FeedRite Feeding Tube

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Problem Statement

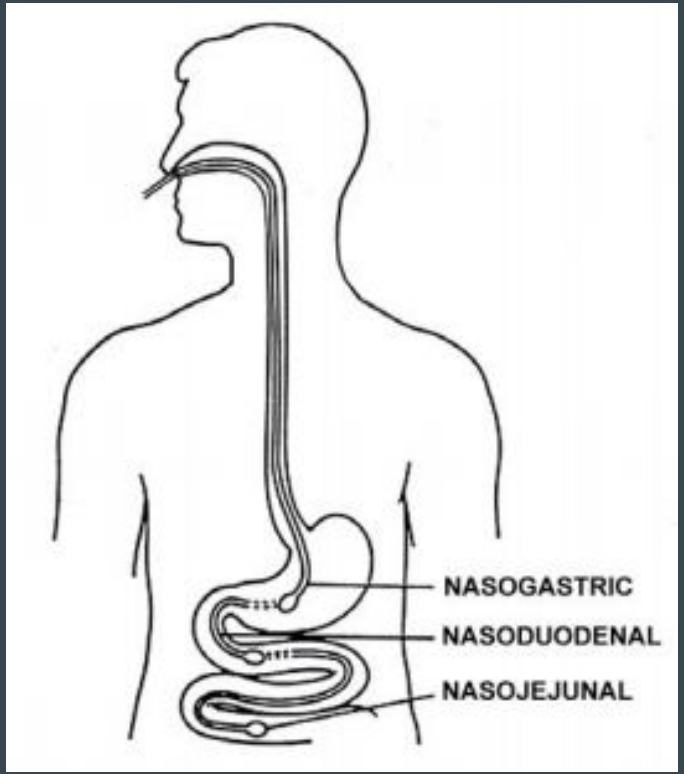
Gastric bypass is an invasive procedure that requires up to 5 days of hospitalization and has a narrow patient population (those with a BMI greater than 40 or greater than 35 with obesity-related conditions; roughly 18 million Americans) in comparison with the rate of obesity in America (78.6 million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

- 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 duodenum and jejunum
- Device must provide real-time updates of tube position

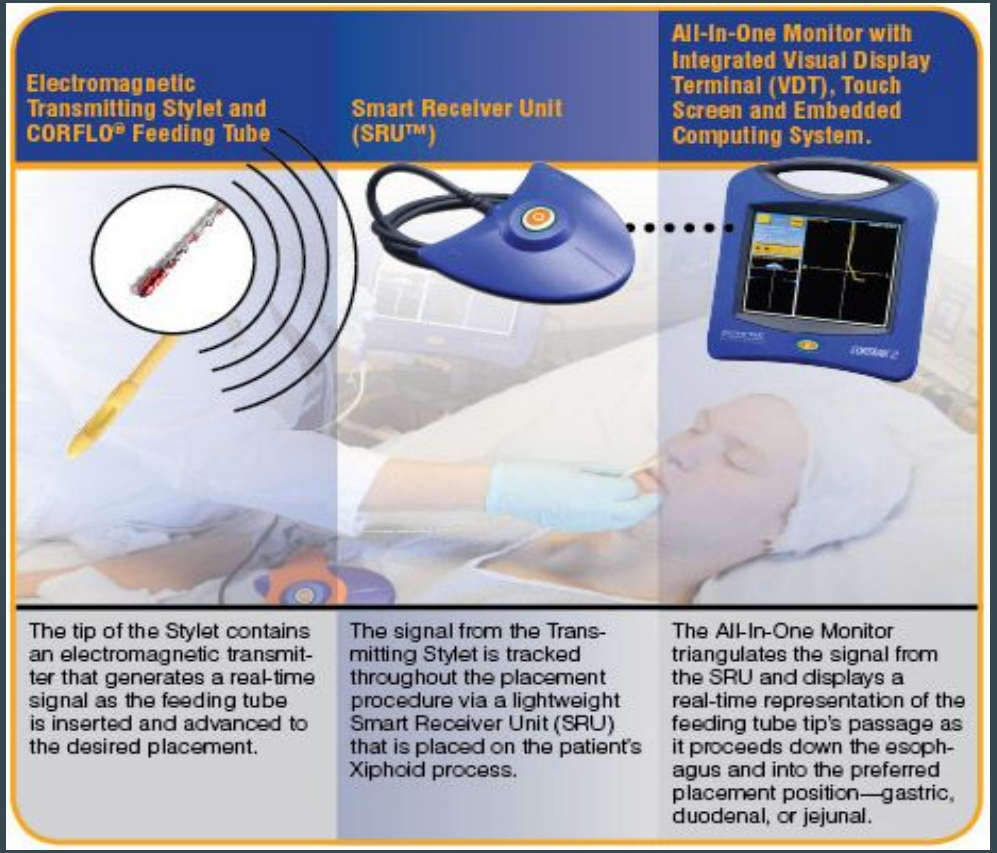
Background

- 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

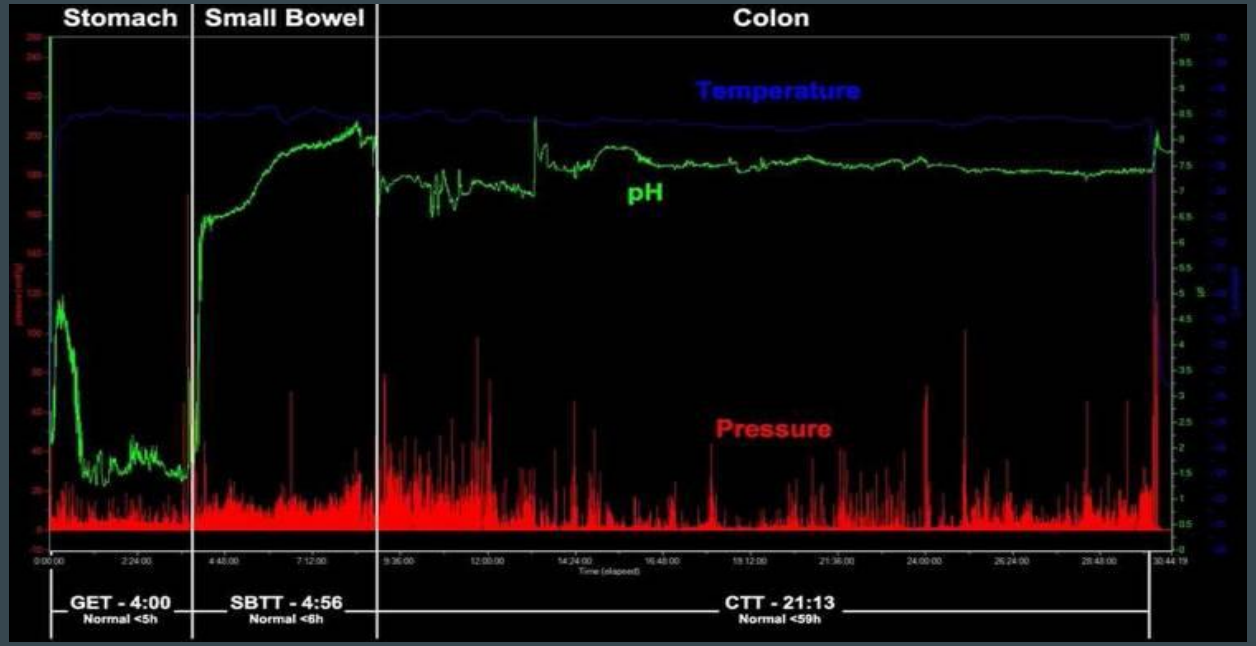
- Alternative Solution: Naso-duodenal Feeding Tube
  - For patients with BMI > 30, or unqualified for gastric bypass surgery because of age or physical conditions
  - Existing device - Cortrak EAS
  - Our design - less expensive, confident placement



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

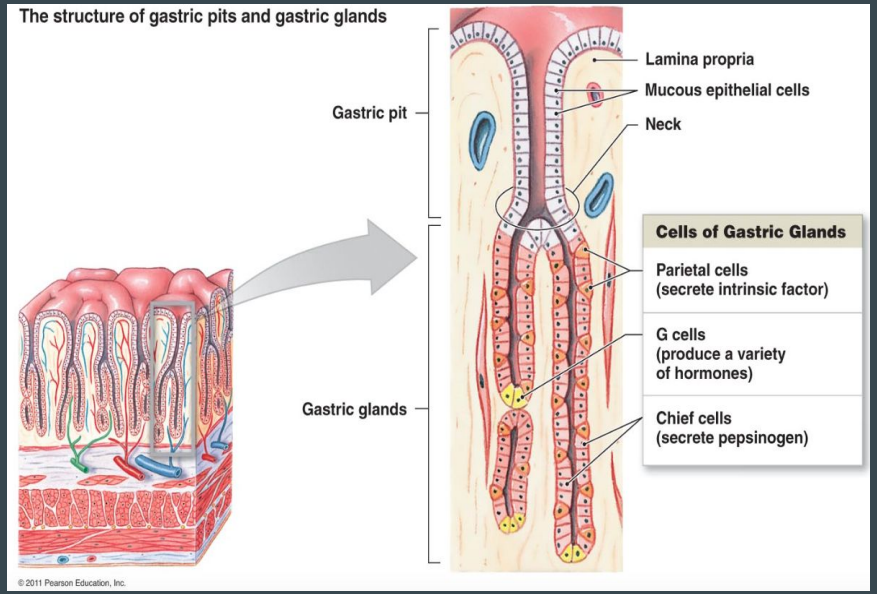
Evidence



Tran, K., Brun, R., & Kuo, B. (2012). Evaluation of regional and whole gut motility using the wireless motility capsule: relevance in clinical practice. *Therapeutic Advances in Gastroenterology*, *5*(4), 249-260.

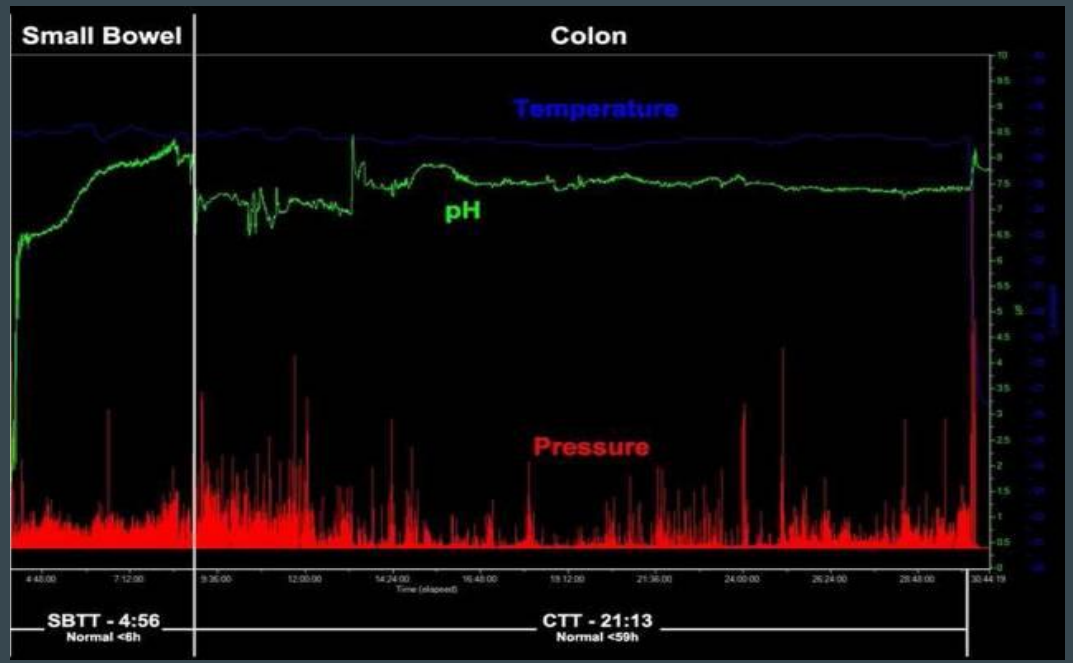
Physiology of Gastrointestinal System–pH

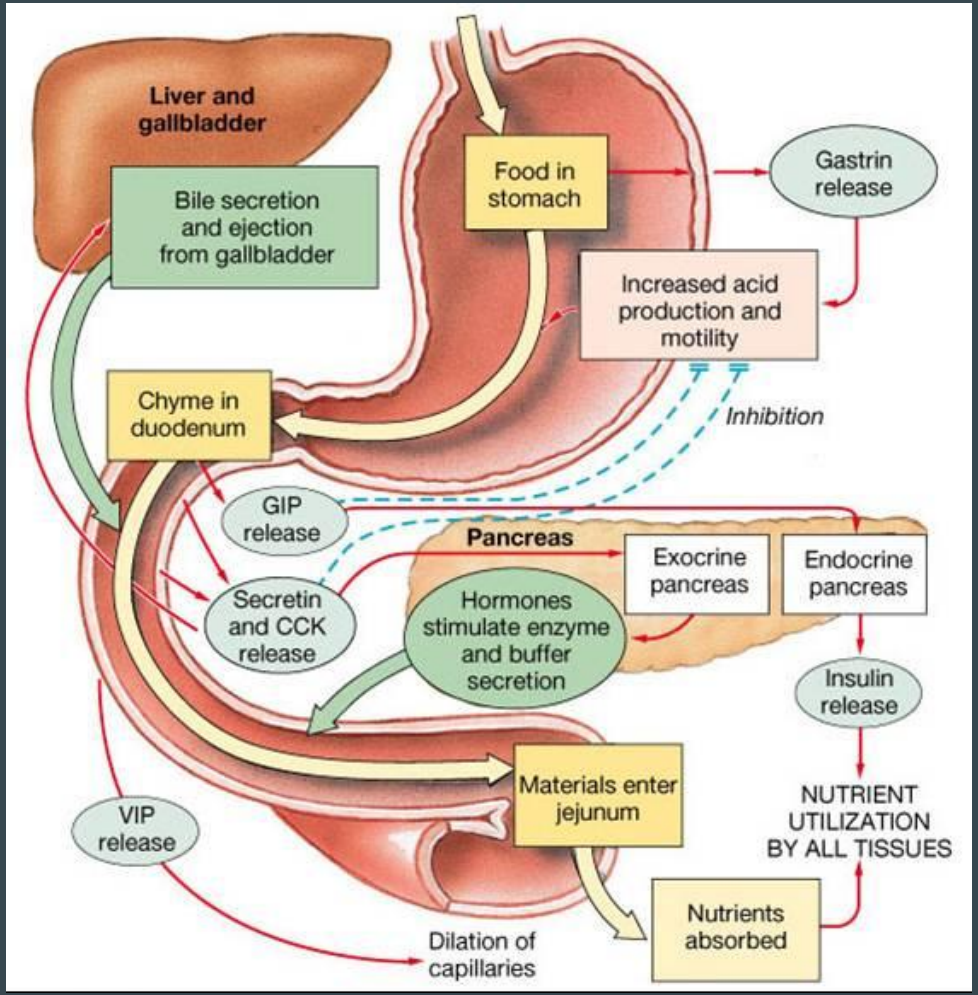
- Saliva (pH range 6.5-7.5)
- Stomach (pH range 1.5-2.5)
  - Parietal cells secrete HCl
  - G cells secrete gastrin
  - Chief cells secrete pepsinogen
- Purpose of low pH: immune barrier to microorganisms, activate digestive enzymes



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

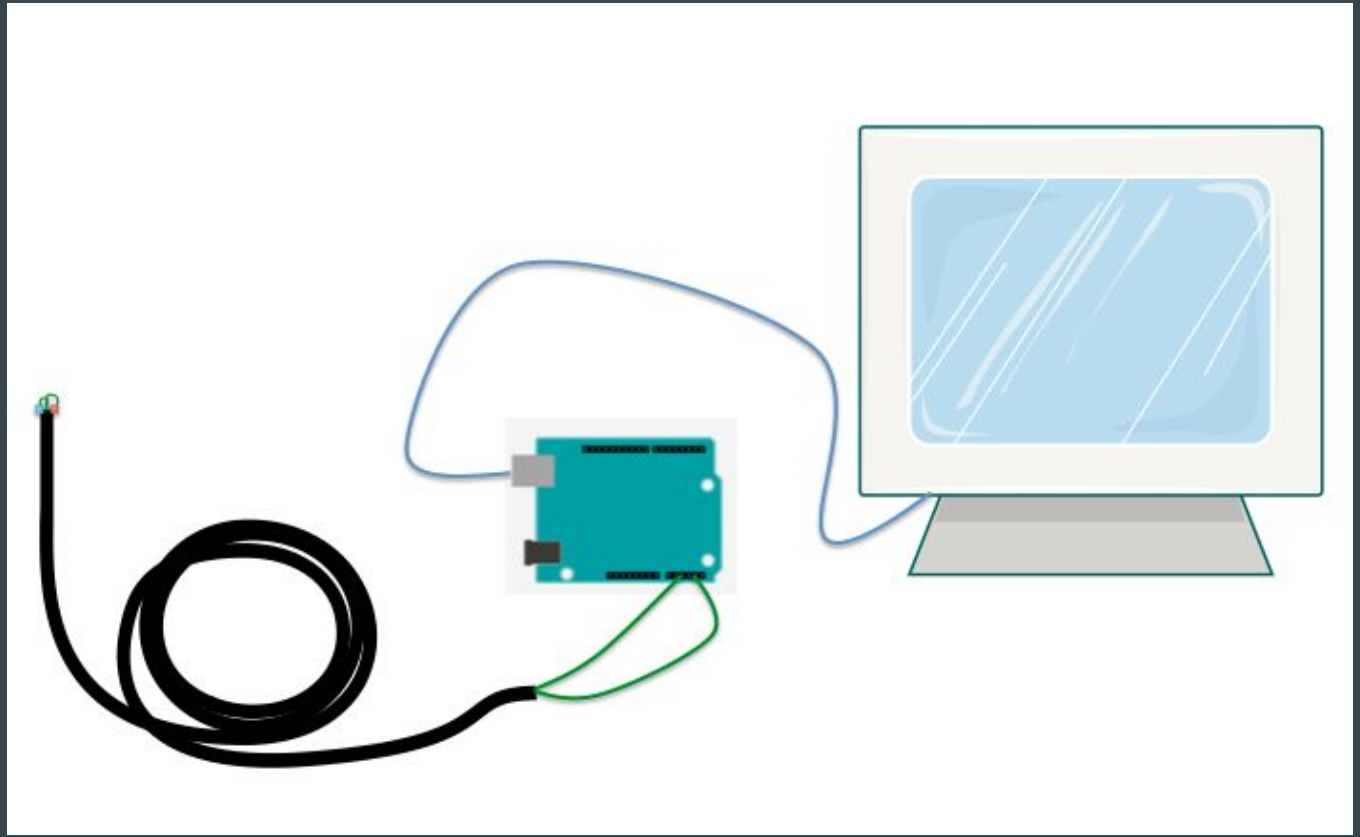
Physiology of Gastrointestinal System–Pressure

- Pressure profile (Kuo et al. [2010]):
-

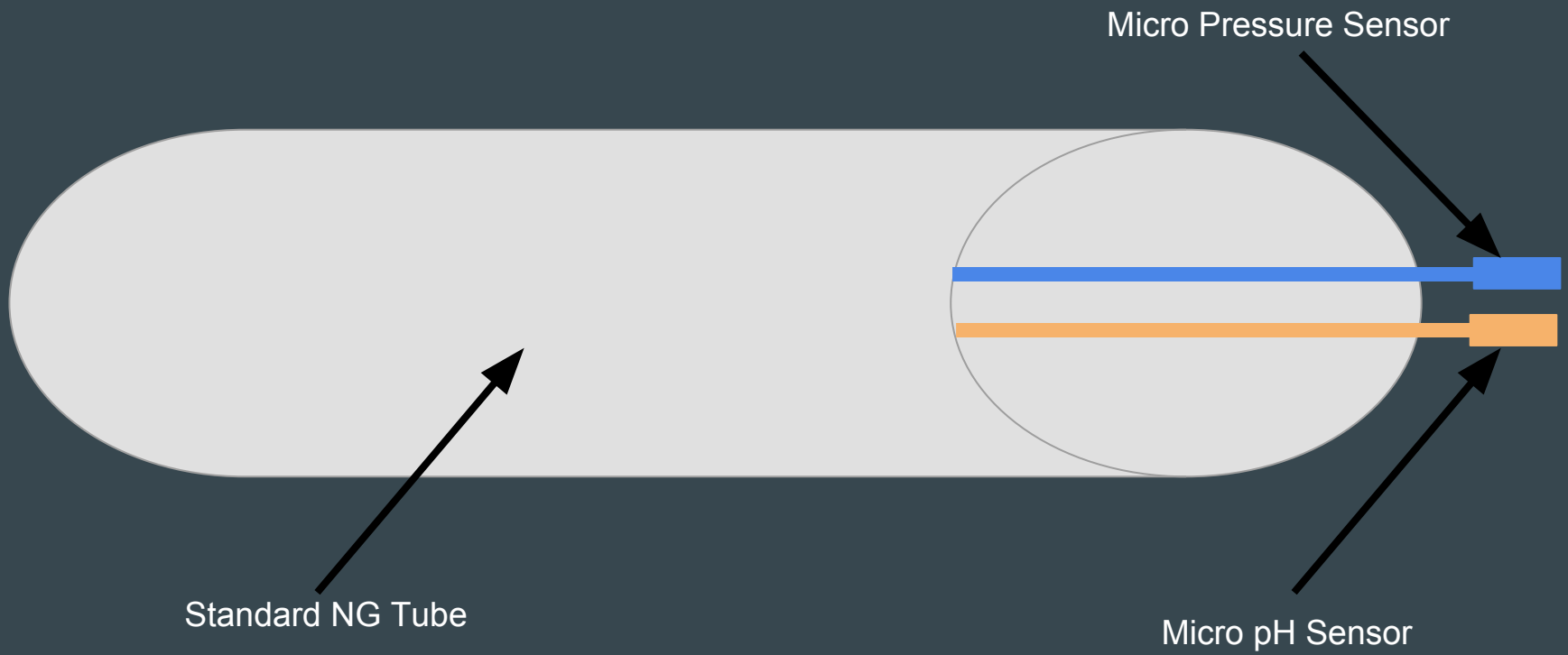
	Area under pressure curve (mmHg/s) (median, n =71)
Stomach	4790 {3091, 6933}
Small intestine	5182 {2791, 7538}

- 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.

Design



Design



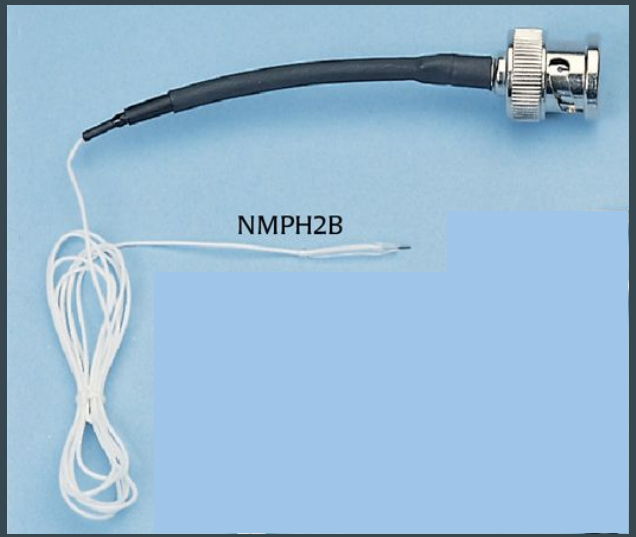
pH Sensor - Option 1

pH Microsensor by PreSens Precision Sensing

Specifications	
Measuring range	5.5 - 8.5 pH
Response time at 25° C	30 sec
Resolution at pH = 7	± 0.01 pH
Accuracy at pH = 7	± 0.05 pH
Drift at pH = 7	< 0.05 pH per day
Temperature range	5 - 50 °C

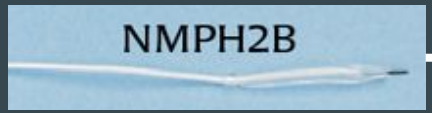
pH Sensor - Option 2

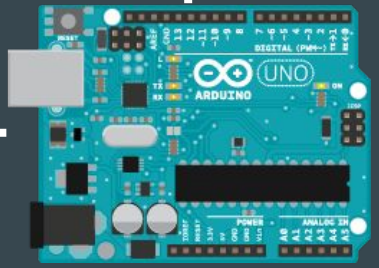
NMPH2B Beetrode Micro pH Electrode by World Precision Instruments



Specifications	
Measuring range	0 - 14 pH
Response time at 25° C	10 sec
Resolution at pH = 7	± 0.01 pH
Drift at pH = 7	< 2.5 mV / 5 min
Temperature range	5 - 50 °C
Tip diameter	100 µm

Circuit Schematic

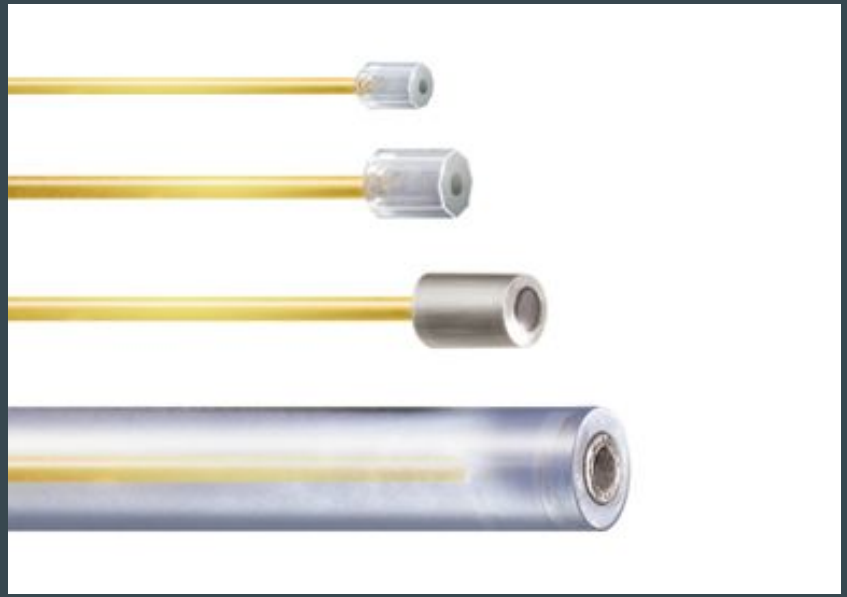




pH = ...

Pressure Sensor

OPP-M Pressure Sensor by OpSens Solutions



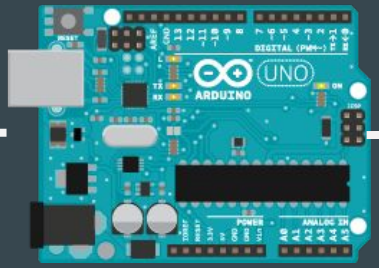
Specifications

	OPP-M250
Dimension (mm O.D.)	0,25 mm OD
Pressure range	- 300 mmHg to + 350 mmHg (relative to atmospheric pressure)
Precision	± 1 mmHg
Resolution	0.2 mmHg
Moisture drift (typical)	< 3 mmHg/28 days
Thermal coefficient of Zero (typical)	0.2 mmHg per °C
Proof pressure	4000 mmHg
Operating temperature	10 °C to 50 °C
Operating humidity range	0-100%
EM/RF/MR/MW susceptibility	Complete immunity
Cable length	1.5 meters standard (Other lengths available)
Optical connector	SC standard
Cable sheathing	Customer specifications

Signal conditioner compatibility:best suited for MiniP OEM board, LifeSens and ProSens;
also compatible with other Opsens WLPI signal.

NOTE: The OPP-M product is designed to be integrated into customer host system but is not approved by the FDA or by any applicable regulatory bodies.

Circuit Schematic



Pressure = ...

Parts Ordered

- EZO embedded pH circuit from Atlas Scientific
- BMP180 Pressure Sensor from Adafruit

New part needed:

- pH Probe from Atlas Scientific

Potential parts for the future:

- pH microsensor by PreSens
- NMPH2B Beetrode Micro pH Electrode by World Precision Instruments
- OPP-M micro-pressure sensor and OEM-MNP Signal Condition by OpSens

Future Directions

- Meet with advisor Dr. Abumrad
  - Discuss ideas for final design
  - Review testing procedures
  - Evaluate first prototype
- Meet with Dr. Mahadevan-Jansen
  - Receive feedback on unfamiliar fiber optic components of design
- Build first prototype
  - Waiting on parts
  - Some elements remain in final design

Grant Proposal Modifications

- Specify target patient population: patients who are not qualified for gastric bypass surgery because of age, physical conditions or other concerns.
- Physiology behind this device - pH and pressure.
- Specifications for pH and pressure sensors, circuit schematic.