## Medtronic

#### Medtronic International, Ltd. (Singapore Branch)

(Co. Reg. No. S98FC5604C) 50 Pasir Panjang Road #04-51 Mapletree Business City Singapore 117384 www.medtronic.com

tel 65.6870.5300 fax 65.6482.0300

## **URGENT MEDICAL DEVICE CORRECTION**

For a Subset of Medtronic Dual Chamber Pacemakers Software Update Now Available

8 October 2019

Dear Healthcare Professional,

#### Attention: Risk management Director and O.R Materials Management

#### CC: The Chairman Medical Board and relevant Head of Departments

In January 2019, Medtronic issued an **Urgent Medical Device Recall** letter regarding a subset of Medtronic dual chamber pacemakers distributed worldwide between 10 March 2017 and 7 January 2019 under the brands **Adapta<sup>TM</sup>**, **Versa<sup>TM</sup>**, **Sensia<sup>TM</sup>**, **Relia<sup>TM</sup>**, **Attesta<sup>TM</sup>**, **Sphera<sup>TM</sup>**, **and Vitatron<sup>TM</sup> A, E, G, Q series**. Devices in the affected subset, when programmed to a dual chamber mode with atrial-sensing, may experience a pacing pause due to a circuit error.

Medtronic has distributed a software update to address the potential for a pacing pause in these devices (software models SW003 v8.2 Adapta/Versa/Sensia, SW010 v8.2 Relia, SW043 v8.2 Attesta/Sphera, VSF20 v8.2 Vitatron and VSF21 v8.2 Vitatron). Your Medtronic Representative will be updating all Medtronic CareLink<sup>™</sup> 2090 and CareLink Encore<sup>™</sup> 29901 Programmers.

#### **Patient Management Recommendations**

After the new software is installed on the Medtronic CareLink<sup>™</sup> 2090 and CareLink Encore<sup>™</sup> 29901 programmers, pacemakers will automatically receive the update at the next in-clinic interrogation. This one-time pacemaker update process may result in a slightly longer interrogation time and is likely to temporarily interfere with the real-time waveform display. **Pacing operation is not impacted.** 

Following receipt of the software update, pacemakers that were programmed to a pacing mode specifically to avoid a circuit error may be reprogrammed to any pacing mode. Once a device is

updated, if the circuit error were to occur, the pacing cycle will automatically reset; this may be observed as a single dropped beat.

Physicians should use medical judgement to prioritize the scheduling of patients to receive the update based on their unique clinical conditions. Consider prioritizing patients who were not able to tolerate programming to a non-susceptible pacing mode and either: have no underlying ventricular escape rhythm; or are at risk for a symptomatic pause until a ventricular escape beat occurs.

#### **Additional Information and Actions**

- Directions for applying these software updates to patient pacemakers and to Medtronic programmers can be found on the enclosed <u>Updating a Pacemaker to Correct the Dual</u> <u>Chamber Circuit Error</u> tip card
- Affected customer to complete the attached Customer Confirmation Form and return it as directed to confirm your receipt and software has been updated and understanding of this information.

We are committed to patient safety and appreciate your prompt attention to this matter. Please share this notification with others in your organization as appropriate.

Sincerely,



QRA Lead SEA Region (Cluster 1)



Chloe Tan QRA Lead SEA Region (Cluster 2)

## **URGENT MEDICAL DEVICE CORRECTION**

For a Subset of Medtronic Dual Chamber Pacemakers

Software Update Now Available

#### ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Physician / HCP/Distributors :	Name:
	Contact:
Address:	Email:
Phone no:	
E-mail:	

The purpose of this form is to confirm that you have read and understand Medtronic's Software Update Now Available for Adapta<sup>TM</sup>, Versa<sup>TM</sup>, Sensia<sup>TM</sup>, Relia<sup>TM</sup>, Attesta<sup>TM</sup>, Sphera<sup>TM</sup>, and Vitatron<sup>TM</sup> A, E, G, Q series Pacemakers letter dated 10 Oct 2019. This letter announces the availability of a software update to address the potential for a pacing pause in a subset of these devices earlier communicated by Medtronic in a letter dated January 2019.

#### □ The Programmer (s) I have at the Facility have been updated with below Software Model(s)

Model Number	Serial #	Software Model

By signing this form, I confirm that I have read and understand the Software Update Now Available for Adapta<sup>™</sup>, Versa<sup>™</sup>, Sensia<sup>™</sup>, Relia<sup>™</sup>, Attesta<sup>™</sup>, Sphera<sup>™</sup>, and Vitatron<sup>™</sup> A, E, G, Q series Pacemakers notification letter, dated 8 October 2019 from Medtronic.

Name: \_\_\_\_\_\_ (print) Signature: \_\_\_\_\_ Stamp: \_\_\_\_\_

Date:\_\_\_\_\_

If you have any questions regarding this Software Update Letter, please contact your Medtronic sales representative.

004-F265 v2.0

# **UPDATING A PACEMAKER** TO CORRECT THE DUAL CHAMBER IPG CIRCUIT ERROR

## This is a 14-step process. Please review these instructions to the last page.

- Identify the patient's implanted pacemaker model. This update applies to the following devices: Adapta<sup>™</sup>, Versa<sup>™</sup>, Sensia<sup>™</sup>, Relia<sup>™</sup>, Attesta<sup>™</sup>, Sphera<sup>™</sup>, and Vitatron<sup>™</sup> A, E, G, Q series.
- 2. Turn on the 2090 or Encore programmer.
- 3. Press "Cancel" on the Find Patient window.

Find Patient Searching Place programming head over	the device.		
Patient Name	Device Type	Serial Number	SelectModel
	Searching	4	Print Queue
			A
			< Programmer
Allow wireless communication	Start	Cancel	Analyzer

4. Tap on "Programmer" icon on the main programmer screen.

View:	Dual chamber pacemakers Single chamber pacemakers	<ul> <li>Tachyarrhythmia devices</li> <li>Other</li> </ul>		
	Single chamber pacemakers	Guier		
MEDTRO	NIC PACEMAKERS:		<u> </u>	
Attest	ta ATDR01			
Attes	ta S ATDRS1			1
Attest	ta L ATDRL1			20
Spher	a SPDR01			Select Mo
Spher	a L SPDRL1			<b>6</b>
Perce	pta Quad CRT-P MRI			
Perce	pta Quad CRT-P MRI - Read From Media			Print Que
Perce	nta CRT-P MRI			
Perce	nta CRT-P MRI - Read From Media			
Seren	a Quad CRT-P MRI			
Seren	a Quad CRT-P MRL - Read From Media			A
Seren	a CRT-P MRI		-1	3
00101			-	< Program
5	Start.	Nominals		Inner
				000
				2

## 5. Tap on "Software".

View:	Dual chamber pacemakers	C Tachyarrhy	/thmia devices	
	<ul> <li>Single chamber pacemakers</li> </ul>	○ Other	Preferences	
MEDTRO	NIC PACEMAKERS:		Time and Date	
Attest	ta ATDR01		Artifact Detection	_
Attest	ta L ATDRL1		Software	6
Spher	a SPDR01		Demonstrations	Select M
Perce	pta Quad CRT-P MRI		Programmer Profile	
Perce	pta Quad CRT-P MRI - Read From Media nta CRT-P MRI		SessionSync Status	Print Qu
Perce	pta CRT-P MRI - Read From Media		SessionSync Network Configuration	
Seren	a Quad CRT-P MRI a Quad CRT-P MRI - Read From Media		RemoteView Network Configuration	1
Seren	a CRT-P MRI		Network Configuration	
5	štart	Nominals	Other Software	
L		-	Tools	000
nd Patien	t	vitatron	Licensing	Anelyz

## 6. Search for the patient's pacemaker model.

Software on This Programmer			
Vision Release: 2090 2.11			
Model	Software Versio	n	
Attesta ATDR01	8.2		
Attesta ATSR01	8.2	-	
Attesta L ATDRL1	8.2		
Attesta S ATDRS1	8.2		62
Auto ID Update	8.7	<u>ا</u> د	Solort Model
Undate History			Glectwoder
Update Name	Time of Upd	ate	æ
			Print Queue
		-	
		-1	11116
		<u> </u>	
			< Programmer
Install from Medtronic	Install from Media	Uninstall Software	000
			000
	A sector in the base	Octup@ocd	Analyzer
Find Patient	Medtronic vitation	Uretech	

7. Verify the software version is 8.2 or higher for the patient's implanted pacemaker model.

If the software version is less than 8.2, stop and contact your Medtronic representative to update the programmer.

## WARNING

If the programmer is running a software version less than 8.2:

- DO NOT run EP Study; and
- **DO NOT** program <u>any</u> parameters under "Clinician Selected..." in the Data Collection Setup window.

**Either action will delete the circuit error correction update** if the device was previously updated, and the patient will be susceptible to circuit error.

Software on This Programmer Vision Release: 2090 2.11	
Model	Software Version
Spectrax SXT 8420, 8422, Sphera L SPDRL1 Sphera SPDR01 Sphera SPSR01 Symbios 7005, 7006	8423 45 1 8.2 8.2 8.2 8.2 v45 v
Update History Update Name	Time of Update
Install from Medtronic	Install from Media Uninstall Software
Find Patient	Medtronic vitatron NoyoMed. (SLifetech

#### 8. Tap on "Find Patient".

Soft	ware on This Program	mer						
Vis	ion Release: 2090 2.	11						
	Model			Software V	ersio	n		
	Spectrax SXT843Sphera L SPDRL1Sphera SPDR01Sphera SPSR01Symbios700	20, 8422, 8423 05, 7006		v45 8.2 8.2 8.2 v45				6)
Upa	date History Update Name			Time of	Upda	ite		Print Queue
							I	a.
	Install from Medtroni	c	Install	from Media		Uninsta	ll Software	< Programmer
F	ind Patient	Hedd	tronic	vitatron	1	NayaMed.	() Lifetech	Analyzer

9. Place the programming head over the patient's pacemaker.



10. Tap on "Start" when the programmer has detected the patient's pacemaker.

-	Find Patient	
	Searching .	
	Select patient then Start.	
	Patient Name Device Type Serial Number	
	0.1.000004	Select Model
	Sphera SPDR01	
		Print Queue
		0
		۲
		< Programmer
_	Start Cancel	Analyzer
L		1999 - 1999 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 -

11. Wait for the interrogation to complete.

Note: Initial interrogation can take up to 2 minutes as the pacemaker downloads the circuit error correction update. Subsequent interrogations will proceed normally.

Quick Look II 22-Apr-2019		Last Session: 19-Apr-2019	Checklist
Remaining Longevity 4 years (minimum: 3 years)	Mode Lower Rate Upper Track Rate	DDDR 50 ppm 120 ppm	 Data
	0.1	0%	Params
	0.1 0.1 10	0% 0% 0.0%	< Tests
	Observations		< Reports
			< Patient
More	ogation 76%	End Session	< Session

## 12. Tap on the Parameters icon.

Quic	k Look II 22-Apr-2019		Last Session: 19-Apr-2019 🔮	Checklist
0	Remaining Longevity 4 years (minimum: 3 years) Last Measured	Mode Lower Rate Upper Track Rate	DDDR 50 ppm 120 ppm	< Data
$\Sigma$	Threshold (V@.4ms)	Pacing AS-VS AS-VP AP-VS AP-VP	>>> 0.0% 0.0% 0.0%	Params Eii: < Tests
	Impedance (ohms) 2,000 - 500 - 250 - 250 - Apr-16 Oct-18 Apr-19	Observations		< Reports
+	More Emergency Interrog	jate	End Session	< Session

## 13. Print the Parameters Report.

Parameters - Therapy 0							Checklist
Modes/Rates			Atrial Lead		Ventricul	Ventricular Lead	
Mode	DDDR		Amplitude	5.000 V	Amplitude	5.000 V	
Mode Switch	h	Off	Pulse Width	0.40 ms	Pulse Width	0.40 ms	< Data
Lower Rate		50 ppm	Sensitivity	0.50 mV	Sensitivity	2.80 mV	
Upper Track	k	120 ppm	Pace Polarity	Bipolar	Pace Polarity	Bipolar	Params
Upper Sens	or	120 ppm	Sense Polarity	Bipolar	Sense Polarity	Bipolar	
🕫 Rate Re	₱ Rate Response		Capture	Off	Capture	Off	< Tests
1	ntrinsic,	/AV	Refractory	/Blanking	Additional	Features	
Intrinsic Ad	ctivation.		PVARP	310 ms	Additional Features	i	< Reports
Paced AV		150 ms	PVAB	180 ms			0
Sensed AV	·	120 ms	j				Ğ
Save		Get	TherapyGuide	Undo	E PB	OGRAM	< ratient
		_					
🔶 Eme	ergency		Interrog	ate	End	Session	< Session

14. Verify the "Device Configuration ID" at the bottom of the Parameters Report starts with "1-".

	Pacemaker Model: Medirsnic Attesta ATDR01 Senal Number: FNB007574 Permanent Parameters Report	Cayong	04/00/01 00 63 PM Software SW043 8 2 CopyrigR (c) Meetions, inc. 2017 Page 2 Ventricular Lead		eters Report	Outcome - cet de Pail Software SW043 8 2 CopyrigM (cet Meditrothic, Inc. 2017 Page 3		
	Atrial Lead	Ventricular Lead			Additional/Interventions		Ventricular High Rate Episodes	
	Amplitude 3.500 V Pulde VAGh 0.40 ms Sensitivitario 50 mV Bensing Assuration On Pace Polarity Unipolar Sense Polarity Unipolar Load Marrido Monitor Oxig	Amplitude Pulice Width Sensing Assurance Poce Polarity Sense Polarity Lead Monitor	5.000 V 1.00 ms 2.80 mV On Unipolar Unipolar Unipolar	RDR Detection Type Steep Non-Comp. Athal Pacing Transtetephonic Monitor Extended Telemetry Extended Marker Implem Detection	Off Off Off Off Standard OffComplete	Detection Rete Detection Reats Terminaton Beats SVT Filter Episode Collection Method Selectable Diagnostic	190 ppm 5 beats 5 teats On Rolling	
	Matanum Impedance 4.000 ohms Minimum Impedance 200 ohms Monitor Sensitivity 8	Maximum Impedance Minimum Impedance Monitor Sensitivity	200 ohms 8	Post Mode Switch Pacing Atrial Preference Pacing	Off Off	Chronic Lead Trend High Rate Detail Include Refractory Senses	On Include	
Device Information							Summed 4 for 4/4 secs	
Device information						Device Information		
							Device Configuration ID: 1-81-A0-82-02	
Device Configura	tion ID: 1-8	1-A0-82-	02					
Loc	ok for "1-"	These	values	may dif	fer			

If it starts with "1-", the pacemaker has been updated successfully. No further action is required.

Otherwise, continue to the next page

Tł	e Device Configuration ID does not appear	The Device Configuration ID starts with "???-"				
•	Reprint the Parameters Report from the Parameters screen. If the report still does not display Device Configuration ID, the programmer has not been updated to a software version required to complete the pacemaker update. Contact your Medtronic representative or Technical Services at 1-800-638-1991 to ensure the programmer software for the patient's device has been updated to at	<ul> <li>Reprint the Parameters Report and recheck the Device Configuration ID.</li> <li>If "???-" is still present, the pacemaker was unable to successfully receive the update.</li> <li>Contact your Medtronic representative or Technical Services at 1-800-638-1991 for additional instructions.</li> </ul>				
	least the software version 8.2.					

Otherwise, which of the two options below apply to the report?