



## 1. DEVICE/EQUIPMENT:

### ELA Medical implantable pacemaker models:

Device Family	Model Numbers
Symphony	DR 2550 and SR 2250.
Rhapsody	DR+ 2530, DR 2510, D 2410 and SR 2210

## 2. PROBLEM:

ELA Medical has advised the MHRA that pacemakers of the above models could malfunction, causing loss of telemetry and pacing output. Changes in device characteristics are not noticeable to allow for detection of loss of pacing output between patient follow-up. All affected devices were manufactured before 1 August 2003.

ELA Medical issued a 'Dear Doctor' letter about this problem to UK clinicians on 27 October 2005 (see Appendix 3)

ELA's analysis of explanted devices has revealed a manufacturing problem, where an inadequately controlled soldering rework process may eventually result in metal migration between electronic components. Metal migration can form an alternative current pathway over time, which results in increased battery drain and loss of pacing output. ELA has identified 2 groups of pacemakers manufactured over different time periods, which have been subjected to a component soldering rework process.

### **Group 1 – manufactured between 6 June 2003 and 31 July 2003 (see Appendix 1 for list of affected serial numbers)**

Analysis of failures from this group of devices identified migration of tin and/or lead from solder pads on a ceramic substrate. Metal migration was confirmed in 10 units and suspected in one other. All these failures have come from a manufacturing batch of 1464 reworked devices, 340 of which have been implanted in the UK. The worldwide failure rate to date for loss of pacing output has been 0.75 %. To date there has been one confirmed UK failure.

ELA has advised that **pacemaker-dependent** patients implanted with devices from this group should be reviewed as soon as possible and consideration given to prophylactic replacement.

ELA has also advised that no change to patient follow-up is warranted for all other patients with devices from this group.

**The MHRA additionally advises** clinicians to review non-pacing-dependent patients as soon as possible and ensure patient follow-up is at intervals of no longer than 6 months, to enable detection of loss of pacing output and/or pacing dependency.

### **Group 2 – manufactured before 6 June 2003 (see Appendix 2 for list of affected serial numbers)**

This second group of devices was also subjected to similar component soldering rework but to a lesser extent. To date no failures have been reported from this group which contains a total of 904 devices, 180 of which have been implanted in the UK.

ELA Medical has not recommended prophylactic replacement nor changes to follow-up frequency for patients implanted with devices from this group.

**The MHRA additionally advises** clinicians to ensure patient follow-up is at intervals of no longer than 6 months for those implanted with a device from this group to enable detection of loss of pacing output and/or pacing dependency.

### 3. ACTION BY:

All cardiologists and cardiac physiologists who manage patients with any of these devices

### 4. ACTION:

- For patients with devices manufactured between 6 June 2003 and 31 July 2003 (Group 1, see Appendix 1):
  - Review pacemaker dependent patients as soon as possible and give consideration to timely prophylactic replacement according to the degree of pacemaker dependency.
  - Review non-pacing-dependent patients as soon as possible and ensure that subsequent follow-up is at intervals of no longer than 6 months to enable detection of loss of pacing output and changes in pacing dependency.
- For **all** patients with devices made before 6 June 2003 (Group 2, see Appendix 2):
  - Ensure patient follow-up is at intervals of no longer than 6 months to enable detection of loss of pacing output and changes in pacing dependency.
- Advise patients to contact their follow-up centre immediately if they experience a resumption of symptoms.
- Report explants to the National Pacing and ICD Database (see Contacts).

Report all incidents of device failure to the NIAIC and ELA Medical

### 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Accident & Emergency Departments
- Cardiac Pacemaker/ICD Physiologists
- Cardiologists with Pacemaker/ICD Responsibilities

### 6. CONTACTS:

Enquiries to the manufacturer and to the National Pacing and ICD Database should be addressed to:

Chantal Cadiou  
Vigilance Manager  
ELA Medical  
Centre d'Affaires La Boursidière  
92357 Le Plessis Robinson Cedex  
France

Tel: +33 1 46 01 36 87  
Fax: +33 1 46 01 36 37

E-mail: [chantal.cadiou@elamedical.com](mailto:chantal.cadiou@elamedical.com)

National Pacing and ICD Database  
PO Box 9205  
Bridge of Weir  
Strathclyde  
PA11 3DZ

Tel: 01505 612 829  
Fax: 01505 612 829

E-mail: [mwc@btconnect.com](mailto:mwc@btconnect.com)

Enquires to NIAIC should quote reference number MDEA(NI)2005/85 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

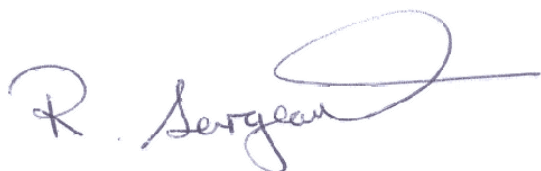
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None required.

A handwritten signature in blue ink that reads "R. Sergeant". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2005/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

## APPENDIX 1 to MDEA(NI)2005/85

List of affected serial numbers for:  
Symphony DR 2550, SR 2250 and Rhapsody DR+ 2530, DR 2510, D 2410, SR 2210 pacemakers  
manufactured **between 6 June 2003 and 31 July 2003 (Group 1)**

249WE100	306WJ034	309WG168	315WI013	315WI138	316WE053	318WJ098
249WG065	306WJ039	309WG170	315WI014	315WI139	316WE055	318WJ100
249WG066	306WJ047	309WG181	315WI015	315WI140	316WE056	318WJ103
302WI013	306WJ067	309WG182	315WI016	315WI141	316WE061	318WJ108
302WI060	306WJ086	309WG190	315WI018	315WI143	316WE064	318WJ111
302WI068	306WJ093	309WG210	315WI019	315WI144	316WE070	318WJ112
302WI079	306WL040	309WG215	315WI020	315WI159	316WE081	318WJ115
302WI143	306WL041	309WG237	315WI022	315WI161	316WE082	318WJ116
302WJ049	306WL043	309WG246	315WI023	315WI164	316WE109	318WJ117
302WL041	306WL051	309WG260	315WI025	315WI166	316WE121	318WJ139
302WL075	306WL076	314WG001	315WI027	315WI168	316WE155	318WJ143
302WL078	306WL080	314WG002	315WI028	315WI169	316WE156	318WJ146
302WL096	309WE001	314WG024	315WI036	315WI171	316WE159	318WJ147
302WL099	309WE002	314WG031	315WI041	315WI172	316WE186	318WJ162
302WL166	309WE013	314WG051	315WI043	315WI174	316WE219	318WJ163
303WE073	309WE018	314WG053	315WI044	315WI175	316WE248	318WJ169
303WE104	309WE019	314WG062	315WI046	315WI177	316WE270	318WJ174
303WE127	309WE027	314WG098	315WI047	315WI178	316WE274	318WJ177
303WG024	309WE032	314WG120	315WI048	315WI190	316WE275	318WJ178
303WG056	309WE037	314WG123	315WI049	315WI193	316WE277	318WJ179
303WG069	309WE057	314WG127	315WI055	315WI202	316WE279	318WJ180
303WG070	309WE092	314WG132	315WI056	315WI207	316WE280	318WJ192
306WE004	309WE100	314WG135	315WI058	315WI209	316WE288	321WE073
306WE006	309WE106	314WG136	315WI060	315WI212	318WJ011	321WE074
306WE016	309WE110	314WG144	315WI062	315WI213	318WJ012	321WE082
306WE019	309WE129	314WG158	315WI063	315WI219	318WJ016	321WE083
306WE022	309WE132	314WG164	315WI065	315WI221	318WJ020	321WE087
306WE039	309WE133	314WG166	315WI066	315WI222	318WJ021	321WE088
306WE054	309WE134	314WG170	315WI067	315WI228	318WJ022	321WE089
306WE056	309WE138	315WG016	315WI068	315WI233	318WJ026	321WE184
306WE071	309WE146	315WG026	315WI069	315WI257	318WJ032	321WE196
306WE072	309WE152	315WG102	315WI071	315WI260	318WJ037	321WE198
306WG055	309WE160	315WG103	315WI074	315WI261	318WJ039	321WE209
306WG057	309WE162	315WG105	315WI078	315WI265	318WJ044	321WE213
306WG066	309WE163	315WG112	315WI081	315WI268	318WJ050	321WE223
306WG219	309WG007	315WG122	315WI083	315WI272	318WJ064	321WE224
306WG238	309WG009	315WG127	315WI084	315WI273	318WJ071	321WE227
306WI046	309WG023	315WG129	315WI085	315WI274	318WJ073	321WE230
306WI054	309WG053	315WG140	315WI090	315WL003	318WJ074	321WE235
306WI056	309WG074	315WG169	315WI093	315WL121	318WJ075	321WE238
306WI059	309WG110	315WG170	315WI096	315WL124	318WJ076	
306WI060	309WG130	315WG176	315WI100	315WL128	318WJ078	
306WI063	309WG138	315WG210	315WI105	315WL135	318WJ080	
306WI065	309WG139	315WG217	315WI111	315WL145	318WJ084	
306WI068	309WG148	315WG283	315WI112	315WL153	318WJ086	
306WJ006	309WG153	315WI001	315WI118	316WE004	318WJ087	
306WJ009	309WG156	315WI002	315WI119	316WE014	318WJ089	
306WJ018	309WG160	315WI006	315WI126	316WE017	318WJ091	
306WJ021	309WG162	315WI007	315WI131	316WE024	318WJ094	
306WJ031	309WG165	315WI011	315WI136	316WE034	318WJ096	

## APPENDIX 2 to MDEA(NI)2005/85

List of affected serial numbers for:  
Symphony DR 2550, SR 2250 and Rhapsody DR+ 2530, DR 2510, D 2410, SR 2210 pacemakers  
manufactured **before 6 June 2003 (Group 2)**

222WA512	244WE089	244WJ061	250WG170
226WG004	244WE090	244WJ067	250WG176
226WG035	244WE092	246WG002	250WG179
226WG037	244WE093	246WG011	250WG183
226WG038	244WE094	246WG022	250WG230
226WG042	244WE095	246WG036	250WG237
226WG051	244WE097	246WG039	302WJ119
226WG057	244WE098	246WG041	302WL012
238WG013	244WE100	246WG061	302WL016
238WG031	244WE102	246WG077	302WL034
241WG010	244WE103	246WG123	302WL085
241WG025	244WE104	246WG147	302WL087
241WG030	244WE106	246WL004	302WL091
241WG033	244WE107	246WL011	302WL104
241WG039	244WE109	249WE001	302WL108
241WG043	244WJ002	249WE004	302WL117
241WG053	244WJ004	249WE009	302WL136
241WG054	244WJ009	249WE046	302WL141
243WG001	244WJ010	249WE060	302WL142
243WG006	244WJ011	249WE061	302WL159
243WG010	244WJ013	249WE062	302WL165
243WG011	244WJ016	249WE063	303WE023
243WG013	244WJ017	249WE092	303WE037
243WG026	244WJ018	249WE099	303WE040
243WG040	244WJ019	249WG020	303WE041
243WG041	244WJ022	249WG021	303WE043
243WG058	244WJ023	249WJ010	303WE046
243WG059	244WJ025	249WJ012	303WE052
243WG062	244WJ032	249WJ053	303WE058
243WG074	244WJ035	249WJ064	303WE064
243WG076	244WJ037	249WJ065	303WE068
243WG082	244WJ038	249WJ068	303WE096
243WG091	244WJ042	249WJ069	303WE123
243WL003	244WJ044	249WJ077	303WE136
244WE076	244WJ045	250WG021	303WE144
244WE077	244WJ047	250WG026	303WE155
244WE080	244WJ048	250WG057	306WL031
244WE081	244WJ051	250WG066	306WL073
244WE082	244WJ052	250WG073	306WL075
244WE083	244WJ053	250WG090	306WL079
244WE084	244WJ054	250WG096	306WL085
244WE085	244WJ056	250WG097	306WL091
244WE086	244WJ057	250WG112	306WL093
244WE087	244WJ059	250WG116	306WL096
244WE088	244WJ060	250WG167	306WL100

## APPENDIX 3 to MDEA(NI)2005/85

ELA Medical letter to UK clinicians 27 October 2005



27 October 2005

Dear

**IMPORTANT MEDICAL DEVICE SAFETY INFORMATION AND CORRECTIVE ACTIONS  
REGARDING ELA MEDICAL SYMPHONY AND RHAPSODY PACEMAKERS MANUFACTURED  
BEFORE AUGUST 1, 2003**

(models Symphony DR 2550, Symphony SR 2250,  
Rhapsody DR+ 2530, Rhapsody DR 2510, Rhapsody D 2410, Rhapsody SR 2210)

Through its continuous post-market surveillance, ELA Medical observed that cessation of pacing output could occur in a limited number of Symphony or Rhapsody pacemakers. No injury or death has been reported.

The cessation of pacing output could occur due to metal migration caused by a specific manufacturing process; this process was conducted systematically in a first group of devices and as deemed necessary in a second group of devices. No measurable change in device characteristics has been identified that could warn of an impending incident; consequently ELA Medical is not recommending more frequent monitoring.

- In the first group, the worldwide failure rate to date for cessation of pacing output has been 0.75 % (0.57 % per year starting one year after manufacture). Pacemaker-dependent patients implanted with units manufactured in this group should be reviewed as soon as possible and consideration given to prophylactic replacement. There are 340 devices in this group in the UK.
- In the second group, the worldwide failure rate to date for cessation of pacing output has been 0.00 % (no cases have occurred, which is consistent with an underlying rate of 0.07 % per year or less). Recently<sup>1</sup> published data indicate that the average failure rate for all pacemakers is approximately 0.15 % per year. Because of the small but non-zero risk associated with device replacement, ELA Medical is not recommending prophylactic replacement in this group. There are 180 devices in this group in the UK.

No case of metal migration has been identified in any device manufactured on or after August 1, 2003. Because the specific manufacturing process was not conducted in this group and no incidents have occurred, all available information indicates that no significant risk exists in this group.

Serial-numbered lists of devices that have been distributed to your center, from the first and second groups, are supplied with this letter.

---

<sup>1</sup> Maisel WH, Pacemaker and ICD Generator Malfunctions, HRS Policy Conference on Pacemaker and ICD Performance, September 16, 2005.

SORIN Group UK Ltd

6 & 8 Sabre Close, Green Farm Business Park, Quedgeley, Gloucester, GL1 4NZ

Tel: 01452 887700 Fax: 01452 887730

Registered In England and Wales Company No 5164784 VAT Number 840 9453 20.

## APPENDIX 3 to MDEA(NI)2005/85



---

Your assistance is appreciated and necessary to assure acceptable performance of this limited number of Symphony and Rhapsody pacemakers. Please complete and return the enclosed response form as soon as possible. If you have any questions, please contact your local Sorin Group / ELA representative.

This notification is being made with the knowledge of the UK Competent Authority, the Medicines and Healthcare products Regulatory Agency (MHRA).

Sincerely,

Enclosure

SORIN Group UK Ltd  
6 & 8 Sabre Close, Green Farm Business Park, Quedgeley, Gloucester, GL1 4NZ  
Tel: 01452 887700 Fax: 01452 887730  
Registered In England and Wales Company No 5164784 VAT Number 840 9453 20.

**APPENDIX 3 to MDEA(NI)2005/85**



---

**Re: IMPORTANT MEDICAL DEVICE SAFETY INFORMATION AND CORRECTIVE ACTIONS  
REGARDING CERTAIN ELA MEDICAL SYMPHONY AND RHAPSODY PACEMAKERS**

I have read and understand the instructions provided in the letter of October 25, 2005.

Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Hospital: \_\_\_\_\_  
Date: \_\_\_\_\_  
Tel. Number: \_\_\_\_\_  
Comments: \_\_\_\_\_  
\_\_\_\_\_

PLEASE FAX OR MAIL COMPLETED RESPONSE FORM TO THE FAX NUMBER OR ADDRESS LISTED BELOW.

SORIN Group UK Ltd  
6 & 8 Sabre Close, Green Farm Business Park, Quedgeley, Gloucester, GL1 4NZ  
Tel: 01452 887700 Fax: 01452 887730  
Registered In England and Wales Company No 5164784 VAT Number 840 9453 20.