

Frequently Asked Questions (FAQs)

Q: What is Max Mobility and how is it related to Permobil?

A: Max Mobility, LLC is a subsidiary of Permobil, Inc. Max Mobility was acquired by Permobil in 2017. Max Mobility is named in communications about this recall because it is the official establishment name on record with the U.S. FDA and associated with the SmartDrive MX2+ Power Assist medical device.

Q: What is the SpeedControl Dial?

A: The SpeedControl Dial is a wired component of the SmartDrive MX2+ Power Assist Device. The SpeedControl Dial connects to the SmartDrive MX2+ motor and is a rotary controller that allows a user to start, stop, and control the speed of the SmartDrive MX2+ Power Assist Device.

Q: Why is Max Mobility/Permobil recalling the SpeedControl Dial?

A: Due to safety and performance issues that have been identified in the SpeedControl Dial, Max Mobility/Permobil has decided to remove it completely from the market.

Q: What part numbers are affected?

A: All SpeedControl Dials are impacted by the issues. Specific part numbers associated with SpeedControl Dials are listed below:

- MX2-3DC (SpeedControl Dial shipped as an independent component/spare part)
- MX2-3DCK (SpeedControl Dial shipped in conjunction with a SmartDrive MX2+ Device)
- MX2-3DCMC (SpeedControl Dial shipped after the first market action/recall was initiated)

Q: Is this the same recall that happened earlier this year?

A: No. While investigating a new complaint received during the existing/prior recall, Max Mobility/Permobil identified a design issue that can lead to performance issues with the SpeedControl Dial. Since the design issue has been part of the SpeedControl Dial since its introduction to the market in April 2022, Max Mobility/Permobil made the decision to recall all SpeedControl Dials out of an abundance of caution. This is a new recall that applies to all SpeedControl Dials, including those that were shipped as replacements under the existing recall.

Q: Is the recall a voluntary decision by Permobil?

A: Yes. Max Mobility/Permobil strives to ensure the quality of our products and safety of our end users as our top priority. Since the SpeedControl Dial has already been subject to recall and the newly identified design issue impacts all units, Max Mobility/Permobil has voluntarily decided to fully withdraw the SpeedControl Dial from the market out of an abundance of caution.

Q: Is this recall mandated by authorities?

A: No. We are voluntarily issuing this recall, and the U.S. Food and Drug Administration has been notified of this action.

Q: What happened to cause a SpeedControl Dial recall?

A: A recall was originally initiated on December 20, 2024, 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 March 28, 2025, and included all units manufactured and distributed up to March 10, 2025. Through ongoing complaint



monitoring and subsequent investigation, Max Mobility/Permobil identified a design issue with the SpeedControl Dial's electrical connection between the Dial and SmartDrive MX2+ motor, which has been part of the SpeedControl Dial since it was first introduced to the market in April 2022. This design issue is subject to a new recall that impacts all SpeedControl Dials, including those subject to the earlier recall and/or Dials that were shipped as replacements during the earlier recall. The design issue may cause a user to experience a continued drive or involuntary movement malfunction. To reduce the likelihood of a potentially hazardous or harmful situation, Max Mobility/Permobil has voluntarily expanded its recall to fully withdraw SpeedControl Dials from the market out of an abundance of caution.

Q: Why didn't you take the SpeedControl Dial off the market earlier this year?

A: The design issue with the SpeedControl Dial's electrical connection to the SmartDrive MX2+ motor was not discovered until June 2025. Now that the issue has been identified and investigated, Max Mobility/Permobil has voluntarily elected to fully withdraw the SpeedControl Dial from the market out of an abundance of caution.

Q: If I am a user of the SpeedControl Dial, what do I do?

A: 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 alternative 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 utilizing an Apple Watch or Samsung Galaxy Watch

A list of compatible wearable devices can be found at: https://www.permobil.com/en-us/products/power-assist/smartdrive-mx2plus-premium-wearables

3. Please click here to visit our website for additional instructions.

You may also contact Customer Experience at (800) 736-0925 for assistance.

Q: If I'm a dealer who sold the SpeedControl Dial, what do I do?

A: 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. Please click here to visit our website for additional instructions.

Q: Do I have to do anything if I have a SpeedControl Dial?

A: 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 alternative 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 utilizing an Apple Watch or Samsung Galaxy Watch

A list of compatible wearable devices can be found at: https://www.permobil.com/en-us/products/power-assist/smartdrive-mx2plus-premium-wearables

3. Please click here to visit our website for additional instructions.

You may also contact Customer Experience at (800) 736-0925 for assistance.

Q: Does the recall apply to the SmartDrive?

A: No, the recall does not apply to the SmartDrive MX2+ Power Assist Device. The recall only applies to the SpeedControl Dial controller.

Q: Can I still use my SmartDrive?

A: Yes. You can still use the SmartDrive MX2+ Power Assist Device with a wired SwitchControl, which can be ordered with an optional Buddy Button, and/or the SmartDrive MX2+ App on your personal wearable device.

Q: Do I have to send the SpeedControl Dial back to Max Mobility/Permobil?

A: No. If you have a SpeedControl Dial, you should stop using it, remove it from your device, and cut the cord to destroy the product. If you wish to return the SpeedControl Dial to Max Mobility/Permobil, you may do so by contacting Customer Experience at (800) 736-0925 and we will provide additional information on how to send your SpeedControl Dial back to Max Mobility/Permobil for quarantine and destruction.

Q: Who is going to pay for the cost to ship my SpeedControl Dial to Max Mobility/Permobil?

A: Max Mobility/Permobil will pay the shipping cost to send your SpeedControl Dial back to us. Please contact Customer Experience at (800) 736-0925 for assistance.

Q: What if I haven't had any issues with my SpeedControl Dial, what do I do?

A: To reduce the likelihood of a potentially hazardous or harmful situation, Max Mobility/Permobil advises you to immediately discontinue use of the SpeedControl Dial and use an alternative method to control your SmartDrive MX2+ Power Assist Device. If you voluntarily disregard this advice, please be aware that the design issue with the SpeedControl Dial can result in an intermittent electrical connection between the Dial and the SmartDrive MX2+ motor, which can cause the following performance issues to 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 these complaints, two (2) involve serious injuries related to bone fractures.

Q: Why is the SpeedControl Dial being recalled if there have only been a few injuries?

A: Max Mobility/Permobil made the decision to recall all SpeedControl Dials out of an abundance of caution. While it believes the likelihood of continued drive or involuntary movement of the SmartDrive MX2+ motor is relatively low, such performance issues, if they occurred, could result in serious injuries.



Q: Is my SpeedControl Dial safe to continue using?

A: No. The SpeedControl Dial is subject to an FDA Class 1 Recall, and we recommend that you immediately discontinue use of the SpeedControl Dial to reduce the likelihood of a potentially hazardous or harmful situation.

Q: How do I know what controller to use with my SmartDrive?

A: While we will have resources to help you learn more about the SwitchControl and wearable device options, it is recommended to reach out to your SmartDrive provider or healthcare provider to determine which controller is best for you.

Q: What if I can't use SwitchControl with my SmartDrive?

A: The SwitchControl can be ordered with a mono jack port to connect with an optional Buddy Button. The optional Buddy Button results in a mounting and placement solution similar to the SpeedControl Dial. If you would like additional information about the Buddy Button or wish to order one, please contact Customer Experience at (800) 736-0925 and we will provide additional information to assist you.

Q: What if I can't use a wearable device with my SmartDrive?

A: Max Mobility/Permobil also offers a SwitchControl, which can be ordered with a mono jack port to connect to an optional Buddy Button. The optional Buddy Button results in a mounting and placement solution similar to the recalled SpeedControl Dial. If you would like additional information about controller options for your SmartDrive, please visit our website or contact Customer Experience at (800) 736-0925 and we will provide additional information to assist you.

Q: What if I just want a refund?

A: The SmartDrive MX2+ Power Assist Device is not affected by this recall and remains functional with alternate control options, including the SwitchControl, which can be ordered with an optional Buddy Button, and via the SmartDrive MX2+ App if using a wearable device. In lieu of a refund for the SpeedControl Dial, these alternate control options are being provided by Max Mobility/Permobil free of charge. If you would like additional information about controller options for your SmartDrive, please visit our website or contact Customer Experience at (800) 736-0925 for assistance.

Q: How long will it take to receive the replacement product?

A: If you choose to receive a SwitchControl or SwitchControl with a Buddy Button to use with your SmartDrive, we anticipate 3-5 business days for processing and shipping time.

Q: Can I get a replacement SpeedControl Dial?

A: No. Max Mobility/Permobil is no longer offering the SpeedControl Dial.

Q: Can I get parts for my SpeedControl Dial?

A: No. Max Mobility/Permobil is not providing repairs or spare parts for the SpeedControl Dial.

Q: How do I get a SwitchControl for my SmartDrive?

A: Please contact Customer Experience at (800) 736-0925 for assistance.

permobil

Q: How do I get the App for my wearable?

A: Please go to: <u>SmartDrive MX2+ Premium Wearables</u> for additional information on how to get the SmartDrive MX2+ App for your personal wearable.

Q: How do I install a SwitchControl?

A: Please visit SmartDrive SwitchControl for instructions on how to install a SwitchControl.

Q: Why does someone from Max Mobility/Permobil keep calling me?

A: Max Mobility/Permobil will make reasonable attempts to notify consumers using alternative contact methods, such as by telephone, if initial email notifications are unsuccessful. The purpose of these phone calls is to ensure consumers are aware of the recall and that the recall is effective. Even if you have been contacted previously as part of an earlier SpeedControl Dial recall, this is a new/expanded recall that impacts all SpeedControl Dials, which will result in additional communications from Max Mobility/Permobil. We request your assistance in acknowledging receipt of the recall and our Customer Experience team is available to assist you with replacing your SpeedControl Dial with a SwitchControl.

Q: Why is someone from the FDA contacting me?

A: As part of their standard procedures for Class 1 recalls, the FDA may independently follow-up with some customers (users, dealers, etc) in order to verify that the recall communication has been received, understood, and that necessary steps have been taken. If you are contacted by someone identifying themselves as representing the FDA, you should not be asked to provide personal financial information or Social Security numbers. The purpose of the call should be to confirm that you received the recall notice and to ask if you have taken the recommended actions. Consumers can verify recall information on the FDA's recall database.