# 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

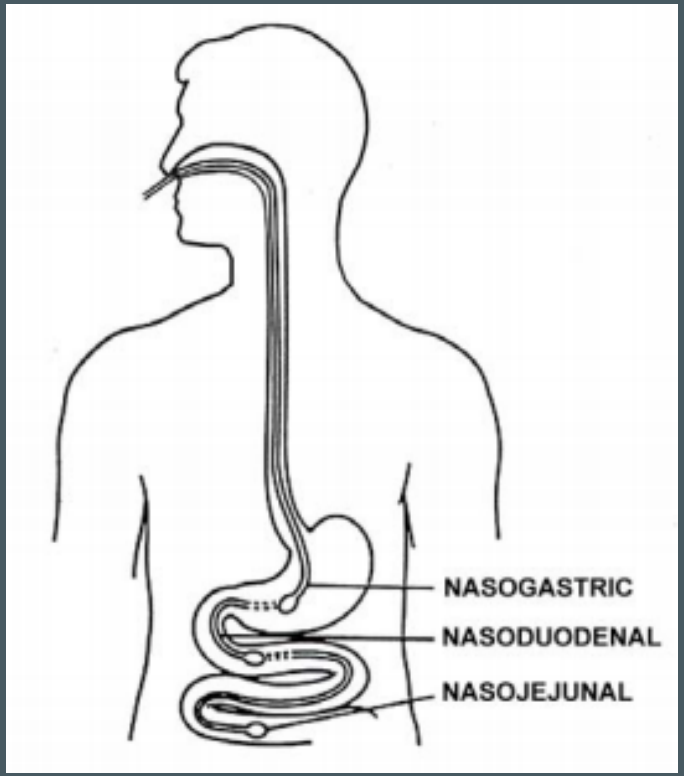
Device must provide real-time updates of tube position

# 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



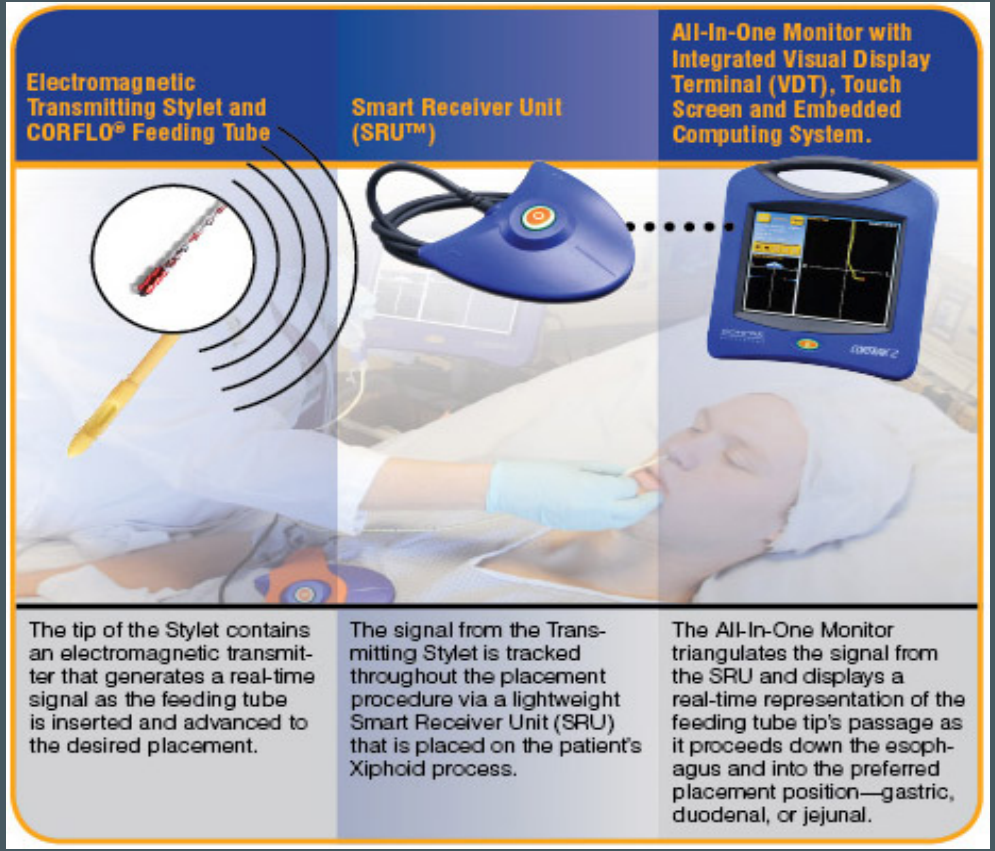
# Background

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

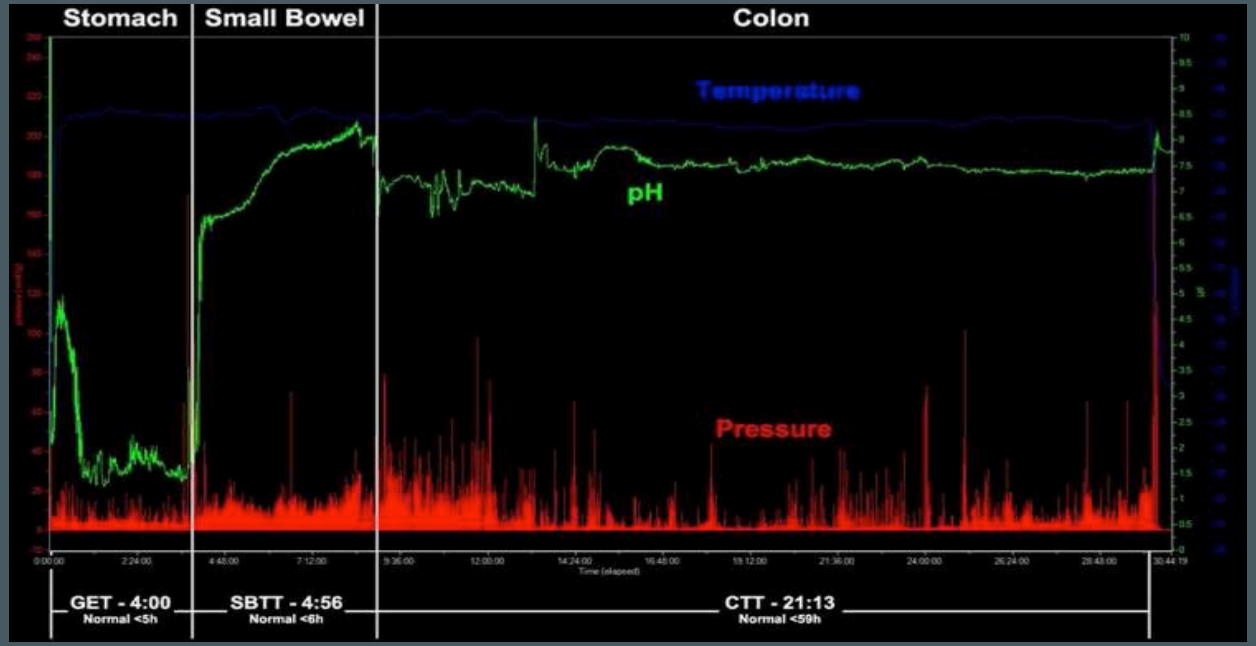
Obesity and Type II Diabetes - 9 % of American adults

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.

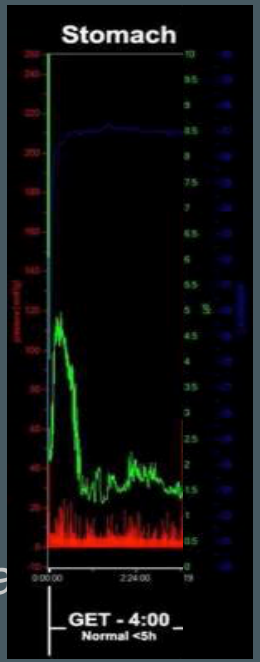
# Physiology of Gastrointestinal System--pH

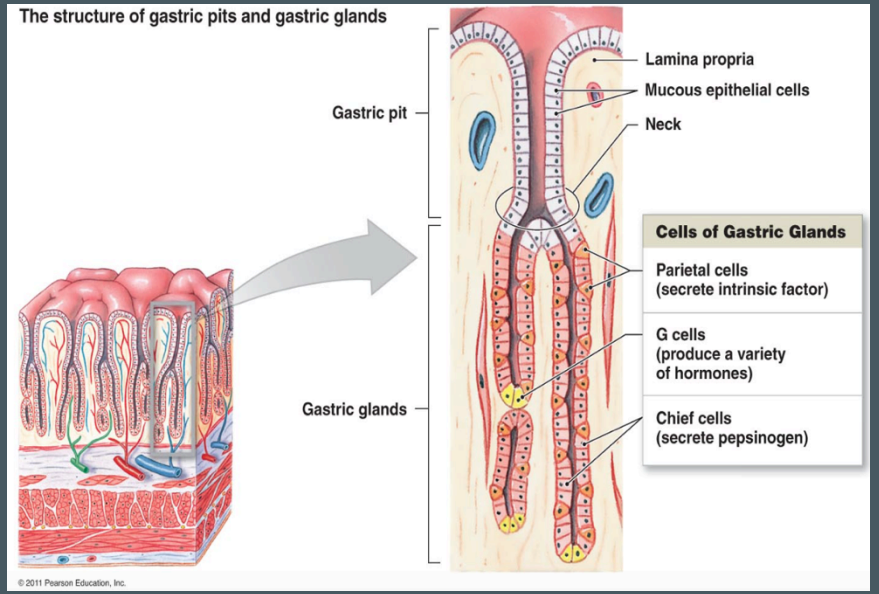
Saliva (pH range 6.5-7.5)

Stomach (pH range 1.5-2.5)

- Parietal cells secrete HCl
- G cells secrete gastrin
- Chief cells secrete pepsinogen

Purpose of low pH: immune ba
to microorganisms, activate
digestive enzymes

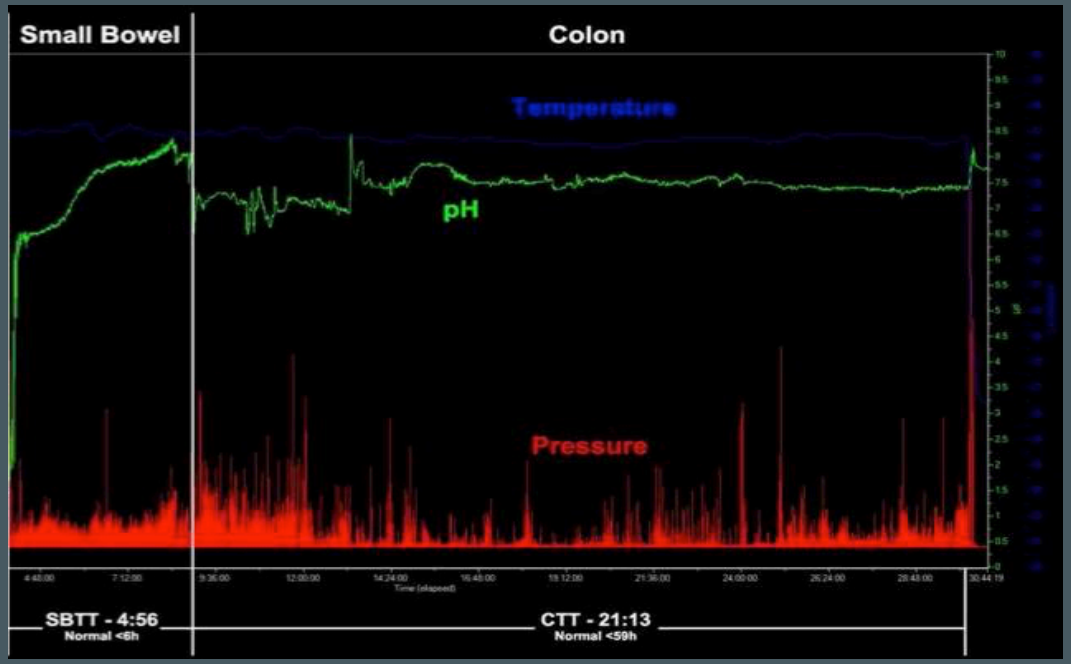


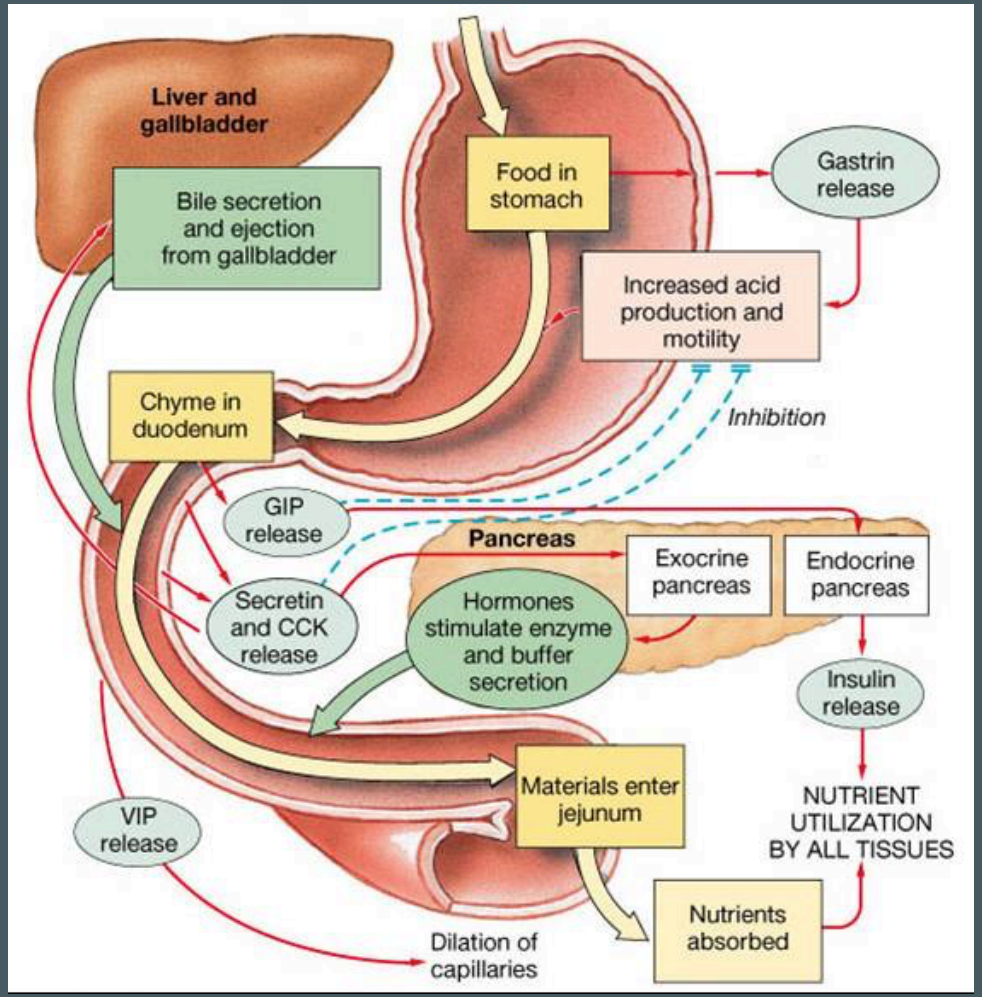



# Physiology of Gastrointestinal System--pH

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




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]):

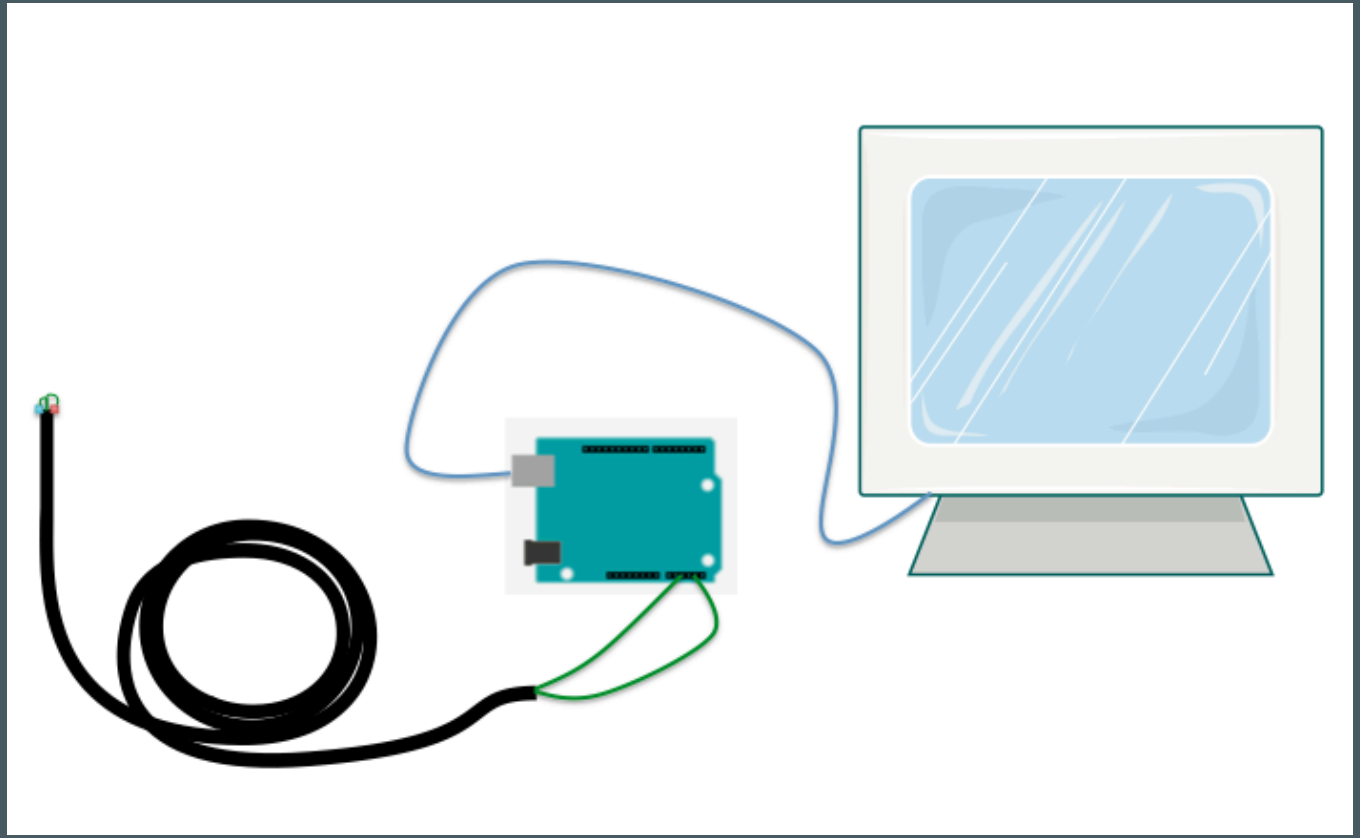
| | Area under pressure curve (mmHg/s)<br>(median, n =71) |
|---|---|
| Stomach | 4790 {3091, 6933} |
| Small intestine | 5182 {2791, 7538} |

Major limitations:

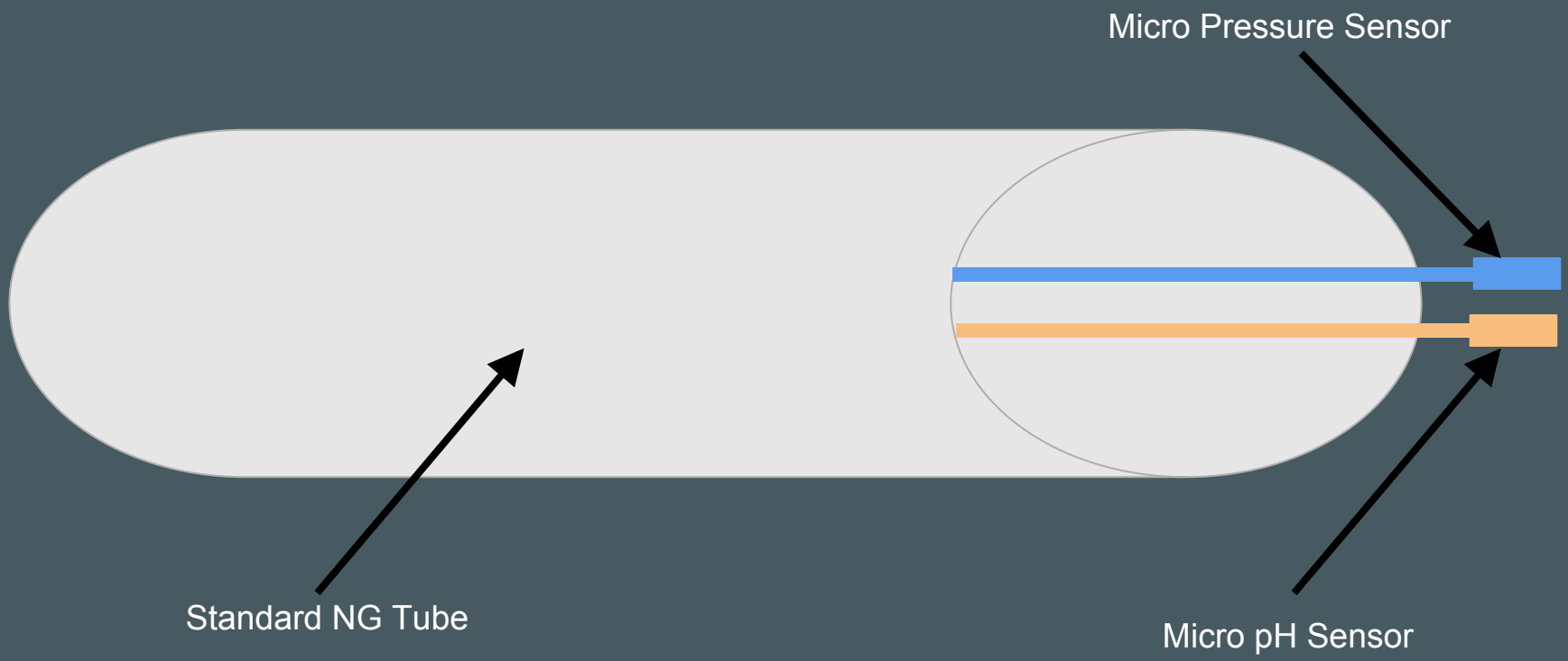
Wide range of pressure in both stomach and small intestine - difficult to differentiate

Gastroparetic patients have about 10% reduction in pressure profile, while

# Design



# Design



# pH Sensor - Option 1

pH Microsensor by PreSens Precision Sensing


| Specifications | |
|---|---|
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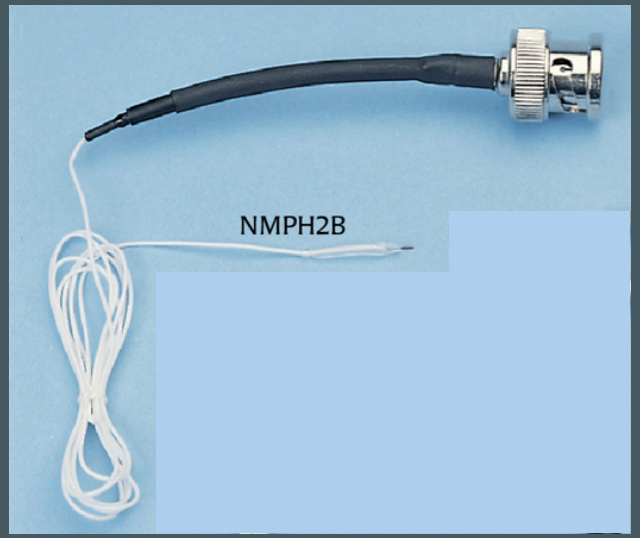
# pH Sensor - Option 2

NMPH2B Beetrode Micro pH Electrode by World Precision Instruments




| Specifications | |
|---|---|
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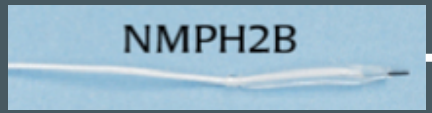
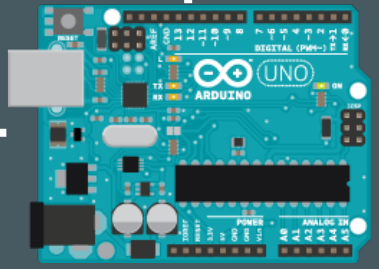
# Circuit Schematic

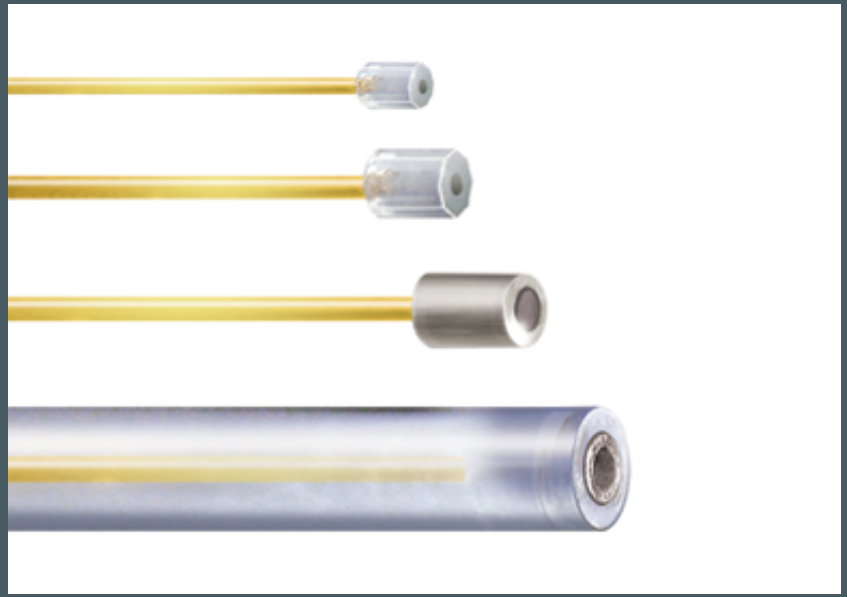




pH = ....

# Pressure Sensor

## OPP-M Pressure Sensor by OpSens Solutions



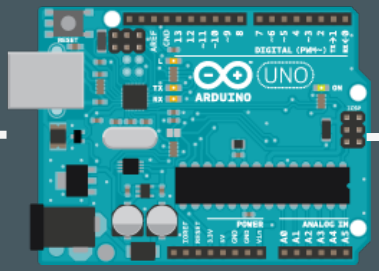
**Specifications**

| | 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

# 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.