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# The initial experience with a subset of recalled Medtronic dual chamber pacemakers

## Pierwsze doświadczenia z dwujamowymi stymulatorami firmy Medtronic objętymi alertem bezpieczeństwa

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### Abstract

**Introduction.** Medtronic released a subset of dual chamber pacemakers that are suspected of a software error that can result in a lack of pacing. The Food and Drug Administration has deemed a class I recall.

**Material and methods.** Medtronic advise reprogramming for patients with susceptible mode to non-susceptible pacing modes that are: DVI, DVIR, DOO(R), VVI, VVIR, VOO(R), VVT, AAI, AAIR, AOO(R), AAT, OVO.

**Results.** 48 patients received an atrioventricular recalled device. Initially the DDD/DDDR mode was programmed in 44 patients and VVI/VVIR mode in the other four patients. The atrial and ventricular lead parameters such as pacing threshold, sensing threshold and impedance were within normal ranges. Pacemaker dependency in atria concerned 16/48 (33.33%) patients and in ventricles 13/48 (27.1%) patients. Three patients complained of fatigue, dizziness and near syncope. In 24 patients, devices were reprogrammed: in 17 (35.41%) patients to the DVIR mode and in seven (14.58%) patients to the VVI(R) mode. Two patients chose to be reprogrammed to the DDDR mode because of intolerance to non-susceptible pacing modes.

**Conclusions.** Only three patients experienced symptoms that may be associated with pacemaker dysfunction; in 24/48 patients we programmed safety mode DVI(R) or VVI(R). The pacemaker dependency concerned almost 33.33% of patients.

Key words: dual chamber pacemaker, recall, Medtronic

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## Introduction

Between 6 March 2017 and 7 January 2019, Medtronic released a subset of dual chamber pacemakers under the brand names Adapta, Versa, Sensia, Relia, Attesta, Sphera, and Vitatron A, E, G, and Q series. These are suspected of a software error that can result in a lack of pacing. There are 13,440 recalled devices in the United States of America, 20,000 in Poland, and a total of 156,957 worldwide [1, 2]. The Food and Drug Administration (FDA) has deemed a class I recall *i.e.* the most serious one [3]. No deaths have been reported. Medtronic estimates that a device in a susceptible pacing mode has a 2.8% chance per month of experiencing a pacing pause of 1.5 seconds or longer. The lower risk concerns patients with preserved own rhythm, since ventricular sensed beats restore full

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**Table 1.** Indications for pacemaker implantation

| Indication for pacemaker implantation | Number of patients [%] |
|---|---|
| Sick sinus syndrome | 23 (47.91) |
| Tachycardia–bradycardia syndrome | 2 (4.17) |
| Advanced atrioventricular block (2:1) | 14 (29.17) |
| Sick sinus syndrome and advanced atrio-ventricular block (2:1) | 2 (4.17) |
| Atrioventricular block and sequential RBBB and LBBB | 1 (2.08) |

RBBB — right bundle branch block; LBBB — left bundle branch block

**Table 2.** Patient characteristics

| Parameter | Number [%] of patients |
|---|---|
| Coronary artery disease | 23/48 (47.91%) |
| Myocardial infarction | 7/48 (14.58%) |
| Hypertension | 39/48 (81.25%) |
| Atrial fibrillation | 18/48 (37.5%) |
| Ischaemic stroke | 5/48 (10.42%) |
| Diabetes mellitus | 17/48 (35.42%) |
| Chronic renal failure | 32/48 (66.67%) |
| Chronic obstructive pulmonary disease | 7/48 (14.58%) |

device functionality. The estimated per patient mortality risk of 0.021% associated with device failure is comparable with the mortality risk of 0.027% associated with device replacement. Medtronic recommends programming to a non-susceptible pacing mode until the software update has been installed. The non-susceptible pacing modes are: DVI, DVIR, DOO(R), VVI, VVIR, VOO(R), VVT, AAI, AAIR, AOO(R), AAT, OVO. The company is developing a software update to fix this problem [1, 2]. The aim of this study was to characterise the subset of patients with implanted recalled devices produced by Medtronic.

## Material and methods

48 patients (25 male, 23 female) underwent pacemaker control due to Medtronic device recall who were implanted between 10 March 2017 and 7 January 2019 in the Outpatient Clinic for Cardiovascular Implantable Electronic Devices. The mean patient age was 75.85 years, with a range from 41 to 95. The main reason for pacemaker implantation was sick sinus syndrome (Table 1). The most frequent observations were hypertension (39/48; 81.25%), coronary artery disease (23/48, 47.91%) and chronic renal failure (32/48; 66.67 %) (Table 2).

### Reprogramming

Medtronic advised reprogramming for patients with susceptible mode and persistent atrial fibrillation into VVI(R) mode, in patients who had no underlying ventricular escape rhythm or who were at risk for a symptomatic pause until a ventricular escape beat occurs. Programming to a non-susceptible mode was recommended and should be followed by routine clinical monitoring. In patients who cannot tolerate a non-susceptible mode, clinical monitoring in susceptible mode can continue or it may be sensible to consider device replacement. The patients remaining in susceptible mode were told to seek immediate medical advice if symptoms appeared [1].

The advice of the Working Group set up by the Polish National Consultants in Cardiology and The Heart Rhythm Section of the Polish Cardiac Society was to coordinate actions, identify patients, contact patients, perform at least two control visits to patients reprogrammed to non-susceptible mode, and perform device exchange in patients who could not tolerate non-susceptible mode [2].

### Definition

Pacemaker dependency is defined as rhythm < 30/min or symptoms present and rhythm between 30 and 40/min.

## Results

48 patients received an atrioventricular recalled device. In 32 patients, this was the first implantation, while in 16 patients it was a device exchange due to the end of battery life. Initially the DDD/DDDR mode was programmed in 44 patients and the VVI/VVIR mode in the other four patients. The atrial and ventricular lead parameters such as pacing threshold, sensing threshold and impedance are set out in Table 3. The mean atrial pacing was 54.3%, range 0 to 99.8%, and the mean ventricular pacing was 95%, range 0.1 to 100%. Pacemaker dependency in atria concerned 16/48 (33.33%) patients and in ventricles 13/48 (27.1%) patients. Three patients complained of fatigue, dizziness and near syncope. In 24 patients, devices were reprogrammed: in 17 (35.41%) patients to the DVIR mode and in seven (14.58%) patients to VVI(R). In two patients DVIR mode was not tolerated, and both these patients decided to be reprogrammed to the DDDR mode.

We identified AHR in 22 patients (11 in patients with a previous diagnosis of atrial fibrillation) and VHR in 10 patients. There were 2,374 AHR episodes, and the mean number of AHR was 55.21, range from 1,235 to 1. While there were 93 VHR episodes, the mean number of VHR was 2.02, range from 62 to 1.

The control visit included interview, examination, device control and reprogramming, presentation of informed consent, and signing the consent — duration time 30 minutes.

**Table 3.** Important parameters from device control

| Parameter | Atrial lead | Ventricular lead |
|---|---|---|
| Mean pacing threshold [V/0.4 ms] | 0.578 | 0.62 |
| Impedance [ohm] | 709.13 | 575.3 |
| Mean maximal sensing threshold [mV] | 3.3 | 21.24 |
| Pacemaker dependency | 13/48 | 16/48 |
| Mean percentage of pacing [%] | 54.3 | 95 |

Although patients were nervous and uncertain nobody asked for device exchange.

## Discussion

We present the initial experience of our Centre with recalled Medtronic devices affected by a circuit error that may lead them to withhold ventricular pacing. Our main finding was that only three patients experienced symptoms that may be associated with pacemaker dysfunction, while in 24/48 patients we programmed safety mode DVI(R) or VVI(R). The pacemaker dependency concerned almost 30% of patients.

In the literature, pacemaker dependency among 3,638 patients was diagnosed in 2.1% of all patients and more frequently was observed in patients with atrioventricular block compared to patients with sick sinus syndrome or atrial fibrillation [4]. In our population, advanced atrioventricular block was diagnosed in 16 patients (33.34%), while sick sinus syndrome and tachycardia–bradycardia syndrome concerned 25 patients (52.08%). Patients with cardiovascular electronic devices experience depressive disorders, and the number of patients affected with such a disorder may increase over time [5]. Unfortunately, stressful information such as the possible dysfunction of a CIED (device recall) may worsen existing disorders.

We designed a control visit that would last for 30 min. All this time was exploited as usually patients needed to be informed twice for better understanding and to calm nerves. 30 min for each of 48 patients means an additional 1,440 min for the Outpatient Clinic for Cardiovascular Implantable Electronic Devices, something that markedly increased the workload. As patients with recalled devices need to be carefully followed up, we scheduled control visits every two months.

This present dual-chamber pacemaker recall comes after last year's Medtronic resynchronisation therapy and implantable cardioverter defibrillator class 1 recall which was due to a manufacturing error preventing electrical shock delivery that was announced on 22 January 2018 [6].

When Maisel et al. [7] analysed pacemaker and implantable cardioverter-defibrillator generator advisory rates in the United States, they found that recalls and safety alerts occur frequently, affect many patients, and appear to be increasing both in number and rate.

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## Conflict(s) of interest

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## Streszczenie

**Wstęp.** Firma Medtronic wypuściła na rynek grupę przedsionkowo-komorowych stymulatorów podejrzanych o błąd oprogramowania, który może prowadzić do wstrzymania stymulacji. Agencja ds. Żywności i Leków objęła powyższe urządzenia alertem klasy pierwszej.

**Materiały i metody.** Firma Medtronic zaleca zmianę programu u chorych stymulowanych w trybie podatnym na wystąpienie błędu na tryb niepodatny, czyli: DVI, DVIR, DOO(R), VVI, VVIR, VOO(R), VVT, AAI, AAIR, AOO(R), AAT, OVO.

**Wyniki.** Przedsionkowo-komorowy stymulator objęty obecnie alertem wszczepiono 48 chorym. U 44 pacjentów początkowo występował tryb DDD/DDDR, natomiast u 4 pacjentów — VVI/VVIR. Parametry elektrod, takie jak próg stymulacji, amplituda sygnału czy oporność, pozostawały w granicach normy. Zależność od stymulatora w przedsionkach dotyczyła 16 spośród 48 (33,33%) pacjentów, natomiast w komorach — 13 spośród 48 (27,1%) chorych. U 3 osób wystąpiły zmęczenie, zawroty głowy, prawie omdlenie. U 24 chorych stymulatory przeprogramowano w tryb bezpieczny — u 17 (35,41%) pacjentów w tryb DVIR, a 7 (14,58%) chorych w tryb VVI(R). Dwóch chorych zdecydowało o powrocie do trybu DDDR z powodu nietolerancji trybów niepodatnych na wystąpienie błędu.

**Wnioski.** Trzech pacjentów doświadczyło objawów, które mogą się wiązać z dysfunkcją stymulatora, u 24 z 48 chorych zaprogramowano tryb bezpieczny [DVI(R) lub VVI(R)]. Stymulatorozależność dotyczyła 33,3% chorych.

Słowa kluczowe: stymulator dwujamowy, alert bezpieczeństwa, alert Medtronic

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## References


1. Urgent Medical Device Recall for a subset of Medtronic dual chamber pacemakers. www.medtronic.com/us-en/healthcare-profesionals/products/product-performance/dual-chamber-pacemaker-recall.html.
2. Zając D, Blicharz J, Przybylski A, Mitkowski P. et al. Opinia Grupy Roboczej powołanej przez Konsultanta Krajowego w dziedzinie kardiologii oraz Zarząd Sekcji Rytmu Serca Polskiego Towarzystwa Kardiologicznego na temat zalecanego postępowania u chorych zagrożonych wstrzymaniem stymulacji w dwujamowych stymulatorach firmy Medtronic. 27 stycznia 2019.
3. www.fda.gov/medical-devices/medical-device-recalls/medtronic-inc-recalls-dual-chamber-implantable-pulse-generators-ipgs-due-possible-circuit-error.
4. Lelakowski J, Majewski J, Bednarek J, et al. Pacemaker dependency after pacemaker implantation. Cardiol J. 2007; 14(1): 83–86, indexed in Pubmed: 18651439.
5. Karczmarewicz G, Ziavina Y, Michalik J, et al. Dlaczego należy diagnozować depresję u chorych z implantowanym układem do elektroterapii serca? Folia Cardiol. 2018; 13(3): 274–278, doi: 10.5603/fc.2018.0053.
6. www.fda.gov/medical-devices-recalls/medtronic-recalls-cardiac-resynchronization-therapy-and-implantable-cardioverter-defibrillatora-due.
7. Maisel WH, Sweeney MO, Stevenson WG, et al. Recalls and safety alerts involving pacemakers and implantable cardioverter-defibrillator generators. JAMA. 2001; 286(7): 793–799, doi: 10.1001/jama.286.7.793, indexed in Pubmed: 11497532.