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CONFIRMED MALFUNCTION DETAILS: PULSE GENERATORS - PACEMAKERS

PULSAR MAX II SR (downsize) Model 1180		Worldwide Distribution: 12,000	Worldwide Confirmed Malfunctions: 2
Electrical	With Compromised Therapy	0	0
Mechanical Component		0	0
Software		0	0
Other		0	0
Battery depletion Non-batteried		0	0
WW Confirmed Malfunctions		0	0

PULSAR MAX II SR Model 7181		Worldwide Distribution: 8,000	Worldwide Confirmed Malfunctions: 1
Electrical	With Compromised Therapy	0	0
Mechanical Component		0	0
Permiss leading component Original Population (Advisory Issue)		0	0
Software		0	0
Other		0	0
WW Confirmed Malfunctions		0	0

PULSAR MAX II DR Model 1280		Worldwide Distribution: 6,000	Worldwide Confirmed Malfunctions: 2
Electrical	With Compromised Therapy	2	2
Mechanical		0	0
Permiss leading component Original Population (Advisory Issue)		0	0
Software		0	0
Other		0	0
Battery depletion Non-batteried		0	0
WW Confirmed Malfunctions		2	2

DISCOVERY II SR (downsize)
Model 1184



Worldwide Distribution: 27,000
Worldwide Confirmed Malfunctions: 2

	With Synchronous Therapy	Other
Electrical	0	0
Mechanical	1	1
Seal plug	1	0
Software	0	0
Other	1	1
Battery depletion	1	1
WW Confirmed Malfunctions	3	3

DISCOVERY II SR
Models 1186/1187



Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 0

	With Synchronous Therapy	Other
Electrical	0	0
Mechanical	0	0
Software	0	0
Other	0	0
Battery depletion	0	0
WW Confirmed Malfunctions	0	0

DISCOVERY II DR (downsize)
Model 1283



Worldwide Distribution: 1,100
Worldwide Confirmed Malfunctions: 3

	With Synchronous Therapy	Other
Electrical	0	0
Mechanical	0	0
Terminals Missing Component Original Regulation Adjustment	0	0
18941 Plug	1	1
Internal solder connection resistor value elementary capacitor	1	1
Software	0	0
Low conductivity of battery static (battery test)	0	0
MEMORY FAILURE	0	0
Other	0	0
Battery depletion	0	0
Unplugged	0	0
Nonperforming	0	0
WW Confirmed Malfunctions	2	2

CONFIRMED MALFUNCTION DETAILS: PULSE GENERATORS - PACEMAKERS

DISCOVERY II DR Models 1284/1286		Worldwide Distribution: 36,000 Worldwide Confirmed Malfunctions: 15		Which Component Failed?	
Electrical		0	0	0	0
Mechanical		2	0	2	0
High voltage testing component (Original Population (Assembly/Issue)		0	0	0	0
Internal device connection through wires in lead or other nodes		1	0	1	0
Software		1	0	1	0
Memory error		0	0	0	0
Other		1	0	1	0
Battery depletion		0	0	0	0
Non-patented		0	0	0	0
WW Confirmed Malfunctions		15	0	15	0

PULSAR MAX SR (downsize) Model 1170		Worldwide Distribution: 18,000 Worldwide Confirmed Malfunctions: 10		Which Component Failed?	
Electrical		1	1	1	1
Mechanical		1	1	1	1
High voltage testing component (Original Population (Assembly/Issue)		0	0	0	0
Software		1	1	1	1
Memory location		0	0	0	0
Other		0	0	0	0
Battery depletion		0	0	0	0
Non-patented		0	0	0	0
WW Confirmed Malfunctions		10	0	10	0

PULSAR MAX SR Model 1171		Worldwide Distribution: 10,000 Worldwide Confirmed Malfunctions: 5		Which Component Failed?	
Electrical		1	1	1	1
Mechanical		0	0	0	0
High voltage testing component (Original Population (Assembly/Issue)		0	0	0	0
Software		0	0	0	0
Memory location		0	0	0	0
Other		0	0	0	0
Battery depletion		0	0	0	0
WW Confirmed Malfunctions		5	0	5	0

DISCOVERY SR
Model 1175

Worldwide Distribution: 100
Worldwide Confirmed Malfunctions: 1

Category	With Component Theory	With Component Theory
Electrical	1	1
High current drain (Advisory issued)	1	1
Mechanical	0	0
Hermetic sealing component (Original Population / Advisory issued)	0	0
Hermetic sealing component (Second Population / Advisory issued)	0	0
Solder	0	0
Other	0	0
WW Confirmed Malfunctions	1	1

DISCOVERY SR (downsize)
Model 1174

Worldwide Distribution: 100
Worldwide Confirmed Malfunctions: 6

Category	With Component Theory	With Component Theory
Electrical	4	6
High current drain (Advisory issued)	1	1
High current drain	1	1
Mechanical	0	0
Hermetic sealing component (Original Population / Advisory issued)	0	0
Hermetic sealing component (Second Population / Advisory issued)	0	0
Solder	0	0
Memory depletion	0	0
Memory location	0	0
Other	0	0
Battery depletion (Not confirmed)	0	0
WW Confirmed Malfunctions	6	6

PULSAR MAX DR
Model 1270

Worldwide Distribution: 2000
Worldwide Confirmed Malfunctions: 109

Category	With Component Theory	With Component Theory
Electrical	9	13
High current drain (Advisory issued)	1	1
Capacitor	1	1
Integrated circuit	1	1
High current drain	3	3
Mechanical	51	57
Hermetic sealing component (Original Population / Advisory issued)	10	10
Hermetic sealing component (Second Population / Advisory issued)	2	2
Solder	0	0
Internal device connection	0	0
Lead through wires	0	0
Telemetry or A/T noise	0	0
Solder bond	0	0
Software	0	0
Overstimulation of battery status (Advisory issued)	0	0
Memory depletion	0	0
Memory location	0	0
Memory error	0	0
Diagnostic data error	0	0
Other	16	18
Battery depletion	0	0
Magnetoresistive Non-volatile	0	0
WW Confirmed Malfunctions	76	109

CONFIRMED MALFUNCTION DETAILS: PULSE GENERATORS - PACEMAKERS

DISCOVERY DR (downsize)
Model 1273

Worldwide Distribution: 25,000
Worldwide Confirmed Malfunctions: 157

Category	Which Component Theories	With Compromised Theory	Total
Electrical		47	124
High current drain (Advisory Issued)	31		
High current drain	16		
Mechanical		13	20
Harmful sealing component (Original Population Advisory Issued)	8		
Feedthrough wires	1		
Electromy or atrial holes	1		
Electromy coil	2		
Solder bond	1		
Software		4	4
Overdriftion of battery status (Advisory Issued)	3		
Memory address	1		
Memory allocation	0		
Diagnostic data error	1		
Other		2	9
Battery depletion (Non-patterned)	2		
WW Confirmed Malfunctions		85	157

DISCOVERY DR
Models 1274/1275

Worldwide Distribution: 23,000
Worldwide Confirmed Malfunctions: 185

Category	Which Component Theories	With Compromised Theory	Total
Electrical		66	128
High current drain (Advisory Issued)	64		
Capacitor	1		
Mechanical		10	40
High current drain	10		
Harmful sealing component (Original Population Advisory Issued)	9		
Sealing	1		
Electromy or atrial holes	1		
Electromy coil	4		
Battery well	1		
Solder bond	1		
Software		2	3
Memory location	2		
Other		5	10
Battery depletion (Non-patterned)	5		
WW Confirmed Malfunctions		80	185

MERIDIAN DDD
Model 0976

Worldwide Distribution: 19,000
Worldwide Confirmed Malfunctions: 46

Category	Which Component Theories	With Compromised Theory	Total
Electrical		19	36
High current drain (Advisory Issued)	17		
High current drain	2		
Mechanical		7	17
Harmful sealing component (Original Population Advisory Issued)	6		
Original Population Advisory Issued	3		
Electromy coil	2		
Solder bond	1		
Software		5	7
Memory address	5		
Diagnostic data error	0		
Other		1	3
Battery depletion (Non-patterned)	1		
WW Confirmed Malfunctions		26	46

MERIDIAN SR
Model 1176

Worldwide Distribution: 19,000
Worldwide Confirmed Malfunctions: 48

	Without Component Theory	With Component Theory	Total
Electrical	7	14	21
High current drain (Advicor/Isacor)	1	7	8
High current drain	6	7	13
Mechanical	2	4	6
High rate sealing component Original Population (Advicor/Isacor)	3	3	6
Feedthrough wire	1	1	2
Telemetry or atrial noise	1	1	2
Telemetry coil	1	1	2
Software	2	2	4
Memory error	1	1	2
Other	1	3	4
Battery depletion Non-patterned	1	3	4
WW Confirmed Malfunctions	27	21	48

MERIDIAN DR
Model 1276

Worldwide Distribution: 27,000
Worldwide Confirmed Malfunctions: 58

	Without Component Theory	With Component Theory	Total
Electrical	18	18	36
High current drain (Advicor/Isacor)	6	16	22
Integrated circuit	1	1	2
High current drain	1	1	2
Mechanical	6	6	12
High rate sealing component Original Population (Advicor/Isacor)	6	6	12
Telemetry or atrial noise	1	1	2
Telemetry coil	1	1	2
Battery weld	1	1	2
Solder joint	1	1	2
Software	1	1	2
Memory error	1	1	2
Other	3	3	6
Battery depletion Non-patterned	1	1	2
WW Confirmed Malfunctions	28	30	58