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 7.86.9/2-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 7.86.9/2-B worden. Als ooit een andere technologie wordt goedgekeurd waarvoor wel een afzonderlijke evaluatiestudie moet worden verricht, zal de nieuwe fiche fiche 7.86.9/3-A worden)

TECHNOLOGIE WAAROP DEZE FICHE BETREKKING HEEFT

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

- de insulinepomp Accu-chek Insight en
- de Dexcom G6 Sensor & Transmitter en
- het logaritme en de afstandsbediening van het DBLG1-systeem van Diabeloop

Insulinepomp :

Fabrikant : Roche Diabetes Care GmbH

Verdeler in België : Roche Diagnostics S.A.

Referenties Roche Diagnostics S.A.:

Omschrijving	*Referentie*
Accu-chek Insight Pump Kit NL*	9029591001
Accu-chek Insight Pump Kit FR*	9029648001
Accu-Chek Insight Flex canule 6 mm 10p	6541801001
Accu-Chek Insight Flex canule 8 mm 10p	6541810001
Accu-Chek Insight Flex canule 10 mm 10p	6541798001
Accu-Chek Insight Tender canule 13 mm 10p	6541836001
Accu-Chek Insight Tender canule 17 mm 10p	6541844001
Accu-Chek Insight Rapid canule 6 mm 25p	8699011001
Accu-Chek Insight Rapid canule 8 mm 25p	8699038001
Accu-Chek Insight Rapid canule 10 mm 25p	8699046001
Accu-Chek Insight tube & adapter 40 cm 10p	6485472001
Accu-Chek Insight tube & adapter 70 cm 10p	6485499001
Accu-Chek Insight tube & adapter 100 cm 10p	6485464001
Accu-Chek Insight Flex LinkAssist 1p	5511097001

* Een kit bevat : de AC Insight pomp + batterij + deksel van het batterijcompartiment + clipcase + handleiding

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

Logaritme: DBLG1-systeem

Fabrikant : Diabeloop S.A.

Verdeler in België : Roche Diagnostics S.A.

Referenties :

Startabonnement voor 1 jaar NL

- 09603808001

  Inhoud 'startabonnement' :
  - Initiatiekit DBLG1 voor het 1ste jaar (zie de referenties hieronder bij "Afstandsbediening DBLG1" voor de inhoud ervan)

- Updates van het product
- Dienstverlening
- Gratis vervanging onder garantie

Vervolgabonnement

- 09605401001

Inhoud 'vervolgabonnement'

- Updates van het product
- Dienstverlening
- Gratis vervanging onder garantie

Afstandsbediening DBLG1 (referenties alleen te gebruiken in geval van een technisch probleem)

- 09546600001 DBLG1-INS-DEXG6-mg/dl-BE-nl

Inhoud van de handset-apparatuur DBLG1

- Afstandsbediening DBLG1
- Oplader voor DBLG1
- Batterij voor DBLG1
- Gebruiksaanwijzing FR/NL

PATIENTEN DIE VOOR DEZE TECHNOLOGIE IN AANMERKING KOMEN

Volwassen patiënten (vanaf de leeftijd van 18 jaar)

- 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.

Alleen patiënten die uiterlijk op 1 augustus 2023 starten met het gebruik van de technologie waarop deze fiche betrekking heeft, komen voor de vergoeding van deze technologie in aanmerking omdat het – rekening gehouden met de vooropgestelde publicatiedatum van het evaluatierapport 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 volwassen patiënten die tijdelijk nog 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

786133 (ambulante patiënten)
786144 (gehospitaliseerde patiënten)

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

Prof. Dr. Laurent Crenier, Hôpital Erasme

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 november 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 mei 2022 tot en met 30 september 2024

DATUM VAN GOEDKEURING VAN DEZE FICHE DOOR HET VERZEKERINGSCOMITE

25/04/2022.

Insulin delivery using the DBLG1 closed-loop algorithm on glycemic control and patient-reported outcomes in adults living with type 1 diabetes: a multicenter real-world observational study in Belgium.

Protocol acronym: INLOOP study – INsulin delivery using the DBLG1 closed-lOop on glycemic cOntrol and PROMs in adults living with type 1 diabetes.

Protocol version : V1 **(**17-11-2021)

Sponsor:

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Table of contents

1. Study synopsis 4
2. Background and rationale 5
3. Trial objective and design 6
   - 3.1 Trial objective 6
   - 3.2 Primary endpoint 6
   - 3.3 Secondary endpoints 6
   - 3.4 Socioeconomic endpoints 7
   - 3.5 Exploratory endpoints 7
   - 3.6 Trial design 7
   - 3.7 Trial flowchart 8
4. Selection and withdrawal of subjects 8
   - 4.1 Inclusion criteria 8
   - 4.2 Exclusion criteria 8
   - 4.3 Expected duration of trial 9
   - 4.4 Methods of recruitment 9
   - 4.5 Withdrawal criteria 9
5. Trial procedures 9
   - 5.1 By visit 9
   - 5.1.1 Demographic and clinical data 9
   - 5.1.2 Questionnaires 10
   - 5.1.3 Laboratory tests 11
   - 5.1.4 CGM-data 11
6. Statistics 12
   - 6.1 Sample size 12
   - 6.2 Analysis 13
7. Quality assurance 13
8. Direct access to source data and documents 13
9. Ethics and regulatory approvals 14
10. Data handling 15
11. Data management 15
12. Publication policy 15
13. Insurance/Indemnity 15
14. Financial aspects 16

15. References …….16

16. Appendix………..19

1. Study synopsis

Title of clinical trial	Insulin delivery using the DBLG1 closed-loop algorithm on glycemic control and patient-reported outcomes in adults living with type 1 diabetes: a multicenter real-world observational study in Belgium.
Protocol acronym / short title	**INLOOP study** - Insulin delivery using the DBLG1 closed-loop on glycemic control and PROMs in adults living with type 1 diabetes.
Sponsor name	ULB-Hôpital Erasme
Principal investigators	Prof. Dr. Laurent Crenier, Prof. Dr. Pieter Gillard
Medical condition or disease under investigation	Adults living with type 1 diabetes who use the DBLG1 hybrid closed-loop insulin delivery system composed of the Dexcom G6 sensor, a Smartphone in which the DBLG1 algorithm is integrated and the Accu-Chek® Insight pump.
Purpose of clinical trial	To evaluate the impact of the DBLG1 hybrid closed-loop system on glycemic control and patient-reported outcomes in adults 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 DBLG1 system.
Sample size	More than 100 adults patients
Summary of eligibility criteria	People with type 1 diabetes, aged 18 years and older who start with the DBLG1 system and who signed the informed consent. The decision about which patient to start is left to the clinical judgement of the treating health care professional.
Maximum duration of observation 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 subcutaneous insulin infusion (CSII), also known as insulin pump therapy. 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) that allows automated insulin delivery (AID). The system consists of a continuous glucose monitoring device (CGM) connected wirelessly to a CSII and, in some cases, to either a dedicated handheld or a smartphone App. The pump then uses an algorithm to control the AID. The algorithm may run directly in the pump or in the handheld/Smartphone App, depending on the technologies. 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 system. Several randomized controlled trials showed that HCL in an outpatient setting is superior to SAP (using a simple algorithm for avoiding hypoglycemia but without full AID) and other types of open-loop systems (not using an algorithm) 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 DBLG1 is a new kind of hybrid closed loop developed by Diabeloop (Diabeloop SA, Paris, France) that recently entered the European market. The DBLG1 system combines an algorithm based on machine-learning within a physiological framework with an expert system and self-learning algorithms (12). In a different way from other systems already on the Belgian market as the Medtronic MiniMed™ 780G (13) and the Tandem t:slim X2 Control-IQTM (14), the algorithm requires patient to record carbohydrate intake only semi-quantitatively, and intensity and duration of planned physical activities (15). A 12-week multicenter randomized controlled crossover trial comparing the DBLG1 system with SAP showed that this system was associated with a greater percentage of time spent in range than SAP (16). 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 on the long-term is however still unclear. We will undertake this 24-month prospective study in a cohort of patients who were started on the DBLG1 system in Belgium. As for the RESCUE trial on SAP (17) and the ongoing INRANGE Study on first generation HCL, 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 DBLG1 Hybrid Closed Loop system 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 DBLG1 system.

3.3 Secondary endpoints

All endpoints are measured from before start to 4, 8,12, 16, 20 and 24 months after start of the DBLG1 system.

- Percentage of time spent in range - *with exclusion of the primary endpoint*
- Percentage of time spent in tight range (sensor glucose 70-140 mg/dl)
- 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
- 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)
- Number and type of diabetes conventions per person

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
- Indications for use
- Number of patients who stop using the system
- 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 DBLG1 system in patients with T1D treated in the participating centers in Belgium. Data from patients with T1D who start(ed) with the DBLG1 between [start of protocol] up to and including [+1 year] 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 DBLG1 system 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: DBLG1 Hybrid Closed-Loop System

The DBLG1 Hybrid closed-loop system consists of the DBLG1 algorithm hosted on a dedicated handset, similar to a smartphone. The handset is connected via Bluetooth with a Roche Accu-Chek® Insight insulin pump and with the Dexcom G6® CGM device. Blood glucose readings are not required. The DBLG1 system automatically adjusts insulin infusion based on CGM readings to reach a default glucose target of 110 mg/dL (other glucose targets and settings are available). Initiation of the algorithm require the following information: patient's body weight, total daily insulin requirements and usual quantified carbohydrate intake for each meal (breakfast, lunch, dinner). Pump basal flow rates are also required as a safety reference. During this observational study we will allow 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

Patients with T1D, aged 18 years and older, who start with the DBLG1 system 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.

4.2 Exclusion criteria

Patients with T1D younger than 18 years and/or patients who do not start with the DBLG1 system in the participating centers and/or who are not able/do not want to sign informed consent are not eligible to participate.

4.3 Expected duration of trial

Inclusion will take place up to and including [1 year duration]. Once informed consent has been obtained, baseline data will be gathered. This could be done partially retrospectively for patients already started with the DBLG1 system before [start date of protocol]. After start of the DBLG1 system, there will be a follow-up period of 24 months per subject. The expected duration of the study will be 3 years in total.

4.4 Methods of recruitment

Once the decision has been made that a patient will start with the DBLG1 system, the patient will be asked to participate in the study and to sign inform consent to have their personal data sent encoded to the central investigation unit in Brussels.

4.5 Withdrawal criteria

Participants can withdraw at any moment during the study. Participants can be withdrawn by the investigator if he considers that deterioration of glycemic control or other significant clinical condition may be a consequence of the use of the DBLG1 system.

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
- Cohabitation / nuclear family / single-parent family / co-parenting
- Date of T1D diagnosis
- Diabetic complications
- Previous diabetes treatment and reasons to switch
- Height
- Weight
- Total daily dose (basal/bolus) of insulin of the past 4 weeks
- Current medication

- Frequency of severe hypoglycemia (assistance needed from third parties) during the last 12 months
- Frequency of diabetic ketoacidosis in the last 12 months
- Frequency and length of hospital admissions for hypoglycemia and/or ketoacidosis during the last 12 months
- Frequency of school/work absence (consultation excluded) during the last 12 months
- Frequency of (unplanned) contacts with the diabetes team during the last 12 months
- Type of diabetes conventions which are active per person

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

- Duration of use of the DBLG1 system
- Weight
- 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) 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

- Questionnaire 1: SF-36, version 2 – validated questionnaire about health-related quality of life (18)
- Questionnaire 2: Gold scale – validated questionnaire about hypoglycemia awareness (19)
- Questionnaire 3: Clarke hypoglycemia awareness survey – validated questionnaire about hypoglycemia awareness (20)
- Questionnaire 4: Hypoglycemia fear survey, behavior and worry, version II (HFS-II) – validated questionnaire about behavior to and worries about hypoglycemia (21,22)

- Questionnaire 5: Problem Areas In Diabetes survey, short form (PAID-SF) – validated questionnaire about emotional problems related to diabetes (23)
- Questionnaire 6: Diabetes Treatment Satisfaction Questionnaire, status (DTSQs) – validated questionnaire about satisfaction of diabetes treatment (24)
- Questionnaire 7: Diabetes Impact and Device Satisfaction Scale – validated questionnaire about satisfaction of diabetes device (25)

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

- 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 7: Diabetes Impact and Device Satisfaction Scale

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 Yourloops. All are software programs designed by Medtronic, Abbott, Dexcom and Diabeloop respectively for storage and graphical display of blood glucose readings and CGM 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 in tight range (sensor glucose 70-140 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 DBLG1 system used in closed-loop mode
- 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 in tight range (sensor glucose 70-140 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 capillary finger sticks per day

6. Statistics

6.1 Sample size

We will include every patient with T1D who starts with the DBLG1 system in the participating centers. It is our estimation that more than 100 patients will use the DBLG1 technology in the period that we analyze. Considering a dropout rate of 25% at one year of treatment, this gives our study still enough power (>80%) for the primary endpoint (change in time in range from before to 12 months after

starting the DBLG1 system) 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 (17). A mean difference of 5% is seen as a clinically significant change for time in range (26).

6.2 Analysis

A linear mixed model will be used to evaluate the changes in continuous variables after start of the DBLG1 system, 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 a 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 ULB-Hôpital ERASME 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 Yourloops , 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 Diabeloop 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 ULB-Hôpital ERASME.

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 Sites are 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, Roche Diabetes Care and Dexcom, Inc will provide a supporting grant for a study data nurse job and the electronic case reporting form.

15. References

1. Nathan DM, Genuth S, Lachin J, Cleary P, Crofford O, Davis M, et al. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;329(14):977–86.
2. Nathan DM, Cleary PA, Backlund J-YC, Genuth SM, Lachin JM, Orchard TJ, et al. Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. N Engl J Med. 2005;353(25):2643–53.
3. Glycemic targets: Standards of medical care in diabetes. Diabetes Care 2021; 44(S1): S73-S84.
4. Rydén L, Grant PJ, Anker SD, Berne C, Cosentino F, Danchin N, et al. ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD: the Task Force on diabetes, pre-diabetes, and cardiovascular diseases of the European Society of Cardiology (ESC) and developed in collaboratio. Eur Heart J. 2013;34(39):3035–87.
5. Wild D, von Maltzahn R, Brohan E, Christensen T, Clauson P, Gonder-Frederick L. A critical review of the literature on fear of hypoglycemia in diabetes: Implications for diabetes management and patient education. Patient Educ Couns. 2007 Sep;68(1):10–5.
6. Boughton CK, Hovorka R. Is an artificial pancreas (closed-loop system) for Type 1 diabetes effective? Diabet Med. 2019;36(3):279–86.
7. Weisman A, Bai J-W, Cardinez M, Kramer CK, Perkins BA. Effect of artificial pancreas systems on glycaemic control in patients with type 1 diabetes: a systematic review and meta-analysis of outpatient randomised controlled trials. Lancet Diabetes Endocrinol. 2017;5(7):501–12.
8. Bally L, Thabit H, Kojzar H, Mader JK, Qerimi-Hyseni J, Hartnell S, et al. Day-and-night glycaemic control with closed-loop insulin delivery versus conventional insulin pump therapy in free-living adults with well controlled type 1 diabetes: an open-label, randomised, crossover study. Lancet Diabetes Endocrinol. 2017;5(4):261–70.
9. Bekiari E, Kitsios K, Thabit H, Tauschmann M, Athanasiadou E, Karagiannis T, et al. Artificial pancreas treatment for outpatients with type 1 diabetes: systematic review and meta-analysis. BMJ. 2018 Apr;361:k1310.
10. Tauschmann M, Thabit H, Bally L, Allen JM, Hartnell S, Wilinska ME, et al. Closed-loop insulin

delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. Lancet. 2018 Oct;392(10155):1321–9.

11. Barnard KD, Wysocki T, Ully V, Mader JK, Pieber TR, H. T, et al. Closing the Loop in Adults, Children and Adolescents With Suboptimally Controlled Type 1 Diabetes Under Free Living Conditions: A Psychosocial Substudy. J Diabetes Sci Technol. 2017;11(6):1080–8.
12. Benhamou PY, Huneker E, Franc S, Doron M, Charpentier G; Diabeloop Consortium. Customization of home closed-loop insulin delivery in adult patients with type 1 diabetes, assisted with structured remote monitoring: the pilot WP7 Diabeloop study. Acta Diabetol. 2018;55(6):549-556.
13. Da Silva J, Lepore G, Battelino T, Arrieta A, Castañeda J, Grosman B, Shin J, Cohen O. Real-world Performance of the MiniMed™ 780G System: First Report of Outcomes from 4'120 Users. Diabetes Technol Ther. 2021 Sep 15. doi: 10.1089/dia.2021.0203. Epub ahead of print. PMID: 34524003.
14. Brown SA, Kovatchev BP, Raghinaru D, Lum JW, Buckingham BA, Kudva YC, et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. N Engl J Med. 2019 Oct 31;381(18):1707–17.
15. Hanaire H, Franc S, Borot S, Penfornis A, Benhamou PY, Schaepelynck P, et al. Efficacy of the Diabeloop closed-loop system to improve glycaemic control in patients with type 1 diabetes exposed to gastronomic dinners or to sustained physical exercise. Diabetes Obes Metab. 2020;22(3):324-334.
16. Benhamou PY, Franc S, Reznik Y, Thivolet C, Schaepelynck P, Renard E, et al; DIABELOOP WP7 Trial Investigators. Closed-loop insulin delivery in adults with type 1 diabetes in real-life conditions: a 12-week multicentre, open-label randomised controlled crossover trial. Lancet Digit Health. 2019; 1(1):e17-e25.
17. Charleer S, Mathieu C, Nobels F, De Block C, Radermecker RP, Hermans MP, et al. Effect of Continuous Glucose Monitoring on Glycemic Control, Acute Admissions, and Quality of Life: A Real-World Study. J Clin Endocrinol Metab. 2018 Mar 1;103(3):1224–32.
18. Roos EP. SF-36 Health Survey Manual and Interpretation Guide. Med Care. 1992.
19. Gold AE, Macleod KM, Frier BM. Frequency of Severe Hypoglycemia in Patients With Type I Diabetes With Impaired Awareness of Hypoglycemia. Diabetes Care. 1994;17(7):697–703.
20. Clarke WL, Cox DJ, Gonder-Frederick LA, Julian D, Schlundt D, Polonsky W. Reduced Awareness of Hypoglycemia in Adults With IDDM: A prospective study of hypoglycemic frequency and associated symptoms. Diabetes Care. 1995 Apr 1;18(4):517–22.
21. Cox DJ, Irvine A, Gonder-Frederick L, Nowacek G, Butterfield J. Fear of hypoglycemia: quantification, validation, and utilization. Diabetes Care. 1987;10(5):617–21.

22. Gonder-Frederick LA, Schmidt KM, Vajda KA, Greear ML, Singh H, Shepard JA, et al. Psychometric Properties of the Hypoglycemia Fear Survey-II for Adults With Type 1 Diabetes. Diabetes Care. 2011 Apr 1;34(4):801–6.
23. Welch GW, Jacobson AM, Polonsky WH. The Problem Areas in Diabetes Scale: An evaluation of its clinical utility. Diabetes Care. 1997 May 1;20(5):760–6.
24. Bradley C, Gamsu DS. Guidelines for Encouraging Psychological Well-being. Diabet Med. 1994 Jun;11(5):510–6.
25. Manning ML, Singh H, Stoner K, Habif S. The Development and Psychometric Validation of the Diabetes Impact and Device Satisfaction Scale for Individuals with Type 1 Diabetes. J Diabetes Sci Technol. 2020 Mar 6;14(2):309–17.
26. Beck RW, Bergenstal RM, Cheng P, Kollman C, Carlson AL, Johnson ML, et al. The relationships between time in range, hyperglycemia metrics, and HbA1c. J Diabetes Sci Technol. 2019 Jul;13(4):614–26.

16. Appendix

Questionnaire 1: SF-36 (version 2)

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.)?

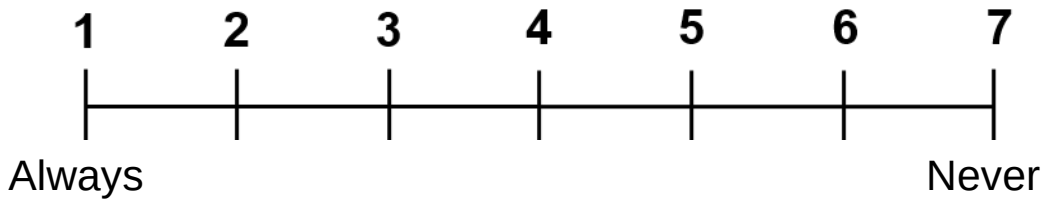
- ☐ all of the time
- ☐ most of the time
- ☐ some of the time
- ☐ a little of the time
- ☐ none of the time

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

	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)** **4.**
   - ☐ Never
   - ☐ Once or twice
   - ☐ Every other month
   - ☐ Once a month
   - ☐ More than once a month

   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: 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 8: Stop questionnaire

NL:

Waarom werd beslist om te stoppen met het hybrid closed-loop (HCL) 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 HCL-systeem.
- ☐ Het HCL- systeem werkte niet adequaat (vb. sensormetingen onjuist, …).
- ☐ De sensor van het HCL-systeem bleef niet goed zitten.
- ☐ De canule van het HCL-systeem bleef niet goed zitten.
- ☐ De patiënt ondervond veel technische problemen met het HCL-systeem.
- ☐ Het HCL-systeem gaf te veel alarmen.
- ☐ Het HCL-systeem gaf te veel nachtelijke alarmen.
- ☐ Het HCL-systeem deed pijn.
- ☐ Het HCL-systeem was moeilijk in gebruik.
- ☐ De toegestane insertieplaatsen waren ontoereikend.
- ☐ Andere:

FR:

Pourquoi a-t-il été décidé de cesser d'utiliser le système en boucle fermée hybride (HCL) ?
(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 d'effets indésirables causés par le système HCL
- ☐ Le système HCL ne fonctionne pas correctement (p.ex., les mesures du capteur sont incorrectes, ...).
- ☐ Le capteur du système HCL n'est pas resté en place correctement.
- ☐ La canule du système HCL n'est pas restée en place correctement
- ☐ Le patient rencontre de nombreux problèmes techniques avec le système HCL.
- ☐ Le système HCL donne trop d'alarmes.
- ☐ Le système HCL donne trop d'alarmes nocturnes.
- ☐ Le système HCL fait mal.
- ☐ Le système HCL est difficile à utiliser.
- ☐ Les sites d'insertion autorisés sont inadéquats.
- ☐ Autre: