VANDERBILT UNIVERSITY

THE STORM LAB

CPS: Synergy: Integrated Modeling, Analysis, and Synthesis of Miniature Medical Devices

Pietro Valdastri, PhD

Assistant Professor of Mechanical Engineering

Director of the STORM (Science and Technologies Of Robotics in Medicine) Lab

Co-PIs: Akos Ledeczi (Vanderbilt University - ISIS), Peter Volgyesi (Vanderbilt University - ISIS), Robert J. Webster III (Vanderbilt University – MEDLab)



Duration: 12/01/2012 — 11/30/2016

INSTITUTE FOR SOFTWARE INTEGRATED SYSTEMS

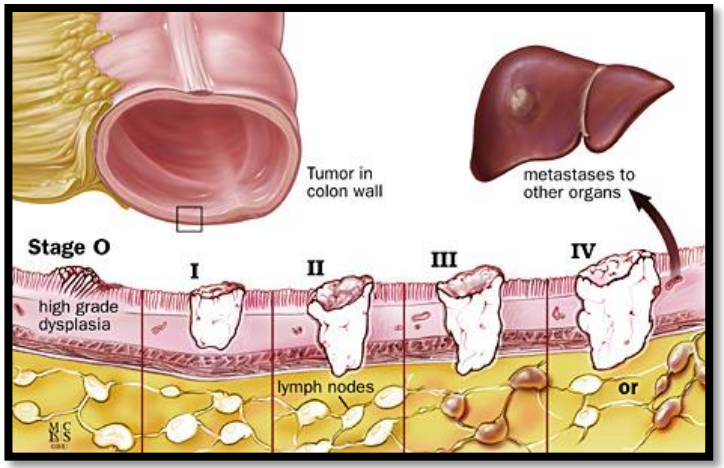
The Motivating Challenge

- Colorectal cancer (CRC) is the 2nd leading cause of cancer-related deaths in US
- If treated during its asymptomatic stage, CRC can be permanently removed in 90% of patients

FLEXIBLE ENDOSCOPY

Colorectal Cancer

1 in 3 adults are not being screened.



Colonoscopy

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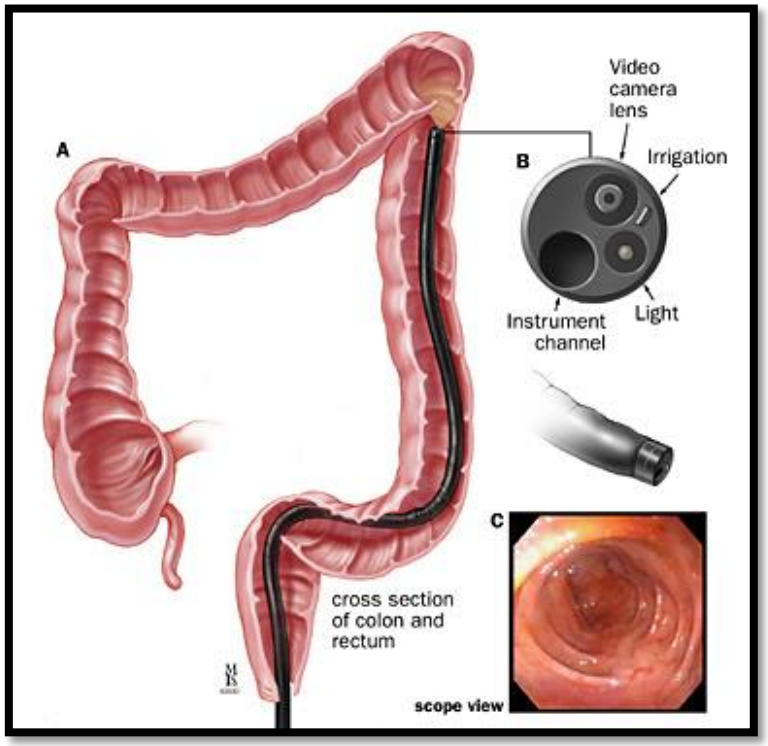

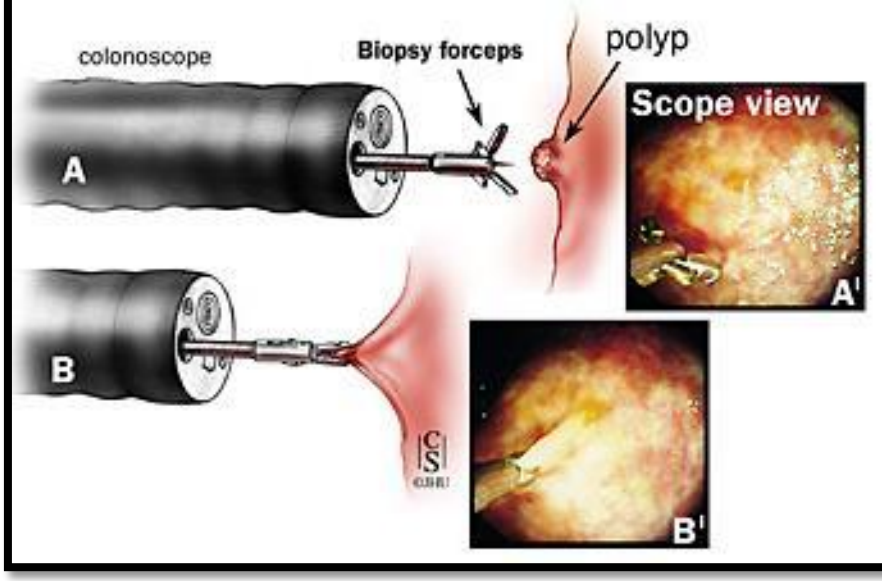

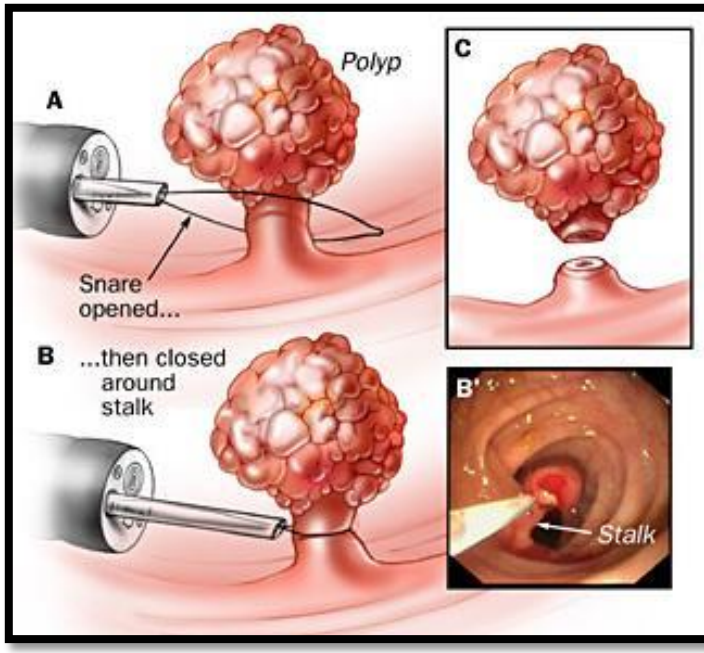

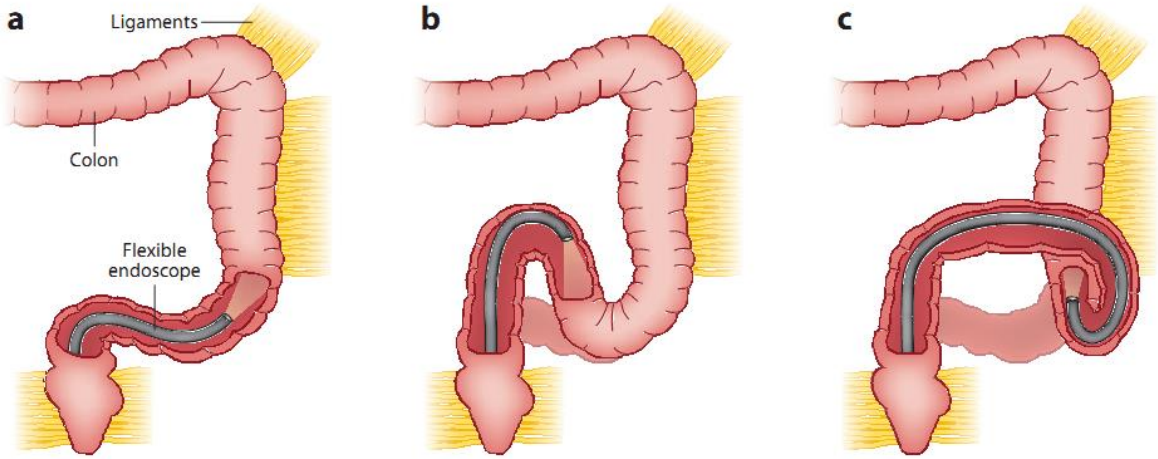

The Motivating Challenge

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FLEXIBLE ENDOSCOPY

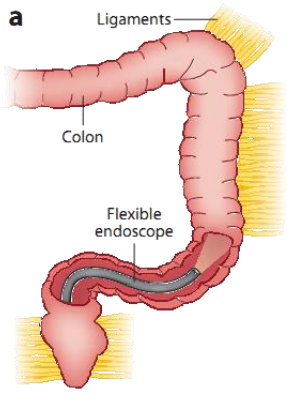
Invasiveness Reduc

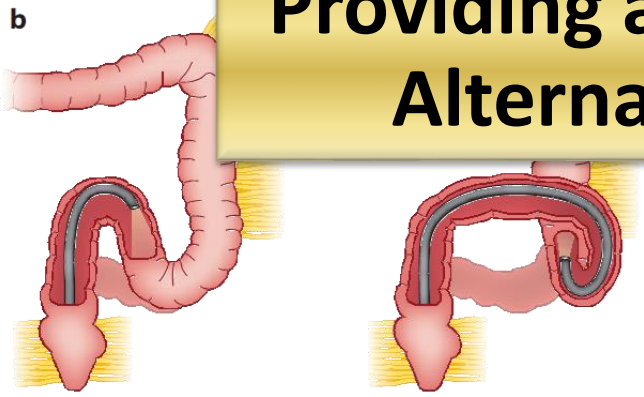
Colorectal Cancer

1 in 3 adults are not being screened.

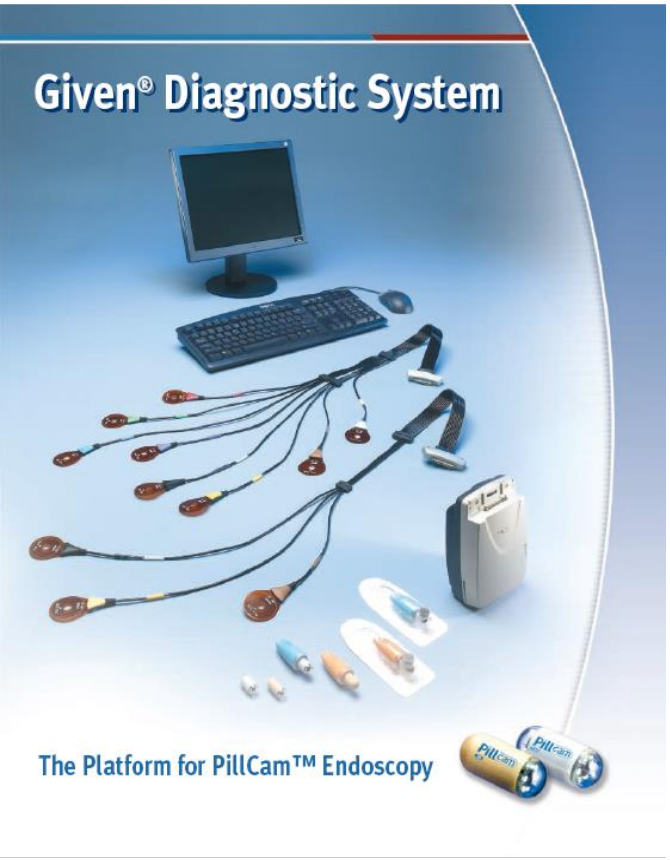
15M Colonoscopy for colorectal cancer screening alone are performed every year in the US

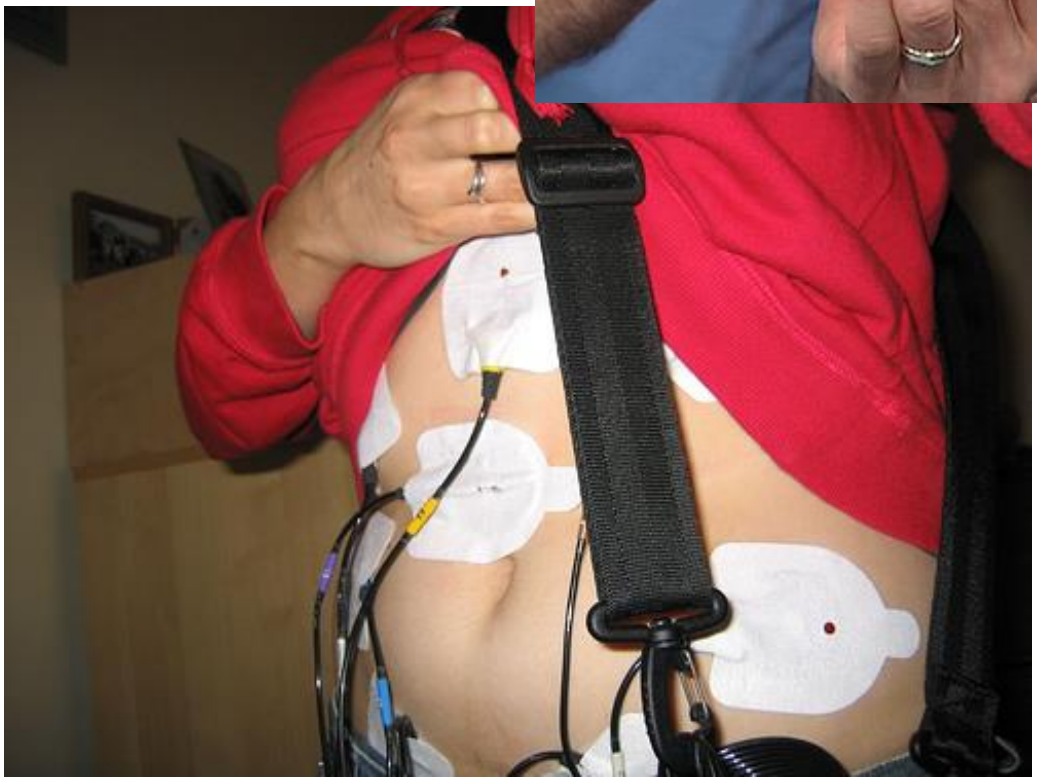
The Motivating Challenge: Providing a Painless (yet Effective) Alternative to Colonoscopy





Capsule Endoscopy – PillCam by Given Imaging (now Covidien/Medtronics)





GI-EN® IMAGING

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Wireless Capsule Colonoscopy – the PillCam COLON 2

	# pts	Adequate cleansing level	Excretion rate *	Sensitivity ** (95% CI)	Specificity** (95% CI)
Eliakim Endoscopy 2009	98	78% (95% CI, 68-86)	81%	89% (70-97%)	76% (72-78%)
Spada GIE 2011	109	85% (95% CI, 73-88)	81%	84% (74-95%)	64% (52-76%)

*within 8 hours post ingestion
** for polyps ≥ 6 mm

NOT EFFECTIVE FOR COLONOSCOPY!

Main Limitations:

- Passive Locomotion
- Collapsed Tissue
- No tools available

The Motivating Challenge

- Colorectal cancer (CRC) is the II leading cause of cancer-related deaths in US
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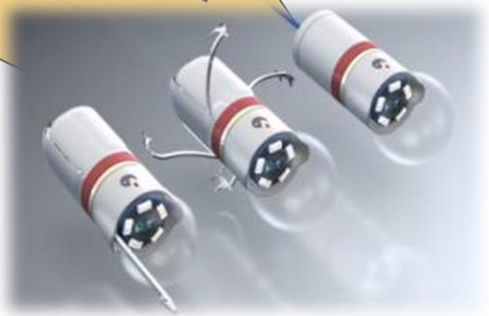
FLEXIBLE ENDOSCOPY

Invasiveness R

CAPSULE ENDOSCOPY

GI Endoscopy

ROBOTIC CAPSULE ENDOSCOPY



The Motivating Challenge: Providing a Painless (yet Effective) Alternative to Colonoscopy

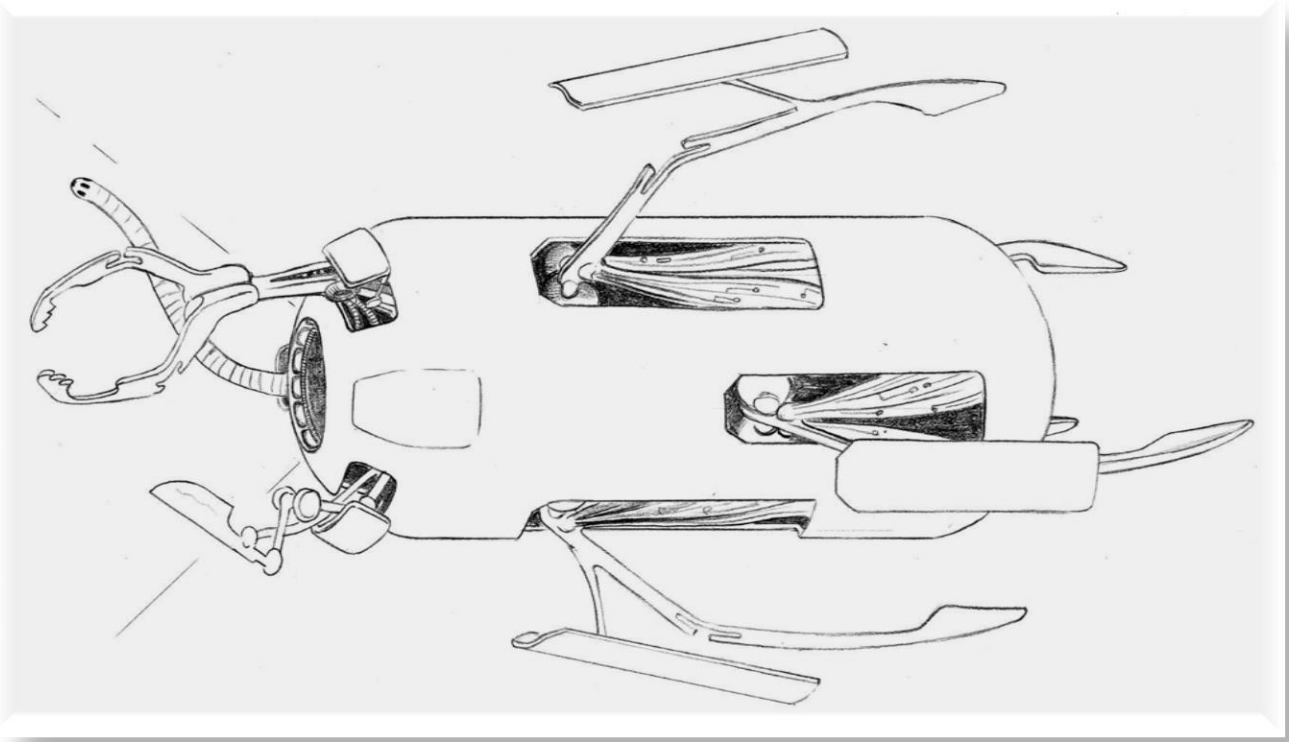
Robotic Capsule Endoscopy

Control Electronics

Radio communication

Power

Active locomotion



Medical sensors

Actuators for tissue interaction

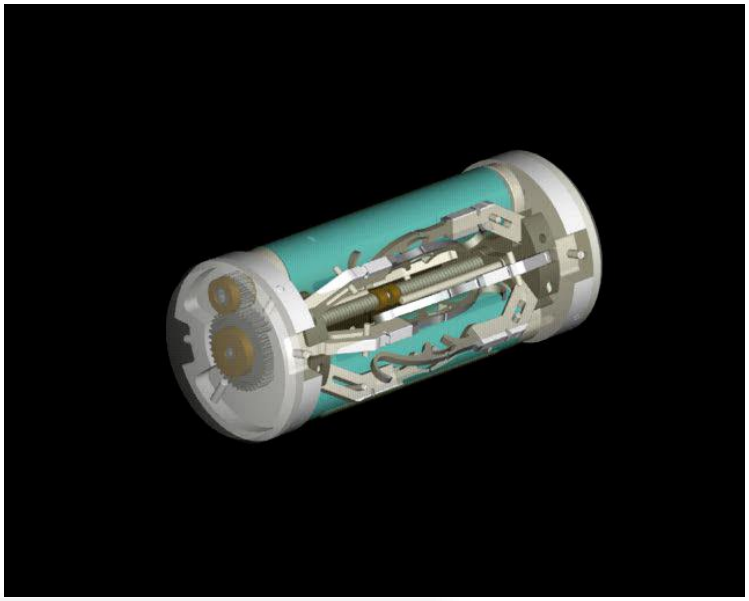
Self diagnostic sensors

Actuators for vision enhancement

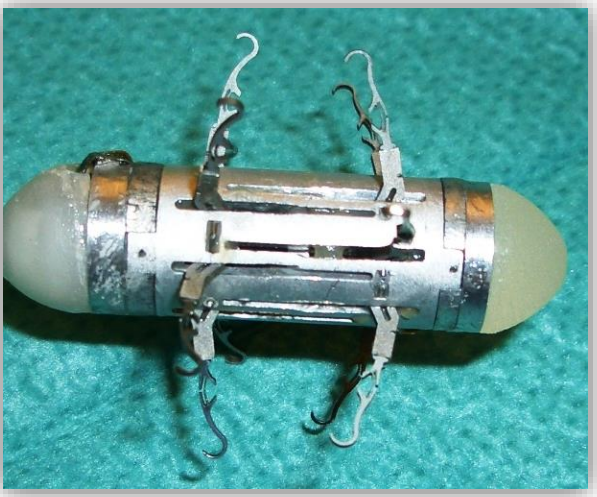
Vision sensor

Everything MUST fit in a capsule volume
(d 11 mm x l 26 mm – for oral intake)
(d 30 mm x l 30 mm – for retrograde access)

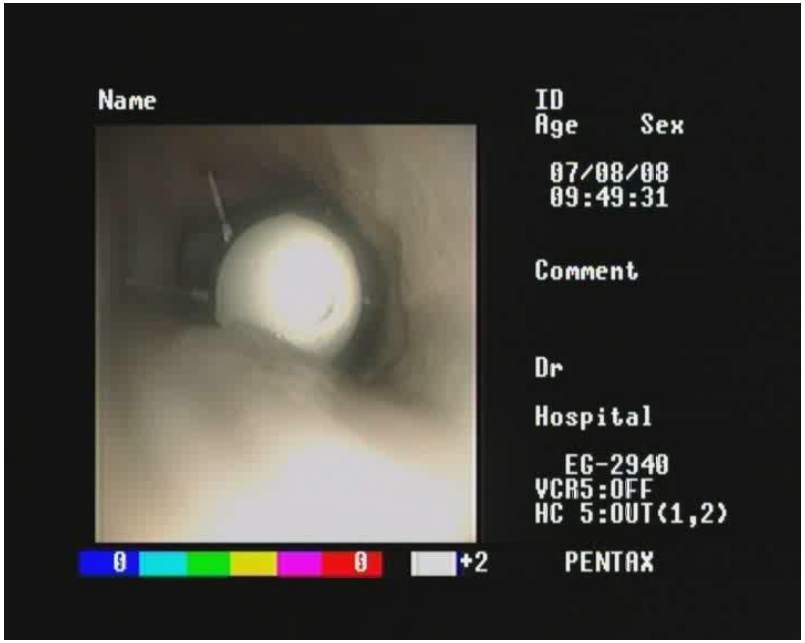
Medical Capsule Robots



Average speed 5 cm/minute
Pulling force 3.8 N→0.66 N per leg



12-leg capsule, Valdastri et al., 2009



P. Valdastri, et al., ARBE, 2012

Medical Capsule Robots

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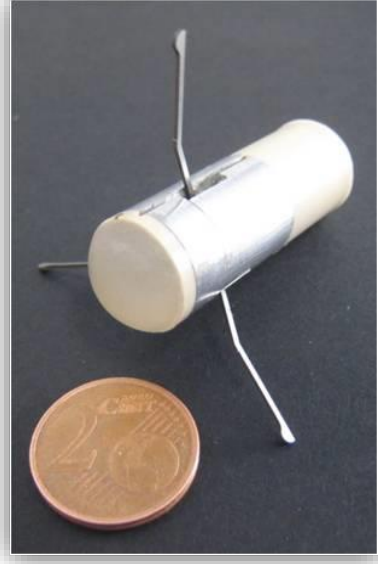
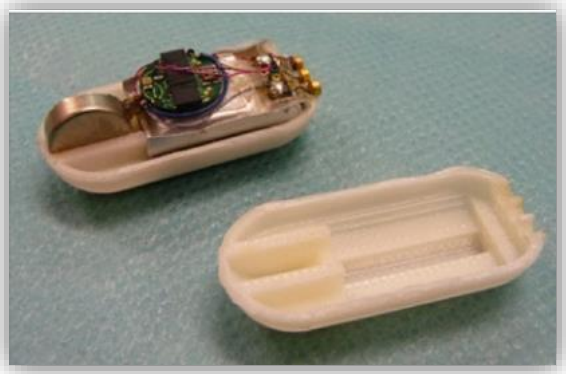
Jellyfish capsule, Valdastri et al., 2011

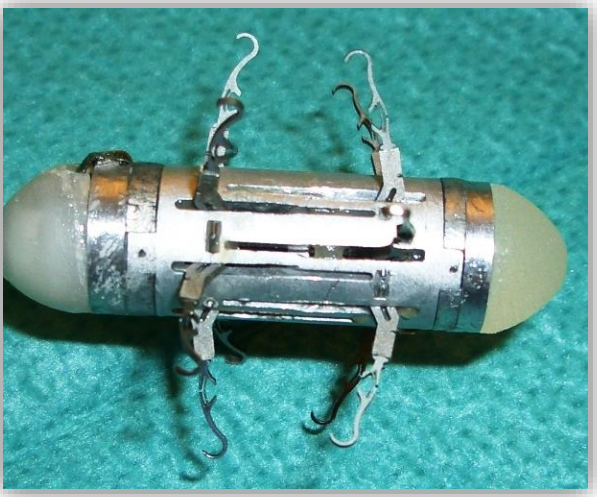
Clip releasing capsule, Valdastri et al., 2008

Hybrid capsule, Simi et al., 2010



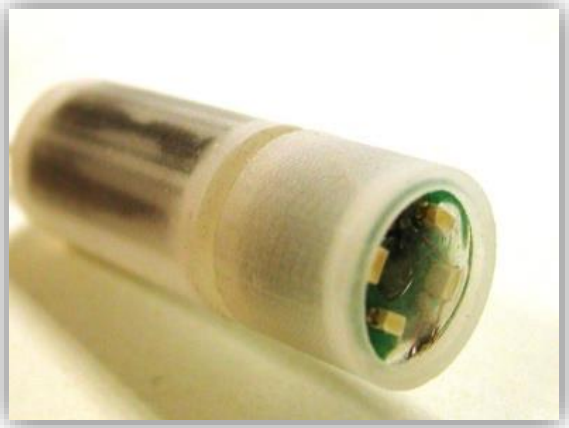
Vibration capsule, Ciuti et al., 2012





12-leg capsule, Valdastri et al., 2009

Magnetic capsule, Ciuti et al., 2010



Biopsy capsule, Simi et al., 2013

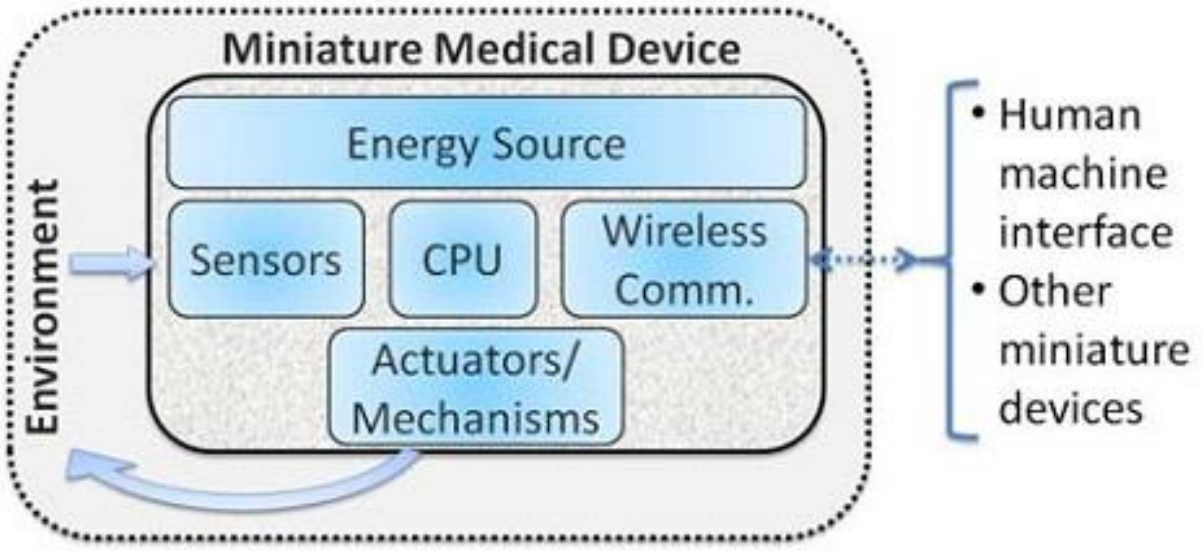
P. Valdastri, et al., ARBE, 2012

A CPS Approach to Systematize Capsule Robot Design

A systematic approach to design of pill-size medical devices is possible by outlining the **crosscutting constraints** for capsule robots:

- ***Size***
- ***Power consumption***
- ***Fail-safe operation***
- ***Wireless communication***
- ***Effective interaction with the surrounding environment***

Given these constraints, it is possible to identify a **general system architecture** for a pill-size medical design



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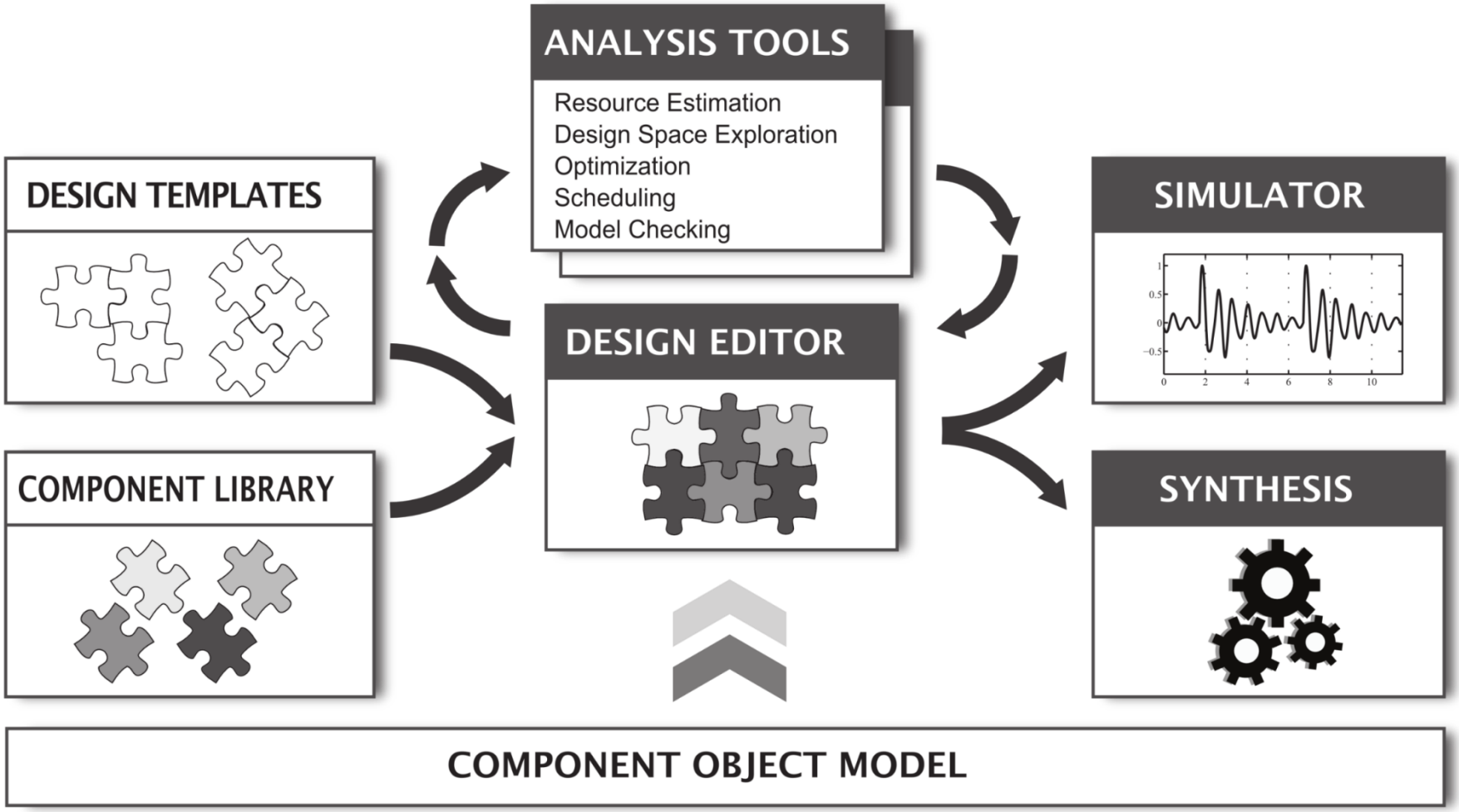
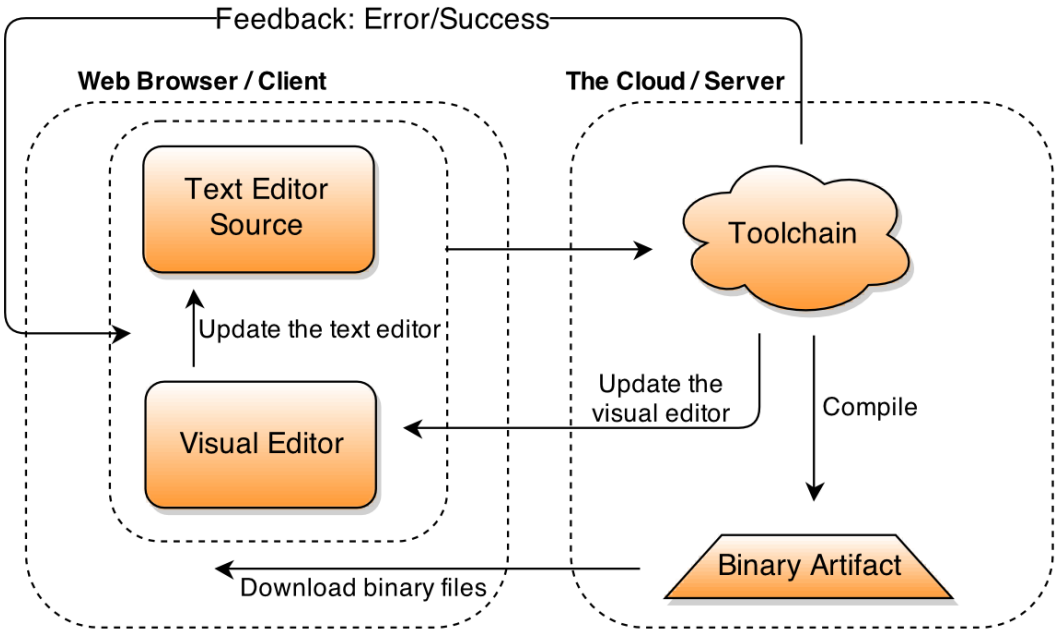
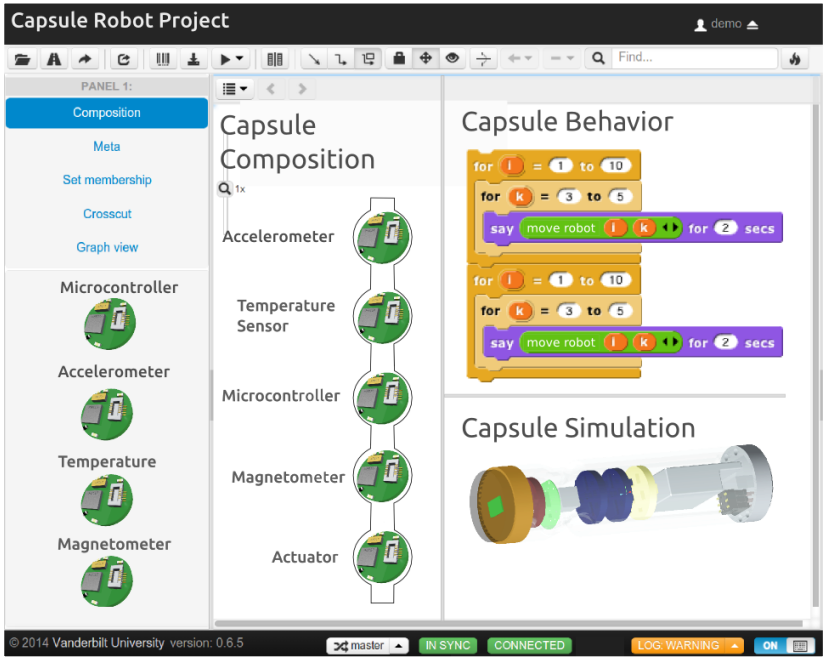


The goal is to **synthesize** application software, computer aided design (CAD) models, and bill of materials with cost estimates with minimal manual guidance

Design Environment Architecture



Visual Editor



- TinyOS has been selected as operating system to enable component based programming

- A web-based design environment for TinyOS based on WebGME (http://webgme.org/) is currently under development

Component Library

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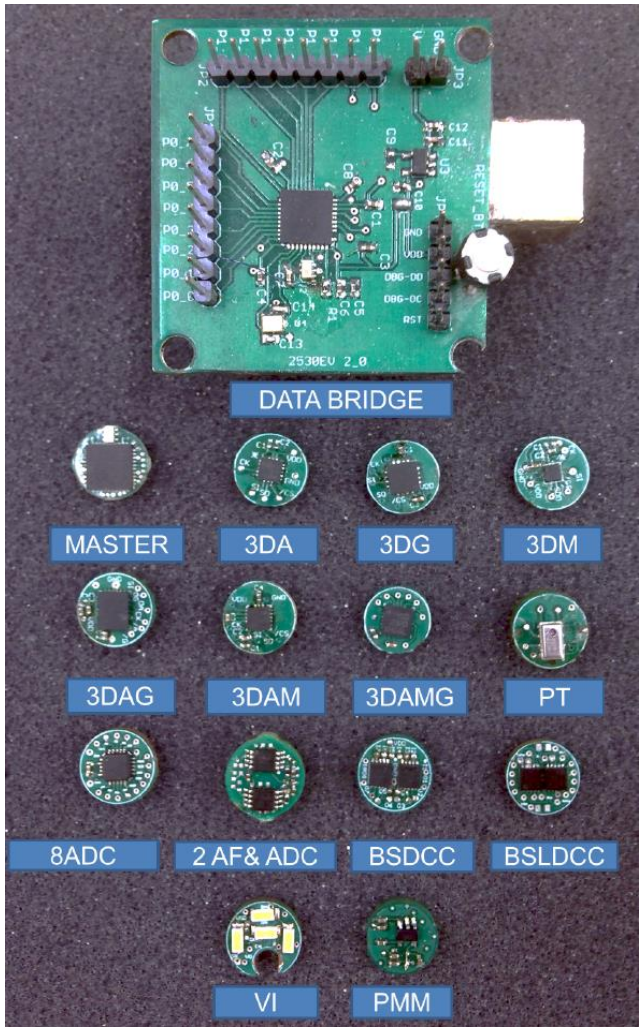
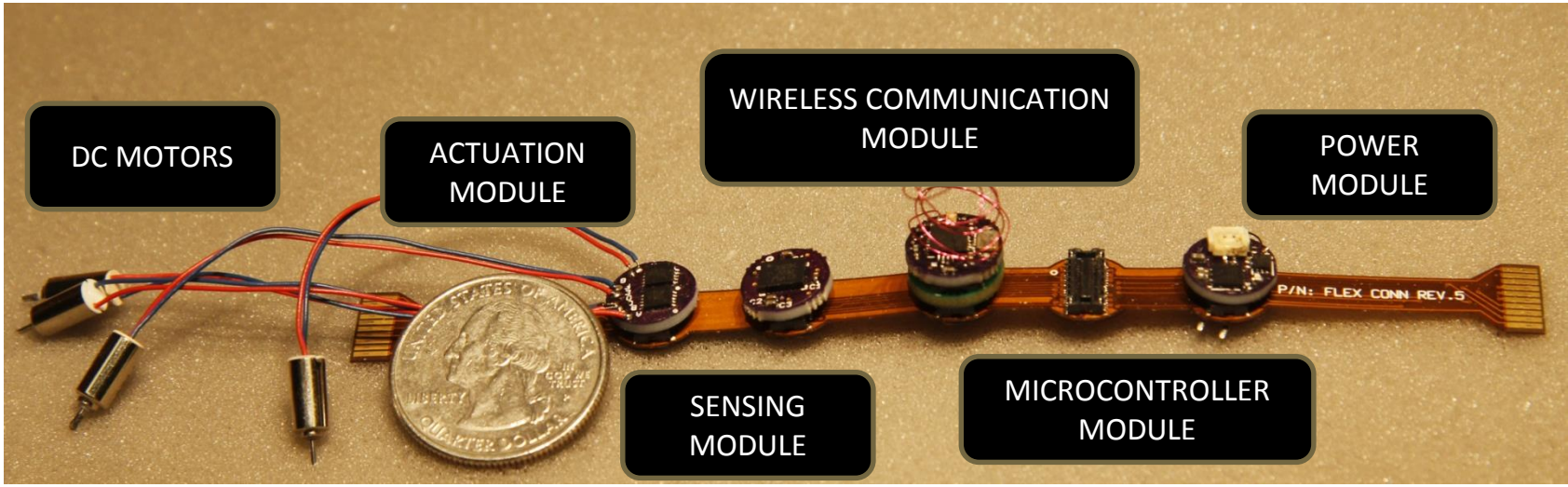


Diameter 9.8 mm

Thickness 3.84 mm

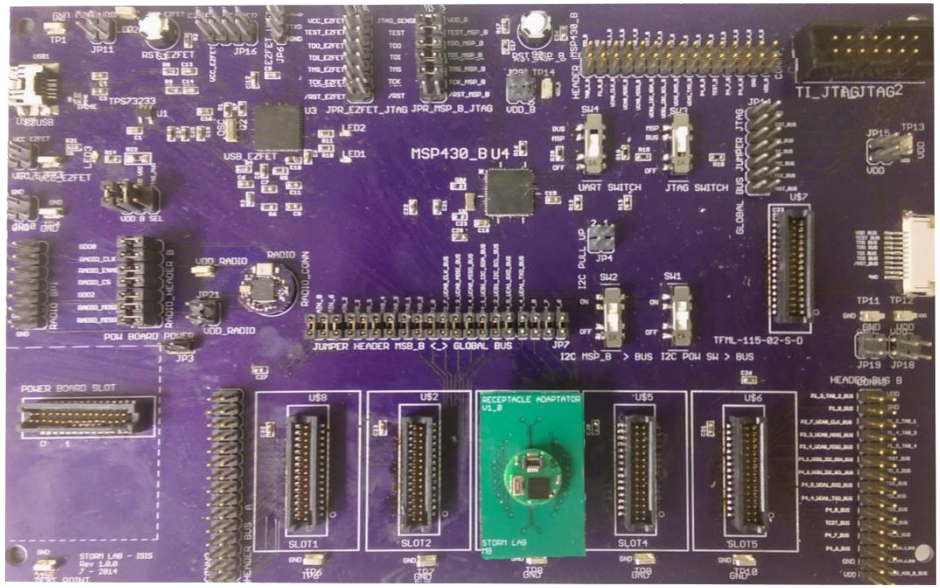
MODULE NAME	FUNCTIONALITY
Wireless CPU	CPU and 2.4 GHz Wireless
Microcontroller	CPU
433 MHz Radio	Wireless Communication
3DA	3D Accelerometer
3DG	3D Gyroscope
3DM	3D Magnetometer
3DAG	3D Accel. – Gyro
3DAM	3D Accel – Magn.
3DAMG	3D Accel. - Gyro.– Mag.
PT	Pression & Temperature
2AF&ADC	2 Ch. Front End ADC
8CHADC	8 Ch. ADC
VI	Vision - Illumination
BSLDCC	Brushless Motor
BSDCC	Brushed Motor
PMM1	Power – Battery Monitor
PMM2	Power- Battery Monitor - Charger

Component Library – Debug and Connectivity



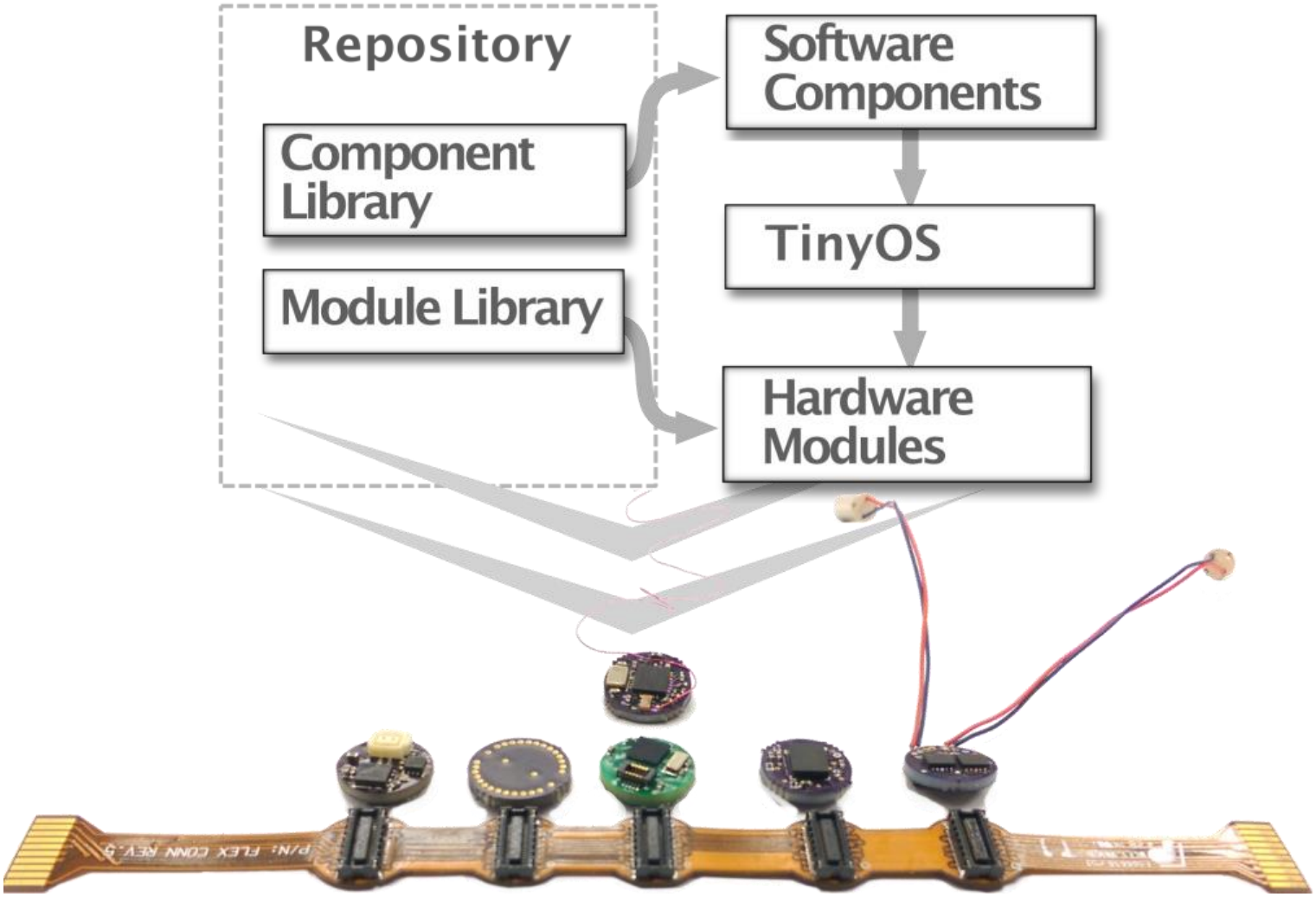
Flexible circuit backbone with plug-n-play connectors

The flexible circuit is designed to fit into a pill once properly folded

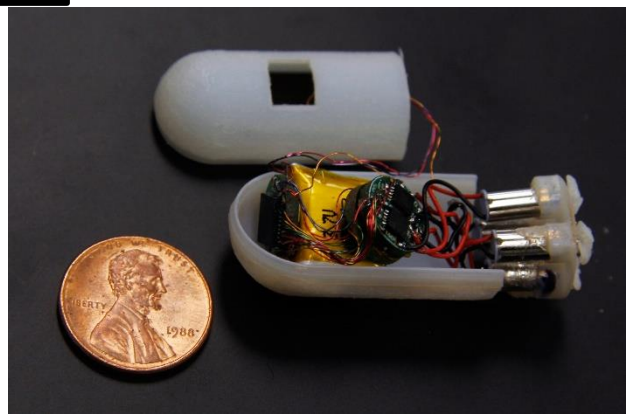


Development board for emulation, programming and debug

Design Environment Architecture

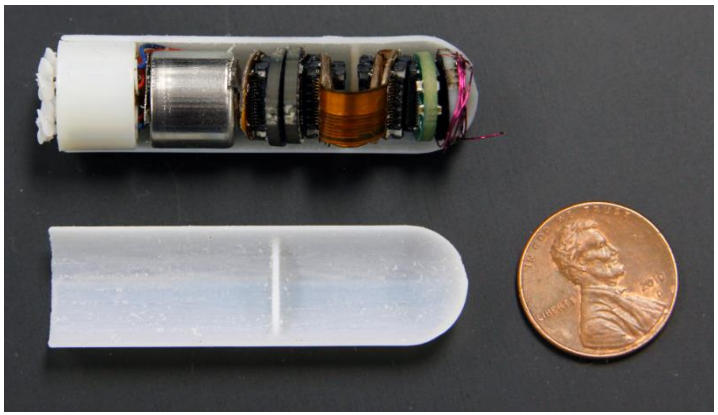


Preliminary Results – Submarine Capsule

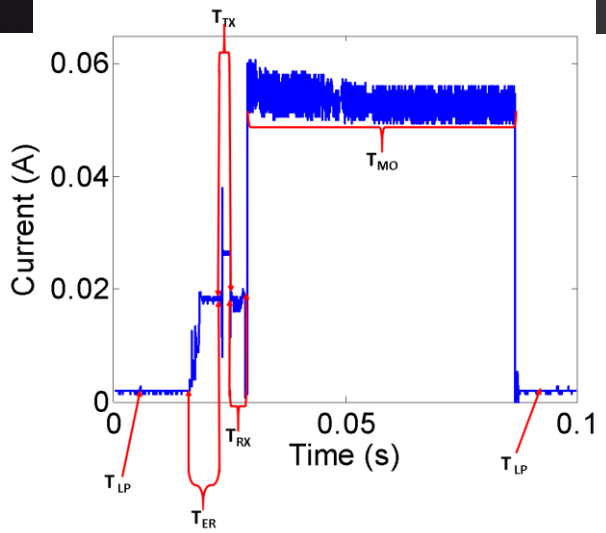


Easier to assembly

Time to prototype reduced



TinyOS is adequate to guarantee real time robotic operation



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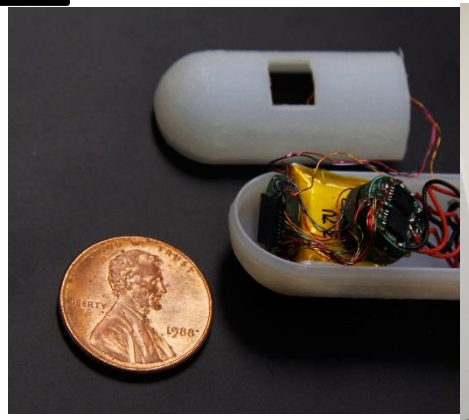

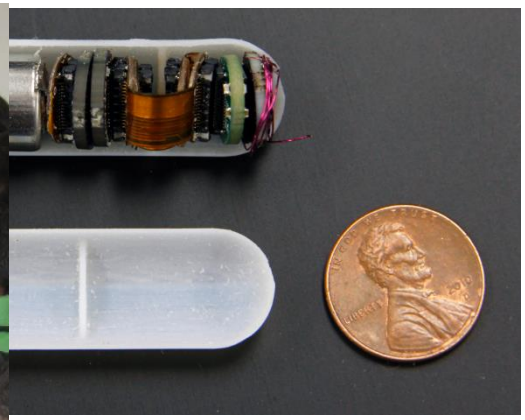

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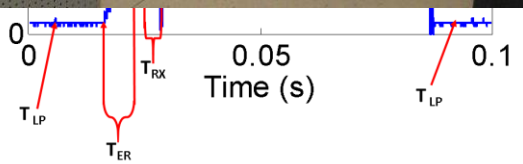
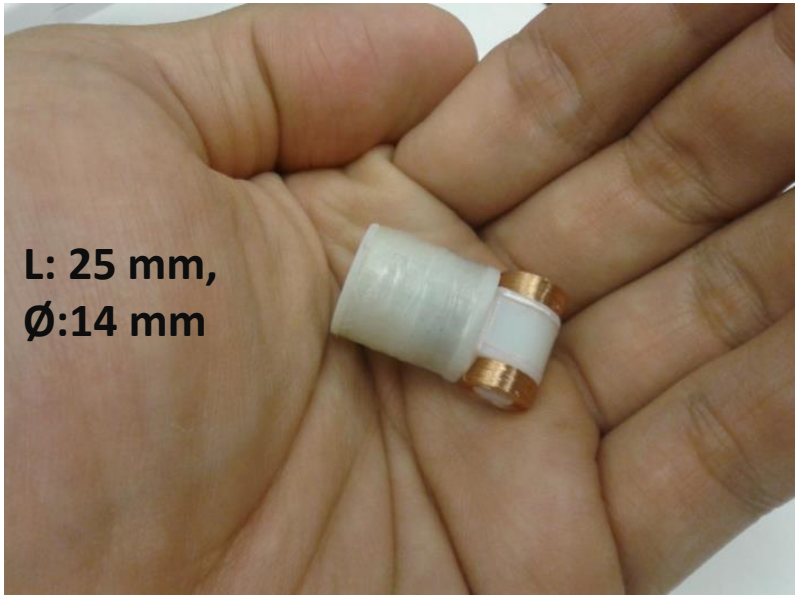
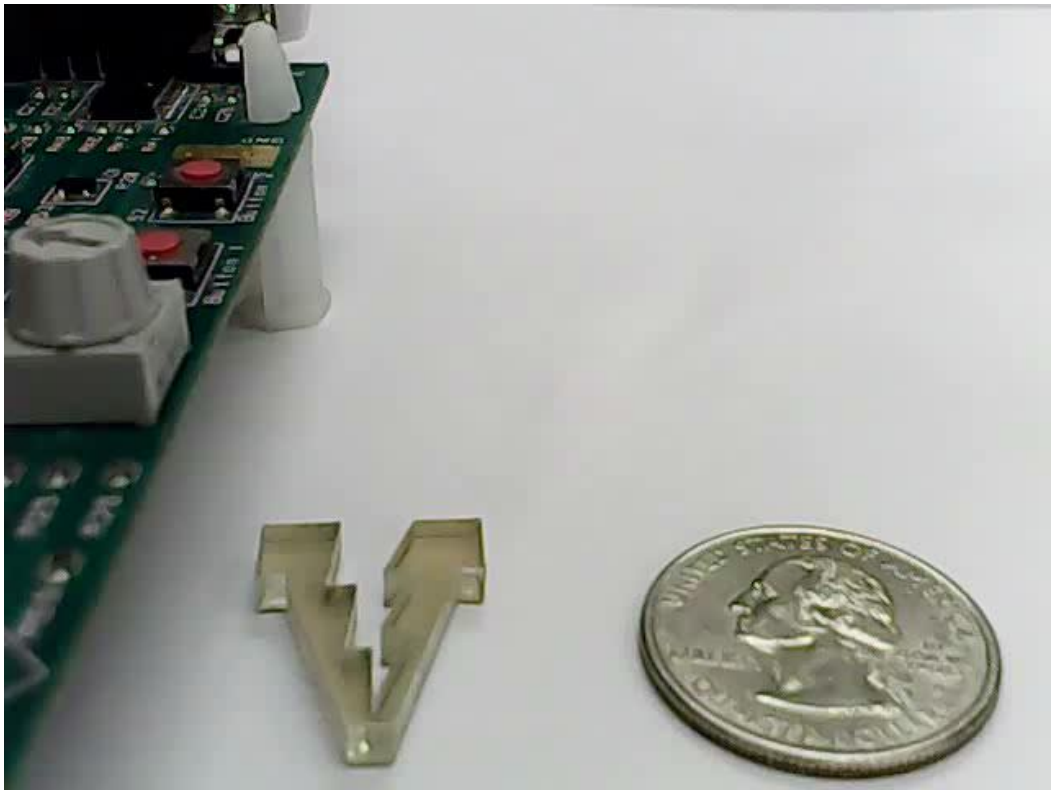


VECTOR
ENDOSCOPIC CAPSULE

Preliminary Results – Localized Drug Delivery Capsule



- Wireless uC
- Coil driver
- Magnet
- Battery



Developed in about 2 months by an undergraduate student (Vanessa Valentine) supported by REU supplement

Looking Forward…

- Further development of the user interface
- Implementation of the simulator module
- Expand component library
- Involve regulatory bodies (FDA)
- Explore the potential as a STEM education tool via an NSF ICorps grant (January-June 2015)
- Promote our open source design environment (both SW and HW modules) in the medical robotics and medical CPS communities

In Summary…..

- We are developing a design environment to accelerate the design of miniature medical devices in general, and medical capsule robots in particular.
- This will lower the barriers for researchers to design and implement new medical capsule robots, with the final goal of replacing colonoscopy with a painless alternative **ASAP!!!**
- We have developed 20 different hardware modules, a flexible backbone for easy connectivity, and a development board
- We have demonstrated that TinyOS can be used effectively to program medical capsule robots
- Our architecture is applicable to miniature wireless devices in general
- More info available at **poster 24F @ 12:25 today**
- Our work is open source available at:
  - http://github.com/SMACproject
  - http://github.com/pillforge

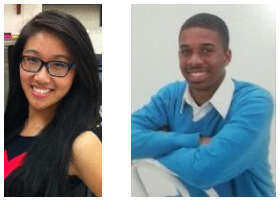
ACKNOWLEDGMENTS

- **NSF** – Grant No. CNS-1239355 - CPS: Synergy: Integrated Modeling, Analysis and Synthesis of Miniature Medical Devices

- My Lab members

- The Undergraduate Students involved

- The High School Students involved



- My Co-PIs at Vanderbilt
  - Akos Ledeczi (Vanderbilt University - ISIS)
  - Peter Volgyesi (Vanderbilt University - ISIS)
  - Robert J. Webster III (Vanderbilt University – MEDLab)

Thanks for your attention

POSTER 24F

WEB: my.vanderbilt.edu/stormlab/
http://github.com/SMACproject
http://github.com/pillforge