PLACE

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

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Auditorium
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9ª Edizione

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HeartLogic: real world data

LA GESTIONE PROATTIVA DEL PAZIENTE SCOMPENSATO

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HF patients management

Where we are:

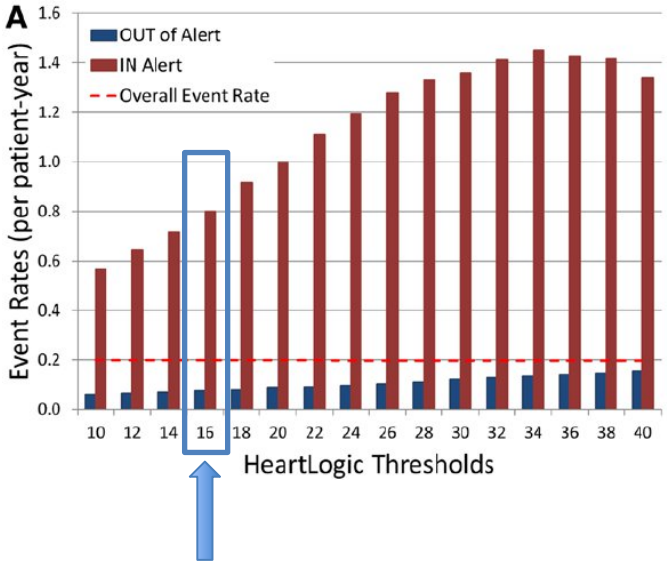
- Remote monitoring is able to provide real-time, continuous data on patients with implantable cardiac devices
- New diagnostic tool on CIEDs is proven to be reliable in early detection HF worsening
- The majority of prior clinical trials have shown limited ability of such RM data to improve clinical outcomes [1-3]

What we need:

- ✓ To properly integrate RM and diagnostic tools into clinical workflow
- ✓ An actionable proactive treatment protocol, in response to alert, in addition to standard clinical care.

1.Bourge RC. et al., J Am Coll Cardiol 2008;51:1073–9.
2.van Veldhuisen DJ. et al., Circulation 2011;124:1719–26.
3.Morgan JM. et al., Eur Heart J 2017;38:2352–60.

From Multisense Study



HeartLogic provides a measure of the risk of an HF event independent of baseline clinical variables.

HF event rate using the nominal threshold

- ❑ **0.08** events/pt-yr OUT of ALERT STATE
- ❑ **0.80** events/pt-yr IN ALERT STATE

x 10

4. Gardner et al., Circ Heart Fail. 2018 Jul;11(7):e004669

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Clinical Impact of HeartLogic adoption

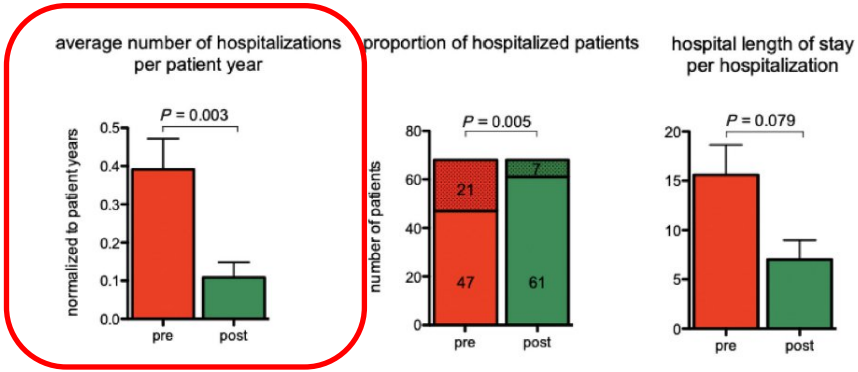
A recent analysis has been conducted in three centers from Belgium, Netherlands and Switzerland to investigate the ability of HeartLogic to reduce the Heart Failure hospitalizations in a one-year after algorithm activation compared with a one-year pre-activation period.

An adjustment in drug therapy or lifestyle has been provided in case of symptoms or signs were detected at the time of contact after HeartLogic alert.

	Pre-activation	Post-activation
Total number of HF admissions	27	7
Total number of 1 day clinic visits	32	42
Total number of ambulatory visits	132	117

The duration of hospitalizations was longer in the pre-activation period than in the post-activation period (16 ±14 vs. 7±5 days; p=0.079)

Strong reduction of HF Hospitalizations after HeartLogic activation



5. Treskes RW et al.. ESC Heart Fail. 2021 Apr;8(2):1541-1551.

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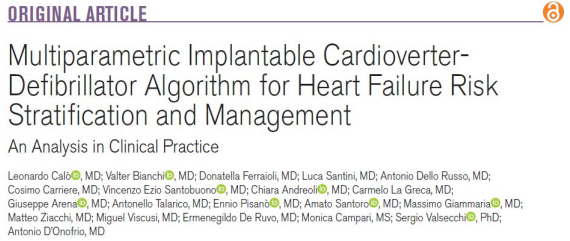
From Italian Multicenter Experience

366 ICD and CRT-D patients in 22 centers with a median follow-up of 11 months:

- **36 HF hospitalizations and 8 HF deaths**
- **273 HeartLogic alerts** (0.76 alerts/patient-year) in 150 patients
- **the time IN the alert state was 11%** of the total observation period.


ORIGINAL ARTICLE

Multiparametric Implantable Cardioverter-Defibrillator Algorithm for Heart Failure Risk Stratification and Management

An Analysis in Clinical Practice

Leonardo Calò, MD; Valter Bianchi, MD; Donatella Ferraioli, MD; Luca Santini, MD; Antonio Dello Russo, MD; Cosimo Carriere, MD; Vincenzo Ezio Santobuono, MD; Chiara Andreoli, MD; Carmelo La Greca, MD; Giuseppe Arena, MD; Antonello Talarico, MD; Ennio Pisanò, MD; Amato Santoro, MD; Massimo Giammaria, MD; Matteo Ziacchi, MD; Miguel Viscusi, MD; Ermenegildo De Ruvo, MD; Monica Campari, MS; Sergio Valsecchi, PhD; Antonio D'Onofrio, MD

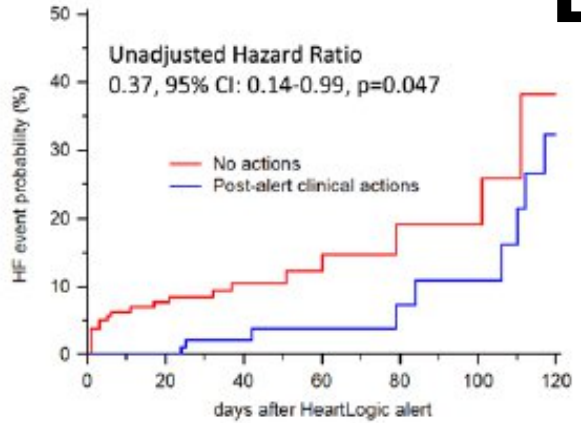
117 (43%) **triggered clinical actions:**

The most frequent actions taken to manage the HF condition detected by the alert were (multiple actions per alert):

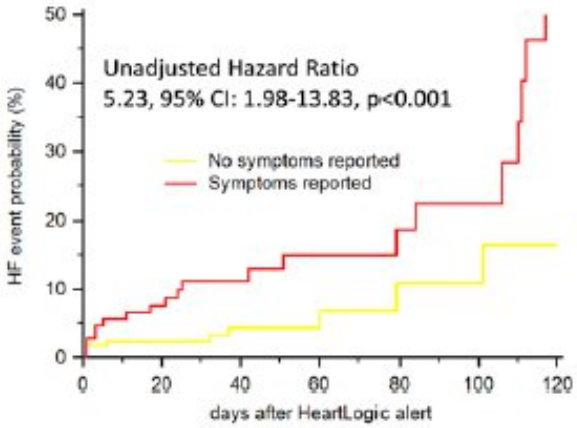
- ✓ **66% diuretic dosage increase**
- ✓ 34% other drug adjustment
- ✓ 6% patient education on therapy adherence
- ✓ 3% device reprogramming

6. Calò L. et al., Circ Heart Fail. 2021;14:e008134

From Italian Multicenter Experience



Taking clinical actions in response to the HeartLogic alert was associated with a **lower risk of HF events.**



The **presence of HF symptoms** at the time of HeartLogic threshold crossing was associated with a **higher risk of HF events.**

6. Calò L. et al., Circ Heart Fail. 2021;14:e008134

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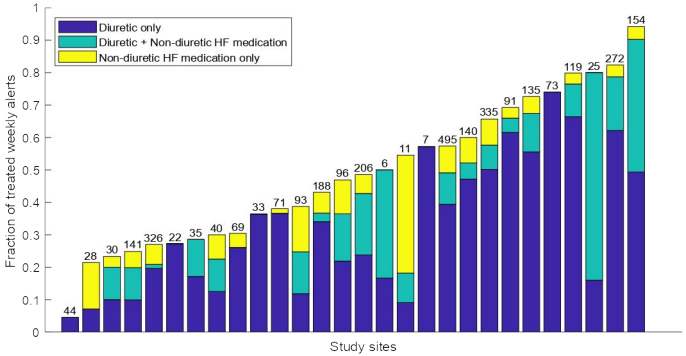
Manage-HF Study

The **MANAGE-HF – Phase** I was a multicenter, observational study that enrolled 200 patients with reduced Ejection Fraction (HFrEF < 35%) and implanted with HeartLogic™ enabled devices.
The study was designed to evaluate HeartLogic integration, utilization safety and efficacy in HF care.

During an average follow-up period of 20.9 months:

- 585 HeartLogic alert occurred (1.76 alert /pt-year)
- The time in alert state was 17% of total observation period.



A large variability in alert response treatment across sites has been observed

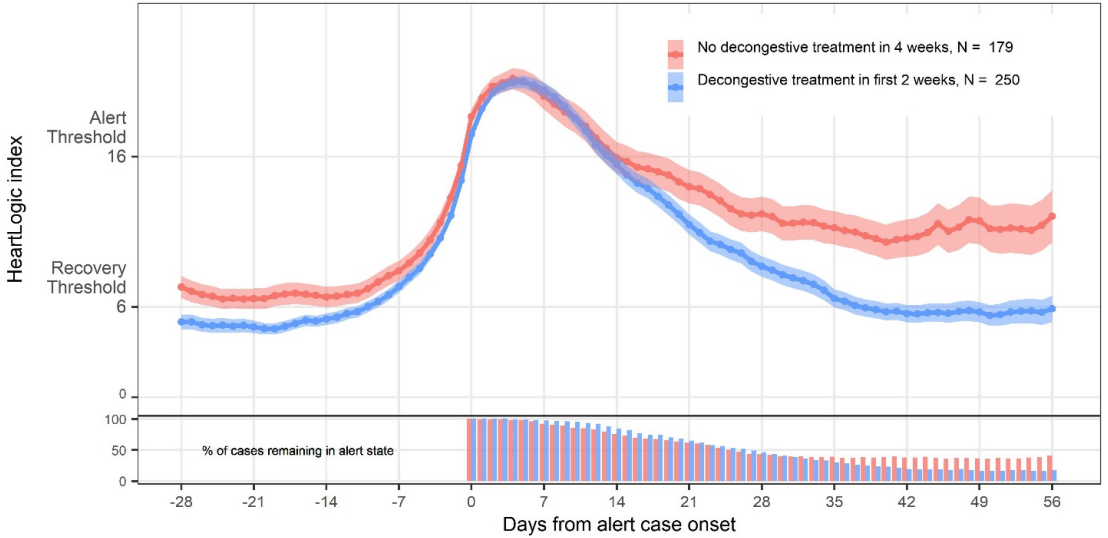
- diuretics augmentation only,
- diuretic + non-diuretic HF medication,
- non diuretic HF medication only

7. Hernandez AF. Et al., J Card Fail. 2022 Aug;28(8):1245-1254

Manage-HF Study

HF treatment was augmented:
- during 74% of the 585 alert cases
- during 54% of the 3290 weekly alerts.

The following HF drug classes were augme
- ❑ **1590 (89%) diuretics,**
- ❑ 185 (10%) beta-blockers,
- ❑ 132 (7%) MRA,
- ❑ 124 (7%) ARNI,
- ❑ 108 (6%) ACE/ARBs,
- ❑ 69 (4%) vasodilators (hydralazine or nit



HeartLogic Index decreased quicker and alert cases resolved quicker when decongestive therapies were given

7. Hernandez AF. Et al., . J Card Fail. 2022 Aug;28(8):1245-1254

CLINICAL INVESTIGATIONS
CLINICAL CARDIOLOGY WILEY

Decongestive treatment adjustments in heart failure patients remotely monitored with a multiparametric implantable defibrillators algorithm

Experience from Italian Clinical Practice:

229 patients in 8 centers
Median follow-up of 17 months
*242 HeartLogic alerts (*0.8 alerts/patient-year)

HeartLogic alert management:

- 105 (44%) alerts were not followed by HF therapy (nonactionable, unexplained, or associated with non-HF-related conditions)
- **137 (56%) alerts triggered clinical actions to treat HF**
  - 56 decongestive treatment augmentations only (increase in the equivalent dose of diuretics or switch to a more bioavailable diuretic)
  - 81 mixed interventions

8. Guerra F et al., Clin Cardiol. 2022 Jun;45(6):670-678. doi: 10.1002/clc.23832.

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CLINICAL INVESTIGATIONS

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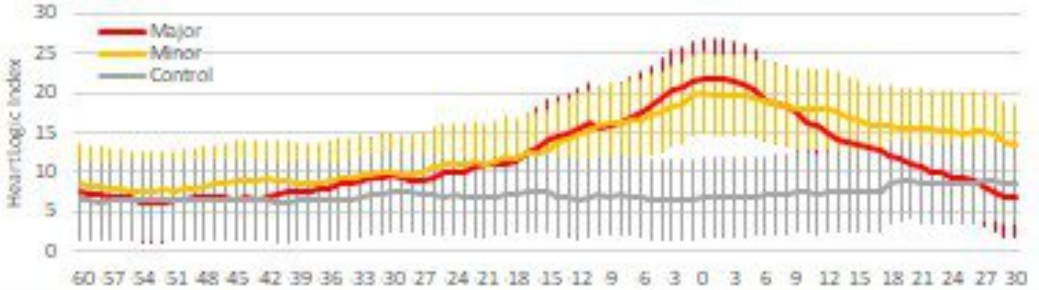
Decongestive treatment adjustments in heart failure patients remotely monitored with a multiparametric implantable defibrillators algorithm

The **alert status resolved more quickly** when **decongestive therapies were timely** (< 2 weeks) and **major** (>2 times the daily dose)

The duration of **"in-alert" status was shorter** when decongestive therapies were **timely** in comparison with late changes (28 days versus 62 days, p<0.001).
Major and minor diuretic augmentations resulted in comparable alerts durations.



Figures. Average HeartLogic index (*day 0 is the first day of the diuretic augmentation.)

8. Guerra F et al., Clin Cardiol. 2022 Jun;45(6):670-678. doi: 10.1002/clc.23832.

CLINICAL INVESTIGATIONS

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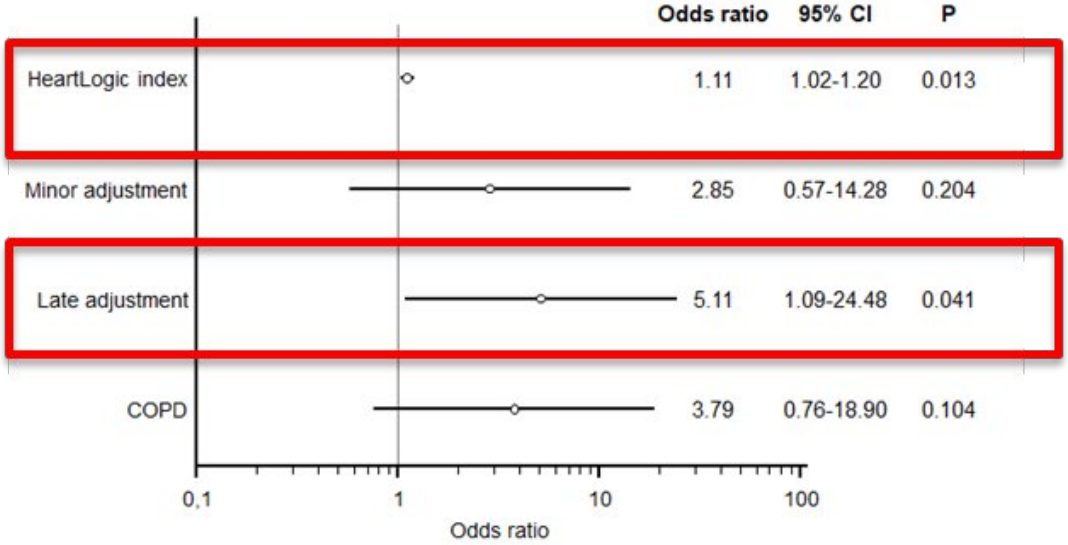


At multivariate analysis **the need of hospitalization** for further treatments to resolve the alert condition was associated with **higher HeartLogic index values** on the day of the diuretics and with **late interventions**

8. Guerra F et al., Clin Cardiol. 2022 Jun;45(6):670-678. doi: 10.1002/clc.23832.

Implantable Defibrillator-Detected Heart Failure Status Predicts Ventricular Tachyarrhythmias

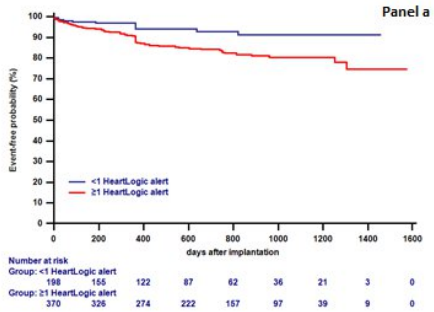
Compagnucci P[1], Casella M[1], Bianchi V[2], Franculli F[3], Vitali F[4], Santini L[5], Savarese G[6], Santobuono VE[7], Chianese R[8], Lavalle C[9], Amellone C[10], Pecora D[11], Calvanese R[12], Stronati G[1], Santoro A[13], Ziacchi M[14], Campari M[15], Valsecchi S[15], Caiò L[16], Guerra F[1], Dello Russo A[1]

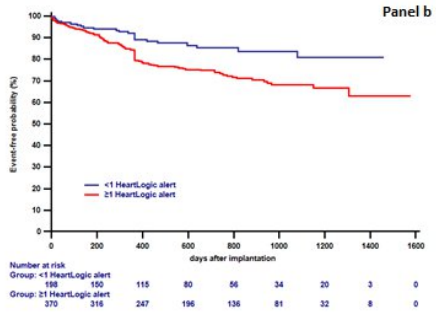
(1) Marche Polytechnic University of Ancona, Ancona, Italy (2) Monaldi Hospital, Naples, Italy; (3) OO.RR. San Giovanni di Dio Ruggi d'Aragona, Salerno, Italy; (4) Sant'Anna University Hospital, University of Ferrara, Ferrara, Italy; (5) "Giovan Battista Grassi" Hospital, Rome, Italy; (6) S. Giovanni Battista Hospital, Foligno, Italy; (7) University of Bari, Policlinico di Bari, Bari, Italy; (8) S. Anna e S. Sebastiano Hospital, Caserta; (9) Policlinico Umberto I, Rome, Italy; (10) "Maria Vittoria" Hospital, Turin, Italy; (11) Fondazione Poliambulanza, Brescia, Italy; (12) Ospedale del Mare, ASL NA1, Naples, Italy; (13)Azienda Ospedaliera Universitaria Senese, Siena, Italy; (14) University of Bologna, Policlinico S.Orsola-Malpighi, Bologna, Italy; (15) Boston Scientific, Milan, Italy; (16) Policlinico Casilino, Rome, Italy.

A recent new analysis from Italian HeartLogic Registry, has been presented during **ESC Congress (August 2022)**

This analysis over 268 patients, showed that **the occurrence of at least one HeartLogic alert** was significantly associated with

- ✓ appropriate shocks (a) (HR: 2.44, 95%CI: 1.49-3.97, p=0.003)
- ✓ any ICD therapies (b) (HR: 1.95, 95%CI: 1.37-2.85, p=0.003).





A time-dependent Cox model revealed that the **weekly IN-alert state was the strongest predictor of ICD shocks** (HR: 2.94, 95%CI: 1.73-5.01, p<0.001), after correction for age, secondary prevention, and use of CRT.

9. Compagnucci et al., ESC Congress 2022, Poster session

- The HeartLogic multisensor index and alert algorithm management could be **safely integrated** into clinical practice.
- The use of HeartLogic algorithm was associated with ***HF treatment augmentation***, early in response to alerts, resulting in more ***rapid reduction of HeartLogic index*** values.
- *Need further analysis from HeartLogic sensors in clinical practice to provide realiable treatment protocol in response to alert in order to facilitate a quickly alert resolution and avoid HF events.*