Reported Device Return Rate and Reason for Out of Service

In accordance with HRS-draft recommended elements in manufacturer product performance reports, Boston Scientific provides the reason(s) for U.S. device explant or out of service if known, for all pulse generator products/product groupings for which U.S. survival probability data are reported. Table 1 also quantifies the number of Boston Scientific devices reported to have been explanted in the U.S., and the number and percentage of explanted devices then returned to Boston Scientific for various product types. The reasons for device explant or out of service consist of normal battery depletion, device upgrade, device malfunction (which includes devices under advisory that have experienced a malfunction), complication related to another system component or clinical conditions such as infection, or "other," a category consisting of patient death, prophylactic device explant, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown. It should be noted that the reason for a device explant or out of service may either be confirmed through laboratory analysis (as in the case of normal battery depletion) or it may be reported to Boston Scientific with no associated returned device or laboratory analysis. Additionally, there may be more than one reason listed for why a device was explanted/taken out of service.

Reported Device Return Rate

U. S. Implant Population (All-Time)

Product Type	Explanted devices reported to Boston Scientific CRM	Reported device return rate
CRT-Ds and CRT-Ps	8,436	5,578 (66%)
ICDs	75,634	49,765 (66%)
Pacemakers	59,235	37,719 (64%)
Total	143,305	93,062 (65%)

Table 1. Explanted device return rate to Boston Scientific CRM.

Reason for Out of Service

	Total U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or a clinical condition[2]	Other[3]
CRT-Ds/Model						
CONTAK RENEWAL 3 RF HE H217/H219	3,000	0	0	0	17	94
CONTAK RENEWAL 3 RF H210/H215	4,000	0	0	1	21	93
CONTAK RENEWAL 3 HE H177/H179	21,000	38	1	27	251	3,532
CONTAK RENEWAL 3 H170/H175	30,000	41	1	46	298	4,827
CONTAK RENEWAL H135	10,000	665	2	92	156	5,004
CRT-Ps/Model						
CONTAK RENEWALTR H120/H125	5,000	16	13	0	34	1,020

[1]Device malfunction consists of all U.S. confirmed malfunctions for a product/product grouping. These include confirmed malfunctions for advisory populations, as well as any other type of malfunction in which a device was returned and confirmed by laboratory analysis to have malfunctioned. U.S. confirmed malfunction counts are reflected in the U.S. Summary tables and in U.S. survival probability data.
[2]System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.
[3]Other consists of: patient death, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.
[4]Counts consist of Boston Scientific pacemaker and Intermedics co-branded pacemaker data.

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		REASON FOR OUT OF SERVICE				
ICDs/Model	Total U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or a clinical condition[2]	Other[3]
VITALITY 2 EL VR T177	3,000	0	3	3	13	132
VITALITY 2 EL DR T167	3,000	1	4	2	20	151
VITALITY 2 VR T175	9,000	1	11	19	49	609
VITALITY 2 DR T165	13,000	4	9	18	64	770
VITALITY DR HE T180	3,000	2	1	0	15	111
VITALITY AVT A155	12,000	10	17	47	100	1,914
VITALITY AVT A135	7,000	37	21	69	70	1,780
VITALITY DS DR T125	16,000	7	18	24	105	1,877
VITALITY DS VR T135	14,000	9	26	19	82	1,785
VITALITY EL T127	3,000	0	2	4	26	232
VENTAK PRIZM 2 DR 1861	43,000	843	148	160	495	19,286
VENTAK PRIZM 2 VR 1860	25,000	108	101	57	226	7,423
VENTAK PRIZM DR HE 1853/1858	10,000	1,711	23	78	136	3,040
VENTAK PRIZM VR HE 1852/1857	8,000	678	27	33	108	2,246
VENTAK PRIZM DR 1851/1856	13,000	4,479	44	260	168	5,698
VENTAK PRIZM VR 1850/1855	8,000	2,235	40	77	90	3,349

[1]Device malfunction consists of all U.S. confirmed malfunctions for a product/product grouping. These include confirmed malfunctions for advisory populations, as well as any other type of malfunction in which a device was returned and confirmed by laboratory analysis to have malfunctioned. U.S. confirmed malfunction counts are reflected in the U.S. Summary tables and in U.S. survival probability data.
[2]System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.
[3]Other consists of: patient death, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.
[4]Counts consist of Boston Scientific pacemaker and Intermedics co-branded pacemaker data.

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Pacemakers/Model	Total U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or a clinical condition[2]	Other[3]
INSIGNIA Ultra SR[†] 1190	10,000	1	7	0	29	1,204
INSIGNIA Ultra DR downsize[†] 1290	33,000	3	18	3	99	2,499
INSIGNIA Ultra DR[†] 1291	12,000	1	8	1	39	625
INSIGNIA Entra SR[†] 1195/1198	9,000	9	6	0	28	2,280
INSIGNIA Entra DR downsize[†] 1296	18,000	14	14	4	53	3,144
INSIGNIA Entra DR[†] 1294/1295	12,000	4	2	6	44	1,990
INSIGNIA Plus SR[†] 1194	23,000	32	38	6	77	6,942
INSIGNIA Plus DR[†] 1297	21,000	39	31	3	105	3,265
INSIGNIA Plus DR downsize[†] 1298	77,000	279	88	33	356	15,422
PULSAR MAX II SR downsize[†] 1180	7,000	49	14	1	25	3,149
PULSAR MAX II SR[†] 1181	1,000	4	4	0	5	511
PULSAR MAX II DR[†] 1280	29,000	261	66	13	152	8,489
DISCOVERY II SR downsize[†] 1184	13,000	110	15	2	53	6,408
DISCOVERY II SR[†] 1186/1187	3,000	17	7	1	15	1,458
DISCOVERY II DR downsize[†] 1283	33,000	2,636	55	17	178	13,336
DISCOVERY II DR[†] 1284/1286	23,000	264	30	8	120	7,542
PULSAR MAX SR downsize[†] 1170	11,000	580	28	6	46	6,188
PULSAR MAX SR 1171	2,000	30	16	6	11	1,344
PULSAR MAX DR[†] 1270	41,000	2,660	110	79	246	17,893

[1]Device malfunction consists of all U.S. confirmed malfunctions for a product/product grouping. These include confirmed malfunctions for advisory populations, as well as any other type of malfunction in which a device was returned and confirmed by laboratory analysis to have malfunctioned. U.S. confirmed malfunction counts are reflected in the U.S. Summary tables and in U.S. survival probability data.
[2]System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.
[3]Other consists of: patient death, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.
[†]Counts consist of Boston Scientific pacemaker and Intermedics co-branded pacemaker data.

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		REASON FOR OUT OF SERVICE				
	Total U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or a clinical condition[2]	Other[3]
DISCOVERY SR downsize[4] 1174	10,000	531	28	78	46	6,188
DISCOVERY SR[4] 1175	3,000	43	6	1	20	1,619
DISCOVERY DR downsize[4] 1273	23,000	6,065	40	147	119	13,167
DISCOVERY DR[4] 1274/1275	13,000	1,103	30	119	91	7,325
MERIDIAN DDD 0976	2,000	35	0	4	13	1,040
MERIDIAN SR 1176	9,000	200	15	18	38	5,594
MERIDIAN DR 1276	16,000	527	16	35	98	8,025

[1]Device malfunction consists of all U.S. confirmed malfunctions for a product/product grouping. These include confirmed malfunctions for advisory populations, as well as any other type of malfunction in which a device was returned and confirmed by laboratory analysis to have malfunctioned. U.S. confirmed malfunction counts are reflected in the U.S. Summary tables and in U.S. survival probability data.
[2]System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.
[3]Other consists of: patient death, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.
[4]Counts consist of Boston Scientific pacemaker and Intermedics co-branded pacemaker data.

U.S. Reports of Acute Lead Observations (Occurring Within First Month of Service)

Boston Scientific strives to provide meaningful product performance information reflective of real-world product experience. Only one-fifth of leads involved in a complication are returned for laboratory analysis. To provide more meaningful lead cumulative survival information, Boston Scientific's lead statistics include all reports of lead malfunctions, whether or not confirmed by laboratory analysis. A lead complication is said to have occurred if any of the following conditions have been met:

- Laboratory analysis of a returned lead determines that the lead was not compliant in form, fit or function at any time while implanted
- Any clinical observation related to a discrepancy with the mechanical integrity and/or impedance measurement of the lead, 30 days or more post-implant.

Lead complications as defined above are included in the lead cumulative survival graphs in previous sections.

Because acute lead performance contributes to overall clinical experience, Boston Scientific provides a summary of U.S. reports of lead observations occurring in the first month of service. Acute lead performance may be subject to a number of factors, including patient-specific clinical conditions and/or varying implant conditions/techniques. To be included in this summary of observations, a lead must first be successfully implanted. These reports may or may not have resulted in clinical action and/or product return to Boston Scientific. Multiple observations are possible for any given lead.

Pacing Leads/Model	Total U.S. Registered Implants	Impedance[1]	Physical Damage/ Mechanical Connection[2]	Dislodgement	Cardiac Perforation	Pacing Capture/ Threshold Issue	Muscle Stimulation	Sensing/ Detection[3]	Noisy Signal Observed	High DFT	Therapy Delivery/ Effectiveness[4]
FLEXTEND Active Fixation 4086/4087/4088	137,000	177	268	695	105	688	48	259	19	0	47
FINELINE II/FINELINE II Sterox[1] Passive Fixation (polyurethane) 4452/4453/4456/4457	90,000	25	39	137	4	162	6	39	6	0	8
FINELINE II EZ/FINELINE II Sterox EZ[1] Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471	174,000	116	121	213	16	227	22	104	11	1	30
FINELINE II/FINELINE II Sterox[1] Atrial J (polyurethane) 4477/4478/4479/4480	28,000	13	33	196	0	97	2	58	5	0	7
FINELINE II/FINELINE II Sterox[1] Passive Fixation (silicone) 4454/4455/4458/4459	10,000	5	12	14	1	16	1	8	2	0	1
FINELINE II EZ/FINELINE II Sterox EZ[1] Positive Fixation (silicone) 4466/4467/4468/4472/4473/4474	29,000	9	39	54	2	34	5	19	4	0	1

CRT Leads/Model	Total U.S. Registered Implants	Impedance[1]	Physical Damage/ Mechanical Connection[2]	Dislodgement	Vein Dissection	Pacing Capture/ Threshold Issue	Muscle Stimulation	Sensing/ Detection[3]	Noisy Signal Observed	High DFT	Therapy Delivery/ Effectiveness[4]
EASYTRAK 3 4548/4549/4550/4522/4524/4525/4527	7,000	9	3	68	2	40	49	6	1	0	1
EASYTRAK 2 4542/4543/4544/4515/4517/4518/4520	29,000	83	24	245	11	154	245	25	2	0	18
EASYTRAK 4537/4538/4510/4511/4512/4513	35,000	43	39	205	6	205	203	28	6	0	17

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U.S. REPORTS OF ACUTE LEAD OBSERVATIONS

	Total U.S. Registered Implants	Impedance[1]	Physical Damage/ Mechanical Connection[2]	Dislodgement	Cardiac Perforation	Pacing Capture/ Threshold Issue	Muscle Stimulation	Sensing/ Detection[3]	Noisy Signal Observed	High DFT	Therapy Delivery/ Effectiveness[4]
Defibrillation Leads/Model											
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0184/0185/0186/0187	52,000	59	82	114	19	110	12	83	54	20	61
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	5,000	19	0	11	1	21	0	6	4	1	4
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0180/0181/0182	2,000	4	5	1	2	3	1	1	1	2	1
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	70,000	78	94	81	18	102	11	121	77	22	67
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	30,000	60	6	55	3	79	2	48	30	7	34
ENDOTAK RELIANCE S Single Coil, Active Fixation 0137/0138	1,000	3	2	0	0	0	0	2	1	1	1
ENDOTAK RELIANCE S Single Coil, Passive Fixation 0127/0128	1,000	0	0	1	0	1	1	2	0	0	0
ENDOTAK ENDURANCE EZ Active Fixation 0154/0155/0156	29,000	21	36	53	2	44	5	177	11	8	54
ENDOTAK ENDURANCE Rx Passive Fixation Steroid Eluting 0144/0145/0146	18,000	21	1	32	0	21	1	30	2	2	18
ENDOTAK ENDURANCE Passive Fixation 0134/0135/0136	3,000	2	0	2	0	9	0	5	0	1	3
ENDOTAK DSP Passive Fixation 0094/0095/0125	36,000	11	18	36	0	26	4	79	1	21	30

[1]Impedance: Low impedance, high impedance, unspecified impedance issue, or shorted lead.
[2]Physical Damage/Mechanical Connection: Damage to electrode, terminal, conductor, insulation, or lead insertion difficulty.
[3]Sensing/Detection: Oversensing, undersensing, intermittent sensing, or non-detection.
[4]Therapy Delivery/Effectiveness: Tachy or brady therapy either not delivered when required, or delivered when not required; non-conversion; or configuration change required.
[5]Counts consist of Boston Scientific pacing lead and Intermedics pacing lead co-branded data.

Product Index

Contact Information

Guidant Europe S.A.
Park Lane
Culliganlaan 2B
1831 Diegem
Belgium
Tel: 32.2.714.14.11
Fax: 32.2.714.14.12

Argentina
Guidant Argentina
Cardiac Pacemakers, Inc.
Av. Pte. Roque Sáenz Peña 832 1st floor
1388 Buenos Aires
Tel: 54.11.4320.4500

Australia
Guidant Australia Pty Ltd.
Level 1, 4 Inglewood Place
Baulkham Hills NSW 2153
Australia
Tel: +61.2.9421.2800
Fax: +61.2.9421.2805

Austria
Guidant Austria GmbH
Vienna Twin Tower
Turm A / 19.0G
Wienerbergstraße 11
1100 Wien
Tel: +43.1.641.8800
Fax: +43.1.641.8800-10

Belgium
Guidant Belgium
Park Lane
Culliganlaan 2B
1831 Diegem
Tel: 32.2.714.16.11

Canada
Guidant Canada
505 Apple Creek Blvd. Unit 4
Markham, Ontario L3R 5B1
Canada
Tel: 905.947.5800
Fax: 905.947.5830

Czech Republic
Guidant International B.V. Czech
Zeleny Pruh 99
14002 Praha 4
Tel: 420.2.96374700

Denmark
Guidant Denmark A/S
Lygten 2 C, 4
DK-2400 Copenhagen NV
Tel: 45.35.87.00.10

France
Guidant France SA
9 Rue d'Estienne d'Orves
F-92504 Rueil Malmaison
Tel: 33.1.47.14.4014
www.guidant.fr

Germany
Guidant GmbH
Wingertshecke 6
D-35392 Giessen
Tel: +49.641.92221.0
Fax: +49.641.92221.606
www.guidant.de

Hong Kong
Guidant Hong Kong
Suite 2201
CRC Mess Mutual Tower
38 Gloucester Road
Wan Chai, Hong Kong
Tel: 852.2827.2338

Italy
Guidant Italia, S.r.l.
Via Cassanese, 224
Palazzo Raffaello
I-20090 Segrate (MI)
Tel: 39.02.269831
www.guidant.it

Japan
Guidant Japan KK
Shinagawa East One Tower 10F
2-16-1, Konan, Minato-ku
Tokyo 108-0075
Japan
Tel: +81.3.6717.0100
Fax: +81.3.6717.0151/0251

The Netherlands
Guidant Nederland B.V.
Kulfmees 56
NL-3435 RG Nieuwegein
Tel: 31.30.602.55.55

New Zealand
Guidant New Zealand
103 Carlton Gore Road, Ground Floor
Newmarket
Auckland
Tel: 64.9.522.9900

Singapore
Guidant Singapore Pte Ltd.
152 Beach Road
#21-07/08 Gateway East
Singapore 189721
Tel: 65.392.0032

Portugal
Guidant Aparelhos Medicos Lda
Avª do Forte, nº 3
Edificio Suécia III, Piso -1
2795 - 504 Carnaxide
Portugal
Tel: +351.21.416.47.20

Spain
Guidant, SA
Crta. Fuencarral
Alcobendas, Km. 15,700
Edf. Europa, nº 1, 3ª planta
E-28108 Alcobendas, Madrid
Tel: 34.91.657.25.45

Sweden
Guidant Sweden AB
Sjöängsvägen 11
S-192 72 Sollentuna
Tel: 46.0.8.594.765.50

Switzerland
Guidant AG
Bundesplatz 1
CH-6300 Zug
Tel: +41.41.728.77.88
Fax: +41.41.287780

United Kingdom
Guidant Ltd.
Hampshire International
Business Park
Crockford Lane
Chineham, Basingstoke
Hampshire UK-RG24 8WH
Tel: 44.1256.374.000

United States
Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA
Tel: 651.582.4000
Fax: 651.582.4166
Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

For more information, visit our website at **www.guidant.com**