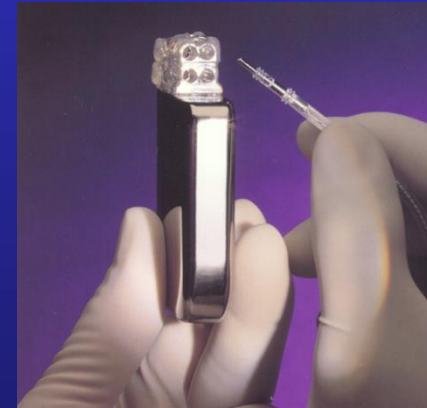


NICE & ESC Guidance for Devices and AF



Mark Squirrell

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British Heart Rhythm Society Certificate of Accreditation Core Module

Mark Squirrell

Conflicts of Interest

Member of Medtronic (UK) Physiologist Advisory Board
Educational Support from St. Jude Medical

Overview of Syllabus Regarding Guidance

CURRENT DVLA REGULATIONS AND NATIONAL GUIDANCE AND POLICY FOR ARRHYTHMIA MANAGEMENT including NSF, NICE etc.
MEDICO-LEGAL ISSUES including informed consent, role of the MHRA, clinical governance and audit, data protection, research ethics.

Sources of Guidance

- **Government** – Driver Vehicle Licensing Authority(DVLA), National Institute for Health and Care Excellence(NICE), Medicine & Healthcare Products Regulatory Authority(MHRA), Department of Health (DH)
- **Royal Colleges**—Royal College of Physicians
- **Professional bodies (UK)** BCVS, BHRS
- **Professional bodies (international)** ESC, EHRA, HRS, ACC/AHA
- **Charities** – Arrhythmia Alliance

Overview of Guidance

- **NSF CAD** – Chapter 8
- **NICE** - Brady Pacing (2005) ICD & CRT (2014) AF (2014) T-LOC (2010)
- **MHRA** — Peri-operative management of Devices (2006)
- **ESC/EHRA** - VT (2009) Vent Arrhythmia and SCD (2009) Syncope (2010) AF (2016) Devices in HF (2010) Pacing & CRT (2013) ***Some jointly with AHA / ACC***
- **BHRS Position Statements** — Catheter Ablation of Persistent AF , Clinical indications for implantable cardioverter defibrillators in adult patients with familial sudden cardiac death syndromes, Standards for Device (2015) & EP Services (2016)
- **DVLA** – Fitness to Drive (2016)

This chapter sets out a quality requirement and markers of good practice to support the NHS services in identifying people who are at increased risk and assessing them and their families to reduce their chances of dying from an arrhythmic condition. In addition to purely clinical care it sets out best practice for ensuring that, for those diagnosed with a potentially life threatening condition, and their families, there is appropriate counselling, advice, information and psychological support.

Coronary Heart Disease

National
Service
Framework

Chapter Eight

Arrhythmias and Sudden Cardiac Death

8



NASPE POSITION STATEMENT

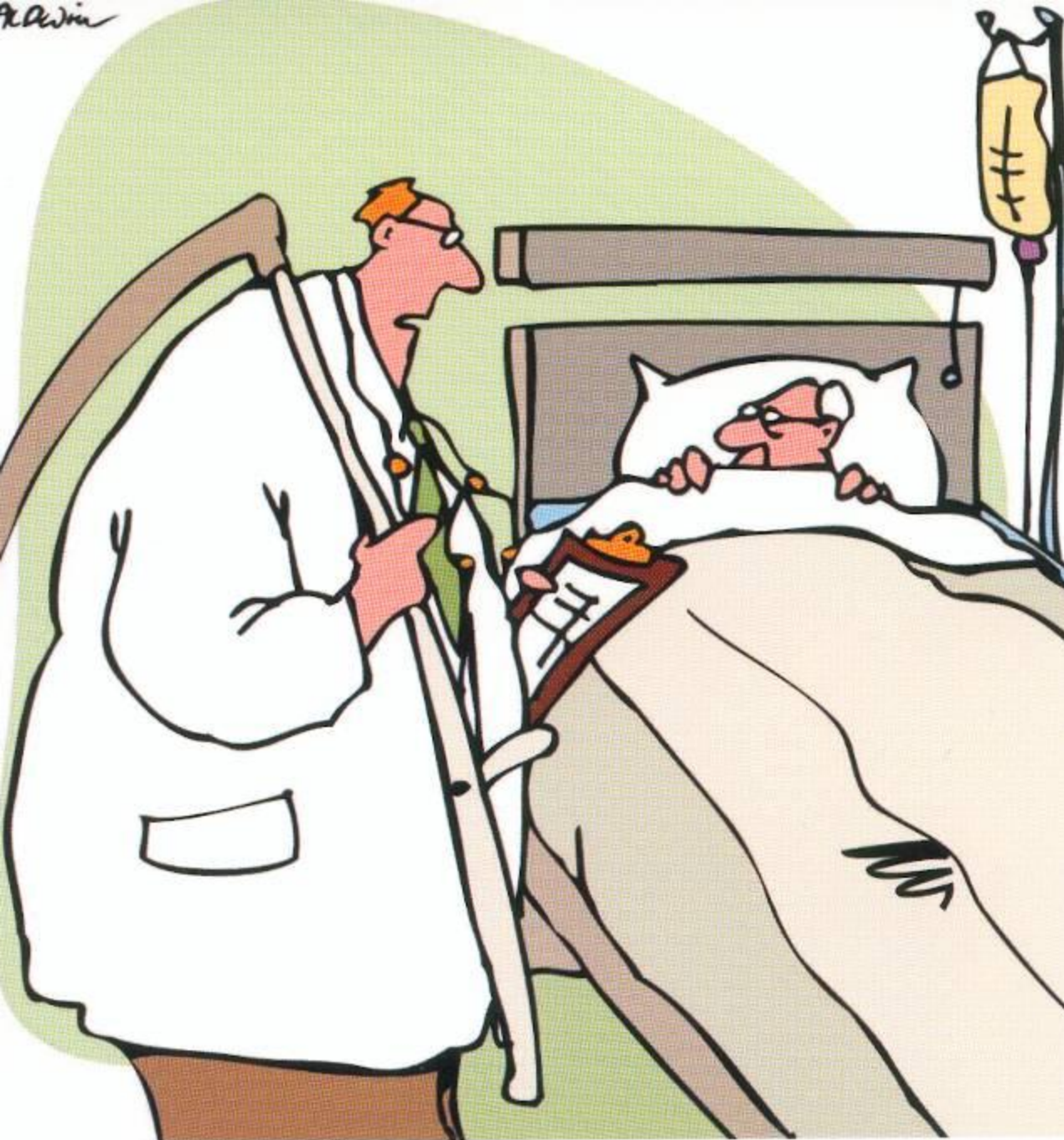
The Revised NASPE/BPEG Generic Code for Antibradycardia, Adaptive-Rate, and Multisite Pacing

ALAN D. BERNSTEIN,* JEAN-CLAUDE DAUBERT,† ROSS D. FLETCHER,‡
DAVID L. HAYES,§ BERNDT LÜDERITZ,|| DWIGHT W. REYNOLDS,#
MARK H. SCHOENFELD,** and RICHARD SUTTON††

From the *Newark Beth Israel Medical Center, Newark, New Jersey, †Centre Cardio-Pneumologique, Hôpital Pontchaillou, Rennes, France, ‡Veteran Affairs Medical Center, Washington, District of Columbia, §Mayo Clinic, Rochester, Minnesota, ||University of Bonn, FR Germany, #University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, **Yale University School of Medicine, New Haven, Connecticut, and the ††Royal Brompton Hospital, London, England

- Revised codes (VVI, DDD etc) to take account of multisite pacing

K. DeWitt



- Patients at risk of sudden cardiac death

"This is difficult for me to explain, so I brought a prop."

TA95 & TA120 Replaced



Updated in June 2014 - TA314

NICE National Institute for
Health and Care Excellence

Implantable cardioverter
defibrillators and cardiac
resynchronisation therapy for
arrhythmias and heart failure
(review of TA95 and TA120)

Issued: June 2014

NICE technology appraisal guidance 314
guidance.nice.org.uk/ta314

ICD for Arrhythmia (TA314)

Secondary Prevention

(in absence of treatable cause)

Survived Sudden Cardiac Arrest (either VT or VF)

VT with syncope or significant haemodynamic compromise

Sustained VT without cardiac arrest or syncope and LVEF<35% (but not worse than NYHA class III)

ICD for Arrhythmia (TA314)

Familial cardiac conditions with high risk of SCD such as Long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or Arrhythmogenic right ventricular dysplasia

Have undergone surgical repair of congenital heart disease

Cardiac Resynchronisation Therapy (TA314)

- ICD with CRT or pacemaker with CRT function recommended as treatment options for people with heart failure who have left ventricular dysfunction with an LV ejection fraction of $<35\%$. (see table)

Table 1 from TA314

| | NYHA class | | | |
|--|--|-------|----------------|---|
| QRS interval | I | II | III | IV |
| <120 milliseconds | ICD if there is a high risk of sudden cardiac death | | | ICD and CRT not clinically indicated |
| 120–149 milliseconds without LBBB | ICD | ICD | ICD | CRT-P |
| 120–149 milliseconds with LBBB | ICD | CRT-D | CRT-P or CRT-D | CRT-P |
| ≥150 milliseconds with or without LBBB | CRT-D | CRT-D | CRT-P or CRT-D | CRT-P |
| LBBB, left bundle branch block; NYHA, New York Heart Association | | | | |

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology, in collaboration with the European Heart Rhythm Association

Authors/Task Force Members: Angelo Auricchio (Switzerland), Giuseppe Boriani (Italy), Jean-Claude Deharo (France), Bulent Gorenek (Turkey), Carsi G. (France), Cecilia Linde (Sweden), Richard Sutton (UK), Panos E. Vardas (Greece)

2012 EHRA/HRS expert consensus statement on cardiac resynchronization therapy in heart failure: implant and follow-up recommendations and management

Developed in partnership with the European Heart Rhythm Association (EHRA), A registered branch of the European Society of Cardiology, in collaboration with the Heart Failure Association (HFA) of the European Society of Cardiology, the American Society of Echocardiography (ASE), the European Association of Echocardiography (EAE) of the European Society of Cardiology

Endorsed by the governing bodies of the European Society of Cardiology

TASK FORCE CHAIRS:

Jean-Claude Daubert (Section Chair), Members: Philip B. Adamson (USA), Ronald D. Berger (USA), John L. Cleland (Representative), Kenneth Dickstein (Representative), Michael Gold (Section Chair), Carsten Israel (Section Chair), Cecilia Linde (Section Chair), Bela Merkely (Hungary), Lluís M. Samir F. Saba (USA), Jerold S. Jagmeet Singh (Section Chair), Panos E. Vardas (Greece), Bruce

2010 Focused Update of ESC Guidelines on device therapy in heart failure

An update of the 2008 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure and the 2007 ESC guidelines for cardiac and resynchronization therapy

Developed with the special contribution of the Heart Failure Association and the European Heart Rhythm Association

Authors/Task Force Members, Kenneth Dickstein (Chairperson) (Norway)*, Panos E. Vardas (Chairperson) (Greece)*, Angelo Auricchio (Switzerland), Jean-Claude Daubert (France), Cecilia Linde (Sweden), John McMurray (UK), Piotr Ponikowski (Poland), Silvia Giuliani Priori (Italy), Richard Sutton (UK), Dirk J. van Veldhuisen (Netherlands)

**Dual-chamber pacemakers
for symptomatic
bradycardia due to sick
sinus syndrome and/or
atrioventricular block**

TA 88

- Note only for Sick Sinus Syndrome and AV block
- Published before UKPace (2000 patient RCT)
- No decision to review or update (Dec 2012)

TA 88 Dual Chamber Pacemakers

Dual chamber pacing indicated except:

- No evidence of impaired AV conduction
 - Use single chamber atrial based pacing
- Patients with continuous A Fib
 - Single chamber ventricular pacing
- Presence of frailty and co-morbidity where risks out way benefits
 - Single chamber alternatives

Transient loss of consciousness (‘blackouts’) management in adults and young people

Issued: August 2010

NICE clinical guideline 109
guidance.nice.org.uk/cg109

- **Clinical Guidance**
109 August 2010
- **Key Priorities**
 - Initial assessment and history
 - ECG
 - Rapid referral
 - Diagnostic tests
 - Frequency of T-LOC

Guidelines for the diagnosis and management of syncope (version 2009)

The Task Force for the Diagnosis and Management of Syncope of the European Society of Cardiology (ESC)

Developed in collaboration with, European Heart Rhythm Association (EHRA)¹, Heart Failure Association (HFA)², and Heart Rhythm Society (HRS)³

Endorsed by the following societies, European Society of Emergency Medicine (EuSEM)⁴, European Federation of Internal Medicine (EFIM)⁵, European Union Geriatric Medicine Society (EUGMS)⁶, American Geriatrics Society (AGS), European Neurological Society (ENS)⁷, European Federation of Autonomic Societies (EFAS)⁸, American Autonomic Society (AAS)⁹

- **Challenges:** classification of syncope, risk stratification, diagnostics based on long term monitoring, use of evidence based therapy

CG 180 Atrial Fibrillation

- New guidance June 2014
(replaces CG36)

NICE National Institute for
Health and Care Excellence

Atrial fibrillation: the management of atrial fibrillation

Issued: June 2014 last modified: August 2014

NICE clinical guideline 180
guidance.nice.org.uk/cg180

NICE has accredited the process used by the Centre for Clinical Practice at NICE to produce guidelines. Accreditation is valid for 5 years from September 2009 and applies to guidelines produced since April 2007 using the processes described in NICE's 'The guidelines manual' (2007, updated 2009). More information on accreditation can be viewed at www.nice.org.uk/accreditation



© NICE 2014

Things to note in the Management of AFib

- Categorisation – Paroxysmal, Persistent, Permanent
- Antithrombotic therapy
 - LAA devices (commissioning by evaluation)
 - New drugs to supplant use of warfarin
- Rate vs. Rhythm control
 - Drugs, Cardioversion, devices
- Catheter Ablation / Surgical Ablation
 - Ablate AV node and pace / PVI

Patient-centred care

This guideline offers best practice advice on the care of adults (aged 18 and over) with

• *Personalised package of care and information*

- Offer people with atrial fibrillation a personalised package of care. Ensure that the package

Referral for specialised management

- Refer people promptly^[1] at any stage if treatment fails to control the symptoms of atrial

Assessment of stroke and bleeding risks

Interventions to prevent stroke

Anticoagulation

Rate and rhythm control

When to offer rate or rhythm control

Things to note from new AF Guidance

- CHA₂DS₂-VASc score (Birmingham 2009) was developed after identifying additional stroke risk factors in patients with atrial fibrillation.
- The HAS-BLED score was developed as a practical risk score to estimate the 1-year risk for major bleeding in patients with atrial fibrillation.
- Separate Guidance published for each of the new anticoagulants TA275, TA249, TA256

Anticoagulation

Anticoagulation may be with apixaban, dabigatran etexilate, rivaroxaban or a vitamin K antagonist.

Antiplatelets

- Do not offer aspirin monotherapy solely for stroke prevention to people with atrial fibrillation.
[new 2014]

New Guidance from 2016

European Heart Journal Advance Access published October 3, 2016



European Heart Journal
doi:10.1093/eurheartj/ehw210

ESC GUIDELINES

2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC

dc



**STANDARDS FOR IMPLANTATION AND FOLLOW-UP OF
CARDIAC RHYTHM MANAGEMENT DEVICES IN ADULTS**
January 2015

1. INTRODUCTION

This document replaces the previous Heart Rhythm UK document "Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults" issued in 2013. It has been produced by a group of cardiac electrophysiologists with an interest in device therapy, cardiac physiologists and specialist nurses drawn from both tertiary centres and district general hospitals, approved by the Council of the British Heart Rhythm Society (BHRS) in 2014. This document will be reviewed by BHRS on a bi-annual basis.

The purpose of the document is to facilitate the safe delivery of evidence based, cardiac device therapy to all patients who need it. It includes identification of patients with device indications, appropriate devices, patient and device follow up, data collection and submission.



**CLINICAL GUIDANCE FOR THE FOLLOW UP OF CARDIAC IMPLANTABLE
ELECTRONIC DEVICES FOR CARDIAC RHYTHM MANAGEMENT**
**(APPENDIX TO STANDARDS FOR IMPLANTATION AND FOLLOW-UP OF
CARDIAC RHYTHM MANAGEMENT DEVICES IN ADULTS)**

January 2015

1. INTRODUCTION

The continuing evolution of device technology has resulted in the production of a range of devices capable of treating bradycardias, complex cardiac tachyarrhythmias and heart failure management. These devices have multiple modalities and programmable features. The challenge of these treatments lies not only in the implantation of the devices but also in comprehensive follow-up of the implanted devices as part of the lifelong management of the patient. As the number and variety of implanted devices increases so does the burden of follow-up and the knowledge required to optimise and troubleshoot their use. This is compounded by the increasing volume of data provided by devices and the increasing sophistication of programming therapy and detection algorithms. As a result of this increasing complexity, inappropriate or incorrect use of these algorithms or other errors with aspects of device programming may result in serious harm to the patient.





Cardiac Rhythm Management in Patients with Congenital Heart Disease

Standards of Care for patients undergoing
catheter ablation and device implantation

Martin Lowe, on behalf of BHRS Council, February 2016

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| 5. Requirements for performing ablation and device implantation | 8 |
| 6. Proposed CHD model of care | 9 |
| References | 11 |

HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations

Developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA).

Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association.

Bruce L. Wilkoff, MD, FHRS,¹ Angelo Auricchio, MD, PhD, FESC,² Josep Brugada, MD, PhD, FESC,³ Martin Cowie, MD,⁴ Kenneth A. Ellenbogen, MD, FHRS,⁵ Anne M. Gillis, MD, FHRS,⁶ David L. Hayes, MD, FHRS,⁷ Jonathan G. Howlett, MD,⁸ Josef Kautzner, MD, PhD, FESC,⁹ Charles J. Love, MD, FHRS,¹⁰ John M. Morgan, MD, FESC,¹¹ Silvia G. Priori, MD, PhD, FESC,¹² Dwight W. Reynolds, MD, FHRS,¹³ Mark H. Schoenfeld, MD, FHRS,¹⁴ Panos E. Vardas, MD, PhD, FESC¹⁵

- Staffing, Industry employed allied professional, levels of care in follow up, device interrogation and programming, home monitoring,



STANDARDS FOR INTERVENTIONAL ELECTROPHYSIOLOGY STUDY AND CATHETER ABLATION IN ADULTS – February 2016

1. INTRODUCTION

This document replaces the previous British Heart Rhythm Society (BQRS) document "Standards for interventional electrophysiology study and catheter ablation in adults" issued in January 2014. It has been compiled by a group of interventional cardiac electrophysiologists, cardiac physiologists and specialist arrhythmia nurses drawn from both secondary and tertiary centres and approved by the Council of the BQRS in February 2016. This document will be reviewed by BQRS Council no later than February 2018.

2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Patient Selection, Procedural Techniques, Patient Management and Follow-up, Definitions, Endpoints, and Research Trial Design

A report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. Developed in partnership with the European Heart Rhythm Association (EHRA), a registered branch of the European Society of Cardiology (ESC) and the European Cardiac Arrhythmia Society (ECAS); and in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS), and the Society of Thoracic Surgeons (STS). Endorsed by the governing bodies of the American College of Cardiology Foundation, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, the Asia Pacific Heart Rhythm Society, and the Heart Rhythm Society

Table 2 Consensus indications for catheter and surgical ablation of AF

| Indications for catheter ablation of AF | Class | Level |
|--|-------|-------|
| Symptomatic AF refractory or intolerant to at least one Class 1 or 3 antiarrhythmic medication | | |
| Paroxysmal: Catheter ablation is recommended* | I | A |
| Persistent: Catheter ablation is reasonable | IIa | B |
| Longstanding Persistent: Catheter ablation may be considered | IIb | B |
| Symptomatic AF prior to initiation of antiarrhythmic drug therapy with a Class 1 or 3 antiarrhythmic agent | | |
| Paroxysmal: Catheter ablation is reasonable | IIa | B |
| Persistent: Catheter ablation may be considered | IIb | C |
| Longstanding Persistent: Catheter ablation may be considered | IIb | C |

ACC/AHA/ESC Guidelines for the Management of Patients With Supraventricular Arrhythmias*

A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Supraventricular Arrhythmias)

Developed in Collaboration with NASPE-Heart Rhythm Society

COMMITTEE MEMBERS

Carina Blomström-Lundqvist, MD, PhD, FACC, FESC, *Co-Chair*
Melvin M. Scheinman, MD, FACC, *Co-Chair*

- Published in 2003
- Atrial tachycardia, AVNRT, Junctional tachycardia, AVRT, WPW, Special circumstances ie pregnancy, SVT with congenital heart disease.

**BRITISH HEART RHYTHM SOCIETY GUIDELINES FOR THE
MANAGEMENT OF PATIENTS WITH CARDIAC IMPLANTABLE
ELECTRONIC DEVICES (CIEDs) AROUND THE TIME OF SURGERY**

Honey Thomas, Andy Turley and Chris Plummer
on behalf of BHRS Council – January 2016

INTRODUCTION

The use of Cardiac Implantable Electronic Devices (CIEDs) for rhythm management include pacemakers for control of bradycardias, implantable cardioverter defibrillators (ICDs) for treatment of life-threatening ventricular tachycardias, biventricular or resynchronisation pacemakers and ICDs for treatment of heart failure using ventricular resynchronisation (CRT-P and CRT-D respectively), implantable loop recorders (ILRs) and insertable cardiac monitors (ICMs) for monitoring cardiac arrhythmias.

These devices fall into 3 categories:

1. ILRs and ICMs which allow for targeted ECG monitoring
2. Cardiac pacemakers – single lead, dual lead or biventricular
3. ICDs–single lead, dual lead or biventricular

Safeguarding public health

MHRA

Guidelines for the perioperative management of patients with implantable pacemakers or implantable cardioverter defibrillators, where the use of surgical diathermy/electrocautery is anticipated.

- Gives guidance for elective and emergency surgery with devices in situ.
- Covers perioperative, operative and post operative periods
- Reduces risk of over sensing and inappropriate shock



Driver & Vehicle
Licensing
Agency

Assessing fitness to drive – a guide for medical professionals



www.gov.uk/dvla/fitnesstodrive

May 2016



Check you are
looking at the most
recent guidance –
Currently May 2016
updates are frequent.
Check current
guidance before the
exam

Arrhythmias

Arrhythmias include:

- sinoatrial disease
- significant atrioventricular conduction defect
- atrial flutter/fibrillation
- narrow or broad complex tachycardia.

Note:

- if a transient arrhythmia occurs during an acute coronary syndrome, the guidance relating to ACS takes precedence (page 46)
- pacemakers are considered separately (page 49).

i

| | Group 1 car and motorcycle | Group 2 bus and lorry |
|--|---|--|
| Arrhythmia likely to cause incapacity | <p>● Must not drive and may need to notify the DVLA.</p> <p>Driving may resume without DVLA notification only after:</p> <ul style="list-style-type: none"> ■ underlying cause has been identified ■ arrhythmia is controlled for at least 4 weeks. <p>Must notify the DVLA if there are distracting or disabling symptoms.</p> | <p>● Must not drive and must notify the DVLA.</p> <p>Licence will be refused or revoked.</p> <p>Driving may be relicensed (provided there is no other disqualifying condition) only after:</p> <ul style="list-style-type: none"> ■ underlying cause has been identified ■ arrhythmia has been controlled for at least 3 months ■ no evidence of significant left ventricular impairment – LV ejection fraction is at least 40% |

Successful catheter ablation

| | Group 1 car and motorcycle | Group 2 bus and lorry |
|--|---|---|
| For arrhythmia causing or likely to cause incapacity | <p>● Must not drive but need not notify the DVLA.</p> <p>Driving may resume after at least 2 days provided there is no other disqualifying condition.</p> | <p>● Must not drive and must notify the DVLA.</p> <p>Driving may resume after 6 weeks provided there is no other disqualifying condition.</p> |
| For arrhythmia not causing nor likely to cause incapacity | <p>● Must not drive but need not notify the DVLA.</p> <p>Driving may resume after at least 2 days provided there is no other disqualifying condition.</p> | <p>● Must not drive but need not notify the DVLA.</p> <p>Driving may resume after 2 weeks provided there is no other disqualifying condition.</p> |

Note: the DVLA bars Group 2 bus and lorry licensing whenever left ventricular ejection fraction is less than 40%

Pacemaker implant

– including box change

| | Group 1 car and motorcycle | Group 2 bus and lorry |
|--|--|---|
| | <p>● Must not drive and must notify the DVLA.</p> <p>Driving may resume after 1 week provided there is no other disqualifying condition.</p> | <p>● Must not drive and must notify the DVLA.</p> <p>Driving may resume after 6 weeks provided there is no other disqualifying condition.</p> |

Unpaced congenital complete heart block

| | Group 1 car and motorcycle | Group 2 bus and lorry |
|---------------------|--|--|
| Asymptomatic | <p>■ May drive and need not notify the DVLA.</p> | <p>● Must not drive and must notify the DVLA.</p> <p>Licence will be refused or revoked permanently.</p> |
| Symptomatic | <p>● Must not drive and must notify the DVLA.</p> <p>Licence will be refused or revoked.</p> | <p>● Must not drive and must notify the DVLA.</p> <p>Licence will be refused or revoked permanently.</p> |

Atrial defibrillator

| | Group 1 car and motorcycle | Group 2 bus and lorry |
|---------------------------------------|--|---|
| Physician or patient activated | <p>▲ May drive provided there is no other disqualifying condition. Must notify the DVLA.</p> | <p>● Must not drive and must notify the DVLA.</p> <p>Driving may be relicensed (provided there is no other disqualifying condition) after the arrhythmia requirements have been met (see Appendix C, page 111).</p> |
| Automatic | <p>▲ May drive provided there is no other disqualifying condition. Must notify the DVLA.</p> <p>Note: also refer to the implantable cardioverter defibrillator (ICD) requirements below.</p> | <p>● Must not drive and must notify the DVLA.</p> <p>Licence will be refused or revoked permanently.</p> |

Note: the DVLA bars Group 2 bus and lorry licensing whenever left ventricular ejection fraction is less than 40%

Implantable cardioverter defibrillator (ICD)

Group 1 car and motorcycle

In all cases of ICD for sustained ventricular arrhythmia associated with incapacity, **driving must stop** for 6 months from the date of ICD implantation and any resumption requires:

- the device being under regular review with interrogation
- no other disqualifying condition.

Group 2 bus and lorry

ICD implantation is a permanent bar to Group 2 licensing. In all cases of ICD implantation (including prophylactic ICD implantation) driving must stop permanently and:

- the DVLA must be notified
- the licence will be refused or revoked permanently.

| | Group 1 car and motorcycle | Group 2 bus and lorry |
|---|--|--|
| ICD for sustained ventricular arrhythmia associated with incapacity | | |
| Without further sequelae | <ul style="list-style-type: none">● Must not drive and must notify the DVLA. Driving may resume after 6 months from a first implant – except that any of the sequelae 1-4 below require further specific restrictions and may require notification to the DVLA. | <ul style="list-style-type: none">● Must not drive and must notify the DVLA. Licence will be refused or revoked permanently. |
| 1. With any shock therapy and/or pacing for symptomatic tachycardia | <ul style="list-style-type: none">● Must not drive and must notify the DVLA. Must not drive for a further 6 months from the time of any shock therapy or pacing for symptomatic tachycardia. | <ul style="list-style-type: none">● Must not drive and must notify the DVLA. Licence will be refused or revoked permanently. |
| 2. With incapacity following implantation or therapy (whether caused by device or arrhythmia) | <ul style="list-style-type: none">● Must not drive and may need to notify the DVLA. Must not drive for 2 years after symptoms of incapacity and must notify the DVLA. Exceptions to this 2 year requirement apply as follows, but the minimum initial restriction after implantation still applies (i.e. must not drive for 6 months). | <ul style="list-style-type: none">● Must not drive and must notify the DVLA. Licence will be refused or revoked permanently. |
| | <ol style="list-style-type: none">1. If therapy delivery was due to an inappropriate cause such as atrial fibrillation or, for example, programming issues:<ul style="list-style-type: none">■ driving may resume 1 month after complete control of any cause to the satisfaction of the cardiologist.2. If therapy delivery was due to sustained ventricular tachycardia or ventricular fibrillation:<ul style="list-style-type: none">■ driving may resume 6 months after event■ provided preventive steps against recurrence have been taken with anti-arrhythmic drugs or ablation procedure, for example■ and provided there is an absence of further symptomatic therapy. | |
| 3. With any revision of electrodes or alteration of anti-arrhythmic drug treatment | <ul style="list-style-type: none">● Must not drive but need not notify the DVLA. Driving may resume 1 month after electrode revision or drug alteration. The minimum initial restriction after implantation still applies (must not drive for 6 months). | <ul style="list-style-type: none">● Must not drive and must notify the DVLA. Licence will be refused or revoked permanently. |
| 4. With defibrillator box change | <ul style="list-style-type: none">● Must not drive but need not notify the DVLA. Driving may resume 1 week after box change. The minimum initial restriction after implantation still applies (must not drive for 6 months). | <ul style="list-style-type: none">● Must not drive and must notify the DVLA. Licence will be refused or revoked permanently. |

ICD for sustained ventricular arrhythmia not associated with incapacity

- | | |
|---|---|
| <ul style="list-style-type: none"> Must not drive for 1 month and may need to notify the DVLA. Driving may resume 1 month after implantation and the DVLA need not be notified, provided: <ul style="list-style-type: none"> presentation was a 'non-disqualifying' cardiac event – i.e. haemodynamically stable sustained ventricular tachycardia without incapacity LV ejection fraction is greater than 35% no fast ventricular tachycardia (VT) induced on electrophysiological study – i.e. RRI interval of less than 250 milliseconds | <ul style="list-style-type: none"> Must not drive and must notify the DVLA. Licence will be refused or revoked permanently. |
|---|---|

continued

Note: the DVLA bars Group 2 bus and lorry licensing whenever left ventricular ejection fraction is less than 40%.

Important to note

ICD guidance is now split into 3 sections

- ICD for sustained ventricular arrhythmia associated with incapacity
- ICD for sustained ventricular arrhythmia not associated with incapacity
- Prophylactic ICD

| | | |
|--|--|---|
| <ul style="list-style-type: none"> during the postimplantation study, any induced VT could be pace-terminated by the ICD twice, without acceleration. Note: should ICD subsequently deliver anti-tachycardia pacing and/or shock therapy (except during normal clinical testing), the DVLA must be notified and the restrictions must be applied as for sustained ventricular arrhythmia associated with incapacity (see page 50). | | |
| Prophylactic ICD | | |
| In asymptomatic individuals with a high risk of significant arrhythmia | <ul style="list-style-type: none"> Must not drive and must notify the DVLA. driving may resume 1 month after implantation (need not notify the DVLA if remains asymptomatic and no ICD therapy needed) should the ICD subsequently deliver anti-tachycardia pacing and/or shock therapy (except during normal clinical testing), the DVLA must be notified and the restrictions must be noted as for sustained ventricular arrhythmia associated with incapacity (see page 50) need not notify the DVLA if remains asymptomatic and no ICD therapy needed. | <ul style="list-style-type: none"> Must not drive and must notify the DVLA. Licence will be refused or revoked permanently. |

Aortic aneurysm

– ascending or descending thoracic and/or abdominal

| | Group 1 car and motorcycle | Group 2 bus and lorry |
|--------------|--|--|
| Low risk | <ul style="list-style-type: none"> May drive and need not notify the DVLA if aneurysm diameter is less than 6 cm. | <ul style="list-style-type: none"> May drive if the aneurysm diameter is less than 5.5 cm. Must notify the DVLA. |
| Managed risk | <ul style="list-style-type: none"> May drive but must notify the DVLA if aneurysm diameter is between 6 cm and 6.4 cm. Driving may be relicensed subject to annual review. | <ul style="list-style-type: none"> Must not drive and must notify the DVLA if the aneurysm diameter is 5.5 cm or greater. Licence will be refused or revoked. Driving may be relicensed after successful surgical treatment without evidence of further enlargement and no other disqualifying condition. |

continued

Note: the DVLA bars Group 2 bus and lorry licensing whenever left ventricular ejection fraction is less than 40%.

Guy's & St. Thomas' Hospitals



NHS Foundation Trust

Heart Rhythm UK position statement on clinical indications for implantable cardioverter defibrillators in adult patients with familial sudden cardiac death syndromes

- An extensive document with detailed information and pathways for all the familial conditions.
- All patients with (or suspected of having) one of these familial sudden cardiac death (SCD) syndromes should be assessed by a clinician with considerable experience in the management of these conditions.
- The electrophysiological study is of limited value in identifying patients at risk of lethal ventricular arrhythmias. Programmed ventricular stimulation has a low predictive accuracy with 50% of both false positive and false negative results.

Brugada syndrome – BHRs Guidelines

- BrS patients presenting with VF /cardiac arrest without reversible precipitant should undergo ICD implantation
- BrS patients with syncope (when VT/VF has not been excluded as the cause of syncope) should undergo ICD implantation
- Spontaneous type 1 ECG without symptoms: a firm recommendation cannot be made at this time
- Asymptomatic individuals who require a drug to induce the type 1 ECG pattern are at low risk of sudden death; risks of ICD likely to outweigh benefits

Garratt, Elliott, Behr et al *Europace* 2010; **12**: 1156-75



Resuscitation Council (UK)



British
Cardiovascular
Society



**Cardiovascular implanted electronic
devices in people towards the end of life,
during cardiopulmonary resuscitation and
after death**

Where there may be a later need to consider deactivation (i.e. in people considering an ICD, including a cardiac resynchronisation therapy-defibrillator (CRT-D) device) this possibility and the reasons for it should usually be explained as part of informed consent to implantation . At routine review appointments people should have the opportunity to discuss concerns regarding any aspect of their device, including end-of-life decisions .

Guidelines for the diagnosis, prevention and management of implantable cardiac electronic device infection. Report of a joint Working Party project on behalf of the British Society for Antimicrobial Chemotherapy (BSAC, host organization), British Heart Rhythm Society (BHRS), British Cardiovascular Society (BCS), British Heart Valve Society (BHVS) and British Society for Echocardiography (BSE)

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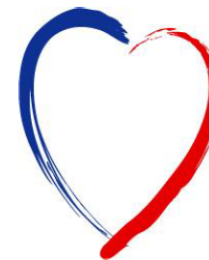
British Heart Rhythm Society

POSITION STATEMENT ON THE OUT OF HOURS MANAGEMENT OF BRADYARRHYTHMIA EMERGENCIES

Nick Linker and Mark Earley on behalf of BHRS Council, January 2016

INTRODUCTION

In cardiac rhythm management there is a particular issue in the provision of emergency pacing. In the UK there are a limited number of hospitals designated as pacing centres and even fewer have expertise in implantable cardioverter defibrillators (ICDs). Hospitals that implant pacemakers may not necessarily offer a 24 hour emergency pacing service.

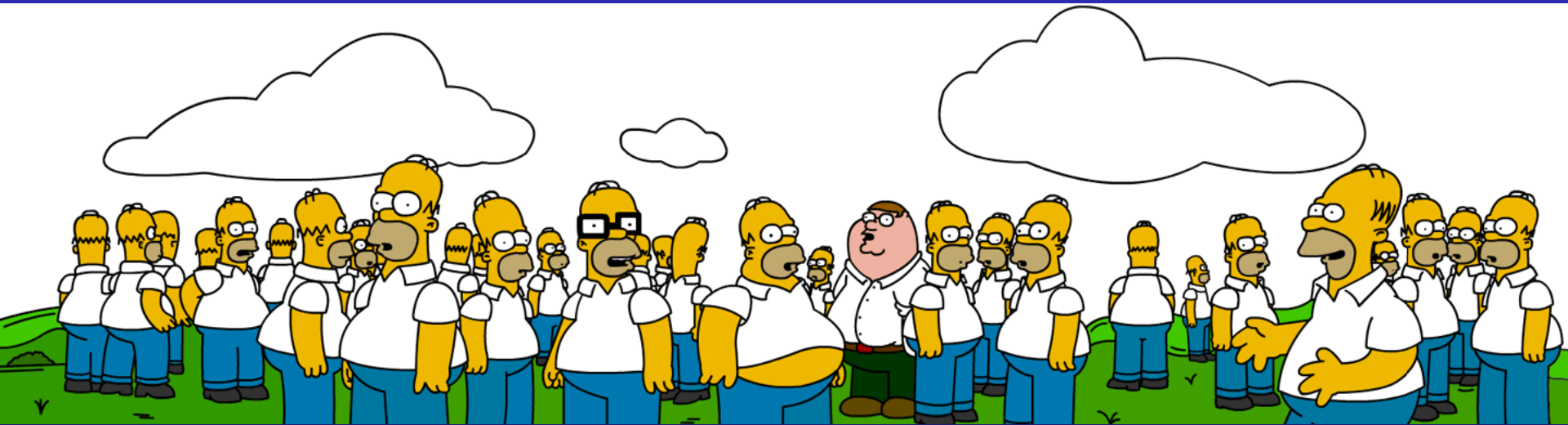


**British Cardiovascular Society
Working Group Report:**

**Out-Of-Hours Cardiovascular Care:
Management of Cardiac Emergencies and
Hospital In-Patients**

September 2016

Remember we are treating
individuals.
Guidance is Guidance



Any Questions

