Executive Summary

A software defect has been identified in specific versions of the Omnipod 5 App. This defect has introduced an error in the bolus calculator where the entry of a decimal separator (period/comma) is not recognized by the device in a defined sequence of events. This may lead to an over-delivery of insulin to the user if the user does not recognize the error on the bolus calculator screen or the confirmation screen prior to starting the bolus.

The issue has resulted in 6 post market complaints to date. Further data analysis is being conducted to determine if there are any unreported events.

In the event of the delivery of a bolus greater than expected, the resulting severity is up to a Severity of 5 due to the potential insulin volume that could be delivered.

Software release 1.2.4 has been developed to correct this issue and is being tracked in CAPA-000082.

Customers with the affected product will be notified of the issue and when available, updated software to correct the issue will be pushed to the devices via over-the-air updates.

Assessment Information

Date:	7 November 2023
Issue Type	Select from the following: ☐ Hardware-mechanical ☐ Hardware-electrical ☒ Software/ Firmware-device ☐ Software/ Firmware-other ☐ Cloud / IT infrastructure / product backend ☐ Label/ Packaging ☐ User Guide/Use Error/Usability ☐ Advertising/ Promotion (excluding user guide) ☐ Storage / Handling / Distribution / Transportation ☐ Sterilization / Microbiology / Environmental Control ☐ Manufacturing / Production & Process Control ☐ Reportable Trend Trigger (per EU MDR Art.88) ☐ Risk review action from Patient Safety Meeting/APR/PSUR/PMCF ☐ Other-Safety ☐ Other-Compliance ☐ Other-Customer Experience
Issue Title (Brief Description):	Decimal/Comma separator entry failing to register when adjusting a bolus amount
Issue Source(s):	The issue was introduced in software release 1.1, 20-April-2023. The first customer complaint was received in June 2023.

Product Information

Brand Name:	Omnipod 5® Automated Insulin Delivery System

Product Information	
Product ID/Reorder Number/SKU:	US: PT-000599- Omnipod 5 App Software Package (provided through Google Play) EU: PT-001323- Omnipod 5 App Software Package (provided on locked-down Controllers (PT-001194 and PT-001193)
UDI/Model/NDC Number:	Omnipod 5 App Software UDI: 1038508112030 EU locked-down Controller UDI: 10385083000190 and 10385083000206
Regulatory Classification	FDA classification: Class II EU classification: Class III
Product Description & Usage:	The Omnipod 5 App software is Android-based software that is provided either on a locked-down Controller or is available to download through Google Play on compatible Android smartphones. The Omnipod 5 App is the user interface that controls the Omnipod 5 Automated Insulin Delivery System. It is used to activate/deactivate Pods, display alerts/alarms, and send insulin delivery commands for execution to the Pod.

Section 1A: Issue Details

Detailed Issue Description / Product Performance:

The bolus calculator in the Omnipod 5 App software versions 1.1 to 1.2.3 is not recording the entry of a leading decimal separator (period or comma) when changing a bolus dose.

This issue **only** occurs if:

- The user uses the bolus calculator to calculate a bolus dose or enters a bolus amount into the Total Bolus box at the bottom of the screen, AND
- The user taps the Total Bolus box to **change** the bolus amount to a value less than 1 unit (1 U), starting with a decimal point (e.g., .3 U), when the decimal fails to register
- The user does not recognize that the bolus amount is wrong and starts the bolus that is larger than intended (e.g., 3 U instead of 0.3 U).

The delivery of more insulin than intended could lead to severe hypoglycemia.

Complaints:

As of Date: 17Nov2023		
Complaint Region	**Number of Complaints**	**Number of Complaints with Regulatory Reports**
US	6	2*

Section 1A: Issue Details

International	0	0

CN-3318885- reportable, CN-3337734, CN-3337728, CN-3000872, CN-3439421, CN-3435491- reportable

*In the two reportable events, the user was delivered more than the intended insulin, this resulted in hypoglycemia necessitating treatment without hospital admission or long-term effects.

Complaint Handling System Query Used:
Summarize the query used, date executed, fields pulled, and associated filters or reference an associated quality record:

Query Used	Omnipod 5 complaints since introduction of software version 1.1 in April 2023. Additionally, a Salesforce query was completed looking for key words contained in general calls.
Date of Query	16Nov2023
Fields Pulled	Complaint ID, case comments, case description, product, RFC, Symptom code
Filters Used	Word search: decimal, comma, bolus incorrect, bolus adjustment Smartphone app complaints for US, Insulet provided controllers for OUS

☐ Not applicable, Rationale:

Denominator Utilized: Indicate denominator utilized (e.g. patient base, installed based, devices shipped, etc.)

30,731 (Omnipod 5 App (compatible smartphone users) plus Insulet-provided locked-down Controllers in UK and Germany) - refer to section 1B

Was a particular query used to obtain the denominator utilized?

☒ Yes. Summarize the query used, date executed, fields pulled, and associated filters or reference an associated quality record:

Active users using the Omnipod 5 App from the Google play store as captured by cloud data and Insulet-provided Omnipod 5 Controllers shipped to UK and Germany and are outside of Insulet control.

☐ Not applicable, Rationale:

Section 1B: Device Impact and Device Populations

Issue Scope / Total number of Impacted Devices and Rationale

This issue was introduced in the Omnipod 5 App software version 1.1 released on 20-April-2023 and is in all subsequent software versions (up to version 1.2.3). Software versions 1.1 to 1.2.3 have only been released in the US for phone control users and for EU locked-down Controllers.

This issue does NOT affect US Insulet provided locked-down Controllers as these devices are on a different build than the affected population.

Region	Devices in Distribution/Activated in the Field	Number of Devices Potentially Impacted – Shipped and out of Insulet Control
United States (US)	20,051*	20,051*
UK	7,458	9,444 shipped as of 3Nov2023
Germany	715	1,236 shipped as of 3Nov2023
Total	28,224- as of 16Nov2023	**30,731**

*"Device" reference for the US market are number of users with Omnipod 5 App smartphone control.

Are any subpopulations <u>of devices</u> and/or device configurations at higher risk?

☒Yes. Subpopulations of devices at greater risk are as follows: Omnipod 5 App software versions 1.1 to 1.2.3 (current). This software is available on Insulet-provided Controllers in the EU (software version 1.2) and in the US through the Google Play for compatible smartphone users.

☐ No

Rationale: NA.

Location(s):	Acton, Massachusetts

Section 2A: Failure Mode Assessment [Section owner(s): LCE]

RMF Failure Mode Assessment:

Omnipod 5 System Hazard Analysis (DD-002257 Rev 15), line item 29915 provides the risk assessment for software defects leading to incorrect dose of insulin.

Failure mode(s) is/are well characterized and understood at this time?

☒ **<u>Yes</u>** (continue below) ☐ No (go next to Section 2B)

Document failure mode(s), if known, that pertain to this issue.

Section 2A: Failure Mode Assessment
[Section owner(s): LCE]

Failure Mode(s): A software defect causes dose administration to be different from what the user intended.

The root cause of the issue is a software error that does not recognize the first entry of a decimal separator in the bolus amount adjusted by the user (details provided in Section 1A).

If "Yes" above, is/are the failure mode(s) anticipated in an existing DFMEA, PFMEA, UFMEA, or equivalent risk document that is part of the RMF?

☒ Yes (fill out remaining section below) ☐ No (go next to Section 2B)

Predicted rate of occurrence of failure mode (if anticipated per above) and number of actual (observed) occurrences of the failure mode:

Per the Omnipod 5 System Hazard Analysis, DD-002257, Rev 15, line item 29915:

Frequency of Occurrence: Mitigated P1 is 2

Likelihood of Detection: Mitigated P2 is 4

Potential Cause(s): Software defect causes dose administered to be different from what user intended.

Potential Effect(s) of Failure: Overdose high

Potential Impact(s): Hypoglycemia (Severity 5)

Section 2B: HHE Section: Hazard / Hazardous Situation / Harm / Other Factors [Section owner(s): PMS&C and LCE]

Hazard and Hazardous Situation:
Overdose high: the failure could lead to an over-delivery of insulin.

Harm(s):

Hypoglycemia

Are any subpopulations of patients or users at higher risk?

☒ Yes. Subpopulations: Users more reactive to insulin may be at higher risk.

☐ No

Rationale: NA.

Exacerbating Factors:
NA

Mitigating Factors:
Bolus delivery requires a 2-step confirmation by the user prior to delivery. There is a progress bar to show the amount of insulin being delivered on the 'Delivering Bolus' screen, where the user can cancel the remaining bolus at any time. A maximum bolus setting must be entered during first time setup, prohibits bolus amounts that exceed this setting. Maximum bolus can be set up to 30 units. This maximum bolus value is determined between the health care provider and the user to set a clinically appropriate amount, based on insulin needs. The pod makes an audible noise as the bolus is in progress to reinforce that insulin is being delivered.

The User Guide provides a Warning instructing users to regularly monitor their glucose levels under the guidance of their healthcare provider to avoid hyperglycemia and hypoglycemia.

Severity of Harm:

Hypoglycemia-S5

SEVERITY OF HARM
(Determined by Clinical/Medical)

Ranking	Description	Definition
1	Negligible	• Potential to result in temporary discomfort or inconsequential injury
2	Marginal	• Potential to result in temporary injury or impairment not requiring medical intervention
3	Significant	• Potential to result in injury or impairment that is reversible with medical intervention.
4	Critical	• Potential to result in permanent (irreversible) impairment
5	Catastrophic	• Potential to result in patient death (life-threatening injury)

Probability of Occurrence of Harm:

The identified issue occurs in a defined device population following a specific sequence of events.

Prior to the user being exposed to the hazardous situation, the user must confirm the requested dose prior to insulin delivery.

For calculation of POH:
The P2 value has been determined to be 4 (see section 2C)

The P1 value for this hazardous situation leading to a harm of Overdose High with a severity of 5 was calculated using the number of reported (severity) complaints per the number of user months for the affected software versions.

Affect Software	User Months
1.1.0	8606
1.2.0	16687
1.2.1	40194
1.2.2	34270
1.2.3	8893
Total	**108650**

P1 rate = 6* (total complaints) / 108650 (user months) = 0.000018
Therefore P1 = 2 per SOP-048 Risk Management

The above calculations are based off post-market data of 6 complaints. Further evaluation of the data is being conducted as there may be other un-reported instances of the event.

POH for P1 = 2 and P2 = 4 is 2 per SOP-048

PROBABILITY OF OCCURRENCE OF HARM

Ranking	POH	Probability of Occurrence of Harm Definition
0	Implausible	The harm is not expected to be experienced in the user population.
1	Improbable	The harm is extremely unlikely to be experienced by any given user; possible to be experienced in the user population.
2	Remote	The harm is unlikely but possible to be experienced by any given user; reasonably expected to occur in the user population.
3	Occasional	The harm is somewhat likely to be experienced at some time by any given user; expected to be experienced many times throughout the user population.
4	Probable	The harm is likely to be experienced occasionally by any given user; expected to be experienced frequently throughout the user population.
5	Frequent	The harm is likely to be experienced by any given user; expected to be experienced continuously throughout the user population.

Other Factors: NA.

Section 2C: HHE Summary Section

Patient Safety Risk Table:

Summary of risk(s) considering all applicable hazardous situations and harms related to the issue from above sections:

Patient Populations / User Populations	Hazardous Situation	Probability of Hazardous Situation (p1)*	Harm	Probability of Hazardous Situation Leading to Harm (p2)	Probability of Harm (p1xp2)	Severity Rank of Harm	Risk Zone
General	**Overdose high**	**2**	**Hypoglycemia**	**4**	**2**	**5**	**Medium**

**The above calculations are based off post-market data of 6 complaints. Further evaluation of the data is being conducted as there may be other un-reported instances of the event.*

Patient Safety Risk Mapping for Population at Greatest Risk per above:

If no population is at greater risk than the general population, map the general population below.

RISK		Probability of Occurrence of Harm (POH)					
		Implausible (0)	Improbable (1)	Remote (2)	Occasional (3)	Probable (4)	Frequent (5)
Severity	Catastrophic (5)			X			
	Critical (4)						
	Significant (3)						
	Marginal (2)						
	Negligible (1)						

No Risk ☐	Low/Risk Zone 1 ☐	Medium/Risk Zone 2 ☒	High/Risk Zone 3 ☐

Is the above Risk Zone different than that anticipated and documented in the risk management file? ☐ Yes ☒ No N

Overall Risk Summary and Acceptability

Based on the available information, the risk of the user receiving an incorrect dose of insulin is medium. This is due to the chain of events required to present the failure, and then the human factor mitigations (confirmation screens) required prior to the exposure of the hazardous situation.

Section 2C: HHE Summary Section

Although the failure occurs when the customer is manually requesting and expecting insulin, compounded by the 2-step confirmation prior to delivery, the potential severity of harm remains assessed as a Severity 5 due to the potential volume of insulin that could be delivered.

Section 3: Actions and Conclusions
[Section owner(s): PMS&C, RA, QO/QS, DQA, and MA]

CAPA-000082 has been opened to document the investigation and any actions taken to prevent recurrence.
The issue correction has been identified and will be deployed in software release 1.2.4

This risk evaluation and the 21CFR part 806 reportability assessment has been escalated to Executive Leadership.

CAPA Initiated or Requested?	☒ Yes CAPA-000082 ☐ No Note: Decision to initiate a CAPA is not required to finalize PISCE/HHE document.
Product Hold Initiated? (QWI-160)	☐ Yes ☒ No Rationale: Currently, there is no product hold. Product disposition is being evaluated as part of CAPA-000082
Advisory Notice / Field Action? (QSP-052)	☒ Yes 806 decision tree attached to this document ☐ No Note: Decision to initiate a field action/advisory notice is not required to finalize PISCE document. *System that will contain evidence of completion: CAPA-000082
Update of Risk Management Files (if applicable) recommended?	The RMF (DD-002257) does contain an analysis of the situation from a system level (SHA-29915). No update is indicated currently. System that will contain evidence of completion: NA
Update of Instructions for Use/User Guide, marketing materials or	An update to the User Guide is not indicated at this time. **System that will contain evidence of completion:** NA

Section 3: Actions and Conclusions [Section owner(s): PMS&C, RA, QO/QS, DQA, and MA]	
website (if applicable) recommended?	
Reassess Threshold (Sustaining actions related continued monitoring- post PISCE)	A reassessment will be conducted if the observed severity of harm increases, or additional root causes are identified.

Section 4: Review and Approval

Function	Title	Printed Name	Signature	Date
Post Market Surveillance	Vice President	Frank DeFazio	See PLM	See PLM
Regulatory Affairs	Senior Director	Julie Perkins	See PLM	See PLM
Medical Affairs	Senior Vice President/Medical Director	Trang Ly	See PLM	See PLM
Quality	Senior Director	Eric Peterson	See PLM	See PLM