Context

Since porphyrins have a correlation with PH levels (PH levels usually being between 8-10 in urine [1]), we will be using PH detection in lieu of spectrometry. As spectrometry would be greatly expensive and inconvenient. This way we are also able to use non hazardous liquid (instead of urine) with various PH levels. Depending on the PH levels the device will indicate if the sample is in the range of porphyria or not, using a light. The liquid that will be tested will be water with various amounts of lemon juice and bleach to increase the lower PH levels.

Customer Definition:

“Porphyria (por-FEAR-e-uh) refers to a group of rare disorders that result from a buildup of natural chemicals called porphyrins in the body.” [2] Since porphyria is a rare disease it is often difficult to diagnose it. Compact machine that uses UV spectrometry to identify porphyrias in urine. More effective and affordable alternative to current methods of identifying porphyrias.

Our customers are likely to be female between the ages of 15-45, and have a genetic predisposition to porphyria since these are all attributes of people who are more likely to be affected by this disease. Due to how uncommon this disease is, it is often misdiagnosed or has a long diagnosis process.

Competitive Landscape:

One of the current forms of diagnosis for porphyria is through Blood tests which attempt to measure porphyrins and their precursors. Blood tests bring a risk to the table and would not be suitable for those with Trypanophobia.

https://www.testing.com/tests/porphyrin-tests/#:~:text=To%20diagnose%20porphyrias%2C%20laboratories%20measure,another%20porphyrin%20precursor%2C%20in%20urine

Another form of testing for porphyria is through stool samples. A test to detect porphyrins in stool may be used to help distinguish between VP and HCP. Stool samples are inconvenient and often take longer as the most people can not produce such a sample on demand. Aditionally this test only differentiates between two types of porphyria.

https://www.testing.com/tests/porphyrin-tests/#:~:text=A%20test%20to%20detect%20porphyrins,rare%20ALA%20dehydratase%20deficiency%20porphyria.

Additionally testing can be on DNA to check for porphyria. DNA testing for porphyria has proved to be the most accurate form of diagnosis. DNA analysis will detect more than 97% of known disease-causing mutations. Unfortunately, this type of testing is only available in one laboratory in the United States.

https://porphyriafoundation.org/for-patients/about-porphyria/testing-for-porphyria/dna-testing-for-porphyria/

Requirement Specifications:

A common medical product validation threshold is a 95% confidence of a 95% device reliability.

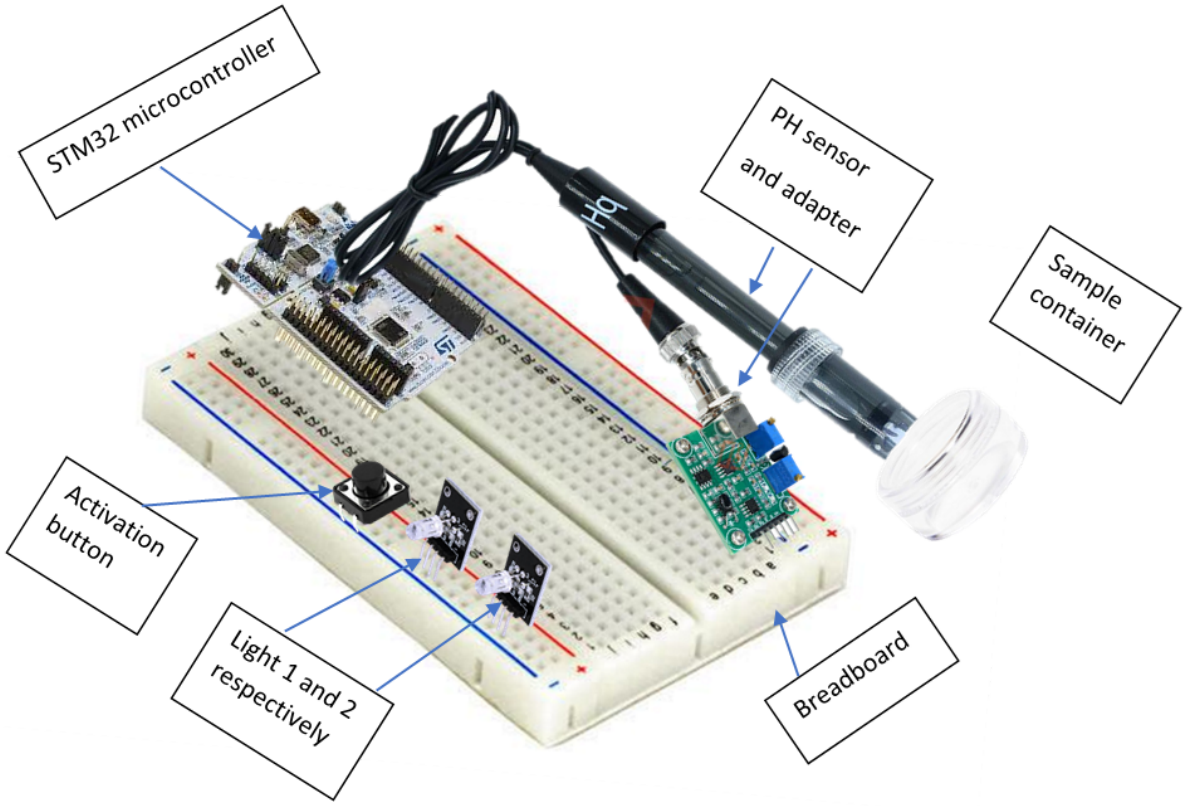
Battery between 10-30V to abide by outline provided

Normal range of porphyrin in urine over a 24 hour period is 20 to 120 µg/L. So our machine must be able to detect discrepancies beyond this range.

We would require a container which can hold at least 4ml

The design must not store or otherwise contain more than 500mJ of energy at any point in time.

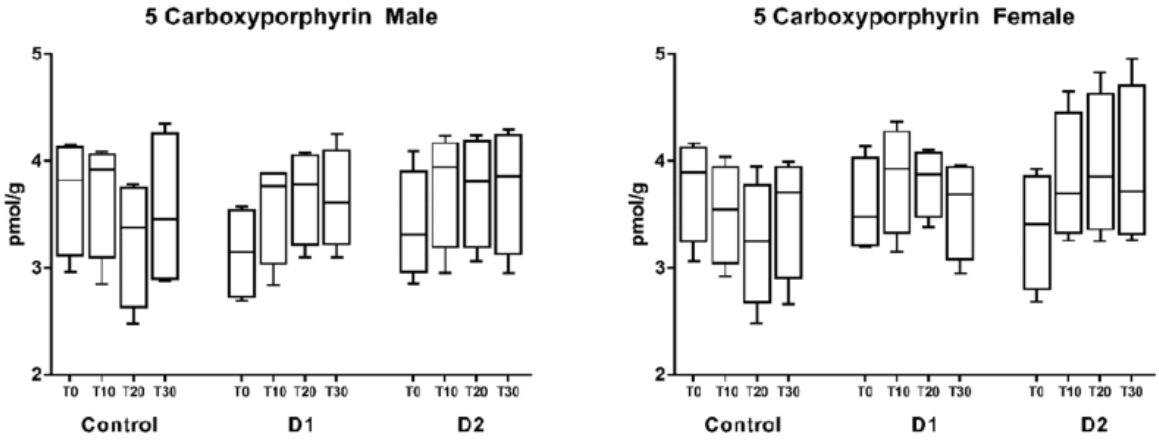
Design


STM32 microcontroller
PH sensor and adapter
Sample container
Activation button
Light 1 and 2 respectively
Breadboard

Scientific or Mathematical Principles

IEC 60086-1:2021 is intended to standardize primary batteries with respect to dimensions, nomenclature, terminal configurations, markings, test methods, typical performance, safety and environmental aspects. Following the standard in battery utilization will help optimize and ensure our components in the machine will work together correctly.

We will be using AAA energizer batteries in order to conform with this standard:



https://www.researchgate.net/figure/Porphyrin-levels-in-feces-of-control-and-exposed-to-lead-acetate-Mean-Standard_fig1_351009987

Outliers:

The first quartile was 2.4 – 3pmol/g

The second quartile was 3- 3.5pmol/g

The third quartile was 3.5 – 3.9 pmol/g

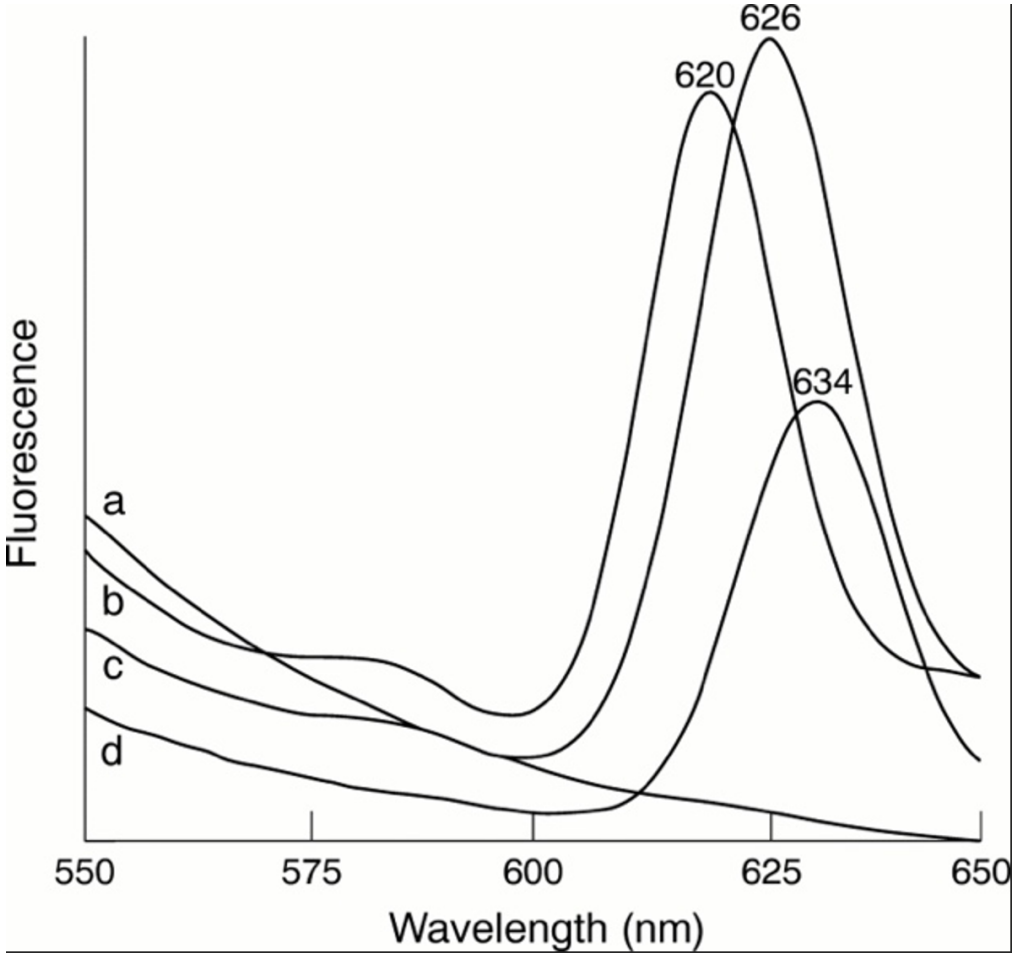
The fourth quartile was 4 – 4.2 pmol/g

Therefore, using outlier = Q¬1 – (1.5IQR) and outlier = Q3 + (1.5IQR):

3 – 1.5* (3.9-3) = 1.65

4.2 + 1.5(3.9-3) = 2.85

Therefore, our microcontroller will execute code that flags results if they are > 2.85 or < 1.65



$A = \varepsilon lc$

The fluorescence of porphyrins is maximized at a wavelength of 626 nm. This is therefore the wavelength we will use with our spectrophotometer to determine the absorption (and therefore concentration) of the porphins in the solution.

For example, if a certain sample turns out to have an absorption of 0.3 and we are using a test tube of width 1 cm and overall volume 2 cm^3:

0.3 = (5.3 cm-1m-1mol¬¬-1¬¬)*1cm*C

C = 0.00057 mol/m3

That is equivalent to 0.057*1012*10-6 = 53 pmol/g

Therefore, since 53> 2.85, the microcontroller will make the LED flash red because the result is out of bounds.

*Note: ε = 5.3 cm−1m−1 at that wavelength for porphyrin, it is a constant that depends on the material itself at a specific wavelength.

https://www.degruyter.com/document/doi/10.1515/hc-2016-0188/html#:~:text=This%20porphyrin%20displays%20a%20molar,1m%E2%88%921%2C%20respectively.&text=Electronic%20absorption%20and%20fluorescence%20spectra%20for%20TDBOPP.

Manufacturing Costs:

STM 32 microcontroller: $34.99 (https://wstore.uwaterloo.ca/ece-198-kit.html)

STmicroelectronics have wafer fabs inAgrate Brianza and Catania (Italy), Crolles, Rousset, and Tours (France), and in Singapore. These are complemented by assembly-and-test facilities located in China, Malaysia, Malta, Morocco, the Philippines, and Singapore. https://shorturl.at/NUW79

Set of 25 ml Containers: $15.39 (https://shorturl.at/egpxT)

Manufactured in China by BENECREAT

Indicator lights: $9.99 (https://shorturl.at/uvCJY)

Manufactured in China DIYables

Electrical tape: $2.78 (https://shorturl.at/wACKX)

Most 3M products are manufactured in the United States

Various sensors and buttons: $20.99 (https://shorturl.at/gmLT4)

HiLetgo products are manufactured in China

Ph Sensor: $15.69 (https://shorturl.at/eluQ2)

Qqmora products are manufactured in China

Breadboard Jumper Wires: $9.38 (https://shorturl.at/kBDX8)

RGBZONE products are manufactured in China

3D printed mold: approx. $12 (https://uwaterloo.ca/rapid-prototyping-centre/3d-printing/cost)

University of Waterloo, Canada

Breadboard: $9.99 (https://shorturl.at/erGSX)

ELEGOO items are manufactured in China

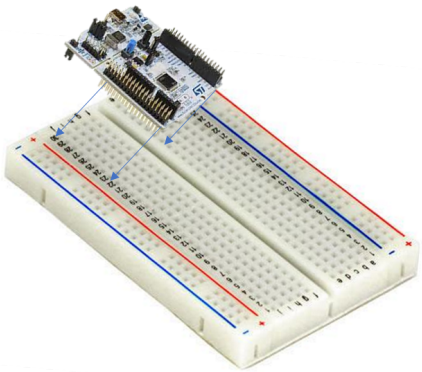
Total price: T = 34.99 + 15.39 + 9.99 + 2.78 + 20.99 + 15.69 + 9.38 +12 = $121.21

Total price plus tax: T + (T*0.13) = $136.97

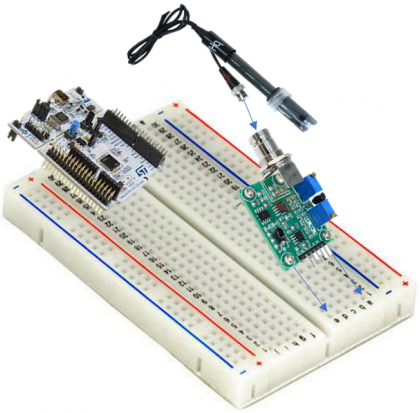
Implementation Costs

USER MANUAL

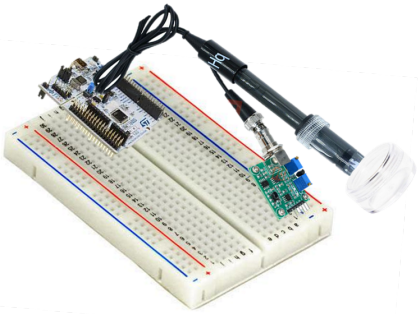
Attach STM32 micro to breadboard



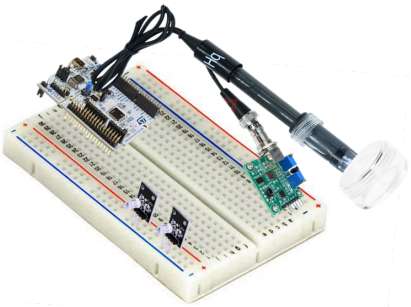
Plug PH sensor into breadboard and feed other end into container



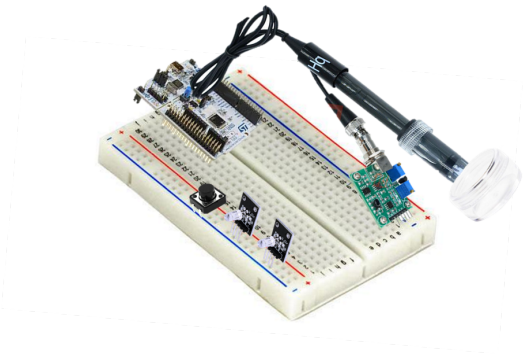
Put Sensor end into Sample container



Install indicator lights into breadboard



Install Button that indicates when to test



Pseudo Code:

```
//light functions
flash_light1();
flash_light2();
flash_light1(bool){
Bool flash1 ();
}
flash_light2(bool){
Bool flash2 ();}
int x = (PH result from sensor)
  // min PH of porphyria in urine
int y = 8;
// max PH of porphyria in urine
int z = 10
If (button_down==true){
if ((x>=8)  &&  (x <= 10)){
flash_ligth1(True);} else{
flash_light2(True);}}
```

When the button is pressed the PH sensor determines the PH of the content in the sample container. After the sensor returns the PH level, the PH is evaluated and if it is within the Porphyria range light 1 turns on if not light 2 turns on indicating the person is not at risk of porphyria.

Risk Analysis

Explosion of batteries in excessive heat
Short circuit causing an electrical fire if it comes in contact with liquids
Radiation from spectrophotometer may be harmful over long periods of time

- As linked below since our machine emits UV and therefore must abide by Canada's Radiation emitting devices act. With specifically the following applying to ours.[4]

- 1 composite label warning user of radiation
- Must have an emergency switch
- When averaged over a detection area of 10 square centimeters, the exposure rate from leakage radiation (averaged over a period not less than five minutes), should not exceed 0.5 milliroentgen per hour at a distance of five centimeters from any accessible external surface.
- The design must not store or otherwise contain more than 500mJ of energy at any point in time.

Energy Analysis

IEC 60086-1:2021 is intended to standardize primary batteries with respect to dimensions, nomenclature, terminal configurations, markings, test methods, typical performance, safety and environmental aspects. Following the standard in battery utilization will help optimize and ensure our components in the machine will work together correctly.

We will be using AA energizer batteries in order to conform with this standard. They have a cell voltage of 1.2 V to 1.5V, this corresponds to 2 to 4 Wh per cell, insuring that we will definitely be abiding by the 30W limit:

Test Plan

1. “A common medical product validation threshold is a 95% confidence of a 95% device reliability.” [5]

- We will use a simulation of urine (saline for control sample and saline with red food colouring dye for the porphyria sample), then test out the system for accuracy.
- The only environmental parameters that pertain to this test are that the spectrophotometer we use is weak enough that it should not radiate enough UV to cause any significant damage.
- test input is a concentration of 2x10^-2 g/mL of red dye and saline for the control.

- When testing 20 times, it must be correct at least 19 times.
- If out of 20 times, it works 19 or 20 times, then it has passed the test.

2. LED brightness measurements of 75+/-25 lumens [6]
- Using the lux iphone application, we can measure the brightness of the LED.
- There are no environmental parameters pertaining to this test. The light is much too weak to consider as light pollution.
- The test input will be the light from green and red LEDs when they are on.
- The brightness must exceed 50 lumens
- If the brightness exceeds the above standard, then the test is passed.

3. Battery less than 30V to abide by outline provided
- Using 2 AA batteries, which will, combined, make between 2.6v - 3.0v
- environmental parameters
- test inputs
- quantifiable measurement standard
- pass criteria

4. Normal range of porphyrin in urine over a 24 hour period is 20 to 120 µg/L. So our machine must be able to detect discrepancies beyond this range.[7]
- Because we are simulating urine using saline for the control sample and saline with red food colouring for the porphyria sample for hygienic purposes, we will place a sample with a very high concentration of red dye to simulate an individual with an extremely high concentration of porphrins.
- The red dye is environmentally friendly (for humans, plants, animals, and aquatic creatures) and will be disposed of in a drain.
- test input is a concentration of 2x10^-2 g/mL of red dye
- 95% accuracy in correctly identifying the excess concentration of red dye.

- If the microcontroller correctly identifies it as porphyria and the red LED lights up, then it has passed the test.

5. We would require a container which can hold at least 4ml
- Usage of spectrophotometer cuvettes and placing samples in them. (https://www.amazon.ca/Globe-Scientific-111137-Polystyrene-Spectrophotometer/dp/B00E3KZI82)
- Plastic cuvettes will be disposed of in recycling (realisticlly, if we had used real urine instead of a simulation, it would be disposed of in special biohazard bins)
- The test input will be to put 4ml in the cuvette and make sure that it does not leak and that it holds at least 4ml.
- All cuvettes will hold 4ml at least 90% of trials.
- Holds at least 4ml without leaking.

[1] Porphyrins, timed urine - children's Minnesota, https://www.childrensmn.org/references/Lab/urinestool/porphyrins-timed-urine.pdf (accessed Oct. 25, 2023).