The ReDS™-HF Study

Evaluation of ReDS™-Guided Patient Management in Ambulatory Heart Failure Patients At-Risk for Re-Hospitalization

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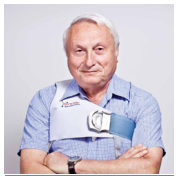
Lung Fluid Status Monitor



SensiVest™
Daily Measurements

SensiCloud™
Physician Portal

- ReDS medical radar technology - enables direct lung fluid quantification
- RF sensors are embedded in the wearable vest
- Short daily measurement session - 90 seconds
- The system includes a cellular communications module that enables automatic data transmission to a secured cloud

Background

- Despite current therapies and disease management approaches, the rate of heart failure hospitalization remains unacceptably high
  - > 3.5 million heart failure hospitalizations annually in EU + US
  - #1 cause of hospital readmission in many geographies
    - > 25% readmission rate at 1 month in US
    - > 50% readmission rate at 6 months in US
    - > $18 billion in annual direct costs of hospitalization in the US
- Current methods for monitoring and managing heart failure patients have not adequately addressed this problem

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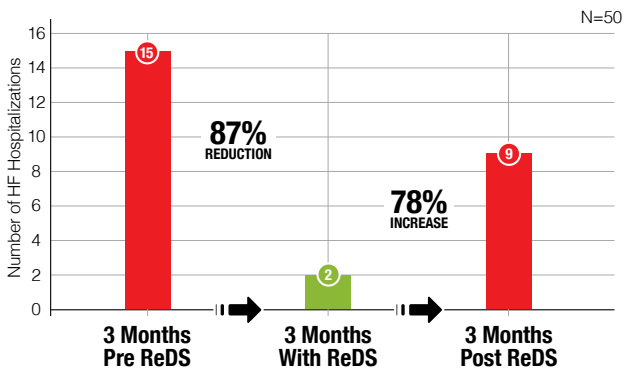
ReDS™-HF Study Design

- Prospective, 3-center, single-arm, intervention study of ReDS guided heart failure management
- **Objective:** Assess the feasibility and safety of heart failure management guided by ReDS as an adjunct to standard of care in outpatients for 90 days following discharge from ADHF hospitalization
- **Primary Endpoint:** Number of heart failure hospitalizations during 90 days of ReDS guided management, compared to the 90 days before and after ReDS guided management
- **Safety:** Number of device related AE during 90 days with ReDS

ReDS™-HF Readmission Reduction - Economic Benefit Feasibility Study



Statistical Analysis

- Study findings show **87% reduction in readmission** between the pre-ReDS period and the ReDS guided management period and **78% readmission reduction** between the post-ReDS period and the ReDS guided management period.
- Comparison between the periods was performed by calculating the **Hazard Ratio (HR)** between the different periods using **Andersen-Gill model** (A-G).
- **3 months Pre-ReDS** - The HR between the pre-ReDS period and the ReDS guided management period was **0.07, 95% CI (0.01-0.54), P = 0.01**
  This represents **14 times more risk for readmission event** in the pre-ReDS period than during the ReDS guided management period.
- **3 months Post-ReDS** - The HR between the ReDS guided management period and the post-ReDS period was **0.11, 95% CI (0.4-0.88), P = 0.037**
  This represents **9 times more risk for readmission event** in the post ReDS period than during the ReDS guided management period.

ReDS Notifications Administration

Notifications were sent to the physicians every time the ReDS readings of a patient crossed a pre-defined threshold.

- **80% of the treatment changes led to fluid reduction (decrease in ReDS readings).** In 81% of the changes, the patient returned to within the pre-defined threshold within a week.
- In 74% of the notifications the physician changed the patients' HF management and in the balance continued follow up.
- The changes in management included medications and diet changes, treatment adherence conversations and threshold adjustments.

Conclusions

- Current findings suggest that ReDS-guided management reduces HF readmissions in patients recently discharged following ADHF hospitalization
- Remote pulmonary fluid assessment with ReDS technology is feasible and may aid in optimizing treatment of patients recently discharged after ADHF hospitalization
- No device related adverse events were noted
- The study described is a feasibility study, a larger randomized controlled trial is currently recruiting

clinical trials.gov
NCT02448342