

**Device Survival Summary** (95% Confidence Interval)

The following table shows ICD 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										
						1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr				
7227	GEM	Oct-98	22,000	3,000	1,824	—	—	148	99.7 +0.1/-0.1	99.6 +0.1/-0.1	99.5 +0.1/-0.1	99.4 +0.1/-0.1	99.2 +0.1/-0.1	99.2 +0.1/-0.1	99.2 +0.1/-0.1	99.1 +0.1/-0.2	99.1 +0.2/-0.2	99.0 +0.2/-0.3 at 112 mo
	Advisories: See page 155 – 1999 Potential Circuit Overload						—	—	—	99.3 +0.1/-0.1	98.9 +0.1/-0.2	98.7 +0.2/-0.2	98.1 +0.2/-0.2	97.2 +0.2/-0.3	94.8 +0.4/-0.4	82.7 +0.8/-0.8	64.6 +1.2/-1.2	13.1 +1.9/-1.8 at 112 mo
7229	GEM IIVR	Jul-99	11,000	40	1,932	—	—	27	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.2	99.7 +0.1/-0.2	99.7 +0.1/-0.2	99.7 +0.1/-0.2
	Advisories: See page 155 – 1999 Potential Circuit Overload; Also see page 165 – Performance note on ICD Battery Discharge Behavior						—	—	—	99.8 +0.1/-0.1	99.4 +0.1/-0.2	99.2 +0.2/-0.2	98.4 +0.3/-0.3	94.1 +0.6/-0.6	82.8 +1.0/-1.1	43.2 +1.6/-1.6	8.3 +1.4/-1.3 at 89 mo	—
7230	Marquis VR	Dec-02	19,000	9,000	52	10 + 21 = 31	10 + 21 = 31	31	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.2 at 71 mo	—	—	—	—
	Advisories: See page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short						(1) (0) (1) (advisory-related subset)	(1) (0) (1) (advisory-related subset)	(1) (0) (1) (advisory-related subset)	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.2 +0.1/-0.2	98.7 +0.2/-0.3	97.3 +0.5/-0.6 at 71 mo	—	—	—
7231	GEM III VR	Dec-00	17,000	7,000	795	10 + 27 = 37	10 + 27 = 37	37	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.2	99.7 +0.1/-0.2	99.7 +0.1/-0.2	99.7 +0.1/-0.2
	See page 165 – Performance note on ICD Battery Discharge Behavior						—	—	—	99.8 +0.1/-0.1	99.4 +0.1/-0.1	99.0 +0.1/-0.2	98.5 +0.2/-0.2	97.0 +0.3/-0.4	87.4 +0.7/-0.8	71.4 +1.4/-1.5	55.8 +2.9/-3.1 at 91 mo	—
7232	Maximo VR	Oct-03	43,000	30,000	47	10 + 25 = 35	10 + 25 = 35	35	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.1/-0.1	—	—	—	—	—
	Advisories: See page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short						(0) + (0) = (0) (advisory-related subset)	(0) + (0) = (0) (advisory-related subset)	(0) + (0) = (0) (advisory-related subset)	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.5 +0.1/-0.1	99.3 +0.1/-0.1	99.1 +0.2/-0.2	—	—	—	—
7271	GEM DR	Oct-98	15,000	2,000	1,370	—	—	96	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.2	99.3 +0.1/-0.2	99.1 +0.2/-0.2	99.0 +0.2/-0.2	99.0 +0.2/-0.2	98.8 +0.2/-0.3	98.8 +0.2/-0.3 at 105 mo
	Advisories: See page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short						—	—	—	99.7 +0.1/-0.1	99.4 +0.1/-0.1	98.8 +0.2/-0.2	97.8 +0.3/-0.3	95.5 +0.4/-0.4	89.3 +0.7/-0.7	75.7 +1.2/-1.2	44.5 +1.8/-1.8	12.6 +2.1/-1.9 at 105 mo
7274	Marquis DR	Mar-02	48,000	15,000	1,495	75 + 75 = 150	75 + 75 = 150	150	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.5 +0.1/-0.1	99.3 +0.1/-0.2	99.3 +0.1/-0.2	99.3 +0.1/-0.2	99.3 +0.1/-0.2	99.3 +0.1/-0.2
	Advisories: See page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short						(36) + (3) = (39) (advisory-related subset)	(36) + (3) = (39) (advisory-related subset)	(39) (advisory-related subset)	99.8 +0.0/-0.0	99.5 +0.1/-0.1	98.6 +0.1/-0.1	97.4 +0.2/-0.2	91.9 +0.4/-0.4	68.4 +1.2/-1.2	42.9 +3.0/-3.1 at 79 mo	—	—

continued

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions		Device Survival Probability (%)												
						Therapy Function Compromised	Therapy Function Not Compromised	Years After Implant												
								1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr				
7275	GEM III DR	Nov-00	20,000	2,000	3,471	11	30	41	99.9	99.9	99.8	99.7	99.7	99.7	99.7	99.7	99.7	99.7	99.7	99.7
	See page 165 – Performance note on ICD Battery Discharge Behavior									99.6	99.0	96.9	90.1	64.5	8.8					
7276	GEM III AT	Feb-01	14,000	1,000	2,700	7	39	46	99.9	99.9	99.7	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5
	See page 165 – Performance note on ICD Battery Discharge Behavior									99.6	98.8	96.1	84.6	50.5	3.7					
7278	Maximo DR	Oct-03	37,000	25,000	194	8	21	29	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
	Advisories: See page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	(0)	(0)		99.9	99.7	99.3	97.7	93.8						
7288	Intrinsic	Aug-04	31,000	22,000	85	6	27	33	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
	Onyx	Mar-04	1,000	1,000	6	1	3	4	99.9	99.7	99.4	98.2	97.8	97.8	97.8	97.8	97.8	97.8	97.8	97.8
7290	Onyx	Mar-04	1,000	1,000	6	1	3	4	99.9	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5
	EnTrust DR	Jun-05	400	300	7	1	2	3	99.8	99.8	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1
D154ATG, D154DRG	EnTrust DR	Jun-05	28,000	22,000	33	6	14	20	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
	EnTrust DR	Jun-05	28,000	22,000	33	6	14	20	99.9	99.7	99.3	99.2	99.2	99.2	99.2	99.2	99.2	99.2	99.2	99.2

continued



Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions			Device Survival Probability (%)							
						Therapy Function Compromised	Therapy Function Not Compromised	Total	Years After Implant							
									1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
D154AWG D164AWG	Virtuoso DR	May-06	62,000	56,000	14	15 + 10 = 25	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.2/-0.5 at 29 mo						
							Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.4 +0.3/-0.5 at 29 mo						
D154VRC	EnTrust VR	Jun-05	14,000	11,000	7	4 + 11 = 15	Excluding Normal Battery Depletion	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.1/-0.1 at 39 mo						
							Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.2 at 39 mo						
D154VWC, D164VWC	Virtuoso VR	May-06	26,000	24,000	7	5 + 3 = 8	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1							
							Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.2							
D224DRG	Secura DR	Aug-08	1,000	1,000	0	0 + 0 = 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 2 mo								
							Including Normal Battery Depletion	100.0 +0.0/-0.0 at 2 mo								
D224VRC	Secura VR	Aug-08	1,000	1,000	0	0 + 0 = 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 2 mo								
							Including Normal Battery Depletion	100.0 +0.0/-0.0 at 2 mo								
D284DRG	Maximo II DR	Mar-08	1,000	1,000	0	0 + 0 = 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 2 mo								
							Including Normal Battery Depletion	100.0 +0.0/-0.0 at 2 mo								
D284VRC	Maximo II VR	Mar-08	400	400	0	0 + 0 = 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 2 mo								
							Including Normal Battery Depletion	100.0 +0.0/-0.0 at 2 mo								