FeedRite Feeding Tube

Alex Heilman
Graham Husband
Katherine Jones
Ying Lin

Problem Statement

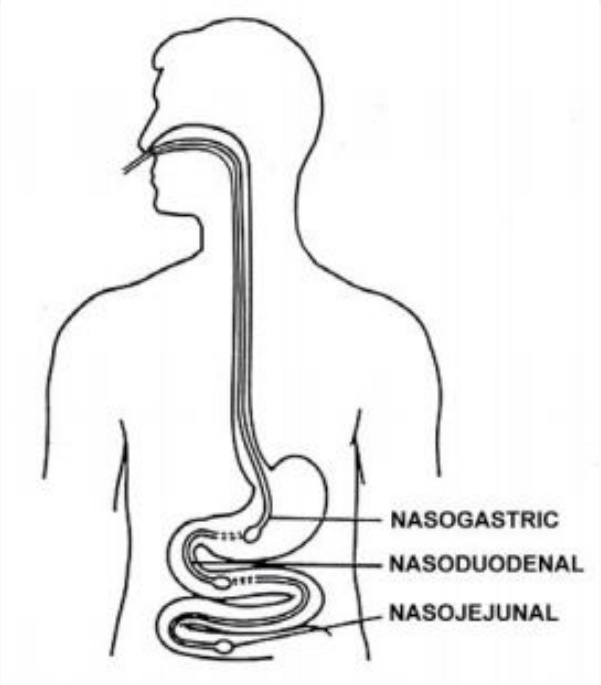
Gastric bypass is an invasive procedure that requires up to 5 days of hospitalization and has a narrow patient population (those with a BMI greater than 40 or greater than 35 with obesity-related conditions; roughly 18 million Americans) in comparison with the rate of obesity in America (78.6 million Americans; defined as BMI > 30). In addition, gastric bypass can cost ~$25,000 (depending on state of residence), reducing the number of patients who receive the procedure to 1% of those who qualify. Current analogs to gastric bypass use naso-duodenal feeding tubes that rely on repeated fluoroscopic procedures and several hours for proper tube placement.

Needs Assessment

- Device must be radiation-free
- Device must integrate a second method that ensures proper tube positioning
- Feeding tube must require 1 outpatient appointment for placement
- Tubing must be biocompatible
- Must be portable such that it can be used throughout a hospital
- Primary placement tool must be detachable from tube after placement
- Device must verify differences between stomach and duodenum
- Device must provide real-time updates of tube position

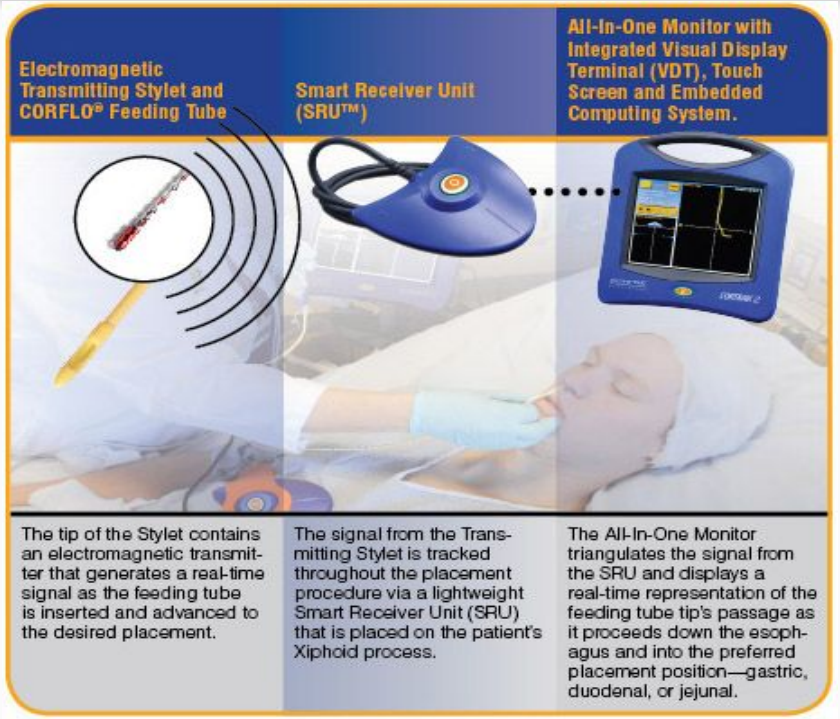
Background

- Problems: Obesity, Type II Diabetes
- Solution: Gastric Bypass Surgery
  - Lose weight, may reverse diabetes
  - Invasive, risky and expensive
  - For patients with BMI > 40, or BMI > 35 with obesity-related conditions



Background

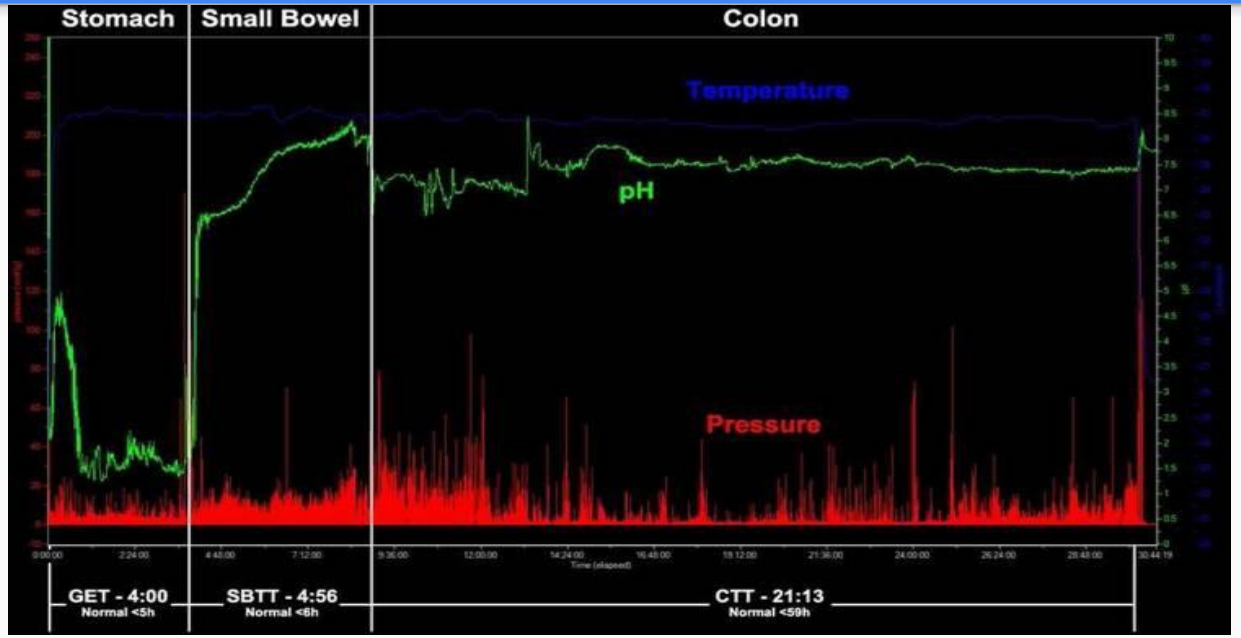
- Alternative Solution: Naso-duodenal Feeding Tube
  - For patients with BMI > 30, or unqualified for gastric bypass surgery because of age or physical conditions
  - Existing device - Cortrak EAS
  - Our design - less expensive, confident placement, placement detection will not interfere with feeding



Potential Market

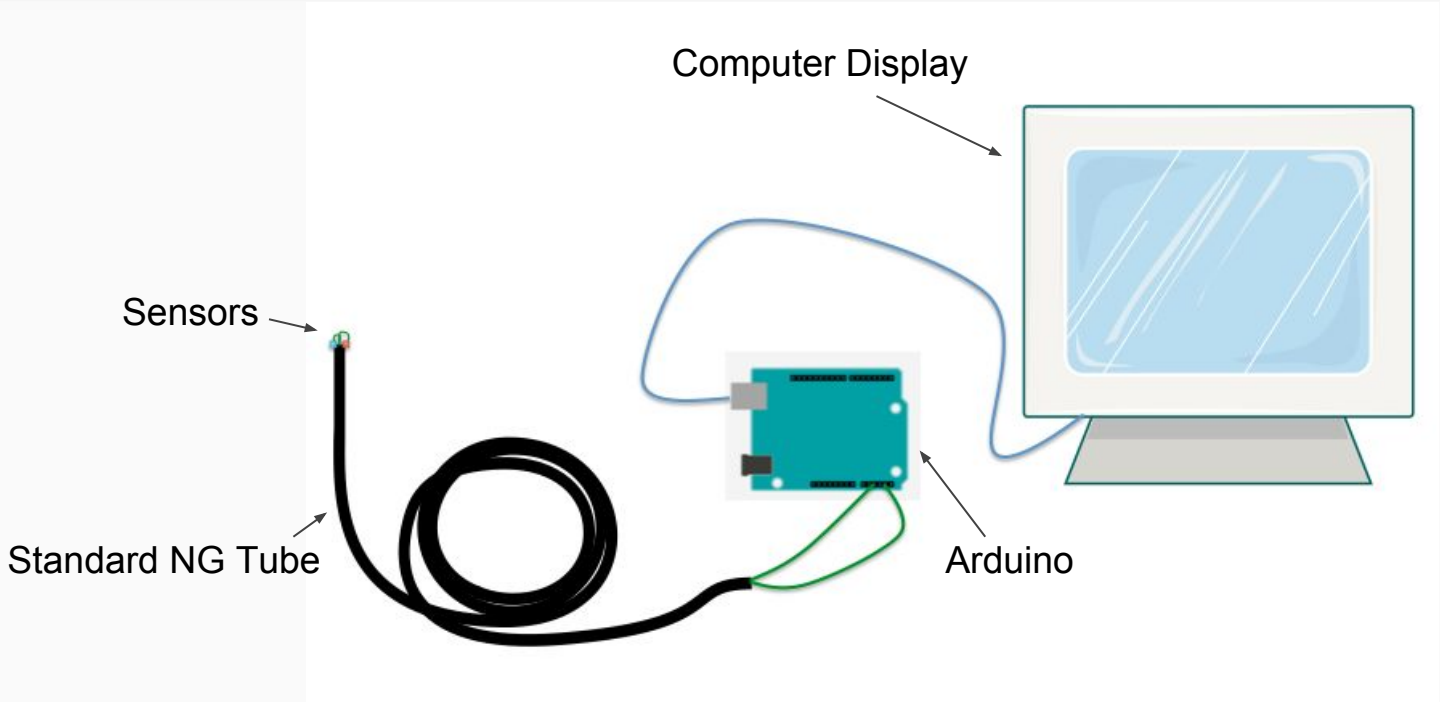
- Obesity and Type II Diabetes - 9 % of American adults
- Gastric Bypass Procedures - 180,000 per year
- Marketing:
  - Medical professionals at hospitals
  - Individual patients at home

Evidence

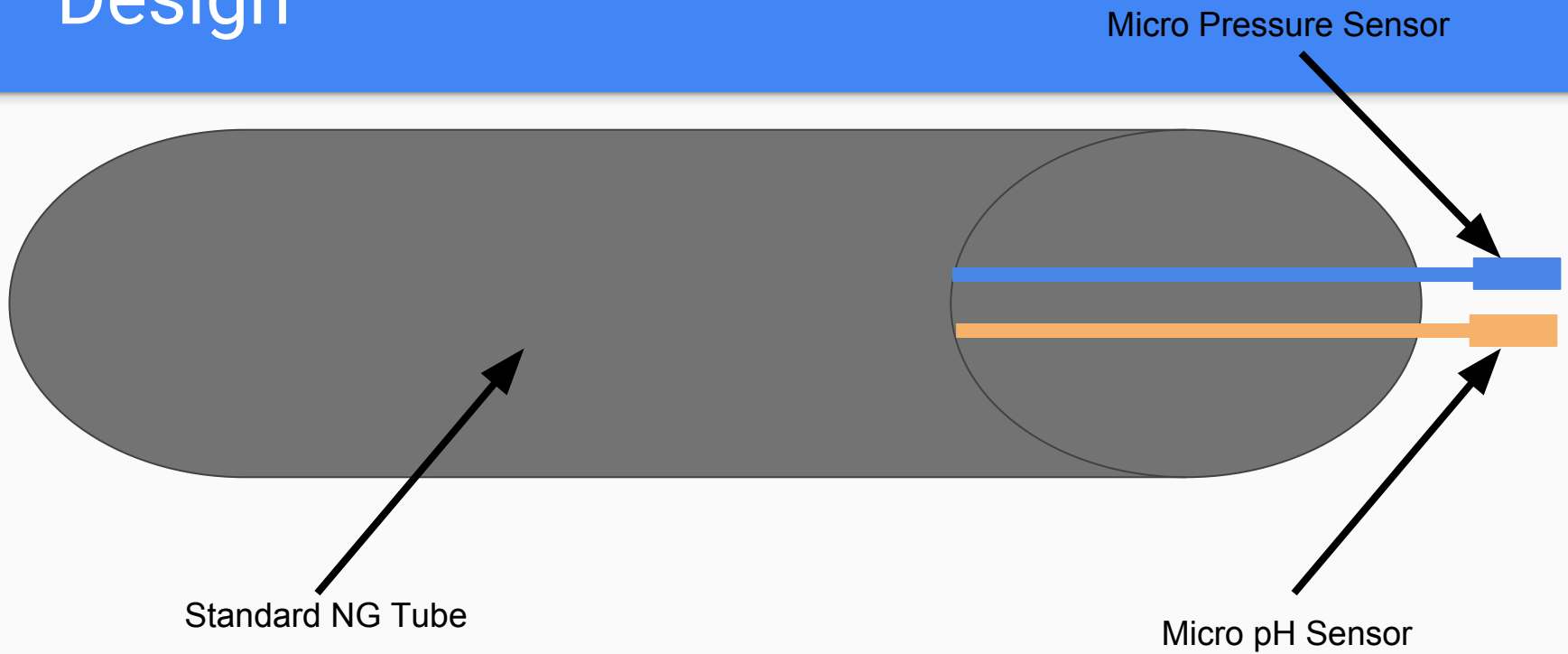


Tran K, Brun R, Kuo B. Evaluation of regional and whole gut motility using the wireless motility capsule: Relevance in clinical practice. *Therap Adv Gastroenterol*. 2012; 5: 249-60.

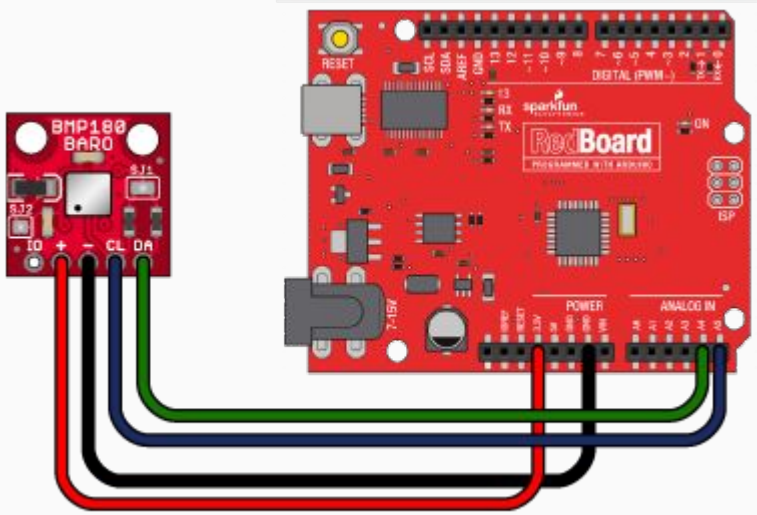
Design



Design



Pressure Probe Setup



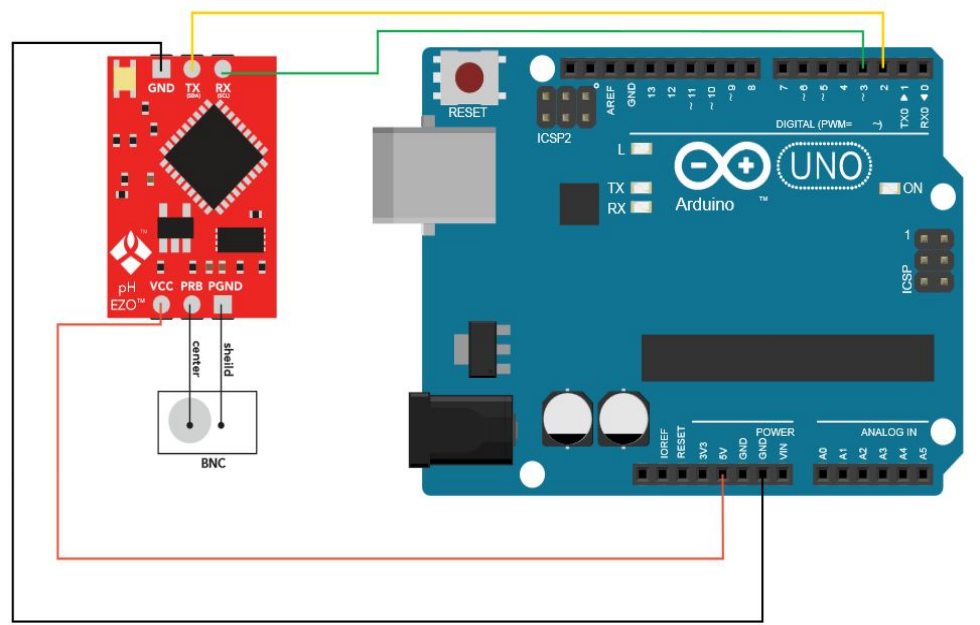

```
      status = pressure.getPressure(P,T);
      if (status != 0)
      {
        Serial.print("absolute pressure: ");
        Serial.print(P,2);
        Serial.print(" mb, ");
        Serial.print(P*0.0295333727,2);
        Serial.println(" inHg");

        p0 = pressure.sealevel(P,ALTITUDE);
        Serial.print("relative (sea-level) pressure: ");
        Serial.print(p0,2);
        Serial.print(" mb, ");
        Serial.print(p0*0.0295333727,2);
        Serial.println(" inHg");

      }
      else Serial.println("error retrieving pressure measurement\n");
    }
    else Serial.println("error starting pressure measurement\n");
  }
  else Serial.println("error retrieving temperature measurement\n");
}
else Serial.println("error starting temperature measurement\n");

delay(5000);
}
```

pH Probe Setup



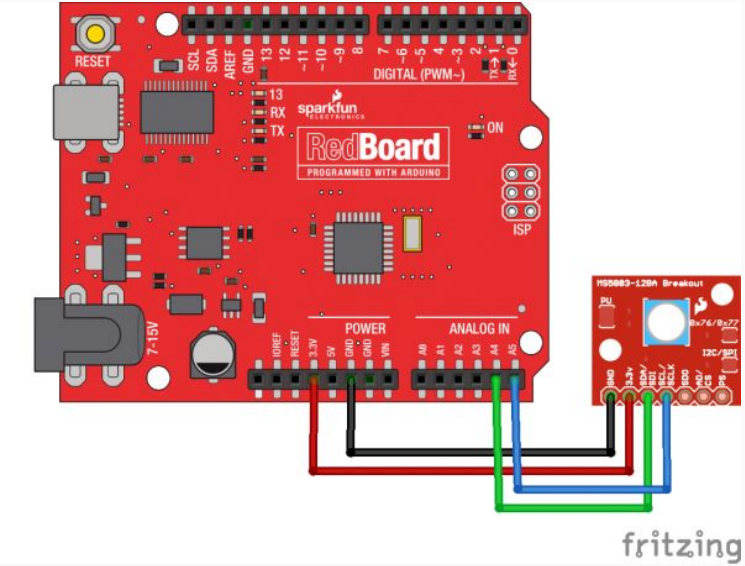

```
void loop() {

  if (input_string_complete) {
    myserial.print(inputstring);
    myserial.print('\r');
    inputstring = "";
    input_string_complete = false;
  }

  if (myserial.available() > 0) {
    char inchar = (char)myserial.read();
    sensorstring += inchar;
    if (inchar == '\r') {
      sensor_string_complete = true;
    }
  }


  if (sensor_string_complete == true) {
    Serial.println(sensorstring);
    if (isdigit(sensorstring[0])) {
      pH = sensorstring.toFloat();
      Serial.print("pH = ");
      Serial.println(pH);
    }
    sensorstring = "";
    sensor_string_complete = false;
  }
```

MS5803-14BA Pressure Sensor



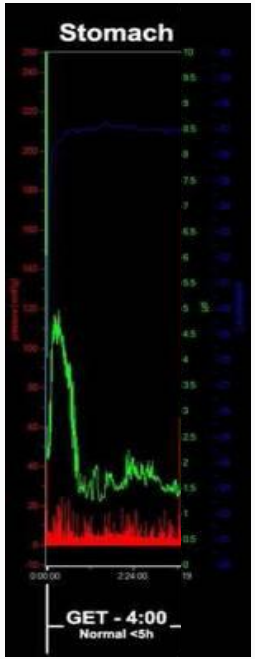
- Compatible with Arduino
- Gel coated sensor
- I2C and SPI connections
- 0 to 10,000 mmHg range
- 0.75 mmHg resolution
- -40 to 85℃ measuring range
- 8.22 ms response time

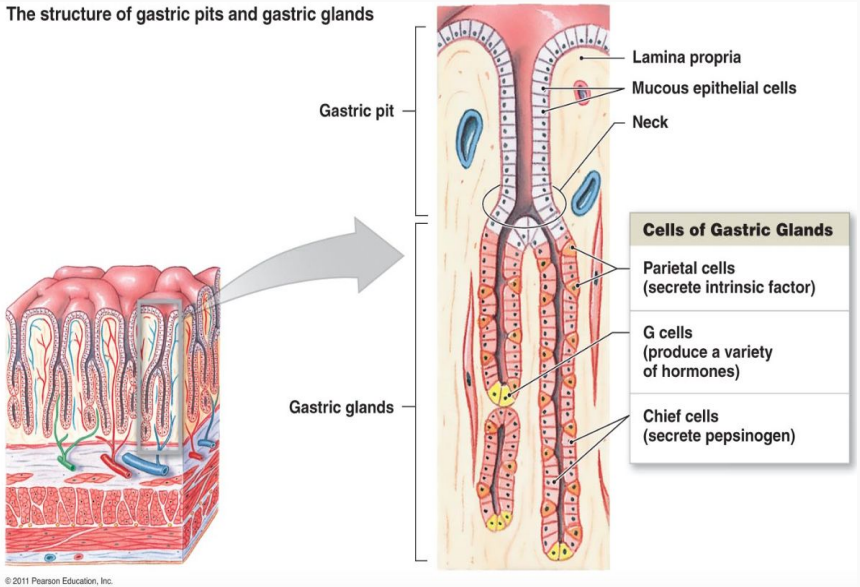
Tubing

- Provided by: VitalityMedical
- Polyurethane
- Important dimensions: Diameter and Length
- 1cm markings
- Feeding port
- Clog-free tip

Physiology of Gastrointestinal System--pH

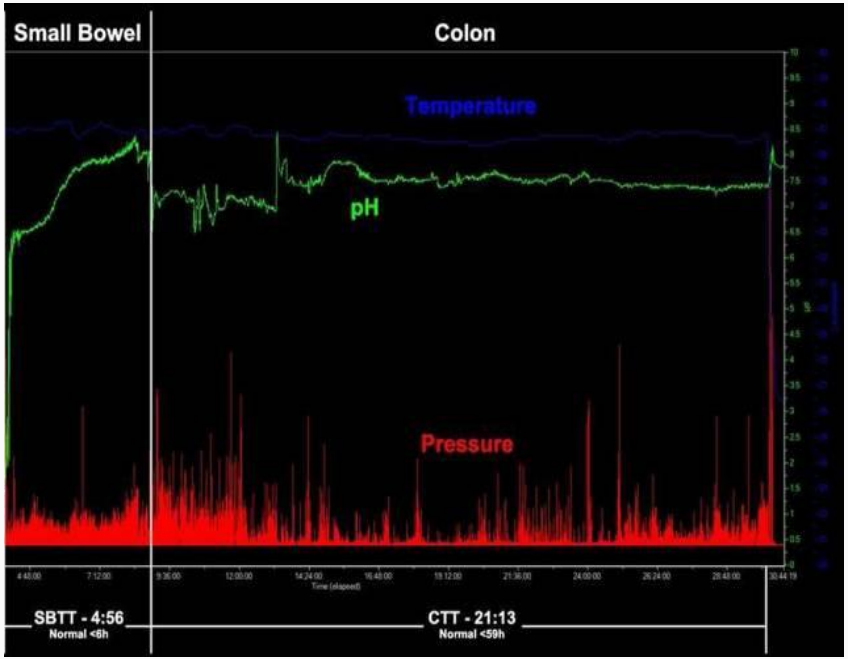
- Saliva (pH range 6.5-7.5)
- Stomach (pH range 1.5-2.5)
  - Parietal cells secrete HCl
  - G cells secrete gastrin
  - Chief cells secrete pepsinogen
- Purpose of low pH: immune barrier to microorganisms, activate digestive enzymes

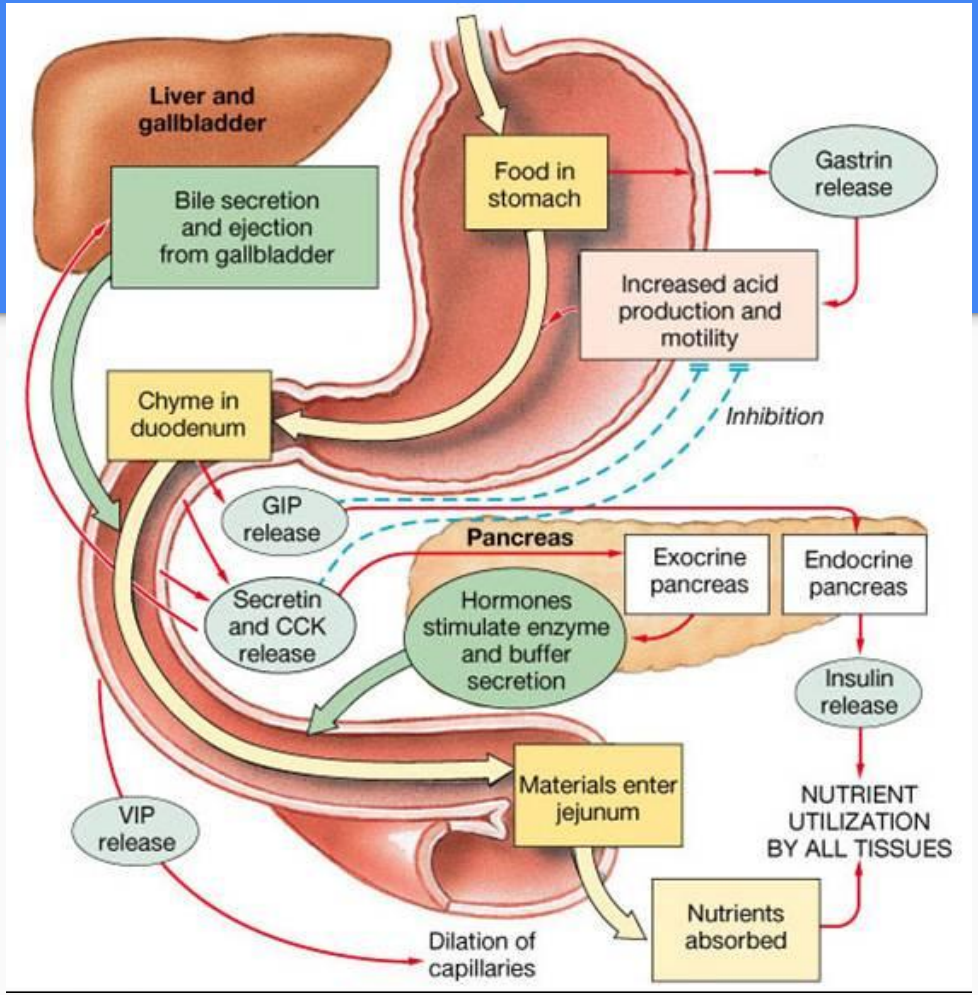




Physiology of Gastrointestinal System--pH

- Duodenum (pH brought to 7)
  - Cholecystokinin (CCK) stimulates release of bile from gallbladder
  - Secretin stimulates the release of sodium bicarbonate from pancreas
  - Brunner's glands produce alkaline secretion
  - Purpose of pH: Activate intestinal enzymes for absorption, deactivate digestive enzymes for breakdown, protect intestinal lining
- Jejunum (pH up to 8)
- Colon (pH stable about 7-7.5)



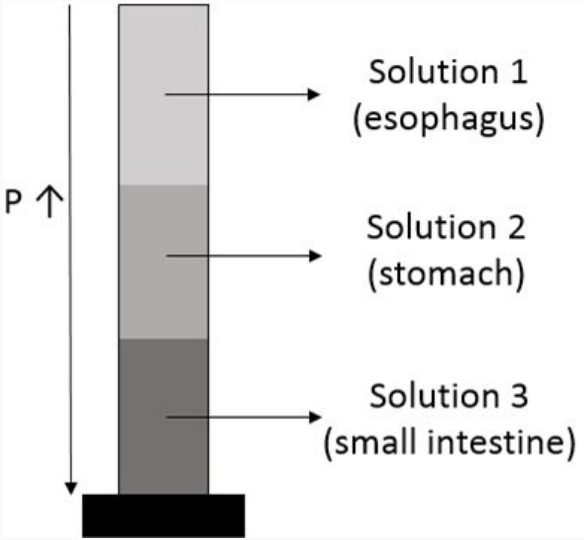

Liver and gallbladder
Bile secretion and ejection from gallbladder
Food in stomach
Gastrin release
Increased acid production and motility
Inhibition
Chyme in duodenum
GIP release
Pancreas
Exocrine pancreas
Endocrine pancreas
Secretin and CCK release
Hormones stimulate enzyme and buffer secretion
Insulin release
Materials enter jejunum
NUTRIENT UTILIZATION BY ALL TISSUES
VIP release
Nutrients absorbed
Dilation of capillaries

Physiology of Gastrointestinal System-- Pressure as a Secondary Indicator

- Pressure profile (Kuo et al. [2010]):
  - Stomach: 4790 {3091, 6933} mmHg/s
  - Small intestine: 5182 {2791, 7538} mmHg/s
- Major limitations:
  - Wide range of pressure in both stomach and small intestine - difficult to differentiate
  - Gastroparetic patients have about 10% reduction in pressure profile, while gastroparetic patients with diabetes have about 15% reduction in pressure profile.
- Solution: look for differences in pressure characteristics instead of absolute changes (lower average level and more constant in stomach, higher average level and more pulsatile in small intestine)

Testing Chamber

- As the tube goes down the cylinder, sensors will detect the changes of pressure and pH at the same time - simulation of feeding tube's passage along digestive system
  - Pressure change: height of cylinder
    - P = Pa + pgd
  - pH change: three layers of solution with different pH
    - Layers formed by solutions with different densities
- Advantages
  - Much safer
  - Less hazardous materials
  - Easier to build and modify
  - Easier to understand for audiences

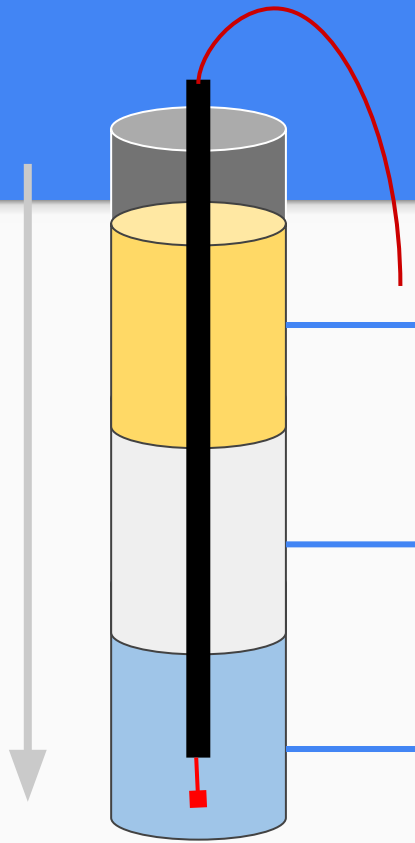


Testing Chamber

Increasing depth and increasing density contribute to increasing pressure readings

$\triangle P = \rho g d$

Estimating 1.00 g/mL, we should have a change of 73.5 mmHg in one meter



Swan Isopropyl Alcohol, 99%
pH 7
density: 0.785g/mL

Heinz Distilled White Vinegar
pH 2.4
density: 1.01 g/mL

Dawn Ultra Concentrated Dishwashing Liquid
pH 9
density: 1.06 g/mL

Testing Chamber Materials

	Density (g/cm^3)	pH
Swan Isopropyl Alcohol, 99%	0.785	7
Heinz Distilled White Vinegar	1.01	2.4
Dawn Ultra Concentrated Antibacterial Hand Soap Dishwashing Liquid	1.06	9

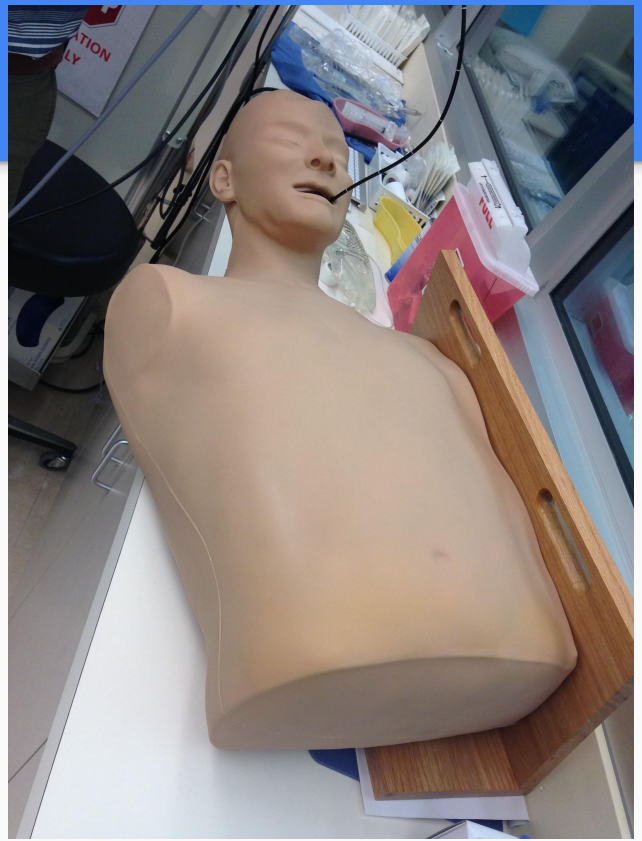
Testing Chamber Materials

1 in. x 5 ft. Furniture Grade PVC Pipe in Clear-- $13.44

1 in. Furniture Grade PVC External Flat End Cap in Clear-- 2 caps X $5.09 each

Testing at CELA

- Upper GI SimMan!
- Advantages:
  - Includes major landmarks in GI tract
  - Test size and shape of tubing
  - Camera and lighting to confirm length of tube necessary and proper placement
- Disadvantages
  - Sensors will not detect changes in pH
  - Cannot insert through nasal cavity
  - Material interaction will not be same as with body
    - Cannot test compatibility and friction



Parts Necessary

Parts to be ordered:

- Testing chamber solutions
- PVC Pipe and caps

Future Directions

- Order parts and contents for testing chamber to begin building
- Receive tubing and test at CELA
- Combine Pressure and pH setups into single file for Arduino
- Begin outlining future designs using microsensors

Grant Proposal Modifications

- Specifications of testing chamber design and testing buffers
- Testing of assembled prototype in SimMan to prove the compatibility in digestive system