

CRT-Ds

CONTAK RENEWAL 3 RF HE Models H217/H219

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 3,000	U.S. Normal Battery Depletion: 100.00%	U.S. Confirmed Malfunction: 100.00%
U.S. Approval Date: February 2005	U.S. Unconfirmed Reports of Premature Battery Depletion: 0	U.S. Unconfirmed Malfunction: 0
U.S. Estimated Active Implants: 3,000	U.S. Average Battery Life: 8.1 Yrs	U.S. Average Device Age: 1.9 Yrs

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)			
Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)
100.00	100.00	100.00	100.00
Malfunction Only: 100.00% @ 8 hrs (exp'd)			

CONTAK RENEWAL 3 RF Models H210/H215

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 4,000	U.S. Normal Battery Depletion: 100.00%	U.S. Confirmed Malfunction: 100.00%
U.S. Approval Date: February 2005	U.S. Unconfirmed Reports of Premature Battery Depletion: 0	U.S. Unconfirmed Malfunction: 0
U.S. Estimated Active Implants: 4,000	U.S. Average Battery Life: 8.1 Yrs	U.S. Average Device Age: 1.9 Yrs

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)			
Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)
100.00	100.00	100.00	100.00
Malfunction Only: 100.00% @ 8 hrs (exp'd)			

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.

CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS - CRT-Ds

CONTAK RENEWAL 3 HE Models H177/H179

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 71,000	U.S. Normal Battery Depletions: 35	U.S. Confirmed Malfunctions: 27	U.S. Confirmed Malfunctions: 27
U.S. Approval Date: June 2007	U.S. Unconfirmed Reports of Premature Battery Depletions: 16	U.S. Unconfirmed Reports of Premature Battery Depletions: 16	U.S. Unconfirmed Reports of Premature Battery Depletions: 16
U.S. Estimated Active Implants: 7,000			

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)
Depletion & Malfunction Only	99.86 (99.86-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)
Malfunction Only	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)
Depletion & Malfunction	99.86 (99.86-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)
Malfunction Only	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)	99.89 (99.89-100.00)

CONTAK RENEWAL 3 Models H170/H175

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 30,000	U.S. Normal Battery Depletions: 4	U.S. Confirmed Malfunctions: 23	U.S. Confirmed Malfunctions: 23
U.S. Approval Date: June 2003	U.S. Unconfirmed Reports of Premature Battery Depletions: 3	U.S. Unconfirmed Reports of Premature Battery Depletions: 3	U.S. Unconfirmed Reports of Premature Battery Depletions: 3
U.S. Estimated Active Implants: 5,000			

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)
Depletion & Malfunction Only	99.85 (99.85-100.00)	99.83 (99.83-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)
Malfunction Only	99.84 (99.84-100.00)	99.78 (99.78-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)
Depletion & Malfunction	99.83 (99.83-100.00)	99.85 (99.85-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)	99.87 (99.87-100.00)
Malfunction Only	99.84 (99.84-100.00)	99.78 (99.78-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)	99.71 (99.71-100.00)

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory. Survival probabilities for CONTAK RENEWAL 3 HE and CONTAK RENEWAL 3 CRT-Ds subject to the 12-May-08 (Low-Voltage Capacitor) advisory not provided because they do not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on this advisory.

CONTAK RENEWAL Model H135

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 10,000
 U.S. Approval Data: September 2002
 U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 665
 U.S. UAG Implants: 1,000 (67 Parametric Battery Depletions)
 U.S. Confirmed Malfunctions: 15
 U.S. Confirmed Malfunctions: 15
 U.S. Confirmed Malfunctions: 15
 U.S. Average Daily Usage: 24.0 hr

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Population Size	Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)
Depleted & Malfunc.	99.31 (91.00-100)	98.62 (82.70-100)	97.79 (64.10-100)	96.88 (41.10-100)	95.89 (21.00-100)	94.83 (1.00-100)	93.71 (0.00-100)	92.54 (0.00-100)
Malfunction Only	99.65 (100-100)	99.65 (100-100)	99.65 (100-100)	99.65 (100-100)	99.65 (100-100)	99.65 (100-100)	99.65 (100-100)	99.65 (100-100)
ASUS (SD) / Survival Probability	99.96 (99.96-100)	99.92 (99.92-100)	99.84 (99.84-100)	99.72 (99.72-100)	99.57 (99.57-100)	99.40 (99.40-100)	99.21 (99.21-100)	99.00 (99.00-100)

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.

CRT-P

CARDIAC RESYNCHRONIZATION THERAPY - CRT LEADS

CONTAK RENEWAL TR Models H120/H125

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 5,000	U.S. Annual Battery Depletions: 18	U.S. Confirmed Malfunctions: 100.00%					
U.S. Approval Date: January 2006	U.S. Unconfirmed Reports of Problems: 0	U.S. Unconfirmed Malfunctions: 0					
U.S. Estimated Active Implants: 1,500	Battery Depletions: 0	U.S. Estimated Active Implants: 1,500					
U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)							
Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
100.00 ±0.00	100.00 ±0.00	100.00 ±0.00	100.00 ±0.00	100.00 ±0.00	100.00 ±0.00	100.00 ±0.00	100.00 ±0.00
Depletion & Malfunction: 89.82 ±0.27 ±0.11			89.82 ±0.27 ±0.11			89.82 ±0.27 ±0.11	
Malfunction Only: 100.00 ±0.00 ±0.00			100.00 ±0.00 ±0.00			100.00 ±0.00 ±0.00	

Survival probability for CONTAK RENEWAL TR CRT-Ps subject to the 23-Jun-09 advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on this advisory.

CRT Leads

EASYTRAK 3 Models 4522/4524/4525/4527/4548/4549/4550

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 7056
 U.S. Approval Date: Aug 09/2009
 U.S. Estimated Active Implants: 6000

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)	Yr. 9 (%)	Yr. 10 (%)
99.63 (0.2/0.1)	99.40 (0.2/mo. (0.4/0.2))								

EASYTRAK 2 Models 4515/4517/4518/4520/4542/4543/4544

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 28000
 U.S. Approval Date: Aug 03/2004
 U.S. Estimated Active Implants: 25000

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)	Yr. 9 (%)	Yr. 10 (%)
99.41 (0.2/0.1)	99.09 (0.2/0.2)	98.17 (0.2/mo. (0.4/0.2))							

EASYTRAK Models 4510/4511/4512/4513/4537/4538

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 35000
 U.S. Approval Date: May 2001
 U.S. Estimated Active Implants: 23900

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)	Yr. 9 (%)	Yr. 10 (%)
99.82 (0.1/0.1)	99.45 (0.1/0.1)	99.14 (0.1/0.1)	98.85 (0.2/0.2)	98.72 (0.4/0.3)	98.72 (0.4/0.3)	98.72 (0.4/0.3)	98.72 (0.4/0.3)	98.72 (0.4/0.3)	98.72 (0.4/0.3)

ICDS

TACHYCARDIA THERAPY - ICDs

VITALITY 2 ELVR Model 1177

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 3,000
 U.S. Approval Date: March 2004
 U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 3
 Without Compromised Therapy: 2
 With Compromised Therapy: 1
 U.S. Average Device Age: 10.2 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Year	Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)
Depletion & Malic	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)
Malfunction Only	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)	99.85 (0.44-0.1)

VITALITY 2 EL DR Model 1167

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 3,000
 U.S. Approval Date: March 2004
 U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 1
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 2
 Without Compromised Therapy: 1
 With Compromised Therapy: 1
 U.S. Average Device Age: 10.5 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Year	Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)
Depletion & Malic	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)
Malfunction Only	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)	99.92 (0.37-0.1)

Survival probabilities for VITALITY 2 EL VR and VITALITY 2 EL DR ICDs subject to the 23-Jun-08 advisory not provided because they do not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on this advisory.

VITALITY 2 VR Model T175

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 9,000
 U.S. Approval Date: March 2004
 U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 1
 U.S. Unconfirmed Reports of Premature Battery Depletions: 3

U.S. Confirmed Malfunctions: 19
 Without Compromised Therapy: 16
 With Compromised Therapy: 3
 U.S. Average Device Age: 9 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Year	Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)	Yr. 9 (%)
Non-Advisory Implants	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97
Depletions & Malfunc.	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97
Malfunction Only	99.95	99.95	99.95	99.95	99.95	99.95	99.95	99.95	99.95



VITALITY 2 DR Model T165

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 13,000
 U.S. Approval Date: March 2004
 U.S. Estimated Active Implants: 12,000

U.S. Normal Battery Depletions: 4
 U.S. Unconfirmed Reports of Premature Battery Depletions: 3

U.S. Confirmed Malfunctions: 18
 Without Compromised Therapy: 15
 With Compromised Therapy: 3
 U.S. Average Device Age: 10.1 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Year	Yr. 1 (%)	Yr. 2 (%)	Yr. 3 (%)	Yr. 4 (%)	Yr. 5 (%)	Yr. 6 (%)	Yr. 7 (%)	Yr. 8 (%)	Yr. 9 (%)
Non-Advisory Implants	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97
Depletions & Malfunc.	99.96	99.96	99.96	99.96	99.96	99.96	99.96	99.96	99.96
Malfunction Only	99.92	99.92	99.92	99.92	99.92	99.92	99.92	99.92	99.92



Survival probabilities for VITALITY 2 VR and VITALITY 2 DR ICDs subject to 12-May-05 (Low-Voltage Capture) and 23-Jun-08 sMISCs are not provided because they do not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on this advisory.

VITALITY BR HE Model T180

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 3,000
 U.S. Approval Date: May 2006
 U.S. Estimated Active Implants: 3,000

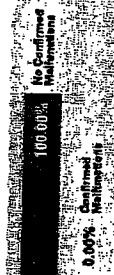
U.S. Normal Battery Depletions: 2
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 0
 Without Compromised Therapy: 0
 With Compromised Therapy: 0
 U.S. Average Device Age: 4.1 mo

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
99.90 (0.10)	99.80 (0.20)	99.67 (0.33)	99.53 (0.47)	99.38 (0.62)	99.23 (0.77)	99.08 (0.92)	98.93 (1.07)

Advisory: 12-May-06 (suspected implants)
 Depletions & Malfunctions Only: 100.00 @ 8 mo, 10.0x+0.0



VITALITY AVT Model A155

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 12,000
 U.S. Approval Date: October 2008
 U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 10
 U.S. Unconfirmed Reports of Premature Battery Depletions: 2

U.S. Confirmed Malfunctions: 47
 Without Compromised Therapy: 16
 With Compromised Therapy: 31
 U.S. Average Device Age: 20.4 mo

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
99.77 (0.23)	99.49 (0.51)	99.07 (0.93)	98.65 (1.35)	98.23 (1.77)	97.81 (2.19)	97.39 (2.61)	96.97 (3.03)

Advisory: 17-Jun-06 and 22-Jul-06*
 Depletions & Malfunctions Only: 99.80 (0.20)



*Devices subject to an advisory. Refer to the Safety Advisory section for more details. Devices may be part of more than one advisory. For the June 17, 2006 and July 22, 2006 advisories, a non-invasive software solution will be available, pending regulatory approval. Survival probability for VITALITY AVT A155 ICDs subject to the 12-May-08 Low-Voltage Capacitor Advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on the advisory.

VITALITY AVT Model A135

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 7,000

U.S. Approval Date: March 2003

U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 37
 U.S. Unconfirmed Reports of Premature Battery Depletions: 29
 U.S. Confirmed Malfunctions: 86
 Without Compromised Therapy: 55
 With Compromised Therapy: 17
 U.S. Average Device Age: 28.6 mo

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Implant Population & Malfunction Only	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Population & Malfunction Only	99.85 (0.17/0.1)	99.64 (0.2/0.1)	99.37 (0.3/0.1)	98.93 (0.4/0.1)	98.37 (0.5/0.1)	97.71 (0.6/0.1)	96.93 (0.7/0.1)	95.93 (0.8/0.1)
Malfunction Only	99.85 (0.17/0.1)	99.75 (0.2/0.1)	99.18 (0.4/0.1)	98.71 (0.5/0.1)	98.18 (0.6/0.1)	97.51 (0.7/0.1)	96.73 (0.8/0.1)	95.73 (0.9/0.1)

VITALITY DS DR Model T125

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 16,000

U.S. Approval Date: July 2003

U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 7
 U.S. Unconfirmed Reports of Premature Battery Depletions: 2
 U.S. Confirmed Malfunctions: 51
 Without Compromised Therapy: 15
 With Compromised Therapy: 19
 U.S. Average Device Age: 16.8 mo

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Implant Population & Malfunction Only	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Population & Malfunction Only	99.91 (0.1/0.0)	99.81 (0.1/0.1)	99.50 (0.3/0.1)	99.11 (0.4/0.1)	98.50 (0.5/0.1)	97.81 (0.6/0.1)	96.93 (0.7/0.1)	95.93 (0.8/0.1)
Malfunction Only	99.93 (0.1/0.0)	99.83 (0.1/0.1)	99.68 (0.3/0.1)	99.28 (0.4/0.1)	98.68 (0.5/0.1)	97.93 (0.6/0.1)	97.03 (0.7/0.1)	96.03 (0.8/0.1)

*Devices subject to an advisory. Refer to the Safety Advisory section for more details. Devices may be part of more than one advisory. For the June 17, 2005 and July 22, 2005 advisories, a non-invasive software solution will be available, pending regulatory approval. Survival probabilities for VITALITY DS DR ICDs subject to the 12-May-06 (Low-Voltage Capacitor) and 23-Jun-06 advisories not provided because they do not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on these advisories.

TACHYCARDIA THERAPY - ICDs

VITALITY DS VR Model T135

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 14,000
 U.S. Approval Date: July 2003
 U.S. Estimated Active Implants: 12,000

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Year	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Depletion & Malfunction	99.89 (0.11)	99.83 (0.17)	99.71 (0.29)	99.51 (0.49)	99.26 (0.74)	98.96 (1.02)	98.52 (1.28)	97.94 (1.54)
Malfunction Only	99.94 (0.06)	99.92 (0.08)	99.82 (0.18)	99.58 (0.42)	99.24 (0.76)	98.80 (1.10)	98.26 (1.44)	97.62 (1.78)

U.S. Confirmed Malfunctions: 19
 Without Compromised Therapy: 13
 With Compromised Therapy: 6
 U.S. Average Device Age: 177 mo

U.S. Normal Battery Depletions: 9
 U.S. Unconfirmed Reports of Premature Battery Depletions: 4

U.S. Confirmed Malfunctions: 18
 Without Compromised Therapy: 13
 With Compromised Therapy: 5
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 18
 Without Compromised Therapy: 13
 With Compromised Therapy: 5
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 18
 Without Compromised Therapy: 13
 With Compromised Therapy: 5
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 18
 Without Compromised Therapy: 13
 With Compromised Therapy: 5
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 18
 Without Compromised Therapy: 13
 With Compromised Therapy: 5
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 18
 Without Compromised Therapy: 13
 With Compromised Therapy: 5
 U.S. Average Device Age: 181 mo

VITALITY EL Model T127

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 3,000
 U.S. Approval Date: July 2003
 U.S. Estimated Active Implants: 3,000

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Year	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Depletion & Malfunction	99.80 (0.20)	99.60 (0.40)	99.30 (0.70)	98.90 (1.00)	98.40 (1.30)	97.80 (1.60)	97.10 (1.90)	96.30 (2.20)
Malfunction Only	99.80 (0.20)	99.80 (0.20)	99.80 (0.20)	99.80 (0.20)	99.80 (0.20)	99.80 (0.20)	99.80 (0.20)	99.80 (0.20)

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 4
 Without Compromised Therapy: 3
 With Compromised Therapy: 1
 U.S. Average Device Age: 181 mo

Survival probabilities for VITALITY DS VR ICDs subject to the 12-May-08 (Low-Voltage Capacitor) and 23-Jun-08 advisories not provided because they do not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on these advisories.
 Survival probability for VITALITY EL ICDs subject to the 23-Jun-08 advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on these advisories.

VENTAK PRIZM 2 DR Model 1861

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 43,000
 U.S. Approval Date: August 2000
 U.S. Estimated Active Implants: 22,000

U.S. Confirmed Malfunctions: 160
 Without Compromised Therapy: 58
 With Compromised Therapy: 102
 U.S. Average Device Age: 5.6 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	99.75 (97.0-99.1)	99.56 (94.0-99.1)	99.11 (92.0-99.1)	98.20 (86.0-99.1)	97.00 (84.0-99.1)	95.50 (82.0-99.1)	94.00 (80.0-99.1)	92.50 (78.0-99.1)
Advisory	99.84 (97.0-99.1)	99.84 (94.0-99.1)	99.61 (92.0-99.1)	99.68 (90.0-99.1)	99.68 (88.0-99.1)	99.68 (86.0-99.1)	99.68 (84.0-99.1)	99.68 (82.0-99.1)
Depletion & Malfunction Only	99.82 (97.0-99.1)	99.62 (94.0-99.1)	99.31 (92.0-99.1)	98.85 (90.0-99.1)	98.27 (88.0-99.1)	97.50 (86.0-99.1)	96.50 (84.0-99.1)	95.25 (82.0-99.1)
Malfunction Only	99.91 (97.0-99.1)	99.84 (94.0-99.1)	99.64 (92.0-99.1)	99.45 (90.0-99.1)	99.27 (88.0-99.1)	99.00 (86.0-99.1)	98.75 (84.0-99.1)	98.50 (82.0-99.1)

VENTAK PRIZM 2 VR Model 1860

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 25,000
 U.S. Approval Date: August 2000
 U.S. Estimated Active Implants: 17,000

U.S. Confirmed Malfunctions: 67
 Without Compromised Therapy: 28
 With Compromised Therapy: 39
 U.S. Average Device Age: 3.18 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	99.68 (97.0-99.1)	99.68 (94.0-99.1)	99.43 (92.0-99.1)	98.85 (90.0-99.1)	98.27 (88.0-99.1)	97.50 (86.0-99.1)	96.50 (84.0-99.1)	95.25 (82.0-99.1)
Depletion & Malfunction Only	99.82 (97.0-99.1)	99.84 (94.0-99.1)	99.77 (92.0-99.1)	99.65 (90.0-99.1)	99.63 (88.0-99.1)	99.63 (86.0-99.1)	99.63 (84.0-99.1)	99.63 (82.0-99.1)
Malfunction Only	99.92 (97.0-99.1)	99.84 (94.0-99.1)	99.77 (92.0-99.1)	99.65 (90.0-99.1)	99.63 (88.0-99.1)	99.63 (86.0-99.1)	99.63 (84.0-99.1)	99.63 (82.0-99.1)

*Devices subject to an advisory. Refer to the Safety Advisory section for more details.
 Survival probabilities for VENTAK PRIZM 2 DR and VENTAK PRIZM 2 VR (CDs) subject to the 23-Jun-08 advisory not provided because they do not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on this advisory.