HRUK Certificate of Accreditation
Specialist Section – Devices

Recalls & Faults
‘How to deal with them’

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Recalls & Faults

- Responsibilities & legislation
- Reporting requirements
- Examples of problems
- Local considerations
- Return of products
- Device & lead extraction

Who is responsible for medical devices

- Role of manufacturer
- Role of Government
- Role of the NHS Trust (Doctor / HCP)
- Role of HRUK
- Role of the patient / public

Manufacturer

- Devices and leads fit for purpose
- Short term testing for CE marking
- Long term post market surveillance (product report documents)
- Field safety corrective actions (FSCA)
- Adverse incident reporting
- Evaluation of extracted devices / leads

Role of NHS Trust

- Professional trained team exists
  - Identified responsible medical consultant
  - Trained & supported physiologists and nurses
- Timely and accurate data returns (CCAD)
- Robust procedures for managing patients under advisory notices (working with manufacture and MHRA)

Role of HRUK

- Support professionals in the field of cardiac devices
- Guidance for device prescription & service provision
- Coordinate and disseminate relevant information from MHRA / manufactures
- Rapid response to MHRA over concerns
- Visits and reviews

Active implanted medical devices directive

Directive 90/385/EEC

A ‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of : diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment.

Active implanted medical devices directive

Directive 90/385/EEC

An ‘active medical device’ means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

An ‘active implantable medical device’ means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

Active implanted medical devices directive

Directive 90/385/EEC

- Device is ‘implanted’ and ‘active’
  - Cardiac Pacemaker
  - Implantable cardioverter defibrillator
  - Leads and adaptors for PPM / ICD
  - Implantable active monitoring devices (ILR)
  - Remember also includes software
- Requires country to have competent authority (MHRA in UK)

Medicines and Healthcare Products Regulatory Agency

An executive agency of the Department of Health

We enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe. No product is risk free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks.

Medicines and Healthcare Products Regulatory Agency

- Adverse incident reporting
- Adverse Incident investigation
- Regulatory & statutory responsibilities
- Protection of patient (consumer protection act 1987)
- Medical devices regulations 2002 & Medical devices (amendments) regulations 2008
- Sanctions to warn, suspend or prohibit

Field Safety Corrective Action (FSCA)

- Comments on drafts of FSCA
- Places FSCA on web site
- Assesses if more than FSCA needs to be undertaken
- Monitors progress of FSCA
- Objective non-commercial opinion
- Track cross industry implications
- Obliged to share information with others

Reporting to the MHRA

www.mhra.gov.uk

Hotline 02070843109

- Loss of function or non delivery of therapy
- Inappropriate / delayed therapy
- Back up / safety mode pacing
- Unexpected battery depletion / status
- Programming problems
- Unexplained changes in lead impedance

Implantable Defibrillators, Pacemakers and Leads: Reporting Adverse Events

MHRA

What Should I Report?

Loss of functionality or non-delivery of therapy
e.g. Loss of pacing, shock therapy, telemetry or programmed settings.

Inappropriate delivery of therapy

Delay in delivery of therapy

Backup and safety mode pacing
If unexplained and/or irreversible, but not due to normal battery depletion.

Unexpected battery depletion
Rapid or premature, given device age and programmed settings.

Uncertain battery status and longevity indicators
If unclear, conflicting or missing, given follow-up frequency.

Programming problems
Any unexpected anomalies during programming that could have an adverse clinical effect.

Change in lead impedance
Grossly abnormal lead impedance changes.

Why Should I Report?

Reporting adverse events helps the MHRA identify and address device-related safety problems.

How Can I Report?

Online at www.mhra.gov.uk
Or download a form from www.mhra.gov.uk and e-mail to: aic@mhra.gsi.gov.uk
or Fax: 020 7084 3109 Hotline: 020 7084 3080

Important Safety Information

Immediate action after an adverse incident:

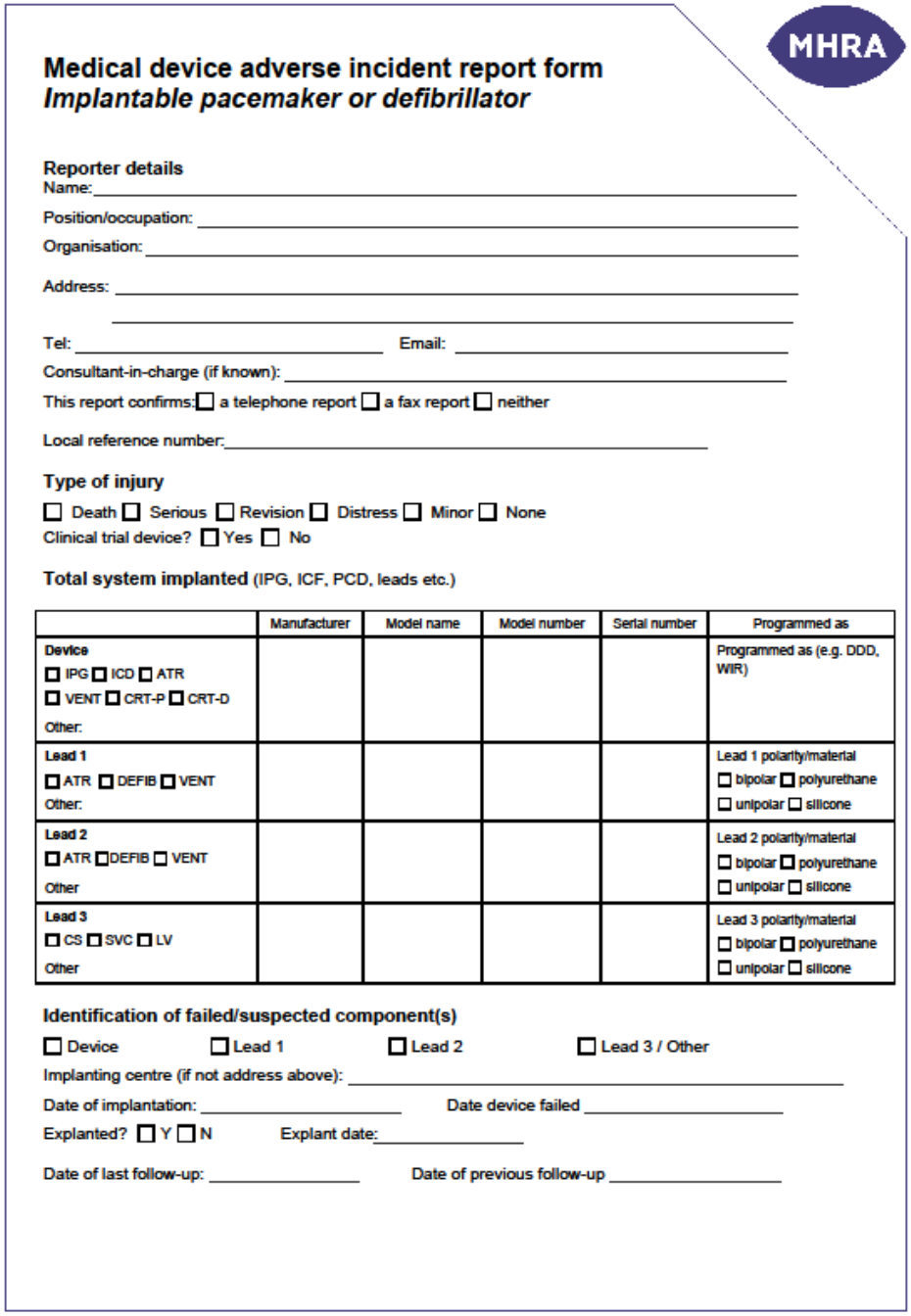
1. Quarantine device if removed
2. Report to MHRA
3. Contact the manufacturer / UK distributor

MHRA Recommendations:

- Devise a local protocol to facilitate adverse incident reporting.
- Ensure new staff and locums are made aware of reporting procedures.

HR-UK
Heart Rhythm UK

Poster should be displayed in implant areas and follow up clinics (available from MHRA)



Medical device adverse incident report form
Implantable pacemaker or defibrillator

MHRA

Reporter details
Name: _____
Position/occupation: _____
Organisation: _____
Address: _____
_____
Tel: _____ Email: _____
Consultant-in-charge (if known): _____
This report confirms: ☐ a telephone report ☐ a fax report ☐ neither
Local reference number: _____

Type of injury
☐ Death ☐ Serious ☐ Revision ☐ Distress ☐ Minor ☐ None
Clinical trial device? ☐ Yes ☐ No

Total system implanted (IPG, ICF, PCD, leads etc.)

	Manufacturer	Model name	Model number	Serial number	Programmed as
Device ☐ IPG ☐ ICD ☐ ATR ☐ VENT ☐ CRT-P ☐ CRT-D Other:					Programmed as (e.g. DDD, WIR)
Lead 1 ☐ ATR ☐ DEFIB ☐ VENT Other:					Lead 1 polarity/material ☐ bipolar ☐ polyurethane ☐ unipolar ☐ silicone
Lead 2 ☐ ATR ☐ DEFIB ☐ VENT Other					Lead 2 polarity/material ☐ bipolar ☐ polyurethane ☐ unipolar ☐ silicone
Lead 3 ☐ CS ☐ SVC ☐ LV Other					Lead 3 polarity/material ☐ bipolar ☐ polyurethane ☐ unipolar ☐ silicone

Identification of failed/suspected component(s)
☐ Device ☐ Lead 1 ☐ Lead 2 ☐ Lead 3 / Other
Implanting centre (if not address above): _____
Date of implantation: _____ Date device failed _____
Explanted? ☐ Y ☐ N Explant date: _____
Date of last follow-up: _____ Date of previous follow-up _____

MHRA on line reporting tool available via the website

Guy's & St. Thomas' Hospitals NHS
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Devolved Governments

- Incidents occurring in Scotland, Northern Ireland and Wales
  The latest guidance on reporting incidents occurring in Scotland, Northern Ireland and Wales is published in:

  Northern Ireland : MDEA(NI)2009/01
  Scotland : SAN(SC)07/01
  Wales : NDA/2004/054.

Notifications

- Dear Doctor Letters (Manufacturers)
  - No formal record
- Pacemaker Technical Notes (MDA)
  - Archived by MHRA 1970's →2002
- Medical Device Alerts (MHRA)
  - Available on line (Jan 2003→)

Recent examples

- Acufix Leads, J retention wire
- Telectronics soft top
- Polyurethane leads (SJM 1010T)
- Medtronic Sprint Fidelis ICD Leads
- St. Jude Medial Riata ICD lead
- Marquis early battery depletion

Local Considerations

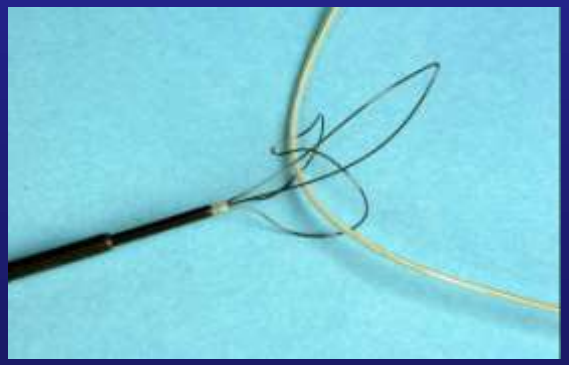
- Device tracking
- Returns to CCAD/ local database
- Managing patients on advisories (paper & electronic records)
- Software upgrades & fixes
- Informing & updating staff (record keeping)
- Local reporting requirements & Safety action bulletins (SABS)

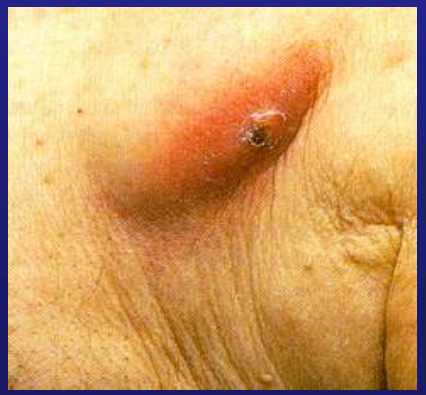
Return of devices for evaluation

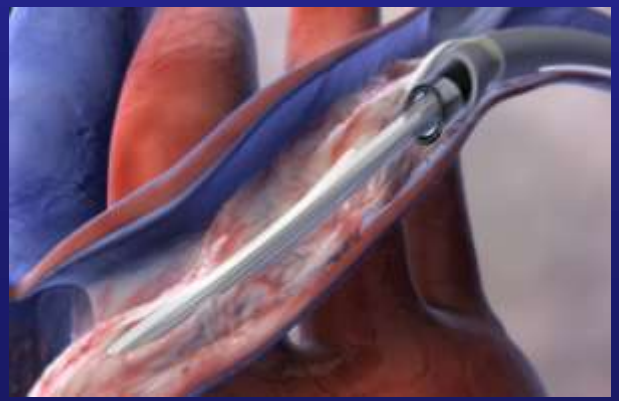
- Company specific instructions
- Bio Hazard & decontamination
- Updates, reports & record keeping

Device System and Lead Extraction

- Experienced centre with cardiac surgery back up
- Choice of manual or technology lead methods of removal







Any Questions