Boston Scientific
Advancing science for life™

RESONATE™ HF
Family of ICDs and CRT-Ds

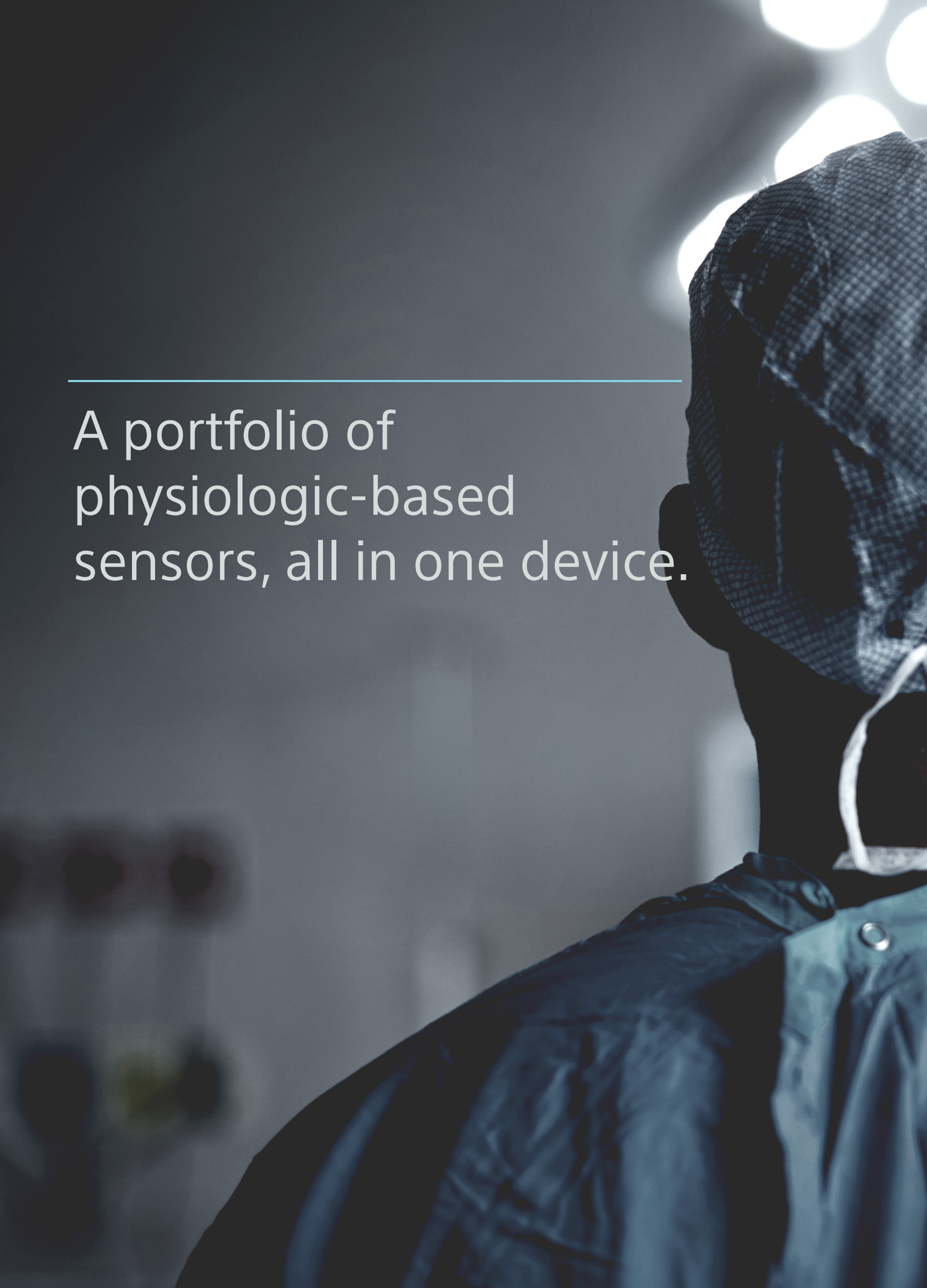
Powerful Solutions. No Compromises.

RIGHTRATE™
Minute Ventilation

SMARTCRT™
Technology

HEARTLOGIC™
Heart Failure Diagnostic

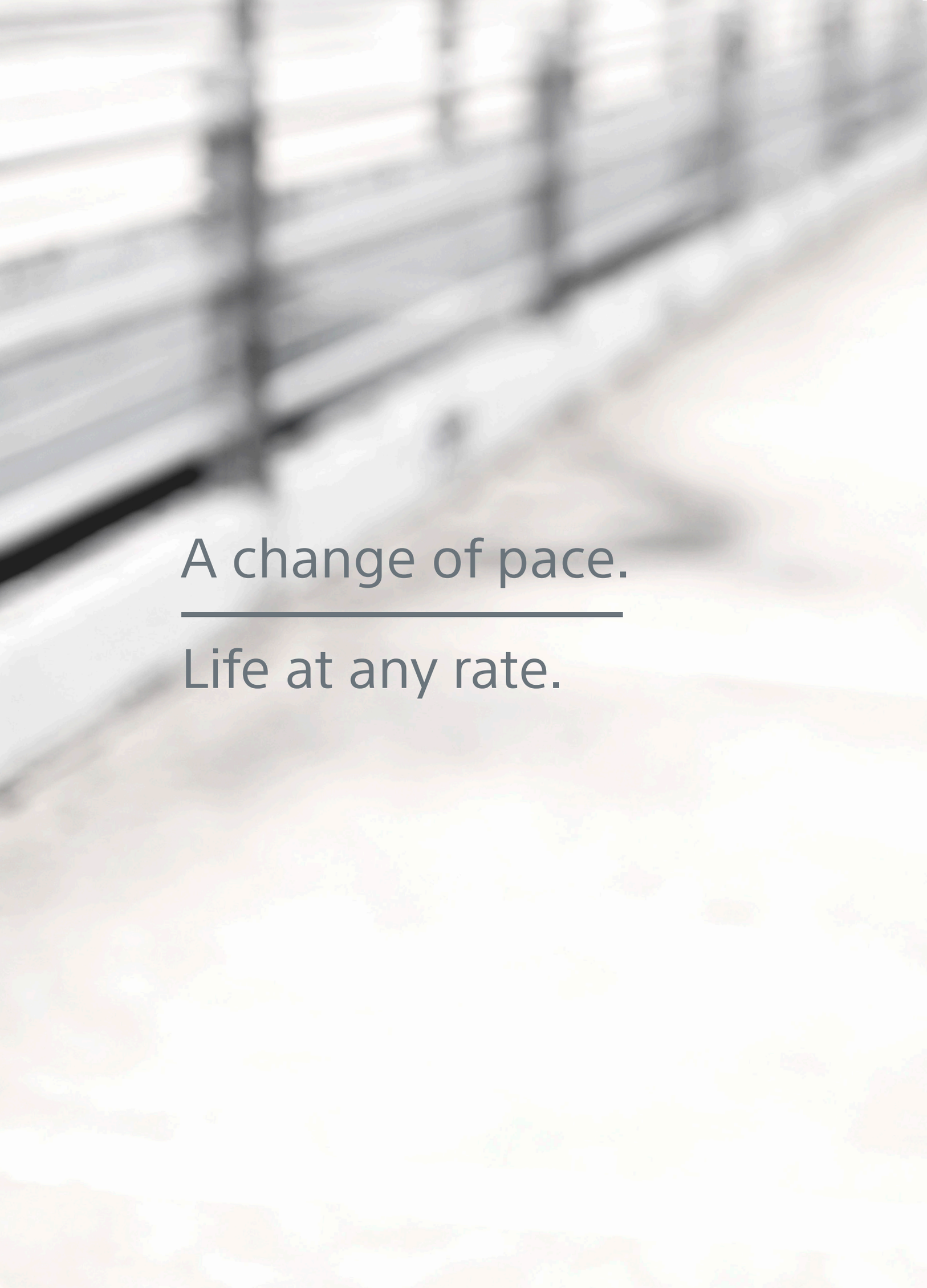
ENDURALIFE™
Battery Technology



A portfolio of physiologic-based sensors, all in one device.

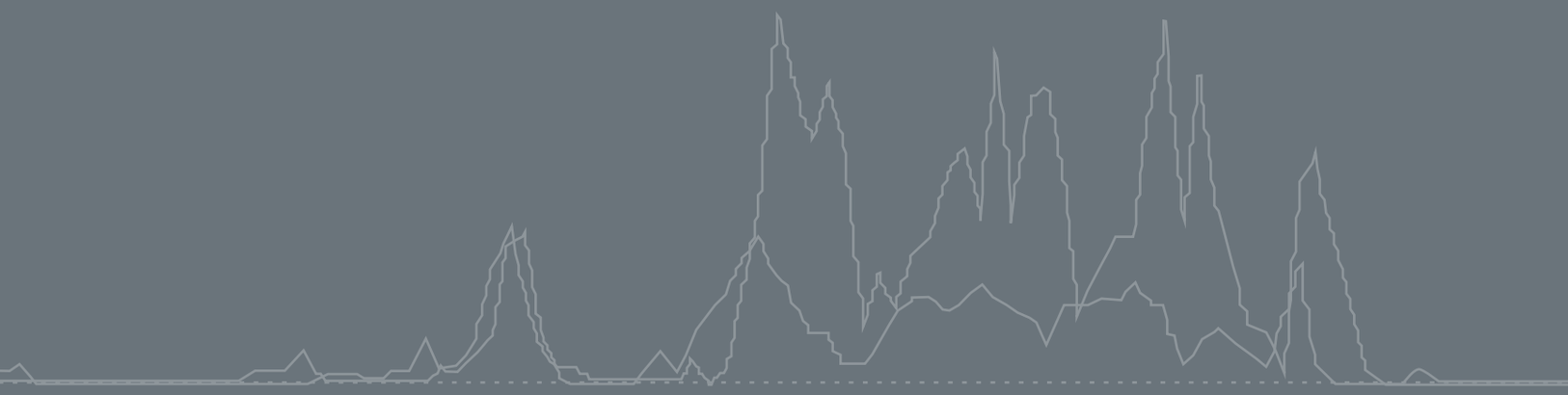
Now there is **RESONATE™ HF.** Only from Boston Scientific.

Get ahead of heart failure with unprecedented insight, control and power. RESONATE™ HF, our groundbreaking line of data-driven ICDs and CRT-Ds, offers an extraordinary, holistic approach to cardiac care. New technology allows you to restore chronotropic competence, accurately predict heart failure events weeks in advance and control programming to maximize response over the long term. All with the battery power to fully leverage device capabilities. Together, these technologies aim to cover more of the potential challenges your patient may encounter. This means a broader base of patients can experience proactive care, all from one device.


A change of pace.
Life at any rate.

50-70%

OF HEART FAILURE PATIENTS HAVE CHRONOTROPIC INCOMPETENCE.[1,2]

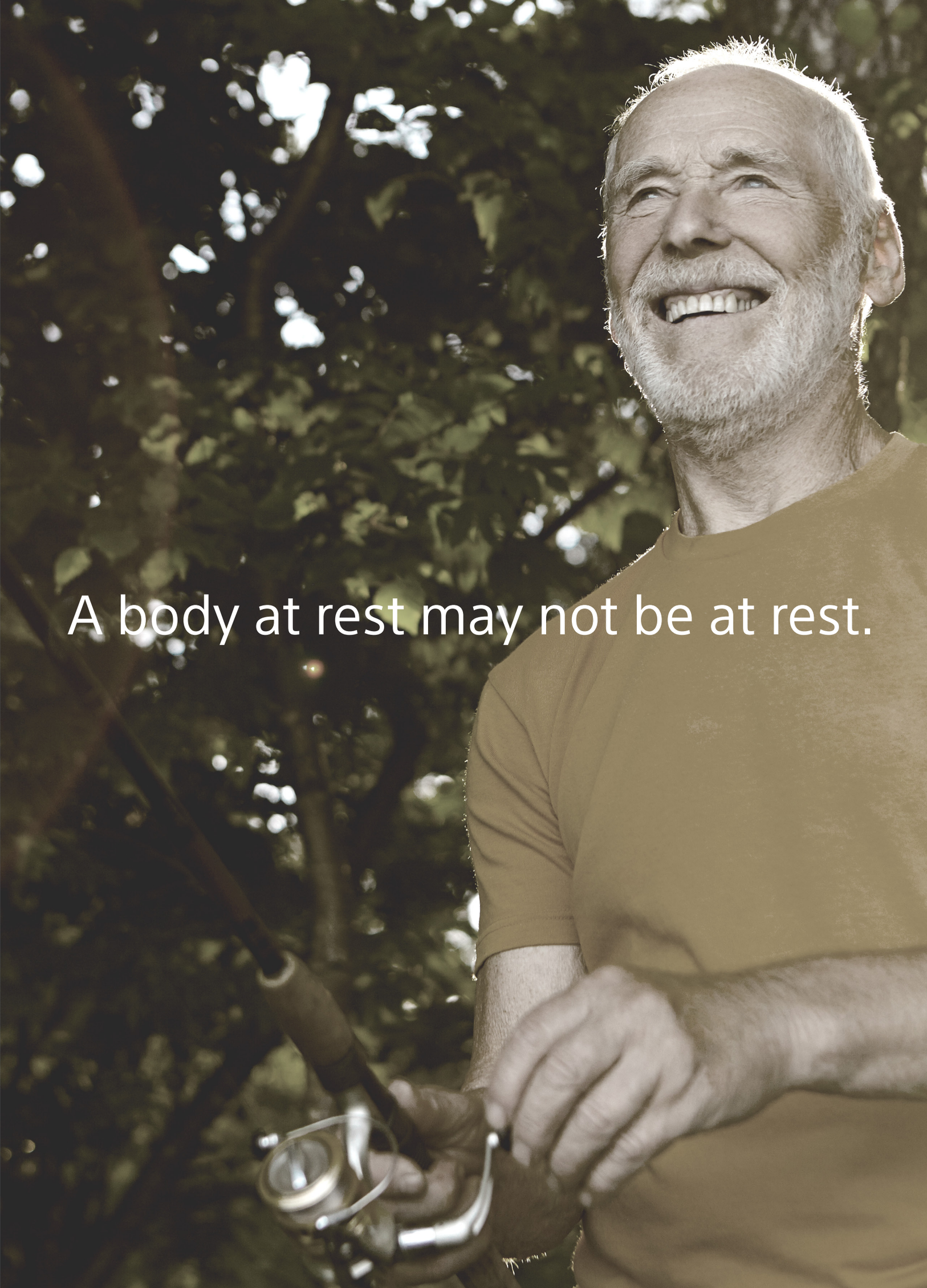


RIGHTRATE™

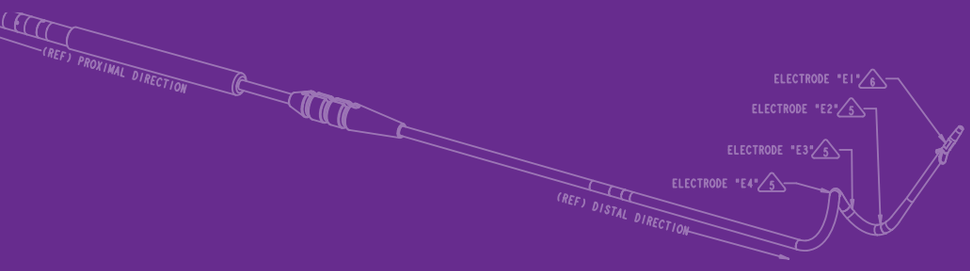
Minute Ventilation

The only sensor clinically proven to restore chronotropic competence.[3]

Minute ventilation is a physiologic sensor that is highly correlated with breathing. It doesn't require motion of the accelerometer and adjusts heart rate based on changes in movement as well as breathing. It's the only sensor clinically proven to restore chronotropic competence.[3,4] And it's only available from Boston Scientific.


A body at rest may not be at rest.

Control to maximize CRT response.



SMARTCRT™
Technology

SmartCRT™ is a systematic, step-by-step approach for maximizing patient response. Customize therapy by using all the features—including MultiSite Pacing—without compromising longevity. Only from Boston Scientific.

OPTIMIZE WHERE, WHEN AND HOW TO PACE.

Where: Each device has 17 vectors, giving you the flexibility to choose the most therapeutic vector for each patient. You'll also have data on RV-LV delay to help you choose the best cathode. And with ACUITY™ X4 leads, you'll be able to pace exactly where you need to.

When: The SmartDelay™ algorithm recommends personalized sensed and paced AV delays to maximize the hemodynamic response. Patients with long RV-LV delay and SmartDelay achieved an ~80% response rate in the SMART-AV trial.[5]

How: Customize treatment using either single-site or multisite pacing, with pacing from two independent LV vectors. SmartVector™ provides simple, automated programming recommendations in less than 5 seconds. In the SMART-MSP clinical trial, 51% of non-responders at 6 months converted to responders at 12 months with MultiSite Pacing on.[6]

Up to

13.3

YEARS PROJECTED LONGEVITY

even with MultiSite Pacing turned on

(Assumes: 2.0V RA, LV-only, 2.0V LV, 700Ω, 15% A pacing, 100% LV pacing, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.)

216

MULTISITE PACING VECTOR COMBINATIONS

77%

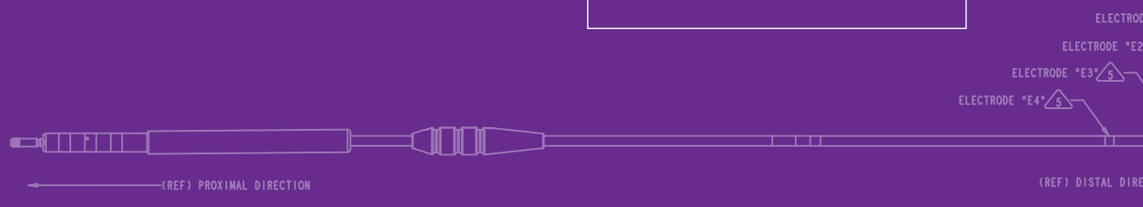
OF PATIENTS

with a spiral lead were paced from a proximal electrode in the NAVIGATE X4 STUDY[7]

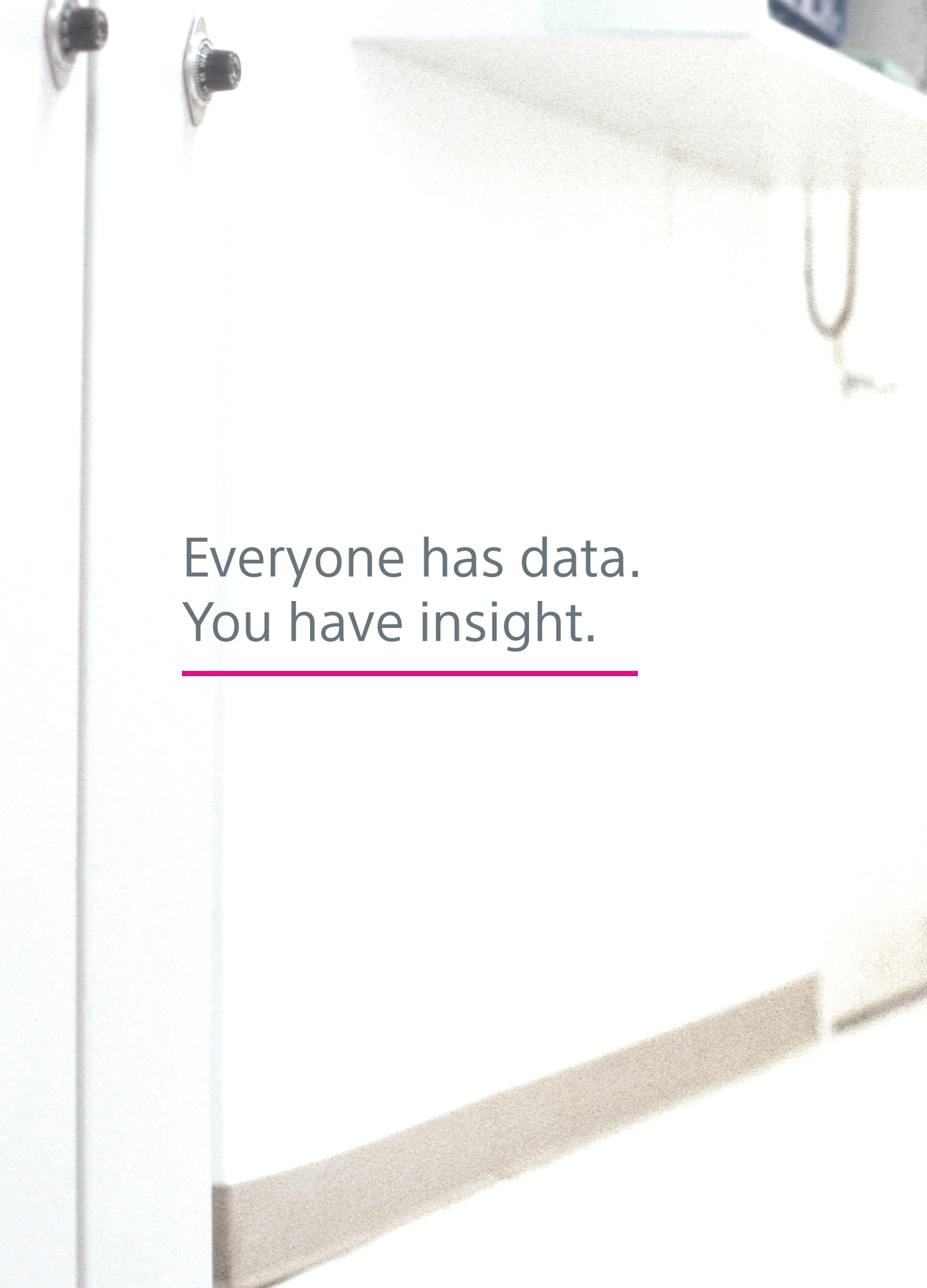
The Boston Scientific SmartCRT Technology, including ACUITY™ X4, VectorGuide™, SmartDelay™, and MultiSite Pacing, can contribute to an over 90% response rate.

90%

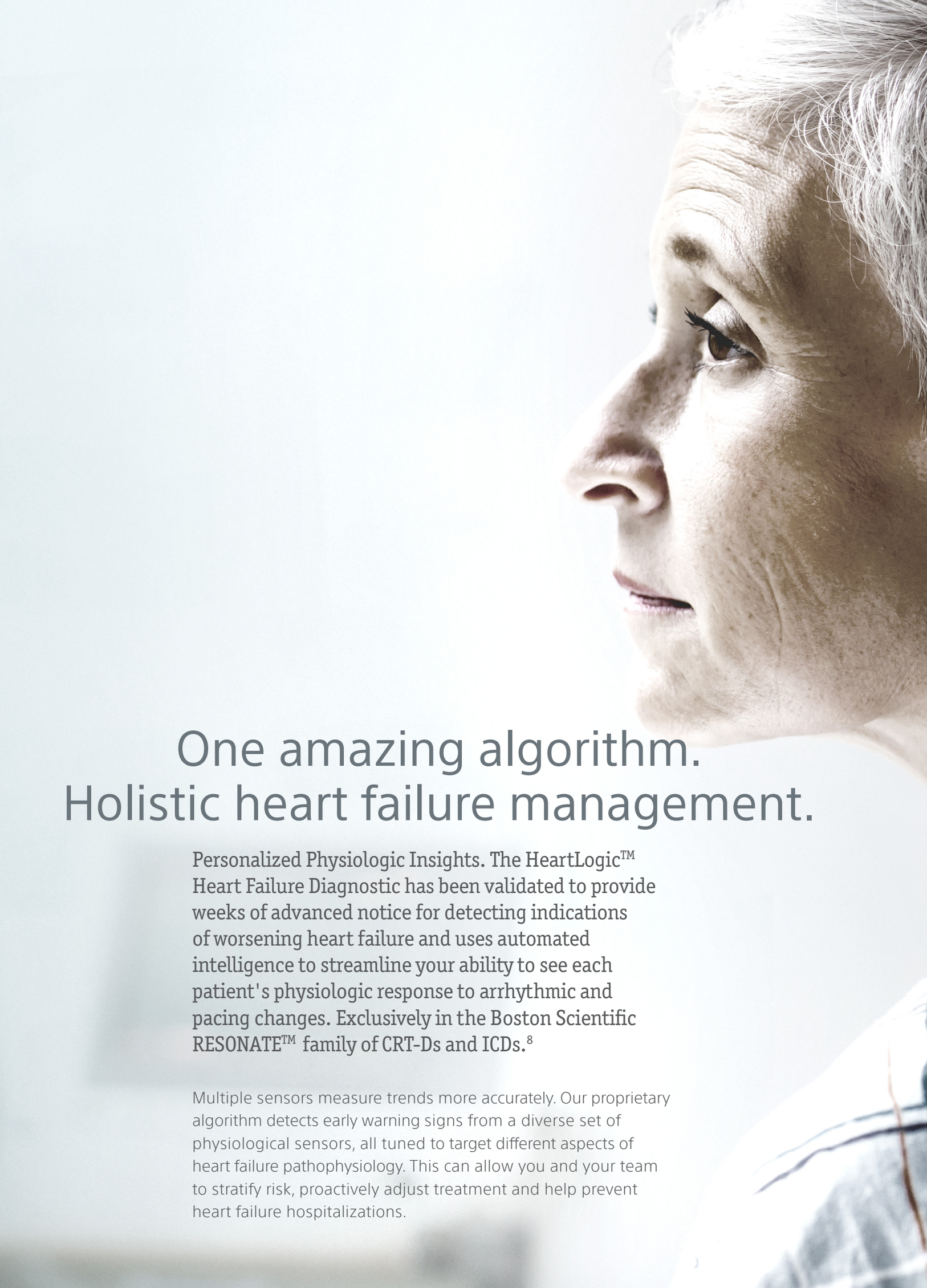
RESPONSE RATE




The smart way to personalize pacing.



Everyone has data.
You have insight.



One amazing algorithm. Holistic heart failure management.

Personalized Physiologic Insights. The HeartLogic™ Heart Failure Diagnostic has been validated to provide weeks of advanced notice for detecting indications of worsening heart failure and uses automated intelligence to streamline your ability to see each patient's physiologic response to arrhythmic and pacing changes. Exclusively in the Boston Scientific RESONATE™ family of CRT-Ds and ICDs.[8]

Multiple sensors measure trends more accurately. Our proprietary algorithm detects early warning signs from a diverse set of physiological sensors, all tuned to target different aspects of heart failure pathophysiology. This can allow you and your team to stratify risk, proactively adjust treatment and help prevent heart failure hospitalizations.

HEARTLOGIC™
Heart Failure Diagnostic

HeartLogic™ uses multiple sensors to track physiological trends and combines them into one composite index that provides insight into a patient's condition. When a patient's numbers change from his or her baseline and exceed your chosen threshold, you'll get an actionable yellow alert through the LATITUDE™ NXT Patient Management System.

HOW SUCCESSFUL IS IT?

The MultiSENSE* study assessed more than 900 patients and validated the alert to have:

70%
SENSITIVITY
in detecting heart failure events[8]

A median of
34
DAYS ADVANCE NOTICE*[8]

<2
TOTAL ALERTS
per patient per year[8]

Data from the MANAGE-HF Phase I clinical trial showed that HeartLogic was integrated into clinical care safely and the following results were noted.[9]

MORE RAPID RECOVERY
of HeartLogic Index

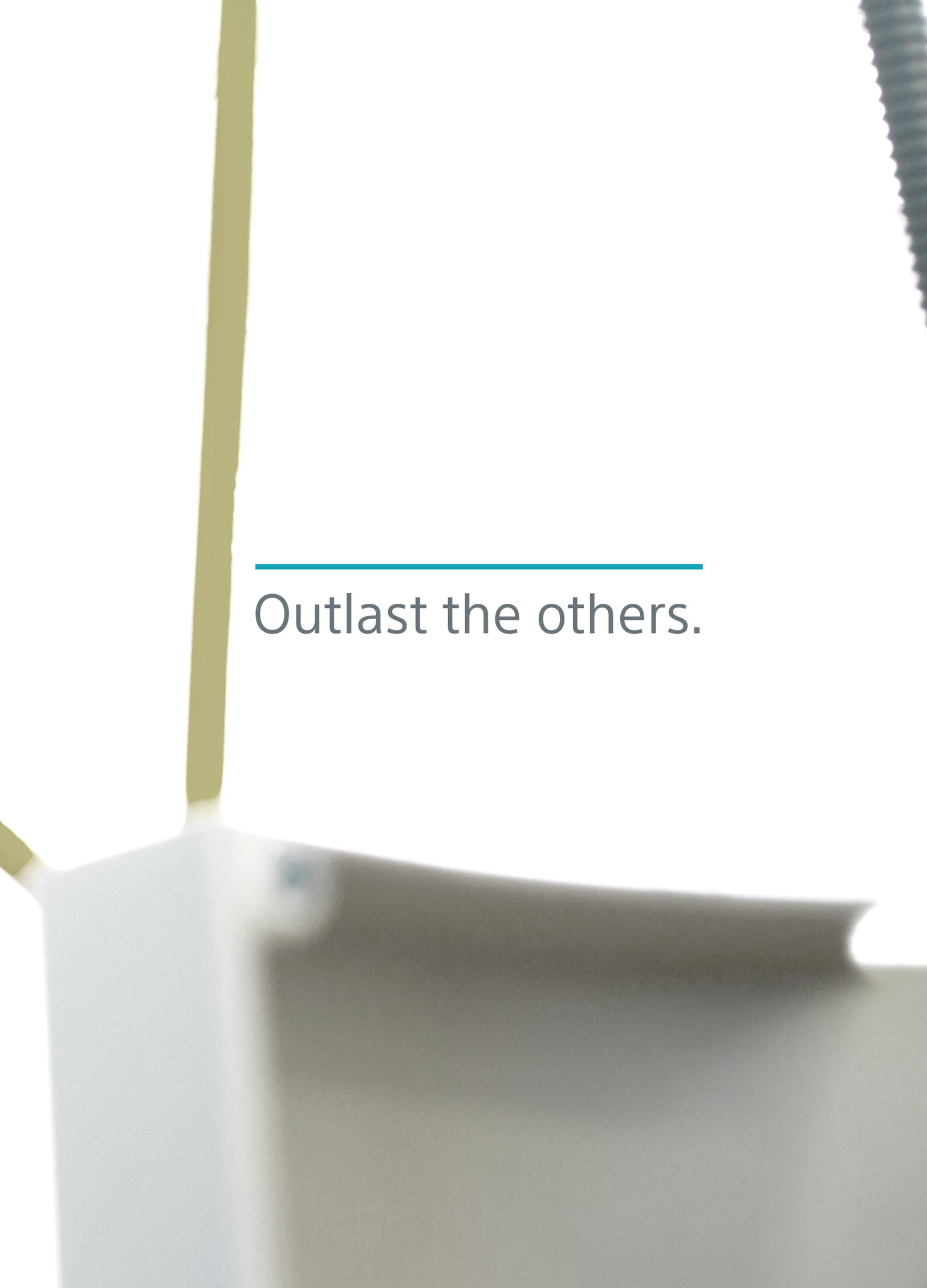
LOWER
NTpro BNP Levels

67% REDUCTION
In HF Hospitalizations Associated with HeartLogic

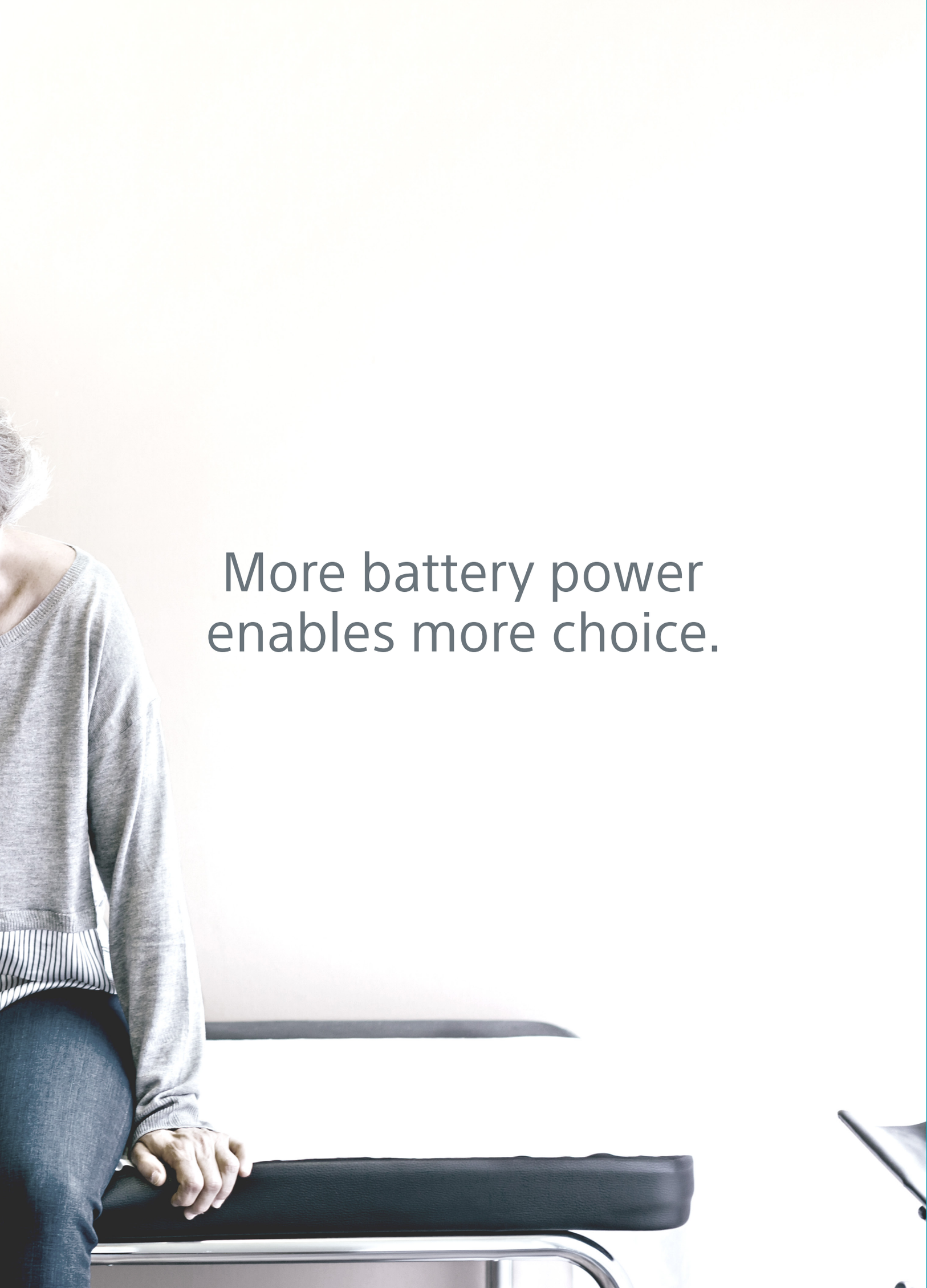
EDUCARE

For more information, training resources and CEU credits, visit heartlogictraining.com.

*The HeartLogic Index and Alert were validated using data from the MultiSENSE study; however, HeartLogic's impact on clinical outcome has not been established. Establishment of the impact will require a post-market trial designed specifically to study clinical outcomes directly related to the use of this feature.



Outlast the others.



More battery power
enables more choice.

ENDURALIFE™
Battery Technology

Up to
13.3
YEARS PROJECTED LONGEVITY
even with MultiSite Pacing turned on
(Assumes: 2.0V RA, LV-only, 2.0V LV, 700Ω, 15% A pacing, 100% LV pacing, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.)

9
CLINICAL STUDIES[10-18]
confirm industry-leading longevity

10
YEARS OF REAL-WORLD DATA[19]

Fully leverage all the device capabilities and maintain industry-leading longevity.

You no longer have to choose between performance and longevity. The RESONATE™ HF family of ICDs and CRT-Ds is powered by EnduraLife,™ the longest-lasting battery on the market. Nine independent studies with over 11,300 patients confirm that Boston Scientific CRT-Ds offer industry-leading longevity, outlasting comparable devices from Medtronic and Abbott.[10-18] Even with MultiSite Pacing turned on, an EnduraLife battery is projected to last for over 13 years. So you have the clinical freedom to make programming decisions that optimize therapy for the patient, not the device, while reducing the need for replacement when the patient may be more susceptible to complications.

Projected longevities for RESONATE HF devices:

VR ICD	Up to 17.5 years*
DR ICD	Up to 16.0 years*
CRT-D	Up to 14.7 years**

NICE

The National Institute for Health and Care Excellence (NICE) recommends EnduraLife™ Battery Technology in Boston Scientific CRT-D devices for treatment of heart failure[20]

* Assumes: 2.0V RA, 2.0V RV, 0% pacing, 700Ω, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.
** Assumes: 2.0V RA, LV-only, 2.0V LV, 700Ω, 15% A pacing, 100% LV pacing, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

What was once out of reach is now in your hands.

You now hold the latest, most advanced technology in your expert hands. With your leadership, we can help slow heart failure progression, reduce decompensation and rehospitalizations, and extend the life expectancy and quality of life for heart failure patients.

To learn more, scan here.

RESONATE™ HF

Family of ICDs and CRT-Ds

- RightRate™ Minute Ventilation
- SmartCRT™ Technology
- HeartLogic™ Diagnostic
- EnduraLife™ Battery Technology
- ImageReady™ MR-Conditional*
- MultiSite Pacing
- PaceSafe™ Auto Thresholds
- LV VectorGuide™
- SmartDelay™ with LV-only Pacing
- Heart Failure Management Report
- Impedance Trend
- Sleep Incline Trend
- Atrial Arrhythmia Report

*In certain models, when conditions of use are met

RIGHTRATE™ Minute Ventilation | **SMARTCRT™** Technology | **HEARTLOGIC™** Heart Failure Diagnostic | **ENDURALIFE™** Battery Technology

Seeking the extraordinary.

We demand to have it all. We seek the insight, control and power to improve patient outcomes. We create the uncommon connections that lead to extraordinary results. No longer do we have to choose between compassion and care. Features and power. Risk and reward. Quality and efficiency. This relentless pursuit is inspired by our colleagues, powered by technology and marked by our success. **We'll never stop.**

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11. J. Williams, R. Stevenson. Contemporary cardiac resynchronization implantable cardioverter defibrillator battery longevity in a community hospital heart failure cohort. Presented at HFSA 2014. http://www.onlinejcf.com/article/.S1071-9164(14)00389-3/full text. Boston Scientific = 53 patients, Medtronic = 28 patients, St. Jude Medical = 10 patients. Four-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
12. Ellis CR, Dickerman DI, Orton JM, et al. Ampere Hour as a Predictor of Cardiac Resynchronization Defibrillator Pulse Generator Battery Longevity: A Multicenter Study. PACE 2016 doi: 10.1111/pace.12831 first published online 11-MAR-2016. The five major institutions performing the study include, at Vanderbilt University, Henry Ford Hospital, University of Michigan, Thomas Jefferson University, Cooper Health System, North Ohio Heart Center. Boston Scientific = 322 patients, Medtronic = 794 patients, St. Jude Medical = 186 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
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15. Provided by Dr. Ernest Lau on 04/29/15 in support of Lau E, Wilson C, Ashfield K, McNair W, McEneany D, Roberts M, Large Capacity LiMnO2 Batteries Extended CRTD Longevity in Clinical Use Compared to Smaller Capacity LiSVO Batteries Over 6 Years. Presented at HRS 2015. Medtronic = 62 patients, Boston Scientific = 27 patients, St. Jude = 66 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
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17. Alam MB, Munir MB, Rattan R, et al. Battery longevity from cardiac resynchronization therapy defibrillators: differences between manufacturers and discrepancies with published product performance reports. Europace 016;doi:10.1093/europace/ euw044. First published online: 22-MAR-2016. Kaplan Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer. Battery Longevity in Cardiac Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude Medical = 57 patients. Previously evaluated these patients at a four-year survival rate calculated using device replacements for battery depletion as indicated by ERI. 2014; Europace (2014) 16,246-51.
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19. BSC data on file. Data current through February 2016. 3,000 patients per device group.
20. https://www.nice.org.uk/guidance/mtg33/.

RESONATE™HF, RESONATE™, RESONATE™X4, VIGILANT™, VIGILANT™X4, MOMENTUM™, MOMENTUM™ X4

INDICATIONS AND USAGE

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: • Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; or • Left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

CONTRAINDICATIONS

There are no contraindications for this device.

WARNINGS

• Always have external defibrillation equipment available during implant and electrophysiologic testing. • Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. • Do not use defibrillation patch leads with the pulse generator system. • Do not use this pulse generator with another pulse generator. • Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. • Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. • For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. This could damage the lead terminal, possibly compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a short within the header. • Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. • When implanting a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Inserting a lead into an incorrect port will result in unanticipated device behavior (potentially leaving the patient without effective therapy). • Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. • Do not use atrial-only modes in patients with heart failure. • Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. • Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zone. • Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. • All devices except for those with an LV: LV-1 lead connection are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. Do not expose patients with non-MR Conditional devices to MRI scanning. Strong magnetic fields may damage the pulse generator and/or lead system, possibly resulting in injury to or death of the patient. • For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. • Do not subject a patient with an implanted pulse generator and/or lead to diathermy. • If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. • Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the Magnet Response programming automatically will be set to Inhibit Therapy. When this happens, the patient should not apply the magnet because tachyarrhythmia therapy could be inhibited.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, follow up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.

POTENTIAL ADVERSE EVENTS

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature: • Air embolism • Allergic reaction • Bleeding • Bradycardia • Cardiac tamponade • Chronic nerve damage • Component failure • Conductor coil fracture • Death • Electrolyte imbalance/dehydration • Elevated thresholds • Erosion • Excessive fibrotic tissue growth • Extracardiac stimulation (muscle/nerve stimulation) • Failure to convert an induced arrhythmia • Fluid accumulation • Foreign body rejection phenomena • Formation of hematomas or seromas • Heart block • Inability to defibrillate or pace • Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing) • Incisional pain • Incomplete lead connection with pulse generator • Infection including endocarditis • Insulating myocardium during defibrillation with internal or external paddles • Lead dislodgment • Lead fracture • Lead insulation breakage or abrasion • Lead perforation • Lead tip deformation and/or breakage • Local tissue reaction • Loss of capture • Myocardial infarction (MI) • Myocardial necrosis • Myocardial trauma (e.g., tissue damage, valve damage) • Myopotential sensing • Oversensing/undersensing • Pacemaker-mediated tachycardia (PMT) • Pericardial rub, effusion • Pneumothorax • Pulse generator migration • Shunting current during defibrillation with internal or external paddles • Syncope • Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation • Thrombosis/thromboemboli • Valve damage • Vasovagal response • Venous occlusion • Venous trauma (e.g., perforation, dissection, erosion) • Worsening heart failure

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following: • Dependency • Depression • Fear of shocking while conscious • Fear that shocking capability may be lost • Imagined shocking • Fear of premature battery depletion • Fear of device malfunction

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: • Allergic reaction to contrast media • Breakage/failure of implant instruments • Prolonged exposure to fluoroscopic radiation • Renal failure from contrast media used to visualize coronary veins

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use/MRI Technical Guide" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. 92436222 B.6

ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL ICD

INDICATIONS AND USAGE

Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS

Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, VIGILANT and MOMENTUM devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Do not expose patients with non-MR conditional devices to MRI scanning. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information.

POTENTIAL ADVERSE EVENTS

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse evets associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide

Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.

92436178 (Rev B)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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