31 GIORNATE CARDIOLOGICHE TORINESI

TURIN
October
24th-26th
2019

Heart failure and remote monitoring of implanted cardiac device

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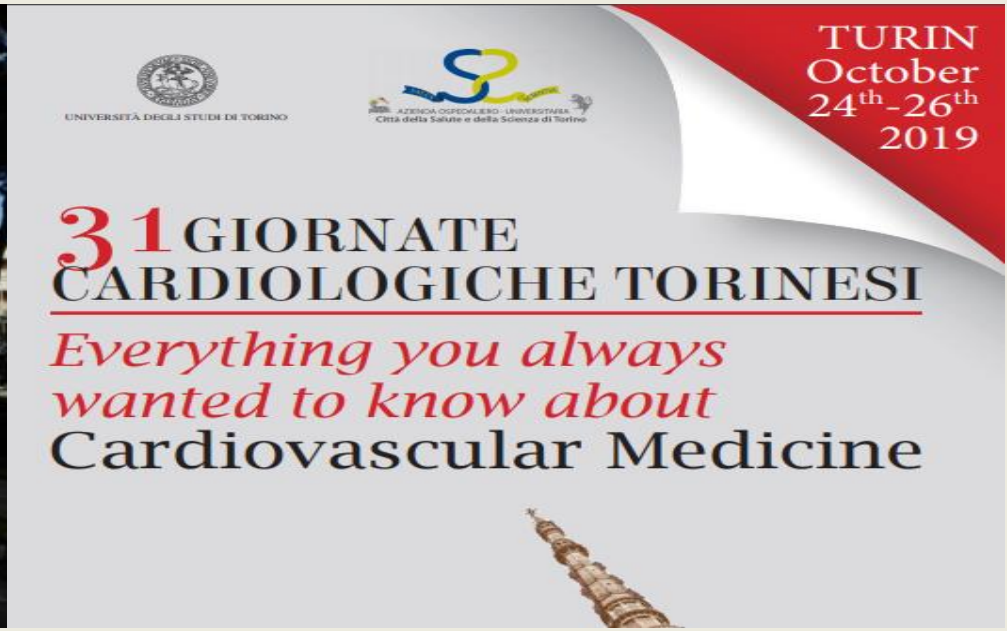
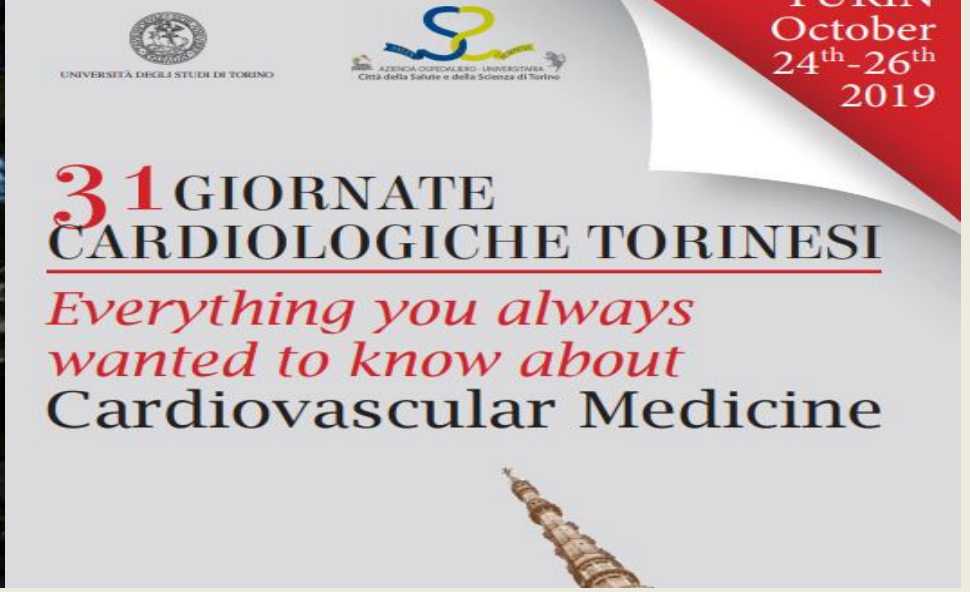


No Conflict of Interest

- **Heart failure remains one of the largest medical problems of our time.**
- **Despite significant advances in medical and device therapy during the past 30 years, the morbidity, mortality, and economic burden of heart failure (HF) remains high.**
- **It is a very costly disease, and in 2010, its total cost in the United States alone was estimated to be $39.2 billion.**



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Outcomes for people with Heart Failure

- **Approximately 1 in 10 patients hospitalized with HF will die in hospital[1]**
- **An estimated 1 in 4 will be readmitted to hospital within one month[1,2]**
- **Around 1 in 3 will die within 1 year[3]**
- **Approximately 1 in 2 will die within 5 years[4]**

- 1 Cowie M, *et al*., Heart Failure Association of the ESC. Improving care for patients with acute heart failure. Before, during and after hospitalisation. 2014.
- http://www.oxfordhealthpolicyforum.org/reports/acute-heart-failure/improving-care-for-patients-with-acute-heart-failure
- 2 Sutherland K. Bridging the quality gap: heart failure. The Health Foundation, editor. 2010.
- http://www.health.org.uk/public/cms/75/76/313/583/Bridging%20the%20quality%20gap%20Heart%20Failure.pdf?realName=cXqFcz.pdf
- 3 Ponikowski P, *et al*. European Society of Cardiology WHFA. Heart Failure. Preventing disease and death worldwide. 2014.
- http://www.escardio.org/communities/HFA/Documents/WHFA-whitepaper-15-May-14.pdf?hot=highlighton
- 4 Stromberg A. The crucial role of patient education in heart failure. *Heart Failure Review* 2005; 7:363-369.

Heart failure is a major clinical concern that impacts patients' quality of life and healthcare economics

Heart failure hospitalizations are associated with an :

8-fold increase in mortality

9-fold increase in recurrent hospitalizations[1]

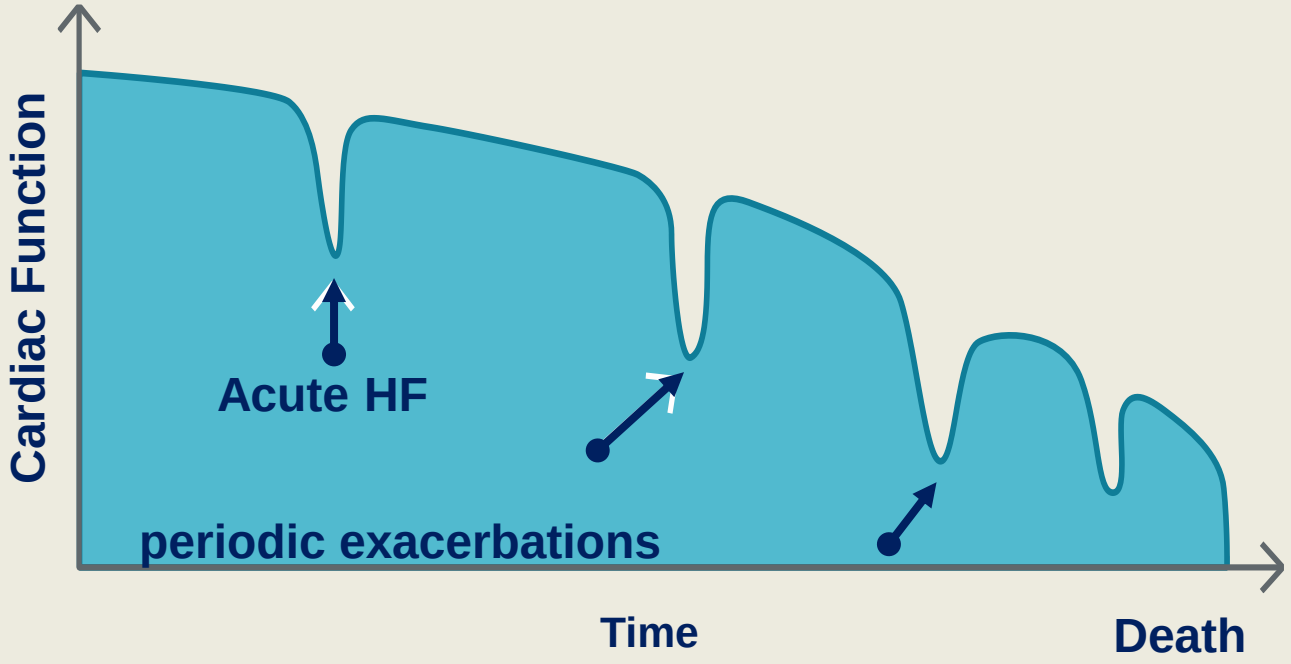
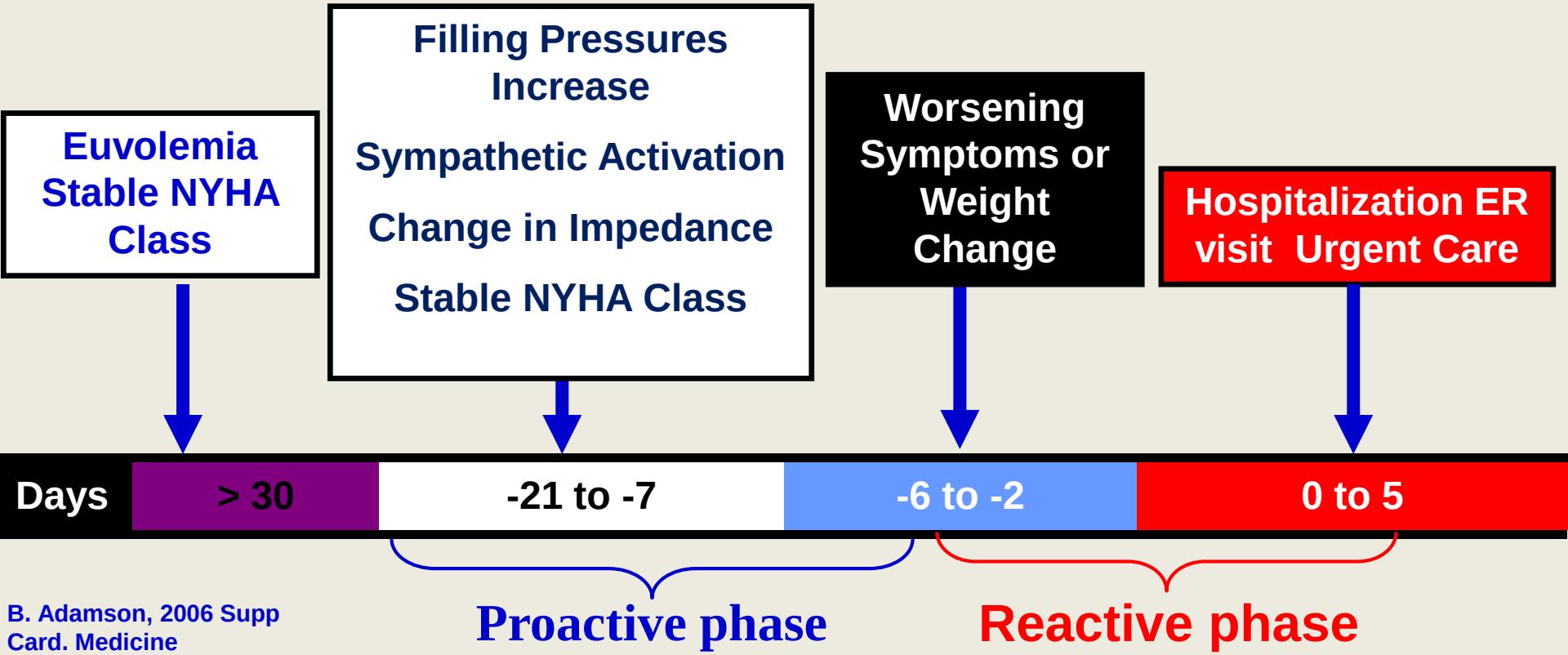


Figure adapted from Goodlin[1]

Acute HF event prevention

Pulmonary congestion is difficult to recognize in its early stages of development because of the late appearance of symptoms before hospitalization



B. Adamson, 2006 Supp Card. Medicine

UNIVERSITÀ DEGLI STUDI DI TORINO

AZIENDA OSPEDALIERO - UNIVERSITARIA
Città della Salute e della Scienza di Torino

October
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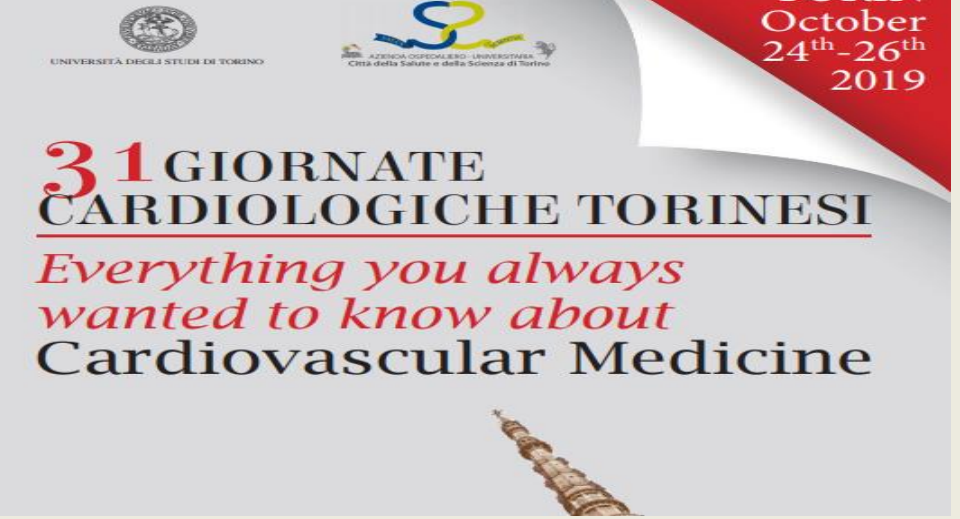
31 GIORNATE
CARDIOLOGICHE TORINESI

Everything you always wanted to know about
Cardiovascular Medicine

Early detection of worsening heart failure by a monitoring implant could enable pre-emptive medical intervention and improve outcomes beyond those achieved with stand-alone implantable devices.

Early diagnosis and intervention may play a crucial role in minimizing major cardiovascular events and reducing hospitalizazion



- **Close monitoring is crucial and can be done through a whole spectrum of modalities and systems.**

- **This monitoring ranges from a nurse-based disease management program, structured telephone support, to remote or telemonitoring with or without the use ICD or ICD-CRT**

HRS Recommentation for Remote Monitoring (RM)

HRS Remote Monitoring Consensus Statement Recommendations		
Device Follow-Up Paradigm	**Class of Recommendation**	**Level of Evidence**
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A
RM should be performed for surveillance of lead function and battery conservation.	I	A
Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.	I	E
RM is useful to reduce the incidence of inappropriate ICD shocks.	I	B-R
RM is useful for the early detection and quantification of atrial fibrillation.	I	A

Primary Results from the MultiSENSE Study

A Multi-Sensor Algorithm Predicts Heart Failure Events in Patients with Implanted Devices

- International, multi-center, non-randomized, clinical study **designed to develop** and **prospectively evaluate** a multi-sensor index and alert for the **early detection of worsening HF**

Key inclusion criteria

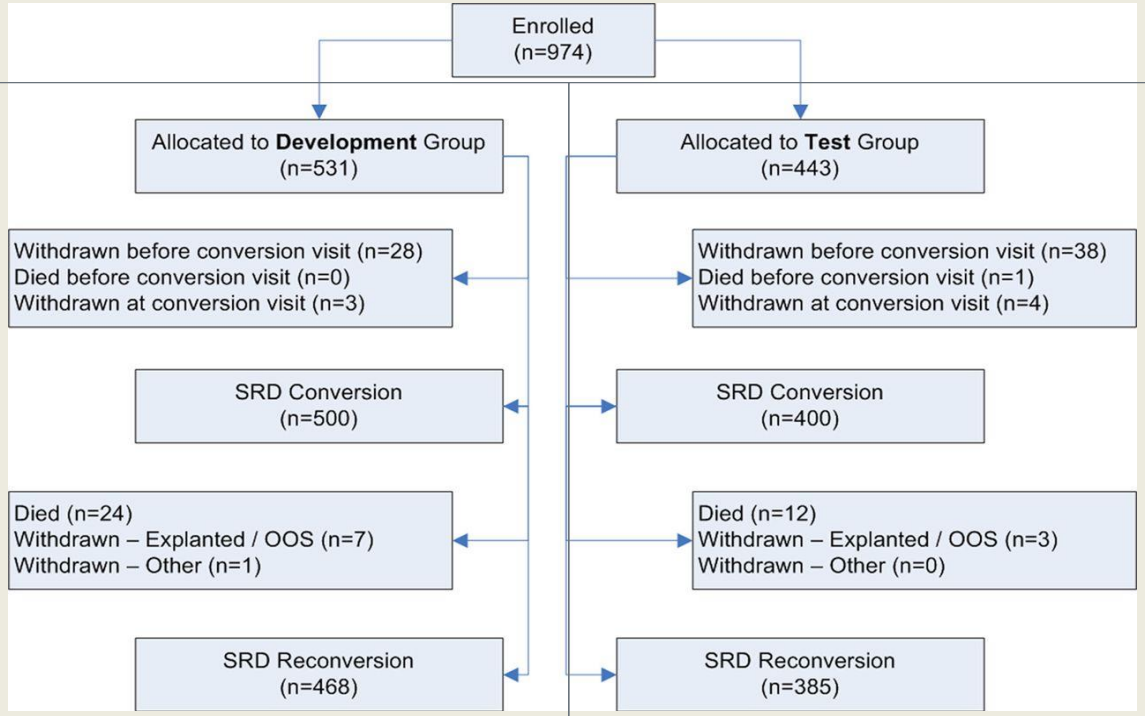
- **Age 18 or above**
- **Currently implanted with a COGNIS CRT-D system**
- **NYHA Class II, III or IV within the last 6 months**

Data was used to develop individual physiologic sensor trends and a

multi-sensor composite alert for worsening heart failure

Development Group 500 patients

Used to develop the algorithm



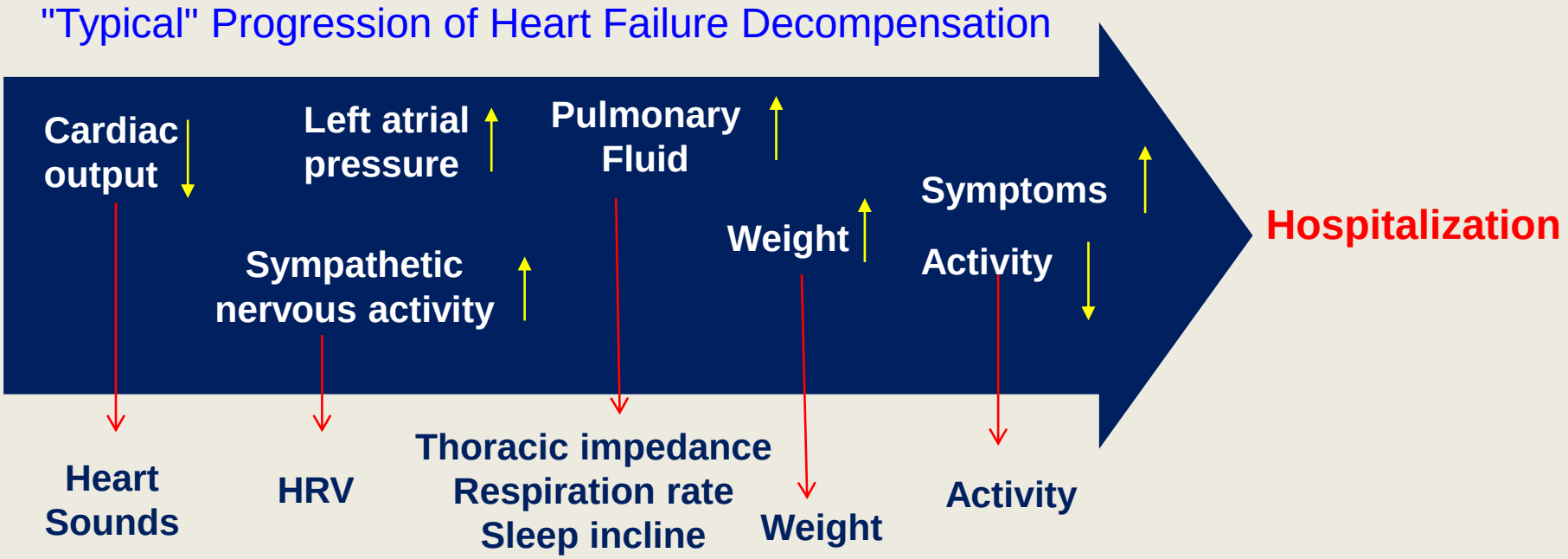
Test Group 400 patients

Used to prospectively validate algorithm

Boehmer, J et al., JACC-HF, 2017;5(3),2 1 6 – 2 5.

Heart failure symptoms of decompensation are possible to identify

Symptoms can vary in presentation and time course, nevertheless, several patterns may precede a decompensation



Early diagnosis and intervention may play a crucial role in minimizing major cardiovascular events and reducing hospitalizazion

Boston Scientific sensors enable the early detection of heart failure decompensation symptoms

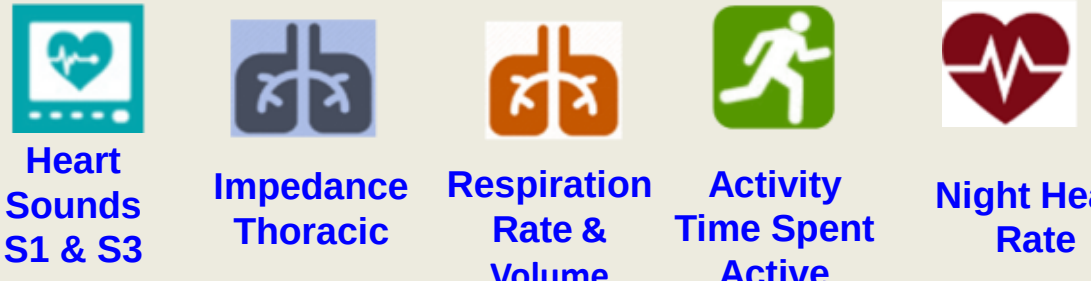
Sensors are intended to represent typical in-office tests and questions

Sensors :	Clinicians ask/do during a physical exam
Heart Sounds	Listen to the heart S3 heart sound
Heart Sounds	Listen to the heart S1 heart sound
Thoracic Impedance	Take chest X-ray for signs of pulmonary edema
Respiratory Rate	"Are you out of breath? Have difficulty breathing?“
Activity Level	"Are you able to get your mail/go upstairs?"
Night Heart Rate	Is resting heart rate elevated?
Weight	"Have you gained weight”

HeartLogic™ Heart Failure Diagnostic

HeartLogic was proven to detect the early warning signs of worsening heart failure by combining data from **5 sensors** into a single composite index.

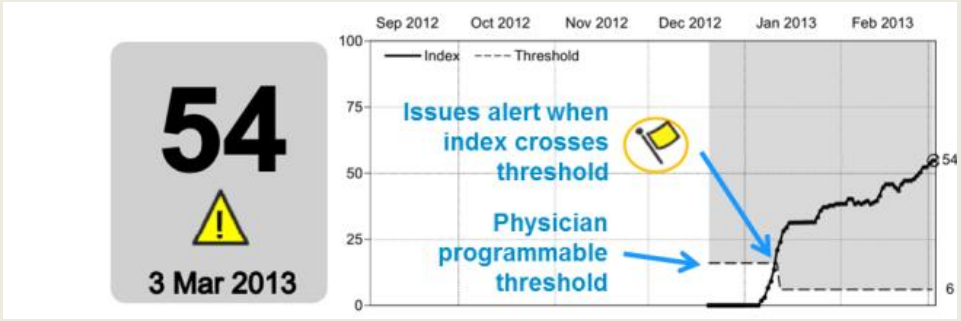
Multiple Sensor Measurements

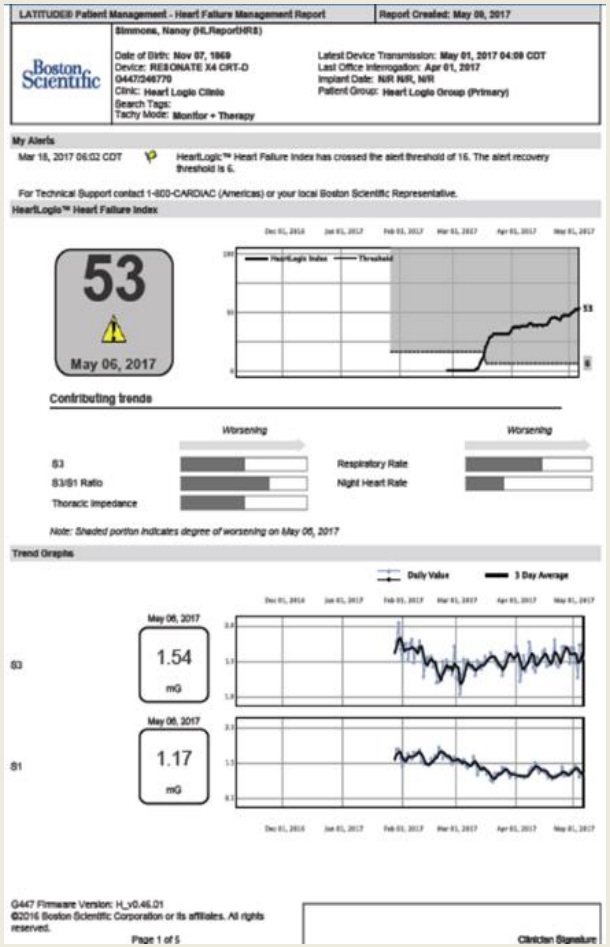


- Heart Sounds S1 & S3
- Impedance Thoracic
- Respiration Rate & Volume
- Activity Time Spent Active
- Night Heart Rate

Combined into a single, simple index with alert

HeartLogic™ Heart Failure Index





Primary Results from the MultiSENSE Study

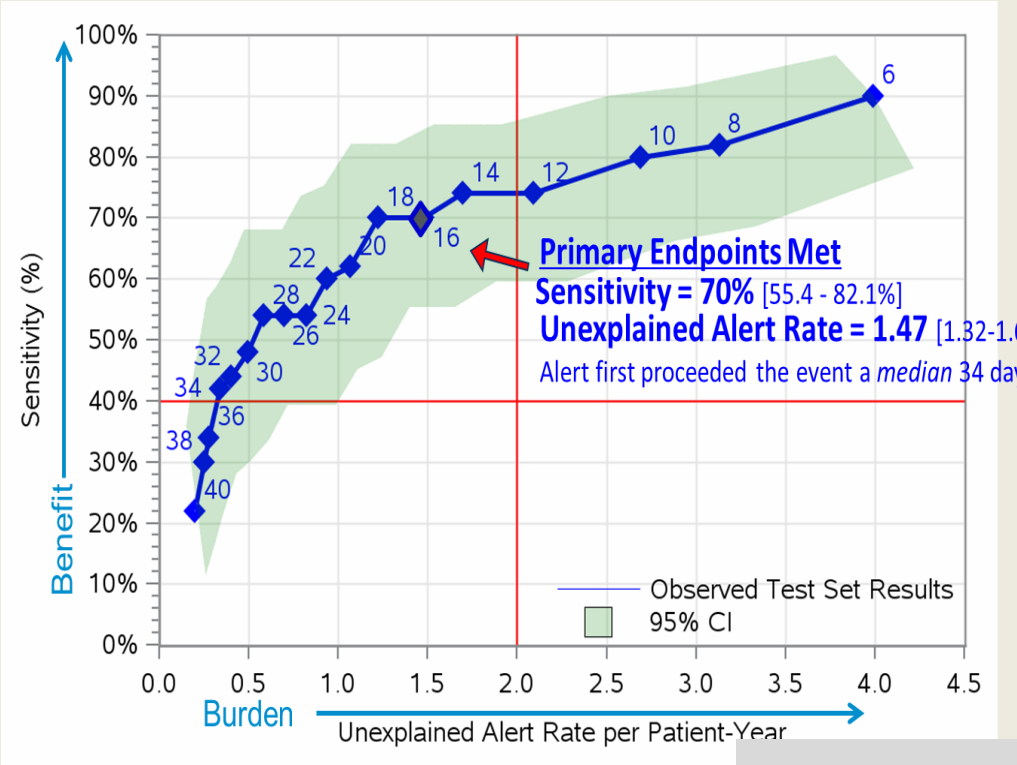
The MultiSENSE Study data demonstrated that HeartLogic

- **Had high sensitivity of 70 %**

in detecting heart failure events at threshold of 16

- **Had a very low burden of less than 2 alerts per patient/ year**

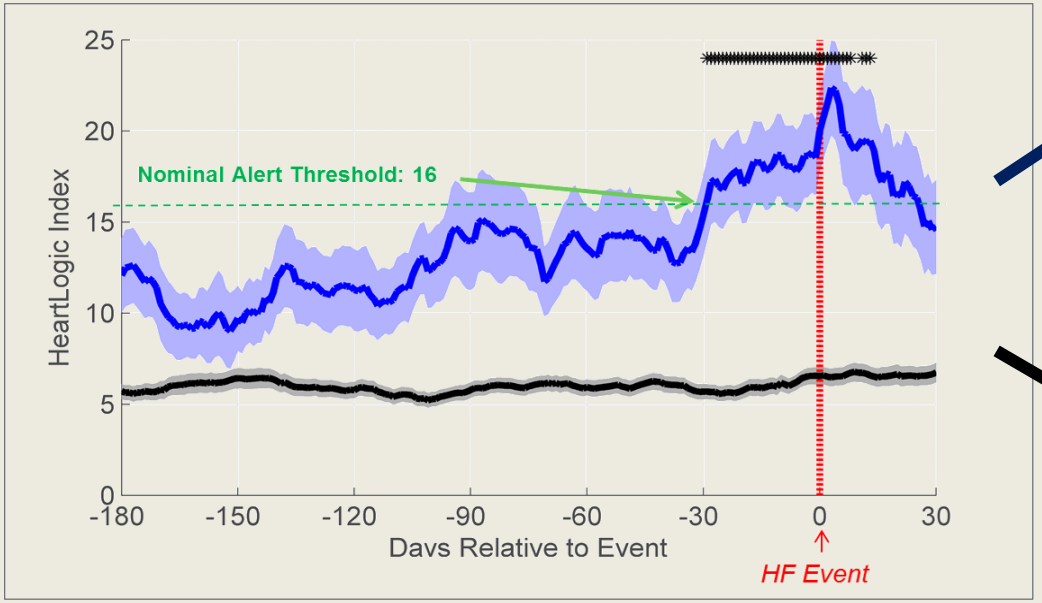
- **May allow several weeks of advanced notice to clinicians of a potential event**



Boehmer, J et al., JACC-HF, 2017;5(3),2 1 6 – 2 5.

HeartLogic™ Index Trends

Compared to 3 month baseline, HeartLogic Index was statistically higher beginning 29 days prior to event.



HeartLogic™ Index in patients **with** Heart Failure Events

HeartLogic™ Index in patients **without** Heart Failure Events

- **Boehmer, J et al., JACC-HF, 2017;5(3),2 1 6 – 2 5.**

Benefit of Multifactorial Approach

Patient A — *Two Observed Cases* — **Patient B**

Which patient
had a Heart Failure Event?

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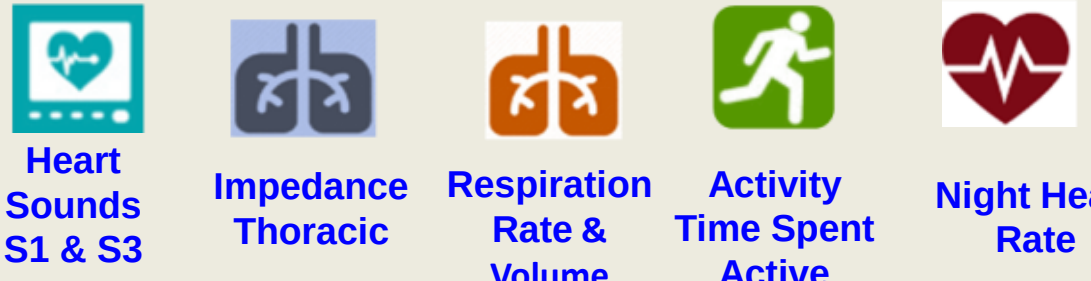

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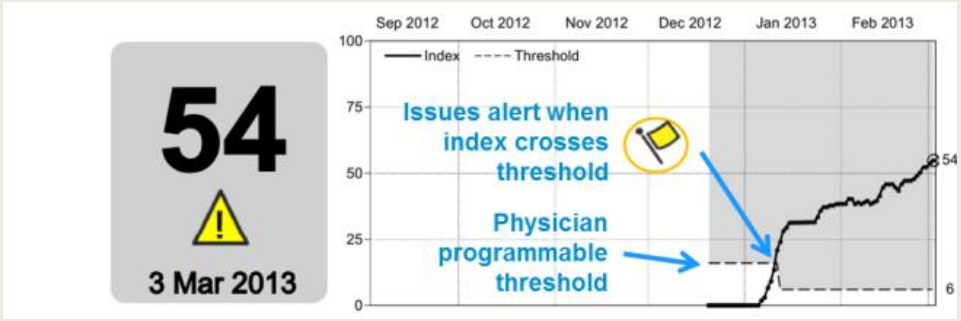

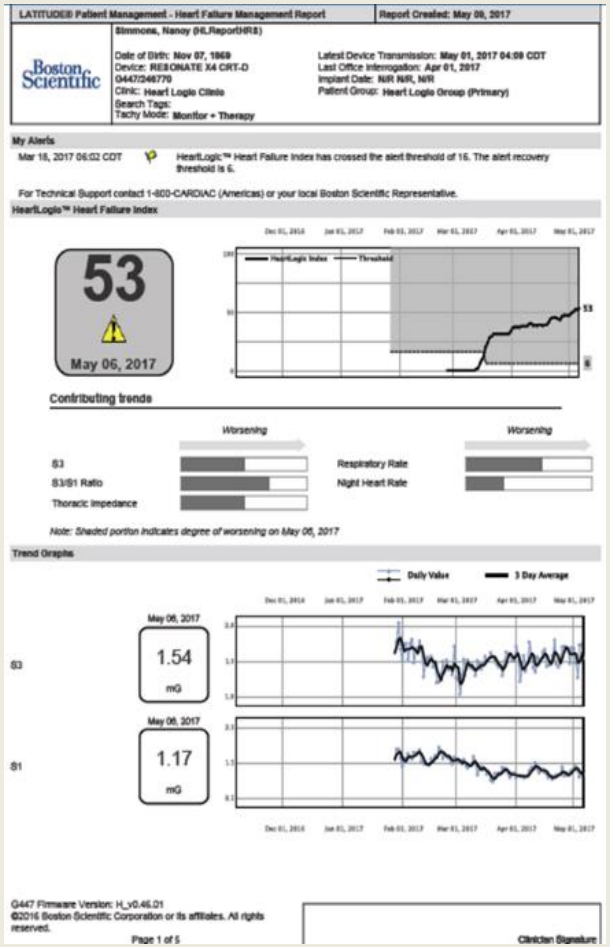

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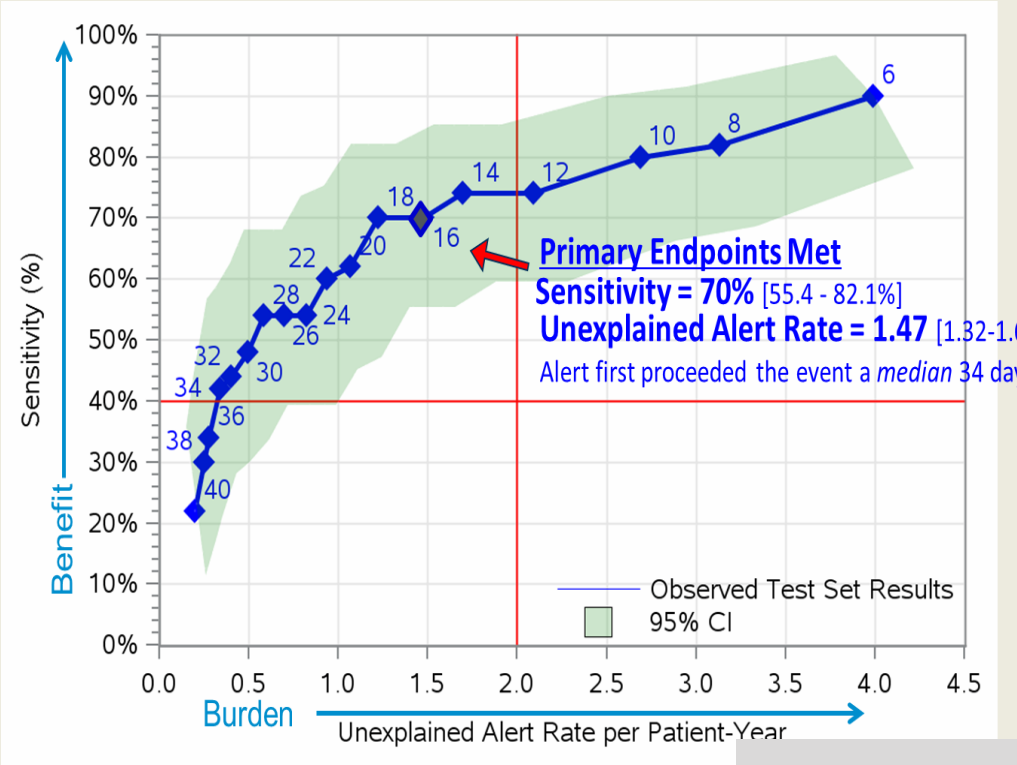

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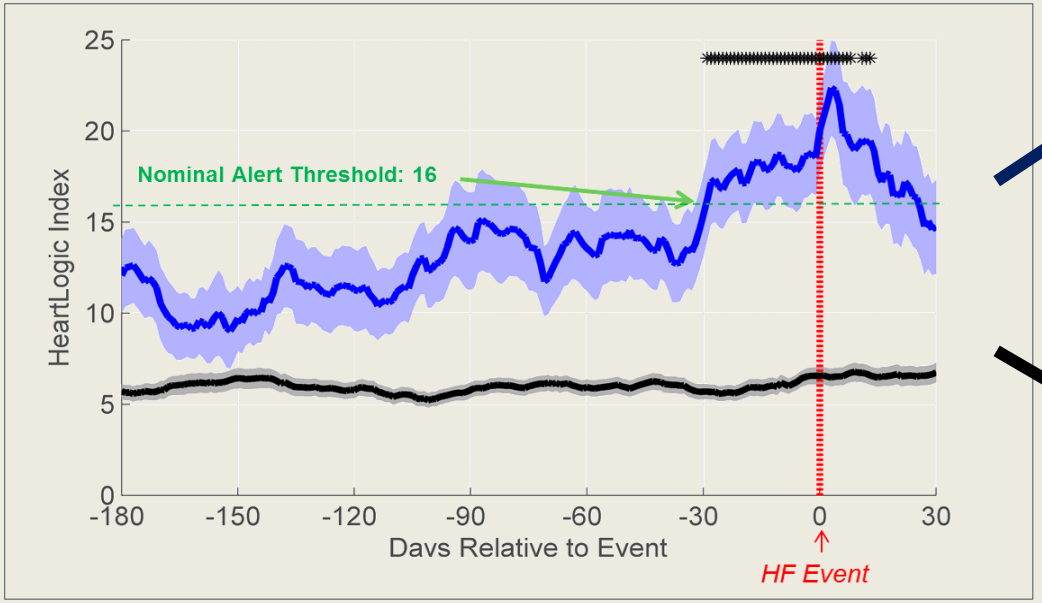

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Benefit of Multifactorial Approach

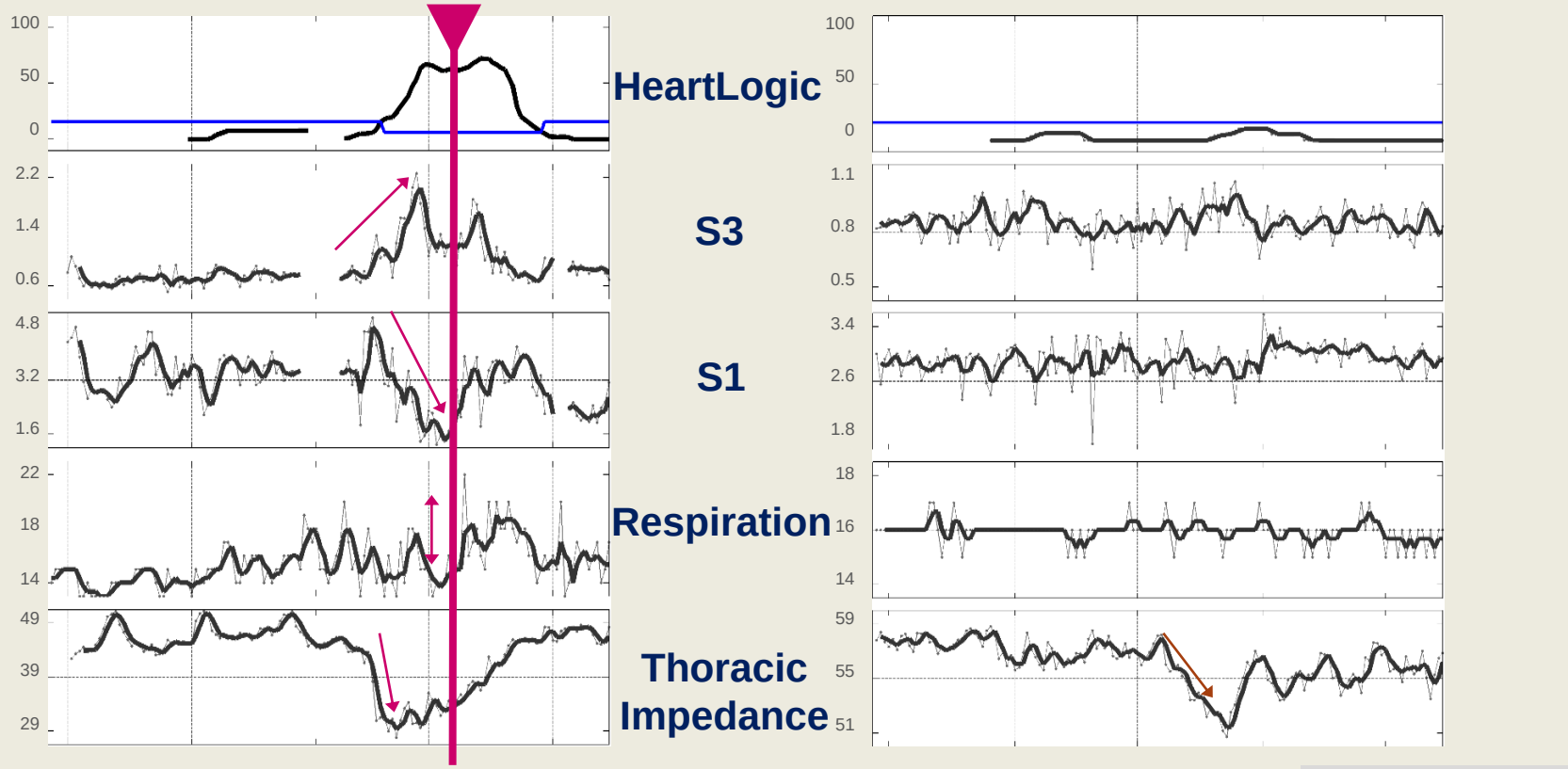
Two Observed Cases

Patient A

Multi-sensor Changes before a HF Event

Patient B

Impedance-only Change with NO Event

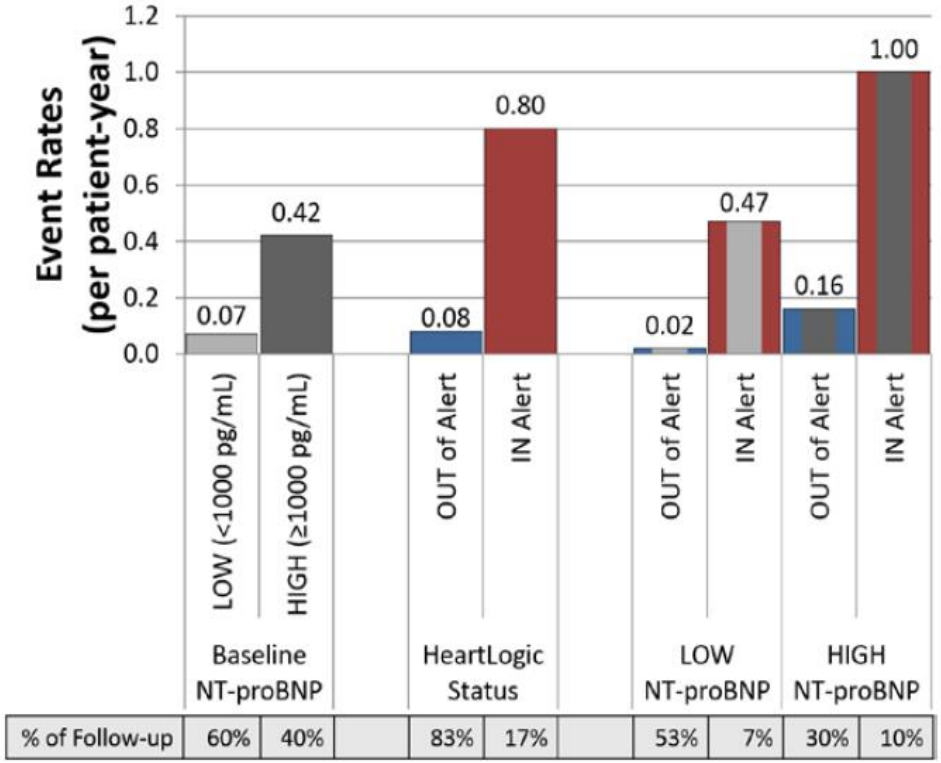


HeartLogic Uses Multiple Sensors

HeartLogic Multisensor Algorithm Identifies Patients During Periods of Significantly Increased Risk of Heart Failure Events

Results From the MultiSENSE Study

Risk Stratification combining NT-proBNP and HeartLogic



Event Rate Ratio compared to lowest risk group:

- **HIGH NT-proBNP**, OUT HL alert: **8.0**
- LOW NT-proBNP, **IN HL alert**: **23.5**
- **HIGH NT-proBNP, IN HL alert**: **50.0**

Gardner et al; Circ Heart Fail. 2018;11:e004669. DOI: 10.1161

ESC HEART FAILURE
ESC Heart Failure (2019)
Published online in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/ehf2.12394

ORIGINAL RESEARCH ARTICLE

Preliminary experience with the multisensor HeartLogic algorithm for heart failure monitoring: a retrospective case series report

Alessandro Capucci[1]*, Luca Santini[2], Stefano Favale[3], Domenico Pecora[4], Barbara Petracci[5], Leonardo Calò[6], Giulio Molon[7], Laura Cipolletta[1], Valter Bianchi[8], Valentina Schirripa[2], Vincenzo E. Santobuono[3], Carmelo La Greca[4], Monica Campari[9], Sergio Valsecchi[9], Fabrizio Ammirati[2] and Antonio D'Onofrio[8]

[1]*Clinica di Cardiologia e Aritmologia, Università Politecnica delle Marche, "Ospedali Riuniti", Via Conca, 71, 60020, Ancona, Italy;* [2]*"Giovan Battista Grassi" Hospital, Rome, Italy;* [3]*University of Bari, Policlinico di Bari, Bari, Italy;* [4]*Fondazione Poliambulanza, Brescia, Italy;* [5]*Fondazione Policlinico S. Matteo IRCCS, Pavia, Italy;* [6]*Policlinico Casilino, Rome, Italy;* [7]*Sacro Cuore-Don Calabria Hospital, Verona, Italy;* [8]*"Unità Operativa di Elettrofisiologia, Studio e Terapia delle Aritmie", Monaldi Hospital, Naples, Italy;* [9]*Boston Scientific Italia, Milan, Italy*

From December 2017 to April 2018, HeartLogic was activated in 67 patients; at the time of activation, HeartLogic initialization had been completed in **58 patients**

Daily index values were available for analysis over a mean observation period of 5±3 months (a total of 24 person-years).

The results from the **blinded phase** favorably compare with those reported in the validation MultiSENSE study:

- **Sensitivity: 100%**
- **Rate of unexplained alerts: 0.41 per patient-year#**
- **Positive predictive value: 58% (14/24)**

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- **The median early-warning time** (i.e. the time between threshold crossing and the event) was **38 days** in the case of hospitalizations and **12 days** in that of minor events reflecting clinical deterioration of HF

	Early-warning time (days)	Time spent in the alert state (days)	Maximum HeartLogic index
HF hospitalizations	38 [15-61]	70 [61-71]	40 [28-40]
HF visits	12 [1-19]	36 [21-51]	24 [20-30]
Therapy discontinuation	20 [9-35] *	24 [22-31]	24 [19-30]

*: time from the trigger event to the HeartLogic alert

Contributing sensors:

Sensors with worsening on the day of the alert threshold crossing					
S3	S3/S1	TI	RR	RSBI	NHR
84%	88%	44%	36%	36%	60%

Preliminary Experience of Remote Management of Heart Failure Patients with the Multisensor HeartLogic Alert.

Antonio D'Onofrio[1], Alessandro Capucci[2], Annamaria Martino[1], Nicola Danisi[4], Domenico Pecora[5], Stefano Favale[6], Giulio Molon[7], Silvana De Martino[8], Valter Bianchi[2], Laura Cipolletta[2], Karim Mahfouz[4], Carmelo La Greca[5], Riccardo Memeo[6], Monica Campari[9], Leonardo Calò[3]

Disclosure: M. Campari is an employee of Boston Scientific. The other authors report no conflicts.

- HeartLogic was activated in **101 patients.**
- At baseline visit, patients underwent clinical assessment and the congestion was assessed and graded as defined by Gheorghiade et al [1]

European Journal of Heart Failure (2010) 12, 423–433
doi:10.1093/eurjhf/hfq045

REVIEW

Assessing and grading congestion in acute heart failure: a scientific statement from the Acute Heart Failure Committee of the Heart Failure Association of the European Society of Cardiology and endorsed by the European Society of Intensive Care Medicine

Congestion grade:

- **None (<1)**
- **Mild (1–7)**
- **Moderate (8–14)**
- **Severe (15–20)**

Components of the score:

- ***Orthopnoea***
- ***Hepatomegaly***
- ***Oedema***
- ***BNP or NT pro-BNP***
- ***6 min walk test***

The proportion of patients with no signs of congestion at baseline visit was higher in the group with HeartLogic index <2 (median value) (Fig. 1)

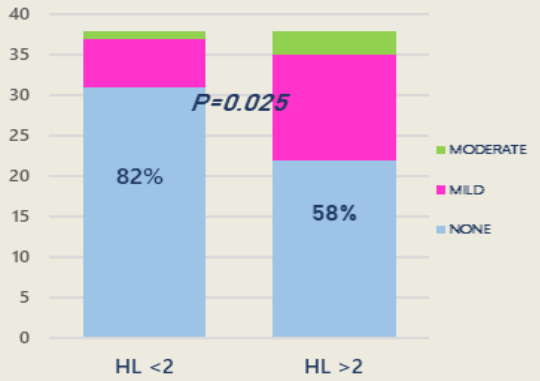

Fig. 1: Congestive grade

During a follow-up of 6±3 months:

- **44 HeartLogic alerts were reported (0.95 alerts/pt-year) in 30 patients**
- **26 (59%) alerts were judged clinically meaningful (i.e. associated with worsening of HF or when influenced the clinician's decision to make changes to the subject's management).**

Preliminary Experience of Remote Management of Heart Failure Patients with the Multisensor HeartLogic Alert

During the observation period **no HF events occurred when HeartLogic index was below the threshold** and **no signs or symptoms of worsening HF** were reported at **567** scheduled monthly remote visits **with index < 16.** The mean delay from alert to the next monthly remote data review was **18±12 days**.

Preliminary Experience of Remote Management of Heart Failure Patients with the Multisensor HeartLogic Alert

- **HeartLogic index** value seems associated with the HF congestion grade, as assessed at standard in-office visit.
- **The HeartLogic index** provides clinically meaningful information for the remote management of HF patients.
- **No HF events** were detected and no worsening signs or symptoms were reported **OUT of HeartLogic** alert, thus healthcare resources may be prioritized elsewhere until a HeartLogic alert occurs.
- **An alert-based remote** follow-up approach allows to detect more efficiently and earlier relevant conditions than a scheduled monthly follow-up strategy.

Selection of Potential Predictors of worsening Heart Failure - **Selene HF STUDY**

- Systematically analyze the trends of the HM variables before hospitalization for heart failure and understand if there are recurring patterns that can be used to define a parameter (SELENE HF-Score) capable of predicting these events.

The study enrolled **918** patients (ICD and CRT-D) followed for a median follow-up of **22.5** (14.1-35.8) **months**, in 34 centers (Italy and Spain). Data were collected for 61 hospitalization for heart failure awarded.

Selection of Potential Predictors of worsening Heart Failure - Selene HF STUDY

- **Primary endpoint**
  - *First* post-implant HF-related hospitalization
- **Secondary endpoint**
  - A composite of
    - Any (first or subsequent) hospitalizations for worsening HF
    - Death for worsening HF
    - Outpatient intravenous interventions (IVI) for worsening HF
- **Blinding**

  Investigators were blinded to HF-related Home Monitoring indices during study duration.

- **Adjudication**

  All wHF hospitalizations, deaths, and IVI were adjudicated by a 3-member independent CEC who reviewed hospital source documents, based on a predefined charter.

Thank You for attention