

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Abbott Medical, The Merlin PCS 3650 programmer Model 3330

Recall Date	Product Description	Recalling Firm	Recall Reason
12/23/2024	The Merlin PCS 3650 programmer Model 3330 The Merlin PCS programmer model 3650 is a portable, dedicated programming system which operates using the Merlin PCS Model 3330 software and is designed to interrogate, program, display data from, and test Abbott Medical implantable devices and leads.	Abbott Medical	Due to a programmer software anomaly, during finalizing of the leadless pacemaker system, a specific sequence of programmer actions combined with a loss of telemetry during a small window (<2 seconds) may cause the finalization step to fail. If this occurs, the Programmer displays a \x1closs of telemetry detected\x1d window, and there is no pacing.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model: 3650 Serial: 21140 UDI:(01)5414734500661(11)230915(21)21140 Model: 3650 Serial: 12060663 UDI:(01)5414734500661(11)240228(21)12060663	10 Merlin PCS Programmer Model 3650 devices (operating with Model 3330 software) distributed in California	November 2024 and Prior

Model: 3650 Serial: 12052305 UDI:(01)5414734500661(11)230907 (21)12052305 Model: 3650 Serial: 23582 UDI:(01)5414734500661(11)240104 (21)23582 Model: 3650 Serial: 17266 UDI:(01)5414734500661(11)240110 (21)17266 Model: 3650 Serial: 20356 UDI:(01)5414734500661(11)240208 (21)20356 Model: 3650 Serial: 12042155 UDI:(01)5414734500661(11)240212 (21)12042155 Model: 3650 Serial: 23466 UDI:(01)5414734500661(11)231025 (21)23466 Model: 3650 Serial: 14910 UDI: (01)5414734500661(11)230921(21) 14910 Model: 3650 Serial: 12044767 UDI:(01)5414734500661(11)090820 (21)12044767		
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For additional information, please visit the [FDA Website](#).