



Medicines and Healthcare products
Regulatory Agency

Medical Device ALERT

Ref. MDA/2005/046

Issued: 26 July 2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION REQUEST	

	Further Information
<p>DEVICE: ELA Medical Alto implantable cardioverter defibrillator (ICD), models: 614, 615, 617, 624, 625 and 627 – supplement to MDA/2005/015. See Appendices for full list of affected serial numbers.</p>	
<p>PROBLEM: Recall due to premature battery depletion and/or prolonged charge time, leading to loss of cardioversion, defibrillation or pacing. In some cases battery failure has occurred within the recommended three monthly follow-up period.</p>	▶
<p>ACTION BY: All cardiologists and cardiac technicians who manage patients implanted with these devices.</p>	
<p>ACTION: Identify patients implanted with affected devices (see Appendices) and see actions listed on page 3 of this Medical Device Alert.</p>	▶
<p>DISTRIBUTED to: NHS Trusts (England) – Chief Executives* Healthcare Commission (CHAI) – Headquarters Primary Care Trusts (England) – Chief Executives* * via CE Bulletin</p>	▶
<p>CONTACTS: Details of manufacturer contacts, National Pacing and ICD Database and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.</p>	▶

▶ Further information supplied in the following pages.

The full text of this notice is on our website: <http://www.mhra.gov.uk>

PROBLEM:

In March 2005 the MHRA issued a Medical Device Alert **MDA/2005/015** regarding ELA Medical implantable cardioverter defibrillators (ICDs), models Alto 614, 615, 617, 624 and 625, where premature battery depletion and/or prolonged charge time could occur in devices manufactured before 17 April 2003. This battery depletion is due to high current consumption resulting from migration of metal (used in the soldering processes) forming unintended current paths between circuit components.

ELA Medical and its supplier introduced modified manufacturing and inspection processes in April 2003, July 2003 and again in August 2004, with the aim of preventing the occurrence of this problem.

Through post-market surveillance, ELA Medical has confirmed that two further groups of Alto ICDs manufactured after 17 April 2003 are also affected by this problem.

ELA Medical has issued four Dear Doctor Letters (DDLs), regarding Alto ICDs, to affected UK implanting and follow-up centres.

- In February 2004, advising clinicians of the problem and reminding them to follow up patients at intervals no greater than three months.
- In July 2004, informing clinicians that increased failure rates had been observed and reiterating the advice that patients should be followed up at intervals of no greater than three months. This DDL also informed clinicians of the availability of a new version of ELAview software (1.26) for its Orchestra programmer. The updated software automatically checks the ICD's existing battery current consumption and battery voltage history since manufacture. If a potentially high current (unsafe) condition is discovered, the programmer displays a warning advising that ICD replacement should be considered.
- In January 2005, informing clinicians that premature battery depletion can, in some cases, occur without warning less than three months after the last follow-up. In such circumstances, three month follow-up will not guarantee protection from malfunction.
- In July 2005, informing clinicians that two further serial number groups of Alto ICDs have exhibited metal migration and again reminding clinicians to follow up patients at intervals no greater than three months. This DDL also advised that un-implanted hospital stock would be replaced by ELA Medical. (Un-implanted hospital stock for these groups is assumed to be zero in the UK).

To date approximately 520 potentially affected devices have been distributed in the UK. The following tables show confirmed failures due to metal migration for the UK (Table 1) and worldwide (Table 2).

Manufacture date	Number of UK devices potentially affected	Number of UK confirmed failures	UK failure rate (%)	UK affected serial numbers
Before 17 April 2003	263	14	5.3 %	Appendix 1
April 2003 to July 2003	60	3	5 %	Appendix 2
August 2003 to August 2004	197	1	0.5 %	Appendix 3
After August 2004	None	None	N/A	None

Table 1: UK incidence of confirmed metal migration to date

PROBLEM (continued):

Manufacture date	Number of devices potentially affected worldwide	Worldwide failure rate (%)
Before 17 April 2003	1,777	7.4 %
April 2003 to July 2003	430	2.6 %
August 2003 to August 2004	1,856	0.1 %
After August 2004	None	N/A

Table 2: Worldwide incidence of confirmed metal migration to date

Due to the uncertainty of device performance between follow-up visits, the MHRA wishes to emphasise to clinicians that battery depletion may occur without warning less than three months after the last follow-up.

Lists of affected serial numbers for the UK can be found in the Appendices to this Medical Device Alert. Serial numbers not included in the Appendices are unaffected by this problem

ACTION:

- Do not implant devices having affected serial numbers (see Appendices).
- Segregate un-implanted devices with affected serial numbers and return them to ELA Medical in accordance with their instructions.
- Be aware that premature battery depletion and/or prolonged charge time may occur within the three month follow-up period recommended by ELA Medical.
- Ensure that follow-up intervals are no greater than three months.
- Identify patients implanted with affected devices who are known to have frequent/recent episodes of arrhythmia (particularly ventricular fibrillation) and those that are pacemaker-dependent, and consider prophylactic explantation or more frequent follow-up.
- Ensure that the Orchestra programmer is installed with ELAview software version 1.26 or later.
- Remind patients to contact their follow-up centre if they experience persistent arrhythmias/resumption of symptoms which remain uncorrected by the device.
- Report all instances of unexpected battery depletion to the MHRA and ELA Medical, especially for any ICDs outside the affected serial number list (see Appendices).
- Report explants to the National Pacing and ICD Database (see Contacts).

ACTION DEADLINES FOR THE SAFETY ALERT BROADCAST SYSTEM (SABS)

Trust managers should ensure that measures to implement the 'Actions' specified above are planned and completed in line with the following SABS deadlines.

Deadline (Action underway): 30 August 2005

Action plan to be agreed and actions started.

Deadline (Action complete): 28 November 2005

All actions to be completed.

Further information about SABS can be found at www.info.doh.gov.uk/sar/cmopatie.nsf

DISTRIBUTION:

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

TRUSTS to:

- Liaison officers (for onward distribution)
- Cardiac pacemaker/ICD technicians
- Cardiologists with pacemaker/ICD responsibilities
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Risk managers

HEALTHCARE COMMISSION (CHAI) to:

- Headquarters (for onward distribution)
- Hospitals in the independent sector

PRIMARY CARE TRUSTS to:

- Liaison officers (for onward distribution)
- Clinical governance leads
- Directors of public health

CONTACTS:

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

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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

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

Enquiries to the MHRA should quote reference number **2003/011/005/241/015** and be addressed to:

Technical aspects:

Ms Julie MacDonald or Mr Peter M Solesbury
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
Vauxhall
London SW8 5NQ

Tel: 020 7084 3343 / 3215

Fax: 020 7084 3106

E-mail: julie.macdonald@mhra.gsi.gov.uk
peter.solesbury@mhra.gsi.gov.uk

Clinical aspects:

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Medicines & Healthcare products Regulatory Agency
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Vauxhall
London SW8 5NQ

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Fax: 020 7084 3111

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Change of address or removal from address list for Healthcare Commission:

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

HOW TO REPORT ADVERSE INCIDENTS

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk
(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

Appendix 1 to MDA/2005/046

List of affected serial numbers for
Alto ICDs manufactured prior to April 17 2003.

003XF002	112XF058	123XF043	210XG051	215XF099	221XG057	244XJ025
003XF025	112XF067	136XF024	210XG056	215XF113	225XG039	244XJ032
007XF007	112XF077	136XF029	211XF006	215XF125	225XG041	244XJ050
007XF013	113XF003	136XF031	211XF058	216XF007	226XG009	244XJ072
007XF014	113XF007	136XF033	211XF064	216XF015	226XG010	244XJ078
007XF020	113XF012	136XF045	213XF008	216XF017	226XG014	244XJ083
007XF029	113XF014	140XF006	213XF011	216XF022	226XG037	244XJ087
007XF033	113XF052	140XF028	213XF019	216XF025	226XG046	246XI016
007XF035	113XF060	140XF029	213XF027	216XF028	226XI523	246XI024
007XF037	113XF073	140XF033	213XF043	216XF036	226XI524	246XI034
007XF043	113XF074	140XF038	213XF052	216XF037	226XI526	246XI038
007XF055	113XF079	140XF044	213XF070	216XF048	226XI529	246XI075
007XF059	114XF031	140XF047	213XF072	216XF053	226XI539	246XJ027
007XF060	114XF064	140XF055	213XF074	216XF057	237XG005	246XJ033
007XF072	114XF076	202XI512	213XF077	216XF068	238XJ006	246XJ044
007XF073	115XF002	203XF003	213XF078	216XF078	238XJ022	246XJ074
020XF023	115XF011	203XF030	213XF093	216XF081	238XJ032	249XJ010
020XF028	115XF016	203XF047	213XF095	216XF099	238XJ033	249XJ013
020XF041	115XF018	203XF048	213XF106	216XF120	238XJ053	249XJ089
020XF048	115XF032	204XF002	213XF109	216XF121	238XJ057	249XJ111
020XF054	115XF034	204XF034	213XF110	216XF130	238XJ059	249XJ116
020XF098	115XF044	204XF038	213XF111	216XF139	242XH590	249XJ120
035XH561	115XF045	204XF058	213XF112	217XF014	242XH596	304XJ010
046XH567	115XF054	210XF029	213XF113	218XF020	242XH597	929XF007
046XH572	115XF072	210XF030	213XF115	221XF013	242XH599	929XF008
046XH574	115XF073	210XF035	213XF120	221XG002	242XH600	944XF506
046XH575	122XF002	210XG004	213XF124	221XG013	243XI005	944XF512
046XH582	122XF011	210XG015	213XF127	221XG016	243XI012	944XF514
046XH585	122XF024	210XG016	213XF128	221XG017	243XI021	944XF517
046XH597	122XF031	210XG020	213XF131	221XG023	243XI025	944XF523
046XH599	122XF033	210XG021	213XF132	221XG024	243XI029	944XF525
046XH606	122XF039	210XG022	213XF138	221XG038	243XI061	944XF526
046XH609	122XF049	210XG032	214XF028	221XG039	243XI063	947XF515
112XF012	123XF011	210XG036	214XF031	221XG042	243XI079	947XF523
112XF028	123XF025	210XG040	214XF039	221XG048	243XI086	947XF526
112XF035	123XF026	210XG041	215XF007	221XG050	244XJ007	
112XF056	123XF031	210XG043	215XF065	221XG052	244XJ010	
112XF057	123XF034	210XG044	215XF070	221XG053	244XJ017	

Appendix 2 to MDA/2005/046

List of affected serial numbers for
Alto ICDs manufactured April 2003 to July 2003.

236XH003	304XJ012
236XH020	304XJ038
241XH010	304XJ049
241XH011	304XJ050
241XH013	304XJ080
241XH015	304XJ082
241XH019	304XJ093
241XH020	304XJ106
241XH049	305XH003
241XH055	305XH013
243XI015	305XH033
246XI009	305XH034
246XI018	305XH036
246XI054	307XJ041
246XI058	307XJ088
246XI059	307XJ117
246XI063	307XJ123
246XJ016	307XJ134
246XJ032	307XJ138
246XJ040	307XJ151
246XJ041	307XJ186
246XJ064	307XJ194
246XJ070	307XJ200
246XJ100	307XJ202
249XJ068	313XJ040
249XJ125	313XJ182
249XJ128	313XJ204
249XJ132	313XJ232
249XJ135	
249XJ138	
249XJ156	
249XJ190	

Appendix 3 to MDA/2005/046

List of affected serial numbers for
Alto ICDs manufactured August 2003 to August 2004.

238XJ018	312XI003	330YA502	351XJ004	407YA607
238XJ026	312XI014	330YA506	351XJ009	407YA610
238XJ039	312XI022	330YA507	351XJ011	407YA612
243XI006	312XI057	330YA514	351XJ033	407YA621
243XI071	312XI058	330YA515	351XJ042	407YA622
246XI051	312XI064	330YA516	351XJ044	407YA623
246XJ056	312XI067	330YA527	351XJ049	407YA625
246XJ095	312XI076	330YA531	351XJ050	407YA627
249XI040	312XI078	330YA537	351XJ057	407YA636
249XI063	312XI079	330YA549	351XJ066	407YA637
249XI099	312XI099	330YA551	402XI058	407YA638
249XJ105	312XI102	339XJ013	402XI062	407YA639
303YA521	312XI105	339XJ027	402XJ004	407YA640
303YA525	313XJ012	339XJ038	402XJ012	407YA641
303YA526	313XJ016	340XJ036	402XJ013	407YA642
303YA552	313XJ028	340XJ041	402XJ016	407YA646
303YA572	313XJ029	340XJ065	402XJ039	407YA648
304XI001	313XJ045	340XJ070	402XJ044	407YA653
304XI020	313XJ082	340XJ074	402XJ047	407YA658
304XI042	313XJ095	340XJ083	402XJ054	407YA661
304XI043	313XJ185	340XJ093	402XJ071	409XI011
304XI062	313XJ201	340XJ103	402XJ084	409XI029
304XI083	313XJ259	340XJ109	403XJ068	409XJ010
304XI092	314XJ004	340XJ123	403XJ070	409XJ011
304XI112	314XJ022	345XJ005	403XJ071	409XJ024
304XI144	314XJ027	345XJ013	403XJ080	409XJ045
304XJ039	314XJ043	345XJ014	403XJ088	411XJ017
304XJ043	314XJ049	345XJ015	403XJ094	411YA022
305XH007	314XJ083	345XJ020	404XI043	413XI015
307XI012	314XJ088	345XJ043	404XI046	413XJ021
307XI014	314XJ091	345XJ044	405XI005	413XJ023
307XI069	314XJ123	345XJ057	405XI006	413XJ030
307XI085	314XJ146	348YA568	406XJ064	414XI023
307XI103	314XJ151	348YA575	407YA597	414XI049
307XI111	314XJ183	348YA579	407YA598	414XI068
307XJ086	314XJ217	350XJ009	407YA599	414XI069
307XJ101	314XJ258	350XJ066	407YA603	414XJ040
307XJ140	314XJ307	350XJ068	407YA605	414XJ075
307XJ236	314XJ310	350XJ084	407YA606	414XJ108
	314XJ326	350YA590		