Autonomous Robust Urine Analysis

ECE 445 Project Proposal

Team 56

Siddharth Garg (ssgarg2)

Jovan Barac (jbarac2)

Patrick Shalton (shalton3)

TA: Amr Ghoname

Professor: Pengfei Song

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 imager 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

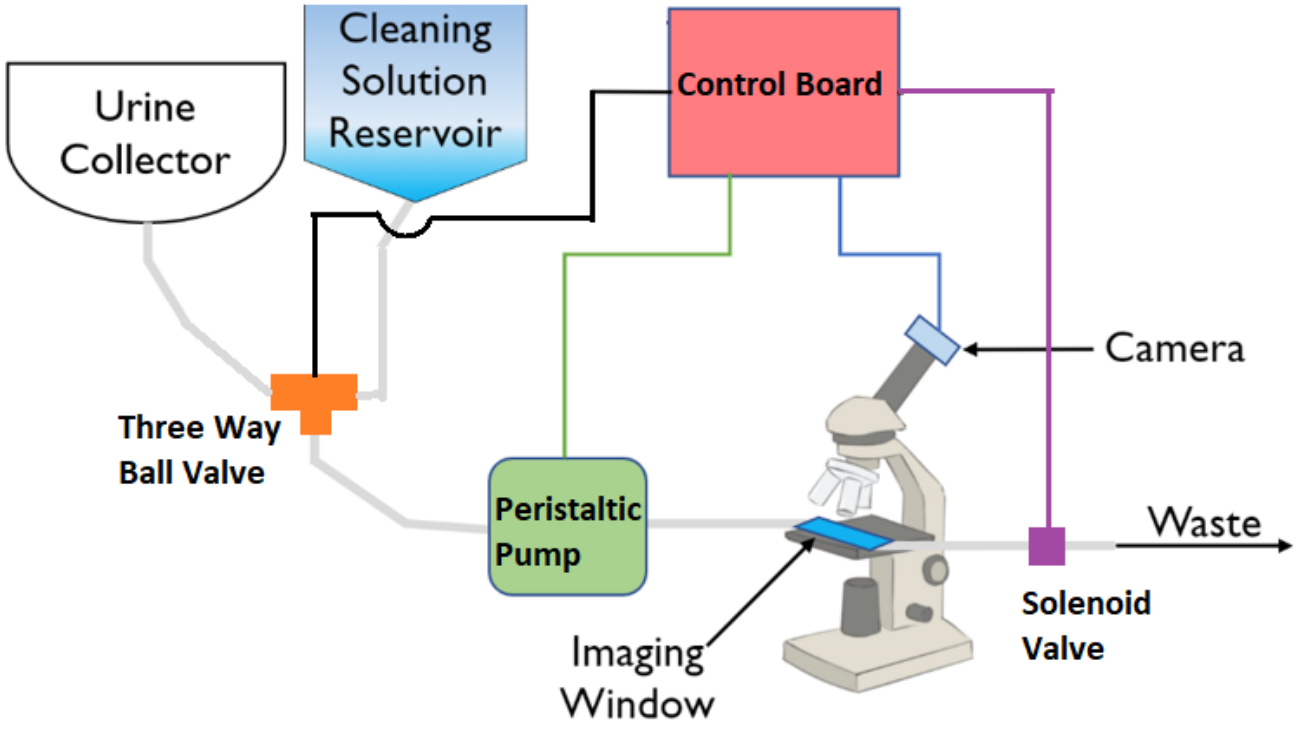

Figure 1: System design overview

1.4 High-Level Requirements

- Leak-free incremental (1-2 mL per cycle) transport of urine and continuous transport of cleaning solution.
- Autonomous system operation.
- 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)

2 Design

2.1 Block Diagram

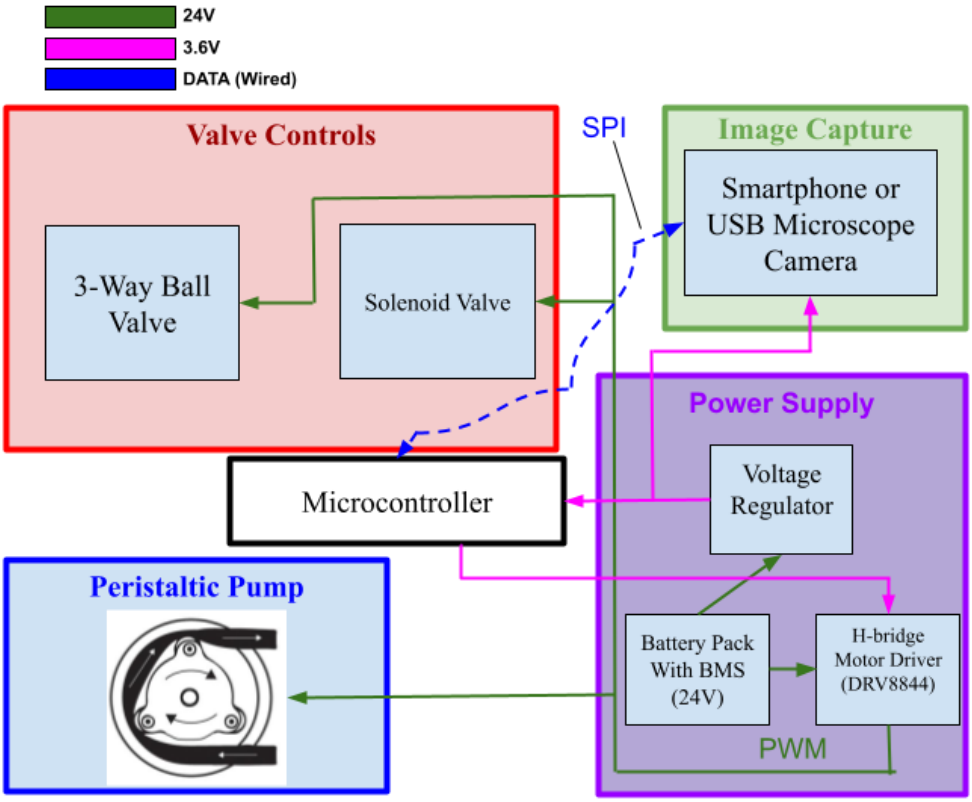

Figure 2: System block diagram

2.2 Subsystem Overview and Requirements

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 Peristaltic Pump

Peristaltic pumps provide very precise control of flow rates whilst 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 acquisition greatly.

Requirement 1: The pump should be able to send samples in increments of 1-2 mL to the imaging window.
Requirement 2: The pump should completely seal off the tube during the imaging process so that the sample is not in motion under the imaging window.

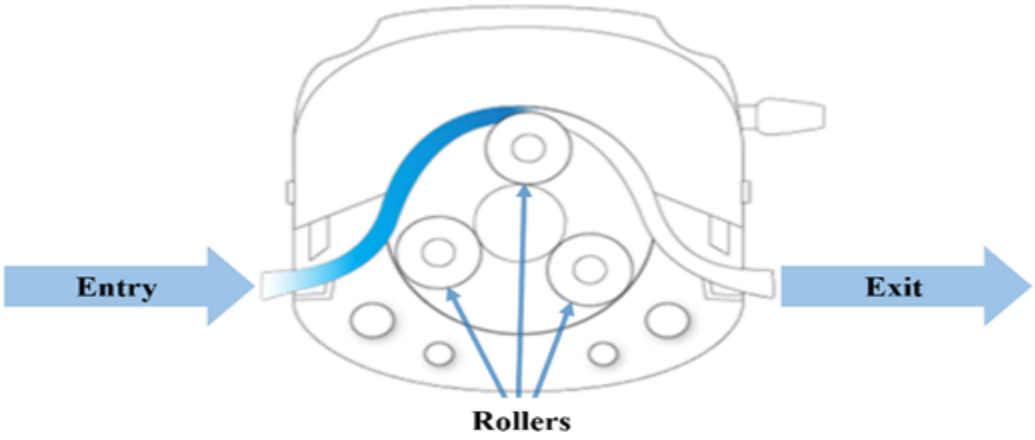

Figure 3: Example of a peristaltic pump

2.2.2 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 1: The images captured should be of sufficient resolution at the selected magnification to identify cells, crystals and bacteria.
Requirement 2: The images should be securely uploaded to a network drive that can only be accessed by the user and their doctor.

2.2.3 Three-way ball valve and solenoid valve

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. This will be used to control flow of liquid from the imaging window to disposal.

The 3-way ball valve will allow for control to flow either urine, cleaning solution, or nothing at all. This was preferred over using two separate solenoid valves because of their power consumption, as one is almost guaranteed to be open at a time. The ball valve eliminates the need to independently control two valves, allowing for more precise control. This will assist in the ability to switch from urine or cleaning solution,

Requirement 1: The valve should be leak free and ensure that there is no cross-contamination from the cleaning solution to the urine sample, compromising the result of the images.

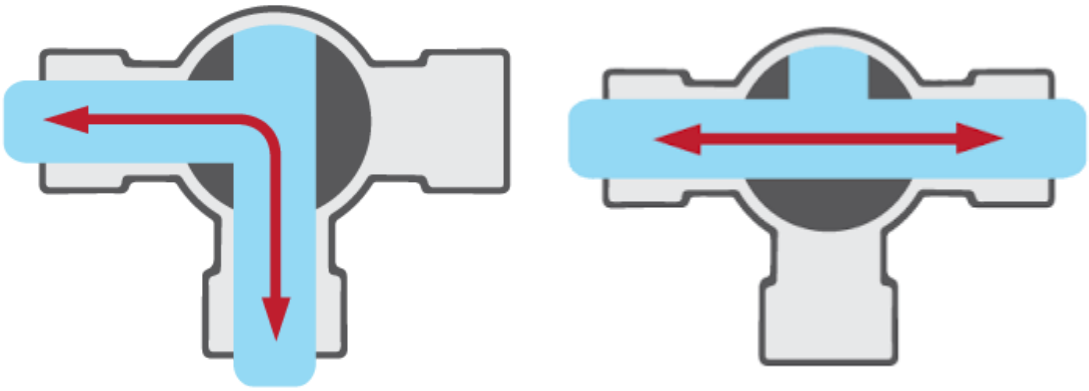

Figure 4: Operation of the ball valve to choose one of the two fluid input streams

2.3 Tolerance Analysis

One process in our project that needs to be deliberately engineered is the precisely controlled amount of urine transported to the slide. If this process is not properly carried out, the result will be a system that either outputs a greater-than-intended amount of urine or does not provide a properly sized sample. To properly satisfy this task, multiple design choices must be considered, such as the flow rate of the pump and the time that is running, the behavior of the pump as it is starting and finishing cycles, the length and size of the tube, and any surface tension that may keep drops from detaching from the tube.

We are using a peristaltic pump in order to address these considerations. The pump has a fixed flow rate of 55mL/min, meaning that it would need to be run for .917 seconds, or 939/1024 seconds, per mL of urine transmitted to the slide. Also, the pump will be connected to the slide through a length of tubing, so the volume of the tubing will need to be considered in the initial flush of every cycle. For instance, the pump uses tubing with a 3/16” diameter, so if a 1” length of tubing connects the pump to the slide, the first flush of every cycle will need to include an extra .45mL of urine in order to accomodate for that volume.

3 Ethics & 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.

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.

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 imagining and liquid transfer capabilities of our project.

References:

[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