RIJKSINSTITUUT VOOR ZIEKTE - EN INVALIDITEITSVERZEKERING

Openbare instelling opgericht bij de wet van 9 augustus 1963
Galileelaan 5/01 - 1210 Brussel

Dienst Geneeskundige Verzorging

OVEREENKOMST INZAKE GEAVANCEERDE OF DURE TECHNOLOGIE BIJ DE DIABETESPATIËNT (GDT)

FICHE WAARMEE HET VERZEKERINGSCOMITE HET GEBRUIK VAN EEN SPECIFIEKE TECHNOLOGIE EN/OF DE BIJHORENDE EDUCATIE IN HET KADER VAN DE GDT-OVEREENKOMST GOEDKEURT

Deze fiche kadert in de overeenkomst inzake geavanceerde of dure technologie bij de diabetespatiënt (GDT-overeenkomst).

*Krachtens deze overeenkomst kunnen alleen technologieën en/of de bijhorende educatie in het kader van de GDT-overeenkomst worden vergoed waarvoor het Verzekeringscomité een **fiche** heeft goedgekeurd.*

Aangezien deze fiche kadert in de GDT-overeenkomst, kan wat in deze fiche staat, nooit los worden gezien van de bepalingen van de GDT-overeenkomst.

Deze fiche past de bepalingen van de GDT-overeenkomst alleen maar toe en wijzigt de bepalingen van de GDT-overeenkomst dus niet, behalve dat deze fiche – in toepassing van de GDT-overeenkomst – bepaalde aspecten van de GDT-overeenkomst preciseert en als dusdanig bijkomende voorwaarden oplegt die samen met de bepalingen van de overeenkomst moeten worden gerespecteerd.

Nummer van deze fiche: fiche 7.86.9/1-A
(noot: als deze fiche ooit gewijzigd moet worden, zonder dat omwille van deze aanpassing een afzonderlijke evaluatiestudie moet worden verricht, zal die nieuwe fiche fiche 7.89./1-B worden. Als ooit een andere technologie wordt goedgekeurd waarvoor wel een afzonderlijke evaluatiestudie moet worden verricht, zal de nieuwe fiche fiche 7.86.9/2-A worden)

TECHNOLOGIE WAAROP DEZE FICHE BETREKKING HEEFT

Hybrid Closed Loop systeem verkregen door het gecombineerd simultaan gebruik door eenzelfde patiënt van

- de insulinepomp Tandem t:slim X2™ met Control-IQ™ technologie en
- de Dexcom G6 Sensor & Transmitter

Insulinepomp :

Fabrikant : Tandem Diabetes Care

Verdeler in België : Air Liquide Medical nv – Activiteit VitalAire

Referenties VitalAire:

36772 INSULIN PUMP CONTROL IQ TSLIM
36864 T:SLIM CARTRIDGE T/LOCK CON (10 p)
36835 INFUSION SET AS30 13mm/60cm GREY(10)
36836 INFUSION SET AS90 6mm/110cm GREY(10)
36837 INFUSION SET AS90 6mm/60cm GREY(10)
36838 INFUSION SET AS90 9mm/60cm GREY(10)
36839 INFUSION SET AS90 9mm/110cm GREY(10)
36840 INFUSION SET AS30 13mm/110cm GREY(10)
36851 INFUSION SET TRUSTEEL 8mm/60cm(10)
36852 INFUSION SET TRUSTEEL 6mm/60cm(10)

Sensor & Transmitter

Fabrikant: Dexcom

Verdeler: Dexcom

Referenties Dexcom:

STS-GS-003 DEXCOM G6 OUS Sensor Kit
STT-GS-003 DEXCOM G6 OUS TRANSMITTER Kit
STK-GS-013 OUS Receiver Kit mg/dl

PATIENTEN DIE VOOR DEZE TECHNOLOGIE IN AANMERKING KOMEN

Volwassen patiënten

- die reeds minimum 12 maanden met intensieve insulinetherapie worden behandeld in het kader van de zelfregulatieovereenkomst voor volwassenen (7.86.0xx.xx of 7.86.1xx.xx) of de insulinepompovereenkomst (7.86.5xx.xx) of uitzonderlijk in het kader van de zelfregulatieovereenkomst voor kinderen en adolescenten (7.86.7xx.xx) en die behoren tot groep A van de zelfregulatieovereenkomst voor volwassenen, en
- die aan de voorwaarden voor een insulinepompbehandeling van één van deze overeenkomsten beantwoorden en
- die ook reeds minimum 12 maanden hun glycemie meten met behulp van een sensor,

alsmede kinderen en adolescenten die minimum 6 jaar oud zijn

- die reeds minimum 6 maanden met intensieve insulinetherapie worden behandeld in het kader van de zelfregulatieovereenkomst voor kinderen en adolescenten (7.86.7xx.xx), en die behoren tot de patiënten die worden vermeld in artikel 6 § 1 van deze overeenkomst, en
- die aan de voorwaarden voor een insulinepompbehandeling van deze overeenkomst beantwoorden en
- die ook reeds minimum 6 maanden hun glycemie meten met behulp van een sensor.

Alleen patiënten die uiterlijk op 31 december 2022 starten met het gebruik van deze technologie, komen voor de vergoeding van deze technologie in aanmerking omdat het – rekening gehouden met de vooropgestelde publicatiedatum van het evaluatierapport en de einddatum van de overeenkomst - alleen voor deze patiënten mogelijk zal zijn om gedurende een jaar de gegevens te verzamelen die vereist zijn volgens het protocol voor de wetenschappelijke evaluatie van deze technologie.

DAGFORFAIT DAT IN HET KADER VAN DE GDT-OVEREENKOMST KAN WORDEN AANGEREKEND VOOR HET GEBRUIK VAN DEZE TECHNOLOGIE

Dagforfait van 6 €

Dit dagforfait is bedoeld om zowel de extra-kosten van het materiaal als de bijkomende educatie die de patiënt nodig heeft, te vergoeden.

Deze vergoeding kan voor patiënten die opgevolgd worden in het kader van de overeenkomsten voor volwassen patiënten, worden gecombineerd met de forfaits voor sensormetingen en met de forfaits voor een insulinepompbehandeling van die overeenkomsten, en kan voor kinderen en adolescenten die opgevolgd worden in het kader van de zelfregulatieovereenkomst voor kinderen en adolescenten worden gecombineerd met een forfait van die overeenkomst. Voor het aanrekenen van het sensorforfait in het kader van deze overeenkomsten dient voor de identificatie van de sensor de identificatiecode 701019999989 op de factuur te worden vermeld.

Deze vergoeding kan alleen worden aangerekend voor patiënten die deelnemen aan de wetenschappelijke evaluatiestudie voor deze technologie.

PSEUDOCODE WAARMEE DEZE TECHNOLOGIE KAN AANGEREKEND WORDEN AAN DE VERZEKERINGSINSTELLINGEN

784991 (ambulante patiënten)
785002 (gehospitaliseerde patiënten)

NAAM VAN DE ONAFHANKELIJKE ONDERZOEKER DIE INSTAAT VOOR DE WETENSCHAPPELIJKE EVALUATIE DIE ARTIKEL 17 VAN DE GDT-OVEREENKOMST VOORZIET

Prof. Dr. Pieter GILLARD, UZ LEUVEN

PROTOCOL VOOR DE WETENSCHAPPELIJKE EVALUATIE VAN DEZE TECHNOLOGIE

Zie de bijlage bij deze fiche, die een precisering vormt van het algemeen evaluatieprotocol dat als bijlage 4 bij de overeenkomst is gevoegd.

EVALUATIERAPPORT EN WETENSCHAPPELIJKE PUBLICATIE

Uiterlijk op 30 april 2024 zal aan het Riziv een gedetailleerd rapport worden bezorgd dat bestemd is voor het Verzekeringscomité en dat de resultaten weergeeft van de gerealiseerde wetenschappelijke evaluatie.

De evaluatie moet ook leiden tot het uitwerken van een wetenschappelijk artikel dat voor publicatie in een peer reviewed wetenschappelijk tijdschrift zal worden aangeboden. Voor deze publicatie wordt echter geen datum vooropgesteld.

PERIODE WAARIN DEZE TECHNOLOGIE KAN WORDEN VERGOED

Van 1 oktober 2021 tot en met 30 september 2024

DATUM VAN GOEDKEURING VAN DEZE FICHE DOOR HET VERZEKERINGSCOMITE

04/10/2021.

The impact of hybrid closed-loop insulin delivery on glycemic control and patient-reported outcomes in people living with type 1 diabetes: a multicenter real-world observational study in Belgium.

Protocol acronym: INRANGE study – the Impact of hybrid closed-loop iNsulin deliveRy in type 1 diAbetes oN GlycEmic control and PROMs

Date of final protocol: 27-08-2021

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Table of contents

1. Study synopsis

Title of clinical trial	The impact of hybrid closed-loop insulin delivery on glycemic control and patient-reported outcomes in people living with type 1 diabetes: a multicenter real-world observational study in Belgium.
Protocol short title/acronym	INRANGE study The impact of hybrid closed-loop insulin delivery in type 1 diabetes on glycemic control and PROMs
Sponsor name	UZ Leuven
Principal investigator	prof. dr. Pieter Gillard, dr. Anissa Messaaoui
Medical condition or disease under investigation	Adults and children living with type 1 diabetes who use the Tandem t:slim X2 Control-IQ™
Purpose of clinical trial	To evaluate the impact of the Tandem t:slim X2 Control-IQ™ on glycemic control and patient-reported outcomes in people living with type 1 diabetes under real-life conditions.
Trial design	Multicenter real-world observational study
Endpoints	Primary: the evolution of time spent in range (sensor glucose 70-180 mg/dL) from before start to 12 months after start of the Tandem t:slim X2 Control-IQ™
Sample size	350 adults and 150 children
Summary of eligibility criteria	People with type 1 diabetes, aged 6 years and older • who are already treated at least 12 months with intensive insulin therapy, and • who satisfy the conditions for insulin pump therapy and • who start with the Tandem t:slim X2 Control-IQ™ in the participating centers and • who signed informed consent are eligible to participate. The decision about which patient to start, is left to the clinical judgement of the treating health care professional.

Maximum duration of treatment of a Subject	24 months of observation

2. Background and rationale

Insulin therapy is of vital importance for people with type 1 diabetes (T1D) and can be administered as multiple daily injections (MDI) or by means of continuous insulin infusion (CSII), also known as insulin pump therapy. T1D patients benefit from intensive insulin therapy, as was already shown by the *Diabetes Control and Complications Trial* (1). Attaining near-normal blood glucose values reduces the risk of diabetic complications (1,2), so that guidelines since long advise an HbA1c <7% (<53 mmol/mol) as an optimal treatment goal for adults with T1D (3,4). Any current exogenous insulin therapy is however associated with risk of developing hypoglycemia (1) often leading to fear of hypoglycemia and thus a barrier to achieve an optimal HbA1c (5).

Self-monitoring of glucose values is essential in order to minimize the risk of hypoglycemia by balancing the insulin dose with current and predicted glucose values. Finding the right balance can be very challenging since it is influenced by factors such as meals, exercise, stress and illness. New technologies have been developed in the past years to support people with T1D in self-monitoring, optimizing insulin therapy and lessen the burden.

One of these new technologies is the hybrid closed-loop insulin delivery system (HCL). This is a form of sensor-augmented insulin pump therapy (SAP), in which a continuous glucose monitoring device (CGM) is integrated into CSII. A subcutaneous glucose sensor connects with a transmitter on the skin that sends the measured values wirelessly to an insulin pump that then uses an algorithm to manage the basal insulin delivery automatically. The system is called a *hybrid* closed-loop (6) because patients have to input their carbohydrate intake and accept a bolus-advise generated by the insulin pump. Several randomized controlled trials showed that HCL in an outpatient setting is superior to SAP regarding glycemic control (7–10). Some trials also studied the effect on quality of life, but no significant difference could be demonstrated (10,11).

The t:slim X2 Control-IQ™ from Tandem Diabetes Care, Inc. (San Diego, CA) recently entered the Belgian market. This system was approved by the FDA in December 2019. A randomized controlled trial comparing Tandem t:slim X2 Control-IQ™ with SAP, showed that this system was associated with a greater percentage of time spent in range than SAP (12). From 2021 onward, this system will fall within a new Belgian diabetes reimbursement program (Advanced and Expensive Technology convention).

Based on the available data, the impact of HCL systems on glycemic control and patient-reported outcome measures (PROMs) under real-life conditions is however still unclear. Therefore we will undertake this 24-month prospective study in a cohort of patients who were started on the Tandem t:slim X2 Control-IQ™ in Belgium. As for the RESCUE trial on SAP (13), this study will help individualize the treatment of T1D patients and provide knowledge about how to attribute healthcare costs in the Belgian healthcare environment of expert centers treating patients with new technologies.

3. Trial objective and design

3.1 Trial objective

The objective of this study is to evaluate the impact of the Tandem t:slim X2 Control-IQ™ on glycemic control and patient-reported outcomes in patients with type 1 diabetes under real-life conditions.

3.2 Primary endpoint

The evolution of percentage of time spent in range (sensor glucose 70-180 mg/dL) from before start to 12 months after start of the Tandem t:slim X2 Control-IQ™.

3.3 Secondary endpoints

All endpoints are measured from before start to 4, 8,12, 16, 20 and 24 months after start of the Tandem t:slim X2 Control-IQ™. As part of the analysis of the results, a comparison will be made between the results of the first year of the treatment by the Tandem t:slim X2 Control-IQ™ and the results of the second year of this treatment.

- Percentage of time spent in range - *with exclusion of the primary endpoint*
- Percentage of time spent in level 2 hypoglycemia (sensor glucose <54 mg/dL)
- Percentage of time spent in level 1 hypoglycemia (sensor glucose <70 mg/dL and ≥54 mg/dL)
- Percentage of time spent below range (sensor glucose <70 mg/dL)
- Percentage of time spent above range (sensor glucose >180 mg/dL)
- Percentage of time spent in level 1 hyperglycemia (sensor glucose >180 mg/dL and ≤250 mg/dL)
- Percentage of time spent in level 2 hyperglycemia (sensor glucose >250 mg/dL)
- Glycemic variability: coefficient of variation (CV), standard deviation (SD)
- Mean glucose concentration
- Change in HbA1c
- Correlation between demographic characteristics and change in HbA1c
- Correlation between clinical characteristics and change in HbA1c
- Quality of life of patients (and for children also their parents)

- Hypoglycemia awareness
- Fear of hypoglycemia
- Distress due to diabetes
- Treatment satisfaction

3.4 Socioeconomic endpoints

- Frequency of severe hypoglycemia
- Frequency of diabetic ketoacidosis
- Number and days of hospital visits and/or admissions because of severe hypoglycemia or diabetic ketoacidosis
- Work and school absenteeism (number of days that a patient was unable to attend work/school due to his/her diabetes (excluding consultation))
- Change in total daily dose of insulin (including basal/bolus proportion)
- Numbers and type of diabetes conventions per person

As part of the analysis of the results, a comparison will be made between the results of the first year of the treatment by the Tandem t:slim X2 Control-IQ™ and the results of the second year of this treatment.

3.5 Exploratory endpoints

- Composite endpoints of HbA1c and time in hypoglycemia <70 mg/dl
- Frequency of (unplanned) contacts with the diabetes team
- Change in body weight, height (for children), and tanner stage (for children)
- Indications for use
- Number of patients who stop
- Reasons for discontinuation - *only in case of discontinuation*

3.6 Trial design

This is a multicenter real-world observational study analyzing data on the use of the the Tandem t:slim X2 Control-IQ™ in patients with T1D treated in the participating centers in Belgium. Data from patients with T1D who start(ed) with the Tandem t:slim X2 Control-IQ™ up to and including December 2022 will be analyzed. Data will be collected during clinical routine follow-up from electronic medical

records, questionnaires, standard of care laboratory tests and CGM-data. Baseline data from before start (up to -12 months) of the Tandem t:slim X2 Control-IQ™ and follow-up data at 4, 8, 12, 16, 20 and 24 months will be analyzed. There are no medical interventions, nor extra visits or laboratory tests planned outside normal clinical routine. Glycemic control and patient-reported outcomes during follow-up will be compared with glycemic control and patient-reported outcome data at baseline.

Investigational device: Tandem t:slim X2 Control-IQ™

The Tandem t:slim X2 Control-IQ™ consists of the Tandem t:slim X2™ insulin pump with Control-IQ™ technology, and integrates with the Dexcom G6® CGM-device via Bluetooth. Blood glucose readings for calibration are not required. The Tandem t:slim X2 Control-IQ™ automatically adjusts basal insulin based on CGM readings to reach a glucose target range between of 112-160 mg/dL. Patients still need to enter their carbohydrate intake and administer meal-time boluses, but the system automatically increases the basal insulin dose or gives automated correction boluses in case of high blood glucose levels. The technology offers optional settings for sleep and exercise, with different glucose targets in order to match the insulin need during these activities. Pump and sensor data are stored at diasend® to facilitate a graphical display of glycemic parameters and control. New versions of the pump software can be downloaded and installed remotely via the user's own computer. During this observational study, we will allow the update of the software updates if made available.

3.7 Trial flowchart

	Up to -12 months *(after giving informed consent)*	**Baseline**	**4m**	**8m**	**12m**	**16m**	**20m**	**24m**
Informed consent		X						
Demographic data	X	X						
Clinical data	X	X	X	X	X	X	X	X
Questionnaires		X	X	X	X	X	X	X
Laboratory tests (*part of routine clinical care*)	X	X	X	X	X	X	X	X
CGM-data		X	X	X	X	X	X	X

4. Selection and withdrawal of subjects

4.1 Inclusion criteria

Adult patients

- who are already treated at least 12 months with intensive insulin therapy within the framework of the selfregulation convention for adults (7.86.0xx.xx or 7.86.1xx.xx) or the insulin pump convention (7.86.5xx.xx) or exceptionally within the framework of the

selfregulation convention for children and adolescents (7.86.7xx.xx) and who belong to group A of the selfregulation convention for adults, and
- who meet the conditions for an insulin pump treatment of one of these conventions, and
- who already mesure their glycemia by means of sensors for at least 12 months,

as well as children and adolescents, aged 6 years and older,
- who are already treated at least 6 months with intensive insulin therapy within the framework of the selfregulation convention for children and adolescents (7.86.7xx.xx) and who belong to the patients mentioned in article 6 § 1 of this convention, and
- who meet the conditions for an insulin pump treatment of this convention, and
- who already mesure their glycemia by means of sensors for at least 6 months.

Only patients with T1D, aged 6 years and older who start with the Tandem t:slim X2 Control-IQ™ in the participating centers and who signed informed consent or gave informed assent (pediatrics) are eligible to participate. The decision about which patient to start, is left to the clinical judgement of the treating health care professional.

4.2 Exclusion criteria

Patients with T1D younger than 6 years and/or patients who do not start with the Tandem t:slim X2 Control-IQ™ in the participating centers and/or who are not able/do not want to sign informed consent or give informed assent (pediatrics) are not eligible to participate.

4.3 Expected duration of trial

Inclusion will take place up to and including December 2022. After start of the Tandem t:slim X2 Control-IQ™, there will be a follow-up period of 24 months per subject. The expected duration of the study will be 4 years in total.

4.4 Methods of recruitment

Once the decision has been made that a patient will start with the Tandem t:slim X2 Control-IQ™ the patient will be asked to participate in the study and to sign consent or give assent (for pediatrics) to have their personal data sent encoded to the central investigation unit in Leuven.

4.5 Withdrawal criteria

Participants can withdraw at any moment during the study. Participants can be withdrawn if the investigator considers that deterioration of glycemic control is a consequence of the use of the Tandem t:slim X2 Control-IQ™.

5. Trial procedures

5.1 By visit

5.1.1 Demographic and clinical data (medical records; partially retrospective)

Only at baseline (up to -12 months before start)

- Date of birth
- Age (to be calculated)
- Sex
- Ethnicity
- Educational attainment of patients (in case of pediatric patients also of their parents)
- Cohabitation / nuclear family / single-parent family / co-parenting
- Date of T1D diagnosis
- Diabetic complications
- Previous diabetes treatment and reasons to switch
- Height
- Weight
- Tanner stage (for children)
- Total daily dose (basal/bolus) of insulin of the past 4 weeks
- Current medication
- Frequency of severe hypoglycemia (adults: assistance needed from third parties; children: hypoglycemia with neurological impairment)
- Frequency of diabetic ketoacidosis
- Frequency and length of hospital admissions for hypoglycemia and/or ketoacidosis
- Frequency of school/work absence (consultation excluded), in case of pediatric patients for children as well as their parents
- Frequency of (unplanned) contacts with the diabetes team
- Type of diabetes conventions which are active per person

At month 4, 8, 12, 16, 20 and 24

- Duration of use of the Tandem t:slim X2 Control-IQ™
- Weight
- Height (for children)
- Tanner stage (for children)
- Total daily dose of insulin of the past 4 weeks
- Current medication
- Frequency of severe hypoglycemia (assistance needed from third parties) during the past 4 months

- Frequency of diabetic ketoacidosis during the past 4 months
- Frequency and length of hospital admissions for hypoglycemia and/or ketoacidosis during the past 4 months
- Frequency of school/work absence (consultation excluded) – in case of pediatric patients for children as well as their parents – during the past 4 months
- Frequency of (unplanned) contacts with the diabetes team during the past 4 months

5.1.2 Questionnaires (Appendix)

Remark: some participating centers already implemented these questionnaires as part of their general practice. If applicable, data will be collected retrospectively.

At baseline

For adult patients:

- Questionnaire 1: SF-36, version 2 – validated questionnaire about health-related quality of life (14)
- Questionnaire 2: Gold scale – validated questionnaire about hypoglycemia awareness (15)
- Questionnaire 3: Clarke hypoglycemia awareness survey – validated questionnaire about hypoglycemia awareness (16)
- Questionnaire 4: Hypoglycemia fear survey, behavior and worry, version II (HFS-II) – validated questionnaire about behavior to and worries about hypoglycemia (17,18)
- Questionnaire 5: Problem Areas In Diabetes survey, short form (PAID-SF) – validated questionnaire about emotional problems related to diabetes (19)
- Questionnaire 6: Diabetes Treatment Satisfaction Questionnaire, status (DTSQs) – validated questionnaire about satisfaction of diabetes treatment (20)
- Questionnaire 10: Diabetes Impact and Device Satisfaction Scale – validated questionnaire about satisfaction of diabetes device (21)

For pediatric patients:

- Questionnaire 11: Gold scale – validated questionnaire about hypoglycemia awareness (15)
- Questionnaire 12: Clarke-C hypoglycemia awareness survey – validated questionnaire about hypoglycemia awareness (16)
- Questionnaire 13: The Children's fear of hypoglycemia scale (HFS-C) – validated questionnaire about behavior to and worries about hypoglycemia in children (22)
- Questionnaire 14: The Diabetes Quality of Life for Youth (DQOLY) questionnaire (23)

For parents of pediatric patients:

- Questionnaire 15: Questionnaire for parents of children and adolescents with diabetes, a part of the HAPPI-D QOL Protocol (Hvidøre, Adolescent, Parent, Professional, Instrument, Diabetes) (24)
- Questionnaire 16: The Parent's fear of hypoglycemia scale – modified version of the Hypoglycemia Fear Survey for use with parents (25)

At month 4, 8, 12, 16, 20 and 24

For adult patients:

- Questionnaire 1: SF-36, version 2
- Questionnaire 2: Gold scale
- Questionnaire 3: Clarke hypoglycemia awareness survey
- Questionnaire 4: Hypoglycemia fear survey, behavior and worry, version II (HFS-II)
- Questionnaire 5: Problem Areas In Diabetes survey, short form (PAID-SF)
- Questionnaire 6: Diabetes Treatment Satisfaction Questionnaire, status (DTSQs)
- Questionnaire 10: Diabetes Impact and Device Satisfaction Scale

For pediatric patients:

- Questionnaire 11: Gold scale
- Questionnaire 12: Clarke-C hypoglycemia awareness survey
- Questionnaire 13: The Children's fear of hypoglycemia scale (HFS-C)
- Questionnaire 14: The Diabetes Quality of Life for Youth (DQOLY) questionnaire
- Questionnaire 7: Extra questions – self-developed questionnaire about expectations towards the use of the Tandem t:slim X2 Control-IQ™

For parents of pediatric patients:

- Questionnaire 15: Questionnaire for parents of children and adolescents with diabetes, a part of the HAPPI-D QOL Protocol
- Questionnaire 16: The Parent's fear of hypoglycemia scale
- Questionnaire 7: Extra questions – self-developed questionnaire about expectations towards the use of the Tandem t:slim X2 Control-IQ™

In case of (early) termination of the study

- Questionnaire 8: Stop questionnaire – self-developed questionnaire about reasons why to stop

5.1.3 Laboratory tests (partially retrospective)

Remark: the measurement of the values described below are part of routine clinical care. No extra samples will be taken as part of this study

At baseline (up to -12 months before start)

- Last known C-peptide value (including plasma glucose at the same time)

At baseline (up to -12 months before start), month 4, 8, 12, 16, 20 and 24

- Last known HbA1c value

5.1.4 CGM-data of the past 4 weeks

Remark: CGM-data will be extracted from CareLink™, LibreView, Clarity or Diasend. All are software programs designed by Medtronic, Abbott, Dexcom and Glooko respectively for storage and graphical display of blood glucose readings and sensor and/or pump data. If applicable, data will be collected retrospectively.

At baseline

- Percentage of sensor use
- Percentage of time spent in level 2 hypoglycemia (sensor glucose <54 mg/dL)
- Percentage of time spent in level 1 hypoglycemia (sensor glucose <70 mg/dL and ≥54 mg/dL)
- Percentage of time spent below range (sensor glucose <70 mg/dL)
- Percentage of time spent in range (sensor glucose 70-180 mg/dL)
- Percentage of time spent above range (sensor glucose >180 mg/dL)
- Percentage of time spent in level 1 hyperglycemia (sensor glucose >180 mg/dL and ≤250 mg/dL)
- Percentage of time spent in level 2 hyperglycemia (sensor glucose >250 mg/dL)
- Number of calibrations per day (if applicable)
- Number of capillary finger sticks per day

At month 4, 8, 12, 16, 20 and 24

- Percentage of sensor use
- Percentage of time spent in level 2 hypoglycemia (sensor glucose <54 mg/dL)
- Percentage of time spent in level 1 hypoglycemia (sensor glucose <70 mg/dL and ≥54 mg/dL)
- Percentage of time spent below range (sensor glucose <70 mg/dL)
- Percentage of time spent in range (sensor glucose 70-180 mg/dL)
- Percentage of time spent above range (sensor glucose >180 mg/dL)
- Percentage of time spent in level 1 hyperglycemia (sensor glucose >180 mg/dL and ≤250 mg/dL)

- Percentage of time spent in level 2 hyperglycemia (sensor glucose >250 mg/dL)
- Number of calibrations per day
- Number of capillary finger sticks per day

6. Statistics

6.1 Sample size

We will include every patient with T1D who starts with the Tandem t:slim X2 Control-IQ™ in the participating centers. It is our estimation that approximately a total of ±350 adult patients and ±150 pediatric patients will use hybrid closed-loop technology in the period that we analyze. This gives our study enough power (>80%) for the primary endpoint (change in time in range from before to 12 months after starting the the Tandem t:slim X2 Control-IQ™) to detect a mean difference of 5% assuming a standard deviation of 10% based on a repeated measures ANOVA (with α=0.05), and assuming a correlation between the time points equal to 0.8. The estimates for the power calculation were obtained from the database used in the RESCUE study (22). A mean difference of 5% is seen as a clinically significant change for time in range (26).

6.2 Analysis

Analyses will be done separately for adult participants, and pediatric participants and their parents.

A linear mixed model will be used to evaluate the changes in continuous variables after start of the Tandem t:slim X2 Control-IQ™, with a random effect of center to handle the correlation between patients of the same center and an unstructured covariance matrix for the four repeated measurements within the same patient. By using a linear mixed model, cases with missing data will still contribute to the analyses. A multivariable ANOVA model will be used to verify if baseline characteristics will moderate the change in glycemic outcome parameters, no covariates will be taken into account a priori. Changes in dichotomous variables will be evaluated by the Cochran's Q-test with post-hoc McNemar's test. The p-value will be defined significant at an α-level of 0.05 or lower.

An overview of the clinical and demographic data at start will be summarized in a table using mean values and standard deviations or medians with the range of interquartile of values.

The data set will comprise all participants for all analyses. Analysis will be performed at the end of the study.

7. Quality assurance

The study teams at each participating site are responsible for the management of the study. The principal investigator and the sub-investigators of the UZ Leuven will communicate with the local centers on a regular basis.

We will use standardized forms and questionnaires which have to be filled out by the study teams and/or patients, in order to collect the right data at the right time. We also developed Study Operating Procedures (SOPs) about how to extract Comma Separated Value (CSV) files from CareLink™, LibreView, Clarity and Diasend software, for the storage of CGM-data.

8. Direct access to source data and documents

The investigators and the institutions will permit trial-related monitoring, audits, EC review and regulatory inspections (where appropriate) by proving direct access to source data and other documents.

9. Ethics and regulatory approvals

This study will be conducted in compliance with the principles of the Declaration of Helsinki (2013), the principles of Good Clinical Practice (GCP) and in accordance with all applicable regulatory requirements. This protocol and related documents will be submitted for review to the Ethics Committees of all the participating sites.

The Study can and will be conducted only on the basis of prior informed consent by the Subjects, or their legal representatives, to participate in the Study. The Participating Site shall obtain a signed informed consent form (ICF) for all patients prior to their enrollment and participation in the Study in compliance with all applicable laws, regulations and the approval of the (local) Ethics Committee, if required. The Participating Site shall retain such ICFs in accordance with the requirements of all applicable regulatory agencies and laws.

The Investigator and the Participating Site shall treat all information and data relating to the Study disclosed to Participating Site and/or Investigator in this Study as confidential and shall not disclose such information to any third parties or use such information for any purpose other than the performance of the Study. The collection, processing and disclosure of personal data, such as patient health and medical information is subject to compliance with applicable personal data protection and the processing of personal data (Regulation (EU) 2016/679 also referred as the General Data Protection Regulation (“GDPR”) and the Belgian Law of July 30 2018 on the protection of natural persons with regard to the processing of personal data).

The collected data will be coded. The research team is obligated to protect the data from disclosure outside the research according to the terms of the research protocol and the informed consent document. The subject's name or other identifiers will be stored separately from their research data and replaced with a unique code to create a new identity for the subject.

All Study data as collected and prepared in the performance of the Study shall be the sole property of Sponsor. The Sponsor hereby grants to the Participating Site a license to use the Study data for its patient care, educational and non-commercial research purposes and, in accordance with the obtained ICF.

10. Data handling

All subjects from which data are collected will receive an identification number (code) to ensure confidentiality of the data. All data collected in this study will be referred to by subject identification number only.

Anonymous data can be shared between participating centers, based on research questions mentioned in this protocol or based on a new study protocol approved by the relevant ethical committees. This is an academic study; study data will not be exchanged with Tandem or Dexcom.

11. Data management

All data will be stored in a secure manner and for a duration in accordance with the Belgian legislation. Data will originally be documented on paper and saved electronically in Castor by the individual sites. Eventually, the whole study database will be constructed in SPSS software for Windows (IBM SPSS Statistics version 25 or newer, Armonk, USA) by the investigators of the UZ Leuven.

12. Publication policy

It is anticipated that the results of the overall Study shall be published in a multicenter publication, involving the data of all clinical sites participating in the Study.

Participating Site in not allowed to publish any data or results from the Study prior to the multicenter publication, provided however that Participating Site is allowed to publish the results generated at the Participating Site if the multicenter publication has not occurred after 12 months from Study database lock.

Publications will be coordinated by the study writing group. Authorship to publication will be determined in accordance with the requirements published by the International Committee of Medical Journal Editors and in accordance with the requirements of the respective medical journal.

13. Insurance/Indemnity

In accordance with the Belgian Law relating to experiments on human persons dated May 7, 2004, Sponsor shall assume, even without fault, the responsibility of any damages incurred by a Study Patient and linked directly or indirectly to the participation to the Study, and shall provide compensation therefore through its insurance.

14. Financial aspects

This is an academic study; there is no sponsorship by medical companies. However, Tandem Diabetes Care and Dexcom, Inc will provide a supporting grant for a PhD researcher and the electronic case reporting form.

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16. Appendix

Questionnaire 1: SF-36

This questionnaire asks about your health. Do you want to answer every question by ticking the appropriate box? If you are unsure about the answer to a question, try to give the most appropriate one.

1. In general, would you say your health is:

- ☐ excellent
- ☐ very good
- ☐ good
- ☐ fair
- ☐ poor

2. Compared to one year ago, how would you rate your health in general now?

- ☐ much better now than a year ago
- ☐ somewhat better now than a year ago
- ☐ about the same as one year ago
- ☐ somewhat worse now than one year ago
- ☐ much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health currently limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. *Vigorous* activities, such as running, lifting heavy objects, participating in strenuous sports.	☐	☐	☐
b. *Moderate* activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐	☐	☐
c. Lifting or carrying groceries.	☐	☐	☐
d. Climbing *several flights of stairs.*	☐	☐	☐
e. Climbing *one flight of stairs.*	☐	☐	☐
f. Bending, kneeling or stooping.	☐	☐	☐
g. Walking *more than one kilometer.*	☐	☐	☐
h. Walking *half a kilometer.*	☐	☐	☐
i. Walking *100 meters.*	☐	☐	☐
j. Bathing or dressing yourself.	☐	☐	☐

4. *During the past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All the time	Regularly	Sometimes	Rare	Never
a. *Cut down the amount of time* you spent on work or other activities.	☐	☐	☐	☐	☐
b. Accomplished *less* than you would like.	☐	☐	☐	☐	☐
c. Were limited in the *kind of work* or other activities.	☐	☐	☐	☐	☐
d. Had difficulty performing the work or other activities (for example, it took extra time).	☐	☐	☐	☐	☐

5. *During the past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problem (such as feeling depressed or anxious)?

	All the time	Regularly	Sometimes	Rare	Never
a. *Cut down the amount of time* you spent on work or other activities.	☐	☐	☐	☐	☐
b. Accomplished *less* than you would like.	☐	☐	☐	☐	☐
c. Didn't do work or other activities as carefully as usual.	☐	☐	☐	☐	☐

6. *During the past 4 weeks*, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- ☐ not at all
- ☐ slightly
- ☐ moderately
- ☐ quite a bit
- ☐ extremely

7. How much pain did you have *during the past 4 weeks*?

- ☐ no
- ☐ very light
- ☐ light
- ☐ moderately
- ☐ serious
- ☐ very serious

8. *During the past 4 weeks*, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐ not at all
- ☐ slightly
- ☐ moderately
- ☐ quite a bit
- ☐ extremely

9. These questions are about how you feel and how things have been with you during *the past 4 weeks*. For each question, please give the answer that comes closest to the way you have been feeling. *How much of the time during the past 4 weeks:*

	All of the time	Most of the time	Sometimes	Rarely	Never
a. Did you feel full of pep?	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps nothing could cheer you up?	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐
f. Have you felt downhearted and blue?	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐

10. *During the past 4 weeks*, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

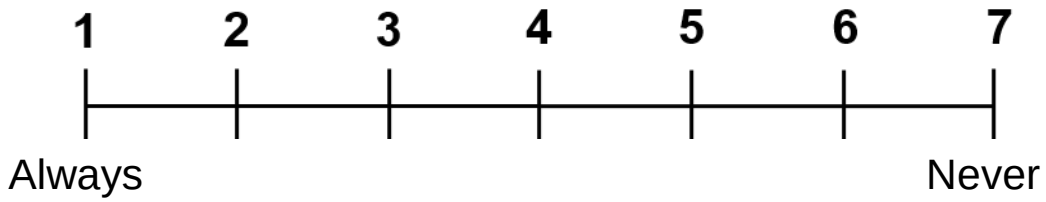
- ☐ all of the time
- ☐ most of the time
- ☐ some of the time
- ☐ a little of the time
- ☐ none of the time

11. For each statement, please give the answer that comes closest to the way you have been feeling.

	Definitely true	Mostly true	I don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people.	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know.	☐	☐	☐	☐	☐
c. I expect my health to get worse.	☐	☐	☐	☐	☐
d. My health is excellent.	☐	☐	☐	☐	☐

Questionnaire 2: Gold scale

Indicate with an "**X**" on the scale down below if you are aware of having a hypoglycemia (1=always aware ⇔ 7= never aware).



Questionnaire 3: Clarke hypoglycemia awareness survey

1. **Check the category that best describes you (check one only).**
   - ☐ I always have symptoms when my blood sugar is low.
   - ☐ I sometimes have symptoms when my blood sugar is low.
   - ☐ I no longer have symptoms when my blood sugar is low.

2. **Have you lost some of the symptoms that used to occur when your blood sugar was low?**
   - ☐ Yes
   - ☐ No

3. **In the past six months how often have you had moderate hypoglycemia episodes? (Episodes where you might feel confused, disoriented or lethargic and were unable to treat yourself)**
   - ☐ Never
   - ☐ Once or twice
   - ☐ Every other month
   - ☐ Once a month
   - ☐ More than once a month

4. **In the past year how often have you had severe hypoglycemic episodes? (Episodes where you were unconscious or had a seizure and needed glucagon or intravenous glucose)**

☐ Never	☐ 4-5 times	☐ 9 times
☐ 1 time	☐ 6 times	☐ 10 times
☐ 2 times	☐ 7 times	☐ 11 times
☐ 3 times	☐ 8 times	☐ 12 times

5. **How often in the *last month* have you had readings <70 mg/dL <u>with</u> symptoms?**
   The answer to question 5 can't be the same as the answer to question 6

☐ Never	☐ 2 to 3 times/week
☐ 1 to 3 times	☐ 4 to 5 times/week
☐ 1 time/week	☐ Almost daily

6. **How often in the *last month* have you had readings <70 mg/dL <u>without</u> any symptoms?**
   The answer to question 6 can't be the same as the answer to question 5

☐ Never	☐ 2 to 3 times/week
☐ 1 to 3 keer	☐ 4 to 5 times/week
☐ 1 times/week	☐ Almost daily

7. **How low does your blood sugar need to go before you feel symptoms?**
   - ☐ Between 60-69 mg/dL (or more)
   - ☐ Between 50-59 mg/dL
   - ☐ Between 40-49 mg/dL
   - ☐ Less than 40 mg/dL

8. To what extend can you tell by your symptoms that your blood sugar is low?

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

Questionnaire 4: Hypoglycemia fear survey, behavior and worry

Below is a list of things people with diabetes sometimes do to prevent a low blood sugar. Please read each item carefully (do not skip any). Tick one of the boxes on the right that best describes how you behave. Think about the **last couple of months.**

	Never	Rarely	Sometimes	Often	Very often
1. Eat something before I go to sleep.	☐	☐	☐	☐	☐
2. Avoid being alone when I'm probably low.	☐	☐	☐	☐	☐
3. Ensure that I have higher blood sugar levels.	☐	☐	☐	☐	☐
4. Keep my blood sugar levels higher when I'm alone for a short time.	☐	☐	☐	☐	☐
5. Eat something when I feel the first symptoms of a low blood sugar.	☐	☐	☐	☐	☐
6. Inject less insulin when I think I'm too low.	☐	☐	☐	☐	☐
7. Keep my glucose levels high when I'm planning to visit a meeting or party for a while.	☐	☐	☐	☐	☐
8. Carry fast acting carbs with me.	☐	☐	☐	☐	☐
9. Avoid exercise when I think I'm too low.	☐	☐	☐	☐	☐
10. Check my blood sugar regularly if I'm planning to visit a meeting or party.	☐	☐	☐	☐	☐

Below is a list of concerns people with diabetes sometimes have. Please read each item carefully (do not skip any). Tick one of the boxes on the right that best describes how often you worry about each item because of low blood sugar. Think about the **last couple of months.**

	Never	Rarely	Sometimes	Often	Very often
1. Not recognizing low blood sugar.	☐	☐	☐	☐	☐
2. Not having food available.	☐	☐	☐	☐	☐
3. Passing out in public.	☐	☐	☐	☐	☐
4. Embarrassing myself or my friends in a social situation.	☐	☐	☐	☐	☐
5. Having a hypoglycemic episode while I am alone.	☐	☐	☐	☐	☐
6. Appearing drunk or stupid.	☐	☐	☐	☐	☐
7. Losing self-control.	☐	☐	☐	☐	☐
8. No one to help during hypoglycemia.	☐	☐	☐	☐	☐
9. Having hypoglycemia while driving.	☐	☐	☐	☐	☐
10. Making mistakes or having accidents.	☐	☐	☐	☐	☐
11. Getting a bad evaluation.	☐	☐	☐	☐	☐
12. Difficulty thinking clearly while being responsible for others.	☐	☐	☐	☐	☐
13. Feeling lightheaded or dizzy.	☐	☐	☐	☐	☐
14. Injuring myself or others.	☐	☐	☐	☐	☐
15. Permanent injury to health	☐	☐	☐	☐	☐
16. Low blood glucose interfering with important things.	☐	☐	☐	☐	☐
17. Becoming hypoglycemic while sleeping	☐	☐	☐	☐	☐
18. Becoming upset and difficult	☐	☐	☐	☐	☐

Questionnaire 5: Problem Areas In Diabetes survey, short form

Diabetes can be emotionally stressful. Which of the following diabetes issues are **currently** a problem for you? Tick the box that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
1. Feeling scared when you think about living with diabetes?	☐	☐	☐	☐	☐
2. Feeling depressed when you think about living with diabetes?	☐	☐	☐	☐	☐
3. Worrying about the future and the possibility of serious complications?	☐	☐	☐	☐	☐
4. Feeling that diabetes is taking up too much of your mental and physical energy every day?	☐	☐	☐	☐	☐
5. Coping with complications of diabetes?	☐	☐	☐	☐	☐

Questionnaire 6: Diabetes Treatment Satisfaction Questionnaire, status

The following questions are concerned with the treatment for your diabetes and your experience over the **past few weeks**. Please answer each question by circling a number on each of the scales (please don't skip any).

1. How satisfied are you with your current treatment?

Very satisfied | 6 ☐ | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ | Very dissatisfied

2. How often have you felt that your blood sugar has been unacceptably high recently?

Most of the time | 6 ☐ | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ | None of the time

3. How often have you felt that your blood sugar has been unacceptably low recently?

Most of the time | 6 ☐ | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ | None of the time

4. How convenient have you been finding your treatment to be recently?

Very convenient | 6 ☐ | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ | Very inconvenient

5. How flexible have you been finding your treatment to be recently?

Very flexible | 6 ☐ | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ | Very inflexible

6. How satisfied are you with your understanding of your kind of diabetes?

Very satisfied | 6 ☐ | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ | Very dissatisfied

7. Would you recommend this form of treatment to someone else with your kind of diabetes?

Yes, I would definitely recommend the treatment | 6 ☐ | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ | No, I would definitely not recommend the treatment

8. How satisfied would you be to continue your present form of treatment?

Very satisfied	6	5	4	3	2	1	0	Very dissatisfied
	☐	☐	☐	☐	☐	☐	☐	

Questionnaire 7: Extra questions

Which items do <u>not</u> work well / are worse than expected with the use of the hybrid closed-loop system? *(more answers possible)*

Device related – *use*	☐ (re)placing parts (replacing sensor, repleting the insulin reservoir etc.) ☐ control system of the pump ☐ discomfort / pain pump ☐ discomfort / pain sensor ☐ pump does not stay in place ☐ sensor does not stay in place ☐ no opinion/not applicable
Device related – *technical aspects*	☐ adequacy (response of pump to hypo- / hyperglycemia) ☐ insulin delivery ☐ system notifications ☐ alerts ☐ nocturnal alerts ☐ number of finger sticks ☐ no opinion/not applicable
Disease related	☐ presence of hypo- / hyperglycemia ☐ flexibility in daily life ☐ worries about diabetes ☐ no opinion/not applicable
Other	☐ trust in the hybrid closed-loop system ☐ other: *(answer freely)* _____ _____ _____ _____ ☐ no opinion/not applicable

Which items do <u>work well / better than expected</u> with the use of the hybrid closed-loop system?
(more answers possible)

Device related – *use*	☐ (re)placing parts (replacing sensor, repleting the insulin reservoir etc.) ☐ control system of the pump ☐ discomfort / pain pump ☐ discomfort / pain sensor ☐ pump does not stay in place ☐ sensor does not stay in place ☐ no opinion/not applicable
Device related – *technical aspects*	☐ adequacy (response of pump to hypo- / hyperglycemia) ☐ insulin delivery ☐ system notifications ☐ alerts ☐ nocturnal alerts ☐ number of finger sticks ☐ no opinion/not applicable
Disease related	☐ presence of hypo- / hyperglycemia ☐ flexibility in daily life ☐ worries about diabetes ☐ no opinion/not applicable
Other	☐ trust in the hybrid closed-loop system ☐ other: *(answer freely)* _____ _____ _____ _____ ☐ no opinion/not applicable

Questionnaire 8: Stop questionnaire

NL:

Waarom werd beslist om te stoppen met het hybrid closed-loop systeem?
(Hieronder staan een aantal voorbeelden, meerdere redenen zijn mogelijk. Indien de juiste reden er niet bij staat, vul dan aan als vrije tekst bij "Andere")

☐ De patiënt had last van bijwerkingen van het hybrid closed-loop systeem.

☐ Het hybrid closed-loop systeem werkte niet adequaat (vb. sensormetingen onjuist, …).

☐ De sensor van het hybrid closed-loop systeem bleef niet goed zitten.

☐ De canule van het hybrid closed-loop systeem bleef niet goed zitten.

☐ De patiënt ondervond veel technische problemen met het hybrid closed-loop systeem.

- [ ] Het hybrid closed-loop systeem gaf te veel alarmen.
- [ ] Het hybrid closed-loop systeem gaf te veel nachtelijke alarmen.
- [ ] Het hybrid closed-loop systeem deed pijn.
- [ ] Het hybrid closed-loop systeem was moeilijk in gebruik.
- [ ] De toegestane insertieplaatsen waren ontoereikend.
- [ ] Andere:

FR:

Pourquoi a-t-il décidé de cesser d'utiliser le système d'administration hybride d'insuline en closed-loop? *(Plusieurs exemples sont présentés ci-dessous, plusieurs raisons sont possibles. Si la raison correcte n'est pas dans la liste, indiquez "Autre" et spécifiez comme texte libre.)*

- [ ] Le patient souffre des effets indésirables du système d'administration hybride d'insuline en closed-loop.
- [ ] Le système d'administration hybride d'insuline en closed-loop ne fonctionne pas correctement (p.ex., les mesures du capteur sont incorrectes, ...).
- [ ] Le capteur du système d'administration hybride d'insuline en closed-loop ne s'est pas assis correctement.
- [ ] La canule du système d'administration hybride d'insuline en closed-loop ne s'est pas assise correctement.
- [ ] Le patient rencontre de nombreux problèmes techniques avec le système d'administration hybride d'insuline en closed-loop.
- [ ] Le système d'administration hybride d'insuline en closed-loop donne trop d'alarmes.
- [ ] Le système d'administration hybride d'insuline en closed-loop donne trop d'alarmes nocturnes.
- [ ] Le système d'administration hybride d'insuline en closed-loop fait mal.

☐ Le système d'administration hybride d'insuline en closed-loop est difficile à utiliser.

☐ Les sites d'insertion autorisés sont inadéquats.

☐ Autre:

Questionnaire 9: DAWN Impact of Diabetes Profile–Family Members

How does the diabetes of the person you live with impact the following aspects of your life?

	Very negative impact 1	Negative impact 2	Slightly positive impact 3	No impact 4	Slightly positive impact 5	Positive impact 6	Very positive impact 7	Not applicable 8
1. Your physical health	☐	☐	☐	☐	☐	☐	☐	☐
2. Your financial situation	☐	☐	☐	☐	☐	☐	☐	☐
3. Your relationship with family, friends and peers	☐	☐	☐	☐	☐	☐	☐	☐
4. Your leisure activities	☐	☐	☐	☐	☐	☐	☐	☐
5. Your work or studies	☐	☐	☐	☐	☐	☐	☐	☐
6. Your emotional well-being	☐	☐	☐	☐	☐	☐	☐	☐
7. Your relationship with the person you live with who has diabetes	☐	☐	☐	☐	☐	☐	☐	☐

Questionnaire 10: Diabetes Impact and Device Satisfaction Scale

1. How satisfied are you with your insulin delivery device?

Very unsatisfied	1	2	3	4	5	6	7	8	9	10	Very satisfied
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

2. How much do you trust your insulin delivery device?

Not at all	1	2	3	4	5	6	7	8	9	10	A lot
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

Please indicate how much you agree or disagree with each statement based on your experience using your insulin delivery device.

My current insulin delivery device …	Strongly disagree									Strongly agree
	1	2	3	4	5	6	7	8	9	10
3. … is easy to use	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4. … helps me have good blood glucose control	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5. … is a hassle to use	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6. … helps me feel more in control of my diabetes	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
7. … is too complicated	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How often do you…?

	Never									Always
	1	2	3	4	5	6	7	8	9	10
8. … have a bad night sleep due to diabetes?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
9. … wake up at night to treat a low blood glucose?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
10. … worry about going low?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11. … miss work, school, chores, or other responsibilities due to diabetes?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Questionnaire 11: Gold scale (for children)

Indicate with an "**X**" on the scale down below if you are aware of having a hypoglycemia (7= never ⇔ 1=always).

Questionnaire 12: Clarke-C hypoglycemia awareness survey

1. **Tick the category that best describes you?**
   - ☐ I always have symptoms when my blood sugar is low
   - ☐ I sometimes have symptoms when my blood sugar is low
   - ☐ I never have symptoms when my blood sugar is low

2. **Have you lost symptoms of hypoglycemia that used to occur when your blood glucose is low?**
   - ☐ Yes
   - ☐ No

3. **In the past 2 months, how often have you had hypoglycemic episodes, where you might feel confused, disorientated, or lethargic and were unable to treat yourself?**
   - ☐ Never
   - ☐ 1 / month
   - ☐ 1 of 2 times
   - ☐ > 1 / month

4. **Over the last 12 months, how often have you had hypoglycemic episodes, where you were unconscious or had a seizure and needed glucagon or intravenous glucose?**
   - ☐ Never
   - ☐ 1 time
   - ☐ 2 times
   - ☐ More times

5. **How often in the last month have you had readings < 70 mg/dl WITH symptoms?**
   - ☐ Never
   - ☐ 1-3 times
   - ☐ 1 time / week
   - ☐ 2-3 times / week
   - ☐ 4-5 times / week
   - ☐ Almost daily

6. **How often in the last month have you had readings < 70 mg/dl WITHOUT any symptoms?**
   - ☐ Never
   - ☐ 1-3 times
   - ☐ 1 time / week
   - ☐ 2-3 times / week
   - ☐ 4-5 times / week
   - ☐ Almost daily

7. **How low does your blood sugar need to go before you feel symptoms?**
   - ☐ 60 - 70 mg/dl
   - ☐ 50 - 59 mg/dl
   - ☐ 40 - 49 mg/dl
   - ☐ < 40 mg/dl

8. **How often do you have symptoms of hypoglycemia when your blood sugar is low?**
   - ☐ Never
   - ☐ Rarely
   - ☐ Sometimes
   - ☐ Often
   - ☐ Always

Questionnaire 13: The Children's fear of hypoglycemia scale

We want to find out more about what low blood sugar makes young people feel and do. Please answer the questions below as honestly as you can.

A. The following is a list of things that young people with diabetes sometimes **do** to **prevent low blood sugar**. Tick the answer that best describes **you**.

	Never	Seldom	Sometimes	Frequently	Almost always
1. Eating big snacks at bedtime.	☐	☐	☐	☐	☐
2. Trying not to be alone if my sugar will possibly be low.	☐	☐	☐	☐	☐
3. Keeping my blood sugar a little high, just to be safe.	☐	☐	☐	☐	☐
4. Keeping my blood sugar higher if I'm going to be alone for a while.	☐	☐	☐	☐	☐
5. Eating something as soon as I feel the first sign of low blood sugar.	☐	☐	☐	☐	☐
6. Using less insulin if I think my blood sugar might get too low.	☐	☐	☐	☐	☐
7. Keep my blood sugar higher if I am going to be away from home.	☐	☐	☐	☐	☐
8. Carrying something with sugar, drink, or food with me.	☐	☐	☐	☐	☐
9. Trying not to exercise too much if I think my sugar is low.	☐	☐	☐	☐	☐
10. Checking my blood sugar levels often, when I go away from home.	☐	☐	☐	☐	☐

B. Below is a list of issues regarding low blood sugar that young people with diabetes sometimes worry about. Tick the answer that best describes **you**.

	Never	Seldom	Sometimes	Frequently	Almost always
11. Not recognizing that my blood sugar is low.	☐	☐	☐	☐	☐
12. Not having food, fruit, or juice with me when my blood sugar gets low.	☐	☐	☐	☐	☐
13. Feeling dizzy, or fainting in public, because of low blood sugar.	☐	☐	☐	☐	☐
14. Having a low blood sugar when I sleep.	☐	☐	☐	☐	☐
15. Embarrassing myself because of low blood sugar.	☐	☐	☐	☐	☐
16. Having a low blood sugar while I am all alone.	☐	☐	☐	☐	☐
17. Looking 'stupid' or awkward in front of other people.	☐	☐	☐	☐	☐
18. Losing control, because of low blood sugar.	☐	☐	☐	☐	☐
19. Having no one around to help me with a hypo.	☐	☐	☐	☐	☐
20. Making a mistake, or having an accident at school.	☐	☐	☐	☐	☐
21. Getting into trouble at school, because of something that happens when my blood sugar is low.	☐	☐	☐	☐	☐
22. Having a seizure.	☐	☐	☐	☐	☐
23. Getting long term complications because of low blood sugar.	☐	☐	☐	☐	☐

24. Feeling dizzy, or lightheaded when blood sugar is low.	☐	☐	☐	☐	☐
25. Having a low blood sugar.	☐	☐	☐	☐	☐

Questionnaire 14: The Diabetes Quality of Life for Youth questionnaire

Explanation: This questionnaire asks about your health. Please answer each question by checking the appropriate box. When in doubt about the answer to a question, try to give the answer that is most applicable.

For young children, ask your parents to help you find your best answers (not your parents').

1. These questions are about how satisfied you are with your life in general.

	Very satisfied	Reasonably satisfied	Neither one nor the other	Somewhat unsatisfied	Very unsatisfied
a. How satisfied are you with the time it takes you to settle?	☐	☐	☐	☐	☐
b. How satisfied are you with the amount of time spent visiting the outpatient clinic?	☐	☐	☐	☐	☐
c. How satisfied are you with the amount of time spent determining your blood sugar?	☐	☐	☐	☐	☐
d. How satisfied are you with your current treatment?	☐	☐	☐	☐	☐
e. How satisfied are you with the flexibility you get for your diet?	☐	☐	☐	☐	☐
f. How satisfied are you with the extent to which diabetes is a major burden on your family?	☐	☐	☐	☐	☐
g. How satisfied are you with your own knowledge of diabetes?	☐	☐	☐	☐	☐
h. Are you satisfied with how you sleep?	☐	☐	☐	☐	☐
i. Are you satisfied with your social contacts and friendships?	☐	☐	☐	☐	☐
j. Are you satisfied with your work, school, and tasks at home?	☐	☐	☐	☐	☐
k. Are you satisfied with your appearance?	☐	☐	☐	☐	☐
l. Are you satisfied with the amount of time you spend on sports?	☐	☐	☐	☐	☐
m. Are you satisfied with your leisure time?	☐	☐	☐	☐	☐
n. Are you satisfied with your life in general?	☐	☐	☐	☐	☐
o. Are you satisfied with your school results?	☐	☐	☐	☐	☐
p. Are you satisfied with how your classmates treat you?	☐	☐	☐	☐	☐
q. Are you satisfied with how often you can just go to school?	☐	☐	☐	☐	☐

2. **If you compare your health to that of your peers, how would you call your health:**
   - ☐ Excellent
   - ☐ Good
   - ☐ Fair
   - ☐ Poor

Explanation: Diabetes can be a burden. Below you can indicate to what extent the topics listed are a problem for you **at the moment**. Tick the answer that best reflects your situation.

For young children, ask your parents to help you find your best answers (not your parents').

	Never	Rarely	Sometimes	Often	Almost always
1. How often do you have pain related to the treatment of diabetes?	☐	☐	☐	☐	☐
2. How often do you feel frustrated by having to do things for diabetes when everyone else sees it?	☐	☐	☐	☐	☐
3. How often are you sick (physically)?	☐	☐	☐	☐	☐
4. How often does diabetes cause things to run differently in your family?	☐	☐	☐	☐	☐
5. How often do you sleep poorly?	☐	☐	☐	☐	☐
6. How often do you find that diabetes limits your social contacts and friendships?	☐	☐	☐	☐	☐
7. How often are you satisfied with yourself?	☐	☐	☐	☐	☐
8. How often do you feel restricted by your diet?	☐	☐	☐	☐	☐
9. How often does diabetes cause you to be unable to do something, such as ride a bike or operate a device (e.g., computer)?	☐	☐	☐	☐	☐
10. How often does diabetes interfere with your sports activities?	☐	☐	☐	☐	☐
11. Because of your diabetes, how often can you not go to work, school, or perform certain tasks at home?	☐	☐	☐	☐	☐
12. How often do you have to explain to others what it means to have diabetes?	☐	☐	☐	☐	☐
13. How often does diabetes interfere or interrupt your free time?	☐	☐	☐	☐	☐
14. How often are you teased because you have diabetes?	☐	☐	☐	☐	☐
15. How often do you feel that because of your diabetes you have to go to the bathroom more often than others?	☐	☐	☐	☐	☐
16. How often does it happen that you eat something you're not supposed to because you don't want to tell people you have diabetes?	☐	☐	☐	☐	☐
17. How often do you hide from others that you have a hypo- or hyperglycemia?	☐	☐	☐	☐	☐
18. How often does your diabetes keep you from participating in school activities (such as joining a play, sports, being a member of the school band,...)?	☐	☐	☐	☐	☐
19. How often does your diabetes keep you from going out to eat with friends?	☐	☐	☐	☐	☐
20. How often do you feel that your diabetes limits you in choosing the profession you want to pursue later?	☐	☐	☐	☐	☐
21. How often do you feel that your parents protect you too much?	☐	☐	☐	☐	☐
22. How often do you find that your parents are way too worried about your diabetes?	☐	☐	☐	☐	☐
23. How often do you find that your parents consider diabetes to be their own disease and not yours?	☐	☐	☐	☐	☐

Explanation: Diabetes can be stressful. Below you can indicate the extent to which the topics listed are a problem for you **at the moment**. Tick the answer that best reflects your situation.

For young children, ask your parents to help you find your best answers (not your parents').

	Never	Rarely	Sometimes	Often	Almost always
1. How often do you worry about whether you will get married?	☐	☐	☐	☐	☐
2. How often do you worry about whether you will ever have children?	☐	☐	☐	☐	☐
3. How often do you worry that you won't get the job you want?	☐	☐	☐	☐	☐
4. How often do you worry that you will faint?	☐	☐	☐	☐	☐
5. How often do you worry about whether you will be able to finish school or training?	☐	☐	☐	☐	☐
6. How often do you worry that your body doesn't look good because you have diabetes?	☐	☐	☐	☐	☐
7. How often do you worry that you will have complications from your diabetes?	☐	☐	☐	☐	☐
8. How often do you worry that someone won't go out with you because you have diabetes?	☐	☐	☐	☐	☐
9. How often do you worry that educators and teachers treat you differently because of your diabetes?	☐	☐	☐	☐	☐
10. How often do you worry that your diabetes will interrupt something you're doing a lot of in school these days (e.g., acting, participating in school team/school band,...)?	☐	☐	☐	☐	☐
11. How often do you worry that because of your diabetes you are lagging behind others for example with dating, going to parties and acting like your friends?	☐	☐	☐	☐	☐

Questionnaire 15: Questionnaire for parents of children and adolescents with diabetes

Explanation: Caring for a child or teenager with diabetes can be difficult for parents. This questionnaire asks about the problems and concerns you experience in managing diabetes. We ask you to check the box that best represents your views on the topics presented below.

1. How much is the load (burden) due to:

	Huge burden	Large burden	Reasonable burden	Hardly a burden	No tax
a. The medical and "nursing" action (injections, blood punctures,...) that you must perform for your child's treatment?	☐	☐	☐	☐	☐
b. The disruption of normal family life because you often have to care for your child with diabetes?	☐	☐	☐	☐	☐
c. Physical or mental problems in your child that require extra attention from you as a parent?	☐	☐	☐	☐	☐
d. General limitations on your child's social activities and school activities?	☐	☐	☐	☐	☐
e. Concerns for your child's future health?	☐	☐	☐	☐	☐

2. Have your child's performance changed since the onset of diabetes? They are:

- ☐ Enhanced
- ☐ Unchanged
- ☐ Slightly worsened

- ☐ Severely deteriorated
- ☐ Not applicable

3. How would you describe your child's quality of life?
- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Bad
- ☐ Very poor

4. How do you feel about your child's quality of life?
- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Bad
- ☐ Very poor

5. (a) Do both parents live at home?
- ☐ Yes
- ☐ No

5. (b) Does the father currently have a job?
- ☐ Yes
- ☐ No

5. (c) Does the mother currently have a job?
- ☐ Yes
- ☐ No

Questionnaire 16: The Parent's fear of hypoglycemia scale

Explanation: This survey is designed to learn more about how people feel and behave when they have low blood sugar. Please answer the following questions as best you can.

A. Below is a list of things that parents of children with diabetes sometimes **do with the intent of affecting low blood sugar**, as well as related problems. Read each item carefully. Tick the answer that best describes **you**.

	Never	Seldom	Sometimes	Frequently	Almost always
1. Getting my child to eat big snacks at bedtime.	☐	☐	☐	☐	☐
2. Avoiding having my child be alone when his/her blood sugar may be low.	☐	☐	☐	☐	☐
3. Allowing my child's blood sugar to be a little high, to be safe.	☐	☐	☐	☐	☐
4. Keeping my child's sugar higher when he/she will be alone for a while.	☐	☐	☐	☐	☐
5. Making my child eat something as soon as he/she feels the first sign of low blood sugar.	☐	☐	☐	☐	☐
6. Reducing my child's insulin when I think his/her blood sugar is too low.	☐	☐	☐	☐	☐
7. Keeping my child's blood sugar higher when he/she plans to be away from me for a while.	☐	☐	☐	☐	☐
8. Having my child carry fast-acting sugar with him/her.	☐	☐	☐	☐	☐
9. Making my child avoid a lot of exercise when I think his/her sugar is low.	☐	☐	☐	☐	☐

10. Checking my child's sugar levels often, if he/she is planning an outing.	☐	☐	☐	☐	☐
11. Getting up in the middle of the night to check on my child to check my child's sugar levels.	☐	☐	☐	☐	☐

B. Concerns: Below is a list of concerns that parents of children with diabetes sometimes have. Please read them all thoroughly. Tick the answers that best describe **how occasionally you are concerned about any item**.

	Never	**Seldom**	**Sometimes**	**Frequently**	**Almost always**
12. That my child doesn't recognize/realize that he/she is having a hypo.	☐	☐	☐	☐	☐
13. That my child does not have food, fruit, or juice with him/her.	☐	☐	☐	☐	☐
14. That my child feels dizzy, or faints in public.	☐	☐	☐	☐	☐
15. That my child has a hypo while sleeping.	☐	☐	☐	☐	☐
16. That my child embarrasses himself/herself or friends/family in a social situation.	☐	☐	☐	☐	☐
17. That my child has a hypo when alone.	☐	☐	☐	☐	☐
18. That my child comes across as "stupid" or clumsy.	☐	☐	☐	☐	☐
19. That my child loses control over his/her behavior to low blood sugar.	☐	☐	☐	☐	☐
20. That there is no one around to help my child during a hypo.	☐	☐	☐	☐	☐
21. That my child makes a mistake, or has an accident at school.	☐	☐	☐	☐	☐
22. That my child gets a bad evaluation at school because of something that happens when his/her sugar level is low.	☐	☐	☐	☐	☐
23. That my child has a seizure or convulsion.	☐	☐	☐	☐	☐
24. That my child develops long-term complications from being frequently low.	☐	☐	☐	☐	☐
25. That my child feels lightheaded, or faints.	☐	☐	☐	☐	☐
26. That my child has a hypo.	☐	☐	☐	☐	☐