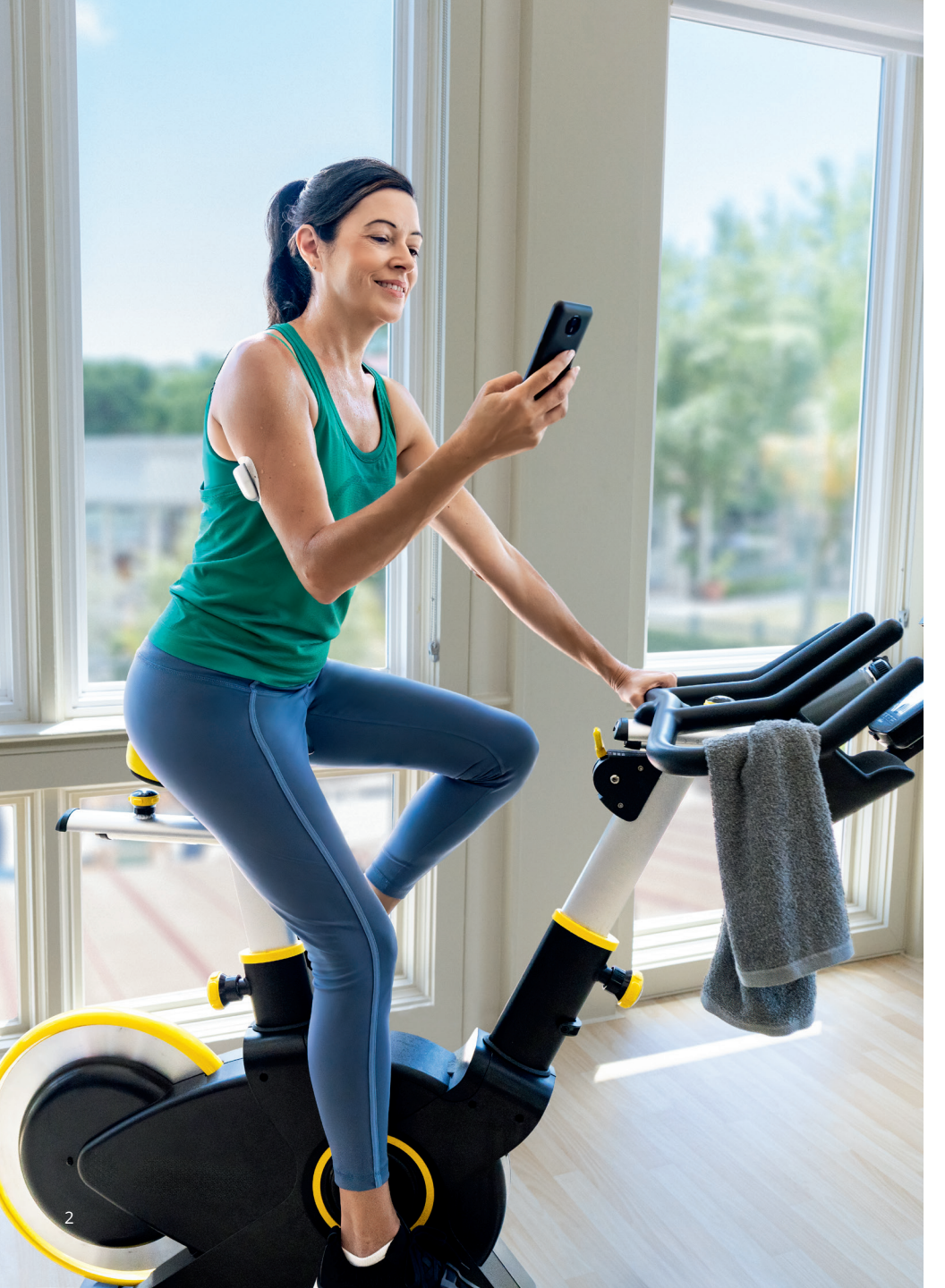
Omnipod® 5 Automated Insulin Delivery System

Important Safety Information



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1 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, multicenter, 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 the Omnipod 5 System use in Automated Mode with a Dexcom G6 Sensor. The primary analysis consisted of A1C and sensor glucose time in range (70–180 mg/dL) results.

The primary safety endpoints included an assessment of severe hypoglycemia 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.

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 a A1C < 10.0% at screening. Subjects < 18 years had to be living with a parent or legal guardian.

Glycemic Results

The tables on the following pages include information on the primary glycemic 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 > 180 mg/dL in adolescents, adults, and children as well as a reduction in median time < 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 glycemic improvement; 2) standard therapy phase was shorter than the Omnipod 5 System phase; 3) minimal use of the 140 and 150 mg/dL Target Glucose settings in adults and adolescents limited the assessment of glycemic results at those settings and, for that reason, results at these Target settings were not included in these results.

Glycemic 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 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, mg/dL (std dev)	183 (32)	160 (15)	-23*	161 (28)	154 (17)	-8*
Avg standard deviation of sensor glucose, mg/dL (std dev)	68 (13)	60 (10)	-9*	57 (14)	49 (11)	-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 % < 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 % < 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 % > 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 % ≥ 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 % ≥ 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 < 70 mg/dL and < 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 standard therapy phase and Omnipod 5 System phase was statistically significant.*

Glycemic 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 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, mg/dL (std dev)	177 (35)	149 (17)	-29*	160 (34)	149 (21)	-11*
Avg standard deviation of sensor glucose, mg/dL (std dev)	61 (15)	48 (12)	-13*	56 (17)	44 (13)	-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 % < 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 % < 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 % > 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 % ≥ 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 % ≥ 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 standard therapy phase and Omnipod 5 System phase was statistically significant.*

Change in A1C Analyzed 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 standard therapy phase and 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)
Hypoglycemia‡	1	0	1
Severe Hypoglycemia§	1	2	3
DKA	1	0	1
Hyperglycemia‖	1	2	3
Prolonged Hyperglycemia**	13	5	18
Other	8	8	16

Results reported as number of events.

‡ *Hypoglycemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycemia.*

§ *Required the assistance of another person,*

‖ *Hyperglycemia requiring evaluation, treatment or guidance from intervention site, or hyperglycemia resulting in a serious adverse event.*

** *Meter blood glucose measuring ≥ 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 Sensor (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected Sensor (CGM-informed SmartBolus Calculator) for 7 days.

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

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

Percent time in glucose range as measured by Sensor	Standard SmartBolus Calculator	CGM-Informed SmartBolus Calculator	Difference
70–180 mg/dL	65.1% (15.4)	63.8% (15.7)	-1.3%
< 70 mg/dL	2.8% (2.7)	2.1% (2.0)	-0.6%*
< 54 mg/dL	0.5% (1.0)	0.3% (0.7)	-0.2%
> 180 mg/dL	32.1% (15.7)	34.0% (16.0)	1.9%
≥ 250 mg/dL	8.2% (6.9)	9.7% (10.3)	1.4%
≥ 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, multicenter, prospective study enrolled 80 children.

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

The primary safety endpoints included the incidence of severe hypoglycemia 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.

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.

Glycemic Results

The tables on the following pages include information on the primary glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System treatment phase. The primary results of the study included change in average A1C% and % time in range (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 > 180 mg/dL as well as a reduction in median time < 70 mg/dL.

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

Glycemic 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 70–180 mg/dL (std dev)	57.2% (15.3%)	68.1% (9.0%)	10.9%*
Avg sensor glucose, mg/ dL, (std dev)	171.1 (30.5)	157.4 (16.8)	-13.7*
Avg standard deviation of sensor glucose, mg/dL (std dev)	64.9 (13.4)	59.6 (10.3)	-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 % < 54 mg/dL (Q1, Q3)	0.24% (0.05, 0.84)	0.26% (0.16, 0.60)	0.06%
Median % < 70 mg/dL (Q1, Q3)	2.19 (0.89, 4.68)	1.94 (1.18, 3.43)	-0.27%*
Avg % > 180 mg/dL (std dev)	39.4% (16.7%)	29.5% (9.8%)	-9.9%*
Avg % ≥ 250 mg/dL (std dev)	14.8% (12.1%)	9.2% (5.6%)	-5.6%*
Avg % ≥ 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 < 70 mg/dL and < 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 standard therapy phase and Omnipod 5 System phase was statistically significant.*

Glycemic 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 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, mg/dL (std dev)	177 (35)	149 (17)	-29*	160 (34)	149 (21)	-11*
Avg standard deviation of sensor glucose, mg/dL (std dev)	61 (15)	48 (12)	-13*	56 (17)	44 (13)	-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 % < 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 % < 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 % > 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 % ≥ 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 % ≥ 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 standard therapy phase and Omnipod 5 System phase was statistically significant*

Change in A1C Analyzed 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 analyzed 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 standard therapy phase and 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
Hypoglycemia‡	0
Severe Hypoglycemia§	0
DKA	0
Hyperglycemia◊	4
Prolonged Hyperglycemia**	20
Other	5

Results reported as number of events.

‡ *Hypoglycemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycemia.*

§ *Required the assistance of another person.*

◊ *Hyperglycemia requiring evaluation, treatment or guidance from intervention site, or hyperglycemia resulting in a serious adverse event.*

** *Meter blood glucose measuring ≥ 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 Sensor (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected Sensor (CGM-informed SmartBolus Calculator) for 7 days. Boluses were calculated using stored pump settings plus user-estimated meal size and/ or either a manually entered glucose value (standard SmartBolus Calculator) or an imported current sensor glucose value and trend (CGM-informed SmartBolus Calculator). Both versions of the SmartBolus Calculator considered insulin on board (IOB) in the bolus calculations. The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the Sensor trend. The primary analysis of the study was to compare the percent of time spent < 70 mg/dL and > 180 mg/dL for the 4 hours after any bolus as measured by Sensor between the two study phases. The results showed that the CGM-informed SmartBolus Calculator provided similar glycemic results as the standard SmartBolus calculator when used in Manual Mode.

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

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

Data is presented as average (standard deviation).

Omnipod 5 Pivotal Study in Adults with Type 2 Diabetes (18–75 years)

The goal of this U.S.-based pivotal study was to assess the safety and efficacy of the Omnipod 5 System in adults with type 2 diabetes aged 18 to 75 years. This study enrolled 343 participants.

A 2-week standard therapy phase where participants used their usual insulin delivery method was followed by 3 months of participants using the Omnipod 5 System. The system was used in Automated Mode with a Dexcom G6 continuous glucose monitor (CGM). The primary safety outcome is that Omnipod 5 does not worsen A1C compared to baseline/standard therapy. The primary effectiveness outcome is that Omnipod 5 lowers A1C compared to baseline/standard therapy.

The study also tested other outcomes for safety and benefit. The results for the primary and safety results are presented in the tables below. See the full *Omnipod 5 Technical User Guide* for secondary results and other data.

Of the 343 participants enrolled, 305 started Omnipod 5 and 289 completed the study. The study population consisted of adults diagnosed with type 2 diabetes on insulin (basal-bolus, basal only, or pre-mix insulin). All participants were required to have an A1C < 12.0% at screening. Those on basal insulin only also had to have an A1C ≥ 7%.

Glycemic Results

The tables on the following pages include information on the glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System phase in adults with type 2 diabetes. The primary result of the study is average change in A1C. Participants experienced an improvement in A1C and % time in range (70–180 mg/dL, 3.9–10.0 mmol/L) after 3 months of Omnipod 5 System use. This was achieved with no increase in hypoglycemia (low blood sugar).

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

Outcome	Standard Therapy†	Omnipod 5†	Change
Avg A1C% (std dev)	8.2% (1.3%)	7.4% (0.9%)	-0.8%*
Avg sensor glucose, mmol/L, mg/dL (std dev)	11.2, 202 (2.8, 50)	9.4, 170 (1.3, 24)	-1.8, -32*
Avg coefficient of variation of sensor glucose, % (std dev)	27.8% (6.3%)	27.1% (5.1%)	-0.7%
% Time glucose range			
Avg % 3.9–10 mmol/L, 70–180 mg/dL (std dev)	45% (25%)	66% (17%)	20%*
Avg % 3.9–7.8 mmol/L, 70–140 mg/dL (std dev)	21% (18%)	33% (17%)	12%*
Avg. % < 3 mmol/L, < 54 mg/dL (std dev)	0.01% (0.02%)	0.04% (0.05%)	0.01%§
Avg % < 3.9 mmol/L, < 70 mg/dL (std dev)	0.2% (0.3%)	0.2% (0.2%)	0.0%§
Avg % > 10 mmol/L, > 180 mg/dL (std dev)	54% (25%)	34% (17%)	-20%*

Avg % > 13.9 mmol/L, > 250 mg/dL (std dev)	20% (22%)	7% (8%)	-12%*
Avg % > 16.9 mmol/L, > 300 mg/dL (std dev)	7.7% (10.3%)	1.8% (2.4%)	-5.2%*

Averages (avg) with standard deviation (std dev) values in brackets.
†Number of participants (n) was 299 for all outcomes above except A1C which was 296.
** Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*
§The difference in the results is non-inferior (not worse) than standard therapy.

Change in A1C Analyzed by Baseline A1C

The table below provides information on the average change in A1C from baseline to the end of the 3 months of Omnipod 5 use grouped by what the baseline A1C was prior to starting Omnipod 5. Those with a higher baseline A1C had a greater decrease in A1C.

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

Baseline A1C	**Avg A1C% Baseline** *(std dev)*	**Avg A1C% Omnipod 5** *(std dev)*	**Change***
< 7.0% (n = 42)	6.5% (0.4%)	6.5% (0.6%)	0.0%
7.0–7.9% (n = 104)	7.5% (0.3%)	7.1% (0.6%)	-0.4%
8.0–8.9% (n = 82)	8.5% (0.3%)	7.6% (0.8%)	-0.8%
≥ 9.0% (n = 68)	10.1% (0.9%)	8.1% (0.9%)	-2.1%

Averages (avg) with standard deviation (std dev) values in brackets.
** Statistical testing not done to assess significance of change between standard therapy phase and Omnipod 5 System phase.*

Quality of Life

The table below provides information on the results of surveys assessing diabetes distress, sleep, and hypoglycemia confidence during the standard therapy phase and the 3-month Omnipod 5 System phase in adults with type 2 diabetes. Participants on Omnipod 5 reported experiencing less diabetes distress.

Outcome†	Standard Therapy†	Omnipod 5	Change
Avg Type 2 Diabetes Distress Assessment System (T2-DDAS) survey score	2.5 (1.0)	2.2 (0.9)	-0.3*
% of participants with high diabetes distress (T2-DDAS ≥ 2.0%)	66%	55%*	
Avg Pittsburgh Sleep Quality Index (PSQI) survey score (std dev)	7.3 (4.0)	7.0 (4.1)	-0.4§
% of participants with poor sleep (PSQI > 5.0)	63%	59%§	
Avg Hypoglycemia Confidence Scale (HCS) survey score (std dev)	3.2 (0.6)	3.3 (0.6)	0.1
% of participants with low hypoglycemia confidence (HCS < 3.0)	32%	25%	

Averages (avg) with standard deviation (std dev) values in brackets.

† Number of participants (n) for T2-DDAS outcomes was 305 for Standard Therapy phase and 301 for Omnipod 5 phase. Number of participants (n) for PSQI outcomes was 304 for Standard Therapy phase and 294 for Omnipod 5 phase. Number of participants (n) for HCS outcomes was 305 for Standard Therapy phase and 300 for Omnipod 5 phase.

** Change between standard therapy phase and Omnipod 5 System phase was statistically significant and clinically meaningful.*

§ Change in total score between standard therapy phase and Omnipod 5 phase was statistically significant, but the change was not clinically meaningful. As a result, participants on Omnipod 5 did not experience improved sleep.

Adverse Events

The table below provides a list of the glycemic adverse events per participant that occurred during the 3-month Omnipod 5 System treatment phase. Severe hypoglycemia was the only severe adverse event that occurred that was related to glycemia. Thirteen non-glycemic serious adverse events were reported during the Omnipod 5 phase. All 13 of those events were not related to Omnipod 5 and resulted in a full recovery except one event of stomach pain due to ascites.

Glycemic Adverse Events during the Omnipod 5 System Phase

Adverse Event Per Participant	Omnipod 5 (n = 305)
Severe hypoglycemia	1
DKA	0
Hyperosmolar hyperglycemic syndrome (HHS)	0

2 Settings and Technical Specifications

Controller Specifications

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

Weight: 5.82 oz (165 grams)

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

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

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

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 startup: Adjacent and touching, with the Pod either in or out of tray, to ensure proper communication during priming.

During normal operation: Within 1.5 meters (5 feet) of each other. Depending on the location, the communication distance may handle separations up to 15 meters (50 feet) away.

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

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

Notification type: Audible and vibratory

Battery: Rechargeable Li-ion battery, 3.8V, 2800 mAh66

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.

Sensor Specifications

For information about Sensor operating specifications, see the Instructions for Use for your compatible Sensor.

Pod Specifications

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

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

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

Startup temperature: above 50°F (10°C)

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

Warm-up time (32° F to 68° F, 0°C to 20°C): 7 minutes

Cool-down time: No time is required for cooldown from maximum storage temperature (86° F, 30°C) to operating temperature.

Reservoir volume (deliverable): 200 units

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

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

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

Insulin concentration: U-100

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

Sterilizing agent: sterilized 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

Compatible Devices

The Omnipod 5 System is the first wearable, on-body, tubeless, automated insulin delivery system. The Omnipod 5 System consists of a tubeless insulin Pod and the Omnipod 5 App on an Insulet-provided Controller or installed on a compatible smartphone. The Omnipod 5 System works with the Dexcom G6 or Dexcom G7 Continuous Glucose Monitoring Systems or the Freestyle Libre 2 Plus Flash Glucose Monitoring Sensor to continuously adapt and automatically deliver insulin according to your personal needs.

Compatible Devices for Use with the SmartBolus Calculator

Device Type	Device Manufacturer	Brand Name
Blood Glucose Meter	All FDA-cleared blood glucose meters	
iCGM	Dexcom	Dexcom G6 Continuous Glucose Monitor Dexcom G7 Continuous Glucose Monitor
	Abbott Diabetes Care	FreeStyle Libre 2 Plus Flash Glucose Monitoring Sensor
Alternate Controller Enabled Insulin Pump (Insulin Pump)	Insulet Corporation	Omnipod 5 ACE Pump (Pod)
Interoperable Automated Glycemic Controller software (Automated Insulin Delivery Software)	Insulet Corporation	SmartAdjust technology

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 or smartphone running the Omnipod 5 App and Pod when in communication range (within 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 or smartphone running the Omnipod 5 App occurs 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 or smartphone. 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 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 22 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	Increase in carb amount value increases amount of suggested bolus dose. Decrease in carb amount value decreases amount of 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)	Increase in sensor glucose value increases amount of suggested bolus dose. Decrease in sensor glucose value decreases amount of 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)	Increase in BG Reading increases amount of suggested bolus dose. Decrease in BG Reading decreases amount of 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: Target Glucose– 200 mg/dL (10 mg/dL increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of 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	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of 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	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of suggested bolus dose.
Reverse Correction ON/OFF	Enter in Omnipod 5 App Settings	If "On," suggested bolus is decreased when glucose is below 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	Increase in setting value may decrease amount of 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 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 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 tap 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 or smartphone, 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 Sensor), Sensor 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).
- Your Minimum Glucose for Calculations.

Bolus Delivery Performance Specifications

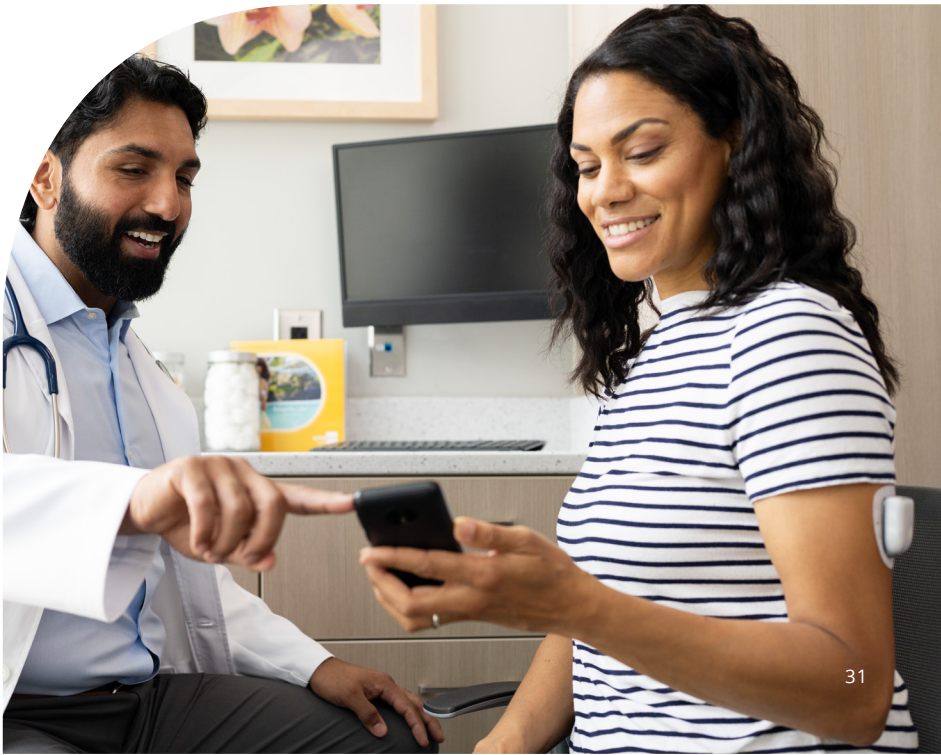
Bolus size: 0.05–30 U in 0.05 U increments

Delivery performance characterization

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 summarizes 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 delivered compared to the requested amount. Each table provides the number and percent 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 percent 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 percent 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 percent 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 percent 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 Maximum (30.0 U) Bolus Request					
Amount (Units)	<7.5	7.5–22.5	22.5–27.0	27.0–28.5	28.5–31.5
(% of settings)	(<25%)	(25–75%)	(75–90%)	(90–95%)	(95–105%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	72/72 (100%)
Amount (Units)	31.5–33.0	33.0–37.5	37.5–52.5	52.5–75.0	> 75.0
(% of settings)	(105–110%)	(110–125%)	(125–175%)	(175–250%)	(> 250%)
Number and percent 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 0.05–30 U/hr in 0.05 U/hr increments. Default is 3.00 U/hr.

Delivery performance characterization

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

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 hyperglycemia.

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	5.5hr
0.05 U/hr basal	51 hr	80 hr (Pod expiration)

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 alarm while an immediate bolus is in progress, the alarm is delayed until completion of the bolus.

Omnipod 5 System Notice Concerning Interference

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Omnipod 5 System Label Symbols

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

Symbol	Meaning
	Do not re-use
	Refer to instruction manual / booklet
	Sterilized using ethylene oxide
	Date of manufacture
	Country of Manufacture–United States of America
	Country of Manufacture–China
	Batch code
	Use-by date
	Catalogue number
	Serial number
	UK Conformity Assessed
	Marking of conformity

Symbol	Meaning
	MR unsafe
	Do not use if package is damaged and consult instructions for use
	Type BF applied part
	Manufacturer
	Country of Manufacture–Malaysia
	Compatible with
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Australian Regulatory Compliance Mark
	Importer

Symbol	Meaning
IP28	Protects persons against access to hazardous parts with fingers and protects against solid foreign object ingress of diameter 12.5 mm or greater; Submersible: Waterproof to 7.6 meters (25 feet) for up to 60 minutes
	Non-pyrogenic fluid path
	Do not dispose with household waste
	Single sterile barrier system
	Compatible with U-100 Insulin Only
FCC ID:	Federal Communication Commission Identifier with number
IC:	Complies with ISED Canada Radio Standards Specifications
	Switzerland Authorized Representative

Symbol	Meaning
IP22	Protects persons against access to hazardous parts with fingers and protects against solid foreign object ingress of diameter 12.5 mm or greater; avoid liquid
	Medical device
RoHS	RoHS compliant
	Single patient multiple use
	Consult instructions for use or consult electronic instructions for use
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
HVIN:	Hardware version identification number
	Authorized representative in the European Community/ European Union

Symbol	Meaning
	(France) The Triman indicates that the product must be sorted or returned to a collection point.
	(France) This product must be separated from conventional perforating DASTRI for recycling.
	(France) Electronic perforating waste must be stored in the secure DASTRI purple box. These purple boxes are distributed free of charge in pharmacies.
	(France) Packaging intended for recycling
	Charging cable
	Fill Syringe and Needle Assembly
	Controller skin

Symbol	Meaning
	Intertek Authorized Product Certification Mark
	(France) This pictogram means that the product contains a piercing object.
	(France) All pharmacies distribute and collect DASTRI needle boxes free of charge from self-treatment patients.
	(France) The puncture waste must be placed in a DASTRI needle box. These needle boxes are distributed by pharmacies.
	Charging adapter
	Pod
	Omnipod 5 Controller

3 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 hyperglycemia or hypoglycemia can result 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 hypoglycemia or hyperglycemia. 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 for 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 hypoglycemia or hyperglycemia.

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 should 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 recognize all functions of the Omnipod 5 System including alerts, alarms, and reminders according to 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 10,000 feet (3,000 meters). 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 hypoglycemia. It is important to check your glucose frequently when flying to avoid prolonged hypoglycemia.

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 hyperglycemia.

Warning: Device components including the Pod, Dexcom G7 Sensor, Dexcom G6 Sensor and Transmitter, and FreeStyle Libre 2 Plus Sensor 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 and smartphone 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 as part), Humalog (insulin lispro), and Admelog (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 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 hypoglycemia. 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 hyperglycemia 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 hyperglycemia and put your health at risk.

Glucose Warnings

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

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

Warning: ALWAYS promptly treat hypoglycemia. Glucose at or below 55 mg/dL indicates significant hypoglycemia (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 (hypoglycemia) according to your healthcare provider's recommendations. Symptoms of hypoglycemia include weakness, sweating, nervousness, headache, or confusion. If left untreated, hypoglycemia can lead to seizure, loss of consciousness, or death.

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

Warning: ALWAYS promptly treat hyperglycemia (high glucose) according to your healthcare provider's recommendations. Symptoms of hyperglycemia include fatigue, thirst, excess urination, or blurry vision. If left untreated, hyperglycemia 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 room if you need emergency medical care. Ask a friend or family member to take you to the emergency room 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 hypoglycemia or hyperglycemia may still occur.

If your sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, 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 hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low sensor glucose values can cause prolonged insulin suspension leading to hyperglycemia, 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 hypoglycemia or hyperglycemia.

Warning: NEVER use a Pod if, while you are filling the Pod, you feel significant resistance while pressing the plunger down 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 that can lead to hyperglycemia.

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 hyperglycemia.

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 dislodged. An improperly inserted, loose, or dislodged cannula could result in under-delivery of insulin which can lead to hyperglycemia.

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 hypoglycemia or hyperglycemia.

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 hypoglycemia.

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 hyperglycemia.

Warning: Do NOT expose your Pod to water t depths greater than 25 feet (7.6 meters) 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 hypoglycemia or hyperglycemia.

Controller and Smartphone 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 others cannot make changes to your insulin therapy which can lead to hypoglycemia or hyperglycemia. Do not share your Controller PIN or your smartphone screen lock security 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.
- Your smartphone device is no longer compatible with use of the Omnipod 5 App.
- The operating system of your smartphone has not yet been tested for safety by Insulet.

Use the Insulet-provided Controller or a different insulin delivery method. Failure to deactivate your Pod and use another form of insulin delivery could result in the over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

Alarms 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 hyperglycemia.

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 hyperglycemia 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 hyperglycemia.

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 hypoglycemia or hyperglycemia.

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

Warning: ALWAYS confirm the Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number you save in the Omnipod 5 App matches the one you are wearing. In cases where more than one person in the household uses a Dexcom Sensor, mismatching numbers could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia and hyperglycemia.

Warning: DO NOT use the Omnipod 5 System with the FreeStyle Libre 2 Plus Sensor if you are taking more than 1000 mg of ascorbic acid (Vitamin C) per day, a substance found in supplements like multivitamins or cold remedies such as Airborne® and Emergen-C®. Taking more than 1000 mg of Vitamin C per day may falsely raise your Sensor readings and result in over-delivery of insulin that could result in severe hypoglycemia.

SmartBolus Calculator Warnings

Warning: AVOID changing your SmartBolus Calculator settings before consulting with your healthcare provider. Incorrect changes could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia. 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 hypoglycemia or hyperglycemia.

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 hypoglycemia or hyperglycemia.

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. Consult with 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 hypoglycemia while the Activity feature is enabled. Hypoglycemia can still occur when using the Activity feature. Follow your healthcare provider's advice on hypoglycemia avoidance and treatment. If untreated, hypoglycemia 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 physician.

Caution: DO NOT use any component of the Omnipod 5 System (smartphone, 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 authorized devices (Omnipod 5 App, Controller, Pod, Dexcom G6 or Dexcom G7, and FreeStyle Libre 2 Plus Sensor). DO NOT attempt to use the Omnipod 5 System with unauthorized devices. Attempting to use the Omnipod 5 System with unauthorized 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 traveling. 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 traveling 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 airplane cabins during flight, the atmosphere pressure in an airplane 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 hypoglycemia or injury. If needed, follow your healthcare provider's treatment instructions.

Caution: NEVER use a blow dryer 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 hyperglycemia.

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 hyperglycemia.

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 the over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

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

Caution: When there is no communication between the Pod and the Controller or smartphone, 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, notifications, and to send new instructions to the Pod. To restore communication try bringing the Controller or smartphone within 5 feet (1.5 m) of the Pod.

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

Controller and Smartphone Precautions

Caution: Connect ONLY to trusted Wi-Fi networks with your Controller or smartphone. 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 or phone to malware. DO NOT connect to public Wi-Fi networks during first-time setup of your Omnipod 5 System.

Caution: DO NOT navigate away from the Omnipod 5 App while you are in the process of making changes to your insulin delivery settings. If you leave the App before you are able to save the setting change and before the App is able to put the setting change into effect, the system will continue to use your last saved settings. As a result, you may continue with therapy settings that you did not intend. If you are unsure about whether your changes were saved, review your settings.

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 screen lock security with anyone.

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

Caution: If you decide later to switch between the Controller and your smartphone, you will need to start setup again on the new device. New setup requires entry of all your personalized settings. Consult with your healthcare provider if you are unsure about how to set up the new device. If you are wearing a Pod and need to switch devices, you will need to deactivate your Pod and activate a new one, since the Pod cannot communicate with two devices at one time.

Caution: DO NOT reset the Omnipod 5 App or clear the App data 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 or clearing App data, 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 hypoglycemia or hyperglycemia.

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 that can lead to hypoglycemia or hyperglycemia.

Caution: DO NOT expose your Controller battery to high heat [> 86ºF (> 30ºC) during storage and > 104ºF (> 40ºC) 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 > 86°F (30°C) during storage and > 104°F (40°C) during use. Extreme cold is defined as < 32°F (0°C) during storage and < 41°F (5°C) during use.

Caution: Use ONLY the USB charging cable and adapter 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 4 feet (1.2 meters) 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.

Smartphone-specific Precautions

Caution: 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. If you do not hear alarms and notifications from your smartphone, you might not make the changes you need to make to your therapy in a timely manner. Your Pod will continue to operate and sound alarms. In addition, if you stop the Omnipod 5 App while sending commands to the Pod, the command can be interrupted and may not be completed.

Caution: DO NOT delete the Omnipod 5 App while you have an active Pod, and DO NOT clear the Omnipod 5 App data. If you do, your Pod will remain active, but you will not be able to control your Pod even if you re-install or re-open the App. You must remove the Pod in order to stop receiving insulin.

Caution: DO NOT attempt to use the Omnipod 5 App on a smartphone device with unauthorized modifications. If you do, you will not be able to use the Omnipod 5 App.

Caution: DO NOT install apps on your smartphone from untrusted sources. These apps may contain malware that may impact use of the Omnipod 5 App. Install apps only from trusted sources (i.e. Google Play or the App Store). If you do not know what an App is, do not install it, regardless of the source.

It is not advised to install any app from a source other than Google Play or the App Store on your smartphone that is running the Omnipod 5 App. Doing so may put you at risk of unintentionally installing malware on your device.

Malware, or "malicious software" from unknown third-parties, is designed to damage your device and/or read your private information. Unknown Apps and unknown downloads are the most common method for spreading malware. Malware could prevent the Omnipod 5 System from functioning as intended, causing over-delivery or under-delivery of insulin, which could lead to hypoglycemia or hyperglycemia.

If you believe you may have an App installed from a third-party source, take steps to delete that App. If you believe you may have malware on your device, discontinue use of your Omnipod 5 System and use an alternate means of insulin delivery until you can resolve. Delete any Apps installed from a third-party source, restore your phone to factory default settings, and contact Insulet Customer Care.

Caution: DO NOT enable any app development settings on your smartphone. Enabling these settings may cause issues with the Omnipod 5 App and prevent normal app operation.

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 hyperglycemia. 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 included fill syringe with each Pod change. Always carry supplies to perform a Pod change should 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 sprays, strong detergents, or solvents on or near your Pod. The use of spray sunscreen, DEET-containing bug spray, personal care sprays, and other aerosols, detergents, and strong chemicals on the Pod can irritate the infusion site or damage the Pod, increasing the risk that the Pod housing will crack. Pod damage may result in the ingress of external fluids which can impact the ability of the Pod to function properly. This may result in the over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

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 or smartphone 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 or smartphone.

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 hyperglycemia.

Caution: ALWAYS check the alarm function when you change the Pod if you suspect any issue with the Pod's sounds to ensure you don't miss important alarms during use.

Caution: ALWAYS make sure you can hear alarms and notifications when paired to alternative audio devices (e.g. Bluetooth speaker, headphones).

Caution: 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. Avoid the use of tools that limit sounds and notifications, including but not limited to:

- Android: Digital Wellbeing, Private Space, Notification cooldown.
- iPhone: Screen Time, Focus Mode, Hide App, Lock 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. 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 receiver with the Omnipod 5 System because the Omnipod 5 System is compatible only with the G6 or Dexcom G7 App on a smartphone.

Caution: During the first 12 hours of use of a FreeStyle Libre 2 Plus Sensor, use a fingerstick reading from a BG meter before making treatment decisions. After the first 12 hours, you can tap "Use Sensor" to use the value and trend in the SmartBolus Calculator.

Troubleshooting Hypoglycemia (Low Glucose)

Blood Glucose (BG) < 70 mg/dL with Symptoms

SmartAdjust technology automatically decreases or pauses insulin delivery every 5 minutes when glucose is below the Target Glucose to protect against hypoglycemia. It will always pause in Automated Mode when your glucose is below 60mg/dL.

Hypoglycemia Symptoms

- Shakiness
- Fatigue
- Hunger
- Sweating
- Cold, clammy skin
- Weakness
- Blurred vision
- Headache
- Rapid heartbeat
- Confusion
- Tingling
- Anxiety
- Drowsiness
- Dizziness
- Personality change

If you have symptoms of low glucose, check your blood glucose.

If your glucose is less than 70 mg/dL:

1. Treat with 5–15 grams of fast-acting carbohydrate. (Fast acting carbs: glucose tablets or gel, juice, regular soda (not diet), sugary candy (not chocolate), honey)
2. Recheck BG in 15 minutes.

If glucose is less than 70 mg/dL or symptoms persist, repeat above steps.

If your glucose remains low after repeated treatments, notify your healthcare provider immediately and/or go to the nearest emergency room.

Important Notes:

- Make sure your blood glucose is at least 100mg/dL before driving or working with dangerous machinery or equipment.
- Even if you cannot check your blood glucose, do not wait to treat symptoms of hypoglycemia.
- If you have hypoglycemia unawareness, check your blood glucose more frequently.
- If glucose was dropping while in Automated Mode, SmartAdjust technology may have decreased or paused insulin for some time already. In these cases, sometimes a smaller amount of carbohydrate can be used to prevent or treat mild hypoglycemia.

Action Plan

Never ignore the signs of low blood glucose, no matter how mild. If left untreated, severe hypoglycemia may cause seizures or lead to unconsciousness. If loss of consciousness, inability to swallow glucose treatment or seizures are experienced or observed take the following action immediately:

- Give glucagon as instructed by healthcare provider
- Call 911
- Notify healthcare provider
- Suspend insulin delivery

Troubleshooting Frequent Hypoglycemia

Check Settings

- Are you in Automated Mode?
- Are you in Manual Mode?
- If in Manual Mode, is the correct basal program in progress?
- If in Manual Mode, is the temp basal (if active) correct?
- Is Target Glucose correct?

Consult your healthcare provider for guidance about adjusting settings and their suggestions for treating hypoglycemia.

Review Recent Activity

Physical activity

- Has your exercise been unusually long or strenuous?
- Have you been unusually physically active? (e.g., extra walking, housework, heavy or repetitive tasks, lifting or carrying?)
- Did you use the Activity feature?
- Did you use a decreased temp basal during this activity?
- Did you consume carbs before, during and/or after activity?

Meals/Snacks

- Did you count the carbs correctly—including subtracting significant fiber?
- Did you bolus with food?
- Did you consume alcohol?

Troubleshooting Hyperglycemia (High Glucose)

Blood Glucose (BG) Reading ≥ 250 mg/dL

Hyperglycemia Symptoms

- Fatigue
- Blurred vision
- Unusual thirst or hunger
- Unexplained weight loss
- Frequent urination (i.e. at night)
- Slow healing of cuts or sores

If you're experiencing symptoms of high glucose:

1. Verify and check your BG reading.
2. If your BG reading is over 250 mg/dL, check your urine or blood ketone level and refer to the table below for next steps.

If your ketone level is:	Trace or Negative	Small (urine) 0.6–0.9 mmol/L (blood)	Moderate to Large (urine) 1.0 or higher mmol/L (blood)
Insulin	Take a correction bolus with the Controller.	Take a correction bolus with a syringe or pen. Change your Pod.	Take a correction bolus with a syringe or pen. Change your Pod.
BG	Recheck in 2 hours. If BG has lowered, return to normal dosing schedule, and monitor BG.	Recheck in 2 hours. If BG has lowered, return to normal dosing schedule, and monitor BG.	Recheck in 2 hours. If BG has lowered, return to normal dosing schedule, and monitor BG.
Ketones	Recheck ketones if your BG at the 2-hour BG check is unchanged or higher.	Recheck blood ketones in 1 hour or urine ketones in 2 hours.	Recheck blood ketones in 1 hour or urine ketones in 2 hours.
Food and Drink	Usual meal plan with extra water or sugar-free fluids.	Usual meal plan with extra water or sugar-free fluids.	Usual meal plan with extra water or sugar-free fluids.
Additional Steps		If BG and ketones remain high after 2 or more treatments with syringe or pen, contact your healthcare provider.	Contact your healthcare provider.

Troubleshooting Frequent Hyperglycemia

Check Settings

- Are you in Automated Mode?
- Do you have the Activity feature enabled?
- Is your Target Glucose correct?
- In Manual Mode, is the correct basal program in progress?
- Temp basal: Do you have a temp basal running that you should have turned off?

Check History Detail

- Alarm history: Did you ignore or not hear alarms that should have been addressed?
- Last bolus:
  - Was the bolus too small?
  - Was the bolus timing correct?
  - Did you account for high-protein or high-fat meal?

Action Plan

There are several factors that can cause hyperglycemia. Common causes include illness, stress, infection, and missed insulin doses. Only rapid-acting insulin is used in your Pod, so you have no long-acting insulin in your body. If an occlusion or other interruption of insulin delivery occurs, your blood glucose may rise rapidly. Do not ignore the signs and symptoms of hyperglycemia.

Check Pod

Check your cannula through the viewing window

- Did the cannula slip out from under your skin?
- Is there blood in the cannula?
- Is there redness, drainage, or other signs of infection around the cannula?

If YES, change your Pod. If you suspect an infection, then call your healthcare provider.

Check Your Infusion Site

- Is there redness or swelling around the Pod and adhesive?
- Is insulin leaking from your infusion site or is there odor of insulin?

If YES, change your Pod. If you suspect an infection, then call your healthcare provider.

Check Your Adhesive Dressing

- Is the adhesive dressing coming loose from your skin?
- Is the Pod becoming detached from the adhesive dressing?

If YES, and if cannula is still inserted properly, you may tape down the Pod or adhesive to prevent further detachment.

If cannula is no longer under your skin, change your Pod.

Check Your Insulin

- Is the insulin used expired?
- Has the insulin used been exposed to extreme temperatures?

If YES, change Pod using a new vial of insulin.

Reminder: If you are experiencing persistent nausea and/or vomiting, or have diarrhea over two hours, contact your healthcare provider immediately.

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

Sick Day Management

Action Plan

Discuss sick day management with your healthcare provider. The below guidelines are recommendations and may differ from your own healthcare provider's guidelines.

Emergency situations

- For BG of 250 mg/dL or more see: Hyperglycemia Action Plan.
- For BG of 70 mg/dL or less (and/or symptoms) see: Hypoglycemia Action Plan.

Throughout an illness

If you have a cold, stomach virus, toothache or other minor illness:

- Check blood glucose more often (every 2–4 hours or at least 4 times a day).
- Check ketones—any time BG is 250 mg/dL or more.
- Use temp basal as directed by your healthcare provider.
- Stay hydrated.
- Monitor urine output.
- Keep a record of information (BG, ketone checks, fluids, and time/amount of urine, vomiting, diarrhea, temperature).

Call your healthcare provider immediately if you have:

- Persistent nausea and/or if you are vomiting or have diarrhea over two hours.
- Difficulty breathing.
- Unusual behavior (such as confusion, slurred speech, double vision, inability to move, jerking movements).
- Persistent high BG and/or positive ketones after treating with extra insulin and drinking fluids.
- Persistent low BG that is not responsive to decreasing insulin and drinking carbohydrate-containing fluids.
- A fever above 100.5°F.
- Moderate to large urine ketones or ≥ 1.0 mmol/L blood ketones.

Reminder

The symptoms of DKA (diabetic ketoacidosis) are much like those of the flu. Before assuming you have the flu, check your BG to rule out DKA. Consult your healthcare provider for further information.

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
- Glucose Sensor 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 physician in case of an emergency.
- Glucagon kit and written instructions for administering glucagon dosage if you are unconscious.

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

My Notes

My Notes

omnipod® 5

For More Information

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

Visit us online at
omnipod.com/guides

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Controller FCC ID: 2ADINN5004L
Controller FCC ID: 2ADINN5004LR1
Pod FCC ID: RBV-029
Pod FCC ID: RBV-029C
Pod FCC ID: RBV-029D

Medical Disclaimer: This handout is for information only and is not a substitute for medical advice and/or services from a healthcare provider. This handout may not be relied upon in any way in connection with your personal health care related decisions and treatment. All such decisions and treatment should be discussed with a healthcare provider who is familiar with your individual needs.

Patent information at www.insulet.com/patents.

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