HeartLogic™
Heart Failure Diagnostic

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HeartLogic™ Implementation Guide

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What is HeartLogic™?

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What is HeartLogic™? 1/3

The purpose of this document is to provide you with support and tools to implement HeartLogic™. It is based on learnings from clinicians and experience gathered by Boston Scientific.

The HeartLogic™ Implementation Guide can be used in different contexts, for example with HF nurses and with or without community HF teams.

Heart failure management involves costly hospitalisations with adverse impact on patient outcome. Heart failure continues to have a major impact on health and healthcare resources in all European countries, consuming 2% of healthcare budget[1]

and accounting for 1.3% of all hospital admissions. It is the most common diagnosis in hospitalised patient aged >65 years[2].

After a first hospitalisation heart failure mortality rate increases, to a 5-year mortality rate of 75%, regardless of LVEF[2]. Therefore, it is critical to do whatever possible to delay disease progression and improve patient outcome.

HeartLogic™ is a powerful clinical tool with the potential to predict incipient heart failure deterioration and implement pre-emptive treatment. Long-term studies are currently exploring its clinical utility.

Heart failure in all European countries accounts for:

2% HEALTHCARE BUDGET[1]

1.3% OF HOSPITAL ADMISSIONS

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What is HeartLogic™? 2/3

HeartLogic is intended to be used by qualified healthcare practitioners via remote monitoring or during heart failure surveillance in a hospital or clinic environment, in conjunction with clinical evaluation as part of clinical standard of practice.

The HeartLogic Index aggregates measurements of heart sounds, thoracic impedance, respiration, night heart rate and activity from multiple device-based sensors and reflects changes over time in the patient's data trend from their respective baseline values.

A HeartLogic alert signifies an increased risk for a heart failure event.

HeartLogic is a device-based algorithm that uses multiple sensors to measure heart sounds, thoracic impedance, respiration, night heart rate and activity to predict possible heart failure events through a single indicator, the HeartLogic Heart Failure Index.

This index is a high performing, single and patient-specific composite index for detecting worsening heart failure.
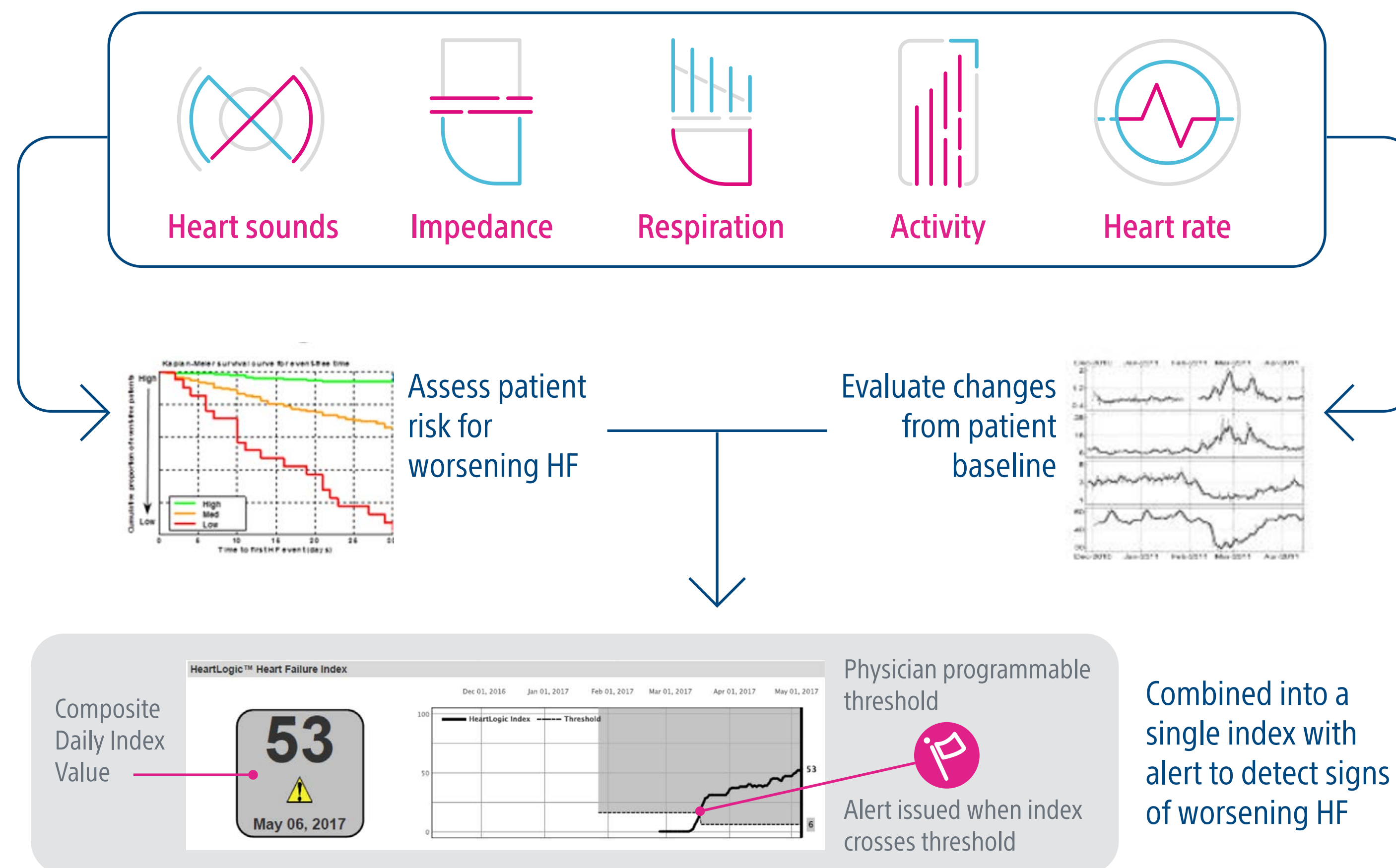
HeartLogic produces an alert via LATITUDE™ NXT if the diagnostic indicates that the patient is at risk of an episode of worsening heart failure, which enables your team at the clinic to take proactive and timely measures to mitigate it.

HeartLogic is available in the RESONATE™ family of Cardiac Resynchronisation Therapy Defibrillator (CRT-D) and Implantable Cardioverter Defibrillator (ICD) devices.

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What is HeartLogic™? 3/3

HeartLogic incorporates multiple sensors with a single composite alert

Heart sounds   **Impedance**   **Respiration**   **Activity**   **Heart rate**

Assess patient risk for worsening HF

Evaluate changes from patient baseline

HeartLogic™ Heart Failure Index

53

⚠

May 06, 2017

Composite Daily Index Value

Physician programmable threshold

Alert issued when index crosses threshold

Combined into a single index with alert to detect signs of worsening HF

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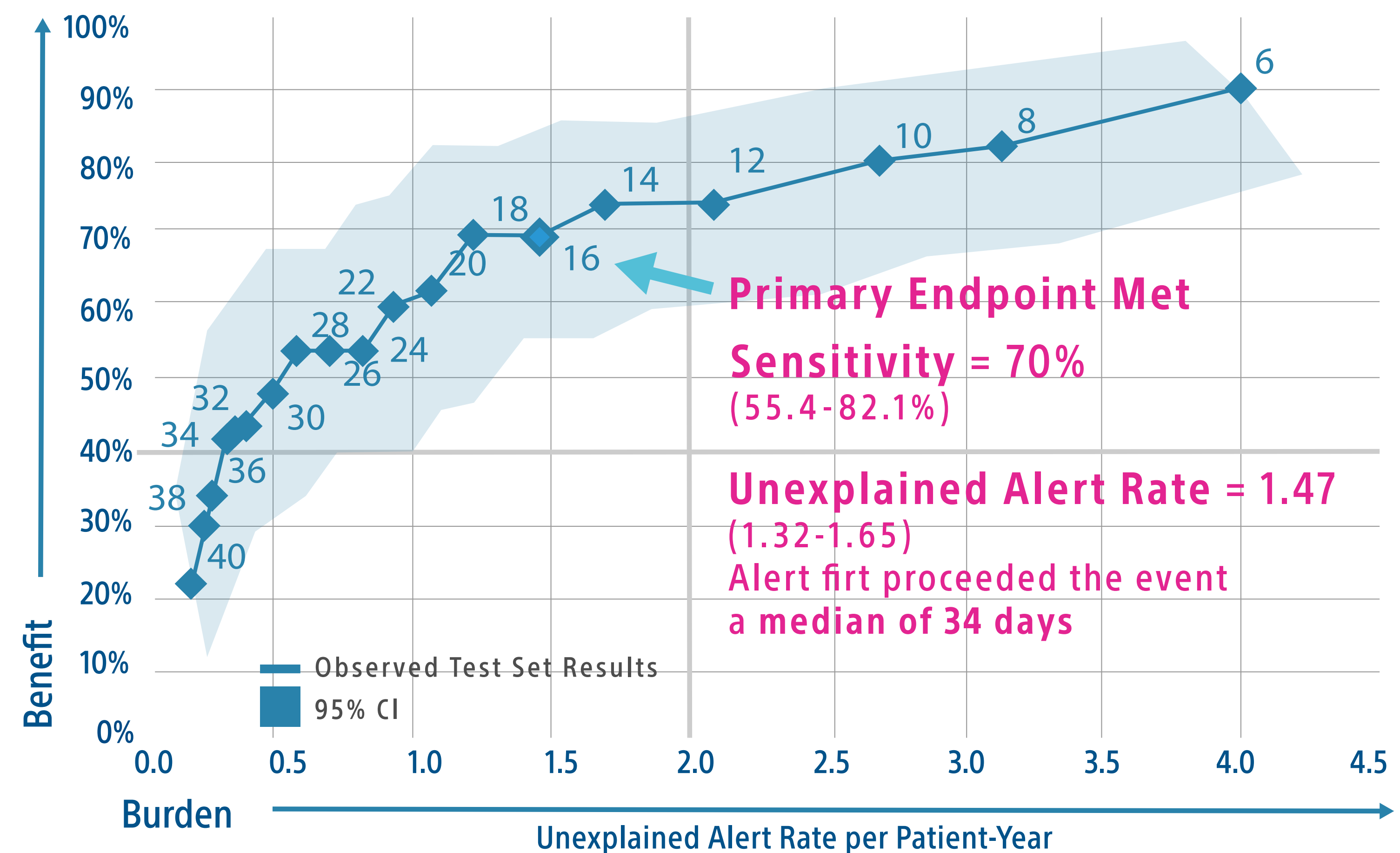1. HeartLogic™ Overview > **Clinical validation: The MultiSense Study**

Clinical validation: The MultiSense Study[3] *1/2*

HeartLogic™ is highly sensitive to the early warning signs for heart failure worsening events, giving the clinic time to risk stratify the patient and determine the appropriate clinical action.

In the MultiSense Study[3], data from multiple sensors were combined in the HeartLogic algorithm to predict worsening heart failure.

Primary Endpoint Met

Sensitivity = 70%
(55.4 - 82.1%)

Unexplained Alert Rate = 1.47
(1.32 - 1.65)
Alert firt proceeded the event
a median of 34 days

Observed Test Set Results
95% CI

Benefit

Burden Unexplained Alert Rate per Patient-Year

The MultiSense Study data demonstrated that HeartLogic met the displayed primary endpoints

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Clinical validation: The MultiSense Study[3]   2/2

Key results from the MultiSense Study demonstrated that HeartLogic™ had:

70%
SENSITIVITY
in detecting heart failure events[3]

34
DAYS ADVANCE NOTICE[3]
as a median

<2
TOTAL ALERTS
per patient per year[3]

Results also showed that the heart failure event rate was 10 times higher when HeartLogic was in alert state, versus when it was not in alert state, and that HeartLogic augmented the prognosis of a baseline NT-proBNP assessment, stratifying patients with up to 50 times higher rate for heart failure events between the lowest risk and the highest risk patient groups.

EDUCARE
Click on the links below for further information:

HEARTLOGIC WORKBOOK

ONLINE TRAINING: HEARTLOGIC HEART FAILURE DIAGNOSTIC

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HeartLogic™
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2. Activating HeartLogic™

LATITUDE™ NXT set-up

HeartLogic™ workflow integration

Risk stratification

Successful practice example

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LATITUDE™ NXT set-up 1/11

Overview

LATITUDE NXT is Boston Scientific's remote patient management platform that delivers clear benefits to your clinical practice and patients. HeartLogic™ can be activated and configured in LATITUDE NXT by setting a yellow alert for the monitored Heart Failure Index. It also provides a programmable threshold.

Three key capabilities

Remote Follow-up
Device interrogation that provides similar data to in-clinic follow-up visits

Designed to minimise patient and clinic burden

Patient Initiated Interrogations (PII)
On-demand interrogation of device (Clinic configures feature via website)

Designed to see data sooner

Remote Monitoring
Additional device and patient monitoring between scheduled follow-ups
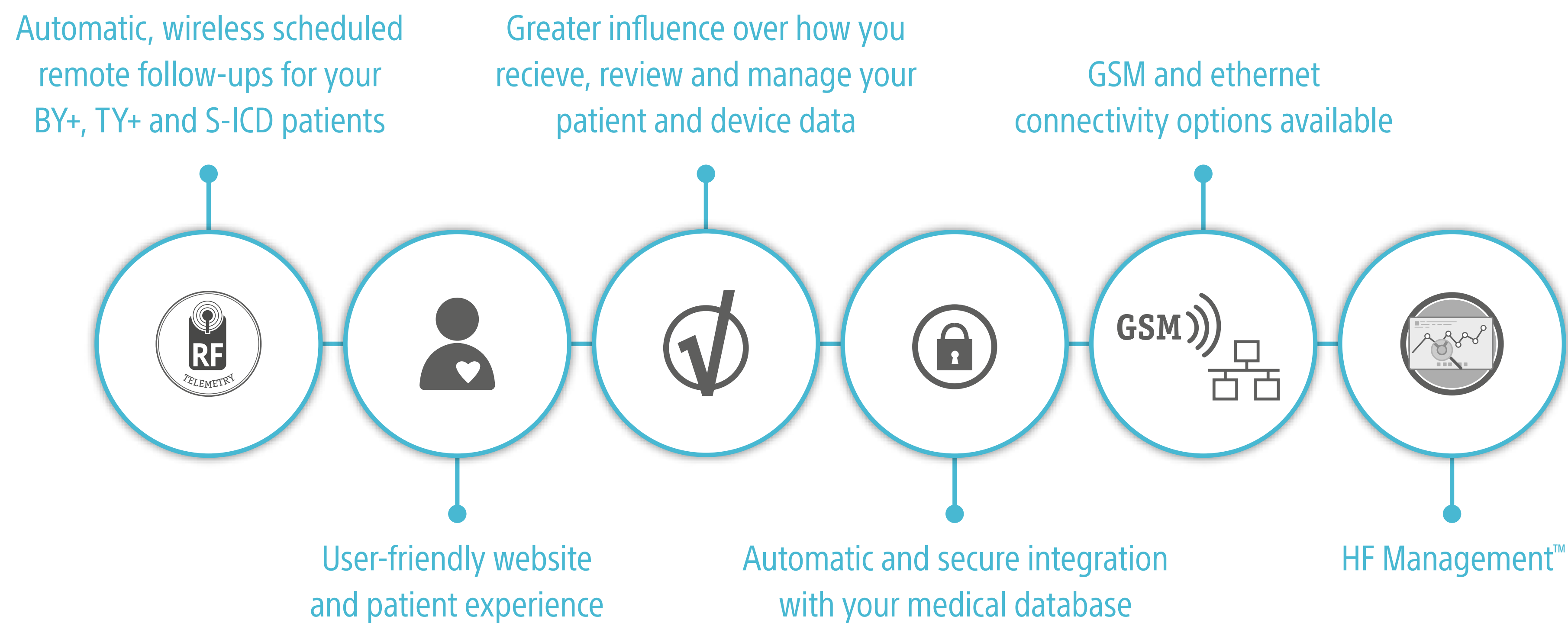
Designed to see changes sooner

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LATITUDE™ NXT set-up 2/11

Automatic, wireless scheduled remote follow-ups for your BY+, TY+ and S-ICD patients

Greater influence over how you recieve, review and manage your patient and device data

GSM and ethernet connectivity options available

User-friendly website and patient experience

Automatic and secure integration with your medical database

HF Management™

The LATITUDE™ NXT system is designed to manage the impact of remote patient management on device battery longevity. All device interrogations are initiated by the communicator, so device longevity is not impacted...

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| 1. HeartLogic™ Overview | 2. Activating HeartLogic™ | 3. Resources | 4. References | |

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LATITUDE™ NXT set-up   3/11

LATITUDE NXT provides a collaborative care model that allows two healthcare professionals to monitor one patient. This enables a device clinic to monitor device-related diagnostics, including red alerts, while a heart failure clinic monitors health-related diagnostic, including any configured yellow alerts.

**MEDICAL PROFESSIONALS/
COLLABORATIVE CARE MODEL**

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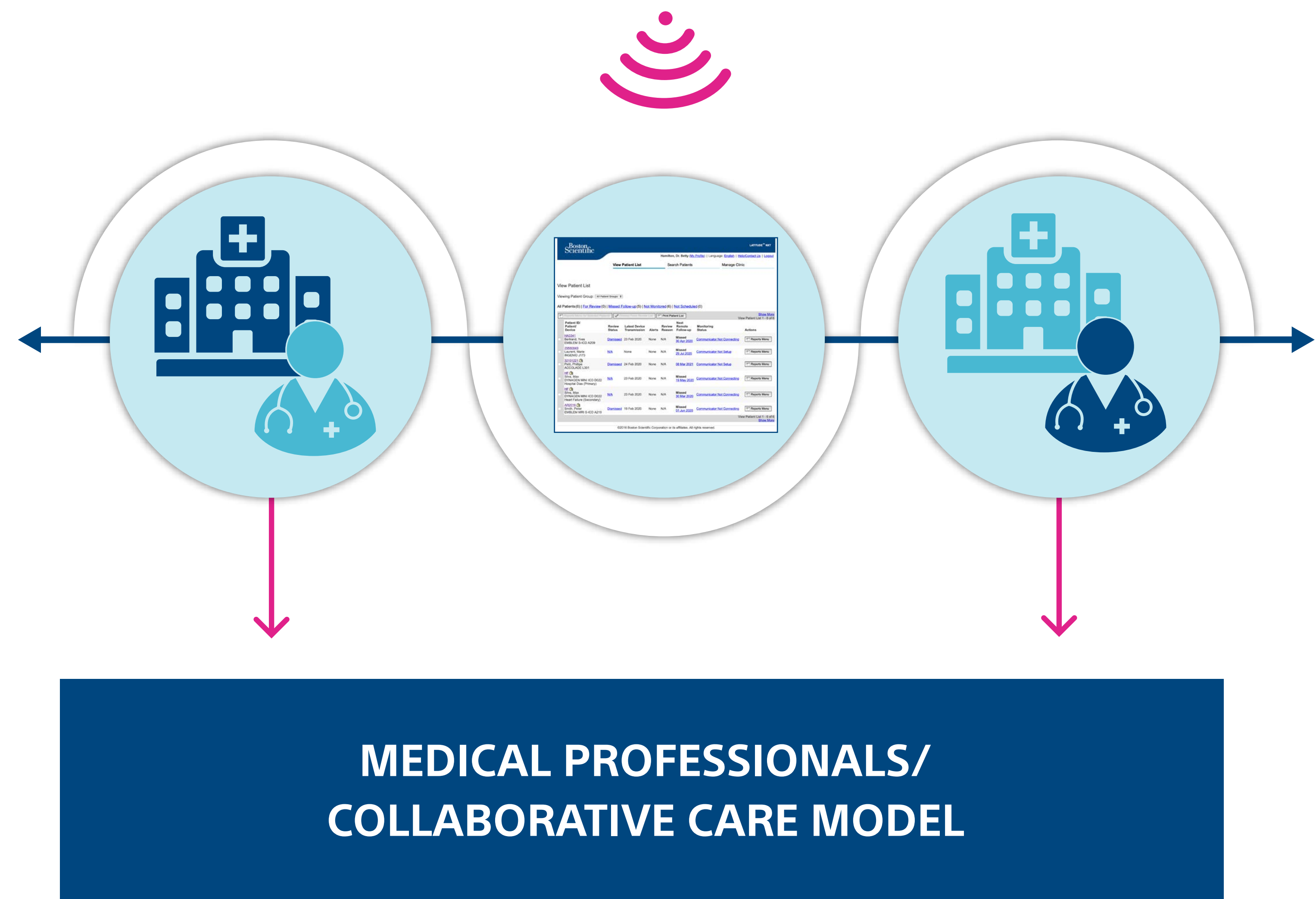
LATITUDE™ NXT set-up 4/11

LATITUDE NXT implementation with HeartLogic™

Heart failure treatment is frequently reactive, and many patients are hospitalised because warning signs are not recognised in time.

Through HeartLogic™ Boston Scientific offers individual sensors that align to each component to help the diagnostic process. Reliance on individual sensors could lead to false alerts and inefficient workflow.

A comprehensive report (Heart Failure Management Report) via LATITUDE NXT details HeartLogic and a diverse set of heart failure sensors.
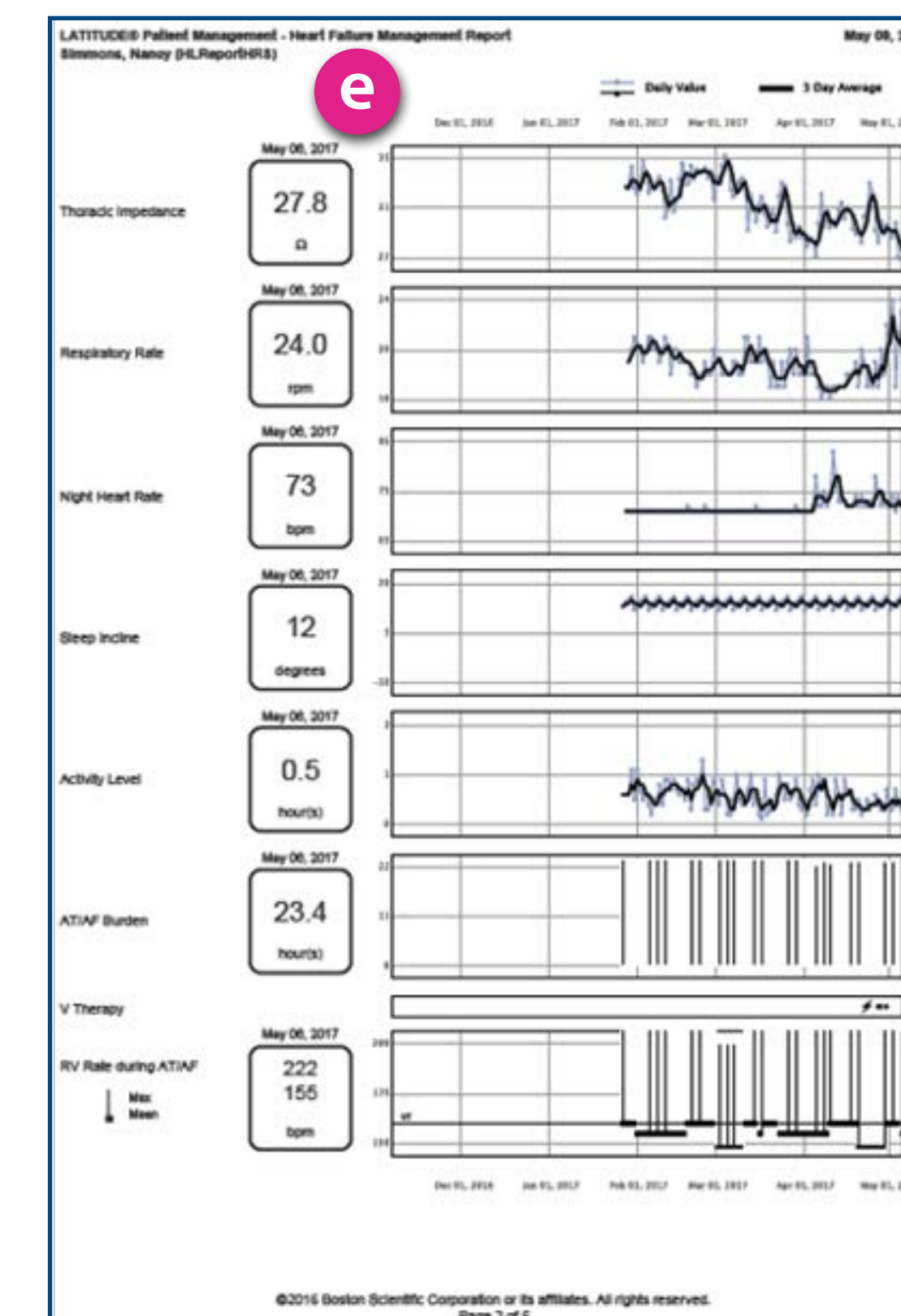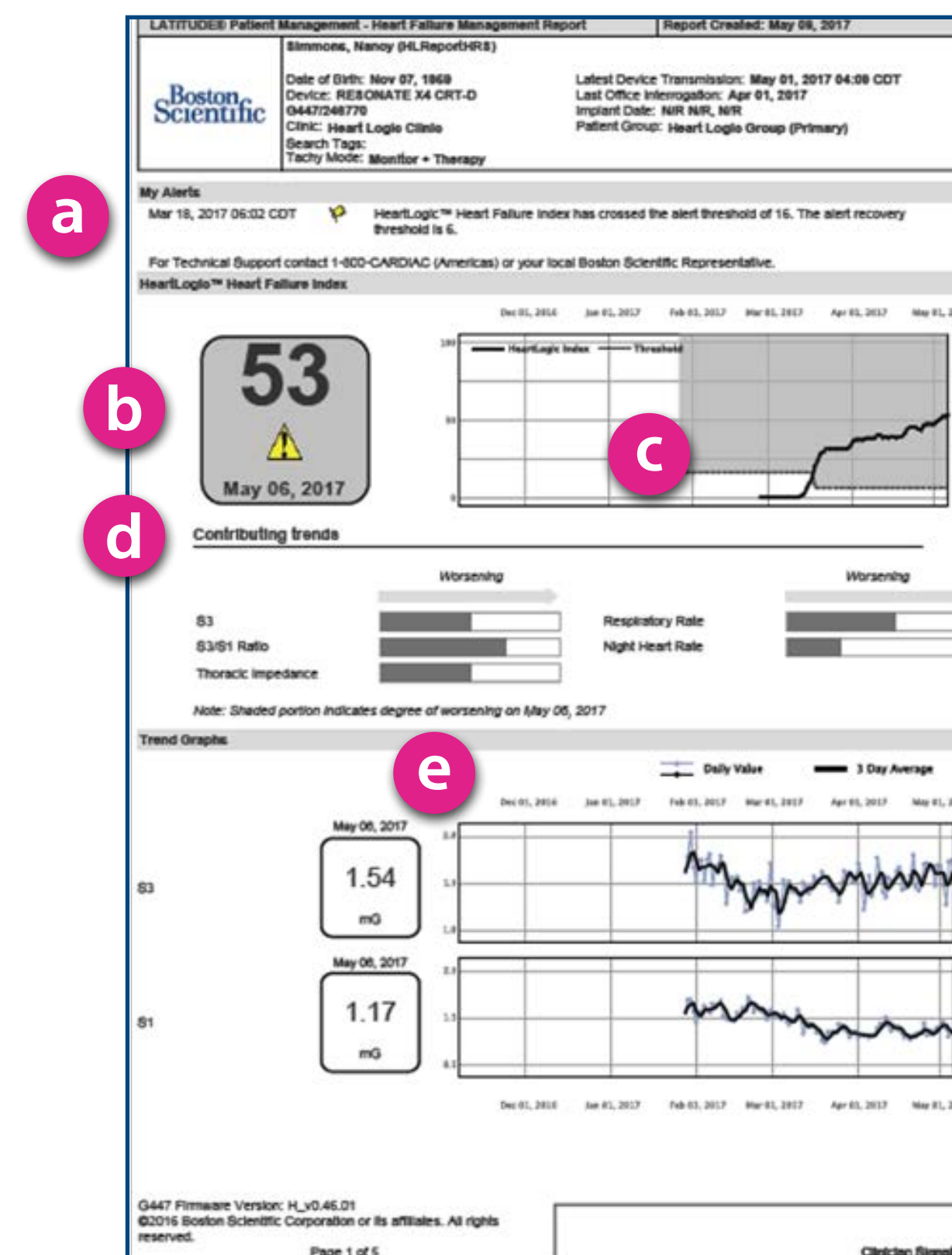
a. HeartLogic alert notification

b. HeartLogic composite index

c. HeartLogic configurable threshold

d. HeartLogic contributing trends

e. HeartLogic detailed trend data

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LATITUDE™ NXT set-up 5/11

There are four main configuration steps for the effective implementation of HeartLogic™ in LATITUDE NXT:

1 HEART FAILURE PATIENT VIEW:

The 'Enable Heart Failure Patient View' gives clinicians responsible for monitoring heart failure patients an option to see the Health tab instead of the Summary tab when reviewing patient data.

2 PATIENT GROUP:

Organises patients with similar alert and schedule configurations into Patient Groups.

3 ALERT MANAGEMENT:

Setting up HeartLogic alerts.

4 WEBSITE NAVIGATION:

How to navigate through the LATITUDE NXT website, view and review alerts and dismiss patients from the review list.*

*It will take up to 37 days from the time of implant to the point at which the device begins compiling index numbers, allowing potential transmission of HeartLogic alerts over LATITUDE NXT, assuming it is programmed ON.

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1. HeartLogic™ Overview   2. Activating HeartLogic™   3. Resources   4. References

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LATITUDE™ NXT set-up 6/11

Website navigation in detail:
Patient details page

Clicking on a patient name will take you to the Summary tab, unless the Enable Heart Failure Patient view is selected.

A HeartLogic™ enabled patient's most recent Heart Failure Index value will be displayed under the Health/Implanted Device Measures section on the Summary tab.

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LATITUDE™ NXT set-up **7/11**

Health tab: most recent daily measurement

Clicking on the **Health** tab will display the most recent HeartLogic™ Heart Failure Index as well as the HeartLogic heart failure related trends.

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LATITUDE™ NXT set-up 8/11

Health tab: contributing trends

Contributing trends are located under the HeartLogic™ Index and Threshold Trends. Each grey bar represents a relative change of the sensors in the direction of worsening HF. These changes will be weighted, based on the patient's risk and other algorithm weighting. The HeartLogic Index measurement box will update with the selected data.

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LATITUDE™ NXT set-up 9/11

Health tab: measurement box

Simply click on a date on the graph and the HeartLogic™ Index measurement box will update itself and display the data for that day.

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LATITUDE™ NXT set-up **10/11**

Health tab: cursor data

Hover over another location on the trend graph and a thin light blue line will appear to compare two data points.

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LATITUDE™ NXT set-up 11/11

Health tab screen: individual trends

Scrolling down shows:

- HeartLogic™ trends
- Weight and blood pressure if assigned to the patient
- Additional heart failure trends
- Arrhythmia trends
- Numerical values

EDUCARE

Click on the links below for further information:

ONLINE TRAINING: MANAGING HEARTLOGIC PATIENTS IN LATITUDE NXT

ONLINE TRAINING: REMOTE PATIENT MANAGEMENT: LATITUDE NXT SYSTEM

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1. HeartLogic™ Overview | 2. Activating HeartLogic™ | 3. Resources | 4. References

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HeartLogic™ workflow integration 1/5

A successful HeartLogic workflow integration in your clinical practice depends on three main pillars:

1 UNDERSTANDING YOUR REMOTE PATIENT MANAGEMENT WORKFLOW AND ALIGNING EXPECTATIONS

2 DEFINING ROLES AND RESPONSIBILITIES

3 EDUCATION AND TRAINING

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HeartLogic™ workflow integration 2/5

1 Are there patients with RESONATE™ devices who could be enrolled on LATITUDE™ NXT?

Yes

2 Do you have selection criteria for remote monitoring and\or HeartLogic?

Yes

3 Do you have a dedicated person responsible for enrolling patients in LATITUDE NXT?

Yes

4 Is there a process to request HeartLogic enablement for these patients?

Yes

5 Is there a specific online follow-up session for reviewing enrolled patients and/or alerts?

Yes

6 Is the online follow-up session integrated with the in-presence follow-up routine?

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1. HeartLogic™ Overview   **2. Activating HeartLogic™**   3. Resources   4. References

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HeartLogic™ workflow integration 3/5

7 How often are patients reviewed? (quarterly, 6 months, 1 year)
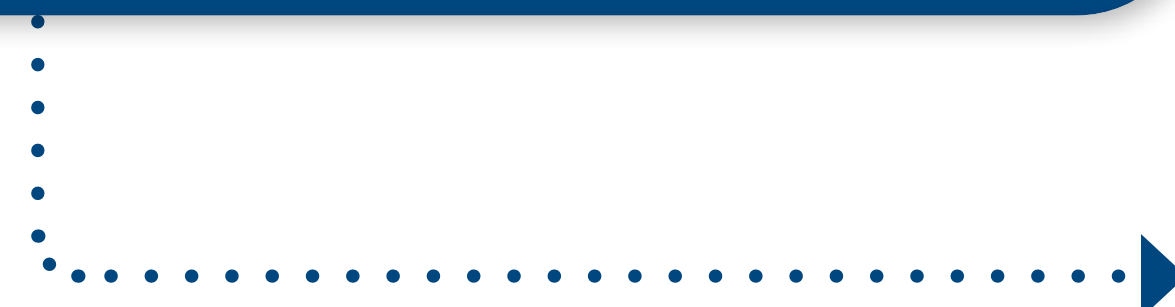
8 Do you have a dedicated person responsible for patient/alert reviews?

9 Is your team working together with the heart failure specialists/General Practitioners on disease management?
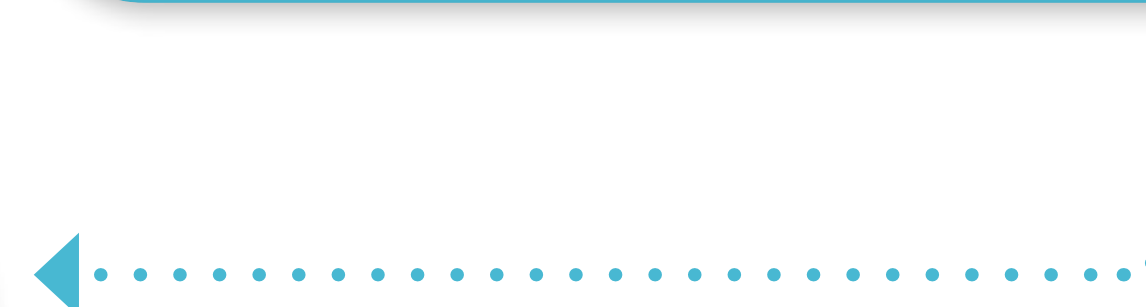
You now have mapped your remote patient management workflow. ✓

In the successful practices share section you will find an example of successful workflows.

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1. HeartLogic™ Overview | **2. Activating HeartLogic™** | **3. Resources** | **4. References**

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HeartLogic™ workflow integration 4/5

Defining roles and responsibilities

Once the assessment of your workflow is complete the next step is to define roles and responsibilities for review of HeartLogic alerts. Clear guidance and a formalised decision-making pathway are needed. In real life we have learned that in the absence of a specific protocol the tendency is to not to respond to alerts. It might be appropriate to delegate initial responsibility to a single person who can make a first triage of the information/alerts and escalate if needed. This person would need to be trained and certified for reviewing HeartLogic alerts.

Education and training

Education and training for you and your team is the third pillar of a successful implementation. It´s critical that everyone is confident in interpreting the information provided by the HeartLogic through the LATITUDE™ NXT system. An effective and reliable HeartLogic alert management clinical process will prompt patient discussions and instigate clinical action to make your practice proactive rather than reactive.

On the following page is an overview of the curriculum and all the necessary tools available on our EDUCARE platform.

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HeartLogic™ workflow integration 5/5

Curriculum overview and necessary tools available on EDUCARE:

Shares with you the interactive video

You need to register on the EDUCARE platform to access content

More in-depth training for the person in charge of remote monitoring in your centre

Navigate through the LATITUDE™ NXT interactive training

For the person responsible for Remote Monitoring

MENU
Managing HeartLogic™ Patients in LATITUDE™ NXT

| LATITUDE™ overview | Integrate HeartLogic™ in LATITUDE™ NXT system | How to navigate in LATITUDE™ NXT and Interpret HeartLogic™ alerts |

VISIT EACH SECTION TO LEARN MORE

NEW IN 2021

During preparation phase

No HeartLogic or limited experience

HeartLogic™ Heart Failure Diagnostic Training

From theory to practice

Your Boston Scientific Educational support

You

HeartLogic technology training

Implement HeartLogic Case-based approach

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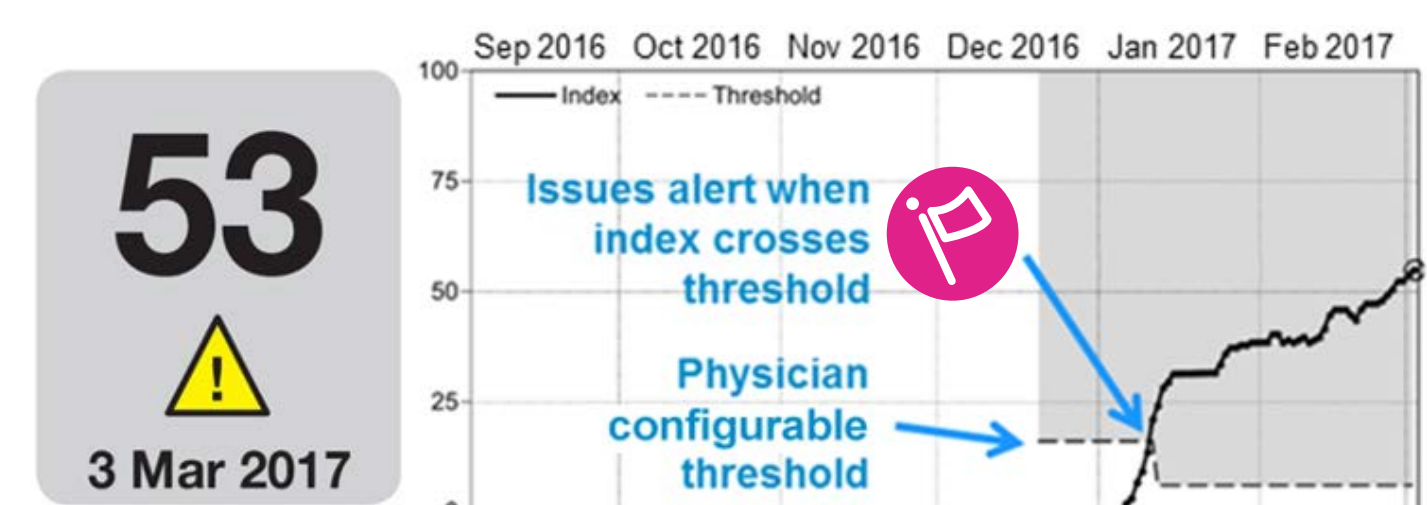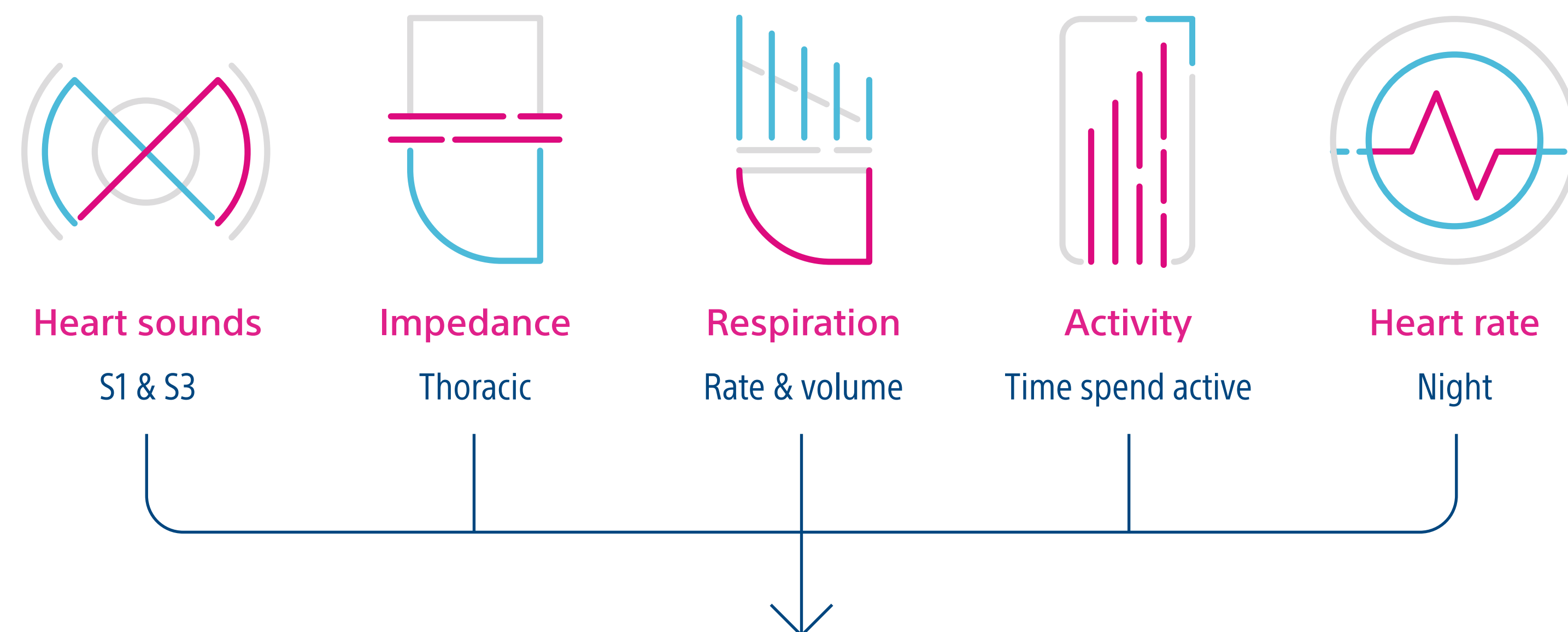*Advancing science for life™*

Risk stratify patients on the basis of HeartLogic™ alerts 1/9

With HeartLogic you can risk stratify your heart failure patients.

Our unique multi-sensor diagnostic technology enables you to predict heart failure events weeks before they would occur, giving you the opportunity to shift from reactive treatment to proactive care. This forewarning of a heart failure event allows time to risk stratify and assess the patient for any required clinical intervention.

It will take up to 37 days from the time of implant to the point at which the device begins compiling index numbers, allowing potential transmission of HeartLogic alerts over LATITUDE™ NXT, assuming it is programmed ON.

HeartLogic incorporates multiple sensors with a single composite alert

Heart sounds	Impedance	Respiration	Activity	Heart rate
S1 & S3	Thoracic	Rate & volume	Time spend active	Night

Multiple sensor measurements combined into a single, simple index with alert.

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Risk stratify patients on the basis of HeartLogic™ alerts

The 3A Process: This is Boston Scientific's process for a clinical workflow following a HeartLogic alert:

ALERT	ASSESSMENT	ACTION

STEP 1:

Alert

The HeartLogic alert and additional heart failure diagnostics are combined into a Heart Failure Management Report and delivered via the LATITUDE NXT™ system

STEP 2:

Assessment

a. Review of trends from the report

b. Assessment of the patient to corroborate the trends

STEP 3:

Action

The steps you and your team decide to take to maintain or adjust therapy

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Risk stratify patients on the basis of HeartLogic™ alerts   3/9

Click on the steps to view in more detail.

1 **ALERT** → **2** **ASSESSMENT** → **3** **ACTION**

HeartLogic **Alert**

Clinician's **Assessment** of the Alert Context

Heart Failure Management Report Review

Patient Discussion

Continue to monitor patient and consider repeating assessment and associated clinical actions per standard of care

Clinical **Action**
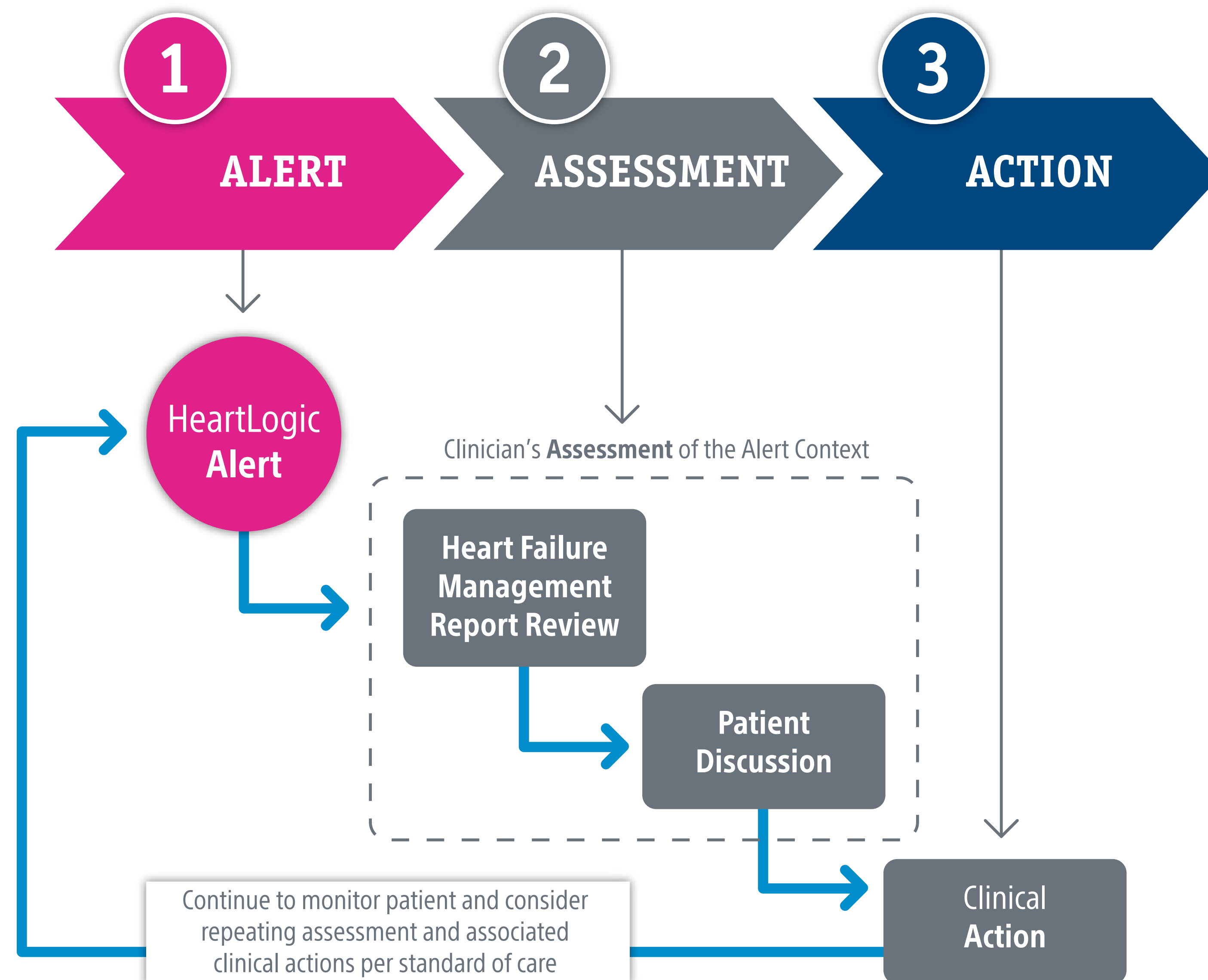
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Risk stratify patients on the basis of HeartLogic™ alerts   4/9

STEP 1:
HEARTLOGIC ALERT

A HeartLogic alert is a part of the HeartLogic Heart Failure Diagnostic, comprised of a composite trend called the HeartLogic Index, a configurable yellow alert and threshold, delivered via LATITUDE™ NXT.

The HeartLogic Index is computed daily and combines measurements from multiple device-based sensors, looking for changes from a historical baseline in a worsening direction and weighting those changes based on a patient's current risk level. Baselines are assessed on data spanning up to three recent months.

When the HeartLogic Index crosses the threshold (nominally set as 16), a HeartLogic alert is issued. Additional alerts will be delivered every seven days if the HeartLogic Index remains above the threshold.

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Risk stratify patients on the basis of HeartLogic™ alerts

STEP 2:
ASSESSMENT OF
THE ALERT CONTEXT

Heart Failure Management Report

Review the Heart Failure Management Report and talk with the patient to assess the context of the alert and identify potential causes. HeartLogic is a sensitive diagnostic tool which can issue an alert before signs and symptoms. The Heart Failure Management Report is a comprehensive summary of diagnostic trends tailored to the management of heart failure. The trends covered in this guide are S3 heart sounds, S1 heart sounds, thoracic impedance, respiratory rate, night heart rate, sleep incline, activity level, AT/AF burden, V therapy, RV rate during AT/AF, mean heart rate, % LV Paced (CRT-D devices only), heart rate variability (SDANN) and weight. The device collects and reports the data daily, and the LATITUDE NXT™ system delivers the data to the clinician. Not all diagnostic trends included in the Heart Failure Management Report are a part of HeartLogic but, viewed together, the data can help you understand the context of the HeartLogic alert.

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Risk stratify patients on the basis of HeartLogic™ alerts   6/9

STEP 2:
ASSESSMENT OF
THE ALERT CONTEXT

Heart Failure Management Report

Here is an overall summary of trend direction and how it correlates to worsening heart failure.
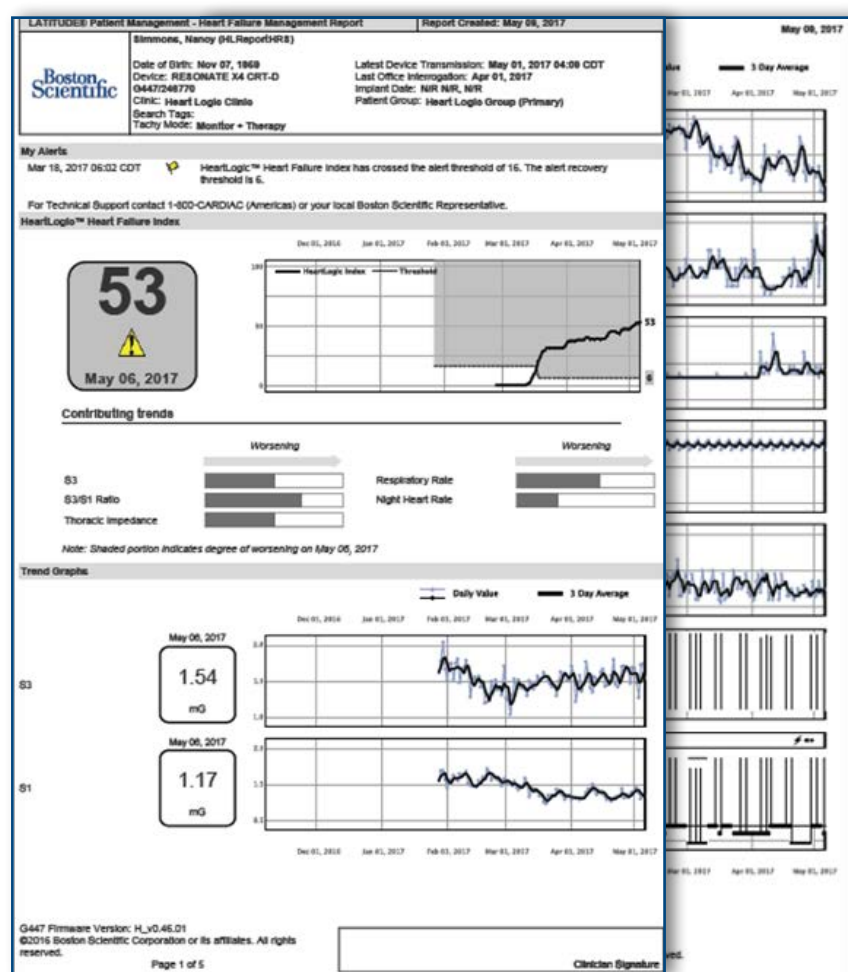
WORSENING HEART FAILURE MAY BE ASSOCIATED WITH...	
...an INCREASE in	...a DECREASE in
S3 Heart Sound	S1 Heart Sound
Respiratory Rate	Thoracic Impedance
Sleep Incline	Activity Level
Night Heart Rate	
AT/AF Burden	
Weight	

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Risk stratify patients on the basis of HeartLogic™ alerts   7/9

STEP 2:
ASSESSMENT OF
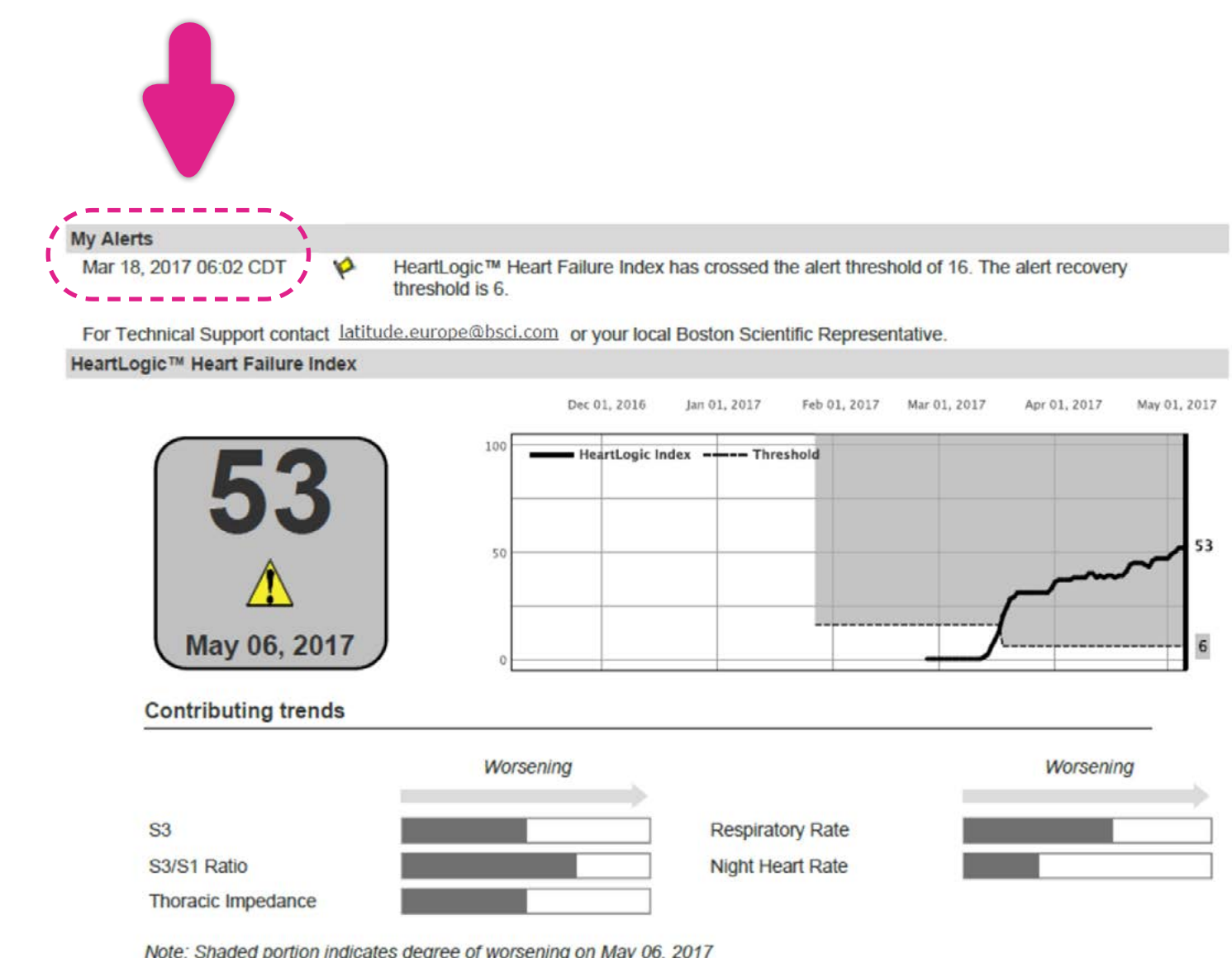## THE ALERT CONTEXT

Heart Failure Management Report

When HeartLogic is enabled within the RESONATE™ CRT-D or ICD and LATITUDE™ NXT is configured appropriately, the clinic may receive alerts when the HeartLogic Index crosses the threshold. An alert signal that the patient is at an increased risk of a Heart Failure event, providing an opportunity to discuss the reasons for the alert with the patient.

It is appropriate to use the Heart Failure Management Report to verify what the CRT-D or ICD is reporting. The summary of the contributing trends is displayed underneath the HeartLogic Index and can help the user to determine the degree of change in each of the individual trends. This report may enable you to quickly determine how/why HeartLogic sent an alert and may help you to isolate physiologic symptoms to interrogate or examine. Telephone follow-up or physical examination of the patient, or both, could confirm the patient's condition and need for therapy.

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Risk stratify patients on the basis of HeartLogic™ alerts 8/9

STEP 2:
ASSESSMENT OF
THE ALERT CONTEXT

Patient Discussion

Talk with your patient to gain additional context for the HeartLogic alert and identify a possible course of action. Talk to the patient by phone or in person, following your standard approach to patient assessment or published guidelines. You will be looking for answers to the following questions...

Are there any specific precipitating factors that can be immediately addressed, such as:

- Medication non-adherence
- Dietary indiscretion
- Use of harmful medications, such as NSAIDs
- Arrhythmia and device therapy (ATP, shocks)
- Reduction or loss of CRT (CRT devices only)
- Recent medication changes
- Recent clinical events especially those requiring infusion of fluids (e.g. surgery)
- Active ischemia
- Non-optimal medical therapy

Are there other signs or symptoms of worsening heart failure, such as:

- Shortness of breath with exertion and/or at rest
- Shortness of breath when lying flat (orthopnoea) or paroxysmal nocturnal dyspnoea)
- Sleeping regularly in a chair or on multiple pillows in bed
- Dry cough or frothy sputum
- Weight gain
- Swelling of abdomen, feet or ankles
- Changes in the frequency of urination
- Fatigue

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Risk stratify patients on the basis of HeartLogic™ alerts   9/9

STEP 3:
CLINICAL ACTION

Having completed your assessment of the Heart Failure Management Report and patient discussion(s), you can consider modifying your patient's treatment and monitoring your patient's condition to ensure safety, as per standard of care.

Depending on the factors causing the HeartLogic alert (Step 2), you should consider one or more of the following actions...

- Reinforce medication compliance
- Repeat patient education on dietary sodium and fluid restriction, daily activity/exercise plan and keeping regular follow-up appointments with his/her healthcare provider
- Address patient therapy related issues, such as worsening atrial burden, loss of CRT pacing, ventricular arrhythmias, etc.
- Treat fluid overload
- Further optimise medical therapies in line with current ESC guidelines

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Successful practice example 1/3

HeartLogic™ is a powerful clinical tool which has the potential to predict incipient heart failure deterioration and thus to allow pre-emptive treatment. Currently long-term studies are exploring its clinical utility. However, its full potential utility probably depends on the way in which it is embedded in clinical practice.

In HeartLogic the steepness and rapidity of change of the single and patient-specific composite index, rather than actual value, appear to be the best indicators of risk. However, an alert is only the beginning; the human interface and subsequent diagnostic and action are key.

Many healthcare systems encourage multidisciplinary team working. Whatever the local scenario it is vital that an effector arm is worked out, individualised and implemented.

A key challenge is changing the mindset that increased diuretics is the immediate response to an alert. It seems sensible to consider a more patient-tailored approach but maintaining consistency in how centres respond to alerts.

In the CHAMPION study a proactive approach, moving away from the current standard of care, improved outcomes. The difficulty in attempting to re-educate HCPs on the value of acting on an alert, rather than waiting for the clinical presentation of symptoms (as this mindset defeats the purpose of HeartLogic-RM and a 'proactive' approach) is that the shift in thinking to responding to numbers instead of symptoms is not yet supported by robust evidence/ guidelines. To aid this there should be focus on the developing evidence base from case reports and single centre studies.

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Successful practice example 2/3

There is also a high variability in patient knowledge levels, both in terms of HF and monitoring technology, even among patients with similar demographics. The importance of patient engagement and the need to understand the human factors that may trigger patient disengagement, including the perception that remote patient management contributes to overall 'burden of treatment', are essential in HeartLogic implementation. HeartLogic may be a useful tool to initiate discussions around lifestyle changes with a patient 'in alert'.

Centres can get advice about education and training. This could be a combination of training on dummy cases/simulation, real-world experience of remote monitoring and the use of HeartLogic. There is such variation in Heart Failure services that even centres that are part of the same healthcare system with similar patient demographics can have hugely different service pressures and this bis why HL use strategies need to be customised for any given clinic's needs whilst recognising that there are key implementation elements that are common to all clinics.

HeartLogic remote patient management aims to increase efficiencies in work burden with optimisation of practices and response. Although the small percentage of patients in alert could increase workload, this is hugely mitigated by enabling focus on patients at greater risk of further deterioration.

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Successful practice example 3/3

HeartLogic™ can also identify patients who should have B-type natriuretic peptide (BNP) and N-terminal-pro-BNP (NT-pro-BNP) testing as patients with higher NT-pro-BNP levels at baseline have a higher risk of events. In this group, and as suggested by the MultiSense data, intervention is more likely to improve clinical outcomes.
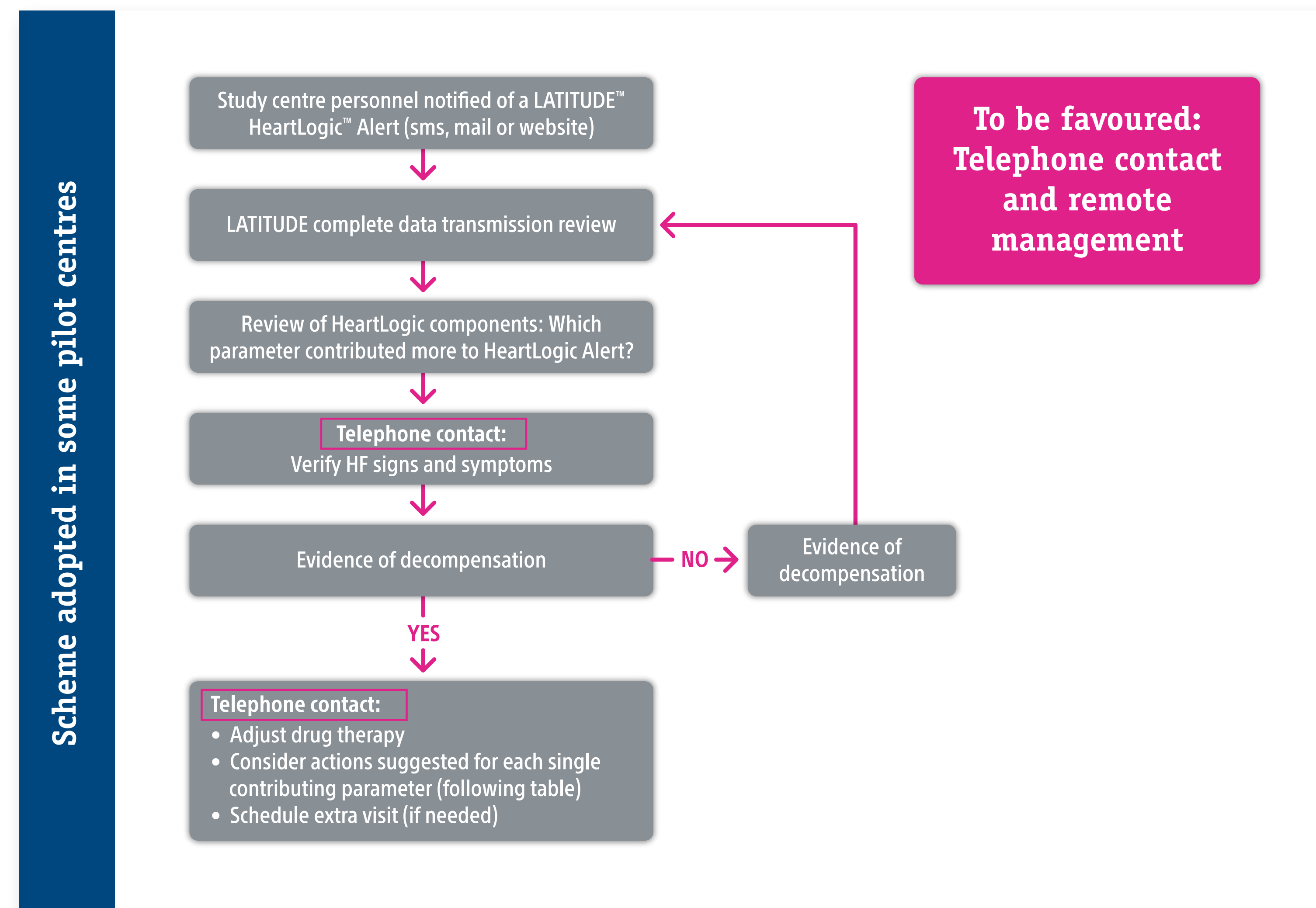
In summary, HeartLogic can enable patients to focus on those patients that have the most potential to benefit from more intensive monitoring, whilst freeing the less sick patients from the burden of unnecessary scrutiny.

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Successful practice example: Follow-up algorithm scheme   1/9

Follow-up algorithm scheme adopted in Italian centres from the preliminary experience from the EU HeartLogic™ Pilot[4]

Scheme adopted in some pilot centres

Study centre personnel notified of a LATITUDE™ HeartLogic™ Alert (sms, mail or website)

↓

LATITUDE complete data transmission review

↓

Review of HeartLogic components: Which parameter contributed more to HeartLogic Alert?

↓

Telephone contact: Verify HF signs and symptoms

↓

Evidence of decompensation — NO → Evidence of decompensation

↓ YES

Telephone contact:
- Adjust drug therapy
- Consider actions suggested for each single contributing parameter (following table)
- Schedule extra visit (if needed)

To be favoured: Telephone contact and remote management

Italian Multicentre experience of remote HF management by means of HeartLogic[5]

Cardiology Division, "Giovan Battista Grassi" Hospital, Rome; Unità Operativa di Elettrofisiologia, Studio e Terapia delle Aritmie", Monaldi Hospital, Naples; Cardiology Division, Università Politecnica delle Marche, Ancona; Cardiology Division, Policlinico Casilino, Rome; Cardiology Division, Fondazione Poliambulanza, Brescia; Cardiology Division, University of Bari, Bari; Cardiology Division, Fondazione Policlinico S. Matteo IRCCS, Pavia; Cardiology Division, Sacro Cuore-Don Calabria Hospital, Verona.

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Successful practice example: Follow-up algorithm scheme   2/9

HeartLogic™ was activated in all heart failure patients with reduced left ventricular ejection fraction (≤35% at the time of implantation) who had received a HeartLogic-enabled ICD or CRT-D device (RESONATE™ family, Boston Scientific) in accordance with standard indications and were enrolled in the LATITUDE™ (Boston Scientific) remote monitoring platform.

During the first in-office visit after activation, demographic data and medical history were recorded and 12-lead electrocardiogram, echocardiographic evaluation and clinical examination were performed. In accordance with a standardised follow-up protocol, remote data reviews and patient phone contacts

were undertaken monthly and at the time of HeartLogic alerts (when the index crossed the nominal threshold value of 16), to assess the patient's decompensation status and, if possible, to prevent further worsening.

In-office first follow-up workflow

| 12-LEAD ELECTROCARDIOGRAM | ECHOCARDIOGRAPHIC | CLINICAL EXAMINATION |

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2. Activating HeartLogic™ > **Successful practice example**

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Successful practice example: Follow-up algorithm scheme   3/9

The organisational model was based on the concept of 'Primary Nursing'.
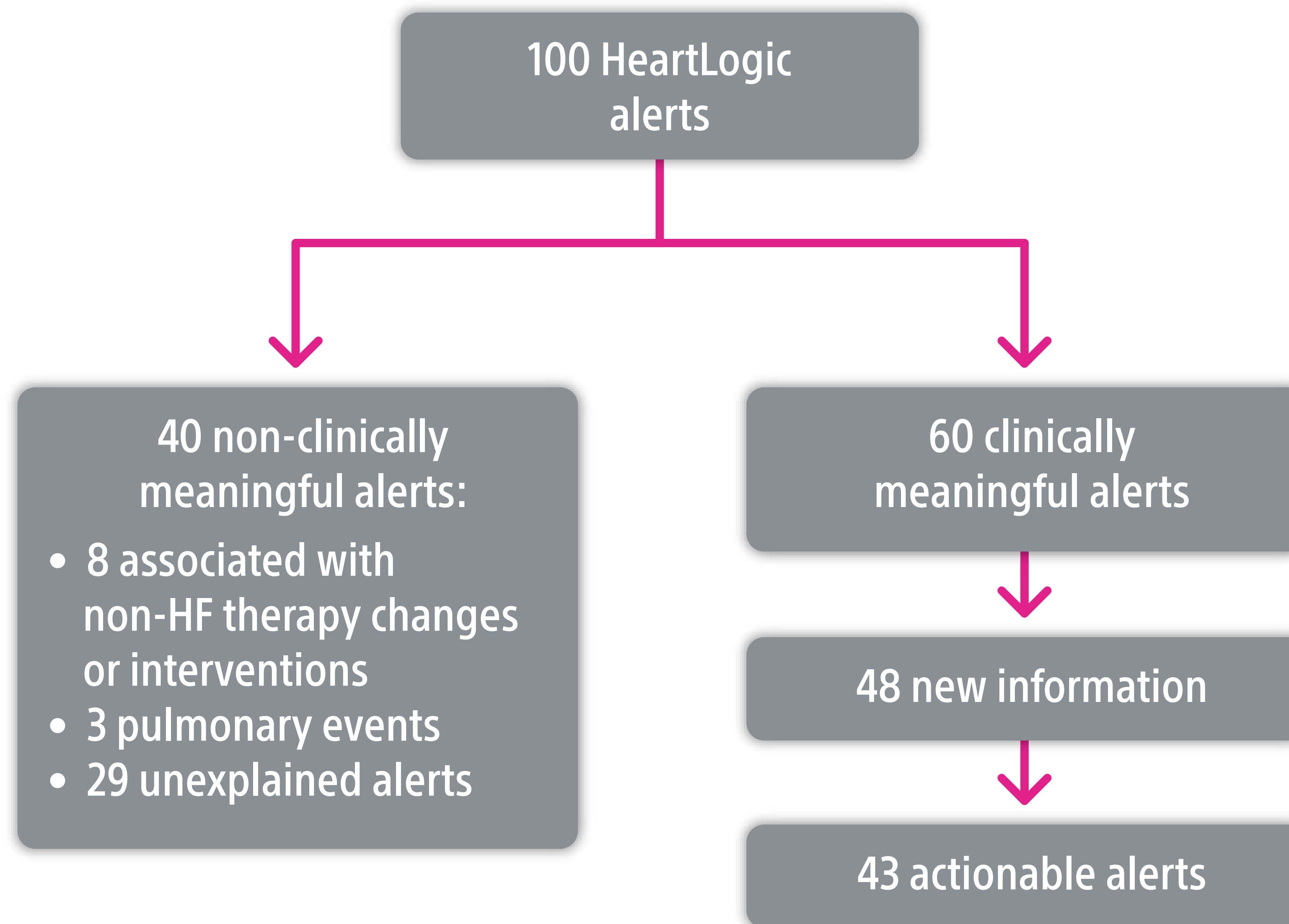Each patient was assigned to an experienced nurse and a doctor in charge.

The **allied professional's duties** included contact with the patient, educational interventions, uploading data to the website, systematic screening of data and identification of critical issues, review of transmissions and alarms, and clinical discussion of critical cases with the physician.

The **physician's tasks** included analysis of critical transmissions submitted by the nurse, clinical evaluation of the patient and related treatment decisions.

In-office examinations were performed every six months, or in the event of clinical decompensation, or at the time of HeartLogic™ alerts, if deemed necessary in order to assess the patient's decompensation status through in-person clinical examination or to implement specific therapeutic actions. The alerts were issued when the combined index crossed the programmable threshold, which was set at 16 (nominal value) in this series. Symptoms (dyspnea on effort, dyspnea at rest, paroxysmal nocturnal dyspnea, orthopnea, fatigue) and signs of HF (S3 gallop, edema,

jugular venous distension, rales) were individually graded and recorded at the baseline and at every in-office visit. Symptoms were also recorded during every phone contact. The graded symptoms were grouped according to severity (from absent to severe), and signs were grouped according to the number of signs observed (from 0 to 4), as previously described. 11 data were collected at the study centres in the framework of a prospective registry.
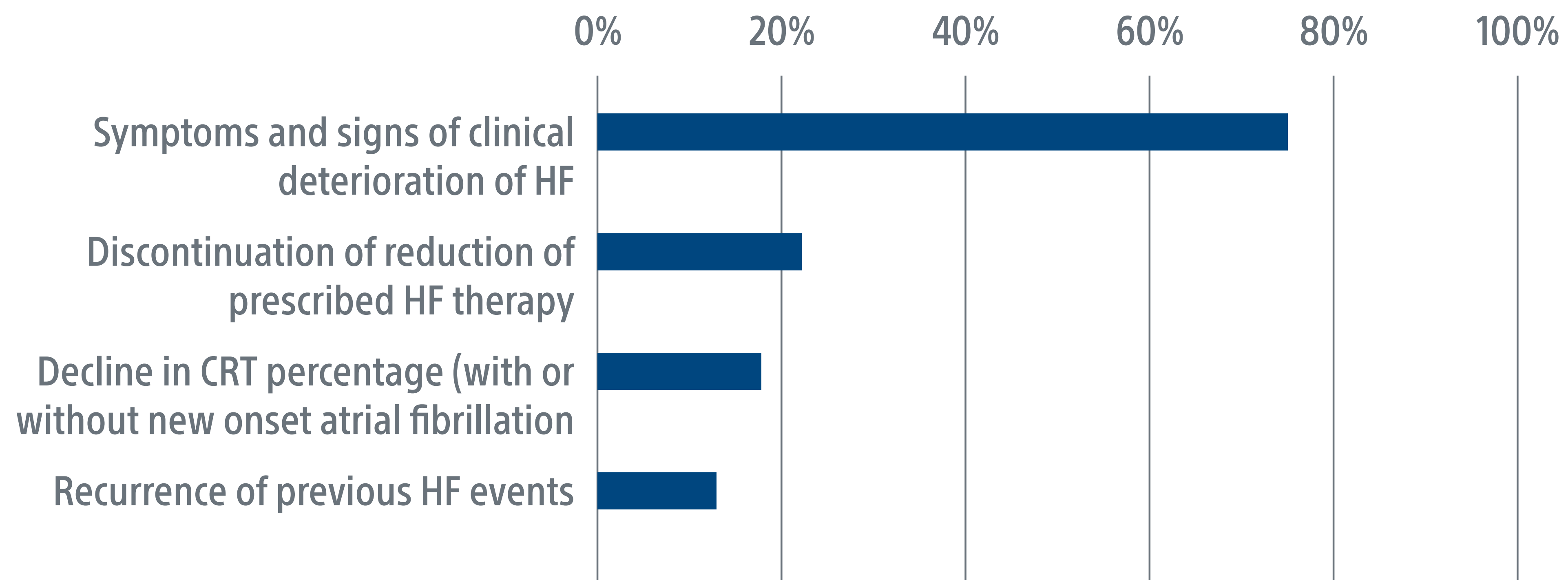
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Successful practice example: Follow-up algorithm scheme   4/9

100 HeartLogic alerts

40 non-clinically meaningful alerts:
- 8 associated with non-HF therapy changes or interventions
- 3 pulmonary events
- 29 unexplained alerts

60 clinically meaningful alerts

48 new information

43 actionable alerts

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Successful practice example: Follow-up algorithm scheme   5/9

Proportion of HF-related conditions associated with HeartLogic alerts judged clinically meaningful (n=60)

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Successful practice example: Follow-up algorithm scheme   6/9

Proportion of triggered actions for actionable
HeartLogic alerts (n=43)

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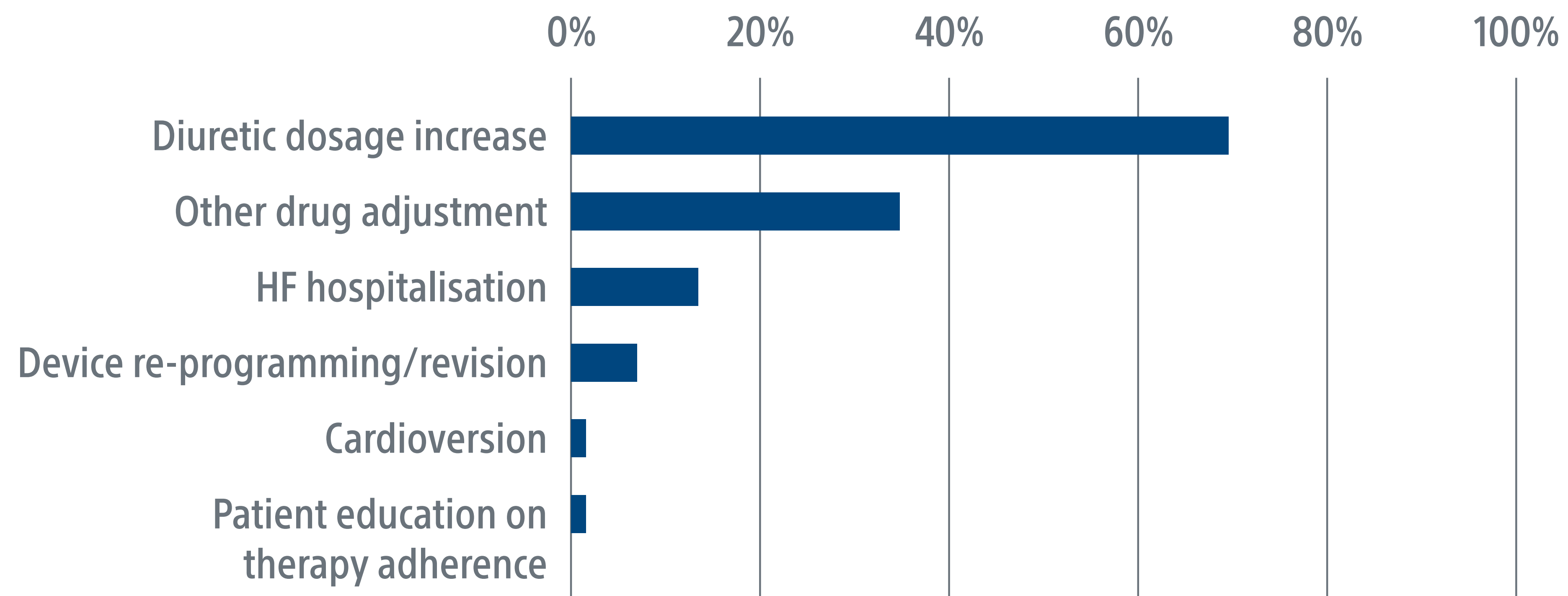
Successful practice example: Follow-up algorithm scheme   7/9

Key take aways: Reduced number of alerts and HeartLogic™ alert work burden (<1 alert per patient-year)

In this analysis, it was found a rate of about one alert per patient-year when the nominal HeartLogic threshold value of 16 was set. Thus, the volume of alert transmissions did not generate a high workload at the centres. The time spent in the alert state was 15% of the total observation period, which was similar to the 17% value recorded in the blinded MultiSense study.

By implementing their predefined management protocol, the centres were able to verify the clinical relevance of the alerts and to confirm the presence of meaningful HF conditions that might necessitate actions.

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Successful practice example: Follow-up algorithm scheme 8/9

Key take aways: High sensitivity and specificity for heart failure events detection

Meaningful heart failure conditions that may necessitate actions were detected in 60% of cases, a higher number than the positive predictive value reported in the MultiSense study (ie, 11.3%), which included in its definition only hospitalisations for worsening HF. A number comparable to the value reported in a previous blinded analysis also included instances of early worsening HF in the calculation. In this study, the most frequent conditions associated with HeartLogic™ alerts were symptoms or signs of clinical deterioration of HF, discontinuation or reduction of prescribed therapy or decline in CRT percentage, in agreement with the previous study. As expected, some alerts identified conditions that the physician was already aware of (e.g. symptoms reported earlier by the patient or signs incidentally detected during scheduled assessments). These alerts did not provide useful new information as they confirmed known conditions, so their management was not a source of additional workload for the centers. Apart from a few HF events that did not require intervention because they were already resolving spontaneously, the majority of alerts resulted in active clinical actions.

Most frequently, the actions consisted of diuretic dosage increase or other drug adjustments and, in many cases, were performed remotely. Less frequently, an unscheduled in-office visit was required, for example, to adjust device programming.

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Successful practice example: Follow-up algorithm scheme   9/9

Key take aways: Positive impact on heart failure clinical outcome and resource management (0.15 hospitalisations/patient-year).

The remote management of HF patients is expected to reduce emergency department/urgent visits, allowing in-office visits to be requested only when immediate intervention is actually needed. The availability of a tool that is able to accurately detect actionable events may facilitate effective remote management and increase the appropriateness of in-office visits.

Reducing hospitalisations is the final goal of every HF management programme as the prognostic importance and cost of hospital admissions are considerable.

In addition to these, some hospitalisations that were not associated with alerts also occurred. Nonetheless, the overall rate of HF hospitalisations was very low (0.15 hospitalisations/patient-year).

In this study, hospitalisations to manage the HF signs detected during in-office visits, according to the HeartLogic™ alert, state events of worsening HF detected by the algorithm were rarely needed.

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3. Resources

EDUCARE educational resources

A. HeartLogic™ diagnostic training

B. Managing HeartLogic™ LATITUDE™ NXT training

C. Alert management guide

D. Webinar

E. Case studies

Patient education and engagement

Clinical resources

A. Clinical compendium

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EDUCARE educational resources:

A. Online training – HeartLogic™ heart failure diagnostic training

Learn about how HeartLogic works and how to interpret and use Heart Failure Management Reports to improve patient outcomes.

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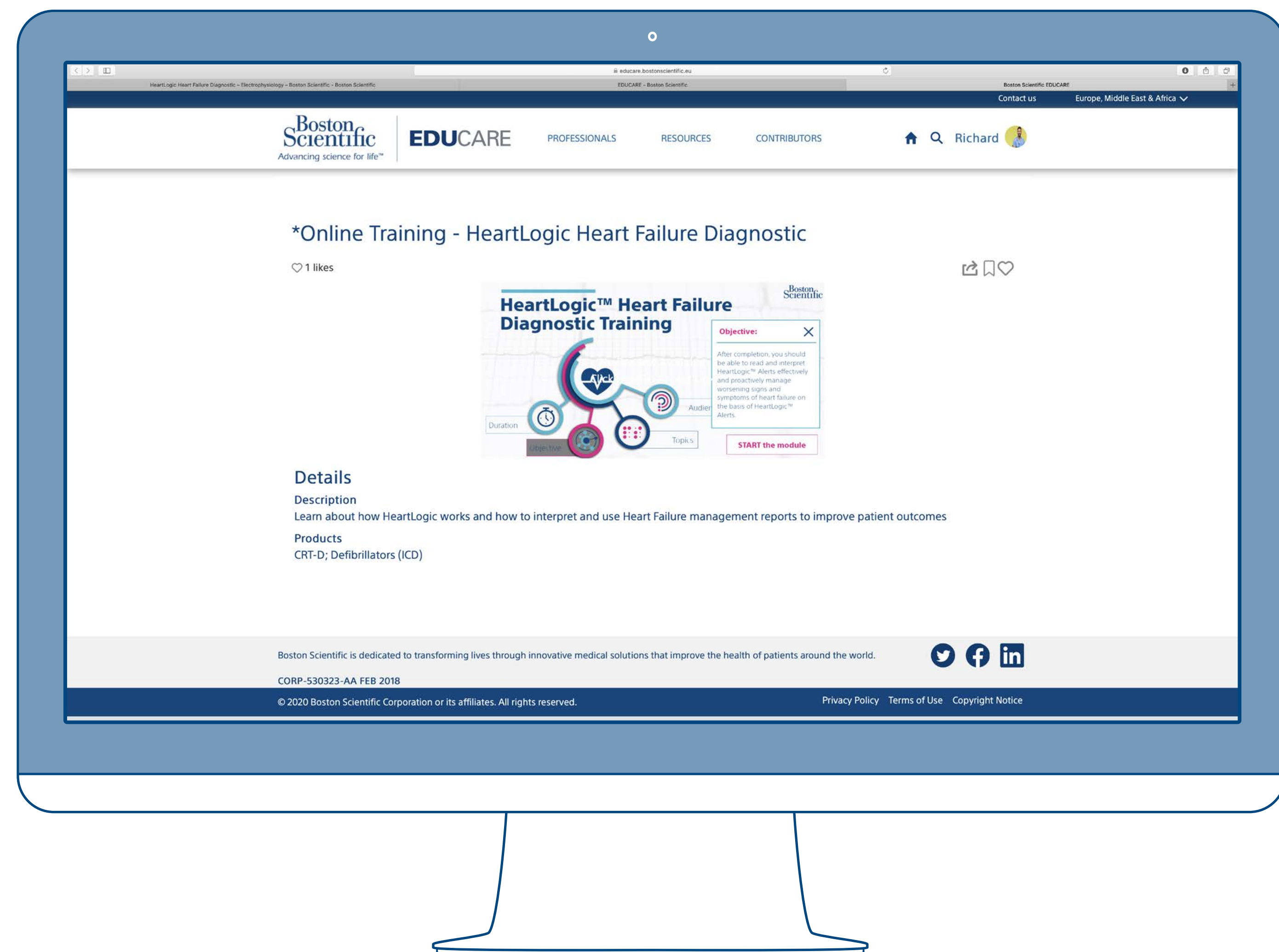
EDUCARE educational resources:

B. Online training – managing HeartLogic™ patients in LATITUDE™ NXT training

Learn about how to integrate HeartLogic in the LATITUDE NXT system and how to navigate in LATITUDE NXT and interpret HeartLogic alerts.
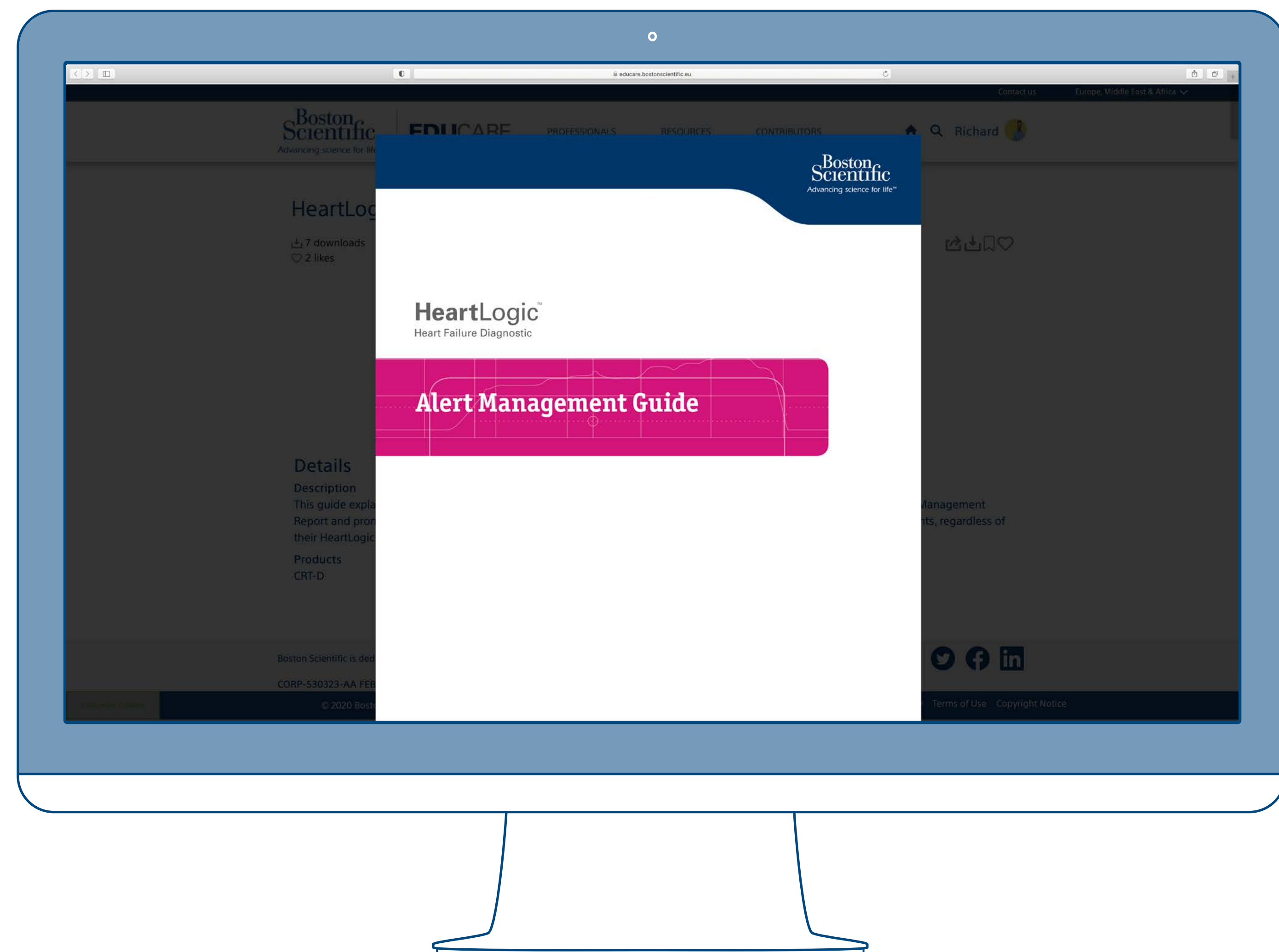
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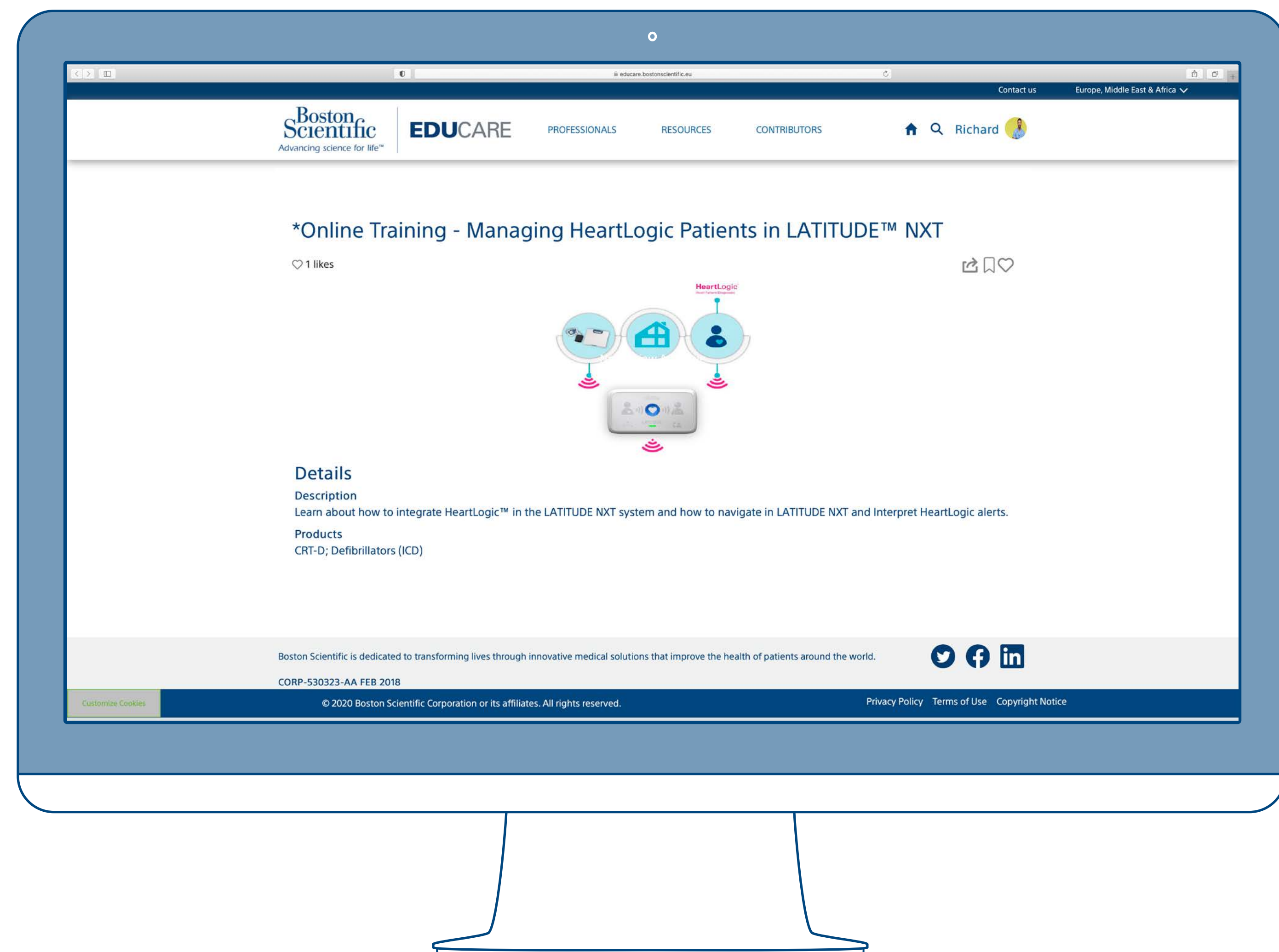
EDUCARE educational resources:
C. Alert management guide

A guide that explains the 3A Process, a clinical workflow where a HeartLogic alert triggers a data review of the Heart Failure Management Report and prompts patient discussions to spur clinical action. Practice standard of care for all patients, regardless of their HeartLogic alert status, when using this guide.
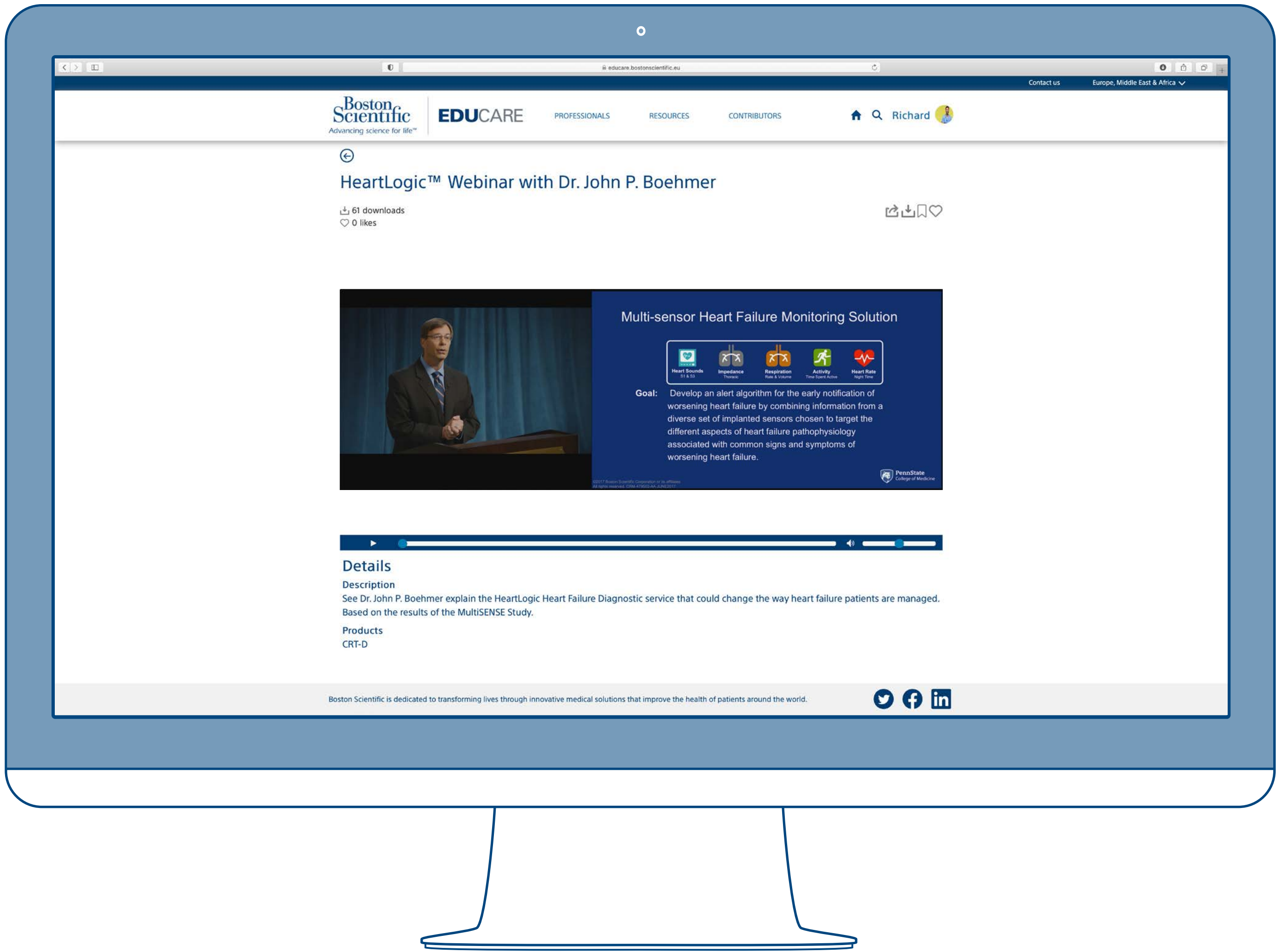
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| 1. HeartLogic™ Overview | 2. Activating HeartLogic™ | 3. Resources | 4. References |

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EDUCARE educational resources:

D. Webinar

Dr. John P. Boehmer explains the HeartLogic™ Heart Failure Diagnostic service that could change the way heart failure patients are managed. Based on the results of the MultiSense Study.

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EDUCARE educational resources:

E. Case studies

1. Prof. Calò

HeartLogic™ in clinical practice

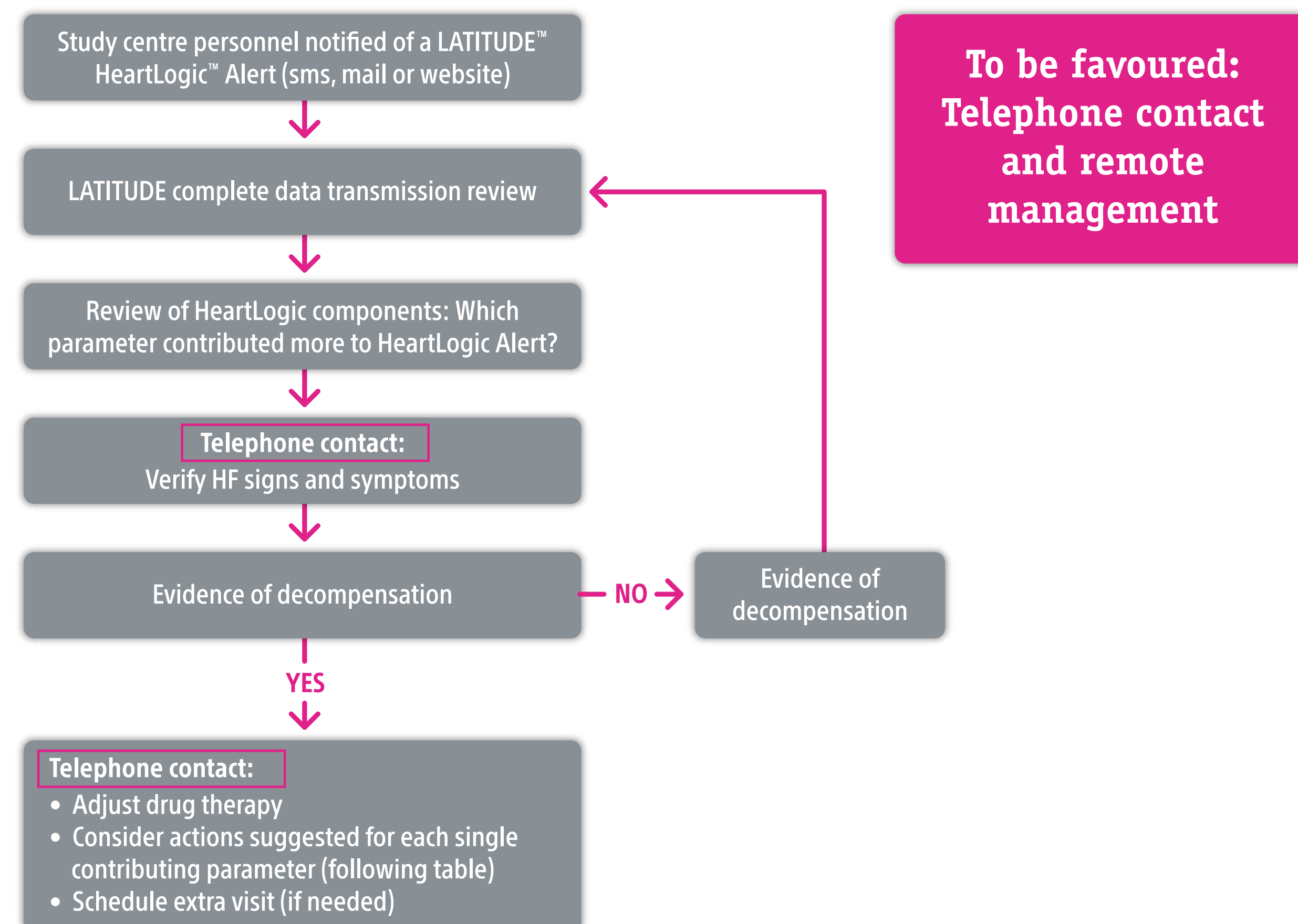**CLICK HERE FOR ACCESS**

2. Prof. Capucci

HeartLogic: new approach
to heart failure

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3. Follow up algorithm scheme

Adopted in Italian centres from
the preliminary experience from
the EU HeartLogic Pilot.[4]

Scheme adopted in some pilot centres

Study centre personnel notified of a LATITUDE™ HeartLogic™ Alert (sms, mail or website)

↓

LATITUDE complete data transmission review

↓

Review of HeartLogic components: Which parameter contributed more to HeartLogic Alert?

↓

Telephone contact:
Verify HF signs and symptoms

↓

Evidence of decompensation — NO → Evidence of decompensation

YES ↓

Telephone contact:
- Adjust drug therapy
- Consider actions suggested for each single contributing parameter (following table)
- Schedule extra visit (if needed)

To be favoured:
Telephone contact and remote management

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1. HeartLogic™ Overview   2. Activating HeartLogic™   3. Resources   4. References

Patient education and engagement

It's imperative to have a clear plan for patient engagement and education. Patients must be actively involved in this process if HeartLogic™ monitoring is to be successful.

Pre-assessment for device implantation may be the optimal time to cover several discussions on HeartLogic education and to help reduce patient anxiety. Here are several suggestions of topics to address on HeartLogic perspective for patient education:

- Therapeutic purpose of LATITUDE™ NXT

- Additional benefits of LATITUDE NXT to the patient

- How and what sensor information HeartLogic would be retrieved from the implanted device

- The process from a hospital perspective

- Likely process/outcomes in the future

- How often they can expect to be contacted

- Practical advice relating to the device (e.g. size, where it needs to be situated in the home etc.)

- Indicators that the hospital are looking at their data

- Language they can expect to hear when contacted

- Reassurance that being contacted by the hospital/other is normal and not something to necessarily worry about

It is also an opportunity to empower your patients to participate in decision making and sharing of information by buying into the idea that the technology is helping them. For example, they may be more likely to share symptoms they would otherwise have ignored, which in turn may support you in taking action. Patients should feel they are able to ask the right questions and be given the information they need.
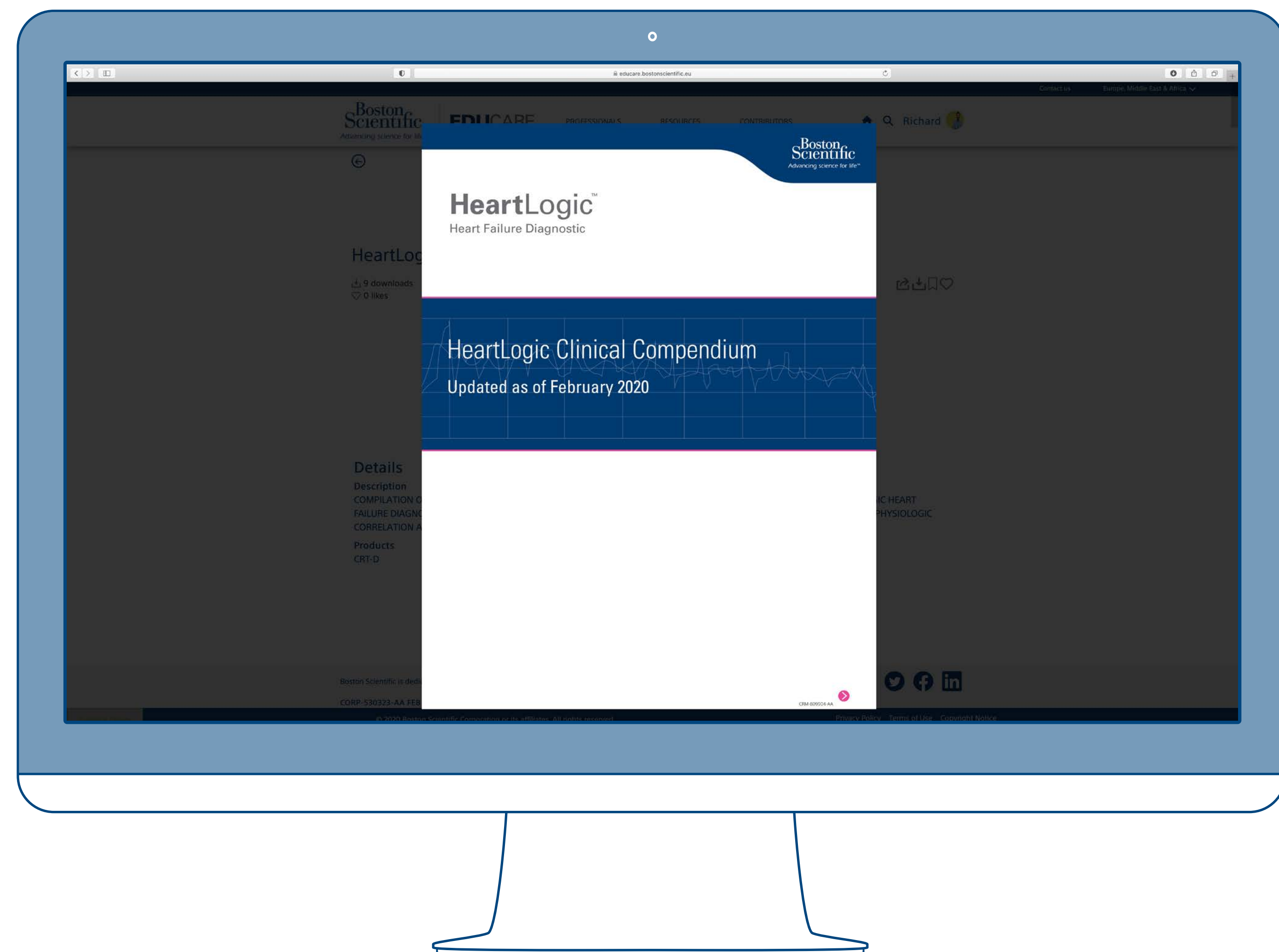
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Clinical resources:

A. Clinical compendium

HeartLogic™ clinical compendium is a compilation of relevant clinical publication references that form the clinical foundation of the HeartLogic heart failure diagnostic. Publications are listed by sensor trend/topic area and then by relevance on feasibility, physiologic correlation and clinical evidence.

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References

1. Wilkins, E. *et al.* European Cardiovascular Disease Statistics 2017. European Heart Network (2017)

2. Amy Groenewegen *et al.* Epidemiology of heart failure. European Journal of Heart Failure (2020), doi:10.1002/ejhf.1858

3. John P. Boehmer *et al.* A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices. JACC: Heart Failure, Volume 5, Issue 3, March 2017, DOI: 10.1016/j.jchf.2016.12.011

4. European HeartLogic™ Pilot Results and 2 HeartLogic™ Case Studies from Europe Pilot Phase including sensors trends, HeartLogic™ Alerts analysis and Learnings discusión, https://educare.bostonscientific.eu/s/Contentdetails?versionId=0681N0000031LZSQA2&share=true

5. Prospective evaluation of the multisensor HeartLogic™ algorithm for heart failure monitoring, Santini *et al.*, Clin Cardiol. 2020;1–7, DOI: 10.1002/clc.23366