



The Cardiac Society  
of Australia and  
New Zealand

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**ANZCDACC Advisory Notice: 1<sup>st</sup> November 2016**

**Device:** LivaNova Field Safety Notice Applicable to REPLY Models D, DR, VDR, SR  
ESPRIT Models D, DR, S, SR, FACIL Model DR pacemakers

**Advisory Grade TGA:** TBA Field Notice

**ANZCDACC Advisory Grade:** Elective/Routine

**Number in Australia at risk: 2248 New Zealand none**

**Risk:** There is the potential with the current programmer software to over-estimate battery longevity and as such there is a potential for premature battery depletion.

**Description:** LivaNova received thirty-one (31) reports worldwide (0.006% incidence) of overestimation of the displayed residual longevity during use of the current programmer software version.

**Presentation:** No patients have been harmed to date. The worst case could be that the device has already reached the End of Life point before the next scheduled follow up. This would have implications especially for pacemaker dependent patients.

The ERI/RRT was reached between follow-up exams in 14 of these 31 cases (0.003%). No permanent injury or death has occurred as a result of the reported events. All pacing function remained intact.

**Advice:** LivaNova are currently upgrading programmer software which should rectify the issue. LivaNova states the underlying battery longevity is not affected and can be accurately calculated by the new software. ANZCDACC advises physicians to ensure their patients' device longevity is assessed with new version programmer software at next allocated review or earlier if the device is approaching ERI/RRT or pacemaker dependent.