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PRACTICAL APPROACH

The Hybrid Closed-Loop System Tandem t:slim X2™ with Control-IQ Technology: Expert Recommendations for Better Management and Optimization

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ABSTRACT

Technological advances in the management of diabetes, especially type 1 diabetes (T1D), have played a main role in significantly improving glycemic control of these patients in recent years. Undoubtedly, the most important advance has been the commercialization of hybrid closed-loop systems (HCL). Their effectiveness places them in the different guidelines from scientific societies as the gold standard for the treatment of people with T1D. However, obtaining the maximum performance from these systems requires a degree of expertise from the professionals who care for these patients. Specifically, the Tandem X2:slim with Control-IQ technology system, due to its features and configuration options and adjustments, allows T1D patients to better adapt the management of diabetes to multiple circumstances in their day-to-day life. It is necessary, however, to follow a systematic process to start the system and also for the subsequent follow-up, which allows its

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optimization in the shortest possible time. This expert recommendation reviews the main features of this HCL system, suggesting how to implement it and optimize its use after gaining experience treating many patients.

Keywords: Artificial pancreas; Automated insulin delivery; Continuous glucose monitoring; Hybrid closed-loop system; Insulin pump; Multiple daily injections; Time in range; Type 1 diabetes; Control-IQ technology

Key Summary Points

Hybrid closed-loop systems (HCL) are the gold standard for the treatment of people with type 1 diabetes (T1D), demonstrating improvements in all the CGM-derived glucometric parameters, quality of life and satisfaction compared to open-loop systems, insulin pump alone and multiple daily insulin injections.

Tandem t:slim X2^{TM} with Control-IQ technology has demonstrated similar results to other HCL systems in pivotal studies and real-world conditions.

The features of this system make it especially suitable for people with T1D who have different work shifts, illnesses, stress, participation in sports, menstrual periods, etc., since it allows establishing up to six personal profiles with different basal insulin rates, insulin-to-carbohydrats ratios (ICR) and correction factors (CF). These different profiles help make the algorithm more or less aggressive according to the patient or the situation.

To obtain the maximum benefits in terms of glycemic control, quality of life and patient satisfaction with the treatment, it is essential to follow a systematic procedure from the moment use of the device is indicated to its implantation, immediate post-implantation adjustments and further adjustments for adaptation to unusual situations.

Adjustments of the different configurable parameters to attain a better adaptation to day-to-day situations require a certain degree of expertise.

A structured program of diabetes education is necessary both at the beginning and during the follow-up of patients who start this treatment.

This article summarizes the recommendations of a group of diabetologists with wide experience with this system, obtained from a practical guideline developed by the group that tries to help professionals who are new to using this therapy to obtain the maximum benefit for patients in the shortest possible time.

The main limitation of these recommendations is whether they can be generalized to other types of T1D populations.

THE CLINICAL ISSUE: AIMING TO FACILITATE AND OPTIMIZE THE USE OF CONTROL-IQ TECHNOLOGY

HCL represents the cutting edge of insulin delivery technology. All of the approved HCLs, with their different characteristics (see Table 1), have demonstrated improvements in time in range of glucose (TIR), HbA1c and time spent in hypoglycemia in multicenter prospective trials

[1–3], enabling achieving the objectives proposed in the consensus of Battelino et al. [4].

Several randomized clinical trials, real-world studies and a meta-analysis have demonstrated the safety [5–7] and effectiveness [8–10] of the Control-IQ system in patients with T1D in a wide range of ages, increasing TIR without increasing the incidence of hypoglycemia. In a 6-month trial involving 168 patients with T1D (4–71 years), the use of Control-IQ system was associated with a greater percentage of TIR than the use of sensor-augmented pump therapy: TIR increased significantly in the Control-IQ group (from 61 ± 17% at baseline to 71 ± 12% at 6 months) whereas control group remained unchanged. TBR was also significantly reduced by − 0.88% and HbA1c by − 0.33%. No serious hypoglycemic events occurred [11].

In a retrospective real-world study of 12-month duration, 9451 adults switching from Basal-IQ to Control-IQ technology (83% with T1D) were evaluated. Significant improvement of TIR was observed (from 63.6% to 73.6%) without significant changes during the 12-month follow-up. Improvement was observed within the first day of Control-IQ use and was present across the age range and the range of baseline glycemic control [12]. Similarly, real-world data obtained from Medicaid and Medicare in the USA showed successful results [13].

Finally, a recent meta-analysis combining datasets from three randomized controlled trials found a reduction in both hyper- and hypoglycemia and an increase of > 10% in TIR in people with T1D using Control-IQ across a broad range of ages (2–72 years old) and patient characteristics. In this meta-analysis, the authors conclude that since no subgroups were identified that did not benefit from Control-IQ, this technology should be strongly considered for all young people and adults with T1D [14]. Despite the strong evidence supporting that Control-IQ can be applied to anyone with T1D, there is no standardized recommendation that facilitates the implementation of this particular HCL system beyond some general guides [15]. The purpose of this report is to provide needed guidance and recommendations to clinicians who are interested in utilizing the HCL Tandem t:slim X2™ with Control-IQ technology and to help improve its use and optimization. Users and providers should have the opportunity to assess the full pros and cons of this system to decide if it is suitable for them. This could be helpful to optimize successful device use and avoid frustration.

Ethical approval

This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

T:SLIM X2™ WITH CONTROL-IQ TECHNOLOGY

Control-IQ™ technology is a feature of the Tandem t:slim X2™ pump that automatically adjusts insulin delivery rates and amounts in response to readings from a continuous glucose monitoring system (CGM). The pump can be used with or without Control-IQ technology enabled.

Indications

The Control-IQ technology is approved for use from 6 years of age, when daily insulin requirements are between 10 and 100 IU and when body weight is between 25 and 140 kg. It can be used with any rapid insulin analog (glulisine, lispro or aspart) but cannot be used with ultrafast insulin analogs (e.g., fast aspart). Currently, its use is contraindicated in pregnant women, patients on hemodialysis or those using hydroxyurea.

Components

Tandem t:slim X2™ with Control-IQ technology comprises a t:slim X2™ insulin pump (Tandem Diabetes Care, San Diego, CA) with an embedded model-based predictive algorithm, integrated with the Dexcom G6 continuous glucose monitoring system (Dexcom, San Diego, CA), which does not require calibration.

Table 1 Main features of the current HCL systems available

	MiniMed 780G®	Control IQ®	Diabeloop®	CamAPS FX®	Omnipod 5®
Glycemic target	100, 110 or 120 mg/dl (5.5, 6.1 or 6.6 mmol/l)	110 mg/dl (6.1 mmol/l)	100–130 mg/dl (6.1–7.2 mmol/l)	80–200 mg/dl (4.4–11.1 mmol/l)	110–150 mg/dl (6.1–8.3 mmol/l)
Age approved	+ 7 years	+ 6 years	+ 18 years	+ 1 year	+ 2 years
Glucose sensor	Guardian 3®, Guardian 4®	Dexcom G6®	Dexcom G6®	Dexcom G6®[a]	Dexcom G6®
Insulin pump	MiniMed 780®	Tandem t:slim X2®	Roche Insight®	YpsoPump®	Omnipod®
Duration of active insulin	2 h, 3 h or 4 h	5 h	Dynamic	2–8 h	2–6 h
Customizable parameters	ICR, duration of active insulin, glycemic target	Basal rate, ICR, CF	Glycemic target, hypoglycemia threshold, aggressivity factors	Glycemic target (up to 8 time segments), ICR	Glycemic target (up to 8 time segments), ICR, CF, duration of active insulin
Non-customizable parameters	Basal rate, CF	Duration of active insulin, glycemic target	Basal rate, CF, duration of active insulin	Basal rate, CF, duration of active insulin	Basal rate
Approved use in pregnancy	No	No	No	Yes	No
Approved insulin	Lispro, aspart	Lispro, aspart	Lispro, aspart	Lispro, aspart, fiasp	Lispro, aspart

HCL hybrid closed-loop, *ICR* insulin-to-carbohydrate ratio, *CF* correction factor
[a]Also approved in Europe with Freestyle Libre 3

The t:slim X2™ insulin pump with color touch screen is smaller than other pumps and holds 300 UI of insulin. This pump is waterproof (tested at 0.91 m for 30 min) and rechargeable via a micro-USB port, and its software can be updated remotely (see Fig. 1).

Modes

Algorithm action Control-IQ technology uses CGM and delivers insulin data to predict glucose levels 30 min ahead and adjust insulin delivery every 5 min accordingly, including automatic correction boluses.

The system has three different modes with some differences regarding the operation of the algorithm (see Table 2):

- In the standard mode, the aim of the algorithm is to maintain glucose levels between 112.5 and 160 mg/dl (6.24 and 8.88 mmol/l). When the predicted glucose value is within the target range, the pump will deliver

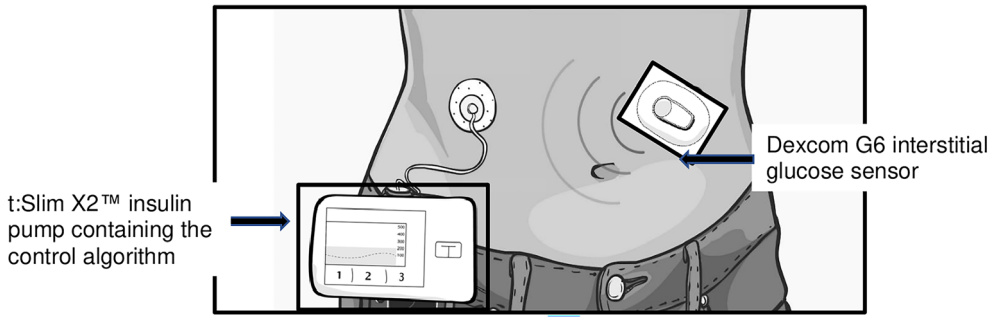

Fig. 1 Schematic representation of the components of the Tandem t:slim X2^{TM} with Control-IQ technology

Table 2 Operation of the three modes available in Tandem t:slim X2^{TM} with Control-IQ technology

	Standard	Sleep activity	Exercise
Automated correction bolus	180 mg/dl (10 mmol/l)	No	180 mg/dl (10 mmol/l)
Increase insulin infusion	160 mg/dl (8.88 mmol/l)	120 mg/dl (6.66 mmol/l)	160 mg/dl (8.88 mmol/l)
Maintain insulin infusion	112.5–160 mg/dl (6.24–8.88 mmol/l)	112.5–120 mg/dl (6.24 - 6.66 mmol/l)	140–160 mg/dl (7.77–8.88 mmol/l)
Decrease insulin infusion	112.5 mg/dl (6.24 mmol/l)	112.5 mg/dl (6.24 mmol/l)	140 mg/dl (7.77 mmol/l)
Stop insulin infusion	70 mg/dl (3.89 mmol/l)	70 mg/dl (3.89 mmol/l)	80 mg/dl (4.44 mmol/l)

insulin at the rate determined by the active personal profile settings. If sensor glucose values are predicted to exceed 160 mg/dl (8.88 mmol/l), basal insulin is increased, whereas if sensor glucose values are predicted to be > 180 mg/dl (10 mmol/l), the system delivers an automatic correction bolus with a target of 110 mg/dl (6.11 mmol/l). If the prediction is that the glucose value falls below 112.5 mg/dl (6.24 mmol/l), basal insulin is decreased, and when the prediction is that glucose values fall below 70 mg/dl (3.89 mmol/l), insulin infusion is interrupted, resuming progressively when the prediction is that glucose will exceed the value of 70 mg/dl (3.89 mmol/l).

- In the sleep activity mode, the aim of the algorithm is to maintain glucose levels between 112.5 and 120 mg/dl (6.24 and 6.66 mmol/l). When the predicted glucose value is within the target range, the pump will deliver insulin at the rate determined by the active personal profile settings. If sensor glucose values are predicted to exceed 120 mg/dl (6.66 mmol/l), basal insulin is increased. In this mode, no automatic correction boluses are delivered. It is recommended to use it systematically, provided that the expected duration of sleep is > 5 h. It can be activated manually or can be programmed (two sleep times are available), and in this case it is automatically deactivated at the end of the period.
- In the exercise mode, the aim of the algorithm is to maintain glucose levels between 140 and 160 mg/dl (7.77–8.88 mmol/l). When the predicted glucose value is within the target range, the pump will deliver insulin at the rate determined by the active personal profile settings. When the prediction is that glucose will exceed 160 mg/dl

(8.88 mmol/l), the basal infusion is increased, and when the prediction is that it will exceed 180 mg/dl (10 mmol/l), self-correcting boluses will be administered with a glucose target of 110 mg/dl (6.11 mmol/l). The basal infusion is reduced when a glucose value < 140 mg/dl (7.77 mmol/l) is predicted and stopped when the glucose value of 80 mg/dl (4.44 mmol/l) is predicted to be reached. This mode must be turned on and off manually. It is recommended to start it 60–90 min before exercising.

Automated Correction Boluses

In the standard and exercise modes, automated correction boluses are delivered only when the maximum basal rate is achieved. The maximum insulin delivery rate is a calculated value dependent on an individual's correction factor (CF) setting (in the active personal profile), total daily insulin estimated by Control-IQ technology based on actual total daily insulin values and current insulin on board (IOB). The total daily insulin value may be updated if there is an important discrepancy between the programmed value and that used for the system. According to that calculation, basal insulin infusion will never exceed 15 IU/h nor will it exceed 50% of the total daily insulin dose in the last 2 h. The amount of the correction bolus is 60% of the calculation based on glucose value and the correction factor (CF) in that period of time. Furthermore, the system does not administer an automatic correction bolus until 1 h after a previous bolus (both meal bolus and self-correction bolus). For an extended bolus, these 60 min do not start until the bolus has been fully delivered.

Required Personal Profile Settings

To use Control-IQ technology, the following personal profile settings must be configured:

- Basal rate
- CF
- ICR (grams/1 IU of insulin)
- Glucose target

Table 3 Main settings of the Tandem t:slim X2™ with Control-IQ and settings of the Tandem t:slim X2 pump

	Control-IQ	T:slim X2 (without Control-IQ)
Maximum basal rate	15 IU/h	15 IU/h
Minimum basal rate	0.1 IU/h	0.1 IU/h
Maximum bolus	25 IU	25 IU (additional bolus of 25 IU)
ICR	1 IU:1 gr–1 IU: 300 g	1 IU:1 gr–1 IU: 300 g
CF	1 IU: 1 mg/dl (0.06 mmol/l)–1 IU: 600 mg/dl (33.3 mmol/l)	1 IU: 1 mg/dl (0.06 mmol/l)–1 IU: 600 mg/dl (33.3 mmol/l)
Extended bolus (duration)	15 min—2 h	15 min—8 h
Temporary basal rate	No	Yes (15 min—72 h)
Insulin active duration	5 h	2–8 h

ICR insulin-to-carbohydrate ratio, *CF* correction factor

In addition to the required personal profile settings, there are two values specific to Control-IQ technology that must be set. These are:

- Weight
- Total daily insulin

Once Control-IQ has been activated, the glucose target is set at 110 mg/dl (6.1 mmol/l) and the duration of active insulin at 5 h. In the event that the system exits Control-IQ, the pump will deliver insulin according to the programmed basal rate, glucose target and insulin duration.

Table 3 shows the main settings and their configuration ranges both when the system is working with Control-IQ technology and when there is an exit from automatic mode.

Custom Settings

The system allows the patient to create up to six personal profiles (basal rate, ICR and CF) to better adapt to different situations in which insulin requirements vary (work shifts, menstrual period, illness or stress, sports, etc.). To improve the effectiveness of the system, adequate adjustment of the three personal profile components is essential.

Boluses

The Control-IQ technology allows administering manual and extended boluses (15 min–2 h). While an extended bolus is being delivered, the system may increase the basal insulin infusion. When Control-IQ technology sets the basal rate to 0 units per hour, due to prediction of a glucose value below range, bolus deliveries will continue. This includes starting a new bolus and any remaining bolus from an extended bolus delivery.

Switch to Programmed Personal Profile

If the CGM connection is lost or stopped for ≥ 20 min, the pump returns to the active personal profile settings until the connection has been restored. Once restored, Control-IQ will resume automatically.

Alerts

The system can display different alerts and alarms on the pump screen, which are accompanied by different sounds and recommendations for their solution.

Table 4 shows a summary of the main alerts and alarms.

Table 4 Main alarms and alerts of the Tandem t:slim X2™ with Control-IQ

Out of range	The transmitter and pump are not communicating or the pump do not receive glucose readings
Control-IQ low alert	Glucose will drop < 70 mg/dl (3.89 mmol/l) or < 80 mg/dl (4.44 mmol/l) if exercise mode is enabled, in the next 15 min
Control-IQ high alert	Control-IQ has increased insulin delivery but detects a sensor glucose reading > 200 mg/dl (11.1 mmol/l) and does not predict that glucose will decrease in the next 30 min
Low transmitter battery	Transmitter battery is low
Transmitter error	The transmitter has failed, and the CGM session has stopped
Calibration error	The sensor cannot calibrate
Calibrate CGM	The system needs a blood glucose value to calibrate
Failed sensor	CGM is not working
CGM unavailable	CGM has been stopped for > 20 min and cannot be used any longer
CGM error	CGM is not working properly
CGM high alert	The most recent sensor glucose reading is at or above the high alert
CGM low alert	The most recent sensor glucose reading is at or below the low alert or the glucose reading is at or below 55 mg/dl (3.05 mmol/l)
CGM rise alert	Glucose levels are rising at 2 mg/dl (0.11 mmol/l) per minute or faster (↑) or at 3 mg/dl (0.17 mmol/l) per minute or faster (↑↑)

DIABETES SOFTWARE MANAGEMENT

Glooko® (Glooko Inc, Ca, USA) is a data management software intended for use in home and professional settings to aid individuals with

Table 4 continued

CGM fall alert	Glucose levels are falling at 2 mg/dl (0.11 mmol/l) per minute or faster (↓) or at 3 mg/dl (0.17 mmol/l) per minute or faster (↓↓)

CGM continuous glucose monitoring

diabetes and their healthcare professionals with review, analysis and evaluation of device data to support an effective diabetes management program [16, 17]. Glooko® connects to compatible medical devices such as Tandem t:slim X2™ (Tandem Diabetes Care Inc., CA, USA) and trackers to allow users to transfer their data to the Glooko® system. The patients need to register and log into their Glooko® account via the mobile app or website. Only then can they upload Tandem t:slim X2™ data to their Glooko® account. To allow patients' healthcare providers to obtain their diabetes management data, a ProConnect Code needs to be added to the account.

Glooko®'s available reports include: Summary (only available in the web platform), Logbook, Overview, Daily Overview, Weekly Overview, Overlay, Insights (only available in the web platform) and Devices. First, users should select a date range for reports. The recommended and default date range for reports is 2 weeks. The glucose data source for reports should be CGM in patients using Control-IQ technology. We suggest the priority use of the Summary, Overview, Daily Overview, Insights and Devices reports for Control-IQ technology [18].

- The *Summary* presents a consolidated view of the most important diabetes metrics. Glucose readings within a time frame are displayed across different ranges. Below the percentage of time, the CGM has been active within the chosen period is shown. Glucose summary data include GMI (glucose management indicator), average, median (midpoint), SD (standard deviation), CV (coefficient of variation), % time CGM active, and highest and lowest CGM values. The attached insulin pie chart displays basal and bolus daily averages for the selected time frame. System Details shows information on different working modes of Control-IQ technology (e.g., sleep, exercise). The Temp basal suspend report allows to better understand how basal suspensions impact on CGM levels.
- *Overview* reports provide information on how glucose levels correlate with insulin, carbohydrates and exercise during the selected time frame.
- The *Daily Overview* reports show information on individual days of the selected period for a more detailed analysis. This report helps identify causes of hypo-/hyperglycemia in a simple manner (presence of manual boluses, excess or defect of corrective boluses, unannounced intakes, etc.).
- The *Insights* reports provide detailed views of insulin data and the frequency of set/site changes providing information of how these changes impact CGM data.
- In the *Devices* report, users can check insulin pump settings (personal patterns, ICR, CF, total daily dose, weight) to help make treatment plan decisions.

The *Logbook* shows the values of glucose, carbohydrates, basal insulin and boluses for each day of the analyzed period with a display similar to that of the traditional capillary blood glucose control notebook.

The *Weekly Overview* is useful to identify those days of the week that are different from the rest (due to schedules, physical activity, etc.). In this case, a different personal profile for different days of the week can be generated.

It is possible to generate a pdf document with all the reports previously selected. A possible order for a better analysis of the different reports is shown in Fig. 2.

IMPLEMENTATION OF CONTROL-IQ SYSTEM

Before Control-IQ implementation, patients should understand the technical aspects of the system and how to address any potential

Fig. 2 Recommended sequence for analysis of the most relevant reports provided by Glooko® and the information provided by each of them

technical or diabetes management issues. A proper estimation of carbohydrate content is essential.

Users should have realistic expectations regarding the use of this HCL system. Only then can a Control-IQ system be implemented after the configuration settings have been established by health professionals.

First, glycemic control objectives are recommended although with the active Control-IQ objective set at 110 mg/dl (6.1 mmol/l) according to international diabetes guidelines.

Second, users should establish two security options to avoid insulin overdosage: maximum bolus and basal rate limit (active Control-IQ can override the last one if necessary). Duration of active insulin can be set from 2 to 8 h, although with active Control-IQ it is automatically set to 5 h. This technology allows to set up different tiers throughout the day for the patient's CF and ICR.

Table 5 Interpretation of the many reports generated in Glooko® and suggested changes of Control-IQ settings accordingly

Report	Data	Recommendation	Suggested changes
Summary	Basal/bolus rate	Approximately 50%/50%	Increase or decrease of basal pattern or CF and ICR
	Difference between average needed total daily basal insulin dose and scheduled total daily basal insulin rate dose	< 10%	Adjust scheduled daily basal insulin to real basal insulin needs
	Control-IQ use	> 95%	Analyze CGM failures or manual disconnections
	Sleep mode use	30–35%	If lower, check configuration of Sleep activity mode
	Exercise mode use	< 15–20%	If higher, check turn off exercise mode after exercise ends
	Low glucose and predictive low glucose suspensions	< 5 h/day	Reduce basal insulin pattern in affected time frames
Overview	Prandial bolus before eating	All food boluses	Explain to patient how this leads to postprandial hyperglycemia
	Forgotten or omitted prandial bolus	0%	Explain to patient how this leads to postprandial hyperglycemia
	Postprandial hyperglycemia	< 180 mg/dl	After excluding late, forgotten or omitted bolus, check and reduce ICR by 20%
Insights	Frequency of infusion set change	3 days	If lower, check individual glycemic variability or infusion set problems. If higher, explain DKA risk to patient
	Decrease and suspension	< 5	Explain to patient how this manual supply suspension affects subsequent glucose levels
Devices	Total insulin dose and patient's weight	Similar to current total daily insulin need and weight	Adjust settings to current insulin dose needs and weight

CF correction factor, *ICR* insulin-to-carbohydrate ratio, *DKA* diabetic ketoacidosis

The basal insulin rate should be programmed based on the patient's previous treatment. In general, it is recommended to adjust the basal daily dose for the Control-IQ system to be approximately 20% lower than the basal daily insulin requirement of the previous MDI treatment. If basal patterns are known (based on Ambulatory Glucose Profile data), multiple segments can be accordingly established. If basal patterns are unknown, a single 24-h basal insulin rate can be scheduled. In people with diabetes transitioning from an insulin pump or

another HCL system to Control-IQ, the configuration settings can be directly transferred.

Control-IQ alerts are pre-set and alert the patient to resolve important situations such as hypo- or hyperglycemic events. Subsequently, we determine the weight and set the total daily insulin dose. These two parameters serve as the starting point for the algorithm to determine the insulin delivery limit achievable with Control-IQ.

Special sleeping operation mode should be programmed. Although the sleep activity can be initiated and stopped manually, it is strongly recommended to set up at least one sleep schedule with 6–8-h duration. Exercise activity mode can only be started and stopped manually, so it does not need an additional configuration.

Finally, it is recommended to keep a copy of the system settings in the medical record and provide a copy to the patient.

Once all the parameters have been configured and the patient has the activated the sensor (with Dexcom G6 a 2-h warm-up is required), the system starts directly in automatic mode.

FOLLOW-UP AFTER CONTROL-IQ IMPLEMENTATION

Short-term Follow-up and First Adjustments

After Control-IQ initiation, glucose control of the patients should be reviewed within the first month to adjust the configuration if necessary. Some Glooko® reports are helpful to attain a better understanding of patients' diabetes control. Interpretation of these reports can lead to different treatment changes (Table 5) (Fig. 3). An example of the summary report from Glooko® and the different aspects to be evaluated are shown in Fig. 3.

Follow-up: Optimization and Adaptation to Patient's Needs

After the first adjustments have been made, it is expected that the system will quickly reach the recommended targets. Nevertheless, optimization of the system to the patient's needs can provide even better results.

Follow-up visits are usually scheduled every 6 months. At these visits, one aim is to review the configuration, ensuring that sleep mode is activated, confirming that the programmed insulin basal rate is similar to the delivered basal insulin, that boluses are being administered before meals and that hypoglycemia is not being overtreated.

The other aim is to check whether the patient can benefit from programming several personal profiles. As Control-IQ has the advantage compared to other HCL systems of using the programmed insulin basal rate in its calculations, the system can be made more or less aggressive by switching between different personal profiles. Most patients can reach the glycemic objectives with just one single personal profile, but, in other cases, the performance of the system can be enhanced by tailoring different personal profiles.

Personal Profiles for Specific Scenarios

It is advisable to create a "safe profile" with a lower basal insulin rate (− 15 to 20%) to use in case CGM is lost for a long time period so the system can work in manual mode (without hypoglycemia protection).

Some patients can suffer from hypoglycemia related to exercise despite activating the exercise mode, and in these cases a good option is to create a less aggressive personalized profile by decreasing the basal rate by 30–50% and increasing CF and ICR by 40–50%. The advice is to switch to this profile 60–90 min before exercise on top of activating the exercise mode until 60–90 min after the exercise ends. If exercise-related hypoglycemia is still a problem, it is usually due to automated boluses, and in these cases a good tip is to administer a very low dose bolus (0.05 IU) just before exercise, which can

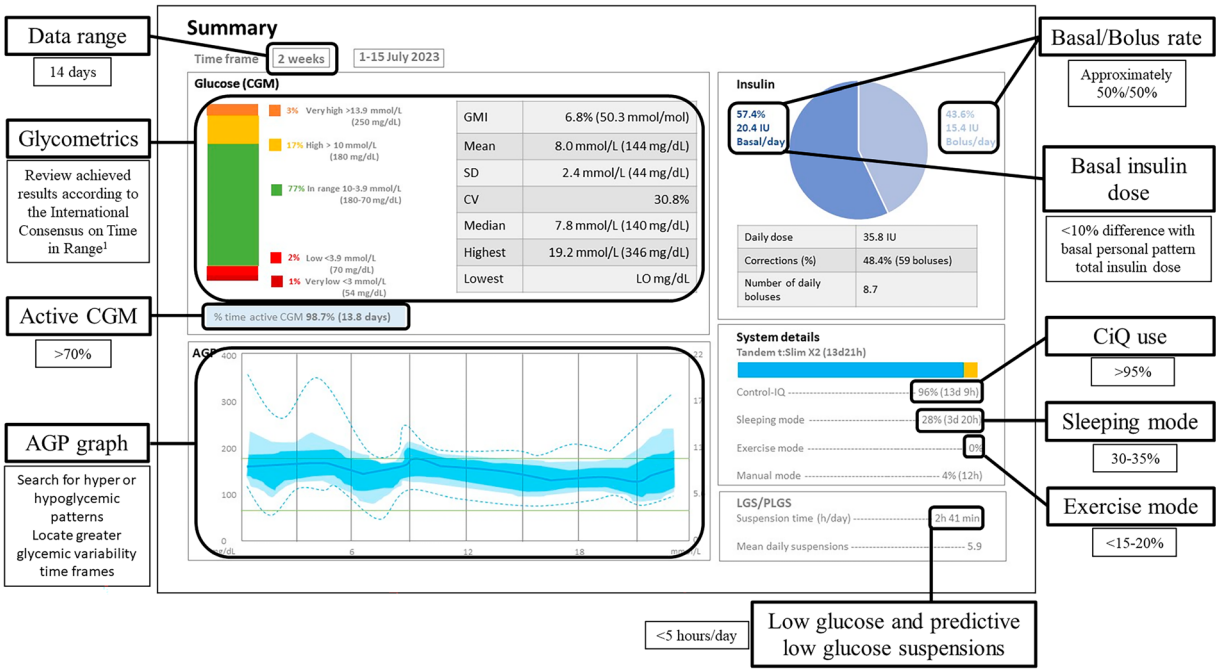

Fig. 3 Example showing the summary report similar to the one provided by Glooko® (created by the authors)

even be cancelled, ensuring that no automated bolus will be administered in the following 60 min [19].

Contrarily, situations like sick days or menstrual periods can be handled by switching to a more aggressive profile increasing the basal rate by 30–50% and decreasing CF and ICR by 20–30%. A similar profile can be created for glucocorticoid use or minor surgery.

It is possible to create up to six personal profiles with different combinations of basal rate, CF and ICR, and this feature can be very helpful in shift workers.

Table 6 summarizes some of the possible personal profiles that can be set.

Top Tips for Achieving Optimal Results with Control-IQ

- Set realistic glycemic targets and expectations with the patient before implementing the system.
- Ensure systematic use of sleep mode by programming one or two sleep mode schedules.
- Set the exercise mode 60–90 min before performing exercise until 60–90 min after the exercise ends.
- Set up to six different tailored personal profiles according to the individual needs.
- Always administer the prandial bolus before eating.
- Compare programmed basal rate with administered basal dose and modify programmed basal rate if necessary.
- Do not overtreat hypoglycemia. Only 3–5 g glucose is usually enough and recommended.
- Ensure timely replacement of consumables.
- Accurately estimate the amount of carbohydrates.
- Adjust weight and total dose if there are significant changes.
- Pause insulin delivery if the pump is turned off.

CONCLUSION

The Control-IQ HCL system is user-friendly, is easy to use and offers an important level of

Table 6 Recommendations for creating personalized profiles in Control-IQ system for specific situations

Specific situation	Basal rate	CF	ICR
Safety profile (sensor loss)	− 15 to 20%	No change	No change
Exercise profile	− 30 to 50%	+ 40 to 50%	+ 40 to 50%
Sick days	+ 30 to 50%	− 20 to 50%	− 20 to 50%
Menstrual period	+ 30%	− 30%	− 30%
Treatment with glucocorticoids	Increase*	Decrease*	Decrease*
Minor surgery	Increase**	Decrease**	Decrease**

CF correction factor, *ICR* insulin-to-carbohydrate ratio

*Amount of increase/decrease depends on the dose, type and route of administration of glucocorticoid therapy

**Amount of increase/decrease depends on the kind of surgery performed and the post-surgical evolution

adaptability to accommodate the diverse needs of individual patients through its customizable tools. Based on the authors' clinical experience, adhering to the proposed recommendations while using the Control-IQ system has potential for improving time spent within target range and minimizing hypoglycemia in a shorter time period. The main limitation of these recommendations is whether they can be generalized to other types of populations with T1D.

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Declarations

Ethical Approval. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

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REFERENCES

1. Templer S. Closed-loop insulin delivery systems: past, present, and future directions. Front Endocrinol (Lausanne). 2022;13: 919942.

2. Seget S, Tekielak A, Rusak E, et al. Commercial hybrid closed-loop systems available for a patient with type 1 diabetes in 2022. Pediatr Endocrinol Diabetes Metab. 2023;29(1):30–6.

3. Phillip M, Nimri R, Bergenstal RM, et al. Consensus recommendations for the use of automated insulin delivery technologies in clinical practice. Endocr Rev. 2023;44(2):254–80.

4. Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. Diabetes Care. 2019;42(8):1593–603.

5. Forlenza GP, Ekhlaspour L, Breton M, et al. Successful at-home use of the Tandem control-IQ artificial pancreas system in young children during a randomized controlled trial. Diabetes Technol Ther. 2019;21(4):159–69.

6. Schoelwer MJ, Robic JL, Gautier T, et al. Safety and efficacy of initializing the control-IQ artificial pancreas system based on total daily insulin in adolescents with type 1 diabetes. Diabetes Technol Ther. 2020;22(8):594–601.

7. Ekhlaspour L, Schoelwer MJ, Forlenza GP, et al. Safety and performance of the Tandem t:slim X2 with control-IQ automated insulin delivery system in toddlers and preschoolers. Diabetes Technol Ther. 2021;23(5):384–91.

8. Kanapka LG, Wadwa RP, Breton MD, iDCL Trial Research Group, et al. Extended use of the control-IQ closed-loop control system in children with type 1 diabetes. Diabetes Care. 2021;44(2):473–8.

9. Isganaitis E, Raghinaru D, Ambler-Osborn L, iDCL Trial Research Group, et al. Closed-loop insulin therapy improves glycemic control in adolescents and young adults: outcomes from the international diabetes closed-loop trial. Diabetes Technol Ther. 2021;23(5):342–9.

10. O'Malley G, Messer LH, Levy CJ, iDCL Trial Research Group, et al. Clinical management and pump parameter adjustment of the control-IQ closed-loop control system: results from a 6-month, multicenter randomized clinical trial. Diabetes Technol Ther. 2021;23(4):245–52.

11. Brown SA, Kovatchev BP, Raghinaru D, et al. Six month randomized, multicenter trial of closed-loop control in type 1 diabetes. N Engl J Med. 2019;381(18):1707–17.

12. Breton MD, Kovatchev BP. One-year real-world use of the Control-IQ advanced hybrid closed-loop technology. Diabetes Technol Ther. 2021;23(9):601–8.

13. Forlenza GP, Carlson AL, Galindo RJ, et al. Real-world evidence supporting tandem control-IQ hybrid closed-loop success in the medicare and medicaid type 1 and type 2 diabetes populations. Diabetes Technol Ther. 2022;24(11):814–23.

14. Beck RW, Kanapka LG, Breton MD, et al. A meta-analysis of randomized trial outcomes for the t:slim X2 insulin pump with control-IQ technology in youth and adults from age 2 to 72. Diabetes Technol Ther. 2023;25(5):329–42.

15. Grupo de Trabajo de Tecnologías de la Sociedad Española de Diabetes. Guía de uso de sistemas de asa cerrada. https://www.sediabetes.org/wp-content/uploads/Guia-Sistemas-de-Asa-Cerrada.pdf. Accesssed 2019.

16. GLOOKO® for clínics: quick start guide. https://docs.glooko.com/Glooko%20for%20Clinics/Web%2023.3/ENGLISH-US%20-%20IFU-0026-00-EN%2025%20Glooko%20for%20Clinics.pdf. Accesssed 2023.

17. GLOOKO® for personal use: quick start guide. https://docs.glooko.com/Report%20Reference%20Guide/Web%2022.6-23.1,%20Mobile%205.23-6.0/ENGLISH%20UK%20-%20IFU-0025-02-UK%2006%20Glooko%20Report%20Reference%20Guide.pdf. Accesssed 2023.

18. Report reference guide. https://docs.glooko.com/Report%20Reference%20Guide/Web%2022.6-23.1,%20Mobile%205.23-6.0/ENGLISH%20US%20-%20IFU-0025-00-EN%2010%20Glooko%20Report%20Reference%20Guide.pdf. Accesssed 2023.

19. Zaharieva DP, Morrison D, Paldus B, Lal RA, Buckingham BA, O'Neal DN. Practical aspects and exercise safety benefits of automated insulin delivery systems in type 1 diabetes. Diabetes Spectr. 2023;36(2):127–36.