Multi-sensing tool

for Minimally Invasive Surgery

D3.1

REPORT ON FUNCTIONAL REQUIREMENTS

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[1] **Please indicate the type of the deliverable using one of the following codes**:
R = Document, report
DEM = Demonstrator, pilot, prototype, plan designs
DEC = Websites, patents filing, press & media actions, videos
DATA = data sets, microdata
DMP = Data Management Plan

[2] **Please indicate the dissemination level using one of the following codes**:
PU = Public
SEN = Sensitive

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1 Introduction

PALPABLE introduces a new generation of MIS (Minimally Invasive Surgery) tools: a novel tactile sensing probe as a palpation tool for identification and visualization of tissue abnormalities. MIS has several advantages (reduced tissue damage, postoperative analgesic requirements & blood loss, decreased hospitalization time, better cosmetic results), but there is limited or none visual, haptic, and tactile feedback in-situ, along with issues of tool dexterity.

The present deliverable focuses on the functional requirements of the probe, according to the existing literature and experts' opinion. Based on experience, the most common cases where palpation sensing would be the most useful will be identified. A literature review on solutions under development or already commercialized will be conducted as well, to identify the gaps for such technologies and the possible added value of PALPABLE. Extensive interviews with a task-force assembled by EAES members encompassing surgeons across multiple specialties will be held towards this end. Using these inputs, several test cases to focus on will be chosen in terms of operation type, surgical experience level etc., and a functional analysis will be completed, considering surgical conditions and ergonomic limitations.

Based on the system specifications established within Task 3.1, we will proceed to determine the hardware and software architecture of the PALPABLE system. This analysis will encompass the hardware and software interfaces between the various modules as well as the associated communication protocols. Particular care will be taken in specifying the interfaces between the various sensing modalities as well as the integration with the flexible end-effector.

1.1 Target organ / human tissue

Ultrasonography is an extremely cheap, safe and minimally invasive diagnostic tool in the hands of a skilful user. It has been an important instrument in abdominal surgery for more than 30 years. Intraoperative ultrasound (IOUS) is an important tool to surgeons, for instance, in gastrointestinal (GI) tract resections for several reasons. It assists the operator in identifying the surgical anatomy with real time imaging and it gives him information about the size and quantity of the tumors with also a good accuracy for detecting small lesions. Different studies have shown the added value of ultrasound during laparotomic GI tract surgery, responsible to let the surgeon change surgical strategy in >20% of cases. The sensitivity of IOUS in a segment-by-segment analysis for colorectal liver metastasis is >95%, higher than CT and MRI. Based on these findings, IOUS should be considered the gold standard for hepatic neoplasms.

Laparoscopic liver surgery is increasingly performed nowadays and has gradually replaced laparotomic surgery for numerous indications. The importance of ultrasound in laparoscopic surgery is even bigger than during open surgery due to the lack of palpation of the liver during laparoscopy. Despite the evident limitations of a more demanding handling technique due to difficult spatial orientation and the fixed entry during laparoscopy, the technique seems difficult to abandon in favour of other intraoperative technology.

In contrast, there is hardly any technology available to inspect and stage hollow viscus organs rather than solid organs. Here the possibility to return to the operator (surgeon) the ability to palpate and discriminate consistency of the different tissue may represent an absolute novelty which could return several advantages in terms of reduced conversion to laparoscopy, higher number of oncologically correct resections, safer dissection through or aside vital organs such as major blood, lymphatic, biliary or urinary vessels. For all cancers treated surgically, one key remaining challenge is the visualization of the margins, not only before the surgery, but also at the OR.

1.1.1 Existing knowledge on tissue characteristics

Historically, cancer has been described as originating from modified cells, because of mutations impacting their growth, their differentiation and their way (not) to die. Now, it is widely acknowledged that the microenvironment surrounding these cells is involved in cancer initiation and progression. The proliferation of cancer cells is linked to a disruption of surrounding structures – including the extracellular matrix (ECM) – through physical and biochemical mechanisms.

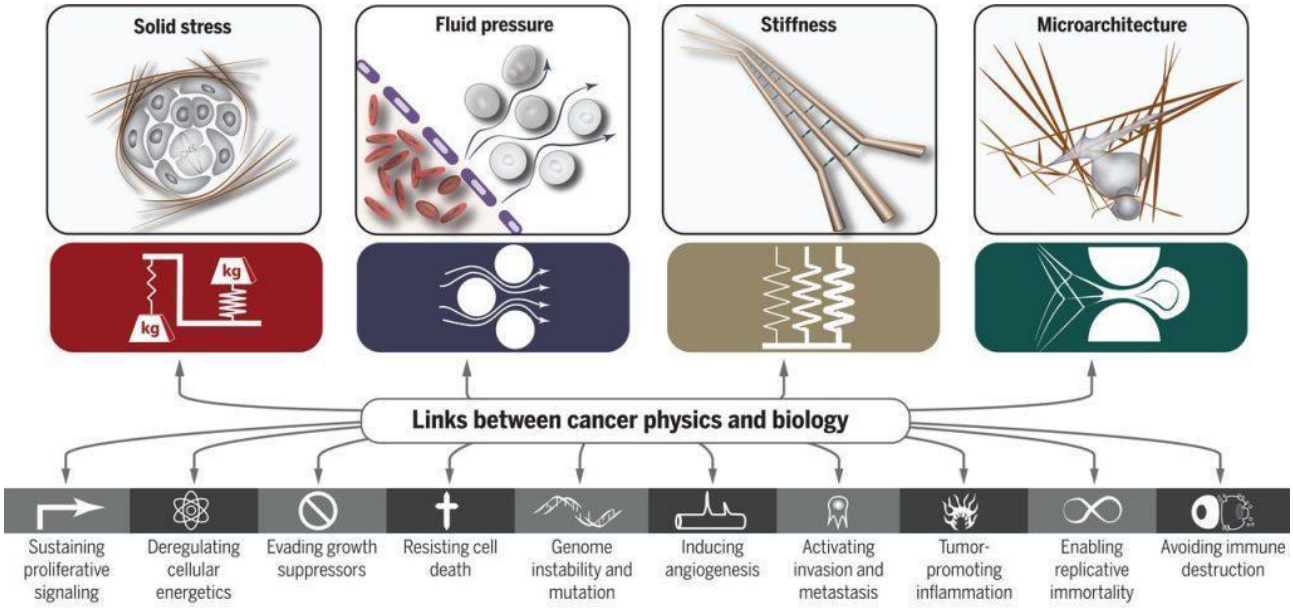

Figure 1 – The four physical traits of cancer, characterizing the main physical changes associated to most tumours

Cancer is generally considered a disease of the cell, caused by mutations in genes that control cell proliferation, death, metabolism, and DNA repair. While biological hallmarks are useful for conceptualizing cancer at the cellular level, the microenvironment surrounding the cancer cell acts as a coconspirator in tumour initiation and progression. As tumours grow, they disrupt the surrounding tissue biochemically and physically. They also recruit normal cells from the surrounding tissue, which further alter the matrix and cellular compositions of the tumour. These perturbations result in physical abnormalities associated with both cancer cells and the microenvironment in which they grow that influence tumour biology and response to treatment.

Cancer traits stemming from the physical abnormalities of tumours may be categorised as: (i) elevated solid stress, (ii) elevated interstitial fluid pressure (IFP) and the resulting fluid flow in the interstitium, (iii) increased stiffness and altered material properties, and (iv) altered microarchitecture, which all can interact synergistically, facilitating cancer cell proliferation and invasion, immune system evasion, and resistance to therapies.

Solid stresses and fluid pressure are the mechanical stresses (force per unit area) contained in, and transmitted by, solid and fluid phases of the tumour, respectively. Solid stresses and fluid pressure are reported in pascals or millimetres of mercury (1 mmHg ≅≅133.3 Pa). Stiffness (elasticity) is defined as the resistance of a material to deformation in response to an applied force, and elastic modulus is reported in pascals. Viscoelasticity defines the resistance of the material to deformation in response to a force applied at a given rate. Most soft tissues, including tumours, exhibit higher resistance to force (e.g., higher stiffness) when the force is applied at high rates. Solid stress, the latent or stored stress in a tissue, should not be confused with elasticity (stiffness) or viscoelasticity

(time-dependent stiffness), which define how much or how fast, respectively, a tissue will deform if a force is applied. A tissue can be stiff (rigid) or soft (compliant), and, independently, it can be under compressive and/or tensile solid stresses or, like most normal tissues, it can be unstressed. The proposed physical traits characterize most cancers, and their distinct origins and consequences make them indispensable to a comprehensive picture of cancer.

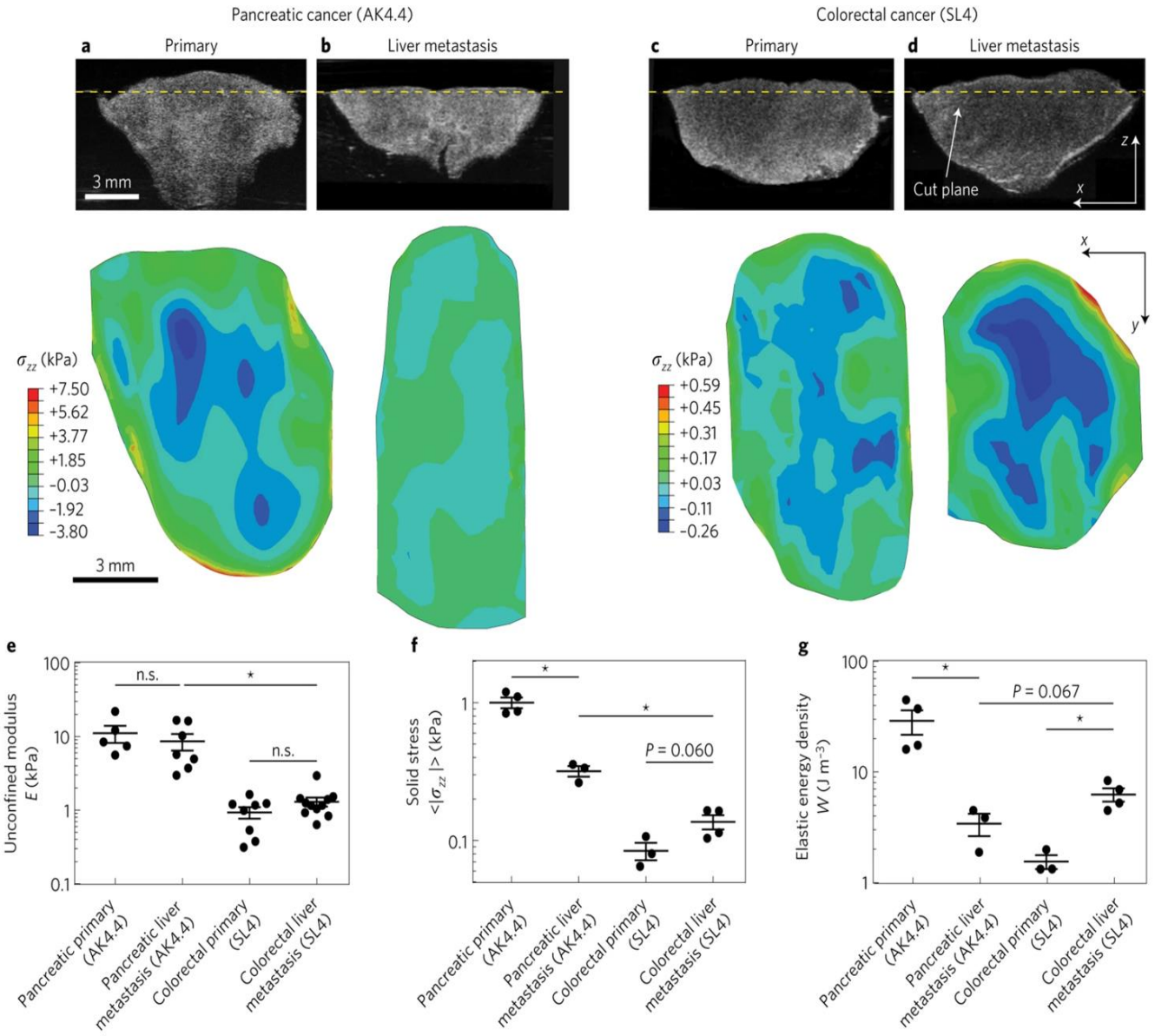

Figure 2 – Solid stress and elastic energy in primary versus metastatic pancreatic and colorectal tumours. a–d, Representative ultrasound images and 2D stress maps are shown for size-matched primary pancreatic ductal adenocarcinoma (PDAC, AK4.4; n = 4 mice) (a), liver metastasis of PDAC (AK4.4; n = 3 mice) (b), primary colorectal carcinoma (SL4; n = 3 mice) (c) and liver metastasis of colorectal carcinoma (SL4; n = 4 mice) (d). e–g, Comparison of Young's modulus (unconfined compression) (e), average solid stress in the z direction, σ_{zz} (f) and elastic energy density (g) in these four tumour models shows that the type of cancer cell is not the only determinant of biomechanical abnormalities: the organ and microenvironment in which the cancer cells reside are equally important in the generation of solid stress and elastic energy in tumours. The data shown are mean ± the standard error of the mean; n.s., not significant; *P < 0.05 (Nia, H., Liu, H., Seano, G. et al. Solid stress and elastic energy as measures of tumour mechanopathology. Nat Biomed Eng 1, 0004 (2017).)

1.1.2 Existing knowledge on probes for tissue characteristics

Existing approaches for early-stage tumour diagnosis of visceral organs largely depend imaging techniques. The most popular ones are based on chromoendoscopy and magnification. Narrow-band imaging (NBI) is a diagnostic tool for visualizing the vessels and surface patterns of colorectal polyps. Developed in 1999, NBI has been reported to provide valuable information regarding the histology of polyps detected during colonoscopy. Since then, many studies have reported the efficacy of NBI-assisted optical diagnosis of colorectal polyp histology. Moreover, NBI-assisted optical diagnosis may enable immediate determination of the appropriate surveillance interval with reduction in the risk of adverse events and health care expenditure. In Japan, several magnifying NBI classifications have been developed for use in clinical practice. However, magnifying colonoscopy is not widely used globally. Therefore, there has been a need for a novel NBI classification that does not require optical magnification.

The Narrow-band imaging International Colorectal Endoscopic (NICE) classification, devised by the Colon Tumor NBI Interest Group, uses the color, vessels, and surface patterns of polyps to classify endoscopic findings without optical magnification. This is the first NBI classification that can be used without optical magnification and is simplified for the ease of use. Previous studies have reported that the NICE classification is helpful for NBI-assisted optical diagnosis of colorectal polyp histology. However, most of these studies were conducted to investigate the diagnostic outcomes of optical diagnosis for differentiating between neoplastic and non-neoplastic colorectal lesions. In contrast, there has been limited research on the diagnostic performance of each type of the NICE classification, and the findings were widely discrepant between the studies.

A more sophisticated technique is based on Raman spectroscopy. This provides biochemical information of tissue samples ex vivo and in vivo and without the need for complicated sample preparation and staining procedures. Raman spectroscopy is used mainly for bladder cancers. For the past decade there has been a rise in applications to diagnose and characterize early cancer in different organs, such as in head and neck, colon and stomach, but also different pathologies, for example, inflammation and atherosclerotic plaques. Bladder pathology has also been studied but only with little attention to aspects that can influence the diagnosis, such as tissue heterogeneity, data pre-processing and model development.

Very soon Hyperspectral will be available on standard scopes for laparoscopy. This will allow to visualise at 4K quality of image the vascularization of the tissue on which we are operating live. This will be disruptive and may represent a gamechanger in the field.

A different way of studying tissue characteristics is provided by ultrasound technology. Ultrasound is composed of sound waves with frequencies greater than 20,000 Hz, which is by approximation the upper threshold of human hearing. Ultrasonic images, also known as sonograms, are created by sending pulses of ultrasound into tissue using a probe. The ultrasound pulses echo off tissues with different reflection properties and are returned to the probe which records and displays them as an image.

Elastography is a relatively new imaging modality that maps the elastic properties of soft tissue. This modality emerged in the last two decades. Elastography is useful in medical diagnoses, as elasticity can discern healthy from unhealthy tissue for specific organs/growths. For example, cancerous tumours will often be harder than the surrounding tissue, and diseased livers are stiffer than healthy ones. There are several elastographic techniques based on the use of ultrasound, magnetic resonance imaging and tactile imaging. The wide clinical use of ultrasound elastography is a result of the implementation of technology in clinical ultrasound machines.

2. PALPABLE Probe Requirements

The probe we are developing is supposed for laparoscopic use mainly. Therefore, it should be easily introduced into the abdomen through standard accesses which are represented by cannulas/trocars. Ideally the probe incorporates multiple sensing modalities and a thin, flexible, pneumatically actuated end-effector (3DOF, 180deg) with distributed sensors for distributed tactile sensing.

It may also be used for endoluminal examination, being the most appealing application, the study of endorectal sessile tumours, to differentiate benign from malignant neoplasms. This would help in indicating the need for a full-thickness excision rather than just an easier submucosal dissection.

All drawings in the following paragraphs represent initial concepts. The modifications described in the corresponding paragraph may not be integrated in the drawings.

2.1 Physical size & compatibility (UNITO, QMUL)

When developing a new laparoscopic instrument, it is of paramount importance that it is accepted by the surgical community. The first thing is to design a tool that is compatible with existing technology that is considered indispensable and non-competitive. Although for a short recent period the possibility of converting most of the laparoscopic demolitive surgery into "single port" surgery was proposed, i.e. through a single access of about 25 mm, this perspective has been gradually abandoned by most centres because objectively more complex than standard multi-port laparoscopic surgery.

2.1.1 Overall probe size

While the initial prototype will be conceived with an outer diameter of 25 mm, to prove technical characteristics and functions, the dimension will be then decreased progressively. The compatibility standard to follow is that of 5- and 10-mm instruments, which can reach 12 mm as routinely in use whenever it is necessary to use larger calibre instruments such as staplers. It is therefore likely that the maximum external diameter of the device we are designing should be able to pass through a 12 mm cannula. Nevertheless, it would be preferrable if the device would be able to pass through a 10 mm cannula (not much of a difference) or even better through a 5 mm cannula. This also would allow a better interaction with the tissue to characterize as the probe could be inserted from various angles according to the available trocars which are mostly 5 mm in diameter. In fact, the smaller the front surface of the tool, the less relevant is the shape of it.

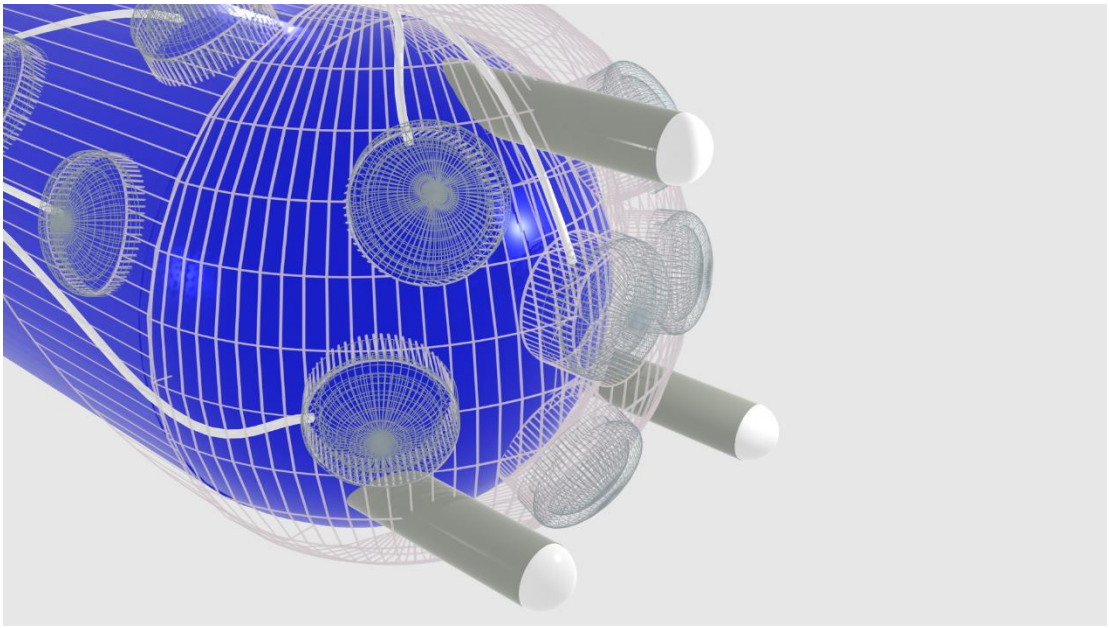

Figure 3 – Overall probe shape

2.1.2 Probe fuselage design

In order to be orientable, it is also essential that the articulating section at the tip is able to "exit" from the inner edge of the cannula for articulating, and yet be short enough not to impact against the surface of the endo-abdominal (eventually endothoracic) organs depending on the applications. It will be necessary to consider the dimensions also to decide the position of the sensors which ideally should be at the tip, but which could also be positioned along the "shaft" of the instrument, provided that the interaction area between the probe and the tissue being explored is optimal. Most probably in the end either the tip will allow an articulation up to 90°, surely not less than 45°, in order to approach the target lesion ideally in all cases, or the sensorised area will be extended laterally from the tip and will cover a 20 mm segment and about 1/3 of the circumference. It seems reasonable to think that the steerable segment of the tip of the tool should be between 25 and 30 mm long. Since the actuation system of the soft part is based pneumatics and probably room air rather than CO2, there must be a sensing mechanism that will sense a disruption of the system and air escaping into the abdominal cavity. This could increase dramatically the abdominal pressure during laparoscopy and once occurs the system must shut down and enable probe removal. For safety preferences and regulatory approvals, energy transfer into the abdominal cavity should be minimized preferably to none. Manipulation of the flexible part should be designed to be easily achieved by one finger on the handle of the laparoscopic instrument as the surgeon will need to manipulate the instrument with one hand leaving only the thumb or index finger for manipulation. Two-handed manipulation could be an interim possibility for a prototype but should be eventually one handed.

2.1.3 Probe fuselage material

From a clinical point of view the material of the fuselage should be obviously biocompatible and extremely resistant to tears. Most realistically, it should be made of a soft and flexible tip attached to a rigid shaft like conventional laparoscopic instruments. But the possibility to have it completely soft and flexible is also considered, provided that external manoeuvrability is reliable. There are no further particular specifications. The design should take in consideration that no small parts could be

dislodged into the abdomen while force is applied on the probe, as well as the edges should be smooth to avoid injury to the organs.

2.1.4 Contact surface area

The contact surface area should be sufficient to determine the nature of the observed structure. In order to extend the inspection to surrounding organs, the surface should be something in between 5 and 10 mm in maximum diameter and a length of up to 20 mm possibly on the side of the shaft in continuity with the tip of the instrument.

2.2 Soft actuation system (HMU)

The soft actuation system is responsible for the articulation from the rear of the distal tip of the tool we are here conceiving. Advantages of a soft robot technology are the lighter construction compared to traditional mechanical tendon activation, that translates also in more space to host fibres/tubes, increased dexterity. Also, being inflatable, the surface of the probe will be more compliant to the tissue.

Through a miniaturized designs of multiarticulate mechanisms we will offer the ability to the proposed probe to become steerable in three-dimensional space following soft robotic principles. Analytical and computational (FEM) models will be developed to optimize the mechanism's operation utilizing soft materials prior to fabrication. The kinematic and computational models will also be used to investigate effects of variation of the mechanism's stiffness and motion as a function of pneumatic pressure that is required so the probe can effectively simulate palpating motions over soft tissue. A range of polymeric and hyper elastic materials that are biodegradable, biocompatible, and sterilizable will be investigated. Casting using moulds as well as melting and compressing fabrication processes will be employed to deliver a miniaturized, monolithic mechanism with a cylindrical shape. This component will be placed at the distal end of the laparoscopic tool to create a single fused composite that incorporates peripheral lumens for its pneumatic pressurization that is required to articulate, and open, through-all lumens located at its centre axis that allow the optical lightguides to reach the multi-sensing photonic probe at the tip. To further reduce the cost of the articulation mechanism the selected fabrication process will be optimized to achieve production in batches using emerging digital fabrication techniques, such as polymeric 3D printing or blow/injection moulding.

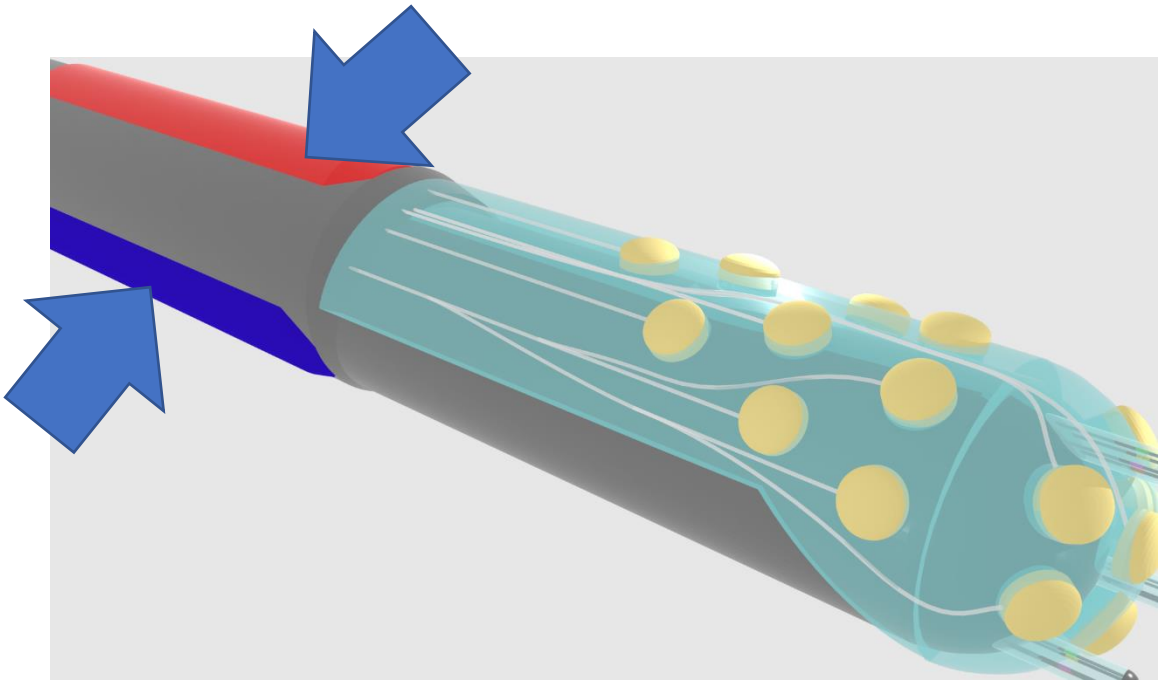

Figure 4 – Soft actuation system

2.2.1 Position of the system with respect to palpable probe

Alignment: The soft actuation system (multiarticulate soft steering mechanism) should be designed and positioned in such a way that it aligns precisely with the palpable probe at the distal end of the laparoscopic tool. This ensures that the actuation forces are transmitted accurately to the probe for effective palpation of human tissue. Optionally a hydraulic mechanism could be provided.

Range of Motion: The system should provide a wide range of motion for the palpable probe, allowing it to articulate in three-dimensional space as per the desired movements during the laparoscopic procedure. The range of motion should be optimized through computational and control modelling and testing to ensure it meets the requirements of the specific surgical task.

Smooth Articulation: The system should enable smooth and controlled articulation of the palpable probe without any jerks or abrupt movements. This ensures precise control and minimizes the risk of tissue damage during the palpation process.

Position Retention: Once the palpable probe is positioned, the soft actuation system should be able to retain the desired position without any unintended movement. This requirement suggests that the soft mechanism has to be provided with variable stiffness, so that it can become rigid when there is need of palpating the tissue. This ensures stability and accuracy in palpation, allowing the surgeon to perform the procedure effectively and safely.

Compatibility: The system should be compatible with the dimensions and design of the palpable probe, ensuring a seamless integration without any interference or misalignment. It should also be compatible with the overall design of the laparoscopic tool, allowing for easy assembly and disassembly as required.

Safety: The system should meet safety requirements for medical devices, including biocompatibility, electrical safety, and risk mitigation. It should not pose any risks to the patient or the surgical team during its operation.

Compliance and Safety Features: The soft actuation system may incorporate compliance and safety features to ensure safe operation. Compliance features may involve incorporating compliant or flexible materials in the actuation mechanism or probe tip to reduce the risk of tissue damage.

Safety features may involve incorporating safety mechanisms, such as pressure relief valves or emergency stop buttons, to prevent excessive forces or unintended actuation.

2.2.2 Length of the system

Reach: The length of the soft actuation system should be sufficient to allow the palpable probe to reach the targeted areas of the GI tract for effective palpation and tissue manipulation. The system should be designed to provide an appropriate reach to access different regions of the GI tract, taking into consideration the anatomical variability among patients. Also, the instrument may be used for transanal endoluminal application with no change in characteristics, being compatible with standard rectoscopes for surgical procedures.

Manoeuvrability: The length of the actuation system should allow for easy manoeuvrability and control of the palpable probe within the confined space of the laparoscopic surgical environment. It should be designed to provide the necessary dexterity to navigate around anatomical structures, such as ribs or blood vessels, and reach the desired target locations of the GI tract.

Ergonomics: The length of the actuation system will be designed to ensure ergonomic operation by the surgeon. Thus, it will facilitate comfortable handling and manipulation of the laparoscopic tool without causing undue strain or fatigue during prolonged use.

Scalability: It would be of great benefit to incorporate the feature of scalability to accommodate different probe lengths, depending on the specific requirements of the surgical procedure or the patient's condition. The ideal goal is to be flexible enough to allow for customization and adaptation to different clinical scenarios.

Compatibility: The length of the actuation system is important to be compatible with other components of the laparoscopic tool, such as the handle, control interface, and other subsystems. It should be designed to seamlessly integrate with the overall system architecture and not interfere with other functionalities or components.

Sterility: The length of the soft actuation system is expected also to meet the sterility requirements of a laparoscopic surgical environment. It should be easy to clean and sterilize and prevent any contamination of the surgical site during the procedure. The instrument will meet the most advanced criteria for sustainability. The initial idea is to have the instrument made of two parts: the part consisting of the sensorised tip, introduced into the body should be made of disposable plastic materials, that according to local laws could be recycled. This part should be solidly attached to a second part consisting of a shaft and a handle where all tube connections will be integrated, in continuity with the disposable tip. This should be made if possible, with durable material which could be reprocessed and reused.

Sterility may be achieved through standard washing/cleaning and sterilization methods, such as autoclaving, ethylene oxide (ETO) gas sterilization, or gamma radiation.

2.2.3 Diameter before and after actuation

The only crucial thing is that the entire device should pass through a standard trocar. Once the probe and articulating area are inside the abdominal cavity and out of the trocar, the diameter can expand more as long as it will be reduced back to the original diameter to enable its passage through the trocar again.

Pre-Actuation Diameter: The soft articulating mechanism should have a pre-actuation diameter to allow for minimally invasive insertion through small incisions commonly used in laparoscopic surgeries.

Post-Actuation Diameter: The soft articulating mechanism is important to have a post-actuation diameter such that it ensures that the expanded mechanism does not cause excessive tissue damage or impede the surgical field of view during the palpation process.

Smooth Diameter Transition: The diameter transition of the soft articulating mechanism from pre-actuation to post-actuation is expected to be smooth and gradual to avoid abrupt changes that may cause tissue trauma or discomfort to the patient.

2.2.4 Minimum and maximum angular motion space

Ideally the approach should be with an incidence of 90° to the surface. Most likely this instead should be in a range between 10° and 40° with very few cases in which we would go close to 90°.

Minimum Angular Motion: The soft actuation system should be capable of achieving a minimum angular motion that allows for precise and controlled manipulation of the palpable probe. The minimum angular motion will be determined based on the desired level of sensitivity and accuracy required for tissue palpation in the GI tract. It is essential that it will be carefully designed to ensure that the system can effectively detect tissue abnormalities and provide the necessary feedback to the surgeon.

Maximum Angular Motion: The soft actuation system should also be capable of achieving a maximum angular motion that provides the required range of motion for effective tissue manipulation during palpation. The maximum angular motion will be determined based on the anatomical constraints of the GI tract and the specific requirements of the palpation procedure. It should be optimized to allow for efficient and comprehensive tissue palpation while minimizing the risk of tissue damage or trauma.

Angular Resolution: The soft actuation system would be beneficial to provide an appropriate angular resolution that allows for precise control and manipulation of the palpable probe. The angular resolution refers to the smallest possible angular increment or step that the system can achieve in its motion. Therefore, the design will contribute to meeting the desired level of precision and sensitivity required for accurate tissue palpation in the GI tract.

Smooth and Controlled Motion: The soft actuation system should provide a smooth and controlled angular motion that allows for precise and gradual movement of the palpable probe. Sudden or jerky motions can cause tissue damage or trauma, and therefore should be minimized. The system should be designed to provide a controlled and gradual motion that ensures safe and effective tissue manipulation during palpation.

Stability: The soft actuation system has to maintain stability during its angular motion to ensure that the palpable probe preserves its intended position and does not deviate from the desired trajectory. The system should be designed to provide sufficient stability to the palpable probe throughout its range of motion, minimizing any unintended movement or wobbling that could compromise the accuracy and safety of the tissue palpation procedure. Additionally, with respect to the angular motion space, we want that the probe is perpendicular to the GI tract tissue and therefore no matter what angle the laparoscopic surgical tool is inserted through the trocar, the soft multiarticulate mechanism is supposed to "fix" the angle to 90 degrees using a closed-loop control. In order to achieve and maintain a perpendicular angle between the probe and the GI tract tissue using a closed-loop control system, some additional functional requirements are listed below:

Closed-Loop Control: The soft multi-articulate mechanism should incorporate a closed-loop control system that can continuously monitor and adjust the angles of the articulations to ensure that the probe remains perpendicular to the GI tract tissue. The closed-loop control system should provide

real-time feedback on the probe's angle and adjust the actuation parameters accordingly to maintain the desired 90-degree angle.

Angle Sensing and Feedback: The system should include angle sensing mechanisms, such as sensors or encoders, to measure the angles of the articulations and provide real-time feedback on the probe's angle to the closed-loop control system. Accurate angle sensing and feedback are crucial for maintaining the perpendicular angle between the probe and the GI tract tissue during the palpation process.

Force Sensing and Feedback: Force sensors on the probe or within the soft multi-articulate mechanism is essential to be placed in order to measure the forces applied to the GI tract tissue during palpation. The force sensors will provide accurate and reliable force feedback to the closed-loop control system, enabling it to adjust the actuation parameters in real-time to maintain the desired force within safe operating limits.

Bend Sensing and Feedback: The system is also great to incorporate bend sensors on the articulations of the soft multi-articulate mechanism to measure the angles or deformations of the articulations. The bend sensors should provide accurate and reliable bend feedback to the closed-loop control system, allowing it to monitor and adjust the articulation angles to maintain the desired 90-degree angle between the probe and the GI tract tissue.

Sensor Calibration and Accuracy: The force and bend sensors should be calibrated to ensure accurate and reliable measurements. The calibration process should be well-defined and repeatable, and the sensors should have sufficient accuracy and resolution to provide reliable feedback for closed-loop control.

Integration of Sensor Feedback: The closed-loop control system should be designed to integrate the feedback from the force and bend sensors in a coherent and effective manner. The system should be able to process and interpret the sensor feedback in real-time to make appropriate adjustments to the actuation parameters, such as pressure, flow rate, or actuator positions, to maintain the desired force and angle during palpation.

Control Algorithm: The closed-loop control system is recommended to have a well-defined control algorithm that considers the force and bend sensor feedback to determine the appropriate actuation parameters. The control algorithm should be designed to be robust, efficient, and adaptable to different tissue characteristics or surgical conditions, and it should be able to respond quickly to changes in force or angle to maintain safe and effective palpation.

Articulation Range and Resolution: The soft multi-articulate mechanism is important to have sufficient range and resolution in the articulations to allow for precise control of the probe angle. The articulations should be able to achieve and maintain the desired 90-degree angle with high accuracy and repeatability, ensuring that the probe remains perpendicular to the GI tract tissue throughout the palpation process.

Articulation Speed and Responsiveness: The articulations of the soft multi-articulate mechanism should be capable of achieving the desired probe angle in a timely manner, allowing for real-time or near real-time adjustments to maintain the perpendicular angle during tissue palpation. The system should be responsive to changes in the probe's position or the tissue's characteristics, and the articulation speed should be optimized to ensure efficient and effective palpation.

Calibration and Initialization: The system should include calibration and initialization procedures to ensure accurate and reliable operation. The calibration process may involve calibrating the angle sensors, establishing the reference angle, and setting the appropriate actuation parameters for the

closed-loop control system. The initialization process may involve initializing the system at the start of each surgical procedure or when changing the probe or other system components.

User Interface: The system should have a user-friendly interface that allows the surgeon to monitor the probe's angle, adjust the actuation parameters, and receive feedback on the system's status. The user interface may include visual displays, control buttons or knobs, and auditory or haptic feedback mechanisms to enable efficient and intuitive control of the system.

Safety Limits and Emergency Stop: The closed-loop control system should include safety limits for force and angle to prevent excessive forces or angles that may cause harm to the patient or the surgical team. If the force or angle exceeds the safety limits, the system should trigger an emergency stop mechanism, such as stopping the articulations or shutting off the actuation, to prevent any potential harm.

System Reliability and Redundancy: The closed-loop control system should be designed with reliability and redundancy features to ensure uninterrupted operation during the surgical procedure. This may include redundant sensors, actuators, or control components, as well as backup power supplies or communication pathways, to minimize the risk of system failure or disruption during surgery.

2.2.5 Material

A range of polymeric and hyperelastic materials that are biodegradable, biocompatible, and sterilizable will be investigated.

Biocompatibility: The materials used in the soft actuation system should be biocompatible, meaning they do not cause any adverse effects when in contact with living tissue. They should be non-toxic, non-irritating, and non-allergenic to prevent any potential harm or complications to the patient during the laparoscopic procedure.

Flexibility: The materials should be flexible to allow for smooth and controlled motion of the actuator and the palpable probe. They should be able to bend, twist, and deform without losing their structural integrity, enabling the desired motion and manipulation of the probe inside the GI tract.

Durability: The materials should be durable and capable of withstanding the forces and stresses associated with the laparoscopic procedure. They should have sufficient mechanical strength, resistance to wear and tear, and fatigue resistance to ensure a long lifespan and reliable performance of the system during repeated use.

Sterilizability: It is recommended that the instrument meets the most advanced criteria for sustainability. Although we are requested to conceive and produce a TRL4 working instrument, the project should take into consideration technical choices that allow extensive reprocessing or recycling of components. The initial idea is to have the instrument made of two parts: the part consisting of the sensorised tip, introduced into the body should be made of disposable plastic materials, that according to local laws could be recycled. This part should be solidly attached to a second part consisting of a shaft and a handle where all tube connections will be integrated, in continuity with the disposable tip. This should be made if possible, with durable material which could be reprocessed and reused.

Reprocessing could be achieved through standard washing/cleaning and sterilization methods, such as autoclaving, ethylene oxide (ETO) gas sterilization, or gamma radiation.

Compatibility with Imaging Techniques: If the soft actuation system is intended to be used in conjunction with imaging techniques, such as intraoperative ultrasound or ultrasonography, the materials used should be compatible with these imaging modalities. They should not interfere with

the quality or accuracy of the imaging and should be transparent or minimally attenuating to the imaging signals.

Ease of Integration: The materials used in the soft actuation system would be beneficial to be integrated into the overall design of the laparoscopic tool. They should be compatible with other components, such as sensors, actuators, and electronics, and should allow for seamless integration without compromising the overall functionality and performance of the system.

Cost-Effectiveness: The overall cost of the laparoscopic tool and the economic feasibility of the system for practical use in a clinical setting is also a inevitable factor to take into account.

2.2.6 Actuation medium/media and piping diameter

Actuation is expected to be pneumatic.

1. Actuation Medium/Media:

- **Proportional Control:** The actuation medium/media should be capable of providing precise and proportional control over the motion of the soft actuation system using proportional control valves. The medium/media should allow for smooth and accurate control of pressure, flow rate, and other properties to achieve the desired actuation performance with fine-grained control.
- **Response Time:** Fast response time to ensure rapid actuation of the soft system in real-time or near real-time. The medium/media should allow for quick changes in pressure or flow rate as commanded by the proportional control valves to enable dynamic and responsive motion of the system.
- **Stability:** Stable and reliable, maintaining consistent properties over time and under varying conditions of temperature, pressure, and other factors. The stability of the medium is crucial for ensuring consistent and consistent and repeatable performance of the soft actuation system during laparoscopic surgery.

2. Piping Diameter:

- **Flow Characteristics**: The piping diameter should be carefully chosen to achieve the desired flow characteristics in the system. This includes considering factors such as laminar flow, turbulent flow, and pressure drop. The diameter should be optimized to ensure efficient flow of the actuation medium/media, avoiding excessive turbulence or pressure drop that may impact the performance of the system.
- **Leakage:** The piping diameter is important to minimize the risk of leakage in the system. Proper sealing and fitting of the piping should be ensured to prevent any unintended leakage of the actuation medium/media, as this can result in loss of actuation performance, contamination, or other adverse effects.
- **Piping Layout:** The layout of the piping should ´prepare for minimizing the risk of kinking, bending, or deformation during actuation. The diameter and material of the piping will be chosen to ensure adequate flexibility and durability to withstand the expected range of motion of the soft actuation system.

2.2.7 Control unit

The control unit should provide precise and intuitive control over the actuation of the soft system, allowing the surgeon to manipulate the multi-articulated mechanism and palpate the GI tract tissue

effectively. The control should be proportional, allowing for fine-grained adjustments to the actuation parameters, such as pressure, flow rate, and motion amplitude, to achieve the desired palpation performance.

User Interface: The control unit should have a user-friendly interface that enables easy and intuitive control by the surgeon or other operating room personnel. The interface should provide clear and meaningful feedback on the actuation parameters and system status, such as pressure readings, motion amplitude, and other relevant information, to assist the surgeon in monitoring and adjusting the system during surgery.

Safety Features: We will try to incorporate safety features to ensure the safe operation of the soft actuation system. This may include emergency stop buttons, pressure limits, motion limits, and other safety measures to prevent unintended or excessive actuation that may cause harm to the patient or the system.

Data Logging and Analysis: The control unit may include functionality for data logging and analysis, allowing for the collection and analysis of actuation parameters, system performance, and other relevant data. This data can be used for post-surgical analysis, system optimization, and quality control purposes.

Connectivity: The control unit may include connectivity features, such as communication interfaces, data transfer capabilities, and remote-control options, to enable integration with other surgical instruments, surgical systems, or external devices for enhanced control, monitoring, and coordination during laparoscopic surgery.

Power Supply: The control unit is recommended to have a reliable and sufficient power supply to ensure uninterrupted operation of the soft actuation system during surgery. This may include backup power options, such as batteries or redundant power sources, to mitigate the risk of power failure and ensure continuous operation of the system.

2.2.8 Actuation time (real-time or near real-time)

As this is supposed to be a diagnostic tool and not an operative one, although real-time would be preferable, near real-time seems also acceptable.

Real-time or Near Real-time Actuation: The soft actuation system should provide actuation response times that are as close to real-time as possible, ensuring minimal delay between the surgeon's input and the system's response. This is crucial for enabling effective palpation of GI tract tissue during surgery, where delays or lags in actuation response could hinder the surgeon's ability to accurately detect tissue abnormalities.

Low Latency: The system should have low latency in actuation, minimizing the delay between the surgeon's input and the actual actuation of the multi-articulated mechanism. Low latency is essential for providing a natural and intuitive control experience, allowing the surgeon to perform palpation manoeuvres smoothly and accurately.

Fast Actuation Speed: The soft actuation system should be designed to achieve fast actuation speeds to enable efficient tissue palpation. Actuation speed can be influenced by various factors, such as pneumatic pressure, flow rate, and mechanical design of the system. Higher actuation speeds can help the surgeon to perform quick and precise palpation manoeuvres, improving the overall performance of the system.

Actuation Stability: The soft actuation system should maintain stable and consistent actuation over time during surgery to ensure reliable and accurate palpation of GI tract tissue. Actuation stability

can be achieved through appropriate pressure regulation, valve control, and system design to minimize fluctuations or drift in actuation parameters during surgery.

Dynamic Control: The soft actuation system should be capable of dynamic control, allowing the surgeon to adjust actuation parameters on-the-fly during surgery as needed. This may include adjusting actuation pressure, flow rate, or motion amplitude during different stages of surgery or in response to tissue characteristics, ensuring adaptability and versatility of the system for varying surgical requirements.

Reliable Actuation: The soft actuation system should provide reliable actuation performance throughout the entire duration of surgery, without experiencing actuation failures or disruptions that may affect the surgeon's ability to palpate GI tract tissue effectively. Reliability in actuation is essential for ensuring uninterrupted and consistent performance of the system during laparoscopic surgery.

2.2.9 Forces to be applied (safe to operate force angle)

Crash tests show that there is hardly no damage when forces up to 1 N are applied to healthy tissue. Ideally pressure sensors to prevent the overtake of this value would be appreciated.

Safe Force Levels: The soft actuation system should apply forces to the GI tract tissue that are within safe and acceptable levels defined by medical guidelines and standards. The force levels should be carefully determined and controlled to prevent tissue damage or trauma during palpation. The system should be designed to provide adequate force feedback to the surgeon, allowing them to apply appropriate force levels while avoiding excessive or harmful forces.

Adjustable Force Levels: The system design will allow adjustable force levels based on the requirements of the specific surgical procedure and the characteristics of the GI tract tissue. This may involve providing adjustable pneumatic pressure, flow rate, or other actuation parameters to control the force levels applied to the tissue. The force levels should be easily adjustable by the surgeon during surgery, allowing for fine-tuning based on tissue characteristics and palpation requirements.

Force Angle Control: The soft actuation system should allow control over the force angle, which refers to the direction in which the force is applied to the tissue. The force angle should be carefully controlled to ensure that the applied force is directed appropriately for effective tissue palpation. This may involve adjusting the orientation or positioning of the multi-articulated mechanism or the probe tip to achieve the desired force angle.

Tissue Sensing and Monitoring: We aim to incorporate tissue sensing and monitoring mechanisms to the soft actuation system in order to provide feedback on tissue characteristics, such as tissue stiffness or tissue response to the applied forces. This feedback can help the surgeon to adjust the force levels and force angles based on real-time tissue feedback, ensuring safe and effective tissue palpation.

2.3 Surface curvature sensors / Multi-core optical fibers (HMU)

A set of 4-core optical fibres will be employed in order to manufacture the distance and surface curvature probe. The role of this subsystem is the mapping of the surface scanned by the operator and at the same time the decoupling of the force applied from the operator from the force applied by the tissue to the stiffness sensors. The creation of this subsystem involves the development of the setup responsible for the proper alignment of the 4 core optical fibres (diffraction pattern setup), the development of the 'all 4 in one go' FBG inscription setup using a concave cylindrical lens and finally

the fabrication of the sensing probe sets, each set consisting of 3 bend sensitive optical fibres (D6.1), all three operating at different wavelengths. Design variations between the different sets will be employed in order to test differences in device performance.

Alternatively, the FRHHI also provides curvature sensors based on single-core optical fibres and FBGs written on the edge of the fibre core. This method is favourable for bigger fibre deflections.

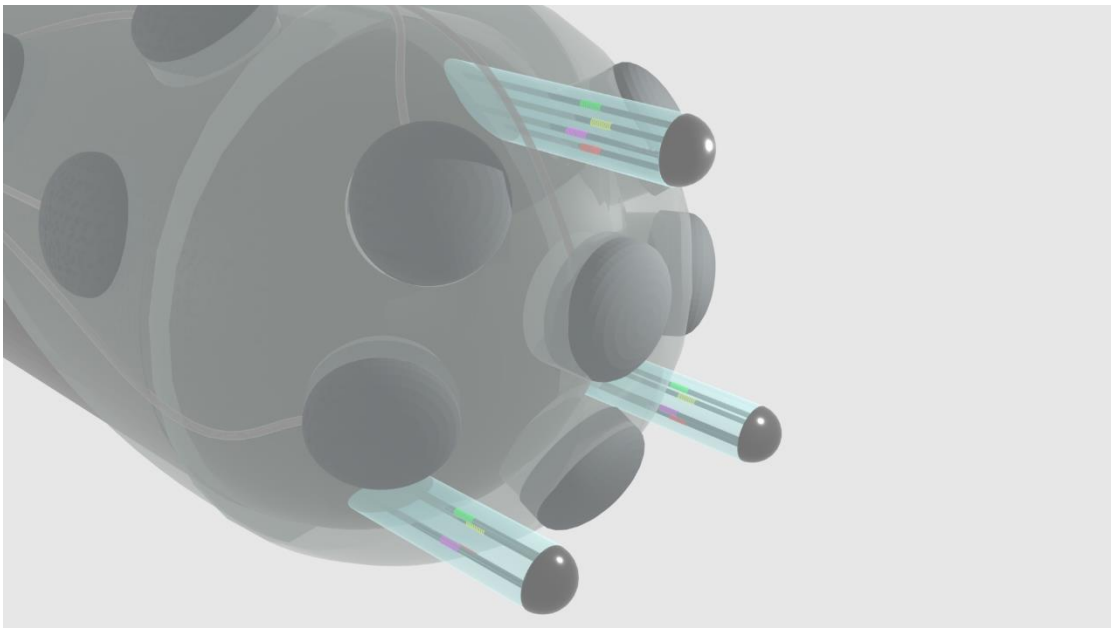

Figure 5 – Multi-core optical fibres

2.3.1 Optical fibre's length

Ideally, the probe surface should be smooth with no sensor subsystem protruding from the surface and everything should be integrated in the probe fuselage. However, since this is not possible, as this would render the surface mapping and the operator force decoupling impossible, the protrusion should be limited to the minimum. Optical fibre placement, protrusion length and optical fibre protection will all be considered in order to minimise the risk of damaging organs by friction during operation of the probe. A longer length of optical fibres increases surface height dynamic range and sensing sensitivity, while a shorter length increases manoeuvrability and is less likely to incur damage to surrounding tissue. Therefore, from a performance point of view, the protrusion length should be kept as short as possible, while retaining the capability to distinguish the minimal surface features that can help reconstruct the surface shape under examination and decouple the force applied by the operator. In order to minimize tissue damage during probe insertion, on demand retraction mechanisms will be explored, - if possible to realize at all, because of technical difficulties - so that this subsystem could be "pushed" inside the fuselage, i.e. it will be kept in a safe position and advanced only when the probe is stabilised in one position.

2.3.2 Optical fibre's placement and pointing direction (probe's fuselage)

In order to map the underlying surface as the probe scans along the target tissue, at least 3 optical fibres should be present and placed in a triangular pattern, as 3 points define a plane. The x,y and z coordinates of each optical fibre will be recorded and a plane will be reconstructed. As the probe scans through the target tissue these reconstructed planes are stitched together to form a 3d view of the scanned tissue as the operator scans around the target area. The triangular lattice formed by

the position of each optical fibre should have a size that can cover the full probe area, so that the underlying area reconstruction can depict the tissue touched by the probe, without any dark spots, namely, each reconstructed plane encompasses all stiffness sensor points developed on or around the probe. The optical fibre pointing direction will be initially parallel to the probe fuselage longitudinal axis, so that optical fibre bending in any direction around a 360° circle is equally favoured. If, however, initial testing suggests otherwise the orientation will be changed according to the probe needs.

2.3.3 Optical fibre's termination

After fabrication of the Fibre Bragg Grating sensors inside the cores of each optical fibre, the optical fibre end-face will be cleaved, and the cladding exposed to the surrounding elements. In this format, it will be impossible to use the optical fibre as part of an endoscopic device, therefore, it will have to be properly terminated for safe use inside a human body. The requirements in this aspect, then, would be the smooth termination of the optical fibre, so that no damage to the human tissue occurs during insertion and operation, biocompatibility and safety in case of accident.

2.3.4 Optical fibre coating (thickness, biocompatibility) and application

As previously mentioned, the optical fibres after the sensor fabrication will be stripped of their protective jacket and new coating will have to be applied. The coating of the optical fibres should be biocompatible, and the surface should be as smooth as possible to prevent friction damage or any other trauma source to the examined organ. In a way, the thicker, the better, however if it's too thick it could compromise the elasticity of the optical fibre and a very thin layer could compromise safety. At the same time, the thickness of the coating should ensure safe operation even during the unlikely event of an accident, namely optical fibre breakage, where the coating should hold the broken piece together with the rest of the body, so that in can be safely removed for repair. Finally, the coating applied must not be thicker than the termination diameter of the optical fibre and should smoothly transition from the optical fibre body to the termination edge.

2.3.5 Maximum bending angle and maximum angle detectable

The protruding optical fibres will bend as they scan across the tissue under question. Given that optical fibre material is fixed (fused silica) as well as the diameter (125μm), the maximum bending angle of each optical fibre can only depend on the protrusion length outside the body of the probe. Several protrusion lengths will be tested during the installation of the optical fibres, in order to examine the golden mean between patient safety and optimal sensing performance in terms of dynamic range and sensitivity.

The maximum angle detectable by the sensor depends on the wavelength shift caused by the bending of the optical fibre and is limited only by the readout unit spectral range. In the case of the probe under question, the maximum bending angle should be at least 90° or more, restricted by the probe design and material mechanical properties.

2.3.6 Resolution of angular detection

The resolution of the angular detection is determined by the spectral resolution of the optical fibre sensor readout unit. The requirement here is that this sensor subsystem should have sufficient bend angle sensing resolution so that it can differentiate between a height difference that would indicate a transition between healthy and malignant tissue. Since, however, this cannot be always known and usually the spectral resolution of such systems is high, the expected resolution is provisioned to be sufficient or higher than that required by the final application. Additionally, given that the spectral

shape of a FBG is known, software fitting to the grating shape can take place to further increase resolution -and in turn angular resolution- a practice common in many commercial FBG interrogation units.

2.3.7 Repeatability of angular detection

Angular detection repeatability is a function of two parameters. Temperature, and wavelength shift detection repeatability. Given that the human body is normally temperature stable and that temperature during operation can be easily monitored, the only factor limiting repeatability is the wavelength detection repeatability of the readout unit in use and will be determined by the specifications of the final unit to be used. The functional requirement in this case is that the angular detection repeatability is lower than the absolute coordinate reconstruction error.

2.3.8 Maximum height detection / minimum feature detection

The azimuthal range of features that can be detected by the surface curvature sensors is determined by the protrusion length, along with the maximum deflection angle.

The minimum feature detectable is a function of readout unit spectral resolution and can be further enhanced by software fitting a Gaussian curve to the grating shape. The application requirement in this case is to have sufficient dynamic range in terms of height detection that can reveal anomalies related to malignant cells.

2.3.9 The above determine the Fibre Bragg Grating design

The functional requirements of the probe determine the design of the Fiber Bragg Gratings in the 4 cores of each optical fibre (or the design of an edge core FBG in the case of single core FBGs). The FBGs should have sufficient spectral spacing between them so that no spectral overlap takes place when operating in the maximum angle detection range. Any spectral overlap will lead to sensor saturation and decrease the sensing dynamic range of the subsystem. In addition, if the readout probe does not support the concurrent interrogation of 3 channels in parallel, the total number of FBGs interrogated under a single channel should be spectrally separated enough, so that no overlap takes place during operation. If the sensor readout unit supports more than 3 individual sensing channels, then this requirement holds true for only the 4 FBGs withing the cores of a single optical fibre. In every case, the largest possible spectral spacings will be pursued, always under the restrictions given the total spectral range of the readout unit.

2.3.10 Optical sensor interrogation speed

As the operator of the device under development scans along the tissue under examination, a surface map should be reconstructed, ideally, in real time. However, as the surface map creation would require the readout and processing of a large number of optical data, real time performance, although desired, can also be substituted by quasi-real-time interrogation speed, which would be technically much easier. However, a large lag between the operator motion and the surface reconstruction cannot be accepted as this would jeopardise the correct calculation of the stiffness detected by the stiffness detection membranes.

2.3.11 Data output format

The optical fibre sensors detect wavelength shifts of the FBGs and intensity changes, which are then converted into solid angles and which are used to determine x,y and z coordinates in space. The data should be output into a format that can be used by the team developing the electronics,

therefore, digital data can be accepted in the form of csv or other machine-readable data format. Due to the data complexity, analogue signals cannot be used in this case.

We will create a VR image of the tumour, by moving repeatedly the probe above the target, while keeping the external camera fixed on top of it. Images obtained will be composed into a broader image allowing the assessment of lateral margins.

2.4 Haptic sensor membrane (QMUL)

The tool will have at the tip a palpation probe and the soft membranes for tactile measurements during palpation procedures. The probe will be designed in a way as to allow the integration of multiple sensors and optical transmission links. The design of the probe structure will be conducted in close collaboration with WP 5 and WP6. Materials for the construction of the probe will be chosen finding a compromise between allowing safe interaction with tissue and enabling tissue deforming for tactile and stiffness sensing. Membranes made of thin layers of silicone rubber will be integrated with the palpation probe allowing the tactile exploration of soft tissue. Each membrane will have the shape of a dome – optical waveguides (WP5) will be integrated to measure membrane deformation. Each membrane will be interrogated by a set of optical waveguides shining light onto the inner reflective surface of the membrane. Any membrane deformation due to interaction with the tissue will be received by the waveguide and can be interpreted as the interaction forces between the palpation finger and the tissue. Using multiple waveguides, complex deformation patterns of the membrane can be identified and provide a clear representation of the mechanical properties of the underlying tissue. The novelty of our approach is that the stiffness of the membrane can be varied across a wide range by changing the air pressure in the chamber behind the membrane. This approach allows us to probe the examined tissue varying the interaction parameter (from soft to stiff) and in this way to acquire a large spectrum of signals which when fused allow us to distinguish between healthy tissue and cancerous tissue. Hydraulically adjusting the chamber pressures will also be explored. Switching among different sensors should be driven by the operator, either mechanically (buttons) or remote control.

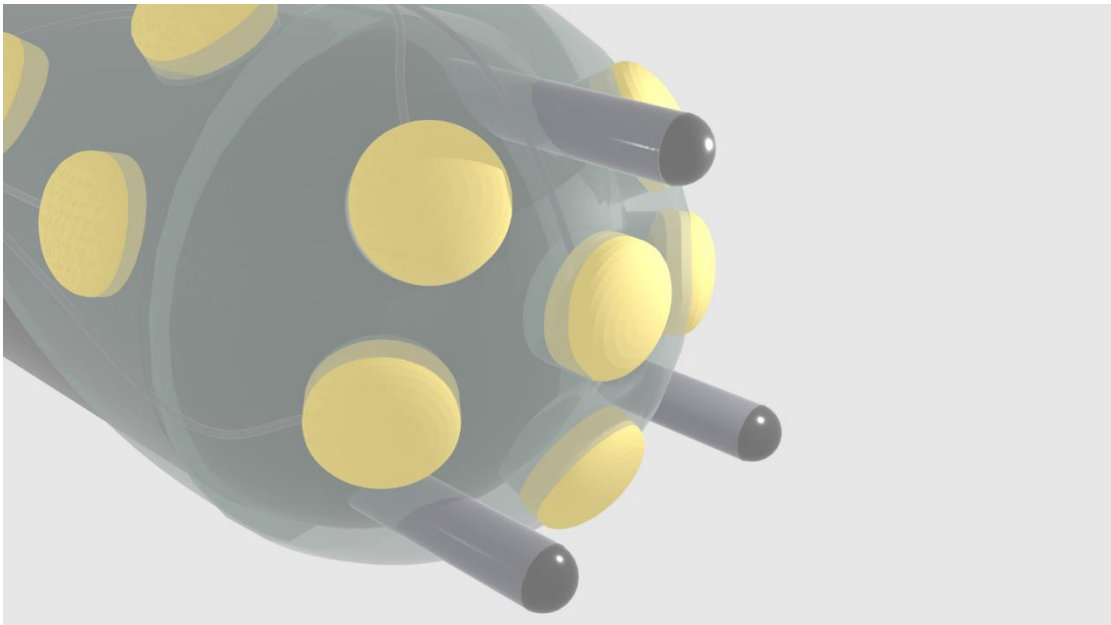

Figure 6 – Haptic sensor membrane

2.4.1 Dynamic force range of the sensing membrane

The sensing membrane would have variable stiffness to allow for a dynamic range of force estimation. This variable stiffness would be governed by varying the pressure inside the chamber of the sensor membrane.

The lower limit of the dynamic range i.e., when no pneumatic pressure is applied inside the chamber, depends on the geometry and material used for the fabrication of the sensing membrane. To ensure a reduced lower limit of the dynamic range and to prevent any issues, including ballooning at elevated internal pressure, the membrane's design needs to be optimized.

2.4.2 Design of the sensing membrane

The diameter and the thickness of the soft sensing membrane are crucial factors for designing a sensor for our application.

For a certain material and force applied, a thinner membrane of larger diameter would deform considerably as compared to a thicker membrane of same diameter. Likewise, for a certain thickness, a membrane with larger diameter would experience larger deformation as compared to the membrane with smaller diameter.

A single sensor membrane needs to be designed keeping in consideration the force range and number of membranes on the sensing probe.

2.4.3 Material (Young's modulus)

Materials for the construction of the probe membranes will be chosen finding a compromise between allowing safe interaction with tissue and enabling tissue deforming for tactile and stiffness sensing. Membranes made of thin layers of silicone rubber will be integrated with the palpation probe allowing the tactile exploration of soft tissue.

The stiffness of the selected material significantly affects its deformation, hence, affects the sensitivity of sensing membrane. As the stiffness of the sensing membrane would be controlled by the pneumatic pressure inside the chamber, selected material should have low elastic modulus. This would allow for a wider range of membrane stiffness. As the light would be reflected from the internal reflective surface of the sensing membrane, the internal layer needs to have good reflective properties. The material should also be bio-compatible and cost-effective.

2.4.4 Optical transmission and sensing

Each sensing membrane would have an emitter optical fibre and a set of receiver optical fibres. Multi-core optical fibres, lined along the hollow body of the sensing probe, can be used to transmit light to and from the sensing membrane.
Polymer Optical Fibres can be used for this purpose however, biocompatibility of these fibres needs to be considered.

2.4.5 Pneumatic pressure regulation/piping

To control the dynamic force range or the stiffness of the sensing membrane, pneumatic pressure needs to be varied inside each sensor membrane. As the pressure variation would be the same in all the sensor membranes on the sensing probes hence, these would be connected internally through a pneumatic piping network.
A pneumatic pressure regulator would be used to regulate this pressure inside the sensor membrane.

2.4.6 Optical Isolation

The haptic sensor membrane detects the variation in the light that is reflected from the membrane's internal reflective surface.

Ambient light noise would interfere with the sensors' ability to detect light changes. The sensor membrane's optical isolation is therefore a crucial functional requirement.

2.4.7 Real-time data acquisition

As the sensing probe needs to interact with organs/tissues, real-time data acquisition and processing is of paramount importance. Any lag in the received data would result in a delayed response, risking control of the probe.

2.5 Haptic sensor waveguides (FRHHI)

A set of optical waveguides shining light will be embedded onto the inner reflective surface of the membrane. Any membrane deformation due to interaction with the tissue will be received by the waveguide and can be interpreted as the interaction forces between the palpation finger and the tissue. Using multiple waveguides, complex deformation patterns of the membrane can be identified and provide a clear representation of the mechanical properties of the underlying tissue. The novelty of our approach is that the stiffness of the membrane can be varied across a wide range by changing the air pressure in the chamber behind the membrane. This approach allows us to probe the examined tissue varying the interaction parameter (from soft to stiff) and in this way to acquire a large spectrum of signals which when fused allow us to distinguish between healthy tissue and cancerous tissue. Hydraulically adjusting the chamber pressures will also be explored.

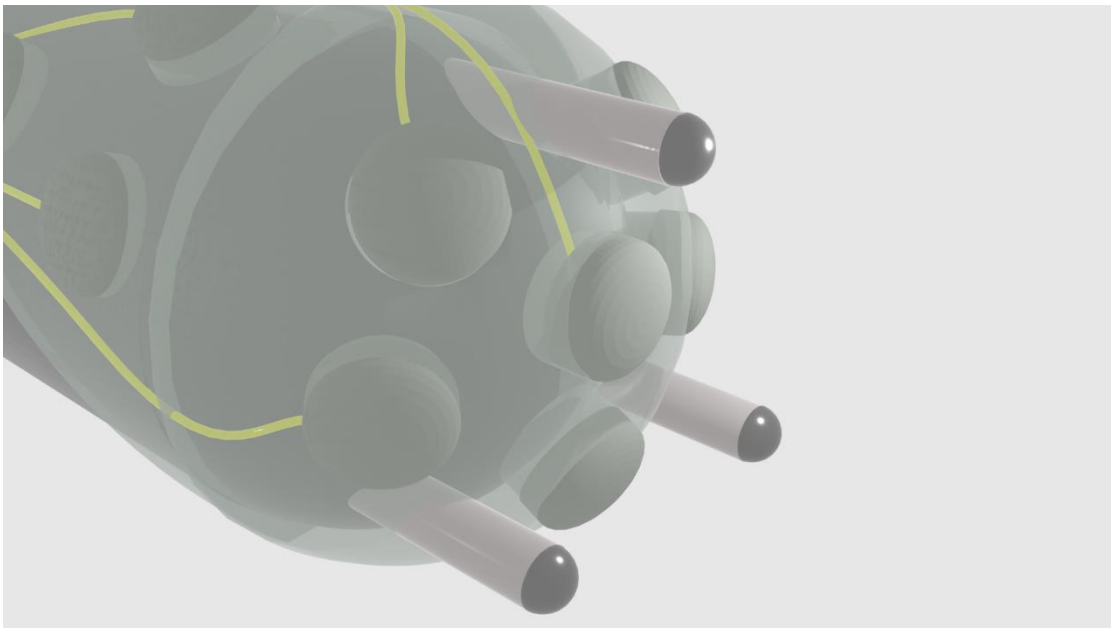

Figure 7 – Haptic sensor waveguides

2.5.1 Definition of parameters of the POFs and waveguides

To ensure a minimal loss while enabling best dynamic sensing range, it is crucial to define the dimensions of the optical waveguide medium. That is, in case of a polymer optical fibre (POF), the

radius of the fibre core, and in case of a rectangular polymer waveguide, the thickness and width of the waveguide, also the geometrical bending radius of the waveguide circuit.

In case of a POF, the limitation lies in the overall dimension of the probe tip itself. For coupling and attenuation with light source or measurement unit, there are usually conventional components on the market available. It is important to find an optimal fibre dimension to provide maximum sensitivity and leaving enough space for sensor units from other work packages at the same time.

For polymer waveguides on the other hand, the overall size of the sensor circuit can be flexibly designed, the challenge however, lies in ensuring a minimum attenuation loss when coupling with external optical units like light source or measurement units.

2.5.2 Refractive index change with respect to surrounding material

Dependent on the wavelength of the coupled light, the relative change of the refractive index can vary. It is important to ensure a higher refractive index for the waveguide material than the media surrounding the waveguide, that is, in case of real application, in a human body, the presumed surrounding atmosphere is most likely under human tissue or blood.

2.5.3 Minimum losses accepted

The minimum losses are dependent on the number of designed measuring points of the whole sensor plane.

2.5.4 Minimum acceptable spacing between channels

The minimum acceptable spacing between each channel should be 10 µm. This is also dependent on the choice of the manufacture method of the sensor circuit and the polymer material itself.

2.5.5 Waveguide substrate material

The material of the waveguide substrate should meet a biocompatibility standard so that it can be eventually applied on human tissue. It is also important to note that, the substrate material should have an influence as small as possible on temperature change between e.g. 20-40 °C (between room temperature and human bodies).

2.6 Haptic sensor array (FRHHI)

Optical fibre sensors are characterised above all else, by the fact that they are insensitive to electromagnetic currents and interference fields and are of minimal dimensions. Optical sensors such as fibre Bragg gratings are used in engineering to monitor such items as bridge components or steel cables. The peculiarity of the FBG is that it only reacts within a certain wavelength range, transmitting all other wavelengths with almost no loss. This makes it possible to write several sensors with different Bragg wavelengths into a single glass fibre. In this way, an entire sensor network can be set up using just a single fibre. Due to their minimal size and low weight, these sensors can also be used in confined or even inaccessible spaces. The glass fibre with the FBG sensor or indeed several FBG sensors can be affixed to the object of interest, such that small changes in the temperature or shape of the object can be detected quickly. As a result of this quest for miniaturisation alongside the integration of various optical components, integrated optics and photonics have developed as a new field in physics, as an analogy to electronics. So-called "lab on a chip" systems offer the possibility of carrying out optical analyses on a single chip. Typically, these systems are based on an integrated optical ridge waveguide and point-by-point inscription with a femtosecond laser and light-based sensors on a substrate. Materials and manufacturing methods,

however, do vary. The main drawback of glass fibres however is the recycling/reusing difficulties they induce.

Within our project, a polymer-based sensor array with a low-cost readout unit will be developed. Besides distributed tactile information, the stiffness of the tissue will also be detected by evaluating the influence of several airflows on the tissue and the variation in contact pressure. This approach lays the foundation for a first all-polymer low-cost haptic sensor array. For the development of this kind of sensor, our approach will be organised into six phases: (1) design of an attenuation based pressure sensor; (2) sensor's dynamic range and accuracy, and initial single-sensor readout system; (3) sensor extension for stiffness measurements; (4) development of a curved sensor- chip; (5) miniaturisation and scale-up; (6) Integration of the sensor array and readout system within the palpation sensor.

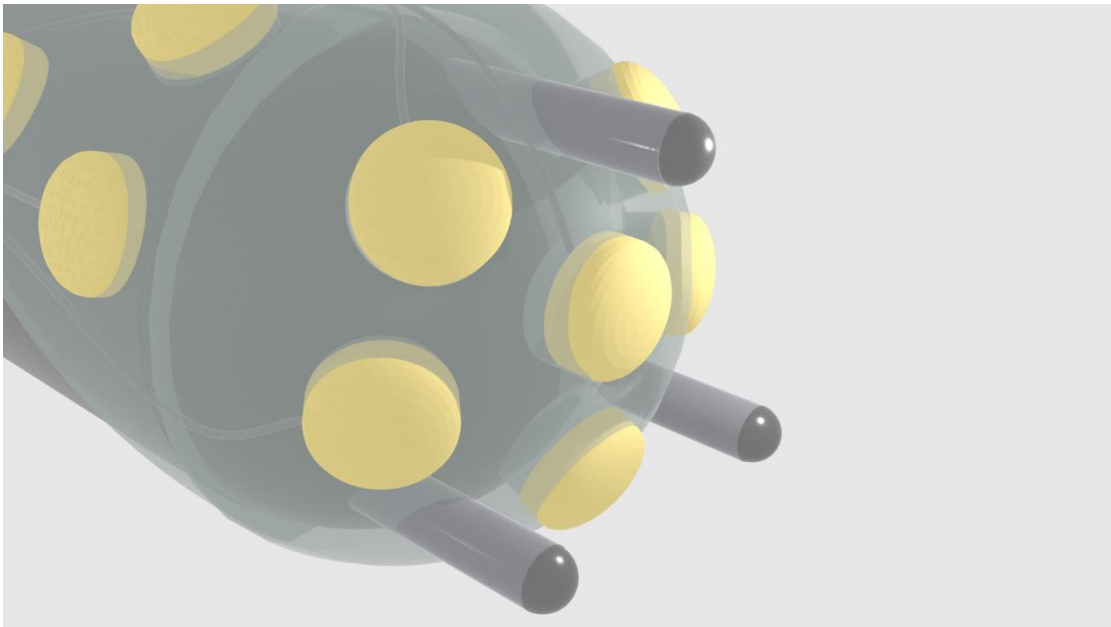

Figure 8 – Haptic sensor array

2.6.1 Dimension of the airflow system

The overall diameter of the tool for the palpation probe is crucial to define the dimension of the airflow system. It is important to find a balanced point ensuring sufficient sensor dynamic range and optimal overall size of the palpable probe.

2.6.2 Number of haptic sensors

The overall possible number of the sensors mainly depends on the final size of each sensor point. The size of the sensor itself depends on the required sensor dynamic range in combination with the applied material.

2.6.3 Sensor position

The position of the haptic sensors should be defined in relation to the airflow system. It is recommended to have one senor on the tool tip and at least one on the side of the tool. Since the sensor circuit is always manufactured on planar surface, the position of the measuring sensor point influences the overall application and performance of the sensor on a non-planar surface.

2.7 Ultrasound probe

As described above, intraoperative ultrasound has become a must in all difficult situation. Despite probes made significant improvements, this is today quite limited to GI tract resections and other solid organs (i.e., unclear location of small pancreatic neoplasms). The technology for ultrasound is already well advanced and for the purpose it does not require major improvement. It seems more reasonable to leave within the probe we are developing, an operative channel through which to introduce a standard probe commercially available. When the importance of this technology may be proven to result indispensable, we will make sure to integrate a real mini-US probe into the probe we are developing.

As an alternative, more effective, we may allocate close to the tip of the probe, a standard sensor for endoscopic ultrasound, while at the same distance from the tip, but opposite on the external circumference, we will allocate our newly conceived sensorised surface. This way, the probe may be used for both applications that look complimentary. In fact, our newly designed sensorised surface will help in determining stiffness of tangible tissue, while endoscopic ultrasound provides structural information about the target starting few mm below the surface.

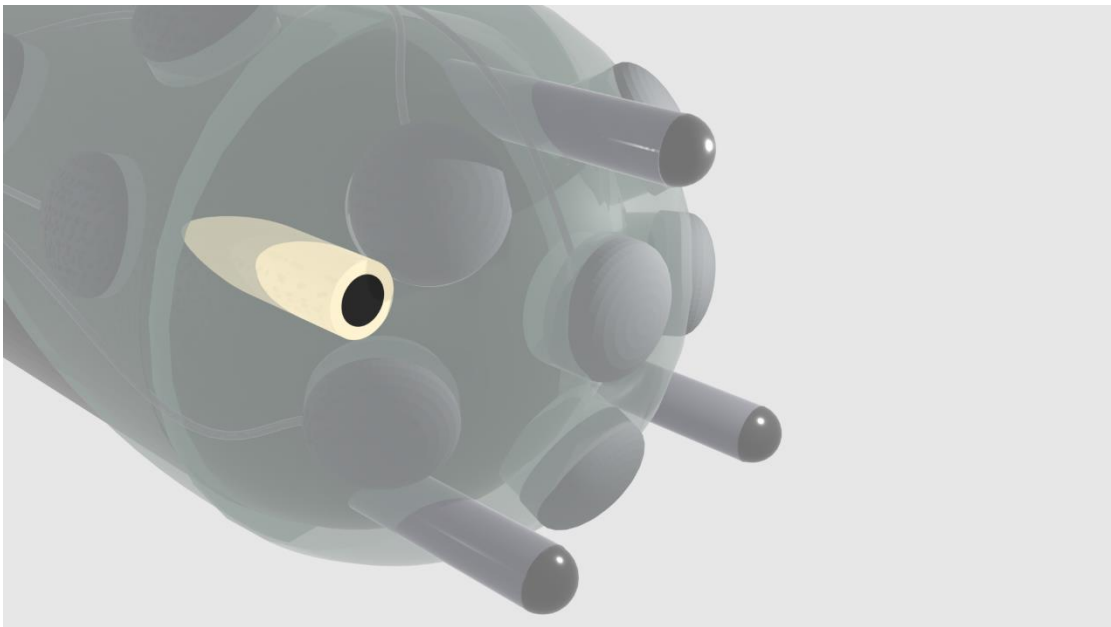

Figure 9 – Ultrasound probe

2.7.1 Sensor size

The probe will integrate a standard mini probe for US derived from those already well performing and available on the market. The size is in a range of 2.8 to 3.7 mm as they are commonly introduced through the working channels of standard flexible endoscopes for gastroenterology. Alternatively, the probe maybe much larger and precise in returning details from imaging. In fact, the most accurate EUS probes are sensors integrated on the side of the shaft, with a contact area of about 1-2 cm2.

2.7.2 Sensor position

The position of the sensor requires to have good access to the tissue to be studied. Therefore, best would be to have it on a side of the front surface. Theoretically it would be also preferrable to have it between 4 and 8 o'clock. As said above, alternatively, the probe maybe much larger and precise

in returning details from imaging. In fact the most accurate EUS probes are sensors integrated on the side of the shaft, with a contact area of about 1-2 cm2. This may offer much better resolution.

2.8 General specifications (UNITO – EAES)

According to the European Commission, the European recovery plan for the economy after Covid-19 aims to make the European economy more circular and more sustainable. The Green Deal on Sustainable Healthcare consists of a formal contract signed by hospitals, government organisations, industrials and universities, and will be used in the European's recovery strategy by stimulating a circular economy by building a more resilient European Union. One of the goals as seen from the Dutch Green Deal on Sustainable Healthcare is to reduce waste. By 2030, the CO_2 emissions from healthcare should be reduced by 49% compared to the 1990 levels, and by 2050 realise a climate neutral situation.

Hospital waste production in high income countries varies between 1.7 and 8.4 kg per bed per day depending on hospital size and activities. For hospitals in Europe ranging from 1.7 kg in the Netherlands to 3.6 kg in Germany, between 3.6-4.0 in Middle East countries such as Kuwait. and in the US these numbers are rising to 8.4 kg. Although, the impact of environmental change on public health has received little consideration. In total 5.9 million tons of medical waste is disposed in the USA by hospitals annually and healthcare produces 8% of the total CO_2 emissions in the US. Subsequently, severe health risks associated with medical waste disposal by hospitals have been reported.

2.8.1 Reusability/Sterilisability/Recyclability

On the one side, the green issue became a must to consider in projecting new technology, especially for medical use, due to the characteristics of the special waste produced in hospitals and in ORs in particular. On the other side, it would be difficult to generate such a sophisticated technology in a reusable fashion. Most-likely the tool will be composed by disposable materials, and all will be projected to be dismantlable, in order to collect original materials and save them.

Although much less likely, the possibility to reuse and sterilise part of it will be explored, of course.

2.8.2 Other

The instrument to be introduced into the body of the patient will be necessarily sterile. Not necessarily all behind the handle controlled by the operator. The tool will be projected in a way to have the back-hand technology reaching the sterile field in the OR easily, with limited cable and hoses, autoclavable and plugged-in before use.

2.9 Optical Readout and Control Unit (THL+BNDL)

2.9.1 Overview

THL will develop the Optical Readout and Control Unit (ORPCU). The aim is to design and construct, in terms of hardware and firmware, a single readout unit that supports optical communication with the probe’s sensors. The ORCPU will demux the various inputs and convert them to standard digital communication protocols able to interface directly a standard PC running the localization algorithms, and the control unit responsible for the pneumatic control. BNDL will develop the pneumatics control box for the actuation of the soft end-effector.

2.9.2 ORCPU I/O

The ORCPU will provide the inputs and outputs of the palpation tool's sensing modules. The ORPCU shall provide optical interrogation of the FBG surface curvature sensors, ultra-short LED driving for the optical circuits of the tactile membranes, as well as CCD camera readouts. In addition, it shall control the pneumatic circuits for the pressurization of the tactile sensing membranes, it shall regulate the pressure and flow for the airflow system that will deform the tissue, and it shall control the pressurization of the flexible end effector's chambers.

The inputs of the ORPCU are the outputs of the PALPABLE tool, while the outputs of the ORCPU are inputs to the PALPABLE tool as well as digital signals to the stiffness reconstruction software.

2.9.3 ORCPU box requirements

The unit should be a closed structure with proper ventilation for cooling and proper connectors for the various inputs and outputs.

The fibre cable connecting the probe with the unit should be a standardized one and its type should be defined by the application's needs in terms of bandwidth and cable length.

2.9.4 ORCPU power requirements

The power input shall be a standard 230 V 50 Hz power supply connection to facilitate the selection of a power source. However, internally, this shall be transformed to a proper power supply for the electronics' requirements.

2.9.5 ORCPU user interface

A simple user interface will be provided to enable trivial troubleshooting. A set of switches and buttons will provide the user the ability to interact with the unit for basic functional operations.

2.9.6 ORCPU electronics

To implement a full optical communication with the optical sensors of the probe, various electronics shall be utilized. More specifically, to interface the FBG curvature sensors and the tactile membranes, an optical source shall be used to provide optical signals of proper wavelength and accuracy. The ORCPU shall also include optical receivers able to read the response of these sensors and convert it to a digital format.

2.9.7 Internal ORCPU structure

The ORCPU includes the optical receiver and electronics accompanied by a computing unit, as well as the pneumatics control unit. The two elements shall communicate efficiently, to close the control loop. Internally, the pneumatics control unit shall receive the digitized output of the sensors to perform the pneumatic control operations.

2.9.8 ORCPU Computing unit

The computing unit of the readout module should be one that supports basic IO operations as well as peripherals to support the digital communication protocols of the application. Protocol conversion usually does not require a lot of resources thus the computing unit should be carefully chosen not to be more powerful than required, to minimize power consumption.

A standard MCU is going to be implemented as a first approach. In case timing constraints are too tight, an appropriate custom FPGA design may be introduced to accelerate the calculations.

2.9.9 ORCPU output to PC

A universal communication protocol shall be used to interface the PC running the stiffness reconstruction software.

2.10 Stiffness Profile Reconstruction (UESS)

2.10.1 Overview

The purpose of this module is to provide an easy-to-interpret visualisation of the stiffness profile of the tissues within the intra-operative field. This will require recording of the stiffness measurements and registering them with the tissue region being palpated. This is essentially a localisation problem where the object being localised in the probe, i.e. the tip of the flexible actuator.

2.10.2 Localisation

The localisation of the palpation measurements with respect to the image of the tissue should allow for a dense mapping of the stiffness profiles within the intra-operative field. The measurements should be persistently registered with the corresponding tissue regions under the assumption that the latter is not overly deformed between different scans with the probe and/or the endoscope.

2.10.3 Visualisation

The visualisation of the stiffness profile should be simple and straightforward, requiring minimal or zero training in order to be interpreted by the surgeons. Colour-based visualisation mechanisms such as heatmaps should be considered. Colour coding should be determined based on experimental results and/or empirical knowledge about the stiffness of healthy and nonhealthy tissues.

2.10.4 Deployment

The algorithmic modules for localising and visualising the stiffness measurements should run on hardware platforms of appropriate form factor such that it can be easily integrated with the probe electronics. The measurement mapping should be updated in near-real time so that the surgeon can readily use the insights delivered.

3. Conclusions

The probe (diam. 5mm, length 15-20mm) should incorporate multiple sensing modalities and a thin, flexible, pneumatically actuated end-effector (3DOF, 180deg) with distributed sensors for distributed tactile sensing.

The probe should consist of the photonic sensing elements and a sphere held at the end of a circular tunnel by a steady flow of air. The sphere is free to rotate in all directions and can move into the channel when pressed against the airflow. When rolling over tissue, the displacement depends on the tissue's stiffness and is picked up by the optical fibre above it.

Optical intensity variation in the sensing element is used to identify tissue stiffness variations. The principle of measurement used is extrinsic light intensity modulation provided through optical fibres. A non-planar photonics circuit (200µm waveguide, 8bit colour depth) for haptic sensor array is developed and interfaced with the probe; this circuit will be engraved on ultra-thin polymeric foil. The foil sensing elements are distributed around & along the probe for multiple sensor inputs for palpation (i.e., stiffness), distance and curvature that are then fused to provide the overall tissue situation. Using thin foils allows for ease of integration with the probe and a straightforward manufacturing process to enable low cost in large volumes.

The end effector is made from disposable or sterilizable materials, both options will be explored for recyclability or reusability respectively.