Remote Monitoring to Detect and Prevent HF Decompensation:

Saturday January 11, 20120

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University of California, San Diego
Heart Failure, Cardiac Transplantation & Mechanical Circulatory Support
Disclosure Information and Patient Consent

No relevant disclosures for either medications or devices discussed in this talk. We will not be discussing off label use of mechanical circulatory support device.

If used, all patient-related pictures during this presentation are from the patient/patient’s loved ones and presented with the patient’s consent.
Discussion Summary

• Challenges in advanced heart failure
• Patient identification for remote monitoring
  - Where did we fail?
• The CardioMEMS experience
  - How can we succeed?
  - Workflow Concentration
• A future for remote monitoring devices
challenges in advanced heart failure.
| 6.2 Million | Adults in the U.S. living with heart failure |
| Close to 600,000 are in the advanced stages |
| 300,000 | Patients die of heart failure in the U.S. annually |
| 50% | Mortality within 5 years of Diagnosis |
| $30.7 Billion | Annual Cost of Heart Failure in the U.S. |

Leading cause of hospitalization in the U.S. and Europe

| Highest readmission rate of any diagnosis related group | 20% at 1 month, and 50% at 6 months |

Heart Failure prevalence in the US is projected to increase 46% by 2030. Patients with HF will rise to 8M in 2030, one in every 33 people.

### Table 1. Projections of the US Population With HF From 2010 to 2030 for Different Age Groups

<table>
<thead>
<tr>
<th>Year</th>
<th>All</th>
<th>18–44 y</th>
<th>45–64 y</th>
<th>65–79 y</th>
<th>≥80 y</th>
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<td>2012</td>
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<td>396,578</td>
<td>1,907,141</td>
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<td>2015</td>
<td>6,190,606</td>
<td>402,926</td>
<td>1,949,669</td>
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<td>2020</td>
<td>6,859,623</td>
<td>417,600</td>
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<td>7,644,674</td>
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<td>2030</td>
<td>8,489,428</td>
<td>450,275</td>
<td>2,000,896</td>
<td>3,857,729</td>
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HF indicates heart failure.
Economic Burden of Heart Failure will continue to rise through 2030

The AHA estimates that the total medical costs for HF are projected to increase to $70B by 2030 → a 2-fold increase from 2013

80% of costs related to hospitalization

*Circ Heart Fail. 2013;6:606-619* Heidenreich et al Forecasting the Impact of Heart Failure
Hospitalizations
Median survival decreases after heart failure-related hospitalization

Average age of heart failure hospitalization in community = 74.77 years

1st
Hospitalization (n=14,374)

2nd
Hospitalization (n=3,358)

3rd
Hospitalization (n=1,123)

4th
Hospitalization (n=417)

References:
Clinical Parameters Worsening

Observed mortality by number of the specific risk factors

One or more of the following risk factors should trigger generalist to refer to an advanced heart failure center:¹⁵
- Systolic blood pressure ≤90 mm Hg
- Creatinine ≥160 μmol/l
- Hemoglobin ≤120 g/l
- No treatment with renin-angiotensin system antagonist
- No treatment with beta-blocker

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<th>NO. AT RISK RISK FACTORS</th>
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<td></td>
<td>530</td>
<td>192</td>
<td>32</td>
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How problematic are readmissions, really?
patient identification for remote monitoring.
"No, it's not water. You seem to be retaining food."
Current HF Management
How well do current tools keep patients stable and out of the hospital?

90% of HF hospitalizations due to symptoms of pulmonary congestion\(^1,2\)

Post-hoc analysis of 463 acute decompensated HF patients from DOSE-HF and CARRESS-HF

AT DISCHARGE

40% moderate to severe congestion\(^3\)

60% absent or mild congestion\(^3\)

AT 60-DAY FOLLOW-UP

TODAY’S TOOLS ARE INADEQUATE at relieving congestion (inpatient) and preventing re-congestion and readmission (outpatient) – even at well-established HF management programs and with the best HF-trained specialists.

41% of previously decongested patients had severe or partial re-congestion\(^3\)

The Iceberg Analogy

Photo by National Geographic
How we have failed?

Patient Selection

- **TIM-HF**
  - 3-lead ECG, BP and weight
  - Participants had stable HF

Patient Flow

- **Tele-HF**
  - Telephone-based interactive voice response
- **Beat-HF**
  - Health-coaching telephone calls: weight, BP and sx

Service Management

- Mayo Clinic Study
  - Telemonitoring in primary care in top 10% of Elder Risk Assessment Index
  - Unclear plan of follow-up. Most PCP-directed ER visits

< 55% patients used device 3 d/w

61% patients half-adherent

How about the Intervention?

Koehler F et al. Circulation 2011;123:1883
Ong et al. JAMA Intern Med 2016;176:310
Current HF Management: How can we get ahead of symptoms associated with acute decompensation?

ambulatory pulmonary artery pressure monitor.
Propective, multicenter
Randomized single-blinded trial
(550 patients)

Inclusion. NYHA III HF
- Age: 18+ yrs
- HF > 3 mos
- No LVEF distinction
  - BB > 3 mos
  - ACEI/ARB > 1 mos
- 1+ HF hospitalization ≤ 12 mos
- BMI ≤ 35 kg/m²
- PA branch diameter 7-15 mm
- Non-pregnant female subjects

Exclusion.
- Active infection
- Recurrent PE or DVT
- Unable to tolerate RHC
- CRT implanted ≤ 3 mos
- Major cardiac event
- GFR < 25mL
- Candidate for OHT ≤ 6 mos
- Congenital heart disease
- Mechanical right heart valves
- Diagnosed coagulation disorder
- Hypersensitivity/allergy to ASA/Plavix

Follow up: month 1, 3, 6, then every 6 months thereafter, up to 36 months

Adamson et al. J Card Fail 2011;17(11)
Cumulative heart failure-related hospitalization

- 28% reduction in the primary end point of HFH at 6 months
- 37% reduction in HF hospitalizations over the entirety of the trial

Interventions Linked to Decrease HFH during Ambulatory PAP Monitoring

Costanzo et al. JACC HF 2016; 4(5):333-44
FDA: communications between nurses and patients went beyond the trial protocol → may have contributed to the reduction in heart failure hospitalizations and limited the ability to evaluate the impact of the CardioMEMS system
### Evaluation of Renal Function from the CHAMPION Trial

<table>
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<th>All Patients</th>
<th>Patients With Chronic Kidney Disease at Baseline (eGFR &lt;60)</th>
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<tr>
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<td>Active Monitoring Group (N = 270)</td>
<td>Blind Therapy Group (N = 280)</td>
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<tr>
<td>Baseline creatinine</td>
<td>1.40 ± 0.47 (270)</td>
<td>1.35 ± 0.42 (280)</td>
</tr>
<tr>
<td>Creatinine change from baseline to 6 months</td>
<td>0.10 ± 0.45 (230)</td>
<td>0.07 ± 0.38 (235)</td>
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<tr>
<td>Baseline GFR</td>
<td>60.4 ± 22.5 (270)</td>
<td>61.8 ± 23.2 (280)</td>
</tr>
<tr>
<td>GFR change from baseline to 6 months</td>
<td>-3.1 ± 17.0 (230)</td>
<td>-1.0 ± 16.4 (235)</td>
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</table>
## Table 5. Heart Failure Hospitalization Rates by Baseline Ejection Fraction Subgroup: 6-Month Primary End Point Period

<table>
<thead>
<tr>
<th>Ejection Fraction</th>
<th>Randomization Group</th>
<th>No. of Heart Failure Hospitalizations</th>
<th>6 mo Rates of Hospitalization for Heart Failure</th>
<th>Incidence Rate Ratio (95% CI; P Value)</th>
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<tr>
<td>≥50%</td>
<td>Treatment group (n=35)</td>
<td>9</td>
<td>0.18</td>
<td>0.50 (0.29–0.86; 0.0129)</td>
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<tr>
<td></td>
<td>Control group (n=31)</td>
<td>10</td>
<td>0.35</td>
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Impact of Practice-Based Management Pulmonary Artery Pressures in 2000 Patients Implanted with the CardioMEMS Sensor

<table>
<thead>
<tr>
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<th>CHAMPION Clinical Trial Cohort Treatment+Control (n=550)</th>
<th>General-Use Cohort (n=2000)</th>
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<tbody>
<tr>
<td>Age, y</td>
<td>61.59±12.83</td>
<td>69.67±12.26</td>
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<tr>
<td>Male sex, n (%)</td>
<td>399 (72.55)</td>
<td>1169 (59.80)</td>
</tr>
<tr>
<td>Ejection fraction ≥40%, %</td>
<td>21.72*</td>
<td>33.79*</td>
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<tr>
<td>Baseline PA pressure, mm Hg</td>
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<tr>
<td>Systolic PA pressure</td>
<td>46.4±14.5</td>
<td>49.7±14.1</td>
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<tr>
<td>Diastolic PA pressure</td>
<td>24.5±9.1</td>
<td>25.4±8.3</td>
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<tr>
<td>Mean PA pressure</td>
<td>31.6±10.7</td>
<td>34.9±10.2</td>
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Post-marketing Adverse Events Related to the CardioMEMS HF System

5500 CardioMEMS HF system implants in the United States - 155 reports (2.8%) describing 177 unique adverse events during the first three years after FDA approval

- 28 reports of PA injury/hemoptysis
- 18 technical challenges with implantation (14 aborted)
- 46 sensor failure, malfunction, or migration
  - 35 require recalibration
- 15 access-site related bleeding/infection
- 5 pulmonary embolism/device thrombosis

PA injury/hemoptysis and deaths were clustered early after device introduction and appeared to stabilize over time
CardioMEMSTM HF System: FDA Approval for Pulmonary Artery Pressure Monitoring on May 28, 2014

This device is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.
Where are we now in 2019 with CardioMEMs?

Controversy remains around the technology, however, based on its approval after a single trial.

Adoption has been limited by **variable payer coverage**, including the lack of a national coverage decision from the Centers for Medicare and Medicaid Services (CMS) in the US.

The **GUIDE-HF trial** (NCT03387813) aims to enroll 3600 patients with NYHA FC II, III, and IV)
addressing workflow.
CardioMEMs Workflow

UCSD Heart Failure
Initiating the Discussion

First discussion with Patient

1. When considering the device, discuss the CardioMEMS HF system in depth with both patient and caregiver.
2. Explain that the CardioMEMS HF system can help better manage the patient’s HF and hopefully avoid future hospitalizations
3. For more information, refer to the patient education section of the CardioMEMS HF system program practice guide.
Setting patients up for Success

Training patients before Implant
1. Once a patient is identified, they will be contacted by the Remote Monitoring team. All patients and caregivers will be contacted to undergo education on their CardioMEMS HF system patient electronics system before implantation.
2. Each patient will keep a blood pressure, heart rate and weight diary for the month prior to their implant.
3. Abbott patient education resources will be provided to each patient.

Setting up patient profile on Merlin.net
1. After a patient is implanted with the CardioMEMS HF system, it is important to appropriately set up the patient for successful remote monitoring.
   • An initial review of the Merlin.net patient profile to update the information should be done the day before implant.
Selection of potential patients

Inclusion Criteria: (all must be met)

- More than one hospitalization for acutely decompensated heart failure < 12 months
- Persistent NYHA Class III symptoms for at least 3 months or elevated BNP > 300
- Presently on optimal evidence based medical and device therapy for heart failure
- Active enrollment with CHF program and run-in period of compliance

Relative Contraindications

- History of poor medical or clinical compliance
- BMI > 35 kg/m² or thoracic circumference > 65cm
- History of CKD (Stage IV or V), GFR < 25 mL/min/m²

Absolute Contraindications

- History of MI or CVA within the past 2 months
- History of recurrent DVT or pulmonary emboli
- Implantation of CRT within past 3 months
- Mechanical Right-sided Heart Valve Replacement
- History of Coagulation disorder or unable to tolerate anti-platelet therapy
CardioMEMs

2-Phased Patient Management Approach

UC San Diego Health System
PHASE I: Post-Implant Considerations

During implant, the implanting doctor will compare PCWP and PAD from the sensor to ensure correlation (If a difference of >5 mmHg is present, consider the variance when establishing PA pressure goals and thresholds) Remember: pressures in the Cath Lab are typically lower than pressure readings at home.

1. At UCSD, we will use sensor PAD pressure as a surrogate for wedge pressure.
2. Patients currently on chronic anticoagulant therapy should restart treatment after sensor implant.
3. Patients not currently treated with chronic anticoagulant therapy should be placed on aspirin (81mg or 325mg) and clopidogrel (75mg) daily for one month following the procedure. After one month, the patient should be on aspirin (or anticoagulation) therapy indefinitely.
PHASE I: Post-Implant Considerations

Right after the implant, during recovery:
1. Check patient’s recovery after the implant procedure.
2. Assess if they understand how to properly take daily readings.
3. We will inform patients we will be contacting within the next couple of days as we monitor the PA pressures. The team will:
   • Set wide thresholds during this optimization phase
   • Review patient’s initial readings to assess PAD trends.
   • Verify the waveform from reading is a physiologic PA pressure waveform

Team will set initial PAD pressure threshold and program on Merlin.net. For the first week, usually 1mmHg above the highest daily pressure reading, and the bottom of threshold 10mmHg below that.
PHASE II: 2-week Post-Implant

- **First 2 weeks**: daily monitor
  - Quality of waveforms
  - Respiratory/positional and diurnal variations
  - Changes before/after medications
  - AM values

- **After PAD is at goal**, we monitor by exception
  - Setting thresholds and only looking if thresholds are crossed
  - If thresholds have not been crossed, we look once a week (for regulatory compliance reasons)

\[
\Delta \text{PAD} > -5 \text{mmHg} \quad \text{Goal PAD} \quad \Delta \text{PAD} > +5 \text{mmHg}
\]

Intervention Intervention
PHASE II: Maintaining Euvolemia

Weeks to months post implant
- Assess PA pressures 2-3 times per week until patient’s pressures are optimized.
- Treat to trends generally lasting 3 or more days; program email notifications accordingly.
- Usually after a month, a trustworthy initial PAD goal for patient can be established.
- Assess thresholds every 2 weeks; adjust and reprogram accordingly on Merlin.net.

Setting target PAD thresholds
- Many clinicians report they program target PAD thresholds 5 mmHg above/below target PAD goal: (i.e. PAD goal = 19 mmHg, PAD thresholds = 14-24 mmHg)

Once, stable, our team will evaluate pressures at least one time per month; reassess goals, and/or reprogram thresholds as needed.
# 2019 Codes for CardioMEMSTM

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<th>CPT Code</th>
<th>2019 w-RVUs</th>
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<tbody>
<tr>
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<table>
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introducing guide-hf.
Clinical outcomes of Pulmonary Artery Pressure-Guided Management in patients with HFrEF

Givertz et al. JACC 2017;70(15):1875-86
What do we know from Clinical Trials:

- PA pressure monitoring with CardioMEMS HF System prevents hospitalizations over an average of 18-month follow-up.
- Quality of life is improved with hemodynamic guided care after 6 months.
- Hemodynamic monitoring can help in management HF patients with preserved LVEF.
Current Indication
• The CardioMEMS HF System is indicated for HF patients who are NYHA Class III, regardless of ejection fraction, who have been hospitalized for heart failure in the previous year.

Concluding Summary
• The CardioMEMS HF System is safe, reliable and clinically proven in clinical trials and real-world settings for the current indication.
• Using the pressure data provides a proactive, personalized approach to prevent acute decompensation in both HFrEF and HFpEF patients.
GUIDE-HF Rationale

Rationale (two-fold)

1. To generate scientific evidence evaluating whether hemodynamic guided heart failure management **prolongs survival** while improving quality of life and functional capacity and decreasing decompensation events leading to hospitalizations.
2. To evaluate **BNP/NT-proBNP** as an alternative method for identifying subclinical congestion in a wide range of symptoms and an at-risk population (**NYHA Class II-IV**) in addition to HFH.
   - Closer look at those who have “minimal” symptoms (NYHA Class II) but have elevated BNP/NT-proBNP.

GUIDE HF is posted on ClinicalTrials.gov
Identifier: NCT03387813
GUIDE-HF Study Arms

Randomized Arm (~ 1000 patients)
- The GUIDE-HF Randomized Arm is a prospective, multi-center, randomized, controlled, single-blind clinical trial of CardioMEMS HF System in **NYHA Class II, III, or IV** Heart Failure with either elevated **NT-proBNP (or BNP)** and/or a **prior HFH**. Subjects will be randomized 1:1 into groups:
  - **Treatment Group**: management of patients based on PA pressure
  - **Control Group**: management of patients per standard of care

Single Arm (~ 2600 patients)
- The GUIDE-HF Single Arm is a prospective, multi-center, single-arm clinical trial of the CardioMEMS HF System in North America in **NYHA Class III** HF patients only, with either elevated **NT-proBNP (or BNP)** and/or a **prior HFH**.
GUIDE-HF Study Design

• Sample Size:
  – GUIDE-HF Randomized Arm
    • Approximately 1000 subjects
    • NYHA Class II, III, or IV HF patients
    • Elevated NT-proBNP (or BNP) and/or prior HFH
  – GUIDE-HF Single Arm
    • Approximately 2600 subjects
    • NYHA Class III HF patients
    • Elevated NT-proBNP (or BNP) and/or prior HFH

• All patients will be implanted with the CardioMEMS HF System

• Study Duration: 12 months
  – All patients will be followed for 12 months (6 month and 12 month follow-up visits)

• Conducted in up to 140 North American centers with ~5 sites in Canada
GUIDE-HF Key Eligibility Criteria

INCLUSION CRITERIA

- Diagnosis and treatment for HF (regardless of LVEF) for > 90 days prior to the date of consent:
  - Stable, optimally titrated guideline-directed medical therapy for at least 30 days
- NYHA Class II, III or IV HF symptoms
- HFH within 12 months and/or elevated NT-proBNP or BNP within 30 days defined as:
  - Subjects with LVEF ≤ 40%: NT-proBNP ≥ 1000 pg/mL (or BNP ≥ 250 pg/mL)
  - Subjects with LVEF > 40%: NT-proBNP ≥ 700 pg/mL (or BNP ≥ 175 pg/mL)
  - Thresholds corrected for BMI over 25 kg/m²

EXCLUSION CRITERIA

- Intolerance to all neuro-hormonal antagonists
- ACC/AHA Stage D refractory HF
- Received or are likely to receive an advanced therapy in the next 12 months
- NYHA Class IV HF patients with continuous or chronic use of scheduled intermittent inotropic therapy for HF or persistence of fluid overload with maximum (or dose equivalent) diuretic intervention
- Glomerular Filtration Rate (eGFR) < 25 mL/min/1.73m² and non-responsive to diuretic therapy, or receiving chronic dialysis
- Enrollment into another trial with an active treatment arm
GUIDE-HF Randomized Arm Endpoints

<table>
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<tbody>
<tr>
<td>Composite of:</td>
</tr>
<tr>
<td>• HFHs</td>
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<tr>
<td>• Urgent HF Visits (emergency department / hospital outpatient observation visits for IV diuretic therapy)</td>
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<tr>
<td>• All-cause mortality</td>
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*All contributing events adjudicated by the CEC*
GUIDE-HF is the first trial to evaluate the impact of hemodynamic monitoring on the combination of:

- Hospitalizations / Urgent HF Visits
- Mortality
- Disease progression
- Functional capacity
- Long-term quality of life

In heart failure patients at high risk for decompensation.
introducing merlin10.
<table>
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<tr>
<th>Patient / Clinician</th>
<th>Notification / Date</th>
<th>Goal / Type</th>
<th>Last Measurement</th>
<th>Last Reading</th>
<th>PA Trend (Last 7 days)</th>
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<td>18 PA: Diastolic</td>
<td>10-05-2018 PAP</td>
<td>19 mmHg</td>
<td>25 15</td>
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<td>19 mmHg</td>
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Showing 1 - 25 of 34
Ambulatory Monitoring team

Monday Morning Team

- Heart Failure Attending (HFA)
- Heart Failure Fellow (HFF)
- Physician Assistants
- Heart Failure RNs

**Red Tier:** check every 2-3 days

**Yellow Tier:** check every week

**Green Tier:** check every month

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<th>Patient / Observer</th>
<th>Notification Date</th>
<th>Goal / Type</th>
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the future of cardiomems.
introducing heartlogic and endotronix.
HeartLogic™ Heart Failure Diagnostics
- a method of proactive care-

HeartLogic™ incorporates multiple sensors with a single composite alert

Available on LATITUDE™ NXT
for patients with
Resonate™ family of
ICDs & CRT-Ds

Heart Sounds
S1 and S3

Impedance
Thoracic

Respiration
Rate & Volume

Activity
Time Spent Active

Heart Rate
Nocturnal

HeartLogic™ incorporates multiple sensors with a single composite alert

53
3 Mar 2017

Issues alert when index crosses threshold

Physician configurable threshold

UC San Diego
SCHOOL of MEDICINE
Cordella and Endotronix Heart Failure Diagnostics
- a method of proactive care-

Daily vital signs, symptoms & patient engagement

Pulmonary Artery Pressure Sensor

Currently in Use

Investigational Product

Adds 20s PAP reading to daily routine
## Cordella and Endotronix Heart Failure Diagnostics

### Patient’s Home

- **Blood Pressure**
- **Heart Rate**
- **Oxygen Saturation**
- **Weight**
- **Single lead ECG**
- **Pulmonary Artery Pressure**
- **Symptoms**
- **Patient Education**
- **Patient Self-management**

### Clinic Portal

- **Review Key Clinical Data**
- **Communicate with Patients**
- **Manage Individualized Care Plans**
- **EMR Integration (meds, labs, patient history, diagnosis)**
- **Personalize Patient Thresholds**

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The diagram illustrates the integration of patient and clinic data through a secure cloud server, enabling real-time communication and personalized care. Cordella and Endotronix together offer innovative solutions for heart failure diagnostics, enhancing patient care and outcomes.
Cordella and Endotronix Heart Failure Diagnostics

- **SIRONA**  First-in-Human: ongoing
- **SIRONA II**  CE Mark Study: Q4 2018
- **PROACTIVE-HF**  IDE Study: Q1 2019
Cordella and Endotronix Heart Failure Diagnostics

1. Subject blinded to PAP Measurements only
2. PAPGHFM-PAP Guided Heart Failure Management
3. GDMT-Guided Directed Medical Therapy
4. Clinician blinded to PAP Measurements only
in summary.

- Early identification of patients who can benefit from close monitoring is essential
- Patient selection is very important is key to the success of your remote monitoring program
- GUIDE-HF is underway, this will be the first prospective look at mortality benefit of the CardioMEMS system.
- Patient management with appropriate MD/APP/RN workflow is extremely important
Just don’t leave your patients hanging

Photo by Carla Lombardo Ehrlich (World Wildlife Foundation)
Feel free to contact me if you have any questions
(point camera at the QR code and follow instructions, no need to take picture)

Thank you.