

PRESENTATION TO MEDCAC

MARCH 22, 2017

HEALTH OUTCOMES IN STUDIES FOR HEART FAILURE
TREATMENT TECHNOLOGIES – MEASURING LUNG FLUID

Disclosures

- Eran Kurman is the VP Sales and Marketing at Sensible Medical and presenting the data in behalf of Aharon Abbo, MD, Chief Medical Officer of Sensible Medical
- Sensible Medical, a medical device manufacturer, and thus has a major interest in Sensible and in these proceedings.
- Dr. Abbo and Mr Kurman are not a member of any federal Advisory Committee and has no intellectual conflict of interest in this meeting.
- Sensible Medical manufactures the ReDS® Vest, an FDA cleared medical device, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications, including living with heart failure or recovering from Coronary Artery Disease or a related event. As such, Sensible Medical has a major interest in these proceedings.

Main Points

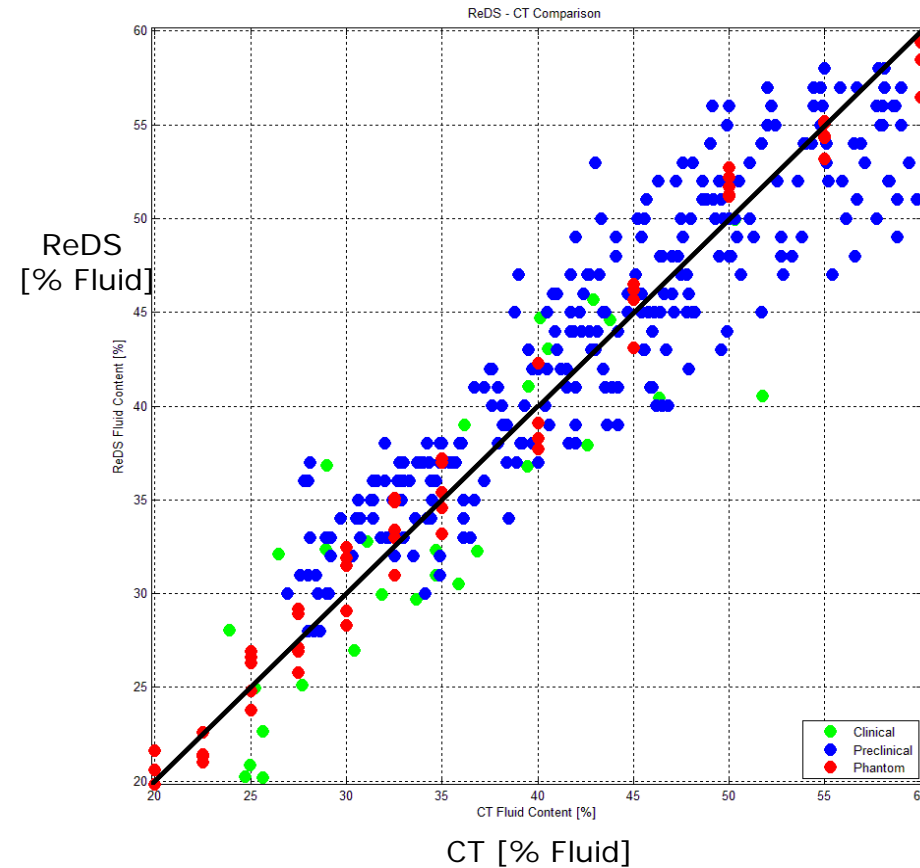
- MEDCAC Should Accept Heart Failure Hospitalization Readmission As a Valid Clinical Endpoint in Appropriate Situations
 - Given CMS use of hospitalization re-admission as a quality and reimbursement metric, it is appropriate to use as a clinical endpoint as well
- MEDCAC should stratify use of endpoints depending upon technology involved
 - The higher the risk to the patient, the higher the level of evidence
 - CMS should adopt continuum of endpoints depending on the risk level of the procedure involved, whether the procedure is invasive or non-invasive, and based upon other appropriate criteria
 - Example:
 - Lower-risk non-invasive devices endpoint may be Hospital readmission reduction
 - Higher risk Implanted devices endpoint may be related to Mortality

Main Points

- MEDCAC Should Adopt ABSOLUTE Lung Fluid Volume as an Acceptable Objective Surrogate Measurement
 - Most HF patients presents with shortness of breath when disease exacerbates due to lung fluid congestion
 - Currently available questionnaires are subjective
 - There are new technologies cleared for marketing that provide an ABSOLUTE measurement of lung fluid (as opposed to a relative change of lung fluid)
 - Lung fluid volume measurement should be considered as a synergetic, absolute outcomes measurement
 - Measurement is simple, non-invasive, inexpensive, and reliable
 - Results are predictive of health outcomes and treatment

Evidence for
ABSOLUTE measurement of lung
fluid

Evidence of Accuracy -ReDS vs. CT - 0.9 Correlation



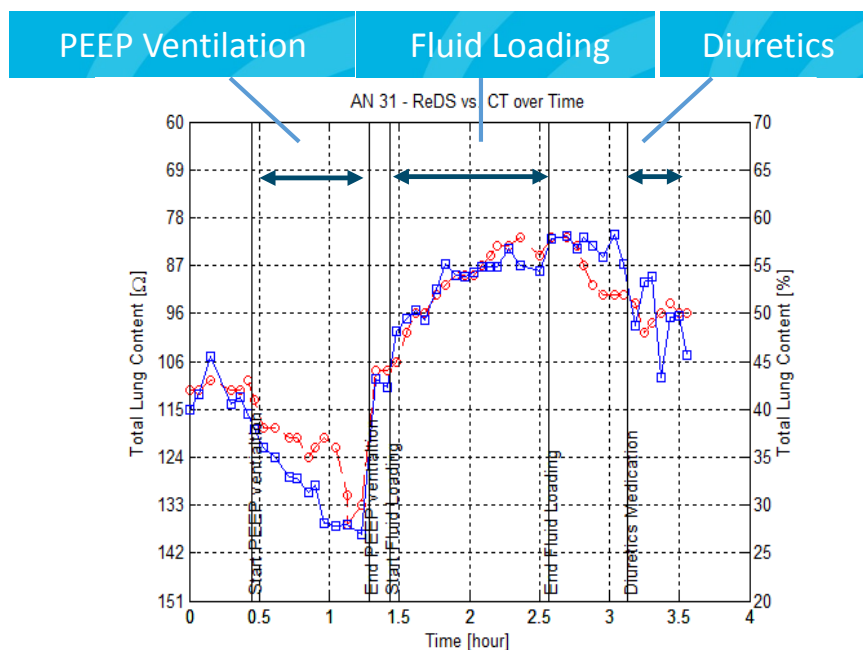
358 Data Points

- Phantom
- Preclinical
- Clinical

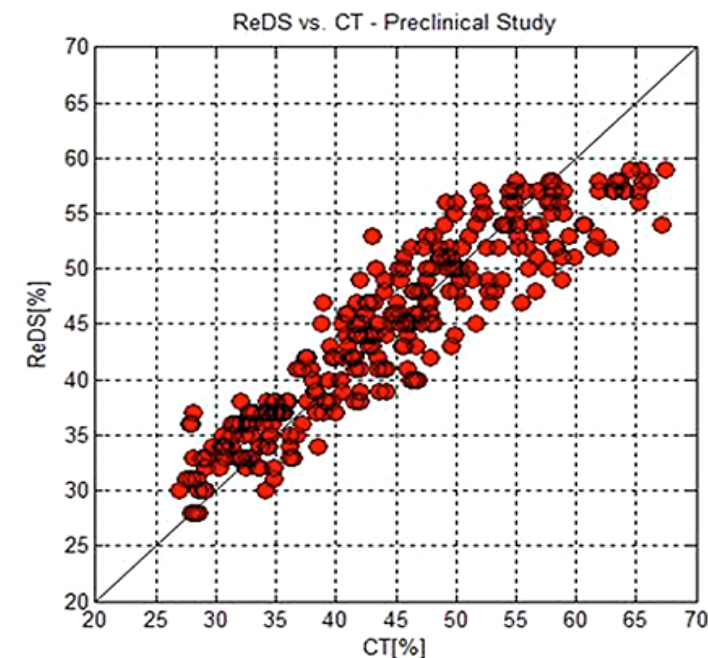


Intraclass correlation coefficient (ICC) 0.9 [0.8-0.95]

Porcine Model Results -- ReDS™ vs CT



One Animal over time



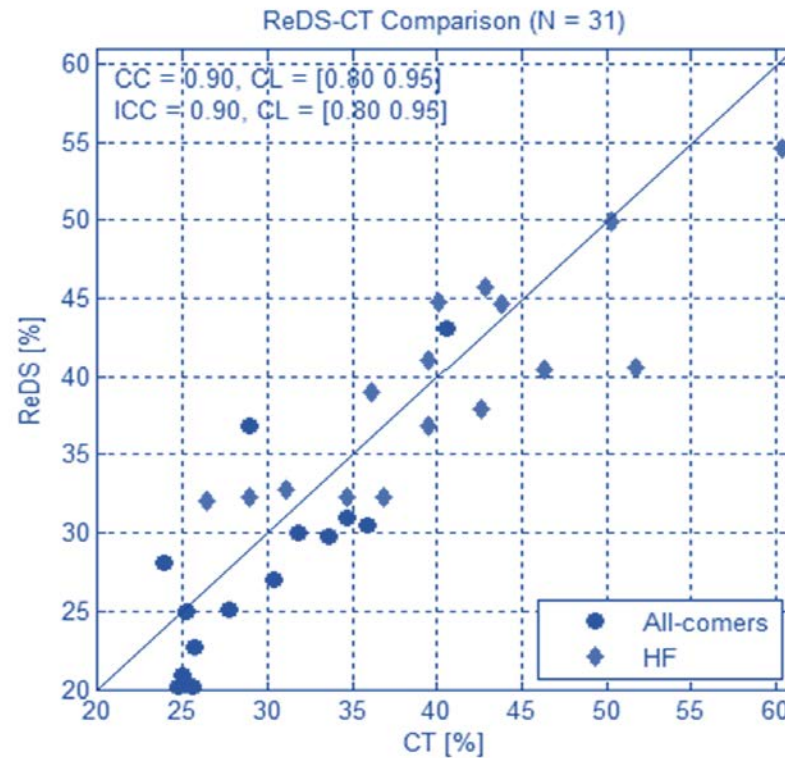
All Animals - 294 data point

Intraclass correlation coefficient (ICC) 0.89 (0.86-0.93)

CT Fluid quantification with commercially available syngo. CT Pulmo3D™ tool (Siemens)

Offer Amir, MD; Dan Rappaport, PhD; Barak Zafrir, MD; William T. Abraham, MD. "A Novel Approach to Monitoring Pulmonary Congestion in Heart Failure: Initial Animal and Clinical Experiences Using Remote Dielectric Sensing Technology" *Congest Heart Fail.* 2013; 19:149-155.

Clinical Results -- ReDS vs CT



ReDS Vs. CT
measurement of lung fluids

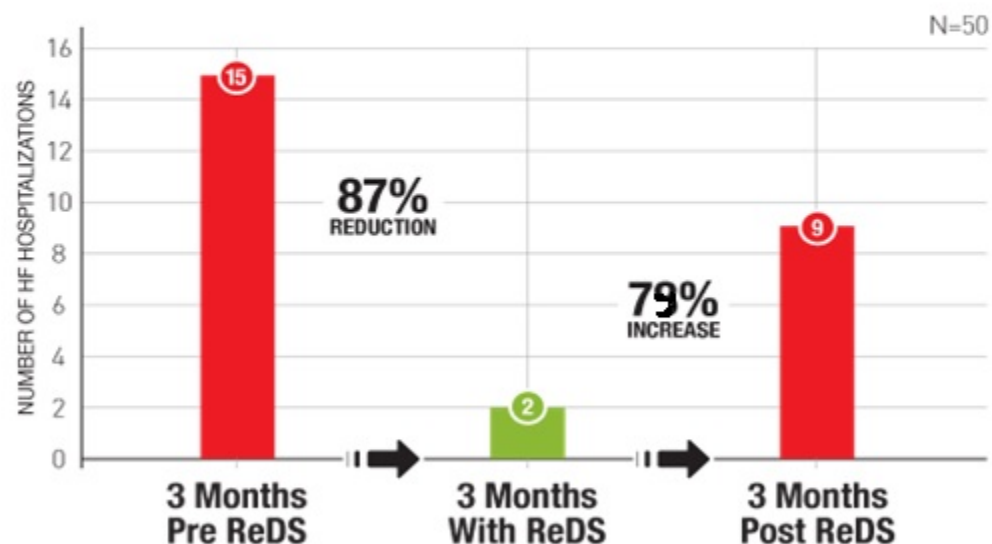
Intraclass correlation coefficient (ICC) 0.9

CT Fluid quantification with commercially available syngo. CT Pulmo3D™ tool (Siemens)

Offer Amir, Zaher S. Azzam, Tamar Gaspar, Suzan Faranesh-Abboud, Nizar Andria, Daniel Burkhoff, Aharon Abbo, William T. Abraham. "Validation of remote dielectric sensing (ReDS™) technology for the quantification of lung fluid status: Comparison to high resolution chest computed tomography in patients with and without acute heart failure." International Journal of Cardiology 221 (2016) 841-846.

ReDS™-Guided Management Reduced the Heart Failure Rehospitalization Rate

ReDS™ -HF Readmission Reduction - Economic Benefit Feasibility Study



Pre vs. ReDS: $P = 0.01$ | Post vs. ReDS: $P = 0.037$

Thank you

Backup Slides

**A CASE STUDY – REDS[®], LUNG FLUID ANALYSIS, AND
THE OBJECTIVE CLINICAL MEASURE OF HEART FAILURE
TREATMENT AND
READMISSION REDUCTION**

The ReDS™ Wearable System: What Is It?

**Radar (RF)
monitoring and
imaging technology**

Military see-through-
wall technology



Cleared for
market in
the USA

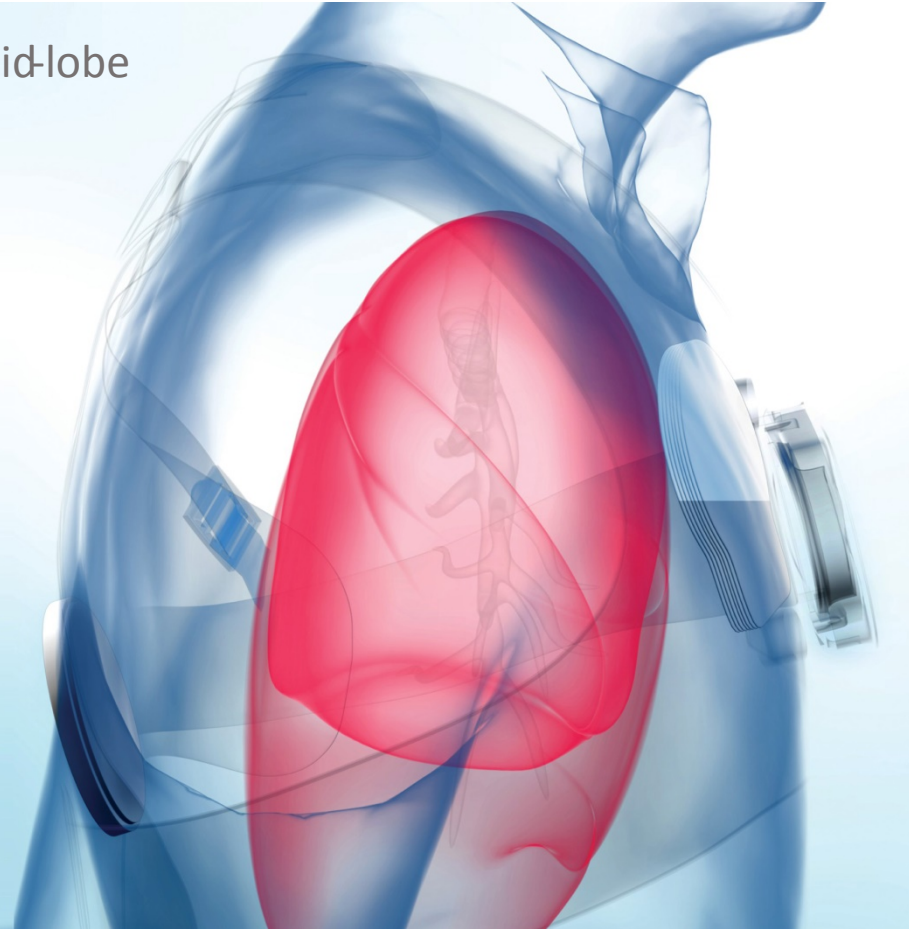
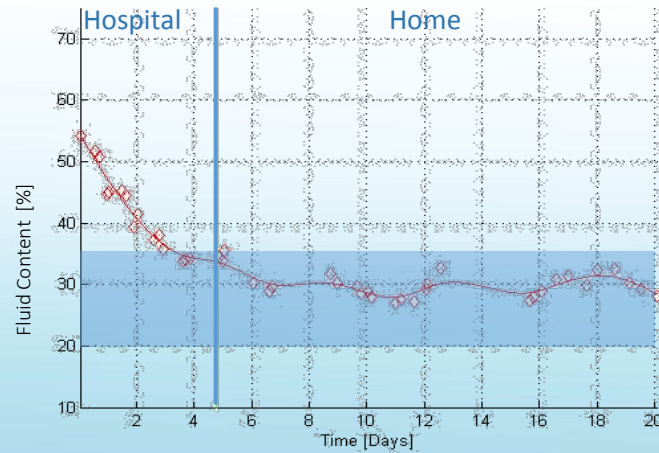


The ReDS™ Wearable System



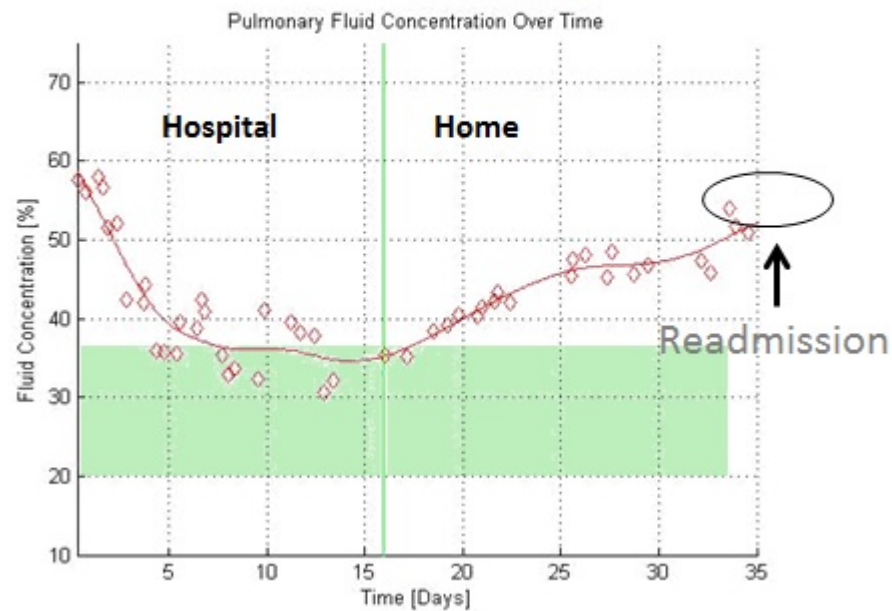
The ReDS™ Wearable System: What Does It Measure?

- Absolute lung fluid content located at right mid-lobe
- Normal lung measures 20-35% fluid content (default target range)

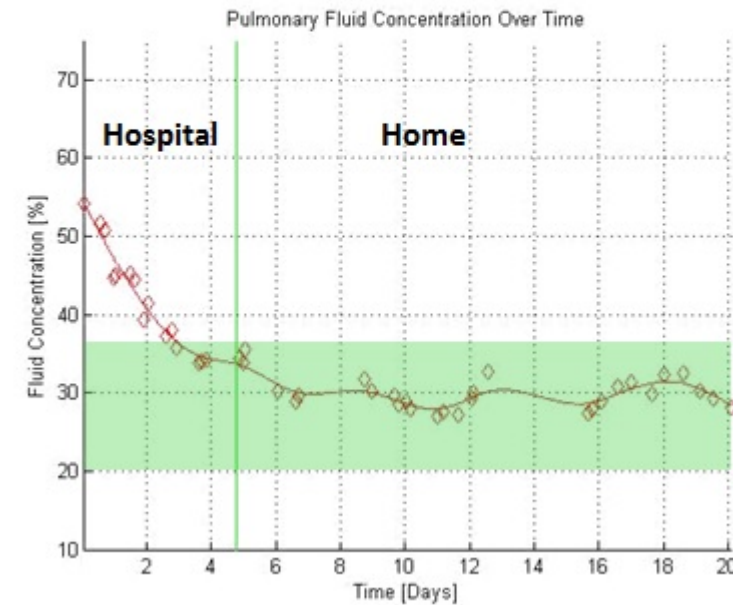


The ReDS™ Wearable System: Heart Failure Monitoring

Standard of care treatment without ReDS™



ReDS™ guided treatment



With ReDS™ patients are kept within their “green” safe zone

MEDCAC Should Recommend Use of Re-hospitalization as a Clinical Outcomes Measure

- CMS adoption of re-hospitalization as a quality measure supports use of re-hospitalization as a clinical outcomes measure as well
 - Alignment of clinical and quality measures should be paramount
 - HF readmission in studies should be adjudicated appropriately and can be done in a consistent method- also across different studies (CMS could advocate a standard)

MEDCAC Should Adopt Lung Fluid Measurement as a Surrogate Endpoint

- Lung fluid measurement is a pathophysiological based objective measure of cardiac treatment efficacy
- Simple and easy to measure, non-invasive measurement, and cost effective
- A direct, HF related, clinical endpoint that has not been effective to measure in the past, but which can be measured today

MEDCAC Should Recommend Risk-Based Levels of Evidence

- Not all clinical trials should require the same level of evidence
 - Invasive devices should require different outcomes than non-invasive devices
 - Procedural risk should be factored into evidence requirements
- Reality is that the “gold standard” of two RCTs is restricting access to treatment for millions with heart failure, who remain inappropriately at risk upon discharge or readmission and potential future heart failure episodes.