max mobility®

SDPT2-23-002

Urgent Medical Device Correction

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

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 through 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, 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
MX2-32K
MX2-32P
MX2-32PK
MX2-33D
MX2-33P
MX2-33PK
MX2-33S
MX2-150
MX2-167

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MX2-32D

Actions Required:
Our records indicate that you have purchased one or more of the impacted units. A list of impacted purchase orders 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/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 dealer or end user and acknowledge that you have read and understood the Urgent Medical Device 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 Max Mobility on US_Box_PushTrackerenduserinfo@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 Max Mobility 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.

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Contact Information:

If you have any questions, please contact Permobil at 1-800-736-0925 or

Any adverse events experienced with the use of this product may be reported using one of the following options:

- Online: By completing and submitting the report online at https://www.accessdata.fda.gov/scripts/medwatch

- Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

We are voluntarily issuing this Urgent Medical Device Correction and the U.S. Food and Drug Administration has been notified of this action.

Max Mobility 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