Autonomous Robust Urine Analysis

ECE 445 Design Document

Team 56

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1. Introduction

1.1 Problem

Urine testing is an important tool for healthcare professionals, as it can be used to show indications of diabetes, kidney disease, liver problems, or a UTI. However, conducting these tests can be quite time consuming, messy, and often not thorough. Urine dipsticks are the most easy to use, but only provide qualitative information from the sample. 24h urine collection, as you would expect, is tedious and invites opportunities for errors to occur. Urinalysis provides more robust quantitative measures than a dipstick can provide, via microscopical examination, but the need for lab facilities and technicians to process makes it not as time efficient as it could be.

Furthermore, doctors spend time preparing sample slides often hours after the samples have been collected. Patients are completely responsible for sample collection which can be messy and uncomfortable for many people. Markers in urine that indicate different types of kidney diseases are only visible with a microscopic exam, yet this is the least common test performed since visual and dipstick tests are quicker and easier to perform. This simplifies the process of urinalysis. Doctors will be sure that urine was imaged while fresh, and will no longer have to handle urine directly when analyzing. Patients will no longer have to collect a urine sample.

1.2 Solution

The proposed solution is to implement an automated system to conduct urinalysis in order to maintain its high fidelity of information while hastening the time to process samples and eliminate need for external labs. The ultimate project would be an all inclusive system with urine collection, image capture, and wireless image transfer, but for the scope of this class, our primary focus will be on the driving of samples in and out of an imaging window and the actual image capture/exportation.

First is a pump that will drive 1-2mL urine samples to our imaging window. That window will have a transparent cavity, with tubes on opposite ends for entry and exit of liquids. This is where the sample will arrive then to be imaged by either a microscope with the imaging attachment or a smartphone device with an external lens peripheral. These images will then be sent to a network drive for image storage so that they can be accessed by a doctor anywhere.

1.3 Visual Aid

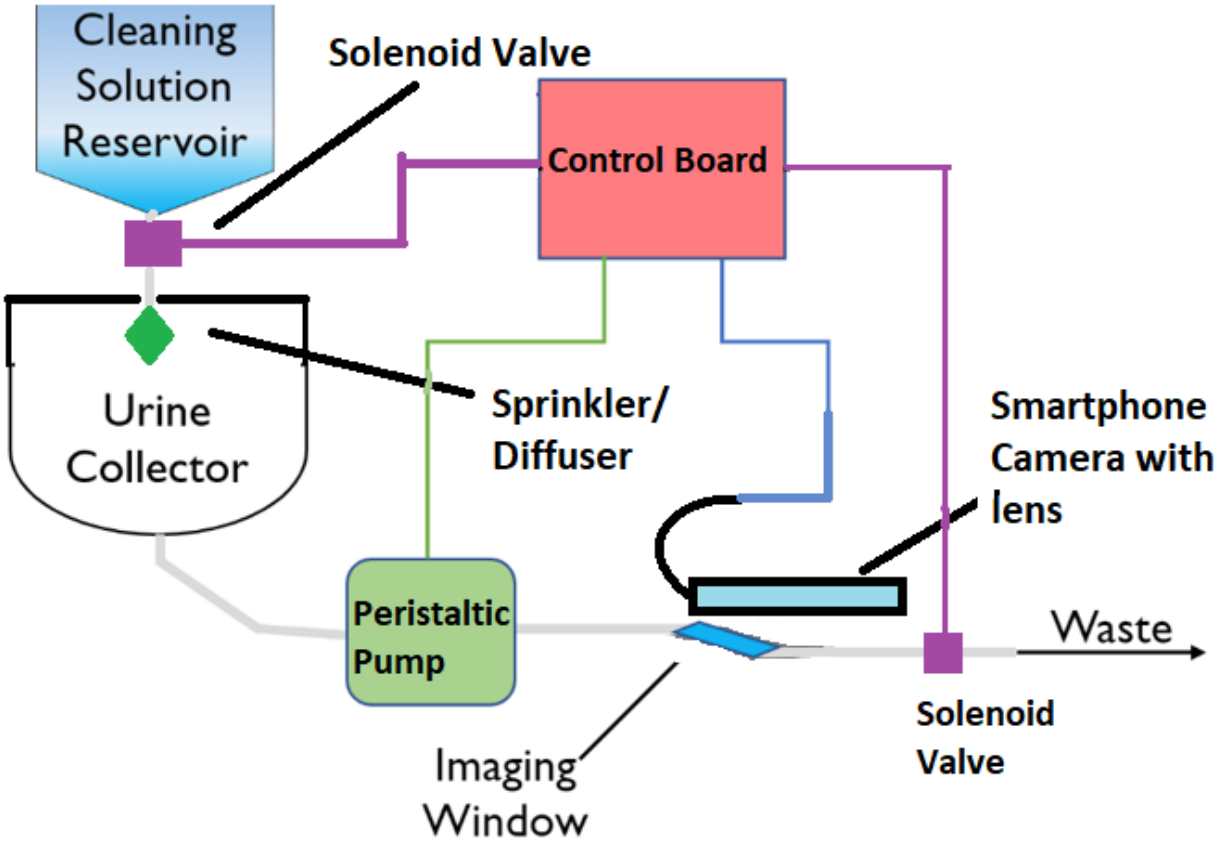

Figure 1: Visual aid for system

1.4 High Level Requirements

1. The filling of both cleaning solution and urine should be the only parts of the system not operated autonomously via the control board.
2. Image acquisition that meets appropriate scale and resolution requirements for a doctor to conduct urinalysis on the sample. (able to view cells of 10 to 50 μm)
3. All aspects should be leak-free, especially near any tubing connections, or near pumps/cameras.

2. Design

2.1 Block Diagram

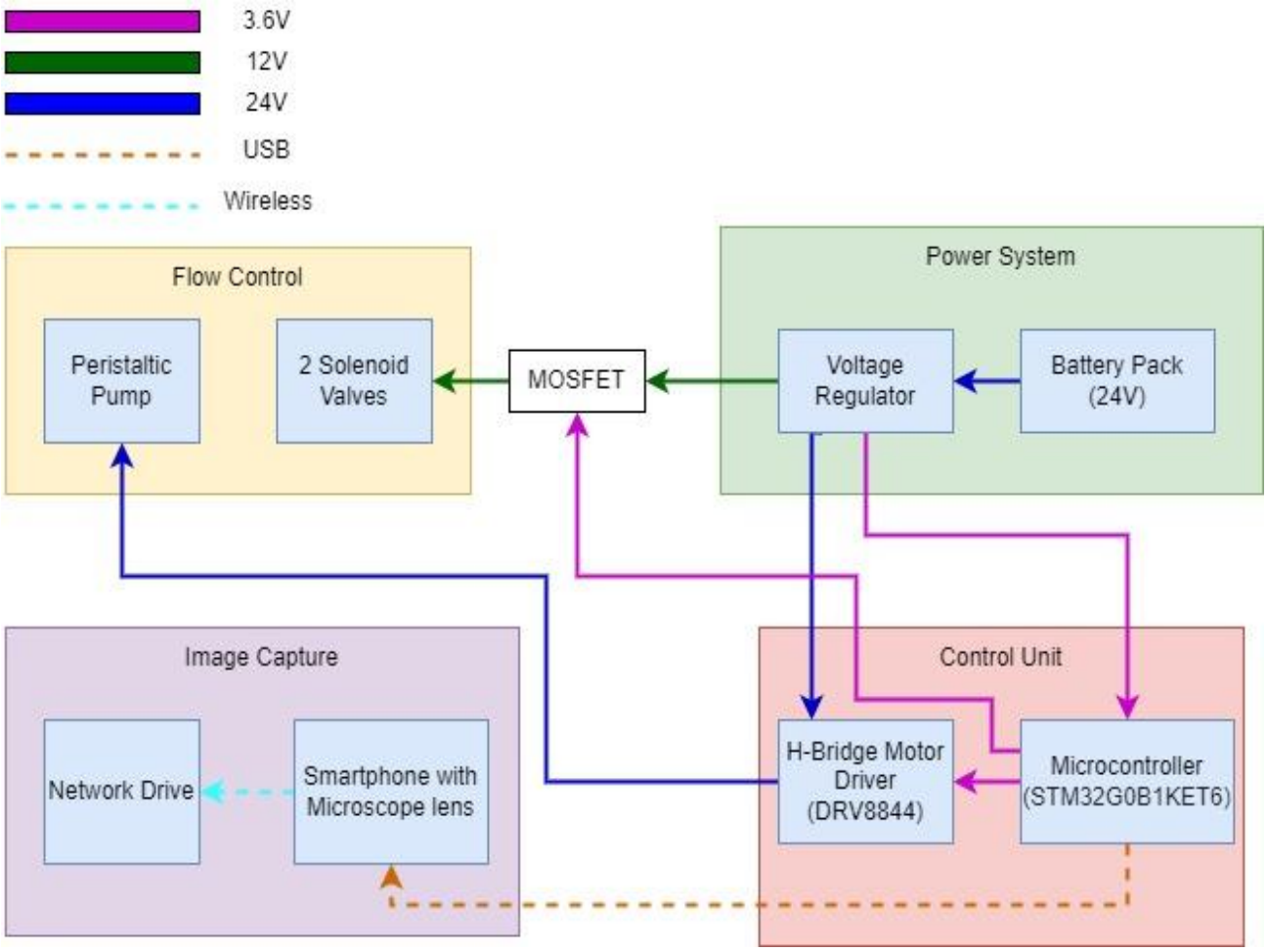

Figure 2: Block diagram of system

2.2 Subsystems

The prototype should take 5 images per sample in order to ensure the entire sample is imaged. To do this, the urine is transported incrementally using the peristaltic pump so new samples are constantly imaged. The microscope camera should be able to image cells from 10 to 50 µm diameter clearly. The system should start flowing when 100 mL of fluid is detected and stop imaging when images from 5 distinct samples have been collected, followed by flushing out the rest of the sample and then a cleaning cycle. Material selection was important in this system design since all materials will need to be urine safe.

2.2.1 Power system

We will use a 24V rechargeable Nickel-metal hydride or Nickel Cadmium battery pack to power the system as the peristaltic motor needs 24V for ideal functionality. The solenoid valves need 12V to open fully and the microcontroller needs 2V - 3.6V to turn on and function. To achieve these voltages, we would use two voltage regulators, 12V and 3.6V each to step-down the voltages for these components.

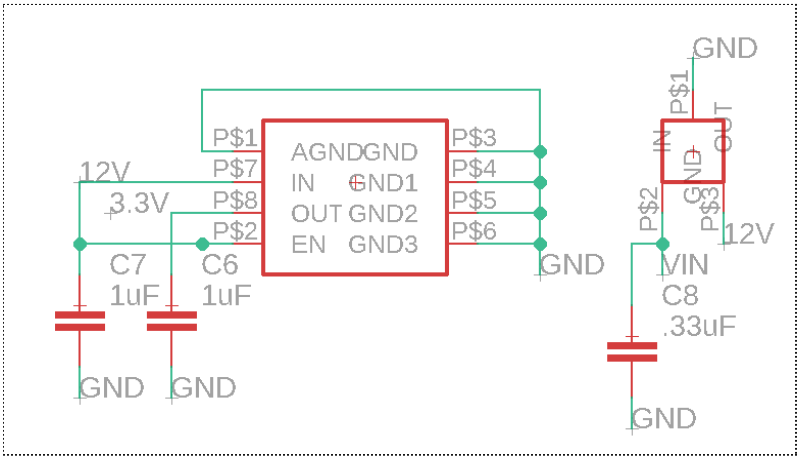

Figure 3: Voltage Regulation schematic

Requirement	Verification
The regulators must maintain an output voltage of 12V±8% and 3.6V ±1%.	With the battery providing an input voltage, the voltage probes from an oscilloscope will be used to measure the voltages.
The regulators must not exceed 125℃	When the regulators are operating, their temperature will be checked with an IR thermometer to ensure it is within bounds.

Table 1: Requirements and verification for power system

2.2.2 Microcontroller

The microcontroller is responsible for maintaining the running cycle of the program and operating the pump, valves and smartphone for imaging. Furthermore, as the system is battery operated, it should consume as little power as possible when not active. We picked this microcontroller due to the presence of a USB interface for the smartphone along with the low-power sleep mode.

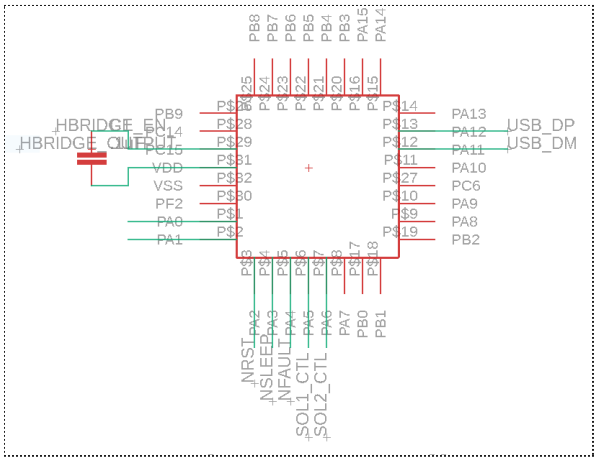

Figure 4: Microcontroller schematic

Requirements	Verification
The microcontroller should be able to operate all the peripherals and communicate with the smartphone	The microcontroller is fully functional if all the other systems pass verifications except the power subsystem.

Table 2: Requirements and verification for Microcontroller

2.2.3 Pump and Solenoid Control

The peristaltic pump will be controlled using an H-bridge motor driver (DRV8844) and solenoid valves will be turned on and off using a MOSFET with control logic coming from the MCU. Diodes will be connected across the solenoids as they are inductors and will still conduct a large current after they have been turned off and potentially damage the MOSFETs.

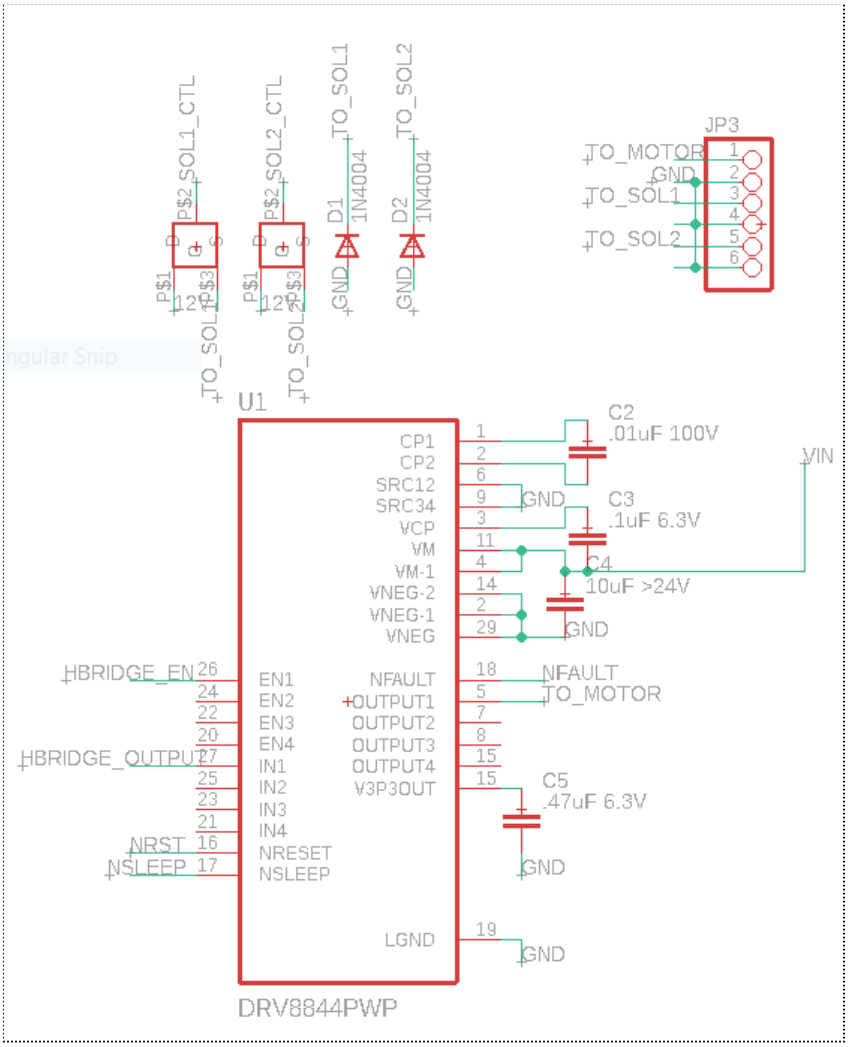

Figure 5: Pump and Solenoid Control schematic

Requirements	Verification
The H-bridge turns the pump on and off at precise timings to ensure the correct amount of fluid has flowed through	The time between turning off the signal to the H-bridge and the pump turning off will be measured and adjusted for in the programming if required

Table 3: Requirements and verification for pump and solenoid control

2.2.4 Peristaltic Pump

Peristaltic pumps provide very precise control of flow rates while not interacting with the liquid directly. This aspect is important, as we do not want to contaminate the samples at any point before imaging. This pump essentially uses rollers to pinch the tubing, creating “pockets” of liquid to exit the pump. This also will help prevent the introduction of bubbles within our sample, which could affect imaging quality greatly.

Figure 6: Fixed-Flow-Rate Metering Pump for Chemicals

Requirements	Verification
The pump should be able to send samples in increments of 1-2 mL to the imaging window.	Run the pump for the amount of time specified to transfer 2mL of liquid. Measure the amount of time that the fluid takes after the pump stops to become stable. Using a precision pipette, extract the fluid to obtain a volumetric analysis of the sample.
The pump should completely seal off the tube during the imaging process so that the sample is not in motion under the imaging window.	The fluid in the tubes should come to a standstill soon after the pump is stopped.

Table 4: Requirements and verification for peristaltic pump

2.2.5 Solenoid Valves

A solenoid valve simply uses the induced EMF from the solenoid to raise a pin, which opens the valve. Thus, the resting position is a closed valve. Since the project requires there to be no contamination of urine, this valve will be special, in the fact that the pin does not close the pipe from inside, but rather pinches upon the tubs from the outside. Solenoid valves will be used between the cleaning solution container and at the end of the mechanism after the imaging window.

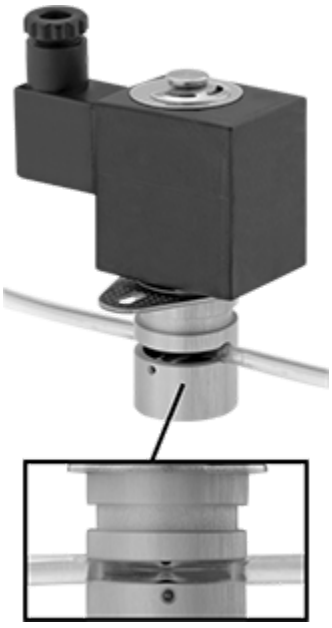

Figure 7: Noncontact Solenoid On/Off Valve

Requirement	Verification
The valve should completely block the flow of fluid when closed.	The tube going through the valve will be connected to a sample container and then the valve will be closed. There should be no leakages for it to pass verification.
There should be no cross-contamination from the cleaning solution to the urine sample, compromising the result of the images.	Place water in the sample container and dyed water in the cleaning solution container. Run the sample transfer, then the cleaning solution solenoid, then the sample transfer again. Check the output from the second sample transfer for color.

Table 5: Requirements and verification for solenoid valves

2.2.6 Smartphone

Currently, we are considering using a smartphone device to do the image capturing of the urine samples. By attaching a fixed external magnification lens to the phone camera, the needed 400x magnification can be realized. However, image fidelity and resolution will need to be evaluated externally to see if this option is viable in place of a microscope. The benefit this implementation would provide is robust control of the camera via an application, which can't be done on the mechanical knobs of a microscope. Also, the phone would have the capability to share the images wirelessly built in, meaning no need for the device to be connected via wire to the viewing console.

If the smartphone approach is not viable, we will utilize a microscope camera, and will have to interact with the native software to ensure pictures from the microscope view are taken autonomously

Requirement	Verification
The images captured should be of sufficient resolution at the selected magnification to identify cells, crystals and bacteria.	Find a common lattice structure with 10μm features. Take pictures and analyze the clarity of the result, checking for sharpness and detail.
The images should be securely uploaded to a network drive that can only be accessed by the user and their doctor.	The smartphone application we will design should be secure and private to the user.

Table 6: Requirements and verification for Smartphone

2.3 Tolerance Analysis

An important factor for us to consider when working with pumps and liquid flow, is to be able to model accordingly with respect to fluid velocity and pressure. That is why we used Bernoulli's Equation between two points in a system (Equation 1).

$$P_1 + \tfrac{1}{2}\rho v_1^2 + \rho g h = P_2 + \tfrac{1}{2}\rho v_2^2 + \rho g h$$

Equation 1: Bernoulli's Equation

Where P is pressure (atm), ρ is density of the liquid kg/m^3, g is gravity (m/s^2), h is height (m), and v is velocity (m/s). For our model we'll determine the flow going into the imaging cavity from the pump and the exit flow to the disposal. We'll also have the appropriate pressures to demonstrate that no pressures possibly exhibited would be of concern.

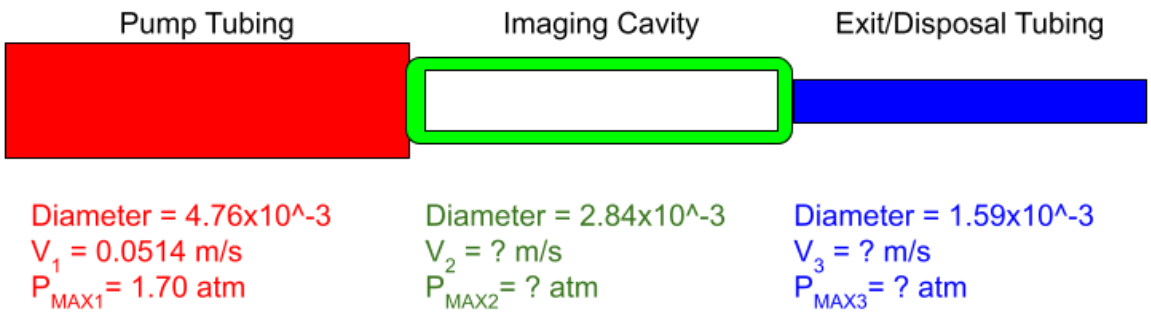

Figure 8: Illustration of Cavity and & Exit Flow System

Diameters of the tubings have been determined by the pump, cavity design, and purchased tubing parameters. The initial velocity was determined by converting the pump's volumetric rate of 55ml/min into m^3/sec , which could be divided by the cross sectional area to determine the velocity of flow. The result was 0.0514 m/s. Our example, shown in figure 8 above, does not have a change in elevation, so any part of the equation with an h term can be ignored. Then we could also solve the velocity between two sections by using the inverse relationship between velocity and cross-sectional areas to formulate a simplified equation for finding the pressure and velocity of the section to the right of the previous (Equation 2).

$$P_{n+1} = P_n + \tfrac{1}{2}\rho(v_n^2 - v_{n+1}^2), \; where \; v_{n+1} = \left(\frac{A_n}{A_{n+1}}\right)^2 v_n$$

Equation 2: Simplified Pressure and Velocity Equations

Which yields these solutions

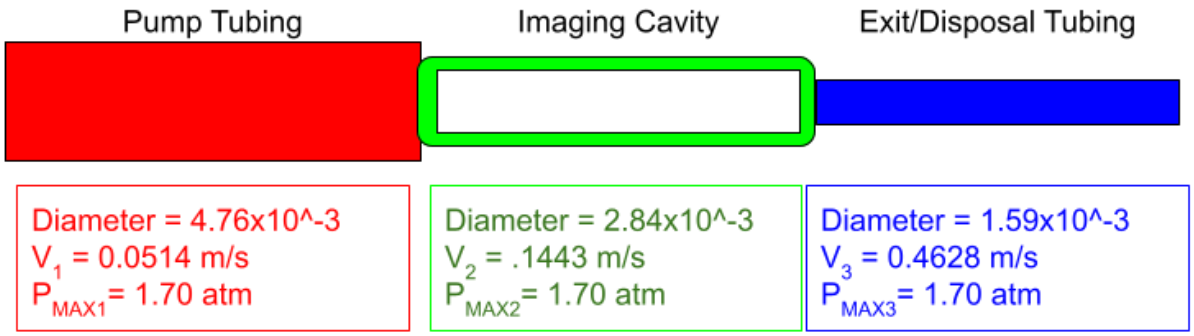

Figure 9: Solved Flow and Pressure Model

Based on the max pressures for each segment, we see that it never exceeds 1.70 atm, or ~25 psi, while an average house has 40 psi for water flow, meaning our upper limit for pressure shouldn't exist at any dangerous levels. These parameters determined, shown in figure 9, can also be used for how long the entire process should take, by using the velocities and cross-sectional areas with tube lengths, but at this moment, no specific lengths of tubing have been specified.

3. Cost and Schedule

3.1 Cost Analysis

We will be assuming a salary of 78k for a nice hourly rate of $40/hr. We also predict that it'll take eight hours a week for about eight weeks, yielding 64 hours for each partner in the project. This equates to a total labor cost of $2,560 from our project group alone. Estimating the cost of labor and services isn't possible at the moment, as the product development of the imaging cavity can not be predicted.

Part Number	Item Name	Manufacturer	Unit Price	Quantity
5431T111	Noncontact Solenoid On/Off Valve for Chemicals, 12V DC, 1/8" OD x 1/16" ID Tube	Not Listed	$128.72	3
33341N23	Fixed-Flow-Rate Metering Pump for Chemicals, Panel-Mount, Clear, 24V DC, 55 ml/min. Flow Rate	Not Listed	$102.60	1
1972T6	Odor-Resistant Silicone Rubber Tubing for Food and Beverage, 5/64" ID, 1/8" OD	Not Listed	$10.29/ft	2
1972T7	Odor-Resistant Silicone Rubber Tubing for Food and Beverage, 1/8" ID, 1/4" OD	Not Listed	$10.55/ft	2
5116K194	Plastic Barbed Tube Fitting for Food and Beverage, Polypropylene Reducer for 1/8" x 3/32" Tube ID	Not Listed	$3.31/pack of 10	1
5116K217	Plastic Barbed Tube Fitting for Food and Beverage, Straight Reducer, for 3/16" x 3/32" Tube ID	Not Listed	$5.79/pack of 10	1
5116K195	Plastic Barbed Tube Fitting for Food and Beverage, Polypropylene Straight Reducer for 3/16" x 1/8" Tube ID	Not Listed	$6.06/pack of 10	1
			Total	$545.60

Table 7: Mechanical Parts List

Part Number	Item Name	Manufacturer	Unit Price	Quantity	Cost
STM32G0B1KET6	STM32G0B1 Access Line MCUs with Extended Memory		$6.93	1	$6.93
DRV8844PWP	60-V, 2.5-A dual H-bridge motor driver with bipolar (+/-30v) supply & independent 1/2-bridge control		$3.036	1	$3.04
ADP1720ARMZ3.3-R7	3.3V Voltage Regulator	Analog Devices	$2.18	1	$2.18
MC7812BDTRKG	12V Voltage Regulator	onsemi	$.82	1	$.82
1N4004	400V Diode	Diodes Incorporated	$.21	2	$.42
CL05A104KA5NNNC	.1uF 25V Capacitor	Samsung	$.10	1	$.10
C1608X7R2A103K080AA	.01uF 100V Capacitor	TDK	$.10	1	$.10
CL21A106KAYNNNE	10uF 25V Capacitor	Samsung	$.20	1	$.20
CL05A474KQ5NNNC	.47uF 6.3V Capacitor	Samsung	$.10	1	$.10
CL31B334KBFNNNE	.33uF 50V Capacitor	Samsung	$.20	1	$.20
CL05A105KQ	1uF 6.3V	Samsung	$.10	2	$.20

5NNNC	Capacitor				
RZF013P01TL	P-Channel MOSFET	Rohm Semiconductor	$.45	1	$.45
				Total	$14.64

Table 8: Electronic parts list

Our total cost for the project with both labor and parts involved is estimated to be a few dimes over $3,120. This excludes any costs evaluation from the machine shop, as it can not be predicted at this phase of the project.

3.2 Schedule

Week	**Siddharth**	**Jovan**	**Patrick**
2/14	Research part number for MCU	Finalize physical design and parts to order with sponsors	Research part number for H-bridge
2/21	Design the circuit schematic	Order pump and valves and research ideal imaging method	Design the circuit schematic and pick parts to be used
2/28	Design first PCB draft and order electronic parts	Formulate the autonomous flow of actions the system takes	Design first PCB draft and order electronic parts
3/7	Validate ordered parts	Assemble physical parts and ensure requirements are met	Begin Programming Microcontroller
3/14 (Spring Break)	Solder PCB and start testing and debugging system as a whole	Start testing and debugging system as a whole	Finish Programming Microcontroller
3/21	Make changes to PCB design and place second order	Continue developing Android application	Make changes to PCB design and place second order
3/28	Construct entire system and start testing the HL-requirements	Construct entire system and start testing the HL-requirements	Construct entire system and start testing the HL-requirements
4/4	Debug any faulty subsystems and finalize project	Debug any faulty subsystems and finalize project	Debug any faulty subsystems and finalize project
4/11	Finish any remaining debugging	Finish any remaining debugging	Finish any remaining debugging
4/18	Mock Demo	Mock Demo	Mock Demo
4/25	Demonstration and Mock Presentation	Demonstration and Mock Presentation	Demonstration and Mock Presentation
5/2	Work on Final Report	Work on Final Report	Work on Final Report

Table 9: Proposed weekly schedule and division of labor

4. Discussion of Ethics and Safety

According to our understanding of FDA guidelines, this product would be classified as a class 1 medical device. However, we are not familiar enough with how to argue if this device is 510(k) exempt, but we believe it to be possible with parallels to other monitoring devices. In respect to sterility of the device, we will follow the precedent outlined in Code of Federal Regulations (CFR), 21CFR876 [1]. This details the various necessities and guidelines for devices involved with urology, specifically diagnostics and/or monitoring devices in our project. We feel with the guidance of our sponsors, that we should have no issue adhering to those guidelines.

Also listed in the CFR is HIPAA, in 45CPR160 & 45CPR164, which characterizes the need for the privacy of patient medical records and the circumstances in which it may be broken. The IEEE code of ethics 1.1[2] and the ACM Code of Ethics and Professional Conduct 1.6[3] make similar calls for the protection of privacy. That is to say that, in the future life cycle of this project, any identification of urinalysis data/results will have to be made uncorrelated to patient information, probably through encrypted methods. However, since we are not analyzing any actual samples from real people, there is no need for encryption methods on our end.

In regards to safety, since we are working with liquids and electronics, maintaining observance over all mechanisms during operation will be necessary to ensure that there are no leaks to cause electrical hazards. We plan to use a battery pack system, so following the correct procedure of handling and wiring them will also be important to take extra attention to. We do not believe the pressure produced from the peristaltic pump will prove to jeopardize the structural integrity of our imaging window, but we will make sure that operation of the pump works as expected in a separate closed system. The use of urine of any kind is not expected to occur during the duration of this project, and we will use stand in solutions to test the imaging and liquid transfer capabilities of our project.

5. Citations

[1] *CFR - Code of Federal Regulations Title 21*. accessdata.fda.gov. (n.d.). Retrieved February 11, 2022, from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=876&showFR=1&subpartNode=21%3A8.0.1.1.25.3

[2] *IEEE Code of Ethics*. IEEE. (1990, December). Retrieved February 11, 2022, from https://www.ieee.org/about/corporate/governance/p7-8.html

[3] *ACM Code of Ethics and Professional Conduct*. ACM. (n.d.). Retrieved February 11, 2022, from https://www.acm.org/code-of-ethics