Insulet Corporation
100 Nagog Park, Acton, MA 01720

November 30, 2023

URGENT: Field Safety Notification

REF: 9056196-11/22/2023-001-C

Urgent Information Regarding the Omnipod® 5 Automated Insulin Delivery System

Affected Product:

Device Description	Software Version	UDI
Omnipod® 5 Controller	Versions 1.2 (current)	10385083000190 10385083000206

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

Dear Valued Customer,

You are receiving this letter as our records indicate you are a user of the Omnipod® 5 Automated Insulin Delivery System. This notice is a voluntary Field Safety Notification related to an issue with the Omnipod 5 bolus calculator. Insulet has received 2 reports of adverse events related to this issue.

This does NOT affect the Omnipod 5 Pods, the Omnipod® DASH Insulin Management System, or the Omnipod® Insulin Management System.

What is the issue?

We have received reports from Omnipod 5 users where the bolus calculator is not recording the decimal point if it is the first value entered when changing a bolus dose. If the user does not recognize the issue, this may lead to delivery of more insulin than intended, which can lead to severe hypoglycaemia.

This issue **only** occurs if:

- You use the bolus calculator to calculate a bolus dose or enter a bolus amount into the Total Bolus box at the bottom of the screen, AND
- You tap the Total Bolus box to change the amount to a value less than 1 unit (1 U), starting with a decimal point (e.g., .3U) when the decimal fails to register
- You do not recognize that the bolus amount is wrong and start the bolus that is larger than you intended (e.g., 3U instead of 0.3U).

Once the bolus dose is confirmed and you tap START, the value that is shown on the screen will be delivered by the system.

How do you avoid giving the wrong bolus amount?

1. When changing a bolus dose to less than 1 unit, **always enter a zero (0) before the decimal** (e.g., enter 0.3 instead of .3)
2. Always check the bolus amount shown in the Total Bolus box before tapping CONFIRM
3. Double-check the amount on Confirm Bolus screen (Figure 1) to make sure this is the amount you want to deliver before pressing START to deliver the bolus
4. Check the amount again while the bolus is in the progress on the Delivering Bolus screen

As stated in our User Guide, it is important to review the bolus amount before you confirm and start the bolus. Omnipod 5 will **always deliver** the amount you confirm and that is shown on the Confirm Bolus screen (Figure 1). This amount can also be checked while the bolus is in progress on the Delivering Bolus screen (Figure 2). If it's not the amount you expected, you can always CANCEL the bolus. To check how much insulin has been delivered, check the Last Bolus box on the home screen or your History Detail.

Figure 1: Confirm Bolus screen

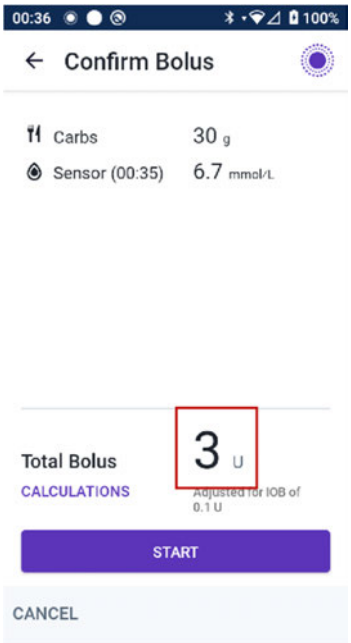
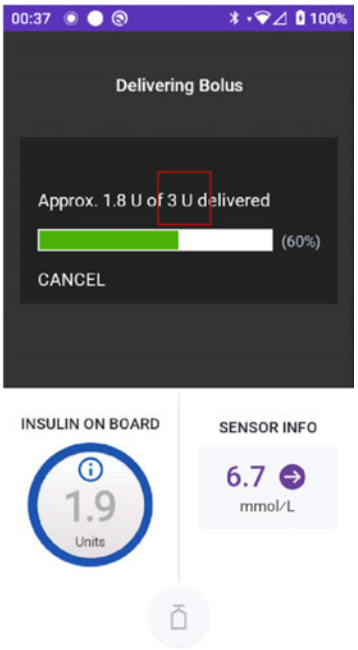


Figure 2: Delivering Bolus screen



Insulet
maker of Omnipod

Is it safe to continue using Omnipod 5?

Yes, it is safe for users to continue using Omnipod 5. If you confirm the bolus amount is the amount of insulin you want to deliver, the system will **always deliver** this amount. Follow the steps detailed above to ensure that, for values under 1 unit (1 U), the decimal point is registered.

When will the issue be fixed?

We are working diligently to correct this issue and expect a software update as soon as possible. We will inform you via email and update our website available. Once available, the update will be pushed to your device. You will not lose settings or history because of this update.

We understand this may impact your experience and are here to support you. If you have any questions regarding the information provided in this Field Safety Notification, please call 0800 011 6132 to speak with a dedicated staff member of the Omnipod Customer Care team who will be available 24 hours a day, 7 days a week.

We are grateful for our Podders who communicated their experience with this issue.

Sincerely,

Senior Vice President, Regulatory Affairs, Quality Assurance, and Compliance
Insulet Corporation