

U.S. Reason for Out of Service

As requested by the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines, Boston Scientific provides reasons for device explant or out of service, if known. The reasons consist of normal battery depletion, unconfirmed premature battery depletion, device upgrade, device malfunction (which includes devices under advisory that have experienced a malfunction), complication related to another system component or clinical condition (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.

The counts for normal battery depletion, unconfirmed premature battery depletion, and device malfunction are reflected in the U.S. survival probability data. Reason for device explant or out of service may either be confirmed through laboratory analysis (as in the case of device malfunction) or it may be reported to Boston Scientific with no associated device return or laboratory analysis. Although a device may be indicated by the health care provider to have been taken out of service for more than one reason, the table below indicates only one reason per device in category counts.

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
COGNIS N118/N119/N120/P106/P107/P108	66,000	32	9	2	93	861	9,307
LIVIAN HE H227/H229/H247/H249	6,000	36	3	2	4	140	1,463
LIVIAN H220/H225/H240/H245	5,000	30	0	2	4	88	1,213
CONTAK RENEWAL 3 RF HE H217/H219	18,000	1,878	25	12	125	526	7,491
CONTAK RENEWAL 3 RF H210/H215	21,000	1,385	21	10	152	493	8,518
CONTAK RENEWAL 3 HE H177/H179	24,000	7,322	91	18	853	596	11,869
CONTAK RENEWAL 3 H170/H175	34,000	10,209	72	29	952	755	17,369

CRT-P/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
CONTAK RENEWAL TR H120/H125	17,000	642	10	114	33	180	6,059

ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
TELIGEN VR E102/E103/F102/F103	33,000	18	0	198	46	349	3,312
TELIGEN DR E110/E111/F110/F111	60,000	28	1	313	60	627	6,364
CONFIENT DR E030/F030	7,000	10	2	79	1	111	1,479
VITALITY 2 EL VR T177	7,000	196	7	135	514	95	1,814
VITALITY 2 EL DR T167	8,000	339	11	133	506	113	2,263
VITALITY 2 VR T175	21,000	1,549	33	352	1,113	268	7,054
VITALITY 2 DR T165	31,000	4,427	74	491	1,087	405	10,499
VITALITY DR HE T180	13,000	293	9	212	276	264	4,746
VITALITY AVT A155	12,000	4,553	47	138	597	185	5,433
VITALITY AVT A135	7,000	2,378	57	69	659	106	3,422
VITALITY DS DR T125	22,000	5,646	67	351	1,149	278	8,896

ICD/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
VITALITY DS VR T135	19,000	3,210	39	304	1,482	236	7,628
VITALITY EL T127	4,000	387	8	50	560	67	1,282
VENTAK PRIZM 2 DR 1861	43,000	11,264	26	409	281	680	27,099
VENTAK PRIZM 2 VR 1860	26,000	6,427	13	381	135	359	14,215
VENTAK PRIZM DR HE 1853/1858	10,000	3,842	94	51	459	196	4,445
VENTAK PRIZM VR HE 1852/1857	9,000	3,372	25	90	338	198	4,206
VENTAK PRIZM DR 1851/1856	13,000	5,038	57	54	279	205	6,481
VENTAK PRIZM VR 1850/1855	8,000	3,087	14	45	105	111	4,050

Pacemaker/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
ALTRUA 60 SR S601	25,000	12	0	117	1	91	4,707
ALTRUA 60 DR downsize S603	73,000	41	7	258	7	340	9,140
ALTRUA 60 DR S602	20,000	8	2	93	3	124	2,813

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
ALTRUA 60 DR EL S606	42,000	6	0	102	5	166	2,592
ALTRUA 40 SR S401	4,000	1	1	13	0	11	803
ALTRUA 40 DR downsize S403	12,000	10	0	18	2	49	1,465
ALTRUA 40 DR S402	2,000	1	0	12	0	6	318
ALTRUA 40 DR EL S404	4,000	0	0	11	0	20	365
ALTRUA 20 SR S201/S204	4,000	3	0	10	0	21	867
ALTRUA 20 DR downsize S203	4,000	3	1	12	0	24	745
ALTRUA 20 DR S202/S205	2,000	1	0	3	0	5	348
ALTRUA 20 DR EL S208	2,000	1	0	6	1	4	267
INSIGNIA Ultra SR [†] 1190	24,000	245	6	187	20	133	12,447
INSIGNIA Ultra DR downsize [†] 1290	76,000	3,577	83	478	260	530	28,309
INSIGNIA Ultra DR [†] 1291	32,000	278	11	254	40	256	10,098
INSIGNIA Entra SR [†] 1195/1198	14,000	147	9	74	6	70	8,659
INSIGNIA Entra DR downsize [†] 1296	24,000	1,754	24	121	74	135	12,544

Pacemaker/Model (cont.)

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
INSIGNIA Entra DR [†] 1294/1295	17,000	308	8	101	29	157	8,020
INSIGNIA Plus SR [†] 1194	27,000	1,106	7	215	20	153	17,869
INSIGNIA Plus DR downsize [†] 1298	90,000	15,732	109	515	325	674	44,890
INSIGNIA Plus DR [†] 1297	27,000	845	11	221	75	231	11,514
PULSAR MAX II SR downsize [†] 1180	7,000	1,448	8	34	4	31	5,102
PULSAR MAX II DR [†] 1280	29,000	8,222	18	171	170	212	16,383
DISCOVERY II SR downsize [†] 1184	13,000	1,786	6	34	5	70	9,963
DISCOVERY II SR [†] 1186/1187	3,000	197	1	19	2	22	2,440
DISCOVERY II DR downsize [†] 1283	33,000	9,535	54	94	28	228	20,324
DISCOVERY II DR [†] 1284/1286	23,000	4,894	9	121	18	166	14,149
PULSAR MAX SR downsize [†] 1170	11,000	1,894	5	35	8	53	7,984
PULSAR MAX DR [†] 1270	41,000	11,181	54	182	217	306	25,462
DISCOVERY SR downsize [†] 1174	10,000	1,063	9	34	91	59	7,988

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
DISCOVERY DR downsize [†] 1273	23,000	6,333	72	39	155	137	14,940
DISCOVERY DR [†] 1274/1275	13,000	2,512	20	39	142	115	8,912
MERIDIAN SR 1176	9,000	950	16	20	20	44	7,359
MERIDIAN DR 1276	16,000	2,591	17	37	41	121	11,643

¹Device 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 U.S. survival probability information.

²System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.

³Other consists of: patient death, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.

[†]Counts consist of Boston Scientific and Intermedics co-branded pacemaker data.