



Field Safety Notice

SpeedControl Dial utilized with SmartDrive MX2+ Power Assist Device

2024-10-06/ Version 1 / Ref. FSCA CAPA 24-015

Dear Valued Customer,

The purpose of this letter is to inform you of a voluntary medical device field correction involving the **SpeedControl Dial component utilized with the SmartDrive MX2+ Power Assist Device**. Impacted products were delivered from 27th August 2023 onwards.

Reason for the Voluntary Field Correction:

The SpeedControl Dial is a wired control option for the SmartDrive power assist device. Through market feedback and subsequent investigation, the legal manufacturer Max Mobility has identified a material change with the printed circuit board assembly (PCBA) in the SpeedControl Dial resulting in inconsistent performance issues. The following are scenarios that may be experienced when an impacted device is used:

- **Continued drive:**
 - The SpeedControl Dial does not fully stop the drive unit when rotated to zero position.
- **Involuntary movement:**
 - Unintended activation of the SmartDrive motor without intentional user input while the SpeedControl Dial is at zero position and dial light is flashing in stand-by-mode.
- **Loss of power to SCD:**
 - When the dial is rotated forward from zero position, SmartDrive motor movement is initiated, and then the SpeedControl Dial unexpectedly shuts down.
- **Failure to start driving:**
 - When the dial is rotated forward from zero position, no SmartDrive motor activation occurs.

Risk to Health:

If you are using an impacted SpeedControl Dial, you **may** experience one of the above performance issues. This **may** result in the SmartDrive motor continuing to run slowly, unexpectedly initiating movement, or stopping unexpectedly. Depending on the scenario, this could lead to serious injury.

Affected Product:

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

Part Number
MX-3DC



Actions Required:

Our records indicate that you have units. To correct the affected product, replacement SpeedControl Dial unit that these will be available from also order SwitchControl buttons free of until the corrected SpeedControl Dial is available.

purchased one of the impacted you will need to request a from your provider. We anticipate February 2025. If required, you can charge from your provider, for use

Please pay attention to the operating instructions included below in this letter if you are continuing to use your SpeedControl dial.

While you are waiting to receive the corrected SpeedControl Dial, the following actions can be taken immediately to reduce the likelihood of a hazardous situation:

- Possible actions for each performance issue outlined above include:
 - **Continued drive:** Press the face of the SpeedControl Dial. This is an alternative stop option to disengage power assist.
 - **Involuntary movement:** Press the face of the SpeedControl Dial. This is an alternative stop option to disengage power assist.
 - **Loss of power to SCD:** Rotate the SpeedControl Dial back to the zero position and re-engage power assist.
 - **Failure to start driving:** No in-field action, a replacement is required.
 - **Contact your provider to swap the switch on the rear of the dial** from "R" (right) to "L" (left). While this results in the controls of the dial performing opposite of what it does when set to "R", this has been shown to address performance issues in some scenarios.
 - **Utilize an alternative wired controller** (SwitchControl) or wearable controller (compatible Apple Watch or Samsung Galaxy Watch once Wear OS app is released).

Contact Information:

If you have any questions, please contact your provider, or Permobil Customer Support 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,

Monika Östlund
Vice President, Quality Assurance and Regulatory Compliance