

Urgent: Product Defect Correction

TGA Recall Reference Number: RC-2023-RN-00473-1

**PushTracker E2 & E3 utilised with SmartDrive MX2+ Power Assist Device
ARTG 202708**

Date: _____

Customer: _____

Address: _____

Dear Valued Customer,

The purpose of this letter is to inform you of a medical device field correction, following consultation with the Therapeutic Goods Administration (TGA), involving the **PushTracker E2 and E3 component utilised with the SmartDrive MX2+ Power Assist Device** (ARTG 202708). Impacted products were manufactured between May 06, 2019 through February 10, 2023.

Reason for the Field Correction:

The PushTracker E2 and E3 is a wearable watch that communicates with a SmartDrive Power Assist Device via the SmartDrive MX2+ Application. Through design and development activities, Max Mobility has identified a software issue with the SmartDrive MX2+ Application operating on Android WearOS. When multiple processes are running on the watch's Central Processing Unit (CPU), the application may fail unexpectedly. If this happens, the motor on the power assist device continues to run and the user may not be able to stop the device using tap gestures.

The software has been corrected in SmartDrive MX2+ Version 1.1.00 and is now available on the Google Play Store.

Risk to Health:

If the user has multiple programs running on the watch, the application may fail. If the application fails when the user is in forward motion, the motor will continue to run and the user will not be able to stop the device using the tap gestures. This could lead to serious injury, for example, running into obstacles or other people.

Affected Product:

The specific model numbers impacted by this issue are shown below:

Part Number
SM-MX2-32K
SM-MX2-32P
SM-MX2-32PK
SM-MX2-33D
SM-MX2-33P
SM-MX2-33PK
SM-MX2-33S
SM-MX2-150

SM-MX2-167
SM-MX2-32D

Actions Required:

Our records indicate that you have purchased one or more of the impacted units. If you are a provider, a list of impacted purchase orders and/or serial numbers is shown in Attachment 1. To correct the affected products, you will need to update your software to SmartDrive MX2+ Version 1.1.00.

Please use the QR Code to access the field action portal at <https://hub.permobil.com/en-au/smartdrive-voluntary-field-action>



- 1) Enter the password **SmartDrivePT2023** to enter the portal.
- 2) Once you enter the portal, you will be asked to enter your contact information, select if you are a provider or end user and acknowledge that you have read and understood the Urgent Product Defect Correction letter.
- 3) If you are a dealer and have distributed the affected product to someone else, you will be asked to select a transmission method. You may either (a) notify your end users directly and include a copy of this notice with your communication or (b) provide end user contact information to Permobil Australia on quality.au@permobil.com and we will contact them for you.
- 4) After acknowledgment, instructions to update your software will be provided.
- 5) Once the update has been completed, you will be asked to verify the correction by confirming version 1.1.00 is shown in the 'About' menu of your software.

If assistance is needed during the software update process, the portal will provide you with access to the Permobil Australia customer support team.

While a user is waiting for the correction, the following actions can be taken immediately to reduce the likelihood of the hazardous situation:

- Discontinue using the PushTracker E2 or E3 and utilise a wired controller (SwitchControl Buttons or SpeedControl Dial) or other wearable controllers (compatible Apple Watch or Samsung Galaxy Watch).
- If you are running multiple applications and experiencing any slowdown with the SmartDrive MX2+ application, close other applications.
- Follow the Instructions for Use and wear the PushTracker snug on your wrist.

Contact Information:

If you have any questions, please contact Permobil Australia at 1300 845 483 or quality.au@permobil.com.

Max Mobility considers end user safety and customer satisfaction our top priorities. We apologise for any inconvenience this may cause you and thank you in advance for assistance in implementing this correction.

Sincerely,



Fiona Taylor

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