

17th October 2022

**URGENT: Medical Device Correction/Field Safety Notification**

Urgent Information Regarding the Omnipod DASH® Insulin Management System

Device Description	Part Number	Serial Number
Omnipod DASH® Personal Diabetes Manager (PDM)	Will vary by region	All serial numbers

Please read this notice in its entirety and acknowledge receipt and understanding of this notice .

Dear Valued Customer,

You are receiving this letter as our records indicate you are a current or past user of the Omnipod DASH® Insulin Management System. This notice is being communicated as a voluntary Medical Device Correction to provide information about the Omnipod DASH Personal Diabetes Manager (PDM) battery and instructions to reduce the risk of DASH PDM battery issues. It is important to note that no injuries have been reported to Insulet as a result of these Omnipod DASH PDM battery issues.

This does NOT affect the Omnipod DASH Pods or the Omnipod® Insulin Management System.

Issue Description: We have received reports from some Omnipod DASH users regarding PDM battery issues, including battery swelling, fluid leaking from the battery and in rare cases, extreme overheating which may pose a fire hazard. Our investigation has determined that the Omnipod DASH PDM is at increased risk if charged to full capacity, in particular, if left to charge for extended periods of time (i.e. overnight). Omnipod DASH PDMs in use more than 18 months may have an increased likelihood of this issue occurring.

Solution : We have identified an update to the Omnipod DASH PDM that will address this issue. We expect to begin shipping updated Omnipod DASH PDMs to all customers in the coming months.

You do not need to call to receive an updated Omnipod DASH PDM, one will automatically be shipped to you when available.

Until you receive your updated Omnipod DASH PDM, please follow the actions below:

Actions to Users:

If you experience any of the following issues, do not charge your Omnipod DASH PDM and promptly contact Hemoglobe’s dedicated Customer Care team specifically trained to help you at +30 217 000 9999:

- The Omnipod DASH PDM back cover is bulging or cannot close. You may need to remove the PDM gel skin to observe any of these issues. Do not apply pressure to the back cover if it is deformed in any way.
- The Omnipod DASH PDM experiences extreme overheating (uncomfortable to hold) or emits an odor while charging, during use, or in storage.

- The Omnipod DASH PDM does not turn on within 45 minutes of being connected to the charger or turns off immediately after being removed from the charger. If your PDM battery loses its charge very quickly (more than you have previously experienced) or if it takes more than 1.5 hours to reach 80% charge, contact Hemoglobe's Customer Care team.

Continue to use your Omnipod DASH PDM if you do not experience any of the symptoms listed above and follow the actions below to reduce the risk of PDM battery issues:

- Do NOT remove the battery from the Omnipod DASH PDM for any reason, even if the User Guide recommends it for troubleshooting. If you are in a situation where removal of the battery is recommended by the User Guide or PDM screen message, do not remove the battery and contact Hemoglobe's Customer Care team at +30 217 000 9999.
- Do NOT continue charging the Omnipod DASH PDM after it reaches 85% of charge. This means you should not charge your device overnight and you should monitor the device while charging .
- Do NOT charge the PDM if the surrounding temperature is 87°F (31°C) or higher . Do not charge the PDM in direct sunlight.
- If the Omnipod DASH PDM is unusually warm, leave the PDM unplugged and idle at room temperature until it cools down. Do not charge the PDM when it feels unusually warm to the touch.
- Do NOT use your Omnipod DASH PDM while it is charging.
- Always inspect your Omnipod DASH PDM before charging (remove gel skin / cover) for any deformity, back cover bulging, battery leakage, signs of damage at the charging port, or difficulty closing the back cover.

We understand this may impact your experience and are here to support you. We will notify you when we start to ship the updated Omnipod DASH PDM.

If you have any questions regarding the information provided in this Medical Device Correction, please call +30 217 000 9999 to speak with a dedicated staff member of the Hemoglobe Customer Care team.

Acknowledgement?

Please email [customersupport@hemoglobe15.com](mailto:customersupport@hemoglobe15.com) or call our Customer Care team on +30 217 000 9999 to confirm receipt and your understanding of this Medical Device Correction.

Kind Regards,



Mike Spears

SVP Regulatory Affairs and Compliance