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**Applications of the Multi-Sensor HeartLogic Heart Failure Monitoring Algorithm during the COVID-19 global pandemic**

**Brief Title:** Remote monitoring during COVID-19

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**Abbreviations:**

HF= heart failure

ICD = implantable cardioverter defibrillator devices

IV = intravenous

LVAD = left ventricular assist device

CRT-D = cardiac resynchronization therapy – defibrillator

**Abstract:**

In the COVID-19 era, the heart failure community has witnessed an unprecedented reduction in heart failure related patient visits and hospitalizations. Social distancing measures present a dilemma for heart failure patients who require frequent surveillance of volume status and vital signs in order to minimize heart failure related symptoms and hospitalizations. With the rise of telemedicine comes an increased focus on remote monitoring technologies. This report describes use of a multisensor device algorithm in implantable cardioverter defibrillator devices by Boston Scientific, called HeartLogic. We present two cases of patients with advanced heart failure who were actively surveilled by the HeartLogic device algorithm to guide care.

## Introduction

The COVID-19 pandemic has had a significant impact on the way we care for patients, particularly, heart failure (HF) patients who are at higher risk for morbidity and mortality (1). The adoption of telehealth has been instrumental though there are inherent limitations (2). A series of remote monitoring technologies are available which can enhance the surveillance of HF signs and assist clinicians with therapeutic interventions (3). Remote monitoring for HF patients is available in several forms- 1) structured telephone support service with frequent review of HF symptoms, weight, medication compliance etc. and medical plan adjusted based on the patients report, 2) Invasive devices implanted to solely monitor surrogates of left ventricular filling pressures eg. CardioMEMS sensor implanted in the pulmonary artery, results of which are transmitted electronically and medical therapy is adjusted based on the trend in the recordings, 3) Monitoring via parameters derived from cardiovascular implantable electronic devices (implantable cardioverter defibrillator devices [ICD] and cardiac resynchronization therapy – defibrillators [CRT-D]) for eg. Medtronic OptiVol monitoring system that evaluates lung impedance as a surrogate of lung water and volume status (3). Another device that falls into the latter category is the Boston Scientific HeartLogic HF algorithm (4). The algorithm encompasses multiple sensors which are embedded within certain Boston Scientific ICD and CRT-D. The algorithm generates a daily HF index score which is a proprietary numeric composite of the following physiologic parameters taken together- 1) heart sounds (S1 and S3), 2) thoracic impedance, 3) respiration rate [and its ratio to tidal volume], 4) heart rate and 5) patient activity (**Table 1**) (4). The device computes every day the deviation of individual sensors from their baseline and calculates a composite index. An alert is triggered when the modular threshold is exceeded (usually set at 16, but can be adjusted by the clinician) signaling a high risk for a HF

event (hospitalization or outpatient intravenous [IV] diuretics). When the patient enters alert status ( $>16$ ) the index threshold is automatically dropped to a recovery value (nominal value 6).

The sensitivity for detection was reported at 70% while the median time from the alert onset to the HF event occurrence was 34 days indicating the potential for a very early warning, signaling worsening HF (4). Patients can be contacted and adjustments in the care plan maybe instituted thus potentially avoiding hospitalization or need for outpatient IV diuretics particularly during the COVID-19 pandemic.

### **Case presentations:**

#### ***Case 1.***

Past Medical History: A 78 year old man with a history of chronic systolic and diastolic HF (LVEF 40-45%), atrial fibrillation status post ablation x 2, ventricular tachycardia, status post CRT-D, severe tricuspid regurgitation and chronic kidney disease. During a prior work-up for infiltrative cardiomyopathy, he was found to have wild type TTR cardiac amyloidosis and was subsequently initiated on tafamidis.

History of presentation: He was last seen in cardiology clinic in March 2020. He underwent an atrioventricular junction ablation in mid-May for non-optimized biventricular pacing in setting of refractory atrial arrhythmias. Within 1 week following ablation the patient went into HeartLogic status. The HeartLogic report indicated an increase in S3, nighttime heart rate, and respiratory rate without a change in thoracic impedance (**Figure 1**).

Management: The patient was called by the HF clinic and reported weight gain and swelling. Oral diuretics were increased. He was then seen in clinic at the end of May and reported a weight gain of 7 lbs since discharge with recurrent signs of right-sided congestion (lower extremity edema and ascites) on exam as well as exertional dyspnea since the cardiac

ablation procedure despite diuretic increase. NT-proBNP was ~1700 pg/dL (up from 890 last month). Oral diuretics were further escalated, however the patient required admission 2 weeks later for IV diuresis. Inpatient IV diuresis corresponds to a gradual improvement in the HeartLogic score (**Figure 1**).

### *Case 2.*

**Past Medical History:** A 35-year-old man with a history of pulmonary embolism, idiopathic dilated cardiomyopathy status post HeartMate 3 left ventricular assist device (LVAD) implant as bridge to decision, and ventricular tachycardia status post ICD.

**History of presentation:** He presented presented via video telehealth visit for evaluation related to dyspnea on exertion, orthopnea, cough and fatigue for 5 days duration. Patient was concerned about worsening HF. He denied any fevers, chills or sick contacts. No bleeding or dark urine.

**Investigations:** On video, he was in no apparent distress. Jugular venous pressure was not elevated. Abdomen was non-distended. There was no visible lower extremity edema. Driveline site was well healed. No studies were obtained as patient declined a face-to-face visit citing concerns about COVID-19 exposure within the clinical setting.

The differential diagnosis included decompensated HF, device malfunction, arrhythmia or acute bronchitis. His LVAD parameters were within normal limits without alarms (Speed: 5500 RPM, Pump Power: 4 watts, Pulsatility index: 5 and Flow: 4 Liters), hence device malfunction or pump thrombosis were unlikely. Review of the transmitted ICD interrogation showed no arrhythmia. The HF index score was 0 and all prior scores were below the alert threshold signifying a low likelihood of a HF event (**Figure 2**). There was no change in the

respiratory rate parameter and his thoracic impedance was trending upwards relative to baseline, suggesting no pulmonary edema.

Management: Sacubitril/valsartan, spironolactone, metoprolol succinate and furosemide (as needed) were continued without changes. The patient was reassured. On telehealth follow up, 1 week later, he was asymptomatic and had safely avoided any direct healthcare contacts. His HF index continues to remain below threshold.

### **Discussion:**

The European Society of Heart Failure Guidelines support the use of remote monitoring devices in improving clinical outcomes (5). Remote monitoring can take many forms as described in the introduction section. Here we reviewed two cases in which the HeartLogic algorithm provided critical data that expedited care delivery, allowed for appropriate triage of patients, with reduction in unnecessary clinic visits. In the first case HeartLogic was used to surveil a challenging patient with amyloid cardiomyopathy prone to fluid retention. Although the patient experienced clinical signs and symptoms of HF at the time of the initial alert the patient did not seek medical care. Delay in seeking care was in large part due to an anxiety of contracting SARS-CoV-2. The second patient highlighted the other end of the utility of remote monitoring, that is, safely managed at home with good clinical outcome without requiring admission or an outpatient visit.

Here we provide a review of our approach to a HeartLogic index alert (**Figure 3**). In brief, this includes intensifying the diuretic regimen and optimizing guideline directed medical therapy after obtaining a detailed history from the patient. Any detected device related issues (eg. <92% CRT pacing or arrhythmia) is evaluated and managed by the care team electrophysiologist. In addition to treatment, the HF algorithm allows for evaluation of other

differential diagnosis as noted in the case review. The HeartLogic data can be used for more than diuretic medication optimization, such as adjusting beta-blockers in response to the recorded heart rate. The activity parameter can facilitate monitoring of how sedentary the patient is, prompting encouragement for more activity. Essentially all the monitored parameters can be utilized in a manner to promote improved HF care and may lead to a reduction in admissions for HF and reduce the need for unnecessary cardiology visits and/or evaluations. Additionally, we demonstrated that the HeartLogic can be applied to LVAD patients. Initially there were concerns that the S3 and S1 sounds may not be appreciated, however, the algorithm senses the “sounds” as distinct vibrations and in our experience the presence of an LVAD has not affected the functionality. This presents yet another group of patients that may benefit from HL monitoring given the inherent limitations of the physical exam in these patients i.e. auscultation of the lung and heart sounds is obscured by the LVAD mechanical hum.

**Conclusion:**

The COVID-19 pandemic has changed how and where we care for patients. Remote HF monitoring and telehealth can allow for optimization of care during this time. The HeartLogic algorithm can be an important tool in the remote monitoring armamentarium. Two prospective studies are currently evaluating the impact of the HeartLogic algorithm on clinical outcomes as part of a registry (Precision Event Monitoring for Patients With Heart Failure Using HeartLogic [PREEMPT-HF, [clinicaltrials.gov #NCT03579641](https://clinicaltrials.gov/ct2/show/study/NCT03579641)]) and as part of a randomized clinical trial (Multiple Cardiac Sensors for the Management of Heart Failure [MANAGE-HF, [clinicaltrials.gov #NCT03237858](https://clinicaltrials.gov/ct2/show/study/NCT03237858)]).



### **Learning Objectives**

1. To recognize the change in methods used to deliver medical care and that avoiding medical care during the COVID-19 pandemic is common among patients.
2. To appreciate the role of heart failure remote monitoring devices, such as the HeartLogic, in providing care for heart failure patients during the COVID-19 pandemic.

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**FIGURE TITLES/LEGENDS**

**Figure 1: Cardiac amyloid patient with heart failure decompensation after elective procedure**

**Figure 2: Left ventricular assist device patient, review of the patients HeartLogic data.**

**Figure 3: Review of a proposed management protocol based of HeartLogic data.**

Abbreviations: GDMT=guideline directed medical therapy, BB=beta blockers,

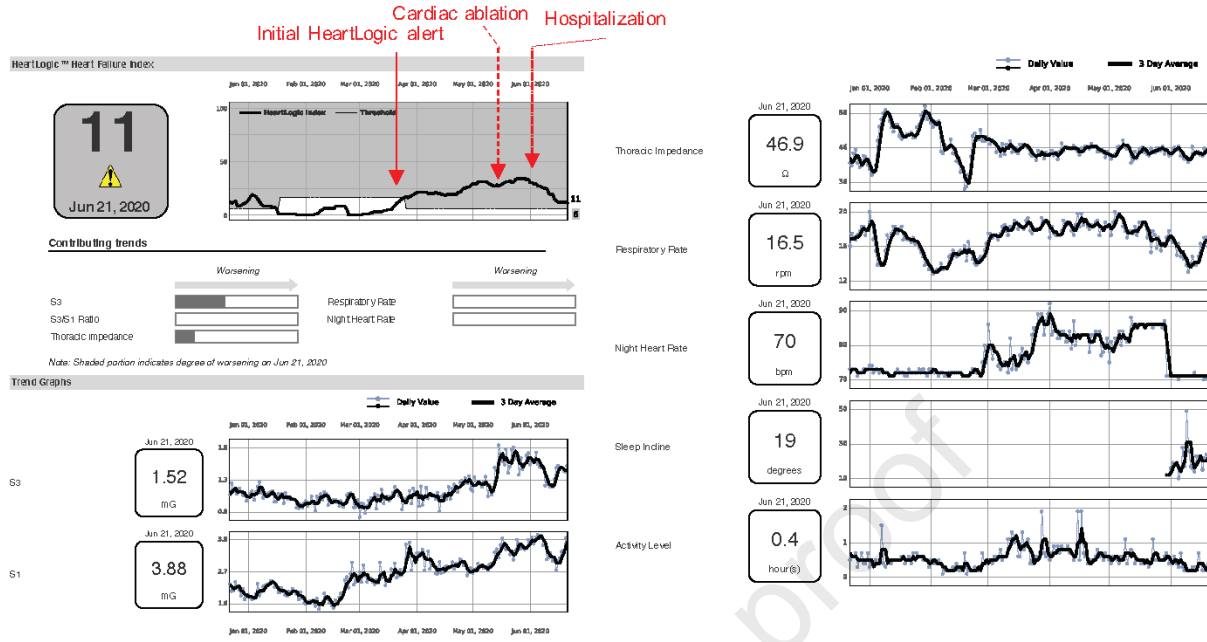
ARNI=angiotensin receptor inhibitor and neprilysin inhibitor, MRA=mineralocorticoid inhibitor,

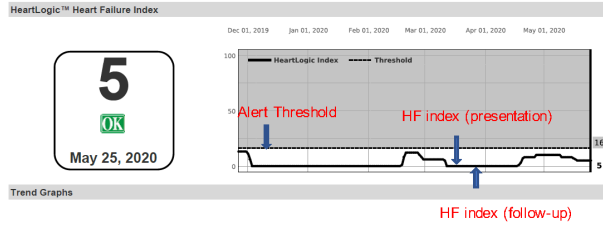
HF=heart failure, BP=blood pressure

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**Table 1: A review of the HeartLogic heart failure index physiologic parameters.**

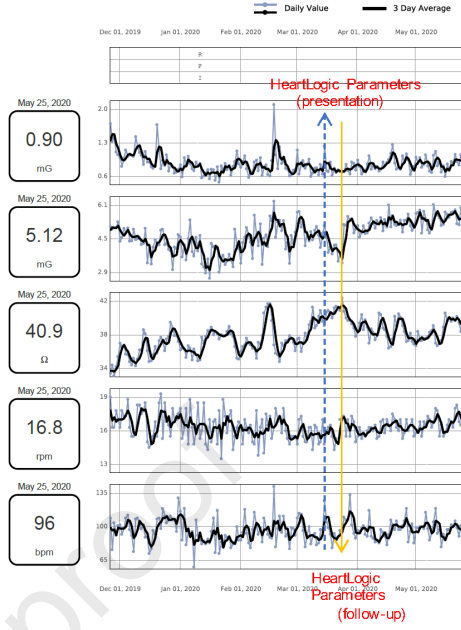
<b>HeartLogic Physiological Variable</b>	<b>Clinical Significance</b>	<b>Directional Change concerning for Worsening HF</b>
S1	Surrogate for ventricular contraction	decrease
S3	Surrogate for early ventricular diastolic filling. Suggesting decreased LV contractility.	increase
Respiratory Rate	Ratio of respiration to tidal volume. Marker of rapid shallow breathing i.e. dyspnea.	increase
Thoracic Impedance	Measure of lung fluid accumulation.	decrease
Activity Level	Gauge of the functional status and how sedentary the patient is.	decrease





R = Counter Reset  
P = Program  
I = Office Interrogation

S3  
S1  
Thoracic Impedance  
Respiratory Rate  
Night Heart Rate



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