



## Field Safety Notice

### SpeedControl Dial utilized with SmartDrive MX2+ Power Assist Device

2025-07-28 / Version 1 / Ref. FSCA CAPA 25-007

Dear Valued Customer,

The purpose of this letter is to inform you that Permobil have voluntarily expanded the medical device field correction involving the **SpeedControl Dial component utilized with the SmartDrive MX2+ Power Assist Device**, due to safety and performance concerns. This voluntary action applies to all SpeedControl Dials in the market. You have been identified as having received a SpeedControl Dial.

#### Reason for the expanded Field Correction:

A field correction was originally initiated on December 20, 2024 (FSCA reference: CAPA24-015) to address a material change with the printed circuit board assembly (PCBA) in SpeedControl Dials manufactured and distributed between August 17, 2023 and March 10, 2025. The legal manufacturer Max Mobility has received 781 complaints associated with the PCVA design of which 5 were for serious injuries involving fractured or broken bones and a concussion.

Through ongoing complaint monitoring and subsequent investigation, the legal manufacturer Max Mobility has identified a design issue with the SpeedControl Dial that can lead to unexpected behaviour of the drive unit. The design issue has been part of the SpeedControl Dial since it was first introduced to the market in April 2022. Specifically, if there is an intermittent electrical connection between the SpeedControl Dial and the SmartDrive MX2+ motor, the following performance issues could occur:

- **Continued drive:**
  - The SmartDrive MX2+ Power Assist Device fails to fully stop when the SpeedControl dial is pressed inward.
- **Involuntary movement:**
  - Unintended activation of the SmartDrive MX2+ motor without intentional user input to the SpeedControl Dial while the dial is at zero position and dial light is flashing in stand-by-mode.

Max Mobility / Permobil has identified 54 complaints that may be associated with this issue of which 2 involve serious injuries related to bone fractures.

#### Risk to Health:

If an individual is using a SpeedControl Dial to control their SmartDrive MX2+ Power Assist Device and experiences one of the performance concerns identified above, they may experience continued drive, and/or involuntary movement. Depending on the scenario, this could lead to minor and/or serious injuries. A minor injury, such as a cut, bruise, scrape, or general soreness, could occur if one of these scenarios occurs at a low overall speed. If travelling at a fast rate of speed and one of these scenarios occurs, there is a potential for serious injury, such as a bone fracture.



There is also a potential risk associated with individuals who may be in close proximity to a user of a SpeedControl Dial if one of these performance failure scenarios were to occur, as the wheelchair powered by the SmartDrive MX2+ Power Assist Device could run or bump into another individual and/or roll over their toes or another extremity.

**Affected Product:**

All SpeedControl Dials are impacted by this issue. Specific model numbers associated with SpeedControl Dials are shown below:



Article Code	Description
MX2-3DC	SPEED CONTROL DIAL KNOB
<b>Part of:</b>	
MX2-SO19	SPEED CONTROL DIAL KIT
MX2-S001	SMARTDRIVE MX2+ 6KMH WITH SPEED CONTROL DIAL EU CHARGER
MX2-S004	SMARTDRIVE MX2+ 9KMH WITH SPEED CONTROL DIAL EU CHARGER
MX2-S007	SMARTDRIVE MX2+ 6KMH WITH SPEED CONTROL DIAL UK CHARGER
MX2-S010	SMARTDRIVE MX2+ 9KMH WITH SPEED CONTROL DIAL UK CHARGER
MX2-S013	SMARTDRIVE MX2+ 6KMH WITH SPEED CONTROL DIAL IT CHARGER
MX2-S016	SMARTDRIVE MX2+ 9KMH WITH SPEED CONTROL DIAL IT CHARGER

**Actions Required:**

Our records indicate that you have purchased one of the impacted units and the following action should be taken immediately:

1. Immediately discontinue use of the SpeedControl Dial to reduce the likelihood of a potentially hazardous or harmful situation
2. Use an alternative method to control the SmartDrive MX2+ Power Assist Device if you have one. Alternative controls include;
  - a. A wired SwitchControl, which can be ordered with a mono jack port to connect with an optional Buddy Button
  - b. Wirelessly through the SmartDrive MX2+ App utilising an Apple Watch or Samsung Galaxy watch

A list of compatible wearable devices can be found at:

<https://www.permobil.com/en-gb/products/power-assist/smartdrive-mx2plus-app>

3. You are required to acknowledge receipt of this Urgent Medical Device Field Safety Notice. This should be completed within 10 days of receipt of this letter. Please use the QR code below to access the field action portal to record your acknowledgement. You will need your "Consignee ID" which is provided in the communication from your provider.

(QR code to be added when portal is published)

**Actions planned to correct the problem:**

To ensure our users have access to a wired method of controlling the SmartDrive MX2+ Power Assist Device, Permobil will replace all SpeedControl Dials with a SwitchControl button. Further instructions



for obtaining replacement SwitchControl buttons will be provided through your provider, as well as instructions on how to properly disposition your SpeedControl Dial.

**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](mailto: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](mailto: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,

A handwritten signature in blue ink, appearing to read "Monika Östlund".

Monika Östlund  
Vice President, Quality Assurance and Regulatory Compliance