SignalHF

Instructions for use

Document Reference	Date
IFU2-IM008-INSTRUCTIONS FOR USE	20240328

Table of contents

Document revisions

Version	Modification
20230324	First version
20230402	Review for MDR regulation
20230705	Indication for use changed to add (over 18 yo)
20230831	Clinical study results summary reported in Section 6, Add the warnings following usability study. Change of version.
20230927	Add of information about artificial intelligence used and the physiological and demographic variables being used by the AI/ML model underlying the device.
20231021	Add of the warning “In patient populations unlikely to have acute decompensation of HF, the use of the algorithm may have less and possibly poor PPV and NPV.” And “The actual numeric “score” does not correlate to a higher percent chance of hospitalization outside of the thresholds specified. The score always needs further investigation.” Add of the performance analysis per manufacturer, device model type and number of leads Changes on intended use and indication for use.
20231117	Update of indication for use + minor modification
20240222	Add of the list of different degrees of contribution in section 3.4.2 Degrees of contribution
20240328	Review for V1.0.2

1 Introduction

This document describes the intended use and operation of the device SignalHF when it is used with a compatible Remote Monitoring Platform.

Device name	**SignalHF** version 1.0.2
Manufacturer	**IMPLICITY** **USA** 185 Alewife Brook Parkway Suite 210, Cambridge, MA 02138 (USA) **Europe** 29 RUE DU LOUVRE 75002 Paris (FRANCE)
Contact information and technical support	support@implicity.com phone USA: (+1) 929 350 7056 (9a.m to 6p.m EST) Europe: +33 (0) 9 61 67 41 14 (9a.m to 6p.m CET)
Basic UDI DI	3770025266IM008RM

Carefully read all instructions prior to use.
Observe all warnings and precautions noted throughout these instructions.
Failure to do so may result in complications in use of this product.

2 SignalHF device information

2.1 Device description

SignalHF is a software as medical device (SaMD) including artificial intelligence (AI) that uses a proprietary and validated algorithm, the SignalHF HF Score, to calculate the risk of a future worsening condition related to Heart Failure (HF). The algorithm computes this HF score using data obtained from (i) a diverse set of physiologic measures generated in the patient's remotely accessible pre-existing cardiac implant (activity, atrial burden, heart rate variability, heart rate, heart rate at rest, thoracic impedance (for fluid retention), and premature ventricular contractions per hour), and (ii) his/her available Personal Health Records (demographics). SignalHF provides information regarding the patient's health status (like a patient's stable HF condition) and also provides alerts based on the SignalHF HF evaluation. Based on an alert and a recovery threshold on the SignalHF score established during the learning phase of the algorithm and fixed for all patients, our monitoring system is expected to raise an alert 30 days (on median) before a predicted HF hospitalization event (see Figure 1).

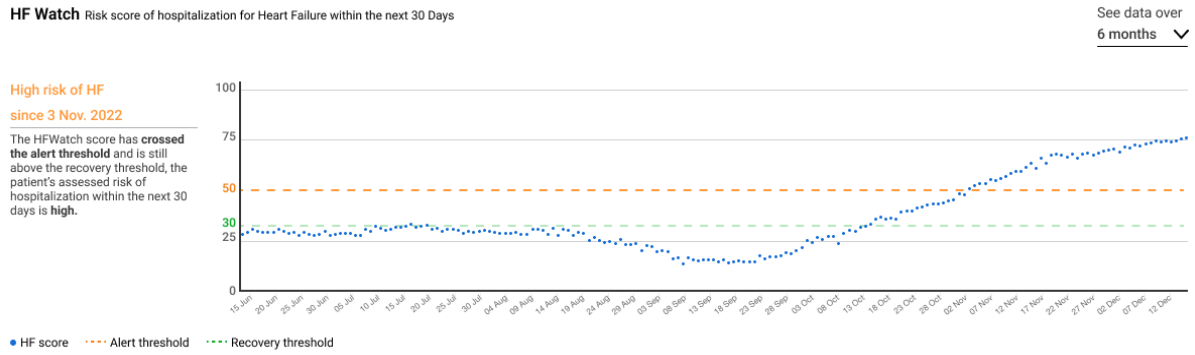


Figure 1. an example of a graph displaying the SignalHF score over time, crossing the alert threshold.

SignalHF does not provide a real-time alert. Rather, it is designed to detect chronic worsening of HF status. SignalHF is designed to provide a score linked to the probability of decompensated heart failure in the near or later future of the patient. This information is intended to be used adjunctively by healthcare professionals in order to better assess when patient therapy should be modified based on their clinical judgement and expertise.

The score and score-based alerts provided through SignalHF can be displayed on any compatible HF monitoring platform, including the Implicity platform. The healthcare professional (HCP) has several options to manage HF patients, like with any adjunct information from remote monitoring. Of course, the HCP's decision is not based solely on the device data which serve as adjunct information.

2.2 Intended use

SignalHF is intended to be used by qualified healthcare professionals (HCPs) as adjunctive information when remotely managing heart failure patients by providing a HF score based on cardiac parameters. The device is designed to be used with physiological data from compatible and patient pre-existing sensors such as cardiac implanted electronic devices (e.g. heart rate, patient activity, thoracic impedance, etc.) along with available clinical parameters (e.g. demographics, comorbidities, and medication).

SignalHF provides adjunctive information enabling assessment of patients' potential heart failure

status and risk of a worsening condition or hospitalization related to heart failure.

SignalHF provides adjunct information for qualified HCPs to use in conjunction with clinical evaluation that is part of standard clinical practice and should not replace standard of care treatment.

2.3 Indication for use

The SignalHF System is intended for use by qualified healthcare professionals (HCP) managing patients over 18 years old who are receiving physiological monitoring for Heart Failure surveillance and implanted with a compatible Cardiac Implantable Electronic Devices (CIED) (i.e., compatible pacemakers, ICDs, and CRTs).

The SignalHF System provides additive information to use in conjunction with standard clinical evaluation.

The SignalHF HF Score is intended to calculate the risk of HF for a patient in the next 30 days. This System is intended for adjunctive use with other physiological vital signs and patient symptoms and information and is not intended to independently direct therapy.

2.4 Intended user

IM008 is intended to be used by qualified healthcare professionals (HCPs) such as heart failure physicians and nurse practitioners, in charge of the remote monitoring program of patients at risk of heart failure decompensation.

2.5 Intended clinical benefit

Among patients implanted with CIEDs, those with pacemakers do not have any HF monitoring solution at their disposal, and only a small fraction of those with ICD/CRT-Ds can benefit from currently approved solutions such as TriageHF (Medtronic), HeartInsight (Biotronik) and HeartLogic (Boston Scientific). SignalHF allows for HF remote monitoring of patients with CIEDs and detects patients who are likely to experience a future worsening condition of HF decompensation, thus improving the prediction of HF decompensations. SignalHF can be used for patients with compatible pacemakers or CRT-P devices to predict HF decompensations. The interest for these patients is to benefit from the same HF prediction technology as patients implanted with an ICD or CRT-D, thus widening the application of HF monitoring solutions.

Clinical Benefit category	Relevant and meaningful clinical benefit parameters	Measurable clinical outcome(s)
Type of clinical benefit for ICD/CRT-D patient population	Reduction in risk of heart failure decompensation Reduction of the number of HF-related hospitalizations	Prediction of HF hospitalizations (%)
Type of clinical benefit for PM/CRT-P patient population	Reduction in risk of heart failure decompensation Reduction of the number of HF-related hospitalizations	Prediction of HF hospitalizations (%)
Clinical performance of the algorithm - magnitude	Patients who would benefit from decompensation prediction	Patients (%) in alert state 30 days before HF hospitalization

2.6 Residual risks

There is no residual risk using SignalHF.

2.7 Contraindications/Limitation

This version of SignalHF is compatible with specified ICD, CRT-D, PM and CRT-P devices.

IM008 is currently compatible with the following CIEDs able to produce thoracic impedance from 3 manufacturers:

- Medtronic PM with 1, 2 leads or CRT-P
- Medtronic ICD with 1, 2 leads or CRT-D
- Biotronik PM with 1, 2 leads or CRT-P
- Biotronik ICD with 1, 2 leads or CRT-D
- Boston Scientific ICD with 1, 2 leads or CRT-D

The INTEGRATOR must make sure not to send to IM008 any data generated by a non-compatible CIED.

Use of the IM008 with devices not specified above as compatible will not yield reliable results. Integrators must display to end users a warning about non-reliability of IM008 HF score for these devices.

SignalHF is not intended for pediatric use.

Warning: In patient populations unlikely to have acute decompensation of HF, the use of the algorithm may have less and possibly poor PPV and NPV.

2.8 Device output labels

The output of SignalHF is an HF risk score and score-based alerts displayed on any compatible HF monitoring platform, including the Implicity platform. The algorithm computes this HF score using data obtained from (i) a diverse set of physiologic or ECG measures generated in the patient's cardiac implant remotely accessible (**activity, atrial burden, heart rate variability, heart rate, heart rate at rest, thoracic impedance** (for fluid retention), and **premature ventricular contractions per hour**), and (ii) his/her available Personal Health Records (**demographics**).

2.9 PHI storage

SignalHF does not store any patient health information (PHI) data permanently. SignalHF is intended to be interfaced with a Remote Monitoring Platform which manages user authentication and PHI permanent data storage.

3 Instructions for use

3.1 Warnings and precautions

- SignalHF should be used within the scope of its intended use and indication for use described in section 2.2.

- SignalHF should be used in accordance with the conditions of these instructions for use and the instructions for use of the remote monitoring platform.

- **Cybersecurity:** SignalHF must be hosted in a secure environment isolated from direct access from the Internet. Requirements are defined in the installation instructions (IFU1-IM008-INSTALLATION INSTRUCTIONS).

- This manual contains screenshot examples. These screenshots are provided for reference only and are not intended to convey actual operating techniques.

- The degree of contribution is not the contributing factor's raw value, but rather it represents the extent to which this factor contributed to the SignalHF score for that day. The values of the contributing factors are presented in separate graphs.

- In patient populations unlikely to have acute decompensation of HF, the use of the algorithm may have less and possibly poor PPV and NPV.

- The actual numeric "score" does not correlate to a higher percent chance of hospitalization outside of the thresholds specified. The score always needs further investigation.

Any concerning incident related to the device should be reported to Implicity and to the competent authority of the Member State in which the user and/or patient is located, and/or other regulatory authorities as appropriate.

3.2 Device installation

Prior to use, SignalHF must be installed on a remote monitoring platform according to the IM008 Installation Instructions. Please refer to this document for information on requirements for Platform compatibility.

3.3 Activation / deactivation of SignalHF

Once authenticated on the Platform, the user (the clinician) should have access to their medical center's settings page, where the user can access Signal HF's documentation and activate or deactivate SignalHF.
The user should find SignalHF's version and short description, and shall be able to download the instructions for use.

The user can also decide at any time to activate or deactivate SignalHF for all the compatible devices associated to his or her medical center in the Platform (by selecting the check box “use the algorithm”), or for some select patients only:

- Once “use” is checked, SignalHF is activated and every new data received from the cardiac implantable electronic device will be processed by SignalHF upon reception by the Platform.
- When “use” is unchecked, SignalHF is deactivated and new data received from the cardiac implantable electronic device will not be processed by SignalHF.

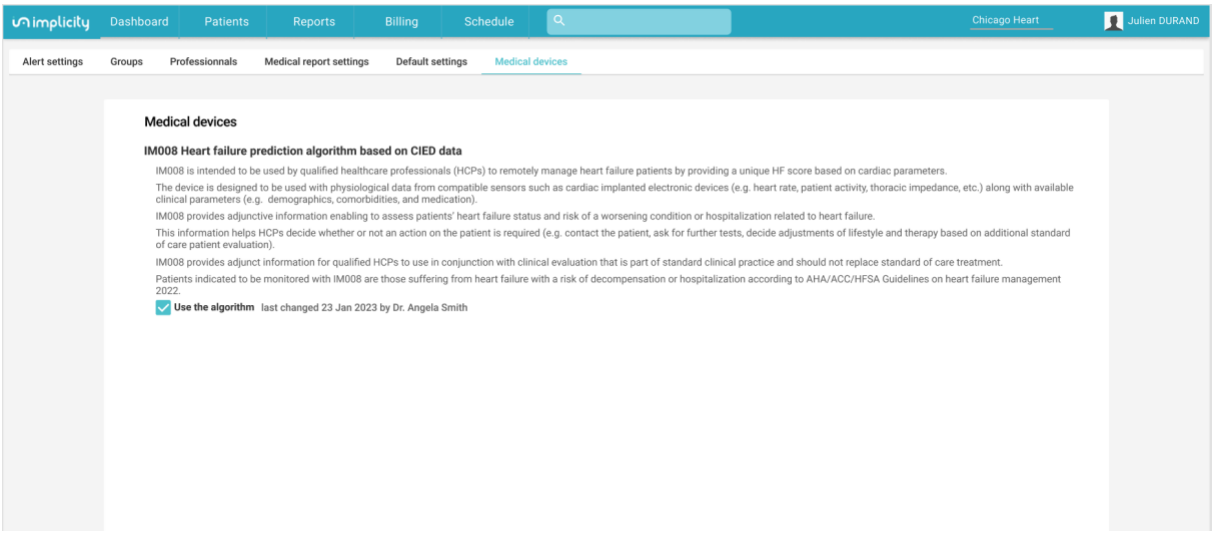
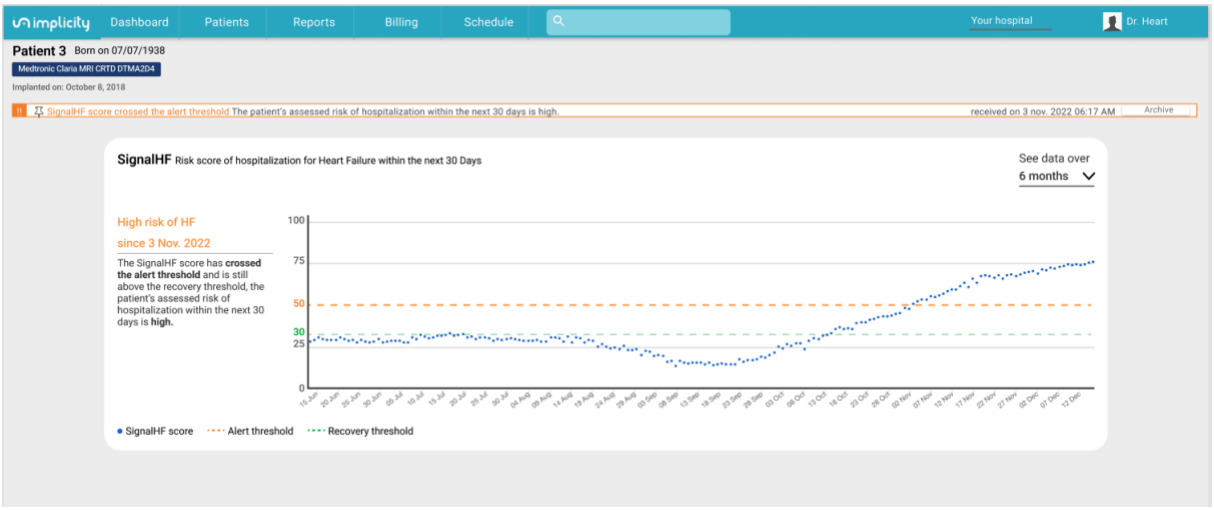


Figure 2. The settings page of the IMPLICITY Remote Monitoring Platform used to activate/deactivate SignalHF.

3.4 SignalHF output

SignalHF output is displayed in a Heart Failure-dedicated section of a Remote Monitoring Platform.
The following screenshot is an example of how SignalHF results can be displayed in the Remote Monitoring Platform.
The monitoring platform using SignalHF should display at least:

- The manufacturer and model type of the cardiac implant of the patient
- The calculated SignalHF score plotted over the following time periods:
    - last month
    - last 3 month
    - last 6 month
- The alert and recovery thresholds
- Degrees of contribution of the contributing factors for each day (see 3.4.2)
- An alert depending on the alert status from SignalHF (see 3.4.3)
- The current SignalHF status label
- CE marked medical device label



3.4.1 HF Risk Status

The IM008 score corresponds to a risk of Heart Failure hospitalization and is associated with both the alert threshold and recovery threshold that were optimized to provide optimal performances regarding all considered endpoints. A higher score corresponds to a higher risk of hospitalization in the next 30 days. The risk status has one of two values:

- Average risk of hospitalization for HF within 30 days : the patient does not have an elevated risk of HF within 30 days based on the CIED data sent to IM008 (details in input feature). A risk of HF can still be present based on other factors like comorbidities and other non CIED physiological data.
- High risk of hospitalization for HF within 30 days : the patient has an elevated high risk of having an Heart Failure episode within the next 30 days based on the CIED data sent to IM008 (details in input feature).

Warning: The actual numeric "score" does not correlate to a higher percent chance of hospitalization outside of the thresholds specified. The score always needs further investigation.

3.4.2 Degrees of contribution

The main contributing factors of the algorithm and their degrees of contribution to the SignalHF score are available for each calculated SignalHF score.

The contributing factors that may have an impact on SignalHF score are:

- Age
- Sex
- Device type
- Atrial Arrythmias
- Ventricular Therapies
- % of pacing
- Ventricular Arrhythmias
- Leads Measurements
- Activity
- AT burden
- Heart Rate
- PVC
- Thoracic Impedance

- Respiratory Rate

Warning: The degree of contribution is not the contributing factor's raw value for that day, but rather it represents the extent to which this factor contributed to the SignalHF score for that day. The values of the contributing factors are presented in separate graphs.

3.4.3 Alerts

SignalHF alerts are displayed on the platform to help draw the user's attention to patients with an elevated risk of hospitalization for heart failure within the next 30 days.

On the first day a patient crosses the alert threshold an alert is generated and displayed on the platform.

Every subsequent day the SignalHF score stays above threshold, the alert is updated to reflect how long the patient has been over the alert threshold.

On the first day a patient crosses the recovery threshold after being in an alert state, the alert is updated to reflect that it is no longer active.

The user should have the option to snooze or archive the alert.

- When the user snoozes the alert, the alert won't be displayed for the next 3 days. After 3 days, it will be updated and displayed again.
- When the user archives the alert, the following day, either (1) if the alert is still active, it will be displayed again, or (2) if the alert is not active anymore, it will not be displayed again.

3.4.4 Data integrity

On any given day, if the data from the patient's CIED could not be processed, or if there has not been enough data to compute a score, the chart will display no value.
If the data could not be processed for a number of days, or if there have not been enough data to compute a score, the chart contains no value for the corresponding days.
If no score has been computed for the plotted period, the chart is empty.

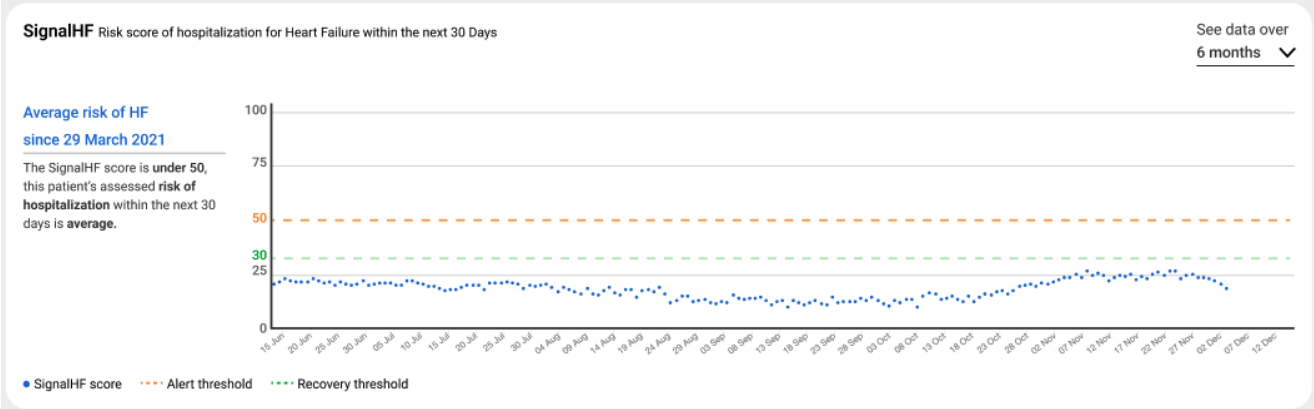
Warning: No value or empty charts do NOT mean that there is no risk for HF.

4 Examples of output results from SignalHF

The following examples show output results from SignalHF.

Example 1

In this example, the patient has an average risk of hospitalization for HF within 30 days.



SignalHF score: 18

Assessed HF risk level: Average risk of hospitalization for HF within 30 days

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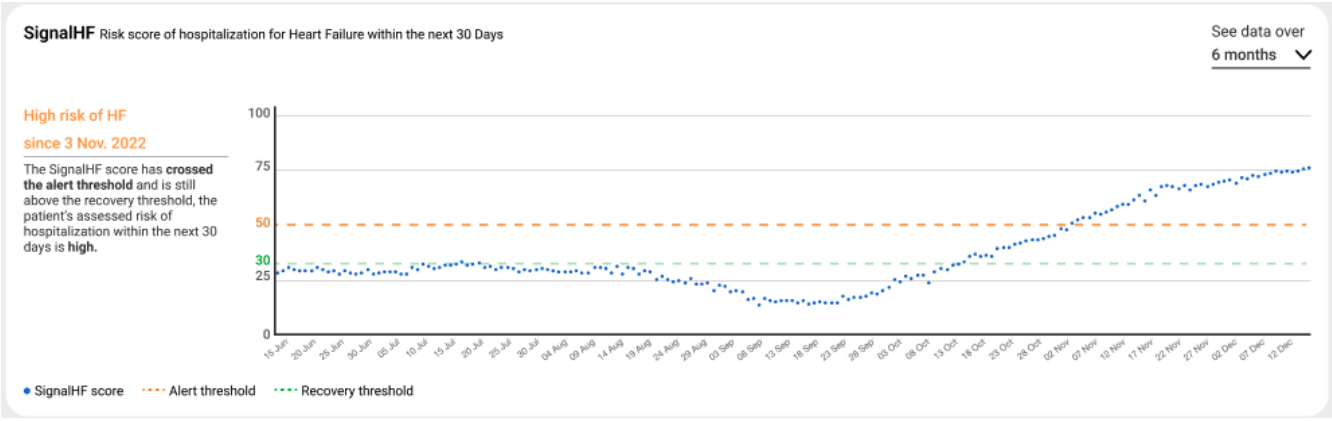
Example 2

In this example, the patient had an average risk, until it started increasing, and crossed the alert threshold on November 3. The patient now has a high risk of hospitalization for HF within 30 days.



SignalHF score: 76

Assessed HF risk level: High risk of hospitalization for HF within 30 days

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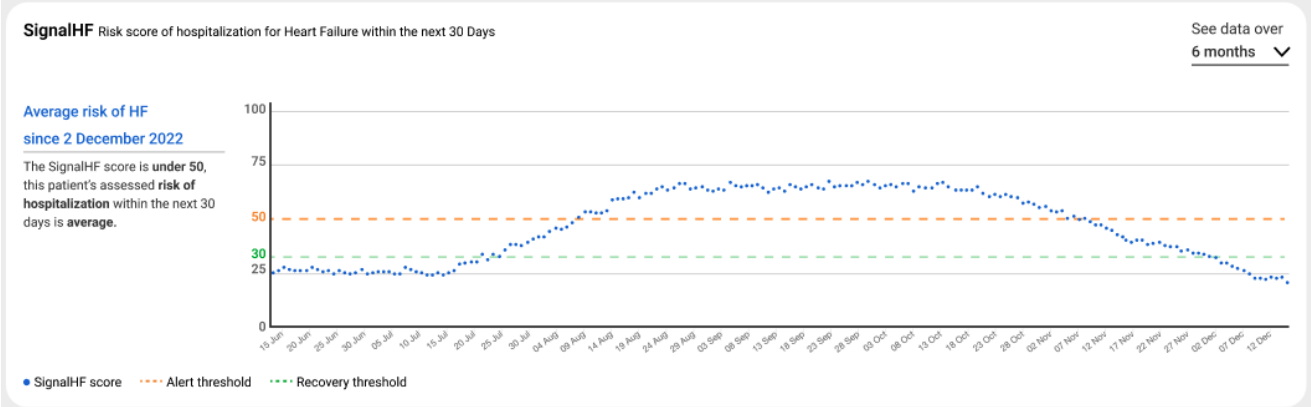
Example 3

In this example, the patient had a high risk alert on August 6. The patient was treated and their risk decreased until it crossed the recovery threshold (green line) on December 2. This patient now has an average risk of hospitalization for HF within 30 days.



SignalHF score: 23

Assessed HF risk level: Average risk of hospitalization for HF within 30 days

5 FORESEE-HF Clinical study

FORESEE-HF Study is a non-interventional clinical retrospective study designed to evaluate a SignalHF score resulting from the combination of multiple sensor measurements collected from multi-brands CIEDs and the data stored in the French national health database "SNDS" in order to detect signs of worsening HF. The follow-up period is defined as 2017-2021.

5.1 Inclusion and exclusion criteria

All patients that meet the following criteria were included in the study:

1. Implanted with a ICD / CRT-D / PM / CRT-P, manufactured by Medtronic, Boston Scientific and Biotronik, compatible with thoracic impedance recording
2. With at least one remote monitoring data transmission during the follow-up period of 2018-2021

Patients were excluded from the trial if they presented data quality issues:

1. Patients with unspecified device type in the retrospective database
2. Patients with multiple devices between 2010 and 2021

5.2 Coprimary endpoints

The coprimary endpoints of the study for ICD/CRT-D devices are:

- Sensitivity for detecting hospitalizations with HF as primary diagnosis > 40%
- Unexplained alert rate per patient-year < 2.0
- 75% of true positive alerts are raised at least 15 days before HF hospitalization event

The coprimary endpoints of the study for pacemaker/CRT-P devices are:

- Sensitivity for detecting hospitalizations with HF as primary diagnosis > 30%
- Unexplained alert rate per patient-year < 2.0
- 75% of true positive alerts are raised at least 15 days before hospitalization event

The population size of patients who match the inclusion criteria and are not excluded is 17,974 (PM 7,360, ICD 5,642, CRT-D 4,116 and CRT-P 856; age 70.0 ± 13.3, male 70.20%).

Demographic Variable	**Train cohort**	**Validation cohort**	**Clinical cohort**
Nb of patients	*7556*	3678	6740
Age (years)	69.2 ± 13.9	70.9 ± 12.3	70.6 ± 13.0
Sex			
Female (%)	28.43	29.50	30.03
Male (%)	71.57	70.50	69.97
Device model			
ICD (%)	33.72	28.17	30.54
CRT-D (%)	23.13	23.33	22.40
Pacemaker (%)	38.49	42.90	42.64
CRT-P (%)	4.66	5.60	4.42
Manufacturer device model			
Biotronik (%)	44.64	43.83	49.75
Boston Scientific (%)	18.99	17.64	10.01
Medtronic (%)	36.37	38.53	40.24
Comorbidities			
Renal failure(%)	10.26	10.47	11.56
Hypertension(%)	37.43	40.33	40.54
Diabetes(%)	15.62	17.84	16.25
Obesity/High BMI(%)	6.93	8.48	11.51

5.2.1 Coprimary Objective Results

SignalHF sensitivity, defined as sensitivity for detecting hospitalizations with HF as primary diagnosis, is above 50% for Medtronic and Boston Scientific ICD and CRT-D devices. For Biotronik ICD and CRT-D products, the sensitivity reaches 70 %. The UAR PPY is always < 1.5 and the lower quartile on alerting time is always > 15 days for ICD and CRT-D from all the manufacturers analyzed, except for Boston Scientific ICD/CRT-D devices, where it is > 15 days on average only. Concerning IPG and CRT-P devices, the sensitivity is 50.4 % for Medtronic devices and 45.3% for Biotronik and UAR PPY is always < 1 for

both manufacturers. Lower quartile on alerting time is > 15 days for Biotronik IPG/CRT-P devices, and on average due to low sample size for Medtronic IPG/CRT-Ps. Therefore, the three co-primary endpoints are reached.

5.2.2 Global Performance

The following presents the performance of SignalHF by device type as it relates to:

- Sensitivity for detecting hospitalizations with HF as primary diagnosis, and
- Unexplained alert rate per patient-year (PPY)
- Lower quartile on alerting time (in days)

All SignalHF performance metrics are available in the Clinical Evaluation Report (CER-IM008)

Endpoints	**ICD/CRT-D population objective**	**SignalHF performance for ICD/CRT-D devices**
Sensitivity (%)	> 40%	59.8% [54.0%; 65.4%]
Unexplained Alert Rate PPY	< 2.0	0.654 [0.614; 0.692]
Lower quartile on alerting time (in days)	> 15 days	35.0 [27.0; 52.0]

Endpoints	**Pacemaker/CRT-P population objective**	**SignalHF performance for pacemaker/CRT-P devices**
Sensitivity (%)	> 30%	45.9% [38.1%; 53.8%]
Unexplained Alert Rate PPY	< 2.0	0.470 [0.441; 0.502]
Lower quartile on alerting time (in days)	> 15 days	37 [24.5; 53.0]

5.2.3 Performance per manufacturer

5.2.3.1 MEDTRONIC

Endpoints	**ICD/CRT-D population objective**	**SignalHF performance for Medtronic ICD/CRT-D**

Sensitivity (%)	> 40%	52.0% [43.6%; 60.2%]
Unexplained Alert Rate PPY	< 2.0	0.30 [0.28; 0.32]
Lower quartile on alerting time (in days)	> 15 days	39.3 [21.0; 59.0]

Endpoints	**Pacemaker/CRT-P population objective**	**SignalHF performance for Medtronic pacemaker/CRT-P**
Sensitivity (%)	> 30%	50.4% [30.6%; 70.2%]
Unexplained Alert Rate PPY	< 2.0	0.71 [0.65; 0.78]
Lower quartile on alerting time (in days)	> 15 days	64.5 [8.0; 119.0]

5.2.3.2 BOSTON SCIENTIFIC

Endpoints	**ICD/CRT-D population objective**	**SignalHF performance for Boston Scientific ICD/CRT-D**
Sensitivity (%)	> 40%	62.5% [46.9%; 75.8%]
Unexplained Alert Rate PPY	< 2.0	0.89 [0.81; 0.97]
Lower quartile on alerting time (in days)	> 15 days	28.0 [13.0; 55.5]

5.2.3.3 BIOTRONIK

Endpoints	ICD/CRT-D population objective	SignalHF performance for Biotronik ICD/CRT-D
Sensitivity (%)	> 40%	70.0% [60.6%; 77.9%]
Unexplained Alert Rate PPY	< 2.0	1.09 [1.00; 1.18]
Lower quartile on alerting time (in days)	> 15 days	39.0 [25.8 ; 60.0]

Endpoints	Pacemaker/CRT-P population objective	SignalHF performance for Biotronik pacemaker/CRT-P
Sensitivity (%)	> 30%	45.3% [36.9%; 53.9%]
Unexplained Alert Rate PPY	< 2.0	0.42 [0.39; 0.46]
Lower quartile on alerting time (in days)	> 15 days	37.0 [25.5; 53.0]

5.2.4 Summary

SignalHF performances are above target performances for all pre-defined patient groups except for Boston Scientific pacemaker/CRT-P devices, for which we did not have enough data for training and evaluation of a HF prediction algorithm.

5.3 Performance analysis per manufacturer, device model type and number of leads

5.3.1 Medtronic ICD/CRT-D devices

Endpoints	ICD/CRT-D population objective	One lead	Two leads	Three leads
Sensitivity (%)	> 40%	43.5% [29.6%; 58.5%]	49.3% [35.8%; 63.0%]	62.7% [48.0%; 75.4%]
Unexplained alert rate PPY	< 2.0	0.24 [0.20; 0.28]	0.31 [0.27; 0.35]	0.34 [0.30; 0.38]
Lower quartile on alerting time (in days)	> 15 days	59.0 [19.0; 163.0]	31.0 [10.0; 55.0]	57.0 [16.0; 96.0]

5.3.2 Medtronic PM/CRT-P devices

Endpoints	Pacemaker /CRT-P population objective	One lead	Two leads	Three leads
Sensitivity (%)	> 30%	16.7% [2.3%; 63.1%]	64.6% [34.5%; 86.3%]	Not available
Unexplained alert rate PPY	< 2.0	0.61 [0.42; 0.84]	0.62 [0.56; 0.68]	0.76 [0.60; 0.93]
Lower quartile on alerting time (in days)	> 15 days	10.0 (CI not computable)	91.8 [20.0; 129.0]	106.3 [98.0; 131.0]

5.3.3 Boston Scientific ICD/CRT-D devices

Endpoints	ICD/CRT-D population objective	One lead	Two leads	Three leads
Sensitivity (%)	> 40%	71.2% [40.3%; 90.0%]	Not available	60.5% [39.4%; 78.4%]
Unexplained alert rate PPY	< 2.0	0.69 [0.56; 0.84]	0.49 [0.38; 0.60]	0.56 [0.49; 0.64]
Lower quartile on alerting time (in days)	> 15 days	52.5 [15.0; 140.3]	53.8 [29.0; 179.0]	43.0 [11.3; 94.0]

5.3.4 Biotronik ICD/CRT-D devices

Endpoints	ICD/CRT-D population objective	One lead	Two leads	Three leads
Sensitivity (%)	> 40%	73.1% [55.4%; 85.6%]	67.5% [50.3%; 81.1%]	63.1% [48.4%; 75.8%]
Unexplained alert rate PPY	< 2.0	0.88 [0.76; 1.01]	0.76 [0.64; 0.88]	0.63 [0.54; 0.71]
Lower quartile on alerting time (in days)	> 15 days	41.0 [22.0; 64.8]	62.75 [30.0; 157.0]	54.0 [18.5; 88.0]

5.3.5 Biotronik PM/CRT-P devices

Endpoints	Pacemaker/ CRT-P population objective	One lead	Two leads	Three leads
Sensitivity (%)	> 30%	29.4% [11.2%; 58.0%]	40.2% [30.9%; 50.2%]	48.0% [26.3%; 70.4%]
Unexplained alert rate PPY	< 2.0	0.46 [0.36; 0.58]	0.31 [0.28; 0.34]	0.45 [0.35; 0.57]
Lower quartile on alerting time (in days)	> 15 days	108.0 [3.0; 395.0]	64.0 [34.0; 105.5]	10.0 [9.0; 34.5]

5.4 Summary

Defibrillators with 1, 2 or 3 leads from all manufacturers, as well as pacemakers with 2 and 3 leads from Medtronic and pacemakers with 1, 2 or 3 leads from Biotronik passed the required performances on every endpoint (sensitivity, unexplained alert rate, median alerting time). The results show in particular no specific group overperforming and causing performance overestimation.

Medtronic Pacemaker 1 lead is the only group not meeting endpoint requirements as defined in the CEP_IM008. However, this population does not have any alternative to assess a potential risk of Heart Failure based on their device data. Implicity believes bringing IM008 to this population could avoid some hospitalization in a population that is for the moment not addressed by any other solution.

Warning: In patient populations unlikely to have acute decompensation of HF, the use of the algorithm may have less and possibly poor PPV and NPV.

6 Material Requirements

The material requirements is available in the installation instruction: IFU1-IM008-Installation Instruction

7 Explanation of Symbols used

Symbol	Name	Description
	Date of manufacture	Symbol indicating the "date of manufacture." The symbol shall be adjacent to the date that the product was manufactured, expressed as four digits for the year and two digits for the month and where appropriate, two digits for the day
	Manufacturer	This symbol displayed on the label is accompanied by the name, address of the manufacturer (Implicity) and product version release date (date of manufacture).
	Medical Device	This symbol is displayed on the label to indicate that the product is a medical device.
	Catalogue Number	This symbol displayed on the label is accompanied by the manufacturer's catalogue number.
	Caution	This symbol displayed on the label is a safety symbol, indicating that there are specific warnings or precautions associated with the device which are not found on the label. These precautions/warnings are described in the Instructions for Use.
	Consult Instruction for Use	This symbol displayed on the label indicates that the Instruction for Use for the device should be consulted. The Instruction for use is Available online.
RxOnly	Rx Only	This symbol displayed on the label is applicable in the United States and means: "CAUTION: Federal law restricts this device to sale by or on the order of a physician."
	UDI	This symbol displayed before the unique device identifier