

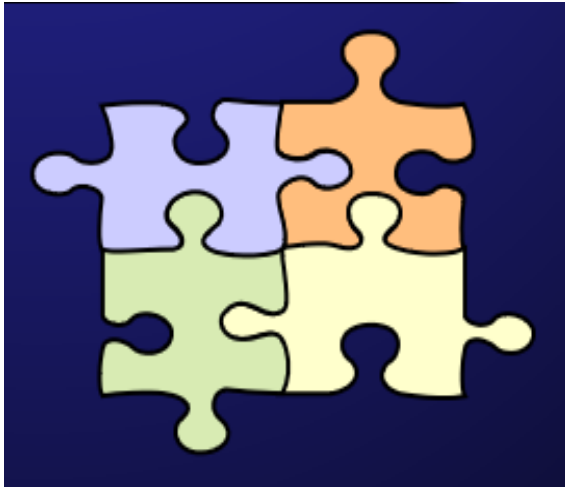
MONITORAGGIO REMOTO E DIGITAL HEALTH

**L'esperienza italiana HeartInsight ACTION:
qual è il miglior modello organizzativo nella
pratica clinica quotidiana?**

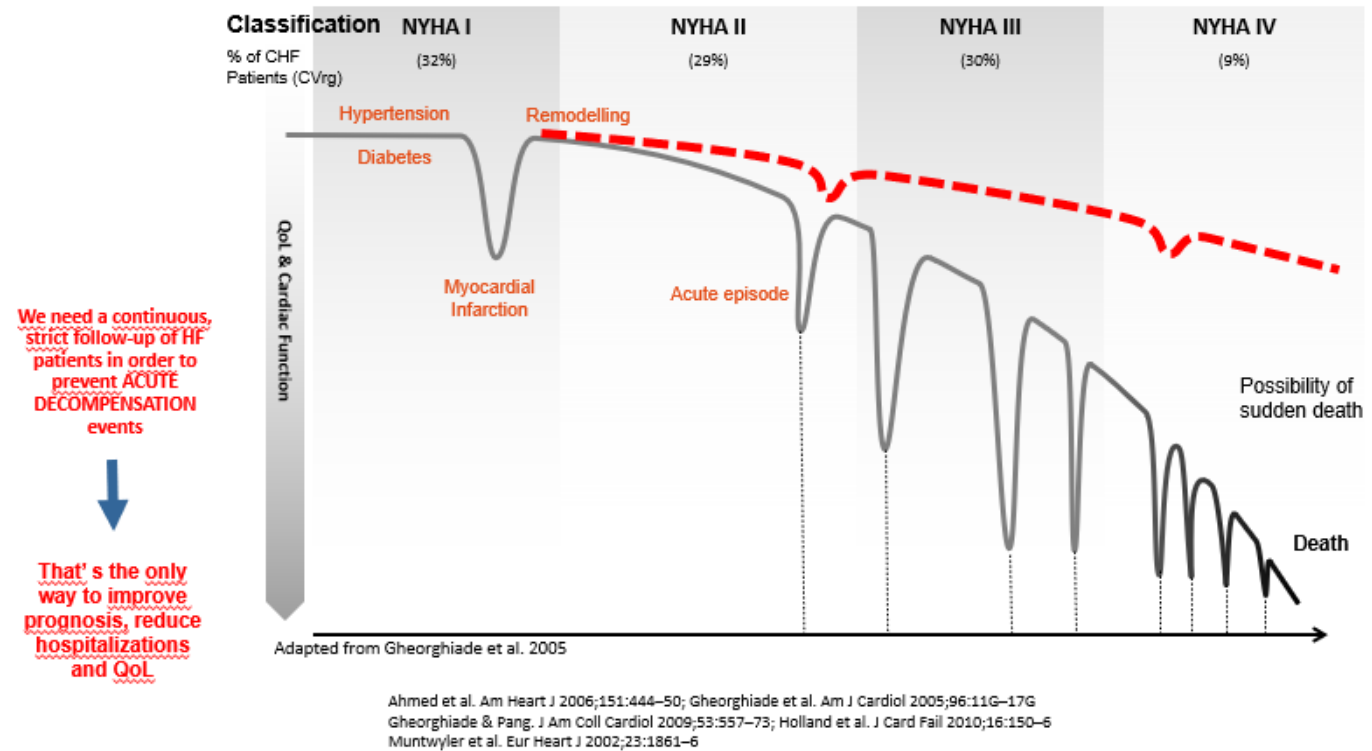
Luca Santini
Divisione di Cardiologia
P.O. G.B. Grassi – Roma

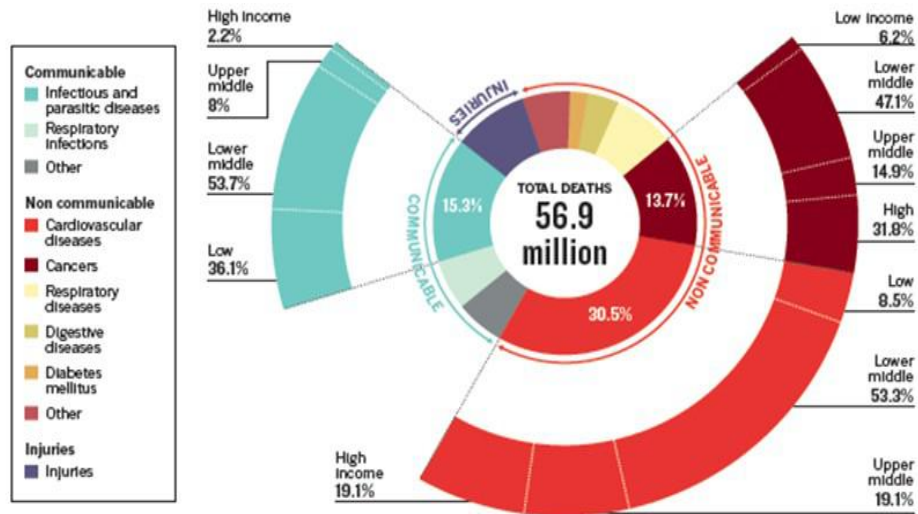


- Updated Optimal Medical Therapy
- Diet Plan/Exercise/Cardiac Rehab
- Device therapy and TC Ablation
- **Routine Monitoring and strict f.u.**



An Updated OMT may modify the progression of HF, reducing mortality and morbidity





- Increasing **chronic patients** and reducing **human and economic resources**
- Cardiovascular diseases are no longer static conditions but **dynamic and multidimensional** ones
- Need for «**precision medicine**»

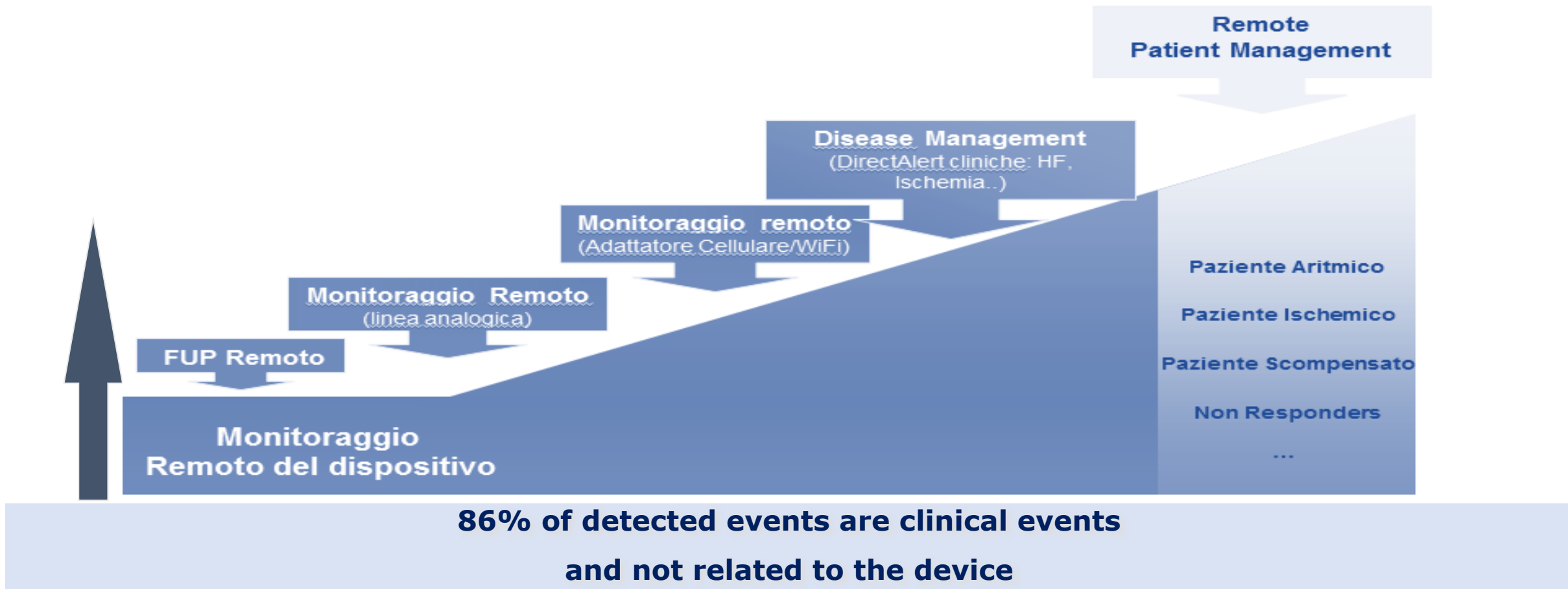


THE ERA OF DIGITALIZATION

what do new generations of patients demand from technology?

- remote follow up as more as possible
- Safety and efficacy of therapeutical strategies
- Authonomy and freedom from hospital accesses and hospitalization
- Technological support in order to live better with their chronic diseases

From Remote Device Monitoring to Remote Patient Management



REMOTE MONITORING IN HF

Conflicting and confusing outcomes: that's why!

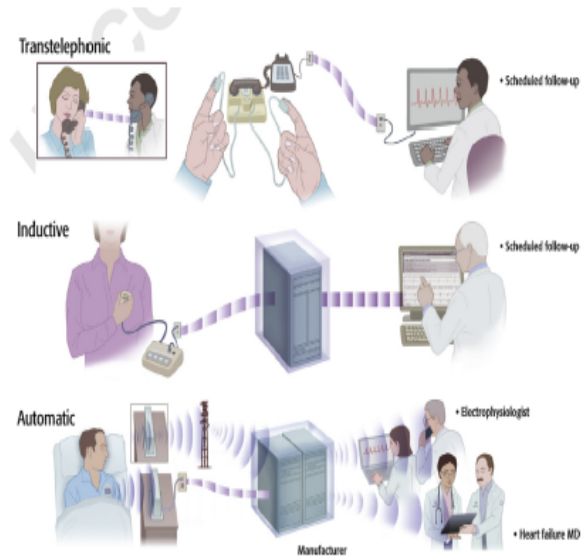


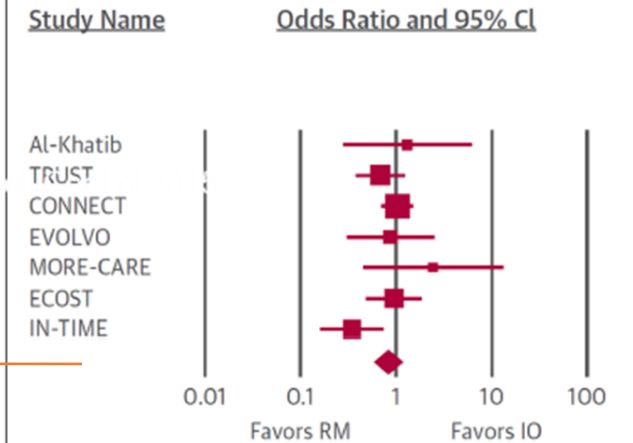
Figure 1 Technologies in use.

Organization

Technology

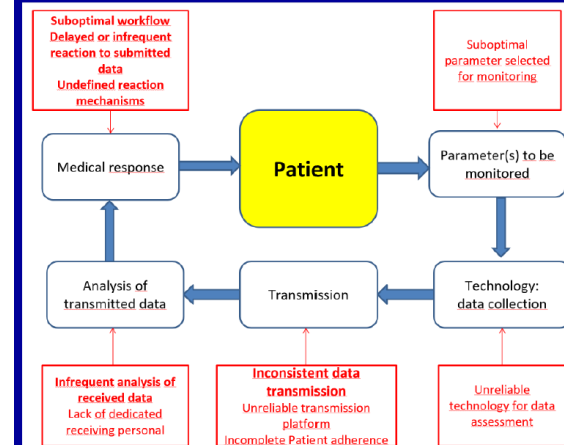
Type of analyzed data

FIGURE 2 All-cause Mortality

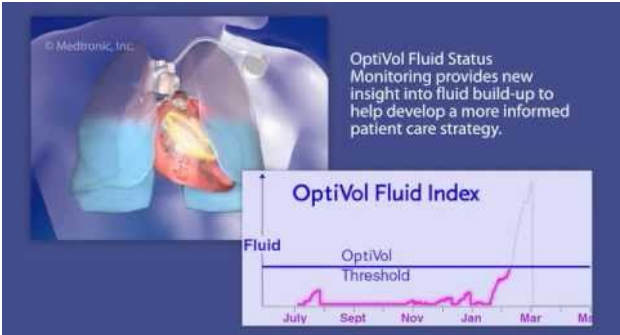


Telemedicine systems combined with ICD/CRT technologies

Remote monitoring of ICD/CRT

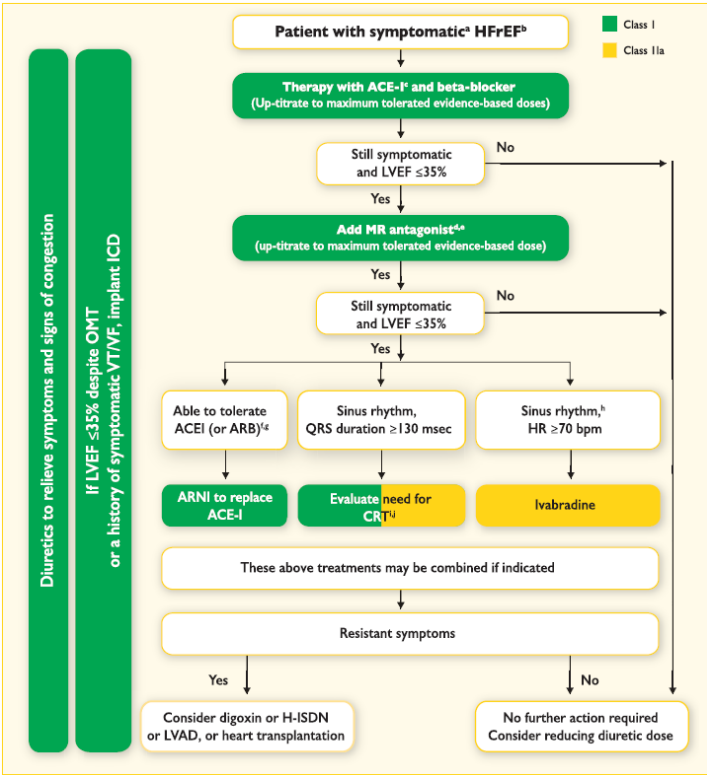


Previous diagnostic features have been developed to monitor the HF course and patient decompensation (e.g. Thoracic Impedance)



With disappointing results in terms of:

- ✓ **predictive ability**
- And neutral or negative
- ✓ **clinical outcome**





European Heart Journal
doi:10.1093/eurheartj/ehw128

ESC GUIDELINES

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

Multiparameter monitoring based on ICD may be considered in symptomatic patients with HFrEF (LVEF $\leq 35\%$) in order to improve clinical outcomes. (Class of recommendation *lib*, level of evidence *B*)



Guidance

Standards and
indicators ▼

Life
sciences ▼

British National
Formulary (BNF)

British National Formulary
for Children (BNFC)

Clinical Knowledge
Summaries (CKS)

About ▼

[Home](#) > [News](#) > [News articles](#)

Heart failure patients to be remotely monitored by technology shown to cut hospitalisations by 50%

Two technologies, HeartLogic and TriageHF, have been recommended in final diagnostic guidance.

News

24 October 2024

NICE approves two remote monitoring systems of heart failure



Combining home monitoring temporal trends from implanted defibrillators and baseline patient risk profile to predict heart failure hospitalizations: results from the SELENE HF study

Antonio D'Onofrio^{1*}, Francesco Solimene², Leonardo Calò³, Valeria Calvi⁴, Miguel Viscusi⁵, Donato Melissano⁶, Vitantonio Russo⁷, Antonio Rapacciuolo⁸, Andrea Campana⁹, Fabrizio Caravati¹⁰, Paolo Bonfanti¹¹, Gabriele Zanutto¹², Edoardo Gronda¹³, Antonello Vado¹⁴, Vittorio Calzolari¹⁵, Giovanni Luca Botto¹¹, Massimo Zecchin¹⁶, Luca Bontempi¹⁷, Daniele Giacomelli¹⁸, Alessio Gargaro¹⁸, and Luigi Padeletti¹⁹

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Received 10 November 2020; editorial decision 15 June 2021; accepted after revision 18 June 2021; online publish-ahead-of-print 15 August 2021

Aims

We developed and validated an algorithm for prediction of heart failure (HF) hospitalizations using remote monitoring (RM) data transmitted by implanted defibrillators.

Methods and results

The SELENE HF study enrolled [redacted] patients (median age 69 years, 81% men, median ejection fraction 30%) with cardiac resynchronization therapy (44%), dual-chamber (38%), or single-chamber defibrillators with atrial diagnostics (18%). To develop a [redacted] risk score, we combined [redacted] with a baseline risk stratification (Seattle HF Model) into one index. The primary endpoint was the first HF hospitalization adjudicated after implantation. After a median follow-up of 22.5 months since enrolment, patients were randomly allocated to the algorithm derivation group ($n=457$; 31 endpoints) or algorithm validation group ($n=461$; 29 endpoints). In the derivation group, the index showed a C-statistics of 0.89 [95% confidence interval (CI): 0.83–0.95] with 2.73 odds ratio (CI 1.98–3.78) for first HF hospitalization per unitary increase of index value ($P<0.001$). In the validation group, sensitivity of predicting primary endpoint was 65.5% (CI 45.7–82.1%), median alerting time 42 days (interquartile range 21–89), and false

(or unexplained) alert rate 0.69 (CI 0.64–0.74) [or 0.63 (CI 0.58–0.68)] per patient-year. Without the baseline risk-stratifier, the sensitivity remained 65.5% and the false/unexplained alert rates increased by $\approx 10\%$ to 0.76/0.71 per patient-year.

Conclusion

[redacted] with

Keywords

Heart failure • Remote monitoring • Implantable cardioverter-defibrillator • Cardiac resynchronization therapy • Hospitalization • Predictors

- The Selene HF study led to the synthesis of a heart failure predictor algorithm based on daily Home Monitoring transmissions

From SELENE HF study to HeartInsight

- **Result : an effective, specific and sensitive algorithm**

SELENE HF study Results adjusted for Real Life



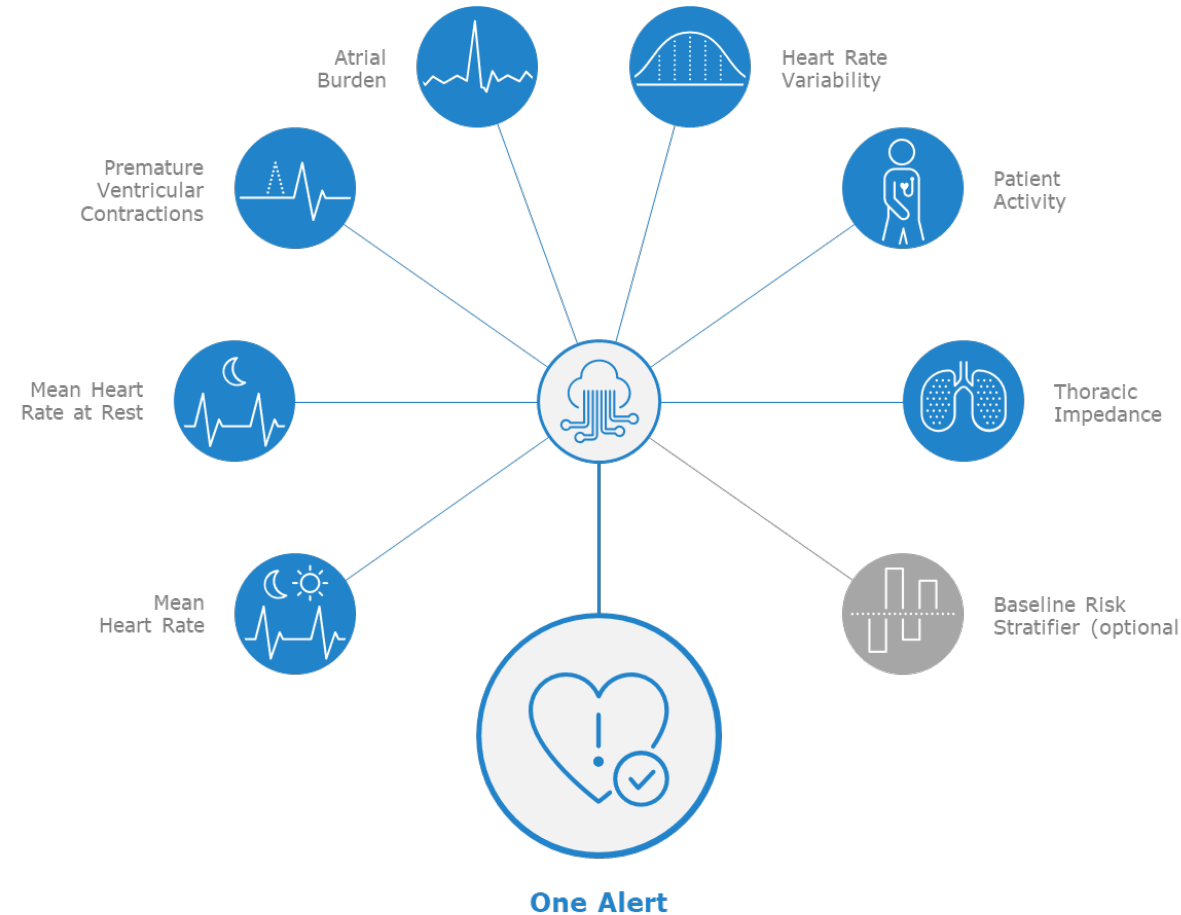
66% Sensitivity



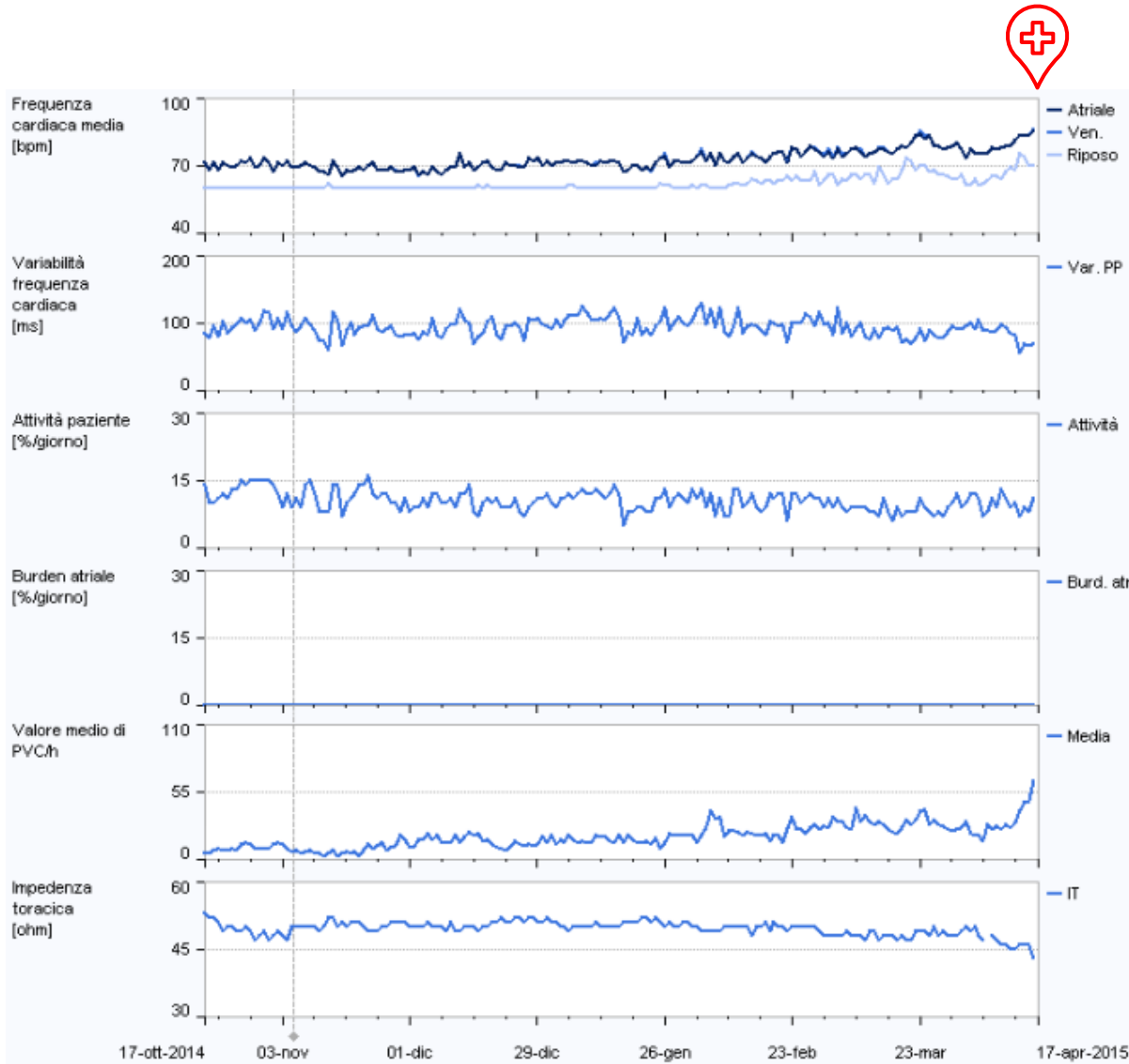
42-day alert time
(median)



0.7 false alert rate per patient year (ppy)
<1 total alerts ppy

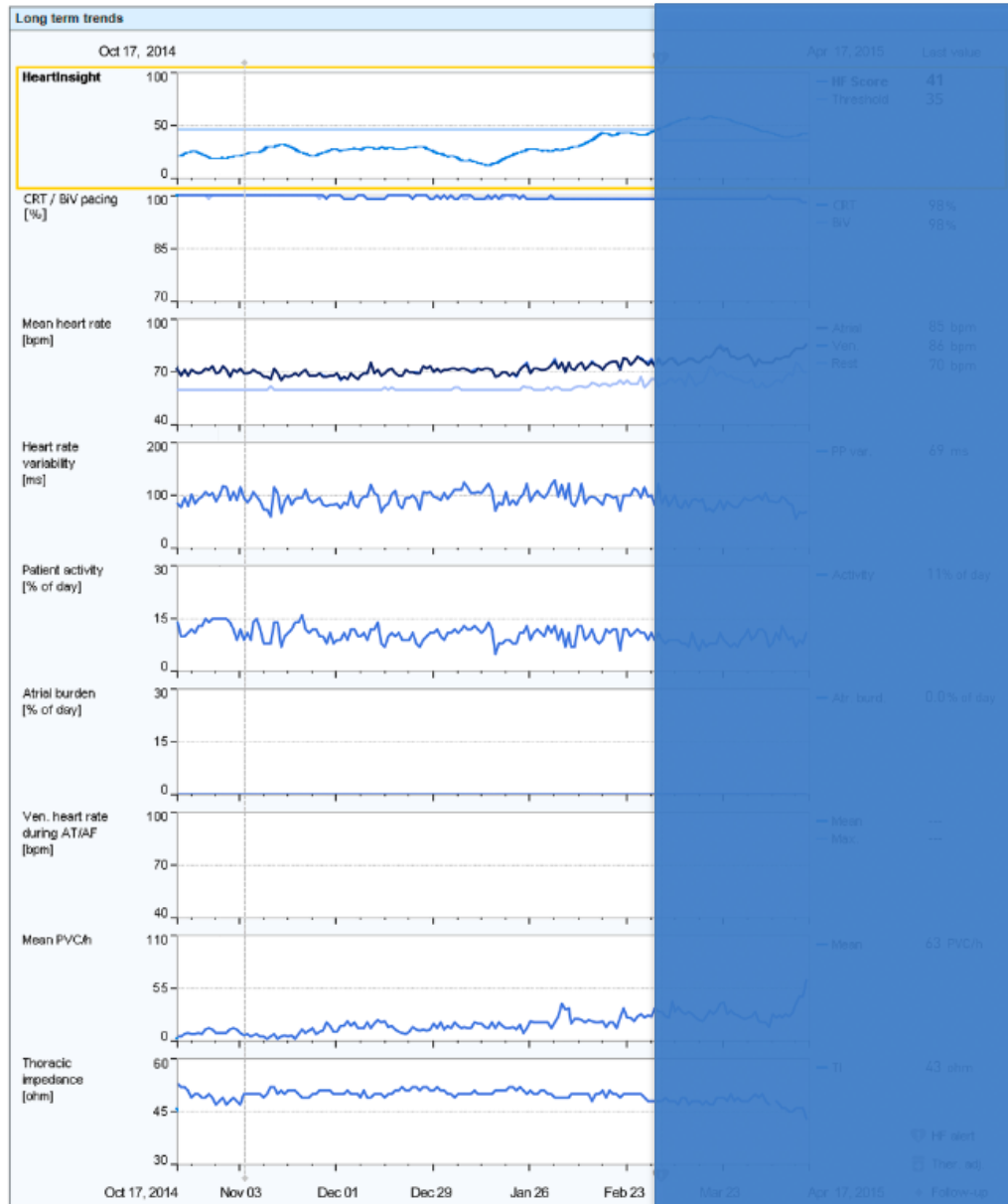


How does HeartInsight works?

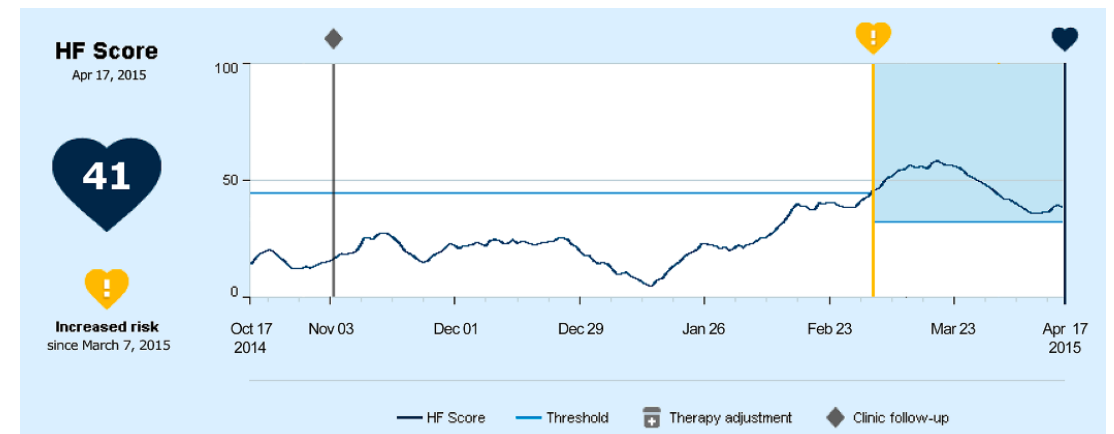


- Increase in mean and resting heart rate
- Reduction in cardiac variability
- Minimal reduction in physical activity
- No atrial arrhythmic episode
- Increase in PVCs
- Reduction in thoracic impedance

How does HeartInsight works?



- The HI alarm comes at a time when it is not easy to see the patient's deterioration by looking at individual parameters.
- As the clinical event approaches, the worsening trends of individual parameters also become more apparent.



Heart Insight – Strenghts

Seattle Heart Failure Model

- Risk stratification= personalizes Algorithm based on each patient in a dinamic fashion

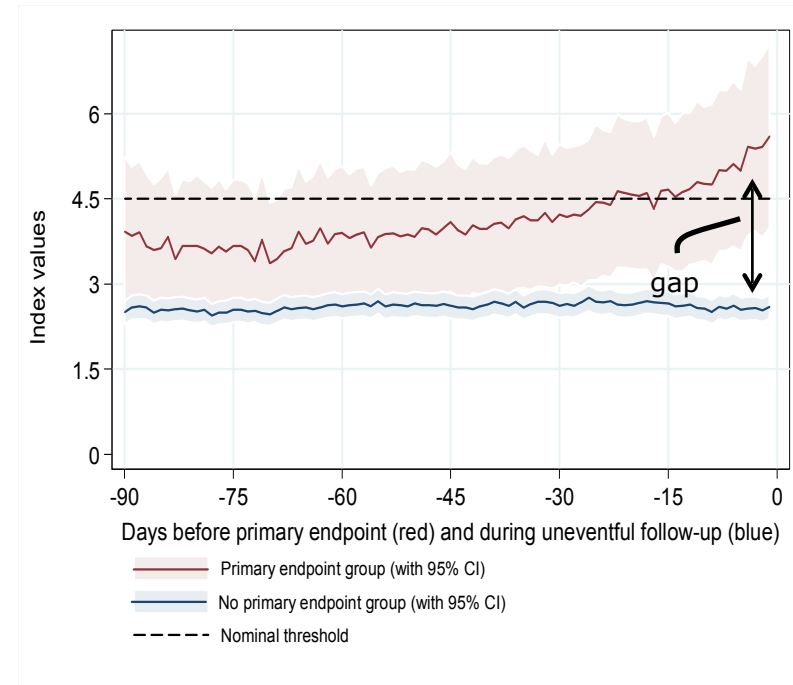
The screenshot shows the 'Patient profile' tab of the Seattle Heart Failure Model interface. The 'Clinical data' sub-tab is selected and highlighted with a green border. The form is divided into four main sections: Clinical, Medication, Diuretics, and Lab Data. Each section contains various input fields for patient information, medication status, and lab results, with buttons for 'Apply', 'Reset', and 'Cancel' at the bottom.

Clinical	
Sex	Female (selected), Male, Unknown
Date of birth	November 06, 1951
Weight	89.5 kg
NYHA	II
Ejection fraction	30 %
Systolic blood pressure	124 mmHg
Ischemic etiology	Yes, No, Unknown (selected)

Medication	
ACE inhibitor	Yes, No, Unknown
Beta blocker	Yes (selected), No, Unknown
Angiotensin receptor blocker	Yes (selected), No, Unknown
Statin	Yes (selected), No, Unknown
Allopurinol	Yes, No, Unknown
Potassium sparing diuretics	Yes, No, Unknown

Diuretics	
Furosemide	50 mg/day
Bumetanide	mg/day
Torsemide	mg/day
Metolazone	mg/day
Hydrochlorothiazide	mg/day

Lab Data	
Hemoglobin	11.4 g/dl
Lymphocytes	22.3 %
Blood uric acid	3.2 mg/dl
Total cholesterol	231 mg/dl
Blood sodium	139 mEq/l



- Improves specificity = I can trust it...

Predicting worsening heart failure hospitalizations in patients with implantable cardioverter defibrillators: is it all about alerts? A pooled analysis of nine trials - Botto et al 2024

Predicting worsening heart failure hospitalizations in patients with implantable cardioverter defibrillators: is it all about alerts? A pooled analysis of nine trials

Giovanni Luca Botto^{1*}, Gianfranco Sinagra², Alan Bulava³,
Alessio Gargaro⁴, Tobias Timmel⁵, Daniele Giacomelli⁶,
Antonio D'Onofrio^{6†}, and Laurence Guédon-Moreau^{7†}

¹U.O. Electrophysiology, ASST Rhodense, 95 Viale Carlo Forlanini, 20024 Garbagnate Milanese (MI), Italy; ²Cardiothoracovascular Department, Cattinara Hospital, ASUGI and University of Trieste, Trieste, Italy; ³Faculty of Health and Social Sciences, Ceske Budejovice Hospital, University of South Bohemia in Ceske Budejovice, Ceske Budejovice, Czech Republic; ⁴Clinical Unit, Biotronik Italia S.p.A., Cologno Monzese (MI), Italy; ⁵Center for Clinical Research, Biotronik SE & Co. KG, Berlin, Germany; ⁶Unità Operativa di Elettrofisiologia, Studio e Terapia delle Aritmie, Monaldi Hospital, Naples, Italy; and ⁷CHU Lille, University of Lille, Lille University Hospital Center, Lille, Hauts-de-France, France

Received 23 November 2023; accepted after revision 25 January 2024; online publish ahead of print 31 January 2024

Aims

To predict worsening heart failure hospitalizations (WHFHs) in patients with implantable defibrillators and remote monitoring, the HeartInsight algorithm (Biotronik, Berlin, Germany) calculates a heart failure (HF) score combining seven physiologic parameters: 24 h heart rate (HR), nocturnal HR, HR variability, atrial tachyarrhythmia, ventricular extrasystoles, patient activity, and thoracic impedance. We compared temporal trends of the HF score and its components 12 weeks before a WHFH with 12-week trends in patients without WHFH, to assess whether trends indicate deteriorating HF regardless of alert status.

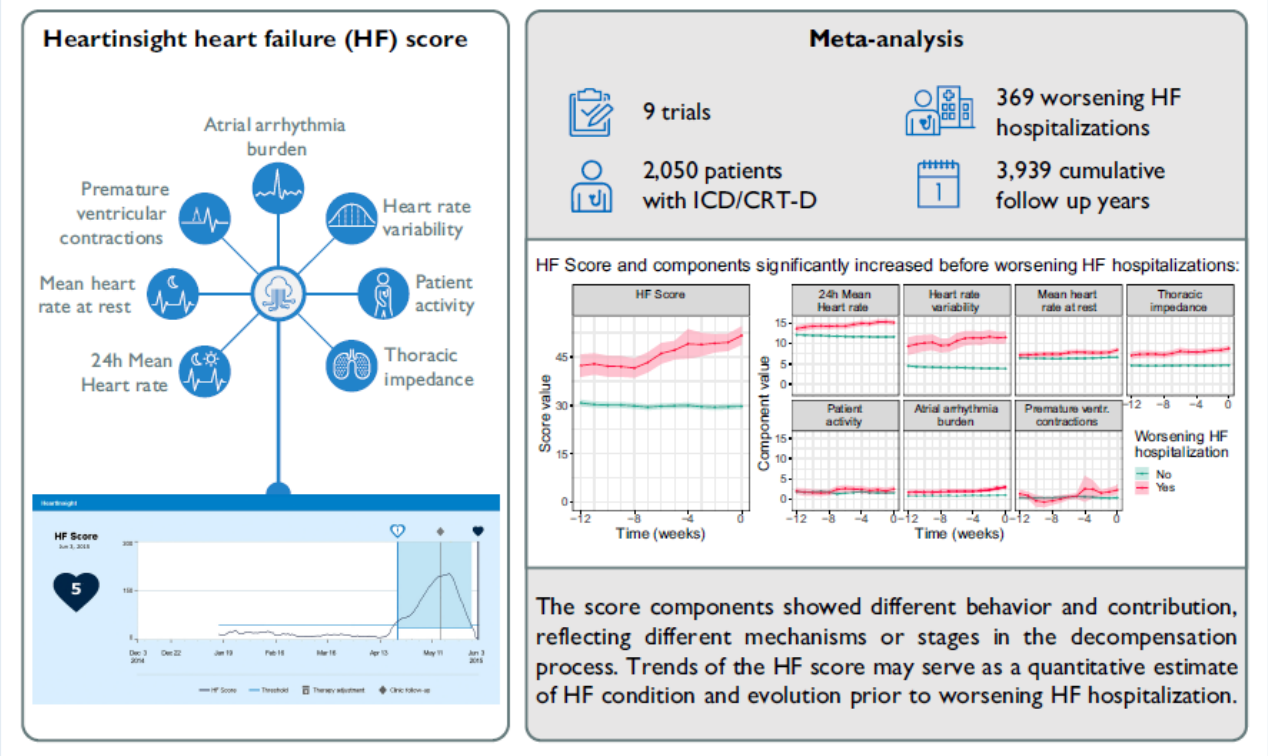
Methods and results

Data from nine clinical trials were pooled, including 2050 patients with a defibrillator capable of atrial sensing, ejection fraction $\leq 35\%$, NYHA class II/III, no long-standing atrial fibrillation, and 369 WHFH from 259 patients. The mean HF score was higher in the WHFH group than in the no WHFH group (42.3 ± 26.1 vs. 30.7 ± 20.6 , $P < 0.001$) already at the beginning of 12 weeks. The mean HF score further increased to 51.6 ± 26.8 until WHFH (+22% vs. no WHFH group, $P = 0.003$). As compared to the no WHFH group, the algorithm components either were already higher 12 weeks before WHFH (24 h HR, HR variability, thoracic impedance) or significantly increased until WHFH (nocturnal HR, atrial tachyarrhythmia, ventricular extrasystoles, patient activity).

Conclusion

The HF score was significantly higher at, and further increased during 12 weeks before WHFH, as compared to the no WHFH group, with seven components showing different behaviour and contribution. Temporal trends of HF score may serve as a quantitative estimate of HF condition and evolution prior to WHFH.

Graphical Abstract



Keywords

Worsening heart failure hospitalization • Predictive algorithm • Heart failure score • Implantable defibrillators • Remote monitoring • Heart rate

Managing HeartInsight – Our Experience

Received: 16 October 2023 | Revised: 26 January 2024 | Accepted: 2 February 2024

DOI: 10.1002/joa3.13032

SPOTLIGHT

Journal of Arrhythmia Open Access **WILEY**

Optimizing remote heart failure management: First experiences with the HeartInsight score for implanted defibrillators

Luca Santini MD, PhD¹  | Francesco Adamo MD, PhD¹ | Nicola Danisi MD¹ |
Karim Mahfouz MD¹ | Carlo Colaiaco MD¹ | Ilaria Finamora MD¹ |
Claudia Sorrentino BSc¹ | Mariagrazia Romano BSc¹ | Alessio Ferrara MSc² |
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Optimizing remote heart failure management: First experiences with the HeartInsight score for implanted defibrillators – Case 2



Trends observation could lead to an erroneous diagnosis of HF

Man, 67-years-old, ischemic cardiomyopathy and reduced LV EF% .
Mean HR and Rest HR increase

Thoracic impedance, HR Variability, Patient Activity decrease
ICD (Intica 5 VR-T DX, BIOTRONIK) in primary prevention in 2018.

Reality check
At implant, SHFM score was -0.052.

Bacterial Pneumonia diagnosis November 23, 2019

Patient Re-Evaluated on February 4th, 2020 in good conditions

HF Score of 26 on a Nominal Threshold of 45
No Alert Set!

How to implement HeartInsight in Clinical Practice?

European Heart Journal Supplements (2023) 25 (Supplement C), C337-C343
The Heart of the Matter
<https://doi.org/10.1093/eurheartjsupp/suad030>



HeartInsight: from SELENE HF to implementation in clinical practice

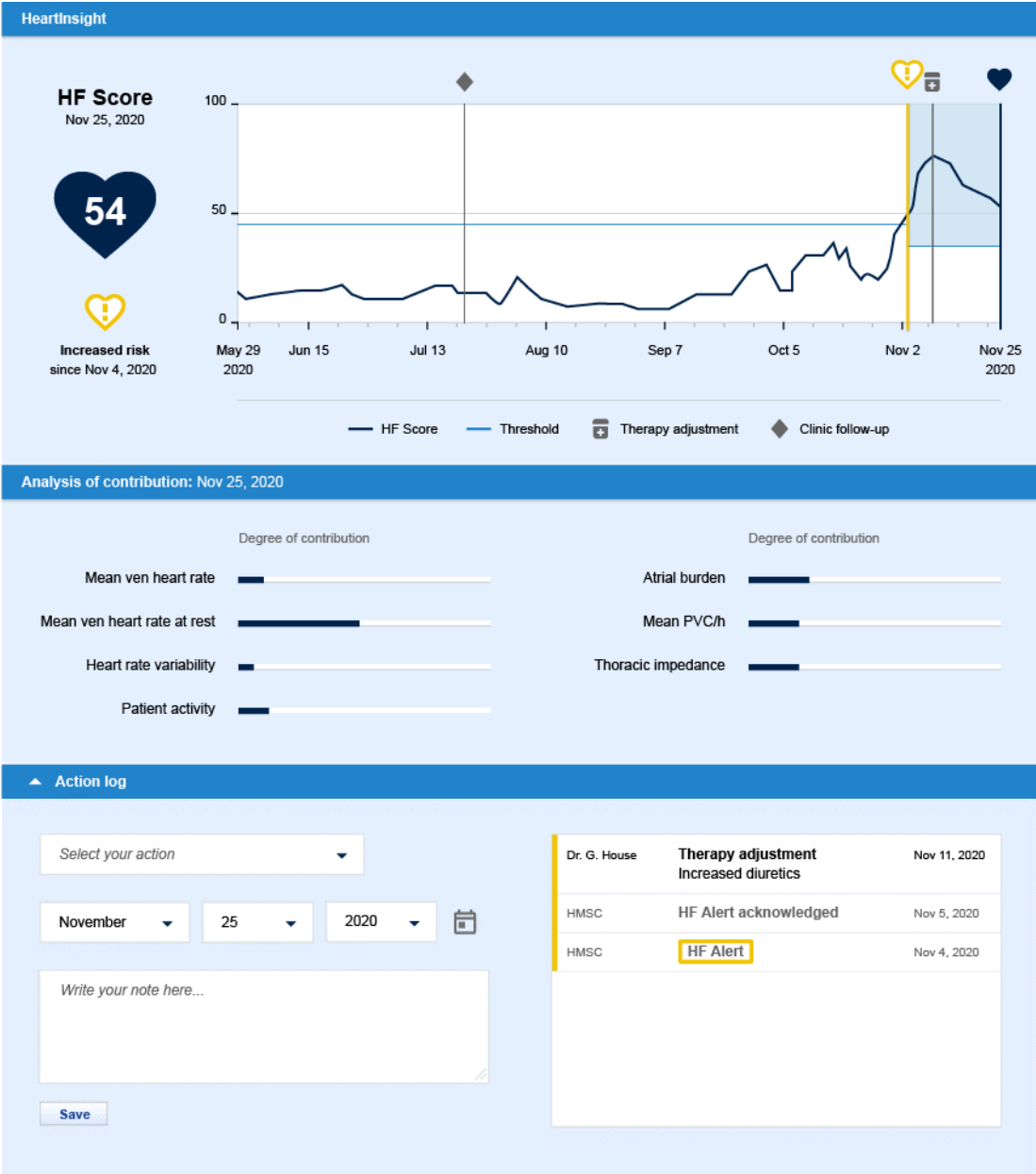
Gabriele Zanutto^{1*} and Alessandro Capucci²

¹Department of Cardiology, Ospedale Magalini di Villafranca (VR), Via Ospedale Marcello Magalini, 2, 37069 Villafranca di Verona (VR), Italy; and ²Department of Biomedical Sciences and Public Health, Università Politecnica delle Marche, Ancona 60121, Italy

KEYWORDS

Cardiac implantable electronic device;
Heart failure;
Cardiac resynchronization therapy;
Implantable cardioverter-defibrillator (ICD);
Remote monitoring

There is strong evidence that remote monitoring in cardiac implantable electronic devices can detect device malfunctions earlier than conventional monitoring and that it can be useful for detecting cardiac arrhythmias, while little data are available for an improved management of heart failure (HF). HeartInsight is a new remote monitoring algorithm developed and validated in the SELENE HF study that combines information from a diverse set of sensors integrated into one alert to detect worsening HF with promising accuracy. However, the shift from detecting technical issues or arrhythmia episodes to early predicting clinical events underscores the need to understand how to properly integrate these tools into the clinical workflow by defining an organizational model and shared guidelines for the management of HF alerts. Here, we critically discuss issues that will be raised by the implementation of this 'enhanced' remote monitoring approach to HF care in daily clinical practice.



but....

Big Data is one of the **biggest and most pervasive evolutions** of the digital world.



Can Big Data be used to improve health and care, predict diseases or change behaviors?



„there's a difference
between knowing the path
and walking the path“
Morpheus, Matrix

**It's not just about the
sensors...**

Uno dei principali motivi del sottoutilizzo dei sistemi di monitoraggio remoto è il **sovraccarico di lavoro**.

Pertanto, un punto cruciale per migliorarne l'adozione e l'implementazione è garantire la loro **sostenibilità**.

Come possiamo riuscirci?



Modello organizzativo

Primary Nursing based workflow

Home  Guide



Ricci et al.: Europace (2013)15;i49-i53

Recommendations for staffing requirements for RM

COR	LOE	Recommendations	References
1	B-NR	1. For the care of patients with CIEDs on RM, a <u>team-based organizational model with formal policies, procedures, and clear definitions of the roles and responsibilities of qualified staff</u> is recommended to optimize all related RM tasks.	1,25,28,29,53,90,102–109
1	B-NR	2. For the care of patients with CIEDs on RM, it is recommended that there is <u>adequate dedicated time</u> to perform all RM tasks, including scheduled and nonscheduled transmissions, patient follow-up, and administrative tasks.	25,28,57,104,106,110
1	B-NR	3. For the care of patients with CIEDs on RM, it is recommended that the staff-to-patient ratios in RM clinics reflect <u>the increasing unscheduled transmission workload</u> .	3,28,59,111,112
2a	C-LD	4. For the care of patients with CIEDs on RM, it is reasonable for clinics to have a minimum of 3.0 full-time equivalents per 1000 patients on RM, comprising both clinical and administrative staff.	27

Workflow strutturato Multidisciplinare

Interventi multidisciplinari raccomandati per la gestione dello scompenso cardiaco cronico

Al fine di ridurre le ospedalizzazioni e la mortalità, le precedenti linee guida raccomandavano l'uso di programmi multidisciplinari di gestione dello scompenso cardiaco (HF-MP)

L'implementazione ottimale di un HF-MP richiede un team multidisciplinare attivo lungo l'intero percorso HF.

McDonagh et al., European Heart Journal (2021) 00, 1128 doi:10.1093/eurheartj/ehab368



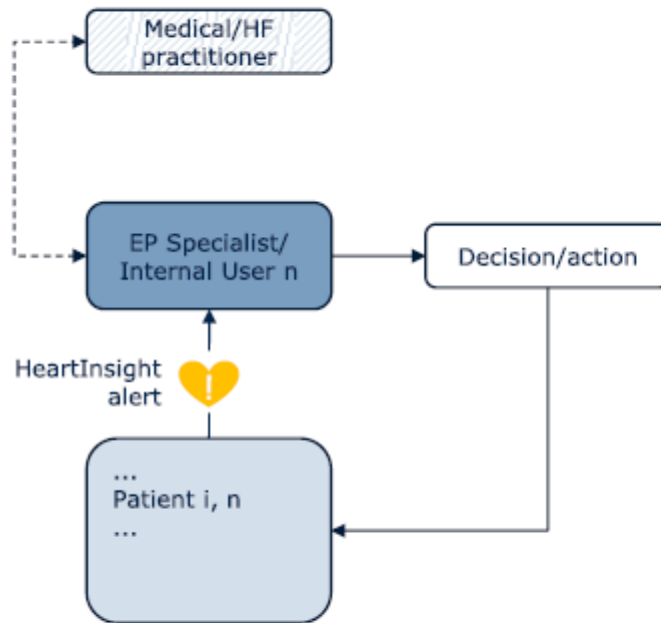
Recommendations	Class ^a	Level ^b
It is recommended that HF patients are enrolled in a multidisciplinary HF management programme to reduce the risk of HF hospitalization and mortality. ^{309,314,315,316}	I	A
Self-management strategies are recommended to reduce the risk of HF hospitalization and mortality. ³⁰⁹	I	A
Either home-based and/or clinic-based programmes improve outcomes and are recommended to reduce the risk of HF hospitalization and mortality. ^{310,317}	I	A
Influenza and pneumococcal vaccinations should be considered in order to prevent HF hospitalizations. ^{315,316}	IIa	B

© ESC 2021

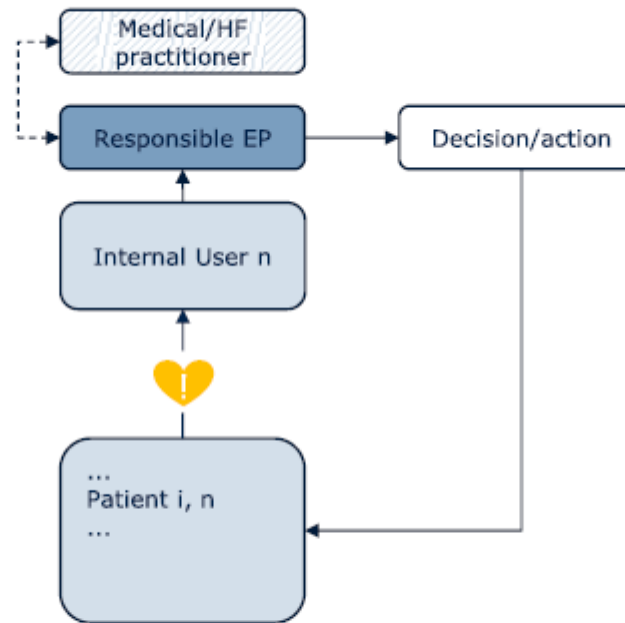
Taking charge of a HeartInsight alert

Home Guide HI Workflow Models (Home Guide Primary Nursing or Home Guide Supervised Network)

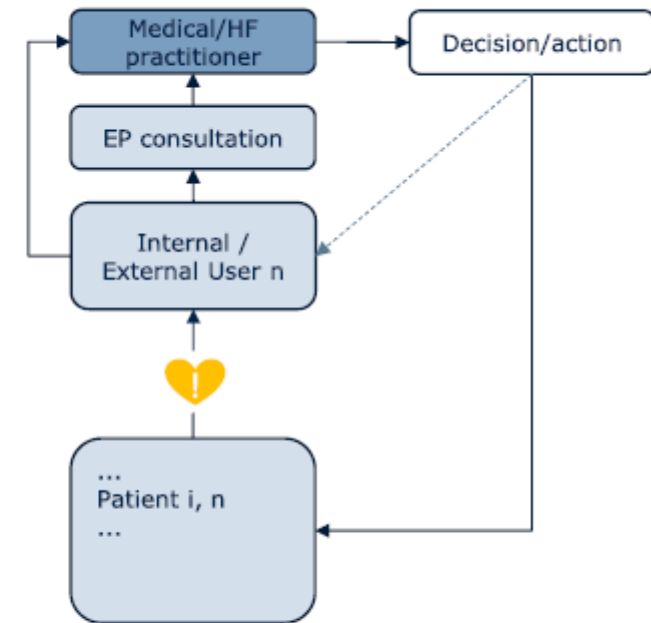
Workflow Model A



Workflow Model B

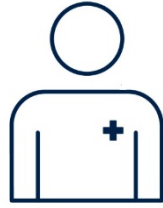


Workflow Model C



- consultation
- involved in the process
- responsible for medical decision

Gestione Remota degli Allarmi e della Diagnostica nei pazienti con CIED



GESTIONE REMOTA

ALLARMI PARAMETRI HF

Monitor HF				
☐	☒	☐	☐	Off
☐	☒	☐	☐	Soglia dell'allarme HF: score
				almeno 45
☐	☒	☐	☐	Terapia di resincronizzazione:
				CRT
☐	☐	☐	☒	stimolazione
				< 85%
☐	☐	☐	☒	Frequenza cardiaca ven. media:
				> 80 bpm
☐	☐	☐	☒	Frequenza cardiaca ven. media a riposo:
				> 80 bpm
☐	☐	☐	☒	PVC/h media:
				> 50 PVC/h

Allarmi inerenti i parametri di gestione dello stato di compenso:

- Frequenza media e media a riposo
- PVC/h
- Predittore HI

Trend di parametri di gestione dello stato di compenso:

- Variabilità Cardiaca
- Attività
- Impedenza Toracica

Solo per Allarme %CRT

GESTIONE DIRETTA



AMBULATORIO CIED

Valutare se chiamare il paziente per una visita ambulatoriale

- Modifica della Programmazione

COMUNICAZIONE



AMBULATORIO HF

Osservazione della diagnostica HM ed Eventuale azione clinica

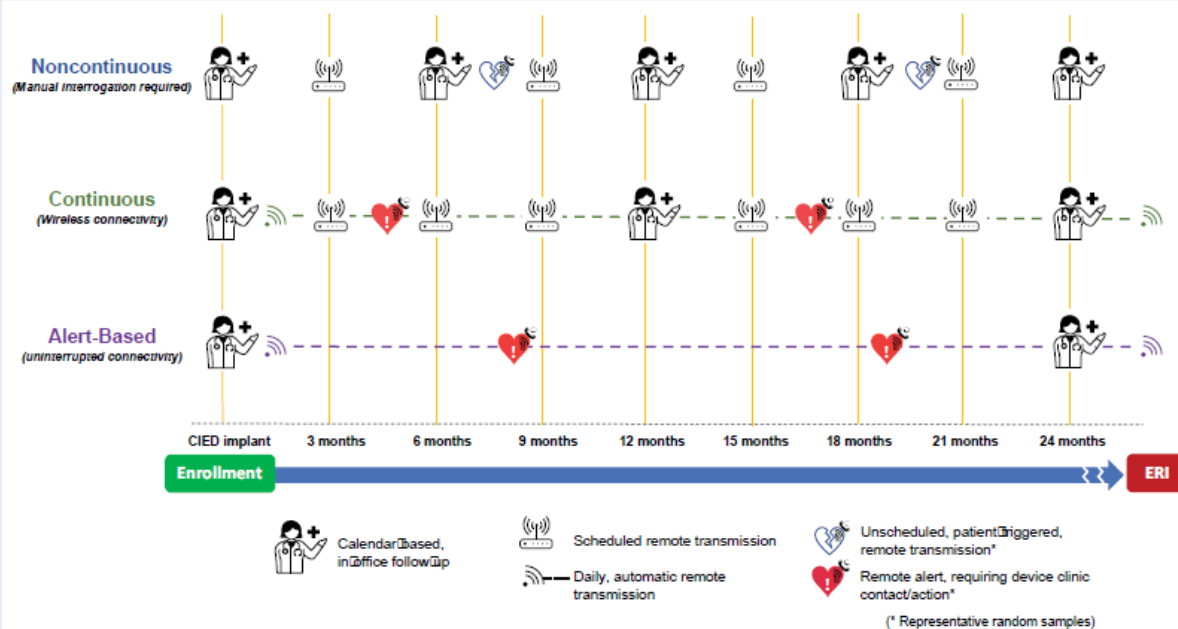
2023 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Practical Management of the Remote Device Clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair)^{1*}, Satish R. Raj, MD, MSCI, FHRS (Co-Chair)^{2*}, Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair)^{3†}, Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair)^{4‡}, Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair)^{5§}, Haruhiko Abe, MD, PhD^{6‡}, Serge Boveda, MD, PhD, FEHRA, FESC^{7†}, Derek S. Chew, MD, MSc, FHRS^{2*}, Jong-Il Choi, MD, PhD, MHS^{8‡}, Nikolaos Dagres, MD^{9†}, Aarti S. Dalal, DO, FACC, FHRS, CEPS-P^{10¶}, Brynn E. Dechert, APN, FHRS, CCDS^{11¶}, Camille G. Frazier-Mills, MD, MHS, CCDS^{12*}, Olivia Gilbert, MD, MSc, FACC^{13#}, Janet K. Han, MD, FACC, FHRS^{14**}, Sherri Hewitt, PharmD^{1†}, Christine Kneeland, BSN^{15*}, Starr DeEllen Mirza^{††}, Suneet Mittal, MD, FHRS^{16*}, Renato Pietro Ricci, MD^{17†}, Mary Runte, PhD^{18††}, Susan Sinclair, NZCS, PGDHSc^{19‡}, Ricardo Alkmim-Teixeira, MD, PhD^{20§}, Bert Vandenberg, MD, PhD^{2,21†}, and Niraj Varma, MA, MD, PhD^{22‡‡}

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2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

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Recommendations for RM considerations

COR	LOE	Recommendations	References
1	A	1. In patients with CIEDs, RM is recommended as part of the standard of care.	1,11,30–38

- (7) A relationship between RM clinics and device manufacturers for bi-directional exchange of ideas for staff training, patient education, patient care services, and management of safety advisories and recalls is imperative.
- (8) Use of third-party resources may offer financial and practical benefits for dealing with increased device clinic volume.
- (9) Pediatric patients with CIEDs on RM require scheduling similar to that for RM of adult patients but may have special needs requiring additional considerations.
- (10) Implantable loop recorders require immediate connectivity to RM with special programming needs based on the patient's clinical indication for the implantable loop recorder.
- (11) Alert-based RM that relies on continuous connectivity allowing for extended time intervals between in-office device interrogations.

Remote monitoring OPTIMIZATION

Remote transmission

	Patient Initiated Interrogation	Alert	Scheduled	Total	Total/y
Total	102055 (28%)	73371 (20%)	183361 (52%)	358787	14,6
Pacemaker	9945	6129	14676	30750	10,5
ICD	25677	18392	45642	89711	10,8
CRT-P	1220	1189	2078	4487	11,3
CRT-D	32825	44951	63077	140853	14,3
S-ICD	32388	2710	57888	92986	29,0
With Alert	2394 (2%)	73371 (100%)	6119 (3%)	81884 (22%)	



App Paziente

Questionario Evento



HMSC

Allarme HeartInsight



Cellulare del Paziente

Notifica sul
Cellulare

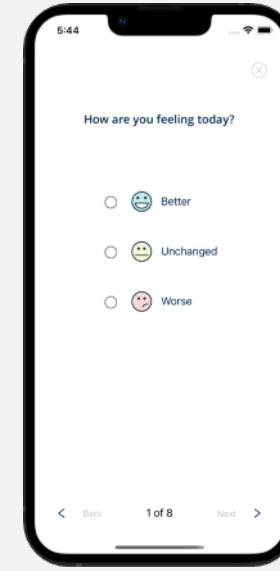
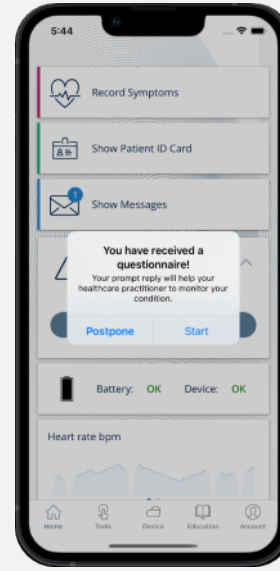
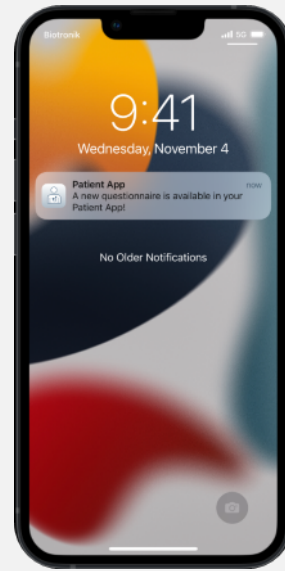
Avviso nella
App

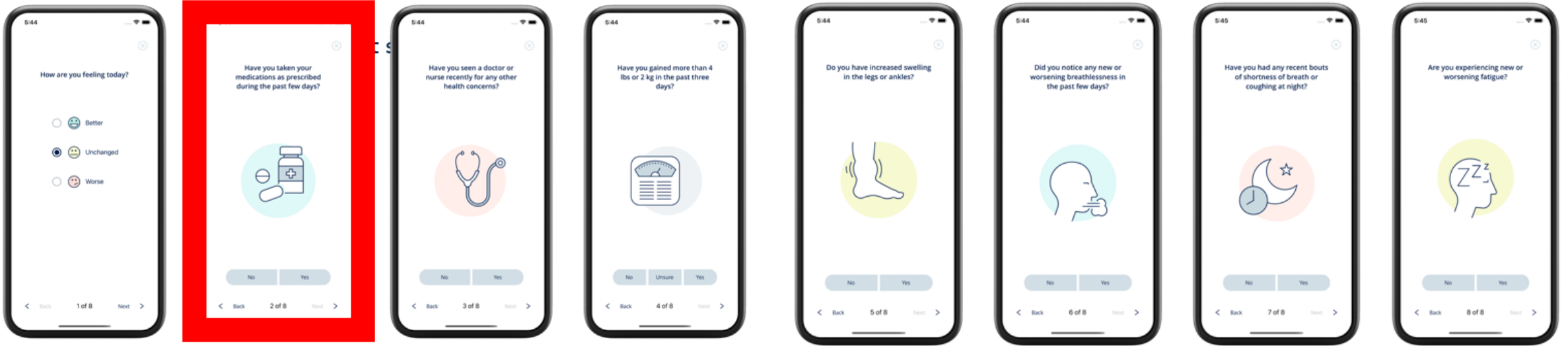
Questionario



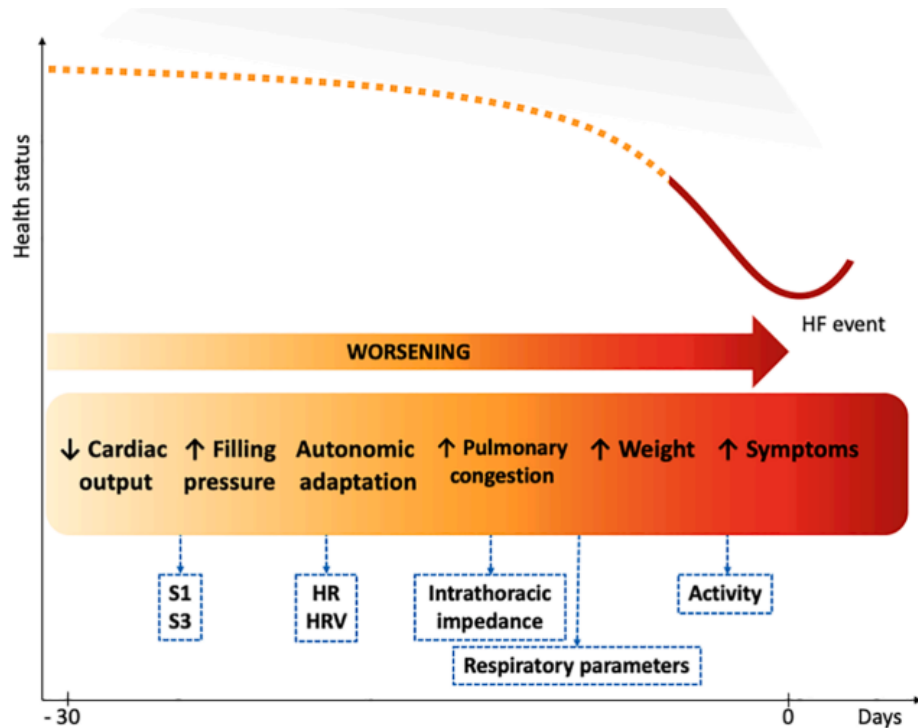
HMSC

Risultato visualizzato su HM





BeActive!



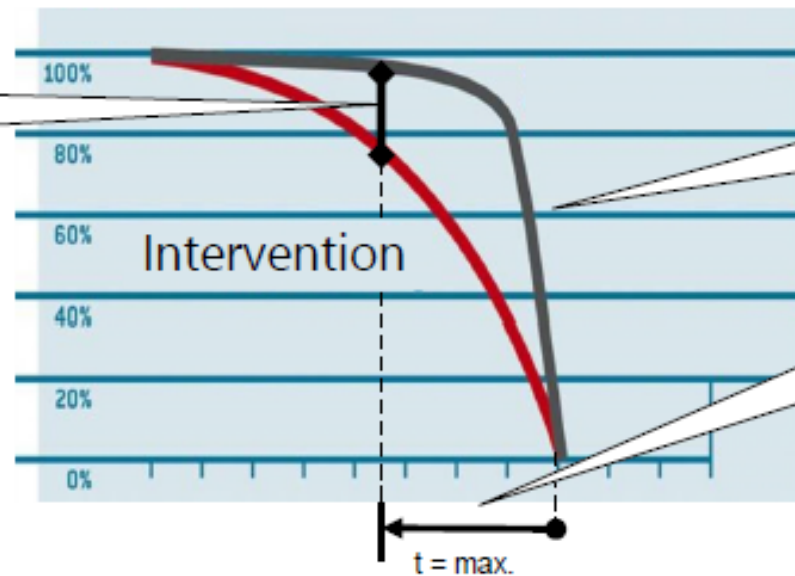
- In most cases, the patient will be asymptomatic when the HI alarm arrives.
- *According to current status of knowledge, there is not an established role for preventing symptoms of congestion in asymptomatic patients*.*
- **Alert-Assess-Action**
 - Every alarm must be carefully analysed.
 - Every patient with an alarm must be carefully assessed (device programming, compliance with prescribed therapy, physical activity,..)
 - Increased decompensation therapy must be considered even in the absence of symptoms*.

*Boriani G, Imberti JF, Bonini N, Carriere C, Mei DA, Zecchin M, Piccinin F, Vitolo M, Sinagra G. Remote multiparametric monitoring and management of heart failure patients through cardiac implantable electronic devices. Eur J Intern Med. 2023;115:1-9.

How to Intervene?

Rationale of Telemedicine for Heart Failure Patients

„I feel healthy“
 $\neq$
„I am healthy“



- Intervention before significant clinical deterioration
- Time for Interventions (hours)

HeartInsight Interface

Identify High HF Risk Patients

Dedicated
Patients
List



 **BIOTRONIK**

Home Monitoring Service Center



Monitoring

Patients for review

Early detection

HM follow-up

QuickCheck

Administration

HeartInsight

All patients

New patient

ReportShare

Received reports

Administration

Users

New user

Patient groups

New patient group

Transmitters

Option templates

Clinic settings

Site tools

Richard Jordan

Nov 11, 2020 11:30 AM

Your patients today

You've got 5 patient for review.

1

2

Early detection

2

Home Monitoring-supported follow-up

0

QuickCheck

1

Administration

HeartInsight

4

You've got 4 patients with HF alert of which 2 unacknowledged.

Message of the day

The Acticor and Rivacor families offer our new **QuickCheck** feature and **IN-TIME HF Alert Template**.

QuickCheck allows you to request fresh Home Monitoring follow-up data, including an IEGM from the implanted device, at any time. If the patient is in range of the CardioMessenger Smart, the data will be typically available within **3-4 minutes**.

The new **IN-TIME HF Alert Template** provides one-click access to the IN-TIME¹ protocol – a proven, outcomes improving care pathway for heart failure patients.

[More news](#)





New section

HeartInsight Interface

Identify High HF Risk Patients

BIOTRONIK Home Monitoring Service Center

Monitoring

- Patients for review
 - Early detection
 - HM follow-up
 - QuickCheck
 - Administration
- HeartInsight**
- All patients
- New patient

ReportShare

- Received reports

Administration

- Users
 - New user
- Patient groups
 - New patient group
- Transmitters
- Option templates

HeartInsight – patients with increased risk for worsening heart failure

Patients 1 - 6 of 6

Search Display 10 20 50 1 - 6 of 6

Patient ID	Finding	Device/SN	Implantation	Comment
Pat1_HF	HF HFalrt, ...	Acticor 7 HF-T QP 12345678	Nov 10, 2019	All patients in HF alert state (increased risk)
Pat2_HF	HF HFalrt, ...	Rivacor7 HF-T QP 87654321	Dec 27, 2019	
Pat3_HF	Lead LeadRV, ...	Acticor 7 HF-T 32345678	Jan 1, 2020	
Pat4_HF	Recordings / Episode Epis, ...	Acticor 7 HF-T 412345678	Feb 2, 2020	
Pat5_HF	Recordings / Episode Epis, ...	Acticor 7 HF-T 52345678	Mar 3, 2020	
Pat6_HF	Lead LeadRV, ...	Intica Neo 7 VR-T DX 10101010	Apr 4, 2020	

View HeartInsight patients with increased risk All patient groups Activated monitoring Extended view

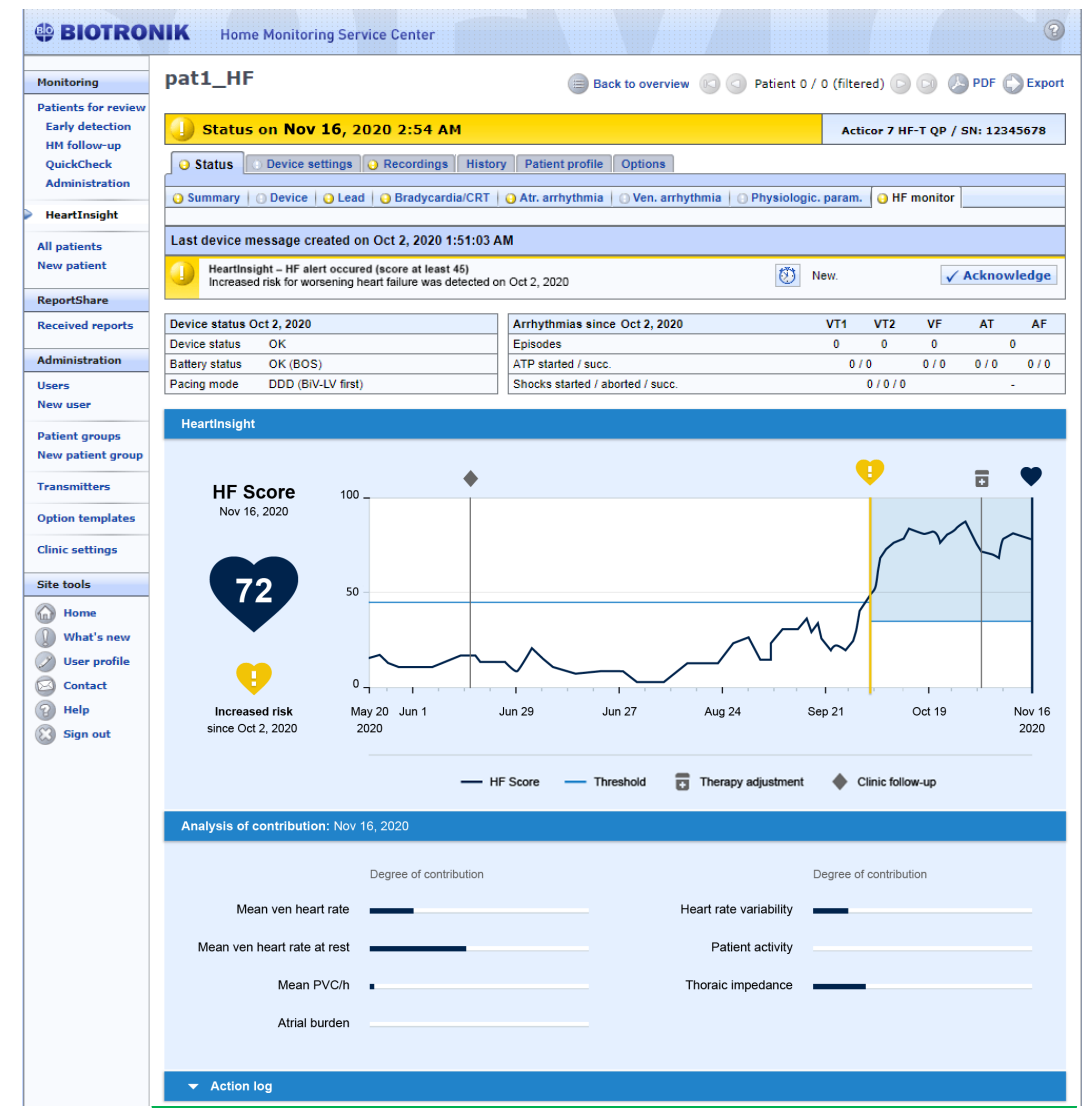
PDF

Additional indicator for
HF patients
(visible on all patient lists)

Direct Link to the
HF Monitor tab of
the patient

HeartInsight Interface

Longitudinal parameter trends and related contributions are integrated into the dashboard



HF Monitor contains all the parameters used in the HeartInsight alert

Results of the HF questionnaire

▲ Patient App

HF questionnaire Nov 5, 2020

Send questionnaire Open Patient App settings

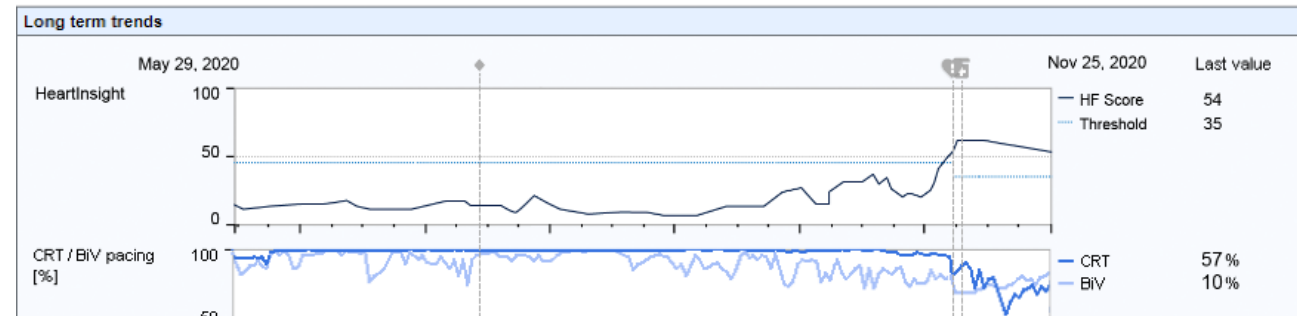
Health status and behavior	Patient response
😊 Self-perceived health status	Worse
💊 Medication adherence	No
👨‍⚕️ Doctor visit due to other health reasons	No

Symptoms	Patient response
💧 Dyspnea	No
🌙 Nocturnal coughing	No
⚖️ Sudden weight gain (>4 lbs or 2 kg)	Yes
🦶 Peripheral edema	No
🧠 Fatigue	No

Manual sending of the questionnaire

Quick access to Patient App settings

Markers of worsening status



HeartInsight - Possible interactions with HMSC in case of alerts



1. If nothing is done

- No change in HMSC
- Patient would remain in all submitted patient lists "Your patients today"
- "HeartInsight" New push notification every seven days

2. Postpone

- No further notification from HeartInsight for the postponed period
- The patient would leave "Your patients today" list

3. Accepted

- No further notification from HeartInsight
- Patient would leave List of patients "Your patients today"
- list "of which x patients not accepted"

In all cases: the patient status remains yellow until the HeartInsight score is below the recovery threshold.

Your patients today
You've got 1 patient for review.

Early detection

Home Monitoring-supported follow-up

QuickCheck

Administration

HeartInsight
You've got 1 patient in alert state, of which 1 patient unacknowledged.

Your patients today
You have 1 patient with activated monitoring.

Early detection

Home Monitoring-supported follow-up

QuickCheck

Administration

HeartInsight
You've got 1 patient in alert state, of which 1 patient unacknowledged.

Your patients today
You have 1 patient with activated monitoring.

Early detection

Home Monitoring-supported follow-up

QuickCheck

Administration

HeartInsight
You've got 1 patient in alert state, of which 0 patients unacknowledged.

The importance of tracking patient actions

Clinical data input for the calculation of the Seattle Heart Failure Model

SHFM is an Optional But Crucial Component of HeartInsight

Seattle Heart Failure Model requires manual input of 23 parameters

- Age, weight, sex, blood pressure
- NYHA class, ejection fraction
- HF drugs
- Laboratory data
- Sex and date of birth identical to the "Patient Data" tab
- Continuously adjusted age
- If all or some data points are not entered, the default mean values of the Selene HF study will be used

We can enter/update data at any time

StatusDevice settingsRecordingsHistoryPatient profileOptionsQuickCheck

Patient dataClinical dataRemote SchedulingLead informationQuickCheck

Clinical	
Sex	Female
Date of birth	Nov 6, 1951
Weight	89.5 kg
NYHA	II
Ejection fraction	30 %
Systolic blood pressure	124 mmHg
Ischemic etiology	Unknown

Medication	
ACE inhibitor	No
Beta blocker	Yes
Angiotensin receptor blocker	Yes
Statin	Yes
Allopurinol	No
Potassium sparing diuretics	No

Diuretics	
Furosemide	50 mg/day
Bumetanide	- mg/day
Torsemide	- mg/day
Metolazone	- mg/day
Hydrochlorothiazide	- mg/day

Lab Data	
Hemoglobin	11.4 g/dl
Lymphocytes	22.3 %
Blood uric acid	3.2 mg/dl
Total cholesterol	231 mg/dl
Blood sodium	139 mEq/l

Last change Richard Jordan on Apr 6, 2021 10:56 AM

Edit

Progetto HeartInsight Action

- Studio retrospettivo sull'utilizzo di un predittore di scompenso cardiaco acuto in pazienti con defibrillatore impiantabile nella pratica clinica quotidiana
- A partire dal Kick-off meeting del 3 Aprile 2025 hanno aderito **43 centri italiani**, tutti dotati di un modello organizzativo per la gestione del controllo remoto e per l'utilizzo di HI. Di questi, 33 hanno già registrato almeno un caso.
- Il Progetto è stato sottomesso al **Comitato Etico Territoriale Lazio Area 2** il 23-OTT-2025.



Centro	n. registrazioni	n. alert
Ospedale di Circolo e Fondazione Macchi di Varese	42	12
Policlinico Umberto I, Roma	36	16
PO Fazzi di Lecce	25	9
Azienda Ospedaliera Carlo Poma, Mantova	23	6
Policlinico Universitario Fondazione Gemelli, Roma	20	--
Osp. Giovanni Paolo II, Ragusa	15	--
Ospedale San Giovanni Bosco, Torino	14	9
Mater Salutis, Legnago	13	--
Federico II Napoli	12	10
Ospedale Civile Santissima Annunziata, Sassari	9	4
Ospedale di Rivoli, Rivoli (TO)	9	--
Ospedale San Paolo, Milano	8	1
UMG Mater Domini, Catanzaro	8	--
Ospedale G. B. Grassi, Lido di Ostia (RM)	7	--
Nuovo Arcispedale Sant'Anna, Cona (FE)	7	3
A.O. Universitaria Maggiore della Carità, Novara	6	2
Ospedale Maria Vittoria, Torino	5	1
Ospedale Pio XI, Desio (MB)	5	1
Ospedale Santa Croce e Carle, Cuneo	4	--
Grande Ospedale Metropolitano Niguarda, Milano	4	--
Ospedale Civile SS. Annunziata, Savigliano (CN)	3	--
Piemonte, Messina	3	--
Osp. Magalini, Villafranca	3	--
Ospedale di Rho	3	--
Ospedale Sandro Pertini, Roma	2	--
Fondazione Toscana "Gabriele Monasterio", Pisa	2	--
Ospedale di Saronno, Saronno (VA)	2	--
Policlinico Bari, Bari	2	--
A.O. Careggi, Firenze	2	--
Osp Morgagni-Pierantoni, Forlì	2	--
P.O. S. Giovanni di Dio Crotone	2	--
Policlinico Tor Vergata, Roma	1	1
Osp. San Bartolo, Vicenza	1	--

HI-Action
status
@31-MAR-2026



391 pazienti registrati da Aprile 2024



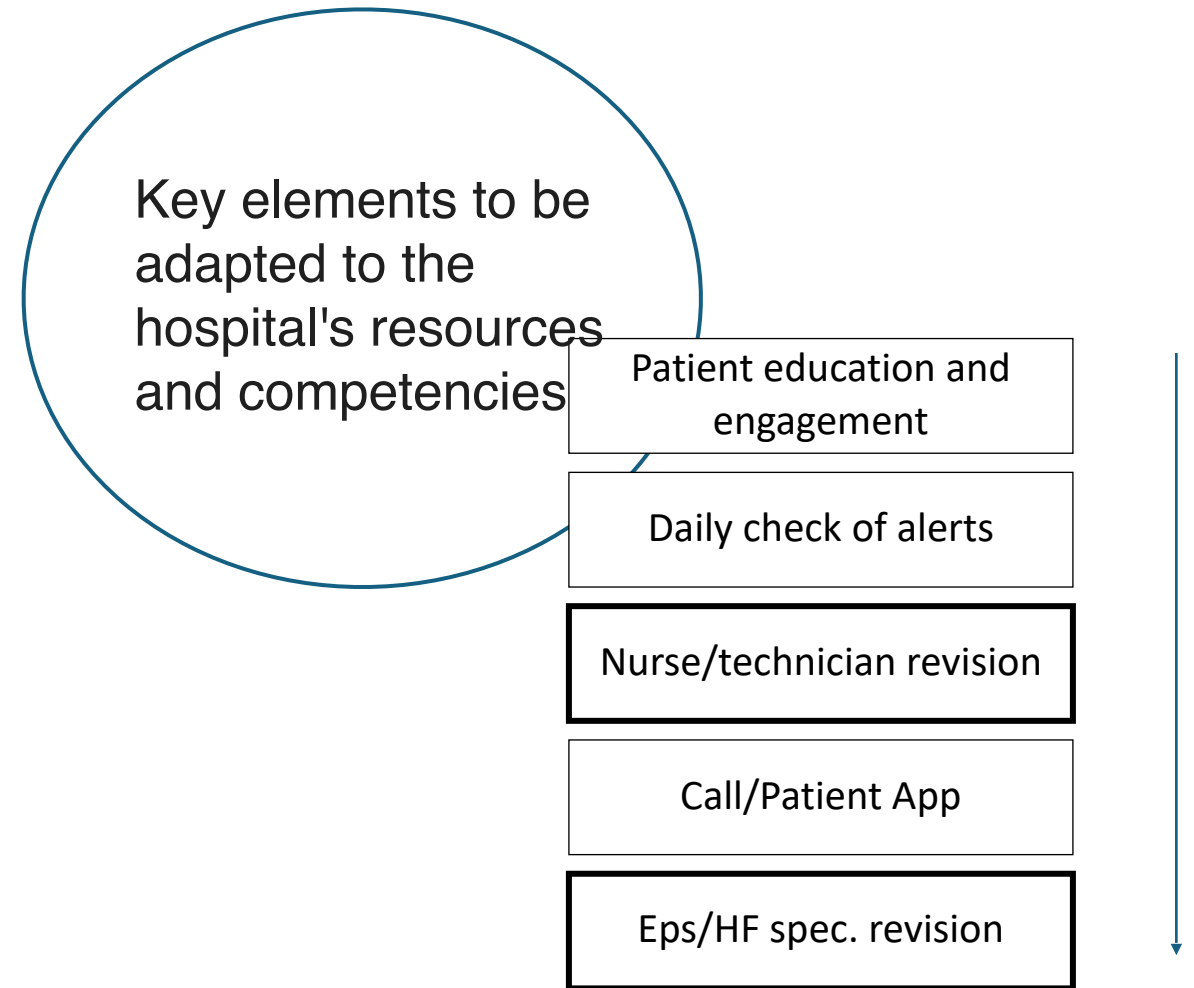
Follow-up medio di 383 gg



157 alert tracciati

Implementing an Optimal Workflow: Recommendations

- 1. Dedicated and in sufficient numbers staff**
- 2. Choose Alert-Based Strategy**
- 3. Patient engagement and flexible interaction modalities**
- 4. dedicated platforms and interoperability with corporate IT systems**
- 5. Timely and Courageous Action**
- 6. Structure a Multidisciplinary Protocol**



Conclusions

- **Telemedicine** (with devices but also non-invasive, if combined with a strict and efficient organisational model) and with the increasingly **real integration of AI**, can improve the management of HF
- Current evidence shows that thanks to recent technological developments **we can predict heart failure flare-ups** in CIEDs patients
- **CIED Remote Heart Failure Monitoring** is able to identify patients during periods of significantly increased risk of heart failure events.
- The use of these algorithms may enable an **efficient use of healthcare resources** for the management of patients with HF, **prioritizing** the attention to the patients who really need a clinical action
- If an **alert based management strategy** is adopted, such a strategy would not generate a high workload for the centers.
- To know whether we will also be able to **PREVENT** exacerbations and reduce hospitalisations, we still have to wait for the results of randomised trials and to gain more experience in real life