IMPLANTABLE DEFRIBRILLATORS
Removal & De Activation

Queries raised from SAIF meetings:

1. How is the high electrical unit affected during Embalming, if it can remain in situ for burial?

   There is a slight inherent danger. The BIE have stated that during the use of a Trochar (the long needle used to extract fluids from the various organs) the needle could pierce or damage the electrical lead, causing the unit to think the heart needs an electrical boost and discharge an electrical shock.

2. The implication that death could occur if the unit is mishandled is extremely alarming.

   The BMA state that only in extreme and very rare cases could death occur, in general a very nasty electric shock will be encountered, the reason for erring on the side of caution is if the recipient of the shock has an unstable heart condition anyway, it could have a fatal consequence

3. Does placing the hand on the unit constitute a risk element ?

   As stated below, a magnet can be placed above the unit to inhibit the shock process, allowing for work to be carried out on the deceased, be careful when moving the magnet away as this can give a signal to the unit that it needs to discharge the shock.

4. Removal for Cremation, how can this be done ?

   It is paramount that the unit is removed before cremation, most units should and could be removed at the hospital source, however due diligence must be paid by the Funeral Workforce who will undoubtedly come into contact with these units.


Under skin image

ICD


Pacemaker

5. Returning of the units to the Cardiology unit raises issues in itself, as these units are classified as Clinical Waste and need to be disposed of according to local authority guidelines.

6. How many de –activation units are there ? and how quickly can they arrive at the needed location ?

MDA/2008/068 - Implantable cardioverter defibrillators - all manufacturers and models

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1. Page 1

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	Immediate action
✓	**Action**
	Update
	Information request

Device: Implantable cardioverter defibrillators – all manufacturers and models.	

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Risk of electric shock to clinicians or mortuary personnel while removing implantable cardioverter defibrillators (ICDs).

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• Need to maintain device/data integrity for ICDs subject to investigation.</td><td>►Page 2</td></tr>
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Clinicians and mortuary personnel who remove ICDs post mortem.</td><td></td></tr>
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Do not remove an implantable cardioverter defibrillator (ICD) without first disabling all high voltage shock therapies.</td><td>►Page 2</td></tr>
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Action deadlines for the Central Alerting System (CAS)	
Deadline (action underway): 20 October 2008	**Deadline (action complete): 23 March 2009**

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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 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.

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.

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Distribution:

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

Trusts to:
CAS liaison officers for onward distribution to all relevant staff including:

- Cardiac physiologists
- Cardiology directors
- Mortuary technicians
- Pathology directors

Primary care trusts to:
CAS liaison officers for onward distribution to all relevant staff including:

- General practitioners

Healthcare Commission (CHAI) to:
Headquarters for onward distribution to:

- Hospitals in the independent sector
- Private medical practitioners

Funeral Associations

National Society of Allied & Independent Funeral Directors

Contacts:

Enquiries to the MHRA should quote reference number **2008/005/001/291/008** and be addressed to:
Technical aspects:
Miss Celina Cundy or Miss Sam Baxter
Medicines & Healthcare products Regulatory Agency
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1 Nine Elms Lane
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National Pacemaker and ICD database:
Mrs Morag Cunningham
PO Box 9205
Bridge of Weir
Strathclyde
PA11 3DZ
Tel/Fax: 01505 612829

Enquiries for Scotland should be directed to:
Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB
Tel: 0131 275 7575
Fax: 0131 314 0722
E-mail: iric@shs.csa.scot.nhs.uk

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; online 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 officer hours)
Medical Device Alerts are available in full text on the MHRA website: http://www.mhra.gov.uk
Further information about **CAS** can be found at
https://www.cas.dh.gov.uk/Home.aspx