

VENTAK PRIZM DR HE
Models 1853/1858

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	7	5	12
*Capacitor	4	1	5
*Relay	2	1	3
*Device tones	1	0	1
*Integrated circuit	0	0	0
*Early ERI declaration	2	0	2
*Oscillator circuit	1	0	1
*Feedthrough filter capacitor	0	0	0
Mechanical	0	0	0
*Seal plug	0	0	0
Software	0	0	0
Other	1	7	8
*Power on Reset	1	0	1
*Battery depletion	0	0	0
*Battery voltage at Implant	0	0	0
*Induced shock	0	0	0
*Non-patterned	0	0	0
WW Confirmed Malfunctions	8	16	24

VENTAK PRIZM VR HE
Models 1852/1857

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	25	9	34
*Capacitor	1	1	2
*Integrated circuit	23	2	25
*Early ERI declaration	0	0	0
Mechanical	1	6	7
*Seal plug	1	0	1
*Hybrid circuit	0	6	6
Software	1	0	1
*Safety mode (Advisory issued)	1	0	1
Other	9	10	19
*Power on Reset	0	1	1
*Battery depletion	0	0	0
*Battery voltage at Implant	0	0	0
*Induced shock	0	0	0
*energy delivery	0	0	0
*Non-patterned	0	0	0
WW Confirmed Malfunctions	36	18	54

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CONFIRMED MALFUNCTION DETAILS: PULSE GENERATORS - ICDs

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VENTAK PRIZM DR
Models 1857/1858

Worldwide Distribution: 15,000
Worldwide Confirmed Malfunctions: 385

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	238	8	246
*Capacitor	4	1	5
*Resistor	1	1	2
*Device tones	4	-	4
*Integrated circuit	6	1	7
*AD module	2	2	4
*Battery depletion	1	1	2
*Early EM degradation	22	1	23
*Oscillator circuit	1	1	2
Mechanical	1	10	11
*Hybrid circuit	1	10	11
Software	52	4	56
*Safety mode (Advisory/lesued)	33	2	35
*Reset during charge	19	2	21
Other	61	11	72
*Power on Reset	4	-	4
*Battery depletion	43	2	45
*Non-patterned	14	8	22
WW Confirmed Malfunctions	362	33	395

VENTAK PRIZM VR
Models 1850/1855

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 145

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	54	8	62
*Capacitor	4	1	5
*Integrated circuit	1	1	2
*Device tones	3	-	3
*Integrated circuit	3	1	4
*AD module	1	1	2
*Early EM degradation	42	1	43
Mechanical	4	1	5
*Hybrid circuit	4	1	5
Software	37	3	40
*Safety mode (Advisory/lesued)	3	2	5
*Reset during charge	3	1	4
Other	28	10	38
*Power on Reset	4	1	5
*Battery depletion	7	6	13
*Induced shock energy delivery	1	-	1
*Non-patterned	16	4	20
WW Confirmed Malfunctions	123	22	145

Pacemakers

INSIGNIA Ultra SR
Model 1190

Worldwide Distribution: 21,000
Worldwide Confirmed Malfunctions: 0

	With Compensated Therapy	Total
Electrical	0	0
Mechanical	0	0
Software	0	0
Other	0	0
WW Confirmed Malfunctions	0	0

INSIGNIA Ultra DR (downsize)
Model 1290

Worldwide Distribution: 2,000
Worldwide Confirmed Malfunctions: 0

	With Compensated Therapy	Total
Electrical	0	0
Mechanical	0	0
Timing or Wires Failure Mode (Advisory/Asystol)	0	0
Circuit connections	0	0
Software	0	0
Underestimation of battery status	0	0
Pace fault detection	0	0
Pacing rate limit	0	0
Other	0	0
Non-pattern	0	0
WW Confirmed Malfunctions	0	0

INSIGNIA Ultra DR
Model 1291

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 0

	With Compensated Therapy	Total
Electrical	0	0
Capacitor	0	0
Mechanical	0	0
Software	0	0
Other	0	0
WW Confirmed Malfunctions	0	0

CONFIRMED MALFUNCTION DETAILS: PULSE GENERATORS - PACEMAKERS

INSIGNIA Entra SR
Models 1195/1198

Worldwide Distribution: 29,000
Worldwide Confirmed Malfunctions: 2

Category	With Compromised Therapy	Without Compromised Therapy
Electrical	0	0
Mechanical	1	1
Timing crystal failure Mode 2 (Advisory/Assured)	1	0
Software	0	0
Other	0	0
WW Confirmed Malfunctions	1	1

INSIGNIA Entra DR (downsize)
Model 1296

Worldwide Distribution: 60,000
Worldwide Confirmed Malfunctions: 5

Category	With Compromised Therapy	Without Compromised Therapy
Electrical	2	2
Mechanical	1	1
Timing crystal Failure Mode 2 (Advisory/Assured)	1	0
Software	0	0
Other	0	0
WW Confirmed Malfunctions	4	1

INSIGNIA Entra DR
Models 1294/1295

Worldwide Distribution: 2,100
Worldwide Confirmed Malfunctions: 9

Category	With Compromised Therapy	Without Compromised Therapy
Electrical	2	2
Mechanical	1	1
Timing crystal Failure Mode 2 (Advisory/Assured)	5	0
Software	1	0
Other	0	0
WW Confirmed Malfunctions	9	0

INSIGNIA Plus SR
Model 1194

Worldwide Distribution: 36,000
Worldwide Confirmed Malfunctions: 6

Category	Without Compensated Therapy	With Compensated Therapy
Electrical	0	1
Mechanical	1	4
Timing system Failure Mode (Atrial/AV/VP/SA/Sp) (Capacitor array)	0	0
Software	1	1
Pacing rate limit	0	0
Other	1	1
Battery depletion	1	1
WW Confirmed Malfunctions	2	6

INSIGNIA Plus DR
Model 1297

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 1

Category	Without Compensated Therapy	With Compensated Therapy
Electrical	0	0
Mechanical	0	0
Timing system Failure Mode (Atrial/AV/VP/SA/Sp) (Capacitor array)	0	0
Software	0	0
Interrupted therapy	0	0
Other	0	1
Non-patterned	0	0
WW Confirmed Malfunctions	0	1

INSIGNIA Plus DR (downsize)
Model 1298

Worldwide Distribution: 10,100
Worldwide Confirmed Malfunctions: 1

Category	Without Compensated Therapy	With Compensated Therapy
Electrical	0	0
Mechanical	0	0
Timing system Failure Mode (Atrial/AV/VP/SA/Sp) (Capacitor array)	0	0
Software	0	0
Interrupted therapy	0	0
Other	0	0
Memory error	0	0
WW Confirmed Malfunctions	0	0