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Mauricio Nahum Leroy The University of Western Ontario

Supervisor Dr. Michael Naish *The University of Western Ontario* Joint Supervisor Dr. Rajni Patel *The University of Western Ontario*

Graduate Program in Mechanical and Materials Engineering A thesis submitted in partial fulfillment of the requirements for the degree in Master of Engineering Science © Mauricio Nahum Leroy 2013

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DESIGN OF A MINIMALLY INVASIVE SINGLE PORT HDR BRACHYTHERAPY APPLICATOR FOR THE TREATMENT OF LUNG CANCER

(Thesis format: Monograph)

by

Mauricio Nahum Leroy

Faculty of Engineering

Department of Mechanical and Materials Engineering

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Engineering Science

The School of Graduate and Postdoctoral Studies Western University London, Ontario, Canada

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Design of a Minimally Invasive Single Port HDR Brachytherapy Applicator for the Treatment of Lung Cancer

Mauricio Nahum Leroy M.E.Sc. Thesis, 2013 Department of Mechanical and Materials Engineering University of Western Ontario

Abstract

Cancer has become the number one cause of death in Canada and lung cancer is its deadliest form. Surgical resection remains as the treatment of choice for most patients; however, in many cases a less aggressive alternative such as brachytherapy may be preferable. Today, HDR brachytherapy is a relatively common procedure but with current techniques and equipment only tumours close to the main bronchi can be reached.

This project describes the design, development and validation of a first prototype of an ultrasound-guided needle guidance system that would enable physicians to perform HDR brachytherapy for the treatment of lung cancer in a minimally invasive manner through the intercostal spaces. The development of the mechanical components is thoroughly described followed by the description of the electronic control system that was developed for this novel mechatronic medical tool. Finally through validation experiments, the approach was shown to be an accurate and viable approach for precisely reaching desired targets with a wide yet flexible needle.

Keywords

Lung Cancer, HDR Brachytherapy, Ultrasound Guidance, Needle Guidance, Minimally Invasive Surgery, Medical Robotics, Ablation Therapy

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Acronyms

- 2D-Two-Dimensional
- 3D Three-Dimensional
- A/D Analog Digital
- ABS Acrylonitrile Butadiene Styrene
- ADC Analog–Digital Converter
- ASCII American Standard Code for Information Interchange
- CAD Computer Aided Design
- CAM Computer Aided Manufacture
- CSTAR Canadian Surgical Technologies and Advanced Robotics
- DOF Degree of Freedom
- EBR External Beam Radiation
- EBUS-TBNA Ultrasound-Guided Trans Bronchial Needle Aspiration
- EDM Electrical Discharge Machine
- EUS- FNA Endoscopic Ultrasound-Guided Fine-Needle Aspiration
- FDA Food and Drug Administration (USA)
- FEA Finite Element Analysis
- FOS Factor of Safety
- HDR High Dose Rate (Brachytherapy)

- ID Inner Diameter
- ISO International Organization for Standardization
- LDR Low Dose Rate (Brachytherapy)
- MIS Minimally Invasive Surgery
- MW Microwave
- Nitinol Nickel Titanium Alloy
- NOTES Natural Orifice Translumenal Endoscopic Surgery
- NSCLC Non-small Cell Lung Cancer
- OD Outer Diameter
- PC Personal Computer
- PD Proportional Derivative (Control)
- PEEK Polyether Ether Ketone
- PID Proportional Integral Derivative (Control)
- RAMI Robot Assisted Minimally Invasive (Procedure)
- RF Radio Frequency
- SCLC Small Cell Lung Cancer
- UBNGD Ultrasound-Based Needle Guidance Device
- UMS University Machine Services
- US-Ultrasound

USB – Universal Serial Bus

 $VATS-Video\ Assisted\ Thoracoscopic\ Surgery$

Chapter 1

1. Introduction

1.1 Motivation

In 2012, there were an estimated 186,400 new diagnosed cases of cancer in Canada and approximately 75,700 cancer deaths, making it the main cause of death in the country [1]. Out of the different types of cancer, lung cancer represents an estimated 14.2% of all the new cancer diagnoses and 26.5% of the cancer related fatalities in Canada, making it the cancer with the 2nd highest incidence rate and 1st highest mortality rate [2]. Lung cancer is an extremely aggressive form of cancer with a 5-year survival rate of only 13% for men and 18% for women [3]. In all, it is expected that one in 13 men and one in 17 women will die of lung cancer [4].

Surgery, accompanied by chemotherapy and/or radiation therapy is the most common form of treatment for lung cancer; however, many patients cannot undergo such aggressive treatments [5] and those who do often experience a reduction in their perceived quality of life and high mortality rates [6]. Therefore, in order to offer treatment options for those who are not suitable for surgery and to offer a better post-operative quality of life for those who are, minimally invasive procedures such as brachytherapy and ablation therapies have been developed and implemented with promising results over the last couple of decades [5, 7–8]. However, the availability of commercial equipment specifically designed for interstitial lung brachytherapy is nonexistent, restricting lung brachytherapy treatments to patients whose tumours can be reached via intraluminal access.

The limited availability of purpose-made devices and the promising results of brachytherapy are the main motivators for the development of a minimally invasive, single port applicator for delivering HDR brachytherapy and potentially other minimally invasive procedures, such as ablation therapy for lung cancer.

1.2 Current Lung Cancer Treatments

The most common treatments for lung cancer today are surgical resection, chemotherapy, radiation therapy (external beam), brachytherapy, ablation therapy, targeted therapies and photodynamic therapy [9, 10]. Since most cancer therapies often combine two or more treatments, it is important to have a certain level of understanding about all current treatments and how can they potentially interact with lung brachytherapy.

1.2.1 Surgical Resection

Surgery is considered a curative option for patients in the early stages of lung cancer, especially for non-small-cell lung cancer (NSCLC). It is often performed in otherwise fairly healthy patients on Stages 1, 2 and 3a of NSCLC to remove their main tumours [11]. Surgery is rarely an option for small-cell lung cancer (SCLC) as it spreads too quickly and aggressively.

Depending on the condition of the patient and size of the tumours, there are three main options for the surgical treatment of lung cancer [11]:

Wedge Resection — Removal of the tumour and surrounding tissue. This option is only viable for patients who were diagnosed early and the tumours located towards the periphery of the lung.

Lobectomy — The most common option, which involves the removal of one of the two or three lobes of the lung.

Pneumonectomy — Removal of the entire lung.

However, surgery remains a very dangerous option with high mortality and morbidity rates that often reduce the quality of life of the patient due to reduced lung capacity and pain [6].

1.2.2 Chemotherapy

Chemotherapy is the treatment of cancer through chemicals that attack cancer cells, but that also have a negative impact throughout the patient's body. Chemotherapy is used as a complementary

treatment to surgery in patients with early stages of lung cancer to increase the possibility of long term survival. It is also used as a main treatment course for patients with SCLC or NSCLC in advanced stages, where surgery is no longer viable. In patients with advanced stages of lung cancer who are not expected to recover, chemotherapy is still recommended for lung cancer as it can extend their life expectancy and improve their quality of life [12].

1.2.3 Ablation Therapy

Thermal ablation therapy refers to a type of therapy that uses either extreme cold or high temperatures to destroy malignant or undesired tissue such as cancerous tumours. Depending on the condition being treated and the zone of the body, different types of energy such as microwave, laser, ultrasound or radiofrequency may be used to produce the heat needed to kill malignant tissue [13]. Ablation therapy usually involves a physician inserting a needle or catheter into the centre of the tissue that needs to be destroyed and then conducting heat into it, killing the undesirable tissue with minimal damage to surrounding areas. Ablation therapy is currently most commonly used to treat heart arrhythmias but it is also widely used to treat other conditions such as osteoid osteomas, hepatocellular carcinoma, hepatic, renal and retroperitoneal tumours, cerebral metastases [13] and more recently pulmonary metastases [14].

Ablation therapy can be performed in a minimally invasive or open laparoscopic surgery scenario. Ablation itself takes only a few minutes and usually has no major side effects, which makes it a good option to treat cancer on patients not strong enough to undergo more aggressive treatments, with some studies showing high survival rates for patients treated for liver cancer with ablation therapy [15, 16].

1.2.4 Radiation Therapy

In physics, radiation is the process in which energetic particles/waves travel through a medium or space. Strictly speaking, radiation is any form of wave in the electromagnetic spectrum, from the longer wavelengths used for radio and TV signals (which are essentially harmless) to the shorter wavelengths of X-rays and Gamma-rays. However, the term radiation usually refers only

to the high frequency waves (frequency above ultraviolet) known as ionizing radiation. Ionizing radiation, which has a very high energy density, is capable of ionizing atoms and causing damage to the DNA molecules [17].

Radiation was discovered in the late 1800s with the term "radioactivity" coined by Marie and Pierre Curie, with Pierre Curie being the first person to suggest that radiation could be used to attack cancerous tumours [17].

Radiation therapy is the use of high energy beams such as gamma rays and X-rays or radioactive material to kill cancer cells. Radiation kills cancer cells by either directly damaging its DNA or by creating free radicals that damage the DNA molecule. Once the DNA of a cell has been damaged beyond repair, it will stop dividing and eventually die. The dead cancerous cell can then be absorbed and discarded naturally by the body. Unfortunately, radiation affects every kind of cell (it cannot target only cancer cells), which limits the amount of radiation that a patient can receive safely [18].

Radiation therapy is generally used in combination with surgery and/or chemotherapy to treat lung cancer or by itself to treat lung cancer in patients who cannot undergo surgery due to health concerns. Radiation therapy can be used prior to surgery to shrink a tumour before extraction, after surgery to kill any remaining cancerous cells, to attack tumours that have metastasized to other parts of the body or as a palliative treatment for patients in advanced stages of cancer [19]. The improvement of medical imaging over the past couple of decades, together with robotic technologies are making radiation therapy a more precise and effective method of treatment [20].

Brachytherapy is a form of radiation therapy in which the tumour is implanted with radioactive seeds. This way the damage to surrounding tissue is minimized when compared to traditional radiation therapy. Brachytherapy is a common treatment for some types of cancer such as prostate, breast, skin, cervical, colon, bladder, and for certain lung cancers – those near or at the main bronchi [21].

1.3 Brachytherapy

With brachytherapy, higher doses of radiation can be delivered to the tumour in shorter amounts of time, limiting the exposure of healthy surrounding tissue since the radiation source is located inside of the tumour. The effects of radioactivity in a person are directly related to the exposure time and the intensity of radiation, which in turn is a function of the power of the source with an inverse quadratic relation to the distance of the source described by the inverse square law [22]:

$$I = \frac{P}{A} = \frac{P}{4\pi r^2} \tag{1.1}$$

where, I is the intensity of radiation, P is the power of the radiation source, and r is the radius (distance) to the source.

Brachytherapy allows doctors to treat cancer by delivering high doses of radiation in a concentrated way to small areas for a short period of time. With this method, the highly concentrated doses of radiation can attack tumours with little or no secondary effects on healthy surrounding tissue. Radiation is delivered through small sealed containers called implants. Depending on the location of the tumour, brachytherapy can be delivered in several ways [21]:

Interstitial — The implant is "injected" inside the tumour.

Intracavitary — The implant is located in special applicators inside a body cavity.

Intraluminal — The implant is located in special applicators inside a body passage.

Surface or mold — The implant is placed on the surface of a tumour

The implants can also be permanent or temporary. Permanent implants, which are commonly used in Low Dose Rate (LDR) Brachytherapy, also known as seeds, are small radioactive pellets, usually 5 mm long, that are deposited in the desired area. The seeds typically remain in place indefinitely and eventually lose their radioactive properties. Temporary implants, used in High Dose Rate (HDR) Brachytherapy, are similar to LDR seeds but are significantly more radioactive. HDR radioactive sources are typically guided into the tumour through hollow

needles or catheters carefully placed in the desired area and left in position for a few seconds or minutes at a time. HDR brachytherapy can be performed in a single session using higher doses or in a series of sessions over a period of weeks, using lower doses per session [21].

1.3.1 LDR Brachytherapy

Low Dose Rate Brachytherapy is usually performed by implanting radioactive seeds inside a tumour. These seeds will be radioactive for a period of several days and will eventually decay naturally [23]. Although the current tendency is towards HDR brachytherapy, LDR brachytherapy remains the most used and researched form of brachytherapy [24] and it is especially common for treating prostate cancer; however, there are certain inconveniences and risks associated with LDR brachytherapy for treating lung cancer such as:

- The patient will be radioactive for several days and will therefore be instructed to limit close contact with people and avoid contact with children and pregnant women [21].
- As the tumours shrink, the seeds may dislodge and migrate to other parts of the patient's body, making seed embolization in the lung a significant risk of LDR brachytherapy [25].

1.3.2 HDR Brachytherapy

High Dose Rate brachytherapy involves, depending on the body part or organ, placing a small plastic catheter or catheters, hollow needle(s) or surface/contact applicators into the tissue where the tumour is, such as the lung, prostate, or skin. Computer-controlled radiation sources (usually Iridium 192) are inserted through the conduits, bombarding the tumour with high doses of radiation. The catheters or applicators are then easily pulled out, and no radioactive material is left in place. A computer-controlled machine, called an afterloader, pushes radioactive seed(s) into the conduits for a preselected amount of time. Because the computer can control how long the seed(s) remain in each of the conduits, doctors are able to control the radiation dose in different regions of the treated organ. The tumour receives a higher dose, while the surrounding tissue receives lower doses. HDR brachytherapy is performed as an outpatient procedure and

each session usually lasts under 30 minutes. Patients typically go through between 1 and 8 sessions within a couple of weeks for a complete treatment [24, 26].

1.4 Current HDR Brachytherapy Technology

Since this work explores the design of a HDR brachytherapy applicator for lung cancer, it is important to understand the technology currently available.

1.4.1 Components in modern HDR Brachytherapy Systems

There are several companies producing HDR brachytherapy equipment and variation exists among them; however, in general, the components that make up modern HDR brachytherapy systems can be classified into three main groups: the afterloader, the applicator, and the imaging and computer control systems.

Afterloader — The radioactive source will be located inside the afterloader. The afterloader will automatically deploy the radioactive material guided by a catheter and guide wire as prescribed by the doctor and software planning.



Figure 1.1 Eckert & Ziegler BEBIG MultiSource Afterloader (used with permission from Eckert & Ziegler BEBIG) [27].

Applicator — Is the part of the system that comes into contact with the patient. The applicators will vary in shape and size according to the region of the body that their use is intended for. There are usually endoscopic guides, needles, or natural orifice applicators that allow the physician place the catheter through which the radioactive source will travel.



Figure 1.2 Applicators for prostate, vaginal/rectum and bronchial HDR Brachytherapy from Eckert & Ziegler (used with permission from Eckert & Ziegler BEBIG) [27].

Planning and Imaging — These are computer systems and software that provide physicians with pre-operative and/or real time imaging of the patient together with sophisticated planning software for precise automatic delivery of the radiation therapy.

It is important to note that, HDR brachytherapy devices and components are classified as Class II regulatory class devices by the FDA, which means a 510k premarket notification is required for launching the products into the United States market [28]. Similar regulations and restrictions must be cleared in Canada through Health Canada and equivalent agencies in other markets.

1.4.2 HDR Brachytherapy Applicators

Knowing and understanding the applicators that are currently commercially available is very important in order to make future developments compatible with existing technologies as well as to ensure that new developments will truly offer additional options or improvements. A summary of applicators offered by the main manufacturers is presented below [27, 29–31].

Intracavitary Applicators are used to deliver brachytherapy in the rectum, vagina, cervix and endometrium. They usually consist of cylinders of varying sizes with one or several channels to adapt to the anatomy of each patient and to control the effective distance between the radioactive source(s) and the tissue. A very wide variety of intracavitary devices are available from Varian[®], IBt Beibig[®], Nucletron[®] and Xoft[®].

Intraluminal Applicators consist of soft flexible catheters guided with endoscopes, bronchoscopes and/or guide wires that serve as a conduit for the radioactive source in the bronchus, trachea, oesophagus, and the upper respiratory system. These can also be used to deliver brachytherapy in other regions of the body such as the bladder and bile duct. Intraluminal applicators are available from Varian®, IBt Beibig® and Nucletron®.

Interstitial Applicators usually consist of external guides or templates used to guide several needles from outside of the body into the desired region. Once the needles are in place, the radioactive sources are guided to specific positions in the needles for the duration of the session. These types of applicators are most commonly used for HDR brachytherapy of the prostate and breast and in to lesser extent, for head and neck tumours close to the skin. Interstitial applicators are available from Varian®, IBt Beibig® and Nucletron®.



Figure 1.3 Breast bridge with fixation buttons for HDR brachytherapy (used with permission from Eckert & Ziegler BEBIG) [27].

Skin and Surface Applicators are used to treat skin cancer and other types of cancerous tumours close to the surface such as in the mouth. There are two main types of applicators; the first one is a flexible mesh that adapts to the contour of the body with many channels that allow for flexibility and precision in the treatment. The other type is the Leipzig-style and similar applicators which consist of a cone or similar shape that holds the radioactive material close to the skin, delivering an even amount of radiation in the area while shielding the radiation from affecting surrounding tissue and people. Surface applicators are available from Xoft®, Varian®, and Nucletron®.

There are many variations and models for every type of applicator available from each brand, as well as a few additional applicators such as the AxxentTM balloon applicator from Xoft® or the mouth and tongue set from IBt Bebig® that do not really fit into any of the previously mentioned categories. Despite this, there are currently no commercially available applicators purposefully designed to deliver HDR lung brachytherapy for tumours away from the main bronchial tubes.

1.5 Project Goals

The main goal of this work is to develop a fully functional, mechatronic handheld device capable of guiding a needle with a high degree of precision into tumours localized within the lung through an intercostal minimally invasive port in order to deliver HDR brachytherapy and ablation therapy. To achieve this goal, the device must be sized for single port Minimally Invasive Surgery (MIS) access and include an ultrasound probe for visualization and a mechanism that can precisely position a needle large enough to fit a standard HDR brachytherapy catheter.

A fully functional prototype of the device should allow physicians to evaluate the feasibility of using the proposed system in a clinical setting as a valid option for delivering lung brachytherapy and serve as a starting point for future developments. This work will include the design, development, manufacture and testing of the mechanical components and mechanisms necessary for a fully functional prototype. It will also include the selection and integration of the actuators and the development of the control systems necessary for its operation.

1.6 Significant Challenges

The most significant challenges associated with the development of the proposed device stem from the requirements to achieve precise needle motion, to handle significant forces, and to be highly reliable, while being able to fit through a port 12 mm in diameter. In order for the device to fit through such a small opening, the components of the system must be designed to be as small as possible. This creates problems since the smaller the pieces, the lower the forces that they can be subjected to before deformation or failure; furthermore, the fact that the device is intended for clinical use imposes substantial safety margins on the design, which requires larger and sturdier parts. Miniaturization also creates significant challenges from the manufacturing perspective, since smaller pieces become more difficult to manufacture and tolerances become tighter, elevating the cost and time needed for construction. Together these factors lead to a design process that is a constant balancing act between the need for miniaturization and the need for a more robust and sturdier system.

The requirement to have real-time visualization of the lung and the tumours for accurate needle placement also represents a challenge. Ultrasound technology is the only option currently available to safely acquire real-time images during a procedure; however, ultrasound images cannot be acquired through air filled or empty mediums such as lungs. In order to provide reliable visualization of a brachytherapy procedure, the ultrasound probe will have to be pressed against the lung and the tumour, which means that the ultrasound probe will have to be introduced into the patient's body. This generates the need to create a system that allows for independent positioning of the ultrasound probe and the needle within the body to accommodate different tumour sizes located in different places within the lung, adding to the complexity of the system and to the number of parts that must fit within the 12 mm port.

The limited available space and the need to have only biocompatible materials within the patient's body will also force the design to have its actuators placed in a housing that will remain outside of the body. Because of this, the forces from the actuators will have to be transmitted through long, thin rods from the housing to the tip of the tool, which generates a very mechanically disadvantageous system. This means that the forces needed at the tip of the instrument will be significantly magnified, greatly increasing the stresses at the motors and at various components and linkages.

1.7 Contributions

With the lack of purpose-made devices to conduct minimally invasive HDR brachytherapy via applicators through the intercostal spaces and the inability of today's intraluminal systems to

reach tumours away from the main bronchi, this project explores a new design that will potentially give physicians an alternative to treat lung cancer patients. The device proposes a novel and unique way of guiding, with the help of ultrasound imaging, a wide (over 2 mm inner diameter) needle through tissue in a minimally invasive manner, and through this needle a catheter for HDR brachytherapy and possibly other applications such as ablation therapy or biopsies. The main contributions of this project are:

1- With no commercially available device to date that enables HDR brachytherapy to be delivered in a minimally invasive way through the chest, this project provides the basis through its innovative design for what could become a new option in lung cancer treatment. To the best of our knowledge, the device is unique as no other system found commercially or in the literature explores the possibility of guiding a needle through lung tissue with the help of an ultrasound transducer inserted through an intercostal space, for the application of HDR lung brachytherapy.

2- A common challenge that physicians face in ultrasound-guided MIS is the difficulty of aligning the instruments or needles being used for the procedure with the plane of view of the ultrasound probe, which is usually inserted into the patient through a separate port. The device discussed herein facilitates visualization of the needle as it travels through the tissue by incorporating the ultrasound transducer into the main tool, thereby guaranteeing that the needle will remain in plane with the ultrasound image.

3- Being able to "bend" stainless steel needles with diameters between 2 mm and 3 mm in order to guide them to position turned out to be a very significant challenge due to the forces required and the fact that the needle would often end up permanently deformed. To address this issue, the idea of a slotted tube for added flexibility was adapted in order to create a wide needle with both flexible and sturdy sections. A pattern was designed to remove material from a section of the needle in such a way to make it resemble a spring. This generated a wide sturdy needle with a very flexible section that allowed the system to easily bend the needle to guide it into position. The application of tubes with flexible slotted sections in the context of needle guiding systems can potentially have many applications beyond this project. This project consisted in the design of a first prototype and setting the very first steps of what could eventually evolve into an alternative procedure for the treatment of lung cancer by incorporating several novel ideas into a unique new device. Furthermore, because of the nature of the system and its proposed operation, this needle guidance system could easily be adapted to work for different procedures and/or in different regions of the body.

1.8 Organization of Thesis

This thesis is organized into six chapters that progress from a background investigation related to lung brachytherapy and minimally invasive lung cancer treatments, to the mechanical and electrical design of the system, to the validation and conclusion of the project.

Chapter 1 – Introduction

The first chapter outlines the motivation and goals of the project. It explores the treatment options currently available to patients suffering from lung cancer, as well as the commercially available technologies for lung brachytherapy. It also describes the general scope of the project as well as its challenges and contributions.

Chapter 2 – Literature Review

This chapter presents research on previous and current advancements related to brachytherapy and lung cancer treatment and, as well, a look into the technology currently being used and developed for lung brachytherapy and minimally invasive surgery. This chapter is divided into four sections, each exploring scientific papers regarding specific topics: lung brachytherapy, ablation therapy, minimally invasive thoracic surgery and robotics-assisted minimally invasive surgery.

Chapter 3 – Mechanical Design

In this chapter, the most extensive in the thesis, the design and manufacturing process of the prototype is described. The chapter starts by presenting an overview of the system and its overall functionality and scope. Afterwards, the design requirements are presented with a strong focus

on the design restrictions that result from the size limitations and force requirements of the system.

In the next section, the different components that comprise the system are described in detail. The device is divided into three main sections: the tip of the system that includes the ultrasound and needle guidance mechanisms, the main shaft of the device and the motor housing. The way each of the sections work and the design choices behind them are described in detail.

Then a chronological description of the evolution of the design is included. After this section, a thorough description of the finite element analysis performed on the most relevant parts of the system is presented together with justification for the selection of 316 stainless steel as the main material for the construction of the prototype. Finally, the manufacturing process is briefly described together with a conclusion that recaps the capabilities and limitations of the whole system.

Chapter 4 – Electronics, Actuator Selection and Control System

Chapter 4 presents an overview of the electric components, such as the motors and microcontrollers used in the prototype, as well as a description of the software developed for the control of the system. The first section provides a simple overview of the electronic components and how the different components interact with each other. Then the requirements for the selection of the actuators as well as the details of the capabilities of the motors are described. In the next section, the control of the device, which is achieved mostly through programming, is described. In this section, the three main elements, or levels, in the overall control system are described: the microcontroller with an ADC module, the C++ program that runs on a personal computer and the EPOS2 motor controllers.

Chapter 5 – Prototype Testing and Validation

In this chapter, the validation setup and process for the device is presented. After a brief introductory section, the experimental methods and setup are presented. In this section, as part of the experimental setup, besides the general description of the setup used for the trials, the

"flexible needle", is presented and described. The next section presents the results of the user trials, which describe the accuracy achieved by expert and novice users of the device as well as a brief statistical analysis of the results. In the next section of this chapter, the validation of the device from the mechanical point of view is presented in the form of a few simple load-carrying tests. This chapter concludes with general remarks on the observed capabilities and limitations of the system.

Chapter 6 – Conclusions

This chapter summarizes the work and contributions presented in the thesis as well as recommendations for the future development of the system.

Chapter 2

2. Literature Review

Presented in this chapter is an overview of the current technologies and studies regarding lung brachytherapy, ablation therapy, single port minimally invasive surgery, robotics-assisted surgery and ultrasound imaging of lung tissue in MIS settings.

2.1 Lung Brachytherapy

Surgical resection remains the procedure of choice for the treatment of cancerous tumours in the lung; however, up to two thirds of diagnosed patients may not be eligible for curative resection due to poor health and diminished pulmonary capacity [5]. Open surgery offers an effective option for removing tumours; however, it has a higher rate of morbidity than minimally invasive options such as brachytherapy [32].

Delivering brachytherapy to the lungs has been extensively researched and used since the 1980s and 1990s in endoluminal settings, percutaneous settings, open surgery settings and in intraoperative settings, usually as a palliative therapy or as a complementary therapy, to surgical resection or external beam radiation therapy [33–35]. Intraoperative lung brachytherapy is a complementary procedure to tumour resection in which radioactive seeds in a vicryl mesh are placed next to the tissue that was adjacent to the tumour in order to kill any cancerous cells that could have been left behind, in an effort to prevent recurrences. Since this procedure is usually performed together with the resection it causes no additional trauma to the patient and it is still a widely used form of lung brachytherapy [36]. However, because brachytherapy is most often used in patients who are too weak to undergo traditional treatments, most surgical approaches to lung brachytherapy other than intraoperative brachytherapy have been phased out in favour of less invasive alternatives such as endoluminal brachytherapy and external beam radiation therapy.

The most common form of brachytherapy currently used for lung cancer is endoluminal (endobronchial) HDR brachytherapy, which has proven to be an effective form of palliative treatment, especially when combined with external beam radiotherapy [37]. Endoluminal or endobronchial brachytherapy is performed by first guiding an applicator, which in this case is a size 5 or 6 French catheter to the tumour site. Once the catheter is in place, an automated afterloader pushes the radioactive source with a guide wire through the catheter and leaves it at the tumour for a preset amount of time [38]. The catheter is set in place with a bronchoscope which is pulled out once the catheter is in place. Once the position of the catheter is confirmed to be in the desired location, the physicians monitor the treatment and patient vital signs from a shielded room. If necessary the remote treatment can be interrupted at any time [38].

Endoluminal brachytherapy is an effective treatment that helps clear obstructed airways with high rates of success in achieving local remission, with [39] reporting 73% of patients achieving remission. However, because of its nature, it can only target tumours that are around or very close to the main bronchi [40] and studies often indicate very low long term survival rates [39], although it is important to mention that in most cases, patients undergoing endoluminal brachytherapy are those whose tumours are considered inoperable due to their advanced stage and/or poor health. Compared to external beam radiation (EBR), brachytherapy offers a similar level of effectiveness, with reduced fatigue and nausea, but results in increased chest pain and dyspnoea; however, significant complications are rare in either case [41]. In general, brachytherapy does not necessarily offer a better alternative to external beam radiation; however, especially for patients who have undergone radiation before, brachytherapy is a safer choice due to the lower amounts of radiation that surrounding tissues are exposed to [41].

Percutaneous interstitial brachytherapy is a modality in which the tumour is reached with needles inserted from outside of the patient's body. Percutaneous brachytherapy is most commonly used to treat tumours in the prostate or breasts but due to advancements in medical imaging and other technologies, other regions of the body, such as the lungs, have been explored. Percutaneous brachytherapy has been used mostly with nonsurgical candidates for small size lung cancer tumours. Most studies show positive results with local retraction of the tumour

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reported in the majority of cases and relatively few complications [5, 42–45], with [43] reporting only minor side effects and [44, 45] reporting some occurrences of pneumothorax.

Low dose rate brachytherapy has also been performed to treat lung cancer, usually as a palliative therapy or complimentary therapy. There has also been a fair amount of research performed on the research and development of medical devices and techniques that prove the viability of delivering LDR brachytherapy to the lungs [32]. Advances in robotics-assisted minimally invasive surgery allow for greater precision in the placement of the radioactive seeds [38, 46–48]. Combined with advances in the field of medical imaging, that provide physicians with a more clear and intuitive image of the procedure, often in real time [47, 49], brachytherapy is becoming a more viable option for treatment.

However, with LDR brachytherapy there is always a significant risk of seeds becoming dislodged and causing damage to other parts of the body, especially due to embolisms [25, 50]. Because of the proximity of the lungs to major blood vessels and vital organs, this can be a more significant issue than it is for LDR brachytherapy treatments in other parts of the body such as the prostate. Also, studies show that HDR and LDR brachytherapy have similar success rates with HDR brachytherapy being more economical. For this reason, since the mid 1990s, the tendency has been to favour HDR brachytherapy over LDR brachytherapy in the treatment of lung cancer [51].

2.2 Ablation Therapy

Percutaneous ablative therapies have been receiving much attention in the last two decades as minimally invasive options for the treatment of focal malignant diseases since they provide certain advantages over traditional surgical resection such as a reduction in morbidity and mortality, lower cost and the ability to perform the procedures on outpatients [13]. In relation to cancer treatments, ablation therapy is most commonly used to treat hepatocellular carcinoma and hepatic metastases [13, 52–53]; however, research and procedures on other tissues are not uncommon, including the use of ablation therapy treatments for lung cancer [14, 54].

The most common form of ablation therapy is radiofrequency (RF) ablation; however, other technologies such as microwave (MW) and laser ablation are being developed and tested as lung cancer treatments. RF ablation therapy is a relatively new technique that is gaining popularity in the treatment of hepatic tumours. It could potentially challenge surgical resection as the treatment of choice as it offers comparable results with fewer side effects [16, 55]. RF ablation therapy is today the most common form of ablation therapy used to treat lung cancer [56]. MW ablation therapy is a newer option for treatment that potentially offers many of the advantages of radiofrequency ablation with some studies claiming it to be superior in terms of offering a larger and more controlled effective area of treatment with reduced procedural pain [10, 57]. Another study [55] suggests very similar results with both types of ablation therapy; however, since it was conducted on rabbits, which are much smaller than humans, the potential advantages of larger effective treatment areas of MW ablation would have been very difficult to appreciate.

With the success of ablation therapy on liver carcinomas, studies have been conducted to evaluate the effectiveness of RF ablation to treat cancerous tumours in other parts of the body including the lung. Because of the limited experience in the use of ablation therapy for lung cancer, most published studies refer to trials performed in animals; however, this treatment has been performed and reported, in a somewhat limited manner, recently in human patients [56]. In a review of recent studies by de Baere [56], he reports several studies where RF ablation therapy has been used with curative intent on lung cancer (as opposed to HDR brachytherapy, which is usually performed with palliative intent) with successful ablation reported in 78% to 96% of tumours under 2 cm but with steeply declining success rates for larger tumours, with only 8% success for tumours over 5 cm. As with HDR brachytherapy, relatively low long-term survival rates are reported [56]; however, as with HDR brachytherapy most patients who undergo ablation therapy are those considered ineligible for surgery due to very poor health.

Other recent studies report effectiveness rates in RF ablation therapy for lung cancer that are also comparable to those reported for HDR brachytherapy, with 73% to 100% [14, 58–59] of the cases achieving a successful ablation in small tumours, compared to the 73% of patients

achieving remission with brachytherapy according to [39]. However in larger tumours, over 3 cm in diameter, the success rate of RF ablation therapy seems to drastically decrease [56, 59]. Comparable to brachytherapy studies [14, 58–60], few serious incidences are reported during the procedures with the most relevant being pneumothorax in about 10% of the patients and pulmonary haemorrhage occurring in about 5% of the cases with no fatalities reported during the procedures.

Laser ablation is another viable form of treatment. In a study with 64 patients, with tumour sizes ranging from 0.4 to 8.5 cm, definitive management of the pulmonary tumours was achieved in 31 of the cases. Pneumothorax occurred in 38% of the cases and perenchymal bleeding in 13% of the cases [61].

Ablation therapy today is almost exclusively delivered interstitially using long needles with tips that heat up once they are placed in position inside the tumour or lesion. However, very recently, methods for delivering ablation therapy using endoscopic endoluminal devices have been reported. Velanovich [62] reports his experience ablating Barrett's epithelium using the BARRx endoluminal device, achieving a 90% success rate ablating the desired region.

Most studies [14, 56, 58–60] conclude that ablation therapy is a feasible option for the treatment of small (under 2 cm or 3 cm, depending on the study) lung cancer tumours with high success rates of achieving ablation with few complications during the procedure, low morbidity, and low pain or discomfort to the patient; however, further investigation is necessary before the advantages and disadvantages of ablation therapy, compared to other traditional and minimally invasive procedures can be definitively established.

2.3 Minimally Invasive Thoracic Surgery

Surgical resection is currently the treatment of choice for lung cancer tumours, with lobectomy being the most common surgical procedure. A lobectomy can be performed as a traditional open chest thoracotomy or as a form of MIS referred to as video-assisted thoracoscopic surgery (VATS). VATS is performed through small incisions, using endoscopic video for guidance and

special instrumentation to reduce trauma. VATS has been performed thousands of times since it was pioneered in 1992 with very good results and clear advantages over traditional thoracotomy, such as shorter average hospitalizations (5.3 days vs. 11.1 days), reduced blood loss (150 ml vs. 300 ml) and less pain reported by patients [63]. However, even though evidence points to MIS as a better choice for treatment, currently only about 5% [38, 64] of lobectomies are performed in a minimally invasive manner, since most surgeons are reluctant to adopt the practice due to longer learning curves, greater difficulty in the procedure, concerns regarding how to deal with unexpected events such as blood loss, and a higher perceived uncertainty as to whether a tumour has been completely removed [63].

One of the newest frontiers in MIS is natural orifice translumenal endoscopic surgery (NOTES), which, as its name states, is the practice of minimally invasive surgery where the body is accessed through a natural orifice. NOTES procedures can be transvaginal (the most common), transgastric, transesophageal or transrectal [65]. NOTES offers an option to patients for surgery with reduced or no external incisions which means no visible scaring and reduced morbidity with studies showing potentially decreased wound infections, fewer incisional hernias, and reduced postoperative pain [66]. NOTES is a promising new approach to surgery; however, it is still in its infancy with very limited number of physicians with experience in the field and very few instruments available for the procedure. Developing instruments for NOTES can be particularly challenging due to the need for instruments with great flexibility and the ability to handle relatively large forces to manipulate tissue (as high as 16 N according to [67]) as well providing the surgeon with feedback and an intuitive control.

Due to the limitations of NOTES regarding expertise, the availability of flexible instrumentation and reach; single port or single incision techniques such as single laparoscopic incision transabdominal (SLIT) surgery [68] or embryonic natural orifice transumbilical endoscopic surgery (E-NOTES) have been gaining traction [69]. Single port MIS surgeries are usually performed in the abdomen using the umbilicus as the point of entry in order to conceal any scaring. These procedures usually involve a single incision through the umbilicus with a single trocar that has multiple channels. Examples of these are the R-PortTM (Advances Surgical

Concepts) that has one 12 mm channel and two 5 mm channels and the Uni-XTM system (Pnavel Systems) with three 5 mm inlets [69]. Some of the challenges regarding single port MIS procedures are the lack of capacity for instrument triangulation that is necessary in many procedures, external instrumental crowding and clashing and limited vision angles [69]. Instruments such as the SPIDERTM surgical system (Transenterix) offer solutions for some of the challenges in E-NOTES [70]; however, due to the novelty of these techniques and instruments there is still a very limited amount of objective information available regarding its advantages and limitations. Very few studies were found regarding single port MIS surgery in the chest area [71] [72] since one of the main motivators for single port MIS surgery is the concealment of the scar, which cannot really be achieved on the chest as it is for abdominal surgery when the umbilicus is used as the entry point.

2.4 Robotics-Assisted Minimally Invasive Surgery

The first robotic device used for surgery was the AESOP, which was a voice controlled robotic camera holder approved to be marketed in 1994 by the US Food and Drug Administration (FDA) as the first surgical robot [73]. However, the most important leap in robotic surgery occurred in the year 2000 when the first model of the da Vinci[®] Surgical System from Intuitive Surgical Inc. was approved for general laparoscopic surgery [73]. Minimally invasive laparoscopic surgery has proven itself to have many advantages over traditional surgery; however, it presents a challenge to physicians since it provides only 2D images with no depth perception, limited number of degrees of freedom (DOF) and crossed controls. These are the challenges that robotics-assisted surgery attempts to improve. The current model of the da Vinci[®] system offers 7 degrees of freedom at the instrument (vs. 4 DOF from typical laparoscopic instruments), 3D stereo vision, more intuitive controls, tremor filtration and motion scaling [73]. By enhancing the capabilities of physicians, robots can potentially reduce trauma, decrease post-operative pain, lower the risk of infection and allow for a faster recovery [38]; however, because of high acquisition and operational costs and a certain degree of resistance to adopt new procedures, especially from more senior physicians, the adoption of the technology has been slow with
relatively few procedures done with the da Vinci[®], which is by far the most widely used surgical robotic system.

A field of minimally invasive procedures that may greatly benefit from robotics is brachytherapy. Intraoperative and interstitial lung brachytherapy have been performed and reported upon in the past and, although considered a feasible method, its use has been phased out in favour of external beam radiation or endoluminal brachytherapy because of several issues such as difficulty in needle insertion and guidance due to the presence of bony structures, blood vessels and major nerves; difficulty in needle orientation and achieving proper depth; involuntary patient movement due to breathing and heartbeat; and unstable holding of the instruments [32]. The added precision of robotic instruments and a greater range of movement could potentially resolve many of those limitations. There have been recent studies and developments in the field of robotics-assisted lung brachytherapy that show promising results in the use of robotics to assist in seed placement for lung cancer brachytherapy [32, 38, 74]. Another added benefit in the use of robotics for brachytherapy procedures is the reduction in exposure of the medical staff to radioactive material, since physicians could conduct more of the procedure from a distance.

2.5 Ultrasound Imaging in Lung MIS Procedures

The use of ultrasound (US) imaging for medical diagnosis and image-guided interventions has been widely studied since the 1940s as a safe and radiation free alternative to X-rays. Significant advancements in the technology has led to widespread adoption within the medical community. Ultrasound imaging is currently widely used in many different kinds of procedures in virtually every part of the human body; however, the use of US imaging in the lung presents unique challenges. The presence of air in the lung is a significant challenge as it prevents the passage of the ultrasound waves, and researchers have debated whether ultrasound imaging in an inflated lung is even at all possible [75–77]. As a result, in most cases the lung has to be deflated for any US guided procedure [76].

Since the 1990s, the use of endoscopic ultrasound probes in video assisted thoracoscopic surgery (VATS) has become increasingly popular due to probe miniaturization and ultrasound

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image improvements with numerous studies proving the feasibility of using ultrasound probes for localizing nodules and other lesions in the lung supplementing or complementing other image modalities such as CT and fluoroscopy [75–76]. While limitations, due to air echo and other artifacts, in the quality of ultrasound images in the lung can be often an issue [78], countless studies over the last two decades have proven the accuracy of US guided MIS procedures in the lung [75–76, 79].

For needle-based procedures, such as biopsies, localized anesthesia application, brachytherapy, the ability to visualize the needle and accurately track its tip in relation to the targeted area is essential. Maintaining the needle in plane with the ultrasound image and keeping it from bending out of plane are constant challenges that physicians have to face in order to accurately reach the desired target [80–81]. Furthermore, traditional out-of-plane and in-plane approaches for US based needle guidance are techniques that rely heavily on the physician's experience and interpretation of the image, where losing or misinterpreting the position of the tip of the needle can introduce delays in the procedure and cause unintentional damage to surrounding tissues [80]. Other factors that can affect the visibility of the needle are its gauge (wider needles are easier to see) and the insertion angle, where long axis (longitudinal) imaging is recommended for shallow angles (under 30 degrees) and short axis (transverse) imaging is recommended for steep angles (over 60 degrees) [81]. While several ideas and solutions are often proposed, such as a laser alignment system suggested by [82], in many cases the physician's experience and ability remain as the most important factors.

Today, the most widely reported and used ultrasound based image guided procedures in the lung are endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) and endobronchial ultrasound-guided trans bronchial needle aspiration (EBUS-TBNA) [79]. These procedures are commonly used to obtain tissue samples, assessing the stage of lung cancer development. These MIS procedures were pioneered in the 1990s and, since the 2000s, have become the preferred methods for obtaining tissue samples for biopsies in the lung, with many studies proving better yield results with significantly reduced trauma to the patient when compared to traditional methods [79, 83–84]. Despite the effectiveness and convenience of EBUS-TBNA, it has a limited reach (equivalent to HDR lung brachytherapy), since the instrument used for the procedure is guided through the bronchi. As a result, tumours located farther away in smaller bronchi cannot be reached [79, 85].

2.6 Conclusions

Surgery and chemotherapy remain as the treatments of choice for lung and other types of cancer because of their proven effectiveness over the years and due to the fact that they tend to be the procedures that physicians have the most experience in. However, because of the advanced age of many patients and the aggressiveness and fast progression of lung cancer, patients are often too weak to undergo aggressive treatments, so alternatives such as EBR, brachytherapy and ablation therapy are needed for curative and palliative treatments. In general, studies show that lung brachytherapy is a procedure with similar success rates as EBR therapy, with EBR being a therapy of choice for patients who have not yet been exposed to significant amounts of radiation. Brachytherapy, especially HDR brachytherapy, is commonly used to treat lung cancer as a last resort in patients who are too weak for surgery and have been exposed previously to too much radiation, since brachytherapy exposes healthy tissue to less radiation than EBR treatments. Ablation therapy is used in a very limited number of locations as it is considered a somewhat experimental procedure for lung cancer. It is proving to be a highly effective therapy but only in tumours of less than 2 cm in diameter.

LDR brachytherapy and interstitial lung brachytherapy treatments have been lately phased out in favour of intraluminal HDR brachytherapy as it is a less invasive and safer form of treatment. However intraluminal brachytherapy is limited to the treatment of tumours located adjacent to bronchi large enough to fit the bronchoscope that is needed to guide the applicator. A device that offers a minimally invasive option to deliver HDR brachytherapy through the intercostal spaces could make HDR brachytherapy a viable treatment option for patients whose tumours are not accessible through the bronchi. Furthermore, such a device, because of similarities in the procedures, could be used or adapted to be used to deliver ablation therapies or even perform biopsies. MIS instruments have proven in numerous studies that they provide a safer option for many procedures with reduced morbidity and pain to the patient while being economically preferable due to a reduced need for post-operative care. However, procedures are not always done in a minimally invasive manner even when the technology and the opportunity exists because those procedures tend to be longer, more difficult and have longer learning curves for physicians. For this reason, designing a simple MIS instrument with intuitive controls is very important.

Robot assisted surgery offers the potential of more accurate and easier controls for minimally invasive procedures but it requires very significant investments in terms of money and training time for physicians. Therefore robot assisted surgery, with systems such as the Da-Vinci, is often only economically feasible (if any) at large well funded healthcare centres.

Ultrasound guided procedures in the lung, despite requiring the lung to be deflated to prevent air pockets from interfering with the US image, are feasible and widely used. This can be observed by the increasing prevalence of ultrasound imaging in VATS since the 1990s. Furthermore, beyond the importance of EBUS-TBNA in the staging of lung cancer, the way in which the aspiration needle is guided in-plane with the ultrasound transducer is of great interest for this project as it represents a viable solution for the challenges involved in ultrasound based needle guidance procedures.

The current state of the art and state of lung cancer research suggests that a simple and economical device that enables physicians to deliver HDR brachytherapy in a minimally invasive manner and provides access to tumours that cannot be reached with current standard procedures may offer a viable treatment option for many patients who would otherwise have no treatment options left. In the following chapters, the design and development of such device will be explored.

Chapter 3

3. Mechanical Design

3.1 Design Overview and Functionality

The system designed and developed for this project is a semi-automated, ultrasound-based needle guidance device (UBNGD) for lung HDR brachytherapy with the potential to be used for other procedures such as lung biopsies and ablation therapy. It is a minimally invasive tool designed to access the lung through the intercostal spaces using a 12 mm port. It has two end effectors at the tip, one that allows an ultrasound transducer to be moved into position and pressed against the tissue and the second one that guides the direction of a needle into the required position. In a clinical setting, two access ports would be necessary to perform a procedure, the first one to introduce a standard laparoscopic camera to gain a view of the chest cavity and the second one for the UBNGD.



Figure 3.1 The CAD design positioned into a lifesize model of a human ribcage (left). The final prototype being tested through a trocar in a human ribcage model (right).

The UBNGD consists of a distal section built from stainless steel and a proximal section prototyped in ABS. The distal section is designed to go into the body and to fit into a standard 12 mm trocar used for MIS. The proximal section houses two 60 watt brushless Maxon[™] EC motors coupled with a spindle drive and a planetary gear head, resulting in a 104:1 reduction to provide high force, high precision linear motion to power the end effectors. The system is controlled with two thumb sticks mounted on the top of the handle. These are connected to a

microcontroller that communicates via a PC with two EPOS2 controllers to control the electric motors. The device is a standalone handheld system with a total length of 50 cm and a weight (not including the cables that connect to the controllers) of 440 g.



Figure 3.2 Handheld prototype (left); the complete system including the controlers and power source(right).

3.2 Design Requirements

Based on input from clinical collaborators, the first requirements that were identified for the UBNGD were: 1) A single port, minimally invasive system that can deliver HDR brachytherapy anywhere in the lung; 2) It should allow the user to directly probe the lung with the ultrasound transducer; 3) It should provide a way of guiding a needle into tumours of different dimensions and at different depths, while keeping the needle aligned with the field of view of the ultrasound.

The most significant and challenging requirement that guided the design of the device was the need to develop a minimally invasive single port device that could fit through a standard 12 mm trocar. A 12 mm trocar is a standardized tube used as an entry port in minimally invasive surgeries to accommodate tools of up to 12 mm in diameter (the trocar itself has an inner diameter of approximately 12.8 mm). All of the necessary components, mechanisms, a needle and ultrasound wires are required to fit within the 12 mm diameter opening.



Figure 3.3 Size 12 MIS trocar.

The greatest challenge related to the size limitations is the fact that making smaller parts inherently made them less capable of withstanding large forces. Because of this, the design process saw several iterations of most of the components, in which their dimensions and configuration had to be modified in order to guarantee that they would be sturdy enough within the specified dimensions. This problem is further compounded by the fact that structures of minimally invasive instruments must be able pass through a small diameter tube, which often results in mechanisms with very poor mechanical advantage.

In the UBNGD, the movement of the electric motor is transmitted to the ultrasound (US) jaw by two long stainless steel rods that push back and forth in the horizontal plane (as seen in Figure 3.4). Because of the small perpendicular distance to the pivot point, some parts, such as the rods and links, are subjected to very significant linear forces in order to generate very modest rotational forces at the ultrasound jaw or the needle guiding tube. Some early calculations based on the first design ideas showed that each rod could see up to 12 times the forces seen at the tip of the ultrasound transducer.



Figure 3.4. Early design sketch showing significant forces used for design considerations.

Figure 3.4 shows that in order to counteract a 10 N force at the tip, the force *F* applied by the rods would have to be $F = \frac{(10 \text{ N})(81 \text{ mm})}{3.5 \text{ mm}} = 231.4 \text{ N}$. This means that each of the two rods (and the mechanism and actuators behind them) would have to be able to produce 115.7 N, which is almost 12 times the force seen at the tip of the ultrasound. Although later designs had slightly better mechanical relations, the need to have components that can cope with high forces and stress remained.

Since the forces play a significant role in the design of the components and material selection, a maximum force applied to the ultrasound transducer had to be established. This turned out to be somewhat challenging since no studies to date have reported concerning the forces used to probe a lung with an ultrasound transducer in a MIS setting. However many studies, several of which took place at CSTAR, discuss the forces needed for a lung palpator and other minimally invasive organ probing systems. A couple of publications using a palpation device intended to identify tumours within the lung recorded peak forces of up to 1.6 N but recommended devices able to handle up to 10 N [86–87]. Another publication recorded peak forces between 2 N and 4 N using a device designed to handle up to 14 N [88]. In another study using a probe with a contact area of 3 cm by 1 cm, it was observed that tissue damage started to become visible when it was subjected to forces above 6 N for a significant amount of time [89]. In another publication describing the design of a palpation instrument with similar dimensions to the UBNGD, it was estimated that in a worst case scenario a force of 20 N could be exerted on the device if the surgeon attempted to lift a human lung [90]. Based on this information, it was

estimated that the expected forces applied to the lung would remain under 2 N in most cases, as the ultrasound device will usually be subjected to smaller forces than a palpator. However, it is also expected that the device may be occasionally exposed to significantly greater forces during normal use. Considering this, a force of 10 N was established as the maximum expected force to be exerted on the ultrasound probe.

For the needle guide, the main force that needs to be considered is the force needed to bend the needle in order to guide it into the desired location. Unfortunately, defining the magnitude of this force at the early stages of design process proved impossible, as it depends on the dimensions, characteristics and material selected for the needle. The selection/design of the needle would take place through trials conducted on the prototype itself. Therefore the initial design considered a force of 10 N acting along the length of the needle guide. In the end, the needles designed for the project turned out to require less than 1 N of force to be bent into position.

Some other considerations and constraints considered for the design include:

1– The UBNGD must be versatile enough in its design to be used as a needle guidance system for brachytherapy, ablation therapy and perhaps other uses such as biopsies.

2– It should be compatible with the probes and needles used for current interventions, which means that the system should be able to accept needles thick enough for ablation therapy and/or to fit a needle wide enough to fit inside it a standard 5 F or 6 F (1.66 mm–2 mm) catheter used for intraluminal lung brachytherapy. The UBNGD was therefore designed to fit a needle with an outer diameter (OD) of up to 3 mm and an internal diameter (ID) greater than 2 mm.

3– The design must incorporate an ultrasound transducer for real time imaging. Furthermore, in order to keep costs low, the system should be designed to be fitted with a previously-developed custom ultrasound transducer with dimensions of $4.5 \times 7 \times 41.75$ mm.

4– The needle should be aligned with the ultrasound transducer in order to ensure that the needle is always in the visual plane of the ultrasound.

5– The device should be biocompatible and sterilizable either by selecting only biocompatible and sterilizable components and materials throughout the device or by designing it

in a way that the non-sterilizable components can be isolated from the patient and disassembled for the sterilization of the components that come into contact with the patient.

6– It should have a maximum targeted weight of 500 g or less, in order to make it light enough to be manually handled.

7– In line with the dimensions of other thoracoscopic devices, the UBNGD should have an effective length (length of the device that can go into the body of a patient, including the jaw) between 30 and 40 cm, plus a handle with length between 12 and 18 cm.

8– The length of the jaw must be at least 5 cm long in order to fit the ultrasound transducer described in Point 3.

In order to achieve high accuracy and ease of use, the device was conceptualized as a semi-automated system, in which the user inputs his/her desired angular speed and direction of the end effectors. Furthermore it should have the capability of positioning the needle within 1 mm of the desired location in the axis dependent on the movement of the needle guide. Note that, in practice the actual 3D accuracy might be significantly lower due to imprecisions in the left-right placement the device over the target and the actual depth of the needle, which will be affected by the ability of the user to interpret US images and manually guide the device into place.

End effector outer diameter	Fits a 12 mm trocar	
Maximum load at US transducer	10 N	
Total weight	Under 500 g	
Effective length	Between 30 and 40 cm	
Length of handle	Between 12 and 18 cm	
Total length	Under 58 cm	
Length of the jaw	Over 5 cm	
Materials	Sterilizable, biocompatible	
Sensor	$4.5 \times 7 \times 41.75$ mm ultrasound transducer	
Control	Semi-automated guidance	
Actuators	Capable of producing a 10N force at the tip of the US	
	jaw.	
Ergonomics	Handheld	
Needle Guidance	In-line with ultrasound transducer,1 mm accuracy, fit needles with ID over 2 mm and OD under 3 mm	

Table 3-1. Summary of Requirements

3.3 Mechanism Design

In this section, the different parts and mechanisms that make up the UBNGD will be discussed in detail. The analysis of the device has been divided into three sections, corresponding to different parts of the system: 1) At the distal end of the device are the ultrasound and needle guidance mechanisms that allow for the positioning of the ultrasound transducer and the positioning of the needle; 2) A shaft connects the guidance mechanisms with the device handle/motor housing; 3) The motor housing, located at the proximal end, serves as a handle and includes controls for the user.

3.3.1 Ultrasound and Needle Guidance Mechanisms

The tip of the device, which includes the mechanisms to guide the ultrasound transducer and needle guidance tube, is perhaps the most significant aspect of the mechanical design of the system, as it offers a unique approach to HDR brachytherapy and includes an original actuation mechanism.



Figure 3.5 Picture of the tip of the device in open and closed positions.

Initial research showed that there were no integrated instruments used for thoracic surgery or in lung brachytherapy that allow direct probing of the lung with an ultrasound transducer and guidance of a needle remaining within the ultrasound field of view. However, a couple of commercially available devices with some of these characteristics were found and some inspiration was drawn from them. The first one is the EBUS-TBNA system by Olympus for Endobronchial US guided biopsies [91], which keeps a biopsy needle aligned with a small ultrasound transducer. The second one is the SPIDER surgical system for minimally invasive single port abdominal surgery [92], which has a mechanism that accomplishes the kind of movements needed for the UBNGD.

Needle Guide

The brachytherapy/ablation/biopsy needle guidance system consists of a tube with an internal diameter of 3 mm that can be positioned to guide the needle as directed by the user according to the size and location of the tumour. The key features of the design are illustrated in Figure 3.7 and are described below:



Figure 3.6. Needle guidance system. See text for description of annotations.

- The needle guidance tube is connected to a circular stainless steel part located inside the outer sleeve of the device through two soldered rectangular pieces using two 1 mm pins. This is the pivot point for its rotational motion.
- 2- The needle guide movement is actuated by a rod that pushes back and forth, transmitting linear movement from motors located in the proximal end of the device.

- 3- The rod is connected to the tube by two links with a pin-to-pin length of 18 mm. The pins at the tube end connect with a rectangular piece that is soldered to the tube. The length of the rectangular part was designed to be as long as possible to maximize contact area.
- 4– The guide tube has an inner diameter of 3 mm to allow for needles large enough to accommodate a 2 mm standard HDR brachytherapy catheter to pass inside them. The outer diameter of the guide tube is 4 mm.

Ultrasound Jaw

The ultrasound transducer is held in place and positioned with a mechanism that is similar to the one described for the needle guidance system. This allows physicians to work from different angles to accommodate larger tumours and to apply pressure to the lung tissue for better ultrasound contact. The key features of the design are illustrated in Figure 3.8 and are described below:



Figure 3.7. Ultrasound jaw mechanism. See text for description of annotations.

- 1– The ultrasound transducer jaw is pinned to a circular part at the end of the shaft. This forms the pivot point for transducer. Note that, to provide a clear path for the transducer signal wires two pins are used, one on either side of the jaw.
- 2– Movement is actuated by two rods that move in parallel back and forth transmitting linear movement from motors located in the proximal end of the device.
- 3- Two links with a pin-to-pin length of 12 mm connect the rods to the ultrasound transducer jaw.

- 4– The jaw part has a groove to fit an electromagnetic tracking sensor if needed.
- 5- The jaw can accommodate a 4.5 mm × 7 mm × 41.75 mm ultrasound transducer designed by Blatek Inc. A 1.19 mm circular hole behind the transducer opening is used for installation of the transducer and signal wires.
- 6– The tip of the ultrasound jaw has rounded edges to avoid tissue damage.

All of the parts in the ultrasound jaw and needle guidance system are connected to each other using 1 mm diameter A2 stainless steel dowel pins that have a yield strength of 450 MPa. Based on experiments reported in [90], these pins can support a load of up to 700 N in a double shear strength test. The pins were fitted in holes machined to a diameter of 1.016 mm.

3.3.2 Shaft of the Device

The shaft of the device that connects the motor housing with the end effectors was built using a stainless steel tube with an outer diameter of 12 mm and an inner diameter of 11 mm, cut in half along its longitudinal axis. Both halves are screwed to seven 11 mm round guides distributed along the length of the shaft. These guides hold the shaft halves in place and serve as guides for the needle, the actuation rods and the signal wires for the ultrasound transducer. The outer sleeve was designed in two pieces to allow for access into the mechanism for maintenance, troubleshooting, and assembly. The shaft has a length from the edge of the motor housing to the opening of the needle guiding tube of 212 mm and 243 mm from the edge of motor housing to the end of the sleeve. The designed length of the shaft results in an effective length for the tool of 325 mm, as measured from the leading edge of the motor housing to the tip of the ultrasound jaw. The key features of the shaft design are illustrated in Figure 3.9 and are described below:



Figure 3.8 Detailed view of the shaft of the device. See text for description of annotations.

- 1- Outer sleeve composed of the upper and bottom half of a 12 mm OD, 0.5 mm thick tube.
- 2– The outer sleeve is fixed to the round guides with M1.6 screws.
- 3- A total of seven round guides are placed along the sleeve. The two at the distal end are manufactured from stainless steel to resist higher stresses and the other five manufactured in PEEK to reduce friction. The two most proximal guides are placed inside the motor housing.
- 4– One 4 mm \times 2.6 mm rectangular channel to run the wires from the ultrasound transducer.
- 5– Three 2.6 mm circular channels for the 2.5 mm rods that transmit motion.
- 6- One 3 mm circular channel for needles with OD under 3 mm.
- 7– The two distal guides connect to the ultrasound and needle guidance mechanisms.

3.3.3 Motor Housing

The final part of the system is the motor housing of the device, which also serves as a handle. The motor housing was designed with inner dimensions built around the motors, while the outer dimensions were designed to be ergonomic and easily held with a single hand. Two thumbstick input devices are fixed to the top and serve as the manual controls for the device.

With the exception of two parts that connect the motors to the driving rods, the parts that make the motor housing for the prototype were built from ABS using a 3D printer. Unlike the shaft and distal mechanisms that are made from stainless steel, less expensive plastic was determined to be suitable for the motor housing. This is due to the fact that the housing parts will

not be subjected to significant stresses and could be designed with looser tolerances. Without the limitation of having to fit everything within a tight space, parts could be made bigger and thicker.

The complete motor housing has a total length of 180 mm, a height of 50 mm (plus an extra 11 mm considering the control thumbsticks) and a width of 28 mm. The key features of the motor housing are illustrated in Figures 3.10 and 3.11 and are described below:



Figure 3.9. Motor Housing. See text for description of annotations.



Figure 3.10. Detailed view the components that make the motor housing. See text for description of annotations.



Figure 3.11 View of the motor housing without the outermost components.

- 1– Exterior housing done in ABS (plastic), formed from two outer halves divided along the same axis as the shaft of the device, allowing for easy access to the internal components.
- 2-3 mm channel for a needle.
- 3– Open back for the motor cables.
- 4– A channel that runs through from the shaft of the device for the wires that come from the ultrasound transducer and the thumb sticks.
- 5– Thumbstick controls. These control the ultrasound and needle position, respectively.
- 6- Rectangular part with two semi-circular cut-outs holds the electric motors and exterior housing in place
- 7- Component screwed to the front of the motors to lock them in place.
- 8– The top motor drives the rod that moves the needle guidance mechanism, the bottom motor drives the two rods that position the ultrasound jaw.
- 9- 50 mm long motor shafts. Because the parts described in Number 11 overlap, each motor is mechanically constrained to move a maximum of 25 mm; however, through software the motor that controls the US jaw is constrained to a range of 12 mm and the one that controls

the needle guide to 18 mm, as these are the maximum displacements required for the operation of the UBNGD.

- 10– Cylindrical rails help keep the motion in line.
- 11– These parts connect the motor shafts to the stainless steel rods that transmit movement to the actuated tip (described in Section 3.3.1). Unlike most of the other components described in this subsection that were manufactured in ABS, these were manufactured in stainless steel due to the stresses and tighter tolerances needed.
- 12– Double shielded ball bearings to accommodate 5 mm diameter shafts and a OD of 8 mm designed to handle up 63,000 rpm.
- 13- The motor housing is connected to the shaft of the device with eight 1.6 mm diameter screws.

3.4 Finite Element Analysis and Material Selection

The Simulation Express Analysis in SolidWorks was used to perform finite element analysis on the modelled parts in order to estimate the amount of stress that they would be subjected to and to help in the selection of the materials to be used in the manufacture of the device. As described in Section 3.2, the main force used for the stress analysis was a 10 N force applied to the tip of the ultrasound jaw. The reaction forces observed due to this 10 N force were the basis for the analysis performed in most of the other components.

The initial analysis performed on earlier models (described in appendix A) showed that with these forces, many of the parts would be observing peak stresses of close to 200 MPa. Due to the need to make the device biocompatible, corrosion resistant and sterilizable, the search for the proper material was focused on stainless steel. An investigation of studies and available medical devices and implants pointed to 316 and 316L stainless steels as the preferred material of choice in implants and other medical devices due to its extremely high resistance to corrosion. However, these materials have nominal yield strengths of 205 MPa and 170 MPa, respectively [93, 94].

Based on the fact that stainless steel is a widely used, well-understood and highly predictable material, a factor of safety (FOS) of 2 was deemed sufficient for a first prototype. This choice is further supported by the fact that, during normal use, the peak forces acting on the instrument would be well below the 10 N design requirement. Considering this FOS and the yield strength of 316 stainless steel, either modifications to the design or a stronger material would be needed.

It was decided that if possible, design modifications were preferable over choosing a harder type of steel. Using a lower carbon, untreated 316 steel not only offers better corrosion resistance properties, but also other advantages. Softer steel is easier, faster and cheaper to manufacture than harder steels, as it is easier for the tools to cut. Furthermore, if the need to make future prototypes capable of withstanding larger forces or the need to use smaller pieces arose, that would be possible by simply selecting a stronger material such as 400 series stainless steel.

Using finite element analysis to identify the locations with the highest stresses, modifications were made to several pieces in an attempt to reduce stress values. Stress concentrations were reduced by adding fillets and curvatures. The space available and the components were also analyzed carefully and their dimensions were increased whenever possible. With these modifications, it was possible to bring the maximum stresses down to around 100 MPa, thereby enabling the use of 316 stainless steel with a factor of safety of 2. All of the stress analysis and calculations presented in this section were done using 316 stainless steel with a yield strength of 205 MPa.

It was calculated that the reaction forces would be the highest exactly at its initial or closed position since the forces transferred from the motor would be acting only on the horizontal axis. As soon as the jaw starts to open, the forces from the motor begin to push the ultrasound at an angle, which having both a horizontal and vertical component, becomes an increasingly efficient way to rotate the ultrasound jaw. Based on the 2D diagram shown in Figure 3.22, the torque, τ , acting on the ultrasound may be described by Equation 3.1:

$$\tau = (Y)(F_1)(\cos\theta) + (X)(F_1)(\sin\theta)$$
(3.1)

As the angle increases, the vertical component of the force becomes larger and the horizontal becomes smaller, and since the distance X (which is perpendicular to the vertical component of the force) is over 5 times larger than the distance Y (which is perpendicular to the horizontal component of the force), the rotating force of the ultrasound will be significantly larger with a larger vertical component of the force. Therefore, when the angle θ is zero, the force F_1 , which is the force applied from the motor, must be at the maximum required value to produce the required torque. It is in this configuration that the largest stresses are observed in all of the components; therefore, the stress analysis will be based on the system in a closed position.



Figure 3.12. Diagram of the Ultrasound Mechanism

With these parameters in mind and the dimensions shown in Figure 3.23, the force F_1 needed to counteract a 10 N force applied at the tip of the ultrasound jaw in a closed position can be calculated: $F_1 = \frac{(10 \text{ N})(81 \text{ mm})}{4.5 \text{ mm}} = 180 \text{ N}$. This means that each of the two rods that transmit power from the motor will be subjected to a 90 N force.



Figure 3.13. Diagram of the ultrasound jaw with dimensions.

Although finite element analysis (FEA) was performed at several stages of the device evolution, only the analysis performed on the manufactured parts is shown here. Due to the continually iterative process followed for the design and redesign of the different parts, where weak spots were identified and modified to achieve a factor of safety (FOS) of 2, many of the final parts ended up having factors of safety very close to 2.

FEA on the Ultrasound Jaw

For the analysis performed, calculations were based on a force of 90 N applied to each of the connection points to the rods that transmit power from the motors, as would be necessary to balance the torque caused by a 10 N force at the tip. In this analysis, the pivot point was set as a fixed point; a vertical force of 10 N was added at the tip and two 90 N forces were added at the connection points with the rods.

The analysis shows that the maximum stresses would occur at the upper proximal corners of the space were the ultrasound transducer is to be fitted. With a maximum stress of 97.15 MPa, this gives us a minimum factor of safety of 2.11 for this part.



Figure 3.14 Von Misses stress analysis on the ultrasound jaw.



Figure 3.15 Regions in red indicate a FOS under 2.5, with the lowest FOS at 2.11.

FEA on the Force Transmission Rods

For the rods, a force of 90 N was applied at one of the pin connectors and the other one was set as a fixed point. The study showed that the highest stress would be seen around the pin hole with a maximum value of 63.2 MPa. This results in a minimum FOS of 3.24. Because of the relative length of the rods, and the elastic nature of steel, deformation was also considered and turned out to be 0.0031 mm in its longitudinal axis, which is small enough to not have a significant impact on the operation of the system. A buckling analysis was not performed due to the fact that the rods are enclosed throughout much of their length and the largest forces during normal operation are expected to occur with the US pressing on tissue, which puts the rods in tension.



Figure 3.16. Von Misses stress analysis on the transmission rods.

FEA on the Connection Links

The links that connect the rods to the ultrasound holder and needle guide were also analysed. The links that are subjected to the most stress are the ones connected to the ultrasound holder, as this part sees slightly larger forces than the needle guide. The maximum stress was observed around the pinholes with a value of 95.1 MPa, resulting in a FOS of 2.16.



Figure 3.17. Shows the von Misses stress analysis on a connection link (left) and in red the areas were the FOS is below 2.5 (right).

FEA on the Needle Guide

The analysis performed on the needle guide was not as straightforward as other pieces of the device. This is primarily due to the fact that, by the time the design was finalized, the needle or needles that would be used in the system had not been selected as several options had to be tested on the actual device before a selection could be made. The most significant force acting on this part results from the needle resisting bending. This force will vary significantly based on the material selected, outer diameter and wall thickness. In order to identify weak spots in the design and to establish an upper limit on the allowable forces, the analysis was performed with an assumed force of 10 N acting evenly throughout the length of the internal wall of the cylinder in a vertical direction. This force is accompanied by a 96.42 N horizontal force acting at the upper pinhole that counteracts the torque generated by the 10 N force. The pin at the pivot point was set as a fixed point. The maximum stress observed was 102.49 MPa at the base of the pseudo-rectangular element on the top, with some significant stress close to 90 MPa also observed around the pinholes at the pivot point. This results in a FOS of 2.

Due to manufacturing limitations, this part, unlike all others analyzed was not manufactured out of a single block of steel. Instead, it was manufactured using stainless steel tube silver-soldered to rectangular elements. These elements were soldered together using the MG 120 silver solder [95] with a tensile strength of 120 MPa, which would not be enough to maintain a FOS of 2. Fortunately, later testing demonstrated that the forces needed to bend the selected needle were significantly less than 10 N.



Figure 3.18. von Misses stress analysis on the needle guide.



Figure 3.19. Highlights the area on the needle guide with the FOS under 2.5.

FEA on the Frontal Round Guide

FEA was also run on the frontal round guides since they would experience significant forces as they are the point of contact with the ultrasound jaw and needle guide. For these analyses, the screw holes were set as fixed points and two forces of 90 N each were added at the pinholes that connect them to the other parts. This test yielded a maximum stress of 100.9 MPa, resulting in a FOS of 2.03.

For the round guides the idea of using PEEK to reduce the friction coefficient with the moving metal parts that would be constantly sliding inside them was considered. The FEA analysis showed that this would not be possible with the two frontal parts as they see considerable forces, requiring the use of stainless steel. However, the other 5 round guides, which would not be subjected to significant forces, were manufactured from PEEK. PEEK or PolyEther Ether Ketone is a relatively hard type of thermoplastic that is easier to machine than steel. PEEK is sterilizable and biocompatible and has a static coefficient of friction with steel of 0.35 compared to a 0.74 coefficient for steel on steel [96, 97].



Figure 3.20. von Misses stress analysis of the front round guide.

FEA on the Shaft Sleeve

The final elements that were analyzed were the upper and bottom sleeves on the shaft of the device. Both would be subjected to similar forces, however, because the bottom sleeve contains an aperture to allow the needle guide to open, it experiences higher stresses. For the analysis, all of the screw holes except for the ones that hold the two frontal round guides were set as fixed points. At the frontal screw holes, forces equivalent to half the forces that the frontal round guides were seeing were applied (half of the force was considered to be acting on the upper sleeve). This gave us a maximum stress of 97.3 MPa, resulting in a FOS of 2.11.



Figure 3.21. von Misses stress analysis of the lower sleeve

With a minimum factor of safety of two, 316 stainless steel was confirmed as the material of choice for most of the device except for 5 of the round guides that were manufactured in PEEK and the motor housing which was made from ABS plastic.

3.6 Conclusions

The iterative design process yielded a 2 DOF handheld device, designed for minimally invasive lung brachytherapy, capable of guiding the direction of a needle up to 3 mm in diameter and also positions an ultrasound transducer. Designed with 316 stainless steel, it guarantees exceptional corrosion resistance and leaves margin to work with harder types of steel if the need arises in future prototypes. The final prototype has the following overall characteristics:

Characteristic	Design Req.	Prototype	Notes
Weight	< 500 g	440 g	Includes motors, excludes cables
Total Length	< 580 mm	505 mm	
Length of SS	300 – 400 mm	325 mm	From the tip of the US holder to the edge of the motor
shaft and tools			housing. It's the maximum length that can go into a patient's body.
Length of actuated part	> 50 mm	114 mm	From the opening of the Needle guider to the tip of the US holder.
Diameter of the tool	Fit within a 12 mm trocar	12 mm (theory) 12.7 mm (max)	The additional 0.7 mm is the maximum measured diameter. This is mostly due to screws not seating properly and a slight deformation of the sleeve halves away from circularity. Fits through a 12 mm trocar.
Max. diameter at the handle	Handheld	60 mm	
Minimum factor of safety	2	2.00	At the needle guidance tube. Designed based on a10 N applied force.
Materials	Sterilizable, biocompatible	316 Stainless steel	Stainless steel is sterilizable and biocompatible

Table 3-2. Mechanical charateristics of the final prototype.



Figure 3.22. Orthogonal view of the final model.

One of the most important characteristics of the mechanical design is the reach that the device can give the user at its actuated tip when targeting tumours. With the needle guide extended to its maximum point and the ultrasound retracted to its original position, the theoretical maximum distance from the target to the ultrasound transducer (at its tip) is 48 mm. This means that in this configuration the maximum radius of the tumour, plus the layer of lung tissue surrounding, it cannot exceed 48 mm. In this configuration the needle will have to travel 51 mm to reach the target point.



Figure 3.23. Mechanical reach of the actuated tip.

Beyond the reach of 48 mm, if the ultrasound holder is also extended to its maximum extent, the theoretical maximum reach of the device increases to a depth of up to 132 mm. Although in theory the device can be used in this way, it is not its intended mode of use nor does it make sense from a medical perspective as brachytherapy treatments are rarely ever used to treat tumours with a diameter larger than 5 cm.



Figure 3.24. Mechanical reach and therefore maximum theoretical sizes of the tumours that can be treated.

The accuracy and resolution of the device from a mechanical perspective is unlimited as all the movements are continuous, these parameters will be better analyzed in the following chapters based on limitations of the motors, software and practical use.

Chapter 4

4. Electronics, Actuator Selection and Control System

4.1 System Overview

The control system for the UBNGD utilizes with two analog thumbsticks positioned on the top of the motor housing that receive input from the user. These thumbsticks are connected to a microcontroller that converts the analog input into a digital value. The digital value is transmitted to a computer, and based on this input and feedback from the motor controllers, a control program instructs the motors on where to and how to move. These instructions from the computer are communicated to two EPOS2 controllers that use the parameters received from the computer to instantly control the amount and profile of the current the motors receive for them to move to the desired position at the desired speed and acceleration. The controllers also monitor the current and receive feedback on the actual position and velocity of the motors from their hall sensors and encoders. All of this is powered by a 24 V power source, with a 5 V regulator feeding the microcontroller and thumb sticks. The complete electronic system that controls the movements of the device is composed of the following components:

1– A **PSR 24 V, 12 A, DC power supply** with three power outputs, two connected to each of the two motor controllers and the third feeding a 5 V power regulator.

2– A **5** V, 0.5 A, MC78M05CT voltage regulator that feeds the thumb joysticks and powers the microcontroller. It is integrated in a circuit with an ON/OFF switch, a LED on light and a resistor and capacitor needed for adequate operation.

3- Two **resistive analog joysticks** used to obtain control input from the operator. Connected to a 5 V source, they will have a voltage output with an approximate range of 1.6 V to 3.6 V depending on their position. These are 2 axis joysticks, however only one axis is used on this device.

4– A **PICAXE 28X1 microcontroller** with analog-digital conversion capabilities. The microcontroller "reads" voltages from 0 V to 5 V and converts them into an 8 bit (0 to 255)

value. Two additional buttons were added: one to reset the device and the other is programmed to start a homing and shutdown sequence for the device. A simple control program is used to interpret and adjust the input value, filter out a range of values and transmit the desired speed to the computer via serial communication. The communication takes place through a serial to USB adapter that creates a virtual serial port in the computer. The microcontroller's analog-digital conversion has a resolution of up to 10 bits.

5– **A PC** running a program written in C++ does most of the "intelligent" control, based on the inputs received from the microcontrollers and the actual position and current feedback from the EPOS2 motor controllers.

6– **Two EPOS2 controllers** control the movement of the electric motors based on velocity and profile inputs from the computer and provide feedback regarding position, velocity, acceleration and current draw.

Two EC 16 60 watt brushless electric motors with hall sensors, coupled with a GP 16 S
 104:1 reduction spindle drive and a position encoder.



Figure 4.1. Diagram of the electronic/control system that runs the UBNGD.

4.2 Actuator Selection

Based on the mechanical design of the system described in Chapter 3, it became evident that an actuator that provides linear motion capable of high forces and high accuracy was going to be needed. The peak force that the actuator powering the ultrasound holder was going to face according to the mechanical considerations was 180 N. This force occurs when the motor tries to counteract a 10 N force applied at the tip at the initial or closed position of the ultrasound holder. However based on Equation 3.1, this force would decrease considerably as the jaw opens. A 10

N force generates an 810 mNm torque. The force needed from the motor to counteract this torque, based on the diagram presented in Figure 4.2 is:

$$F_1 = \frac{\tau}{Y\cos\theta + X\sin\theta} \tag{4.1}$$

As a reference, the force needed from the motor to counteract 10 N at the tip was calculated at several positions: 180 N when $\theta = 0^{\circ}$, 99 N when $\theta = 10^{\circ}$, and 44 N when $\theta = 45^{\circ}$. It is also important to consider that 10 N at the tip was estimated as a peak mechanical force, not a force that would be encountered constantly during normal operation. For the motor selection purposes, maximum constant forces of 99 N with peaks of 180 N were considered.



Figure 4.2. Diagram of the ultrasound mechanism.

Other considerations for the actuation system were high precision and a stroke length of at least 12 mm for each of the motors. The desired velocity of the motors would need to be at least large enough to allow the user to move the device through its complete range of motion in about 10 seconds, which results in an average linear speed of about 1.2 mm/s. However, in order to keep the rotational motion of the ultrasound holder and the needle guide constant, the linear speed of the motor would have to vary, moving more slowly near the closed position and faster near the open position, so faster speed capabilities would be desirable.

The characteristics of high force, high precision, yet relatively slow speed led to the selection of a leadscrew/ballscrew type of drive with a high ratio gearbox coupled with an

electric motor. The Spindle Drive GP 16S by Maxon Motors was selected [98]. The characteristics of the selected spindle drive are outlined in Table 4-1.

Table 4-1 Comparison of the requirements for the UBNGD vs. technical capabilities of the Maxon
GP 16S Spindle Drive.

	Required Value	GP 16S
Max. Static Axial Load	180 N	500 N
Max. Feed Force (Intermittent)	180 N	403 N
Max. Feed Force (Continuous)	99 N	184 N
Feed Velocity	1.2 mm/s	3.8 mm/s (at 12,000 rpm input)
Mechanical Position Accuracy		44 μm
Max. recommended input speed		12,000 rpm
Reduction		104:1
Number of stages		3
Lead		2 mm
Max. efficiency, including spindle		71%
Weight		61 g
Average backlash, no load		2°
Mass inertia, gear head + spindle		.05 gcm ²
Spindle length		120 mm (cut to 59 mm)

Based on the reduction, lead, efficiency and other parameters, it was calculated that the motor required to achieve the desired speeds and forces would have to provide a torque greater than 0.87 mNm and ideally be capable of speeds up to 12,000 rpm. The spindle drive was paired with an EC 16, 60 watt brushless electric motor [99] with a 512 pulses-per-revolution encoder. Some of the characteristics of the EC 16 motors are outlined in Table 4-2.

 Table 4-2 Characteristics of the Maxon EC 16 motors.

Power	60 watt
Nominal voltage	24 V
Nominal speed	39,000 rpm
Nominal current	3.37 A
Nominal torque	17.3 mNm

With a nominal torque over 17 times the minimum required and speed over 3 times the maximum recommended speeds for the spindle drive the EC 16 far exceeded the requirements of the system. Although a less powerful motor could have been selected, the EC 16 was an ideal choice for the motor, as it is available in a sterilizable version — a valuable characteristic for

future prototypes that may be used in vivo trials. With the motor working well below its capabilities, thermal characteristics were not analyzed in detail.

In terms of the positioning accuracy of the system, with a 512 pulses-per-revolution encoder and a 104:1 reduction gearbox, the system would be able to control the position to 1/53,248 of a revolution or 0.00676° . With a lead of 2 mm, this results in a theoretical linear accuracy of $0.037 \ \mu$ m, which is a far exceeds the mechanical accuracy of the system. Furthermore, as with any quadrature encoder, the system is actually able to differentiate movement as small as 1/4 of a pulse, resulting in accuracy up to 4 times higher, making the maximum possible theoretical accuracy of the motor with this encoder of under 10 nanometers.

4.3 Actuator Control

In this system, there is a level of control occurring simultaneously in three places, in order to achieve the desired movement of the motors. First, the PICAXE microcontroller reads the position of the thumbsticks, the state of two buttons and performs an analog-digital conversion of these inputs to build a packet of information that is transmitted to the PC. In the PC, through a program developed in C++, most of the "high level" intelligence takes place, commanding the motor controllers based on input from the microcontroller and feedback from the motor controllers. Finally, low-level control takes place in the motor controllers. The motor controllers perform proportional–integral (PI) or proportional–integral–derivative (PID) control (depending on the operating mode chosen for the motors) following the instructions and parameters set from the computer. Under this scheme, a master–slave configuration from the microcontrollers.

4.3.1 Control Program in the Microcontroller

The PICAXE 28X has an integrated analog/digital (A/D) module that allows it to read analog inputs from most of its input ports. The microcontroller can be programmed to resolve the analog input as a 10-bit value (a 1024 step resolution) or as an 8 bit value (a 256 step resolution). Due to the physical inaccuracies inherent to the thumbsticks, the inability of humans to resolve the
position of the thumb stick beyond 1/256 of a step and the ease of managing a number contained in a single byte, the 8 bit reading was selected. Under this configuration, the microcontroller assigns a value in the range of 0 to 255 that is proportional to an input voltage that ranges from 0 to 5 volts. The thumbsticks used in the prototype provide values from approximately 70 to 215 (the values read from each thumb stick were not identical) when moved through their full range. It was also observed that when released, and they had mechanically returned to their central position, the resulting value for the neutral position could range between 127 and 147.

In addition to the thumbsticks, the microcontroller was connected to two push buttons, one serving as a hard reset to restart the program by cutting and restoring electrical power to the microcontroller and another one programmed to initiate a homing and shutdown sequence.

Figure 4.3 describes the process that happens at the microcontroller, the code used can be seen in Appendix E.



Figure 4.3. Block diagram of the logic at the microcontroller. The # denotes that the ASCII string of the value is transmitted.

The communication of the values happens as a single string because serial communication was by far the slowest process happening in the microcontroller. Originally the program transmitted each of the variable values independently as three serial communication instructions. However, this slowed down the microcontroller to about 4 cycles per second, causing a delay of approximately 250 ms between the user pushing the thumb stick and the motor moving, which was noticeable. By sending all the information as a single string, the system sped up to about 10 cycles per second, reducing the delay to 100 ms, which is essentially unnoticeable.

The communication with the PC was set to be done using a standard serial port protocol with a baud rate of 9600, 8 data bits, no parity, and 1 stop bit, which is the standard communication mode built into the microcontroller's software. Because most modern PCs, especially laptop computers don't have serial ports anymore, a virtual serial port was created with the communication occurring physically through the USB port.

4.3.2 Control Program in the PC (C++ program)

Most of the high level logic behind the semi-automated movement of the motors takes place in a program written in C++ running on a PC. C++ is an object oriented programming language that allows for modular programming, where usually a "main" program calls on functions from other classes to perform functions. This way, different sections of the program can be modified independently without a direct effect on unrelated functions. For this project, three source files were developed. The first one, "TwoMotorMain", contains the main body of the program, the second one, "TwoMotorController", contains the functions necessary for serial communication with the microcontroller. In addition to these files, three header files were used, two where the objects are declared and a third (obtained from Maxon Motors) that includes the definitions for the functions used to control the motors.

Described briefly, the logic of the main function programmed in C++ is the following: First the variables are initialized and three objects are created: "motor0" and "motor1", to control each motor, and "com0" for communications with the microcontroller. Then, the EPOS2 controllers are initialized by setting up communication ports, establishing the zero position of the motors and finally setting them to "Profile Velocity Mode". Next, the communication with the microcontroller is setup. The parameters for the velocity profile are then established, setting both acceleration and deceleration to 20,000 rpm/s. After the initial setup process, the motors move forward slightly to reach the position where $\theta = 0$ at the end effectors. If no error code is received, the program goes into its main loop where communication with the microcontroller takes place and the movement of the motors is controlled.

Inside the main loop, the program starts by communicating with the microcontroller and obtaining the string of values that contains the state of the finalization button and the position of the thumbsticks. The string is converted into a numeric value and then divided into the three components (button, position of thumbstick 1 and position of thumbstick 2). The values of the thumbsticks, which range from approximately 70 to 215, are proportionally converted into desired speeds with 142 set as a speed of 0, any value smaller as a negative speed and values over 142 as positive speeds, using a range that goes roughly from -1,300 rpm to 1,300 rpm. Then the program obtains the actual position of the motors from the EPOS2 controllers. The value received represents the number of "quadrature counts" or qc relative to its initial position. One pulse from the encoder is equal to 4 qc. As a reference, one millimetre of linear motion at the spindle is equivalent to 26,624 pulses or 106,496 qc. The velocity of the motors is linearly adjusted relative to their position to compensate for the fact that the rotational speed of the end effectors is not constant relative to the linear speed of the motors. Because of this linear adjustment, the top speed of the motors can reach approximately 11,000 rpm when the maximum speed is requested by the user and the device jaws are close to their fully open position. At this point the program calculates the position of the end effectors in degrees and displays it to the user. The program then "requests" the average current being drawn from the motors. If the position of the motors and the current drawn is within pre-established boundaries, the motors will move at a speed proportional to the position of the thumbsticks; otherwise, they stop. At this point the program cycles and the speed of the motor is refreshed.

At every loop, the program also tests the state of the finalization button. If it is pressed, the main loop breaks and a finalization sequence starts. The device begins to slowly close itself until it reaches its mechanical limit and a current spike indicates to the control system to stop the motors. This guarantees that the device will always return to its "zero" position before it is powered off. After the zero position is reached, the program disables and closes the EPOS2 controllers, closes the serial port that was used to communicate with the microcontroller and finally closes itself.

Other than the main function, the program uses 6 other functions that belong to the "TwoMotorController" class and 3 functions that belong to the "SerialCom" class. These functions contain the details needed to perform the control of the motors and the serial communication with the microcontroller. The logic used in the main function of the C++ program is described in Figure 4.4. The code and the details regarding the program can be found in Appendix F.



Figure 4.4. Block diagram of the main function used in the C++ code for the UBNGD

4.3.3 Motor Current Limit

An important feature of the control program that is covering in more detail is the current limit imposed on the motors. As described in the previous section, the motors can generate up 17 times the needed torque if pushed to their maximum. With a factor of safety of only two for many mechanical components, the motors could easily destroy the device if they are pushed beyond their intended operation. In "ProfileVelocityMode", which is the control mode used in this device, the motor controllers always try to maintain the velocity of the motors to be as close as possible to the velocity requested by the user. If the motors encounter a load, the controller will draw more current as needed to maintain a constant velocity. However, in the program developed for the UBNGD, at every loop, the computer requests a current reading from the controllers. If the average of the current reading and the previous reading exceeds 400 mA, the system immediately stops the motors and warns the user who will have to acknowledge the warning before being able to move the motors again.

As a reference, the "no-load" current of the motors is 167 mA (at 39,000 rpm) and their rated maximum continuous current is 3.37 A. For the validation tests discussed in Chapter 5, a 400 mA limit was used, allowing the system to lift approximately up to 500 grams (which translates a force of approximately 5 N) at the tip of the ultrasound transducer without stopping. This limit can be easily modified within the C++ code to allow for looser or stricter force regulation depending on the needs of the user. For testing and validation of the mechanical limits of the system, higher current limits were used to allow for testing with 10 N of force at the tip of the US transducer. For the finalization routine, a limit of 190 mA is used since no additional external loads are expected while the system is shutting down, allowing for a more "sensitive" detection of the mechanical limit of the movement.

4.3.4 Proportionality of Motor Speed Relative to the Position of the Motors

Another important feature of the control program is that the speed of the motors is adjusted relative to the position of the linear drive. Because of the mechanical design of the device, the

rotation speed of the end effectors is not constant relative to the linear speed of the lead-screw connected to the motor.

In the earlier versions of the C++ program used to control the velocity of the actuators of the UBNGD, the instantaneous velocity sent to the motor controllers was proportional to the position of the thumbsticks. If the user requested maximum velocity by pushing the thumbstick to the end of its range, the motors would spin at 1,300 rpm; if a slower speed was desired, the user would have to move the thumbstick a fraction of its full range. This approach allowed for a constant linear velocity at the motor's spindle drive and the rods that transmit power to the actuated tip; however, because of the design of the device, a constant velocity at the rods did not translate into a constant rotational speed of the ultrasound jaw and needle guide.



Figure 4.5. Profile of the ultrasound jaw when opened to 25°.

Based on Figure 4.4, the angular position θ of the ultrasound holder is equal to inverse sine of the vertical component of the length of the link over the length L_{US} :

$$\theta = \sin^{-1} \frac{L_{\rm y}}{L_{\rm US}} \tag{4.2}$$

 L_y by the Pythagorean theorem can be calculated as:

$$L_Y = \sqrt{(L_L^2 - L_X^2)^2}.$$
 (4.3)

 L_X is equal to the length of the link L_L minus the linear distance that the motor has moved forward (L_1). Therefore, the angular position of the ultrasound jaw (θ) relative to the linear displacement of the motor (L_1) is:

$$\theta = \sin^{-1} \frac{\sqrt{L_{\rm L}^2 - (L_{\rm L} - L_1)^2}}{L_{\rm US}}$$
(4.3)

By substituting $L_{\rm L} = 12.14$ mm and $L_{\rm US} = 21.5$ mm, which are constant values, the Equation 4.3 can be simplified to:

$$\theta = \sin^{-1} \frac{\sqrt{24.28 L_1 - L_1^2}}{21.5}$$
(4.4)

It becomes evident that the relation between θ and the linear displacement of the motors, and therefore the relationship of the angular velocity of the ultrasound jaws and the linear velocity of the motors, is non-linear. For example, in a motor movement from the linear position 0 mm to 0.25 mm, the ultrasound jaw rotates 26° per mm of motor movement (0.45378 rad/mm) compared to a relationship of 1.1 deg/mm (0.01919 rad/mm) around the linear position of 8 mm. However, it is important to provide the user with an angular velocity that feels constant to make the device easier and more intuitive. Using a sinusoidal equation to provide a perfectly constant rotational speed turned out to be impractical as the function produced speed values above the 12,000 rpm mechanical limit of the spindle drive when targeting a rotational velocity of 4°/sec (0.069 rad/s) close to the open position. Furthermore, when the device was tested using the sinusoidal "adjustment" it felt as if the movement started out too slow. Therefore a linear relation was used that produced angular speeds near 4 deg/sec throughout most of the movement range, with slightly faster angular speeds at the beginning and slightly slower speeds when the ultrasound jaw was almost fully open.

Instead of setting 1,300 rpm as the maximum speed that could be requested by the user, the maximum speed, ω_{max} , was established as a function of the current linear position of the rods, as described in Equation 4.4:

$$\omega_{\rm max} = 52 L_1 + 650. \tag{4.4}$$

In this case, the values are scaled to the values used in software; 1 mm of linear displacement is equal to 21.37 units (L_1) and the angular velocity (ω) is given in rpm. For example, with the user pushing the thumbstick to the maximum, with the device at its closed position or ($L_1 = 0$) the motors would move at 650 rpm. As the device moves, this velocity is dynamically adjusted. For example, by the time the ultrasound jaw's motor has moved 4 mm ($L_1 = 85.5$), if the user is still pushing the thumbstick to the maximum, the motor would move at 5,095 rpm. By dynamically adjusting the speed of the motors based on their position, a more constant rotational speed of the ultrasound jaw and needle guide is obtained.

Figure 4.6 shows a comparison between the angular velocity of the ultrasound jaw along the linear range of movement at a constant motor speed of 1,300 rpm and at the variable speed obtained from Equation 4.4.



Figure 4.6. Angular speed at which the ultrasound would move if the maximum speed of the motors was left constant at 1,300 rpm (left) vs the angular speed at which the ultrasound moves using the profile used in the C++ code.

From the graphs in Figure 4.6, it can be seen that a relatively simple linear adjustment to the speed of the motors proportional to the position of the motor results in a fairly constant speed that is close to 4 deg/sec at the ultrasound jaw throughout most of its range of motion (which is close to 34°). If the speed of the motor was left at a constant speed of 1,300 rpm, a huge spike at

the initial angular velocity of the ultrasound is observed, followed by a very steep decline and very low speeds through most of the range of motion.

A similar analysis was performed on the needle guide; however, its angular velocity was set close to 2.5 deg/sec since its angular range of motion is smaller (close to 19°). This allows for both parts to move through their range of motion in a similar amount of time. It takes approximately 6 seconds for the ultrasound jaw and needle guide to move through their range using the current settings.

4.3.5 Low Level Control using the EPOS2 Motor Controllers

The low level control for the motors occurs within the EPOS2 Motor Controllers and it happens automatically based on the parameters preset by the user and the target velocities and accelerations requested by the C++ program. In order for the controllers to perform their function, the user has to first input specific information about the hardware being used, such as the type of motor, maximum speed and current, encoder resolution, etc. The regulator gains are then tuned—this can be done automatically by the system or the values can be input by the user; for this work, the automatic option was used.

The controller has many options in terms of motion control based on position, velocity or current control. The UBNGD is programmed to operate using the "Profile Velocity Mode". The profile velocity mode receives data from a high level controller, such as the C++ code or the EPOS GUI, including the desired velocity, acceleration, and deceleration. This data is used to automatically determine the necessary current to make the EC motor move with the desired characteristics using a profile velocity trajectory generator.



Figure 4.7. EPOS profile velocity mode [100] – the target velocity is fed dinamically by the computer, other parameters are set during the initialization sequence of the program.

The target velocity is fed to the controller in rpm, the acceleration in rpm/s and, if other modes are being used, the target position is fed in qc and the current in mA. In the final version of the software used for the UBNGD, the acceleration and deceleration were set to 20,000 rpm/s and the velocity varies dynamically according to the user input and position of the motors according to the description of the velocity control outlined in Section 4.3.4. The acceleration of 20,000 rpm/s was selected empirically through device testing; a slower acceleration gives the sensation of delay and slow response, and higher accelerations result in larger current spikes. Based on these inputs, the profile velocity generator creates a velocity profile which by default is trapezoidal.

The controller has predefined Proportional-Integral (PI) and Proportional-Integral-Derivative (PID) control schemes for the different motion options available. The profile velocity mode uses a PI control scheme.

4.4 Conclusions

In the end, the UBNGD has an easy and intuitive control system that should allow clinicians to guide the direction of a needle with high accuracy, without the need for complex or expensive systems such as robots. The two thumbsticks provide the user with simple one-handed control of both end effectors, allowing variable speed control for precision and convenience. The multi-level semi-automated control system includes user safety features to guarantee that the movement of the device will not exceed its intended range and prevents mechanical loads that

may damage the components, while adjusting the motor speed to achieve a smooth and constant angular velocity at the end effectors.

Chapter 5

5. Prototype Testing and Validation

5.1 Introduction

In this chapter, the performance of the system is explored in order to assess the capabilities of the design and to obtain input from users, in an effort to identify its strengths and areas for improvement. The testing and validation of the device consisted of gathering information in two main areas: 1) Evaluating the capabilities of the device from the perspective of potential users and 2) evaluating the mechanical design.

To test the functionality and accuracy of the UBNGD, two trials were conducted, one involving 12 novices and the other one involving 4 expert volunteers using the device on a setup using a chest cavity model built from acrylic to simulate MIS conditions and a phantom comprising small targets set inside agar gel cubes to simulate tissue. The novice and expert volunteers were asked to guide the tip of a needle as close as possible to a set of targets using the proposed device, additionally, the novices were asked to perform the same task without the device, using only an ultrasound probe and video from an endoscopic camera. Through these tests, data was gathered to statistically analyze objective information such precision and time to task completion. In addition, subjective feedback was gathered regarding issues such as ease of use and comfort in order to help future prototype development.

From the mechanical perspective, the UBNGD was tested by pushing to its theoretical mechanical limits in order to validate the design. A test that involved lifting a 10 N load applied to the tip of the ultrasound jaw was performed to test whether the prototype was able to manage the loads that it was designed to handle.

5.2 Preparations and Developments for the User Trials

Before the trials could be run, a few issues had to be resolved. The first challenge was the fact that the design needed a wide yet very flexible needle to function correctly. Second, a way to precisely measure the accuracy of the placements of the tip of the needle relative to the targets was needed. Finally, it was also determined that the users required an easy and intuitive way to estimate the path of the needle at any combination of positions of both the ultrasound transducer and the needle guide.

5.2.1 Developing a "Flexible Needle"

The design of the UBNGD requires a needle that has an inner diameter of over 2 mm to accommodate the passage of a 6 F catheter, is longer than 50 cm to go through the device, and is to be sturdy enough to be able to puncture tissue without breaking or bending too much, yet is flexible enough to bend with the device. Standard LDR brachytherapy needles are flexible enough, but not nearly wide or long enough for the needs of the device. Ablation needles are not long enough or flexible enough to work on the device. Therefore a custom-made needle would have to be used.

Stainless steel tubes of different diameters and wall thicknesses were tested for the device. Tubes with thin enough walls could be bent with forces within the design capabilities of the UBNGD; however, pushing them in and out was difficult, due to friction and the bending forces involved. Another problem was that the tubes became permanently deformed which would affect precision. The shape memory alloy Nitinol (nickel titanium alloy) was also tested. Nitinol was easier to bend and retained its shape without being permanently deformed, however, the forces needed to push it in and out of the device on an angle were too big to be a practical solution. Plastic materials such as polypropylene tubing were also explored, on their own and in attempts to add plastic sections to steel tubes to produce needles with both flexible and sturdy sections. In the end, this approach was abandoned due to the need for custom-made tubes sizes that required a minimum order of several hundred metres, which was impractical and

economically unfeasible as only a few centimetres were required. Furthermore, we lacked the technical capabilities to fuse polypropylene sections into a metallic tube.

Finally, a solution was found based on the recommendation of a research colleague. It was suggested that by making small cuts in the tubes, a somewhat spring-like section of the steel tube that would be flexible enough to bend with the device could be produced. A wire EDM (electrical discharge machine) was used to cut the profile of the needle in an attempt to make it more flexible. A stainless steel tube with an OD = 2.41 mm and ID = 2.16 mm was selected and a pattern consisting of 0.9 mm equilateral triangles was cut out of the top and bottom of the tube.



Figure 5.1. Lateral view of the model used to cut out a pattern on a stainless steel tube to make it more flexible.

The profile successfully made the needle more flexible and easier to push forth and back through the device with the needle guide open at an angle. Unfortunately, this profile was still not ideal as it remained deformed after use and after several cycles of bending and stretching, it broke.



Figure 5.2. Photograph of the stainless steel needle with a pattern cut out to make it more flexible.

In order to improve this performance, 5 other patterns were tested, 2 of which were based on the original pattern, but using different sizes and distribution of the triangular cut-outs and the other 3 patterns based on patterns observed in another metallic device designed to be flexible. Two of those patterns broke after repeated cycles of bending and stretching and another one was considered too soft. Therefore, the two remaining patterns behaved in a very similar way and were deemed appropriate to be used in the trials. They offered the required flexibility, showed no visible permanent deformation and had very low material stress, which reduces the risk of it breaking after repeated normal use.



Figure 5.3 Profile used to make the needle flexible as used in the trials.



Figure 5.4. Alternate profile used to make the needle flexible.

Once the profiles were selected, two stainless steel tubes with a OD = 2.41 mm and ID = 2.16 mm were cut to a length of 54 cm and a 70 mm long profile was cut into each, at a distance of 65 mm from the tip of the tube. Finally a 45° bevel cut at the tip was made in order to make the tubes sharper and to better resemble the needles used in clinical settings. Although both needles performed very well when tested on the device, at the end, only the pattern shown in Figure 5.3 was used for the trials to guarantee uniformity while testing. For the manual (VATS setting) comparisons, straight tubes (without any profile cut into them) were used as the added flexibility would only make the manual procedure more difficult.



Figure 5.5. 45° bevel tip used on the needles for the trial.

5.2.2 Accuracy Measurement

Unlike LDR brachytherapy, where seeds are deposited into a target and then have the distance from seed to target measured, in HDR brachytherapy or biopsies no object is left behind to facilitate a measurement. Therefore, a system that allows the position of the needle tip and the targets to be determined is necessary. For this, the Aurora system by NDI proved to be a very useful tool. The Aurora is an electromagnetic tracking system designed especially for medical applications that can track the position of millimetric seed-like sensors in 3D space with an accuracy of just under 0.6 mm.

For the validation trials conducted as part of this work, 4 sensors were used simultaneously; 1 was placed at the tip of the needle and 3 others were placed inside the agar gel attached to 3 mm metallic spheres used as targets. The subjects were instructed to use ultrasound imaging to find the targets contained within the gel and then to try to put the tip of the needle as close as possible to the targets fitted with the Aurora sensors. When the subject expressed that they believed they had reached the target, the coordinates of the sensors were saved and used to estimate the distance between the tip of the needle and the target.

Because the standard software included did not have the functionality that was needed for the trials, a program was developed using C++. This program was developed to save the coordinates of the sensors and a time stamp into a text file at the press of a button. The Aurora system by default locates the 3D coordinates of the centre of the 8 mm long sensor, however, because the coordinates of the tip of the sensor located at the tip of the needle are required, the program also displaces the coordinate system 4 mm towards the tip of the sensor to better represent the position of the needle tip.

5.2.3 Position Display for the User

Once the device goes into the chest cavity, it becomes impossible to directly see the position of the ultrasound jaw and needle guide of the UBNGD. Therefore, it became important to provide the user with information to allow him/her to estimate the path that the needle takes in different

configurations. To this end, three functions were added to the program to allow it to calculate and display the angle of the ultrasound, the angle of the needle guide and an estimate of the linear distance from the ultrasound transducer at which the needle would cross at the middle of the ultrasound image.



Figure 5.6. The display shown here to the right, instantly displays the angle and distance information to the user.

5.3 Experimental Setup and Protocol – User Trials

With the goal of evaluating the accuracy of the prototype, an experiment was designed to allow us to measure in 3D space the position of a series of targets and the tip of the needle guided by the device. In addition to accuracy and precision measurements, the time to task completion was measured and the ease of use was evaluated through a questionnaire.

5.3.1 Experimental Setup

In order to obtain accuracy measurements for the device and to simulate conditions similar to the ones that would be faced by a clinician during laparoscopic surgery, the setup shown in Figures 5.7 and 5.8 was utilized. The setup consists of the following components:



Figure 5.7 Experimental setup. See text for description of annotations.



Figure 5.8. Experimental setup as seen inside the thoracoscopic box.

- 1– Ultrasound display including and depth scale on screen.
- 2- Laparoscopic camera display.
- 3- Display with the device position information for the user including the angular position of the ultrasound guide, needle guide and estimated depth at which the needle would show up in the ultrasound display in the current configuration.
- 4– Laparoscopic camera with a 30 degree view angle.
- 5– Ultrasound probe. The probe is attached at the front to the device, keeping it aligned and at a fixed position with respect to the ultrasound jaw at all times. The ultrasound probe is not necessary for normal operation of the device as its design includes an ultrasound transducer; however, the custom transducer was not available for the tests reported herein.
- 6– UBNGD.
- 7– Plexiglass thoracoscopic surgery training box, which models the thorax of a patient and blocks the direct line of sight of the user in order to simulate MIS conditions.
- 8– Workspace. The agar gel cubes with the targets are held in place at the bottom of a container filled with water. The water was necessary for quality ultrasound images, as the ultrasound probe sits almost 1 cm above the ultrasound jaw when the jaw is in contact with the agar gel.
- 9– The Aurora tracking system was placed under the thoracoscopic surgery training box.
- 10– Actuated tip of the device.
- 11– Plastic part holding the device and the ultrasound probe together.
- 12– Endoscopic ultrasound probe.
- 13- Agar gel cube with 3 targets and Aurora sensors embedded in the cube.

Within the submerged workspace, three metallic spheres 3 mm in diameter were fixed, each 4 mm from the tip of an Aurora sensor placed within a plastic sleeve (the centre of the coordinate system of the sensors is 4 mm from their tip). The spherical targets and associated sensors were placed within the agar gel at random positions and depths for the trials. The agar gel was cut into cubes of approximately 10 cm length by 4 cm depth and 3 cm width. The agar gel was held in place by a piece of wood with two metallic hooks nailed to the bottom of the water receptacle. A piece of white wood shown in Figure 5.9 (right) was added to the back to help keep the agar from being dislodged from the hooks.



Figure 5.9. Shows a metallic target attached to the Aurora sensor (left) and the sensors within the agar gel as used for the trials (right).

It is important to mention that the ultrasound probe was fitted for the trials only because the custom-made ultrasound transducer that should be contained within the device was not implemented in this early stage due to cost and time constraints. In reality, a procedure with the UBNGD should only need two ports: one for the laparoscopic camera and the other for the device. Furthermore, the trials were first attempted without being submerged in water by filling the space between the ultrasound probe and the device with agar gel, but the ultrasound image turned out to be of very poor quality, so the setup with the device submerged in water was chosen.

5.3.2 Experimental Method

Two similar trials were conducted, the first one with 12 novice users and the second one with 4 expert users. Expert users were surgeons or residents invited to test the device and novice users were those without any formal medical training.

After the consent form was signed, the participants were instructed as to how the UBNGD works and were taught how to interpret the ultrasound images in order to identify the targets. The participants were instructed to try to touch the targets with the tip of the needle or at least try to get it as close as possible to the target. Once the participant thought that he/she touched the target or got as close as possible to it, they were instructed to stay still and verbally

express that they had reached the target so that the coordinates of the sensor in the tip of the needle and the sensors in the agar gel could be recorded. The participants were unable to feel when the needle reached the target, however in many cases, the contact could be observed in the ultrasound image as the target moved due to the contact with the needle. The participants were allowed to introduce and pull back the needle as many times as they felt was necessary to reach the target. They were told that the accuracy of the positioning was to be recorded as well as the time it took them to reach each target.

At the beginning of the trial, the participants were given unlimited time to practice with one agar gel cube containing three targets. During the practice time, nothing was recorded and they were given constant instructions and feedback regarding the use of the device, interpretation of ultrasound images and their accuracy in their attempts to hit the targets. The target could be identified in the ultrasound image as a shiny circle with a long shadow below it and often the Aurora sensor was also visible as a line under the target. The participants were asked to touch the target, not the sensor.



Figure 5.10. Ultrasound image of one spherical metallic target.

Participants were instructed to first scan the gel from side to side in order to identify the targets in the ultrasound. Once a target was identified, they were asked to use the device's displayed distance, as shown in Figure 5.6, to set the depth of the needle according to the depth shown to the left of the ultrasound image, push the needle forward and if needed, fine tune the direction visually.



Figure 5.11 Ultrasound image showing the needle approaching a target.

Once the participant felt ready to start the trials, they had to reach 3 targets with the tip of the needle in each of 3 agar gel cubes, for a total of 9 data points. Once the trial started there was no more feedback given to the participants regarding his/her accuracy and positioning; however, questions regarding the interpretation of ultrasound images were answered. Each time the participant expressed a target had been reached, the 3D coordinates of all sensors (3 targets + 1 at the tip of the needle) were saved. Using the translational and rotational coordinates of the 6-DOF electromagnetic sensor at the tip of the needle and a transformation matrix within the C++ program, the coordinates for the needle were shifted 4 mm towards the tip of the needle in order

to obtain needle tip location instead of the coordinates of the centre of the 8 mm sensor. The system was also setup to shift the Z coordinates of the target sensors 2 mm upwards in order to place the coordinates at the centre of the target instead of the centre of the sensor. After the trial was finished, the coordinates were used to calculate the distance from the tip of the needle to the targets. At each data point, the target closest to the needle was saved and the coordinates of the other two sensors were discarded. The system also recorded a date and time stamp on each measurement. This time stamp was used to calculate the time it took the participants to go from the first to the second target and then from the second to the third target.

In order to obtain some comparison data, the novice users were also requested to perform the same task without the device. With aid of the ultrasound probe and the laparoscopic camera they were asked to manually guide the needle into the target in a setup meant to resemble videoassisted thoracoscopic surgery (VATS). As before, they could first practice for as long as they needed and then 9 measurements were taken from 3 gel cubes each with 3 targets. The needle used for the manual task was of similar diameter and length to the one used with the UBNGD, but without the flexible section. In order to avoid any bias, in an alternating manner, half the participants performed the test with the UBNGD first and half the participants performed the manual test first.



Figure 5.12 Trial performed manually on a VATS setup without the device.

Once the users completed the trials they were given a questionnaire to assess their experience. They were asked to rate from 1 to 5, with 5 meaning that they completely agree and 1 that they completely disagree, the following items regarding their experience with the device:

- Ease of use of the device
- Accuracy provided by the controls
- Comfort and ergonomics of the device
- Size of the handle of the device
- Weight of the device
- Whether they felt that the device provides an advantage vs. manual placement
- Range of movement
- Speed

They were also asked to provide open feedback regarding:

- The controls
- Ergonomics
- Functionality
- Best qualities of the system
- Qualities that need improvement

5.3.3 Variations in the Setup and Method for the Experts' Trials

After the trials performed with novice users were completed, another set of trials were conducted with 4 expert participants. Although this trials were conducted using the same basic setup, there were some variations in the experimental method.

1– The experts only conducted the trials with the device; they did not perform the manual (VATS) placement of the needle. This was decided because performing lung brachytherapy using hand–guided needles is not a standard medical procedure and because this way, the results obtained with expert users could be better compared to results found in other publications.

2– The number of attempts to get the needle in place was counted in order to obtain data that would be comparable to other similar studies [101, 102]. Counting the number of attempts with novices turned out to be impractical and too subjective due to the wide variation in how they manipulated the device.

3- Three open questions were added to the end of the questionnaire: the first one regarding the possibility of the device being adopted by clinicians and changes necessary for the device to be used on patients. The second question inquired whether the device could indeed aid in a lung HDR procedure and whether the device could be used for other procedures. Finally, space was provided for general comments from a medical perspective.

4– Considering the discomfort and difficulties observed during the novices' trials with the ultrasound probe and following a recommendation from a clinician, the ultrasound probe and the device were held together by their handles, making the system heavier but more stable.



Figure 5.13. Experimental setup used in the trials with experts.

Because of these changes, the data gathered from experts will be handled as an independent study from the novice trials.

Novice and expert trials were conducted under an appropriate ethics protocol (file 103761).

5.4 User Trial Results

5.4.1 Novice Trials

With the UBGND, a total of 108 measurements from 12 participants were taken. Out of these measurements it was decided that the results obtained from one of the participants had to be

eliminated as it was considered that this participant was a statistical outlier. This participant was clearly unable to perform the tasks correctly with the manual (VATS) setup, with a mean accuracy of 17.55 mm compared to 5.46 mm of the second least accurate participant. Furthermore, all of the outlier participant's 9 measurements were within the 10 least accurate measurements. The following analysis and discussion is based on the elimination of the outlier participant's results from both the device and manual trials (although the results with the device were in line with other participants).

Regarding the accuracy obtainable with the device, measuring the distance from the tip of the needle to the centre of the target, the results indicate a mean of 3.46 mm, a median of 3.42 mm and a standard deviation of 1.42 mm. The most accurate participant had a mean distance to the target of 2.70 mm and the least accurate participant had a mean distance of 5.39 mm. To assess timing, the time that it took the participants to go from the first target to the second target and then from the second to the third target of each gel cube was recorded. Six measurements were recorded from each of the participants for a total of 66 measurements from the 11 valid participants. Out of these 66 measurements, 2 measurements were further discarded as statistical outliers¹. Of the remaining 64 measurements, a mean of 71 s, a median of 59 s and a standard deviation of 50 s was calculated. The fastest participant had a mean of 28 s and the slowest participant a mean of 158 s.

Without the device, using a VATS procedure, 99 measurements from the same 11 participants were recorded. For accuracy, a mean distance of 3.82 mm, a median of 3.29 mm and a standard deviation of 2.27 mm were obtained. The most accurate participant had a mean distance to the target of 1.96 mm and the least accurate a mean distance of 5.46 mm (the outlier had a mean distance of 17.55 mm). For timing, with a total of 65 measurements (66 minus one outlier¹) a mean of 62 s, a median of 44 s and a standard deviation of 48 s was observed. The fastest participant had a mean of 32 s and the slowest participant had a mean of 160 s.

¹ In total, 3 time measurements (2 from the device test and 1 from the manual test) of over 5 minutes were discarded as outliers. In all 3 occasions this was caused by the agar gel becoming dislodged from its position and the time it took to re-set it in place.

	Accuracy, distance to centre of target (mm)					Time between targets (seconds)					
	Mean	Median	Std.	Most acc.	Least acc.	Mean Median		Std.	Fastest	Slowest	
			dev.	participant	participant			dev.	participant	participant	
Device	3.46	3.42	1.42	2.70	5.39	71	59	50	28	158	
Manual	3.82	3.29	2.27	1.96	5.46	62	44	48	32	160	
(VATS)											

Table 5-1 Summary of results obtained with the novice trials

With the device we obtained marginally better results in terms of mean accuracy but marginally slower times between targets. In order to establish if these results are statistically significant, a one-way analysis of variance (ANOVA) was performed using an online calculator [103]. The calculation returned a *p*-value of 0.183 for accuracy and of 0.299 for time. In both cases, this indicates that the variation in the results is not statistically significant.

As a reference, if we consider the measurements from the participant that was considered an outlier, with the device we get a mean distance to target of 3.62 mm with a standard deviation of 2 mm and with the manual (VATS) setup a mean of 4.97 mm with a standard deviation of 4.81 mm.

With this first prototype of the UBGND, the obtained results are very similar to those that can be achieved manually in terms of accuracy and time. However, a significantly smaller standard deviation and the fact that, unlike the VATS setup, all of the participants were able to correctly perform the task indicate that the UNGND enables more precise results with better consistency, regardless of the skill of the participant.

In order to better illustrate the precision of the device, for each of the data points, the distance in the X axis, the distance in the Y axis and the distance in the Z axis from the tip of the needle to the target was also calculated. By plotting these distances in 2D scatter plots, as shown in Figures 5.15–5.17, the distribution of the targeting points relative to the target itself can be visualized. On the setup used for the trials, the X axis represents the left-right movements of the user, the Y axis the forth and back movement and the Z axis the up and down movements.



Figure 5.14. 3D coordinate system of the Aurora as used in the trials.

In Figures 5.17–5.19, the points represent the position of the needle at each of the 108 recorded points relative to the position of the target (which is located at the origin of each chart).



Figure 5.15. X-Y scatter plot of the recorded points relative to the target for the manual (VATS) trial (left) and the trial with the UBGND (right). Axes indicate distances in mm.



Figure 5.16. Y-Z scatter plot of the recorded points relative to the target for the manual (VATS) trial (left) and the trial with the UBGND (right). Axes indicate distances in mm.



Figure 5.17. scatter plot of the recorded points relative to the target for the manual (VATS) trial (left) and the trial with the UBGND (right). Axes indicate distances in mm.

The results obtained with the UBGND clearly show more consistent results regardless of the user's skill, with virtually no outliers.

5.4.2 Novice Users Feedback

Once they finished with the trials, the novice users were asked to rate from 1 to 5 (1—strongly disagree to 5—strongly agree) a number of statements regarding the device. The results that were obtained are reported in Table 5-2.

	No of times the option was selected:				tion	Mean	Comments	
	1	2	3	4	5			
The controls of the device are intuitive and easy to use			1	5	6	4.42		
The controls provided the accuracy needed to accomplish the tasks performed			2	8	2	4.00		
The handle feels ergonomic and comfortable		1	3	7	1	3.67		
The size of the handle is appropriate for your hands			4	3	5	4.08	Too big(2)	
The device is light enough to hold and maneuver easily		4	6	1	1	2.92	Too heavy (2)	
The device provides an advantage when guiding the needle compared to manual placement					12	5.00		
The range of movement of the ultrasound and needle guides is sufficient				4	8	4.42	Too narrow(1) Too wide (1)	
The speed of movement is adequate				3	9	4.75	Too slow (2)	

Table 5-2. Feedback from questionnaire given to novice users.

The feedback that was obtained from the open-ended questions is reported in Table 5-3.

Note that, the answers provided by the participants have been paraphrased and grouped together.

Table 5-3. Comments from novice users to the open questions on the questionnaire.

Positive Feedback (No. of mentions)	Negative Feedback/Recommendations (No. of mentions)					
 Easy to use/easy controls (11) The angle of the needle can be controlled/accuracy of needle placement (8) Easy to find the needle in the US image/Needle is aligned with the device (5) Great/useful to have the depth information (4) Adequate size (2) Easier with the device than done manually (2) Is ergonomic (2) Enjoyed using the device (2) Good range of movement 	 Too heavy (8) Having the ultrasound not integrated with the device was problematic (8) There should be a way to hold the device in place once the target is found (3) Controls hard to reach/position control sticks elsewhere (3) Device is too big/bulky (2) Please put all the information in just one screen Add tremor reduction Controls were confusing Difficult/awkward to push the needle 					

5.4.3 Experts Trials

With the UBGND, a total of 34 measurements from 4 participants were analyzed (9 measurements from each of the 4 participants, minus 2 skipped readings, as will be explained below). Accuracy results, with the distance measurements from the tip of the needle to the centre of the target, show a mean of 2.44 mm, a median of also 2.44 mm and a standard deviation of 0.88 mm. The most accurate participant had a mean distance to the target of 1.87 mm, and the least accurate participant a mean distance of 2.76 mm. To assess timing, the time that it took the participants to go from the first target to the second target and then from the second to the third target of each gel cube was recorded. This resulted in a total of 22 measurements, 6 from every one of the 4 participants, minus two skipped readings. Out of these 22 measurements, a mean of 50.2 s, a median of 38 s and a standard deviation of 29.1 s was calculated. The fastest participant had a mean of 31.8 s and the slowest participant a mean of 80.2 s.

As expected, the expert users achieved better accuracy and shorter times. This can be attributed mostly to their better interpretation of ultrasound images and their familiarity with similar devices for MIS procedures.

It is important to mention that two readings from one expert user could not be taken because the agar gel became completely destroyed before reaching the third target on two occasions. This was due to excessive pressure being applied on the gel with the ultrasound transducer and by constantly repositioning the needle while extended, which essentially cut through the agar.

The number of attempts required to hit the target were also recorded, with the exception of one expert participant who on several occasions reached the target by "cutting" through the agar with the needle instead of retracting and repositioning after a failed attempt. Thus, out of a total of 27 targets from 3 experts, by counting the number of attempts to reach each target, a mean of 1.22 and a median of 1 was observed. Overall, out of the 27 targets, the target was reached on the first attempt in 21 occasions and on 6 occasions the target was reached on the second attempt.

	Acc	uracy, dist	ance to	Time	e between	targets	Number of attempts to hit		
	cent	er of targe	t (mm)		(seconds))	target		
	Mean	Median	Std dev	Mean	Median	Std dev	Mean	Median	
Device	2.44	2.44	0.88	50.2	38	29	1.22	1	

Table 5-4. Summary of results obtained from the experts trials.

As with the novice trials, for each of the data points, the distance in the X axis, the distance in the Y axis and the distance in the Z axis from the tip of the needle to the target was calculated. All these distances were plotted in on 2D scatter plots, Figures 5.18–5.20, which illustrate how the targeting points are distributed relative to the target itself. Note that, the scale in these plots is very different to the scale used to present the data from the novice trials.



Figure 5.18 X-Y scatter plot of the recorded points relative to the target with the device. Axes indicate distance in mm.


Figure 5.19. Y- scatter plot of the recorded points relative to the target with the device. Axes indicate distance in mm.



Figure 5.20. X-Z scatter plot of the recorded points relative to the target with the device. Axes indicate distance in mm.

It can be observed that in the experts trials there aren't any statistical outliers and that the measurements are all packed together very closely. A clear bias in the Y axis of about 1.5 mm can also be observed. This can be explained by the fact that most experts were capable of hitting the target with the needle directly from the front, leaving the tip of the needle in fact 1.5 mm away from the centre of the target (which were metallic balls with a radius of 1.5 mm).

5.4.4 Expert User Feedback

The expert users, as with the novices, were asked to rate from 1 to 5 (1—strongly disagree to 5—strongly agree) a number of statements regarding the device. The results that were obtained are reported in Table 5-5.

	No of times the option was selected:			tion	Mean	Comments	
	1	2	3	4	5		
The controls of the device are intuitive and easy to use				3	1	4.25	
The controls provided the accuracy needed to accomplish the tasks performed			1	1	2	4.25	
The handle feels ergonomic and comfortable	1		2		1	3	Separate US uncomfortable (1)
The size of the handle is appropriate for your hands			1	1	2	4.25	Too Small (1)
The device is light enough to hold and maneuver easily	2				2	3	Too heavy (1)
The device provides an advantage when guiding the needle compared to manual placement			1	1	2	4.25	
The range of movement of the ultrasound and needle guides is sufficient				2	2	4.5	Too wide (1)
The speed of movement is adequate					4	5	

Table 5-5. Feedback from	questionnaire applied	to novice users
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The feedback that was obtained from the open-ended questions is reported in Table 5-6. Note that, the answers provided by the participants have been paraphrased and grouped together.

Positive Feedback (No. of mentions)	Negative Feedback/Recommendations (No. of
	mentions)
• Good functionality (2)	• Too heavy (2)
• Easy to use/easy controls (1)	• Having the ultrasound not integrated with
• The angle of the needle can be	the device was problematic (2)
controlled/accuracy of needle placement	• Device is too big/bulky (2)
(1)	• Please put all the information in just one
• Easy to find the needle in the US	screen (2)
image/Needle is aligned with the device (1)	• Needle should be bigger proximally and
• Adequate size (1)	smaller distally (1)
• Multiple imaging modalities (camera +	• Remove the control that is not needed (1)
US) (1)	• Test the device on a liver and lung (1)

Table 5-6.	Comments from	expert users	to the open	questions on the	questionnaire.
				1	1

Experts were also asked to give feedback based on their medical experience. They were asked if such a device could be adopted by clinicians, if any changes were needed before it could be used in the OR, whether or not they believed the system would be effective in delivering lung brachytherapy and if they thought it would be useful for other procedures or regions of the body.

In general, the comments agreed that the system could be adopted by the medical community given some adjustments such as making it lighter, making it a single port system, and by improving the handle. Comments also agreed that the device would be useful for lung brachytherapy and one expert mentioned biopsies as a procedure that could be performed with the device.

5.4.5 Comparison of Results with Similar Studies

Although no other publications were found regarding similar needle guidance systems for intercostal HDR lung brachytherapy, it is important to compare the accuracy of the device with other systems that may have a similar functionality. Two studies were selected for the comparison, the first one by Trejos et al. [101] and the second one by Ma et al. [102]. Both studies compared the placement accuracy of LDR brachytherapy seeds into agar gel cubes using manual, video-assisted and robotic setups. Because LDR seeds are placed using a needle, the results obtained from these tests can be easily compared to the results obtained during the

validation of the prototype. Table 5-7 summarizes the experimental setup and method of the current and comparative studies.

	Novice Trials	Expert Trials	Trejos et al [101]	Ma et al [102]
Number of	108-9 = 99 (each	34	80 (each	128 (each
measurements	technique)		technique)	technique)
Number of	12-1 = 11 Novices	4 Experts	4 Novices	2 Experts
participants				2 Novices
Techniques being	VATS ¹	UBNGD	Manual ²	Manual ²
measured	UBNGD		VATS ¹	VATS ¹
			RAMI ³	$ZEUS^4$
Measured	Accuracy ⁵	Accuracy ⁵	Accuracy ⁶	Accuracy ⁶
variables	Time ⁷	Time ⁷	Time ⁸	Time ⁸
		No. of attempts	No. of attempts	No. of attempts

Table 5-7 Summary of the studies being compared. See text for details.

- 1. VATS or video assisted thoracoscopic surgery refers to a setup using an acrylic thoracoscopic box to simulate video assisted endoscopic surgery without direct line of sight between the user and the target.
- 2. Manual placement refers to direct freehand manual injection of the seeds into the gel with the user having direct line of sight to the target and no other obstacles in the way.
- 3. RAMI or robot assisted minimally invasive procedure. In this setup the users used a remote console to control an AESOP robot holding a seed injector and a ZEUS robot controlling an ultrasound probe.
- 4. The ZEUS robot was used to move a seed injector in a somewhat similar setup to the one described in RAMI.
- 5. Accuracy was measured by calculating the distance of the coordinates obtained using the Aurora system between a sensor at the tip of the needle and sensors in the targets.
- 6. Accuracy was calculated by estimating the distance from the LDR seeds to the centre of the targets measured using radiograph images of the agar cubes after the trials and then subtracting the radius of the target and seed.
- 7. Refers to the time it took the subjects to go from one target to the next.
- 8. Refers to the time required to perform each task (reaching the target).

In order to compare the accuracy results between studies, 1.5 mm was subtracted from the distances calculated in the novice and expert trials, as it is the diameter of the target and therefore the minimum distance that can be achieved in theory. It is important to mention, however, that approximately 6% of the readings had a distance slightly less than 1.5 mm. This can be attributed to the Aurora's margin of error of 0.6 mm and slight imprecision in the placement of the targets relative to the sensors. To those readings, a distance of 0 mm was assigned.

	Mean distance ± St Dev (mm)	Median No. of Attempts	Median Time (s)
Novice Trials*	· · ·	•	
VATS	2.35 ± 2.24	NA	59
UBNGD	1.98 ± 1.38	NA	44
Expert Trials*			
UBNGD	0.99 ± 0.81	1	38
Trial by Trejos et al. [10	1]		
Manual	2.7±1.3	2	29
VATS	2.5±1.5	4	104
RAMI	0.9 ± 0.7	1	40.5
Trial by Ma et al. [102]			
Manual	2.19±1.09	1	3
VATS	3.10±2.11	4	87
ZEUS	4.6±3.16	3	65

Table 5-8 Summary of results from comparable trials.

*Unlike Tables 5–1 and 5–4, the mean distance and standard deviation in Table 5–8 was estimated by subtracting the 1.5 mm radius of the target from each distance measurement.

Based on the metric presented in Table 5-8, the UBNGD and the RAMI trials were the only ones that could deliver mean accuracies under 2 mm, which according to [102], is a biological and clinically acceptable error in brachytherapy procedures.

5.5 Mechanical Testing

Beyond testing the functionality and accuracy of the device, the mechanical design was also assessed. With most of the mechanical design revolving around the premise that the device should be capable of lifting 10 N from the tip of the ultrasound transducer, a very simple test was setup. The device was held in place by the shaft and weight was hung with a hook from the tip of

where the ultrasound transducer goes. The weight was lifted and returned with the device under user control, as shown in Figure 5.21. With a hook weighing 0.105 kg, 0.1 kg weights were added one by one and then lifted and returned. At the end, a total of 10 weights plus the hook were lifted totalling 1.105 kg or 10.84 N.



Figure 5.21. Device lifting 1.105 kg at its tip.

The device was then turned upside down and the same test was conducted, this time lifting the weight as the device closed, Figure 5.22. In both configurations, the device was able to operate normally under full load.



Figure 5.22. Device lifting 1.105 kg at its tip at an inverted position.

5.6 Conclusions

When considering accuracy, the novice tests indicate that the UBNGD provides only marginally better results when comparing mean values. However, if the standard deviation of the accuracy measurements is analyzed, significantly smaller values are achieved with the device. Therefore, it can be concluded that although the device may not provide a significant improvement in accuracy when compared to manual placement, it does provide more consistent readings regardless of the skill and expertise of the user. Additionally, while it was not measured directly, it was observed that the learning curve during the practice runs was significantly faster with the UBNGD than with the manual VATS setup. The expert tests returned even better accuracy values, and although this again was not measured, the learning curve was extremely fast with most experts feeling comfortable enough to start testing within a few minutes of using the device. When comparing the accuracy of the device with other studies, we can see that the novices achieved better accuracy with the device than the results achieved on any study on a VATS setup. The experts, together with the RAMI setup, achieved the best accuracy of any setup in any of the considered studies. In general, the UBNGD was able to achieve, depending on the measurement, either significantly or at least marginally better accuracy than any non-robotic trial and comparable values to those achieved with the best robotic trials with more repeatable values, less dependence on the skill and expertise of the user and faster learning curves. Perhaps even more important, based on the metric used for comparison purposes in Table 5-8, the UBNGD was one of the few setups capable of delivering a mean error under 2 mm, which is considered to be an acceptable error during brachytherapy procedures. Furthermore, it is believed that the accuracy of the device could be significantly better if tested with the ultrasound transducer integrated in the way that it was designed to be, as the probe that was used added weight to the system and made it harder for the users to maneuver the device comfortably.

The time that it took the users to reach the target was very similar with the UBNGD to results achieved with VATS and other robotic systems without a significant advantage or disadvantage.

It is also important to mention, that with the expert trials, most users were able to hit the target on their first attempt, compared to the median number of attempts of 4 reported in other VATS studies. This is important because a reduced number of attempts translates to reduced damage to healthy tissue in real procedures.

From the feedback obtained from the users, it can be concluded that the controls are accurate and easy enough for most users. Having the needle in line with the ultrasound sensor and the way that it is controlled were much appreciated features that contributed to greater accuracy and a reduced number of attempts required to hit the targets. Interestingly enough, 100% of the novices felt strongly that the device gave them an advantage over the manual placement of the needle, even though some of them actually performed better without the device. This indicates that the device was well liked and users may be easily adopted for use. It was also evident that users felt the device was too heavy, as this was the most common complaint among both novices and experts. The second most common complaint was the fact that the ultrasound transducer was not integrated into the device and that may have had a somewhat negative impact on the performance of the device during the trials. For future developments it will be essential to have an ultrasound transducer integrated into the device, as intended in order to obtain results that should reflect the true capabilities of the UBNGD.

Mechanically, the device proved to be able to withstand the forces it was designed to resist, evidenced both by the weight lifting test and the fact that there wasn't a single incidence during the novice and experts trials in which the device failed in any way. The only incidences that occurred during testing were an Aurora sensor failure and the agar gel becoming dislodged on a few occasions. Both of these issues are unrelated to the design of the system.

Chapter 6

6. Conclusions

Based on the tested capabilities of the UBNGD, the prototype provides a starting point for a device that will allow clinicians to perform HDR brachytherapy and other treatments, with accuracy, consistency and short learning curve. With continued development, the proposed system will enable HDR brachytherapy and other lung treatments in an MIS setting, following the proposed procedure:

6.1 Overview, Contributions and Concluding Remarks

Based on the tested capabilities of the system, the prototype sets a roadmap to develop a device that will allow clinicians to perform HDR brachytherapy and other treatments, with accuracy, consistency and short learning curve. If development continues, with the proposed system it will be possible to conduct HDR brachytherapy and other lung treatments in a MIS setting following the proposed procedure:

- 1. Insert a laparoscopic camera through a minimally invasive port to locate the targeted lung and area of interest.
- 2. Insert the device through a second 12 mm port in the intercostal space.
- 3. Guide the ultrasound transducer, based on the video feed from the laparoscopic camera, into position over the area were the tumour is suspected to be located.
- 4. Scan the suspected area with the ultrasound transducer to precisely locate the tumour.
- 5. Hold the device in place on top of the tumour.
- 6. Based on the image obtained from the ultrasound and the preoperative images, open the needle guide to align the needle with the centre of the tumour or the targeted area.
- 7. Push the needle manually until the desired location is reached, guided by the live ultrasound image. Based on the first studies conducted for the validation of the initial prototype, skilled physicians can reach the target with 1 mm accuracy.

- 8. Fix the device in place (likely using a mechanical support system that is yet to be developed).
- 9. Push a standard HDR brachytherapy catheter all the way to the tip of the device.
- 10. Connect the other end of the catheter to the brachytherapy after-loader.
- 11. At this point, the personnel may leave the room and the brachytherapy is delivered remotely following the current standards of practice.
- 12. Once the radiation has been delivered to the patient, the personnel returns and pulls out the equipment.

Other treatments such as ablation therapy or biopsies would follow the same procedure steps 1 to 7, followed by the steps specific to the procedure.

The UBNGD enables physicians to perform a new procedure to deliver HDR brachytherapy to patients who suffer from lung cancer and whose tumours are located away from the main bronchi and therefore cannot be reached with current endoscopic techniques.

This project also proposes an innovative single port device that keeps the needle aligned with the ultrasound transducer. This approach allows for better visualization of the needle and an easier way to guide into position than traditional endoscopic techniques.

Finally, pushed by the requirements of the UBNGD a slotted tube design was adapted in order to create a needle with a wide diameter that can be easily bent into position, that beyond HDR brachytherapy could be adapted in the future for different procedures.

6.2 Recommendations and Future Work

Based on the testing results and the feedback gathered from participants and experts, the concept of the UBNGD appears to be good and may someday become a viable option for HDR lung brachytherapy and other minimally invasive procedures; however, several areas of improvement have been identified for future prototypes.

Reduction to One Degree of Freedom and Weight Reduction

The most common complaint from the participants was the device's weight, which made it uncomfortable for users to maneuver the device for a long period of time. At the same time, it was observed that the controls for moving the ultrasound up and down weren't really necessary and most users in fact did not use that function. Therefore, it is recommended that a future prototype could be reduced to just one degree of freedom, leaving the movement of the needle guide as it is but fixing the ultrasound transducer in place. This way, the weight could be reduced by removing one electric motor. However, before eliminating a degree of freedom completely, additional trials under less ideal conditions, such as in-vivo testing, must be undertaken to ensure that the ultrasound's degree of freedom is not an essential feature.

Length Reduction for the Tip of the Device

With the final prototype ready, and in the context of the size of an average chest cavity, it became evident that the actuated tip of the device could be too long to fit properly in some patients. With the current prototype, it is necessary to have the device at least 11.5 cm inside of the chest cavity to be able to operate it or else the movement of the needle guide is restrained by the trocar and/or the ribs. Depending on the size of the patient and/or the location of the tumour it may not be possible to insert the tip of the UBNGD far enough into the patient for interference-free operation.



Figure 6.1. Actuated tip of the UBNGD.

In order to reduce the length, it may be worth analyzing the possibility of using a sector or curved array ultrasound transducer instead of the current linear array in order to reduce the size of the transducer without reducing the field of view. Furthermore, the needle guide could have its length reduced in half and shift the pivot point to the tip of the sleeve instead of 30 mm into the sleeve as it is currently fixed. These changes could potentially cut the length of the tip in half. The main setback would be that the mechanical advantage of the system would be reduced and a smaller angular moment would be achievable at the tip with the current linear forces. However, if we consider the prospect of fixing the ultrasound transducer in place and with the very easy-to-bend needles that were developed as part of this work, the expected forces that will be needed for the device would be significantly lower than the ones originally considered.



Figure 6.2. Sketch of the proposed changes to the tip of the UBGND.

Single Screen Display

Develop a single screen display that combines the ultrasound image with the angular and vertical position currently being displayed in an additional screen as text. Using the information from the system, a virtual line could be drawn into the ultrasound image to depict the projected path of the needle at any configuration, allowing clinicians to more easily target the tumours in a single attempt. This projected line could move as the position of the needle guide moves.

Develop or Adapt a Passive Holder for the System

Once the tumour has been localized and the needle is in place, a passive instrument that holds the device in place will be necessary for the clinician to introduce the catheter through the needle for a biopsy or HDR brachytherapy. Furthermore, for HDR brachytherapy the clinician is required to leave the room so as not to be exposed to radiation. As a result, a passive holder is indispensable part of a complete solution.

Better Portability or Increased Integration with Robotic Systems

A study including expert opinion and cost analysis should be conducted to determine whether the development path for the device should include a more portable standalone system or a more robust robotic system.

A standalone system would allow the device to be easier and cheaper to adopt in hospitals that do not have access to sophisticated robotic surgery systems. In this case, it would be important to develop a purpose-built, smaller and lighter single microcontroller integrated into the device to deal with the controls and motor(s) in the system. Furthermore, the system could be powered by a battery making it a truly standalone system that doesn't rely on a power source, a computer and multiple controllers. This added weight would be compensated by eliminating most of cables that currently come out of the device and add a significant amount of weight.

Another suggested option would be to integrate the device into current robotic systems and perhaps even integrate augmented reality and electromagnetic tracking into the system. This more complex approach has the potential to provide even better accuracy than a standalone system but would also limit the potential for adoption by hospitals due to higher costs and higher technological requirements.

Better Insulation for the Motors

Prior to the testing, it was observed that moisture carried at the tip of the needle can potentially drip onto the motors as it is pulled out of the device, as the tip of the needle passes through the motor housing. However minimal the amount of water (or bodily fluids such as blood) that can reach the motors, over the long term it may cause malfunctions or even be an electric hazard, in addition to concerns regarding sterilization. This can be easily fixed by removing and inserting the needle after and before each procedure from the front instead of the back (and perhaps making slight modifications to the design to force the needle to be removed from the front). Another solution would be to modify the design to make a completely isolated passage for the needle through the motor housing, which based on the current design, would only be possible if a motor is indeed removed from the system.

Add a Failsafe Mechanism to Avoid the Movement of the Needle Guide while the Needle is Extended

Based on observations from the trials, adding a failsafe mechanism to prevent the needle guide form moving while the needle is extended could be a worthwhile safety feature. With the forces that the UBNGD is capable of delivering, if a user commands the needle guide to move while the needle is inserted in tissue, the needle could potentially cut through the tissue or break inside of the patient's body. Ideally, needle guide motion would be disabled when an extended needle is detected.

Reduce the Number of Screws used in the Shaft of the Device

Although a minor recommendation, reducing to 4, or even just 2 screws, instead of the 8 screws being used to keep in place every PEEK round guide would simplify the manufacture and assembly of the device without compromising its functionality or durability in any way. The front stainless steel round guide, as well as the round guide at the back that connects the shaft of the device with the motor housing, however, should retain their 8 screw design as these parts experience significant forces.

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Appendix A – Design Evolution

As with most engineering designs, arriving to a final working prototype was a highly iterative process. In this section, the evolution of the device will be described in order to provide some insight into many of the design details. A total of 11 SolidWorks prototypes were analyzed and two ABS models were printed at $2\times$ scale prior to the manufacture of the final prototype. Additionally, two layouts of the control interface were built.



Figure A.1. First concept sketched in SolidWorks (left) and final design that was prototyped (right).

The first CAD prototype only, known as "Prototype 0" illustrated the mechanical actuation concept for the needle guidance system relative to a fixed position for the ultrasound transducer:



Figure A.2. View of the tip of the CAD "Prototype 0".

The first full CAD prototype (which at this point excluded the motor housing) had 3 degrees of freedom, besides the angular motions of the final prototype, the ultrasound could be

moved forth and back by sliding the part shown in red which was not fixed to the sleeve. At this stage, all parts fit within a diameter of 12 mm.



Figure A.3. First full CAD prototype of the device.

In the next major iteration of the device, the system was reduced to the current two degrees of freedom as the forth and back movement of the ultrasound was deemed to be an unnecessary degree of freedom. Also, the pivot point for the needle guidance mechanism was moved towards the proximal end (instead of being in the same plane as the ultrasound jaw) for added mechanical advantage.



Figure A.4. Second CAD prototype.

In the third iteration of the CAD prototype, several changes were made based on preliminary finite element analysis (FEA) results and some manufacturing considerations. The links that connect the US jaw and needle guide with the rods are given a circular profile around the pins for added shear force resistance at their connecting points. The needle and rods are guided through a series of semicircular guides instead of channels that run through the length of the shaft for easier manufacture, the sleeve is extended to the edge of the US jaw for added protection, fillets are added to the connection points of the US jaw, as early analysis indicated a large stress concentration.



Figure A.5. Third CAD prototype, the first one to be physicaly built.

At this stage, the first physical prototype was built in plastic using a 3D printer. Because of limitations of the printer and material properties of the plastic, this early prototype was built at a $2\times$ scale. This prototype served to validate the mechanism as well as helped to identify weak points in some of the parts.



Figure A.6. First physical prototype built at 2x scale using a 3D printer.

Based on the observations made at the first physical prototype, some changes were made in order to allow it to better cope with the applied forces and to simplify the manufacturing process. The connection points at the ultrasound jaw and needle guide were altered and reinforced, as they were identified as the most likely failure points. The sleeve of the shaft was "cut in half" for easier assembly and maintenance. The needle guide was extended up to the edge of the ultrasound sensor. The semicircular guides were changed for circular guides, replacing the long channel that guided the US wires and serve to hold the sleeve halves in place. This fourth CAD prototype was also built at $2\times$ scale with a 3D printer, proving that the new design could in fact withstand bigger forces.



Figure A.7. The fourth CAD prototype (left) and its physical prototype (right).

At this point of the design process, the electrical components and motors were selected and a motor housing was designed to accommodate them. With a clearer understanding at this point of the forces that would be affecting the system, several small changes were made based on FEA analysis, expert feedback and manufacturing capabilities. Fillets were added to the connecting points of the needle guide; a 1 mm extension was added below the ultrasound jaw around the space that holds the US transducer down, to fully enclose the sensor; the length of the shaft was increased to accommodate obese patients, in line with other similar medical instruments; the rods that transmit power from the motors were changed from a square to a circular profile to simplify manufacture of the circular guides; and contact areas at some linkages were extended for increased strength.



Figure A.8. Full prototype including the motor housing.

With the full CAD prototype ready and after extensive analysis, the final prototype manufacturing began.



Figure A.9. First fully functional prototype inlcuding the first motor housing and electronic components.

For the testing and validation process, the motor housing and electric connections were redesigned to make the device smaller, more comfortable and ergonomic for the user. All electronics were moved from the handheld part of the system, leaving only the thumbsticks.



Figure A.10. Final prototype.

Appendix B – Manufacturing Process

In this section, the manufacturing process will be briefly described, as well as some of the design choices that were made based on the manufacturing capabilities at our disposal. All the mechanical parts that comprise the system were manufactured in one of three ways, depending on their characteristics:

- 1- Computer assisted manufacturing CAM micromachining system
- 2- Traditional manufacturing techniques
- 3- Rapid prototyping system (3D printer)

Micro-machined Parts using a CAM System

Parts with complex shapes that required a high level of precision were manufactured using a G4-ULTRA CNC Micro-Machining Center by Atometric [104]. The system has an XYZ resolution of 0.1 μ m and a dynamic accuracy of 2 μ m, which allows for very precise manufacture. The user interface uses standard G-Code. This code can be semi-automatically generated from the SolidWorks files.



Figure B.1. Atometric G4-ULTRA CNC MicroMachining Center.

The parts shown in Figure 3.34 were manufactured in this way. Thanks to the flexibility and precision of the system, these parts were manufactured from single blocks of stainless steel (except for 5 of the round guides that were manufactured out of a cylinder of PEEK), with only minimal modifications in the design needed to accommodate the radius of the cutting tools.



Figure B.2. Parts manufactured using a precision CAM system, from left to right: The first two pieces connect the motor spindle drive to the rods that transmit power to the tip of the device. The round guides serve as channels along the shaft of the device to guide the needle and rods. The ultrasound holder².

Other Metal Parts

Other stainless steel parts were machined using more traditional processes. This work was performed at University Machine Services (UMS) at Western. The parts manufactured at UMS were the stainless steel parts that required a high degree of precision but could be more easily manufactured out of commercially available parts. Many of these parts required modifications from how they were originally designed to accommodate manufacturing limitations and/or to simplify the manufacturing process. The outer sleeve of the shaft was manufactured out of a 12 mm OD, 11 mm ID stainless steel tube cut in half with holes drilled for the screws. The upper and bottom halves were cut from different sections of the tube in order to guarantee that the dimensions would remain precise, since the cutting process removes some material. The needle guide was manufactured using a stainless steel tube with additional blocks silver-soldered at the tip and back end where the pins fit. The area of contact of the silver-soldered parts was increased

² Micro-machined parts were manufactured by CSTAR research associate Abelardo Escoto.

from the original design for increased strength. The links that connect the power transmitting rods to the ultrasound jaw and needle guide were cut from a stainless steel plate and their shape was modified to simplify their manufacture. The rods are 2.5 mm diameter solid cylinders of stainless steel with their ends flattened out for assembly with the links. These rods were originally meant to have a square profile but making square shaped holes in the round guides was impractical.



Figure B.3. Parts manufactured at UMS. From left to right: The bottom sleeve of the shaft, the needle guide, one of the links, a rod with a flattened tip for assembly..

Parts Manufactured in ABS using a 3D Printer

Those parts that did not require high precision or tight tolerances and were not going to be exposed to high stresses were manufactured using a 3D printer. A 3D printer allows for virtually unlimited flexibility in the shapes of the parts while being the fastest and cheapest method of manufacture. All of the parts done in ABS are part of the motor housing and were designed with loose tolerances and thicker walls.



Figure B.4 Parts manufactured using with a 3D printer, from left to right: An inner part that holds the motors in place and the outer shell of the motor housing, the lower and upper halves of the motor housing, a frontal constraint that helps hold the motors in place and guide the needle.

Assembly

Once the parts were completed, the assembly took place. All the movable joints were connected using 1 mm A2 stainless steel pins fitted into 1.016 mm holes. The sleeves in the shaft were connected to the round guides using M1.6 A2 stainless steel screws. This turned out to be one of the most challenging parts of the assembly since the space in the bottom half only allowed for 2 mm long screws, and the smallest available screws were 3 mm in length. This turned into a lengthy process of filing down screws to make them fit. Also, in order to keep the outer diameter small and even enough to fit through a 12 mm trocar, flat head screws were used which meant a conical hole had to be used in the outer sleeve to fit the screws into the sleeve. The motor housing was easier to assemble, due to its larger dimensions; most parts are held in place with a combination of friction and M1.6 and M2 screws.

Appendix C – Ethics Approval (No 103761)



Research Ethics

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Prof. Rajnikant Patel File Number:103761 Review Level:Delegated Approved Local Adult Participants:18 Approved Local Minor Participants:0 Protocol Title:Assessment of New Device for Minimally Invasive Needle Guidance System for Lung Biopsies and HDR Brachytherapy Department & Institution:Engineering/Electrical & Computer Engineering,Western University Ethics Approval Date:June 14, 2013 Expiry Date:December 31, 2013 Documents Reviewed & Approved & Documents Received for Information: Version Document Name Comments Date Recruitment E-mail 2013/04/23 Recruitment Items 2013/04/23 Instruments Image of the needle guiding system to be tested Subjective Feedback Questionnaire. To be answered by 2013/04/23 the participants after the trials. 2013/04/23 Western University Protocol Revised Letter of Consent Form 2013/05/23 Information & Consent Revised Letter of Changes and corrections are highlighted in yellow 2013/05/23 Information & Consent

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canadar/CH Good Chincal Practices Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gibert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRR revisitation number IRR 00000040

(ethics officer signature)

Signature

Ethics Officer to Contact for Further Information

| (ethics officer contact info) |
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Appendix D – Copyright Permission



Appendix E – Basic Stamp Code used in the Microcontroller

main:	Main program tag
readadc a.3, b2 readadc a.2, b1 readadc b.5, b6	Reads the analog input at ports a.3, a.2 and b.5 and stores the values in variables b2, b1 and b6.
if b6>200 then : gosub syson : else : gosub sysoff : endif	If $b6 > 200$, calls subroutine to assign $b3=1$, else $b3=0$
if b2>127 and b2<147 then : gosub b2cero : endif if b1>127 and b1<147 then : gosub b1cero : endif	If the values of b1 or b2 are between 127 and 147, they are given the value 142, which will be interpreted by the computer as a neutral (0) no-move position.
serrxd b0	Waits indefinitely for communication from PC, stores input in b0 (the value is irrelevant, the wait is to guarantee the PC and microcontroller are synchronized)
if b1 < 10 then underten if b1 < 100 then underhun	If the value of b1 is under 10 or under 100, zeros are added to keep the value of b2 in the same position of the string that will be transmitted to the PC
sertxd(#b2,#b1,#b3) goto main	Transmits an ASCII string comprised of the numbers in the variables b2, b1 and b3.
underhun: sertxd(#b2,#0,#b1,#b3) goto main	Transmits an ASCII string comprised of the numbers in the variables b2, b1 and b3 with a zero between b2 and b1.
underten: sertxd(#b2,#0,#0,#b1,#b3) goto main	Transmits an ASCII string comprised of the numbers in the variables b2, b1 and b3 with two zeros between b2 and b1.
syson: b3=1 return	The following are the subroutines used to assign the values of b3, b2 and b1 if the conditions are met in the if statements above.
sysoff: b3=0 return	
b2cero: b2=142 return	
b1cero: b1=142 return	

Appendix F - C++ Code

Main Function:

```
int main()
{
       int accel;
    long velocity0;
       long velocity1;
       int oncontrol;
                                                           Initialization of the variables that will be used in
       int vel adjust0;
                                                           this function.
       int vel adj ust1;
       long position0;
       long position1;
       doubl e degpos0;
       double degpos1;
       bool error control = false;
       bool errorcontrol 1 = false;
       bool errorcontrol 2 = false;
       bool homeerror = false;
       bool currentlimit1 = 0;
       bool currentlimit2 = 0;
       bool returntocero = false;
       int movecontrol = 0;
       int a:
       int b:
       int comcontrol = 0;
                                                           Creation of the objects motor0 and motor1
                                                           belonging to the class TwoMotorController
       TwoMotorController motor0;
       TwoMotorController motor1;
                                                           Creation of the object Com0 of the class
                                                           SerialCom
       SerialCom comO;
       errorcontrol 1 = motor0. initialize(0);
                                                           Call the initialize function for motor0 and motor1
       errorcontrol 2 = motor1.initialize(1);
                                                           and the setupport function for com0. If there is an
       comcontrol = com0.setupport();
                                                           error during the initialization, the variables
                                                           errorcontrol or comcontrol return with a "0".
       if(errorcontrol1 && errorcontrol2 &&
comcontrol)
                                                           If there were no errors, it outputs a phrase to let
       {
                                                           know the user that the set up process was correct.
       cout << "Setup and Initialization correct
" << errorcontrol << errorcontrol 2 << comcontrol
<< endl;
       errorcontrol =1;
        }
       if(errorcontrol)
       cout << "Acceleration set to 20,000 " <<
                                                           If there were no errors up to this point, the
endl;
                                                           parameters of the movement, such as the
       accel = 20000;
                                                           acceleration are set. Acceleration to 20,000rpm/s
       errorcontrol 1 =
```
```
motor0.setparameters(accel);
        errorcontrol 2 =
                                                             Parameters set on motor0
motor1.setparameters(accel);
        }
                                                             Parameters set on motor1
        if(errorcontrol && errorcontrol1 &&
errorcontrol 2)
                                                             If there are no errors so far, the program goes into
        {
                                                             a small loop to position the motors in the desired
                bool loopcontrol = true;
                                                             location to start the operation of the system.
                while(loopcontrol)
                                                             The program gets feedback about the electric
        currentlimit1=motor0.getcurrent(200);
                                                             current being used.
        currentlimit2=motor1.getcurrent(200);
                                                             -Sets the velocity of the motors to 1000 rpm
                        velocity0 = -1000;
                                                             -Get the actual position of the motors (in gc from
                        velocity1= -1000;
                                                             the initial position)
                        position0=motor0.getpos();
                                                             -Adjust the value of the position to an easier to
                        position1=motor1.getpos();
                                                             handle scale (Movement range from approx. 0 to
                        position0=position0/-5000;
                                                             200)
                        position1=position1/-5000;
                         if(position0>15)
                                                             If the motor0 reaches position "16", it stops.
                         {
                                 velocity0=0;
                                                             If the motor1 reaches position "8", it stops.
                        if(position1>7)
                         {
                                 velocity1=0;
                         if (currentlimit1 ||
                                                             If the current used exceeds 200 mA, the motion
currentlimit2)
                                                             stops (a current spike at this step usually means a
                                                             mechanical barrier or limit)
                        velocity0 = 0;
                        velocity1 =0;
                                                             Command motor to move at set velocity (1000
                        }
                                                             rpm if the motor is inside the position and current
                        motor0.movemotor(velocity0);
                                                             limits; 0 otherwise)
                        motor1.movemotor(velocity1);
                        if(velocity0==0 &&
                                                             If the velocity of both motors is set to 0, the loop
velocity1==0)
                                                             ends. (Both motors with velocity set to 0 will
                         {
                                                             mean that the target position has been reached)
                                 loopcontrol = false;
                        }
                }
        }
        if(errorcontrol && errorcontrol1 &&
                                                             If there were no errors in the initialization
errorcontrol 2)
                                                             process, the "main" loop starts.
        {
        bool loopcontrol = true;
                                                             Calls the function used to communicate with the
        int counter = 0;
                                                             microcontroller, receives a 7 digit number that
        while(loopcontrol)
                                                             describes the state of a button and 2 thumbsticks
                {
                movecontrol = com0. readwrite();
                                                             Assigns the least significant digit to oncontrol
                                                             Assigns the rest of the values to move ontrol
                oncontrol = movecontrol \% 10;
```

```
move control = move control / 10;
                                                            Assigns to "a" the 3 least significant digits of
                                                            movecontrol
                a = move control \% 1000;
                                                            Assigns to "b" the 3 most significant digits of
                b= movecontrol / 1000;
                                                            movecontrol
                velocity0 = (a-142) * 18
                                                            The velocity is scaled from 70 to 208 to approx.
                                                            -1,300 rpm to 1,300 rpm with 142 = 0
                velocity1 = (b-142) * 18;
                                                            Obtain the position of the motors
                position0=motor0.getpos();
                position1=motor1.getpos();
                                                            Position scaled down to make it more "user
                position0=position0/-5000;
                                                            friendly"
                position1=position1/-5000;
                                                            Position adjusted to a new "zero"
                position0=position0-16;
                position1=position1-8;
                                                            Angular position of the end effectors calculated
                degpos0=getdegrees(position0);
                                                            from the position of the motors
                degpos1=getdegrees2(position1);
                vel adj ust0=abs(posi ti on0);
                                                            Velocity of the motors is adjusted according to
                vel adj ust1=abs(posi ti on1);
                                                            the linear position of the motors.
                velocity0 =
(vel oci ty0*(vel adj ust0+12.5)/25);
                velocity1 = 
(vel oci ty1*(vel adj ust1+12.5)/25);
                                                            Position of the end effectors printed on screen to
                cout << "Ultrasound position in
                                                            be referenced by the users
degrees " << degpos0 << " Needle position " <<
degpos1 << endl;
                                                            Calls a function to read the electric current of the
       currentlimit1=motor0.getcurrent(400);
                                                            motors and establish if any had exceeded 400 mA
        currentlimit2=motor1.getcurrent(400);
                if ((position0 > 182 && velocity0
                                                            If the position of the motors is outside this range,
<0) || (position0<1 && velocity0>0))
                                                            their velocity is set to 0 to make them stop if they
                {
                                                            are moving in a direction that would make them
                        velocity0 =0;
                                                            overshoot their range.
                }
                if ((position1 > 182 && velocity1
<0) || (position1<1 && velocity1>0))
                {
                        velocity1 =0;
                                                            If the current limit is exceeded, the motors'
                if (currentlimit1 || currentlimit2)
                                                            velocity is set to zero and a warning is displayed
                {
                                                            for the user.
                        velocity0 = 0;
                        velocity1 =0;
                        motor0. movemotor(velocity0);
                        motor1.movemotor(velocity1);
                        cout << "Warning movement</pre>
force limit reached adjust controls and press
                                                            Waits for an input (any input) from the keyboard
enter to continue "
                       << endl;
                                                            before resuming the program.
                        getchar();
                                                            If the finalization button is pressed, the loop will
                if (oncontrol < 1)
                                                            break and the motors stop moving briefly.
```

```
loopcontrol = false;
                        returntocero = true;
                        velocity0=0;
                        velocity1=0;
                        motor0. movemotor(velocity0);
                                                           Displays a notice to the user that the loop is over.
                        motor1.movemotor(velocity1);
                        cout << "Loop is over " <<
endl;
                }
                                                           Motors are commanded to move at the
                motor0.movemotor(velocity0);
                                                           established speed
                motor1.movemotor(velocity1);
                }
        }
                                                           If the loop was broken, the velocity of the motors
        velocity1 = 1000;
                                                           is set to 1,000 rpm for them to return home.
        velocity0 = 1000;
        while (returntocero)
        {
                                                           Function to read current and check if it exceeds
        currentlimit1=motor0.getcurrent(190);
                                                           190 mA.
        currentlimit2=motor1.getcurrent(190);
                                                           If the 190mA is exceeded, motors' speed is set to
                if(currentlimit1==1)
                                                           zero.
                {
                        velocity0 = 0;
                if(currentlimit2==1)
                {
                        velocity1=0;
                if(velocity0==0 && velocity1==0)
                                                           If both motors are no longer moving, the loop
                {
                        velocity0 = 0;
                                                           will end.
                        velocity1 = 0;
                        returntocero=fal se;
                }
                                                           Motors move until the current is exceeded
                motor0.movemotor(velocity0);
                                                           (mechanical limit reached)
                motor1.movemotor(velocity1);
        }
                                                           Final communication with the microcontroller to
        movecontrol = com0.readwrite();
                                                           allow it to loop one last time.
        motor0. fi nal i ze();
        motor1. fi nal i ze();
                                                           Communications with the motor controllers and
        com0. fi nal com();
                                                           microcontroller is finalized.
        return 0;
}
```

Name:	Mauricio Nahum Leroy
Post-secondary education and degrees:	Instituto Tecnológico y de Estudios Superiores de Monterrey - Campus Santa Fe Mexico City, Mexico 2004–2008 B.E.Sc., Mechatronics Engineering
Related work experience:	Teaching Assistant MME4452 – Robotics and Manufacturing Automation MME9610 – Applied Measurement and Sensing Systems MME4425 – Mechanical Vibrations The University of Western Ontario 2012–2013