Pod will directly receive CGM values wirelessly and automate insulin delivery depending on your needs.

The system is designed to continue delivering insulin in the absence of your Controller or smartphone, so you will not be alerted that the Pod and display device are out of range of one another if you choose to leave your Controller and/or smartphone behind.

Although your Omnipod 5 System does not require the Controller to be nearby to continue your insulin delivery in Manual Mode or Automated Mode, the Controller and/or smartphone provide(s) you with important information about recent insulin delivery, alerts, and alarms that come from your Pod, and allows you to deliver a bolus.

> **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.

26.7. Deleting the Omnipod 5 App

If you delete the Omnipod 5 App from your smartphone, all your settings and insulin history will be removed. If you choose to download the Omnipod 5 App later, you will have to go through the setup process again, entering all your insulin therapy settings.

> **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.

Before you begin

- Use the pages at the end of this *User Guide* to write down all of your settings, in case you need them later. If you use a smartphone, you may wish to take screenshots or photos of your Omnipod 5 App settings to keep for future reference.
- If you wish to stop receiving insulin, remove your Pod.

To delete the Omnipod 5 App:

1. Open Google Play.
2. Tap Menu.
3. Tap My apps & game.
4. Tap on the app or game.
5. Tap Uninstall.

26.8. Device Complaints

If you have a problem with your System, contact Customer Care at 1-800-591-3455. You may be asked to share device data.

To share device data:

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

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

If this occurs: Data upload is pending.

If this occurs: Data upload is full.

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Appendix

Summary of Settings and Options

The options for the various Omnipod 5 Automated Insulin Delivery System settings are:

Time format	12-hour
Time zone	GMT-11:00 to GMT+13.00.
Daylight Savings Time	ON or OFF. Default based on date and time zone.
Date format	MM/DD/YYYY
Screen time-out	30, 60, 120 seconds. Default is 30 seconds.
PIN	4 digits from 0 to 9.
Dexcom G6 transmitter serial number	6 characters.
Maximum Basal Rate	Select one value between 0.05-30 U/hr in 0.05 U/hr increments. Default is 3.00 U/hr.
Basal rate	Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	Maximum of 12.
Basal rate segments	24 per Basal Program.
Activity feature	Range: 1 to 24 hrs In increments of 1 hour
Temp basal	%, units/hr, or OFF. Default is OFF. Duration: 30 min to 12 hrs in 30-min increments.
Temp basal (set to %)	Range: 100% decrease (0 U/hr) to 95% increase from current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in increments of 0.05 U/hr.
Temp basal presets	Maximum of 12.
Glucose Goal Range (for blood glucose history)	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments .
BG reminder	ON or OFF. Default is OFF. Maximum of 4 active at one time. A reminder can occur between 30 min and 4 hrs after a bolus is started. Set in 30-minute increments.
Custom reminder	Maximum of 4. Set to Daily, One time only, OFF.
Target Glucose value	Maximum of 8 segments; 110 to 150 mg/dL in 10 mg/dL increments.

Correct Above threshold	Maximum of 8 segments; Target Glucose to 200 mg/dL in 1 mg/dL increments.
Minimum Glucose for Calculations	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL.
Insulin-to-carb (IC) ratio	Maximum of 8 segments; 1 to 150 g carb/U in 0.1 g carb/U increments.
Correction (sensitivity) factor	Maximum of 8 segments; 1 to 400 mg/dL in 1 mg/dL increments. Default is 50 mg/dL.
Reverse Correction	ON or OFF. Default is ON.
Duration of insulin action	2 to 6 hours in 30-minute increments. Default is 4 hours.
Bolus size	Range: 0.05-30 U in 0.05 U increments.
Extended bolus	%, Units, or OFF. Default is OFF. 30 minutes to 8 hours in 30-minute increments.
Pause insulin	30 minutes to 2 hours.
Low Pod Insulin advisory	10 to 50 units in 1-unit increments. Default is 10.0 U.
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours.
Pod Shut-Off timer	OFF, or 1 to 24 hours in 1-hour increments. Default is OFF.
History screen display	Rolling 90-day period.
Language	English.

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 (0°C to 20°C): 7 minutes

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

Reservoir volume (deliverable): 200 units

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

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

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

Operating relative humidity range: 20 to 85%, non-condensing

Storage relative humidity range: 20 to 85%, non-condensing

Operating atmospheric pressure: 700 hPa to 1060 hPa

Storage atmospheric pressure: 700 hPa to 1060 hPa

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.05 U

Flow Capability:

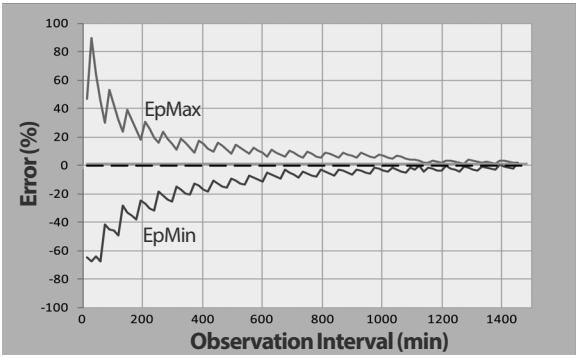
Prime rate: 0.05 unit per second.
Basal: Programmable by the user in 0.05 U increments up to 30.0 U per hour
Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

Delivery accuracy (tested per IEC 60601-2-24):

Basal: ± 5% at rates ≥ 0.05 U/hr
Bolus: ± 5% for amounts ≥ 1.0 unit
± 0.05 units for amounts < 1.0 unit

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

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



Controller Specifications

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

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 5 feet (1.5 m) of each other. Depending on the location, the communication distance may handle separations up to 50 feet (15 meters) 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 mAh

Battery life: Full charge covers approximately 2 days of typical use after 2 years.

Controller Service Life: 2 Years

Shelf Life (Starter Kit): 18 months

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

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

Dexcom Specifications

For information about Dexcom operating specifications, see the *Dexcom G6 CGM System User Guide*.

Protection from Over-Infusion or Under-Infusion

The Pod software monitors the infusion rate. If an error that would result in over-infusion or under-infusion is detected and cannot be corrected, insulin delivery stops, and an alarm sounds.

Blockage (occlusion) detection

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin which can lead to hyperglycemia or diabetic ketoacidosis (DKA) (see" Blockage Detected" on page 163).

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.

Performance Characteristics

The Omnipod 5 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Insulet.

Delivery performance characterization

Basal Delivery: In order 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). Water was used as a substitute for insulin. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

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.

Bolus Delivery: In order 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). Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid delivered was used to assess pumping accuracy.

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 below 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) **(% of settings)**	<0.0125 (<25%)	0.0125-0.0375 (25-75%)	0.0375-0.045 (75-90%)	0.045-0.0475 (90-95%)	0.0475-0.0525 (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) **(% of settings)**	0.0525-0.055 (105-110%)	0.055-0.0625 (110-125%)	0.0625-0.0875 (125-175%)	0.0875-0.125 (175-250%)	>0.125 (>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) (% of settings)	<1.25 (<25%)	1.25-3.75 (25-75%)	3.75-4.50 (75-90%)	4.50-4.75 (90-95%)	4.75-5.25 (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) (% of settings)	5.25-5.50 (105-110%)	5.50-6.25 (110-125%)	6.25-8.75 (125-175%)	8.75-12.50 (175-250%)	>12.50 (>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) (% of settings)	<7.5 (<25%)	7.5-22.5 (25-75%)	22.5-27.0 (75-90%)	27.0-28.5 (90-95%)	28.5-31.5 (95-105%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	72/72 (100%)
Amount (Units) (% of settings)	31.5-33.0 (105-110%)	33.0-37.5 (110-125%)	37.5-52.5 (125-175%)	52.5-75.0 (175-250%)	>75.0 (>250%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)

Omnipod 5 System Label Symbols

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

Symbol	Meaning
	Single-use only
	Consult accompanying documents
STERILE EO	Sterilized using ethylene oxide
	Date of manufacture
LOT	Batch code
	Use by date
REF	Reference number
SN	Serial number
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 25 feet (7.6 meters) for up to 60 minutes
	Pod

Symbol	Meaning
	MR unsafe
	Do not use if package is damaged
	Type BF applied part
	Manufacturer
	Keep dry
	Storage temperature, Operational temperature
	Storage relative humidity, Operational relative humidity
	Storage atmospheric pressure, Operational atmospheric pressure
	Non-pyrogenic fluid path
	Charging cable

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
	Do not dispose with household waste
CE	Marking of conformity

Symbol	Meaning
Rx ONLY	Prescription only
RoHS	RoHS compliant
EC REP	Representative in the European Community

Omnipod 5 System Notice Concerning Interference

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

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 the equipment does cause harmful interference to radio and television reception, the user is encouraged to try to correct the interference by one of the following measures:

- Move or relocate the Omnipod 5 System.
- Increase the separation between the Omnipod 5 System and the other device that is emitting or receiving interference.
- Consult the dealer or an experienced radio/TV technician for help.

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 CGM wireless communication definition

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

For additional information on communication errors in the Omnipod 5 System, see Chapter 21. 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.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod 5 System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

The Omnipod 5 System has been tested and found to have acceptable immunity to emissions from RFID and EAS systems.

The Omnipod 5 System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment.

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod 5 System fails due to electromagnetic disturbances, you may need to replace it.

Portable and mobile radio frequency (RF) communications equipment can affect the function of medical electrical equipment.

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

Care should be taken if the Omnipod 5 System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod 5 System should be observed to verify normal operation in this setting.

The Omnipod 5 System communicates by low-level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The Omnipod 5 System communicates with the following characteristics:

Frequency: 2.400-2.480 GHz, digitally modulated, with an effective Isotropic radiated power of 1.14mW

The Omnipod 5 System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

> **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.

Electromagnetic Emissions

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should ensure that is used in such an environment.

Emissions	Compliance according to	Electromagnetic environment
RF Emissions (CISPR11)	Group 1	The Pod, Controller, and CGM emit low-level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected.
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments, including domestic establishments.
Harmonic Emissions (IEC 61000-3-2)	Class A	
Voltage Fluctuations/ Flicker Emissions (IEC 61000-3-3)	$P_{st} \leq 1.0$ $P_{lt} \leq 0.65$ $d_c \leq 3\%$ $d_{max} \leq 4\%$ $d_{(t)} \geq 200$ ms during a voltage change should be $\leq 3\%$	

Electromagnetic Immunity

The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.

Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ± 15 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.

Electromagnetic Immunity			
Electrical Fast Transient/burst (IEC 61000-4-4)	± 2 kV power supply lines ± 2 kV Input DC Power Port ± 1 kV input/output lines	± 2 kV power supply lines ± 2 kV Input DC Power Port ± 1 kV input/ output lines	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Conducted Disturbances induced by RF fields (IEC 61000-4-6)	3V 150 KHz-80 MHz 6V in ISM and amateur radio bands between 150 KHz and 80 MHz	3V 150 KHz-80 MHz 6V in ISM and amateur radio bands between 150 KHz and 80 MH	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

Electromagnetic Immunity			
Voltage Dips, Short Interruptions, Voltage Variations on Power Supply input lines (IEC 61000-4-11)	70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250/300 cycles	70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical domestic, commercial, or hospital environment. If the user requires continued operation during power mains interruptional, it may be necessary to use an uninterruptible power supply or a battery.
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz–2.7 GHz	10 V/m	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

The table below lists the immunity levels at specific test frequencies for testing the effects of some wireless communication equipment. The frequencies and services listed in the trable are representative examples in various locations where the System may be used.

Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380–390	TETRA 400	Pulse modulation b)18Hz	1.8	0.3	27

450	430–470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704–787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800. ODEM 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
1720 1845 1970	1700–1990	G GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2450-2570	Bluetooth WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	0.2	0.3	9
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9

a) For some services, only the uplink frequencies are included
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be worst case.

This table lists the immunity levels at specific test frequencies for Proximity Magnetic Fields Range of 9 kHz to 13.56 MHz

Test Frequency	Modulation	Immunity Test Level (A/m)
30kHz a)	CW	8
134.2 kHz	Pulse modulation b) 2.1 kHz	65 c)
13.56 MHz	Pulse modulation b)	7.5 c)

a) This test is applicable only to ME equipment and ME systems intended in a HOME HEALTHCARE ENVIRONMENT.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) RMS before modulation is applied

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. In order to assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Customer's Bill of Rights

Mission Statement

Insulet Corporation is dedicated to designing, developing, and distributing products that provide superior treatment options and lifelong health benefits for people with diabetes.

Scope of Services

Insulet Corporation's scope of services is limited to providing the Omnipod 5 Automated Insulin Delivery System.

The Omnipod 5 System consists of the Pod and the handheld, wireless Controller or compatible smartphone running the Omnipod 5 App, which programs the Pod with insulin delivery instructions.

Compliance

The Omnipod 5 Automated Insulin Delivery System is manufactured and distributed by Insulet Corporation. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact us at 1-800-591-3455 (from outside the United States, 1-978-600-7850).

Inquiries

Representatives are available to answer product-related inquiries 24 hours per day at our toll-free number, 1-800-591-3455 (from outside the United States,

1-978-600-7850). For all other questions, concerns, or complaints, please contact us between the hours of 8:30 am and 6:00 pm Eastern Time, Monday through Friday, at 1-800-591-3455 (from outside the United States, 1-978-600-7850). We will respond immediately whenever possible; some issues may take up to 14 days to resolve.

CHAP Accredited

Insulet Corporation has been accredited by the Community Health Accreditation Program (CHAP) since 2007. To learn more about CHAP or to communicate concerns that you have been unable to resolve directly with the company, please visit www.chapinc.org or call CHAP at 1-800-656-9656.

Customer's Bill of Rights and Responsibilities

You have the right to:

1. Receive considerate and respectful service.
2. Receive service without regard to race, creed, national origin, sex, age, disability, sexual orientation, illness, or religious affiliation.
3. Expect confidentiality of all information pertaining to you, your medical care and service. Please review our HIPAA Privacy Notice later in this section.
4. Receive a timely response to your request for service.
5. Receive continued service.
6. Select the medical equipment supplier of your choice.
7. Make informed decisions regarding your care planning.
8. Understand what services will be provided to you.
9. Obtain an explanation of charges, including policy for payment.
10. Agree to or refuse any part of the plan of service or plan of care.
11. Voice complaints without fear of termination of service or other reprisals.
12. Have your communication needs met.

You have the responsibility to:

1. Ask questions about any part of the plan of service or plan of care that you do not understand.
2. Use the equipment for the purpose for which it was prescribed, following instructions provided for use, handling care, safety and cleaning.
3. Supply Insulet Corporation with insurance information necessary to obtain payment for services.
4. Be accountable for charges not covered by your insurance. You are responsible for settlement in full of your account.

5. Notify us immediately of:
    a. Equipment failure, damage, or need of supplies.
    b. Any change in your prescription or physician.
    c. Any change or loss in insurance coverage.
    d. Any change of address or telephone number, whether permanent or temporary.

Limited Express Warranty, Disclaimer, and Limitation of Remedies for the Controller and Pods

LIMITED EXPRESS WARRANTY, DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES FOR THE Omnipod 5 AUTOMATED INSULIN DELIVERY SYSTEM HANDHELD CONTROLLER AND PODS (United States of America)

LIMITED EXPRESS WARRANTY COVERAGE

Limited Warranty Coverage for the Omnipod 5 Automated Insulin Delivery System Handheld Controller

Subject to the terms and conditions stated herein ("Limited Express Warranty"), Insulet Corporation ("Insulet") warrants to you, the original purchaser of the Omnipod 5 Automated Insulin Delivery System ("Omnipod 5 System"), that, if Insulet determines, during the period of four (4) years from the date of purchase, that the Omnipod 5 System handheld hardware Controller ("Controller") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will either repair or replace, at its sole option, the Controller. This four-year (4) warranty period applies only to new Controllers and, in the event the Controller is repaired or replaced, the warranty period shall not be extended or reset. Thus, if Insulet replaces a Controller under this Limited Express Warranty, the warranty coverage for the replacement Controller shall expire four (4) years from the date of purchase of the original Controller.

Limited Warranty Coverage for the Omnipod 5 Automated Insulin Delivery System Pods

Subject to this Limited Express Warranty, Insulet warrants to you, the original purchaser of the Omnipod 5 Automated Insulin Delivery System, that, if Insulet determines, during the period of eighteen (18) months from the date of manufacture and seventy-two (72) hours from the time of activation, that an unexpired Omnipod 5 Automated Insulin Delivery System Pod ("Pod") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will replace the Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e., occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before and on or before a time no more than seventy-two (72) hours before you notify Insulet of the claim).

This eighteen (18) month and seventy-two (72) hour warranty period apply only to new Pods and, in the event a Pod is replaced, the warranty period shall not be extended or reset. Thus, if Insulet replaces a Pod under this Limited Express Warranty, the warranty coverage for the replacement Pod shall expire either eighteen (18) months from the manufacture date of the original Pod or seventy-two (72) hours from the time of activation of the original Pod, whichever occurs first.

LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS

Claim Procedure

To be eligible for this Limited Express Warranty, you must notify Insulet of the claimed defect with the Controller or the Pod within the applicable warranty periods by calling Customer Care at 1-800-591-3455 (from outside the USA: 1-978-600-7850). For a claim involving the Controller, you must provide the Controller serial number and a description of the claimed defect. For a claim involving a Pod, you must provide the Pod lot number and a description of the claimed defect. You may also be required to verify the date of purchase of the Controller and/or the Pod, the manufacture date of the Pod and the time of activation of the Pod. Your failure to follow any of the above steps may result in the denial of coverage under this Limited Express Warranty. Unless Insulet elects to repair the Controller (which may include, but is not limited to, a repair kit or replacement part(s) Insulet provides) or refers you to a third party, you must obtain a prior authorization and return the Controller or the Pod to Insulet. The Controller or Pod must be properly packaged and returned to Insulet according to the instructions provided in the Return Merchandise Authorization, or RMA, Kit. With a prior authorization, Insulet will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the Controller or Pod to Insulet under this Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover repairs performed or replacements provided by any person or entity other than Insulet, except those performed or provided by third parties to which you were explicitly referred by Insulet.

Proof of Purchase

In order to verify the date of purchase, the date of manufacture, or the time of activation and to determine if the claim under this Limited Express Warranty is within the applicable warranty periods, Insulet may require that you provide a valid proof of purchase, manufacture or activation. Your failure to provide a valid proof of purchase, manufacture or activation, as determined by Insulet, may result in the denial of coverage under this Limited Express Warranty.

Exclusions

This Limited Express Warranty covers only the original purchaser and cannot be transferred or assigned with the sale, rental or other transfer of the Controller or of the Pod to any other person or entity.

This Limited Express Warranty will apply only if the Controller or the Pod at issue has been used in accordance with the Omnipod 5 Automated Insulin Delivery System User Guide and/or other written instructions provided by Insulet. THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE Controller OR THE POD HAVE BEEN:

- Altered, changed or modified by any person or entity other than Insulet;
- Opened, serviced or repaired by any person or entity other than Insulet;
- Damaged by an act of God or other "force majeure" like event;
- Damaged by misuse, abuse, negligence, accident, unreasonable use, or improper handling, care or storage;
- Damaged by wear and tear, causes unrelated to defective materials or workmanship or other circumstances outside of the reasonable control of Insulet.

This Limited Express Warranty does not apply to test strips, batteries that are not provided by Insulet, other accessories, or related products provided by third parties (e.g., data management tools, CGMs).

This Limited Express Warranty does not extend to design defects (i.e. claims that the Controller or the Pod should have been designed in a different way).

DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES

REPAIR OR REPLACEMENT AS PROVIDED UNDER THE ABOVE LIMITED EXPRESS WARRANTY OF THE CONTROLLER OR THE POD IS YOUR EXCLUSIVE REMEDY AND THE ENTIRE OBLIGATION OF INSULET. THIS EXCLUSIVE REMEDY SHALL NOT BE DEEMED TO HAVE FAILED ITS ESSENTIAL PURPOSE SO LONG AS INSULET IS WILLING AND ABLE TO REPAIR OR REPLACE A CONTROLLER OR A POD WITH DEFECTS IN MATERIALS OR WORKMANSHIP IN THE MANNER PRESCRIBED BY THE ABOVE LIMITED EXPRESS WARRANTY.

ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.

IN NO EVENT SHALL INSULET CORPORATION, ITS SUPPLIERS, DISTRIBUTORS, SERVICE PROVIDERS, AND/OR AGENTS BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY A DEFECT IN THE CONTROLLER OR A POD OR BY A BREACH OF THE ABOVE LIMITED EXPRESS WARRANTY, WHETHER SUCH CLAIM IS BASED IN WARRANTY, CONTRACT, TORT OR OTHERWISE.

Important Additional Provisions

Insulet Corporation does not warrant the suitability of the Controller or the Pod or the Omnipod 5 Automated Insulin Delivery System for any specific person as health care and treatment are complex subjects requiring the services of qualified health care providers.

The above Limited Express Warranty gives you specific legal rights, and you may also have other rights which vary by jurisdiction. The above Limited Express Warranty applies only to Controllers and the Pods that were originally sold for use in the United States of America.

Note that some jurisdictions do not allow the exclusion of implied warranties or the limitation of indirect, special, incidental, or consequential damages, so the above exclusions or limitations may not apply to you. Insulet Corporation's liability in such jurisdictions shall be limited to the maximum extent permitted by law. Such limitations shall include but are not limited to the following: any implied warranties that cannot be disclaimed under the law of a particular jurisdiction are limited, to the extent allowed by law, to the time period covered by the above limited express warranty, or to the applicable time period provided by law, whichever period is shorter.

No Other Warranty or Agreement

Unless modified in writing and signed by both Insulet and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between Insulet and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in a Controller, a Pod, or an Omnipod 5 Automated Insulin Delivery System. No employee, agent or other representative of Insulet or any other party is authorized to make any product warranty or agreement applicable to a Controller, a Pod, or an Omnipod 5 Automated Insulin Delivery System in addition to those made in the foregoing..

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included with the Omnipod 5 Automated Insulin Delivery System, please return any Omnipod 5 Automated Insulin Delivery System products (including any Controller and Pods) to Insulet in exchange for a full refund. Failure to return such Omnipod

5 Automated Insulin Delivery System products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

Rev: January 2021

HIPAA Privacy Notice

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

This notice of privacy practices (the "HIPAA Privacy Notice") describes how we may use and disclose your Medical Information to carry out treatment, payment or health care operations and for other purposes that are permitted or required by law, including by the Health Insurance Portability and Accountability Act, and all regulations issued thereunder ("HIPAA"). It also describes your rights to access and control your Medical Information. As used herein, "Medical Information" is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health or condition and related health care services.

Uses and Disclosures of Medical Information

We will only use and disclose your Medical Information as permitted by law. Except for disclosures outlined in this HIPAA Privacy Notice and/or permitted by law, we will obtain your written authorization before using your Medical Information or disclosing it to any outside persons or organizations. Most uses or disclosures of your Medical Information constituting psychotherapy notes will be made only after receiving your written authorization. We will not use or disclose your Medical Information for purposes of marketing, except as permitted by law and/or outlined in this HIPAA Privacy Notice. We will not sell your Medical Information, without first obtaining your written authorization. You may revoke any written authorization you have provided to us at any time, except to the extent that we have made any uses or disclosures of your Medical Information in reliance on such authorization. To revoke a previously issued authorization, please send your request in writing, along with a copy of the authorization being revoked to our Privacy Officer. If a copy of the applicable authorization is not available, please provide a detailed description and date of the same to our Privacy Officer.

There are some situations where we may use or disclose your Medical Information without your prior written authorization, as described further below:

Uses and Disclosures of Your Medical Information Related to the Treatment and Services Provided By Us

Treatment, Payment and Health Care Operations: We may use your Medical Information for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive without your authorization. We may use or disclose Medical Information about you without your authorization for several other reasons.

Example of Treatment: In connection with treatment, we may use your Medical Information to provide you with one of our products.

Example of Payment: We may use your Medical Information to generate a health insurance claim and to collect payment on invoices for services and/or medical devices provided.

Example of Health Care Operations: We may use your Medical Information in order to process and fulfill your orders and to provide you with customer service.

Appointment Reminder and Other Communications: We may use or disclose your Medical Information without your prior written authorization to provide you or others with, among other things, (i) appointment reminders; (ii) product/supply reorder notifications; and/or (iii) information about treatment alternatives or other health-related products and services that we provide.

Family, Friends and Emergencies: If you require emergency treatment and we are unable to obtain your consent, we may disclose your Medical Information to a family member or relative who is involved in your care.

Marketing: We may use or disclose your Medical Information to provide you with marketing communications about the health-related products and services that we provide, and about products, services, treatment or healthcare providers that may be of interest to you.

Additional Categories of Uses and Disclosures

Required By Law: We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.

Public Health: We may disclose your Medical Information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for the purpose of preventing or controlling disease, injury or disability. We may also disclose your Medical Information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

Communicable Diseases: We may disclose your Medical Information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight: We may disclose Medical Information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the healthcare System, government benefit programs, other government regulatory programs and civil rights laws.

Food and Drug Administration: We may disclose your Medical Information to a person or company as directed or required by the Food and Drug Administration: (i) to collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (ii) to track FDA-regulated products, (iii) to enable product recalls, repairs or replacement, or look back (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of look back), or (iv) to conduct post-marketing surveillance.

Legal Proceedings: We may disclose your Medical Information in the course of any judicial or administrative proceeding (i) in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), and (ii) in certain conditions in response to a subpoena, discovery request or other lawful process, after we receive satisfactory assurance that the party seeking the information has reasonably attempted to notify you of the request or has reasonably attempted to secure a qualified protective order (in a court or administrative tribunal, or by stipulation) to limit disclosure of your Medical Information.

Law Enforcement: We may disclose Medical Information, as long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include: (i) legal processes otherwise required by law, (ii) limited information requests for identification and location purposes, (iii) pertaining to victims of a crime, (iv) suspicion that death has

occurred as a result of criminal conduct, (v) in the event that a crime occurs on the premises of the practice, and (vi) medical emergency in which it is likely that a crime has occurred.

Research: We may disclose your Medical Information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your Medical Information.

Criminal Activity: Consistent with applicable federal and state laws, we may disclose your Medical Information, if we believe the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.

Military Activity and National Security: When the appropriate conditions apply, we may use or disclose Medical Information of individuals who are Armed Forces personnel (i) for activities deemed necessary by appropriate military command authorities, or (ii) to foreign military authority if you are a member of that foreign military service. We may also disclose your Medical Information to authorized federal officials for conducting national security and intelligence activities.

Workers' Compensation: We may disclose your Medical Information as authorized to comply with workers' compensation laws and other similar legally-established programs.

Inmates: We may use or disclose your Medical Information to a correctional institution or law enforcement official if you are an inmate of a correctional facility and your physician created or received your Medical Information in the course of providing care to you, and disclosure is necessary for (i) providing you with health care; (ii) the health and safety of you, other inmates, or others at the correctional institution; or (iii) the administration and maintenance of the safety, security, and good order of the correctional institution.

Required Uses and Disclosures: Under the law, we must make disclosures to you when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements of HIPAA.

Non-identifiable Information: We may use or disclose your Medical Information if we have removed from it any information that is personally identifiable to you.

Your Rights

The following is a statement of your rights with respect to your Medical Information and a brief description of how you may exercise these rights.

You Have the Right to Inspect and Copy Your Medical Information: This means you may inspect and obtain a copy of Medical Information about you, provided, however, that applicable law may limit your ability to inspect or copy certain types of records. In certain circumstances, if we deny your request to review Medical Information, you may have a right to have this decision reviewed. If you would like to make a request to review your Medical Information, please download our Request Form at

https://omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. If your request is honored, we may charge a nominal fee for photocopying expenses. Please contact our Privacy Officer if you have questions about access to your Medical Information.

You May Have the Right to Amend Your Medical Information: If you believe that the Medical Information we have about you is incorrect or incomplete, you may ask us to make an amendment to your Medical Information. You may request an amendment as long as the Medical Information is still maintained in our records. If you would like to make a request to review your Medical Information, please download our Request Form at

https://omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information.

You Have the Right to Request a Restriction of Your Medical Information: You may ask us not to use or disclose any part of your Medical Information for the purposes of treatment, payment or healthcare operations. You may also request that any part of your Medical Information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this HIPAA Privacy Notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. Except as otherwise provided in this HIPAA Privacy Notice, we are not required to agree to a restriction that you may request. We are required to agree to your request to restrict disclosure of your Medical Information to a health plan if (i) the disclosure is to carry out payment or healthcare operations and is not otherwise required by law; and (ii) your Medical Information pertains solely to a healthcare item or service for which you or someone (other than the health plan) on your behalf, has paid us in full. If we agree to the requested restriction, we may not use or disclose your Medical Information in violation of that restriction unless it is needed to provide emergency treatment. If you would like to request a restriction of the use of your Medical Information, please download our Request Form at

https://omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting a restriction of the use of your Medical Information.

You Have the Right to Request to Receive Confidential Communications From Us By Alternative Means or at an Alternative Location: We will accommodate reasonable requests to receive confidential communications from us by alternate means or at an alternative location. We may also limit this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not request an explanation from you as to the basis for the request. Please make this request in writing to our Privacy Officer.

You Have the Right to Receive an Accounting of Certain Disclosures We Have Made, if any, of Your Medical Information: This right applies to disclosures for purposes other than treatment, payment or healthcare operations as described in this HIPAA Privacy Notice. It excludes disclosures we may have made to you, for a facility directory, to family members or friends involved in your care, for notification purposes, for national security or intelligence purposes, to correctional institutions or law enforcement officials, or as part of a limited data set. You have the right to receive specific information regarding these disclosures that occurred after April 14, 2003, or as otherwise provided for under applicable law. You may request a shorter timeframe. The right to receive this information is subject to certain exceptions, restrictions and limitations. If you would like to request an accounting of certain disclosure of your Medical Information, please download our Request Form at

https://omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an accounting of the disclosures of your Medical Information.

You Have The Right to Obtain a Copy of this HIPAA Privacy Notice: You have the right to obtain a paper copy of this HIPAA Privacy Notice from us, upon request, even if you have agreed to accept this notice electronically. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request form at

https://omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form.

Our Duties

Generally: We are required by law to maintain the privacy and security of your Medical Information and to provide you with notice of our legal duties and privacy practices with respect to Medical Information, and to notify you if there is a breach resulting in disclosure of your unsecured Medical Information.

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the "Revised HIPAA Privacy Notice"). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our website at https://Omnipod.com. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request Form at

https://omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form.

What To Do If You Have a Problem or Question

If you have any further questions relating to this HIPAA Privacy Notice or if you have a problem or complaint, please contact us in writing or by phone at:

Insulet Corporation
Attn: Privacy Officer
100 Nagog Park
Acton, MA 01720
866-941-0155

Furthermore, if you believe that Insulet has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Secretary of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201 or by calling (877) 696-6775. Insulet will not retaliate against you for filing such a complaint.

Effective Date: August 11, 2004

Revision Dates: April 1, 2009, September 20, 2013, April 22, 2014 and September 2, 2014

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My Settings

Use these pages to keep track of your important settings. Remember to update your information if you change or add settings.

Basal Program 1

Name_____ **Basal rate**

midnight	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr

Basal Program 2

Name_____ **Basal rate**

midnight	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr

Basal Program 3

Name_____ **Basal rate**

midnight	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr

Basal Program 4

Name_____ **Basal rate**

midnight	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr
_____	to	_____	_____	U/hr

Target Glucose

Time segment			**Target Glucose:** Bolus Calculator aims for this value		**Correct Above:** Suggest correction if glucose is above	
midnight	to	_____	_____	mg/dL	_____	mg/dL
_____	to	_____	_____	mg/dL	_____	mg/dL
_____	to	_____	_____	mg/dL	_____	mg/dL
_____	to	_____	_____	mg/dL	_____	mg/dL
_____	to	_____	_____	mg/dL	_____	mg/dL
_____	to	_____	_____	mg/dL	_____	mg/dL
_____	to	_____	_____	mg/dL	_____	mg/dL
_____	to	_____	_____	mg/dL	_____	mg/dL

Correction Factor

Correction Factor for each time segment			**1 unit of insulin decreases glucose by**
midnight	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL

Insulin-to-Carbohydrate Ratio (IC Ratio)

IC Ratio for each time segment			**1 unit of insulin covers**
midnight	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb

Duration of Insulin Action

Time that insulin remains "active" in the body after a bolus _____ hrs

Temp Basal Presets

Name	**Rate**	**(circle measurement)**
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %

Favorite Foods

Name	**Grams of carbohydrates**
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb

Max Basal Rate

Upper limit for basal rates in a Basal Program or temp basal ___U/hr

Max Bolus

Maximum amount of insulin that you can request in a single bolus ___U/hr

My Notes

omnipod 5

Pod shown without the necessary adhesive.

Insulet Corporation
100 Nagog Park
Acton, MA 01720
1-800-591-3455 | 1-978-600-7850
omnipod.com

PT-000369

FCC ID: 2ADINN5004L
Controller

FCC ID: RBV-029
Pod

FCC ID: RBV-029C
SAW Pod

Reference #: PDM-USA-H001-MG PT-000369-AW Rev. 007 01/22