



## The FDA-cleared AI Algorithm<sup>1</sup> That Predicts HF Hospitalizations



### Addressing Heart Failure: A Vital Concern for Patients and Health Systems

- » HF affects 64 million<sup>2</sup> people globally
- » HF is a leading cause of hospitalization over the age of 65 in the US<sup>3</sup>
- » Hospitalizations for HF place financial burden on healthcare systems
- » Reducing HF hospitalizations requires a multifaceted approach, including strategies for prevention and early detection

### SignalHF, the First Manufacturer-Agnostic HF Prediction Score Based on Cardiac Implantable Electronic Devices (CIED) Data

- » SignalHF<sup>4</sup> is an FDA-cleared AI algorithm
- » Uses data collected from CIEDs (PM, CRT-P, ICD, CRT-D)
- » Algorithm is agnostic for Biotronik, Boston Scientific and Medtronic CIEDs using 90 days of physiological data, demographics, lead measurements and episodes & therapies
- » Evaluates the risk of HF hospitalizations in the next 30 days
- » Generates alerts for SignalHF score above alert threshold

### SignalHF Performance<sup>5</sup>

	SignalHF by Implicit FORESEE HF (ICD/CRT-D)	SignalHF by Implicit FORESEE HF (IPG/CRT-P)
Sensitivity	60%	46%
Unexplained Alert Rate PPY	0.66	0.47
Lower Quartile on Alerting Time <sup>6</sup> (in days)	35	37

### Advancing Care Quality for Individuals with Heart Failure

- » Identify indications of deterioration in heart failure patients
- » Evaluate the risk of hospitalizations due to heart failure
- » React by adjusting the care and treatment for your heart failure patients

<sup>1</sup> SignalHF is an FDA-cleared Class II medical device, see the instructions for use for more information.

<sup>2</sup> Groenewegen, A., Rutten, F. H., Mosterd, A., & Hoes, A. W. (2020). Epidemiology of heart failure. *European Journal of Heart Failure*, 22(8), 1342–1356. doi:10.1002/ehf.1858

<sup>3</sup> Healthcare Cost and Utilization Project (HCUP). (2011). HCUP Facts and Figures: Statistics on Hospital-Based Care in the United States, 2009. Agency for Healthcare Research and Quality (US).

<sup>4</sup> SignalHF is compatible with ICD/CRT-D from Medtronic, Boston Scientific and Biotronik and IPG/CRT-P from Medtronic and Biotronik able to measure thoracic impedance.

<sup>5</sup> "Heart Failure Events Prediction Algorithm for Patients Implanted With Multi-brand CIED – FORESEE-HF Study/Results". N. Varma. EHRA 2024

<sup>6</sup> Number of days before the event when the alert is reached (for 75% of the events)



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## Heart Failure at a glance

1

Latest alerts if the score is above the threshold

2

Current SignalHF status indicating the decompensation risk estimation for the patient within the next 30 days

3

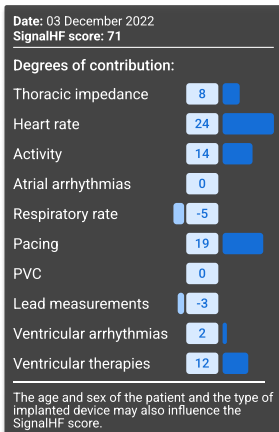
Display of SignalHF score evolution over the last 6 months

4

Based on main contributing factors, cardiologists are able to look directly at the patient's physiological data and confirm SignalHF risk assessment



## An explicable and actionable score



» Leverage contributing factors to quickly pinpoint relevant physiological signals

» Identify clear next steps based on SignalHF's assessment:

- ◇ Check patient symptoms, with a phone call or an automated SMS
- ◇ Pause the alert to follow up on the patient in a few days
- ◇ Adapt medication