Cedar

Healthcare Technology Research Centre

ENDURALIFE Technical Report

Authors: Megan Dale
Justin McCarthy
Andrew Cleves
Grace Carolan-Rees

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GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Summary

CRT-D devices provide cardiac resynchronisation therapy, with the additional function of defibrillation. The CRT-D is a single device containing a battery, capacitor, microprocessor and other electronic components. The battery cannot be replaced separately. Connected to the CRT-D, are 3 leads which conduct stimulation and measurements to and from the heart. Device longevity is important if it means that patients avoid surgery for device replacement, thus avoiding the risk of complications.

The battery, its capacity and chemistry are only a part of the factors that give the device longevity. The CRT-D contains complex electronics and has many functions. A combination of the amount of stored energy, how it is stored, and how it is efficiently delivered will determine the potential lifetime of the device. The patient's demands on the device will affect the longevity of any device that is actually implanted.

A simple analogy is that if you compare a small car with 40 litres of fuel or a minibus with 60 litres of fuel, it is easy to see which has more energy stored in the fuel tank (capacity), but less obvious to know which will drive more miles – particularly if one vehicle is going on the motorway, and the other is driving through cities or hilly mountain roads (longevity).

There is a rapidly evolving market in CRT-Ds, and for a product where longevity is a key feature, real time clinical tests cannot be completed until many years after the device is on the market. By the time that clinical trial results, or data based on product returns, are available it is likely that the device will have altered or have been superseded.

The EAC were asked to address four questions that came from MTAC committee discussions:

1. Are ENDURALIFE-powered CRT-D devices smaller compared to new generation non-ENDURALIFE powered CRT-D devices?

Comparison of device volumes based on data available in the device manuals showed that ENDURALIFE-powered CRT-D devices have a smaller volume compared to currently available non-ENDURALIFE powered CRT-D devices. The comparison does not give information on the clinical significance of the smaller size. Additional information in Section 5 and Appendix A.

2. When were "new generation" competitor devices with longer life batteries developed and what chemistries are they based on?

Newer devices are frequently introduced, with smaller or larger changes in the technology. The device longevity is determined by a combination of all the technologies involved in the device. Most currently available devices are based on either a lithium / carbon monoflouride - silver vanadium oxide hybrid (Li/CFx-SVO), or like ENDURALIFE battery technology, lithium / manganese dioxide (Li/MnO_2). The dates different devices were introduced is listed in Appendix A, with additional devices in Appendix B.

3. What are the important factors that relate to the demands placed on a CRT-D device (e.g. pacing, shocks) and battery longevity?

There are parameters that can be set by the clinician, and demands that depend on the day to day demands of the patient. These include the percentage of pacing that is required, the number of defibrillation shocks delivered, the strength of the stimulus required to pace the heart, remote monitoring functions and the use of additional sensors that are used to improve pacing. Examples, with their impact on longevity are listed in section 3.

4. How does the technical evidence on Enduralife battery technology support the claims made by the company?

Boston Scientific provided several detailed protocols for test methods and some summarised results. This gives an indication of the test methods and the amount of testing involved in battery development. It would not be in the remit of a technical assessment report to assess the entirety of the process, and the full data and modelling would be highly confidential. This is understandable, but limits the information that can be taken from the testing reports to having better insight into the processes used to ascertain accurate battery life.

Tests and calculations are not standardised between manufactures and no inferences can be drawn from this information for devices produced by other manufacturers. Further information is available in section 7.

Contents

Glossary

Explanations are provided only in terms of the context of understanding this report, and are not a scientific definition of the terms.

APT	Accelerated pulse test
ATP	Anti-tachycardia pacing
BOS	Beginning of service
Capacity	The amount of charge stored in the battery
DDD Mode	Pacing is enabled for the right atrium and both ventricles
DDDR	DDD mode with sensors to detect normal changes in heart rate, for instance due to exercise.
DF-1 /IS-1	The type of lead connection to the CRT-D. DF-1/IS-1 has 3 connectors with separate connecting pins for leads providing shocks and leads providing pacing
DF-4	The type of lead connection to the CRT-D. DF-4 connections have only one single connector pin which provides all the connections required.
EGM	Electrogram, recording of physiological electrical activity
EOS	End of service
ERI	Elective replacement indicator – an approaching battery end of life alertalarm that still allows a minimum of 3 months device operation before surgical replacement use.
High Voltage (HV) Capacitor	Used as a means of storing charge at a higher voltage than the battery voltage, for use in defibrillation shocks.
Impedance	A measure of the complex resistance of current flowing from the CRT-D to the heart. Higher impedance results in lower currents.
Joules (J)	Unit of energy (for a battery the energy stored is the voltage multiplied by the charge).
Li/CFx-SVO	Lithium / carbon monoflouride - silver vanadium oxide hybridHybrid Carbon Monoflouride/ lithium/silver vanadium oxide; a battery chemistry
Li/MnO_2	Lithium / manganeseses dioxide; a battery chemistry
Li-SVO	Lithium / silver vanadium oxide; a battery chemistry

Onset EGM	Electrogram giving information on cardiac behaviour prior to a shock being delivered
PPR	Product performance report
Pulse amplitude	The strength of the stimulus (V)
Pulse width	The duration of the stimulus (msS)
Remote ttelemetry	A means of interrogating the CRT-D and adjusting parameters wirelessly
RRT	Recommended replacement time (equivalent to ERI)
Transformer	A means of obtaining higher voltages that that provided by the device battery
VVI Mode	Ventricular pacing mode. Pacing and sensing are is only enabled for the ventricles.

1 CRT-D Technology

CRT-D devices provide cardiac resynchronisation therapy, with the additional function of defibrillation. This brief introduction concentrates on factors that alter how long the battery is likely to last (longevity), and is very simplified. A more detailed, plain English description of principles is available from pacemaker plus.

The CRT-D contains a battery, high voltage (HV) capacitor, microprocessor and other electronic components, combined into one device. Connected to this, via the header are 3 leads which conduct stimulation (pacing / defibrillation) and measurements (sensing) to and from the heart.

Implantation of a CRT-D involves placement of the 3 leads via the venous system into the heart, as shown in figure 1. All three leads use the same entry route via the right atrium; two are placed directly inside the right atrium and right ventricle. A third lead is used to stimulate the left ventricle. As there is no direct access to the left ventricle from the right atrium, the third lead is fed into the coronary sinus vein leading from the right atrium around the left ventricle.

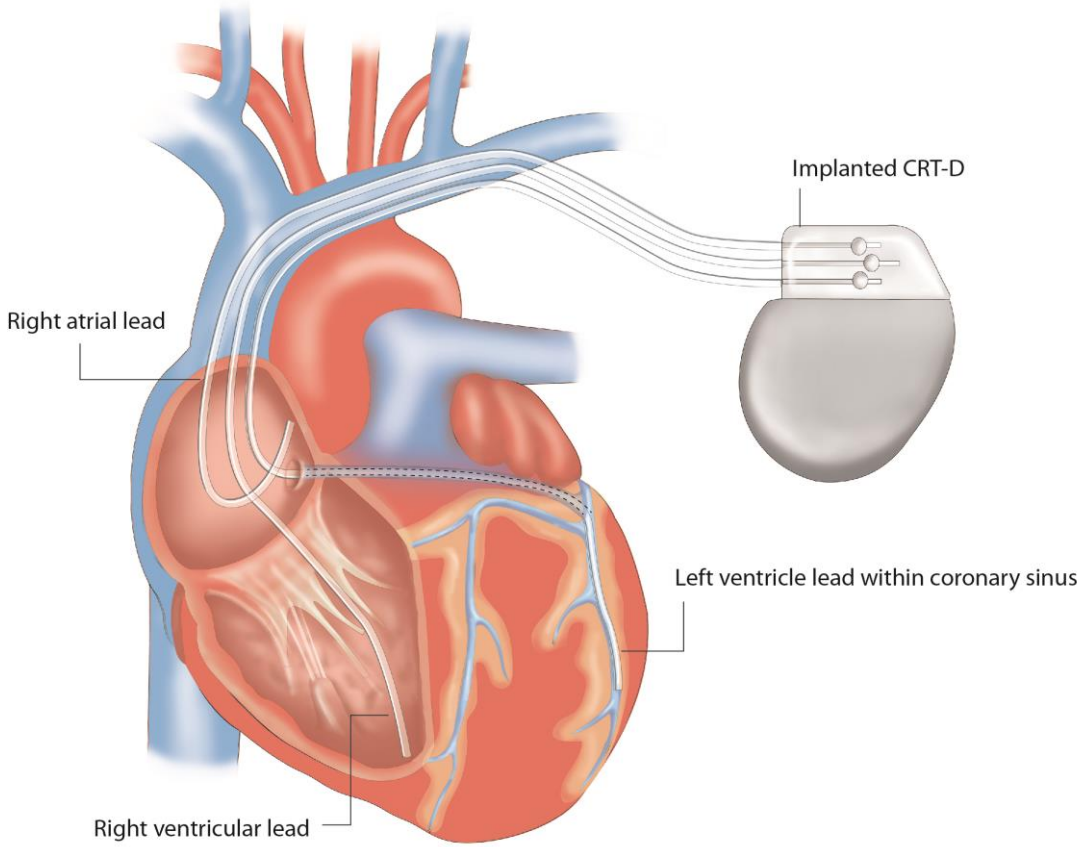


Figure 1 – CRT-D lead placement within heart (J.Sharp, Media Resources, Cardiff University)

The CRT-D device itself is inserted into a pocket underneath the subcutaneous fat near the patient's collar bone.

The atrial lead can be used to monitor atrial activity and co-ordinate ventricular activity. In addition, if a low heart rate is detected, the atrial lead will supply a stimulus to ensure that the heart rate is adequate (pacing).

The ventricular leads are used to ensure that the ventricles pump simultaneously, giving a more efficient pumping mechanism. This is the cardiac resynchronisation function of a CRT-D. It may be coordinated with the atrial contraction that is detected by the atrial sensor, or paced separately to ensure adequate blood flow, and to avoid any problematic rhythms in the atria being continued through to ventricular activity. In most CRT-D settings the aim of treatment is to maintain the optimum output from the heart by using ventricular stimulation all the time (100% bi-ventricular pacing). Atrial pacing would be used as needed, and may vary from 0 to 100% for different patients and at different times. The CRT-D senses the atrial rate and will start pacing if the heart's natural rate is too slow, or there are pauses between beats that are too long.

If sensors detect a serious heart arrhythmia that requires defibrillation (ventricular tachycardia or ventricular fibrillation), then the CRT-D will provide a defibrillation shock to restore normal rhythm.

Additional sensors such as accelerometers and respiratory monitors can give information on the patient's activity and are used to differentiate between abnormal heart activity and normal heart activity that is induced by exercise. This information is used to optimise the speed of biventricular pacing and to avoid unnecessary defibrillation shocks.

After implanting the CRT-D, the clinician programmes it to adjust the settings for that patient. This ensures that the device is optimised both in terms of providing the best support and therapy for the patient, and in terms of optimising its efficiency and thus maximising battery life.

Once in use, clinicians will monitor the patient regularly to ensure that the device is functioning correctly and still providing the optimum therapy for the patients. Monitoring can be done remotely by tele-monitoring systems where the device links wirelessly to a base station in the patient's home, and is also done in clinic using wand telemetry. Data can be stored and downloaded from the device, for example, to give information on cardiac behaviour prior to a shock being delivered (onset EGM).

The amount of data storage and processing within the CRT-D will affect battery longevity.

When the battery nears the end of its life a warning is given to the clinician, known as the elective replacement indicator (ERI). The ERI ensures that at the point of the alert the battery is still capable of 3 months safe patient therapy including no pacing and 6 shocks, or 100% pacing and 3 shocks (BS EN 45502-2-2-2008 Part 2-2).

2 CRT-D Devices and technical terms

Boston Scientific CRT-D devices contain ENDURALIFE battery technology, based on lithium / manganese dioxide ($LiMnO_2$)chemistry, with a voltage of approximately3 V and a usable capacity of 1.9 Ampere-hours (Ah). The capacity is the amount of charge stored in the battery. A capacity of 1 Ah means that the battery could supply a current of 1 amp for 1 hour – or a battery with a capacity of 1.9 Ah could theoretically supply a current of 0.0217 mA for 10 years. The total energy within the battery is the voltage multiplied by the charge, and power is the rate at which the energy is used (voltage multiplied by current). The batteries are built into the CRT-D and cannot be replaced.

However, a CRT-D is a complex device with many different functions, each with different power requirements. How these are met can be seen as how efficiently the device uses the battery capacity that is available. A simple analogy is that if you compare a small car with 40 litres of fuel or a minibus with 60 litres of fuel, it is easy to see which has more energy stored in the fuel tank, but less obvious to know which will drive more miles – particularly if one vehicle is going on the motorway, and the other is driving through cities or hilly mountain roads. The demands placed upon the battery vary with different CRT-D functions for example:

- Cardiac monitoring and pacing have a low power demand; battery capacity is depleted at a slow rate.

- W telemetry and data processing, when they are in use, have a medium power demand.
- Defibrillation, when required, has a high power demand; battery capacity is depleted at a fast rate.

Different battery chemistries perform very efficiently at a single level of power demand, but the CRT-D battery must be able to supply all of these functions with the power that each require.

The challenge is not only to make a small size, long life battery, but to build this into a CRT-D where the combination of battery and device circuitry meet these conflicting demands for as long as possible. The CRT-D must be able to meet all the functions fully throughout the device life, and have a predictable profile of battery depletion to ensure safe replacement. How the functions are met varies between devices and manufacturers and this will also affect the charge depleted from the battery.

Although a CRT-D battery will typically have a nominal voltage of around 3.2V, higher voltages than this are used for defibrillation. CRT-D devices use a combination of electronics with a transformer, to step the voltage up to that required for the defibrillation shock. The high voltage charge is stored in a high voltage capacitor. The time that it takes to charge the capacitor ready for use is one of the specifications found in the manual, and is shorter for a new battery and longer for a battery nearing the end of its useful life. The device also needs to have mechanisms for providing the different voltages for different functions, and the way it does this will impact on the efficiency of the device, and thus the battery lifetime.

For some manufacturers, the defibrillation HV capacitor is charged periodically even if the patient does not require a therapeutic shock. The purpose of this is both as maintenance to the HV capacitor (reformation), and to check that the defibrillation function is still working correctly. The charge is gradually discharged through a special high voltage resistor to ensure that the patient does not receive an inappropriate shock. Boston Scientific state that the capacitor will be charged at least 3 times a year, even if no therapeutic shocks are provided.

3 Factors that affect longevity

Boston Scientific Instructions for Use for CRT-Ds states that for AUTOGEN, DYNAGEN, INOGEN and ORIGEN devices, longevity may change as shown in table 1. The explanation is provided by the EAC and does not come from the device manual.

Table 1. Change in longevity with different factors for Boston Scientific devices: AUTOGEN, DYNAGEN, INOGEN and ORIGEN.

Factor	Change in longevity	Explanation
Pacing rate increase	Decrease	The rate at which the heart is paced. This will be set by the clinician to suit the patient's symptoms

Pacing pulse amplitude increase	Decrease	These change the amount of energy delivered to stimulate the heart. The clinician will set the lowest possible threshold to ensure that stimulation occurs when needed. This will be adjusted during follow up clinics.
Pacing pulse width increase	Decrease	
% of paced to sensed events increase	Decrease	Depends on both the rate set by the clinician, and the patient's condition. Atrial pacing will occur when the patient's own heart beat has longer gaps between beats than the rate set on the pacemaker. The percentage paced may change over time.
HV Capacitor charging frequency increase	Decrease	How often the defibrillation HV capacitor is fully charged. This may not result in a shock, if the patient recovers, or if the charge if for HV capacitor reformation purposes.
MV / Respiratory Sensor programmed OFF for device life	Increase by 2 months.	Sensors are used to help the pacing function interpret the heart rhythm appropriately, for instance to tell when someone is running, rather than experiencing an abnormally fast heart beat. The sensors use power to collect and process the data. MV: Minute Ventilation
Patient Triggered Monitor programmed ON for 60 days	Decrease by 5 days	
1 additional hour ZIP wandless telemetry	Decrease by 7 days	Communications with the device all use power, the more communication, the more power is used, however the data may be important to optimise treatment.
5 patient initiated Latitude interrogations a week for a year	Decrease by 29 days	
1 additional maximum energy defibrillation shock	Decrease by 16 days	This will be mainly dependant on the patient's health, although sensors and algorithms to avoid inappropriate shocks are also important.
6 hours MRI protection mode	Decrease by 2 days	
Additional 6 months in Storage mode prior to implant	Decrease by 39 days	If the device is in storage before implantation, the battery capacity will be slowly reduced. The longevity quoted by manufacturers normally allows for 6 months storage before

		implantation

Other parameters that are listed when longevity is quoted are:

Impedance of the leads: Impedance is a measure of the complex resistance of current flowing from the CRT-D to the heart. A high lead impedance reduces the amount of current (or charge over a given time) taken from the battery. The total impedance between the patient and the device will depend on both the lead characteristics, and the patient characteristics where the lead is implanted.

Type of pacing: VVI pacing synchronises the ventricles only independently of atrial activity. DDD pacing monitors and paces the atrial activity and also the ventricles. DDDR can be used to describe a setting that in addition to DDD can detect a need for increased cardiovascular activity, and respond accordingly (for example during exercise).

Quadripolar leads: These are used for left ventricular (LV) leads with some device models. LV leads are harder to position optimally, so quadripolar leads have 4 electrodes, allowing the clinician to choose which ones to activate. The implication is that there are a range of current pathways possible allowing the clinician to optimise both the device efficiency (and therefore longevity) and the clinical effect. Optimum positioning could mean choosing the combination of highest impedance and lowest pulse amplitude and width for effective pacing. "The *AUTOGEN X4, ORIGEN X4, DYNAGEN X4 and INOGEN X4 devices are* available with quadripolar leads*. Note that the DYNAGEN and ORIGEN models are not available in the UK*.

Pacing thresholds: This is the minimum amount of energy that must be delivered to stimulate the heart. Both the pulse amplitude (voltage) and duration can be set to adjust the energy delivered. Ideally the energy delivered is as low as possible to be effective, minimising the consumption of battery power. Thresholds are also used during check-ups to test the device and lead connection. A change in threshold could indicate a problem with the lead, or a change in the patient's condtion

4 Standards

International standards are available that address the following areas for CRT-Ds:

- how CRT-D batteries should be tested
- how device longevity should be calculated and reported for a given device
- how actual device longevity should be monitored and reported.

In most cases they do not give fully described methods or specifications. The information below is summarised in plain English, please see the original documents for the official wording.

BS ISO 5841-2:2014 Implants for surgery — Cardiac pacemakers Part 2: Reporting of clinical performance of populations of pulse generators or leads describes a method for reporting actual

performance of devices, and this is utilised in the production of PPRs. Annex A of the standard explains the method fully, and this is discussed in the ENDURALIFE Assessment report.

European Standard BS EN 45502-2-2-2008 Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) sets out tests to ensure that the device can withstand different conditions without damage to the device or to the patient, if already implanted. Tests include mechanical shock, temperature changes, electromagnetic fields, external defibrillation, high frequency surgery and magnetic fields. For longevity it requires that the device manual includes estimated life of the device as a function of the number of shocks delivered, spaced uniformly over the estimated lifetime. The manufacturer is free to specify most of these parameters, making comparision between devices difficult.

Manufacturers are required to ensure that there is a prolonged service period of at least 3 months after the device has reached ERI (which warns of battery depletion). During this period the CRT-D should be able to achieve tests that ensure the patient will be safely able to use the device in the remaining 3 months.

The French Health Authorities (Haute Autorité de Santé) published a document in June 2015 “Evaluation des défibrillateurs cardiaques automatiques implantables avec sonde(s) endocavitaire(s)” which does give detailed parameters that should be used when stating longevity predictions up to the elective replacement indicator. If these are adopted by manufacturers it may aid comparisons in the future.

In addition standards are available relating to electromagnetic compatibility and connectors (BS ISO 14117:2012, BS EN 50077:1993).

An additional ISO standard is available (ISO 14708-2:2012 ED2. Implants for surgery. Active implantable medical devices. Cardiac pacemakers). It has not yet been adopted in Europe, but is currently under consideration for adoption.

5 Technical specifications of CRT-D devices and batteries

CRT-D devices tend to be flat and thin, with an irregular rounded shape. Therefore the easiest comparator for size is to consider the volume of the device. All CRT-D manuals list the dimensions, volume and mass of the entire implantable device. The size of the battery is not reported, and is not relevant, since the battery is an integral non-replaceable component of the CRT-D.

A table is included in the appendices giving the dimensions, weight, mass, battery type, capacity and nominal voltage for devices listed on manufacturers websites, with values taken from manuals which are also available on the manufacturers website.

Figure 2 shows the volumes of the different CRT-D models, by manufacturer. The devices are not shown in any particular order, and include different battery chemistries. It can be seen that Boston Scientific devices are generally slightly smaller than other devices. This finding does not indicate how clinically significant this difference may be to patients. One manufacturer states that dimensions are

taken after connectors are removed, but not all give details; it is possible that slightly different assumptions are made by different manufacturers.

Figure 2. Volumes of CRT-D devices, by manufacturer. Models are in no particular order, but represent the models listed on the manufacturer website in June 2016.

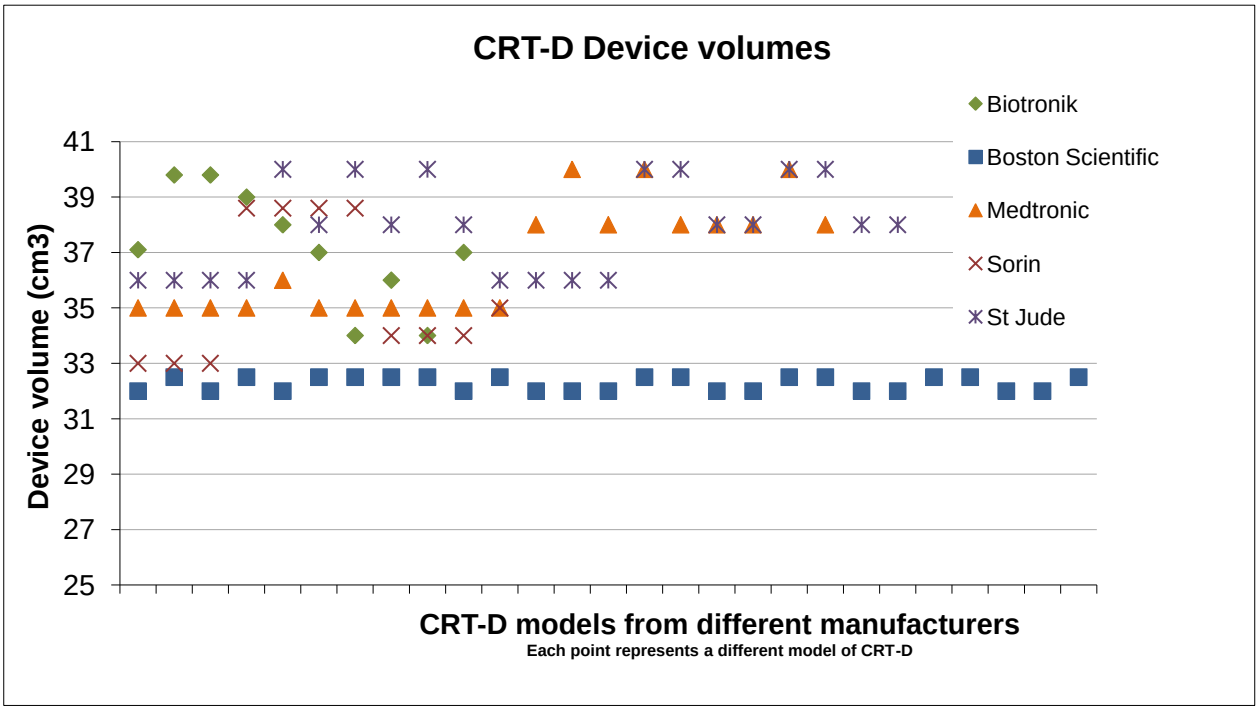
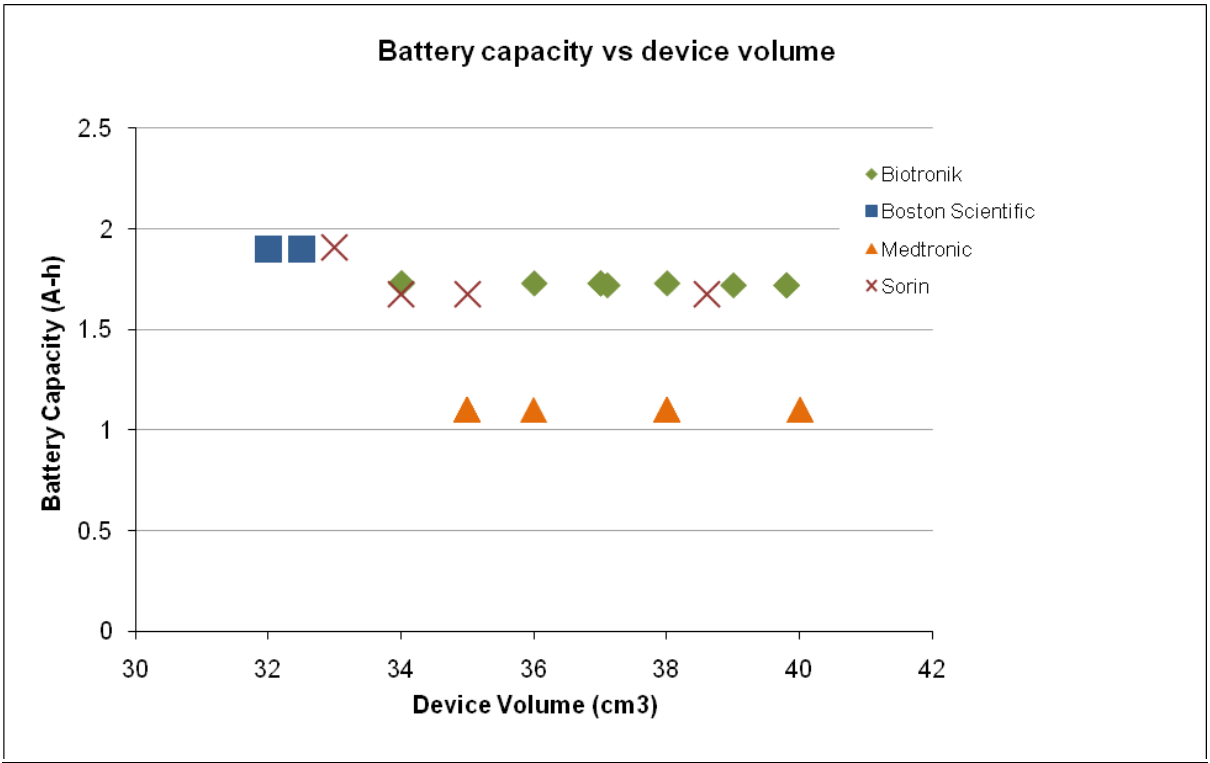


Figure 3 represents the battery capacity and the complete device (including the battery) volume. The data shows that there is not a clear relationship between battery capacity and device volume. Many manufacturers use the same battery (with the same capacity) in different models, and different models may have the same dimensions, meaning that several devices are represented by one data point on the graph. The battery size is important, but the size and shape of other components will contribute to the total implanted device size. Equally the battery capacity is important for longevity, but there are many other factors in both the device and the battery that determine the lifetime in any given clinical situation.

Figure 3. Battery capacity (Ah) against device volume (cm^3)



6 Longevity projections

There are four sources of information about device life:

- **Device manuals giving projected lifetimes** for devices with a variety of different settings, specified by the manufacturer, based on bench tests.
- **Information directly from a device in use, giving projected lifetimes for that device only**, based on detected settings and use, combined with bench testing information.
- **Product Performance Reports giving longevity probabilities based on r**eturned devices and pub**lished by the manufacturer**
- **Clinical studies giving observed lifetimes** for devices.

Table 2. Types of longevity projections

	Strengths	Limitations
Projected longevity based on bench testing and algorithms, reported in manual	Data available for new models as soon as placed on the market Clinicians can see predicted longevity for settings most appropriate to their use	Prediction rather than reporting clinical data. Only as good as test procedures and the algorithm used Settings may not reflect clinical realities Different manufacturers choose to report different settings, and therefore results are not comparable Single figure given for longevity, rather than a graph of survival against time
Projected longevity for a particular device implanted in a patient, at that point in time.	Clinicians can see predicted longevity for the device in use, based on the use experience to date with that patient. Allows prediction of ERI for that particular patient Prediction includes current battery state, and patient usage	This is still a prediction, and depends on quality of test procedures and the algorithm used. This only gives information on one device at a single point in time, as implanted into a specific patient.
Product Performance Reports (PPR)	Data from large numbers of real patients Some data is available after the device has been on the market for over 1 year Although under-reporting of unrelated deaths is an issue, manufacturers compensate for this by adjusting to a 10% mortality baseline.	Data is usually collected passively, resulting in under-reporting of malfunctions Assumption that devices are still functioning unless they are returned, or the manufacturer notified. There may be a selection bias where some models are chosen for patients that require more energy draining functions. Data can only show device survival for the length of time that the device has been implanted By the time a complete longevity curve is available the device type is likely to have been superseded.
Clinical trials	Data actively collected from an appropriate group of patients Allows comparative data for different devices for the same length of time and populations (or with known variations in population).	Study has to run over a long time to collect longevity data, this is also expensive. By the time a complete longevity curve is available the device type is likely to have been superseded. Patient numbers may be small

The international standard, BS EN 45502-2-2:2008 does not give complete specifications for how longevity should be tested or defined. This means that each manufacturer will have slightly different test protocols and different calculations for extrapolating the estimated longevity.

There is guidance on the information that should be presented in the device documentation, however the number of variable settings and conditions for each device mean that the information presented on longevity by manufacturers is not easily comparable.

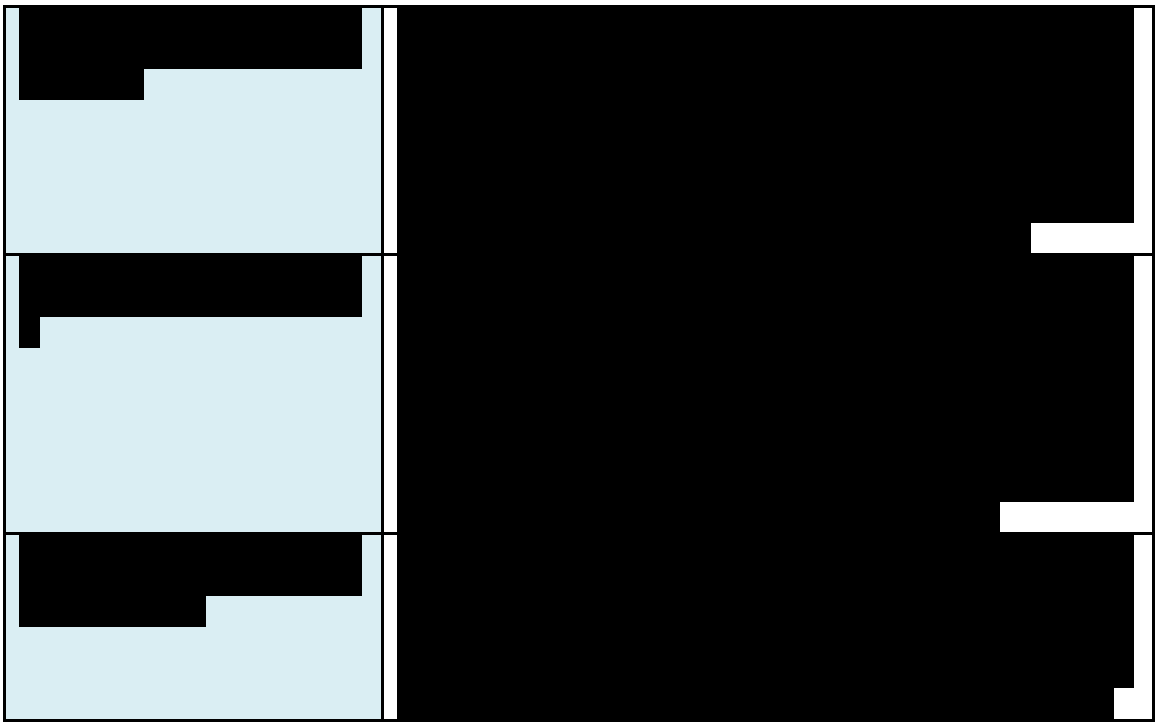
PPR data collection is described in the ENDURALIFE Assessment Report, and the reporting is based on recommendations by the US Heart Rhythm Society Task Force and BS ISO 5841-2:2014. Boston Scientific PPR is based on US registered implants, using a returned product analysis. Any reporting of data based on real life use in patients can only extend to as many years as the device has been available, and when looking at the longest implanted devices, the sample size tends to be very small, as these have been implanted when the device was new to market.

Tests and calculations used by Boston Scientific for predicting longevity are described in section 7.

7 Boston Scientific battery testing

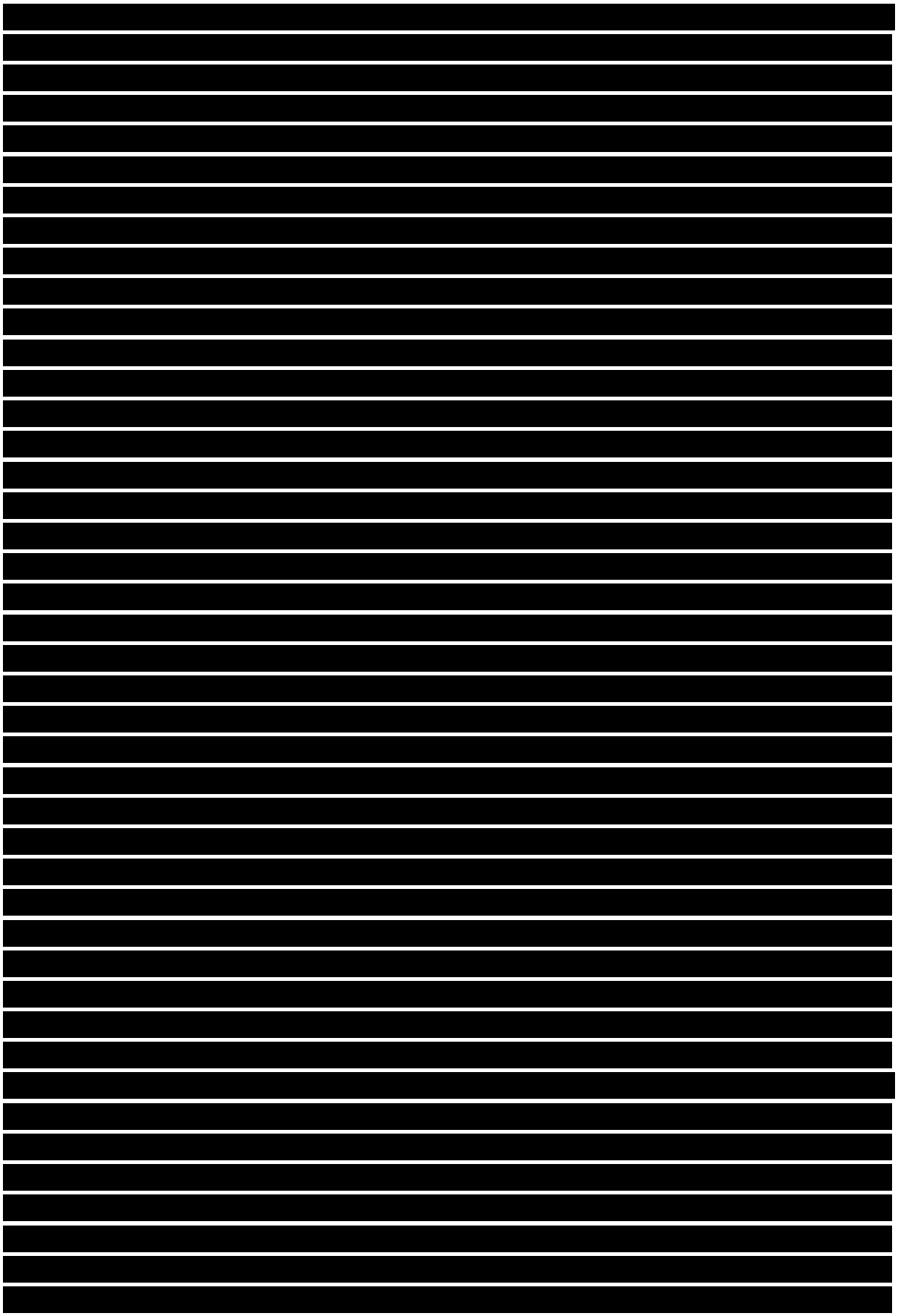
Cedar requested battery test information (protocols and results) form Boston Scientific, and the information provided (table 3) was an example of protocols that Boston Scientific were able to share with the NICE committee. All reports are strictly commercial in confidence.

Table 3. Test reports provided by Boston Scientific (BSC)



Therefore components of the CRT-D system are tested separately and their characteristics used in an algorithm for longevity prediction.

[redacted]



[redacted]

Limitations

Cedar have not seen the full test results for the tests described, although some results were submitted. The test results are combined with data from other tests and used as inputs into an algorithm. It would not be in the remit of a technical assessment report to assess the entirety of the process, and the full data and modelling would be highly confidential. This is understandable, but

limits the information that can be taken from the testing reports to having better insight into the processes used to ascertain accurate battery life.

Tests and calculations are not standardised between manufactures and no inferences can be drawn from this information for devices produced by other manufacturers.

References

Device manuals are available from manufacturers websites for all devices listed. Accessed June 2016

PPR data is taken from PPR reports submitted by Boston Scientific. PPR reports for each manufacturer are also available on line on the manufacturer websites.

Boston Scientific. COGNIS TELIGEN Li-MnO2 Readiness Report, supplied in confidence to EAC, June 2016

Boston Scientific. Life Test 4, Life Test 5 Longevity Report, supplied in confidence to EAC, June 2016

Boston Scientific. Li-MnO2 Cell Life Test 4 Protocol, supplied in confidence to EAC, June 2016

Boston Scientific. NG-3 PG Electrical DVT Report RevA4 (Extract: Section 4.3.2 Longevity Estimate), supplied in confidence to EAC, June 2016

BS EN 45502-2-2-2008 Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)

BS EN 50077:1993. Specification for low profile connectors (IS-1) for implantable pacemakers.

BS ISO 14117:2012. Active implantable medical devices. Electromagnetic compatibility. EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices.

BS ISO 5841-2:2014 Implants for surgery — Cardiac pacemakers Part 2: Reporting of clinical performance of populations of pulse generators or leads

Haute Autorité de Santé, Evaluation des défibrillateurs cardiaques automatiques implantables avec sonde(s) endocavitaire(s) June 2015

ISO 14708-2:2012 ED2. Implants for surgery. Active implantable medical devices. Cardiac pacemakers. (This ISO standard has not been adopted in Europe, but is currently under consideration for adoption.)

Robinson, C. Pacemakers made easy. PacemakerPlus. http://www.pacemakerplus.com/pacemakers-made-easy/ Accessed June 2016

Appendix A. Dimensions table

The list of devices is based on those shown on manufacturer's website (accessed via UK settings where possible) June 2016. Information is from downloadable manuals for each device, other than date and warranty which were requested from manufacturers.

Device	Year released	Warranty (years)	Version	Device dimensions W x H x D (mm)	Device mass (g)	Device volume (cm3)	Battery description	Battery chemistry	Capacity (Ampere hours)	Nominal voltage
Biotronik										
Lumax 300		[redacted]		66 x 55 x 12	83	37.1	GREATBATCH GB 2491:	Li/CFx-SVO	1.72 Ah	3.2
Lumax 340	pre 2008 - 2013[1]			66 x 59 x 13	94	39.8	GREATBATCH GB 2491:	Li/CFx-SVO	1.72 Ah	3.2
Lumax 540*	pre 2008 - 2014[1]			66 x 59 x 13	94	39.8	LITRONIK LiS 3192 R7:	Li/MnO2	1.72 Ah	3.2
							GREATBATCH GB 2491:	Li/CFx-SVO	1.72 Ah	3.2
Lumax 740 (same data for proMRI)	2012 - 2015[1]			66 x 59 x 13	94	39	LITRONIK LiS 3192 R7:	Li/MnO2	1.72 Ah (1.59 to ERI)	3.2 (2.85 at ERI)
							GREATBATCH GB 2491:	Li/CFx-SVO	1.72 Ah (1.59 to ERI)	3.2 (2.5 at ERI)
Inventra HF-QP	2014[1]	[redacted]		65 x 58.5 x 12.5	92	38	LITRONIK 3411 RR	Li/MnO2	1.73 Ah (1.59 to ERI)	3.2 (2.85 at ERI)
Inventra HF-T	2014[1]	[redacted]	DF-1:	65 x 58.5 x 12.5	88	37	GREATBATCH GB 2992:	Li/CFx-SVO	1.73 Ah (1.59 to ERI)	3.2 (2.5 at ERI)
			DF-4:	65 x 56 x 12.5	88	36				
Itrevia 5/7 HF-T	2014[1]	[redacted]	DF-1:	65 x 58.5 x 11	83	34	LITRONIK 3410 RR	Li/MnO2	1.52 Ah (1.39 to ERI)	2.85 at ERI
			DF-4:	65 x 56 x 11	82	33				
			As above				GREATBATCH GB 2992:	Li/CFx-SVO	1.73 Ah (1.39 to ERI, 5 series, 1.6A to ERI, 7 series)	2.5 at ERI

Device	Year released	Warranty (years)	Version	Device dimensions W x H x D (mm)	Device mass (g)	Device volume (cm3)	Battery description	Battery chemistry	Capacity (Ampere hours)	Nominal voltage
Itrevia 5/7 HF-T QP	2014[1]	[redacted]		65 x 58.5 x 11	87	36	As above, both battery types			
Ilesto Pro MRI 5/7			DF-1:	65x58.5x11	83	34	LITRONIK 3410 RA/RR	Li/MnO2	1.52 Ah (1.39 to ERI)	2.85 at ERI
			DF4:	65x56x11	82	33				
							GREATBATCH GB 2992:	Li/CFx-SVO	1.73 Ah (1.39 to ERI, 5 series, 1.6A to ERI, 7 series)	(2.5 at ERI)
Idova			DF-1:	65x58.5x12.5	88	37	LITRONIK 3411 RR	Li/MnO2	1.73 Ah (1.59 to ERI)	2.85 at ERI
			DF4:	65x56x12.5	87	36				
			As above				GREATBATCH GB 2992:	Li/CFx-SVO	1.73 Ah (1.59 to ERI	2.5 at ERI
Boston Scientific – Voltages not stated										
Energen CRT-D (in manual, but not UK website)	2011-2015[1]	[redacted]	P142	61.7 x 77.0 x 9.9	72	32	Enduralife 401988	Li/MnO2	1.9 Ah Usable capacity. (0.17 Ah after ERI)	
			P143	61.7 x 79.5 x 9.9	72	32				
Punctua CRT-D (in manual, but not UK website)	2011-2015[1]	[redacted]	P052	61.7 x 77.0 x 9.9	72	32	Enduralife 401988	Li/MnO2	1.9 Ah Usable capacity. (0.17 Ah after ERI)	
Punctua NE CRT-D (in manual, but not UK website)	2011-2015[1]	[redacted]		61.7 x 77.0 x 9.9	72	32.5	Enduralife 401988	Li/MnO2	1.9 Ah Usable capacity. (0.17 Ah after ERI)	
INCEPTA CRT-D	2012-2015[1]	[redacted]	P162	61.7 x 77.0 x 9.9	72	32	Enduralife 401988	Li/MnO2	1.9 Ah Usable capacity. (0.17 Ah after ERI)	
			P163	61.7 x 79.5 x 9.9	72	32.5				
			P165	61.7 x 79.5 x 9.9	72	32.5				
Cognis CRT-D (in manual, but not UK website)	2008-2015[1]	[redacted]	P106	61.7 x 79.5 x 9.9	72	32.5	Enduralife 401988	Li/MnO2	2.0 Ah Usable capacity. (0.16 Ah after ERI)	
			P107	61.7 x 79.5 x 9.9	72	32.5				

Device	Year released	Warranty (years)	Version	Device dimensions W x H x D (mm)	Device mass (g)	Device volume (cm3)	Battery description	Battery chemistry	Capacity (Ampere hours)	Nominal voltage
			P108	61.7 x 77.0 x 9.9	72	32				
Autogen CRT-D	2014[1]	[redacted]	G172	53.7 x 81.88 x 9.9	73.6	32.5	Enduralife 401988	Li/MnO2	1.9 Ah Usable capacity. (0.15 Ah after ERI)	
			G173	53.7 x 80.8 x 9.9	72.8	32				
			G175	53.7 x 80.8 x 9.9	72.9	32				
			G177	53.7 x 80.8 x 9.9	73.4	32				
			G179	53.7 x 80.8 x 9.9	73.8	32.5				
Inogen CRT-D	2014[1]	[redacted]	G140	53.7 x 81.8 x 9.9	73.6	32.5	Enduralife 401988	Li/MnO2	1.9 Ah Usable capacity. (0.15 Ah after ERI)	
			G141	53.7 x 80.8 x 9.9	72.8	32				
			G146	53.7 x 80.8 x 9.9	73.4	32				
			G148	53.7 x 81.8 x 9.9	73.8	32.5				
Dynagen CRT-D	Not on UK market	Not on UK market	G150	53.7 x 81.8 x 9.9	73.6	32.5	Enduralife 401988	Li/MnO2	1.9 Ah Usable capacity. (0.15 Ah after ERI)	
			G151	53.7 x 80.8 x 9.9	72.8	32				
			G156	53.7 x 80.8 x 9.9	73.4	32				
			G158	53.7 x 81.8 x 9.9	73.8	32.5				
Origen CRT-D	Not on UK market	Not on UK market	G050	53.7 x 81.8 x 9.9	73.6	32.5	Enduralife 401988	Li/MnO2	1.9 Ah Usable capacity. (0.15 Ah after ERI)	
			G051	53.7 x 80.8 x 9.9	72.8	32				
			G056	53.7 x 80.8 x 9.9	73.4	32				
			G058	53.7 x 81.8 x 9.9	73.8	32.5				
Medtronic (volume with connector ports unplugged)										
Amplia MRI Quad CRT-D SureScan	2016[1]	[redacted]		73 x 51 x 13	80	35	Medtronic Energy and Component Centre,	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2

Device	Year released	Warranty (years)	Version	Device dimensions W x H x D (mm)	Device mass (g)	Device volume (cm3)	Battery description	Battery chemistry	Capacity (Ampere hours)	Nominal voltage
CRT-D D1		[redacted]					M945899A			
Amplia DF4	2016[1]	[redacted]		74 x 51 x 13	81	35	Medtronic Energy and Component Centre, M945899A	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Compia MRI Quad CRT-D SureScan CRT-D D1	2016[1]	[redacted]		74 x 51 x 13	81	35	Medtronic Energy and Component Centre, M945899A	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Compia MRI Quad CRT-D SureScan CRT-D DF4	2016[1]	[redacted]		74 x 51 x 13	81	35	Medtronic Energy and Component Centre, M945899A	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Viva Quad XT CRT-D D1	2013[1]	[redacted]		74 x 51 x 13	82	36	Medtronic Energy and Component Centre, 945899	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Viva Quad XT CRT-D DF4	2013[1]	[redacted]		74 x 51 x 13	81	35	Medtronic Energy and Component Centre, 945899	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Viva Quad S CRT-D DF4	2013[1]	[redacted]		74 x 51 x 13	81	35	Medtronic Energy and Component Centre, 945899	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Viva XT CRT-D D1	2012[1]	[redacted]		74 x 51 x 13	80	35	Medtronic Energy and Component Centre, 945899	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Viva XT CRT-D DF4	2012[1]	[redacted]		73 x 51 x 13	80	35	Medtronic Energy and Component Centre, 945899	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Viva S CRT-D D1	2012[1]	[redacted]		73 x 51 x 13	80	35	Medtronic Energy and Component Centre, 945899	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2
Viva S CRT-D DF4	2012[1]	[redacted]		73 x 51 x 13	80	35	Medtronic Energy and Component Centre, 945899	CFx Li/SVO	1.0 Ah (0.1 after RRT)	3.2

Device	Year released	Warranty (years)	Version	Device dimensions W x H x D (mm)	Device mass (g)	Device volume (cm3)	Battery description	Battery chemistry	Capacity (Ampere hours)	Nominal voltage
		[redacted]								
Protecta XT CRT-D D1	2010 - 2016[1]	[redacted]		69 x 51 x 15	68	38	Medtronic Energy and Component Centre, 161455	LiSVO	1.0 Ah (0.1 after RRT)	3.2
Protecta XT CRT-D DF4	2010 - 2016[1]	[redacted]		69 x 51 x 15	73	40	Medtronic Energy and Component Centre, 161455	LiSVO	1.0 Ah (0.1 after RRT)	3.2
Protecta CRT-D D1	2010 - 2016[1]	[redacted]		69 x 51 x 15	68	38	Medtronic Energy and Component Centre, 161455	LiSVO	1.0 Ah (0.1 after RRT)	3.2
Protecta CRT-D DF4	2010 - 2016[1]	[redacted]		66 x 51 x 15	73	40	Medtronic Energy and Component Centre, 161455	LiSVO	1.0 Ah (0.1 after RRT)	3.2
“other “ on website										
Consulta CRT-D	2008 - 2015[1]	[redacted]		69 x 51 x 15	68	38	Medtronic Energy and Component Centre, 161455	LiSVO	1.0 Ah (0.1 after RRT)	3.2
Concerto II CRT-D	2008 - 2015[1]	[redacted]		69 x 51 x 15	68	38	Medtronic Energy and Component Centre, 161455	LiSVO	1.0 Ah (0.1 after RRT)	3.2
Maximo II	2008 - 2015[1]	[redacted]		69 x 51 x 15	68	38				
Insync Sentry CRT-D				73 x 51 x 15	78	40				
Insync II Marquis				73 x 51 x 14	77	38				
Sorin – battery chemistry not stated										

Device	Year released	Warranty (years)	Version	Device dimensions W x H x D (mm)	Device mass (g)	Device volume (cm3)	Battery description	Battery chemistry	Capacity (Ampere hours)	Nominal voltage
Platinum Sonr CRT-D	2015[1]	[redacted]		73 x 54.3 x 11.1	86	33	Greatbatch Quasar High Rate GB 3070	Quasar High Rate	2.192 BOS to EOS 1910	BOS: 3.24 V RRT: 2.62 V EOS: 2.5 V
Platinum CRT-D	2015[1]	[redacted]	1711	73x54.3x11.1	86	33	Greatbatch Quasar High Rate GB 3070	Quasar High Rate	2.192 BOS to EOS 1910	BOS: 3.24 V RRT: 2.62 EOS: 2.5
	2015[1]	[redacted]	1741	:72.3 x 54.3 x 11.1	87	33				
Intensia Sonr CRT-D				68.4 x 73.4 x 11	96	38.6	Greatbatch Quasar High Rate GB 2593	Quasar High Rate	1.964 BOS to EOS 1675	BOS: 3.25 RRT: 2.66 EOS: 2.5
Intensia CRT-D				68.4 x 73.4 x 11	95	38.6	Greatbatch Quasar High Rate GB 2593	Quasar High Rate	1.964 BOS to EOS 1675	BOS: 3.25 RRT: 2.66 EOS: 2.5
Paradym RF Sonr CRT-D				69.5 x 73.4 x 11	95	38.6	Greatbatch Quasar High Rate GB 2593	Quasar High Rate	1.964 BOS to EOS 1675	BOS: 3.25 RRT: 2.66 EOS: 2.5
Paradym RF CRT-D				69.5 x 73.4 x 11	95	38.6	Greatbatch Quasar High Rate GB 2593	Quasar High Rate	1.964 BOS to EOS 1675	BOS: 3.25 RRT: 2.66 EOS: 2.5
Paradym 2 Sonr CRT-D				61.8 x 73.4 x 11	92	34	Greatbatch Quasar High Rate GB 2593	Quasar High Rate	1.964 BOS to EOS 1675	BOS: 3.25 RRT: 2.66 EOS: 2.5
Paradym 2 CRT-D				61.8 x 73.4 x 11	92	34	Greatbatch Quasar High Rate GB 2593	Quasar High Rate	1.964 BOS to EOS 1675	BOS: 3.25 RRT: 2.66 EOS: 2.5
Paradym				61.8 x 73.4 x 11	92	34	Greatbatch Quasar High Rate GB 2593	Quasar High Rate	1.964 BOS to EOS 1675	BOS: 3.25 RRT: 2.66 EOS: 2.5

Device	Year released	Warranty (years)	Version	Device dimensions W x H x D (mm)	Device mass (g)	Device volume (cm3)	Battery description	Battery chemistry	Capacity (Ampere hours)	Nominal voltage
Paradym Sonr triV				64.3 x 73.4 x 11	93	35	Greatbatch Quasar High Rate GB 2593	Quasar High Rate	1.964 BOS to EOS 1675	BOS: 3.25 RRT: 2.66 EOS: 2.5
St Jude Medical – capacity not stated										
Unify Assura	2013 (original 2012) [1]	[redacted]	CD3257-40	79 x 40 x 14	78	36	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3257-40Q	73 x 40 x 14	77	36	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3261-40	79 x 40 x 14	78	36	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3261-40Q	73 x 40 x 14	77	36	Greatbatch Medical; Model 2850	CFx-SVO		3.2
Unify Assura		[redacted]	CD3361-40	79 x 40 x 14	78	36	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3361-40C	79 x 40 x 14	78	36	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3361-40Q	73 x 40 x 14	77	36	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3361-40QC	73 x 40 x 14	77	36	Greatbatch Medical; Model 2850	CFx-SVO		3.2
Quadra Assura	2013 (original 2012) [1]	[redacted]	CD3265-40	83.1 x 41 x 14	83	40	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3265-40Q	75 x 41 x 14	80	38	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3267-40	83.1 x 41 x 14	83	40	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3267-40Q	75 x 41 x 14	80	38	Greatbatch Medical; Model 2850	CFx-SVO		3.2

Device	Year released	Warranty (years)	Version	Device dimensions W x H x D (mm)	Device mass (g)	Device volume (cm3)	Battery description	Battery chemistry	Capacity (Ampere hours)	Nominal voltage
Quadra Assura		[redacted]	CD3367-40	83.1 x 41 x 14	83	40	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3367-40C	83.1 x 41 x 14	83	40	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3367-40Q	75 x 41 x 14	80	38	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3367-40QC	75 x 41 x 14	80	38	Greatbatch Medical; Model 2850	CFx-SVO		3.2
Quadra Assura MP	2014[1]	[redacted]	CD3271-40	83.1 x 41 x 14	83	40	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3271-40Q	75 x 41 x 14	80	38	Greatbatch Medical; Model 2850	CFx-SVO		3.2
Quadra Assura MP		[redacted]	CD3371-40	83.1 x 41 x 14	83	40	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3371-40C	83.1 x 41 x 14	83	40	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3371-40Q	75 x 41 x 14	80	38	Greatbatch Medical; Model 2850	CFx-SVO		3.2
			CD3371-40QC	75 x 41 x 14	80	38	Greatbatch Medical; Model 2850	CFx-SVO		3.2

[1] Data requested from manufacturers

Appendix B. Longevity table for Boston Scientific

Longevity predictions are only comparable if based on exactly the same parameters. It has not been possible to obtain data on exactly the same parameters, and therefore other manufacturers are not included in this table. Longevity predictions, and the parameters used are available device manuals on manufacturer websites.

Name of Device	Year of launch / Comment on generation if appropriate	Device settings	Projected longevity
Boston Scientific			
COGNIS™ CRT	February 2008	Projected longevity provided based on specific parameters as defined by the French Health Authority (Haute Autorité de Santé) Decree published in the Journal Officiel de la République as of 22 January 2016 100% of rate responsive pacing of the atrium and 2 the ventricles with all functions ON (including EGM and rate response); pacing amplitude: 2,5 V for 2 ventricles and atrium; pulse duration: 0.5 ms; Lower rate limit: 70 min-1; pacing impedance: 500 Ω ± 1%;	7.07 years[2,3]
ENERGEN™ CRT	February 2011		7.07 years[2,3]
PUNCTUA™	February 2011		7.07 years[2,3]
PUNCTUA™ NE CRT	February 2011		7.26 years[2,4]
INCEPTA™ CRT	July 2012		7.07 years[2,3]
AUTOGEN™ CRT	February 2014		7.46 years[2]
INOGEN™ CRT	February 2014		7.46 years[2]
DYNAGEN™ CRT	N/A – not launched in UK market		N/A – not launched in UK market
ORIGEN™ CRT	N/A – not launched		N/A – not launched in UK market

Name of Device	Year of launch / Comment on generation if appropriate	Device settings	Projected longevity
	in UK market	remote monitoring continuously on and 12 full report transmissions per year; 12 HV capacitor charges at maximum energy for therapy (in addition to normal capacitor re-forms) until ERI).	

[3] Projected longevity estimates for Cognis, Energen, Punctua and Incepta are based on weekly remote monitoring full transmissions and as such will be underestimating the projected longevity based on the settings defined above

[4] Punctua NE is not enabled to provide remote monitoring; projected longevity estimate excludes remote monitoring requirements from settings defined above

Appendix C. Product Performance Report data

Data from PPR reports, Reporting combined normal depletions and malfunctions in US, unless otherwise stated											
	US approval date	yr 1	yr2	yr3	yr4	yr5	yr6	yr 7	yr 8	yr 9	yr 10
Boston Scientific (shaded lines are the number of devices in sample)											
Autogen (worldwide)		No data									
Dynagen / Inogen / Origen	April 2014	99.89%	99.89%								
		2793	364								
Incepta / Energen / Punctua	Nov 2011	99.94%	99.9%	99.63%	99.09%						
		41663	25646	10166	410						
Cognis	May 2008	99.93%	99.84%	99.66%	99.21%	98.03%	96.63%				
		31536	28145	24853	19954	6520	201				
Biotronik											
Ilesto 7	Sept 2013	99.9%									
Lumax 340	Feb 2007	99.8%	99.6%	98.8%	96.6%	89.5%	73.4%				
Lumax 540	May 2009	100%	99.8%	99.3%	97.4%	82.3%					
Lumax 740	Sept 2012	100%	99.7%								
Medtronic (only included over 1000 implants, shaded lines are the number of devices in sample)											
Viva Quad S (DTBB1QQ)	July 2014	100%	99.9%	99.7% (30 months)							
		40149	8598	135							
Viva S (DTBB1D4)	Jan 2013	As above , these devices grouped for reporting									
Viva S (DTBB1D1)	Jan 2013										
Viva Quad XT (DTBA1QQ)	July 2014										
Viva Quad XT (DTBA1Q1)	July 2014										

Viva XT (DTBA1D4)	Jan 2013										
Viva XT (DTBA1D1)	Jan 2013										
Protecta (D334TRM)	Nov 2011	99.9%	99%	95.4%	87.5%	82.1% (51 months)					
		55392	49055	26938	4127	760					
Protecta (D334TRG)	Mar 2011	As above , these devices grouped for reporting									
Protecta XT (D314TRM)	Nov 2011										
Protecta XT (D314TRG)	Mar 2011										
Maximo II (D284 TRK)	Sept 2008	99.7%	98.2%	92.9%	79.8%	54.7%	30.2%	26.4 (at 74 months)			
		12761	11425	9375	6445	2578	295	115			
Concerto II (D274TRK)	Aug 2009	99.7%	98.5%	93.4%	81.1%	60.3%	41.2% (at 67 months)				
		25329	23157	20180	15117	4969	394				
Consulta (D224TRK)	Sept 2008	99.6%	98.3%	92.8%	80.7%	60.4%	31.9%	18.6% (74 months)			
		57528	51958	42528	30282	12359	883	113			
Consulta (D204TRM)	Jan 2012	As above , these devices grouped for reporting									
Concerto (C154DWK)	May 2006	99.4%	97.9%	92.9%	79.1%	47.1%	17.0%	2.3% (80 months)			
		68101	59870	50658	38642	19933	5842	275			
Sorin (dates are for market release, not CE mark or US approval)											
		Excluding normal battery depletion									
Ovatio 6750	April 2005	100.0%	99.9%	99.8%	99.8%	99.8%	99.8%				
Intensia 174	Nov 2013	100.0%									
Intensia SonR 184	Nov 2013										
Paradym 8750	April 2008	100.0%	100.0%	99.8%	99.8%	99.8%	99.8%				
Paradym SonR 8770	Nov 2007										
Paradym 2 8752	June 2013	100.0%	100.0%								
Paradym 2 SonR 8772	March 2014										
Paradym RF 9750	Sept 2010	99.9%	99.9%	99.9%	99.9%						

Paradym RF SonR 9770	Sept 2010										
St Jude (dates are given for US approval only)											
Quadra Assura™ CRT-D CD3365-40Q	June 2013	99.8%	99.7%								
Quadra Assura™ CRT-D CD3365-40C	June 2013	99.8%	99.4%								
Unify Assura™ CRT-DCD3357-40Q	June 2013	99.7%	99.6%								
Unify Assura™ CRT-D CD3357-40C	June 2013	99.9%	99.7%								
Quadra Assura™ CRT-DCD3265-40Q	May 2012	99.8%	99.8%	99.5%							
Quadra Assura™ CRT-DCD3265-40	May 2012	99.9%	99.7%	99.6%							
Unify Assura™ CRT-D CD3257-40Q	May 2012	99.9%	99.7%	98.9%							
Unify Assura™ CRT-DCD3257-40	May 2012	99.8%	99.7%	98.6%							
Unify Quadra™ CRT-D CD3249-40Q	Nov 2011	99.9%	99.8%	99.4%	98.8%						
Unify Quadra™ CRT-DCD3249-40	Nov 2011	99.9%	99.9%	99.6%							
Unify™ CRT-DCD3231-40Q	May 2010	99.8%	99.7%	99.1%	97.2%	93.1%					
Unify CD3231-40	May 2010	99.8%	99.6%	98.4%	95.4%	90.5%					
Promote + CD3211-36Q	Feb 2009	99.6%	99.1%	98.0%	93.8%	83.3%	59.4%				
Promote + CD3211-36	Feb 2009	99.6%	99.5%	98.2%	93.4%	78.0%	50.2%				
Promote RF 3207-36	Sept 2007	99.7%	99.2%	97.8%	94.8%	86.2%	59.6%	34.5%			
Atlas + HF V-343	Nov 2004	99.7%	98.9%	95.2%	84.5%	60.4%	30.9%	12.9%	10.5%	9.8%	9.7%