

SmartPill



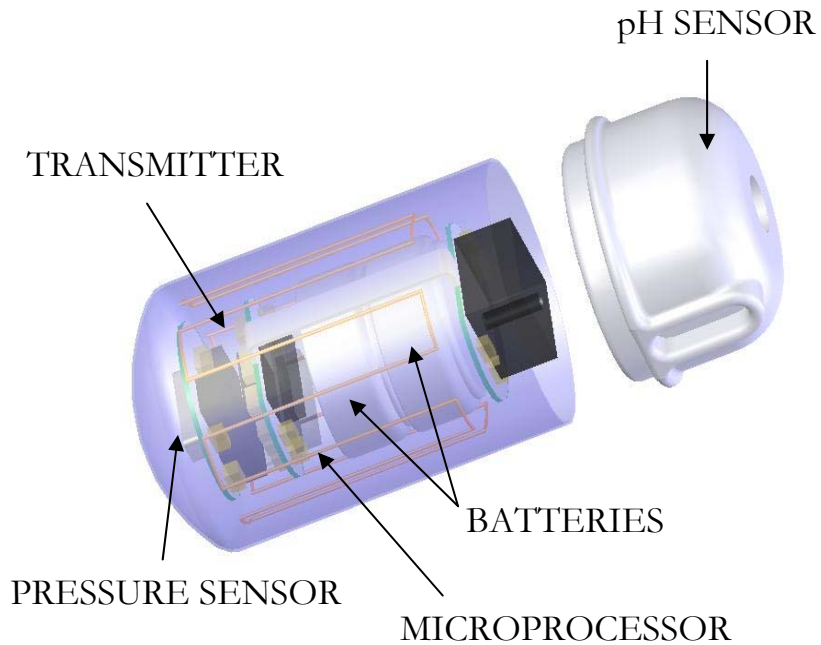
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(1088-2008)

pH.p Capsule



Sensors

- Pressure +/- 5mmHg (+/-10% >100mmHg)
- pH +/- 0.5 units
- Temp +/- 0.5 C

Profile

- Battery > 5 days
- Size 13mm x 26mm (1/2" x 1")
- Single use disposable
- Patient Contacting Materials all Biocompatible

SmartPill Data Receiver



- Worn on belt or lanyard
- 5+ day battery life
- Companion docking station provides PC interface and battery recharging
- Live monitoring capability

What does SmartPill do?

Measures

pressure

pH

temperature

Provides

segmented GI transit

gastric emptying time

combined small/large bowel transit time

*ICJ transit**

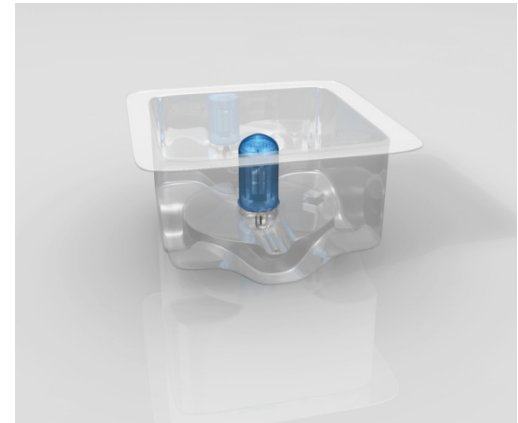
total GI transit time

manometric patterns

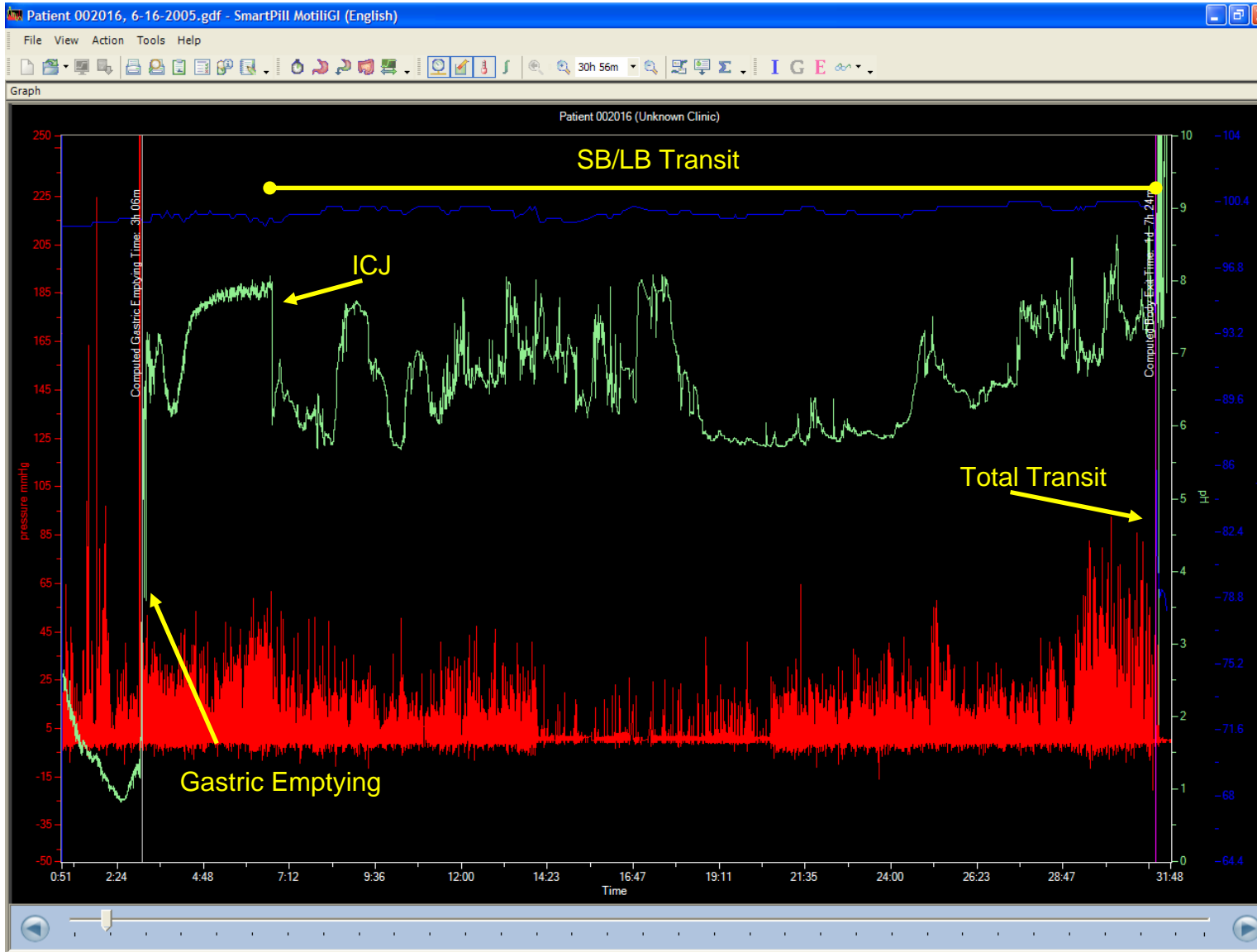
pressure contraction frequencies

pressure contraction amplitudes

- consistent with catheter based technologies



What does SmartPill do?



- pH profile
- pressure patterns
- temperature

Development of Platform

Indication for Use	Disease Addressed
Gastric Emptying Time	Gastroparesis
Whole Gut and Colonic Transit	Constipation/Diarrhea
GET for Type 2 Diabetes	Diabetes/Insulin Management
Small Bowel Bacterial Overgrowth	SBBO, IBS
Drug Efficacy	Gastroparesis, Constipation, IBS, GERD

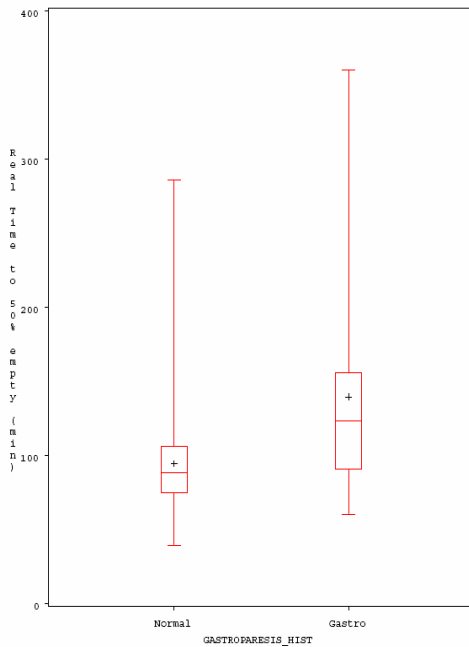
Summary Statistics

Parameter	T50 (Median)	T90 (Median)	GET (Median)
Healthy	88 min	160 min	215 min
Gastros	123 min	237 min	360 min*
Correlation to Scintigraphy	0.50	0.82	

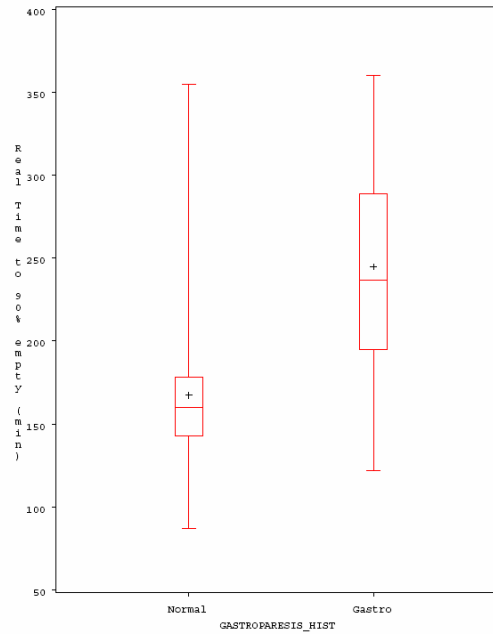
Censored at 360 min.

Healthy vs Gastro Transit

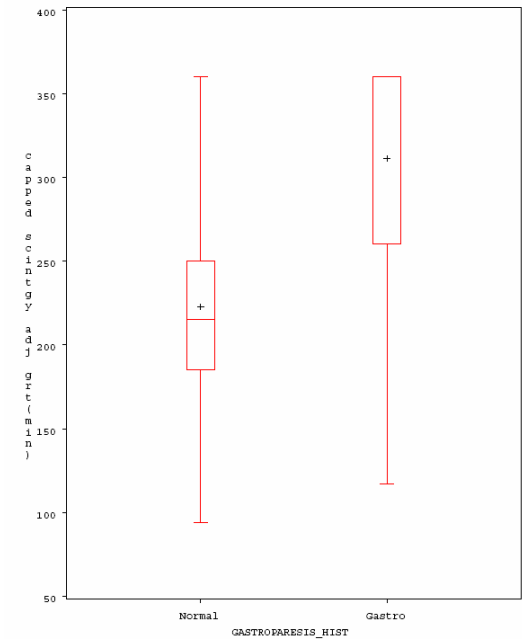
T50 Scintigraphy



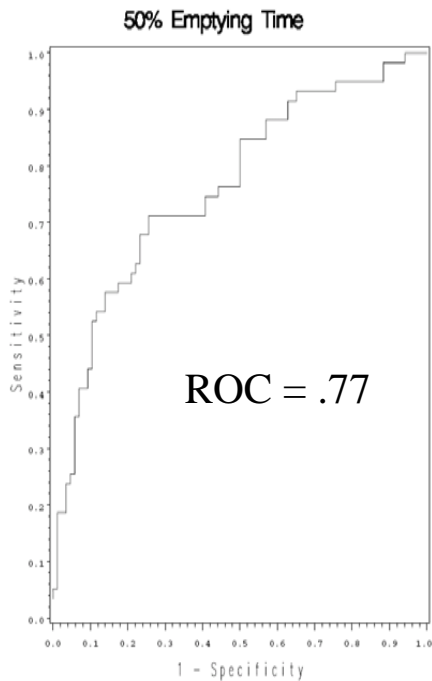
T90 Scintigraphy



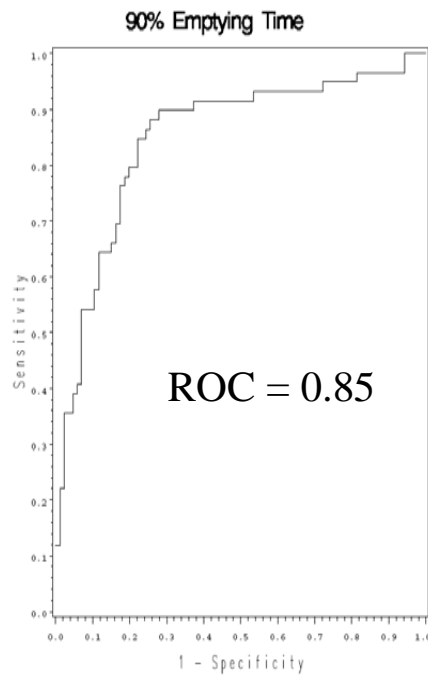
GET



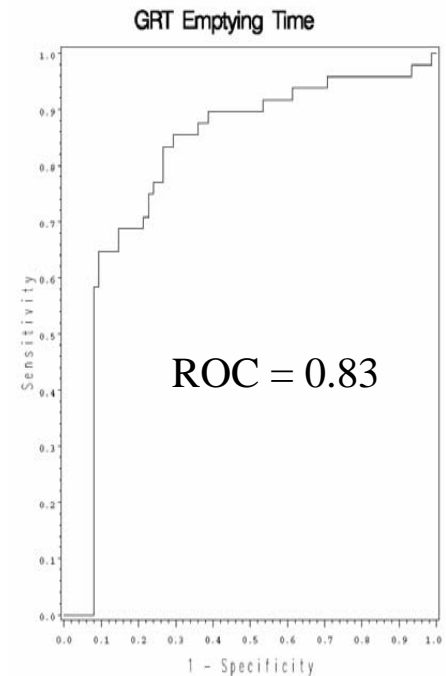
Measure of SmartPill's Diagnostic Utility (ROC Curves)



Sensitivity = 0.69
Specificity = 0.75



Sensitivity = 0.90
Specificity = 0.72



Sensitivity = 0.85
Specificity = 0.72

Whole Gut Transit in Constipation Comparison to Sitzmarks: Preliminary Trial Results

- **Multi-site Study (9 sites)**
 - 165 subjects
- **Day 0**
 - Meal
 - Sitzmarks
 - SmartPill
- **Day 2**
 - X-ray
- **Day 5**
 - X-ray
 - Conclude SmartPill Study

Whole Gut Transit Study Results

- All subjects passed SmartPill by Day 21
 - 15 subjects retained SmartPill beyond Day 5
- No serious adverse events
- SmartPill Cutoffs Established
 - Normal Colonic Transit (CTT)
 - < 44hours (Males)
 - < 59 hours (Females)
 - Normal Whole Gut Transit (WGTT)
 - < 52 hours (Males)
 - < 73 hours (Females)
- 35 subjects (4 controls, 31 constipated) had > 5 Sitzmarks retained at Day 5

Correlation of Smartpill with radiopaque markers

		SP Spearman Correlation to Day 2 and Day 5 Sitzmarks	
		Normal	Constipated
Day 2 Sitzmarks	CTT	0.70	0.61
	WGTT	0.73	0.56
Day 5 Sitzmarks	CTT	0.46	0.60
	WGTT	0.44	0.58

Number of Observations → Normal – CTT (78), ADJOBTTT (82); Constipated - CTT (68), ADJOBTTT (71)

Prob > |r| under H0: Rho=0 → <0.001