University of Pittsburgh
Senior Design – BioE 1160-1161

Central Venous Cannulation: Venous Entry Device

Jenn Adams

Janet Chan

Evan Hill

Matt Wolf

Central Venous Cannulation: Venous Entry Device

- Overview / Background
- Market
- Connector Design and Production
- Handle Design and Production
- Pressure Sensor Design
- Simulator Design
- Validation and Verification

Central Venous Cannulation

- Definition: Insertion of a catheter into a vein leading directly to the heart (Internal jugular most common)
- Purpose:
  - Administer IV fluids when no peripheral veins are accessible
  - Administer drugs that cannot be given peripherally (Vasodilation/constriction drugs)
  - Measurement of central venous pressure

Problems

Steps 1 - 3:

1. Needle inserted into IJ
    - Bulky syringe: physician discomfort, mistakes lead to multiple insertions, lead to infection
2. Tubing connected to check venous entry
    - Blood exposed when removing syringe from needle: infection
    - Significant free space needed to lower and raise tubing
    - Blood exposed during lowering and raising: infection
3. Guide wire inserted into vein through needle
    - Needle short and light, difficult to keep steady while inserting guide wire: complex

Market

By the numbers:

- 5 million CVC procedures per year
- 2.013 incidents of infection every 1000 patients (year 2000)
- = 10,000 procedures complicated by infection.
- CVC complications costs: $6,000 to $90,000 per patient[1]
- Estimating $10,000 per complication, yearly expenses: $100 million

Vast majority of infections occur during steps 1 – 3…

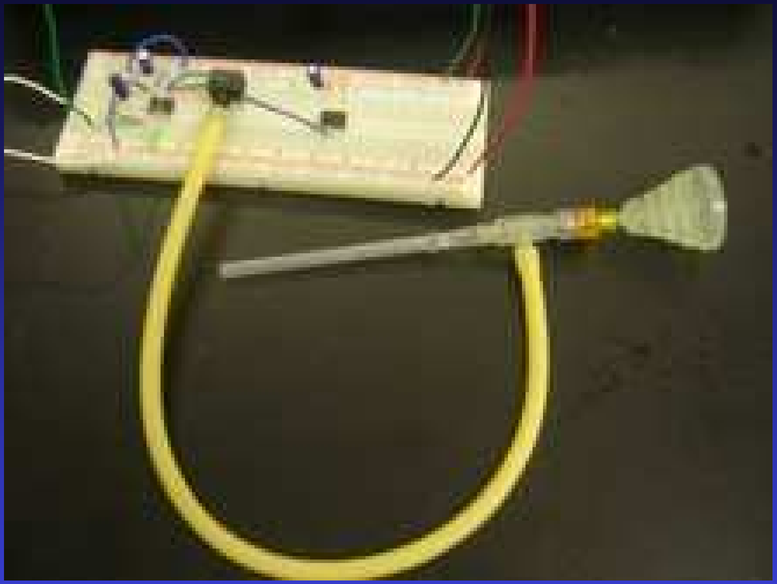
Solution: Combine these 3 steps!

1. Moretti E.W. et al. "Impact of central venous catheter type and methods on catheter-related colonization and bacteremia." *Journal of Hospital Infection*. 2005. 61:139-145.

Device Design

- The design must address the issues which cause complications with the current CVC method
- New design consists of three parts:
  - A three way connector with a one way valve
  - A handle
  - A pressure sensor

Intended Final Device Design



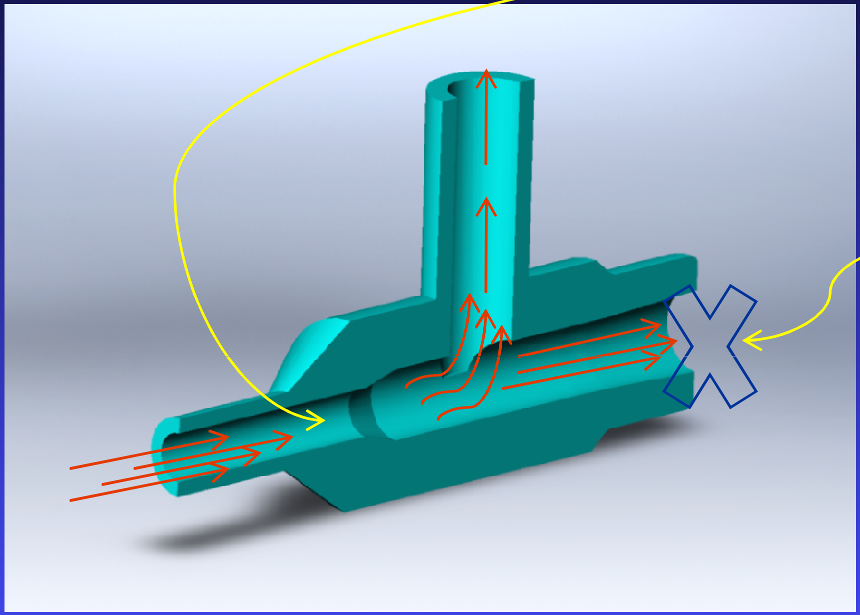
Current device with circuit pressure sensor

Intended device with miniaturized pressure sensor

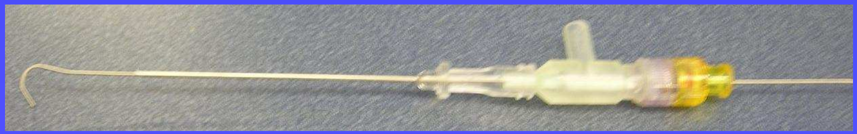
Three Way Connector

- Provides ports for needle, sensor, and handle
- Handle and needle are in line with each other
- Pressure sensor is perpendicular
- Clear plastic casing for visualizing blood flow
  - Currently SLA

Three Way Connector



- The internal cavity allows blood flow from the vessel
- A duckbill checkvalve fits into the back port
  - Guide wire can be inserted through valve



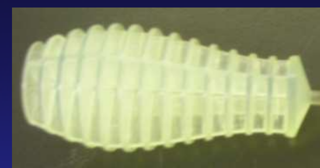
Support Handle

- Provides a counter weight to rest on the clinician's hand
  - Does not require awkward hand positions
  - Allows the clinician more mobility
  - Increased comfort should lead to reduced error in placement

Handle Prototypes

Initial clinician feedback indicated a screw driver-like handle to be held as a pencil would provide comfort and stability

1



Clinician feedback: Too fat

2

Clinician feedback: Too long

Less moment arm, more control

3

Clinician feedback: Too light

4

Just right

Device Prototype Production

- Current prototype was fabricated at the Swanson Center by stereo lithography
- Suggested final three-way connector material: polyethylene
  - Cheap
  - Easy to grip firmly with latex gloves
  - Transparent for visualizing blood flow
  - Easily sterilized
- Suggested final support material: rubber coated high density polyethylene

Pressure Sensor

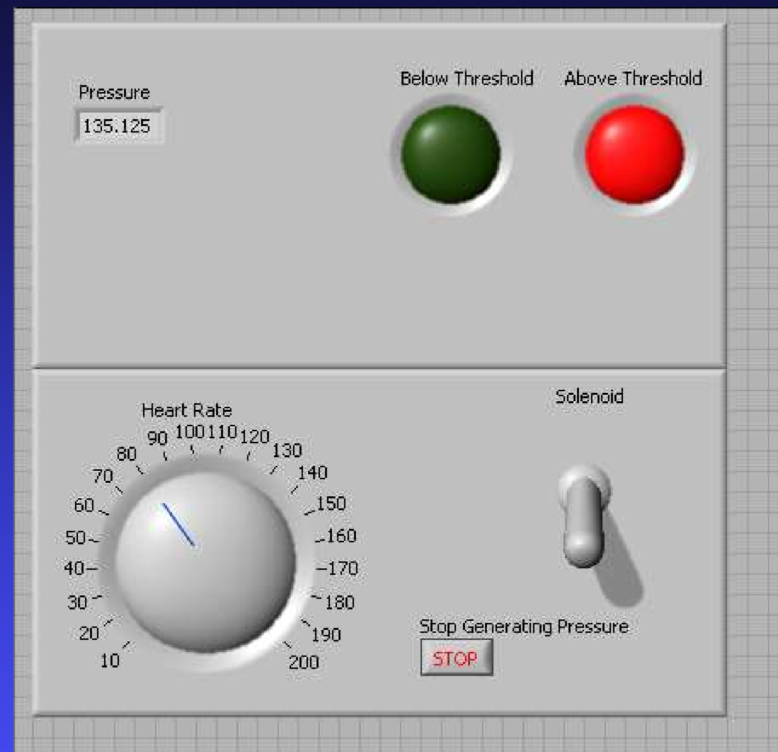
- Key aspect of device design
  - Eliminates syringe
  - Eliminates additional pressure checking step
  - Provides continuous pressure readings to clinician

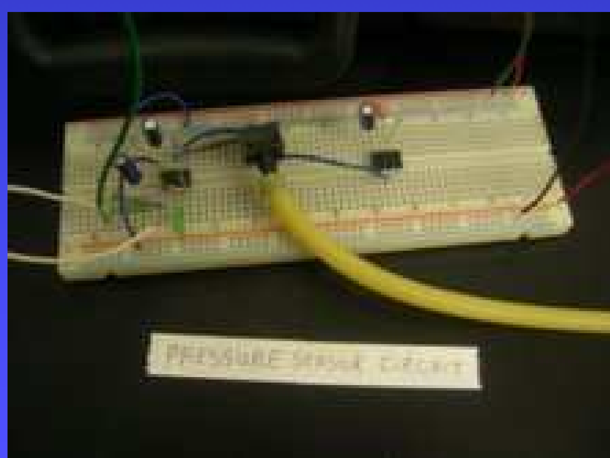
Pressure Sensor

- Currently the PX05 Pressure Sensor from Omega
  - Tubing from the pressure sensor port allows blood to flow to the sensor
  - Transducer has a voltage output that can be read through LabVIEW
  - LabVIEW converts the voltage to pressure and then provides an output to the display

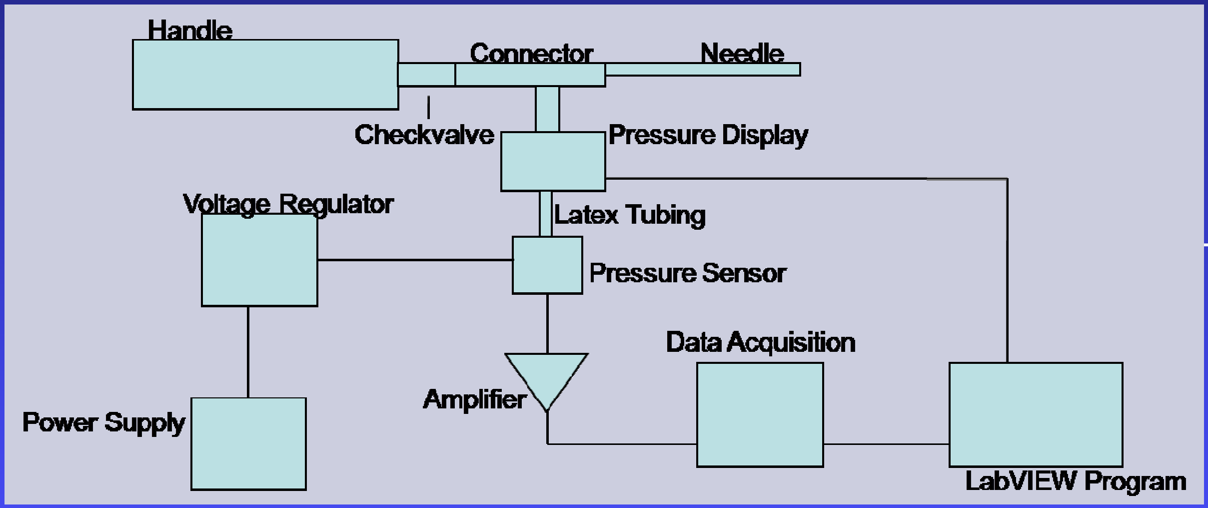
Pressure Sensor

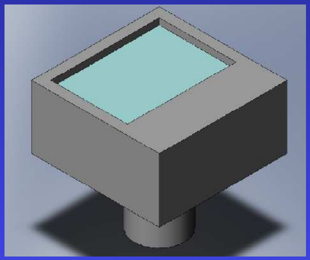
- Images of the current circuit (bottom) and the LabVIEW readout (right)





Pressure Sensor



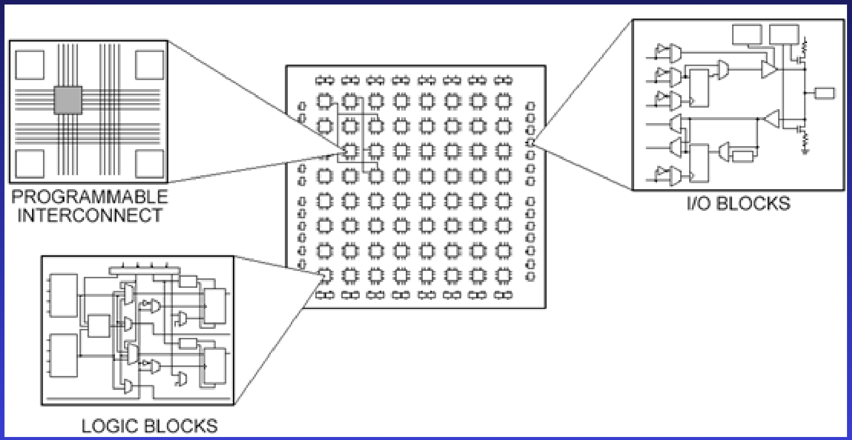


Current Pressure Sensor Schematic

Desired Pressure Sensor Display

Pressure Sensor

- Eventually all parts of the pressure sensor circuit can be incorporated on an FPGA chip and fit into the small display case



http://zone.ni.com/devzone/cda/tut/p/id/3357

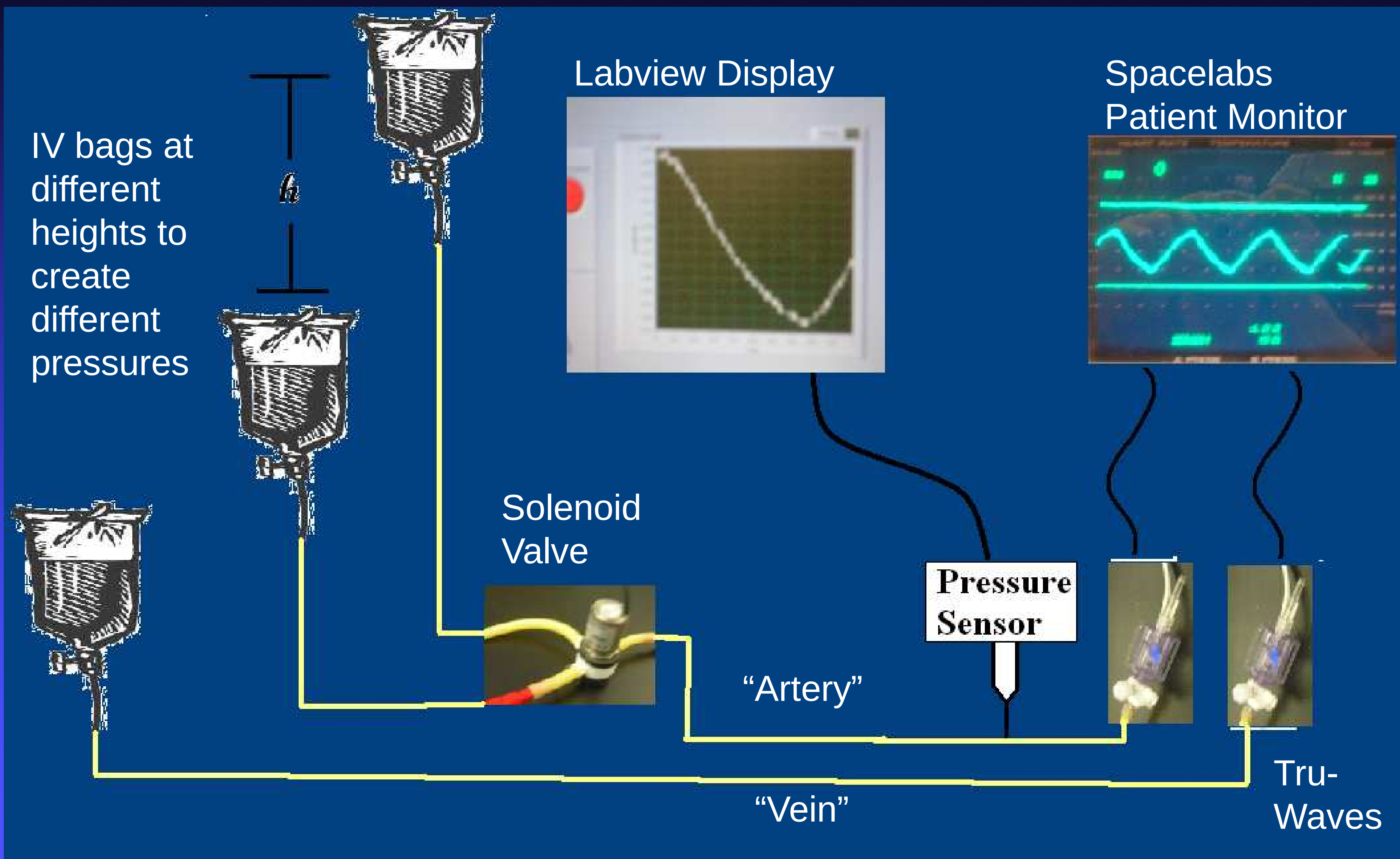
Proof of Concept of the Pressure Sensor

- Can the pressure sensor distinguish high (~80mmHg) from low (~7mmHg) i.e. above/below 30 mmHg?
- Need to simulate arterial and venous pressures to test this goal

Pressure Generating Apparatus

- To give control over a range of pressures & pulsatility
- Venous pressure:
  - IV bag of known height: to generate pressure following $P = \rho g h$ (estimate!)
- Arterial pressure:
  - 2 IV bags of different heights (same concept)
  - Connect to a solenoid valve to switch between the two and thus create pulsatility
- Verify the pressures/pulsatility from the simulator using a Patient monitor from Dr. Timothy Maul

Pressure Generating Apparatus



Demonstration Video

Verification of Device

- Goal is for it to correctly distinguish between high and low pressures >90% of the time over a range of pressures
  - Tested both arterial and venous at different heights
  - Compare our LabView display with the patient monitor to verify that the pressures are correct (within 4mmHg)

	Correct Pressures	Incorrect Pressures	Correct Light	Incorrect Light
Venous	12	0	12	0
Arterial	9	1	10	0

Results: Correct pressure identification in 21 out of 22 trials (95.5% success rate)

How Does it Compare to the PDS?

- Original goals:
  - ✓ Differentiate High/Low pressure
  - ✗ Recognize pulsatility
  - ✗ Display Waveform
  - ✓ LED display
  - ✓ Ergonomic handle
  - ✓ Cost: no greater than $5 more
  - ✓ Fit within 1x1 cm display case

Clinician Evaluation

- Device not ready for med students or large-scale clinical testing…
- Dr. William McIvor (anesthesiologist extraordinaire) will provide preliminary feedback
- After using the device he will be asked to complete a survey
  - Did he feel comfortable using it?
  - Was it easy to understand?
  - What was the most undesirable aspect?

Division of Labor

- Janet Chan: Documentation
- Evan Hill: Handle and Connector Prototype and Verification
- Jennifer Adams: Pressure Sensor and Verification
- Matt Wolf: Pressure Simulator and Verification

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Questions

Additional Reference

Central Venous Access and Monitoring, Dr Graham Hocking, Frimley Park Hospital, Portsmouth Road, Frimley, Camberley, Surrey, GU16 5UJ