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Improvement of a Vocal Fold Imaging System

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Systems Engineering Class SYS 625

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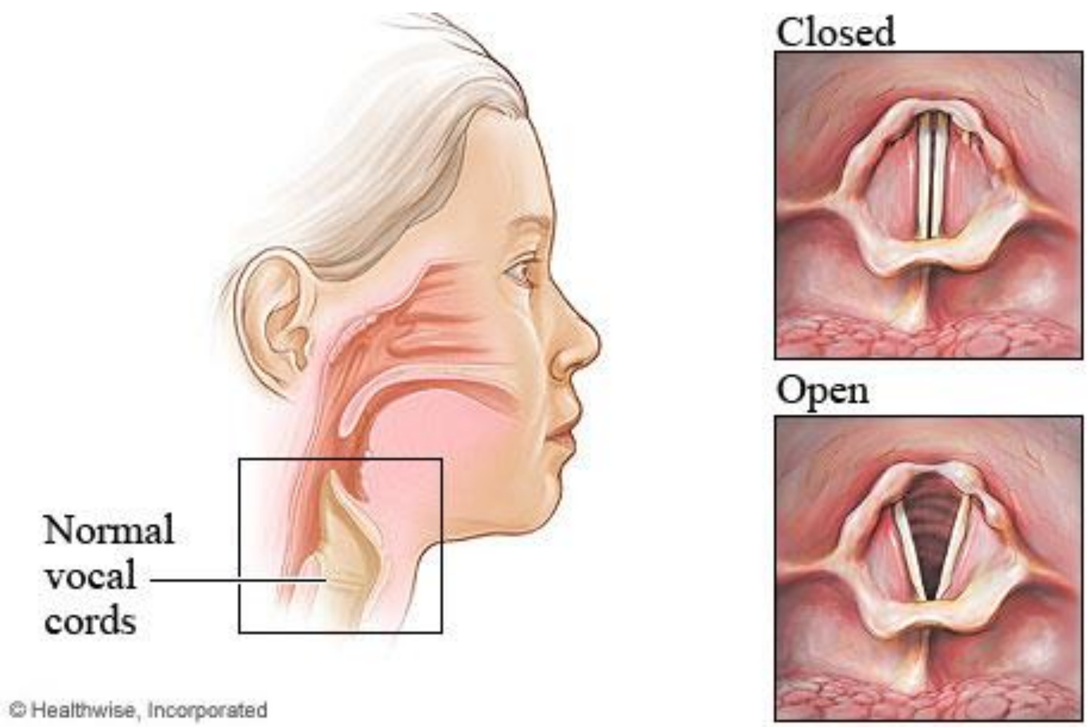
1. Executive Summary

Medical professionals can better serve their patients through continual update of their imaging tools. A wide range of pathologies and disease may afflict human vocal cords or, as they're also known, vocal folds. These diseases can affect human speech hampering the ability of the patient to communicate. Vocal folds must be opened for breathing and the closed to produce speech. Currently methodologies to image markers of potential pathologies are difficult to use and often fail to detect early signs of disease. These current methodologies rely on a strobe light and slower frame rate camera in an attempt to obtain images as the vocal folds travel over the full extent of their motion.



In contrast to the current system, the newly proposed system relies on high frame rate digital cameras to capture high definition images that can be compiled into slow motion movies. These movies will be played back to the medical professionals for diagnosis. Additionally, the images captured by the new camera will undergo image processing to highlight areas of asymmetry in the vocal fold motion, which are indicative of disease. The new system will utilize existing endoscopes and light sources to reduce cost and risk while minimizing the learning process of the new tool for the medical professionals.

2. Mission Description

Humans communicate using vocal folds in the throat. Air is expelled from the lungs over tightened vocal folds to produce speech or singing. The vocal folds, also known as vocal cords, are located within the larynx at the top of the trachea (Figure 1). The vocal folds must open to allow breathing and tighten closed to speak or sing (Figure 2). A wide range of pathologies can affect vocal folds. These pathologies can have significant impact on the patient's quality of life owing to the role of vocal folds in breathing and communication. Additionally, surgeries in and around a patient's airway carry significant risk due to the potential for compromising the patient's airway. For these reasons, high quality, accurate imaging is required prior to undertaking surgery and additionally, imaging systems must allow for as early a diagnosis as possible.

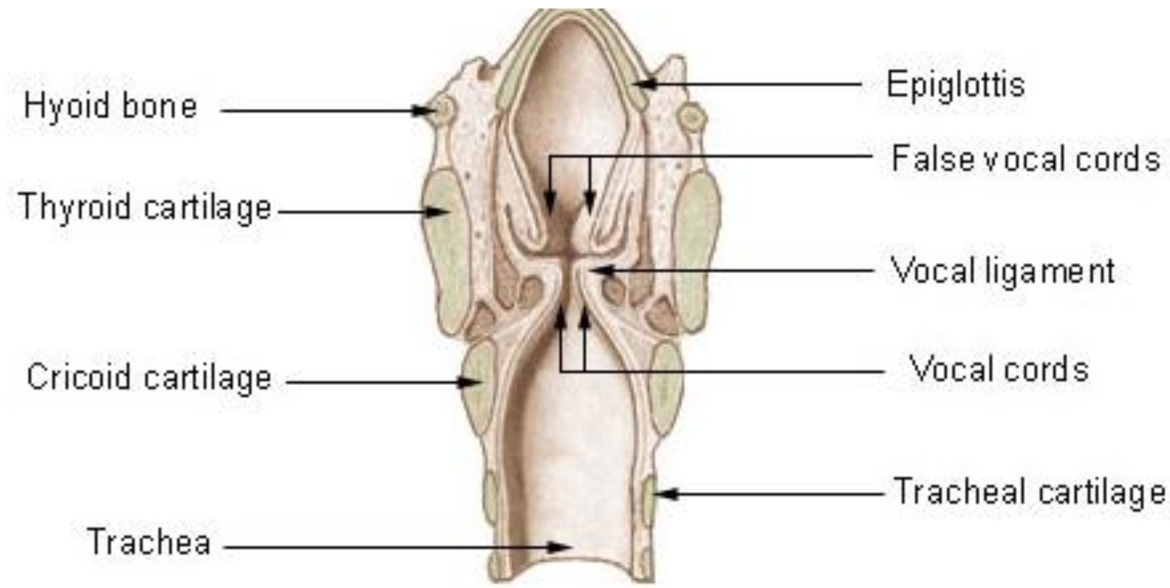


Figure 1

This document focuses on the instrument used to provide images of the vocal folds to the medical professional. Currently, the imaging system used consists of an optical fiber based endoscope used to transmit light to and from the vocal folds and a camera. Two methods can be used to obtain information: 1) a continuous light may be used to view or capture still images or 2) to view moving vocal folds a strobed light is utilized. For the latter of these methods, since vocal folds move too quickly to be viewed with the human eye, the light source is strobed (quickly switched on and off) in an attempt to acquire images over the entire vibration of the vocal fold to give the medical professional objective diagnostic information.

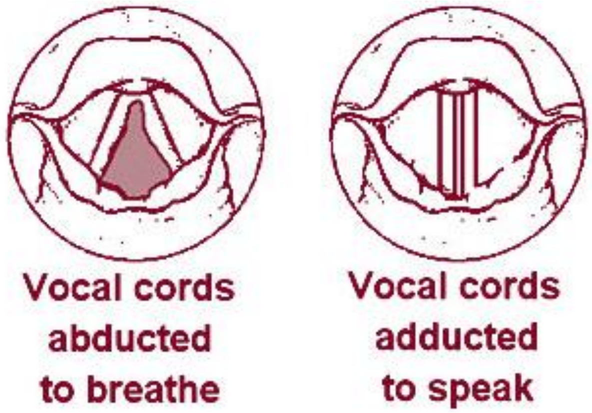


Figure 2

The major drawback of the strobed techniques lie in their inability to measure subtle changes in frequencies that may be a symptom of impaired or diseased vocal folds. If the vocal folds are moving at asymmetric frequencies that is an indication of disease, however these subtle changes are often not visible using the strobed method. In some cases, the instruments include software to sync the strobed light to the frequency of the vocal fold, again focusing purely on the normal physiology and masking subtle indicators of disease.

a. Mission;

Medical professionals need an optical instrument capable of imaging moving vocal folds that will enhance their ability to identify subtle changes in the frequencies of active vocal folds earlier than current methods while leveraging existing equipment and practices.

b. Goals;

The current imaging system does not adequately image the vocal folds as they are moving masking potential disease. The new instruments should;

- Improve existing imaging capability of vibrating vocal folds
- Provide software tools to identify subtle changes in vocal fold vibration during out-patient exam
- Maintain or improve patient and medical professional safety

c. Objectives;

- Provide adequate resolution over entire vocal fold image
  - Estimated at 0.5mm resolution over 76.2mm diameter
- Identify normal and asymmetric frequencies over typical human range with frequency resolution adequate to differentiate areas of disease.
  - 100-300 Hz is typical human vocal fold frequency range
- Maintain or shrink physical footprint of imaging equipment in exam room
  - Equipment must be housed in currently used 5.5-foot-tall by 2.5-foot square towers
- Maintain or decrease exam time
  - Currently 2-3 minutes

d. Business Rationale:

- Current imaging instrument does not readily provide desired information
    - Frame rate is too slow to view asymmetries in vocal fold movement
    - Prevents medical professionals from providing an early, accurate diagnosis
- Medical professional want to provide early, objective accurate diagnosis for their patients and need the tools to do this
    - Quality imaging allows detection of problems earlier when they are more treatable
    - Quality images also provide surgeons with information required for a successful surgery
- Hospital Administrators want to supply their doctors with up to date, high quality, cost effective equipment

e. Stakeholders

The stakeholders are shown in figure 3. Clearly the stakeholders most interested in the improvement of this instrument are the patients and medical professionals. They are highlighted as the active stakeholders.

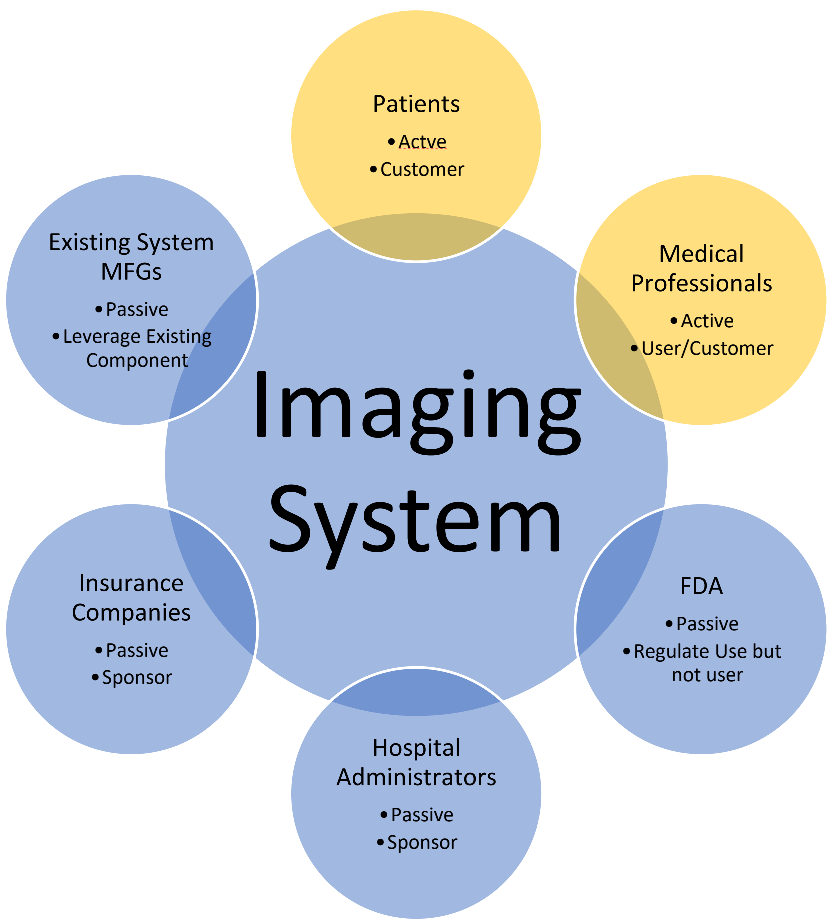


Figure 3

To that end, two medical professionals were interviewed. The questions they were asked centered around two main points:

- What are the drawbacks of the current strobe and endoscope based vocal fold imaging system?
- If you could have an ideal method of vocal fold imaging what would it do for you?

The tables below summarize their input. Note that due to patient privacy laws, the medical professionals were asked to also answer questions from the perspective of the patient.

1. Active Stakeholders

	Medical Professionals Expectations	
1.	Use existing fiber optic endoscope with prehensile end capable of articulating	Characteristic
2.	Must provide clear visual of asymmetric vocal fold pathology for diagnosis	Capability
3.	Measure vocal folds and movement, identify abnormal pathology manifested by multiple frequencies on vocal folds more accurately	Capability
4.	Patient is awake and able to follow requests to move vocal folds	Characteristic
5.	Use during outpatient appointment, 2-3 minute allotted for exam	Characteristic
6.	Intuitive software controls	Characteristic
7.	Clear, easy to use software display to visualize pathology for accurate diagnosis	Characteristic
8.	Software to analyze endoscopic findings	Capability

	Patient Expectations	
9.	Accurate diagnosis	Characteristic
10.	Fast Diagnosis	Characteristic
11.	Comfortable outpatient exam	Characteristic

2. Passive Stakeholders

Passive stakeholders include those who regulate the use of medical devices, the FDA as well as those who would fund the purchase or use of the equipment, namely the hospital administrators and health insurance providers.

	Existing Equipment Manufacturers Expectations	
1.	Leverage existing components as much as possible, in particular, existing endoscopes/ light sources	Characteristic
2.	Leverage existing processes	Characteristic
3.	Maximize system capabilities while minimizing changes	Capability

	FDA Expectations	
4.	Provide accurate diagnosis	Characteristic
5.	Patient safety (Appropriate light levels, electrical grounding, ergonomics)	Characteristic
6.	Medical professional (operator) safety	Characteristic

	Hospital Administrators Expectations	
7.	Cost effective (biggest bang for their investment buck)	Characteristic
8.	Must be safe for patient and medical professional	Characteristic
9.	Fit easily into existing equipment carts used in existing exam rooms	Characteristic

	Health Insurance Expectations	
10.	Must be cost effective	Characteristic

f. Sacred Expectations/ Key Stakeholder Acceptance Criteria

	Sacred Expectations
1.	Patient must not be harmed
2.	Patient must be able to follow medical professional requests to move vocal folds
3.	Must provide images capturing asymmetric or abnormal vocal fold movement to display for medical professional
4.	Cost effective
5.	User interface and display must be clear, fast, and easy to use with one hand

3. As-is Reference Architecture Diagram

To understand the proposed system concept, it is helpful to discuss the reference architecture of the currently used imaging system.

a. "As-Is" Contextual Description of Current Imaging System

Vocal cords are currently imaged in two ways; 1) flexible fiber optic scope with prehensile end that is inserted into the nose and 2) a rigid scope with angled mirrors that is inserted through the mouth. Both options are shown in a single system in Figure 4.

Figure 4

Both approaches can use a constant direct light source to capture a video of vocal fold movement at a possibly very slow frame rate or add a strobe light that syncs with vocal fold movement to view the mucosal wave. The mucosal wave of the vocal folds moves too quickly to see with the naked eye at 100 – 300 Hz. Since we are focusing on observing asymmetries in the vocal folds, we will only consider the strobed methodology as the "As-is" technology. Typical imaging instruments currently available on the market use a camera and strobe light to capture images at 30 frames per second and rely on repetitive imaging to obtain enough frames to capture the full extent of the mucosal wave. Some vocal fold imaging instruments use software to sync the strobe light with the vocal fold movement to improve the images, however, using the strobe light in this way however may obscure subtle changes in the symmetry of the movement of the vocal folds since the software will sync the light to the most prevalent frequency. The medical professional then interprets the images gathered to provide a diagnosis to the patient. This is shown in an operational context diagram in figure 5. It is expected that this operational context will remain in the improved design with only the imaging system itself being updated.

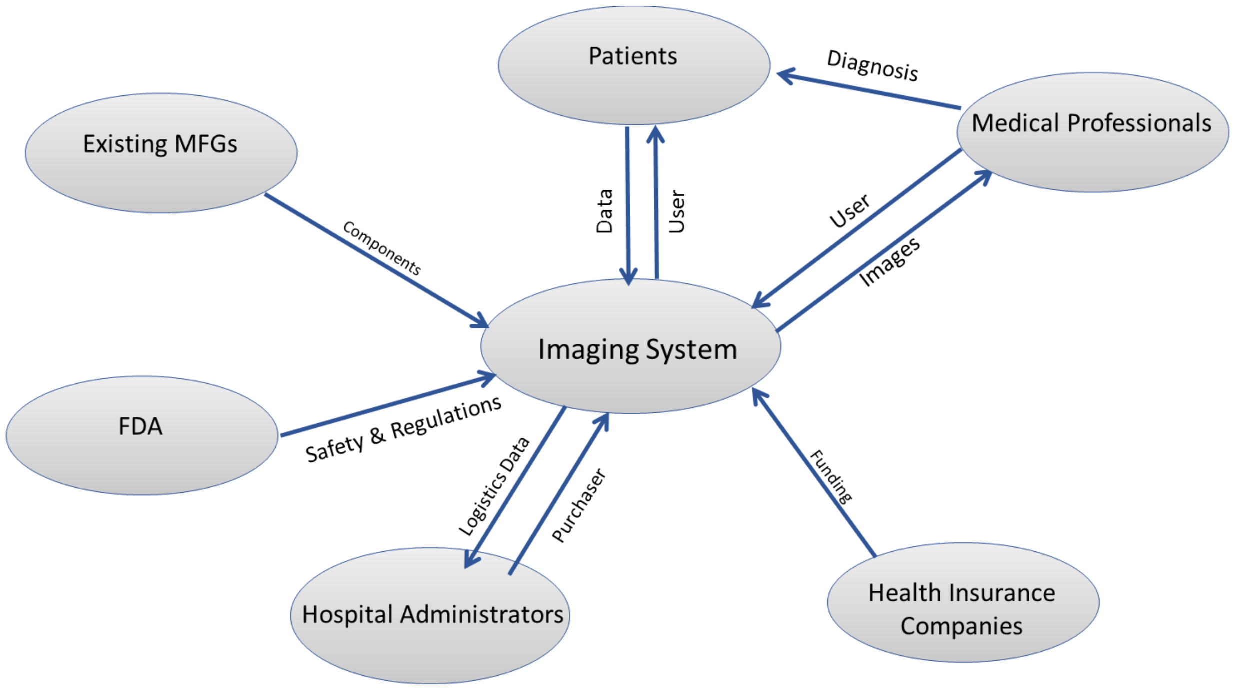


Figure 5

4. Operational Scenarios

The operation of the imaging system will largely remain the same to minimally disrupt medical professionals and their patients. This also makes the new system easily adopted and cost effective and as market-competitive as possible. However, the improved, new system itself will provide new capabilities to the medical professional in the form of enhanced images and analysis of the vocal folds. The scenarios listed below identify the various interfaces and abilities required for the new system.

The System will:

- Image the vocal folds
    - While the vocal folds are stationary
    - While vocal folds are in motion
        - E.g. Patient is directed to make “eeeeeee” or “ooooooo” sounds during exam
- Record all images and analyze frequency content while storing all content in the patient’s records
- Allow the medical professional to focus on specific portions of the vocal folds as necessary

Both scenarios start with the medical professional first deciding the imaging is necessary and numbing the patients nose. The endoscope is then positioned and a still image is acquired. The endoscope may be positioned to focus on specific portions of the vocal folds as needed. If a diagnosis is made at this point the exam concludes. If required, the patient will be asked to make “eeeeeee” or “ooooo” sounds while the medical professional views the movement in a slow-motion video to allow the medical professional to view the motion of the vocal folds. As with the still imaging, if deemed pertinent by the medical professional the endoscope may be positioned to focus on specific portions of the vocal folds. The imaging system at this point can display this motion slowed down using a strobe light currently or other high frame rate cameras in the future to provide information on the frequency content to the medical professional. At this point a diagnosis is provided to the patient. At all times patient safety is of utmost importance.

a) Imaging Stationary Vocal Folds

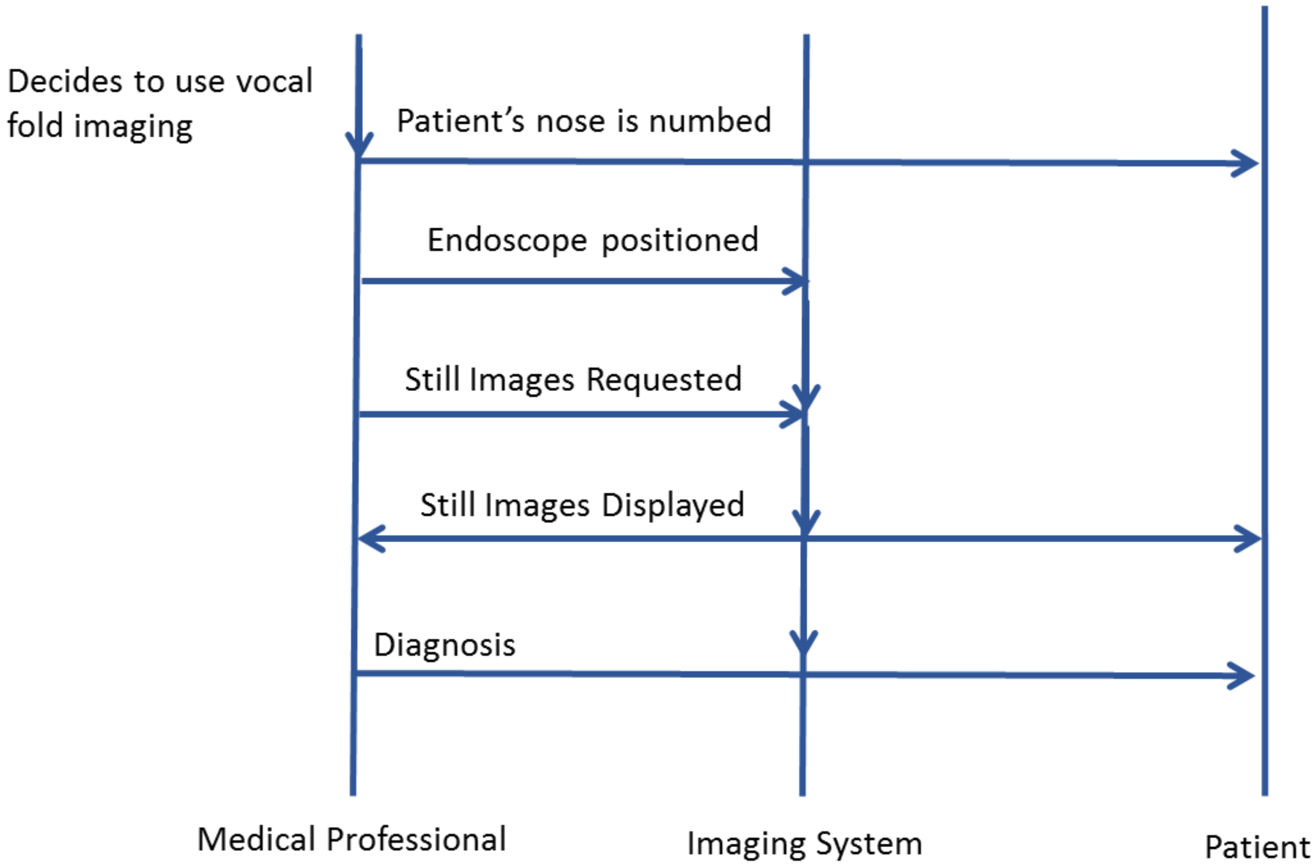


Figure 6

b) As-Is method of Imaging Moving Vocal Folds with Analysis to Display Frequency Content

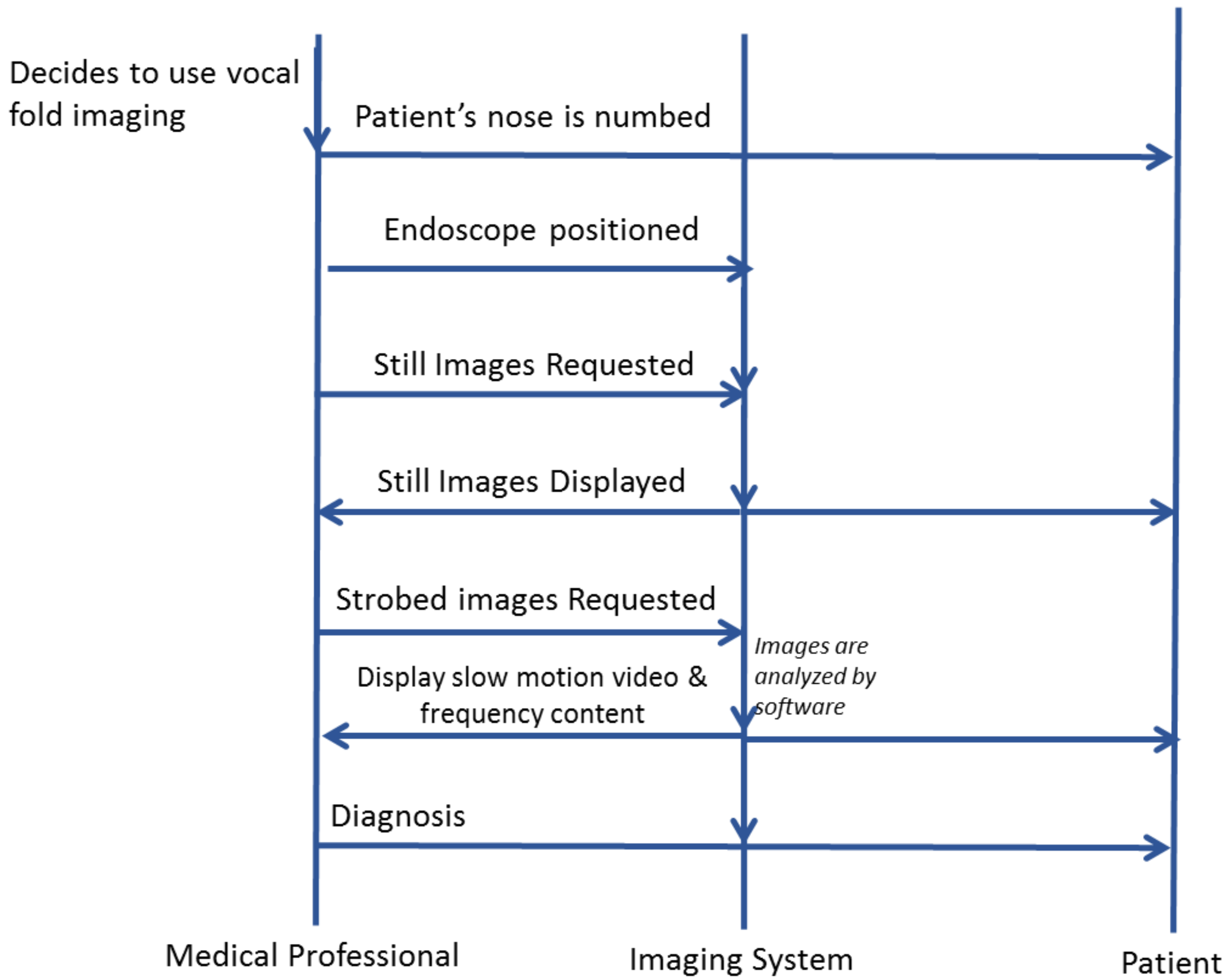


Figure 7

5. Pugh Matrix for alternative concepts & Identification of concept selected

a) Potential Concept Definitions

1. Use existing endoscope and light source with high frame rate camera to record vocal fold movement for slow motion playback to medical professional
2. Use existing endoscope and light source with new high frame rate camera to record vocal fold movement with additional image processing to analyze spatial frequency content of vocal folds to provide slow motion playback with frequency information displayed over image
3. Use new endoscope with zoom capability with a new long wave light source to focus on slices of the vocal cord to produce MRI-like data for medical professional with image processing to illustrate different frequencies at different zoomed slices
4. Use existing endoscope and strobed light source with analysis to sync strobe light to vocal fold movement, add image processing capability to display frequency content to medical professional
5. Use fold mirror and existing light source with high speed camera to capture images for slow motion video playback and image processing to highlight frequency content

b) Pugh Matrix

Potential concepts are scored below with 3 the high score and 1 the low score.

	Concept 1	**Concept 2**	**Concept 3**	**Concept 4**	**Concept 5**
Patient must not be harmed	3	3	2	3	2
Awake and Alert Patient	3	3	2	3	2
High Quality Images of abnormal pathology	2	3	3	1	2
User interface must be fast, clear and intuitive.	3	3	2	2	2
Cost effective	3	3	1	3	2
Summation	**14**	**15**	**10**	**12**	**10**

By comparing the potential concepts with the correlation to the sacred expectations we can see that Concept 2 is an obvious choice. With only a new high frame rate camera substituted for the current camera used along with new software to display frequency content over the images this concept provides significantly expanded capability without significant cost or changes to the current exam process.

6. Architectural Concept Diagram

The architectural diagram for the new system is shown in Figure 8. This system includes a high frame rate digital camera coupled with software analysis to show frequency content of the full extent of the vocal folds. The software analysis will include a new display for the medical professional. The components changing are shown in light blue. The light source and endoscope will not change. This will simplify FDA approval and allow the medical professionals to continue using favored tools.

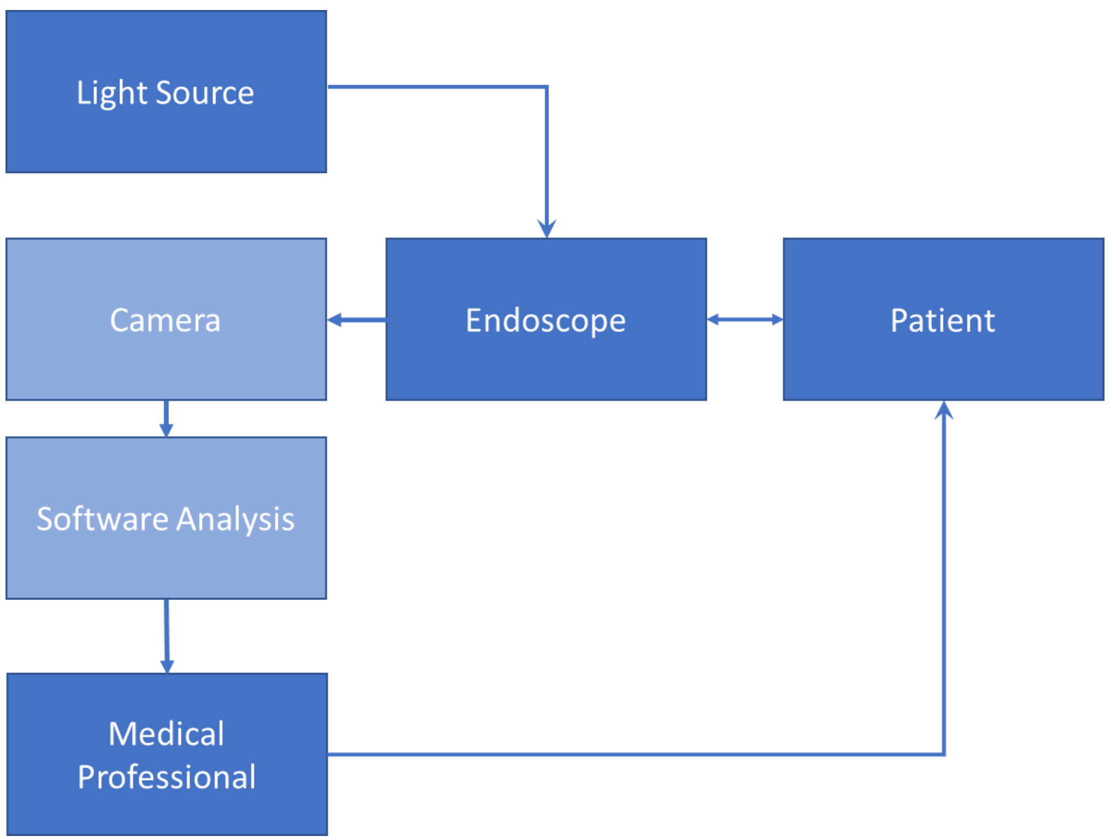


Figure 8

A sequence diagram for the new system is shown in figure 9. Note there is now a step removed. The analysis software in the new system will display the frequency content along with the slow-motion images rather than displaying a strobed image that the medical professional must decipher. This additional analysis and high frame rate video will likely shorten the exam time since all the required images will be captured the first time and analyzed using software and not solely relying on the medical professional's visual analysis.

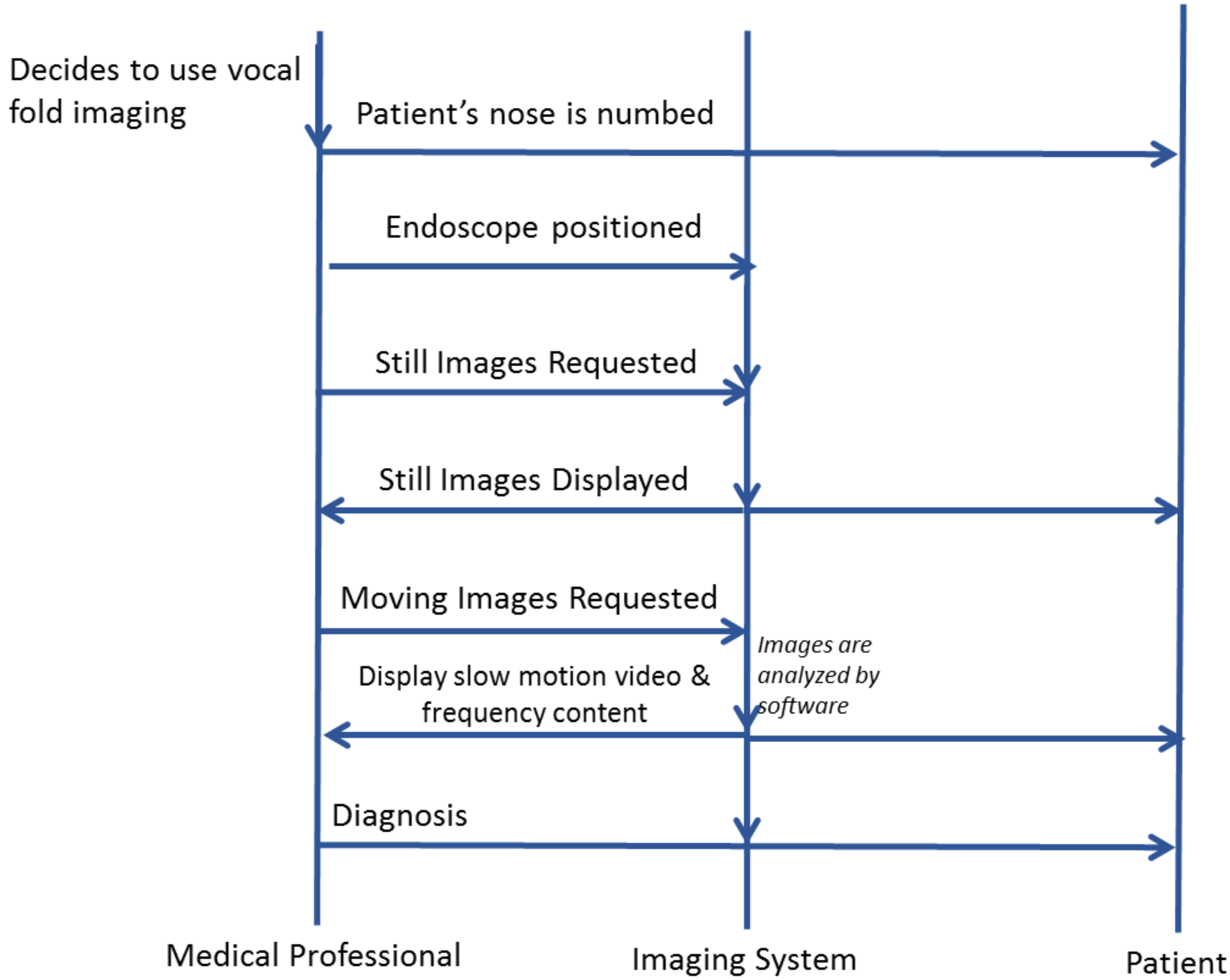


Figure 9

7. Concept of Operations

A potential sequence of operations within an exam is shown in the table below.

Seq #	Event and Description
1.	Medical professional decides to use imaging system to view vocal folds
2.	Patient consents
3.	Patient's nose is numbed
4.	Imaging system is powered on
5.	Endoscope is inserted into patients nose and positioned to view the vocal folds
6.	Still images are captured and stored
7.	Patient is instructed to say "eeeeeee" or other instructions per the medical professional
8.	Imaging system records images at 5000 frames per second for 8 seconds
9.	Software analyzes frequency content
10.	Slow motion playback is displayed for medical professional
11.	Frequency analysis is overlaid on still image
12.	All data is stored
13.	Steps 6-12 are repeated as required. E.g. patient says "ooooooo"
14.	Data from exam is stored under patient's record

8. Decomposition of the System Functional Architecture to the First Sub Function Level

Since the software analysis is changing significantly and providing significant new functionality. The software analysis function will be shown in greater detail. This type of decomposition could be performed for the additional core functionalities of the new system, but for simplicity and brevity, only the software analysis piece is decomposed in Figure 10.

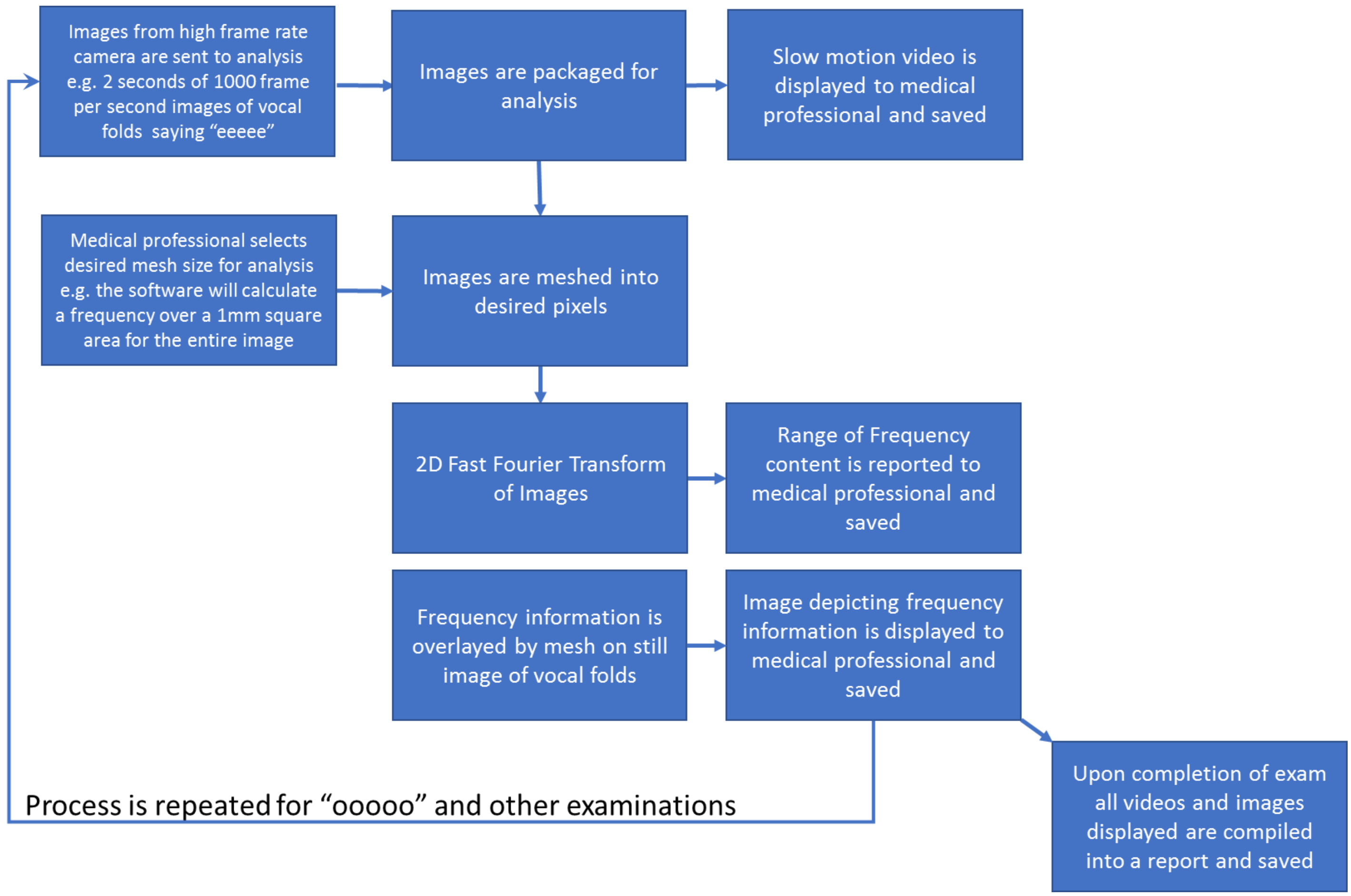


Figure 10

9. Top Level System Requirements

To draft the system requirements stakeholder input along with design requirements for the chosen concept were considered. For a subset of characteristic expectations, a QFD was employed to identify concrete requirements. The QFD helps to identify areas where the system requirements should be focused as they most closely correlate to the stakeholder's sacred expectations. A table containing a subset of top level requirements follows the QFD matrix.

a) QFD Analysis of Key Characteristics Against Selected Concept

Weight/ Importance	Direction of improvement Minimize (↓) or Maximize(↑)	↓	↓	↑	↑
		Cost	Time for exam and analysis	Image and frequency resolution	Utilizes existing endoscopes & Light Sources
9	Patient Safety	3	0	0	3
3	Awake & Alert Patient	0	3	1	3
9	Improved images of moving vocal folds	9	1	9	1
3	Automated frequency analysis	3	9	9	0
1	Clear graphical user interface (GUI) for analysis display	0	9	9	0
	Sum	117	54	120	45
	Legend; H = 9, M= 3, L= 1, No Correlation = 0				

Figure 11

b) Top Level System Requirements

A subset of top level system requirements is shown in the table below. This subset of requirements is by no means exhaustive but for simplicity and to demonstrate conceptual understanding only 10 requirements are shown.

	Requirement	Related Expectation
1.	The system shall not use a 10 mW or lower light source that will not burn or harm the patient.	Section 2.f, Expectation 1
2.	The system shall be capable of collecting 5000 frames per second	Section 2.f Expectation 3
3.	The system shall have enough memory to store at least 5, 8 second videos recorded at 5000 frames per second	Section 2.f Expectation 3
4.	The system shall record 1024 x 1024 pixel images	Section 2.f Expectation 3
5.	The system shall provide frequency information over mesh ranging from 1mm- 1cm square regions of the image	Section 2.f Expectation 3
6.	The system shall provide frequency measurements with 0.25Hz resolution	Section 2.f Expectation 3
7.	The system equipment shall fit within a 5.5-foot-tall by 2.5-foot square standard equipment storage tower	Section 2.e. Expectation 9
8.	The system shall use a COTS nasal endoscope	Section 2.f Expectation 2
9.	The system shall include a display that plays back slow motion video	Section 2.f Expectation 2
10.	The system shall include a display that shows frequency content overlaid on a color high definition image of the vocal cords	Section 2.f Expectation 2

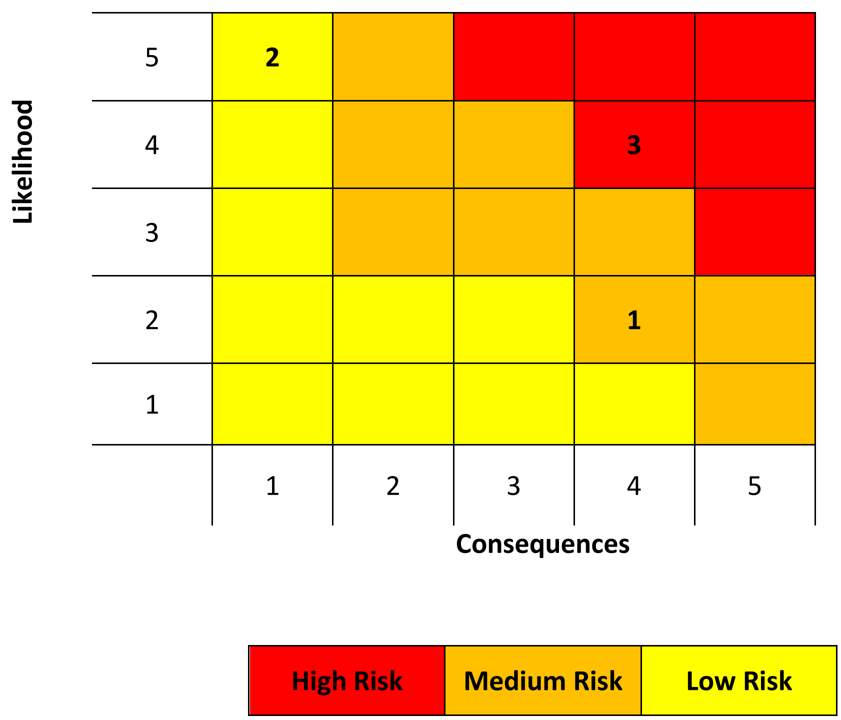
10. Risks and Proposed Mitigations

3 Potential risks plus mitigations are outlined below

	Risk	Mitigation
1.	Light source not bright enough to adequately illuminate vocal folds	Include an illumination power budget early in the design process, measure reflectivity of a wide range of human vocal folds
2.	New software analysis and controls require FDA approval	Review regulations extensively early in the software design process
3.	COTS endoscopes do not provide adequate resolution	Research available endoscopes, new design possible but will require FDA approval

c) 5x5 Risk Classification Matrix

This matrix assigns each technical risk a level of consequence and a level of likelihood. Likelihood ranges from a 1, lowest probility, to 5, high probability. Consequences range from a 1, slight system impact, up to a 5, complete system failure.



11. Reflective Essay

Over the course of this project I noticed a couple points: 1) concisely asking a few questions in your stakeholder interviews up the likelihood busy medical professionals will talk to you, and 2) if my Pugh matrix or QFD diagram does not appear to be complete it is likely I have missed a sacred expectation and should go back and ask myself if the system only delivered on the current set of sacred expectations would it be successful.

I spoke with 2 different medical professionals. A nurse practioner who specializes in ears, noses and throats and a surgeon within the same specialty. I was aware of their enthusiasm for new tools to better care for their patients but that they were also incredibly busy. It became obvious that to obtain the information needed I had to formulate the right questions and I would not have multiple iterations to do so. The portion of the video on what makes a good system engineer by the gentleman from NASA came to mind where he mentions asking the right questions. I found that both medical professionals enthusiastically responded to questions about what they found lacking in their current tools and both responded particularly enthusiastically to the question "If I could snap my fingers and give you the perfect tool, what would it do for you?" At that point I was generally buried under an avalanche of medical jargon that was graciously explained as I asked clarifying questions. Throughout this process, I noted that if I do not have full, open communication with my stakeholders it was very unlikely the system will be successful as it would not match their expectations. I believe this is the most useful lesson I learned throughout this process.

As I got to the portion of my report where I began to create a QFD, I found myself wanting to add a line about ease of use for the medical professional. Since they usually have one hand on the endoscope, they need a simple user interface that they can operate with one hand. At this point I realized that if the system was difficult to use, it would not be successful. I then went back and added a sacred expectation to ensure the user interface was taken into account and propagated that expectation through the Pugh matrix and QFD diagram. I find it useful that this is a recursive process and lends itself to continual refinement. Clearly it is better to notice and issue through the preparation vs after the system is built.

Through this process, I certainly learned that asking the right questions is of utmost importance and additionally that continuous refinement saves rework down the design process.