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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™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ 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™ 2090 and CareLink Encore™ 29901 Programmers.

Patient Management Recommendations
After the new software is installed on the Medtronic CareLink™ 2090 and CareLink Encore™ 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

1) Directions for applying these software updates to patient pacemakers and to Medtronic programmers can be found on the enclosed Updating a Pacemaker to Correct the Dual Chamber Circuit Error tip card

2) 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,

[redacted]

QRA Lead
SEA Region (Cluster 1)

[redacted]

Chloe Tan
QRA Lead
SEA Region (Cluster 2)

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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™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ 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™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ 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.

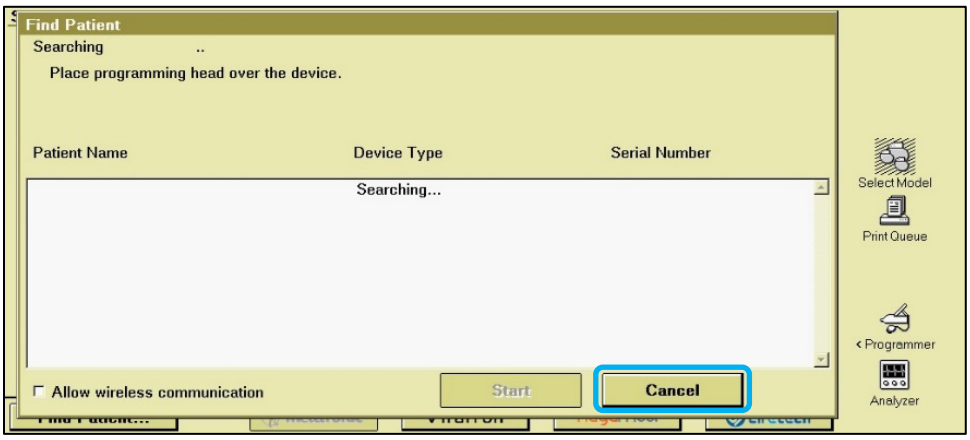
UPDATING A PACEMAKER TO CORRECT THE DUAL CHAMBER IPG CIRCUIT ERROR

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

1. Identify the patient's implanted pacemaker model.
   This update applies to the following devices: Adapta™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ A, E, G, Q series.

2. Turn on the 2090 or Encore programmer.

3. Press "Cancel" on the Find Patient window.



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

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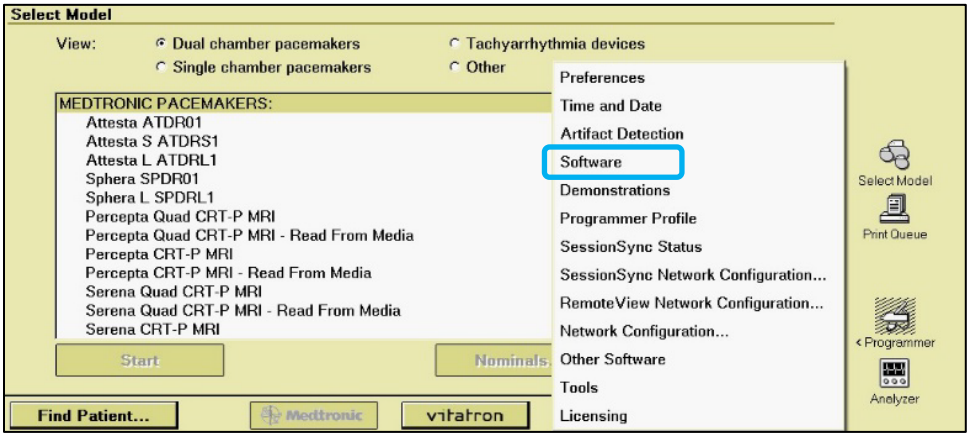
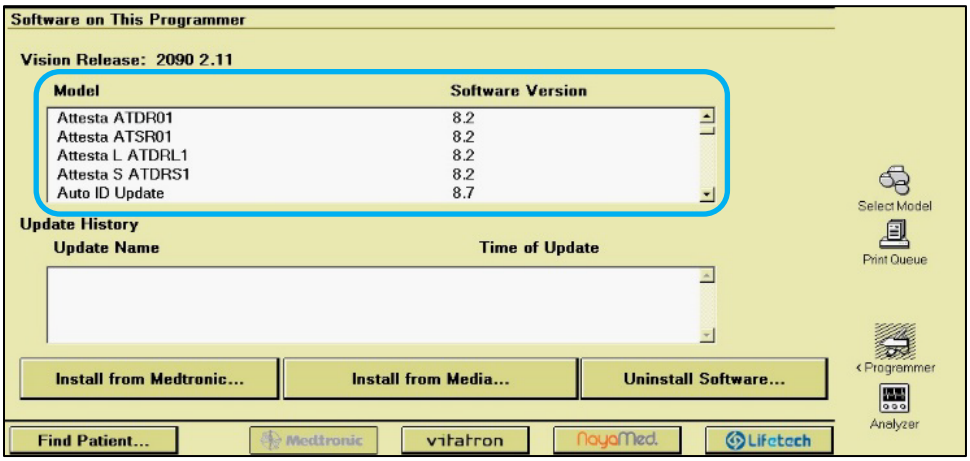
5. Tap on “Software”.



6. Search for the patient’s pacemaker model.



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

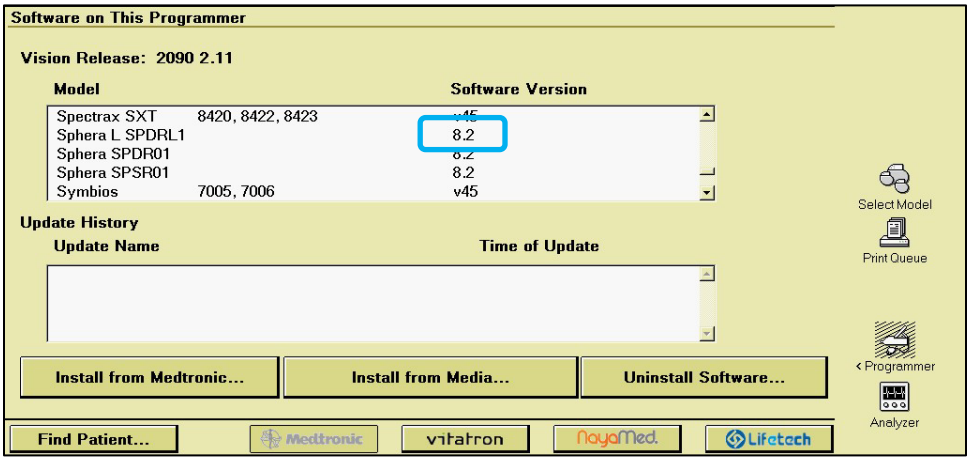
   If the software version is less than 8.2, stop and contact your Medtronic representative to update the programmer.

WARNING

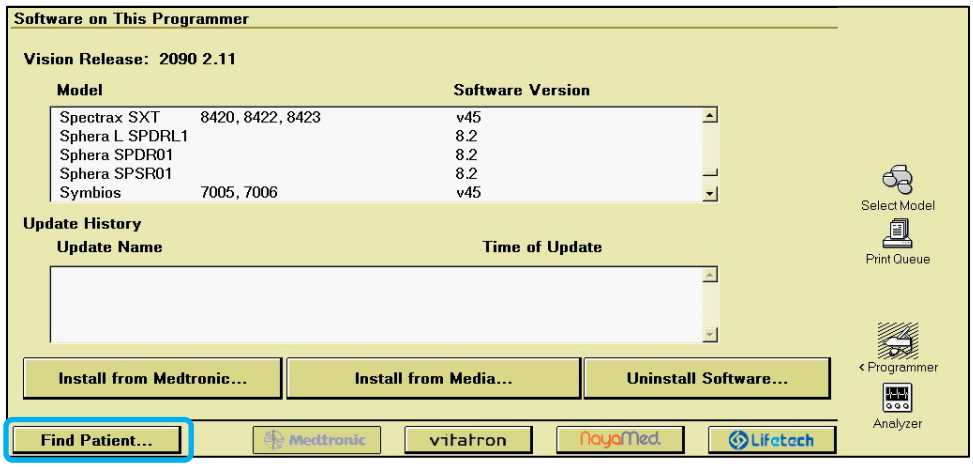
If the programmer is running a software version less than 8.2:

- **DO NOT** run EP Study; and
- **DO NOT** program any 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.



8. Tap on "Find Patient".



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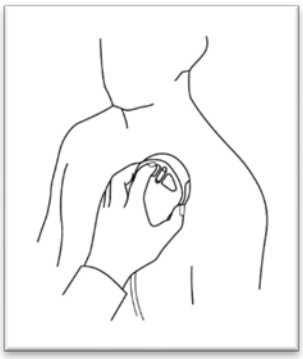
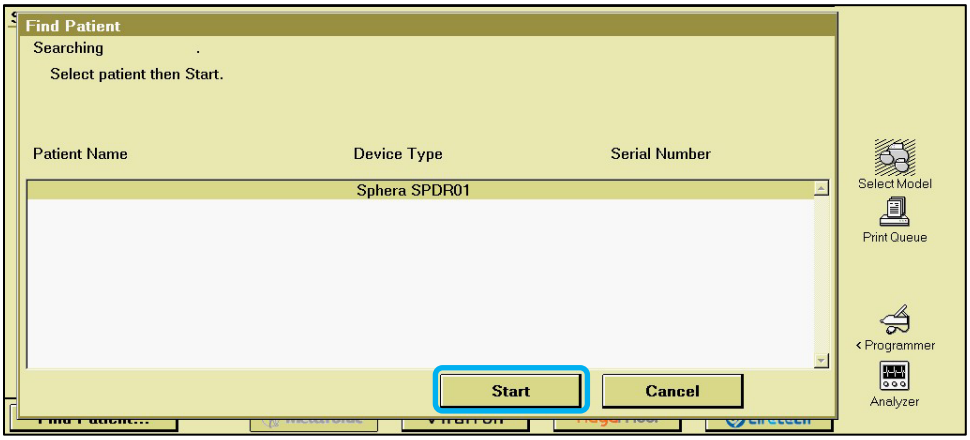
9. Place the programming head over the patient's pacemaker.

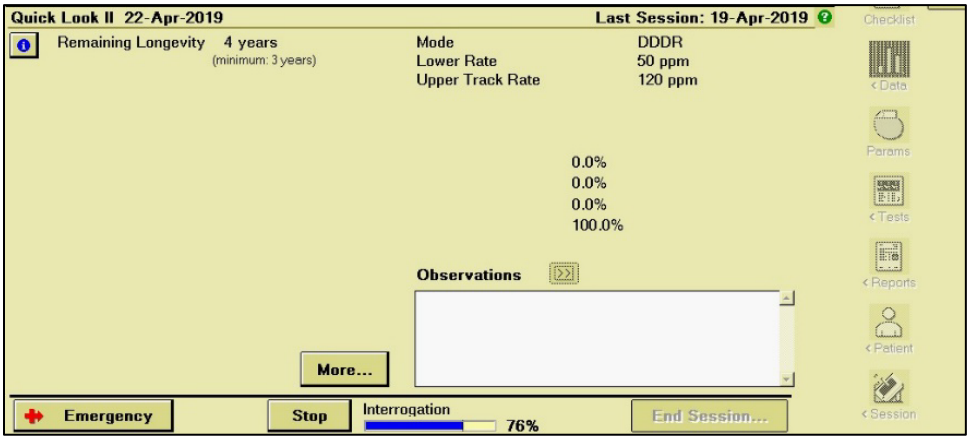


10. Tap on "Start" when the programmer has detected the patient's pacemaker.



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.



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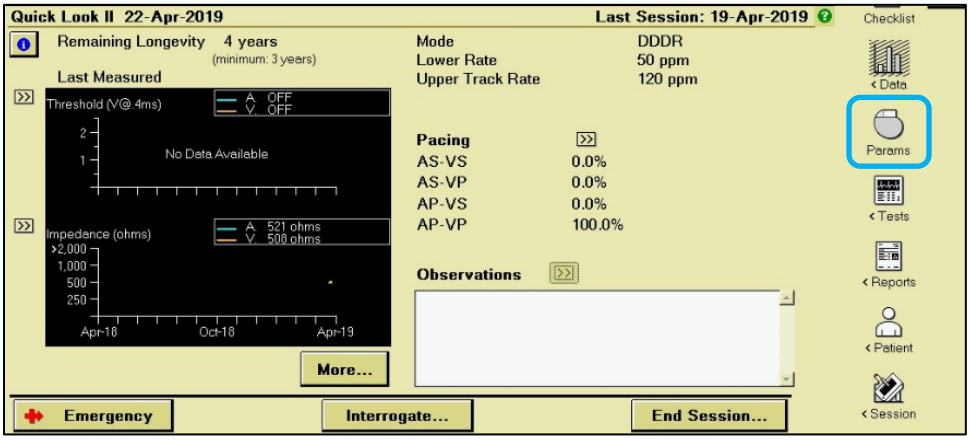
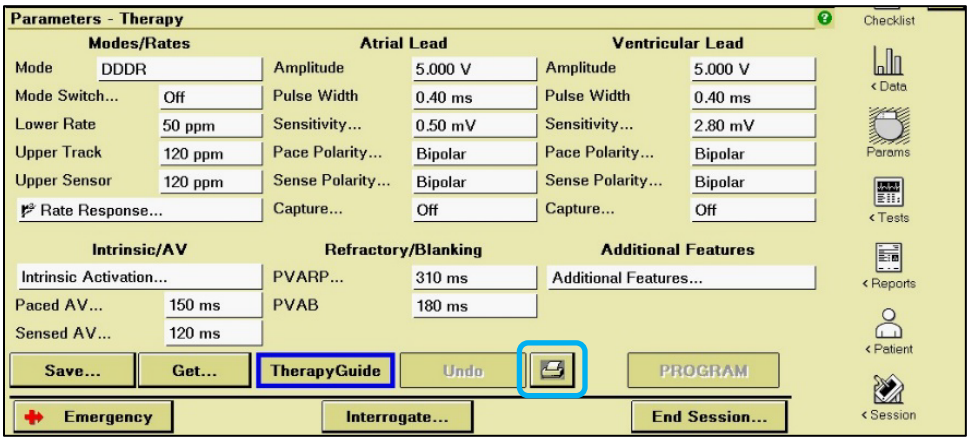
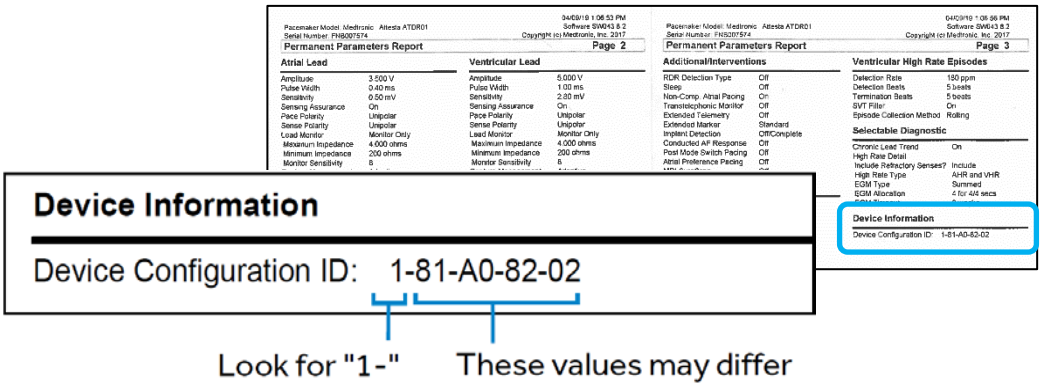
12. Tap on the Parameters icon.



13. Print the Parameters Report.



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



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

Otherwise, continue to the next page

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

The 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 least the software version 8.2.	• Reprint the Parameters Report and recheck the Device Configuration ID. • If "???-" is still present, the pacemaker was unable to successfully receive the update. • Contact your Medtronic representative or Technical Services at 1-800-638-1991 for additional instructions.