

Heart failure and sudden cardiac death: key facts and implantable heart rhythm devices (ICDs, CRT-Ds)

What is Heart Failure (HF) and Sudden Cardiac Death (SCD)?

Despite its name, HF does not mean that the heart suddenly stops functioning. HF is a progressive condition where the heart cannot pump enough blood to meet the body's needs efficiently. The condition begins when the heart is weakened due to structural or functional damage (e.g. following a heart attack or persistent high blood pressure). Over time, the failing heart no longer contracts as strongly or is as coordinated as before, further affecting its ability to pump. The heart needs to work harder to keep blood circulating around the body. This causes stress to the heart leading to the heart muscle enlarging, further weakening it and progressing the heart failure.¹

SCD is usually defined as death due to cardiac causes occurring within 1 hour of the onset of symptoms.²

Key facts and figures on HF and SCD

- Heart failure has developed into a major burden in the Western world, which increasingly affects millions of people.³
- HF is predicted to increase substantially over the coming decades in Europe.⁴
- Over 500,000 people in the UK have been diagnosed with heart failure⁵
- 15 million people are living with heart failure in Europe.⁶
- More than 350,000 people in Europe die each year due to SCD.⁷
- Approximately 75–80% of the 70,000 sudden cardiac deaths in England and Wales in 2010 could be attributed to ventricular arrhythmias (abnormal heart rhythms caused by problems in the electrical conduction system of the heart).⁸
- Heart failure constitutes one of the biggest hospitalisation costs facing the National Health Service (NHS) in the UK with over 5% of emergency admissions and 2% of all NHS inpatient bed days.⁹
- This burden is only set to increase because heart failure is the only cardiovascular disease on the rise. There are many treatments available to treat the symptoms and causes of heart failure but many patients have persistent and progressive symptoms and overall prognosis is poor.¹⁰

The role of CRTs and ICD devices

Implantable cardioverter defibrillators (ICDs) are proven to be the most effective therapy to protect against SCD.¹¹ They have transformed the lives of many people with life-threatening arrhythmia. They work by administering an electrical shock to the heart (defibrillation) to reset the heart's rhythm and restore normal blood flow throughout the body.

Cardiac Resynchronization Therapy (CRT) devices have an established role in treatment of heart failure. CRT devices stimulate both of the heart's lower chambers so that they are



"synchronised" and become more efficient in pumping blood around the body. There are two types of CRT devices:

- 1. CRT-Ps are specific pacemakers with the added capability to re-synchronise the heart.
- 2. CRT-Ds have a further facility to defibrillate the heart if a person is at risk from lifethreatening arrhythmias.

The importance of device longevity and EnduraLife[™] Battery Technology¹³⁻²¹

As patients live longer, increased device battery longevity is vital and can lead to fewer replacement procedures and a lower risk of complications. Reducing re-intervention can also have an important impact on the UK health system, offering substantial savings to commissioners and increased efficiency for cardiac services able to treat more new patients at no additional costs.

EnduraLife Battery Technology delivers the longest projected longevity and significantly outperforms industry averages, even with enhanced features and MultiSite Pacing^a turned on - confirmed by real-world, independent post-market studies.

EnduraLife Battery Technology was developed by Boston Scientific's highly skilled team of battery engineers and the batteries that go into our ICDs and CRT-Ds are manufactured in-house, because traditional batteries were struggling to deliver the longevity and flexibility required for high voltage devices.

Boston Scientific current portfolio features the world's longest-lasting ICDs and CRT-Ds, with real-world longevity projections of nine to 13 years. Nine independent studies confirmed that Boston Scientific CRT-Ds offer industry-leading longevity.

Resonate family of CRT-D devices

In February 2017, Boston Scientific launched the <u>RESONATE™</u> cardiac resynchronisation therapy defibrillator (CRT-D) systems in Europe, a new family of devices featuring SmartCRT technology, which received CE Mark and are now available for heart failure patients across Europe.

The Resonate family is supported by the company's EnduraLife battery technology.

EnduraLife can offer up to 14.7 years battery life, 13.3 years with MultiSite Pacing switched on, meaning physicians and patients alike can have full confidence in the longevity of these devices.

NICE guidance on EnduraLife[™] Battery Technology for treating patients with heart failure²²

In March 2017, the National Institute for Health and Care Excellence (NICE) issued medical technology guidance recommending the use of Boston Scientific CRT-D powered by EnduraLife Battery Technology for treating patients with heart failure who have left ventricular dysfunction with a left ventricular ejection fraction (LVEF) of 35% or less.

NICE concluded that:

 EnduraLife battery-powered CRT-Ds can improve outcomes for patients, reduce the number of overall replacement surgeries, and save the NHS approximately £6 million in the first five years.

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^a Multisite pacing: when the device delivers pacing stimuli at multiple sites within the same vein.

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- The savings were made due to costs associated with early replacement procedures, such as a reduction in hospital admissions, bed days and procurement costs.
- Replacement procedures also equated to a reduction in associated costs accrued from post-operative complications and infections - both of which also have a measurable impact on morbidity and mortality.

Media contacts

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https://www.nice.org.uk/guidance/cg108/resources/costing-report-134800813 ¹⁰ Eur Heart J - 2013:34;2281–2329-doi:10.1093/eurheartj/eht150

¹¹ European utilization of the implantable defibrillator: has 10 years changed the 'enigma'? Europace 2010;12:1063-1069. ¹³ Haarbo J, Hjortshoj S, Johansen J, Jorgensen O, Nielsen J, Petersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. Presented at HRS 2014. http://ondemand.hrsonline.org/common/presentation-detail.aspx/15/35/1241/9000. Boston Scientific = 136 patients, Medtronic = 651 patients, St. Jude Medical = 1,587 patients, Bitronik = 369 patients. Time to exchange of the device because of battery depletion or device failure recorded in the Danish ICD Registry was the endpoint. The four-year survival rate

for devices in the Danish Registry study was 81.1% for Medtronic and 95.7% for Boston Scientific (P<0.01). ¹⁴ 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/fulltext. 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. ¹⁵ Ellis CR, Dickormon DL, Ottor, 114, 114

Ellis CR, Dickerman DI, Orton JM, Hassan S, Good EG, Okabe T, Andruilli JA, Quan KJ, Greenspon AJ. 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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²⁰Alam MB, Munir MB, Rattan R, Adelstein E, Jain S, Saba S. 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. ²¹ Shabanna Din, Shabanna, Mcgee, Rao, Archana, Wright, Jay D. Longevity of implantable cardioverter defibrillators: The impact of device manufacturer and device type on device longevity were assessed. Europace. 2015 Nov 25; . Epub 2015 Nov 25. Total patients = 3436. Cardiostim Abstract 2016. Total patients = 1489 ²² NICE. Medical technology guidance ENDURALIFE-powered CRT-D devices for treating heart failure. March 2017