Summary of Safety and Clinical Performance

Insulet Corporation

Omnipod® 5 Automated Insulin Delivery System

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This Summary of Safety and Clinical Performance (SSCP) is intended to provide Healthcare Professionals with access to an updated extended summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the User Guide/Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to healthcare providers, intended users, or patients.

1) DEVICE IDENTIFICATION AND GENERAL INFORMATION

A) DEVICE TRADE NAME(S)

Omnipod® 5 Automated Insulin Delivery System

B) MANUFACTURER'S NAME, ADDRESS, AND SINGLE REGISTRATION NUMBER

Insulet Corporation

100 Nagog Park,

Acton, MA 01720

US-MF-000007948

C) BASIC UNIQUE DEVICE IDENTIFICATION-DEVICE IDENTIFIER

The Basic UDI-DI for the Omnipod 5 Automated Insulin Delivery System is 0385083000145.

D) YEAR WHEN THE DEVICE WAS FIRST CE-MARKED

2022.

E) MEDICAL DEVICE NOMENCLATURE DESCRIPTION/TEXT

EMDN Code: Z120402160103 (Portable Insulin Microinfusers Integrable to Systems for Continuous Glucose Monitoring)

F) CLASS OF DEVICE

Class III device in accordance with Annex VIII, Rule XXII of the EU Medical Device Regulation (MDR) 2017/745.

G) AUTHORISED REPRESENTATIVE NAME, ADDRESS, AND SINGLE REGISTRATION NUMBER

Insulet Netherlands B.V.

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SRN: NL-AR-000002337

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PRRC: Claire Verheijen

H) NOTIFIED BODY (NB) AND THE NB'S SINGLE IDENTIFICATION NUMBER

The name of the Notified Body (NB) that will validate this SSCP is BSI -NL and the NB's single identification number is 2797.

2) INTENDED USE OF THE DEVICE

A) INTENDED PURPOSE

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

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

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

B) INDICATION(S) AND INTENDED/TARGET POPULATION(S)

Indications for use

- For the management of type 1 diabetes in persons aged 2 and older requiring insulin.
- Operates as an automated insulin delivery system when used with compatible Continuous Glucose Monitors (CGM).
    - When in automated mode, the Omnipod 5 System is designed to assist people with type 1 diabetes in achieving glycaemic targets set by their healthcare providers. It is intended to modulate (increase, decrease or suspend) insulin delivery to operate within predefined threshold values using current and predicted CGM values to maintain blood glucose at variable target glucose levels, thereby reducing glucose variability. This reduction in variability is intended to lead to a reduction in the frequency, severity, and duration of both hyperglycaemia and hypoglycaemia.
- Can also operate in a manual mode that delivers insulin at set or manually adjusted rates.

Target Populations

Intended users: The Omnipod 5 System is designed for people with type 1 diabetes of ages 2 years and older who have a prescription for NovoLog®/NovoRapid®, Humalog® or Admelog®/Insulin lispro Sanofi® U-100 insulin and who are able to understand and follow the instructions for use.

Intended patient population: People with type 1 diabetes of ages 2 years and older who have a prescription for NovoLog®/NovoRapid®, Humalog® or Admelog®/Insulin lispro Sanofi® U-100 insulin and who are able to understand and follow the instructions for use.

C) CONTRAINDICATIONS AND/OR LIMITATIONS

The Omnipod 5 System is NOT recommended for people who:

- Are unable to monitor blood glucose levels as recommended by their healthcare provider

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

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

3) DEVICE DESCRIPTION

A) DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

The Omnipod 5 Automated Insulin Delivery System is a single hormone insulin delivery system intended for the management of type 1 diabetes.

The Omnipod 5 System is a hybrid-closed loop insulin delivery system that can operate in either Manual Mode, where it functions as a standard insulin pump delivering at pre-programmed basal rates, or Automated Mode, delivering insulin automatically based on the calculations of the automated insulin delivery algorithm. The algorithm takes into account several factors including the user's current CGM value and trend, Total Daily Insulin (TDI), and pre-set target glucose.

At any time, regardless of Mode, the user has the option to deliver a bolus dose of insulin, either by manually inputting a value, or by receiving a suggested dose from the Bolus Calculator that takes into account several factors including CGM value and trend, user-entered carbohydrates, and target glucose.

The Omnipod 5 Automated Insulin Delivery System is comprised of two components:

- Omnipod 5 Pod (Infusion pump with automated insulin delivery algorithm).
- Omnipod 5 App (software), installed on the Omnipod 5 Controller (otherwise known as the Insulet-provided locked-down controller).

The Figure below shows the Omnipod 5 System with the interoperable Dexcom G6 CGM.

B) PREVIOUS GENERATION(S) OR CONFIGURATIONS OF THE DEVICE

Omnipod 5 Controller Kit configurations:

Part #	Model #	Product Description
PT-000973-YY	SKT-XXX-M001-G-MG-XXX	ASM, Omnipod® 5, Starter Kit XXX-XXX (mg/dL)
PT-000973-YY	SKT-XXX-M001-G-MM-XXX	ASM, Omnipod® 5, Starter Kit XXX-XXX (mmol/L)
PT-000974	PDM-M001-G-MG	ASM, Omnipod® 5, Controller Kit (mg/dL)
PT-000975	PDM-M001-G-MM	ASM, Omnipod® 5, Controller Kit (mmol/L)
PT-001077	SKS-M001-10-MG-XXX	ASM, Omnipod 5 Starter Set, XXX-MG
PT-001078	SKS-M001-10-MM-XXX	ASM, Omnipod 5 Starter Set, XXX-MM

* XXX denotes country and/or language and YY denotes number assigned to kit variant.

Omnipod 5 Pod configurations:

Part #	Model #	Product Description
PT-000438	POD-BLE-H1-529	ASM, Sterile, 10-Pack Pod, Omnipod® 5
PT-000536	POD-BLE-H1-525	ASM, Sterile, 5-Pack Pod, Omnipod® 5
PT-000435 PT-000886 PT-001049	POD-BLE-H1-520	ASM, Sterile, 1 Pod Sealed Tray, Omnipod® 5

C) INFORMATION ABOUT MEDICINAL SUBSTANCES IN THE DEVICE, IF ANY

There is no medicinal substance within the device.

The Omnipod 5 System is indicated for use with Novolog/NovoRapid, Humalog and Admelog/Insulin lispro Sanofi U-100 insulin.

D) DESCRIPTION OF ACCESSORIES/OTHER DEVICES AND PRODUCTS, WHICH ARE INTENDED TO BE USED IN COMBINATION WITH THE DEVICE, IF ANY

i) Description of Accessories Intended to be Used in Combination with the Device

N/A

ii) Description of Other Devices and Products Intended to be Used in Combination with the Device

Dexcom G6 Continuous Glucose Monitor and the Dexcom App are required for use of the Omnipod 5 System in Automated Mode.

4) RISKS AND WARNINGS

Users are advised to contact their healthcare professional if they believe that they are experiencing side-effects related to the device or its use or if they are concerned about risks. This document is not intended to replace the user's consultation with their healthcare professional as and when needed.

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative (contact information provided in Section 1 of this SSCP) and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:
https://ec.europa.eu/health/md_sector/contact_en

A risk is defined as an exposure to potential harm and is determined based on its probability and severity. The probability is estimated based on relevant historical data and expert judgement. Determination of

acceptable risk is based on achieving recognised standards of risk management, comparison of risks of alternative treatment options for the same intended patient population and treatment indication, and evaluation of clinical study data. Harm can refer to physical injury or damage to the health of people, or damage to property or the environment and so the term 'risk' includes both clinical and non-clinical harms.

A) RESIDUAL RISKS AND UNDESIRABLE EFFECTS

Residual risks are defined as those risks remaining after risk control measures have been implemented. If residual risks are not deemed acceptable, further risk control measures or modification of the device or intended use may be considered. Alternatively, manufacturers may gather and review data and literature to determine if the benefits of the intended use outweigh the residual risk. Undesirable effects can be understood as any unwanted side-effect/adverse event (AE) related to the device and that is experienced by the patient and/or can be diagnosed and/or measured in the patient.

Residual risks and potential side effects for this device under conditions of normal operation and normal use can be summarized as follows:

- Allergic reaction or skin irritation due to patient allergy or sensitivity to acrylic adhesives or skin irritation due to patient having fragile or easily damaged skin.
- Hyperglycaemia or hypoglycaemia (caused by inaccurate CGM values while the device is functioning as designed and under conditions of normal use).
- Infection and signs of infection such as bleeding, pain, and skin irritation including redness.

Potential Risks

- The Omnipod 5 System uses CGM values and trends to calculate insulin delivery. If the CGM values are inaccurate, the System could deliver an inaccurate dose of insulin which can lead to hypoglycaemia or hyperglycaemia.
- The Omnipod 5 System uses information and settings that you enter to calculate and adjust insulin delivery. If the information you enter is inaccurate, the System could deliver an inaccurate dose of insulin which can lead to hypoglycaemia or hyperglycaemia.
- Wearing a Pod might cause infection. Be aware of signs of infection, including bleeding, pain, and skin irritation (including redness). See your healthcare provider if irritation occurs.
- Kinks in the cannula or dislodging of the cannula can interrupt insulin delivery. Glucose that does not decrease after a bolus, or other unexplained high glucose, are signs of a blockage or other interruption in insulin delivery.
- Air bubbles in the Pod or cannula can affect insulin delivery. If there is a large amount of air in the Pod, the System could deliver an inaccurate dose of insulin which can lead to hypoglycaemia or hyperglycaemia.
- Infusion site complications like scar tissue and infection can make insulin delivery less effective. Glucose that does not decrease after a bolus, or other unexplained high glucose, is a sign of ineffective insulin delivery.
- Hardware defects, software glitches, and Pod failures can cause an interruption in insulin delivery. A Pod failure can lead to hyperglycaemia or diabetic ketoacidosis. Keep your Omnipod 5 Controller on and nearby to ensure you are notified of recent insulin delivery and important alarms and messages.

Adverse Events

The referenced User Guide (see Section 8B of this SSCP) contains a table that provides a full list of the adverse events that occurred during the 3-month Omnipod 5 System treatment phase. There were 3 severe hypoglycaemia events not attributable to the Omnipod 5 System automated insulin delivery or system malfunction and 1 DKA event from a suspected infusion site failure. Other related, but non-glycaemic adverse events included infection or irritation at infusion site (2 children, 2 adolescents/adults).

B) WARNINGS AND PRECAUTIONS

Note: refer to the referenced User Guide for all warnings and precautions.

Warnings & Precautions for Patients

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

ALWAYS promptly treat hyperglycaemia (high glucose) according to your healthcare provider's recommendations. Symptoms of hyperglycaemia include fatigue, thirst, excess urination, or blurry vision. If left untreated, hyperglycaemia can lead to diabetic ketoacidosis (DKA), or death. DO NOT wait to treat DKA. If left untreated, DKA can quickly lead to breathing difficulties, shock, coma, or death.

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.

See your healthcare provider if skin irritation occurs.

Additional general warnings include:

- Glucose below 3.9 mmol/L (70 mg/dL) may indicate hypoglycaemia (low glucose). Glucose above 13.9 mmol/L (250 mg/dL) may indicate hyperglycaemia (high glucose). Follow your healthcare provider's suggestions for treatment.
- Monitor your glucose with the guidance of your healthcare provider. Undetected hyperglycaemia or hypoglycaemia can result without proper monitoring. ALWAYS follow your healthcare provider's guidance on appropriate glucose monitoring to avoid hyperglycaemia and hypoglycaemia.
- 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.
- ONLY use rapid-acting U-100 NovoLog®/NovoRapid® (insulin aspart), Humalog® (insulin lispro), and Admelog®/Insulin lispro Sanofi® (insulin lispro) insulin in the Omnipod 5 System as they have been tested and found to be safe for use with this system.
- DO NOT start to use your system or change your settings without adequate training and guidance from your healthcare provider. Initiating and adjusting settings incorrectly can result in over-delivery or under-delivery of insulin, which could lead to hypoglycaemia or hyperglycaemia.
- Read all the instructions provided in the referenced User Guide (see Section 8B of this SSCP) before using the Omnipod 5 System.

Note: refer to User Guide referenced in Section 8B for all warnings and precautions.

Warnings & Precautions for Healthcare Professionals

Refer to summarized warnings and precautions listed above. For a full listing of warnings and precautions, refer to the referenced User Guide in Section 8B of this SSCP.

C) SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION, (FSCA INCLUDING FSN) IF APPLICABLE

A Field Safety Corrective Action (FSCA) is an action taken by a manufacturer to report any reason leading to the device being changed or recalled from the market so that it cannot be bought and used. Once taken off the market, any problems can be safely fixed before the device is sold again.

At the time of the latest revision of this SSCP, there has been one FSCA for Omnipod 5.

Date:	Action Type	Description:	Market(s) Affected
14-Nov-2022	Medical Device Correction	Omnipod 5 Controller charging port and cable damage due to heat generated by a poor connection between the cable and the port.	USA

5) SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

A) CLINICAL BACKGROUND OF THE DEVICE

Type 1 diabetes mellitus is a chronic metabolic disorder, the major pathophysiologic mechanism of which is the lack of insulin production due to autoimmune destruction of the pancreatic β -cells. The majority of the cases occur in childhood and early adulthood, although approximately one-quarter of the cases are diagnosed later in their life. (Chalakova T, 2021) (Schoelwer MJ, 2021).

In T2D, insulin levels may be normal, or even elevated, but insulin resistance in peripheral tissues leads to inadequate insulin action, resulting in hyperglycaemia. (Latres E, 2019) Type 2 diabetes is often undiagnosed.

There are currently 351.7 million people of working age (20–64 years) with diagnosed or undiagnosed diabetes (Williams, et al., 2019). Current statistics state there are 352.1 million patients worldwide with impaired glucose tolerance (Lovic D, 2020).

Currently, people with T1D and some with T2D need to monitor their blood glucose frequently and self-inject with appropriate amounts of insulin. To achieve optimal care, patients must carefully plan their schedules around their care activities. They also have to

continuously make difficult decisions and calculations regarding their treatment regimen, notably by considering dietary intakes and lifestyle factors. This behavioral burden of care can elicit distress and frustration among patients, especially among those who struggle to attain their target glycaemia levels.

Hybrid Closed-Loop (HCL) and artificial pancreas device systems are an efficacious and safe approach for treating outpatients with diabetes. Today, the decision to provide the most appropriate treatment for a person with diabetes is complex and needs to be individualized and determined by a collaboration between all involved. In the market, multiple systems are required so patients and their care givers can choose what best fits their needs. These needs include: tubeless pumps, implanted sensors, systems allowing for user adjustment of glycaemic goals, communication to significant others, phone-based or pump-based controller systems, more complicated systems and simple systems based on the preferences of the user, systems that allow for significant user input and systems that take over control of glucose management tasks, and choices to cover a range of costs and the need to wear multiple devices and infusion sets. All these needs and wants must be assessed and acknowledged for each patient.

The outpatient use of HCL systems is safe and improves glucose control outcomes when compared with other insulin therapies. The benefits are demonstrated both in single and dual-hormone algorithms and in full- or semi-closed loop control. Use of HCL systems shows significant levels of decreased HbA1c levels, increased time in range, and reduced time spent in hypoglycaemia or hyperglycaemia. Additionally, many studies showed fear of hypoglycaemia, Diabetes Quality of Life, Diabetes Treatment Satisfaction, and diabetes distress improved, while the percentage of patients with poor sleep quality was reduced.

The Omnipod® 5 is intended to reduce the frequency, severity and duration of both hyperglycaemia and hypoglycaemia as well as maintain blood glucose at recommended target levels through modulation of insulin delivery using CGM feedback, therefore reducing glucose variability.

B) THE CLINICAL EVIDENCE FOR THE CE-MARKING

Completed clinical studies include:

- **Evaluating the Safety and Effectiveness of the Omnipod Horizon™ Automated Glucose Control System in Patients with Type 1 Diabetes NCT04196140**

This study investigated the safety and efficacy of the Omnipod 5 System in 240 people with type 1 diabetes ages 6 to 70 years old. Participants used their usual therapy for 2 weeks, followed by 13-weeks using Omnipod 5 and a 12 month extension. Omnipod 5 was found to be safe and effective during 15 months of total use.

Link to publication: https://doi.org/10.2337/dc21-0172

Link to abstract: https://diabetesjournals.org/diabetes/article/71/Supplement_1/33-OR/146776/33-OR-ADA-Presidents-Select-Abstract-Glycemic

- **Evaluating the Safety and Effectiveness of the Omnipod Horizon™ Automated Glucose Control System in Children with Type 1 Diabetes Aged 2.0-5.9 years: Preschool Cohort NCT04476472**

  This study assessed the safety and efficacy of the Omnipod 5 System in 80 people with type 1 diabetes ages 2 to 5.9 years old. Participants used their usual therapy for 2 weeks, followed by 13-weeks using Omnipod 5 and a 9 month extension. Omnipod 5 was found to be safe and effective during 12 months of total use.

  Link to publication: https://doi.org/10.2337/dc21-2359

  Link to abstract: https://diabetesjournals.org/diabetes/article/71/Supplement_1/33-OR/146776/33-OR-ADA-Presidents-Select-Abstract-Glycemic

- **Prepivotal Evaluation of the Safety and Effectiveness of the Omnipod Horizon Automated Glucose Control System in Patients with Type 1 Diabetes NCT04176731**

  This study evaluated the efficacy and safety of the Omnipod 5 algorithm's Target Glucose setting options in 36 people with type 1 diabetes ages 6 to 70 years old. Participants used their usual therapy for 2 weeks, followed by 2 weeks using Omnipod 5 at different Target Glucose settings. All five options for Target Glucose were found to be safe and effective.

  Link to publication: https://doi.org/10.1089/dia.2020.0546

- **Evaluating the Safety and Effectiveness of the Omnipod Horizon™ CGM-informed Bolus Calculator in Patients with Type 1 Diabetes NCT04320069**

  This study looked at the safety of the Omnipod 5 SmartBolus Calculator in 25 people with type 1 diabetes ages 6 to 70 years old. The participants used Omnipod 5 in Manual Mode for 7 days without a connected glucose sensor, followed by 7 days with a connected glucose sensor. The CGM-informed SmartBolus Calculator showed results of less time in hypoglycaemia within 4 hours of a bolus.

  Link to publication: https://doi.org/10.1089/dia.2021.0140

- **Evaluating the Safety and Effectiveness of the Omnipod® 5 Automated Insulin Delivery System in Patients with Type 2 Diabetes NCT04617795**

  This feasibility study evaluated the safety and efficacy of the Omnipod 5 System in 24 people with type 2 diabetes ages 18-75 years. All participants used their usual therapy for 2 weeks followed by 8 weeks of Omnipod 5 System use with the caveat that those previously on basal insulin-only used Omnipod 5 in manual mode for 2 weeks before the 8-week Omnipod 5 phase. Omnipod 5 was found to be safe and effective.

- **Automated Insulin Delivery for INpatients With DysGlycemia (AIDING) Feasibility NCT04714216**

  This feasibility study evaluated the feasibility, safety, and efficacy of the Omnipod 5 System in 16 people with type 1 and type 2 diabetes in non-ICU medical surgery units. All participants used the Omnipod 5 System until discharge or up to 10 days. The system was found to be feasible, safe, and effective.

  Ongoing clinical studies include:

- **Efficacy and safety of the Omnipod 5 System Compared to Pump Therapy in the Treatment of Type 1 Diabetes: a Randomized, Parallel-group Clinical Trial NCT05409131**

  The objective of this study is to evaluate the safety and efficacy of the Omnipod 5 System compared to pump and continuous glucose monitor (CGM) therapy in people with type 1 diabetes ages 18 – 70 years old. Participants will use their usual therapy for 2 weeks, followed by randomization to either Omnipod 5 with Dexcom G6 CGM or the participant's current insulin pump with Dexcom G6 CGM for 13 weeks.

C) AN OVERALL SUMMARY OF THE CLINICAL PERFORMANCE AND SAFETY

As demonstrated through clinical evaluation, among the current therapeutic options for patients with diabetes, the Omnipod® 5 is a state-of-the-art choice. The benefit/risk profiles, safety, performance and intended benefit of the subject devices for the intended target groups and medical indications are acceptable and the Omnipod® 5 Automated Insulin Delivery System remains to be state of art and is in conformance with the GSPRs as stated in MDR (2017/745). The Omnipod® 5 is safe and effective for use during the day and night.

D) ONGOING OR PLANNED POST-MARKET CLINICAL FOLLOW-UP (PMCF)

Post-Market Clinical Follow-Up (PMCF) is the collection of information about the safety and performance of a device after it has been on the market. Post-Market Clinical Follow-Up activity can help to determine if there are any previously unknown risks of a device.

In addition to the ongoing clinical studies indicated above, per established procedures and plans, further clinical evaluation and ongoing post-market surveillance, including PMCF, will be performed to determine any new or previously unidentified risks that would cause a change in the benefit/risk ratio. In addition, the evaluations will review any changes to state-of-the-art and ensure continued clinical safety and clinical performance.

6) POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Background on Available Therapeutic Options

The landmark Diabetes Control and Complications Trial (DCCT), conducted from approximately 1975 – 1993, demonstrated the benefit of intensive glycaemic control on diabetes complications in T1D. (Schoelwer MJ, 2021) After the DCCT ended, study teams continued to track more than 90% of the participants. The follow-up study, called the Epidemiology of Diabetes Interventions and Complications (EDIC), assessed the

incidence of heart attack, stroke, and heart surgery, as well as diabetic complications related to the eyes, kidneys, and nerves. The EDIC study found that intensive blood glucose control reduced the risk of events associated with cardiovascular disease by 42% and lowered the risk of non-fatal heart attack, stroke, or death from cardiovascular causes by 57%. The studies showed that person with T1D can significantly improve their prognoses through improved glucose control, particularly if they start controlling their glucose levels when they are young. Similar benefit was demonstrated in the United Kingdom Prospective Diabetes Study (UKPDS) in T2D (Zeller WP, 2020) (Dovc K B. T., 2020) (Chalakova T, 2021).

Specifically, maintaining blood glucose in a target range (3.9–10.0 mmol/L; 70–180 mg/dL) can help to prevent complications related to hyperglycaemia (>10.0 mmol/L; >180 mg/dL) and hypoglycaemia (<3.9 mmol/L; <70 mg/dL). (Wilmot EG, 2021) (Tyler NS, 2020) Prolonged exposure to hyperglycaemia can result in a number of complications throughout the body, including several macrovascular (ischemic heart disease, stroke and peripheral artery disease) and microvascular (neuropathy, nephropathy and retinopathy) complications. Additionally, increased day-to-day fasting glucose variability was shown to be associated with higher risk of severe hypoglycaemia and all-cause mortality. (Chalakova T, 2021) (Wilmot EG, 2021) (Cobry EC B. C., 2020). (Cernea S, 2020).

Despite the evidence of the importance of reduced glycaemic variability on long term complications, the advancements in the treatment methods and increased uptake of diabetes technology, many patients with T1D are still not meeting the recommended HbA1c goals. Between 2016 and 2018, only 17% of youth and 21% of adults were meeting the goals recommended by the American Diabetes Association (ADA). (Wilmot EG, 2021) A recent Association of British Clinical Diabetologists (ABCD) audit of percent TIR measures for people with diabetes showed substantial variation in target glucose ranges used by clinicians, with only 15% of 2,191 cases using the recommended 3.9–10 mmol/l range. Glucose-lowering strategies, aiming for better control of diabetes metabolic disorders as well as lifestyle changing campaigns are needed to reduce the incidence of the previously mentioned manifestations. (De Ridder F, 2019) (Dovc K B. T., 2020) (Lovic D, 2020) (Wilmot EG, 2021).

Accordingly, the diabetes community of researchers and innovators are finding many promising methods to assist those with diabetes requiring insulin. These methods are described below.

A) GENERAL DESCRIPTION OF AND BENEFITS-RISKS OF THERAPEUTIC ALTERNATIVES

- Continuous intraperitoneal insulin infusion (CIPII):
  - Continuous intraperitoneal insulin infusion (CIPII) with implantable pump has been employed for almost 30 years as an alternative route for insulin delivery when subcutaneous insulin therapy has failed. This route allows a faster, after meal, glucose normalization with reproducible and more predictable insulin profiles even than continuous subcutaneous insulin infusion. The current uses of CIPII are limited to those with severe subcutaneous insulin resistance, poor glycaemic control with high daily insulin doses, severe hypoglycaemia during

subcutaneous insulin therapy, skin disorders, subcutaneous site issues, lipoatrophy with subcutaneous insulin and “brittle diabetes” (Pasquini S, 2020).

- Portal insulin delivery, oral insulin delivery, buccal insulin delivery, nasal insulin delivery:
  - Portal insulin delivery, oral insulin delivery, buccal insulin delivery, nasal insulin delivery (Intranasal insulin-delivery) are all in pre-clinical or clinical study stages, have been discontinued, or not ready for use in those less than 18. (Zuberi Z, 2020).

- Pancreas and Islet Transplantation:
  - Pancreas and islet transplantation are considered, at present, last resort approaches to the treatment of type 1 diabetes, suitable only for those with significant burden of hypoglycaemia where other approaches have failed. Because of the nature and risks of the associated immunosuppressive regimen, such treatments are not practicable for children and young people (Boughton, 2020b).

- Continuous Subcutaneous Insulin Infusion and Continuous Glucose Monitoring:
  - The subcutaneous route of administration is widely preferred method for administration of insulin because of the ease of self-administration, high bioavailability, relatively controlled onset of action, and flexibility in dosing. Continuous subcutaneous insulin infusion (CSII) pumps and Continuous Glucose Monitoring (CGMs) are becoming standard of care for many individuals with T1D. As of 2018, across the T1D Exchange, insulin pump use was 63% of patients and CGM use was 30%, with the largest increases occurring in children (Cobry EC B. C., 2020) (Latres E, 2019).

- Hybrid Closed-Loop (HCL) Systems or Artificial Pancreas Device Systems:
  - Systems that automate the delivery of insulin are referred to by several names. Since the technology is new, a common device name is still in flux. Some names include: Automated Insulin Delivery (AID), Closed Loop (CL), Artificial Pancreas Device System (APDS), bionic pancreas, and Artificial Pancreas (AP). First-generation systems currently automate only insulin delivery. The term hybrid closed-loop reflects the need for user input as delays in subcutaneous insulin absorption mean user-initiated mealtime insulin delivery (bolusing) is required (Boughton, 2020b). Hybrid Closed-Loop systems consist of three components: an insulin pump, a continuous glucose monitoring system, and an algorithm that determines insulin delivery. These systems combine the sensing information provided by continuous interstitial fluid glucose monitors and the actuation capabilities of insulin pumps with closed-loop algorithms, which calculate the optimal insulin delivery amount based on current, and sometimes future, predictions of glucose trends, and deliver this

insulin autonomously via the insulin pump—a process that is repeated every one or five minutes (depending on the sensor model) (Schoelwer MJ, 2021).

7) SUGGESTED PROFILE AND TRAINING FOR USERS

Insulet executed a comprehensive human factors and usability engineering process that followed and complied with the standards IEC 62366:2015-1 and HE75:2009 as well as the FDA's guidance document, Applying Human Factors and Usability Engineering to Medical Devices – Issued February 3, 2016. A robust validation evaluation was performed to demonstrate safe and effective use of the Omnipod® 5 System with intended users in the expected use environments, including associated training and accompanying documentation.

General user profile and training requirements include:

- Willingness to use the device and monitor glucose in accordance with the User Guide, the CGM manufacturer's instructions, and as trained and instructed by one's healthcare provider and Omnipod 5 Trainer.
- Adequate vision and/or hearing to recognize all functions of the Omnipod 5 System including alerts, alarms, and reminders according to instructions.

Refer to the User Guide referenced in Section 8B of this SSCP for more user training requirements and instructions.

8) REFERENCES

A) REFERENCE TO ANY HARMONISED STANDARDS AND COMMON SPECIFICATIONS APPLIED

No common specifications (CS) apply.

The following standards apply:

STANDARD:	STANDARD TITLE:	VERSION:
EN ISO 13485	Medical devices – Quality management systems – requirements for regulatory purposes	2016+AC:2018
EN ISO 14971	Medical devices – Application of risk management to medical devices	2019
EN 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2006+A12:2014
EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	2015
EN 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	2010+A1:2015
EN 60601-1-8	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests	2007+A11:2017

STANDARD:	STANDARD TITLE:	VERSION:
	and guidance for alarm systems in medical electrical equipment and medical electrical systems	
EN 60601-1-10	Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral standard: Requirements for the development of physiologic closed-loop controller	2008+A1:2015
EN 60601-1-11	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2015
EN 60601-2-24	Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers	2015
EN 62304	Medical device software – Software life-cycle processes	2006+A1:2015
EN 82304-1	Health Software -. Part 1: General requirements for product safety	2017
EN 62366-1	Medical devices – Application of usability engineering to medical devices	2015+AC:2016
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	2018
EN ISO 10993-3	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2014
EN ISO 10993-4	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	2017
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	2009
EN ISO 10993-6	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	2016
EN ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals	2008+AC:2009
EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	2013
EN ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for system toxicity	2018
EN ISO 10993-12	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	2012
EN ISO 10993-17	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances	2009
EN ISO 10993-18	Biological evaluation of medical devices – Part 18: Chemical characterization of materials	2009
EN ISO 11135	Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices	2014+A1:2019
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	2017
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
EN 1041	Information supplied by the manufacturer of medical devices	2008+A1:2013

The following guidance documents apply:

- MDCG 2019-9 Summary of safety and clinical performance: A guide for manufacturers and notified bodies
- MDCG 2019-16 Guidance on Cybersecurity for medical devices
- MDCG 2020-1 Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software
- MDCG 2020-5 Clinical Evaluation – Equivalence: A guide for manufacturers and notified bodies
- MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC: A guide for manufacturers and notified bodies
- MEDDEV 2.7/1 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
- MEDDEV 2.12-1 rev.8 Guidelines on a Medical Devices Vigilance System
- Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev.8

B) INSTRUCTIONS FOR USE/USER GUIDE:

PT-001246 / PT-001298 - User Guide / Tech. User Guide, Omnipod 5, G6, English-UK, mmol/L

PT-001247 / PT-001301 - User Guide / Tech. User Guide, Omnipod 5, G6, German, mg/dL

PT-001248 / PT-001299 - User Guide / Tech. User Guide, Omnipod 5, G6, German, mmol/L

PT-001249 / PT-001302 - User Guide / Tech. User Guide, Omnipod 5, G6, French mg/dL

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9) REVISION HISTORY

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
Revision 0 (Version 1)	*28 SEP 2021*	*Original*	*☐ Yes* *Validation language:* *☐ No (only applicable for Class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)* *☒ N/A (first version)*
Revision 1 (Version 2)	*14-Mar-2023*	*Removal of references to system control via 3rd-party mobile phone;* *Update of clinical study data / status.*	*☒ Yes* *Validation language: English* *☐ No (only applicable for Class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)*
Revision 2 (Version 3)	*31-May-2023*	*Amendment of Basic UDI_DI* *Amendment of part #s for devices and user guides.*	*☒ Yes* *Validation language: English* *☐ No (only applicable for Class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)*