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Improving and extending lives by treating arrhythmias

Advice to all departments carrying out Cardiac Rhythm Management implantation and follow-up procedures – a reminder of the importance of reporting to MHRA (updated)

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Dear Colleague,

As you are most likely aware Boston Scientific have recently issued a field safety notice regarding the use of Minute Ventilation (MV) sensors on some of their cardiac devices.

BHRS would like to encourage all departments implanting the affected devices or those responsible for outpatient care of patients with affected devices to make themselves fully aware of the potential issues and to familiarise themselves with the guidance provided by Boston Scientific.

BHRS remains concerned that issues such as this could remain under-reported and dismissed as lead failure. This in turn could result in additional invasive procedures being performed, exposing patients to unnecessary risk. BHRS would like to encourage extra vigilance when reviewing devices where the programming features minute ventilation sensor, even in the 'passive' state. Where inhibition of pacing due to sensor activity is a theoretical possibility it is recommended to review all programmed settings and adjust as appropriate.

BHRS is at times contacted regarding suspected adverse incidents involving Cardiac Implantable Electronic Devices and therefore BHRS would like to remind colleagues of the importance of reporting all actual or suspected adverse incidents involving medical devices to the MHRA in order that any issues can be identified and addressed promptly. The MHRA (Medicines and Healthcare products Regulatory Agency) is the body responsible for regulating medicines, medical devices and blood components for transfusion in the UK. Recognised globally as an authority in its field, the MHRA is an executive agency of the Department of Health. BHRS would like to encourage

departments offering CRM services to be vigilant for issues relating to the above, or indeed any other adverse incidents that may occur involving implanted cardiac devices.

• In England reporting should be via the 'Yellow Card Scheme'. Please follow this link to report an incident or for more information: https://yellowcard.mhra.gov.uk/

• In Scotland reporting should be via the 'Incident Reporting and Investigation Centre' (IRIC). Please follow this link to report an incident or for more information: http://www.hfs.scot.nhs.uk/services/incident-reportingand-investigation-centre-iric-1/how-to-report-anadverse-incident/

• In Northern Ireland reporting should be via the 'Northern Ireland Adverse Incident Centre' (NIAIC). Please follow this link to report an incident or for more information: https://www.healthni.gov.uk/articles/reporting-adverse-incident

• In Wales reporting should be via MHRA (Wales). Please follow this link to report an incident or for more information: http://www.wales.nhs.uk/sites3/page.cfm?orgid=465&p id=56203

For further resources and information relating to this issue please see appendix for additional items of interest.

Yours Sincerely,

Holly Daw

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on behalf of British Heart Rhythm Society (BHRS) | www.bhrs.com

Appendix:

http://www.bhrs.com/files/files/News%20Alerts/170921-dm-The%20importance%20of%20reporting%20to%20the%20MHRA%20-%20A%20recent%20concern.pdf

Appearance of MV oversensing – example