Medtronic

Urgent Field Safety Notice
Adapta™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ A, E, G, Q Pacemakers
Software Update

September 2019

Medtronic reference: FA857 Phase II

Dear Physician or Healthcare Professional,

In January 2019, Medtronic issued an Urgent Field Safety Notice 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** (see enclosed letter). 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 received approval to distribute 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). Medtronic Representatives or authorized personnel 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
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 Chamber Circuit Error</u> tip card.

The Competent Authority of your country has been notified of this action.

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.

If you have any questions, please contact your Medtronic Representative at <XXXX>.

Sincerely,

Local / BU Manager

<u>Enclosure:</u>
- January 2019, Urgent Field Safety Notice letter
- Updating a Pacemaker to Correct the Dual Chamber Circuit Error tip card.

Medtronic

Urgent Field Safety Notice
For a Subset of Medtronic Dual Chamber Pacemakers
Recall and Patient Management Recommendations

January 2019

Medtronic reference: FA857

Dear Physician or Healthcare Professional,

This letter is to inform you of a voluntary recall and distribution suspension affecting a subset of Medtronic dual chamber pacemakers distributed worldwide between 10 March 2017 and 7 January 2019 under the brand names **Adapta™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ A, E, G, Q series**. Please note that not all devices within these brand names are affected by this recall. This letter contains a description of the issue and programming recommendations.

Devices in the affected subset, when programmed to a dual chamber mode with atrial-sensing, may experience a circuit error that affects device functionality. See Table 1 for modes that are susceptible to this circuit error. For this error to occur, a unique combination of events must take place while the device is processing an atrial-sensed event. If this error occurs, the device will be unable to provide pacing until a ventricular-sensed event (VS) is detected. Once a VS is detected, normal pacing functionality is restored immediately. If a VS is not detected, the device will withhold both atrial and ventricular pacing. In addition, until a VS is detected, the device will be unable to initiate a session with a programmer, initiate a session with a CareLink™ remote monitor, or respond to a magnet. Single chamber and dual chamber pacing modes that do not sense atrial activity are not susceptible to this circuit error (see Table 1).

Table 1: Identification of modes susceptible/not susceptible to circuit error

Modes susceptible to circuit error	Modes NOT susceptible to circuit error
DDD, DDDR	VVI, VVIR
DDI, DDIR	DVI, DVIR
VDD	AAI, AAIR
ADI, ADIR	VOO, VOOR
VDI, VDIR	AOO, AOOR
ODO	DOO, DOOR
OAO	OVO
MVP - when operating in DDD, DDDR, DDI or DDIR mode	VVT, AAT

Through 4 January 2019, Medtronic is aware of four (4) reported occurrences in two (2) patients where a pause in pacing therapy was clinically apparent due to this circuit error. These reported events occurred in three (3) devices from a total of 156,957 devices sold worldwide. No deaths have been reported as a result of this issue.

Patient risk is determined by the patient's underlying cardiac rhythm and whether the device is in a susceptible pacing mode as described above. Through our analysis of this issue, Medtronic estimates that on average, 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. Risk is minimized in patients who have an escape rhythm adequate to prevent syncope during a loss of ventricular pacing, since a VS restores full device functionality. No risk of a pause due to this circuit error exists for patients programmed to a non-susceptible pacing mode.

The root cause for this issue is related to a design change to an integrated circuit in a subset of devices that were distributed between 10 March 2017 and 7 January 2019.

Medtronic is developing a software update that can be installed into affected devices to correct this issue. Medtronic estimates submission of this software update to regulatory agencies by the 2nd half of 2019. Upon subsequent regulatory approval, Medtronic will notify customers of its availability. Until that time, Medtronic is providing the patient management recommendations described below and depicted in Appendix A.

Patients and clinicians may determine if a specific device is affected by looking up the serial number on Medtronic's Product Performance website: http://wwwp.medtronic.com/productperformance/

Medtronic records indicate that your facility may have product inventory potentially affected by this issue. As a result, Medtronic requests that you immediately take the following actions:

1. Segregate and remove all unused affected product from your inventory.
2. Return all unused affected product in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary.

Medtronic

Patient Management Recommendations

We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Physician Quality Panel (IPQP), **Medtronic recommends programming to a non-susceptible pacing mode as the primary mitigation for patients implanted with an affected device until the software update has been installed**. Specific patient risk assessment and programming recommendations are outlined below and provided in Appendix A.

- **For patients whose device is programmed to a non-susceptible mode (see Table 1), no action is needed at this time. Continue routine clinical monitoring.**

- **For patients whose device is programmed to a susceptible mode and are continually in persistent atrial fibrillation, reprogramming the device to the non-susceptible VVI or VVIR mode is recommended to eliminate risk due to this issue until the software update has been installed. Continue routine clinical monitoring.**

- **For patients whose device is programmed to a susceptible mode and either: *have no underlying ventricular escape rhythm; or are at risk for a symptomatic pause until a ventricular escape beat occurs,* programming to a non-susceptible mode is recommended to eliminate risk due to this issue until the software update has been installed. Continue routine clinical monitoring.**

- **For patients who do not 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,* continue clinical monitoring in a susceptible mode until the software update is available, or consider device replacement.**
    - The estimated per patient mortality risk due to this issue is 0.021% when programmed to a susceptible pacing mode over the estimated time until the software update becomes available. This risk is comparable to the Medtronic estimated per-patient mortality risk associated with a device replacement (0.027%) *.
    - If a patient reports symptoms consistent with a pacing pause, and you would like assistance assessing whether a patient had a pause due to this issue, contact your Medtronic representative.

- **Advise patients remaining in a susceptible mode to seek immediate medical attention if they experience new or unexpected symptoms consistent with a pacing pause.**

- **Other than reprogramming to a non-susceptible pacing mode, no additional programming options have been identified to mitigate this issue.**

The Competent Authority of your country has been notified of this action.

Please share this notification with others in your organization as appropriate.
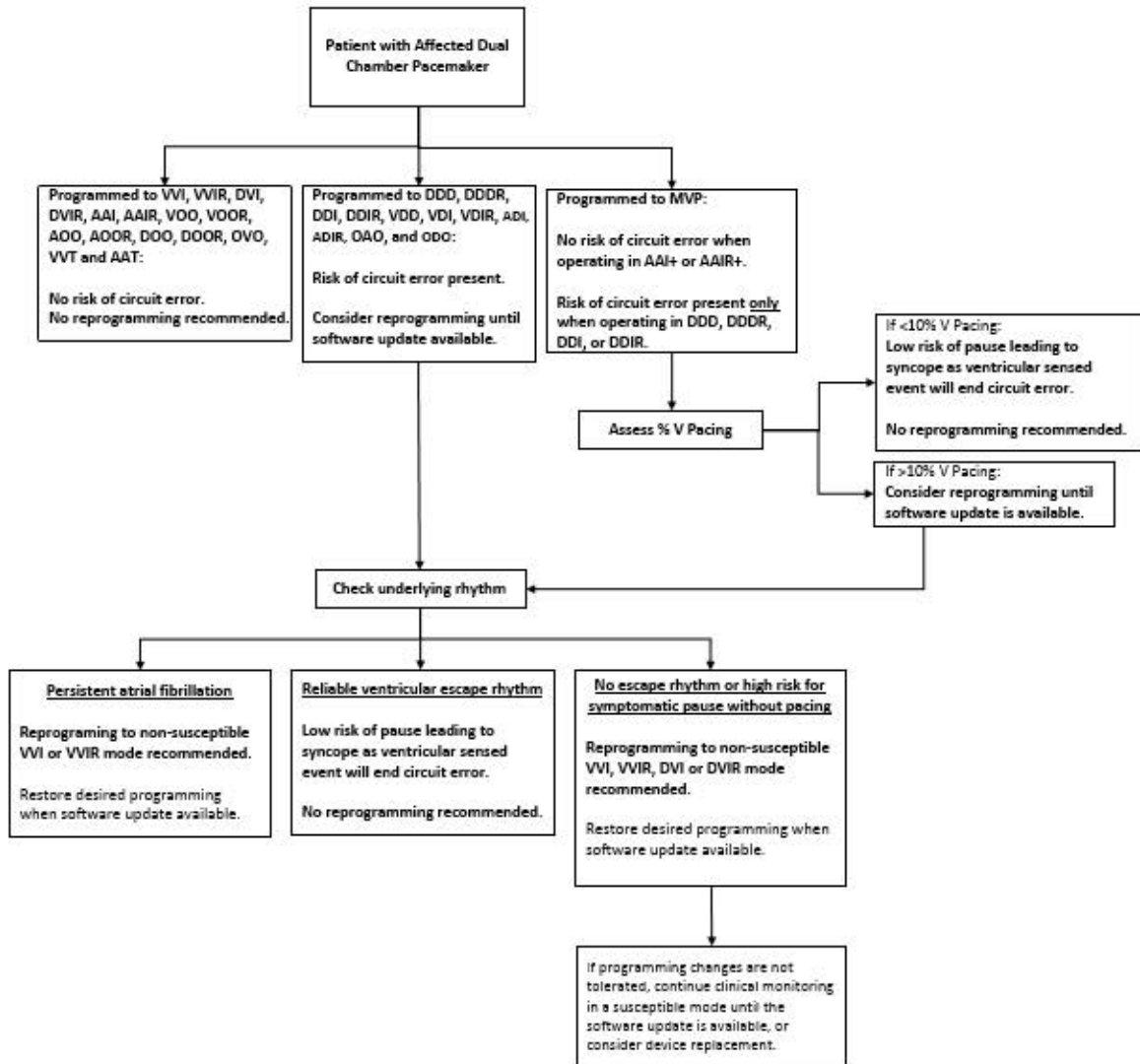
We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

If you have any questions, please contact your Medtronic Representative at <XXXX>.

Sincerely,

* Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; MRCS: MDT2260884, Version 2.0, 11/02/2015.

Medtronic

Appendix A: Programming decision flow chart

```
                    ┌─────────────────────────┐
                    │  Patient with Affected   │
                    │  Dual Chamber Pacemaker  │
                    └─────────────────────────┘
```

Patient with Affected Dual Chamber Pacemaker

Programmed to VVI, VVIR, DVI, DVIR, AAI, AAIR, VOO, VOOR, AOO, AOOR, DOO, DOOR, OVO, VVT and AAT:

No risk of circuit error.
No reprogramming recommended.

Programmed to DDD, DDDR, DDI, DDIR, VDD, VDI, VDIR, ADI, ADIR, OAO, and ODO:

Risk of circuit error present.

Consider reprogramming until software update available.

Programmed to MVP:

No risk of circuit error when operating in AAI+ or AAIR+.

Risk of circuit error present <u>only</u> when operating in DDD, DDDR, DDI, or DDIR.

Assess % V Pacing

If <10% V Pacing:
Low risk of pause leading to syncope as ventricular sensed event will end circuit error.

No reprogramming recommended.

If >10% V Pacing:
Consider reprogramming until software update is available.

Check underlying rhythm

Persistent atrial fibrillation

Reprograming to non-susceptible VVI or VVIR mode recommended.

Restore desired programming when software update available.

Reliable ventricular escape rhythm

Low risk of pause leading to syncope as ventricular sensed event will end circuit error.

No reprogramming recommended.

No escape rhythm or high risk for symptomatic pause without pacing

Reprogramming to non-susceptible VVI, VVIR, DVI or DVIR mode recommended.

Restore desired programming when software update available.

If programming changes are not tolerated, continue clinical monitoring in a susceptible mode until the software update is available, or consider device replacement.

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.

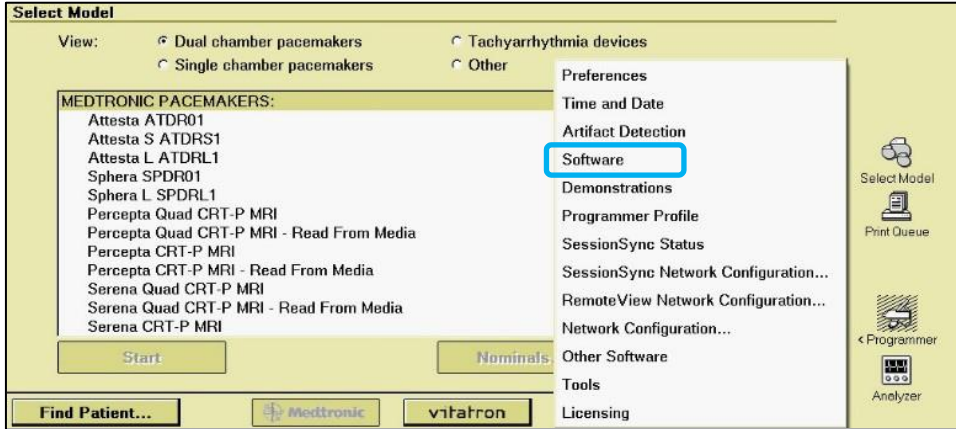3. Press "Cancel" on the Find Patient window.
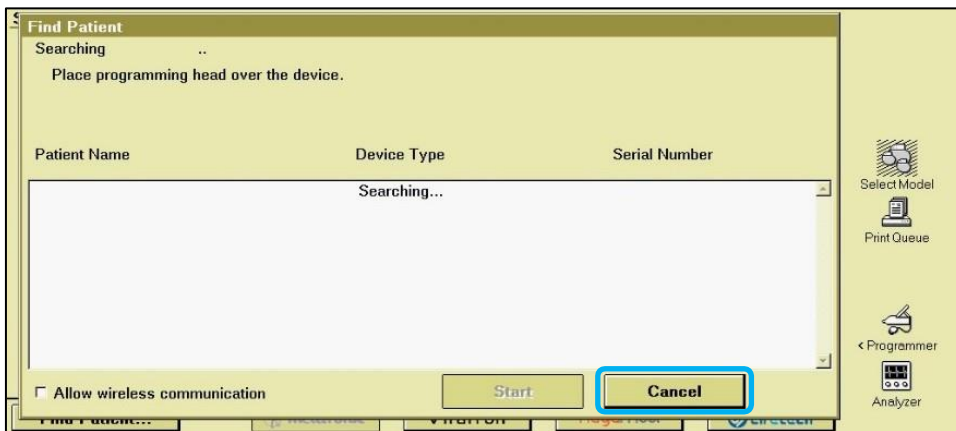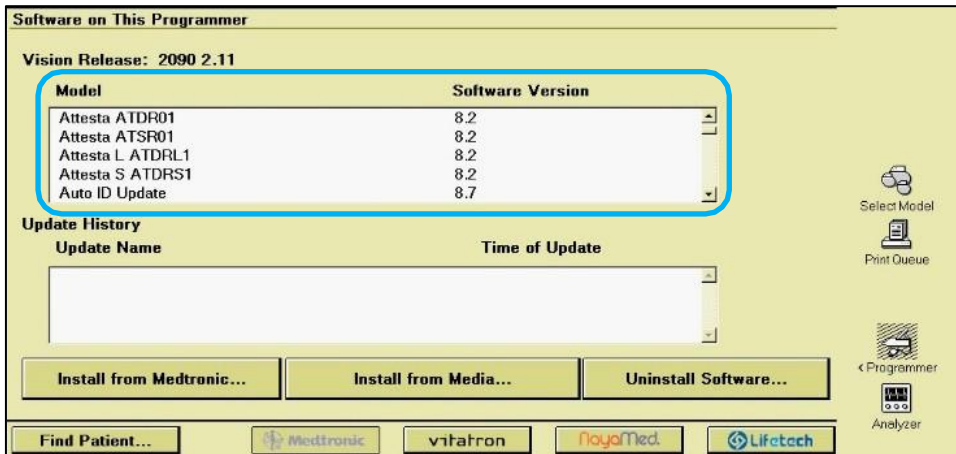

4. Tap on "Programmer" icon on the main programmer screen.

5. Tap on "Software".

6. Search for the patient's pacemaker model.

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.

---
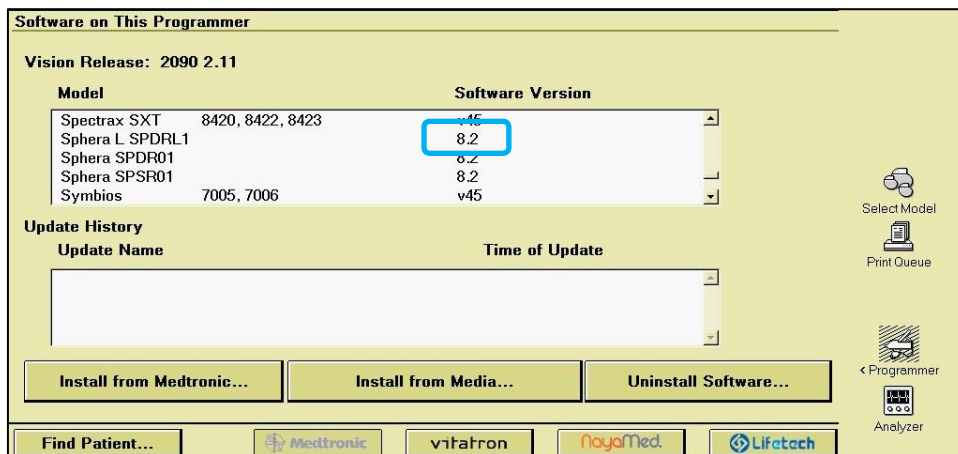
8. Tap on "Find Patient".
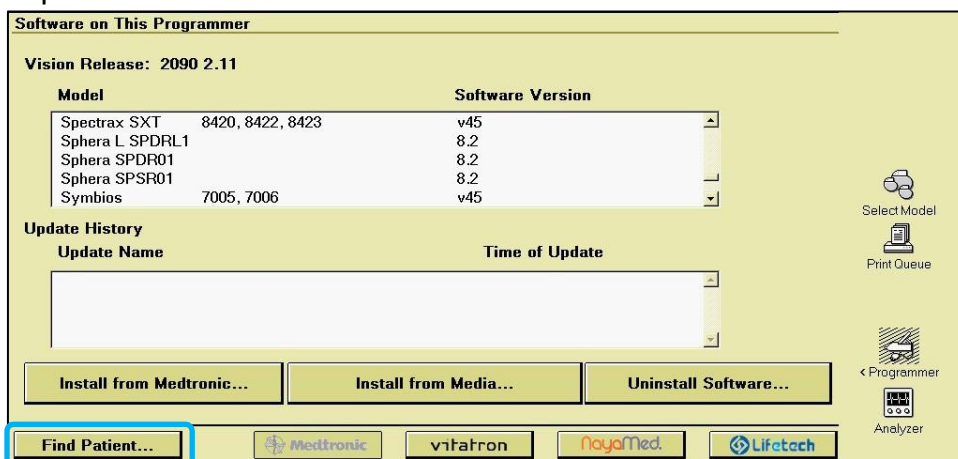
Continue to the next page

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

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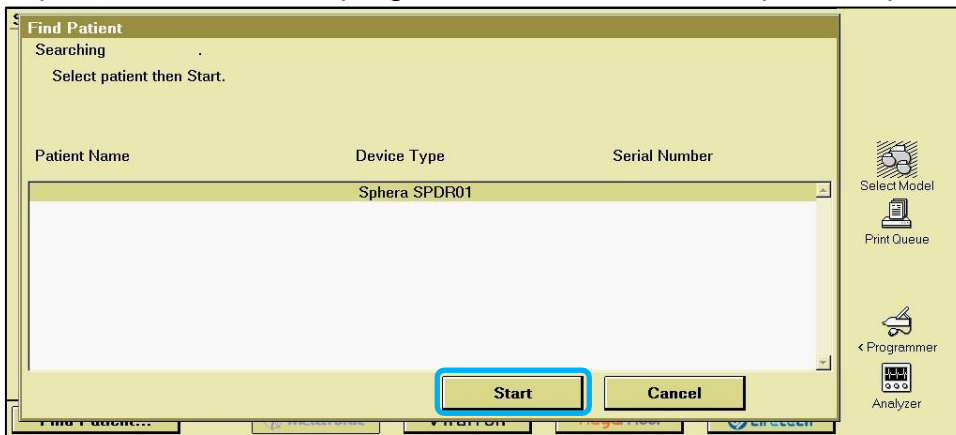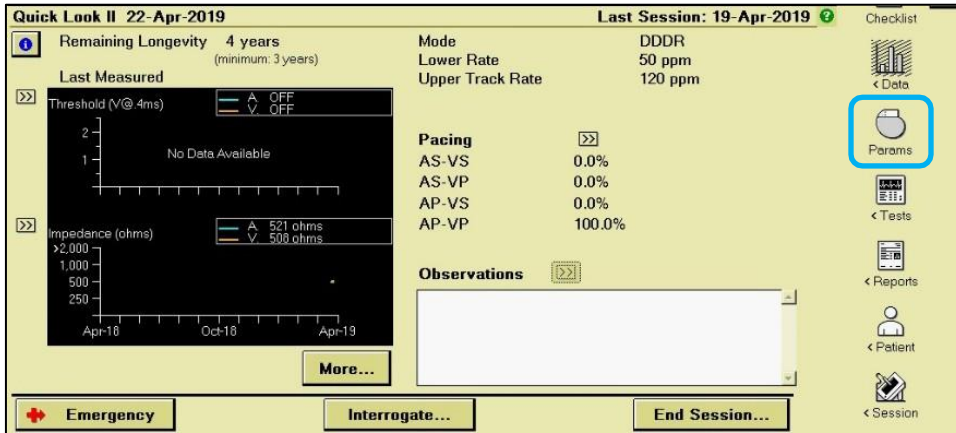

11. Wait for the interrogation to complete.

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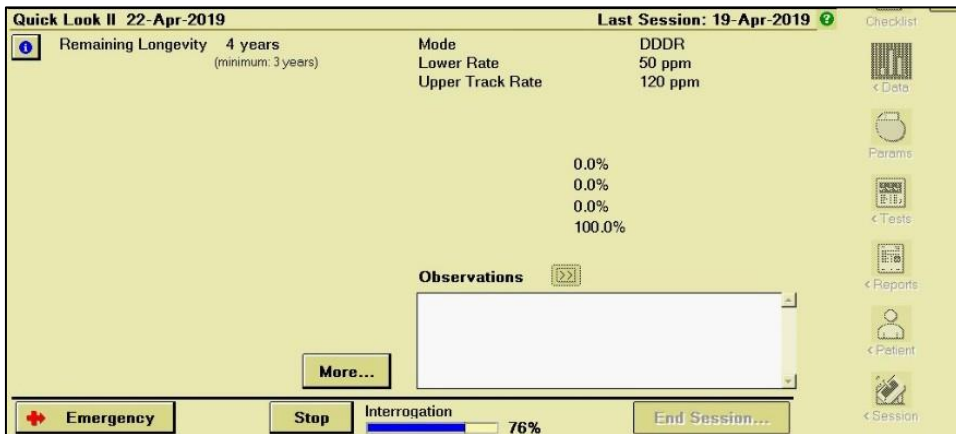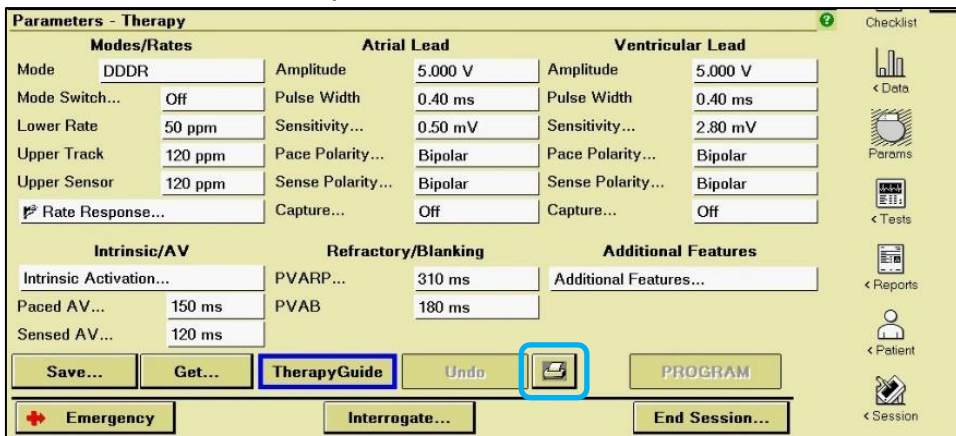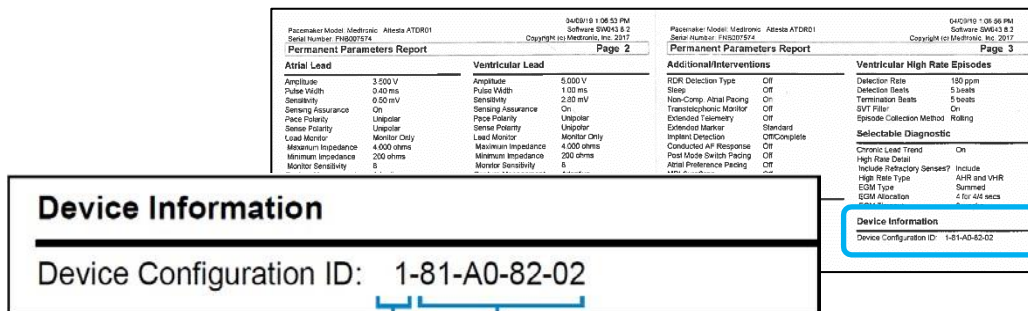
12. Tap on the Parameters icon.

13. Print the Parameters Report.

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

Look for "1-"   These values may differ

**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 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 for additional instructions.