Division of Biomedical Engineering

Department of Human Biology

University of Cape Town

Development of a Novel Mobile Flexible Hysteroscopy System for Outpatient Procedures without General Anaesthesia

Thesis

In fulfilment of the requirements for the degree:

PhD in Biomedical Engineering

Edmund Wessels (WSSEDM001)

Supervisor: Prof Sudesh Sivarasu

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Aan Holly, Mira, en my familie,
sonder julle sou ek nie.

Declaration

I, Edmund Grey Wessels, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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Abstract

Introduction: Hysteroscopy is regarded as the gold standard for evaluating and treating abnormal uterine conditions and while typically performed in the operating room with general anaesthesia, office procedures without general anaesthesia has been proven to be safe and efficient. However, shortcomings with existing hysteroscopy systems, such as patient discomfort and equipment cost, impede the adoption and success of office hysteroscopy. This research project aimed to develop a new hysteroscopy system that was more accessible to gynaecologists by reducing cost, eliminating equipment requirements, and improving the patient experience. This increases the rate of office hysteroscopy and, as a result, improves patient access to the procedure.

Materials & Methods: By reviewing the current hysteroscopy landscape, need criteria were determined and translated into design requirements to guide the design and development of the new hysteroscopy system. The design process followed an iterative prototyping approach where prototypes were built on the previous version until a system that met all the design requirements was developed. The prototype system then underwent verification testing to establish the design specifications to compare against the design requirements and, if successful, proceed to validation testing through a comparative usability trial. The trial protocol was developed according to the IEC 62366-1:2015 standard using an ISO 14971:2019 risk analysis as input. The trial involved 10 gynaecologists performing simulated procedures with the prototype and a standard system, thereafter, providing feedback through a System Usability Scale, a post-session questionnaire, and a procedure review form.

Results & Discussion: The outcome of the design process was a mobile flexible hysteroscopy system with a single-use sheath with a channel for distention media. The prototype was all-in-one with a built-in camera, light source, and battery power source, and it could be operated single-handedly. It was verified to have a 260mm working length, 4.2mm diameter scope with a 236° bending range, 79 minutes of continuous usage, and the disposable sheath could isolate the system while fully submerged and supply saline solution at over 200 mmHg pressure. The trial results showed the prototype system to have higher usability than the standard, scoring 86 and 67, respectively. Furthermore, less experienced gynaecologists scored the prototype system much higher than the standard, indicating it was easier to use. This was further shown in the post-session questionnaire, where a Mann-Whitney U test determined the significance between ratings of the two systems, and the prototype system was found to be significantly easier to clean, set up, and use. Finally, the procedure review form confirmed all participants could perform a hysteroscopy procedure with the prototype system without using tools such as a speculum or tenaculum. The prototype system was therefore validated as a functional hysteroscopy system that successfully incorporated features to address the identified shortcomings of existing hysteroscopy systems.

Conclusion: The research project, therefore, successfully achieved its aim, having developed the prototype hysteroscopy system that could increase the adoption of office hysteroscopy procedures. This is possible through the system requiring no additional equipment and sterilisation facilities while offering an improved user and patient experience through the user-friendly design, minimal diameter flexible scope, and not requiring tools during procedures. Future work could be aimed at refining the hysteroscopy system and preparing it for the first human testing to demonstrate clinical safety and efficacy.

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- My wife, Holly, who was willing to marry and start a family with an unemployed student. You and our daughter give me reason to endure.
- To Christ my Saviour, through which I drew strength.

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List of Abbreviations and Acronyms

Area Under Curve	**AUC**
Computational Fluid Dynamic	**CFD**
Computer Aided Design	**CAD**
Diagnostic Hysteroscopy	**DH**
Disposable Sheath	**DS**
Finite Element Analysis	**FEA**
Handheld Base	**HB**
Human Research Ethics Committee	**HREC**
International Electrotechnical Commission	**IEC**
International Organisation of Standards	**ISO**
Mobile Visualisation Platform	**MVP**
Polyethylene Terephthalate Glycol	**PETG**
Polytetrafluoroethylene	**PTFE**
Pulse Width Modulation	**PWM**
Receiver Operating Characteristics	**ROC**
Saline Infusion Sonohysterography	**SIS**
Shape Memory Alloy	**SMA**
Stereolithography	**SLA**
Smart Bending Mechanism	**SBM**
System Usability Scale	**SUS**
Transvaginal Sonography	**TVS**
United States Dollar	**USD**
University of Cape Town	**UCT**

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1 Introduction

Hysteroscopy is a valuable procedure for diagnosing and treating abnormal conditions within the uterus, and while typically performed in the operating theatre, can also be conducted in the offices of gynaecologists without general anaesthesia. However, the existing equipment limit the adoption and application of in office procedures due to several shortcomings. This research aims to develop a new hysteroscopy system that addresses the shortcomings of current systems and evaluate its efficacy as a solution. This chapter will introduce the research by first discussing the background and problem identification, followed by the research approach, question, aims, objectives, research scope and finally, an overview of the thesis.

1.1 Background and Problem Identification

In the field of gynaecology, hysteroscopy is a procedure for viewing and operating in the uterus by inserting a long, narrow telescope known as a hysteroscope through the vagina and cervix. A complete hysteroscopy system consists of a hysteroscope connected to a light source, camera, and display screen to allow the user to observe the inside of the uterus (Pados & Makedos, 2015). Furthermore, a gas or fluid is pumped through the hysteroscope to enlarge the uterine cavity for improved visualisation and operative procedures are performed by inserting surgical instruments (Cooper et al., 2011).

Hysteroscopy offers an excellent minimally invasive method for diagnosing and treating uterine conditions (Santos-Paulo, 2019). Compared to alternative methods of uterine evaluation, the diagnostic performance of hysteroscopy was found to be significantly better (Grimbizis et al., 2010). Given its efficacy, hysteroscopy is acknowledged as the gold standard for uterine cavity evaluation (Mairos & Di Martino, 2016). In terms of settings, hysteroscopy is traditionally performed in the operating room with general anaesthesia applied to the patient. However, the development of small-diameter and flexible hysteroscopes has allowed for successful procedures in the office (Jacobs et al., 2005). This led to the "no-touch" form of hysteroscopy, which refers to inserting the hysteroscope without a speculum or anaesthesia (Sharma et al., 2005). Office operative hysteroscopy has shown its feasibility, safety, and effectiveness giving way to the "see and treat" modality and avoiding the costs and risks involved with general anaesthesia and hospital admission (Moawad et al., 2014).

Following the successful performance of office hysteroscopy, the further development of hysteroscopy systems that aimed to improve the office hysteroscopy experience for both patient and clinician continued. These developments led to more mobile hysteroscopy systems by either combining equipment or replacing the entire system with an all-in-one handheld device (Connor, 2015). Equipment sterilisation requirements were also reduced by using disposable components that allow back-to-back procedures (Salazar & Isaacson, 2018). In turn, the patient's experience was improved by implementing semi-rigid scopes with reduced diameters that lowered discomfort during procedures.

However, although office hysteroscopy offers several benefits, it still remains underutilised (Isaacson, 2002). This is due to the perceived notion by both patient and

physician that office hysteroscopy without general anaesthesia is too painful (Cicinelli, 2010). The low use is further attributed to the expensive equipment costs, skills required to perform office hysteroscopy, and setup requirements (Salazar & Isaacson, 2018). Flexible hysteroscopes, while shown to lower patient discomfort, are rarely used due to higher cost, fragility, and increased effort to sterilise (Jacobs et al., 2005). As a result, hysteroscopy is still typically performed under general anaesthesia in the operating room with rigid hysteroscopes.

While recent developments have addressed some of the shortcomings of previous hysteroscopy systems, no one system that offers a solution to all the physician's and patient's needs has been placed. Therefore, A gap exists for an innovative hysteroscopy system that provides a complete solution to the problems preventing adoption and success of office hysteroscopy procedures, and in doing so, provide increased patient access to a valuable healthcare tool.

1.2 Research Approach

This research project consisted of two major components, firstly, the design and development of a hysteroscopy system according to the requirements established by reviewing the current landscape, and secondly, performing verification and validation testing on the developed system to determine its efficacy as a solution against the requirements. The design and development process followed an iterative approach whereby prototyping focused on addressing critical technical challenges, and each subsequent prototype produced incorporated findings from the previous. The verification and validation testing determined if the device was designed correctly and if the correct device was designed. It was done by verifying the design through simulation and bench testing and validating it through user interaction and comparison with existing devices.

1.2.1 Research Question

Following the observation of several hysteroscopy procedures, interviews with gynaecologists, and a literature review of the hysteroscopy landscape, the research question for this project was proposed: could a new hysteroscopy system be developed that incorporates features to address the identified shortcomings of current technologies and successfully demonstrate its efficacy when used to perform procedures and compared to a typical hysteroscopy system?

1.2.2 Aim

The research aims to develop a new hysteroscopy system for application outside of the operating theatre, verify it through simulated and bench testing, and validate it with a comparative usability trial.

1.2.3 Objectives

The objectives of the study are broadly categorised into prototype design, verifying the technical specifications of the prototype, and validating its efficacy. The objectives are broken up into secondary objectives for clarification. The primary and secondary objectives are as follows.

- Iterative design of the hysteroscopy system prototype:
  - Establish the design requirements of the hysteroscopy system.
  - Identify and prioritise the subsystems of the hysteroscopy system.
  - Develop prototypes of the system that demonstrate prioritised subsystems until a prototype meets all the design requirements.
- Performing mechanical characterisation and *in-silico* testing on the final prototype to verify its design specifications:
  - Testing functional parameters of the prototype.
  - Simulate aspects of the prototype to evaluate performance.
  - Record the design specifications to compare against design requirements.
- Performing design validation on the final prototype by:
  - Perform a risk analysis on the prototype to determine the tasks of the usability trial protocol.
  - Perform a comparative usability trial between the prototype and a standard hysteroscopy system with gynaecologists.
  - Evaluate the usability trial results to determine the prototype's efficacy.

1.2.4 Study Scope & Limitations

The scope of the study is limited in the following ways:

- Prototypes are developed in a university lab environment; as such, certain requirements of medical devices, for example sterility and biocompatibility, ordinarily need to be met, however are beyond the scope of the study.
- As a result, human trials are outside the scope because the prototypes needed to meet the requirements.
- The prototypes will be evaluated against requirements for performing hysteroscopy outside of the operating theatre established through literature and analysed for efficacy through gynaecologists performing mock procedures.
- The study focuses on developing a prototype hysteroscopy system that demonstrates its potential for performing procedures outside of the operating theatre. Therefore, design choices and testing details were limited to achieving the focus.

1.2.5 Thesis Overview

This thesis details the development process of a novel hysteroscopy system and the testing thereof. An overview of the thesis structure is shown in Figure 1.1 below.

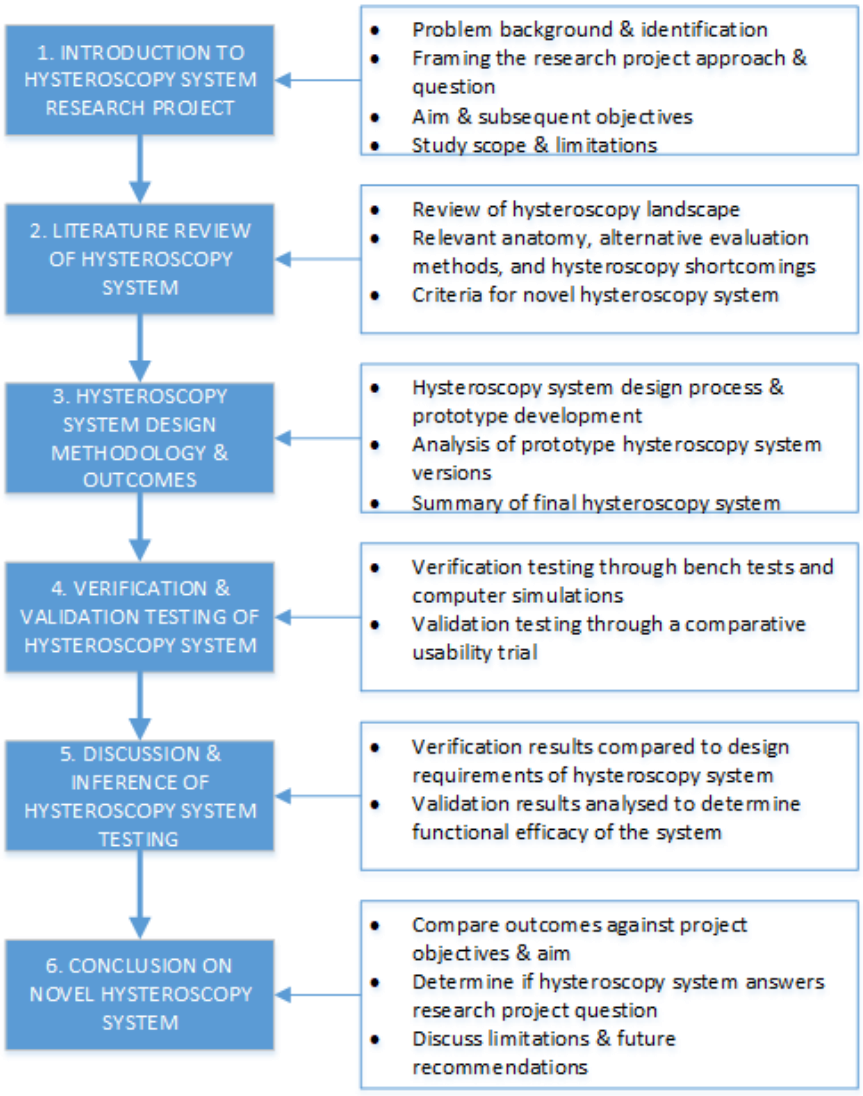


Figure 1. 1-1 Thesis Overview

Chapter 1 provides a brief background to the study and the problem identification, followed by the aims and objectives to answer the proposed research question. **Chapter 2** examines the literature regarding the current landscape of hysteroscopy to understand aspects such as the relevant anatomy, conditions, procedure settings, and equipment used. This culminates in the criteria drawn from this examination for a novel hysteroscopy system. **Chapter 3** details the design process of the hysteroscopy system by showing each prototype developed and how it guided the subsequent prototype's design—ending with a detailed breakdown of the final prototype. **Chapter 4** presents the verification and validation testing of the final hysteroscopy prototype. The verification section includes function testing and simulations performed with the results; the validation section details the comparative usability trial performed on the prototype and the results thereof. **Chapter 5** discusses the prototype's overall functional efficacy by

analysing the verification and validation testing results. The original need criteria established will be used to determine if the prototype offers a successful solution. **Chapter 6** concludes the thesis with the outcomes achieved and shows the research question was answered. Recommendations for future development of the prototype hysteroscopy system are provided as well.

2 Literature Review

This chapter reviews the relevant aspects of the research project's target clinical field, gynaecology. This includes a basic overview of the anatomy of the female genitalia, specifically looking at the uterus. A description of the existing methods for evaluating the uterine cavity follows this. The research project aims to develop one of the methods of uterine evaluation, namely diagnostic hysteroscopy; the specific aspects of this method will, therefore, be described in further detail. This includes an overview of the procedure, existing hysteroscopy systems, their shortcomings, and the criteria for developing a new hysteroscopy system.

2.1 Relevant Anatomy of Female Genitalia

Understanding the methods for evaluation of the uterine cavity requires knowledge of the female genitalia's anatomy. This ensures that each method discussed is fully understood by providing a clear image of where and how each is performed. Describing the anatomy also seeks to highlight where potential faults or limitations of evaluation methods may occur.

2.1.1 The Vagina

The vagina is a fibromuscular tube and is capable of considerable distention, the tube inclines posteriorly at an angle of approximately 45° with the vertical plane of the body (Ball et al., 2014), as shown in Figure 2.1. The entrance to the vagina, the vaginal orifice, forms part of the external female genitalia. Located at the upper end of the vagina is a blind vault into which the cervix projects. The cervix divides the vagina into four fornices. The shallow anterior fornix or anterior cul-de-sac, the deep posterior fornix or posterior cul-de-sac, and the lateral fornices (Ball et al., 2014). The fornices are of clinical significance because the internal pelvic organs can be palpated through their thin walls (Ball et al., 2014). The length of the vagina, however, varies as the anterior vaginal length is approximately 6 to 9 cm, while the posterior length is approximately 8 to 12 cm (Baggish & Karram, 2020; Gershenson et al., 2021). This broadly describes the vagina, however, the exact shape cannot be characterised as reported by Barnhart et al. (2006), as a result of variables such as parity, age, and height causing variation.

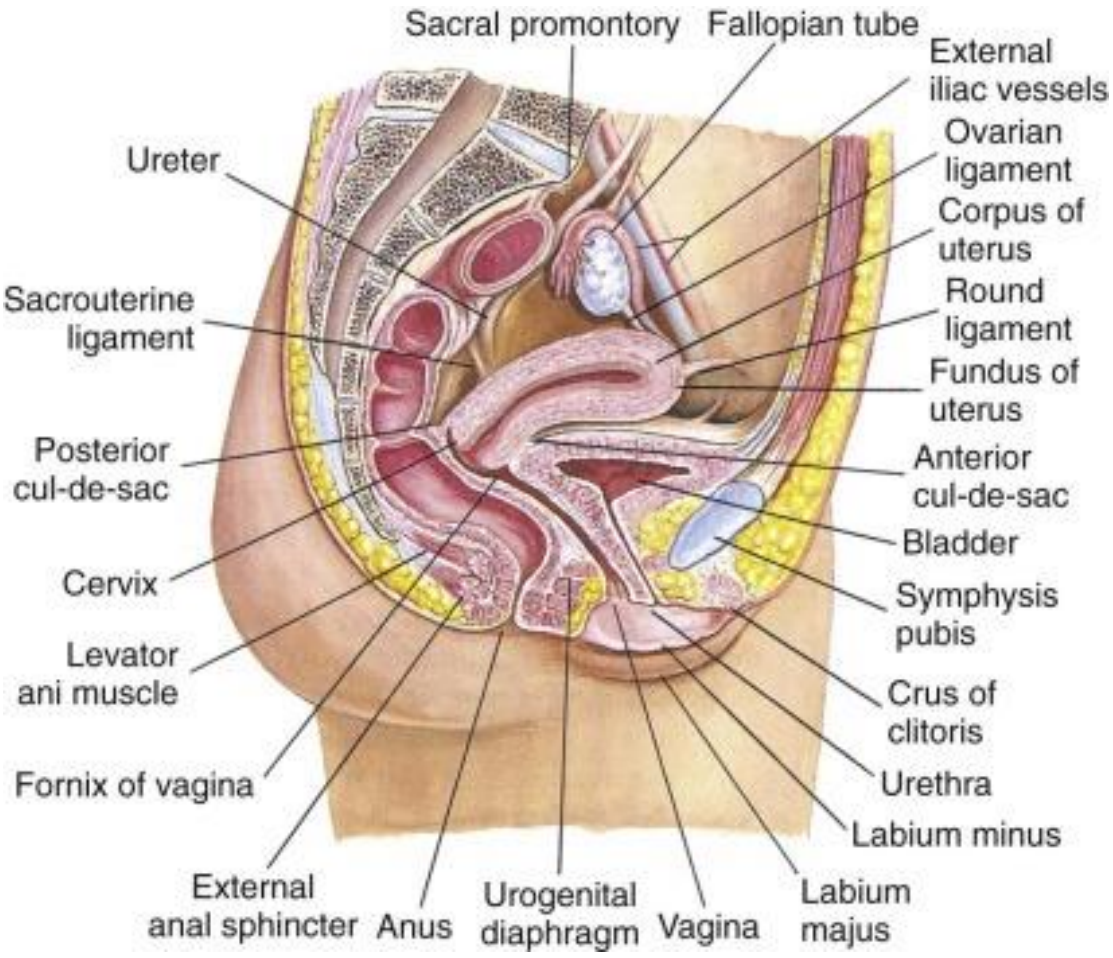


Figure 2-1 Cross Section of the Female Pelvis (Ball et al., 2014)

2.1.2 The Cervix

The cervix is described as a barrel-shaped structure that consists predominantly of fibrous tissue (Ball et al., 2014). The cervix extends from its external cervical os, to its internal cervical os where it continues into the uterine cavity. These two openings are connected by the cervical canal as shown in Figure 2.2. The external os in women who have not given birth vaginally is small and circular while in women who have had vaginal deliveries, it is linear or oval (Swartz, 2014). The cervical canal is fusiform in shape, and its length and width vary; it is usually 2.5 to 3 cm in length and 7 to 8 mm at its widest point according to Gershenson et al. (2021). The cervical canal opens into the vagina at the external os and the uterine cavity at the internal os as seen in Figure 2.2. Direct visualisation of the cervix for examination is achieved with the aid of a speculum, as seen in Figure 2.3.

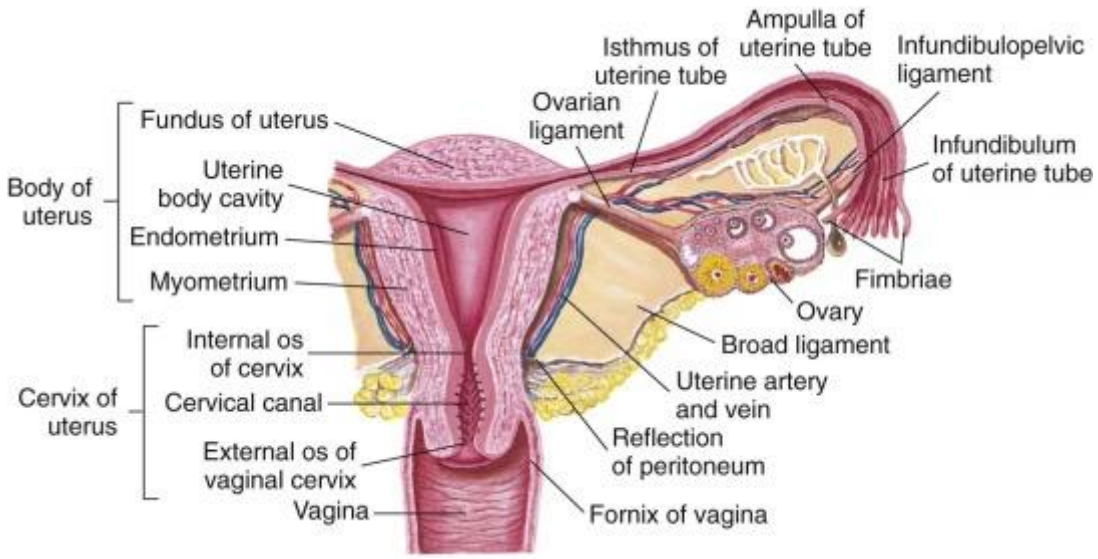


Figure 2-2 Cross Section of the Cervix and Uterus (Ball et al., 2014)

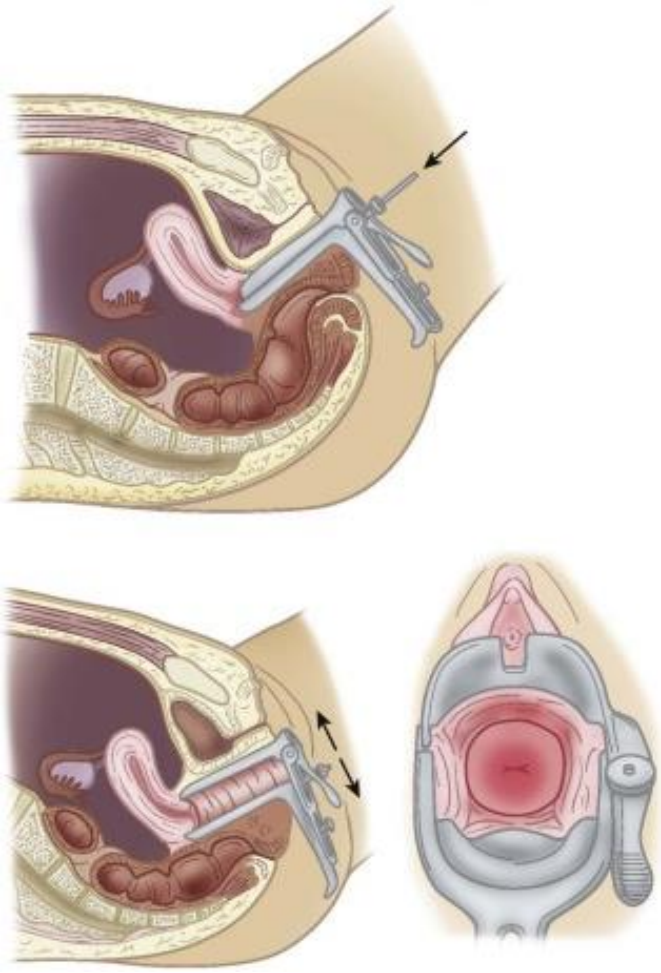


Figure 2-3 Examination of Cervix with Speculum (Ball et al., 2014)

2.1.3 The Uterus

The uterus is a hollow, muscular, pear-shaped organ situated in the pelvic cavity (Ball et al., 2014), as seen in Figure 2.2. Its size depends on previous pregnancies and the hormonal status of the female (Gershenson et al., 2021). The uterus of a nulliparous woman, one who hasn't given birth, is approximately 5.5 to 8 cm long and 3.5 to 5 cm across at its widest point (Ball et al., 2014; Gershenson et al., 2021). In a parous woman, one who has given birth, the uterus is on average 9 to 10 cm long, and 6 to 7 cm wide (Ball et al., 2014; Gershenson et al., 2021). Typically, an angle of at least 90° is formed between the axis of the vagina and the axis of the uterus (Gershenson et al., 2021; Standring, 2020), this can be seen in Figure 2.1. This position is known as anteversion, such that the uterine fundus is anterior to the uterine cervix. However, this position differs, and it is possible for the uterus to be either anteflexed, anteverted, retroverted, or retroflexed (Swartz, 2014), as shown in Figure 2.4, leading to different angles between the uterus and the vagina.

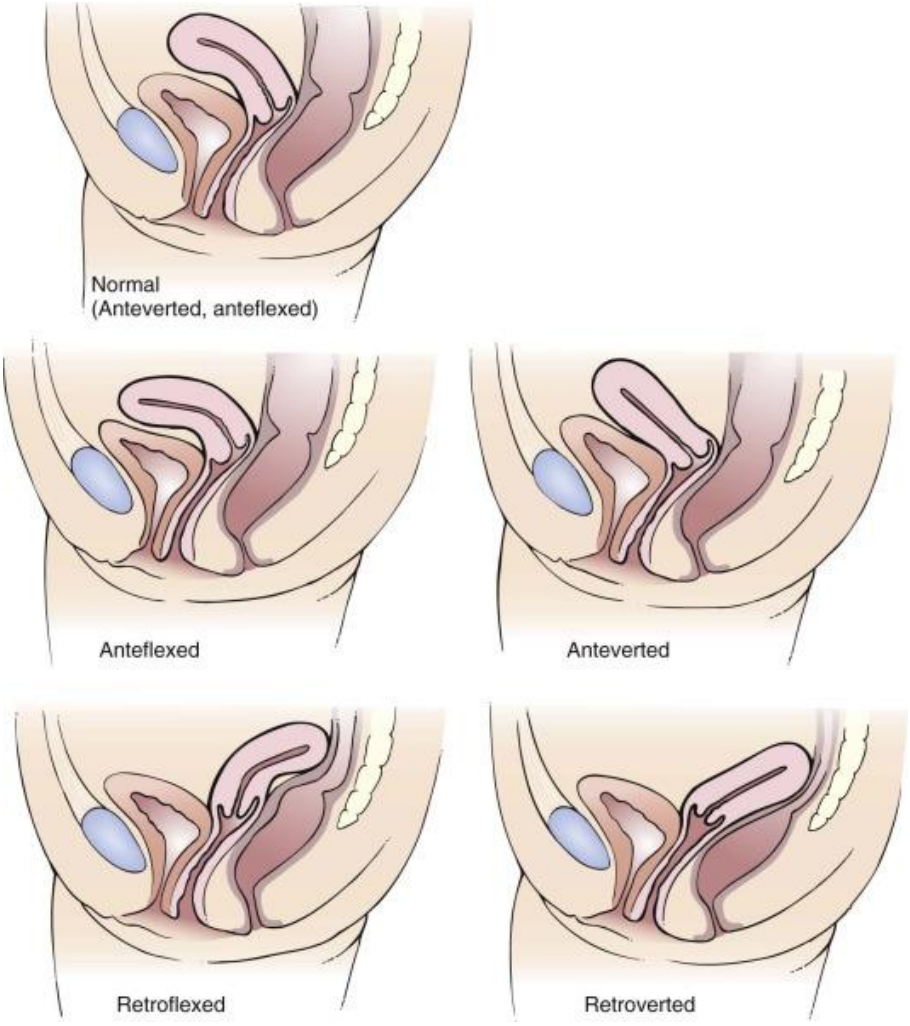


Figure 2-4 Common Uterine Positions (Swartz, 2014)

2.1.4 Summary of Key Anatomical Features

In summary, successfully navigating the anatomy of the female genitalia into the uterine cavity requires taking note of key features discussed in Section 2.1. A hysteroscope, for example, would need to pass through the length of the vaginal canal and cervix, then navigate around the angle created by the axes of the vagina and uterus which depends on the position of the uterus. Table 2.1 below lists the features that would impact a hysteroscope when navigating the anatomy during a procedure. The requirements listed alongside the anatomical features in Table 2.1 will be used in the development process of the hysteroscopy system described in Chapter 3 of this thesis.

Table 2.1 Key Anaotomical Features & Requirements

Anatomical Feature	Requirement
Vagina length	12 cm based on maximum length of posterior vaginal length[1,2]
Length of cervix	3 cm based on maximum length[1]
Angle of uterus	90° angle between uterus and vagina[1,3]
Uterus length	10 cm based on maximum length in parous women[1,2]
Uterus width	3.5 cm based on minimum width in nulliparous women[1,2]
Total length	25 cm combining vagina, cervix, and uterus length

[1](Gershenson et al., 2021); [2](Ball et al., 2014); [3](Standring, 2020)

2.2 Methods for Uterine Evaluation

Different methods for evaluation of the uterine cavity exist that provide the ability to visualise its structural components. Although similar, each diagnostic method has a focus. Factors such as simplicity, accuracy, and degree of invasiveness further differentiate methods and influence the application thereof. While office hysteroscopy is the theme of this research project, the alternative methods of in-office evaluation are discussed in this section to ensure this decision is justified.

2.2.1 Transvaginal Sonography (TVS)

Transvaginal sonography uses an ultrasound probe that is placed directly into the vagina to obtain detailed images of the cervix and uterus. TVS has traditionally been the first-line diagnostic tool for uterine evaluation, and most gynaecologists are familiar with the

technique as it forms part of basic training in obstetrics and gynaecology (di Spiezio Sardo et al., 2016). The close proximity of the probe to the uterus allows for use of high frequency transducers which provides better image quality and anatomic detail (Rumack et al., 2005). The goal of a TVS examination is to exclude pathological conditions and thereby make endometrial sampling unnecessary (Lalchandani & Phillips, 2003). TVS is an easy, fast, and cheap technique that is less invasive, and generally painless without complications (Abd Elkhalek et al., 2016; Lalchandani & Phillips, 2003).

2.2.2 Saline Infusion Sonohysterography (SIS)

Saline infusion sonohysterography is an ultrasound technique where the uterus and contents of the uterine cavity are analysed through the use of high contrast medium (Zinna et al., 2015). It is a low-tech, low-cost, and low pain score enhancement of TVS (Lalchandani & Phillips, 2003). SIS involves the instillation of sterile saline solution into the uterine cavity under ultrasound guidance. The saline is injected through a special transcervical catheter inserted into the uterus. The saline distends the cavity, thereby showing structural abnormalities, while the uterus is scanned systematically, and appropriate images are recorded (Brown et al., 2000). However, compared to TVS, due to the catheters used, SIS is more invasive investigation that causes discomfort to patients and occasionally a vasovagal attack (Lalchandani & Phillips, 2003).

2.2.3 Diagnostic Hysteroscopy (DH)

Diagnostic hysteroscopy is an evaluation method that involves the use of a telescopic device, known as a Hysteroscope, to observe the uterine cavity directly. The Hysteroscope may be either rigid or flexible and employs a sheath to deliver distention media as it travels through the vagina, cervix and into the uterine cavity (Unfried et al., 2001). The sheath also provides working channels for the insertion of operative instruments. These instruments are used to perform simple operations such as a biopsy. DH can be performed either in-office or as a day-case procedure, in the operating theatre where full fitness to work occurs more quick after an in-office procedure (Lalchandani & Phillips, 2003). The advantage of direct visualization and the ability to treat in the same procedure has resulted in hysteroscopy generally being accepted as the gold standard for evaluation of the uterine cavity (di Spiezio Sardo et al., 2016).

2.2.4 Comparison of Methods

Numerous studies have been performed to investigate and compare the efficacy of the uterine evaluation methods mentioned (Grimbizis et al., 2010; Kelekci et al., 2005; Soguktas et al., 2012). TVS is highly applicable, non-invasive and typically used as a first line investigation, SIS provides improved visualization by distending the uterine cavity while still being well tolerable, and finally, hysteroscopy offers the advantage of direct visualization of the uterine cavity. The performance of these methods was evaluated by comparing factors such as diagnostic accuracy, procedure time, and pain scores. In a study conducted by Kelekci et al. (2005) TVS, SIS and DH were assessed to determine each technique's ability to detect intracavitary abnormalities. Kelekci et al. (2005) reported that SIS and DH had a similar diagnostic performance, however SIS was found

to be less painful for patients than DH. In this study office hysteroscopy was performed using a 3.5mm rigid Hysteroscope in an outpatient setting without anaesthesia. Kelekci et al. (2005) concluded that SIS may be useful and non-invasive, however hysteroscopy still enabled the option for simultaneous diagnosis and treatment.

Grimbizis et al. (2010) reported performing a more precise statistical method to compare different diagnostic techniques. The study implemented a receiver operating characteristics (ROC) analysis to compare the diagnostic performances of TVS, SIS, and DH in a statistically rigorous fashion. The analysis results are shown in Figure 2.5 with the ROC curves for each technique. Grimbizis et al. (2010) stated that while hysteroscopy remains an expensive, interventional method, it was found to be the better diagnostic technique for any endometrial abnormality. Suna Soguktas et al. (2012) determined the overall effectiveness of TVS, SIS, and DH in a third study by comparing the area under the curve (AUC) values. The study found that although DH is invasive, expensive, and uncomfortable when compared to TVS and SIS, it offers superior diagnostic performance and allows biopsy to be taken.

A comparative summary of the characteristics of TVS, SIS, and DH are shown in Table 2.2 below. From the comparison and studies performed by Grimbizis et al. (2010), Kelekci et al. (2005) and Soguktas et al. (2012) it can be concluded that diagnostic hysteroscopy offers the highest performance regarding uterine evaluation combined with the ability to treat in the same procedure. However, hysteroscopy is limited in its application because of the high cost, invasiveness, and complexity involved with procedures in the operating theatre.

Table 2.2 Comparative Summary of Uterine Evaluation Methods

METHOD	TVS	SIS	DH
ACCURACY[1, 2, 3]	Lower value than SIS	Comparative value to DH	Highest diagnostic performance
PROCEDURE TIME[1, 4, 5]	Rapid procedure	Rapid procedure	Time consuming
DIFFICULTY[4, 5]	Simple, basic training	Simple procedure	Most complex procedure
COST[3, 4, 5]	Low cost	Low cost	High cost
INVASIVENESS[3, 4]	Least invasive	Invasive catheter	Most invasive with hysteroscope
SETTING[4]	In-office	In-office	In-office or operating theatre
OPERATIVE ABILITY[4]	Requires follow-up operation	Requires follow-up operation	Treatment in same procedure

[1](Kelekci et al., 2005); [2](Grimbizis et al., 2010); [3](Soguktas et al., 2012); [4](Lalchandani & Phillips, 2003); [5](Abd Elkhalek et al., 2016)

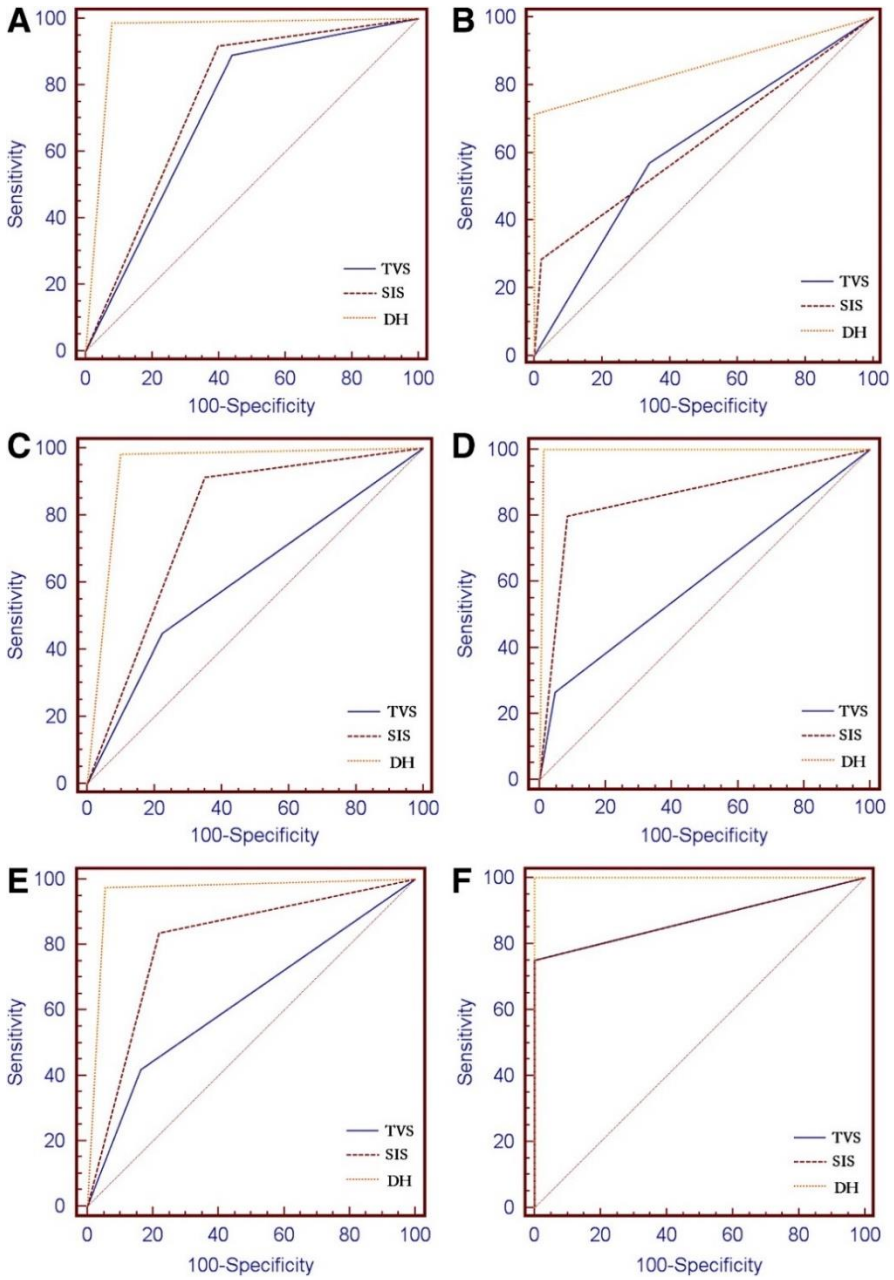


Figure 2-5 Receiver Operating Characteristics of Uterine Evaluation Methods for A. Any Endometrial Pathology, B. Endometrium Diseases, C. Intracavitary Masses, D. Myomas, E. Polyps, F. Structural Abnormalities (Grimbizis et al., 2010)

2.3 Hysteroscopy for Uterine Evaluation and Treatment

Hysteroscopy has been identified as the gold standard (Ma et al., 2017; Mairos & Di Martino, 2016), allowing for diagnosing and treating uterine conditions in the same procedure, resulting in the 'see and treat' methodology. However, potential shortcomings do exist that effect the application of hysteroscopy. This section aims to identify these shortcomings by reviewing the procedure and current equipment used to perform hysteroscopy as well as the findings of literature in the hysteroscopy landscape.

2.3.1 Hysteroscopy Procedure

Hysteroscopy is typically performed in hospitals or in the offices of the medical professional (Capmas et al., 2016). The procedure involves the following steps (Zelivianskaia & Robinson, 2022).

- The patient is placed in the lithotomy position for access to the vagina.
- A speculum may then be inserted into the vagina to hold it open.
- The hysteroscope is then inserted into the vagina and gently moved through the cervix into the uterus as seen in Figure 2.6 below.

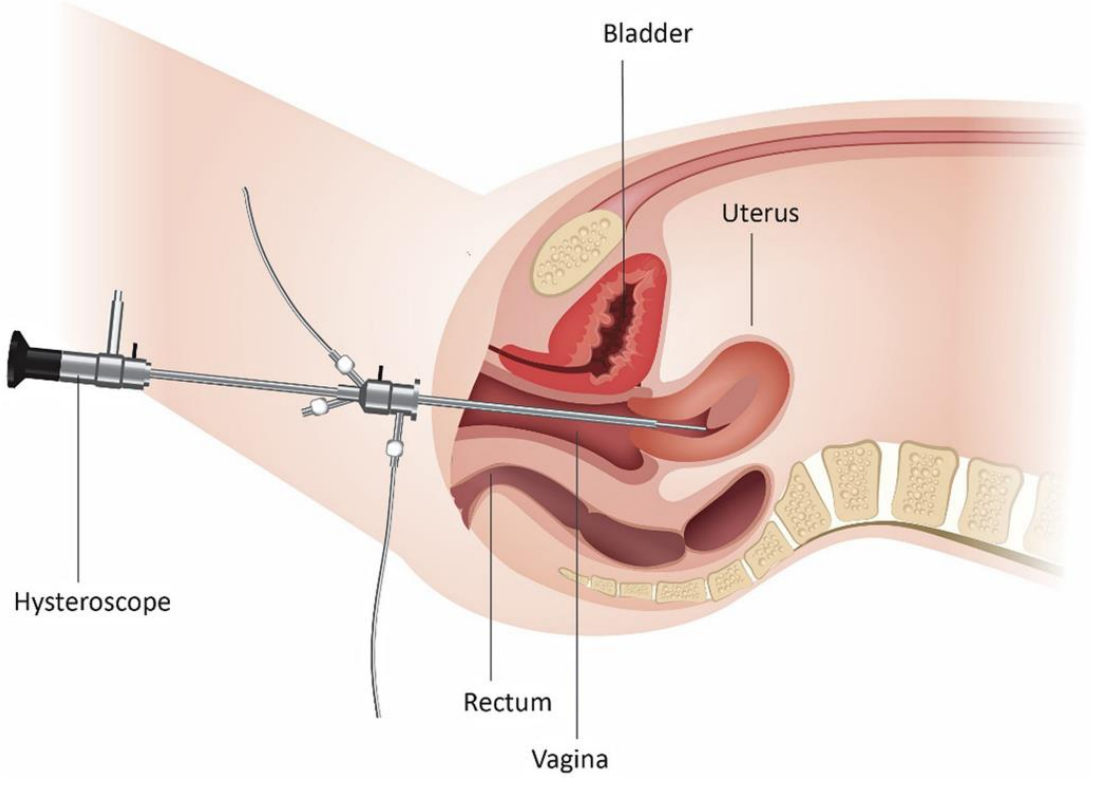


Figure 2-6 Hysteroscopy Procedure with Rigid Hysteroscope (*Outpatient Hysteroscopy*, 2018)

- If entry is difficult, a tenaculum may be used to grasp and position the cervix to gain entry with the hysteroscope.

- Through the hysteroscope, a distention media, typically saline solution or carbon dioxide gas, is pumped into the uterus to expand it and clear away any blood and mucus. The different options for distention media are shown in Figure 2.7 below.

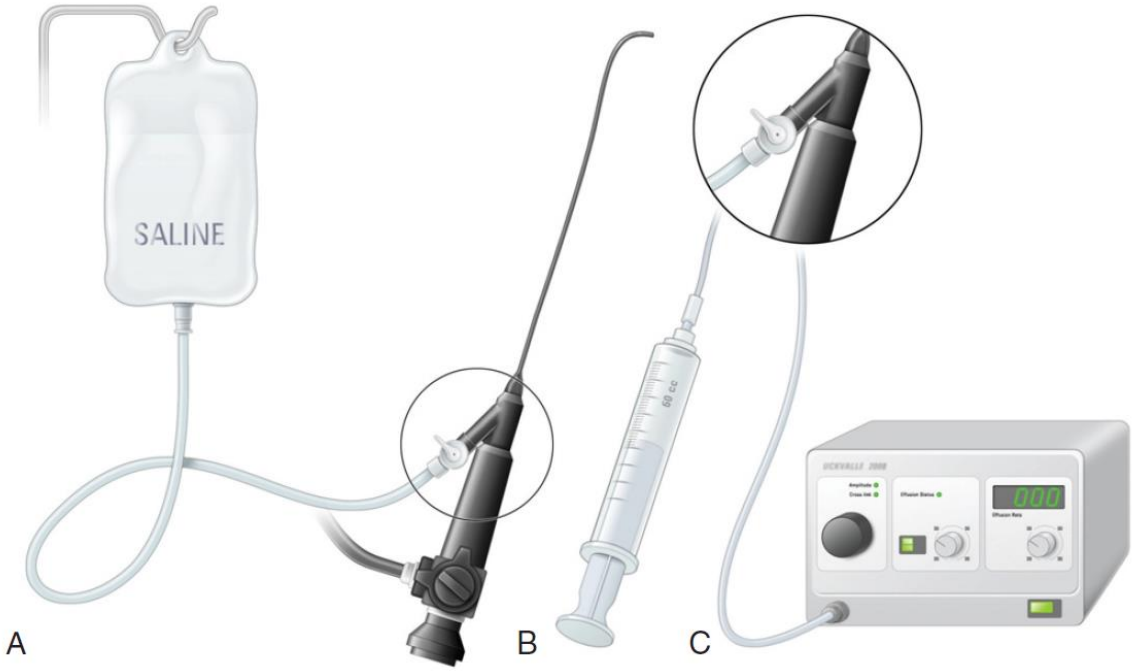


Figure 2-7 Distention Media Options used in Hysteroscopy: A. Gravity Saline Infusion B. Syringe Saline Infusion C. Carbon Dioxide Insufflator (Bradley & Falcone, 2008)

- Light generated from an external source and connected to the hysteroscope, is shone through the hysteroscope, allowing the physician to examine the uterine cavity.
- A video camera mounted on the hysteroscope is used to display the live image on a screen for the physician to view. Images can be captured during the procedure for later review.
- If needed, small instruments are inserted through the hysteroscope sheath into the uterine cavity to perform surgeries such as taking biopsies or removing polyps.
- The physician manipulates the hysteroscope by rotating and tilting it to observe the entire uterine cavity fully.
- Hysteroscopy procedures lasts between 10 to 15 minutes (Isaacson, 2002), once the procedure is completed, the hysteroscope is removed from the patient and sterilised for reuse.

The general procedure of hysteroscopy is described as above; however, different hysteroscopy systems exist that impact factors of the hysteroscopy procedure.

2.3.2 Existing Hysteroscopy Systems

The current hysteroscopy systems used consist of different components to enable procedures to be carried out. The primary component being the hysteroscope, which can be either rigid or flexible (Unfried et al., 2001).

2.3.2.1 Rigid Hysteroscope

The 5 mm rigid hysteroscopes are the most commonly used to perform hysteroscopy procedures and consist of two components: the inner rod lens telescope and the outer sheath (Campo et al., 2005). The telescope is inserted into the outer sheath and fixed in place as shown in Figure 2.8 below.

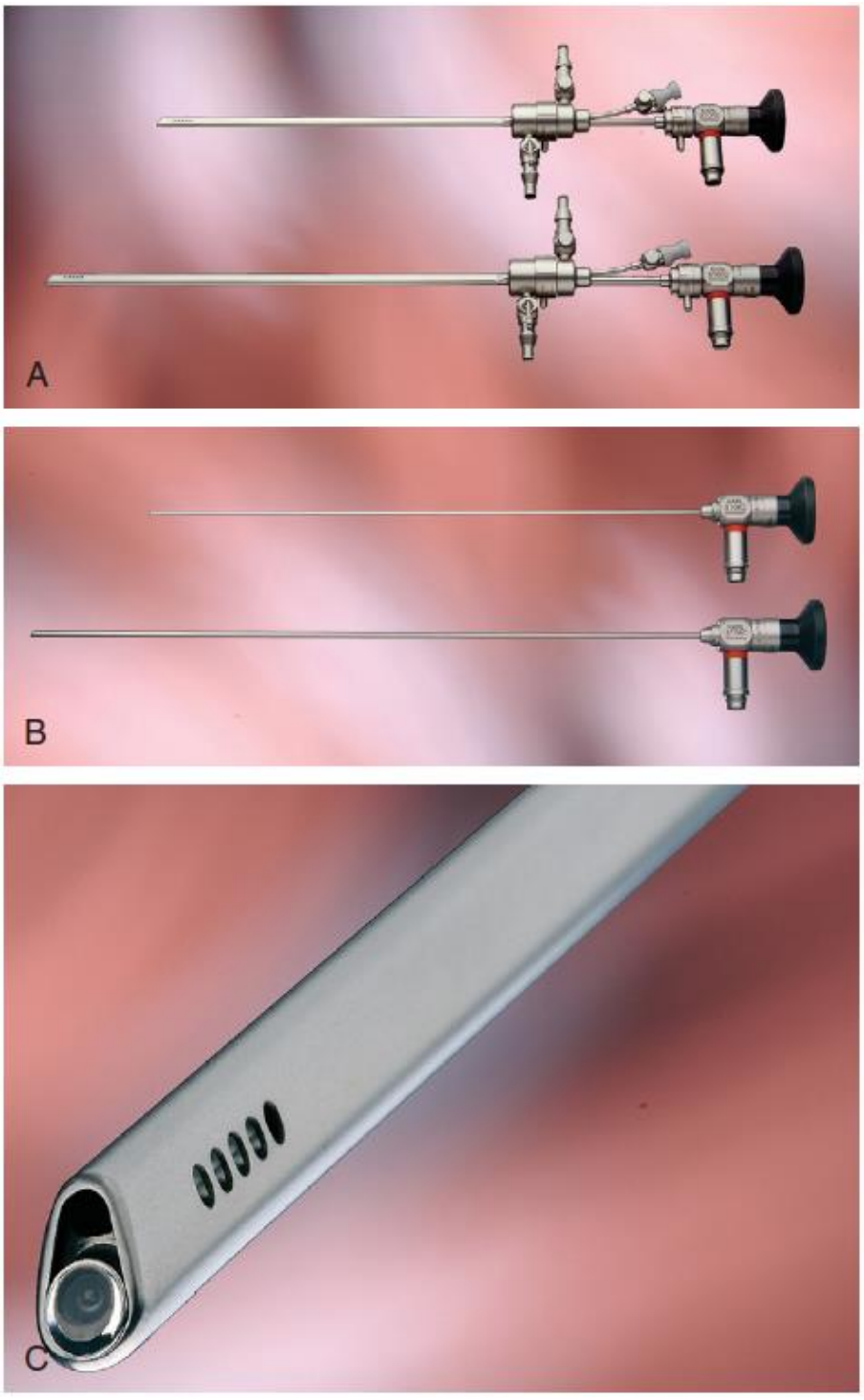


Figure 2-8 A. Rigid Hysteroscope in Sheath B. Hysteroscope without Sheath C. Close-up of Assembled Rigid Hysteroscope (Bradley & Falcone, 2008)

The viewing angle through the lens of the hysteroscope can be varied as shown in Figure 2.9 below, with 30° being the typical level of deflection that provides additional utility when examining the uterine cavity.

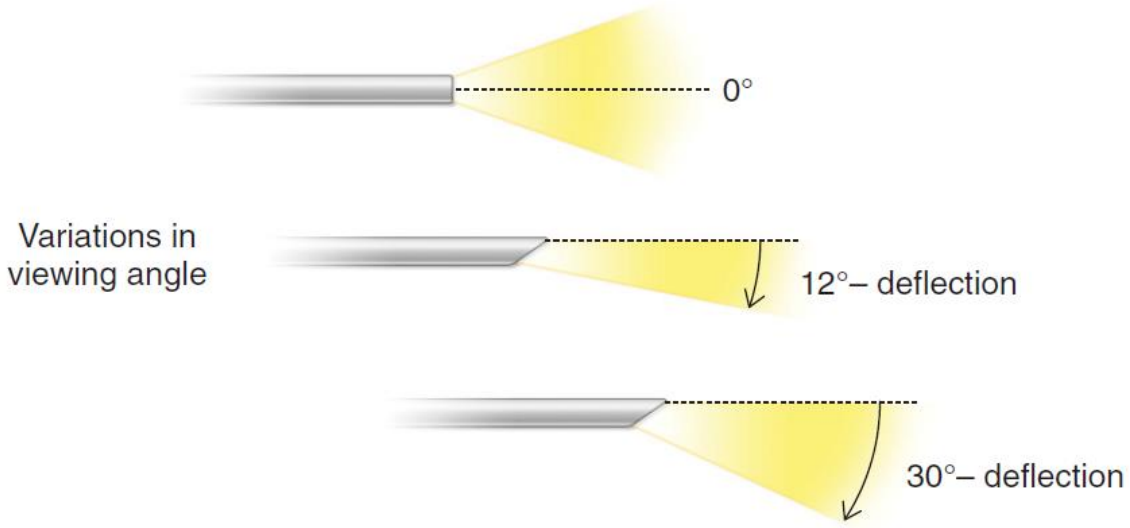


Figure 2-9 Rigid Hysteroscope Viewing Angles (Bradley & Falcone, 2008)

Developments with rigid hysteroscopes have led to reducing the outer diameter to improve the both the patient and physician experience, while maintaining excellent visual quality (Cicinelli et al., 2003).

2.3.2.2 Flexible Hysteroscope

The other main type of hysteroscopes are flexible hysteroscopes that offer several benefits during use. These hysteroscopes have a bidirectional bendable distal tip that is capable of angulation up to 100° in some devices (Isaacson, 2002). This allows for easier navigation through the patient's anatomy or around obstructions as shown in Figure 2.10 below.

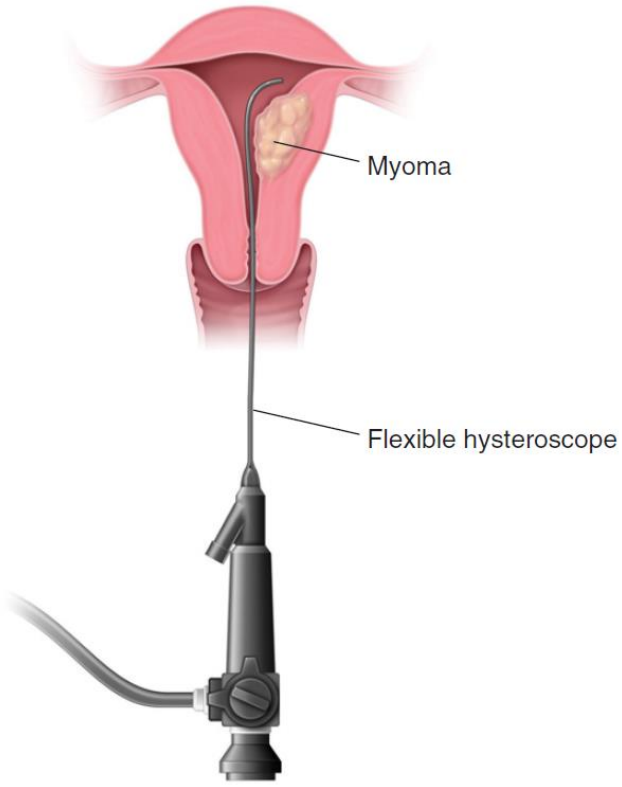


Figure 2-10 Flexible Hysteroscope Navigating Obstruction (Bradley & Falcone, 2008)

Both types of hysteroscopy systems described thus far require additional equipment for operation that increases the cost of setting up for in-office procedures, which also impacts the potential application of office hysteroscopy (Isaacson, 2002).

2.3.2.3 Additional Equipment

The standard hysteroscopy systems used consist of the hysteroscope and several pieces of additional equipment. Figure 2.11 below shows the basic setup for performing office hysteroscopy.

Figure 2-11 Office Hysteroscopy Setup Showing the Gynaecological Chair, Hysteroscopy Stack, and Distention Media (Pados & Makedos, 2015)

This setup has a gynaecological chair, video camera, monitor, light source, light cable, and pressure cuff for a fluid distention medium (Kolhe, 2015). Additionally, the facility should be equipped to sterilise the hysteroscope and accessories. The suitable sterilisation method depends on the hysteroscope's manufacturer's guidelines, a commonly used method is autoclaving. The guidelines for sterilisation would include additional cleaning steps required or the duration for which equipment remains sterilised.

2.3.2.4 New Hysteroscopy Systems

Developments with hysteroscopy systems have continued, leading to miniaturised hysteroscopes, more mobile equipment, and all-in-one systems with built-in cameras, light sources, and display. Examples of these new develops are shown in Figure 2.12 below.

Figure 2-12 New Developments in Hysteroscopy Showing (left) A Mobile Camera with a Light Source and (right) an Endosee Hysteroscopy System (Emanuel, 2013)

The Endosee shown on the right in the Figure above is an example of hysteroscopy systems that have single use components. The Endosee uses a single use cannula that includes the camera and light source while the handheld component and screen are reusable. This allows the system to avoid intense sterilisation between uses (Harris, 2013).

While current and new hysteroscopy systems allow physicians to perform procedures, several shortcomings have been identified that effect the application of hysteroscopy outside of the operating theatre.

2.3.3 Shortcomings Preventing Office Hysteroscopy

Hysteroscopy is an effective, minimally invasive procedure that allows for direct visualisation and examination of the uterine cavity. While hysteroscopy has typically been performed in the operating theatre with patients undergoing general anaesthesia, office hysteroscopy without general anaesthesia is found to be successful, safe, and tolerated by patients (Isaacson, 2002). Compared to performing in the operating theatre, office hysteroscopy offers a decrease of anaesthesia-associated risks, time-cost effectiveness, and faster recovery. However, office hysteroscopy remains underutilised, and procedures are still performed in the operating theatre. Isaacson (2002) estimated that only 15% of gynaecologists in the US routinely perform office hysteroscopy, while Cooper and Clark (2013) stated that in 2010, 70% of diagnostic hysteroscopies were performed under general anaesthesia in the UK. These numbers are likely to have changed, however, the reasons provided for low office hysteroscopy rates may not have changed.

The reasons for low rates for office hysteroscopy are often stated to be inadequate management of pain, cost prohibitions for purchasing the necessary equipment, and the

high level of expertise required to perform office hysteroscopy (Salazar & Isaacson, 2018).

2.3.3.1 Patient Discomfort

Pain experienced by patients during office hysteroscopy is one of the primary factors impacting the feasibility and rate of successful procedures. The diameter of the hysteroscope being used has been shown to contribute to the pain levels during a procedure significantly (Romani et al., 2013). Office Hysteroscopies are generally performed with 5mm instruments, more recent hysteroscopes with diameters of 3.5mm resulted in less painful procedures (Cicinelli, 2010). Numerous other studies (Campo et al., 2005; de Freitas Fonseca et al., 2014; del Valle et al., 2016) have reported similar findings showing that smaller diameter instruments reduce pain; however, when using a rigid hysteroscope, discomfort at the introduction of the scope and during the procedure is still experienced (Capmas et al., 2016). This is due to up and down and side-to-side motions necessary to inspect the uterine cavity (Unfried et al., 2001). This problem is addressed using flexible hysteroscopes that can navigate the patient's canal with less motion and, thereby, less pain than rigid hysteroscopes. Flexible hysteroscopes are even capable of negotiating the cervical canal of acutely an acutely anteverted or retroverted uterus (Marsh & Duffy, 2004).

However, flexible hysteroscopy systems have several disadvantages that hamper its use; higher cost to purchase and maintain equipment, increased effort for sterilisation and often not autoclavable, greater frailty due to fibreoptics used, and more incredible difficulty to use (Salazar & Isaacson, 2018; Sardo et al., 2015; Unfried et al., 2001; Vitale et al., 2020).

An additional measure to reduce patient pain is the vaginoscopy technique, or the 'no touch' approach. This refers to where the hysteroscopy is introduced into the vagina, through the cervical canal, and into the uterine cavity without the need for a speculum or tenaculum. This technique is associated with significantly less procedural pain (Ekin et al., 2009).

The type of distention media used in office hysteroscopy was not found to affect pain when either saline or carbon dioxide was used, according to a systematic review completed by De Silva et al. (2021). However, saline was associated with less unsatisfactory images, faster procedures, higher patient satisfaction, and improved diagnosis confidence of gynaecologists.

2.3.3.2 Level of Expertise Required

Studies reported that office hysteroscopy was perceived to require a level of skill to perform (Cicinelli, 2010; Isaacson, 2002), however, the developments in hysteroscopes benefited the physician as well in this regard. Campo et al. (2005) determined in a trial evaluating factors influencing the success rate of office hysteroscopy, that the skill of the operator is not important when small diameter hysteroscopes are used. A study conducted by Pluchino et al. (2010) also found that gynaecologist experience was not important when using small diameter scopes, however, they also found that adverse effects and complication rates were affected by experience level. Therefore, both instrument size and training level played critical roles for well tolerated procedures.

2.3.3.3 Cost of Equipment

While developments have succeeded in addressing factors impacting the rates of office hysteroscopy, the cost of equipment potentially remains a barrier to gynaecologists. Isaacson (2002) reported that the basic office hysteroscopy package costs approximately $5000USD without the hysteroscope. Rigid hysteroscopes are priced at approximately $2500USD and flexible hysteroscopes between $5000USD and $7000USD. A more recent study completed by Munro et al. (2022) developed an economic model comparing different hysteroscopy systems. These included traditional systems and purpose-built systems such as the Endosee in the previous Figure 2.12. The primary costs of two traditional systems and one purpose-built system are given in Table 2.3 below. The purpose-built system has a single use camera and light source cannula.

Table 2.3 Cost of Hysteroscopy Systems (Munro et al., 2022)

Hysteroscopy System	Total Equipment Cost (USD)	Consumable Cost (USD)
Traditional A	53 599	0
Traditional B	62 549	0
Purpose-Built	3 295	175

The above Table highlights the incredibly high up-front cost for procuring traditional hysteroscopy systems, that still exclude additional minor instruments. The purpose-built systems offer an alternative solution to performing office procedures, however with a consumable per-use cost that can be prohibitively high as stated by Wright and Simko (2021).

2.3.4 Summary of Hysteroscopy Systems

Current hysteroscopy systems use either rigid or flexible hysteroscopes, where each type offers different advantages or disadvantages that influence the gynaecologist's decision making when procuring equipment for in-office procedures. Table 2.4 below summarises the advantages and disadvantages of the types of hysteroscopes following the findings of the literature review.

Table 2.4 Advantages & Disadvantages of Hysteroscope Type

HYSTEROSCOPE TYPE	RIGID	FLEXIBLE
ADVANTAGES	• Miniature scope sizes available (Romani et al., 2013) • High quality images (Unfried et al., 2001) • Vaginoscopic technique (Sharma et al., 2005)	• Significantly less pain than rigid (Unfried et al., 2001) • No cervical dilation required (Sardo et al., 2015)

		• Able to navigate different uteri (Marsh & Duffy, 2004)
DISADVANTAGES	• Pain dependent on size, operator skill level (Pluchino et al., 2010) • Motions during use cause pain (Siristatidis et al., 2010) • Requires additional equipment (Kolhe, 2015) • High cost (Isaacson, 2002)	• May require tools to enter cervix (Marsh & Duffy, 2004) • Much higher cost (Jacobs et al., 2005) • Increased effort to clean, disinfect, and sterilise (Salazar & Isaacson, 2018) • Reduced image quality (Unfried et al., 2001) • Fragile (Salazar & Isaacson, 2018) • Greater difficulty to use (Sardo et al., 2015)

In summary, both rigid and flexible hysteroscopes offer several advantages when performing office hysteroscopy procedures. Rigid hysteroscopes have undergone developments to produce miniature diameter scopes that not only reduce the pain experienced by patients but allow for less skilled operators to perform procedures. Additionally, these still produce excellent images and when combined with the vaginoscopic technique, further reduces the pain. However, the pain caused is dependent on the size of the scope and the operator's experience as motions during the procedure result in greater discomfort. Lastly the rigid scopes still require expensive additional equipment, causing the overall cost of equipment to be a barrier for adoption.

Flexible hysteroscopes offer an improvement by reducing the pain during procedures even further, without needing cervical dilation and can navigate even acutely anteverted or retroverted uteri. However, these scopes are even more costly than rigid scopes while potentially requiring use of a speculum or tenaculum to enter the cervix which also increases the difficulty to use. Flexible scopes require increased effort to clean, disinfect, sterilise and are more fragile than rigid scopes, these factors potentially limit the adoption of flexible scopes for in-office procedures despite the decreased patient discomfort.

2.4 Proposed Hysteroscopy System Need Criteria

The review of the current hysteroscopy landscape showed that while being a safe and effective procedure outside of the operating theatre, several factors reduce the application of office hysteroscopy procedures. It is the aim of this research project to develop a hysteroscopy system that addresses the shortcomings of existing systems that could potentially increase the adoption of office procedures, thereby increasing the access for patients. To achieve this, the need criteria of a proposed hysteroscopy system

should be established. Need criteria represent what a potential solution should do without specifying how it will do it. Essentially guiding the process of developing a solution without immediately determining what the exact solution is.

The need criteria for the hysteroscopy system are focused on three factors: the patient, the physician, and the facility. By addressing the shortcomings of current systems with regards to the three factors, the proposed system would provide the means for increasing the application of office hysteroscopy. Based on the literature review of the relevant anatomy, alternative evaluation methods, current hysteroscopy systems, and observing hysteroscopy procedures while interacting with gynaecologists, the need criteria selected are listed in the Table 2.5 below.

Table 2.5 Need Criteria of Proposed Hysteroscopy System

FACTOR	SHORTCOMING	NEED CRITERIA
Patient	Causes of patient discomfort	Small diameter and flexible
	Use of tools such as speculum or tenaculum	Able to apply vaginoscopic technique
Gynaecologist	Difficult to use	User friendly design
	High effort to clean	Disposable components
Facility	High setup cost	Eliminate additional equipment
	Requires sterilisation	Isolate equipment from environment

The need criteria shown in Table 2.5 represents what impedes the adoption and success rate of office hysteroscopy procedures. A hysteroscopy system that meets these need criteria would present a solution that would be more affordable, easier to use, set up and clean, while reducing patient discomfort. Essentially addressing the shortcomings of hysteroscopy systems that prevent or discourage gynaecologists from performing office hysteroscopy procedures. The need criteria from Table 2.5 will be used in the subsequent design process as design inputs to guide the development of the proposed hysteroscopy system.

3 FlexiGyn – A Mobile Flexible Hysteroscopy System

This chapter describes the design methodology for developing the hysteroscopy system. The design requirements of the proposed hysteroscopy are presented, followed by an overview of the prototypes developed that include findings gained from each. The chapter ends with an overview of the final prototype design, the outcome, a basic overview of its operation, and a summary of the design outcomes.

3.1 Design Methodology

The design methodology of this research project followed a V-model approach, as shown by Figure 3.1 below. This model represents the developed novel hysteroscopy system's design process that begins with the identification of identifying the need criteria through thorough background research. These criteria were then translated into measurable design requirements to guide the prototyping stage. Further simplification of the prototyping stage was achieved by dividing the hysteroscopy system into subsystems representing different functions. The subsystems were then prioritised according to the anticipated level of technical challenge, which determined the order for prototyping, beginning with the most challenging subsystem.

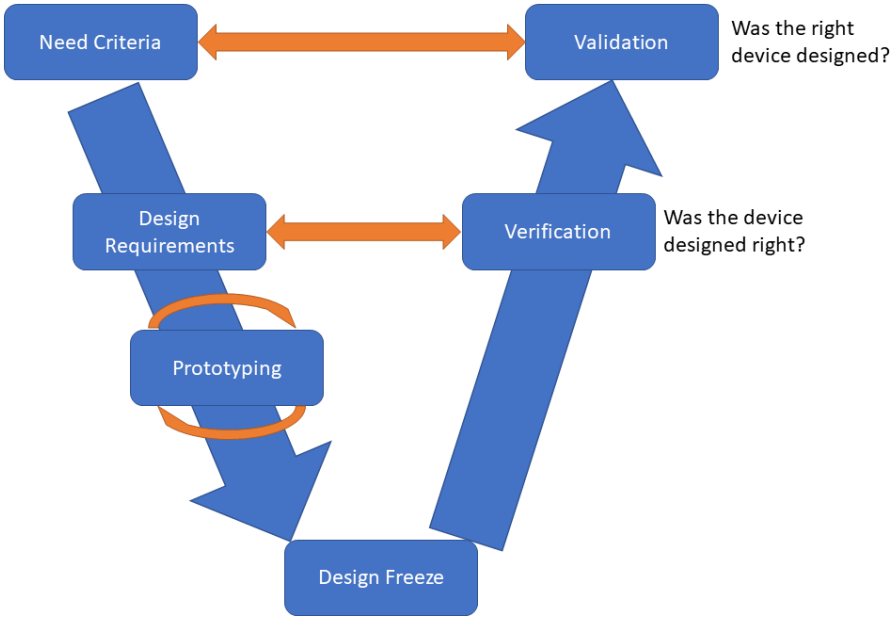


Figure 3-1 Design Methodology V-Model. The model shows the design approach of the research project that consisted of translating need criteria to design requirements, prototyping around the requirements, and the performing verification and validation on the resulting prototype.

Prototype development was an iterative process that was repeated until a prototype was produced that, through initial evaluation, seemed to meet all design requirements. The design was then frozen and taken into the next stage, verification testing. The purpose of verification was to compare the prototype system against the design requirements to

determine if it successfully demonstrated the requirements. Testing consisted of bench tests and computer simulations to assess to what extent the prototype system met the requirements.

If a prototype demonstrated its capability to a sufficient level, it would proceed to the final stage of the V-model, validation testing. Validation determined if a prototype performed its intended use successfully and to what level according to the initial need criteria established. This involved user testing of the prototype and comparison with the current standard systems used. The research project would be concluded following a prototype that passed the validation stage.

3.1.1 Design Requirements

According to the V-model, the need criteria established in Chapter 2 should be translated into design requirements. This process is necessary to move from 'what a system needs to do' to 'how a system will do it' and is crucial for the prototyping stage. Table 3.1 below shows the proposed hysteroscopy system's need criteria and related design requirements. These requirements were determined from the background research and interviews conducted with gynaecologists.

Table 3.1 Design Requirements of Proposed Hysteroscopy System

NEED CRITERIA	DESIGN REQUIREMENT
Small diameter and flexible	• Diameter < 4.7 mm[1] • Flexible with 100° bidirectional bending[2, 3] • Working length => 250 mm[2]
Able to apply vaginoscopic technique	
User friendly Design	• Handheld and mobile user-friendly device • Built-in camera, light source, and display • Battery powered for 10-minute procedures[4]
Eliminate additional equipment	
Disposable components	• Disposable, single-use sheath • Distention media channel for saline solution up to 200 mmHg pressure[1]
Isolate equipment from environment	

[1](Siristatidis et al., 2010); [2](Table 2.1); [3](Marsh & Duffy, 2004); [4](Oraif, 2016)

The design requirements represent the parameters of a tangible hysteroscopy system that this research project aims to develop. These requirements were assigned to the hysteroscopy subsystems to guide the prototyping process further and is discussed in more detail in the following section.

3.1.2 Hysteroscopy Subsystems

The system's design is an iterative process; prototypes are adjusted and modified to improve functionality. The design of the sub-systems is an integral part of the design process, as each represents a parameter that influences the overall efficacy. Figure 3.2 below shows the hysteroscopy subsystems with high-level components and functions. From the figure, these are the Smart Bending Mechanism (SBM), Mobile Visualisation Platform (MVP), Handheld Base (HB), and Disposable Sheath (DS). Each subsystem would be prototyped until the design requirements were met and integrated to build a complete hysteroscopy system. However, the development of the subsystem prototypes would occur in order of the technical difficulty of each to focus on refining the high-risk components of the hysteroscopy system for a more time-efficient process.

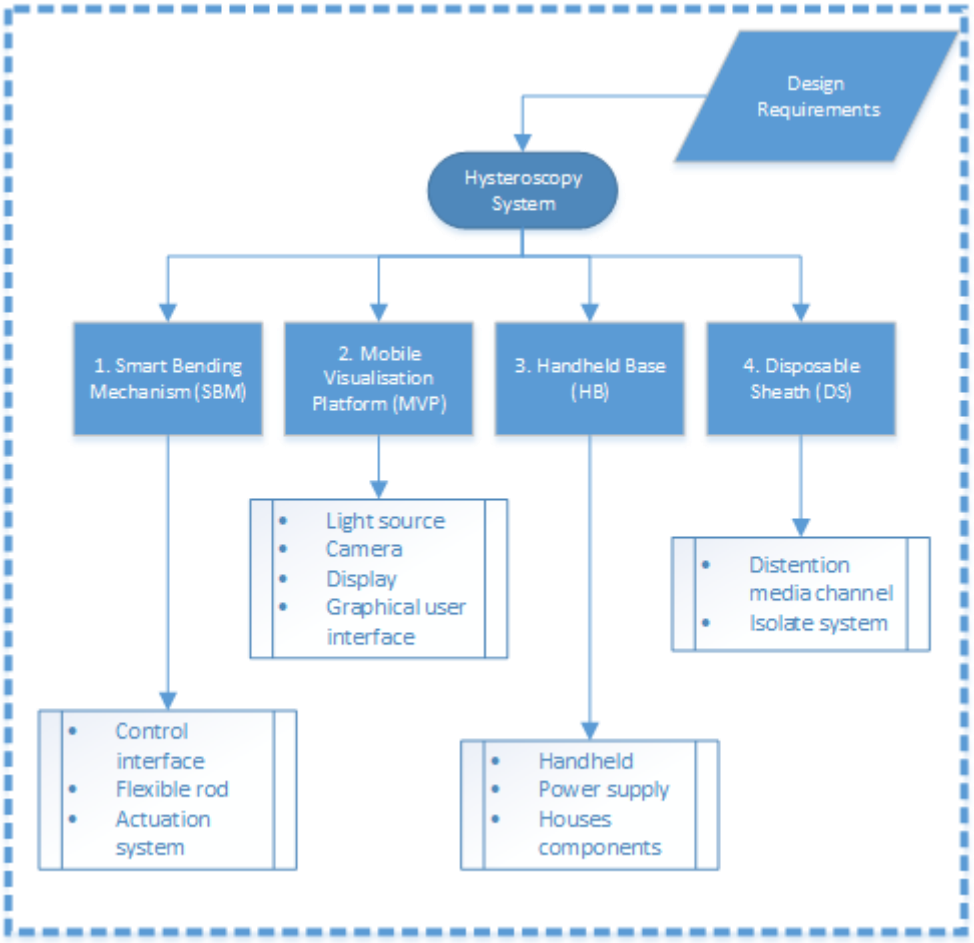


Figure 3-2 Proposed Hysteroscopy Sub-Systems. The proposed hysteroscopy was broken up into sub-systems with the main functions listed for each sub-system.

- Smart Bending Mechanism – the SBM has the highest technical challenge as it determines the system's flexibility and diameter. These two factors will determine how easily the user can navigate the patient's anatomy while avoiding causing too much pain due to excessive motions. The control interface of the SBM should also be simple and intuitive to use to ensure users with varying levels of experience can use the system. Lastly, the SBM should allow for integration of the MVP and being integrated into the Handheld Base.

- Mobile Visualisation Platform – This subsystem provides the means for viewing and displaying images during the hysteroscopy procedure with sufficient light sources and a graphical user interface for the operator to adjust settings. The MVP must meet the size limitations of the system and integrate into the Smart Bending Mechanism while the display forms part of the Handheld Base.
- Handheld Base – The primary purpose of the HB is to house the power supply and electronics of the system while integrating the other subsystems. It will, therefore, be designed around the form factor of these components. The user should be capable of holding and operating the system with a single hand, and the base should allow for this.
- Disposable Sheath – The Disposable Sheath is the final subsystem to be prototyped once the other subsystems have been developed to an acceptable standard. This is due to the sheath being heavily dependent on the size and shape of the components it will be placed over. Prototyping the sheath too early will likely lead to designs being redone too often; therefore, it's more efficient to develop sheaths once the other subsystems are nearing completion. The primary purpose of the sheath is to isolate the main reusable system from the environment during procedures to avoid it requiring intense sterilisation between uses. The distention media supply would, therefore, need to be connected through the sheath, and the visuals should not be obscured when the sheath is in place.

3.2 Prototype 1 – Proof of Concept

A proof-of-concept prototype of the proposed hysteroscopy system was developed to demonstrate the feasibility of the SBM, MVP, and HB in one device. The concept resulted from a brainstorming session focused on how controlled bending of a hysteroscope could be achieved. Figure 3.3 below shows the initial Computer Aided Design (CAD) model of the flexible tip that was part of the SBM concept.

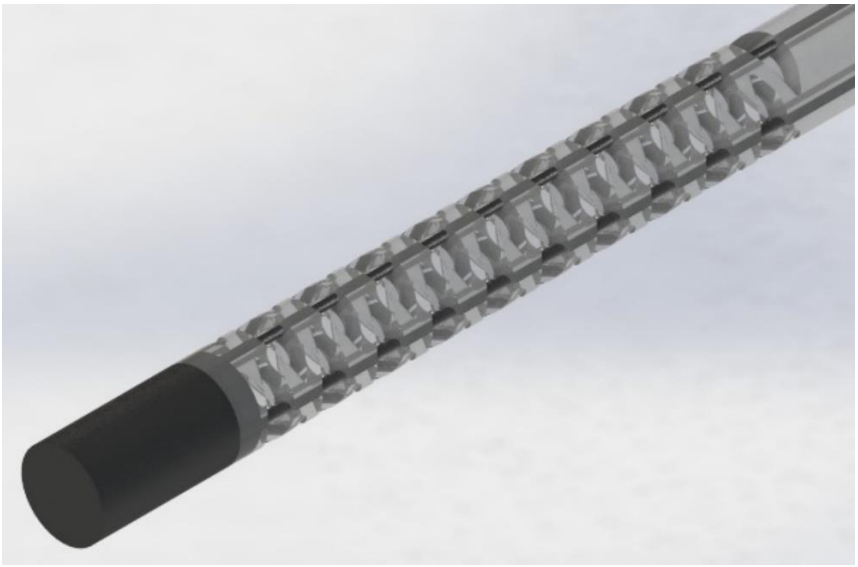


Figure 3-3 Flexible Tip Concept. The concept consisted of a camera module mounted on the distal tip with actuation wires connected that ran through a segmented flexible rod.

The concept involved the use of nitinol wires for its actuation of the bending of motion. Nitinol is a known as a shape memory alloy (SMA) and has widespread uses in medical devices due to its properties. SMA wires are able to contract like muscles when electrically driven or heated and can be stretched out again as it cools back down. These wires are ideal for producing motions in applications that have limited size constraints and were therefore selected for the Smart Bending Mechanism concept.

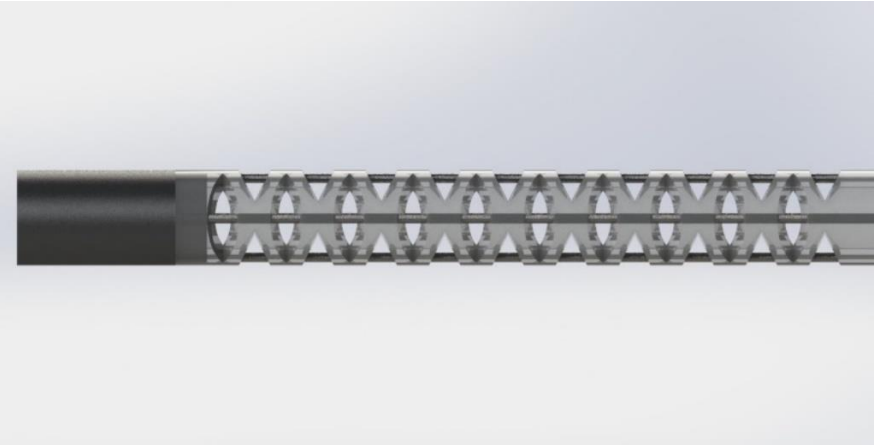


Figure 3-4 Side View of Flexible Tip. The view shows the segmentation of the flexible rod to facilitate the bending motion when the actuation wires are contracted.

As shown in the above Figure 3.4, the nitinol wires run along the length of the flexible rod, and towards the distal end, the rod is segmented. The purpose of these segments is to facilitate and localise bending when a wire is electrically activated. As the wire contracts, the segmented rod bends towards the side of the activated wire, the user would therefore be able to contract the bending direction depending on which wire is activated, while allowing the flexible rod to remain completely flexible.

A prototype of this concept was built using the following materials and is shown in the below Figure 3.5 with the Handheld Base (HB), Smart Bending Mechanism (SBM), and Mobile Visualisation Platform (MVP) subsystems labelled.

- The Handheld Base was 3D printed out of ABS plastic material and designed for the controls of the SBM to be mounted and hold its power supply.
- The Smart Bending Mechanism was constructed using an 8 mm, 2-lumen catheter with segments manually measured and cut out of. The catheter had nitinol wires mounted for each segment that was fixed in the Handheld Base and connected to a control circuit powered by a battery.
- The Mobile Visualisation Platform consisted of a 7mm android endoscope camera with built-in LED lights that was guided through the SBM and fixed to the distal end. The camera connected directly to an android smartphone was used as a display.

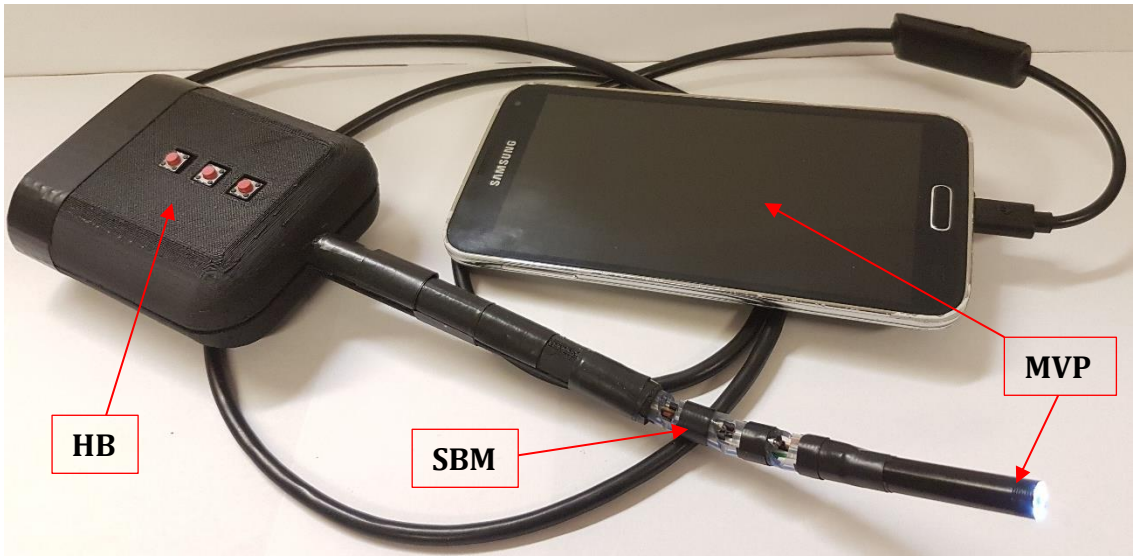


Figure 3-5 Proof of Concept Prototype. The prototype consisted of (HB) the Handheld Base, (SBM) the Smart-Bending Mechanism, and (MVP) the Mobile Visualisation Platform

The proof-of-concept prototype system demonstrated the feasibility of the three core subsystems of the proposed hysteroscopy system. Specifically, the potential of the SBM by using nitinol wires to produce bending motions which is shown in Figure 3.6 below. However, several issues were identified with the prototype that needed to be considered for the next, these are summarised in Table 3.2 below.

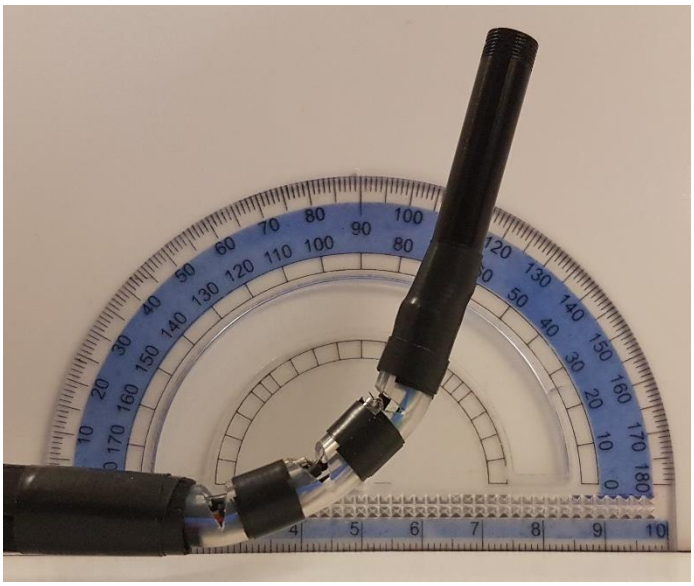


Figure 3-6 Proof of Concept Bending Tip. The bending capabilities of the prototype was measured using a protractor and was able to bend 70°.

Scale – The scale of the prototype, 8 mm, exceeded the size requirement specified and needs to be greatly reduced. This can primarily be done by sourcing smaller components and improving manufacturing methods. Additionally, the working length of 150 mm needs to be extended to meet the design requirement.

Flexibility – The prototype was only capable of motion in one direction, up to 70°, which did not satisfy the requirements. This was due to constraints from manufacturing by hand which would need to be improved upon. The scope was primarily rigid as well and would require redesigning to make the scope flexible.

Accuracy – The nitinol wires produced bending motion when activated but immediately began stretching back to normal when deactivated, as a result the prototype did not maintain positions which would affect accuracy of procedures. Improvements to the bending mechanism should be made to maintain fixed positioning.

Table 3.2 Prototype 1 Issues & Interventions

ASPECT	ISSUE	INTERVENTION
Scale	• 8 mm diameter • 150 mm working length	• Replace camera module with smaller unit • Extend portion of catheter tubing
Flexibility	• 70° one way bending • Rigid scope	• Add additional nitinol wires for bi-directional bending • Increase the number of segments to improve the bending angle • Extended catheter length for flexibility
Accuracy	• Unable to maintain bending position	• Improve control system by maintain activation • maintain position through mechanical design

The subsequent prototype would focus on addressing the issues of the proof-of-concept prototype.

3.3 Prototype 2 – Multiple Direction Bending

The second prototype aimed to improve the Smart Bending Mechanism further, following the proof-of-concept demonstration as this was identified as a critical subsystem for developing a flexible hysteroscopy system. Several design changes were made which resulted in the CAD model of the system shown in Figure 3.7 below.

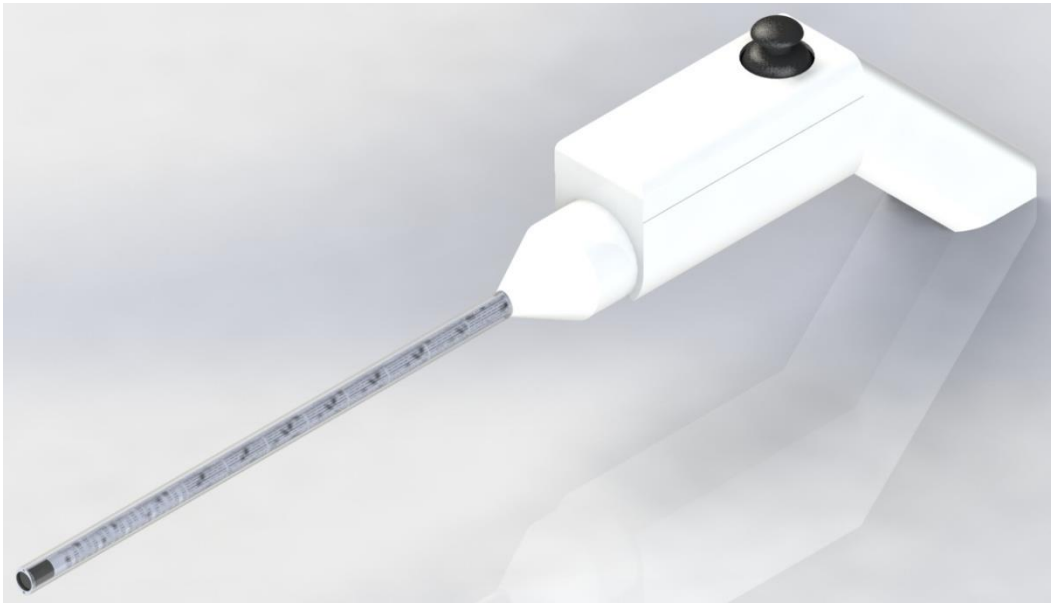


Figure 3-7 Prototype 2 Concept. The changes made to the prototype included a handheld grip and potentiometer joystick to control the bending mechanism that had improved bending and added directions.

The design changes consisted of the following:

- The Handheld Base was redesigned to fit better into the user's hand while providing additional space for the large controls and electronics of the Smart Bending Mechanism. The HB was still produced by 3D printing ABS material.
- The Smart Bending Mechanism underwent several changes to improve its functionality. The first was using guides along the flexible rod to maintain the position of the wires to ensure bending occurs in a specific direction, as shown in Figure 3.8. Additionally, a rig was used to produce the segmented portions of the flexible rod with more consistency. The nitinol wires were also replaced with nitinol springs that provided increased contraction distances, resulting in greater bending motion as shown in Figure 3.9. The redesigned SBM had 4 nitinol springs that allowed for bending in 4 directions that were activated independently through a potentiometer joystick. When the joystick was pushed into a direction, it would activate the corresponding spring for the direction. Furthermore, the joystick was connected to a microcontroller that activated the springs through a pulse width modulated (PWM) signal. PWM is often used to control speeds of motors, in this application it is used to control the speed of the nitinol spring contraction, thereby allowing for a more controlled motion.
- The Mobile Visualisation Platform was slightly improved by using a camera module with a much smaller 4 mm diameter that still connected to a smartphone for displaying the camera view. The details of the camera module are provided in the manufacturer's datasheet in Appendix G.

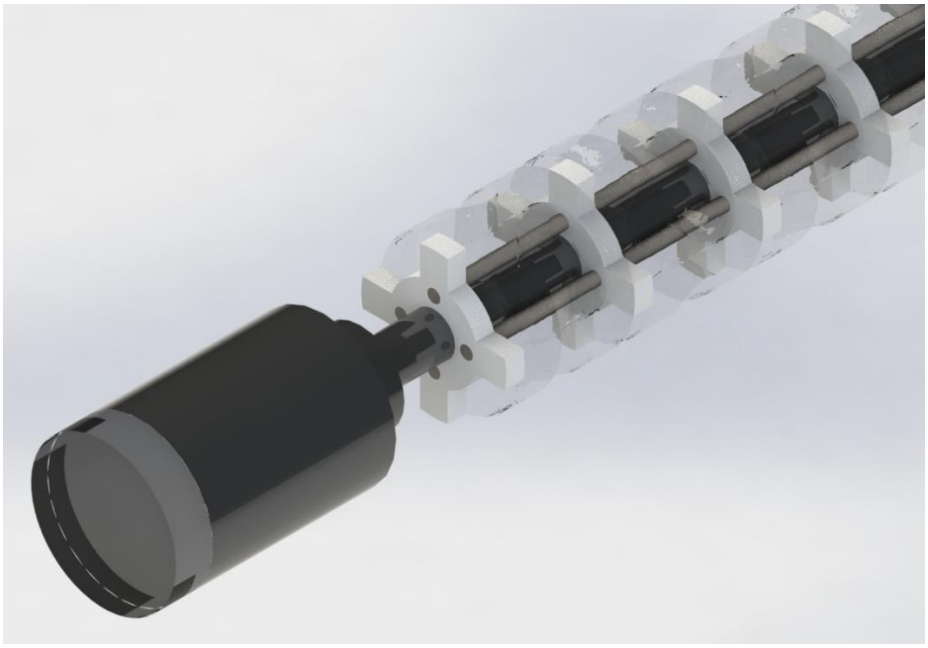


Figure 3-8 Flexible Tip with Wire Guides. Wires guides were added to the prototype to avoid actuation wires becoming entangled to preserve the bending motion.

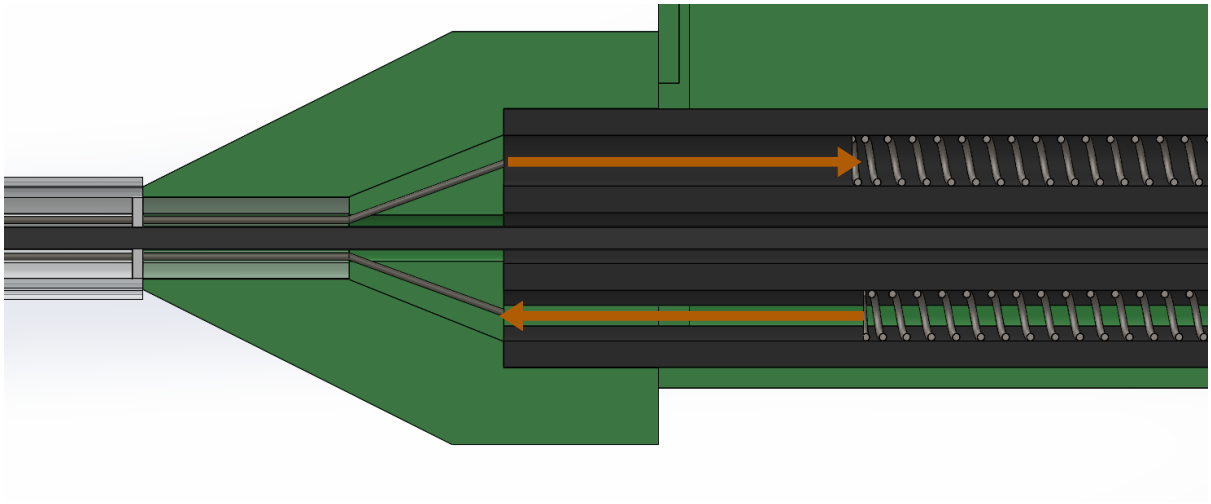


Figure 3-9 Prototype 2 Bending Mechanism. The bending mechanism implemented shape memory alloy springs that acted as pairs, when one contracts the opposite spring extends.

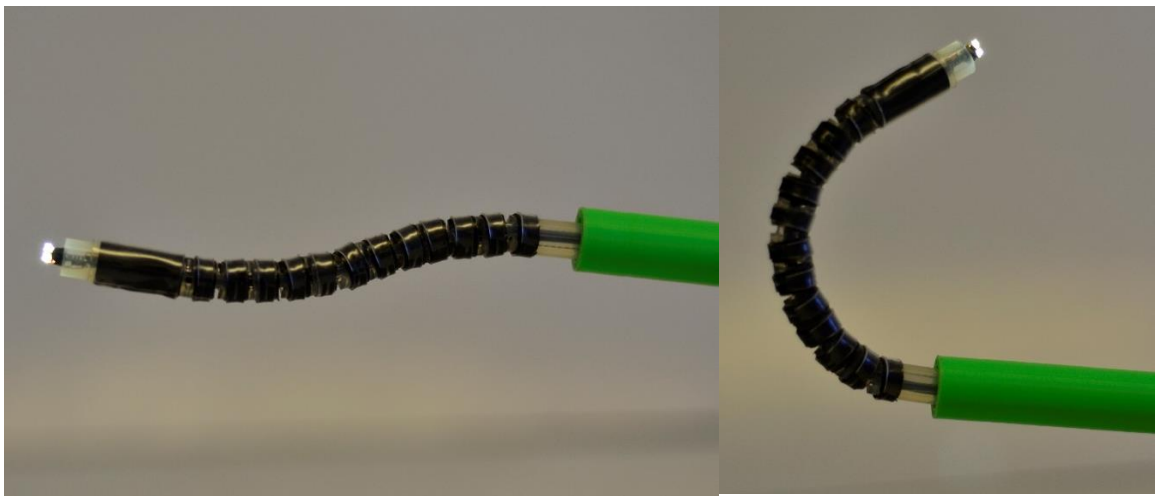


Figure 3-10 Prototype 2 Bending Tip. The bending motion of the prototype was improved to produce greater bending while also bending in multiple directions.

The completed system prototype is shown in Figure 3.11 below. A rigid tube was added to a portion of the flexible rod, this was used to make handling the completely flexible rod easier. Without the tube, it is difficult to guide the tip of the flexible rod, which is a common problem with flexible scopes. The nitinol springs added another advantage over using wires, after activation the springs would not immediately extend again, thereby maintaining the current position of the tip. The nitinol springs, would however, require a bias force to be extended again before it can be reactivated. The mechanism was designed so that nitinol springs would act as opposing pairs, as one activates, it would extend the spring on the opposite side.

Figure 3-11 Prototype 2 Completed. The prototype improved on the previous with a smaller diameter camera, multiple bending directions and greater bending angles.

While the prototype offered improved functionality compared to the previous version, it did not yet meet all the requirements of the proposed hysteroscopy system. Issues that required further refinement are outlined in Table 3.3 below.

Scale – The overall size of the flexible rod is still beyond the minimum diameter requirement. Although a smaller diameter camera was used, the diameter was increased by the flexible rod around it and remained at 8 mm. The current design of the flexible rod is the limiting factor preventing the diameter from being reduced. The following version of the prototype would drastically need to decrease the diameter of the flexible rod to achieve the requirement.

Flexibility – The flexibility of the rod was improved through both degree of bending, up to 100°, and number of bending directions, up/down and left/right. However, navigating the patient's anatomy would require smaller bending motions, the current length of the bending tip would be unable to fully bend in the environment. The flexible rod also required the rigid tube as the fully flexible length resulted in difficulty when handling. The rigidity of the rod would need to be increased to facilitate easier handling.

Accuracy – The spring configuration did improve the accuracy of the Smart Bending Mechanism. The springs were better able to hold the position of the tip after being and when not activated. However, due to requiring a bias force to be reset, repeated large bending motions could not be achieved. The microcontroller providing a PWM signal did improve the bending motion by controlling the speed of contraction and would be taken into the next version.

Table 3.3 Prototype 2 Issues & Interventions

ASPECT	ISSUE	INTERVENTION
Scale	• 8 mm diameter of flexible rod	• Replace flexible tube with custom parts or smaller component
Flexibility	• Length of bending tip • Flexible scope difficult to handle	• Replace bending tip with smaller parts to reduce length • Balance rigidity and flexibility of scope
Accuracy	• Resetting nitinol springs after contraction	• Improve mechanical interaction between opposing nitinol springs to reset

The next prototype version of the hysteroscopy system would aim to reduce the diameter of the flexible rod to be capable of performing procedures while improving the bending mechanism even further.

3.4 Prototype 3 – All-in-one System

The third version of prototype hysteroscopy system was developed as the first complete system. The design had reached a satisfactory stage where the Disposable Sheath subsystem could also be developed to complete the system. This section will provide a brief description of the third prototype to showcase to the major components and sub-assemblies of the device, the CAD model the prototype is shown in Figure 3.12 below.

Figure 3-12 Prototype 3 Concept. Prototype 3 included an integrated screen and improved camera insertion rod design to reduce the size.

The research project aimed to develop a mobile flexible hysteroscopy system that can be held and operated single-handedly. It consists of the following sub-assemblies:

- An ergonomically designed handheld base that houses the electronics, batteries, bending mechanism, and controls of the system.
- The camera insertion rod that is made of two lengths; a semi flexible length of Polytetrafluoroethylene (PTFE) tube and a distal tip of rolling segments that contain the camera and light source.
- A disposable single use sheath that covers the camera insertion rod during procedures, the sheath has a transparent cap for visual clarity and an additional liquid channel for connecting the distention media source.

Each of the sub-assemblies and their major components will be discussed briefly in the section.

3.4.1 Handheld Base and Mobile Visualisation Platform

The handheld base was a critical component of the hysteroscopy system, not only did it need to house all the electronics and provide attachment for other components, but it needed to fit comfortably in one hand while not being too heavy. These factors played a

role in the ergonomics of the system which have a substantial influence on the overall usability of the device. Figure 3.13 shows a transparent view of the handheld base with the components inside.

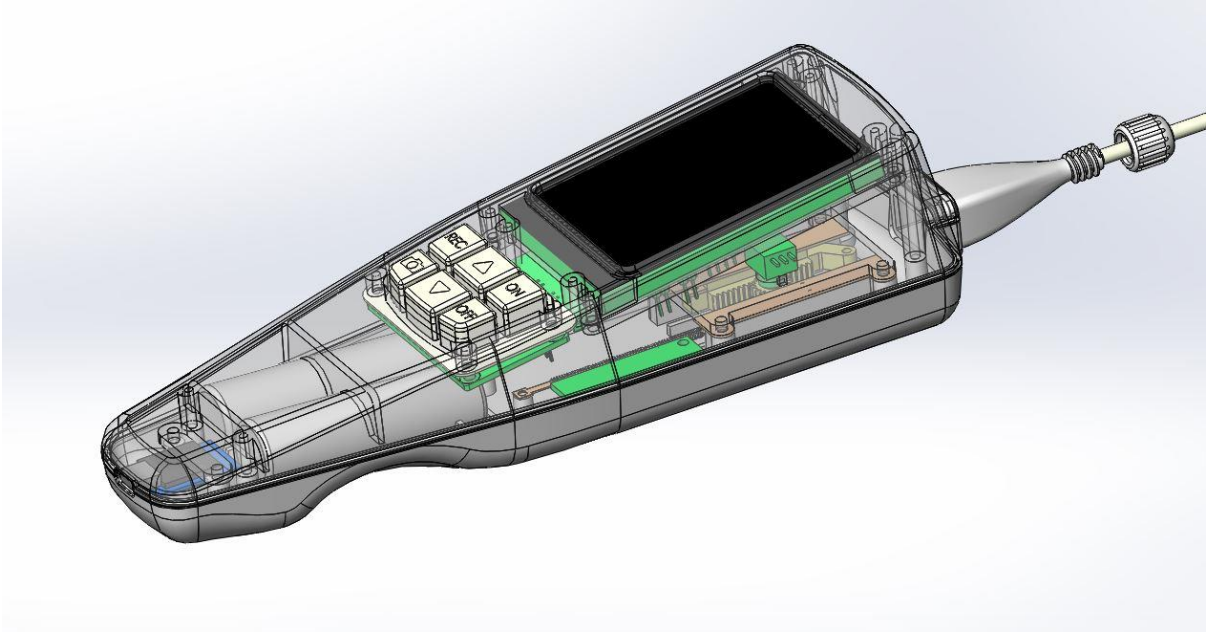


Figure 3-13 Prototype 3 Transparent View. The handheld base was redesigned to incorporate the integrated screen along with redesigned bending mechanism and electronics.

Table 3.4 shows the major components of the Handheld Base alongside a brief description of each components' function.

Table 3.4 Handheld Base Components

COMPONENT	FUNCTION
Nozzle	Provides attachment and securing of the camera insertion rod to the handheld base.
Outer Shell	Holds inner components secure and firmly in place while offering comfortable grip for user.
Power Supply Unit	Consists of batteries and charging module that provide power to the electronics.
User Interface	Consists of the integrated touchscreen display and buttons that are used to operate the display and provide visualisation.
Electronics	Primary components are the microcomputer, spring driver circuit and voltage regulator that controls the software and operation of the device.

Bending Mechanism	The bending mechanism is controlled by user input and moves to bend the distal tip of the camera insertion rod during operation.

The function critical components of the handheld base will be discussed in more detail as follows.

3.4.2 Smart Bending Mechanism

The most important component of the handheld base is the bending mechanism within, it allows for navigation around the anatomy of the patient to improve both patient comfort and procedure outcome. Figure 3.14 shows a close-up of the bending mechanism. Table 3.5 shows the parts of the bending mechanism, it consists of a rack and pinion linear actuator. Each rack connects to a Nitinol spring on one end, and a pulling wire on the other that feeds through the camera insertion rod and attaches to the tip of the rolling segments. The pinion of the actuator is mounted onto a rotating potentiometer that allows it to the turn. As the pinion turns the potentiometer, it sends a signal to the microcomputer that uses it to determine how much the linear actuator has moved. This is for providing feedback to the user on the current degree of bending during procedures for both entry and removal of the device.

Figure 3.15 shows how the linear actuator moves during activation of one spring. There are two major advantages in using the linear actuator setup in the device. When not moving, the opposite sides keep the system rigid and maintains the current position. This allows the user to observe a specific area when found. The second advantage is during motion, as one side contracts, the opposite side is extended. This provides slack in the system to ensure full bending motion of the tip can occur.

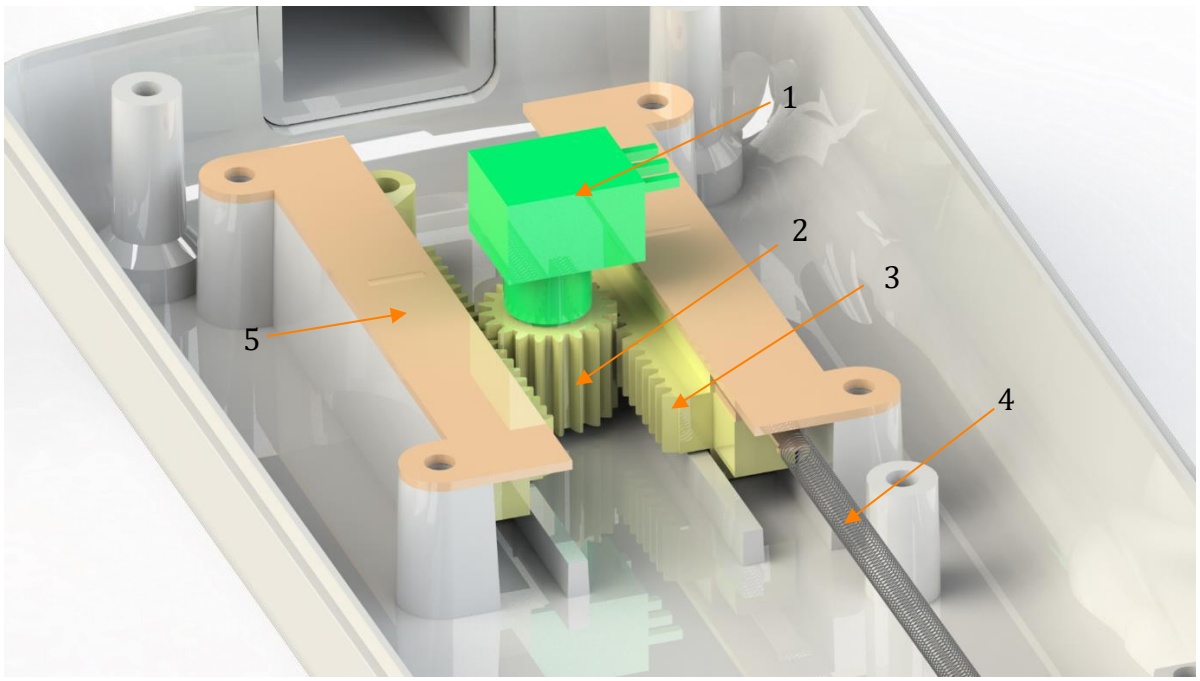


Figure 3-14 Bending Mechanism. The components of the Bending Mechanism are (1) Rotating Potentiometer, (2) Pinion Gear, (3) Rack Gear, (4) Nitinol Spring, and (5) Conductive Rail.

Table 3.5 Bending Mechanism Parts

PART NUMBER	NAME	FUNCTION
1	Rotating Potentiometer	Relays position feedback
2	Linear Actuator Pinion Gear	Turns racks and potentiometer
3	Linear Actuator Rack Gear	Pulls wires in camera insertion rod and turns pinion
4	Activating Nitinol Spring	Contracts when activated to move the attached rack
5	Conductive Rail	Provides power to the spring during activated motion

When the bending mechanism is activated as shown in Figure 3.15, the following steps occur:

1. User presses button to move in the camera tip, this causes the corresponding Nitinol spring to activate through the conductive rail and begin to contract.
2. As the Nitinol spring contracts, it pulls on the attached rack which pulls on the wire attached to the tip of the camera insertion rod, causing it to bend in a specific direction.

3. The movement of the rack causes the pinion to rotate that relays a signal to the microcomputer through the potentiometer and also moves the opposite rack in an opposing direction.
4. The second rack is moved towards to the camera tip, thereby providing slack to the attached wire which ensures the wire being pulled can move without resistance, while also extending the nitinol spring connected to reset it for activation.

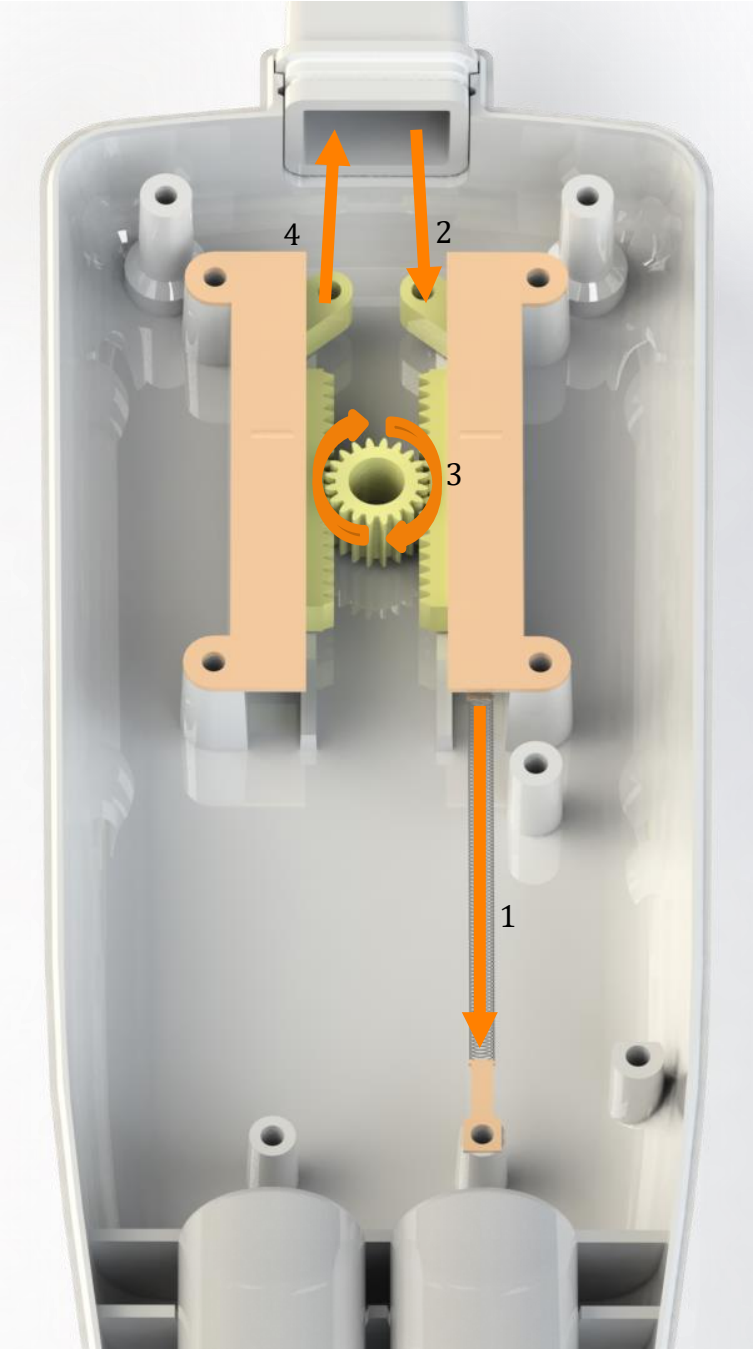


Figure 3-15 Bending Mechanism Activation. The activation of the mechanism results in the (1) spring contraction, (2) connected rack gear moving, (3) pinion gear rotation, (4) opposite rack gear moving.

The completely assembled handheld base with inner components is shown in Figure 3.16.

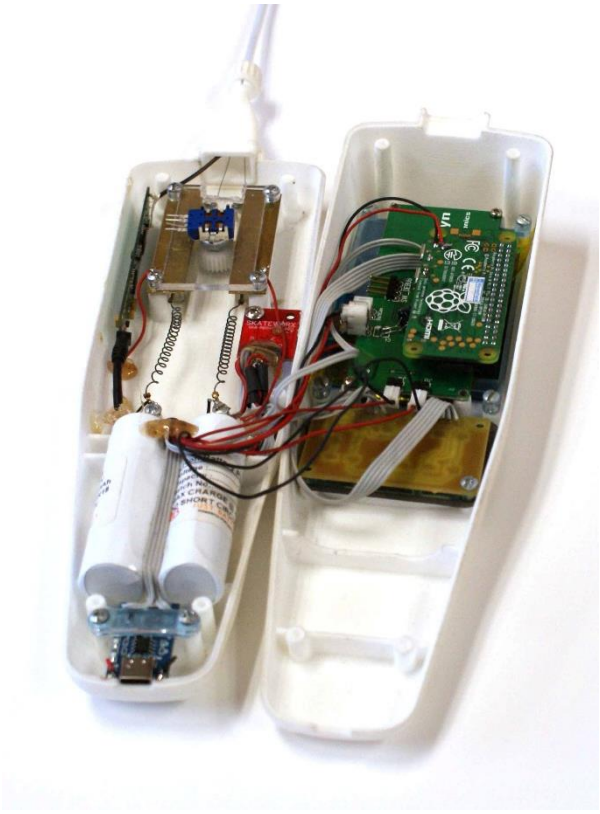


Figure 3-16 Assembled Handheld Base

Camera Insertion Rod

The Camera Insertion Rod consists of two separate lengths as mentioned, the flexible PTFE tube that the camera and pulling wires feed through and the segmented bending tip. This is shown in Figure 3.17. A camera with a smaller diameter of 2.5 mm replaced the previous camera used, the details of which are shown in the manufacturer's datasheet in Appendix G.

Figure 3-17 Camera Insertion Rod. The rod had two separate lengths, the flexible PTFE tube, and the segmented bending tip.

The flexible PTFE tube is rigid enough to prevent kinking when the bending mechanism is activated to ensure controlled bending only occurs at the tip of the rod. The tip of the rod is designed to allow for bending in two directions, depending on which pulling wire is activated. A close-up of the segmented tip is shown in Figure 3.18.

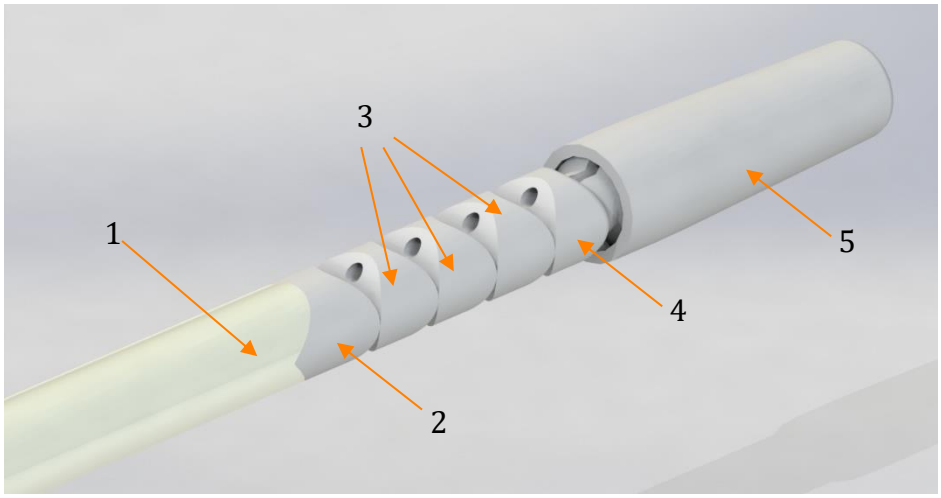


Figure 3-18 Segmented Tip Close-Up. The tip consisted of (1) PTFE Tube, (2), Lock Segment, (3), Rolling Segment, (4) Head Segment, and (5) Cap Segment.

The segmented tip is made up of several distinct segments that perform different functions as shown in Table 3.6. Figure 3.19 shows the cap segment unscrewed to show the camera within.

Table 3.6 Segmented Tip Parts

PART NUMBER	NAME	FUNCTION
1	PTFE Tube	Provides required working length and protects wiring
2	Lock Segment	Design to fit into the PTFE tube and lock into place to prevent segment rolling freely
3	Rolling Segment	Designed to roll across adjacent segments to result in bending of the tip when wires are pulled
4	Head Segment	Fastening point for the pulling wires that are held in place together with threaded cap segment
5	Cap Segment	Threaded cap segment that screws onto the head segment and covers the camera

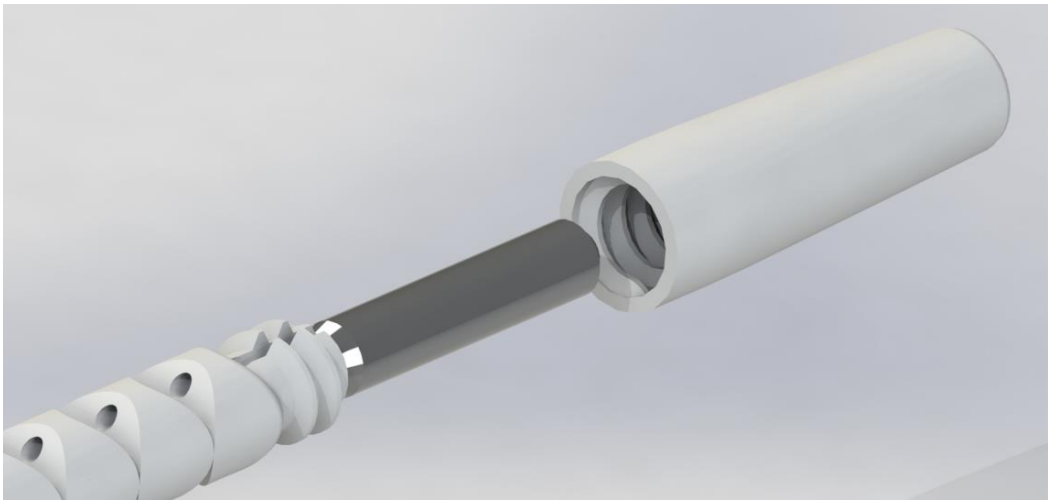


Figure 3-19 Unscrewed Cap Segment. The Cap Segment screwed in place to secure the camera module in the distal tip.

The final dimensions of the camera insertion rod were 375mm in length with an outer diameter at the widest point of 4.90mm as shown in Figure 3.20.

Figure 3-20 Camera Insertion Rod Diameter. A digital vernier calliper was used to measure the rod diameter of 4.90 mm.

The bending capabilities of the camera rod tip is shown in Figure 3.21. The camera tip was roughly capable of bending up to 130° in two directions which equalled a total of 260° of bending.

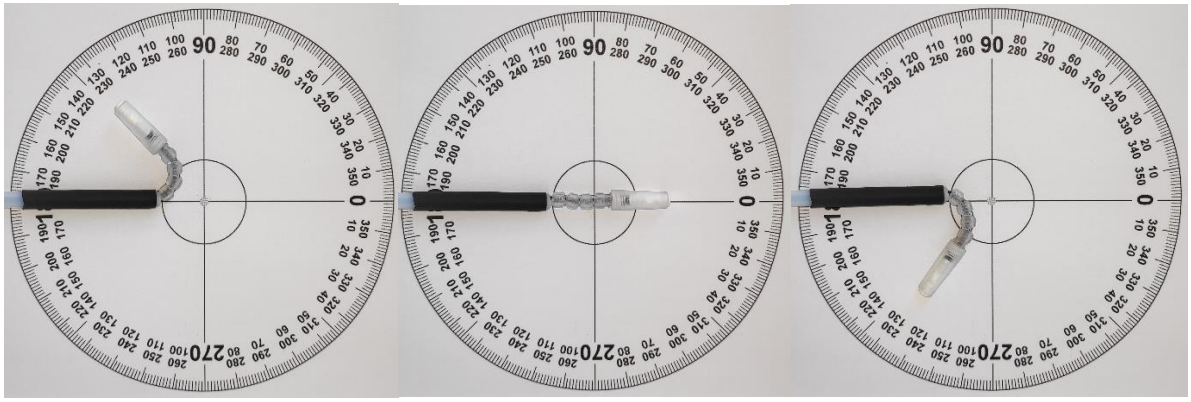


Figure 3-21 Camera Tip Bending. The bending capabilities of the tip was measured using a 360° protractor and was able to bend 130° up and 130° down.

3.4.3 Disposable Sheath

The final major component of the hysteroscopy system is the disposable single use sheath, which also proved to be one of the most challenging due to the constraints. The sheath needed to perform sevaral key functions to facilitate success during device operation and procedures, these were:

- Visual Clarity – The sheah should not impede the clarity of the camera to an extent that made use difficult.
- Size – The outer diameter of the system should not be increased to drastically with the sheath on that would prevent successful entry into the uterine cavity.
- Flexibility – The sheath must be flexible enough to not impede the bending motion of the camera tip.
- Additional channel – the sheath needed to provide an additional channel for distention media to be pumped through, this is necessary to inflate the uterine cavity for observation.

The above factors combined made the production of working sheath prototype difficult as the manufacturing methods to produce the required materials would be too costly on a small scale. The sheaths therefore needed to be prototyped with materials and methods available in the UCT Medical Devices Lab. The final prototype is shown in Figure 3.22.

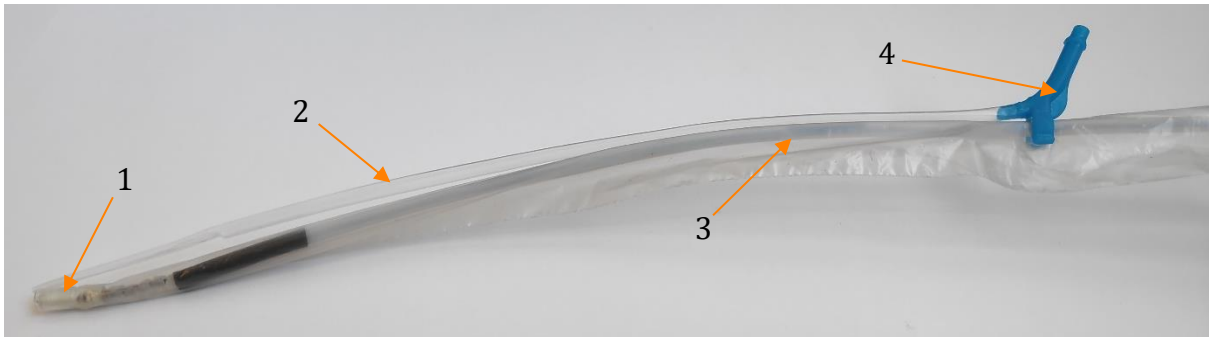


Figure 3-22 Disposable Sheath. The components of the sheath are (1) Transparent Rigid Cap, (2) Liquid Channel, (3) Outer Sheath, (4) Fluid Connector.

The disposable sheath components were made of the following materials and manufacturing methods:

1. A transparent rigid cap was vacuum-formed from 0.5mm thick transparent polyethylene terephthalate glycol (PETG) sheets. The cap maintained visual clarity while providing a rigid base for attaching other parts.
2. A soft thermoplastic tubing was used as the liquid channel. The tube was formed into a flat oval shape at the tip to reduce the overall diameter of the sheath slightly.
3. Soft 0.02mm plastic film was heat sealed together to make the outer sheath that covers the camera insertion rod. This film was soft enough to not impede the bending but strong enough to stay leak proof during use.
4. A fluid connector was stereolithography (SLA) 3D printed to clip onto the camera insertion rod firmly to hold the disposable sheath in place. The connector could then be connected through standard tubing to the fluid source commonly used.

The prototype sheath was successfully produced using the materials and methods discussed above. The final diameter of the camera insertion rod with the sheath was 6.55mm as shown in Figure 3.23, while the increase was not insignificant, it did not prevent insertion through the model cervix used for bench testing as shown in Figure 3.24. Figure 3.24 also shows bending was still capable with the sheath however the extent of bending was slightly reduced but not unacceptable. Finally, the visual clarity through the sheath is shown in Figure 3.25 and with the light source set to a lower brightness, there was no visible reduction in clarity. However, as the brightness was increased, some reflection on the cap would occur to a point that visuals were completed obscured. This would need to be addressed in future iterations to ensure varying degrees of light intensity can be used without obscuring vision.

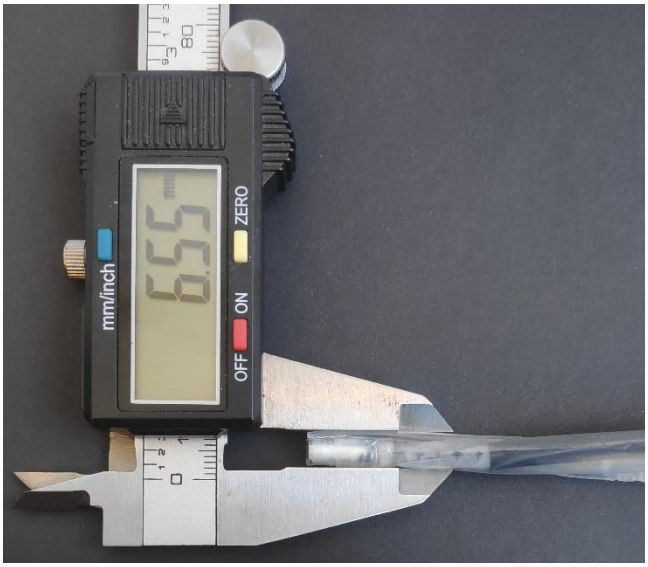


Figure 3-23 Camera Insertion Rod Diameter with Disposable Sheath. A digital vernier calliper was used to measure the diameter with the sheath on and was 6.55 mm.

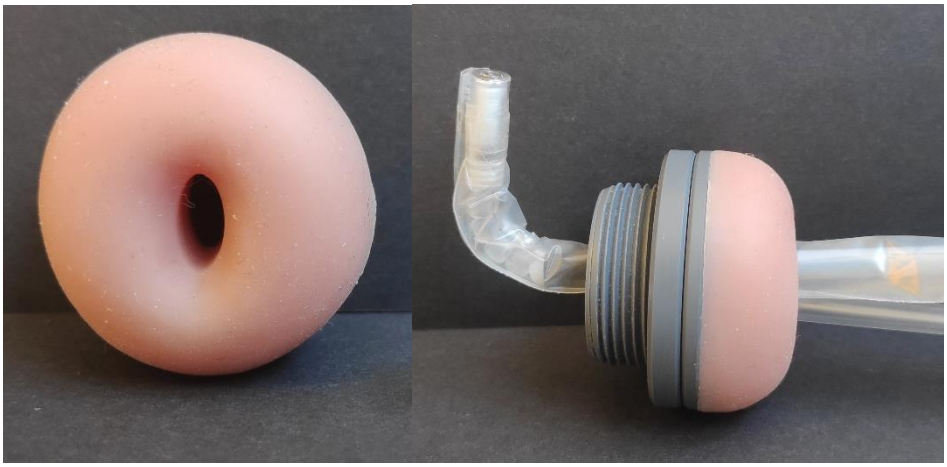


Figure 3-24 Model Cervix Insertion and Bending with Sheath. The sheath was found to reduce the bending capability of the tip when in place.

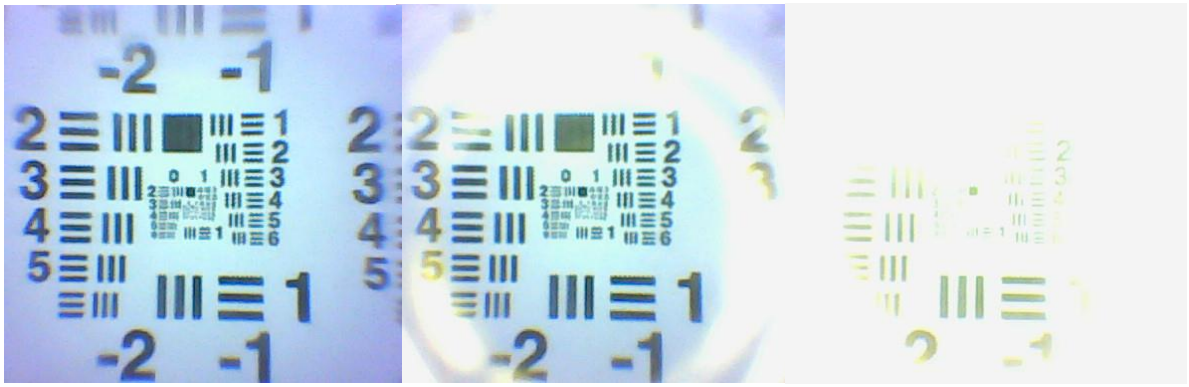


Figure 3-25 Visual Clarity at Increasing Brightness through Sheath. The sheath reduced the visibility due to the LED light reflecting back as the brightness increased.

3.4.4 Prototype 3 Design Outcomes

The completed third version prototype, when compared to the design requirements, presented a system that nearly met all the requirements for the proposed hysteroscopy system. However, several key issues with the prototype were identified that required further refinement before the design could be frozen, these are listed in Table 3.7.

Bending Mechanism – Initially the concept for prototype 3's bending mechanism included a potentiometer for providing feedback to the user regarding the current degree of bending. However, the potentiometer's shaft was too stiff, resulting in the mechanism being unable to operate. The pinion gear was instead mounted with bearings onto a fixed shaft which resulted in a smooth operation. The potentiometer was left out of the design going forward.

Flexibility – The flexibility of the rod and tip was improved from the previous design, while able to reduce the diameter of the rod at the same time. However, the rod was potentially too flexible, as it tended to buckle when attempting to pass through the model cervix. As a result, it would require a redesign in the next version.

Display – The decision was made to integrate the display into the handheld base, instead of using a separate smartphone. This was done to avoid compatibility issues that was resulting from different connection types, and to improve ease of use during operation. A smartphone resulted in the user having to hold it with their hand while operating the device with the other. However, the display of the prototype had two major issues; the first being the angle and the second was the low refresh rate. The angle caused the user to either bend over the device or rotate the device to properly view the screen, this was not conducive to ease of use and excessive motion of the device would cause patient discomfort. The low refresh rate of the screen made navigation with the device difficult as the delay on the screen could result in mistake occurring. These two issues would need to be addressed going forward.

Sheath – A prototype of the disposable sheath was successfully built as part of this version. While it was able to isolate the main device from the environment and provide a distention media channel, it did have issues to refine. The diameter of the sheath needed reduction as it influenced the final diameter of the system. The flexibility of the sheath would also need improvement as it reduced the bending ability of the system to an unacceptable degree. Lastly, the visibility through the sheath needed refinement as with the current version, increasing the LED brightness would result in losing visuals.

Table 3.7 Prototype 3 Issues & Interventions

ISSUE	ISSUE	INTERVENTION
Bending Mechanism	• Potentiometer stiffness impacting pinion gear rotation	• Pinion gear mounted with bearings on fixed shaft
Flexibility	• Flexible scope prone to buckling when entering cervix	• Redesign to create separate rigid and flexible portions
Display	• Screen angle not ergonomic • <15 fps screen refresh rate	• Raise screen angle • Replace microcontroller with higher computing power
Sheath	• 6.55 mm diameter of sheath • Stiffness reduced bending to 90° • Loss of image when increasing LED brightness	• Manufacture sheath out of thinner and softer material • Replace cap with more transparent material

The subsequent prototype would focus primarily on the issues discussed in Table 3.7 above as the system was nearing completion.

3.5 Prototype 4 – Miniaturisation & Optimisation

The fourth version prototype focused on miniaturising and optimising the third version of the hysteroscopy system. The third version demonstrated its potential by nearly meeting all of the design requirements pending further refinement. Therefore, the next

version left areas that performed satisfactory unchanged, and solely focused on solving the issues identified in the previous section. This resulted in the CAD model of the prototype shown in Figure 3.26 below.

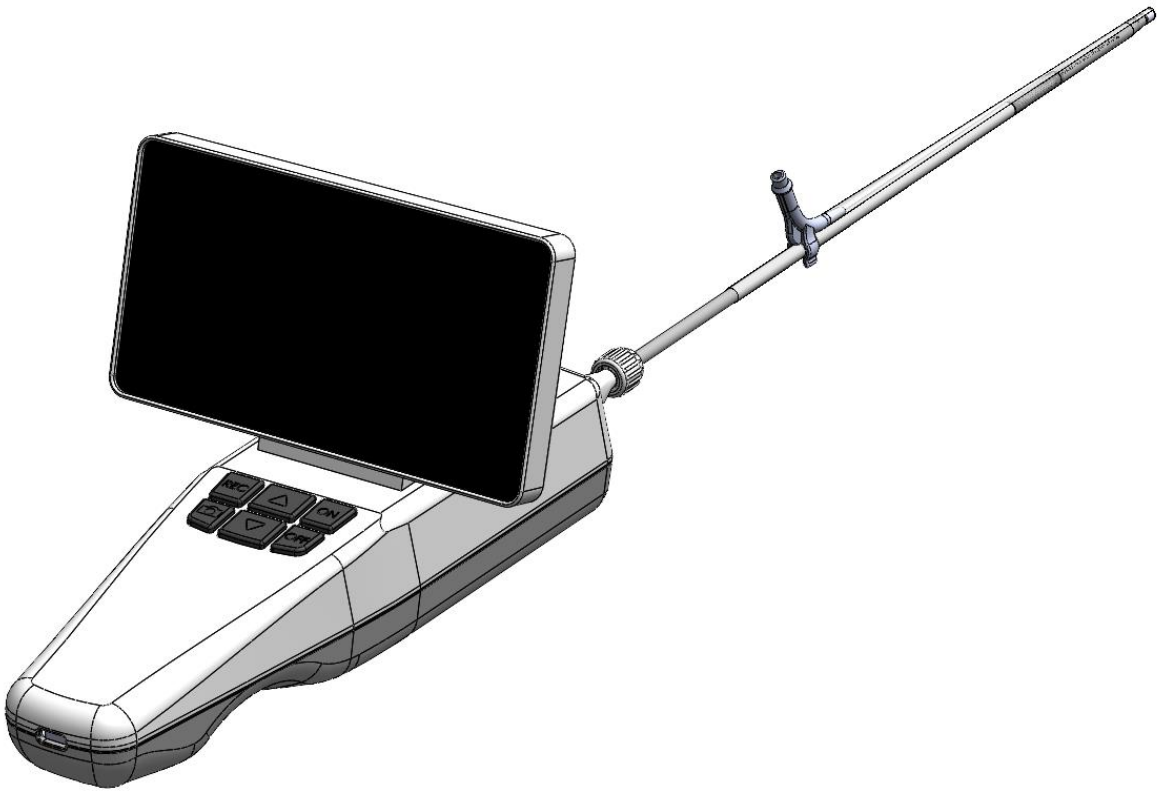


Figure 3-26 Prototype 4 Concept. The prototype focused on improving aspects of the previous prototype by addressing ergonomics, bending capabilities, and diameter.

This prototype improved the following aspects from the previous version:

- The mobile visualisation platform replaced the display screen and microcomputer to improve the refresh rate of the camera feed. The screen was also raised at an angle to improve the view during operation.
- The smart bending mechanism had the flexible insertion rod redesigned to provide more rigidity for navigating through the cervix while maintaining flexibility for the patient's experience.
- The disposable sheath was redesigned to reduce the diameter, improve visibility, and increase flexibility. These three factors should improve the functionality of the system with the sheath in place.

These aspects are discussed in greater detail in the subsequent sections.

3.5.1 Handheld Base and Mobile Visualisation Platform

Overall, the design of the handheld base did not undergo drastic changes from the previous version, with the only major change being the angle of the display screen that is better seen in Figure 3.27 below.

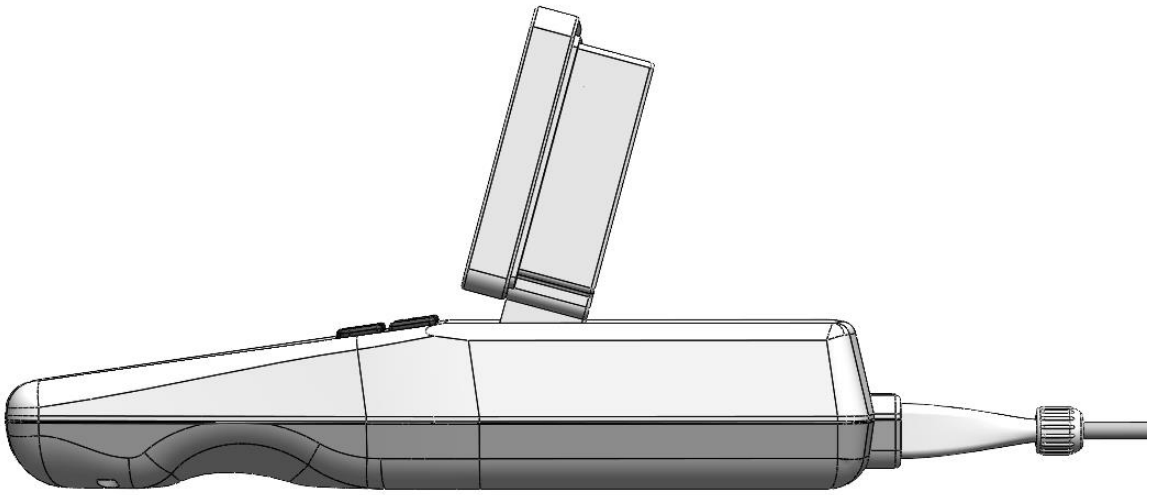


Figure 3-27 Prototype 4 Side View. The adjusted screen angle is shown to improve ergonomics for the user during operation.

This angle change should allow the user to maintain the position of the device without having to adjust the device or their position during operation. Additionally, the mobile visualisation platform replaced the display screen with a larger one to provide the user with a larger image to view. The microcomputer from the previous version was also replaced with a more computationally powerful one to ensure a live video feed could be displayed that did not suffer from low refresh rates and delay.

3.5.2 Smart Bending Mechanism

The actuating mechanism of the Smart Bending Mechanism was left unchanged from the previous version as it was capable of controlled bidirectional bending to the degree required. Figure 3.28 below shows the actuation mechanism of this prototype version.

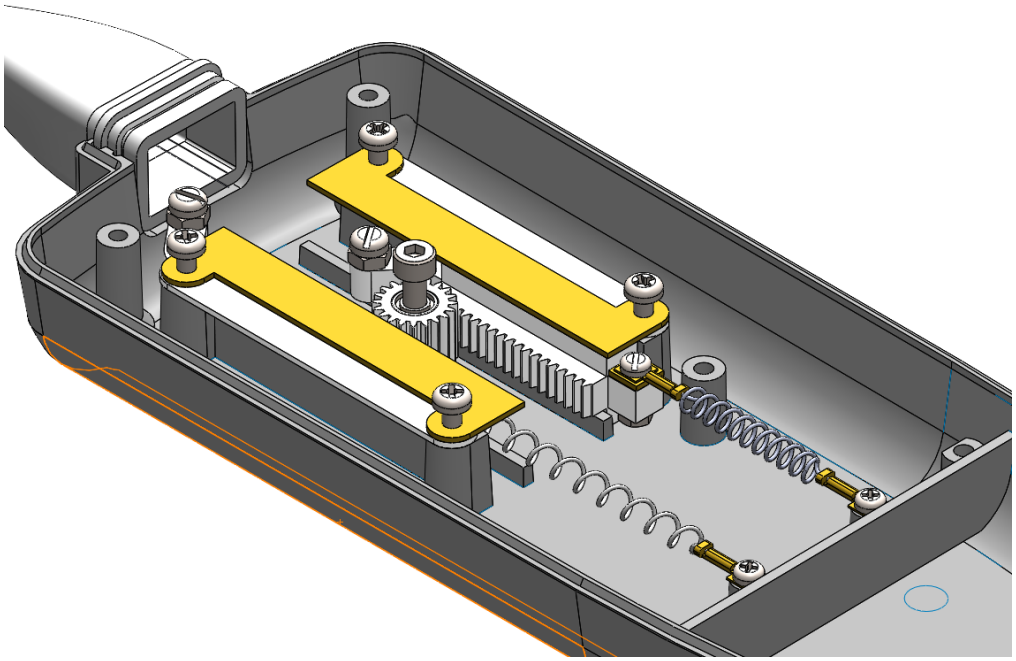


Figure 3-28 Prototype 4 Smart Bending Mechanism. The bending mechanism remained unchanged from the previous prototype.

The most critical element of the Smart Bending Mechanism was the flexible insertion rod. It was crucial to both miniaturise and optimise this component to meet the final design requirements to ensure navigating through the anatomy could be done successfully. The previous prototype was both too flexible and its diameter too large. The final version of the flexible rod is shown in Figure 3.29.

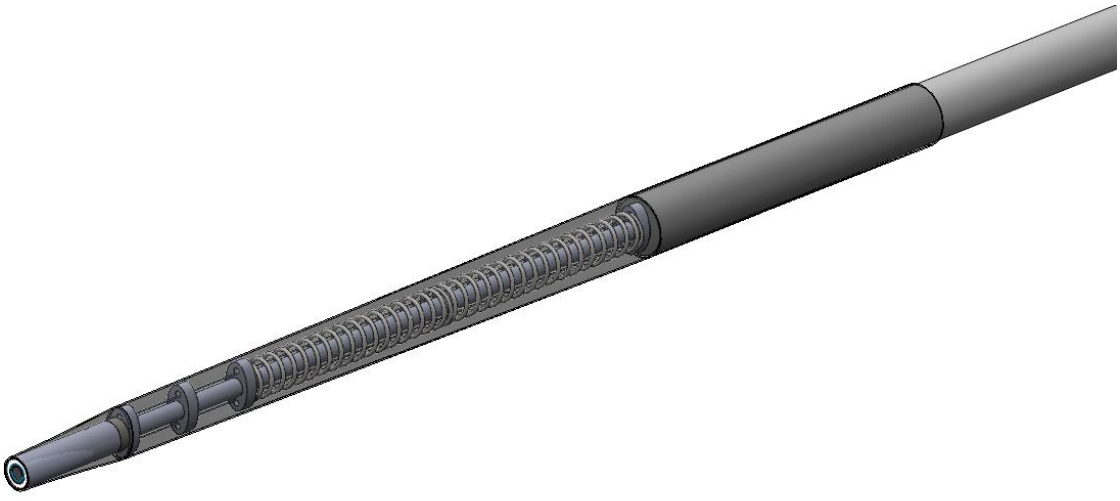


Figure 3-29 Prototype 4 Flexible Rod. The redesign rod included a semi-rigid plastic tube, springs for a flexible portion, and spaced wire guides for the bending tip.

The flexible insertion rod consisted of three distinct portions. Most of the length was a semi-rigid plastic tube stiffer than the previously used PTFE tubing. The increased

stiffness would aid in guiding the tip of the device without needing to use additional tools. The second portion of the rod was made of springs, with a wire guide at each end. The guide separated the wires coming from the device while the springs provided increased flexibility that is able to navigate around the patient's anatomy while still maintaining its form. The last portion of the flexible rod is the distal bending tip consisting of three equal spaced wire guides and the camera module, a closeup of this portion is shown in Figure 3.30 below.

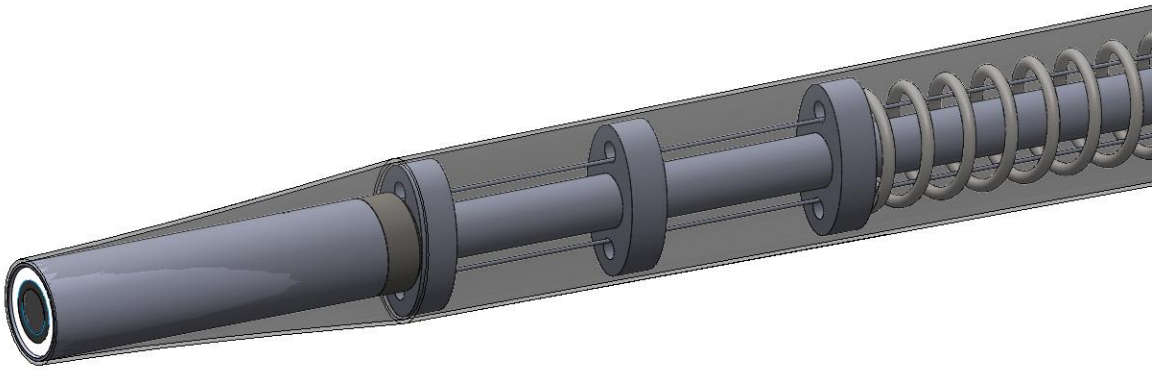


Figure 3-30 Prototype 4 Flexible Rod Closeup. The spaced wire guides are shown that allowed the diameter to be reduced while improving bending.

The three wire guides in the tip performed similarly to the rolling segments from the previous prototype. The wires connected to the bending mechanism were fixed at the last guide, and when pulled, would cause the tip to bend towards the corresponding side of the wire. The wire guides in this configuration reduced the diameter and length of the bending tip while still allowing for maximum bending to be achieved. The result of the updated flexible insertion rod is a semi-rigid design with a minimal bending tip and small diameter for navigating the patient's anatomy. The camera module remained the same from the previous prototype and the details are listed in the manufacturer's datasheet in Appendix G.

3.5.3 Disposable Sheath

The disposable sheath required several improvements from the previous version to meet the requirements. These improvements focused on the flexibility, size, and visibility of the sheath. The subsequent sheath design is shown in Figure 3.31 below.

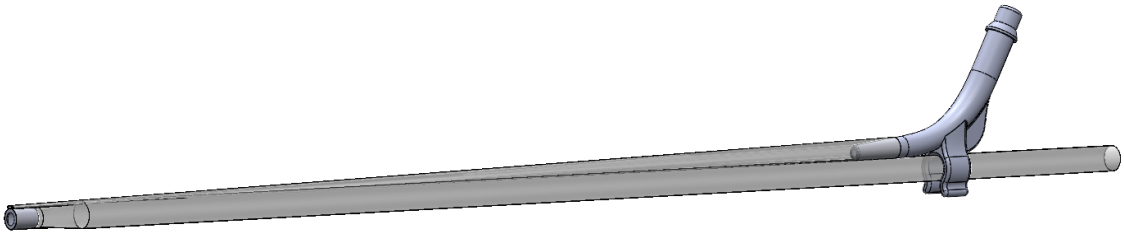


Figure 3-31 Disposable Sheath Concept. The redesigned sheath concept implemented plastic film instead of tubing to and a separate transparent cover.

The design left the fluid connector unchanged from the previous version as it was able to connect to the distention media source through standard connectors. The first change to the design was the distention media tube. Previously, plastic tubing was used that reduced the flexibility of the sheath and increased its diameter. Instead, a tube was manufactured similar to the main sheath that covers the device. Plastic film was heat sealed to form a tapered tube that was connected to the tip of the sheath with a waterproof soft plastic adhesive. The edges of both the main sheath and the distention tube were sealed with this adhesive for reinforcement. The second major redesigns occurred on the tip of the sheath, a section of which is shown in Figure 3.32 below.

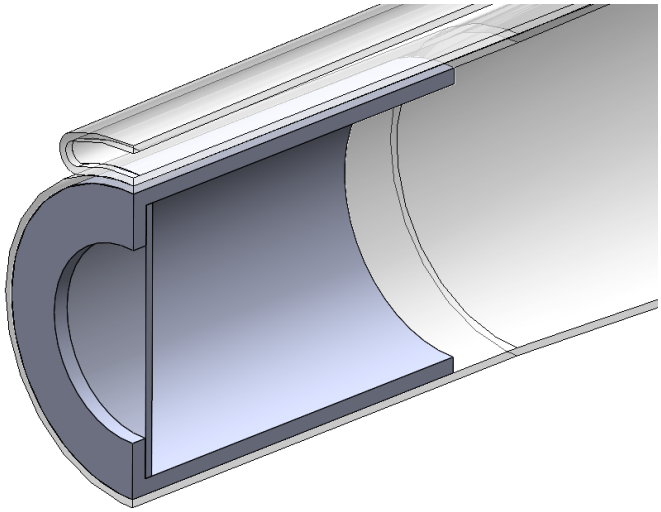


Figure 3-32 Disposable Sheath Closeup Section View. The transparent cover was used to improve visibility through the sheath without light reflecting.

As seen from Figure 3.32, the tip of the sheath was redesigned to consist of a 3D printed cap and a separate transparent cover. The previous design of vacuum formed caps would distort the camera image, instead transparent discs were punched from acetate sheets that would provide better visibility. These discs were press fitted into the caps and secured with the waterproof adhesive before the plastic film tube was attached, completing the sheath. The result being a flexible sheath that reduced diameter and improved transparency.

3.5.4 Prototype 4 Design Outcomes

The fourth version of the proposed hysteroscopy system prototype was successfully constructed and is shown in Figure 3.33 below. This prototype successfully implemented the changes made to the previous version.

Initial evaluation of the prototype showed that it would meet all design requirements outlined for the proposed hysteroscopy system. Based on this, the decision was made to freeze the current design and proceed to the next stage of the development process, the verification and validation testing. If the testing at any point results in unsuccessful results, the design would be unfrozen and redesigned.

During the development of the hysteroscopy system, a US patent application based on the technology was filed on the 5th of March 2019 and was granted on the 22nd of November 2022. The patent publication number is 20190269301.

Figure 3-33 Prototype 4 Completed.

3.5.5 Prototype 4 Operation

The typical operation of the developed hysteroscopy system is described as follows:

1. The button layout of the hysteroscopy system is shown in Figure 3.34 and perform the functions outlined in Table 3.8.

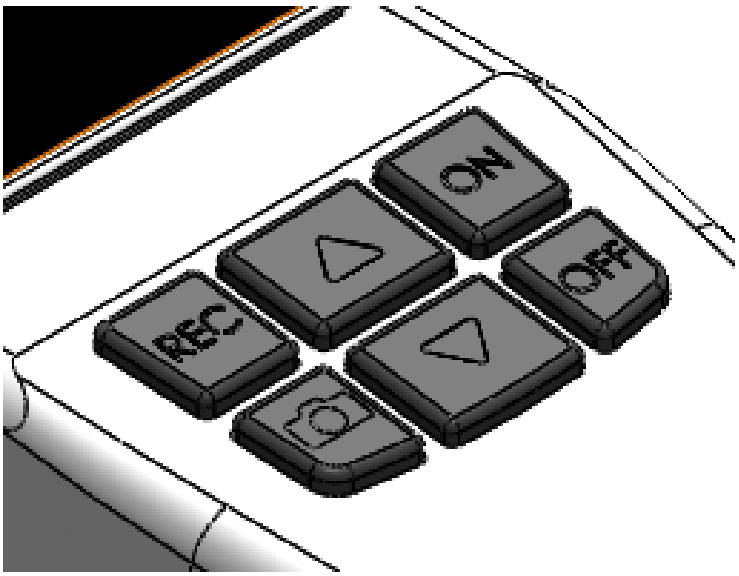
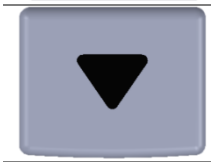


Figure 3-34 Prototype 4 Controls. The user is able to control bending up or down, record images and videos, and switch the device on and off.

Table 3.8 Prototype 4 Button Functions

BUTTON	FUNCTION
	**Capture Button –** when pressed captures the current image displayed on screen and saves it in a designated folder for viewing later.
	**Record Button –** when pressed immediately begins recoding a video and only ends recording once the button is pressed again. The record video is saved in a designated folder for viewing later.
	**Up Button –** when pressed bends the tip in the upwards direction in relation to the device, refer to Figure 4.5 for showcase of bending. The tip bends as long as the button is pressed and will maintain bent position when released.
	**Down Button –** when pressed bends the tip in the downwards direction in relation to the device, refer to Figure 4.5 for showcase of bending. The tip bends as long as the button is pressed and will maintain bent position when released.
	**On Button –** switches the device on when pressed.

	**Off Button –** switches the device off when pressed.

2. The user starts by pressing the "On" button on the device, once the microcomputer has switched on, the user starts the camera software by using the touchscreen display to launch the software. The camera will switch on automatically and the live view will be displayed on the screen as shown in Figure 4.6.
3. The user can use the software to adjust camera settings such as white balance or contrast. If the camera settings are satisfactory, the user can proceed on to the next step.
4. The disposable sheath is then fitted onto the main device by sliding the insertion rod into the main channel of the sheath. Once the tip of the rod is flush against the sheath cap, the fluid connector is connected to the rod as shown in Figure 3.35.

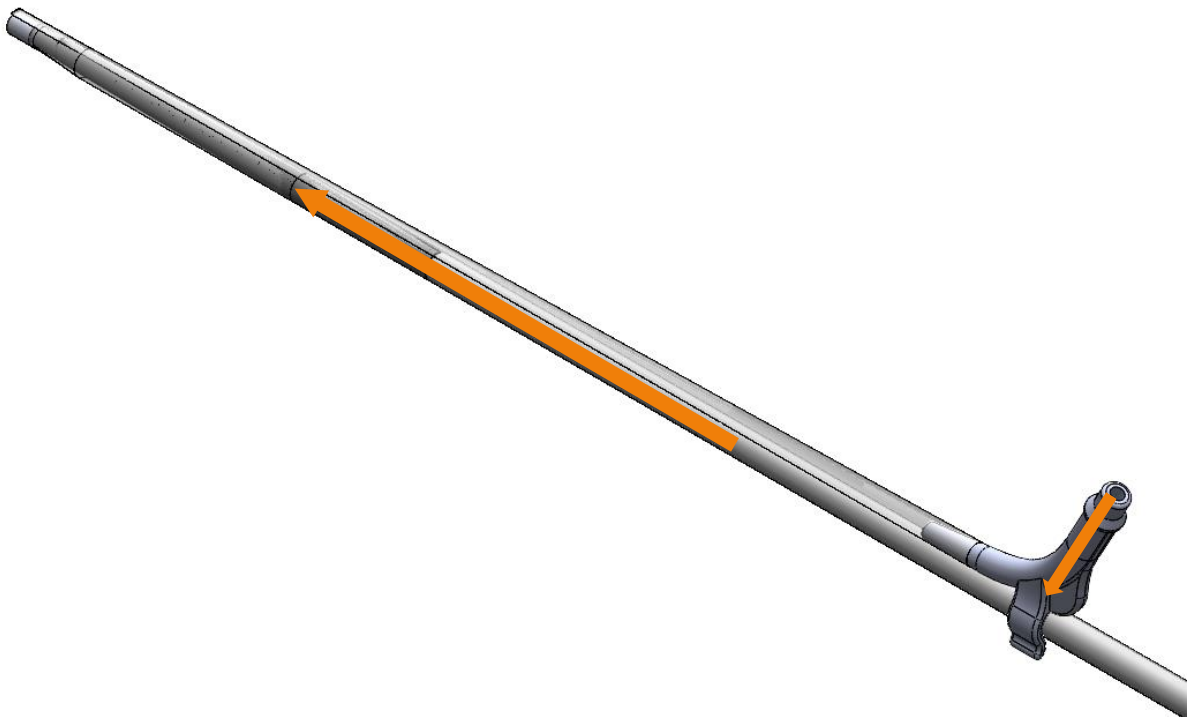


Figure 3-35 Disposable Sheath Fitment. The camera rod is first inserted through the outer sheath, then the fluid connector is clipped on, and the tubing is connected.

5. The distention media source can then be connected to the fluid connector of the sheath and the flow through the sheath can be tested by opening the fluid supply.
6. After the sheath is in place and distention media source is connected, the procedure may begin.
7. The user then navigates through the anatomy of the patient adjusting the guidable tip with the controls as necessary, as shown in Figure 3.36.

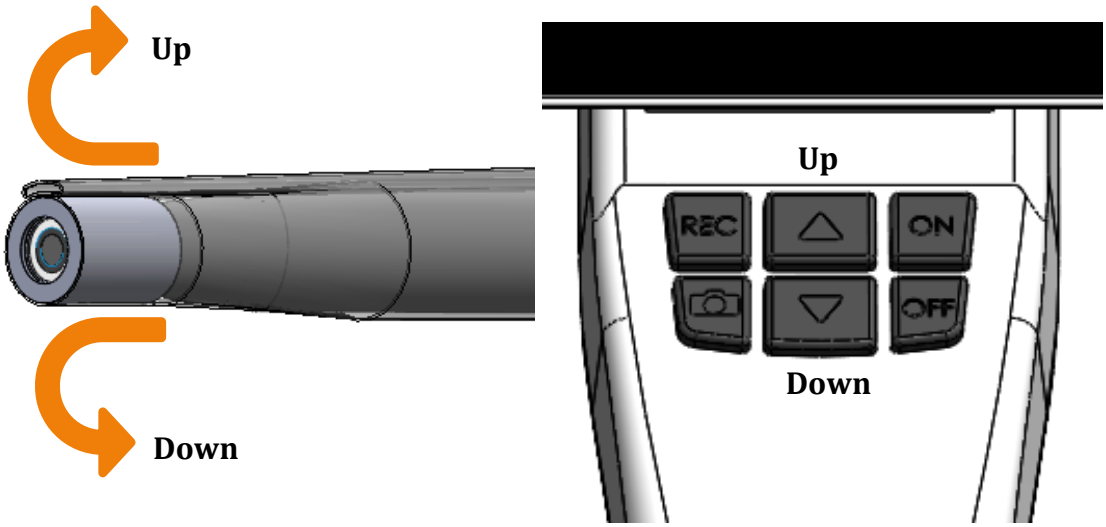


Figure 3-36 Prototype 4 Bending Tip Controls. The bending mechanism is controlled to either bend up or down through user input.

8. Although the device only provides bidirectional bending either up or down, the user can view left or right by rotating the entire device as shown in Figure 3.37 to gain full viewing capabilities.

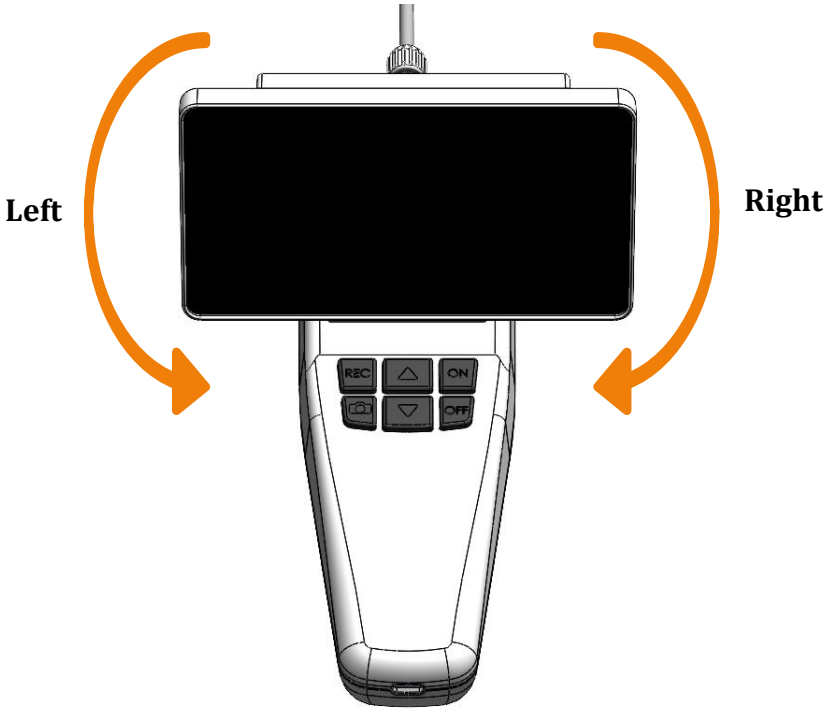


Figure 3-37 Prototype 4 Rotation for Left/Right Viewing. Observing either left or right involves the user rotating the entire device left or right.

9. Once the procedure is completed, the user can remove the device from the patient, disconnect the media supply, and remove the sheath. The sheath is then disposed of, and the main device is switched off and wiped down.

3.6 Summary of Design Process & Outcomes

This chapter presented the design methodology followed to develop the proposed hysteroscopy system according to the design requirements established from the need criteria identified. An iterative prototyping process was completed where after a prototype was produced, issues were analysed, and improvements were made to the follow up prototype. This process repeated until a prototype system was developed that based on initial review, met all the design requirements, and could proceed into verification testing. A summary of the design process of each prototype is discussed below and describes the key outcomes, issues, and improvements of each prototype developed. Table 3.9 provides a comparison of the different prototypes against the design requirements outlined for the proposed hysteroscopy system.

Version 1: Proof of Concept – This prototype served as the proof of concept for the proposed hysteroscopy system and specifically the bending mechanism that implemented shape memory alloy for achieving bending motion. It demonstrated the concept of a mobile hysteroscopy system with built in camera and light source which remove the need for bulky additional equipment. However, the prototype needed to be scaled down and further improve its bending tip.

Version 2: Multiple Directional Bending – The version 2 prototype focused on refining the bending mechanism concept from the previous. It successfully implemented SMA springs instead of wires that offered greater contraction lengths that in turn would result in larger bending motions. Together with a dedicated spring control circuit, and a spring for each direction, the prototype was able to produce bending motions in the up/down and left/right directions. The diameter of the tip remained too large, however, and the prototype still lacked the disposable sheath component to complete the hysteroscopy system.

Version 3: All-in-One System – Prototype 3 successfully represented a complete hysteroscopy system that aligned with the proposed need criteria. It did so by reducing the diameter of the tip through improved manufacturing methods while also refining the bending mechanism. Furthermore, the disposable sheath component was completed, meaning the prototype demonstrated all features could successfully be integrated. However, disposable sheath presented several issues: the sheath increased the diameter and reduced the flexibility of the scope tip to an unacceptable level. The visibility through the sheath was also a critical issue, as the brightness of the LEDs were increased, reflection would obscure the vision.

Version 4: Miniaturisation and Optimisation – The final prototype produced addressed the critical issues with the previous version while further improving the user experience. The diameter of the scope was further reduced that even together with the improved sheath, resulted in a diameter well within the maximum size requirement. The improved sheath design also did not impact the flexibility or visibility of the system thereby producing a system that could undergo full verification testing

Table 3.9 Design Requirements Versus Prototypes Comparison

DESIGN REQUIREMENT	PROTOTYPE 1	PROTOTYPE 2	PROTOTYPE 3	PROTOTYPE 4
Diameter < 4.7 mm	8 mm	8 mm	6.55 mm with sheath	4.17 mm with sheath
Flexible with 100° bidirectional bending	70° one way	100° up/down and left/right	130° up/down	120° up, 116° down
250 mm working length	150 mm	250 mm	200 mm with sheath	260 mm with sheath
Handheld and mobile user-friendly device	Handheld, requires 2 hands	Handheld, requires 2 hands	Handheld, operated with 1 hand	Handheld, operated with 1 hand*
Built-in camera, light source, and display	Separate display using smartphone	Separate display using smartphone	All-in-one system, low quality display	All-in-one system, 1080p display
Battery powered for 10-minute procedures	Battery powered, 9v alkaline battery	Battery powered, 7,4v lithium-ion battery	Battery powered, 7,4v lithium-ion battery	Battery powered, 7,4v lithium-ion battery*
Disposable, single-use sheath	Not implemented	Not implemented	Low visibility, thick, and stiff sheath	Transparent, thin, and flexible sheath
Distention media channel, saline solution up to 200 mmHg pressure	Sheath not implemented	Sheath not implemented	Distention media channel present	Distention media channel present*

FAILED DESIGN REQUIREMENT | **PASSED DESIGN REQUIREMENT** | **UNSATISFACTORY PASS**

***To be confirmed in verification and validation testing**

4 FlexiGyn – Verification and Validation

This chapter discusses the detailed testing process performed on the developed prototype hysteroscopy system. The consist of a breakdown of the testing methodology to show the high level stages, followed by the verification and validation testing chapters. The verification testing explains the tests performed to establish the design specifications of the prototype while the validation testing details the setup and results of the usability test testing conducted on the prototype.

4.1 Testing Methodology

A flowchart of the testing methodology followed is shown in Figure 4.1 below. Upon completion of the prototyping stage, the current prototype would undergo verification and validation testing. If the prototype failed either stage of testing, the project would go back to prototyping to fix the cause of testing failure.

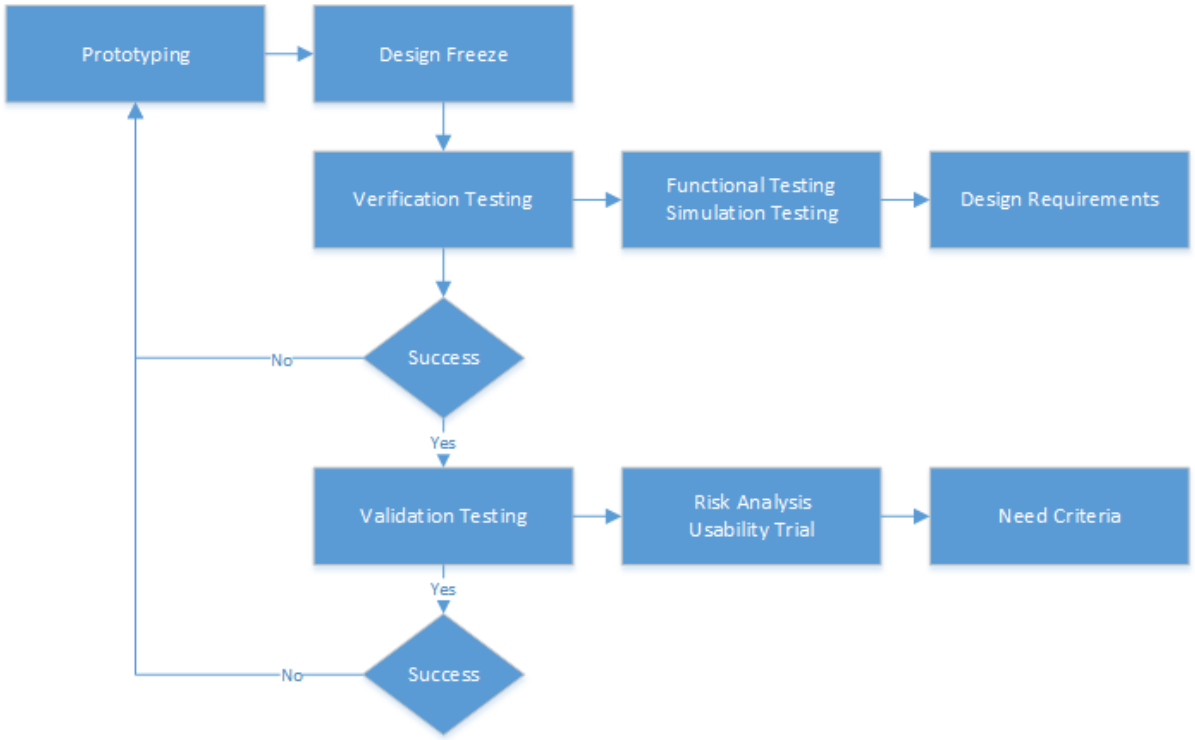


Figure 4-1 Testing Methodology. The testing methodology aimed to first verify the prototype through functional and simulated testing compared to the design requirements, then validate it through a comparative usability trial to determine if need criteria were met.

The purpose of each stage of testing is further described as follows:

- Verification – "Was the device designed correctly?" The first testing stage determines the technical specifications of the developed hysteroscopy system to compare against the design requirements outlined by the research project. This essentially confirms if the hysteroscopy system can function as intended by the design, which is the first

step required to prove its viability as a solution to the research problem. Verification consists of testing components, subsystems, and the integrated system by measuring and simulating functional aspects of each. The results are used to determine the system's design specifications. These specifications represent the simulated and functional parameters such as dimensions, component lifespan, and power consumption.

- Validation – "Was the correct device designed?" The second testing stage is to determine if the developed hysteroscopy can successfully perform its intended use. This is done through simulated scenarios with real users and comparing the prototype against an existing system. The project aims to develop a hysteroscopy system and validation testing essentially confirms whether what was produced can function as a hysteroscopy system. This consist of performing a risk analysis and a usability trial. The risk analysis aims to evaluate the prototype for potential hazardous use scenarios to inform the usability trial protocol. The usability trial has users complete use scenarios with the prototype while being observed and collect their feedback. The outcome of the usability trial is used to validate the developed system against the need criteria and its capability as a hysteroscopy system.

4.2 Verification

This chapter details the verification tests performed on the prototype hysteroscopy system. The tests consisted of determining functional parameters, computer simulations on components, and calculations using measurements to determine specifications. The chapter concludes by summarising the design specifications of the hysteroscopy system and comparing it with the design requirements of the research project. Successfully meeting the requirements will allow the developed system to progress to the next testing stage.

4.2.1 Functional Parameters

The tests performed on the hysteroscopy system and the main subsystems are outlined as follows. Tests were performed on individual components, as well as on combined subsystems to determine functional parameters after integration.

4.2.1.1 Handheld Base

The handheld base's function was providing the platform for integration of the subsystems while housing the electronics and power supply unit of the system. The result needed to be held and operated with a single hand while being comfortable and avoid straining the user. These aspects could be investigated by the designer but required validating by end users, as such would form part of the validation testing process. One parameter could be measured, however, the weight of the device, as shown in Figure 4.2 below.

Figure 4-2 Prototype Weight. The entire prototype was weighed on a scale and found to weigh 500 g.

The final weight of the device was 500g as measured using a digital scale. This weight was deemed acceptable and as stated would be further evaluated by the actual users during the validation testing stage. The handheld base also successfully integrated all subsystems and electronics, confirming the system to be all-in-one without the need for additional equipment to operate.

4.2.1.2 Smart Bending Mechanism

The parameters of the smart bending mechanism were critical when considering the design requirements of the proposed hysteroscopy system. The SBM would directly influence the design outcomes that determined potential viability of the hysteroscopy system as a solution. The following tests were therefore performed to measure these parameters.

The working length of the hysteroscopy was determined by the length of the flexible rod with the disposable sheath in place. This was measured as shown in Figure 4.3 below from the distal tip to the fluid connector of the sheath. The total working length was measured to be 260mm.

Figure 4-3 Working Length of Prototype. The working length was measured with a ruler and with the sheath on found to be 260 mm.

The diameter of the flexible rod with the disposable sheath was the next parameter to be measured, a digital vernier calliper was used as shown in Figure 4.4 below. The outer

diameter of the hysteroscopy system with the disposable sheath was measured to be approximately 4.2mm.

Figure 4-4 Outer Diameter with Sheath on. A digital vernier calliper was used to measure the diameter of the rod with the sheath and was approximately 4.2 mm.

The final critical parameter of the SBM was the bending capability with the disposable sheath in place. This parameter was measured using a 360° protractor with the bending tip placed over and activated to bend in both directions as shown in Figure 4.5 below.

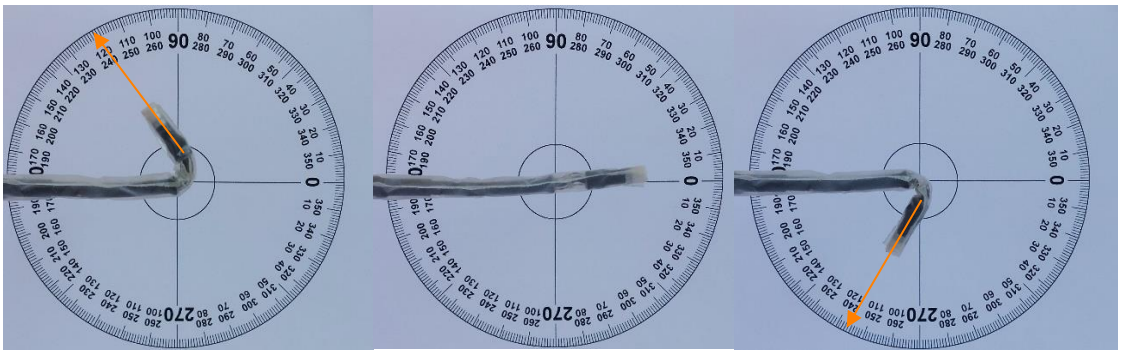


Figure 4-5 Bending Angles of Prototype. The bending angle was measured with a 360° protractor and was able to bend 120° up and 116° down.

The SBM's bending capability was measured to be 120° degrees upwards and 116° degrees downwards resulting in a total bending range of 236° degrees.

The flexible rod of the SBM also influenced the system's ability to navigate the patient's anatomy during procedures. The designer successfully navigated a model; however, this parameter would be validated in the usability trial by real users.

4.2.1.3 Mobile Visualisation Platform

The mobile visualisation platform's parameters revolved around the quality of visuals. These included the framerate of the camera view displayed on the screen, as well as the

effect of the disposable sheath on the visibility. These parameters were tested and measured as follows.

The framerate of the camera display was tested by switching on the hysteroscopy system, starting the camera software, and recording the framerate while the camera is on. The software indicated the framerate displayed on the screen which could be compared against the framerate of the camera as stated on the manufacturer's datasheet to determine if any delay or framerate loss is occurring. Figure 4.6 below shows a screen capture of the display during this test.

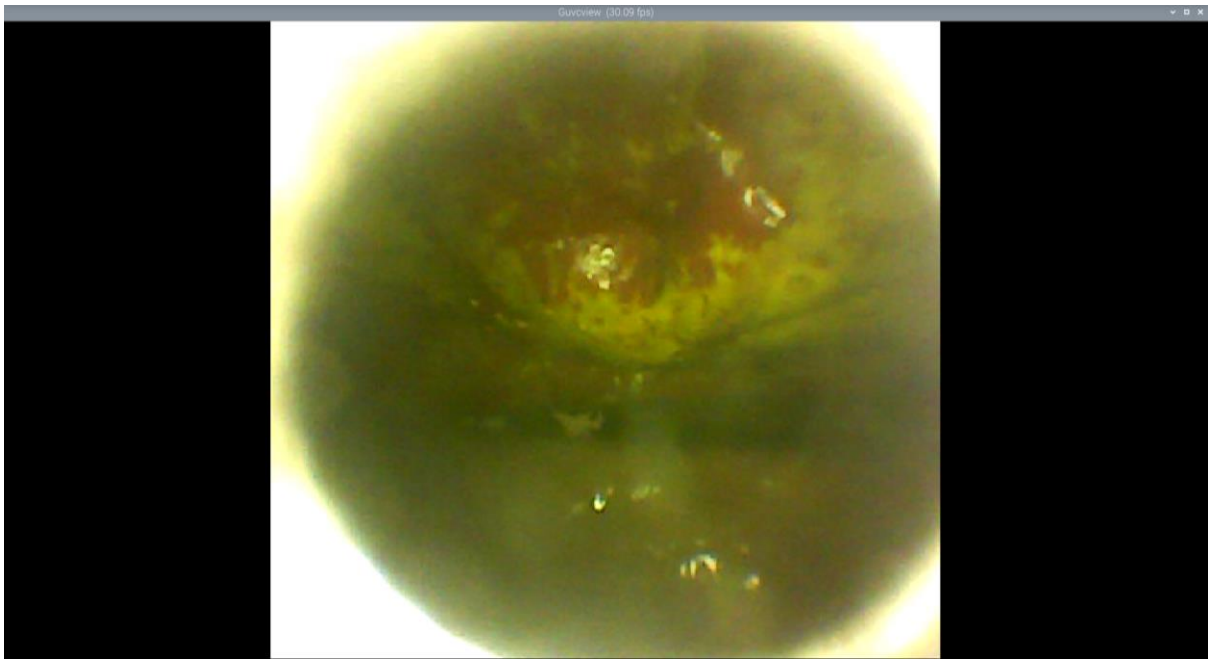


Figure 4-6 Framerate of Displayed Camera Feed. The framerate of the camera display matched the framerate of the camera module listed in the manufacturer's datasheet of 30fps.

A consistent framerate of 30fps was recorded during the test which matches the manufacturer’s datasheet of what the camera is capable of.

The visibility parameters of the MVP with the disposable sheath in place required testing as with previous prototypes the sheath greatly affected the image quality. The parameters tested were image quality with and without the sheath, with the sheath and varying intensity of LED brightness, and finally the image quality with the sheath in a submerged environment.

The image displayed by the camera with and without the disposable sheath in place is shown in Figure 4.7 below.

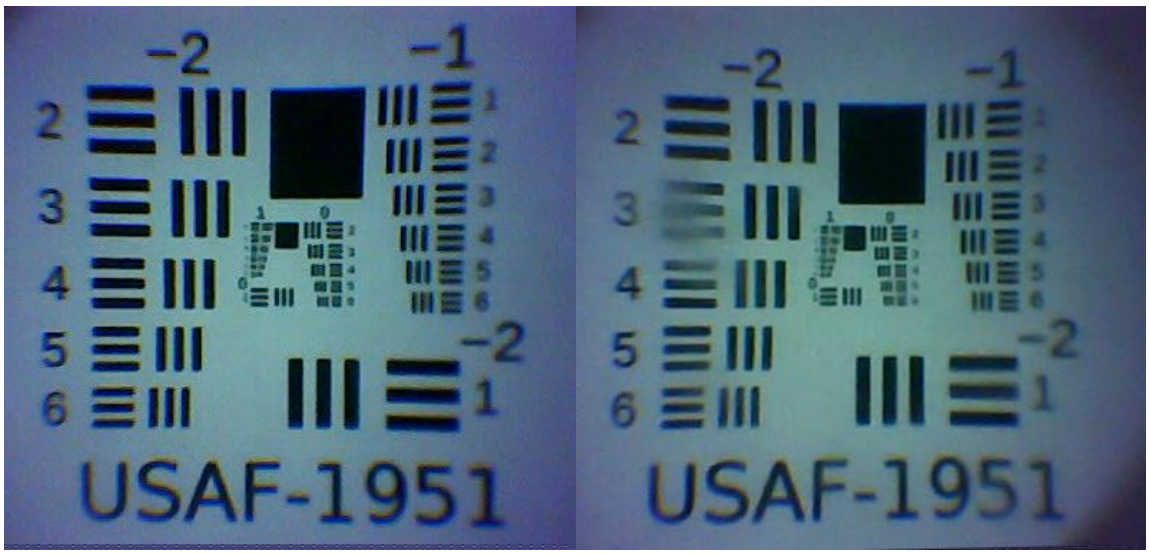


Figure 4-7 Image Quality with Sheath On vs. Off. The visibility through the sheath (right) versus without the sheath (left) was compared and found to be acceptable with little loss in visibility.

The next test recorded the image displayed by the camera with the sheath in place at different levels of LED brightness, these images are shown in Figure 4.8 below.

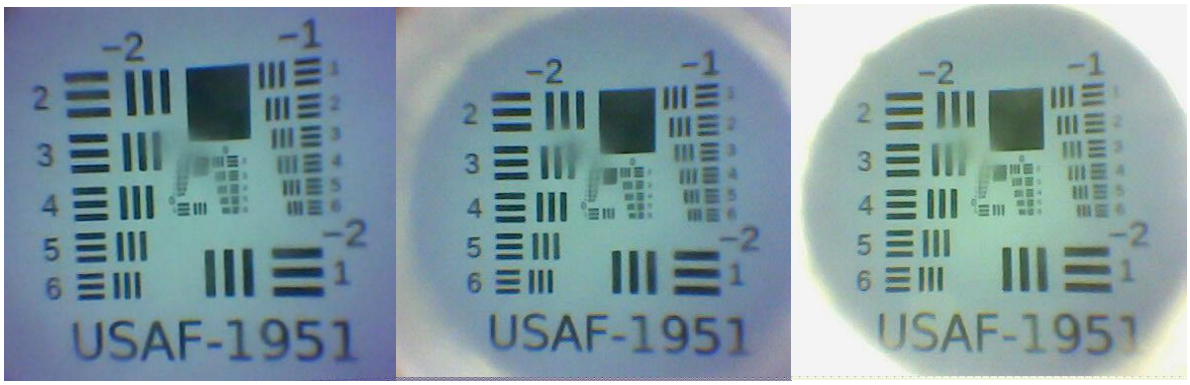


Figure 4-8 Image Quality with LED Increasing Brightness. Left to right, the visibility through the sheath with increasing levels of LED brightness was tested to confirm visuals were possible at each level.

Several images were also recorded with the sheath in place while using the prototype to investigate the cavity of a uterus model. These images are shown in Figure 4.9 below.

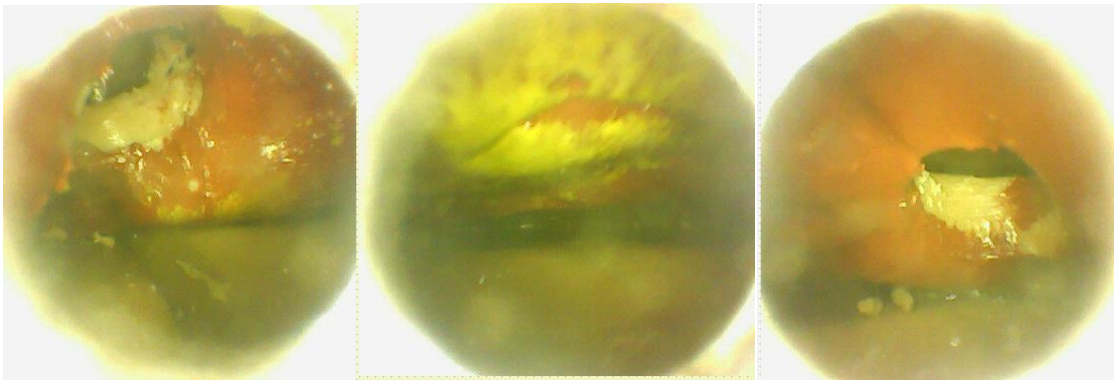


Figure 4-9 Uterine Cavity Images with Sheath on. The uterine cavity of a hysteroscopy simulator was observed with the sheath on and was able to observe the entire cavity.

The final the test performed was recording the image displayed by the camera with the sheath on while submerged. The images below in Figure 4.10 show the results of this test.

Figure 4-10 Submerged Uterine Cavity Images with Sheath on. A uterus model was submerged, and the device was used to observe the cavity to confirm its ability to function while fully submerged.

An additional test was performed to measure the temperature of the LEDs on the tip of the prototype with the sheath in place. According to the United States of America Food & Drug Administration (2018) guidance document on hysteroscopy systems, the temperature at any patient-contacting part of the system should not exceed 41°C. A temperature probe of a digital multi-meter was fixed to the tip of the prototype using polyimide film heat resistant tape. An initial temperature was recorded with the system off, thereafter the system was switched on with the LEDs set to maximum brightness. The system was left in this state for 10 minutes and the temperature was recorded again. The results of these two tests are shown in Figure 4.11 below.

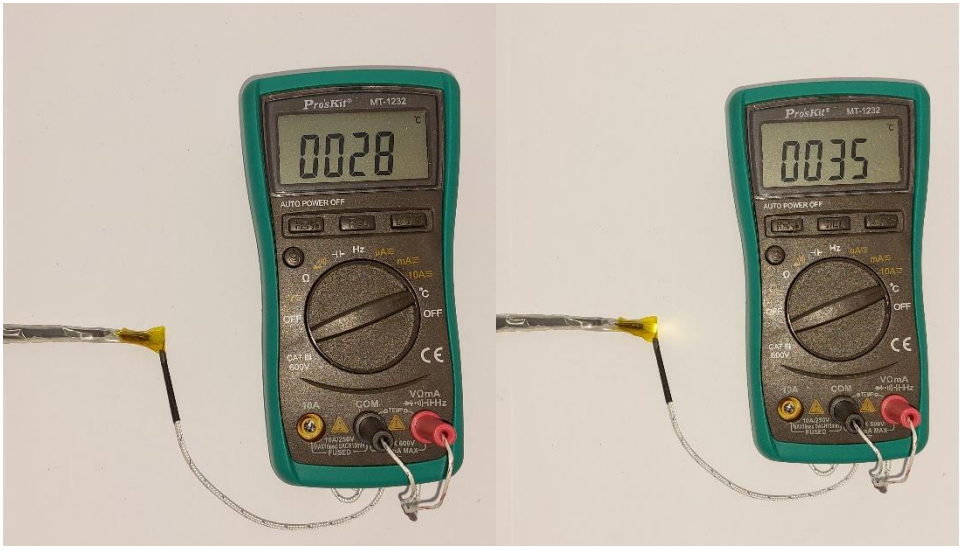


Figure 4-11 LED Temperature Test Result. A temperature probe was fixed over the LEDs to measure the temperature after 10 minutes. The temperature was measured to be 35°C.

The temperature probe measured a maximum of 35°C after 10 minutes and which is below the required 41°C.

4.2.1.4 Disposable Sheath

The disposable sheath has two elements that required testing: the distention media channel and the main device channel. The distention media channel was tested to determine if it could supply media at the pressure required while the main channel was tested to measure its capability of isolating the device at the working pressures.

The distention media channel was tested using a pressure infusion cuff with a 1000ml saline solution bag shown in Figure 4.12 below.

Figure 4-12 Pressure Cuff with Saline Bag

The disposable sheath was then connected to the saline solution bag through standard irrigation tubing as shown in Figure 4.13 below. The pressure was then raised to 210mmHg.

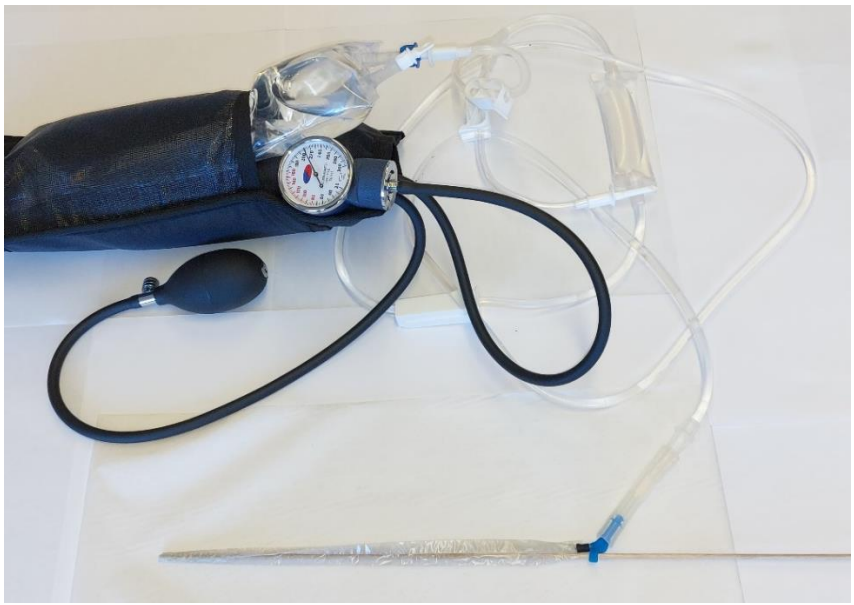


Figure 4-13 Distention Media Channel Pressure Test Setup. The pressure cuff was using to raise the pressure of the saline bag to 210 mmHg and connected to the distention media channel of the sheath.

The channel was then opened, and the saline solution allowed to flow through. Figure 4.14 below shows the flow through the distention media channel of the sheath.

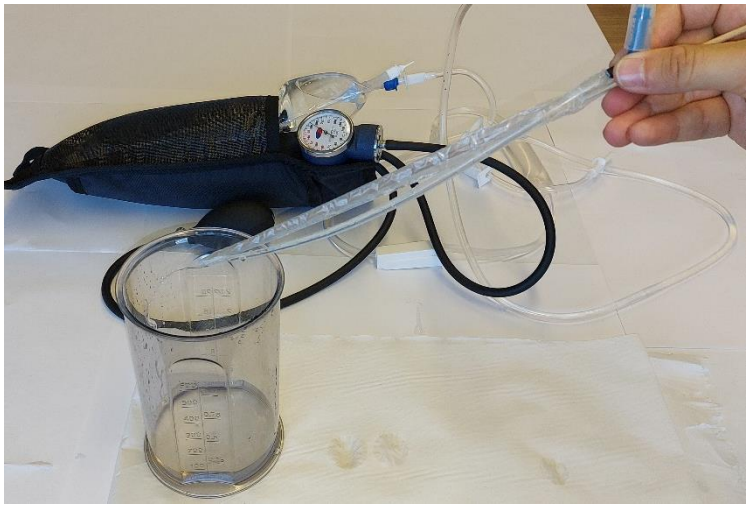


Figure 4-14 Distention Media Channel Flow. The distention medial channel was tested by allowing the saline to flow through while connected to the pressure cuff.

The same pressure infusion cuff was used to test the pressure capability of the main device channel on the sheath. The irrigation tubing was inserted into the channel on fastened in place, as shown in Figure 4.15 below.

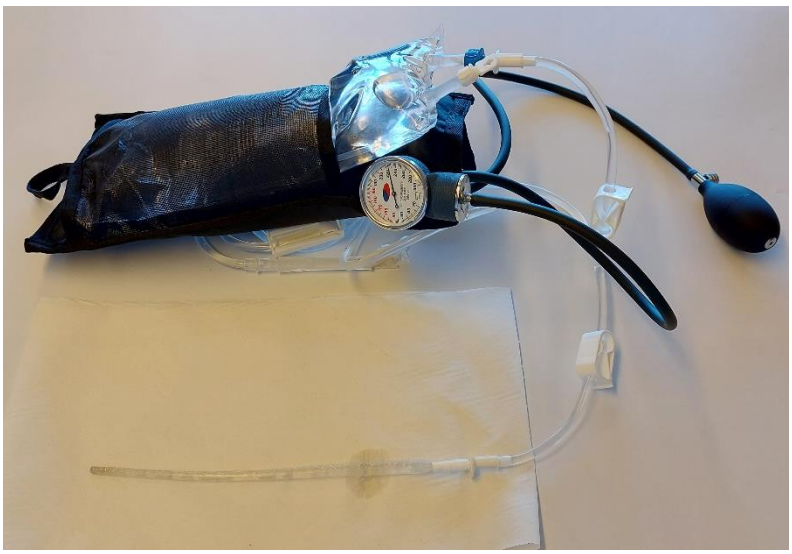


Figure 4-15 Main Sheath Channel Pressure Test. The outer sheath was connected to the saline bag in the pressure cuff and the pressure was raised to 225 mmHg. This resulted in a small leak towards the base of the sheath but no leak was observed at the tip.

The pressure was raised to 225mmHg, and the channel was opened to saline solution. A small leak was observed towards the base of the sheath as can be seen in Figure 4.15 above, the tip of the sheath did not produce any observable leaks.

4.2.2 Battery Life Calculations

The developed hysteroscopy system should be capable of operating for the full duration of a procedure without requiring recharging. Tests were therefore completed to measure the current drawn by the electronics and bending mechanism activation to calculate the expected lifespan of the specific battery used. Figure 4.16 below shows the block diagram of the entire system circuit.

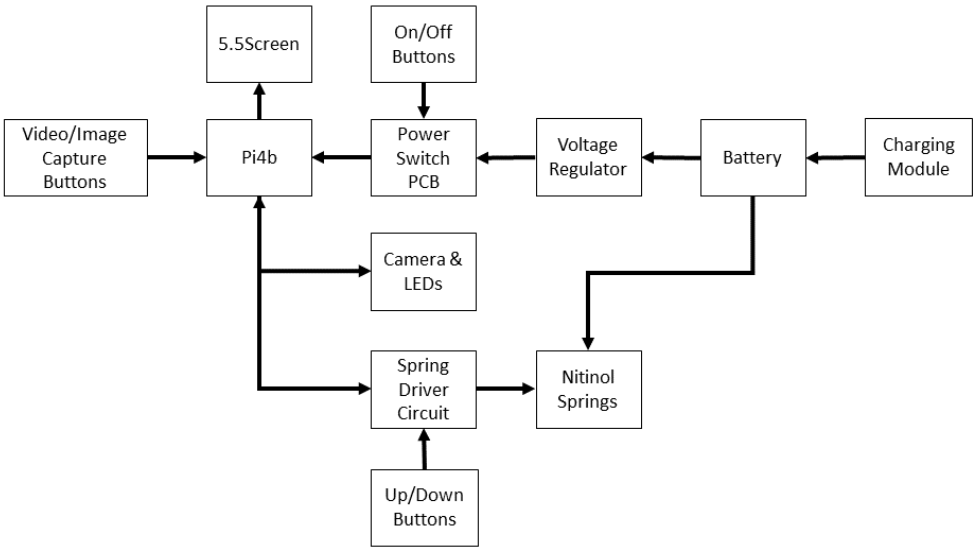


Figure 4-16 Prototype 4 Circuit Block Diagram. The major components of the electronics are shown in the diagram.

Figure 4.16 above indicates the two major power drawing components in the system; the microcomputer that powers all components directly connected, and the nitinol springs that are activated by the spring driver circuit but powered directly by the battery. Measuring the current draw of these two components would provide the information required to calculate the battery lifespan.

The current measurement for microcomputer was setup by connecting a digital multi-meter in series between the battery and the voltage regulator. The system was then fully switched on, camera display enabled, and LEDs set to maximum brightness. The measurement shown on the multi-meter was then recorded, the setup for this measurement is shown in Figure 4.17 below.

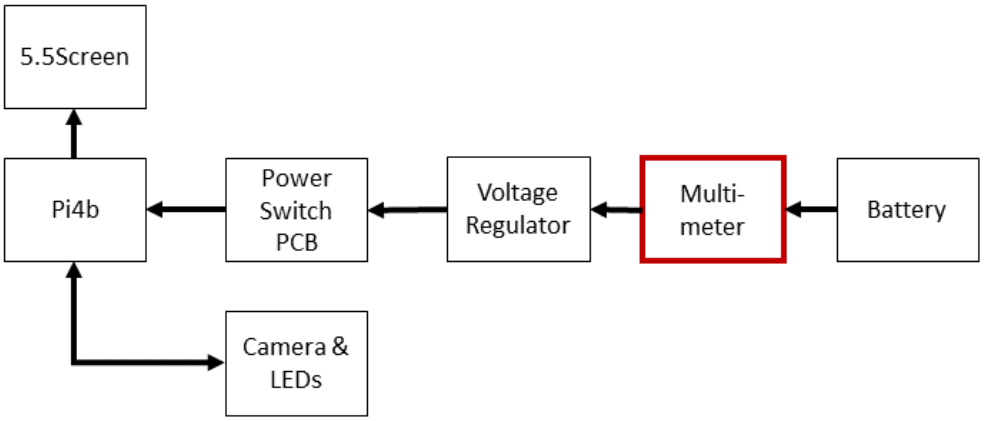


Figure 4-17 Prototype 4 Current Measurement Setup. Highlighted in a red box is the multi-meter connected in series between the battery and the voltage regulator to measure the current drawn.

A measurement of 1.052 A was recorded during this test. Measuring the current drawn by the nitinol springs during activation required a different setup. A duplicate of the

bending mechanism circuit was built and connected to the battery of the system to isolate and measure the current draw of the nitinol spring. The setup of this configuration is shown in Figure 4.18 below.

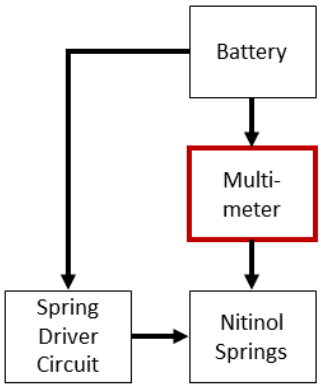


Figure 4-18 Nitinol Spring Current Measurement Setup. A multi-meter is highlighted in the red box that is connected in series between the battery and nitinol springs to measure the current drawn by the springs during activation.

The multi-meter was connected in series between the spring and battery and the current draw when activated was recorded for several activations. These measurements are shown in Table 4.1 below. The time taken to fully contract the spring was recorded alongside the current measured.

Table 4.1 Nitinol Spring Contraction Time vs. Current

	Contraction Time (s)	**Current (A)**
	1.410	0.92
	1.520	0.92
	1.530	0.91
	1.520	0.92
	1.530	0.93
Average	1.502	0.92

The battery has a capacity of 2.6 Ah, to calculate the lifespan the following equation is used.

$$Time(h) = \frac{Capacity(Ah)}{Current(A)}$$

The battery lifespan when powering the microcomputer and connected components can then be calculated as follows.

$$\frac{2.6Ah}{(1.052A + 0.92A)} = 1.32h$$

However, the current drawn of the nitinol spring is not continuous as it only draws current when activated. The battery lifespan is therefore dependent on the number of activations during a procedure. The conservative calculation performed estimates the battery lifespan assuming the microcomputer and nitinol spring are fully activated until the battery runs out, the result being 1.32 hours which exceeds the average duration of a hysteroscopy procedure.

4.2.3 Finite Element Analysis of Nitinol Springs

Finite Element Analysis (FEA) is a numerical method used for the predication of how a component behaves under certain conditions. FEA software allows engineers to perform simulations to reduce the number of experiments and optimise designs. The stresses experienced by the nitinol springs in the hysteroscopy system can be estimated through a FEA which is ideal for the purposes of this research project as the experiments required to determine the stresses are beyond the project scope.

4.2.3.1 Load Measurement

The purpose of the nitinol spring FEA is therefore to estimate the stresses experienced to determine the rough number of activations cycles the springs are capable of according to the manufacturer's datasheet. The first step to required is measuring the load placed on the spring when activated. The fully assembled hysteroscopy system with the disposable sheath in place was used during this test to ensure the full load is measured.

A 5N spring balance was connected to one of the gear racks at the spring connecting end. The spring balance was then pulled in the direction of the spring contraction, essentially acting in place of the nitinol spring. During this action, the force measured on the spring balance from the start of the motion to the end was recorded. This motion represented the full activation of a nitinol spring that would bend the tip from one side to the other. Table 4.2 below shows the force measured at the start of the motion, and the force at the end of the motion.

Table 4.2 Bending Mechanism Load Measurements

Force Measured (N)	
Motion Start	Motion End
2.5	3.5

The increase in force measured is likely due to the increased resistance of the tip as it nears the maximum bending position. These measurements represent the load placed on the spring during activation and results in the stresses experienced. The load was used in the FEA to simulate these stresses.

4.2.3.2 Nitinol Material Properties

The software chosen to perform the FEA is Ansys Workbench 2022 as it provided access to a pre-built shape memory effect material that implement Auricchio's SMA model (Auricchio & Sacco, 1997). Ansys, however, requires seven constants for the material parameters, these are listed in Table 4.3 below.

Table 4.3 Ansys Shape Memory Effect Model Material Constants

CONSTANT	MEANING	PROPERTY
C1	h	Hardening parameter
C2	T_0	Reference temperature
C3	R	Elastic Limit
C4	β'	Temperature scaling Parameter
C5	$\overline{\varepsilon_L}$	Max. transformation strain as defined in Aurrichio's model
C6	E_M	Martensite modulus
C7	m	Lode dependency parameter

These material parameters unfortunately are not all provided by the nitinol spring manufacturer. Boufayed (2021) provides expressions of the seven inputs as a function of parameters typically known which can be used to calculate the inputs. The expressions used to calculate the unknown inputs are listed in Table 4.4 below.

Table 4.4 Expressions for Unknown Material Constants

Constant	Corresponding expression
C1	$2\beta(M_s - M_f)/3\gamma$
C3	$\beta(A_s - M_f)/\sqrt{6}$
C4	$\beta\sqrt{(2/3)}$
C5	$\gamma\sqrt{(3/2)}$
C7	0

In the above Table 4.4, C7 characterises the material's different response between tension and compression. The nitinol springs are subjected to tension only as such C7 can be set to zero without effecting the model. Table 4.5 below lists the material properties known or assumed based on similar materials used in similar studies.

Table 4.5 Known Material Properties of Nitinol Spring

PROPERTY	SYMBOL	VALUE
Austenite Young's Modulus	E_A	75GPa
Martensite Young's Modulus	E_M	28GPa
Martensite Start Temperature	M_s	72°C
Martensite Finish Temperature	M_f	62°C
Austenite Start Temperature	A_s	88°C
Austenite Finish Temperature	A_f	98°C
Poisson's Ratio	v	0.33
Max. Transformation Strain	γ	7%
Slope of the transformation lines in the state diagram	β	8MPa/°C

All of the values in Table 4.5 above were obtained from the manufacturer of the nitinol springs (Dynalloy, n.d.), excluding the value for the slope of transformation lines in the state diagram, β. This value was assumed to be 8MPa/°C as in studies by Moore and Bruck (2002), Churchill et al. (2010), Boufayed (2021), and El Mtili et al. (2022) the value ranged between 7.8 MPa/°C to 8.3 MPa/°C where each study used nitinol from the same manufacturer as used in this research project.

Using the material properties in Table 4.5 above and the expressions for the unknown constants, the values for the seven constants of the Ansys model were calculated, the values are shown in Table 4.6 below.

Table 4.6 Calculated Ansys Material Constants

Constant	Value
C1	761.9MPa
C2	62°C
C3	84.91MPa
C4	6.5MPa/°C
C5	8.6%
C6	28GPa
C7	0

After calculating the values of the seven constants, a static structural analysis was setup in Ansys Workbench and the nitinol material with the shape memory effect model was added.

4.2.3.3 Nitinol Spring Geometry

A 3D model is required to perform the FEA on, subsequently a simplified model of the nitinol spring was developed with the physical dimensions of actual spring. The dimensions of spring model are listed in Table 4.7 below.

Table 4.7 Nitinol Spring Model Dimensions

Dimension	Value
Outer Diameter	3.45mm
Wire Diameter	0.51mm
Number of Coils	10
Pitch	No Pitch

The spring model used for the FEA is shown in Figure 4.19 below.

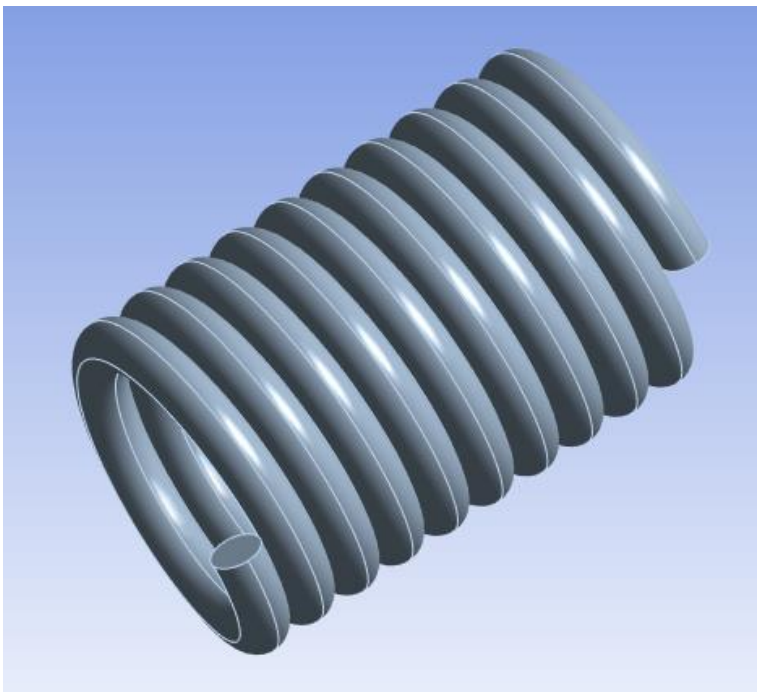


Figure 4-19 Nitinol Spring CAD Model. The model is based on the dimensions of the fully compressed nitinol spring used in the system.

4.2.3.4 Boundary Conditions and Thermomechanical Loads

The spring's boundary conditions were setup to resemble those in the bending mechanism. Therefore, the spring was fixed at one end while the mechanical load was applied to the other end, additionally the spring was limited to displacement along the y-axis simulate the fixed movement in the mechanism. The boundary conditions of the spring are shown in Figure 4.20 below.

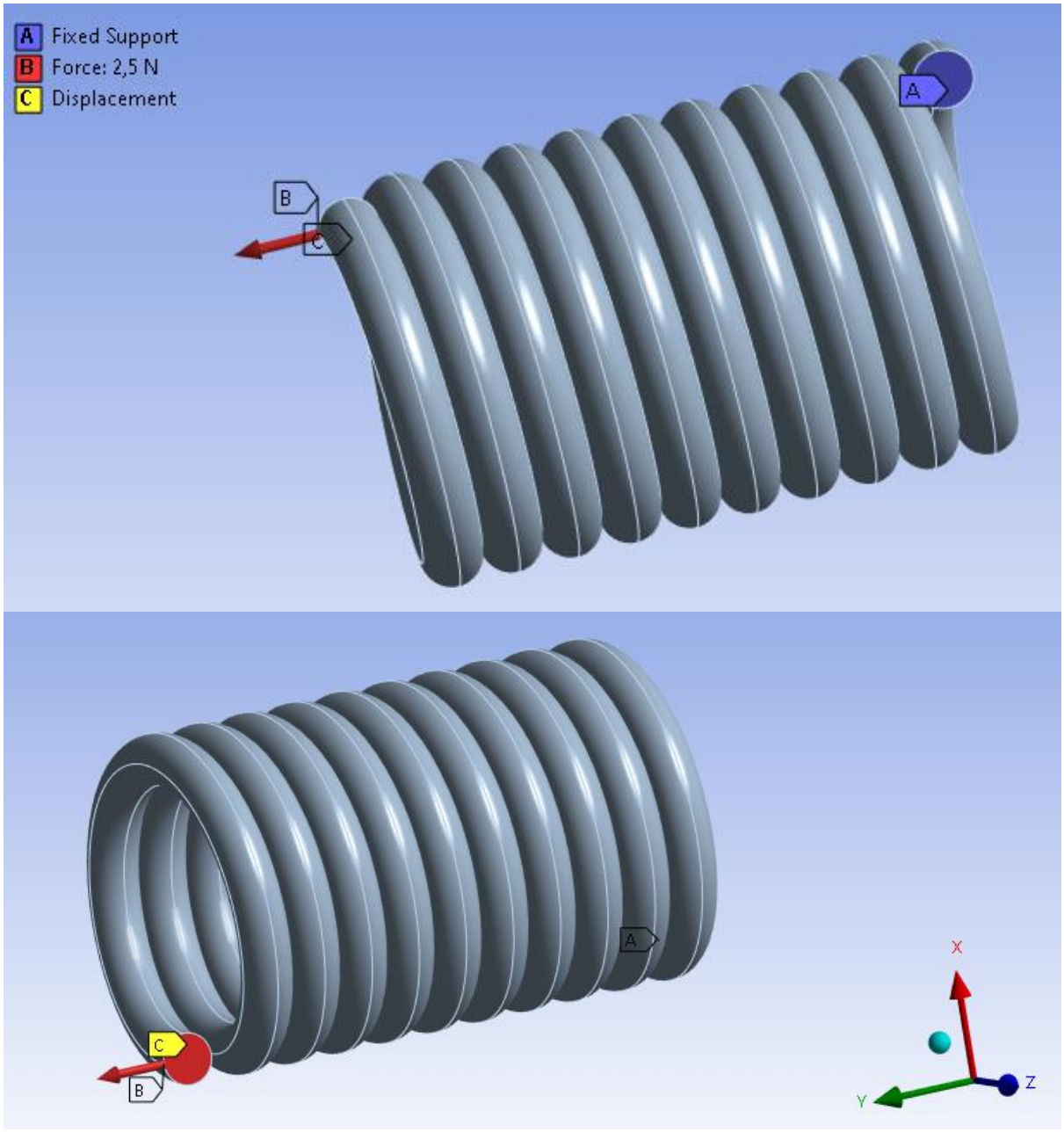


Figure 4-20 Model Boundary Conditions. The conditions are (A) Fixed end, (B) 2.5 N force applied in the Y axis, (C) Displacement was limited along the Y axis.

The temperature of the spring was assumed to be applied uniformly across the body and varied according to time, as shown in Figure 4.21 below.

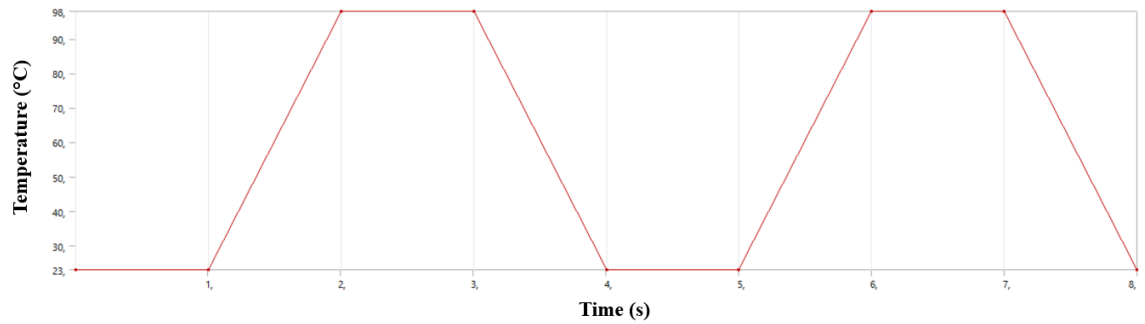


Figure 4-21 Thermal Load vs Time. A thermal load of 98°C was applied over 1 second for two activations of the nitinol spring.

The thermal load in Figure 4.21 above represents two full activation cycles of the nitinol spring. The start of an activation cycle occurs when the spring's body temperature is raised to 98°C, at this temperature the spring is fully contracted and is kept at this temperature for 1 second while the load is being applied. The spring is then cooled down to ambient temperature again to end the activation cycle. A cycle is then repeated to determine if any change in stresses experienced occurred.

The mechanical load on the spring was also setup to apply two cycles of loading and unloading along with the two activation cycles. Figure 4.22 below shows a load applied to the spring, with the maximum load being applied during the contraction cycle. This would result in the greatest potential stresses as when the spring is attempting to fully contract, the highest load is being applied.

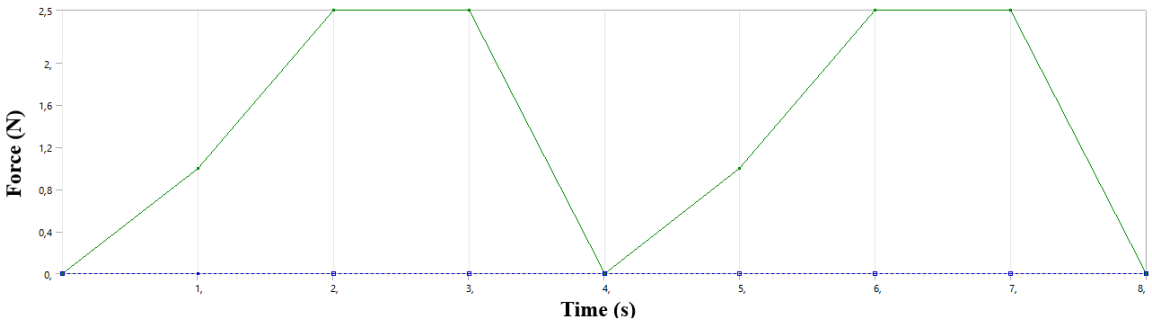


Figure 4-22 Mechanical Load vs Time. A mechanical load of 2.5 N was applied for 1 second to the nitinol spring for two activation cycles.

4.2.3.5 Finite Element Mesh

A mesh for the FEA was generated by using 3D structural elements of the type SOLID186. Mesh convergence was assessed by reducing the element size of the mesh, and comparing the equivalent stresses produced by each mesh. The details of the different meshes generated are listed in Table 4.8 below.

Table 4.8 FEA Mesh Details

	Mesh 1	Mesh 2	Mesh 3	Mesh 4
Element Size	Default	0.2mm	0.16mm	0.1275mm
Number of Elements	2750	7408	11560	21750
Number of Nodes	14542	36171	56137	105957

The equivalent stress along the same edge of the spring model was used to compare the results produced by each mesh, Figure 4.23 below shows the edge selected.

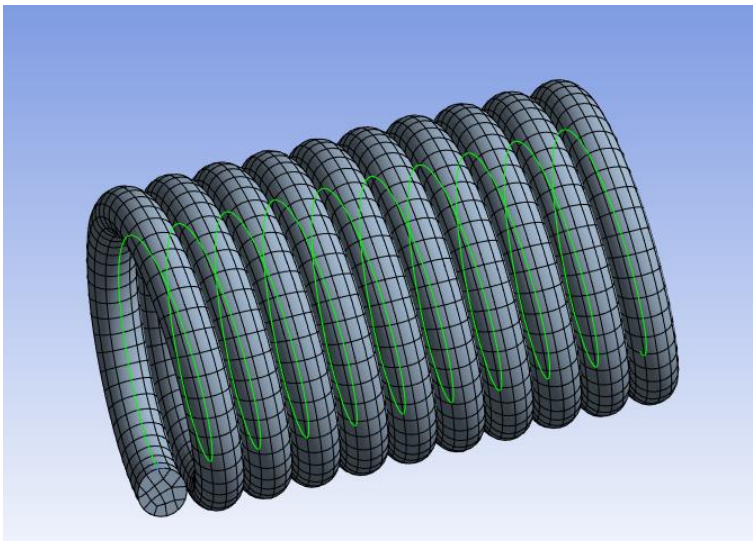


Figure 4-23 Selected Edge for Mesh Comparison. The selected edge in the nitinol spring model was used to compare the results of different meshes to determine the appropriate mesh.

The results of the equivalent stress along the specified edge produced by each mesh are shown in Table 4.9 below.

Table 4.9 Equivalent Stress Results per Mesh

	Mesh 1	Mesh 2	Mesh 3	Mesh 4
Minimum (MPa)	18.631	16.695	16.324	12.041
Maximum (MPa)	68.111	84.621	85.238	89.220
Average (MPa)	52.810	68.584	69.308	71.911
Maximum Value Over Time (MPa)	196.27	200.31	199.63	201.00

After the results were compared, the 2nd generated mesh was selected as the fixed mesh for the FEA. This mesh produced results for the maximum stress and maximum value over time that differed from the 4th mesh by less than 6%, while completing in a much faster time.

4.2.3.6 Mechanical Loading Results

The equivalent stress experienced by the nitinol spring under three different loading conditions was produced using the boundary conditions, thermal load, and fixed mesh. Figure 4.24 below shows the different loads applied.

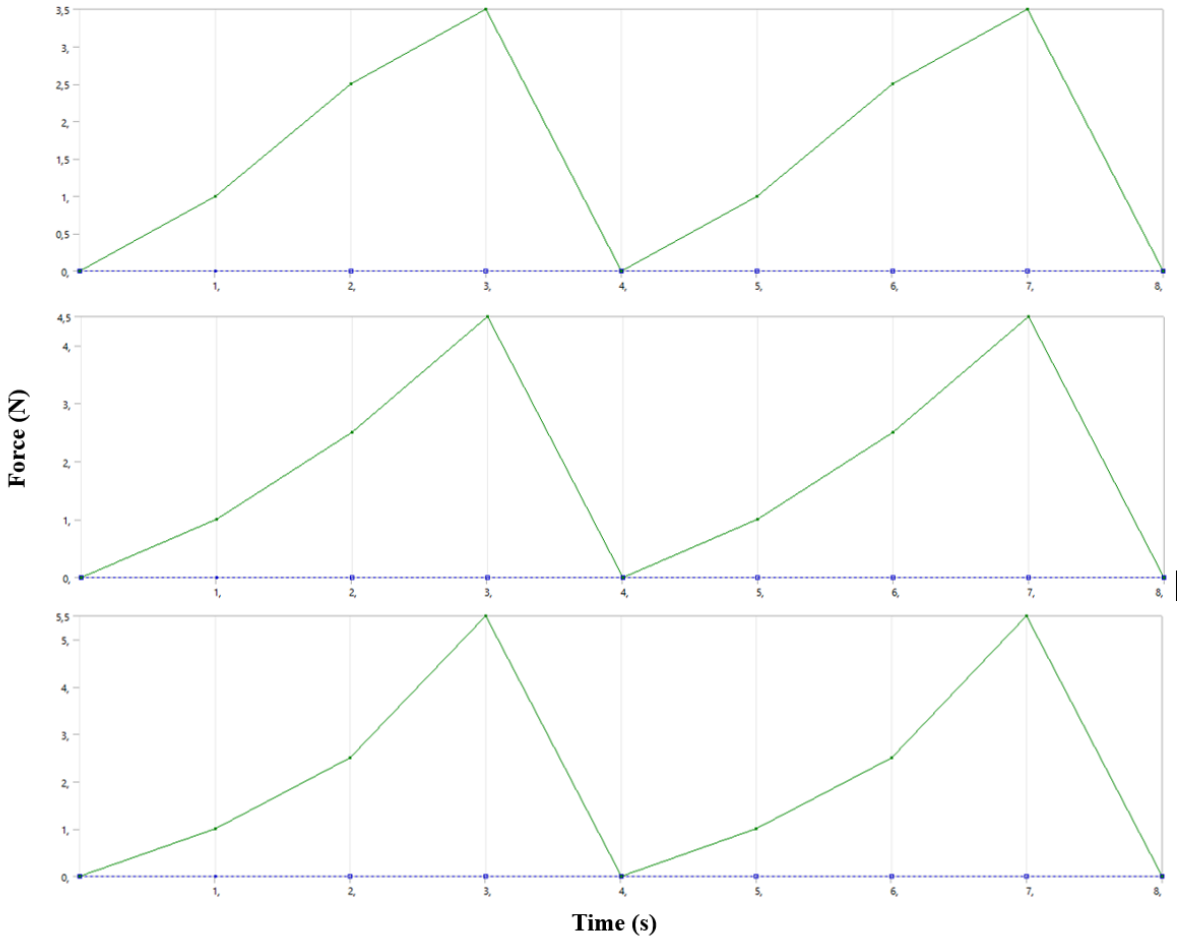


Figure 4-24 Mechanical Load Scenarios Applied. Three different loading scenarios were applied to the nitinol spring model which were (top) 3.5 N, (middle) 4.5 N, and (bottom) 5.5 N.

In each case, the load is set to 2.5N at the start of the contraction period, and for each scenario raised to 3.5N, 4.5N, and 5.5N, respectively by the end of the contraction. The equivalent stress experienced across the spring body during the 3.5N loading cycle at three different time steps is shown in Figures 4.25, 4.26, and 4.27 below.

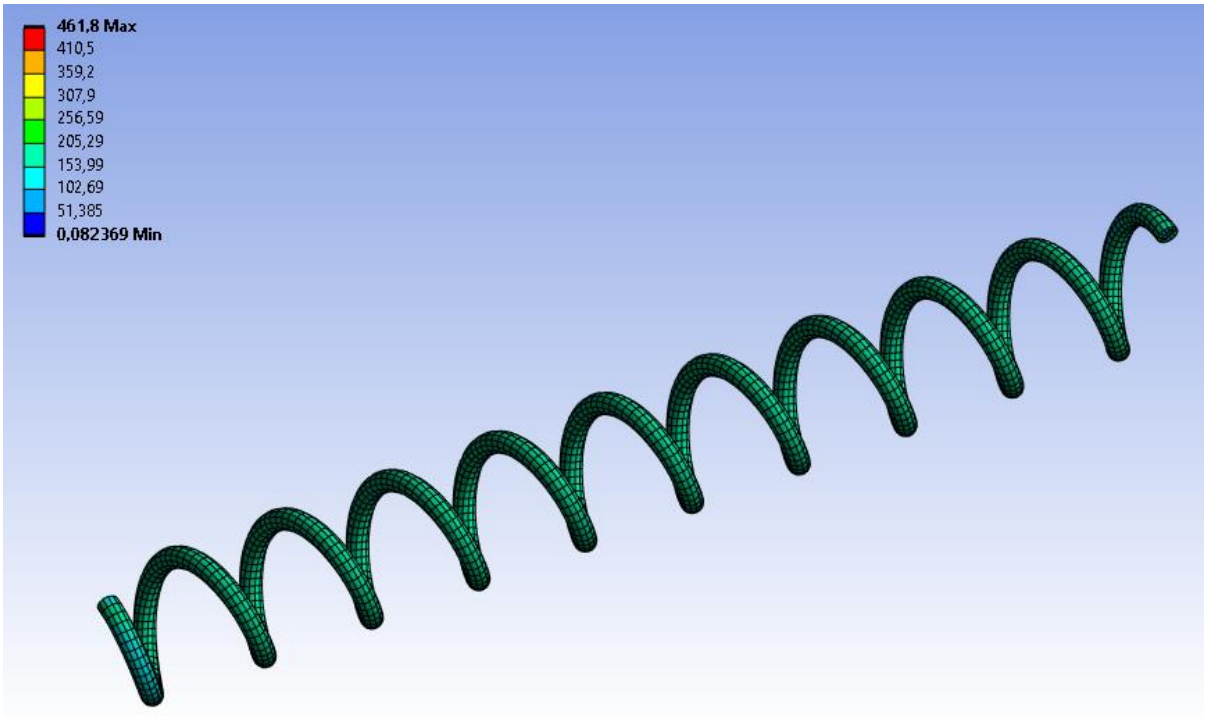


Figure 4-25 Equivalent Stress at 1.9394s Time Step. The time step shows the stress at the moment before the contraction begins during the 3.5 N load scenario.

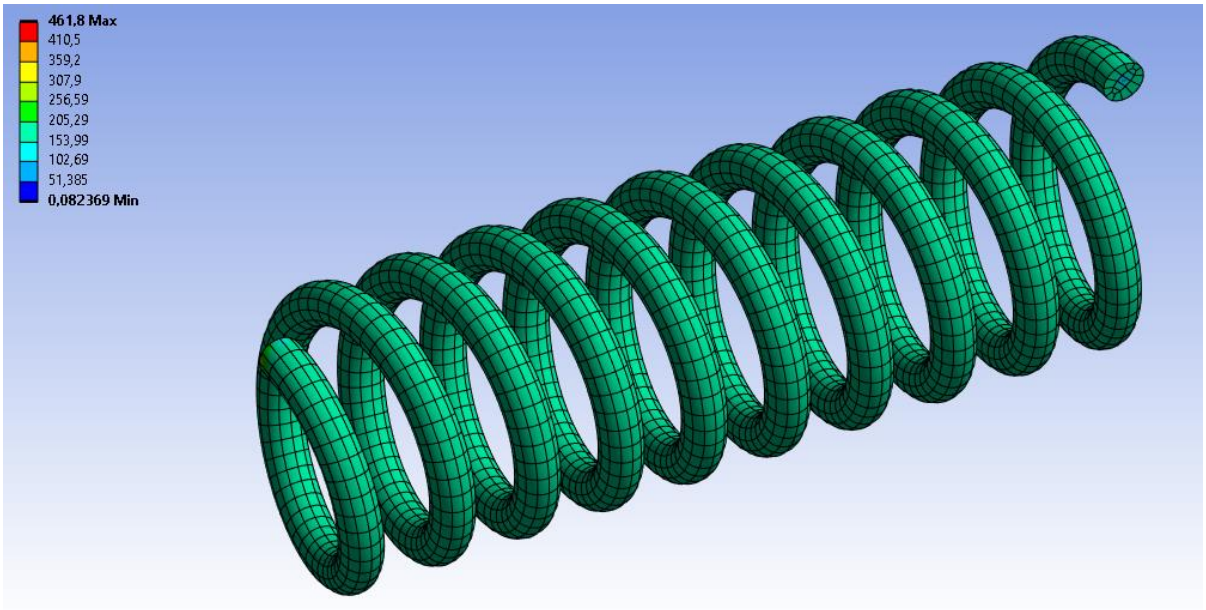


Figure 4-26 Equivalent Stress at 2.0202s Time Step. The time step shows the stress at the time of the initial contraction during the 3.5 N load scenario.

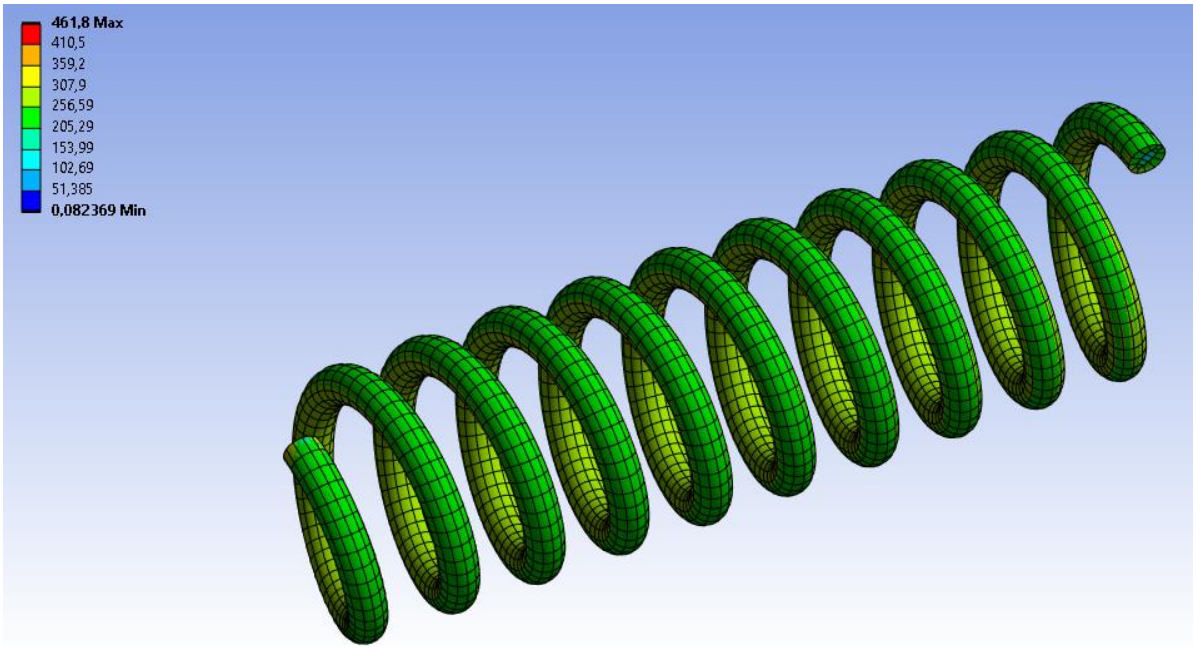


Figure 4-27 Equivalent Stress at 2.9899s Time Step. The time step shows the stress at the end of the contraction during the 3.5 N load scenario.

The three Figures above show the spring at the moment before contraction begins, initial contraction occurs, and the end of the contraction where the load is at its highest value. The maximum stress within the spring is experienced at the end of a contraction as seen from Figure 4.27, the point at which this stress occurs is shown in Figure 4.28 below.

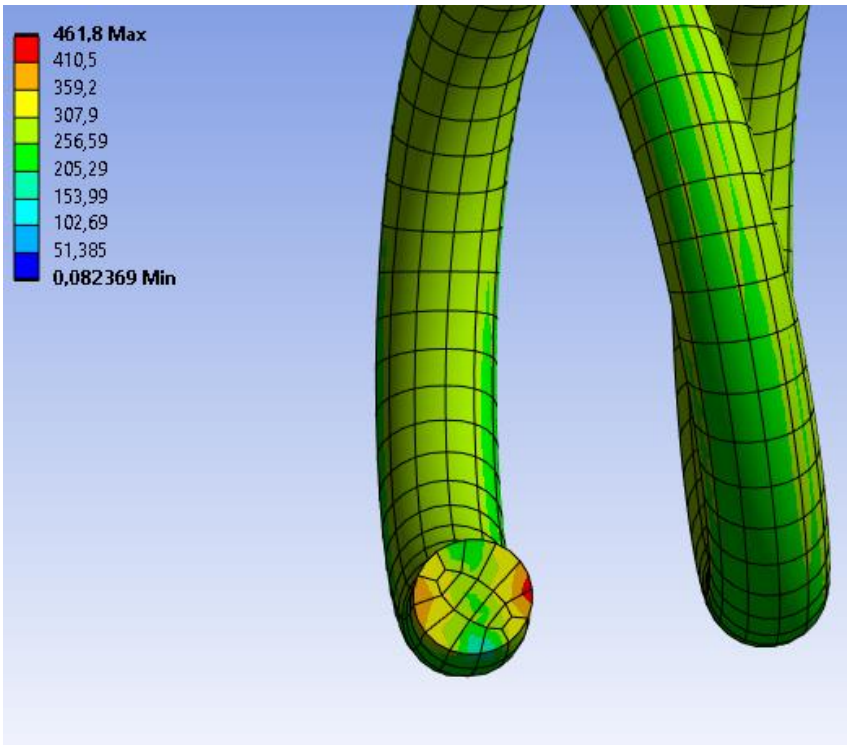


Figure 4-28 Spring Free End Stresses. The maximum stress occurred on the free end of the nitinol spring model at the end of the 3.5 N load scenario.

A section of elements along the spring body was analysed to calculate the maximum stress experienced without the location in Figure 4.28 above. The result of this analysis is shown in Figure 4.29 below.

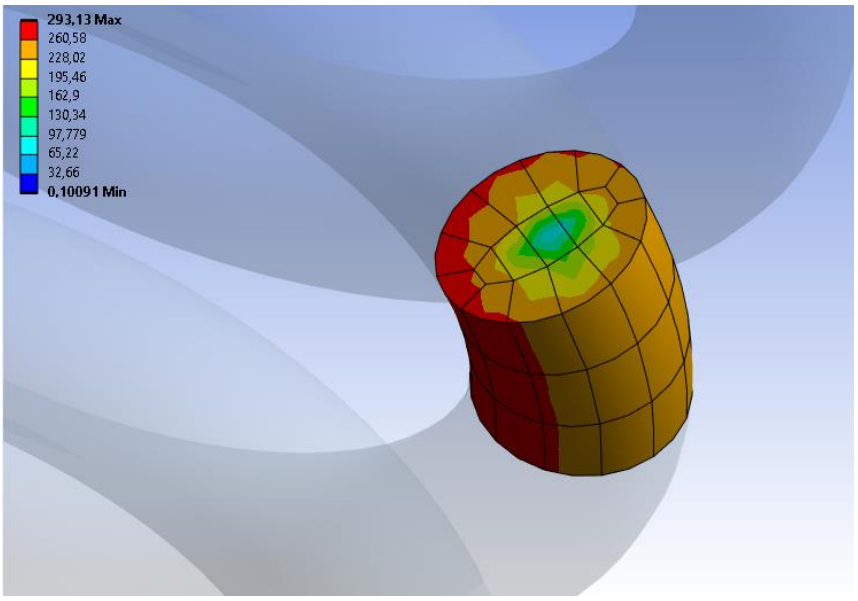


Figure 4-29 Spring Body Section Stresses in 3.5N Scenario. The spring body section was isolated from the free end that resulted in the highest stress to determine the maximum stress in the body of the spring.

The element group in Figure 4.29 above provides a narrower look at the stress experienced in the spring at the point of maximum loading. This setup was repeated for the remaining two loading scenarios as shown in Figures 4.30 and 4.31 below.

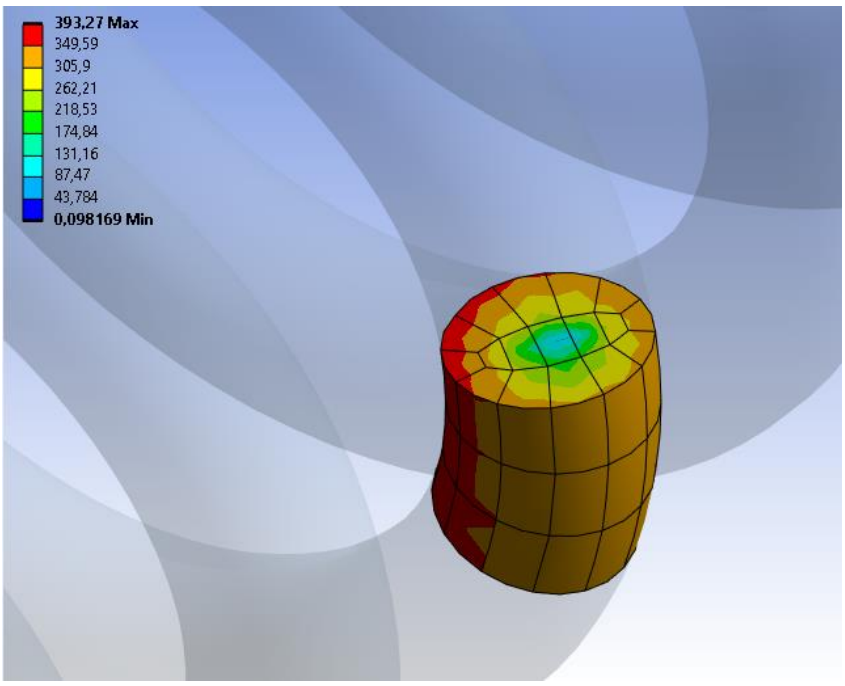


Figure 4-30 Spring Body Section Stresses in 4.5N Scenario. The spring body section was isolated from the free end that resulted in the highest stress to determine the maximum stress in the body of the spring.

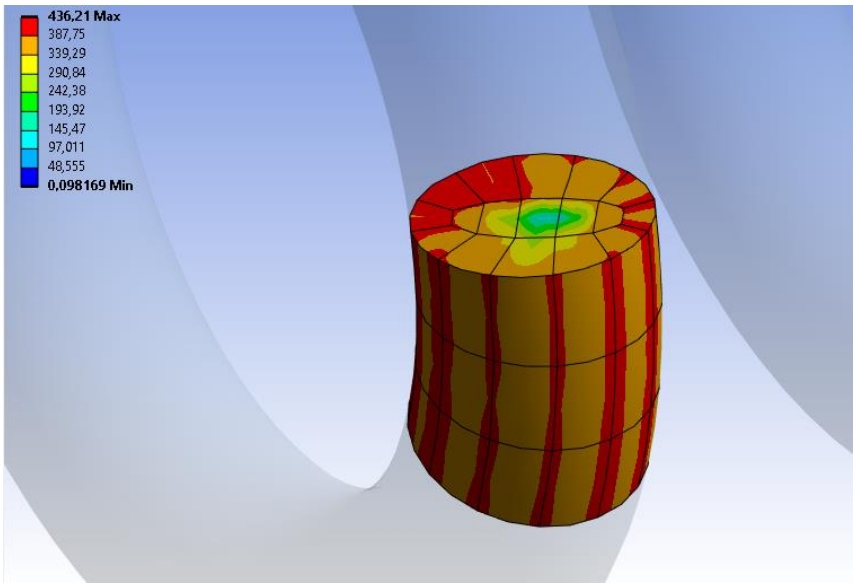


Figure 4-31 Spring Body Section Stresses in 5.5N Scenario. The spring body section was isolated from the free end that resulted in the highest stress to determine the maximum stress in the body of the spring.

The results of the three loading scenarios are shown in Table 4.10 below, Figure 4.32 and 4.33 shows the average and maximum stress respectively, during the 3.5N loading scenario. The remaining graphs of the average and maximum stress experienced during the different load scenarios are shown in Appendix A.

Table 4.10 Equivalent Stresses on Body Section during Load Scenarios

Scenario at 3s Timestep	3.5N Load	4.5N Load	5.5N Load
Maximum Stress (MPa)	293.12	393.26	423.64
Average Stress (MPa)	243.79	307.95	377.33

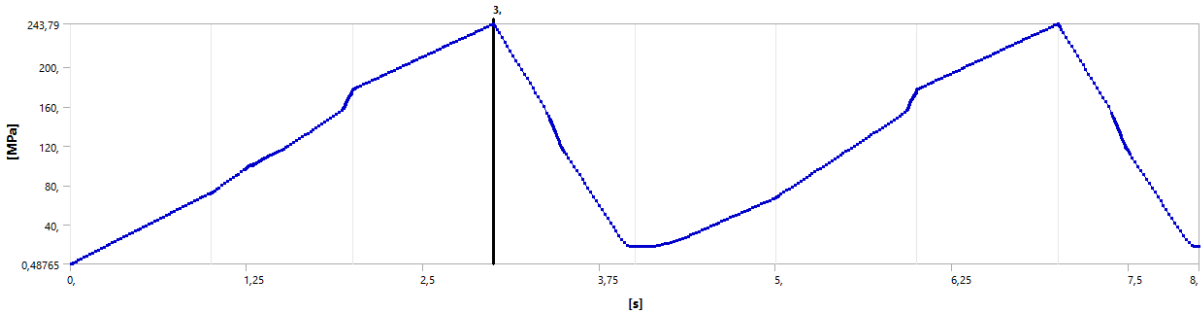


Figure 4-32 Average Stress Graph for 3.5N Loading Scenario. The graph shows the highest average stress occurring during the 3.5N load scenario at the 3s timestep which resulted in 243.79MPa.

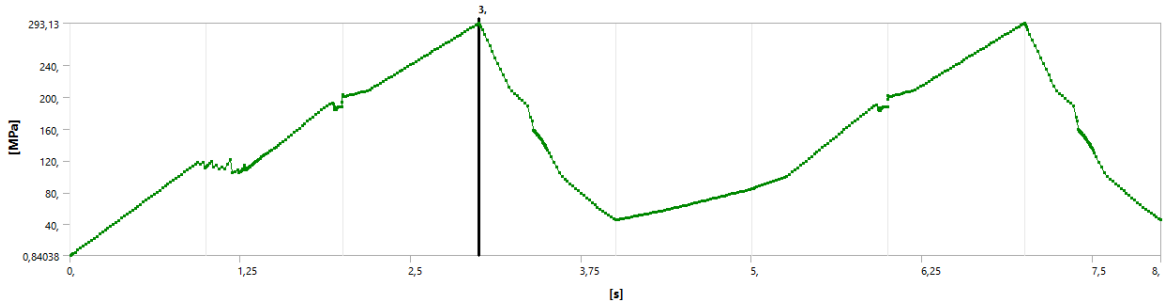


Figure 4-33 Maximum Stress Graph for 3.5N Loading Scenario. The graph shows the highest maximum stress occurring during the 3.5N load scenario at the 3s timestep which resulted in 293.12MPa.

According to the nitinol spring's manufacturer, the yield strength of the material is over 354MPa and is capable of exerting this force for a single pull, however, to have repeat cycling it is recommended to use no more than 2/3 of this level or 230MPa. Table 4.10 above and Figure 4.32 shows the 3.5N load scenario produces an average stress at maximum 6% greater than the recommended stress for repeat cycling while the maximum stress, seen on Figure 4.33, is still less than the yield stress. As a result, repeat cycling is possible under the applied load.

However, the 4.5N and 5.5N load scenarios are unlikely to produce repeat cycling in the nitinol spring. The 4.5N load may result in a low number of cycles as the average stress is below the yield stress, as seen in Table 4.10. Repeating cycles is therefore possible but permanent deformation will occur with each cycle as the maximum stress exceeds the

yield stress. A 5.5N load on the spring would prevent even a single cycle from completing as it exceeds the yield stress of the nitinol spring.

4.2.3.7 FEA Limitations

The FEA performed has several limitations:

- Material properties were not experimentally confirmed as this was beyond the scope of the project.
- The model therefore would need further verification to confirm the accuracy of the results, the first step being confirming the material properties of the nitinol spring.
- The physical nitinol springs are capable of repeat cycling in the prototype produced, however, the FEA was performed to provide insight into the longevity of the springs without needing to damage the limited number of springs available.

4.2.4 Computational Fluid Dynamic Model of Enclosure

A Computational Fluid Dynamics (CFD) analysis can be performed to predict the fluid flow and heat transfer occurring in a model under specified conditions. CFD can be used to perform a thermal analysis to determine temperature distribution and potential hot spots in a design. The nitinol springs used for actuation in the developed hysteroscopy system operate at relatively high temperatures, a thermal analysis should therefore be conducted to ensure the user or system are not affected.

4.2.4.1 CFD Analysis Configuration and Assumptions

A transient external analysis was configured using Solidworks 2020 Flow Simulation as the CFD software tool. The analysis was configured as transient as it would be limited to simulating 10 minutes of using the hysteroscopy system's bending mechanism to determine the temperatures after the duration. The analysis was specified to be external to consider the effects of the environment on the model together with the internal temperatures. The following major assumptions were made after configuring the analysis.

- The fluid modelled is air with environment conditions set to 20°C and 101kPa.
- Radiation effects are neglected, conduction and convection heat transfer will be considered.
- Heat generation from sources is assumed to be uniform.
- Thermal contact resistance between surfaces is ignored.
- Material properties were obtained from Solidworks material database, the nitinol material properties were defined according to manufacturer's information.
- The thermal effect of the nitinol springs alone was considered, the heat generated by minor components was assumed to be negligible to improve the efficiency of the computation.

- The handheld base model was simplified to analysis the enclosure around the nitinol springs, large openings were closed with lids to avoid additional flow entering the enclosure.

4.2.4.2 Simplified Enclosure Model

The model of the developed hysteroscopy system required simplification to focus on the thermal effect of the nitinol springs, reduce computational time of the analysis, and avoid factors that could influence the results, such as flow through openings. Figure 4.34 below shows the simplified model of the enclosure, with unnecessary components removed and openings sealed with lids.

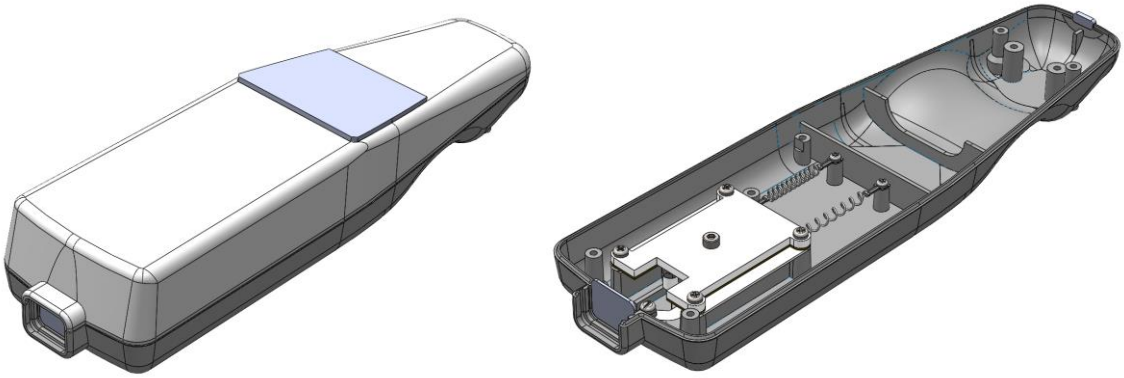


Figure 4-34 Simplified Enclosure Model for CFD Analysis. The simplified enclosure implemented lids to seal the internal housing of the model and removed unnecessary components to reduce computational time.

Figure 4.34 above was used to simulate the internals of the enclosure for the CFD analysis with the two nitinol springs setup in the configuration shown.

4.2.4.3 Boundary Conditions

The boundary conditions of the analysis are the environmental conditions within the boundary domain, these are set as 20°C and 101kPa to represent ambient temperature and pressure used in the analysis. Similarly, the initial temperature of solids is set to 20°C. The charging port at the end of the enclosure is also setup as an outlet to the environment while initial flow velocities of the boundary domain are set to zero in all directions.

4.2.4.4 Mesh Refinement

Mesh is required for CFD analysis which should be refined to ensure mesh independence when conducting the simulation. Solidworks Flow Simulation allows for generation of a basic mesh that automatically refines cells as required, the initial level of refinement can be adjusted to develop produce a basic mesh with cells already refined to a certain level. The mesh for the CFD analysis was produced with an initial refinement level set to 3 which was then increased up to an initial refinement level of 5. The details of these two meshes are shown in Table 4.11 below.

Table 4.11 CFD Meshes

Initial Refinement	Level 3	Level 5
Total Cells	277 396	447 296
Fluid Cells	175 169	342 524
Solid Cells	102 227	104 772

Figure 4.35 below provide a side-by-side comparison of the two meshes to provide a visual indication of the difference initial cells of the mesh.

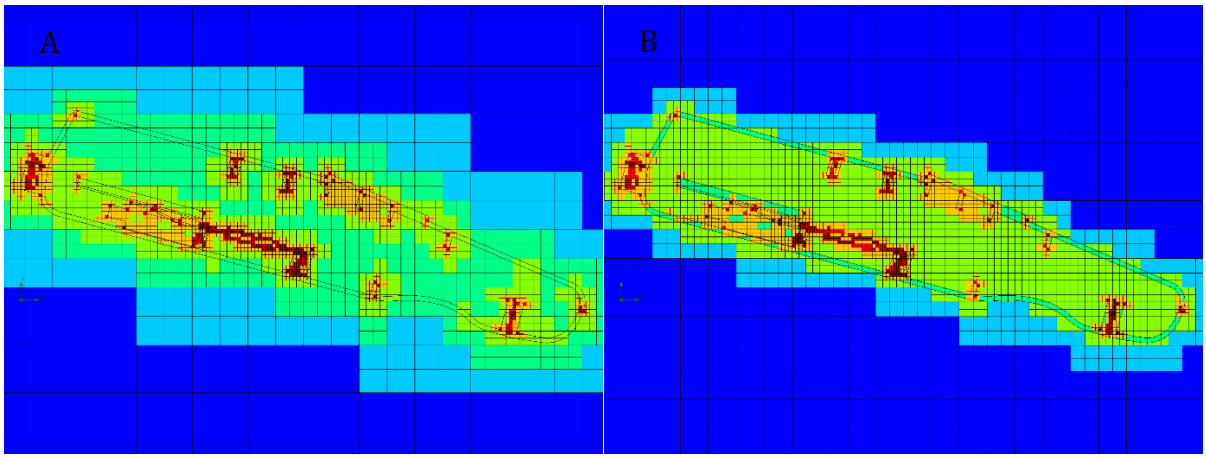


Figure 4-35 A. Level 3 Refinement Mesh, B. Level 5 Refinement Mesh. The level 3 mesh refinement resulted in 277 396 cells while the level 5 resulted in 447 296 cells.

An initial analysis with the meshes produced results that were concluded not to be significantly different, therefore the mesh with refinement level 3 was selected as it was computationally more efficient. The analysis performed with each mesh produced maximum temperatures that differed by 0.18%.

4.2.4.5 Thermal Analysis Results

Two scenarios were simulated using the model, boundary conditions, and mesh described. These scenarios represented different use conditions of the nitinol springs, the first simulated both nitinol springs at maximum temperature of 98°C for the full duration of the analysis, and the second scenario simulated a user activating a different spring every 5 seconds for a 1 second activation at 98°C. Both scenarios represented worst case scenarios, however, were analysed to determine the thermal analysis in the most extreme case.

A cut plot showing temperatures of the fluid resulting from the analysis of scenarios one and two are shown in Figures 4.36 and 4.37 below. The Figures show a sectioned view of the enclosure the end of each scenario.

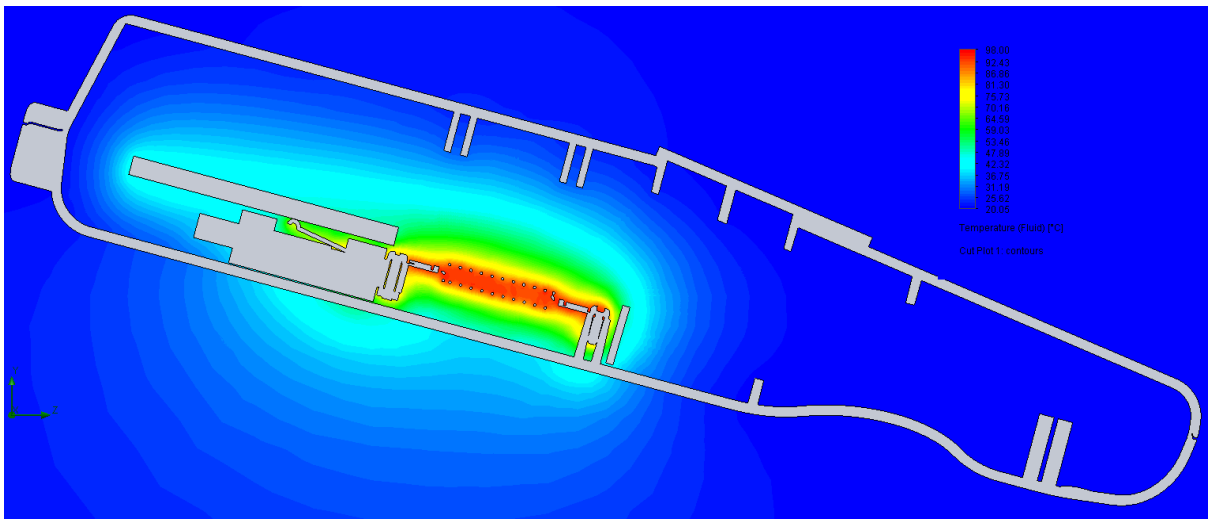


Figure 4-36 Air Temperature in Scenario 1. The scenario involved raising the temperature of both nitinol springs to 98°C for the full duration of the 10-minute analysis.

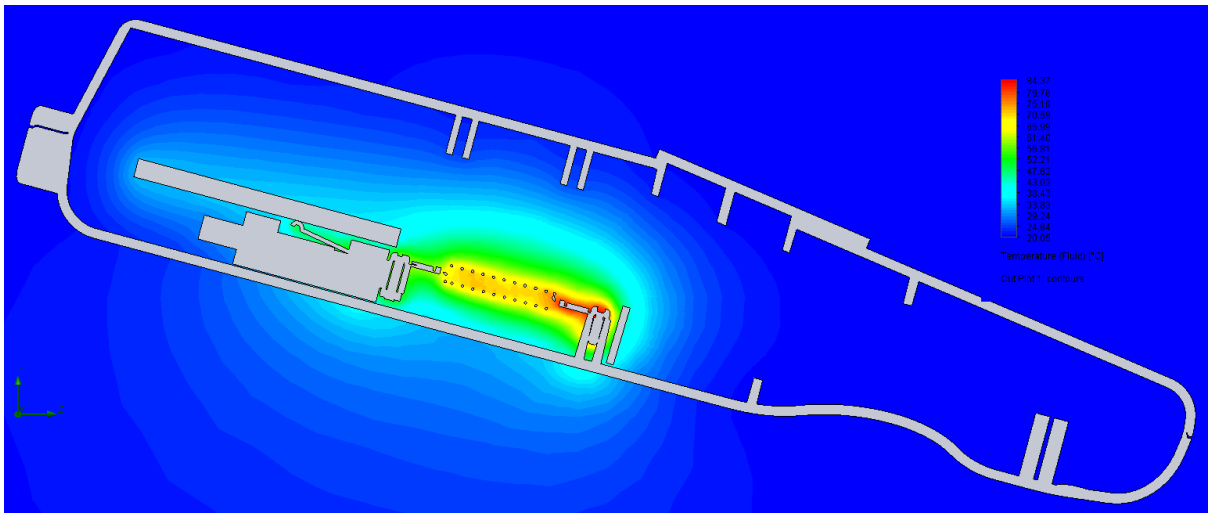


Figure 4-37 Air Temperature in Scenario 2. The scenario involved alternating activation of each spring every 5 seconds for a 1 second activation at 98°C for the duration of the 10-minute analysis.

From Figures 4.36 and 4.37, the temperature of air around the nitinol spring in the section increases drastically closer to the surface of the spring, reaching 98.00°C in scenario 1 and 84.37°C in scenario 2. However, the temperature of the air in scenario 2 reaches the maximum in an area closer to the fixed end of the spring. This is likely due to the other end connected to the rack gear is connected to the conductive brass arm which is transferring heat away. The fixed end results in the temperature increase due to the lack of additional conductive material acting as heat sinks. Compared to scenario 1, where the springs are not switched off, the air along the entire spring length reaches a maximum temperature is the rate of heat transfer is insufficient.

The outside temperatures of the enclosure for each scenario were also examined and are shown in Figures 4.38 and 4.39 below, these can be used to determine the potential temperature a user is exposed to when handling the enclosures during each scenario.

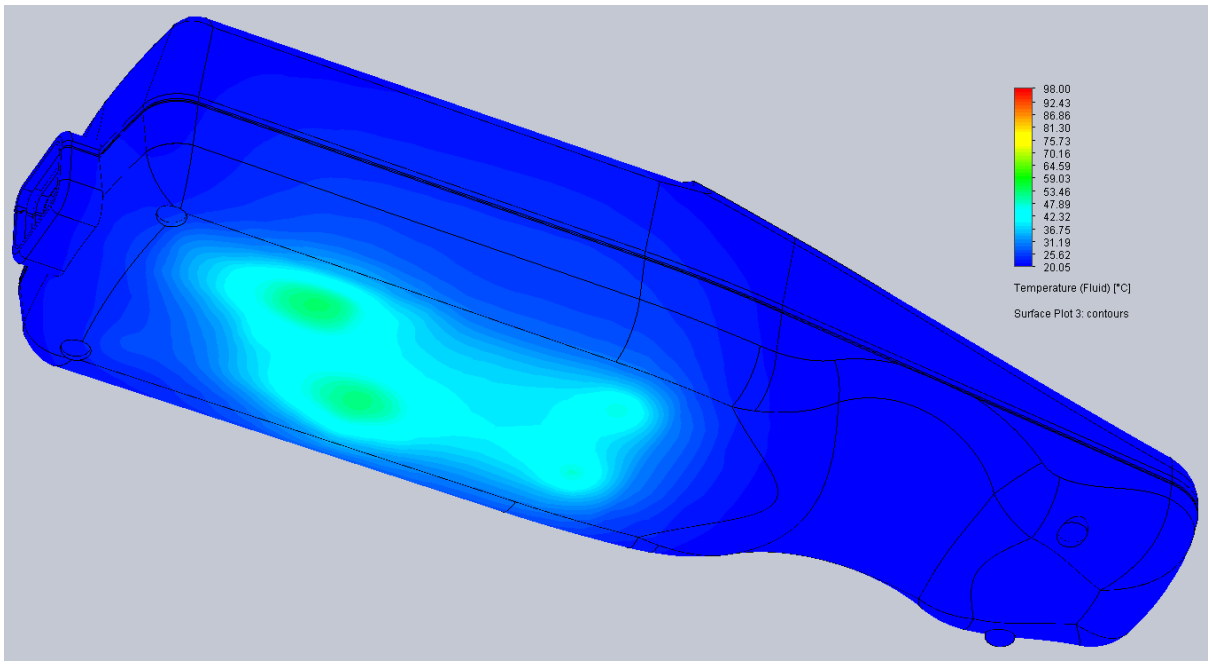


Figure 4-38 Enclosure Surface Temperature in Scenario 1. The surface temperature of the enclosure from scenario 1 reached approximately 65°C.

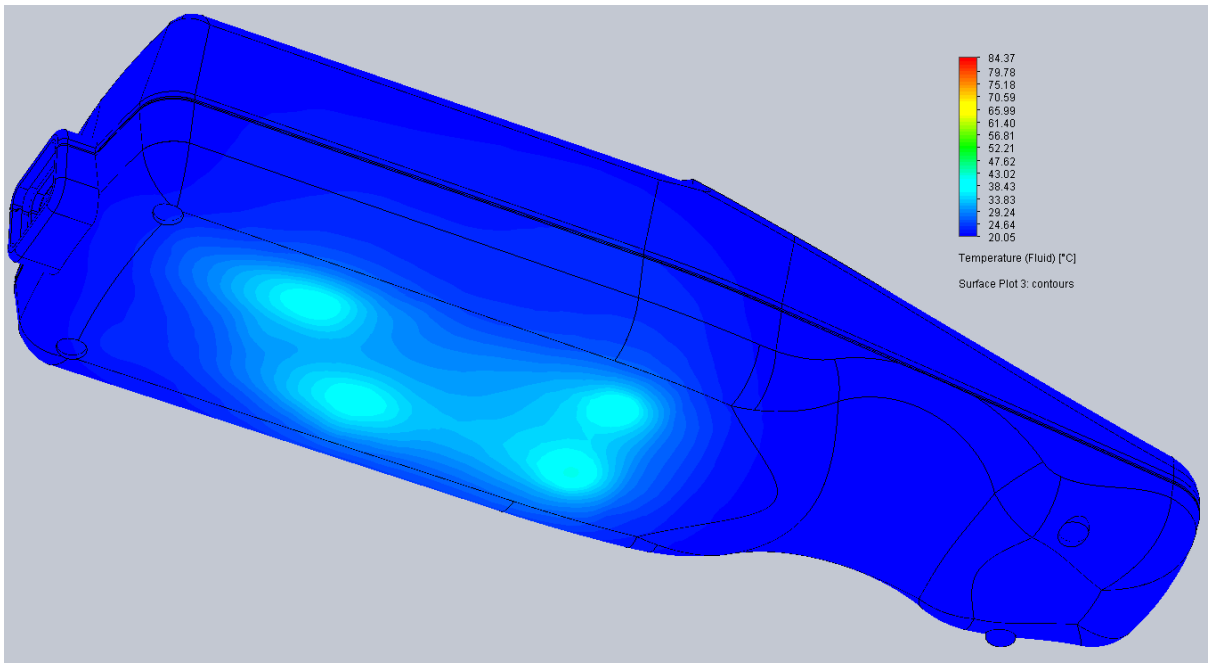


Figure 4-39 Enclosure Surface Temperature in Scenario 2. The surface temperature of the enclosure from scenario 2 reached approximately 38°C

The majority of the enclosure surface is observed to remain at ambient temperature, however, hot spots on the surface below the nitinol springs occur, as seen from the

Figures. Scenario 1 results in spots reaching up to approximately 65°C while scenario 2 had temperatures reaching up to approximately 38°C. While the first scenario resulted in temperatures that are harmful to the user when handled, scenario 2 shows the enclosure can likely be handled even in the simulated use case without injury.

Although the CFD analysis performed was simplified, it provided an initial understanding of thermal effects the nitinol springs have on surroundings. In the case of scenario 1, if the controls failed and the springs are activated continuously, the scenario shows how the temperature could drastically increase. Scenario 2 does not result from failure, however, could occur through user interaction in an extreme case. The results of scenario 2 fortunately do not indicate it would harm the user, and the majority of air inside the enclosure does not exceed normal operating temperatures of typical electronic systems. The enclosure material is a made of Polyamide 12 which has a melting point at 185°C according to its datasheet (Sinterit, 2022) and is therefore not in risk.

4.2.4.6 Preliminary Validation of Thermal Analysis Results

Validating the results of the thermal analysis simulation is required to ensure the device is safe to be held and operated by users in the next stage of testing. A simplified test was performed, as a preliminary validation, given more extensive validation of the CFD model would form part of future work and is beyond the scope of this project. Figure 4.40 below shows the setup of the equipment used to perform the test. A thermocouple was fixed outside on the housing over the location shown to have a high temperature in the simulation. The temperature of the thermocouple was displayed on the connected multi-meter and measured with an infrared thermometer for confirmation. Both nitinol springs were fully activated by connecting each directly to a DC power supply, bypassing the circuits, to avoid potentially damaging the electronics of the device.

Figure 4-40 Thermal Analysis Validation Testing Setup. The setup consisted of a thermocouple fixed to a spot on the enclosure shown in the simulation to reach

the highest temperature while an infrared thermometer was used to confirm the reading. A DC power supply was used to fully activate both springs during the testing.

Two scenarios were tested, for scenario 1 the springs were each powered by 1 Amp for 10 minutes and the temperature was measured at 2-minute intervals. Immediately following this, scenario 2 occurred where the current was increased to 2 Amps, and temperature was again measured at 2-minute intervals. This was to measure the temperature when the springs were continuously powered through the circuit, and a worst-case scenario were a short circuit occurred and the springs were oversupplied. The results of the two scenarios are shown in Table 4.12 below.

Table 4.12 Thermal Validation Testing Results

Time (minutes)	Scenario 1 (°C)	Scenario 2 (°C)
0	31	33
2	31	34
4	31	35
6	31	36
8	31	37
10	32	38

Table 4.12 shows the highest temperature reached during the worst-case scenario 2 was 38°C, which is within safe operating conditions for device use. This does, however, confirm that that model would need to be refined to simulate the temperature of the device more accurately. However, for the purposes of this project it was deemed sufficient to continue with the validation testing of the prototype.

4.2.5 Summary of Verification Results

The results of the verification testing stage are summarised in Table 4.13 below. These results represent the design specifications of the developed hysteroscopy system that are compared against the design requirements proposed by the research project. The specifications of the final prototype against the previous prototypes were shown in Table 3.9 in Chapter 3.

Table 4.13 Design Specifications and Requirements

Design Requirement	Design Specification
Diameter < 4.7 mm	4.2 mm diameter with sheath on

Flexible with 100° bidirectional bending	Flexible tip, 120° upwards bending, 116° downwards bending
250 mm working length	260 mm working length with sheath
Handheld and mobile user-friendly device	Handheld, 500 g weight, able to operate single handedly
Built-in camera, light source, and display	Built-in camera, light source, and display
Battery powered for 10-minute procedures	Battery powered, 79 minutes of continuous usage
Disposable, single-use sheath	Disposable, single-use sheath
Distention media channel, saline solution up to 200 mmHg pressure	Distention media able to supply saline solution over 200 mmHg pressure

Failed Requirement	**Passed Satisfactory**	**Passed Pending Validation**

Beyond the specifications shown in Table 4.13, simulated testing was performed to determine the longevity and heat generation of the nitinol springs used in the device. The FEA showed the nitinol springs experienced stresses within the allowed range for repeated cycles as stated by the manufacturer. The CFD analysis and validation testing thereof confirmed the handheld base remained below the maximum temperature for safe and comfortable usage. The design specifications of the hysteroscopy system therefore successfully met the design requirements to pass the verification testing stage of the research project. This excludes the design requirement of user friendly, as although the system was designed with simple operation and usability in mind, validation by actual users of the hysteroscopy system will most accurately determine if this requirement was met. The prototype hysteroscopy system therefore progressed to the validation testing stage.

4.3 Validation

Following the successful completion of the verification stage, the developed hysteroscopy system proceeded into the validation stage. As mentioned before, the purpose of validation is to confirm whether the prototype system can perform its intended use. Testing this involves performing a risk analysis to identify potential hazardous use scenarios, this information is then used to develop the usability trial protocol. The usability trial will validate the device through real user interaction and feedback.

4.3.1 Risk Analysis

A risk analysis is required by the International Electrotechnical Commission (IEC) as per the standard for application of usability engineering to medical devices (IEC 62366-1:2015) and should be done according to the standard for application of risk management to medical devices (ISO 14971:2019). The purpose of a risk analysis is to identify hazards

and subsequently, estimate the associated risk as shown in Figure 4.41 below. Risk has two key components: the probability of occurrence of harm, and the consequences or severity of that harm. Risks relate to injury to both the patient and user but can also be related to damage to property.

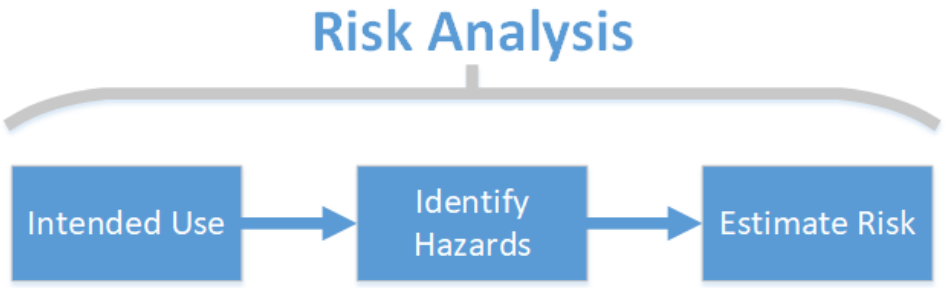


Figure 4-41 ISO 14971 Risk Analysis Steps. The steps consist of determining the Intended Use of the Device, Identifying potential Hazards, and Estimating the associated Risk.

Hazards are the potential sources of harm when using a medical device, therefore, to identify hazards, the device's intended use should be fully described and examined.

4.3.1.1 Device Intended Use

The intended use of the developed hysteroscopy system is described in Table 4.14 below.

Table 4.14 Hysteroscopy System Intended Use

Intended Use	The hysteroscopy system developed is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic procedures. The indications for diagnostic hysteroscopy include: • Abnormal uterine bleeding • Infertility and pregnancy wastage • Evaluation of abnormal hysterosalpingogram • Intrauterine foreign body • Amenorrhea and pelvic pain
Intended Users	Gynaecologists
Use Environment	Hospitals and physician offices
Operating Principles	The hysteroscopy system is handheld, battery powered consisting of a reusable device and single-use disposable sheath. The reusable device has a flexible bidirectional bending tip with a built-in CMOS camera and LED light source. The user switches on the device to view the camera feed on a built-in display while controls enable the user to bend the tip in two directions, capture images, and record videos. The bending tip is actuated by a mechanism using nitinol springs housed in the base of the

	reusable device. The user fixes the single-use sheath over the flexible tip before use. The sheath consists of a main channel for the device with a transparent cap for the camera and light source. An additional distention media channel is provided on the sheath with a fluid connector that the user connects a fluid supply to. After use, the user disconnects the fluid supply and removes the sheath from the reusable device. The sheath is disposed of while the device is switched off and connected to a micro-USB power supply.

The intended use of the hysteroscopy system serves as input for identifying use-related hazards and hazardous situations.

4.3.1.2 Identification of Hazards

Table 4.15 below lists the hazards associated with the hysteroscopy system based on the intended use. For each identified hazard, the designer considered sequences or combination of events for the potential cause and the resulting effect of the hazard. Hazards resulting from user interaction were specifically considered and are highlighted in Table 4.15 as these would guide the usability trial design. Hazards relating to the current stage of development and use were considered sufficient, as a total product life cycle risk analysis was beyond the scope of the research project.

Table 4.15 Hysteroscopy System Use Related Hazards

System Component	Hazard	Risk ID	Cause	Effect
Disposable Sheath	Disposable sheath displacement	R_1	User places sheath incorrectly on device or does not fasten with fluid connector	Reduction of image quality or complete loss of visuals result in procedure failure or misdiagnosis
	Disposable sheath tear	R_2	User uses excessive force when placing the sheath	Cross contamination between environment and reusable device leading to infection or device damage
	Excessive distention media pressure/flow	R_3	User does not manage media flow or over pressurises the saline bag	Fluid overload in the patient, distention medical channel burst
	Fluid connector disconnection	R_4	User does not properly connect media tubing to connector	Loss of fluid flow, extended procedure duration
	Fluid connector fastener break	R_5	Faulty design leading to material failure when placing fluid connector	Discarded disposable sheath, component wastage, cost to user
	Sheath transparent cap failure	R_6	Excessive force breaking tip when placing disposable sheath due to design fault or material weakness	Discarded disposable sheath, component wastage, cost to user
	Distention media channel separation	R_7	Channel separating from main sheath during procedure due to faulty connection	Unable to distend uterine cavity, procedure restart, patient and user time wasted

	Transparent cap blocking vision	R_8	Low quality or damaged material used to produce transparent sheath cap	Unable to perform procedure, discarded disposable sheath, cost to user
Smart Bending Mechanism	Bending tip malfunction	R_9	User activates the bending control for too long, causing the nitinol spring to burnout	Damage to device, unable to retract device when inside of patient, possible uterine perforation
		R_{10}	Loss of power due to user not charging device	Unable to retract device when inside of patient, possible uterine perforation
		R_{11}	User activating bending while tip is obstructed from moving, causing nitinol springs to over-stress	Damage to device, unable to retract device when inside of patient, possible uterine perforation
		R_{12}	User accidently switches off device during use	Unable to continue with procedure until device has restarted
	Mechanism mechanical failure	R_{13}	Mechanism locking or failing due to gear teeth breaking due to faulty manufacturing and poor design	Device unable to function, user unable to retract device if bent inside patient, harm to patient
	Mechanism electrical failure	R_{14}	Short circuit in electronics due to cleaning error causing failure to bending mechanism	Loss of function, device failure, unable to perform procedure or procedure failure
	Actuation wires breaking or disconnect	R_{15}	Actuation wires disconnecting due to poor manufacturing or material fault	Loss of function, device failure, unable to perform procedure or procedure failure
	Wire guide failure	R_{16}	Wire guide breakage due to poor design or manufacturing fault	Reduced functionality in bending mechanism, procedure failure

	Control button failure	R_{17}	Button failure due to mechanical fault or poor design	Device bending locked, procedure failure, harm to patient
	Conductive rail failure	R_{18}	Mechanism unable to activate due to poor connection with conductive rail due to design or manufacturing fault	Device unable to function, user unable to perform procedure
Mobile Visualisation Platform	Display screen malfunction	R_{19}	Loss of power due to user not charging device	Unable to retract device when inside of patient, possible uterine perforation
		R_{20}	User accidently switches off device during use	Unable to continue with procedure until device has restarted
	Camera failure	R_{21}	Camera fails due to manufacturing fault or user disconnection	User cannot perform or complete procedure until reconnected or replaced
	LED failure	R_{22}	LEDs fail due to manufacturing fault or user disconnection	User cannot perform or complete procedure until reconnected or replaced
	Low LED brightness	R_{23}	User fails to adjust LED brightness during procedure	User cannot perform or complete procedure until brightness is adjusted
	Camera image orientation	R_{24}	Camera is in the wrong orientation due to manufacturing fault	User disorientated when using device and unable to complete procedure
Handheld Base	Flexible rod excessive motion	R_{25}	User drops device during use as a result of rotating for view	Uterine perforation, possible damage to device
		R_{26}	User attempts to manually guide bending tip instead of using controls	Uterine perforation, possible damage to device

	Excessive force on nozzle	R_{27}	User applies excessive force to nozzle causing breakage while manoeuvring	Device damaged, flexible rod disconnected from device
	Handheld base damaged	R_{28}	Device is dropped by user	Device damaged, internal components damaged resulting in device failure
	Screen housing disconnect	R_{29}	Screen housing separating from device due to poor design or manufacturing	Device damaged and user unable to perform or complete procedure
	Unable to charge	R_{30}	Charging module not fixed in placed due to poor manufacturing prevent access	User able to charge device for use
	Loose internal components	R_{31}	Internal components not adequately fixed in place due to poor manufacturing	Device loss of function, component damage

After identifying the use related hazards, a risk estimation was completed to determine if any of the identified risks should prevent the device from proceeding into the validation testing stage. Unacceptable risks would require possibly redesigning the device before the usability trial could occur. As mentioned, for the purposes of developing the usability trial protocol, only use related hazards were included in the risk estimation. The remaining hazards were due to design, material, and manufacturing and would therefore not form part of the usability of the device. Instead, if any of these hazards appeared, a fault analysis would be performed to determine the cause and an attempt to mitigate the hazard would be done.

4.3.1.3 Risk Estimation

Various methods for estimating risk can be used, and when suitable data is available, a quantitative risk estimation can be performed. However, without the data, a qualitative analysis of risk estimation can suffice. Given the lack of data regarding the newly developed hysteroscopy system, a qualitative analysis for risk estimation was used.

A risk matrix was used to estimate the risks associated with each hazardous situation. The rows and columns of the matrix represented the two components of risk: probability and severity respectively. Each column and row represented a different level of severity or probability. Table 4.16 and Table 4.17 below show the description of these levels.

Table 4.16 Risk Severity

Level	**Description**
Significant	Death or loss of function, device replacement
Moderate	Minor injury, repairable device damage
Negligible	Will not cause injury or device damage

Table 4.17 Risk Probability

Level	**Description**
High	Likely to happen, frequent
Medium	Can happen, but not frequently
Low	Unlikely to happen, rare

Risks are placed into the risk matrix according to its probability and severity. The resulting risk matrix is shown in Figure 4.42 below.

The initial risk estimation performed with the risk matrix shown in Figure 4.42 below did not identify any unacceptable risks. However, risks were identified that would require possible mitigation, while the remaining risks were deemed to be acceptable. Risk mitigation would not occur at this time, instead the results of the risk analysis will be used to develop the usability trial protocol. The results of the usability trial would provide a better understanding of the cause of the use related hazards which in turn would best inform how to mitigate the risks, if necessary.

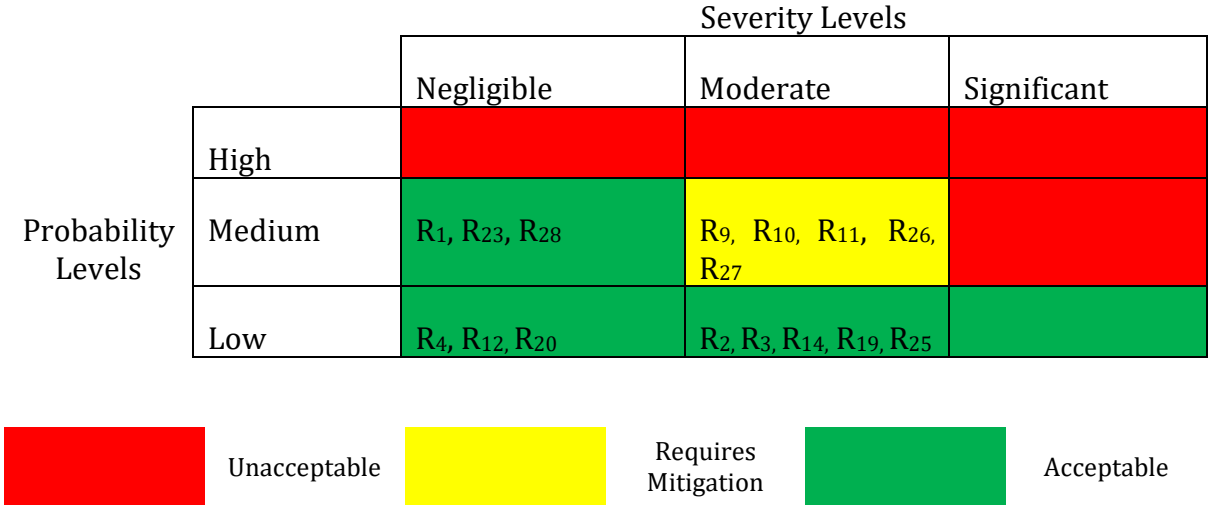


Figure 4-42 Risk Matrix. The risk matrix was used to identify potential unacceptable risks by comparing the probability and severity levels of each identified risk. This resulted in risks being classified as either (red) unacceptable, (yellow) requires mitigation, or (green) acceptable.

4.3.2 Usability Trial

The application of usability engineering is becoming more relevant as medical practice increases use of medical devices for diagnosis and treatment of patients. The concern of inadequate medical device usability is the increase of use errors that consequently result in injuries or death. The purpose of the usability trial in this research project is therefore to validate the developed hysteroscopy system and ensure it is safe and effective to use.

The usability trial protocol was designed according to the International Electrotechnical Commission (2015) IEC 62366-1:2015 standard for application of usability engineering to medical devices. This standard specifies the process for a designer to analyse, develop and evaluate the usability of a medical device, as such was used referred to frequently during the trial design. An overview of the main elements of the trial protocol designed is shown in Table 4.18 below.

Table 4.18 Usability Trial Protocol Overview

Item	Protocol Element
1	Test Purpose
2	Test Method Overview
3	Test Items (medical device and accessories)
4	Test Materials (supporting materials)
5	Test Environment

6	Test Participants (user groups, number, and selection criteria)
7	Test Personnel (staff roles and responsibilities)
8	List of Tasks (based on hazard related use scenarios)
9	Data Collection Techniques and Methods
10	Data Analysis Methods
11	Usability Test Script (Moderator Guide)
12	Test Protocol Templates (data collection forms)

The complete usability trial protocol templates are provided in the Appendix C, while a brief explanation of key trial elements is described in this section.

4.3.2.1 Test Method Overview

An overview of the usability test is shown in Figure 4.43 below, it will consist of participants from select user groups performing task-based use scenarios with the developed hysteroscopy system as well as with a standard existing hysteroscopy system. Data will be collected in two parts, by test staff observing the users while tasks are performed, and users providing feedback by completing test protocol templates. The usability test will be performed under conditions of simulated use, in a mock hospital wardroom with a mannequin as the patient.

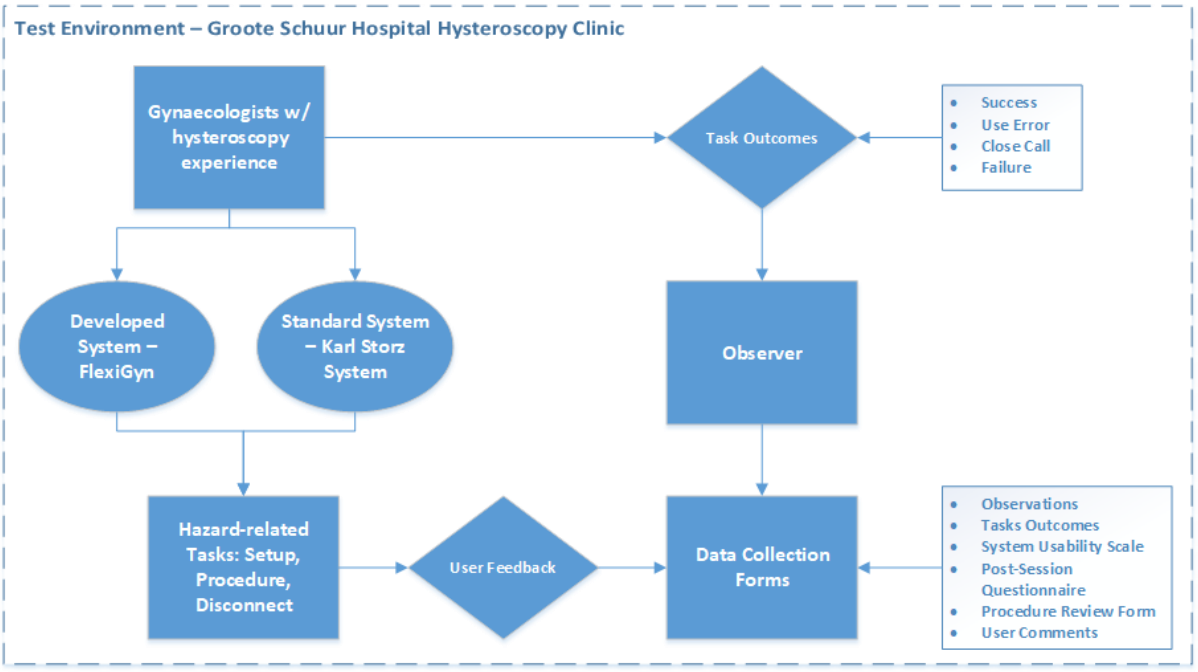


Figure 4-43 Usability Test Overview. The overview shows the Test Environment, Participants, Testing Equipment, Tasks, and Data Collection Methods.

4.3.2.2 Test Items and Materials

The test items consist of the medical device and its accessories being evaluated. In this case, the developed hysteroscopy system with the disposable sheath is undergoing evaluation. The system and accessories used in the usability test is shown in Figure 4.44 below.

Figure 4-44 Hysteroscopy System and Disposable Sheath. The newly developed hysteroscopy system and disposable sheath accessory to be used in the testing.

The additional supporting materials required for the usability test are the irrigation tubing, distention media supply, and the standard existing hysteroscopy system that will be used for comparison. Figure 4.45 below shows the irrigation tubing and distention media supply used for the testing.

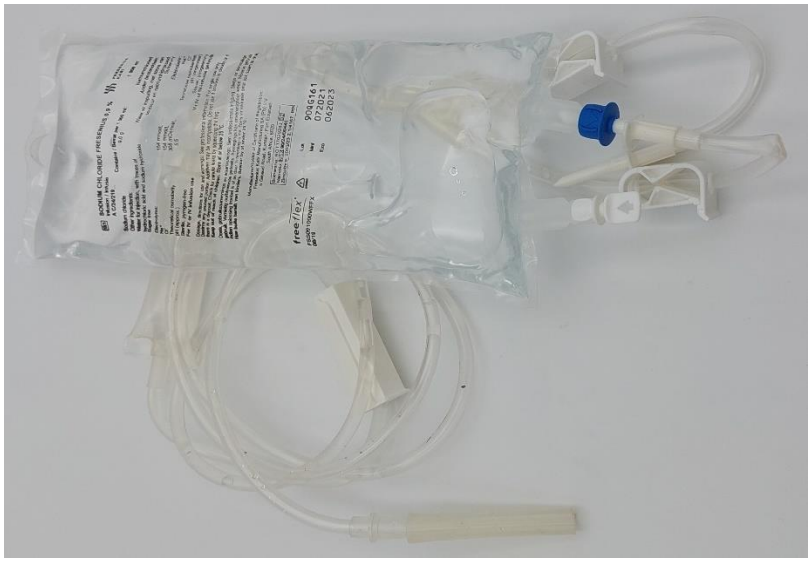


Figure 4-45 Saline Bag with Irrigation Tubing

The irrigation tubing and media supply are compatible with both hysteroscopy systems used. The standard hysteroscopy system selected was the Karl Storz HOPKINS II Telescope, BETTOCCHI Inner Sheath, and TELE PACK+, as shown in Figure 4.46 below.

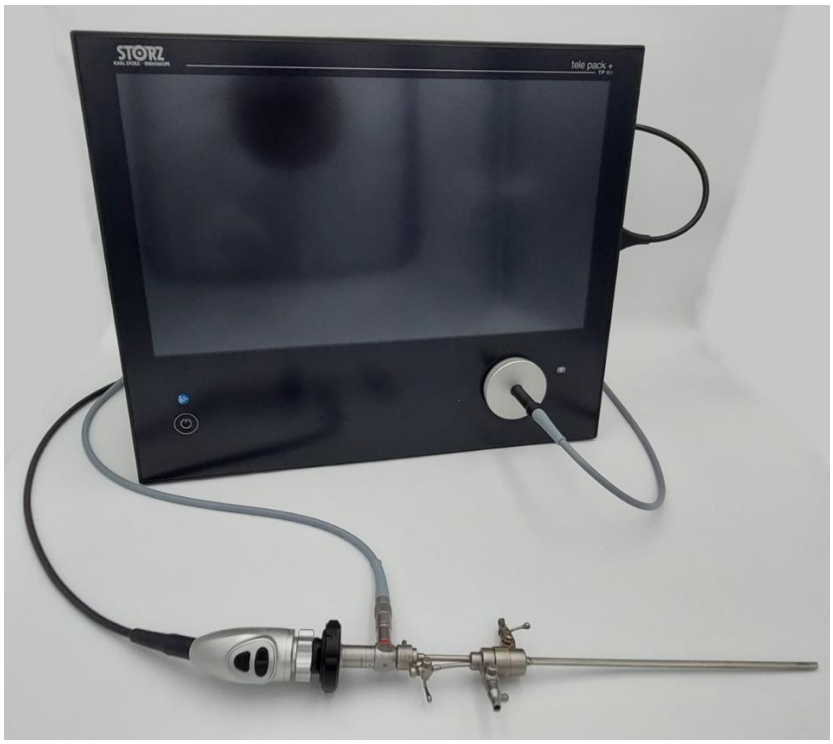


Figure 4-46 Comparison Hysteroscopy System. The comparison hysteroscopy system consisted of the Karl Storz Hopkins 2 Telescope, Bettocchi Inner Sheath, and Tele Pack+.

4.3.2.3 Test Environment

The usability test environment selected was the Hysteroscopy Clinic in Groote Schuur Hospital as it provided a simulated environment identical to that of normal procedures while being located in close proximity to potential participants for their convenience. A Gaumard Hysteroscopy Simulator was setup in the place of a patient for performing procedures on. The simulator is an adult sized female lower torso skills trainer used to practice hysteroscopy procedures, therefore an ideal model for testing the developed hysteroscopy system on. Figure 4.47 below shows the hysteroscopy similar setup in the clinic room.

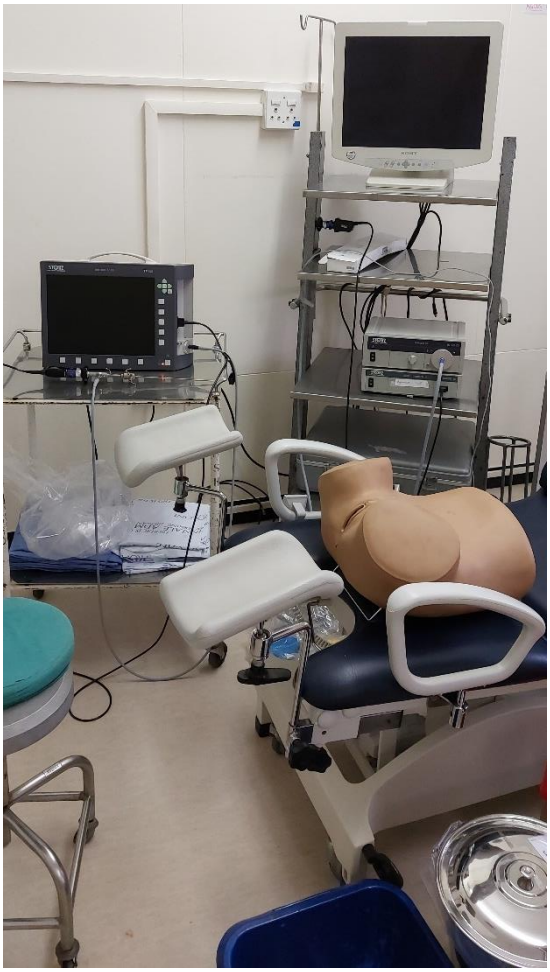


Figure 4-47 Usability Test Setup. The test took place in the Hysteroscopy Clinic at Groote Schuur Tertiary Hospital and used a Gaumard Hysteroscopy Simulator as the patient.

4.3.2.4 Test Participants

Selection test participants for the usability test involved determining the appropriate user representatives for the evaluated medical device, developing selection criteria for participants within the user population, and determining the number of participants for taking part.

The medical device being tested is a hysteroscopy system designed for use by gynaecologists and are therefore the users. The only selection criteria for the potential participants from the gynaecologist population was having performed a hysteroscopy procedure at least once.

According to the usability standard 62366-1 (IEC 62366-1:2015), smaller sample sizes (e.g. 5-8) are typically sufficient to uncover major user related design issues as the law of diminishing returns applies after five participants are tested. The standard illustrates this with Table 4.19 below.

Table 4.19 Cumulative Probability of Detecting a Usability Problem (IEC 62366-1:2015)

Value in %

USABILITY defect probability of occurrence	Number of test participants													
	1	2	3	5	6	7	8	10	15	20	25	50	75	100
1,0	1	2	3	5	6	7	8	10	14	18	22	39	53	63
3,0	3	6	9	14	17	19	22	26	37	46	53	78	90	95
5,0	5	10	14	23	26	30	34	40	54	64	72	92	98	99
10	10	19	27	41	47	52	57	65	79	88	93	99	100	100
15	15	28	39	56	62	68	73	80	91	96	98	100	100	100
25	25	44	58	76	82	87	90	94	99	100	100	100	100	100
50	50	75	88	97	98	99	100	100	100	100	100	100	100	100
75	75	94	98	100	100	100	100	100	100	100	100	100	100	100
90	90	99	100	100	100	100	100	100	100	100	100	100	100	100

Table 4.19 above shows the cumulative probability of detecting a usability problem based on the probability of the defect occurring and the number of participants. Using this table, it was decided to use a sample size of 10 participants assuming the probability of the defect occurring is 25% which leads to a cumulative probability of detecting a problem of 94%.

Recruiting participants will be based on availability as physicians time is immensely limited. However, the test will ideally include participants with varying levels of hysteroscopy experience. Specifically, split between qualified gynaecologists and gynaecology registrars.

4.3.2.5 List of Tasks

The tasks performed by users in the usability test should include all hazard-related use scenarios. Based on the background research, observations and risk analysis performed, the following task list was developed for the usability test.

- Task 1 – Fitment of the disposable sheath on the hysteroscopy system and connecting the distention media supply tubing.
- Task 2 – Use the hysteroscopy system to perform a diagnostic hysteroscopy on the simulator.
- Task 3 – Disconnect the distention media tubing and remove the disposable sheath from the hysteroscopy system.

The tasks list for the standard hysteroscopy system is similar and is as follows.

- Task 1 – Assembling the hysteroscopy system by inserting the hysteroscope into the sheath, connecting the camera, light source, and distention media tubing.
- Task 2 – Perform a diagnostic hysteroscopy procedure on the simulator.
- Task 3 – Disconnect all accessories from the hysteroscope.

4.3.2.6 Data Collections Techniques

The usability test data that will be collected includes:

- Task completion status,
- Descriptions of observed use errors, close calls, and use difficulties,
- Participants' comments about device interactions,
- Participants' reported root causes of their use errors and close calls, and
- Participants' subjective ratings about the device

This data will be collected using two methods: from the observations of the test personnel (objective data) and participants' debriefing interviews (subjective data). Details on these two methods are as follows:

Objective data – during the usability test, while participants perform each use scenario, the test personnel will observe and record their performance on each task and sub-tasks as one of the following: correct use, use error, close call or use difficulty. This will be noted on the forms shown in Appendix C. Additionally, all spontaneous comments made by participants during the performance will also be noted.

Subjective data – Upon completing all tasks with a particular hysteroscopy system, the participant will be asked to complete three forms to provide feedback regarding the system used. These forms are a System Usability Scale, Post-Session Questionnaire, and Procedure Review Form. These forms are described in greater detail as follows:

- System Usability Scale (SUS) – a 10 question survey using a 5-point Likert scale. The SUS is a widely used means for assessing usability of devices that is regarded as an industry standard (Bangor et al., 2008; Sauro, 2011).
- Post-Session Questionnaire – A set of questions on the different aspects of the hysteroscopy system rated by the user according to a 5-point Likert scale. A section is also provided for user comments.
- Procedure Review Form – A hysteroscopy procedure review form based on forms used currently. The form allows users to report on the outcome of the procedure in terms of diagnosis, additional tools used, or ease of entry.

4.3.2.7 Data Analysis Methods

After completing the usability test, the data collected will be analysed in the following ways.

Task Outcome and Observations

The first set of data analysed is the outcome of tasks and observations recorded by the test staff. These will be reviewed to establish the root cause of any use errors that occurred. If any tasks were unsuccessful or difficulties were observed, the cause will also be determined by reviewing the observations and user feedback.

System Usability Scale

The SUS scores are calculated using a formula to produce a score between 0 to 100, however, these scores are not percentages but rankings according to the scale shown in Figure 4.48 below.

Figure 4-48 System Usability Scale with Adjective Rating (Smyk, 2020). The adjective ratings range from worst imaginable to best imaginable with an acceptability score costing of three sections from (red) Not Acceptable, (yellow) Marginal, to (blue) Acceptable.

The above scale will therefore be used to determine the outcome of the SUS for each hysteroscopy system tested. Based on the SUS score, it will be determined if a system is usable or not. The score of the hysteroscopy systems will also be compared to determine the usability of the new system compared to the existing system.

Post-Session Questionnaire

The questionnaire consists of 24 questions using a 5-point Likert scale with additional space for test participants to provide comments on the hysteroscopy system. The questions collect a participant's subjective rating of different areas regarding the hysteroscopy system. The user comments provide additional information for review after analysing the task outcomes and answers of the post-session questionnaire.

While the individual ratings to questions in the questionnaire can indicate potential issues in certain areas of the hysteroscopy system, the primary purpose is to compare the results of the two hysteroscopy systems to establish if the participants view the developed hysteroscopy to be equal or better than the existing system. An appropriate statistical analysis method would be required to determine this.

The Mann-Whitney U test was selected to determine the statistical significance of the post-session questionnaire results. By treating the two hysteroscopy systems as the independent groups, and the answers to a question by participants as ordinal variables, the Mann-Whitney U test can calculate whether the difference between the two systems for a specific question is significant.

Procedure Review Form

The procedure review form provides data regarding the outcome of the diagnostic hysteroscopy procedure performed by participants. The results will be manually reviewed to assess the capabilities of the developed hysteroscopy system and compare it to the outcomes produced using the standard system. Specific outcomes that will be considered is the ability to navigate into the uterine cavity and fully observe the cavity.

4.3.2.8 Ethics Approval

The usability test required an application be filed for ethics approval with the Human Research Ethics Committee (HREC) at the UCT. The letter of approval, HREC reference number 753/2019, is found in the Appendix D together with an extension approval.

4.3.3 Results of Validation Testing

The aim of the research project was to develop a hysteroscopy system that addresses the needs of both the patient and physician. The purpose of the validation testing was determining if the developed hysteroscopy system could function as a hysteroscopy system and fulfil the need criteria outlined by the research project. The results would therefore indicate the potential of the developed hysteroscopy as an answer to the research question. The usability test was method for validating the hysteroscopy system.

The usability test was successfully completed with 10 participants performing mock procedures with both the developed and standard hysteroscopy system for comparison. The raw data collected during the test was transcribed and is provided in Appendix E, this section will discuss the results of each data form collected and provide a summary of the key findings.

4.3.3.1 Deviations from Test Protocol

The usability testing initially took place at the Hysteroscopy Clinic in Groote Schuur Hospital. The test was planned to conclude within 3 weeks after the required number of participants were tested. However, due to scheduling constraints, the 3-week period passed without the total number of participants having been reached. As a result, another week of testing was added, this testing took place at New Somerset Hospital as the Hysteroscopy Clinic was no longer available. Testing took place in a meeting room which unfortunately did not allow for testing the fluid flow through the sheaths. The participants testing at New Somerset Hospital could fit the sheath, connect accessories, and remove the sheath but not test the flow. No other deviations to the test protocol were experienced.

4.3.3.2 Task Outcome

Participants were tasked with performing use scenarios with the hysteroscopy systems while the test staff observed recorded the outcome of tasks. The details of the 10 participants are presented in Table 4.20 below.

Table 4.20 Usability Test Participant Details

Participant ID	Profession & Qualifications	Hysteroscopy Experience (Years)
A1	Doctor, MBChB, Registrar	<1
B1	MBChB, FCOh	15
C1	Obs & Gynae Consultant, MBChB, FCOG(SA), Mmed(O&G)	6
D1	Medical Officer, MBChB	1
E1	Obstetric Registrar, MBChB, FCOG	3
F1	Medical Specialist, FCOG	15
G1	MBChB, FCOG, MMED	9
H1	Obs & Gynae Medical Registrar	<1
I1	Doctor, Obs & Gynae Registrar, MBChB	<1
J1	OBGYN Consultant, MBChB, FCOG	3

The usability test involved participants completing 3 tasks with each hysteroscopy system, during which the test staff noted the outcome of the task and if use errors occurred, the potential cause. Table 4.21 below presents the results of tasks in a success (1) or failure (0) metric. Tasks 1 to 3 were performed with the developed system while tasks 4 to 6 with the standard system. From Table 4.21 it is seen that all participants were able to successfully perform the tasks with the developed system and the standard hysteroscopy system.

Table 4.21 Usability Test Task Outcome by Participant

ID	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6
A1	1	1	1	1	1	1
B1	1	1	1	1	1	1
C1	1	1	1	1	1	1

D1	1	1	1	1	1	1
E1	1	1	1	1	1	1
F1	1	1	1	1	1	1
G1	1	1	1	1	1	1
H1	1	1	1	1	1	1
I1	1	1	1	1	1	1
J1	1	1	1	1	1	1
Successes	10	10	10	10	10	10
Completion Rate	100%	100%	100%	100%	100%	100%

No use errors occurred during the completion of the tasks for any participants and the outcome of the tasks indicated the developed hysteroscopy system could perform hysteroscopy procedures on the simulator.

4.3.3.3 System Usability Scale

The task outcome did indicate the developed hysteroscopy could perform procedures, however, measuring the usability of the system provided further understanding of its efficacy. The scores of the System Usability Scale for each hysteroscopy system by participants is shown in Table 4.22 below, together with the adjective rating that corresponds to the score. The highlighted columns indicated the registrar participants.

Table 4.22 System Usability Scale Results

ID	A1	B1	C1	D1	E1	F1	G1	H1	I1	J1	AVG
Developed	90.0	85.0	67.5	80.0	90.0	97.5	97.5	95.0	75.0	82.5	86.0
	Excellent	Excellent	OK	Good	Excellent	Excellent	Excellent	Excellent	Good	Good	Excellent
Standard	47.5	85.0	57.5	85.0	77.5	85.0	100.0	45.0	57.5	32.5	67.3
	Poor	Excellent	OK	Excellent	Good	Excellent	Best Imaginable	Poor	OK	Worst Imaginable	OK

The results of the SUS scores are an average score of **86.0** and **67.3** for the System Usability Scale for developed and the standard hysteroscopy systems, respectively, is considered an **EXCELLENT** and **OK** rating according to adjective rating scale. Additionally, the average score for the new system by registrars was 87.5 compared to the average of the remaining participants which was 85.0. However, the average score for the standard system given by registrars was 56.8 compared 74.2 by the remaining participants.

Overall, the results of the SUS showed that the perceived usability of the developed hysteroscopy system to be excellent.

4.3.3.4 Post-Session Questionnaire

The results of the post-session questionnaire consist of two parts; the 24 Likert scale questions, and the participants' comments. The answers to the questions provided feedback regarding aspects of the hysteroscopy system, but the primary purpose of these questions was to draw comparison between the new and standard system. In doing so, determine if the new system performed to the same degree of the standard system, and is therefore an effective hysteroscopy system. The participants' comments will be reviewed separately to highlight any key findings.

Results of Post-Session Questions

The Mann-Whitney U test was used to determine the significance of each answer in the post-session questionnaire comparing the two hysteroscopy systems. The following assumptions were made:

- The hysteroscopy systems will be treated as the two independent groups with a sample size of 10 each.
- The crossover period between participants testing different hysteroscopy systems is assumed to be long enough for them to forget their prior experience and can be treated as being an independent group.
- The dependent variables are the Likert scale questions measured at the ordinal level and significance of questions will be determined individually.
- The variables are not normally distributed, and the distribution does not have the same shape, the Mann-Whitney U test will therefore be used to compare mean ranks.
- A significance level of 5% is chosen.
- The null hypothesis states that there is no significant difference between the ratings of the two hysteroscopy systems.

The Mann-Whitney U test was conducted using SPSS, and the results are shown in Table 4.23 below, the significance of each question together with the decision are shown in the table.

Table 4.23 Mann-Whitney U Test Results Summary

Category	Question	Sig.	Decision
General Usability	1. I can quickly get the equipment ready for use.	0.043	Reject the null hypothesis.
	2. I can successfully get the equipment ready for use without assistance.	0.075	Retain the null hypothesis.
	3. I know when the equipment is working properly.	0.529	Retain the null hypothesis.

	4. The equipment is easy to clean.	0.005	Reject the null hypothesis.
	5. The equipment was easy to hold and operate with one hand.	0.280	Retain the null hypothesis.
	6. I did not feel strained during or after using the equipment.	0.631	Retain the null hypothesis.
User Interface	7. I found the position of the controls comfortable and easy to use.	0.853	Retain the null hypothesis.
	8. I am satisfied with the size, quality, and position of the display screen.	0.315	Retain the null hypothesis.
	9. I found the controls to be fast and responsive to my input.	0.280	Retain the null hypothesis.
Disposable Sheath	10. I can easily connect the media tubing to the sheath.	0.013	Reject the null hypothesis.
	11. I can quickly place the sheath on the scope.	0.013	Reject the null hypothesis.
	12. I am satisfied with the flow through the sheath.	0.950	Retain the null hypothesis.
Device Controls	13. I know how to adjust the machine's controls.	1.000	Retain the null hypothesis.
	14. I can comfortably operate the machine's controls.	1.000	Retain the null hypothesis.
	15. I can quickly adjust the machine's controls when I need to.	0.684	Retain the null hypothesis.
	16. I am satisfied with what it takes to adjust the machine's controls.	0.247	Retain the null hypothesis.
Frequency of Trouble	17. I had difficulty placing the sheath over the scope.	0.083	Retain the null hypothesis.
	18. I had difficulty using the controls while holding the device.	0.019	Reject the null hypothesis.
	19. I had difficulty observing the screen during the procedure.	0.436	Retain the null hypothesis.

	20. I found the visual clarity of the device to be lacking.	0.912	Retain the null hypothesis.
	21. I had difficulty getting the equipment ready for use.	0.063	Retain the null hypothesis.
	22. I had difficulty manoeuvring the tip of the scope.	0.968	Retain the null hypothesis.
	23. I had difficulty removing the scope from the patient.	0.436	Retain the null hypothesis.
	24. I found it difficult to remove the sheath from the scope.	0.113	Retain the null hypothesis.

The highlighted questions in Table 4.23 produced ratings that were significantly different between the hysteroscopy systems. Examining the mean ranks of the ratings for each question gives the direction of the difference to determine which hysteroscopy system had the higher rating. The mean ranks for each of these questions is shown in Figures 4.49, 4.50, 4.51, 4.52, and 4.53 below.

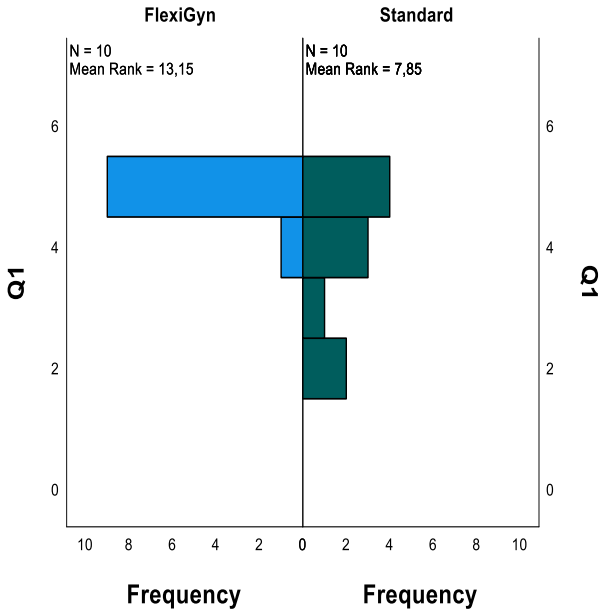


Figure 4-49 Q1 Mean Ranks. The ratings for (blue) the new hysteroscopy system and (green) the standard system for Question 1 "I can quickly get the equipment ready for use."

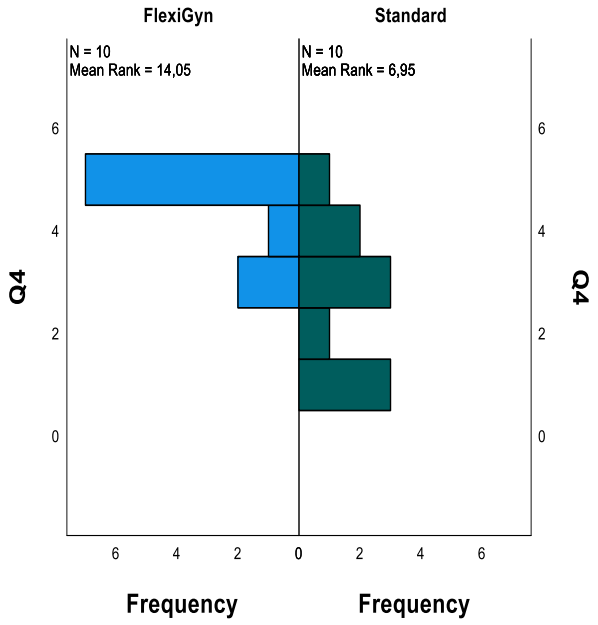


Figure 4-50 Q4 Mean Ranks. The ratings for (blue) the new hysteroscopy system and (green) the standard system for Question 4 "The equipment is easy to clean."

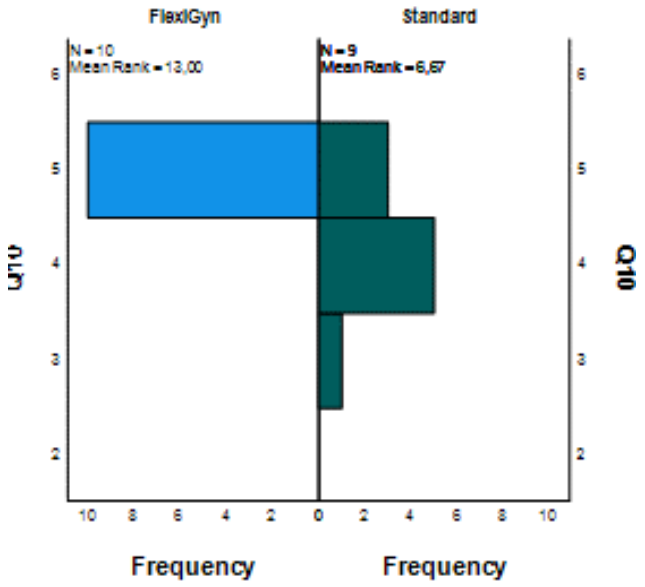


Figure 4-51 Q10 Mean Ranks. The ratings for (blue) the new hysteroscopy system and (green) the standard system for Question 10 "I can easily connect the media tubing to the sheath."

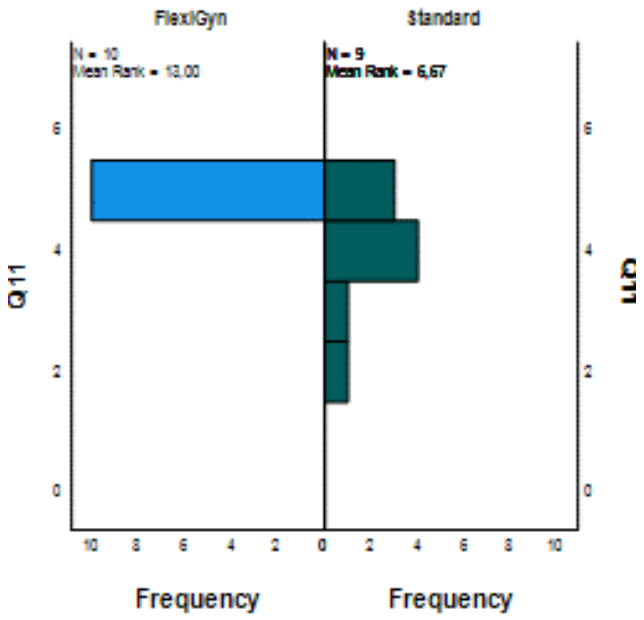


Figure 4-52 Q11 Mean Ranks. The ratings for (blue) the new hysteroscopy system and (green) the standard system for Question 11 "I can quickly place the sheath on the scope."

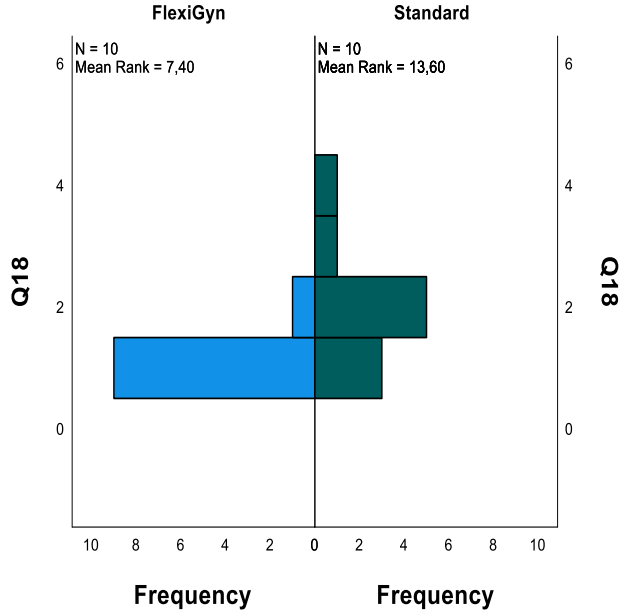


Figure 4-53 Q18 Mean Ranks. The ratings for (blue) the new hysteroscopy system and (green) the standard system for Question 18 "I had difficulty using the controls while holding the device."

The results of comparing the mean ranks for each question are shown in Table 4.24 below. The post-session questionnaire contains questions that rate the systems either negatively or positively, it is therefore important to consider this when the rating is significantly different. The alignment of the questions is included in Table 4.24 below for clarification.

Table 4.24 Mean Ranks Comparison with Question Alignment

Question	FlexiGyn	Standard	Direction	Alignment
Q1	13.15	7.85	FlexiGyn	Positive
Q4	14.05	6.95	FlexiGyn	Positive
Q10	13.00	6.67	FlexiGyn	Positive
Q11	13.00	6.67	FlexiGyn	Positive
Q18	7.40	13.60	Standard	Negative

As shown in Table 4.24 above, for questions 1, 4, 10, and 11 the FlexiGyn system was rated significantly different to the standard system and for these questions a higher rating indicated a positive result. However, question 18 was negatively aligned, a higher rating would indicate the participant agreeing with the negative statement. For question 18 the standard system was rated higher than the FlexiGyn system, which translates to FlexiGyn being rated better.

The results of the post-session questionnaire therefore show a non-significant difference between the ratings for the FlexiGyn and standard hysteroscopy system. However, certain questions that produced ratings significantly different, were in favour of the FlexiGyn system indicating a higher rating compared to the standard system.

Participant Comments

The post-session questionnaire also collected the feedback of the participants after using each hysteroscopy system. These comments were transcribed and are included in the Appendix E. The comments were reviewed and sorted into categories that corresponded to aspects of the FlexiGyn system, the results of this review are shown in Table 4.25 below.

Table 4.25 Summary of Participants Comments

Aspect of FlexiGyn	Comments Summary
User Interface	Some participants found the controls to be too fast and sensitive resulting in the device's tip bending more than required, past the target area of observation. Participants would then need to correct this by activating bending in the opposite direction.
General Usability	Several comments mentioned the weight of the device and the screen during use. The device needs to be rotated either left or right with one hand to observe certain areas. As a result, strain is placed on some users from having to rotate the heavy device and turn their necks to view the screen that rotates with the device.

Device Controls	The position and size of the controls affected some participants. Specifically, the placement of the on/off buttons near to the motion buttons and the stiffness of the buttons.

The comments highlight how the FlexiGyn system could be refined and improved in future development to increase its usability.

4.3.3.5 Procedure Review Form

The procedure review form completed by participants collected data on aspects of the procedure itself. The results of the of procedure review form were transcribed and are found in the Appendix E. The importance of the form was participants indicating the ease of entry through the cervix, if tools were required, and if both ostia of the fallopian tubes were observed. These procedure outcomes determine if the hysteroscopy was capable of fully viewing the uterine cavity during the procedure. Table 4.26 below lists these outcomes for each participant.

Table 4.26 Procedure Review Form Results

ID	Device	Entry	Speculum Used	Ostium Right	Ostium Left
A1	FlexiGyn	Easy	No	Seen	Seen
	Standard	Easy	No	Seen	Seen
B1	FlexiGyn	Easy	No	Seen	Seen
	Standard	Easy	No	Seen	Seen
C1	FlexiGyn	Moderate	No	Seen	Seen
	Standard	Easy	No	Seen	Seen
D1	FlexiGyn	Moderate	No	Seen	Seen
	Standard	Easy	No	Seen	Seen
E1	FlexiGyn	Easy	No	Seen	Seen
	Standard	Easy	No	Seen	Seen
F1	FlexiGyn	Easy	No	Seen	Seen
	Standard	Easy	No	Seen	Seen
G1	FlexiGyn	Easy	No	Seen	Seen
	Standard	Easy	No	Seen	Seen

H1	FlexiGyn	Easy	No	Seen	Seen
	Standard	Easy	No	Seen	Seen
I1	FlexiGyn	Easy	No	Seen	Seen
	Standard	Easy	No	Seen	Seen
J1	FlexiGyn	Moderate	No	Seen	Seen
	Standard	Easy	No	Seen	Seen

Table 4.26 above shows all participants were able to gain entry through the cervix with both devices, no speculum was used, and participants were able to observe both ostia with each hysteroscopy system. However, three participants found the entry through the cervix with the FlexiGyn system moderate. This was expected as according to the background research, entry with flexible hysteroscopes is more difficult in certain cases.

4.3.4 Summary of Validation Results

The purpose of the validation testing was determining if the developed hysteroscopy system performed as intended. This entailed users successfully conducting procedures with the system. While this would validate its basic function, whether the system was safe, effective, and usable would require additional validation. This was confirmed by comparing the developed system to an existing standard by collecting system usability scale scores and rating device aspects to compare the results. If the developed system produced scores and ratings equal to or better than standard system, it could be concluded that the system is as effective, in terms of usability, as the standard system.

The results of the comparative usability test to validate the developed system's safety and efficacy were therefore as follows. The developed system was tested by 10 gynaecologists who all successfully completed every assigned task related to use scenarios with the system, which included performing a diagnostic hysteroscopy on a simulator. No use errors occurred during the testing and participants filled in the usability scale, post-session questionnaire and procedure review forms. The results of these forms were compared to those of a standard system that the same participants completed, after using the system to perform the same procedure.

The system usability scale score of the developed system was 86.0 compared to the 67.3 of the standard system. This score placed the usability of the developed system in the excellent category. A Mann-Whitney U test was performed on the questions rating aspects of the hysteroscopy systems with the null hypothesis that the developed system was not rated significantly different to the standard and significance level of 5%. The test result indicated that the developed system was not rated significantly different to standard for all but 5 questions. These questions indicated ratings that were significantly between the two systems, however, the developed system was rated higher for each of these questions. Therefore, the Mann-Whitney U test indicated that the ratings of the developed system were either higher or not significantly different to the standard system. Lastly, the

procedure review form indicated that each participant was able to enter the uterine cavity and fully observe it, with participants finding the entry easy or moderate.

The validation testing therefore confirmed the developed system could successfully perform as a hysteroscopy system and had excellent usability. Aspects of the system were not rated significantly different to a standard system or were rated higher in certain aspects. The developed system received favourable comments with additional feedback for future developments.

5 Discussion & Inference

This chapter will provide a discussion of key findings drawn from the results of verification and validation testing. Specifically relating these findings to the research question and aim of the project. This chapter will also highlight the limitations of the research project and make recommendations for the future research opportunities based on the findings.

The research project aimed to design and develop a hysteroscopy system that incorporated aspects, identified from background research, that would increase the adoption and success rate of office hysteroscopy procedures. Upon completion of this hysteroscopy system, the project would proceed with testing to determine if it meets requirements established for office procedures thereafter compare it with an existing system through user interaction to determine if it can function as a hysteroscopy system to a sufficient degree. The purpose of this aim was to answer the research question of the project and indicate the potential of the developed system as an alternative to existing standard hysteroscopy systems that may lead to more frequent office procedures with a higher success rate.

A new hysteroscopy system was successfully developed after several iterations of prototyping, that underwent the two stages of testing planned to determine its efficacy. These two stages consisted of verification and validation testing that evaluated different aspects of the developed system for different outcomes.

5.1 Verification Testing Discussion

The results of the verification testing performed to establish the design specifications of the developed hysteroscopy system were presented in Table 4.12 in section 4.2.5. These design specifications were compared to the initial design requirements, and which were achieved and allowed the developed system to proceed to the next stage of testing.

The design requirements, however, represented a critical aspect for achieving the project's aim. These requirements were determined from the literature review as requirements that would not only allow for successful office procedures, but also allow more physicians to equip themselves and as a result, increase the rate and access of office hysteroscopy. Each design requirement was selected to produce that outcome.

It is therefore important to discuss the design specifications of the developed system and how it impacts the aimed outcome. The first specifications being the mobility of the system, which is shown by being a completely handheld device, with built-in camera, light source, and display while weighing 500g. The system has added mobility by being battery powered which can last up to 79 minutes with continuous usage. These features and the resulting mobility would potentially alleviate a burden placed on the physician when procuring existing systems requiring costly additional equipment. Similar to newer all-in-one hysteroscopy systems shown in the literature review that cost much less than standard systems. However, these systems often had high consumable costs due to expensive disposables. The developed system attempted to solve this problem with a simple disposable sheath that does not include expensive components. A sheath was

successfully developed for the system which provided a separate channel for distention media while not negatively impacting visual quality and system functionality to an unacceptable degree. The sheath was tested with saline solution as the medium which adds additional advantages during procedures.

Overall, the developed system offered high mobility with less equipment and sterilisation requirements while still offering flexibility. Existing flexible hysteroscopes, while improving both the patient and physician experience, are often avoided due to cost and cleaning difficulties. The developed system offered the benefit of a flexible system with a tip capable of bidirectional bending of at least 220° without comprising the cleaning and maintenance requirements.

The final design specification to consider is the diameter of the developed system. Including the disposable sheath, the system had a diameter of 4.2mm. The typical hysteroscope used for office procedures has a diameter of 5mm with the sheath, and although capable of successful procedures, this diameter does increase the pain experienced by patients. Smaller hysteroscopes with diameters less than 3.5mm are available which greatly reduce the patient pain while being easier to use for the physician. The diameter of the developed system would therefore allow for office procedures to be performed according to the existing equipment used, however would potentially result in more pain than the 3.5mm scopes. The impact of the combined smaller scope and flexibility could however impact both the pain and experience as it would reduce motions that cause discomfort as shown by studies.

The design specifications of the developed system therefore suggest it is capable of performing successful office hysteroscopy procedures according to requirements established through the literature review. While potentially offering several benefits in terms of mobility, less equipment required, and easier cleaning processes.

5.2 Validation Testing Discussion

The validation testing aimed to determine if the verified developed system could indeed function as a hysteroscopy system. The only way to prove this was allowing real users to perform hysteroscopy procedures with the system. Additionally, by comparing the developed system to an existing standard, the efficacy could potentially be determined. The validation stage of this research project was successfully completed with the developed hysteroscopy, the results of which indicated the system could perform as hysteroscopy system during simulated use.

The validation was testing consisted of a comparative usability trial with the developed system and an existing one. This trial included three methods of determining efficacy, the system usability scale, a post-session questionnaire, and procedure review form. These methods directly collected user feedback while a test observer also noted the success of tasks performed during the trial by users with the hysteroscopy systems. Participants recruited for the trial performed a mock procedure with the developed system and thereafter with the standard one, after each procedure they provided feedback with the three methods. Each of the three methods provided different insights regarding the efficacy of the system being tested.

The system usability scale is a standard measure of usability used in numerous studies. The results can be used to determine how usable a system is, which plays a crucial role in medical devices. The less usable a device is, the more likely use errors are to occur which can lead to harm. The results of SUS for the developed system indicated it has excellent usability. Furthermore, of the 10 participants, 4 were registrars with little hysteroscopy experience. When dividing the participants into two groups, the registrar group and the rest, key findings are suggested in the SUS score. The two groups scored the developed system on average similarly, however, the average SUS score of the standard system by the registrar group was lower compared to the average score by the rest of the participants with more experience. This suggests that the initial experience of new users with the standard system is more difficult, leading to poor usability while more experience improves the user's knowledge and usability as a result. This correlates with studies showing that less experienced gynaecologists have more difficulties performing office hysteroscopy, potentially due to the poor initial user experience.

The post-session questionnaire was developed for users to rate specific aspects of a hysteroscopy system that could also be compared with other systems. The questionnaire also collected user comments for further analysis. The questionnaire rated aspects such as general usability, user interface, the sheath accessory, device controls, and frequency of trouble. Each of the aspects had questions relating to the aspect. The results of each question were compared between hysteroscopy system to determine significant differences. The statistical analysis performed on the results determined the aspects of the developed system were not rated significantly different to the standard one. Therefore, the data suggests that the developed system is as effective as the standard system when comparing the aspects in the post-session questionnaire. However, certain questions were rated significantly different. A closer review of these questions showed that developed system was rated more favourable in each case the result was significantly different. The specific questions are listed in Table 5.1 below.

Table 5.1 Questions Rated Significantly Different

Num.	Question
1	I can quickly get the equipment ready for use.
4	The equipment is easy to clean.
10	I can easily connect the media tubing to the sheath.
11	I can quickly place the sheath on the scope.
18	I had difficulty using the controls while holding the device.

Question 1, 4, 10, and 11 related to readying the system for use, connecting the sheath and cleaning the system. The developed system was rated significantly better than the standard one for these questions which suggests it would be more efficient to prepare, use, and maintain than the standard system. This is an important finding when considering the reasons for low use of existing flexible systems that are difficulty to maintain and clean. Given the developed system is a flexible hysteroscope, the results

suggest it solves the difficulties of flexible system in this regard. Question 18 relates to user friendliness of the hysteroscopy systems. The developed system was designed to improve the user experience with easier access to controls which the results suggest it has achieved, when compared to the standard hysteroscopy system.

The comments provided by users regarding to the developed hysteroscopy system were overall positive and suggested possible improvements, some of the comments are highlighted in Table 5.2 below.

Table 5.2 Highlights of Participant Comments

Comment
"Would definitely want this type of device – would definitely improve access and allow easy outreach hysteroscopy clinics"
"Would make in office assessment possible/easier"
"Great for outpatient diagnostic setting"

These comments were highlighted as it relates to the use of the developed system outside of the operating theatre. The aim of the project is to develop a hysteroscopy system for outpatient settings and comments confirming this, positively suggest the viability of the system for office procedures. The results of the post-session questionnaire further supported the potential of the developed hysteroscopy system.

The procedure review form and tasks outcomes observed can be discussed together. These results indicated that the developed hysteroscopy could successfully be used to complete a simulated hysteroscopy procedure during which the uterine cavity was fully observed without the use of a speculum or tenaculum. Each participant was able to produce this outcome, suggestion the developed system can be used a hysteroscopy system with the vaginoscopy technique. Avoiding use of speculum and tenaculum reduces the pain experienced by patients, as shown in several studies. It was therefore crucial for the developed system to demonstrate this capability during the simulated use.

The results of the verification and validation testing suggests the developed hysteroscopy is a solution to the shortcomings current systems, however, limitations of the research project should be acknowledged the impact the findings. The prototype developed was produced and assembled by hand in the UCT MedTech Medical Devices Lab, as a result, the physical quality of the prototype could be improved. The prototype was sufficient for the small-scale testing completed to demonstrate the feasibility of the concept. Additionally due to the prototype being lab built, human testing could not be performed as this requires manufacturing standards beyond the current prototype for safety purposes. The simulations performed on the prototype designed were also limited to confirm the prototype would be able to undergo small-scale testing without failure, more extensive simulations would be required to establish the full life cycle of the system, however that is beyond proof of concept purposes. Finally, a small sample size of 10 participants were used to test the device, while this number is sufficient for usability according to the ISO 62366 standard, further testing with different user groups could

provide additional data to support the aim. However, recruiting gynaecologists was difficult due to limited availability and the sample size was therefore deemed sufficient.

The research project aimed to demonstrate the potential a new hysteroscopy system that overcomes the shortcomings of existing system when used outside of the operating theatre. Practically, the developed system represents an alternative to existing systems with wider application in the real world. The mobility factor could allow hysteroscopy procedures to be performed not only in office, but field hospitals in rural areas. Thereby providing access to this gold standard procedure to a greater population of patients. The developed system showed the potential of all-in-one mobile platforms for endoscopic procedures and use of simple disposables. Newer developments in hysteroscopy are high cost, single-use systems that are not viable solutions for every resource setting. The developed system shows the benefits of reusable systems that incorporate new technologies that are still accessible to physicians.

Future research opportunities can also focus on building the findings regarding what impact user-friendliness has on less experienced gynaecologists when performing procedures. Testing this with a larger sample size with more distinct groups could provide further insight on how user-friendly designs could lead to higher success rates when user experience level is considered. Comparing the developed system to an existing flexible hysteroscopy system also presents an opportunity. No flexible hysteroscopy was available for comparison during this research project and testing its usability and aspects would further guide the development of the new system.

5.3 Summary of Key Findings & Inferences

In summary, the research project successfully developed a new hysteroscopy system and verified its capability to perform office hysteroscopy according to literature established requirements, which in turn was validated by real users successfully performing simulated procedures. The new hysteroscopy system was able to perform to the same efficacy when compared to an existing system during the simulated use according to a small sample of gynaecologists. Table 5.3 and 5.4 below summarises the key findings and subsequent inferences of the verification and validation testing of the new hysteroscopy system.

5.3.1 Verification Findings & Inferences Summary

The Mobile All-in-One System

The need criteria of the proposed system included removing the need for additional equipment while also reducing the setup cost. The developed system was shown to be completely mobile, able to be operated single handedly, and battery powered. These factors successfully solve the related need criteria, as a result, gynaecologists would be able to setup their offices for hysteroscopy procedures without purchasing the typical equipment needed, thereby reducing the cost. This in turn should allow more gynaecologists to equip themselves for office procedures.

Minimal Diameter Flexible Scope

Key need criteria related to improving the patient experience during the procedure which greatly affects the success rate of office procedures. Gynaecologists are also hesitant to perform office procedures due to the perceived pain caused to patients. Two findings directly impact patient discomfort, the system's minimal diameter is less than the standard scope used, while the flexible tip removes the need for excessive motions during the procedures. These two factors reduce pain according to the literature, which should in turn assure gynaecologists and patients when the system is used.

Single-Use Disposable Sheath

Alongside reducing setup cost and equipment requirements, removing the need for sterilisation facilities, and improving the cleaning process for flexible scopes would further improve the adoption of the new hysteroscopy system. Literature showed that while flexible scopes offered improved user and patient experience, the effort to clean and sterilise prevented the widespread use combined with the higher cost. The single-use sheath developed greatly simplifies the cleaning process, potentially avoiding the need for intense sterilisation. The system is therefore able to offer the benefits of a flexible scope without the drawbacks.

Table 5.3 below lists each key finding and the subsequent inference from the verification testing results on the developed hysteroscopy system.

Table 5.3 Verification Key Findings & Inferences

Finding	Inference
• 4.2 mm diameter • Flexible bidirectional bending tip, 120° up / 116° down	• In-office procedure capability • Reduced pain • Eliminates excessive motion
• Built-in camera, light source, and display • Handheld, 500 weight, operated single handedly • Battery powered, 79 minutes usage	• No additional equipment • Reduced setup cost • Easier to setup • More accessible to gynaecologists
• Disposable, transparent, and single-use sheath	• Simplified cleaning process • Removes need for intense sterilisation

5.3.2 Validation Findings & Inferences Summary

Ease of Cleaning

The ease of cleaning the system and using the single-use sheath was validated in the usability trial by gynaecologists as shown in the results and comments received. This further confirmed the new system's advantage of current systems that limit adoption due to cleaning requirements and sterilisation facilities. Performing in office procedures with

the new system would therefore be easier to begin, without requiring the gynaecologists to potentially purchase, set up, and maintain dedicated sterilisation facilities.

Ease of Use

Skill level when performing hysteroscopy procedures was shown to impact the outcomes of procedures and therefore a user-friendly system was required. The usability of the new device was not only reported as excellent by the trial participants, but less experienced gynaecologists found the device more usable than the existing standard. This shows that a need existed for a more user-friendly design that would allow new users to learn and operate the device in a quicker turnaround time. The new system could encourage users to try the device with less risk during the initial use given its higher usability.

Successful Vaginoscopy Procedures

Confirming the new system was not only able to function as a hysteroscopy system but do so without the need for speculum or tenaculum, validated the design met all the need criteria. Not requiring tools during procedures greatly reduces the patient discomfort, as stated in the literature review. Being able to perform procedures without tools was therefore a crucial requirement that could only be confirmed by real users. The new hysteroscopy system successfully incorporated all the features that addresses shortcomings of existing devices.

Table 5.4 below lists each key finding and the subsequent inference from the validation testing results on the developed hysteroscopy system.

Table 5.4 Validation Key Findings & Inferences

Finding	Inference
• Ease of cleaning	• No sterilisation facilities required • Low maintenance • Easy to replace sheath
• Easy to use • User-friendly design	• Reduces skill requirement • Better procedure outcomes for less skilled users
• Successful procedures • No tools required	• Performs as hysteroscopy system • Vaginoscopy technique with flexible scope • Reduced patient discomfort

6 Conclusion

This chapter concludes the research project by providing a summary of the main objectives, discussing the subsequent outcomes, and how these contribute to the aim and research question of the project as well as the value thereof. Additionally, it will also consider the limitations of the research and in conjunction, the proposed future research that could expand of the findings of the research project.

The research project aimed to develop a hysteroscopy system for application outside of the operating theatre to answer the research question posed. This involved incorporating features into the hysteroscopy system that specifically address the shortcomings of existing equipment that impede the adoption and success rate of office hysteroscopy procedures. The project achieved this aim by completing three main objectives to produce, verify, and validate the proposed hysteroscopy, which are summarised as follows.

- **Iterative design of the hysteroscopy system prototype –** establish design requirements of the hysteroscopy system for input to the design process, identify subsystems, and repeat the development process until a prototype meets all design requirements.
- **Performing mechanical characterisation and *in-silico* testing on the final prototype to verify its design specifications –** setup tests for measuring the design specifications, build models to simulate the performance, and verify design specifications against design requirements.
- **Performing design validation on the final prototype –** perform a risk analysis on the prototype to develop usability trial protocol, conduct comparative usability trial with existing standard and gynaecologists, validate the efficacy of the prototype.

All three objectives were successfully completed, and a summary of each objective is discussed along with the key outcomes in the following sections.

6.1 Design of the Hysteroscopy System

The design process of the hysteroscopy system began with translating identified need criteria into design requirements. The need criteria were selected based on the review of the hysteroscopy landscape and consisted of criteria that would increase the adoption and success rate of office hysteroscopy. The design requirements were the input to the design process that would ensure a viable solution was developed. These requirements focused on increasing patient comfort, improving the user experience through ease of use and reduced cleaning requirements, and reducing the cost and equipment burden of the system.

The prototyping process followed an iterative approach where development focused on critical subsystems of the hysteroscopy system initially, only including the remaining subsystems once a satisfactory design was completed. As a result, the initial prototypes demonstrated the feasibility of a mobile system that incorporated all the components that would typically be additional equipment, namely the screen, camera, and light source. A

bending mechanism using shape memory alloy was also developed to produce a flexible scope as part of the requirements.

The third prototype demonstrated a complete hysteroscopy system, including a single-use sheath for suppling distention media during procedures. This prototype was an all-in-one system with an integrated screen, light source, and camera with a guidable flexible tip capable of 260° bending. However, the sheath limited the functionality by increasing the diameter over 5mm, the maximum requirement for office hysteroscopy. The sheath also obscured the image as the LED light source was increased which needed to be redesigned. The sheath improvements, combined with miniaturisation and optimisation was the focus for the fourth prototype.

The final prototype successfully implemented changes to the sheath with improvements to the device as well. The screen angle and display were adjusted for a more ergonomic experience, while the diameter of the scope was further reduced. The new scope with the sheath was now only 4.2mm in diameter, less than the maximum requirement. Additionally, the sheath visibility was improved, allow maximum LED brightness without obscuring the image. There was a slight decrease in bending range, now only 236° but this deemed acceptable given the decrease in diameter.

6.1.1 Conclusion & Key Outcomes

The result of the design process was the development of a complete hysteroscopy system that was mobile with built-in components, battery powered, a guidable flexible tip, and a single-use sheath that could supply saline solution through a distention media channel. A US patent application based on the developed hysteroscopy system was filed, and subsequently granted on the 22nd of November 2022 with the patent number US011503988B2 and is shown in Appendix F. The design process was deemed successful, completing the objective, and the prototype proceeded into the verification stage of testing. The key outcomes of this objective were as follows.

- Design requirements of a hysteroscopy system for performing in-office procedures that address shortcomings of existing systems.
- A granted US patent based on the hysteroscopy system developed by the design process.

6.2 Verification of the Hysteroscopy System

The objective of the verification stage was to determine if the device was designed correctly and consisted of functional and simulated testing to determine the design specifications of the hysteroscopy system. These specifications would then be compared with the design requirements outlined for the hysteroscopy system, and if met, allow the system to proceed into the last stage of testing.

The design requirements represented not only what was necessary for the developed hysteroscopy system to function, but also what was deemed crucial to improve the adoption for office procedures while increasing the procedure success rate. The corresponding design specifications therefore needed to be verified through testing to

ensure all requirements were met. This testing was broken down into individual functional and simulated tests to assess the performance of the system.

The test showed that the hysteroscopy system achieved all design requirements, by verifying the design specifications. This included confirming the 260mm working length, 4.2mm diameter scope with sheath on, and 236° bending range that according to the design requirements, allow it successfully perform office procedures with reduced pain because of the smaller size and smaller motions. The handheld device weighed 500g and could be operated singled handedly no additional equipment required, which in turn would reduce the setup costs for operation. The battery life was calculated to be at least 79 minutes of continuous usage, allow for back-to-back 10-minute procedures to be performed. The single-use sheath was able to supply saline solution at over 200mmHg pressure and isolate the scope when fully submerged without obscuring vision, even with maximum LED brightness. The sheath would therefore reduce cleaning efforts for the device and potentially remove the need for sterilisation equipment in office. A finite element analysis was performed to determine the stresses acting on the SMA springs in the device, which showed an average stress of 243.79MPa, 6% greater than the recommended stress for repeat cycling but lower than the yield strength of 354MPa, which was deemed sufficient. Lastly, a computational fluid dynamics analysis was performed to simulate the temperature of the handheld device during use which showed the temperature of the enclosure only reaching 38°C in certain locations which was well within the comfortable range for use.

6.2.1 Conclusion & Key Outcomes

Overall, the verification testing confirmed the prototype met the design requirements, which according to the literature reviewed, should allow it to perform office-based hysteroscopy procedures while offering advantages over the standard systems used. Verifying the design specifications of the developed hysteroscopy system against the design requirements successfully completed the second objective of the project. The prototype system's ability to function as a hysteroscopy system would need to be validated in the final stage of testing. The following key outcomes resulted from completing the objective.

- Preliminary finite element analysis on the nitinol springs used in the prototype's bending mechanism.
- Basic computational fluid dynamic model for a thermal analysis on the prototype due to nitinol spring heat generation.
- Verified design specifications of the developed hysteroscopy system.

6.3 Validation of the Hysteroscopy System

The final objective of the research project was validating the developed hysteroscopy to determine if the correct device was designed to address the identified problem. Validation essentially confirms if the new system can perform the function of a hysteroscopy system, and this required testing if actual users can successfully complete a procedure with the prototype. The objective consisted of three parts, performing a risk

analysis as input for a usability trial protocol, conducting the usability trial, and evaluating the results of the trial.

The risk analysis identified use-related hazards and hazardous situations that served as input for the usability trial protocol. The purpose of the trial was not only to validate the hysteroscopy system but identify potential causes of use error. The trial was designed according to the IEC 62366-1:2015 standard on application of usability engineering to medical devices, and according to this standard, a sample size of 10 participants was selected with an assumed 25% probability of a defect occurring that lead to a cumulative probability of 94%. The sample group consisted of gynaecologists with varying degrees of experience in hysteroscopy procedures.

The data from the trial was collected through observations, comments, a System Usability Scale, post-session questionnaire, and a procedure review form. Additionally, the new developed hysteroscopy system was compared to the existing standard system by having participants repeat procedures and complete the same forms with the standard. The trial successfully took place between two locations, Groote Schuur Hospital Hysteroscopy Clinic and New Somerset Hospital.

During the usability trial, all participants were able to successfully complete each task with both hysteroscopy systems resulting in procedures being completed. The SUS scores of the systems, however, differed with the new scoring 86.0 and the standard scoring 67.3 averaged across the participants. When separating the participants in qualified gynaecologists and registrars, the results showed a notable finding. The registrars scored the usability of the standard much lower than the new system. The overall score of the new system, together with this finding, indicated that the system had excellent usability, especially so with less experienced users who found the standard system difficult to use. This correlates with the need criteria for a more user-friendly system to facilitate adoption of office-based hysteroscopy.

The post-session questionnaire allowed for comparing individual aspects of the two hysteroscopy systems to gain further insights for the validation. A Mann-Whitney U test was performed with the null hypothesis stating there is no significant difference between the ratings of systems, with a 5% significance level. The results showed that there was either no significant difference between the systems, or in certain aspects, the new system was found to be significantly better. The aspects scored higher related to preparing the system, cleaning, and using the controls during the procedure. This showed that the new system was comparative to the existing standard when used to perform hysteroscopy while being easier to clean, maintain, and use. This finding fulfils the need criteria that required the system to be easy to clean, with less setup, and be user-friendly. This shows the new systems potentially solves the shortcomings of existing flexible hysteroscopy system, that are reported to be difficult to clean and maintain, which increases the viability of the new system for office-based procedures.

The procedure review form reports if participants were able to successfully complete the procedure by fully observing the uterine cavity, and whether additional tools were required to do so. Overall, all participants complete the procedure without the need for a speculum and tenaculum, the last need criteria for the developed system to reduce patient discomfort while showing it can perform as intended. This completed the

validation of the new hysteroscopy system, showing it could be used to complete vaginoscopic or 'no-touch' hysteroscopy procedures in-office.

6.3.1 Conclusion & Key Outcomes

In conclusion, following the successful completion of the final objective, the research project achieved the aim of developing a novel hysteroscopy system, verifying its specifications, and validating its function. The resulting system provides an answer to the research question, confirming its efficacy compared to the existing standard, while offering advantages focused on improving the adoption for office hysteroscopy with increased procedure success rates. As part of the final objective being achieved, the following key outcomes were produced.

- A risk analysis of the developed hysteroscopy system according to ISO 14971 standard for application of risk management to medical devices.
- A usability trial protocol for hysteroscopy systems according to IEC 62366-1 standard for application of usability engineering to medical devices.
- A validated hysteroscopy system capable of performing vaginoscopy procedures in a simulated use environment.

6.4 Project Limitations & Future Research

The research project successfully developed, verified, and validated a novel hysteroscopy system for outpatient procedures without general anaesthesia. However, the solution potential of the developed system was affected due to limitations in the research project. The primary limitation is being unable to test the system on patients to confirm its efficacy and receive patient feedback regarding pain. Clinical trials would, therefore, confirm the viability of the developed system. However, this was beyond the project's scope due to time and budget constraints, and testing was limited to simulated procedures and user experience, which still plays a critical role in the efficacy of medical devices. Furthermore, while the sample size was limited, it was sufficient according to usability standards and no use errors occurred during testing. Potential bias with the participants does exist as the test could not include any participants who had no hysteroscopy experience due to limited participant availability. Comparing the feedback of the developed system with a standard system using participants with no prior hysteroscopy experience would be beneficial to ensure no bias. However, finding these participants would be difficult, as it requires knowledge of the relevant anatomy and procedure without direct experience with hysteroscopy systems. Additionally, testing different hysteroscopy systems such as flexible or mini-diameter scopes would provide further data to confirm the findings of this research project. Additional systems were unfortunately not accessible for testing in this project, and the typical rigid scope was the only system included in the testing and comparison.

Based on these limitations, future research should include more unique user groups and different hysteroscopy systems. By using the data collection methods of the validation testing, future research can add to the findings of this research project to build additional insights into how different users perceive the hysteroscopy systems and where other systems excel or fail according to users. This would further aid the development of

hysteroscopy systems guided by user feedback. In terms of device development, producing a version of acceptable standards for first-in-human testing should be a priority to determine both the patient experience and the actual viability of the hysteroscopy system. Continued work on the single-use sheath would also form part of this research. Especially focusing on material selection for biocompatibility and that can undergo initial sterilisation for usage. The potential of the sheath could be expanded upon to explore development of a sheath compatible with existing hysteroscopy systems, which could alleviate certain shortcomings identified without the need for replacing the entire system. Finally, while the focus of this research project was hysteroscopy, other endoscopic applications could form part of future research to assess the viability of the developed system as a platform technology. Endoscopes are similar in design, with length and diameter being the major difference, therefore the new system could potentially be redesigned with minimal changes for different applications. In summary, the future research recommendations based on the project outcomes are as follows.

- **Biocompatibility and sterility of hysteroscopy system and accessories** – The next stage of development for the hysteroscopy system should involve material selection that ensures the system is biocompatible and can undergo sterilisation. The components that come into contact with the patient would need to be compliant with ISO 10993 which involves passing tests for cytotoxicity, irritation, sensitisation, and systemic toxicity. This primarily affects the disposable sheath used to isolate the main hysteroscopy system from the patient. In terms sterility, the disposable sheath should be sterilised before use, for example with ethylene oxide which is used for single-use medical products. The main hysteroscopy system, given no direct contact with the patient, should be manually disinfected with a combination process of sanitising wipes and 70% isopropyl alcohol to avoid damaging the equipment through intense sterilisation. These sterilisation processes should be compliant with ISO 11135 and combined with the biocompatibility would prepare the hysteroscopy system for passing clearance for patient trials.
- **Image analysis for diagnostic efficacy of the hysteroscopy system –** Determining the diagnostic efficacy of the new hysteroscopy system should be investigated in future work. This should specifically involve performing an image analysis on characteristics of the images captured by the new system and comparing these to images compared by a standard system. The new hysteroscopy system incorporated an off-the-shelf camera module that should be further investigated to determine how it impacts the diagnostic efficacy to ensure the resolution, field of view, and depth of field of the camera are suitable for evaluating the uterine cavity. Additionally, calibration testing should be incorporated to add a scale bar to the camera display during use so the operator may estimate the size of objects during the procedure.
- **Comprehensive cost analysis of the new hysteroscopy system –** Understanding the full cost of the new hysteroscopy system would determine if it is an appropriate solution to the current hysteroscopy landscape as setup cost of the existing equipment is a limiting factor for adoption. However, to perform a full cost analysis, the system would need to undergo industrialisation to produce a final bill of materials and confirm cost to manufacture. This should be performed in the next stage of development as part of the preparation for clinical trials as the industrialised system and its components would likely comply with the

biocompatibility and sterility requirements. Additional testing to determine the life cycle of components would also be included to determine maintenance and replacement costs of the system to complete the cost analysis. The results of the analysis should be compared to the existing equipment to confirm the new system is a more accessible solution comparatively in terms of cost.

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Appendix A. Finite Element Analysis Results

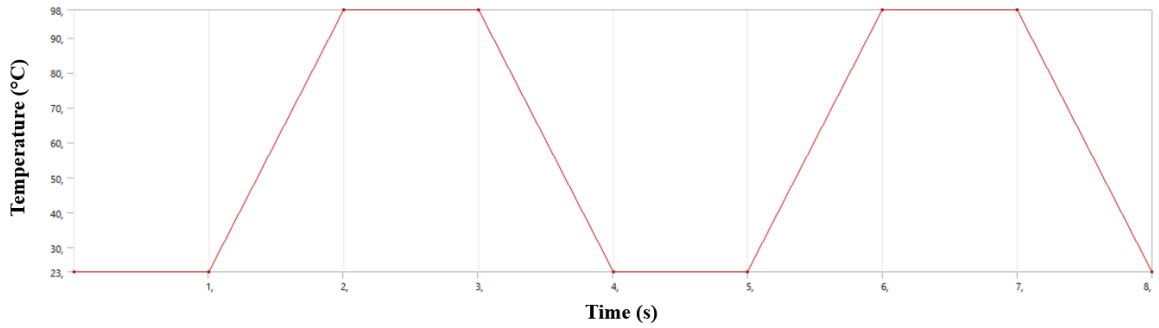


Figure A.1 Temperature vs. Time

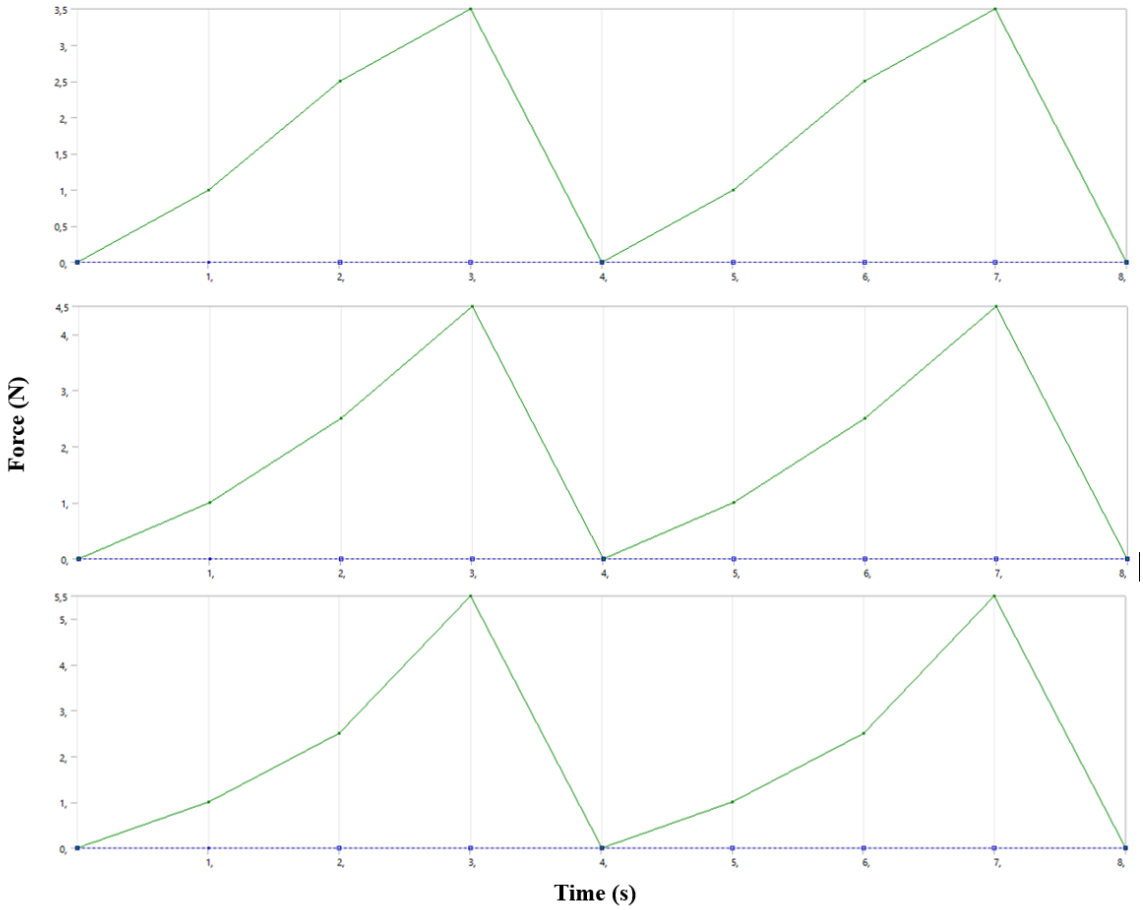


Figure A.2 Force vs. Time for Loading Scenarios

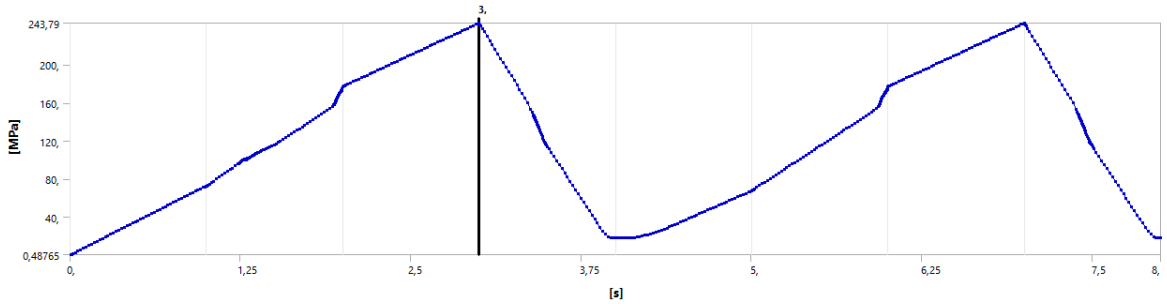


Figure A.3 Average Stress vs. Time for 3.5N Loading Scenario

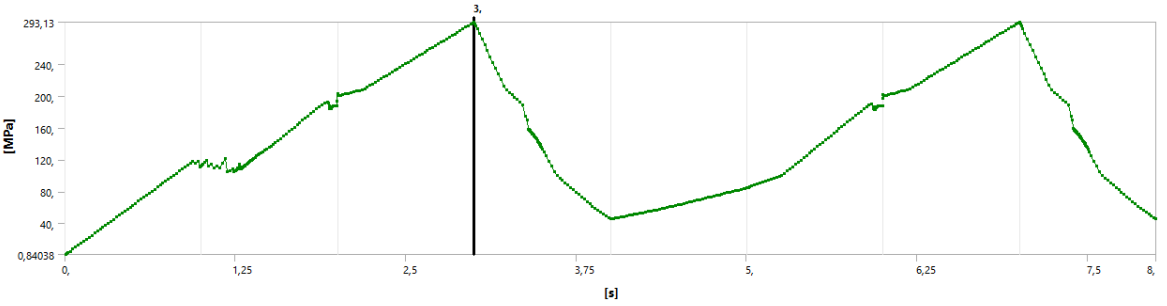


Figure A.4 Maximum Stress vs. Time for 3.5N Loading Scenario

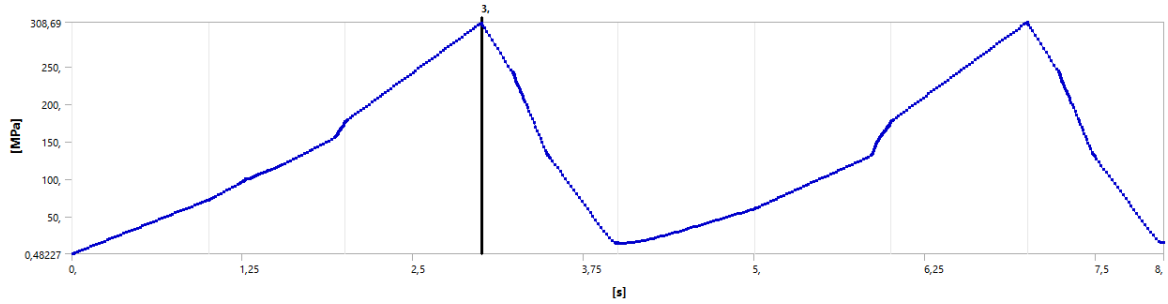


Figure A.5 Average Stress vs. Time for 4.5N Loading Scenario

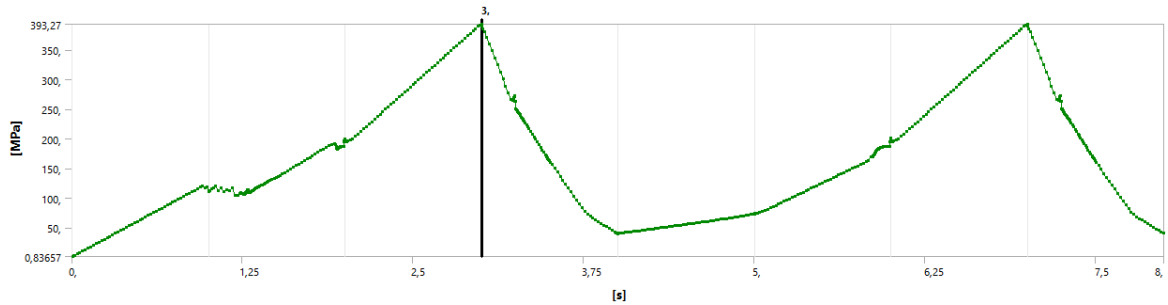


Figure A.6 Maximum Stress vs. Time for 4.5N Loading Scenario

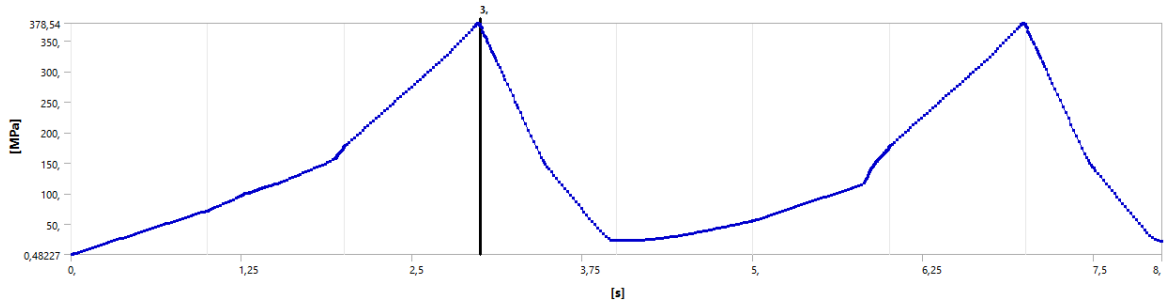


Figure A.7 Average Stress vs. Time for 5.5N Loading Scenario

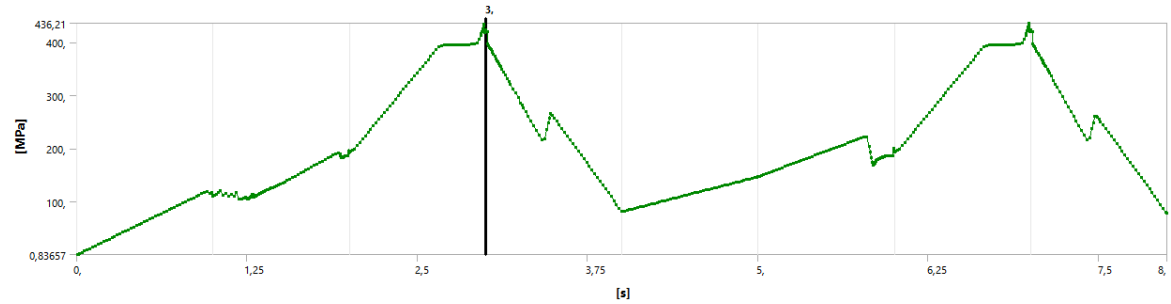


Figure A.8 Maximum Stress vs. Time for 5.5N Loading Scenario

Appendix B. Comparison of Prototypes

Figure B.1 Prototype 1 – Proof of Concept

Figure B.2 Prototype 2 – Multiple Directional Bending

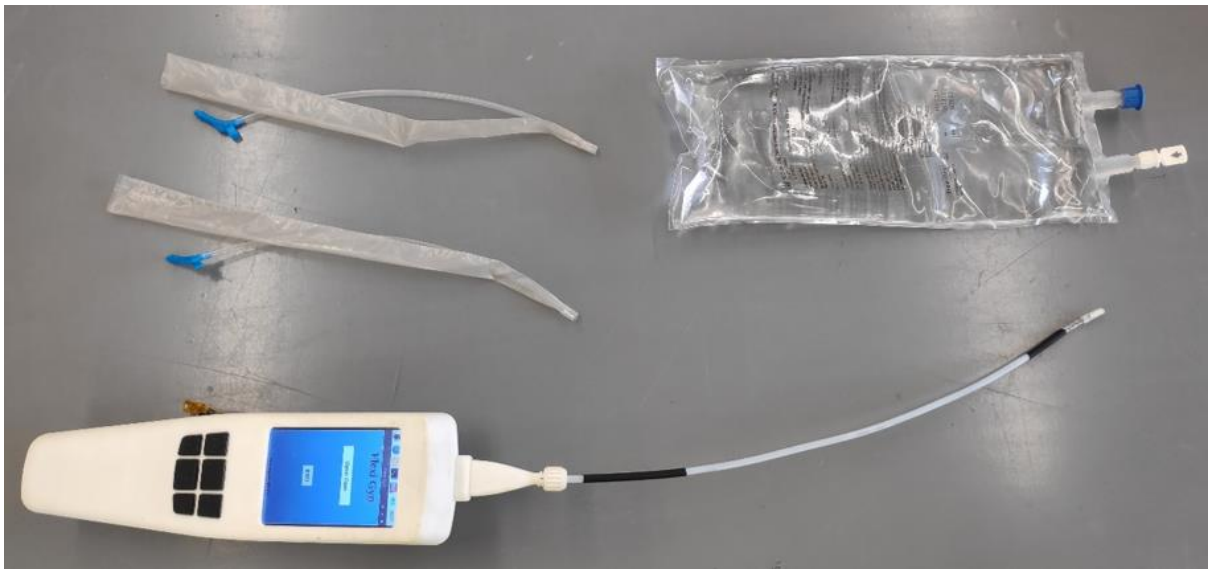


Figure B.3 Prototype 3 – All-in-One System with Single-Use Sheath

Figure B.4 Prototype 4 – Miniaturised & Optimised

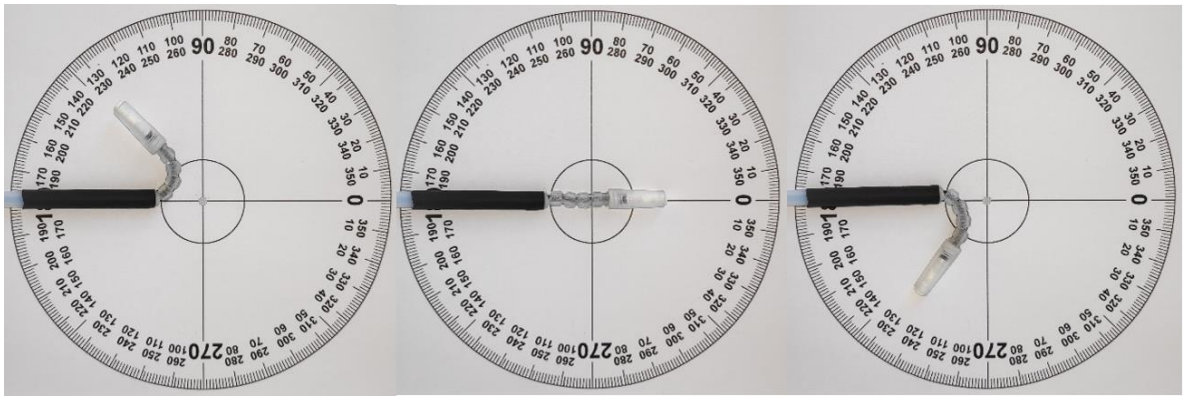


Figure B.5 Prototype 3 Bending range

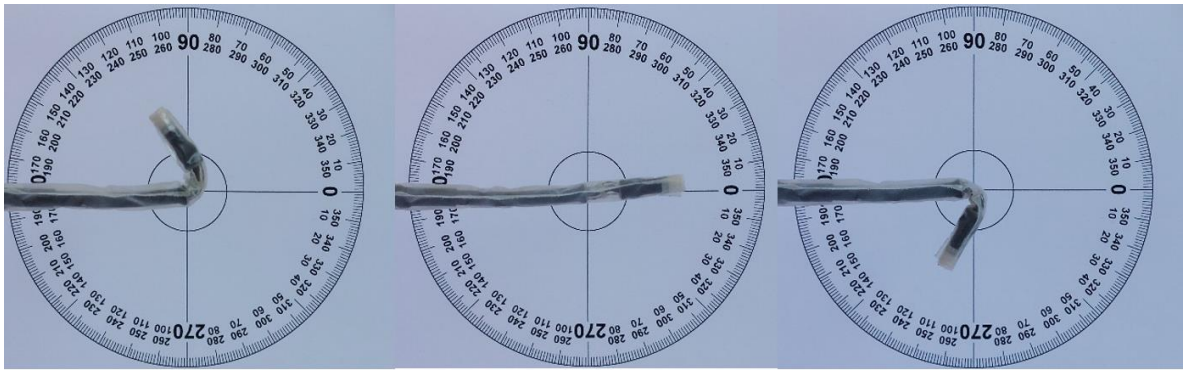


Figure B.6 Prototype 4 Bending Range

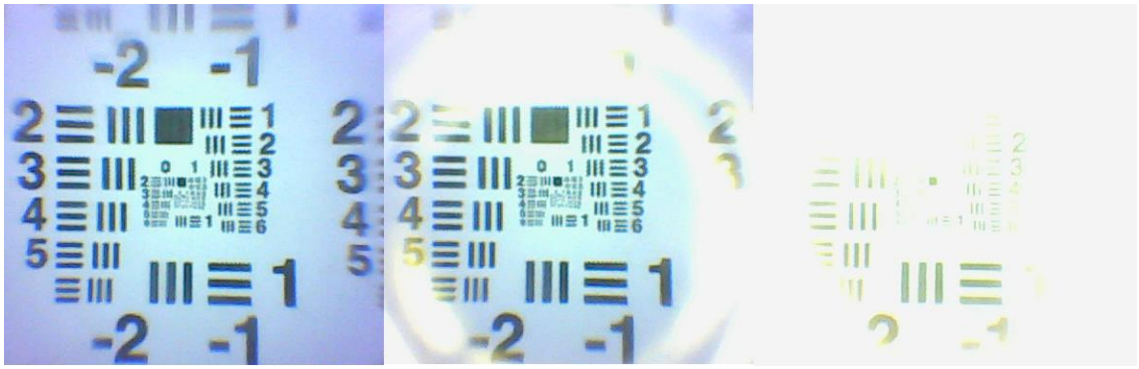


Figure B.7 Prototype 3 LED Brightness Levels with Sheath on

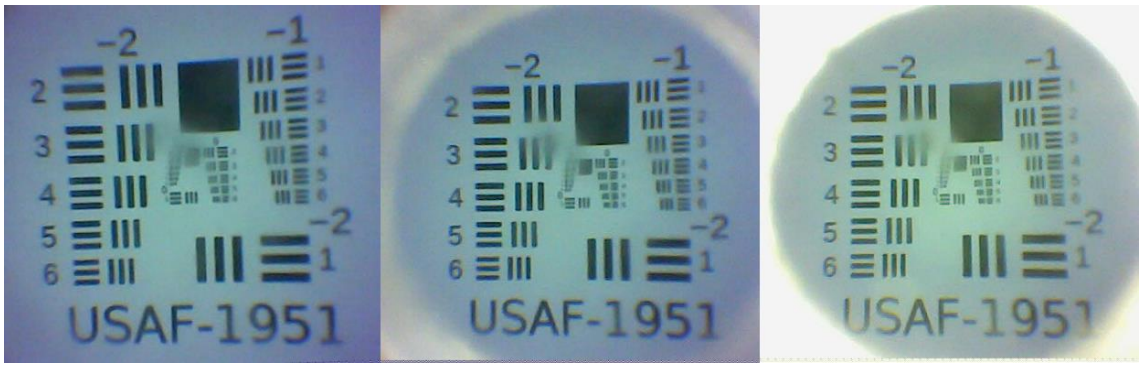


Figure B.8 Prototype 4 LED Brightness Levels with Sheath on

Appendix C. Usability Trial Templates

Task Stages and Completion: Pass/Fail Parameters.

Outcome	Abbreviation
Success (correct use)	S
Success with Observed Difficulty	SOD
Close Call (error occurred but was recovered)	CC
User Error (user does not complete task i.e. fail)	UE
Not Applicable (blocked by a previous task)	NA

Type of Error	Detail
Failure to set up correctly	Ability of participant to set up device and connect to accessories correctly
User misinterprets controls and activate wrong function	Controls are close together and user accidently pushes the wrong button than intended
Breaking or tearing of components	Typical user applied force exceeds breaking strength of component
Errors of cleaning	Ease of cleaning both during patient use and between patients (smooth and easy to wipe down, minimum nooks/trims etc.) Ease of preparation for next patient Ease/accuracy during reassembly if disassembled during cleaning Errors (and risks) associated with poor cleaning and/or failure to replace contaminated parts

Objective Data Collection Form (Moderator Form)

Participant Details	
Participant Number	
Profession & Qualifications	
Hysteroscopy Experience (Years)	

Task	Outcome	Comments/Issues
1		
2		
3		
4		
5		
6		

System Usability Scale

	Strongly Disagree				Strongly Agree
	1	2	3	4	5
1. I think that I would like to use this system frequently.	○	○	○	○	○
2. I found the system unnecessarily complex.	○	○	○	○	○
3. I thought the system was easy to use.	○	○	○	○	○
4. I think that I would need the support of a technical person to be able to use this system.	○	○	○	○	○
5. I found the various functions in this system were well integrated.	○	○	○	○	○
6. I thought there was too much inconsistency in this system.	○	○	○	○	○
7. I would imagine that most people would learn to use this system very quickly.	○	○	○	○	○
8. I found the system very cumbersome to use.	○	○	○	○	○
9. I felt very confident using the system.	○	○	○	○	○
10. I needed to learn a lot before I could get going with this system.	○	○	○	○	○

Post-Session Questionnaire

Strongly Agree (5) – Agree (4) – Neutral (3) – Disagree (2) – Strongly Disagree (1)							Comments/Issues
General Usability	**1**	**2**	**3**	**4**	**5**	**N/A**	
1. I can quickly get the equipment ready for use.	○	○	○	○	○	○	
2. I can successfully get the equipment ready for use without assistance.	○	○	○	○	○	○	
3. I know when the equipment is working properly.	○	○	○	○	○	○	
4. The equipment is easy to clean.	○	○	○	○	○	○	
5. The equipment was easy to hold and operate with one hand.	○	○	○	○	○	○	
6. I did not feel strained during or after using the equipment.	○	○	○	○	○	○	
User Interface	○	○	○	○	○	○	
7. I found the position of the controls comfortable and easy to use.	○	○	○	○	○	○	
8. I am satisfied with the size, quality, and position of the display screen.	○	○	○	○	○	○	
9. I found the controls to be fast and responsive to my input.	○	○	○	○	○	○	
Disposable Sheath	○	○	○	○	○	○	
10. I can easily connect the media tubing to the sheath.	○	○	○	○	○	○	
11. I can quickly place the sheath on the scope.	○	○	○	○	○	○	
12. I am satisfied with the flow through the sheath.	○	○	○	○	○	○	
Device Controls	○	○	○	○	○	○	
13. I know how to adjust the machine's controls.	○	○	○	○	○	○	
14. I can comfortably operate the machine's controls.	○	○	○	○	○	○	
15. I can quickly adjust the machine's controls when I need to.	○	○	○	○	○	○	

16. I am satisfied with what it takes to adjust the machine's controls.	○	○	○	○	○	○	
Frequency of Trouble	○	○	○	○	○	○	
17. I had difficulty placing the sheath over the scope.	○	○	○	○	○	○	
18. I had difficulty using the controls while holding the device.	○	○	○	○	○	○	
19. I had difficulty observing the screen during the procedure.	○	○	○	○	○	○	
20. I found the visual clarity of the device to be lacking.	○	○	○	○	○	○	
21. I had difficulty getting the equipment ready for use.	○	○	○	○	○	○	
22. I had difficulty maneuvering the tip of the scope.	○	○	○	○	○	○	
23. I had difficulty removing the scope from the patient.	○	○	○	○	○	○	
24. I found it difficult to remove the sheath from the scope.	○	○	○	○	○	○	

Overall Impression & Additional Comments

Procedure Review Form

CADAVER: A B C Device Used: FlexiGyn ☐ Karl Storz ☐

Entry: Easy ☐ Moderate ☐ Difficult ☐ Not Possible ☐

Speculum Used: Yes ☐ No☐ Size: S ☐ M ☐ L ☐

Cervix: Normal ☐ Abnormal ☐

Describe_____

Cervical Canal: Normal ☐ Abnormal ☐

Describe_____

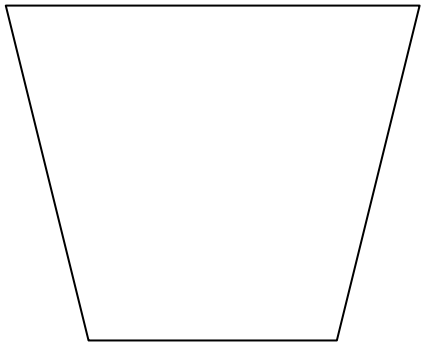
Cavity: Normal ☐ Atrophy ☐ Abnormal ☐

Describe_____

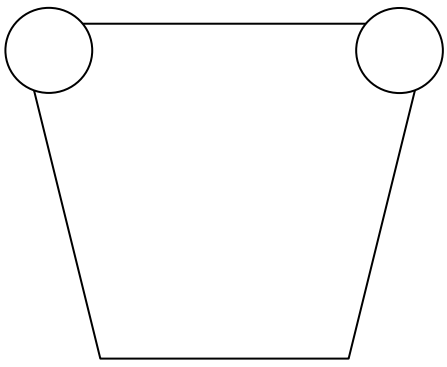
Fibroid ☐ Polyp ☐ Size_____

Possible Malignancy: Describe_____

Anterior:



Posterior:



Ostium Seen Right ☐
Ostium Seen Left ☐

Participant Consent Form and NDA

I agree to participate in the study conducted by the University of Cape Town's Medical Devices Laboratory.

I understand that participation in this usability study is voluntary, and I agree to immediately raise any concerns or areas of discomfort during the session with the study administrator.

I agree to honour the confidential nature of this trial. I acknowledge and confirm that I will not divulge to any party any confidential information including and not limited to the workings of the device used in this trial and the results obtained within the trial. I agree to keep confidential information confidential and to protect the confidentiality of such confidential information with the same degree of care with which I protect the confidentiality of my own information.

I consent to be photographed/videoed and further authorise that the photographs/videos may be used or published for any project-related purpose.

Please sign below to indicate that you have read, and you understand the information on this form and that any questions you might have about the session have been answered.

Date: _____

Printed Name: _____

Signed Name: _____

Thank you!

We appreciate your participation.

Appendix D. Ethics Approval for Usability Trial

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone (021) 406 6626
Email: Olivia.langenhoven@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

15 November 2019

HREC REF:753/2019

A/Prof S. Sivarasu
Department of Human Biology
Anatomy Building, Room 7.17

Dear A/Prof Sivarasu

PROJECT TITLE: ***SAFETY AND EFFICACY TESTING OF FLEXIBLE HYSTEROSCOPY SYSTEM (PHD DEGREE - MR EDMUND WESSELS)***

Thank you for submitting your new study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has formally **approved** the above-mentioned study subject to the following conditions:

1. An instrument is introduced into the reproductive system of female bodies to see whether it is able to fit correctly and move adequately. There is no damage caused and the bodies are able to be used in this way. We are covered by donor consent and the National Health Act. Often the bodies have already undergone a hysterectomy, in which case that body will not be used in this study.

Approval is granted for one year until the 30 November 2020.

We acknowledge that the student: Mr Edmund Wessels will also be involved in this study.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Please quote the HREC reference number in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.9.22
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	21/9/2021

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown.
Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Comments to PI from the HREC
Thank you for the documents AR

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	30/07/2021		
HREC REF Number	753/2019	Current Ethics Approval was granted until	30/11/2020
Protocol title	Safety and Efficacy Testing of a Flexible Hysteroscopy System (Phd Degree – Mr Edmund Wessels)		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?		☐ Yes	☑ No
If yes, could you please provide the HREC Reference number for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Assoc. Prof. Sudesh S Varasu		

Note: Please complete the Closure form (FHS018) once study is completed within the approval period

Appendix E. Usability Trial Results

Table E.1 Usability Trial Participant details

Participant	A1
Profession & Qualifications	Doctor, MBChB, Registrar
Hysteroscopy Experience in Years	<1

Participant	F1
Profession & Qualifications	Medical Specialist, FCOG
Hysteroscopy Experience in Years	15

Participant	B1
Profession & Qualifications	MBChB, FCOh
Hysteroscopy Experience in Years	15

Participant	G1
Profession & Qualifications	MBChB, FCOG, MMED
Hysteroscopy Experience in Years	9

Participant	C1
Profession & Qualifications	Obs & Gynae Consultant, MBChB, FCOG(SA), Mmed(O&G)
Hysteroscopy Experience in Years	6

Participant	H1
Profession & Qualifications	Obs & Gynae Medical Registrar
Hysteroscopy Experience in Years	<1

Participant	D1
Profession & Qualifications	Medical Officer, MBChB
Hysteroscopy Experience in Years	1

Participant	I1
Profession & Qualifications	Docotr, Obs & Gynae Registrar, MBChB
Hysteroscopy Experience in Years	<1

Participant	E1
Profession & Qualifications	Obstetric Registrar, MBChB, FCOG
Hysteroscopy Experience in Years	3

Participant	J1
Profession & Qualifications	OBGYN Consultant, MBChB, FCOG
Hysteroscopy Experience in Years	3

Table E.2 FlexiGyn System Usability Scale Question Answers per Participant

FlexiGyn Prototype System										
Question	**A1**	**B1**	**C1**	**D1**	**E1**	**F1**	**G1**	**H1**	**I1**	**J1**
1	4	4	4	5	4	5	5	5	4	3
2	1	1	1	1	1	1	1	1	1	1
3	4	4	4	4	4	5	5	5	5	4
4	1	1	3	2	1	1	2	2	1	2
5	4	4	5	4	4	5	5	4	4	4
6	1	2	4	2	1	1	1	1	4	1
7	5	3	5	4	5	4	5	5	2	5
8	1	1	3	2	1	1	1	1	3	2
9	4	5	2	4	4	5	5	5	5	4
10	1	1	2	2	1	1	1	1	1	1
SUS Score	90	85	67.5	80	90	97.5	97.5	95	75	82.5
AVG	86									

Table E.3 Standard System Usability Scale Question Answers per Participant

Standard Hysteroscopy System										
Question	**A1**	**B1**	**C1**	**D1**	**E1**	**F1**	**G1**	**H1**	**I1**	**J1**
1	4	5	4	5	4	5	5	5	4	3
2	4	1	3	2	2	1	1	3	2	4
3	4	5	2	4	3	5	5	3	3	2
4	4	1	3	2	1	1	1	5	3	5
5	3	5	4	4	4	5	5	5	4	4
6	4	1	1	1	1	1	1	2	2	3
7	2	3	2	4	4	3	5	2	2	1
8	2	1	2	1	2	2	1	4	2	4
9	3	1	5	5	4	5	5	2	4	4
10	3	1	5	2	2	4	1	5	5	5
SUS Score	47.5	85	57.5	85	77.5	85	100	45	57.5	32.5
AVG	67.25									

Table E.4 FlexiGyn vs. Standard SUS Scores per Participant

Participant	**A1**	**B1**	**C1**	**D1**	**E1**	**F1**	**G1**	**H1**	**I1**	**J1**	**AVG**
FlexiGyn	90	85	67.5	80	90	97.5	97.5	95	75	82.5	**86**
Standard	47.5	85	57.5	85	77.5	85	100	45	57.5	32.5	**67.25**

Table E.5 FlexiGyn Post-Session Questionnaire Results

FlexiGyn Prototype System												
Question	**A1**	**B1**	**C1**	**D1**	**E1**	**F1**	**G1**	**H1**	**I 1**	**J1**	**AVG**	
1	5	5	5	4	5	5	5	5	5	5	4.90	General Usability
2	4	5	5	4	5	5	5	5	5	5	4.80	
3	3	4	4	4	5	5	5	4	4	4	4.20	
4	5	3	5	4	3	5	5	5	5	5	4.50	
5	5	5	3	3	1	5	5	5	4	3	3.90	
6	1	5	2	4	5	5	5	5	2	4	3.80	
7	3	4	5	4	4	4	5	4	5	4	4.20	User Interface
8	5	4	4	4	4	5	5	5	4	4	4.40	
9	5	4	5	5	2	4	2	5	4	2	3.80	
10	5	5	5	5	5	5	5	5	5	5	5.00	Sheath
11	5	5	5	5	5	5	5	5	5	5	5.00	
12	5	4	4	4		4				5	4.33	
13	3	4	5	4	5	5	3	5	5	5	4.40	Device Controls
14	3	5	5	4	5	5	3	5	5	4	4.40	
15	3	5	4	4	4	4	3	5	4	3	3.90	
16	4	3	5	4	4	4	2	5	5	4	4.00	
17	1	1	1	1	1	1	1	1	1	1	1.00	Frequency of Trouble
18	1	1	1	1	1	1	1	1	1	2	1.10	
19	2	1	4	1	1	1	1	1	1	1	1.40	
20	2	1	1	2	1	1	1	5	2	1	1.70	
21	3	1	1	1	1	1	1	1	1	1	1.20	
22	3	3	4	3	2	1	4	1	1	4	2.60	
23	2	1	2	1	1	1	1	1	1	1	1.20	
24	1	1	1	1	1	1	1	1	1	1	1.00	

Table E.6 Standard Post-Session Questionnaire Results

Standard Hysteroscopy System												
Question	**A1**	**B1**	**C1**	**D1**	**E1**	**F1**	**G1**	**H1**	**I 1**	**J1**	**AVG**	
1	3	5	4	4	5	5	5	2	4	2	3.90	General Usability
2	2	5	2	4	5	5	5	1	3	4	3.60	
3	4	5	5	4	5	5	5	2	4	4	4.30	
4	1	3	1	3	5	4	1	3	4	2	2.70	
5	3	5	4	2	1	3	5	4	4	1	3.20	
6	3	5	4	5	5	5	5	3	5	2	4.20	
7	3	4	4	5	5	3	5	4	5	2	4.00	User Interface
8	3	5	5	5	5	5	5	5	5	2	4.50	
9	2	5	5	5	5	5	5	3	5	4	4.40	

10	3	5	4	5		4	5	4	4	4	4.22	Sheath
11	3	5	4	5		4	5	4	4	2	4.00	
12	2	5	4	5		4	5	4		4	4.13	
13	3	5	5	5	5	5	5	3	4	4	4.40	Device Controls
14	3	5	5	5	5	5	5	3	4	4	4.40	
15	3	3	4	5	5	5	5	2	4	4	4.00	
16	3	4	4	5	5	5	5	5	5	4	4.50	
17	3	1	2	1		1	1	3		4	2.00	Frequency of Trouble
18	2	2	2	2	1	2	1	3	1	4	2.00	
19	3	1	1	1	1	2	1	4	1	4	1.90	
20	2	1	1	2	1	1	1	2	1	2	1.40	
21	3	1	2	2	1	2	1	4	1	4	2.10	
22	3	3	1	2		4	1	4	1	4	2.56	
23	2	1	1	1	1	2	1	3	1	2	1.50	
24	2	1	3	1		1	1	2	1	2	1.56	

Table E.7 FlexiGyn Participant Comments

Participant	Comments
A1	"Will take some getting use to and not work so hard with my hand like the traditional rigid scope" "It is very sensitive and will need to get used to that" "The device controls are very sensitive to light manipulation and that will take time (not ample) just to control the urge to use excessive manipulation. Don't think the learning curve for use will be too steep"
B1	"System is simple and easy to use" "Controls are accessible and comfortable" "Image quality good – adequate for diagnostic scope"
C1	"Screen positioning could be adjustable or weighted to face the operator despite the device being angled." "Is pressure high enough?" "When device is angled, screen is moved. A stationary screen may be better." "Moves too fast" "Need to neutralize tip's position before removal" "I like the innovation in this filed in this country/continent. It's definitely needed and would sell well across the continent if priced well." "A few adjustments would make the device great to use as noted above."
D1	"I think this is a brilliant concept" "As a prototype – good proof of concept" "Would definitely want this type of device – would definitely improve access and allow easy outreach hysteroscopy clinics"
E1	"A little heavy to use with one hand' "Put power button on side?" "Small scope size – may help with narrow cervix however device feels very flexible, I wonder if it might be difficult to enter a narrow cervix" "Is the device robust – hard to say with a prototype, would worry if might get easily broken"

F1	"Excellent idea" "Would make in office assessment possible/easier" "White balance feature would be useful"
G1	"Easy to use. Light weight." "The disposable sheath is a great idea!" "The controls are a bit tricky, something more sleek with slower reaction time would be better"
H1	
I1	"Head + neck turning" "Great for outpatient diagnostic setting" "Needs adjustments for instruments + procedures" "Add software to turn screen when rotating scope sideways"
J1	"Easy to use overall" "Little bit heavy to rotate with one hand as my hands are small" "Obviously will be easier once streamlined"

Table E.8 Standard Participant Comments

Participant	Comments
A1	"Now I'm used to the setting up of this device from just using it regularly. But it took time for me to can get to effortless setting up of the device. It does take more manipulation on the operator than the proposed device and there is no extensive cleaning in-between usage."
B1	"I am very familiar with this system having used it for >15 years and therefore felt very comfortable using it."
C1	"Several patients needed to master use of scope" "Bias with regard to answering usability questions on the betocchi scope – very used to it (after years of experience)"
D1	"More cumbersome than disposable sheath" "Two handed for camera manipulation"
E1	"Viewing angle requires a second hand"
F1	"Equipment size and cumbersome setups can be problematic for mobile use"
G1	
H1	"Standard hyst equipment much harder to use than the prototype!"
I1	
J1	"Difficult to assemble" "Had to learn how to use it as everything is opposite"

Table E.9 Usability Trial – Procedure Form Feedback

Participant	**A1**	
Device	FlexiGyn	Standard
Entry	Easy	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervical Canal	Normal	Normal
Cavity	Abnormal	Abnormal
Cavity Description	Mass noted on anterior aspect of the cavity	Inflamed anterior aspect with irregular mass noted

Fibroid/Polyp		
Possible Malignancy	Irregular, red	Irregular mass lesion
Anterior	Drawn image	Same drawn image
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**B1**	
Device	FlexiGyn	Standard
Entry	Easy	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervical Canal	Normal	Normal
Cavity		
Cavity Description	Anterior endometrium erythematous and irregular	Anterior uterine wall endometrium erythematous and irregular
Fibroid/Polyp	Fibriod/Polyp	Fibriod/Polyp
Possible Malignancy	Suspicious	Suspicious
Anterior	Drawn image	Same drawn image
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**C1**	
Device	FlexiGyn	Standard
Entry	Moderate	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervical Canal	Abnormal	Normal
Canal Description	Inflamed anterior ridge	Inflamed anterior border
Cavity	Abnormal	Abnormal
Cavity Description	Inflamed abnormal area over anterior wall, malignancy?	Superior/anterior wall abnormality, malignancy?
Fibroid/Polyp		
Possible Malignancy		
Anterior	Drawn image	Same drawn image
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**D1**	
Device	FlexiGyn	Standard
Entry	Moderate	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervical Canal	Normal	Normal
Cavity	Normal	Normal
Cavity Description		
Fibroid/Polyp		
Possible Malignancy	Lesion anterior wall	Lesion on anterior wall
Anterior		

Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**E1**	
Device	FlexiGyn	Standard
Entry	Easy	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervical Canal	Normal	Normal
Cavity		
Cavity Description	Submucosal fibroid	
Fibroid/Polyp		
Possible Malignancy		
Anterior	Image drawn	No image
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**F1**	
Device	FlexiGyn	Standard
Entry	Easy	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervix Description	Normal looking external cervical os	
Cervical Canal	Normal	Normal
Cavity	Atrophy	Abnormal
Cavity Description		Raised area anterior surface
Fibroid/Polyp		
Possible Malignancy		
Anterior		
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**G1**	
Device	FlexiGyn	Standard
Entry	Easy	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervical Canal	Normal	Normal
Cavity	Normal	Normal
Cavity Description		
Fibroid/Polyp		
Possible Malignancy		
Anterior		
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**H1**	
Device	FlexiGyn	Standard

Entry	Easy	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervix Description	Lesions or discoloration	
Cervical Canal	Normal	Normal
Canal Description	Lesions	Side lesion? Fibroid vs polyp
Cavity	Atrophy	Atrophy
Cavity Description	White patches? Adhesions noted	White lesion?
Fibroid/Polyp		
Possible Malignancy		
Anterior		
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**I1**	
Device	FlexiGyn	Standard
Entry	Easy	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervical Canal	Normal	Normal
Cavity	Abnormal	Atrophy
Cavity Description		
Fibroid/Polyp	Fibroid	
Possible Malignancy	Endometrial	Endometrial
Anterior	Image Drawn	Same image drawn
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen
Participant	**J1**	
Device	FlexiGyn	Standard
Entry	Moderate	Easy
Speculum Used	No	No
Cervix	Normal	Normal
Cervical Canal	Normal	Normal
Cavity	Atrophy	Abnormal
Cavity Description		
Fibroid/Polyp		
Possible Malignancy		Mass anterior wall
Anterior	Image drawn, “atrophy”	Same image drawn, “mass”
Posterior		
Ostium Right	Seen	Seen
Ostium Left	Seen	Seen

Appendix F. US Patent US011503988B2

US011503988B2

(12) **United States Patent**
Wessels et al.

(10) **Patent No.: US 11,503,988 B2**
(45) **Date of Patent: Nov. 22, 2022**

(54) **ENDOSCOPIC DEVICE**

(71) Applicant: **University of Cape Town**, Cape Town (ZA)

(72) Inventors: **Edmund Grey Wessels**, Cape Town (ZA); **Sudesh Sivarasu**, Kenilworth (ZA)

(73) Assignee: **University of Cape Town**, Cape Town (ZA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 552 days.

(21) Appl. No.: **16/292,650**

(22) Filed: **Mar. 5, 2019**

(65) **Prior Publication Data**

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(30) **Foreign Application Priority Data**

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(51) **Int. Cl.**
A61B 1/00 (2006.01)
A61B 1/005 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 1/0058*** (2013.01); ***A61B 1/00006*** (2013.01); ***A61B 1/0053*** (2013.01); ***A61B 1/0055*** (2013.01); ***A61B 1/0057*** (2013.01); ***A61B 1/00103*** (2013.01); ***A61B 1/00135*** (2013.01); ***A61B 1/00137*** (2013.01)

(58) **Field of Classification Search**
None
See application file for complete search history.

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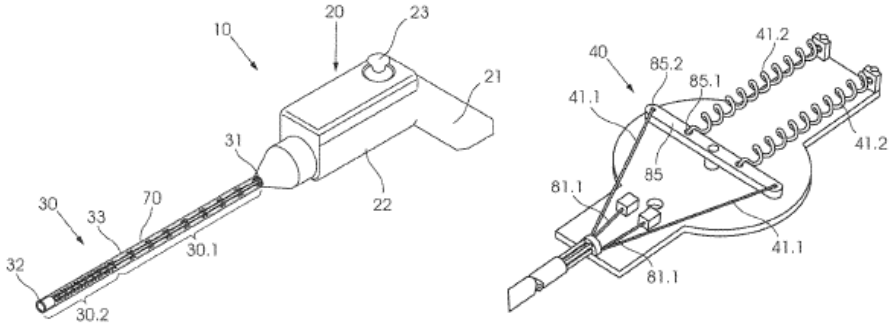
Primary Examiner — Timothy J Neal
(74) *Attorney, Agent, or Firm* — The Webb Law Firm

(57) **ABSTRACT**

This invention relates to an endoscopic device, and more particularly but not exclusively to an endoscopic device suitable for use in diagnostic and/or surgical procedures. The endoscopic device includes a base and a shaft extending from the base. The shaft is at least partially flexible and includes a bending section that is selectively displaceable between a straight configuration and a bent configuration. The endoscopic device also includes an actuation arrangement for selectively displacing the bending section between the straight and bent positions. The actuation arrangement includes at least one actuator which is at least partially made from a shape memory alloy, and which is configured to displace the bending section of the shaft when electric current is passed therethrough. The actuator is located inside the base of the device.

11 Claims, 7 Drawing Sheets



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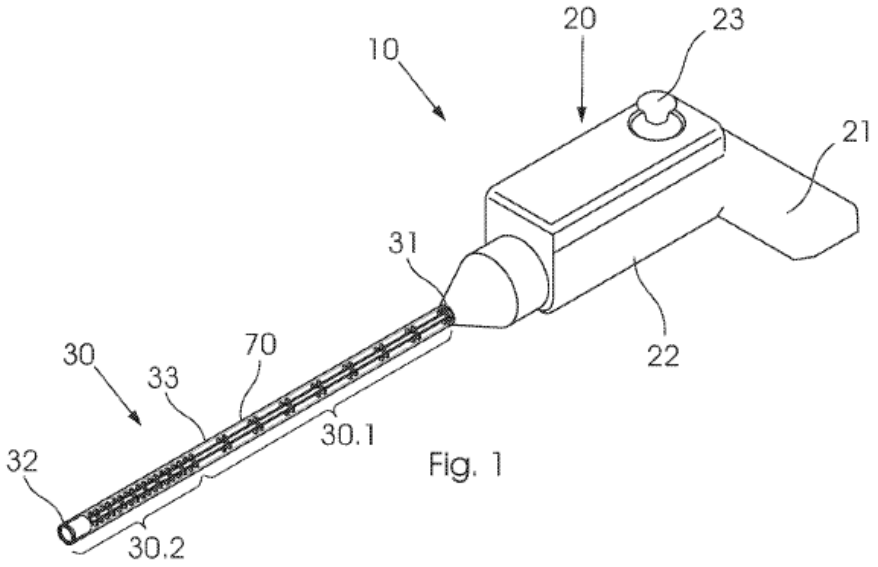
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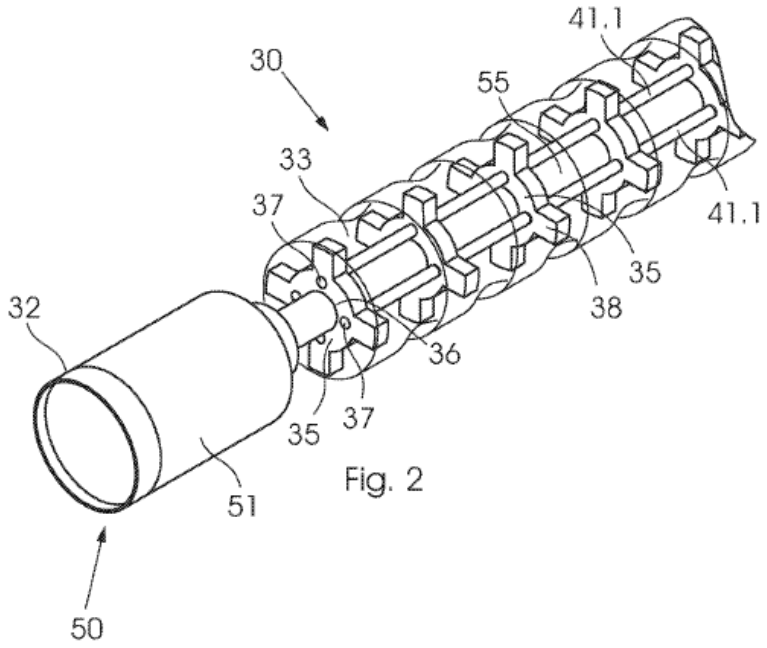
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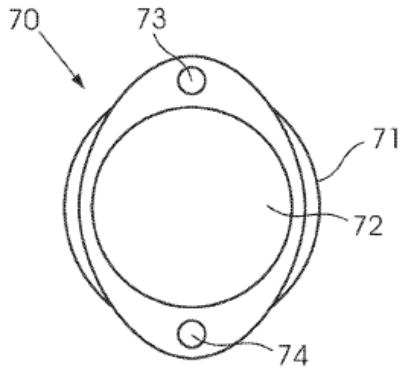

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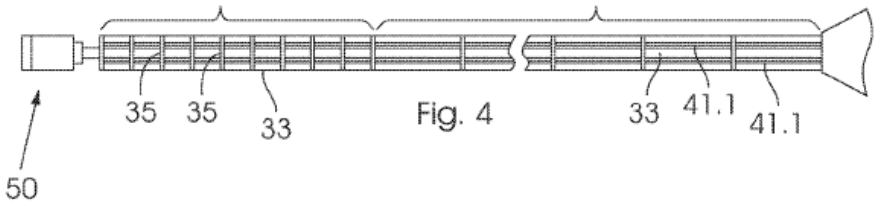

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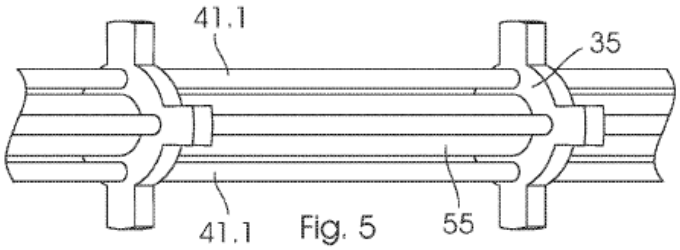

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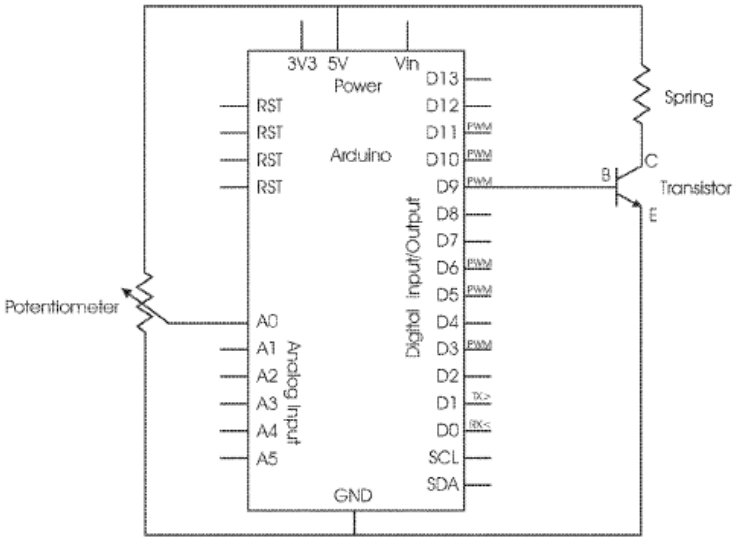
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5V
Vin
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RST
RST
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D9
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D6
D5
D4
D3
D2
D1
D0
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PWM
TX>
RX<
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A2
A3
A4
A5
Analog Input
GND
Potentiometer
Spring
B
C
E
Transistor

Fig. 6

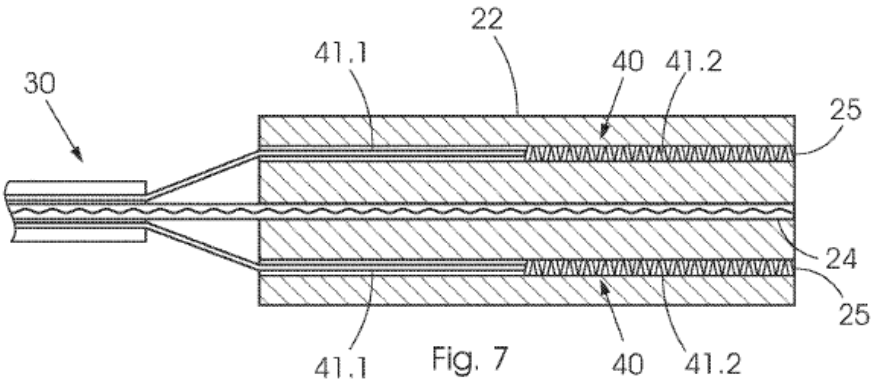
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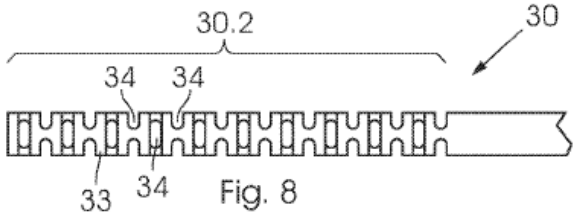
Fig. 7



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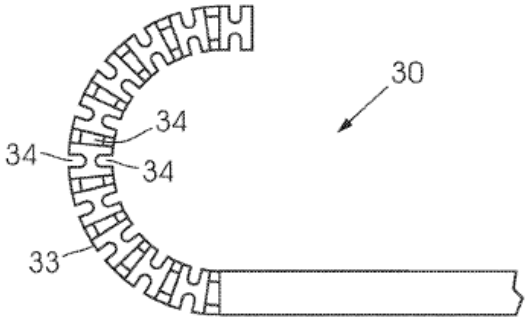

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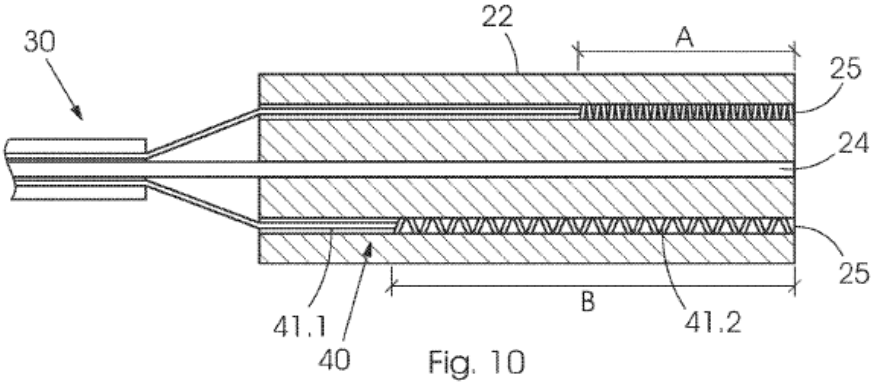
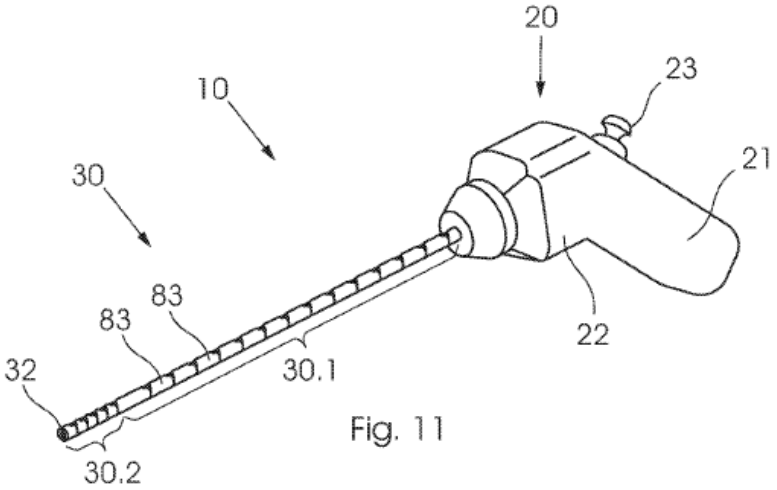


Fig. 10



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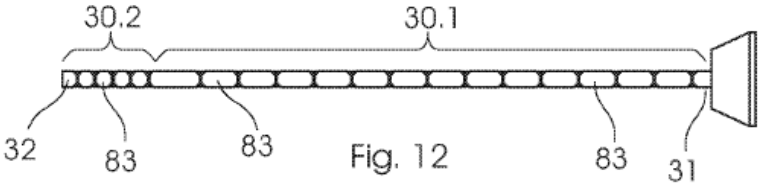


Fig. 12

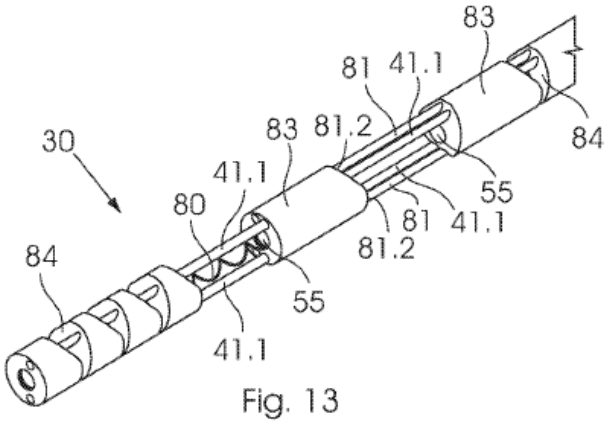


Fig. 13

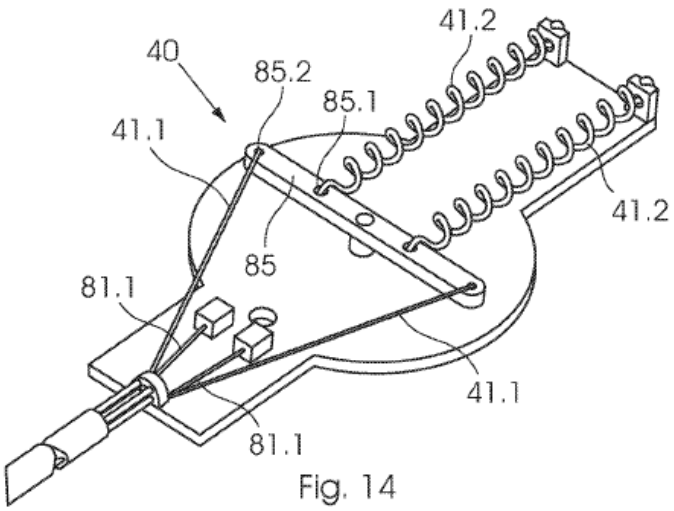


Fig. 14

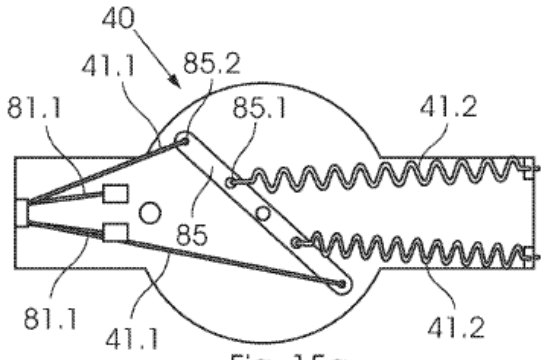
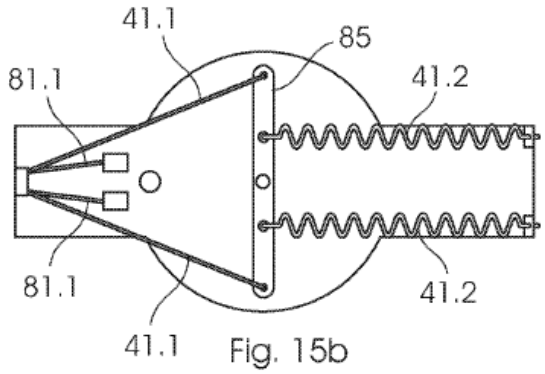


Fig. 15a



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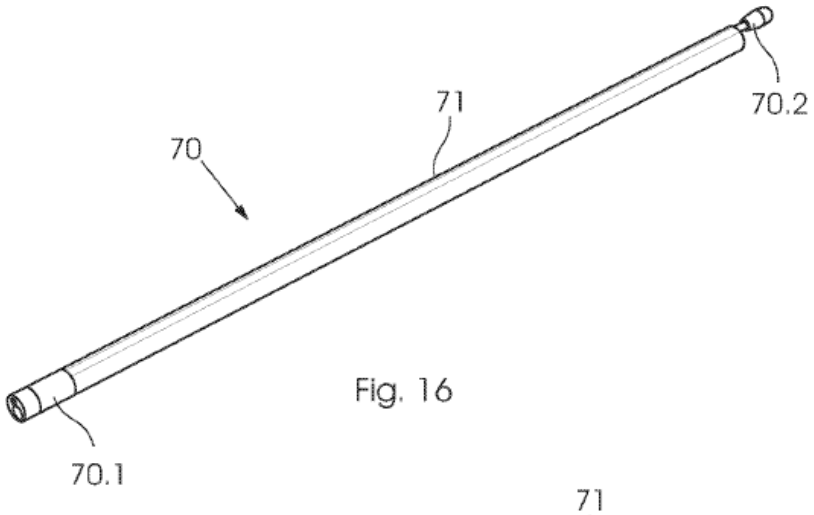


Fig. 16

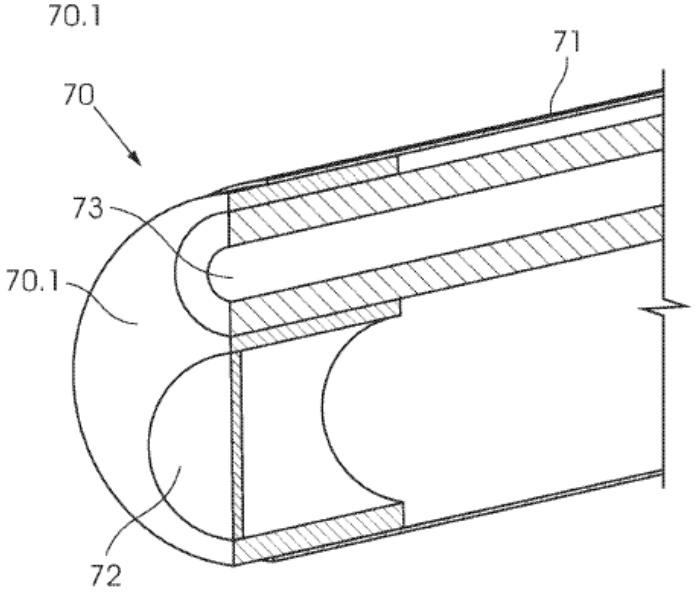


Fig. 17

ENDOSCOPIC DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to United Kingdom Patent Application No. 1803497.5 filed Mar. 5, 2018, the disclosure of which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to an endoscopic device, and more particularly but not exclusively to an endoscopic device suitable for use in diagnostic and/or surgical procedures.

Description of Related Art

In this specification, the term endoscopy, or an endoscopic procedure, refers to the procedure used to examine the interior of a hollow organ or cavity of the body, and may furthermore also entail a surgical procedure involving such organ of cavity. Some examples of endoscopic procedures include a hysteroscopy, laparoscopy and colonoscopy. The term endoscopy is specifically not limited to the procedure used to examine a patient's digestive tract, which is a procedure that is sometimes specifically referred to as an endoscopy.

An endoscope is used in an endoscopic procedure. An endoscope is essentially an illuminated optical, typically slender and tubular instrument, which can be used for visual examinations and diagnoses, but which can also be used to perform, or to assist in performing, surgery. An endoscope typically consists of a rigid or flexible tube, an illumination system used to illuminate the organ, cavity or object under consideration, an imaging system for transmitting an image from a lens of the endoscope to the user, and additional channels for use in the endoscopic procedure, for example a distention media channel and an operative instrument working channel. In more conventional endoscopes the imaging system is often in the form of a relay lens arrangement or a bundle of fiber optics, but in more modern and sophisticated endoscopes the imaging system is in the form of a camera that transmits an image to a screen.

Flexible endoscopes are known in the art. A flexible endoscope includes a flexible (or at least partially flexible) shaft which has a distal bending end with limited selective bending capability. In one example such a flexible endoscope includes a proximal shaft (which may be flexible or rigid) and a distal bending section, which is selectively angularly displaceable. In this example the endoscope has a pair of cords, so-called angulation wires, which run along the length of the shaft section and the bending section. Levers or a gear on the operator end, for example actuated by way of an actuation lever or an angulation knob, pull the cords differentially, resulting in the angular displacement of the bending end. A number of disadvantages are associated with this configuration. The bending end can only be displaced in a single plane, and the entire device therefore needs to be rotated should different viewing angles outside the displacement plane be required. The process is furthermore also often a two-handed process, which makes it difficult to maneuver the device whilst being simultaneously being busy with a surgical procedure. Finally, the actuation mechanism is a manual process—i.e. the angulation wires have to be tensioned manually, which is cumbersome, and which do not allow for complicated angulation wire configurations, and hence multi-directional bending of the bending section.

An example of a flexible, selectively bendable endoscopic surgical device, and more particularly a flexible wrist for such a device, is disclosed in U.S. Pat. No. 8,337,521. The wrist includes a tube having longitudinal holes or lumens distributed around a circumferential zone of the tube for receiving actuation cables or angulation wires therethrough. The tube is flexible to permit bending in pitch and yaw by pulling the cables. The hollow centre of the tube provides room for end effector cables such as gripping cables. There are typically at least four lumens, but more cables may be provided, as indicated in the specification. The proximal ends of the cables are connected to an actuator mechanism, for example such as an assembly including a gimbal plate disclosed in U.S. Ser. No. 10/187,248. This mechanism facilitates the actuation of selected cables in a coordinated manner so as to provide a bendable or steerable member in which the flexible wrist bending angle and direction can be controlled. Alternatively, a separately controlled linear actuation mechanism may be used to tension each cable, or cable pairs looped over a pulley. In both actuator configurations mentioned above, the bending is achieved by exerting a mechanical pulling force on the cables in order to tension the same, and the actuation mechanism required to give effect to accurate control of the device is therefore expensive, bulky and cumbersome, for example as shown in U.S. Ser. No. 10/187,248.

More recently, there have been developments insofar as using shape memory alloys (SMA) in endoscopes in order to improve the actuation and control of selectively bendable endoscopes. This generally involves the use of a shape memory actuator which contracts in response to an electrical current being passed therethrough.

EP0533050 discloses a bending operation apparatus designed such that a bending portion which can be bent/deformed is formed at the distal end of an insertion portion, and the proximal end portion of the insertion portion is connected to an operating portion on the manual operation side which serves to remotely control a bending operation of the bending portion. The apparatus includes three angle wires arranged in the bending portion, three actuators for independently operating the three angle wires, and a control means for arbitrarily controlling the operating amounts of the three angle wires through the three actuators. In one embodiment of this invention the actuators are in the form of SMA coils mounted inside the insertion portion of the apparatus. A significant of shortcoming are associated with the design disclosed in EP0533050 is that the SMA coils have a relatively large diameter in context of the endoscope dimensions, and the number of actuators that can be used is therefore limited if the diameter of the inserting portion is to be kept to a minimum. In addition, EP0533050 also does not disclose how the deformation of the SMA coils will occur in order to return to the bending portion to its unbent position.

Another example of a SMA based bending mechanism is disclosed in EP0764424. In this case the mechanism includes two SMA coils near the tip of the endoscope, which configuration is used to avoid buckling in the bending portion. This configuration is, however, not ideal from a miniaturisation and fabrication perspective. The degree of movement will be limited significantly if the size of the device of this kind of configuration is to be reduced. The mechanism also shows examples of achieving multiple directional bending by placing SMA coils at equal intervals

between joint along the inner tube. Again, the use of multiple SMA coils complicates the design, and also adds to the general size of the mechanism.

In order further to illustrate the shortcomings of existing endoscopes, reference is now made to specific shortcomings associated with hysteroscopies. A hysteroscopy is a procedure that entails using an endoscopic device, in this case a hysteroscope, inserted through the vaginal canal and cervix, to directly inspect the inside of the uterus. Surgical instruments can also be inserted through the hysteroscope's working channel to perform operative procedures. Most hysteroscopes have rigid shafts, which cause immense discomfort and which requires the patient to undergo general anesthesia, thus necessitating the procedures to be performed in the operating theatre. These hysteroscopes also require bulky additional equipment for providing light sources and visual interfaces, which limit the mobility of the entire system. These factors result in very high costs for what is a relatively simple and minimally invasive procedure. As mentioned above, endoscopic device with limited angular maneuverability is known in the art, but even these devices do not provide sufficient flexibility when performing a hysteroscopy. Due to the very nature of an endoscope it will be readily apparent that there will always be a need to reduce the size of these devices, in particular the diameter of the insertion sections. In present configurations, particular those where the actuating means are located in the insertion section, a reduction in size is however often associated with a reduction in functionality, which is also not ideal.

A further disadvantage associated with existing endoscopes in general is that almost the entire device has to be sterilized after use. The sterilization process poses a risk of damage to the components of the device, and also reduces the lifespan of the device. It has been proposed for parts of endoscopic devices to be disposable in order to reduce the need for sterilization, and also for a disposable sheath to be fitted over the central body of the endoscope, thus reducing the need for the serialization of components in use covered by the sheath. For example, US2016/0367119 discloses a handheld surgical endoscope that has a disposable, single-use handle, cannula and distal tip. The distal tip, however, includes the LED illumination and an imaging module that feeds live video to a re-usable display module that connects off-axis to the disposable handle. It will be appreciated that it is not ideal for the entire tip, including the camera and light, to be disposable, as the tip constitutes a costly component. Similarly, US2016/0174819 discloses an endoscopic device having a re-usable portion including a handle, electronics and an integrated display screen while a fluid hub, and a single use portion including a cannula which includes a CMOS imaging module and LED lighting. It will be appreciated that in both the above examples, it is not ideal for the entire tip or cannula, including the camera and light, to be disposable, as this does not make financial sense.

It is accordingly an object of the invention to provide a surgical device that will, at least partially, alleviate the above shortcomings.

It is also an object of the invention to provide a surgical device which will be a useful alternative to existing surgical devices.

SUMMARY OF THE INVENTION

According to the invention there is provided an endoscopic device including:

a base;

a shaft extending from the base; wherein the shaft is at least partially flexible and includes a bending section that is selectively displaceable between a straight configuration and a bent configuration; and

an actuation arrangement for selectively displacing the bending section between the straight and bent positions;

wherein the actuation arrangement includes at least one actuator which is at least partially made from a shape memory alloy, and which is configured to displace the bending section of the shaft when electric current is passed therethrough;

characterized in that the actuator is located inside the base of the device.

There is provided for the actuator to be in the form of a helical coil or spring.

In one embodiment there is provided for an angulation wire to extend from the actuator towards the bending section of the shaft, in order for displacement of the actuator to be transmitted to the bending section.

A first end of the angulation wire may be secured to or relative to the actuator, and the second end of the angulation wire may be secured to a distal end of the shaft.

There is provided for a pivotable arm to be located between the actuator and the angulation wire, with an end of the actuator and an end of the angulation wire secured to the pivotable arm in order for actuation of the actuator resulting in displacement of the pivoting arm, with the pivotable arm in turn displacing an end of the angulation wire.

There is provided for the pivotable arm to be connected to a rotary measurement sensor, such as a potentiometer, that allows the control system of the bending mechanism to determine the current position of the bending section.

There is also provided for a biasing means to be located in the bending section in order to support the bending section and urge it towards an unbent configuration.

The biasing means may be in the form of a helical spring.

Preferably the actuating arrangement includes at least two actuators in the form of two helical springs.

A further feature of the invention provides for the shaft to include a non-bending section which is at least partially flexible, and which can be configured between a flexible condition in which some flexibility is present in the non-bending section, and a stiff condition in which substantially no flexibility is present in the non-bending section.

There is provided for at least one shape memory alloy stiffening wire to extend from the base into and along the non-bending section, with an end of the stiffening wire being secured to an end of the non-bending section, in order for contraction of the stiffening wire to result in contraction of the non-bending section of the shaft, thus resulting in the non-bending section becoming rigid.

In one embodiment of the invention the actuator is located inside a hollow bore provided in the base, with a first end of the biasing means secured relative to the base, and a second end of the biasing means secured to an end of the angulation wire.

There is provided for the shape memory alloy to be a nickel titanium alloy, and more particularly nitinol.

A further feature of the invention provides for the endoscopic device to include an imaging system and an illumination arrangement.

The imaging system may include a camera located at a distal end of the shaft.

The illumination arrangement may include a light source, for example a LED, located at a distal end of the shaft.

There is provided for the shaft to include a hollow core suitable for receiving wiring for the imaging system and the illumination arrangement.

The angulation wires may be spaced apart about the core at equal intervals.

A still further feature of the invention provides for the endoscopic device to include a disposable sheath configured and dimensioned to fit around the shaft.

There is provided for the sheath to be made of a flexible material.

The sheath may be a tubular element having a hollow bore suitable for receiving the shaft.

The sheath may also include at least one, preferably at least two, enclosed channels extending longitudinally along the periphery of the sheath.

Another feature of the invention provides for the endoscopic device to include a control arrangement for controlling the actuation arrangement, the control arrangement including a control system and a control knob, wherein displacement of the control knob results in the control system causing electricity to be conducted through a selected actuation element.

The control knob may be in the form of a thumb stick provided on the base.

According to a further aspect of the invention there is provided a method of bending a bending section of an endoscopic device, the method including the steps of:

providing an endoscopic device as described above; and

causing electricity to be passed through an actuator of the endoscopic device.

According to a still further feature of the invention there is provided a disposable sheath, suitable for use with an endoscopic device, the disposable sheath including an elongate, flexible tubular body having a hollow bore suitable for receiving the shaft, and at least one enclosed channels extending longitudinally along the periphery of the sheath.

The sheath is furthermore characterised in that it does not include a camera and/or a light source.

BRIEF DESCRIPTION OF THE DRAWINGS

An embodiment of the invention is described by way of a non-limiting example, and with reference to the accompanying drawings in which:

FIG. **1** is a perspective view of the endoscopic device in accordance with a first embodiment of the invention;

FIG. **2** is a perspective view of a distal end of a shaft of the endoscopic device of FIG. **1**, excluding a disposable sheath that, in use, fits around the shaft;

FIG. **3** is an end view of the distal end of FIG. **2**, also including the disposable sheath;

FIG. **4** is a side view of the shaft or insertion section of the endoscopic device of FIG. **1**, excluding the disposable sheath that, in use, fits around the shaft;

FIG. **5** is an enlarged perspective view of part of the shaft of FIG. **2**, excluding a tubular member forming part of the shaft;

FIG. **6** is a schematic representation of a control circuit of the endoscopic device;

FIG. **7** is a cross-sectional side view of a front part of the base of the endoscopic device of FIG. **1**;

FIG. **8** is a side view of a tube forming part of the shaft of the endoscopic device;

FIG. **9** is a side view of the tube of FIG. **8** in which a bending section of the shaft has been bent;

FIG. **10** shows the base of the endoscopic device as depicted in FIG. **7**, when the shaft is in a bent configuration;

FIG. **11** is a perspective view of the endoscopic device in accordance with a second embodiment of the invention;

FIG. **12** is a side view of the shaft or insertion section of the endoscopic device of FIG. **1**;

FIG. **13** is a perspective view of a front end of the shaft or insertion section, excluding the disposable sheath that, in use, fits around the shaft, and also excluding some sections of the shaft in order more clearly to show the inside of the shaft;

FIG. **14** is a perspective view of an actuation arrangement located inside the base of the endoscopic device;

FIG. **15***a* is a plan view of the actuation arrangement of FIG. **14**, with the bending section of the shaft in a bent position;

FIG. **15***b* is a plan view of the actuation arrangement of FIG. **14**, with the bending section of the shaft in a straight position;

FIG. **16** is a perspective view of a disposable sheath for use with the device; and

FIG. **17** is an enlarged cross-sectional view of an end cap of the sheath of FIG. **16**.

DETAILED DESCRIPTION OF INVENTION

Before any embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," or "having" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. Unless specified or limited otherwise, the terms "mounted," "connected," "supported," and "coupled" and variations thereof are used broadly and encompass both direct and indirect mountings, connections, supports, and couplings and are thus intended to include direct connections between two members without any other members interposed therebetween and indirect connections between members in which one or more other members are interposed therebetween. Further, "connected" and "coupled" are not restricted to physical or mechanical connections or couplings. Additionally, the words "lower", "upper", "upward", "down" and "downward" designate directions in the drawings to which reference is made. The terminology includes the words specifically mentioned above, derivatives thereof, and words or similar import. It is noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the," and any singular use of any word, include plural referents unless expressly and unequivocally limited to one referent. As used herein, the term "include" and its grammatical variants are intended to be non-limiting, such that recitation of items in a list is not to the exclusion of other like items that can be substituted or added to the listed items.

Referring to the drawings, in which like numerals indicate like features, a non-limiting example of an endoscopic device in accordance with the invention is generally indicated by reference numeral **10**.

Reference is first made to the endoscopic device as shown in FIGS. **1** to **10**.

The endoscopic device **10** includes a base **20**, and an elongate shaft **30** extending from the base **20**. The endo-

scopic device **10** can furthermore be connected to a display screen (not shown), for example the screen of a smartphone or any other digital display. For the purposes of this description the display screen, and the method of communication between the endoscopic device **10** and the display screen, is not described in detail, as it does not form part of the gist of the invention.

The base **20** of the endoscopic device **10** can generally be divided into a body **22**, and a handle **21** extending from the body **22**. A control knob **23**, which in this example takes form of a thumb stick, is located on the body **22**, and is conveniently accessible by a thumb of a user when the user engages the handle **21** of the endoscopic device **10**. A central bore **24** (seen in FIGS. **7** and **10**) extends into the body **22** of the base **20**, and defines an auxiliary channel for receiving wiring that extends from the imaging system **50** and the illumination arrangement **60** as is discussed in more detail below. A plurality of actuation bores **25** are also provided in the body **22**, and are radially spaced apart from the central bore **24**. The actuation bores **25** are spaced around the body **22** at equal intervals, and are parallel to the central bore **24**. In this particular example, four actuation bores **25** are provided, and are located at 90° intervals relative to one another. In use, angulation elements **41** extend through the actuation bores **25**, as is discussed in more detail below.

The insertion section or shaft **30** of the endoscopic device **10** is of an elongate configuration, and can be functionally divided into a non-bending section **30.1**, and a bending section **30.2**. It should be noted that in this specification the term "non-bending" denotes a part of the shaft that cannot be remotely deformed in a controlled manner. However, this part of the shaft can still be flexible and can therefore, if it is indeed flexible, still be bent upon insertion of the endoscopic device **10** should that be a requirement. In other embodiments, the non-bending section **30.1** may also be completely rigid. The non-bending section may also be selectively adjusted between rigid or partially flexible states, as illustrated in the second embodiment of the invention described in more detail below. The shaft **30** has a proximal end **31** that is, in use, connected to the base **20**, and a distal end **32** which is in use the terminal end of the shaft furthest away from the base **20**.

In this embodiment the shaft **30** includes a central tube **55** that extends through central openings **36** provided in adjacently located, spaced apart spacers **35**. Each spacer **35** is substantially star or cross-shaped, and includes a plurality of spokes **38** extending radially outwardly from a proximal zone of the spacer **35**. In use, the outer ends of these spokes **38** support a hollow outer tube **33** extending along the length of the shaft **30**. The outer tube **33** may be made from an at least partially flexible material. Notches or grooves **34** are provided in the tube **33**, and more particularly in the bending section **30.2** of the tube, as is seen in FIGS. **8** and **9**. These grooves or notches **34** enable the outer tube **33**, and hence the shaft **30**, to be easily bendable in the bending section **30.2**. The grooves or notches **34** are furthermore staggered so as to enable the outer tube **33**, and hence the shaft **30**, to be displaceable in different directions. The grooves or notches **34** are typically in the form of circumferentially orientated slots that do not extend more than half of the circumference of the tube **33**. It will be appreciated that the configuration of the shaft may change, provided the construction is such that the shaft is at least partially bendable, in particular at the bending section. Instead of a tubular element with notches, the shaft may for example also include a plurality of tubular segments that are located end to end, and which are at least partially angularly displaceable relative to one another.

A plurality of auxiliary holes **37** are also provided in each spacer **35**. These auxiliary holes **37** are radially outwardly located from the central cavity **36** of the spacer **35**, and in this example are located at the base of each spoke **38** of each spacer **35**. The auxiliary holes **37** are configured and dimensioned for receiving angulation wires **41.1** extending along the length of the shaft **30**. In the illustrated embodiment four auxiliary holes **37** are provided, but the number of holes will depend on the number of angulation elements **41** used, as is discussed in more detail hereinbelow.

The endoscopic device **10** includes an actuation arrangement **40** which enables the bending section **30.2** to be selectively displaced in a desired direction, and to a desired extent. The actuation arrangement **40** includes a plurality of angulation elements **41**, which are in use actuated by passing an electric current therethrough. In this embodiment, each angulation element **41** comprises an angulation wire **41.1** as well as an actuator **41.2**, as can be best seen in FIG. **7**. Each actuator **41.2** in this example takes the form of a helical coil or spring, and is located in an auxiliary bore **25** of the base **20**, with a first end of each spring secured, and hence stationary, relative to the base **20**. An end of each angulation wire **41.1** is in turn secured to a freely displaceable opposite end of each actuator **41.2**, and extends from the auxiliary bore **25** in the body **22** into the shaft **30** of the endoscopic device **10**. The angulation wire **41.1** runs along the length of the shaft **30**, and more particularly extends through the auxiliary holes **37** provided in the spacers **35** of the shaft **30**. A distal end of each angulation wire **41.1** is secured relative to the distal end **32** of the shaft **30**. The configuration of each angulation element **41** is such that the bending section **30.2** of the shaft **30** will be displaced if the effective length of an angulation element **41** is reduced. More particularly, the bending section **30.2** will be displaced towards the angulation element **41** that is being contracted.

There is provided for either the angulation wires **41.1** or the actuators **41.2**, or both the angulation wires **41.1** and the actuators **41.2** to be made from a SMA. In a preferred embodiment only the actuators **41.2** are made from a SMA, and electricity is, in use, only passed through the actuators **41.2**, and not through the angulation wire **41.1**. In one embodiment the SMA is a nickel titanium alloy, and more particularly nitinol. This results in the angular angulation element **41** contracting when electric current is passed therethrough. When such an angulation element **41** contracts (denoted by A in FIG. **10**), an opposing angulation element **41** is caused to extend (denoted by B in FIG. **10**). The extended and contracted elements will maintain the position they are in once the circuit is interrupted. The bending section will again straighten when the extended angulation element is activated, causing it to contract and the opposite contracted element to extend.

A control system **80**, shown in FIG. **6**, controls the displacement of the endoscopic device **10**, and converts the relative position of the control knob or thumb stick **23** to an appropriate electrical current passed from a source of electricity through the relevant angulation element **41**. In this example, the control system consists of an Arduino Nano microcontroller and a thumb-stick potentiometer and transistor, which then controls the angulation element, and in this particular example the nitinol spring **41.2**. The design and construction of the control system may take many different forms, but the salient feature is that movement of

some control appendix (e.g. the control knob) is converted into an electrical current that is passed through a corresponding actuator.

The endoscopic device **10** also includes an imaging system **50** and an illumination arrangement **60** allowing the user the necessary visual feedback required to utilise the device. In this embodiment the imaging system **50** is in the form of a camera **51** mounted at a distal end **32** of the shaft **30**, and the illumination arrangement **60** includes at least one LED, which is also located at a distal end **32** of the shaft and which illuminates the area to be observed by the camera **51**. Importantly, the camera and the LED are mounted on the shaft **30** of the device, and not on a disposable sheath **70** surrounding the shaft.

The disposable sheath **70** is locatable on the shaft **30**, and in use covers the shaft, the imaging system **50** and the illumination arrangement **60**. This sheath **70** can be removed after the endoscopic device **10** has been used, and is disposable because no expensive components form an integral part of the sheath. As shown in FIG. **3**, the sheath is in the form of a tubular body **71** adapted snugly to fit over that shaft **30** of the endoscopic device **10**. A lens **72** is provided at the end of the sheath **70** and in use is located operatively in front of the camera **51**. A working channel **73**, for receiving instruments, and a distension immediate channel **74**, through which distension media can be injected, also form part of the sheath **70**. The disposable sheath covers the entire shaft, isolating it from the surrounding environment and ensuring sterility. The sheath is therefore made from a material that is suitable for sterilization and medical use. The purpose of this is to allow the flexible shaft and base to be reusable, whilst require minimal sterilization after use.

A further adaptation of the disposable sheath is shown in FIGS. **16** and **17**. In this embodiment the sheath **70** comprises separate components which, although requiring some pre-use assembly, will be simpler and cheaper to produce. The sheath **70** includes an independent flexible, tubular section **71**, with an end cap **70.1** provided at one end of the tube, and a further internal tube extending between the end cap **70.1** and the open end of the tubular section **71**. A valve **70.2** is provided at the open end of the internal tube. A tip of the shaft **30** is inserted into the tubular section **72** from the end where the valve **70.2** is located, and is pushed all the way to the end cap **70.1** where it is locked in place. A lens **72** is provided in the cap, and isolates the shaft **30** from the working environment while ensuring image clarity and light is transferred. The internal tube acts as a distention medical channel, and is in flow communication with a complementary distension outlet **73** provided in the end cap **70.1**. A distention source (not shown) is in use attached to the valve **70.2**, in order for distension media to be conveyed along the internal tube to the distension opening **73** at the distal end cap **70.1**. The primary reusable device therefore never comes into contact with either the distention media or working environment. The sheath shown in the drawings include two internal channels—one for the shaft of the device, and one for distension media, but it will be appreciated that one or more additional channels can be provided, with each such channel being in flow communication with an appropriate opening in the end cap **70.1**. It is important to note that the sheath used in this invention is a disposable sheath, and is not a permanent sheath as is associated with the prior art.

The use of the endoscopic device **10** is now described with specific reference to a hysteroscopy. A hysteroscopy procedure involving the endoscopic device **10** commences by attaching the sterilized sheath **70** over the bending shaft **30**. A dispenser of distention media is then inserted into the designated channel **74** on the sheath **70** and the outflow is tested. The device **10** is then switched on, and the connected tablet/smartphone (not shown) displays the camera's visual feed. The shaft **30**, and hence the camera **50**, is then inserted into the vaginal canal and guided through while distention media is used to open the canal. When the cervix is reached, an inspection of the entrance can be conducted before the distal end **32** of the shaft **30** is guided through the cervix into the uterus. Once inside the uterine cavity, the operator can control the bending of the shaft to visualise the entire cavity without having to maneuver the entire device.

The bending process is broken up into three steps, which are user input, spring actuation, and finally bending of the shaft. The user activates the bending of the shaft in the chosen direction by pushing the thumb-stick **23**. The potentiometer of the thumb-stick then sends an analogue variable to the microcontroller, which variable increases to a maximum value corresponding to how much the thumb-stick is displaced. The analogue variable is then converted into to digital value, which determines the power supplied through use of the Pulse Width Modulator (PWM) on the microcontroller. The transistor is activated by the PWM, which in turn activates the actuator **41.2** in the circuit. The actuator then contracts until the thumb-stick is released. During this contraction the corresponding wire is pulled, causing the notched part of the bending section **30.2** to bend in the specified direction. When an actuator contracts, the actuator on the opposing side extends, which in turn enables the shaft to return to its original state by contracting the opposing actuator, as shown in FIG. **10**.

The resulting bending motion varies based on how much the actuator contracts. FIG. **9** shows the shaft bending up to 180°, with any displacement between 0° and 180° being feasible. Images of any significant areas identified can be recorded and if necessary, an operative instrument can be inserted, through the working channel **73**, to perform a procedure. Once the diagnosis or operation is completed, the operator can slowly withdraw the device, while its flexibility ensures easy extraction. After removal, the sheath is detached and disposed while the system is cleaned with sterilizing wipes. The system is then stored while the images captured are downloaded from the tablet/smartphone for future reference.

A second embodiment of the invention is now described with reference to FIGS. **11** to **15**. The basic principle and operating methodology remains the same, and the discussion that follows below will focus on some of the salient differences only.

As is seen in FIGS. **11** and **12**, the shaft or insertion section **30** still comprises a bending section **30.2** and a non-bending section **30.1**. The bending section **30.2** is controlled by the actuating arrangement **40** located in the base **20** of the device and acts similarly to the previous design. The non-bending section **30.1** of the shaft is somewhat flexible (as may also be the case with the first embodiment), however in this case the non-bending section **30.2** can be activated or adjusted to become substantially rigid. When activated, it maintains whichever position it is in at the moment of activation. Accordingly, if the non-bending section is slightly angularly displaced, it will stay in that position and become substantially rigid when activated. This allows the shaft to easily navigate channels when flexible, and by stiffening it prevents buckling when bending of the tip is initiated. The activation capability will be discussed in more detail with reference to FIG. **13** below.

FIG. **13** shows a more detailed view of the redesigned shaft or insertion section **30**. The shaft **30** still includes a central tube or passage **55** allowing for instrumentation. However, a compression spring **80** is now also located in this channel, and is referred to as a guide spring. The guide spring is located in the bending section **30.2** of the shaft and ensures that even bending occurs, while at the same time preventing any kinking of wire inside the channel. The spring **80** also aids in returning the bending section **30.2** to its straight position after bending. In this embodiment, ends of the angulation wires **41.1** are still connected to the distal end of the bending section, with opposite ends being connected to the bending actuating arrangement **40** in the base **20** at the other end. The angulation wires may be made from a SMA for the sake of convenience, but does not need to have the SMA functionality. In this embodiment, no current will be passed through the angulation wires **41.1**, and they merely act as transmitters of displacement emanating from the actuators **41.2**. There is therefore also specifically provided for the angulation wires not to be made from SMA. The structure of the shaft **30** includes a number of tubular segments **83** with convex ends, thus resulting in tapering gaps **84** being formed between adjacent segments. The gaps between the segments allow for some angular movement between these segments.

Two additional wires (in this case SMA wires referred to as stiffening wires **81**), are provided in the non-bending section **30.1** of the shaft. As mentioned above, in context of this specification "non-bending" does not mean that this section cannot bend at all, but merely indicates that this section is not the part that is bend in a controlled and directed manner. This section will preferably still be somewhat flexible to assist in manoeuvring the insertion section, but it would also be beneficial if this section could be completely rigid when needed. The stiffening wires **82** provides this functionally. Two stiffening wires **82** are located in the non-bending section of the shaft **30**, and terminal ends are connected to a last segment **83** of the non-bending section **30.1**. Opposite ends **81.1** of the stiffening wires are secured to the base **20**, and are connected to an electrical source. Notably, the stiffening wires are not connected to the actuation arrangement **40**. When relaxed, the wires **81** allow the non-bending section of the shaft to bend as a result of the slack provided between the segments **83**. However, once activated, the wires **81** contract, pulling the segments **83** together which results in the non-bending section **30.1** stiffening. These SMA wires do no cause any bending to occur, and instead only provide a contraction force to pull segments together. The operation of the device therefore remains unchanged from the previous design, with only the activation of the SMA wires being added.

The actuation arrangement or bending mechanism **40** housed within the base **20** of the device **10** is shown in FIGS. **14** and **15**. The figures show two SMA actuators in the form of springs or coils **41.2** which allow for two bending directions in the bending section **30.2**. Additional mechanisms can, however, be added to provide more bending directions by using the extra space available in the base **20**. The actuation arrangement operates conceptually similarly to the previous design, with the addition of the pivot arm **85** shown in the figures. The actuators **41.2** are fixed at one end and the other end is fixed to connecting points **85.1** on the pivot arm **85**. The angulation wires **41.1** protruding from the shaft are also connected to connecting points **85.2** on the pivot arm **85**. In different embodiments, the connecting points for both the springs and the wires can be located at different positions along the arm **85** so as to increase or decrease the contraction length or bending amount produced. The pivot arm can serve to increase or decrease the effective actuation stroke of the actuators. The introduction of the pivot arm **85** therefore provides increased design and operational flexibility. Although not specifically shown in the drawings, the pivot arm **85** is also connected to a rotary measurement sensor, such as a potentiometer, that allows the control system of the bending mechanism to determine the current position of the bending section. This in turns allows the control system accurately to maintain a bending position. The introduction of the pivot arm **85** is therefore also beneficial from a control perspective.

The bending operation of the mechanism is shown in FIGS. **15***a* and **15***b*. The operation performs in the same way as the previous design with the addition of the pivot arm **85**. When an actuator **41.2** is activated, its contraction causes the pivot arm **85** to rotate in the direction of the contraction. Subsequently, the wire connection **85.2** on the corresponding side of the pivot arm **85** is pulled towards the actuated actuator, resulting in the bending of the bending section **30.2**. The actuator **85** on the opposite side of the pivot arm **85** is extended when the arm **85** rotates, which also provides slack to the connection or angulation wire **41.1** on the non-contracting side. This ensures that an accurate and even bending motion is produced. To return to its previous position, or continue bending in the opposite direction, the extended actuator is actuated. The actuation arrangement **40** of the second embodiment is bulkier than that shown in the first embodiment, but important benefits are associated with the second arrangement that justifies the increase in size. It is, however, even more imperative in this case for the actuation arrangement **40**, and in particular the actuators in the form of the SMA coils or springs **41.2**, to be located in the base **20** of the device **10**.

The invention seeks to address a number of market gaps by developing a reusable and mobile endoscopic system through several novel implementations. Although the invention is particularly useful for performing hysteroscopies, the application is by no means limited to hysteroscopies. In the case of a hysteroscopy, the invention is useable without the need for general anaesthesia by having an entirely flexible shaft with small outer diameters. This ensures minimal discomfort is experienced by the patient. It achieves this by implementing a novel bending mechanism that does not involve any motors, thereby reducing the size and cost while still allowing for bending to occur.

The invention is also reusable through the application of a disposable sterilized sheath, which provides the sterile environment for procedures while preventing the main reusable components from having to undergo damaging sterilization.

The mobility of the system is achieved by having a built-in camera and light source, while the visual interface is supplied by connecting the device to a smartphone or tablet.

Of particular importance is the smart bending mechanism used to control the bending of the flexible shaft. It implements a unique nickel-titanium alloy, also known as nitinol, spring that contracts like a muscle when an electrical current is supplied to it. Using these springs, the invention can produce the required bending motions to fully observe a cavity or organ. This spring system eliminates the need for motors and not only reduces the size of the device, but is considerably less costly than devices known in the art. The user controls and activates multiple springs separately, each for a specific direction. This allows the user to accurately bend the shaft up to 180° in four directions. Existing flexible

endoscopes, and in particular hysteroscopes, are only capable of bending up to 110° in a single direction.

Another important aspect of the invention is that the actuation arrangement of the device in accordance with the invention is located in the base of the device, as opposed to the shaft or insertion section as has been proposed in the prior art. This is not a simple design choice, but was arrived at in order to achieve a number of important benefits. Some of these are listed below:

Moving the actuation arrangement, and in particular the actuators or SMA coils, into the base allows for reducing the diameter of the shaft or insertion rod.

The additional space available in the base allows for increased number and different lengths of actuators to be used. This allows the bending mechanism to produce a greater degree and complexity of bending motions.

By placing the actuators in the base, the hollow diameter of the rod has additional space for channels and instrumentation.

The activation of the actuators results in heat exposure to its surroundings. By placing the actuators in the base, it avoids exposing the working environment to heat generated when activating the actuators. The actuators can also be insulated more easily in the base.

The design greatly simplifies fabrication and miniaturisation by reducing complexity of the shaft. Furthermore, shafts with functional differences (such as longer lengths, increased number of channels, etc.) can be swapped by disconnecting it from the base and reconnecting a different one.

Placing the actuators in the base allows for increased contraction length and pulling force to be produced.

The actuators, and in particular the two coils, act as opposing pairs. When one coil contracts, it pulls on and extends the coil on the opposite side. This ensures that slack is provided for the side of the bending tip not undergoing contraction and avoids causing buckling in the rod.

In summary, the inventors believe that the new device will present at least the following benefits over the prior art:

1. Reusable

The main components of the system are reusable, with only a cheap sterile sheath being the disposable component. This is to prevent the entire system from having to undergo intense sterilization after use, which is potentially damaging and reduces its number of uses. By being reusable the invention also reduces the costs of procedures. The sheath also provides working channels for distention media and operative instruments, which allows for the same system to be used for both diagnostic and operative procedures.

2. Mobile

The system implements a built-in CMOS camera and LED light source, eliminating the need for bulky additional equipment. The visual display component is provided by connecting the device to a smartphone, tablet, or laptop which are readily available and cheaper than the typical monitors used by existing technologies. The overall system is therefore highly portable.

3. Flexible

The flexibility of the invention is crucial as it allows for successful procedures without general anaesthesia and outside of the operating theatre. The invention not only offers a completely flexible shaft portion but through a novel smart bending mechanism, allows the operator the control the bending motion to observe the entire uterine cavity. The system is therefore capable of bending up to 180° in 4 directions.

4. Accessibility

Patient access to endoscopic procedures such as a hysteroscopy is greatly increased with the invention by not only reducing the costs involved but by allowing for procedures to take place outside of the operating room. Thereby allowing access to rural areas where hospitals are less equipped or for gynaecologists to perform in office procedures.

It will be appreciated that the above is only one embodiment of the invention and that there may be many variations without departing from the spirit and/or the scope of the invention. It is easily understood from the present application that the particular features of the present invention, as generally described and illustrated in the figures, can be arranged and designed according to a wide variety of different configurations. In this way, the description of the present invention and the related figures are not provided to limit the scope of the invention but simply represent selected embodiments.

The skilled person will understand that the technical characteristics of a given embodiment can in fact be combined with characteristics of another embodiment, unless otherwise expressed or it is evident that these characteristics are incompatible. Also, the technical characteristics described in a given embodiment can be isolated from the other characteristics of this embodiment unless otherwise expressed.

The invention claimed is:

1. An endoscopic device comprising:

a base including a body and a handle;

a shaft having a proximal end connected to the base; wherein the shaft is at least partially flexible and includes a bending section that is selectively displaceable between a straight configuration and a bent configuration; and

an actuation arrangement for selectively displacing the bending section between the straight and bent configurations;

wherein the actuation arrangement includes at least two actuators which are at least partially made from a shape memory alloy, and which are configured to displace the bending section of the shaft when electric current is passed therethrough;

wherein the two actuators are configured to act as an opposing pair in order for one actuator to extend when the other actuator contracts, and

wherein each actuator is located inside the base of the device, with at least one angulation wire extending from each actuator through the shaft towards the bending section in order for displacement of the actuator located inside the base to be transmitted to the bending section of the shaft.

2. The endoscopic device of claim **1**, wherein the actuators are in the form of helical coils or springs made from a shape memory alloy.

3. The endoscopic device of claim **1**, wherein a first end of the angulation wire is secured to or relative to the each of the actuators, and a second end of the angulation wire is secured to a distal end of the shaft.

4. The endoscopic device of claim **1**, wherein a pivotable arm is located between the actuators and the angulation wires, and wherein an end of each actuator and an end of each angulation wire are secured to the pivotable arm in order for actuation of one of the actuators to result in

displacement of the pivoting arm, with the pivotable arm in turn displacing the end of the angulation wire.

5. The endoscopic device of claim **4**, wherein the pivotable arm is connected to a rotary measurement sensor that allows a control system of the bending mechanism to determine the current position of the bending section.

6. The endoscopic device of claim **5**, wherein the rotary measurement sensor is a potentiometer.

7. The endoscopic device of claim **1**, wherein a biasing means is located in the bending section in order to support the bending section and urge it towards an unbent configuration.

8. The endoscopic device of claim **7**, wherein the biasing means is in the form of a helical spring.

9. The endoscopic device of claim **1**, wherein the shaft includes a non-bending section which is at least partially flexible, and which can be configured between a flexible condition in which some flexibility is present in the non-bending section, and a stiff condition in which substantially no flexibility is present in the non-bending section.

10. The endoscopic device of claim **9**, wherein at least one shape memory alloy stiffening wire extends from the base into and along the non-bending section, with an end of the stiffening wire being secured to an end of the non-bending section, in order for contraction of the stiffening wire to result in contraction of the non-bending section of the shaft, thus resulting in the non-bending section becoming rigid.

11. The endoscopic device of claim **1**, further including a disposable sheath configured and dimensioned to fit around the shaft.

* * * * *

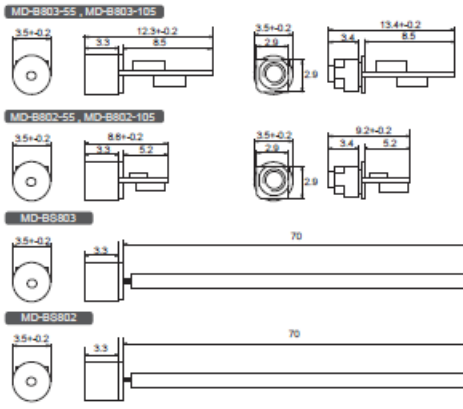
Appendix G. Camera Module Datasheets

Prototype 2 Camera Module Datasheet – MD-B803L-105-01

MISUMI Electronics Corp.
Manufacturer & Exporter

CCIQ II COLOR CAMERA

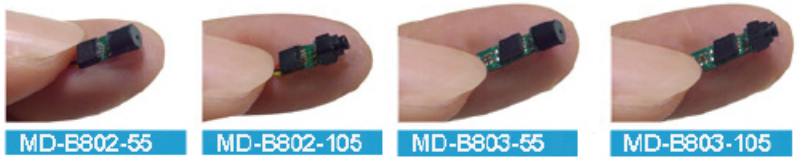
Board Type

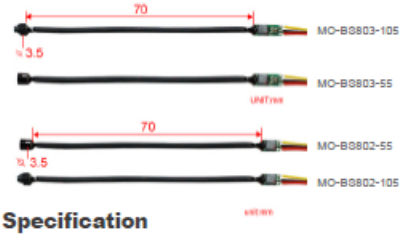


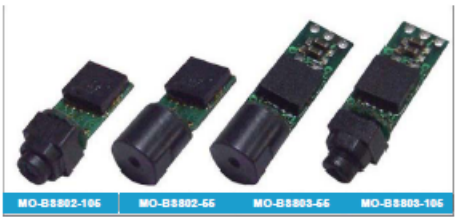
Feature

- 1/18" Color CMOS Camera
- Compact size.
- LENS Diameter :Ø 3.5 only
- High Performance.
- Competitive Price!
- LED Light x 2

UNIT: ± 0.2 mm







Specification

Model	MD-B802-55	MD-B802-105	MD-B803-55	MD-B803-105	MD-BS802-55	MD BS802-105	MD-BS803-55	MD-BS803-105
Number of effective pixels	320X240							
Image sensor	1/18" Color CMOS UVC Camera							
Resolution(TV Lines)	240 TV Lines							
S/N Ratio	more than 48dB							
Minimum illumination	2 Lux/ F1.2							
Electronic shutter	1/50-1/157000							
Horizontal sync frequency	NTSC(EIA) -15.734kHz							
Vertical sync frequency	NTSC(EIA) - 60Hz							
Camera consumption	0.45							
Video output	1Vp-p , 75ohm composite							
Storage temperature	-30 to 60 Degree C							
Working temperature	-10 to 45 Degree C							
Built-in Lens	0.96mm / F2.8	0.77mm / F3.0	0.96mm / F2.8	0.77mm / F3.0	0.96mm / F2.8	0.77mm / F3.0	0.96mm / F2.8	0.77mm / F3.0
Power source	DC 3.3 V							
Power current	35 mA							
Dimension (mm)	Ø3.5 x 8.6	Ø3.5 x 9.2	Ø3.5 x 12.3	Ø3.5 x 13.4	(a) 3.5 x 3.3 mm , (b) 5.2 x 3.3 mm	(a) 3.5 x 3.4 mm , (b) 5.2 x 3.3 mm	(a) 3.5 x 3.4 mm , (b) 6.5 x 3.3 mm	(a) 3.5 x 3.4 mm , (b) 8.5 x 3.3 mm

MISUMI Manufacturer & Exporter
TEL:886-2-22266303 E-mail:mscctv@ms9.hinet.net
FAX:886-2-22225620 Web site: http://www.misumi.com.tw

Prototype 3 & 4 Camera Module Datasheet – MD-V1001L-120

MISUMI

1/18" COLOR CMOS CAMERA

B1001 SERIES

Unit: ± 0.5 mm

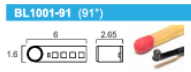
Feature

- Mini Size,
- High Sensitivity,
- High Performance!

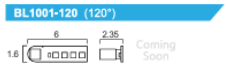
B1001 No Lens

B1001-120 (120°)

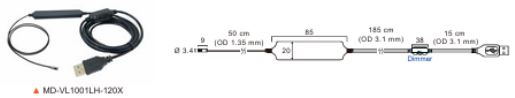
BL1001-91 (91°)



BL1001-120 (120°)



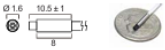
1001



▲ MD-VL1001LH-120X

B1001-91 (91°)

T1001-120 (120°)



V1001LH-120 (120°)

VL1001LH-120 (120°)

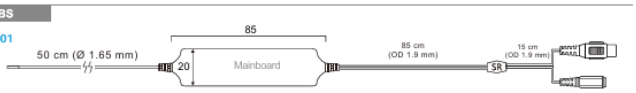
Specification

Model No.	B1001	BL1001
Dimensions (mm)	Ø 1.48	1.6 x 6
Orientation	Front View	Side View
Camera Type	Board Type	
Video Format	MJPEG / YUV (UVC); NTSC / PAL (CVBS)	
Image Sensor	1/18" Color CMOS Camera Module	
Resolution	400 x 400 @ 30 fps	
Pixel Size (um)	1.75 x 1.75	
Image Area (mm)	0.74 x 0.71	
Sensitivity (Lux.Sec)	1000 mV	
Dynamic Range	65.8 dB @ 4x gain	
S/N Ratio	36.8 dB	
Scan Mode	Progressive	
Shutter	Rolling	
Lens	Please Check Model Information Table	
View Angle	Please Check Model Information Table	
Focus Distance (mm)	Infinity	
LED	N/A (Optional)	
Storage Temp.	-30 to 60 Degree C	
Working Temp.	-10 to 60 Degree C	
Interface	USB 2.0; CVBS	
Power Supply	5V (UVC); 5~12 V (CVBS)	
Power Current	170 mA (Max.)	
Microphone	N/A	
Operation System (UVC)	Win XP, Win Vista, Win 7, Win 8, Win 10 Linux, MAC OSX	

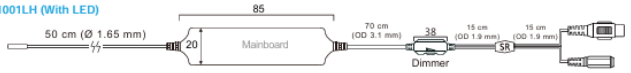
* Working temperature means the camera device, not environment temperature.

CVBS

MO-T1001

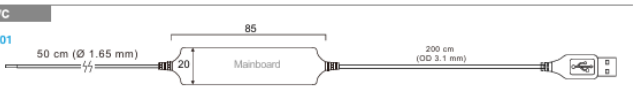


MO-V1001LH (With LED)

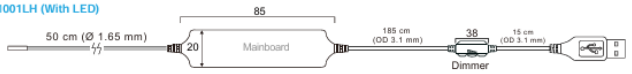


UVC

MD-T1001



MD-V1001LH (With LED)



MISUMI

1/18" COLOR CMOS CAMERA

B1001 SERIES

Unit: ± 0.5 mm

MD-V1001LH-120D

SERIES	CONNECTOR	CAMERA BODY	DISPLAY	MICROPHONE	LED	LENS
(F)M Basic	CVBS O RCA / DC J Phone Jack Q M8 Waterproof	Front View (V)B Board Type T Tube Type V Tube Type	Color / B/W / Dimensions 1001 / 100M1 / Ø 1.48	N/A None	N/A None White L Normal LH High-Intensity 91° Lens Only Infrared L9 IR 940 nm L8 IR 850 nm	Code / Specification / View Angle 120 / 0.418 mm / F 5.0 / 120° 91 / 0.5 mm / F 3.6 / 91° 90 / 0.505 mm / F 4.0 / 90°
*F Snapshot and Freeze Frame (for UVC only)	UVC (USB) D Type A M Micro-B (OTG) T Type C	Side View (V)BL Board Type (V)SL Forming Type TL Tube Type VL Tube Type *V Dimmer Controller				

CABLE

Code	O.D	UVC (Max)	CVBS (Max)	Note
D	Ø 0.65	180 cm	180 cm	Available To Add LED
I	Ø 1.0	300 cm	300 cm	LED Unavailable
C	Ø 1.2	180 cm	140 cm	LED Unavailable
S	Ø 1.3	200 cm	200 cm	Available To Add LED
X	Ø 1.35	210 cm	130 cm	Available To Add LED
E	Ø 1.6	600 cm	600 cm	Available To Add LED
B	Ø 1.65	150 cm	130 cm	Available To Add LED
N/A	Ø 1.85	190 cm	160 cm	Available To Add LED

* Cable OD unit mm

* IR 940nm or IR 850nm LED is suggested to choose B/W camera type.
* Camera with LED light source is suggested to use lens with larger F-Stop number.
* Camera appearance or other requirements are applicable for customization.

Connector Information

MISUMI Electronics Corp. TEL: 886-2-2226-6303 | FAX: 886-2-2222-5620 | mscctv@misumi.com.tw | www.misumi.com.tw