Omnipod® 5 Automated Insulin Delivery System

User Guide

INDICATIONS FOR USE

The **Omnipod 5 Automated Insulin Delivery System** is a single-hormone insulin delivery system intended to deliver U-100 insulin subcutaneously for the management of type 1 diabetes in persons aged 2 and older requiring insulin.

The Omnipod 5 System is intended to operate as an automated insulin delivery system when used with compatible Continuous Glucose Monitors (CGM).

When in Automated Mode, the Omnipod 5 System is designed to assist people with type 1 diabetes in achieving glycaemic targets set by their healthcare providers. It is intended to modulate (increase, decrease or suspend) insulin delivery to operate within predefined threshold values using current and predicted sensor glucose values to maintain blood glucose at variable target glucose levels, thereby reducing glucose variability. This reduction in variability is intended to lead to a reduction in the frequency, severity and duration of both hyperglycaemia and hypoglycaemia.

The Omnipod 5 System can also operate in a Manual Mode that delivers insulin at set or manually adjusted rates.

The Omnipod 5 System is intended for single-patient use. The Omnipod 5 System is indicated for use with NovoLog®/NovoRapid®, Humalog® and Admelog® / Insulin lispro Sanofi® U-100 insulin.

CONTRAINDICATIONS

The Omnipod 5 System is NOT recommended for people who:

- Are unable to monitor glucose as recommended by their healthcare provider
- Are unable to maintain contact with their healthcare provider
- Are unable to use the Omnipod 5 System according to the instructions
- Are taking hydroxyurea, as it could lead to falsely elevated sensor glucose values and result in the over-delivery of insulin, which can lead to severe hypoglycaemia
- Do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms and reminders

Device components including the Pod, Sensor and Transmitter must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan or diathermy treatment. In addition, the Controller should be placed outside of the procedure room. Exposure to MRI, CT or diathermy treatment can damage the components.

COMPATIBLE INSULINS

The Omnipod 5 Automated Insulin Delivery System is compatible with the following U-100 insulins: NovoLog®/ NovoRapid®, Humalog® and Admelog® / Insulin lispro Sanofi®.

WELCOME TO OMNIPOD® 5

New Omnipod 5 User

Receiving training and understanding the Instructions for Use are needed BEFORE using your new Omnipod 5 System. Follow these steps to get started:

1. **Receive Training**
   Learning how to use your Omnipod 5 System the correct way is important for safe and effective use. Different training methods to learn how to use your system are available based on your and your healthcare provider's preferences. Your healthcare provider can help you to coordinate and set up appropriate training.
2. **Freedom Is Yours!**
   You'll then be ready to enjoy the benefits and flexibility of your new Omnipod 5 System.

If you have questions, please contact Customer Care.

Contents

To access the complete Omnipod 5 System Technical User Guide

At any time while using Omnipod 5, you can access or request the Omnipod 5 Technical User Guide.

1. Download or print a digital copy:
   - Scan this QR code with your smartphone
   - Visit omnipod.com/guides
2. Request to receive a free printed copy:
   - Online request form at omnipod.com/guides

1 Omnipod 5 System Overview

The Omnipod 5 App

- on the Controller provided
- sends commands to the Pod
- displays glucose and insulin information from the Pod
- used to issue meal and correction boluses

The Pod

- delivers insulin to your body
- receives commands from the Omnipod 5 App
- receives sensor glucose values from the Dexcom G6 Sensor
- sends sensor glucose values to the Omnipod 5 App
- automatically adjusts insulin delivery in Automated Mode

The Dexcom G6 Sensor

- sends sensor glucose values to the Pod and to the Dexcom G6 app
- does not communicate directly with the Omnipod 5 App
- cannot communicate with a Dexcom G6 receiver while paired with a Pod

For Sensor-specific information, refer to your *Dexcom G6 CGM System Instructions for Use.*

Omnipod 5 App screens are for educational purposes only. Consult your healthcare professional before using these features and for personalised recommendations.

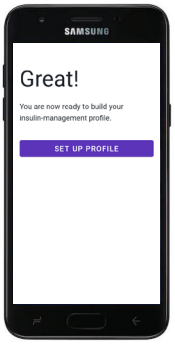
2 Set Up Your Omnipod 5 App

Omnipod 5 App Setup

The Omnipod 5 App comes installed on the Controller provided. Connectivity to mobile data or Wi-Fi is important when using the Omnipod 5 System. Make sure to connect to your home or work Wi-Fi network.

Initial pump therapy settings, provided by your healthcare provider, are needed to set up your Omnipod 5 App.

- Hold down the Power button to turn it on



The Omnipod 5 App will guide you through setup. Make sure to read each screen and carefully enter information.

An Omnipod ID is needed for setup. You will be prompted to sign in or be directed to create a new ID.

Setup is complete after entering your personalised initial pump therapy settings (provided by your healthcare provider).

Dexcom G6 not included

You can set up & start your Dexcom G6 before or after setting up your Omnipod 5 App. You must use the Dexcom G6 mobile app and cannot use a Dexcom G6 receiver. Please consult the *Dexcom G6 CGM System Instructions for Use* for more information.

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Omnipod 5 App Security on Your Controller

After you set up your provided Controller, the Lock and PIN screens appear whenever you wake up your Controller.

The Lock screen displays:

- Your selected background image
- Today's date and time
- Your customised message
- The current system mode
- The amount of insulin on board
- Any alarm or notification messages

Unlock your Controller

Instructions to "wake up" or "unlock" the Controller mean doing the following:

1. Press and release the Power button.
2. Unlock the Lock screen by either swiping left to right or by swiping up from the bottom. The PIN screen appears.
3. Enter your 4-digit PIN.
4. Tap OK. The Home screen or your most recent screen appears.

Lock your Controller

To lock your Controller when you are finished using it:

► Press the Power button briefly. This locks the Controller by putting it to sleep.

Note: Keep your Controller in a safe, accessible location.

Forgotten your PIN?

If you have problems with your PIN, contact Customer Care. For contact information, see your Contact Card.

3 Set Up a New Pod

Prepare

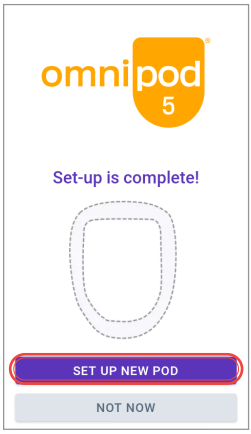
Gather the following supplies:

- Omnipod 5 Controller
- Unopened Omnipod 5 Pod
- Alcohol prep swabs
- A vial of room-temperature rapid-acting U-100 insulin approved for use with Omnipod 5

Wash your hands with soap and water

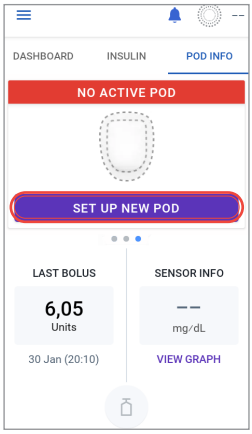
Clean the top of the insulin vial with an alcohol prep swab

On the Omnipod 5 App, locate the Pod activation screen



- After first-time setup, tap **SET UP NEW POD**

OR



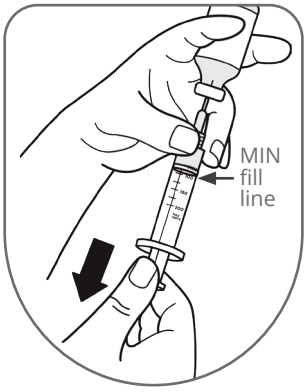
- From the POD INFO tab on the Home screen, tap **SET UP NEW POD**

Fill the Pod

Prepare the fill syringe

- Remove the fill needle and syringe from the Pod's tray. Keep the Pod in its tray during setup. Twist the needle clockwise onto the top of the syringe for a secure fit. Do not use any other type of needle or filling device besides the syringe provided with each Pod.
- Remove the protective needle cap by carefully pulling it straight off the needle.

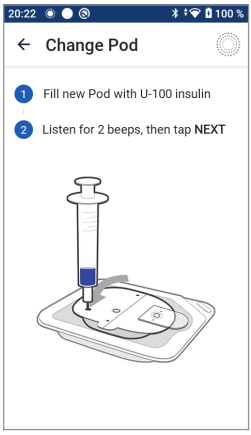
Fill the syringe

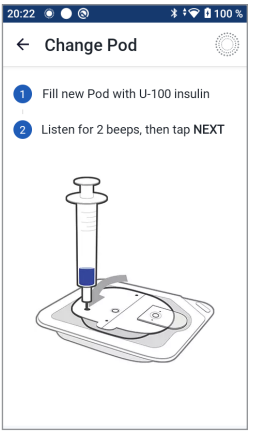


- Gently pull back on the plunger to draw air into the syringe equal to the amount of insulin you will use. You must fill the syringe with at least 85 units of insulin (MIN fill line). Insert the needle into the vial and push the plunger in to inject the air.
- With the syringe still in the vial, turn the vial and syringe upside down. Slowly pull the plunger to withdraw the insulin. Tap or flick the filled syringe to remove any bubbles.

Fill the Pod

- Remove the needle from the vial and insert it straight down into the fill port. An arrow on the white paper backing points to the fill port. Slowly push the plunger down to completely fill the Pod.
- The Pod will beep twice to indicate the Omnipod 5 Pod is ready to proceed.



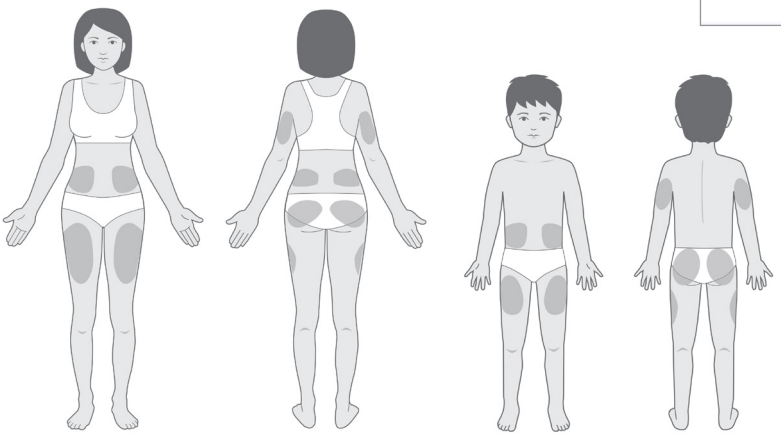


Activate the Omnipod 5 Pod

- With the Pod still in its tray, place it next to and touching the controller to ensure proper communication. Tap **NEXT** on the controller. The system will perform a series of safety checks and automatically primes the Pod.

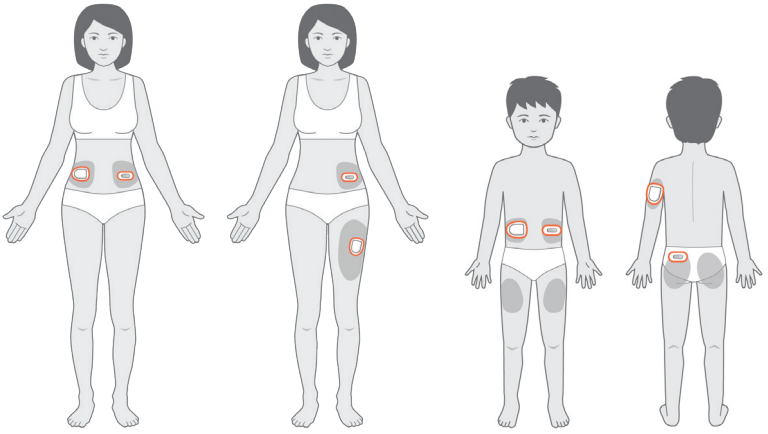
Pod Placement

Adults and Children



Sensor Placement

The Pod and Sensor should be worn within the line of sight, which means worn on the same side of the body in such a way that the two devices can "see" one another without your body blocking their communication.



Omnipod 5 App screens are for educational purposes only. Consult your healthcare professional before using these features and for personalised recommendations.

Guidelines for Pod Site Selection

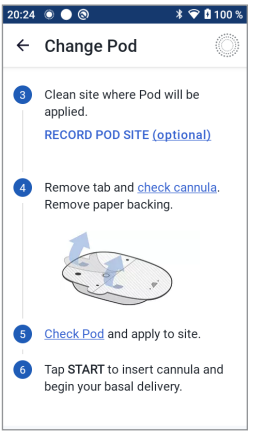
- Place at least 8 cm (3 inches) from your Sensor site, as indicated in your *Dexcom G6 System Instructions for Use.*
- Place within the line of sight of the Sensor for the best connectivity.

  Note: Line of sight means that the Pod and Sensor are worn on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.
- Ideal sites have a layer of fatty tissue.
- Ideal sites offer easy access and viewing.
- The site should be at least 2.5 cm (1 inch) away from the previous site to avoid skin irritation.
- The site should be at least 5 cm (2 inches) away from your navel.
- Avoid sites where belts, waistbands or tight clothing may rub against or dislodge the Pod.
- Avoid sites where the Pod will be affected by folds of skin.
- Avoid placing the Pod over a mole, tattoo or scar, where insulin absorption may be reduced.
- Avoid areas of the skin with an active infection.

Apply the Pod

Your Pod is now ready for application and insertion.

- Carefully follow the on-screen instructions. For more information, please refer to "Activating and Changing Your Pod" in your *Omnipod 5 System Technical User Guide*.
- Check the infusion site after insertion to ensure that the cannula was properly inserted.



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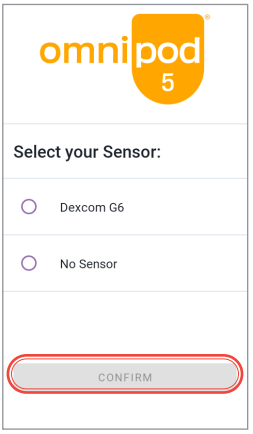
4 Connect the Pod and Sensor

Locate your Dexcom G6 Transmitter Serial Number (SN) from the back of the Transmitter OR from the Transmitter box

Step 1: Locate Manage Sensor Screen



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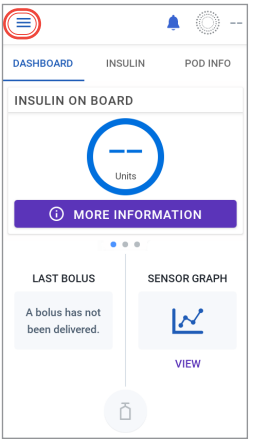
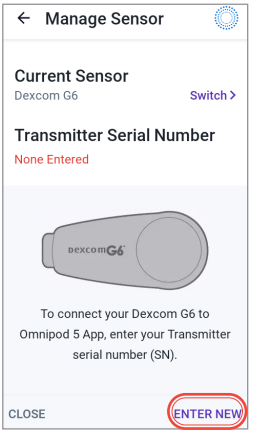


From first-time setup after Pod activation

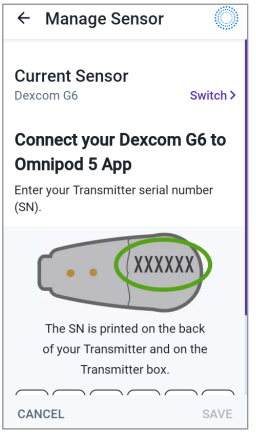
From the Home screen

- Tap the Menu button
- Tap Manage Sensor

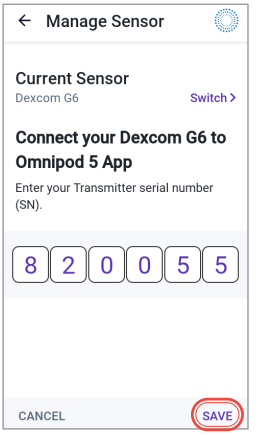
Step 2: Enter & Save New Transmitter Serial Number (SN)



- Tap **ENTER NEW**



- Tap the first box to enter the Transmitter serial number (SN)



- Tap **SAVE**

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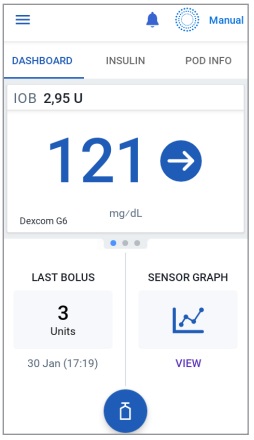
Omnipod 5 System Modes

System Modes

The Omnipod 5 System has two operating modes:
Automated Mode and Manual Mode

Automated Mode

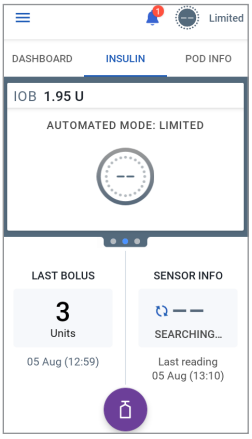
- Adjusts every 5 minutes
- Adapts by updating your total daily insulin with every Pod change



Manual Mode

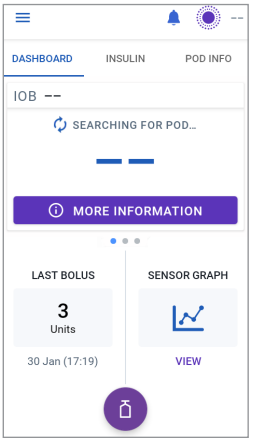
- Uses your Basal Programme

System States



Automated Mode: Limited

- Pod is not receiving sensor glucose values
- System constantly compares Automated Adaptive Basal Rate with Manual Basal Programme and uses whichever is lower



No Pod Communication

- Pod status is unknown
- Bring Controller closer to Pod

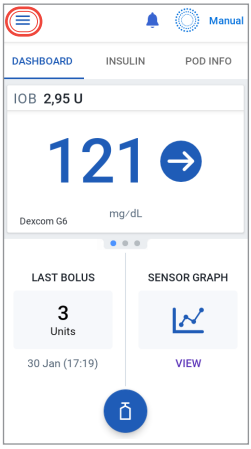
	Manual Mode	Automated Mode
How it works		
Basal Insulin Delivery	Insulin is delivered according to the active Basal Programme	Insulin is delivered and adjusted automatically based on sensor glucose values and 60-minute prediction. When sensor glucose values are not available for adjustments, in Automated: Limited, the System constantly compares Automated Adaptive Basal Rate and Manual Basal Programme and uses whichever is lower
Bolus Insulin Delivery	Insulin is delivered using the SmartBolus Calculator or entered manually	Insulin is delivered using the SmartBolus Calculator or entered manually
Connected Sensor	Not required. If connected, sensor glucose values are displayed, stored in history, and available for use in SmartBolus Calculator	Required. Sensor glucose values used for automated insulin delivery are displayed, stored in history, and available for use in SmartBolus Calculator

	Manual Mode	Automated Mode
What you can do		
Basal Programmes	Edit, create new, and activate Basal Programmes. Does not impact Automated Mode	Edit Target Glucose to impact automated insulin delivery. Cannot modify Basal Programmes in Automated Mode
Basal Insulin Delivery	Start and cancel Temp Basal rate, create Temp Basal Presets	Start and cancel the Activity feature
Bolus Calculator Settings	Edit Bolus Settings	Edit Bolus Settings
Bolus Insulin Delivery	Deliver and cancel Immediate and Extended Boluses	Deliver and cancel Immediate Boluses
Pod Changes	Activate and Deactivate Pods	Deactivate Pods. When a Pod is deactivated, the System switches to Manual Mode. After you activate a new Pod, you'll be prompted to switch to Automated Mode
Manage Sensor	View and modify Transmitter serial number (SN)	View Transmitter serial number (SN)
Pause and Start Insulin	Manually pause insulin for a specified duration of up to 2 hours. Manually start insulin	System automatically pauses automated insulin delivery based on sensor glucose value/prediction. Switch to Manual Mode to manually pause insulin delivery
History Details	Review History Details	Review History Details. Auto Events tab shows microbolus deliveries from Automated Mode
BG Entry	Enter blood glucose readings to save in History Details	Enter blood glucose readings to save in History Details
How you will be notified	Refer to Sections 2 & 5 of the Omnipod 5 System Technical User Guide for a detailed list of alarms and notifications	

Note: In Automated Mode, your Adaptive Basal Rate will be updated with every Pod change. Adaptive Basal Rate is a continuous baseline that the System can adjust up or down every 5 minutes in response to your sensor glucose values.
For your first Pod, since the System doesn't have any history yet, your total daily insulin and initial Adaptive Basal Rate are estimated from the Basal Programme you entered during setup.

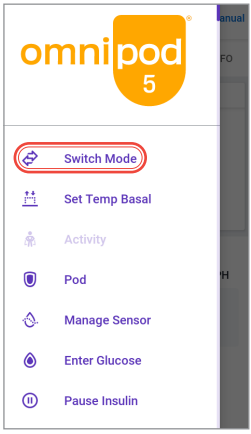
Switch to Automated Mode

1



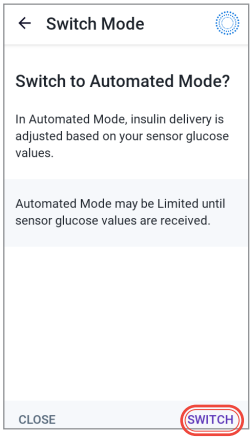
- Tap the Menu button on the Home screen

2



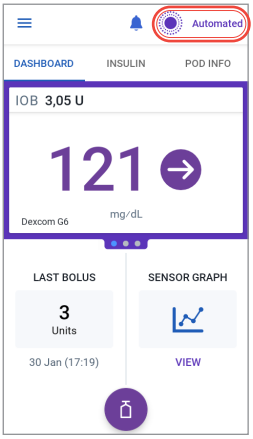
- Tap **Switch Mode**

3



- Tap **SWITCH**
- An active Pod and a saved Transmitter serial number (SN) within the Omnipod 5 App are required

4

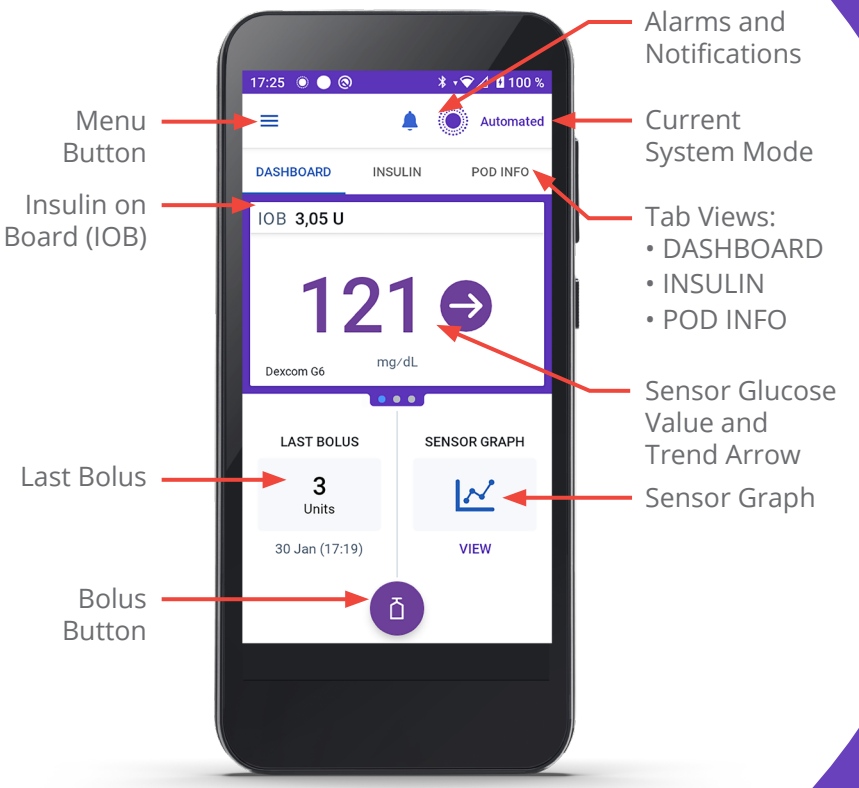


- Confirm that the mode switched. Automated should be indicated at the top right of the screen.

Note: Before switching to Automated Mode, an active temp basal, extended bolus or insulin pause must first be cancelled.

6 Get to Know the App

Omnipod 5 App Home Screen



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Glucose Trends and Indicators

Automated Manual

121 Trending steady

121 Trending steady

68 Falling rapidly

258 Rising slowly

SENSOR GLUCOSE VALUE COLOUR KEY:

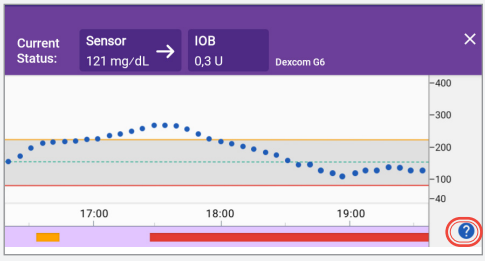
The sensor glucose value and trend arrow will change colour depending on your Glucose Goal Range.

- Sensor glucose value within Glucose Goal Range (Manual Mode)
- Sensor glucose value within Glucose Goal Range (Automated Mode)
- Sensor glucose value below Glucose Goal Range (Automated & Manual Modes)
- Sensor glucose value above Glucose Goal Range (Automated & Manual Modes)

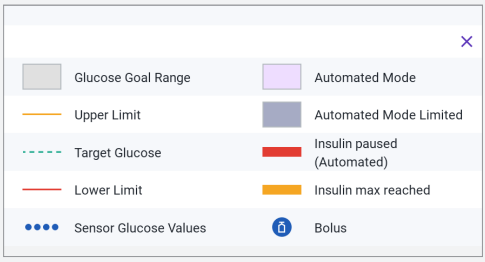
Note: A sensor glucose value will not be displayed if in Limited or No Pod Communication states

View Sensor Graph

• Tap **VIEW** on the Sensor Graph



• Tap the question mark icon to view the Graph Legend



• Sensor Graph Legend

Note: The Sensor Graph differs slightly in appearance depending on the Mode

Alarms and Notifications

The Omnipod 5 System generates different types of alarms and notifications. Alarms repeat every 15 minutes until acknowledged. Alarms that sound on the Pod must be acknowledged in the Omnipod 5 App.

See Chapters 13 and 24 in the full Omnipod 5 System Technical User Guide for more details on these alarms and notifications.

Hazard Alarms

Hazard alarms are high-priority alarms that indicate a serious problem has occurred, and you may need to remove your Pod.

Hazard alarms related to the App

Omnipod 5 App Error	The System detected an error with the App. The Controller may restart.
Omnipod 5 Memory Corruption	The System detected an error with the App. The Controller will be reset. All settings will be deleted. Remove your Pod.
System Error	The System detected an error with the App. Remove your Pod.

Hazard alarms related to the Pod

Blockage Detected	The System detected a blockage (occlusion) in the Pod's cannula. Insulin delivery has stopped. Remove your Pod.
Pod Error	The System detected an error with the Pod. Insulin delivery has stopped. Remove your Pod.
Pod Expired	The Pod has reached the end of its operating life. Insulin delivery has stopped. Remove your Pod.
Pod Out of Insulin	The Pod is empty. Insulin delivery has stopped. Remove your Pod.
Pod Shut-Off	The Pod has stopped delivering insulin because you have set a Pod Shut-Off time and did not respond to the Pod Shut-Off Advisory alarm. Insulin delivery has stopped. Remove your Pod.

Advisory Alarms

Advisory alarms are lower-priority alarms that indicate that a situation exists that needs your attention. Advisory alarms may escalate to a Hazard alarm.

Advisory alarms related to the Pod

Low Pod Insulin	The amount of insulin in your Pod is below the value you specified in Settings. Escalates to Pod Out of Insulin Hazard alarm if ignored. Change your Pod soon.
Pod Expired	The Pod has expired and will stop delivering insulin soon. Will sound once per hour until it escalates to Pod Expired Hazard alarm. Change your Pod soon.
Pod Shut-Off	The Pod will stop delivering insulin soon because of the Pod Shut-Off time you specified in Settings. Tap OK to acknowledge and avoid escalating to a Pod Shut-Off Hazard Alarm.
Start Insulin	The time period you specified to pause insulin has ended. Tap START INSULIN to restart insulin and avoid hyperglycaemia.

Advisory alarm related to Glucose

Urgent Low Glucose	Your sensor glucose value is 55 mg/dL or below. Consider eating fast-acting carbs to treat hypoglycaemia.

Advisory alarms related to Automated Mode

Missing Sensor Values	In Automated Mode, the Pod has not received sensor glucose values for an hour. The System will operate in Automated: Limited until new values are received.
Automated Delivery Restriction	In Automated Mode, the System has been working to bring your glucose into range but has not seen your glucose change the way it expected. This alarm can let you know to step in and check your Sensor, your Pod and your glucose. Switch to Manual Mode for 5 minutes or longer to acknowledge this alarm.

Notifications

Action item notifications are for technical System tasks that need your attention, such as App settings or updates. Reminder notifications are related to diabetes management actions you may want to perform.

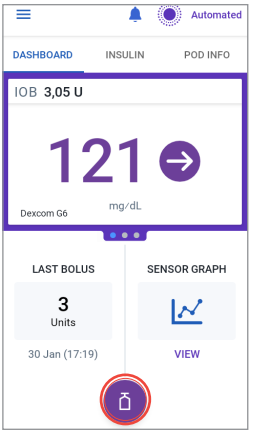
7 Key Insulin Delivery Actions

Deliver a Bolus

Automated Manual

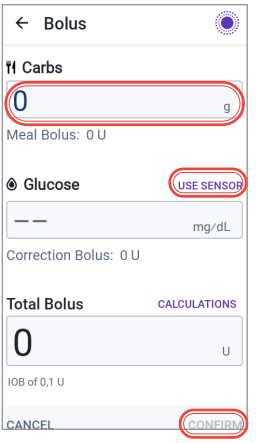
Note: The USE SENSOR button is active only when Omnipod 5 is receiving sensor glucose values
Note: Extended Bolus is available only in Manual Mode

1



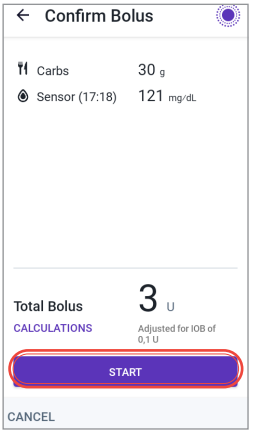
- Tap the Bolus button on the Home screen

2



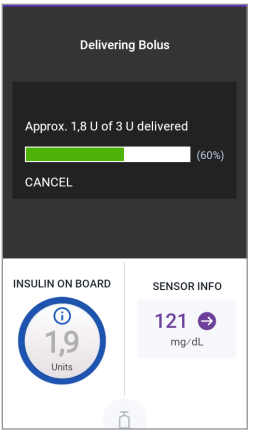
- Tap on the Carbs field to manually enter carbs
- Tap **USE SENSOR** to use the sensor glucose value and trend, or add a blood glucose reading by tapping the Glucose field
- Tap **CONFIRM**

3



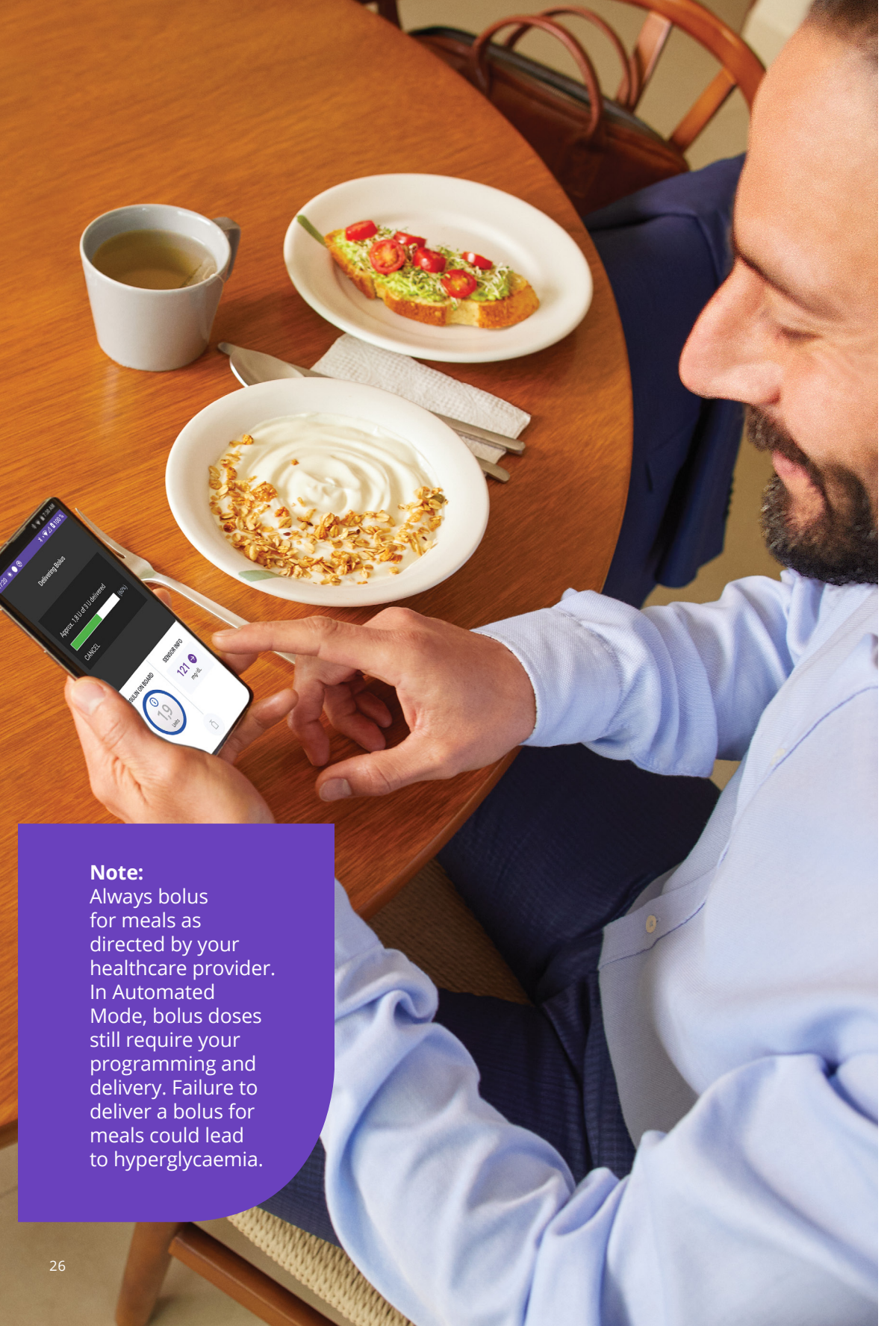
- Review entries are correct
- Tap **START** to begin bolus insulin delivery

4



- The Home Screen will display the bolus delivery progress

Omnipod 5 App screens are for educational purposes only. Consult your healthcare professional before using these features and for personalised recommendations.



Note:
Always bolus for meals as directed by your healthcare provider. In Automated Mode, bolus doses still require your programming and delivery. Failure to deliver a bolus for meals could lead to hyperglycaemia.

7 KEY INSULIN DELIVERY ACTIONS (continued)

Start the Activity Feature

Automated

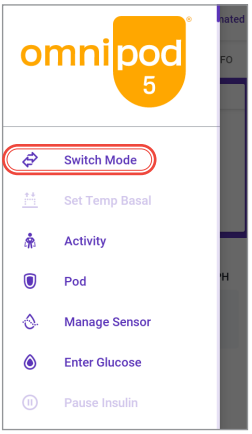
Note: The Activity feature is available only in Automated Mode

The Activity feature of the Omnipod 5 System can be enabled for times when there may be a decrease in insulin needs, like exercise. It will set the Automated Mode Target Glucose to 150 mg/dL and reduce insulin delivery. Note: the Activity feature does not change the Target Glucose used in bolus calculations.

1

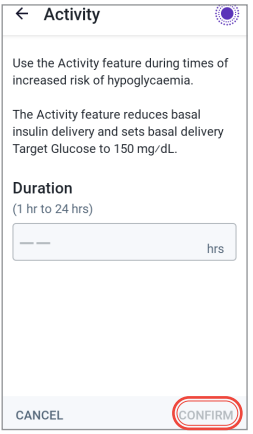
- Tap the Menu button on the Home screen

2



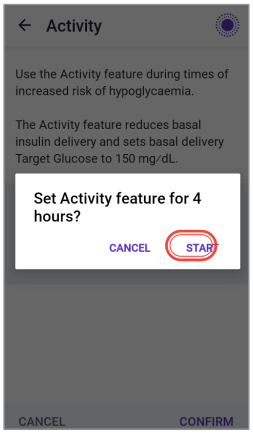
- Tap **Activity**

3



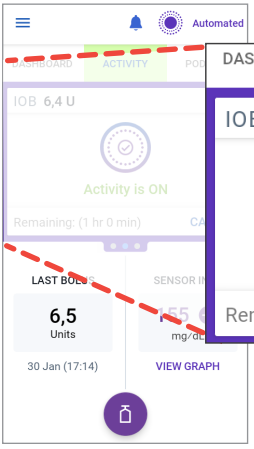
- Set Duration (1-24 hrs)
- Tap **CONFIRM**

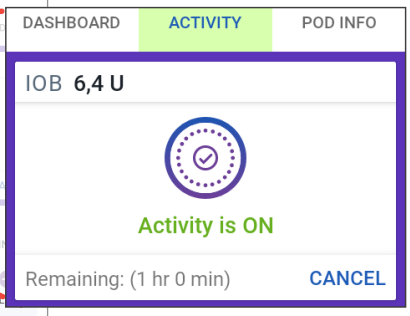
4



- Tap **START**

5





- Confirm Activity now shows on the home screen

Omnipod 5 App screens are for educational purposes only. Consult your healthcare professional before using these features and for personalised recommendations.

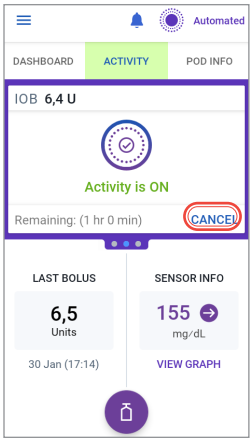
7 KEY INSULIN DELIVERY ACTIONS (continued)

Cancel the Activity Feature

Automated

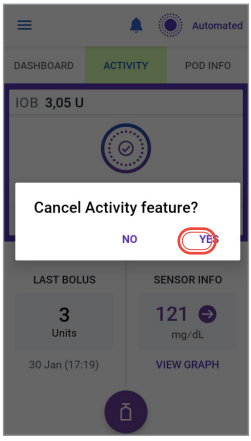
You can cancel the Activity feature at any time. Upon cancellation or expiry of the defined time period, full automated basal delivery starts on its own and the Omnipod 5 System returns to using the user-defined Target Glucose.

1



- Tap **CANCEL** on the ACTIVITY Tab

2



- Tap **YES**

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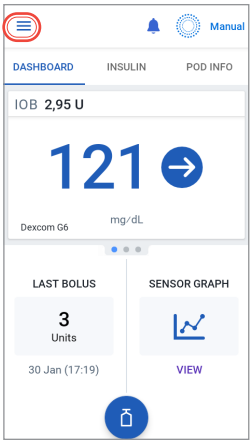
Pause Insulin Delivery

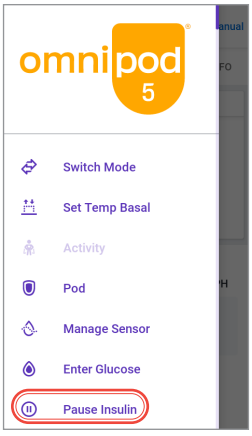
Manual

1



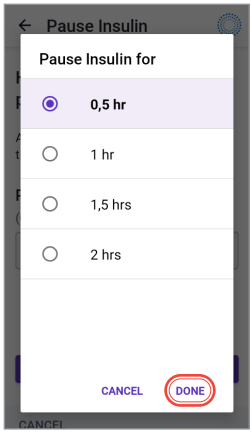
- Tap the Menu button on the Home screen

2



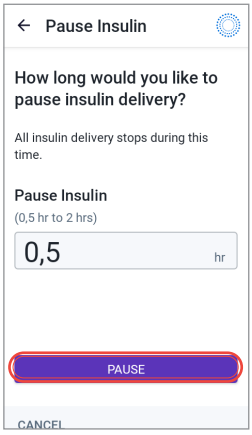
- Tap **Pause Insulin**

3



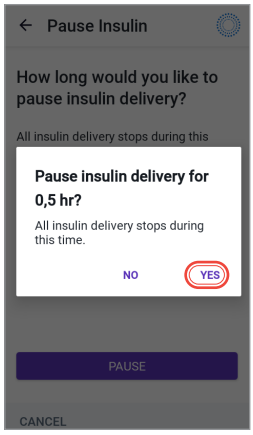
- Use the scroll wheel to tell the System how long you'd like to pause insulin for

4



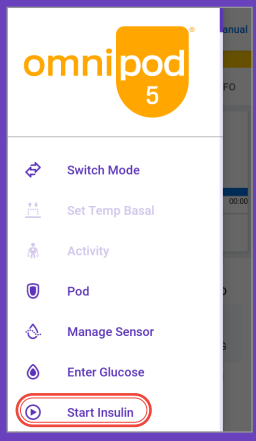
- Tap **Pause**

5



- Tap **YES** to confirm insulin pause

Start Insulin Delivery



- Tap **Start Insulin**
- Follow the Menu instructions to start insulin

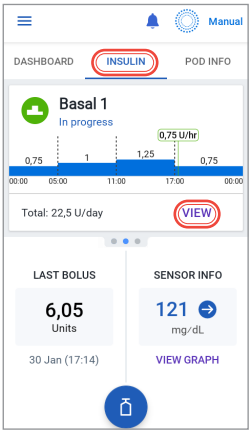
Insulin delivery does not automatically start at the end of the paused period. You must tap **START INSULIN** to start insulin delivery.

Editing a Basal Programme

Manual

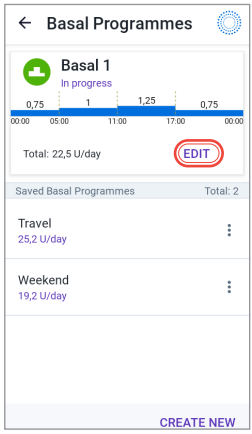
Note: Editing a Basal Programme only causes impacts and can only be performed in Manual Mode.

1



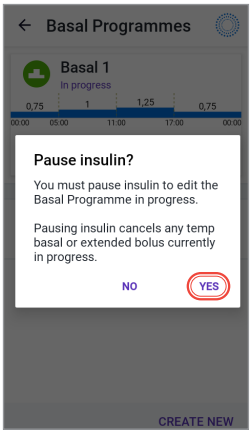
- Tap the INSULIN tab on the Home screen
- Tap **VIEW**

2



- Tap **EDIT**

3



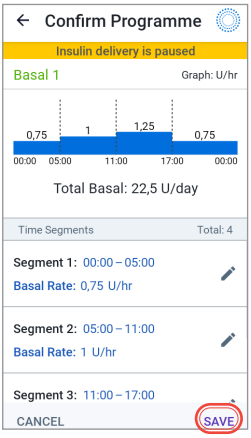
- Tap **YES**

4

- Tap to edit a programme or tap **NEXT** to edit basal time segments and rates

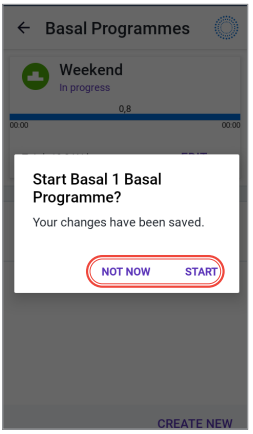
Omnipod 5 App screens are for educational purposes only. Consult your healthcare professional before using these features and for personalised recommendations.

5

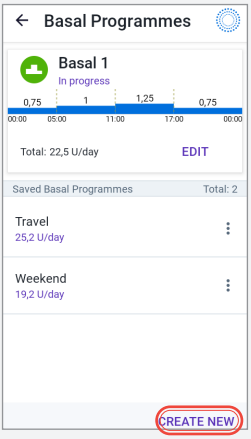


- Tap the time segment to edit
- Tap **SAVE** after confirming edits in the basal programme

6



- To start the Basal Programme now, tap **START**. Otherwise, tap **NOT NOW** to save for use at a later time.



Additional Basal Programmes

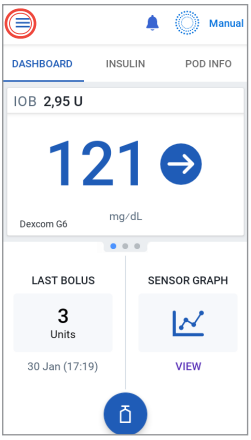
- Additional Basal Programmes can be created by navigating to the Menu button>Basal Programmes and tapping **CREATE NEW**
- Tap the Programme Name field to enter a descriptive name for the new Basal Programme
- Tap **NEXT** and define the basal segments one at a time

Set a Temporary Basal Rate

Manual

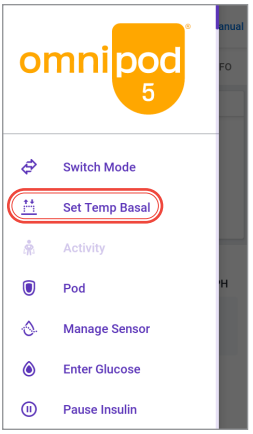
Note: Temp Basal is available only in Manual Mode

1



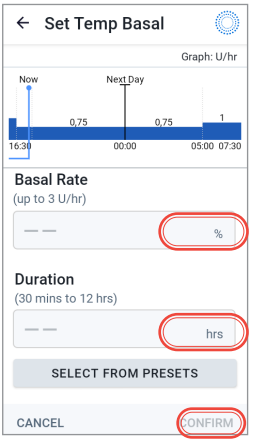
- Tap the Menu button on the Home screen

2



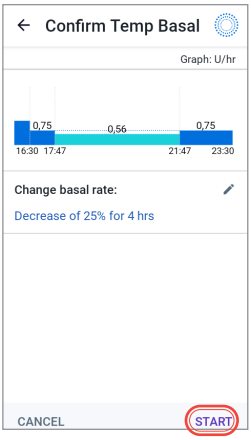
- Tap **Set Temp Basal**

3



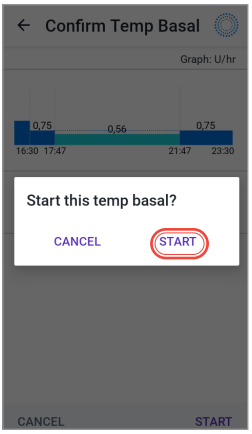
- Tap the Basal Rate entry box and select % change
  Note: The up arrow indicates an increase. The down arrow indicates a decrease.
- Tap the Duration entry box and select time duration
- Tap **CONFIRM**

4

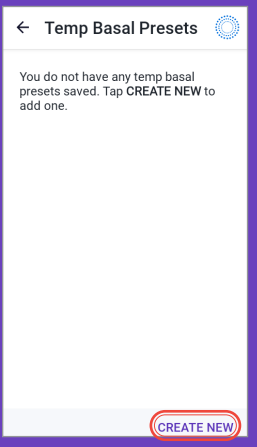


- Review selections are correct and tap **START**

5



- Tap **START**



Temp Basal Preset

Temp Basal Presets can be created if there is a temp basal that you use often.

- Navigate to the Temp Basal Presets screen by tapping Menu>Temp Basal Presets. From here, you can create a new Temp Basal Preset or edit existing Temp Basal Presets.

8 Clinical Evidence for Omnipod 5

Omnipod 5 Pivotal Study in Children, Adolescents and Adults (6-70 years)

The goal of the pivotal study of the Omnipod 5 System was to assess the safety and efficacy of the system. This single-arm, multicentre, prospective study enrolled 112 children (6 to 13.9 years) and 128 adolescents and adults (14 to 70 years).

A 2-week standard-therapy phase (usual insulin regimen) was followed by 3 months of Omnipod 5 System use in Automated Mode. The primary analysis consisted of A1C and sensor glucose time in range (3.9–10 mmol/L, 70–180 mg/dL) results.

The primary safety endpoints included an assessment of severe hypoglycaemia and diabetic ketoacidosis (DKA) events. An analysis of the secondary endpoints and additional metrics was also performed. An analysis of the primary and safety results are presented in the following tables. See the full *Omnipod 5 Technical User Guide* for secondary results.

Of the 240 subjects enrolled, 98% completed the trial (111 children and 124 adolescents and adults). The study population consisted of people with type 1 diabetes for at least 6 months. All subjects were required to have an A1C <10.0% at screening. Subjects <18 years had to be living with a parent or legal guardian.

Glycaemic Results

The tables on the following pages include information on the primary glycaemic results from the standard-therapy phase compared to the 3-month Omnipod 5 System treatment phase.

Adolescents, adults and children experienced improvements in overall A1C and time in range after 3 months of Omnipod 5 System use. This was achieved with a reduction of time >10 mmol/L (>180 mg/dL) in adolescents, adults and children, as well as a reduction in median time <3.9 mmol/L (<70 mg/dL) in adolescents and adults.

Some limitations to the study include: 1) single-arm design with no control group which could lead to an over-estimate of glycaemic improvement; 2) standard-therapy phase was shorter than the Omnipod 5 System phase; 3) minimal use of the 7.8 and 8.3 mmol/L (140 and 150 mg/dL) Target Glucose settings in adults and adolescents limited the assessment of glycaemic results at those settings and, for that reason, results at these Target settings were not included in these results.

Glycaemic Results Overall (24 hours)

Characteristic	Children (6 to 13.9 years) (n=112)			Adolescents & Adults (14 to 70 years) (n=128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg A1C% (std dev)	7.67% (0.95%)	6.99% (0.63%)	-0.71%*	7.16% (0.86%)	6.78% (0.68%)	-0.38%*
Avg % time 3.9–10 mmol/L, 70-180 mg/dL (std dev)	52.5% (15.6%)	68.0% (8.1%)	15.6%*	64.7% (16.6%)	73.9% (11.0%)	9.3%*
Avg sensor glucose, mmol/L, mg/dL (std dev)	10.2, 183 (1.8, 32)	8.9, 160 (0.8, 15)	-1.3, -23*	8.9, 161 (1.6, 28)	8.6, 154 (0.9, 17)	-0.3, -8*
Avg standard deviation of sensor glucose, mmol/L, mg/dL (std dev)	3.8, 68 (0.7, 13)	3.3, 60 (0.6, 10)	-0.5, -9*	3.2, 57 (0.8, 14)	2.7, 49 (0.6, 11)	-0.5, -8*
Avg coefficient of variation of sensor glucose, % (std dev)	37.5% (5.1%)	37.0% (3.9%)	-0.4%	35.2% (5.7%)	31.7% (4.7%)	-3.5%*
% Time in Glucose Range						
Median % <3 mmol/L, <54 mg/dL (Q1, Q3)	0.10% (0.00, 0.41)	0.23% (0.08, 0.42)	0.04%	0.22% (0.00, 0.77)	0.17% (0.06, 0.28)	-0.08%*
Median % <3.9 mmol/L, <70 mg/dL (Q1, Q3)	1.38% (0.42, 2.67)	1.48% (0.65, 2.23)	0.06%	2.00% (0.63, 4.06)	1.09% (0.46, 1.75)	-0.89%*
Avg % >10 mmol/L, >180 mg/dL (std dev)	45.3% (16.7%)	30.2% (8.7%)	-15.1%*	32.4% (17.3%)	24.7% (11.2%)	-7.7%*
Avg % ≥13.9 mmol/L, ≥250 mg/dL (std dev)	19.1% (13.1%)	9.6% (5.4%)	-9.4%*	10.1% (10.5%)	5.8% (5.5%)	-4.3%*
Avg % ≥16.7 mmol/L, ≥300 mg/dL (std dev)	8.5% (8.9%)	3.5% (2.9%)	-5.1%*	3.7% (5.5%)	1.7% (2.5%)	-2.0%*

Most of the primary and secondary results are presented as averages (avg) with standard deviation (std dev) values in brackets. Time in range <3.9 mmol/L (<70 mg/dL) and <3 mmol/L (<54 mg/dL) is reported as medians with interquartile ranges in brackets (Q1, Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

**Change between the standard-therapy phase and the Omnipod 5 System phase was statistically significant.*

Glycaemic Results Overnight (12:00AM to 6:00AM)						
Characteristic	**Children (6 to 13.9 years) (n=112)**			**Adolescents & Adults (14 to 70 years) (n=128)**		
	Standard Therapy	**Omnipod 5**	**Change**	**Standard Therapy**	**Omnipod 5**	**Change**
Avg % time 3.9–10 mmol/L, 70–180 mg/dL (std dev)	55.3% (19.0%)	78.1% (10.8%)	22.9%*	64.3% (19.5%)	78.1% (13.9%)	13.8%*
Avg sensor glucose, mmol/L, mg/dL (std dev)	9.8, 177 (1.9, 35)	8.3, 149 (0.9, 17)	-1.5, -29*	8.9, 160 (1.9, 34)	8.3, 149 (1.2, 21)	-0.6, -11*
Avg standard deviation of sensor glucose, mmol/L, mg/dL (std dev)	3.4, 61 (0.8, 15)	2.7, 48 (0.7, 12)	-0.7, -13*	3.1, 56 (0.9, 17)	2.4, 44 (0.7, 13)	-0.7, -12*
Avg coefficient of variation of sensor glucose, % (std dev)	34.6% (7.1%)	31.9% (5.6%)	-2.8%	35.0% (7.9%)	28.9% (5.8%)	-6.2%*
% Time in Glucose Range						
Median % <3 mmol/L, <54 mg/dL (Q1, Q3)	0.00% (0.00, 0.30)	0.09% (0.02, 0.32)	0.02%	0.00% (0.00, 1.06)	0.09% (0.02, 0.30)	0.00%*
Median % <3.9 mmol/L, <70 mg/dL (Q1, Q3)	0.78% (0.00, 2.84)	0.78% (0.37, 1.49)	0.01%*	2.07% (0.50, 5.54)	0.82% (0.31, 1.62)	-0.86%*
Avg % >10 mmol/L, >180 mg/dL (std dev)	42.2% (20.0%)	20.7% (10.8%)	-21.5%*	32.1% (20.2%)	20.7% (14.1%)	-11.3%*
Avg % ≥13.9 mmol/L, ≥250 mg/dL (std dev)	16.3% (15.0%)	5.4% (5.1%)	-10.9%*	10.6% (12.7%)	4.8% (7.0%)	-5.7%*
Avg % ≥16.7 mmol/L, ≥300 mg/dL (std dev)	6.7% (9.1%)	1.8 (2.5%)	-4.8%*	4.2% (8.0%)	1.5% (3.1%)	-2.7%*
**Change between the standard-therapy phase and the Omnipod 5 System phase was statistically significant.*						

Change in A1C Analysed by Baseline A1C

The table below provides information on the average change in A1C% from baseline to the end of the 3-month Omnipod 5 System treatment phase. Adolescents, adults and children experienced a reduction in A1C after 3 months of Omnipod 5 System use regardless of baseline A1C < 8% or ≥ 8% category.

Subgroup Analysis of Change in Average A1C(%) by Baseline A1C(%)						
	Baseline A1C <8% (n=105)			Baseline A1C ≥8% (n=23)		
Adolescents & Adults	**Baseline**	**Omnipod 5**	**Change**	**Baseline**	**Omnipod 5**	**Change**
A1C% (std dev)‡	6.86% (0.59%)	6.60% (0.53%)	-0.27%*	8.55% (0.42%)	7.63% (0.67%)	-0.91%*
	Baseline A1C <8% (n=73)			Baseline A1C ≥8% (n=39)		
Children	**Baseline**	**Omnipod 5**	**Change**	**Baseline**	**Omnipod 5**	**Change**
A1C% (std dev)‡	7.11% (0.50%)	6.69% (0.44%)	-0.45%*	8.73% (0.63%)	7.56% (0.54%)	-1.18%*

**Change between the standard-therapy phase and the Omnipod 5 System phase was statistically significant*
‡Average A1C values are reported with standard deviation values in brackets.

Adverse Events

The table below provides a full list of the adverse events that occurred during the 3-month Omnipod 5 System treatment phase.

Adverse Events During the Omnipod 5 System Phase			
Adverse Event Type	Children (6 to 13.9 years) (n=112)	Adolescents & Adults (14 to 70 years) (n=128)	Total (6 to 70 years) (n=240)
Hypoglycaemia‡	1	0	1
Severe Hypoglycaemia§	1	2	3
DKA	1	2	1
Hyperglycaemia‖	1	2	3
Prolonged Hyperglycaemia**	13	5	18
Other	8	8	16

Results reported as number of events.
‡ *Hypoglycaemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycaemia.*
§ *Required the assistance of another person*
‖ *Hyperglycaemia requiring evaluation, treatment or guidance from the intervention site, or hyperglycaemia resulting in a serious adverse event.*
** *Meter blood glucose measuring ≥16.7 mmol/L (≥300 mg/dL) and ketones >1.0 mmol/L.*

CGM-informed SmartBolus Calculator Clinical Study in Children, Adolescents and Adults

A study was conducted on 25 participants with type 1 diabetes aged 6-70 years to assess the Omnipod 5 CGM-informed SmartBolus Calculator.

During Phase 1, participants used the Omnipod 5 system in Manual Mode for the first 7 days without a connected CGM (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected CGM (CGM-informed SmartBolus Calculator) for 7 days.

The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the sensor glucose trend. The primary analysis of the study was to compare the percentage of time spent <3.9 mmol/L (<70 mg/dL) and >10 mmol/L (>180 mg/dL) for the 4 hours after any bolus, as measured by CGM between the two study phases. The results indicate that the use of the CGM-informed SmartBolus Calculator was associated with less time in hypoglycaemia within 4 hours of bolusing.

Comparison of Glycaemic Measures from Phase 1 (Standard SmartBolus Calculator) and Phase 2 (CGM-Informed SmartBolus Calculator) for the 4 hours After any Bolus (n=25)

Percentage time in glucose range as measured by CGM	Standard SmartBolus Calculator	CGM-Informed SmartBolus Calculator	Difference
3.9–10 mmol/L (70–180 mg/dL)	65.1% (15.4)	63.8% (15.7)	-1.3%
<3.9 mmol/L (<70 mg/dL)	2.8% (2.7)	2.1% (2.0)	-0.6%*
<3 mmol/L (<54 mg/dL)	0.5% (1.0)	0.3% (0.7)	-0.2%
>10 mmol/L (>180 mg/dL)	32.1% (15.7)	34.0% (16.0)	1.9%
≥13.9 mmol/L (≥250 mg/dL)	8.2% (6.9)	9.7% (10.3)	1.4%
≥16.7 mmol/L (≥300 mg/dL)	2.0% (2.6)	2.6% (3.7)	0.6%

Data is presented as: average (standard deviation). Significant differences (p<0.05) are highlighted with an asterisk.

Omnipod 5 Clinical Study in Very Young Children

The goal of this study was to assess the safety and effectiveness of the Omnipod 5 System in children with type 1 diabetes aged 2 to 5.9 years. This single-arm, multicentre, prospective study enrolled 80 children.

A 2-week standard-therapy phase (usual insulin regimen) was followed by 3 months of Omnipod 5 System use in Automated Mode. The primary analysis consisted of A1C and sensor glucose time in range (3.9–10 mmol/L, 70–180 mg/dL) results.

The primary safety endpoints included the incidence of severe hypoglycaemia and diabetic ketoacidosis (DKA). An analysis of the secondary endpoints and additional metrics was also performed. An analysis of the primary and safety results are presented in the following tables. See the full *Omnipod 5 Technical User Guide* for secondary results.

Of the 80 participants enrolled, 100% completed the trial. The study population consisted of children diagnosed with type 1 diabetes based on the investigator's clinical judgement. All participants were required to have an A1C <10.0% at screening. Participants had to be living with a parent or legal guardian.

Glycaemic Results

The tables on the following pages include information on the primary glycaemic results from the standard-therapy phase compared with the 3-month Omnipod 5 System treatment phase. The primary results of the study included change in average A1C% and % time in range (3.9–10 mmol/L, 70–180 mg/dL). Participants experienced improvements in A1C and overall time in range after 3 months of Omnipod 5 System use. This result was achieved with a reduction of time >10 mmol/L (>180 mg/dL) as well as a reduction in median time <3.9 mmol/L (<70 mg/dL).

Some limitations of the study include: 1) single-arm design with no control group, which could lead to an over-estimate of glycaemic improvement; 2) standard-therapy phase was shorter than the Omnipod 5 System phase.

Glycaemic Results Overall (24 hours)			
Characteristic	**Standard Therapy**	**Omnipod 5**	**Change**
Avg A1C% (std dev)	7.4% (1.0%)	6.9% (0.7%)	-0.55%*
Avg % time 3.9–10 mmol/L, 70–180 mg/dL (std dev)	57.2% (15.3%)	68.1% (9.0%)	10.9%*
Avg sensor glucose, mmol/L, mg/dL, (std dev)	9.5, 171.1 (1.7, 30.5)	8.7, 157.4 (0.9, 16.8)	-0.8, -13.7*
Avg standard deviation of sensor glucose, mmol/L, mg/dL (std dev)	3.6, 64.9 (0.7, 13.4)	3.3, 59.6 (0.6, 10.3)	-0.3, -5.3*
Avg coefficient of variation of sensor glucose, % (std dev)	38.1% (5.5%)	37.7% (4.0%)	-0.4%
% Time in Glucose Range			
Median % <3 mmol/L, <54 mg/dL (Q1, Q3)	0.24% (0.05, 0.84)	0.26% (0.16, 0.60)	0.06%
Median % <3.9 mmol/L, <70 mg/dL (Q1, Q3)	2.19 (0.89, 4.68)	1.94 (1.18, 3.43)	-0.27%*
Avg % >10 mmol/L, >180 mg/dL (std dev)	39.4% (16.7%)	29.5% (9.8%)	-9.9%*
Avg % ≥13.9 mmol/L, ≥250 mg/dL (std dev)	14.8% (12.1%)	9.2% (5.6%)	-5.6%*
Avg % ≥16.7 mmol/L, ≥300 mg/dL (std dev)	6.0% (7.3%)	3.2% (2.8%)	-2.7%*

Most of the primary and secondary results are presented as averages (avg) with standard deviation (std dev) values in brackets. Time in range <3.9 mmol/L (<70 mg/dL) and <3 mmol/L (<54 mg/dL) is reported as medians with interquartile ranges in brackets (Q1, Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.
**Change between the standard-therapy phase and the Omnipod 5 System phase was statistically significant.*

Glycaemic Results Overnight (12:00AM to 6:00AM)			
Characteristic	**Standard Therapy**	**Omnipod 5**	**Change**
Avg % time 3.9–10 mmol/L, 70–180 mg/dL (std dev)	58.2% (18.7%)	81.0% (10.0%)	22.8%*
Avg sensor glucose, mmol/L, mg/dL (std dev)	9.3, 168.1 (1.8, 33.3)	7.8, 140.7 (0.9, 16.4)	-1.5, -27.4*
Avg standard deviation of sensor glucose, mmol/L, mg/dL (std dev)	3.2, 58 (0.8, 14.0)	2.5, 45.5 (0.6, 10.8)	-0.7, -12.5*
Avg coefficient of variation of sensor glucose, % (std dev)	34.7% (6.6%)	32.1% (5.2%)	-2.6%*
% Time in Glucose Range			
Median % <3 mmol/L, <54 mg/dL (Q1, Q3)	0.00% (0.00, 0.97)	0.18% (0.06, 0.53)	0.00%
Median % <3.9 mmol/L, <70 mg/dL (Q1, Q3)	1.66% (0.40, 4.21)	1.58% (0.65, 2.89)	-0.44%*
Avg % >10 mmol/L, >180 mg/dL (std dev)	38.4% (20.1%)	16.9% (10.3%)	-21.5%*
Avg % ≥13.9 mmol/L, ≥250 mg/dL (std dev)	13.0% (13.2%)	3.9% (3.9%)	-9.1%*
Avg % ≥16.7 mmol/L, ≥300 mg/dL (std dev)	4.3% (6.7%)	1.2% (1.6%)	-3.1%*

**Change between the standard-therapy phase and the Omnipod 5 System phase was statistically significant.*

Change in A1C Analysed by Baseline A1C

The table below provides information on the average change in A1C% from baseline to the end of the 3-month Omnipod 5 System treatment phase, analysed by baseline A1C%. Participants experienced a reduction in A1C after 3 months of Omnipod 5 System use regardless of baseline A1C <8% or ≥8% category.

Subgroup Analysis of Change in Average A1C(%) by Baseline A1C(%)

	Baseline A1C <8% (n=55)			Baseline A1C ≥8% (n=25)		
	Baseline	Omnipod 5	Change	Baseline	Omnipod 5	Change
A1C% (std dev)‡	6.9% (0.6%)	6.6% (0.6%)	-0.31%*	8.5% (0.5%)	7.5% (0.4%)	-1.06%*

**Change between the standard-therapy phase and the Omnipod 5 System phase was statistically significant.*
‡Average A1C values are reported with standard deviation values in brackets.

Adverse Events

The table below provides a full list of the adverse events that occurred during the 3-month Omnipod 5 System treatment phase.

Adverse Events During the Omnipod 5 System Phase

Adverse Event Type	Omnipod 5
Hypoglycaemia‡	0
Severe Hypoglycaemia§	0
DKA	0
Hyperglycaemia‖	4
Prolonged Hyperglycaemia**	20
Other	5

Results reported as number of events.
‡ *Hypoglycaemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycaemia.*
§ *Required the assistance of another person.*
‖ *Hyperglycaemia requiring evaluation, treatment or guidance from the intervention site, or hyperglycaemia resulting in a serious adverse event.*
** *Meter blood glucose measuring ≥16.7 mmol/L (≥300 mg/dL) and ketones >1.0 mmol/L.*

CGM-informed SmartBolus Calculator Clinical Study in Very Young Children

A study was conducted on 5 participants with type 1 diabetes aged 2-5.9 years to assess the Omnipod 5 CGM-informed SmartBolus Calculator in Manual Mode.

During Phase 1, participants used the Omnipod 5 system in Manual Mode for the first 7 days without a connected CGM (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected CGM (CGM-informed SmartBolus Calculator) for 7 days.

The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the sensor glucose trend. The primary analysis of the study was to compare the percentage of time spent <3.9 mmol/L (<70 mg/dL) and >10 mmol/L (>180 mg/dL) for the 4 hours after any bolus, as measured by CGM between the two study phases. The results showed that the CGM-informed SmartBolus Calculator provided similar glycaemic results to the standard SmartBolus calculator when used in Manual Mode.

Comparison of Glycaemic Measures from Phase 1 (Standard SmartBolus Calculator) and Phase 2 (CGM-Informed SmartBolus Calculator) for the 4 hours After any Bolus (n=5)

Percentage time in glucose range as measured by CGM	Standard SmartBolus Calculator	CGM-Informed SmartBolus Calculator	Difference
3.9–10 mmol/L (70–180 mg/dL)	59.6% (7.1%)	62.8% (15.5%)	-3.15%
<3.9 mmol/L (<70 mg/dL)	5.16% (4.99%)	4.03% (3.28%)	-1.13%*
<3 mmol/L (<54 mg/dL)	1.47% (1.88%)	0.81% (0.91%)	-0.66%
>10 mmol/L (>180 mg/dL)	35.2% (10.3%)	33.2% (18.5%)	-2.03%
≥13.9 mmol/L (≥250 mg/dL)	9.4% (5.7%)	7.9% (6.4%)	-1.55%
≥16.7 mmol/L (≥ 300 mg/dL)	2.33% (2.69%)	1.99% (2.05%)	-0.34%

Data is presented as: average (standard deviation).

9 Settings and Technical Specifications

Controller Specifications

Size: 143.92 mm high x 67.57 mm wide x 12.33 mm deep (5.67” x 2.66” x 0.49”)

Weight: 165 grams (5.82 oz)

Screen active area: 56.16 mm wide x 120.58 mm high (2.21” x 4.75”)

Operating temperature range: 5°C to 40°C (41°F to 104°F)

Storage temperature range: 0°C to 30°C (32°F to 86°F)

Operating relative humidity range: 20% to 90%, non-condensing Storage relative humidity range: 20% to 90%, non-condensing Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Communication distance: The Controller and Pod should be:

- At start-up: Adjacent and touching, with the Pod either in or out of the tray, to ensure proper communication during priming.
- During normal operation: Within 1.5 metres (5 ft) of each other. Depending on the location, the communication distance may handle separations of up to 15 metres (50 ft) away.

Alarm type: Audible. Output: ≥45 db(A) at 1 metre

IP (Ingress Protection) rating for moisture and dust: IP22 (protected from touch by fingers and objects 12.5 millimetres or larger; not well-protected from water - avoid liquid)

Notification type: Audible and vibratory

Battery: Rechargeable Li-ion battery, 3.8 V, 2,800 mAh

Battery Operational Life: Full charge covers approximately 36 hours with typical use.

Controller Service Life: Approximately 2 years (based on 300-500 charge cycles) with typical use

Shelf Life (Starter Kit): 18 months

Battery charger operating line voltage: 100 to 240 VAC, 50/60 Hz

Only use the Noetic-approved power adapter (Insulet PN PT-000428) with the Controller.

Dexcom Specifications

For information about the Dexcom operating specifications, see the *Dexcom G6 CGM System Instructions for Use*.

Pod Specifications

Size: 3.9 cm wide x 5.2 cm long x 1.45 cm high (1.53" x 2.05" x 0.57")

Weight (without insulin): 26 grams (0.92 oz)

Operating temperature range: Pod operating environment of 5°C to 40°C (41°F to 104°F).

Start-up temperature: above 10°C (50°F)

Storage temperature range: 0°C to 30°C (32°F to 86°F)

Warm-up time (0°C to 20°C): 7 minutes

Cooldown time: No time is required for Cooldown from the maximum storage temperature (30°C) to the operating temperature.

Reservoir volume (deliverable): 200 units

Cannula insertion depth: 4 to 7 mm (0.16-0.28 in)

Depth of insulin infusion: ≥4 mm (≥0.16 in)

IP (Ingress Protection) rating for moisture and dust: IP28 (protected from touch by fingers and objects 12.5 millimetres or larger; protected from water to a depth of up to 25 feet (7.6 metres) for up to 60 minutes)

Insulin concentration: U-100

Alarm type: Audible. Output: ≥45 db(A) at 1 metre

Sterilising agent: sterilised using ethylene oxide

Operating relative humidity range: 20 to 85%, non-condensing Storage relative humidity range: 20 to 85%, non-condensing Operating atmospheric pressure: 700 hPa to 1060 hPa

Storage atmospheric pressure: 700 hPA to 1060 hPA

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

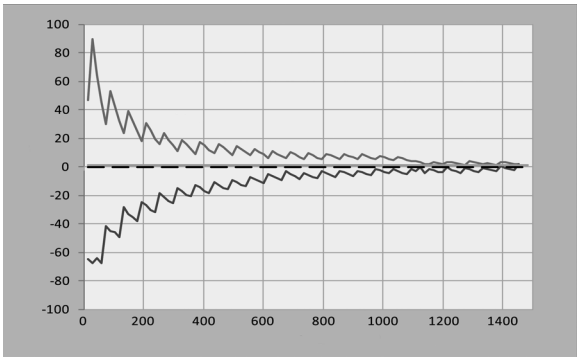
Maximum volume infused under single-fault conditions: 0.05 U

Flow Capability:
Prime rate: 0.05 units per second.
Basal: Programmable by the user in 0.05 U increments up to 30.0 U per hour
Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

Delivery accuracy (tested per IEC 60601-2-24):
Basal: ±5% at rates ≥0.05 U/hr
Bolus: ±5% for amounts ≥1.0 unit
±0.05 units for amounts <1.0 unit

Note: You should consider bolus dose accuracy when setting a bolus dose. When using the lowest bolus dose allowable (0.05 units), the actual bolus delivered may be as low as 0.00 units or as high as 0.10 units.

Accuracy test results: The following graph shows the flow accuracy of the Pod against given time periods. The measurements were made using a Pod with a basal rate of 0.5 µL/hr (which delivers 0.05 U/hr of U-100 insulin) at a high operating temperature. The overall mean percentage flow error was 1.40%.



Compatible Devices

The Omnipod 5 System is the first wearable, on-body, tubeless, automated insulin delivery system, when used with the Dexcom G6 Continuous Glucose Monitoring System, to continuously adapt and automatically deliver insulin according to your personal needs. The Omnipod 5 System consists of a tubeless insulin Pod and the Omnipod 5 App on an Insulet-provided Controller.

Quality of Service

The Omnipod 5 System includes two wireless transmission pathways. Insulet defines the quality of service of the Omnipod 5 System for each of the two pathways:

Omnipod 5 App to Pod wireless communication definition

Successful transfer of commands, data and alarms between the Controller and Pod when in the communication range (within 1.5 metres (5 ft) during normal operation). The Omnipod 5 App informs the user when transfer of commands, data and alarms is unsuccessful. For Insulin Delivery commands, the system performance requirements state that communication between the Pod and the Controller occur within 8 seconds at a reliability rate of 95%. The Omnipod 5 App will inform the user when there are communication errors between the Pod and the Controller. When such an error occurs, the Omnipod 5 App will beep once every 10 seconds and the communication failure will continue to be indicated within the Omnipod 5 App until the communication error is resolved.

Pod to Sensor wireless communication definition

The percentage of sensor glucose values successfully received by the Pod when the Sensor and Pod attempt to communicate every 5 minutes. The System performance requirements state that at least 80% of sensor glucose values will be successfully received by the Pod when the Sensor is worn within the line of sight of the Pod. The System informs the user of missing sensor glucose values in real time by the dashes on the home screen or by missed dots on the Sensor Graph.

For additional information on communication errors in the Omnipod 5 System, see Chapter 21 of the Technical User Guide. To maintain quality of service when other devices operating in the 2.4 GHz band are around, the Omnipod 5 System uses the coexistence features provided by Bluetooth wireless technology.

SmartBolus Calculator Inputs & Settings

The following table describes what each SmartBolus Calculator setting does, how you can adjust them, and how they are used to calculate a suggested bolus.

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Carbs (grams) 0.1 – 225 g (0.1 g increments)	Enter in SmartBolus Calculator	Increasing the carb amount value increases the amount of the suggested bolus dose. Decreasing the carb amount value decreases the amount of the suggested bolus dose.
Sensor Glucose Value (mg/dL) 40 – 400 mg/dL (1 mg/dL increments)	Select Use Sensor within SmartBolus Calculator (Value comes from your connected Sensor)	Increasing the Sensor Glucose Value increases the amount of the suggested bolus dose. Decreasing the Sensor Glucose Value decreases the amount of the suggested bolus dose.
Blood Glucose Reading (mg/dL) 20 – 600 mg/dL (1 mg/dL increments)	Enter in SmartBolus Calculator (Value comes from your blood glucose meter)	Increasing the BG Reading increases the amount of the suggested bolus dose. Decreasing the BG Reading decreases the amount of the suggested bolus dose.
Maximum Bolus 0.05 – 30 U (0.05 U increments)	Enter in Omnipod 5 App Settings or during First-Time Setup	Limits amount of single-bolus dose.
Extended Bolus (Manual Mode only) ON/OFF	Enter in Omnipod 5 App Settings or during First-Time Setup	Allows for bolus delivery over a user-selected period of time.

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Target Glucose & Correct Above Target Glucose: 110 – 150 mg/dL Correct Above: 10 – 200 mg/dL (10 mg/dL increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First-Time Setup	Increasing the setting value decreases the amount of the suggested bolus dose. Decreasing the setting value increases the amount of the suggested bolus dose.
Minimum Glucose for Calculations 50 – 70 mg/dL (1 mg/dL increments)	Enter in Omnipod 5 App Settings	Disables SmartBolus Calculator when glucose is at or below setting value.
Insulin to carb ratio 1 – 150 g (0.1 g increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First-Time Setup	Increasing the setting value decreases the amount of the suggested bolus dose. Decreasing the setting value increases the amount of the suggested bolus dose.
Correction Factor 1 – 400 mg/dL (1 mg/dL increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First-Time Setup	Increasing the setting value decreases the amount of the suggested bolus dose. Decreasing the setting value increases the amount of the suggested bolus dose.
Reverse Correction ON/OFF	Enter in Omnipod 5 App Settings	If "On", the suggested bolus is decreased when glucose is below the Target Glucose value.
Duration of insulin action 2 – 6 hours (0.5 hour increments)	Enter in Omnipod 5 App Settings or during First-Time Setup	Increasing the setting value may decrease the amount of the suggested bolus dose for longer periods.
Note: The Extended Bolus feature can only be used in Manual Mode. All other therapy settings are used similarly in both Manual and Automated Modes.		

Considerations about SmartBolus Calculator Recommendations

Keep the following in mind when using the SmartBolus Calculator and reviewing its recommendations:

- The SmartBolus Calculator uses your SmartBolus Calculator settings for the time when you are requesting a bolus.
- The SmartBolus Calculator refreshes values every 5 minutes. If you do not start your bolus within 5 minutes of entering the SmartBolus Calculator, the Omnipod 5 System will need to clear the screen so that it has the latest IOB and Sensor information. When changing time zones, always check your IC Ratio and Correction Factor settings for the new time to ensure it still meets your body's true insulin needs.

- The SmartBolus Calculator will suggest doses depending on the carbs you enter and the glucose value at that time. Check the nutritional content of your meals to ensure the carbs entered is as accurate as possible. Only enter BG readings that have been obtained with the last 10 minutes or use Sensor. These factors will make sure that the SmartBolus Calculator suggests a bolus dose that is suitable for you.

If your Sensor Glucose Value or trend does not match your symptoms or expectations, use a fingerstick blood glucose reading in the SmartBolus Calculator.

When programming and delivering boluses, always confirm that the values you enter and the suggested bolus dose you receive are what you intend and align with what you want at that time.

The Omnipod 5 System has features that help with preventing unintended delivery amounts.

Delivery Limitations	Description
Maximum Bolus Setting	The SmartBolus Calculator will not deliver boluses that exceed the Maximum Bolus Setting you entered (0.05 -30 U). For example, if you rarely deliver more than 5 U boluses, and you set the Maximum Bolus Setting at 5 U, the system will prevent you from delivering anything greater than this amount.
Blood Glucose Reading Time Out	The SmartBolus Calculator will not calculate a suggested bolus dose using a blood glucose reading you entered from the Main Menu (☰) that is older than 10 minutes. You will need to enter a more recent blood glucose reading within the SmartBolus Calculator.
SmartBolus Calculator Time Out	The SmartBolus Calculator considers the values you input for a given bolus calculation, valid for up to 5 minutes from initial entry of the value into the SmartBolus Calculator. If 5 minutes or more have elapsed, you will be notified that you must refresh the SmartBolus Calculator and input the values again.
Time Zones	The SmartBolus Calculator relies on accurate, updated insulin delivery history and data logging from your Omnipod 5 System. If a time zone change is detected by the Controller, the system will notify you. Update time zones on your Omnipod 5 App according to your healthcare provider's guidance.

Factors Used in the SmartBolus Calculator Calculations

The SmartBolus Calculator accounts for the following when it calculates a bolus:

- Your current glucose (manually entered or from the Sensor), sensor glucose trend (if sensor glucose value is used), Target Glucose, Correct Above threshold and Correction Factor.
- The carbs you are about to eat or drink and your IC Ratio.
- Your Duration of Insulin Action and insulin on board (IOB).
- Minimum Glucose for Calculations.

Performance Characteristics

The Summary of Safety and Clinical Performance (SSCP) is available at www.omnipod.com/sscp. The SSCP is also available in the European Database on Medical Devices (EUDAMED) website (https://ec.europa.eu/tools/eudamed), where it is linked to the Basic UDI-DI. The Basic UDI-DI for Omnipod 5 is 0385083000145W.

Bolus Delivery Performance Specifications

Bolus size: 0.05-30 U in 0.05 U increments

Delivery performance characterisation

To assess bolus delivery accuracy, 12 Pods were tested by delivering a minimum, intermediate and maximum bolus amount (0.05, 5.00 and 30.0 Units).

The following table summarises the typical bolus performance observed for the requested minimum-, intermediate- and maximum-size bolus for all pumps tested. For each individual target bolus size, the number of boluses observed is shown along with the average (mean), minimum and maximum units delivered as measured by a scale.

Individual Bolus Accuracy Performance	Target Bolus Size (Units)	Mean Bolus Size (Units)	Min Bolus Size (Units)	Max Bolus Size (Units)
Min Bolus Delivery Performance (n=5987 boluses)	0.05 U	0.050 U	0.00 U	0.119 U
Intermediate Bolus Delivery Performance (n=300 boluses)	5.00 U	5.01 U	4.49 U	5.37 U
Max Bolus Delivery Performance (n=72 boluses)	30.00 U	30.05 U	29.56 U	30.62 U

The tables that follow show, for each requested bolus size, the range of amount of insulin that was observed to have been delivered compared with the requested amount. Each table provides the number and percentage of delivered bolus sizes observed within the specified range.

Amount of Insulin Delivery for a Minimum (0.05 U) Bolus Request					
Amount (Units)	<0.0125	0.0125-0.0375	0.0375-0.045	0.045-0.0475	0.0475-0.0525
(% of settings)	(<25%)	(25-75%)	(75-90%)	(90-95%)	(95-105%)
Number and percentage of boluses within range	61/5987 (1%)	639/5987 (10.7%)	1284/5987 (21.4%)	504/5987 (8.4%)	1100/5987 (18.4%)
Amount (Units)	0.0525-0.055	0.055-0.0625	0.0625-0.0875	0.0875-0.125	>0.125
(% of settings)	(105-110%)	(110-125%)	(125-175%)	(175-250%)	(>250%)
Number and percentage of boluses within range	504/5987 (8.4%)	1192/5987 (19.9%)	582/5987 (9.7%)	121/5987 (2%)	0/5987 (0%)

Amount of Insulin Delivery for an Intermediate (5.00 U) Bolus Request					
Amount (Units)	<1.25	1.25-3.75	3.75-4.50	4.50-4.75	4.75-5.25
(% of settings)	(<25%)	(25-75%)	(75-90%)	(90-95%)	(95-105%)
Number and percentage of boluses within range	0/300 (0%)	0/300 (0%)	1/300 (0.3%)	4/300 (1.3%)	287/300 (95.7%)
Amount (Units)	5.25-5.50	5.50-6.25	6.25-8.75	8.75-12.50	>12.50
(% of settings)	(105-110%)	(110-125%)	(125-175%)	(175-250%)	(>250%)
Number and percentage of boluses within range	8/300 (2.7%)	0/300 (0%)	0/300 (0%)	0/300 (0%)	0/300 (0%)

Amount of Insulin Delivery for a Minimum (30.0 U) Bolus Request					
Amount (Units) (% of settings)	<7.5 (<25%)	7.5-22.5 (25-75%)	22.5-27.0 (75-90%)	27.0-28.5 (90-95%)	28.5-31.5 (95-105%)
Number and percentage of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	72/72 (100%)
Amount (Units) (% of settings)	31.5-33.0 (105-110%)	33.0-37.5 (110-125%)	37.5-52.5 (125-175%)	52.5-75.0 (175-250%)	>75.0 (>250%)
Number and percentage of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)

Basal Delivery Specifications

Basal rate: Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.

Maximum Basal Rate: Select one value between 0.05 and 30 U/hr in 0.05 U/hr increments. Default is 3.00 U/hr.

Delivery performance characterisation

To assess basal delivery accuracy, 12 Pods were tested by delivering at low, medium and high basal rates (0.05, 1.00 and 30.0 U/hr).

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium and high basal rate settings for all pumps tested, with no warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.05 U/hr)			
Basal Duration (Number of units requested)	1 hour (0.05 U)	6 hours (0.30 U)	12 hours (0.60 U)
Amount Delivered	0.049 U	0.30 U	0.59 U
[min, max]	[0.00, 0.12]	[0.13, 0.57]	[0.34, 0.99]
Medium Basal Rate Delivery Performance (1.00 U/hr)			
Basal Duration (Number of units requested)	1 hour (1.00 U)	6 hours (6.00 U)	12 hours (12.00 U)
Amount Delivered	0.99 U	5.97 U	11.88 U
[min, max]	[0.65, 1.55]	[5.06, 6.87]	[10.53, 13.26]

High Basal Rate Delivery Performance (30.00 U/hr)		
Basal Duration (Number of units requested)	1 hour (30.00 U)	6 hours (180.00 U)
Amount Delivered	29.82 U	179.33 U
[min, max]	[28.85, 31.39]	[177.49, 181.15]

Note: A measurement at the 12-hour period with a 30.0 U/hr basal rate is not applicable to the Omnipod 5 System as the reservoir will empty at approximately 6 ⅔ hours at this rate.

Blockage (Occlusion) Detection

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin, which can lead to hyperglycaemia or diabetic ketoacidosis (DKA).

Caution: ALWAYS check your glucose frequently when you use very low basal rates. Checking your glucose frequently can alert you to the presence of a blockage (occlusion). Blockages can result in hyperglycaemia.

A blockage (occlusion) is an interruption in insulin delivery from the Pod. If the Omnipod 5 System detects a blockage, it sounds a hazard alarm and prompts you to deactivate and change your Pod.

A blockage hazard alarm sounds when an average of 3 units to 5 units of missed insulin occurs. The following table depicts blockage detection for three different situations when using U-100 insulin. For example, if the Pod's cannula becomes blocked when delivering a 5 U bolus, 35 minutes may pass before the Pod sounds a hazard alarm.

	Time between blockage and Pod alarm	
	Typical time	Maximum time
5.00 U bolus	33 minutes	35 minutes
1.00 U/hr basal	3.0 hr	5.5 hr
0.05 U/hr basal	51 hr	80 hr (Pod expiry)

If a blockage spontaneously clears up, a volume of insulin could be released. That volume would not exceed the volume of the programmed insulin intended for delivery.

If your Omnipod 5 System detects a potential blockage to your insulin delivery, it will set a blockage alarm to sound. If a blockage alarm is set to sound while an immediate bolus is in progress, the alarm is delayed until completion of the bolus.

Omnipod 5 System Label Symbols

The following symbols appear on the Omnipod 5 System or its packaging:

Symbol	Meaning
	Single-use only
	Consult the accompanying documents
STERILE EO	Sterilised using ethylene oxide
	Date of manufacture
LOT	Batch code
	Use-by date
REF	Reference number
SN	Serial number
IP28	Protects persons against accessing hazardous parts with fingers and protects against the ingress of solid foreign object of 12.5 mm in diameter or greater; Submersible: Waterproof to 7.6 metres (25 ft) for up to 60 minutes
	Pod

Symbol	Meaning
	MR unsafe
	Do not use if the package is damaged
	Type BF applied part
	Manufacturer
	Keep dry
	Storage temperature, Operational temperature
	Storage relative humidity, Operational relative humidity
	Storage atmospheric pressure, Operational atmospheric pressure
IP22	Protects persons against accessing hazardous parts with fingers and protects against the ingress of solid foreign object of 12.5 mm in diameter or greater; avoid liquid
	Charging cable

Symbol	Meaning
	Non-pyrogenic fluid path
	Do not dispose of with household waste
CE	Marking of conformity
CH REP	Switzerland Authorised Representative

Symbol	Meaning
MD	Medical Device
RoHS	RoHS-compliant
EC REP	Representative in the European Community
	Product is intended for recycling and should not be placed in the normal bin

10 Staying Safe while Using the Omnipod 5 System

General Warnings

Warning: Read all the instructions provided in the Instructions for Use before using the Omnipod 5 System. Monitor your glucose with the guidance of your healthcare provider. Undetected hyperglycaemia or hypoglycaemia can develop without proper monitoring.

Warning: DO NOT start to use your system or change your settings without adequate training and guidance from your healthcare provider. Initiating and adjusting settings incorrectly can result in over-delivery or under-delivery of insulin, which could lead to hypoglycaemia or hyperglycaemia. Settings that impact insulin delivery mainly include: Pod Shut-Off, basal rate(s), Max Basal Rate, Max Bolus, Correction Factor(s), Insulin to Carb (IC) Ratio(s), Minimum Glucose for Calculations, Target Glucose and Correct Above, and Duration of Insulin Action.

Warning: DO NOT rely upon the Instructions for Use in any way in connection with your personal healthcare, related decisions and treatment. The Instructions for Use are informational only and not intended as medical or healthcare advice, or recommendations to be used for diagnosis, treatment or any other individual needs. The Instructions for Use are not a substitute for medical or healthcare advice, recommendations and/or services from a qualified healthcare provider. All such decisions and treatment should be discussed with a qualified healthcare provider who is familiar with your individual needs.

Warning: DO NOT use the Omnipod 5 System if you are unable or unwilling to use it as instructed by the Instructions for Use and your healthcare provider. Failure to use this system as intended could result in over-delivery or under-delivery of insulin, which can lead to hypoglycaemia or hyperglycaemia.

Warning: ALWAYS keep an emergency kit with you to quickly respond to any diabetes emergency or in the case that your Omnipod 5 System stops working. Always carry supplies to perform a Pod change in case you need to replace your Pod at any time.

Warning: DO NOT use the Omnipod 5 System if you do not have adequate vision and/or hearing to recognise all functions of the Omnipod 5 System, including alerts, alarms and reminders, according to the instructions.

Warning: DO NOT use the Omnipod 5 System at low atmospheric pressure (below 700 hPA). You could encounter such low atmospheric pressures at high elevations, such as when mountain climbing or living at elevations above 3,000 metres (10,000 feet). Change in atmospheric pressure can also occur during take-off with air travel. Unintended insulin delivery can occur if there is expansion of tiny air bubbles that may exist inside the Pod. This can result in hypoglycaemia. It is important to check your glucose frequently when flying to avoid prolonged hypoglycaemia.

Warning: DO NOT use the Omnipod 5 System in oxygen-rich environments (greater than 25% oxygen), which include home or surgical areas that use supplementary oxygen and hyperbaric chambers. Hyperbaric, or high-pressure, chambers are sometimes used to promote healing of diabetic ulcers or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to oxygen-rich environments could result in combustion of the Pod or Omnipod 5 Controller, which can cause severe burns to the body.

Warning: DO NOT use the Omnipod 5 System in high-atmospheric-pressure environments (above 1060 hPA), which can be found in a hyperbaric chamber. Hyperbaric, or high-pressure, chambers are sometimes used to promote healing of diabetic ulcers or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to high-atmospheric-pressure environments can damage your Pod and Omnipod 5 Controller, which could result in under-delivery of insulin, which can lead to hyperglycaemia.

Warning: Device components including the Pod, Dexcom G6 Sensor and Transmitter may be affected by strong radiation or magnetic fields. Device components must be removed (and the Pod and Sensor should be disposed of) before X-ray, Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) scan (or any similar test or procedure). In addition, the Controller should be placed outside of the procedure room. Exposure to X-ray, MRI or CT treatment can damage these components. Check with your healthcare provider on Pod removal guidelines.

Warning: DO NOT expose any Omnipod 5 System products or supplies to extreme temperatures, as this results in them not functioning properly. Store all Omnipod 5 System products and supplies, including unopened Pods, in a cool, dry place.

Insulin Warnings

Warning: ONLY use rapid-acting U-100 NovoLog® (insulin aspart), Humalog® (insulin lispro) and Admelog® / Insulin lispro Sanofi® (insulin lispro) insulin in the Omnipod 5 System, as they have been tested and found to be safe for use with this system. NovoLog, Humalog and Admelog / Insulin lispro Sanofi are compatible with the Omnipod 5 System for use up to 72 hours (3 days). Follow your healthcare provider's directions for how often to replace the Pod.

Warning: AVOID administering insulin, such as by injection or inhalation, while wearing an active Pod, as this could result in hypoglycaemia. The Omnipod 5 System cannot track insulin that is administered outside of the system. Consult your healthcare provider about how long to wait after manually administering insulin before you start Automated Mode.

Warning: ALWAYS be prepared to inject insulin with an alternative method if insulin delivery from the Pod is interrupted. You are at increased risk for developing hyperglycaemia if insulin delivery is interrupted because the Pod only uses rapid-acting U-100 insulin. Failure to have an alternative method of insulin delivery can lead to very high glucose or diabetic ketoacidosis (DKA). Ask your healthcare provider for instructions for handling interrupted insulin delivery.

Warning: NEVER use insulin that is expired or cloudy in the Pod, as it may be damaged. Using damaged or expired insulin could cause hyperglycaemia and put your health at risk.

Glucose Warnings

Warning: ALWAYS follow your healthcare provider's guidance on appropriate glucose monitoring to avoid hyperglycaemia and hypoglycaemia.

Warning: Glucose below 70 mg/dL may indicate hypoglycaemia (low glucose). Glucose above 250 mg/dL may indicate hyperglycaemia (high glucose). Follow your healthcare provider's suggestions for treatment.

Warning: ALWAYS promptly treat hypoglycaemia. Glucose at or below 55 mg/dL indicates significant hypoglycaemia (very low glucose). If left untreated, this could lead to seizure, loss of consciousness or death. Follow your healthcare provider's recommendations for treatment.

Warning: ALWAYS promptly treat glucose below 70 mg/dL (hypoglycaemia) according to your healthcare provider's recommendations. Symptoms of hypoglycaemia include weakness, sweating, nervousness, headache or confusion. If left untreated, hypoglycaemia can lead to seizure, loss of consciousness or death.

Warning: DO NOT wait to treat hypoglycaemia (low glucose) or symptoms of hypoglycaemia. Even if you cannot check your glucose, waiting to treat symptoms could lead to severe hypoglycaemia, which can lead to seizure, loss of consciousness or death.

Warning: ALWAYS promptly treat hyperglycaemia (high glucose) according to your healthcare provider's recommendations. Symptoms of hyperglycaemia include fatigue, thirst, excess urination or blurry vision. If left untreated, hyperglycaemia can lead to diabetic ketoacidosis (DKA) or death.

Warning: DO NOT wait to treat DKA. If left untreated, DKA can quickly lead to breathing difficulties, shock, coma or death.

Warning: ALWAYS treat "LOW" or "HIGH" sensor glucose values and "LOW" or "HIGH" blood glucose readings according to your healthcare provider's recommendations. These values can indicate potentially serious conditions requiring immediate medical attention. If left untreated, these situations can quickly lead to diabetic ketoacidosis (DKA), shock, coma or death.

Warning: NEVER drive yourself to the emergency department if you need emergency medical care. Ask a friend or family member to take you to the emergency department or call an ambulance.

Warning: ALWAYS be aware of your current sensor glucose value, trust how your body feels and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode, with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycaemia or hyperglycaemia may still occur.

If your sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter and consider treatment and/or Sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate sensor glucose values.

* Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycaemia, seizure, loss of consciousness or death.
* Erroneously low sensor glucose values can cause prolonged insulin suspension, leading to hyperglycaemia, DKA or death.

If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in the Instructions for Use, contact your healthcare provider.

Pod Warnings

Warning: ALWAYS dispose of the Pod according to local waste disposal guidelines. The Pod is considered biohazardous after use and can potentially transmit infectious diseases.

Warning: DO NOT use a Pod if you are sensitive to or have allergies to acrylic adhesives, or have fragile or easily damaged skin. Applying a Pod under these circumstances could put your health at risk.

Warning: DO NOT allow small children access to small parts, such as the Pod and its accessories, including the tab. Small parts could be swallowed and pose a choking hazard. If ingested or swallowed, these small parts could cause internal injury or infection.

Warning: NEVER inject large bubbles or pockets of air when filling the Pod with insulin. Air in the system takes up space where insulin should be and can affect insulin delivery. Doing so could result in over-delivery or under-delivery of insulin, which can lead to hypoglycaemia or hyperglycaemia.

Warning: NEVER use a Pod if, while you are filling the Pod, you feel significant resistance while pressing down the plunger on the fill syringe. Do not try to force the insulin into the Pod. Significant resistance may indicate that the Pod has a mechanical defect. Using this Pod could result in under-delivery of insulin, which can lead to hyperglycaemia.

Warning: DO NOT apply a Pod if you see the cannula is extended beyond the adhesive backing after the tab on the Pod is removed. This cannula cannot be inserted, resulting in under-delivery of insulin, which could lead to hyperglycaemia.

Warning: ALWAYS check the infusion site often to make sure the cannula is properly inserted and secured to the Pod. Verify that there is no wetness or scent of insulin, which may indicate that the cannula has been dislodged. An improperly inserted, loose or dislodged cannula could result in under-delivery of insulin, which can lead to hyperglycaemia.

Warning: NEVER inject insulin (or anything else) into the fill port while the Pod is on your body. Attempting to do so may result in the over-delivery or under-delivery of insulin, which could lead to hypoglycaemia or hyperglycaemia.

Warning: DO NOT apply a new Pod until you have deactivated and removed the old Pod. A Pod that is not deactivated properly can continue to deliver insulin as programmed, putting you at risk of over-delivery of insulin, which can lead to hypoglycaemia.

Warning: DO NOT continue using an activated Pod that fails to beep during a diagnostic test. The Pod should be changed immediately. If the Omnipod 5 App fails to beep during a diagnostic test, call Customer Care immediately. Continuing to use the Omnipod 5 System in these situations may put your health and safety at risk.

Warning: DO NOT expose a Pod to direct sunlight for long periods of time. Remove your Pod prior to using hot tubs, whirlpools or saunas. These conditions could expose the Pod to extreme temperatures and may also affect the insulin inside the Pod, which could lead to hyperglycaemia.

Warning: Do NOT expose your Pod to water at depths greater than 7.6 metres (25 ft) or for longer than 60 minutes because damage to the Pod can occur. This could result in over-delivery or under-delivery of insulin, which can lead to hypoglycaemia or hyperglycaemia.

Controller Warnings

Warning: ALWAYS identify the Omnipod 5 App as yours before using it. Using someone else's Omnipod 5 App can result in incorrect insulin delivery for both of you.

Warning: ALWAYS keep your Omnipod 5 App secure and within your control to ensure that others cannot make changes to your insulin therapy, which can lead to hypoglycaemia or hyperglycaemia. Do not share your Controller PIN with anyone.

Warning: ALWAYS contact Customer Care if your Omnipod 5 System Controller is damaged and not working properly. If a Controller replacement is needed, ALWAYS consult with your healthcare provider to get instructions on using other backup insulin delivery methods, like insulin injections. Make sure to check your glucose frequently.

Warning: You will NOT be able to use the Omnipod 5 App if:

* You have not installed a required update to the Omnipod 5 App
* An update for the Omnipod 5 App is not yet available to fix a known issue

Use a different insulin delivery method. Failure to deactivate your Pod and use another form of insulin delivery could result in over-delivery or under-delivery of insulin. This can lead to hypoglycaemia or hyperglycaemia.

Alarm Warnings

Warning: ALWAYS respond to Hazard Alarms as soon as they occur. Pod Hazard Alarms indicate that insulin delivery has stopped. Failure to respond to a Hazard Alarm could result in under-delivery of insulin, which can lead to hyperglycaemia.

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin, which can lead to hyperglycaemia or diabetic ketoacidosis (DKA)

Warning: You must use the Omnipod 5 App within 15 minutes of the onset of the Pod Shut-Off advisory alarm. If you do not respond to this alarm within this time, the Omnipod 5 App and Pod sound a hazard alarm and your Pod stops delivering insulin, which can lead to hyperglycaemia.

Sensor Warnings

Warning: ALWAYS make sure you are using the Sensor per manufacturer's instructions. Do not extend the sensor wear beyond the recommended duration and do not start a Sensor past its Use-By date. The Omnipod 5 System relies on accurate, current sensor glucose values to determine your insulin needs. Incorrect use of the Sensor could result in over-delivery or under-delivery of insulin, which could lead to hypoglycaemia or hyperglycaemia.

Warning: Do NOT use the Omnipod 5 System if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anaemia. Your Dexcom G6 readings could be falsely elevated and could result in over-delivery of insulin, which can lead to severe hypoglycaemia.

Warning: ALWAYS confirm that the Dexcom G6 Transmitter serial number (SN) you save in the Omnipod 5 App matches the one you are wearing. In cases where more than one person in the household uses the Dexcom G6, mismatching Transmitter serial numbers (SN) could result in over-delivery or under-delivery of insulin, which can lead to hypoglycaemia and hyperglycaemia.

SmartBolus Calculator Warnings

Warning: AVOID changing your SmartBolus Calculator settings before consulting your healthcare provider. Incorrect changes could result in over-delivery or under-delivery of insulin, which can lead to hypoglycaemia or hyperglycaemia. Settings that impact bolus calculations mainly include: Max Bolus, Minimum Glucose for Calculations, Correct Above, Correction Factor(s), Insulin to Carb (IC) ratio(s), Duration of Insulin Action and Target Glucose.

Warning: ALWAYS check your glucose frequently when you use the extended bolus function to avoid hypoglycaemia or hyperglycaemia.

Warning: AVOID entering a blood glucose reading that is older than 10 minutes. If you use a reading older than 10 minutes, the bolus calculator could calculate and recommend an incorrect dose, which could result in over-delivery or under-delivery of insulin. This can lead to hypoglycaemia or hyperglycaemia.

SmartAdjust Technology Warnings

Warning: DO NOT use SmartAdjust technology in pregnant women, critically ill patients and those on dialysis. The safety of SmartAdjust technology has not been evaluated in these populations. Talk to your healthcare provider if any of these conditions apply to you before using SmartAdjust technology.

Warning: SmartAdjust technology should NOT be used by anyone under the age of 2 years old. SmartAdjust technology should also NOT be used in people who require less than 5 units of insulin per day, as the safety of the technology has not been evaluated in this population.

Warning: ALWAYS monitor for symptoms of hypoglycaemia while the Activity feature is enabled. Hypoglycaemia can still occur when using the Activity feature. Follow your healthcare provider's advice on hypoglycaemia avoidance and treatment. If untreated, hypoglycaemia can lead to seizure, loss of consciousness or death.

General Precautions

Caution: Federal (US) law restricts this device to sale by or on the order of a doctor.

Caution: DO NOT use any component of the Omnipod 5 System (Controller, Pod) if you suspect damage after an unexpected event such as dropping or hitting on a hard surface. Using damaged components may put your health at risk as the system may not be working properly. If you are unsure if one or more of your components are damaged, stop using the system and call Customer Care for support.

Caution: ONLY use the Omnipod 5 System with authorised devices (Omnipod 5 App, Controller and Pod, and Dexcom G6). DO NOT attempt to use the Omnipod 5 System with unauthorised devices. Attempting to use the Omnipod 5 System with unauthorised devices could interrupt your insulin delivery and put your health and safety at risk.

Caution: ALWAYS be aware of possible changes to your time zone when travelling. If you do not update your time zone, your insulin therapy will be delivered based on your old time zone, which may cause disruptions in your insulin delivery schedule and inaccurate history logs. Talk to your healthcare provider about how to manage your insulin delivery while travelling between time zones.

Caution: ALWAYS check your glucose frequently during amusement park rides and flying, or other situations where sudden changes or extremes of air pressure, altitude or gravity may be occurring. Though the Omnipod 5 System is safe to use at atmospheric pressures typically found in aeroplane cabins during flight, the atmospheric pressure in an aeroplane cabin can change during flight, which may affect the Pod's insulin delivery. Rapid changes in altitude and gravity, such as those typically found on amusement park rides or flight take-off and landing, can affect insulin delivery, leading to possible hypoglycaemia or injury. If needed, follow your healthcare provider's treatment instructions.

Caution: NEVER use a hairdryer or hot air to dry the Controller or Pod. Extreme heat can damage the electronics.

Caution: ALWAYS check your glucose frequently when you use very low basal rates. Checking your glucose frequently can alert you to the presence of a blockage (occlusion). Blockages can result in hyperglycaemia.

Caution: ALWAYS tap START INSULIN to start insulin delivery after a pause period has ended during Manual Mode use. Insulin delivery does not automatically start after a pause. If you do not start insulin delivery, you could develop hyperglycaemia.

Caution: AVOID storing Omnipod 5 System components and supplies in a place where children, pets or pests may access. Unintended access could result in damage to system parts or impact their sterility.

Caution: DO NOT use a Pod if the sterile packaging is open or damaged, the Pod has been dropped after removal from the package, or the Pod is expired, as the Pod may not work properly and increase your risk of infection.

Caution: ALWAYS check your glucose prior to delivering a bolus so you are better informed on how much to take. Delivering a bolus without checking your glucose could result in over-delivery or under-delivery of insulin, which can lead to hypoglycaemia or hyperglycaemia.

Caution: DO NOT make changes or modifications to any component of the Omnipod 5 System that have not been authorised by Insulet Corporation. Unauthorised tampering with the System can revoke your right to operate it.

Caution: When there is no communication between the Pod and the Controller, the Pod continues delivering insulin according to settings active on the Pod before losing communication. For example, automated insulin delivery from the Pod will continue in Automated Mode. Restoring communication is needed to see your system status and notifications, and to send new instructions to the Pod. To restore communication, try bringing the Controller within 1.5 metres (5 ft) of the Pod.

Caution: DO NOT use portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Omnipod 5 System, as it may impact the communication between your Controller and your Pod.

Controller Precautions

Caution: Connect ONLY to trusted Wi-Fi networks with your Controller. AVOID connecting to public Wi-Fi networks, such as those found in airports, coffee shops, etc, as these networks are not secure and could result in exposing your Controller to malware. DO NOT connect to public Wi-Fi networks during first-time setup of your Omnipod 5 System.

Caution: ALWAYS keep your Controller safe and within your control to ensure others cannot make changes to your insulin therapy. Do not share your Controller PIN with anyone.

Caution: ALWAYS make sure your battery has adequate charge prior to installing a software update.

Caution: DO NOT reset the Omnipod 5 App before checking with your healthcare provider. This will erase all of your settings, Adaptive Basal Rate and history, and require you to change your active Pod. Before resetting, make sure you have a current record of your settings and a new Pod with supplies to use when restarting the app.

Controller-specific Precautions

Caution: AVOID turning Automatic Time Zone OFF on the Controller. If you turn Automatic Time Zone OFF, your Controller will not be able to detect when your device time zone and insulin delivery time zone do not match. Delivering insulin based on a different time zone than your local time may cause errors in insulin delivery and data logging, which can lead to hypoglycaemia or hyperglycaemia.

Caution: ALWAYS plug in and charge your Controller when you see the low-battery message. If the battery charge becomes critically low, the Controller turns itself off and you will not receive a low-battery hazard alarm. Without the use of the Controller, you will not be able to make changes to your insulin delivery, which could result in the over-delivery or under-delivery of insulin, which can lead to hypoglycaemia or hyperglycaemia.

Caution: DO NOT expose your Controller battery to high heat [>30°C (86°F) during storage and >40°C (104°F) during use]. Do not puncture, crush or apply pressure to your battery. Failure to follow these instructions could result in an explosion, fire, electric shock, damage to the Controller or battery or battery leakage.

Caution: DO NOT expose your Controller to extreme temperatures while in storage or during use. Extreme heat or cold can cause the Controller to malfunction. Extreme heat is defined as >30°C (86°F) during storage and >40°C (104°F) during use. Extreme cold is defined as <0°C (32°F) during storage and <5°C (41°F) during use.

Caution: Use ONLY the USB charging cable that you received in the box with your Controller. AVOID using alternative charging cables or other accessories, as they may damage the Controller or affect the way it charges in the future. If you must use a different cable, use only cables less than or equal to 1.2 metres (4 ft) in length.

Caution: DO NOT place the Controller in or near water because the Controller is not waterproof. Failure to do so could result in damage to the Controller.

Caution: DO NOT use solvents to clean your Controller. DO NOT immerse your Controller in water as it is not waterproof. The use of solvents or immersion in water could result in damage to the Controller.

Caution: DO NOT allow debris or liquid to get into the USB port, speaker, sound/vibrate button or Power button while cleaning the Controller. Failure to do so could result in damage to the Controller.

Caution: ONLY press the Power button on the Controller for less than 1 second or you may accidentally turn the power off. If the Controller displays a message asking if you would like to "Power Off", tap outside the message to cancel the message. If you accidentally power off your Controller, you can miss important notifications and alarms from the Omnipod 5 App. If you do not hear alarms and notifications from your Controller, you might not make the changes you need to make to your insulin therapy in a timely manner. The Pod will alarm regardless of whether the state of the Controller is On or Off.

Caution: Do not use the Controller if it appears damaged or is not working as it should. Do not use the Controller if its screen is broken.

Pod Precautions

Caution: ALWAYS activate a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin, which can lead to hyperglycaemia. If another Pod is not available, use a different insulin delivery method.

Caution: ALWAYS insert the fill syringe into the fill port and not into any other location on the Pod. Do not insert the fill syringe more than once into the fill port. Use only the fill syringe and needle that came with your Pod. The fill syringe is intended for single-use only and should only be used with the Omnipod 5 System. Failure to follow the instructions above may result in damage to your Pod.

Caution: NEVER reuse the Pod or fill syringe or try to use a fill syringe that did not come with your Pod. Always dispose of the used Pod and fill syringe according to local disposal guidelines. Only use a new Pod with the fill syringe included with each Pod change. Always carry supplies to perform a Pod change in case you need to replace your Pod at any time.

Caution: ALWAYS follow these steps in preparing your site. If your site is not cleaned properly or if your hands are dirty, you increase your risk of infection.

* Wash your hands.
* Clean the top of the insulin vial with an alcohol prep swab.
* Clean your infusion site with soap and water or an alcohol prep swab, and let it dry completely.
* Keep sterile materials away from any possible contamination.

Caution: ALWAYS apply the Pod as directed. If you are applying a Pod in a place that does not have a lot of fatty tissue, squeeze the skin around the Pod until after the cannula has inserted. Blockages (occlusions) may result if you do not use this technique for lean areas.

Caution: ALWAYS rotate insulin infusion sites to help prevent infusion-site complications like scar tissue and infection. Rotating insulin infusion sites reduces the risk of scarring. Using a site with scar tissue can lead to problems with insulin absorption.

Caution: ALWAYS check for signs of infection often. If an infusion site shows signs of infection:

* Immediately remove the Pod and apply a new Pod at a different infusion site.
* Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.

If you see blood in your cannula, check your glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected high glucose, change your Pod.

Caution: Use caution while cleaning the Pod on your body. Hold the Pod securely so the cannula does not kink and the Pod does not detach from your skin.

Caution: DO NOT use strong detergents or solvents such as cleaning solutions, aerosol sunscreen or aerosol bug spray on your Pod. The use of such items can irritate the infusion site or damage the Pod.

Alarm Precautions

Caution: ALWAYS respond to Pod Expired, Low Pod Insulin and Pod Shut-Off Advisory Alarms when they occur. These alarms escalate to Hazard Alarms if no action is taken. When Hazard Alarms occur, insulin delivery stops.

Caution: AVOID leaving your Controller in a place that would prevent you from hearing alarms and notifications from your Omnipod 5 App. Delivery of insulin in Manual Mode or Automated Mode continues as programmed if you move away from your Controller.

Caution: Permanently silencing a Pod alarm requires the Pod to be removed from your body. Once removed and discarded, promptly activate a new Pod to avoid going too long without insulin, which could lead to hyperglycaemia. Caution: ALWAYS check the alarm function when you change the Pod if you suspect any issue with the Pod's sounds to ensure that you don't miss important alarms during use.

Caution: AVOID setting your Controller to Silent, Vibrate or any other setting that prevents you from hearing alarms and notifications from your Omnipod 5 App. If you do not hear alarms and notifications from your Controller, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able see the Alarm or Notification displayed on the Omnipod 5 App.

Sensor Precautions

Caution: You cannot use the Dexcom G6 receiver with the Omnipod 5 System because the Omnipod 5 System is compatible only with the G6 app on a smartphone.

Taking Care of Your Controller and Pod

Pod and Insulin Storage

Extreme heat or cold can damage Pods and cause them to malfunction.

It is especially important to store your insulin in a well-controlled environment. Inspect insulin before using it; never use insulin that looks cloudy or discoloured. Insulin that is cloudy or discoloured may be old, contaminated or inactive.

Check the insulin manufacturer's instructions for use and the insulin's expiry date.

Controller Storage and Care

When you are not using your Controller, store it in a convenient, nearby location that is cool and dry.

Long-term storage of your Controller

If you are not going to use your Controller for an extended period of time, allow your battery to reach approximately 50% to 60% charge. Then press and hold the Power button to turn the Controller OFF.

Controller Battery Care

The Controller provided uses a rechargeable lithium polymer battery. The battery cannot be removed from your Controller. If there is a problem with your battery or charger, contact Customer Care.

Safe Use of the Controller Battery

To safely use the rechargeable battery:

- Store and charge the Controller in a cool, dry place out of direct sunlight to prolong battery life. Avoid leaving the Controller in a car where temperature extremes can permanently damage the battery.
- Your Controller may become warm after prolonged use or when exposed to high temperatures. If your Controller becomes hot to the touch, unplug the USB cable if it is plugged in, and avoid touching or holding the Controller. Place it in a cool location and allow it to cool down to room temperature.
- Do not expose the charger to liquids, including water, rain or snow, as this can cause malfunction. If the battery or charger is exposed to liquid, allow it to dry.
- Do not place the Controller on or in heating devices, such as microwave ovens, stoves or radiators. The battery may explode if overheated.
- Do not drop the Controller.
- Only use an Insulet-approved charger to charge your Controller. Using unapproved chargers can cause the battery to explode or damage the Controller, and may void the warranty.

Device Complaints

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Contact details for the manufacturer can be found in the inside front cover of this document (see “Contacts and Important Information” on page i of the Technical User Guide). The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/health/md_sector/contact_en

If you have a problem with your System, contact Customer Care using the information on the provided Contact Card. You may be asked to share device data.

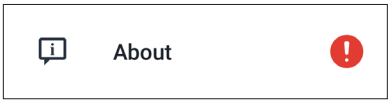
To share device data:

1. Ensure a working Wi-Fi connection.
2. Go to: Menu button (☰) > About
3. Tap Send files to Customer Care .
4. Enter the PIN provided by Customer Care.

If you see an exclamation mark (!) icon, alert your Customer Care representative. Navigate to the Home Screen to clear the (!) icon. If the icon persists, restart your controller.

If this occurs: Data upload is pending.

If this occurs: Data upload is full.



Emergency Kit Should Include:

- Several new, sealed Omnipod 5 Pods
- A vial of rapid-acting U-100 insulin
- Syringes or pens for injecting insulin
- Glucose tablets or another fast-acting source of carbohydrate
- Dexcom G6 Continuous Glucose Monitor (CGM) System and supplies
- Blood glucose meter and test strips
- Ketone test strips
- Lancing device and lancets
- Alcohol prep swabs
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod 5 System
- Phone numbers for your healthcare provider and/or doctor in case of an emergency
- Glucagon kit and written instructions for administering a glucagon dosage if you are unconscious

Always follow the Omnipod 5 System instructions. Failure to do so could result in under-delivery or over-delivery of insulin, which can lead to hypoglycaemia and hyperglycaemia.

Please refer to the *Omnipod 5 System Technical User Guide* for all instructions for use.

omnipod® 5

For More Information

Please refer to your Omnipod® 5 Automated Insulin Delivery System Technical User Guide

Visit us online at omnipod.com

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MD CE 2797

Controller Model: PDM-M001-G-MG

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