Product Performance Report

CARDIAC RHYTHM MANAGEMENT
MAY 2021

MicroPort

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1 MicroPort CRM commitment to Quality

At MicroPort CRM, we are committed to constantly delivering innovative medical devices and services that meet customer expectations and are safe, effective and compliant with quality standards and regulations.

Translating innovation into clinically meaningful technology, our CRM systems are imagined, designed and built to improve health and save lives.

Across the globe, MicroPort CRM strives to ensure the highest levels of performance and quality throughout the entire product life cycle, and to provide timely and reliable information on device performance to physicians and patients.

This May 2021 Edition of MicroPort CRM's Product Performance Report embodies our commitment to update the product performance information regularly and communicate it to physicians and patients. Our performance report is published online semi-annually at www.crm.microport.com. This new edition includes performance data collected through December 31, 2020 and incorporates the latest information about the company's most recent leads and pulse generators (pacemakers, ICDs (Implantable Cardioverter Defibrillators), CRT devices (Cardiac Resynchronization Therapy)), as well as the most recent updates about product advisories.

As a company, we believe that every patient is important and should be treated equally, and we aim for full transparency with our physicians and patients. Because our products are globally marketed, with the majority of patients outside the United States, the MicroPort CRM division provides worldwide data in its Product Performance Report to ensure that patients, physicians and regulators are better and sooner informed.

This report is reviewed by an independent Product Performance Monitoring Board, in compliance with the Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines[1,2].

We continually seek your input to help us enhance our product performance, and we encourage you to provide your comments and suggestions to your local representative. We also urge you to inform your local representative immediately about any indication of potential problem with our devices. Your contributions play a key role in communicating accurate and vital product performance information.

We thank you for your support.

Andrea VINCON

Vice President of Quality Assurance

[1] Carlson MD, Wilkoff BL, Maisel WH, Ellenbogen KA, Saxon LA, Prystowsky EN, et al. Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines. Heart Rhythm 2006; 3(10):1250-73

[2] Maisel WH, Hauser RG, Hammill SC, Hauser RG, Ellenbogen KA, Epstein AE, Hayes DL, et al. Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines Developed in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA). Heart Rhythm 2009; 6(6): 869-885

2 Definitions and methods

2.1 General definitions

This May 2021 Edition of the MicroPort CRM Product Performance Report was prepared in accordance with ISO 5841-2[3], an international standard for reporting the clinical performance of populations of pulse generators or leads. The third edition of this ISO standard was published in 2014; as part of the revision process, the recommendations from the May 2009 AdvaMed[4] Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads[5] have been incorporated.

Cumulative survival probability is calculated using the standard actuarial method with confidence intervals using Greenwood's method. **Cumulative survival probability** is the estimated probability of a unit's surviving from the time of implant to the end of a given interval without **device malfunction**. This estimation includes only events confirmed by the manufacturer's analysis, for which records include an implant date and an event or explant date. Because not all devices are returned to MicroPort CRM for analysis, limitations of passive follow-up are encountered. Data on survival from malfunction (excluding normal battery depletion) are based on returned product analysis. MicroPort CRM does not utilize any prospective, active device follow-up to assess device survival. As such, the survival data likely underestimate malfunction rates.

Device malfunction occurs when a device is **out of specification** after implant or otherwise fails to perform as intended; **normal battery depletions** are not considered to be out of specification.

Note
Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed.

A **confirmed malfunction** is the malfunction of an implanted device confirmed by returned product analysis, not including induced malfunctions.

Out of specification means having one or more product characteristics outside the limits established by the manufacturer for clinical use.

According to the international standard ISO 5841-2, and in accordance with the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines[1], **normal battery depletion** is the condition when:

- *a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50th percentile) predicted longevity at default (labeled) settings, or*
- *a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using the longevity calculation tool available at the time of product introduction, calculated using the device's actual use conditions and settings.*

When an implantable pulse generator is returned – and if the return is associated with a complaint – the determination of normal battery depletion is based on returned device analysis using the second criterion of the above Heart Rhythm Society Task Force definition. When an implantable pulse generator is not returned, the physician determines whether the explant is attributed to normal battery depletion.

[3] International Organization for Standardization. International Standard ISO 5841-2:2014(E), Implants for surgery – Cardiac pacemakers – Part 2: Reporting of clinical performance of populations of pulse generators or leads. 2014; Third edition.
[4] Advanced Medical Technology Association
[5] AdvaMed final guidance document dated 21 May 2009 is available at https://www.advamed.org/resource-center/industry-guidance-uniform-reporting-clinical-performance-cardiac-rhythm-management

2.2 Pulse Generator Malfunctions

For pulse generators, **malfunctions** are further separated into malfunctions with compromised therapy or malfunctions without compromised therapy:

- **Malfunction with compromised therapy** is the condition where a device is shown through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Therapy is considered to have been compromised if no therapy is available or critical patient-protective pacing or defibrillation therapy is not available. Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; or intermittent malfunction in which therapy is compromised while in the malfunction state.
- **Malfunction without compromised therapy** is the condition where a device is shown through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies are not impacted are included here. Examples include (but are not limited to): error affecting diagnostic functions, data storage; malfunction of a component that causes the battery to lose power quickly enough to result in premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; or telemetry failure.

2.3 Lead reporting data

Product performance reporting data on lead models marketed after 2005 comply with the ISO 5841-2. Application of this methodology shall be extended to all future lead models upon addition to this report.

2.3.1 Acute and chronic lead complications reporting

In accordance with the ISO 5841-2, non-returned leads associated with a complaint are classified as acute lead complications (leads implanted for 30 days or less) or chronic lead complications (leads implanted for more than 30 days) when at least one of the clinical observations categories has been reported (see hierarchical list below), and the lead was

1) modified either electrically or surgically to remedy the situation, OR

2) left in use based on medical judgment despite a known clinical performance issue

Categories of lead clinical observations (in descending hierarchical order):

- **Cardiac Perforation:** Penetration of the lead tip through the myocardium, clinically suspected and confirmed by chest x-ray, fluoroscopy, echocardiogram, or visual observation, which results in clinical symptoms, typically degradation of pacing/ICD lead electrical performance (high thresholds), chest pain, or tamponade.
- **Conductor Fracture:** A mechanical break within a lead conductor (includes connectors, coils, cables and/or electrodes) observed visually, electrically, or radiographically.
- **Lead Dislodgement:** Radiographic, electrical or electrocardiographic evidence of electrode displacement from the original implant site or electrode displacement that adversely affects pacing and/or lead performance.
- **Failure to Capture:** Intermittent or complete failure to achieve cardiac stimulation (atrial or ventricular) at programmed output delivered outside of the cardiac refractory period. Sudden

and significant increase in the pacing threshold value (elevated thresholds compared to previous measured value) at which 2:1 safety margin can no longer be achieved.

- **Oversensing:** Misinterpretation of cardiac or non-cardiac events as cardiac depolarization, *e.g.* T-waves, skeletal muscle potentials, and extra cardiac electromagnetic interference (EMI).
- **Failure to Sense (undersensing):** Intermittent or complete loss of sensing or failure to detect intended intrinsic cardiac signals (atrial or ventricular) during non-refractory periods at programmed sensitivity settings.
- **Insulation Breach:** A disruption or break in lead insulation observed visually, electrically, or radiographically.
- **Abnormal Pacing Impedance:** Pacing impedance is considered abnormal if a measurement is < 200 Ω or > 3000 Ω (based on lead model and measurement range of the device).
- **Abnormal Defibrillation Impedance:** Defibrillation impedance is considered abnormal if a measurement is < 20 Ω or > 200 Ω (based on lead model and measurement range of the device). Including high or low shock impedance when attempting to deliver a shock.
- **Extracardiac Stimulation:** Clinical observation of inadvertent nerve/muscle stimulation other than cardiac muscle.
- **Other:** Specific proprietary attributes of a lead such as sensors which affect a lead's ability to perform as designed or remain in service.

Acute and chronic complications shall also include leads removed from service and returned for analysis, where analysis was inconclusive because only portions of the lead were available, or the returned lead was damaged by the explantation process, or where returned product analysis could not determine an out of specification condition.

2.3.2 Mechanical Lead malfunctions (Returned Leads)

Conclusive returned device investigation results of the lead models marketed after 2005 are classified into one of the following four categories of confirmed malfunctions:

- **Conductor Fracture:** Conductor break with complete or intermittent loss of continuity that could interrupt current flow (*e.g.* fractured conductors). This type of malfunction includes any conductor fracture such as those associated with clavicle flex-fatigue or crush damage.
- **Insulation Breach:** Any breach of inner or outer lead insulation. Examples include: 1) proximal abrasions associated with lead-on-lead or lead-on-AIMD contact in the pocket, 2) mid-lead insulation damage caused by clavicle flex-fatigue or crush, suture or suture sleeve, insulation wear in the region of vein insertion, and 3) distal region wear due to lead-on-lead (intracardiac), lead-on-heart valve or lead-on-other anatomy contact.
- **Crimps, Welds, and Bonds:** Any interruption in the conductor or lead body associated with a point of connection.
- **Other:** Includes specific proprietary lead mechanical attributes, such as lead incorporated sensors, connectors (*e.g.* IS-1, DF-1, IS-4, DF-4), or seal rings.

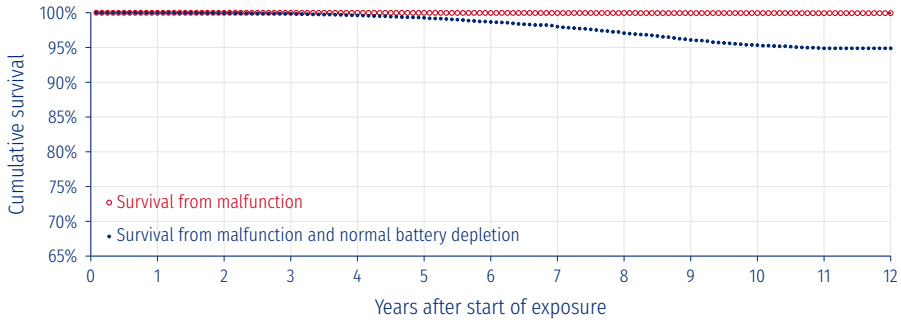
Note
The term "extrinsic" has been removed from the lead confirmed malfunctions in the 2014 version of the ISO 5841-2 standard, but the category of lead complication previously associated with this term is now accounted for in the lead complications (Acute or Chronic).

2.4 Survival graphs

Each survival graph shows "cumulative survival" on its Y-axis. This refers to the probability that the device will remain in the patient's body without malfunction during the interval from the time the device is implanted up until the point in time shown on the X-axis.

Figure 1 provides an example of the presentation format used in the survival graphs:

Reply DR



Cutoff date: 31-Dec-2020	Market release date	Dec-2006	Worldwide malfunctions	99
Analysis stops at 144 months	Worldwide implants	223672	Devices with compromised therapy	30
or < 500 active implants	Estimated active implants	203223	Devices without compromised therapy	69
	Estimated normal battery depletion	7616		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.99	99.99	99.99	99.98	99.98	99.97	99.96	99.96	99.95	99.95	99.94	99.94
Upper confidence interval (+) in %	0.00	0.00	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Lower confidence interval (-) in %	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01

Figure 1

Below, we define each of the data elements in Figure 1 above:

Reply DR	Model designations for devices covered by each cumulative survival graph appear above the corresponding graph.
Cutoff date	The graph and table contain all applicable data in the manufacturer's sales and analysis records as of the cutoff date shown at the lower left side of the corresponding graph.
Analysis stops at M months or < N active implants	Cumulative survival probability is presented for device models with 500 or more estimated active implants and for any devices covered by a Field Safety Notice regardless of the number of estimated active implants. For Implantable Pulse Generators (IPGs), the survival analysis is extended for as long as their exposure duration, up to a maximum of 12 years. For leads, the survival analysis is extended for as long as their exposure duration, up to a maximum of 20 years.
Market release date	Date of the first market approval for the device model shown in the graph (earlier of these dates if several models are presented).
Worldwide implants	Number of devices of the models shown in the graph that have been implanted worldwide.

Estimated active implants	Number of devices estimated in service worldwide at the cutoff date. As the manufacturer collects worldwide data passively, *i.e.* uses returned products to assess product performance, under-reporting could bias the analysis. To correct this potential bias, the analysis uses device-tracking data collected in the United States for same or similar types of devices, to estimate the fraction of exposed devices withdrawn each month for: - reasons not related to the functioning of the device - loss to follow-up - normal battery depletion - patient death
Estimated normal battery depletion	Number of devices estimated out of service worldwide due to normal battery depletion at the cutoff date. See definition of "normal battery depletion" in Section 2.1 on page 7. To correct potential bias due to under-reporting of normal battery depletion worldwide, when the same or similar models are marketed in the United States, the analysis uses US device-tracking data to estimate the fraction of exposed devices withdrawn each month for normal battery depletion. In order to account for potential bias due to under-reporting of normal battery depletion, a device that has not been returned but whose explant was attributed to normal battery depletion – by the physician – is therefore added to the normal battery depletion statistics. "Estimated normal battery depletion" is shown only for device models marketed in the United States; this field contains "Not available" when US device-tracking data is missing.
Worldwide malfunctions	Number of devices confirmed out of specification worldwide after implant, except due to normal battery depletion.
Years after start of exposure	Number of years the device remains in the body after the device is implanted. When the date of implant is unknown, the analysis uses an estimate based on available evidence – between the date of sale and the expiration date – as a surrogate for date of implant. Similarly, when the explant date is not identifiable, the first known reference is used (*e.g.* date of a letter from the physician to the subsidiary, date the manufacturer became aware of the event...). The survival analysis calculates time to the nearest day; however, for convenience, the graphs and tables report time in years.
Cumulative survival curves	Each survival graph contains the survival curve for freedom from malfunction, in red. When the device is marketed in the United States, a second survival curve for normal battery depletion and malfunction is shown on the same graph (the lower curve), in blue. A table provides annual values corresponding to the upper curve, with confidence limits.
Devices with and without compromised therapy	The number of malfunctions with and without compromised therapy is documented in a table below the survival curves data.

Note that the exposure time for each implant begins on the date of distribution as the implant date is often not known. Some survival curves may appear to have a maximum years of exposure greater than the time since the market release date. This can be caused by products used in clinical trials prior to commercial release.

For the newest models, due to progressive sales ramp-up, reaching the criterion for inclusion in this report (*i.e.* 500 or more estimated active implants) can take a long time for some models. Combining

same or similar models together allows including survival data in the Product Performance Report much earlier than it would be possible reporting them separately.

Because we use device-tracking data collected in the US for same or similar types of devices to estimate the data related to normal battery depletion, and due to lower sales volume in the US, reaching a significant number of US reports for normal battery depletion (threshold is set to 10) can also take a long time for some models. Therefore same or similar devices might be combined together, and they will be reported separately when there is enough US reports for normal battery depletion for each device model.

Field Safety Notices associated with the products are also indicated; each Field Safety Notice is described in Section 6 of this report, pp. 59-101. Cumulative survival graphs are presented separately for non-Field Safety Notice and Field Safety Notice device populations (when applicable): survival graphs for non-Field Safety Notice device populations are presented in the actual device model section (for device models with 500 or more estimated active implants), and survival graphs for Field Safety Notice device populations are presented in Section 6 of the report, thus providing the healthcare community with clinically relevant, patient-specific device performance.

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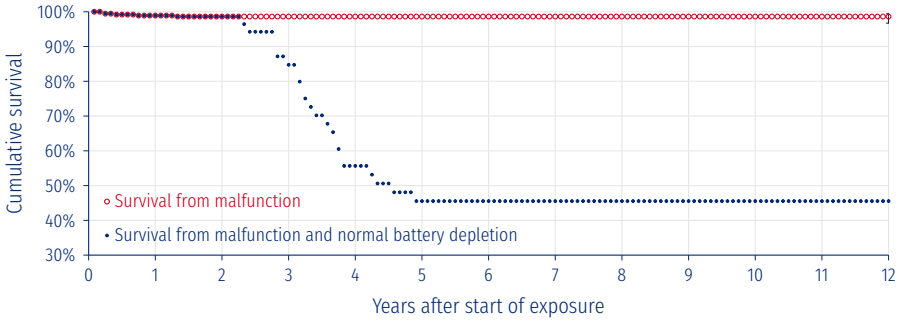
3 Cardiac Resynchronization Therapy (CRT)

3.1 Cardiac Resynchronization Therapy Defibrillators (CRT-D)

3.1.1 Alto MSP 617 - Alto 2 MSP 627

Alto MSP 617
Alto 2 MSP 627



Cutoff date: 31-Dec-2020	Market release date	Jun-2002	Worldwide malfunctions	5
Analysis stops at 144 months	Worldwide implants	366	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	131	Devices without compromised therapy	3
	Estimated normal battery depletion	184		

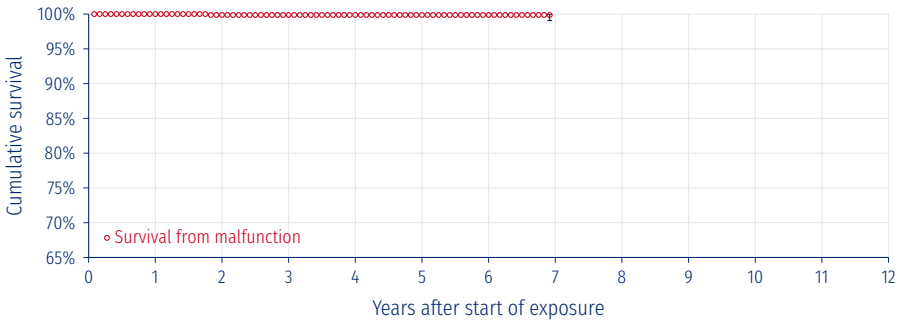
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	98.90	98.62	98.62	98.62	98.62	98.62	98.62	98.62	98.62	98.62	98.62	98.62
Upper confidence interval (+) in %	0.69	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80
Lower confidence interval (-) in %	1.80	1.90	1.90	1.90	1.90	1.90	1.90	1.90	1.90	1.90	1.90	1.90

A Field Safety Notice was issued for a limited number of Alto 2 MSP 627 devices and all Alto MSP 617 devices. Please refer to Sections 6.1.1 to 6.1.3, pp. 59-64. Note that the survival data above is presented for Alto 2 MSP 627 devices manufactured after August 2004, *i.e.* for non Field Safety Notice device population.

3.1.2 Intensia CRT-D 174 - Intensia SonR CRT-D 184

Intensia CRT-D 174
Intensia SonR CRT-D 184



Cutoff date: 31-Dec-2020	Market release date	Nov-2013	Worldwide malfunctions	1
Analysis stops at 144 months	Worldwide implants	771	Devices with compromised therapy	1
or < 500 active implants	Estimated active implants	713	Devices without compromised therapy	0
	Estimated normal battery depletion	Not available		

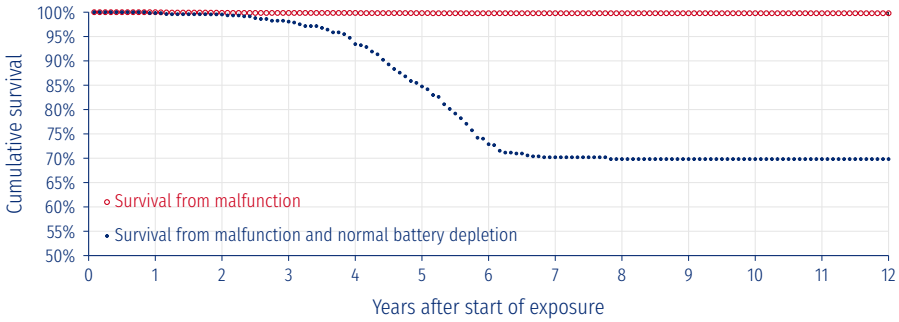
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	99.87	99.87	99.87	99.87	99.87						
Upper confidence interval (+) in %		0.11	0.11	0.11	0.11	0.11						
Lower confidence interval (-) in %		0.81	0.81	0.81	0.81	0.81						

A Field Safety Notice was issued for Intensia devices. Please refer to Section 6.1.7, pp. 68-71.

3.1.3 Ovatio CRT 6750

Ovatio CRT 6750



Cutoff date: 31-Dec-2020	Market release date	Apr-2005	Worldwide malfunctions	8
Analysis stops at 144 months	Worldwide implants	3955	Devices with compromised therapy	6
or < 500 active implants	Estimated active implants	2452	Devices without compromised therapy	2
	Estimated normal battery depletion	1134		

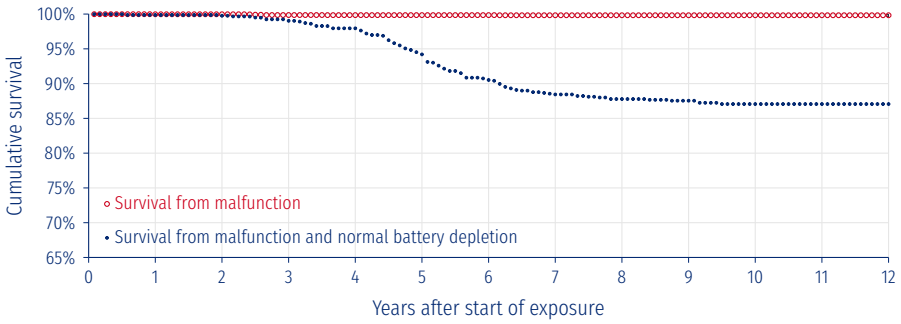
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	99.87	99.85	99.85	99.82	99.79	99.79	99.79	99.79	99.79	99.79	99.79
Upper confidence interval (+) in %		0.07	0.08	0.08	0.10	0.11	0.11	0.11	0.11	0.11	0.11	0.11
Lower confidence interval (-) in %		0.18	0.19	0.19	0.20	0.21	0.21	0.21	0.21	0.21	0.21	0.21

A Field Safety Notice was issued for Ovatio devices. Please refer to Section 6.1.7, pp. 68-71.

3.1.4 Paradym CRT-D 8750

Paradym CRT-D 8750



Cutoff date: 31-Dec-2020	Market release date	Apr-2008	Worldwide malfunctions 10
Analysis stops at 144 months	Worldwide implants	5966	Devices with compromised therapy 2
or < 500 active implants	Estimated active implants	4790	Devices without compromised therapy 8
	Estimated normal battery depletion	708	

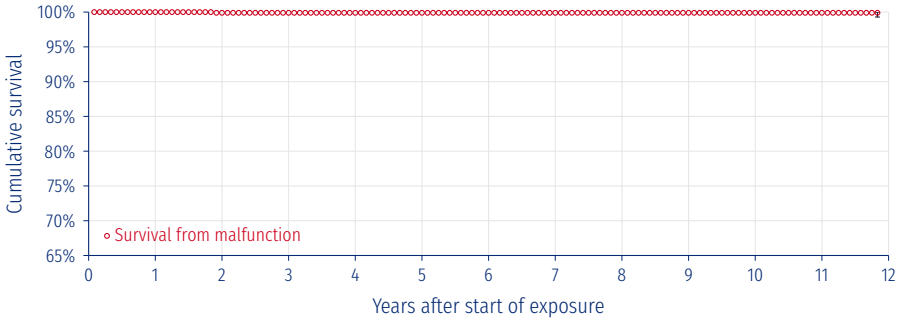
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.97	99.97	99.86	99.85	99.85	99.85	99.83	99.83	99.83	99.83	99.83	99.83
Upper confidence interval (+) in %	0.03	0.03	0.07	0.07	0.07	0.07	0.08	0.08	0.08	0.08	0.08	0.08
Lower confidence interval (-) in %	0.10	0.10	0.14	0.14	0.14	0.14	0.15	0.15	0.15	0.15	0.15	0.15

Field Safety Notices were issued for Paradym devices. Please refer to Sections 6.1.4 to 6.1.5, pp. 65-67 and Section 6.1.7, pp. 68-71.

3.1.5 Paradym CRT-D SonR 8770 - SonR TriV 8970

Paradym SonR CRT-D 8770
Paradym SonR TriV 8970



Cutoff date: 31-Dec-2020	Market release date	Nov-2007	Worldwide malfunctions 1
Analysis stops at 144 months	Worldwide implants	1049	Devices with compromised therapy 0
or < 500 active implants	Estimated active implants	951	Devices without compromised therapy 1
	Estimated normal battery depletion	Not available	

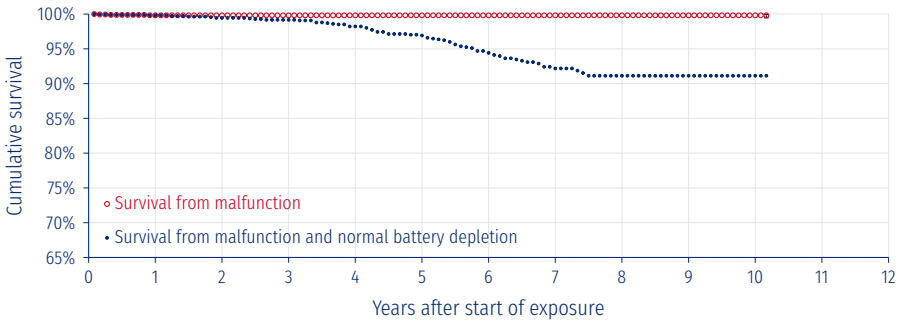
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	99.90	99.90	99.90	99.90	99.90	99.90	99.90	99.90	99.90	99.90	
Upper confidence interval (+) in %		0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	
Lower confidence interval (-) in %		0.61	0.61	0.61	0.61	0.61	0.61	0.61	0.61	0.61	0.61	

Field Safety Notices were issued for Paradym devices. Please refer to Sections 6.1.4 to 6.1.5, pp. 65-67 and Section 6.1.7, pp. 68-71.

3.1.6 Paradym RF CRT-D 9750

Paradym RF CRT-D 9750



Cutoff date: 31-Dec-2020	Market release date	Sep-2010	Worldwide malfunctions	3
Analysis stops at 144 months	Worldwide implants	1704	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	1471	Devices without compromised therapy	1
	Estimated normal battery depletion	111		

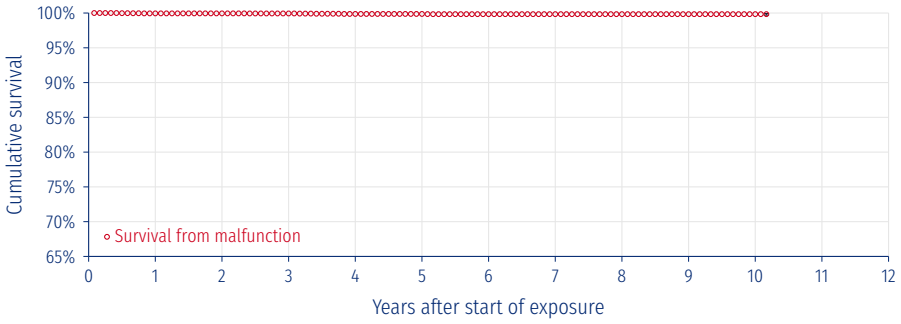
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.82	99.82	99.82	99.82	99.82	99.82	99.82	99.82	99.82	99.82		
Upper confidence interval (+) in %	0.12	0.12	0.12	0.12	0.12	0.12	0.12	0.12	0.12	0.12		
Lower confidence interval (-) in %	0.37	0.37	0.37	0.37	0.37	0.37	0.37	0.37	0.37	0.37		

A Field Safety Notice was issued for Paradym RF devices. Please refer to Section 6.1.7, pp. 68-71.

3.1.7 Paradym RF SonR CRT-D 9770

Paradym RF SonR CRT-D 9770



Cutoff date: 31-Dec-2020	Market release date	Sep-2010	Worldwide malfunctions	10
Analysis stops at 144 months	Worldwide implants	6347	Devices with compromised therapy	3
or < 500 active implants	Estimated active implants	5754	Devices without compromised therapy	7
	Estimated normal battery depletion	Not available		

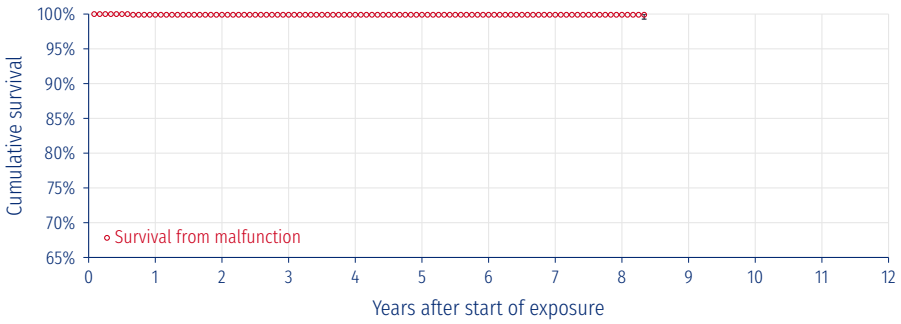
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.95	99.95	99.94	99.87	99.87	99.84	99.84	99.84	99.84	99.84		
Upper confidence interval (+) in %	0.03	0.03	0.04	0.06	0.06	0.08	0.08	0.08	0.08	0.08		
Lower confidence interval (-) in %	0.10	0.10	0.11	0.13	0.13	0.14	0.14	0.14	0.14	0.14		

A Field Safety Notice was issued for Paradym RF devices. Please refer to Section 6.1.7, pp. 68-71.

3.1.8 Paradym 2 CRT-D 8752 - SonR CRT-D 8772

Paradym 2 CRT-D 8752
Paradym 2 SonR CRT-D 8772



Cutoff date: 31-Dec-2020	Market release date	May-2012	Worldwide malfunctions	1
Analysis stops at 144 months	Worldwide implants	966	Devices with compromised therapy	1
or < 500 active implants	Estimated active implants	893	Devices without compromised therapy	0
	Estimated normal battery depletion	Not available		

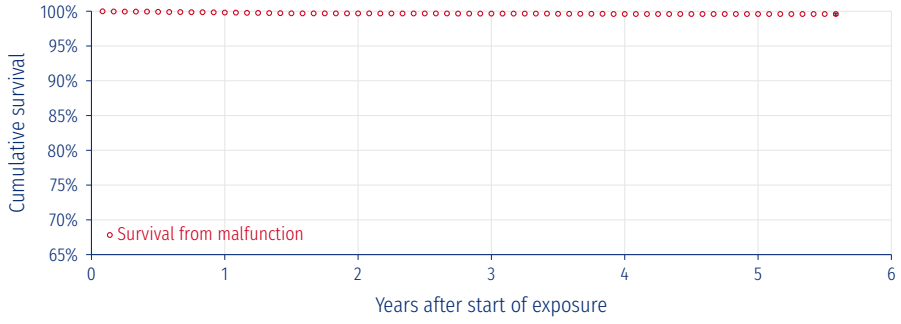
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.90	99.90	99.90	99.90	99.90	99.90	99.90	99.90				
Upper confidence interval (+) in %	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09				
Lower confidence interval (-) in %	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63				

A Field Safety Notice was issued for Paradym 2 devices. Please refer to Section 6.1.7, pp. 68-71.

3.1.9 Platinium CRT-D 1711 - SonR CRT-D 1811 - CRT-D 1741 - SonR CRT-D 1841 - 4LV CRT-D 1744 - 4LV SonR CRT-D 1844

Platinium CRT-D 1711
Platinium CRT-D 1741
Platinium SonR CRT-D 1811
Platinium SonR CRT-D 1841
Platinium 4LV CRT-D 1744
Platinium 4LV SonR CRT-D 1844



Cutoff date: 31-Dec-2020	Market release date	Jun-2015	Worldwide malfunctions	34
Analysis stops at 72 months	Worldwide implants	11345	Devices with compromised therapy	15
or < 500 active implants	Estimated active implants	10911	Devices without compromised therapy	19
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	99.81	99.69	99.66	99.60	99.60	
Upper confidence interval (+) in %	0.07	0.09	0.10	0.12	0.12	
Lower confidence interval (-) in %	0.11	0.13	0.14	0.18	0.18	

Field Safety Notices were issued for Platinium devices. Please refer to Sections 6.1.8 to 6.1.12, pp. 72-81.

3.1.10 Cardiac Resynchronization Therapy Defibrillators (CRT-D) synopsis

The table presented below summarizes device information:

Models	Family	Market release date	Worldwide implants	Estimated active implants	Estimated normal batt. depletion	Worldwide malfunctions	Devices with compromised therapy	Devices without compromised therapy
Alto MSP 617, Alto 2 MSP 627	Alto	Jun-02 Aug-04	366	131	184	5	2	3
Intensia CRT-D 174, Intensia SonR CRT-D 184	Intensia	Nov-13 Nov-13	771	713	-	1	1	0
Ovatio CRT 6750	Ovatio	Apr-05	3955	2452	1134	8	6	2
Paradym CRT-D 8750	Paradym	Apr-08	5966	4790	708	10	2	8
Paradym SonR CRT-D 8770, Paradym SonR TriV 8970	Paradym	Nov-07 Jun-14	1049	951	-	1	0	1
Paradym RF CRT-D 9750	Paradym RF	Sep-10	1704	1471	111	3	2	1
Paradym RF SonR CRT-D 9770	Paradym RF	Sep-10	6347	5754	-	10	3	7
Paradym 2 CRT-D 8752, Paradym 2 SonR CRT-D 8772	Paradym 2	May-12 Mar-14	966	893	-	1	1	0
Platinium CRT-D 1711, Platinium CRT-D 1741, Platinium SonR CRT-D 1811, Platinium SonR CRT-D 1841, Platinium 4LV CRT-D 1744, Platinium 4LV SonR CRT-D 1844	Platinium	Oct-15 Nov-15 Jun-15 Jun-15 Apr-17 Jan-16	11345	10911	-	34	15	19

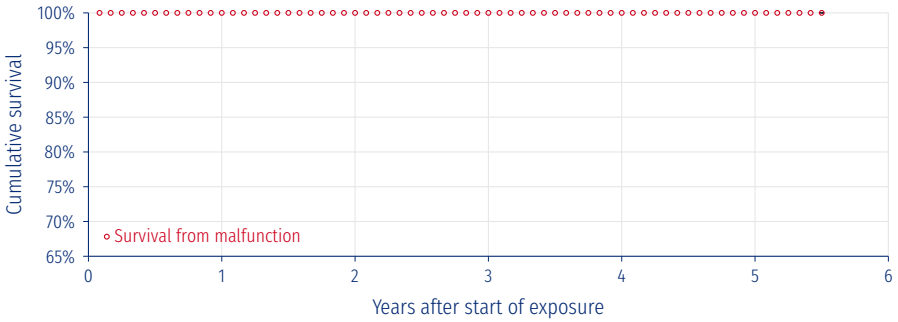
The table presented below summarizes cumulative survival probability from malfunction:

		Cumulative survival from malfunction (%) as a function of years after implant											
Models	Family	1	2	3	4	5	6	7	8	9	10	11	12
Alto MSP 617, Alto 2 MSP 627	Alto	98.90	98.62	98.62	98.62	98.62	98.62	98.62	98.62	98.62	98.62	98.62	98.62
Intensia CRT-D 174, Intensia SonR CRT-D 184	Intensia	100	99.87	99.87	99.87	99.87	99.87						
Ovatio CRT 6750	Ovatio	100	99.87	99.85	99.85	99.82	99.79	99.79	99.79	99.79	99.79	99.79	99.79
Paradym CRT-D 8750	Paradym	99.97	99.97	99.86	99.85	99.85	99.85	99.83	99.83	99.83	99.83	99.83	99.83
Paradym SonR CRT-D 8770, Paradym SonR TriV 8970	Paradym	100	99.90	99.90	99.90	99.90	99.90	99.90	99.90	99.90	99.90	99.90	
Paradym RF CRT-D 9750	Paradym RF	99.82	99.82	99.82	99.82	99.82	99.82	99.82	99.82	99.82	99.82		
Paradym RF SonR CRT-D 9770	Paradym RF	99.95	99.95	99.94	99.87	99.87	99.84	99.84	99.84	99.84	99.84		
Paradym 2 CRT-D 8752, Paradym 2 SonR CRT-D 8772	Paradym 2	99.90	99.90	99.90	99.90	99.90	99.90	99.90	99.90				
Platinium CRT-D 1711, Platinium CRT-D 1741, Platinium SonR CRT-D 1811, Platinium SonR CRT-D 1841, Platinium 4LV CRT-D 1744, Platinium 4LV SonR CRT-D 1844	Platinium	99.81	99.69	99.66	99.60	99.60							

3.2 Cardiac Resynchronization Therapy Pacemakers (CRT-P)

3.2.1 Reply CRT-P

Reply CRT-P



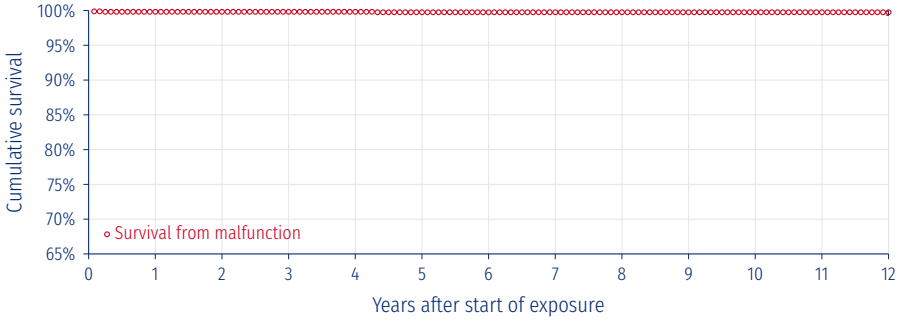
Cutoff date: 31-Dec-2020	Market release date	Jul-2015	Worldwide malfunctions	0
Analysis stops at 72 months	Worldwide implants	1314	Devices with compromised therapy	0
or < 500 active implants	Estimated active implants	1279	Devices without compromised therapy	0
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	100	100	100	100	100	
Upper confidence interval (+) in %						
Lower confidence interval (-) in %						

3.2.2 Talent 3 MSP 353 - Talent MSP AF 343 - MSP 313

Talent MSP 313
Talent MSP AF 343
Talent 3 MSP 353



Cutoff date: 31-Dec-2020	Market release date	Jun-2002	Worldwide malfunctions	4
Analysis stops at 144 months	Worldwide implants	1629	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	1392	Devices without compromised therapy	2
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.82	99.82	99.82	99.82	99.75	99.75	99.75	99.75	99.75	99.75	99.75	99.75
Upper confidence interval (+) in %	0.12	0.12	0.12	0.12	0.16	0.16	0.16	0.16	0.16	0.16	0.16	0.16
Lower confidence interval (-) in %	0.39	0.39	0.39	0.39	0.41	0.41	0.41	0.41	0.41	0.41	0.41	0.41

3.2.3 Cardiac Resynchronization Therapy Pacemakers (CRT-P) synopsis

The table presented below summarizes device information:

Models	Family	Market release date	Worldwide implants	Estimated active implants	Worldwide malfunctions	Devices with compromised therapy	Devices without compromised therapy
Reply CRT-P	Reply CRT-P	Jul-15	1314	1279	0	0	0
Talent MSP 313, Talent MSP AF 343, Talent 3 MSP 353	Talent	Jun-02 Jul-02 Jul-02	1629	1392	4	2	2

The table presented below summarizes cumulative survival probability from malfunction:

		Cumulative survival from malfunction (%) as a function of years after implant											
Models	Family	1	2	3	4	5	6	7	8	9	10	11	12
Reply CRT-P	Reply CRT-P	100	100	100	100	100							
Talent MSP 313, Talent MSP AF 343, Talent 3 MSP 353	Talent	99.82	99.82	99.82	99.82	99.75	99.75	99.75	99.75	99.75	99.75	99.75	99.75

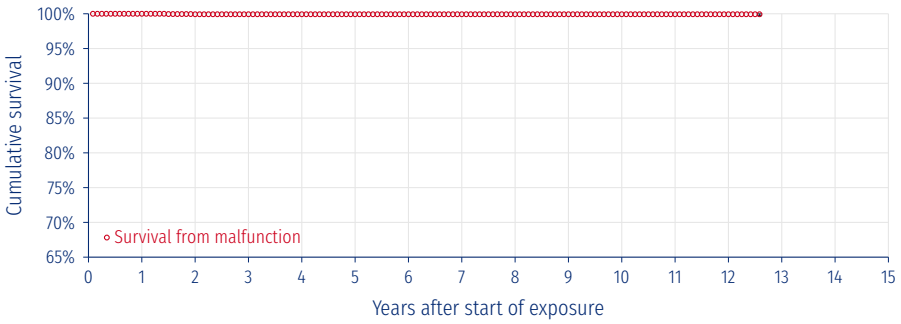
3.3 Cardiac Resynchronization Therapy leads

3.3.1 Celerity 2D - 3D - Pilot

The Celerity lead models are/will be reported in Biotronik's Product Performance Report[6], provided that they reach the inclusion criteria (Refer to the Celerity and Corox sections).

3.3.2 Situs OTW BW28D - OTW BW28D MV

Situs OTW BW28D
Situs OTW BW28D MV



Cutoff date: 31-Dec-2020	Market release date	May-2008	Worldwide malfunctions	2
Analysis stops at 180 months	Worldwide implants	2956	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	2330	Devices without compromised therapy	0

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant															
Years after implant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Cumulative survival from malfunction in %	100	99.93	99.93	99.93	99.93	99.93	99.93	99.93	99.93	99.93	99.93	99.93			
Upper confidence interval (+) in %		0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05			
Lower confidence interval (-) in %		0.21	0.21	0.21	0.21	0.21	0.21	0.21	0.21	0.21	0.21	0.21			

Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	1
Insulation Breach	0	0
Crimps, Welds, and Bonds	0	0
Other	0	0
All lead malfunctions	0	1

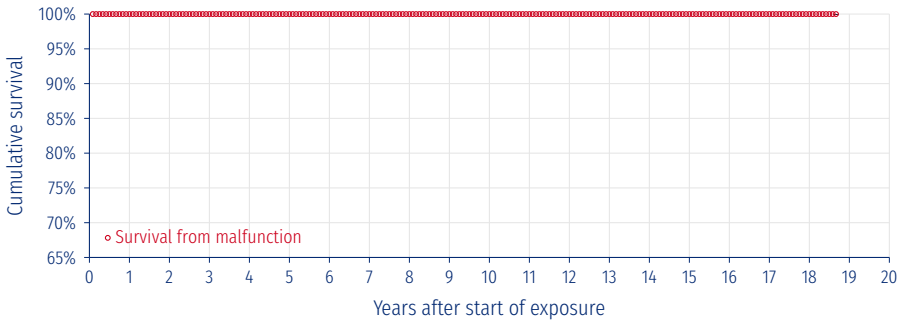
Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	0	0
Conductor Fracture	0	0
Lead Dislodgement	2	0
Failure to Capture	0	0
Oversensing	0	0
Failure to Sense (undersensing)	0	0
Insulation Breach	0	0
Abnormal Pacing Impedance	1	1
Abnormal Defibrillation Impedance	0	0
Extracardiac Stimulation	0	0
Other	0	0
All lead complications	3	1

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

[6] Biotronik's PPR document is available on Biotronik's website at:
https://www.biotronik.com/en-gb/healthcare-professionals/product-performance-report

3.3.3 Situs OTW UW28D

Situs OTW UW28D

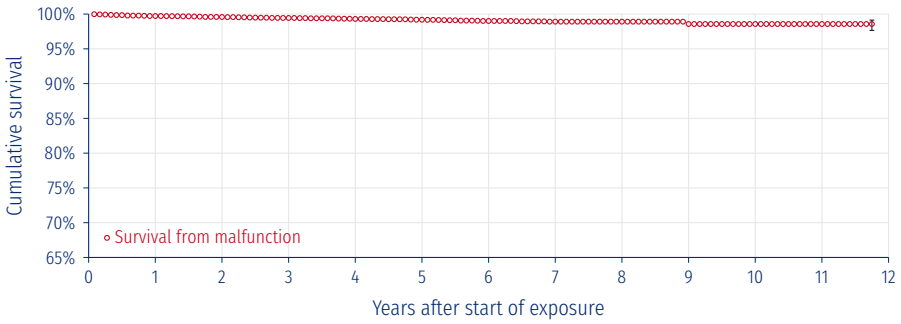


Cutoff date: 31-Dec-2020	Market release date	Jun-2002	Worldwide malfunctions	0
Analysis stops at 240 months	Worldwide implants	3675	Devices with compromised therapy	0
or < 500 active implants	Estimated active implants	2595	Devices without compromised therapy	0

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant																				
Years after implant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Cumulative survival from malfunction in %	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100		
Upper confidence interval (+) in %																				
Lower confidence interval (-) in %																				

3.3.4 SonRtip

SonRtip



Cutoff date: 31-Dec-2020	Market release date	Dec-2011	Worldwide malfunctions	75
Analysis stops at 144 months	Worldwide implants	9280	Devices with compromised therapy	39
or < 500 active implants	Estimated active implants	8060	Devices without compromised therapy	36

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant												
Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.72	99.58	99.44	99.30	99.19	99.01	98.91	98.91	98.57	98.57	98.57	
Upper confidence interval (+) in %	0.09	0.12	0.14	0.16	0.18	0.21	0.23	0.23	0.56	0.56	0.56	
Lower confidence interval (-) in %	0.13	0.16	0.18	0.21	0.23	0.27	0.30	0.30	0.92	0.92	0.92	

Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	6
Insulation Breach	0	9
Crimps, Welds, and Bonds	0	3
Other	0	0
All lead malfunctions	0	18

Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	2	1
Conductor Fracture	0	0
Lead Dislodgement	1	4
Failure to Capture	3	10
Oversensing	1	18
Failure to Sense (undersensing)	0	1
Insulation Breach	0	0
Abnormal Pacing Impedance	0	2
Abnormal Defibrillation Impedance	0	0
Extracardiac Stimulation	0	0
Other	1	21
All lead complications	8	57

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

Note that the survival curve for this product includes data from leads that were involved in pre-market clinical studies.
A Field Safety Notice was issued for SonRtip leads. Please refer to Section 6.3.3, pp. 100-101.

3.3.5 Cardiac Resynchronization Therapy leads synopsis

The table presented below summarizes device information:

Models	Family	Market release date	Worldwide implants	Estimated active implants	Worldwide malfunctions	Devices with compromised therapy	Devices without compromised therapy	Devices returned and analyzed
Situs OTW BW28D, Situs OTW BW28D MV	Situs	May-08 May-08	2956	2330	2	2	0	N/A*
Situs OTW UW28D	Situs	Jun-02	3675	2595	0	0	0	N/A*
SonRtip	SonR	Dec-11	9280	8060	75	39	36	0

*Only available for our most recent models

The table presented below summarizes cumulative survival probability from malfunction:

		Cumulative survival from malfunction (%) as a function of years after implant																			
Models	Family	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Situs OTW BW28D, Situs OTW BW28D MV	Situs	100	99.93	99.93	99.93	99.93	99.93	99.93	99.93	99.93	99.93	99.93	99.93								
Situs OTW UW28D	Situs	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100		
SonRtip	SonR	99.72	99.58	99.44	99.30	99.19	99.01	98.91	98.91	98.57	98.57	98.57									

4 Tachycardia therapy

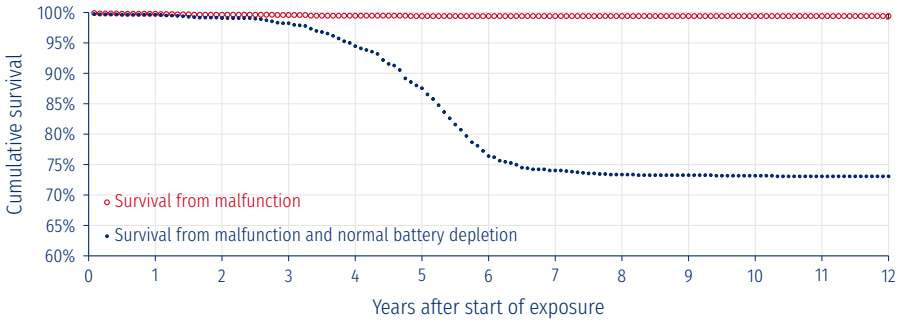
4.1 Implantable Cardioverter Defibrillators (ICDs)

4.1.1 Alto DR 614 - VR 615

A Field Safety Notice was issued for Alto DR 614 and Alto VR 615 devices. Please refer to Sections 6.1.1 to 6.1.3, pp. 59-64.

4.1.2 Alto 2 DR 624

Alto 2 DR 624



Cutoff date: 31-Dec-2020	Market release date	Jul-2002	Worldwide malfunctions	11
Analysis stops at 144 months	Worldwide implants	1920	Devices with compromised therapy	6
or < 500 active implants	Estimated active implants	1228	Devices without compromised therapy	5
	Estimated normal battery depletion	484		

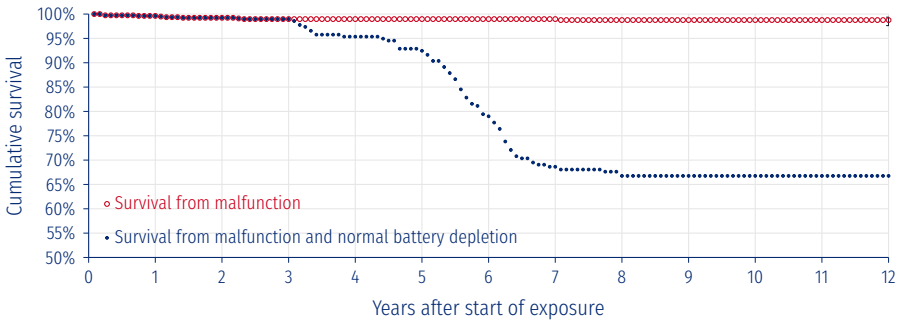
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.79	99.63	99.58	99.47	99.41	99.41	99.41	99.41	99.41	99.41	99.41	99.41
Upper confidence interval (+) in %	0.13	0.19	0.21	0.24	0.26	0.26	0.26	0.26	0.26	0.26	0.26	0.26
Lower confidence interval (-) in %	0.35	0.40	0.42	0.45	0.47	0.47	0.47	0.47	0.47	0.47	0.47	0.47

A Field Safety Notice was issued for a limited number of Alto 2 DR 624 and Alto 2 VR 625 devices. Please refer to Sections 6.1.1 to 6.1.3, pp. 59-64. Note that the survival data above is presented for devices manufactured after August 2004, *i.e.* for non Field Safety Notice device population.

4.1.3 Alto 2 VR 625

Alto 2 VR 625



Cutoff date: 31-Dec-2020	Market release date	Sep-2002	Worldwide malfunctions	9
Analysis stops at 144 months	Worldwide implants	784	Devices with compromised therapy	7
or < 500 active implants	Estimated active implants	446	Devices without compromised therapy	2
	Estimated normal battery depletion	241		

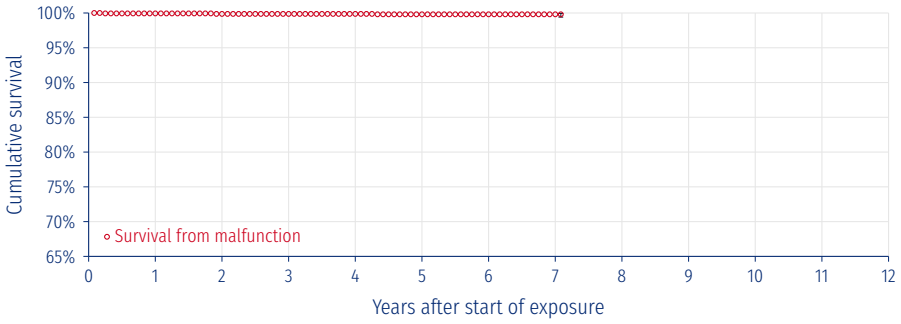
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.62	99.23	98.97	98.97	98.97	98.97	98.97	98.77	98.77	98.77	98.77	98.77
Upper confidence interval (+) in %	0.26	0.42	0.51	0.51	0.51	0.51	0.51	0.59	0.59	0.59	0.59	0.59
Lower confidence interval (-) in %	0.80	0.94	1.02	1.02	1.02	1.02	1.02	1.14	1.14	1.14	1.14	1.14

A Field Safety Notice was issued for a limited number of Alto 2 DR 624 and Alto 2 VR 625 devices. Please refer to Sections 6.1.1 to 6.1.3, pp. 59-64. Note that the survival data above is presented for devices manufactured after August 2004, *i.e.* for non Field Safety Notice device population.

4.1.4 Intensia DR 154 - VR 124

Intensia DR 154
Intensia VR 124



Cutoff date: 31-Dec-2020	Market release date	Nov-2013	Worldwide malfunctions	3
Analysis stops at 144 months	Worldwide implants	1609	Devices with compromised therapy	1
or < 500 active implants	Estimated active implants	1487	Devices without compromised therapy	2
	Estimated normal battery depletion	Not available		

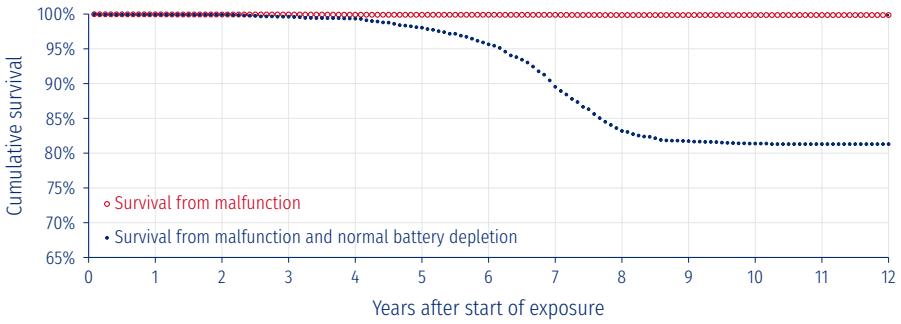
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.94	99.87	99.87	99.87	99.81	99.81	99.81					
Upper confidence interval (+) in %	0.05	0.09	0.09	0.09	0.13	0.13	0.13					
Lower confidence interval (-) in %	0.38	0.38	0.38	0.38	0.40	0.40	0.40					

A Field Safety Notice was issued for Intensia devices. Please refer to Section 6.1.7, pp. 68-71.

4.1.5 Ovatio DR 6550

Ovatio DR 6550



Cutoff date: 31-Dec-2020	Market release date	May-2005	Worldwide malfunctions 15
Analysis stops at 144 months	Worldwide implants	11471	Devices with compromised therapy 13
or < 500 active implants	Estimated active implants	8205	Devices without compromised therapy 2
	Estimated normal battery depletion	2000	

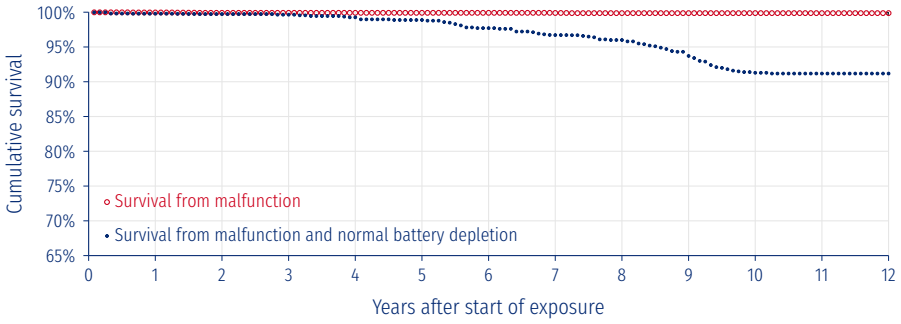
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.96	99.94	99.94	99.91	99.90	99.90	99.89	99.86	99.86	99.86	99.86	99.86
Upper confidence interval (+) in %	0.03	0.03	0.03	0.04	0.04	0.04	0.05	0.06	0.06	0.06	0.06	0.06
Lower confidence interval (-) in %	0.06	0.07	0.07	0.08	0.08	0.08	0.08	0.09	0.09	0.09	0.09	0.09

A Field Safety Notice was issued for Ovatio devices. Please refer to Section 6.1.7, pp. 68-71.

4.1.6 Ovatio VR 6250

Ovatio VR 6250



Cutoff date: 31-Dec-2020	Market release date	May-2005	Worldwide malfunctions 7
Analysis stops at 144 months	Worldwide implants	5494	Devices with compromised therapy 5
or < 500 active implants	Estimated active implants	4439	Devices without compromised therapy 2
	Estimated normal battery depletion	445	

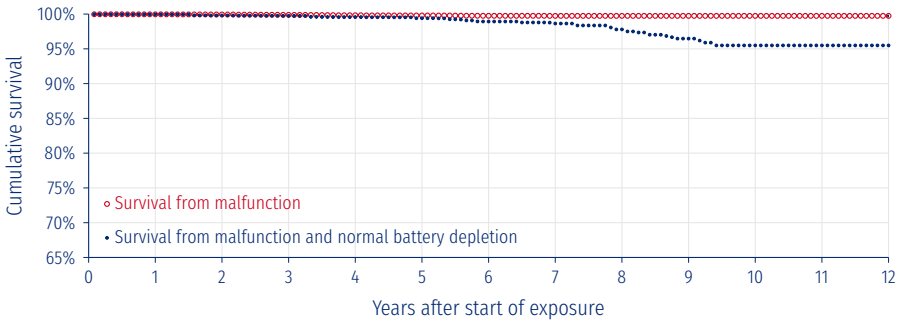
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.96	99.91	99.91	99.91	99.91	99.91	99.89	99.87	99.87	99.87	99.87	99.87
Upper confidence interval (+) in %	0.03	0.05	0.05	0.05	0.05	0.05	0.06	0.07	0.07	0.07	0.07	0.07
Lower confidence interval (-) in %	0.11	0.13	0.13	0.13	0.13	0.13	0.14	0.15	0.15	0.15	0.15	0.15

A Field Safety Notice was issued for Ovatio devices. Please refer to Section 6.1.7, pp. 68-71.

4.1.7 Paradym DR 8550

Paradym DR 8550



Cutoff date: 31-Dec-2020	Market release date	Nov-2007	Worldwide malfunctions 25
Analysis stops at 144 months	Worldwide implants	9850	Devices with compromised therapy 12
or < 500 active implants	Estimated active implants	8941	Devices without compromised therapy 13
	Estimated normal battery depletion	297	

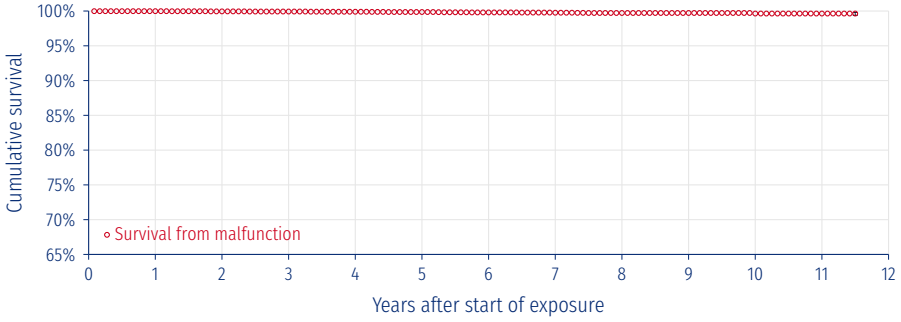
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.96	99.94	99.89	99.83	99.80	99.75	99.74	99.74	99.74	99.74	99.74	99.74
Upper confidence interval (+) in %	0.03	0.03	0.05	0.06	0.07	0.08	0.08	0.08	0.08	0.08	0.08	0.08
Lower confidence interval (-) in %	0.07	0.07	0.09	0.10	0.11	0.12	0.13	0.13	0.13	0.13	0.13	0.13

Field Safety Notices were issued for Paradym devices. Please refer to Sections 6.1.4 to 6.1.7, pp. 65-71.

4.1.8 Paradym VR 8250

Paradym VR 8250



Cutoff date: 31-Dec-2020	Market release date	Jun-2008	Worldwide malfunctions 16
Analysis stops at 144 months	Worldwide implants	5878	Devices with compromised therapy 6
or < 500 active implants	Estimated active implants	5207	Devices without compromised therapy 10
	Estimated normal battery depletion	Not available	

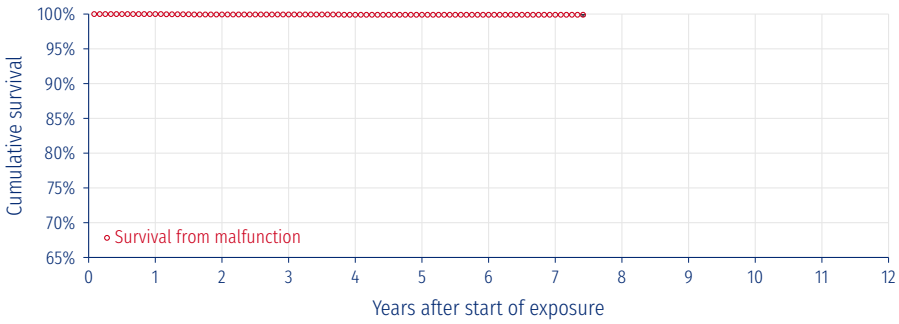
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.98	99.95	99.93	99.90	99.86	99.80	99.76	99.72	99.72	99.64	99.64	
Upper confidence interval (+) in %	0.01	0.04	0.04	0.06	0.07	0.09	0.10	0.11	0.11	0.16	0.16	
Lower confidence interval (-) in %	0.10	0.11	0.12	0.13	0.14	0.16	0.17	0.19	0.19	0.28	0.28	

Field Safety Notices were issued for Paradym devices. Please refer to Sections 6.1.4 to 6.1.7, pp. 65-71.

4.1.9 Paradym 2 DR 8552 - VR 8252

Paradym 2 DR 8552
Paradym 2 VR 8252



Cutoff date: 31-Dec-2020	Market release date	Jun-2013	Worldwide malfunctions	3
Analysis stops at 144 months	Worldwide implants	3184	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	2947	Devices without compromised therapy	1
	Estimated normal battery depletion	Not available		

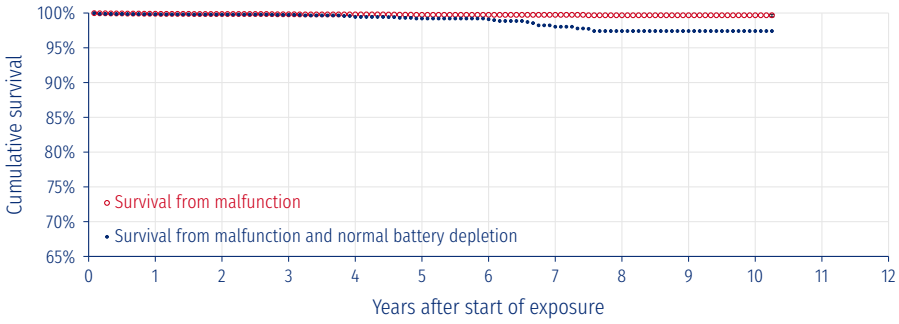
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	99.94	99.94	99.90	99.90	99.90	99.90					
Upper confidence interval (+) in %		0.05	0.05	0.07	0.07	0.07	0.07					
Lower confidence interval (-) in %		0.19	0.19	0.20	0.20	0.20	0.20					

A Field Safety Notice was issued for Paradym 2 devices. Please refer to Section 6.1.7, pp. 68-71.

4.1.10 Paradym RF DR 9550

Paradym RF DR 9550



Cutoff date: 31-Dec-2020	Market release date	Sep-2010	Worldwide malfunctions	14
Analysis stops at 144 months	Worldwide implants	5090	Devices with compromised therapy	5
or < 500 active implants	Estimated active implants	4688	Devices without compromised therapy	9
	Estimated normal battery depletion	73		

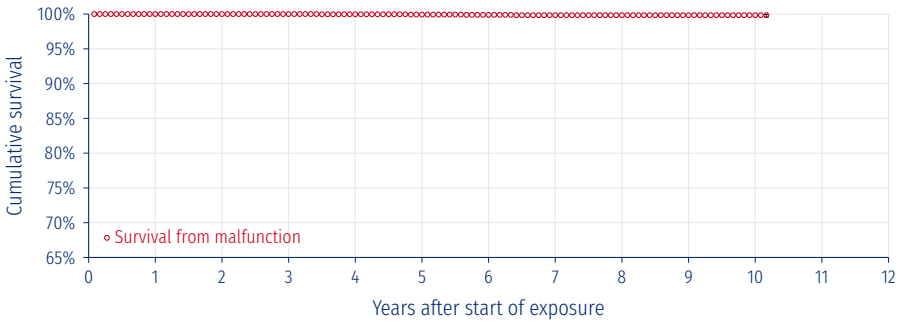
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.90	99.86	99.82	99.80	99.74	99.74	99.74	99.68	99.68	99.68		
Upper confidence interval (+) in %	0.06	0.07	0.09	0.09	0.11	0.11	0.11	0.14	0.14	0.14		
Lower confidence interval (-) in %	0.14	0.15	0.16	0.17	0.19	0.19	0.19	0.24	0.24	0.24		

A Field Safety Notice was issued for Paradym RF devices. Please refer to Section 6.1.7, pp. 68-71.

4.1.11 Paradym RF VR 9250

Paradym RF VR 9250



Cutoff date: 31-Dec-2020	Market release date	Sep-2010	Worldwide malfunctions	4
Analysis stops at 144 months	Worldwide implants	3129	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	2850	Devices without compromised therapy	2
	Estimated normal battery depletion	Not available		

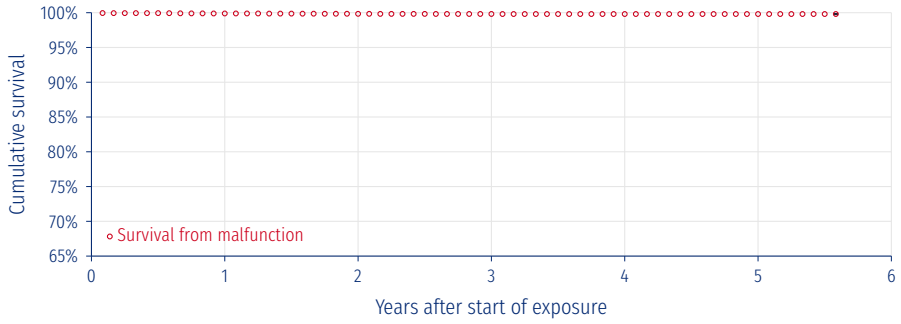
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	100	100	99.97	99.93	99.89	99.84	99.84	99.84	99.84		
Upper confidence interval (+) in %				0.03	0.05	0.08	0.10	0.10	0.10	0.10		
Lower confidence interval (-) in %				0.21	0.21	0.23	0.28	0.28	0.28	0.28		

A Field Safety Notice was issued for Paradym RF devices. Please refer to Section 6.1.7, pp. 68-71.

4.1.12 Platinium DR 1510/1540 - VR 1210/1240

Platinium DR 1510
Platinium DR 1540
Platinium VR 1210
Platinium VR 1240



Cutoff date: 31-Dec-2020	Market release date	May-2015	Worldwide malfunctions	28
Analysis stops at 72 months	Worldwide implants	18040	Devices with compromised therapy	14
or < 500 active implants	Estimated active implants	17343	Devices without compromised therapy	14
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	99.89	99.84	99.82	99.81	99.81	
Upper confidence interval (+) in %	0.04	0.05	0.06	0.06	0.06	
Lower confidence interval (-) in %	0.06	0.08	0.08	0.09	0.09	

Field Safety Notices were issued for Platinium devices. Please refer to Sections 6.1.8 to 6.1.12, pp. 72-81.

4.1.13 Implantable Cardioverter Defibrillators (ICDs) synopsis

The table presented below summarizes device information:

Models	Family	Market release date	Worldwide implants	Estimated active implants	Estimated normal batt. depletion	Worldwide malfunctions	Devices with compromised therapy	Devices without compromised therapy
Alto 2 DR 624	Alto	Jul-02	1920	1228	484	11	6	5
Alto 2 VR 625	Alto	Sep-02	784	446	241	9	7	2
Intensia DR 154, Intensia VR 124	Intensia	Nov-13 Nov-13	1609	1487	-	3	1	2
Ovatio DR 6550	Ovatio	May-05	11471	8205	2000	15	13	2
Ovatio VR 6250	Ovatio	May-05	5494	4439	445	7	5	2
Paradym DR 8550	Paradym	Nov-07	9850	8941	297	25	12	13
Paradym VR 8250	Paradym	Jun-08	5878	5207	-	16	6	10
Paradym 2 DR 8552, Paradym 2 VR 8252	Paradym 2	Jun-13 Jun-13	3184	2947	-	3	2	1
Paradym RF DR 9550	Paradym RF	Sep-10	5090	4688	73	14	5	9
Paradym RF VR 9250	Paradym RF	Sep-10	3129	2850	-	4	2	2
Platinium DR 1510, Platinium DR 1540, Platinium VR 1210, Platinium VR 1240	Platinium	May-15 May-15 May-15 May-15	18040	17343	-	28	14	14

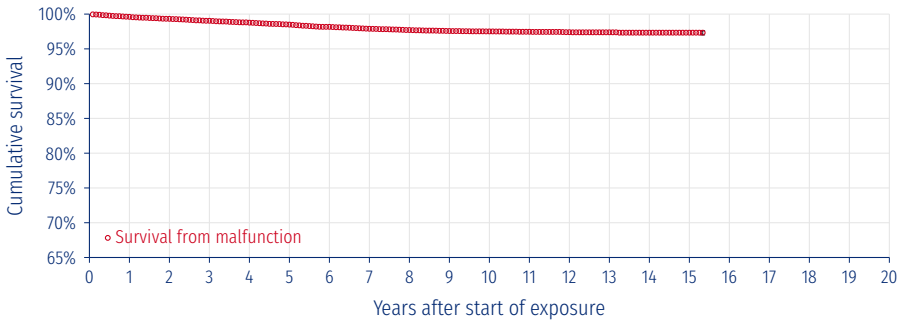
The table presented below summarizes cumulative survival probability from malfunction:

		Cumulative survival from malfunction (%) as a function of years after implant											
Models	Family	1	2	3	4	5	6	7	8	9	10	11	12
Alto 2 DR 624	Alto	99.79	99.63	99.58	99.47	99.41	99.41	99.41	99.41	99.41	99.41	99.41	99.41
Alto 2 VR 625	Alto	99.62	99.23	98.97	98.97	98.97	98.97	98.97	98.77	98.77	98.77	98.77	98.77
Intensia DR 154, Intensia VR 124	Intensia	99.94	99.87	99.87	99.87	99.81	99.81	99.81					
Ovatio DR 6550	Ovatio	99.96	99.94	99.94	99.91	99.90	99.90	99.89	99.86	99.86	99.86	99.86	99.86
Ovatio VR 6250	Ovatio	99.96	99.91	99.91	99.91	99.91	99.91	99.89	99.87	99.87	99.87	99.87	99.87
Paradym DR 8550	Paradym	99.96	99.94	99.89	99.83	99.80	99.75	99.74	99.74	99.74	99.74	99.74	99.74
Paradym VR 8250	Paradym	99.98	99.95	99.93	99.90	99.86	99.80	99.76	99.72	99.72	99.64	99.64	
Paradym 2 DR 8552, Paradym 2 VR 8252	Paradym 2	100	99.94	99.94	99.90	99.90	99.90	99.90					
Paradym RF DR 9550	Paradym RF	99.90	99.86	99.82	99.80	99.74	99.74	99.74	99.68	99.68	99.68		
Paradym RF VR 9250	Paradym RF	100	100	100	99.97	99.93	99.89	99.84	99.84	99.84	99.84		
Platinium DR 1510, Platinium DR 1540, Platinium VR 1210, Platinium VR 1240	Platinium	99.89	99.84	99.82	99.81	99.81							

4.2 Defibrillation leads

4.2.1 Isoline 2CR5 - 2CR6 - 2CT6

Isoline 2CR5
Isoline 2CR6
Isoline 2CT6



Cutoff date: 31-Dec-2020	Market release date	Dec-2005	Worldwide malfunctions 330
Analysis stops at 240 months	Worldwide implants	13446	Devices with compromised therapy 261
or < 500 active implants	Estimated active implants	11739	Devices without compromised therapy 69

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Cumulative survival from malfunction in %	99.61	99.32	99.04	98.77	98.49	98.17	97.89	97.71	97.57	97.51	97.46	97.40	97.38	97.33	97.33					
Upper confidence interval (+) in %	0.09	0.13	0.15	0.17	0.19	0.22	0.23	0.24	0.25	0.26	0.26	0.27	0.27	0.28	0.28					
Lower confidence interval (-) in %	0.12	0.16	0.18	0.20	0.22	0.24	0.26	0.27	0.28	0.28	0.29	0.30	0.30	0.32	0.32					

Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	9
Insulation Breach	1	74
Crimps, Welds, and Bonds	0	1
Other	0	0
All lead malfunctions	1	84

Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	0	1
Conductor Fracture	0	5
Lead Dislodgement	7	5
Failure to Capture	2	13
Oversensing	5	188
Failure to Sense (undersensing)	1	2
Insulation Breach	0	1
Abnormal Pacing Impedance	0	8
Abnormal Defibrillation Impedance	1	22
Extracardiac Stimulation	0	0
Other	0	0
All lead complications	16	245

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

Field Safety Notices were issued for Isoline leads. Please refer to Sections 6.3.1 to 6.3.2, pp. 97-100.

4.2.2 Vigila 1CR - 1CT - 2CR - 2CT

The Vigila lead models are reported in Biotronik's Product Performance Report[7], provided that they reach the inclusion criteria (Refer to the Vigila and Linox sections).

4.2.3 Volta 1CR - 1CT - 2CR - 2CT

The Volta lead models are/will be reported in Biotronik's Product Performance Report[7], provided that they reach the inclusion criteria (Refer to the Volta and Linox smart sections).

[7] Biotronik's PPR document is available on Biotronik's website at:
https://www.biotronik.com/en-gb/healthcare-professionals/product-performance-report

4.2.4 Defibrillation leads synopsis

The table presented below summarizes device information:

Models	Family	Market release date	Worldwide implants	Estimated active implants	Worldwide malfunctions	Devices with compromised therapy	Devices without compromised therapy	Devices returned and analyzed
Isoline 2CR5, Isoline 2CR6, Isoline 2CT6	Isoline	Dec-05 Dec-05 Dec-05	13446	11739	330	261	69	0

The table presented below summarizes cumulative survival probability from malfunction:

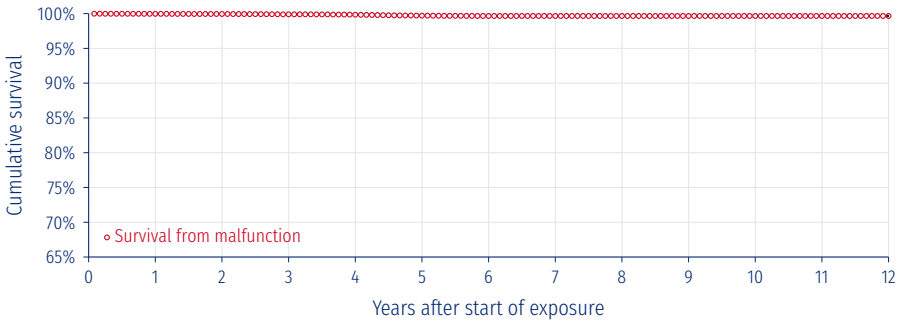
		Cumulative survival from malfunction (%) as a function of years after implant																			
Models	Family	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Isoline 2CR5, Isoline 2CR6, Isoline 2CT6	Isoline	99.61	99.32	99.04	98.77	98.49	98.17	97.89	97.71	97.57	97.51	97.46	97.40	97.38	97.33	97.33					

5 Bradycardia therapy

5.1 Pacemakers

5.1.1 Elect DR - D - VDR - SR - DRM - SRC

Elect D
Elect DR
Elect DRM
Elect SR
Elect SRC
Elect VDR



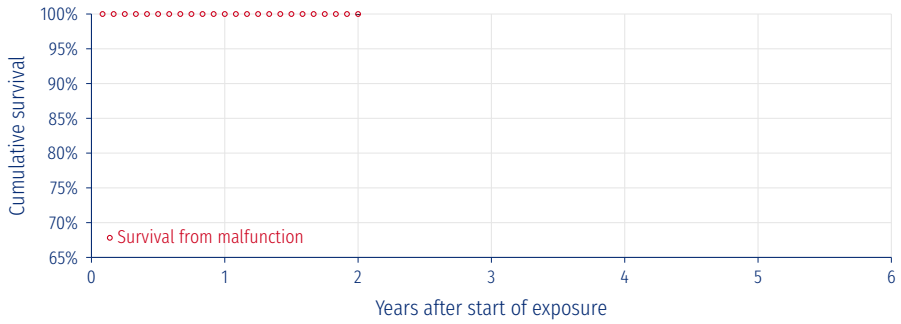
Cutoff date: 31-Dec-2020	Market release date	Jan-2001	Worldwide malfunctions	64
Analysis stops at 144 months	Worldwide implants	19715	Devices with compromised therapy	40
or < 500 active implants	Estimated active implants	16547	Devices without compromised therapy	24
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.97	99.95	99.90	99.85	99.71	99.66	99.66	99.66	99.66	99.66	99.66	99.66
Upper confidence interval (+) in %	0.02	0.02	0.04	0.05	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07
Lower confidence interval (-) in %	0.04	0.04	0.06	0.07	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09

5.1.2 ENO DR - SR

ENO DR
ENO SR



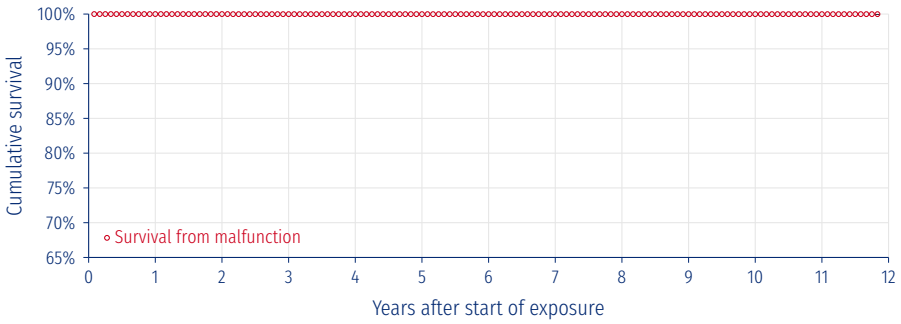
Cutoff date: 31-Dec-2020	Market release date	Dec-2018	Worldwide malfunctions	0
Analysis stops at 72 months	Worldwide implants	32339	Devices with compromised therapy	0
or < 500 active implants	Estimated active implants	32075	Devices without compromised therapy	0
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	100	100				
Upper confidence interval (+) in %						
Lower confidence interval (-) in %						

5.1.3 Esprit DR - D - SR - S

Esprit D
Esprit DR
Esprit S
Esprit SR



Cutoff date: 31-Dec-2020	Market release date	Jan-2009	Worldwide malfunctions	17
Analysis stops at 144 months	Worldwide implants	143718	Devices with compromised therapy	9
or < 500 active implants	Estimated active implants	134856	Devices without compromised therapy	8
	Estimated normal battery depletion	Not available		

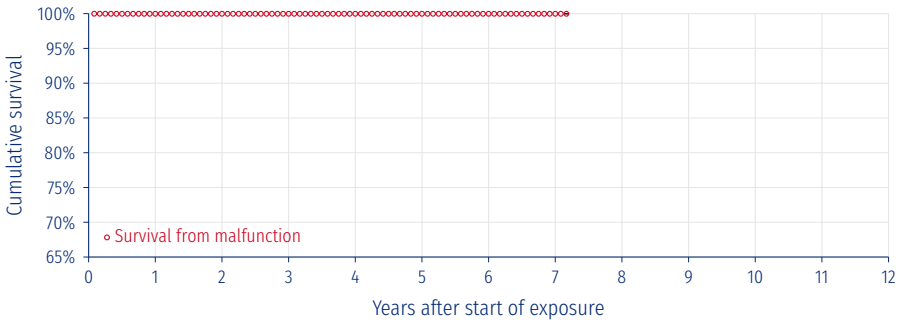
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	100	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	
Upper confidence interval (+) in %	0.00	0.00	0.00	0.00	0.00	0.01	0.01	0.01	0.01	0.01	0.01	
Lower confidence interval (-) in %	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	

Field Safety Notices were issued for Esprit devices. Please refer to Sections 6.2.4 to 6.2.6, pp. 84-91.

5.1.4 Kora 100 DR - SR

Kora 100 DR
Kora 100 SR



Cutoff date: 31-Dec-2020	Market release date	Nov-2013	Worldwide malfunctions	12
Analysis stops at 144 months	Worldwide implants	53072	Devices with compromised therapy	7
or < 500 active implants	Estimated active implants	50593	Devices without compromised therapy	5
	Estimated normal battery depletion	Not available		

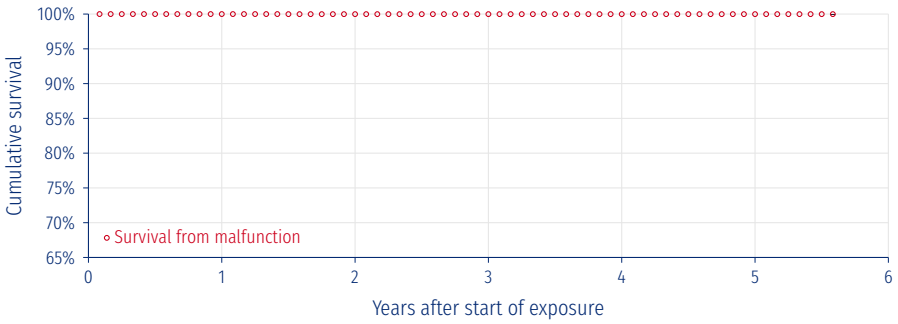
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.98	99.98	99.98	99.98	99.98	99.98	99.98					
Upper confidence interval (+) in %	0.01	0.01	0.01	0.01	0.01	0.01	0.01					
Lower confidence interval (-) in %	0.02	0.02	0.02	0.02	0.02	0.02	0.02					

A Field Safety Notice was issued for Kora devices. Please refer to Section 6.2.6, pp. 87-91.

5.1.5 Kora 250 DR - SR

Kora 250 DR
Kora 250 SR



Cutoff date: 31-Dec-2020	Market release date	Feb-2015	Worldwide malfunctions	8
Analysis stops at 72 months	Worldwide implants	127619	Devices with compromised therapy	4
or < 500 active implants	Estimated active implants	123952	Devices without compromised therapy	4
	Estimated normal battery depletion	Not available		

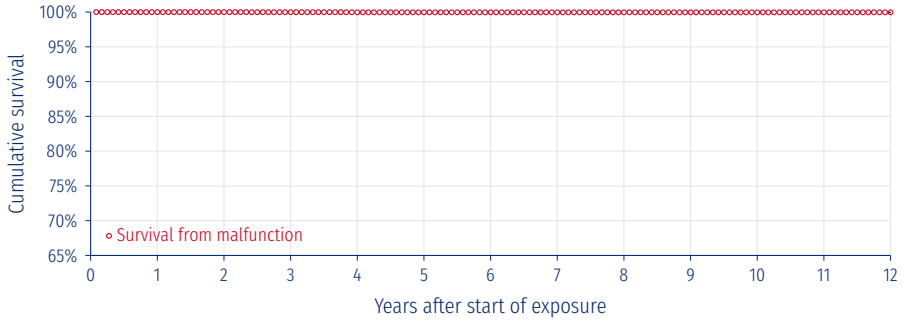
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	100	99.99	99.99	99.99	99.99	
Upper confidence interval (+) in %	0.00	0.00	0.00	0.00	0.00	
Lower confidence interval (-) in %	0.01	0.01	0.01	0.01	0.01	

A Field Safety Notice was issued for Kora devices. Please refer to Section 6.2.6, pp. 87-91.

5.1.6 Neway DR - D - SR - VDR - NewLiving CHF - DR - SR

Neway D
Neway DR
Neway SR
Neway VDR
NewLiving CHF
NewLiving DR
NewLiving SR



Cutoff date: 31-Dec-2020	Market release date	Dec-2002	Worldwide malfunctions	19
Analysis stops at 144 months	Worldwide implants	47455	Devices with compromised therapy	6
or < 500 active implants	Estimated active implants	41064	Devices without compromised therapy	13
	Estimated normal battery depletion	Not available		

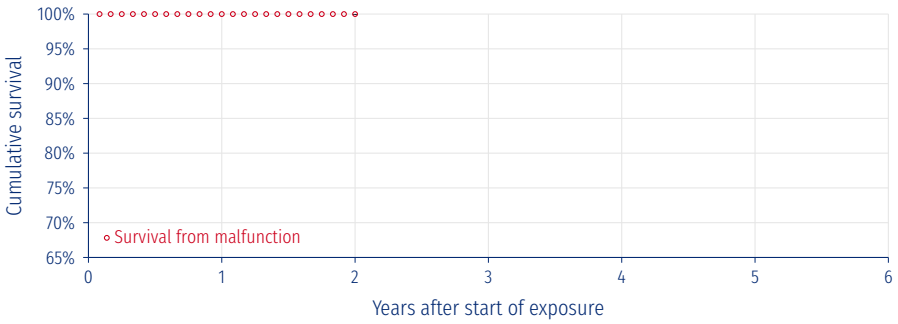
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.99	99.99	99.98	99.96	99.96	99.96	99.96	99.96	99.96	99.96	99.96	99.96
Upper confidence interval (+) in %	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Lower confidence interval (-) in %	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02

A Field Safety Notice was issued for a limited number of Neway DR devices. Please refer to Section 6.2.1, p. 82.

5.1.7 OTO DR - SR

OTO DR
OTO SR



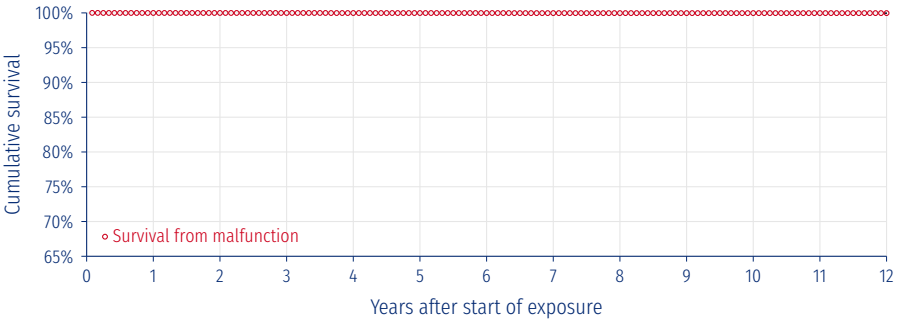
Cutoff date: 31-Dec-2020	Market release date	Dec-2018	Worldwide malfunctions	0
Analysis stops at 72 months	Worldwide implants	2985	Devices with compromised therapy	0
or < 500 active implants	Estimated active implants	2958	Devices without compromised therapy	0
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	100	100				
Upper confidence interval (+) in %						
Lower confidence interval (-) in %						

5.1.8 Reply D - VDR - Facil DR

Reply D
Reply VDR
Facil DR



Cutoff date: 31-Dec-2020	Market release date	Apr-2007	Worldwide malfunctions	7
Analysis stops at 144 months	Worldwide implants	32065	Devices with compromised therapy	5
or < 500 active implants	Estimated active implants	29932	Devices without compromised therapy	2
	Estimated normal battery depletion	Not available		

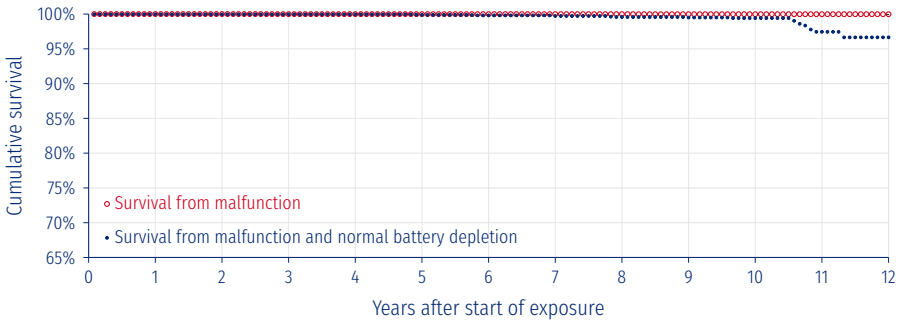
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.99	99.99	99.99	99.98	99.98	99.98	99.97	99.97	99.97	99.97	99.97	99.97
Upper confidence interval (+) in %	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Lower confidence interval (-) in %	0.02	0.02	0.02	0.02	0.02	0.03	0.03	0.03	0.03	0.03	0.03	0.03

Field Safety Notices were issued for Reply devices. Please refer to Sections 6.2.2 to 6.2.6, pp. 82-91.

5.1.9 Reply SR

Reply SR



Cutoff date: 31-Dec-2020	Market release date	Apr-2007	Worldwide malfunctions	9
Analysis stops at 144 months	Worldwide implants	63968	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	59876	Devices without compromised therapy	7
	Estimated normal battery depletion	643		

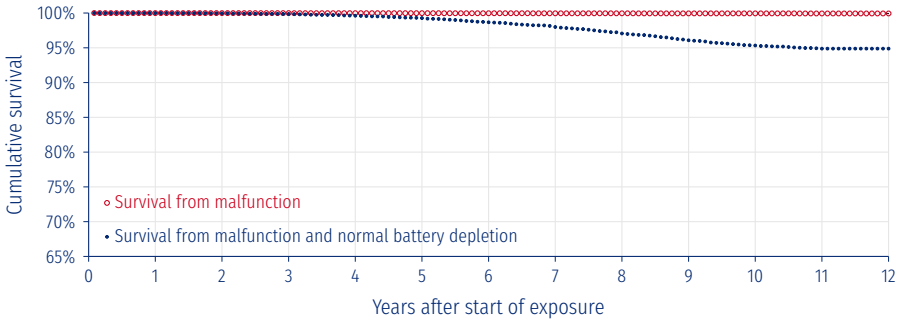
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	100	99.99	99.99	99.99	99.99	99.99	99.99	99.98	99.98	99.98	99.98
Upper confidence interval (+) in %	0.00	0.00	0.00	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Lower confidence interval (-) in %	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.02	0.02	0.02

Field Safety Notices were issued for Reply devices. Please refer to Sections 6.2.2 to 6.2.6, pp. 82-91.

5.1.10 Reply DR

Reply DR



Cutoff date: 31-Dec-2020	Market release date	Dec-2006	Worldwide malfunctions	99
Analysis stops at 144 months	Worldwide implants	223672	Devices with compromised therapy	30
or < 500 active implants	Estimated active implants	203223	Devices without compromised therapy	69
	Estimated normal battery depletion	7616		

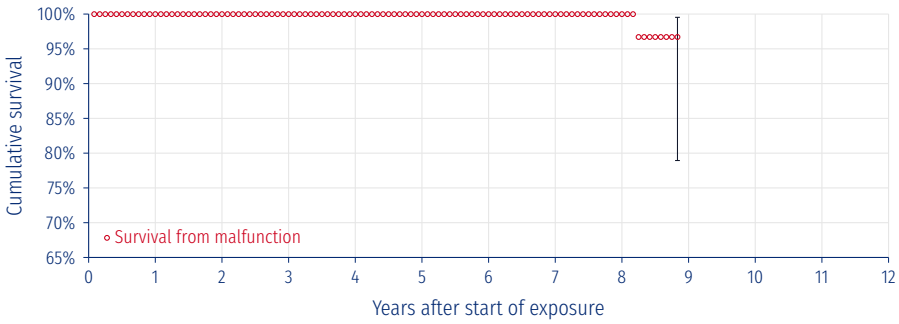
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.99	99.99	99.99	99.98	99.98	99.97	99.96	99.96	99.95	99.95	99.94	99.94
Upper confidence interval (+) in %	0.00	0.00	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Lower confidence interval (-) in %	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01

Field Safety Notices were issued for Reply devices. Please refer to Sections 6.2.2 to 6.2.6, pp. 82-91.

5.1.11 Reply 200 DR - SR

Reply 200 DR
Reply 200 SR



Cutoff date: 31-Dec-2020	Market release date	Feb-2012	Worldwide malfunctions	9
Analysis stops at 144 months	Worldwide implants	61462	Devices with compromised therapy	7
or < 500 active implants	Estimated active implants	58454	Devices without compromised therapy	2
	Estimated normal battery depletion	Not available		

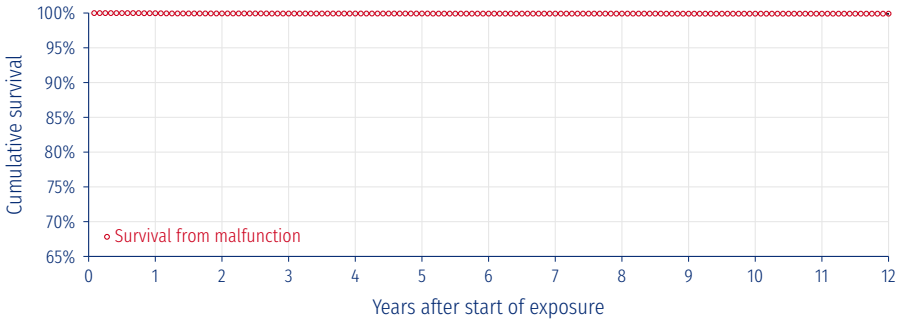
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99				
Upper confidence interval (+) in %	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01				
Lower confidence interval (-) in %	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01				

A Field Safety Notice was issued for Reply 200 devices. Please refer to Section 6.2.6, pp. 87-91.

5.1.12 Rhapsody D 2410 - S 2130

Rhapsody D 2410
Rhapsody S 2130



Cutoff date: 31-Dec-2020	Market release date	May-2003	Worldwide malfunctions	14
Analysis stops at 144 months	Worldwide implants	14126	Devices with compromised therapy	11
or < 500 active implants	Estimated active implants	12313	Devices without compromised therapy	3
	Estimated normal battery depletion	Not available		

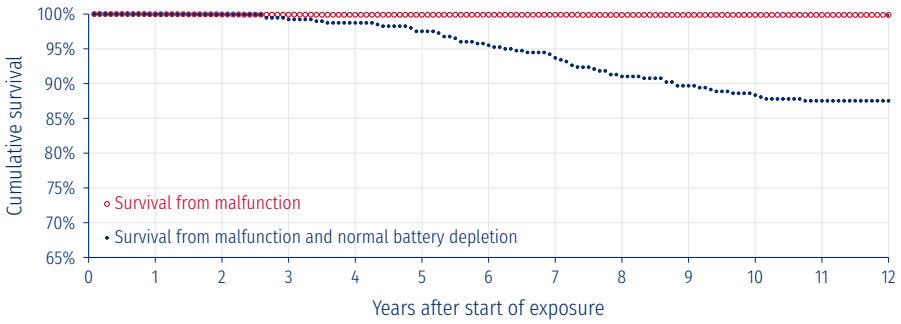
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.97	99.94	99.93	99.93	99.93	99.92	99.92	99.92	99.91	99.91	99.91	99.91
Upper confidence interval (+) in %	0.02	0.03	0.03	0.03	0.03	0.04	0.04	0.04	0.04	0.04	0.04	0.04
Lower confidence interval (-) in %	0.05	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.07	0.07	0.07	0.07

Field Safety Notice were issued for a limited number of Rhapsody devices. Please refer to Sections 6.2.7 to 6.2.9, pp. 92-96.

5.1.13 Rhapsody DR 2510

Rhapsody DR 2510



Cutoff date: 31-Dec-2020	Market release date	May-2003	Worldwide malfunctions	6
Analysis stops at 144 months	Worldwide implants	5297	Devices with compromised therapy	5
or < 500 active implants	Estimated active implants	3656	Devices without compromised therapy	1
	Estimated normal battery depletion	613		

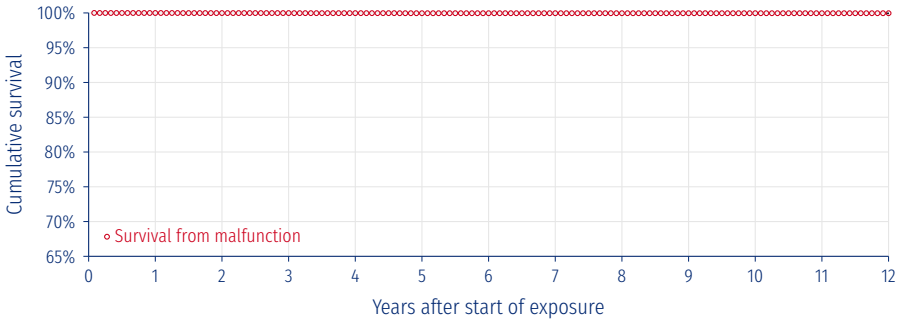
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.98	99.94	99.92	99.90	99.90	99.90	99.90	99.88	99.88	99.88	99.88	99.88
Upper confidence interval (+) in %	0.02	0.04	0.05	0.06	0.06	0.06	0.06	0.07	0.07	0.07	0.07	0.07
Lower confidence interval (-) in %	0.12	0.12	0.13	0.14	0.14	0.14	0.14	0.15	0.15	0.15	0.15	0.15

Field Safety Notices were issued for a limited number of Rhapsody devices. Please refer to Sections 6.2.7 to 6.2.9, pp. 92-96.

5.1.14 Rhapsody SR 2210

Rhapsody SR 2210



Cutoff date: 31-Dec-2020	Market release date	Jun-2003	Worldwide malfunctions	5
Analysis stops at 144 months	Worldwide implants	12138	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	10597	Devices without compromised therapy	3
	Estimated normal battery depletion	Not available		

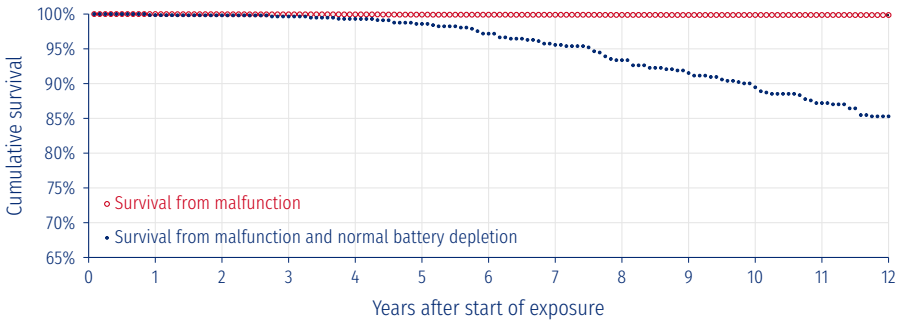
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.99	99.98	99.98	99.97	99.96	99.96	99.96	99.96	99.96	99.96	99.96	99.96
Upper confidence interval (+) in %	0.01	0.01	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Lower confidence interval (-) in %	0.05	0.05	0.05	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06

Field Safety Notices were issued for a limited number of Rhapsody devices. Please refer to Sections 6.2.7 to 6.2.9, pp. 92-96.

5.1.15 Rhapsody+ DR 2530

Rhapsody+ DR 2530



Cutoff date: 31-Dec-2020	Market release date	May-2003	Worldwide malfunctions 17
Analysis stops at 144 months	Worldwide implants	13439	Devices with compromised therapy 6
or < 500 active implants	Estimated active implants	9304	Devices without compromised therapy 11
	Estimated normal battery depletion	1793	

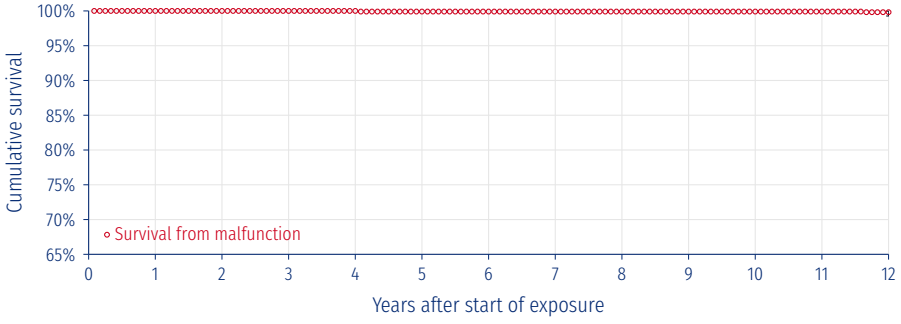
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	99.98	99.96	99.95	99.92	99.91	99.90	99.88	99.87	99.87	99.87	99.86
Upper confidence interval (+) in %		0.02	0.02	0.03	0.04	0.04	0.04	0.05	0.05	0.05	0.05	0.05
Lower confidence interval (-) in %		0.05	0.05	0.06	0.07	0.07	0.07	0.08	0.08	0.08	0.08	0.09

Field Safety Notices were issued for a limited number of Rhapsody devices. Please refer to Section 6.2.7, pp. 92-93 and Section 6.2.9, p. 96.

5.1.16 Sole SR - DR

Sole SR
Sole DR



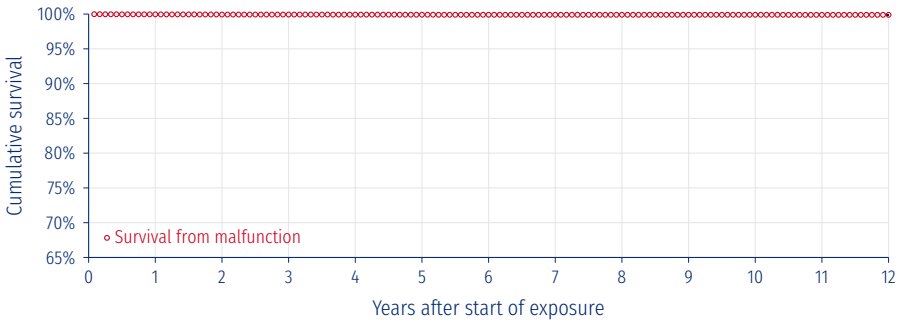
Cutoff date: 31-Dec-2020	Market release date	Mar-2002	Worldwide malfunctions 2
Analysis stops at 144 months	Worldwide implants	1178	Devices with compromised therapy 1
or < 500 active implants	Estimated active implants	1037	Devices without compromised therapy 1
	Estimated normal battery depletion	Not available	

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	100	100	100	99.91	99.91	99.91	99.91	99.91	99.91	99.91	99.82
Upper confidence interval (+) in %					0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.14
Lower confidence interval (-) in %					0.54	0.54	0.54	0.54	0.54	0.54	0.54	0.55

5.1.17 Symphony D 2450 - VDR 2350 - SOLE VDR

Symphony D 2450
Symphony VDR 2350
Sole VDR



Cutoff date: 31-Dec-2020	Market release date	Apr-2003	Worldwide malfunctions	11
Analysis stops at 144 months	Worldwide implants	10444	Devices with compromised therapy	6
or < 500 active implants	Estimated active implants	9112	Devices without compromised therapy	5
	Estimated normal battery depletion	Not available		

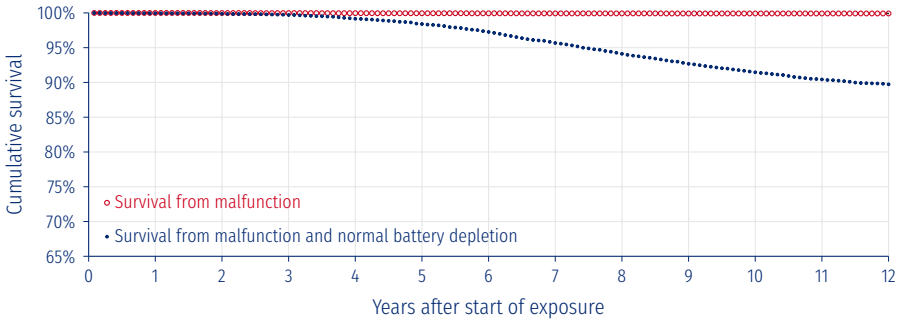
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.96	99.93	99.93	99.92	99.91	99.90	99.90	99.90	99.90	99.90	99.89	99.89
Upper confidence interval (+) in %	0.02	0.04	0.04	0.04	0.04	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Lower confidence interval (-) in %	0.06	0.07	0.07	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.09	0.09

Field Safety Notices were issued for a limited number of Symphony devices. Please refer to Sections 6.2.9 to 6.2.10, p. 96.

5.1.18 Symphony DR 2550

Symphony DR 2550



Cutoff date: 31-Dec-2020	Market release date	Mar-2002	Worldwide malfunctions	87
Analysis stops at 144 months	Worldwide implants	113739	Devices with compromised therapy	30
or < 500 active implants	Estimated active implants	89982	Devices without compromised therapy	57
	Estimated normal battery depletion	11489		

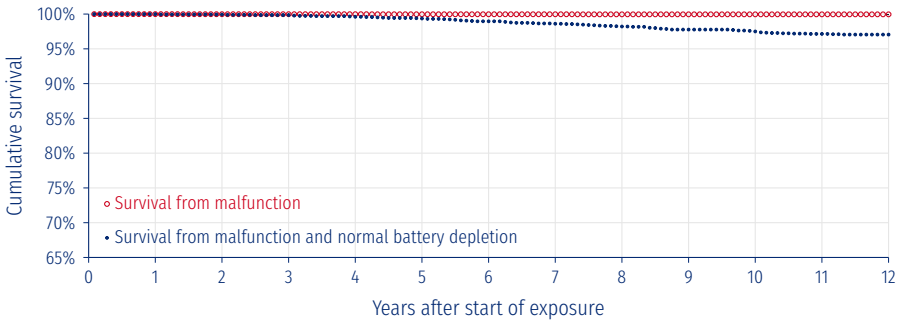
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.99	99.98	99.97	99.96	99.95	99.94	99.93	99.93	99.92	99.92	99.92	99.92
Upper confidence interval (+) in %	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.02	0.02
Lower confidence interval (-) in %	0.01	0.01	0.01	0.01	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02

Field Safety Notices were issued for a limited number of Symphony devices. Please refer to Sections 6.2.7 to 6.2.10, pp. 92-96.

5.1.19 Symphony SR 2250

Symphony SR 2250



Cutoff date: 31-Dec-2020	Market release date	Oct-2002	Worldwide malfunctions	11
Analysis stops at 144 months	Worldwide implants	30440	Devices with compromised therapy	4
or < 500 active implants	Estimated active implants	25607	Devices without compromised therapy	7
	Estimated normal battery depletion	995		

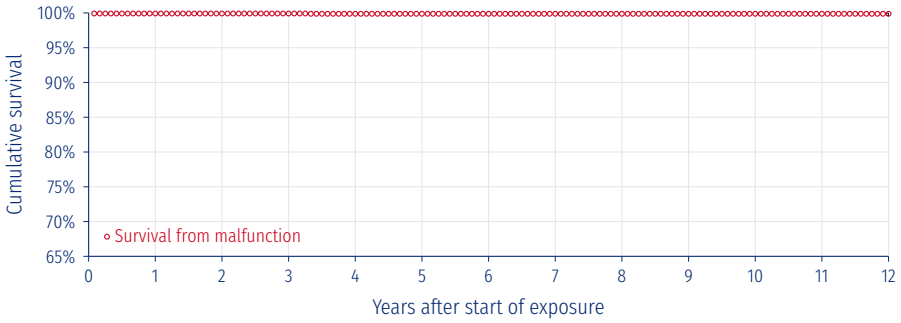
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.99	99.98	99.98	99.98	99.97	99.97	99.97	99.96	99.96	99.96	99.96	99.96
Upper confidence interval (+) in %	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.02	0.02	0.02	0.02	0.02
Lower confidence interval (-) in %	0.02	0.02	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03

Field Safety Notices were issued for a limited number of Symphony devices. Please refer to Section 6.2.7, pp. 92-93, Section 6.2.9, p. 96 and Section 6.2.10, p. 96.

5.1.20 Talent AF 243

Talent AF 243



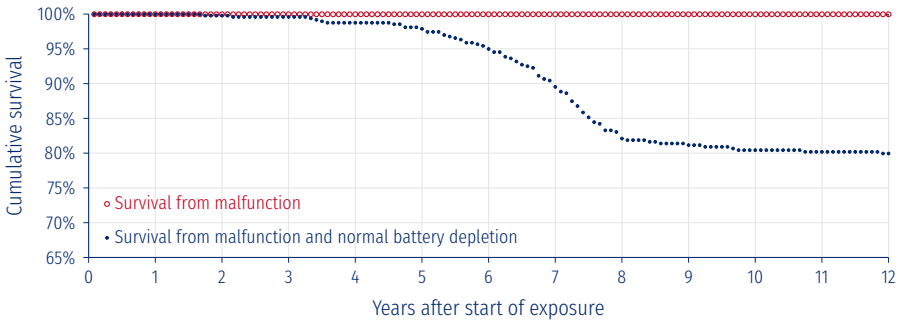
Cutoff date: 31-Dec-2020	Market release date	Mar-2001	Worldwide malfunctions	3
Analysis stops at 144 months	Worldwide implants	2557	Devices with compromised therapy	1
or < 500 active implants	Estimated active implants	2149	Devices without compromised therapy	2
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.92	99.92	99.92	99.88	99.88	99.88	99.88	99.88	99.88	99.88	99.88	99.88
Upper confidence interval (+) in %	0.06	0.06	0.06	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08
Lower confidence interval (-) in %	0.23	0.23	0.23	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25

5.1.21 Talent II SR 133

Talent II SR 133



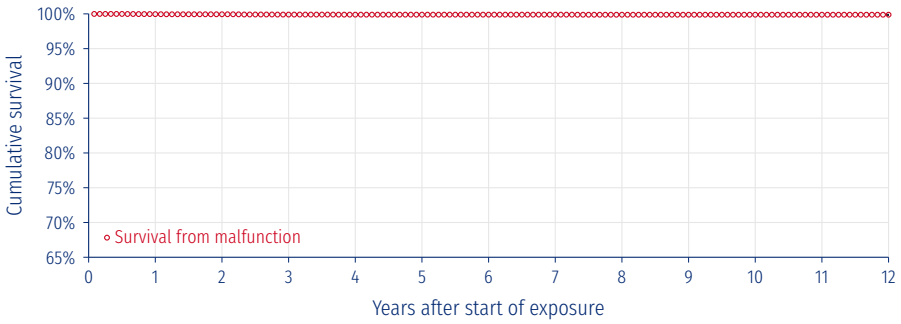
Cutoff date: 31-Dec-2020	Market release date	Sep-2001	Worldwide malfunctions	2
Analysis stops at 144 months	Worldwide implants	6558	Devices with compromised therapy	1
or < 500 active implants	Estimated active implants	4021	Devices without compromised therapy	1
	Estimated normal battery depletion	1184		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.98	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97
Upper confidence interval (+) in %	0.01	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Lower confidence interval (-) in %	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09

5.1.22 Talent 3 DR 253 - VDR 263

Talent 3 DR 253
Talent 3 VDR 263



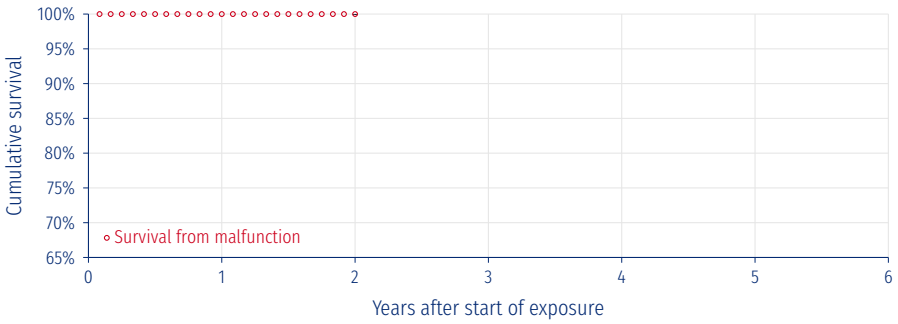
Cutoff date: 31-Dec-2020	Market release date	Jul-2002	Worldwide malfunctions	12
Analysis stops at 144 months	Worldwide implants	9938	Devices with compromised therapy	8
or < 500 active implants	Estimated active implants	8494	Devices without compromised therapy	4
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.96	99.94	99.90	99.89	99.89	99.89	99.89	99.88	99.88	99.88	99.88	99.88
Upper confidence interval (+) in %	0.03	0.03	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Lower confidence interval (-) in %	0.07	0.07	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09

5.1.23 TEO DR - SR

TEO DR
TEO SR



Cutoff date: 31-Dec-2020	Market release date	Dec-2018	Worldwide malfunctions	0
Analysis stops at 72 months	Worldwide implants	12689	Devices with compromised therapy	0
or < 500 active implants	Estimated active implants	12580	Devices without compromised therapy	0
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	100	100				
Upper confidence interval (+) in %						
Lower confidence interval (-) in %						

5.1.24 Pacemakers synopsis

The table presented below summarizes device information:

Models	Family	Market release date	Worldwide implants	Estimated active implants	Estimated normal batt. depletion	Worldwide malfunctions	Devices with compromised therapy	Devices without compromised therapy
Elect D, Elect DR, Elect DRM, Elect SR, Elect SRC, Elect VDR	Elect	Jan-01 Apr-01 Apr-01 Apr-01 Apr-01 Apr-01	19715	16547	-	64	40	24
ENO DR, ENO SR	ENO	Dec-18 Dec-18	32339	32075	-	0	0	0
Esprit D, Esprit DR, Esprit S, Esprit SR	Esprit	Jan-09 Jan-09 Jan-09 Jan-09	143718	134856	-	17	9	8
Kora 100 DR, Kora 100 SR	Kora 100	Nov-13 Nov-13	53072	50593	-	12	7	5
Kora 250 DR, Kora 250 SR	Kora 250	Feb-15 Feb-15	127619	123952	-	8	4	4
Neway D, Neway DR, Neway SR, Neway VDR, NewLiving CHF, NewLiving DR, NewLiving SR	Neway	Feb-03 Dec-02 Feb-03 Feb-03 Feb-05 Dec-04 Aug-05	47455	41064	-	19	6	13
OTO DR, OTO SR	OTO	Dec-18 Dec-18	2985	2958	-	0	0	0
Reply D, Reply VDR, Facil DR	Reply	Apr-07 Apr-07 Apr-07	32065	29932	-	7	5	2
Reply SR	Reply	Apr-07	63968	59876	643	9	2	7
Reply DR	Reply	Dec-06	223672	203223	7616	99	30	69
Reply 200 DR, Reply 200 SR	Reply 200	Feb-12 Feb-12	61462	58454	-	9	7	2
Rhapsody D 2410, Rhapsody S 2130	Rhapsody	May-03 Jun-03	14126	12313	-	14	11	3
Rhapsody DR 2510	Rhapsody	May-03	5297	3656	613	6	5	1
Rhapsody SR 2210	Rhapsody	Jun-03	12138	10597	-	5	2	3
Rhapsody+ DR 2530	Rhapsody	May-03	13439	9304	1793	17	6	11
Sole SR, Sole DR	Sole	Oct-02 Mar-02	1178	1037	-	2	1	1
Symphony D 2450, Symphony VDR 2350, Sole VDR	Symphony	Apr-03 Apr-03 Apr-03	10444	9112	-	11	6	5
Symphony DR 2550	Symphony	Mar-02	113739	89982	11489	87	30	57
Symphony SR 2250	Symphony	Oct-02	30440	25607	995	11	4	7
Talent AF 243	Talent	Mar-01	2557	2149	-	3	1	2
Talent II SR 133	Talent	Sep-01	6558	4021	1184	2	1	1
Talent 3 DR 253, Talent 3 VDR 263	Talent	Jul-02 Dec-02	9938	8494	-	12	8	4
TEO DR, TEO SR	TEO	Dec-18 Dec-18	12689	12580	-	0	0	0

5.1 Pacemakers

« Go back to Table of Contents

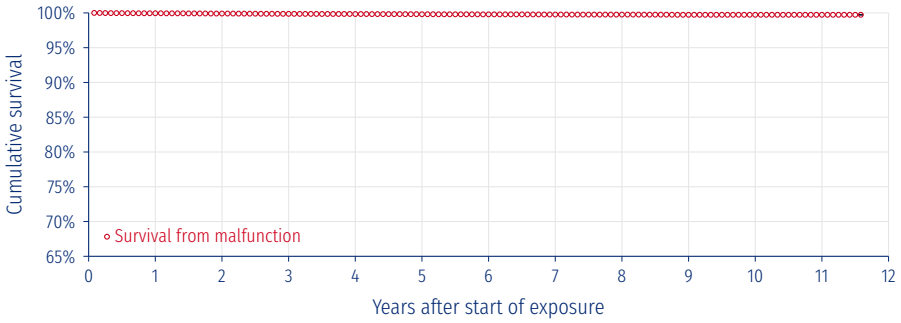
The table presented below summarizes cumulative survival probability from malfunction:

		Cumulative survival from malfunction (%) as a function of years after implant											
Models	Family	1	2	3	4	5	6	7	8	9	10	11	12
Elect D, Elect DR, Elect DRM, Elect SR, Elect SRC, Elect VDR	Elect	99.97	99.95	99.90	99.85	99.71	99.66	99.66	99.66	99.66	99.66	99.66	99.66
ENO DR, ENO SR	ENO	100	100										
Esprit D, Esprit DR, Esprit S, Esprit SR	Esprit	100.00	100.00	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	
Kora 100 DR, Kora 100 SR	Kora 100	99.98	99.98	99.98	99.98	99.98	99.98	99.98					
Kora 250 DR, Kora 250 SR	Kora 250	100.00	99.99	99.99	99.99	99.99							
Neway D, Neway DR, Neway SR, Neway VDR, NewLiving CHF, NewLiving DR, NewLiving SR	Neway	99.99	99.99	99.98	99.96	99.96	99.96	99.96	99.96	99.96	99.96	99.96	99.96
OTO DR, OTO SR	OTO	100	100										
Reply D, Reply VDR, Facil DR	Reply	99.99	99.99	99.99	99.98	99.98	99.98	99.97	99.97	99.97	99.97	99.97	99.97
Reply SR	Reply	100.00	100.00	99.99	99.99	99.99	99.99	99.99	99.99	99.98	99.98	99.98	99.98
Reply DR	Reply	99.99	99.99	99.99	99.98	99.98	99.97	99.96	99.96	99.95	99.95	99.94	99.94
Reply 200 DR, Reply 200 SR	Reply 200	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99				
Rhapsody D 2410, Rhapsody S 2130	Rhapsody	99.97	99.94	99.93	99.93	99.93	99.92	99.92	99.92	99.91	99.91	99.91	99.91
Rhapsody DR 2510	Rhapsody	99.98	99.94	99.92	99.90	99.90	99.90	99.90	99.88	99.88	99.88	99.88	99.88
Rhapsody SR 2210	Rhapsody	99.99	99.98	99.98	99.97	99.96	99.96	99.96	99.96	99.96	99.96	99.96	99.96
Rhapsody+ DR 2530	Rhapsody	100	99.98	99.96	99.95	99.92	99.91	99.90	99.88	99.87	99.87	99.87	99.86
Sole SR, Sole DR	Sole	100	100	100	100	99.91	99.91	99.91	99.91	99.91	99.91	99.91	99.82
Symphony D 2450, Symphony VDR 2350, Sole VDR	Symphony	99.96	99.93	99.93	99.92	99.91	99.90	99.90	99.90	99.90	99.90	99.89	99.89
Symphony DR 2550	Symphony	99.99	99.98	99.97	99.96	99.95	99.94	99.93	99.93	99.92	99.92	99.92	99.92
Symphony SR 2250	Symphony	99.99	99.98	99.98	99.98	99.97	99.97	99.97	99.96	99.96	99.96	99.96	99.96
Talent AF 243	Talent	99.92	99.92	99.92	99.88	99.88	99.88	99.88	99.88	99.88	99.88	99.88	99.88
Talent II SR 133	Talent	99.98	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97
Talent 3 DR 253, Talent 3 VDR 263	Talent	99.96	99.94	99.90	99.89	99.89	99.89	99.89	99.88	99.88	99.88	99.88	99.88
TEO DR, TEO SR	TEO	100	100										

5.2 Pacing leads

5.2.1 Beflex RF45D - RF46D

Beflex RF45D
Beflex RF46D



Cutoff date: 31-Dec-2020	Market release date	Dec-2009	Worldwide malfunctions 232
Analysis stops at 144 months	Worldwide implants	137650	Devices with compromised therapy 146
or < 500 active implants	Estimated active implants	121524	Devices without compromised therapy 86

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant												
Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.95	99.91	99.87	99.84	99.81	99.79	99.77	99.76	99.73	99.73	99.73	
Upper confidence interval (+) in %	0.01	0.02	0.02	0.02	0.02	0.03	0.03	0.03	0.04	0.04	0.04	
Lower confidence interval (-) in %	0.01	0.02	0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05	0.05	

Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	0
Insulation Breach	2	62
Crimps, Welds, and Bonds	0	0
Other	0	0
All lead malfunctions	2	62

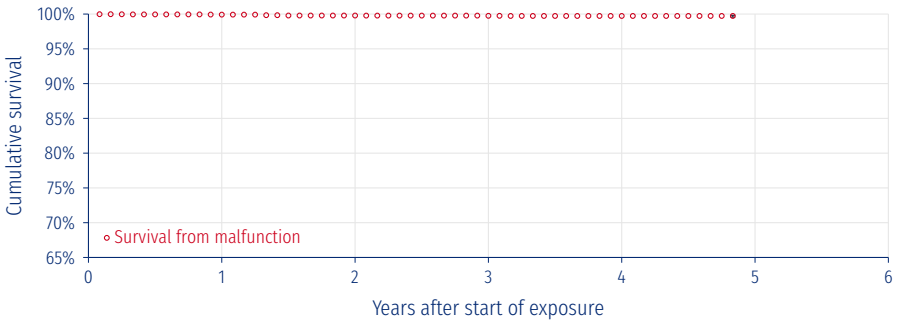
Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	66	4
Conductor Fracture	0	1
Lead Dislodgement	94	12
Failure to Capture	101	67
Oversensing	5	72
Failure to Sense (undersensing)	4	1
Insulation Breach	0	4
Abnormal Pacing Impedance	3	5
Abnormal Defibrillation Impedance	0	0
Extracardiac Stimulation	0	2
Other	0	0
All lead complications	273	168

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

Note that the survival curve for this product includes data from leads that were involved in pre-market clinical studies.

5.2.2 Petite 44 ERJB - 52 ERB - 52 ERJB - 52 RJB - 58 ERB - 58 RB

Petite 44 ERJB
Petite 52 ERB
Petite 52 ERJB
Petite 52 RJB
Petite 58 ERB
Petite 58 RB



Cutoff date: 31-Dec-2020	Market release date	Feb-2016	Worldwide malfunctions 16
Analysis stops at 72 months	Worldwide implants	6086	Devices with compromised therapy 9
or < 500 active implants	Estimated active implants	5565	Devices without compromised therapy 7

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant						
Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	99.92	99.79	99.75	99.73		
Upper confidence interval (+) in %	0.05	0.09	0.10	0.10		
Lower confidence interval (-) in %	0.12	0.15	0.16	0.17		

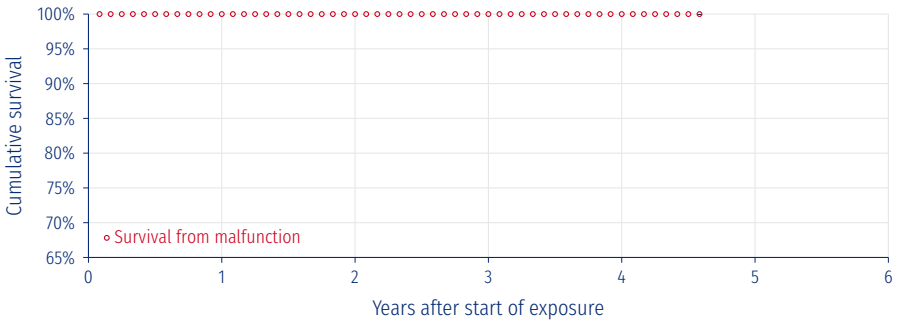
Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	0
Insulation Breach	0	1
Crimps, Welds, and Bonds	0	0
Other	0	0
All lead malfunctions	0	1

Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	1	0
Conductor Fracture	0	0
Lead Dislodgement	24	3
Failure to Capture	4	3
Oversensing	0	5
Failure to Sense (undersensing)	0	1
Insulation Breach	0	0
Abnormal Pacing Impedance	0	3
Abnormal Defibrillation Impedance	0	0
Extracardiac Stimulation	0	0
Other	0	0
All lead complications	29	15

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

5.2.3 PY2 52 ENV - 52 ER - 52 RU - 58 ENV - 58 ER - 58 RU

PY2 52 ENV
PY2 52 ER
PY2 52 RU
PY2 58 ENV
PY2 58 ER
PY2 58 RU

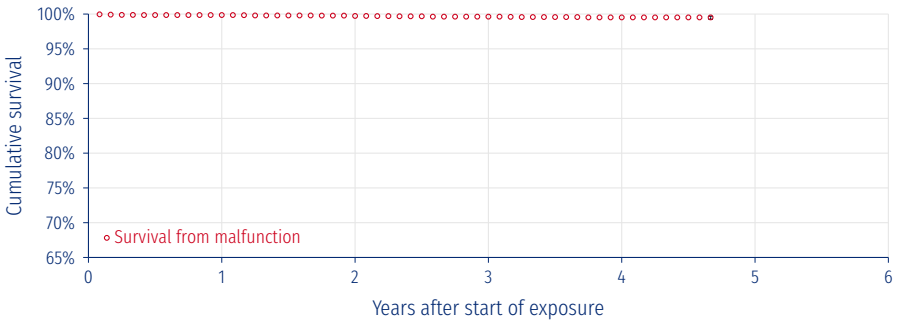


Cutoff date: 31-Dec-2020	Market release date	Feb-2016	Worldwide malfunctions	0
Analysis stops at 72 months	Worldwide implants	4790	Devices with compromised therapy	0
or < 500 active implants	Estimated active implants	4458	Devices without compromised therapy	0

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant						
Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	100	100	100	100		
Upper confidence interval (+) in %						
Lower confidence interval (-) in %						

5.2.4 Screwvine 44 - 52 - 58

Screwvine 44
Screwvine 52
Screwvine 58



Cutoff date: 31-Dec-2020	Market release date	Jun-2016	Worldwide malfunctions	20
Analysis stops at 72 months	Worldwide implants	4974	Devices with compromised therapy	14
or < 500 active implants	Estimated active implants	4540	Devices without compromised therapy	6

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant						
Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	99.86	99.73	99.63	99.52		
Upper confidence interval (+) in %	0.07	0.11	0.14	0.17		
Lower confidence interval (-) in %	0.15	0.20	0.22	0.27		

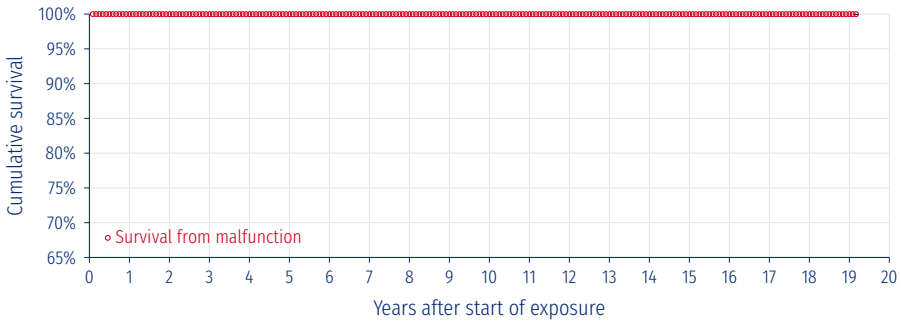
Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	0
Insulation Breach	1	2
Crimps, Welds, and Bonds	0	0
Other	0	0
All lead malfunctions	1	2

Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	0	0
Conductor Fracture	0	0
Lead Dislodgement	3	1
Failure to Capture	2	6
Oversensing	0	10
Failure to Sense (undersensing)	0	0
Insulation Breach	0	0
Abnormal Pacing Impedance	1	0
Abnormal Defibrillation Impedance	0	0
Extracardiac Stimulation	0	0
Other	0	0
All lead complications	6	17

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

5.2.5 Stelid II BJF24D - BJF25D

Stelid II BJF24D
Stelid II BJF25D



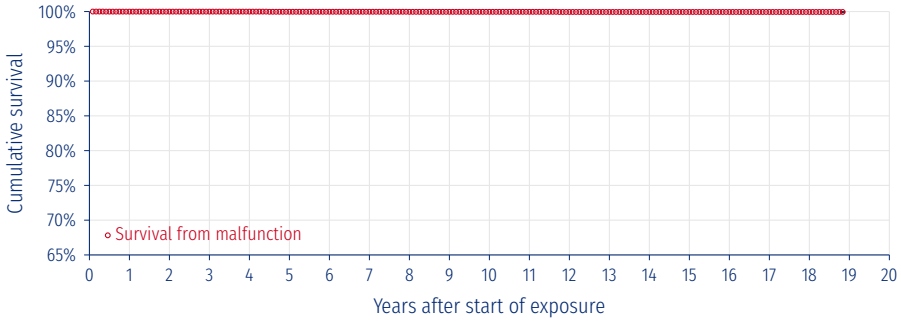
Cutoff date: 31-Dec-2020	Market release date	Feb-2001	Worldwide malfunctions	3
Analysis stops at 240 months	Worldwide implants	38620	Devices with compromised therapy	1
or < 500 active implants	Estimated active implants	28159	Devices without compromised therapy	2

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Cumulative survival from malfunction in %	100	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	
Upper confidence interval (+) in %	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
Lower confidence interval (-) in %	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	

5.2.6 Stelix II BRF24D - BRF25D - BRF26D

Stelix II BRF24D
Stelix II BRF25D
Stelix II BRF26D



Cutoff date: 31-Dec-2020	Market release date	Dec-2001	Worldwide malfunctions	4
Analysis stops at 240 months	Worldwide implants	7893	Devices with compromised therapy	3
or < 500 active implants	Estimated active implants	5693	Devices without compromised therapy	1

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Cumulative survival from malfunction in %	99.99	99.99	99.99	99.99	99.97	99.97	99.97	99.96	99.96	99.96	99.96	99.94	99.94	99.94	99.94	99.94	99.94	99.94		
Upper confidence interval (+) in %	0.01	0.01	0.01	0.01	0.02	0.02	0.02	0.03	0.03	0.03	0.03	0.04	0.04	0.04	0.04	0.04	0.04	0.04		
Lower confidence interval (-) in %	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.09	0.09	0.09	0.09	0.11	0.11	0.11	0.11	0.11	0.11	0.11		

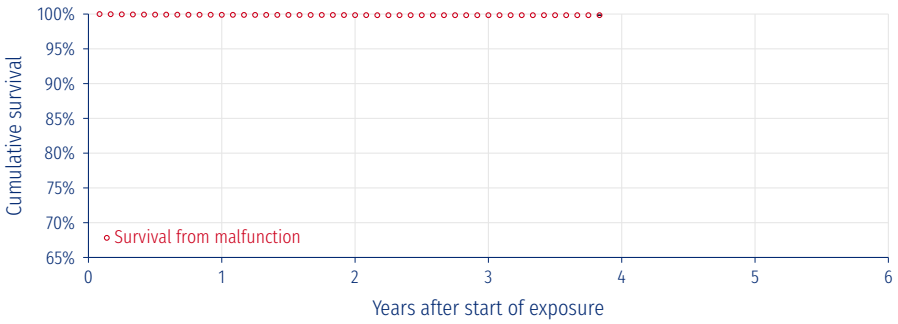
5.2.7 Tilda JT - R - T

The Tilda lead models are reported in Biotronik's Product Performance Report[8], provided that they reach the inclusion criteria (Refer to the Tilda and Selox/Setrox sections).

[8] Biotronik's PPR document is available on Biotronik's website at:
https://www.biotronik.com/en-gb/healthcare-professionals/product-performance-report

5.2.8 Vega R45 - R52 - R58

Vega R45
Vega R52
Vega R58



Cutoff date: 31-Dec-2020	Market release date	Apr-2017	Worldwide malfunctions	97
Analysis stops at 72 months	Worldwide implants	79018	Devices with compromised therapy	32
or < 500 active implants	Estimated active implants	75471	Devices without compromised therapy	65

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant						
Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	99.89	99.85	99.84			
Upper confidence interval (+) in %	0.02	0.03	0.03			
Lower confidence interval (-) in %	0.03	0.03	0.04			

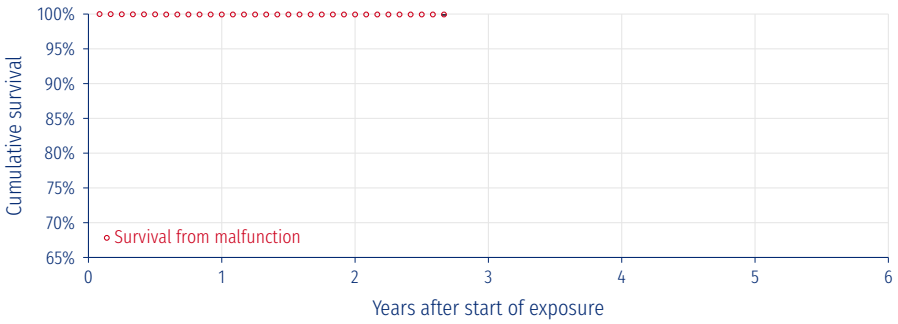
Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	0
Insulation Breach	3	12
Crimps, Welds, and Bonds	0	0
Other	0	0
All lead malfunctions	3	12

Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	56	12
Conductor Fracture	0	0
Lead Dislodgement	75	20
Failure to Capture	53	35
Oversensing	3	13
Failure to Sense (undersensing)	0	1
Insulation Breach	0	0
Abnormal Pacing Impedance	2	1
Abnormal Defibrillation Impedance	0	0
Extracardiac Stimulation	0	0
Other	0	0
All lead complications	189	82

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

5.2.9 XFine JX24D - JX25D

XFine JX24D
XFine JX25D



Cutoff date: 31-Dec-2020	Market release date	Apr-2018	Worldwide malfunctions	4
Analysis stops at 72 months	Worldwide implants	7544	Devices with compromised therapy	1
or < 500 active implants	Estimated active implants	7295	Devices without compromised therapy	3

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant						
Years after implant	1	2	3	4	5	6
Cumulative survival from malfunction in %	99.94	99.94				
Upper confidence interval (+) in %	0.04	0.04				
Lower confidence interval (-) in %	0.10	0.10				

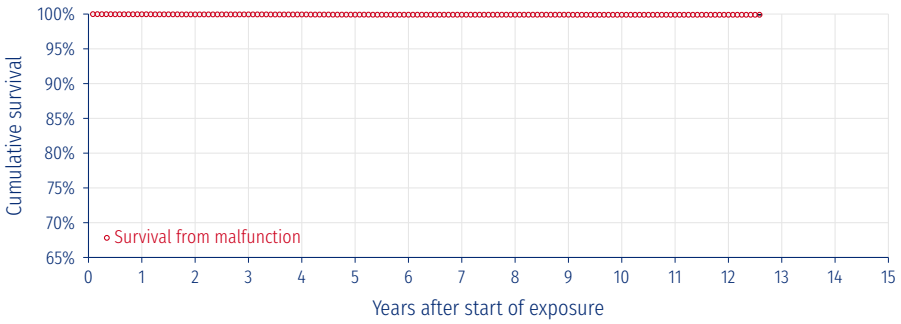
Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	0
Insulation Breach	0	0
Crimps, Welds, and Bonds	0	0
Other	0	0
All lead malfunctions	0	0

Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	0	0
Conductor Fracture	0	0
Lead Dislodgement	15	2
Failure to Capture	4	2
Oversensing	0	0
Failure to Sense (undersensing)	0	0
Insulation Breach	0	0
Abnormal Pacing Impedance	0	0
Abnormal Defibrillation Impedance	0	0
Extracardiac Stimulation	0	0
Other	0	0
All lead complications	19	4

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

5.2.10 XFine TX25D - TX26D

XFine TX25D
XFine TX26D



Cutoff date: 31-Dec-2020	Market release date	Apr-2008	Worldwide malfunctions 40
Analysis stops at 180 months	Worldwide implants	53898	Devices with compromised therapy 31
or < 500 active implants	Estimated active implants	46134	Devices without compromised therapy 9

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Cumulative survival from malfunction in %	99.97	99.95	99.95	99.94	99.92	99.91	99.91	99.91	99.91	99.90	99.90	99.90			
Upper confidence interval (+) in %	0.01	0.02	0.02	0.02	0.02	0.03	0.03	0.03	0.03	0.03	0.03	0.03			
Lower confidence interval (-) in %	0.02	0.02	0.02	0.03	0.03	0.03	0.04	0.04	0.04	0.04	0.04	0.04			

Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	1	2
Insulation Breach	0	4
Crimps, Welds, and Bonds	0	0
Other	0	0
All lead malfunctions	1	6

Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	0	1
Conductor Fracture	0	2
Lead Dislodgement	6	2
Failure to Capture	6	17
Oversensing	0	7
Failure to Sense (undersensing)	0	0
Insulation Breach	0	0
Abnormal Pacing Impedance	0	4
Abnormal Defibrillation Impedance	0	0
Extracardiac Stimulation	0	0
Other	0	0
All lead complications	12	33

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

5.2.11 Pacing leads synopsis

The table presented below summarizes device information:

Models	Family	Market release date	Worldwide implants	Estimated active implants	Worldwide malfunctions	Devices with compromised therapy	Devices without compromised therapy	Devices returned and analyzed
Beflex RF45D, Beflex RF46D	Beflex	Dec-09 Dec-09	137650	121524	232	146	86	0
Petite 44 ERJB, Petite 52 ERB, Petite 52 ERJB, Petite 52 RJB, Petite 58 ERB, Petite 58 RB	Petite	May-16 Jun-16 Mar-16 Feb-16 Jun-16 Feb-16	6086	5565	16	9	7	0
PY2 52 ENV, PY2 52 ER, PY2 52 RU, PY2 58 ENV, PY2 58 ER, PY2 58 RU	PY2	Apr-16 Apr-16 Feb-16 Apr-16 Apr-16 May-16	4790	4458	0	0	0	0
Screwvine 44, Screwvine 52, Screwvine 58	Screwvine	Jun-16 Jun-16 Jun-16	4974	4540	20	14	6	0
Stelid II BJF24D, Stelid II BJF25D	Stelid	Feb-01 Feb-01	38620	28159	3	1	2	N/A*
Stelix II BRF24D, Stelix II BRF25D, Stelix II BRF26D	Stelid	Dec-01 Dec-01 Dec-01	7893	5693	4	3	1	N/A*
Vega R45, Vega R52, Vega R58	Vega	Apr-17 Apr-17 Apr-17	79018	75471	97	32	65	0
XFine JX24D, XFine JX25D	XFine	Apr-18 Apr-18	7544	7295	4	1	3	0
XFine TX25D, XFine TX26D	XFine	Apr-08 Apr-08	53898	46134	40	31	9	0

*Only available for our most recent models

5.2 Pacing leads

« Go back to Table of Contents

The table presented below summarizes cumulative survival probability from malfunction:

		Cumulative survival from malfunction (%) as a function of years after implant																			
Models	Family	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Beflex RF45D, Beflex RF46D	Beflex	99.95	99.91	99.87	99.84	99.81	99.79	99.77	99.76	99.73	99.73	99.73									
Petite 44 ERJB, Petite 52 ERB, Petite 52 ERJB, Petite 52 RJB, Petite 58 ERB, Petite 58 RB	Petite	99.92	99.79	99.75	99.73																
PY2 52 ENV, PY2 52 ER, PY2 52 RU, PY2 58 ENV, PY2 58 ER, PY2 58 RU	PY2	100	100	100	100																
Screwvine 44, Screwvine 52, Screwvine 58	Screwvine	99.86	99.73	99.63	99.52																
Stelid II BJF24D, Stelid II BJF25D	Stelid	100.00	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	99.99	
Stelix II BRF24D, Stelix II BRF25D, Stelix II BRF26D	Stelid	99.99	99.99	99.99	99.99	99.97	99.97	99.97	99.96	99.96	99.96	99.96	99.94	99.94	99.94	99.94	99.94	99.94	99.94		
Vega R45, Vega R52, Vega R58	Vega	99.89	99.85	99.84																	
XFine JX24D, XFine JX25D	XFine	99.94	99.94																		
XFine TX25D, XFine TX26D	XFine	99.97	99.95	99.95	99.94	99.92	99.91	99.91	99.91	99.91	99.90	99.90	99.90								

6 Field Safety Notices and product advisories

6.1 Cardioverter defibrillators

6.1.1 Alto and Alto 2, Group 1

Original date of Field Safety Notice: February 2004

Field Safety Notice description

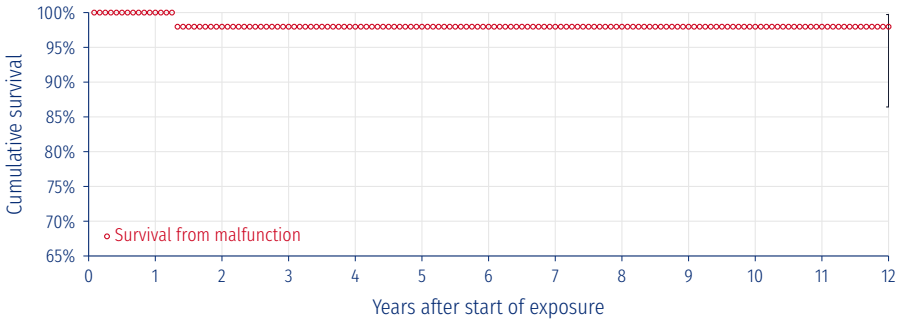
A Field Safety Notice was issued for this group of devices that were manufactured before April 17, 2003 (Group 1). The notification states that premature battery depletion and/or prolonged charge time can occur due to metal migration, in a limited number of Alto and Alto 2 implantable cardioverter defibrillators (models DR 614, VR 615, MSP 617, DR 624, and VR 625). Premature battery depletion and/or prolonged charge time can result in unavailability of pacing, cardioversion, and defibrillation therapy. This condition can occur between two follow-up visits. No permanent adverse effect on a patient's health has been reported.

Patient recommendations

The notification recommends strictly observing a follow-up interval of three (3) months for these devices, in conformance with recommendations provided in the user's manual. Depending on the circumstances, those patients known to have frequent recent episodes of ventricular fibrillation might be at greater risk if the device does not perform as expected between follow-up visits. Those patients could require prophylactic explantation or more frequent visits. Other patients, including pacemaker-dependent patients, could also benefit from prophylactic explantation or more frequent visits.

Alto MSP 617 Group 1

Alto MSP 617 - GR 1



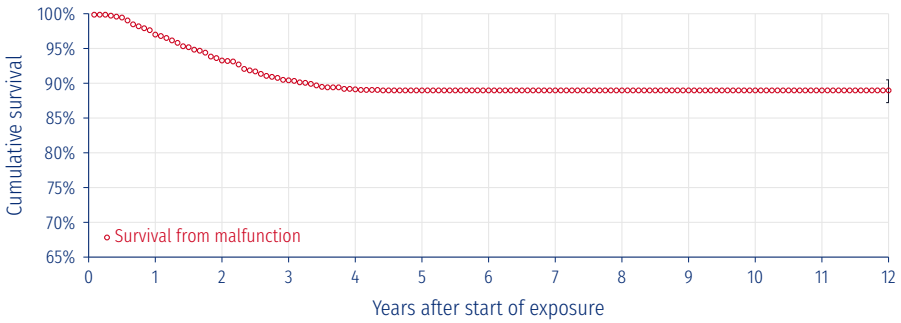
Cutoff date: 31-Dec-2020	Market release date	Jun-2002	Worldwide malfunctions	1
Analysis stops at 144 months	Worldwide implants	50	Devices with compromised therapy	0
or < 500 active implants	Estimated active implants	39	Devices without compromised therapy	1
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	97.97	97.97	97.97	97.97	97.97	97.97	97.97	97.97	97.97	97.97	97.97
Upper confidence interval (+) in %		1.75	1.75	1.75	1.75	1.75	1.75	1.75	1.75	1.75	1.75	1.75
Lower confidence interval (-) in %		11.54	11.54	11.54	11.54	11.54	11.54	11.54	11.54	11.54	11.54	11.54

Alto 2 DR 624 - Alto DR 614 Group 1

Alto DR 614 - GR 1
Alto 2 DR 624 - GR 1



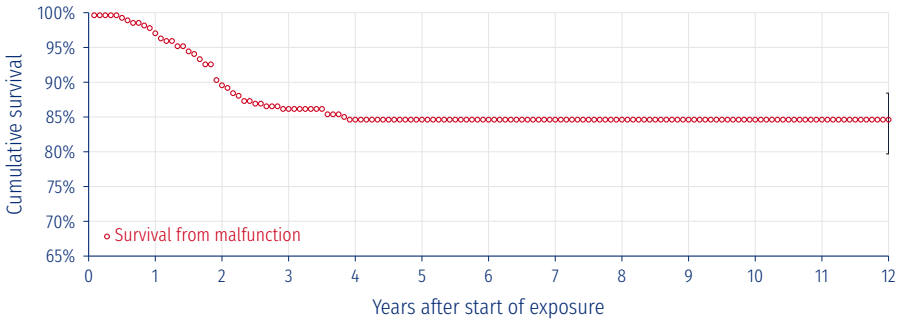
Cutoff date: 31-Dec-2020	Market release date	Jan-2001	Worldwide malfunctions	156
Analysis stops at 144 months	Worldwide implants	1448	Devices with compromised therapy	88
or < 500 active implants	Estimated active implants	1012	Devices without compromised therapy	68
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	97.00	93.27	90.42	89.12	88.97	88.97	88.97	88.97	88.97	88.97	88.97	88.97
Upper confidence interval (+) in %	0.77	1.19	1.42	1.51	1.52	1.52	1.52	1.52	1.52	1.52	1.52	1.52
Lower confidence interval (-) in %	1.02	1.43	1.65	1.74	1.75	1.75	1.75	1.75	1.75	1.75	1.75	1.75

Alto 2 VR 625 - Alto VR 615 Group 1

Alto VR 615 - GR 1
Alto 2 VR 625 - GR 1



Cutoff date: 31-Dec-2020	Market release date	May-2002	Worldwide malfunctions	41
Analysis stops at 144 months	Worldwide implants	273	Devices with compromised therapy	24
or < 500 active implants	Estimated active implants	182	Devices without compromised therapy	17
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	97.04	89.56	86.16	84.62	84.62	84.62	84.62	84.62	84.62	84.62	84.62	84.62
Upper confidence interval (+) in %	1.47	3.11	3.61	3.81	3.81	3.81	3.81	3.81	3.81	3.81	3.81	3.81
Lower confidence interval (-) in %	2.87	4.32	4.75	4.92	4.92	4.92	4.92	4.92	4.92	4.92	4.92	4.92

6.1.2 Alto and Alto 2, Group 2

Original date of Field Safety Notice: July 2005

Field Safety Notice description

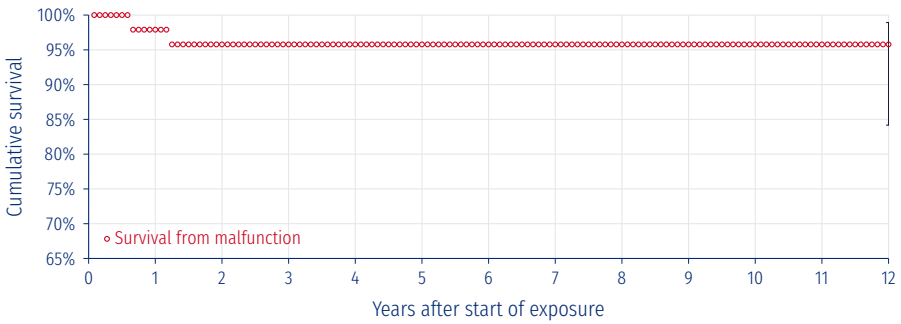
The Field Safety Notice described above for Group 1 was extended to this second group of devices manufactured from April 17, 2003 through July 31, 2003 (Group 2). No permanent adverse effect on a patient's health has been reported in this group.

Patient recommendations

The Field Safety Notice recommends strictly observing a follow-up interval of three (3) months for these devices, in conformance with recommendations provided in the user's manual. Depending on the circumstances, those patients known to have frequent recent episodes of ventricular fibrillation might be at greater risk if the device does not perform as expected between follow-up visits. Those patients could require prophylactic explantation or more frequent visits. Other patients, including pacemaker-dependent patients, could also benefit from prophylactic explantation or more frequent visits.

Alto MSP 617 Group 2

Alto MSP 617 - GR 2



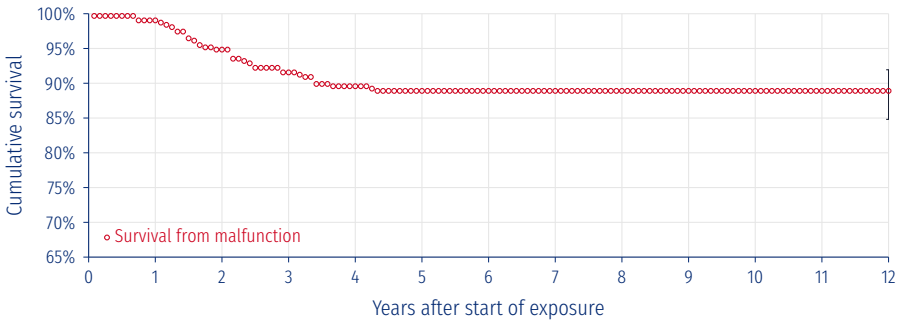
Cutoff date: 31-Dec-2020	Market release date	Jun-2002	Worldwide malfunctions	2
Analysis stops at 144 months	Worldwide implants	48	Devices with compromised therapy	0
or < 500 active implants	Estimated active implants	37	Devices without compromised therapy	2
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	97.90	95.78	95.78	95.78	95.78	95.78	95.78	95.78	95.78	95.78	95.78	95.78
Upper confidence interval (+) in %	1.80	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15
Lower confidence interval (-) in %	11.89	11.61	11.61	11.61	11.61	11.61	11.61	11.61	11.61	11.61	11.61	11.61

Alto 2 DR 624 - Alto DR 614 Group 2

Alto DR 614 - GR 2
Alto 2 DR 624 - GR 2



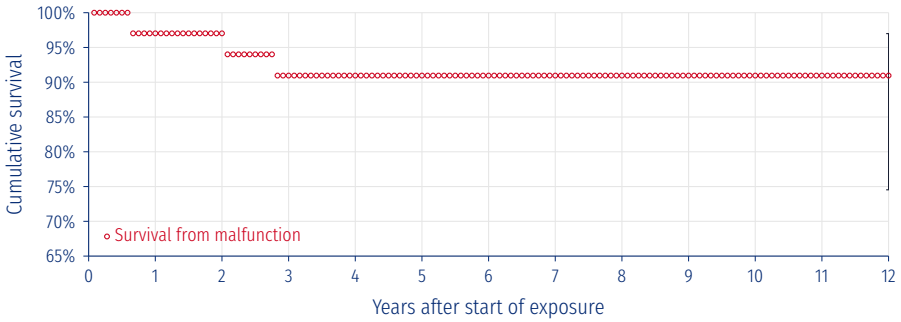
Cutoff date: 31-Dec-2020	Market release date	Jan-2001	Worldwide malfunctions	34
Analysis stops at 144 months	Worldwide implants	315	Devices with compromised therapy	18
or < 500 active implants	Estimated active implants	224	Devices without compromised therapy	16
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.04	94.84	91.56	89.57	88.90	88.90	88.90	88.90	88.90	88.90	88.90	88.90
Upper confidence interval (+) in %	0.65	1.97	2.61	2.94	3.04	3.04	3.04	3.04	3.04	3.04	3.04	3.04
Lower confidence interval (-) in %	1.98	3.13	3.71	4.00	4.09	4.09	4.09	4.09	4.09	4.09	4.09	4.09

Alto 2 VR 625 - Alto VR 615 Group 2

Alto VR 615 - GR 2
Alto 2 VR 625 - GR 2



Cutoff date: 31-Dec-2020	Market release date	May-2002	Worldwide malfunctions	3
Analysis stops at 144 months	Worldwide implants	34	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	26	Devices without compromised therapy	1
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	97.03	97.03	90.96	90.96	90.96	90.96	90.96	90.96	90.96	90.96	90.96	90.96
Upper confidence interval (+) in %	2.54	2.54	6.03	6.03	6.03	6.03	6.03	6.03	6.03	6.03	6.03	6.03
Lower confidence interval (-) in %	16.28	16.28	16.43	16.43	16.43	16.43	16.43	16.43	16.43	16.43	16.43	16.43

6.1.3 Alto and Alto 2, Group 3

Original date of Field Safety Notice: July 2005

Field Safety Notice description

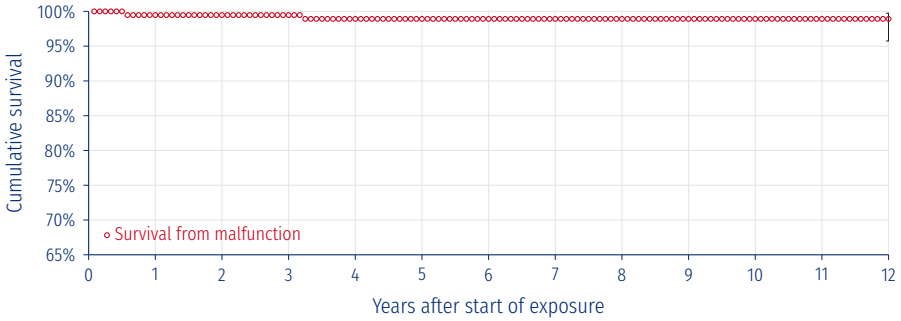
The Field Safety Notice described above for Group 1 was extended to this third group of devices, manufactured from August 2003 through August 2004 (Group 3). No permanent adverse effect on a patient's health has been reported in this group. Although a Field Safety Notice was issued for this group, performance compares favorably with published data indicating that the average malfunction rate for all ICDs was approximately 1% per year[9].

Patient recommendations

In Group 3, the Field Safety Notice recommends strictly observing a follow-up interval of three (3) months for these devices, in conformance with recommendations provided in the user's manual.

Alto 2 MSP 627 - Alto MSP 617 Group 3

Alto MSP 617 - GR 3
Alto 2 MSP 627 - GR 3



Cutoff date: 31-Dec-2020	Market release date	Jun-2002	Worldwide malfunctions	2
Analysis stops at 144 months	Worldwide implants	190	Devices with compromised therapy	2
or < 500 active implants	Estimated active implants	151	Devices without compromised therapy	0
	Estimated normal battery depletion	Not available		

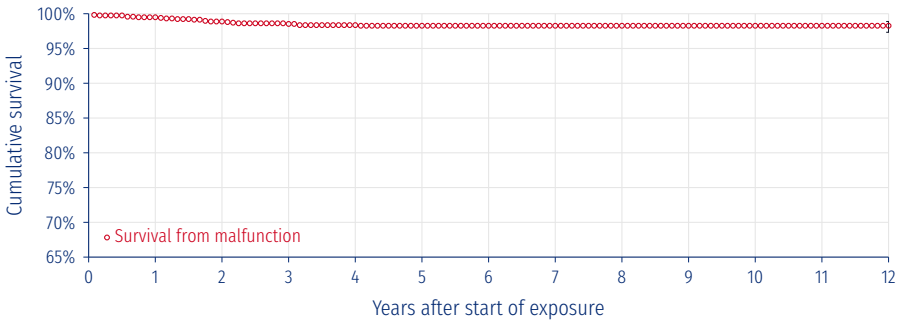
Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.47	99.47	99.47	98.92	98.92	98.92	98.92	98.92	98.92	98.92	98.92	98.92
Upper confidence interval (+) in %	0.46	0.46	0.46	0.81	0.81	0.81	0.81	0.81	0.81	0.81	0.81	0.81
Lower confidence interval (-) in %	3.17	3.17	3.17	3.17	3.17	3.17	3.17	3.17	3.17	3.17	3.17	3.17

[9] Maisel WH. Pacemaker and ICD Generator Malfunctions. Policy Conference on Pacemaker and ICD Performance presented by the Heart Rhythm Society and the Food and Drug Administration. September 16, 2005.

Alto 2 DR 624 - Alto DR 614 Group 3

Alto DR 614 - GR 3
Alto 2 DR 624 - GR 3



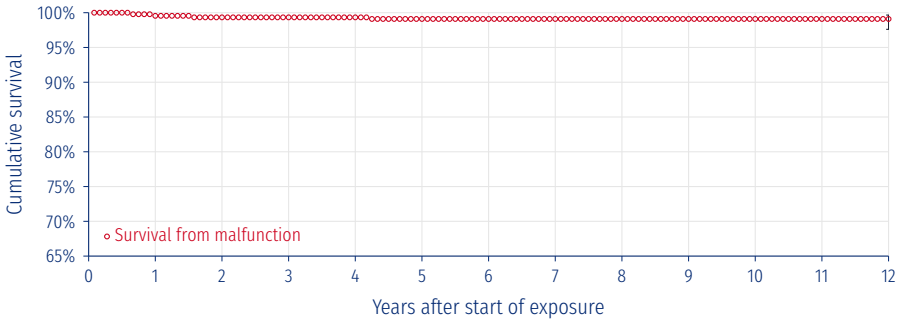
Cutoff date: 31-Dec-2020	Market release date	Jan-2001	Worldwide malfunctions 20
Analysis stops at 144 months	Worldwide implants	1179	Devices with compromised therapy 15
or < 500 active implants	Estimated active implants	930	Devices without compromised therapy 5
	Estimated normal battery depletion	Not available	

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.49	98.88	98.53	98.36	98.27	98.27	98.27	98.27	98.27	98.27	98.27	98.27
Upper confidence interval (+) in %	0.28	0.47	0.55	0.59	0.61	0.61	0.61	0.61	0.61	0.61	0.61	0.61
Lower confidence interval (-) in %	0.62	0.80	0.88	0.92	0.94	0.94	0.94	0.94	0.94	0.94	0.94	0.94

Alto 2 VR 625 - Alto VR 615 Group 3

Alto VR 615 - GR 3
Alto 2 VR 625 - GR 3



Cutoff date: 31-Dec-2020	Market release date	May-2002	Worldwide malfunctions 4
Analysis stops at 144 months	Worldwide implants	453	Devices with compromised therapy 3
or < 500 active implants	Estimated active implants	360	Devices without compromised therapy 1
	Estimated normal battery depletion	Not available	

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.55	99.33	99.33	99.33	99.10	99.10	99.10	99.10	99.10	99.10	99.10	99.10
Upper confidence interval (+) in %	0.33	0.45	0.45	0.45	0.56	0.56	0.56	0.56	0.56	0.56	0.56	0.56
Lower confidence interval (-) in %	1.33	1.40	1.40	1.40	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49

6.1.4 Paradym DR, Paradym CRT-D and Paradym CRT-D SonR

Original date of Field Safety Notice: June 2010

Field Safety Notice description

A Field Safety Notice was issued for a rare software anomaly in Paradym DR 8550, CRT 8750 and CRT SonR 8770 device models. The issue is not related to any device component malfunction. A software update will be available to correct the issue.

The notification stated that this software anomaly could occur only under a rare and specific sequence of events:

- First, the criteria to charge the shock capacitors (due to a ventricular arrhythmia) and the criteria to mode switch (due to an atrial arrhythmia) are met exactly at the same time;
- Second, the device delivers a shock (*e.g.* due to a sustained ventricular arrhythmia).

In the unlikely event that both of these conditions occur, the indicated devices will lose the ability to sense/pace and to deliver further therapy.

A software update has eliminated this risk. The new software was automatically downloaded during next interrogation with programmer software version Smartview 2.22 in Europe / Smartview 2.22UG1 in the US.

Patient recommendations

Revised programmer software (Smartview 2.22 in Europe / Smartview 2.22UG1 in the U.S.)[10] for Orchestra programmer has been distributed to correct this rare software anomaly.

[10] Correction released in June 2010 in Europe, Japan and the US

6.1.5 Paradym ICDs and PhD feature

Original date of Field Safety Notice: April 2011

Field Safety Notice description

A Field Safety Notice was issued in relation to potential pacing inhibition with Paradym ICDs, when the PhD feature is programmed ON and when the device is connected to high-polarization defibrillation leads. The notification is not related to any ICD device component malfunction.

PhD is a follow-up monitoring feature based on Minute Ventilation (MV) information, which is measured through the ventricular defibrillation lead. Measurements are displayed by the programmer under the "PhD-Clinical Status" screen. This feature is automatically activated when the shock therapy is programmed ON. The notification stated that ventricular oversensing associated with the PhD feature could result in bradycardia episodes or syncope; no permanent injury or death has occurred as a result of the identified anomaly.

Ventricular oversensing was related to Minute Ventilation (MV) pulse current injection, as observed on the intra-cardiac EGMs; when oversensing was sustained, pacing was inhibited.

There was no risk of inappropriate ATP or shock therapy; as soon as a Ventricular Fibrillation (VF) or Fast Ventricular Tachycardia (Fast VT) is detected, the PhD feature is temporarily switched OFF to confirm presence or absence of an arrhythmia, until slow rhythm is recovered:

- If the VF / Fast VT is confirmed, ATP or shock therapy is delivered based on the programmed device settings.
- If not, no therapy is delivered.

When the PhD feature was reprogrammed OFF, the oversensing phenomenon did not recur.

During laboratory testing, Sorin CRM reproduced the issue and observed ventricular oversensing due to the PhD feature when the Paradym ICD was connected to defibrillation leads from several manufacturers, including Sorin CRM previous generation defibrillation leads. When oversensing was reproduced with a specific lead model, high-polarization was measured for that lead. When PhD was programmed OFF, no such oversensing occurred.

Potentially affected units

In the U.S. and Canada, PhD is available in Paradym CRT-D 8770 only; therefore the notification does not affect the other Paradym models in those countries.

Outside the U.S. and Canada, Paradym VR 8250, DR 8550, CRT-D 8750 and 8770 are affected by this notice.

The PhD feature was not available in previous Sorin CRM ICDs, which are therefore not affected by this notice.

Patient management recommendations

Since it is not possible to provide a determination whether a specific lead is a high-polarization lead the following recommendations were provided:

- **For patients with affected devices: 1)** Patient and device programming records should be reviewed for each patient with an affected device to determine if the patient is pacemaker-dependent and the PhD feature is programmed ON or OFF; **2)** If the PhD feature is programmed ON and the patient is pacemaker-dependent, Sorin CRM recommends that a prompt follow-up be scheduled to switch OFF the PhD feature in order to eliminate the risk of pacing inhibition.

- **For future implants:** Sorin CRM recommends that PhD feature be programmed OFF for pacemaker-dependent patients in order to eliminate the risk of pacing inhibition.

A software update to automatically switch OFF PhD upon device interrogation was developed (Smartview 2.28) and made available by the end of July 2011[11] . This software update also removed the PhD feature from all new Paradym devices. For Paradym models included in the Clepsydra clinical study, this software upgrade was made available at the end of the study. This has eliminated the risk of pacing inhibition due to oversensing associated with the PhD feature.

6.1.6 Paradym CRT-D Patient Booklets in US and Canada

Original date of the advisory: April 2011

Advisory description

This product advisory was issued in relation to the inclusion of an incorrect Patient Booklet[12] into the commercial packaging of a limited number of Paradym DR & Paradym VR ICD models distributed in the US and in Canada. The Patient Booklet of Paradym CRT-D model (ICD with resynchronization therapy) was packaged with Paradym DR and VR ICD models manufactured by Sorin CRM for the US and Canada. 491 devices were shipped to the US and 37 devices to Canada with the incorrect Patient Booklet.

It is important to note that only the Patient Booklet's version was incorrect: the device packaging included the proper Physician's Implant Manual and device identification labels.

The issue is not related to any safety consideration and did not involve any risk to patients.

Corrections implemented

The company determined that there is no risk of adverse event associated with this labeling error: contents of the Paradym CRT-D Patient Booklet mostly differ from the contents of Paradym DR and VR ICDs Patient Booklet by additional informative data included in the CRT-D Patient Booklet about heart failure disease and associated therapies, which do not apply to patients implanted with an ICD. Importantly there is no difference regarding the information about patient recommendations (hospital discharge, follow-up visits, unit replacement, warnings and precautions, etc.) and user assistance information[13].

For affected units that were not yet implanted (*i.e.* units either still in the Sorin CRM warehouse, or in trunk locations of Sorin CRM field representatives, or in hospital inventory), Sorin CRM instructed its field representatives to attach the correct Patient Booklet as an addendum to the device's external packaging, along with a cover letter explaining the discrepancy.

[11] SmartView 2.28 released in July 2011 in Europe
SmartView 2.28J released in July 2011 in Japan
SmartView 2.34UG1 released in March 2013 in US
SmartView 2.40UG2 released in March 2014 in Canada

[12] The Patient Booklet is provided to the patient after implant of the defibrillation system (ICD and lead(s)). This booklet contains various informative materials such as:
- Information about the heart's functioning, its diseases and associated therapies
- Instructions to the patient : recommendations, warnings, precautions, hazards, contacts, ...
- Information on the implanted system (description, serial numbers, ...)

[13] User assistance information: On the last page of the Patient Booklet, the physician or the hospital staff can fill a blank form to provide the patient with information on his/her device, such as device serial number, physician references, medications, etc.

6.1.7 Ovatio, Paradym, Paradym RF, Paradym 2 and Intensia – Undetectable battery depletion in the event of recurrent shock capacitor charging

Original date of Field Safety Notice: April 2017

Field Safety Notice description

In the event of a right ventricular lead issue (*e.g.* broken or disconnected lead), recurrent shock capacitor charging due to ventricular oversensing may result in depletion of the ICD or CRT-D battery. Because the battery status is not updated for a 24-hour period following a charge, battery depletion may remain undetectable during the 24 hours following the last charge. Recurrent charging will stop either after deactivation of the shock therapies, or when the oversensing stops, such as in the case of a lead revision.

Annex 1 provides a list of warnings and observations that can potentially be displayed in case of a lead issue or battery depletion.

If an updated battery status is not obtained prior to the lead revision, the need for an ICD or CRT-D replacement cannot be assessed. If the battery is found to be depleted after the lead revision, adequate therapy may not be available and the patient may have to undergo another surgical procedure to replace the ICD or CRT-D.

Patient recommendations

If you have decided to revise the right ventricular lead due to oversensing issues, the following steps should be taken:

- Prior to lead revision:
  - o Deactivate the shock therapies to avoid further charging[14],
  - o Wait 24 hours[14], and
  - o Re-interrogate the ICD or CRT-D to check the updated battery status. If RRT is reached, initiate a device replacement.

  Or
- If it is not possible to wait 24 hours prior to replacing the lead, the lead revision may be performed as scheduled and the device may be replaced prophylactically during the same procedure since the battery status is unknown.

[14] These operations should be performed by medical personnel in an appropriate care unit, with resuscitation equipment present, and after having weighed the benefit/risks for the patient.

Annex 1

List of potential warnings

Ovatio[15]	Paradym family[16]	Paradym RF family[17]	RMS[18]	Warnings/Observations potentially displayed by the programmer or received through the Remote Monitoring System
X	X			[2] Charge time > 40 s: x. Defibrillation system potentially ineffective.
X	X	X		[3] Low shock impedance. Defibrillation system potentially ineffective.
X				Load resistance of last shock < 0 ohm
X	X	X	X	[4] Last shock impedance > 150 ohms. Defibrillation system potentially ineffective.
X	X			[6] Ventricular lead impedance < 200 ohms: x Defibrillation system potentially ineffective.
		X	X	[6] Ventricular lead impedance < x ohms: x, x/x/x. Defibrillation system potentially ineffective.
X	X			[7] Right ventricular lead impedance < 200 ohms: x Defibrillation system potentially ineffective.
		X	X	[7] RV lead impedance < x ohms: x, x/x/x. Defibrillation system potentially ineffective.
X	X			[8] Left ventricular lead impedance < 200 ohms: x
		X	X	[8] LV lead impedance < x ohms: x, x/x/x.
X	X			[10] Ventricular lead impedance > 3000 ohms: Defibrillation system potentially ineffective.
		X	X	[10] Ventricular lead impedance > x ohms: x, x/x/x. Defibrillation system potentially ineffective.
X	X			[11] Right ventricular lead impedance > 3000 ohms: Defibrillation system potentially ineffective.
		X	X	[11] RV lead impedance > x ohms: x, x/x/x. Defibrillation system potentially ineffective.
X	X			[12] Left ventricular lead impedance > 3000 ohms
		X	X	[12] LV lead impedance > x ohms: x, x/x/x.
		X	X	[14] RV shock electrode continuity > 3000 Ohms x/x/x. Defibrillation system potentially ineffective.
	X			[15] Ventricular shock electrode continuity > 3000 Ohms: defibrillation system ineffective.
X				[16] Ventricular shock electrode continuity ABNORMAL : defibrillation system potentially ineffective.
X	X	X	X	[17] Battery depletion detected (end of life indicator): replace the device. Magnet rate (min^{-1}) : x
X				[18] ERI (Elective Replacement Indicator) detected: plan to replace device. Magnet rate (min^{-1}) : x
	X	X	X	[18] R.R.T. (Recommended Replacement Time) detected: plan to replace device.
X	X	X		[19] Abnormal battery voltage values from x/x/x to x/x/x. Defibrillation system potentially ineffective.
X	X	X		[20] Abnormal battery voltage measured since x/x/x. Defibrillation system potentially ineffective.
X				[28] Last battery voltage measurement abnormal.
	X	X		[29] Last battery voltage measurement abnormal.
X	X			[34] Last charge time (s): x. Defibrillation system ineffective.
X	X			[35] Max energy charge time > 40 s: x Defibrillation system potentially ineffective.
X	X			[37] Last saved ventricular lead impedance < 200 ohms: x (x x x), defibrillation system potentially ineffective.
X	X			[38] Last saved right ventricular lead impedance < 200 ohms: x (x x x), defibrillation system potentially ineffective.
X	X			[39] Last saved left ventricular lead impedance < 200 ohms: x (x x x)
X	X			[41] Last saved ventricular lead impedance > 3000 ohms (x x x), defibrillation system potentially ineffective.

6.1 Cardioverter defibrillators

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Ovatio[15]	Paradym family[16]	Paradym RF family[17]	RMS[18]	**Warnings/Observations potentially displayed by the programmer or received through the Remote Monitoring System**
X	X			[42] Last saved right ventricular lead impedance > 3000 ohms (x x x), defibrillation system potentially ineffective.
X	X			[43] Last saved left ventricular lead impedance > 3000 ohms (x x x)
	X			[45] Low shock impedance detected on x x x: defibrillation system ineffective.
	X			[46] High shock impedance detected on x x x: defibrillation system ineffective.
	X			[47] Excessive electrical consumption detected on x x x. Risk that system is ineffective.
	X			[48] Max shock energy ineffective on x x x
	X			[50] Suspected abnormal ventricular lead impedance on x x x (x): defibrillation system potentially ineffective.
	X			[51] Suspected abnormal right ventricular lead impedance on x x x (x): defibrillation system potentially ineffective.
	X			[52] Suspected abnormal left ventricular lead impedance on x x x (x).
	X			[53] Abnormal RV coil impedance on x x x: defibrillation system ineffective.
	X			[54] Abnormal SVC coil impedance on x x x: defibrillation system ineffective.
	X			[55] Insufficient electrical performance detected on x x x: defibrillation system ineffective.
	X			[56] Charge time > 25 s on x x x: defibrillation system potentially ineffective.
	X			[57] R.R.T. (Recommended Replacement Time) detected on x x x: plan to replace device.
		X		[58] Last shock energy delivered (J) : x. Defibrillation system potentially ineffective.
X	X			Delivered energy of last shock (J) : x
		X	X	[62] Excessive charge time detected. Defibrillation system potentially ineffective.
		X		[63] xV lead impedance < x ohms: x, x/x/x. (Applicable to TriV only)
		X		[64] xV lead impedance > x ohms: x, x/x/x. (Applicable to TriV only)
	X			[73] The last battery voltage measurement was performed more than 3 days ago. An updated measurement will be displayed 24hrs after the latest capacitor charge.
		X	X	[A1] Low shock impedance on x/x/x. Defibrillation system potentially ineffective.
		X	X	[A2] High shock impedance on x/x/x. Defibrillation system potentially ineffective.
		X	X	[A4] Max shock energy ineffective on x/x/x.
		X	X	[A9] Ventricular lead impedance < x ohms: x, x/x/x, x. Defibrillation system potentially ineffective.
		X	X	[A11] Ventricular lead impedance > x ohms: x, x/x/x, x. Defibrillation system potentially ineffective.
		X	X	[A13] RV lead impedance < x ohms: x, x/x/x, x. Defibrillation system potentially ineffective.
		X	X	[A15] RV lead impedance > x ohms: x, x/x/x, x. Defibrillation system potentially ineffective.
		X	X	[A17] LV lead impedance < x ohms: x, x/x/x, x.
		X	X	[A19] LV lead impedance > x ohms: x, x/x/x, x.
		X	X	[A21] RV shock electrode continuity > 3000 Ohms on x/x/x. Defibrillation system potentially ineffective.
		X	X	[A24] Excessive Charge Time, x/x/x. Defibrillation system potentially ineffective.
		X	X	[A25] R.R.T. (Recommended Replacement Time) detected x/x/x: plan device replacement.
		X	X	[A27] Percentage of V pacing in CRT less than [programmed threshold]%: [dd/mon/yyyy].
		X	X	[A28] AT/AF Daily Burden higher than [programmed threshold]: [value measured], [dd/mon/yyyy].

6.1 Cardioverter defibrillators

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Ovatio[15]	Paradym family[16]	Paradym RF family[17]	RMS[18]	**Warnings/Observations potentially displayed by the programmer or received through the Remote Monitoring System**
		X	X	[A31] Shocks delivered, x/x/x.
		X	X	[A32] Ineffective shocks delivered, x/x/x.
		X	X	[A33] V oversensing suspected.
		X		[A35] xV lead impedance < x ohms: x, x/x/x, x. (Applicable to TriV only)
		X		[A37] xV lead impedance > x ohms: x, x/x/x, x. (Applicable to TriV only)

[15] Ovatio VR 6250, Ovatio DR 6550, Ovatio CRT 6750
[16] PARADYM VR 8250, PARADYM DR 8550, PARADYM CRT-D 8750, PARADYM SonR 8770
[17] PARADYM SonR TriV 8970, PARADYM 2 VR 8252, PARADYM 2 DR 8552, PARADYM 2 CRT-D 8752, PARADYM 2 SonR CRT-D 8772, PARADYM RF VR 9250, PARADYM RF DR 9550, PARADYM RF CRT-D 9750, PARADYM RF SonR 9770, INTENSIA VR 124, INTENSIA DR 154, INTENSIA CRT-D 174, INTENSIA SonR CRT-D 184
[18] Remote Monitoring System

6.1.8 Platinium – 30Hz pacing and inductive telemetry

Original date of Field Safety Notice: July 2016

1. Information about ventricular fibrillation induction test using 30Hz pacing burst with RF telemetry

   Field Safety Notice description

   As of June 30, 2016, the company received four (4) reports (*i.e.* 0.087%) of programmer screen freeze during 30Hz pacing while the test was launched using RF telemetry. The space bar of the programmer keyboard, as well as the buttons on the programmer screen remained unresponsive (buttons grayed out) during the delivery of the 30Hz burst, making it impossible to stop the test before the end of the programmed burst duration[19]. If ventricular fibrillation is effectively induced, and the user wants to prematurely interrupt the 30Hz pacing, there can be a delay in the delivery of the shock therapy which may prolong the syncope.

   Patient recommendations

   After consulting with our CRM independent Product Performance Monitoring Board, the company recommends the following:

   - As soon as the next programmer software version is available[20], it should be used to perform any new implantation of PLATINIUM devices or any new VF induction.
   - Until the time the new programmer software version is available:
     - o When performing induction tests, shocks on T-wave can be used as an alternative to 30Hz pacing.
     - o When performing 30Hz induction test using RF telemetry, the company recommends the following:
       - Program short 30Hz burst durations, and re-iterate the 30Hz pacing burst if ventricular fibrillation is not induced on the first attempt.
       - Even if the programmer screen freezes, the 30Hz pacing burst can still be interrupted through a Rescue Shock or a Nominal command.
       - Launching a Rescue Shock will trigger an immediate charge of the device capacitors followed by the delivery of a 42 Joules shock.
       - Selecting the Nominal settings will force the device to use the Nominal values, including arrhythmia detection and arrhythmia therapy parameters.

2. Information about inductive telemetry

   Field Safety Notice description

   As of June 30, 2016, the company received six (6) reports (*i.e.* 0.13%) of loss of inductive telemetry function during patient follow-up, whereas inductive telemetry was fully functional at device implantation. As a consequence, it was not possible to interrogate the device and the follow-up could not be completed.

   Patient recommendations

   After consulting with our CRM independent Product Performance Monitoring Board, the company recommends the following: For future PLATINIUM implants:

[19] The burst duration is programmable between 1 second and 30 seconds.
[20] Smartview 2.54 released in September 2016 in Europe
Smartview 2.54J released in September 2016 in Japan
SmartView 2.54UG1 released in April 2017 in Canada

- The "RF for Remote Monitoring" setting is turned ON automatically when shocks are programmed ON. The company recommends that you leave this feature programmed ON, even if your patient is not enrolled in Remote Monitoring.

For patients already implanted with PLATINIUM devices:

- During the next follow-up[21], verify that the "RF for Remote Monitoring" setting is programmed ON. If not, reprogram it ON.
- If you do not succeed in interrogating the device using inductive telemetry, please contact your company representative. In most cases, recovery of the inductive telemetry function will be possible through a dedicated procedure.

6.1.9 Platinium – Overconsumption following ElectroStatic Discharge or MRI scan

Original date of Field Safety Notice: July 2017

Field Safety Notice description

There are two issues discussed in this letter:

1. An electronic component used in a specific hardware version of Platinium devices has been found to be sensitive to electrostatic discharge (ESD) potentially generated during the implant surgery. The discharge can trigger overconsumption of current, leading to reduced device longevity (5% longevity loss per month). The overconsumption is detectable upon interrogation of the device during follow-up visit and it can be stopped by resetting the device. Although the overconsumption is stopped after this reset, the residual longevity displayed by the programmer may temporarily be underestimated.
2. Although Platinium devices are not currently approved as MRI conditional and are therefore contraindicated for MRI, the company is aware that some patients implanted with a Platinium device have undergone an MRI scan based upon medical judgment weighing the benefits and risks of the procedure. When exposure to an MRI's magnetic field occurs, overconsumption can occur and the battery voltage will decrease to 2.80V. At this level, the device remaining longevity is 25% of the initial longevity.

Neither of the issues described above affects the therapeutic functions of the device. All sensing, pacing and shock delivery capabilities will remain functional.

How did this affect patients?

No permanent injury or death has occurred as a result of these issues.

As of June 16th , 2017, the company has received eighteen (18) reports of overconsumption associated with ESD exposure at implant (issue #1), out of the 9386 devices that can be affected by this issue (*i.e.* 0.19%). Specifically:

- The device associated with the first issue reported was explanted before it could be corrected by reset;
- Twelve (12) were corrected by reset within the 3 months after implant, resulting in less than 15% reduction in longevity; and
- Five (5) were corrected by reset in the 4 to 10 month time frame post-implant, resulting in a greater longevity reduction.

As of June 16th, 2017, the company has received four (4) reports of overconsumption and premature device replacement attributed to MRI scans (issue #2), out of the 9386 devices that can be affected by

[21] It is recommended that a routine follow-up examination be done one month after discharge, and then every three months until the device nears the replacement date.

this issue (*i.e.* 0.04%). The overconsumption led to premature device replacement in the four (4) cases reported after the MRI scans. In one (1) of these four cases, the patient reported feeling a sensation of heat in the area of device.

Actions taken by the company to address these issues

1. Since May 18th, 2017, the company has stopped releasing Platinium devices with the electronic component that can potentially adversely react to either an ESD generated at implant or the MRI's magnetic field. Platinium devices with a new version of this electronic component have been made available.
2. The company is initiating a correction of the affected implanted devices and a removal of the non implanted affected devices.
3. To eliminate the risk of overconsumption caused by interaction with the MRI's magnetic field, the company developed a new software version[22] that has been approved and will be deployed shortly. All implanted devices will be automatically upgraded upon interrogation by a programmer updated with the new software. Your company representative will inform you as soon as the new software is available and will assist you in upgrading your programmer.

Advise on action to be taken by the user

1. Identify and quarantine affected Platinium devices that are still in your inventory. To determine if a device is subject to this advisory and could potentially present with a risk of overconsumption, your company representative can assist you in the identification of these products as necessary[23].
2. Return Platinium devices that are subject to this advisory to the company by contacting your company representative or your local Customer Service and referencing this communication to initiate a return and credit of unused product. Your company representative can assist you in the return of these products as necessary.
3. In order to mitigate the potential risks associated with both triggering events (ESD at implant or MRI scan), the company recommends physicians follow-up the patients at the periodicity already stated in the implant manual[24], especially:
    - Before the patient is discharged and at each subsequent follow-up, it is advisable to check the battery status and the occurrence of system warnings;
    - It is recommended that a routine follow-up examination be done one month after discharge, and then every three months until the device nears the replacement date.
4. The company does not recommend anticipating patient visits, provided that the instructions for use are followed.
5. If the warning "[A3] Technical issue" is displayed, then this indicates that the device is affected by the overconsumption caused by an ESD at implant. Without delay, please contact your company representative who will organize the reset of the device. A second reset may be necessary in order to correct the estimation of the residual longevity displayed by the programmer. It will be organized at the next scheduled patient visit.

[22] SmartView 2.56 released in July 2017 in Europe
SmartView 2.56J released in July 2017 in Japan
SmartView 2.56UG1 released in November 2017 in US
SmartView 2.56UG2 released in December 2018 in Canada

[23] The following sentence has been removed, as the mentioned website is not available anymore: To determine if a device is subject to this advisory and could potentially present with a risk of overconsumption, please go and check its serial number on the following website: www.livanova.com/platinium-fsn.

[24] For instance, Implant Manual reference U456C (section 8) in Europe.

WARNINGS: Please refer to the Online Help for more details.
[A3] Technical issue on 8/Jul/2016. Defibrillation system potentially ineffective. Contact Sorin.

6.1.10 Platinium – Risk of intermittent contact in the DF4 connectors

Original date of Field Safety Notice: March 2018

Field Safety Notice description

On a subset of Platinium ICDs or CRT-Ds DF4 models, a component of the DF4 connector was identified as potentially defective leading to intermittent loss of contact. As a consequence, high values of continuity measures on the defibrillation coils or noise on the right ventricular channel may be observed. This issue could also lead to absence of ventricular pacing therapy and/or inappropriate shock. Delivery of defibrillation shock is unaffected.

How did this affect patients?

No permanent injury or death has occurred as a result of these issues.

As of January 31st, 2018 the company has received six (6) reports on Platinium devices about this issue out of the 6947 Platinium devices equipped with a DF4 connector distributed over the same period of time (0.09%). All six events were detected within the first month after implantation.

- There were three (3) reports of high intermittent RV coil continuity, and
- Three (3) reports of right ventricular noise and/or inappropriate shock.

Five (5) devices out of six (6) were explanted.

Actions taken by the company to address these issues

The company is initiating a recall of non implanted Platinium devices that may present with a defective DF4 connector.

Advise on action to be taken by the user

1. Identify and quarantine affected Platinium devices that are in your inventory. Refer to Attachment 2 to determine if a device from your inventory is subject to this advisory. Your company representative will assist you in the identification of these products as necessary.
2. Return Platinium devices that are subject to this advisory to the company by contacting your company representative or your local Customer Service and referencing this communication to initiate a return and credit or replacement of unused product. Your company representative will assist you in the return of these products as necessary.
3. The company does not recommend anticipating patient visits, provided that the instructions for use are followed[25]. Standard follow-up practices allow the detection of high values of continuity measures or right ventricular noise.

[25] It is recommended that a routine follow-up examination be done one month after discharge, and then every three months until the device nears the replacement date. For instance, refer to the Implant Manual reference:
- U902A for Europe, sections 5.12 and 8.1
- U904A for US, sections 14.12 and 17.1

6.1.11 Platinium – Loss of pacing and sensing following hardware failure, leading to absence of automatic detection of an arrhythmia requiring defibrillation shock therapy

Original date of Field Safety Notice: July 2018

Field Safety Notice description

On a subset of Platinium ICD and CRT-D devices, a specific hardware configuration was identified as potentially defective over time, leading to overconsumption, immediately followed by loss of pacing and sensing capabilities in all cavities. As a result of the loss of sensing capability, the device cannot identify an arrhythmia that would require a defibrillation shock therapy.

How did this affect patients?

No permanent injury or death has been reported as a result of this issue. As of June 30th, 2018, MicroPort CRM has received five (5) reports on Platinium devices about this issue out of the 1637 Platinium devices released for distribution that may be subject to the issue (0.31%). MicroPort CRM has not identified a specific time frame during which the problem is more likely to occur. Nevertheless, all five events were detected within the first year after implantation. In only one (1) case, the patient reported feeling weakness. All five devices were replaced.

Actions taken by MicroPort CRM to address these issues

1. Since June 26th, 2018, MicroPort CRM has stopped releasing Platinium devices having the potentially defective hardware configuration. Platinium devices with unaffected hardware configurations have been made available.
2. MicroPort CRM is initiating a removal of the non implanted Platinium devices that may present with this hardware failure and providing recommendations for managing implanted patients.

Advise on action to be taken by the user

1. Identify and quarantine affected Platinium devices that are still in your inventory. **Appendix 2** provides the list of the devices subject to this advisory that were shipped to your center. Your MicroPort CRM representative will assist you in the identification of these products as necessary. In addition, if you would like to determine if a device is subject to this advisory, please go and check its serial number on the following website: www.crm.microport.com/platinium-fsn-2018-001.
2. Return Platinium devices that are subject to this advisory to MicroPort CRM by contacting your MicroPort CRM representative or your local Customer Service and referencing this communication to initiate a return and credit or replacement of unused product. Your MicroPort CRM representative will assist you in the return of these products as necessary.

Patient management recommendation

1. Perform patient follow-up every three months. In order to mitigate the potential risks associated with the loss of the device pacing and sensing capabilities, MicroPort CRM recommends physicians follow-up the patients at the periodicity already stated in the implant manual[26] and in the international guidelines[27], especially:
    a. Before the patient is discharged and at each subsequent follow-up, it is advisable to check the battery status and the occurrence of system warnings;

[26] For instance, Implant Manual reference U456C (section 8) in Europe and Australia, U459C (section 17) in the USA, UA069A (section 17) in Canada, available at www.microportmanuals.com

[27] HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations - Bruce L. Wilkoff & al. – Europace 2008;10:707-25

   b. It is recommended that a routine follow-up examination be done one month after discharge, and then every three months until the device nears the replacement date.

2. MicroPort CRM does not recommend rescheduling patient visits, provided that the three-month follow-up periodicity is applied.
3. MicroPort CRM recommends physicians check for proper sensing and pacing during each follow-up.
4. If one or more of the items listed below is/are observed during follow-up, then hardware failure may have occurred. Without delay, please contact your MicroPort CRM representative. Refer to the **Appendix 1** showing some examples. There is no audible or vibratory alert on Platinium ICD and CRT-D devices.

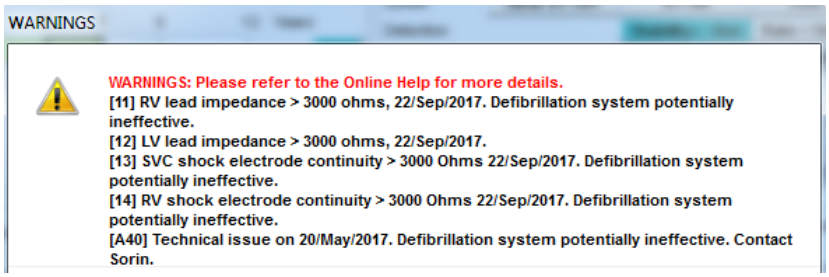
   a. The warning "Technical issue" indicates that overconsumption was detected. A steep decrease of the battery voltage may be visible on the battery curve.
   b. Warnings on high lead impedances in all cavities.
   c. Loss of sensing capability will result in flat EGMs and 100% pacing in the statistics.

5. Enroll patients in SmartView™ remote monitoring and verify that the *"RF for Remote Monitoring"* setting is programmed ON. System alert checks are automatically performed on a daily basis. Integrity alerts cannot be deactivated, such as the overconsumption alert and the battery depletion alert. Verify that the high lead impedance and continuity alerts are programmed ON. Centers will automatically receive notification of such alerts overnight. On the SmartView website, verify that the "Monitoring Interruption" notification is activated (in the "Clinic Notification Settings" tab), so that the center receives a notification in case of interruption in the communication between the server and the Platinium device for 14 consecutive days. For patients currently enrolled in SmartView™, remind them of the importance of using remote monitoring.
6. MicroPort CRM does not generally recommend physicians prophylactically replace the Platinium device. However, special consideration should be given in the following circumstances:

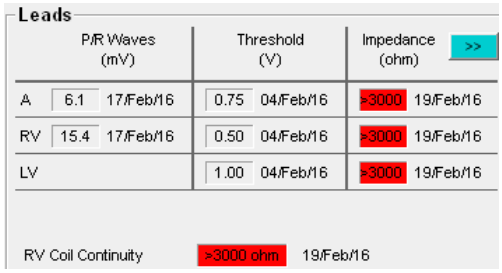
   a. For pacing dependent patients or those with high ventricular arrhythmia burden the relative risk of device failure versus that associated with device replacement should be assessed on an individual patient basis.
   b. In case of a surgical procedure involving the patient's defibrillation system, already scheduled for other causes than the one related to the Platinium device (*e.g.* lead revision), MicroPort CRM recommends physicians prophylactically replace the Platinium device, if subject to this advisory, during the same procedure.

APPENDIX 1

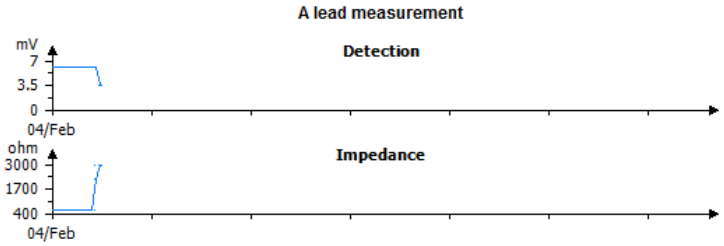
Examples of observations resulting from the hardware failure subject to this advisory



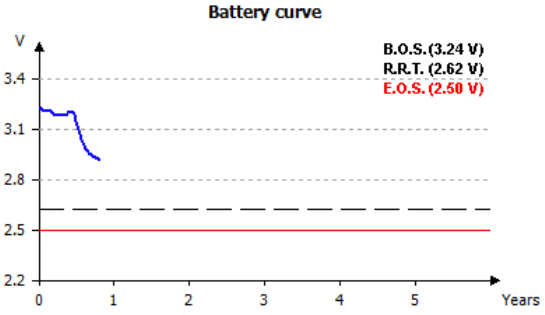
Warnings for high lead impedances and continuities
Warning for overconsumption



Warnings for high lead impedances and continuities



Atrial lead impedance curve showing a sudden increase of the impedance



Time to RRT:	5 - 7 Years
Last value measured :	2.91 V - 21/Sep/2017
Last charge to 42J:	05/April/2017
Energy beg./end:	0.1/42.2 J
Charge time:	12.0 s
Last shock:	-
Zone of delivery:	-
Energy stored/delivered:	-/- J
Duration:	-
Charge time:	-
Impedance:	-
Battery reforming date:	-
Total number of charges:	1
Total time of RF transmission:	49min 23s

Battery curve showing a steep decrease of the battery voltage

6.1 Cardioverter defibrillators

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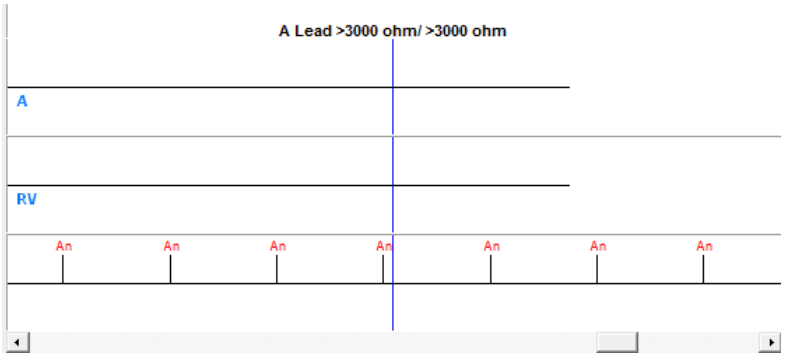
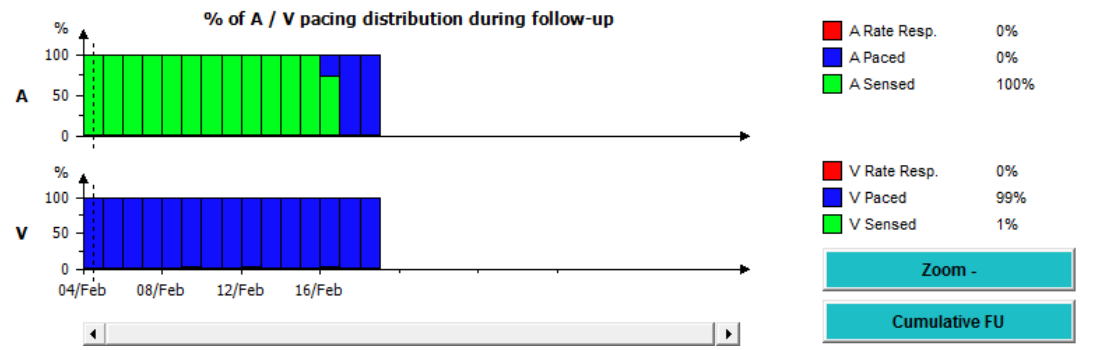


Flat EGMs



Statistics showing 100% pacing

When the failure described in this Field Safety Notice occurs, the device will no longer pace or sense. Due to the absence of sensing, the algorithm will send a pacing command for 100% of the cardiac cycles. The pacing spikes are not delivered due to the hardware failure, but 100% pacing statistics will be shown.

6.1.12 Platinium – Release of a new software version to maintain therapies in implanted Platinium devices in case of occurrence of the hardware failure described in the Field Safety Notice issued in July 2018

Original date of Field Safety Notice: December 2018

Field Safety Notice description

On a subset of Platinium ICD and CRT-D devices, a specific hardware configuration was identified as potentially defective over time, leading to overconsumption, immediately followed by loss of pacing and sensing capabilities in all cavities. As a result of the loss of sensing capability, the device cannot identify an arrhythmia that would require a defibrillation shock therapy.

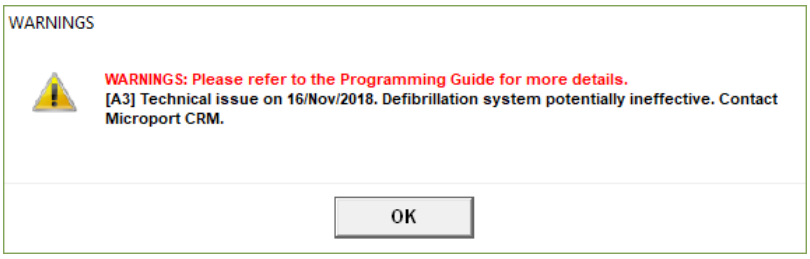
How did this affect patients?

No permanent injury or death has been reported as a result of this issue. As of December 14th, 2018, no new report has been received since the Field Safety Notice CRM-SAL-2018-001.

Actions taken by MicroPort CRM to address these issues

MicroPort CRM is releasing a new software version. Your MicroPort CRM representative will inform you as soon as the new programmer software version[28] is available and assist you in upgrading your programmer. All implanted devices interrogated with this new version will then be automatically upgraded. This software will ensure that pacing and sensing functionalities are preserved if a patient from your population is affected by the hardware failure. As sensing is preserved, the device will be able to identify and treat any tachyarrhythmia that would require a defibrillation shock therapy.

This new software is not able to eliminate the underlying hardware failure. The overconsumption resulting from the failure will not be interrupted. **The warning "Technical issue" will be raised, indicating that overconsumption has been detected. This alert will be sent remotely or observed during in-clinic follow-up. A minimum service period of 45 days after hardware failure is guaranteed.**



Advise on action to be taken by the user

If you would like to determine if a device is subject to this advisory, please go and check its serial number on the following website: www.crm.microport.com/platinium-fsn-2018-001.

Your MicroPort CRM representative will assist you in the identification of these products as necessary.

Patient management recommendation

1. Enroll patients in SmartView™ remote monitoring and verify that the *"RF for Remote Monitoring"* setting is programmed ON. Your MicroPort CRM representative will assist you in this process.
2. Recommendations related to patient in-clinic or remote follow-up remain unchanged. Recommendations 1 to 3 of the Field Safety Notice CRM-SAL-2018-001 still apply:

[28] SmartView 2.60 released in December 2018 in Europe
SmartView 2.60J released in October 2018 in Japan

i. Perform patient follow-up every three months.
ii. MicroPort CRM does not recommend rescheduling patient visits, provided that the three-month follow-up periodicity is applied.
iii. MicroPort CRM recommends physicians check for proper sensing and pacing during each follow-up.

3. Recommendations related to the software upgrade:
   i. Upgrade your programmer with the updated software version. Your MicroPort CRM representative will inform you as soon as the new programmer software version is available and assist you in upgrading your programmer.
   ii. Interrogate Platinium devices with the upgraded programmer during patient in-clinic follow-up. During the first interrogation, the updated software will be loaded in the Platinium devices. **MicroPort CRM recommends that this first interrogation with an upgraded programmer take place as soon as practically possible and not later than three months after your programmer update.**
   iii. **Priority should be given to pacing dependent patients or those with high ventricular arrhythmia burden so that they receive the updated software sooner.**
4. Once the software update has been loaded, and provided that the patient is enrolled in SmartView™ remote monitoring, prophylactic device replacement is no longer recommended. If the patient is not enrolled in SmartView™ remote monitoring, the recommendation 6 of the Field Safety Notice CRM-SAL-2018-001 is still applicable: "MicroPort CRM does not generally recommend physicians prophylactically replace the Platinium device. However, special consideration should be given in the following circumstances:
   i. For pacing dependent patients or those with high ventricular arrhythmia burden the relative risk of device failure versus that associated with device replacement should be assessed on an individual patient basis.
   ii. In case of a surgical procedure involving the patient's defibrillation system, already scheduled for other causes than the one related to the Platinium device (*e.g.* lead revision), MicroPort CRM recommends physicians prophylactically replace the Platinium device, if subject to this advisory, during the same procedure."
5. In case a failure of the integrated circuit arises, the alert "Technical issue" is triggered. There is no audible or vibratory alert on Platinium ICD and CRT-D devices. Without delay, please contact your MicroPort CRM representative, who will confirm if device replacement needs to be scheduled.

6.2 Pacemakers

6.2.1 Neway DR models distributed in Europe

Original date of Field Safety Notice: July 2007

Field Safety Notice description

A Field Safety Notice was issued in relation to a limited series of 45 cardiac pacemakers, Neway DR model, distributed in Europe. The notification states that these devices contained a version of a microcontroller integrated circuit that did not allow automatic storing of the data coming from the intracardiac EGM (IEGM) into the device memory. To overcome this limitation, storing of data was performed by a dedicated software routine. This software routine caused additional current drain that reduced longevity in devices with the IEGM activated, compared to the devices with the IEGM deactivated. Available programmer software did not take into account the additional current required for the IEGM function when estimating the remaining longevity.

Patient recommendations

A revised programmer software (SmartView 2.06 for Orchestra programmer – version 3.6.04 for PMP 2000 programmer or higher versions) was distributed to calculate the remaining longevity accurately with or without IEGM enabled. For all of the devices included in this Field Safety Notice, a prompt follow-up visit and device interrogation was recommended utilizing this revised programmer software.

6.2.2 Programmer software version associated with Reply SR

Original date of Field Safety Notice: September 2007

Field Safety Notice description

A Field Safety Notice was issued for an anomaly in programmer software, Smartview version 2.06 or earlier, when reprogramming Reply SR single chamber cardiac pacemakers (distributed in Europe). The notification stated that when the chamber was set to "V" (pacemaker connected to a lead implanted in the ventricle), reprogramming of the pulse amplitude and pulse width was not effective, and they remained equal to the as-shipped values (3.5 V amplitude, 0.35 ms pulse width). When the chamber was set to "A" (pacemaker connected to a lead implanted in the atrium), each programmable parameter – including pulse amplitude and pulse width – could be reprogrammed as expected. This software anomaly affected Reply SR single chamber pacemakers only; other pacemaker models were not affected.

Patient recommendations

Revised programmer software (SmartView version 2.08 for Orchestra programmer[29]) was distributed to correct this unexpected behavior. For some of the devices included in this Field Safety Notice (Reply SR single chamber models set to "V" chamber), and based upon the evaluation of specific criteria (*e.g.* pacemaker reprogrammed after implant or not, pacemaker dependency, pacing threshold results at implant), a prompt follow-up visit and device interrogation were recommended utilizing this revised programmer software to check the programmed settings and correct the pulse amplitude and pulse width, when needed.

[29] Released in October 2007 in Europe

6.2.3 Additional information on lead connections to Reply pacemakers

Original date of the Technical Note: September 2008

Technical Note description

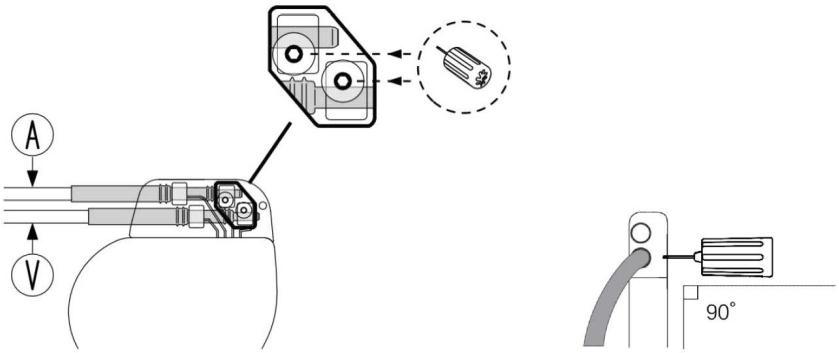
A Technical Note was voluntarily issued to reinforce instructions to ensure proper lead connection with Reply pacemakers at implant. The issue of this Technical Note followed an increased incidence of complaints relating to the screwdriver and setscrew. None required surgical re-intervention, but some devices were returned.

Analysis showed that the screwdriver was not fully inserted in the setscrew's hex cavity, which damaged the setscrew. To address this, Sorin CRM added an inspection step in manufacturing to eliminate any silicone adhesive inadvertently remaining in the setscrew's hex cavity (due to a gluing operation of the silicone setscrew cap during the manufacturing process), and provided a reminder and additional instructions to ensure the wrench is fully inserted.

A dedicated video was posted on Sorin CRM website in February 2009 to illustrate these instructions; it is available at
http://www.crm.microport.com/wp-content/uploads/2019/06/Pacemaker-lead-connection.mp4.

Below is the corresponding text describing the steps to connect the leads to the pacemaker:

> *Insert the lead into the port. Verify the full insertion. Insert the wrench through the screwdriver slot into the setscrew below. Very limited tilting of the wrench is a clear indication that it is fully inserted into the setscrew hex cavity. Turn clockwise until you hear a clicking sound. Pull on the lead to verify it is properly connected. Excessive tilting of the wrench is a clear indication of improper insertion. DO NOT TIGHTEN THE SCREW IN CASE OF EXCESSIVE TILTING. If this happens, gently adjust the wrench until it is completely engaged with the setscrew hex cavity and tilting is limited. You may now proceed as usual. The lead will be properly connected.*



Refer to the user's manual furnished with the device for intended uses and relevant warnings, precautions, side effects, and contraindications.

Refer to the user's manual furnished with the device for complete instructions for use.

This Technical Note was classified by the FDA as a Recall class II in September 2009.

Patient recommendations

Not applicable. The Technical Note provided a reminder and additional instructions to ensure the wrench is fully inserted.

6.2.4 European programmer software version 2.24 and Reply / Esprit pacemakers

Original date of Field Safety Notice: April 2011

Field Safety Notice description

A Field Safety Notice was issued in relation to a programmer software anomaly in the European 2.24 programmer software version when interrogating Reply and Esprit pacemakers:

- Only devices manufactured between November 2008 and mid-October 2010 could be affected by the issue if they are interrogated with 2.24 version (refer to the note below about potentially affected devices);
- 24 hours after a first interrogation with 2.24 version, a magnet rate of 30 min^{-1} is displayed upon new device interrogation on the programmer screen; if a magnet is applied, the pacemaker reverts to magnet mode (asynchronous mode) with a magnet rate of 30 min^{-1}. The battery depletion curve is also incorrect. **The battery impedance and the residual longevity are not affected by the software anomaly**;
- In addition, if the initial interrogation is performed prior to implant, then an "End Of Life" warning is also displayed upon device interrogation;

The anomaly only relates to the pacing rate (30 min^{-1}) during magnet test and does not affect other functions of the device; once the magnet is removed, the device reverts to programmed settings.

This programmer software anomaly does not affect any other Sorin implantable devices.

Immediate action

Sorin CRM stopped installation of 2.24 software version. In case this version was already installed on a programmer, Sorin promptly installed a software version preventing new devices from being affected upon interrogation.

Patient recommendations

The notification recommended that physicians continue to use the battery impedance and residual longevity to determine time for device replacement.

A programmer software update addressing this anomaly (Smartview 2.28) was developed and made available by the end of July 2011. The erroneous magnet rate was automatically corrected upon interrogation with this programmer software.

Before this software update was made available, devices that had already been interrogated with 2.24 could be reset to normal operation with the previous programmer software version (a dedicated Technical Note was issued which described the steps to follow).

Depending on the circumstances (*e.g.* for pacemaker-dependent patients undergoing surgery during which the magnet could be applied to avoid pacing inhibition), physicians may consider scheduling a follow-up for devices that have already been interrogated with 2.24 to correct the magnet rate (with the procedure described in the Technical Note or with the 2.28 or higher revision).

Note
The potentially affected devices have the following eight-character serial number configuration:

Models	**Serial number configuration** (where x is any alphanumeric character)		
Reply DR	8xx**ZK**xxx	9xx**ZK**xxx	0xx**ZK**xxx
Reply D	8xx**ZL**xxx	9xx**ZL**xxx	0xx**ZL**xxx
Reply VDR	8xx**ZM**xxx	9xx**ZM**xxx	0xx**ZM**xxx
Reply SR	8xx**ZN**xxx	9xx**ZN**xxx	0xx**ZN**xxx
Esprit DR	8xx**ZP**xxx	9xx**ZP**xxx	0xx**ZP**xxx
Esprit D	8xx**ZR**xxx	9xx**ZR**xxx	0xx**ZR**xxx
Esprit SR	8xx**ZS**xxx	9xx**ZS**xxx	0xx**ZS**xxx
Esprit S	8xx**ZT**xxx	9xx**ZT**xxx	0xx**ZT**xxx

6.2.5 Overestimation of the residual longevity displayed by the programmer - Reply / Esprit / Facil pacemakers

Original date of Field Safety Notice: November 2013

Field Safety Notice description

As of October 15, 2013, Sorin CRM received eight (8) reports out of more than 300 000 REPLY, ESPRIT or FACIL pacemakers implanted worldwide (*i.e.* 0.0027%), in which the devices were found at ERI/RRT (Elective Replacement Indicator/Recommended Replacement Time) while the time to ERI indicated by the programmer during the previous follow-up was indicating an ERI at a later date.

These eight (8) devices were programmed with high pulse amplitude and width combined with a high percentage of paced events, which explains why they had already reached ERI. The longevity of these devices is conforming to specifications. No permanent injury or death has occurred as a result of the reported events. At the time of the follow-up, pacing functions of the device were maintained in each reported event.

In-depth investigation of these reported events revealed that:

- The calculated residual longevity (*i.e.* the remaining time until the ERI) was overestimated.
- Because of this incorrect information, the follow-up dates might not have been adjusted when nearing the ERI; the ERI or EOL (End of Life) could therefore be reached between two follow-up exams, or during the follow-up exam itself.
- The overall longevity of the devices is not affected and corresponds to what is stated in the instructions for use.

Sorin CRM actions to address the issue

Sorin CRM has taken corrective actions to address this issue. A new programmer software version was developed and made available by the end of November 2013 for Europe and Japan (Smartview 2.40 / Smartview 2.40J), and by the end of March 2014 in the US (Smartview 2.40UG1) to correct the Time to ERI and its presentation through the color-coded gauge.

Patient management recommendations

After consulting with Sorin CRM's independent Product Performance Monitoring Board, Sorin CRM recommends:

- To consider checking the battery impedance of the last follow-up exam. In case the battery impedance is greater than or equal to 3.5kΩ, a follow-up visit must be scheduled within a maximum of 6 months from the last follow-up visit.
- When pacemaker operation is checked by the simple application of a magnet, a magnet rate less than 95 min^{-1} should trigger a follow-up exam in the pacemaker centre.

- As a general rule, a maximum of 6 month follow-up interval when the battery impedance becomes greater than or equal to 3.5kΩ. This recommendation should also be followed subsequent to the installation of the new programmer software version.

New recommendations have been issued. Please refer to section 6.2.6.

6.2.6 Improved residual longevity displayed by the programmer – Reply pacemakers

Original date of Field Safety Notice: September 2016

Field Safety Notice description

As of August 31, 2016, the company received thirty-one (31) reports (*i.e.* 0.006%) of overestimation of the displayed residual longevity during use of the current programmer software version[30]. Pacing functions were maintained between follow-ups in all thirty-one (31) reported cases; the RRT[31] was reached between follow-up exams in 14 of these 31 cases (0.003%). No permanent injury or death has occurred as a result of the reported events. In-depth investigation of these reported events revealed that the overall device longevity and battery capacity is unaffected, meeting device specifications. Analysis of these cases and real-time battery depletion tests determined that the root cause was due to greater than expected variability in battery discharge profiles.

The overall longevity of REPLY, ESPRIT, FACIL[32], REPLY 200, REPLY 250[33], KORA 100, KORA 250 and REPLY CRT-P pacemakers is NOT impacted by this change and corresponds to what is stated in the instructions for use.

Company actions to address the issue

The company has taken corrective actions to address this issue. We will release a new programmer software version[34] to improve the Time to RRT. The new programmer software version displays a more accurate estimated residual longevity, corresponding to a typical battery discharge profile. In addition, when approaching the RRT, it provides a minimal residual longevity estimation to cover the variability in battery characteristics. Also, the residual longevity is re-calculated upon changes in programmed settings during a follow-up session.

Patient management recommendations

After consulting with the company CRM's independent Product Performance Monitoring Board, the company recommends:

[30] The following versions are concerned:
- SmartView 2.40 to 2.50 in European Community
- SmartView 2.40J to 2.50J in Japan
- SmartView 2.40UG1 (and 2.40UC1) to 2.50UG1 (and 2.50UC1) in US
- SmartView 2.42UG2 in Canada

[31] RRT: Recommended Replacement Time. Formerly described as ERI or Elective Replacement Indicator.
[32] FACIL pacemakers are only commercialized in Japan.
[33] Reply 250 is limited to the AUTOMAAT clinical study.
[34] SmartView 2.54 released in September 2016 in European Community
SmartView 2.54J released in September 2016 in Japan
SmartView 2.52UG1 and 2.52UC1 released in January 2017 in US
SmartView 2.54UG2 released in April 2017 in Canada

6.2 Pacemakers

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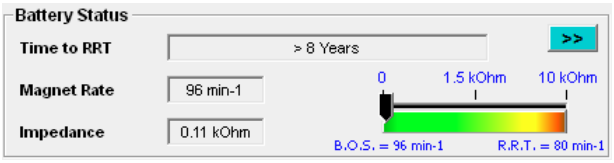
#	Recommendation	Applicable to the following patients	Applicable to the following models
1	Pending the first pacemaker interrogation with the new programmer software: For **pacemaker-dependent** patients implanted with **single** or **dual** chamber pacemaker models, you should consider checking the battery impedance and the residual longevity displayed during the last follow-up exam. Based on these two values, the Annex 2 provides the new recommended follow-up interval.	Pacemaker-dependent patients	All, except Reply CRT-P
2	Once the programmer software is upgraded: When the minimal estimated residual longevity displayed by the new programmer software version is less than or equal to 12 months: a. We recommend conducting patient follow-up visit at an interval that is between the minimal and the typical residual longevities displayed by the programmer, without exceeding 12 months (i.e. the annual standard follow-up). b. For pacemaker-dependent patients, we recommend conducting patient follow-up visit at an interval equal to the minimal residual longevity displayed by the programmer. Refer to Annex 1.	2.a: Non pacemaker-dependent patients 2.b: Pacemaker-dependent patients	All
3	When the residual longevity indicators are not available through the programmer, a maximum of 6 month follow-up interval should be applied when the battery impedance becomes greater than or equal to 3.5 kΩ. *This recommendation applies now, and remains applicable after the upgrade.*	All	All
4	When pacemaker operation is checked by the simple application of a magnet: a magnet rate less than 95 min^{-1} should trigger a follow-up exam in the pacemaker centre, and in any case the follow up interval should not be greater than 6 months. *This recommendation applies now, and remains applicable after the upgrade.*	All	All
5	Annual standard follow-up. *This recommendation applies now, and remains applicable after the upgrade.*	All	All
6	The device should be replaced as soon as the RRT point is reached. The RRT is defined as follows: • 10kΩ (magnet rate of 80min^{-1}) for single and dual chamber pacemaker models • 8.5kΩ (magnet rate of 80min^{-1}) for Reply CRT-P *This recommendation applies now, and remains applicable after the upgrade.*	All	10kΩ for non CRT-P models 8.5kΩ for Reply CRT-P

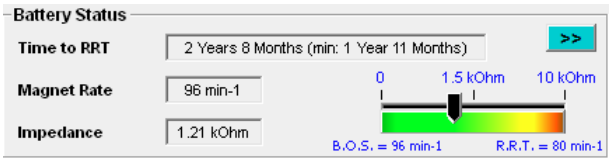
Annex 1

The new programmer software version displays a more accurate estimated residual longevity, corresponding to a typical battery discharge profile. In addition, when approaching the RRT, it provides a minimal residual longevity estimation to cover the variability in battery characteristics. Also, the residual longevity is re-calculated upon changes in programmed settings during a follow-up session. With the new programmer software version, the Time to RRT is displayed as follows:

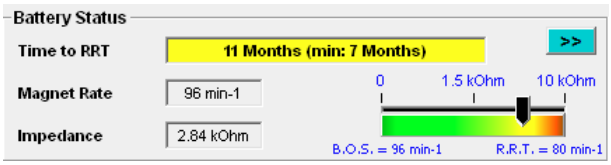
- If the typical estimated time to RRT is >3 years, the "typical time to RRT" is displayed and the corresponding text field background is grey.



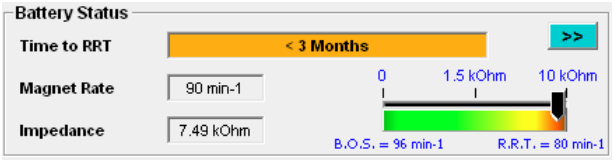
- If the typical and minimal estimated time to RRT are between 3 months and 3 years, the "typical time to RRT in years and months (Minimal time to RRT)" are displayed and:
  - the corresponding text field background is grey, if the minimal estimated time to RRT is >12 months;



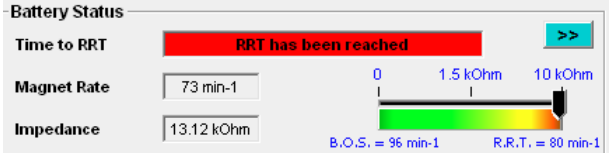
  - The corresponding text field background is yellow, if the minimal estimated time to RRT is ≤12 months. A Warning will be displayed "In the current conditions of use, the minimum residual longevity ≤ 12 months.";



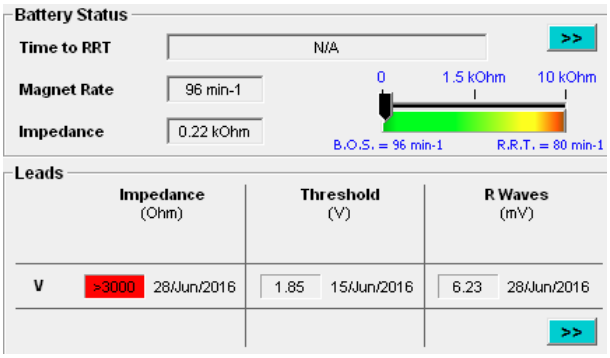
- If the minimal estimated time to RRT is <3 months, "< 3 months" is displayed and the corresponding text field background is orange. A Warning will be displayed: "In the current conditions of use, the minimum residual longevity ≤ 3 months."



- If the RRT has been reached, "RRT has been reached" is displayed and the corresponding text field background is red.



- "NA" is displayed in the text field, and the corresponding text field background is grey:
  - If less than 5 minutes statistics are available (*i.e.* first interrogation at implant, device reset),
  - If lead impedance is abnormal (< 200 and ≥ 3000 Ω) in any of the programmed cavity.



Annex 2

The table in Annex 3 provides the new recommended follow-up interval for pacemaker-dependent patients implanted with single or dual chamber pacemaker models[35]

- REPLY Models D, DR, VDR, SR
- ESPRIT Models D, DR, S, SR
- FACIL Model DR
- REPLY 200 Models DR, SR
- REPLY 250 Model DR[36]
- KORA 100 Models DR, SR
- KORA 250 Models DR, SR

Pending the availability of the new programmer software version: for pacemaker-dependent patients implanted with single or dual chamber pacemaker models, you should consider checking the battery impedance and the residual longevity displayed during the last follow-up exam[37]. Based on these two values, and provided that the settings were not reprogrammed during the last follow-up, the table in Annex 3 provides the new recommended follow-up interval (X months). A follow-up visit must be scheduled within a maximum of X months from the last follow-up visit. During the next follow-up:

- If the battery impedance is greater than or equal to 10 kOhms, the pacemaker should be replaced.
- If the battery impedance is inferior to 10 kOhms:
  - o If your programmer software is not upgraded yet, use the table overleaf to schedule the follow-up interval.
  - o If your programmer software is upgraded[38]: When the minimal estimated residual longevity displayed by the new programmer software version is less than or equal to 12

[35] This recommendation does not apply to patients implanted with Reply CRT-P model.
[36] Reply 250 is limited to the AUTOMAAT clinical study.
[37] If the last follow-up exam was performed with a SmartView version before 2.40 (in Europe); 2.40J (in Japan); 2.40UG1 (in US); 2.42UG2 (in Canada), the Annex 3 cannot be used to schedule the follow-up interval. Contact your company representative.
[38] To one of the following versions:
- SmartView 2.54 version (or higher) in European Community
- SmartView 2.54J (or higher) in Japan
- SmartView 2.52UG1 and 2.52UC1 (or higher) in US
- SmartView 2.54UG2 (or higher) in Canada

months, we recommend conducting patient follow-up visit at an interval that is between the minimal and the typical residual longevities displayed by the programmer, without exceeding 12 months (*i.e.* the annual standard follow-up). For pacemaker-dependent patients, we recommend conducting patient follow-up visit at an interval equal to the minimal residual longevity displayed by the programmer.

Annex 3

Recommended follow-up interval (X months)		Battery impedance displayed at last follow-up (kOhms)												
		1.0 kΩ	1.5 kΩ	2.0 kΩ	2.5 kΩ	3.0 kΩ	3.5 kΩ	4.0 kΩ	4.5 kΩ	5.0 kΩ	5.5 kΩ	6.0 kΩ	6.5 kΩ	7.0 kΩ
Time to RRT displayed at last follow-up[39] (months)	34 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	33 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	32 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	31 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	30 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	29 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	28 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	27 M	12 M	12 M	12 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA	NA
	26 M	12 M	12 M	9 M	9 M	9 M	12 M	NA	NA	NA	NA	NA	NA	NA
	25 M	12 M	12 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	24 M	12 M	12 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	23 M	12 M	9 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	22 M	12 M	9 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	21 M	12 M	9 M	9 M	6 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	20 M	9 M	9 M	6 M	6 M	6 M	9 M	NA	NA	NA	NA	NA	NA	NA
	19 M	9 M	9 M	6 M	6 M	6 M	6 M	9 M	NA	NA	NA	NA	NA	NA
	18 M	9 M	9 M	6 M	6 M	6 M	6 M	9 M	NA	NA	NA	NA	NA	NA
	17 M	9 M	6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA	NA
	16 M	9 M	6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA	NA
	15 M	6 M	6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA	NA
	14 M	6 M	6 M	6 M	3 M	3 M	6 M	6 M	6 M	NA	NA	NA	NA	NA
	13 M	6 M	6 M	3 M	3 M	3 M	3 M	6 M	6 M	NA	NA	NA	NA	NA
	12 M	6 M	3 M	3 M	3 M	3 M	3 M	6 M	6 M	NA	NA	NA	NA	NA
	11 M	6 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	6 M	NA	NA	NA	NA
	10 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	NA	NA	NA	NA
	9 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	NA	NA	NA	NA
	8 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	NA	NA	NA
	7 M	3 M	3 M	ASAP	ASAP	ASAP	ASAP	3 M	3 M	3 M	3 M	NA	NA	NA
	6 M	3 M	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	3 M	3 M	3 M	ASAP	NA	NA
	5 M	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	NA
	4 M	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP

- This table should be used for pacemaker-dependent patients implanted with single or dual chamber pacemaker models: REPLY Models D, DR, VDR, SR; ESPRIT Models D, DR, S, SR; FACIL Model DR; REPLY 200 Models DR, SR; REPLY 250 Model DR; KORA 100 Models DR, SR; KORA 250 Models DR, SR;
- This table does not apply to patients implanted with Reply CRT-P model;
- If the last follow-up exam was performed with a SmartView version before 2.40 (in Europe); 2.40J (in Japan); 2.40UG1 (in US); 2.42UG2 (in Canada), this table cannot be used to schedule the follow-up interval. Contact your company representative.
- If some of the following settings were reprogrammed during the last follow-up, this table may not be applicable: pacing mode, pacing amplitude(s), pulse width(s), rate response, sensors, auto-threshold, basic rate. If the reprogramming tends to increase the current consumption (*e.g.* higher pacing amplitude, longer pulse width etc.), contact your company representative. If the reprogramming tends to decrease the current consumption, it is safe to use the above table.
- NA: Not Applicable. NA indicates that it is not possible that this combination (battery impedance; Time to RRT) was displayed during the last follow-up.
- ASAP: a follow-up should be scheduled without delay. We recommend that this anticipated follow-up take place within 1 month from the previous follow-up visit.

[39] If the last follow-up exam was performed with a SmartView version before 2.40 (in Europe); 2.40J (in Japan); 2.40UG1 (in US); 2.42UG2 (in Canada), the Annex 3 cannot be used to schedule the follow-up interval. Contact your company representative.

6.2.7 Symphony and Rhapsody, Group 1

Original date of Field Safety Notice: October 2005

Field Safety Notice description

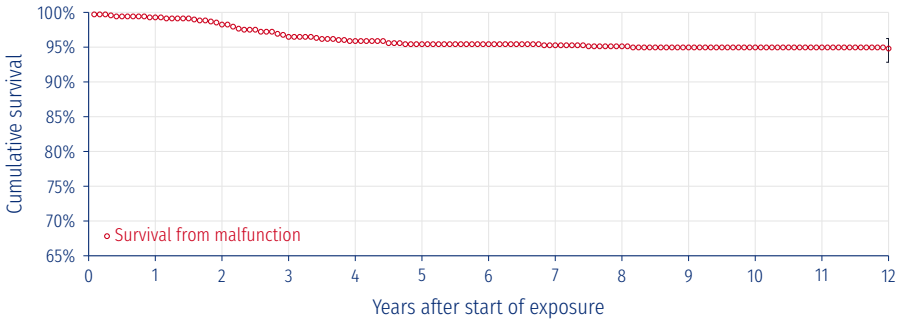
A Field Safety Notice was issued for this group of devices. A no-output condition was observed in a limited number of Symphony or Rhapsody pacemakers (models Symphony DR 2550, Symphony SR 2250, Rhapsody DR+ 2530, Rhapsody DR 2510, Rhapsody D 2410, Rhapsody SR 2210), due to metal migration caused by a manufacturing process performed systematically in this population, identified as Group 1. No injury or death has been reported in this group.

Patient recommendations

The notification states that no measurable change in device characteristics was identified that could warn of an impending incident. Consequently, the Field Safety Notice does not recommend more frequent monitoring. Depending on the circumstances, pacemaker-dependent patients implanted with units manufactured in this group could require prophylactic replacement.

Symphony DR 2550 Group 1

Symphony DR 2550 - GR 1



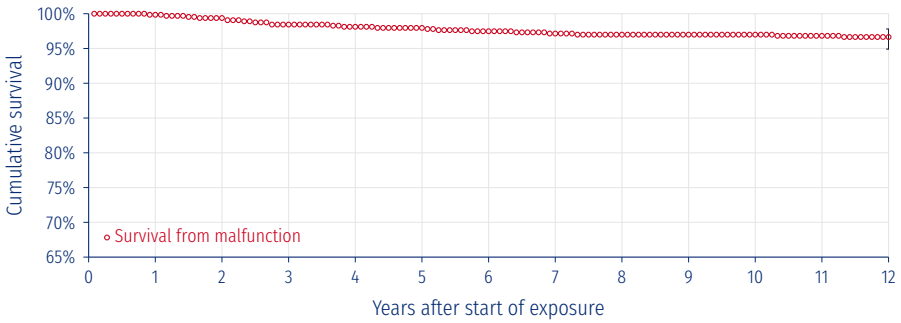
Cutoff date: 31-Dec-2020	Market release date	Mar-2002	Worldwide malfunctions	35
Analysis stops at 144 months	Worldwide implants	693	Devices with compromised therapy	28
or < 500 active implants	Estimated active implants	560	Devices without compromised therapy	7
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.28	98.25	96.48	95.88	95.43	95.43	95.27	95.12	94.96	94.96	94.96	94.80
Upper confidence interval (+) in %	0.42	0.75	1.15	1.26	1.34	1.34	1.36	1.39	1.41	1.41	1.41	1.44
Lower confidence interval (-) in %	1.01	1.31	1.69	1.79	1.87	1.87	1.89	1.92	1.94	1.94	1.94	1.97

Rhapsody DR 2510 - SR 2210 - + DR 2530 Group 1

Rhapsody DR 2510 - GR 1
Rhapsody SR 2210 - GR 1
Rhapsody+ DR 2530 - GR 1



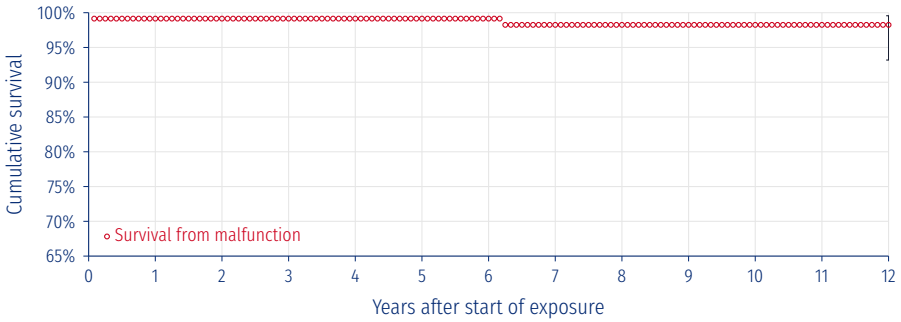
Cutoff date: 31-Dec-2020	Market release date	May-2003	Worldwide malfunctions 21
Analysis stops at 144 months	Worldwide implants	653	Devices with compromised therapy 18
or < 500 active implants	Estimated active implants	535	Devices without compromised therapy 3
	Estimated normal battery depletion	Not available	

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.85	99.38	98.44	98.12	97.96	97.48	97.15	96.99	96.99	96.99	96.82	96.65
Upper confidence interval (+) in %	0.13	0.39	0.72	0.81	0.85	0.97	1.04	1.08	1.08	1.08	1.12	1.15
Lower confidence interval (-) in %	0.94	1.02	1.32	1.41	1.45	1.56	1.63	1.67	1.67	1.67	1.71	1.74

Rhapsody D 2410 Group 1

Rhapsody D 2410 - GR 1



Cutoff date: 31-Dec-2020	Market release date	May-2003	Worldwide malfunctions 2
Analysis stops at 144 months	Worldwide implants	118	Devices with compromised therapy 2
or < 500 active implants	Estimated active implants	98	Devices without compromised therapy 0
	Estimated normal battery depletion	Not available	

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	99.15	99.15	99.15	99.15	99.15	99.15	98.25	98.25	98.25	98.25	98.25	98.25
Upper confidence interval (+) in %	0.73	0.73	0.73	0.73	0.73	0.73	1.31	1.31	1.31	1.31	1.31	1.31
Lower confidence interval (-) in %	5.02	5.02	5.02	5.02	5.02	5.02	5.06	5.06	5.06	5.06	5.06	5.06

6.2.8 Symphony and Rhapsody, Group 2

Original date of Field Safety Notice: October 2005

Field Safety Notice description

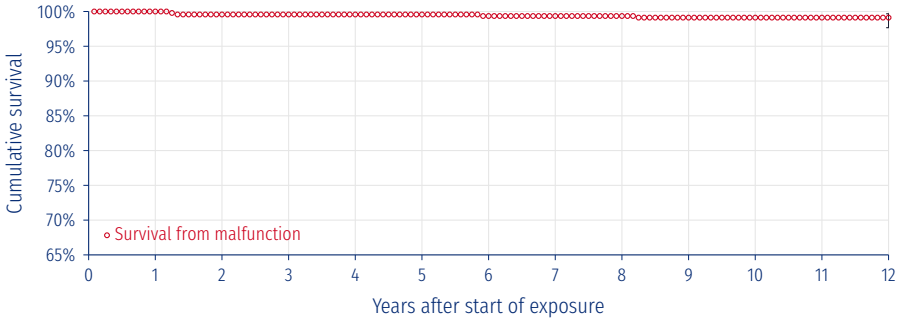
A manufacturing process that caused malfunctions described in Group 1 above was also performed for some devices in this second population identified as Group 2, although no similar malfunctions have been reported. Consequently, the Field Safety Notice described above also included Group 2.

Patient recommendations

No measurable change in device characteristics was identified that could warn of an impending incident. Consequently, the Field Safety Notice does not recommend more frequent monitoring. For Group 2, because published data indicate that the average malfunction rate for all pacemakers is approximately 0.15% per year[40], and because of the small but non-zero risk associated with device replacement, the Field Safety Notice does not recommend prophylactic replacement.

Symphony DR 2550 Group 2

Symphony DR 2550 - GR 2



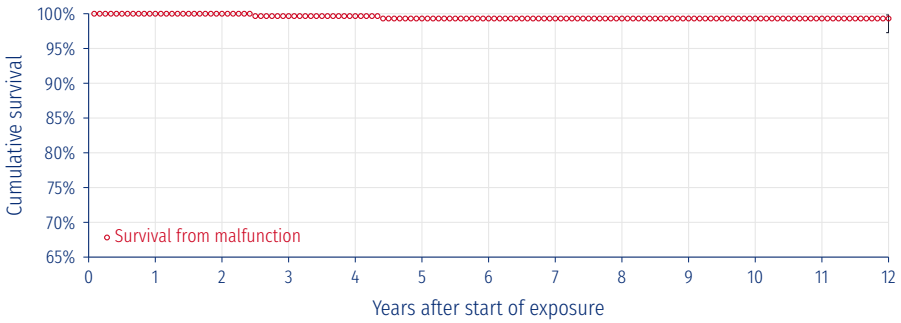
Cutoff date: 31-Dec-2020	Market release date	Mar-2002	Worldwide malfunctions	4
Analysis stops at 144 months	Worldwide implants	472	Devices with compromised therapy	3
or < 500 active implants	Estimated active implants	395	Devices without compromised therapy	1
	Estimated normal battery depletion	Not available		

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant												
Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	99.57	99.57	99.57	99.57	99.35	99.35	99.35	99.12	99.12	99.12	99.12
Upper confidence interval (+) in %		0.32	0.32	0.32	0.32	0.44	0.44	0.44	0.55	0.55	0.55	0.55
Lower confidence interval (-) in %		1.27	1.27	1.27	1.27	1.36	1.36	1.36	1.45	1.45	1.45	1.45

[40] Maisel WH. Pacemaker and ICD Generator Malfunctions. Policy Conference on Pacemaker and ICD Performance presented by the Heart Rhythm Society and the Food and Drug Administration. September 16, 2005.

Rhapsody DR 2510 - SR 2210 Group 2

Rhapsody DR 2510 - GR 2
Rhapsody SR 2210 - GR 2



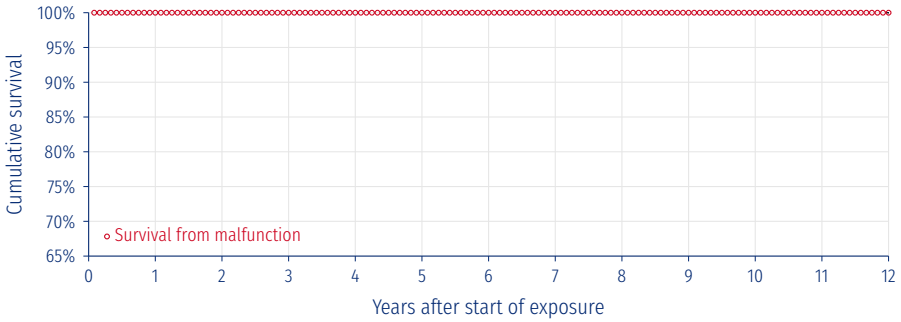
Cutoff date: 31-Dec-2020	Market release date	May-2003	Worldwide malfunctions 2
Analysis stops at 144 months	Worldwide implants	301	Devices with compromised therapy 0
or < 500 active implants	Estimated active implants	253	Devices without compromised therapy 2
	Estimated normal battery depletion	Not available	

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	100	99.66	99.66	99.31	99.31	99.31	99.31	99.31	99.31	99.31	99.31
Upper confidence interval (+) in %			0.29	0.29	0.51	0.51	0.51	0.51	0.51	0.51	0.51	0.51
Lower confidence interval (-) in %			2.05	2.05	2.03	2.03	2.03	2.03	2.03	2.03	2.03	2.03

Rhapsody D 2410 Group 2

Rhapsody D 2410 - GR 2



Cutoff date: 31-Dec-2020	Market release date	May-2003	Worldwide malfunctions 0
Analysis stops at 144 months	Worldwide implants	130	Devices with compromised therapy 0
or < 500 active implants	Estimated active implants	110	Devices without compromised therapy 0
	Estimated normal battery depletion	Not available	

Cumulative survival from malfunction (excluding normal battery depletion) with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12
Cumulative survival from malfunction in %	100	100	100	100	100	100	100	100	100	100	100	100
Upper confidence interval (+) in %												
Lower confidence interval (-) in %												

6.2.9 Symphony and Rhapsody: 7 units

Original date of Field Safety Notice: November 2008

Field Safety Notice description

A Field Safety Notice was issued in relation to a limited series of 7 units of Symphony / Rhapsody cardiac pacemakers, for which the absence of a metallic spring was confirmed through retrospective inspection of the manufacturing records. This metallic spring is used to help ensure the contact between a proximal terminal of the pacemaker and a proximal ring of an IS-1 pacing lead, *i.e.* to ensure proper operation in BIPOLAR configuration; device operation in UNIPOLAR configuration was not affected by this Notice. No injury or death has occurred as a result of the absence of this component.

Patient recommendations

As the absence of this component only affected device operation in bipolar configuration, it was recommended to re-program the pacing and sensing polarities to UNIPOLAR in the concerned chamber. Depending on the circumstances (patient's conditions, identified chamber with a missing spring, polarity of the implanted lead and programmed settings during the last follow-up visit), a prompt follow-up visit was recommended to re-program the polarities to Unipolar. It was also recommended to mark patient records – including the patient identification card – to indicate that these polarities must remain Unipolar.

6.2.10 Symphony: 1 unit

Original date of Field Safety Notice: July 2010

Field Safety Notice description

A Field Safety Notice was issued in relation to 1 unit of Symphony cardiac pacemaker, for which the absence of a metallic spring was confirmed through retrospective inspection of the manufacturing records; this retrospective analysis was an extension of the above described analysis (please refer to Section 6.2.9, p. 96 for more details). This metallic spring is used to help ensure the contact between a proximal terminal of the pacemaker and a proximal ring of an IS-1 pacing lead, *i.e.* to ensure proper operation in BIPOLAR configuration; device operation in UNIPOLAR configuration was not affected by this Notice. No injury or death has occurred as a result of the absence of this component.

Patient recommendations

The same recommendations as those described in Section 6.2.9, p. 96 were provided.

6.3 Leads

6.3.1 Isoline 2CR6 defibrillation leads - incorrect Use Before Date

Original date of Field Safety Notice: October 2011

Field Safety Notice description

This Field Safety Notice was issued in relation to 32 Isoline 2CR6 defibrillation leads that had been labeled with an incorrect and extended Use Before Date ("UBD"). A batch of Isoline leads had been labeled with an incorrect UBD that was greater than the maximum 36-month shelf-life specified for this product. As labeled, the shelf-life period had been incorrectly indicated as 43 months. Review of manufacturing records associated to this batch identified that the date printed on the labels was 5 May 2013, while the correct UBD of 21 September 2012 should have been indicated.

The in-depth investigation revealed that the error resulted from a labeling software anomaly. Corrective actions were implemented at the manufacturing level to avoid recurrence of such an anomaly.

Patient recommendations

The company pro-actively performed this Field Safety Notice in order to account for all of the affected leads:

- For leads that had already been implanted, the date of implant was requested; no other action was required relative to implanted leads, since such leads had been implanted prior to the correct UBD.
- For leads remaining in local inventory, instructions were given to return the leads to a Sorin representative.

6.3.2 Isoline defibrillation leads, models 2CR5, 2CR6 and 2CT6 - internal insulation breach

Original date of Field Safety Notice: January 2013

Field Safety Notice description

As of December 31, 2012, 30 cases of internal insulation breach under the RV or SVC defibrillation coil, out of 13500 units implanted worldwide (0.222%), had been confirmed by the analysis conducted on returned products. In each of the 30 identified cases, the internal insulation breach of the silicone lumen was observed under the RV and/or SVC defibrillation coil, *i.e.* where the microcables were not coated with ETFE[41], resulting in a contact between the conductors, thus leading to low pacing impedance and/or ventricular oversensing, and/or inappropriate therapy. It should be noted that in case of ventricular oversensing, pacing was inhibited.

These leads had been implanted for a mean duration of 1.4 years (from 2 months to 4.5 years). No early indicator that could have warned of a potential issue was identified in those cases. Visual inspection of each of the 30 returned products revealed presence of unusual torsion and/or compression. In depth investigation determined that the insulation abrasion by the microcable of the Isoline lead models under the RV or SVC defibrillation electrode may be attributed to particular and rare implant conditions that induce bending, compression and/or torsion on the lead, thus promoting internal abrasion of the silicone lumen by pushing the microcable against the lumen wall. However, such torsion and/or compression are barely detectable through X-ray imaging. The insulation breach itself is not visible through X-ray imaging because of its position under the defibrillation coil. No conductor

[41] Ethylene tetrafluoroethylene (fluorine based plastic)

externalization was observed and no conductor externalization was possible since the conductor wires are secured within the lead by the defibrillation coil itself.

No permanent serious injury or death was reported as a result of the confirmed malfunction.

Details about potentially affected leads

This information affects Isoline defibrillation leads, models 2CR5, 2CR6 and 2CT6[42]. The 2CR5 and 2CR6 models have a retractable screw fixation mechanism while the 2CT6 model has tined fixation.

Isoline leads are integrated bipolar leads with two defibrillation coils. The lead body contains three conductors, which are encased by a multi-lumen silicone tube: one pacing/sensing conductor and two defibrillation microcables. Both microcables are protected with an ETFE polymer coating, except under each defibrillation coil.

Patient management recommendations

Sorin CRM recommended to discontinue implantation of Isoline leads and provided the following recommendations for management of patients implanted with Isoline leads:

- Leads which are not implanted yet, shall not be used and should be returned to Sorin CRM.
- Prophylactic replacement or removal of any Isoline lead was not recommended in patients whose Isoline lead has not shown any electrical malfunction, considering the low occurrence rate of the issue. In such cases of absence of electrical malfunction evidence, standard follow-up intervals should be applied (3-month intervals, as recommended in the Sorin ICD labeling); reprogramming of VT/VF detection parameters could be evaluated (such as extending the persistence[43]); however, this should be weighed against delaying appropriate therapy. At the next routine follow-up, patients should be informed to contact their physician should they experience shock therapy.
- Physicians were encouraged to regularly monitor their patients implanted with Isoline leads, as recommended in the HRS/EHRA expert consensus on the monitoring of Cardiovascular Implantable Electronic Devices[44], including battery voltage, pacing & sensing operation, lead impedances, arrhythmias detected by the device, etc. Careful review of recorded treated and non-treated episo-des was also recommended.
- In case of evidence of a lead issue, physicians were encouraged to consider replacing the lead, while weighing the risks and benefits of extracting the lead compared to capping it and leaving it in place. The decision to remove a lead should be taken on an individual basis, as described in HRS guidelines[45]. Any event associated to a potentially defective Isoline lead should be reported to Sorin CRM, and any extracted lead should be returned to Sorin CRM for analysis.
- When the Isoline lead is connected to a remote monitoring enabled ICD or CRT-D device, physicians were obliged to consider appropriate alert parameter(s) programming. For the Paradym RF family, the following recommendations relative to programming of alerts were provided :
    - o RF communication to ”ON”
    - o Alerts to ”ON”

[42] Since the commercial release in 2005, these leads had been manufactured in France or in Italy by ”ELA Medical” or ”Sorin CRM”. Although the manufacturer name changed over time (from ELA Medical to Sorin CRM), the commercial name of the product remained ”Isoline”.
[43] Refer to pulse generator IFUs, for non Sorin ICD’s manufacturer
[44] HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations - Bruce L. Wilkoff & al. – Europace 2008;10:707-25
[45] Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management - Bruce L. Wilkoff and al. Heart Rhythm July 2009; 6 :7 : 1085-1104

6.3 Leads

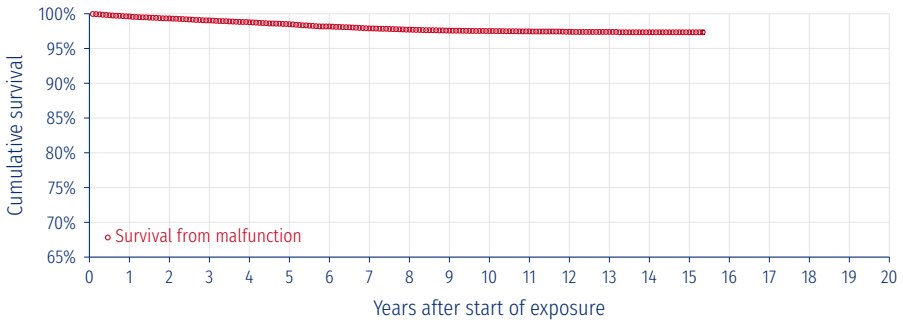
« Go back to Table of Contents

Type of Alerts	Parameter	Programmable value
Clinical Alerts	V oversensing	ON
Tachy Therapy Alerts	Shock delivered	All shocks
Leads Alerts	Abnormal RV lead impedance	ON Low Limit: 200 Ohm

- At the time of the device replacement, a remote enabled ICD or CRT-D should be considered.

Isoline 2CR5 - 2CR6 - 2CT6

Isoline 2CR5
Isoline 2CR6
Isoline 2CT6



Cutoff date: 31-Dec-2020	Market release date	Dec-2005	Worldwide malfunctions 330
Analysis stops at 240 months	Worldwide implants	13446	Devices with compromised therapy 261
or < 500 active implants	Estimated active implants	11739	Devices without compromised therapy 69

Cumulative survival from malfunction with 95% confidence interval, as a function of years after implant

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Cumulative survival from malfunction in %	99.61	99.32	99.04	98.77	98.49	98.17	97.89	97.71	97.57	97.51	97.46	97.40	97.38	97.33	97.33					
Upper confidence interval (+) in %	0.09	0.13	0.15	0.17	0.19	0.22	0.23	0.24	0.25	0.26	0.26	0.27	0.27	0.28	0.28					
Lower confidence interval (-) in %	0.12	0.16	0.18	0.20	0.22	0.24	0.26	0.27	0.28	0.28	0.29	0.30	0.30	0.32	0.32					

Lead malfunctions	Without compromised therapy	With compromised therapy
Conductor Fracture	0	9
Insulation Breach	1	74
Crimps, Welds, and Bonds	0	1
Other	0	0
All lead malfunctions	1	84

Lead complications	Acute lead complications	Chronic lead complications
Cardiac Perforation	0	1
Conductor Fracture	0	5
Lead Dislodgement	7	5
Failure to Capture	2	13
Oversensing	5	188
Failure to Sense (undersensing)	1	2
Insulation Breach	0	1
Abnormal Pacing Impedance	0	8
Abnormal Defibrillation Impedance	1	22
Extracardiac Stimulation	0	0
Other	0	0
All lead complications	16	245

Note: the above survival curve only accounts for Lead malfunctions and Chronic lead complications; it does not include Acute lead complications, in accordance with the international standard ISO 5841-2.

6.3.3 SonRtip endocardial pacing leads - Lead handling

Original date of Field Safety Notice: February 2012

Field Safety Notice description

This Field Safety Notice was issued as a preventative action to ensure the safe and effective use of the SonRtip endocardial pacing lead with contractility sensor. This lead is an active fixation atrial lead with a fixed helix. This fixed helix is protected by a PEG coating (sugar coating) to prevent damage while advancing the lead through the patient's venous anatomy.

As part of Sorin CRM's post-market surveillance system, two reports were received where part or all of the fixation helix of the SonRtip lead remained in the myocardium after the lead had been removed. No permanent injury or death occurred as a result of these issues. The investigation of both reports tends to demonstrate that an excessive number of turns was applied to the lead during fixation.

The SonRtip lead does not include an extendable-retractable fixation mechanism, usually associated with a large number of turns during its fixation. On the contrary, the SonRtip lead has a fixed helix. Its fixation in the myocardium is achieved by applying 4 (maximum 6) clockwise turns to the lead. Excessive turns may cause damage to the fixation helix and/or to the lead body.

Recommendations

Sorin CRM pro-actively communicated to physicians involved in SonRtip lead implantations about the importance of following the instructions for use, and specifically, communicated the number of turns to be applied to fixate the helix in the myocardium. Furthermore, it was advised that all recommendations and warnings included in the Implant Manual be followed and respected.

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7 Retired Products

Models that are listed below have reached the 20 year mark and are no longer distributed. As a result, these models have been removed from the current PPR. The table below lists all the retired products and the corresponding PPR where they were last reported.

PPR Model	Last PPR Reported
S 200 AB	November 2017
S 80 JB	November 2017
S 80 TB	November 2017
S 80 UTS	November 2017
Stelid BS45D	November 2017
Stelid BS46D	November 2017
Stelid BT45D	November 2017
Talent DR 213	November 2017
Brio DR 212	May 2018
Brio DR 222	May 2018
Brio SR 112	May 2018
Talent D 210	May 2018
Talent SR 113	May 2018
Brio D 220	May 2019
Stelix BR45D	May 2019
Stelix BR46D	May 2019
Stelid II BTF25D	November 2019
Stelid II BTF26D	November 2019
Diapason	May 2020
Diapason C	May 2020
Elect XS	May 2020
Elect XS C	May 2020
Elect XS Plus	May 2020
Elect XS Plus C	May 2020
Hepta 4B	May 2020
Situs LV UC28D	May 2020
Situs LV UL28D	May 2020
Stelid II UTF26D	May 2020
Swift 1CT 4041	May 2020
MiniBest	November 2020
Talent II DR 233	November 2020

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