

# CRT-Ds

**CONTAK RENEWAL 3 RF HE**  
Models H217/H219

Worldwide Distribution's,000  
Worldwide Confirmed Malfunctions

Electrical	0	0	0	0
Mechanical	0	0	0	0
Software	0	0	0	0
Other	0	0	0	0
WWW.ConfirmMalfunctions				

WWW.ConfirmMalfunctions

**CONTAK RENEWAL 3 RF**  
Models H210/H215

Worldwide Distribution's,000  
Worldwide Confirmed Malfunctions

Electrical	0	0	0	0
Mechanical	0	0	0	0
Software	0	0	0	0
Other	0	0	0	0
WWW.ConfirmMalfunctions				

WWW.ConfirmMalfunctions

**CONTAK RENEWAL 3 HE**  
Models H177/H179

Worldwide Distribution's,000  
Worldwide Confirmed Malfunctions

Electrical	0	0	0	0
Mechanical	0	0	0	0
Software	0	0	0	0
Other	0	0	0	0
WWW.ConfirmMalfunctions				

WWW.ConfirmMalfunctions

41 Boston Scientific, CRM 2006 Product Performance Report published September 7, 2006  
 CONFIRMED MALFUNCTION DETAILS: PULSE GENERATORS - CRT-Ds/CRT-P



# ICDs

## VITALITY 2 ELVR Model IT177

Worldwide Distribution: 8,000  
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	0	0	0
Mechanical	1	1	2
Seal plug	1	0	1
Software	0	0	0
Other	1	1	2
Non-patterned	1	1	2
WW Confirmed Malfunctions	2	1	3

## VITALITY 2 EL DR Model IT167

Worldwide Distribution: 6,000  
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	0	0	0
Mechanical	2	2	4
Seal plug	2	0	2
Software	1	1	2
Other	1	1	2
Battery voltage at Implant	1	0	1
Non-patterned	1	1	2
WW Confirmed Malfunctions	3	1	4

## VITALITY 2 VR Model IT175

Worldwide Distribution: 19,000  
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	6	1	7
Low voltage capacitor (Aluminum / Leaky)	1	0	1
Capacitor	1	0	1
High current drain	1	0	1
Mechanical	1	1	2
Seal plug	1	0	1
Software	1	0	1
Other	1	0	1
Non-patterned	1	0	1
WW Confirmed Malfunctions	8	1	9

CONFIRMED MALFUNCTION DETAILS: PULSE GENERATORS - ICDs

**VITALITY 2 DR**  
Model 1165

Worldwide Distribution: 17,000  
Worldwide Confirmed Malfunctions: 20

Category	With Compromised Therapy	Total
Electrical	14	17
Low-voltage capacitor (Advisory issued)	13	1
High current drain	1	2
Mechanical	1	1
Seal plug	1	1
Seal plug	0	0
Software	0	0
Other	1	1
Non-patterned	1	1
<b>WW Confirmed Malfunctions</b>	<b>18</b>	<b>20</b>

**VITALITY DR HE**  
Model 1180

Worldwide Distribution: 4900  
Worldwide Confirmed Malfunctions: 0

Category	With Compromised Therapy	Total
Electrical	0	0
Mechanical	0	0
Software	0	0
Other	0	0
<b>WW Confirmed Malfunctions</b>	<b>0</b>	<b>0</b>

**VITALITY AVT**  
Model A155

Worldwide Distribution: 19,000  
Worldwide Confirmed Malfunctions: 48

Category	With Compromised Therapy	Total
Electrical	7	13
Low-voltage capacitor (Advisory issued)	6	1
Capacitor	0	3
High current drain	0	3
Mechanical	0	1
Seal plug	0	1
Transformer	0	1
Software	0	21
Memory latching (Advisory issued)	0	21
Other	0	3
Battery depletion	0	1
Early replacement indicator	0	1
Non-patterned	0	1
<b>WW Confirmed Malfunctions</b>	<b>17</b>	<b>48</b>

**VITALITY AVT**  
Model A135

Worldwide Distribution: 8,000  
Worldwide Confirmed Malfunctions: 76

	Without Compromised Therapy	With Compromised Therapy	Total
<b>Electrical</b>	3	2	5
*Capacitor	2	2	2
*High current drain	1	0	1
<b>Mechanical</b>	1	2	3
*Seal plug	1	2	2
*Seal plug	0	0	0
<b>Software</b>	13	13	13
*Memory bleaching (Advisory issued)	13	0	13
<b>Other</b>	51	3	54
*Early replacement indicator	46	0	46
*Non-patterned	5	3	8
<b>WW Confirmed Malfunctions</b>	88	20	78

**VITALITY DS DR**  
Model T125

Worldwide Distribution: 16,000  
Worldwide Confirmed Malfunctions: 24

	Without Compromised Therapy	With Compromised Therapy	Total
<b>Electrical</b>	9	3	12
*Low voltage capacitor (Advisory issued)	9	0	9
*High current drain	0	3	3
<b>Mechanical</b>	3	3	6
*Seal plug	3	2	5
*Transformer	0	1	1
<b>Software</b>	2	0	2
<b>Other</b>	4	3	7
*Scanning	3	1	4
*Early replacement indicator	1	0	1
*Non-patterned	1	2	3
<b>WW Confirmed Malfunctions</b>	15	9	24

**VITALITY DS VR**  
Model T135

Worldwide Distribution: 14,000  
Worldwide Confirmed Malfunctions: 19

	Without Compromised Therapy	With Compromised Therapy	Total
<b>Electrical</b>	7	2	9
*Low voltage capacitor (Advisory issued)	5	2	7
*Capacitor	2	0	2
<b>Mechanical</b>	0	2	2
*Seal plug	0	2	2
*Seal plug	0	0	0
<b>Software</b>	1	1	2
<b>Other</b>	1	2	3
*Scanning	1	0	1
*Early replacement indicator	0	2	2
*Non-patterned	0	0	0
<b>WW Confirmed Malfunctions</b>	13	6	19

CONFIRMED MALFUNCTION DETAILS: PULSE GENERATORS - ICDs

**VITALITY EL**  
Model 1127

Worldwide Distribution: 3,000  
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
<b>Electrical</b>			0
<b>Mechanical</b>	2	1	3
#Screw	1	-	1
#Seal plug	1	1	2
<b>Software</b>			0
<b>Other</b>	1	1	2
Non-patterned	1	-	1
<b>WW Confirmed Malfunctions</b>	3	1	4

**VENTAK PRIZM 2 DR**  
Model 1861

Worldwide Distribution: 51,600  
Worldwide Confirmed Malfunctions: 201

	Without Compromised Therapy	With Compromised Therapy	Total
<b>Electrical</b>	23	11	40
#Capacitor	21	6	27
#Integrated circuit	2	3	5
#Resistor	1	1	2
#Device tones	3	1	4
#Integrated circuit	1	1	2
#High current drain	1	1	2
<b>Mechanical</b>	26	50	76
#Short circuit (pre-April 2002 PRIZM 2 DR) (Advisory issued)	1	1	2
#Screw	1	19	20
#Seal plug	2	2	4
#Header	3	1	4
#Circuit connection	2	1	3
#Short circuit	2	1	3
<b>Software</b>	3	1	4
#Software download	3	1	4
#Impedance measurements	1	-	1
#Memory location	1	1	2
<b>Other</b>	47	28	75
#Power on Reset	2	4	6
#Battery depletion	23	1	24
#Battery voltage at implant	2	1	3
#Sensing	3	1	4
#Early replacement indicator	1	1	2
Non-patterned	15	23	38
<b>WW Confirmed Malfunctions</b>	111	90	201

**VENTAK PRIZM 2 VR**  
Model 1860

Worldwide Distribution: 38,600  
Worldwide Confirmed Malfunctions: 80

	Without Compromised Therapy	With Compromised Therapy	Total
<b>Electrical</b>	10	6	16
#Capacitor	8	6	14
#Device tones	1	-	1
<b>Mechanical</b>	10	13	23
#Screw	8	7	15
#Seal plug	1	1	2
#Vagal plug	1	1	2
#Header	2	4	6
<b>Software</b>	1	1	2
#Software download	1	1	2
#Memory location	1	-	1
<b>Other</b>	64	15	79
#Power on Reset	3	-	3
#Battery depletion	6	5	11
#Sensing	1	1	2
Non-patterned	12	9	21
<b>WW Confirmed Malfunctions</b>	45	35	80