Omnipod® 5 Academy

Optimising of Care

omni**pod**
academy

connect & learn

Learning objectives

This module will enable learners to:

- Understand the Omnipod 5 Glooko data management system

- Understand the key insights of Omnipod 5 Glooko data

- Become familiar with the clinical considerations for Omnipod 5 optimisation and everyday use

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'Data management by individuals with diabetes and their providers is essential to understand the effectiveness of AID and impact of behavioural modifications, particularly with regard to meal bolusing and exercise'[1]

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'The use of AID systems is based on CGM data, and its success may be measured in improved CGM outcomes such as TIR... Clinicians can explain (to patients) how they interpret CGM data, including TIR, TAR, TBR, mean glucose, Glycemic Management Index (GMI) and glycemic variability'[2]

1. Sherr J., et al. Automated insulin delivery: benefits, challenges, and recommendations. A Consensus Report of the Joint Diabetes Technology Working Group of the European Association for the Study of Diabetes and the American Diabetes Association. Diabetologia 66 (3-22). 2023.
2. Philipp M, et al. Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice. Endocrine Reviews, 2022, 00, 1–27
Sha V.N. and Garg S.K. Standardized Hybrid Closed-Loop System Reporting. Diabetes Technology & Therapeutics.May 2021.323-331.

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Benefits of data management systems for PWDs and HCPs

PWD

Share data with the care team

View patterns and gain insight

Track glucose and insulin data

HCP

Modernize Workflow

Gain Insight

Can improve collaboration between PWD and HCP

PWD : Person with Diabetes
HCP: Healthcare Professional
https://glooko.com/providers/
https://glooko.com/patients/

Benefits of Glooko partnership

Streamline workflow
Upload insulin and glucose data to one platform

Improve Collaboration
HCPs and PWDs have access to the same graphs and reports

Gain insight to support optimising of care
Provide ability for Joint decision-making

https://glooko.com/providers/
https://glooko.com/patients/

Notes:

Glooko connectivity is different with Omnipod 5

Omnipod® and Omnipod DASH® Systems	Omnipod® 5 System
Upload data through wire connection	**One-time account linking during onboarding**

OR

PC or Mac Computer

Cloud-to-cloud communication open

Omnipod 5 Data Management

- **Eliminates in-clinic uploads**
  - One-time account linking during patient onboarding
  - Automatic data flow via Glooko® Proconnect Code

- **Supports remote and in-person care**
  - Wireless data uploads hourly*
  - Sim card and Wi-Fi

- **Actionable insights to support treatment decisions**
  - Combined CGM and insulin data
  - Quickly identify trends for personalized care

1. Must be connected to Wi-Fi or cellular data and Omnipod 5 users must have Wi-Fi or cellular data access to receive updates in Glooko.
Glooko is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

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Omnipod 5® Onboarding*

For optimal data management experience, this path should ideally be completed as one journey

*Omnipod 5 onboarding needs to occur prior to system first-time set-up on a computer or mobile phone

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Importance of PRO connect code

Getting started on Omnipod 5

Connecting to Glooko

Glooko is the Omnipod 5 data management platform that enables you to:-
- See your glucose and insulin data.
- Share your real-time data with your Healthcare Professional (HCP) to support informed system adjustments

✓ We recommend that you link your Omnipod ID to your Glooko account. If you do not have a Glooko account you can create one during setup.

✓ Ask your HCP for their clinic's ProConnect code to share your diabetes data.

ProConnect Code: _____

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Intended Interpretation Flow

- Designed to simplify data and draw focus to areas users can impact

- Design is meant to follow 1-2-3 method

- Weekly and Daily Report are only necessary if issues are found when reviewing Summary report

Summary Report	Weekly Report	Daily Report
Quickly identify positives and challenges	Drill down to identify causes of positives and/or challenges	Deeper understanding of specific causes

Graphs are for illustrative purposes only and created from US experience

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Summary Report:

Snapshot of **key statistics** and **aggregated information** to quickly identify positives and challenges to support patient care.

Broken down into two categories:
- **CGM Information**
- **Insulin Information**

Graphs are for illustrative purposes only and created from US experience

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Weekly Report:

Drill down into the weekly **chronological details** to identify causes and patterns.

Broken down into three categories:
- **CGM Information**
- **Insulin Information**
- **Additional Statistics**

Graphs are for illustrative purposes only and created from US experience

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Daily Report:

Deeper understanding of specific causes and details for every user and system action throughout a day.

Broken down into four categories:
- **CGM Information**
- **Insulin Information**
- **Additional Statistics**
- **Key/Legend**

Graphs are for illustrative purposes only and created from US experience

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Weekly and Daily Report Legend

Graphs are for illustrative purposes only and created from US experience

System (Omnipod 5)
- ⚡ Automated Mode
- ▣ Automated: Activity
- ▣ Automated: Limited
- ✦ Manual

Glucose
- ⦂⦂⦂ Before Meal Target Range (70-130 mg/dL)
- ▢ After Meal Target Range (70-180 mg/dL)
- ■ Above Range
- ■ In Target Range
- ■ Below Range

Types of Readings
- ● BG Readings
- ● Pump BG
- ◆ Calibrations
- ⋯ CGM Readings
- ⬆ Above 400 (Pump BG)
- ⬆ Above 400
- ■ Carbs
- ■ Exercise

Insulin Dose
- ▨ Bolus (Delivered)
- ▨ Bolus (Undelivered)
- ▢ Combo Bolus
- ▢ Extended Bolus
- ■ Basal
- ■ Premixed
- ■ Custom
- ■ Suspended
- ⇕ Override

Basal Delivery - Omnipod 5
- ▨ Automated Delivery
- ▨ Automated Max Delivery
- ■ Automated Pause

Basal
- Scheduled Basal Rate
- Temp Basal Rate
- Suspend
- LGS/PLGS
- Set/Site Change
- Resevoir Change
- Pump Alarm: Hazard
- Pump Alarm: Advisory

Devices (Settings) Report:

Basal Profile: Used in Manual Mode
- ▪ Max Basal Rate: Does not impact algorithm
- ▪ Temp Basal: Manual Mode feature

Bolus Settings:
- ▪ Insulin:Carb Ratio
- ▪ Sensitivity (Correction Factor)
- ▪ BG Target Range (Target Glucose)
- ▪ BG Correction Threshold (Correct Above): Only affects boluses
- ▪ Active Insulin Time: Only affects boluses
- ▪ Reverse Correction: Defaulted ON
- ▪ Extended Bolus: Manual Mode feature

Graphs are for illustrative purposes only and created from US experience

How to View Sensor Graph

History information on the Omnipod 5 App*

*The Omnipod 5 App is only available on the Insulet provided Controller at the time of launch

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Therapy Transition Considerations

- Set realistic expectations[1]
- Assessment: Ensure initial insulin settings are appropriate for the body weight, physiology, and clinical needs of the user
- Prior therapy for pivotal trial participants included Multiple Dose Insulin (MDI), Continuous Subcutaneous Inulin Infusion (CSII), and Automated Insulin Delivery (AID) devices
  - MDI: Base settings upon standard calculations for CSII
  - CSII: Evaluate basal/bolus distribution to determine if modifications are needed to current system's settings
  - AID: Programmed settings can differ from automated delivery, evaluate if current settings accurately represent automated insulin delivery
- Implement follow-up visits[2]

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1. Berget C, Sherr JL, DeSalvo DJ, Kingman RS, Stone SL, Brown SA, Nguyen A, Barrett L, Ly TT, Forlenza GP. Clinical Implementation of the Omnipod® 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People With Diabetes. Clinical Diabetes. Published online ahead of print, October 22, 2021.
2. Philipp M, et al. Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice. Endocrine Reviews, 2022, 00, 1–27

Therapy Transition Considerations: Follow-up visit

- Early clinical follow-up is recommended to reduce risk of treatment discontinuation
- Follow-up plans should include the following :
  - Assess system use and user trust in system
  - Reinforce appropriate expectations
  - assess whether any parameters (eg: Insulin Carbohydrate Ratio (ICR)*, Insulin Correction Factor (ICR), and glucose targets) should be altered to optimize time in range
  - Troubleshooting
- Content, timing and format should be personalised for each user
  - Timing: ideally within the first 2 to 4 weeks after device initiation
  - Format: phone calls with data review, videoconference or in-person visits

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*It is common for Insulin to carbohydrate (I:C ratios) to be strenghtened for Omnipod 5. Changes between basal and bolus insulin distribution are typical and may be expected.

1. Berget C, Sherr JL, DeSalvo DJ, Kingman RS, Stone SL, Brown SA, Nguyen A, Barrett L, Ly TT, Forlenza GP. Clinical Implementation of the Omnipod® 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People With Diabetes. Clinical Diabetes. Published online ahead of print, October 22, 2021.
2. Philipp M, et al. Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice. Endocrine Reviews, 2022, 00, 1–27

SmartAdjust™ Technology Adaptivity

Pod One
- **Assess** initial settings; basal ~40-50% of TDI[1]
- Uses the **active Basal Program** to *estimate* TDI and determine the initial Adaptive Basal Rate
- Automated max delivery more **restrained**[2]

Pod Two*
- Uses **insulin delivery history (basal + bolus)** to *calculate* TDI and updates the Adaptive Basal Rate
- Automated max delivery is no longer restrained; no greater than 4x the Adaptive Basal Rate

Ongoing Use
- Adaptive Basal Rate **updates** with each **Pod change** based upon user's **TDI** from previous Pods

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Tip: Important to **bolus** for carbs and corrections as needed to inform System of **TDI needs**

1 | 2 | 3

1. Berget C, Sherr JL, DeSalvo DJ, Kingman RS, Stone SL, Brown SA, Nguyen A, Barrett L, Ly TT, Forlenza GP. Clinical Implementation of the Omnipod Automated Insulin Delivery System: Key Considerations for Training and Onboarding People With Diabetes. Clinical Diabetes.
2. Forlenza GP, Buckingham BA, Brown SA, Bode BW, Levy CJ, Criego AB, Ly. First Outpatient Evaluation of a Tubeless Automated Insulin Delivery System with Customizable Glucose Targets in Children and Adults with Type 1 Diabetes. Diabetes Technol TheTT, et alr. 2021; 23(6):410-424.

Notes:

Omnipod® 5 System: Adjustable Settings

Automated Mode

Target Glucose is the **ONLY** setting that directly impacts Automated Mode:
- 110-150 mg/dL (6.1-8.3 mmol/L) in 10 mg/dL (0.55mmol/L) increments
- Up to 8 segments in 24hrs
- Target Glucose used for AID and correction boluses

SmartBolus Calculator Automated & Manual Mode

SmartBolus Calculator settings impact suggested **bolus** doses in **BOTH** modes:
- Target Glucose & Correct Above
- Insulin to Carb Ratio
- Correction Factor
- Duration of Insulin Action
- Reverse Correction
- Minimum Glucose for Calculations

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Notes:

SmartBolus Calculator

- Uses the user-programmed Insulin to **Carb Ratio, Correction Factor**, and **Duration of Insulin Action** for meal and manual correction boluses

- When using **sensor** value **also** uses the sensor rate of change (trend) to adjust the suggested bolus calculation

- **Correct Above Value** - The SmartBolus Calculator will only suggest a correction if the current glucose is above the Correct Above value

- **Reverse Correction** – reduces suggested bolus when the current glucose is below the Target Glucose value

- **Extended Bolus** available in Manual Mode only

- **Minimum Glucose** - Cannot give a bolus with the SmartBolus Calculator if the glucose is at or below the Minimum Glucose value

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Omnipod® 5 System: Focus on Select Adjustable Settings

- **Insulin to Carb Ratio**
  - May need to be made more aggressive if postprandial hyperglycemia observed

- **Correction Factor**
  - Only relevant for user-initiated boluses
  - Will not affect AID function
  - May need to be optimised if persistent hyperglycemia 1-3 hours after correction bolus

- **Active insulin time (duration of insulin action)**
  - User-directed boluses only , not used in the algorithm

- **Target Glucose** setting is a good way to adjust aggressiveness of the algorithm

Berget C, Sherr JL, DeSalvo DJ, Kingman R, Stone S, Brown SA, Nguyen A, Barrett L, Ly T, Forlenza GP. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People with Diabetes. Clin Diabetes. 2022;40(2):168-184.

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Optimization: Focus on Postprandial Hyperglycemia

- **Strengthen Insulin to Carb Ratio** to get more bolus insulin for meals

- **Pre-bolus 15-20 minutes prior to eating** (especially if insulin delivery is suspended leading up to bolus)

- Consider turning **Reverse Correction OFF** if glucose is often below Target Glucose at mealtimes followed by post-meal hyperglycemia

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Berget C, Sherr JL, DeSalvo DJ, Kingman R, Stone S, Brown SA, Nguyen A, Barrett L, Ly T, Forlenza GP. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People with Diabetes. Clin Diabetes. 2022;40(2):168-184.

Trouble Shooting Hyperglycaemia

Hyperglycaemia after meals:

- Strengthen I:C ratios by 10-25%
- Bolus 15-20 min before meal
- Turn OFF Reverse Correction
- Explore missed boluses & use of the bolus calculator

Hyperglycaemia unrelated to meals:

- Lower Target Glucose value
- Explore bolusing habits. Failure to bolus for meals and corrections leads to low TDI, which impacts adaptive basal rate
- Considering strengthening Correction Factor

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Berget C, Sherr JL, DeSalvo DJ, Kingman R, Stone S, Brown SA, Nguyen A, Barrett L, Ly T, Forlenza GP. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People with Diabetes. Clin Diabetes. 2022;40(2):168-184.

Troubleshooting: Hypoglycemia due to Overrides (1)

- User *overrides* correction bolus doses leading to hypoglycemia

- Automated insulin delivery increases dramatically to address hyperglycemia resulting in additional IOB

- Emphasize patience with hyperglycemia and follow SmartBolus Calculator recommendations

January 16th, 2023 - 10:00am

Correction	1.4 u
IOB	(2.4 u)
Suggested	1.4 u
Delivered	2 u

Berget C, Sherr JL, DeSalvo DJ, Kingman R, Stone S, Brown SA, Nguyen A, Barrett L, Ly T, Forlenza GP. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People with Diabetes. Clin Diabetes. 2022;40(2):168-184.

Notes:

Troubleshooting: Hypoglycemia due to Overrides (2)

- User *overrides* correction bolus doses leading to hypoglycemia

- Automated insulin delivery increases dramatically to address hyperglycemia resulting in additional IOB

- Emphasize patience with hyperglycemia and follow SmartBolus Calculator recommendations

October 3rd, 2022 - 4:23pm

IOB	(7.95 u)
Delivered	3 u

Berget C, Sherr JL, DeSalvo DJ, Kingman R, Stone S, Brown SA, Nguyen A, Barrett L, Ly T, Forlenza GP. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People with Diabetes. Clin Diabetes. 2022;40(2):168-184.

Notes:

Bolus Table allows for detailed assessment of Overrides

Daily Report

Boluses

Bolus Table only shows the first 10 bolus events for the day.

	1 1:05 a	2 10:58 a	3 4:15 p	4 4:56 p	5 5:58 p	6 8:03 p	7	8	9	10
Bolus Delivered	3	1.75	7	4	3	3.25	-	-	-	-
Suggested	1.8	1.75	10.95	0.55	0.65	3.25	-	-	-	-
MEAL	0	0	6.46	0	0	0	-	-	-	-
Correction	1.8	1.75	3.35	0.55	0.65	3.25	-	-	-	-
Insulin On Board	1.6	0.9	0	5.8	6.15	1.75				
Initial	-	-	-	-	-	-	-	-	-	-
Extended	-	-	-	-	-	-	-	-	-	-
Duration	-	-	-	-	-	-	-	-	-	-

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Trouble Shooting Hypoglycaemia

Hypoglycaemia after meals:

- Adjust Insulin to Carbohydrate Ratios if hypoglycaemia within 2 hours after a meal
- Assess if users have been overriding bolus calculator recommendations

Hypoglycaemia unrelated to meals:

- Adjust correction factor if hypoglycaemia after correction bolus
- Raise Target Glucose (e.g. during the night)
- Assess if hypoglycemia is related to exercise; consider using Activity Feature (start 1-2 hours prior to exercise)

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Berget C, Sherr JL, DeSalvo DJ, Kingman R, Stone S, Brown SA, Nguyen A, Barrett L, Ly T, Forlenza GP. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People with Diabetes. Clin Diabetes. 2022;40(2):168-184.

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Case Study 1

Move from Omnipod DASH® to Omnipod® 5

- Diagnosed as having type 1 diabetes for 1 year
- Omnipod DASH® + Dexcom G6® CGM
- A1c 7.1% (54 mmol/mol)
- Time In Range (TIR) 74%
- 10 boluses/day

Case Study 1: Week 1 on Omnipod 5

CGM Summary Report

- Time In Range 58%; Time Below Range 0%
- Patterns of postprandial hyperglycemia:
  - Lunch, dinner
  - Bedtime snack causing highs overnight
- 12 boluses/day, ~40% overrides, 38% bolus insulin

Glucose - Time In Range
- 11% Very High > 250 mg/dL
- 31% High 181-250 mg/dL
- 58% Target Range 70-180 mg/dL
- 0% Low 54-69 mg/dL
- 0% Very Low < 54 mg/dL

Summary
GMI N/A
Average 175 mg/dL
% Time CGM Active 100% (7 days)

SD 60 mg/dL
CV 34.4%
Median 167 mg/dL
Highest 360 mg/dL
Lowest 65 mg/dL

Ambulatory Glucose Profile (AGP)

Insulin
62% 26.5 units Basal/Day
38% 16.3 units Bolus/Day
Daily Dose 42.9 units
Overrides (%) 38.1% (32 boluses)
Bolus/Day 12

System Details
Insulet Omnipod® 5 (sa 20h)
Automated Mode 100% (sa 20h)
Automated: Limited 4% (0h)
Automated: Activity 1% (0h)
Manual Mode 0%

Diet
Carbs/Day 186.5g
Entries/Day 6.7

Fitness
No fitness tracker connected

Comments

Graphs are for illustrative purposes only and created from US experience

Case Study 1: Identify Solutions and Plan

Week View Report

- Strengthen Insulin to Carb Ratio afternoon/evening by 10%

- Strengthen Correction Factor by 10% all day

- Educate to follow SmartBolus Calculator recommendations for correction boluses

Graphs are for illustrative purposes only and created from US experience

Case Study 1: Week 2: Reduced Burden & Improved Glycemia

CGM Summary Report

- Fewer boluses, fewer overrides

- Less work; improved quality of life

- TIR increased from 58% to 77% in 1 week after strengthening bolus doses
  - *Insulin to Carb Ratio most important*

Graphs are for illustrative purposes only and created from US experience

Notes:

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Case Study 2

Move from Multiple Daily Injections to Omnipod® 5

- Diagnosed with type 1 diabetes for 11 years
- Multiple Daily Injections + Dexcom G6® CGM
- A1c >12% for previous year, last visit A1c 13.6% (125 mmol/mol)
- Time In Range 10%
- Missing most insulin injections and feeling "burned out" by diabetes care

Case Study 2: Week 1 on Omnipod 5

CGM Summary Report

- TIR 42%; TBR 0%
- Patterns of hyperglycemia all day
- 6 carb boluses/day, using SmartBolus Calculator

Glucose - Time In Range

34%	Very High > 250 mg/dL	
24%	High 181-250 mg/dL	
42%	Target Range 70-180 mg/dL	
0%	Low 54-69 mg/dL	
0%	Very Low < 54 mg/dL	

Summary

GMI N/A
Average 213 mg/dL
% Time CGM Active 98.4% (6.5 days)

SD 76mg/dL
CV 35.7%
Median 207mg/dL
Highest HImg/dL
Lowest 69mg/dL

Ambulatory Glucose Profile (AGP)

Insulin
63% 43.5 units Basal/Day
37% 25.6 units Bolus/Day
Daily Dose 69.1 units
Overrides (%) 2.1% (1 boluses)
Bolus/Day 6.9

System Details
Insulet Omnipod® 5 (at 12h)
Automated Mode 100% (at 12h)
Automated: Limited 2% (2h)
Automated: Activity 0%
Manual Mode 0%

Diet
Carbs/Day 344.3g
Entries/Day 5.9

Fitness
No fitness tracker connected

Comments

Graphs are for illustrative purposes only and created from US experience

Case Study 2: Identify Solutions and Plan

Week View Report

- Strengthen Insulin to Carb Ratio all day by 25%
- Continue to bolus for meals and snacks

Graphs are for illustrative purposes only and created from US experience

Case Study 2: Week 2: Big Improvement in TIR

CGM Summary Report

- TIR increased from 42% (week 1) to 60% (week 2)
- TDI dropped from 69 U to 56 U
- Fewer boluses/day, but still ~4+ bolus entries
- Started using Activity feature as glucose came into range more
- Raised overnight Target Glucose to 120 mg/dL to increase comfort

Graphs are for illustrative purposes only and created from US experience

Notes:

Automated Mode: Limited

- Reasons for occurrence:
    1. **Missing Sensor values in Omnipod 5 App**
    2. **Automated Delivery Restriction Alarm**
- SmartAdjust technology will compare the basal rate in Manual Mode at that time of day and the Adaptive Basal Rate for the Pod and chooses the lesser of the 2 rates
- Without sensor glucose information, the rate delivered in Automated Mode: Limited will not adjust up or down for current or predicted glucose

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Automated Mode: Limited

- System delivers basal insulin based on a calculation of user-entered settings and past insulin delivery
- Reasons for occurrence:
    1. **Missing sensor values** in Omnipod 5 App: the Pod is not receiving sensor values
        - Sensor warm-up (2 hours)
        - Problem with the CGM
        - Pod & CGM unable to communicate due to placement
    2. **Automated Delivery Restriction** alarm:
        - When insulin delivery has either been paused for too long or at maximum delivery for too long, System will enter Limited state until user acknowledges alarm screens and switches to Manual Mode

Feb 10, 9:41 pm

Automated Delivery Restriction

!

Omnipod 5 App has switched to **Automated Mode: Limited**.

Insulin delivery has been either:

- Paused for too long, **or**
- At maximum delivery for too long

Your CGM may need calibration or a new sensor.

NEXT

Notes:

Automated Mode: Limited

Missing CGM Values in Omnipod® 5

- Pod is no longer receiving sensor values
- After 20 minutes, System shows "Automated Mode: Limited" and is not fully automating basal delivery
- When sensor communication is restored, full automated insulin delivery resumes
- After 60 minutes of continuously not receiving a CGM sensor value an audible alarm sounds

What should you do?

- Check the Dexcom G6 app to see if CGM values are present. If not, troubleshoot sensor issue.
- Make sure Pod and CGM are within direct line of sight & on the same side of the body.

Automated Mode: Limited

Pod & Sensor in direct line of sight

Pod — — Sensor

Sensor

— Pod

Adult placement examples

Pod —
— Sensor
Sensor —

Pod —

Paediatric placement examples

Pod placement examples

Up, down or slight angle

Horizontal or diagonal

Up, down or slight angle

Front

Back

Automated Mode: Limited

Automated Delivery Restriction Alarm

Feb 10, 9:41 pm

Automated Delivery Restriction

!

Omnipod 5 App has switched to **Automated Mode: Limited**.

Insulin delivery has been either:
· Paused for too long, **or**
· At maximum delivery for too long

Your CGM may need calibration or a new sensor.

NEXT

- Insulin was either paused for too long or at maximum delivery for too long while in Automated Mode

What should you do?

- Tap NEXT to see the next screen

- Use a BG meter to confirm blood glucose & troubleshoot based on BG; tap NEXT

- Tap SWICTH TO MANUAL MODE.

- After 5 minutes in Manual Mode and you are confident that your Pod and CGM are working well, you can switch back to Automated Mode

Set Realistic Expectations for Omnipod® 5 with Users

- Glucose levels may run higher in first days of use

- Glycemic control will improve across time as system updates TDI with each Pod change, but results will not be perfect

- User will need to let go of some control of insulin delivery
  - Patience with hyperglycemia: system designed to gradually bring glucose levels to the defined Target Glucose across 2-4 hours
  - May see short insulin suspensions even when glucose level is above target- this is ok and expected

What to expect from this technology

First Pod

- Automated Mode can be activated immediately
- Estimates TDI based on the programmed basal rate
- Maximum automated insulin delivery is restrained
- After 48 hours of wear and a subsequent Pod change, SmartAdjust™ technology uses insulin delivery history to set the adaptive basal rate
- Initial safety restraints are removed

Ongoing Wear

- SmartAdjust™ technology continues to adapt based on insulin delivery history
- Glycaemia should improve across time from a few days to a few weeks
- Encourage bolusing for meals and corrections as needed
- The more precise the inputs are to the algorithm during this time, the faster it can adapt
- Inputs include basal/bolus ratio, target glucose, Insulin:Carb Ration, Duration of Insulin Action

Optimisation

- Adjust target glucose setting as needed
- Adjust SmartBolus Calculator settings as you would traditional pump therapy, including insulin to carbohydrate ratio, correction factor, and duration of insulin action

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The ABCs of Best Practices

Assess

- Insulin delivery history and bolusing habits
- Starting settings reflect physiological needs & are safe and effective in Manual Mode
- Programmed basal rates account for **40-50% of TDI** to optimize initiation

Bolus

- Bolusing for **carbs** is essential. Bolus insulin should make-up 50-60% of TDI
- Bolus **15-20 minutes before eating**
- Avoid overriding suggested boluses as **hypoglycaemia can occur** due to IOB from automated insulin delivery

Consider

- Adjusting Target Glucose to impact automated insulin delivery
- **Consider strengthening IC ratios** as a key lever to adjust bolus insulin
- Using the Activity feature for times of reduced insulin needs

How to View Sensor Graph

History information on the Omnipod 5 App*

*The Omnipod 5 App is only available on the Insulet provided Controller at the time of launch

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Glooko

- If desired and consented to, confirm and review Glooko account.
  (The health care practitioner will need to have provided their unique "ProConnect" code)

- No data upload is needed at the clinic. Data updated every hour*

- Follow up with your healthcare provider. If you are not seeing results that you desired, discuss what settings could be adjusted to meet your goals, improve your time in range etc.

*Must be connected to WiFi or cellular data, and Omnipod® 5 users must have WiFi or cellular data access to receive updates in Glooko®.

Alarms and Notifications

Hazard Alarms

High priority alarms that indicate a serious problem has occurred and a Pod change may be needed

Advisory Alarms

Lower priority alarms that indicate a situation exists that needs attention

Reminder Notifications

Reminder of an action that should be performed

"Check Alarms" within Settings verifies that the Omnipod® 5 App and Pod's alarms and vibration functions are working properly. This also helps to distinguish between the alarm types. This can be done in Manual Mode when insulin is paused.

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Notes:

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No Pod Communication

- Pod communication was not established with the Omnipod® 5 App

What should you do?

- Depending on the communication issue, the Omnipod® 5 App offers you options to help you resolve it. It is in your best interest to leave any options to DISCARD or DEACTIVATE POD as the last choice after trying the other option(s)

- Move the device with the Omnipod® 5 App closer to the Pod

- Tap MORE INFORMATION for potential causes and suggested actions

Missing CGM Values in Omnipod® 5

- Pod is no longer receiving CGM values

- After 20 minutes, system shows "Automated Mode: Limited" and is not fully automating basal delivery

- When the System enters Limited state, SmartAdjust™ technology never gives more than the Basal Program that would be active in Manual Mode

- When CGM communication is restored, full automated insulin delivery resumes

What should you do?

- Make sure the Pod and CGM are in direct line of sight

- Check the Dexcom G6 app to see if CGM values are still being received

Notes:

Automated Delivery Restriction Advisory Alarm

- Only occurs in Automated Mode
- Insulin has been paused for too long, or delivering the maximum amount for too long

What should you do?

- Confirm your BG using a meter
- Follow screens and confirm your blood glucose
- Switch to Manual Mode for at least 5 minutes

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Importance of Alerts and Alarms

- Keep the Omnipod 5 App and Dexcom G6 app close by in order to respond to alerts and alarms

- Do not stop the Omnipod 5 App in a way that stops it from running in the background (called force stopping) on your smartphone.

  - The Omnipod 5 App must be open or be running in the background in order to display and sound alarms on the smartphone. If the App is not running, you could miss important alarms and notifications on the smartphone, and you might not make the changes you need to make to your therapy in a timely manner.

- AVOID setting your Controller or smartphone 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 or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner.

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