Cardiac Implantable Electronic Devices (CIEDs), necessary considerations: Magnetic Resonance Imaging (MRI) Compatible devices.

V1.1

November 2014
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1. Introduction

1.1. Traditionally Cardiac Implantable Electronic Device (CIED) patients were not allowed to undergo Magnetic Resonance Imaging (MRI) scanning due to concerns that the MRI scanner would:

1.1.1. damage the device
1.1.2. interfere with the device function or
1.1.3. cause the device (where it has the capability) to deliver therapy in the form of anti-tachycardia pacing or a shock.

In an era where MRI scanning is being utilised more frequently, the CIED companies have responded by ensuring many of their devices are MRI compatible, but not all devices are.

1.2. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

2.1. This policy has been drawn up to provide some guidance around the necessary considerations prior to implantation of a MRI compatible CIED.

3. Scope

3.1. This document provides guidance for any professional involved in the implantation of CIEDs at the Royal Cornwall Hospital. This will include:

- Administrative staff booking patients for a CIED implant
- Nursing staff checking the patient in for their CIED implant
- Cardiac Physiologists either listing patients for a generator change or involved in the implant procedure
- Any member of the MDT either referring patients to a colleague for consideration of CIED or listing patients for a CIED
- Consultant Cardiologists and Cardiology Specialist Registrars involved in the implant procedure

4. Definitions / Glossary

4.1. Abbreviations:

- MRI  Magnetic Resonance Imaging
- CIED  Cardiac Implantable Electronic Device
- WHO  World Health Organisation

5. Ownership and Responsibilities

This section provides an overview of the strategic and operational roles and responsibilities for the development, management and implementation of the policy/procedure.

5.1. Role of the Cardiology speciality arrhythmia lead

The Cardiology Speciality Arrhythmia lead is responsible for:

- Reviewing this document every 3 years (or sooner if new, relevant national guidelines are published)
5.2. Role of the managers
The line managers are responsible for:
- Ensuring staff are aware of, and act upon, the Trust's procedural documents.
- Implementing the procedural documents for the areas in which they apply.
- Notifying all new and existing staff on how to access both current and archived Trust procedural documents.
- Ensuring that all staff members have access to the Trust intranet site to enable access to published procedural documents.
- Ensuring that all staff members are aware of their responsibility in maintaining compliance with Trust documents.

5.3. Role of the Cardiology speciality governance group
The Cardiology speciality governance Group is responsible for:
- Signing off the reviewed document prior to upload to the document library

5.4. Role of the referrer
Any professional referring a patient to Cardiology for consideration for CIED must:
- Inform Cardiology if the patient has a condition that is likely to require an MRI scan post CIED implantation. This information must be highlighted by the referrer at the time of referral.

5.5. Role of the Cardiology professional listing a patient for a CIED procedure
Any member of staff listing a patient for a CIED procedure must:
- Ensure that they clearly specify whether the patient either does or does not require an MRI compatible device.

5.6. Role of the booking staff
Any member of staff booking a patient requiring a CIED onto a procedure list must:
- Ensure that the person who has listed the patient has clearly specified that the patient either does or does not require an MRI compatible device.
- If this information is not present, the request needs to be discussed with the professional requesting the procedure before the patient can be listed for their procedure.

5.7. Role of the Cardiac Physiologist immediately prior to implant
Immediately prior to the patient being prepared and draped for their procedure, the Cardiac Physiologist, assisting the implanter, must:
- Check with the implanter whether an MRI compatible CIED system is required or not.
- Show the implanter the MRI compatible CIED system (if required) prior to opening the sterile packaging.
- Prior to the implant procedure commencing, respond to the WHO question “is the required equipment available and in date” with information about whether an MRI compatible system is required or not.
5.8. **Role of the CIED implanter**
Immediately prior to the patient being prepared and draped for their procedure, the CIED implanter must:
- Inform the Cardiac Physiologist whether an MRI compatible CIED system is required **or not**.
- Check the CIED system is MRI compatible **or not** prior to the sterile packaging being opened.

5.9. **Role of the staff member completing the WHO checklist prior to commencing the CIED procedure**
Prior to the procedure commencing, the member of staff completing the WHO checklist will ask **“is the required equipment available and in date”**. They must:
- Ensure the Cardiac Physiologist states whether the patient requires an MRI compatible system **or not**.
- This response must be documented on the WHO checklist.

5.10. **Role of Individual Staff**
All staff members are responsible for:
- Making themselves aware of the procedural documents that relate to their role and responsibilities.
- Complying with agreed Trust procedural documents where they apply.
- Raising any queries about implementation of Trust documents with their line manager.
- Alerting their line manager of any non-compliance with procedural documents where it is noted and represents an actual risk to the Trust, its staff, patients or the public.
- Contacting the CITS Service Desk (01209 881717) if experiencing difficulties accessing the electronic Document Library.

6. **Standards and Practice**
6.1. Where a patient meets the following criteria they **must** be considered for an MRI compatible CIED system:

   - 6.1.1. Established on-going plan for regular MRI Imaging
   - 6.1.2. The life time risk of requiring MRI scanning is high
   - 6.1.3. A medical condition where no alternative imaging modality exists
   - 6.1.4. A medical condition where MRI scanning might be anticipated, factoring in the move towards MRI as gold standard for cardiac imaging.

7. **Dissemination and Implementation**
7.1. This document will be disseminated electronically to all relevant stakeholders once published. It will also be available on the RCHT Document library.
7.2. There are no previous versions of this document.
8. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Use of MRI compatible devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>The Arrhythmia lead</td>
</tr>
<tr>
<td>Tool</td>
<td>All pacing procedures are audited through data collected on the CVIS database</td>
</tr>
<tr>
<td>Frequency</td>
<td>A report can be pulled from the database as and when required.</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>A report can be compiled for speciality or commissioning groups as required.</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>The Arrhythmia lead and the Cardiology speciality will undertake subsequent recommendations and action planning for any or all deficiencies and recommendations within reasonable timeframes.</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Required changes to practice will be identified and actioned within 1 month. A lead member of the team will be identified through speciality governance structures to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders</td>
</tr>
</tbody>
</table>

9. Updating and Review

9.1. This document will be updated by the Arrhythmia Clinical lead every 3 years.
9.2. Revisions will be made ahead of the review date if new, relevant national guidelines are published. Where the revisions are significant and the overall policy is changed, the Arrhythmia Clinical lead will ensure the revised document is taken through the standard consultation, approval and dissemination processes.
9.3. Where the revisions are minor, e.g. amended job titles or changes in the organisational structure, approval will be sought from the Executive Director responsible for signatory approval, and can be re-published accordingly without having gone through the full consultation and ratification process.

9.4. Any revision activity will be recorded in the Version Control Table as part of the document control process.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.
10.2. *Equality Impact Assessment*

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
## Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Cardiac Electronic Implantable Devices (CIEDs), necessary considerations: Magnetic Resonance Imaging (MRI) Compatible devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td></td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>01/11/14</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>01/11/17</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Author: Joanna Davies, Clinical Nurse Specialist heart Function and Interim Cardiology Speciality Clinical Governance and audit lead</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 253018</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Guidelines for the necessary considerations prior to implantation of a MRI compatible CIED</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Cardiac Electronic Implantable Device (CIED) Pacemaker (PPM) Implantable Cardioverter Defibrillator (ICD) Cardiac Resynchronisation Therapy (CRT) Magnetic Resonance Imaging (MRI).</td>
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<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director – Dr Rob Parry</td>
</tr>
<tr>
<td>Date revised:</td>
<td>First Issue</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>New Document</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Consultant Cardiologists Members of The Cardiology Speciality Governance group</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>Dr Andy Virr, Divisional Director</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not Required</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
</tr>
<tr>
<td>Document Library Folder/Sub Folder</td>
<td>Clinical / Cardiology</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Links to key external standards</td>
<td></td>
</tr>
<tr>
<td>Related Documents:</td>
<td></td>
</tr>
<tr>
<td>Training Need Identified?</td>
<td>No training needs other than relevant staff familiarising themselves with this document.</td>
</tr>
</tbody>
</table>

Version Control Table

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2014</td>
<td>V1.1</td>
<td>Initial Issue</td>
<td>Joanna Davies, Clinical Nurse Specialist heart Function and Interim Cardiology Speciality Clinical Governance and audit lead</td>
</tr>
</tbody>
</table>

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.
## Appendix 2. Initial Equality Impact Assessment Form

### Name of the strategy / policy / proposal / service function to be assessed (hereafter referred to as policy) (Provide brief description):

<table>
<thead>
<tr>
<th>Directorate and service area: Medicine ED &amp; WCH division Cardiology speciality</th>
<th>Is this a new or existing Policy?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New</td>
</tr>
</tbody>
</table>

| Name of individual completing assessment: Joanna Davies | Telephone: 01872253018 |

### 1. Policy Aim*

**Who is the strategy / policy / proposal / service function aimed at?**

This document provides guidance for any professional involved in the implantation of CIEDs at the Royal Cornwall Hospital.

### 2. Policy Objectives*

**To provide a clear, speciality agreed pathways around decision making for MRI compatible pacing devices implanted at the Royal Cornwall Hospital**

### 3. Policy – intended Outcomes*

**Availability of a robust, measureable, Speciality agreed pathways for decision making around MRI compatible pacing devices implanted at the Royal Cornwall Hospital.**

### 4. *How will you measure the outcome?*

Outlined in section 8 of this document.

### 5. Who is intended to benefit from the policy?

Patients requiring implantation of MRI compatible CIEDs at RCHT and those members of the MDT involved at any level in the implantation of these devices.

### 6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?

Yes, Workforce

### 6b) If yes, have these *groups been consulted?*

Yes

### 6c) Please list any groups who have been consulted about this procedure.

- All Consultant Cardiologists
- Cardiology Speciality Group

### 7. The Impact

Please complete the following table.

Are there concerns that the policy **could** have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Policy and Procedure Template
<table>
<thead>
<tr>
<th>Category</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (male, female, transgender / gender reassignment)</td>
<td>✔</td>
</tr>
<tr>
<td>Race / Ethnic communities / groups</td>
<td>✔</td>
</tr>
<tr>
<td>Disability - Learning disability, physical disability, sensory impairment and mental health problems</td>
<td>✔</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td>✔</td>
</tr>
<tr>
<td>Marriage and civil partnership</td>
<td>✔</td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td>✔</td>
</tr>
<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td>✔</td>
</tr>
</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation - this excludes any policies which have been identified as not requiring consultation. or
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended. | Yes | No |

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director | Date of completion and submission

Names and signatures of members carrying out the Screening Assessment

| 1. | 2. |

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed ____________________

Date ____________________