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**Reference: Confirm RX™ ICM Incorrect Low Battery Indicator**

Dear Madam or Sir,

Please be informed that Abbott is advising US physicians that exposure to sub-freezing temperatures during our supply chain process caused a transient battery voltage drop for a small number of Confirm Rx™ Model DM3500 Insertable Cardiac Monitoring (ICM) devices.

The physician communication will provide information regarding updated Merlin™ programmer software version 24.2.x which will allow physicians to detect the presence of a Confirm Rx™ device incorrect low battery indicator prior to implant. Additionally, the programmer software will provide a mechanism to resolve the incorrect display for already implanted devices.

Overall, we have experienced a 0.41% rate of incorrect display due to cold temperatures experienced by the device, prior to implant, during recent winter months in the United States.

All complaints received to date have been associated with US devices. There have been no complaints reported outside the US for this issue.

Review of data on Merlin.net™ confirms there are zero instances of incorrect battery indicator in Confirm Rx™ devices OUS due to this issue.

The observed difference between US and OUS devices is most likely due to differences in the supply chain process outside the US.

I hope the information provided above explain that a Field Safety Notice is not necessary in countries outside the USA. If you have any further questions please contact your local QA representative.

Yours sincerely,



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