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FSCA Ref: SDPT2-23-002

Field Safety Notice
PushTracker E2 & E3 utilized with SmartDrive MX2+ Power Assist Device

May 5, 2023

Dear Valued Customer,

The purpose of this letter is to inform you of a voluntary medical device field correction involving the **PushTracker E2 and E3 component utilized with the SmartDrive MX2+ Power Assist Device.** Impacted products were manufactured between May 06, 2019 and February 10, 2023.

Reason for the Voluntary 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, the legal manufacturer 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	Description
MX2-32K	Pushtracker E2
MX2-32P	PushTracker E2Basic (Pre installed)
MX2-32D	PushTracker 2 Germany (Preinstalled)
MX2-33S	Pushtracker E3
MX2-33P	PushTracker E3Basic (Pre installed)
MX2-33D	PushTracker 3 Germany (Preinstalled)
MX2-167	SmartDrive MX2+ 6kmh incl PushTracker 2 or 3
MX2-150	SmartDrive MX2+ Demo 9kmh with PushTracker E2/E3 basic (preinstalled)
MX2-151	SmartDrive MX2+ Demo 6kmh with PushTracker E2/E3 basic (preinstalled)
MX2-177	SmartDrive MX2+ Demo EU with PushTracker E2/E3 basic (preinstalled)
MX2-178	SmartDrive MX2+ Demo UK with PushTracker E2/E3 basic (preinstalled)

Actions Required:
Our records indicate that you have purchased one or more of the impacted units. To correct the affected products, you will need to update your software to SmartDrive MX2+ Version 1.1.00.

1) Based on the information provided, please identify the impacted customers and/or users that need to take action. If you require a list of impacted serial numbers, please contact your local Permobil customer support team.

2) Notify all impacted customers and/or users directly by forwarding the communication below.

Actions required by identified customers and/or users of the affected product:

1) Please use the QR Code or link below to access the voluntary field correction portal at https://hub.permobil.co.uk/field-correction-portal/pushtracker.

2) You will be asked to enter your contact information, including who notified you of the voluntary field correction, and your PushTracker serial number.

3) After providing this information, you will have step by step instructions to work through the actions required to update your software to SmartDrive MX2+ Version 1.1.00.

4) Once the update has been completed, you will be asked to verify the correction by confirming version 1.1.00 as 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 technical 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 utilize 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 Customer service at +46 60 787 90 60 or customer_support_se@permobil.com

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer using the address: incident.report@permobil.com , as this provides important feedback.

We are voluntarily issuing this Field Safety Notice and the applicable Competent Authorities have been notified of this action.

Permobil considers patient safety and customer satisfaction our top priorities. We apologize for any inconvenience this may cause you and thank you in advance for assistance in implementing this correction.

Sincerely,

Mark Elliott
Vice President, Quality Assurance and Regulatory Compliance