

DRAFT

nn January 2021

URGENT: FIELD SAFETY NOTICE

Urgent Information Regarding the User Guide supplied with the Omnipod DASH® Insulin Management System

FSCA REF. 9056196-01/22/2021-001-C

Affected Product:

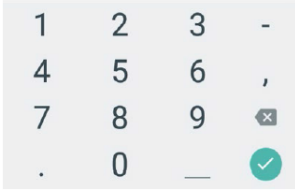
Device Description	User Guide Revision
Omnipod DASH® Insulin Management System	Rev 00n to Rev 00n

Dear Valued Customer,

You are receiving this important safety information as our records indicate that you are a current user of the Omnipod DASH™ System. As the manufacturer of the Omnipod DASH™ System, customer safety is Insulet's top priority.

In line with this it has come to our attention that there is an error in the Omnipod DASH® User Guide text. Specifically, on page 6 of the User Guide, the text states that the comma (,) is not used for the decimal on the PDM, when in fact it is the period (.) that is not used. The specific extract from the User Guide is shown below.

Original Content



Using a number pad

Tap a number to add it to the entry field. Tap the **period (.)** to add a **decimal point**. Tap the backspace icon (⌫) to delete the most recent entry from the entry field. The **comma (,)**, dash (-), and underscore (_) are not used.

Tap the green checkmark (✓) to accept the entered number. You can also tap outside the number pad to accept the entered number.

Incorrect content (highlighted in bold) – shown in current User Guide

Updated Content

1	2	3	-
4	5	6	,
7	8	9	✕
.	0	—	✓

Using a number pad
Tap a number to add it to the entry field. Tap the **comma (,)** to add a **comma**. Tap the backspace icon (✕) to delete the most recent entry from the entry field. The **decimal point (.)**, dash (-), and underscore (—) are not used.

Tap the green checkmark (✓) to accept the entered number. You can also tap outside the number pad to accept the entered number.

Correct content (highlighted in bold)

Potential risks associated with the User Guide error

If a user presses the period (.) as a decimal separator when entering a bolus value, this decimal separator will not be recognised by the device and any numbers entered after the period could result in a larger value than intended. If the user fails to recognize this at the time of entry and delivers the incorrect bolus amount, this could result in over-delivery of insulin. Over-delivery of insulin could lead to hypoglycaemia. Incorrect entry is a known risk that can be alleviated by visual check of the user-requested bolus, max bolus settings established on set-up, and double user conformation before delivery.

Please note that no injuries have been reported to date because of this issue.

What action is being taken to correct this issue?

Insulet has undertaken a formal update of page 6 of the Omnipod DASH® User Guide to correctly indicate the use of the comma (,) instead of the period (.) as the decimal separator. This amended section of the User Guide is contained as an Annex to this Field Safety Notice.

Please also be reminded that the device is designed to require the entry of a maximum bolus limit as determined by your treating physician, during initial PDM set up. Any bolus of insulin delivered cannot exceed this maximum set limit (range from 0.05 to 30U). During routine use, there is a requirement for you to confirm the bolus amount to be delivered is correct before any insulin is delivered.

What are the next steps?

Please refer to the attached Annex in reference to page 6 of the User Guide as opposed to referring to the instructions in the existing User Guide. We recommend you place this insert at p.6 in your User Guide. Please ensure that the comma is always used when entering bolus values. In accordance with applicable rules, this corrective action is implemented with the knowledge of the relevant competent authorities.

ACTION REQUIRED BY YOU:

Please electronically confirm your understanding of this Field Safety Notification by going to the webpage the link below and following the instructions on screen:

Webpage link If you would like additional information, our Customer Care is available 24/7 on 0800 xxxxx (+xxxxx when calling from abroad) or by email omnipodXX@insulet.com.

Yours sincerely,

Privacy Policy

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Enc. Annex 1: Copy of the User Guide Insert

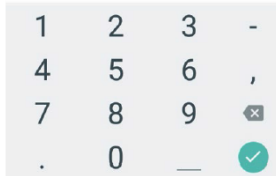


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100 Nagog Park Drive
Acton, MA 01720

OMNIPOD DASH® SYSTEM USER GUIDE UPDATE *CHAPTER 1, PAGE 6*

Original Content

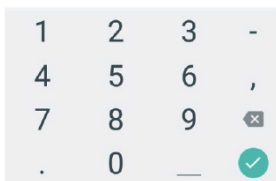


Using a number pad

Tap a number to add it to the entry field. Tap the **period (.)** to add a **decimal point**. Tap the backspace icon (**x**) to delete the most recent entry from the entry field. The **comma (,)**, dash (-), and underscore (**_**) are not used.

Tap the green checkmark (**✓**) to accept the entered number. You can also tap outside the number pad to accept the entered number.

Updated Content



Using a number pad

Tap a number to add it to the entry field. Tap the **comma (,)** to add a **comma**. Tap the backspace icon (**x**) to delete the most recent entry from the entry field. The **decimal point (.)**, dash (-), and underscore (**_**) are not used.

Tap the green checkmark (**✓**) to accept the entered number. You can also tap outside the number pad to accept the entered number.

NOTE: The bolded content in the above paragraphs identify the content differences.

omnipod.com

PT-000543-01-AW Rev. 001 10/20


Effective Date: 12NOV2020

DRAFT

nn January 2021

URGENT: FIELD SAFETY NOTICE

Urgent Information Regarding the User Guide supplied with the Omnipod DASH® Insulin Management System

FSCA REF. 9056196-01/22/2021-001-C

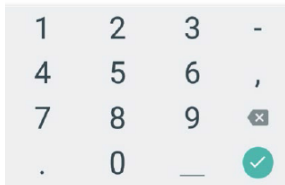
Affected Product:

Device Description	User Guide Revision
Omnipod DASH® Insulin Management System	Rev 00n to Rev 00n

Dear Valued Distributor

You are receiving this letter as our records indicate that you are supporting current users of the Omnipod DASH® System. As the manufacturer of the Omnipod DASH® System, customer safety is Insulet Corporation’s top priority. In line with this, we are writing to you with important information regarding the User Guide supplied with the Omnipod DASH® System.

It has come to our attention that there is an error in the Omnipod DASH® User Guide text. Specifically, on page 6 of the User Guide, the text states that the comma is not used for the decimal, when in fact it is the period that is not used. The specific extract from the User Guide is shown below.



Original Content

Using a number pad
Tap a number to add it to the entry field. Tap the **period (.)** to add a **decimal point**. Tap the backspace icon (x) to delete the most recent entry from the entry field. The **comma (,)**, dash (-), and underscore (_) are not used.

Tap the green checkmark (✓) to accept the entered number. You can also tap outside the number pad to accept the entered number.

Incorrect content (highlighted in bold) – shown in current User Guide

Updated Content

1	2	3	-
4	5	6	,
7	8	9	✕
.	0	—	✓

Using a number pad
Tap a number to add it to the entry field. Tap the **comma (,)** to add a **comma**. Tap the backspace icon (✕) to delete the most recent entry from the entry field. The **decimal point (.)**, dash (-), and underscore () are not used.

Tap the green checkmark (✓) to accept the entered number. You can also tap outside the number pad to accept the entered number.

Correct content (highlighted in bold)

Potential risks associated with the User Guide error

If a user presses the period (.) as a decimal separator when entering a bolus value, this decimal separator will not be recognised by the device and any numbers entered after the period could result in a larger value than intended. If the user fails to recognize this at the time of entry and delivers the incorrect bolus amount, this could result in over-delivery of insulin. Over-delivery of insulin could lead to hypoglycaemia. Incorrect entry is a known risk that can be alleviated by visual check of the user-requested bolus, max bolus settings established on set-up, and double user confirmation before delivery.

Please note that no injuries have been reported to date because of this issue.

What action is being taken to correct this issue?

Insulet has undertaken a formal update of page 6 of the Omnipod DASH® User Guide to correctly indicate the use of the comma (,) instead of the period (.) as the decimal separator.

The amended section of the User Guide has been developed into an Insert that will be provided to all users ahead of a formal update to the main User Guide that is planned to be available in March 2021. A copy of this Insert is provided as an Annex to this Field Safety Notice.

Additionally, applicable training materials are being updated to reflect the change in the User Guide and emphasise the need to use the comma as the decimal separator when entering bolus values.

Please also be reminded that the device is designed to require the entry of a maximum bolus limit as determined by the treating physician, during initial PDM set up. Any bolus of insulin delivered cannot exceed this maximum set limit (range from 0.05 to 30U). This number should be clinically appropriate and personalized for each patient. During routine use, there is a requirement for the user to confirm the bolus amount to be delivered is correct before any insulin is delivered.

What are the next steps?

Please forward this letter onto any appropriate recipients within your organisation who are supporting users of the Omnipod DASH® System.

A patient letter is being provided to you to be forwarded to all Omnipod DASH® System users that you support. In addition a Healthcare Professional letter is attached for you to forward to all Healthcare Professional contacts who train patients on the Omnipod DASH™ System.

Furthermore, please refer to the updated training materials when onboarding users to ensure that users understand that the comma must be used in entering bolus values.

In order to ensure the effectiveness of this Notice, we request the following information from you:

- Acknowledgement by return of email that you have received this Field Safety Notice and understand what is required of you
- Confirmation of the number of users that you currently support and the number of users that have been successfully issued with the patient letter

In accordance with applicable rules, this corrective action is implemented with the knowledge of the relevant competent authorities.

If you have any questions regarding the information provided, please contact (relevant contact at Insulet).

Yours sincerely,

Enc. Annex 1: Copy of the User Guide Insert

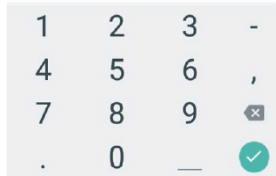


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OMNIPOD DASH® SYSTEM USER GUIDE UPDATE *CHAPTER 1, PAGE 6*

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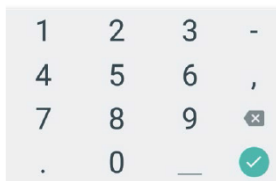


Using a number pad

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Tap the green checkmark (✓) to accept the entered number. You can also tap outside the number pad to accept the entered number.

Updated Content



Using a number pad

Tap a number to add it to the entry field. Tap the **comma (,)** to add a **comma**. Tap the backspace icon (**x**) to delete the most recent entry from the entry field. The **decimal point (.)**, dash (-), and underscore (_) are not used.

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PT-000543-01-AW Rev. 001 10/20



Effective Date: 12NOV2020

DRAFT

Email title: Important User Guide Correction Omnipod DASH™ System

nn January 2021

URGENT: FIELD SAFETY NOTICE

Urgent Information Regarding the User Guide supplied with the Omnipod DASH® Insulin Management System

FSCA REF. 9056196-01/22/2021-001-C

Affected Product:

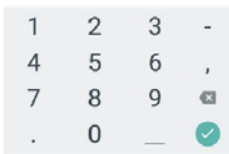
Device Description	User Guide Revision
Omnipod DASH® Insulin Management System	Rev 00n to Rev 00n

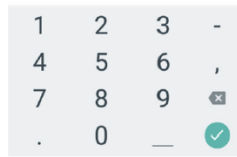
Please review this Field Safety Notification carefully. Once you have done so, it is essential to electronically confirm that you have understood the contents of this Field Safety Notification by clicking the: “Yes, I understand” link at the end of this notice.

Dear Healthcare Professional,

You are receiving this letter as our records indicate that you are supporting current users of the Omnipod DASH® System. As the manufacturer of the Omnipod DASH® System, customer safety is Insulet Corporation’s top priority. In line with this, we are writing to you with important information regarding the User Guide supplied with the Omnipod DASH® System.

It has come to our attention that there is an error in the Omnipod DASH® User Guide text. Specifically, on page 6 of the User Guide, the text states that the comma (,) is not used for the decimal on the PDM, when in fact it is the period (.) that is not used. The specific extract from the User Guide is shown below.

	<p>Utilisation du pavé numérique</p> <p>Appuyez sur un chiffre pour l'ajouter au champ de saisie. Appuyez sur le point (.) pour ajouter un séparateur décimal. Appuyez sur l'icône de retour arrière (↩) pour supprimer le dernier caractère saisi dans le champ. La virgule (,), le tiret (-) et le tiret du bas (⌵) ne sont pas utilisés.</p> <p>Appuyez sur la coche verte (✔) pour valider le chiffre saisi. Vous pouvez également appuyer en dehors du pavé numérique pour valider le chiffre saisi.</p>
<p>Incorrect content (highlighted in bold) – shown in current User Guide</p>	



Utilisation du pavé numérique

Appuyez sur un chiffre pour l'ajouter au champ de saisie.
Appuyez sur la **virgule (,)** pour ajouter une **virgule**.
Appuyez sur l'icône de retour arrière (X) pour supprimer la saisie la plus récente du champ de saisie. Le **point représentant la décimale (.)**, le tiret (-) et le tiret du bas () ne sont pas utilisés.

Appuyez sur la coche verte (✓) pour valider le chiffre saisi.
Vous pouvez également appuyer en dehors du pavé numérique pour valider le chiffre saisi.

Correct content (highlighted in bold)

Potential risks associated with the User Guide error

If a user presses the period (.) as a decimal separator when entering a bolus value, this decimal separator will not be recognised by the device and any numbers entered after the period could result in a larger value than intended. If the user fails to recognize this at the time of entry and delivers the incorrect bolus amount, this could result in over-delivery of insulin. Over-delivery of insulin could lead to hypoglycaemia. Incorrect entry is a known risk that can be alleviated by visual check of the user-requested bolus, max bolus settings established on set-up, and double user confirmation before delivery.

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What are the next steps?

Please refer to the attached Annex in reference to page 6 of the User Guide as opposed to referring to the instructions in the existing User Guide. We recommend you place this insert at p.6 in your User Guide.

Furthermore, please refer to the updated training materials that will follow when onboarding users to ensure that users understand that the comma must be used in entering bolus values.

A patient letter is also being provided to you to be forwarded to all Omnipod DASH® System users that you support.

In accordance with applicable rules, this corrective action is implemented with the knowledge of the relevant competent authorities.

ACTION REQUIRED BY YOU:

Please electronically confirm your understanding of this Field Safety Notification by clicking the link below:

Yes, I understand

If you have any questions regarding the information provided, please contact Customer Care on 0800 **NNNNNNNNNN** (+NN NN NN NN NN) when calling from abroad) which is available 24 hour a day, seven days a week or email omnipod-NN@insulet.com.

Yours sincerely,

Mike Spears
Senior Vice President Regulatory Affairs and Compliance

Enc. Annex 1: Copy of the User Guide Insert

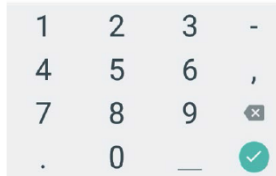


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OMNIPOD DASH® SYSTEM USER GUIDE UPDATE *CHAPTER 1, PAGE 6*

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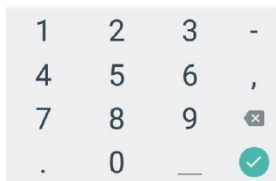


Using a number pad

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Tap the green checkmark (**✓**) to accept the entered number. You can also tap outside the number pad to accept the entered number.

Updated Content



Using a number pad

Tap a number to add it to the entry field. Tap the **comma (,)** to add a **comma**. Tap the backspace icon (**x**) to delete the most recent entry from the entry field. The **decimal point (.)**, dash (-), and underscore (_) are not used.

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PT-000543-01-AW Rev. 001 10/20



Effective Date: 12NOV2020