera to tissue.

Synthesis

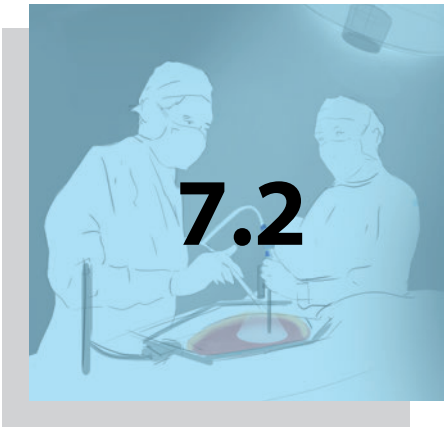
This chapter will entail the ideation of the product system. First, the chapter will shine light on the system part that should exclude interference of light on the surgical site. The next chapter will contain the ideation of a manner to standardise the position of the scope towards the object. Lastly, an advice regarding the mechanical arm will be given.

< Fig 6.2. **Early prototype**

7 Light

Fig 7.1. **Surgical team during surgical procedure (Salisburry, 2017).**

During the assessment of an ICG it is important to minimise the interference of external factors to ensure a more objective assessment of the ICG fluorescence and thereby the tissue perfusion of the ROI. Light interference from light sources other than that of the imaging equipment, play a crucial role. Furthermore, we see that sufficient lighting conditions inside the room are crucial for the surgical team to adequately perform their surgical actions and build their mental model. Dependent on the lighting conditions inside the rooms, four different lighting directions are compiled. Inside this chapter the four different directions are discussed and assessed on their feasibility regarding the surgical workflow and technical requirements of an objective ICG assessment.



Four different
lighting scenario's

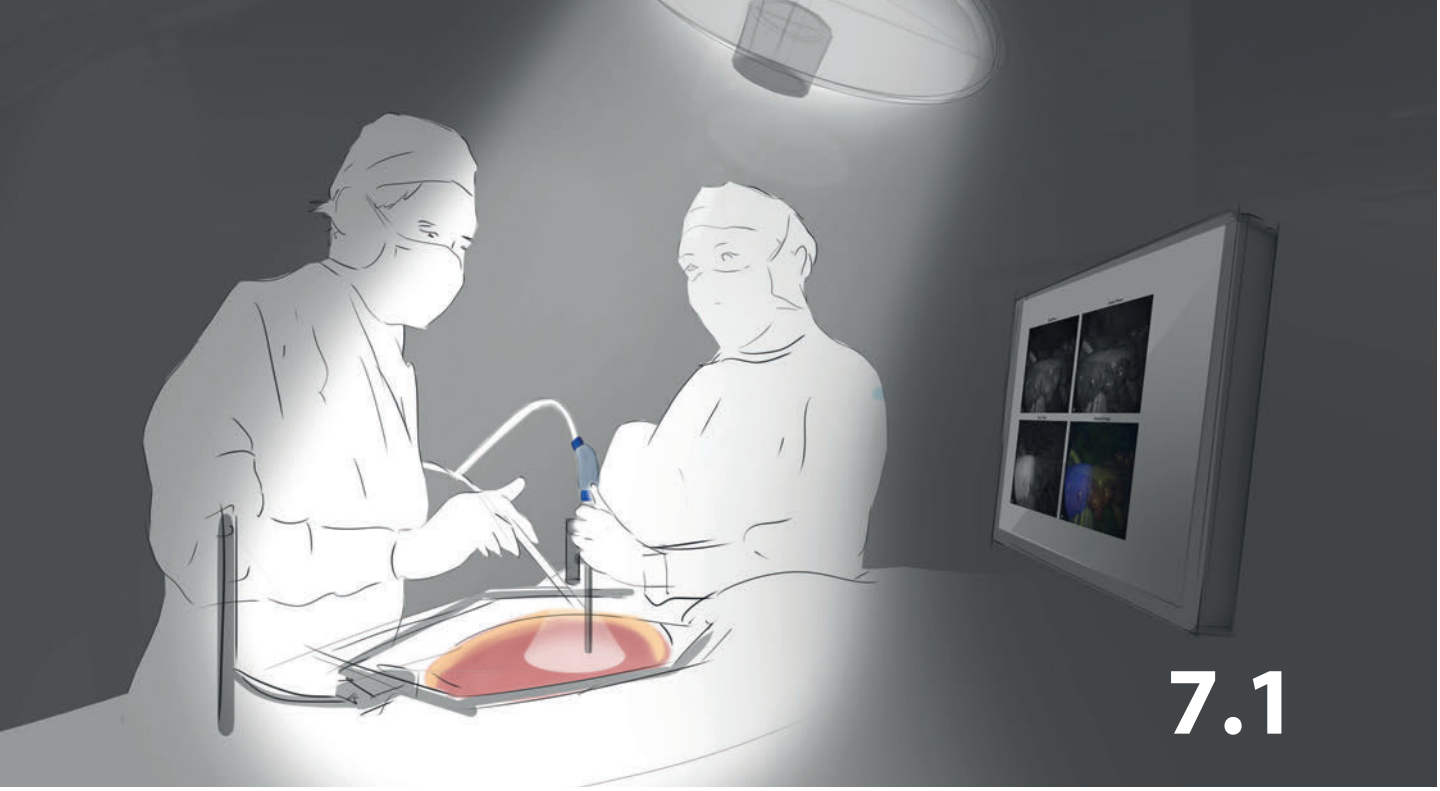


Fig 7.2. **Visualisation of scenario with normal (current) lighting.**

7.1 Full access

This direction aims to respect the full workflow by leaving the current working environment as it is, see figure 7.2. The surgical team and others in the room would thereby have adequate lighting at all times and be able to build their mental model without any hinder as all data sets can be addressed, see figure 7.3.

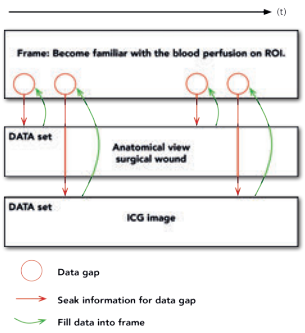


Fig 7.3. **Accessibility of both data sets.**

7.1.1 Feasibility

7.1.1.1 *Surgical lighting on*

Figure 7.4 shows the lighting environment in OR 6 when the surgical lights are on. In figure 7.5 it is clearly visible that the ICG spectrum (600 – 900 nm) is violated and thus will interfere with the ICG assessment. For this reason, this direction is evaluated as not feasible for an ICG assessment.

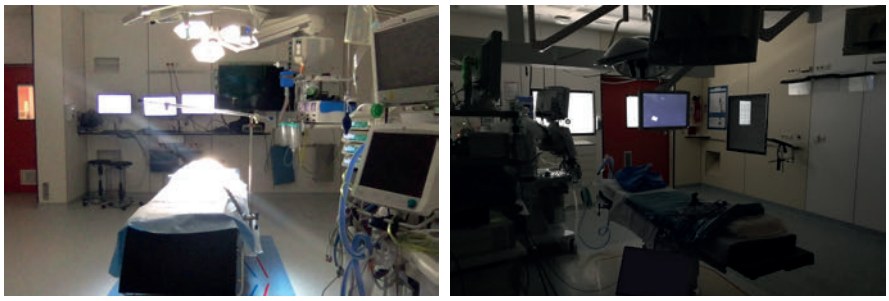


Fig 7.4. **lighting OR6 with surgical light and dark lighting scenario of OR4.**

7.1.1.2 *Surgical lighting off*

Currently, the lights of the OR are switched off while assessing the ICG. Figure 7.4 shows this dark scenario in operation room 4. The shutters on the windows adjacent to the corridor are shut, however light shines into the room. Figure 7.6 depicts this light spectrum and its interference in the ICG spectrum. Though the interference is small, the ICG spectrum is violated and it can't be excluded that this won't influence the final assessment. Especially when we take the Quantum

Efficiency (Q.E.) of approximately 5% for the ICG into account. By a rough estimation we can calculate the expected irradiance of the ICG.

$$Quantum\ flux\ E = \frac{\left(I * \lambda * \left(5.03 * 10^{15}\left[\frac{1}{m^2 * s}\right]\right)\right)}{6.02 * 10^{17}\left[\frac{1}{\mu mol}\right]\ (Avogadro\ number)} = \mu E$$

$$Quantum\ flux\ Excitation\ light\ = \frac{\left(0.08\ \left(\frac{W}{m^2}\right) * 780[nm] * \left(5.03 * 10^{15}\left[\frac{1}{m^2 * s}\right]\right)\right)}{6.02 * 10^{17}\left[\frac{1}{\mu mol}\right]} = 0.522\ \mu E$$

$$Quantum\ flux\ Emission\ light\ \ (ICG) = 0.522\ \mu E * \frac{1}{20} =\ 0.026\ \mu E$$

$$Irradiance\ Emission\ light\ \ (ICG) = \frac{830\ [\mathrm{nm}] * (0.826 * 10^{-2})}{0.026} = 0.0038\ W/m^2$$

If we depict this irradiance in the graph, see figure (X), we see that the environmental light is still one fifth of the fluorescence irradiation. Nevertheless, we must note that this calculation is a rough approximation.

7.1.2 Conclusion

We aim to exclude all external light in the ICG spectrum. This is not met in the current dark-scenarios in the operation theatres and thus this direction is assessed not sufficient for an ICG assessment.

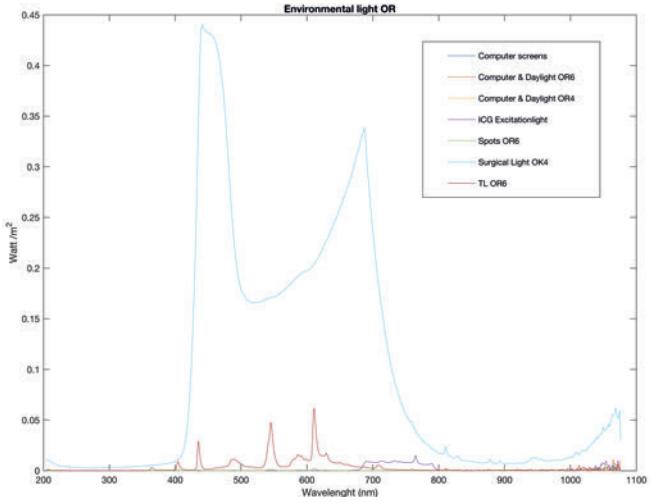


Fig 7.5. **Various light spectra available in OR6/4**

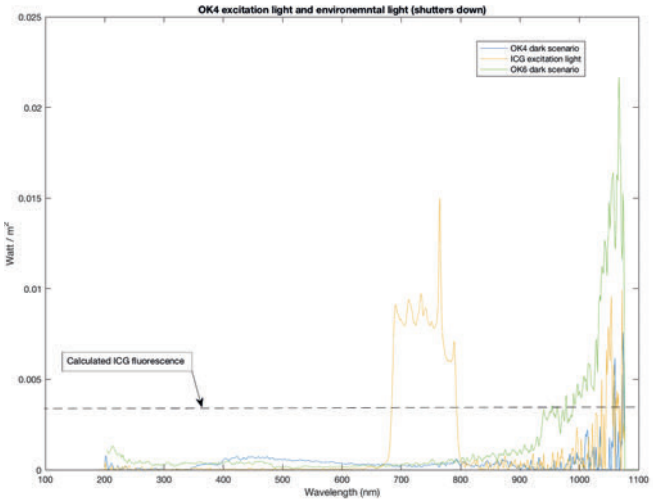


Fig 7.6. **Various light spectra available in OR6/4**

7.2

Fig 7.7. **Visualisation of scenario with altered lighting.**

7.2 Adjusted light conditions

This direction aims to respect the full workflow by leaving the current working environment as much intact as it is but, by using filters in front of lights or windows, making sure no light will interfere with the ICG assessment, see figure 7.7. If this is possible, all data sets can still be addressed, although the trueness of the colour, especially R9, will most probably not be met, see figure 7.8.

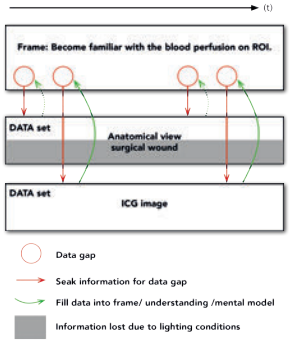


Fig 7.8. **Accessibility of both data sets, however with altered presentation of information.**

7.2.1 Feasibility

Not all lights in the room do interfere with the ICG spectrum. Spots in the ceiling (450 – 650 nm) could be left on to provide sufficient (non-surgical) lighting in the room for the staff, see figure 7.9 & 7.10. According to Zhu et al. (2014), a cool mirror from 3M (3M Cool Mirror Film 330) can be used in front of the surgical lights to discard them from transmitting wavelengths above 650 nm. Nonetheless, 3M put a hold on the research and production of these filters and an alternative filter is not on the market. Alternative filters that are found were not transparent or did not reflect the spectrum used for the ICG assessment. Thereby these filters will, most likely, alter the lighting conditions and thus should be disassembled during non-ICG assessment procedures. Next to the light of the lamps there are other wavelengths above 650 nm inside the room. Especially, in OR4 the daylight spectrum interferes with the ICG spectrum, see figure 7.9. It is hard to determine whether these wavelengths are derived from the daylight or have other sources (i.e. radiation from equipment inside the room).

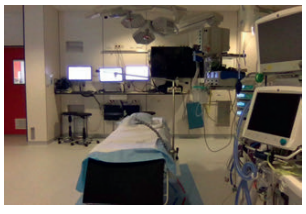


Fig 7.9. **Lighting scenario in OK6 in which only the spots are turned on.**

7.2.2 Conclusion

Not all lighting in the room does interfere with the ICG. Nonetheless, we still observe interfering wavelengths when all lights are off. The origin of these wavelength is hard to determine, and thus unsure if covering the lights and windows with filters will exclude this interference. Furthermore, this would become expensive and time consuming. To conclude: a more sufficient option would be to cover the surgical site instead of the light sources.

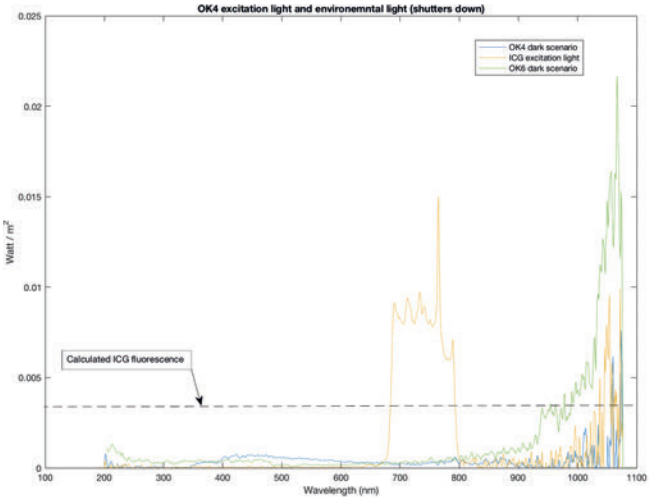


Fig 7.9. **OK4 Dark scenario spectrum with excitation- and emission light.**

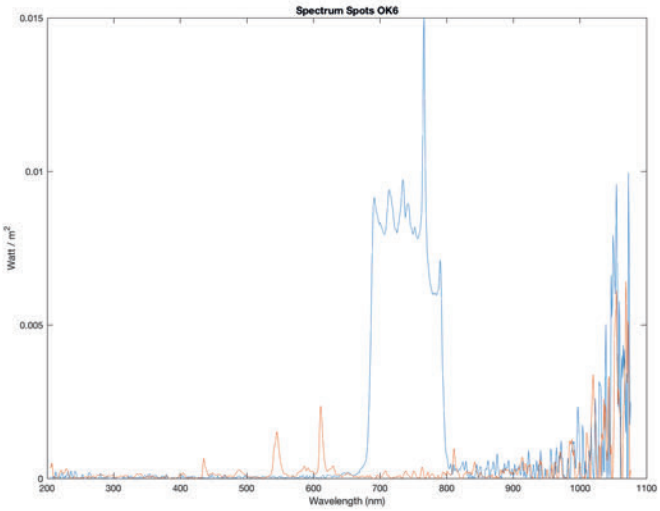


Fig 7.10. **OK6 spectrum om spots**

Companies contacted for filter information:

3M (Netherlands)
tel: (+31) 15 78 22 333
www.3m.com
woostveen@mmm.com

Edmund optics
tel:+44 01 404 788 600
www.edmundoptics.eu

SkyFuel (America)
tel: (+1) 303.330.0276
www. skyfuel.com
info@skyfuel.com

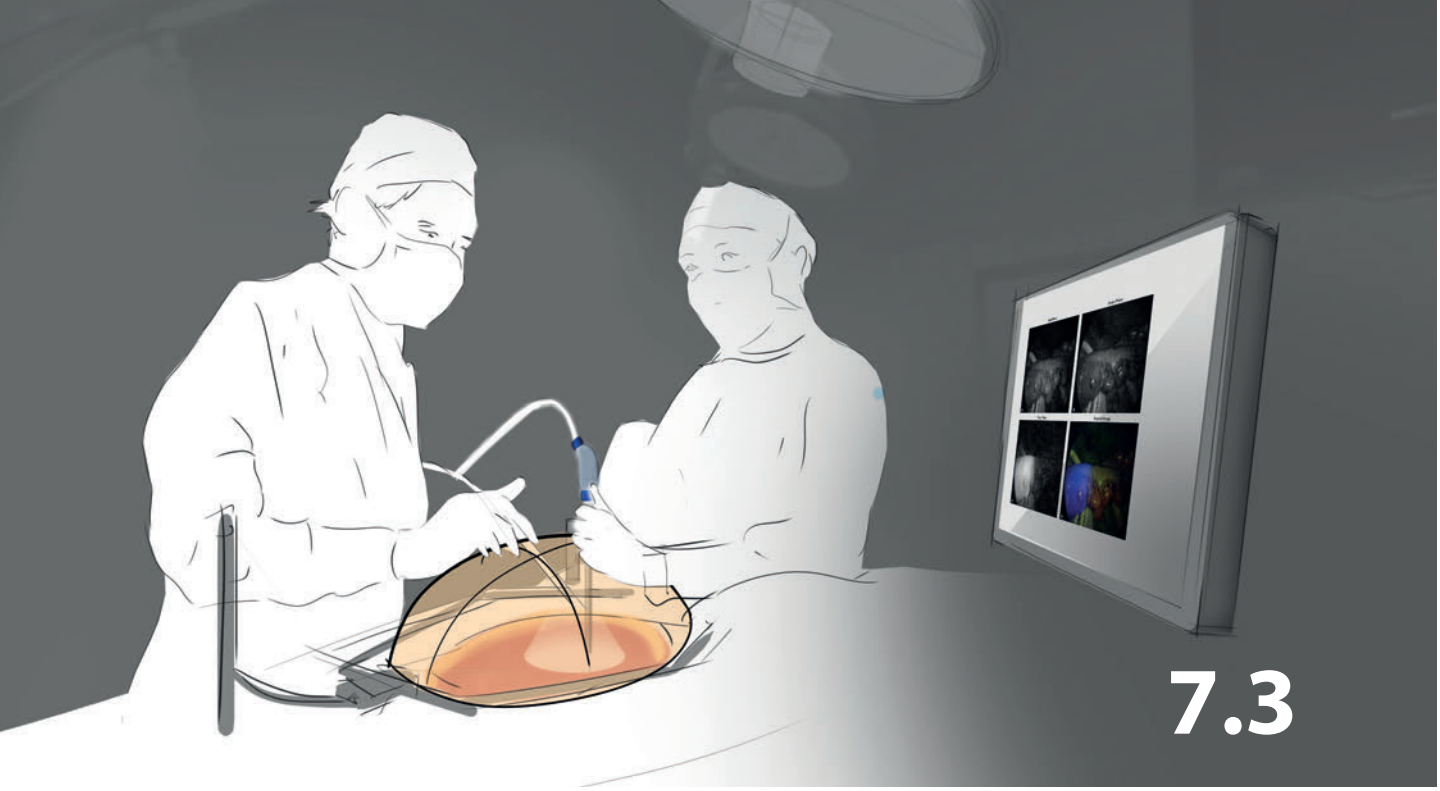
LEE filters (England)
tel: +44 (0)1264 366245
http://www.leefilters.com

Praezisions Glass & Optik GmbH (Germany)
tel: +49 (0) 2371 77679 - 58
www.pgo-online.com
sk@pgo-online.com

Spectrum Thin Films (America)
tel: 631-901-1010
spectrumthinfilms.com
Derek@spectrumthinfilms.com

Midwest Optical Systems, Inc.
tel: 847-306-3707 119
midopt.com
sw@midopt.com

Knight Optical (England)
tel: +44 16 22 85 9 444
www.knightoptical.com
gabriel.boxall@knightoptical.com



7.3

Fig 7.11. **Visualisation of scenario with transparent cover over ROI.**

7.3 Transparent cover

This direction assumes that the lighting condition inside the room can't be controlled and so will always interfere with the ICG fluorescence and therefore a filter will be used to cover the surgical site, see figure 7.11. This filter cover will block access during the actual assessment, however due to its transparency it will leave the data sets as much intact as possible. Nevertheless, colour and brightness will shift due do the filter, see figure 7.12.

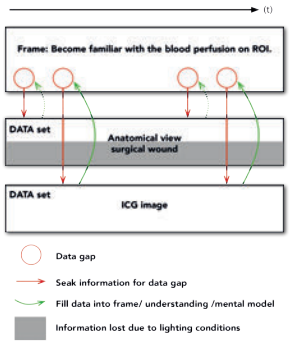


Fig 7.12. **Accessibility of both data sets, however with altered presentation of information.**

7.3.1 Feasibility

To have benefit from this direction, the filter should pass the visual spectrum up to 650 nm, so a clear view is achieved. The use of colour filters was researched and found insufficient, see figure 7.13. And according to John Cuff (personal communication, June 6, 2018) from the company Lee Filters, colour filters are not competed when wavelengths higher than the visual spectrum need to be blocked, and a hot mirror filter should be used. This same advice is given by Matthijs van

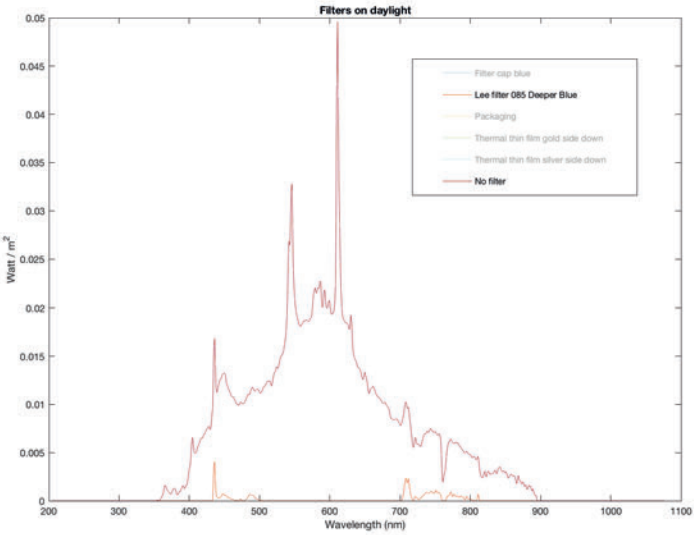


Fig 7.13. **Measurement of daylight with colour filters. Depicted the most viable colour filter, nevertheless propagated with wavelenghts in the ICG region.**

Hengstrum, mecanical engineer, (personal communication, June 8, 2018). A hot mirror is a specialised dielectric mirror, also known as a dichroic filter, that reflects infra-red light. Figure 7.15 shows an example of a light spectrum behind a hot mirror that would be applicable in our application. According to Derek Schomberg, from Spectrumthinfilms (personal communication, June 6, 2018), these filters can, however, not be applied on anything flexible (e.g. a thin film or PVC transparent sheet) as they would crack. More important, these filters are subjected to the angle of incidence of the light, the higher the angle the lower the efficiency of the filter. According to Stephan Koethe from Praezisions Glas & Optik GmbH (personal communication, June 14, 2018) the maximum size of a hot mirror is 240mm x 316 mm, which has a price tag of €380,-

Fig 7.14. **Range of different colour filters that where tested during this project.**

7.3.2 Conclusion

Transparent cover material to exclude light interference at the surgical site is researched. We looked at colour filters and a hot mirror filter. The first cannot block the unwanted wavelengths and is excluded. The latter does block these wavelengths, however cannot reach its full potential for the various angles of incidence of the light in the room. Thereby, flexibility and price are a downside. Altogether, the viability of a transparent cover over the ROI is low.

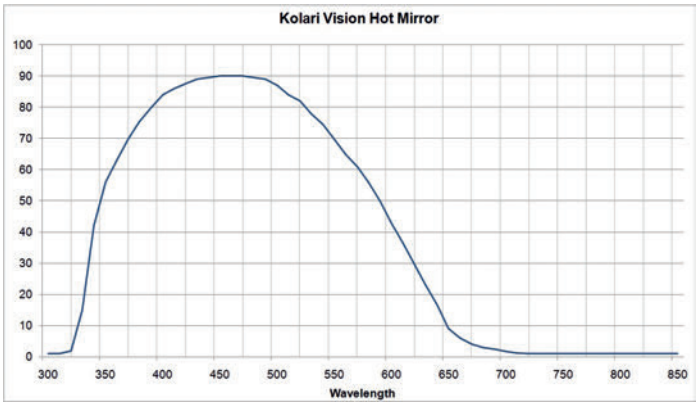
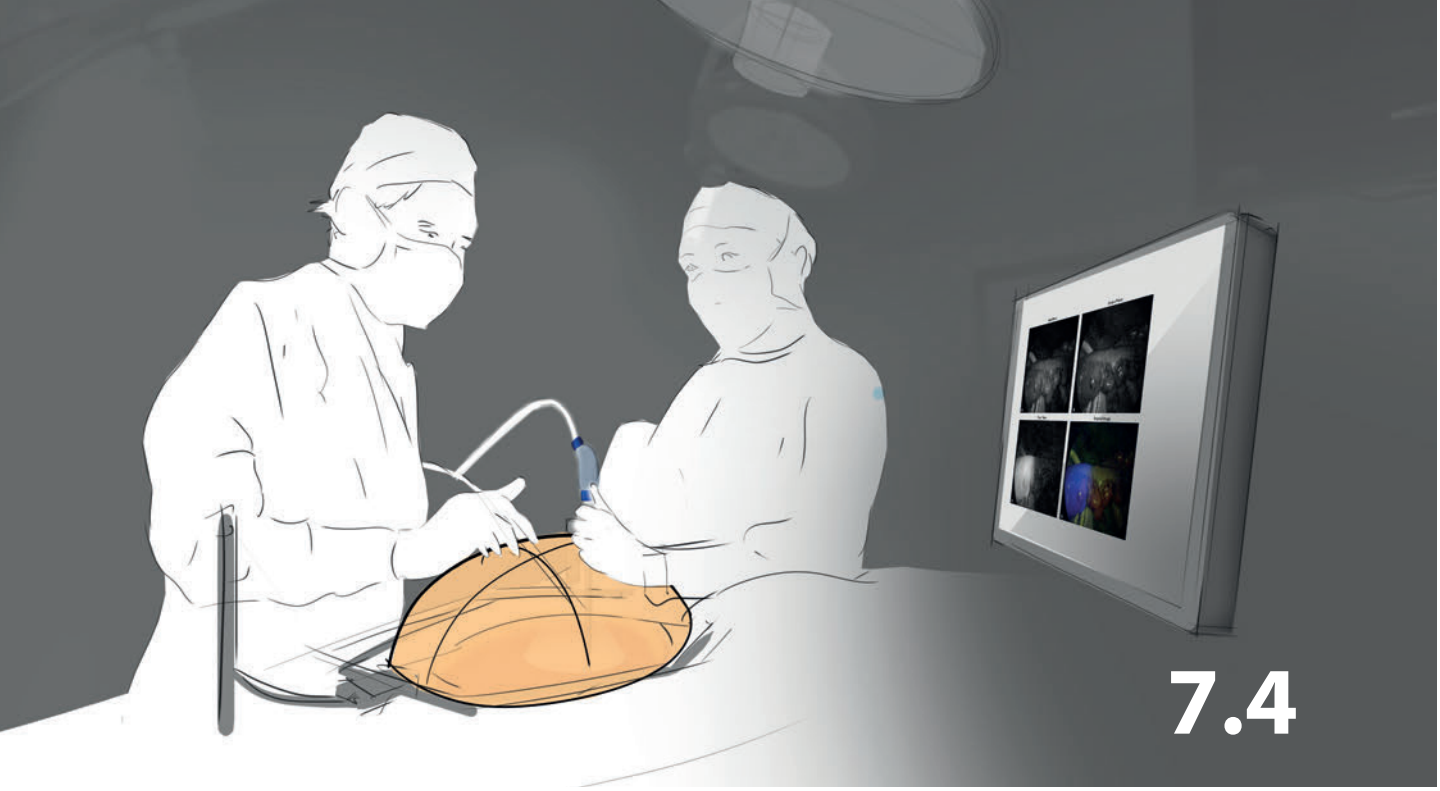


Fig 7.15. **Spectrum block of hot mirror filter.**



7.4

Fig 7.16. **Visualisation of scenario with cover over ROI.**

7.4 Non-transparent cover

This direction contains a non-transparent cover over the surgical site, see figure 7.16. It will have the biggest impact on the workflow and mental model as the anatomical view is blocked during the ICG assessment and thus the surgical team must depend more on their visual memory, see figure 7.17. However, it will exclude interference of external light.

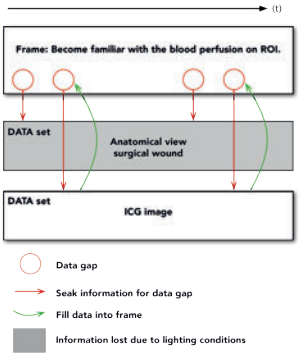


Fig 7.17. **No accessibility of Anatomical data set during ICG procedure**

7.4.1 Feasibility

The most practical manner would be to use a surgical drape to cover the wound, however they do not block wavelengths above 650 nm, see figure (X). Nevertheless, an adjusted surgical drape might do the trick. A thermal thin film used in emergency blankets to keep a victim warm reflects up to 97% of radiated heat and via a test it is seen that it does also with our desired spectrum, see figure 7.18 & 7.19. As earlier discussed this MPET thin film can be implemented into a surgical drape.

7.4.2 Conclusion

To block interference of external light sources in the OR, a complete cover over the surgical site seems the most viable direction. Although, it will have impact on the workflow and mental model of the surgical team.

Fig 7.18. **Light measurement with and without a thermal sheet cover.**

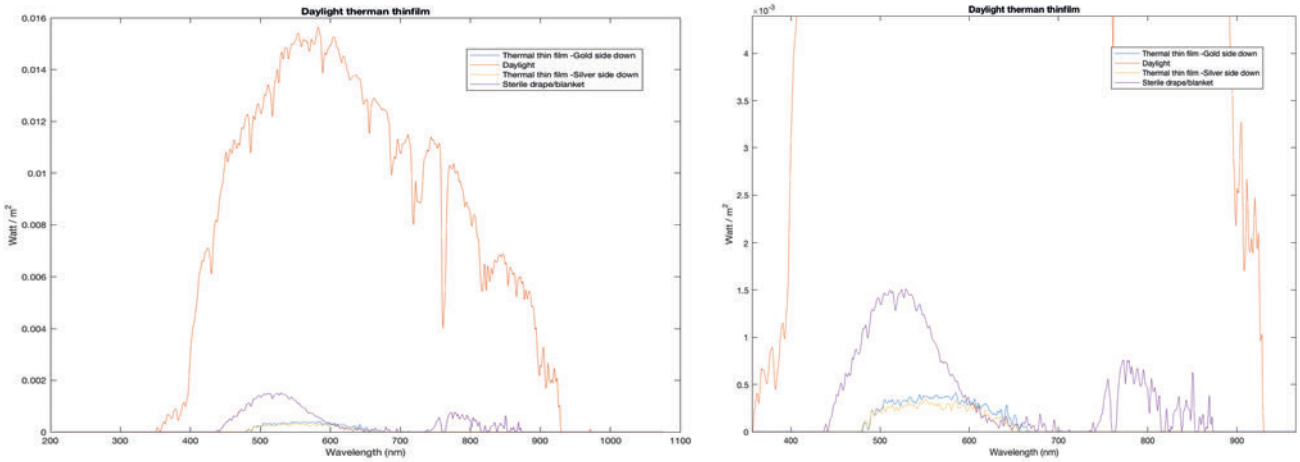


Fig 7.19. **Light measurement with and without a thermal sheet cover, (right) zoomed in on the ICG Spectrum. Visible that the thermal sheet (blue and yellow lines) does block wavelengths from approximately 680 nm and thus clears the ICG spectrum from light interference.**

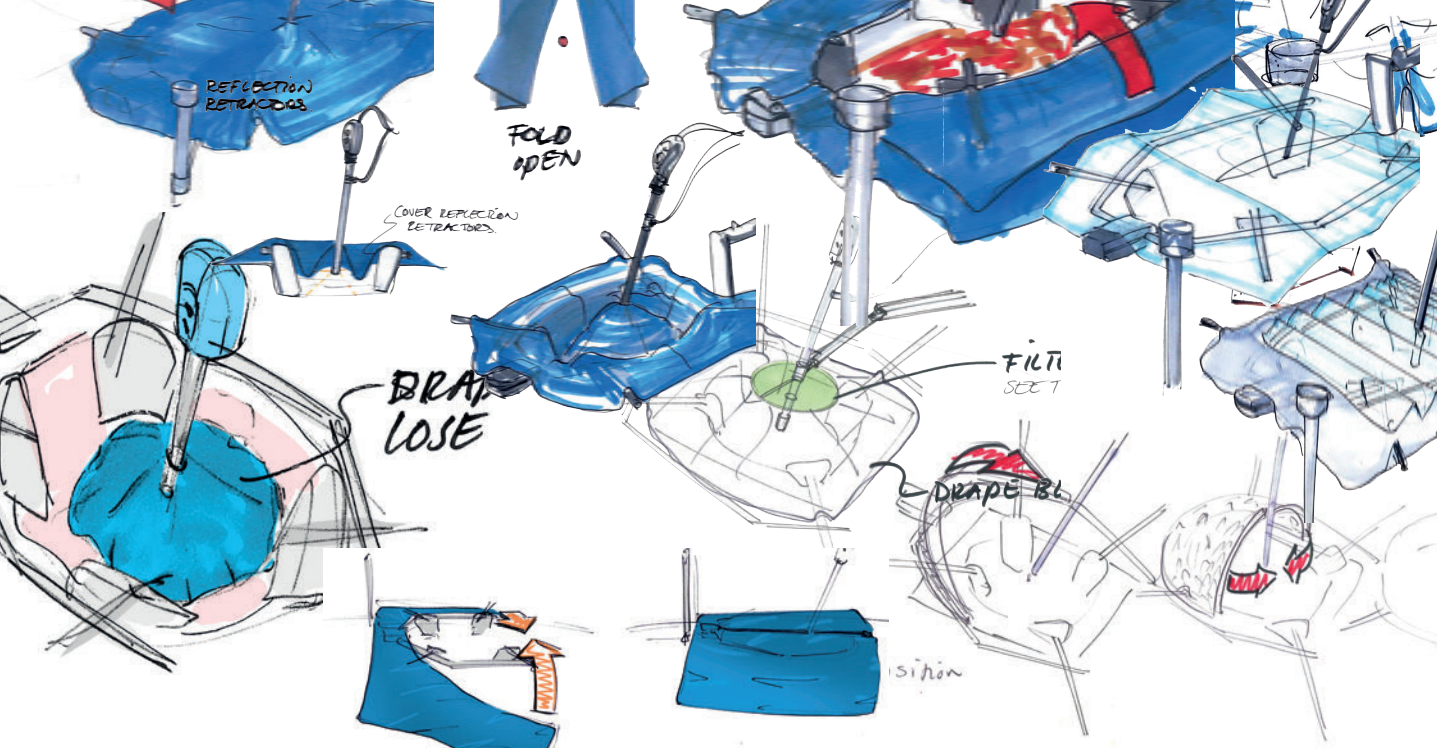


Fig 7.20. **Skechtes of various cover ideas.**

7.5 Excluding light

While an ICG assessment is made, interference of external light must be excluded to gain a more objective ICG output image. As for material optical properties a non-transparent cover is to be used, see chapter 7.4. The surgical wound must be covered in such a manner that light from above, sideways and from between the omnitract and patient does not reach the surgical site, see figure 7.21. The cover is irrevocable in the sterile field and it can't be ruled out that it will touch the surgical wound. This should be possible without harming the patient.

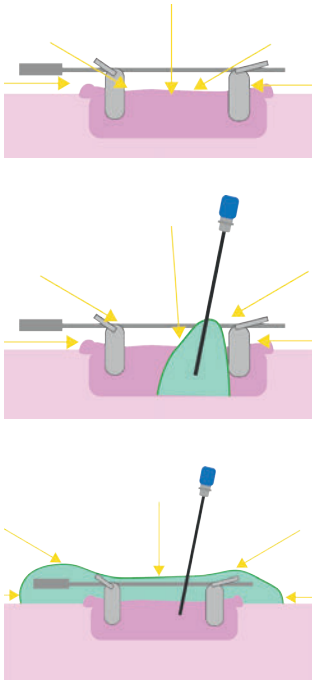


Fig 7.21. **Incidence light on surgical wound.**

Fig 7.22. **Internal cover.**

Fig 7.23. **External cover.**

7.5.1 Workflow

The cover may not block the view of the ICG camera or block the ability to adequately position the camera. Two directions are chosen to elaborate on; an internal cover (figure 7.22) and an external cover (figure 7.23). In both instances the camera must be positioned prior to closing the cover as the anatomical view is needed to position the camera.

7.5.2 Direction internal cover

An internal cover could prevent reflection on surgical instruments, which is a great benefit. Thereby it could solely cover the ROI whereby access to the remaining surgical wound remains. By means of a phantom model of the abdomen some tests have been conducted, wherein different sizes and materials were used. Size, rather than stiffness or flexibility of the material, has a great influence on the ease wherewith the cover can be positioned. This caused problems for the internal cover. The view of the scope got blocked in many occasions (figure 7.24F), even when a widener was used to clear the view (figure 7.24G) or an internal stiffer frame (figure 7.24H) and thus attention had to be paid to keep the scope view clear. By means of a smaller cover this issue could be eliminated. However, this smaller size could not cover the total ROI and light was not blocked.

7.5.2.1 *Conclusions*

An internal cover may be difficult to position, especially during surgery. This is

dependent on the size of the cover in comparison with the size of the surgical wound and the height of the scope to the ROI. Regarding these issues and the prospect of these issues and time consumption during the surgery this direction is put to a hold.

Fig 7.24. **A: Phantom. B: Placement of internal cover. C: Internal cover, with many folds. D: Smaller internal cover. E: Smaller internal cover with insufficient range. F: Blocked scope view. G: Widener on scope. H: Internal frame of Bubblewrap.**

7.5.3 Direction external cover

An external drape would fall over the entire omnitract and thereby eliminate light from the total surgical wound, see figure 7.21. Two directions were tested; one in which two identical drapes are to be used and one in which one drape with addition is used.

7.5.3.1 *External cover | Design one*

By means of two drapes the surgical site is covered. To avoid the drapes falling into the surgical wound, a clip is added to the scope and by means of cuts in the drapes the covers are placed in overlapping position, see figure 7.25. During a test on the abdominal phantom, it was assessed that the drapes would need to have either several cuts, or the direction will demand a very big cover to overlap around the scope as the position of the scope may differ in X, Y and Z direction. Thereby, it took considerable time during the test to check the seams for light penetration. An additional clamp on the scope is needed to keep the drape in place and prevent it from falling into the cavity (figure 7.27). The upside of the design is that the drapes only need an extra layer of MPET and that thereby the production is easy.

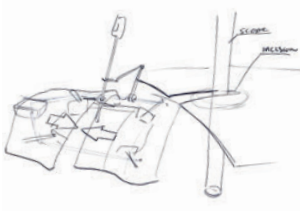


Fig 7.25. **External cover existing out of two drapes with cuts to fold around scope.**

Conclusion

The use of these two drapes need too much attention and demands to much time and is therefore assessed as unwanted.

Fig 7.26. **Cuts of the two drapes fold around the scope.**

Fig 7.27. **Widener clamp on scope.**

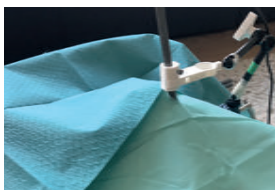


Fig 7.28. **Large seams to check for light penetration.**

7.5.3.2 *External cover | Design two*

The second design consists of two pieces, namely a main cover and an additional round top cover, see figure 7.29. A hole is added in the main cover to intercept the largest movements of the scope and partially leave open the anatomical view on the ROI. When the scope is placed, the hole is covered by the round top cover. No issues with the drape sagging into the surgical wound where observed during the tests, nevertheless this should be tested in a real scenario. The drape can be folded in a specific manner whereby the hole is facing down to be placed easier on correct position over the ROI, see figure 7.30 for the workflow.

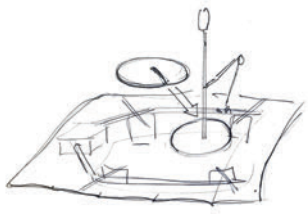


Fig 7.29. **External cover consisting out of a big drape with hole and a cover piece.**

7.5.4 Conclusion

Adding a hole in a drape is seen as an effective and viable manner to exclude light from the ROI and is the direction the we will further elaborate on.

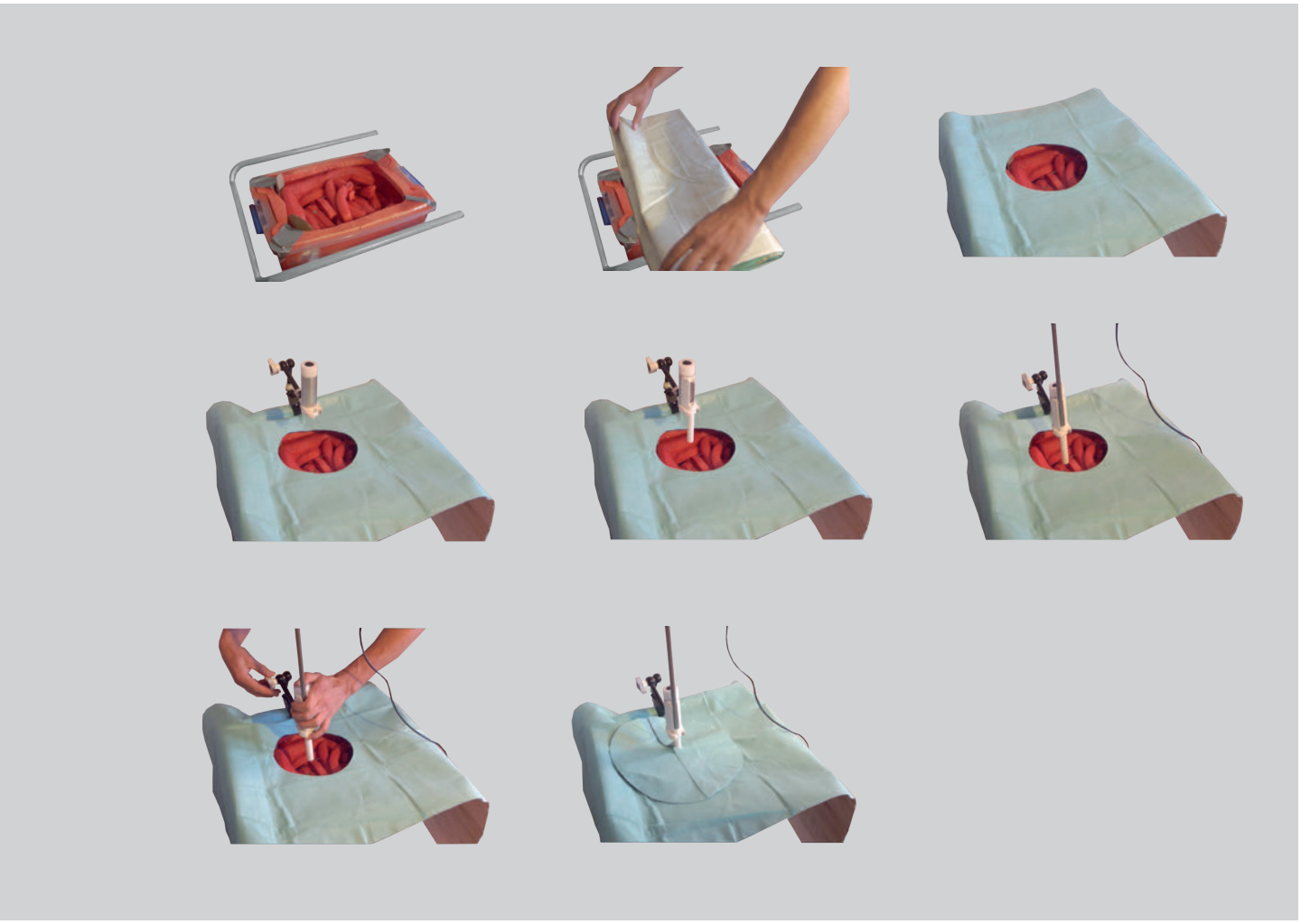


Fig 7.30. **First prototype of the drape final design. From left to right, starting above: Phantom model, placing big drape, unfolding drape, placing camera, placing scope-mount, placing scope, position camera, cover hole. Note this this figure depicts a leap in this thesis as it already shows a glimpse of the scope addon.**

Fig 7.31. **First prototype of the drape final design.**

8 Distance

Fig 8.1. **Sketch of measurement device**

To measure the distance from camera to region of interest a measurement device (MD) is needed. This chapter will entail the creation of the device. First, the working principles will be discussed after the design will take shape.

8.1 General design principle

Speed of the system is important regarding workflow and ICG assessment. Ideally the system can be used without prolonging surgical time and thus, as preparing unsterile devices with sterile sleeves is a time-consuming procedure, the aim is to create a device that can be presented on the OR under sterile conditions. To do so the device will be a standalone device that entails its own power supply, measurement and feedback system. In this manner no wires are needed, and the device won't need an additional sterile drape and can potentially be provided to the surgical team under sterile conditions.

8.2 Measure

To measure the distance from scope tip to region of interest, a Time of Flight (ToF) sensor is used, see figure 8.2. By measuring the time between sending a light pulse of 940 nm and receiving its reflection on the ROI the distance is calculated in millimetres. By its wavelength it will not interfere with the ICG spectrum and is therefore useful in this project.

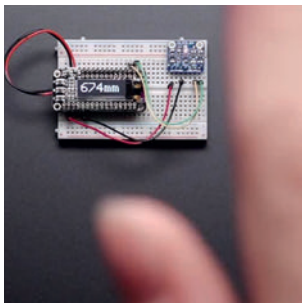


Fig 8.2. **Time of flight sensor. Reprinted from Adafruit (n.d.).**

8.2.1 Other manners

Other directions, such as an analogue solution showed in figure 8.3, are excluded as it would take more time and steps to position the scope and might cause unsafe situations, as close contact with the tissue would be needed. Next, an ultrasonic sensor with the same working principle as a ToF sensor however working with sound is tested, see figure 8.4. This sensor is discarded for this project as it could not detect through glass which is needed for a watertight design regarding sterilisation. All the aforementioned can't detect the slope of the camera to the object which could

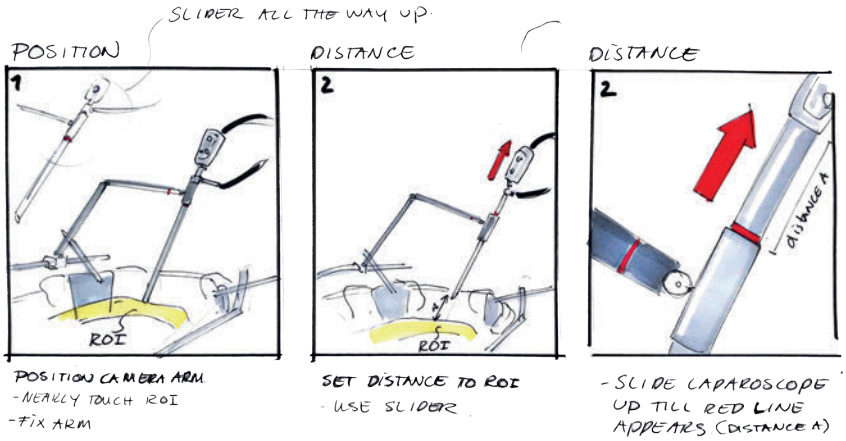


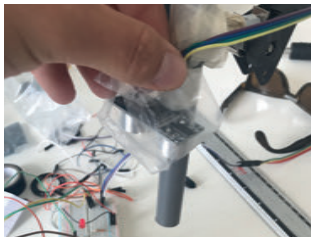
Fig 8.3. **Analogue solution, whereby the scope is first located to nearly touch the ROI and then pulled back a certain standardized distance.**

be beneficial regarding the tissue penetration depth of the excitation light. This can be done either by making use of camera disparity, see figure 8.5 or with a laser pattern, see figure 8.4. Nonetheless, the first is not accurate enough for small details and the latter would give bright spots on the ROI that will challenge the dynamic range of the camera. This issue can be eliminated by filming the ROI in modalities, so no bright spots of the lasers will be detected by the camera. Nevertheless, the landscape of the ROI is rough, and therefore would already be difficult to detect slopes. Altogether detecting slopes seems somewhat too difficult within the timespan of this project.

Conclusion

Detecting slope to improve penetration depth of the excitation light is too complicated for this project. The design will detect the most important acquisition factor, namely distance by means of a time of flight sensor.

Fig 8.4. **Ultrasoon sensor, not capable to measure through glass or sterile sleeve.**



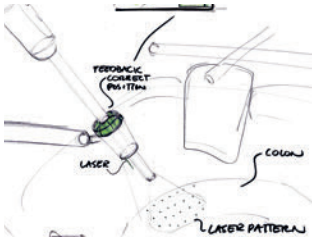


Fig 8.5. **Laser pattern. By projecting a laser pattern on a surface the landscape can be calculated via a camera and computer.**

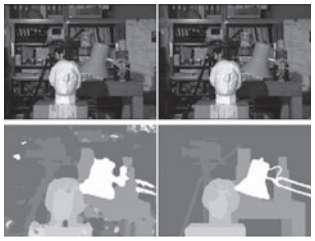


Fig 8.6. **Disparity image and Depth map. By assessing the disparity between images of two camera with the same focus point distance can be calculated. Adapted from Domínguez-Morales, Jiménez-Fernández, Paz-Vicente, Linares-Barranco, & Jiménez-Moreno (2012).**

8.3 Communicate

Measuring the distance is only useful when it can be communicated to the surgical team. Proper and understandable feedback is thus important. According to Hinze-hoare (2004), it is important that the feedback is familiar, which can be done using commonly understood metaphors. For the distance measurement device, the metaphor that is chosen is a parking sensor, where the interval between sound beeps correlates to a certain distance. During the positioning of the arm the attention of the camera operator alters between the anatomical site, the ICG monitor, the scope and the surgeon. Ideally the feedback is observed without interference of the workflow. This could either be done by haptic, visual or audible feedback. All require some considerations.

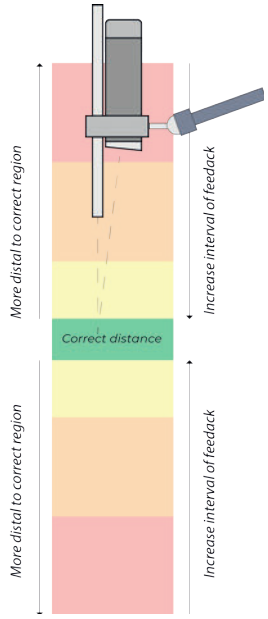


Fig 8.7. **Correlation between distance and feedback interval as seen in parking sensors.**

8.3.1 Sound

Beeping sound is a common audible feedback from medical devices (e.g. anaesthetics device) and could therefore be confused as feedback of other devices when the sound lacks differentiation or could alert personnel when the source or meaning of the sound is not clear. On the other hand, it does not solely communicate to the camera operator and thus adequate positioning of the camera can be verified by for example the surgeon. On the technical side, the sound level will decrease due to a watertight enclosed design. After measurement it is observed that the sound level of an 80dB buzzer enclosed in a watertight design will reach up to 58dB, which is in the average sound level of the operation theatre.

8.3.2 Visual

The source of visual feedback might be clearer than audible feedback. Though, this feedback might interfere with the ICG spectrum or might not be visible when the design is hold by hand, see figure 8.8. Shining light on the ROI is not an option, although it can be seen by the camera operator on the monitor and by the view on the anatomy, as it could not only interfere with the ICG spectrum but could thereby give a confusing ICG output image, see figure 8.9.

8.3.3 Haptic

Haptic feedback on the other hand is not subjected to issues with a watertight design, visibility or issues with confusion of the source of sound. However, it is only noticeable by the user and it is not clear if it can communicate the distance well enough. To determine if solely vibration is an adequate feedback a user test is set up.

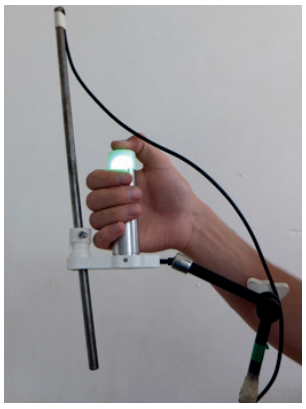


Fig 8.8. **Light feedback in product**

8.3.4 Design

In the design the feedback of distance measured between scope tip and correct position alters in interval of vibrations according to the distance, see figure 8.7. In the test, three feedback codes with different interval vibrations were tested. A total of 5 participants were asked to set the device to, as they thought was the correct distance according to the feedback, whereby they primarily had to look on a screen that showed the scope view, see figure 8.10. In this qualitative test they were asked on their opinion on clarity of the feedback and ease to set the device to the correct position while solely looking at the output image in front of them.

8.3.4.1 *Results*

All five participants were able to set the device to the correct position at their first attempt by means of the haptic feedback. As a conformation for adequate positioning they expected the device to continuously vibrate. In one of the feedback programs the vibrator had a very small interval in the correct distance region instead of a continuous vibration and this was therefore conceived as confusing. As the distance region of the different intervals were small, the feedback became clearer and it was easier for the participants to know if they were close to the correct distance. The device gives a short vibration after 2 seconds when the button is pressed to inform the user the device is active. For the participants this came too late. Ideally this feedback should be instant, however due to the software on the Arduino board it is not possible without rewriting the software on the chip.

Fig 8.9. **Shine feedback light on ROI.**

8.3.5 Conclusion

Haptic feedback seems the most viable feedback in a surgical environment and can adequately communicate distance to the user.

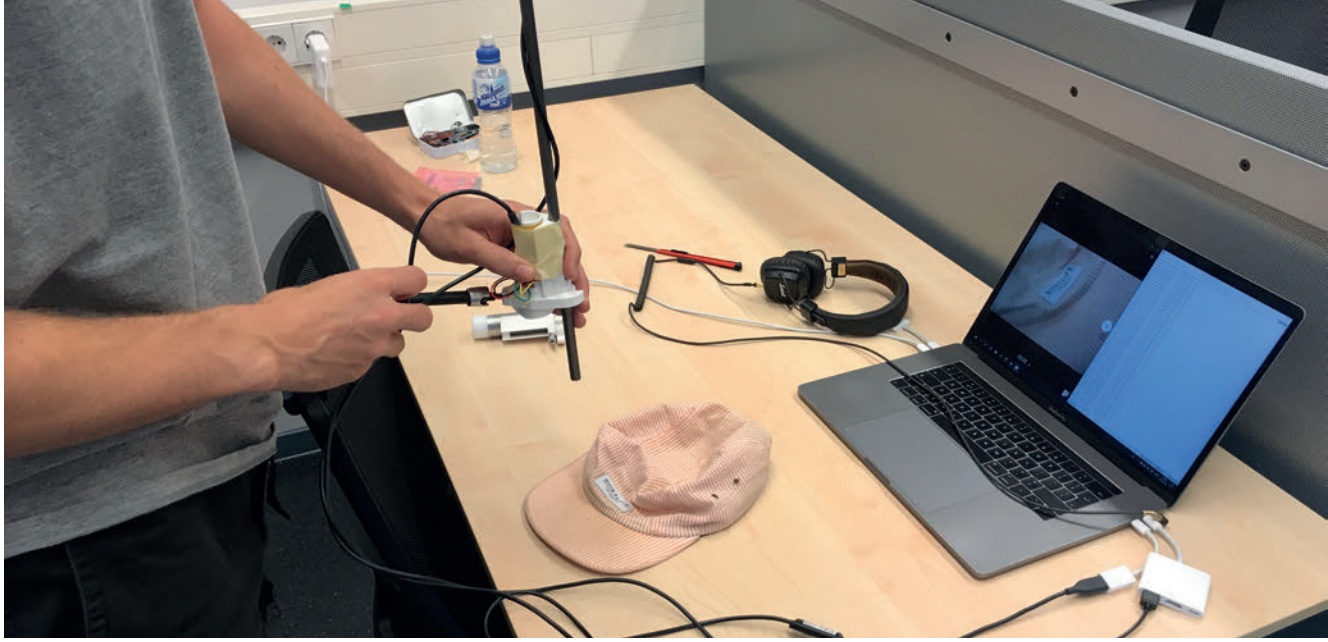
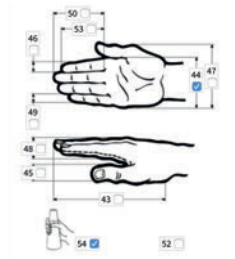


Fig 8.10. **Usertest with haptic feedback.**

8.4 Shape

Regarding sterilisation the device must be watertight. For this reason, a round shape is chosen as it can meet this requirement by means of gaskets and thread connections, much like a flashlight. The measurement device will thereby serve to position the system and so an ergonomic handling is needed. According to Patkin (2001), an ergonomic grip shape for cylinders should have a diameter of 30 to 40 mm. The lengths should at least be 99 mm regarding hand sizes up to P95, see figure 8.11. The position of the device should be between scope and arm, to be operated ergonomically for both left- and right-handed people, see figure 8.12. In a second test, see figure 8.13 and 8.14, it is observed that placing the module above the arm mount is easier and people did understand better how to hold the device. Thereby, this leaves more room for a cover over the ROI and decreases the change of fingers in front of the sensor.



populations	Dutch adults 20–30, male
measures	P95
Grip circumference (mm)	156
Hand width (without thumb) (mm)	99

Fig 8.11. **Dined hand measures P95 (DINED database, n.d.).**

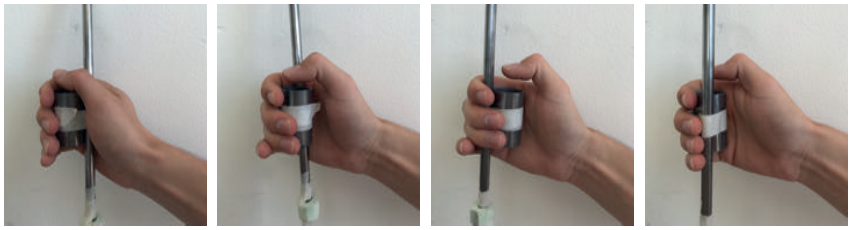


Fig 8.12. **Test with MD and scope configurations.**

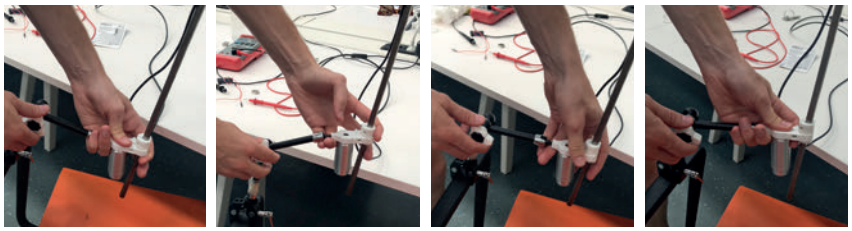


Fig 8.13. **Different postures to hold the device.**

Fig 8.14. **Test with different configurations.**

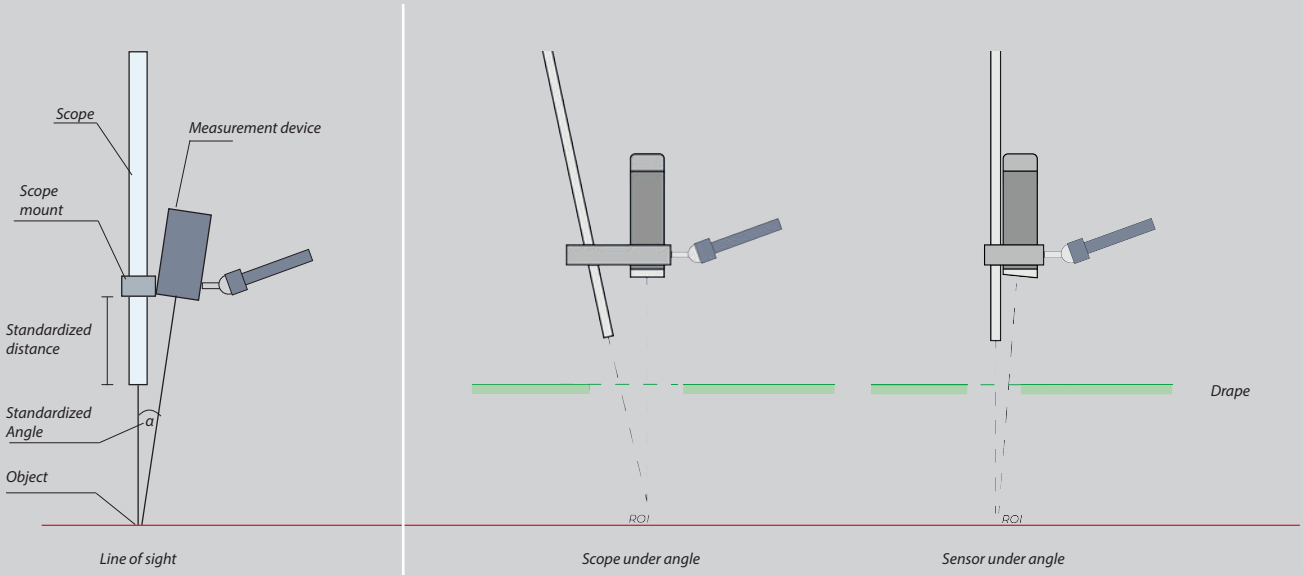


Fig 8.15. left: **Sensor and scope line of sight; angle needed**

Fig 8.16. right: **Scope under angle and sensor under angle.**

Fig 8.17. **Viability test with sensor in angled position.**

8.4.1 Distance to object and focus point

As both scope and distance sensor have a straight line of sight it is necessary to place them under an angle, so both will obtain the same focus point, see figure 8.15. The focus point of both the devices should be at 100 mm (Y-axes) from the scope tip to the ROI, which is the usual distance during open surgery. Initially the scope was set under an angle to keep the design of the MD simpler. However, the scope could not be placed close to the MD, as holding the device would become unergonomic and thus a focus angle of 12 degrees was needed. Consequently, the posture of wrist must compensate for this focus angle again leading to non-ergonomic postures. Additionally, placing the sensor and scope further from each other, and thereby the lines of sight, chances that the sensor would detect the distance to the drape instead of the ROI increase, see figure 8.16. To overcome these issues the focus angle is taken care by in the measurement device instead of the scope, see figure 8.16.
In the design iteration the sensor is placed under a focus angle of 5 degrees and allows a closer configuration of scope and MD and decreases the chance the sensor will detect an incorrect distance (i.e. distance to drape). However, this issue cannot completely be ruled out as it would need a sensor with the same line of sight as the scope. It is observed that the scope does not interfere with the line of sight of the distance sensor if the scope tip is set at a desired 80 to 100 mm below the sensor, see figure 8.17.

8.5 Workflow

8.5.1 Scope mount

Performing a baseline measurement during the surgery to calibrate the device (i.e. measure distance between sensor and scope tip) would be time consuming during the surgery and leave room for error. Therefore, the sensor will have a pre-set correct distance from scope to object. Consequently, this standardised distance must be incorporated somewhere else in the design. Basically, there are two options to do so: either a mount is clamped to the scope on the correct distance, or the distance is incorporate into the MD by means of shape. The first can be done by the scrub

nurse or at the sterilisation department. In figure 8.19 some of the ideas for a mount are shown. Although a scope mount would most probably skip one assembly action during the surgery, it also comes with some drawbacks. One of them is that it would need proper assembly on a correct height whereby we cannot rule out any mistakes. This can be avoided with a permanent mount, whereby the single attachment can be controlled more easily. However, the Hopkins II laparoscope is not only used for open surgery and the mount would obstruct a laparoscopic surgery. Therefore, we choose to go for a mount that incorporates the correct distance by means of shape, see figure 8.18. The mount can be assembled during the surgery without time consuming precise positioning.

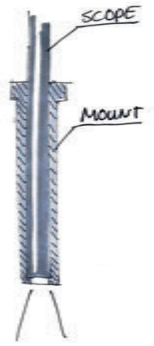


Fig 8.18.**Scope mount: by means of the shape the correct distance is incorporate into the design.**

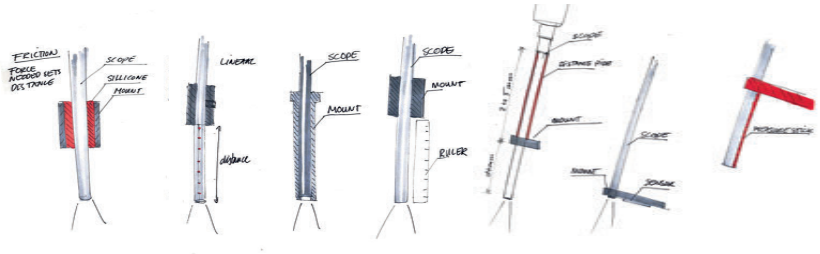


Fig 8.19. **Selection of ideation sketches regarding standardization of distance from scope tip to sensor**

8.5.2 Mounting scope and measurment device

A rigid connection to attach the scope to the measurement device is needed. Regarding the workflow it should be fast and simple. Multiple solutions are possible but regarding the workflow and the clear visual feedback if the device is adequately clamped or not a quick mount lever will be used, see figure 8.20. Thereby the clamp can be set to a certain clamping force to ensure adequate clamping or avoid too much force that may damage the scope or other parts.

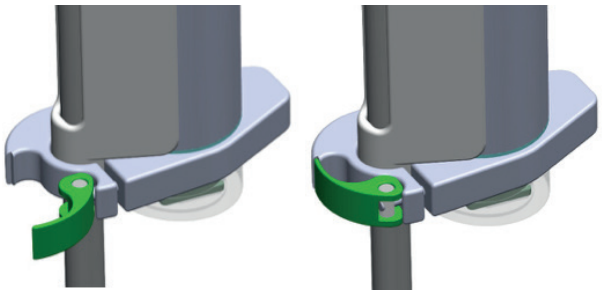
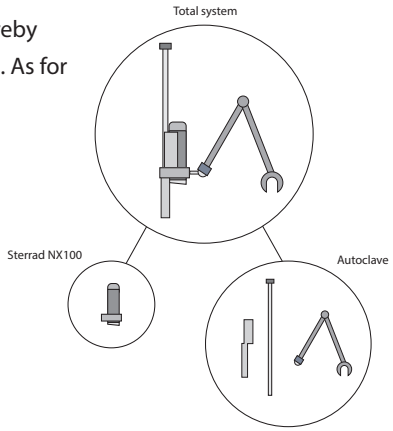


Fig 8.20.**Quick clamp lever connection, clear visual feedback if open or closed. Geometry is copied from a excisting aluminium quick clamp lever of Ruland.com**

8.5.3 Sterilization

For the design it is important that it does fit into the workflow of the surgical team. Ideally the whole system can undergo the same sterilisation program and can be presented under sterile conditions on the operation theatre and thereby avoid additional steps by the surgical team to make the device ready for use. As for sterilisation requirements the product is split into the following:

- The mechanical arm (autoclave)
- The measurement device and mount (Sterrad NX100)
- Scope (autoclave)
- Scope mount (autoclave)



Due to the electronics inside the MD it can't withstand the high temperatures inside the autoclave and should be sterilised by means of the Sterrad NX100. However, the disinfection can be done in the conventional manner (i.e. washing machine). As the arm and measurement device need to be attached during the surgery by the scrub nurse this connection should be fast and rigid. It is chosen to advice a quick fit connection with a lock such as developed by Mediflex medical solutions, see figure 8.21. This makes it possible to alter in workflow, as it can either be done by the scrub nurse, yet with the same ease and speed by the camera operator.

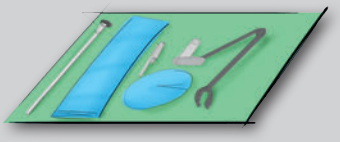
Fig 8.21. **Quick Fix Hexagonal Fitting by Mediflex Surfical Products (n.d.)**

8.5.4 Workflow

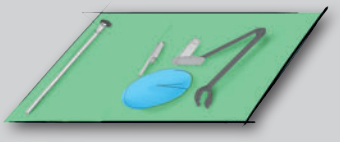
The workflow of the system on the OR is presented in figure (X). The scrub nurse receives the arm, measurement device, scope and scope mount under sterile conditions from the circulating nurse. The second step is to mount the measurement device to the arm, whereby the scope mount can already be inserted in the mount of the MD or be clammed on the scope. After the region of interest is determined and the sterile drape is installed, the arm and measurement device can be mounted on the omnitract. After the camera is put onto the scope, the scope can be set to its correct aqcuisition position.

> Fig 8.22. **Workflow and setup of scrubnurse's tray**

Tray scrubnurse

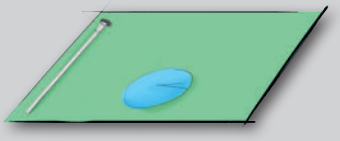


Determine region of interest

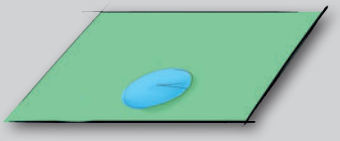


Hands surgical drape

Hands MD and scope mount

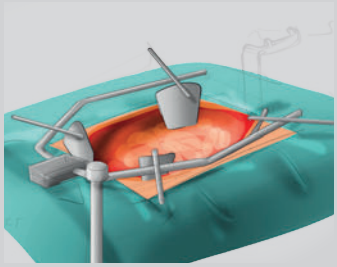


Hands scope

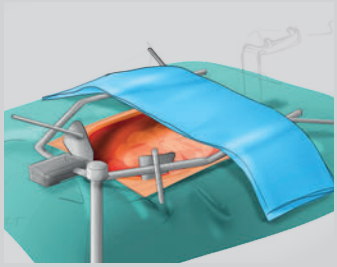


Hands cover piece

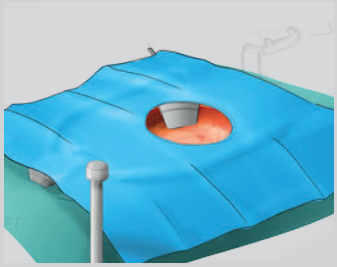
Surgical site



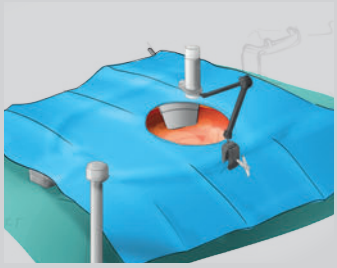
Determine region of interest



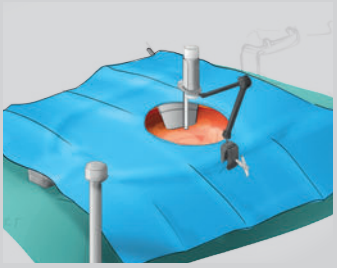
Place drape over ROI



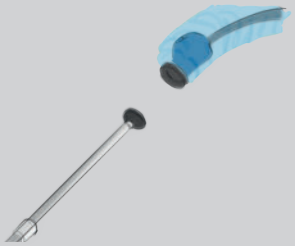
Unfold drape and reveil ROI



Place arm and MD on omnitract

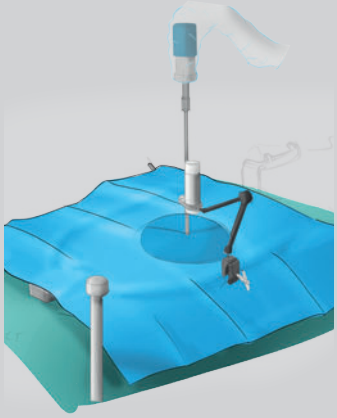


Place scope mount on MD



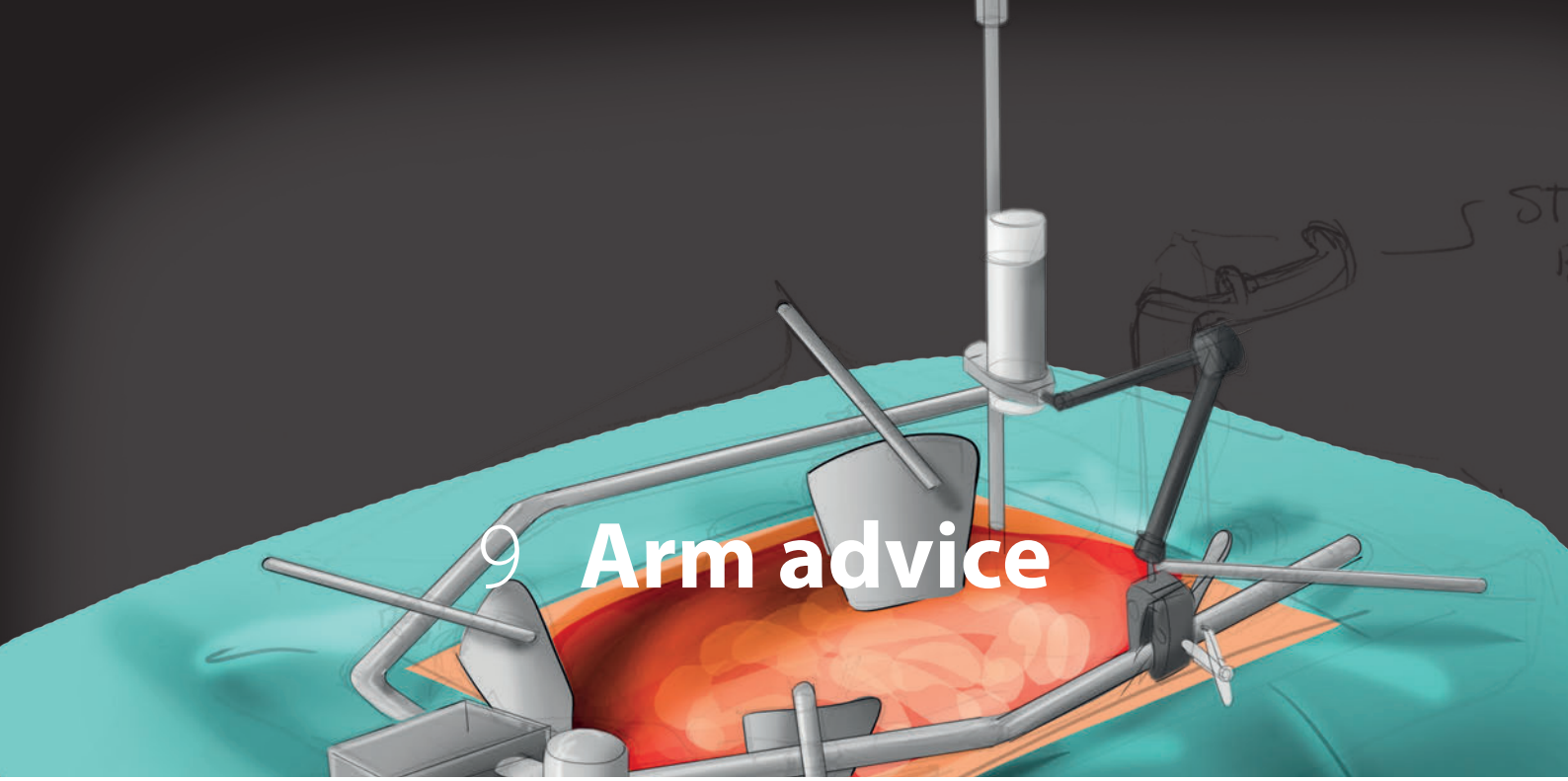
Attach scope and (sterile) camera

Place scope on MD



Place additional cover piece

Perform ICG-FA assessment



9 Arm advice

Fig 9.1. **Arm placed on wishbones of omnitract.**

As for the timespan of the project it is not achieved to fully design a mechanical arm for the system. Though, in this chapter an advice will be given.

9.1 Aim

The aim for the project is to design a product system that can be implemented into the surgical procedure without significantly prolonging the surgical time. We have seen that the arm can have a great impact on the ease and speed of the ICG procedure. Ideally the arm can be presented under sterile conditions as a single product system (i.e. handheld size with no separate parts that needs assembling during the surgery).

9.2 Location

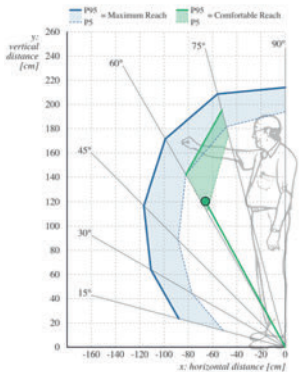


Fig 9.2. **Comfortable reach for P95 to P5 for height of arm placed on omnitract wishbones (DINED database, n.d.).**

In conclave with Dennis Schaap and prof dr. Jakimowicz it is determined that placing the system on the wishbones of the omnitract would be the most sufficient solution regarding workflow (i.e. speed and ease of placement) and would decrease the needed range of the arm and thus its volume, see figure 9.1. For ergonomic posture of the surgeons the table height should be set to 64 to 77 cm above floor level according to Berquer, Smith, & Davis (2002). The omnitract wishbones will then approximately be 120 cm above floor level, taking a P95 patient chest depth into account (DINED, 2018). According to the ergonomic data of DINED, placement of an arm in this position would be in the comfortable reach area of P5 up to P95, see image 9.2. Furthermore, a position on the wishbones will not take in too much valuable space in the surgical work field in comparison with a movable trolley (e.g. such as the Quest system). Placement on the surgical table rail is not advised due to a non-ergonomic height and as observed as often difficult due to the sterile drapes. Holding the camera by hand is excluded as the surgeon or camera operator performs actions during the ICG whereby two hands are needed. Moreover, a stable image acquisition is key and would most probably need an expensive stabilizing

system if hold by hand. We must note that placing an arm on the omnitract is not properly tested within this project. And therefore, it is unclear if the stability of the image acquisition would be adequate. Nevertheless, prof. Jakimowicz and Dennis Schaap foresee no major issues with the stability of the camera view when firmly mounted on the wishbones of the omnitract.

9.2.1 Mount

A point that does need more attention is the mount on the wishbones, as its fixation lacks a form-lock in the direction of the moment force which is created by the weight of the arm and thus solely depends on its fixation by means of friction, see figure 9.3. This could potentially lead to unsafe situations if the friction force is not adequate, see appendix chapter 2. The wishbones of the omnitract have a diameter of 10 to 15 mm and the mount should be able to clamp around them even when surgical drapes are placed in between. By a simple test it is seen that the clamping arm, used by the prototype, can hold a weight of 2 kg stable on its place, see figure 9.4. However, we must note that it requires a tight fit, even when rubbers are applied. Inadequately set clamping force of the mount is a failure we cannot exclude in the prototype. The issue might be resolved if a lever is used that ensures a permanent and standardised friction force, see figure 9.5. If the issue would still occur, an alternative location would be to mount the arm on the sterile field post of the omnitract, see figure 9.6. This location would have almost the same benefits as a mount on the wishbones yet does include a form-lock in the moment force direction of the arm. Although the arm would need a longer range as it is more distal to the ROI see figure 9.7.

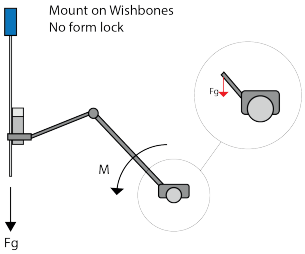


Fig 9.3. **Mount on omnitracts wishbones, solely dependent on friction.**

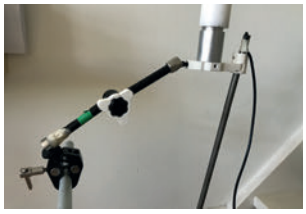


Fig 9.4. **Simple test whereby mount is clamped on 15 mm bar holding a weight of 2 kg.**

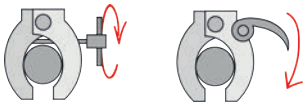


Fig 9.5. **Mount with a lever to incorporate minimum standarized friction force.**

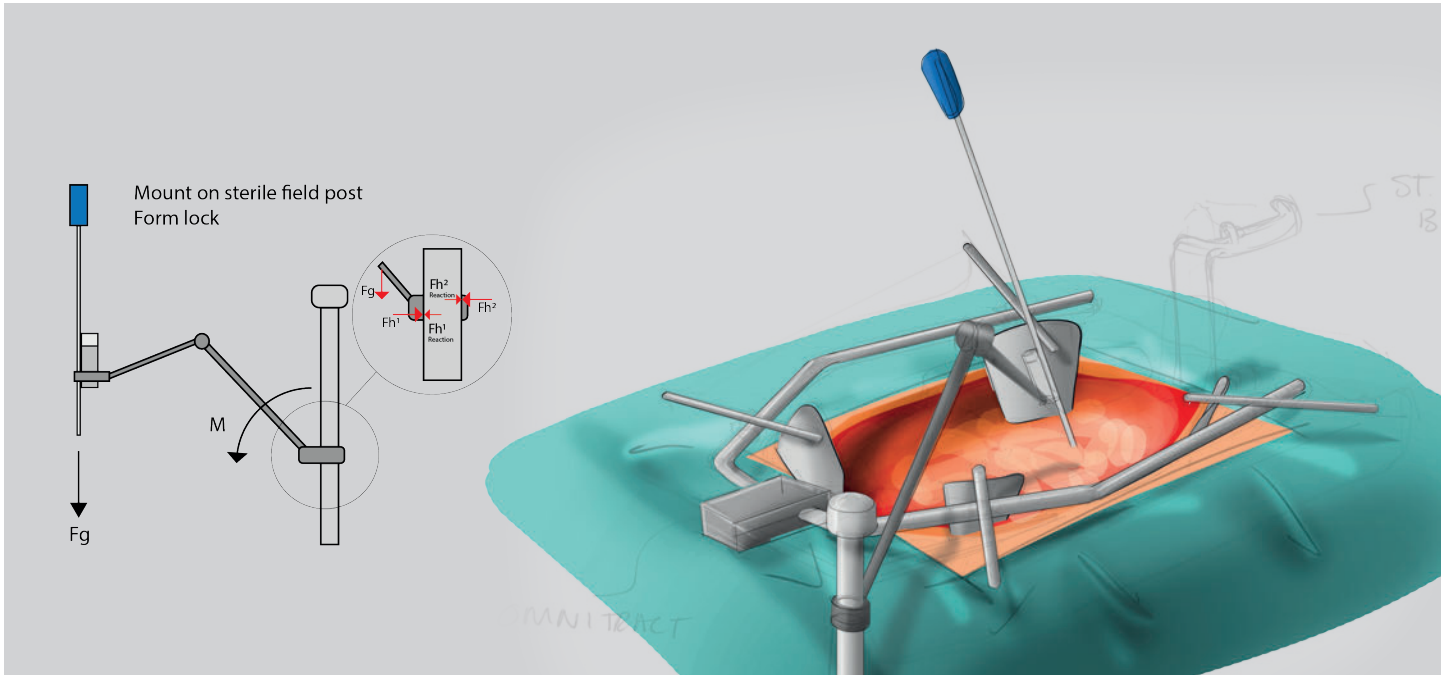


Fig 9.6. left: **Mount on sterile field post whereby shape mount is included.**

Fig 9.7. right: **Mount on sterile field post.**

9.3 Type of arm

In the prototype an articulating arm is used, see figure 9.8. By means of this arm it is possible to position the camera on its place and fixate the lot with one hand. Although we see an ease in adequate positioning of the camera towards an object with the MD and arm however, the fixation of the system on its position is bound to some issues. Currently these issues occur when the hinge in the arm is not set to

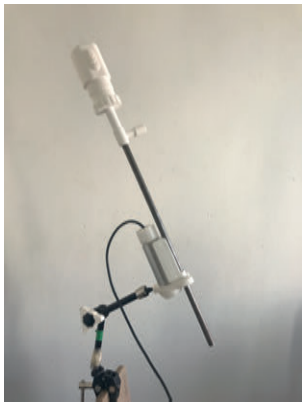


Fig 9.8. **Test model on articulating arm.**

an adequate friction force which results in a sacking of the arm and thereby moving away from the correct distance. And more important, this sacking can lead to unsafe situation as the arm may 'fall' into the surgical wound and thus may cause harm to the patient, see figure 9.9. This issue needs more research but could be resolved by ensuring a permanent minimal friction force on the hinges or by making use of a flexible arm that already incorporate this permanent fiction force.

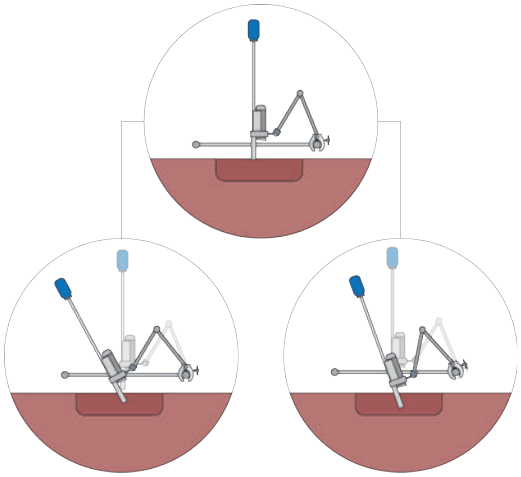


Fig 9.9. **Failure modes of arm. Either by lack of friction in arm or on arm mount.**

9.4 In-vivo & Ex-vivo

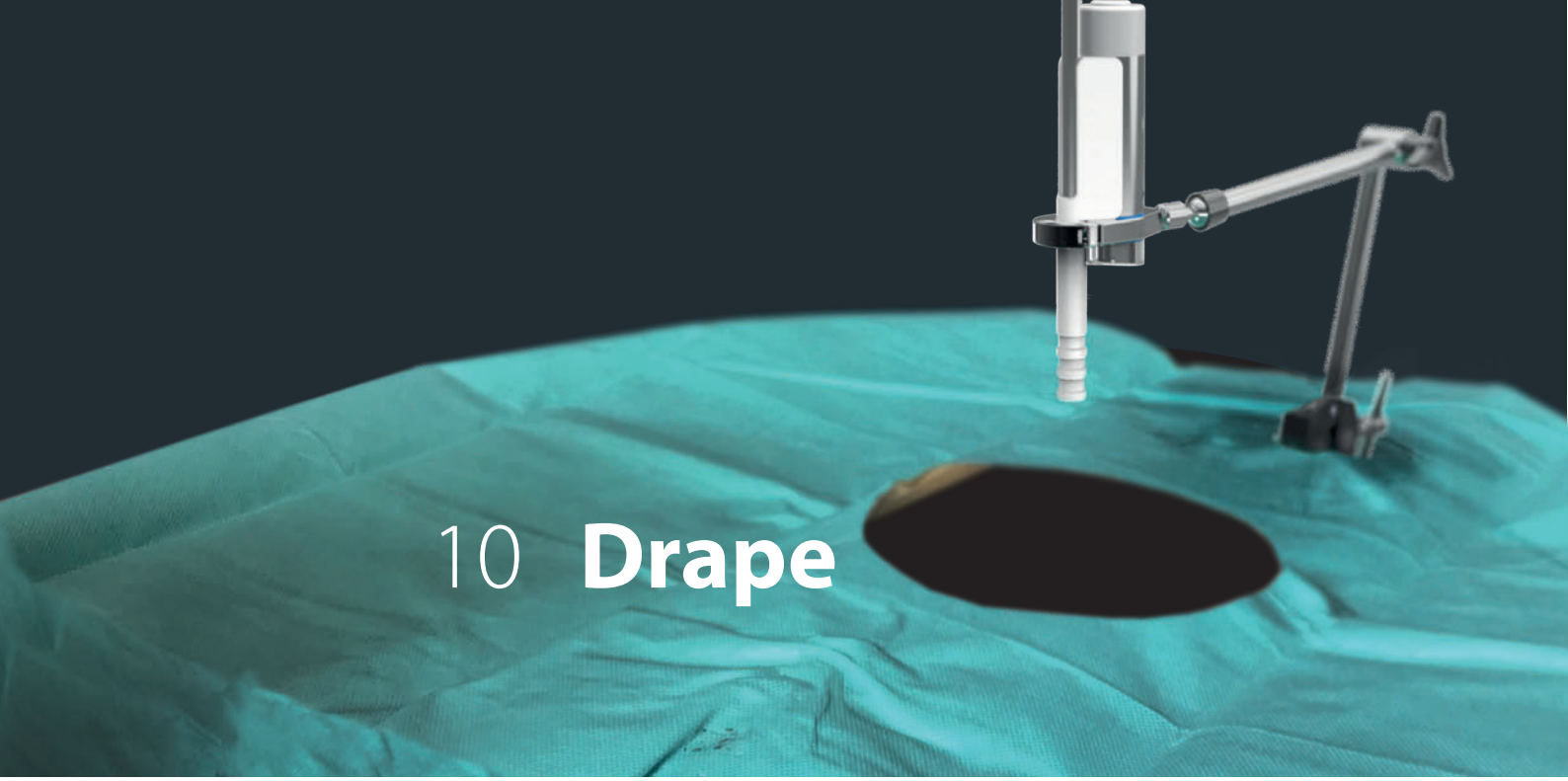
Currently the design will make use of a mechanical arm that can be attached on the omnitract. By doing so, little space is invaded, and the camera can be placed close to the ROI. Nevertheless, in an ex-vivo situation attention should be paid on where to place the arm.

9.5 Conclusion

To conclude, the design of the arm needs more development to ensure a safe product. However, in a test setup with the purpose to validate the hypothesis of this project in a pre-clinical study the prototype arm seems to be competent when operated with care and precision.

Embodiment

This chapter will present the embodiment of the system. First it will start with the embodiment of the sterile drape and end with the measurement device.



10 Drape

Fig 10.1. **Drape with hole (prototype closeup)**

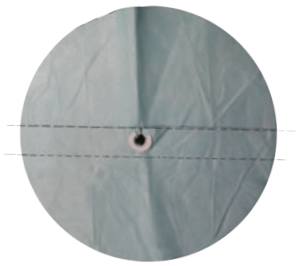


Fig 10.2. **Additional cover consisting out of two identical drape pieces and a plastic fixation ring. Dotted line represents the overlap of the two identical drape pieces.**

The cover of the surgical site to block interference of external light exists out of two parts; the surgical-site-cover with a hole and an additional cover piece to cover this hole, see image 10.1 & 10.2. They are placed over the ROI in the order, earlier shown in figure 8.22. The hole, with a diameter of 250 mm, ensures that the camera can be positioned with a clear view on the ROI (estimated width of 300 mm on a P95 patient), see figure 10.3. It thereby declines the width of the drape as less movement in X-direction is needed. This is important as the drape may not enter the unsterile area below the surgical table, although it will lay on top of already

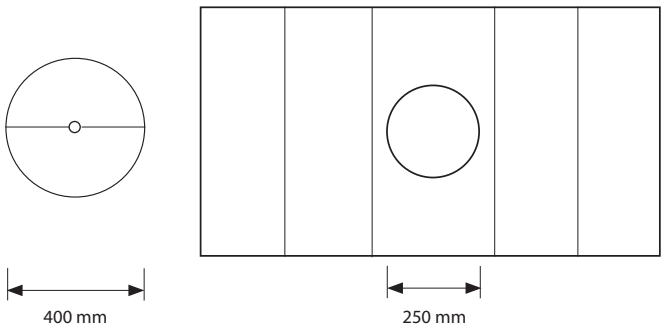


Fig 10.3. **Drape measures**

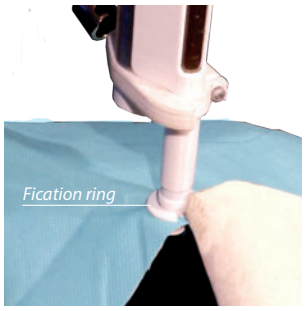
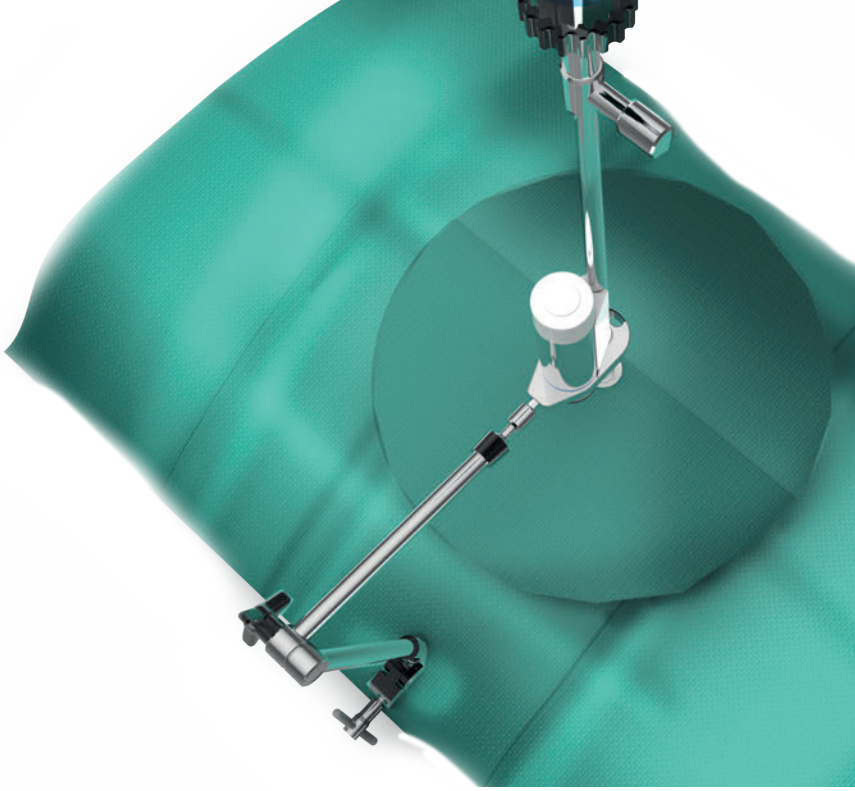


Fig 10.4. **Fictation of additional cover on scope mount with ring.**

placed surgical drapes over the patient. To ensure the additional piece will cover the lot, it has a diameter of 400 mm. The additional drape cover consists out of two identical drape parts that are glued together on one side, see figure 10.5 & 10.2. By doing so, it ensures an overlap to cover the open seam necessarily to wrap the piece around the scope. Although in the tests we did not observe any issues with the drape sacking into the surgical wound, it is an issue that could occur and would unwantedly prologue the procedure. Therefore, an additional plastic part is glued to the drape pieces that will clamp around the scope ensuring its position, see figure 10.4. The outer dimensions of the surgical-site-cover could not be specified in detail. But by means of a simple set up with surgical bed, omnitract and person this can be determined quickly.

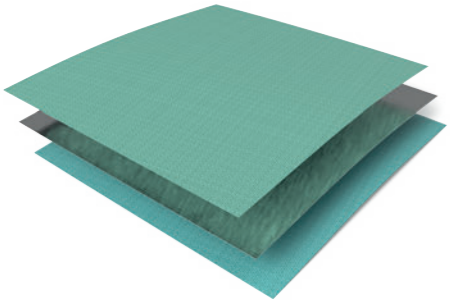


< Fig 10.5. **Addditional cover piece, consisting out of two identical drape segments.**

> Fig 10.6. **topview covers**

10.1 Material and MDR

We know that MPET (PET thin film with an aluminium additive) blocks the unwanted wavelengths and according to Susanne Verstraten (personal communication, April 28, 2018) implementing this material in a surgical drape is possible, within the existing production line. As it cannot be guaranteed that the drape will not touch the patient the material layers of excising surgical drapes will be used as a basis. And thus, the layer configuration will be as seen in figure 10.7. The material or product may not harm the patient and therefore it is important to know if a material such as MPET may truly be implemented into a surgical drape. The use of a metallised PET thin film imbedded in a surgical drape is as far as we can note new to the market. Though, aluminium is becoming a more general material in the medical industry. According to Hogg (2014), the biocompatibility of aluminium ensures safe contact to human skin and can even be used as a barrier coating for packaging material of implantable medical devises and has found its use in orthopaedic implants (Ratner, Hoffman, Schoen, & Lemons, 2004). According to Andreas Vavra (personal communication, August 8, 2018), project manager at Laufenberg GmbH Release Liners, they do have aluminised PETP film (produced by Heuck Folien GmbH) in their portfolio that can be implemented into a surgical drape to reflect ICG spectrum wavelengths with the necessary FDA grades and additional BfR grade. And thus this would be the material of use.



Nonwoven toplayer (PE)
Absorbent, flued control layer

Middle layer (MPET)
Impermeable membrane
impermeable to light

nonwoven bottom layer (PE)
Patient confort layer

Fig 10.7. **Material configuration**

11 Measurement device

Fig 11.1. **Measurement device on wishbones of omnitract.**

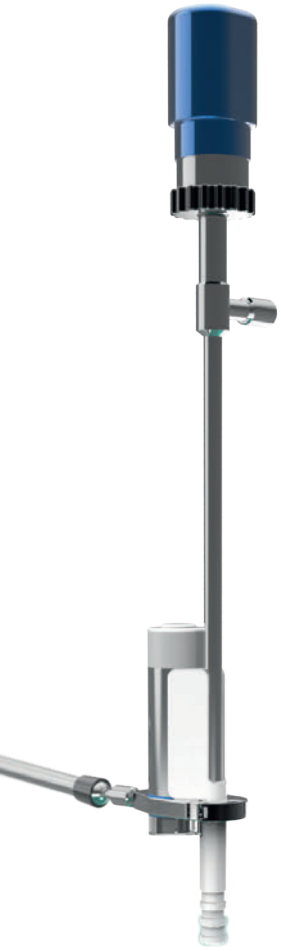
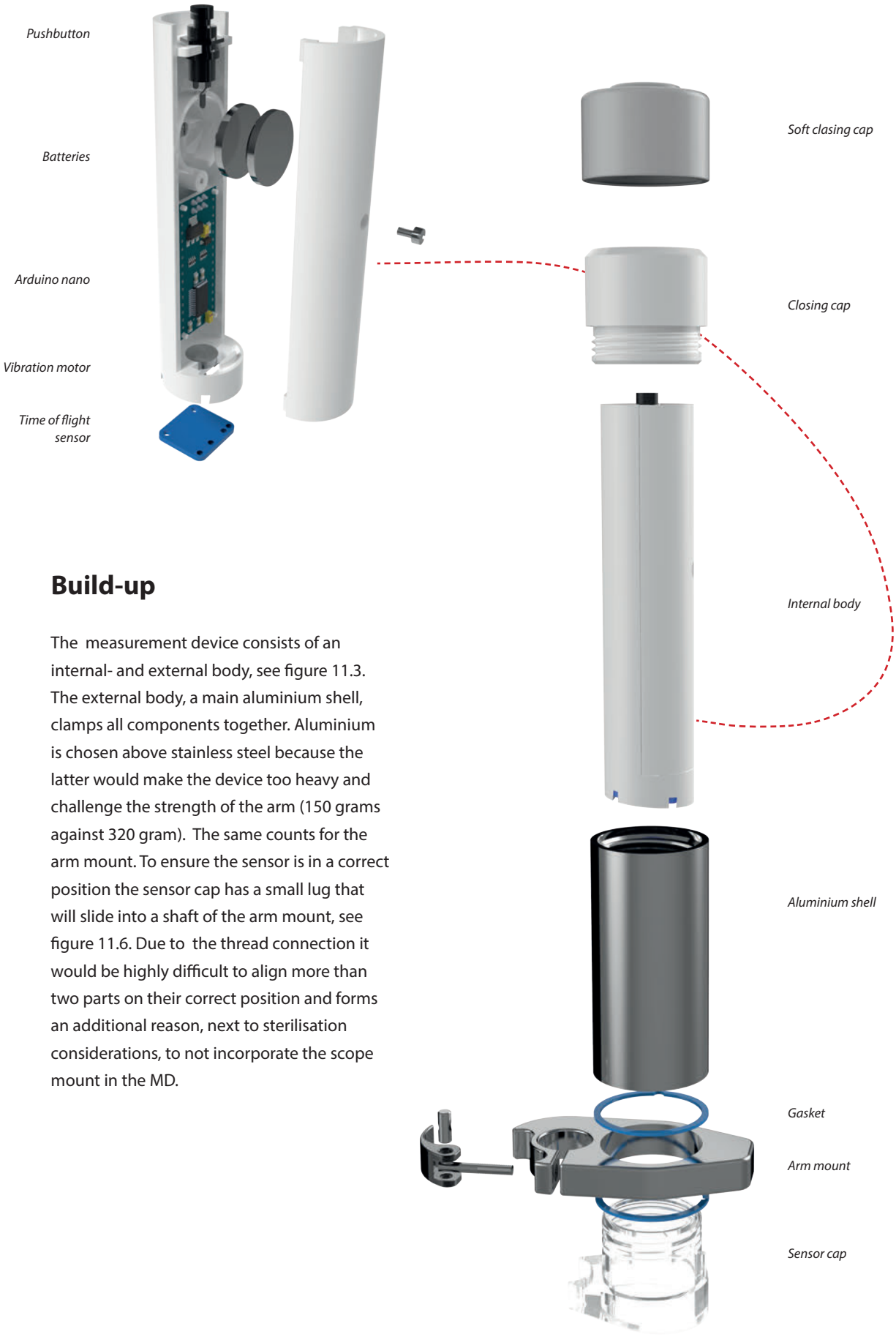


Fig 11.2. **Measurement device.**

In this chapter the embodiment of the measurement device will be explained. But first some general notes will be given to explain certain decision:

- The product is designed around the components that were available at the time of this project. Some components could be smaller or could be even be customized (i.e. Printed Circuit Board). However as for the time span and prototype purpose only standardized electronic components are used.
- As for the MDR the electronics should be in an enclosed body, without any current leakage to the outside.
- As the product will only deserve its viability by a successful outcome of the study to determine if the prototype will enhance objectification of the ICG acquisition it is tried to design a product that can be made without high investments (e.g. high injection mould costs).

The product system consists out of three modules next to the scope and camera, namely: the scope mount, the measurement device and the arm, see figure 11.1. The MD is operated by means of a single pushbutton that must be pressed during the whole distance measurement phase. This ensures a longer lifetime of the rechargeable batteries but moreover prevent continuous haptic feedback. Due to the line of sight of the distance sensor the current product is designed to be used with a straight forward 0-degree telescope. The scope is mounted on the arm by means of a separate scope mount. Both are clamped with a lever. The design is made watertight by means of gaskets, which is a commonly used manner for surgical equipment, for example in autoclavable camera heads. Although the aim of the design is a sterilisation of the assembled product, designing for sterilisation is bound to several aspects and success can only be determined by actual sterilisation. To be absolutely sure the system can be sterilised, the internal components are composed in its own assembly, see figure 11.3. In this manner the internal component can easily be extracted and remounted when sterilisation of the total product needs further design iterations.



11.1 Build-up

The measurement device consists of an internal- and external body, see figure 11.3. The external body, a main aluminium shell, clamps all components together. Aluminium is chosen above stainless steel because the latter would make the device too heavy and challenge the strength of the arm (150 grams against 320 gram). The same counts for the arm mount. To ensure the sensor is in a correct position the sensor cap has a small lug that will slide into a shaft of the arm mount, see figure 11.6. Due to the thread connection it would be highly difficult to align more than two parts on their correct position and forms an additional reason, next to sterilisation considerations, to not incorporate the scope mount in the MD.

Fig 11.3. **Exploded view of measurement device**

Fig 11.4. **Seams of pushbutton.**

Fig 11.5. **Covering softcover over pushbutton.**

11.1.1 Push button

To control the device a simple pushbutton is chosen over already existing IP79 classified buttons (IP Class denotes degree of protection against intrusion of materials such as dust and moist). Although it would improve the simplicity to make the product watertight, the working principle of these buttons would decrease the ergonomics of the device as they make use of capacitive technology. It would be hard for the user to know if they are continuously pressing the button. Thereby it is unsure if they could be operated wearing various surgical hand cloves. As for the working principle of the used pushbutton, seams in the product that are uneasy to sterilise, cannnot be avoided, see figure 11.4. Placing a rubber cap inside the product would not decrease this issue and thus it is chosen to use a soft cap over the total closing cap. In this manner it will fall over the pushbutton and between the thread connection of closing cap and shell. It will thereby not only serve as a soft pushbutton, but also as a gasket, see figure 11.5. To fulfil its application, the material should be able to work as a moist barrier, pushbutton and gasket. A commonly used shore A grade for a gasket is 60 (Experts Gasket & Seals LLC, 2018). UV Silicone 60A MG (USP Class VI) material with a shore A grade of 60 does meet these requirements and can be 3D printed by means of a bio-plotter (Envisiontec, 2018). The costs of this part will lay around: €30,-The possibility to injection moulding this part is excluded due to the purpose of the design (i.e. prototype) and regarding investment costs.

Fig 11.6. **Transparent sensor cap, with small lug and shaft in arm-mount.**

11.1.2 Sensor cap

The sensor needs a clear window to operate correctly. This can be done by making use of a glass-like window and gaskets for a watertight seal. However, this will leave deep seams and as the window should be under the same angle of the sensor, it might be hard to ensure its water tightness. Therefore, it is chosen to make the window- and closing part of the body out of one single transparent piece, see figure 11.6. Due to the angle inside the part two production possibilities are feasible, either injection moulding or 3D printing. CNC milling is not feasible due to unavoidable geometrics inside the part according to Hilko Maris from Metaalwinkel BV (personal communication, July 18, 2018). Liquid Silicone Rubber (LSR), does meet our optical demands regarding our sensor with a light transmission of 94% and a refraction index of 1.42 (Protolabs, 2017), a medical grade and even a possibility to autoclave (SIMTEC, 2018). However, the investments costs to use this material are high as injection moulding needs moulds. Though the moulds for LSR are low in comparison to for example ABS, it is, with an investment cost of €4500,- determined to be too high for a prototype. 3D printing will therefore be the chosen production manner. The part will be made by Stereolithography from Accura® ClearVue material. This material is biocompatible (UPS Class VI) and can meet high optical requirements (Luminous Transmittance of 87.2%)(3D Systems, 2018). The costs of the part will approximately be €60,- (3D-systems.com n.d.).

Fig 11.7. **Scope mount**

11.1.3 Scope mount

By means of shape it ensures a standardised distance from scope tip to sensor. By means of a tight clamp fit at the top the scope is hold onto its position, see figure 11.7. The scope mount will be produced by 3D printing. Biocompatible Polyamide is a commonly used material for medical prototypes and can be autoclaved. Production costs will be around €18,-.

11.1.4 Arm mount

The arm mount is made of CNC-milled aluminium, likewise the lever to fixate the scope mount. The hexagonal rod to position the Quick Fix Hexagonal Fitting will be fixated by means of a small screw. The costs will approximately cost €30,-

11.1.5 Internal electronics and body

The components compiling the internal body for the electronics will be 3D printed. This will keep the costs low and would not require any investments. The two parts will be made from Poly Amide, a commonly used 3D print material in the medical field. The system entails the following electronic components, see figure 11.8:

- Time of flight sensor VL53L0X (a € 15,-)
- Arduino nano v3 (a € 21,-)
- Vibration motor (a € 2,-)
- Push button (a € 0,50)
- 2x 3V 250mAh rechargeable battery (a €5,-)

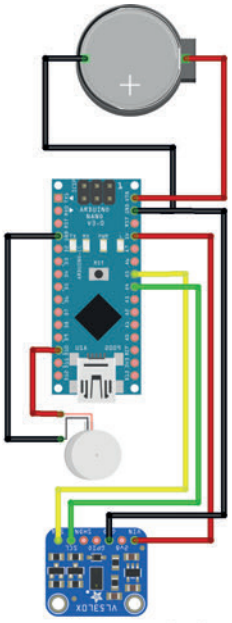


Fig 11.8. **Schematic view of electronic components (source Fritzing)**

11.1.6 Code

The language that is used to program the device is Arduino. The development of the code knew several iterations . In the first programs the feedback did delay the distance measurement whereby the device did not react directly on changes in distance. In the final program this was solved by separating the distance measurement and the corresponding feedback by means of using a Millisec() function. The final software code can be found in appendix chapter 3.

11.1.7 Costs

All together the prototype can be produced for approximately €230,-. To keep costs low it is advised to see whether an interplay with, for example, the Leidsche Instrumenten Makers can be established.

12 Proposal & Evaluation

Fig 12.1. **Detail view on MD.**

During this project it is attempted to design a system that could play a role in further research on objectification of ICG output images. In this chapter the final design proposal will be discussed and evaluated. Whether this project has been truly successful can only be determined after analysing the results of the pre-clinical test, wherein we look if the product system truly improves the objectification of the ICG output.

The final design proposal consists out of two segments, a device to standardize the acquisition position of the camera (i.e. the distance) and a drape design to exclude external wavelengths in the acquisition site. Due to its modular and simple character it could fit into the surgical workflow without extensively prolonging the surgical time. The system does not provide in all the challenges as described in the initial design brief as stated in chapter 1.3. Controlling reflections of light on tissue and surgical equipment is not implemented into the design. On the one hand as this demands technical details that could not be accomplished during this project, or as this issue is too complicated for the timespan, and on the other hand as it requires a combination of hardware and software. This demands a teamwork, that initially would be set up with the Technical University of Eindhoven. However, this interplay could not be achieved during this project.
Detecting slope of camera to tissue could improve the penetration depth of the excitation light. Due to the complexity of detecting this slope it is not accomplished in the design and the current system only provides a distance measurement. Furthermore, as the design is still in its prototype phase, it will need further development to evolve into a surgical tool that can seamlessly be implemented in daily practice. Aspects such as safety and sterilization need further improvements. Thereby, it would be interesting to establish an interplay with, for example, the Leidsche Instrumenten Makers for further production details. Further details on improvements are given in chapter 13.

Fig 12.2. >> **Poster of setup.**

To come to an end, it was established within this project to design a functional prototype that can be used in a pre-clinical research to validate if controlling the external factors do enhance the objectification of the ICG output images.

13 Recommendations

Fig 13.1. **Prototype**

In this chapter we will address the most important recommendations regarding the proposed design and findings for further research and developments. Starting with an elaboration on the prototype followed by some general issues regarding the ICG-FA technique.

13.1 Prototype to a mature design

Although several aspects were evaluated in meetings with Dennis Schaap and prof. dr. Jakimowicz, a comprehensive user test with the whole system is not conducted. Such user test could reveal some, perhaps latent aspects that would need further elaboration and thus it is advices to conduct this user test. It could be executed in an operation theatre with an abdominal phantom and some roleplaying of the surgical team. Inside this phantom a spectrometer can be implemented to determine the excising light spectrum during the ICG-FA procedure. Only then, can truly be determined if the system fulfil its functional role and practicality in the procedure.

13.1.1 Scope mount

The current scope mount makes use of friction to fixate the scope. Consequently, it does need some force to put the scope into position. Ideally the scope can click into this position, so less force is needed. This could be achieved with some minor geometric changes. Another possibility would be to do some more research into a softer 3D-biocompatible-print material. Currently, this was not found, however this could improve the simplicity of the fixation as both scope and scope-mount could then be fixated by means of the lever of the arm-mount as initially planned.

13.1.2 Quest system

The current system is designed to fit the Karl Storz system. Nevertheless, the Catharina Hospital makes frequent use of the Quest Spectrum system, as it can be used with a wider range of contrast dyes. This system is bound to the same issues regarding objectivity. It might therefore be interesting to research if, with some changes, the proposed design could fit this camera.

13.1.3 Material

As the prototype demands some specialized materials this is a factor that could not have been tested within the embodiment. The window in front of the Time of Flight sensor will irrevocably affect the measurement of the sensor. In tests it is observed that different transparent materials in front of the sensor will not affect the precision of the sensor, however will influence the calibration distance. Therefore, the correct distance region of the sensor in the code must be adapted to the material.

13.1.4 Scope

Currently, the system is designed around the Hopkins II scope with a length of approximately 320 mm. However, shorter scopes are available and because this length is not necessarily needed in open-surgery a shorter scope could be used. This will not only decrease the weight of the scope, but moreover will decrease the moment arm and thus the force on the system mount, see figure 13.2.

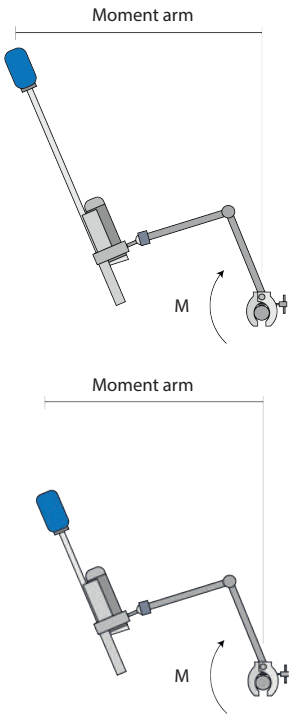


Fig 13.2. **Moment force on arm mount will decrease by a shorter scope.**

13.1.5 Feedback

The current distance feedback does not differentiate between measurement above and below the correct ICG-acquisition distance. In the Failure mode and effects analysis in appendix (X), we see that this could theoretically lead to unsafe situations. To avert these situations an additional feedback signal could be implemented when the scope tip is dangerously close to the tissue. This could for example be done by a short sound signal.

13.1.6 Power

The prototype is powered by means of two coin-cell batteries. Currently, we do not now the lifetime of these batteries and the frequency they need to be charged. At the moment the device does not provide a signal when batteries are low and need to be changes. Implementing this into the design would increase its reliability.

13.1.7 Arm advice

As the thesis only contains an advice on the mechanical arm to position and fixate the scope onto its position, it needs more elaboration. Especially the fixation needs more research. The range of the arm is currently calculated by means of assumed measurements in a CAD model. However, this would need a proper testsetup to gain more understanding on the needed range.

13.2 Software

During this project no in depth research is conducted regarding the software, however it plays a crucial role in the objectification of an ICG assessment. In this chapter some notes will be made of interesting finds that can relate to the software.

13.2.1 Mental model

To build a mental model of the tissue perfusion of the ROI it is important that the assessor has access to a view of the anatomical site and ICG. Mostly the image registration view is used, but when a more detailed understanding of the ICG is needed the assessor turns to the solely ICG output image. Not all software of the systems on the market do provide the three images at once. Nevertheless, to gain a solid understanding, all three are needed and it is advised to provide them simultaneously.

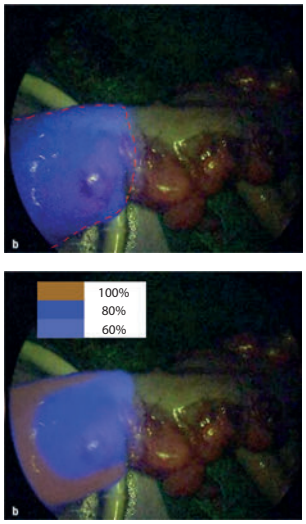


Fig 13.3. **View with fluorescence threshold outline above and below view with percentages of fluorescence intensity.**

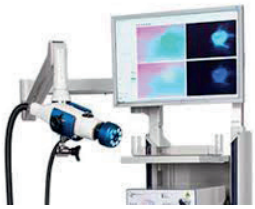


Fig 13.4. **Quest Spectrum system. Software with large white areas.**

13.2.2 **Image recognition**

Before the surgeon has obtained an understanding of the blood perfusion two translations have passed. The first is the translation done by the Karl Storz system and the second is the translation of the output images by the surgeon. Still, if the acquisition factors are controlled and the output images give true objective results amongst patients it is still not guaranteed that the surgeon will draw correct conclusions. Software might be a solution to overcome this issue. By image recognition software it is possible to filter differences in fluorescence intensities and provide the user with a more informative image. For example, this can be done by grading the fluorescence or adding an outline of the fluorescence area. Or if acquisition is truly objective even percentages of perfusion might be implemented, see figure 13.3. Another possibility that can be made feasible by means of software is to map an ICG image over a new anatomical view (i.e. under almost the same acquisition position but on a later time). This could be useful if an objective ICG image is made and the surgeon might want to have a second look without any surgical drapes blocking his view.

13.2.3 **Light screen**

The output monitor is ideally close to the surgical wound with a clear view for the surgeon and camera operator. Due to this, it is unavoidable that light from the monitor will reach the anatomical site. Depending on the colours the screens show wavelengths in the ICG spectrum are transmitted. Colours used for the software should therefore be considered. Currently, some of the screens do have large areas of white, see figure 13.4. It is advised to consider using other colours (e.g. black or other colours out of the ICG spectrum) to lower transmittance of wavelengths inside the ICG spectrum. For more information, see appendix 1.

13.2.4 **Colours**

During the project it is seen that ICG fluorescence signals are depicted with various colours on different ICG-FA systems or software packages. As these outputs are subjected to the perception of the individual surgeon, it seems better to search for a standardized colouring for the ICG output images.

13.3 Aqcuisition conditions

13.3.1 **D-light**

In the analysis part of this thesis an advice is given to standardise the intensity of the white light of the Karl Storz as its light violates the ICG spectrum. This could, for example, be done by adding a sign on the embodiment of the D-light with the recommended light intensity.

13.3.2 **Additional sensors**

We discussed that although the output image might show objective results the final assessment is still dependent on the translation of the images to the mental model of the surgeon. Ideally, we could obtain all acquisition factors and present their values to the surgeon in order to fill possible knowledge gaps in his or her mental model. Factors such as, distance and slope of camera to object, light conditions surrounding the ROI, temperature conditions of the ROI and possibly ICG blood concentration. During this project this was not feasible, however transmitting this data to a monitor can be implemented in a redesign.

13.3.3 Light conditions

The light conditions wherein the assessment is to be made can be measured by means of a spectrometer. Currently these spectrometers are too big to be implemented in a handheld device, nonetheless, according to Analytics-World (2018) the company Hamamatsu developed just such a thing, see figure 13.5. In this size it could be an option to implement it in the system, although the size of the add-on (i.e. size of the measurement device) must not obstruct the workflow.

Fig 13.5. **Mini-spectrometer from Hamamatsu's spectroscopy solutions. (Analytics-World, 2018).**

13.3.4 Temperature

As blood flow is temperature dependent an insight in the temperature of the ROI might fill another knowledge gap of the surgeon. This correlation is relative to the patient and thus would need a relative temperature image. This can be done by means of a thermograph image and thus the system could benefit from a thermo-camera. Either placed externally or even internally in the system as these camera sensors keep getting smaller, see image 13.6.

Fig 13.6. **Micro-thermocamera (Flytron, 2018).**

13.4 Workflow and lighting

13.4.1 Light

Currently, time is lost in the ICG procedure to turn of the light, due to a malfunction in the communication between the surgical team and anaesthetist. This is bound to the fact that the anaesthetic personnel are not always aware of their role in the procedure.

Possibilities to overcome this issue might involve:

- Providing a clear insight in the procedure at all times whereby upcoming events are made visible for all personnel (e.g. via screens).
- The possibility for the surgical team to control the light in the OR and thereby rule out any communication issues with personnel not directly involved in the procedure.

13.4.2 ICG injection

The contrast dye is stored inside a glass bottle. We cannot exclude pre-surgical enhancements of the dye in the bottle, as we do not know the optical properties of the glass. However, this might infleunce the final ICG assessment. It could be a valuable researchproject to obtain this information and consider its findings in the ICG procedure (e.g. administer the contrast dye under dimmed light conditions).

14 Reflection

Fig 14.1. **Michiel Jansz. Van Mierevelt & Pieter van Mierevelt, Anatomische les van doktor Willem van der Meer, 1617. Collection Prinsenhof, Delft. Photograph by Theun Okkerse.**

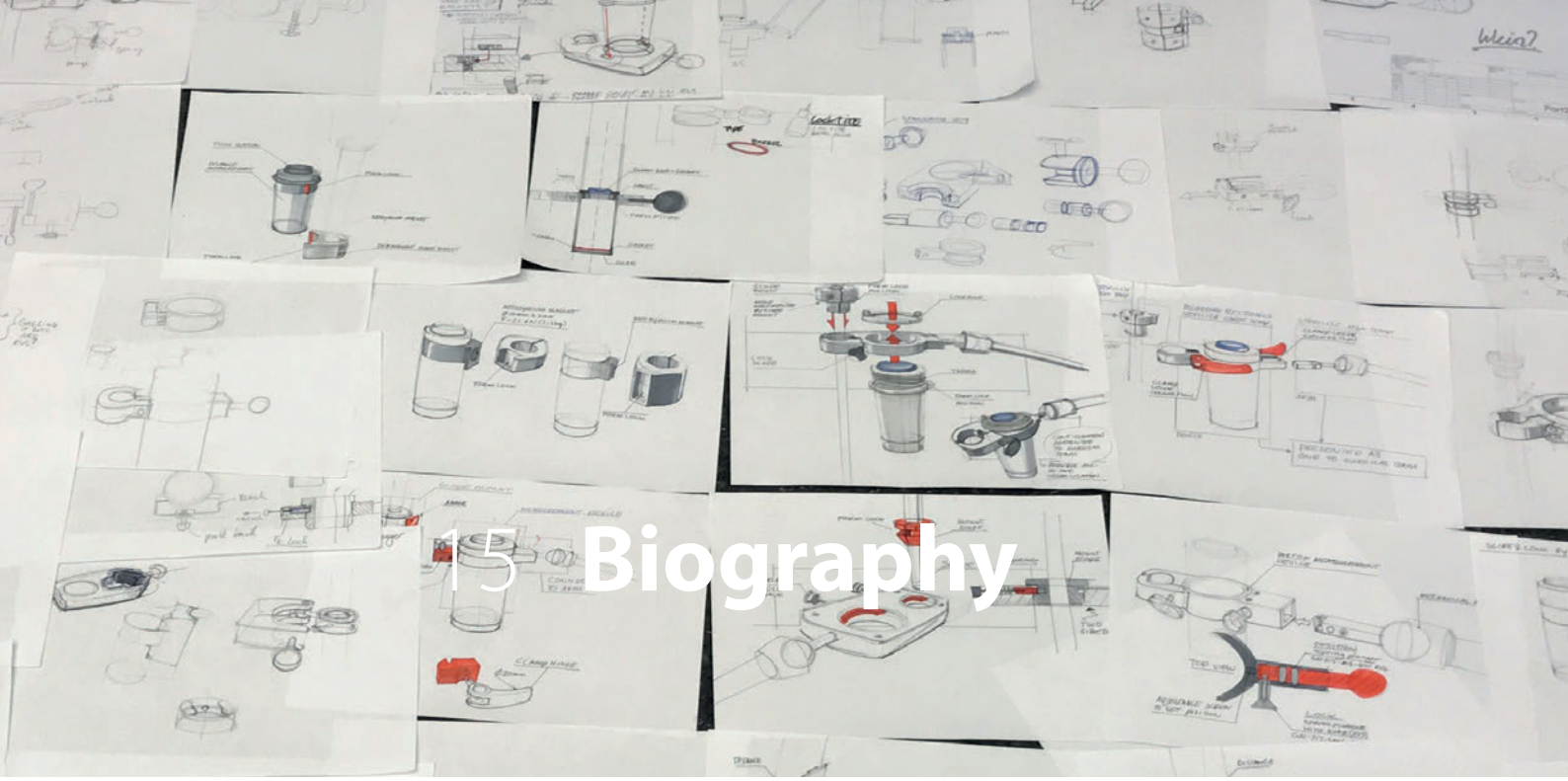
At the time of writing I look back at this project with some pride. It has been a very interesting time wherein I learned a lot, a thing I really noted when writing the summary of this thesis. It took me some effort compiling a text that is understandable for anyone interested in this thesis that is not acquainted with the medical and technical jargon. This specific reader was the equivalent of myself at the start of this project. And so, getting familiar with the context took me some time. How does light actually work, what is it that surgeons precisely do, how would I react while attending an open surgery and can I prove my ability as a designer in this surgical field were some of the questions I had and needed to answer. A lot of questions that sometimes scared me but most of all made me curious. And although, sometimes I had the feeling the project did not progress quick enough, I am glad I got the opportunity to really take the time to become familiar with the context.

Every now and then I updated my supervisors, however looking back I should have done this more often. Not only to get the team on the same page, but also for myself. In this project I rediscovered that my personal preference is to work in a team, having quick discussions, a rich variety of viewpoints and the, sometimes, crucial clash of opinions and thus compromises.

Being assertive is important while designing, especially in the medical world where the professionals do have demanding schedules.

An vital aspect leading to my joy in this project was its variety and comprehensiveness. It was a relish to have the opportunity to do a lot of research whereby the results had direct impact on the concepts and final design.

Last but not least, this project really confirmed to me that I made the correct decision to direct my masters into a medical direction. Altogether, I am glad that this project may end my master industrial design and resume my professional life.



15 Biography

Fig 15.1. **View on different sketches made during this thesis project.**

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Appendices

This chapter will include the study on the lighting conditions in the operation theatres of the Catharina Hospital, the Failure Mode and Effect Analysis (FMEA) and the Arduino code that runs the prototype.

1 Light measurment

Fig 1. **Measurements at operation theatre 6.**

1.1 Abstract

Interference from external light sources in the operation theatre (i.e. other light sources than Karl Storz) with the excitation and emission light associated with the contrast dye ICG can lead to unreliable assessment results. The ideal scenario for the ICG contrast dye is an environment wherein only the specific excitation and emission light exists. This is in contradiction with the needs of the surgical team to have clear vision on the anatomical site, hence; in the operation theatre multiple light sources are present. In this research we present the measured light conditions of two operation rooms at the Catharina hospital to uncover if they do interfere with the ICG spectrum. In the results we see interference with the ICG spectrum by almost all lights inside the rooms. And thus, room lighting should be adjusted or the ICG acquisition site should be covered to exclude interference.

1.2 Introduction

IImaging techniques, such as Indocyanine Green based Fluorescence Angiography, have the potential to guide surgeons with real time information invisible for the naked eye during a surgery. The wavelengths wherein ICG operates, 700 to 900 nm, is called the NIR window. In this spectrum region absorption of photons by molecules inside the human body, scattering and tissue autofluorescence is relatively low (Shikayama, 2016). Special imaging systems are required to excite the contrast dye and reveal its fluorescence to the surgical team. The assessment of the output images of the imaging techniques is done by the perception of the surgical staff, and thus experience and a solid understanding of the technique is required. Standardization of the output of these techniques is therefore highly important and any interference of external factors should be avoided. Interference from external light sources in the operating theatre (i.e. other light sources than Karl Storz) containing a light spectrum that is in the excitation and emission region of the ICG contrast dye is assumed to lead to unreliable results. The ideal scenario for ICG is an environment wherein only excitation and emission (700 to 900 nm) light from

a specific controlled light source exists. This scenario is in contradiction with the need of the surgical team to have clear vision on the anatomical site, hence; in the operating theatre multiple light sources and spectra are present. These external light sources may affect the output image of the ICG in various ways. In this study we aim to discover which light sources in the operation theatres of the Catharina Hospital do interfere with the ICG registration. There are four scenarios wherein external light can affect the registration.

- *Scenario 1:* The ICG contrast dye is enhanced by light sources other than the controlled excitation light of the equipment following uncontrolled enhancement.
- *Scenario 2:* There are light sources in the environment, other than the emission light of the ICG, with the same wavelength, that are registered by the Karl Storz system as being emission light of the ICG.
- *Scenario 3:* Autofluorescence due to excitation of the surrounding tissue of the Region of Interest by certain wavelengths from the environmental light and emits the same wavelengths as the ICG and thus, is registered as being emission light of the ICG.
- *Scenario 4:* There is an overlap between the excitation light to enhance the contrast dye and the emission spectrum the contrast dye emits. Whereby excitation light is wrongly assumed to be emission light of the ICG, resulting in a false positive.

1.2.1 ICG

The contrast dye ICG is enhanced by specific wavelengths where after it emits a different spectrum of longer wavelengths. This shift in wavelengths is caused by a change in energy when the excitation light energy is absorbed by the molecules of the contrast dye and thereby promotes delocalized electrons from a ground state to a higher energy level. When this energy level returns to its ground state, energy is emitted in the form of photons, that can be observable as fluorescence. The peak absorption of the ICG contrast dye is around 780 nm and its emission peak is seen around 820 nm (Shikayama, 2016).

1.3 Method and setup

This study was conducted during daytime (i.e. between 14:00 h-16:00 h) in operation theatre 6 and 4 of the Catharina Hospital in times when no surgery was performed. The measurements are carried out by a StellarNet 3000 Black Comet spectrometer, equipped with a sensor head with an angular view of 180 degrees and a wavelength

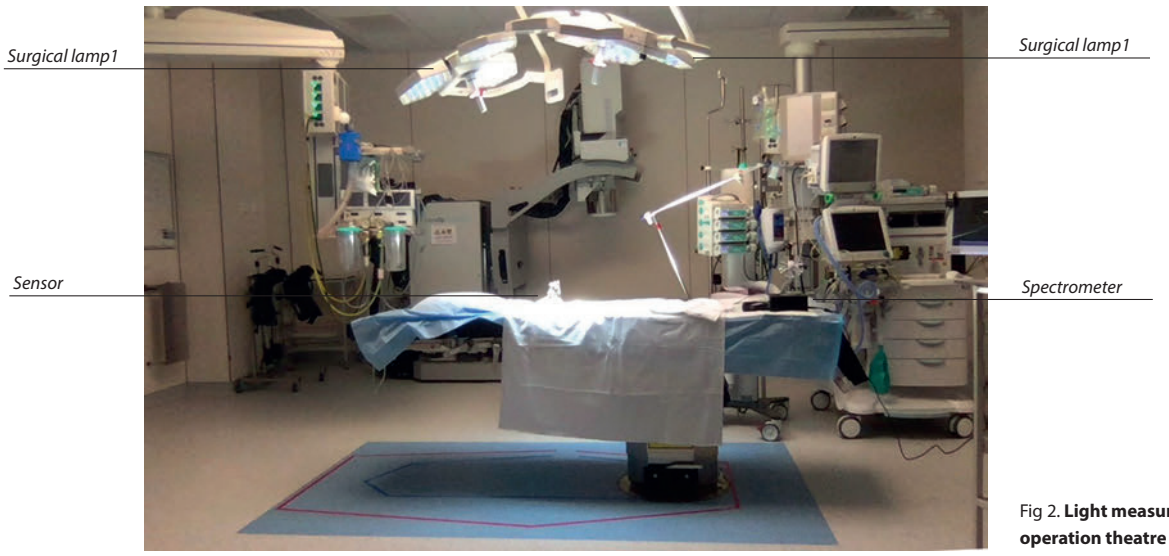


Fig 2. **Light measurement setup at operation theatre 6.**

range of 200 to 1100 nanometre. The sensor was placed on the operation table, positioned in such a manner that it represents the location of the abdominal cavity in times of gastrointestinal open surgery, see figure 2. Data per scenario was obtained by the average of 10 measurements taken every 155 ms.

1.3.1 Operation theatre

The operation theatres can differ in layout and thereby in light conditions. In operating theatre 6 the environmental light consists out of 7 TL-lightboxes and 6 LED spots in the ceiling, the surgical lights consist out of 2 surgical lights and a plenum light. Other light sources are computer screens in the room and light incidence of daylight via windows in the two doors adjacent of the corridors, see figure 3. In operation theatre 4 the environmental light consists out of 7 TL-lightboxes and 6 LED spots in the ceiling, the surgical lighting consists out of 2 surgical lights and a plenum light. Other light sources are computer screens in the room and light incidence of daylight via windows of the adjacent corridors. In both rooms the windows are equipped with shutters to avert daylight from the corridors coming into the room.

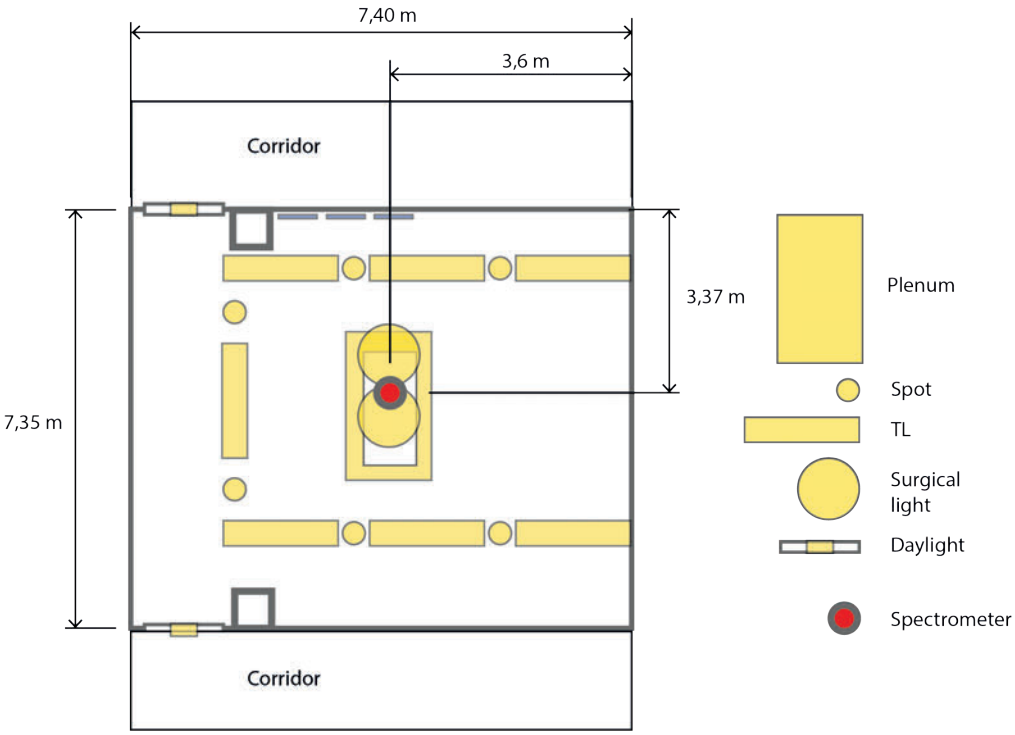


Fig 3. **Layout and light plan of operation theatre 6 at the Catharina Hospital.**

1.3.2 Measurement scenario

Multiple measurements are conducted from different lighting scenario's: (if not stated otherwise, lights are switched to their full brightness level).

- *Dark scenario*: All lights in the operation theatre are switched off, except for the computer screens on the side of the room and the shutters of the door are closed for daylight to come in, see figure 4A.
- *Dark scenario and daylight*: All the lights in the operation theatre are switched off,

except for the computer screens on the side of the room and the shutters of the door are open for daylight to come in, see figure 4B.

- *Surgical light 1*: only surgical light 1 is on, see figure 4C.
- *Surgical light 2*: only surgical light 2 is on, see figure 4D.
- *Surgical light 1 & 2*: only surgical lights 1 and 2 are on, see figure 4E.
- *Surgical lights 1 & 2 dimmed*: only surgical light 1 and 2 are on in minimal brightness setting, see figure 4F.
- *Plenum:* only the plenum above the operation table is switched on, see figure 4G.
- *Spots:* only the spots from the environmental lights are switched on, see figure 4H.
- *TL:* only the TL lightboxes from the environmental light are switched on, see figure 4I.

Fig 4. **Different light scenarios inside operation theatre 6 of the Catharina Hospital.**

1.4 Results

1.4.1 Environmental light sources

The environmental light sources include, the computer screen light, daylight through the window, spots and TL light boxes. In the dark scenario's (1 and 2) the light spectrum is mostly in the infrared region, see figure (5A). In the Spot scenario we see some speaks around 600 nm and higher intensities at the infrared region, see figure (5B). In the TL scenario observed peaks were at 430, 440 and 600 nm, see figure (5C). Figure (5D), shows the various lights in one spectrum view. Clearly shown is that the TL lights have the greatest intensity compared to the other environmental light sources.

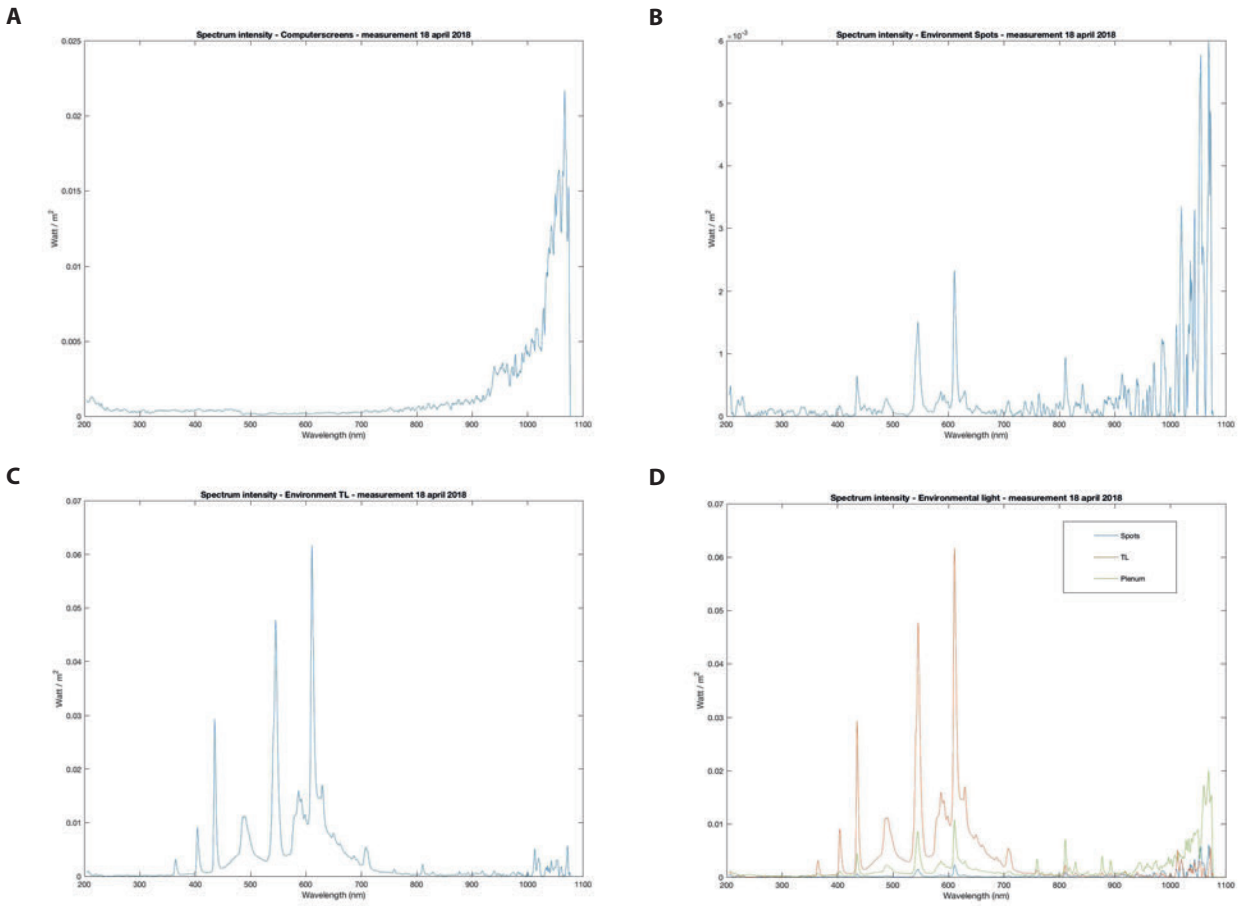


Fig 5. **Light measurements OR6**

1.4.2 Surgical light sources

During a surgery the plenum and the surgical lights are the primarily light sources for the surgical site. The surgical lights provide the highest intensity of light in a spectrum ranging from 400 till 1400 nm, with peaks at 450 and 1000 nm, see figure 6. The plenum provides diffuse light to illuminate the working area. It provides a 'soft' and spread light, with intensity peas at 550 and 600 nm, see figure (5). Note that the speaks in the region of 900 to 1100 nm are bound to the computer screens in the room.

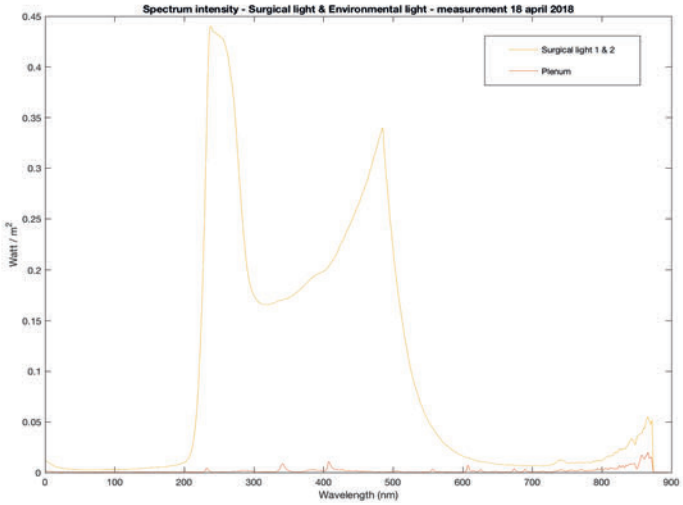


Fig 6. **Surgical light spectrum**

1.4.3 All lights

When mapping all light spectra in a graph it is clearly visible that the surgical lights have the most power, see figure 7.

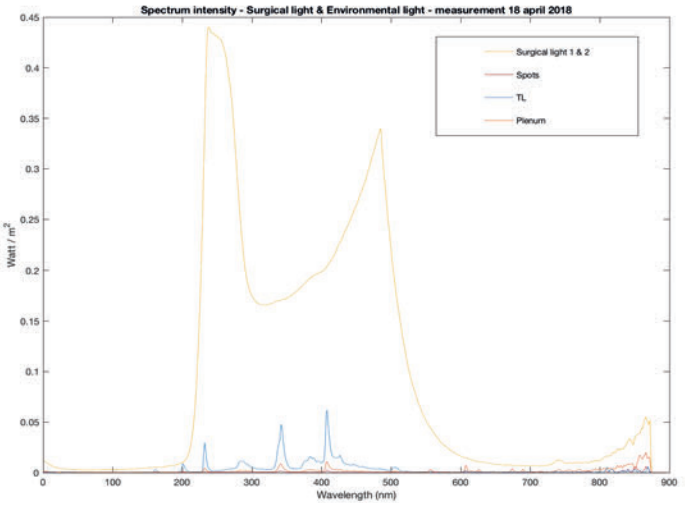


Fig 7. **Different light spectra of light sources in OK6**

1.4.4 OR6 and OR4

The two rooms wherein the measurements are conducted differ in size and setup. And we see a difference in the dark that is currently used during the ICG procedures, see figure 8.

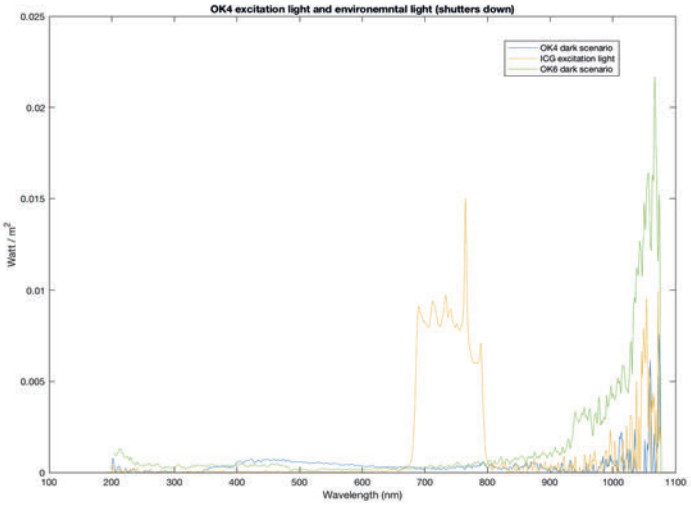


Fig 8. **Dark scenario of OK6 and OK4**

1.4.5 ICG emission

Measuring the ICG fluorescence intensity could not be achieved within this research, however by means of calculations its intensity is estimated. The ratio of absorbed and emitted photons is called the Quantum efficiency Q.E. and is expressed by:

Q.E.(%)=Fluorescence/Excitation x 100%

According to Kusano et al. (2016), the Q.E. of ICG is common to be 1.2%, however they do state that the relationship between the concentration and fluorescence intensity is nonlinear and thus quantitative measurements are difficult. And thus we

see in research of Malachowski & Zmija (2010) a Q.E. for ICG in water of 4%. However, they do state that this percentage is lower for ICG in blood. As a reference we will therefore take a safer ICG Q.E. of 5% for this project to estimate the amount of interference of external light.

$$Quantum\ flux\ E = \frac{\left(I * \lambda * \left(5.03 * 10^{15}\left[\frac{1}{m^2 * s}\right]\right)\right)}{6.02 * 10^{17}\left[\frac{1}{\mu mol}\right]\ (Avogadro\ number)} = \mu E$$

$$Quantum\ flux\ Excitation\ light\ = \frac{\left(0.08\left(\frac{W}{m^2}\right) * 780[nm] * \left(5.03 * 10^{15}\left[\frac{1}{m^2 * s}\right]\right)\right)}{6.02 * 10^{17}\left[\frac{1}{\mu mol}\right]} = 0.522\ \mu E$$

$$Quantum\ flux\ Emission\ light\ \ (ICG) = 0.522\ \mu E * \frac{1}{20} = \ 0.026\ \mu E$$

$$Irradiance\ Emission\ light\ \ (ICG) = \frac{830\ [\mathrm{nm}] * (0.826 * 10^{-2})}{0.026} = 0.0038\ W/m^2$$

1.5 Additional tests

1.5.1 Computer screen

During the surgery the monitor of the ICG Karl Storz system is placed next to the surgical table, so the camera operator, surgeon and system operator can see the output images. This monitor might become a source of light interference with the registration of the ICG. In an additional setup we tested the emittance spectrum of a monitor (Dell S2715H) displaying different colours.

1.5.1.1 Results:

The monitor emits different wavelengths as colour of the screen changes, see figure 8A. Not clearly visible in the graph is the spectrum of a monitor displaying a black image. In figure 9 the spectrum measurement of the black monitor scenario is displayed, with one peak at 530 nm.

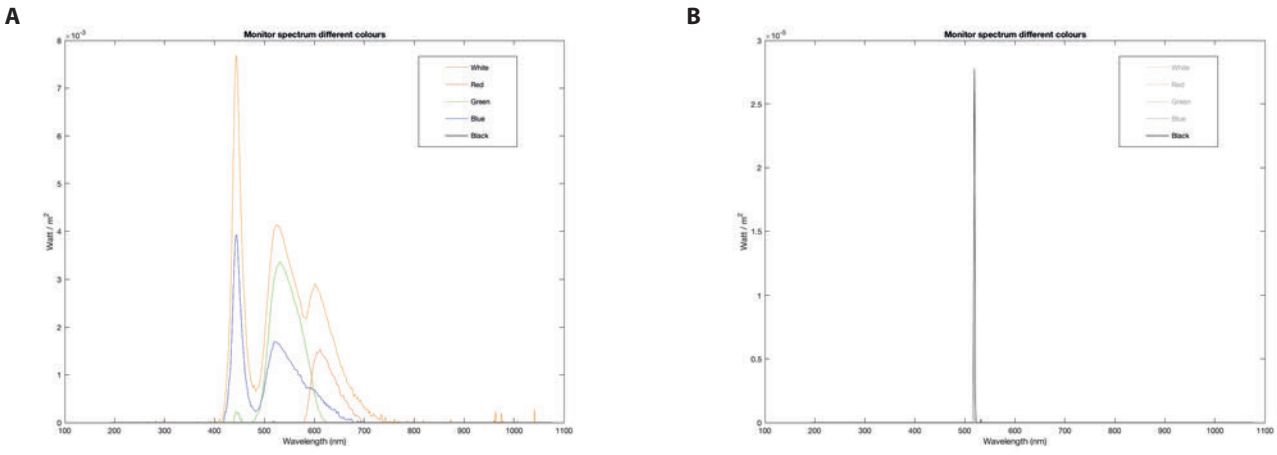


Fig 9. **A: spectrum screen depicting different colours. B: spectrum screen depicting black colour.**

1.5.1.2 Conclusion

The light spectrum this monitor emits is strongly dependent on the colours on the screen. White-, red- and blue light will transmit light in the wavelength of the ICG. A monitor that is based on black colours will interfere less with the ICG spectra.

1.5 Conclusion and discussion

The Karl Storz equipment works with excitation light filter of 805 nm and an emission light filter of 835 nm. This requires that all external other lights should not have wavelengths in these regions to control fluorescence of the ICG by means of controlled excitation and emission light. We see that the surgical light does interfere with the ICG spectrum in a significant manner and thus should be turned off during this assessment. Thereby we see that their spectrum range is outside the visual spectrum that cannot be observed by the human eye, approximately 400-760 nm (Fodor, Ullmann, & Elman, 2011). Thus, a part of the spectrum is in fact not utalized and could be eliminated by means of filters. However, still interference in the excitation and or emission light will occur. Although the plenum light has a lower intensity in comparison with the surgical lights it contains wavelengths inside the ICG spectrum and thus, should be turned off as well. The same goes for the spectrum of the TL lights and Spots. Whether the emitted light of the computer screens will interfere with the ICG spectrum is strongly related to the colours they depict. By making smart choices in the colours used in the software of the ICG, interference of this light can be lowered or even eliminated. When we depict the estimated ICG fluorescence intensity in figure 10, we see an interference of the daylight spectrum inside the ICG spectrum of approximately 20% of the ICG intensity. We determined this to be too high as we aim to exclude any external wavelengths inside this region.

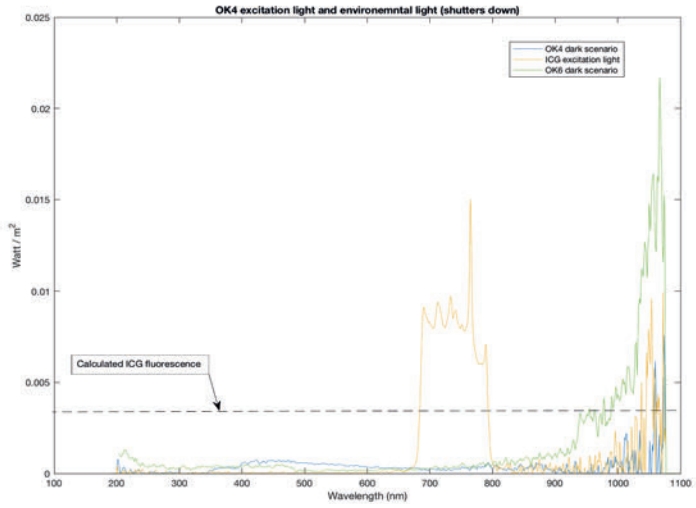
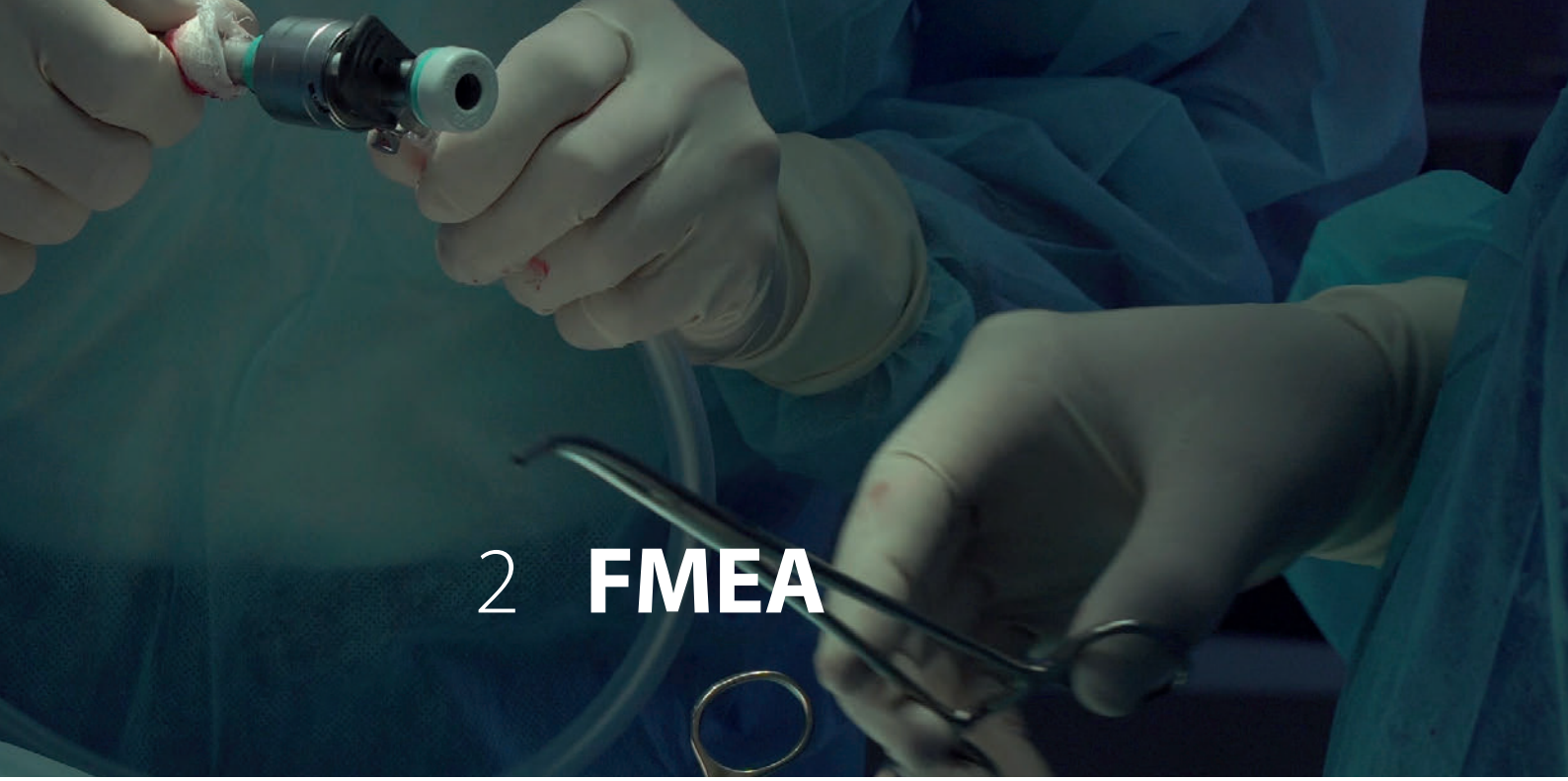


Fig 10. **Black room spectrum scenario including excitation light measurement and emission light estimation.**

Next, in this measurement not all wavelength sources could be determined, especially in the infrared region. These wavelengths could be derived from daylight inside the room, or be radiation of devices inside the operation rooms. To conclude, we see interference of almost all lights inside the operation rooms with the ICG spectrum and thus we cannot be sure that ICG output images in the current procedure are not influenced. To address this issue the lights sources inside the rooms should be altered, or the ICG acquisition covered.



2 FMEA

We see an ease in adequate positioning of the camera towards an object with the measurement device and arm, however the fixation of the system on this position is bound to some issue. In the current arm used for the prototype we see these issues occur when the arm mount or hinge in the arm is not set to an adequate friction force which results in a sacking of the arm and thereby moving away from the correct distance. And more important, this sacking can lead to unsafe situation as the arm may fall into the surgical wound and thus may cause harm to the patient, see figure 2.1.

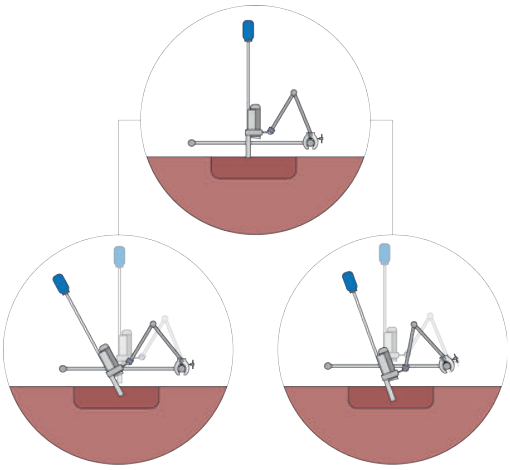


Fig 2.1. **Issues inadequate friction fixation in arm or arm mount and consequences.**

This issue is bound to the working principle of the arm and arm mount:

- The arm is fixated by means of friction on the ball-socket hinges and thus when the friction is insufficient the position of these two hinges is not secured.
- The arm mount is fixated on the omnitract solely by means of friction and as the shape of the omnitract wishbones is round an additional form lock to secure positioning is missing.

To overcome these issue multiple solutions are possible:

- Ensure a minimum amount of permanent friction in the hinges that can carry the device. Movements should be done by means of applying additional force.
- By making use of a Flexible arm that can already be set to a minimum amount of permanent friction.
- Reconsider placement of the arm on the sterile field post of the omnitract. The issue will drop due to a vertical position of the pole.

2.1 Conclusion

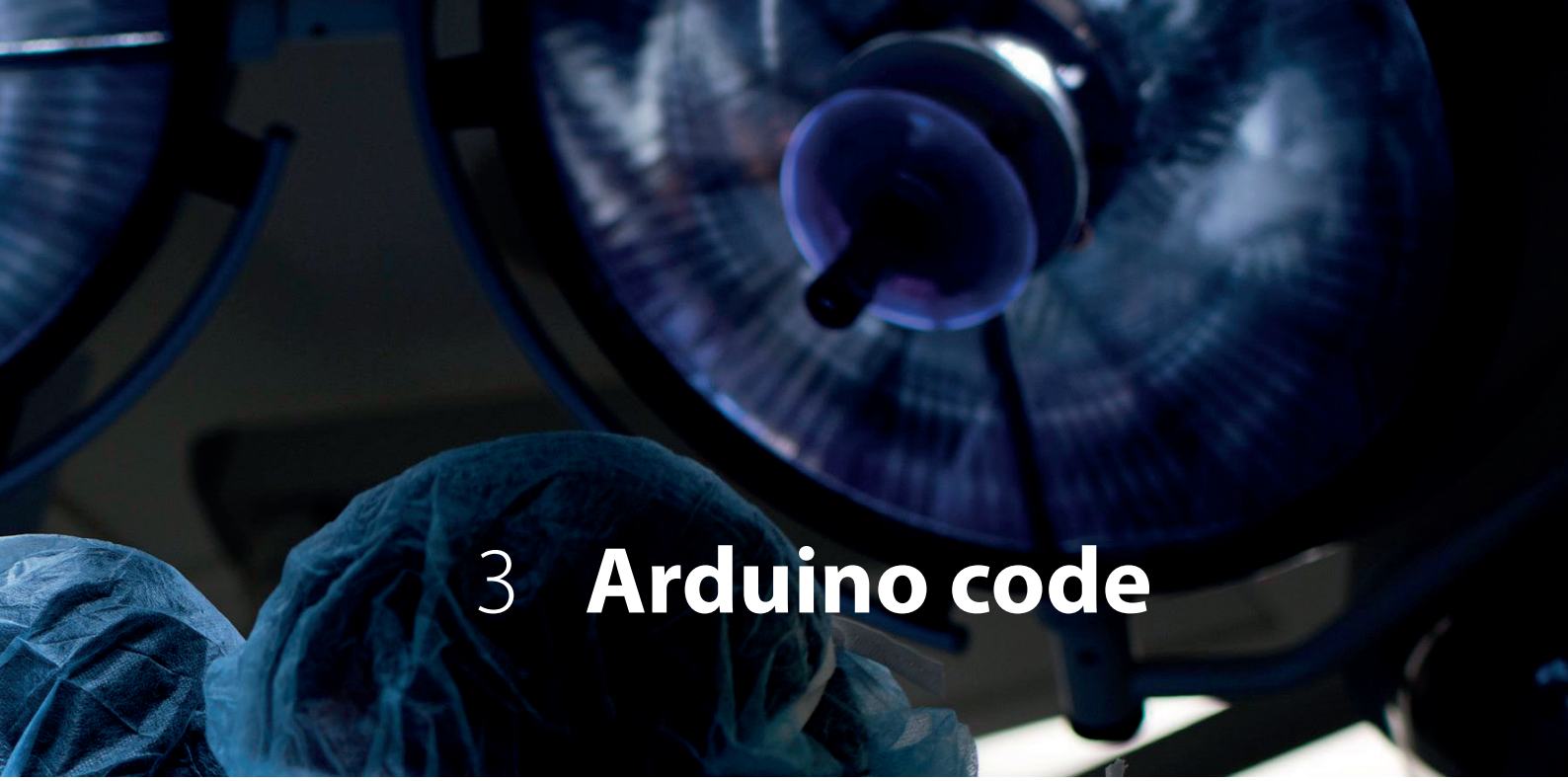
Before the device can be implemented into a surgical procedure some further development is needed. Especially the arm does need attention, as the current arm used in the prototype obtains a high score in a risk analysis. Mainly because the system cannot guarantee adequate friction in hinges and mount on the omnitract. Sacking of the system into the surgical wound can therefore not be eliminated. For a more detailed view on possible risks of the system see table below.

Name	J.W. Okkerse
Product	ICG acquisition system
Date	2018 - August - 9

Risk Acceptability Matrix

		SEVERITY				
		Negligible (2) | *No or negligible risk to patient*	**Minor** (4) | *Slight costumer inconvenience; little to no effect on product performance, non-vital fault*	**Serious** (6) | *Short term injury or impairment requiring additional medical intervention to correct (e.g. reoperation)*	**Major** (8) | *Severe, long-term injury; potential disability*	**Critical** (10) | *Loss of limb; life-threatening injury*
OCCURANCE	**Improbable** (2) | 1 in 100	F	I			
	Remote (4) | 1 in 1000	J	E	B - K		
	Occasional (6) | 1 in 10000				A	
	Propable (8 | 1 in 100000					C - D
	Frequent (10) | 1 in 1000000					

Reference Letter to Risk Acceptability Matrix	Component	Potential failure mode	Potential effect(s) of failure	SEVERITY	Potential cause(s) of failure	OCCURRENCE	Current process controls to prevent failure mode	Current process controls to detect failure mode	DETECTION	RISK PRIORITY NUMBER	RANK PRIORITY	Recommended actions	Briefly describe your reasoning
A	Arm scope position	Scope is set too close to the anatomical site	Scope may come in contact with the surgical wound/patient.	8	1. No restriction in movement in Z direction of the scope. 2.No alarm feedback on movement or the arm too close movement to the surgical wound in Z direction.	6	User may detect this via the output image of the scope.	NON	2	96	3	1.Arm movement in Z direction is limited to avoid touching the surgical wound. 2.Alarm feedback is given when scope is too close to object.	When an alarm signal is send to the user as the scope enters a potentially dangerous distance range to the the surgical site, a notification could warm the user and prevent the potential harm.
B	Omnitract	Omnitract wishbones are not set to a stable joint friction	Wishbones of the omnitract lower due to weight of camera system .	6	Wishbones lower resulting in a shift of position of the retractors and camera system. Potentially leading to harm to the patient.	4	Handle of omnitract to clamp system knows to presents, open and closed. In the closed scenario friction would be sufficient.	NON	4	96	3		
C	Arm	Arm is not set to an adequate fixture friction.	Scope may sack into the surgical site and may cause potential harm to the patient	10	1. User forgets to tighten joint (hinge) of the arm. 2. User does not put adequate friction on the joint (hing) of the arm.	8	NON	NON	8	640	1	1. Making use of an preset tention whereby force is needed to move the arm. (force needed > gravitational force of the system).	1.The problem occurs due to insufficient tention in the hinges of the arm. If the minimum friction force is adequate to hold the arm into place the issue will be precluded.
D	Arm mount	Arm mount is not set to an adequate friction clamping force.	Scope may sack into the surgical site and may cause potential harm to the patient	10	1. User forgets to put adequate clamping force on the arm mount. 2. User does not put adequate clamping force on the arm mount. 3. Mount has no grip on surface.	8	NON	NON	8	640	1	1.2.Using presets in clamping force, ensuring adequate clamping . 3. Mount is fixated by means of a shape lock.	1.The problem occurs due to insufficient tention in the hinges of the arm. If the minimum friction force is adequate to hold the arm into place the issue will be precluded. 2. Currently the arm is fixed on a round tube (i.e. the wishbones of the omnitract). If for example this round shape would be square rotation of the mount due to inadequate friction will be eliminated.
E	Scope mount	Scope fails positioning	Scope mount falls into surgical wound	2	Scope mount is not fixated in holder and clamps on scope while scope is released and falls from scope into the surgical wound.	4	NON	NON	2	16	7	Scope mount can not be released until scope is disassembled from mount.	Will prevent separation of scope mount.
F	Scope mount	Scope mount is installed upside down	No measurement possible and/or extra time needed to remount scope mount	2	No form lock for attachment	2	NON	NON	1	4	11	NON	NON
G	Scope mount	Scope mount is not installed	No clamp of scope on arm mount	8	Scope may hit the surgical wound	2	Scope does not fit the mount	NON	1	16	7	Scope cannot be attached, that is by form, in holder and thus scope mount cannot be forgotten to be installed.	See recommended actions.
H	Measurement device	Current leakage	Patient is in contact with current leakage	4	Electronics are not enclosed in a current blocking embodiment	2	NON	NON	10	80	5	Ensure electronics are enclosed in an enclosed plastic body	Plastic does not transfer current and thus no current leakage may occur.
I	Feedback	Feedback is not unambiguously.	Action performed other than feedbacks intention. Device is lowered to much. May touch Surgical wound	4	The feedback below the correct distance is the same, however opposite, for the regions above the correct distance. This may cause confusion.	2	NON	Detect distance of the scope toward the tissue via naked eye and ICG monitor.	2	16	7	Differentiation of feedback frequency below and above correct distance region.	By doing so this could increase the clarity of the position of the scope.
J	Batteries	Batteries run out of power	MD does not measure or false measurements may be given.	2	No power, no sensor detection.	4	NON	NON	1	12	10	Feedback of low batteries or standard procedure of changing batteries when not used.	Ensure batteries are charged when product is in use.
K	Mount	Access to surgical wound is blocked by surgical drape that is clamped between arm mount and omnitract.	Time is lost in case surgical team has to quickly access the surgical wound	6	Drape is clamped between arm mount and omnitract and can not be removed without disassembling the arm.	4	NON	NON	2	48	6	Either two options: Or the surgical drape is not clamped between arm mount and omnitract or the arm mount can be removed by means of a quick release.	When the surgical drape is not clamped it can be removes fast and easily. The most time will be spend on disassembly of arm mount, thus when this can be done quickly the issue might be resolved.



3 Arduino code

The prototype reacts to distance by means of Arduino software. The software development knew several iterations to improve reaction time and intelligibility of the feedback. Mostly by changing intervals of haptic vibration corresponding to the measured distance.

The code, shown below and spread over two colons, starts with the parameters that determine its reaction, whereafter they are implemented into commands for the device.

```
#include "Adafruit_VL53L0X.h"

//SENSORS AND OUTPUT
    const int Vib = 10;
    const int LED = 11;
    int frequency =300;

//TIME
    unsigned long previousMillis = 0;
    int ledState = LOW;

//Distances
//out of range
    int outofrangeLOW = 50;
    int Xbegin = 0;
    int Xend = 100;
    int Abegin = 100;
    int Aend = 130;
    int Bbegin = 130;
    int Bend = 170;
    int Cbegin = 170;
    int Cend = 200;

//Correct
    int Dbegin = 200;
    int Dend = 230;
    int Ebegin = 230;
    int Eend = 260;
    int Fbegin = 260;
    int Fend = 290;
    int Gbegin = 290;
    int Gend = 330;
    int Zbegin = 330;
    int Zend = 600;
    int outofrangeHIGH = 330;

//INTERVALS
    long ZOnTime = 50;      // milliseconds of on-time
    long ZOffTime = 800;    // milliseconds of off-time
    long XOnTime = 50;      // milliseconds of on-time
    long XOffTime = 800;    // milliseconds of off-time

//Phase A
    long AOnTime = 150;     // milliseconds of on-time
    long AOffTime = 200;    // milliseconds of off-time
//Phase B
    long BOnTime = 100;     // milliseconds of on-time
    long BOffTime = 120;    // milliseconds of off-time
//Phase C
    long COnTime = 100;
    long COffTime = 70;
//Phase D - feedback on correct distance
    long DOnTime=10000;
    long DOffTime=1;
//Phase E
    long EOnTime = 100;
    long EOffTime = 70;
//Phase F
    long FOnTime = 100;     // milliseconds of on-time
    long FOffTime = 120;
//Phase G
    long GOnTime = 100;
    long GOffTime = 300;
Adafruit_VL53L0X lox = Adafruit_VL53L0X();

void setup() {
    pinMode(LED, OUTPUT);
    pinMode(Vib, OUTPUT);
//device is on
    digitalWrite(Vib, HIGH);
    digitalWrite(LED,HIGH);
```

```
        delay(300);
        digitalWrite(Vib,LOW);
        digitalWrite(LED,LOW);
        Serial.begin(115200);
        // wait until serial port opens for native USB devices
        while (! Serial) {
        delay(1); }

        Serial.println("Adafruit VL53L0X test");
        if (!lox.begin()) {
        Serial.println(F("Failed to boot VL53L0X"));
        while(1);}
// power
        Serial.println(F("VL53L0X API Simple Ranging example\n\n")); }

void loop() {
        unsigned long currentMillis = millis();
        VL53L0X_RangingMeasurementData_t measure;
        Serial.print("Reading a measurement... ");
        lox.rangingTest(&measure, false); // pass in 'true' to get debug data printout!
        if (measure.RangeStatus != 4) {  // phase failures have incorrect data
        Serial.print("Distance (mm): "); Serial.println(measure.RangeMilliMeter);
//out of range
        if (measure.RangeMilliMeter >=Zbegin && measure.RangeMilliMeter <=Zend){
        if((ledState == HIGH) && (currentMillis - previousMillis >= ZOnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= ZOffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);    // Update the actual LE
        } }
// Phase A
        if (measure.RangeMilliMeter >=Abegin && measure.RangeMilliMeter <=Aend){
        if((ledState == HIGH) && (currentMillis - previousMillis >= AOnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= AOffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);    // Update the actual LE
        } }
//Phase B
        if (measure.RangeMilliMeter >Bbegin && measure.RangeMilliMeter <=Bend){
        if((ledState == HIGH) && (currentMillis - previousMillis >= BOnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= BOffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);    // Update the actual LE
        }}
//Phase C
        if (measure.RangeMilliMeter >Cbegin && measure.RangeMilliMeter <=Cend){
        digitalWrite(LED,LOW);
        if((ledState == HIGH) && (currentMillis - previousMillis >= COnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= COffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);    // Update the actual LE
        }}
//Phase D Correct
        if (measure.RangeMilliMeter >Dbegin && measure.RangeMilliMeter <=Dend){
        digitalWrite(LED,HIGH);
        if((ledState == HIGH) && (currentMillis - previousMillis >= DOnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        digitalWrite(LED, HIGH);
        //tone (ledPin, frequency,ledState);
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= DOffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);   // Update the actual LE
        digitalWrite(LED,LOW);
        //tone (ledPin, frequency,ledState);
        }}
//Phase E
        if (measure.RangeMilliMeter >Ebegin && measure.RangeMilliMeter <=Eend){
        digitalWrite(LED,LOW);
        if((ledState == HIGH) && (currentMillis - previousMillis >= EOnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= EOffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);   // Update the actual LE
        }}
//Phase F
        if (measure.RangeMilliMeter >Fbegin && measure.RangeMilliMeter <=Fend){
        if((ledState == HIGH) && (currentMillis - previousMillis >= FOnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= FOffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);   // Update the actual LE
        }}
//Phase G
        if (measure.RangeMilliMeter >Gbegin && measure.RangeMilliMeter <=Gend){
        if((ledState == HIGH) && (currentMillis - previousMillis >= GOnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= GOffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);   // Update the actual LE
        }}
//out of range
        if (measure.RangeMilliMeter >=Xbegin && measure.RangeMilliMeter <=Xend){
        if((ledState == HIGH) && (currentMillis - previousMillis >= XOnTime))
        {
        ledState = LOW;  // Turn it off
        previousMillis = currentMillis;  // Remember the time
        digitalWrite(Vib, ledState);  // Update the actual LED
        }
        else if ((ledState == LOW) && (currentMillis - previousMillis >= XOffTime))
        {
        ledState = HIGH;  // turn it on
        previousMillis = currentMillis;   // Remember the time
        digitalWrite(Vib, ledState);    // Update the actual LE
        }
        }
        }
        else {
        Serial.println(" out of range ");
        digitalWrite(Vib, LOW);
        }
        }
```