AUSTRIAN RESEARCH CENTERS
SEIBERSDORF

ACCREDITED TESTING LABORATORY (NO. 32)
for Electromagnetic Compatibility

DUPLICATE

EXPERT OPINION

NO. **EE-EMV-S-154/01**

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

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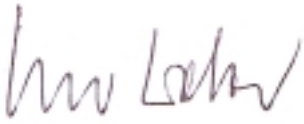
This Expert Opinion contains Pages 1 to 41

Date: 2001-03-20

Expert  for Director 

Comments:
The test results refers exclusively to the test subject.
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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

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:	C
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

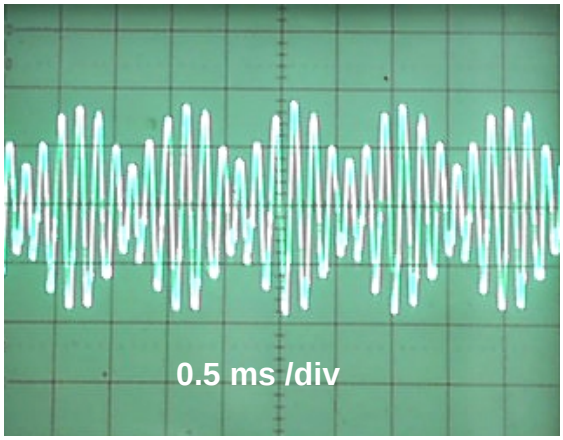


Figure 2.: Wave form (time domain) of the magnetic field emitted by the 02PN10

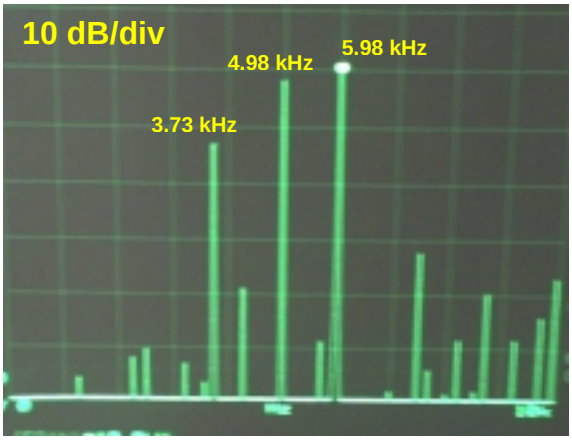


Figure 3.: Frequency spectrum of the magnetic field emitted by the 02PN10

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.

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

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

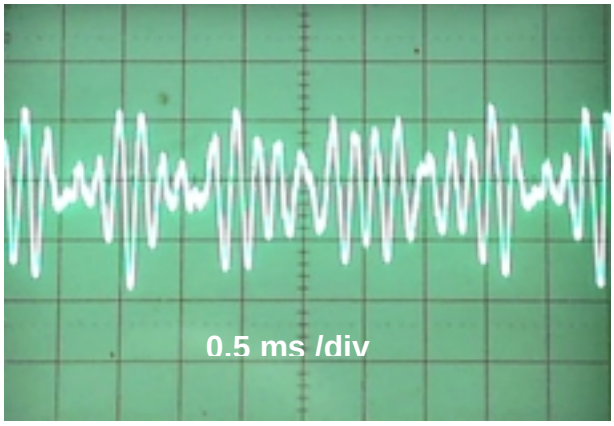


Figure 5: Wave form (time domain) of the magnetic field emitted by the PMD2/PTZ

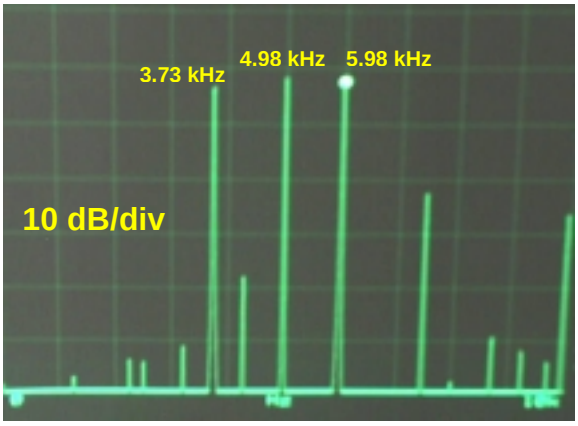
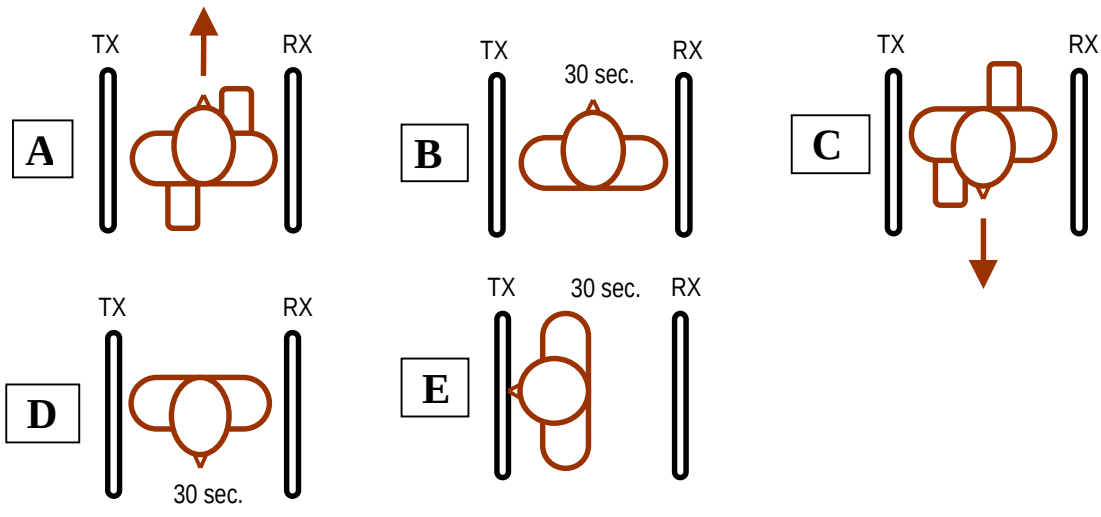


Figure 6: Frequency spectrum of the magnetic field emitted by the PMD2/PTZ

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).



Situation A: Walking through the metal detector, left shoulder towards the transmitting panel
Situation B: Standing between the metal detector posts for 30 seconds, left shoulder towards the transmitting panel
Situation C: Walking through the metal detector, right shoulder towards the transmitting panel
Situation D: Standing between the metal detector posts for 30 seconds, right shoulder towards the transmitting panel
Situation E: Standing between the metal detector posts for 30 seconds, breast towards the transmitting panel

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.

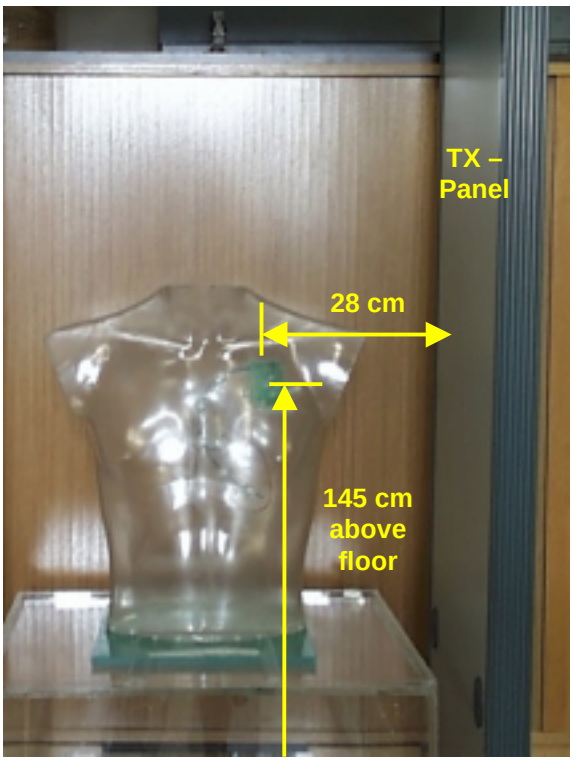


Figure 8: Exposure Situation B. Standing in the centre of the Metal Detector Gate, the implant closer to transmitting panel

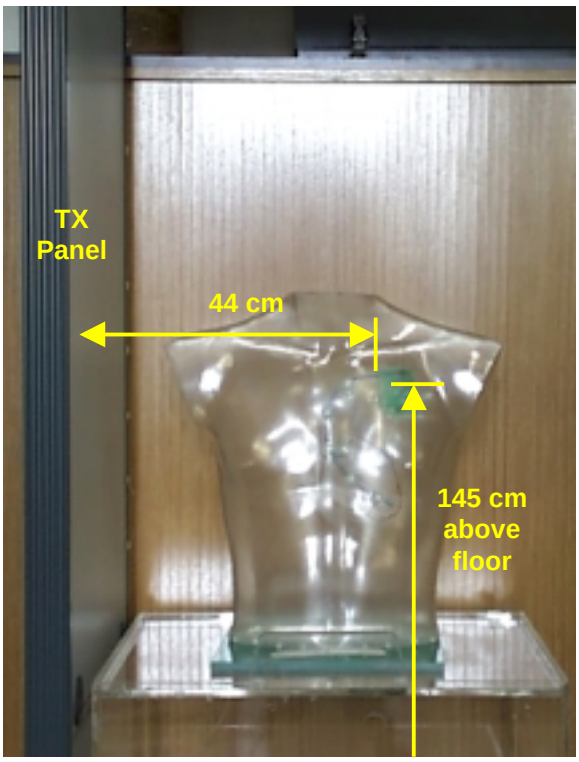


Figure 9: Exposure Situation D. Standing in the centre of the Metal Detector Gate, the implant closer to receiving panel

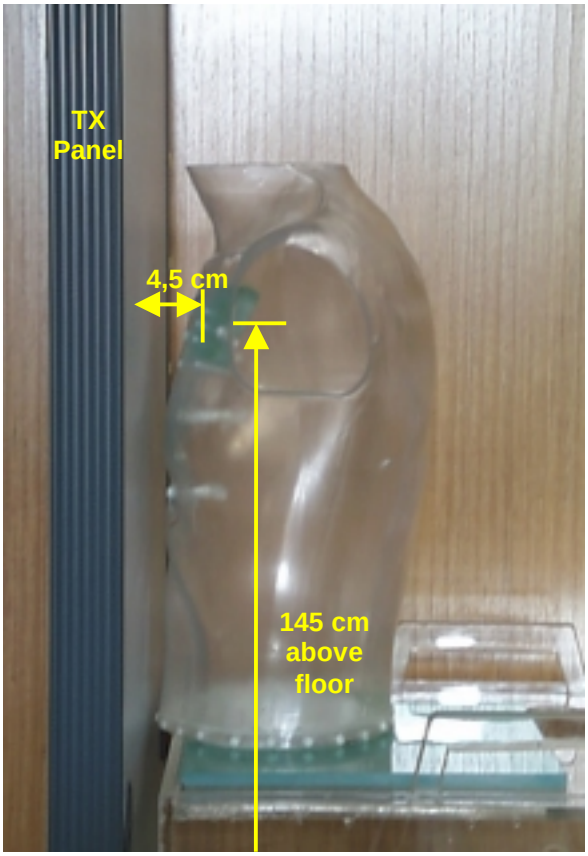


Figure 10: Exposure Situation E. Standing in front of the transmitting panel with the breast as close as possible to the panel

	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.

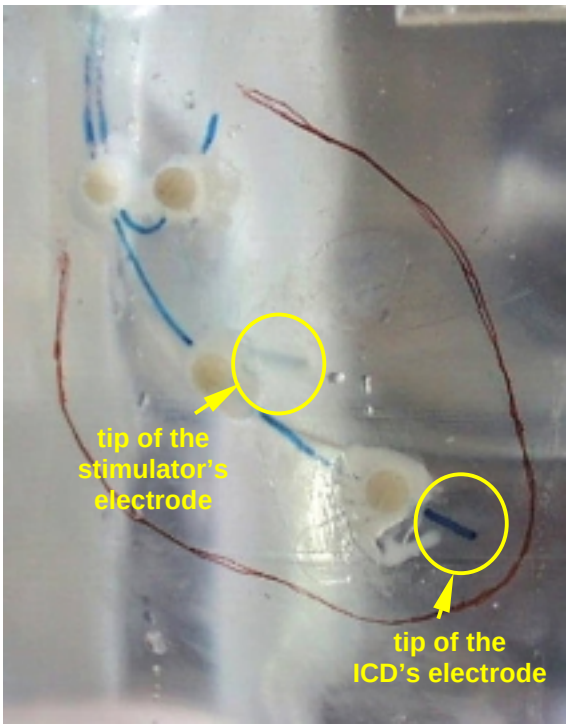


Figure 11: Location of the stimulator's and the ICD's electrodes

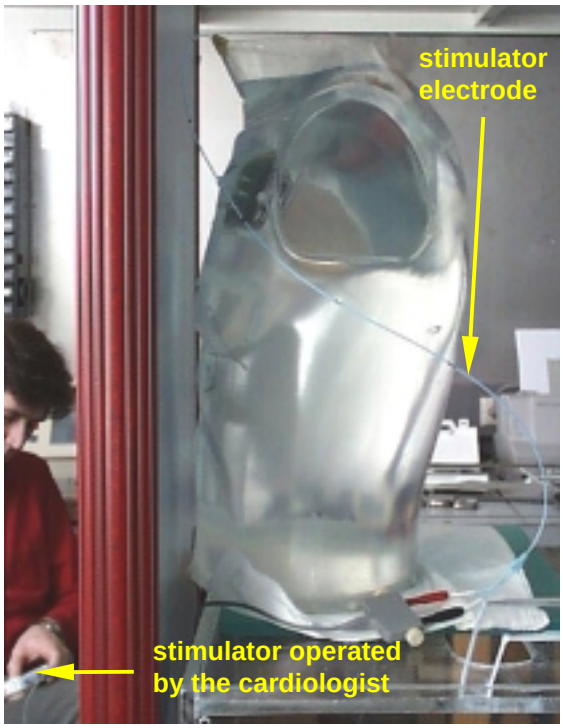


Figure 12: Phantom in worst case exposure situation during the stimulation test

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

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 the left-pectoral implantation 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.

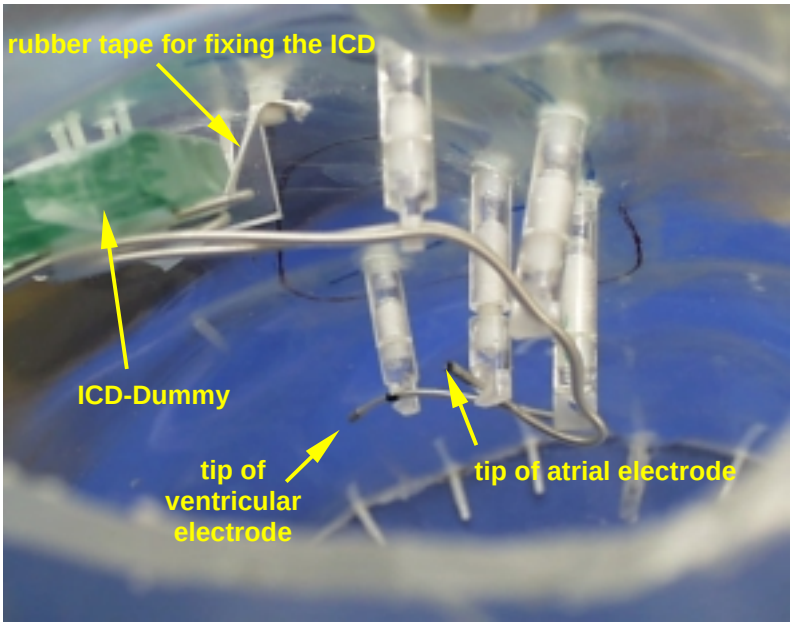


Figure 14: View from the top back into the neck of the phantom. The ICD-dummy is fixed in its fixture by a rubber tape. The atrial and ventricular electrodes are fixed in special mounting pins reflecting the conditions of a two chamber ICD. The electrodes on the photograph are not applicable to ICDs.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

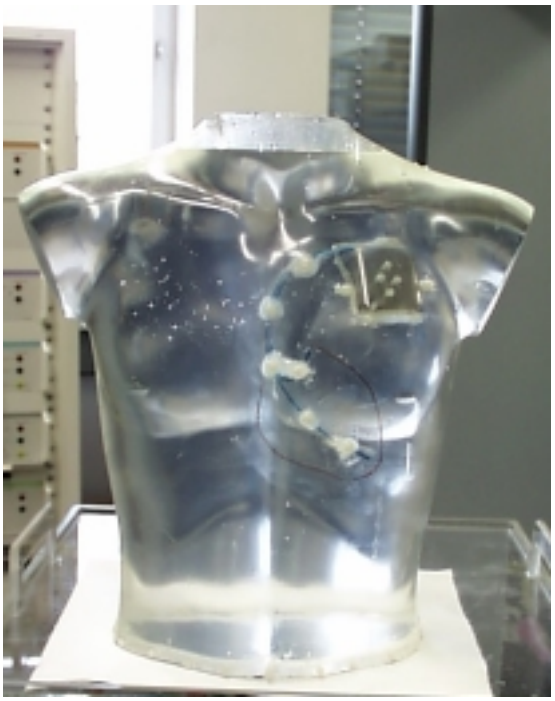


Figure 15: Phantom with implanted ICD

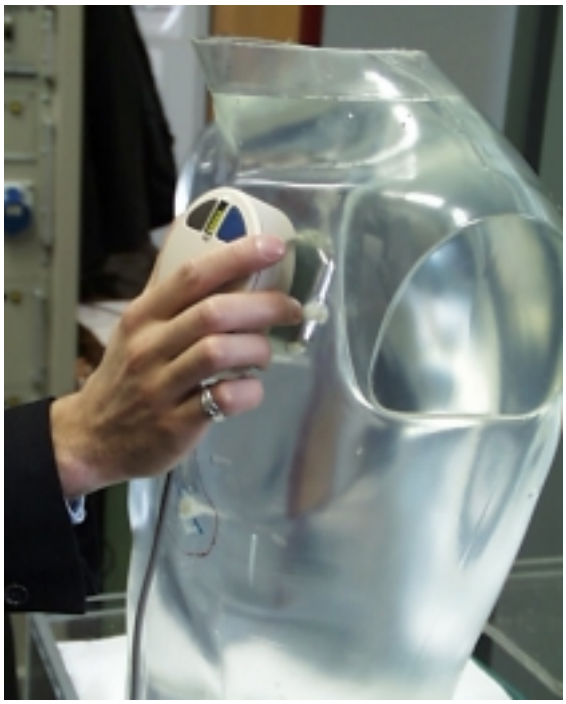


Figure 16: Phantom during the read out of the ICD's event storage

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.	ICD Model	Vendor	Type of Electrode	
			true bipolar	integrated bipolar
1	Micro Jewel II 7223 Cx	Medtronic (USA)	x	x
2	Micro Jewel 7221	Medtronic (USA)	x	x
3	Jewel PCD 7219	Medtronic (USA)	x	x
4	GEM 7227	Medtronic (USA)	x	x
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.

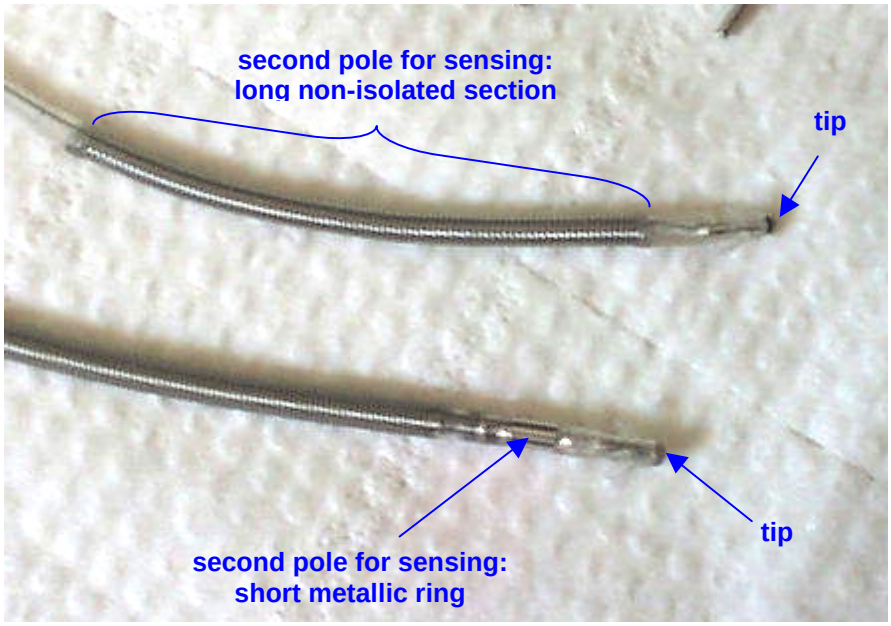


Figure 17: Lead sections of one 'integrated bipolar' (top) and one 'true bipolar' (bottom) electrode type.

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)

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.

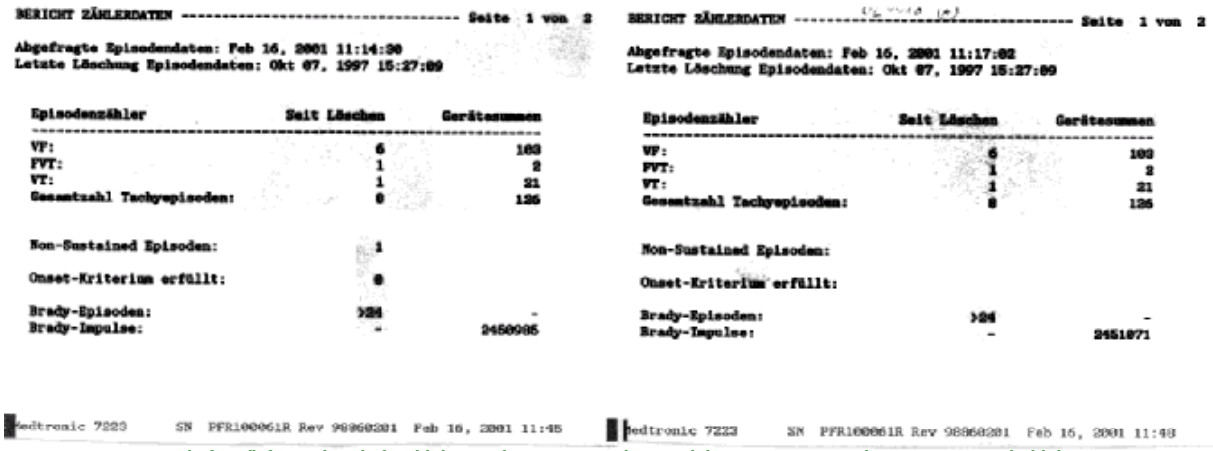
b) Currently implanted ICDs have integrated pacemakers reacting differently to magnet exposure than usual pacemakers; the integrated pacemakers of the tested devices paced properly throughout the exposition episodes.

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 ECG-memory 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



BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

Abgefragte Episodendaten: Feb 16, 2001 11:14:30
Letzte Löschung Episodendaten: Okt 07, 1997 15:27:09

Episodenzähler	Seit Löschen	Gerätesummen
VF:	6	103
FVT:	1	2
VT:	1	21
Gesamtzahl Tachyepisoden:	8	126
Non-Sustained Episoden:	1	
Onset-Kriterium erfüllt:	0	
Brady-Episoden:	>24	-
Brady-Impulse:	-	2450985

BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

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Letzte Löschung Episodendaten: Okt 07, 1997 15:27:09

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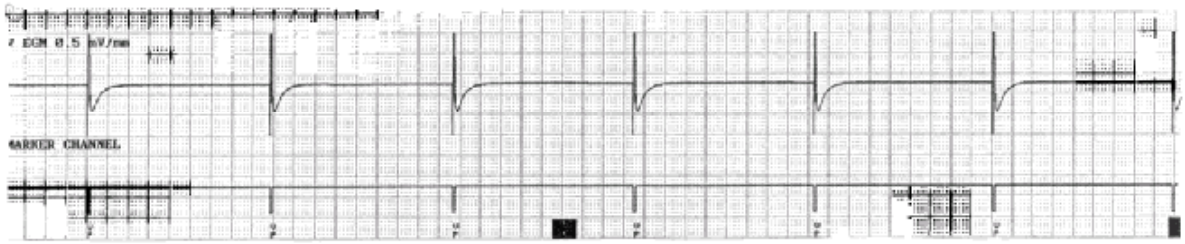
FVT:	1	2
VT:	1	21
Gesamtzahl Tachyepisoden:	8	126
Non-Sustained Episoden:		
Onset-Kriterium erfüllt:		
Brady-Episoden:	>24	-
Brady-Impulse:	-	2451071

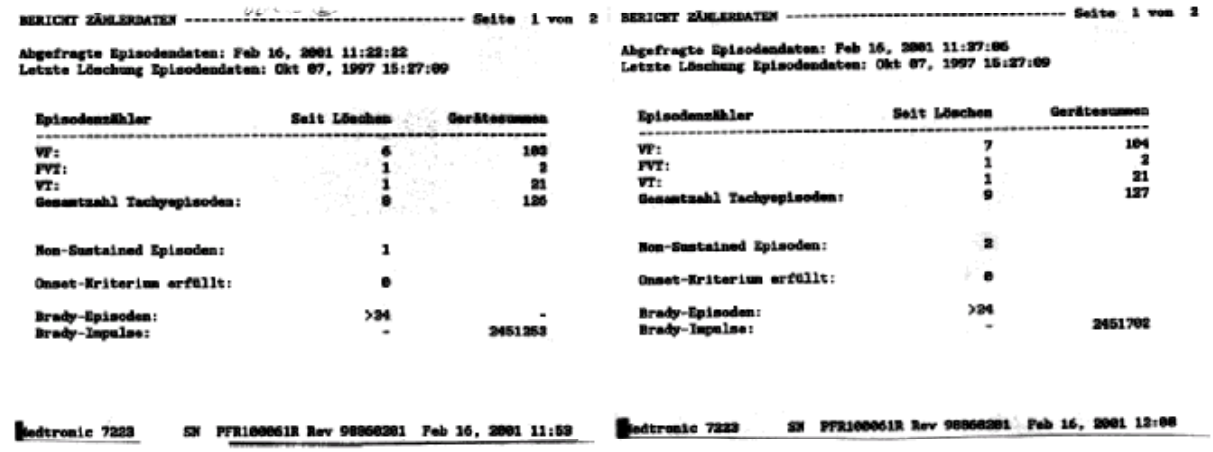
edtronic 7223 SN PFR100061R Rev 98860201 Feb 16, 2001 11:45

edtronic 7223 SN PFR100061R Rev 98860201 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.



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



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VT:	1	21
Gesamtzahl Tachyepisoden:	8	126
Non-Sustained Episoden:	1	
Onset-Kriterium erfüllt:	0	
Brady-Episoden:	>24	-
Brady-Impulse:	-	2451253

BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

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Letzte Löschung Episodendaten: Okt 07, 1997 15:27:09

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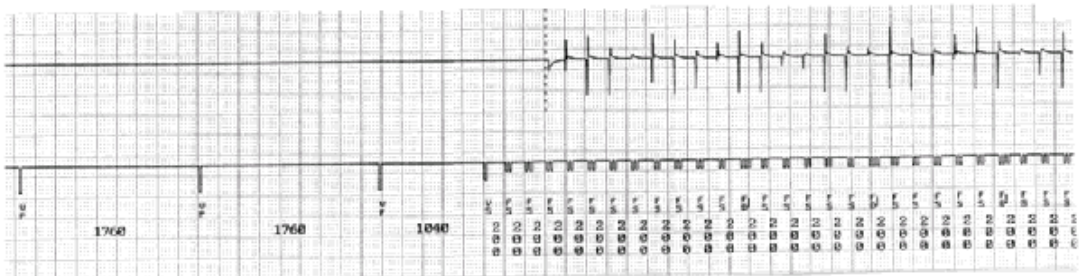
FVT:	1	2
VT:	1	21
Gesamtzahl Tachyepisoden:	9	127
Non-Sustained Episoden:	2	
Onset-Kriterium erfüllt:	0	
Brady-Episoden:	>24	
Brady-Impulse:	-	2451702

edtronic 7223 SN PFR100061R Rev 98860201 Feb 16, 2001 11:59

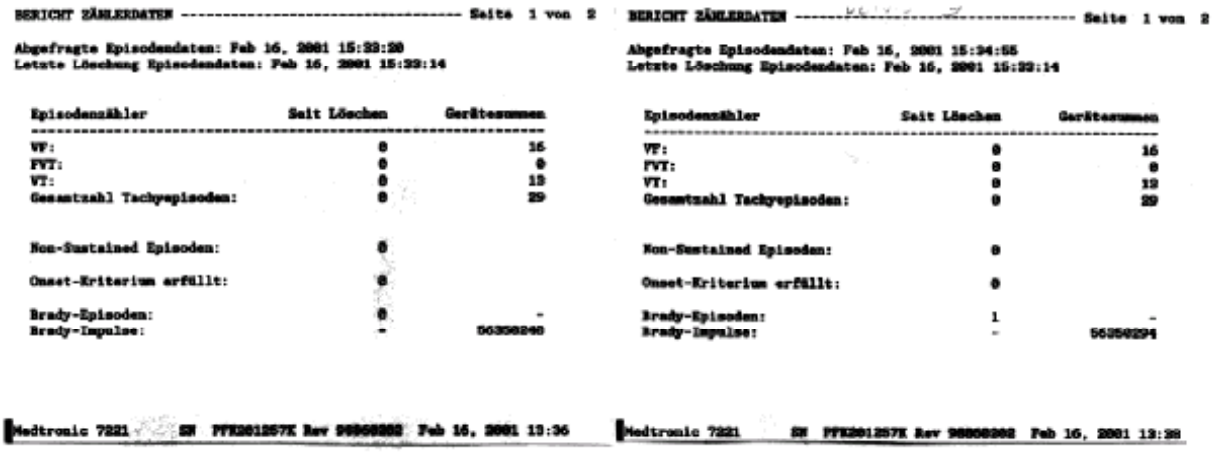
edtronic 7223 SN PFR100061R Rev 98860201 Feb 16, 2001 12:08

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



BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

Abgefragte Episodendaten: Feb 16, 2001 15:33:20
Letzte Löschung Episodendaten: Feb 16, 2001 15:33:14

Episodenzähler	Seit Löschen	Gerätesummen
VF:	0	16
FVT:	0	0
VT:	0	13
Gesamtzahl Tachyepisoden:	0	29
Non-Sustained Episoden:	0	
Onset-Kriterium erfüllt:	0	
Brady-Episoden:	0	-
Brady-Impulse:	-	56356240

Medtronic 7221 SN PFK2012S7K Rev 90868202 Feb 16, 2001 13:36

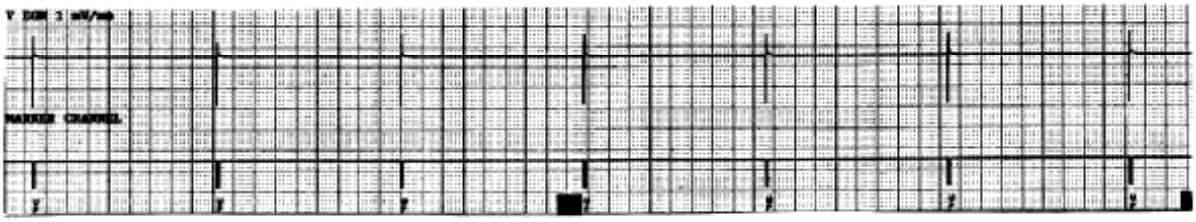
BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

Abgefragte Episodendaten: Feb 16, 2001 15:34:55
Letzte Löschung Episodendaten: Feb 16, 2001 15:33:14

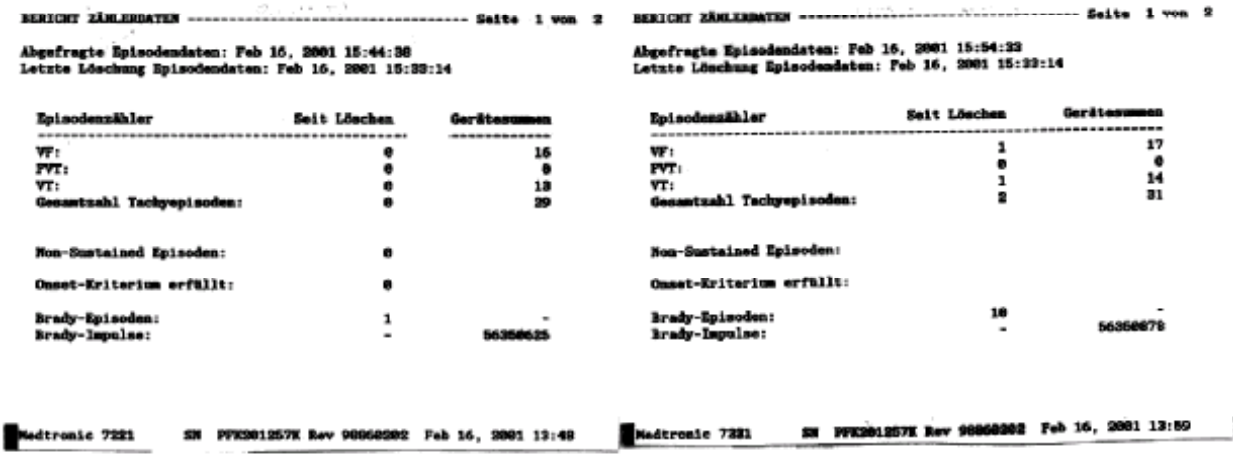
Episodenzähler	Seit Löschen	Gerätesummen
VF:	0	16
FVT:	0	0
VT:	0	13
Gesamtzahl Tachyepisoden:	0	29
Non-Sustained Episoden:	0	
Onset-Kriterium erfüllt:	0	
Brady-Episoden:	1	-
Brady-Impulse:	-	56356294

Medtronic 7221 SN PFK2012S7K Rev 90868202 Feb 16, 2001 13:38

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.



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



BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

Abgefragte Episodendaten: Feb 16, 2001 15:44:38
Letzte Löschung Episodendaten: Feb 16, 2001 15:33:14

Episodenzähler	Seit Löschen	Gerätesummen
VF:	0	16
FVT:	0	0
VT:	0	13
Gesamtzahl Tachyepisoden:	0	29
Non-Sustained Episoden:	0	
Onset-Kriterium erfüllt:	0	
Brady-Episoden:	1	-
Brady-Impulse:	-	56356625

Medtronic 7221 SN PFK2012S7K Rev 90868202 Feb 16, 2001 13:48

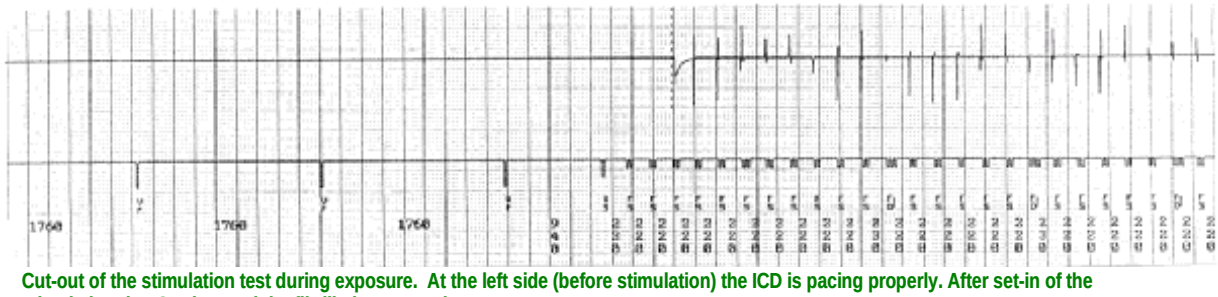
BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

Abgefragte Episodendaten: Feb 16, 2001 15:54:33
Letzte Löschung Episodendaten: Feb 16, 2001 15:33:14

Episodenzähler	Seit Löschen	Gerätesummen
VF:	1	17
FVT:	0	0
VT:	1	14
Gesamtzahl Tachyepisoden:	2	31
Non-Sustained Episoden:		
Onset-Kriterium erfüllt:		
Brady-Episoden:	10	-
Brady-Impulse:	-	56356679

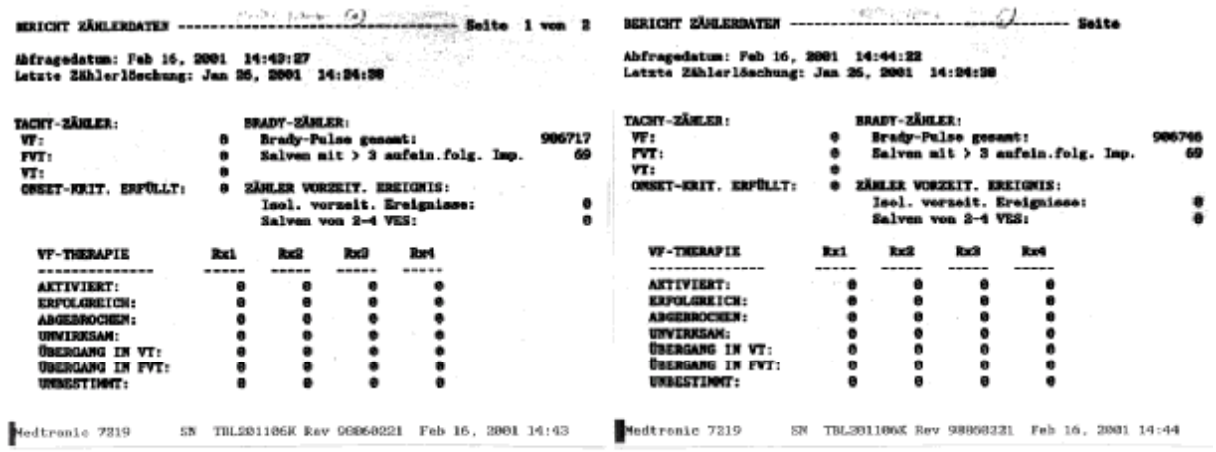
Medtronic 7221 SN PFK2012S7K Rev 90868202 Feb 16, 2001 13:59

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.

Example Results for ICD Model Jewel PCD 7219



BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

Abfragedatum: Feb 16, 2001 14:43:27
Letzte Zählerlöschung: Jan 26, 2001 14:24:38

TACHY-ZÄHLER:		BRADY-ZÄHLER:	
VF:	0	Brady-Pulse gesamt:	906717
FVT:	0	Salven mit > 3 aufein.folg. Imp.	69
VT:	0		
ONSET-KRIT. ERFÜLLT:	0	ZÄHLER VORZEIT. EREIGNIS:	
		Isol. vorzeit. Ereignisse:	0
		Salven von 2-4 VES:	0

VF-THERAPIE	Rx1	Rx2	Rx3	Rx4
AKTIVIERT:	0	0	0	0
ERFOLGREICH:	0	0	0	0
ABGEBROCHEN:	0	0	0	0
UNWIRKSAM:	0	0	0	0
ÜBERGANG IN VT:	0	0	0	0
ÜBERGANG IN FVT:	0	0	0	0
UNBESTIMMT:	0	0	0	0

Medtronic 7219 SN TBL301106K Rev 98860221 Feb 16, 2001 14:43

BERICHT ZÄHLERDATEN ---------- Seite

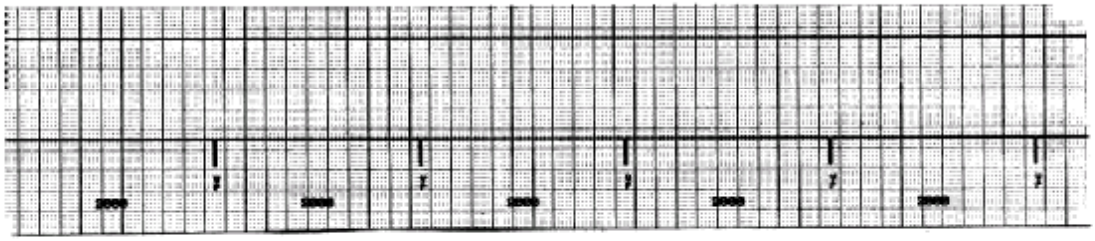
Abfragedatum: Feb 16, 2001 14:44:22
Letzte Zählerlöschung: Jan 26, 2001 14:24:38

TACHY-ZÄHLER:		BRADY-ZÄHLER:	
VF:	0	Brady-Pulse gesamt:	906766
FVT:	0	Salven mit > 3 aufein.folg. Imp.	69
VT:	0		
ONSET-KRIT. ERFÜLLT:	0	ZÄHLER VORZEIT. EREIGNIS:	
		Isol. vorzeit. Ereignisse:	0
		Salven von 2-4 VES:	0

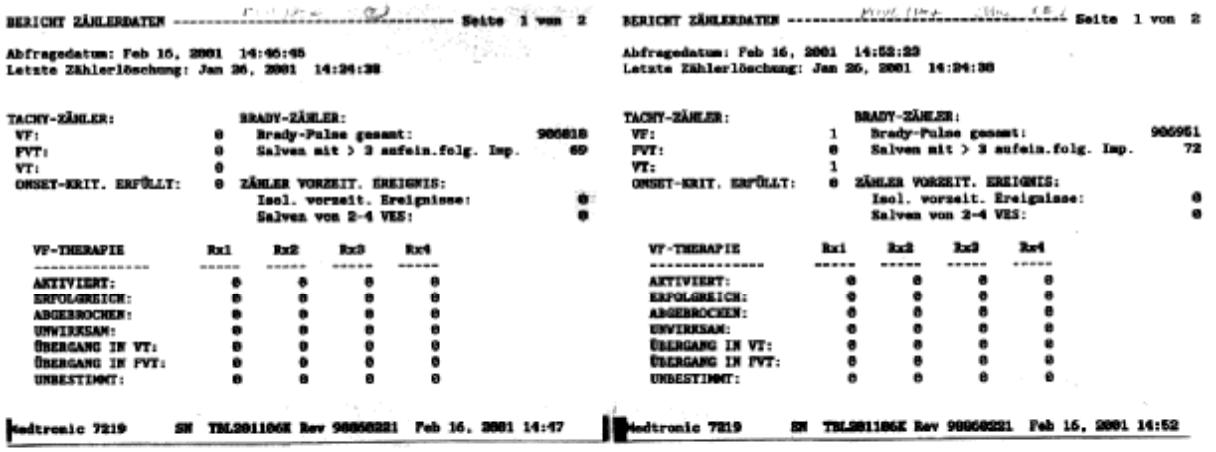
VF-THERAPIE	Rx1	Rx2	Rx3	Rx4
AKTIVIERT:	0	0	0	0
ERFOLGREICH:	0	0	0	0
ABGEBROCHEN:	0	0	0	0
UNWIRKSAM:	0	0	0	0
ÜBERGANG IN VT:	0	0	0	0
ÜBERGANG IN FVT:	0	0	0	0
UNBESTIMMT:	0	0	0	0

Medtronic 7219 SN TBL301106K Rev 98860221 Feb 16, 2001 14:44

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.



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



BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

Abfragedatum: Feb 16, 2001 14:46:45
Letzte Zählerlöschung: Jan 26, 2001 14:24:38

TACHY-ZÄHLER:		BRADY-ZÄHLER:	
VF:	0	Brady-Pulse gesamt:	906818
FVT:	0	Salven mit > 3 aufein.folg. Imp.	69
VT:	0		
ONSET-KRIT. ERFÜLLT:	0	ZÄHLER VORZEIT. EREIGNIS:	
		Isol. vorzeit. Ereignisse:	0
		Salven von 2-4 VES:	0

VF-THERAPIE	Rx1	Rx2	Rx3	Rx4
AKTIVIERT:	0	0	0	0
ERFOLGREICH:	0	0	0	0
ABGEBROCHEN:	0	0	0	0
UNWIRKSAM:	0	0	0	0
ÜBERGANG IN VT:	0	0	0	0
ÜBERGANG IN FVT:	0	0	0	0
UNBESTIMMT:	0	0	0	0

Medtronic 7219 SN TBL301106K Rev 98860221 Feb 16, 2001 14:47

BERICHT ZÄHLERDATEN ---------- Seite 1 von 2

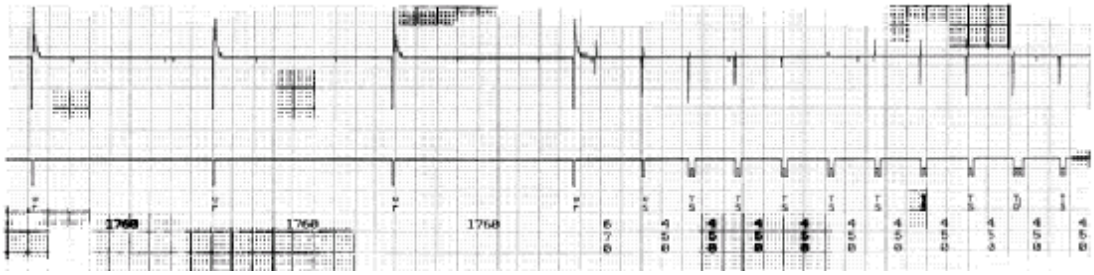
Abfragedatum: Feb 16, 2001 14:52:29
Letzte Zählerlöschung: Jan 26, 2001 14:24:38

TACHY-ZÄHLER:		BRADY-ZÄHLER:	
VF:	1	Brady-Pulse gesamt:	906961
FVT:	0	Salven mit > 3 aufein.folg. Imp.	72
VT:	1		
ONSET-KRIT. ERFÜLLT:	0	ZÄHLER VORZEIT. EREIGNIS:	
		Isol. vorzeit. Ereignisse:	0
		Salven von 2-4 VES:	0

VF-THERAPIE	Rx1	Rx2	Rx3	Rx4
AKTIVIERT:	0	0	0	0
ERFOLGREICH:	0	0	0	0
ABGEBROCHEN:	0	0	0	0
UNWIRKSAM:	0	0	0	0
ÜBERGANG IN VT:	0	0	0	0
ÜBERGANG IN FVT:	0	0	0	0
UNBESTIMMT:	0	0	0	0

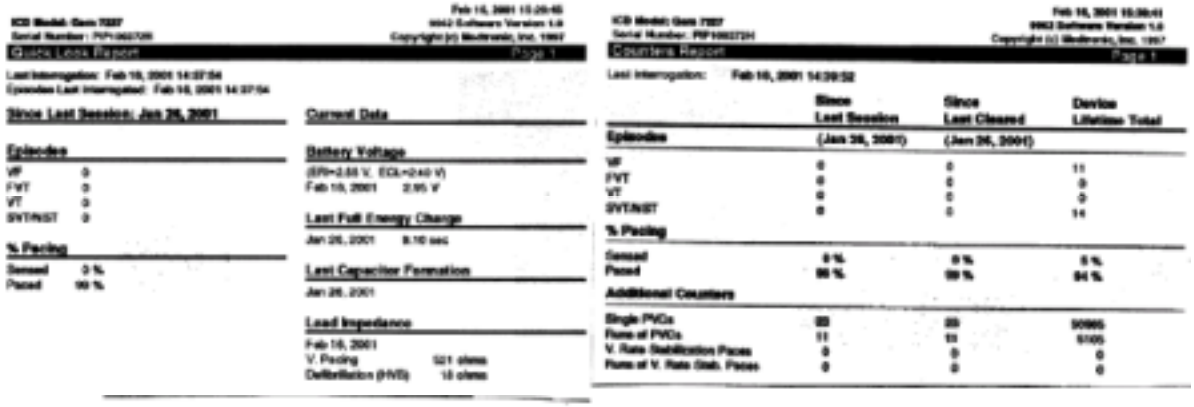
Medtronic 7219 SN TBL301106K Rev 98860221 Feb 16, 2001 14:52

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.

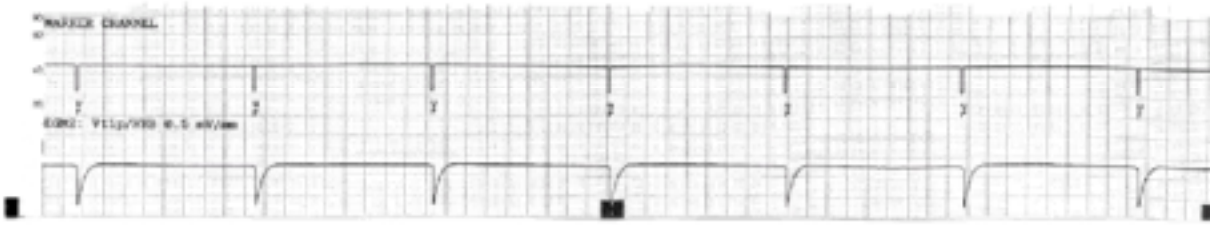


Cut-out of the stimulation test during exposure. At the left side (before stimulation) the ICD is pacing properly. After set-in of the stimulation the ICD detected the fibrillation correctly.

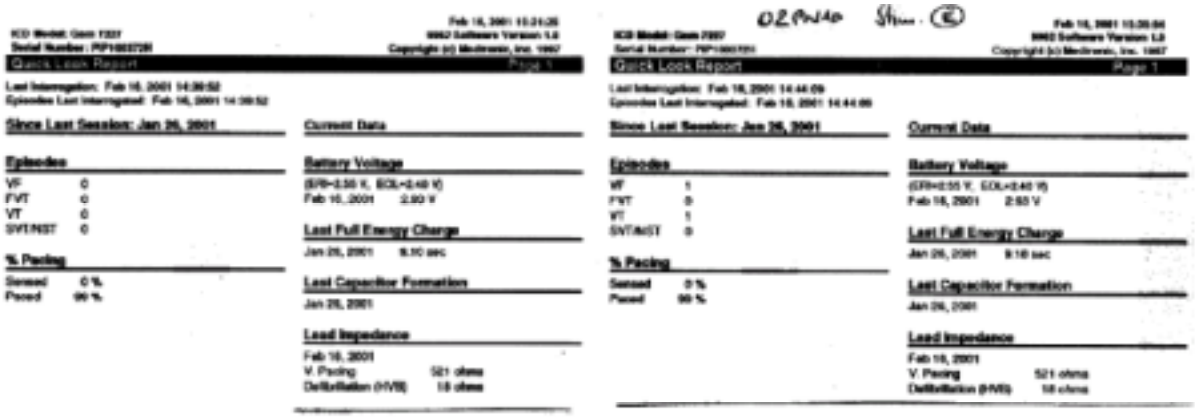
Example Results for ICD Model GEM 7227



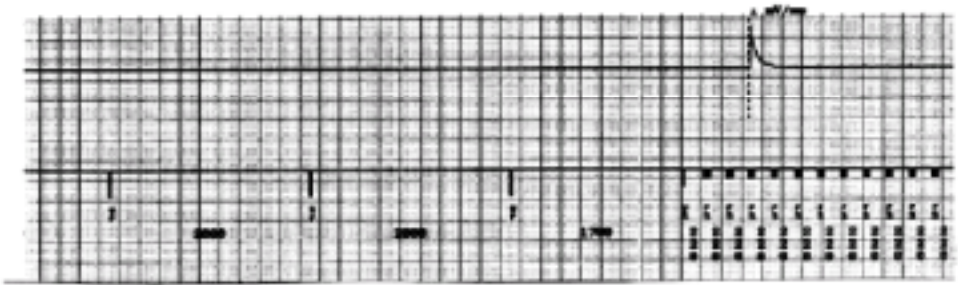
Event counter status before (left page) and after (right page) exposure to the metal detector systems. The event counter hold the same values before and after exposure, i.e. no episodes are falsely sensed during exposure.



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

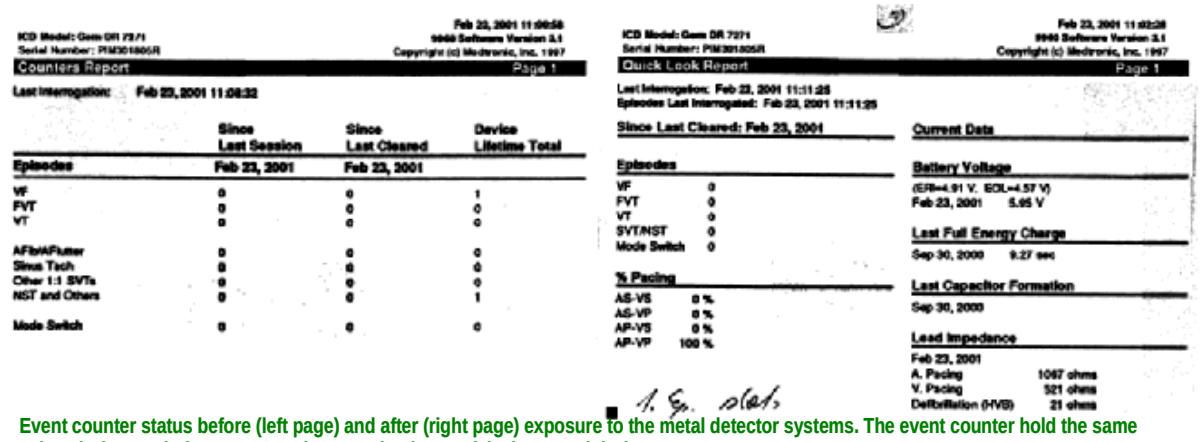


Event counter status before (left) and after (right) exposure to the metal detectors during the stimulation test. The event counters for ventricular fibrillation (VF) as well as ventricular tachycardia (VT) are increased by 1, i.e. the episodes were detected properly by the ICD during exposure.



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.

Example Results for ICD Model GEM DR 7271



Counters Report — Page 1

Last Interrogation: Feb 23, 2001 11:08:32

Episodes	Since Last Session Feb 23, 2001	Since Last Cleared Feb 23, 2001	Device Lifetime Total
VF	0	0	1
FVT	0	0	0
VT	0	0	0
AFib/AFlutter	0	0	0
Sinus Tach	0	0	0
Other 1:1 SVTs	0	0	0
NST and Others	0	0	1
Mode Switch	0	0	0

Quick Look Report — Page 1

Last Interrogation: Feb 23, 2001 11:11:25
Episodes Last Interrogated: Feb 23, 2001 11:11:25

Since Last Cleared: Feb 23, 2001

Episodes	
VF	0
FVT	0
VT	0
SVT/NST	0
Mode Switch	0

% Pacing	
AS-VS	0 %
AS-VP	0 %
AP-VS	0 %
AP-VP	100 %

Current Data

Battery Voltage
(ERI=4.91 V, EOL=4.57 V)
Feb 23, 2001 5.95 V

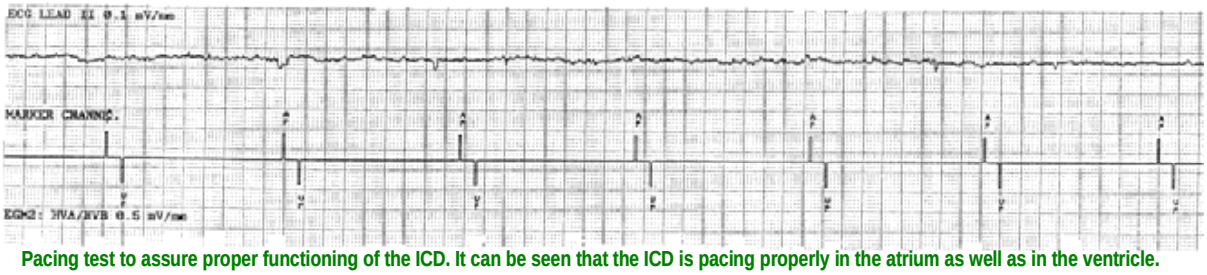
Last Full Energy Charge
Sep 30, 2000 9.27 sec

Last Capacitor Formation
Sep 30, 2000

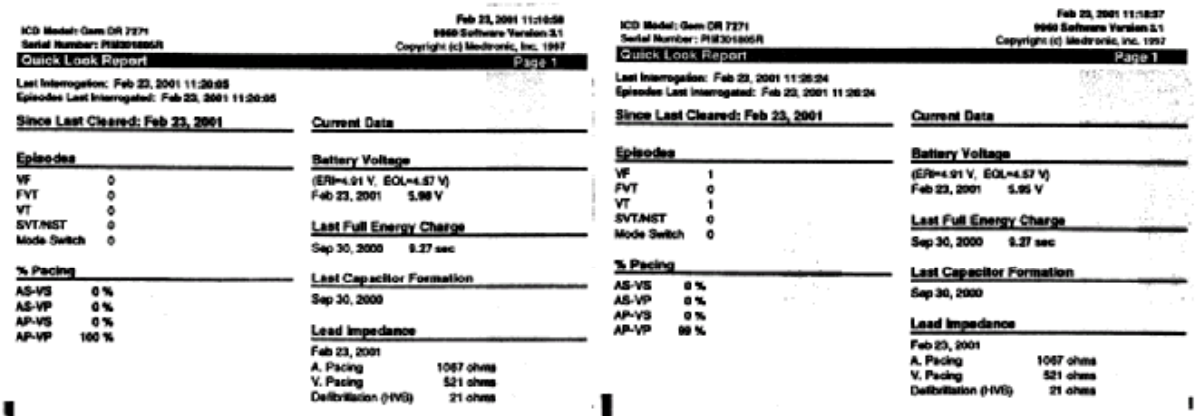
Lead Impedance
Feb 23, 2001

A. Pacing	1067 ohms
V. Pacing	521 ohms
Defibrillation (HVB)	21 ohms

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.



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.



Quick Look Report — Page 1

Last Interrogation: Feb 23, 2001 11:20:05
Episodes Last Interrogated: Feb 23, 2001 11:20:05

Since Last Cleared: Feb 23, 2001

Episodes	
VF	0
FVT	0
VT	0
SVT/NST	0
Mode Switch	0

% Pacing	
AS-VS	0 %
AS-VP	0 %
AP-VS	0 %
AP-VP	100 %

Current Data

Battery Voltage
(ERI=4.91 V, EOL=4.57 V)
Feb 23, 2001 5.98 V

Last Full Energy Charge
Sep 30, 2000 9.27 sec

Last Capacitor Formation
Sep 30, 2000

Lead Impedance
Feb 23, 2001

A. Pacing	1067 ohms
V. Pacing	521 ohms
Defibrillation (HVB)	21 ohms

Quick Look Report — Page 1

Last Interrogation: Feb 23, 2001 11:26:24
Episodes Last Interrogated: Feb 23, 2001 11:26:24

Since Last Cleared: Feb 23, 2001

Episodes	
VF	1
FVT	0
VT	1
SVT/NST	0
Mode Switch	0

% Pacing	
AS-VS	0 %
AS-VP	0 %
AP-VS	0 %
AP-VP	99 %

Current Data

Battery Voltage
(ERI=4.91 V, EOL=4.57 V)
Feb 23, 2001 5.95 V

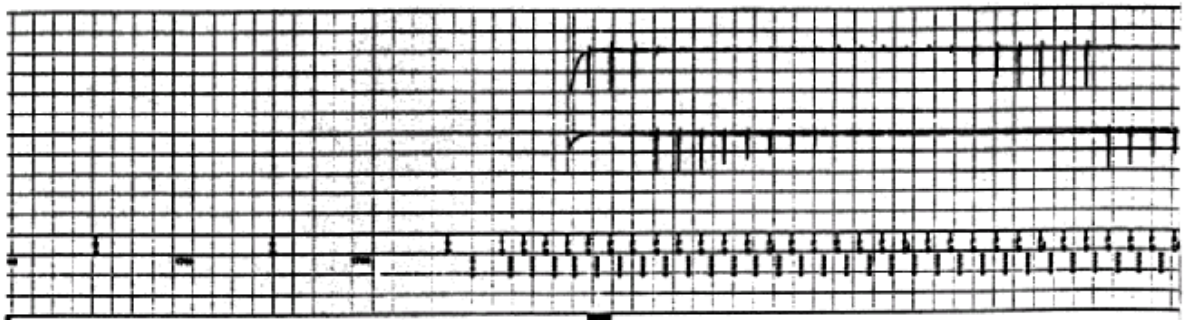
Last Full Energy Charge
Sep 30, 2000 9.27 sec

Last Capacitor Formation
Sep 30, 2000

Lead Impedance
Feb 23, 2001

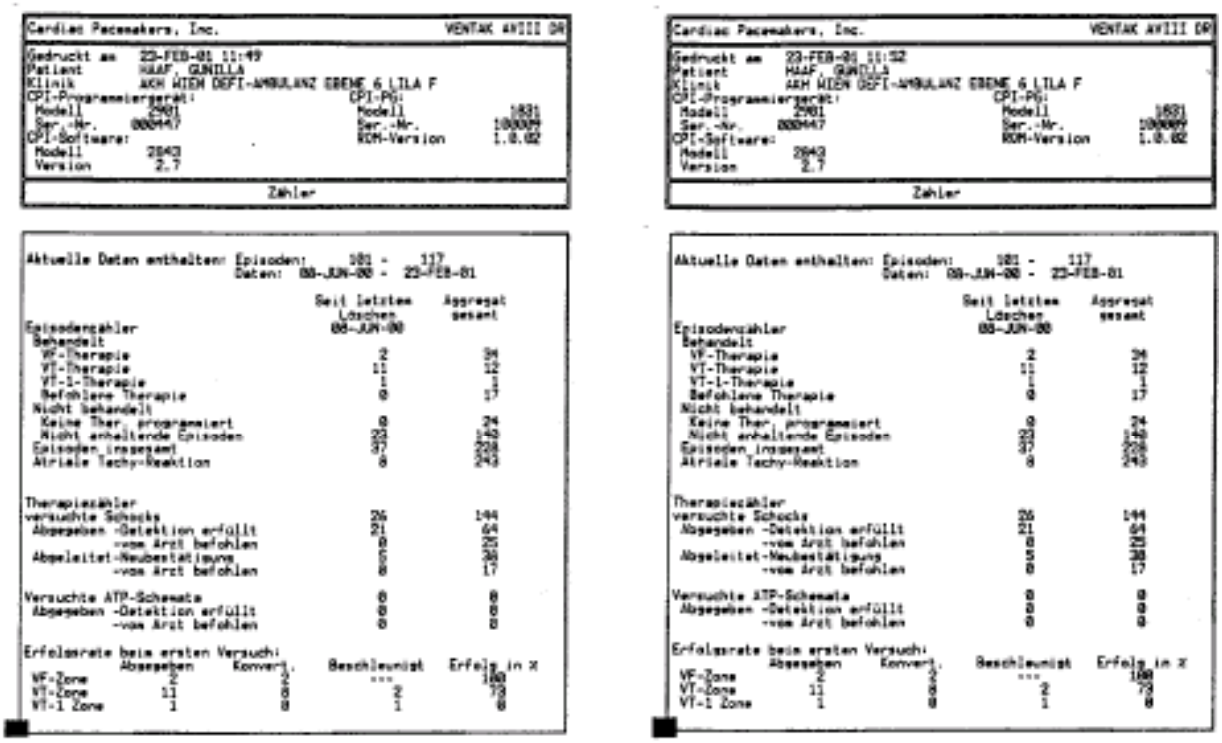
A. Pacing	1067 ohms
V. Pacing	521 ohms
Defibrillation (HVB)	21 ohms

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.

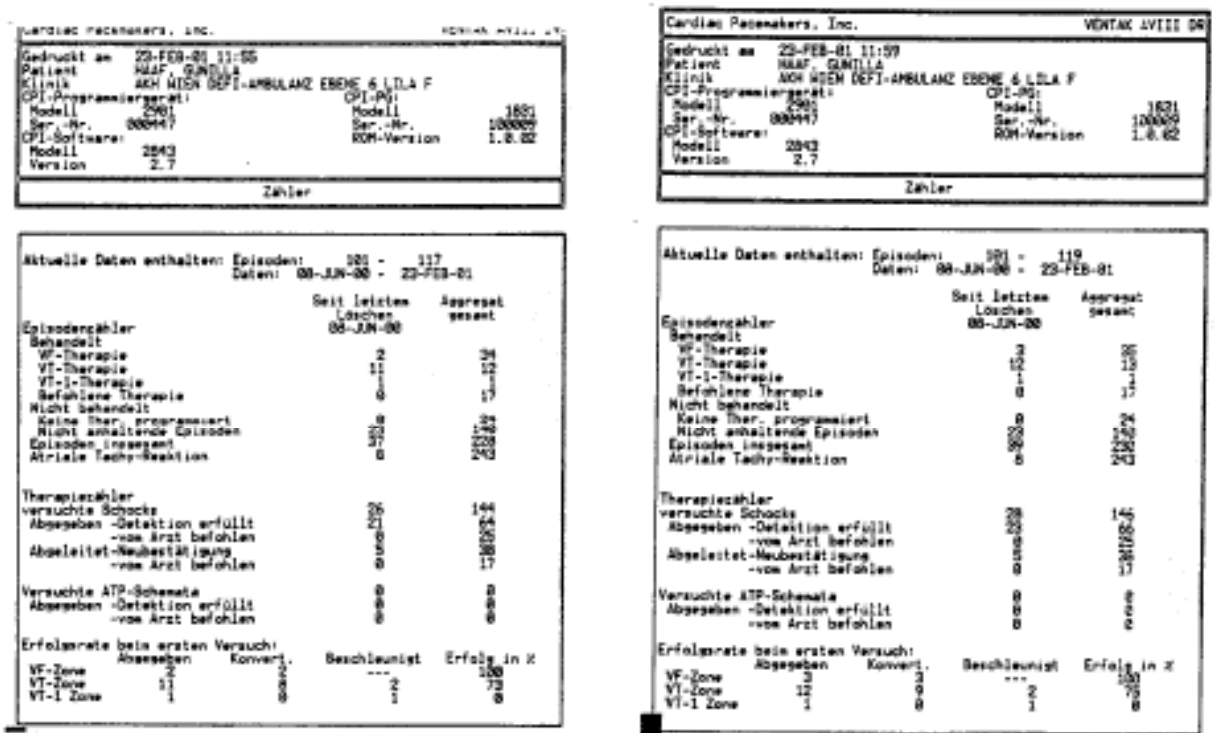


Cut-out of the stimulation test during exposure. At the left side (before stimulation) the ICD is pacing properly. After set-in of the stimulation the ICD detected the fibrillation correctly.

Example Results for ICD Model VENTAK AVIII DR

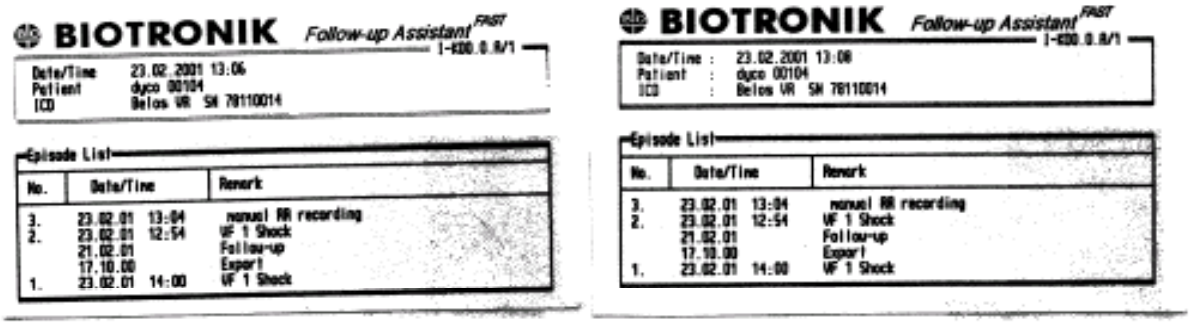


Event counter status before (left page) and after (right page) exposure to the metal detector systems. The event counter hold the same values before and after exposure, i.e. no episodes are falsely sensed during exposure.



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



BIOTRONIK Follow-up Assistant FAST

Date/Time 23.02.2001 13:06
Patient dyco 00104
ICD Belos VR SN 70110014

Episode List

No.	Date/Time	Remark
3.	23.02.01 13:04	manual RR recording
2.	23.02.01 12:54	VF 1 Shock
	21.02.01	Follow-up
	17.10.00	Export
1.	23.02.01 14:00	VF 1 Shock

BIOTRONIK Follow-up Assistant FAST

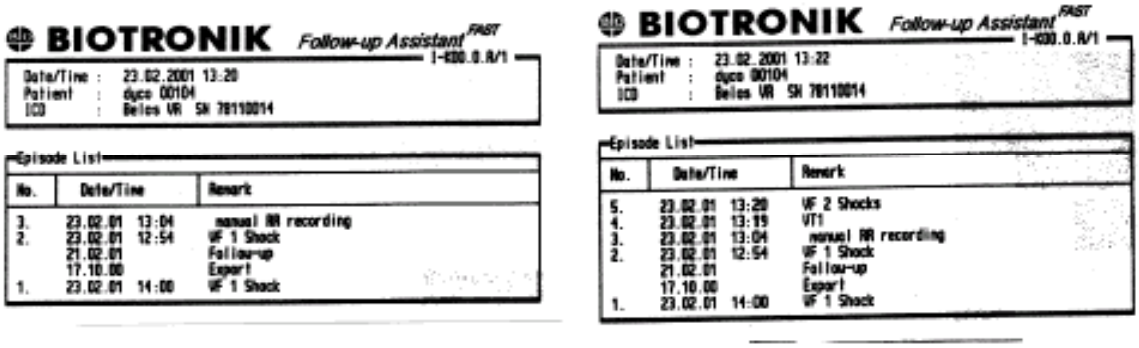
Date/Time : 23.02.2001 13:08
Patient : dyco 00104
ICD : Belos VR SN 70110014

Episode List

No.	Date/Time	Remark
3.	23.02.01 13:04	manual RR recording
2.	23.02.01 12:54	VF 1 Shock
	21.02.01	Follow-up
	17.10.00	Export
1.	23.02.01 14:00	VF 1 Shock

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.

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



BIOTRONIK Follow-up Assistant FAST

Date/Time : 23.02.2001 13:20
Patient : dyco 00104
ICD : Belos VR SN 70110014

Episode List

No.	Date/Time	Remark
3.	23.02.01 13:04	manual RR recording
2.	23.02.01 12:54	VF 1 Shock
	21.02.01	Follow-up
	17.10.00	Export
1.	23.02.01 14:00	VF 1 Shock

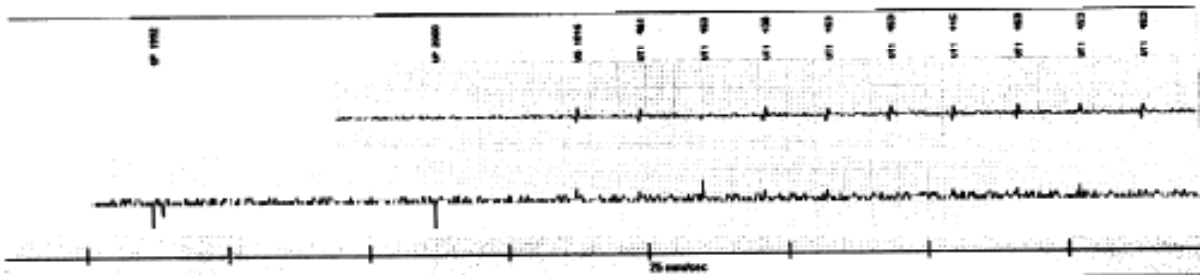
BIOTRONIK Follow-up Assistant FAST

Date/Time : 23.02.2001 13:22
Patient : dyco 00104
ICD : Belos VR SN 70110014

Episode List

No.	Date/Time	Remark
5.	23.02.01 13:20	VF 2 Shocks
4.	23.02.01 13:19	VT1
3.	23.02.01 13:04	manual RR recording
2.	23.02.01 12:54	VF 1 Shock
	21.02.01	Follow-up
	17.10.00	Export
1.	23.02.01 14:00	VF 1 Shock

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 signal[1].

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

$A = 500\ cm^2$

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 V for the 02PN10

V_{pp} = 0.24 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

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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.

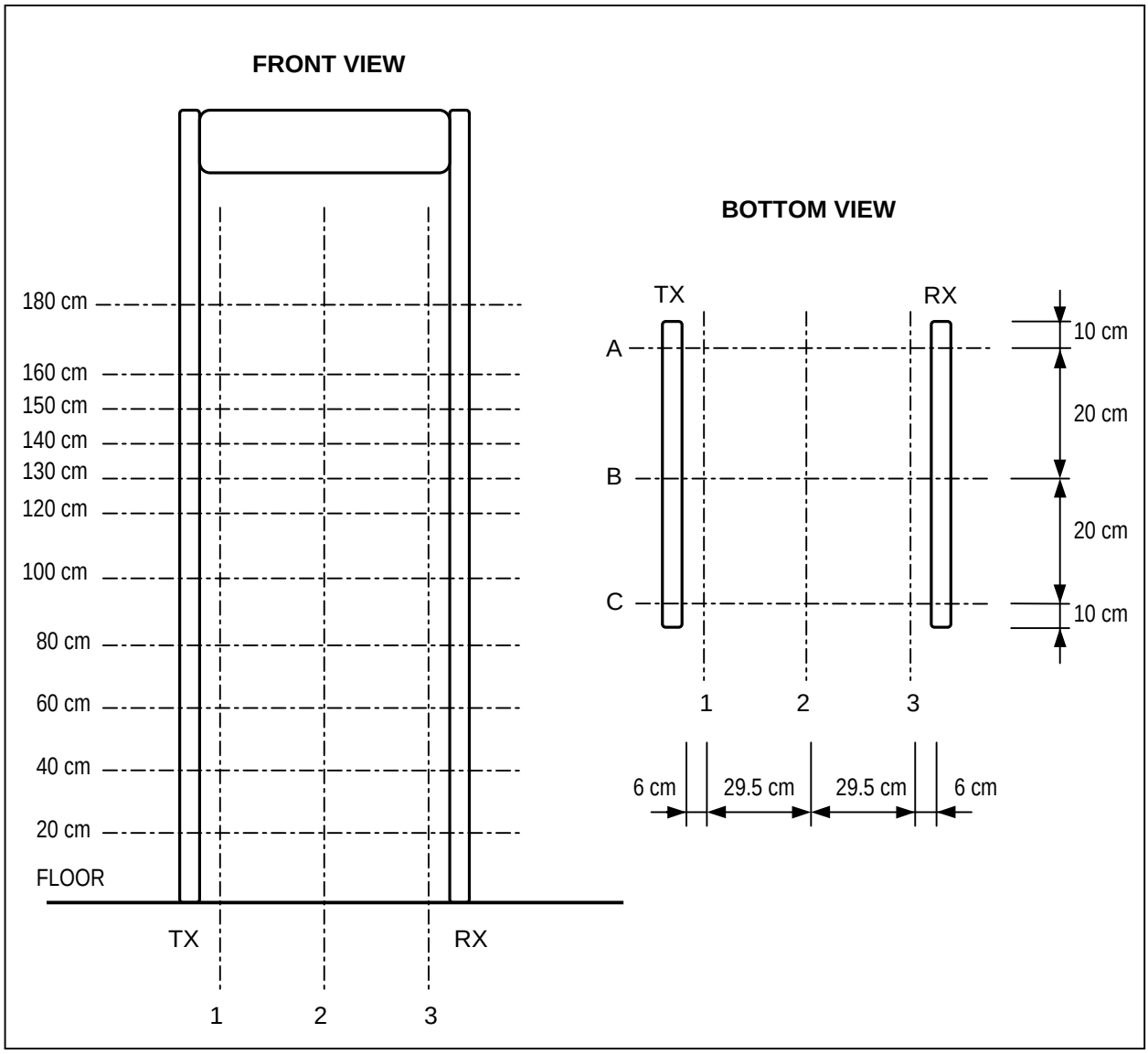

Figure A.1: Definition of measurement grid for the measurements of magnetic induction.

Metal Detector Type 02PN10

		magnetic Induction B_{rms} [µT]		
		A	**B**	**C**
1	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
	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
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
	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
3	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
	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

Table A.1: 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]		
		A	**B**	**C**
1	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
	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
2	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
	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
3	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
	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

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

A.2 Parameter Settings of examined ICD Models

Micro Jewel II 7223 Cx

```
PARAMETERWERTEBERICHT -------------------------------- Seite  1 von  4

     AKTIV.     INTERV.
    --------    --------
VF   AUS         400 ms
FVT  AUS         600 ms
VT   AUS         600 ms

      NID          NID
     INITIAL    NEU-ERK.
    ---------   --------
VF    12/16        6/8
VT        8          4

Empfindl.(mV):    0,15

             ZUSÄTZL. VT-ERKENNUNGSKRITERIEN
          ------------------------------------
STABILITÄT     AUS
     ONSET     AUS
EGM-BREITE     AUS

EGM-Ableitun   P-/S nach P+/S        EGM-Bereich (mV):          ±7,5

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PARAMETERWERTEBERICHT -------------------------------- Seite  2 von  4

VF-THERAPIE:              1       2       3       4       5       6
                       ------- ------- ------- ------- ------- -------
VF-Therapiestatus:       AUS     AUS     AUS     AUS     AUS     AUS
Energie(J):               30      30      30      30      30      30
Impulsform:             BIPH    BIPH    BIPH    BIPH    BIPH    BIPH
Strompfad:              AX>B    AX>B    AX>B    AX>B    AX>B    AX>B
               VF Nach Erster Ladung bestätigen:          JA
FVT-THERAPIE:             1       2       3       4       5       6
                       ------- ------- ------- ------- ------- -------
FVT-Therapiestatus:      AUS     AUS     AUS     AUS     AUS     AUS
Therapie-Art:           RAMP+     KV      KV      KV      KV      KV
# Initial-Impulse:         3
R-S1 Interv. =(%RR):      75
S1S2(RAMP+)=(%RR):        69
S2SN(RAMP+)=(%RR):        66
Interv.-Abn.(ms):
# Sequenzen:               5
SMART-Modus:             AUS
Energie(J):                      20      30      30      30      30
Impulsform:                    BIPH    BIPH    BIPH    BIPH    BIPH
Strompfad:                     AX>B    AX>B    AX>B    AX>B    AX>B
           Mindestintervall Antitachy-Stim. (ms):      200

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```
PARAMETERWERTEBERICHT -------------------------------- Seite  3 von  4

VT-THERAPIE:              1       2       3       4       5       6
                       ------- ------- ------- ------- ------- -------
VT-Therapiestatus:       AUS     AUS     AUS     AUS     AUS     AUS
Therapie-Art:           RAMP      KV      KV      KV      KV      KV
# Initial-Impulse:         6
R-S1 Interv. =(%RR):      91
S1S2(RAMP+)=(%RR):
S2SN(RAMP+)=(%RR):
Interv.-Abn.(ms):         10
# Sequenzen:               5
SMART-Modus:             EIN
Energie(J):                      30      30      30      30      30
Impulsform:                    BIPH    BIPH    BIPH    BIPH    BIPH
Strompfad:                     AX>B    AX>B    AX>B    AX>B    AX>B

        Mindestintervall Antitachy-Stim. (ms):      200

GEM.ANTITACHY-STIMULATIONSTHERAPIE:  GEM. KV-THERAPIE:
  Impulsdauer(ms):            1,6      KV-Verzögerung(ms):          0
  Amplitude(V):               8,0
  Ausbl.n.Stim.(ms):          240

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```
PARAMETERWERTEBERICHT -------------------------------- Seite  4 von  4

Stimulationsmodus:   VVI      Amplitude(V):        3,0   ( 5,0)
Stimul.freq(/min):    34      Impulsdauer(ms):     0,6   ( 1,6)
Hysterese(/min):     AUS      Ausbl.n.Stim.(ms):   240   ( 240)
Empfindl.(mV):      0,15      () = Beim Laden und Post-Schock.

SPEICHEROPTION:                                       10 Min EGM

  EPISODENDATEN:
    EGM vor Tachykardiebeginn speichern:                    NEIN
    EGM beim Laden speichern:                                 JA

  EREIGNISTRENDDATEN:
    Aufzeichnungslänge:                                  90 Tage
    Aufzeichnung Ereignistrends starten am:  Okt 10, 1997 07:27
    Vorzeitige Ereignisreizschwelle (%):                      69

  R-R-INTERVALLDATEN:
    Speicherungslänge:                                      KURZ

HOLTER-TELEMETRIE:
  Dauer (Stunden):                                           AUS

INT. FÜR AUTO. KONDENSATORAUFL. (Mon):                         6
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PARAMETERWERTEBERICHT ---------- Seite 1 von 4

	AKTIV.	INTERV.
VF	AUS	400 ms
FVT	AUS	230 ms
VT	AUS	600 ms

	NID INITIAL	NID NEU-ERK.
VF	12/16	6/8
VT	8	4

Empfindl.(mV): 0,15

ZUSÄTZL. VT-ERKENNUNGSKRITERIEN

STABILITÄT	AUS
ONSET	AUS

EGM-ABLTG: HVA nach HVB EGM-BEREICH(mV): ±15

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PARAMETERWERTEBERICHT ---------- Seite 2 von 4

VF-THERAPIE:	1	2	3	4	5	6
VF-Therapiestatus:	AUS	AUS	AUS	AUS	AUS	AUS
Energie(J):	34	34	34	34	34	34
Impulsform:	BIPH	BIPH	BIPH	BIPH	BIPH	BIPH
Strompfad:	AX>B	AX>B	AX>B	AX>B	AX>B	AX>B

VF Nach Erster Ladung bestätigen: NEIN

FVT-THERAPIE:	1	2	3	4	5	6
FVT-Therapiestatus:	AUS	AUS	AUS	AUS	AUS	AUS
Therapie-Art:	BURST	KV	KV	KV	KV	KV
# Initial-Impulse:	6					
R-S1 Interv. =(%RR):	84					
S1S2(RAMP+)=(%RR):						
S2SN(RAMP+)=(%RR):						
Interv.-Abn.(ms):	10					
# Sequenzen:	3					
Energie(J):		34	34	34	34	34
Impulsform:		BIPH	BIPH	BIPH	BIPH	BIPH
Strompfad:		AX>B	AX>B	AX>B	AX>B	AX>B

Mindestintervall Antitachy-Stim. (ms): 200

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PARAMETERWERTEBERICHT ---------- Seite 3 von 4

VT-THERAPIE:	1	2	3	4	5	6
VT-Therapiestatus:	AUS	AUS	AUS	AUS	AUS	AUS
Therapie-Art:	BURST	RAMP	RAMP+	KV	KV	KV
# Initial-Impulse:	6	8	3			
R-S1 Interv. =(%RR):	78	81	81			
S1S2(RAMP+)=(%RR):			69			
S2SN(RAMP+)=(%RR):			66			
Interv.-Abn.(ms):	10	10				
# Sequenzen:	4	4	4			
Energie(J):				34	34	34
Impulsform:				BIPH	BIPH	BIPH
Strompfad:				AX>B	AX>B	AX>B

Mindestintervall Antitachy-Stim. (ms): 200

GEM.ANTITACHY-STIMULATIONSTHERAPIE:		GEM. KV-THERAPIE:	
Impulsdauer(ms):	1,6	KV-Verzögerung(ms):	0
Amplitude(V):	8,0		
Ausbl.n.Stim.(ms):	240		

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PARAMETERWERTEBERICHT ---------- Seite 4 von 4

Stimulationsmodus:	VVI	Amplitude(V):	2,0 (5,0)
Stimul.freq(/min):	34	Impulsdauer(ms):	0,5 (1,6)
Hysterese(/min):	AUS	Ausbl.n.Stim.(ms):	240 (240)
Empfindl.(mV):	0,15	() = Beim Laden und Post-Schock.	

SPEICHEROPTION: 10 Min EGM

EPISODENDATEN:
- EGM vor Tachykardiebeginn speichern: JA
- EGM beim Laden speichern: JA

EREIGNISTRENDDATEN:
- Aufzeichnungslänge: 90 Tage
- Aufzeichnung Ereignistrends starten am: Dez 10, 1999 14:54
- Vorzeitige Ereignisreizschwelle (%): 69

R-R-INTERVALLDATEN:
- Speicherungslänge: KURZ

HOLTER-TELEMETRIE:
- Dauer (Stunden): AUS

INT. FÜR AUTO. KONDENSATORAUFL. (Mon): 6

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PARAMETERBERICHT ---------- Seite 1 von 4

	AKTIV.	INTERV.
VF	AUS	400 ms
FVT	AUS	240 ms
VT	AUS	600 ms

	NID INITIAL	NID NEU-ERK.	STABILITÄT	ONSET
VF	12/16	6/8		
VT	8	4	AUS 50 ms	AUS 81%

Empfindl.(mV): 0,15

VF-THERAPIE:	1	2	3	4
Therapiestatus:	AUS	AUS	AUS	AUS
Energie(J):	34	34	34	34
Impulsform:	BIPH	BIPH	BIPH	BIPH
Strompfad:	B>AX	B>AX	B>AX	B>AX

VF Nach Erster Ladung bestätigen: JA

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PARAMETERBERICHT ---------- Seite 2 von 4

FVT-THERAPIE:	1	2	3	4
FVT-Therapiestatus:	AUS	AUS	AUS	AUS
Therapie-Art:	BURST	KV	KV	KV
# Initial-Impulse:	6			
R-S1 Interv. =(%RR):	84			
S1S2(RAMP+)=(%RR):				
S2SN(RAMP+)=(%RR):				
Interv.-Abn.(ms):	10			
# Sequenzen:	3			
Energie(J):		34	34	34
Impulsform:		BIPH	BIPH	BIPH
Strompfad:		B>AX	B>AX	B>AX

Mindestintervall Antitachy-Stim. (ms): 200

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PARAMETERBERICHT ---------- Seite 3 von 4

VT-THERAPIE:	1	2	3	4
VT-Therapiestatus:	AUS	AUS	AUS	AUS
Therapie-Art:	BURST	RAMP	KV	KV
# Initial-Impulse:	8	8		
R-S1 Interv. =(%RR):	84	81		
S1S2(RAMP+)=(%RR):				
S2SN(RAMP+)=(%RR):				
Interv.-Abn.(ms):	10	10		
# Sequenzen:	5	5		
Energie(J):			34	34
Impulsform:			BIPH	BIPH
Strompfad:			B>AX	B>AX

Mindestintervall Antitachy-Stim. (ms): 200

GEM.ANTITACHY-STIMULATIONSTHERAPIE:		GEM. KV-THERAPIE:	
Impulsdauer(ms):	1,6	KV-Verzögerung(ms):	0
Amplitude(V):	8,4		
Ausblendz. n. Stim.(ms):	300		

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PARAMETERBERICHT ---------- Seite 4 von 4

Stimulationsmodus:	VVI	Empfindl.(mV):	0,15
Stimul.freq(/min):	30	Hysterese(/min):	AUS
Amplitude(V):	5,6	Ausblendz. n. Stim.(ms):	300
Impulsdauer(ms):	0,5		

EGM-ABLTG: P-/S nach P+/S
EGM-BEREICH(mV): ±15

INT. FÜR AUTO. KONDENSATORAUFL. (Mon): 3

EGM-SPEICHERUNG:
Status: EIN
Gesamtaufz.dauer pro Episode (Sek.): 2,5

HOLTER-TELEMETRIE:
Dauer (Stunden): AUS

DEFINITION VORZEITIGES EREIGNIS:
Schwelle (%): AUS

Medtronic 7219 SN TBL201106K Rev 98860221 Feb 16, 2001 14:32

ICD Model: Gem 7227
Serial Number: PtP100372H

Feb 16, 2001 15:19:26
9962 Software Version 1.0

Parameter Settings Report — Page 1

Detection

	Enable	Interval (Rate)
VF	Off	400 ms (150 bpm)
FVT	Off	280 ms (214 bpm)
VT	Off	600 ms (100 bpm)

Number of Intervals to Detect

	Initial NID	Redetect NID
VF	12/16	6/8
VT	12	4

Sensitivity

Ventricular	0.15 mV

Ventricular SVT Criteria

VT Stability	Off
EGM Width	Off

ICD Model: Gem 7227
Serial Number: PtP100372H

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9962 Software Version 1.0

Parameter Settings Report — Page 2

VF Therapies	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
VF Therapy Status	Off	Off	Off	Off	Off	Off
Energy	35 J	35 J	35 J	35 J	35 J	35 J
Pathway	AX>B	AX>B	AX>B	AX>B	AX>B	AX>B
Reconfirm VF after initial charge?	No					

FVT Therapies	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
FVT Therapy Status	Off	Off	Off	Off	Off	Off
Therapy Type	CV	CV	CV	CV	CV	CV
Initial # Pulses						
R-S1 Interval=(%RR)						
S1S2(Ramp+)=(%RR)						
S2SN(Ramp+)=(%RR)						
Interval Dec						
# Sequences						
Smart Mode						
Energy	35 J	35 J	35 J	35 J	35 J	35 J
Pathway	AX>B	AX>B	AX>B	AX>B	AX>B	AX>B
Anti-Tachy Pacing Minimum Interval		200 ms				

ICD Model: Gem 7227
Serial Number: PtP100372H

Feb 16, 2001 15:19:52
9962 Software Version 1.0

Parameter Settings Report — Page 3

VT Therapies	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
VT Therapy Status	Off	Off	Off	Off	Off	Off
Therapy Type	Burst	Ramp	CV	CV	CV	CV
Initial # Pulses	8	8				
R-S1 Interval=(%RR)	84 %	81 %				
S1S2(Ramp+)=(%RR)						
S2SN(Ramp+)=(%RR)						
Interval Dec	10 ms	10 ms				
# Sequences	5	5				
Smart Mode	Off	Off				
Energy			35 J	35 J	35 J	35 J
Pathway			AX>B	AX>B	AX>B	AX>B
Anti-Tachy Pacing Minimum Interval		200 ms				

Shared Anti-Tachy Pacing Therapy

V. Amplitude	8 V
V. Pulse Width	1.6 ms
V. Pace Blanking	240 ms

Shared VF, FVT, and VT Therapy

Progressive Episode Therapies	Off

ICD Model: Gem 7227
Serial Number: PtP100372H

Feb 16, 2001 15:20:03
9962 Software Version 1.0

Parameter Settings Report — Page 4

Modes/Rates

Mode	VVI
Lower Rate	34 ppm
Hysteresis	Off

Ventricular Rate Stabilization

V. Rate Stabilization	Off

Ventricular Lead

Amplitude	4 V
Pulse Width	0.4 ms
Sensitivity	0.15 mV
Pace Blanking	200 ms

Post Shock Ventricular Pacing

Amplitude	1 V
Pulse Width	0.1 ms
Pace Blanking	200 ms

GEM 7227 (continuation)

ICD Model: Gem 7227
Serial Number: PIP100372H

Feb 16, 2001 15:20:14
9962 Software Version 1.0

Parameter Settings Report — Page 5

Telemetered and Stored EGM

	EGM 1	EGM 2 (used for EGM Width)
EGM Source	Vtip to Vring	Vtip to HVB
EGM Range	+/- 8 mV	+/- 8 mV
Store this channel?	Yes	Yes

Store EGM during charging?	Yes
Store EGM before tachycardia starts?	No

Additional Setup

Device Date/Time	Feb 16, 2001 14:28
Holter Telemetry	Off
Premature Event Threshold	69 %

Auto Cap Formation

Minimum Auto Cap Formation Interval	6 month

ICD Model: Gem 7227
Serial Number: PIP100372H

Feb 16, 2001 15:20:25
9962 Software Version 1.0

Parameter Settings Report — Page 6

Sound tone for:	Enable-Urgency	Threshold
V. Pacing Lead Impedance Out of Range	Off	
Defibrillation (HVB) Lead Impedance Out of Range	Off	
Low Battery Voltage	Off	
Excessive Charge Time	Off	
Number of Shocks Delivered in an Episode	Off	
All Therapies in a Zone Exhausted	Off	

ICD Model: Gem DR 7271
Serial Number: PIM301805R

Feb 23, 2001 10:27:31
9960 Software Version 3.1
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Parameter Settings Report — Page 1

Detection

	Enable	Interval (Rate)
VF	Off	400 ms (150 bpm)
FVT	Off	ms (bpm)
VT	Off	600 ms (100 bpm)

Number of Intervals to Detect

	Initial NID	Redetect NID
VF	12/16	6/8
VT	12	4

Sensitivity

Atrial	0.15 mV
Ventricular	0.15 mV

Dual Chamber SVT Criteria

AFib/AFlutter	Off
Sinus Tach	Off
Other 1:1 SVTs	Off

Ventricular SVT Criteria

VT Stability	Off

ICD Model: Gem DR 7271
Serial Number: PIM301805R

Feb 23, 2001 10:27:42
9960 Software Version 3.1
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Parameter Settings Report — Page 2

VF Therapies	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
VF Therapy Status	Off	Off	Off	Off	Off	Off
Energy	35 J	35 J	35 J	35 J	35 J	35 J
Pathway	AX>B	AX>B	AX>B	AX>B	AX>B	AX>B
Reconfirm VF after initial charge?	Yes					

FVT Therapies	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
FVT Therapy Status						
Therapy Type	None	None	None	None	None	None
Initial # Pulses						
R-S1 Interval=(%RR)						
S1S2(Ramp+)=(%RR)						
S2SN(Ramp+)=(%RR)						
Interval Dec						
# Sequences						
Smart Mode						
Energy						
Pathway						
Anti-Tachy Pacing Minimum Interval		200 ms				

ICD Model: Gem DR 7271
Serial Number: PIM301805R

Feb 23, 2001 10:27:53
9960 Software Version 3.1
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Parameter Settings Report — Page 3

VT Therapies	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
VT Therapy Status						
Therapy Type	None	None	None	None	None	None
Initial # Pulses						
R-S1 Interval=(%RR)						
S1S2(Ramp+)=(%RR)						
S2SN(Ramp+)=(%RR)						
Interval Dec						
# Sequences						
Smart Mode						
Energy						
Pathway						
Anti-Tachy Pacing Minimum Interval		200 ms				

Shared Anti-Tachy Pacing Therapy

V. Amplitude	8 V
V. Pulse Width	1.6 ms
V. Pace Blanking	240 ms

Shared VF, FVT, and VT Therapy

Progressive Episode Therapies	Off

ICD Model: Gem DR 7271
Serial Number: PIM301805R

Feb 23, 2001 10:28:05
9960 Software Version 3.1
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Parameter Settings Report — Page 4

Modes/Rates

Mode	DDD
Mode Switch	Off
Lower Rate	34 ppm
Upper Tracking Rate	120 ppm

A-V Intervals

Paced AV	180 ms
Sensed AV	250 ms
Rate Adaptive AV	Off

Rate Therapy Features

V. Rate Stabilization	Off

Post Shock Pacing

A. Amplitude	4 V
A. Pulse Width	1.6 ms
A. Pace Blanking	240 ms
V. Amplitude	6 V
V. Pulse Width	1.6 ms
V. Pace Blanking	240 ms

Atrial Lead

Amplitude	4 V
Pulse Width	0.4 ms
Sensitivity	0.15 mV
Pace Blanking	200 ms

Ventricular Lead

Amplitude	4 V
Pulse Width	0.4 ms
Sensitivity	0.15 mV
Pace Blanking	200 ms

Refractory

PVARP	150 ms
PVAB	100 ms

Refractory Features

PMT Intervention	Off
PVC Response	Off
V. Safety Pacing	Off

GEM DR 7271 (continuation)

ICD Model: Gem DR 7271
Serial Number: PIM301805R

Feb 23, 2001 10:28:16
9960 Software Version 3.1

Parameter Settings Report Page 5

Telemetered and Stored EGM

	EGM 1 (A or V)	EGM 2 (V)
EGM Source	Atip to Aring	HVA to HVB
EGM Range	+/- 8 mV	+/- 8 mV
Store this channel?	Yes	Yes

Store EGM during charging?	Yes
Store EGM before tachycardia starts?	No

Additional Setup

Device Date/Time	Feb 23, 2001 10:36
Holter Telemetry	Off
Premature Event Threshold	69 %

Auto Cap Formation

Minimum Auto Cap Formation Interval	6 month

ICD Model: Gem DR 7271
Serial Number: PIM301805R

Feb 23, 2001 10:28:27
9960 Software Version 3.1

Parameter Settings Report Page 6

Sound tone for:	Enable-Urgency	Threshold
A. Pacing Lead Impedance Out of Range	Off	
V. Pacing Lead Impedance Out of Range	Off	
Defibrillation (HVB) Lead Impedance Out of Range	Off	
Low Battery Voltage	Off	
Excessive Charge Time	Off	
Number of Shocks Delivered in an Episode	Off	
All Therapies in a Zone Exhausted	Off	

Ventak AVIII DR

Cardiac Pacemakers, Inc. VENTAK AVIII DR

Gedruckt am 23-FEB-01 11:19
Patient HAAF, GUNILLA
Klinik AKH WIEN DEFI-AMBULANZ EBENE 6 LILA F

CPI-Programmiergerät:		CPI-PG:	
Modell	2901	Modell	1831
Ser.-Nr.	000447	Ser.-Nr.	100009
CPI-Software:		ROM-Version	1.0.02
Modell	2843		
Version	2.7		

Parameterbericht

PG-Konfiguration

Tachy Mode	Aus
Tachy-Zonen	2
Zuletzt programmiert	23-FEB-01 11:15

VT-Zone

Anfängl. Detektion	
Frequenz	100 - 150 min-1
Intervall	600 - 400 ms
Dauer	1,0 s
Onset	AUS %
Und/Oder	--
Stabilität	
Inhibieren falls instabil	AUS ms
Schock falls instabil	AUS ms
A Fib Frequenzgrenze	AUS min-1
A Fib Stabilität	-- ms
V Freq > A Freq	--
Anhaltende Frequenzdauer (SRD)	-- min:s
Redetektion	
Redetektionsdauer	1,0 s
Post-Schock-Dauer	1,0 s
Post-Schock-Stabilität	AUS ms
Post-Schock A Fib Freq.Grenze	AUS min-1
Post-Schock A Fib Stabilität	-- ms
Post-Schock V Freq > A Freq	--
Post-Schock anhaltende Frequenzdauer	-- min:s

ATP-Therapie:	ATP1	ATP2
Schema	Ausgesch.	Ausgesch.
Anzahl der Bursts	AUS	AUS
Impulse pro Burst		
Anfänglich	--	--
Inkrement	-	-
Maximum	--	--
Kopplungsintervall	-- --	-- --
Abnahme	-- ms	-- ms
Burstzykluslänge	-- --	-- --
Rampabnahme	-- ms	-- ms
Scanabnahme	-- ms	-- ms
Mindestintervall	-- ms	-- ms
ATP-Zeitlimit	AUS min:s	

Schocktherapie	
Schock 1	31 J
Schock 2	31 J
Max Schocks	31 J

VF-Zone

Anfängl. Detektion	
Frequenz	≥ 150 min-1
Intervall	≤ 400 ms
Dauer	1,0 s
Redetektion	
Redetektionsdauer	1,0 s
Post-Schock-Dauer	1,0 s
Schocktherapie	
Schock 1	31 J
Schock 2	31 J
Max Schocks	31 J

Therapiemerkmale

Schocks	
Schockform	Biphasisch
Polarität	INITIAL
Committed Schock	NEIN
ATP	
*Atriale ATP-Amplitude	5,0 V
*Atriale ATP-Impulsdauer	1,0 ms
Ventr.ATP Amplitude	7,5 V
Ventr.ATP-Impulsdauer	1,0 ms

*Nur während EP-Test verfügbar

Brady-Stimulation

Norm. Brady-Stimul.	
Betriebsart	DDD
Untere Frequenzgr	40 min-1
Max. Trackingfrequenz	80 min-1
Adaptive Frequenz	
Max. Sensorfrequenz	-- min-1
*Aktivitätsschwelle	--
*Reaktionszeit	-- s
*Anpassungsfaktor	--
*Erholungszeit	-- min
Dyn. AV-Verzög.	AUS
AV-Verzögerung	150 ms
Minimale Verzög.	-- ms
Detekt.AV-Offset	AUS ms
Hysteresefrequenz	-- min-1
Frequenzglättung	
Glättung b.Anst.	AUS %
Glättung b.Abfall	AUS %
*Störreaktion	DOO
ATRIAL	
Impulsdauer	0,5 ms
Amplitude	5,0 V
Refraktärzeit-PVARP	150 ms
PVARP-Verlänger.	AUS ms
VENTRIKULÄR	
Impulsdauer	0,5 ms
Amplitude	7,5 V
Refr. nach Stim./LRL	150 ms
Dynamische MTR Refraktärzeit	150 ms
Atriale Tachy-Reakt.	
*Auslösefrequenz	120 min-1
*Dauer	20 Zyk
*Fallback-Dauer	00:15 min
*ATR/VTR Fallback LRL	40 min-1

Post-Schock-Brady-Stim.	
Betriebsart	DDD
Untere Frequenzgr	40 min-1
Max. Trackingfrequenz	80 min-1
Adaptive Frequenz	
Max. Sensorfrequenz	-- min-1
*Aktivitätsschwelle	--
*Reaktionszeit	-- s
*Anpassungsfaktor	--
*Erholungszeit	-- min
Dyn. AV-Verzög.	AUS
AV-Verzögerung	150 ms
Minimale Verzög.	-- ms
Detekt.AV-Offset	AUS ms
Hysteresefrequenz	-- min-1
Frequenzglättung	
Glättung b.Anst.	AUS %
Glättung b.Abfall	AUS %
*Störreaktion	DOO
*Stim.Verzög.	3,0 s
Stim. Periode	0:30 min:s
ATRIAL	
Impulsdauer	2,0 ms
Amplitude	5,0 V
Refraktärzeit-PVARP	250 ms
PVARP-Verlänger.	AUS ms
VENTRIKULÄR	
Impulsdauer	2,0 ms
Amplitude	7,5 V
Refr. nach Stim./LRL	250 ms
Dynamische MTR Refraktärzeit	240 ms
Atriale Tachy-Reakt.	
*Auslösefrequenz	120 min-1
*Dauer	20 Zyk
*Fallback-Dauer	00:15 min
*ATR/VTR Fallback LRL	40 min-1

*Diese Parameter sind für normale u. Post-Schock-Stimul. gleich

Magnet-/Piepton-/EGM-Funk.

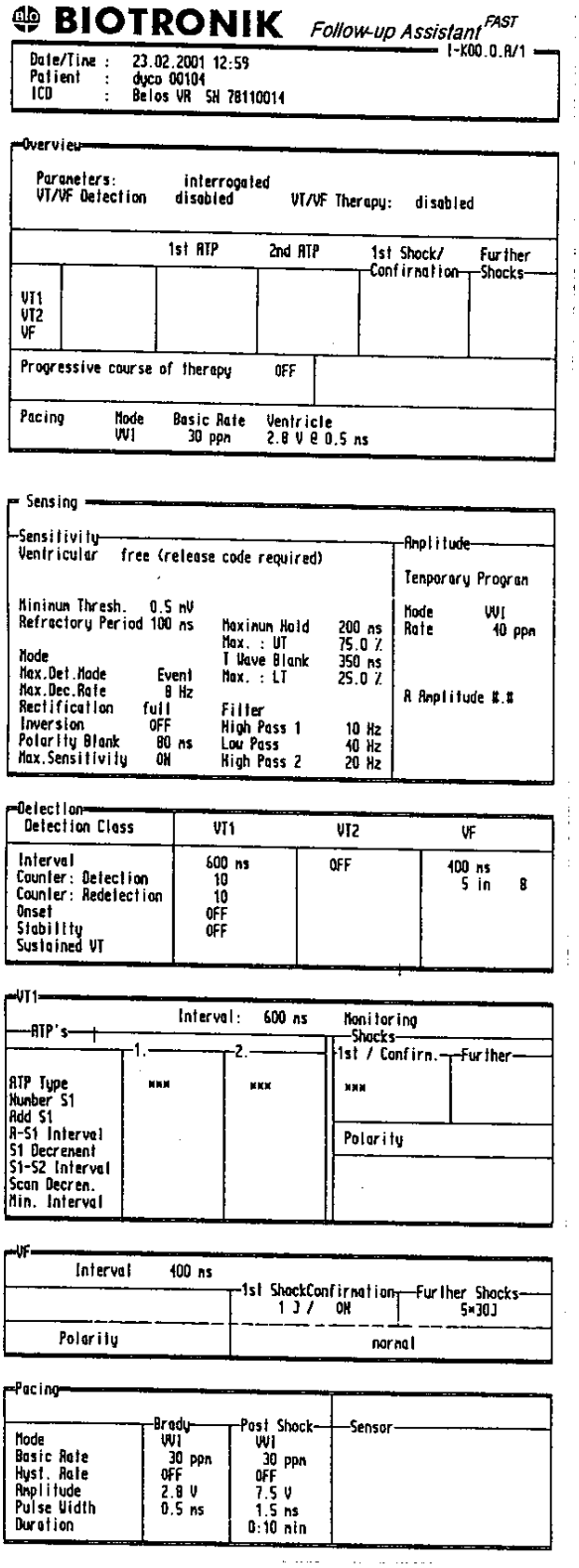
Magnetfunktion	EIN
Tachy-Modus mit Magnet verändern	AUS
Piepton während Kondensatoraufladung	AUS
Piepton bei dedektierten ventrikulären Ereignissen und stimulierten ventrikulären Ereignissen	AUS
Piepton, wenn ERI erreicht ist	EIN
Elektrogrammspeicher	
Atrial	EIN
Ventrikulär	AUS
Schock	EIN
Onset	EIN

Einstellung der Empfindlichkeit

Atriale Empfindl.	Nominell
Ventr. Empfindlichkeit	Kleiner

Alle Energien angegeben wie gespeichert.
Ende des Berichts

Belos VR



BIOTRONIK Follow-up Assistant FAST

I-K00.0.A/1

Date/Time : 23.02.2001 12:59
Patient : dyco 00104
ICD : Belos VR SN 78110014

Overview

Parameters: interrogated
VT/VF Detection disabled VT/VF Therapy: disabled

	1st ATP	2nd ATP	1st Shock/ Confirmation	Further Shocks
VT1				
VT2				
VF				

Progressive course of therapy OFF

Pacing Mode VVI Basic Rate 30 ppm Ventricle 2.8 V @ 0.5 ms

Sensing

Sensitivity
Ventricular free (release code required)

Minimum Thresh. 0.5 mV
Refractory Period 100 ms
Mode
Max.Det.Mode Event
Max.Dec.Rate 8 Hz
Rectification full
Inversion OFF
Polarity Blank 80 ms
Max.Sensitivity ON

Maximum Hold 200 ms
Max. : VT 75.0 %
T Wave Blank 350 ms
Max. : LT 25.0 %

Filter
High Pass 1 10 Hz
Low Pass 40 Hz
High Pass 2 20 Hz

Amplitude
Temporary Program
Mode VVI
Rate 40 ppm
R Amplitude #.# mV

Detection

Detection Class	VT1	VT2	VF
Interval	600 ms	OFF	400 ms
Counter: Detection	10		5 in 8
Counter: Redetection	10		
Onset	OFF		
Stability	OFF		
Sustained VT			

VT1

Interval: 600 ms Monitoring

ATP's	1.	2.	Shocks 1st / Confirm.	Shocks Further
ATP Type	***	***	***	
Number S1				
Add S1				
R-S1 Interval				
S1 Decrement				
S1-S2 Interval				
Scan Decren.				
Min. Interval				

Polarity

VF

Interval 400 ms

	1st ShockConfirmation	Further Shocks
	1 J / ON	5*30J
Polarity	normal	

Pacing

	Brady	Post Shock	Sensor
Mode	VVI	VVI	
Basic Rate	30 ppm	30 ppm	
Hyst. Rate	OFF	OFF	
Amplitude	2.8 V	7.5 V	
Pulse Width	0.5 ms	1.5 ms	
Duration		0:10 min	