

Before/During Implant Procedure – Worldwide Malfunctions: Pulse Generators

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling (e.g. radiation) is not reported as device malfunction here.

The majority of before/during implant pulse generator confirmed malfunctions in the Mechanical category are issues occurring within the connector block (e.g. stuck setscrews, seal plug/ring issues). The Electrical category is comprised of confirmed malfunctions involving electrical components such as batteries and capacitors, and also includes fault codes encountered at implant. The Software category consists primarily of confirmed malfunctions that result in telemetry issues. Confirmed malfunctions in the Labeling and Packaging categories include product labeling/identification issues and damage to sterile packaging, respectively. The Other category is comprised of non-patterned confirmed malfunctions.


CRT-D/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
COGNIS N118/N119/N120/P106/P107/P108	86,000	19	49	2	22	0	0
LIVIAN HE H227/H229/H247/H249	6,000	2	1	0	2	0	0
LIVIAN H220/H225/H240/H245	6,000	0	1	0	2	0	0
CONTAK RENEWAL 4 RF HE H239	1,000	14	0	0	0	0	0
CONTAK RENEWAL 4 RF H230/H235	8,000	45	2	0	1	0	0
CONTAK RENEWAL 4 HE H197/H199	7,000	7	7	0	0	0	0
CONTAK RENEWAL 4 H190/H195	17,000	1	13	1	2	0	0
CONTAK RENEWAL 4 AVT HE M177/M179	1,000	0	2	0	1	0	0
CONTAK RENEWAL 4 AVT M170/M175	2,000	1	0	0	1	0	0
CONTAK RENEWAL 3 RF HE H217/H219	18,000	368	4	5	5	0	0



Before/During
Implant Procedure

CRT-D/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
CONTAK RENEWAL 3 RF H210/H215	21,000	492	9	1	7	0	0
CONTAK RENEWAL 3 HE H177/H179	23,000	60	45	0	9	0	0
CONTAK RENEWAL 3 H170/H175	34,000	46	67	0	15	0	0
CONTAK RENEWAL 2 H155	6,000	1	6	0	5	0	0
CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
CONTAK RENEWAL TR 2 H140/H145	26,000	1	8	0	1	0	0
CONTAK RENEWAL TR H120/H125	17,000	0	11	0	3	0	0
ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
TELIGEN VR E102/E103/F102/F103	50,000	2	33	2	19	0	0
TELIGEN DR E110/E111/F110/F111	75,000	4	42	1	23	0	0
CONFIENT DR E030/F030	8,000	1	3	0	0	0	0
VITALITY 2 EL VR T177	16,000	3	5	0	3	0	0
VITALITY 2 EL DR T167	14,000	5	8	0	2	0	0
VITALITY 2 VR T175	37,000	13	13	0	9	0	0
VITALITY 2 DR T165	42,000	16	20	2	25	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ALTRUA 60 SR S601	44,000	1	6	0	1	0	0
ALTRUA 60 DR EL S606	53,000	0	8	0	1	0	0
ALTRUA 60 DR downsize S603	95,000	0	23	0	1	0	0
ALTRUA 60 DR S602	43,000	1	11	0	2	0	0
ALTRUA 50 SR S501	13,000	0	1	0	0	0	0
ALTRUA 50 DR downsize S502	22,000	0	2	0	0	0	0
ALTRUA 50 DDD downsize S503	5,000	1	1	0	0	0	0
ALTRUA 50 VDD downsize S504	4,000	0	0	0	0	0	0
ALTRUA 50 SSI S508	2,000	0	0	0	0	0	0
ALTRUA 40 SR S401	6,000	0	2	0	0	0	0
ALTRUA 40 DR EL S404	6,000	0	0	0	0	0	0
ALTRUA 40 DR downsize S403	15,000	0	4	0	1	0	0
ALTRUA 40 DR S402	3,000	1	3	0	0	0	0
ALTRUA 20 SR S201/S204	15,000	0	2	0	0	0	0
ALTRUA 20 DR EL S208	5,000	0	0	0	0	0	0
ALTRUA 20 DR downsize S203	11,000	0	1	0	0	0	0



 Before/During
 Implant Procedure

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ALTRUA 20 DR S202/S205	3,000	1	0	0	1	0	0
ALTRUA 20 DDD S207	1,000	0	0	0	0	0	0
ALTRUA 20 SSI S206	3,000	0	0	0	0	0	0
INSIGNIA Ultra SR [†] 1190	48,000	3	3	1	4	0	0
INSIGNIA Ultra DR downsize [†] 1290	124,000	3	3	1	6	0	0
INSIGNIA Ultra DR [†] 1291	51,000	1	8	1	4	0	0
INSIGNIA Entra SR [†] 1195/1198	51,000	1	0	3	5	0	0
INSIGNIA Entra DR downsize [†] 1296	47,000	1	7	6	3	0	0
INSIGNIA Entra DR [†] 1294/1295	35,000	0	6	4	9	0	0
INSIGNIA Plus SR [†] 1194	51,000	1	5	13	5	0	0
INSIGNIA Plus DR downsize [†] 1298	140,000	3	16	30	7	0	1
INSIGNIA Plus DR [†] 1297	47,000	0	7	8	7	0	1
INSIGNIA AVT [†] 0482/0882/0982/1192/1292	51,000	1	1	0	3	0	0

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