

Date

[patient info name and address]

Dear xx,

RE: Advisory– Boston Scientific Pacemaker and Cardiac Resynchronization Therapy (CRT) Devices – Risk of Shorter Than Expected Battery Life

Boston Scientific, the manufacturer of your cardiac device, has recently shared that there may be a problem with some pacemaker and cardiac resynchronization (CRT) pacemaker devices that were implanted in BC.

What is the advisory?

The device may experience an issue near the end of its expected battery life. Though the battery remains ok, the device has the potential to reset itself to a safety mode, meaning that the pacemaker function may not be ideal or meet your needs. It is important to note that not all pacemakers and CRTs are affected by this advisory. However, we are committed to ensuring patients receive clear communication.

Boston Scientific has developed a device software upgrade to limit the risk of your device to reset to safety mode. This software upgrade is recommended for your device.

Is my device affected by this advisory?

We have identified that your device may be at risk of experiencing this behaviour. This means that the device may need to be replaced earlier than expected. This is more likely to happen in the last 4 years of battery life and may require the device be replaced prior to the battery being exhausted.

What will happen next?

1. Your device doctor or Device Clinic will contact you if there is a need to reschedule your next in-person visit.
2. During your next in-person visit they will check your device, complete the software update and confirm its proper function.
3. Your follow up visits will remain on the same schedule.
4. It is very important that you continue to attend all of your scheduled device clinic appointments. If you have remote monitoring already (Latitude) at home, please make sure it is connected and working. Your Device Clinic can help you with this.
5. While at home, your remote monitoring system (Latitude), will send an alert to your device doctor or Device Clinic if an issue detected.

6. Your device doctor will discuss with you the best way to manage this advisory for your clinical condition. This may mean admission to hospital for replacement of your device.
7. If device replacement is required, your device team will make all of the arrangements.

Our Commitment to You

We are sorry for the inconvenience or anxiety this may cause you. The risk of this advisory affecting the function of your device remains low, and your device clinic will make arrangements to ensure your device continues to function optimally. We are committed to your safety and to the highest standards of care. The actions listed above address this problem and ensure that we are able to continue to provide you with safe and effective treatment. As always, your views are very important to us and we want to make sure that you have all the information.

Yours sincerely,

Device Clinic