

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/071

Issued: 23rd September 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section								
Medical Device/Equipment: Implantable cardioverter defibrillators – all manufacturers and models.	▶ ①								
Problem: <ul style="list-style-type: none"> • Risk of electric shock to clinicians or mortuary personnel while removing implantable cardioverter defibrillators (ICDs). • Risk of explosion during ICD incineration. • Need to maintain device/data integrity for ICDs subject to investigation. 	▶ ②								
Action by: Clinicians and mortuary personnel who remove ICDs post mortem.	▶ ③								
Action: Do not remove an implantable cardioverter defibrillator (ICD) without first disabling all high voltage shock therapies.	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">Hospices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td></td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	Hospices	Chief Executive of each HSS Trust		Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥								
Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)									
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; color: magenta;"> Acknowledge Receipt of Alert: 26th Sept 2008 </td> <td style="width: 33%; color: magenta;"> Action Under Way: 20th Oct 2008 </td> <td style="width: 33%; color: magenta;"> Action Complete: 23rd March 2009 </td> </tr> </table>	Acknowledge Receipt of Alert: 26 th Sept 2008	Action Under Way: 20 th Oct 2008	Action Complete: 23 rd March 2009	▶ ⑦					
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

Implantable cardioverter defibrillators – all manufacturers and models.

2. PROBLEM:

The MHRA continues to receive reports of electric shocks sustained by mortuary personnel and medical practitioners during removal of ICDs after death. ICD removal is necessary prior to cremation, or when the ICD is needed for analysis/testing due to a suspected device malfunction.

Care during ICD removal

ICDs are normally implanted in the pectoral region, but older units may have been implanted in the abdominal cavity (usually in the rectus sheath). When an ICD is removed, the sensing pathway may be disturbed, particularly if the wire to the heart is cut. This may cause the ICD to detect noise from the cut lead and deliver an electric shock. The shock is normally delivered between the exposed electrode(s) on the heart lead, and the metal casing of the ICD. Any shock accidentally delivered to the personnel handling the device could be very uncomfortable, although it is unlikely to be harmful.

Note: ICDs contain a magnetic switch that is used during clinical programming. Placing a magnet over the implant site will inhibit shock therapy in nearly all ICD models, depending upon how the device is programmed. If attempting to inhibit shock therapy by magnet placement, care should be taken to ensure the magnet is kept very close to the ICD at all times, as separation may restore the potential for shock delivery. ICDs that are temporarily disabled and removed will therefore need to be packaged appropriately and labelled to prevent accidental shock to personnel.

ICD battery explosion

ICDs usually contain a lithium battery, which may explode if exposed to high temperatures (such as those used in the incineration of clinical waste). Ensure that ICDs are not disposed of by incineration.

3. ACTION BY:

Clinicians and mortuary personnel who remove ICDs post mortem.

4. ACTION:

Before removal, identify the manufacturer and model name of the implant.

There are several options for this:

- Consult the hospital or GP patient records or the patient's device registration card (this may be held by a relative).
- Consult the National Pacemaker and ICD Database (see details below).
- Review an X-ray of the device in situ where the manufacturer's radiopaque identification symbol can be observed (a list of X-ray ID marks is available from all ICD manufacturers and the MHRA).
- Make a lateral incision across the implant location to reveal the ICD casing (the ICD is usually implanted with the manufacturer/device legend outermost). When making an incision, take care to avoid the coiled heart lead, which may be located behind or adjacent to the ICD.

Reprogramming or disabling the ICD

- Once the ICD manufacturer/model details have been established, contact the patient's follow-up centre (or contact the nearest cardiac centre) to obtain reprogramming support to permanently set the device to a non-shock delivery mode. This may require onward referral by the local cardiac centre to a specialist ICD follow-up centre and may take some time to arrange.
- Following ICD reprogramming, ensure that this action has been clearly recorded in the

- accompanying patient documentation.
- If programming support cannot be made available then the device and leads should be removed intact. Personnel involved should take care to insulate themselves by wearing appropriate rubber gloves and boots to avoid possible shocks.

Disposal of the ICD

- Do not dispose of the ICD by incineration.
- If possible, advise the implanting hospital of patient death and the intention to remove/dispose of the ICD. The hospital may wish for the information stored in the device to be accessed for patient records or may require return of the ICD for full analysis and return to the manufacturer.

Where the ICD is subject to an adverse incident investigation

- Prior to removal and reprogramming, carry out a full ICD interrogation using an appropriate programmer. Print hard copies of all device parameter settings and internal memory data areas and save all parameter settings electronically (e.g. 'save to disk').
- Ensure that the complete system (including heart leads) is removed intact. Do not cut the heart leads.

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:

- Cardiac physiologists
- Cardiology directors
- Mortuary technicians
- Pathology directors
- Independent Health and Social Care Providers – Private Hospitals & Clinics

6. CONTACTS:

Enquiries to NIAIC should quote reference number MDEA(NI)2008/071 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

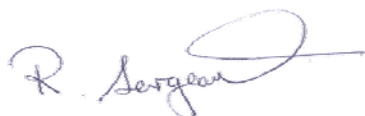
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
26th Sept 2008

Action Under Way:
20th Oct 2008

Action Complete:
23rd March 2009



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)2007/01. 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

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