

Guidelines of the Polish Society of Pediatric Endocrinology and Diabetology and Pediatric Section of Diabetes Poland on insulin therapy using hybrid closed-loop systems in children and adolescents with diabetes in Poland

Zalecenia Polskiego Towarzystwa Endokrynologii i Diabetologii Dziecięcej oraz Sekcji Pediatricznej Polskiego Towarzystwa Diabetologicznego dotyczące insulinoterapii z zastosowaniem systemów hybrydowych pętli zamkniętych u dzieci i młodzieży z cukrzycą w Polsce

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List of abbreviations

AGP – ambulatory glucose profile

AID – automated insulin delivery

APS-DIY – Artificial Pancreas System - Do it Yourself

BOHB – beta-hydroxybutyric acid

CGM – continuous glucose monitoring

CSII – continuous subcutaneous insulin infusion

HCL – hybrid closed loop

ICR – insulin to carb ratio (insulin-to-carbohydrate ratio)

ISF – insulin sensitivity factor

MARD – mean absolute relative difference

MDI – multiple daily injections

PLGS – Predictive Low Glucose Suspend

PTD – Diabetes Poland

PTEIDD – Polish Society of Pediatric Endocrinology and Diabetology

QALY – quality-adjusted life years

T1D – type 1 diabetes

rtCGM – real-time CGM

SG – sensor glucose

TBR – time below range, < 70 mg/dl

TIR – time in range, 70–180 mg/dl

TITR – time in tight range, 70–140 mg/dl

Abstract

Currently, hybrid closed loop (HCL) systems represent the most advantageous therapeutic option for people with diabetes requiring intensive insulin therapy. They make it possible to achieve optimal metabolic control of the disease in any age group while improving the quality of life of children and adolescents with diabetes and their families.

Therefore, we present recommendations for the use of HCL systems in children and adolescents focusing on systems currently available in Poland. These systems should be the first choice in terms of method of insulin therapy in the paediatric population. They can be implemented at any stage of diabetes management. These recommendations are based on scientific evidence and experts' experience. They include principles for the initiation, optimisation, and ongoing management of HCL therapy, as well as the required HCL-related education.

Key words: diabetes mellitus, hybrid closed loop, automated insulin delivery systems, insulin therapy, continuous glucose monitoring.

Streszczenie

Obecnie systemy hybrydowej pętli zamkniętej (HCL) są najkorzystniejszą opcją terapeutyczną dla osób z cukrzycą, wymagających intensywnej insulinoterapii. Umożliwiają osiągnięcie prawidłowego wyrównania metabolicznego choroby w każdej grupie wiekowej z równoczesnym podniesieniem jakości życia dzieci i młodzieży z cukrzycą oraz ich rodzin.

W związku z powyższym przedstawiamy zalecenia, dotyczące stosowania systemów HCL u dzieci i młodzieży, koncentrując się na systemach obecnie dostępnych w Polsce. Systemy te powinny być pierwszym wyborem pod względem metody prowadzenia insulinoterapii w populacji pediatrycznej. Można je wdrożyć w każdym momencie leczenia cukrzycy. Niniejsze zalecenia zostały oparte na dowodach naukowych oraz doświadczeniach własnych ekspertów. Obejmują zasady dotyczące rozpoczynania, optymalizacji i bieżącego zarządzania terapią HCL oraz wymaganej edukacji zdrowotnej w tym zakresie.

Słowa kluczowe: cukrzyca, hybrydowa pętla zamknięta, automatyczne systemy podawania insuliny, insulinoterapia, ciągłe monitorowanie stężenia glukozy.

Introduction

Type 1 diabetes (T1D) is characterised by an absolute insulin deficiency. Unfortunately, despite the use of modern insulin therapies, insulin pumps, and continuous glucose monitoring (CGM) systems, a significant number of individuals living with T1D still fail to achieve their therapeutic goals. Moreover, T1D continues to drastically reduce life expectancy—by nearly 12 years in Poland compared to those without diabetes [1]. This ongoing challenge highlights the need for new methods that enable optimal metabolic control while also ensuring a good quality of life for people with diabetes. The broader adoption of new diabetes technologies, including hybrid closed loop (HCL) systems, by facilitating better glycaemic control, offers hope for reclaiming the years of life lost due to diabetes.

Automated insulin delivery (AID) systems use real-time CGM (rtCGM) data integrated into a control algorithm that automatically adjusts insulin delivery rates via Continuous Subcutaneous Insulin Infusion (CSII, i.e. an insulin pump). Currently available HCL systems can automatically reduce or suspend basal insulin infusion when glucose levels drop, and increase insulin delivery when glucose levels rise, aiming to maintain a preset target glucose level [2].

AID systems significantly improve metabolic control, both in terms of reducing HbA1c and increasing time spent within the recommended glycaemic range, as well as in reducing hypoglycaemia. Reports indicate that the average time in the range 70–180 mg/dl (time in range – TIR) for individuals using various HCL systems is around 76%, compared to 45–60% for those using other forms of therapy combined with continuous glucose monitoring [3, 4]. Additionally, improvements have been demonstrated in time in the tight range of 70–140 mg/dl (time in tight range – TITR), especially during nighttime hours [4–6].

The therapeutic efficacy of AID systems, understood as achieving time within the recommended range, has been demonstrated across a broad population of individuals with T1D in all age groups, both in randomised controlled trials and in real-world evidence studies. These results have proven stable and sustained over the years [3, 4]. The use of HCL has also not been associated with an increase in users' body weight [7, 8].

Achieving glycaemic targets still requires the user to program mealtime boluses; however, even an inaccurate estimation of the carbohydrate content in a meal allows TIR to be maintained at the recommended level [9]. A particularly impor-

tant aspect of using HCL systems is the significant reduction of therapeutic decisions made by a person with diabetes. The algorithm handles them on its own leading to a significant improvement in a life quality. It also reduces the burden of living with diabetes. A decrease in anxiety related to hypoglycaemia is also highlighted. Improving nighttime glycaemia leads to better sleep quality, not only for the person with diabetes but also for their family [10–15].

The therapeutic effectiveness of HCL systems is also evaluated through health economics analyses. Numerous studies have demonstrated that these systems are cost-effective interventions for individuals with T1D, particularly compared to a range of other non-HCL methods. A recently published study confirmed that HCL systems are cost-effective in every scenario despite higher incremental costs [16]. This is because HCL systems generate sufficient gains in quality-adjusted life years (QALY) to outweigh the additional costs, bringing them below the willingness-to-pay thresholds of healthcare payers in various countries. In the conducted analyses, the QALY benefits were primarily attributed to reducing the incidence of diabetes-related complications (such as diabetic ketoacidosis, severe hypoglycaemic episodes, and micro- and macrovascular complications) [17]. Additionally, in some cases, the reduction in anxiety related to hypoglycaemia – not only for the person with diabetes but also for their caregivers – contributed to these benefits. In this context, the impact of HCL systems on the quality of life of caregivers – who are integral partners in therapy – particularly in alleviating the mental stress and burdens associated with caregiving, is invaluable.

Compelling scientific evidence has led several scientific societies worldwide, including Diabetes Poland (PTD), to develop recommendations that clearly identify HCL systems as the therapy of choice for all individuals with T1D, particularly those with suboptimal glycaemic control [18]. For many patients who have been unable to achieve acceptable glycaemic control over the years due to various reasons, the use of HCL systems may be the only way to improve metabolic control of diabetes and reduce the risk of complications.

In light of this, we present the recommendations of the Polish Society of Paediatric Endocrinology and Diabetology (PTEIDD) and the Paediatric Section of Diabetes Poland (PTD) regarding the use of closed loop systems in children and adolescents, focusing on HCL systems commercially available in Poland (as of August 2024).

1. Automated insulin delivery systems available in Poland

1.1. Available systems

The number of commercially available AID systems worldwide is growing. These systems operate on the principle of HCL, meaning that all of them still require the user to administer meal-time boluses [19–21]. The following systems are used: MiniMed™ 780G, CamAPS® FX with mylife™ YpsoPump®, Tandem t:slim™

X2 Control IQ™, and systems utilising tubeless pumps (so-called “patch” pumps: Omnipod® 5, Tandem Mobi®, DBLG1™ System Diabeloop, Medtrum TouchCare® Nano System) [19–21].

In Poland, two commercial HCL systems are available: the MiniMed™ 780G system from Medtronic and the CamAPS® FX, which connects the mylife™ YpsoPump® with the Dexcom G6® CGM system (Dexcom G7® is currently planned). These systems are discussed in detail in Table I. Other configurations of these systems may be available in different countries [19–21].

Table I. Commercial hybrid close loop (HCL) systems currently available in Poland along with their components and basic parameters [19–23]

HCL System	SmartGuard™	CamAPS® FX
Components	MiniMed™ 780G	mylife™ YpsoPump®
Insulin pump	Medtronic Simplera Sync™	Dexcom G6® + transmitter
CGM system	Medtronic Guardian™ 4 + transmitter Medtronic Guardian™ 3 + transmitter	
Sensor replacement period	Every 7 days	Every 10 days
Transmitter replacement period	Every 12 months (Guardian™ 3, Guardian™ 4)	Every 3 months
Sensor calibration	Simplera Sync™, Guardian™ 4 – on demand Guardian™ 3 – at least every 12 hours	On-demand
Sensor warm-up period (initialization time)	2 hours (Simplera Sync™, Guardian™ 4) 40 - 120 min. (Guardian™ 3)	2 hours
User age according to sensor registration	≥ 2 years old (Simplera Sync™) ≥ 7 years old (Guardian™ 4) No age restrictions (Guardian™ 3)	≥ 2 years old
MARD (children)	10,2% (Simplera Sync™) 10,6% (Guardian™ 4) 8,7% (Guardian™ 3)	7.7–10.1%
Algorithm	PID with Fuzzy Logic and MPC	MPC
Registration of the HCL algorithm		
• age	7–80 years old	≥1 year old
• body weight	Not applicable	10–300 kg
• daily insulin dose	8–250 units per day	5–350 units per day
• special situations		Pregnancy
Registration (of insulin)	Rapid and ultra-rapid-acting insulin analogues	Rapid and ultra-rapid-acting insulin analogues, including diluted insulin analogues
Pump operation time in manual mode required to start the algorithm	At least 48 hours starting from midnight after starting the pump	Not required
Bolus administration	Using the pump Dose graduation in 0.025 units	Using the pump or application on the Android system Dose graduation in 0.1 units
Platform for the HCL algorithm	Insulin pump (additional device is not required)	Android system on an external device (a compatible smartphone is required)

Table I. Commercial hybrid close loop (HCL) systems currently available in Poland along with their components and basic parameters [19–23] (cont.)

HCL System	SmartGuard™	CamAPS® FX
Simplified description of the algorithm's operation	Automatic basal delivery (auto-basal) Auto-corrections (automatic correction boluses) in case of glucose > 120 mg/dl (6.7 mmol/l) and maximum auto-basal. The algorithm modifies meal boluses (safe bolus)	The algorithm provides basal delivery (in the report "basal") by administering automatic extended boluses. The regular basal delivery of the pump is turned off in automatic mode
Parameters on which the HCL algorithm is based	Daily insulin dose from the last 2–6 days, read from the pump by the algorithm Target glucose value Active insulin time Continuously adapting algorithm. The algorithm updates data every midnight	Body weight and daily insulin dose – entered by the user. Body weight requires regular updates. Target glucose value Continuously adapting algorithm
Adjustment of basal delivery by the HCL algorithm	Every 5 minutes	Basal delivery stopped (zero); extended bolus administered every 8–12 minutes
Target glucose value for the HCL algorithm in mg/dl (mmol/l)	Default 100 mg/dl (5.5 mmol/l), additional possible settings: 110 and 120 mg/dl (6.1 and 6.7 mmol/l)	Personalized values between 80–198 mg/dl (4.4–11 mmol/l), default setting at 104 mg/dl (5.8 mmol/l) Possibility to set different target values during the day in 30-minute intervals
Parameters modifiable by the user in automatic mode	ICR ratios Target glucose value for automatic basal (as above) Active insulin time (2–8 hours)	ICR ratios Target glucose value for automatic basal (as above) Body weight
Parameters NOT modifiable by the user in automatic mode	Basal delivery Insulin sensitivity Temporary target value (only 150 mg/dl is possible to be set) Target glucose value for correction boluses (one value 120 mg/dl)	Active insulin time Basal delivery Insulin sensitivity
Additional HCL features that the patient can use	Temporary target (150 mg/dl) – can be set for 30 minutes to 24 hours Temporary modification of the target glucose value – 100, 110, 120 mg/dl Correction bolus initiated by the user – dose calculated by the algorithm based on the entered glucose value is not modifiable by the user	"Ease Off" – raises the target glucose value by 45 mg/dl and reduces the "aggressiveness" of the algorithm; significantly reduces insulin delivery and stops it at glucose < 140 mg/dl. Can be set for a period up to 24 hours "Boost" – a more aggressive algorithm action, increases insulin delivery by ~35%; if glucose reaches the target value, the algorithm will not lower it further. Can be activated for a period up to 13 hours Correction bolus initiated by the user – dose calculated by the algorithm based on the entered glucose value is modifiable by the user Meal marking: • Meal or snack • Hypoglycaemia treatment • Slow-absorbing meal

Table 1. Commercial hybrid close loop (HCL) systems currently available in Poland along with their components and basic parameters [19–23] (cont.)

HCL System	SmartGuard™	CamAPS® FX
Return to manual mode	When? Loss of CGM data – when basal delivery is provided based on pump history and not CGM readings for ≥ 4 hours. Manual suspension of insulin delivery and no resumption for 4 hours. Exceeding the time of minimum basal delivery (3–6 hours, depending on the situation) or maximum basal delivery (for 7 hours) – requires user intervention to maintain automatic mode operation. Manual deactivation of automatic mode	Loss of CGM data Loss of connection with CGM Loss of connection between the pump and CamAPS® FX application No internet connection for more than 28 days Manual deactivation of automatic mode
	Manual mode Uses the last basal rate entered in manual mode PLGS function can be used if CGM is active	Uses the last basal rate entered into the pump in manual mode. Boluses can still be administered through the CamAPS® FX app
User interface	On the pump	On a compatible Android smartphone
Smartphone integration	View only (Android or iOS operating system)	On a compatible Android smartphone
Smartwatch integration	The MiniMed app on the smartwatch with iOS reads and shows data from the app on the phone.	Not available
Default-set alarms (cannot be switched off by user)	For glucose < 45 mg/dl For glucose > 250 mg/dl lasting > 3 hours	Urgent low glucose alarm < 55 mg/dl When the phone is completely muted (the “do not disturb” option), the sound of alarms/alerts can be muted
Remote real-time data sharing with a third party (therapy partner) requires an internet connection to enable data sharing	Through the CareLink™ Connect application (real-time sharing and notifications)	With the use of the “Companion” function, the mylife CamAPS FX app allows users to share their data with therapy partners. Text messages alerts are also possible
Data platform	CareLink™ Personal (data transmitted manually or via smartphone)	Diasend®, Glooko® (not available to users in Poland), mylife Cloud planned to be available from September 2024
Sharing HCL system data with the therapeutic team	Automatic data transfer from CareLink™ Personal to CareLink™ System after account synchronization Report generated in a pdf file from CareLink™ Personal	Report generated in a pdf file by the application

AID – automated insulin delivery; CGM – continuous glucose monitoring; MARD – mean absolute relative difference between CGM values and reference values; PLGS – predictive low-glucose suspend; ICR – insulin to carb ratio

PID: Proportional-Integral-Derivative (e.g., MiniMed™ systems): Essentially, this system continuously adjusts the current operation path, similar to steering a ship: the target is in sight, but the influence of wind and waves must be constantly corrected. Consequently, there is a mathematical error between actual values and the desired target, which can be calculated and minimised.

MPC: Model Predictive Control (CamAPS® FX, Control IQ™): A dynamic reference model forms the basis of the system's „actual” operation, and the current development of values is compared with the reference values. The amount that the manipulated variable needs to be changed to restore the model is calculated. The variable is modified in real time, and predictions are made for modification in subsequent time intervals.

The algorithm “learns” from past insulin deliveries and meal boluses to adapt to daily insulin requirements, adjusting both day-to-day and post prandial. **Fuzzy Logic (part of the automatic correction bolus algorithm in the MiniMed™ 780G system):** Fuzzy logic is the science of reasoning, thinking, and inferring, which recognises that not everything is true or false in the real world. The main elements of a fuzzy controller are numerous inputs and rules for single or multiple outputs organised according to the form IF (input data) – THEN (output).

In HCL systems, instead of the typical distinction between basal insulin (the basic insulin dose) and boluses, there is rather a distinction between insulin delivery initiated by the algorithm and insulin delivery initiated by the user.

Other examples of commercial HCL systems available in the European Union [19–21] are as follows:

- the Tandem Control IQ™ (based on the Tandem™ t:slim™ X2 pump and Dexcom G6® or G7® CGM or FreeStyle Libre® 2 Plus) is registered for individuals aged 6 years and older. The target glucose value of the algorithm can be set every 30 minutes within a range of 110 to 160 mg/dl (6.1 to 8.9 mmol/l); the system has additional options such as a sleep mode (which increases the aggressiveness of the algorithm) and 6 exercise modes;
- SmartAdjust (based on the tubeless Omnipod® 5 pump and Dexcom G6® CGM), which is registered for individuals aged 2 years and older; the target glucose value can be set in 60-minute intervals (with values of 110, 120, 130, 140, 150 mg/dl [6.1, 6.7, 7.2, 7.8, or 8.3 mmol/l]). The user can use the SmartBolus calculator, which utilises CGM data and trends in its calculations.

Some users also utilise “Artificial Pancreas System – Do it Yourself” (APS-DIY) systems, which they create themselves based on commercial devices and algorithms often made available from the Internet for free (open source). Since these algorithms do not have registration, their use remains the responsibility of the person with diabetes and/or their caregivers.

Regardless of the HCL system being used, including APS-DIY, all individuals should receive the same support from the diabetes care team in managing their diabetes therapy.

1.2. Automatic mode setting

Each HCL system, in addition to the mandatory manual mode settings (including basal infusion and the bolus calculator, see Table IV), requires the input of parameters necessary for functioning in automatic mode (Table II) [19–21].

In the MiniMed™ 780G system, before starting operation in automatic mode, in addition to setting the target blood glucose level, it is usually recommended to adjust the duration of the active insulin time (Table II).

For the CamAPS® FX system, the initial activation of automatic mode requires the patient's data to be entered: body weight and daily insulin dose. Additionally, the algorithm uses the entered insulin-to-carbohydrate ratios. If the user wishes to administer an additional bolus manually, they can use the previously entered correction factor and target value in the bolus calculator. In the pump settings, 2 identical basal rates must always be entered (in case the automatic mode is turned off). Access to the CamAPS® FX application is granted after completing training developed by the application creators, confirmed by a physician [22].

2. Indications and contradictions for hybrid closed loop therapy

2.1. Indications

HCL systems are recommended for all children and adolescents with diabetes requiring intensive insulin therapy, provided that the following conditions are met:

- they accept the principles of this treatment method;
- they have no contraindications for its use;
- the technical requirements for using the specific HCL system are met.

Every person with T1D has the right to use the HCL system from diagnosis. The earliest possible initiation of HCL therapy is justified and recommended for every child with T1D.

2.2. Contraindications

Contraindications for HCL therapy are consistent with the contraindications for therapy using personal insulin pumps according to PTD [18]:

1. Certain psychological disorders in the person with diabetes and/or parents/caregivers that, in the opinion of the attending physician, prevent the safe use of a personal insulin pump.
2. Certain eating disorders that, in the opinion of the attending physician, prevent the safe use of a personal insulin pump.
3. Intellectual disabilities in parents/caregivers of children under 13 years old that prevent understanding the principles of intensive insulin therapy and pump operation or dependence on alcohol and psychoactive substances. For children aged 13–16 years, the decision to use HCL should be made individually based on the child's ability to operate the insulin pump and manage therapy under increased supervision from the diabetes therapeutic team and a family assistant.
4. Unjustified absences from medical appointments (attending only one appointment per year or missing appointments) at the diabetes clinic.
5. Non-compliance or misunderstanding of the principles of intensive basal-bolus insulin therapy (lack of proper self-monitoring of blood glucose, lack of ketone body monitoring in situations of prolonged hyperglycaemia).
6. More than one episode of severe ketoacidosis within a year during the use of HCL.
7. Non-compliance with personal hygiene standards.

Table II. Initial settings for HCL systems commercially available in Poland [4, 19–22]

SmartGuard™ (MiniMed™ 780G)	CamAPS® FX
Target glucose value [mg/dl]	
100*	104*
110	80–198 range
120	
Active insulin time (hours)	
2*	No adjustment possible
2–8 range	

* indicates optimal, default (factory) settings

2.3. Use of hybrid closed loop systems beyond registered age
According to the PTEiDD's position (https://pteidd.pl/index_subpage.php/?n=3), in the case of children younger than the age for which a given system is registered, the attending physician makes the decision to initiate its use individually. This decision is based on the current available knowledge and in accordance with the principles of evidence-based medicine, after obtaining the consent of the parents/caregivers.

- 2.4. Temporary discontinuation of hybrid closed loop therapy**
- Problems with using sensors or infusion sets (e.g. severe skin reactions) – requiring the cessation of using the pump or CGM system that is part of the HCL system.
 - Malfunction of HCL system components (insulin pump, CGM system, smartphone in the case of the CamAPS® FX application).
 - Period of complete remission not requiring insulin administration or partial remission requiring only basal insulin administration.
 - At the patient's request (e.g. during holidays, sports competitions).
 - Period of additional illness during which insulin requirements change rapidly, and the automatic mode modifies insulin delivery too slowly.

3. Education on the use of the hybrid closed loop system

The scope of training depends on the duration of diabetes (e.g. newly diagnosed, reintroduction of therapy after a period of complete remission), the type of insulin therapy previously used, the type of insulin pump, and the glucose monitoring method [24] (Table III).

- Complete training on the use of the HCL system includes the following points:
- general information on available systems and maintenance costs, including the principles of reimbursement in Poland, with personalised selection of HCL by the person with diabetes and their caregivers, as well as members of the therapeutic team;
 - basics of insulin therapy in a basal-bolus system;
 - nutritional principles in diabetes, including recognising and evaluating food quality and calculating the number of carbohydrates in a meal, at least at a basic level;
 - technical operation of HCL system components: the insulin pump and the CGM system;
 - familiarity with all system functions: manual and automatic modes, "basic" and "automatic mode" bolus calculators, evaluation and interpretation of active insulin, automatic and manual corrections, using applications that enable connection with the treating centre, therapy partners, smartwatch, contact with the helpline;
 - management during physical activity, hypoglycaemia, hyperglycaemia, ketonaemia/ketonuria, acute infection, gastroenteritis, and system malfunction;
 - analysis and interpretation of reports in the patient's application/computer application;
 - modification of system settings.

Training should conclude with a positive result on a knowledge and skills test confirmed by a member of the therapeutic team.

For individuals with diabetes who have daily insulin requirements below the threshold for activating the automatic insulin delivery function (e.g. small children, partial remission period), dilution of insulin may be considered. Ideally, the dilution should be performed using a diluent specifically designed for insulin (which is difficult to get in Poland) or with a 0.9% NaCl

Table III. Key training elements during the implementation of HCL therapy in different patient groups

Patients	Basics of basal-bolus therapy in CSII	Infusion set insertion	Sensor insertion, CGM usage	Technical training on pump usage	Principles of therapy in manual mode	Principles of therapy in automatic mode
Newly diagnosed diabetes	Yes	Yes	Yes	Yes	Yes	Yes
Multiple injections	Yes	Yes	Yes	Yes	Yes	Yes
Pumps from other manufacturers		Yes	Yes	Yes	Yes	Yes
CGM system from another manufacturer			Yes	Yes	Yes	Yes
Pump from the same manufacturer				Update	Update	Yes

CSII – continuous subcutaneous insulin infusion; CGM – continuous glucose monitoring

solution. The degree of insulin dilution depends on the individual's daily insulin dose. Parents/caregivers must undergo appropriate training in insulin dilution techniques. Additionally, it is necessary to place information about the degree of insulin dilution on the pump [25].

4. Principles for initiating the therapy

The principles for initiating therapy typically vary depending on the specific HCL system used. However, all HCL systems require the setting of essential parameters for manual mode operation, including basal infusion and bolus calculations [2].

The timing for activating automatic mode depends on the clinical situation of individual's with diabetes. For most individuals who have previously used insulin pumps and regularly utilised CGM systems, the automatic mode can be activated as soon as the system requirements are met. For children beginning therapy with a personal insulin pump (e.g. those newly diagnosed with diabetes or previously treated with multiple daily injections, MDI), it is advisable to remain in manual mode for an extended period. This duration should be tailored to the person to allow them to develop the necessary skills to manage therapy in manual mode (i.e. in the case of the MiniMed™ 780G, using the predictive low-glucose suspend [PLGS] algorithm). For individuals with highly variable daily insulin requirements using the MiniMed™ 780G system, the period of manual mode use may also need to be extended.

4.1. MiniMed™ 780G System

Before initiating the automatic SmartGuard™ mode, 2 parameters must be set: target glucose level and insulin activity time. The system also utilises insulin-to-carbohydrate ratio (ICR) settings. Automatic mode can be activated after 48 hours of using manual mode, starting from midnight after the pump is connected. The recommended optimal settings are a target glucose level of 100 mg/dl and an insulin activity time of 2 hours [26, 27]. Evidence from studies and clinical practice suggests that these settings should be used from the start of therapy in most individuals because they allow for the highest percentage of time spent within range and a tight time in range without increasing the risk of hypoglycaemia.

More conservative settings (target glucose of 110 or 120 mg/dl, insulin activity time of more than 2 hours) may be advisable at the beginning of therapy, particularly when glucose levels should not be lowered too rapidly. This approach is especially relevant for individuals with hypoglycaemia unawareness, fear of hypoglycaemia, advanced retinopathy, or very young children.

The temporary target (set at 150 mg/dl) is used during physical activity or in situations with an increased risk of hypoglycaemia (e.g. gastrointestinal infections with diarrhoea/vomiting).

4.2. CamAPS® FX

The first activation of the CamAPS® FX automatic mode requires the individual's data to be entered, including body weight and average total daily insulin dose. Any significant

change in body weight must be updated in the application's settings. Automatic mode is activated as soon as CGM data are available. The algorithm's default target glucose value is 104 mg/dl. A higher target glucose value can be set for individuals with hypoglycaemia unawareness, fear of hypoglycaemia, advanced retinopathy, or very young children. Different target values can be set for specific time intervals during the day.

The Boost function can be used during an increased insulin requirement (e.g. during infections, menstruation, stress, or increased food intake).

The Ease-off function is used when there is a reduced insulin requirement or an increased risk of hypoglycaemia. It is particularly useful during physical activity.

Both the Boost and Ease-off modes can be scheduled in advance to start at a specific time.

4.3. Mealtime boluses

In traditional pump therapy, the doses for mealtime boluses are calculated using a bolus calculator (Table IV) [28].

The settings for the bolus calculator parameters (except active insulin time) vary depending on the time of day, which is why they are programmed in time intervals. Typically, the ICR is lowest in the morning, i.e. during breakfast/the first meal of the day.

In HCL systems, the algorithm calculates the bolus dose based on the entered carbohydrate amount and the user-set ICR and target glucose values in automatic mode. Additionally, it is based on the analysis of data from previous days (particularly considering hypoglycaemic episodes), the current glucose level (SG), the trend in glucose changes, the amount of active insulin, and the insulin sensitivity factor (ISF) calculated by the algorithm. In the MiniMed 780G system, the safe meal bolus feature is designed to maintain SG above 50 mg/dl for the next 4 hours. If SG is expected to drop below 80 mg/dl within 2 hours, the algorithm will reduce the dose by 25% or more (to the highest safe dose).

In CSII therapy, the effectiveness of the mealtime dose depends on the accuracy of calculating the number of grams of carbohydrates in the meal and the correct setting of the ICR. Less precise estimation of the amount of carbohydrates based on the size of the meal leads to poorer metabolic control of diabetes.

Table IV. Parameters of the bolus calculator

Insulin-to-Carbohydrate Ratio (ICR): The amount of carbohydrates in grams per 1 unit of insulin
Active insulin time
Insulin Sensitivity Factor (ISF): The amount by which 1 unit of insulin lowers blood glucose (usually calculated using the 1800 rule) [28]
Target Glucose: The glucose level to which the blood glucose will be corrected

In HCL systems, the ability to automatically administer insulin based on changing glucose levels allows for slightly less rigorous calculation of the number of carbohydrates consumed. For individuals who have difficulty counting carbohydrates, a portion size system (i.e. estimated portions, known as a fixed meal), such as "large meal" – 60 g, "standard meal" – 40 g, "small meal" – 20 g of carbohydrates, can be used. The number of grams of carbohydrates in a portion size system (large-standard-small meal) depends on the child's age and the average daily calorie intake. It has been shown that more accurate calculations of carbohydrate intake lead to better metabolic control of diabetes [9, 29]. For older individuals, it is suggested not to exceed 60 grams of carbohydrates per meal. Meals containing more carbohydrates may require individualised insulin dose adjustments.

Furthermore, it has been demonstrated that in HCL systems, not administering a mealtime bolus for meals containing up to 20 g of carbohydrates does not significantly affect TIR. This can be useful for individuals who cannot administer boluses independently and when their temporary caregivers (e.g. teachers, preschool staff) refuse to administer them. In such cases, small meals without boluses can be planned at school/preschool (for small children, the allowable carbohydrate portions not requiring a bolus may be smaller, proportional to body weight).

Not only the amount of carbohydrates but also the protein and fat content modulate the glycaemic response. In HCL systems, protein-fat meals generate an additional insulin dose

Table V. Insulin dosing for mealtime boluses principles

To achieve good metabolic control of diabetes using HCL systems, it is crucial to administer mealtime boluses correctly: • Administer boluses 15 minutes BEFORE meals, not during or after meals. Administering the bolus during or after the meal may result in initial hyperglycaemia followed by hypoglycaemia, and in subsequent days, the system may reduce the mealtime bolus dose • Administer boluses before EVERY meal containing carbohydrates (note that studies show that snacks up to 20 grams of carbohydrates, even without a mealtime bolus, do not cause significant glucose spikes – however, such moderate increases still contribute to glycaemic variability and should be avoided whenever possible) • If there are difficulties in calculating the number of grams of carbohydrates in meals, predetermined carbohydrate amounts can be used for individual meals (carbohydrate portions corresponding to small, standard, or large/very large meals, depending on the child's age and body weight) • If the algorithm calculates a bolus dose of zero units, it must be confirmed, because this will record the meal in the pump's memory and ensure the correct operation of the algorithm

that is administered automatically. However, high-fat foods can cause a prolonged rise in glucose levels beyond 2 hours after insulin administration, which is not compensated for by automatic insulin delivery. In such situations, to increase the insulin dose for this type of meal:

- in the MiniMed™ 780G system, you can administer an additional mealtime bolus. To do this, enter approximately 20–30% of the carbohydrates entered before the meal 1.5 hours after the initial mealtime bolus. It is also acceptable to enter them into the system immediately after the meal;
- in the CamAPS® FX system, you can activate the Boost function at the beginning of the meal or increase the number of grams of carbohydrates by at least 30% and mark the meal as slowly absorbed.

4.3.1. Timing of bolus administration

Mealtime boluses should be administered approximately 15 minutes before the meal [30–32]. If the meal contains high-glycaemic index foods, it may be advisable to administer the bolus even earlier or optionally, to "increase the bolus dose". The timing of bolus administration before consuming carbohydrates is particularly important because it helps prevent a sudden postprandial glucose spike. Following an initial rise in glucose levels, the system automatically increases the algorithm-modulated insulin dose, significantly increasing the amount of active insulin. The accumulation of insulin from a delayed mealtime bolus, increased basal rate, and auto-corrections may result in hypoglycaemia.

If hypoglycaemia occurs before a meal, it is recommended to treat the hypoglycaemia first, and after glucose values stabilise, administer the mealtime bolus and begin the meal.

4.3.2. Missed or delayed mealtime bolus

If a meal bolus is skipped or delayed (not administered before the meal), it is suggested that half of the amount of carbohydrates consumed be entered and the suggested bolus be administered within 30-60 minutes of starting the meal. If the meal bolus is delayed by more than 60 minutes after the start of the meal, it is recommended not to administer the meal bolus, because the system will automatically begin correcting blood glucose by increasing the automatic insulin supply. Alternatively, a correction dose initiated by the user can be administered by entering the current glucose level and zero carbohydrates (if blood glucose is within the recommended range, insulin administration is not advised) (Table V).

4.4. Correction dose of insulin

- The MiniMed 780G system automatically calculates and administers correction boluses. Additionally, a user-initiated correction dose can be given by entering the blood glucose value from a glucose meter into the system.
- The CamAPS® FX system automatically calculates and administers a correction dose of insulin. Additionally, after manually entering glucose levels in the bolus calculator (and zero grams of carbohydrates), the system calculates an additional correction dose.

- Administering a correction dose by entering fictional (i.e. not really consumed) amounts of carbohydrates („fake carbs”) into the HCL system may affect the system’s ability to respond appropriately to the situation, potentially reducing overall system performance and increasing glycaemic variability.

5. Treatment modifications

1. In the case of persistent postprandial hyperglycaemia, one should do the following [33]:
 - Ensure that the mealtime bolus is administered at the appropriate time before the meal and that the actual number of grams of carbohydrates consumed is accurately entered.
 - Decrease the ICR.
 - Review the composition of the meal (e.g., an increased proportion of fats and proteins).
2. If the TIR (time in range) is too low, one should:
 - Check the settings of the automatic mode parameters:
 - MiniMed™ 780G: Lower the target glucose and/or shorten the active insulin time, and check if the auto-correction function is enabled.
 - CamAPS® FX: Lower the target glucose and ensure the current body weight is correctly entered.
 - Assess postprandial glucose as mentioned above.
3. If the TBR (Time Below Range) is too high:
 - During nighttime:
 - MiniMed™ 780G: Increase the target glucose value or extend the active insulin time, and sometimes activate the temporary target for a few hours at night.
 - CamAPS® FX: Increase the target glucose.
 - After meals: Review the ICR and assess adherence to mealtime bolus administration guidelines (e.g. boluses given after meals).

6. Physical activity management

When using HCL during physical activity, there is an option to activate functions that modify insulin dosing, known as the “sports mode”:

- In the MiniMed™ 780G system, this function is called the Temporary Target; it raises the target glucose level for the algorithm to 150 mg/dl and additionally turns off the administration of auto-correction boluses.
- The CamAPS® FX application has an “Ease-off” function, which temporarily raises the target glucose level and more quickly suspends insulin delivery when a drop in glucose below the target level is anticipated. This function can be programmed to activate temporarily, which can be useful for children and adolescents who may forget or are unable to activate this function. It is also possible to periodically increase the target glucose level, for example, to 150 mg/dl.

Guidelines for managing physical activity:

1. “Sports Mode”:
 - Use this mode during physical activity lasting longer than 30 minutes; it is essential during prolonged or all-day physical activities.

- Activate 90–120 minutes before the planned physical activity.
 - In the case of an increased risk of hypoglycaemia after physical activity, maintain it for an additional 30–120 minutes after the activity.
2. Reduction of mealtime bolus:
 - A bolus administered within 2 hours before physical activity requires a reduction in the insulin dose by 25% (in some individuals, this reduction may need to be greater, even up to 30–50%) by adjusting the number of carbohydrates entered into the “bolus” function.
 - The degree of reduction depends on the current glucose level, the type, and the duration of the planned physical activity.
 - In many situations, modifying the bolus requires decisions based solely on the individual’s own experiences.
 3. Management of hypoglycaemia risk before and during physical activity:
 - Carbohydrate consumption should be limited to 5–10 minutes before starting the activity – carbohydrates should not be entered into the system.
 - Before unplanned physical activity, it is often necessary to consume an additional portion of carbohydrates.
 - Consuming carbohydrates earlier than 20 minutes before physical activity may cause the system to increase insulin delivery, which can result in hypoglycaemia.

Before starting physical activity, checking glucose levels, the amount of active insulin, and the dose delivered as basal are essential to prevent hypoglycaemia. This is especially important for unplanned physical activity.

For sports that require disconnection of the pump, insulin delivery must be stopped during the pump disconnection. Otherwise, the algorithm accounts for the insulin that was not delivered to the person’s body.

7. Management of hyperglycaemia and presence of ketones

In the case of persistent hyperglycaemia > 250 mg/dl (CGM data), the following steps are recommended:

- Verify the result by measuring blood glucose with a glucose meter.
- If hyperglycaemia persists for more than 2 hours without a known cause, it is recommended that the infusion set be replaced.
- Administer a user-initiated correction bolus in automatic mode. If there is no response within 90 minutes, the next correction should be administered using an insulin pen/syringe. This correction is more effective because, in the case of infusion set occlusion and multiple pump correction attempts, the amount of active insulin registered by the system may be falsely elevated, preventing the administration of an additional bolus.
- If a correction dose of insulin is administered using an insulin pen, the automatic mode should be turned off for 2 to 4 hours to prevent the system from administering additional corrections while the insulin from the pen is still active.
- For hyperglycaemia lasting > 4 hours, monitoring blood or urine ketone levels is necessary.

- If blood glucose exceeds 350–400 mg/dl, it is advisable to administer the first correction dose using a pen/syringe and replace the infusion set and insulin immediately.
- A particularly dangerous situation indicating the presence of ketoacidosis is when blood glucose exceeds 250–300 mg/dl (usually for longer than 4 hours), and the blood concentration of beta-hydroxybutyric acid (BOHB) is above 3 mmol/l (or ketones in urine are high $\geq +++$). In such a situation, the individual requires immediate medical staff attention.

8. Management of hypoglycaemia

When using an HCL system, hypoglycaemia is usually caused by an overly large meal bolus, greater-than-expected physical activity, or an illness accompanied by vomiting/diarrhoea/malabsorption. In the event of impending hypoglycaemia, the system will suspend insulin delivery. Therefore, half the usual dose of carbohydrates required in standard therapy is often sufficient to treat hypoglycaemia [19, 34].

- Treat hypoglycaemia episodes with 0.15 g of carbohydrates per kg of body weight (maximum 8 g), except in cases of hypoglycaemia induced by physical activity or significant overestimation of the carbohydrate content/meal bolus.
- It is important not to administer an additional portion of carbohydrates before 15–20 minutes have passed because this could lead to hyperglycaemia and, consequently, exacerbate glycaemic fluctuations.
- In the MiniMed™ 780G system, the amount of carbohydrates administered for hypoglycaemia treatment is not entered into the system.
- In the CamAPS® FX system, the carbohydrate amount should be entered with the note „hypoglycaemia treatment”.

9. Hybrid closed loop management during additional illnesses

Situations where insulin requirements suddenly deviate significantly from “patterns” of previous days can be challenging for HCL systems. Currently available commercial HCL systems administer insulin based on algorithms that partially rely on insulin doses from preceding days, which may prevent appropriate automatic insulin adjustments during acute infections. These systems do not account for ketone levels in the body, which also has significant practical implications.

The basic principles of management during acute illnesses do not differ from those applicable to all children treated with insulin [18, 35]. Even during infections, efforts should be made to maintain blood glucose levels within the 70–180 mg/dl range and keep ketone levels normal or minimal.

9.1. Management during acute infections accompanied by hyperglycaemia

For blood glucose levels >250 mg/dl persisting for more than 4 hours or in the presence of vomiting or ketonaemia, switch to manual mode and follow the procedures described in the “Management of Hyperglycaemia” section and in accordance with the PTD recommendations [18–20].

9.2. Management during acute illnesses accompanied by reduced insulin dose (e.g. gastroenteritis)

9.2.1. MiniMed™ 780G System

In cases of reduced insulin doses and declining glucose levels, the MiniMed™ 780G system reduces or stops the automatic delivery of basal insulin. To minimise the risk of hypoglycaemia, the “Temporary Target” option can be used, keeping in mind that it is set for a specific period, up to a maximum of 24 hours, and may need to be repeated afterwards. Alternatively, a temporary target of 120 mg/dl or 110 mg/dl can be selected if a lower value was previously chosen. With low glucose levels, even after entering meal carbohydrates, the system may suggest a dose of zero units; it is important to confirm this dose because it informs the algorithm that a meal has been consumed, preparing it to act more aggressively if glucose levels rise. When “starvation ketones” appear, it may be advisable to enter the amount of consumed carbohydrates (and administer the meal bolus) approximately 10 minutes after starting the meal – when an increase in sensor glucose (SG) begins to be visible; however, this suggestion requires further verification in subsequent studies.

If low glucose levels persist or hypoglycaemia recurs, switching to manual mode and temporarily using the predictive low-glucose suspend (PLGS) algorithm may be more beneficial. In this case, it is also possible to periodically reduce the basal rate.

9.2.2. CamAPS® FX System

The algorithm attempts to reduce insulin delivery by calculating it for the next 2.5–4 hours. If this is insufficient and low glucose levels persist, the personal target glucose level can be increased for part or all of the day. The “Ease-off” function can also help prevent glucose levels from dropping further.

10. Management during surgical procedures

Currently, there is no evidence to suggest that HCL systems can be safely used during the perioperative period. However, some paediatric diabetes centres, based on their own experience, continue to use these systems in full functionality during certain minor procedures performed under anaesthesia [36].

Based on the available literature (mainly expert opinions [21]) it can be suggested that when using HCL systems during minor procedures, it may be beneficial to activate the Temporary Target function (in the MiniMed™ 780G system) or set a higher personal target glucose level, or use the “Ease-off” function in the CamAPS® FX system. Maintaining insulin delivery through a personal insulin pump during procedures under general anaesthesia is possible only if the anaesthesiology team accepts this method and if close interdisciplinary collaboration with a diabetologist is possible within the facility.

For major procedures planned for more than 2 hours that require skipping more than one meal, it is necessary to switch to intravenous insulin therapy and follow the guidelines for “major procedures” as described in the PTD recommendations [18].

All emergency procedures should be performed according to the principles applicable to “major procedures” [18].

11. Management during radiological examinations

Table VI shows the management during radiological examinations [37, 38].

During radiological examinations performed under sedation (e.g. MRI and CT in small and uncooperative children), insulin therapy should be managed according to the guidelines for minor surgical procedures, considering the remarks for procedures in individuals using a pump. Based on their own experiences, some paediatric diabetes centres continue to use HCL systems in full functionality during short-term sedation. However, there is currently no scientific evidence to confirm their complete safety in the perioperative/sedation period.

12. Hospitalisation of a person with diabetes using hybrid closed loop in non-diabetes units

The use of HCL is recommended during hospitalisation in non-diabetes units, provided it is not contraindicated due to the clinical condition or the needs related to the treatment or diagnostics being performed. In the case of children and younger adolescents, parental or guardian supervision over the system's operation is necessary.[21, 39].

13. Use of hyperglycaemia-inducing medications (steroids) in individuals using hybrid closed loop

The issues associated with steroid therapy in the treatment of T1D are primarily related to significant changes in insulin sensi-

tivity and insulin requirements, both when starting and when suddenly stopping their use. The management should be tailored to the individual, considering the steroid dosage, the planned duration of treatment, any plans for prolonged tapering of steroids, and the HCL system in use.

For short-term treatment with very high doses of steroids, it may be necessary to switch to manual mode in the Medtronic MiniMed™ 780G and CamAPS® FX systems. In the case of CamAPS® FX, consideration may be given to using the "Boost" function and/or setting lower target glucose values.

For individuals on long-term steroid therapy or those who plan to taper the dose gradually, it is recommended that HCL be continued under close supervision by the diabetes care team. The system may require modification of settings. After discontinuing steroids, to reduce the risk of hypoglycaemia, it may be helpful to temporarily set higher target values for 24–48 hours [20].

14. Pregnancy in adolescents using hybrid closed loop

During pregnancy and postpartum, insulin requirements change rapidly and significantly. It is important to note that lower target glucose values (63–140 mg/dl) are recommended during pregnancy, necessitating frequent adjustments to therapy. Therefore, constant and frequent adjustments of the HCL system settings could help achieve better metabolic control of diabetes [40, 41].

Currently, only the CamAPS® FX system is officially registered for use during pregnancy. During pregnancy, setting the target glucose level to below 100 mg/dl is recommended.

The MiniMed™ 780G system is not yet registered for use during pregnancy. However, studies have shown that this system does not worsen obstetric outcomes and improves metabolic control at night [42].

Table VI. Management with HCL systems during radiological examinations

	Devices comprising the HCL system	
	Personal insulin pump	CGM
Magnetic resonance imaging (MRI)	The pump must be disconnected, and the infusion set must be removed. The pump, infusion set (and smartphone in the case of CamAPS FX) should not be in the MRI room	Not approved by manufacturers for use during the examination. It is recommended that all CGM sensors be removed during MRI scans. After the examination, it is advisable to resume operation in manual mode, or if a new sensor is available, immediately resume automatic mode after its installation and activation
Computed tomography (CT)	Disconnection of the pump is recommended (manufacturer's advice); reports suggest that covering the pump with a lead apron may suffice. The infusion set may remain in place	Not approved by manufacturers for use during the examination. According to studies, exposure to CT may have a limited impact on MARD
X-ray	The pump and infusion set can remain in place if they do not obstruct the imaged area	Not approved by manufacturers for use during the examination. Exposure to X-rays may have a limited impact on MARD

15. Technical issues in using hybrid closed loop
- Differences between CGM readings and glucometer measurements are especially noticeable during episodes of hypoglycaemia or when there are rapid and significant fluctuations in glucose levels.
 - Certain medications can noticeably impact the accuracy of CGM readings (e.g. acetaminophen and hydroxyurea).
 - The body's hydration level can affect the accuracy of CGM readings.
 - It is essential to stay vigilant and cross-check CGM readings with glucometer measurements if the individual experiences symptoms that do not align with the CGM readings.
 - Inflammatory skin reactions at the site of the sensor or infusion set may occur, which can be due to skin irritation, an allergic reaction to the device material, the adhesive, or the

Table VII. Analysis of the HCL system reports

1. General overview Assessment • Daily insulin dose per kilogram of body weight • Ratio of insulin dose initiated by the system/algorithm to the dose initiated by the user (colloquially the ratio of “automated basal” to “bolus amount”, the meaning of the latter may be different depending on AID system, e.g. may include or not “automated corrections”) • Evaluation of CGM usage time and time spent in automatic mode – minimum 85% • Achievement of glycaemic targets according to the AGP (Ambulatory Glucose Profile) report
A. If the individualised goals have been met, no changes are necessary
B. If the individualized goals have not been met, the individual's behaviour and system settings should be evaluated Common issues in using HCL systems include: • Insufficient time spent in automatic mode (including inadequate use of the sensor) • Missed meal boluses (either too few boluses or too few carbohydrates entered into the system). Late administration of meal boluses • Entering “false”/fictional carbohydrate amounts (with or between meals) Assessment of insulin dosing settings in automatic mode: • Insulin-to-Carb Ratio (ICR) • Active Insulin Time (for MiniMed™ 780G) • Target Glucose Value • Current Body Weight entered into the system (for CamAPS® FX) • Activation of Automatic Corrections (for MiniMed™ 780G) • Maximum Bolus Dose Settings

products used before device application. There can also be hypertrophy or hypotrophy of the subcutaneous tissue at the infusion set site.

16. Guidelines for conducting visits for individuals using hybrid closed loop – what to focus on, what to modify, and how to analyse the report
- 16.1. Guidelines for conducting a visit for an individual treated with an hybrid closed loop system
- The use of HCL systems is based on data from continuous glucose monitoring (CGM). The success of the therapy can be measured by the improvement in CGM parameters, such as time in range (TIR), time below range (TBR), coefficient of variation (CV), and time in tight range (TITR).

2. Modification of manual mode settings a) During each visit, verify whether the programmed basal insulin dose is adequate for the patient's needs (typically around 40% of the total daily insulin dose, lower % in younger children) b) Check the insulin sensitivity factor in the bolus calculator c) Review and adjust the target blood glucose levels in the bolus calculator as needed
3. Other aspects a) Proper selection of cannula insertion sites and care for infusion sites b) Over-treatment of hypoglycaemia c) Management during physical activity d) Use of additional pump functions (e.g. temporary target, ease-off, boost) e) Management during additional illnesses
4. Alarm settings Analysis of the number of alarms and customization of settings. In the case of CamAPS® FX, when the phone is fully muted (using the “Do Not Disturb” option), the sound of alarms/alerts may be silenced. It is recommended that the “Sound Test” and “Vibration Test” be performed in the Alerts menu to ensure that alerts emit sound/vibrate on the device
5. Safety a) Check the pump's condition to ensure there are no cracks, display issues, or button malfunctions b) Remind about sick day rules/managing unexpected hyperglycaemia c) Remind about the principles of preventing diabetic ketoacidosis
6. Encourage the patient to make the best daily decisions independently

- A diabetes management visit must be based on data from HCL system reports, allowing for proper interpretation of results and modification of insulin therapy settings.
- The HCL report, typically covering 14 days, provides insight into insulin therapy settings and CGM parameter outcomes

16.2. Report analysis and patient visit

The analysis of the HCL report and the information discussed/verified during the visit should include the elements presented in Table VII.

Summary

Currently, HCL systems represent the most advantageous therapeutic option for individuals with diabetes who require intensive insulin therapy. They not only improve metabolic control of diabetes but also enhance the quality of life for children and adolescents with diabetes, as well as their families. For this reason, HCL systems should be the first choice regarding insulin therapy methods within the paediatric population. HCL systems can be implemented at any stage of diabetes management, whether in patients with newly diagnosed T1D or those with a longer disease duration, regardless of the previously used insulin therapy method. For many patients who have been unable to achieve good metabolic control using traditional intensive insulin therapy methods, applying HCL systems may be the only way to improve metabolic control and reduce the risk of acute and chronic complications of the disease.

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Conflict of interest

A. Szadkowska – Scientific advisory board and/or lecturer for Medtronic, Dexcom/Proglukemia, Abbott, Ypsomed, Roche, Ascensia Diabetes Care.

A. Chobot – Scientific advisory board and/or lecturer for Medtronic.

B. Głowińska-Olszewska – Scientific advisory board and/or lecturer for Medtronic, Abbott.

P. Jarosz-Chobot – Scientific advisory board and/or lecturer for Medtronic, Dexcom/Proglukemia, Abbott, Ypsomed, Ascensia Diabetes Care.

B. Mianowska – Scientific advisory board and/or lecturer for Abbott, Air Liquide Santé International, Dexcom/Proglukemia, Medtronic, Ypsomed, Synoptis/Neuca.

M. Myśliwiec – Scientific advisory board and/or lecturer for Medtronic, Dexcom/Proglukemia, Abbott, Ypsomed, Ascensia Diabetes Care.

A. Szypowska – Scientific advisory board and/or lecturer for Medtronic, Abbott, Dexcom/Proglukemia, Synoptis/Neuca, Ascensia.

A. Zubkiewicz-Kucharska – Scientific advisory board and/or lecturer and conference grant recipient for Medtronic, Abbott, Synoptis/Neuca, Dexcom/Proglukemia, Roche, Ascensia Diabetes Care.

M. Walczak – no conflicts.

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