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Improvement of Continuous Larynx Examination test equipment

Bachelor's thesis in Mechanical Engineering
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REPORT BACHELOR THESIS

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<u>Short abstract</u>

Utstyret som er i bruk under en CLE (Continuous Larynx Examination) test på Øre-nese-hals avdelingen ved St. Olavs hospital, Trondheim, er gjennom bruk er oppdaget som lite praktisk, ubehagelig for pasient og ikke tilstrekkelig nok for undersøkelsen. Denne oppgaven beskriver utviklingen av nytt testutstyr som skal motvirke desse problemene.

The current equipment in use during a CLE (Continuous Larynx Examination) test at the Ear-nose-throat division at St. Olavs hospital, Trondheim, has been through found to be insufficiently practical, uncomfortable for patients and struggles to provide sufficient quality for diagnostic purposes. This thesis describes the development of new test equipment that eliminates these problem areas.

| <u>Stikkord</u>

Medisinsk utstyr

Bilde diagnostisering

Produkt utvikling | <u>Keywords</u>

Medical equipment

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Product development |

Preface

This bachelor thesis was written as the final requirement for obtaining a Bachelor of Science degree in Mechanical Engineering at the Norwegian University of Science and Technology (NTNU)). The research presented in this thesis was conducted over the course of January to May 2023, and focuses on improving the current testing procedure for the diagnosis of Exercise Induced Laryngeal Obstruction (EILO) using medical imaging.

EILO is a condition that affects many people, both professional athletes and amateurs, and can lead to difficulty breathing and impaired performance. The current testing procedure involves using a medical camera inserted into the nasal cavity during exercise, which can be uncomfortable for the patient and difficult to perform accurately. Our goal was to improve the current testing procedure, by introducing and analysing new testing protocols and equipment.

Our research project was conducted by a team of three students: Hege Grytten, Paulius Liachovas, and Tora Aasheim Nymark. Throughout the project, we had the privilege of collaborating closely with medical professionals at St. Olavs hospital, and we want to give our special thanks to the team at the Operating Room of the Future (FOR), who provided us with invaluable opportunity to conduct our research. We are deeply grateful to our supervisor, Andrei Lobov, for his unwavering support, expert guidance, and valuable feedback that helped us to shape our research into its final form. We would also like to express our sincere appreciation to all those who supported us throughout the thesis period.

Working as a group has been an enriching experience that allowed us to combine our skills, knowledge, and perspectives to achieve our goals. Each member of the group brought their unique strengths and ideas, which helped us to conduct the research more efficiently and to produce a higher quality result. We would like to thank each other for the collaboration and hard work that went into this project.

Abstract

The current equipment at St. Olavs hospital used to diagnose Exercise Induced Laryngeal Obstruction (EILO) with the help of a Continuous Larynx Examination (CLE), suffers from several prevalent problems. A proper EILO diagnosis requires physicians to be able to see abnormalities within the patient's larynx during strenuous exercise. This is done by inserting a thin endoscope camera through the nasal cavity until the endoscope reaches a point where it has a direct line of sight of the larynx and the vocal cords. The current equipment sometimes fails to provide sufficient information to the physicians due to the footage's instability and lack of clarity. Additionally, the current setup to hold the endoscope in place during exercise is unreliable and uncomfortable, and tends to fail during the test, causing the test to be restarted. It is also a difficult and time-consuming setup, which causes the physicians to drastically reduce the amount of CLE-test procedures performed.

Delving into the prevalent areas of improvement, and using existing research from studies, articles, and journals, in addition to communicating with the physicians at St. Olavs hospital, this bachelor thesis presents a variety of different possible concepts, that could be implemented as solutions to the current issues. It also evaluates these concepts, to determine which are the most effective to test and implement within the scope of the thesis. As a result, better setup equipment for holding the endoscope in place was developed, footage stability and clarity were improved, the setup-time was drastically reduced and the patient's comfort was increased. Additionally, further research areas were provided, that were only investigated on a surface level due to the limitations of this thesis.

Sammendrag

Det nåværende utstyret på St. Olavs hospital som blir brukt til å diagnostisere Exercise Induced laryngeal obstruction (EILO) ved hjelp av Continuous Larynx Examination (CLE), har flere utbredte problemer. En riktig EILO diagnose krever at legene kan se abnormiteter i pasientens strupehode under anstrengende trening. Dette gjøres ved å føre et tynt endoskopkamera gjennom nesehulen til endoskopet når et punkt hvor det har en direkte siktlinje til strupehodet og stemmebåndene. Det nåværende utstyret klarer noen ganger ikke å gi tilstrekkelig informasjon til legene på grunn av opptakenes ustabilitet og mangel på klarhet. I tillegg er det nåværende oppsettet for å sette endoskopet på plass under trening upålitelig og ubehagelig, og har en tendens til å mislykkes under testen, noe som fører til at testen må startes på nytt. Det er også et vanskelig og tidkrevende oppsett, som fører til at legene drastisk reduserer antallet CLE-testprosedyrer som utføres.

Ved fordypning i de utbredte forbedringsområdene, og ved bruk av eksisterende forskning fra studier, artikler og journaler, i tillegg til kommunikasjon med legene ved St. Olavs hospital, vil denne bacheloroppgaven presentere en rekke ulike mulige konsepter som kan implementeres som løsninger til de aktuelle problemstillingene. Oppgaven evaluerer også disse konseptene for å finne ut hvilke konsept som er mest effektivt å teste og implementere innenfor oppgavens omfang. Som et resultat ble det utviklet bedre utstyr for å holde endoskopet på plass, bildestabiliteten og klarheten ble forbedret, oppsetts tiden ble drastisk redusert og pasientens komfort ble økt. I tillegg ble det gitt ytterligere forskningsområder som kun ble undersøkt på overflatenivå på grunn av begrensningene i denne oppgaven.

Abbreviation

ANN   Artificial Neural Network

AV   Audio and Video

CAD   Computer-Aided Design

CAE   Computer-Aided Engineering

CLE   Continuous Larynx Examination

CMOS   Complementary Metal Oxide Semiconductor

COTS   Commercial off-the-shelf

CPAP   Continuous Positive Airway Pressure

D   Dimensional

EILO   Exercise Induced Laryngeal Obstruction

ENT   Ear, Nose and Throat

FIVE   Flexible Intubation Videoendoscope

FOG   Fiber Optic Gyroscopic-Sensors

FOR   Operating Room of the Future

FPV   First-Person View

HDMI   High-Definition Multimedia Interface

HLS   Hypertext Transfer Protocol (HTTP) Live Streaming

HTTP   Hypertext Transfer Protocol

MEMS   Micro Electro-Mechanical Systems

NTNU   Norwegian University of Science and Technology

NTSC   National Television Standard Committee

PAL   Phase Alternating Line

PLA   Polylactic Acid

RTMP   Real-Time Messaging Protocol

SD   Secure digital

SW   SolidWorks

TCP   Transmission Control Protocol

UDP   User Datagram Protocol

USB   Universal Serial Bus

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1 Introduction

1.1 What is EILO?

Exercise Induced Laryngeal Obstruction (EILO) is a potential diagnosis for individuals who experience breathing difficulties during exertion and lack relevant medical conditions such as asthma. Studies have indicated that EILO may be prevalent in up to 6-8% of adolescent populations and up to 35% among athletes [42] [48]. EILO symptoms are non-specific and can vary from person to person, including chest or throat tightness, cough, inspiratory wheeze, changes in voice, and difficulty breathing during strenuous exercise. While symptoms generally resolve after a period of rest, they may reoccur if exertion is resumed at a similar level. Proper diagnosis and treatment planning for EILO is crucial for improving the quality of exercise for those affected. In many cases, correct breathing techniques can alleviate or manage symptoms, and in more severe cases, surgical intervention may be necessary. Many individuals who report having EILO symptoms often tend to be misdiagnosed with asthma, and experience none or very minor benefits from the resulting asthma treatment procedures [30] [42]. It is therefore important that a proper diagnostic procedure is used in order to correctly diagnose the patients' condition.

1.2 Diagnosing EILO

Currently, one of the most effective means of diagnosing EILO is through the use of Continuous Larynx Examination (CLE). This diagnostic approach is widely regarded as the industry gold standard, owing to its effectiveness in providing accurate diagnosis [39]. During a CLE-test, the patient is required to engage in rigorous physical activity, with a camera inserted through the nasal cavity down to the larynx[1], reaching the point of exhaustion or symptom-limiting distress. While this test can be performed using a range of activities, running on a treadmill is the most common, given its physically demanding nature and ease of setup. Other activities such as swimming or hiking have also been proven feasible but may be difficult or impractical for most medical facilities to undertake [65]. Camera devices vary depending on the institution performing the test, however, the important requirements are that it has to be thin enough to fit through the nasal cavity, it does not cause any allergic or otherwise negative bodily reactions within the patient, and that it can provide a clear enough footage of the larynx during the test so that a proper diagnosis could be given [49] [50].

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[1]**Larynx** the area at the top of the throat that contains the vocal cords [51]

1.3 Problem definition

The current test setup at St. Olav hospital for diagnosing EILO has a number of limitations that reduce the effectiveness and reliability of the test. The first stage of testing patients for EILO is heavily based on patient history and symptoms, this can be unreliable as displayed symptoms can vary for every patient and often does not provide a full scope of the patient's condition. Often, static endoscopy is performed, where the doctor inserts a video endoscope into the larynx area through the nasal cavity while the patient is sitting still, to observe if there are any abnormalities present. This stage is used to remove any other potential candidates for the displayed symptoms, such as high stomach acidity, genetic disorders, birth conditions etc.
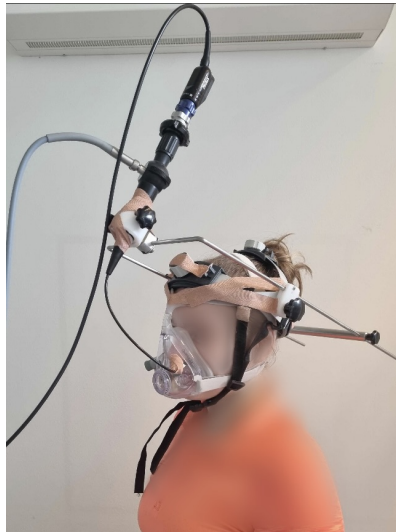
Figure 1: Current setup

If the patient is to be fully tested for EILO, then the current setup requires patients to exercise on a treadmill while wearing a mask with a wired video endoscope, attached to a helmet. During the procedure, doctors observe video footage that is transmitted through the video endoscope, of the potential abnormalities in the larynx that the patient may display during high-intensity training. This is a crucial objective of the procedure, as the severity and cause of these abnormalities decide the treatment plans for the patient. Patients have given feedback that the equipment is uncomfortable and can limit them from performing the exercise task to the fullest, this may increase the inaccuracy of the test as it does not reflect the patient's real-world exercise habits and conditions. When the patient is running at high intensities and speeds, the video endoscope starts to shake significantly due to the motion of the patient running. This results in noticeably decreased footage clarity, to the point where the video feed may not provide a clear or complete view of the larynx during exercise, which can make it difficult to get an accurate diagnosis. In addition, the accumulation of saliva on the camera lens during the procedure can impair visibility and interfere with image acquisition.

1.3.1 Current diagnostic equipment at St. Olavs hospital

- Flex.Intubat. Videoendoscope 4.0x65. Supplied by Karl Storz retailer.

- C-MAC® Monitor for Complementary Metal Oxide Semiconductor (CMOS) Endoscopes. This monitor is supplied by Karl Storz retailer.

(a) Flex.Intubation Videoendoscope 4.0x65

(b) C-MAC® Monitor

(c) Endoscope setup with C-MAC® Monitor
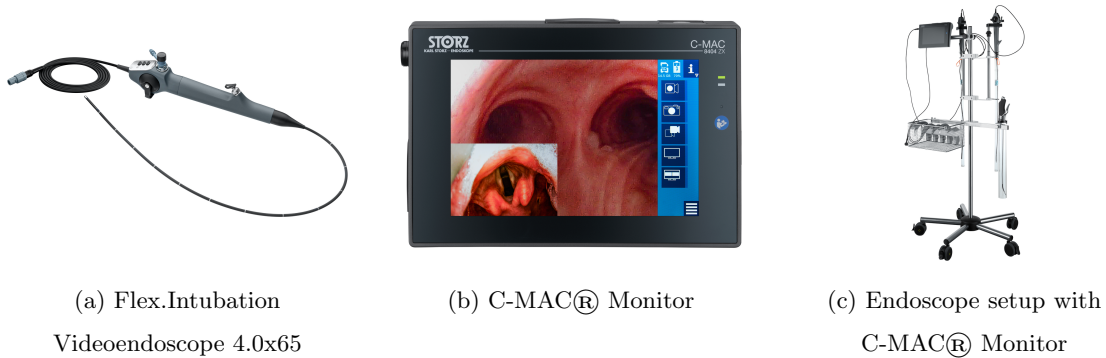
Figure 2: Current diagnostic equipment

1.4 Thesis scope and objectives

The goal of this thesis is to research how to improve the different areas for the current setup and to provide solutions to some of the key issues presented in the setup. This thesis aims to:

- Improve patient satisfaction, and the overall quality and reliability of the diagnosis by improving the current CLE-test setup equipment

- Provide effective methods on how to increase footage clarity by reducing the accumulation of saliva

- Improve video stability with the use of different methods for footage stabilisation

This thesis will also evaluate different possible approaches to these issues and provide a systematic evaluation of the positives and negatives. Ultimately this thesis will provide the direction for further research within this field.

1.5 Structure

This thesis is divided into multiple chapters where firstly it will look into the necessary theoretical background needed to approach each key issue within the thesis. It will then go into the methods used to design, validate and evaluate different concepts that could be used to improve the setup. Moreover it will present the different concepts and criteria for how they are evaluated. The thesis

will also look into the concepts that have been chosen and developed, and the results that were achieved when implementing these concepts. Lastly, it will discuss further areas for improvement and future research.

2 Theory

The current test setup at St. Olavs hospital has challenges and areas in need of improvement that affect both the patients and the physicians. In this chapter, the theory behind the current test setup and its challenges will be further presented with a focus on the mechanical, electronic and humancentric[2] elements.

2.1 Areas of improvement

For the purposes of this thesis, five different improvement categories that fall under three different elements will be proposed. This category and element link, will be called an area of improvement. Three of these categories, being the Increase of the functionality of the test setup and improvement of the footage stability and clarity, fall under both mechanical and electronic elements. The two categories that fall under the humancentric element are, the increase of the comfort of the patient and the ease of use of the equipment.

	Mechanical	Electronic	Humancentric
Increase functionality			
Footage stabilisation			
Footage clarity			
Patients comfort			
Ease of use			

Table 1: Improvement areas

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[2] **Humancentric** Focusing on human beings [34]

2.2 Mechanical areas of improvement

2.2.1 Functionality
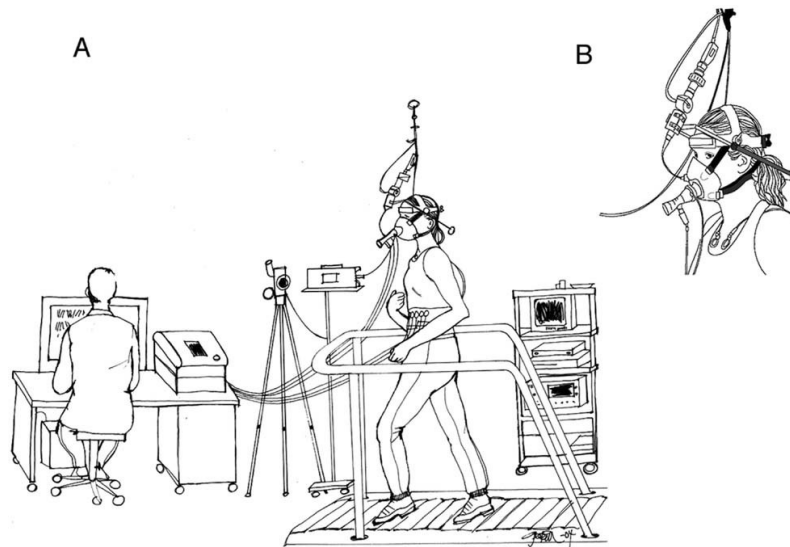
Figure 3: CLE-test setup

The CLE-test was developed by a group of doctors at Haukeland University Hospital to be able to distinguish between asthma and EILO. This method consists of a medical endoscope, headgear, and a viewing monitor, making it possible to record and analyse the vocal cords during high-intensity training [18]. The headgear is there to hold the endoscope stable during the test and was specially developed to hold the endoscope and camera in place. [32].

The headgear consists of a metal frame that is fastened to a surgical headlamp helmet. On the front of this frame the endoscope is fastened, and due to the weight of the endoscope, a weight rod is placed on the back of the frame for counterbalance, as shown in the Figure 3 [32]. This means that the construction is quite heavy, making it uncomfortable for the patient to exercise with, and due to heavy cables connected to the endoscope from the ceiling, possibly dangerous. The setup also consists of a mask to hold the camera tube in place. The mask itself is not designed to restrain the camera from moving during the test, instead, the camera tube is fastened to the mask with medical tape. The mask covers both the mouth and nose, making the air inside the mask hot and clammy, which elevates the level of discomfort for the patient.The setup that has been used, can be seen in Figure 4.
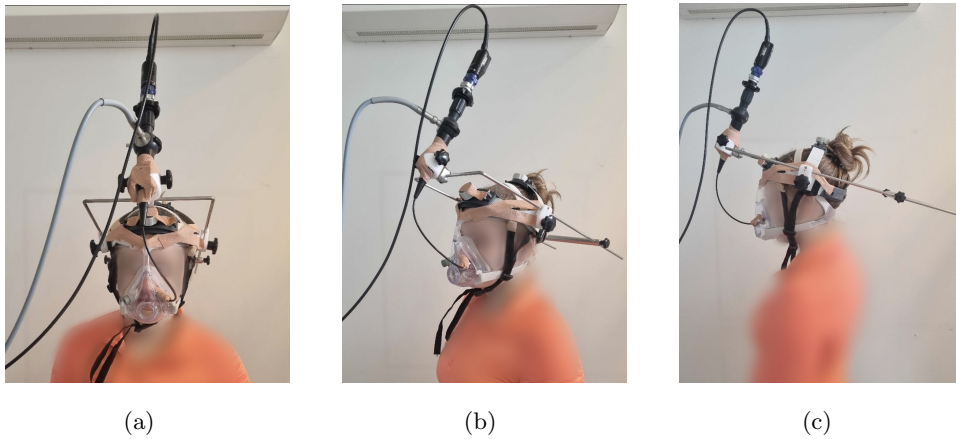
Figure 4: Setup

In the recent years there have been some developments of the setup. Due to wear and tear to the endoscope, a switch to single-use Flexible Intubation Videoendoscope (FIVE) has been made. The single-use FIVE, shown in Figure 5, is much lighter than the previous endoscope, which means that the metal frame is no longer necessary, making the setup easier for the patient to exercise with. The single-use FIVE is then fastened to the headgear with medical tape. This is is not ideal when sweat and hair are involved, and it is time-consuming for the physicians to set up [26]. The physicians at St. Olav hospital have been made aware of this new setup, but it has not yet been used at their division.

Figure 5: Single-use FIVE

2.2.2 Mechanical stability

One of the key issues that is prevalent during the CLE procedure is unstable footage. While running on a treadmill during the CLE-test, the patient performs a wide range of motions, which causes the camera to move and therefore destabilising the footage. This issue is relatively severe, causing the diagnostic quality to decrease due to the inability of the footage to consistently provide clear and stable imagery for the diagnosticians to analyze. Instability, or unstable footage, is footage that includes any unwanted motion within it. This motion may result from either a low or high frequency motion of the camera and can be caused by various sources, including camera operators who move or shake the camera, or the device or environment to which the camera is mounted,

causing vibrations, or shaking [29]. Any unwanted motion of the camera that is introduced to the footage, can make it hard to focus on the actual motion that is being filmed, degrading its quality. It is therefore important, especially for medical diagnosis, that any unwanted motion in the footage is reduced to a minimum. The process of removing unwanted motion from the footage is called video stabilisation.

The two main categories within the field of video stabilisation are mechanical and digital stabilisation [57]. When addressing mechanical stabilisation it can be divided into two main groups: physical and active stabilisation.

Physical stabilisation

Physical stabilisation means physically restraining the camera from moving. This can for example be something as simple as the use of a tripod to keep a camera stable [29]. When it comes to using physical stabilisation, the closer the restraint is to the actual camera lens the better. This means that for a CLE test, the physical restraint should be as close as possible to the end of the camera tube. The camera tube is inserted into the nasal cavity, which is a narrow passage, meaning it does not have many degrees of freedom to move sideways. That results in the easiest way for the camera to move is up and down the nasal cavity. This is also where the weight of the endoscope will naturally pull the endoscope tube with it. Figure 6 displays a free-body diagram that shows the inertial forces that act on the endoscope while it is inside the nasal cavity.
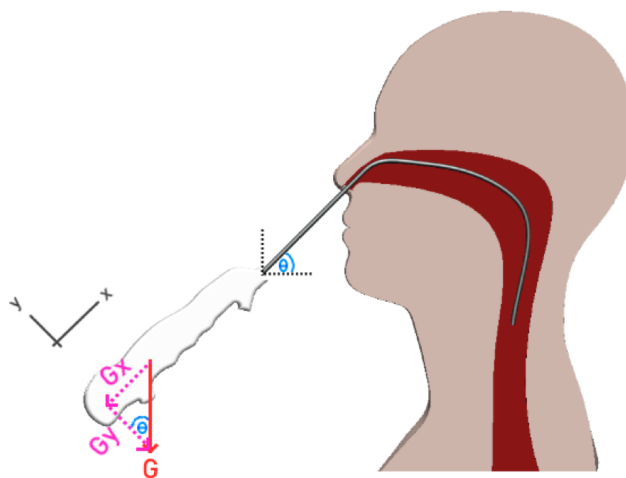
Figure 6: Free body diagram

$$G_x = G \cdot \sin\theta = m \cdot g \cdot \sin\theta \tag{1}$$

$$G_y = G \cdot \cos\theta = m \cdot g \cdot \cos\theta \tag{2}$$

where:

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G = The gravitational force

m = mass of the object concentrated in the center of gravity

g = gravitational acceleration $\approx 9.81 m/s^2$

θ = angle of inclination determined from the angle of the patients nasal entry

By adding a physical stabilisation this will reduce the movement the camera tube experiences from the forces.

Active stabilisation

Active stabilisation is a method where the footage is actively stabilised using sensors and motors [58]. It consists of two stages, motion detection and motion compensation. In the motion detection stage, sensors such as gyroscopes or accelerometers built on Micro Electro-Mechanical Systems (MEMS), Fiber Optic Gyroscopic-Sensors (FOG) or similar technologies, could be used to detect any motion that the camera itself experiences while filming [19]. This sensor data is then used to move the camera to the opposing direction of the detected motion using motors or manipulators. This effectively counteracts the motion and holds the camera in place. It can also be directly sent to a video signal processing unit, that takes inputs both from the camera and the gyroscope and adjusts the output accordingly with the help of software [43] [63].

2.2.3   Clarity

During the CLE procedure, there has been observed a significant accumulation of human saliva and condensation on the endoscope lens. This causes the quality of the video to be negatively impacted by reducing the overall clarity and visibility of the footage. To understand why this happens, an explanation of why liquids stick to surfaces needs to be presented.

There are two main forces that are responsible for a liquid sticking to a solid surface, cohesive and adhesive forces. Cohesive force is a term used to collectively describe intermolecular forces that are acting amongst the molecules in the liquid. These are hydrogen bonding and van der Waals forces, and they are responsible for the liquid's property of resisting separation. Adhesive forces refer to attractive forces between different substances. These are mechanical and electrostatic forces. When a liquid sticks to a surface this phenomenon is called "wetting", and it means that forces between the liquid and the surface are strong enough that they force the liquid to stick to the surface more than the liquid itself. Cohesive forces are the reason why liquids often form "droplets" on some surfaces. If the surface chemistry is highly water repellent i.e., has low adhesive force, the liquid will tend to stick to itself rather than the surface, forming a droplet [54].
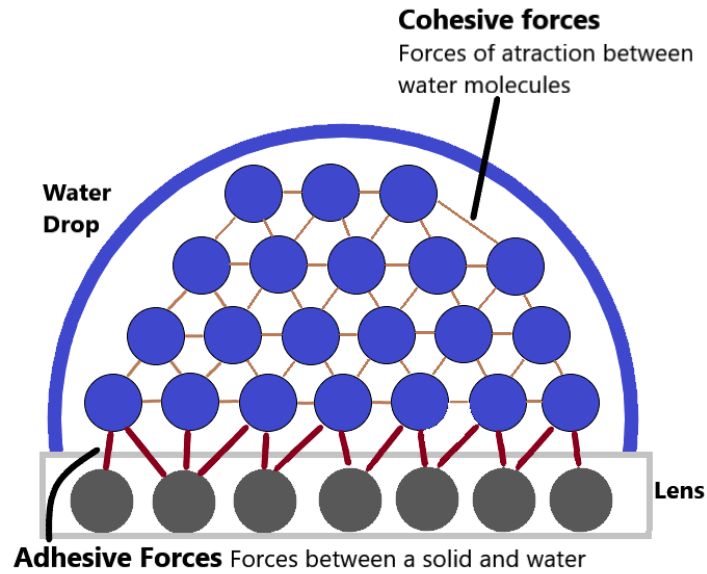
Figure 7: Illustration of Cohesive and Adhesive forces

Categorising a surface material based on its adhesive forces can be done in two ways. If the surface has low surface energy, in other words low adhesive force, it is classified as hydrophobic, - "afraid of water". If the surface has high surface energy, i.e., high adhesive force, it is categorised as hydrophilic, "loving water" [1]. This means that the contact angle between the liquid and the surface, on a flat non-inclined smooth surface, will either decrease or increase depending on the surface's adhesive properties. Mathematically this can be expressed using Young's Equation for Contact Angles [28].

$$\cos \theta_Y = \frac{\sigma_{\text{SV}} - \sigma_{\text{SL}}}{\sigma_{\text{LV}}} \tag{3}$$

Where:

1. θ_Y is the Young's contact angle

2. σ_{SV} is the surface tension of the solid-vapour interface

3. σ_{SL} is the surface tension of the solid-liquid interface

4. σ_{LV} is the surface tension of the liquid-vapour interface

A surface will be categorised as hydrophilic if the contact angle is greater than 90° θ, and hydrophobic when the contact angle is lower than 90° θ. Ideally, a theoretical absolute hydrophilic surface would have a contact angle of 0° θ, while a theoretical absolute hydrophobic surface would have a contact angle 180° [60].

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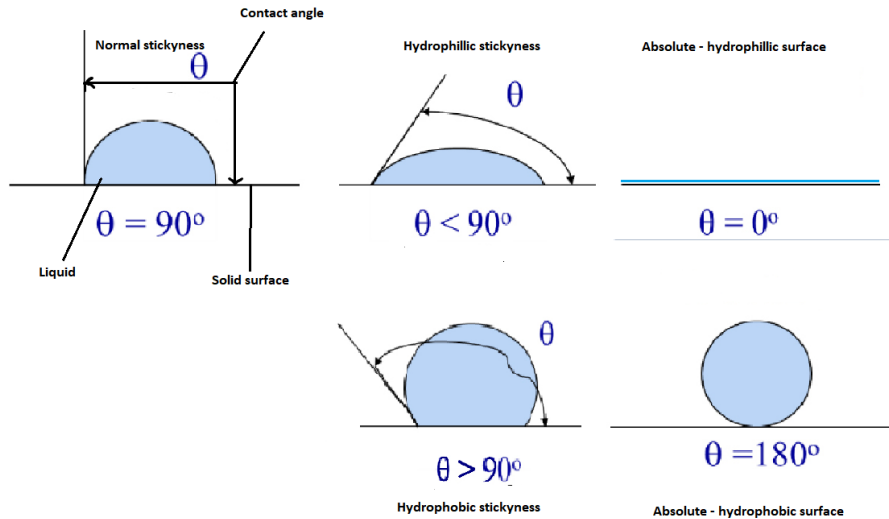
Figure 8: Surface contact angles

The criterion that needs to be met if a liquid is to be removed from a solid surface is that the external forces dragging the liquid away from the surface must be greater than the adhesive forces holding the liquid on the surface. In most cases, this external force is gravity, which either forces the liquid to roll off the surface in the form of a droplet or spread the liquid throughout the surface evenly, forcing any excess liquid with no access to the surface also to slide off [21] [40].

Surface topography and geometry also play a vital role in deciding how the liquid interacts with it. Many modern superhydrophobic and superhydrophilic property exerting surfaces have advanced surface geometry that either helps to increase or decrease contact angles [60].

In cases where there exists a difference in temperature between the surface and the surroundings, condensation may take place. This is because condensation or "fogging", is a phase change, whereby water in the vapor phase turns into liquid water when in contact with a solid surface at a lower temperature [10]. In today's industry, there are two main broad ways to categorize the prevention of condensation. Either by controlling the environment or by tuning the affinity between a solid surface and the liquid by coating the surface or by directly modifying the surface features [23].

2.3 Electronic areas of improvement

2.3.1 Functionality

During a CLE-test, the patient is at all times wired with cables connecting the endoscope to a viewing monitor. Due to the concern of entanglement and a reduction of the patient's freedom to

maneuver as they please, there exists a high desire amongst the physicians and patients to make the test setup wireless.

The definition of wireless streaming is the transmission of audio and video content in a continuous flow over a wireless internet connection. [64]

A wireless streaming process can be explained in the following simplified terms. It starts with the raw video data getting captured from a camera. An encoder then compresses the data into a media file to be easily transmitted. A transcoder then decompresses the media file and converts it into a format that can be made accessible to a wider selection of users. Streaming protocols and formats are then implemented for the specific use of the stream. A streaming monitor is then used to view the desired footage.

VIDEO CAPTURE   ENCODER   TRANSCODER   STREAMING PROTOCOLS AND FORMATS   VIEWING DEVICE
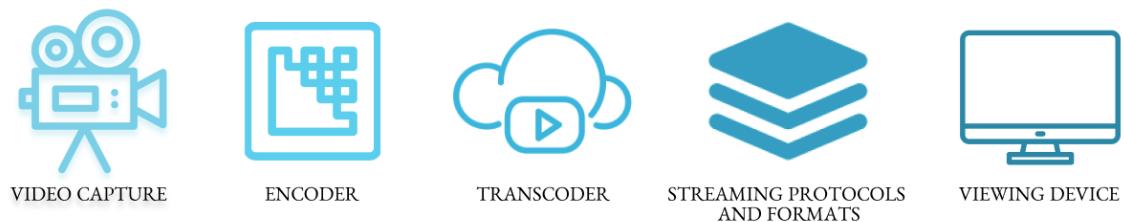
Figure 9: Livestream process

Video capture: To start the process of video streaming a camera needs to be used to capture and record images of the desired objects. From here the process of achieving a good video feed starts. When choosing the camera to be used for live streaming, several criteria should be used [15].

- Clean High-Definition Multimedia Interface (HDMI) Port: This allows the camera to send a video feed without any user interface elements.

- Power supply: The camera needs to be either connected to a power source during use or have access to a battery that can last for the duration of the desired run time.

- Video quality: The quality that is desired for the specific use of the camera needs to be taken into consideration. Aspects to take note of are the output resolution[3], and frame rate[4].

Encoder: Video encoding is converting the video signal into a streaming media file. The process consists of compressing the raw data into a package. This is done to take away the data that is not needed and therefore reduce the bandwidth[5]. This allows the data to be easier transmittable [61].

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[3]**Resolution** is a measurement of the number of pixels that can be contained on a display screen [8]
[4]**Frame rate** is the number of individual frames the camera captures per second [14]
[5]**Bandwidth** a measurement of the amount of information that can be sent between computers [13]

An encoder can be in the form of a software program, that can be installed and run on, for instance, a computer with a camera. It can also take the form of a hardware appliance, that has the sole purpose of encoding that can be directly connected to the camera in some cases [31].

Transcoder: Transcoding is the conversion of one type of video media file to another. It takes the already encoded data and converts it so that it is more compatible with several playback devices. This is most commonly done by changing the file size and bitrate. Resizing a video file is called transizing, and it implements adapting the resolution to match the displaying monitor. A transcoder usually takes the form of a streaming service or cloud-based streaming platform [55].

Streaming protocols and formats: A streaming protocol is a set of rules that determine how data travels from one communication platform to another. These rules are divided into layers to form a protocol stack. Each layer focuses on a specific function but still cooperates with each other. The number of layers determines the complexity of the protocol [56].

To make the communication platforms communicate with each other both the output device and the receiving platform need to support the same protocol to work. Some standardization in the industry has been developed to have a larger reach to a greater consumer base. There are now a few major protocols that are most commonly used, but have different areas of focus. The list below displays the most common live-streaming protocols in use at the moment [37].

- Hypertext Transfer Protocol (HTTP) Live Streaming (HLS)

- Real-Time Messaging Protocol (RTMP)

- Transmission Control Protocol (TCP)

- User Datagram Protocol (UDP)

Streaming monitor: The last step of having a successful live stream is to have a viewing device that allows the users to actually see the content on a screen. The most popular devices are mobile phones, computers, tablets, and TV's.

2.3.2 Digital Stabilisation

Stabilisation can also be achieved with the help of digital tools. Digital stabilisation or image processing, uses software tools to reduce the instability of the footage. This method is especially attractive for applications where mechanical or active stabilisation techniques are hard to implement. This method does not necessarily require the use of hardware, and instead relies on different software algorithms to detect and remove unwanted motion [53]. However, the use of sensors can provide crucial information to the software regarding what is to be considered camera motion and what is motion within the footage itself. Digital video stabilisation is divided into two parts,

motion video analysis and modelling, and motion correction and video stabilisation. The point of these two steps, is to identify what is the unwanted motion, remove that motion as much as possible and to reconstruct the video to make it more visually pleasing or realistic [29].

2.4 Humancentric elements

When it comes to working with people, especially in the medical industry, the humancentric element is important not to neglect. If not taken it into consideration it can have a negative impact on both the patients and the physicians.

2.4.1 Patient's comfort

Patient comfort and satisfaction is a crucial element of successful medical care as it can affect patient compliance with medical recommendations and therapeutic plans. A dissatisfied patient may search for alternative treatment options, disregarding medical advice and jeopardising the effectiveness of their treatment [9]. Therefore, it is imperative to ensure that medical procedures are satisfactory to patients, enabling the provision of optimal care [46].

Improving patient satisfaction could be achieved by focusing on enhancing the comfortability of equipment and achieving greater levels of patient-doctor communication. While enhancing equipment comfort may not directly contribute to patient compliance, it can improve patient satisfaction, enabling them to focus better on the procedure. Effective communication can also increase patient satisfaction by promoting better understanding of their medical condition and treatment requirements [12].

An important tool for enhancing communication and improving patient satisfaction is showing patients the footage of their medical tests. Showing patients a visualisation of their symptoms can help them understand their condition better and increase their overall experience of the procedure. This approach has already shown to improve patient satisfaction to a certain extent [41].

2.4.2 Ease of use

If physicians have to work with equipment that is difficult to use, the general eagerness to use the said equipment is very low. The effect this can have on the physicians is that they may dread doing procedures. This can also lead to feelings of embarrassment due to making the patients use equipment that is not up to the standard that it should be. This is exactly what the physicians at St.Olav hospital are suffering from, where the difficult and time consuming setup of the current test equipment, demoralizes the physicians, and reduces the frequency of the tests as a result [25].

Another significant downside to using the current CLE test equipment is that it has shifted the

focus of the test from the well-being of the patient and getting the right diagnosis, to focusing on the equipment. There is a constant worry that the equipment will fail and the test needs to be stopped and restarted, and therefore wasting a significant amount of time. During some failure scenarios, there is even a risk of the equipment causing damage to the patient. This is especially prevalent if the patient, due to the excessive exercise, falls or in the worst case scenario faints, with the heavy equipment still attached to them. This again reduces the quality of the procedure by negatively affecting the humancentric element.

3 Method

In this chapter, the methods that have been used to design, validate, produce, and evaluate different concepts will be presented.

3.1 Design development

3.1.1 Design iteration

An iterative engineering design process was used to develop concepts eligible to fix the problems defined in the thesis. Iterative means it repeats the previous steps as many times as necessary to have a desirable outcome [24] [67]. It consists of 5 main steps.

Step 1: Problem definition
What is the problem?
What are the necessary requirements and limitations
Why is it important to find a solution to this problem?
What are the expectations of the finished design?
Step 2: Research
Brainstorm ideas.
Research the ideas and explore the different possibilities.
Step 3: Develop
Select an approach and develop a design. Make a model or prototype.
Step 4: Test and evaluation
Expose the design for the realistic obstacles and procedures it will endure when being used,
use the results from the test to determine the flaws of the design, and what it might be missing.
Step 5: Iterate
Redesign in regards to what was discovered during the testing and evaluation.
Repeat the process.

Table 2: Iterative engineering design process

3.1.2 CAD

When developing a design, using a 3D modeling program can be a very useful tool to make a virtual model of the design. During the mechanical engineering education at NTNU, the students are introduced to different types of 3D-modelling programs. Due to the project members having previous experience with SolidWorks (SW), it was chosen as the program to be used. SW can provide both Computer-Aided Design (CAD) and Computer-Aided Engineering (CAE).

CAD is a computer software that supports the design process and helps create, modify, analyze and enhance a design [17]. CAE offers simulations and analysis on designs in SW, making it possible to determine if the design meets the required criterion for the part [16].

Both CAD and CAE will be used to develop and validate the mechanical concepts proposed in this thesis.

3.2   Validation method

When choosing the best methods to validate a design it is important to know the largest failure modes that are most likely to occur with the design. When talking about mechanical designs one must often have several validation methods, the most common is to do preliminary calculations, simulations and analysis, and physical testing with prototypes and test hardware.

3.2.1   Calculations

With mechanical designs, one often needs to do some types of calculations to get a numerical answer to the external forces that act on the parts of the design. Calculations can often be used as a parameter for the geometry of the part, for instance one can calculate a load that the designed part needs to withstand, it is therefore the parameter that decides the geometry the part needs to have to withstand, in addition to be able to choose the right material as well. One can have several types of calculations done for mechanical designs, such as tensile, compression, shear, torque, tear, fatigue, friction, etc. The type of calculations needed for a design has to be selected with the purpose of the part and the environment the part will be subjected to.

3.2.2   Simulations and analysis

Simulation and analysis are also often used, especially when the design has a nonlinear geometry and makes it difficult to calculate correctly manually. A simulation and analysis program, such as SW, is a program that uses calculations, material properties, and CAD model geometries to try to predict how the object will react and behave under different physical conditions [11]. One often uses simulations to find the vulnerabilities and failure modes in the design before the production starts.

One can do many types of simulations and analyses, for example, structural analysis, heat transfer, fluid flow, mass transport, or even electromagnetic potential.

3.2.3   Testing

The goal of this thesis, is for a physical product to be designed and produced. Therefore it is highly desired that the design will be put through testing to see if it can withstand the real-life forces and effects that it will be enduring when used.

To save on time and costs, one typically makes prototypes first with a production method and material that is abundant and cheap. In the mechanical engineering industry, 3D printing is a very handy tool to do exactly this.

When creating a prototype it is important to keep in mind what you want the prototype to tell you. Because the prototype is not a true copy of the product that is to be produced, therefore it is most like not able to withstand real use. For instance, if the prototype is not made in the right material it will most likely not stand the force load applied to it. A few examples of what prototyping is good for is to see how the design will integrate with other components in use, how it visually looks, and also its ease of assembly. One can also use a prototype to see if the design works in practical manners, for instance, to see if it's easy to get your hands in a place where you need to tighten a nut or fasten a screw.

After iterations have been done and the prototype design looks good, then it's desirable to create a set for test hardware with the desired material to see if the design can really fulfill all of its required functionality.

3.3   Production method

When deciding on a production method, it is important to consider different factors to ensure efficiency, quality and cost effectiveness. These factors are product design, production volume, time-to-market, cost considerations and material selection [33].

Product design: Some production methods are better suited for more complex geometries, while others are better suited for simpler shapes. Therefore it is important to asses how well the production method matches the product design.

Production volume: The production volume plays a significant role in determining the appropriate production method. Different methods vary in capabilities and efficiencies at different scales. For small production volumes, methods like manual assembly or prototyping techniques can be suitable, while high-volume production may require automated or mass production methods.

Time-to-market: The speed at which the product needs to be brought to the market also needs to be considered. Some production methods, such as 3D-printing or rapid prototyping, offer quick turnaround times, making them favourable for rapid product development. However, other methods, like tooling for injection molding, may have longer setup times but higher production

rates once established.

Cost considerations: Cost is crucial when selecting a production method. It involves evaluating both upfront investment costs and ongoing production costs. Production methods with high initial setup cost may be more cost-effective in the long run for large production volumes, like tooling for injection molding. While for small production volumes, methods with lower setup costs, such as additive manufacturing, may be more economical.

Material selection: Different production methods have limitations to the material they can process. Some methods may be more suited for plastics, such as injection molding or 3D-printing, while others may be more appropriate for metals, such as casting or forging. It is important to consider the compatibility between the chosen production method and the desired material or materials for the product [35].

3.4   Evaluation method

In order to effectively evaluate proposed concepts with each other, a systematic evaluation matrix called PUGH matrix will be used. This is a matrix that firstly weighs the importance of different criteria that are relevant to the design, and then evaluates whether the proposed concepts fulfil these criteria better, worse or the same as the current concept in use. The importance weighting will be represented by numerical values ranging from 1, the lowest, to 10, the highest. These values will be assigned based on the assumptions made throughout the concept development chapter. They will determine the importance that each criteria has, for the concept to have a successful implementation and a positive impact on the overall result.

There will be three different numerical concept evaluation values within the PUGH matrix. These values will depend on how well the new concept fulfills the relevant criteria. The concept will either be evaluated as more than 0, meaning it will be better than the current concept in use. It will be evaluated as 0 if it is evaluated to be the same as the current concept and it will be evaluated as less than 0 if it is worse than the current concept. These values will go from 10 to -10, depending on how much better or worse the new design is compared to the current design, but also to its other proposed alternatives. Values will be heavily influenced by assumptions and approximations made, and therefore may not be an entirely accurate metric of evaluation, however they will still provide a general basis used for comparisons.

After these values are assigned, the importance weight will be multiplied with the concept evaluation values, and the following results will be summed up. The concepts will be evaluated based on this sum, the higher the value, the better the concept. Potential experiments will only be performed with the concepts that are evaluated the highest.

The evaluation categories that will be used are; Functionality, Availability, Production possib-

ilities and Costs. The descriptions and relevance of these categories will depend on the concepts proposed.

An example of a PUGH matrix, where Design number 1 ends up being the best concept can be found in Table 3

Criteria	Importance Weigting	Current Design	Design #1	Design #2	Design #n...
Size	10	0	6	-3	0
Weight	5	0	0	2	-2
Price	6	0	-10	0	1
Implementation	4	0	5	4	4
		Sum:	20	-4	12
		Rank:	1	3	2

Table 3: Example of a PUGH matrix

Functionality: depends on the type of concept that is being evaluated. It consists of what kind of task the proposed concept will provide a solution to and what kind of requirements does it have to adhere to. Examples of functionality could be how easy the design is to use, how difficult its implementation is, how much it weighs, what kind of forces it can tolerate etc. The core functionality will vary for each concept and therefore a different criteria will be applied when evaluating said concepts, the importance of which, will be determined by assumptions made in the concept development section.

Availability: describes how accessible the proposed concept or its components are. Examples of low availability would be necessary parts or materials that are not accessible within the time frame of this study.

Production possibilities: represent how difficult and accessible a concept production method is. This category will be mostly relevant for parts developed throughout this study. An example of low production possibilities would be a design that requires production methods beyond what is accessible for this study.

Costs: represent how expensive the development, implementation or acquisition of a proposed concept would be. Examples of high costs would be price ranges that are beyond the budget of this study.

4 Concept development

When continuing to research concepts for this thesis, it was clear that cameras that are used for medical purposes have to be classified as medical equipment and therefore have to follow strict guidelines set by the Norwegian Medicines Agency [36]. The concepts are therefore based on the assumption that the single-use FIVE, Figure 5, already available at St. Olavs hospital, is the medical endoscope that will be used.

- Flexible Intubation Videoendoscope (FIVE), for single use. This video endoscope is supplied by Karl Storz retailer.

The physical parameters from the single-use FIVE can be found in Table 4.

Parameters		Units
Camera tube outre diameter	3.5	mm
Camera tube length	650	mm
Singe-use FIVE handle dimensions	$160 \times 20 \times 40$	mm [L×W×H]
Singe-use FIVE weight	100	g

Table 4: Parameters

4.1 Mechanical concepts

The primary function of the test setup is to have a good view of the patient's larynx during a high-intensity exercise. To ensure this new functions have been added to the current test setup as it was deemed not functional enough.

- Ability to adjust the mask and headgear to each patient's anatomy and preference.

- Fasten the endoscope handle to the patient's body.

- Ability to adjust the distance from the camera lens to the patient's larynx.

- Reduce the accumulation of saliva on the camera lens

4.1.1 Headgear

When researching to develop the new headgear, the consensus was that the concepts should involve having a type of helmet or face mask so that the contraption is located on the patient's head. This is due to the restricted movement the patient would have if we were to be fastened on any other parts of the body. In addition, to make the setup easier for the physicians, and hopefully eliminate

the need for medical tape, a holder for the endoscope was designed. This was designed to house the endoscope handle and hold it in place during the test. The holder should be fastened to a fastening bracket that is attached to the headgear, or directly to the headgear itself. This makes it possible to insert the camera into the nasal cavity and find the right position, and then easily place the endoscope handle in the holder.

Headlamp helmet

The headlamp helmet that has been used at St. Olavs hospital in the recent time, is made out of plastic with some flexibility. It has a tightening mechanism on the top and back that are quite bulky and often loosens during activity. The tightening mechanism is centered on the back of the head, this makes it hard to fasten the single-use FIVE handle to the helmet due to limited space. A possibility is to fasten the endoscope on the side of the headgear, but this risks irritation on the back of the ear from the endoscope hitting or moving along the ear.

(a) Side view (b) Top view

Figure 10: Headlamp helmet

The first design for the holder was to design a housing that allows for the endoscope to be inserted easily, and also has slots for the camera and and monitors cable to exit the holder. To attach the holder to the helmet, the first design was to add some protrusions with side groves. These was added so that the flexible material on the side of the helmet could be pushed into the groves. This is shown in Figure 11.
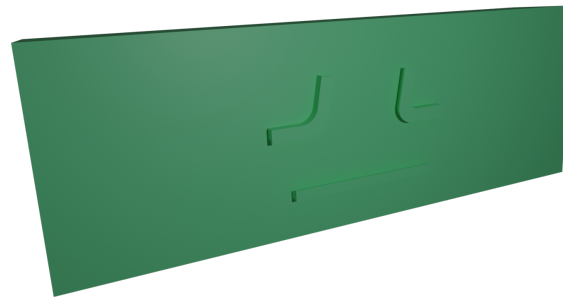
Figure 11: Holder for headlamp helmet

After some evaluation this was deemed not secure enough and added the risk of the holder falling off during the test, the idea of then adding a fastening bracket was brought to light.

The design for the holder and bracket locking mechanism and integration was to add slots into the back of the holder and add some protrusions on the back of the bracket that fits perfectly within the slot. These protrusions also have grooves cut out on both sides of it so that the protrusions can slide into the holder and then slide down to ensure it stays in place. The locking mechanism is shown in Figure 12.
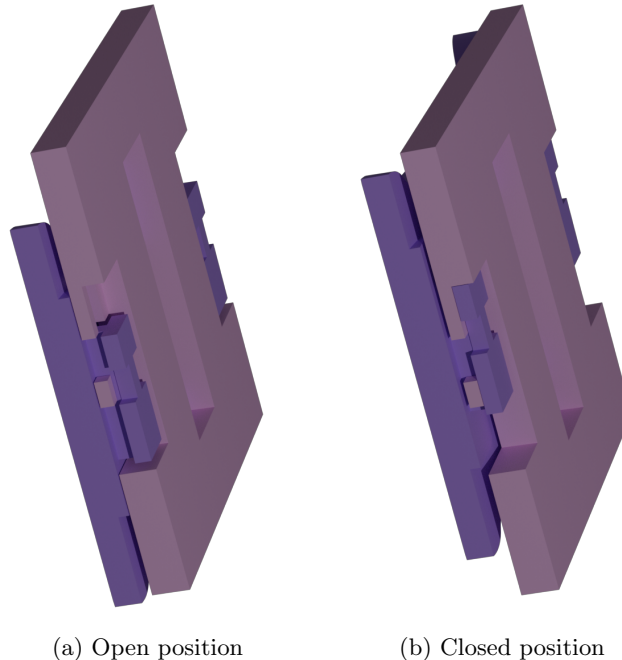
(a) Open position   (b) Closed position

Figure 12: Locking mechanism

The first design for using a bracket and holder with this locking mechanism was designed to fit with the headgear that is already in use at St. Olavs hospital. This will also be placed on the side

of the helmet due to the previously mentioned challenges of having it centered on the head.

The bracket is designed in two parts that connect with each other. One side is on the backside of the helmet strap, and then the front piece can be attached over the helmet strap locking it in the middle of the two pieces. This allows the holder and bracket to stay in place, while still being able to adjust the size of the headgear. The Holder will then be placed onto the protrusions on the bracket and the slid down into locked position. The design for the holder and bracket designed for the headlamp helmet is showed in Figure 13, with an iterated geometry of the holder.
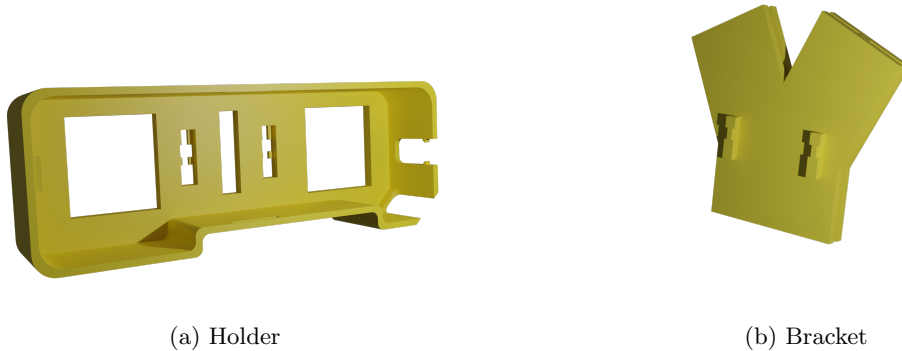

(a) Holder

(b) Bracket

Figure 13: Headlamp helmet: Holder and bracket

By having the holder/bracket located on the side of the head, due to its size, it can easily come in contact with the ear of the patient and possibly irritate it. This also means that the camera tube will have a bigger loop since that holder is closer to the nose than if it were to be fastened to the back of the head. This creates extra movement of the camera tube that translates to shaking of the camera inside the larynx. Since this concept is a helmet and fastening mechanism, one also needs to add a separate face mask so that the camera tube will be guided easily into the nasal entry.

Headband

The second concept to be considered was using a headband made of elastic material, like the one shown in Figure 14. This was thought of due to the fact that it is specifically made to fit the head, and the size can easily be adjusted. For instance, a headband from a headlamp is made to carry some weight from the headlamp, which often varies from 200-300 g. This meant it would be no problem for the headband to carry the weight of the FIVE. These types of headbands often have one or two stripes of silicon on the inside for some added grip to reduce the risk of the headband slipping and moving around when running on the treadmill.
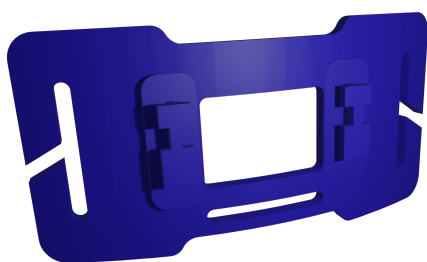
Figure 14: Headband

To attach the endoscope, the first design again was to add a holder directly to the headband. This holder was specifically designed to be able weave the headband into alternating tabs on the back of the holder shown in Figure 15.

Figure 15: Holders fastened directly to headgear

Due to the size of the holder, being 17cm long, and the curvature of the head, there would be some space between the headband and the head at the ends of the holder. This can add instability and the tabs are more easy to break. To counteract this, a concept of adding a fastening bracket was also implemented here, with the same locking mechanism as presented in the previous section.

(a) Bracket
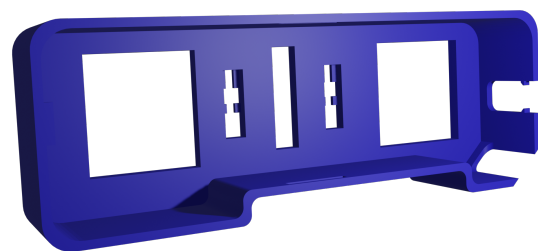
(b) Holder

Figure 16: Holder and bracket

This bracket has a slight curve made to fit the back of the head so it is more comfortable for the patient. It has one opening on each side where the fabric from the headband can slide into before the patient takes it on, and then adjust the position by sliding it along the elastic band. For

this concept, the endoscope holder can be fastened to the far back of the patient's head, meaning it does not generate as big of a loop as the previous concept. However, since this also is just a headpiece, one also needs to add a separate face mask.

CPAP-mask

To make it easy for the hospital, it was desirable to use equipment that hospitals already use or can easily get a hold of. A Continuous Positive Airway Pressure (CPAP)-mask was discovered as a potential alternative, as it already contains both a mask and headgear.
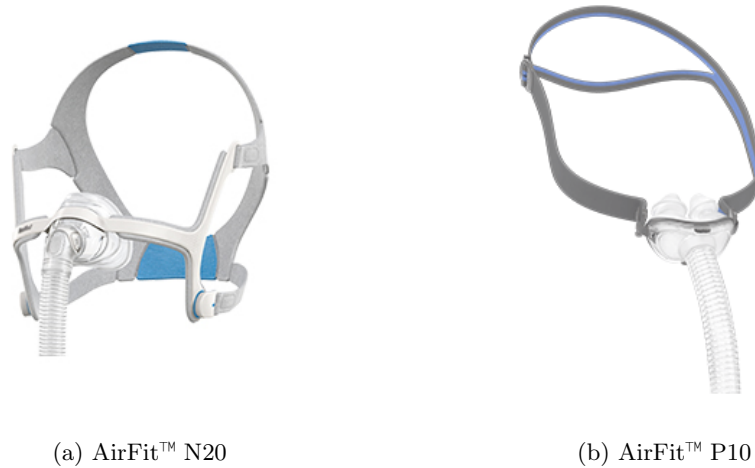
(a) AirFit™ N20

(b) AirFit™ P10

Figure 17: CPAP-mask

The CPAP-masks shown in Figure 17 [2] [3], are the masks that were available at St. Olavs hospital during this project. As seen in Figure 17 these two headgears are quite different. Figure 17a shows a complex and stable headgear with several adjustment starps, while Figure 17b has a simple one-strand band. Due to the exercise and movement during the CLE-test, and the possibility of fastening the endoscope to the headgear, the AirFit™ N20 was considered to be the better choice of the two.

The holder and bracket configurations from the previous were desirable to implement into this concept as well. This also played out well due to the fact that the holder and bracket could be placed securely on the lower strap of the CPAPmask at the back of the head. At first it was presumed this strap is located to low on the patients head and could therefore collide with the shoulders or neck if the patient moves its head too much to the side. However, after conducting simple tests of attaching the holder and bracket to the CPAP-mask and wearing them while jumping and running, it was quickly determined that this implementation worked great and had no restrictions.

Criteria	Importance Weighting	Current Design	Headlamp helmet	Headband	CPAP-mask
Adjustability	8	0	6	10	10
Weight	10	0	0	9	10
Ease of assembly	8	0	3	1	10
Accessibility	4	0	5	4	10
		Sum:	92	194	300
		Rank:	3	2	1

Table 5: PUGH matrix for mask and headgear

4.1.2 Mask

Due to heavy activity and breathing during the test, it was desirable to have a mask only covering the nose, as described in section 2.2.1. A mask as shown in Figure 18 would therefore be a good mask. This mask is the same that is used in the CPAP-mask AirFit™ N20, described in Section 4.1.1. The mask has a silicon pillow that fits around the nose, making it comfortable for the patient. The opening of the mask is also placed right in front of the nostrils, which makes it easy to insert the camera tube in to the nasal cavity.

(a) Front view   (b) Side view

Figure 18: Mask

4.1.3 Length adapter
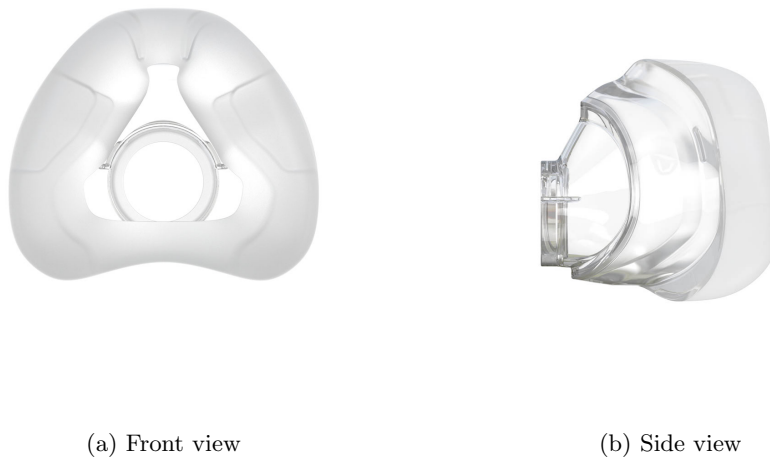
One of the primary functions the physicians wanted to integrate into the new design is to be able to adjust the distance of the camera lens to each patient's larynx. This involves keeping the ability to manipulate the camera tube during the insertion into the patient's nasal cavity and to find the correct location, while looking through the video feed shown on the monitor. Once the

correct position is identified, the camera tube must be easily locked in place, and if necessary, easily loosened and re-adjusted.

To achieve this, some concepts of an adjustable length adapter started to take form. The length adapter needs to overcome the requirements stated above in addition to easily be integrated with the the separate mask and headgear.

Cable clamp

Cable clamps are a product typically used for cable routing when handling electronics. Since the camera tube of the single-use FIVE is in the shape of a cable, the idea is to use the design of this already functioning product as an inspiration for a design that is specified for the intended use.
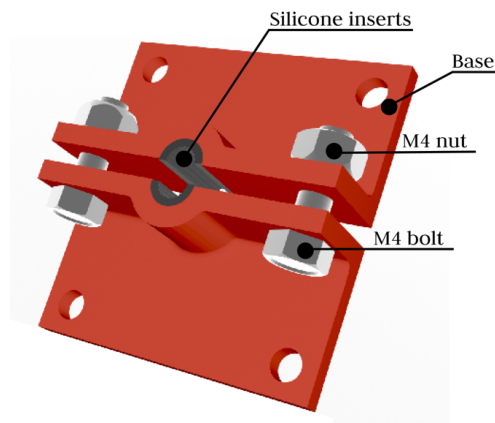
Figure 19: Cable clamp

The cable clamp design consists of 3 parts. The base, silicone inserts, and connection bolts w/nuts. The base has 2 mounting holes on each side allowing it to be attached to the face mask using silicone plugs. The camera tube is to be inserted into the round opening in the center. In the opening alongside the edges are silicone inserts with ridged edges to create friction with the camera tube when tightened. The two base parts are squeezed together using M4 bolts and nuts. The bolts are placed into the side holes on the base bracket and when the camera tube is in its correct position, one tightens the two nuts to apply pressure on the camera tube and hold it tight.

Cable gland connector

The second concept takes inspiration from a cable gland, which is also a type of cable routing product that is used in the industry, especially to allow for the routing of cables into a chamber as it has a sealing property to it.
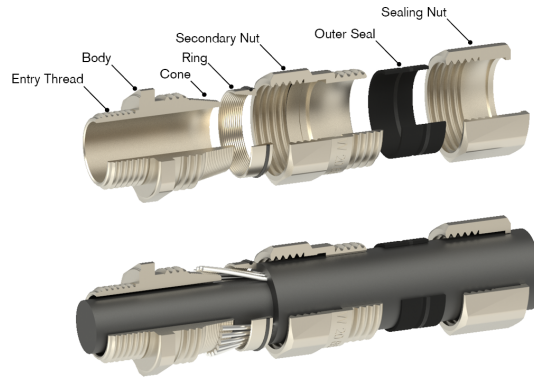
Figure 20: Cable gland Exploded view created by Andyremel [7]

For the first iteration of this concept, the plan was to make the parts of the cable gland separately to perfectly fit with the desired parameters for the sing-use FIVE, and then have more freedom with the integration of the cable gland to the mask. A design that then consists of a ground plate, a silicone tube, a removable tightener, and a fastening nut was created.
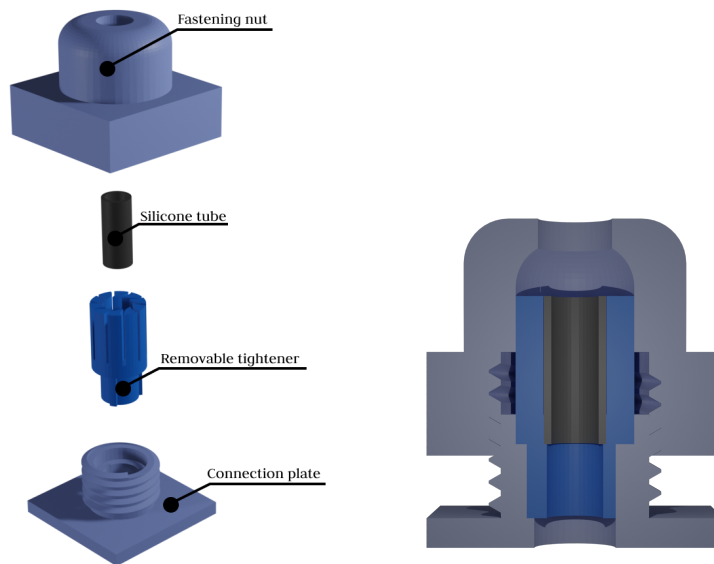
(a) Exploded view   (b) Section view

Figure 21: Length adapter v1

The ground plate has an extruded cylinder in the center with outside threads. The inside has a slight edge in addition to 3 grooves for the removable tightener to slide into and rest on. The removable tightener is designed to apply pressure to the camera tube by squeezing the silicone tube when spherical pressure is applied to the "blades" at the top of the tightener.

The silicone tube in the center with an inner diameter is 1mm larger than the camera tube, allowing for easy insertion without friction. The silicone tube is glued to the base and the removable tightener.

The fastening nut provides the necessary spherical pressure, as it has a conical shape on the inside that narrows as it is tightened. The matching threads on the base and the nut allow for easy tightening until the desired rigidity is achieved. The outer shape of the tightening nut is designed to be tightened by hand, with a square shape and large sides for a good grip.

When going through the iteration process it was quickly discovered that it was not necessary to redesign a cable gland to fit for our purposes as the selection of COTS cable glands are wide and can easily be integrated into the design. Therefore an iterated concept was developed that took the assumption of using a Nippon PG7 Cable Gland. This concept only consist of two parts: The Nippon PG7 cable gland and mask adapter.
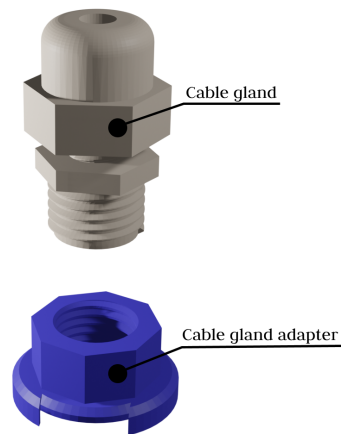
Figure 22: Cable gland connector

The mask adapter is designed to fit with the opening hole on the AirFit™ N20 mask in between the silicone pillow and the top plate that has a click-on connection. This allows the adapter to get trapped in the middle of the two parts. The adaptor has two edges on the side that extrudes downwards, with two opening on either side of it to allow for the space for the clinic-on connection. This also ensures that the adaptor won't rotate as it stooped by this connection.

The adapter has inside threads in the inside that matches the cable gland, therefore the physicians can insert the cable gland onto the adapter by screwing it in place and then later on when the camera lens is in its right position, tighten the top nut on the cable gland to tighten around the camera tube.

The PUGH matrix evaluating adjustable length adapter concepts can be found in Table 6.

Criteria	Importance weighting	Current Solution	Cable clamp	Cable gland connector
Ease of implementation	8	0	5	8
Ease of adjustment	10	0	5	8
Accessibility	3	0	-1	-1
Cost	3	0	-1	-1
		Sum:	84	138
		Rank	2	1

Table 6: Evaluation of adjustable length adapter concepts

4.1.4 Cable clip

When all the equipment is fastened, the camera tube would have a loop from the adjustable length adapter to the back of the head. While the patient is running during the test, this loop could create extra forces to the adjustable length adapter, and possibly pull on the camera tube giving unwanted movement to the footage. To avoid this, a cable clip was designed. This cable clip, shown in Figure 23, can be fastened to the side of the mask frame with adhesive tape.
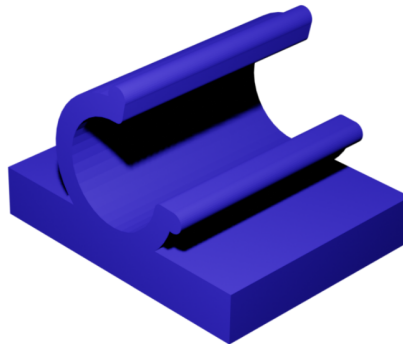
Figure 23: Cable clip

4.1.5 Reduce accumulation of saliva on the lens

A potential method for reducing saliva buildup on the the camera lens would be to cover the lens in a transparent hydrophobic or hydrophilic coating. These methods use either a hydrophilic substance, such as an anti-fogging coating or a hydrophobic substance, such as a hydrophobic spray to change the adhesiveness of the surface. These two methods surprisingly achieve very similar results while working in the opposite manners. However, hydrophobic coatings tend to suffer from condensation problems, by creating high surface tension, they force the water droplets to condense into small droplets, and because hydrophobic surfaces to not repel water vapour, they tend to increase condensation [44] [60]. This could be mitigated with the introduction of a preheater. This is a device that heats the endoscope lens to match the temperature of the body, which significantly

reduces condensation. A potential combination of a preheater that reduces condensation and hydrophobic coating that reduces adhesiveness could be used to achieve positive results. Prices for endoscopic preheaters when looking into reputable retailers and producers online can range anywhere from 1500 NOK to 10000 NOK.

PRODUCER	WEBSITE	PRICE US($)
Midical EXPO	https://www.medicalexpo.com/	250-400
Karl Storz	https://www.karlstorz.com/no/en/index	150-800
DeRoyal	https://www.deroyal.com/home	100-300
Webslinger	https://www.websinger.at/en/	±200

Table 7: List of possible preheater prices acquired after contacting relevant producers

On the other hand, anti-fogging, or hydrophilic coatings have been shown to be successful in solving both condensation and adhesiveness issues. In some studies, this has been shown to prevent condensation due to the temperature differences between the lens and the body, and prevent blood from sticking on the camera lens [47] [23]. Anti-fogging coatings tend to also be more readily available for medical usage. This means that finding an anti-fogging coating that is certified for human use is easier than its hydrophobic counterpart. Most hospitals, including St. Olavs hospital, already have some sort of anti-fog solution present, due to their wide spread application possibilities, meaning that it's implementation could be cost free.

Another method to solve both condensation and saliva accumulation issues could be to modify the lens itself. The lens modification, often referred to as mechanical lens modification, is a method where the lens features are modified on a microscopic scale, in a way which the lens itself becomes hydro-phobic or hydrophilic, with anti-condensation properties [38]. This is a promising strategy where the need to apply a coating is removed, however it requires that the endoscope would be produced with the lens installed. This means that the manufacturing process has to be modified, which can sometimes increase manufacturing costs significantly, reducing the benefits of the method. In some cases, the manufacturing process is not able to be modified and this method becomes unfeasible. The precise cost of this is uncertain, and depends on the equipment and procedure that is implemented to achieve this. However, modifying manufacturing lines can often cost very large sums of money [6].

The PUGH matrix evaluating saliva removal concepts can be found in Table 8.

Criteria	Importance weighting	Current Solution	Anti-fog Coating	Hydrophobic coating	Preheater and hydrophobic coating	Lens Modification
Implementation Difficulty	7	0	0	-1	-6	-10
Implementation costs	5	0	0	-2	-4	-8
Accessibility	8	0	0	-1	-2	-8
Reduction of saliva accumulation	10	0	3	5	5	9
Reduces condensation	5	0	2	-2	4	9
		Sum	40	15	-8	-39
		Rank	1	2	3	4

Table 8: Evaluation of methods to remove saliva

With the use of this PUGH matrix, it was concluded that the easiest and most effective method for saliva removal, would be the implementation of Anti-fog Coating.

4.1.6 Mechanical and active stabilisation

There are numerous methods that are used to achieve mechanical stabilisation such as tripods or gimbals [4], however for the purpose of this study, mechanical stabilisation methods are either very hard to implement or unfeasible. In this study, the endoscope camera is hanging freely above the larynx inside the patient's throat. This prevents most physical restraints from being applied to the end of the camera itself. The most promising method that could be used to achieve a positive outcome would be to have a better attachment mechanism at the entry point which is the nasal cavity. Physically restraining the endoscope's camera thread at the nasal cavity could reduce the overall shakiness experienced during the procedure.

Active stabilisation methods are equally difficult to implement. Firstly, these sensors can be influenced by outside factors, such as temperature changes and unrelated vibrations, which can lead to inaccurate readings. Sensors that can differentiate and reduce the unrelated outside factors often tend to be very highly priced, and difficult to access. FOG that specialise in accurate low volume sensory data collection, tend to cost somewhere around 75000 NOK depending on the manufacturer and the accuracy requirements [62]. Alternatively, a MEMS based sensor could be used. MEMS sensors are much cheaper than their FOG counterparts, costing somewhere around the 2000 NOK range, but they do suffer from poor reliability compared to FOG. These sensors can be influenced by outside factors, such as temperature changes and unrelated vibrations called "signal noise", which can lead to inaccurate readings [52]. These inaccuracies can be counter measured with the use of signal noise filtering algorithms. There are four main groups of algorithms that are used to filter signal noise namely, Kalman-filter-based algorithms, adaptive-based algorithms, simple filter algorithms, and compensation-based algorithms. The choice depends on the application and the environment of the procedure [22].

Motors and micro manipulators also tend to have a price variation. The price of the micro manipulators can vary in the range anywhere from 150.000 NOK to 1.000.000 NOK. However lower production cost, more readily available manipulators have been proposed that are in the range of 20000 NOK [5]. These devices have yet to become readily available and still require further testing to evaluate their feasibility. If such a method were to be implemented, a non-single-use endoscope would have to be implemented instead of the currently used single-use FIVE. Sensors and manipulators would have to be implemented onto the part of the endoscope that is inside the patient's body. Having a single-use endoscope would pose an issue where sensors and manipulators would have to be reapplied every time before the procedure.

Further research and testing is required to deduce whether active stabilisation could have a

beneficial effect on the study's results given its high costs and difficult implementation.

The PUGH matrix evaluating mechanical stabilisation concepts can be found in Table 9.

Criteria	Importance Weighting	Current Solution	Physical Restraint at nasal cavity	Active Stabilisation (Sensors And Motors)
Implementation Difficulty	8	0	0	-10
Accesibility	8	0	0	-8
Implementation Cost	7	0	1	-10
Stability improvement	10	0	4	10
		Sum	47	-144
		Rank	1	2

Table 9: Evaluation of mechanical and active stabilisation methods

With the use of this PUGH matrix, it was concluded that the cheapest and easiest method would be to introduce a physical restraint at the nasal cavity.

4.2 Electronic concepts

4.2.1 Wireless video feed

Wireless streaming encoder

The first concept idea was to implement a Commercial off-the-shelf (COTS) wireless streaming encoder provided by DDMALL [20].

Figure 24: Wireless streaming encoder

This is a portable HDMI encoder that is designed to connect to the camera's signal source with an HDMI interface, and a USB connection to a power source, either from the camera or a second source. The encoder is connected through Wi-Fi to the streaming monitor solely via a web-based user interface.
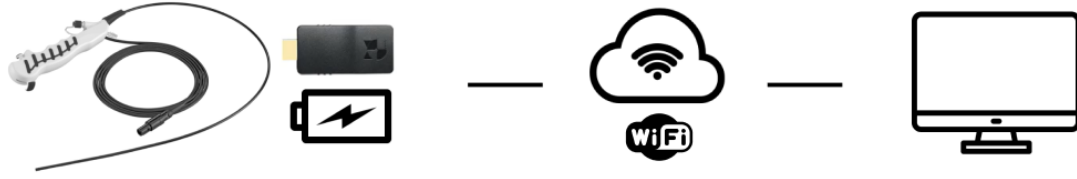
Figure 25: Wireless streaming encoder process

Specifications:

Videoinput	HDMI
Resolution	1080p
Frame rate	8Mbps
Weight	25g
Dimentions	75x32x15mm
Power consumption	2.6W
Power supply	5V/1 A (USB)
Protocol support	RTMP, TCP, UDP, Multicast, Unicast

More detailed specifications can be found in the technical datasheet in Appendix D.1.

To connect the camera to the encoder, one either have to connect the connection cable to the encoder or connect the encoder directly to the camera circuit board that is located in the endoscope handle. Given from the datasheet, the connection between the endoscope to the monitor is an 8-pin REDEL[6] connector, but due to the discretion of the producers, the pin layout is not open for the public. Therefore, to have this connection made, there would have to be made a REDEL/HDMI adapter in collaboration with the producers to get a satisfactory connection. At this moment in time, there are no standardized adapters for this interface in the market.

Wireless FPV Transmitter and Receiver

The second concept is to add a COTS wireless First-Person View (FPV) Transmitter and receiver set provided from Wolfwhoop [68].

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[6]**REDEL** is a brand that produces plastic circular connectors often used in medical equipment

Figure 26: Wireless FPV Transmitter and Receiver Set

This is a wireless streaming set ordinarily designed to use for drones. The set includes a transmitter and a receiver. The transmitter is to be connected to a camera using 3 pin connection wires; camera ground, camera video output and input signal, in addition to two wires connected to a power source; ground and power.
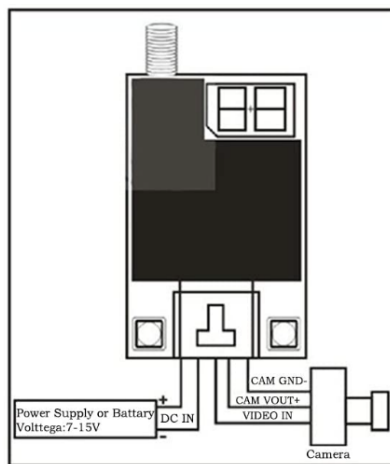

Figure 27: Transmitter pin layout

The transmitter uses an antenna to transmit the video captured from the camera. The receiver then receives this video signal with a second antenna and converts it into a file that a viewing monitor can stream. The receiver has two Audio and Video (AV) outports and a power port. The receiver and the viewing monitor can be connected by a AV/MiniJack cable.

Figure 28: Receiver pin layout and AV/MiniJack cable

As mentioned previously, the pin layout of the single-use FIVE is not open to the public. Therefore, here as well the connection between the transmitter and the single-use FIVE needs to be made in collaboration with the producers to ensure a satisfactory connection.
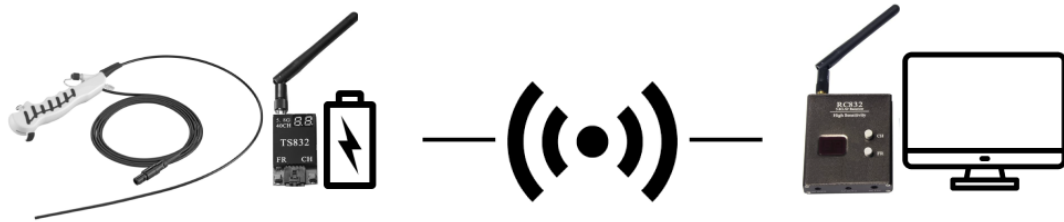

Figure 29: Wireless Transmitter and Receiver process

Specifications	Transmitter	Reciever
Frequency	5.8GHz	5.8GHz
Video Format	NTSC/PAL	NTSC/PAL
Supply	Current: 220 mA	Power: DC 12V
Weight	22g	85g
Dimentions	54x31x10mm	80x65x15mm
Transmitting distance	3000m open area	N/A

More detailed specifications can be found in the technical datasheet in Appendix D.2.

The PUGH matrix evaluating wireless video feed concepts can be found in Table 10.

Criteria	Importance weighting	Current Solution	Wireless encoder	Wireless FPV transmitter and reciever
Resolution	7	0	-1	-2
Ease of integration	9	0	-2	-1
Ease of use	10	0	8	5
Accessibility and costs	4	0	-4	-1
		Sum	39	23
		Rank	1	2

Table 10: Evaluation of wireless streaming feed

4.2.2 Digital stabilisation

There are several different stabilisation algorithms that have been proposed in the digital stabilisation sector. The differences between these algorithms often lie within how they estimate motion, how accurate motion detection is, how they correct for this detected motion and whether they use a 3-Dimensional (D), 2.5D or a 2D motion model [27] [45]. These algorithms have their own strengths and weaknesses, and so far, not a single algorithm that can be applied to every situation effectively and quickly has been developed [29]. For example, while 3D motion models provide a higher accuracy of stabilisation, 2D models offer lower computational time which in some cases is essential [53].

Alternatively, there is a growing interest for video stabilisation in the machine Deep Learning field. It has been shown that Deep learning algorithms can be trained in order to provide a more universal and accurate stabilisation approach, with lower computational costs than what was previously possible [66] [69]. However, deep learning requires huge datasets of carefully hand-picked good quality data if they are to be effectively trained. In other words, the competence of the Deep Learning or Artificial Neural Network (ANN) algorithms depends on the quality of the data it has been trained on, and this training usually requires very large datasets, which are sometimes hard or impossible to access. This lack of datasets is the main issue holding Artificial Neural Networks or Deep Learning back [59].

For this study, a list of criteria has been made given the limitations and the hardware used.

- Easy to use

- Fast processing time

- Effective stabilisation

These are the three main criteria that need to be met if digital stabilisation is to be implemented. Firstly, it is important that the program is easy to use, meaning that it must be usable by untrained personnel. Most of the personnel who will be using this program do not have prior training or experience in video editing. This means that the program must be simple and intuitive to use,

preferably there should be no more than a couple of button presses as inputs required from the user. Secondly, the stabilisation must be done in a relatively short amount of time. Usually, the whole procedure takes about an hour at most, and the patient receives their diagnosis at the end of the procedure. The length of the video filmed varies from 5-15 minutes, depending on the amount of time it takes for the patient to experience and display their symptoms.

Stabilising in real time with the current setup is not possible due to hardware limitations. If the video were to be streamed and saved on an external storage system or a computer instead of the currently used C-MAC, then real time stabilisation could be achieved, however, this would require a wireless setup to be implemented which is beyond the scope of this study. Currently, the video needs to be extracted from the C-MAC using an Secure digital (SD) card or a Universal Serial Bus (USB)-drive and uploaded into a machine that stabilises the video. This means that the 5–15-minute video must be stabilised after the test, and due to the tight schedule of the hospital, it must be done in at most 10 minutes. Stabilisation time relies on two factors, computational processing capacity of the machine performing the stabilisation, and the algorithm used [29]. This means that to achieve fast stabilisation a powerful computer must be used to calculate a time efficient algorithm. Lastly the program needs to produce positive results. If the processed video is no more stable than the original, or if the video becomes unintelligible or makes it harder for physicians to see the symptoms, then implementing such a digital stabilisation approach becomes counterproductive.

There are two ways to find a suitable program for this task. Video stabilisation software can either be program coded from scratch or downloaded from a list of already available options. Coding the program is a difficult and time-consuming task. While this would be the most optimal option, as a program that is tailored exactly for the purpose of stabilising endoscopic footage with relevant parameters can be made, such an approach is also beyond the scope of this study, as coding such a program requires significant amount of testing, coding expertise and good understanding of the implementation of mathematical algorithms and techniques employed by the program. Therefore, an already existing stabilisation software will instead be tested to see if it can meet the required criteria. The explored programs can be found in Table 11.

Name of the program	Website	Main strengths	Main weaknesses
NUKE	https://www.foundry.com/products/nuke-family/nuke	Offers excellent video editing capabilities including video stabilisation	Requires advanced knowledge of video editing to use effectively and stabilisation takes a long time
VEGAS pro	https://www.vegascreativesoftware.com/us/edit/	Can stabilise wide range of videos with little quality loss due to the software's in-built video reparation algorithms	Requires significant amount of video editing knowledge to use effectively
Adobe premiere Pro	https://www.adobe.com/products/premiere	Offers great stabilisation performance and cover a wide range of lightning and background conditions	Requires some amount of video editing knowledge to use effectively and the warp stabiliser that is used by the program takes very long time to complete.
Deshaker, a plugin for Video Dub	http://www.guthspot.se/video/deshaker.html (https://www.virtualdub.org/)	Open-source program, no video editing knowledge required to use	Struggles with low resolution videos by reducing the quality of the video significantly, depending on the settings, can take a long time to stabilise a video, can sometimes desynchronize audio
Gyroflow	https://gyroflow.xyz/	Open-source program, fast stabilisation, very little to no video editing knowledge required to use	Relies heavily on sensor data that are used to correct for motion to produce good results, some resolutions are not supported
Shotcut	https://shotcut.org/	Open-source program, supports many video formats and resolutions	Requires some amount of video editing knowledge to use, stabilisation can take a long time and struggles to stabilise videos with poorly lit backgrounds, can sometimes desynchronize audio

Table 11: Programs explored while looking into video stabilisation software

The PUGH matrix evaluating digital stabilisation concepts can be found in Table 12.

Criteria	Importance weighting	Current Solution	Adobe premiere Pro	NUKE	VEGAS PRO	Deshaker	Gyroflow	Shotcut
Prior training or knowledge requirement	10	0	-7	-7	-7	-1	-2	-3
Computational time	9	0	-6	-7	-5	-1	-1	-2
Video Stabilisation	7	0	7	6	7	3	3	4
Stabilisation algorithm adaptability	7	0	8	7	8	3	0	4
Cost	3	0	-2	-2	-2	0	0	0
		Sum	-34	-48	-16	23	-8	8
		Rank	5	6	4	1	3	2

Table 12: Evaluation of digital stabilisation software

With the use of this PUGH matrix, it was concluded that easiest and most effective software to perform tests with, would be the Deshaker plugin for VirtualDub.

5 Results

In this section, the chosen design for the different sections in the overall new test setup will be presented in addition to the results of the validation methods used to determine the feasibility of the design.

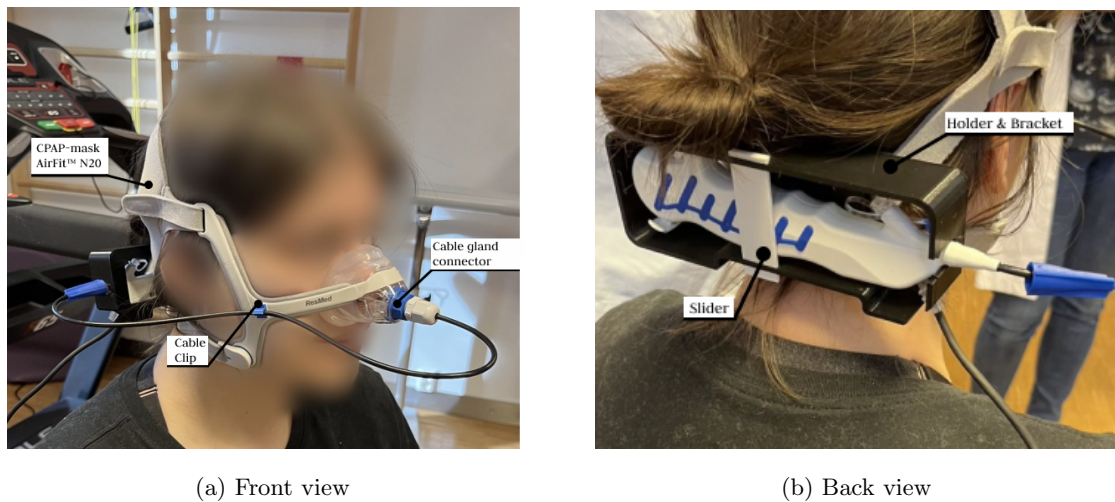## 5.1 Design Overview

(a) Front view

(b) Back view

Figure 30: Design overview

The final design consists of the CPAP-mask AirFit™ N20 and with the holder and bracket configuration designed for the mask. The cable gland connector is the chosen length adapter alongside the single design for the cable clip.
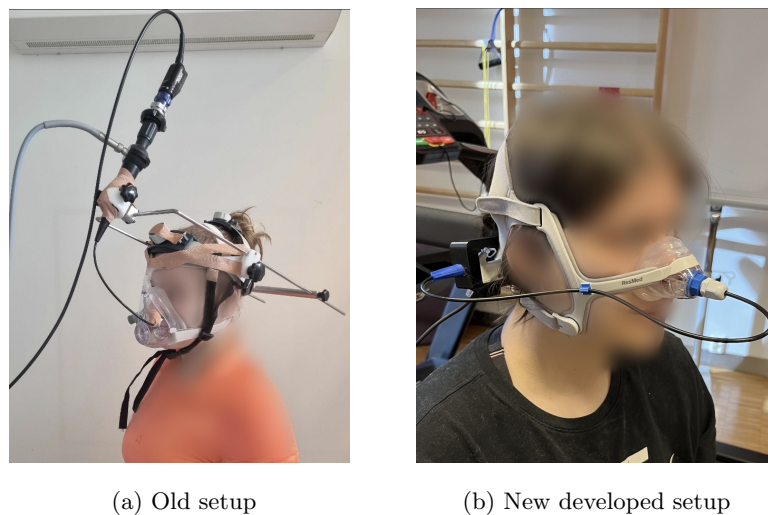

(a) Old setup

(b) New developed setup

Figure 31: Old and new setup

The AirFit™ N20 CPAP-mask was considered to be the best alternative for the headgear due to the fact that it is already integrated with both a mask and headpiece. In addition to this it has a sturdy structure designed and easy to adjust. The holder and bracket designed to fit the CPAP mask was naturally chosen to be implemented as well . The cable gland connector was chosen to be the most ease of use design for the adjustable length adapters, and gives that physicians aces to ease adjustments when needed. The last iteration of the cable gland connector was made to fit the the CPAP mask so it is easily assembles with the rest of the chosen equipment.

All designed parts are to be produces by using 3D printing with PLA. This is due to the fact that, for sanitary reasons, the length adapter has to be be single-use and can therefore be mass-produced for very cheap and then not having to evaluate if the adapter looses it functionality after wear and tear. Machine drawings for all the parts can be found in Appendix B.

Overall, the changes made to the CLE-test setup have proven to improve the following areas:

	Mechanical	Electronic	Humancentric
Increase functionality	✓Adjust the mask and headgear to each patient's anatomy and preference	✓Researching possibilities to make the CLE-test wireless	
	✓Fasten the endoscope handle to the patient's body		
	✓Adjust the distance from the camera lens to each patients larynx		
Stabilisation	✓Reduce the effect the patient's motion has on the stability of the video feed	✓Removing footage instability with the help of post-processing	
	✓Stabilising the footage enough for the physicians to give a proper diagnosis		
Footage clarity	✓Reducing the amount of saliva accumulated on the camera lens		
Patients comfort			✓Reducing the weight of the test equipment
			✓Eliminating the need to stop and restart the test for adjustments
Ease of use			✓Reduce test time
			✓Easily adjustable both before and after the test has started

Table 13: Improvements

5.2 Results of the Experiments

5.2.1 Preliminary calculations and analysis

As a preliminary validation method before conducting any test, calculations and analysis were executed to get an idea of the scope of forces that acts on the different parts of the test setup.

Calculations

The maximum forces acting on the holder and the bracket configuration was assumed to be the worst case scenario for any of the parts included in the new test setup. This is due to the fact that while it is a light design, its still the largest concentration of mass in the setup.
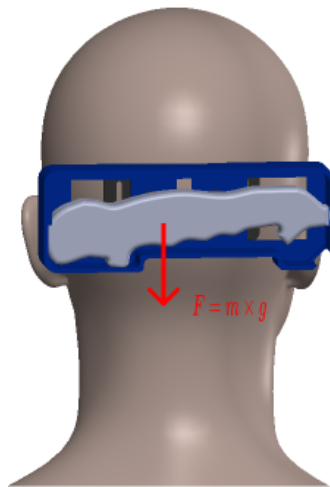

Figure 32: Free body diagram

The maximum force that acts on the holder and bracket configuration is calculated to 3.43 N. The performed calculations can be found in Appendix C.1.

Analysis

To determine if the parts could be 3D printed in Polylactic Acid (PLA), or produced in any other type of material, a finite element analysis was run based on the force calculated in the previous section.
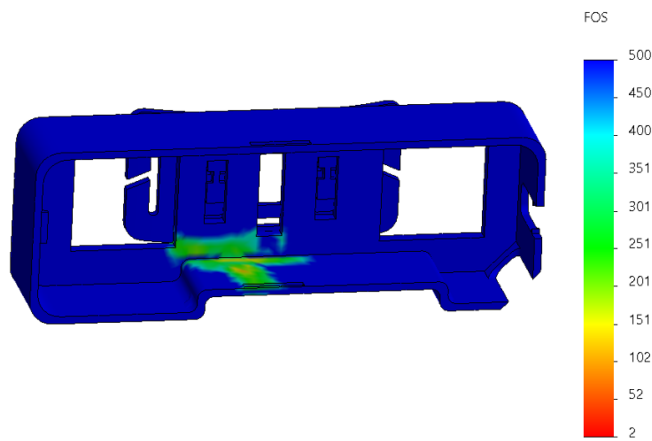
Figure 33: Factor of safety

The holder/bracket configuration resulted in having a safety factor of minimum 115, it was therefore determined that it was more than sturdy enough to use PLA 3D printing as a production method. More detailed review of the analysis can be found in Appendix C.2.

5.2.2 CLE-Test

A complete CLE-test with a suspected EILO patient was conducted at the Ear, Nose and Throat (ENT) division at St. Olavs hospital with the newly developed test equipment.

The new equipment passed the functionality criteria, as the physicians that partook in the test stated that the equipment was easy to set up and to adjust as needed. They also stated that the footage was more stable than previously and that it was easier to perform an accurate diagnosis of the patient from the outcomes of the test.
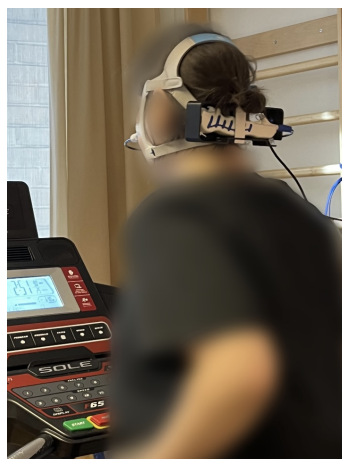

Figure 34: CLE-test

A detailed description of the performed test is displayed in the test Appendix A.1.

5.2.3 Testing hydrophilic coating

Two tests were performed to verify the effectiveness of applying hydrophilic coating to the camera lens before a CLE-test to reduce the total accumulation of saliva on the lens. The first test was a preliminary water test to verify the integrity of the concept and evaluate if it is necessary to continue the research. During this test, a significant reduction in camera obstruction was observed. This is illustrated in Figure 35.

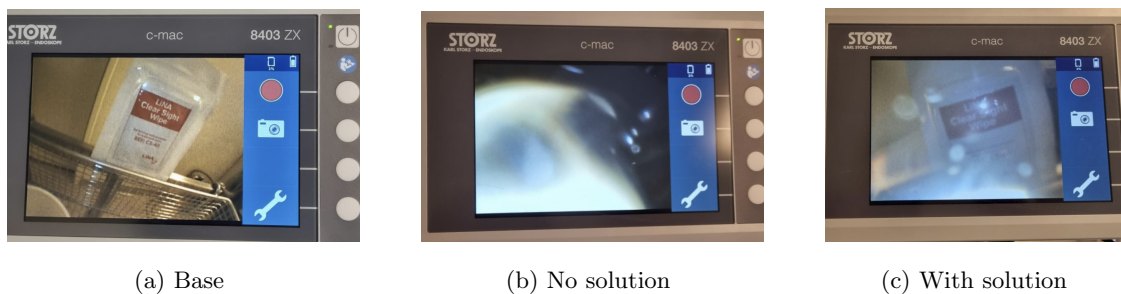(a) Base   (b) No solution   (c) With solution

Figure 35: Footage quality

These results were also demonstrated to and discussed with the physicians present, and their feedback was very positive to implemet it in an actual CLE test. This first test demonstrated that hydrophilic coatings could help to minimize the footage quality reduction caused by the obstruction liquids create during procedures, however, a second test, during the actual CLE procedure needed to be done to verify if this would work in a CLE test application. The results of the second test are illustrated in Figure 36.

(a) Accumulation of saliva before running   (b) Residual saliva during running
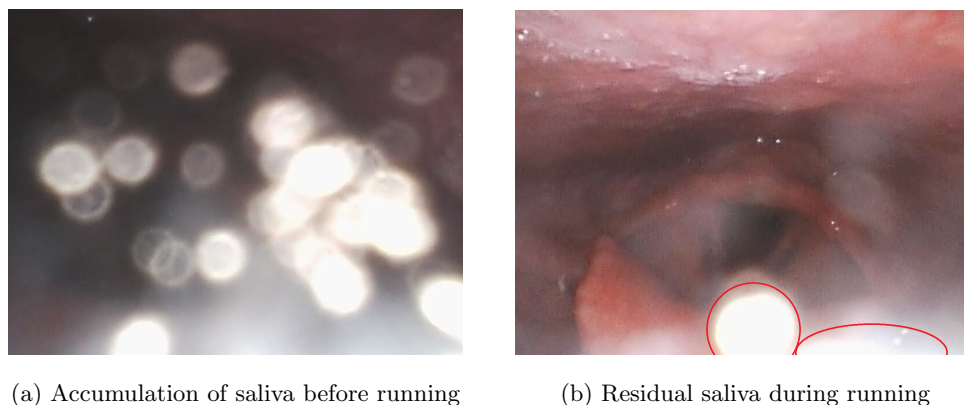
Figure 36: Saliva in the throat around the lens before and after the patient starts to run

The areas that are circled in red highlight, are lens flares that are created by light reflecting from the small droplets of saliva. However, while still present, these droplets are small enough so that the diagnosis is not impeded by the saliva that is present.

For more detailed descriptions of the tests, refer to Appendix A.2 and A.3.

5.2.4 Improved Footage stability

Two techniques were used to stabilise footage filmed by the FIVE during the CLE-test. The first technique was implemented in the form of a cable gland connector at the entrance to the nasal cavity. This achieved mechanical stabilisation due to it physically preventing the cable from rotating or moving vertically. This did not eliminate the motion of the camera; however, it did significantly reduce the shakiness of the footage. According to the physicians, the footage was noticeably more stable than during the previous tests, and it was evident within the footage that the camera itself had minimal unwanted motion. Most of the motion within the footage was caused by the expansion and contraction of the patient's throat physically pushing the camera from side to side while the patient was breathing heavily due to running. This meant that it was significantly easier for physicians to see the symptoms and give a proper diagnosis to the patient. Images illustrating the footage during the procedure can be seen in Figure 37.
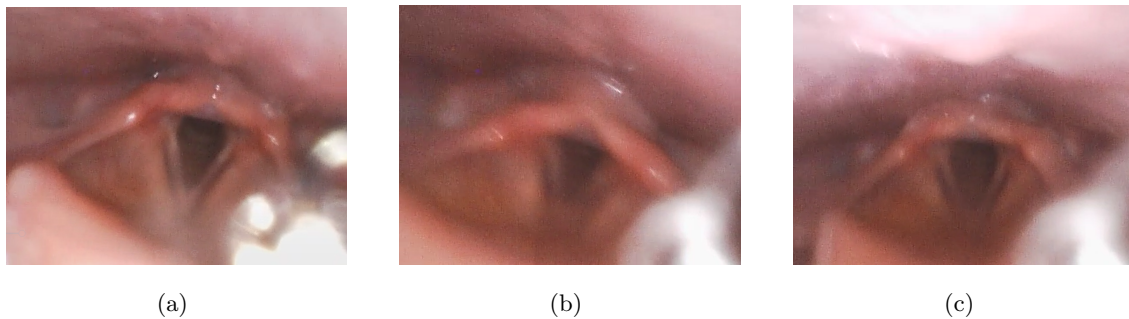

(a) (b) (c)

Figure 37: Images of the footage captured during CLE-test

The second technique was video post-processing after the test using VirtualDub's plugin De-shaker. Due to the footage already being reliably stable as a result of the cable gland, only minimal improvements were produced with the application of post-processing. Images illustrating the difference can be seen in Figure 38.

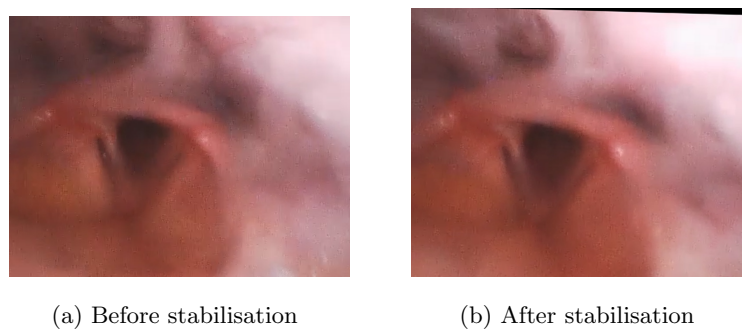(a) Before stabilisation (b) After stabilisation

Figure 38: Example of stabilisation

There were two different stabilisation depths applied. To stabilise the video on low depth, it took the length of the video, 10 minutes 14 seconds, in addition to the extraction time of 59 seconds

for a total of 11 minutes and 13 seconds. For the higher depth stabilisation, the extraction time increased to 1 minute and 29 seconds bringing the total up to 11 minutes and 43 seconds.

Overall, the minimal difference in stability and the relatively high processing time, make post processing stabilisation only applicable in scenarios where the original video is highly unstable.

For more detailed information and evaluation regarding the tests refer to appendix A.4.

6 Discussion

6.1 Improvements and future research

After conducting the final test of the complete system there were mainly three aspects that were in need of some improvements:

Ventilation hole: The main task for further development is to add ventilation to the mask due to the difficulty the patient had with breathing thru the nose after the test was conducted.

Cable management: Another concern is that the cable connecting the single-use FIVE were to entangle with the monitor or the treadmill. This created a desire to make a cable guiding system that does not restrict the movement of the patient but can keep the cable from moving all over the place.

Versatile design: Lastly, a desire from the physicians, is that the design should be able to integrate with the full masks (a mask that covers both the nose and mouth) that are sometimes used during a CLE-test to measure O_2 intake and outtake of the patient.

While cable management is a improvement that can be done on the developed concept, it can also be researched further in the form of making the setup wireless. A wireless setup would eliminate the risk of entanglement, and also open the possibility of implementing the test for other types of sports.

6.2 Self-evaluation

This thesis set out to improve some of the key areas within the CLE-test procedure performed at St. Olavs hospital. These areas were; stability, ease of use, video clarity and patient satisfaction. Throughout this study, multiple plausible solutions have been proposed and evaluated, and further experimentation was performed on the best evaluated concepts. Furthermore, the best performing solutions were tested on a real patient during a live CLE-test, to evaluate the effectiveness of the proposed concepts.

The results show that these concepts managed to achieve significant positive results in each of the four key improvement areas. While the scope and the possibilities were significantly reduced due to the limitation on the resources and time available for the thesis, a very positive overall result was achieved. However, the limitations left some of the proposed, but unexplored possibilities as potential further research, which if researched further, could significantly improve the results of the CLE-test. Overall, based on the opinion of the group members, and the personnel at St. Olavs hospital who collaborated with the research group, this thesis managed to achieve its goals and in doing so, created opportunities for further improvements.

6.3   Our way forward: What happens next

After conducting the final CLE-test, it was brought to light by the physicians that they want to implement this new test equipment as the new standard for the CLE-test procedure conducted at St. Olavs hospital. Therefore, in collaboration with FOR, this bachelor group will continue the work after the time scope of this thesis is over, and start a production line to provide St. Olav hospital with the new test equipment. The long goal is to iterate the products, taking the improvements stated in 6.1 into consideration, and reach out to all ENT divisions in Norway to make the equipment to be the national standard.

7   Conclusion

The goal of this thesis was to address the limitations associated with the equipment used in the Continuous Larynx Examination (CLE)-test for diagnosing Exercise Induced Laryngeal Obstruction (EILO). These limitations consisted of low test reliability, which was caused by the test setup failing due to the setup being held together with medical tape. Low patient and physician satisfaction, which was caused by the equipment being heavy and uncomfortable, in addition to being difficult and time-consuming to set up. It suffered from low stability, due to the medical tapes' inability to fully prevent the endoscope's camera thread from moving, and low video clarity, which was caused by saliva sticking to the camera lens.

Introducing new components such as the holder, bracket, cable clip and adjustable length adapter, has played a crucial role in enhancing patient satisfaction and simplifying the setup process for physicians. These additions effectively secure the equipment, ensuring greater comfort for patients and ease of use for medical professionals. Stability was addressed by replacing medical tape with an adjustable length adapter attached to the nose mask, which has effectively minimized camera movement, resulting in more stable footage. Additionally, the implementation of stabilisation software, such as deshaker, has further contributed to improving the overall stability of the recorded video. Furthermore, modifications to the testing procedure, such as the application of anti-fog coating to the lens before the test, have resulted in improved clarity of the captured footage. This coating managed to reduce lens fogging and saliva accumulation, and as a result, the visibility of the larynx during the examination has been significantly enhanced.

These results were made possible to integrate and test thanks to the excellent cooperation and communication between our group members and the personnel working at St. Olavs hospital and Operating Room of the Future.

There is still significant potential for further improvements to the system. The research done shows that some less accessible and more expensive solutions could be applied, that would potentially be even more effective than the results demonstrated in this thesis. Developing a fully wireless video transmission system could make the system portable, making it applicable in more branches of sports like swimming or hiking. Another possibility is the modification lens of the endoscope's camera lens, which could be altered to make it completely hydrophobic, potentially preventing any saliva from sticking to it and removing the need for applying a coating before the procedure. Moreover, a gyroscopic based active stabilisation system using micro-manipulators could be implemented, to completely stabilise the camera and prevent it from moving entirely. Lastly, an Artificial Neural Network trained to stabilise and recognize larynx data could be used to provide more colour contrast and stability to an already existing larynx footage, making it easier for the physicians to see the symptoms. All of these solutions are vast and broad topics, that were sadly beyond the scope of this thesis.

In summary, this thesis has managed to provide a set of solutions to the existing problems and limitations affecting the CLE test setup for diagnosing EILO. These advancements have significantly improved the accuracy and effectiveness of the diagnostic process. The findings from this study provide a solid foundation for further research and development in the field, with the aim of refining and optimizing test procedures to achieve enhanced diagnostic results and contribute to the advancement of EILO diagnosis.

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Appendix

A Test Appendix

A.1 Test of developed CLE prototypes

Test of developed CLE prototypes

0	3	0	5	2	0	2	3

Purpose: *The purpose of this test*

To verify the applicability of the newly developed CLE test prototypes

Users: *The names of the people involved with this test*

Mechanical engineering students
Grytten, Hege
Nymark, Tora Aasheim
Liachovas, Paulius

Physicians at St.Olavs Hospital
Jacobsen, Yngve Melheim
Midtlyng, Tove Helen

Patient
Anonymous

Test Equipment & Set-Up Description: *Description of what kind of equipment was used and the set-up.*

Student developed parts
- Bracket
- Holder
- Cable clip
- Adjustable length adapter
- Connection clip

Preexisting medical equipment
- LiNA Clear sight Wipe: Sterile Tissue AntiFog Solution for endoscopic Optics
- AirFit^{TM} N20
- Flexible intubation videoendoscope (FIVE)
- Running Treadmill
- C-MAC® Monitor for CMOS Endoscopes

SD-card for video download

Safety concerns: *State any safety concerns and how to mitigate them*

Safety concern:	Concern definition:	Risk:	Mitigation approach
Cable entanglement	Cable connecting the laryngoscope to the C-MAC monitor is a long cable and has a possibility of getting caught in items during the CLE test.	Laryngoscope can be pulled out of the patient.	Hospital provides personnel that supervises the test and makes sure no entanglement occurs.
Faulty 3D printed parts	Faulty production of the 3D printed parts, resulting in them not holding the applied loads and breaking.	Faulty length adapter: Laryngoscope can end up sliding both up and down the larynx.	Do a function test of the exact test parts beforehand of the CLE test
		Faulty bracket/holder: Laryngoscope can be pulled out of the patient.	

Test Procedure: *Description of how the test will be performed.*

- Step 1: Connect the base of the adjustable length adapter to the AirFit™ N20 mask.
- Step 2: Connect the bracket to the back on AirFit™ N20 head strap.
- Step 3: Attach a cable clip to the AirFit™ N20 mask frame with double sided tape.
- Step 4: The patient equips the mask and adjust the straps as needed.
- Step 5: Slide the adjustable cable gland onto the camera tube; note the orientation of the cable. gland needs to be so the threads are facing toward the camera.
- Step 6: Camera tube is inserted into the nasal cavity by the physicians.
- Step 7: When the desired placement of the camera has been found, slide the cable gland upwards to the base and fasten it by screwing it into the threaded hole.
- Step 8: Tighten the top nut to the glad to keep the camera in place.
- Step 9: Put the laryngoscope inside the holder, use the slider to keep it in place.
- Step 10: Attach the holder to the bracket.
- Step 11: Connect the loose camera tube to the cable clip attached to the AirFit™ N20 mask frame.
- Step 12: Connect the laryngoscope cable to the C-MAC monitor.
- Step 13: Perform the CLE test as ran procedure given by St.Olavs hospital.

Test Criteria: *Description of what would constitute success and failure.*

- Easier set-up for the physicians
- Camera stays in the right position during the test
- Footage is stable
- Possibility to easily adjust camera position during the test
- Equipment can withstand the weight and forces it experiences

Test Results: *Quantify the results of the test.*

Due to needing a patient to perform the CLE test, the process was restricted to perform the test just one time.

There were no troubles attaching the 3D printed parts to the headgear before the test and they stayed in place in the entire duration of the test.
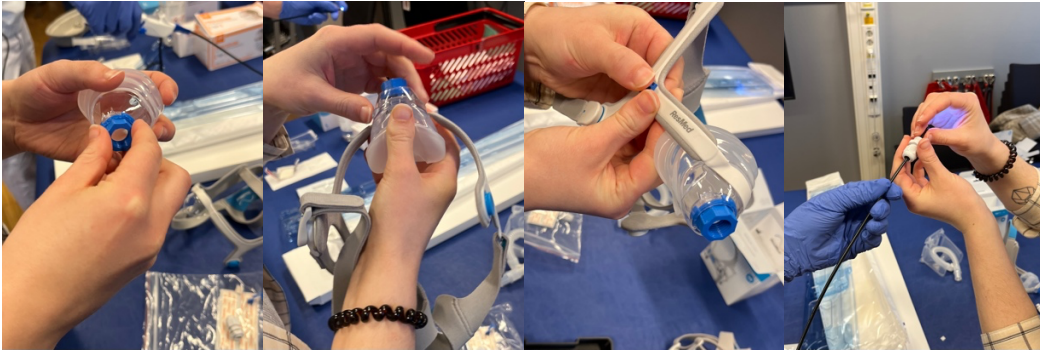
Some adjusting of the mask needed to be done to fit the patient's head size and to get the right angle to the nasal cavity.

After the camera tube was inserted and the placed the laryngoscope into the holder, a few more adjustments were needed to get the right distance to the larynx. This was done easily by unscrewing the length adjuster and fastening it again.

The patient ran on the treadmill for about 10 minutes, with a 2-minute break at about the halfway point. The footage was slightly unstable due to the motions of the patient running and the movements in the throat generated from heavy breathing. According to the physician's feedback, the footage was much more stable compared to the previous setup.

The camera stayed in the same place during the entirety of the test, it did not loosen or slide up and down.

During the test, the patient breathed through the mouth. However, after the test when the patient is done running and the symptoms started showing, the physicians wanted to see what happens when the patient starts breathing through the nose to normalize the movement of the larynx. Because the mask is completely airtight, this was not possible to do. Therefore some feedback was received to add air ventilation to the mask.

Discussion of Results: *Discussion of the results in light of the pass / fail criteria of the test*

Criteria	Pass	Fail
Easier set-up for the physicians		
Camera stays in the right position during the test		
Footage is stable		
Possibility to easily adjust camera position during the test		
Equipment can withstand the weight and forces it experiences		

Conclusion: *If success, description of the impact of the results. If Failure, description of the remedial measures that should be taken.*

The new test setup held up the pass criteria set for the test.
With the general conclusion from the physicians, it successfully reduced the set-up time, and the footage was more stable than previous setup. It was easier to do adjustments through the test to get the best results.

Further improvement suggestions were adding air ventilation to the mask and looking into applying the same features to a full mask (a mask that covers both nose and mouth) to have the possibility of measuring the intake of O2 and the inflow and outflow ratio when breathing (VO2 test).

Hege Grytten
Signature

Tora Aasheim Nymark
Signature

Paulius Liachovas
Signature

A.2   AntiFog solution test

AntiFog solution test|

2	4	0	4	2	0	2	3

Purpose: *The purpose of this test*

During a CLE test, a videoendoscope is inserted into the patient's nasal cavity to get an image of the larynx. During this procedure the physicians at St.Olavs hospital have discovered that the saliva occupied in the patient's throat sticks to the camera lens and gives an unclear image. This test is preformed to see if adding a AntiFog solution to the camera lens before the procedure will eliminate or reduce the risk of an unclear image.

Users: *The names of the people involved with this test*

Mechanical engineering students
Grytten, Hege
Nymark, Tora Aasheim
Liachovas, Paulius

Physicians at St.Olavs hospital
Jacobsen, Yngve Melheim
Midtlyng, Tove Helen

Test Equipment & Set-Up Description: *Description of what kind of equipment was used and the set-up.*

- LiNA Clear sight Wipe: Sterile Tissue AntiFog Solution for endoscopic Optics
- Flexible video endoscope (FIVE), single use. This videoendoscope is supplied by Karl Storz retailer.
- C-MAC® Monitor for CMOS Endoscopes. This monitor is supplied by Karl Storz retailer.
- Water
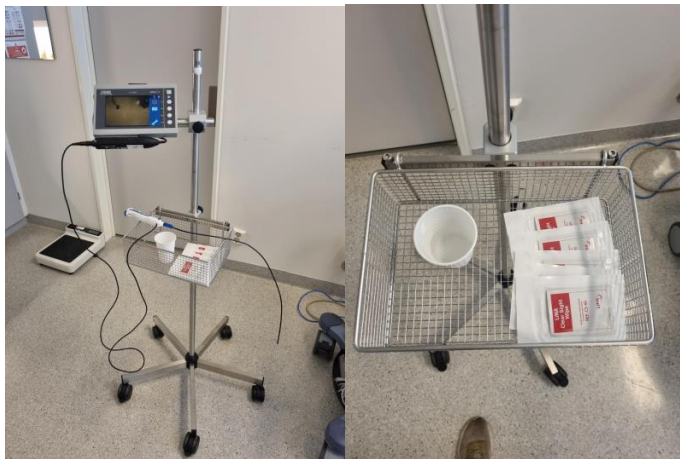
Safety concerns: *State any safety concerns and how to mitigate them*

N/A

Test Procedure: *Description of how the test will be performed.*

Step 1: Connect the videoendoscope to the monitor and make sure it is working correctly.
Step 2: Take note of the video quality without doing anything, this is the base quality.
Step 3: Dip the camera into the water and then visually check the video quality. Perform this several times to check to see if it has the same outcome each time.
Step 4: Dry all the water off the camera.
Step 5: Add the AntiFog solution to the camera lens.
Step 6: Repeat step 3

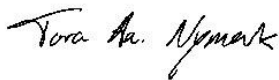Test Criteria: *Description of what would constitute success and failure.*

- Visibly noticeable difference of clarity
- No negative impact on the current quality
- Physicians at St.Olavs hospital opinions after evaluating the results

Test Results: *Quantify the results of the test.*

Test #1: Discover the base quality
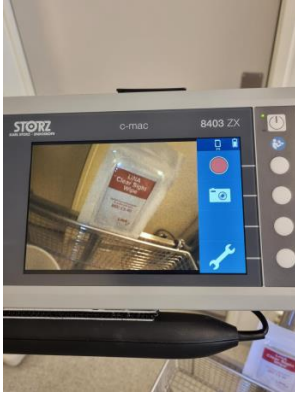
Test #2: Regular quality (no solutions added)

After being dipped in water for 5 seconds, the camera lens accumulated a water droplet at the tip of the camera creating an image obstruction. The image became very unclear and therefore not viable for use in diagnostics.
This procedure was performed several times to see if the water droplet accumulated every time, and it did.
After shaking the camera vigorously the droplet disappeared and the quality went back to its base quality.

Test #3: AntiFog solution added
This was done by imitating how the doctors add antifog solution, which was by simply tapping the end of the endoscope at the wipe containing anti/fog solution a couple (3-4) times before dipping it into water.
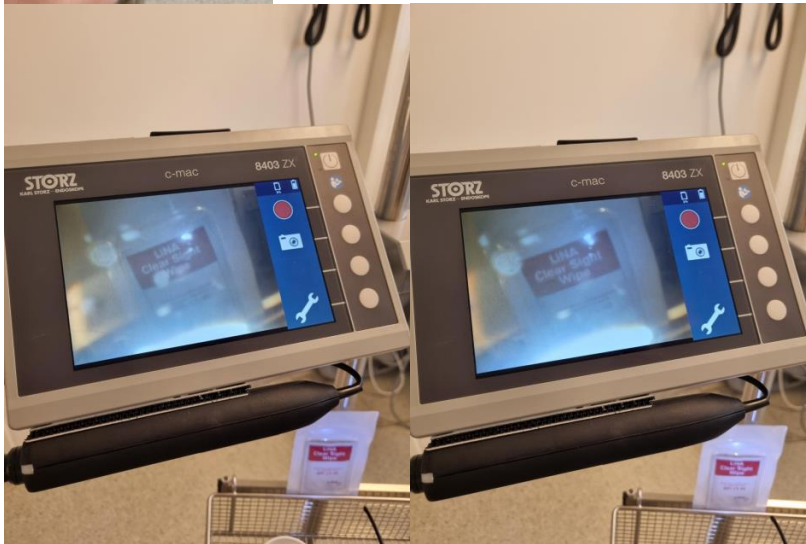
Water still accumulated on the camera lens, however the amount of water was significantly smaller and it was more evenly distributed over the entire camera lens. This is due to the nature of hydrophilic coatings, where they tend to disperse the liquid evenly. The clarity was, however, still slightly worse compared to the base quality. Same as test # 2, when shaking the camera vigorously the droplet disappeared, and the quality went back to its base quality.

Discussion of Results: *Discussion of the results in light of the pass / fail criteria of the test*

Criteria	Pass	Fail
Notice visibly difference of clarity		
No negative impact on the current quality		
Physicians at St.Olavs hospital opinions after evaluating the results		

Conclusion: *If success, description of the impact of the results. If Failure, description of the remedial measures that should be taken.*

In light of the results, and with the discussion of the physicians at St.Olav hospital, it was determined that

the

AntiFog solution has the potential to reduce the build-up of saliva, however, it needs a more thorough

testing. It will therefore be implemented in a full scale CLE test.

Hege Grytten
Signature

Tora Aasheim Nymark
Signature

Paulius Liachovas
Signature

A.3   AntiFog during CLE-test

Anti-fog/hydrophilic coating portion for the test of developed CLE prototypes

0	3	0	5	2	0	2	3

Purpose: *The purpose of this test*

To verify the applicability and effectiveness of the anti-fog coating during the CLE test

Users: *The names of the people involved with this test*

Mechanical engineering students
Grytten, Hege
Nymark, Tora Aasheim
Liachovas, Paulius

Physicians at St.Olavs Hospital
Jacobsen, Yngve Melheim
Midtlyng, Tove Helen

Test Equipment & Set-Up Description: *Description of what kind of equipment was used and the set-up.*

- LiNA Clear sight Wipe: Sterile Tissue AntiFog Solution for endoscopic Optics

- Flexible video endoscope (FIVE), single use. This video endoscope is supplied by Karl Storz retailer.

- C-MAC® Monitor for CMOS Endoscopes. This monitor is supplied by Karl Storz retailer

Safety concerns: *State any safety concerns and how to mitigate them*

N/A

Test Procedure: *Description of how the test will be performed.*

After setting up the test with the newly developed CLE test prototypes, the tip of the endoscope will be dipped onto the LiNA Clear sight Wipe's surface, which contains the Anti-fog solution. Then the procedure proceeds as per standard for St. Olav's personnel.

Test Criteria: *Description of what would constitute success and failure.*

The most important part of this test is to verify that Anti-fog solution can be applied on the camera lens before the test to significantly reduce residual saliva that accumulates on the lens. It is also important that the anti-fog solution will not negatively affect the results of the procedure.

Test Results: *Quantify the results of the test.*

The residual saliva was significantly reduced during the procedure. According to the physicians, the amount of saliva present on the lens was significantly smaller than during the previous tests where no anti-fog solution was applied.

While the patient was stationary during the test, a large amount of saliva accumulated inside the patient's throat. This accumulated saliva completely enveloped the camera which made it impossible to see anything clearly.

Image demonstrating the accumulation of saliva:

This was mitigated by two factors. Firstly, the doctors gave the patient a cup of water which washed away some of the saliva. Secondly, the saliva naturally dissipated after the patient started running. The importance of this test came after the saliva had dissipated from the throat, and it was important to see how much saliva was stuck to the camera lens as residue.

Image illustrating the footage clarity after the patient started to run:

(The area circled in red highlights the amount of residue stuck to the lens)

There were still some small droplets of saliva that stuck to the surface, and in some instances created a lens flare effect because of the light reflecting from the droplets. And the "misty" look that the video got was also a result of the anti-fog solution applying a small layer of saliva throughout the lens due to its nature to distribute liquids through the surface.

Images displaying the small droplets of residual saliva during the test:
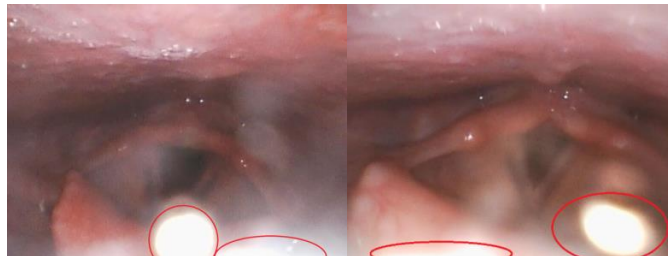
However, while still present, these small droplets did not impede the ability of the physicians to perform the diagnosis. Some of these droplets later slid off the lens, due to the vibrations that the patient's body was experiencing while running, and to the way anti-fog interacts with multi layered coats of liquids on its surface.

An instance later in the test where no saliva was present anymore:

The footage was observed throughout the test and results discussed live with the physicians

Discussion of Results: *Discussion of the results in light of the pass / fail criteria of the test*

Criteria	Pass	Fail
Notice visibly difference of clarity		
No negative impact on the current quality		
Physicians at St.Olavs opinions after evaluating the results		

Conclusion: *If success, description of the impact of the results. If Failure, description of the remedial measures that should be taken.*

The opinion on the results by the physicians was very positive, and by reviewing evidence it was concluded that the application of anti-fog solution onto the FIVE lens had significant positive impact on the clarity of the footage, increasing the quality of the diagnosis as a result.

Hege Grytten
Signature

Tora Aasheim Nymark
Signature

Paulius Liachovas
Signature

A.4   Stabilisation

Stabilising video footage using post processing software

0	8	0	5	2	0	2	3

Purpose: *The purpose of this test*

The purpose of this test is to see if the post processing software can be used on footage of a CLE test with positive results

Users: *The names of the people involved with this test*

Mechanical engineering students
Grytten, Hege
Nymark, Tora Aasheim
Liachovas, Paulius

Test Equipment & Set-Up Description: *Description of what kind of equipment was used and the set-up.*

A computer using Microsoft Windows 10 with a 64-bit operating system

VirtualDub video editing program/software

Deshaker plugin for VirtualDub

FFMpeg Plugin for VirtualDub

Safety concerns: *State any safety concerns and how to mitigate them*

N/A

Test Procedure: *Description of how the test will be performed.*

The procedure consists of downloading the program, installing correct plugins, using the program to stabilise a video, and extracting the video from the program.

Firstly, VirtualDub needs to be downloaded from the website; https://www.virtualdub.org/, the computers operating system that will be used during the test is Microsoft Windows 10. Then the downloaded file is unzipped and VirtualDub is ready to be used, no installation needed. Following this, two plugins have to be downloaded. These plugins are Deshaker; downloaded from http://www.guthspot.se/video/deshaker.htm and is used to stabilise the video. The second plugin that is needed is FFMpeg; downloaded from https://codecpack.co/download/FFInputDriver.html and is used in order for the VirtualDub program to be able to read and open a variety of different video formats, that is necessary to perform this test.

To install both plugins, there is an empty Plugins32 or Plugins64 (depending on the operating system) folder located in the VirtualDub location folder:

Name	Date modified	Type	Size
plugins64	20/04/2023 10:01	File folder	
copying	27/10/2013 15:21	File	18 KB
Deshaker31_64	20/04/2023 09:50	WinRAR ZIP archive	1,850 KB
frameserver64	27/10/2013 15:21	Registration Entries	2 KB
vdlaunch64	27/10/2013 15:59	Application	4 KB
vdremote64.dll	27/10/2013 15:59	Application extens...	71 KB
vdsvrlnk64.dll	27/10/2013 15:59	Application extens...	57 KB
vdub64	27/10/2013 15:59	Application	10 KB
Veedub64	27/10/2013 16:00	Application	4,162 KB
Veedub64.vdi	27/10/2013 16:00	VDI File	325 KB
VirtualDub	27/10/2013 16:01	Compiled HTML H...	249 KB
VirtualDub-1.10.4-AMD64	20/04/2023 09:52	WinRAR ZIP archive	2,158 KB
VirtualdubFFMpegPlugin_setup_2000_X8...	20/04/2023 09:59	WinRAR ZIP archive	58,407 KB

Where all the plugins must be uploaded to:

Name	Date	Type	Size	Tags
Deshaker_64.vdf	14/09/2014 13:22	VDF File	3,555 KB	

Uploading the Deshaker Plugin that was downloaded into the empty Plugins 64 folder

| Name	Date modified	Type	Size
ffdlls	12/01/2021 15:58	File folder	
Deshaker_64.vdf	14/09/2014 13:22	VDF File	3,555 KB
FFBwDif.vdf	11/01/2021 22:08	VDF File	309 KB
FFDeband.vdf	11/01/2021 22:08	VDF File	321 KB
FFDeblock.vdf	11/01/2021 22:08	VDF File	319 KB
FFInputDriver_64.vdplugin	12/01/2021 15:57	VDPLUGIN File	551 KB
FFNIMeans.vdf	11/01/2021 22:08	VDF File	310 KB
FFSmartBlur.vdf	11/01/2021 22:08	VDF File	313 KB
FFUnSharp.vdf	11/01/2021 22:08	VDF File	319 KB
FFVagueDenoiser.vdf	11/01/2021 22:08	VDF File	310 KB
readme	27/10/2013 15:21	Text Document	1 KB

**Uploading the FFMpeg plugin into the same folder**

73

After these plugins have been installed, the program can be run by double clicking the Veedub64.exe file:

| | vdub64 | 27/10/2013 15:59 | Application | 10 KB |
| | Veedub64 | 27/10/2013 16:00 | Application | 4,162 KB |
| | Veedub64.vdi | 27/10/2013 16:00 | VDI File | 325 KB |

This opens the VirtualDub Program with all the relevant plugins necessary:
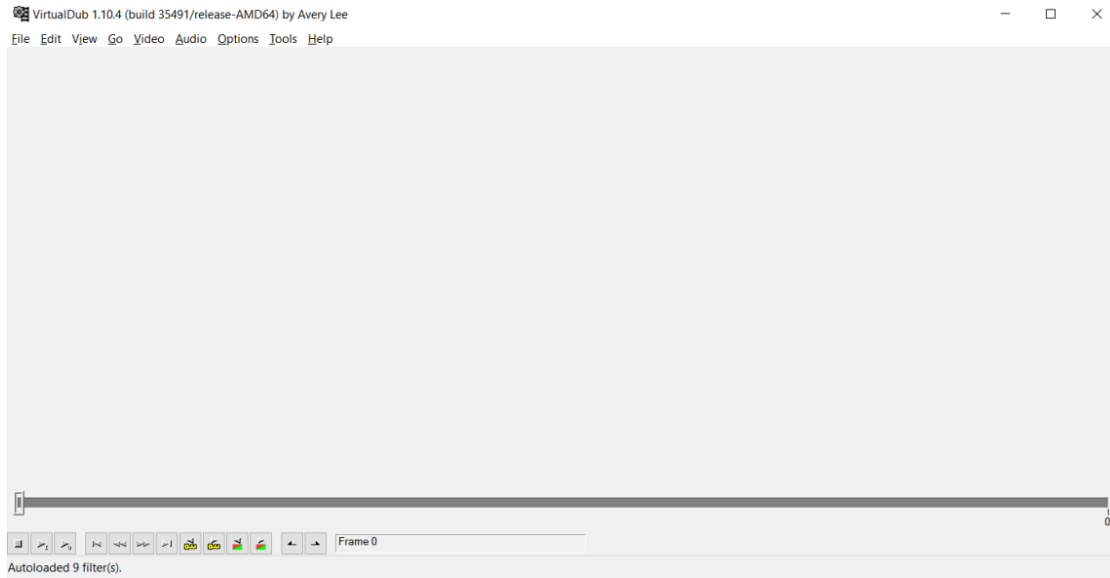
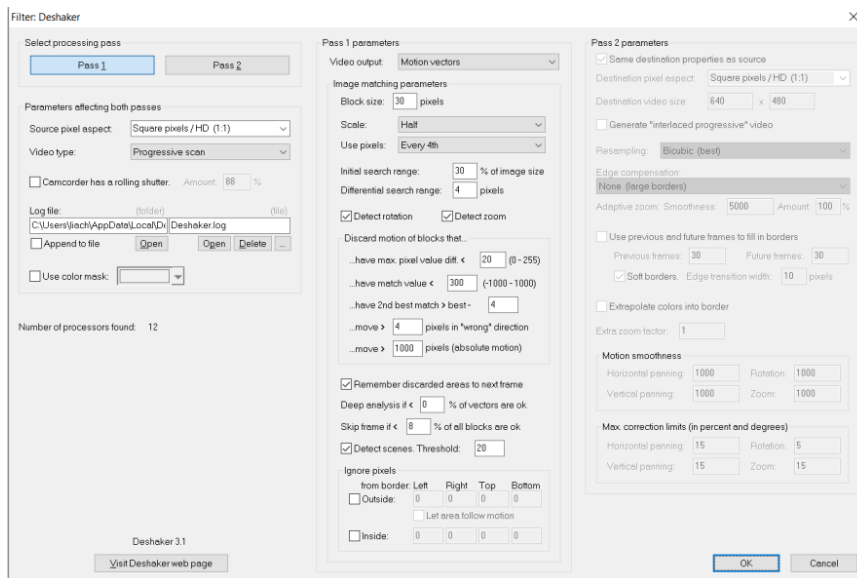To edit the video, the video must be opened by pressing CTRL+O or by navigating to the toolbar at the top of the program:
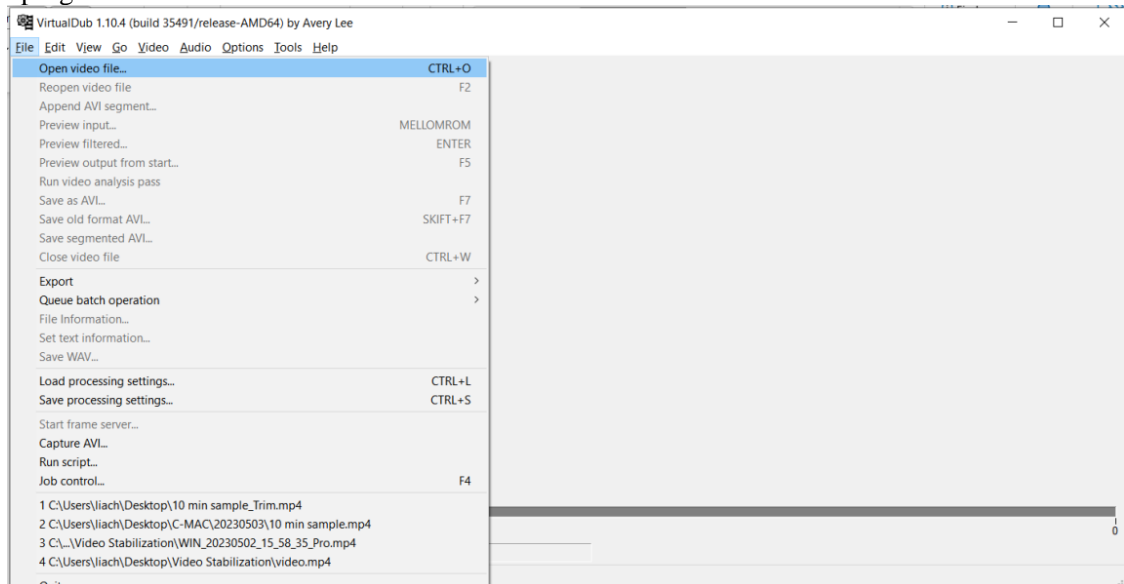
Then, after the correct video has been chosen and opened within the program, the Deshaker filter is applied by following these steps:
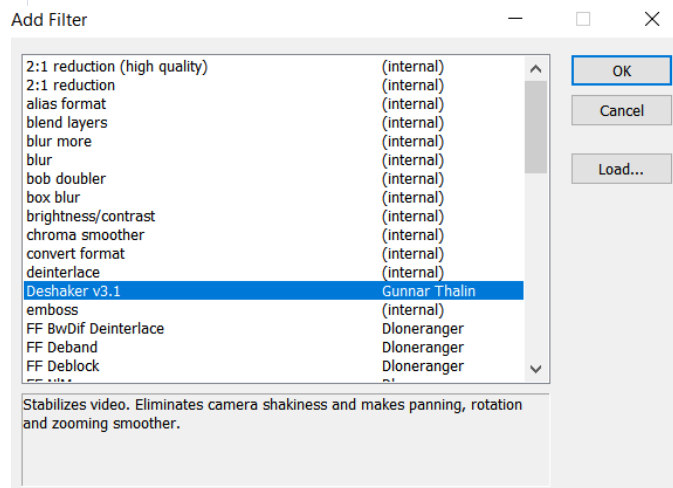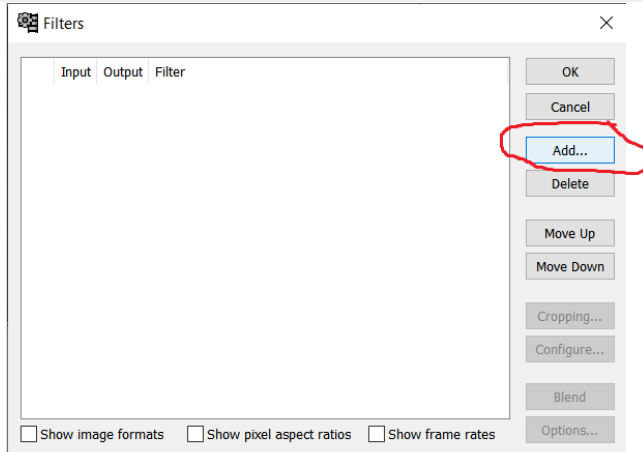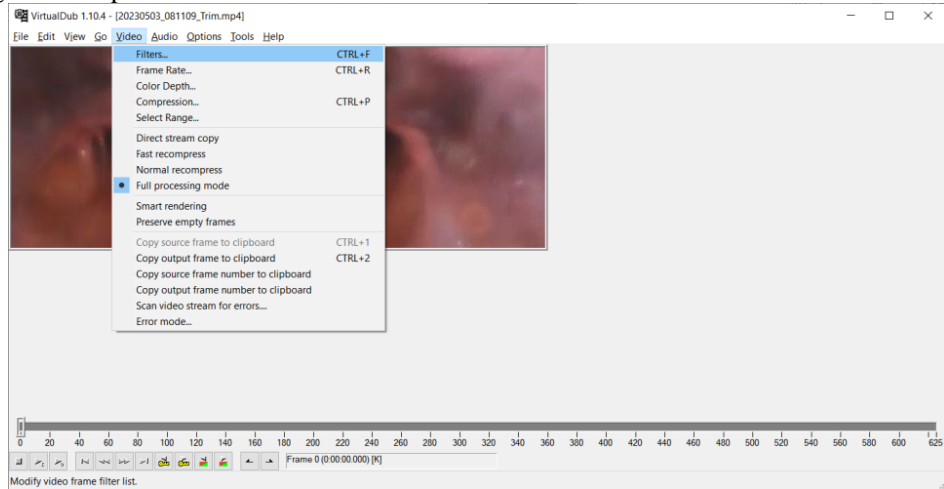
After the filter is chosen, a detailed settings tab open:

To keep the program as simple as possible to use, two modus of settings are used, guided by the plugins built in short explanations. The first setting will be faster and less accurate, the second will be slower but more accurate.
The faster but less accurate settings:
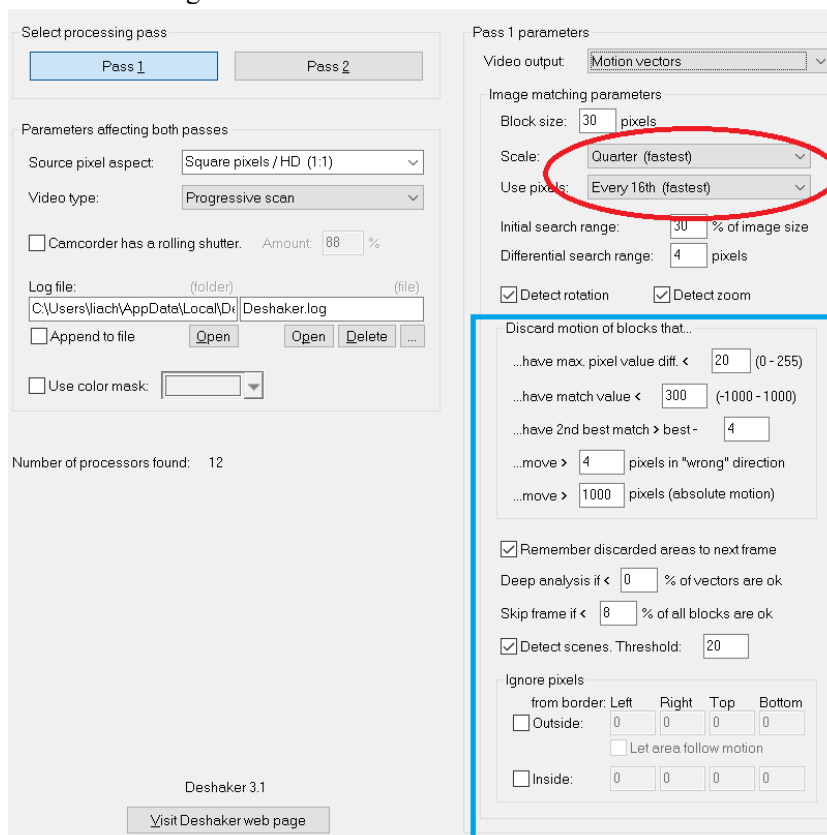
The slower but more accurate settings:
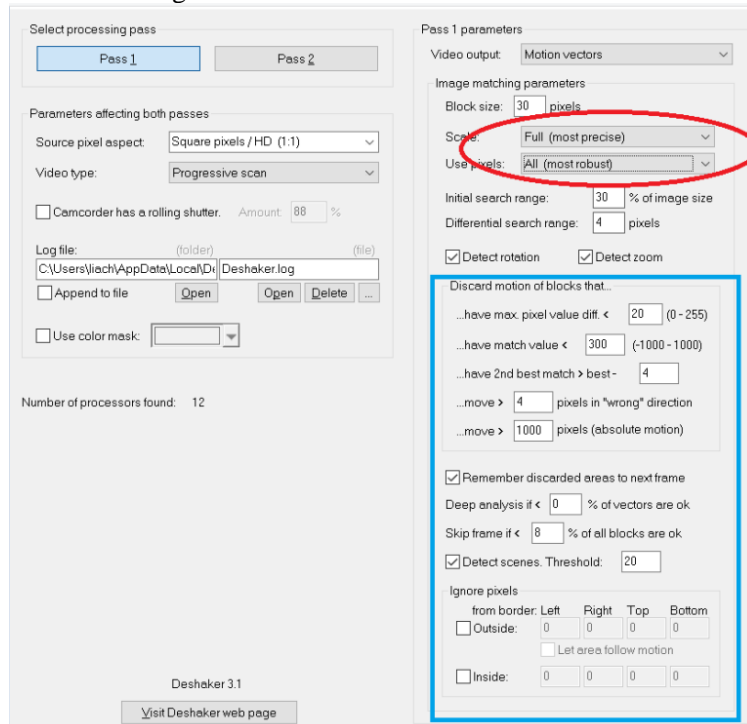
The area highlighted in blue offers more customizable options for scanning the video for camera motion. These can also significantly impact the quality of and the computational time required for the stabilisation process, however, these will not be explored during this test.

After the correct setting are chosen, the video must run through its entire length where the Deshaker algorithm scans for camera motion using motion vector analysis:
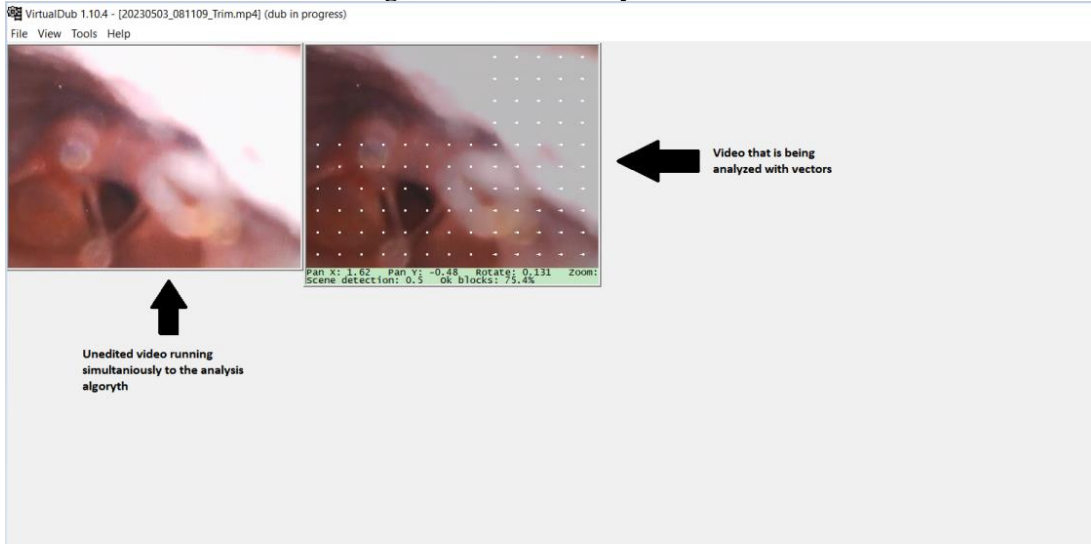
After the analysis is done, a correct processing method must be chosen by using the pass 2 of the Deshaker filter settings menu. To access it, the filter menu must be opened again:
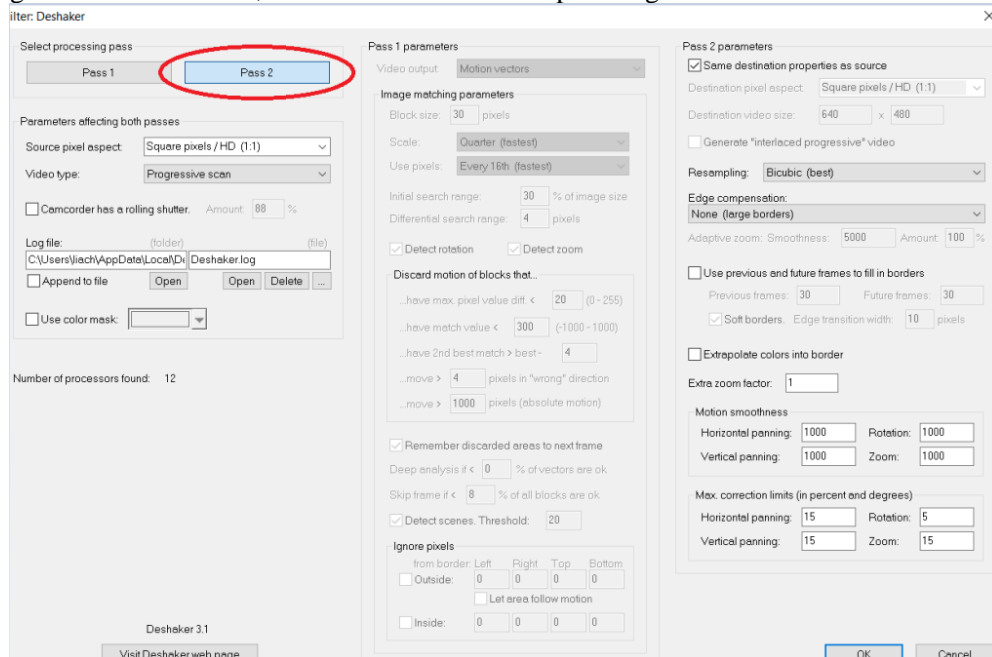
For the sake of simplicity and to easier see evidence of how much the video is cut/edited, only one option will be chosen:
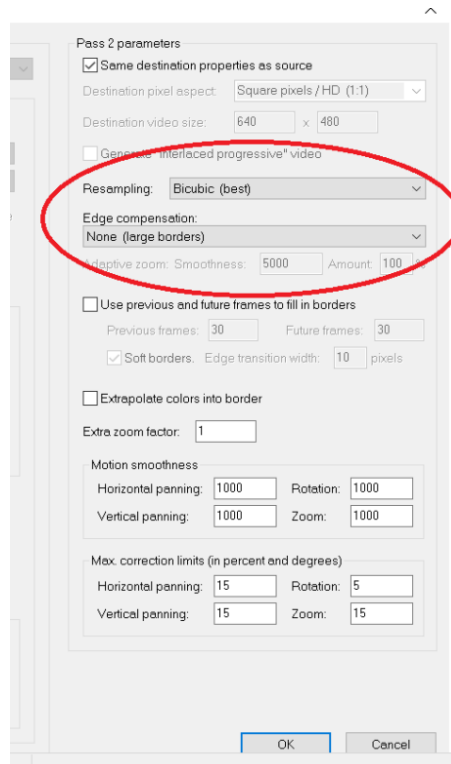
After those settings are chosen, the video is then saved as an .avi file and is ready to be viewed:
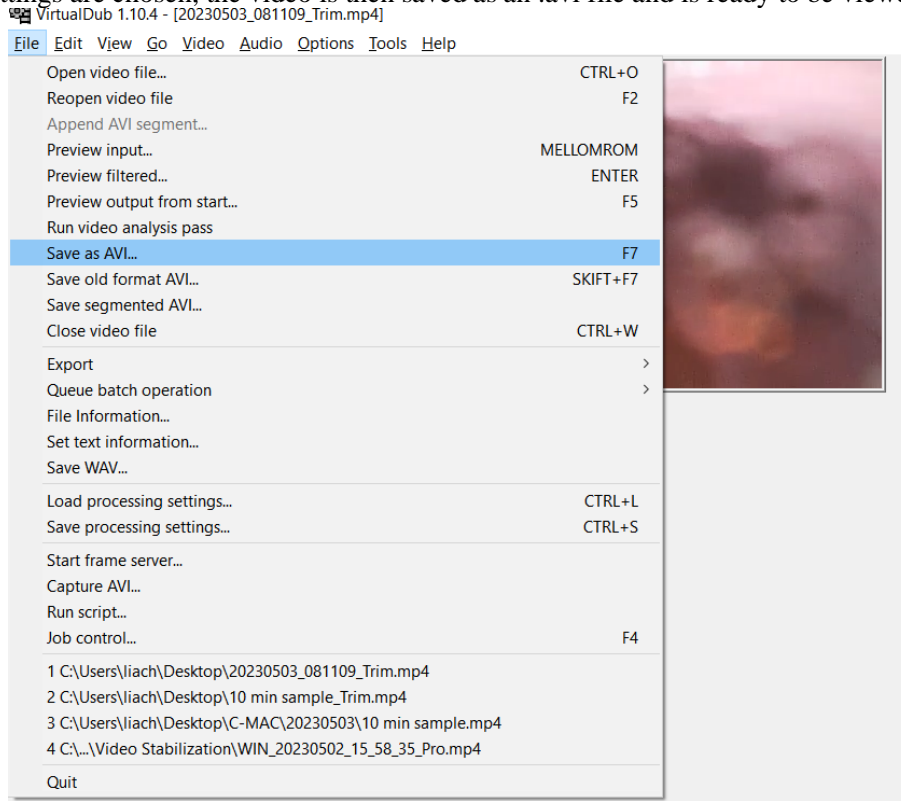
These tests, excluding the installation process, will be performed by a group member with no prior knowledge on how to use the program, only using the instructions provided above.

Test Criteria: *Description of what would constitute success and failure.*

The video must be more stable and more readable than the original video, the instructions and the use of the program must be intuitive and simple enough for a person without any prior knowledge to perform the stabilisation process and the computational time must be no more than 15 minutes, when stabilising the 10-minute video used as the test example. In other words, this criterion means that the stabilisation process must not take more than the length of the original video, plus additional 5 minutes for the computational time needed to extract the finished footage. This is done to not increase the time a patient has to wait for their diagnosis too drastically and to simulate the real-life application requirements of this process after the procedure.

Using a computer with these specifications:

Processing time:

Processor unit: Intel(R) Core(TM) i7-9750H CPU @ 2.60GHz 2.59 GHz
Installed RAM: 16GB
Graphics processing unit: Nvidia GeForce GTX 1660 Ti

The program was able to complete the faster but less accurate test in exactly the time length of the video which was 10 minutes and 14 seconds and the extraction time took 59 seconds for a total of 11 minutes and 13 seconds, and the slower but more accurate test in also 10 minutes and 14 seconds, however the extraction time increased to 1 minute and 29 seconds bringing the total up to 11 minutes and 43 seconds.

Quality:

The faster but lower accuracy test produced mixed results. While the quality of the video stability was on par or better than the original at some points in the video, some other parts became unusable. This is because the stabilisation software on lower accuracy mode tends to mistake the movement of the throat and/or the apparent movement caused by the lens flare on the camera lens, as camera movement. It then adjusts for this apparent movement making the footage too shaky to be used for diagnosis.

Example of positive stabilisation instance on lower accuracy mode:
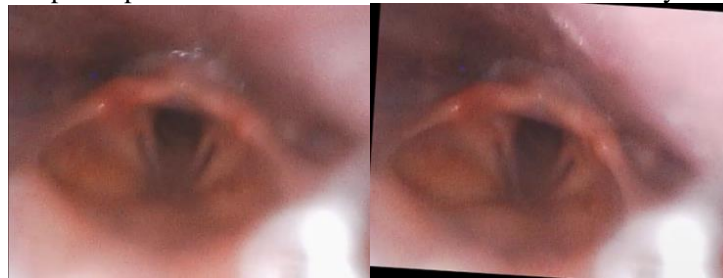
The stabilised image is on the right. The stabilisation software keeps the focal point of the procedure, which is the larynx, always within the center of the video. This makes it easier to focus on the larynx when watching the video, however it does introduce black borders because of splicing some of the video's edges to remove unwanted motion.

Negative example of the stabilisation instance on lower accuracy mode:
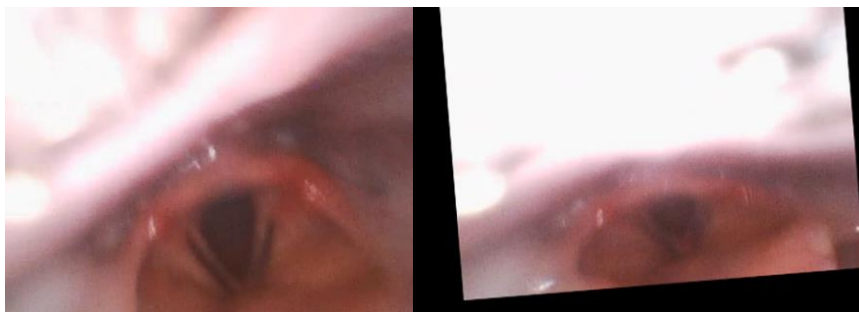
Stabilised video is on the right. Due to the algorithm not being able to discern from what was motion of the camera and motion within the video, too much splicing took place which warped the video too much, and it became significantly less readable than its non-stabilised origins.

The slower but more accurate test, however, performed significantly better. There were no instances throughout the 10-minute video where the algorithm mistook any motion within the video as camera motion. Throughout the whole video it either kept the same quality as the original or had slight improvements on its stability

Some of the examples from the video:
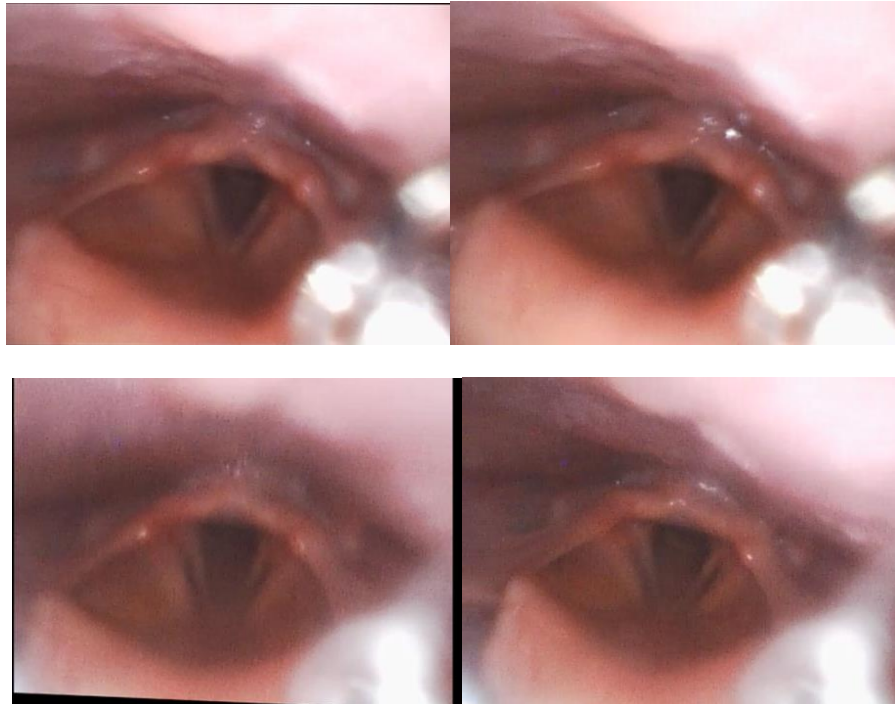
The stabilised examples are on the left. It is difficult to see any substantial increase in quality because the video is already very stable after the implementation of the cable gland locking mechanism. However, with the higher accuracy test stabilised video, the larynx is far more focused and easier to see than in the original video. This is because the algorithm successfully focused directly onto the larynx and made it stay within the center of the video by cutting out corners of frames containing significant amounts of unwanted motion and additionally counteracting some of the vibrations and rotations present in the original video.

Ease of use:

The group member with no prior knowledge about the program only needed a simple explanation using the instructions provided previously to successfully stabilise the videos.

Overall evaluation:

The faster method failed to increase the overall quality of the video, by significantly decreasing it at certain points within the video.
The slower but more accurate method, however, successfully increased the video quality.
The faster but less accurate test did not save a significant enough amount when compared to the slower but more accurate test to justify using it.

Discussion of Results: *Discussion of the results in light of the pass / fail criteria of the test*

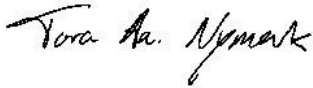| The faster but less accurate test:		
Criteria	**Pass**	**Fail**
Ease of use		
Video quality increase		
Computational time		
The slower but more accurate test:		
Ease of use		
Video quality increase		
Computational time		

Conclusion: *If success, description of the impact of the results. If Failure, description of the remedial measures that should be taken.*

Using this test's results, it is concluded that using the more accurate settings on the Deshaker plugin for VirtualDub is a reliable way to increase the footage stability and quality for the CLE test.

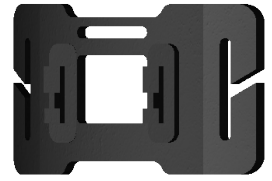Hege Grytten
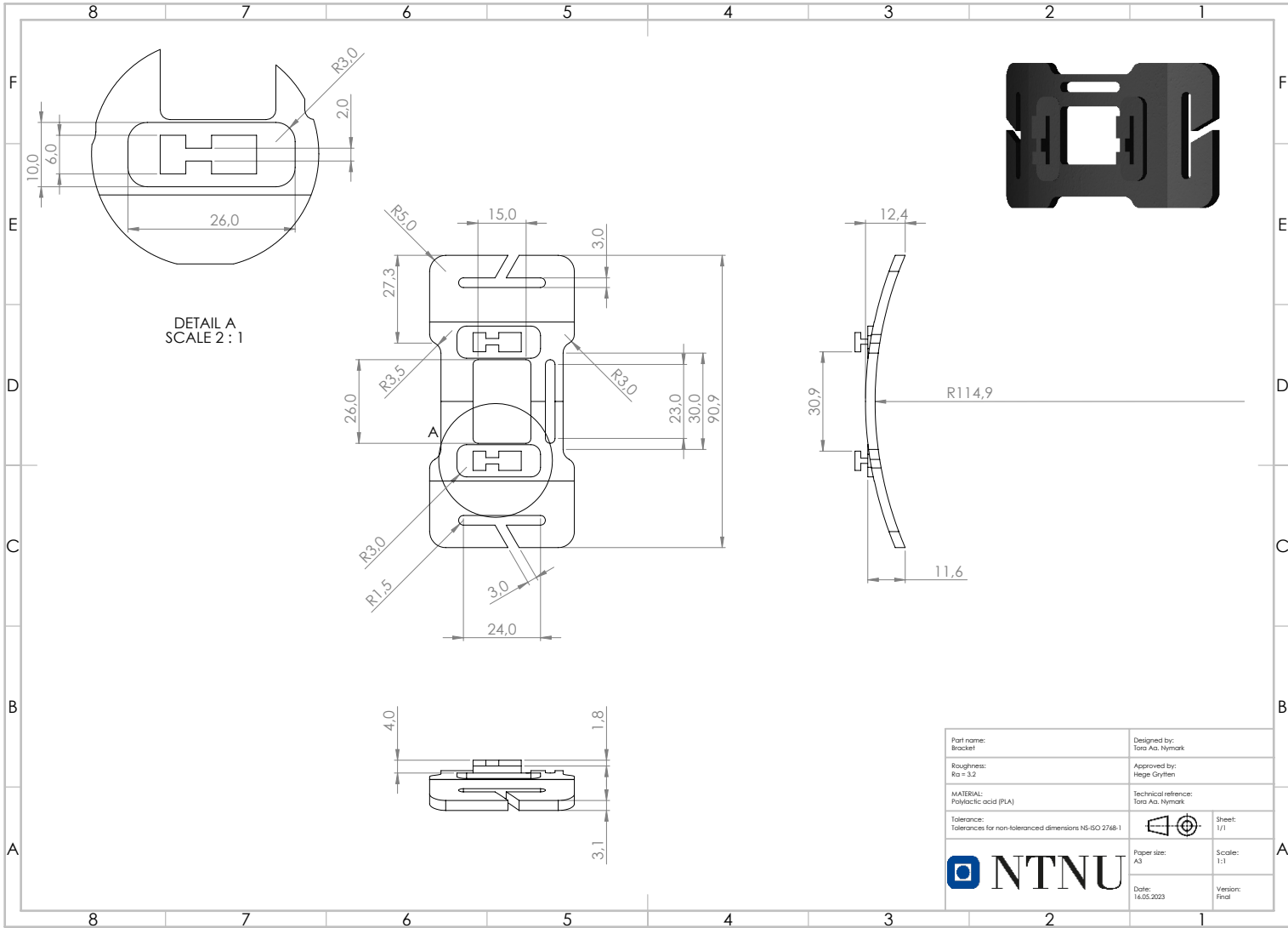
Signature

Tora Aasheim Nymark

Signature

Paulius Liachovas

Signature

B Machine drawings

B.1 Machine Drawing Bracket

DETAIL A
SCALE 2 : 1

| Part name:
Bracket | Designed by:
Tora Aa. Nymark | |
| Roughness:
Ra = 3.2 | Approved by:
Hege Grytten | |
| MATERIAL:
Polylactic acid (PLA) | Technical refrence:
Tora Aa. Nymark | |
| Tolerance:
Tolerances for non-toleranced dimensions NS-ISO 2768-1 | | Sheet:
1/1 |
| Paper size:
A3 | | Scale:
1:1 |
| Date:
16.05.2023 | | Version:
Final |

NTNU

B.2   Machine Drawing Holder

DETAIL E
SCALE 1.5 : 1

DETAIL D
SCALE 2 : 1

SECTION C-C

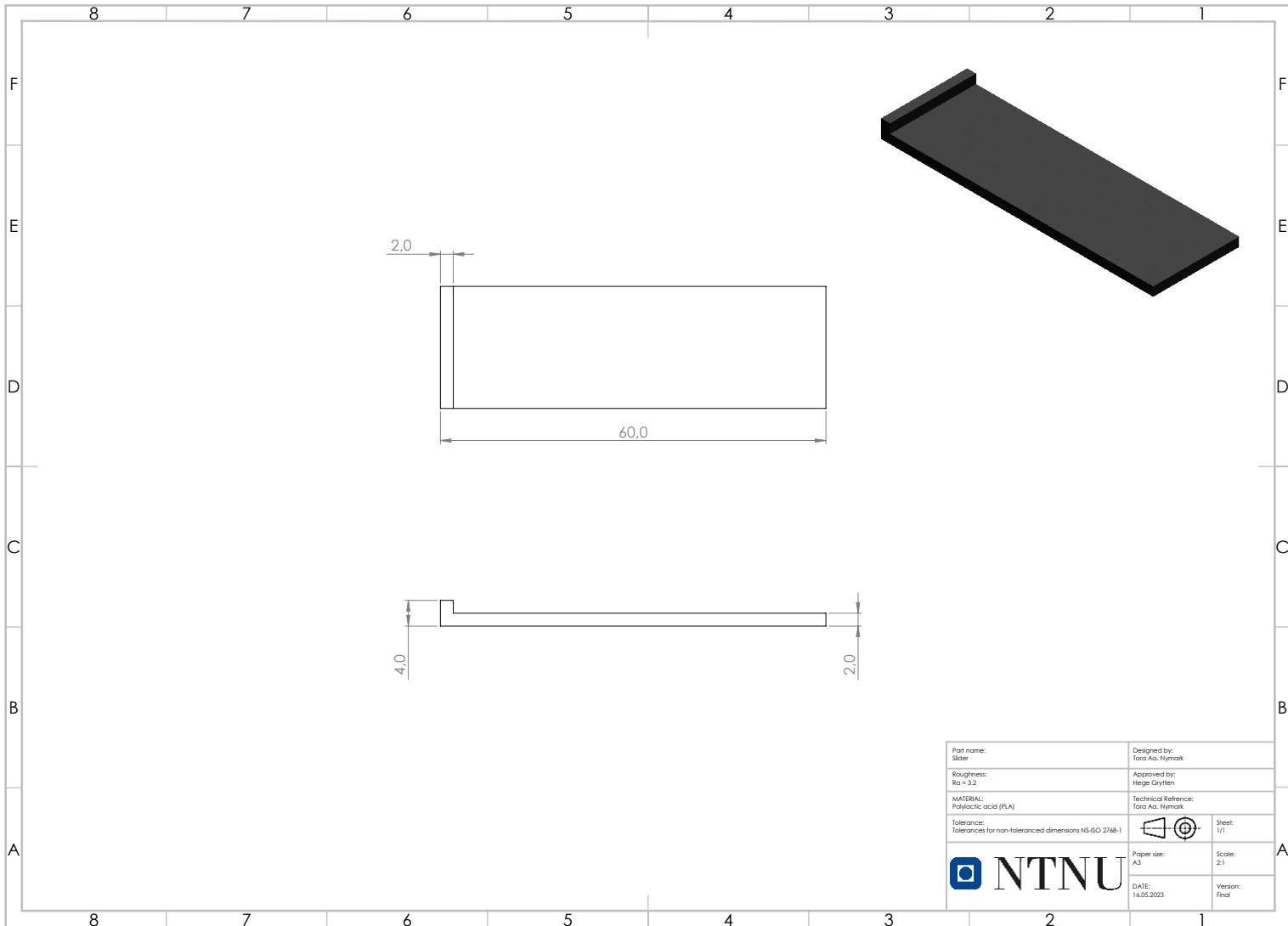| Part name: Holder | Designed by: Tora Aa. Nymark | |
Roughness: Ra = 3.2	Approved by: Hege Grytten	
MATERIAL: Polylactic acid (PLA)	Technical Refrence: Tora Aa. Nymark	
Tolerance: Tolerance for non-toleranced dimensions NS-ISO 2768-1		Sheet: 1/1
Paper size: A3		Scale: 1:1
NTNU	Date: 16.05.2023	Version: Final
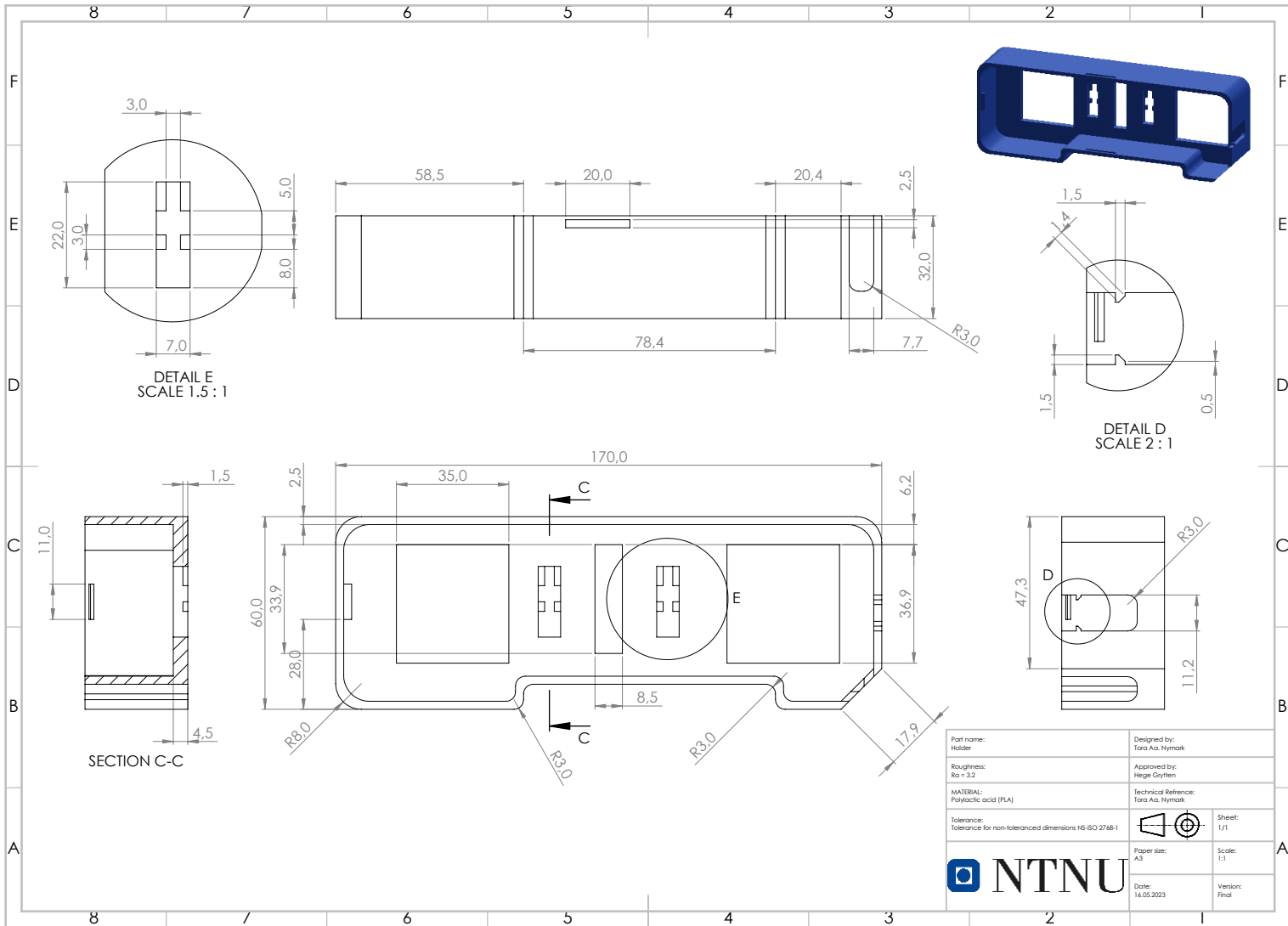
B.3 Machine Drawing Slider

2,0

60,0

4,0

2,0

Part name:
Slider

Designed by:
Tora Aa. Nymark

Roughness:
Ra = 3.2

Approved by:
Hege Grytten

MATERIAL:
Polylactic acid (PLA)

Technical Refrence:
Tora Aa. Nymark

Tolerance:
Tolerances for non-toleranced dimensions NS-ISO 2768-1

Sheet:
1/1

Paper size:
A3

Scale:
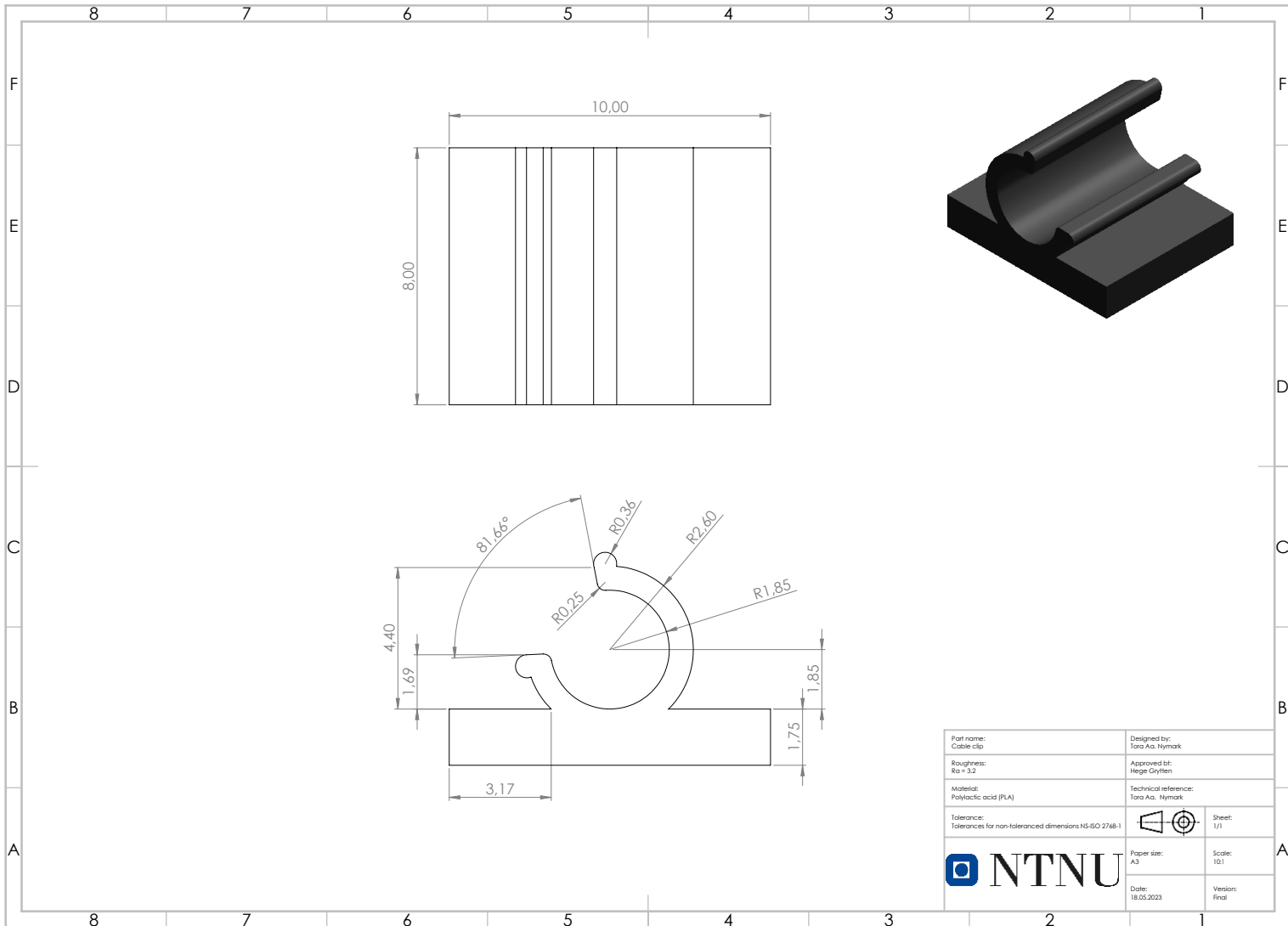2:1

NTNU

DATE:
16.05.2023

Version:
Final

B.4 Machine Drawing Cable Clip

10,00

8,00

81,66°

R0,36

R2,60

R0,25

R1,85

4,40

1,69

1,85

1,75

3,17

Part name:	Designed by:
Cable clip	Tora Aa. Nymark
Roughness:	Approved bt:
Ra = 3.2	Hege Grytten
Material:	Technical reference:
Polylactic acid (PLA)	Tora Aa. Nymark
Tolerance: Tolerances for non-toleranced dimensions NS-ISO 2768-1	Sheet: 1/1
Paper size: A3	Scale: 10:1
Date: 18.05.2023	Version: Final

NTNU

B.5   Machine Drawing Mask adapter

M12 x 1.5 mm

1.00 X 45°

10,0

SECTION A-A

Ø12.0

7.5

R10.5

R12.5

A   A

19,5

8,0

4,0

13,0

3,0

Part name: Mask adapter		Designed by: Tora Aa. Nymark	
Roughness: Ra = 3.2		Approved bt: Hege Grytten	
Material: Polylactic acid (PLA)		Technical reference: Tora Aa. Nymark	
Tolerance: Tolerances for non-toleranced dimensions NS-ISO 2768-1			Sheet: 1/1
	Paper size: A3		Scale: 2:1
NTNU	Date: 18.05.2023		Version: Final
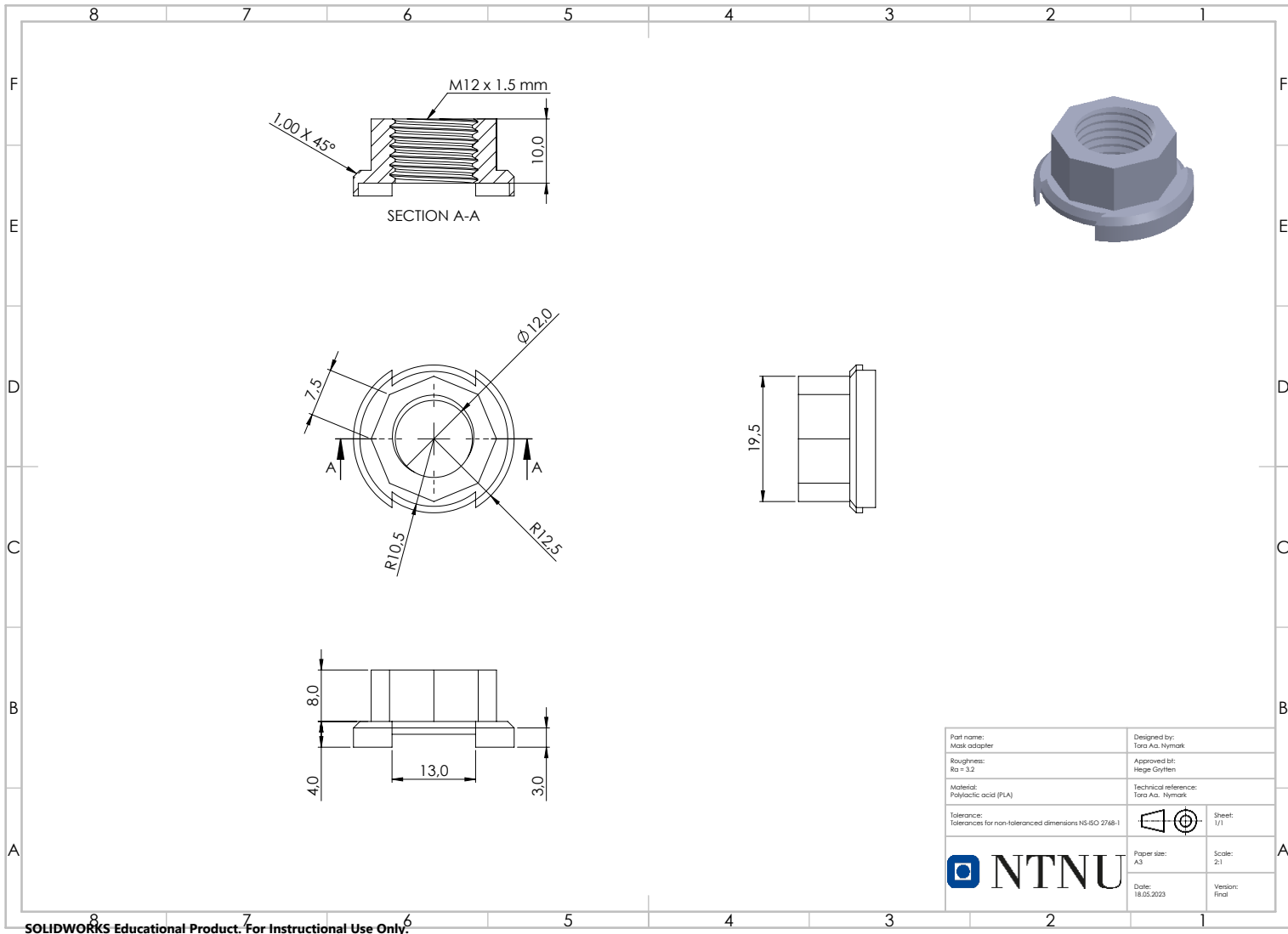
C   Calculations

C.1 Calculation Appendix

Holder and bracket calculations

Problem statement:

The holder/bracket design holds the weight of the laryngoscope handle during a CLE test. To ensure that the parts are strong enough to hold the laryngoscope handle in place during the one must calculate the forces action on the holder/bracket to later be used in a structural simulation.

Figure:
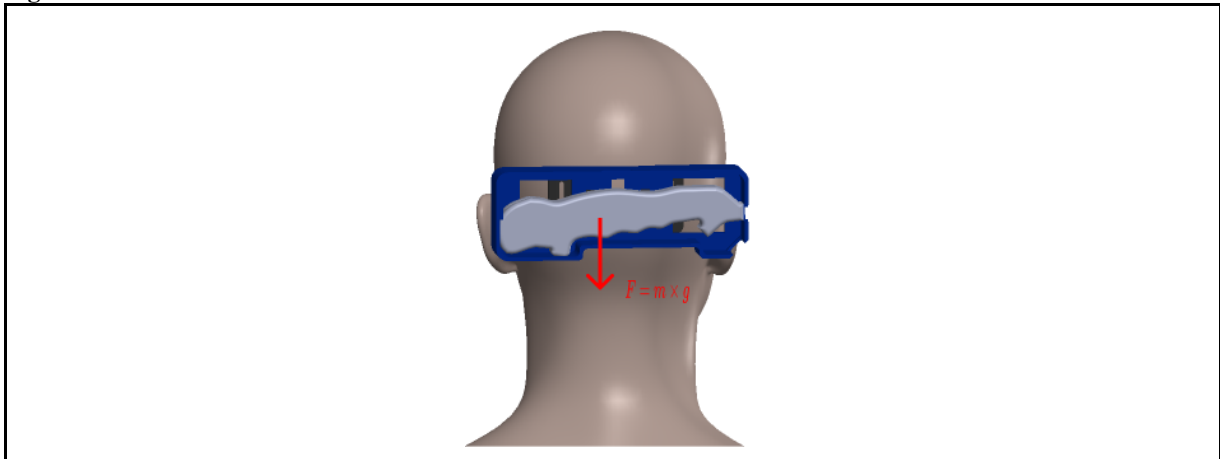
Assumptions and approximations:

When looking into the impact forces of running it concludes with the fact that the impact force is vary in magnitude in between 1.5 to 5 times the body weight.

This was then used to assume that the worst case for the holder/bracket configuration is the weight of the laryngoscope handle times 5.
Since this force will be a gravitational force, it will be a point load acting in the laryngoscope handles center of gravity.

Physical laws:

$\sum F = m \cdot a = m \cdot g$
$\quad m = \text{mass}$
$\quad a = \text{acceleration}$
$\quad g = \text{gravitational acceleration} \approx 9.81 \text{m/s}^2$

Calculations

$\sum F = 5 \cdot m \cdot a = 5 \cdot m \cdot g$
$\quad = 5 \cdot 0.07 \text{kg} \cdot 9.81 \text{m/s}^2$
$\quad = 3.43 \text{N}$

Reasoning, discussion and verification:

The results show that the force acting on the holder/bracket configuration is quite small, which is as predicted due to the laryngoscope handle being quite light.

Final results:

The maximum load the bracket/holder configuration needs to withstand is 3.43N located in the laryngoscope handles center of gravity.

C.2   Analysis and simulation Appendix

FEA Holder/Bracket

Introduction:

In this report the holder/bracket configuration is analysed with a static structural Finite Element Analysis.

Material definition:

Material	Density [kg/m^3]	Yield Strength [MPa]	Poisson Ratio [-]	Young's Modulus [GPa]
PLA	1240	60	0.394	2.34

Mesh properties:

Element type	Mesh control
Solid mesh: Tetrahedal	Size: 1.6mm

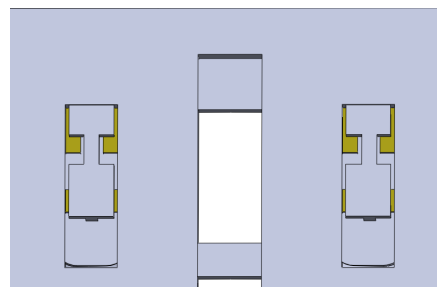**Illustration of mesh:**
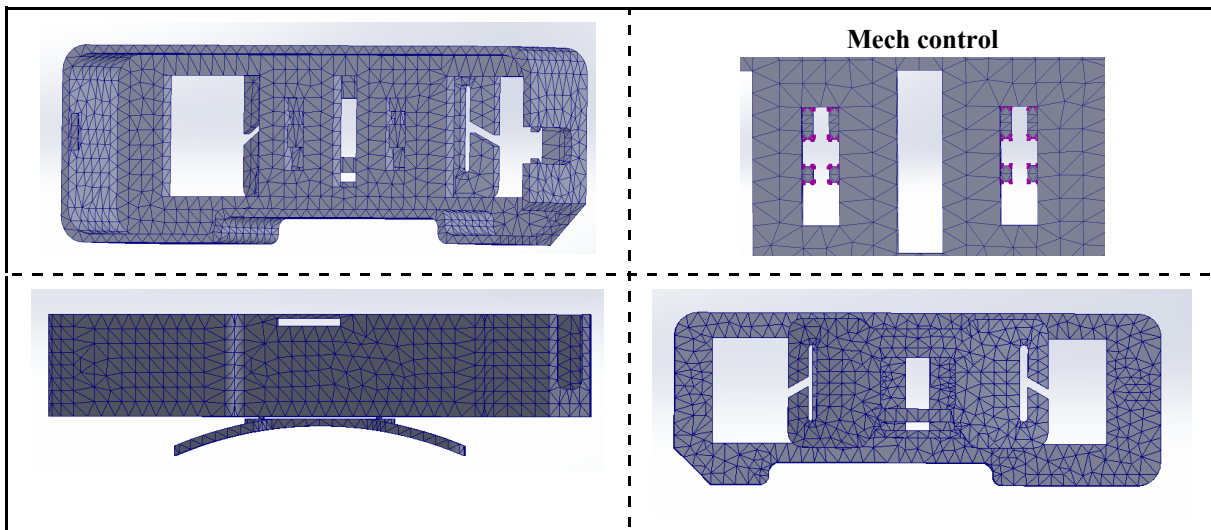
Connections: *[Illustrate connections and define connection properties]*

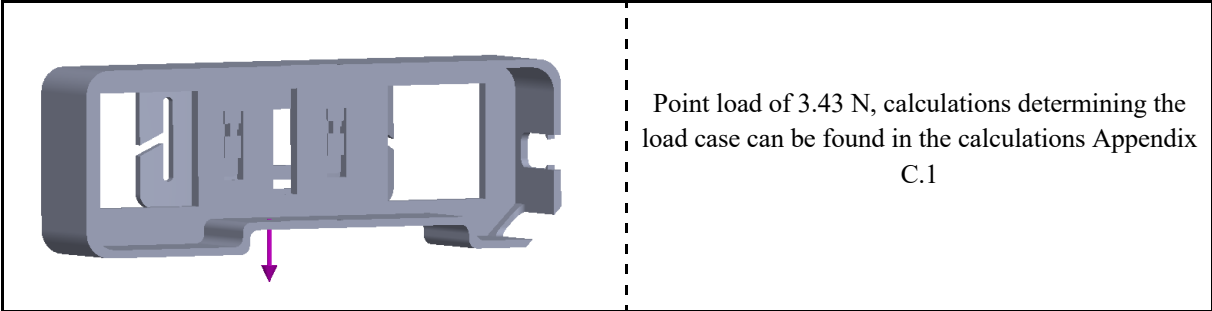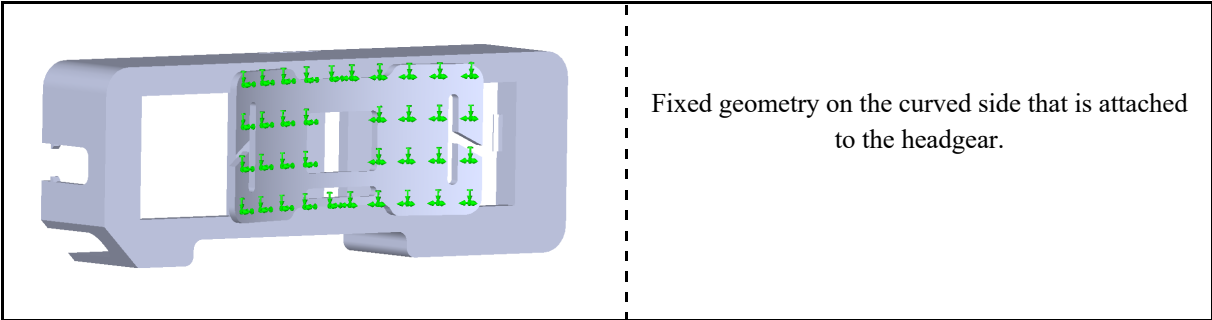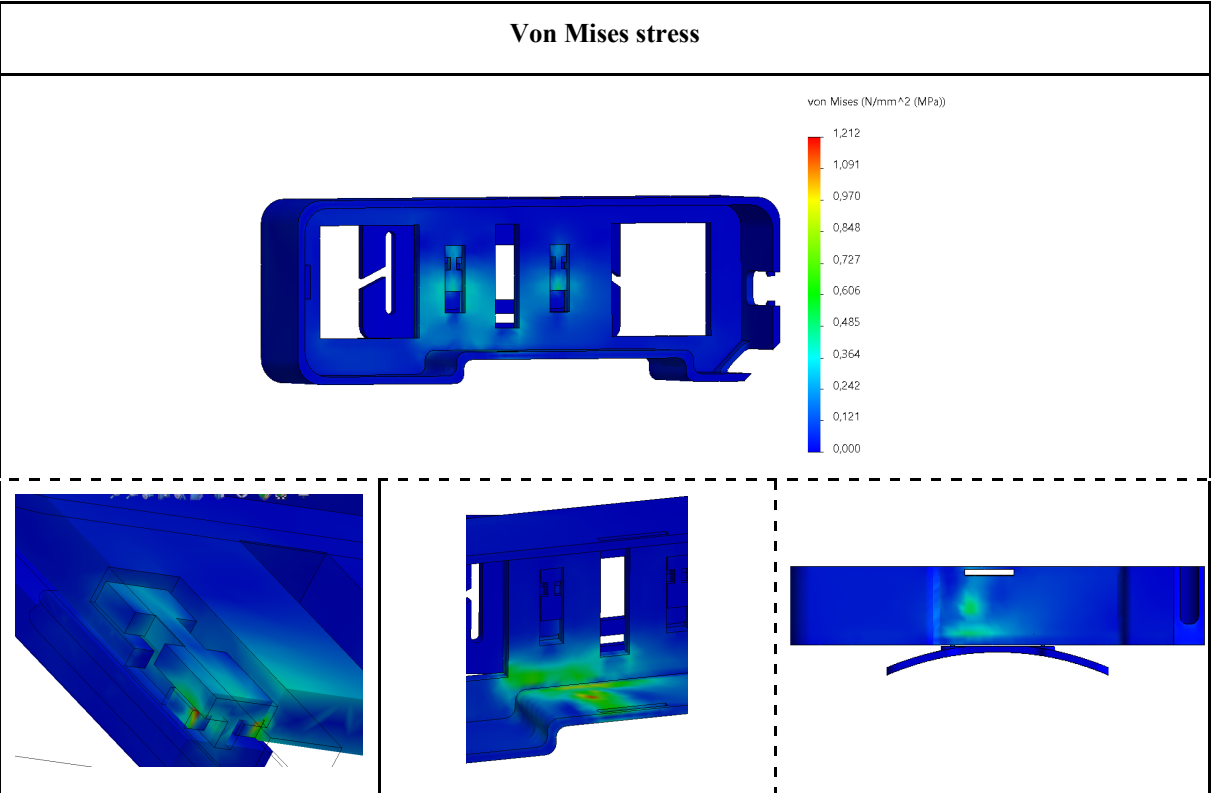|	
Local contact set between the front face of the holder fastening mechanism, and the back face of the bracket fastening mechanism.	
Connection type	Contact sets
Mechanical behavior	Creates contact between the two parts and enables penetration
All contact sets:	
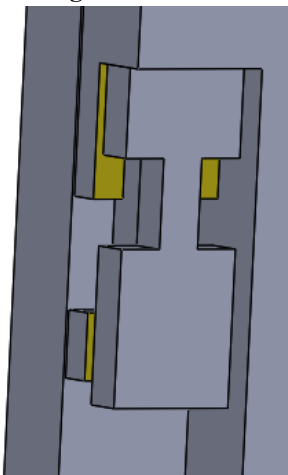
Loading: *[Illustrate the loading type. Include a brief description of where the loading is applied and the magnitude of the loading]*
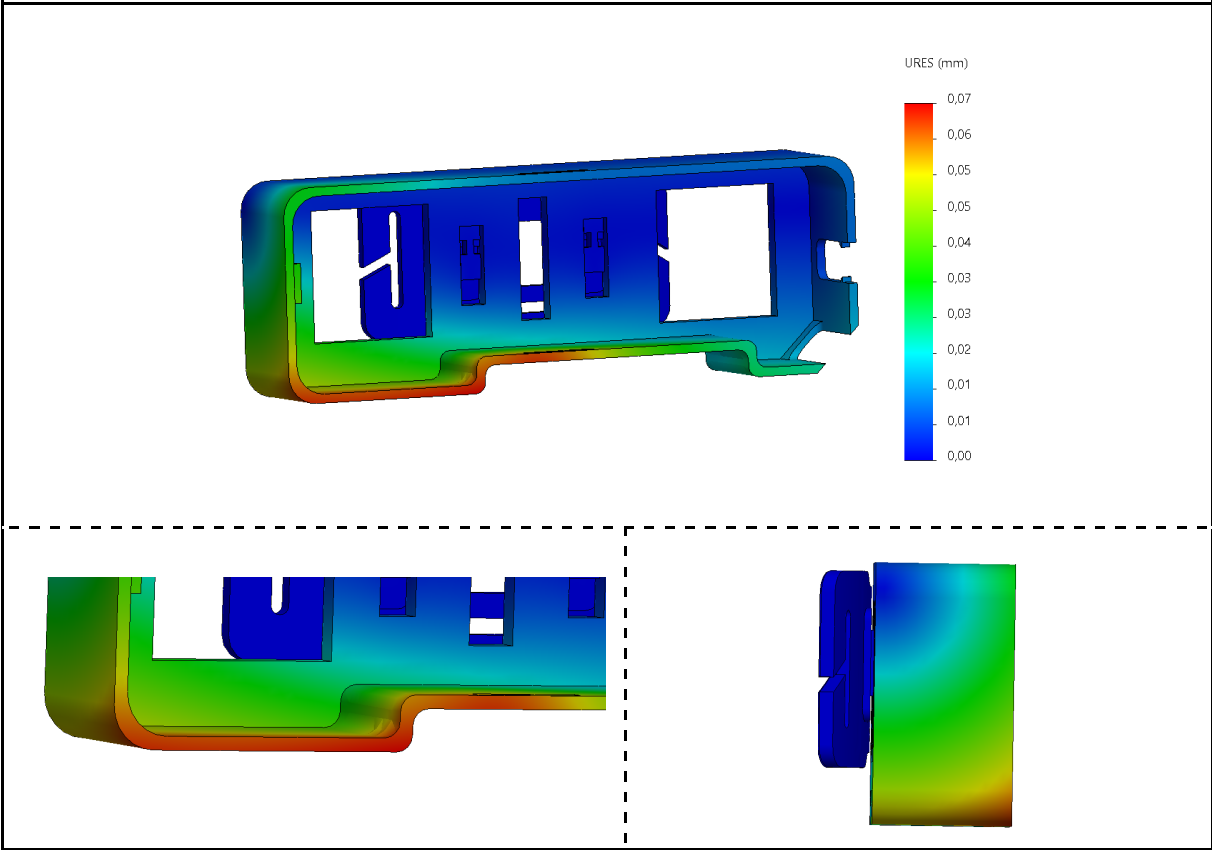
	Point load of 3.43 N, calculations determining the load case can be found in the calculations Appendix C.1

Boundary conditions:

	Fixed geometry on the curved side that is attached to the headgear.

Results: *[Present all relevant results]*

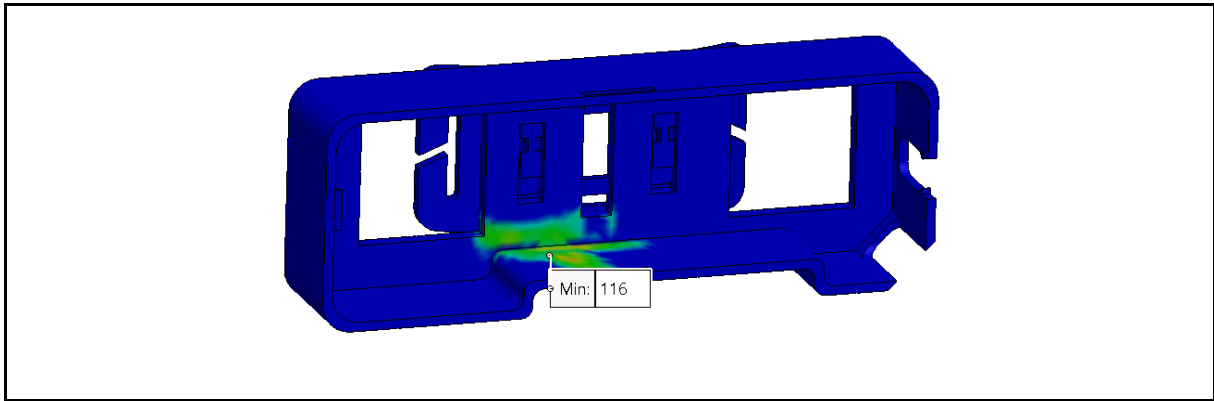| Von Mises stress |
|---|
| |
| |

General displacement

Factor of safety
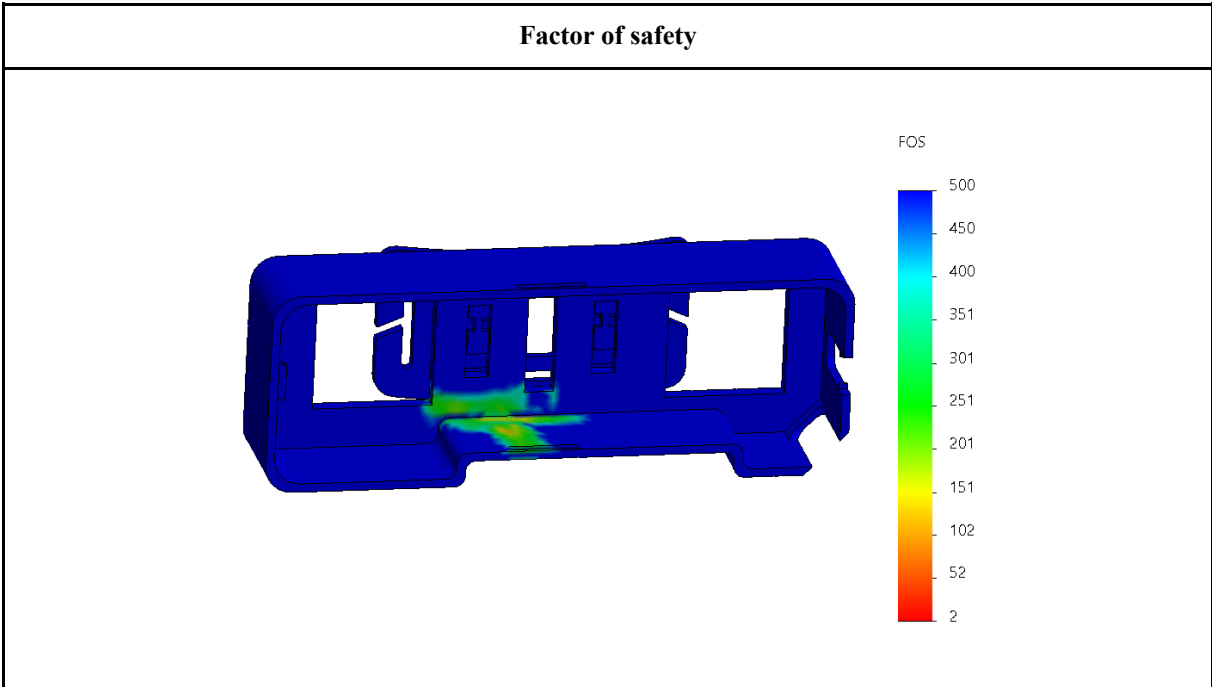
Discussion:

With a safety factor of minimum 116 it is clear that the holder/bracket configuration can withstand the forces it is affected by during a CLE test.
The simulation validates the intuitive knowledge that the stress concentrations should occur where the point load is placed, in addition to the contact surfaces of the two parts.

Conclusion:

The results from this analysis shows that the holder/bracket configuration can withstand the applied forces generated from the weight of the laryngoscope handle during a CLE test.

D   Technical data

D.1 Technical data: DDMALL Encoder

Specifications

Power Supply	5V/1 A （USB cable powered ）
Power Consumption	2.6W
Work Temperature	-10~65℃ （14~149℉）
Storage Temperature	-20~85℃ （-4~185℉）
Work Humidity	10%- 90%RH (Non-condensing)
Weight	25g/0.055lbs
Dimension	75mm(L)*32mm(W)*12mm(H)/ 2.95×1.26× 0.59in
MTBF(mean time between failures)	30,000h
Video Input Stanard	HDMI 1.3, HDCP1.4
Video Codec	H.265/HEVC and H.264/AVC
Supported Protocols	RTP, RTSP, RTMP, RTMPS, UDP, TCP, Multicast and Unicast.
Supported Input Resolution	1080p@60Hz/50Hz/30Hz, 1080i@60Hz/50Hz, 720p@60Hz/50Hz/30Hz
Supported Output Resolution	1080p@30Hz, 720p@60Hz/30Hz, 960×720@60Hz, 960×540@60Hz, 640×480@60Hz, 360×200@60Hz
Pixel Clock	165MHz (max)
Video Bitrate	128Kbps~8192Kbps
Audio Input Standard	HDMI, 3.5mm analog Line in
Audio Encoding Format	G.711u, AAC
Audio Bitrate	32kbps~256Kbps
Wireless Standard	802.11a/n/ac 5G， 802.11b/g/n 2.4G
Control Method	Web UI
AP Mode Wi-FI Info.	SSID：HEV-2KW；password：12345678
AP Mode Default IP	192.168.1.252
WEB UI login credentials	Default user/password：admin/admin
GOP	Tunable
Compression Profile	BaseLine, Main, High

D.2 Technical data FPV Transmitter and Reciever

Wolfwhoop WT832 WR832 5.8GHz 40CH 600mW Wireless FPV Transmitter and Receiver for Drones

Overview

Features:
40 channels: 5 bands and all frequencies compatible
Two switching buttons: easy to change frequency channels and bands
Two digital display: real-time positioning which frequency band and which channel received
Power off memory: replay the very last frequency band and channel

Specification for TS832 Transmitter:
Modulated: Wideband FM Modulation
40 channels: Cover A, b, E, F, r bands
Supply current: 220 mA
Frequency: 5.8GHz 5 bands 40 channels, with Raceband: 5658-5917MHz
Transmitting distance: > 3000m (open area)
Transmitter connector:RP SMA female
Antenna connector: RP SMA male
Audio carrier Frequency: 6.5 MHz
Audio Input Level: 0.5 ,2.0 Vp-p
Audio Input Impedance: 10K Ohm
Output Impedance: 50 Ohm
Operating Voltage:7-16V
Operating Temperature: -10 +85 ℃
Output Power: 27-28 dBm
Video Format: NTSC/PAL
Video Band Width: 0-8.0 MHz
Video Input Level: 0.8,1.0,1.2 Vp-p
Video Input Impedance: 75 Ohm
Weight: 22g
Dimension (L×W×H): 2.12×1.23×0.39 inches

Specification for RC832 Receiver:
Power Supply: DC 12V
Working Frequency: 5.8GHz
Sensitivity: ≤-90 dBm
Type Standard: NTSC/PAL
Consumption Current: 200mA, Max
Receiver connector: RP SMA female
Antenna connector: RP SMA male
Available Channel: 40CH
Antenna Gain: 2dbi
Audio Carrier: 6.5MHz
Audio Output Level: 1.0 Vp-p Typ 10 K Ohm
Antenna impedance: 50 Ohm
Antenna Input Impedance: 50 Ohm TYP
Video impedance: 75 Ohm
Video Format : NTSC/PAL
Video Output Level: 1.0 Vp-p Typ 75 Ohm
Dimension: 80x65x15mm
Weight: 85g
Dimension (L×W×H): 3.15×2.56×0.59 inches

Package:
1 x WR832 5.8GHz 40CH FPV Receiver
1 x WT832 5.8GHz 40CH FPV Transmitter
2 x Antenna
2 x Power cable
1 x AV cable
1 x User manual