Safety Alert on Two St Jude Medical's Pacemakers - Accent DR and Anthem CRT-P

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After assessment on a field safety note filed by an American medical device manufacturer, St Jude Medical, on safety concerns on two of its pacemakers, Accent DR and Anthem CRT-P, respectively, the Department of Health (DH) today (September 23) cautions medical practitioners, especially cardiologists, about the message and also advises that affected patients should consult their attending physicians. The fault involves invalid low lead impedance measurements.

A DH spokesman assists with explanation on the technical background, "The lead impedance value is an indicator to reflect the condition of the lead circuit that connects the pacemaker to the heart. In those pacemakers which have been programmed to switch polarity, an out of range reading may cause them to switch the lead polarity to unipolar. However, it is reassuring that both the pacing and sensing functions of such devices will not be affected, although sometimes clients can hear audible notifiers, or the mishap may present itself at the next clinic follow-up as varying values recorded in lead impedance trend graphs."

St Jude Medical's records indicated that the pacemakers were initially marketed in July 2009 and Hong Kong has been importing them since September that year.
"Amongst the stock, 16 pieces of Accent DR model PM2212 and 13 pieces of Anthem CRT-P model PM3212 are known to be involved in the present incident. Although the rates of occurrence of the defects are low, 0.01% for Accent DR and 1.6% for Anthem CRT-P, and thus far, there has not been notification of related adverse event either here or overseas, we are given to understand that the manufacturer's local representative in Hong Kong will get in touch with individual responsible physicians for necessary corrective actions as soon as possible," the spokesman remarks.

"To ensure readings will be accurate, a new version of the programme software will be loaded onto programmers for the pacemakers," the spokesman reveals.

A DH spokesman also comments that, “Though the manufacturer will reach out to their clients via doctors, possible implantation of defective devices in international travellers passing through Hong Kong makes we think that it will only be prudent for DH to bring the news to our community for individual's necessary action.”

The manufacturer has set up a hotline (9682 0488) for related enquiries and DH will be monitoring the progress of the corrective action.

Back Back to Top

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