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

**August 2017**

Dear Colleague,

A concern has been raised recently of the possibility of interaction between rate response sensor activity based on minute ventilation and the increased sensitivity features available on some pacemakers and CRT-P devices. It has been suggested this could result in over-sensing and failure to deliver pacing therapy. BHRS is concerned that issues such as this could remain under-reported and dismissed as 'simple' lead failure due to time since implant or damage during recent generator change procedure. 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 using minute ventilation sensor and enhanced sensitivity are in use.

A minute ventilation sensor calculates the respiratory rate using transthoracic impedance by delivering a low amplitude current. This current should be too small to be detected by the device, however, it is possible that where increased resistance / impedance occurs in the presence of enhanced sensitivity the current delivered may be sufficient to be detected by the device and misinterpreted as intrinsic myocardial signal. Where inhibition of pacing due to sensor activity is a theoretical possibility it is recommended to review all programmed settings and adjust as appropriate. For example enhanced sensitivity may not be required and fixed sensitivity may be more suitable (particularly where patients are pacemaker dependant). It is recommended that extra care is necessary where older leads or leads with high resistance / impedance are in situ.

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-reporting-and-investigation-centre-iric-1/how-to-report-an-adverse-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.health-ni.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&pid=56203

Yours Sincerely,

Holly Daw

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on behalf of
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