FeedRite Feeding Tube

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Problem Statement

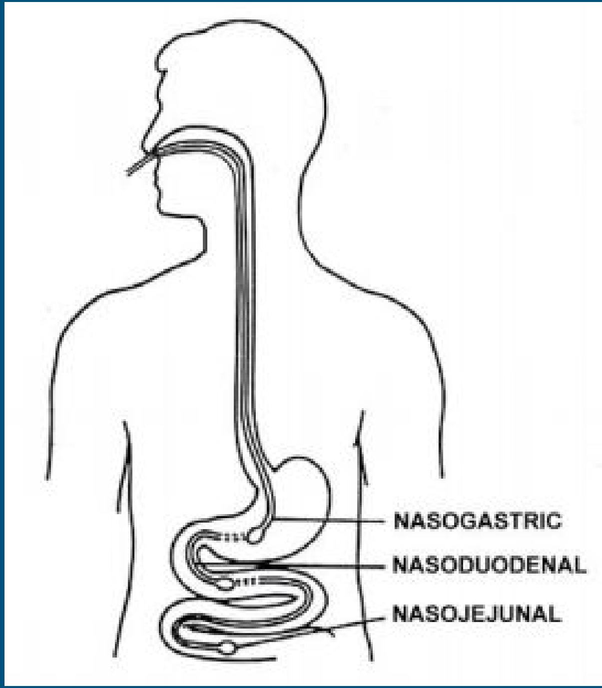
Gastric bypass is an invasive procedure that requires up to 5 days of hospitalization and has a narrow patient population (those with a BMI greater than 40 or greater than 35 with obesity-related conditions; roughly 18 million Americans) in comparison with the rate of obesity in America (78.6 million 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

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

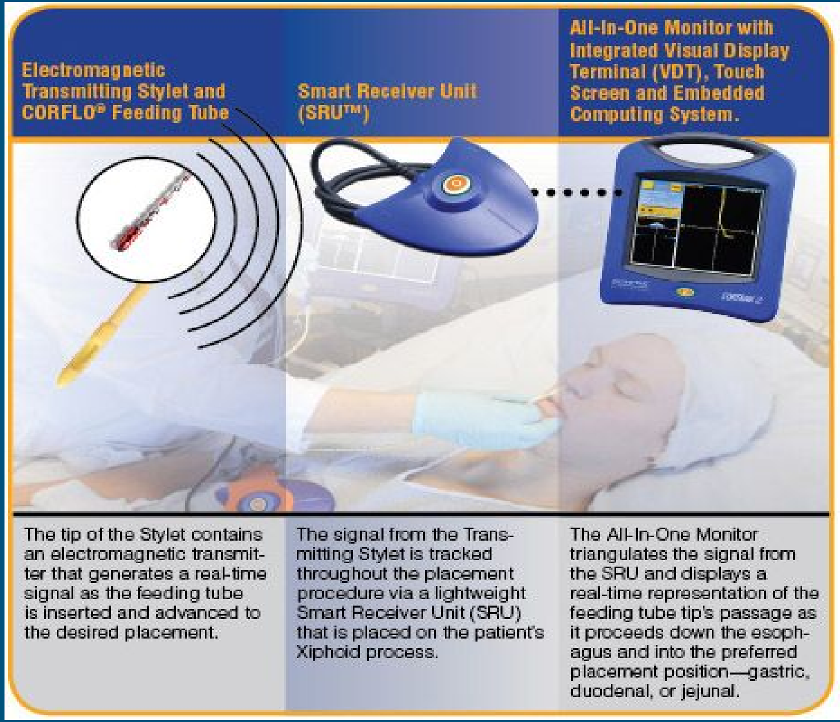
Background

- Problems: Obesity, Type II Diabetes
- Solution: Gastric Bypass Surgery
    - The stomach is divided into upper, smaller portion and lower, larger portion. The smaller portion is reconnected to the jejunum while bypassing the duodenum.
    - May reverse diabetes, lose weight
    - Invasive, risky and expensive
    - For patients with BMI > 40, or BMI > 35 with obesity-related conditions



Background

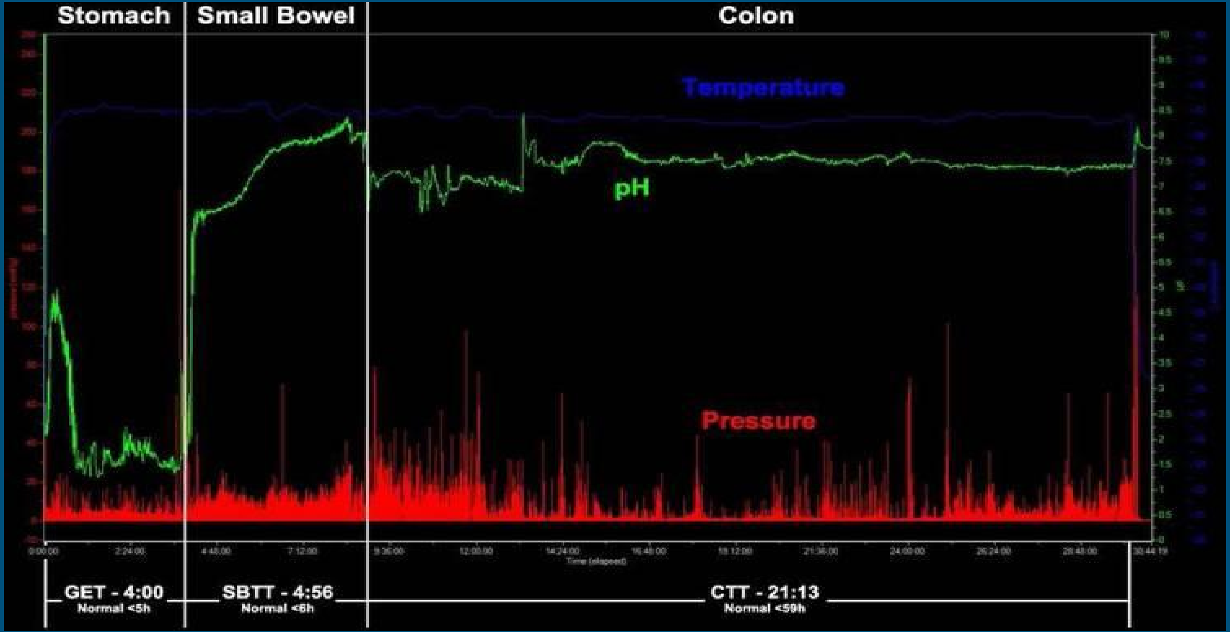
- Alternative Solution: Naso-duodenal Feeding Tube
  - For patients with BMI > 30, or unqualified for gastric bypass surgery because of age or physical conditions
  - Existing device - Cortrak EAS
  - Our design - less expensive, confident placement, placement detection will not interfere with feeding



Potential Market

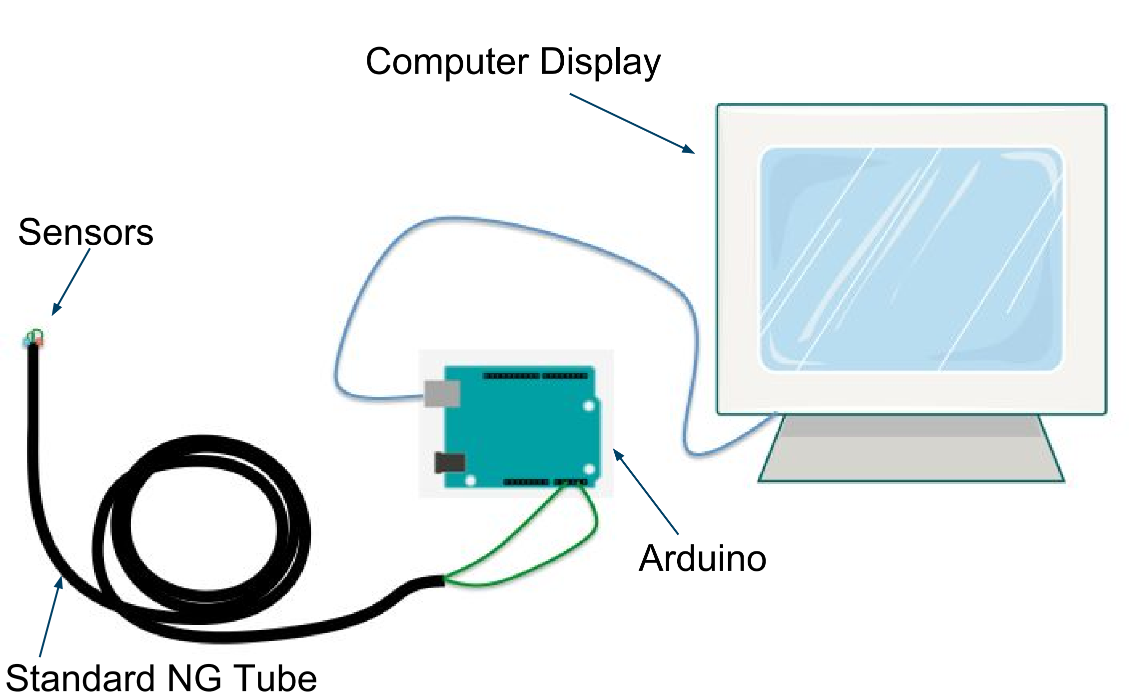
- Obesity and Type II Diabetes - 9 % of American adults
- Gastric Bypass Procedures - 180,000 per year
- Marketing:
    - Medical professionals at hospitals
    - Individual patients at home

Evidence

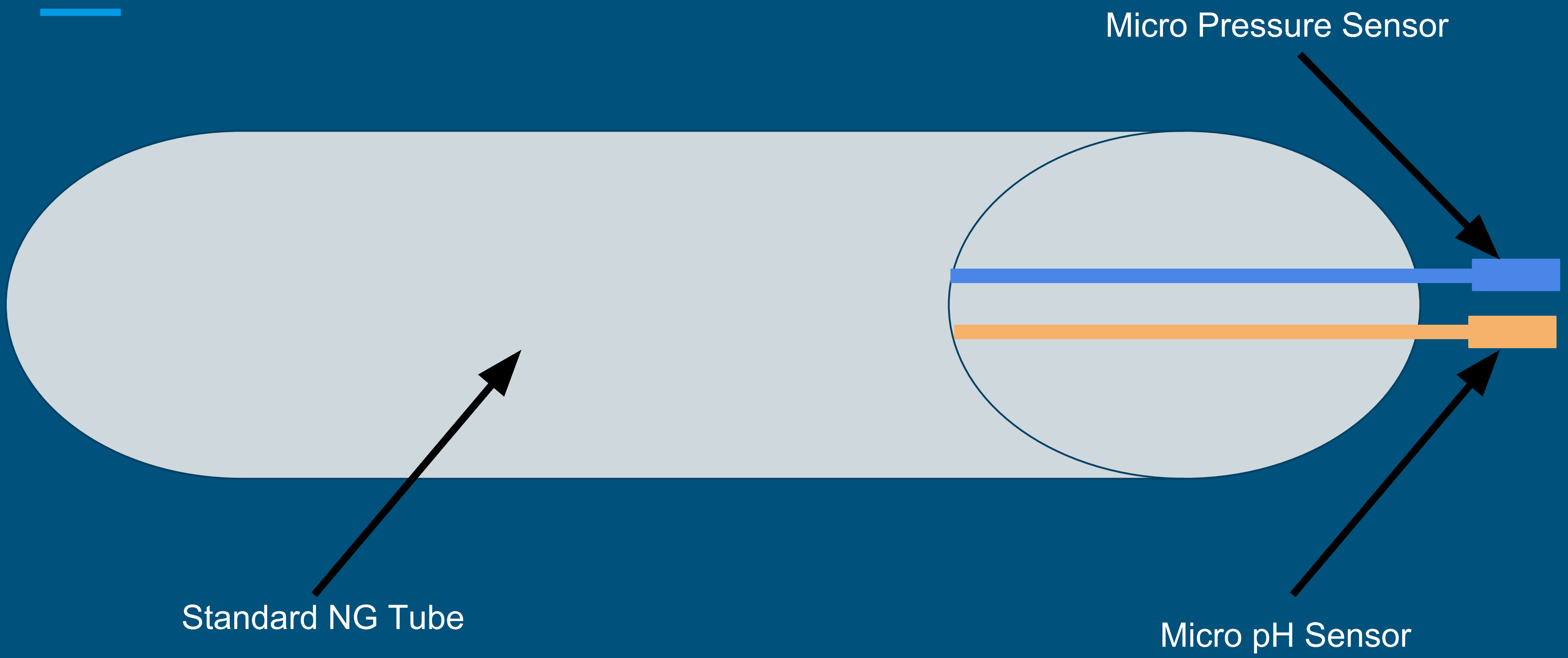


Tran K, Brun R, Kuo B. Evaluation of regional and whole gut motility using the wireless motility capsule: Relevance in clinical practice. *Therap Adv Gastroenterol.* 2012; 5: 249-60.

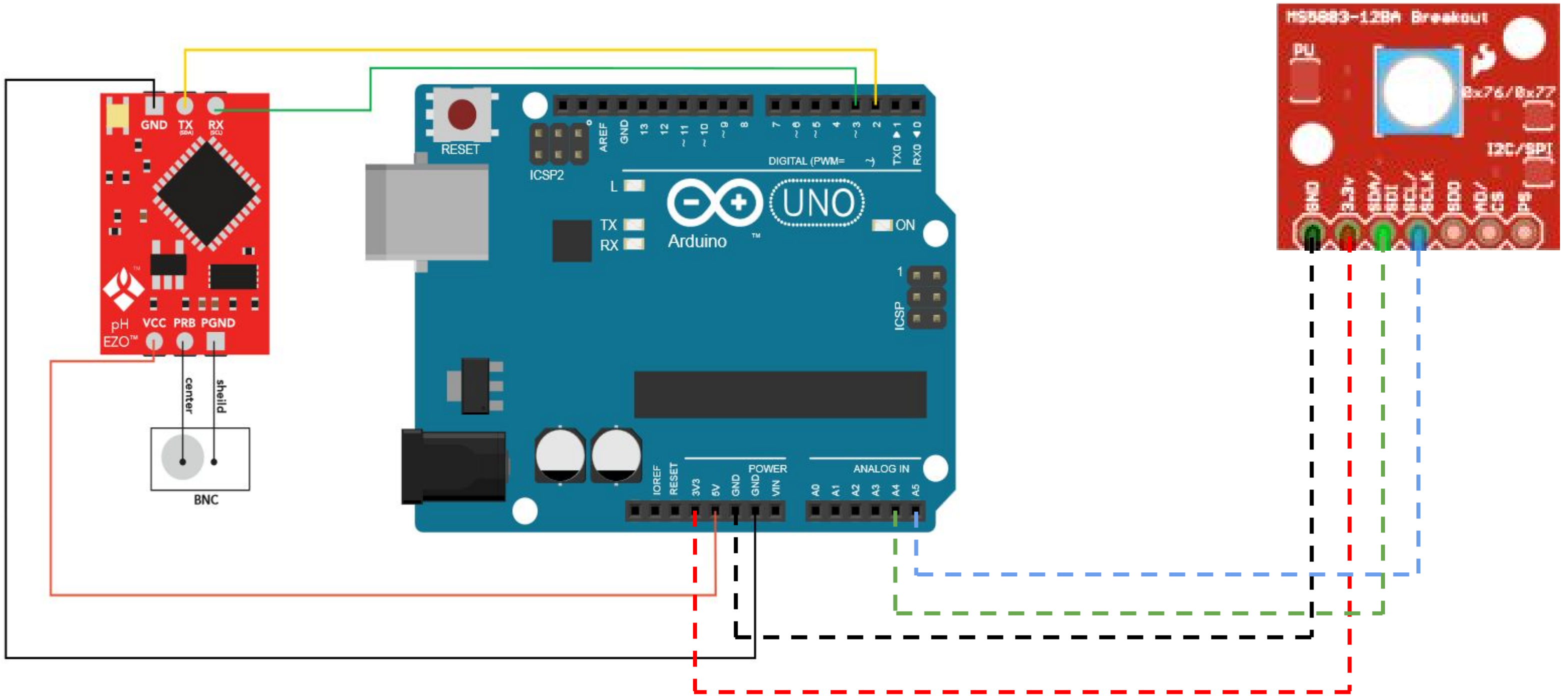
Design



Design



pH Probe Setup

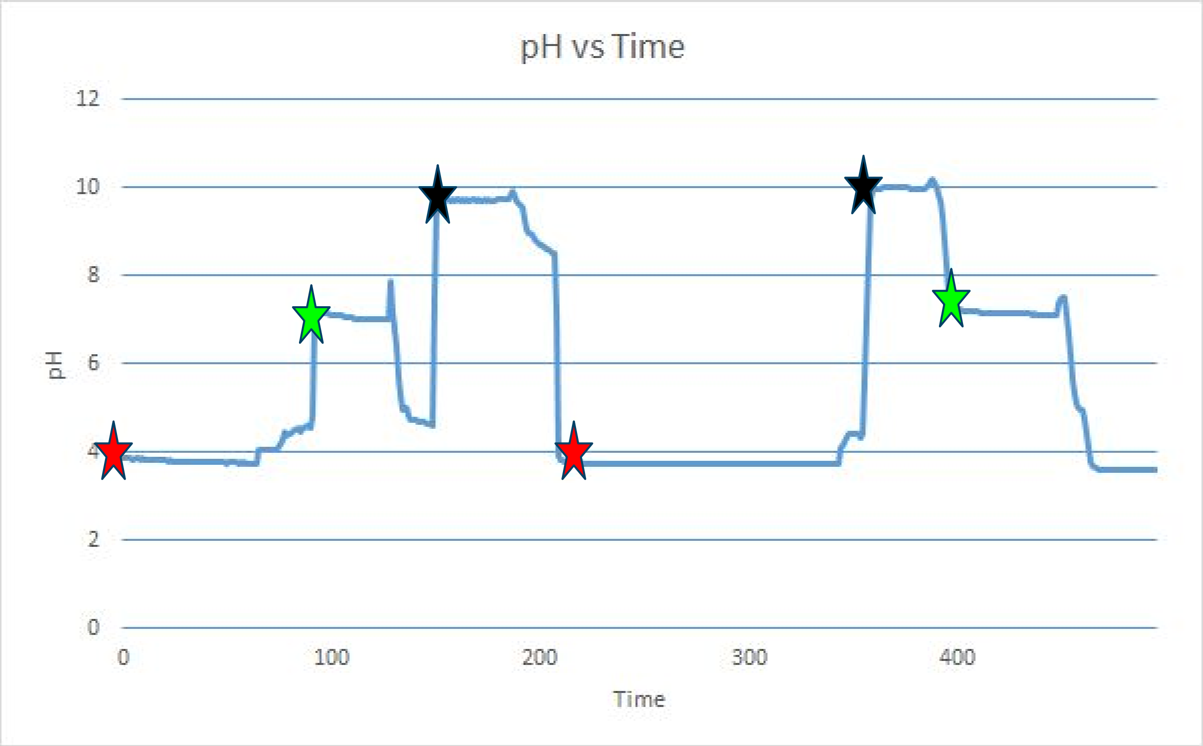


pH Calibration

- Used Atlas Scientific's prescribed sensor calibration method
- Compared sensor reading to three known pH values at 4, 7, 10

Expected pH Value	Average % difference per data point
4.00	-6%
7.00	-2%
10.00	-0.9%

pH Probe Calibration



MS5803-14BA Pressure Sensor

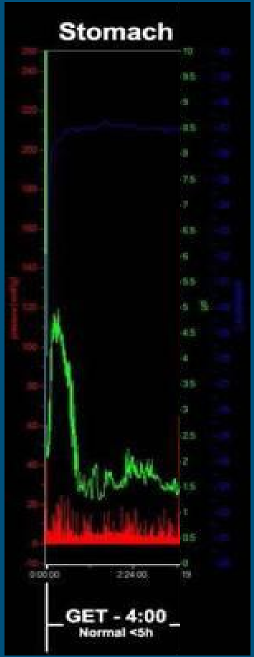
- Gel coated sensor
  - May or may not need to waterproof board
- I2C connection
  - Possibility to use SPI as well
- Appropriate range, resolution, operating temperature zone, and response time
- Initial calibration
  - Measured 745.0 mmHg
  - Actual 759.9 mmHg
  - % Error 1.96%

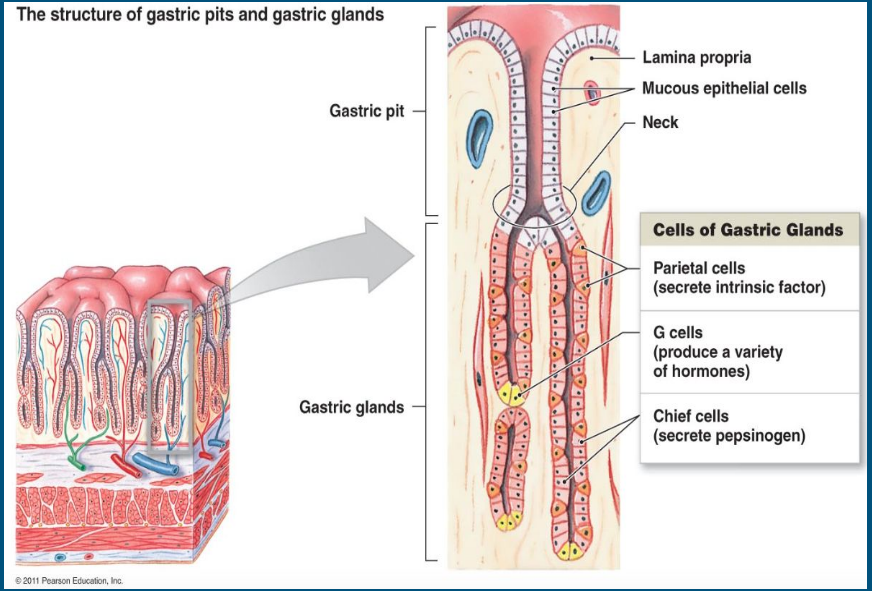
Tubing

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

Physiology of Gastrointestinal System--pH

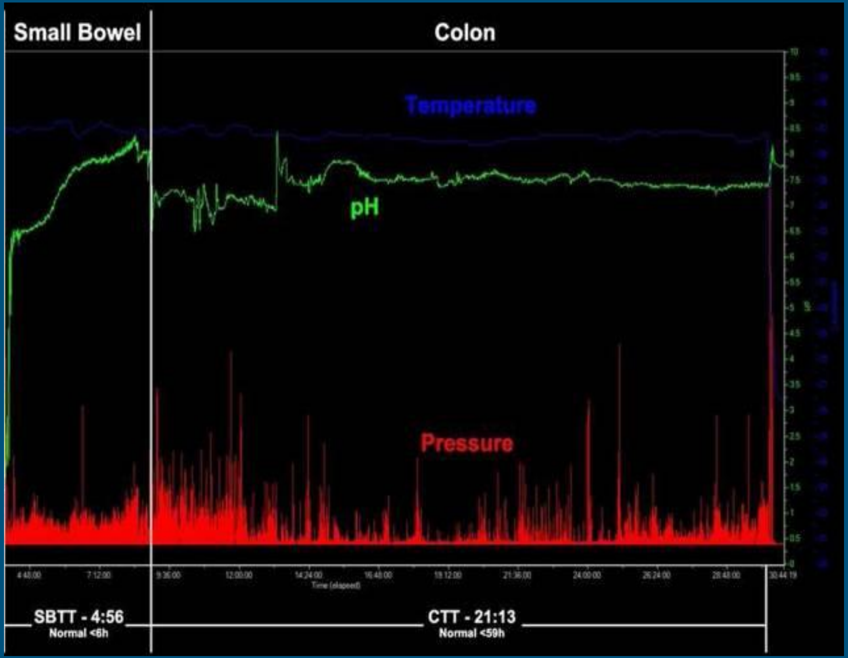
- Saliva (pH range 6.5-7.5)
- Stomach (pH range 1.5-2.5)
  - Parietal cells secrete HCl
  - G cells secrete gastrin
  - Chief cells secrete pepsinogen
- Purpose of low pH: immune barrier to microorganisms, activate digestive enzymes

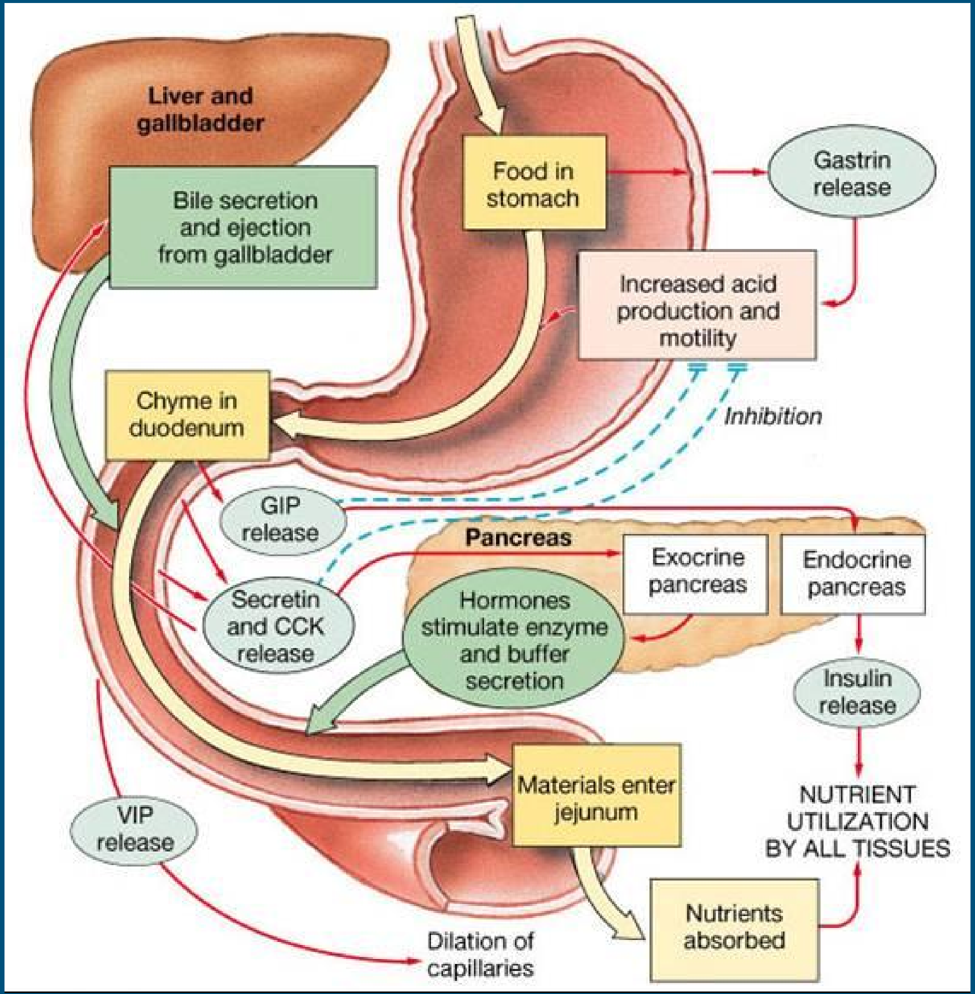




Physiology of Gastrointestinal System--pH

- 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)





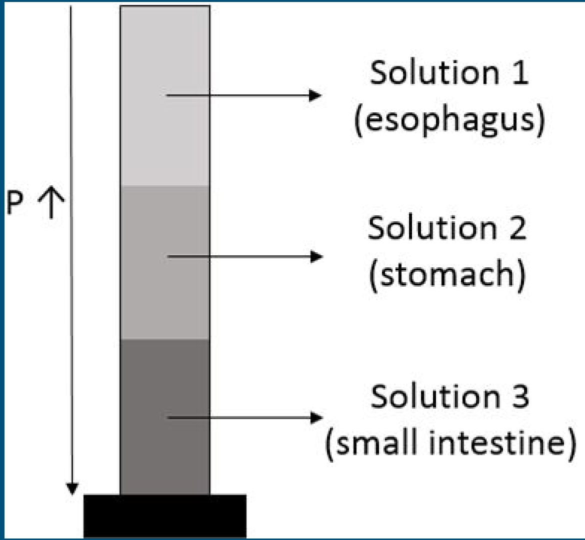
Liver and gallbladder
Bile secretion and ejection from gallbladder
Food in stomach
Gastrin release
Increased acid production and motility
Inhibition
Chyme in duodenum
GIP release
Pancreas
Exocrine pancreas
Endocrine pancreas
Secretin and CCK release
Hormones stimulate enzyme and buffer secretion
Insulin 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
- Wide range of pressure in both stomach and small intestine - difficult to differentiate based merely on pressure
- Solution: examine the frequency and magnitude of pressure spikes instead of actual pressure measurements (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

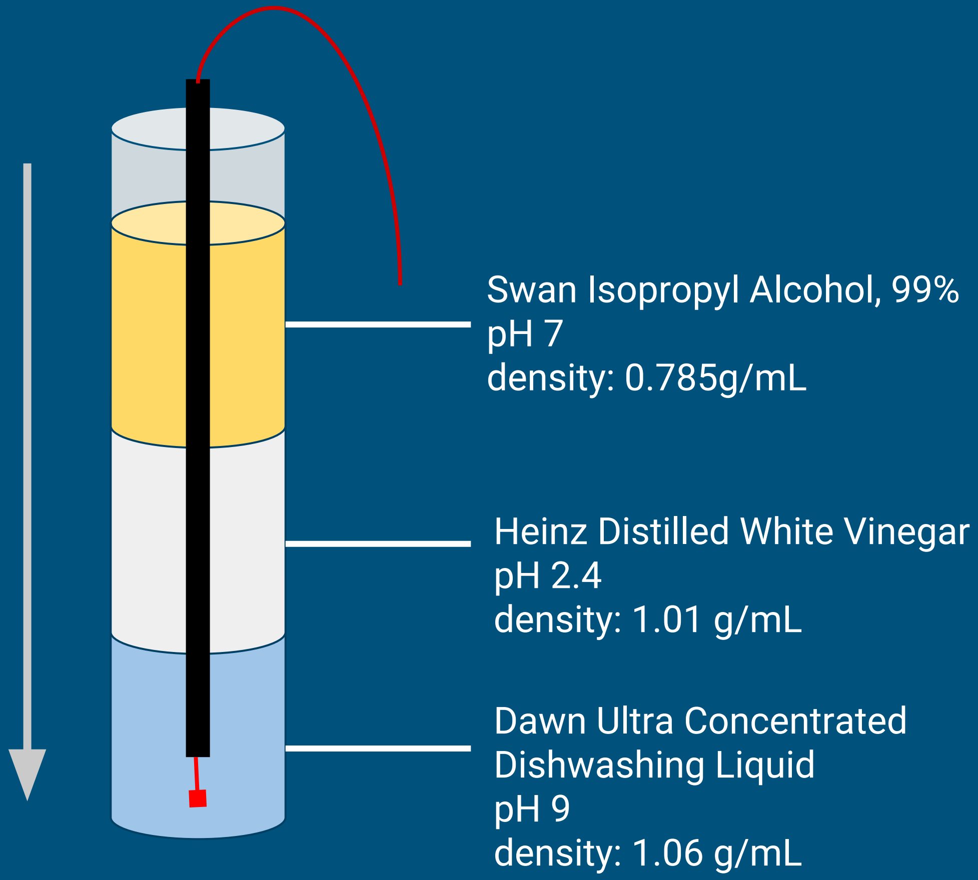


Testing Chamber

Increasing depth and increasing density contribute to increasing pressure readings

$\triangle P = \rho g d$

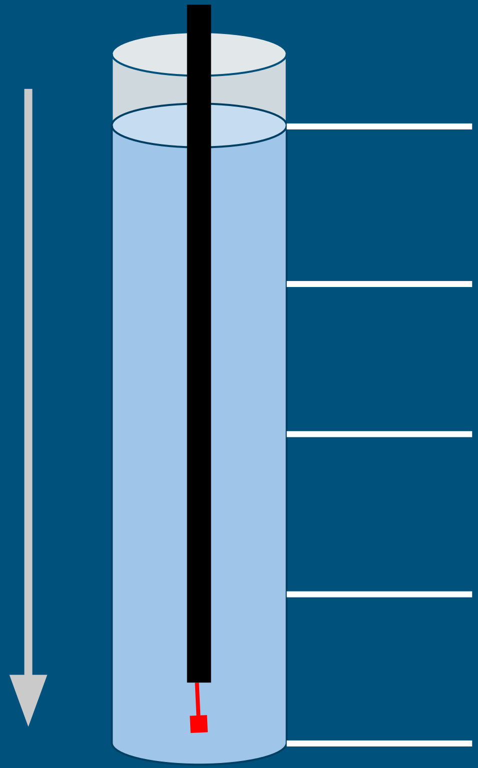
Estimating 1.00 g/mL, we should have a change of 73.5 mmHg in one meter



Expected Pressure Changes

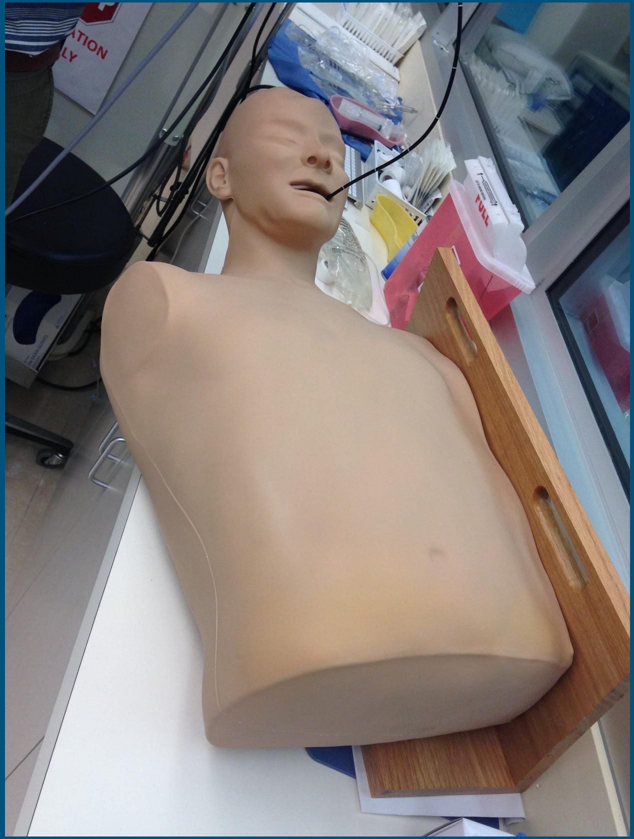
$\Delta P = \rho g d$

Depth (feet)	Expected Pressure (mmHg)
0	760
1	782
2	805
3	828
4	851
5	874



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 biocompatibility and friction



CELA

- Testing tubing in upper GI model
- Place camera (CELA) within tube as we guide tube down GI tract
  - Identify position of landmarks to mark expected changes in pH and pressure
  - Optimize length of tubing to minimize extra materials
  - Additional indication of estimated placement of feeding tube in average patient

Additional Design Components

- Casing to improve portability
- User Interface
- LED screen to display simple output
- Bluetooth communication for wireless device
- Eliminate breadboard

Parts Necessary

- Additional Design Components
  - LED Screen
  - 3D Printed Casing
  - Bluetooth communication
- PVC pipe has not been delivered

Future Directions

- CELA
  - Test and optimize size of tubing
  - Mark points of interest along GI tract to indicate estimated location
- Calibrate pressure sensor once PVC Piping arrives
- Meeting with Dr. Abumrad
  - Begin outlining future designs using microsensors
- Create easy-to-use UI
- Portable housing

Grant Proposal Modifications

- Additional design components
- Calibration of pH and pressure sensors