



Examinations of Implantable Cardioverter Defibrillators Exposed to the Electromagnetic Fields of CEIA Metal Detectors **02PN10** and **PMD2/PTZ**

Ordered by: C.E.I.A. S.p.A. Costruzioni Elettroniche Industriali – Automatismi Zona ind. Le Viciomaggio, 54/G I-52040 VICIOMAGGIO – Arezzo, Italy

Internal Order No: ITM/1.82.00039.00-S162

This Expert Opinion contains Pages 1 to 41

Date:

2001-03-20

Expert

for Director

m lah

Comments:

The test results refers exclusively to the test subject. The production or transmission of extracts of the present report is subject to authorisation by the testing laboratory

> ÖSTERREICHISCHES FORSCHUNGSZENTRUM SEIBERSDORF GES.M.B.H A-2444 Seibersdorf, Tel. ++43/2254/780-0, Fax: ++43/2254/740-60; Server http://www.arcs.ac.at, e-mail: seibersdorf@arcs.ac.at; Sitz der Gesellschaft und Registergericht: Wien; Firmenbuchnummer: FN II 5980i, UID-Nr.: ATU14703506; DVR 0594636

On:

SUMMARY

For investigating the possibility of malfunctions of Implantable Cardioverter Defibrillators (ICDs) in the electromagnetic fields of the CEIA Metal Detectors 02PN10 and PMD2/PTZ numerous tests were performed on 7 different ICD models of 3 different vendors. For the tests each of the ICDs was positioned realistically in a liquid-filled (0.03 molar NaCl solution) homogeneous torso phantom. Afterwards it was exposed to the electromagnetic fields of the metal detectors, considering several exposure situations including also worst case scenarios, e.g. when the ICD is as close as possible to the transmitting antenna of the metal detectors. Prior to each exposure the event storage of the ICD was read out and the proper function of the implant was checked. Immediately after each exposure the event storage of the ICD was read out again and checked for detection of extraordinary events and delivery of inadequate defibrillation shocks during the exposure. Furthermore the ability to detect appearing tachycardia properly during exposure in the field area was checked for each device in the worst case position. In total 132 different tests were performed. In none of the considered scenarios any influence on the ICD-function caused by the electromagnetic field of the metal detectors could be found. Due to the fact that in all tests the metal detector systems were operated on a special test-power level which produces a magnetic field strength which is twice the magnetic field strength produced in normal operation, it can be stated that the metal detector systems 02PN10 and PMD2/PTZ provide a safety margin in magnetic field strength of at least a factor of 2 with respect to the examined ICD models in the considered test conditions.

CONTENT

2
3
4
4
4
4
6
5
9
2
4
5
7
5
7
8
0
0
3

1. INTRODUCTION AND SCOPE

1.1 General

The progress in biomedical engineering leads to an increasing application of highly sophisticated electronic implants, especially for patients suffering from heart conditions. The most known type of this kind of implants is the cardiac pacemaker which is successfully used for many years for the treatment of many 'bradycardia-type' heart conditions.

For treating 'tachycardia-type' heart conditions, i.e. if the heart tends to beat too fast or tends to fibrillation, Implantable Cardioverter Defibrillators (ICDs) were developed in the recent years and they are successfully applied nowadays. Based on statistic data from the United States and Germany (see [1] and [2]) it can be estimated that in the developed countries more than a million people are dying from the sudden heart death every year. In most of these cases the reason is either a ventricular tachycardia (VT) or ventricular fibrillation (VF). In view of these data and due to the fact that ICDs are able to terminate VTs and VFs at a very high rate of probability (>90 %) it becomes obvious that ICDs are life saving devices which will be increasingly deployed in future medicine.

1.2 Short Description of Implantable Cardioverter Defibrillator's Functionality

An ICD is an electrical generator which is most commonly implanted in the left breast region (left pectoral). From the ICD one or two electrodes are leading into the heart for the purpose of sensing the natural electrical heart signals and for delivering defibrillation shocks if needed. Due to the fact that modern ICDs have also the capability to pace the heart (pacemaker function) also pacing signals are delivered over the electrode(s). In a simple description of the function of an ICD it can be said that the ICD electrically monitors the heart via its electrode(s) and in case of detecting VF or VT it delivers an electric defibrillation shock to the heart for terminating the event. In technical terms this can be understood as 'resetting' the heart's conduction system. Besides the simplified function described above today's ICDs have enormous variability with respect to its parameter settings such as detection thresholds, timing parameters, etc., which is needed to satisfy the different demands of different patients (and therefore different physiological conditions). Furthermore they have the capability to store extraordinary events within the natural heart signal so that the time and date of such events and eventually delivered defibrillation shocks can be reviewed by the cardiologists during routine examinations of the patients.

1.3 Electromagnetic Interference of Implantable Cardioverter Defibrillators

Although medical devices have to comply restrictive standards for Electromagnetic Compatibility (EMC) it cannot be assumed that they are immune against all possible electromagnetic disturbance-scenarios. The potential of interference is especially high, if the disturbing signal is similar (in its time domain or frequency domain behaviour) to natural possible heart signals. In this case it is possible, for example, that the ICD falsely interprets the disturbing signal as the heart signal and therefore acts improperly. For example, if the ICD interprets the disturbing signal as a ventricular fibrillation it would deliver a defibrillation shock although the patient's heart is working properly. Although filter techniques at the input detection circuit of ICDs and pacemakers became more sophisticated in recent years there are several reported cases and investigations where ICD malfunction was caused by electric and

electronic devices people use in their daily live (see for example [3] - [10]). In this regard furthermore the increasing concern leads to several systematic investigations on the potential of disturbing ICDs by different electric and electronic devices (see [11] - [26]).

The work described herein intends to show if there exists a serious risk for ICD patients when they are passing the CEIA Metal Detector Gates 02PN10 and PMD2/PTZ.

2. FINDINGS

All examinations took place on 26th January, 16th February, and 23rd February, 2001 at the EMC laboratory of the Austrian Research Centers.

All parts of the examinations which were directly connected to the handling and operating of the ICD models were executed and/or supervised by Dr. Günter Stix who is an assistant medical director at the department of cardiology of Vienna University and who has several years of experience in the field of ICD therapy.

2.1 Description of Devices under Test (DUT)

Both tested devices are Metal Detector Gates consisting of multiple transmitting antennas embedded in the TX panel, multiple receiving antennas embedded in the RX panel and a central electronic unit. The transmitting antennas create continuous wave magnetic fields in the frequency range of about 3 kHz to 6 kHz. Distortions of the magnetic fields in the receiving antennas due to metallic devices in the field area are recognised by the central electronic unit which gives an alert signal. During the measurements the equipment was functioning properly.

Metal Detector Type 02PN10

Manufacturer: CEIA-S.p.A. Zona Industriale Viciomaggio, 54 52040 VICIOMAGGIO (Arezzo) ITALY

S/N: 20006030021

The programmable parameters of the device were set as follows for all examinations.

Sensitivity SE:	15	Alarm Volume AV:	1
Max. Detection Speed DS:	5	Min. Volume MV:	0
Min. Detection Speed LS:	3	Alarm Tone AT:	2
Lower Zone Coefficient LC:	0	Baud Rate BR:	9600
Upper Zone Coefficient UC:	0	Self-Check Level SL:	С
Noise Limitation NL:	0	Gate 'IN' Direction GD:	1
Transmit Channel CH:	0	Power Level PO:	2
Alarm Duration AD:	1P		

Remark: Power Level '2' (used for all examinations described herein) is implemented only for test purpose. In normal condition the maximum Power Level supported by the 02PN10 is '1' which produces only half the magnetic field strengths of Power Level 2.

The values of the other parameters do not influence the characteristics of the emitted fields.

The resulting magnetic field pattern for the parameter settings given above is shown in Annex A.1.

Figure 1 shows a photograph of the device, figures 2 and 3 show the shape (in the time domain) and the frequency spectrum of the emitted signal, respectively.



Figure 1.: Photograph of the Metal Detector 02PN10



Figure 2.: Wave form (time domain) of the magnetic field emitted by the 02PN10



Figure 3.: Frequency spectrum of the magnetic field emitted by the 02PN10

Metal Detector Type PMD2/PTZ

Manufacturer: CEIA-S.p.A. Zona Industriale Viciomaggio, 54 52040 VICIOMAGGIO (Arezzo) ITALY

S/N: 20006030025

The programmable parameters of the device were set as follows for all examinations.

15	Alarm Duration AD:	1P
5	Alarm Volume AV:	3
3	Min. Volume MV:	0
0	Alarm Tone AT:	2
0	Baud Rate BR:	9600
1	Self-Check Level SL:	С
0	Gate 'IN' Direction GD:	1
0	Power Level PO:	2
	15 5 3 0 0 1 0 0 0	 Alarm Duration AD: Alarm Volume AV: Min. Volume MV: Alarm Tone AT: Baud Rate BR: Self-Check Level SL: Gate 'IN' Direction GD: Power Level PO:

Remark: Power Level '2' (used for all examinations described herein) is implemented only for test purpose. In normal condition the maximum Power Level supported by the PMD2/PTZ is '1' which produces only half the magnetic field strengths of Power Level 2.

The values of the other parameters do not influence the characteristics of the emitted fields.

The resulting magnetic field pattern for the parameter settings given above is shown in Annex A.1.

Figure 4 shows a photograph of the device, figures 5 and 6 show the shape (in the time domain) and the frequency spectrum of the emitted signal, respectively.



Figure 4: Photograph of the Metal Detector PMD2/PTZ



Figure 5: Wave form (time domain) of the magnetic field emitted by the PMD2/PTZ



Figure 6: Frequency spectrum of the magnetic field emitted by the PMD2/PTZ

2.2 Examination Method

In order to approach realistic situations each of the ICD models and the electrode(s) connected to it were positioned in a homogeneous liquid-filled phantom of the upper human body during the interference-tests (for details of the phantom, see section 2.3). In order to take into account the most common exposure scenarios as well as worst case scenarios 5 different exposure situations were considered for each examined ICD model (A-E according to figure 7).



Figure 7: Considered exposure situations

Before positioning an ICD model in the phantom its detection threshold was set to the minimum possible value (corresponding to maximum detection sensitivity). All other parameters were set to typical values. The detailed parameter settings used during the examinations are listed in Annex A.2 for all examined ICD models.

Prior to each exposure the event storage of the ICD was read out and the pacing function of the ICD was checked to ensure proper functioning. After each exposure the event storage was read out again and reviewed by the cardiologist looking for any extraordinary events like falsely detection of tachycardia or fibrillation or delivery of defibrillation shocks. This procedure was performed for all examined ICD models in all considered exposure scenarios according to figure 7 and for both metal detector devices. Figures 8 to 10 show photographs of different exposure situations during the examination.

The approximate undisturbed values of magnetic induction (i.e. without the presence of the phantom) at the location of the implant can be derived from the phantom's position and the field pattern of the metal detector devices (see annex A.1). They are listed in table 1 for both metal detectors and for exposure situations B, D, and E. For exposure situation A and C (walking through the metal detector gates, i.e. when the phantom is moved through the metal detectors) the values of exposure situations B and D correspond to the maximum values for situations A and C, respectively.



Figure 8: Exposure Situation B. Standing in the centre of the Metal Detector Gate, the implant closer to transmitting panel



Figure 9: Exposure Situation D. Standing in the centre of the Metal Detector Gate, the implant closer to receiving panel



Figure 10: Exposure Situation E. Standing in front of the transmitting panel with the breast as close as possible to the panel

	magnetic induction B _{rms} [µT]												
	02PN10 PMD2/PTZ												
Exp. Situation A	max. 22.9	max. 24.0											
Exp. Situation B	22.9	24.0											
Exp. Situation C	max. 2.0	max. 1.8											
Exp. Situation D	2.0	1.8											
Exp. Situation E	42.4	45.0											

Table 1: Approximate undisturbed values of magnetic induction at the location of the implant in the considered exposure situations. Derived from the magnetic field pattern (see Annex A.1) by averaging of adjacent measurement values

In addition to testing if the ICD falsely detects tachycardias or fibrillation due to the electromagnetic fields of the metal detectors, the proper detection of really appearing tachycardias was also tested for each ICD in the worst case exposure situation, when the phantom is brought as close as possible to the transmitting panel of the metal detectors (E according to figure 7). This type of test was made by using a special stimulation device (as used also in medicine) which allows delivery of electrical stimulation pulses of arbitrary amplitude and frequency into the phantom liquid. For this purpose the electrode of the stimulator was immersed into the phantom liquid and its tip was positioned in proximity to the ICD-electrode in the heart region. After positioning the phantom in the metal detector gate

a stimulation sequence of **tachycardia** (140 min⁻¹ for 15 sec.) - pause for 30 sec. - fibrillation (280 min⁻¹ for 15 sec.) was applied to the phantom. Afterwards the event storage was read out to check if the ICD has recognised the tachycardias correctly. Figure 11 shows the location of the stimulator's electrode tip in proximity to the ICD-electrode. Figure 12 shows a photograph of the phantom during the test.



Figure 11: Location of the stimulator's and the ICD's electrodes



Figure 12: Phantom in worst case exposure situation during the stimulation test

2.3 Phantom Preparation

For approaching realistic conditions with respect to the position of the ICDs and their electrodes and for taking into account the electric properties of real tissue a special homogeneous phantom was used for all examinations. It consists of a synthetic, electrically non-conductive shell which was filled with 0.03 molar NaCl solution, reflecting the average electric conductivity of muscle tissue. The reference value for electric conductivity of muscle tissue in the working frequency range of the metal detectors was assumed to be 0.33 S/m according to [27]. A 0.03 molar NaCl solution meets this conductivity value in the considered frequency range within ± 5 %. Due to the fact that the emitted fields of the metal detectors are predominantly magnetic, permittivity plays a minor role and can be neglected in this special case. For anatomically realistic positioning of the implants and their electrodes the phantom shell was equipped with special mountings. Figure 13 shows a front view of the phantom. In the upper left breast region an ICD-dummy (green coloured block of plastic) is fixed in the ICD mounting. This position of the ICD reflects the left-pectoral implantation method which is commonly used today. The approximate outline of the heart and the way of the electrodes are drawn on the surface of the phantom. Figure 14 shows a view from the top back into the

EE-EMV-S 154/01

neck of the phantom. The mounting pins for fixing the electrodes of the ICDs can be seen. It must be mentioned that the electrodes which can be seen in figure 14 are not applicable for ICDs. They were inserted only for demonstration purpose to show the electrodes' positions in case of two chamber devices.



Figure 13: Front view of the phantom. The approximate outline of the heart (red) and the positions of the electrodes (blue) are drawn on the phantom's surface. In the upper left breast region an ICD-dummy (green coloured) is mounted according to left-pectoral implantation the method. The mounting for the ICD is designed in a way to allow a liquid layer of about 1 cm between the implant and the phantom shell to reflect the corresponding tissue layer.



Figure 14: View from the top back into the neck of the phantom. The ICD-dummy is fixed in its fixture by a rubber tape. The atrial and ventricular electrodes are fixed in special mounting pins reflecting the conditions of a two chamber ICD. The electrodes on the photograph are not applicable to ICDs. They are used for demonstration only in this figure.

Figure 15 shows the phantom with an ICD already implanted. Figure 16 shows the phantom during the read out procedure of the event storage immediately before the first exposure.



Figure 15: Phantom with implanted ICD



Figure 16: Phantom during the read out of the ICD's event storage

2.4 Examined ICD Models

In total 7 different ICD models of 3 important vendors (including MEDTRONIC, which is by far the most important one) were selected for the interference tests. The selection aimed at achieving a representative sample of todays ICD market. Table 2 lists the examined ICD models and the ventricular electrode types used in combination with the ICDs.

Nr		Vondor	Type of Electrode									
INT.		Venuor	true bipolar	integrated bipolar								
1	Micro Jewel II 7223 Cx	Medtronic (USA)	Х	Х								
2	Micro Jewel 7221	Medtronic (USA)	Х	Х								
3	Jewel PCD 7219	Medtronic (USA)	Х	Х								
4	GEM 7227	Medtronic (USA)	Х	Х								
5	GEM DR 7271	Medtronic (USA)		x ¹⁾								
6	Ventak AVIII DR	CPI Guidant (USA)		x ¹⁾								
7	Belos VR	Biotronik (Germany)		X								

¹⁾ In case of the Two-Chamber ICD models GEM DR 7271 and Ventak AVIII DR a bipolar lead were used as the atrial sensing electrode.

Table 2: Examined ICD models, vendors and types of electrodes used in this investigation

Considering both types of ventricular electrodes commonly used might be important because they differ significantly with respect to the detection area in the heart from which the sensing signals are derived. In case of the integrated bipolar electrode type the electric signal appearing between the electrode's tip and a relatively long, electrically non-isolated section of the lead is taken as the sensed signal (see figure 17). In this case it is possible to partly include also atrial signals in the resulting sensing, also in case of single chamber ICDs. The other considered electrode type, the so called 'true bipolar electrode' detects the sensing signals between its tip and a short metallic ring close to the tip (see figure 17). In this case only ventricular signals are contributing to the resulting sensing.



Figure 17: Lead sections of one 'integrated bipolar' (top) and one 'true bipolar' (bottom) electrode type.

Figure 18 and 19 show exemplary photographs of one of the considered two-chamber models and one of the considered single-chamber models, respectively.



Figure 18: The single-chamber ICD model 'Belos VR' (Biotronik)



Figure 19: The two-chamber ICD model 'GEM DR 7271' (Medtronic)

EE-EMV-S 154/01

By using the selected 7 ICD models and the different electrode combinations today's situation of implanted ICDs is covered to a large extent. The vendors of ICDs considered in this work are covering more than 90 % of today's ICD market. Taking into account true bipolar electrodes as well as integrated bipolar electrodes gives a coverage of more than 99 % of the electrode configurations used today. That means that the selected sample of implants can be considered representative.

2.5 Measurement Equipment Used

EM-Field Analyser EFA 3 Wandel &Goltermann S/N: E-0029 ID-No.: E0676

B-Field Sensor BN2245/90.10 Wandel & Goltermann S/N: E-0004 ID-No.: E0677

Oscilloscope Tektronix 465 Tektronix S/N: 102171

Dynamic Signal Analyser HP 3562A Hewlett Packard S/N: 3216A05806

2.6 Results

In none of the performed 132 tests any influence on the ICDs function due to the electromagnetic fields of the Metal Detector 02PN10 and PMD2/PTZ could be found:

- a) Although the ICDs were programmed for maximal sensitivity (minimal threshold parameters) in respect to signal detection, there was no arrhythmic event detected falsely by the tested devices.
- b) Currently implanted ICDs have integrated pacemakers reacting differently to magnet exposure than usual pacemakers; the integrated pacemakers of the tested devices paced properly throughout the exposition episodes.
- c) All simulated episodes of ventricular tachycardia (heart rate 140/min) and of ventricular fibrillation (heart rate 280/min) were detected and classified properly by the tested ICD-systems.
- d) No damage to any parts of the hardware and software of the ICD-systems (RAM for ECGmemory and retrieval, battery, capacitors, etc) could be found.

Pages 18 to 24 exemplary show significant printouts for each examined ICD model extracted from the complete set of more than thousand interrogation-pages (interrogated from the implants) used for the evaluation of the experiments.

Example Results for ICD Model Micro Jewel II 7223 Cx

SERICHT ZÄHLERDAT agte Epis Löscher isodandaten: Feb 16, 2001 11:14:30 ag Episodendaten: Okt 07, 1997 15:27:09

02 - - - 10 (m) SERICRY SÄHLERDATEN

2001 11:17:02 07, 1997 15:27:09 g Epis

Episodenzähler	Seit Löschen	Gerätesunnen	Episodenzähler	Seit Läschen	Gerätesunnen
VP: FVT: VT: Gesantzahl Tachyepiseden:	i	163 2 21 125	VF: FVT: VT: Gesentzahl Tachyspisoden:	1	103 2 21 126
Non-Sustained Episoden:	8.1		Non-Sustained Episoden:		
Onset-Kriterium erfüllt:	1. A A A A A A A A A A A A A A A A A A A		Onset-Kriterium erfüllt:		
Brady-Episoden: Brady-Impulse:	324	2450985	Brady-Episoden: Brady-Inpulse:	304	2451071

Medtronic 7223 SN PFR100061R Rev 96960201 Feb 16, 2001 11:45 edtronic 7223 SN PFR100061R Rev 98868281 Feb 16, 2001 11:48 Event counter status before (left page) and after (right page) exposure to the metal detector systems. The event counter hold the same values before and after exposure, i.e. no episodes are falsely sensed during exposure.



REPICET 2ÅHL

Pacing test to assure proper functioning of the ICD. It can be seen that the ICD is pacing properly.

000 ंकेल Seite 1 von 2 RICHT ZÄHLERDATEN ----aten: Feb 16, 2001 11:22:22 odendaten: Okt 07, 1997 15:27:06 gte Epis

ar Episod

11:37:06 1997 15:27:09 te Epi g Epis

Episodenzähler	Seit Lõechen Ge	rätesumen
WF: FVT: VT: Genemizahl Tachyspisoden:		103 2 21 125
ion-Sustained Episoden:	1	
Anset-Kriterinn erfüllt:	•	
Brady-Episoden:	>34	2451252

Seit L VF: FVT: VT: 7119

vp.	7	104
EVT:	1	2
VT:	1	21
Generatizahl Tachyopisoden:	9	127
Non-Sustained Episoden:		
Onset-Kriterium erfüllt:		
Brady-Episoden:	>24	
Brady-Impulse:	-	2451702

1

SN PFR100061R Rev 98866281 Pab 16, 2001 12:08 SN PFR100061R Rev 98060201 Feb 16, 2001 11:53 Sedtronic 7223 dtromic 7223 Event counter status before (left page) and after (right page) exposure to the metal detector systems during the stimulation test. The event counter for ventricular fibrillation (VF) is increased by 1, i.e. the episode was detected properly by the ICD during exposure.



Stimulation test during exposure. At the left side (before stimulation) the ICD is pacing properly. After set-in of the stimulation the ICD detected the fibrillation correctly.

Example Results for ICD Model Micro Jewel 7221

gefragte Episodendaten: Fab i tute Löschung Episodendaten:	6, 2001 15:33:20 Feb 16, 2001 15:33:1	•	Abgefragte Episodendaten: Feb 16, 2001 15:34:55 Letzte Löschung Episodendaten: Feb 16, 2001 15:33:14												
Episodenzähler	Sait Löschen	Gerätesumen.	Episodenzähler Sai	it Löschen Garä	terumen										
IT :	:	16	VT:	•	16										
T:	.	13	VT:		19										
esantzahi ischyepisoden:	• • • • •	8	Gesawiishi Tachyepisoden:	•	29										
on-Sustained Episoden:	•		Non-Sustained Episoden:	•											
mset-Kriterium erfüllt:			Onset-Kriterium erfüllt:	•											
rndy-Episoden: rndy-Impulse:		56358240	Brady-Episoden : Brady-Ingalao :	-	6359294										
tronic 7221 58 PF82013	67K Rev 98868282 Fe	16, 2001 13:35	Medtronic 7221 SH PFR201257K A	ev 96668262 Pab 16,	2001 13:1										
ent counter status before (le	eft page) and after (ri ure, i.e. no episodes	ght page) exposure are falsely sensed d	to the metal detector systems. The even luring exposure.	ent counter hold the	same										
a : =V-=															
THE CHANNEL															
		The second second second second second second second	the second se	the second	CONTRACTOR OF THE										
					ļ										
Pacing test to assure proper	functioning of the IC	CD. It can be seen th	at the ICD is pacing properly.		1 . 1 . 1										
Pacing test to assure proper	functioning of the IC	CD. It can be seen th	Abgefragte Episodendaten: Feb 16, 29 Letzte Lönchung Episodendaten: Feb 16, 29	5- 01 15:54:33 6, 2001 15:32:14	1te 1 vo										
Pacing test to assure proper sour zin protection afragte Rpisodeminten: Feb 1 ate Léschung Rpisodeminten:	functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:33:14	CD. It can be seen th	Abgefragte Episodendaten: Feb 16, 29 Letate Löschung Episodendaten: Feb 10	50 1 15:54:33 6, 3001 15:33:14 t Löschen Gerät	its 1 vo										
Pacing test to assure proper sour 23. Expanses efregte Spisodendaten: Feb 1 rte Ldechang Spisodendaten: pisodenzähler	functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:33:14 Seit Löschen	CD. It can be seen th Seite 1 von 2 Geritasumm 16	Abgefragte Episodendaten: Feb 16, 204 Letate Länchung Episodendaten: Feb 17 Typisodensähler 501 VF: VF:	50 01 15:54:33 6, 3001 15:33:14 t Löschen Gerät	1ta 1 vo										
Pacing test to assure proper neur zim monares sfragte Bpisodendaten: Feb 1 ste Lischng Bpisodendaten: pisodenzähler f: f: esemtsahl Tachyepisoden:	functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:33:14 Seit Löschen	CD. It can be seen th Seite 1 von 3 Gerätesumen 16 9 18 29	Abgefragte Episodendaten: Feb 16, 29 Letzte Löschung Episodenten: Feb 16, 20 Letzte Löschung Episodendaten: Feb 16, 20 Letzte Löschung Episode	5 01 15:54:33 6, 2001 15:39:14 t Lönchen Gerät 1 0 1 2	ita 1 vo 17 17 14 31										
Pacing test to assure proper A congression of the second	functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:33:14 Seit Löschen	CD. It can be seen th Sette 1 von 2 Geritesumm 16 9 13 29	Alterate Linchurg Episodendaten: Feb 16, 294 Letate Linchurg Episodendaten: Feb 16, 294 Letate Linchurg Episodendaten: Feb 16, 294 Letate Linchurg Episodendaten: Feb 17 Wr: FVT: VT: Gesentucht Tachyepisoden: Non-Sustained Episoden: Const-Episoten:	5.54:33 6, 2001 15:32:14 t Löschen Gerät 0 1 2	ita 1 wo										
Pacing test to assure proper ICHT 210 ERDATES effragte Episodendaten: Feb 1 tte Ldochung Episodendaten: pisodenzähler F: F: F: ensstahl Tachyepisoden: no-Sustained Episoden: met-Eriterium erfüllt:	functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:33:14 Seit Löschen	CD. It can be seen th Seite 1 von 2 Geritesumm 16 9 13 29	Abgefragts Episodenisten: Feb 16, 200 Episodenzähler Seiv VY: FVT: VT: Gesantzahl Tachyepisoden: Non-Sustained Episoden: Omset-Eriterim erfallt: Englo-Sustained Episoden:	5. 5. 5. 5. 5. 5. 5. 5. 5. 5.	its 1 wo										
Pacing test to assure proper ECHT Zim ERDATES sfragte Episodendaten: Feb 1 ste Löschung Episodendaten: pisodenzähler F: T: T: somstahl Tackyepisoden: m-Sustained Episoden: mot-Eriterim erfüllt: rady-Episoden: rady-Episoden: rady-Episoden:	functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:83:14 Sett Löschen 0 0 1 -	CD. It can be seen the Seite 1 von 2 Gerätessmen 16 13 29 56356625	Abgefragts Episodendaten: Feb 16, 26 Letzte Löschung Episodens: Feb 16, 26 VF: VF: VF: VF: VF: VF: VF: VF: VF: VF:	5	1ts 1 vo 										
Pacing test to assure proper CHT Zim_ERDATES sfragte Episodendaten: Feb 1 ste Löschung Episodendaten: pisodenzähler f: f: r: m-Sustained Episoden: uset-Eritarium erfällt: *ady-Episoden: *ady-Impulse:	functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:33:14 Seit Löschen	CD. It can be seen th Seite 1 von 3 Gerätesumen 16 9 13 29 56366625	At the ICD is pacing properly.	50 01 15:54:23 6, 2001 15:32:14 t Löschen Gerät 1 0 1 2 10 - t	1ts 1 wo										
Pacing test to assure proper Corr Zischenares afragte Episodendaten: Feb 1 the Löschung Episodendaten: pisodenzähler T: : : : : : : : : : : : : :	6, 2001 15:44:36 Feb 16, 2001 15:33:14 Seit Löschen 0 1 - 57K Bev 900662002 Feb	CD. It can be seen th Seite 1 von 3 Gerätesumen 16 9 15 29 56356625 16, 3091 13:48 xxposure to the meta	At the ICD is pacing properly.	10 10 10 10 10 10 10 10 10 10	1ts 1 vo 17 0 14 31 00566678 2001 13:1										
Pacing test to assure proper ACMT Zim ERNATES Stragte Episodeniaten: Peb 1 the Loschung Episodeniaten: pisodenzähler P: T: r: remestained Episoden: met-Exiterium erfullt: redy-Episoden: met-Exiterium erfullt: redy-Episoden: remie 7221 SN PYRS012 ent counter status before (hr rillation (VF) as well as ven	Functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:33:14 Solt Löschen 1 - 57K Rev 90062202 Feb eff) and after (right) e tricular tachycardia (CD. It can be seen the CD. It can be seen the Selite 1 you 2 Geritesum 16 13 29 56356635 16, 2001 13:49 xposure to the meta VT) are increased b	At the ICD is pacing properly.	10 10 10 10 10 10 10 10 10 10	11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1										
Pacing test to assure proper IGHT ZIM ERDATEN effragte Episodensisten: Feb 1 rite Löschung Episodensisten: pisodenzähler F: r: r: r: r: r: r: r: r: r: r	functioning of the IC	CD. It can be seen the Seite 1 von 2 Gerätessmen 16 9 13 29 56356625 564, 2001 13:49 Exposure to the meta VT) are increased b	At the ICD is pacing properly.	10 10 10 10 10 10 10 10 10 10	1te 1 vo 1te 1 vo 17 14 11 13 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 11 14 15 14 15 15 15 15 15 15 15 15 15 15										
Pacing test to assure proper Inter Zin Entering afragte Episodendaten: Feb 1 te Löschung Episodendaten: pisodenzähler F: F: F: F: F: F: F: F: F: F:	functioning of the IC 6, 2001 15:44:38 Feb 16, 2001 15:83:14 Sett Löschen 0 0 1 - 57K Bev 90062202 Feb eff) and after (right) et tricular tachycardia (CD. It can be seen the seen th	Advertises 7221	10 10 10 10 10 10 10 10 10 10	1ts 1 *** 1ts 1 *** 17 0 14 31 **********************************										
Pacing test to assure proper Corr Zin ERDATES afragie Episodeniaten: Feb 1 te Löschung Episodendaten: pisodenzähler F: F: comtahl Tachyepisoden: m-Sustained Episoden: m-Sustained Episoden: met-Eritarim erfällt: rady-Episoden: ady-Impulse: F: romie 7221 SN PPESO12 ent counter status before (hrillation (VF) as well as ven	functioning of the IC	CD. It can be seen the	At the ICD is pacing properly.	10 10 10 10 10 10 10 10 10 10	11 1 40 11 1 40 11 17 11 11 11 11 11 11 11 11 11										
Pacing test to assure proper Corr zin Ennates stragte Episodeniaten: Peb 1 tte Lösching Episodeniaten: pisodenzähler T: remesstained Episoden: meSustained Episoden: meSustaine	functioning of the IC	CD. It can be seen the Selte 1 von 2 Geritessmin 16 9 13 29 56356625 16, 2001 13:49 Exposure to the meta VT) are increased by	At the ICD is pacing properly.	10 10 10 10 10 10 10 10 10 10	11 1 40 17 0 14 31 65566678 2661 13:1 for ventr ing expo:										
Pacing test to assure proper NEW 230 EPDATES Stragte Episodeniaten: Feb 1 tte Locchang Episodeniaten: pisodenzähler T: T: m-Sastained Episoden: mot-Eriterium erfüllt: reale 7221 SN PPESD12 ent counter status before (hr rillation (VF) as well as ven	functioning of the IC	CD. It can be seen the	At the ICD is pacing properly.	10 10 10 10 10 10 10 10 10 10	4te 1 vo 17 0 14 31 xoscee72 2001 13:0 for ventri ing expos										
Pacing test to assure proper ECHT ZIRLERDATES STracts Episodeniaten: Feb 1 rts Lösching Episodeniaten: pisodenzähler F: T: r: sesstained Episoden: sest-Eriterim erfüllt: redy-Episoden: sest-Eriterim erfüllt: redy-Episoden: set-Eriterim serfüllt: redy-Episoden: set-Eriterim serfüllt: redy-Episoden: set-Eriterim serfüllt: redy-Episoden: set-Eriterim serfüllt: redy-Episoden: set-Eriterim serfüllt: redy-Episoden: set-Eriterim serfüllt: redy-Episoden: set-Eriterim serfüllt: redy-Episoden: set-Eriterim serfüllt: set-Eriterim set-Eriterim serfüllt: set-Eriterim serfüllt: set-Eriterim set-Eriterim serfüllt: set-Eriterim set-Eriterim serfüllt: set-Eriterim set-Eriterim set-Eriter	functioning of the IC	CD. It can be seen the seen th	At the ICD is pacing properly.	5. 115:54:33 6. 2001 15:33:14 10 1 10 12 10 10 10 10 10 10 10 10 10 10	11										

stimulation the ICD detected the fibrillation correctly.

Example Results for ICD Model Jewel PCD 7219

BRICHT ZÄRLERDATES	<i>1</i> 17	in parts	6)	Se	ite 1 von 2	BERICHT ZÄHLERDATEN	16	en en der d		J s	eite	
Abfragedatum: Feb 16, Letzte Zählerlöschung:	2001 1 Jan 25	4:43:27	4:24:38			Abfragedatum: Feb 16, Letzte Zählerlöschung:						
TACHY-ZÄHLER: VF: FVT: VI: CRSET-ARIT, ERPOLLT:	8 8 8 8 2	RADY-ZÄHL Brady-Pe Salven s ÄHLER VOS Isol. vo Salven v	ER: ilse gena it > 3 : szelt. E rzelt. 1 von 2-4 V	nt: ufein.folg. EIGNIS: ireignisse: VES:	906717 Imp. 69 0 8	TACHY-ZÄHLER: VF: PVT: VT: ONSET-KRIT. ERPÜLLT:		IADY-ZÄHL Brady-Pu Salven m IMLER VOR Isol. ve Salven v	ER: lso gesa it > 3 a ZEIT. ER cseit. E on 2-4 V	nt: nfein.folg EIGNIS: reignisse: TS:	;. Imp.	986746 69 8
VF-THERAPIE AKTIVIERT: ERPOLOREICH: Abgesnochen: Unnieksam: Geergang im VT: Unectient: Unnectient:	Rx1 0 0 0 0 0 0	Ref 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	8x3	Ref 0 0 0 0 0 0		VF-THERAPIE AKTIVIERT: ERFOLGMEICH: Abgebrochen: Unvirusan: Usergang in VT: Usergang in VT: Unbestinnt:	821 0 0 0 0	Rx2	803 8 9 9 9 9 9	Ref 0 0 0 0 0 0 0		
Medtranic 7219 57	N THL22	1186K Rev	968682	21 Feb 16.	2001 14:43	Medtronic 7219 57	TBL-20	1106% Rev	9885822	11 Feb 16.	. 2001 1	4:44

Event counter status before (left page) and after (right page) exposure to the metal detector systems. The event counter hold the same values before and after exposure, i.e. no episodes are falsely sensed during exposure.

		I			- 1			E	E				E	ł			E	L	Ţ	1	4				 -					1111						i.		<u>liij</u>	11	i.		ŀ	:	
	11418 14 114 1							14-1 2012																				and the second sec															Classific Barrier	
-			-			F		ŧ	ŧ	1	1010		ŧ	ŧ	i i	i	į.		ŧ	÷	-			T				÷	-		T	-	ł	+	+		111	11	1	111	h	Ē		Ĥ
							1									Ĭ					-			;			10				1													

Pacing test to assure proper functioning of the ICD. It can be seen that the ICD is pacing properly.

SN

TEL201106K Rev 988

(# / Sel 114+ MAYE BERICHT ZÄHLERDATEN 3 BERICHT ZÄHLES Abfragedatum: Feb 16, 2001 Letzte Zählerlöschung: Jam 14:45:45 Feb 16, 2001 14:52:29 26, 2001 14:24:30 Abfre Letzte Zählerlösch ur: Jan Let Jam -2001 14:24:30 TACHY-ZÄHLER: VF: PVT: VT: OMSET-ERIT. TACHY-ZÄHLER VF: PVT: VT: ly-Pulse mit > 3 sufein.folg 6.1 a mit l 3 aufein KRIT. ERFÜ RIT. VORZETT. EREIGNIS vorseit. Ereigni VES: Ŀ Is **101**. zeit. z 2-4 Ereignis VES: Salv VF-THERAPIE VT-THERAPIE Red Red. Bart 2-1 2-4 TVIERT a ANTIVIERT: REICH ŧ ŧ EBROCHEN CHEN: 00000 WTRESAN. . VIRE! 0 8 ANG IN VT ANG IN VT: ANG IN PVT 0000 11 STI NT:

trenic 7219 221 Feb 16, 2001 14:47 Hedtronic 7219 Event counter status before (left) and after (right) exposure to the metal detectors during the stimulation test. The event counters for ventricular fibrillation (VF) as well as ventricular tachycardia (VT) are increased by 1, i.e. the episodes were detected properly by the ICD during exposure.

85

TBL281186K Rev 989

Feb 16, 2001 14:52



Cut-out of the stimulation test during exposure. At the left side (before stimulation) the ICD is pacing properly. After set-in of the stimulation the ICD detected the fibrillation correctly.

Example Results for ICD Model GEM 7227

Contraction General Rame	Genn 7207 Ber: Putrasolitasi SSR Dilli post	Pelo 14, 2001 15 20:45 1952 Schwars Version 1.8 Copyright (r) Michtronic, Inc. 1967 1225 3	Kib Model: Gass 1927 Social Humber: PEP108272H ROMANIAN HISPORT	Feb 18, 3001 18,384 9953 Sarinawa Ranakan 1, Capperigini (j) Bindhenris, Inc. 19 52,118							
Last between	pation: Feb 10, 2001 14:37:54		Last Interception: Feb 10, 20	91 14 29 52							
Since Las	Deseice: Jan 28, 2001	Carrent Data	and the state	Last Secsion	Since Last Cleared	Device Lifetime Total					
En la catala			Episodes	(Jan 36, 2001)	(Jan 26, 2001)						
VF FYT VT SVTAUST	0 0 0 0	diffe-3.6 V. EDL-2x8 V Effe-3.6 V. EDL-2x8 V Last Full Energy Change Jan 26, 201 B.10 arc	W FVT VT SVTAST 3. Pacing	:		11 0 11					
Second Paced	0%. 10%	Last Capacitor Fermation An 26, 2001	fersal Pased Additional Counters								
		Laad Impedance Feb 16, 2001 V. Rocing S21 alema Delitellacion (HND) 18 alema	Single PACs Runs of PACs V. Runs Statistics Paces Runs of V. Rate Stat. Paces	11	1	50905 5105 0 0					

Event counter status before (left page) and after (right page) exposure to the metal detector systems. The event counter hold the same values before and after exposure, i.e. no episodes are falsely sensed during exposure.





KD Books Sector Russ Opened Vice	laan 1227 ar : PP1002730 Mil 2200273 allan: : Fals 16, 2001 14:20:52	Feb 16, 3001 15.24.25 BBC2 Sufferen Yarman 1.4 Cappingte (d) Machines, Inc. 1967 S2575 S	Constant	Comm 7997 har- 797-100-101 2014 Feb (2017 price: Feb 10, 201	20140	Shin ©	Fub 10, 3001 10,00.00 2002 Software Variation L2 opright (c) Mediments, Inc. 1007 E203203
Episodes La	e interregated: Feb 16, 3001 14 39:52	Common Dana	Episodes La	at Interregated. Fo	e 16, 2001 14,44,05	-	
Server Last	Section: 26, 26, 261	Current Data	Since Las	C Seaster: Jan	26, 2001	Oursent Data	
Episodes		Bettery Voltage	Episodes			Battery Voltage	
VF FVT VT SVENST	0 0 0	(FR-426 Y, SCK-440 Y) Peb H4, 2001 2:30 V Last Pull Exergy Charge	vr rvt vi svinist			(SRI-ESS Y, EOL Feb 16, 2001 Last Full Energy Jan 26, 2001	-0.40 %) 2.50 V Y Charge 8.10 Mc
Semed Paced	0%. #7	Last Capacitor Formation Jan 26, 2001	Second Pased	**		Last Capacitor Jan 24, 2001	Fermation
		Laad Impedance Feb 16, 2001 V. Pochg S21 oken Delizifiation (HVB) 18 oken				Land Impedance Feb 16, 2001 V. Pesing Deliteitation (PMI	521 olma 10 till olma

Event counter status before (left) and after (right) exposure to the metal detectors during the stimulation test. The event counters for ventricular fibrillation (VF) as well as ventricular tachycardia (VT) are increased by 1, i.e. the episodes were detected properly by the ICD during exposure.

2 2 2 2 2 2 2 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		1	
		11111	

Cut-out of the stimulation test during exposure. At the left side (before stimulation) the ICD is pacing properly. After set-in of the stimulation the ICD detected the fibrillation correctly.

Example Results for ICD Model GEM DR 7271

ICD Medal: Gen OR 7271 Serial Number: PM201805R Counters Report		sed Cepyrigte (Feb 23, 2001 11:00:58 8 Selfware Version 3.1 (c) Meditronic, Inc. 1997 (23)(c) 1	ICD Nodel: Cam DR 7274 Serial Humber: PM 321305R Oltrick Look Réport	Feb 23, 3001 11 d3238 9948 Software Version 3.1 Copyright (c) Medironic, Inc. 1977 Espiral
Last Interrogation: Feb 23, 200	11:08:32			Lest Interrogation: Feb 23, 2001 11:11:25 Episodes Last Interrogated: Feb 23, 2001 11:11:25	1. 使用和效
	Since Last Session	Since Last Cleared	Device Lifetime Total	Since Last Cleared: Feb 23, 2001	Current Data
Episodes	Feb 23, 2001	Feb 23, 2001		Episodes	Battery Voltage
WF FVT VT AFExAFbuner Simus Tuch Other 11 SVTs Other 11 SVTs Node Switch	0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0	1 0 0 0 1 0	VF 0 PVT 0 VTNST 0 Mode Switch 0 <u>% Pacing</u> AS-VS 0% AS-VF 0% AP-VP 0% AP-VP 100%	(ERe-4.91 V. EOL-4.57 V) Feb 23, 2001 5.45 V Last Full Energy Charge Sep 30, 2009 9.27 set Last Capacitor Formation Sep 30, 2000 Lead Impedance Feb 23, 2001 A. Pacing 1047 shms V Pacing 51 shms

Event counter status before (left page) and after (right page) exposure to the metal detector systems. The event counter hold the same values before and after exposure, i.e. no episodes are falsely sensed during exposure.

ECG LEAD II 0.1 sV/sm		1 110 1 100		tin fan far	line a			1 101					d a						i: finter	
											100		12							
	man	1 mm	177	mpr-		*****		-		ww			- ere	-	 		÷			
				CINESTING 1		Contract of	-	++	++											
MARKER CHANNES.		2			2		itir i	2	11			^			•					2
		1								910111							110	1111		
		1			1			T				T						11		T
EGH2: HVA/HVB 0.5 mV/mm		2			¥			1				¥				2				2
		100	100000							1						121		100		

Pacing test to assure proper functioning of the ICD. It can be seen that the ICD is pacing properly in the atrium as well as in the ventricle.

ICD Model: Gen OR 7271 Serial Number: Philopisticity Chilicki Londo Parantel	Feb 23, 2001 11:10:58 8666 Software Vanison 3.1 Copyright (c) Medironic, Inc. 1997	KD Bodel: Gen Off 7271 Seile Number: PH201605R Chlick Look Réport	Feb 23, 2001 11:18:37 9460 Software Vanies 3.1 Copyright (c) Moderaria, inc. 1937 22(19) 3
Last Interrogation: Feb 23, 2001 11:20:05 Episodes Last Interrogated: Feb 23, 2001 11:20:05	Professional Sector	Lesi Interrogation: Feb 23, 2001 11:38:24 Episodes Last Interrogated: Feb 23, 2001 11:20:24	internet and a second se
Since Last Cleared: Feb 23, 2001	Current Data	Since Last Cleared: Feb 23, 2001	Current Data
Enizodas	Battery Voltage	Episodea	Battery Voltage
VF 0 FVT 0 VT 0 SVT/MST 0 Mode Switch 0	(ERI=<11 V, EOL=4.57 V) Feb 23, 2001 5.68 V Last Full Energy Charge Sep 30, 3000 8.27 sec	VF 1 FVT 0 VT 1 SVT.NST 0 Mode Sentch 0	(ER=491 V, EOL=4.57 V) Feb 23, 2001 5.95 V Last Full Energy Charge Sep 30, 2000 5.27 sec
% Pacing AS-V3 0% AS-VP 0% AP-V9 0% AP-VP 160%	Last Capacitor Formation Sep 30, 2000 Lead Impedance Fab 23, 2001 A. Pacing 1087 ohms V. Pacing 521 ohms Daibrillation (HVS) 21 ohms	5 Pacing AS-V5 0% AS-V9 0% AP-V3 0% AP-VP 60%	Last Capacitor Formation Sap 30, 2000 Lasd Impedance Feb 23, 2001 A. Pecing 1067 ohms V. Pecing 521 ohms Deforitation (HVIS) 21 ohms

Event counter status before (left) and after (right) exposure to the metal detectors during the stimulation test. The event counters for ventricular fibrillation (VF) as well as ventricular tachycardia (VT) are increased by 1, i.e. the episodes were detected properly by the ICD during exposure.

		┼┼┼┼┼┼┽╎┼┼┼╎╏╏╏
		┨┫┫┨┫┫╗┥┥┥┥╣╹┈┥
	╉╉╋╋╧╋╋	+++++++++++++++++++++++++++++++++++++++
┝╌┠╼╆╼┿╼╉╍┥╼╄╍┥╼╄╼╋╼╋╸╋╸╋╸╋╸╋	╪╺╞╍╏╺╡╺╡╸╡╺╞╸╡╺╡╸╡╸	
		1 1 1 2 3 3 3 3 4 3 5 3 5 3 5 3 5 3 5 5 5 5 5 5
╺┼┼┼╴┦┼┼┼╴┨╗┙┼╸┼╶┼╴┫╶┨╸	<u>* * * * * * * * * * * * * * * * * * * </u>	
╶╅╍┥╼┫╌┫╼┫╌┫╼┫╴	+++++++++++++++++++++++++++++++++++++++	<mark>╉╴╉╴┇╶┇╶┇┊┇┊┇┊┇</mark> ┊┇═┫ ╺┇╸┇╸┇╸ ╋┿╋┿╋┿

Cut-out of the stimulation test during exposure. At the left side (before stimulation) the ICD is pacing properly. After set-in of the stimulation the ICD detected the fibrillation correctly.

EE-EMV-S 154/01

Example Results for ICD Model VENTAK AVIII DR

Cardias Pecenators, Inc.	VENTAK AVIII DR	Cardias Pacanaters, Inc.	VENTAK AVIII D
Gedruckt as 25-FID-81 11:49 Patient HEAF, GANILLA Klinik AKH HIDM OSFI-AMBU, OT-Programmiergersti Nodell 2901 Ser.4H. 000H47 OFI-Softwarer Hodell 2240 Version 2.7	ANZ EBEME 6 LILA F CPI-P6: 1831 Sectal 1831 SerMr. 100007 Stri-Version 1.0.02	Sednuckt as 23-FEB-01 11:32 Petiant HLAF GMULLA Klinik AAH HIEN GEFL-AMBULAN Of Joggrammiergerek: Nodell 22001 SarNr. 2000H47 OFI-Seftware: Nodell 2240 Varsion 2.7	Z EBEME 6 LILA F CPI-PG: 1831 SerMr. 1990007 BOH-Version 1.0.62
Zih	le*	Zahle	·
Aktuelle Deten enthelten: Episode Daten:	117 68-,09-08 - 23-FE8-81	Aktuelle Gaten enthalten: Episoden: Gaten: G	181 - 117 9-J.H-00 - 23-FEB-01
Esissiengahler Behandelt WF-Derapie VT-Derapie VT-Derapie Befolzen Derapie Nicht behandelt Keine Ther, programmiert Nicht behandelt Reine Jener, programmiert Nicht anbeiterde Episoden Esissien, ingesamt Alriale Techy-Reaktion	Seit Istates Apprepat Losden, sesent 05-04-00 2 34 11 12 1 12 1 12 1 12 1 12 1 12 1 12 1	Episodewikhler Befarwikit VF-Deropie VT-Leropie Befohlere Deropie Nicht betardelt Keine Ther, programmiet Nicht schaltende Episoden Episoden, jrogenet Atriele Techy-Reaktion	Sett letzten Appresat Lauchen sesent 05-JUN-00 2 94 11 12 13 12 14 17 9 17 9 24 27 149 37 208 8 249
Therapiezähler versuchte Schecks Abgepeten -Getektion erfällt vom Artt befohlen Abgeleitet-Neubestatievne vom Artt befohlen	26 144 21 64 8 22 8 17	Therapies Anier versuchte Schocke Mogegeben -Detaktion erfüllt Abgeleitet-Neckentatigung -ven Arat befahlen	26 144 21 69 6 25 5 28 6 17
Versuchte ATP-Schemate Abgegeben -Deteition erfüllt -van Arst befohlen	0 0 0 0 0 0	Versuchts AIP-Schemata Abgegeben -Detskticen erföllt -rom Arst befohlen	0 0 0 0 0
Erfelasrete beis ersten Versuch: VF-Zone Absesten Konvert VT-Zone 11 8 VT-1 Zone 1 8	. Beachleunist Erfelg in X 2 73 1 6	Erfolgsrate bein ersten Verauch: Vergans Zbesseben Konvert. VFridage 11 8 VI-1 Zone 1 9	Beschleunist Erfels in X 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

Event counter status before (left page) and after (right page) exposure to the metal detector systems. The event counter hold the same values before and after exposure, i.e. no episodes are falsely sensed during exposure.



Event counter status before (left) and after (right) exposure to the metal detectors during the stimulation test. The event counters for ventricular fibrillation (VF) as well as ventricular tachycardia (VT) are increased by 1, i.e. the episodes were detected properly by the ICD during exposure.

Example Results for ICD Model Belos VR

@	BIOTRO	NIK Follow-up Assistant		BIOTRO	Follow-up Assistant
Dete Petie ICD	Time 23.02.2001 ant dyco 00104 Belos VR	13:06 54 78110014	Date Pati 100	/Time : 23.02.200 ent : dycs 0010 : Belos VR	1 13:08 4 58 78110014
-69199	le List-	-5.41 ST 1990			
No.	Oste/Tine	Revert	NO.	Date/Tine	Renark
3. 2.	23.02.01 13:04 23.02.01 12:54 21.02.01 17.10.00 23.02 01 14:00	nanual RF recording W 1 Stock Falles-up Esport VF 1 Stock	3. 2. 1.	23.02.01 13:04 23.02.01 12:54 21.02.01 17.10.00 23.02.01 14:00	nanusi AA recording VF 1 Skock Follou-up Espart VF 1 Skock

Event counter status before (left page) and after (right page) exposure to the metal detector systems. The event counter hold the same values before and after exposure, i.e. no episodes are falsely sensed during exposure.

•••••		
	25 ownheet	

Pacing test to assure proper functioning of the ICD. It can be seen that the ICD is pacing properly.

4	BIOTRO	NIK Follow-up	Assistant FAST	@	BIO	TRO	NIK /	allow-up A	ssistant ^{(ABY}
Date Pati ICD	/Time : 23.02.2001 ent : duce 00104 Belos VR	13:20 Sk 78110014	1-600.0.8/1	Date Pati 100	/fixe: ent: :	23.02.2001 dycs 90104 Belics VR	13:22 SH 70110014		
-Epi so	de List-			Episa No.	de List-	ine	Senark		
10. 3. 2. 1.	Date/Time 23.02.01 13:04 23.02.01 12:54 21.02.01 17:10.00 23.02.01 14:00	Revark aanual Mirecording Will Shock Fallaarup Expert Will Shack	State and State	5. 4. 3. 2.	23.02.0 23.02.0 23.02.0 23.02.0 21.02.0 17.10.0 23.02.0	13:20 13:19 13:04 12:54 14:00	WF 2 Shocks VT1 nanuel RR re WF 1 Shock Fallow-up Espart WF 1 Shock	cording	

Event counter status before (left) and after (right) exposure to the metal detectors during the stimulation test. The event counters for ventricular fibrillation (VF) as well as ventricular tachycardia (VT) are increased by 1, i.e. the episodes were detected properly by the ICD during exposure.



Cut-out of the stimulation test during exposure. At the left side (before stimulation) the ICD is pacing properly. After set-in of the stimulation the ICD detected the fibrillation correctly.

2.7 Theoretical Considerations regarding the Limits for Protection from Malfunction due to electromagnetic Interference according to EN50061:

Beside several other aspects regarding the safety of implantable cardiac pacemakers the European standard documents EN 50061 [28] and EN50061/A1 [29] provide reference levels for disturbing signals. Pacemakers which are compliant to the mentioned documents must not be influenced in their function when these signals are connected to their input. In the subsection 6.3.2 'Protection from malfunction due to electromagnetic interference' of the mentioned documents these reference levels are given in terms of voltage (peak-to peak values) at the pacemaker's input caused by an external disturbing electromagnetic field. At frequencies in the range of the working frequency of the metal detector systems 02PN10 and PMD2/PTZ (approximately 3 kHz to 5 kHz) this reference level is defined as $1V_{pp}$ for a continuous wave signal¹.

Assuming similar sensing behaviour of pacemakers and implantable cardioverter defibrillators it is useful to apply the mentioned reference levels also to the latter devices, although EN50061 per definition deals only with pacemakers and do not belong to implantable cardioverter defibrillators in its scope.

With respect to the metal detector systems under scope a conservative estimate for the voltage at the pacemaker's input induced by the external field (emitted by the metal detector systems) could be derived using Faraday's law

$$V_{pp} = 2 * \sqrt{2} * 2 * \pi * f * B_{rms} * A$$

where V_{pp} is the induced peak to peak Voltage, f is the frequency, B_{rms} is the average magnetic induction in the area of the implant and its electrodes (breast region), and A is the loop area determined by the electrode/implant arrangement in the phantom.

Measurement results showed that the average (undisturbed) magnetic induction B at the breast region in the worst case scenario is (compare with table 1):

for 02PN10: $B_{rms} = 42.4 \ \mu T$ for PMD2/PTZ: $B_{rms} = 45.0 \ \mu T$

The maximum frequency f emitted by the metal detector systems is (valid for both systems):

f =6 kHz

Based on a very pessimistic assumption the maximum loop area A is taken as

 $A = 500 \text{ cm}^2$

which is a rather high value and can therefore be considered as an absolute worst case assumption.

¹ The reference value of 1 V_{pp} of a continuous wave signal belongs only to protection from malfunction. The reference value for protection against sensing electromagnetic interference is much more restrictive and is defined for a pulsed signal of specific shape (see subsection 6.3.3 of EN 50061/A1).

Using the formula given on the previous page this lead to induced peak-to-peak voltages at the implant's input of

 $V_{pp} = 0.23 \text{ V}$ for the 02PN10 $V_{pp} = 0.24 \text{ V}$ for the PMD2/PTZ.

Both values are clearly below the reference level of 1 V given in EN50061 and EN50061/A1, respectively.

Assuming that implantable cardioverter defibrillators behave similar to pacemakers regarding their susceptibility to disturbing electromagnetic fields, this means that implantable cardioverter defibrillators which would meet the requirements of EN50061 and EN50061/A1 should not show malfunction due to the electromagnetic fields in the walk through area of the metal detector systems 02PN10 and PMD2/PTZ.

3 JUDGEMENT

In none of the examined exposure scenarios in the electromagnetic fields of the CEIA Metal Detector Models 02PN10 and PMD2/PTZ **any influence** on the function of the considered models of Implantable Cardioverter Defibrillators (ICDs) could be found.

Due to the fact that in all the tests all ICD models were programmed at their maximum sensitivity (minimum intervention threshold) and the metal detector systems were operated on a special test-power level which produces a magnetic field strength twice the magnetic field strength produced in normal operation, it can be stated that the metal detector systems 02PN10 and PMD2/PTZ provide a safety margin in magnetic field strength of at least a factor of 2 with respect to the examined ICD models in the considered test conditions.

Therefore passing the CEIA Metal Detector Models 02PN10 and PMD2/PTZ working in normal operation can be considered safe for patients carrying one of the examined ICD models.

Due to the fact that the ICD models examined in this work are a representative sample of the present ICD market, it follows that the tested Metal Detectors present a **very high ratio of safety** with respect to today's implanted ICD models.

Expert in Charge:

Dipl. Ing. Gernot Schmid

This report may not be published except in full, unless permission for the publication of an approved extract has been obtained in writing from the director. It does not of itself impute to the subject of test any attributes beyond those shown by the data contained herein.

REFERENCES

- Meyenburg RJ., Kessler KM., Castellanos A., "Sudden cardiac death. Sructure, function, and timedependence of risk.", *Circulation 1992*, 85 Suppl 1: I2-I10
- [2] Andresen D., Behrens S., Brüggemann T, Ehlers HC., "Indikationen und Richtlinien zur Therapie.", from Wieholt D., Ulbricht LJ., Gülker H., "Implantierbare Kardioverter Defibrillatoren.", Stuttgart – New York 1997; 4-11
- [3] Ferrick K., Kim S., Brodman R., Fisher J., "Inadverent AICD inactivation while playing bingo", *American Heart Journal*, vol. 121, no. 1, pp. 206 207, 1991
- [4] Karson T., Grace K., Denes P., "Stereo speaker silences automatic implantable cardioverterdefibrillator", *The New England Journal of Medicine*, vol. 320, no. 24, pp. 650, 1989
- [5] Madrid A., Sánches A., Bosch E., Fernández E., "Dysfunction of implantable defibrillators caused by slot machines", *Pace*, vol. 20, Part II, pp. 212 214, 1997
- [6] Santucci P., Haw J., Trohman R., Pinski S., "Interference with an implantable defibrillator by an electronic antitheft surveillance device", *New England Journal of Medicine*, vol. 339, no. 19, pp. 1371 1374, 1998
- [7] Seifert T., Block M., Borggrefe M., Breithardt G., "Erroneous discharge of an implantable cardioverter defibrillator caused by an electric razor", *Pace*, vol. 18, pp. 1592 1594, 1995
- [8] Man K., Davidson T., Langberg J., Morady F., "Interference from a hand held radiofrequency remote control causing discharge of an implantable defibrillator", *Pace*, vol. 16, pp. 1756 1758, 1993
- [9] Mc Ivor M., "Environmental electromagnetic interference from electronic article surveillance devices: Interactions with an ICD", *Pace*, vol. 18, pp. 2229 – 2230, 1995
- [10] Glotzer T., Gordon M., Sparta M., Radoslovich G., "Electromagnetic interference from a muscle stimulation device causing discharge of an implantable cardioconverter defibrillator", *Pace*, vol. 21, pp. 1996 – 1998
- [11] Vlay S., "Electromagnetic interference and ICD discharge related to chiropractic treatment", *Pace*, vol. 21, pp. 2009 2013, 1998
- [12] Barbaro V., Bartolini P., Bellocci F., Donato A., "Electromagnetic interference of digital and analog cellular telephones with implantable cardioverter defibrillators: In vitro and in vivo studies", *Pace*, vol. 22, pp. 626 – 634, 1999
- [13] Bassen H., Moore H., Ruggera P., "Cellular phone interference testing of implantable cardiac defibrillator, in-vitro", *Circulation*, vol. 92, no. 8, p. I-738, 1995
- [14] Bassen H., Moore H., Ruggera P., "Cellular phone interference testing of implantable cardiac defibrillators in vitro", *Pace*, vol. 21, pp. 1709 – 1715, 1998
- [15] Fetter J., Ivans V., Benditt G., Collins J., "Digital cellular telephone interaction with implantable cardioverter – defibrillators", *Journal of the American College of Cardiology*, vol. 31, no. 3, pp. 623 – 628, 1998
- [16] Gieles O., "Letters to the editor: Cellular phone interference testing of implantable cardiac defibrillators in vitro", Pace, vol.22, pp. 401 – 402, 1999
- [17] Hayes D., Carrillo R., Findlay G., Embrey M., "State of the science: Pacemaker and defibrillator interference from wireless communication devices", *Pace*, vol. 19, pp. 1419 – 1430, 1996
- [18] Becker G., Johnson D., "Study of pacemaker and implantable cardioverter defibrillator triggering by electronic article surveillance devices", *Pace*, vol. 22, pp.542 545, 1999

EE-EMV-S 154/01

- [19] Groh W., Boschee S., Englstein E., Miles W., "Interactions between article surveillance systems and implantable cardioverter defibrillators", *Circulation*, pp. 387 392, 1999
- [20] Mathew P., Lewis C., Neglia J., Krol R., "Interaction between electronic article surveillance systems and implantable defibrillators: Insights from a fourth generation ICD", *Pace*, vol. 20, pp. 2857 – 2859, 1997
- [21] Mc Ivor M., Johnson D., Reddinger J., Mayotte M., Abstract: Study of pacemakers and implantable cardioverter defibrillators triggering by electronic article surveillance devices", *Europace '97 Abstract 138*, *Pace*, vol. 20, Part II, pp. 1473, 1997
- [22] Mc Ivor M., Reddinger J., Floden E., Sheppard R., "Study of peacemaker and implantable cardioconverter defibrillator triggering by electronic article surveillance devices (SPICED TEAS)", *Pace*, vol. 21, pp. 1847 – 1861, 1998
- [23] Mc Ivor M., Sheppard R., "SPICED TEAS manuscript: Study of pacemaker and implantable cardioverter defibrillator triggering by electronic article surveillance devices, *Pace*, vol. 22, pp.540 – 545, 1999
- [24] Embil J., Geddes J., Foster D., Sandeman J., "Return to arc welding following defibrillator implantation", *Pace*, vol. 16, 1993, pp. 2313 – 2318, 1993
- [25] Fetter J. G., Benditt D. G., Stanton M. S., "Electromagnetic interference from welding and motors on implantable cardioverter-defibrillators as tested in the electrically hostile work site", *Journal of the American College of Cardiology*, vol. 28, no. 2, pp. 423 – 427, 1996
- [26] Schmitt C., Brachmann J., Waldecker B., Navarrete L., "Implantable cardioverter defibrillator: Possible hazards of electromagnetic interference", *Pace*, vol. 14, pp. 982 – 984, 1991
- [27] CENELEC prEN 50357 "Evaluation of human exposure to elektromagnetic fields from devices used in Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar applications", July 2000.
- [28] CENELEC EN 50061:1988 E "Safety of implantable cardiac pacemakers", 1988.
- [29] CENELEC EN 50061:1988/A1:1995 E "Safety of implantable cardiac pacemakers", August 1995.

ANNEX

A.1 Magnetic Field Pattern of Devices under Test

Prior to the interference tests the magnetic induction in the field area between the transmitting and the receiving panel of the Metal Detectors under test was measured at measurement points according to the grid shown in figure A.1. The measurement results are listed in table A.1 and A.2 for the 02PN10 and the PMD2/PTZ, respectively.





Metal Detector Type 02PN10

		magnetic Induction B _{rms} [µT]					
		Α	В	С			
	Height 20 cm	55.1	52.9	55.4			
	Height 40 cm	58.6	49.5	49.7			
	Height 60 cm	43.0	38.0	45.5			
	Height 80 cm	47.3	36.2	37.4			
	Height 100 cm	40.5	39.0	39.0			
1	Height 120 cm	42.6	36.4	39.2			
	Height 130 cm	43.9	38.4	39.5			
	Height 140 cm	41.7	44.0	43.2			
	Height 150 cm	39.1	34.0	48.2			
	Height 160 cm	41.2	38.8	41.2			
	Height 180 cm	44.1	41.4	41.2			
	Height 20 cm	4.2	4.7	3.6			
	Height 40 cm	4.9	6.0	5.0			
	Height 60 cm	4.6	4.5	4.0			
	Height 80 cm	3.6	3.7	2.8			
	Height 100 cm	3.4	3.7	3.0			
2	Height 120 cm	3.2	3.8	3.3			
	Height 130 cm	3.2	3.3	2.8			
	Height 140 cm	3.2	3.6	3.0			
	Height 150 cm	3.8	3.8	3.0			
	Height 160 cm	3.6	3.5	3.0			
	Height 180 cm	3.4	3.6	2.9			
	Height 20 cm	1.2	1.3	1.1			
	Height 40 cm	1.2	1.3	1.1			
	Height 60 cm	1.0	1.1	1.0			
	Height 80 cm	0.84	0.90	0.83			
	Height 100 cm	0.77	0.85	0.79			
3	Height 120 cm	0.75	0.81	0.75			
	Height 130 cm	0.73	0.79	0.73			
	Height 140 cm	0.72	0.78	0.72			
	Height 150 cm	0.71	0.77	0.72			
	Height 160 cm	0.71	0.76	0.70			
	Height 180 cm	0.67	0.72	0.66			

<u>**Table A.1:**</u> Magnetic field pattern in the field area of 02PN10 according to measurement grid shown in figure A.1.

Metal Detector Type PMD2/PTZ

		magnetic Induction B _{rms} [µT]					
		Α	В	С			
	Height 20 cm	35.5	38.3	36.5			
	Height 40 cm	41.9	39.4	35.0			
	Height 60 cm	39.1	41.2	39.6			
	Height 80 cm	50.7	37.7	37.9			
	Height 100 cm	37.0	44.5	38.4			
1	Height 120 cm	44.8	43.0	38.5			
	Height 130 cm	43.2	43.6	37.6			
	Height 140 cm	39.4	48.6	43.0			
	Height 150 cm	38.4	42.2	46.2			
	Height 160 cm	41.0	44.0	40.9			
	Height 180 cm	41.2	47.1	41.7			
	Height 20 cm	2.5	3.3	2.5			
	Height 40 cm	2.6	3.2	2.6			
	Height 60 cm	3.8	2.8	2.2			
	Height 80 cm	2.4	2.4	2.0			
	Height 100 cm	3.2	3.0	2.3			
2	Height 120 cm	2.7	3.1	2.3			
	Height 130 cm	2.3	2.8	2.3			
	Height 140 cm	2.8	3.8	2.8			
	Height 150 cm	2.8	3.2	2.5			
	Height 160 cm	3.2	3.3	2.7			
	Height 180 cm	3.2	3.7	2.0			
	Height 20 cm	0.53	0.58	0.53			
	Height 40 cm	0.48	0.53	0.50			
	Height 60 cm	0.40	0.43	0.40			
	Height 80 cm	0.37	0.38	0.35			
	Height 100 cm	0.43	0.44	0.40			
3	Height 120 cm	0.46	0.49	0.44			
	Height 130 cm	0.46	0.50	0.50			
	Height 140 cm	0.47	0.52	0.49			
	Height 150 cm	0.49	0.56	0.53			
_	Height 160 cm	0.52	0.61	0.59			
	Height 180 cm	0.58	0.67	0.65			

<u>Table A.2:</u> Magnetic field pattern in the field area of PMD2/PTZ according to measurement grid shown in figure A.1.

38 BIPH AX>B AUS KV 30 BIPH AXUB AUS --- Seite 4 von 2 von NEIN JA INT. FÜR AUTD. KONDENSATORAUFL. (Mon): 6 Medtronic 7223 SN PFR100061R Rev 98860201 Feb 16, 2001 11:29 ø 90 Tage Okt 10, 1997 07:27 69 ø PFR100061R Rev 98860201 Feb 16, 2001 11:29 10 Min EGM **GRZ** AUS (5,0) (1,6) (240) () - Beim Laden und Post-Schock. AX>B AUS KV BIPH 96 BIPH AX>B 88 Seite ø ഹ 200 3,0 0,6 240 AUS 30 BIPH AX>B SIPH Б E CXT 4 Ausbl.n.Stim.(ms): Mindestintervall Antitachy-Stim. (ms): Impulsdauer(ms): VF Nach Erster Ladung bestätigen AXOB AUS 30 BIPH 30 BIPH AUS AXOB Amplitude(V): Aufzeichnung Ereignistrends starten am: e, EGM vor Tachykardiebeginn speichern: EGM beim Laden speichern: Vorzeitige Ereignisreizschwelle (%): BIPH 20 BIPH AX>B 8 AX>B AUS KV AUS \$ N 1 AUS RAMP+ BIPH AX>B 8 თ 75 69 66 ß AUS н VVI 34 AUS 0,15 Aufzeichnungslänge: 1 Speicherungslänge: NS PARAMETERWERTEBERICHT EREIGNISTRENDDATEN: R-R-INTERVALLDATEN: PARAMETERWERTEBERICHT R-S1 Interv. *(%RR): S1S2(RAMP+)=(%RR): Stimulationsmodus: Stimul.freq(/min): FVT-Therapiestatus: Dauer (Stunden): HOLTER-TELEMETRIE: EPISODENDATEN: VF-Therapiestatus # Initial-Impulse: S2SN(RAMP+)=(%RR): Hysterese(/min): Interv.-Abn.(ms): SPEICHEROPTION: Empfindl.(mV): edtronic 7223 Therapie-Art: FVT-THERAPIE SMART-Modus: VF-THERAPIE: # Sequenzen: Energie(J): Impulsform: Energie(J): Impulsform: Strompfad: Strompfad: 4 4 AUS KV 30 BIPH AX>B 0 ±7,5 3 von PFR100061R Rev 98860201 Feb 16, 2001 11:29 1 von ە PFR100061R Rev 98860201 Feb 16, 2001 11:29 AUS KV АХ>В 96 BIPH Seite Seite ŝ 200 KV-Verzögerung(ms): EGM-Bereich (mV): AUS 30 BIPH AX>B GEM. KV-THERAPIE: 4 Mindestintervall Antitachy-Stim. (ms): 30 BIPH AX>B AUS ZUSÄTZL. VT-ERKENNUNGSKRITERIEN ŝ 30 Hqia AX>B AUS GEM.ANTITACHY-STIMULATIONSTHERAPIE: N 1,6 8,9 240 10 5 EIN AUS RAMP 91 91 EGM-Ableitun P-/S nach P+/S H 6/8 NEU-ERK. SN SN 400 ms 600 ms 600 ms 0,15 PARAMETERWERTEBERICHT PARAMETERWERTEBER J CHT INTERV. NID Aushl.n.Stim.(ms): AUS AUS AUS R-S1 Interv. "(%RR) Impulsdauer(ms): Amplitude(V): VT-Therapiestatus: Initial-Impulse: S1S2(RAMP+)=(%RR): S2SN(RAMP+)=(%RR): Interv.-Abn.(ms) Medtronic 7223 Empfindl.(mV): edtronic 7223 Therapie-Art: 1 VT-THERAPIE: ω SMART-Modus: INITIAL 12/16 Sequenzen: Impulsform: Strompfad: Energie(J): ARTIV. ONSET EGM-BREITE UIN STABILITÄT AUS AUS AUS 555 55

A.2 Parameter Settings of examined ICD Models

Micro Jewel II 7223 Cx

4

EE-EMV-S 154/01



34



35

ICD Model: Cam 7277				Feb 16	8, 2001 15:19:26						Feb 16	2001 15:19:40
Serial Number: PIP100372	н		ŏ	pyright (c) Medi	tronic, Inc. 1997	Serial Number: PIP1003	HZL			Copy	9962 Softwr right (c) Medu	rre Version 1.0 onic, inc. 1997
Parameter Settings	Report				Page 1	Parameter Setting	s Report					Page 2
Detection		<u>s</u>	tricular SV	r Criteria		VF Therapies	Rx1	Rz	Rx3	Rx4	Ràs	Rx6
Enable Inte	erval (Rate)	7	Stability	₹		VF Therapy Status	ð	5	₹	5	₹	ð
VF Off 400 n	ns (150 bpm)	D	d Width	5		Energy	35.1	35 J	35 J	35 J	35 J	35 J
FVT Off 280 r VT Off 600 n	ns (214 bpm) ns (100 bpm)					Pathway Recordirm VF after initi:	AX>B II charge?	No Bexe	AX>B	AX>B	AX>B	AX>B
Ab						FVT Therapies	Rxt	Bx2	Rx3	Rx4	Rx5	Hx6
CAUTION OF MUREIVALS (Detect	1				FVT Therapy Status	ð	ð	ð	5	ð	5
Initial NID Red	etect NID					Therapy Type	Ş	S.	5	5	i∂	50
VF 12/16 6/8					5.	Initial # Pulses						
VT 12 4						R-S1 Interval=(%RR)						
Sensitivity						S152(Ramp+)=(%RR) S2SN(Ramp+)=(%RR)						
Vantricitian 0.15 mV		I				Interval Dec						
						# Sequences						
						Smart Mode	ž	35	1 20	- 36	- 20	- 10
						Pathway	AX>B	AXSB	AXA	ΩΣ>R	AXSR	L CE AYAR
						Anti-Tachy Pacing Minin	um interval	200 ms				
ICD H odel: Gem 7727				Feb 16	, 2001 15:19:52						Feb 16,	2001 15:20:03
Setial Number: PIP100372	-		S	pyright (c) Medh	ronic, inc. 1997	Serial Number: PIP1003	72H			Copyr	9962 Softwa John (c) Liedin	re Version 1.0 xria. Inc. 1997
Parameter Settings	Report				Page 3	Parameter Setting	s Report			<i>(</i>		Pade 4
VT Therapies	Rx1 Rx2	Rx3	Rx4	Rxs	Rx6	Modes/Rates			Ventric	thar Load		D
VT Therapy Status	5 5	5	5	₹	ę	Mode V			Amolina			
i herapy Type Initial # Distance	Burst Ramp	S	2	Ş	S	Lower Rate 34 ppn	-		Pulse Wi	det ,	4 v 4 ms	
R-S1 Interval=(%RR)	8 8 8 8					Hysteresis Off			Sensitivit		15 mV	
S1S2(Ramp+)=(%RR)	2					Ventricular Rate Sta	ollization		Pace Bla	nking 2(30 ms	
S2SN(Ramp+)=(%RR)	:					V. Rate Stabilization	5		Post Sh	ock Ventri	cular Pacin	6
Emercal Dec	10 ms 10 ms								Amplitud		>	
Smart Mode	, ອັ								Pulse Wi	e F	1 ms	
Energy		35 J	35.J	35 J	35 J				Pace Bla	nking 20	0 ms	
Arti-Tachy Pacing Minimun	n interval 200 m	AX2B	AX>B	AX>B	AX>B							
Shared Arti-Tachy Dac	ing Thereau											
DEA AIMPLIANIN DAIL	and merapy			and VI Ther	ZdDX							
V. Amplitude 8 \ V. Pulse Width 1.6 n V. Pace Blanking 240 n	~ \$ 5	6a/d	ressive Episoc	le Therapies	ŧ							

GEM 7227

EE-EMV-S 154/01

ICD Model: Gem 7227 Serial Number: P1P100372H	Cop	Feb 16, 2001 15-20:14 9962 Software Version 1.0 yright (c) Medironic, inc. 1997	ICD Model: Gem 7227 Serial Number: PIP100372H	ð	Feb 16, 2001 15.20:25 9962 Software Version 1,0 yright (c) Medtronic, Inc. 1997
Parameter Settings Report		Page 5	Parameter Settings Report		Page 6
elemetered and Stored EGM			Sound tone for:	Enable-Urgency	Threshold
EGM 1	EGM 2 (used for EGM Width)		V. Pacing Lead Impedance Out of Range	5	
GM Source Vip to Vring GM Range +/- 8 mV tore this channel? Yes	Vtip to HVB +/-8 mV Yes		Defibrillation (HVB) Laad Impedance Out of Range Low Battery Vokage Excessive Charge Time Number of Shocks Delivered in an Ectsode	ಕಕಕ	
ore EGM during charging? ore EGM before tachycardia starts?	Yes No		All Therapies in a Zone Exhausted	5	
dditional Setup					
avioe Date/Time Feb Siter Telemetry Off emature Event Threshold 69	16, 2001 1428 %				
uto Cap Formation					
nimum Auto Cap Formation Interval	6 month				

GEM 7227 (continuation)

EE-EMV-S 154/01

ICD Wodel: Gem DR 7271 Serial Murder: PIM301805R			ço	Feb 9960 Sof vright (c) Me	23, 2001 10:27:31 Iware Version 3.1 dtronic, inc. 1997	ICD Model: Gem DR i Serial Number: PIM30	7271 31805R			ទី	Feb 9960 So pvright (c) M) 23, 2001 1 Miware Vers Jedironic, In	0-27:42 sion 3.1 ic. 1997
Parameter Settings Report					Page 1	Parameter Settin	rgs Report					Pa	ige 2
Detection		Dual	Chamber S	VT Criteri		VF Therapies	Rxt	Rx2	Rx3	Rx4	Rx5	œ	lx6
Enable Interval (Rate)		AFib/	AFlutter	ð		VF Therapy Status	5	₹	₽	ð	₽	0	Ę
VF Off 400 ms /150 hom	-	- Sinus	Tach	g		Energy	35 J	35 J	35 J	35 J	35 J	'n	5.1
	- F	Other	1:1 SVTs	₽		Pathway Reconfirm VF after in	AX>B itial charce?	AX>B Yes	AX>B	AX>B	AX>	8	84%
VI OII 600 ms (100 bpm	÷	Vent	ricular SVT	Criteria		FVT Therapies	, FX	Rx2	Rx3	Rx4	Bx5	Rx6	
Number of Intervals to Detect		V1 St	ability	đ		EVT Therany Status							
Initial NID Redetect NID VF 12/16 6/8			1			Therapy Type Initial # Pulses	None	Name	None	None	Nome	None	ĸ
VT 12 4 Someticians						R-S1 [merva⊫(%HH) S1S2(Ramp+)={%RF coctv(Pamp+)=/%DE	- 26						
VIIVIII STATE		,				Interval Dec	h						
Ventricular 0.15 mV						# Sequences							
						Smart move Energy							
						Pathway Ant-Lachy Pacing Mi	nimum Interva	200 200					
						8	:						
				£	23, 2001 10:27:53						đa đa	23, 2001 10	28:05
ICU Model: Gem DR 7271 Serial Number: P1M301805R			Cop	9960 Sol wright (c) Me	tware Version 3.1 dtronic, Inc. 1997	ICD Wodel: Gem DR Serial Number: PIM3	7271 31805R			Cop	9960 Sof syright (c) He	ftware Versi edtronic, In	on 31 c. 1997
Parameter Settings Report					Page 3	Parameter Settin	ngs Report					Pa	ge 4
VT Therapies Rx1	Rx2	Rx3	Rx4	Rx5	Rx6	Modes/Rates			Atrial	Lead			
VT Therapy Status Therman Tune						epow	000		Amplit	ude atrate	4 <		
Initial # Putses	RION	BUOM	BUON	REIDA		Mode Switch Lower Rate	B bbu		Sensiti	with	0.15 mV		
R-S1 Interval=(%RR) S1S2/Barreta=(%BD)						Upper Tracking Rate	120 ppm		Pace	Blanking	200 ms		
S2SN(Ramp+)=(%RR)						A-V Intervals			Ventr	icular Lead	-		
Interval Dec				I		Paced AV	180 ms		Amplit	epn	4 V		
# Sequences						Sensed AV	250 ms		Pulse	Vidth	0.4 ms		
Sinar mode Energy						Rate Adaptive AV	5		Censiti Dana P	Vity Nankimi	200 ms		
Pathway						Rate Therapy Fea	tures		 	Ê. N			
Anti-Tachy Pacing Minimum Interval	200 ms					V. Rate Stabilization	₹		Refra	ctory			
Shared Anti-Tachy Pacing Thera	Y	Shan	ed VF, FVT,	and VT TI	erapy	Post Shock Pacin	9		PVARI PVAB	150 m 100 m	ខ្ម		
V. Amplitude 8 V V. Dubo Witter		Progre	ssive Episod	e Therapies	£	A. Amplitude	4 V		Refra	ctory Feat	ures	,	
V. Pace Blanking 240 ms						A. Pulse Width	1.6 ms 240 mc		DAT	Tenterror	ŧ		
					,	A. Pace blanking V. Amblitude	6 V			lesponse	5 5		
					-	V. Pulse Width V. Para Rlanking	1.6 ms 240 ms		V. Safe	ety Pacing	ŧ		
							2						

GEM DR 7271

38

Feb 23, 2001 10:28:27 9960 Software Version 3.1 Copyright (c) Medinoric, Inc. 1997 Page 6 Threshold Enable-Urgency ちちちちちちち A. Pacing Lead Impedance Out of Range V. Pacing Lead Impedance Out of Range Defibritation (HVB) Lead Impedance Out of Range Low Battery Vortage Low Battery Vortage Excessive Charge Time Mumber of Shocks Delivered in an Episode All Therapies in a Zone Exhausted ł ICD Model: Gem DR 7271 Serial Number: PIN301805R Parameter Settings Report Sound tone for: Feb 23, 2001 10:28:16 9960 Software Version 3.1 Copyright (c) Meditronic, Inc. 1997 Page 5 Feb 23, 2001 10:36 Off 69 % HVA to HVB +/- 8 mV Yes EGM 1 (A or V) EGM 2 (V) Minimum Auto Cap Formation Interval 6 month Xes No Store EGM during charging? Store EGM before tachycardia starts? Atip to Aring +/- 8 mV Yes Telemetered and Stored EGM ICD Model: Gem DR 7271 Serial Number: PIN201805R Parameter Settings Report Additional Setup Device Date/Time Hofter Telemety Premature Event Threshold Auto Cap Formation EGM Source EGM Range Store this channel?

GEM DR 7271 (continuation)

Ventak AVIII DR

Cardiac Pacemakers, Inc.	VENTAK AVIII OR	Brady-Stieulation	
Gedruckt as 23-FF8-01 11:19		Norm. Brady-Stimul.	·····
Patient HAAF, GUNILLA		Betriebsart	D00
CPI-Programmiergerät: CPI-	PG:	Max. Trackingfrequenz	80 min-1
Modell 2901 Mod	•11 1831	Adaptive Frequenz	
CPI-Software: ROM	-Version 1.0.02	*Aktivitätsschwelle	
Modell 2843 Version 2.7		■Reaktionszeit Månpassuogsfaktor	5
		"Erholungszeit	min
Parameterbericht		AV-Verzögerung	150 as
		Minimale Verzög.	as
		Hysteresefrequenz	min-1
Pu-Konfiguration		Glättung b.Anst.	AUS 2
Tachy Mode	Aus	Glättung b.Abfall	AUS 2
		=Störreaktion	D00
Zuletzt programmiert Z3-	11:15	Impulsdauer	0,5 ms
		Amplitude Refraktärzeit-PVARP	5,0 V
		PVARP-Verlänger,	AUS as
VI-20ne		Impulsdauer	6,5 ms
Anfängl. Detektion	100 - 150 picel	Amplitude Refe. pach Stim. / SL	7,5 V
Intervall	600 - 400 ms	Dynamische MIR Refraktärzeit	150 as
Onset	AUS 2	Atriale lacny-keaxt. ≚Auslósefrequenz	120 min-1
Und/Oder Stabilität		¥Dauer *Fallback-Dauer	20 Zyk 20:15 = in
Inhibieren falls instabil	AUS as	*ATR/VTR Fallback LRL	40 min-1
Schock falls instabil A Fib Frequenzarenze	AUS ms AUS min-1	Post-Schock-Brady-Stim.	
A Fib Stabilität	as	Betriebsart	000 49 min-1
Anhaltende Frequenzdauer (SRD)	min:s	Hax, Trackingfrequenz	80 ∎in-1
Redetektion		Adaptive Frequenz	min-1
Redetextionsdauer	1,0 .	#Aktivitätsschwelle	
Post-Schock-Stabilität	AUS ms	*Anpassungsfaktor	
Post-Schock A Fib Freq.Grenze Post-Schock A Fib Stabilität	AUS min-1	≚Erhalungszeit Dvn. AV-Verzös.	AUS
Post-Schack V Freq) A Freq		AV-Verzägerung Minista Verzäg	150 ms
rost-schock annaltende rrequenzdader	#in-s	Detekt.AV-Offset	AUS ms
AIP-Therapie: AIP1 Schema Aussesch.	ATP2 Ausgesch.	Hysteresetrequenz Frequenzglättung	min-1
Anzahl der Bursts AUS	AUS	Glättung b.Anst.	AUS %
<u> </u>			
Impulse pro Burst		Glättung b.Abfall	AUS 2
Antanglich		=Störreektion	poo
Naxioua Kooolupesistervall	:	stim.Verzög.	3,0 s 0:30 m.in:s
Abnahme ms	es	ATRIAL	2.0
Rampabnahae as	m5	Amplitude	5,6 V
Scanabnahae ms Mindestintervall ms	85	Refraktärzeit-PVARP PVARP-Verlänger.	250 ms AUS ms
ATP-Zeitlimit A	US min:s	VENTRIKULAR	0 0
Schocktherapie		Amplitude	7,5 V
Schock 1 Schock 2	31 J 31 J	Refr. nach Stim. A.R. Dynamische MTR Refraktärzeit	250 ms 240 ms
Max Schocks	.31 J	Atriale Tachy-Reakt.	100 - 1 - 1
		*Dauer	20 Zyk
		=rallback-Dauer =ATR/VTR Fallback LRL	00:15 #in 40 #in-1
VF-Zone		Niera Parasatan sind für senala u. Best Salas	k-Stimul al-ich
Anfängl, Detektion		=Diese Parameter Sind für normale D. Fost-Schuc	k-Straut, gierca
Fraquenz Intervall	≥ 150 min-l ≤ 400 ms		
Dauer	1,0 s	Harris Cluster CCH Fact	
Redstektion		nagnet-/riepton-/con-runk.	
Redetektionsdauer Post-Schock-Dauer	1.0 s 1.0 s	Magnetfunktion Tachy-Modus ait Magnet verändarg	EIN AUS
Cohasithaana ja		Piepton während Kondensatoraufladung	AUS
Schock 1	31 1	und stimulierten ventrikulären Ereignissen	sen AUa
Schock Z Max Schocks	31 J 31 J	Piepton, wenn ERI erreicht ist Elektrogrammspeicher	EIN
	<u> </u>	Atrial	EIN
		Schock	EIN
Therapiemerknale		Onset	EIN
Schoole			
Schockform	Biphasisch	Einstellung der Empfindlichkeit	1
Polarität Committed Schock	INITIAL NEIN	Atriale Empfindl. Ventr - Empfindlichkeit	Nominell Kleiner
ATG		Tentes - SuperingElEnkels	
AIP #Atriale ATP-Amplitude	5,0 V		
Atriale ATP-Impulscaver	1,0 ms 7 5 V	Alle Energien angegeben wie gespeichert.	
Ventr.ATP-Impulsdauer	1,6 ms	- Line des Derichts	
Nur während EP-Test verfügbar			

Belos VR

Date, Pati ICD	/Tine : 2; ent : dy : Be	3.02.2001 12:59 co 00104 los VR SN 7811	N Foll	<i>ow-up Assistant</i> 	D.A/1
Overv Para	ieu	interrogal	ed		
VT/V	/F Detection	i disabled		herapy: disabled	
VT1				Confirmation St	ur ther locks-
VIZ VF				i i	
VF Progre	Issive cours	e of therapy	OFF		

Ventricular fre	e (release	code required)		-Anplitud Tenporar	ie y Program
Nininum Thresh. Refractory Period Node Nax.Det.Node Nax.Dec.Rate Rectification Inversion Polarity Blank Max.Sensitivity	0.5 nV 100 ns Event 8 Hz full OFF 80 ns 0N	Maxinun Hold Max. : UT T Vave Blank Max. : LT Filler High Pass 1 Low Pass High Pass 2	200 ns 75.0 % 350 ns 25.0 % 10 Hz 40 Hz 20 Hz	Kode Rate A Anplit	VVI 10 pp n ude #.#

Detection Class	VT1	VT2	VF
Interval Counter: Detection Counter: Redetection Onset Stability Sustained VT	600 ns 10 10 0FF 0FF	QFF	100 ns 5 in 8

	Inter	val: 600 ns	Nonitoring	······································
RTP Type Nunber S1 Add S1	-1	2 HKH		nFurther
S1 Decrement S1 Decrement S1-S2 Interval Scan Decrem. Min. Interval			Polarity	

Interval	400 ns		
 		-1st ShockConfirmation	-Further Shocks
 		1 J / OK	5×30J
Polarity		nori	na l

Node Bosic Rote	Bredy Wi 30 pen	Post Shock-	-Sensor
Hyst. Rate Replitude Pulse Vidth Duration	0FF 2.8 V 0.5 ms	0FF 7.5 V 1.5 ns 0:10 nin	