

Device Survival Summary (95% Confidence Interval)

The following table shows CRT device survival estimates with 95% confidence intervals. Estimates are shown both with and without normal battery depletions included.

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US)		Device Survival Probability (%)											
						Therapy Function Compromised	Therapy Function Not Compromised	Years After Implant											
						31 + 253 = 284	Total	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr			
7289	InSync II Marquis	Jul-03	28,000	1,000	5,905	31 + 253 = 284	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	98.7 +0.2/-0.2	98.0 +0.2/-0.3 at 49 mo	98.0 +0.2/-0.3	98.0 +0.2/-0.3						
	Advisories: See page 140 – 2005 Potential Premature Battery Depletion Due to Battery Short					(9) + (0) = (9) (advisory-related subset)	Including Normal Battery Depletion	99.7 +0.1/-0.1	96.8 +0.2/-0.3	82.7 +0.6/-0.6	5.4 +0.7/-0.6 at 49 mo	19.6 +0.9/-0.9							
7297	InSync Sentry	Nov-04	9,000	2,000	933	1 + 30 = 31	Excluding Normal Battery Depletion	100.0 +0.0/-0.1	99.9 +0.1/-0.1	99.6 +0.1/-0.2	99.5 +0.2/-0.2 at 52 mo	99.5 +0.2/-0.2							
							Including Normal Battery Depletion	99.7 +0.1/-0.1	97.7 +0.3/-0.4	89.3 +0.8/-0.8	31.8 +3.9/-3.8 at 52 mo	66.4 +1.4/-1.5 at 47 mo							
7299	InSync Sentry	Apr-05	31,000	15,000	1,458	6 + 49 = 55	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 47 mo	99.7 +0.1/-0.1							
							Including Normal Battery Depletion	99.8 +0.0/-0.1	97.9 +0.2/-0.2	89.6 +0.4/-0.5	60.0 +2.4/-2.5 at 47 mo	60.0 +2.4/-2.5							
7303	InSync Maximo	Jun-04	17,000	3,000	2,590	6 + 60 = 66	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.6 +0.1/-0.1	99.4 +0.1/-0.2 at 54 mo	99.4 +0.1/-0.2							
							Including Normal Battery Depletion	99.8 +0.1/-0.1	97.7 +0.2/-0.3	88.8 +0.6/-0.6	17.2 +1.7/-1.6 at 54 mo	64.0 +1.0/-1.0							
7304	InSync Maximo	Apr-05	19,000	10,000	715	2 + 27 = 29	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.2	99.7 +0.1/-0.2							
							Including Normal Battery Depletion	99.8 +0.1/-0.1	98.0 +0.2/-0.3	90.9 +0.6/-0.6	65.7 +3.1/-3.3	65.7 +3.1/-3.3							
8040	InSync	Aug-01	15,000	2,000	675	21 + 7 = 28	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.1	99.9 +0.0/-0.1	99.6 +0.1/-0.2	99.6 +0.1/-0.2							
							Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	98.2 +0.2/-0.3	84.2 +0.9/-1.0	84.2 +0.9/-1.0							
8042	InSync III	Feb-03	31,000	17,000	324	3 + 3 = 6	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1							
							Including Normal Battery Depletion	100.0 +0.0/-0.0	99.2 +0.1/-0.1	99.2 +0.1/-0.2	87.1 +1.3/-1.4	87.1 +1.3/-1.4							

continued

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US)		Device Survival Probability (%)									
						Therapy Function Compromised	Therapy Not Function Compromised	Years After Implant									
								1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	
C154DWK, C164AWK, C174AWK (Non-advisory population)	Concerto	May-06	74,000	59,000	363	17 + 52 = 69	Total	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.4 +0.3/-0.4 at 34 mo							
	See page 144 – Performance note on Anomalies in MOSFET Integrated Circuit Technology							Excluding Normal Battery Depletion	99.8 +0.0/-0.0	97.4 +0.2/-0.2	90.7 +1.5/-1.7 at 34 mo						
C154DWK, C164AWK, C174AWK (Advisory population)	Concerto	May-06	4,000	2,000	97	3 + 159 = 162	Total	99.9 +0.1/-0.2	99.5 +0.2/-0.4	87.1 +2.1/-2.5 at 34 mo							
	Advisories: See page 136 – 2009 Potential Reduced Device Longevity							Excluding Normal Battery Depletion	99.7 +0.1/-0.3	97.0 +0.6/-0.7	63.1 +3.3/-3.5 at 34 mo						
D224TRK	Consulta CRT-D	Sept-08	9,000	8,000	1	1 + 1 = 2	Total	100.0 +0.0/-0.1 at 8 mo	99.8 +0.1/-0.3 at 8 mo								
	See page 144 – Performance note on Anomalies in MOSFET Integrated Circuit Technology							Excluding Normal Battery Depletion	99.8 +0.1/-0.3 at 8 mo								
D284TRK	Maximo II CRT-D	Sept-08	3,000	3,000	1	0 + 0 = 0	Total	100.0 +0.0/-0.0 at 8 mo	99.9 +0.1/-0.3 at 8 mo								
	Advisories: See page 136 – 2009 Potential Reduced Device Longevity							Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo	99.9 +0.1/-0.3 at 8 mo							