Implantable Hemodynamic Monitoring

The Future of Heart Failure Disease Management

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Objectives: 1) Update on Cardiomens monitoring device 2) Understanding indications for implantation of the device 3) Cardiology training on how to implant the device

I have no financial disclosures.

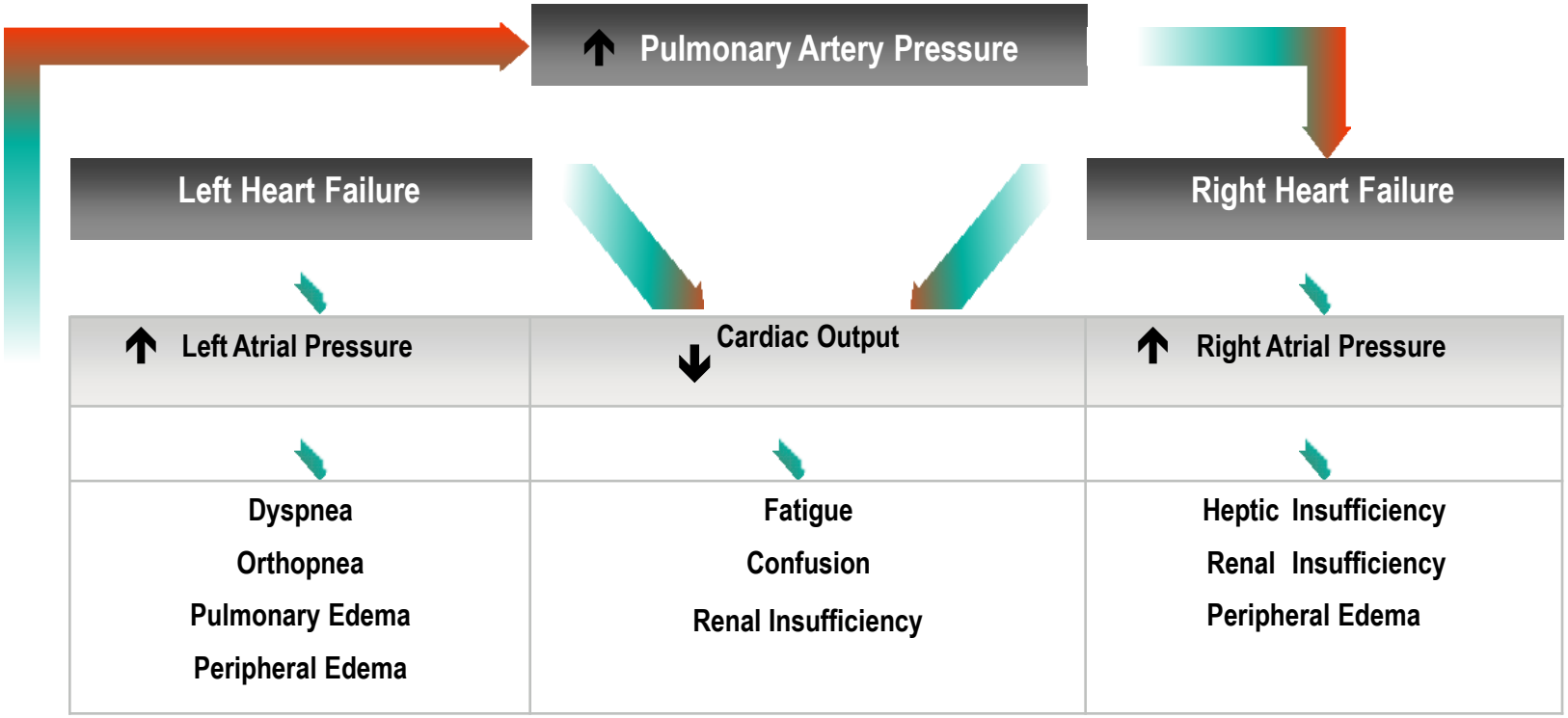
CASE

Sarah Jones is a 64 year old Hispanic female with a history of a ischemic cardiomyopathy with a depressed ejection fraction of 30%. She is on optimal medical treatment with Lasix, Spironolactone, Coreg, Digoxin, and Lisinopril. She is compliant with her medical therapy. She has been admitted four times to a community hospital in the last year. When she gets admitted, weight gain of 30lbs is noted due to fluid overload.

She is frustrated as is her family, because she is taking her medications as instructed and still experiences symptoms of fluid overload. She is looking for a way to stay at home and not seek medical attention every 4 months for massive fluid overload in the hospital.

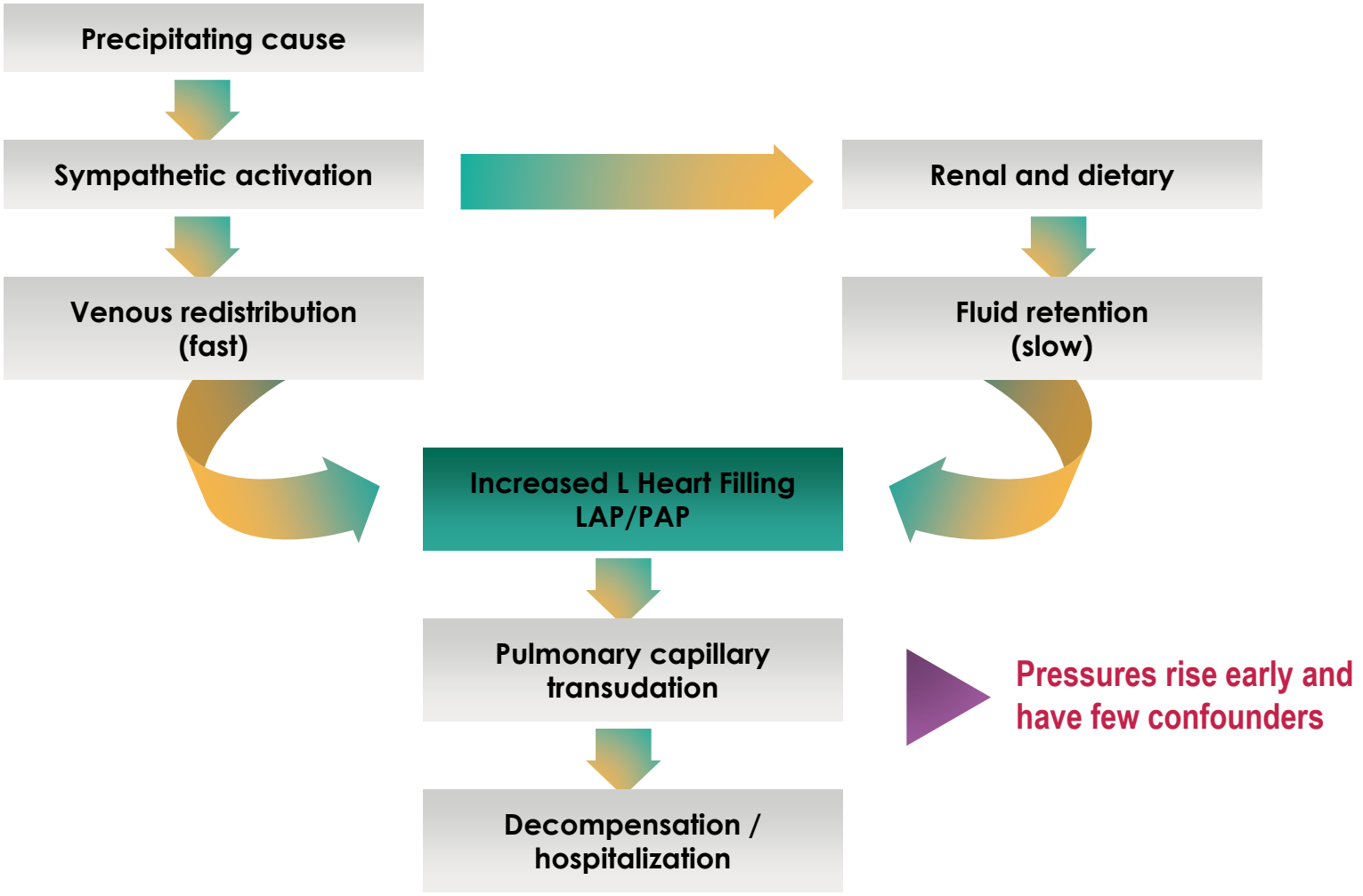
She has had a recent CardioMEMS device inserted, she has not be hospitalized in over 6 months. Her physicians monitor her hemodynamics every week remotely and adjust her diuretics according to her pulmonary pressures.

INCREASES IN PRESSURE START THE CYCLE OF WORSENING HEART FAILURE



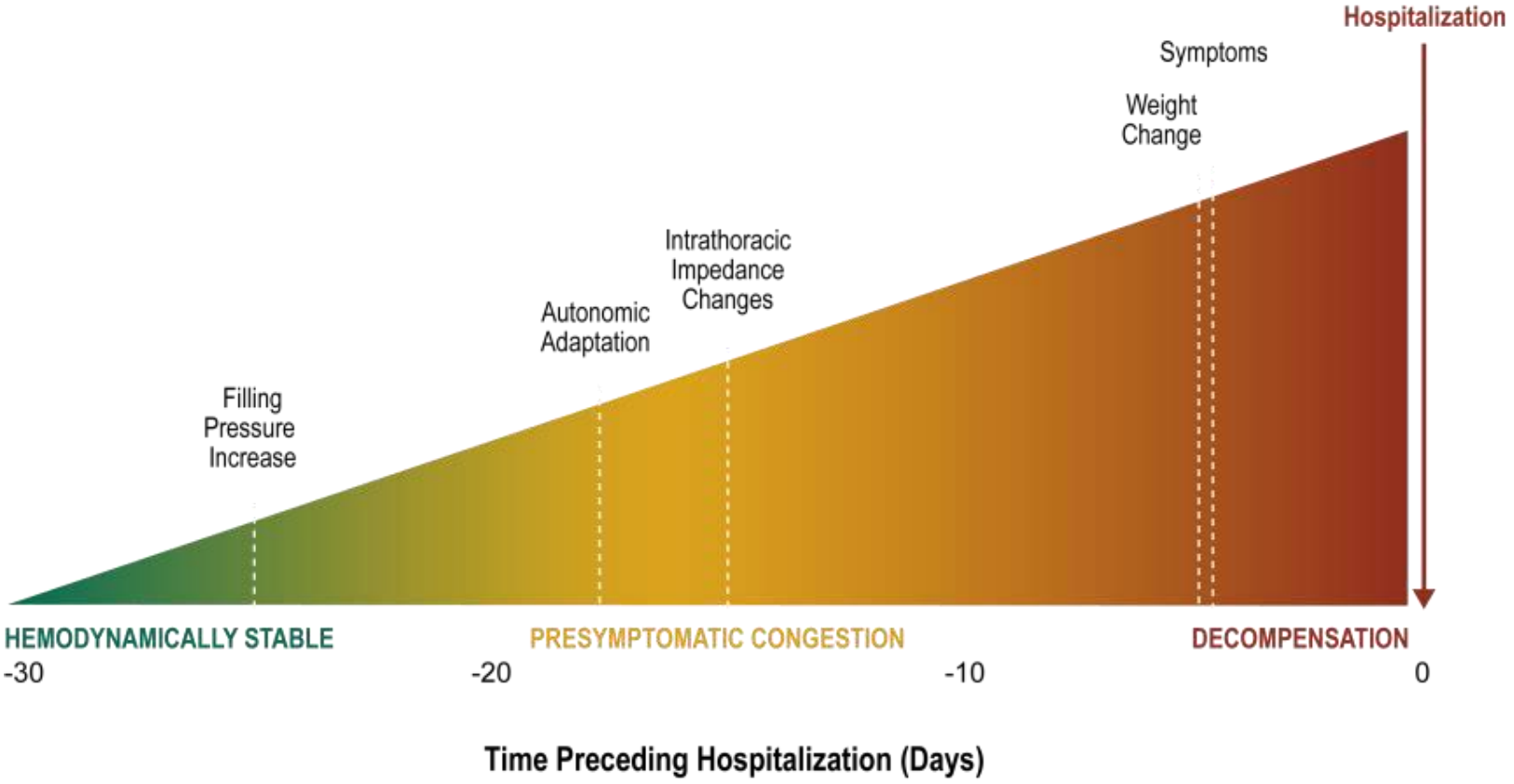
Adapted from *Jaski BE, "Basics of Heart Failure A Problem Solving Approach"*

Mechanisms of Worsening Heart Failure



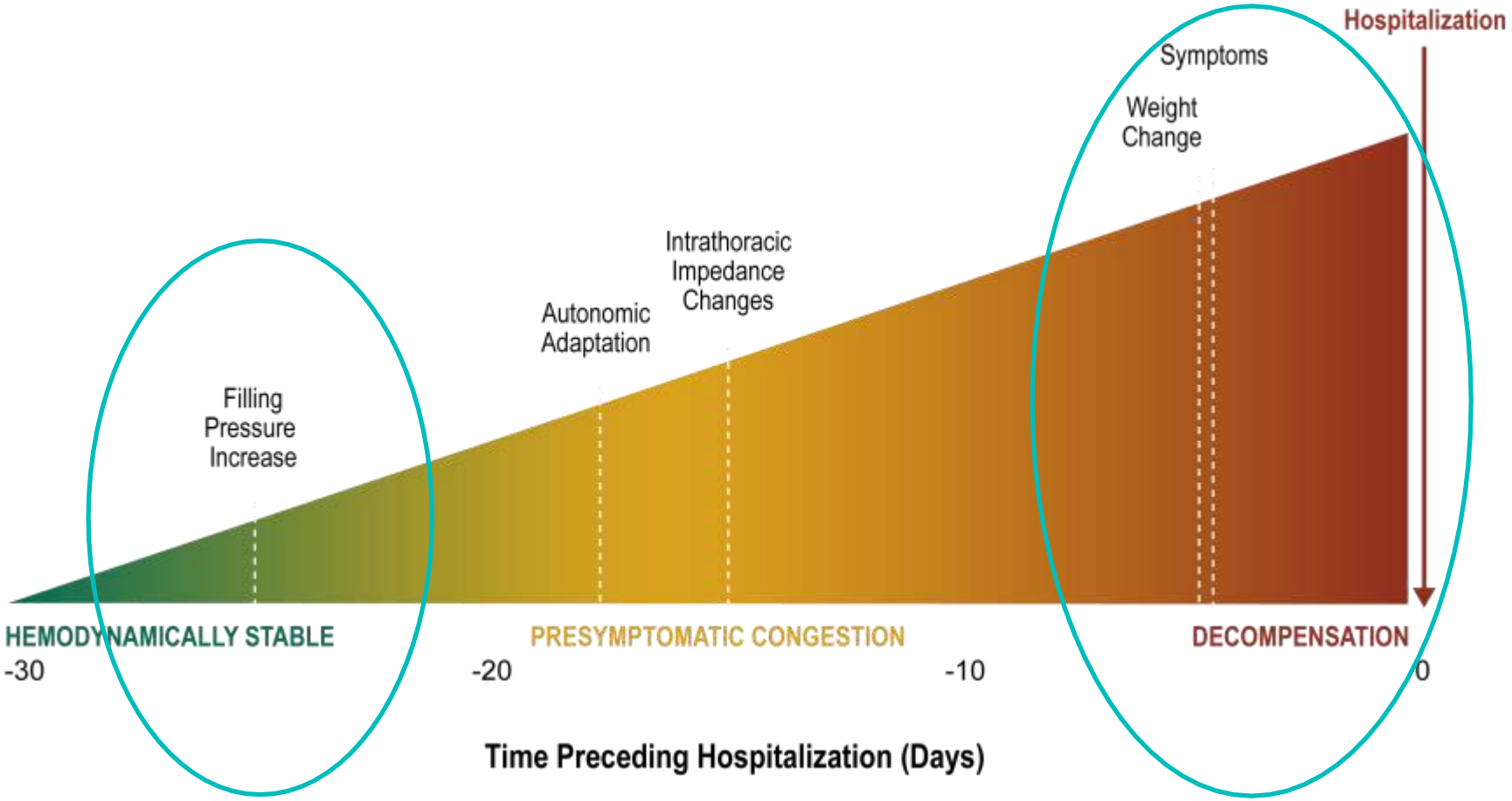
Time Course of Decompensation

- **Physiologic Markers of Acute Decompensation**



Graph adapted from Adamson PB, et al. Curr Heart Fail Reports, 2009.

Physiologic Markers of Acute Decompensation

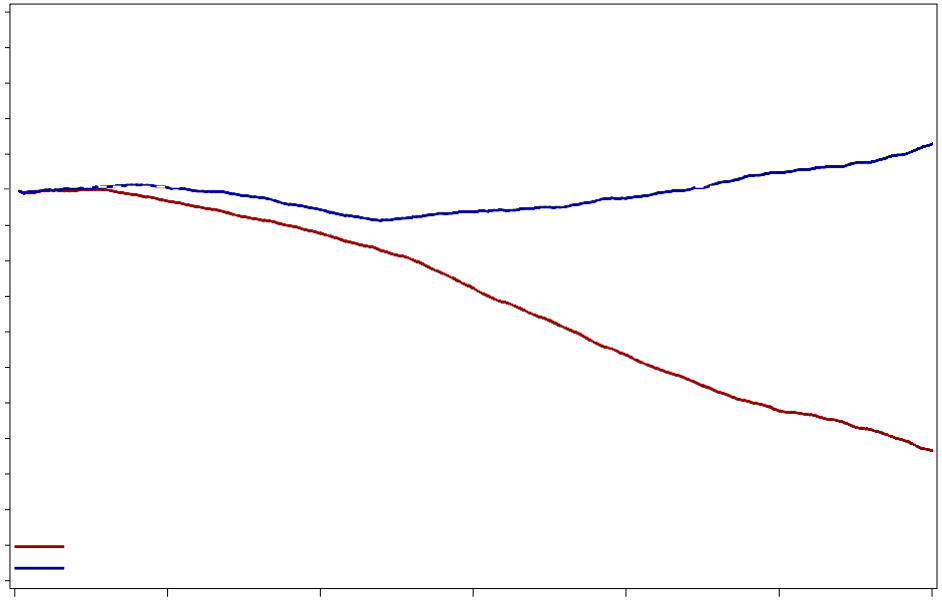


Graph adapted from Adamson PB, et al. Curr Heart Fail Reports, 2009.

CHAMPION Clinical Trial: By Targeting Pressure Ranges and Titrating Medications, Overall PA Pressures Can Be Reduced

Compared to the control group, patients managed with PA pressure had persistently lower mean PA pressures over the treatment period.

CHAMPION Clinical Trial: PA Pressure Mean Change from Baseline



Monitoring of PA pressure with the CardioMEMS™ HF System allows managing the pressure spikes that lead directly to exacerbation, as well as the long-term trends.

Abraham WT, et al. Lancet, 2011.

MANAGING PRESSURES IN THE HEART FAILURE PATIENT

Pressures		Patient
When patients are stable	→	▪ Their pressures remain very stable over time.
When patients decompensate	→	▪ Pressures increase, leading to exacerbation.
The pressures return to baseline when the exacerbation is treated and volume returns to normal	→	▪ Pressures reflect the underlying volume state in HF patients. ▪ Strongly supports the hypothesis that measuring those pressures frequently or continuously using implantable devices and managing those pressures may be a superior management strategy.
Managing to targeted pressure ranges	→	▪ Can reduce overall pressures and ultimately lead to a reduction in HF events.

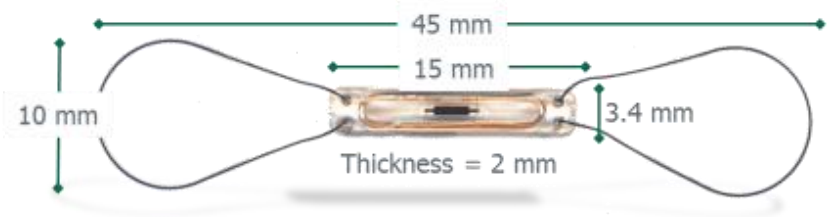
Adamson PB, et al. Curr Heart Fail Reports, 2009

CardioMEMS™ HF System

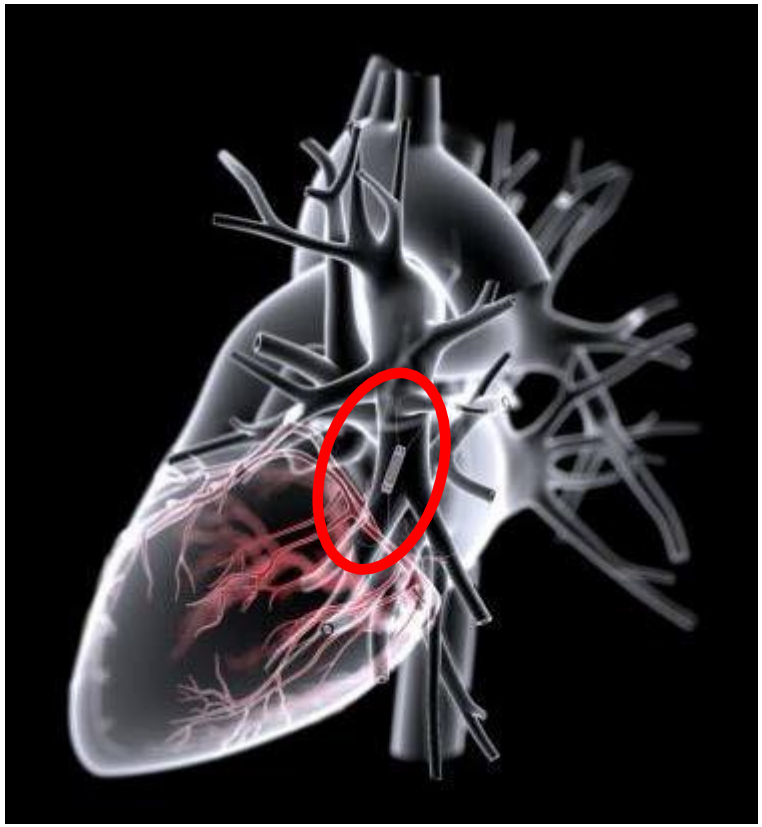
Pulmonary Artery Pressure Sensor		Patient Electronics System		CardioMEMS™ HF System Website
				

CARDIOMEMS™ HF SYSTEM

The pulmonary artery pressure sensor is implanted via a right heart catheterization procedure via femoral vein approach.

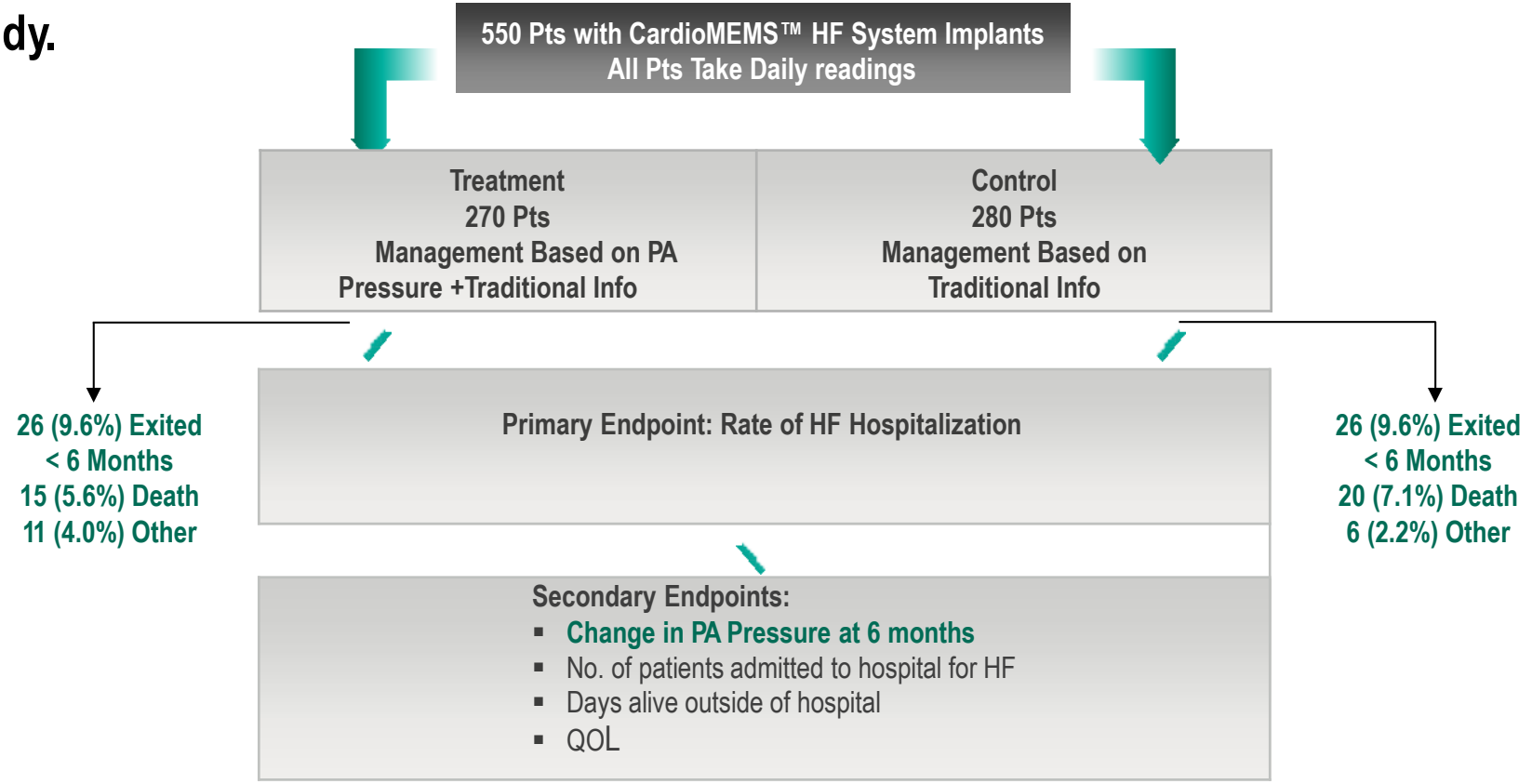


Target location for pulmonary artery pressure sensor



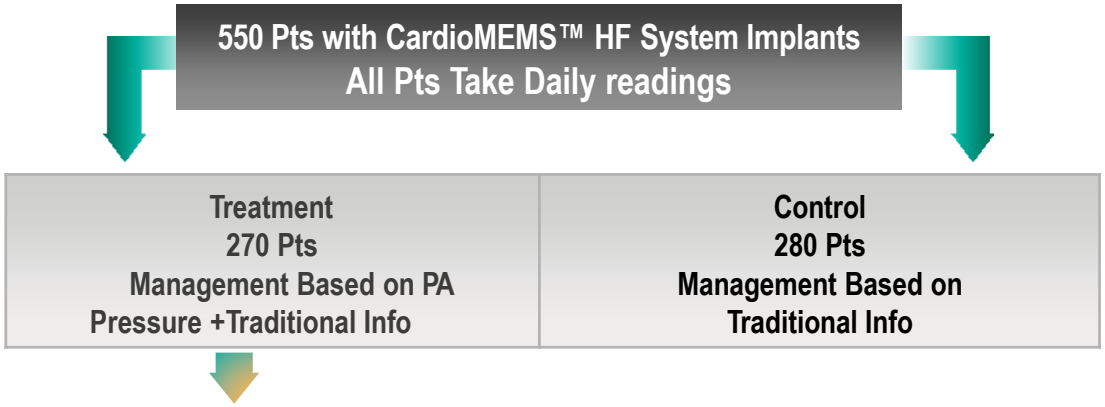
CHAMPION CLINICAL TRIAL: THE EFFECT OF PULMONARY ARTERY PRESSURE-GUIDED THERAPY ON HF HOSPITALIZATIONS VS. STANDARD OF CARE

Patients with moderate NYHA class III HF for at least 3 months, irrespective of LVEF and a HF hospitalization within the past 12 months were included in the study.



Abraham WT, et al. Lancet, 2011.

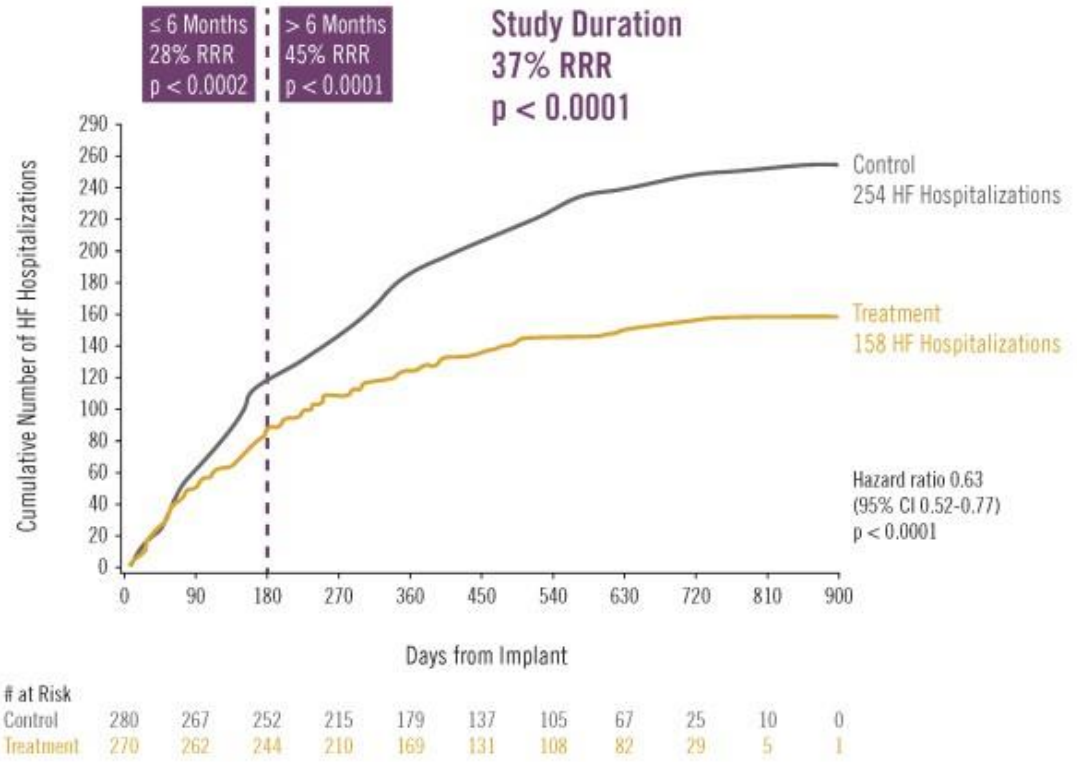
CHAMPION CLINICAL TRIAL: MANAGING TO TARGET PA PRESSURES



PA Pressures were managed to target goal pressures by physicians with appropriate titration of HF medications.

- Target Goal PA Pressures:
  - PA Pressure systolic 15 – 35 mmHG
  - PA Pressure diastolic 8 - 20 mmHG
  - PA Pressure mean 10 – 25 mmHG

CHAMPION Clinical Trial: PA Pressure- guided Therapy Reduces HF Hospitalizations



Patients managed with PA pressure data had significantly fewer HF hospitalizations as compared to the control group.

Abraham WT, et al. Lancet, 2011.

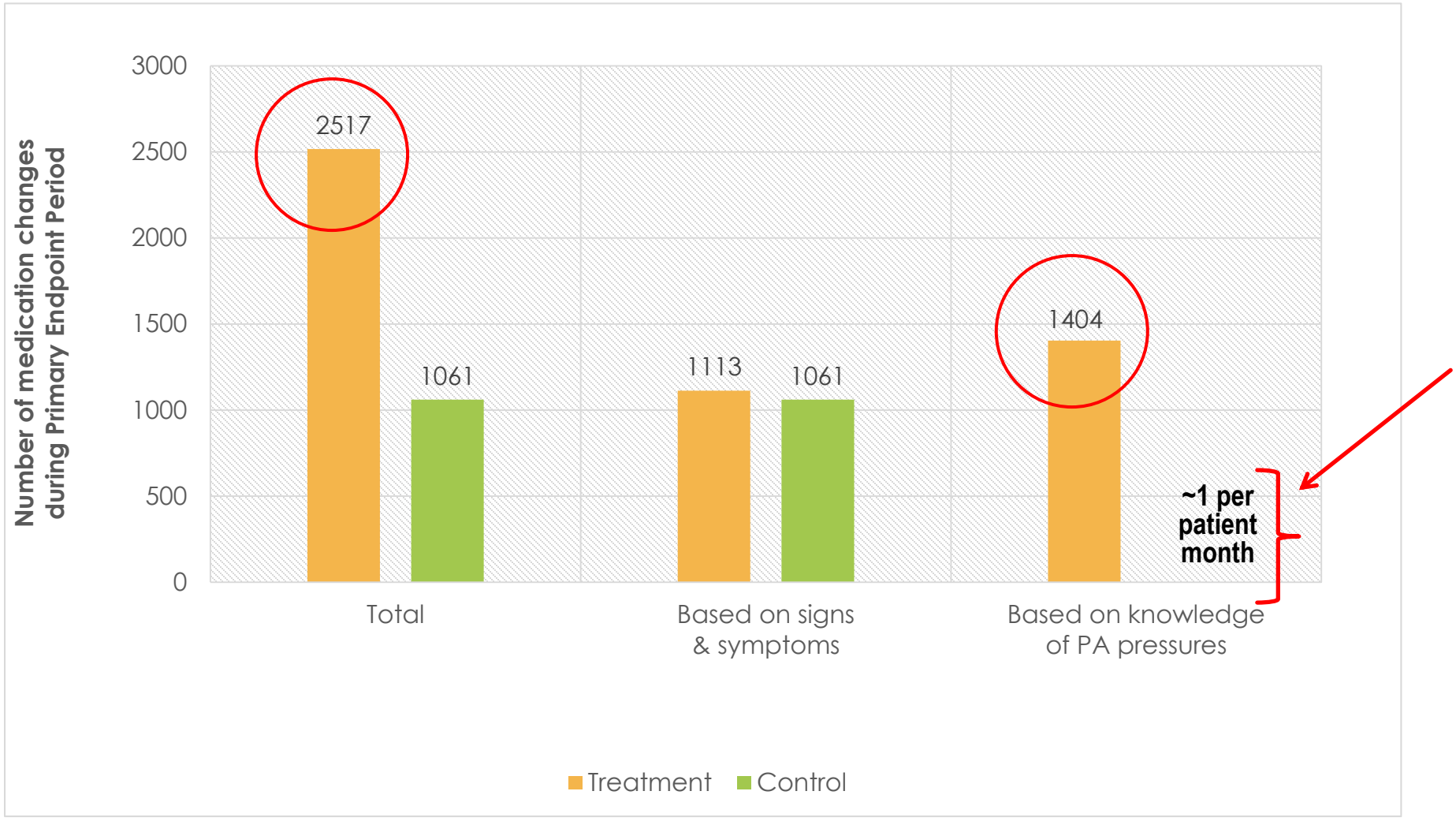
CHAMPION CLINICAL TRIAL: BOTH PRIMARY SAFETY ENDPOINTS AND ALL SECONDARY ENDPOINTS WERE MET AT 6 MONTHS

		Treatment (n = 270)	Control (n = 280)	P-value
Primary Safety Endpoints	**Device-related or system-related complications**	3 (1%)	3 (1%)	
		Total 8 (1%)*		< 0.0001
	Pressure-sensor failures	**0**	0	< 0.0001
Secondary Endpoints	Change from baseline in PA mean pressure (mean AUC [mm Hg x days])	**-156**	33	0.008
	Number and proportion of patients hospitalized for HF (%)	55 (20%)	80 (29%)	0.03
	Days alive and out of hospital for HF (mean ± SD)	174.4 ± 31.1	172.1 ± 37.8	0.02
	Quality of life (Minnesota Living with Heart Failure Questionnaire, mean ± SD)	**45** ± 26	51±25	0.02

*** Total of 8 DSRCs including 2 events in Consented not implanted patients (n = 25)**

Abraham WT, et al. Lancet, 2011.

CHAMPION Clinical Trial: Reasons for Medication Changes



CHAMPION Clinical Trial: The Number Needed to Treat (NNT) to Prevent One HF-related Hospitalization is Lower vs. Other Therapies

Intervention	Trial	Mean Duration of Randomized Follow-Up	Annualized Reduction in HF Hospitalization Rates	NNT per year to Prevent 1 HF Hospitalization
Beta-blocker	COPERNICUS	10 months	33%	7
Aldosterone antagonist	RALES	24 months	36%	7
CRT	CARE-HF	29 months	52%	7
Beta-blocker	MERIT-HF	12 months	29%	15
ACE inhibitor	SOLVD	41 months	30%	15
Aldosterone antagonist	EMPHASIS-HF	21 months	38%	16
Digoxin	DIG	37 months	24%	17
Angiotensin receptor blocker	Val-HeFT	23 months	23%	18
Angiotensin receptor blocker	CHARM	40 months	27%	19
PA pressure monitoring	**CHAMPION**	**17 months**	**33%**	**4**

Summary: CHAMPION Clinical Trial

Pulmonary Artery Pressure

↓

Medication Changes based on Pulmonary Artery Pressure ($p < 0.0001$)

↓

Pulmonary Artery Pressure Reduction ($p = 0.008$)

↓

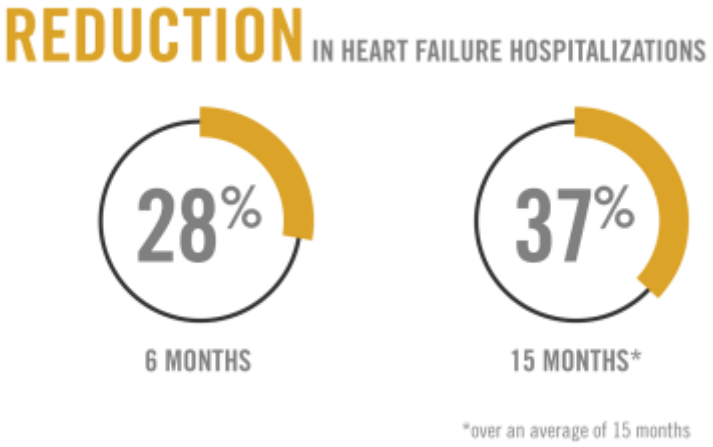
Reduction in Heart Failure Hospitalizations ($p < 0.0001$)

↓

Quality of Life Improvement ($p = 0.024$)

Managing pressures to target goal ranges:

- PA Pressure systolic 15–35 mmHg
- PA Pressure diastolic 8–20 mmHg
- PA Pressure mean 10–25 mmHg



CARDIOMEMS™ HF SYSTEM PULMONARY ARTERY PRESSURE MONITORING

<u>Indications</u>:

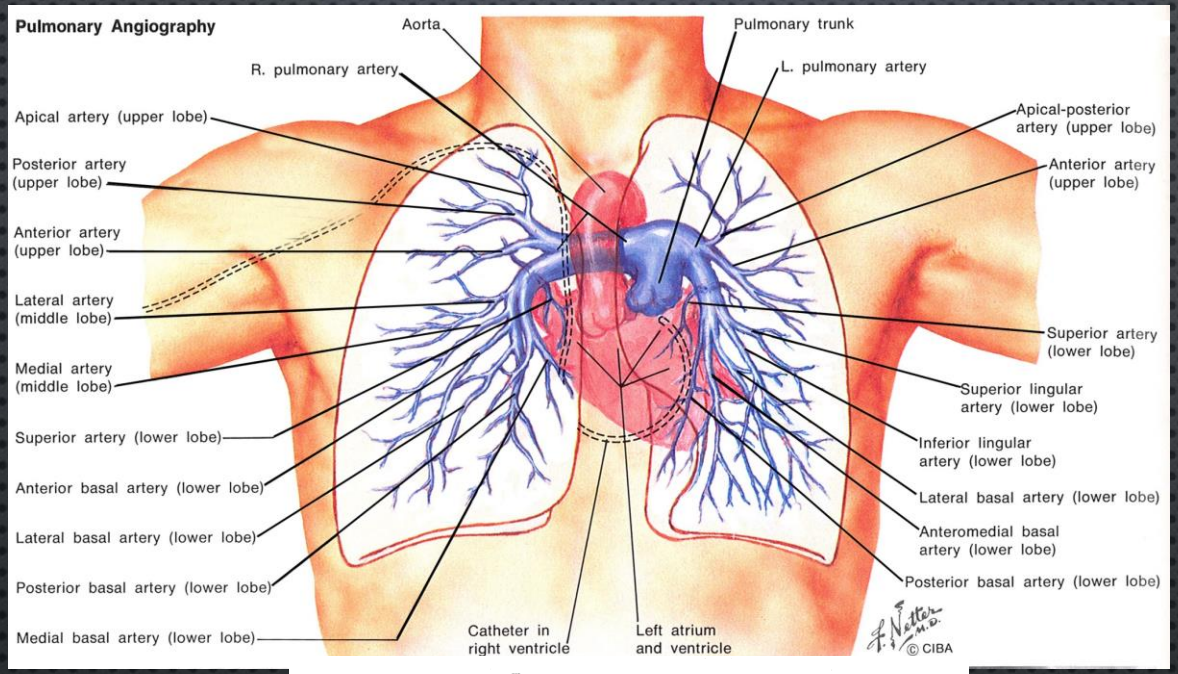
1) CHF diastolic or systolic NY Heart Class III

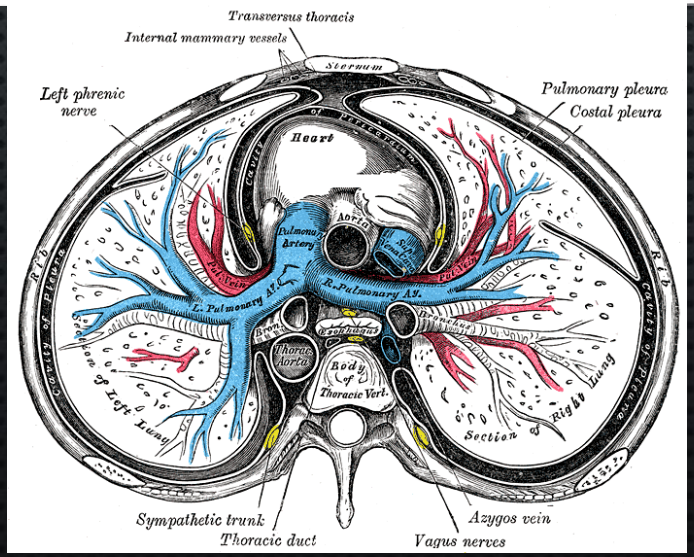
2) One admission for heart failure within the last year for at least 48hrs in duration

3) Covered by Medicare

- Pulmonary Artery Anatomy
- Sensor Design
- Implant Procedure Setup
- Implant Procedure

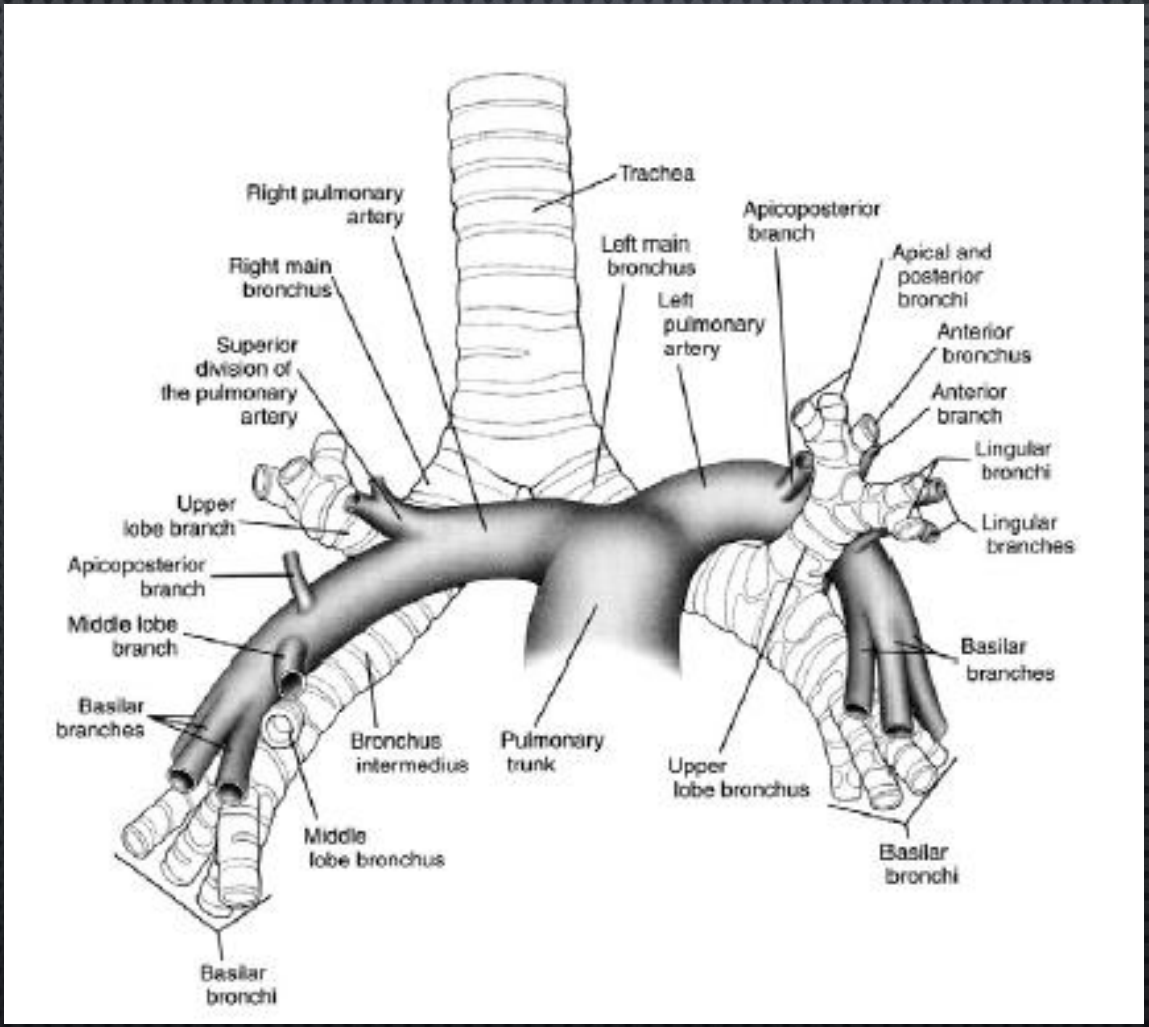
INTRODUCTION: PULMONARY ARTERY ANATOMY





Images from Anatomy of the human body (1918) Grays anatomy

PULMONARY ARTERY ANATOMY



Frechette, E. 2006. Semin Thorac Cardiovasc Surg 18:77-84.

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INTRODUCTION: PULMONARY ARTERY ANATOMY

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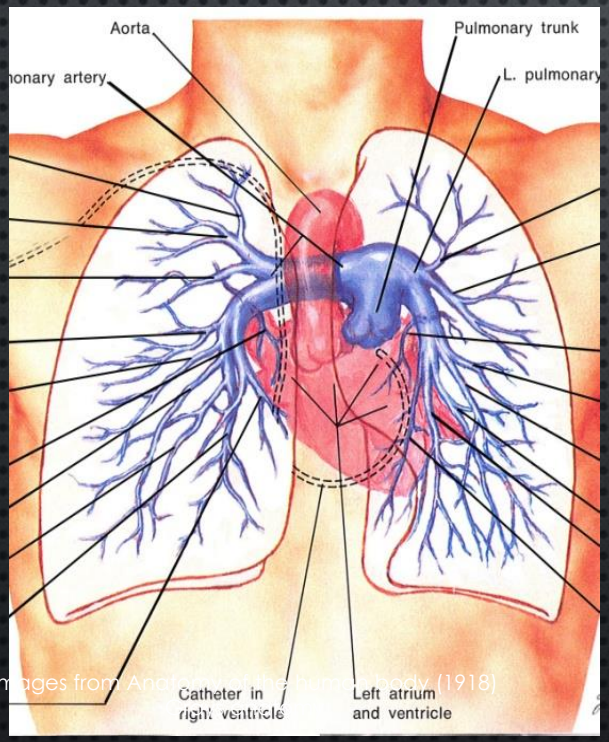

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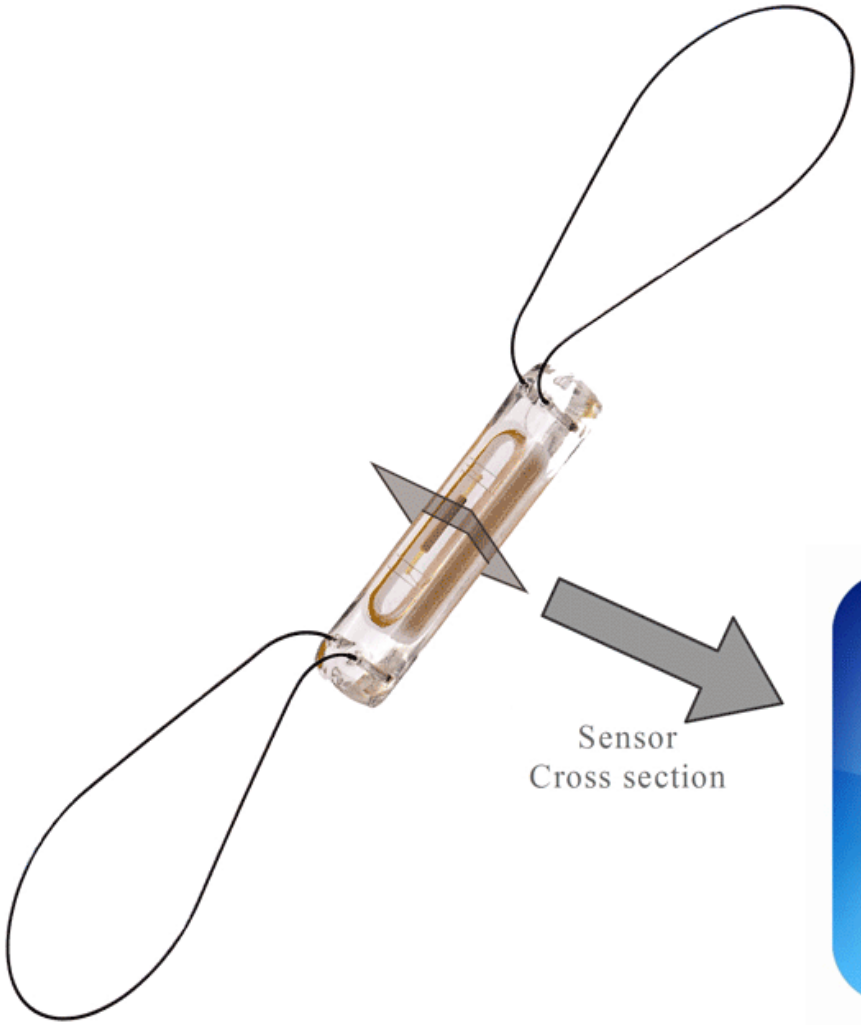
Images from Anatomy and Physiology Study (1918)

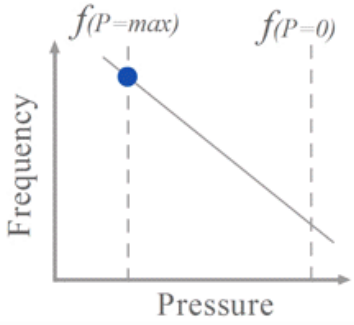
Pulmonary Artery Placement Rationale:

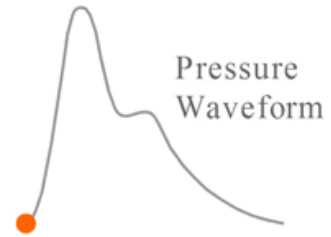
- LV filling pressure is the focus for improved management of HF
- Pulmonary Artery Pressure (PAP) correlates with LV filling pressure in HF
- Right side of heart – no stroke risk, simple procedure
- No active fixation required

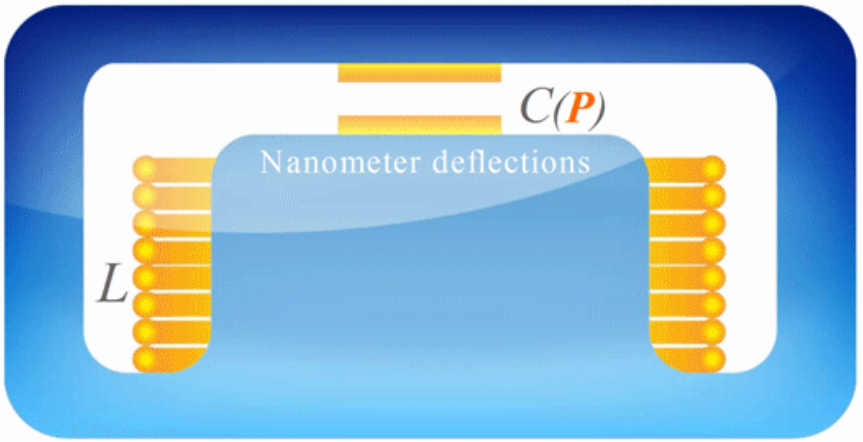


Sensor
Cross section

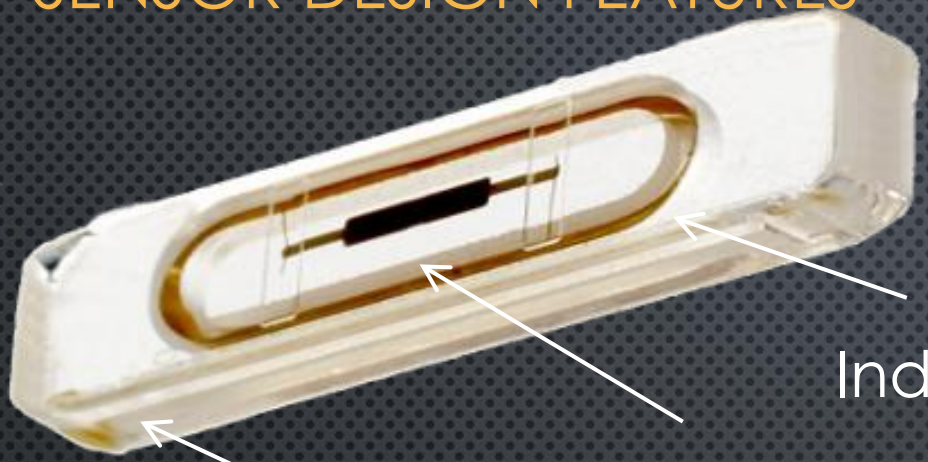
$$f = \frac{1}{2\pi\sqrt{L\ C(P)}}$$







SENSOR DESIGN FEATURES



Important Features:

- Design Simplicity = ↑ Reliability
- Stable Performance
  - Material Selection
  - Hermeticity
  - Rigid Sensing Element
- No Internal Power Supply

SENSOR DESIGN FEATURES

MEMS features:

Design:
Rigid Deflecting "Membran
1 µm Capacitor Gap
1 nm Deflection / mm Hg

Multiple sensors fabricated in a wafer batch

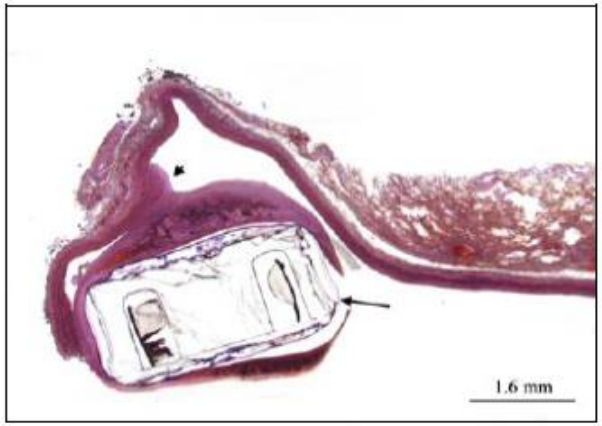


Figure 5: Device in pulmonary artery – 1.25x
Device (long arrow); Attachment to arterial wall (short arrows)

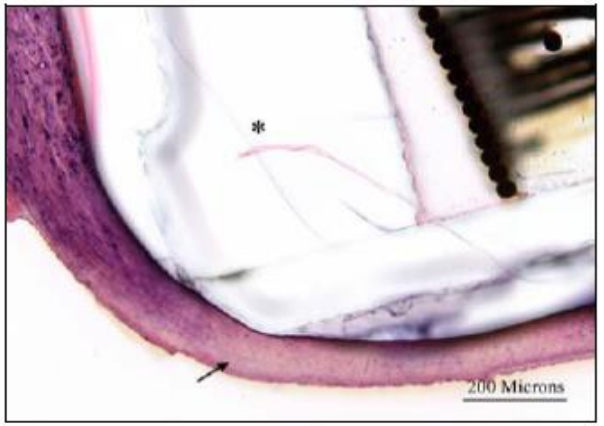
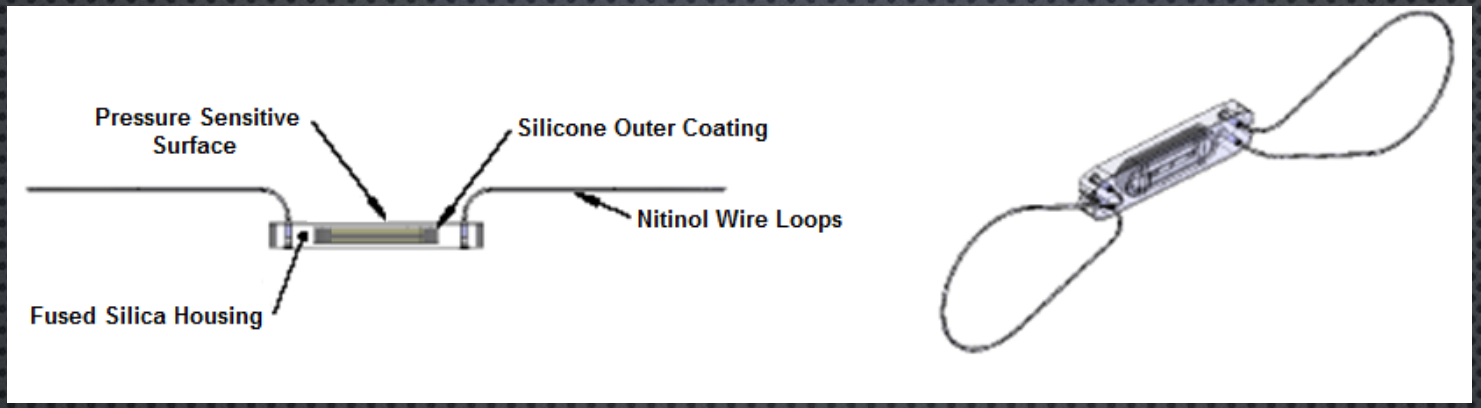


Figure 6: Device in pulmonary artery – 10x
Stable mature pseudointima (double arrow)
Wire (white arrow); Device (asterisk)

Images from histopathology report at CMEMS

SENSOR DESIGN: EXTERNAL FEATURES



HF Sensor Design Features:

Length: 15 mm

Width: 3.5 mm

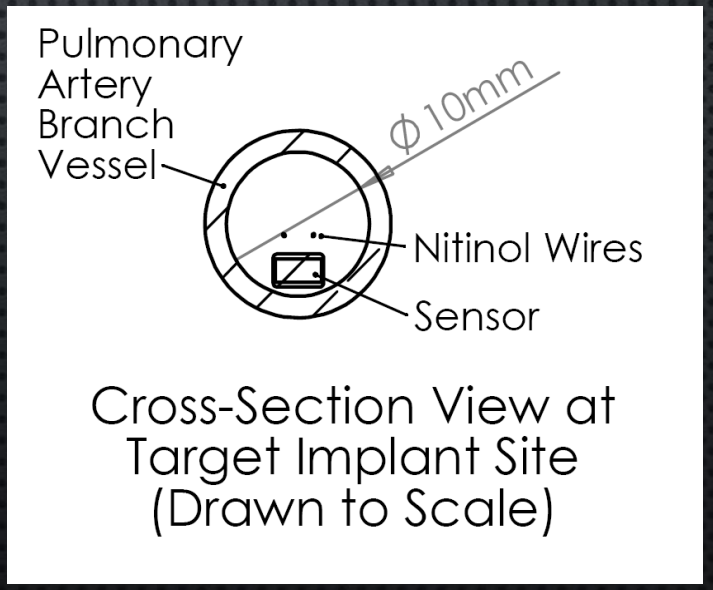
Height: 2.0 mm

Wire Loops: 10 mm diameter

Total Length with Loops: 4.5 cm

Wire Loop Function:

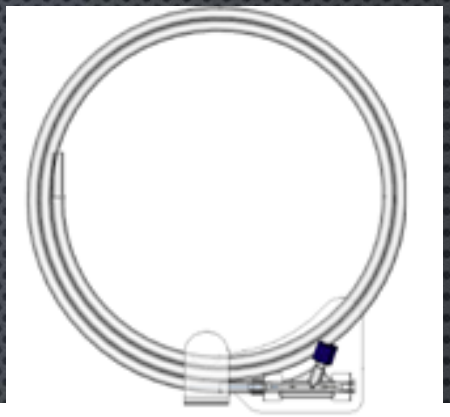
- Maintain alignment with vessel
- Prevent distal embolization

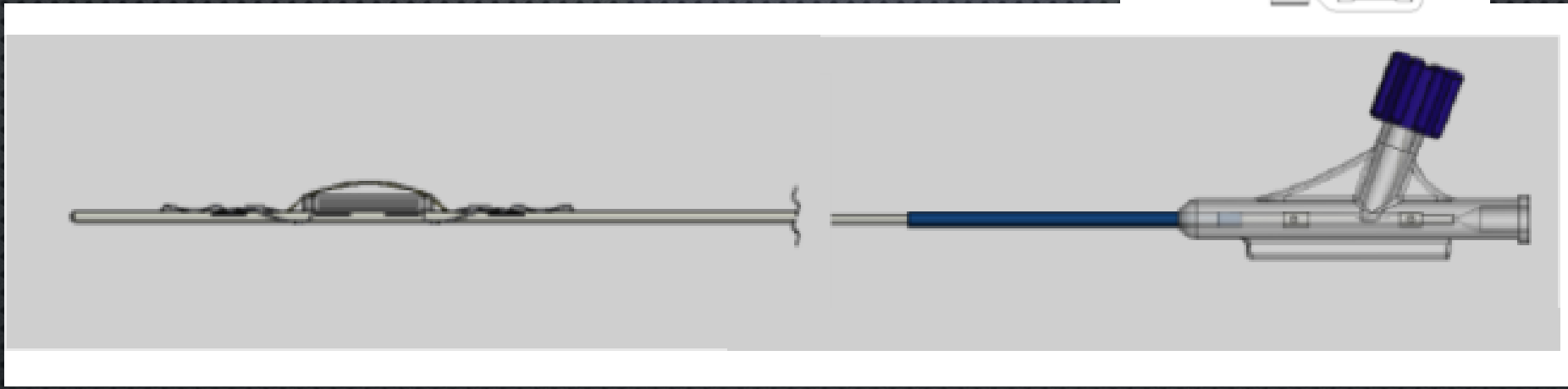


Cross-Section View at Target Implant Site (Drawn to Scale)

PA SENSOR DELIVERY SYSTEM

Sensor/Monitor Loaded on Catheter Shaft





- Shaft Configuration: Over-the-Wire
- Guidewire Compatibility: 0.018”x260 cm
- Usable Length: 120 cm
- Introducer Sheath Compatibility: 12 Fr

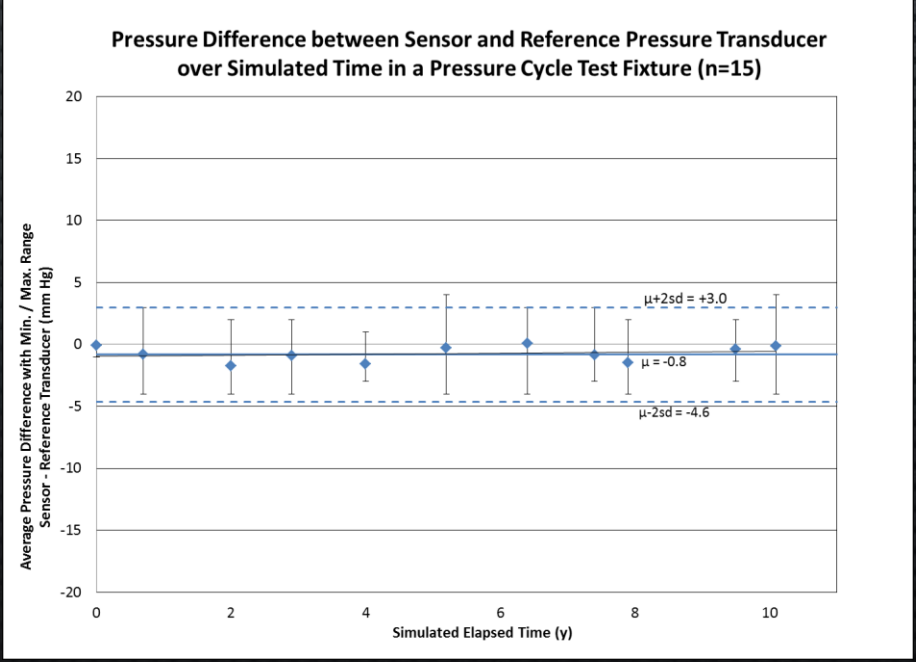
SENSOR ACCURACY OVER EXTENDED TIME

In laboratory testing, sensors were:

- Immersed in body temperature water (37°C)
- Exposed to > 10 years of cardiac pressure cycles at 74bpm (>400 million cycles).
- Measurements periodically compared to standard blood pressure transducer.

Results:

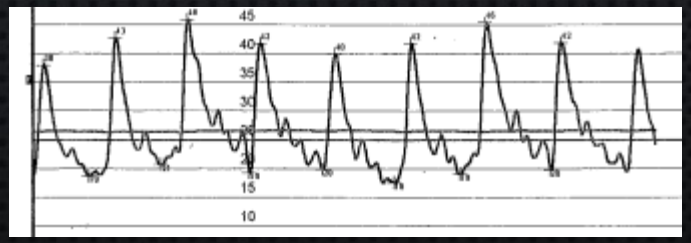
- Close agreement with reference measurement for all sensors.
- Stable performance over time, with mean drift rate -0.1 ± 0.4 mm Hg / year.

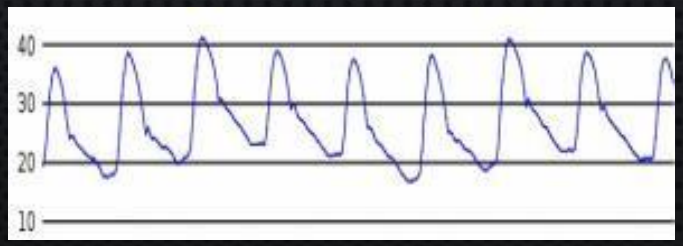


Images from TR-1002-108 from Atlanta test report

INHERENT DIFFERENCES BETWEEN SENSOR AND SWAN-GANZ MEASUREMENT SYSTEMS

	Swan Ganz	CardioMEMS Sensor
Measurement Method	Pressure registered outside the body transmitted by a column of fluid.	Direct measurement inside bloodstream.
Dynamic Error	System over or under-dampening causes waveform overshoot or dampening artifact.	No overshoot or dampening related artifact.
Mean Pressure (Leveling) Error	1.3 mm Hg error / 1 cm transducer height level misalignment. Leveling error effect compounds for difference of 2 readings. $[\sqrt{(Error_1{}^2 + Error_2{}^2)}]$	Consistent position, no leveling required.

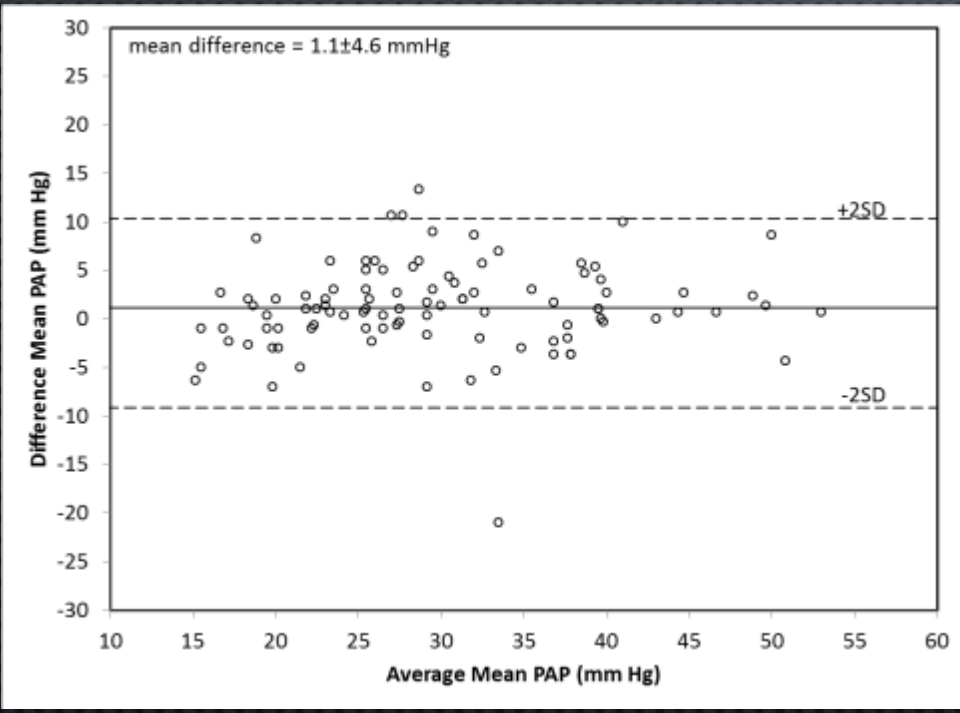




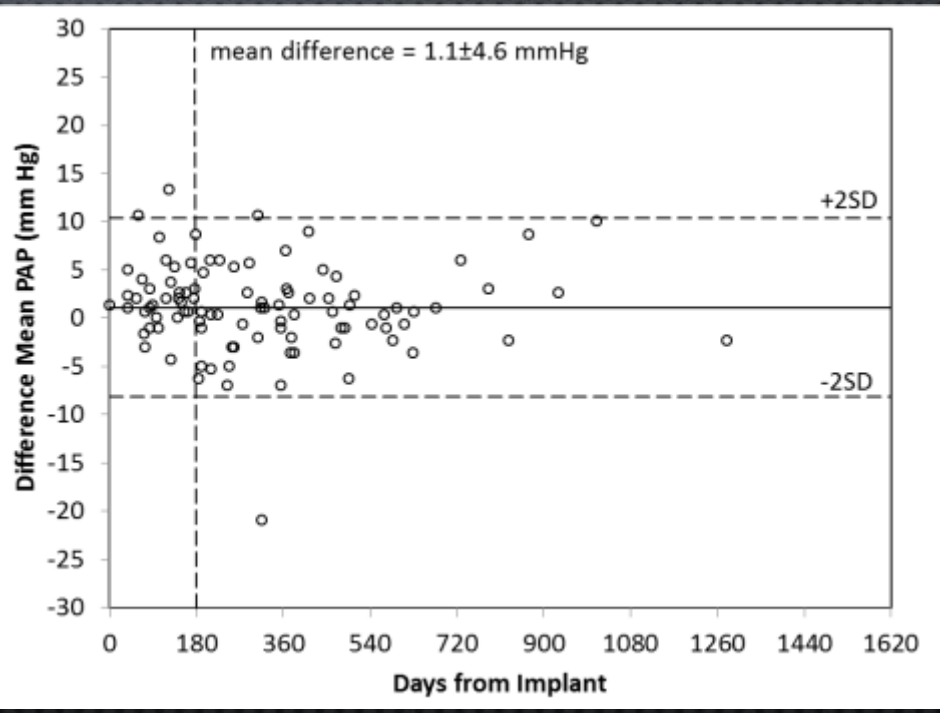
SYSTEM CLINICAL PERFORMANCE VALIDATION

Sensor compared to PA catheter pressure measurements during 98 follow-up RHC's for 52 patients.

Bland-Altman Agreement Plot



Agreement vs. Elapsed Time Plot



PAP Agreement Mean = 1.1 mm Hg

Stable PAP agreement over extended timeframes.

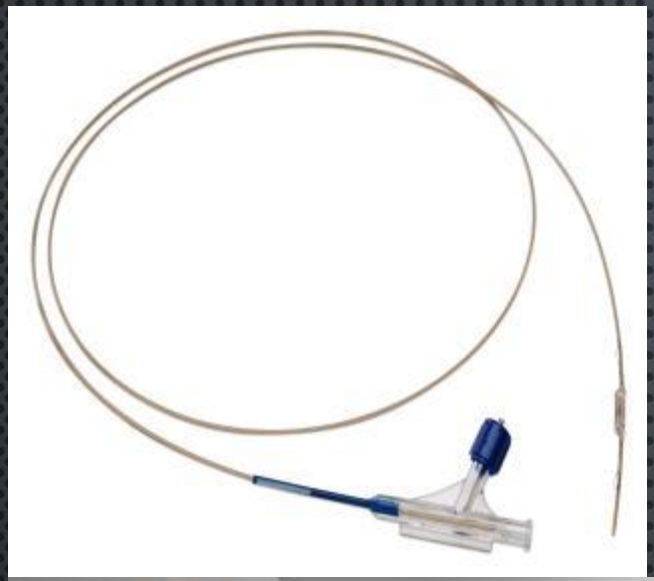
Data from the CHAMPION clinical study report

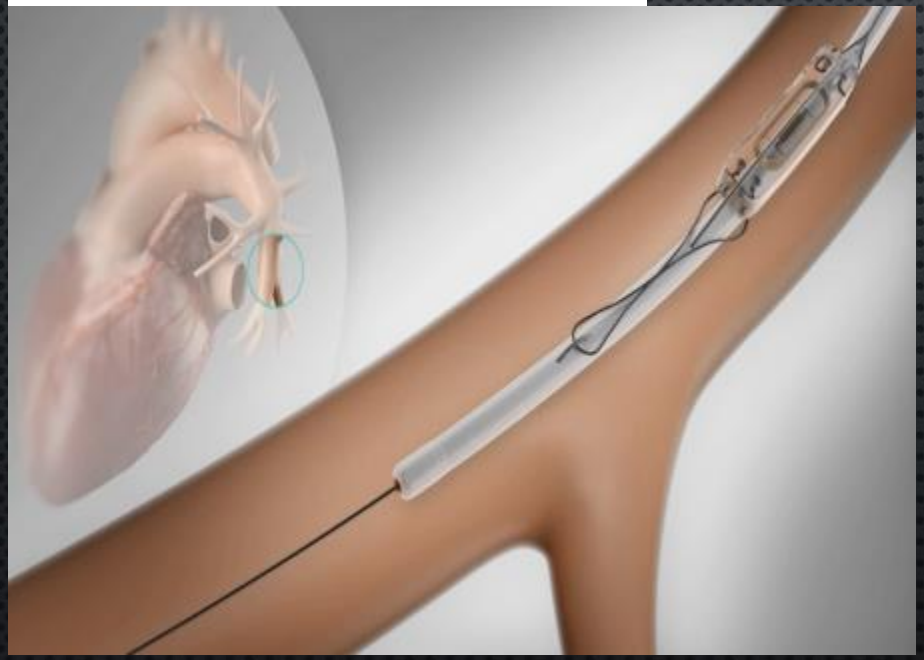
IMPLANT PROCEDURE SETUP

1. **Procedure Accessories**
2. **Hospital Electronics Setup**

Implant Procedure Set-Up and Accessories

Procedure Accessory	Options		Product Code
PA Catheter	7Fr x 110cm Swan-Ganz (SG) with (TD)	If thermodilution (TD) needs to be performed and use one catheter for access and all RHC measurements.	Any
	7Fr x 110cm Pulmonary Wedge Catheter	More steerable than SG and better angiogram. Pressures and Modified Fick CO can be measured – No TD.	Arrow AI-07127
			Medtronic 150075
Introducer Sheath	SJM Fast-Cath, 12Fr		406128
	SJM Ultimum EV, 12Fr		407655
	Terumo Pinnacle, 11Fr		RSS101
Delivery Guidewire Options	SJM, CardioMEMS Guidewire, 0.018" x 260cm (Stiff Nitinol)		CM2010
	Covidien/EV3, Nitrex, 0.018"x300cm (Stiff Nitinol)		N183002
	Cook Roadrunner, 0.018" x 300cm (Stiff Nitinol)		G07584
	Abbott, Hi-Torque Steelcore, 0.018"x300cm (SS)		1003282
	Boston Scientific, Platinum Plus, 0.018" x 260cm (SS)		46-732
	Boston Scientific, Thru-Way, 0.018" x 300cm (SS)		49-283
	Boston Scientific, V-18 ControlWire, 0.018" x 300cm (SS)		46-854





CardioMEMS™ Guidewire

Implanting the CardioMEMS™ PA Sensor requires a 0.018"/0.46 mm x 260-300 cm fixed core guidewire with straight or angled tip (no J-tip)

There are commercially available wires which meet the minimum requirements for sensor implant such as:

- Covidien/EV3™Nitrex™, 0.018" x 300 cm
- Abbott Hi-Torque Steelcore ™ 0.018" x 300 cm

Many acceptable wires are not readily available in most cath labs. Wires with a stainless steel core that are commonly available have significant drawbacks:

- The tip of a stainless steel guidewire is prone to kink during use which complicates guidewire removal post sensor release
- 0.018" stainless steel wires are stiffer than necessary for the sensor implant procedure, which may increase the risk of guidewire related vessel injury

The CardioMEMS™ Guidewire:

- Uses a stiff grade Nitinol core wire which provides an appropriate level of support for the sensor implant procedure
- The distal tip is more kink resistant than stainless steel alternatives

HOSPITAL ELECTRONICS SETUP

Patient Information

Sensor Information

From wireless download or manual entry

From USB flashdrive provided in sensor package

IMPLANT PROCEDURE

1. Access PA with PA Catheter:
   - Insert PA Catheter through a 12 Fr sheath placed in the femoral vein
   - With balloon inflated, advance PA Catheter to a wedge position within the lower lobe of the left or right PA
   - Measure PAP, PCWP, and CO

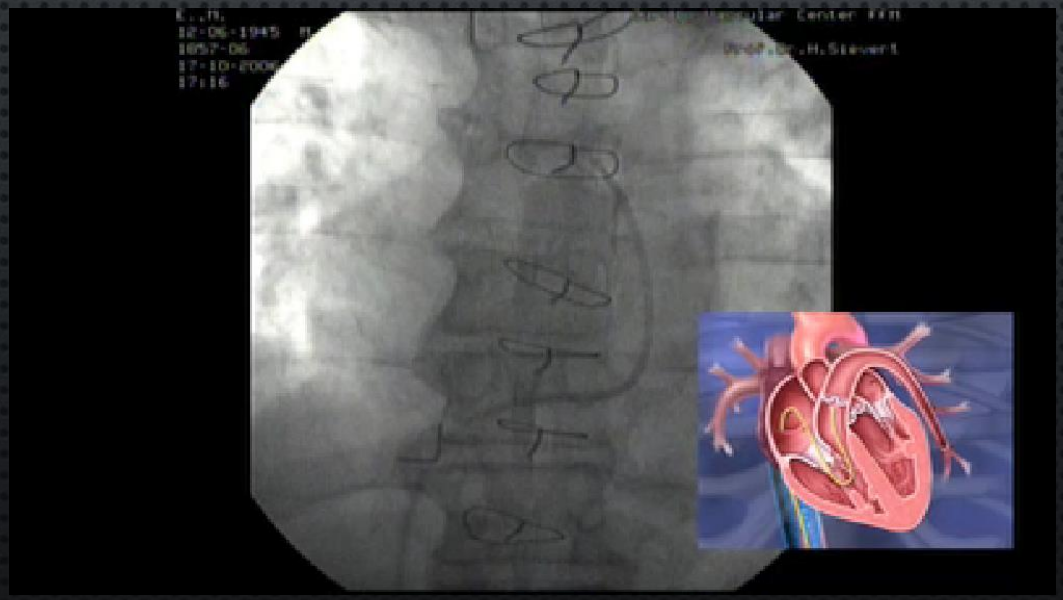
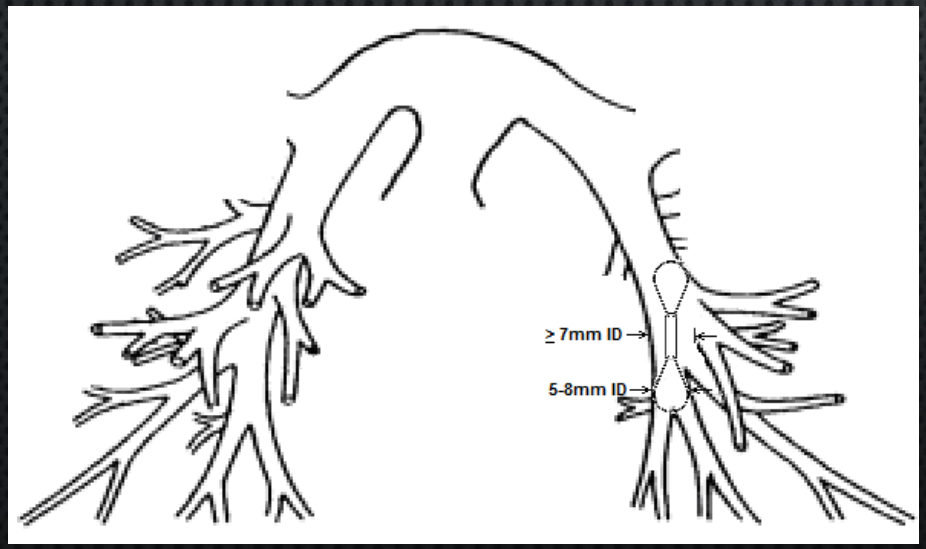
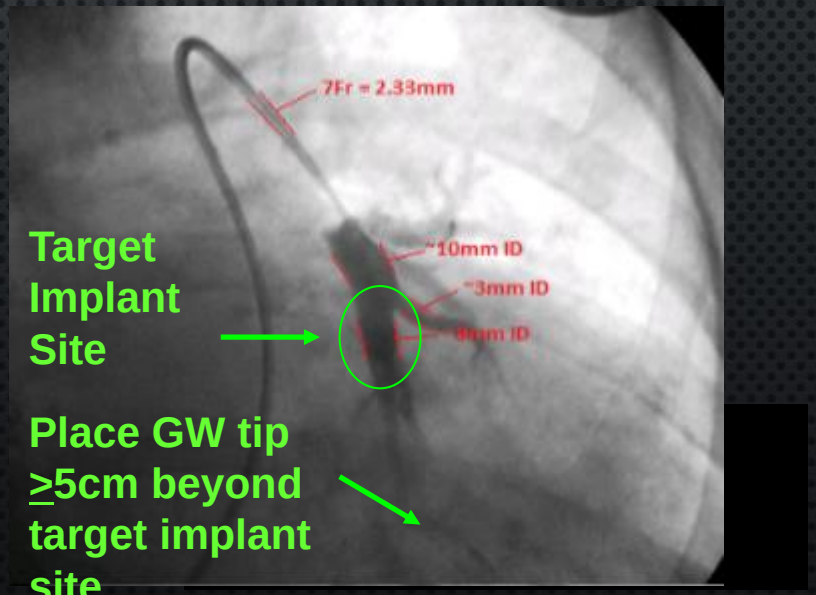


Image from OUS feasibility clinical study data

IMPLANT PROCEDURE

2. Identify and Access Target Implant Site
   - Perform angiogram (5cc) through the PA catheter.
     - Target implant vessel is within the lower lobe of either lung and the vessel is directed towards the feet and back.
     - Vessel diameter is ≥ 7 mm and has < 30 degree angulation where body of Sensor will be placed.
     - Vessel diameter is ≤ 8 mm where the distal loop of Sensor will be placed.
   - Place delivery guidewire across the target implant site.
   - Retract and remove the PA catheter while maintaining guidewire position.

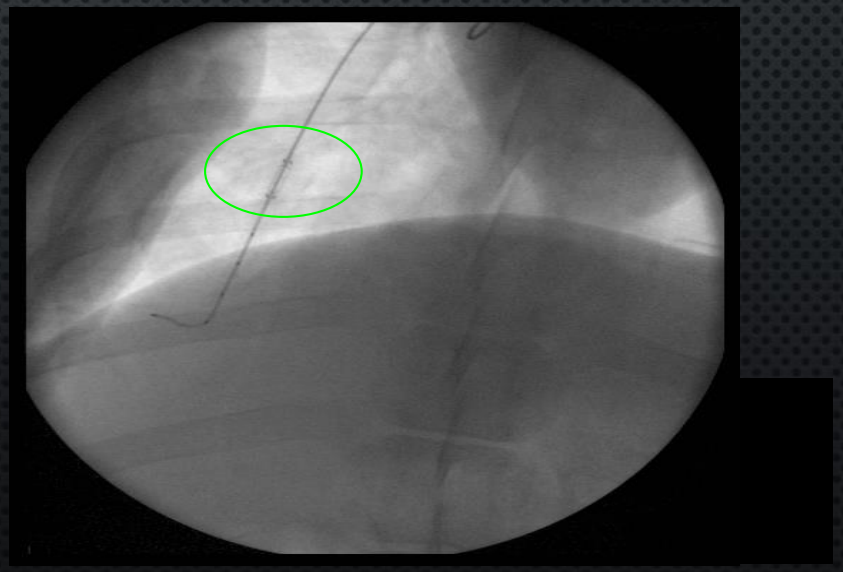




IMPLANT PROCEDURE

3. Introduce and Deploy Sensor:

- Remove the sensor from the package and flush the guidewire lumen with saline.
- Introduce the sensor delivery catheter over the guidewire through the sheath and into position at the target implant site.
- Release the sensor: Unscrew the cap on the delivery catheter hub, then retract and remove the wires from the catheter.
- Retract and remove the delivery catheter while maintaining guidewire and sensor position.



IMPLANT PROCEDURE

4. Prepare for Baseline Calibration
   - Insert the PA catheter over the guidewire into the main PA.
   - Remove the guidewire.
   - Position the PA catheter tip approximately 5-10 cm proximal to the sensor or within the opposite lung and measure PA pressure.
   - Acquire the sensor signal using the Hospital Electronics System antenna placed under the patient's back centered under the sensor position.

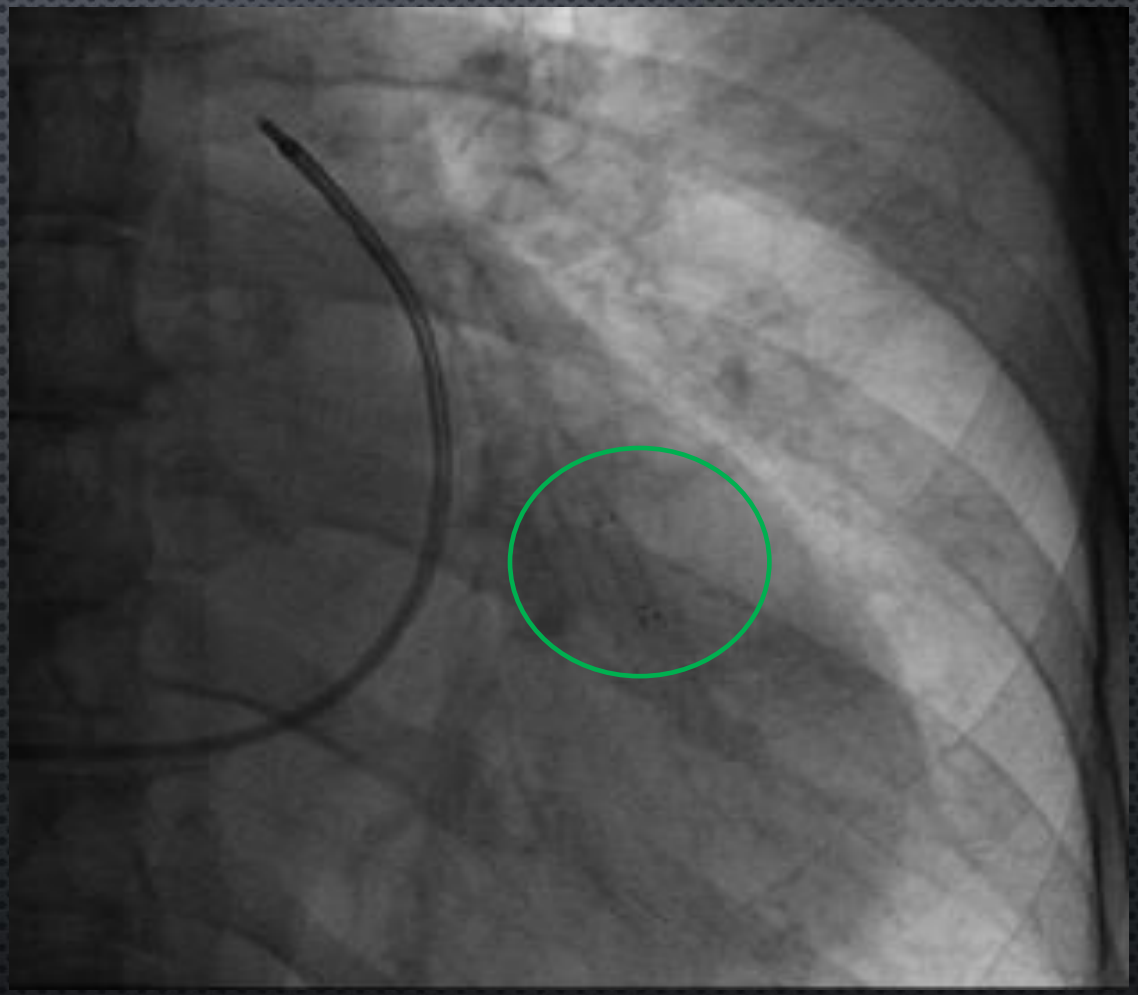


Image from CHAMPION clinical study data

IMPLANT PROCEDURE

5. Baseline Calibration and Procedure Completion

- Set Mean PA Pressure Baseline
- Set Cardiac Output Baseline
- Press the "Take Reading" button to capture baseline reading(s)
- Remove antenna from under patient's back
- Remove pulmonary artery catheter and introducer sheath
- Close venous access site per standard-of-care

TROUBLESHOOTING TIPS

Procedure Step	Challenge	Recommended Solution
Accessing PA with PA Catheter	Difficulty advancing through heart to PA	1. Use guidewire to assist. 2. Use alternate catheter. Pulmonary wedge catheter is more steerable.
Angiogram	Angiogram is unclear	1. Perform angiogram with balloon wedged or partially wedged. 2. Use pulmonary wedge catheter with larger lumen for better image.
Sensor Delivery	Difficulty advancing sensor through heart	1. Bring the sensor back to the tip of the sheath and rotate 180 degrees. Then re-advance. 2. If catheter or sensor is unable to pass, do not persist with this same pathway. Carefully remove sensor under fluoro through the sheath, rolling sensor as it enters the tip of the sheath. Remove guidewire and re-float the Swan-Gantz ™ catheter. After doing this, repeat the PA and 45 deg. LAO angiograms to confirm proper guidewire placement. Repeat delivery.

TROUBLESHOOTING TIPS

Procedure Step	Challenge	Recommended Solution
Sensor Delivery	Guidewire position lost during sensor insertion	Refer to the angiogram roadmap and determine if by advancing the wire the target vessel can be cannulated. If there is a possibility the guidewire is not in the target vessel, retract and remove delivery catheter. Reintroduce PA access catheter to repeat angiograms and place guidewire across target implant site.
Catheter Retraction	Sensor movement with catheter retraction	Advance and retract delivery catheter in small increments until independent movement is confirmed. Retract catheter while leaving sensor in position.

TROUBLESHOOTING TIPS

Procedure Step	Challenge	Recommended Solutions
Guidewire Retraction	Sensor movement with guidewire retraction	**Preventative Measures:** 1. Straighten guidewire tip prior to retracting past sensor. This may be done proactively by retracting into delivery catheter tip prior to removing delivery catheter. 2. A nitinol core guidewire is less prone to tip kinking vs. stainless steel guidewires, which facilitates retraction without sensor movement. **Solutions** 1. Use a torque device on guidewire to spin as it is being retracted to break contact friction between the sensor and guidewire. 2. If GW retraction without sensor movement is not possible, advance PA catheter over guidewire and position ~5cm proximal to sensor. Remove slack from PA catheter shaft before inflating balloon. Inflate balloon and slowly advance the balloon just proximal to sensor. Take care not to tangle balloon with sensor or advance balloon past sensor. Use balloon as a proximal stop to block sensor movement and retract guidewire. Deflate balloon and re-position it away from the sensor for measurements.

TROUBLESHOOTING TIPS

Procedure Step	Challenge	Recommended Solutions
Readings	Pressure waveform pulse amplitude is not consistent with PA catheter pressure waveform pulse amplitude.	1. Ensure cables are cleared away of the antenna. 2. Move the finder up and down +/- 30 mm Hg to confirm there is not a stronger, more pulsatile signal in these other locations. 3. The sensor could be wedged in a too small vessel or pressure waveform could be dampened by thrombus on sensor. Investigate with Swan-Ganz angiogram proximal to sensor. Reposition sensor by intravascular means and/or address thrombus. Confirm normal press pulse pressure waveform prior to procedure completion. Note that repositioning during the implant procedure should be possible, but it will not likely not be possible to reposition later.

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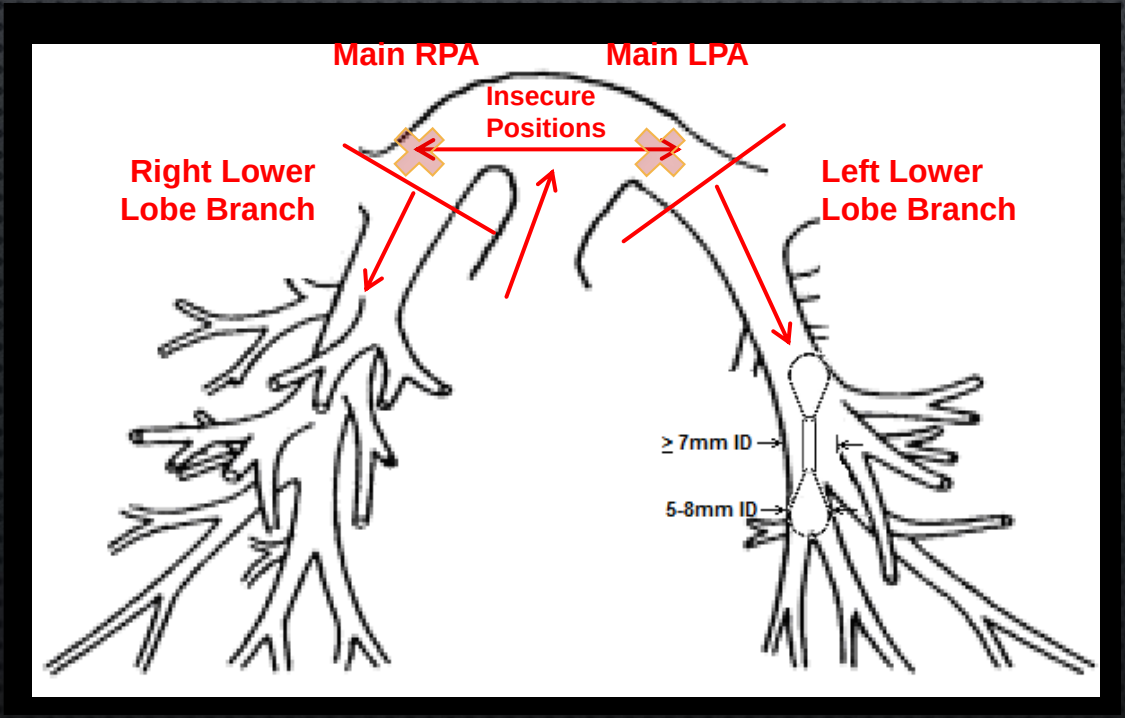
SENSOR MIGRATION POST RELEASE

- Sensor migration within the PA (e.g. left to right) may occur if:
  - Sensor is proximally placed near the left or right main PA.
  - Sensor position is affected during retraction and removal of the Swan-Gantz™ catheter at the end of the procedure

- Sensor placed in the proximal left or right PA has increased potential to shift position in the timeframe shortly following the procedure



GUIDELINES FOR PREVENTING SENSOR MIGRATION POST RELEASE

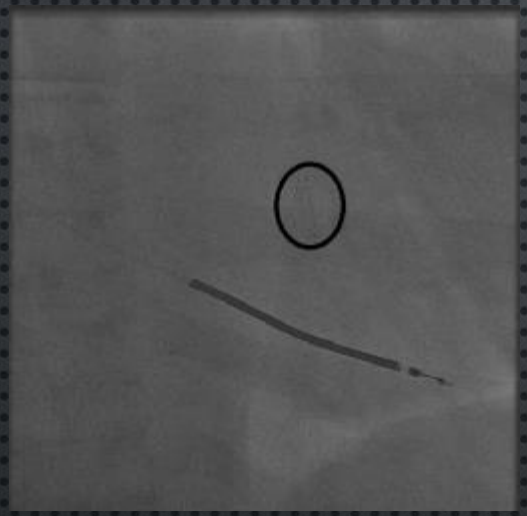
Consistent with IFU requirements:

- Ensure sensor is securely placed within lower lobe, after end of primary curve
- Target distal loop placement in a vessel with ID 5-8 mm
- Monitor sensor position under fluoroscopy during retraction of delivery catheter, guidewire, and Swan-Gantz™ catheter (SG) catheter from the pulmonary artery. Confirm acceptable sensor position after each retraction is completed
- Confirm final position of sensor at end of procedure after SG removal with sensor cine image captured upon completion of each case
  - Note that if sensor position changed during the procedure due to catheter or guidewire movement, it is important to capture this piece of information to differentiate from movement post procedure
- If there is difficulty with signal acquisition soon after the implant procedure and all existing troubleshooting steps have been performed, attempt reading with the antenna positioned under the opposite side lung. If successful, a chest X-ray is appropriate to confirm
  the position

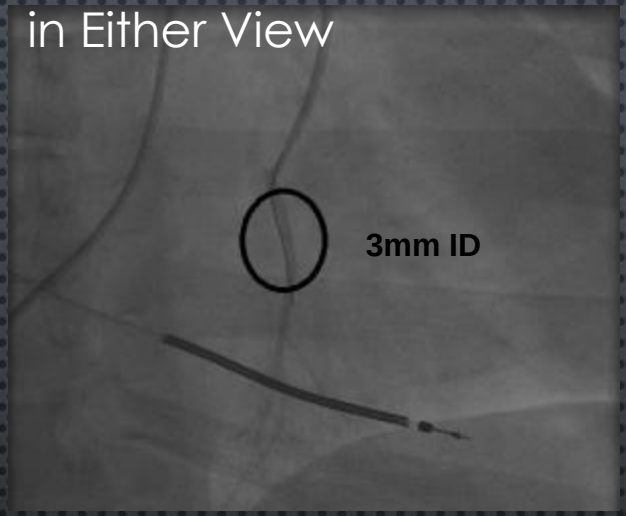
SENSOR PLACEMENT IN VESSEL WITH ID <7MM

Example:

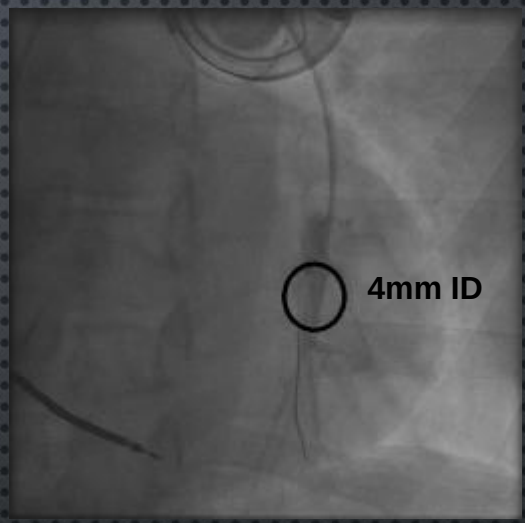
Sensor Position



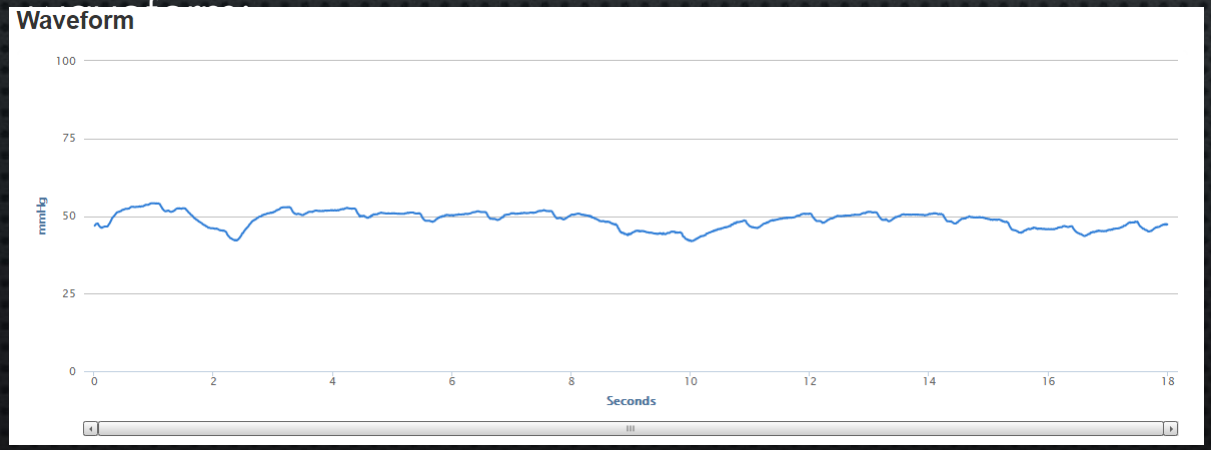
Corresponding Position on Angiograms Too Small in Either View



or



Placement in too small vessel has dampened effect on pressure



- Respiratory excursions apparent, with dampened pulsatility
- May confirm this is real pressure signal (not artifact) by effect of valsalva maneuver or breath hold
- May affect ability to use the sensor as intended

SENSOR PRE-IMPLANT SCREENING TEST PROCEDURE

The pre-implant sensor screening test is an optional test to confirm sensor function prior to use in the implant procedure. If sensor function cannot be confirmed in this screening test, return the sensor via the RMA process for further assessment.

Sensor Pre-Implant Screening Test:

1. Enter Initial Implant mode on the hospital electronics per standard procedure configured with sensor information
2. Move the hospital electronics finder to -20 mmHg position
3. Remove pouch from carton
4. Hold center of pouch Tyvek header over center of antenna
5. Tilt pouch until 99% signal strength is confirmed with pouch header in contact with
   the antenna
6. Slowly pull sensor away from antenna and confirm that signal strength reduces to approximately 50% at approximately 6 inches or greater distance
   Note, if signal strength does not decrease as pouch is pulled away, repeat test with antenna oriented at a different angle
7. Position electronics finder position at 30 mmHg, the default starting position

BASELINE (MEAN PRESSURE) RECALIBRATIONS

Background

- Sensor baseline (mean pressure) recalibration was required in 3.4% of cases in the CHAMPION study

Potential Cause

- Abnormal mechanical loading associated with the biological overgrowth around the sensor is a potential cause
- Reduce potential need for recalibration by following all placement guidelines

Determining Need to Recalibrate

- Per IFU:

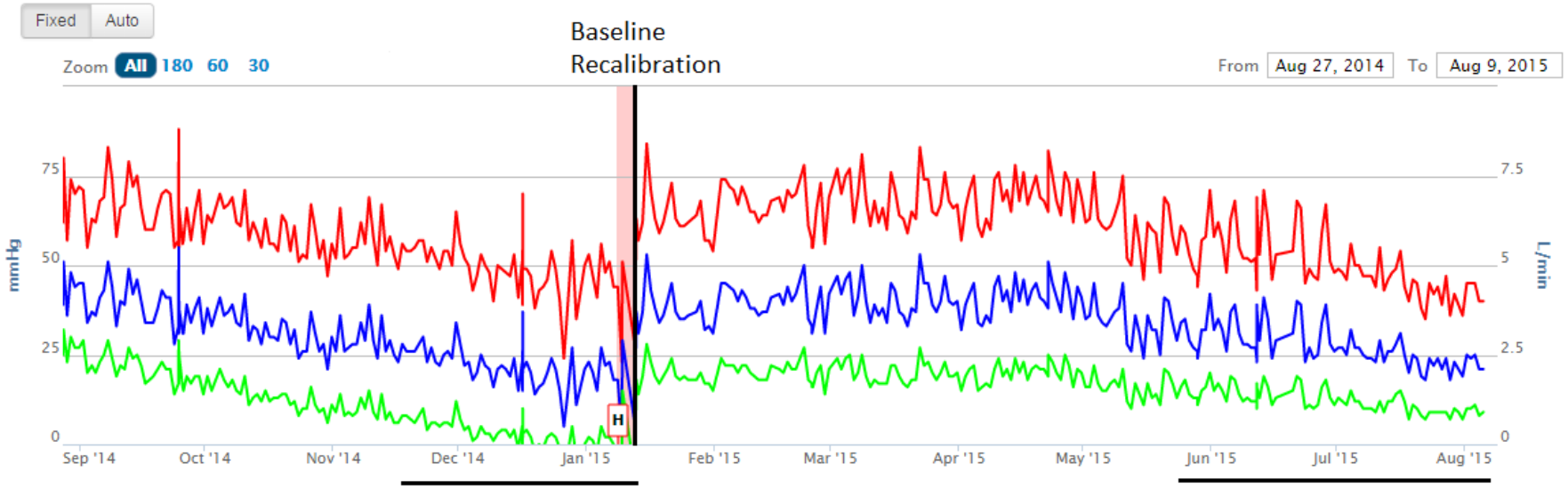
Signs of mean pressure measurement error include the following:

- Gradual mean pressure changes without a corresponding proportional change in the pulse pressure (systolic-diastolic pressure)
- Negative mean pressures

If either feature is observed, temporarily suspend use of the pressure information for management of the patient and contact Technical Support for further assistance. A right heart catheterization may be needed to recalibrate the Baseline (mean pressure) in order to continue use of
the system.

BASELINE (MEAN PRESSURE) RECALIBRATIONS

Example Pressure Trend with Recalibration



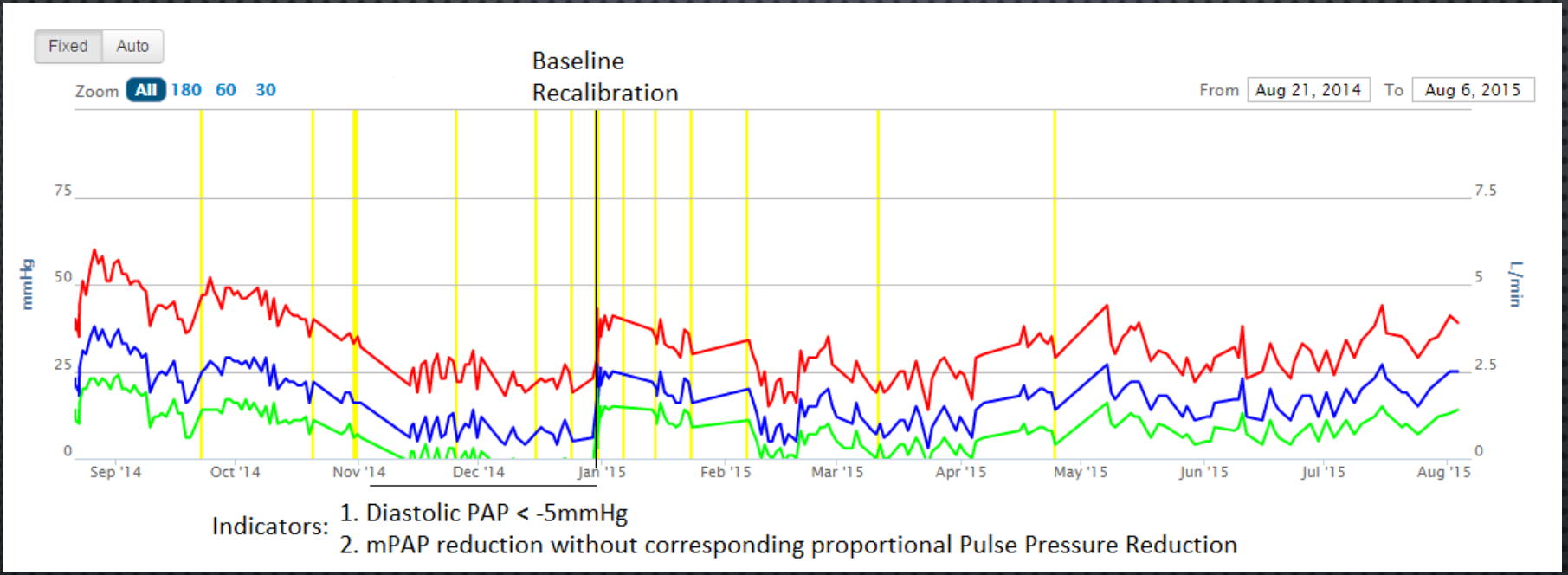
Indicators

1. Mean PAP decrease >20mm Hg without proportional decrease in pulse pressure.
2. Negative diastolic PAP.

Appropriate / Normal Reduction in mPAP with proportional reduction in pulse pressure

BASELINE (MEAN PRESSURE) RECALIBRATIONS

Example Pressure Trend with Recalibration



Indicators:
1. Diastolic PAP < -5mmHg
2. mPAP reduction without corresponding proportional Pulse Pressure Reduction

BASELINE (MEAN PRESSURE) RECALIBRATIONS

If Sensor Data is in Question:

1. Notify area and internal HF specialists for further assessment.
2. Relay assessment to applicable users.
3. If a need for recalibration is determined:
    1. The patient should continue to collect data.
    2. The patient's physician and nurses should suspend use of data to manage patient until it can be recalibrated.

Sensor Baseline (Mean Pressure) Recalibration:

Recalibrations must be performed under the direction of and according to the method prescribed by the patient's physician.

- A new RHC with the baseline calibration step repeated is recommended as the gold standard.
- If a new RHC is not clinically warranted, non-invasive approaches include:
    - The RVSP can be estimated by Echo Doppler (tricuspid regurgitation jet velocity or pulmonary acceleration time). The difference between RVSP and Sensor SPAP provides a recalibration correction amount
    - mPAP can also be estimated using sensor data based on the baseline proportional relationship with pulse pressure

  Non-invasive estimates should be corroborated using both non-invasive methods prior to recalibration.