

Medtronic

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Coroners Court of Victoria
65 Kavanagh Street
Southbank
Victoria 3006

Attention: Josh Munro

Re: Investigation into the death of John C Prohasky

We refer to the Finding without Inquest dated 24 June 2016 and received by Medtronic on 30 June 2016, regarding the Victorian Coroners investigation into the death of Mr Prohasky.

The Coroner has made the following recommendation to Medtronic Australasia Pty Ltd (**Medtronic**):

With the aim of maintaining important data records, I recommend that Medtronic Australia [sic] Pty Ltd, in consultation with its parent company, install additional data retention technology to its Paradigm insulin pump, or implement a policy whereby the historic data contained in any insulin pump devices under review is salvaged as a matter of priority, to prevent the possibility of it becoming corrupted.

It is not possible to modify the design of the Medtronic MiniMed® Paradigm® Insulin Pump (the **Paradigm**). The Paradigm is being slowly phased out globally due to the ongoing development of Medtronic's next generation of Insulin Pumps. The next generation of Medtronic Insulin Pump, the Medtronic Minimed 640G, has been available in Australia since January 2015. However, the Diabetes business of Medtronic has reviewed and amended its process for arranging the return of all Medtronic Insulin Pumps under coronial review and the salvage of historic data in such circumstances.

Before discussing Medtronic's policy, we must first briefly explain the device memory capabilities of the Paradigm and the function of the Medtronic's Carelink® Network.

1. Device memory in a Medtronic MiniMed Paradigm® Insulin Pump

When used by a pump user, the Paradigm will capture key events and information surrounding the management of the pump user's diabetes and the operation of the Paradigm software. This information can be downloaded onto a computer as two types of files:

- (a) History Files; and
- (b) Trace Files.

History Files contain information relating to the management of the pump user's diabetes, including, but not limited to:

- Pump user settings;
- Insulin delivery events such as boluses and change in basal delivery profiles;
- Blood glucose entries;
- Sensor glucose values;
- Alerts and alarms; and
- Administrative changes such as time, date and battery changes.

Trace Files contains both the information in the History Files and detailed information on the operation of the Paradigm software, including, but not limited to:

- Button presses;
- Pump stroke type, size and encoder counts; and
- Function calls for critical operations such as calculations and error checks.

History Files can be used to allow healthcare professionals to review the management of the pump user's diabetes, and both History and Trace Files can be used by trained Medtronic representatives through our 24 hour Global Helpline (1800 777 808) to assist a pump user with troubleshooting.

History Files and Trace Files are both stored in the Paradigm's memory chip (known as **SRAM**) on what is known as a 'First In First Out' basis. This means that during use information is continually stored in the SRAM and when the SRAM becomes full, older data is overwritten by the newer data. Under normal usage, the Paradigm will overwrite History Files and Trace Files after 1 – 2 days.

The SRAM in the Paradigm must be continually powered in order to retain the History Files and Trace Files. The SRAM is powered by an internal non-removable battery which is separate from, but charged by, the primary AAA battery. If the primary AAA battery is removed, the internal battery has enough energy to retain the History Files and Trace Files in the SRAM for approximately 5 – 10 days from the date the Primary AAA battery is removed.

2. Carelink®

Carelink is a web-based system that allows a pump user to manually upload data from the Paradigm (or other Medtronic Insulin Pumps) as well as from continuous glucose monitors and supported blood glucose meters. In order to do this, the pump user must possess a CareLink USB. This USB is designed to communicate between the pump user's devices and any computer with an internet connection. The pump user must enroll on the Carelink website and, once enrolled, the pump user can upload data to Carelink. Every data upload requires the pump user to log into the Carelink website and initiate the data upload manually.

Only History Files can be uploaded to Carelink by a pump user, and not all pump users upload their data regularly to Carelink. If uploaded by a pump user, the History Files are saved by the Carelink system and are stored indefinitely. In the circumstances of a pump user's death, if they have uploaded their History Files to Carelink, Medtronic is able to download these History Files after receiving a request by the Coroner, together with consent from the deceased's next of kin or healthcare professional.

The upload or download of Trace Files requires technical support from Medtronic. A specific confidential code must be entered into the users Carelink account (similar to an admin entry code). A Trace File upload may take 20-30 minutes to complete. Duration and success of the upload may vary depending on the quality of the internet connection, therefore we generally recommend these uploads take place at Medtronic's head office in Sydney.

3. Actions taken to limit the loss of information after a request.

As the Paradigm will only retain the data in the SRAM for approximately 5 – 10 days once the primary AAA battery is removed, Medtronic's process for arranging the return of Medtronic Insulin Pumps under coronial review and the salvage of historic data in such circumstances has been reviewed and amended. We have set out a brief outline of the process below.

1. Once notified of a pump user's death and subsequent coronial investigation Medtronic's objective is provide prompt assistance to the Coroner.
2. If Medtronic is notified that the Coroner has identified that a pump user was using a Medtronic Insulin Pump at the time of their death, that the Insulin Pump cannot be ruled out as a possible cause/contributory factor to death and a coronial investigation is taking place, whoever is notified within Medtronic will request that the Coroner place a call to our Customer Service team on the 24 hour Global Helpline (1800 777 808). Medtronic will, of course, accept any form of notification (email, in person to a representative etc.) but our Global Helpline staff are trained to specific deal with this type of notification.
3. The Global Helpline will:
 - (a) take down the necessary information from the caller;
 - (b) advise the caller that the AAA battery should not be removed and that the Medtronic Insulin Pump should not be used until download of files can be made;
 - (c) if the caller is in possession of the deceased's Carelink USB, attempt to perform a History File download during the phone call; and
 - (d) arrange for the expedited collection of the Medtronic Insulin Pump. The Global Helpline will notify the Medtronic Diabetes Support Services (**DSS**) Team at the Medtronic Head Office in Sydney. The DSS team will then arrange for a medical courier to collect the device and return it promptly to the Head Office. The AAA battery will not need to be removed for this to take place.
4. Alongside this, Medtronic has also updated the instructions for the Global Helpline so that Medtronic Insulin pump users are encouraged to upload data to Carelink more often, thereby allowing more historical data to be retained and available.

4. New Generation Insulin Pumps

Medtronic's next generation Insulin Pump, the Medtronic Minimed 640G is designed with non-volatile memory. Non-volatile memory means that the SRAM does not have to be powered in order to retain data. The 640G also has more memory than the Paradigm which means it will be able to operate for a longer period of time before overwriting. Under normal usage, the 640G will overwrite Trace Files after 11 days, significantly longer than the Paradigm.

Yours sincerely



Michele Blanshard
Business Director
Diabetes, Australia and New Zealand
Medtronic Australasia Pty Ltd