

Urgent Recall

TGA Recall Reference Number: RC-2025-RN-00687-1
SpeedControl Dial utilised with SmartDrive MX2+ Power Assist Device
ARTG 202708
(All models: MX2-850-3DC, MX2-3DC, MX2-3DC-MC)

Consignee ID: AP4C-IVQGIY

Dear Valued Customer,

The purpose of this letter is to inform you, following consultation with the Therapeutic Goods Administration (TGA), that Max Mobility/Permobil has expanded its recall scope of the **SpeedControl Dial**, a wired control option for the SmartDrive MX2+ Power Assist Device, due to safety and performance concerns. This recall applies to all SpeedControl Dials manufactured and distributed between the dates of April 25, 2022 to July 8, 2025. You have been identified as having received an impacted SpeedControl Dial.

Relation to Existing/Prior Recall:

A recall (Ref No. RC-2024-RN-01155-1) was originally initiated on January 9, 2025 to address a material change with the printed circuit board assembly (PCBA) in SpeedControl Dials manufactured and distributed between the dates of August 17, 2023 and November 21, 2024. The recall was later expanded on April 24, 2025 and included all units manufactured and distributed up to February 28, 2025. Information about the prior recall can be found using the following link: <https://hub.permobil.com.au/speed-control-dial-recall>.

This new expanded recall supersedes the previous recall and applies to all SpeedControl Dials in the market, including replacements received under the previous recall.

Reason for Expanded Field Removal:

Through ongoing complaint monitoring and subsequent investigation, Max Mobility/Permobil identified a new design problem with the SpeedControl Dial that may lead to unexpected behaviour of the SmartDrive MX2+ motor. This design problem has been part of the SpeedControl Dial since it was first introduced to the market in April 2022 and impacts all SpeedControl Dials manufactured and distributed, which occurred between April 25, 2022 to July 8, 2025. Specifically, if there is an intermittent electrical connection between the SpeedControl Dial and SmartDrive MX2+ motor, the following performance problems 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.

Risk to Health:

If an individual is using a Max Mobility/Permobil 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 a user is 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 problem, including SpeedControl Dials that were replaced as part of the existing/prior recall. Specific part numbers associated with SpeedControl Dials are shown below:

| Part Number |
|-------------|
| MX2-850-3DC |
| MX2-3DC |
| MX2-3DC-MC |

Actions Required if you are an End User:

If you have a SpeedControl Dial, please take the following actions immediately:

1. Immediately discontinue use of the SpeedControl Dial to reduce the likelihood of a potentially hazardous or harmful situation.
2. Use an alternate method to control the SmartDrive MX2+ Power Assist Device. Alternate controls include:
 - A wired SwitchControl, which can be ordered with a mono jack port to connect with an optional Buddy Button
 - 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-au/products/power-assist/smartdrive-mx2plus-premium-wearables>
3. You are required to acknowledge that you received this Urgent Recall letter. Please complete within 10 days of receipt of the letter. Please use the QR code below to access the field action portal to record your acknowledgement:



Actions Required if you are a Dealer or Distributor:

If you possess or distributed a SpeedControl Dial, please take the following actions immediately:

1. Since all SpeedControl Dials are impacted by this recall, remove SpeedControl Dials from your sellable / distribution inventory.
2. Even if you have no inventory, you are required to acknowledge that you received this Urgent Recall letter. This should be completed within 10 days of receipt of the letter. Please use the QR code below to access the field action portal to record your acknowledgement:



3. Immediately contact any customers you have distributed the device to and provide a copy of this notice. Alternatively, you may provide end user contact information to Max Mobility/Permobil through the online portal so that Max Mobility/Permobil can contact them directly.

Actions planned by Max Mobility/Permobil to correct the problem:

Max Mobility/Permobil has suspended distribution of the SpeedControl Dial, and the SpeedControl Dial is no longer an available control option for the SmartDrive MX2+ Power Assist Device. However, the SmartDrive MX2+ Power Assist Device is not impacted by this recall and can still be used with alternative control options. Max Mobility/Permobil will assist you with replacing your SpeedControl Dial with an alternate control. The wired SwitchControl, discussed above, can be provided free of charge with a mono jack port to connect with an optional Buddy Button. The Buddy Button is a third-party accessory option, provided through Permobil, which is a switch that provides further tactile feedback and is larger than our standard SwitchControl. Assistance with replacement is free of charge. The SmartDrive MX2+ Power Assist Device can also be controlled via an App using a wearable device. Please visit our website [here](#) to learn more about the available alternative control options for the SmartDrive MX2+ Power Assist Device. If you are unsure which control option is best for you, we recommend that you reach out to your SmartDrive dealer and/or prescribing clinician.

Our website also contains information and instructions for how to remove and dispose of your SpeedControl Dial and how to install and use alternate controllers.

Scanning the QR code above will take you to a portal to record your acknowledgment of this recall notice and order a replacement controller.

Contact Information:

If you require assistance or have further enquiries regarding this recall, please contact Permobil Australia at 1300 845 483 or SmartDriveAction_AU@permobil.com. Customer Service and Technical Support is available Monday to Friday from 9:00am to 5:00pm AEST.

Max Mobility/Permobil considers the safety of our end users and customer satisfaction as our top priorities. We apologise for any inconvenience this may cause and thank you for your assistance in implementing this recall.

Sincerely,



Fiona Taylor
Country Manager, Permobil Australia